Atellica NEPH 630 System

Instruction Manual
2023-02

siemens-healthineers.com

SIEMENS Healthineers

1 Introduction 8
1.1 About this manual 8
1.2 Orientation tips 8
1.3 Identification 9
1.4 Service 9
1.5 Warranty 9
1.6 Ordering information 9
1.7 Third-party software copyrights 10
1.8 Trademarks 13
1.9 Manual version history 13

2 Safe handling 14
2.1 Intended use 14
2.1.1 System functions 14
2.2 Intended user 14
2.3 Reporting of serious incidents 15
2.4 General safety information 15
2.4.1 Operator qualification 15
2.4.2 Electrical safety 15
2.4.3 Mechanical safety 16
2.4.4 Operational safety 17
2.4.5 Safe handling of samples, reagents, controls, standards, and consumables 18
2.4.6 Limitations of the quantitative determination of proteins 20
2.4.7 Safe handling of personal data 20
2.4.8 IT security measures 21
2.4.9 Security whitepaper 22
2.5 Safety messages 22
2.6 Symbols 22
2.7 Statutory provisions 25

3 Life cycle 26
3.1 Delivery 26
3.2 Installation 26
3.3 Non-operation 26
3.4 De-installation 27
3.5 Movement 27
3.6 Disposal 28

4 Description of the hardware 29
4.1 Overview of the analyzer 29
4.2 Functional units 30
4.2.1 Covers 30
4.2.2 LEDs 30
4.2.3 Sample rotor 31
4.2.4 Reagent rotor 31
4.2.5 Dilution station 32
4.2.6 Wet station 33
4.2.7 Cuvette rotor 34
4.2.8 Transfer arm and probe 35
4.2.9 Syringe 37
4.2.10 Power module 37

4.3 Components inside the analyzer 38
4.3.1 Air bubble detector 38
4.3.2 Barcode reader 38
4.3.3 Dilutor 39
4.4 External and peripheral devices 39
4.4.1 Peripheral devices 40
4.4.2 LIS (optional) 40
4.5 Consumables and accessories 41
4.5.1 Sample rotor segments 41
4.5.2 Reagent rotor segments 44
4.5.3 N Cuvette segments for BN ProSpec 46
4.5.4 Dilution strips 46
4.5.5 N Evaporation Caps for Control Vials (2.5 mL) and N Evaporation Caps for Reagent Vials (5 mL) 46
4.5.6 Liquid containers, level sensors, and tubing 47
4.5.7 Probe cleaner bottle 49
4.6 Reagents, standards, and controls 50

5 Description of the software 51
5.1 Overview of the screen 51
5.2 General elements 52
5.2.1 Status buttons 52
5.2.2 Common display functions in dialogs 53
5.2.3 Common action buttons 55
5.2.4 Flags and symbols 55
5.2.5 Function keys 58
5.3 Dialogs 59
5.3.1 About 59
5.3.2 Access cuvette segments and dilution strips 59
5.3.3 Access reagents 61
5.3.4 Access samples 61
5.3.5 Add request 61
5.3.6 Calibration 64
5.3.7 Check probe 66
5.3.8 Clean probe 66
5.3.9 Configuration 67
5.3.10 Control details 73
5.3.11 Definitions 74
5.3.12 Hardware check - probe 81
5.3.13 Help 81
5.3.14 Initialize analyzer 82
5.3.15 Kinetics - Measurement curves 82
5.3.16 Kinetics - Reference curve 83
5.3.17 Lab journal 84
5.3.18 Loading cuvette segments and dilution strips 87
5.3.19 Loading reagents 89
5.3.20 Loading reagents, graphic overview 90
5.3.21 Loading reagents, identify reagents and controls 93
5.3.22 Loading samples 95
5.3.23 Log on 100
5.3.24 Logbook 101
5.3.25 Message window 102
5.3.26 New 103
5.3.27 Open lot data file 105

5.3.28 Pre-loading 106
5.3.29 Print preview 107
5.3.30 Print raw data 109
5.3.31 Purge tubings 109
5.3.32 QC 110
5.3.33 Remote control 110
5.3.34 Repeat 111
5.3.35 Replace syringe 112
5.3.36 Replace system liquids and empty waste container 112
5.3.37 Request controls 113
5.3.38 Rinse system 114
5.3.39 Sample details 114
5.3.40 Select path for backup file 115
5.3.41 Show curve 116
5.3.42 Special dilution 118
5.3.43 Status 119
5.3.44 System 124

6 Configuring the system 128
6.1 Adding a standard lot 128
6.2 Configuring cyclic control measurements 128
6.3 Deactivating cyclic control measurements for an assay 129
6.4 Adding a user-defined control 129
6.5 Adding an assay to a user-defined control 131
6.6 Editing assay settings in a user-defined control 132
6.7 Deleting a user-defined control 134
6.8 Adding a control lot 134
6.9 Deleting a control lot 135
6.10 Adding a profile 136
6.11 Adding an assay to a profile 136
6.12 Removing an assay from a profile 136
6.13 Deleting a profile 137
6.14 Adding a sample rotor segment ID 137
6.15 Deleting a sample rotor segment ID 138
6.16 Configuring the immersion depth for cups used with a cup-in-tube segment 138
6.17 Configuring unit and reference range of an assay 140
6.18 Setting automatic re-measurement and automatic release 141
6.19 Configuring printouts 142
6.20 Setting the display of results in the lab journal 142
6.21 Setting the default sort sequence in the lab journal 142
6.22 Setting the language 143
6.23 Configuring significant digits of the sample ID 143
6.24 Configuring the LIS connection 144

7 Preparing for the analysis 145
7.1 Starting the system 145
7.2 Emptying the waste container 146
7.3 Replacing system liquids 147
7.4 Loading cuvette segments and dilution strips 148
7.5 Loading lot data 150
7.6 Preparing reagents and controls 150
7.7 Loading reagents and controls 153
7.8 Preparing a sample rotor segment for use 155

8 Performing the analysis 158
8.1 Identifying a reagent or control 158
8.2 Loading standards and user-defined controls 159
8.3 Measuring a control 161
8.4 Repeating a control measurement 162
8.5 Loading barcoded samples 163
8.6 Assigning STAT status to a barcoded sample 166
8.7 Pre-identifying non-barcoded samples and non-barcoded STAT samples 167
8.8 Loading non-barcoded samples and non-barcoded STAT samples 168
8.9 Loading sample rotor segments 171
8.10 Identifying a sample or standard with unreadable barcode 172
8.11 Requesting a job for a sample manually 173
8.12 Repeating a job for a sample manually 174
8.13 Refilling a sample tube 175
8.14 Unloading samples 176
8.15 Unloading standards 177
8.16 Unloading reagents and controls 178
8.17 Displaying data in the lab journal 179
8.18 Displaying sample and control details 180
8.19 Displaying measurement curves 180
8.20 Releasing results 180
8.21 Printing results 181
8.22 Sending control results for evaluation 181
8.23 Measuring the reference curve for an assay 182
8.24 Repeating the measurement of a reference curve 183
8.25 Displaying a reference curve 184
8.26 Activating an invalid reference curve 185
8.27 Deleting a sample ID from the lab journal 185
8.28 Removing previous assignments of sample IDs 186
8.29 Using cup-in-tube segments 187
8.30 Using Eppendorf cup segments 190
8.31 Using Hitachi cup segments 193
8.32 Using cup-behind-tube segments 195

9 Finishing the analysis 199
9.1 Rinsing the system 199
9.2 Creating a backup 199
9.3 Shutting down the system 200
9.4 Emptying the waste container 202

10 Performing maintenance and cleaning 203
10.1 List of tasks 204
10.2 Weekly tasks 205
10.2.1 Checking the functioning of the probe 205
10.2.2 Cleaning the probe 206
10.2.3 Cleaning the wet station 208
10.2.4 Cleaning the reagent rotor and the reagent rotor housing 210
10.2.5 Checking the syringe for leaks 211
10.2.6 Cleaning the water container 212
10.2.7 Checking the tubing of the containers 213
10.2.8 Checking the tubing of the probe 213
10.3 Monthly tasks 215
10.3.1 Purging the tubing 215
10.3.2 Replacing the water filter 217

10.3.3 Cleaning the level sensors 218
10.4 Yearly tasks 221
10.4.1 Replacing the syringe 221
10.4.2 Replacing the tubing of the containers 225
10.5 As needed tasks 229
10.5.1 Shutting down the system for maintenance 229
10.5.2 Cleaning the surface of the system 229
10.5.3 Cleaning the sample rotor and the sample rotor housing 229
10.5.4 Cleaning the segments 231
10.5.5 Cleaning the dilution station, the cuvette rotor, and the cuvette rotor housing 231
10.5.6 Cleaning the waste container 234
10.5.7 Cleaning the peripheral devices 234
10.5.8 Replacing the probe cleaner bottle 235
10.5.9 Preparing the purging solution 236
10.5.10 Preparing the hypochlorite solution 236
10.6 Atellica® NEPH 630 System maintenance log 238

11 Troubleshooting 241
11.1 Carrying out troubleshooting 241
11.2 Hardware troubleshooting 242
11.2.1 Hardware troubleshooting chart 242
11.2.2 Inserting reagent rotor segments 243
11.2.3 Checking the level of samples visually 244
11.2.4 Checking the level of reagents or controls 245
11.2.5 Checking the geometry of the probe 247
11.2.6 Replacing the fuses 247
11.2.7 Replacing the probe assembly 250
11.2.8 Troubleshooting the syringe 266
11.3 Software troubleshooting 267
11.3.1 Message window 267
11.3.2 Status bar 271
11.3.3 Dialog Status 278
11.3.4 Dialog Lab journal 278
11.3.5 Dialog Loading 284
11.3.6 Dialog Calibration 293
11.3.7 Dialog System 293
11.3.8 General software problems 296
11.4 Entering a logbook entry 300
11.5 Exporting logbook entries 301

12 Technical specifications 302
12.1 Analyzer 302
12.1.1 Operating conditions 304
12.1.2 Storage conditions 305
12.1.3 I/O ports 305
12.2 Computer 305
12.3 Consumables 305
12.3.1 Sample rotor segments 306
12.3.2 Reagent rotor segments 307
12.3.3 Cuvette segments 307
12.3.4 Dilution strips 307
12.3.5 Evaporation caps 307

12.4 Sample tubes, cups, and vials 307
12.4.1 Sample tubes 308
12.4.2 Special cups and vials 308
12.5 Adapters 308
12.6 Barcodes 308
12.6.1 Sample and user-defined control barcodes 309
12.6.2 Reagent barcodes 310

13 Appendix 311
13.1 Principle of operation 311
13.1.1 Handling of samples 311
13.1.2 Handling of reagents 311
13.1.3 Handling of standards 312
13.1.4 Handling of controls 313
13.1.5 Dilutions 313
13.1.6 Handling of lot data and calibration data 314
13.1.7 Calibration 314
13.1.8 Processing of assays 316
13.1.9 Processing of reference curves 319
13.1.10 Processing of control measurements 321
13.1.11 Plausibility check 321
13.1.12 Formula test 322
13.2 Principle of measurement 322
13.2.1 Nephelometry 322
13.2.2 Optical path of beam 323
13.2.3 Principle of immunochemical protein determination 325
13.2.4 Methods of determining the protein concentration at different times 328
13.3 Communications 329

14 Revision Information 330

Index 331

1 Introduction

This chapter gives introductory information.

1.1 About this manual

This manual describes the use of the Atellica® NEPH 630 System in clinical laboratories.

The description is limited to the primary operating functions and information required at times when the system is off or when the online help is not available.

This manual is only valid in conjunction with other user manuals available electronically on the system or in print.

Depending on the operating system, the selected languages, and regional settings, screenshots in this manual can differ from the display on the screen.

1.2 Orientation tips

	Indicates a hint Is used to provide information on how to avoid operating errors or information emphasizing important details
	Indicates the solution of a problem Is used to provide troubleshooting information or answers to frequently asked questions
●	Indicates a list item
✓	Indicates a prerequisite Is used for a condition that has to be fulfilled before starting a particular procedure
◆	Indicates a 1-step procedure or procedural steps to solve a problem
1 2 3	Indicate steps within procedures
➔	Indicates a link to related information as well as previous or next steps
→	Indicates the result of a procedural step or a procedure
Italic	Is used for references
Bold	Is used for table or figure titles and to identify window titles, menu items, function names, buttons, and keys, for example, the button **Enter**
Menu > Menu item	Is used for the navigation to a certain submenu entry
Orange	Is used to emphasize particularly important sections of the text

1.3 Identification

The model numbers of the Atellica NEPH 630 system and the accessories used with the system are:

Product	SMN	REF
Atellica NEPH 630 system	11239861	OVLI02
N Predilution Wells	10446521	OVIC11
N Cuvettes Segments for BN ProSpec	10446539	OVLK31
N Evaporation Caps for Control Vials (2.5 ml)	10446534	OVLC21
N Evaporation Caps for Reagent Vials (5 ml)	10446535	OVLC31

1.4 Service

Siemens Healthineers and its representatives are available to repair the system during customary local office hours. If service is required at any other time, contact Siemens Healthineers service or a local Siemens Healthineers representative. In the following, "Siemens Healthineers service" refers to both Siemens Healthineers service or any local representative authorized by Siemens Healthineers. Information about how to reach Siemens Healthineers service is provided when the system is installed, or visit siemens-healthineers.com to find contact information.

Siemens Healthineers will provide information about the availability and cost of updates.

The scope of agreed service is included in the service contract.

1.5 Warranty

Siemens Healthineers and its representatives guarantee that the system shows no defects after installation, and during operation if operated according to this manual. For more information on warranty, contact Siemens Healthineers service. The warranty is not valid for damage that occurs as a consequence of non-observance of this manual. Only perform maintenance as described in this manual. Incorrect interventions on the system void the warranty and can result in service charges.

Repairs and servicing must only be carried out by persons authorized by Siemens Healthineers.

Only use the system as intended. If the system is not used as intended, Siemens Healthineers disclaims all liability for damage to the system.

1.6 Ordering information

Only use original Siemens Healthineers consumables, accessories, and spare parts. Order these only from Siemens Healthineers. For ordering information, see the Siemens Healthineers product catalog or contact Siemens Healthineers service.

1.7 Third-party software copyrights

This device includes open source software. Such software is provided by Siemens Healthineers under the terms of the open source software licenses applicable to such software, and is distributed **without any warranty** as set forth in the corresponding licenses. Those terms require that Siemens Healthineers provide the following notices and information to the purchaser of this device. Where required by the specific license terms, Siemens Healthineers will make the source code for such open source software available upon request from Siemens Healthineers in accordance with the terms of the relevant open source license. Versions of the **GNU General Public License (GPL)** and **Lesser General Public License (LGPL)** are available at www.gnu.org. Versions of the Apache License are available at http://www.apache.org/licenses/.

The **Apache License** Version 2.0 reads:

Terms and conditions for use, production, and distribution.

1. Definitions.

“License” shall mean the terms and conditions for use, reproduction, and distribution as defined by Sections 1 through 9 of this document.

“Licensor” shall mean the copyright owner or entity authorized by the copyright owner that is granting the License.

“Legal Entity” shall mean the union of the acting entity and all other entities that control, are controlled by, or are under common control with that entity. For the purposes of this definition, “control” means (i) the power, direct or indirect, to cause the direction or management of such entity, whether by contract or otherwise, or (ii) ownership of fifty percent (50 %) or more of the outstanding shares, or (iii) beneficial ownership of such entity.

“You” (or “Your”) shall mean an individual or Legal Entity exercising permissions granted by this License.

“Source” form shall mean the preferred form for making modifications, including but not limited to software source code, documentation source, and configuration files.

“Object” form shall mean any form resulting from mechanical transformation or translation of a Source form, including but not limited to compiled object code, generated documentation, and conversions to other media types.

“Work” shall mean the work of authorship, whether in Source or Object form, made available under the License, as indicated by a copyright notice that is included in or attached to the work (an example is provided in the Appendix below).

“Derivative Works” shall mean any work, whether in Source or Object form, that is based on (or derived from) the Work and for which the editorial revisions, annotations, elaborations, or other modifications represent, as a whole, an original work of authorship. For the purposes of this License, Derivative Works shall not include works that remain separable from, or merely link (or bind by name) to the interfaces of, the Work and Derivative Works thereof.

"Contribution" shall mean any work of authorship, including the original version of the Work and any modifications or additions to that Work or Derivative Works thereof, that is intentionally submitted to Licensor for inclusion in the Work by the copyright owner or by an individual or Legal Entity authorized to submit on behalf of the copyright owner. For the purposes of this definition, "submitted" means any form of electronic, verbal, or written communication sent to the Licensor or its representatives, including but not limited to communication on electronic mailing lists, source code control systems, and issue tracking systems that are managed by, or on behalf of, the Licensor for the purpose of discussing and improving the Work, but excluding communication that is conspicuously marked or otherwise designated in writing by the copyright owner as "Not a Contribution."

"Contributor" shall mean Licensor and any individual or Legal Entity on behalf of whom a Contribution has been received by Licensor and subsequently incorporated within the Work.

2. Grant of Copyright License.

Subject to the terms and conditions of this License, each Contributor hereby grants to You a perpetual, worldwide, non-exclusive, no-charge, royaltyfree, irrevocable copyright license to reproduce, prepare Derivative Works of, publicly display, publicly perform, sublicense, and distribute the Work and such Derivative Works in Source or Object form.

3. Grant of Patent License.

Subject to the terms and conditions of this License, each Contributor hereby grants to You a perpetual, worldwide, non-exclusive, no-charge, royaltyfree, irrevocable (except as stated in this section) patent license to make, have made, use, offer to sell, sell, import, and otherwise transfer the Work, where such license applies only to those patent claims licensable by such Contributor that are necessarily infringed by their Contribution(s) alone or by combination of their Contribution(s) with the Work to which such Contribution(s) was submitted. If You institute patent litigation against any entity (including a cross-claim or counterclaim in a lawsuit) alleging that the Work or a Contribution incorporated within the Work constitutes direct or contributory patent infringement, then any patent licenses granted to You under this License for that Work shall terminate as of the date such litigation is filed.

4. Redistribution.

You may reproduce and distribute copies of the Work or Derivative Works thereof in any medium, with or without modifications, and in Source or Object form, provided that You meet the following conditions:

a. You must give any other recipients of the Work or Derivative Works a copy of this License; and

b. You must cause any modified files to carry prominent notices stating that You changed the files; and

c. You must retain, in the Source form of any Derivative Works that You distribute, all copyright, patent, trademark, and attribution notices from the Source form of the Work, excluding those notices that do not pertain to any part of the Derivative Works; and

d. If the Work includes a "NOTICE" text file as part of its distribution, then any Derivative Works that You distribute must include a readable copy of the attribution notices contained within such NOTICE file, excluding those notices that do not pertain to any part of the Derivative Works, in at least 1 of the following places: within a NOTICE text file distributed as part of the Derivative Works; within the Source form or documentation, if provided along with the Derivative Works; or, within a display generated by the Derivative Works, if and wherever such third-party notices normally appear. The contents of the NOTICE file are for informational purposes only and do not modify the License. You may add Your own attribution notices within Derivative Works that You distribute, alongside or as an addendum to the NOTICE text from the Work, provided that such additional attribution notices cannot be construed as modifying the License.

You may add Your own copyright statement to Your modifications and may provide additional or different license terms and conditions for use, reproduction, or distribution of Your modifications, or for any such Derivative Works as a whole, provided Your use, reproduction, and distribution of the Work otherwise complies with the conditions stated in this License.

5. Submission of Contributions.

Unless You explicitly state otherwise, any Contribution intentionally submitted for inclusion in the Work by You to the Licensor shall be under the terms and conditions of this License, without any additional terms or conditions. Notwithstanding the above, nothing herein shall supersede or modify the terms of any separate license agreement you may have executed with Licensor regarding such Contributions.

6. Trademarks.

This License does not grant permission to use the trade names, trademarks, service marks, or product names of the Licensor, except as required for reasonable and customary use in describing the origin of the Work and reproducing the content of the NOTICE file.

7. Disclaimer of Warranty.

Unless required by applicable law or agreed to in writing, Licensor provides the Work (and each Contributor provides its Contributions) on an "AS IS" BASIS, WITHOUT WARRANTIES OR CONDITIONS OF ANY KIND, either express or implied, including, without limitation, any warranties or conditions of TITLE, NON-INFRINGEMENT, MERCHANTABILITY, or FITNESS FOR A PARTICULAR PURPOSE. You are solely responsible for determining the appropriateness of using or redistributing the Work and assume any risks associated with Your exercise of permissions under this License.

8. Limitation of Liability.

In no event and under no legal theory, whether in tort (including negligence), contract, or otherwise, unless required by applicable law (such as deliberate and grossly negligent acts) or agreed to in writing, shall any Contributor be liable to You for damages, including any direct, indirect, special, incidental, or consequential damages of any character arising as a result of this License or out of the use or inability to use the Work (including but not limited to damages for loss of goodwill, work stoppage, computer failure or malfunction, or any and all other commercial damages or losses), even if such Contributor has been advised of the possibility of such damages.

9. Accepting Warranty or Additional Liability.

While redistributing the Work or Derivative Works thereof, You may choose to offer, and charge a fee for, acceptance of support, warranty, indemnity, or other liability obligations and/or rights consistent with this License. However, in accepting such obligations, You may act only on Your own behalf and on Your sole responsibility, not on behalf of any other Contributor, and only if You agree to indemnify, defend, and hold each Contributor harmless for any liability incurred by, or claims asserted against, such Contributor by reason of your accepting any such warranty or additional liability.

End of terms and conditions

For **Linux Kernel v3.13.5** under the GNU GPL v2:

© 2014 Linux Community

© 2015 Richard Theil (modifications regarding patches br-0001-Config, linux-0001-ehcixinc, linux-0002-r4sig, linux-0003-ngpio, linux-0004- pselect, linux-0005-cmdforce, linux-0006-xelitex, linux-0007-binimgdts, linux-0009-emilxdefconfig and linux-0011-timerns)

© 2015 Siemens Healthcare Diagnostics Products GmbH, Xilinx Inc. and Michal Simek (modifications regarding patch linux-0008-emilxdtb)

© 2015 Siemens Healthcare Diagnostics Products GmbH (modifications regarding patch linux-0010-bdideviceremove)

For **u-boot Universal Boot Loader, v2014.01** under the GNU GPL v2:

© 2014 Wolfgang Denk, DENX Software Engineering

For **log4net, v1.2** under the Apache Software License, Version 2.0:

© 2004–2015 Apache Software Foundation

1.8 Trademarks

Atellica and Advia are trademarks of Siemens Healthineers.

All other trademarks are the property of their respective owners.

1.9 Manual version history

Manual			Software	
Version	**Date**	**Changes**	**Full version**	**Release version**
1.0 (not published)	2016-10	First version	1.0.0	1
1.1 (not published)	2017-01	Update	1.0.0	1
1.2	2017-04	Update	1.0.0	1
1.3	2018-04	Update	1.1.0	1
01	2021-10	Update	1.1.1	1
02	2023-02	Update	1.1.1	1

2 Safe handling

This chapter describes the intended use of the system and gives general safety instructions.

2.1 Intended use

The Atellica NEPH 630 System is used for the automated quantitative determination of proteins in serum, plasma, urine, and CSF by means of nephelometry. The system is intended for in vitro diagnostic use in combination with defined IVD devices in clinical laboratories by trained personnel.

Intended use of accessories

N Predilution Wells	The predilution wells are used to prepare pre-dilutions of samples, controls, and standards.
N Cuvettes Segments for BN ProSpec	The cuvettes hold dilutions, reagents, and buffer for the measurement of the protein concentration in the cuvette rotor.
N Evaporation Caps for Control Vials (2.5 ml)	Evaporation caps are used to minimize evaporation and to extend the on-board stability of reagents and controls.
N Evaporation Caps for Reagent Vials (5 ml)	Evaporation caps are used to minimize evaporation and to extend the on-board stability of reagents and controls.

2.1.1 System functions

The system functions are:

- Preparation of pre-dilutions in the dilution cups for samples, standards, and controls
- Pipetting (dispensing) of all required reagents, samples, and sample dilutions
- Reaction incubation in the rotor cuvettes
- Optical measurement of the rotor cuvettes
- Calculation and flagging, if required, of the measurement results

The Atellica NEPH 630 system is a walk-away analyzer. After entering the job list and loading the analyzer with the necessary reagents, standards, and controls, up to 45 samples can be loaded simultaneously onto the analyzer. Processing occurs automatically.

2.2 Intended user

The system is intended for laboratory professional use only.

2.3 Reporting of serious incidents

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

2.4 General safety information

The system has been inspected for technical safety before distribution. To maintain this status and to ensure hazard-free operation:

- Always follow the instructions in this manual.
- Keep this manual for future reference unless you obtain a new version of the manual.
- If an addendum is published, read the addendum. The information in the addenda reflects the current status and supersedes other information in the corresponding manual, if applicable.
- Only use the system as intended. If the system is not used as intended, Siemens Healthineers disclaims all liability for any personal injury and property damage.
- Only perform maintenance as described in this manual and in the instruction manual of the system. If maintenance is not performed as described or if maintenance other than described in this manual and in the instruction manual of the system is performed, Siemens Healthineers disclaims all liability for any personal injury and property damage.
- The tool that is required to open the housing for maintenance or replacement work must be retained by the system owner. Access to the tool must be controlled.
- Always follow good laboratory practice.
- Make sure the operating and storage conditions are met, see (➔ Page 304 *Operating conditions*) and (➔ Page 305 *Storage conditions*).

2.4.1 Operator qualification

Risk of death and serious injury due to lack of knowledge. To avoid this hazard:

- The system must be operated and maintained only by persons whose skills, knowledge, and practical experience qualify them to do so, and who have been trained in its operation and maintenance.
- The system must only be opened for maintenance or replacement work by specially trained users.
- For information on available training options and suggested duration and frequency of such training, contact Siemens Healthineers service.

2.4.2 Electrical safety

Risk of electric shock when coming into contact with live parts. Even when the system is switched off, some components, for example, capacitors, can be live as they can still be electrically charged. Death or serious injury can result. To avoid this hazard:

- To de-energize the analyzer, unplug the supply cable from the power supply socket.

- Connect the system only to a socket with a ground contact (earth).
- Only use double insulated extension cables with a protective conductor and ground contact.
- Only use checked cables for the connection between the analyzer and the associated computer and monitor.
- Never disconnect the ground contacts from the line.
- Never interrupt the protective conductor inside or outside the system.
- Never remove protective guards or fused components.
- Ensure that all surfaces, including the floor, are dry when using and maintaining the system.
- Make sure that the power switch is easily accessible.
- If the system needs to be opened for maintenance or replacement, follow the instructions given in the relevant procedures.

Risk of short-circuit by spilled liquids that can come into contact with live parts. Damage to the system can result. To avoid this hazard:

- Never pour liquids or place containers with liquid on top of the system.
- Disconnect the mains plug immediately if liquid is spilled into the system.

Risk of malfunctions in nearby electrical devices due to radio interference. The system complies with the emission and immunity requirements described in IEC 61326-2-6. The analyzer has been designed and tested according to CISPR 11 Class A. In a domestic environment, it can cause radio interference. To avoid this hazard:

- Assess the electromagnetic environment prior to operating the system.
- Use the cables supplied.
- Use shielded cables and plugs if external devices are connected, for example, a printer or a network.

Risk of malfunctions of the system such as incorrect results due to radio interference from other electrical devices. To avoid this hazard:

- Do not operate strong electromagnetic transmitters, for example, mobile phones, walkie-talkies, door openers, or elevators, in the vicinity of the system.
- In places where the quality of the power supply line is poor or impacted by other electrical devices, consider the use of an external uninterruptible power supply (UPS).

2.4.3 Mechanical safety

Risk of serious injury due to moving parts. To avoid this hazard:

- Never bypass or remove safety devices, for example, cover switches.
- Maintenance described in this manual that has to be carried out on the open analyzer while connected to a power source must only be done by specially trained users. Specially trained users must be familiar with the hazards associated with such action.

- Keep clear of moving parts when the system is in operation or maintenance is performed. Long hair, necklaces, bracelets, and similar objects can get caught in moving parts.

2.4.4 Operational safety

Risk of burns due to combustion of flammable liquids. Death or serious injury can result. To avoid this hazard:

- Keep flammable liquids away from heat or open flame.
- Place the system in a well-ventilated area.

If a flammable liquid has been spilled, immediately take the following measures to prevent combustion:

- Eliminate all sources of ignition.
- Remove flammable liquid with a non-combustible absorbent material.
- Vent the room.

Risk of explosion due to ignition caused by sparks generated by the switch contacts of the system. Death or serious injury can result. To avoid this hazard:

- Never operate the system in an environment containing explosive mixtures of oxygen, hydrogen, or other flammable gases.

Risk of damage to the eyes due to the laser beam of the barcode reader. Minor or moderate injury can result. To avoid this hazard:

- Do not look directly into the laser beam of the barcode reader.
- Do not place any reflective objects in front of the laser beam of the barcode reader.

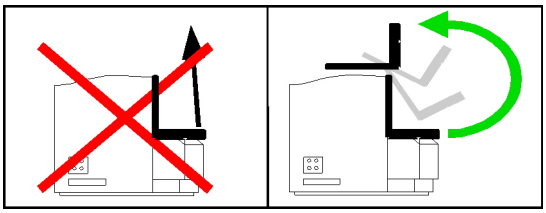


The system uses a covered laser beam to identify the barcode labels on tubes and vials. The beam of the used laser is protected from possible directly viewing.

Risk of property damage due to inaccurate handling of the system. Rough handling can disturb or damage internal components. Improper interventions on the system void the warranty and can result in service work having to be charged for. To avoid this hazard:

- Always handle the system with care.
- Switch off the system and secure it against accidental operation if there is visible damage to the system.
- Only carry out maintenance and repair work or replace parts as described in this manual.
- Only use Siemens Healthineers spare parts.
- Only use liquids for rinsing, cleaning, and purging which have been authorized by Siemens Healthineers.
- Do not use solvents or abrasive cloths to clean the system.

- Only open the covers of the system as displayed below.



Risk of property damage due to organic solvents, acids, alkalis, or other inorganic solvents affecting parts of the system. To avoid this hazard:

- Only use agents for cleaning and purging as described in this manual.

Modifications of the system software can affect the operation of the analyzer. To avoid this hazard:

- Do not modify the system software, for example, do not update the operating system or install any software not authorized by Siemens Healthineers.
- Only use virus-free USB flash drives or other data carriers with the computer.

Steam, solvents, and acid vapors can affect the operation of the system. To avoid this hazard:

- Select a place to set up the system where it will be least affected by steam, solvents, and acid vapors.

Risk of the reagent rotor overheating due to blocked air inlet and outlet area of the reagent rotor cooler. To avoid this hazard:

- Make sure the required space for ventilation is sufficient, see (➔ Page 302 *Dimensions and weight*).

2.4.5 Safe handling of samples, reagents, controls, standards, and consumables

Risk of infection due to potentially infectious material. Samples, reagents, controls, standards, consumables, and parts of the system which have come into contact with this material are potentially infectious. Death or serious injury can result. To avoid this hazard:

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask, according to national and local standards and regulations.
- Handle potentially infectious material in accordance with good laboratory practice, for example, as described in CLSI documents available at www.clsi.org.
- Only open covers as described in this manual.
- Avoid contact of the skin and mucosa with potentially infectious material.
- See the instructions for use of the reagents, controls, and standards as well as the application sheets.
- Check with local waste disposal authorities for specific requirements regarding potentially infectious material.
- Discard potentially infectious material according to national and local standards and regulations.

Risk of microbial contamination and particulate growth in the tubing that can lead to incorrect results. Incorrect results can lead to misdiagnoses and incorrect treatment. To avoid this hazard:

- Only use water with a low microbial content (≤ 100 CFU/mL) and particle content, as described, for example, in PH.EUR.NT2000 or in the United States Pharmacopeia (USP), monograph: Purified Water.

Risk of incorrect results due to incorrect level detection. Incorrect results can lead to misdiagnoses and incorrect treatment. To avoid this hazard:

- Ensure that the water used has a conductivity of > 30 µS/cm.
- In the case of water with a lower conductivity, for example, purified water, water for injections, or Siemens Healthineers purified water diluent, add 10 mL system diluent to 10 L water.

Risk of incorrect results. Incorrect results can lead to misdiagnosis and incorrect treatment. To avoid this hazard:

- Do not use whole-blood samples.
- When using third-party reagents, validate that Siemens Healthineers assays are not affected by carry-over.
- Measure controls for each assay.
- Monitor the stability of samples, reagents, controls, and washing solution, see the instructions for use.
- Do not store system liquids in the refrigerator. For more information, see the instructions for use of the buffer and diluent.
- Do not pool or refill buffer and diluent.

Risk of irritation of the skin and mucous membranes due to reagents, standards, controls, and liquids for cleaning and purging. Minor or moderate injury can result. To avoid this hazard:

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask, according to national and local standards and regulations.
- Pay attention to the information from the manufacturer regarding the compatibility of the gloves with the materials and liquids used.
- Follow all product instructions from the manufacturer.

Risk of property damage due to incorrect handling of samples, reagents, controls, standards, and consumables. To avoid this hazard:

- Only use approved Siemens Healthineers consumables.
- Keep all sample or reagent segments and any dilution frames away from sunlight and heat.
- See the instructions for use that are supplied with the reagents, controls, standards, and consumables.

Risk of pollution due to incorrect waste disposal. Damage to the environment can result. To avoid this hazard:

- Discard waste material according to national and local standards and regulations.

2.4.6 Limitations of the quantitative determination of proteins

Immunochemical techniques are subject to the limitations imposed by the Heidelberger-Kendall curve, whereby 2 different concentrations can be responsible for a single measurement signal.

In the case of fixed time nephelometry, the ascending branch of the Heidelberger-Kendall curve is extended by optimizing the course of the reaction so that most plasma proteins' measurement signals fall at the left side of the Heidelberger-Kendall curve, even at very high concentrations, see (➔ Page 325 *Heidelberger-Kendall curve*).

In individual cases, a very high protein concentration in the sample, for example, urine, could lead to questionable results. If this is the case, additional measurements must be taken (total protein determination, protein test strips, measurements using higher dilutions) in order to exclude the possibility that an antigen excess has occurred. The analyzer performs a pre-reaction for several assays. Samples in which an antigen excess is detected in the pre-reaction are automatically re-measured at a higher dilution.

Turbidity and particles in the samples can interfere with measurements. Particles that have been formed in incompletely coagulated serum and/or plasma or through the denaturization of proteins, or that may be present in urine and CSF samples (crystals, cells) must be removed by centrifugation before measurement.

Control sample and inter laboratory test sample results can vary depending on the measurement method used, since the techniques used to prepare them may differ or the samples may be old. It may therefore be required to evaluate these results according to method-specific target values.

Rheumatoid factors

In individual cases, the reaction could be disturbed by very high concentrations of rheumatoid factors (RF). The rheumatoid factors bind to the antibodies in the antigen-antibody complexes, leading to an increase in the size of the aggregates. The addition of special supplementary reagents can reduce this effect.

For more information on the RF concentration up to which the measurements are valid, see the instructions for use of the reagents.

Monoclonal immunoglobulins

Since monoclonal immunoglobulins (paraproteins) react differently with the antibodies used in the assays because of their structure, implausible results should be checked with other techniques (immunofixation, immunoelectrophoresis).

In immunochemical measurement methods, such samples can give different results at different dilutions.

2.4.7 Safe handling of personal data

The system processes personal data of both patients and laboratory staff. Personal data of the patient includes the patient's name, sex, and age, the patient ID, sample ID, sample results, notes, and other data. Some of these data are necessary for the use of the system according to its intended purpose, for example, sample ID and sample result. The personal data of the laboratory staff consists of their login data.

Risk of loss of privacy protection. To avoid this hazard:

- Before entering any personal data, consider carefully whether it is mandatory to enter this data. Personal data must be adequate, relevant, and limited to what is necessary in relation to the purposes for which they are processed.
- Only enter personal data in the fields explicitly provided for the respective type of input (for example, name, age, sex), not in fields provided for other personal data or any fields that allow free input. For example, the patient name must **not** be entered in the sample ID field. Only under this condition can protective measures implemented in the software become effective.
- When printing personal data, for example, from the laboratory journal, make sure that these printouts cannot be viewed by unauthorized persons.
- When exporting personal data, make sure that these exported data cannot be accessed by unauthorized persons.

2.4.8 IT security measures

This chapter describes the system's minimum IT networks and security requirements.

Hardware requirements

The device runs under the following minimum hardware requirements: Intel Celeron G540 Dual 2.5 GHZ 2M SKT, 8GB DDR3 SDRAM, 256 GB hard drive (or SSD) for the operating system and installed software. Communication via Can bus between subsystems and the main computer.

IT network characteristics

This product communicates to a LIS system using a serial RS-232 connection. To connect to the Smart Remote Services (SRS) infrastructure, a network connection is required. In such cases, the following network controls are in place:

- The host-based firewall is configured to block all unsolicited inbound connections
- Web browsing is disabled
- Access to SMB shares is blocked by default
- Remote access is controllable by the operator
- IPv6 tunneling techniques are disabled
- No wireless connectivity is built in
- All unnecessary ports have been closed

Security measures

The following security measures are in place:

- McAfee Embedded Control allow lists provide protection against malware infections
- Properly configured firewall blocks unwanted connections
- Audit logging ensures transparency (operating system only)
- Timely patching is available via SRS
- Hardened operating system drastically reduces the attack surface

Security and software/data updates are provided via the document library as secure update packages. These packages can be manually installed by the device operator using the Secure Download software. Continuous vulnerability assessment and remediation is performed throughout the complete product lifecycle by Siemens Healthineers.

Protection against unauthorized access	System includes role-based access, including separate accounts for routine operation and service tasks with strong password enforcement

2.4.9 Security whitepaper

For more information about specifications for software, hardware, network characteristics, and security controls, see the security whitepaper. This technical information is not part of the instruction manual, and is intended for the IT professional.

2.5 Safety messages

All safety messages must be observed to avoid hazardous situations which can result in death, injury, or damage to the equipment.

The following explains the signal words and their meanings.

Signal word	Meaning
WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury
CAUTION	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury
NOTICE	Indicates a hazardous situation which, if not avoided, could result in potential damage to property

The following explains the structure of safety messages.

⚠ WARNING

This section states nature and source of the hazard.

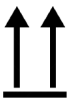
This section states potential consequences of not avoiding the hazard. This section can be combined with the previous section.

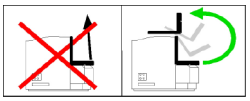
- This section lists preventive actions to avoid the hazard.

2.6 Symbols

This chapter describes all symbols except symbols in the software.

Symbol	Meaning
ACCESSORIES	Accessories
ANALYZER	Analyzer
CH REP	Authorized representative in Switzerland
BUFFER	Buffer
SMN	Catalog number

Symbol	Meaning
	CE mark
	China RoHS marking The number in the center indicates the environmental protection use period (in years).
	Computer
	Consult instructions for use
	Content is fragile and must be handled with care
	Contents
	Cuvettes
	Date of manufacture
	Unique device identification barcode
	Diluent
	Do not re-use
	EAC marking
	Evaporation caps
	Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Handle with care
	In vitro diagnostic medical device
	Indicates correct upright position of the transport package
	Keep away from sunlight and heat

Symbol	Meaning
	Keep dry
KEYBOARD	Keyboard
LOT	Lot data
MANUALS	Manuals
	Manufacturer
	Only open covers of the system as displayed
RxOnly 	Prescription device Only applicable in the USA
	Product line: Plasma Proteins
	Power off
	Power on
PREDIL WELLS	Predilution wells
	Protective earth, protective ground Identifies any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
REF	Registration reference number
	Remove caps from sample tubes before loading.
	Stacking of the transport package is not allowed and no load should be placed on the transport package.
SYSTEM	System
	Temperature limit

Symbol	Meaning
	Ukraine mark
	Warning: Assembly is susceptible to electrostatic charge
	Warning: Biological risks The labeled area can come into contact with potentially infectious material. The safety instructions for infectious material must be observed, see (➔ Page 18 *Safe handling of samples, reagents, controls, standards, and consumables*).
	Warning: Consult instructions for use for important cautionary information
	Warning: Laser beam
	Waste electrical and electronic equipment For more information, see (➔ Page 28 *Disposal*).

Symbols

2.7 Statutory provisions

The system bears a CE mark which certifies that the product meets the requirements of the following European directives:

- In vitro diagnostic medical devices Regulation (EU) 2017/746
- Directive on restriction of hazardous substances 2011/65/EU

Unauthorized changes to this product are not covered by the CE mark and the related Declaration of Conformity.

The system also meets the requirements of the following European directives:

- Directive on waste electrical and electronic equipment 2012/19/EU
- Battery Directive 2006/66/EC

The system has been developed, tested, and manufactured in accordance with IEC 61010-2-101, ISO 14971, IEC 61326-2-6, IEC 62304, and IEC 62366.

The product has been tested in accordance with IEC 61326-2-6. The product corresponds to CISPR 11 Class A regarding electromagnetic compatibility (EMC).

The system owner takes on the obligations arising from the national legislation about the operation of in vitro diagnostic medical devices.

3 Life cycle

This chapter describes the stages the system goes through, from delivery to disposal, and the requirements involved for the user with each stage.

3.1 Delivery

The system is delivered by Siemens Healthineers service.

For information on the scope of delivery, see the Quick Starter manual delivered with the system.

To check the delivery, proceed as follows:

1 Check the transport containers for signs of external damage.

2 If the transport containers show any visible signs of damage, inform Siemens Healthineers service immediately.

3.2 Installation

The system must be installed by Siemens Healthineers service.

WARNING

Incorrect installation of the system

Death or serious injury can result. Damage to the system can result.

- The system must only be installed by Siemens Healthineers service.
- Contact Siemens Healthineers service with regard to installation of the system.

The system is supplied without any power supply cables. Power supply cables that correspond to the requirements of the particular country must be used, for example, VDE, CSA-C22.2, No. 21, or CSA-C22.2, No. 49, see (→ Page 304 *Electrical conditions*).

3.3 Non-operation

To prepare the system for a period of more than 1 week of non-operation, proceed as follows:

WARNING

When the system is shut down for more than 2 hours, the buffer in the tubing and in the buffer reservoir can crystallize. The concentration of the buffer can change. False results can occur.

Death or serious injury to the patient can result.

- Before the system is shut down for more than 2 hours, rinse the system with water.
- Insert the level sensor of the buffer container into a container with at least 1 L of water.

Crystallization of the buffer in the tubing and in the buffer reservoir can change the concentration of the buffer. Delay of results can occur.

1 Clean the system, see (➔ Page 203 *Performing maintenance and cleaning*).

2 Contact Siemens Healthineers service with regard to non-operation of the system.

3.4 De-installation

The system must be de-installed by Siemens Healthineers service.

WARNING

Incorrect de-installation of the system

Death or serious injury can result.

- The system must only be de-installed by Siemens Healthineers service.
- Contact Siemens Healthineers service with regard to de-installation of the system.

3.5 Movement

The system must be moved by Siemens Healthineers service.

CAUTION

Incorrect movement of the system

Minor or moderate injury can result. Damage to or misalignment of the system can result.

- The system must only be moved by Siemens Healthineers service.
- Make sure the storage conditions are met.
- Contact Siemens Healthineers service with regard to movement of the system.

3.6 Disposal

In the European Union, disposal of the system is regulated by Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), and corresponding national transpositions.

Siemens Healthineers is committed to taking back and recycling electrical and electronic equipment in areas where the above mentioned directive is enforced.

In areas where the above mentioned directive is not enforced, contact Siemens Healthineers service with regard to disposal of the system.

Depending on the applications, parts of the system may be contaminated with biohazardous or hazardous chemical material.

To dispose of the system, proceed as follows:

WARNING

Infection due to contaminated material

Death or serious injury can result.

- Treat contaminated material according to national and local standards and regulations.
- Before movement or disposal, disinfect parts of the system that may be contaminated according to national and local standards and regulations.
- To get assistance, contact Siemens Healthineers service.

NOTICE

Pollution due to improper waste disposal

Damage to the environment can result.

- Contact Siemens Healthineers service with regard to disposal of the system.
- Do not treat electrical and electronic equipment as unsorted municipal waste.
- Check with the local waste disposal contractor for specific requirements regarding disposal.
- Collect waste electrical and electronic equipment separately, and return them to Siemens Healthineers in areas where the above mentioned directive is enforced.

1 De-install the system, see (➔ Page 27 *De-installation*).

2 Contact Siemens Healthineers service with regard to disposal of the system.

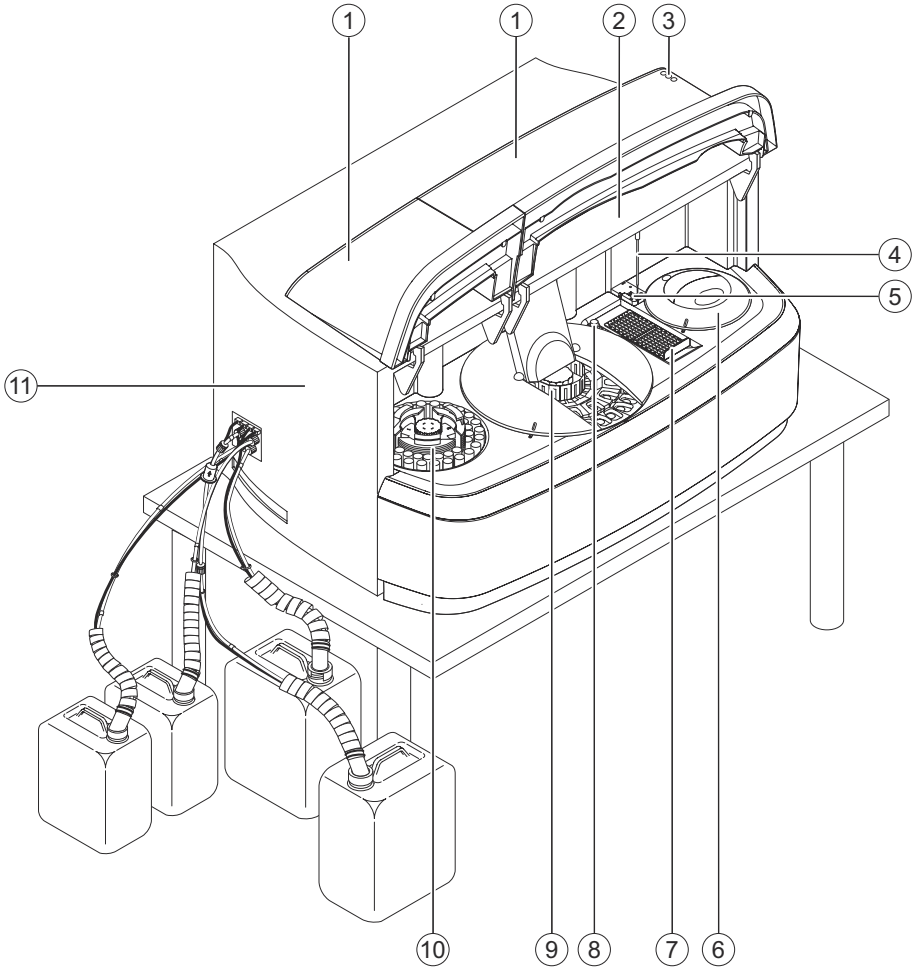
3 Dispose of the system according to national and local standards and regulations.

4 Description of the hardware

This chapter describes the operation and the functions of the hardware.

4.1 Overview of the analyzer

The analyzer is displayed in the figure below.



Front view of the analyzer

(1) Covers
(2) Power module (hidden)
(3) Display windows for LEDs
(4) Probe
(5) Wet station
(6) Cuvette rotor
(7) Dilution station
(8) Probe cleaner bottle
(9) Reagent rotor
(10) Sample rotor
(11) Syringe (hidden)

4.2 Functional units

This chapter describes the functional units of the analyzer.

4.2.1 Covers

The covers protect the operator from injury that could be caused by moving parts inside of the system. Both covers are equipped with sensors that detect the opening of the covers.

When opening of the covers is requested via the software, routine processing is interrupted for a defined period. During this time reagents and some consumables can be loaded onto the system. A message indicates that the covers can be opened.

Right cover

The right cover gives access to the reagent rotor, the dilution station, the wet station, the cuvette rotor, and the probe.

When the right cover is opened without access being requested via the software, a stop function is triggered and routine processing is interrupted.

Do not open the cover without access being requested via the software.

The system does not resume processing until the right cover has been closed. After the right cover has been closed, the system performs the following tasks:

- The stop function is canceled.
- Interrupted pre-dilutions are repeated automatically.

Left cover

The left cover gives access to the sample rotor.

When the left cover is opened without access being requested via the software, no stop function is triggered, but:

- The sample rotor stops moving.
- The probe no longer moves to the sample rotor.

Do not open the cover without access being requested via the software.

4.2.2 LEDs

3 LEDs are located in the upper right corner at the front of the analyzer. The LEDs indicate the overall status of the system, see the table below.

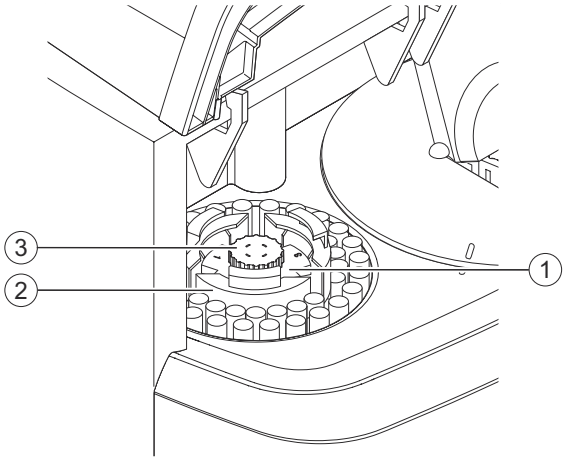
Color and marking	Explanation
Green	The system is running without problems.
Yellow	The system is initializing or is in its warming up phase. – or – The system is continuing processing but cannot complete processing.

Color and marking	Explanation
Red	A problem has occurred. The system cannot continue processing.

Explanation of the LED colors

4.2.3 Sample rotor

The sample rotor is located at the left side of the analyzer, behind the left cover, see the figure below.



Sample rotor

(1) Sample rotor
(2) Sample rotor segment
(3) Handwheel

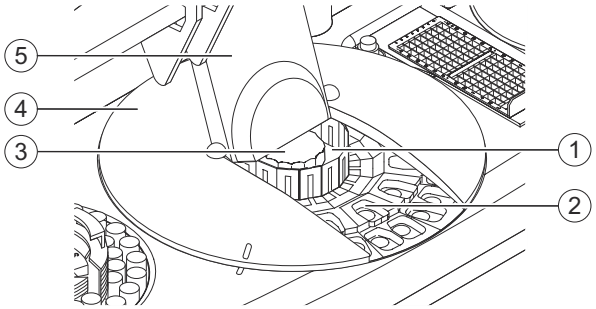
The sample rotor can hold 3 segments with tubes for samples, standards and user-defined controls, or special cups. The segment positions are consecutively numbered from 1–3. A maximum of 45 samples can be placed. The sample rotor is fixed to the analyzer by a handwheel.

When the left cover is closed, the sample rotor turns, bringing the barcode strips of the sample rotor segments into the scanning area of the barcode reader, see (→ Page 41 *Sample rotor segments*).

The barcode reader scans which positions for sample rotor segments are occupied, see (→ Page 38 *Barcode reader*).

4.2.4 Reagent rotor

The reagent rotor is located in the center of the analyzer, behind the right cover, see the figure below.



Reagent rotor

(1) Reagent rotor
(2) Reagent rotor segment
(3) Handwheel
(4) Reagent rotor cover
(5) Access lid of the reagent rotor cover

The reagent rotor can hold 15 segments for reagents and controls. The segment positions are consecutively numbered from 1–15. The reagent rotor is fixed to the system by a handwheel.

The reagent rotor is cooled to approximately 8 °C. The reagent cooler is positioned underneath the reagent rotor. When the system is used continuously, reagents and controls do not have to be removed and stored in the refrigerator. Condensation in the reagent rotor is drained into the waste container.

The reagent rotor is covered to ensure constant temperature. The reagent rotor cover has an access lid for loading reagent rotor segments during routine processing. The access lid is fitted with a sensor. If the access lid is not closed properly, the system will not start processing.

When the access lid of the reagent rotor is opened, a timing device is started. When the opening time of the access lid exceeds 10 minutes, the reagent cooler turns off. After the access lid has been closed, the reagent rotor must be cooled down again to approximately 8 °C. Routine operation is resumed once the temperature is reached.

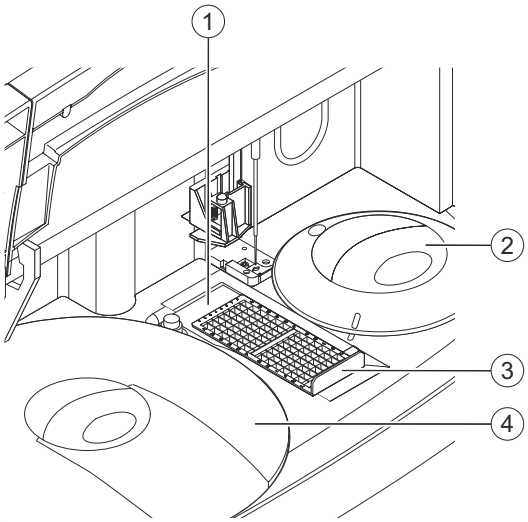
When the access lid of the reagent rotor cover has been closed, the reagent rotor turns, bringing the reagent rotor segments into the scanning area of the barcode reader, see (➔ Page 44 *Reagent rotor segments*).

The barcode reader scans if the reagent rotor segment is a reagent segment or a control segment, see (➔ Page 38 *Barcode reader*).

Reagent and control vials must be fitted with evaporation caps before they are loaded in the reagent rotor. When a reagent or control is required, the relevant vial is moved to the pipetting position. The system opens the evaporation cap, the probe aspirates liquid, and the system closes the evaporation cap, see (➔ Page 46 *N Evaporation Caps for Control Vials (2.5 mL) and N Evaporation Caps for Reagent Vials (5 mL)*).

4.2.5 Dilution station

The dilution station is located between the reagent rotor and the cuvette rotor, behind the right cover, see the figure below.



Dilution station

(1) Dilution station
(2) Cuvette rotor cover
(3) Dilution frame
(4) Reagent rotor cover

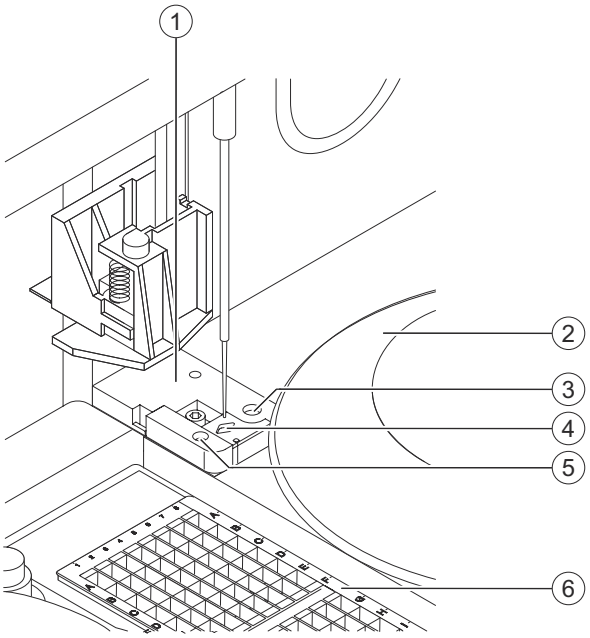
The dilution station consists of a dilution frame in which the dilution strips are inserted. The dilution frame can hold a maximum of 2 x 8 dilution strips. The dilution frame does not need to be fully loaded, see (➔ Page 46 *Dilution strips*).

When the right cover is closed, a light barrier is used to check whether the dilution frame has been inserted. The system checks whether dilution strips are present by moving the probe to the relevant position and following the outline of the dilution cup. If no outline is detected, no dilution strip is present. The amount of liquid in the dilution cups is determined by a filling level check executed by the probe.

In order to prepare pre-dilutions, the system moves the dilution frame so the required dilution cup is positioned in the pipetting position.

4.2.6 Wet station

The wet station is located between the dilution station and the cuvette rotor, behind the right cover, see the figure below.



Wet station

(1) Wet station
(2) Cuvette rotor cover
(3) Fountain area
(4) Dispensing area
(5) Buffer reservoir
(6) Dilution station

The wet station is connected to the buffer container, the diluent container, the water container, and the waste container. Excess liquid is discharged to the waste container.

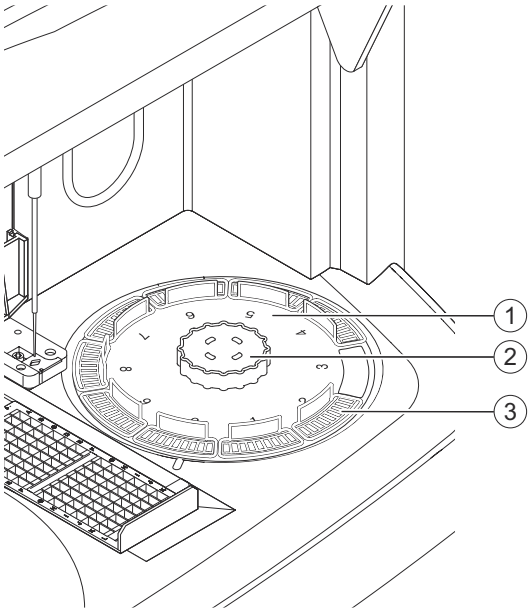
In the fountain area, the probe is cleaned externally with water by immersion through an injection ring. Excess water is discharged to the waste container. When the probe is not in operation, the probe is dipped into the fountain area to prevent it from drying out.

In the dispensing area, the probe dispenses liquid waste and performs internal cleaning with diluent. Liquid waste is discharged to the waste container.

The buffer reservoir contains the buffer required for certain assays. The buffer reservoir is supplied with buffer from the buffer container so that the re-filling process of buffer does not interrupt the routine. The filling level in the buffer container is checked by the level detection of the probe.

4.2.7 Cuvette rotor

The cuvette rotor is located at the right side, behind the right cover, see the figure below.



Cuvette rotor

(1) Cuvette rotor
(2) Cuvette segments
(3) Handwheel

The cuvette rotor can hold 10 cuvette segments, each comprising 9 cuvettes. The segment positions are consecutively numbered from 0–9. The cuvette rotor is fixed to the system by a handwheel, see (➔ Page 46 *N Cuvette segments for BN ProSpec*).

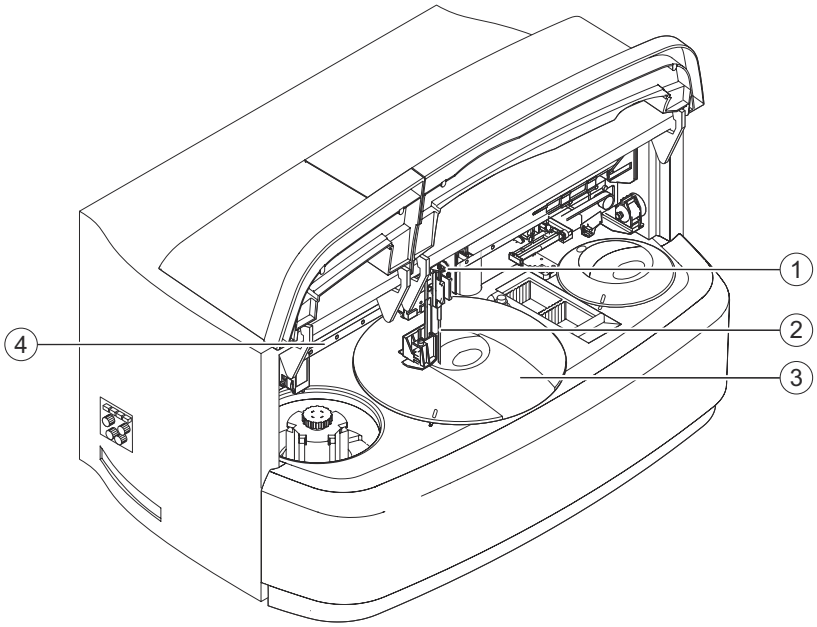
The cuvette rotor is heated to approximately 37 °C. The cuvette rotor is surrounded by an insulator.

The cuvette rotor is covered to ensure constant temperature. The cuvette rotor cover has a hole for pipetting. The cuvette rotor cover is fitted with a sensor. If the cuvette rotor cover is not closed properly, the system will not start processing.

When the right cover is closed, the system scans the cuvette segments. The differentiation between unused cuvettes and used cuvettes is performed through blank readings. Measurements are taken during the movement phases of the cuvette rotor.

4.2.8 Transfer arm and probe

The transfer arm with the probe is located in the upper part of the analyzer. The transfer arm moves along a guide rail stretching the width of the housing, see the figure below.



Transfer arm

(1) Transfer arm
(2) Probe
(3) Reagent rotor cover
(4) Guide rail

The transfer arm can move horizontally and vertically. The transfer arm has a fitting for mounting the probe and is flexibly mounted to prevent damage. Sensors on the probe detect when the tip contacts a hard object.

When evaporation caps of reagents and controls have to be opened, the lower part of the transfer arm pushes down on 1 out of 2 cylindrical pins on the reagent rotor cover. The evaporation cap is then opened by rotation of the reagent rotor.

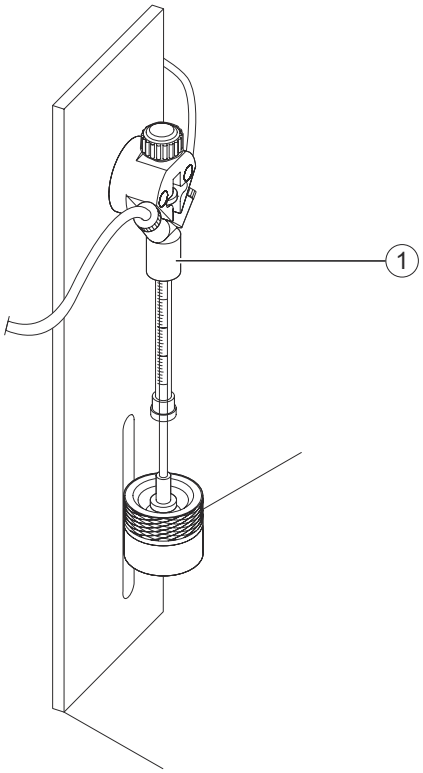
The probe is mounted to the transfer arm. The probe performs the following tasks:

- Pipetting samples, controls, and standards into the dilution cups
- Preparing pre-dilutions in the dilution cups
- Pipetting reagents, buffer, and pre-dilutions into the cuvettes
- Mixing liquids in the dilutions cups and cuvettes through vibration of the probe
- Pipetting undiluted samples into the cuvettes
- Heating liquids to approximately 37 °C within the probe
- Checking for loaded dilution strips
- Determination of the filling level of liquid in a sample, standard, control, or reagent container, in the dilution cups, the cuvettes, the probe cleaner bottle, and the buffer reservoir

The probe is cleaned after every transfer step.

4.2.9 Syringe

The syringe is located at the left side, behind the sample rotor, see the figure below.



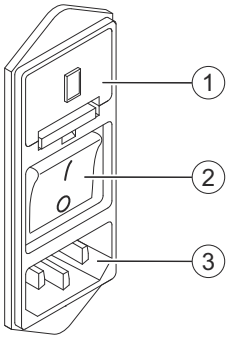
Syringe

(1) Syringe

The syringe has a volume of 500 µL. The syringe is connected to the probe and supplies the probe with diluent and water. Valves control which liquid is supplied to the probe or aspirated by the probe.

4.2.10 Power module

The power module is located at the right side of the alayzer, see the figure below.



Power module

(1) Fuse holder
(2) Main switch
(3) Power supply socket

The fuse holder contains 2 fuses.

The main switch has the following positions:

- Position **0**: The system is off.
- Position **I**: The system is on.

The system has to be connected to a wall outlet that meets the electrical conditions, see (→ Page 304 *Electrical conditions*).

4.3 Components inside the analyzer

This chapter describes the components inside the analyzer.

4.3.1 Air bubble detector

The air bubble detector is located at the left side of the analyzer, next to the syringe. When air bubbles are detected in the diluent tubing, the system rinses the diluent tubing. If air bubbles are still detected, the system stops processing. Then the diluent has to be replaced.

4.3.2 Barcode reader

The barcode reader is located between the sample rotor and the reagent rotor. The barcode reader is mounted in a way that it can turn either to the sample rotor or to the reagent rotor.

The barcode reader is active only during scanning.

The barcode reader performs the following tasks:

- Identifying sample rotor segments: The barcode reader scans the barcode label at the left side of the sample rotor segments and thus identifies sample, standard, cup-in-tube, cup-behind-tube, Eppendorf cup, and Hitachi cup segments.
- Identifying empty positions in sample rotor segments: The barcode reader scans every position of the sample rotor segments. If the position in front is empty, the barcode strip on the sample rotor segment is scanned.
- Identifying samples and standards in sample rotor segments: The barcode reader scans every position of the sample rotor segments. If a vial with a barcode is present, the vial is identified. If no barcode is present or if the barcode cannot be scanned, the sample or standard information has to be entered manually.
- Identifying reagent rotor segments: The barcode reader scans every position of the reagent rotor segments. If a position is empty, the barcode on the back of the segment is scanned and thus the segment is either identified as a reagent or a control segment. If all positions are occupied, the barcodes on the vials are scanned and thus the segment is either identified as a reagent or a control segment. If no barcode is present on the vials or if the barcode cannot be scanned, the reagent or control information has to be entered manually.

If no barcode on any vial of a reagent rotor segment can be scanned, the positions are displayed as empty in the dialog **Loading reagents**. The barcodes of the vials cannot be entered manually. To enter the reagent or control information manually, separate the vials on different reagent rotor segments.

For more information on the barcode reader, see (→ Page 303 *Barcode reader*)

4.3.3 Dilutor

The dilutor is located at the left side of the analyzer, on the rear side of the syringe. The dilutor consists of pumps and valves.

The dilutor is connected to the following components:

- Liquid containers (water, buffer, diluent, waste)
- Syringe
- Wet station
- Reagent rotor

The dilutor transfers and regulates liquids as follows:

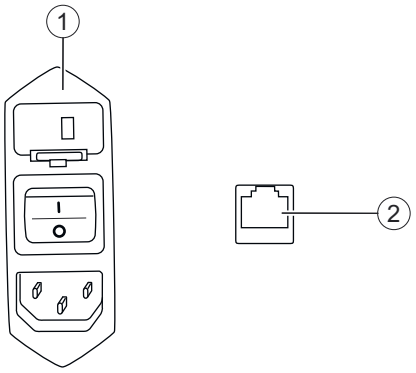
- Diluent from the diluent container to the probe
- Water from the water container to the probe and to the wet station
- Buffer from the buffer container to the wet station
- Liquid waste from the wet station and from the reagent rotor to the waste container

A valve next to the syringe regulates the flow of liquids:

- When the valve is open, the syringe is without function. The system dispenses diluent via the probe to the diluent station or rinses the probe with water.
- When the valve is closed, the syringe builds up excess pressure or low pressure so the probe dispenses or aspirates sample, reagent, standard, control, or buffer.

4.4 External and peripheral devices

The system can be connected to several external and peripheral devices. The connections are located at the right side of the analyzer, beside the power module, see the figure below.



Connections for external devices

(1) Power module
(2) Ethernet port

The power module consists of multiple elements, see (➔ Page 37 *Power module*).

The serial ports can be used for additional devices, for example, LIS.

The Ethernet port is used to connect the system to a computer.

4.4.1 Peripheral devices

Peripheral devices include:

- Computer
- Monitor
- Keyboard
- Mouse
- Printer (optional)

The system is connected to a computer. The computer performs the following tasks:

- Enabling communication between operator and system
- Enabling dialog selections
- Enabling the input of sample information
- Printing dialogs
- Communication with the LIS, if available

4.4.2 LIS (optional)

The system can be connected to a laboratory information system (LIS) via a serial RS-232 port. For more information, see the data interface manual.

The LIS sends orders to the system and receives results.

4.5 Consumables and accessories

This section lists consumables and accessories for the system. For ordering information, see the Siemens Healthineers product catalog or contact Siemens Healthineers service.

Instructions for using the consumables and accessories are given in the respective procedures.

4.5.1 Sample rotor segments

The various types of sample rotor segments are identified by differently colored plain text labels located on the grip of the sample rotor segment. These plain text labels have numbers, the segment IDs, corresponding to the barcode label located at the left side of the sample rotor segment. The first 2 digits of the segment ID identify the type of sample rotor segment, the next 2 digits identify the running number within the type of the sample rotor segment. The running number on the plain text label is copied in larger type size.

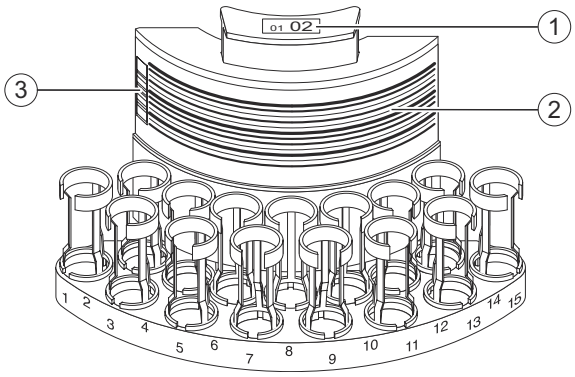
The barcode label is attached vertically at the left side of the sample rotor segment and contains an additional empty digit and check digit. The plain text label and the barcode label are delivered on barcode sheets in pairs and must be attached as such.

Each sample rotor segment is fitted with adapters to hold different kinds of cups, tubes, and vials. Behind the adapters, a barcode strip is attached for the barcode reader to identify empty positions, see (➔ Page 38 *Barcode reader*).

The adapters ensure that the cups, tubes, and vials are always centered in their position. This reduces the residual volume. For each type of sample rotor segment, a maximum probe immersion depth is defined in the software.

Barcode labels on cups, tubes, or vials must be aligned towards the outer edge of the sample rotor segment. Adapters have openings so the barcodes can be scanned.

Sample segment

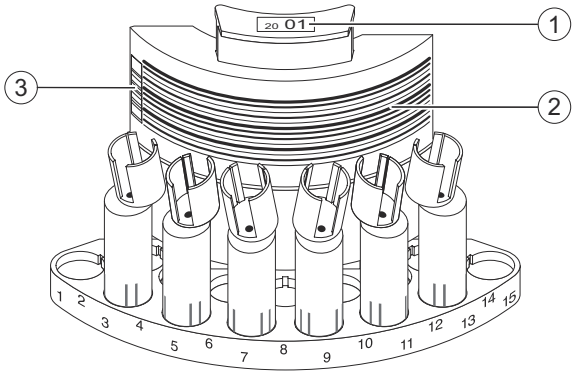


Sample segment

(1) Plain text label
(2) Barcode strip
(3) Barcode label

Sample segments are fitted with adapters to hold up to 15 sample tubes, see (➔ Page 306 *Sample rotor segments*).

Standard segment

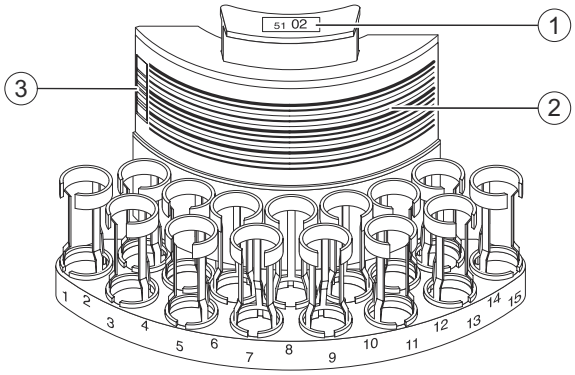


Standard segment

(1) Plain text label
(2) Barcode strip
(3) Barcode label

Standard segments are fitted with adapters to hold up to 6 standard vials. Only positions 3, 5, 7, 9, 11, and 13 must be used, see (➔ Page 306 *Sample rotor segments*).

Cup-in-tube segment

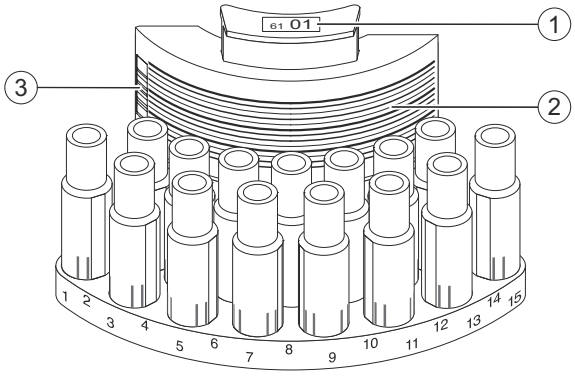


Cup-in-tube segment

(1) Plain text label
(2) Barcode strip
(3) Barcode label

Cup-in-tube segments are identical in construction to sample segments. Cup-in-tube segments are fitted with adapters to hold up to 15 sample tubes. All common cups, including Dimension cups from Siemens Healthineers, can be used within the tubes, see (➔ Page 306 *Sample rotor segments*).

Eppendorf cup segment

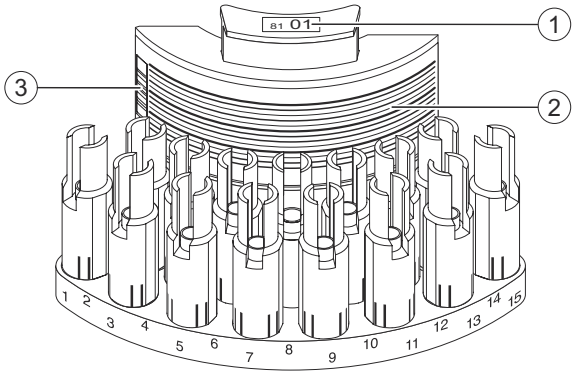


Eppendorf cup segment

(1) Plain text label
(2) Barcode strip
(3) Barcode label

Eppendorf cup segments are fitted with adapters to hold up to 15 Eppendorf cups, see (➔ Page 306 *Sample rotor segments*).

Hitachi cup segment

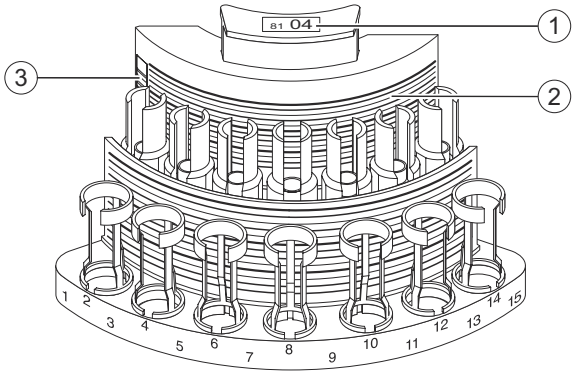


Hitachi cup segment

(1) Plain text label
(2) Barcode strip
(3) Barcode label

Hitachi cup segments are fitted with adapters to hold up to 15 Hitachi cups, see (➔ Page 306 *Sample rotor segments*).

Cup-behind-tube segment

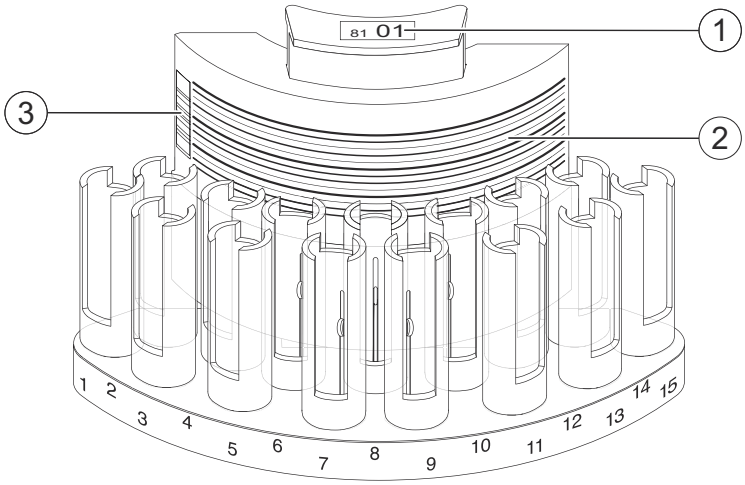


Cup-behind-tube segment

(1) Plain text label
(2) Barcode strip
(3) Barcode label

Cup-behind-tube segments are fitted with 2 rows of adapters to hold up to 7 sample tubes and 7 cups. The lower row holds empty sample tubes with barcodes that identify the sample behind. The upper row holds the cups with the sample material, see (➔ Page 306 *Sample rotor segments*).

False bottom tube segment



False bottom tube segment

(1) Plain text label
(2) Barcode strip
(3) Barcode label

False bottom tube segments are fitted with adapters to hold up to 15 False bottom tubes, see (➔ Page 306 *Sample rotor segments*).

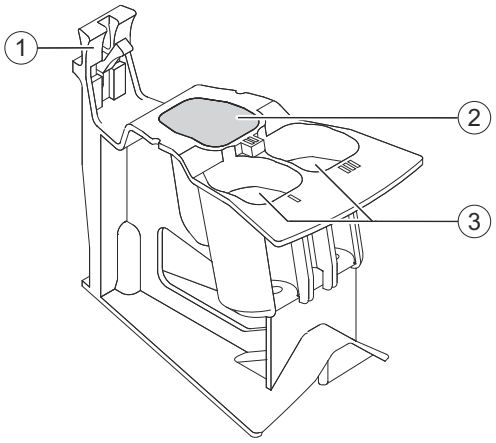
4.5.2 Reagent rotor segments

2 types of reagent rotor segments are identified by differently colored grips and different barcode labels. The barcode labels are attached vertically at the back of every position for reagent or control vials for the barcode reader to scan the type of reagent rotor segment, see (➔ Page 38 *Barcode reader*).

Reagent and control vials are positioned at an 11° angle to allow optimal reagent and control consumption. Reagent and control vials must be fitted with evaporation caps before they are placed in the reagent rotor segments, see (➔ Page 46 *N Evaporation Caps for Control Vials (2.5 mL) and N Evaporation Caps for Reagent Vials (5 mL)*).

Barcode labels on reagent and control vials must be positioned in the direction of the outer edge of the reagent rotor segment. The reagent rotor segments have openings so the barcodes can be scanned.

Reagent segment

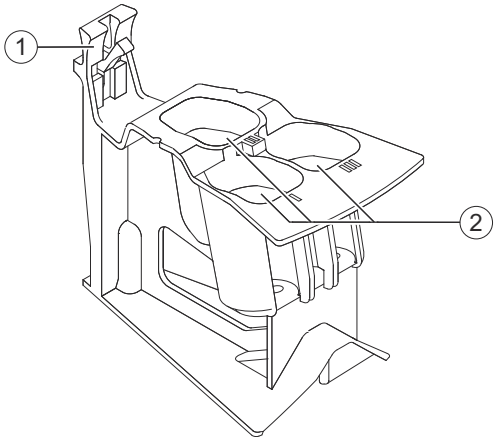


Reagent segment

(1) White grip
(2) Locked position
(3) Positions for reagent vials

The reagent segment has 2 positions for reagent vials in the outer area. The inner position is locked, see (➔ Page 307 *Reagent rotor segments*).

Control segment



Control segment

(1) Yellow grip
(2) Positions for control vials

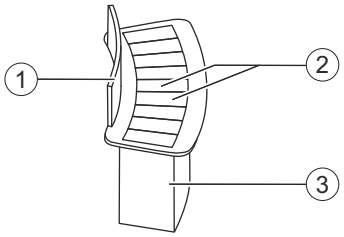
The control segment has 3 positions for control vials:

- 2 outer positions
- 1 inner position

For more information, see (➔ Page 307 *Reagent rotor segments*).

4.5.3 N Cuvette segments for BN ProSpec

This product is suitable for Atellica NEPH 630 analyzers.



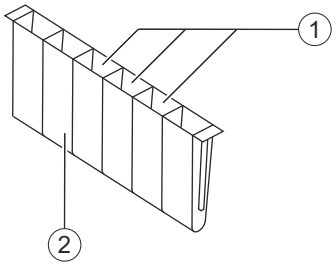
Cuvette segment

(1) Grip
(2) Cuvettes
(3) Cuvette segment

Each cuvette segment consists of 9 cuvettes and is wrapped in a plastic pouch. The cuvettes hold dilutions, reagents, and buffer for the measurement of the protein concentration in the cuvette rotor.

The cuvette segments have a grip with which they can be handled without touching the surfaces of the cuvettes, see (➔ Page 307 *Cuvette segments*).

4.5.4 Dilution strips



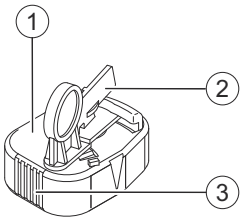
Dilution strip

(1) Dilution cups
(2) Dilution strip

Each dilution strip consists of 6 dilution cups. The dilution cups are used to prepare pre-dilutions of samples, controls, and standards, see (➔ Page 307 *Dilution strips*).

4.5.5 N Evaporation Caps for Control Vials (2.5 mL) and N Evaporation Caps for Reagent Vials (5 mL)

This product is suitable for Atellica NEPH 630 analyzers.



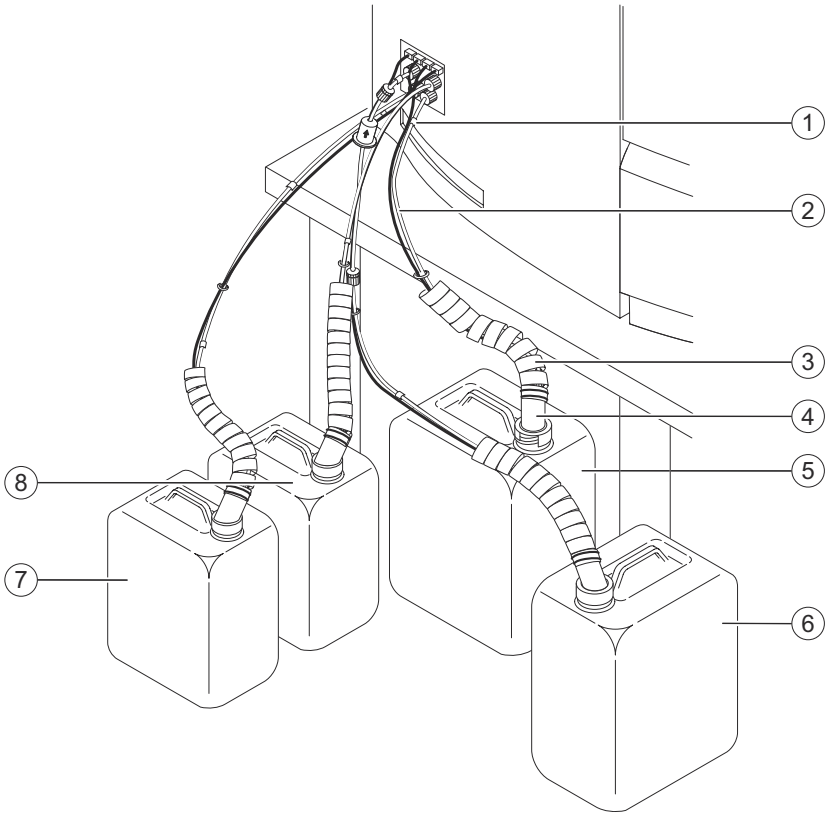
Evaporation cap

(1) Evaporation cap
(2) Slider
(3) Vertical striation

Evaporation caps are used to minimize evaporation and to extend the on-board stability of reagents and controls. The vertical striation on the evaporation cap and the barcode on the label of the vial must be aligned, see (➔ Page 307 *Evaporation caps*).

4.5.6 Liquid containers, level sensors, and tubing

The liquid containers are connected to the left side of the system, see the figure below.



Liquid containers, level sensors, and tubing

(1) Colored marking
(2) Tubing
(3) Spiral tube
(4) Level sensor
(5) Waste container
(6) Water container
(7) Buffer container
(8) Diluent container

The filling levels of the 4 liquid containers are checked by level sensors attached to the tubing and inserted into the liquid containers. Insufficient filling levels of water, buffer, and diluent as well as a too high filling level of liquid waste are displayed by the software.

When a container is empty or, in the case of the waste container, full, a stop function is triggered. The software requests to refill the liquid or empty the waste container. When the liquid is refilled or the waste container is emptied, the tubing is automatically rinsed after confirmation.

The liquid containers are supplied in 5 L or 10 L volumes. The tubing bears differently colored markings, see the table below.

Liquid	Volume	Color	Liquid delivered to
Diluent	5 L	Blue	Probe
Buffer	5 L	Red	Wet station
Water	10 L	White	Probe and wet station

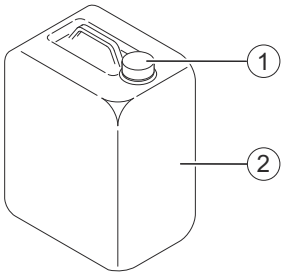
Liquid	Volume	Color	Liquid delivered to
Waste	10 L	Green	-

Characteristics of the liquid containers

Spiral tubes are fitted around the tubing and cable to prevent bends in the tubing.

The distance between the liquid containers and the table edge is restricted to 80 cm. The restriction can only be changed by Siemens Healthineers service.

Buffer container

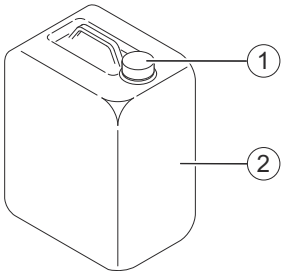


Buffer container

(1) Screw cap
(2) Buffer container

Buffer is required to prepare the dilution for certain assays. Detailed descriptions of the buffer, its handling, and its applications are provided on the label of the buffer container.

Diluent container

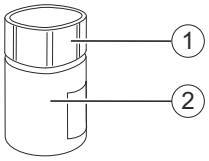


Diluent container

(1) Screw cap
(2) Diluent container

Diluent is required to prepare pre-dilutions and to rinse the inside of the probe. Detailed descriptions of the diluent, its handling, and its applications are provided on the label of the diluent container.

4.5.7 Probe cleaner bottle



Probe cleaner bottle

(1) Screw cap
(2) Probe cleaner bottle

Probe cleaner is required to clean the probe after every transfer step for assays with extremely adhesive proteins. The probe cleaner bottle is located between the reagent rotor and the dilution station. Detailed descriptions of the probe cleaner, its handling, and its applications are provided in the corresponding instructions for use.

4.6 Reagents, standards, and controls

Detailed descriptions of the reagents, standards, and controls, their handling, their applications, and the performance of the reagents are provided in the corresponding instructions for use.

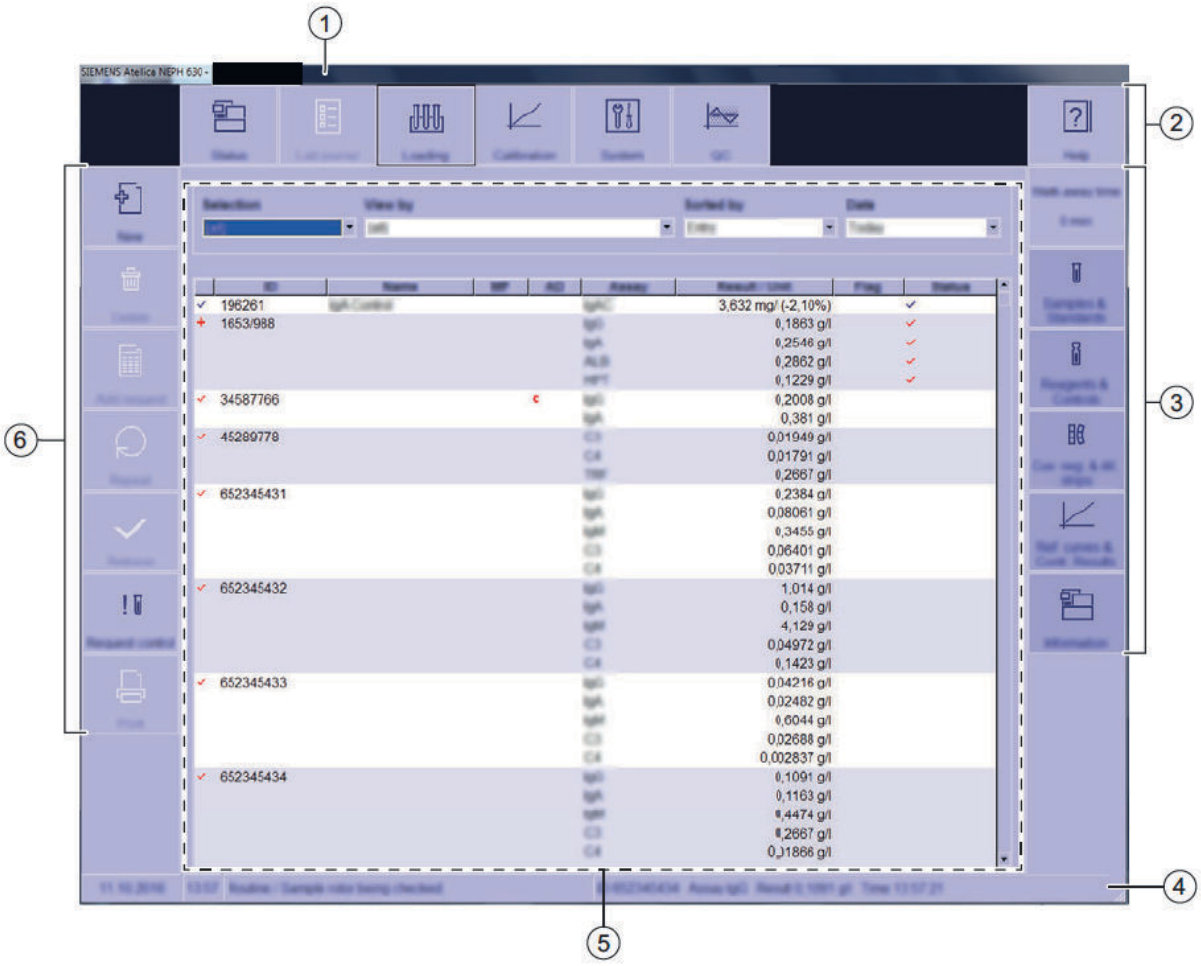
5 Description of the software

This chapter describes the operation of the software.

5.1 Overview of the screen

The figure below shows an **example** of a lab journal, displaying all information levels.

The **example** uses the decimal separators of the English software version. Note that the representation of the decimal separators varies by country.



Overview of the screen

(1) Title bar
(2) Navigation bar
(3) Status bar
(4) Status line
(5) Dialog
(6) Action bar

Elements of the screen are explained in the table below.

Information	Explanation
Title bar	The title bar displays the title of the active dialog, corresponding to the selected routine and action.
Navigation bar	The navigation bar is used to access the dialogs of the system via routine buttons. The routine button displayed with a white icon is inactive. The corresponding routine is currently displayed in the dialog.
Status bar	The status buttons in the status bar display the status of various parts of the system. For more information on the status buttons, see (➔ Page 52 *Status buttons*).
Status line	The status line displays date, time, the action currently performed by the system, and details of the job last finished by the system.
Dialog	The dialog displayed is dependent on the active routine.
Action bar	The action bar displays action buttons as appropriate to each dialog. Action buttons displayed with white icons are inactive. The corresponding action is not available.

Elements of the screen

5.2 General elements

This chapter describes general elements of the software that are used in multiple dialogs.

5.2.1 Status buttons

The status buttons are displayed to the right of most dialogs. The status buttons are explained in the table below.

Button	Explanation
Walk-away time – or – **Unfinished jobs**	Estimated walk-away time – or – Number of unfinished jobs The user can change the displayed text by clicking the button.
Samples & Standards	Status of the level of samples and standards loaded in the sample rotor
Reagents & Controls	Status of the level of reagents and controls loaded in the reagent rotor
Cuv. seg. & dil. strips	Status of cuvette segments loaded in the cuvette rotor and dilution strips loaded in the dilution station
Ref. curves & Contr. results	Status of the required reference curves and control results

Button	Explanation
Information	Status of the following environmental conditions and parts of the system: • Temperatures (ambient temperature, temperature in the reagent rotor, temperature in the cuvette rotor, temperature in the probe) • Left cover, right cover, access lid of the reagent rotor cover, and cuvette rotor cover • Filling levels of the system liquids • Filling level of the waste container • Connection to the analyzer

Status buttons

The status buttons display the status of various parts of the system by means of colors. If multiple problems for a specific part of the system are detected, the color of the problem with the highest priority is displayed first. The colors are explained in the table below.

Color	Explanation
Red	The requested jobs cannot be processed. The system is not operating.
Yellow	The requested jobs cannot be completely processed. If the user does not resolve the problem, the status button will change to red soon. – or – The system is warming up.
Blue	All material required is available and valid, the system is operating. All requested jobs can be processed.

Colors of status buttons

When the user places the mouse pointer over a red or yellow status button, a tool tip text specifying the problem is displayed. Only after a problem is solved, the next problem is displayed in the tool tip text.

When the user clicks a red or yellow status button, there are 2 possibilities:

- The dialog where the problem can be resolved is displayed.
- The dialog **Logbook** that provides detailed information on the problem is displayed.

5.2.2 Common display functions in dialogs

This chapter describes common display functions used in multiple dialogs.

Select

In some dialogs, the user can select and de-select rows, dilution strips, or cuvette segments, see the table below.

Selection	Action
Select 1 row, dilution strip, or cuvette segment.	Click the row, dilution strip, or cuvette segment.
De-select 1 row, dilution strip, or cuvette segment.	Hold the **Ctrl** key, then click the row, dilution strip, or cuvette segment again.

Selection	Action
Select a series of consecutive rows, dilution strips, or cuvette segments.	Click the first row, dilution strip, or cuvette segment, then hold the **Shift** key while clicking the last row, dilution strip, or cuvette segment.
De-select a series of consecutive rows, dilution strips, or cuvette segments.	Hold the **Shift** key, then click the last row, dilution strip, or cuvette segment that should be included in the new selection.
Select multiple rows, dilution strips, or cuvette segments.	Click the first row, dilution strip, or cuvette segment, then hold the **Ctrl** key while clicking every row, dilution strip, or cuvette segment.
De-select multiple rows, dilution strips, or cuvette segments.	Hold the **Ctrl** key, then click the rows, dilution strips, or cuvette segments again.
Select all rows, dilution strips, or cuvette segments.	Only in the dialog **Lab journal**: Hold the**Ctrl** key, then press the key **A**.

Select rows, dilution strips, or cuvette segments

Scroll

Some dialogs provide scroll functions, see the table below.

Button or slider	Explanation	Action
	Scroll up	Click or click and hold
	Scroll down	Click or click and hold
	Scroll left	Click or click and hold
	Scroll right	Click or click and hold
	Slide vertically or horizontally	Drag

Scroll functions

Adjust column widths

In some dialogs, the user can adjust column widths by clicking the left or right border of the table heading and dragging it to the left or to the right. The user can reset the default column width with a right-click on the mouse within the dialog.

Sort

In some dialogs, the user can sort the data in tables by clicking in the heading of the corresponding column.

Filter

In some dialogs, the user can filter the displayed data. Filters are indicated by an arrow right of a drop-down list, for example,  .

Master navigation

Some dialogs provide so-called master navigation. In the dialog, the user can browse the items of the master dialog, that is, the higher-level dialog from which the current dialog was displayed via an action button. Master navigation is a shortcut for going back to the master dialog, selecting a neighboring item, and displaying the current dialog again, see the table below.

Button	Explanation
	Selects the previous item in the master dialog

Button	Explanation
	Selects the next item in the master dialog
	Selects the first item in the master dialog
	Selects the last item in the master dialog

Master navigation

5.2.3 Common action buttons

The action bar displays action buttons as appropriate to each dialog. Action buttons common to various dialogs are explained in the table below.

Action button	Explanation
Apply	Saves the data in the dialog
Cancel	Cancels the current process
Close	Closes the dialog without saving
Delete	In the dialog **Lab journal**: Deletes results permanently or deletes sample or control IDs permanently which are no longer on-board In all other dialogs: Deletes all selected items finally
De-select all	De-selects all items in the dialog
Print	Prints the selected data with or without a preview, see (➔ Page 107 *Print preview*)
Save	Saves data and closes the dialog
Select all	Selects all items in the dialog

Common action buttons

5.2.4 Flags and symbols

Flags and other symbols in various dialogs and on printed pages are explained in the table below.

Flag / symbol	Printed pages	Dialog	Column	Explanation
	**STAT**	**Lab journal**	Left column	The sample is processed as a STAT sample.
	**M**	**Lab journal**	Left column	Jobs are requested for the sample but the sample is missing.
	**M**	**Lab journal**	Left column	Jobs are requested for the control but the control is missing.
	-	**Loading reagents**	Left column	This is a reagent.

Flag / symbol	Printed pages	Dialog	Column	Explanation
	-	**Loading reagents**	Left column	This is a control.
	-	**Calibration**	**Flag**	**Controls**: The control is empty or insufficient. **Reagents**: The reagent is empty or insufficient.
	...	**Lab journal**	**Status**	**Samples**: The sample is being measured. **Controls**: The control is being measured.
	-	**Calibration**	**Flag**	**Assays**: A new reference curve has been requested or is being measured. **Reagents**: The reference curve has been requested.
	E	**Lab journal**	**Flag**	A hardware problem has occurred or a resource was low during processing of the sample. The measurement was canceled. This flag is called a technical flag.
	E	**Lab journal**	**Flag**	A hardware problem has occurred or a resource was low during processing of the control. The measurement was canceled. This flag is called a technical flag.
	M	**Lab journal**	**Status**	The sample is missing.
	M	**Lab journal**	**Status**	The control is missing.
	-	**Calibration**	**Flag**	**Assays**: At least 1 valid reference curve is active but not all relevant reagents are onboard. **Reagents**: The reference curve is valid and active but not all relevant reagents are onboard. – or – The reference curve is not active.
	-	**Lab journal**	Left column	All jobs for the sample have been processed.
	-	**Lab journal**	Left column	All jobs for the control have been processed.
	R	**Lab journal**	**Status**	The sample result has been released.
	R	**Lab journal**	**Status**	The control result has been released.
	-	**Calibration**	**Flag**	**Assays**: At least 1 valid reference curve is active, all relevant reagents are on-board. **Reagents**: The reference curve is valid and active, all relevant reagents are on-board.
	-	**Calibration**	**Flag**	**Assays**: All reference curves are invalid. **Reagents**: The reference curve is invalid.

Flag / symbol	Printed pages	Dialog	Column	Explanation
	-	**Calibration**	**Flag**	Assays: A new reference curve was measured but another reference curve is valid and active. Reagents: The reference curve was measured but is not valid.
< (value)	<	**Lab journal**	**Result/Unit**	Samples: The sample result is below the measurement range. Controls: The control result is below the measurement range.
> (value)	>	**Lab journal**	**Result/Unit**	Samples: The sample result is above the measurement range. Controls: The control result is above the measurement range.
	?	**Lab journal**	**MP**	Different manual pre-dilutions of the sample were detected by the system.
	a	**Lab journal**	**AD**	The dilution used for the measurement of the sample is 1 : 1 and differs from the initial dilution.
	a	**Lab journal**	**AD**	The dilution used for the measurement of the control is 1 : 1 and differs from the initial dilution.
	A	**Lab journal**	**MP**	The sample is manually pre-diluted 1 : 5.
	b	**Lab journal**	**AD**	The dilution used for the measurement of the sample is 1 : 5 and differs from the initial dilution.
	b	**Lab journal**	**AD**	The dilution used for the measurement of the control is 1 : 5 and differs from the initial dilution.
	B	**Lab journal**	**MP**	The sample is manually pre-diluted 1 : 20.
	c	**Lab journal**	**AD**	The dilution used for the measurement of the sample is 1 : 20 and differs from the initial dilution.
	c	**Lab journal**	**AD**	The dilution used for the measurement of the control is 1 : 20 and differs from the initial dilution.
	d	**Lab journal**	**AD**	The dilution used for the measurement of the sample is 1 : 100 and differs from the initial dilution.
	d	**Lab journal**	**AD**	The dilution used for the measurement of the control is 1 : 100 and differs from the initial dilution.
	e	**Lab journal**	**AD**	The dilution used for the measurement of the sample is 1 : 400 and differs from the initial dilution.
	e	**Lab journal**	**AD**	The dilution used for the measurement of the control is 1 : 400 and differs from the initial dilution.
	f	**Lab journal**	**AD**	The dilution used for the measurement of the sample is 1 : 2,000 and differs from the initial dilution.
	f	**Lab journal**	**AD**	The dilution used for the measurement of the control is 1 : 2,000 and differs from the initial dilution.

Flag / symbol	Printed pages	Dialog	Column	Explanation
g	g	**Lab journal**	**AD**	The dilution used for the measurement of the sample is 1 : 8,000 and differs from the initial dilution.
g	g	**Lab journal**	**AD**	The dilution used for the measurement of the control is 1 : 8,000 and differs from the initial dilution.
h	h	**Lab journal**	**AD**	The dilution used for the measurement of the sample is 1 : 32,000 and differs from the initial dilution.
h	h	**Lab journal**	**AD**	The dilution used for the measurement of the control is 1 : 32,000 and differs from the initial dilution.
h	h	**Lab journal**	**Flag**	The control result is above confidence range.
H	H	**Lab journal**	**Flag**	The sample result is above reference range.
H	S	**Lab journal**	**Status**	The sample result has been sent to the LIS, if available.
H	S	**Lab journal**	**Status**	The control result has been sent to the LIS, if available.
i	i	**Lab journal**	**AD**	The dilution used for the measurement of the sample is no standard dilution.
i	i	**Lab journal**	**AD**	The dilution used for the measurement of the control is no standard dilution.
l	l	**Lab journal**	**Flag**	The control result is below confidence range.
L	L	**Lab journal**	**Flag**	The sample result is below reference range.
O	O	**Lab journal**	**Flag**	The formula test of the sample cannot be evaluated.
P	P	**Lab journal**	**Flag**	The manual pre-dilution of the sample is doubtful.
X	X	**Lab journal**	**Flag**	The turbidity of the sample is above the defined threshold.
X	X	**Lab journal**	**Flag**	The turbidity of the control is above the defined threshold.
Y	Y	**Lab journal**	**Flag**	The level of the cup-in-tube sample cannot be found.
No flag	-	**Calibration**	**Flag**	No released reference curve is available for the assay, reagent, or supplementary reagent.

Flags and symbols in dialogs

5.2.5 Function keys

Some actions can be accessed by pressing function keys on the keyboard, see the table below.

Function key	Button	Dialog	Explanation
F1	**Help**	Various dialogs	Displays the online help, see (➔ Page 81 *Help*)
Alt + **F4**	**Exit**	**Status**	Shuts down the system

Function keys

5.3 Dialogs

This chapter describes every dialog of the software.

At the beginning of each dialog description, 1 or more paths to find the dialog within the software are specified.

5.3.1 About

Path to the dialog:

- **System > About**

The dialog is used to view the current version of the software and its components, see the table below.

Information	Explanation
SIEMENS ANEPH630	Version of the system software
Revision	Revision number
ComServer	Internal version of the communication software
Viewer	Internal version of the viewer software
NSAAnalyser	Internal version of the control software

Software components

5.3.2 Access cuvette segments and dilution strips

Paths to the dialog:

- **Loading > Cuv. seg. & dil. strips > Access**
- **System > Cuv. seg. & dil. strips**

The dialog is used to access the cuvette rotor and the dilution frame. The user has to follow the instructions displayed during the process.

The dialog is divided into 2 areas, see the table below.

Information	Explanation
Dilution strips	Graphic of the dilution frame with dilution strips and the single dilution cups Letters and digits in the graphic correspond with the letters and digits affixed to the dilution frame. When access was obtained via the action button **Access**, the action button **Dilution strips**, or the action button **Cuv. seg. & dil. strips**, the user can select and de-select replaced dilution strips in the graphic or use common action buttons, see (➔ Page 53 *Select*) and (➔ Page 55 *Common action buttons*). The colors and markings of the dilution strips and single dilution cups have different meanings, see (➔ Page 60 *Colors and markings of the dilution strips and dilution cups*).
Cuvettes	Graphic of the cuvette segments with the single cuvettes Digits in the graphic correspond with the digits affixed to the cuvette rotor. When access was obtained via 1 of the action buttons **Access**, **Cuvettes**, or **Cuv. seg. & dil. strips**, the user can select and de-select replaced cuvette segments in the graphic or use common action buttons, see (➔ Page 53 *Select*) and (➔ Page 55 *Common action buttons*). The colors and markings of the cuvette segments and single cuvettes have different meanings, see (➔ Page 60 *Colors and markings of the cuvette segments and cuvettes*).

Areas in the dialog Access cuvette segments and dilution strips

Color and marking	Explanation
Dark blue, no marking	The dilution cup is in use or has been assigned to a requested job.
Light blue, no marking	No dilution strip is placed in this row.
White, no marking	The dilution cup is available.
White, **X**	The dilution cup is no longer required. When all dilution cups in a dilution strip are marked with an **X**, the dilution strip can be removed.

Colors and markings of the dilution strips and dilution cups

Color and marking	Explanation
Dark blue, no marking	The cuvette is in use or has been assigned to a requested job.
Light blue, no marking	No cuvette segment is loaded in this row.
White, no marking	The cuvette is available.
White, **X**	The cuvette is no longer required. – or – The blank value of the empty cuvette is above the limit. The cuvette is refused. When all cuvettes in a cuvette segment are marked with an **X**, the cuvette segment can be removed.

Colors and markings of the cuvette segments and cuvettes

Action buttons

The special action buttons are only available by using this path to the dialog:

- **System > Cuv. seg. & dil. strips**

For special action buttons, see the table below.

Action button	Explanation
Cuvettes	Gives access to cuvette segments
Dilution strips	Gives access to dilution strips
Cuv. seg. & dil. strips	Gives access to cuvette segments and dilution strips

Special action buttons

5.3.3 Access reagents

Paths to the dialog:

- **Loading > Loading reagents > Access**
- **System > Reagents**

The dialog is used to request access to the reagent rotor.

After the system displays a corresponding message, the user can open the right cover to access the reagent rotor.

5.3.4 Access samples

Paths to the dialog:

- **Loading > Loading samples > Access**
- **System > Samples**

The dialog is used to request access to the sample rotor.

After the system displays a corresponding message, the user can open the left cover to access the sample rotor.

5.3.5 Add request

Path to the dialog:

- **Lab journal > Add request**

The dialog is used to manually. Enter sample data and patient data for an existing sample ID. To request jobs, see the table below.

Sample data

Sample ID	Sample ID	-
STAT	Short turnaround time Dilutions already in the cuvette rotor are measured, then the STAT sample is prepared and measured.	Select

Sample data

Number of selected assays	Number of assays selected in the list of assays below	-
Manually pre-diluted	Manual pre-dilution of the sample, see (➔ Page 63 *Manual pre-dilution*) The user can only select a manual pre-dilution if no job has been requested. The system automatically incorporates the manual pre-dilution into the calculated result.	Select

Patient data

First name	First name Maximum 20 characters	Enter
Initial	Abbreviation of the middle name 1 character	Enter
Last name	Last name Maximum 20 characters	Enter
Date of birth	Date of birth The format of the date depends on the settings of the operating system of the computer.	Enter
Practice assigned ID	ID assigned by the referring practice Maximum 30 characters	Enter
Laboratory assigned ID	ID assigned by the laboratory Maximum 20 characters	Enter
Additional Patient ID	Any additional ID assigned by the laboratory Maximum 20 characters	Enter
Comment	Any additional comment on the patient Maximum 100 characters	Enter

Assays

Specimen type	Filters the assays in the list of assays below by specimen type, see (➔ Page 63 *Specimen type*)	Select
-	The list below the specimen type displays assays available for the selected specimen. The colors in the list of assays have different meanings, see (➔ Page 63 *Colors in the list of assays*).	Select
Profile	Available profiles, see (➔ Page 76 *Profiles*) The user can add profiles to the job list by selecting the corresponding table cell. Selected profiles are highlighted dark blue.	Select
Profile no.	Running number of the profile	Select

Assays

Assays	Assays assigned to the profile The user can add assays to the job list by selecting the corresponding table cell.	Select

Sample and patient data

Information	Explanation
1 : 1	Sample is not manually pre-diluted, default setting.
1 : 5	Sample is manually pre-diluted 1 : 5.
1 : 20	Sample is manually pre-diluted 1 : 20.

Manual pre-dilution

Information	Explanation
(All)	Assays for use in all specimen types
Serum	Assays for use in serum only
Urine	Assays for use in urine only
CSF	Assays for use in CSF only
Plasma	Assays for use in plasma only

Specimen type

Color	Explanation
White	Assay has not been requested.
Dark blue	Assay has been requested but is not yet applied.
Light blue	Assay has been requested but was not yet processed.

Colors in the list of assays

Navigation The user can scroll through the selected sample IDs by using the buttons for master navigation in the top left corner, see (➔ Page 54 *Master navigation*).

Action buttons For special action buttons, see the table below.

Action button	Explanation
Special dilution	Displays the dialog **Special dilution**, see (➔ Page 118 *Special dilution*)

Action button	Explanation
Host job list	Requests the job list from the LIS, if available, for the selected sample IDs A job list is only sent back by the LIS and added to the lab journal when the following conditions are met: • A connection to the LIS is established. • A job list for the selected sample ID exists with the LIS.

Special action buttons

5.3.6 Calibration

Path to the dialog:

- **Calibration**

The dialog is used to view, manage, and check reference curves.

The dialog is divided into 3 areas, see the table below.

Information	Explanation
Assays	Assays that have been defined and are active are displayed in a table, see (➔ Page 64 *Assays*).
Reagents	When the user selects an assay in the area **Assay**, the reagent lots that are on-board, were used or are required to measure the reference curve are displayed in a table. The system stores up to 3 lots for each reagent, see (➔ Page 65 *Reagents*).
Supplementary reagents	When the user selects an assay in the area **Assay**, the supplementary reagents that were used or are required to measure the reference curve, if applicable, are displayed in a table. The system stores 1 lot for each supplementary reagent, see (➔ Page 65 *Supplementary reagents*).

Calibration

Information	Explanation
Flag	Flag, if applicable, see (➔ Page 55 *Flags and symbols*)
Assay no.	Assay number The assay number is provided by Siemens Healthineers.
Assay	Abbreviation of the assay
No. of curves	Number of reference curves available for the assay

Assays

The user can filter the entries in the table by using the 2 filters above the table, see the table below.

Filter	Setting	Explanation
Specimen type	**(All)**	Assays for use in all specimen types
	Serum	Assays for use in serum only
	Urine	Assays for use in urine only
	CSF	Assays for use in CSF only
	Plasma	Assays for use in plasma only
Status ref. curve	**(All)**	All assays
	Invalid	Assays with invalid reference curves
	In process	Assays with reference curves that are being measured
	Missing	Assays with missing reference curves

Filter for assays

Information	Explanation
Flag	Flag, if applicable, see (➔ Page 55 *Flags and symbols*)
Reagent	Abbreviation of the reagent
Lot no.	Reagent ID An ID comprises 6 characters, 4 characters for the identifier number and 2 characters for the lot number. If the lot number is replaced by --, the reagent is not on-board.

Reagents

When the user changes the lot of a reagent, the measurement of the reference curve must be repeated.

Reference curves for which 2 reagents are required must be deleted before a newly measured reference curve can be activated.

Information	Explanation
Flag	Flag, if applicable, see (➔ Page 55 *Flags and symbols*)
Reagent	Abbreviation of the supplementary reagent Only supplementary reagents are displayed whose change of lot does not affect the validity of the reference curve.
Lot no.	ID of the supplementary reagent An ID usually comprises 6 characters, 4 characters for the identifier number and 2 characters for the lot number. For supplementary reagents, the lot number is not displayed, as a change of the lot does not affect the validity of the reference curve.

Supplementary reagents

Action buttons For special action buttons, see the table below.

Action button	Explanation
Delete	Deletes the reference curve measured with the reagent lot selected. Jobs using the deleted reference curve will be canceled. Jobs using a deleted curve cannot be evaluated. If the reference curve of an affected assay is measured with 2 reagents, both reagent lots need to be replaced before the existing reference curve can be deleted.
Show curve	Displays the dialog **Show curve**, see (➔ Page 116 *Show curve*)
Measure	Measures the reference curve for an assay with the selected reagent lot The action button is deactivated when 3 valid reference curves are available for a reagent.
Repeat	Repeats the measurement of the reference curve for an assay with the selected reagent lot. Repeating the measurement of a valid reference curve will cancel all jobs using this valid reference curve. Only 1 valid reference curve of a specific reagent lot can be used by the system. If a valid reference curve is repeated and the new reference curve is also valid, the new reference curve will be used. The original reference curve is retained. If the new reference curve is deleted, the original reference curve will be used again.

Special action buttons

5.3.7 Check probe

Path to the dialog:

- **System > Check probe**

The dialog is used to check the probe for possible blockage and correct shape. The user has to follow the instructions displayed during the process.

Action buttons For special action buttons, see the table below.

Action button	Explanation
Check	Checks the probe for possible blockage and correct shape

Special action buttons

5.3.8 Clean probe

Path to the dialog:

- **System > Clean probe**

The dialog is used to clean the probe. The user has to follow the instructions displayed during the process.

Action buttons For special action buttons, see the table below.

Action button	Explanation
Park probe for cleaning	Moves the transfer arm to a parking position where the probe can be cleaned

Special action buttons

5.3.9 Configuration

Path to the dialog:

- **System > Configuration**

The dialog is used to configure the software, to define new sample rotor segments, and to delete defined sample rotor segments.

The dialog is divided into 8 tabs, see the table below.

Information	Explanation	Default setting	Action
Language	Available languages of the software Logbook entries entered before a change of language are not updated. Logbook entries entered after a change of language are displayed in the new language.	**English**	Select
Connection	Configuration of the connection between analyzer and computer The connection is configured during the installation of the system by Siemens Healthineers service, see (➔ Page 68 *Information on the tab Connection*). The user should not change the configuration.	See (➔ Page 68 *Information on the tab Connection*)	Enter and select
Host	Configuration of automatic re-measurements, automatic release of results, and sample ID settings for barcodes and for the LIS, if available, see (➔ Page 69 *Information on the tab Host*)	See (➔ Page 69 *Information on the tab Host*)	Select
Password	Configuration of password check during the start of the system and management of user accounts User accounts and password check are configured during the installation of the system by Siemens Healthineers service. The user should not change the configuration. The user's access rights are only defined by the user account. An audit trail is not possible. For more information, see (➔ Page 100 *Log on*).	De-activated	Select or de-select
Sample segments	Definition of new sample rotor segments and deletion of existing sample rotor segments, see (➔ Page 72 *Information on the tab Sample segments*)	See (➔ Page 72 *Information on the tab Sample segments*)	Enter
Address / Analyzer	Name and address of the laboratory and analyzer ID Data entered on the tab is displayed and printed as a header, see (➔ Page 72 *Information on the tab Address / Analyzer*).	See (➔ Page 72 *Information on the tab Address / Analyzer*)	Enter

Information	Explanation	Default setting	Action
User settings	User settings, see (➔ Page 72 *Information on the tab User settings*)	See (➔ Page 72 *Information on the tab User settings*)	Select
Result report	Deactivates or activates the extended result report The extended result report can be useful for Siemens Healthineers service in case of system problems. The extended result report is not required during normal operation. The setting becomes active only after the software is restarted.	De-activated	Select or de-select

Configuration

Connection On the tab **Connection**, the connection between analyzer and computer is set.

The connection between analyzer and computer is configured during the installation of the system by Siemens Healthineers service. The user should not change the configuration, see the table below.

Timeout			
Timeout for confirmation [sec.]	Length of time the computer waits for an answer from the analyzer	**60**	Enter
Timeout for event [sec.]	Length of time a single component of the computer waits for an answer from another component	**30**	Enter
Interface			
TCP/IP	Connection established via an Ethernet cable	Activated	Select
Serial	Connection established via a serial cable (RS-232)	De-activated	Select
Connection			
IP address	IP address of the analyzer	**192.168.35.20**	Enter
IP port	IP port of the analyzer	**35001**	Enter
Check connection after [sec.]	Interval in which the system checks the connection between analyzer and computer The interval is not changed immediately. A re-start of the viewer software is required.	**60**	Enter

Information on the tab Connection

Host On the tab **Host**, the user can activate and deactivate automatic re-measurements and automatic release of results, see the table below.

Information	Explanation	Default setting	Action
Automatic remeasurement	Automatic repetition of measurements that are outside the measurement range Re-measurements are done with the next higher or lower dilution for as long as the measurement result is outside the measurement range. Measurements from a cup-in-tube segment cannot be repeated automatically.	Activated	Select
Automatic release	Automatic release of valid results and subsequent sending to the LIS, if available Results inside the reference range are automatically released and sent to the LIS. Automatic release is only active when **Automatic remeasurement** is selected. Automatic release is indicated by flags and symbols, see (➔ Page 69 *Automatic release of results*).	De-activated	Select
Significant digits of sample ID			
2 rows of digits	The digits represent the numbers 1–29 and identify the position of the rectangles below, for example, both rectangles on the left have the number 1, both rectangles on the right have the number 29. Each number represents 1 of the 29 characters of a sample ID for barcoded samples.	-	-
Host	The rectangles represent the digits in the sample ID. The digits are sent from the LIS to the system together with the job list. The colors of the rectangles have different meanings, see (➔ Page 71 *Colors of the rectangles*).	All rectangles selected	Select or de-select
Barcode	The rectangles represent the digits in the sample ID. The digits are sent from the system to the LIS together with the results. They are always a subset of the digits selected in the line **Host**. When the user selects or deselects rectangles in the line **Barcode**, the corresponding rectangles in the line **Host** are automatically updated by the system. The colors of the rectangles have different meanings, see (➔ Page 71 *Colors of the rectangles*).	All rectangles selected	Select or de-select

Information on the tab Host

Flag/symbol	Explanation	Automatic release
	A hardware problem has occurred or a resource was low during processing of the sample. The measurement was canceled.	No Result can be released manually but will be defined as invalid by the LIS, if available.

Flag/symbol	Explanation	Automatic release
	A hardware problem has occurred or a resource was low during processing of the control. The measurement was canceled.	No Result can be released manually but will be defined as invalid by the LIS, if available.
< (Value)	The sample or control result is below the measurement range.	Yes
> (Value)	The sample or control result is above the measurement range.	Yes
	The dilution used for the measurement of the sample is 1 : 1 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the control is 1 : 1 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the sample is 1 : 5 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the control is 1 : 5 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the sample is 1 : 20 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the control is 1 : 20 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the sample is 1 : 100 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the control is 1 : 100 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the sample is 1 : 400 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the control is 1 : 400 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the sample is 1 : 2,000 and differs from the initial dilution.	Yes
	The dilution used for the measurement of the control is 1 : 2,000 and differs from the initial dilution.	Yes

Flag/symbol	Explanation	Automatic release
g	The dilution used for the measurement of the sample is 1 : 8,000 and differs from the initial dilution.	Yes
g	The dilution used for the measurement of the control is 1 : 8,000 and differs from the initial dilution.	Yes
h	The dilution used for the measurement of the sample is 1 : 32,000 and differs from the initial dilution.	Yes
h	The dilution used for the measurement of the control is 1 : 32,000 and differs from the initial dilution.	Yes
h	The control result is above confidence range.	Yes
H	The sample result is above reference range.	Yes
i	The dilution used for the measurement of the sample is no standard dilution.	Yes
i	The dilution used for the measurement of the control is no standard dilution.	Yes
l	The control result is below confidence range.	Yes
L	The sample result is below reference range.	Yes
X	The turbidity of the sample is above the defined threshold.	No Result can be released manually.
X	The turbidity of the control is above the defined threshold.	No Result can be released manually.

Automatic release of results

Color	Explanation
Dark blue	Information in this position represents a part of the sample ID and is sent between the system and LIS.
Light blue	Information in this position is not being sent between the system and LIS.
White	Information in this position is additional information and is sent from the LIS to the system.
Red	This position is invalid because it is selected in the line **Barcode** but is not a subset of the line **Host**.

Colors of the rectangles

Sample segments

On the tab **Sample segments**, the user can define new sample rotor segments and delete existing sample rotor segments, see the table below.

Information	Explanation	Default setting	Action
New segment	New segment ID of a sample rotor segment The segment ID must comprise 6 digits, see (→ Page 306 *Sample rotor segments*).	Empty input field	Enter
Segment list	List of existing sample rotor segments	All entries deselected	Select

Information on the tab Sample segments

Address / Analyzer On the tab **Sample segments**, the user can define new sample rotor segments and delete existing sample rotor segments, see the table below.

Information	Explanation	Default setting	Action
Name of laboratory	Name of the laboratory or company Maximum 255 characters, letters and digits, no special characters	Empty input field	Enter
Street	Street name and number, if applicable Maximum 255 characters, letters and digits, no special characters	Empty input field	Enter
Zip code	Zip code Maximum 6 characters, digits only	Empty input field	Enter
City	City or town Maximum 255 characters, letters and digits, no special characters	Empty input field	Enter
Country / State	Country Maximum 255 characters, letters and digits, no special characters	Empty input field	Enter
Phone	Phone number Maximum 29 characters, digits only	Empty input field	Enter
Analyzer ID	Analyzer ID 5 characters, letters and digits, no special characters	Empty input field	Enter

Information on the tab Address / Analyzer

Data entered on the tab **Address / Analyzer** is displayed in the header of the printed pages.

User settings On the tab **User settings**, the user can change various settings, see the table below.

Information	Explanation	Default setting	Action
Show results	The user can define whether all results or only the most recently measured result is displayed in the lab journal. When the user selects **Only last result**, all results are only displayed in the dialog **Sample details**.	**All results**	Select

Information	Explanation	Default setting	Action
Sort sequence in the lab journal	The user can define the default sort sequence in the lab journal. Various options are available, see (➔ Page 86 *Sorting order in the lab journal*).	**Entry**	Select
Display assays	The user can define whether assays are sorted by assay number or alphabetically.	**Assay no.**	Select
Print	The user can activate or deactivate the print preview, see (➔ Page 72 *User settings*). If printing without preview is selected, the data is printed directly.	**With preview**	Select
Replacement of cuvette segments or dilution strips	The user can define whether the closing of the right cover already serves as a confirmation for replacement or if a confirmation procedure is followed.	**Terminate by closing the cover**	Select

Information on the tab User settings

Action buttons For special action buttons, see the table below.

Action button	Explanation
Add	Adds a new segment ID to the list of existing sample rotor segments The button is displayed when the tab **Sample segments** is selected.
Basic settings	Deactivates or activates the extended result report The button is displayed when the tab **Result report** is selected.

Special action buttons

5.3.10 Control details

Path to the dialog:

- Routine button **Lab journal** > double-click a line with a requested job or a measurement result for a control

The dialog is used to view details of a control measurement.

In the top left corner, the control ID and the control name are displayed, preceded by a symbol, if applicable. For more information, see (➔ Page 55 *Flags and symbols*).

The table displays details for all control measurements. Column headings are explained in the table below.

Information	Explanation
Status	Status of measurements, represented by symbols, if applicable, see (➔ Page 55 *Flags and symbols*)
Assay	Abbreviation of the assay

Information	Explanation
Result/Unit	Measurement result and corresponding unit If a measurement result is above the measurement range, the upper limit is displayed additionally, with the symbol **>**, for example, > 16.3 g/L. If a measurement result is below the measurement range, the lower limit is displayed additionally, with the symbol **<**, for example, < 0.1439 g/L.
Flag	Flag, if applicable, see (➔ Page 55 *Flags and symbols*)
Deviation	Deviation from the reference value in % If the deviation from the reference value is exceeded, the control result is outside the confidence range. The permitted deviation is defined in the dialog **Definitions**, on the tab **Controls**, see (➔ Page 76 *Controls*).
AD	Not applicable for controls
Time	Time at which the job was finished

Column headings

Every control result is compared to the confidence range and the reference range of the selected method. If the control result is outside of at least 1 of these 2 ranges, the control result will be displayed as invalid in the dialog **Lab Journal**.

Control results, which are displayed as invalid in the dialog **Lab Journal** and are not flagged h or l, are inside the confidence range and can be considered as valid.

Action buttons For special action buttons, see the table below.

Action button	Explanation
Repeat	Displays the dialog **Repeat**, see (➔ Page 111 *Repeat*)
Kinetics	Displays the dialog **Kinetics**, see (➔ Page 82 *Kinetics - Measurement curves*)

Special action buttons

5.3.11 Definitions

Path to the dialog:

- **System > Definitions**

The dialog is used to establish or change definitions for profiles, controls, standards, units, and cups.

The dialog is divided into 6 tabs, see the table below.

Information	Explanation
Profiles	Definition of profiles Profiles define a set of assays that will be requested when the profile is manually assigned to a sample ID, see (➔ Page 76 *Profiles*).
Controls	Definition of controls provided by Siemens Healthineers and user-defined controls, see (➔ Page 76 *Controls*)
Units	Definition of units, see (➔ Page 79 *Units*)
Immersing depth	Definition of the immersing depth for cup-in-tube segments, see (➔ Page 79 *Immersing depth*)
Control lots	Definition of control lots, see (➔ Page 80 *Control lots*)
Standard lots	Definition of standard lots, see (➔ Page 81 *Standard lots*)

Definitions

Action buttons For special action buttons, see the table below.

Action button	Explanation
New	Profiles: Adds a new row to the table The user can enter a name for the new profile in the left table cell and add assays to the profile by selecting the corresponding table cell. Profile name: Maximum 255 characters, letters and digits, no special characters Controls: If the name of a user-defined control is selected in the table: The user can add any assay to the user-defined control via the dialog **Control details**, see (➔ Page 77 *Components of the dialog Control details for controls provided by Siemens Healthineers*). If no control name is selected in the table: The user can add a new user-defined control to the table via the dialog **Control details**, see (➔ Page 78 *Components of the dialog Control details for user-defined controls*). The action button is only visible on the tabs **Profiles** and **Controls**, see (➔ Page 76 *Profiles*) and (➔ Page 76 *Controls*).
Change depth	Displays a confirmation dialog and, after confirmation, a table and a graphic, see (➔ Page 79 *Immersing depth*) The action button is only visible on the tab **Immersing depth**, see (➔ Page 79 *Immersing depth*).

Action button	Explanation
Reset	Resets the variable Z of the selected cup-in-tube segment to the default setting The action button is only visible on the tab **Immersing depth** after the value of the variable Z has been changed, see (➔ Page 79 *Immersing depth*).
Lot ID	Control lots: Adds a new control lot of the selected control to the table Standard lots: Adds a new standard lot of the selected standard to the table The user can enter the new lot ID in the left table cell and enter reference values by selecting the corresponding table cell. Lot ID: 2 digits Reference value: Maximum 11 digits including decimal point The action button is only visible on the tabs **Control lots** and **Standard lots**, see (➔ Page 80 *Control lots*) and (➔ Page 81 *Standard lots*).

Special action buttons

Profiles

On the tab **Profiles**, the user can add, edit, and delete profiles.

Profiles are displayed in a table. The table heading lists all available assays by their abbreviation. The left column lists the existing profiles. The colors and markings of the table cells are explained in the table below.

Color and marking	Explanation
White, no marking	Assay is not assigned to the corresponding profile.
White, **X**	Assay is assigned to the corresponding profile.

Colors and markings of table cells

The user can select and de-select profile names. When the user selects profile names, the corresponding table rows are highlighted dark blue, see (➔ Page 53 *Select*).

The user can add assays to and remove assays from existing profiles by selecting or de-selecting the corresponding table cell.

Controls

On the tab **Controls**, the user can view and edit detailed information on assays assigned to controls provided by Siemens Healthineers, and add and delete user-defined controls.

Controls are displayed in a table. The table heading lists all available assays by their abbreviation. The left column lists the existing controls. The colors and markings of the table cells are explained in the table below.

Color and marking	Explanation
Dark gray, no marking	Assay is not assigned to the corresponding control.

Color and marking	Explanation
White, **X**	Assay is assigned to the corresponding control.

Colors and markings of table cells

The user can select and de-select control names. When the user selects control names, the corresponding table rows are highlighted dark blue, see (➔ Page 53 *Select*).

The names of **controls provided by Siemens Healthineers** are displayed in green. The user can view and edit detailed information on assays assigned to a control in the dialog **Control details** by clicking the corresponding table cell. The components of the dialog **Control details** are explained in the table below.

Information	Explanation	Default setting	Action
Name	Control name	-	-
ID	Identifier number of the control	-	-
Assay	Abbreviation of the assay and assay number	-	-
Permitted deviation	Permitted deviation from the reference value in % The value entered defines the confidence range for the assay. If a control result is outside the confidence range, it is flagged in the lab journal, see (➔ Page 55 *Flags and symbols*).	**15**	Enter
Dilution	Dilution used for the measurement of the assay	Depending on the assay	Select
At the beginning	A control measurement is performed before the system processes requested jobs for this assay. This component is used to define cyclic control measurements.	De-selected	Select or de-select
all ... measurements	A control measurement is performed after the entered number of requested jobs for this assay. Example: When **50** is entered in the input field, 50 requested jobs are measured for this assay. The 51st measurement is a control measurement. This component is used to define cyclic control measurements.	No entry	Enter
At the end	A control measurement is performed after the system has processed the requested jobs for this assay. This component is used to define cyclic control measurements.	De-selected	Select or de-select
Precision	The control results are sent to the quality control software. For more information, see the documentation of the quality control software.	De-selected	Select
Accuracy	The control results are sent to the quality control software. For more information, see the documentation of the quality control software.	Selected	Select

Components of the dialog Control details for controls provided by Siemens Healthineers

The names of **user-defined controls** are displayed in black.

Identifier numbers 9900 to 9999 are reserved for user-defined controls by the system.

Siemens Healthineers recommends to use only these identifier numbers for user-defined controls.

The user can add and delete user-defined controls, and view and edit detailed information on assays assigned to a user-defined control in the dialog **Control details** by clicking the corresponding table cell. The components of the dialog **Control details** are explained in the table below.

Information	Explanation	Default setting	Action
Name	Control name Maximum 255 characters, letters and digits, no special characters	-	Enter
ID	Identifier number of the control Digits 9900 to 9999	-	Enter
Treat sample as user-defined control	Sample IDs starting with the entered identifier number will automatically be treated as user-defined controls by the system, if selected.	Selected	Select or de-select
Assay	Abbreviation of the assay and assay number	-	Select
Permitted deviation	Permitted deviation from the reference value in % The value entered defines the confidence range for the assay. If a control result is outside the confidence range, it is flagged in the lab journal, see (→ Page 55 *Flags and symbols*).	**0**	Enter
Dilution	Dilution used for the measurement of the assay	Depending on the assay	Select
At the beginning	A control measurement is performed before the system processes requested jobs for this assay. This component is used to define cyclic control measurements.	Selected	Select or de-select
all ... measurements	A control measurement is performed after the entered number of requested jobs for this assay. Example: When **50** is entered in the input field, 50 requested jobs are measured for this assay. The 51st measurement is a control measurement. This component is used to define cyclic control measurements.	**1**	Enter
At the end	A control measurement is performed after the system has processed the requested jobs for this assay. This component is used to define cyclic control measurements.	De-selected	Select or de-select
Precision	The control results are sent to the quality control software. For more information, see the documentation of the quality control software.	Selected	Select

Information	Explanation	Default setting	Action
Accuracy	The control results are sent to the quality control software. For more information, see the documentation of the quality control software.	De-selected	Select

Components of the dialog Control details for user-defined controls

Units

On the tab **Units**, the user can assign units and reference ranges to assays.

Units and reference ranges are displayed in a table. Column headings are explained in the table below.

Information	Explanation	Default setting	Action
-	Abbreviation of the assay	-	-
Unit	Unit of the assay Depending on the assay, the user can select different units. When the user saves a changed unit, the lower limit of the reference range and the upper limit of the reference range are converted accordingly.	Depending on the assay	Select
Lower limit of reference range	Lower limit of the reference range of the assay The lower limit is provided by Siemens Healthineers and can be changed by the user to a value suitable for the laboratory. If a result for this assay is below the reference range, the result is flagged in the lab journal, see (➔ Page 55 *Flags and symbols*).	Depending on the assay	Enter
Upper limit of reference range	Upper limit of the reference range of the assay The upper limit is provided by Siemens Healthineers and can be changed by the user to a value suitable for the laboratory. If a result for this assay is above the reference range, the result is flagged in the lab journal, see (➔ Page 55 *Flags and symbols*).	Depending on the assay	Enter

Information on the tab Units

Immersing depth

On the tab **Immersing depth**, the user can edit the immersion depth of the probe into cups held in cup-in-tube segments. The number on the plain text label of cup-in-tube segments starts with **51**.

After clicking the action button **Change depth** and a confirmation, a table and a graphic are displayed in the dialog. In the table, the user can change the value of the variable Z for all defined cup-in-tube segments that are not on-board. Column headings are explained in the table below.

Information	Explanation	Default setting	Action
Segment ID	Segment ID of the cup-in-tube segment The colors of the segment ID texts are explained in the table below.	-	-

Information	Explanation	Default setting	Action
Z [mm]	Distance from the bottom edge of the cup-in-tube segment to the inner base of the cup Digits 3.9–99.9 When the user changes this value, the distance representing Z displayed in the graphic changes accordingly.	3.9	Enter

Information on the tab Immersing depth

Color	Explanation
Black	Variable Z has not been adapted.
Blue	Variable Z has been adapted.

Colors of the segment ID texts

The graphic displays a cup inserted into a tube. The graphic illustrates that the immersion depth depends on the variable Z. The higher the value of the variable Z, the smaller becomes the immersion depth.

A default value for the variable Z is provided by Siemens Healthineers for all defined cup-in-tube segments. The user has to adapt the default value to the cups used with a cup-in-tube segment before this cup-in-tube segment is loaded in the sample rotor. Only 1 type of cup can be used in a specific cup-in-tube segment, as the immersion depth must be the same for all cups.

Control lots

On the tab **Control lots**, the user can view and edit lot data for existing control lots and add new control lots.

Lot data is displayed in a table. The table heading lists all available assays by their abbreviation and the assigned unit. The left column lists all control lots by their abbreviation and the control ID. An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number. If the lot number is replaced by --, no reference values have been defined for this control.

The colors and content of the table cells are explained in the table below.

Color and content	Explanation
Gray, no content	Assay is not assigned to the corresponding control, see (➔ Page 76 *Controls*).
White, no content	Assay is assigned to the corresponding control but no reference value is defined for the assay. The user can only enter reference values for control lots with lot numbers.
White, (Value)	Assay is assigned to the corresponding control, the value is the defined reference value for the assay. The user can edit the reference value by selecting the table cell and editing the value.

Colors and content of table cells

The user can select and de-select control lots by clicking the control name. When the user selects a control lot, the table row is highlighted dark blue.

Standard lots

On the tab **Standard lots**, the user can view and edit lot data for existing standard lots and add new standard lots.

Lot data is displayed in a table. The table heading lists all available assays by their abbreviation with the assigned unit. The left column lists all standard lots by their abbreviation and the standard ID. An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number. If the lot number is replaced by --, no reference values have been defined for this standard.

The colors and content of the table cells are explained in the table below.

Color and content	Explanation
Gray, no content	Assay is not assigned to the corresponding standard.
White, no content	Assay is assigned to the corresponding standard but no reference value is defined for the assay. The user can only enter reference values for standard lots with lot numbers.
White, (Value)	Assay is assigned to the corresponding standard, the value is the defined reference value for the assay. The user can edit the reference value by selecting the table cell and editing the value.

Colors and content of table cells

The user can select and de-select standard lots by clicking the standard name. When the user selects a standard lot, the table row is highlighted dark blue.

5.3.12 Hardware check - probe

Path to the dialog:

- **System > Hardware check**

The dialog is used to check if the probe is bent or not properly adjusted.

The user has to follow the instructions displayed during the process.

5.3.13 Help

Path to the dialog:

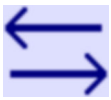
- **Help**

The dialog displays the online help. The online help is displayed in a browser window.

Depending on the user settings, the dialog is either split in 2 columns or not split. The user can display other chapters and change the view of the dialog, see below.

Buttons displayed when the dialog is split in 2 columns

Content	Displays the table of contents on the left
Index	Displays the index on the left
Search	Displays a search area on the left

Buttons displayed when the dialog is split in 2 columns	
	Closes the table of contents
	Displays the previous chapter in the manual
	Displays the next chapter in the manual
	Displays the table of contents on the left

Button displayed when the dialog is not split	
	Displays the chapter of contents and other buttons to navigate in the manual

Buttons of the online help

When the dialog is split in 2 columns, the user can adjust column widths by clicking the middle border of the columns and dragging it to the left or to the right.

5.3.14 Initialize analyzer

Path to the dialog:

- (automatically displayed)

The dialog is displayed during the start of the viewer software and indicates that the viewer software is waiting for a response from the analyzer.

5.3.15 Kinetics - Measurement curves

Paths to the dialog:

- **Sample details > Kinetics**
- **Control details > Kinetics**

The dialog is used to view the measurement curves of results. Details on the measurement are displayed above and below the measurement curve, see the table below.

Information	Explanation
ID	Samples: Sample ID Controls: Control ID
Dilution	Dilution used for the measurement
Assay	Abbreviation of the assay and assay number

Information	Explanation
-	Date and time of the measurement
Pre-value	Value of the pre-reaction If no pre-reaction has occurred, the detail is not displayed.
Start value	Start value of the reaction
Difference value	Difference between the end value and the start value of the reaction
Reagents	Abbreviation of the reagents used for the measurement and reagent IDs An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number.
Calibration	Date and time of the calibration

Kinetics

Navigation between measurement curves

The user can scroll through the selected results by using the buttons for master navigation in the top left corner, see (➔ Page 54 *Master navigation*).

5.3.16 Kinetics - Reference curve

Path to the dialog:

- **Calibration > Show curve > Kinetics**

The dialog is used to view the kinetics of a reference curve at the various dilution steps for the assay displayed in the dialog **Show curve**.

Details on the measurement are displayed above and below the graph, see the table below.

Information	Explanation
ID	Standard ID An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number.
Dilution	Dilution used for the measurement
Assay	Abbreviation of the assay and assay number
-	Date and time of the measurement
Pre-value	Value of the pre-reaction If no pre-reaction has occurred, the detail is not displayed.
Start value	Start value of the reaction
Difference value	Difference between the end value and the start value of the reaction

Information	Explanation
Reagents	Abbreviation of the reagents used for the measurement and reagent IDs An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number.

Details on the measurement

Navigation between dilution steps

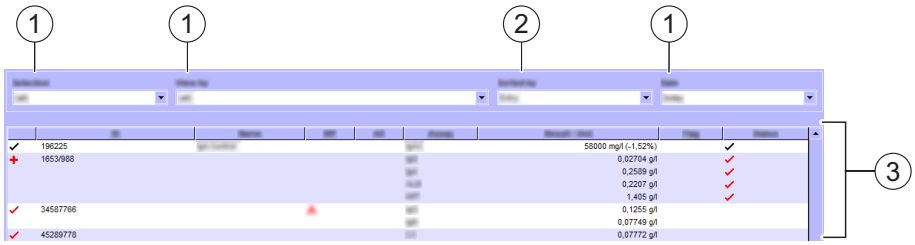
The user can scroll through the dilution steps by using the buttons for master navigation in the top left corner, see (➔ Page 54 *Master navigation*).

5.3.17 Lab journal

Path to the dialog:

- **Lab journal**

The dialog is used to manage jobs and to display results in a table, see the table below.



Details of the dialog Lab journal (example)

(1) Filters
(2) Sorting
(3) Table

Information on samples, STAT samples, controls, assays, and results is displayed in a table. Column headings are explained in the table below.

Information	Explanation
-	Common information on samples and controls, represented by symbols, if applicable, see (➔ Page 55 *Flags and symbols*)
ID	**Samples**: Sample ID A sample ID comprises 1–29 characters. **Controls**: Control ID A control ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number. Only controls that are on-board and identified are displayed.
Name	**Samples**: Patient name, if available **Controls**: Control name
MP	Manual pre-dilution of samples, represented by symbols, if applicable, see (➔ Page 55 *Flags and symbols*)

Information	Explanation
AD	Assay dilution: Requested special dilution of samples, represented by symbols, if applicable, see (➔ Page 55 *Flags and symbols*)
Assay	Abbreviation of the requested assay
Result/Unit	**Samples**: Measurement result and corresponding unit **Controls**: Measurement result, corresponding unit, and deviation from the reference value in % If a measurement result is above the measurement range, the upper limit is displayed additionally, with the symbol >, for example, > 16.3 g/l. If a measurement result is below the measurement range, the lower limit is displayed additionally, with the symbol <, for example, < 0.1439 g/l.
Flag	Flag, if applicable, see (➔ Page 55 *Flags and symbols*)
Status	Status of the requested job for samples and controls, represented by symbols, if applicable, see (➔ Page 55 *Flags and symbols*)

Column headings

Filters in the lab journal

The user can filter the entries in the lab journal by using the 3 filters above the table, see the table below.

Filter	Setting	Explanation
Selection	**(All)**	Jobs for all samples and controls
	Samples	Jobs for all samples
	STATs	Jobs for STAT samples only
	Controls	Jobs for controls
View by	**(All)**	Jobs for all samples and controls
	Out of measurement range	Jobs whose result is out of measurement range
	Out of reference range	Jobs whose result is out of reference range When the user selects this filter setting, the filter **Selection** is automatically set to **Samples**. The filter **Selection** is not reset automatically.
	Invalid controls	Invalid control measurements When the user selects this filter setting, the filter **Selection** is automatically set to **Controls**. The filter **Selection** is not reset automatically.
	Missing	Missing samples and/or controls, depending on the setting of the filter **Selection**
	Not sufficient	Jobs for which the volume of the sample or control is not sufficient

Filter	Setting	Explanation
	Samples on-board without jobs	Samples that are on-board but for which no jobs are requested When the user selects this filter setting, the filter **Selection** is automatically set to **Samples**. The filter **Selection** is not reset automatically.
	Samples on-board	Samples that are on-board When the user selects this filter setting, the filter **Selection** is automatically set to **Samples**. The filter **Selection** is not reset automatically.
	Samples with result	Jobs for samples that already have a result When the user selects this filter setting, the filter **Selection** is automatically set to **Samples**. The filter **Selection** is not reset automatically.
	Pending requests	Jobs for samples and controls that have not yet been processed
Date	**Today**	Jobs and results for all samples and controls that have been requested or measured today
	(Date)	Results for all samples and controls that have been measured on the selected date The results for the last 14 days can be displayed.

Filter for entries in the lab journal

Sorting order in the lab journal

The user can sort the entries in the lab journal, see the table below.

Information	Explanation
ID	The samples and controls are sorted by ascending ID. IDs comprising blocks of letters and digits are first sorted alphabetically by the block of letters and subsequently numerically by the block of digits. IDs of the same length comprising only digits are sorted numerically.
Status	The samples and controls are sorted by their processing status. Succession: • Samples and controls that have finished processing • Samples and controls whose jobs have been partly processed or whose jobs are still in process • Samples and controls that are not on-board Within each group, samples and controls are sorted by ascending ID, see above.

Information	Explanation
Position	The sample and control IDs are sorted by their position on the sample rotor segments. Succession: • Sample rotor segment 1, positions 1–15 • Sample rotor segment 2, positions 1–15 • Sample rotor segment 3, positions 1–15 • Samples that are not on-board
Entry	The sample and control IDs are sorted by the date and time when an ID was created on the system.

Sorting samples and controls

The default sort sequence is set in the dialog **Configuration**, on the tab **User settings**, see (➔ Page 72 *User settings*).

Action buttons

For special action buttons, see the table below.

Action button	Explanation
New	Displays the dialog **New**, see (➔ Page 103 *New*)
Add request	Displays the dialog **Add request**, see (➔ Page 61 *Add request*)
Repeat	Displays the dialog **Repeat**, see (➔ Page 111 *Repeat*)
Release	Releases selected results and sends selected results to the LIS, if available
Request control	Displays the dialog **Request controls**, see (➔ Page 113 *Request controls*)

Special action buttons

5.3.18 Loading cuvette segments and dilution strips

Path to the dialog:

- **Loading > Cuv. seg. & dil. strips**

The dialog is used to give an overview of the cuvette segments and the dilution strips.

The dialog is divided into 2 areas, see the table below.

Information	Explanation
Dilution strips	Graphic of the dilution frame with dilution strips and the single dilution cups Letters and digits in the graphic correspond with the letters and digits affixed to the dilution frame. The colors and markings of the dilution strips and single dilution cups have different meanings, see (➔ Page 88 *Colors and markings of the dilution strips and dilution cups*).

Information	Explanation
Cuvettes	Graphic of the cuvette segments with the single cuvettes Digits in the graphic correspond with the digits affixed to the cuvette rotor. The colors and markings of the cuvette segments and single cuvettes have different meanings, see (➔ Page 88 *Colors and markings of the cuvette segments and cuvettes*).

Areas in the dialog Loading cuvette segments and dilution strips

Color and marking	Explanation
Dark blue, no marking	The dilution cup is in use or has been assigned to a requested job.
Light blue, no marking	No dilution strip is placed in this row.
White, no marking	The dilution cup is available.
White, **X**	The dilution cup is no longer required. When all dilution cups in a dilution strip are marked with an **X**, the dilution strip can be removed.

Colors and markings of the dilution strips and dilution cups

Color and marking	Explanation
Dark blue, no marking	The cuvette is in use or has been assigned to a requested job.
Light blue, no marking	No cuvette segment is loaded in this row.
White, no marking	The cuvette is available.
White, **X**	The cuvette is no longer required. – or – The blank value of the empty cuvette is above the limit. The cuvette is refused. When all cuvettes in a cuvette segment are marked with an **X**, the cuvette segment can be removed.

Colors and markings of the cuvette segments and cuvettes

Action buttons

For special action buttons, see the table below.

Action button	Explanation
Samples	Displays the dialog **Loading samples**, see (➔ Page 95 *Loading samples*)
Reagents	Displays the dialog **Loading reagents**, see (➔ Page 89 *Loading reagents*)
Access	Displays the dialog **Access cuvette segments and dilution strips**, see (➔ Page 59 *Access cuvette segments and dilution strips*)

Special action buttons

5.3.19 Loading reagents

Path to the dialog:

- **Loading > Loading reagents**

The dialog displays an overview of the reagents and controls loaded in the reagent rotor segments via a table.

Column headings of the table are explained in the table below.

Information	Explanation
-	Common information on reagents and controls, represented by symbols, if applicable, see (➔ Page 55 *Flags and symbols*)
Reagent	Abbreviation of the reagent or control
Lot no.	ID of the reagent or control An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number. If a reagent or control could not be identified, a **?** is displayed.
Required [µl]	Volume of the reagent or control required for requested jobs
Available [µl]	Available volume of the reagent or control
Seg / Pos	Number of the reagent rotor segment and number of the position on the reagent rotor segment where the reagent or the control is loaded
Status	Status of the reagent or control, see (➔ Page 89 *Status of reagents and controls*)

Column headings

Information	Explanation
Available	Reagents and controls that are on-board and not empty
Empty	Reagents and controls that are empty
To be identified	Reagents and controls that are on-board but could not be identified
Not required	Reagents and controls that are on-board but are not required for requested jobs
Insufficient	Reagents and controls that are on-board but whose volume is not sufficient for requested jobs
Missing	Reagents and controls that are required for requested jobs but are not on-board

Status of reagents and controls

The user can filter the entries in the table by using the 2 filters above the table, see the table below.

Filter	Setting	Explanation
Selected by	**(All)**	Reagents and controls

Filter	Setting	Explanation
	Controls	Controls only
	Reagents	Reagents only
Reagent status	**(All)**	Reagents and controls that are on-board or are required for requested jobs
	To be identified	Reagents and controls that are on-board but could not be identified
	Not required	Reagents and controls that are on-board but are not required for requested jobs
	Insufficient	Reagents and controls that are on-board but whose volume is not sufficient for requested jobs
	Missing	Reagents and controls that are required for requested jobs but are not on-board

Filter for reagents and controls

Action buttons For special action buttons, see the table below.

Action button	Explanation
Samples	Displays the dialog **Loading samples**, see (➔ Page 95 *Loading samples*)
Graphic	Displays a graphical overview of the reagent rotor and the reagent rotor segments, see (➔ Page 90 *Loading reagents, graphic overview*)
Cuv. seg. & dil. strips	Displays the dialog **Loading cuvette segments and dilution strips**, see (➔ Page 87 *Loading cuvette segments and dilution strips*)
Identify	Displays the dialog **Loading reagents** with a list of reagents and controls, see (➔ Page 93 *Loading reagents, identify reagents and controls*)
Access	Displays the dialog **Access reagents**, see (➔ Page 61 *Access reagents*)

Special action buttons

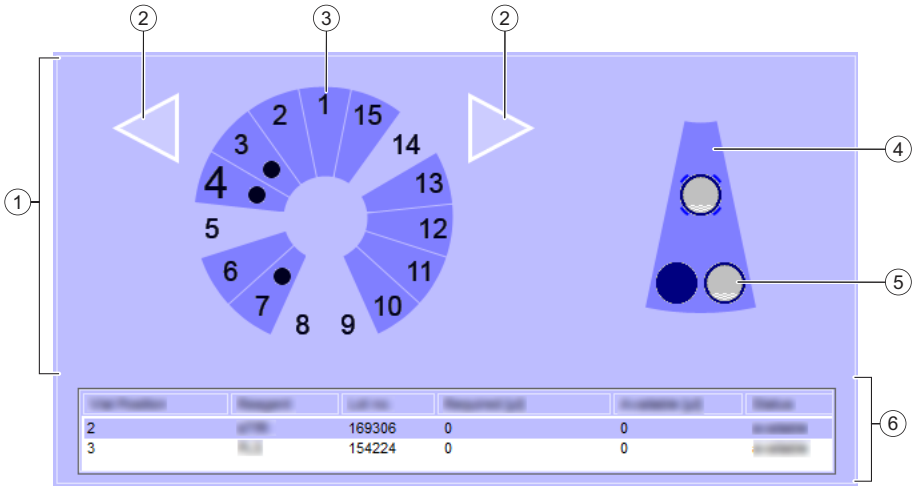
5.3.20 Loading reagents, graphic overview

Path to the dialog:

- **Loading > Loading reagents > Graphic**

The dialog displays an overview of the reagents and controls loaded in the reagent rotor segments via a graphic.

The dialog is divided into a graphic and a corresponding table, see the figure below.



Graphic overview of the dialog Loading reagents (example)

(1) Graphic
(2) Navigation buttons
(3) Diagram of the reagent rotor
(4) Diagram of the selected reagent rotor segment
(5) Vial position
(6) Table

The table below the graphic provides additional information on the reagents or controls. This information is displayed for the reagent rotor segment selected in the diagram of the reagent rotor. The components of the dialog are explained in the table below.

Graphic

Navigation buttons	Select the next reagent rotor segment to the left or to the right	Click
Diagram of the reagent rotor	Schematic overview of the 15 segments of the reagent rotor The numbers in the schematic overview correspond with the digits affixed to the reagent rotor. If a reagent rotor segment is selected, its number is enlarged in the schematic. If at least 1 position of the reagent rotor segment is empty, the reagent rotor segment is marked with a black dot. The colors of the reagent rotor segments have different meanings, see (➔ Page 92 *Colors of the reagent rotor segments*).	Select
Diagram of the selected reagent rotor segment	Schematic overview of the selected reagent rotor segment with all positions The digits in the schematic overview correspond with the digits affixed to the reagent rotor.	-
Vial position	The number of positions depends on the type of the reagent rotor segment, see (➔ Page 45 *Reagent segment*) and (➔ Page 45 *Control segment*). The selected position is framed by blue lines and highlighted in the table below. If a reagent or control could not be identified, a **?** is displayed in the position. The colors and markings of the vial positions have different meanings, see (➔ Page 92 *Colors and markings of the vial positions*).	Select

Table

Vial position	Number of the position on the reagent rotor segment where the reagent or the control is loaded	-
Reagent	Abbreviation of the reagent or control	-
Lot no.	ID of the reagent or control An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number. If a reagent or control could not be identified, a **?** is displayed.	-
Required [µl]	Volume of the reagent or control required for requested jobs	-
Available [µl]	Available volume of the reagent or control If a reagent or control with 2 different lot numbers is on-board, the volume for the second lot number is displayed as **0**. The correct volume of the second lot number is only displayed when the first lot number has been used up.	-
Status	Status of the reagent or control, see (➔ Page 89 *Loading reagents*)	-

Graphic overview of the dialog Loading reagents

Color	Explanation
Blue	All positions have been identified.
Yellow	At least 1 position could not be identified.
-	No reagent rotor segment is loaded. – or – A reagent rotor segment is loaded but no position could be identified.

Colors of the reagent rotor segments

Color and marking	Explanation
Dark blue, no marking	Position is empty.
Completely filled with white wavy lines, no marking	The reagent or control is identified. The level is above 500 µL.
Completely filled with white wavy lines, **?**	The reagent or control is unidentified. The level is above 500 µL.
Blue and partly filled with white wavy lines, no marking	The reagent or control is identified. The level is below 500 µL.
Blue and partly filled with white wavy lines, **?**	The reagent or control is unidentified. The level is below 500 µL.

Colors and markings of the vial positions

Action buttons For special action buttons, see the table below.

Action button	Explanation
Samples	Displays the dialog **Loading samples**, see (➔ Page 95 *Loading samples*)
Reagents	Displays the dialog **Loading reagents**, see (➔ Page 89 *Loading reagents*)
Cuv. seg. & dil. strips	Displays the dialog **Loading cuvette segments and dilution strips**, see (➔ Page 87 *Loading cuvette segments and dilution strips*)
Identify	Displays the dialog **Loading reagents** with a list of reagents and controls, see (➔ Page 93 *Loading reagents, identify reagents and controls*)
Access	Displays the dialog **Access reagents**, see (➔ Page 61 *Access reagents*)

Special action buttons

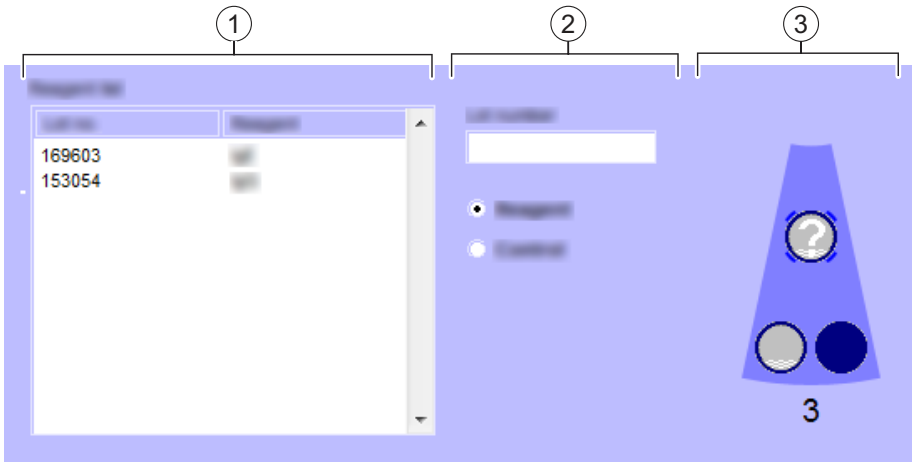
5.3.21 Loading reagents, identify reagents and controls

Path to the dialog:

- **Loading > Loading reagents > Identify**

The dialog is used to manually identify reagents and controls that are already on-board but whose barcode could not be read. After the manual identification, the assigned data is retained unless the reagent rotor segment is removed from the system.

The dialog is divided into 3 areas, see the figure below.



Identify reagents and controls (example)

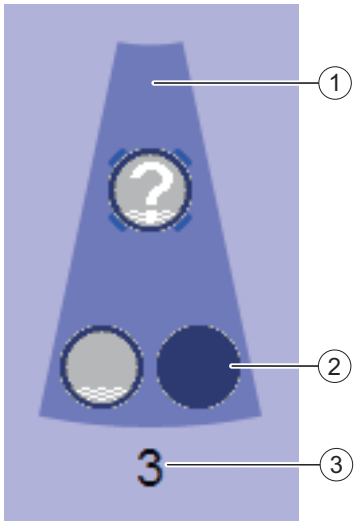
(1) **Reagent list**
(2) Data area
(3) Graphic of the reagent rotor segment

The areas of the dialog are explained in the table below.

Information	Explanation	Action
Reagent list		
Lot no.	ID of the identified reagent or control An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number.	Select
Reagent	Abbreviation of the reagent or control	Select
Data area		
Lot number	ID of the reagent or control that has to be identified manually An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number.	Enter
-	**Reagent** or **Control**	Select
Graphic of the reagent rotor segment		
-	Reagent rotor segment with at least 1 unidentified reagent or control, see figure below.	Select

Information in the areas of the dialog

The data for an unidentified reagent or control can be selected in the **Reagent list** or entered in the data area.



Graphic of the reagent rotor segment

(1) Reagent rotor segment
(2) Vial position
(3) Number of the reagent rotor segment

The components of the graphic are explained in the table below.

Information	Explanation
Reagent rotor segment	Schematic overview of the reagent rotor segment with all positions

Information	Explanation
Vial position	The number of positions depends on the type of the reagent rotor segment, see (➔ Page 45 *Reagent segment*) and (➔ Page 45 *Control segment*). The selected position is framed by blue lines. If a reagent or control could not be identified, a **?** is displayed in the position. The colors and markings of the vial positions have different meanings, see (➔ Page 95 *Colors and markings of the vial positions*).
Number of the reagent rotor segment	Number of the reagent rotor segment The digit corresponds with the digits affixed to the reagent rotor.

Components of the graphic

Color and marking	Explanation
Dark blue, no marking	Position is empty.
Completely filled with white wavy lines, no marking	The reagent or control is identified. The level is above 500 µL.
Completely filled with white wavy lines, **?**	The reagent or control is unidentified. The level is above 500 µL.
Blue and partly filled with white wavy lines, no marking	The reagent or control is identified. The level is below 500 µL.
Blue and partly filled with white wavy lines, **?**	The reagent or control is unidentified. The level is below 500 µL.

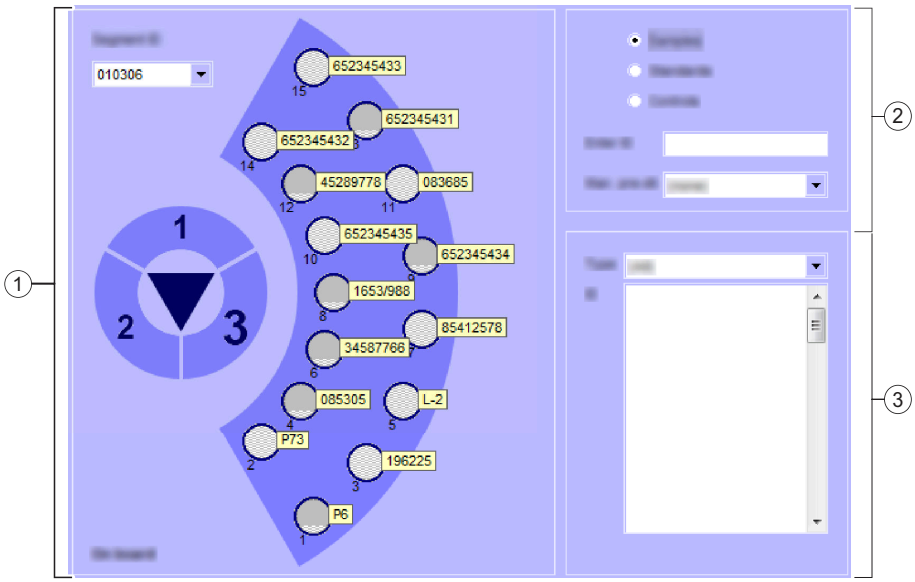
Colors and markings of the vial positions

5.3.22 Loading samples

Path to the dialog:

- **Loading**
- **Loading > Loading samples**

The dialog is used to manually identify samples, standards, and user-defined controls and to give an overview of the sample rotor segments. The dialog is divided into 3 areas, see the figure below.



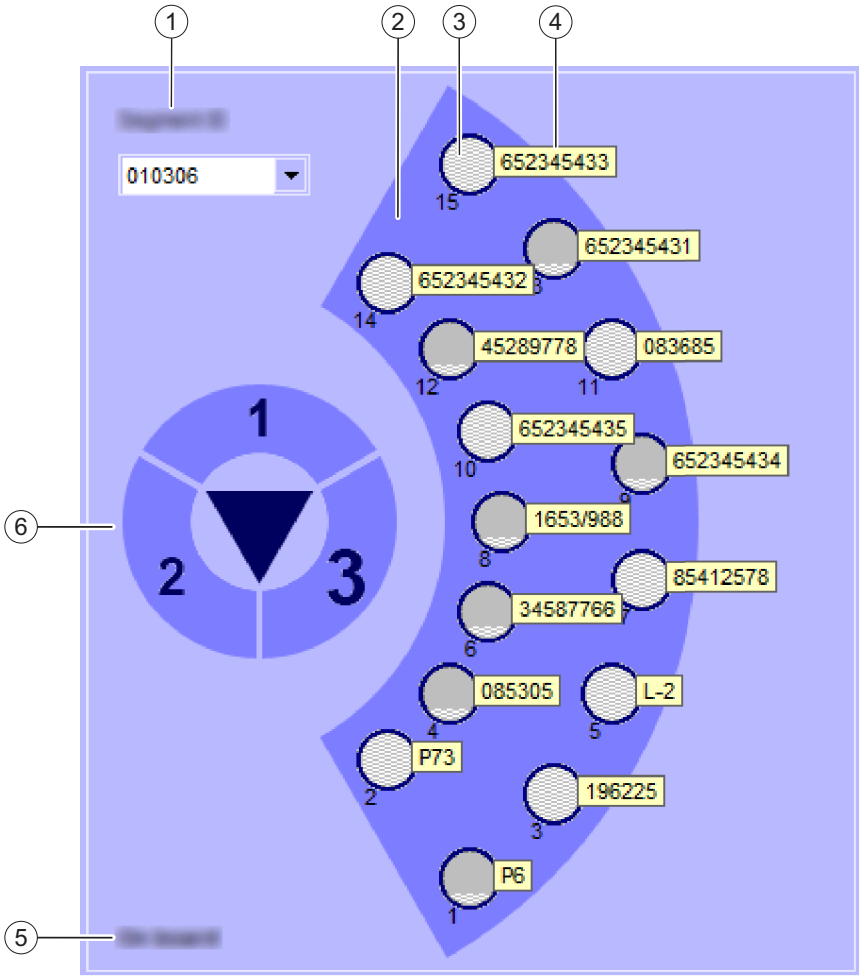
Overview of the dialog Loading samples (example)

(1) Left area
(2) Top right area
(3) Bottom right area

The areas of the dialog are explained in the table below.

Information	Explanation
Left area	Schematic overview of the sample rotor and the sample rotor segments, see figure below Components of the left area are explained in the table (➔ Page 97 *Components of the dialog*).
Top right area	Manual identification or entry of new samples, standards, or user-defined controls Components of the top right area are explained in the table (➔ Page 97 *Components of the dialog*).
Bottom right area	IDs of samples or standards that have been created in the lab journal but have not yet been loaded on a sample rotor segment Components of the bottom right area are explained in the table (➔ Page 97 *Components of the dialog*).

Loading samples



Left area of the dialog Loading samples (example)

(1) **Segment ID**
(2) Diagram of the selected sample rotor segment
(3) Position on the selected sample rotor segment
(4) ID of the loaded sample, standard, or user-defined control
(5) Status of the selected sample rotor segment
(6) Diagram of the sample rotor

Information	Explanation	Action
Components of the left area		
Segment ID	Segment ID of the selected sample rotor segment The list contains all sample rotor segments defined in the dialog **Configuration**, on the tab **Sample segments**. The selected sample rotor segment is displayed on the right, see (➔ Page 71 *Sample segments*) and (➔ Page 41 *Sample rotor segments*).	Select
Diagram of the selected sample rotor segment	Schematic overview of the selected sample rotor segment with all positions	-

Information	Explanation	Action
Components of the left area		
Position on the selected sample rotor segment	The selected position is framed by blue lines. The number of positions depends on the type of the sample rotor segment. The positions in the schematic overview correspond with the digits affixed to the sample rotor segment, see (→ Page 41 *Sample rotor segments*). If a sample, standard, or user-defined control could not be identified, a **?** is displayed in the position. The colors of the positions on the sample rotor segment have different meanings, see (→ Page 98 *Colors and markings of the positions on the sample rotor segment*).	Select
ID of the loaded sample, standard, or user-defined control	If a sample, standard, or user-defined control is loaded in a position of the sample rotor segment, its ID is displayed to the right of the position.	-
Status of the selected sample rotor segment	Status of the selected sample rotor segment The sample rotor segment can be on-board or not on-board.	-
Diagram of the sample rotor	Schematic overview of the 3 positions of the sample rotor The digits in the schematic overview correspond with the digits affixed to the sample rotor. If a sample rotor segment is selected, the number of its position is enlarged in the schematic. The colors of the sample rotor segments have different meanings, see (→ Page 99 *Colors of the sample rotor segments*).	Select
Components of the top right area		
-	**Samples**, **Standards**, or **Controls**	Select
Enter ID	ID of the sample, standard, or user-defined control Enter the ID of the sample, standard, or user-defined control that could not be identified. – or – Enter a new sample. Maximum 29 characters, letters and digits, no special characters	Enter
Man. predil.	Manual pre-dilution of the sample	Select
Components of the bottom right area		
Type	Filter by STAT samples, samples, or standards	Select
ID	ID of samples or standards that have not yet been loaded	Select

Components of the dialog

Color and marking	Explanation
Dark blue, no marking	Position is empty.

Color and marking	Explanation
Completely filled with white wavy lines, no marking	The sample, standard, or control is identified. The cup, tube, or vial is full.
Completely filled with white wavy lines, **?**	The sample, standard, or control is unidentified. The cup, tube, or vial is full.
Blue and partly filled with white wavy lines, no marking	The sample, standard, or control is identified. The cup, tube, or vial is not full.
Blue and partly filled with white wavy lines, **?**	The sample, standard, or control is unidentified. The cup, tube, or vial is not full.
Blue, no marking	Position is pre-loaded but the sample rotor segment is not yet on-board the system, see (➔ Page 106 *Pre-loading*).

Colors and markings of the positions on the sample rotor segment

Color	Explanation
Blue	At least 1 sample, standard, or user-defined control is still required. The sample rotor segment should not be removed.
Blue and yellow	At least 1 sample, standard, or user-defined control is still required. At least 1 position could not be identified. The sample rotor segment should not be removed.
Green	All jobs relating to the samples, standards, or user-defined controls loaded on the sample rotor segment have been processed. The sample rotor segment can be removed.
Green and yellow	At least 1 sample, standard, or user-defined control could not be identified. The sample rotor segment can be removed nonetheless.
Dark gray	The sample rotor segment is on-board but no sample, standard, or user-defined control is loaded.
-	No sample rotor segment is loaded in this position.

Colors of the sample rotor segments

Action buttons For special action buttons, see the table below.

Action button	Explanation
Reagents	Displays the dialog **Loading reagents**, see (➔ Page 89 *Loading reagents*)
Cuv. seg. & dil. strips	Displays the dialog **Loading cuvette segments and dilution strips**, see (➔ Page 87 *Loading cuvette segments and dilution strips*)

Action button	Explanation
Auto loading	Displays the dialog **Pre-loading** for the selected samples, see (➔ Page 106 *Pre-loading*)
Level detection	Measures the level of the selected sample, standard, or user-defined control The detected level is displayed via colors, see (➔ Page 98 *Colors and markings of the positions on the sample rotor segment*).
Access	Displays the dialog **Access samples**, see (➔ Page 61 *Access samples*)

Special action buttons

5.3.23 Log on

Path to the dialog:

- (automatically displayed on log on)

If a password check was configured during the installation of the system by Siemens Healthineers service, the dialog is displayed after the start of the viewer software.

With the password check it is possible to assign different users different user roles. The user can work according to the assigned user role, see (➔ Page 100 *User role*).

The components of the dialog are explained in the table below.

Information	Explanation	Action
Name	User name	Enter
Password	Password, the characters are displayed as asterisks	Enter

Components of the dialog Log on

User role

User role	Access level	Access rights
Lab technician	1	Request orders for samples and controls Perform backups The system runs calibrations automatically, if configured. Load and manage lot data Perform maintenance Configure specific settings Configure maintenance Restore backed up data
Lab manager	2	All

User roles and access rights

5.3.24 Logbook

Path to the dialog:

- **System > Logbook**

The dialog is used to view system entries and manual entries in the logbook.

The logbook entries are displayed in a table, see the table below.

Information	Explanation
Date/Time	Date and time when an event or a problem occurred or when a manual entry was made A rectangle is displayed left of the date. The colors of the rectangle have different meanings, see (➔ Page 101 *Colors in the logbook*).
Source	Source of the logbook entry
Category	Category of the logbook entry
Error code	Error code of logbook entries The error code of manual entries is always **0**.
Description	Short description of the problem or text of the manual entry

Logbook entries

The color of the rectangle displayed left of the date in the logbook is explained in the table below.

Color	Explanation
Red	Problem that leads to the system not operating The requested jobs cannot be processed.
Yellow	Problem that will lead to the system not operating The requested jobs cannot be completely processed. If the user does not resolve the problem, the status button will soon change to red.
Green	Problem that does not lead to the system not operating All requested jobs can be processed.

Colors in the logbook

When a system entry is selected, more information is displayed below the table, see the table below.

Information	Explanation
Explanation	Instructions on how to resolve the problem

Details on system entries

The user can filter the logbook entries by using the 2 filters above the table, see the table below.

Filter	Setting	Explanation
Period	**Today**	Logbook entries from today
	Last 7 days	Logbook entries from the last 7 calendar days
	(All)	Logbook entries from the last 14 calendar days
Gravity	**(All)**	All logbook entries
	Red + yellow	System entries of category 1 and 2, see (➔ Page 101 *Logbook entries*)
	Red	System entries of category 2, see (➔ Page 101 *Logbook entries*)
	Stop error	System entries due to a hardware problem that prevented the system from working

Filter for logbook entries

Action buttons For special action buttons, see the table below.

Action button	Explanation
Manual entry	Displays the confirmation dialog **Entry** The user can enter information on system-relevant issues in the text field, for example, to record the replacement of the syringe. Maximum 255 characters, entries with more than 255 characters will not be displayed.
Export	Exports all logbook entries filtered by the selected period to the file **LogBook.asc**

Special action buttons

5.3.25 Message window

Path to the dialog:

- (automatically displayed)

The message window is an information dialog which displays system messages. If multiple problems are detected, the system message regarding the problem that occurred first is displayed first.

The components of the message window are explained in the table below.

Information	Explanation	Action
Messages	Number of unacknowledged system messages	-
Date	Date when the system message was generated	-
Time	Time when the system message was generated	-
Cause	Cause of the system message	-

Information	Explanation	Action
Explanation	Recommendation on how to respond to the system message	-
Ok	Acknowledges the current system message The system message is closed. If there are further system messages, the next system message is displayed.	Click

Message window

The message window is always displayed in the front. The user can move the message window anywhere on the screen and continue working.

System messages that have not been acknowledged before the system is shut down are displayed again after restart of the system.

5.3.26 New

Path to the dialog:

- **Lab journal > New**

The dialog is used to manually assign sample data and patient data to samples before loading them in the sample rotor. The dialog is also used to request jobs, see the table below.

Sample data

Sample ID	Sample ID A sample ID for non-barcoded samples comprises 1–29 characters, letters and digits, no special characters, spaces at the beginning or at the end of the sample ID are ignored.	Enter
Batch input	The user can enter groups of samples for serial analyses. The same assays are requested for all samples. The sample ID is followed by a sequentially-assigned batch number. A maximum number of 99 can be entered.	Enter
STAT	Short turnaround time Dilutions already in the cuvette rotor are measured, then the STAT sample is prepared and measured.	Select
Number of selected assays	Number of assays selected in the list of assays below	-
Manually pre-diluted	Manual pre-dilution of the sample, see (➔ Page 104 *Manual pre-dilution*) The system automatically incorporates the manual pre-dilution into the calculated result.	Select

Patient data

First name	First name Maximum 20 characters	Enter

Patient data

Initial	Abbreviation of the middle name 1 character	Enter
Last name	Last name Maximum 20 characters	Enter
Date of birth	Date of birth The format of the date depends on the settings of the operating system of the computer.	Enter
Practice assigned ID	ID assigned by the referring practice Maximum 30 characters	Enter
Laboratory assigned ID	ID assigned by the laboratory Maximum 20 characters	Enter
Additional Patient ID	Any additional ID assigned by the laboratory Maximum 20 characters	Enter
Comment	Any additional comment on the patient Maximum 100 characters	Enter

Assays

Specimen type	Filters the assays in the list of assays below by specimen type, see (➔ Page 104 *Specimen type*)	Select
-	The list below the specimen type displays assays available for the selected specimen. Selected assays are highlighted dark blue.	Select
Profile	Available profiles, see (➔ Page 76 *Profiles*) The user can add profiles to the job list by selecting the corresponding table cell. Selected profiles are highlighted dark blue.	Select
Profile no.	Running number of the profile	Select
Assays	Assays assigned to the profile The user can add assays to the job list by selecting the corresponding table cell.	Select

Sample and patient data

Information	Explanation
1 : 1	Sample is not manually pre-diluted, default setting
1 : 5	Sample is manually pre-diluted 1 : 5
1 : 20	Sample is manually pre-diluted 1 : 20

Manual pre-dilution

Information	Explanation
(All)	Assays for use in all specimen types

Information	Explanation
Serum	Assays for use in serum only
Urine	Assays for use in urine only
CSF	Assays for use in CSF only
Plasma	Assays for use in plasma only

Specimen type

Action buttons For special action buttons, see the table below.

Action button	Explanation
Special dilution	Displays the dialog **Special dilution**, see (➔ Page 118 *Special dilution*)
Host job list	Requests the job list from the LIS, if available A job list is only sent back by the LIS when the following conditions are met: • A sample ID is entered. • A connection to the LIS is established. • A job list for the selected sample ID exists with the LIS. The lab journal does not automatically display the data from the job list.

Special action buttons

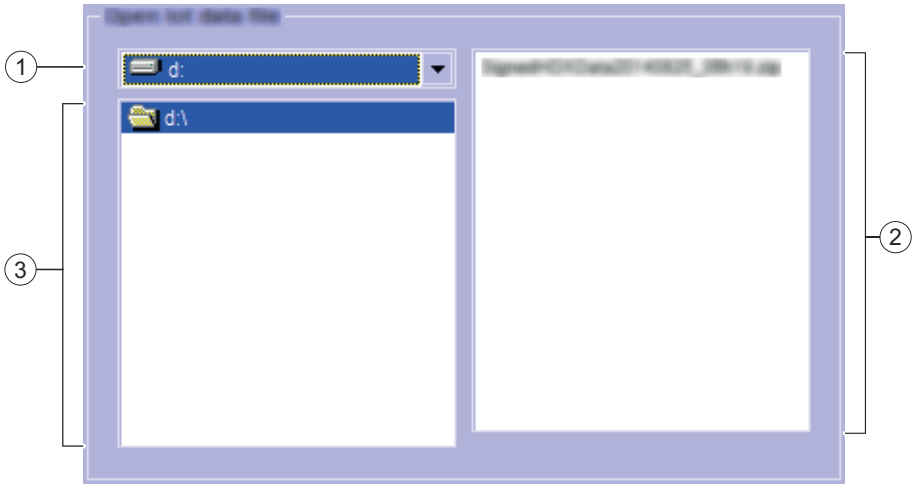
5.3.27 Open lot data file

Path to the dialog:

- **System > Lot data file**

The dialog is used to load lot data to the system from a lot data file provided by Siemens Healthineers.

The dialog is divided into 3 areas, see the figure below.



Open lot data file

(1) Drive
(2) Files
(3) Path

The areas of the dialog are explained in the table below.

Information	Explanation	Action
Drive	Drive names of the computer	Select
Files	Selected path The lot data is loaded from a lot data file in the selected folder.	Double-click
Path	Files with the extension **.txt**, **.zip**, or **.sd**	Select

Areas of the dialog

The user can select the drive and path where the lot data is stored. The lot data contains the current lot numbers and assigned values of controls and standards provided by Siemens Healthineers.

For information on downloading the lot data, see the Document Library Download Instruction Manual.

Lot data for each control lot can be viewed in the dialog **Definitions**, on the tab **Control lots**, see (➔ Page 80 *Control lots*).

Lot data for each standard lot can be viewed in the dialog **Definitions**, on the tab **Standard lots**, see (➔ Page 81 *Standard lots*).

5.3.28 Pre-loading

Path to the dialog:

- **Loading > Auto loading**

The dialog is used to assign non-barcoded samples to sample rotor segments that are not on-board, see the table below.

The dialog is only available for samples that are displayed in the lab journal but are not assigned to a sample rotor segment.

Information	Explanation	Action
Number of positions to be loaded	Number of samples that were selected in the dialog **Loading samples**	-
Segment ID	Segment ID of sample rotor segments that are not on-board The user can select 1 or more sample rotor segments to which the selected samples will be assigned by the system.	Select
Free positions	Number of positions available on the sample rotor segment	Select

Pre-loading

The user must manually load non-barcoded samples on the selected sample rotor segments according to the assignment. This assignment is also called pre-loading.

5.3.29 Print preview

Path to the dialog:

- **Print**

The action button is available in several dialogs.

If printing with preview is selected in the dialog **Configuration**, on the tab **User settings**, a print preview is displayed every time the user clicks **Print**. The print preview displays the pages as they will be printed.

If printing without preview is selected in the dialog **Configuration**, on the tab **User settings**, data is printed directly, see (➔ Page 72 *User settings*).

The information displayed in the header of the print preview is explained in the table below.

Information	Explanation
-	Dialog name of which the print preview is displayed
SIEMENS ANEPH630	System name
Laboratory	Name and address of the laboratory or company entered in the dialog **Configuration**, see (➔ Page 72 *Address / Analyzer*)
Phone	Phone number of the laboratory or company entered in the dialog **Configuration**, see (➔ Page 72 *Address / Analyzer*)
Serial no.	Analyzer ID entered in the dialog **Configuration**, see (➔ Page 72 *Address / Analyzer*)
Version	Version of the system software
Operator	User name used for logging on, if applicable
Printing date	Printing date
Printing time	Printing time

Header of the print preview

In the footer of the print preview, the number of the current page and the total number of pages is displayed.

The user can scroll through the pages, print or export 1 or more pages, and zoom the pages in and out, see the table below.

Button	Explanation
	Displays the first page
	Displays the previous page
	Displays the next page
	Displays the last page
	Stops the transfer of data (spooling)
	Displays the print settings, see (➔ Page 108 *Print settings*)
	Displays the export settings, see (➔ Page 109 *Export settings*)
	Zooms the pages in or out

Buttons of the print preview

Information	Explanation	Action
Printer	Available printers	Select
All	All pages are printed.	Select
Pages	A page range is printed.	Select
From	The first page that is printed	Select or enter
To	The last page that is printed	Select or enter
Copies	Number of copies	Select or enter
Collate Copies	Print the copies collated 1 after another	Select
OK	Starts printing and closes the dial	Click

Information	Explanation	Action
Cancel	Closes the dialog without printing	Click

Print settings

Information	Explanation	Action
Format	Format of the exported data	Select
Destination	Destination of the exported data	Select
OK	Starts the export and closes the dialog	Click
Cancel	Closes the dialog without exporting	Click

Export settings

To the right of the buttons, information on the data sets in the print preview is displayed.

5.3.30 Print raw data

Path to the dialog:

- **System > Print raw data**

When printing with preview is selected in the dialog **Configuration**, on the tab **User settings**, a print preview for raw data is displayed every time the user clicks **Print raw data**. Raw data is displayed in a list, see the table below.

Information	Explanation
Cuv.	Number of the cuvette used for the measurement
Date	Date of the measurement
Time	Time of the measurement
Assay	Abbreviation of the assay
Identification	Sample ID, standard ID with abbreviation of the standard, or control ID with abbreviation of the control
Dil.	Dilution used for the measurement
Start	Start value of the reaction, measured after 7.5 s
Value	End value of the
PrerVal.	Value of the pre-reaction If no pre-reaction has occurred, the value is **0**.
Flag	Flag, see (➔ Page 55 *Flags and symbols*)

Information in the print preview for raw data

5.3.31 Purge tubings

Path to the dialog:

- **System > Purge tubings**

The dialog is used to purge the tubing. The user has to follow the instructions displayed during the process.

Action buttons

For special action buttons, see the table below.

Action button	Explanation
Start purging	Starts the purging of the tubing
Start rinsing	Starts the rinsing of the tubing

Special action buttons

5.3.32 QC

Path to the dialog:

- **QC**

The button **QC** is deactivated if the quality control software is not installed. If the quality control software is installed, the button is active. Clicking the button opens the quality control software, see the documentation of the quality control software.

5.3.33 Remote control

Path to the dialog:

- (automatically displayed when Siemens Healthineers service requests remote control)

The dialog is used to accept or reject a remote control request of Siemens Healthineers service or the Atellica Process Manager, see the table below.

Information	Explanation	Action
Accept	Accepts remote control	Select
Reject	Rejects remote control	Select
Auto reject	Automatically rejects remote control after the displayed number of seconds	-

Accept or reject remote control

The user can distinguish a remote control request by Siemens Healthineers service or Atellica Process Manager by means of the displayed information, see the table below.

Information	Explanation
Accept or reject remote control by Siemens Healthineers service?	Remote control request by Siemens Healthineers service
Accept or reject remote control by Atellica Process Manager?	Remote control request by a user of Atellica Process Manager

When the dialog is activated for a remote control from the Atellica Process Manager, the confirmation requests have to be accepted for every single remote control. After deactivating the dialog for a remote control from the Atellica Process Manager, the confirmation requests will be accepted automatically.

If a remote control is running, a notification is displayed in front of the screen. The notification is flagged with the string Remote control. The user can drag and drop the notification anywhere on the screen.

The dialog for a remote control by the Atellica Process Manager can be deactivated by Siemens service.

5.3.34 Repeat

Paths to the dialog:

- Re-measure assays for samples:

  Lab journal > Repeat

  Sample details > Repeat

- Re-measure 1 assay for a control:

  Lab journal > Repeat

  Control details > Repeat

The dialog is used for the following:

- Definition of special dilutions and new dilution series for re-measurements of multiple assays of multiple samples
- Definition of special dilutions and new dilution series for the re-measurement of 1 assay of 1 control

If a measurement is repeated, it is given priority processing. The parts of the dialog are explained in the table below.

Information	Explanation	Action
Sample ID / Assay	**Samples**: Sample ID and selected assays **Controls**: Control ID and selected assay	-
Special dilution	Special dilutions for the selected assay, see (➔ Page 112 *Special dilution*) The colors and markings of the table cells have different meanings, see (➔ Page 112 *Colors and markings of table cells*).	-
New dilution series	If the check box is selected, new dilutions are prepared for the re-measurement. If the check box is de-selected and dilutions prepared previously are still valid according to the defined dilution stabilities, these dilutions are used for the re-measurement. If the check box is de-selected and the corresponding dilution is already expired, a new dilution is prepared by default.	Select

Repeat

Information	Explanation	Action
-	Special dilutions available for the assay selected in the list **Sample ID / Assay**	-
(Assay)	Abbreviation of the assay	Select
Measurement range	Measurement range for the special dilution	-

Special dilution

Color and marking	Explanation
Dark gray, no marking	Special dilution is not available for the assay.
White, no marking	Special dilution is available but not assigned to the job.
White, **X**	Special dilution is available and assigned to the job.
Yellow, no marking	Initial dilution for the assay, not assigned to the job The initial dilution is provided by Siemens Healthineers.
Yellow, **X**	Initial dilution for the assay, assigned to the job The initial dilution is provided by Siemens Healthineers.

Colors and markings of table cells

5.3.35 Replace syringe

Path to the dialog:

- **System > Replace syringe**

The dialog is used to replace the syringe. The user has to follow the instructions displayed during the process.

5.3.36 Replace system liquids and empty waste container

Path to the dialog:

- **System > System liquid & waste**

The dialog is used to confirm the replacement of system liquids and the draining of the waste container, see the table below.

Information	Explanation	Action
Replaced system liquid	System liquid that has been replaced The selected system liquids are used to rinse the system after confirmation. The number of rinsing cycles required is determined by the system.	Select
Waste container	Waste container has been emptied	Select

Replace system liquids and empty waste container

5.3.37 Request controls

Path to the dialog:

- **Lab journal > Request controls**

The dialog is used to request control measurements via a table. The parts of the dialog are explained in the table below.

Information	Explanation	Action
Table heading	All assays with at least 1 valid reference curve	-
Left column of the table	Controls defined in the dialog **Definitions**, on the tab **Controls** The colors and markings of the table cells have different meanings, see (➔ Page 113 *Colors and markings of table cells*).	-
New dilution series	If the check box is selected, new dilutions are prepared for the re-measurement. If the check box is de-selected, the dilutions prepared previously are used for the assay.	Select

Request controls

The user can assign assays to a job by clicking the corresponding table cell. The colors and markings of the table cells are explained in the table below.

Color and marking	Explanation
Dark gray, no marking	Assay is not available in the control.
White, no marking	Assay is not assigned to the job.
White, **X**	Assay is assigned to the job.

Colors and markings of table cells

If multiple lots of a control are on-board, a dialog is displayed in which the user can select the required lot by clicking it.

If valid reference curves for multiple lots of a reagent are available, a dialog is displayed in which the user can select the required lot by clicking it.

Action buttons

For special action buttons, see the table below.

Action button	Explanation
Cyclic control	Activates cyclic control measurements Cyclic control measurements can only be activated after the corresponding components are defined in the dialog **Definitions**, on the tab **Controls**, see (➔ Page 76 *Controls*). Jobs for cyclic control measurements persist when control measurements are requested manually via the action button **Measure**.
Measure	Requests the selected control measurements

Special action buttons

5.3.38 Rinse system

Path to the dialog:

- **System > Rinse system**

The dialog is used to rinse the system.

Information in the dialog is explained in the table below.

Information	Explanation	Action
System liquid	System liquid to be used for rinsing	Select
Number of rinsing cycles	Number of rinsing cycles The maximum number of rinsing cycles is **5**.	Enter

Rinse system

5.3.39 Sample details

Path to the dialog:

- Routine button **Lab journal** > double-click a line with a requested job or a measurement result of a sample

The dialog is used to view patient data and information on all sample results.

In the top left corner, the sample ID is displayed, preceded by a symbol, if applicable, see (→ Page 55 *Flags and symbols*).

Area Patient data

The area **Patient data** displays information on the patient, if available, see the table below.

Information	Explanation
First name	First name
Initial	Abbreviation of the middle name, if applicable
Last name	Last name
Date of birth	Date of birth The format of the date depends on the settings of the operating system of the computer.
Practice assigned ID	ID assigned by the referring practice
Laboratory assigned ID	ID assigned by the laboratory
Additional Patient ID	Any additional ID
Comment	Any additional comment on the patient

Patient data

Table below the area Patient data

The table below the area **Patient data** displays details for all sample results, for example, repeated measurements. Column headings are explained below.

Information	Explanation
Status	Status of results, represented by symbols, if applicable, see (➔ Page 55 *Flags and symbols*)
Assay	Abbreviation of the assay
Result/Unit	Measurement result and corresponding unit If a measurement result is above the measurement range, the upper limit is displayed additionally, with the symbol **>**, for example, > 16.3 g/L. If a measurement result is below the measurement range, the lower limit is displayed additionally, with the symbol **<**, for example, < 0.1439 g/L.
Flag	Flag, if applicable, see (➔ Page 55 *Flags and symbols*)
Dilution	Dilution used for the measurement
AD	Assay dilution: Requested special dilution of the assay, represented by symbols, if applicable, see (➔ Page 55 *Flags and symbols*)
Time	Time at which the job was finished

Column headings

Action buttons For special action buttons, see the table below.

Action button	Explanation
Repeat	Displays the dialog **Repeat**, see (➔ Page 111 *Repeat*)
Kinetics	Displays the dialog **Kinetics**, see (➔ Page 82 *Kinetics - Measurement curves*)

Special action buttons

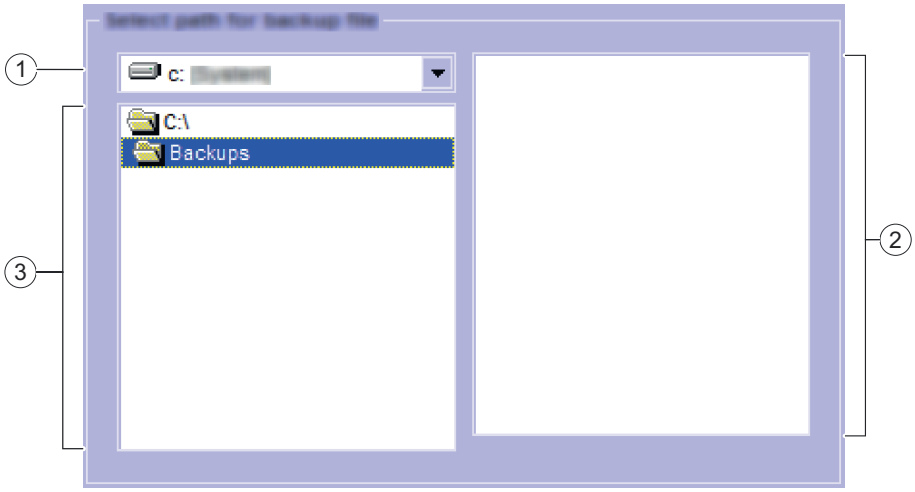
5.3.40 Select path for backup file

Path to the dialog:

- **System > Backup**

The dialog is used to create backups of all data required for operation, for example, calibration data and system configuration.

The dialog is divided into 3 areas, see the figure below.



Select path for backup file

(1) Drive
(2) Files
(3) Path

The areas of the dialog are explained in the table below.

Information	Explanation	Action
Drive	Drive names of the computer	Select
Files	Selected path The backup is created in the selected folder.	Double-click
Path	Files with the extension **.txt**	-

Areas of the dialog

The user can select the drive and path where the backup will be created. The path is displayed in the dialog.

Backup data can only be restored by Siemens Healthineers service.

5.3.41 Show curve

Path to the dialog:

- **Calibration > Show curve**

The dialog is used to check the reference curves of an assay or a reagent lot selected in the dialog **Calibration**.

The system tags the supporting points with red crosses and calculates the resulting reference curve.

The reference curve is displayed double-logarithmically. The concentration at which the supporting point was measured is displayed at the x-axis. The value at the supporting point is displayed at the y-axis. The user can change the measurement unit of the concentration in the dialog **Definitions**, on the tab **Units**, see (➔ Page 79 *Units*).

If an assay was selected in the dialog **Calibration**, the user can scroll through the reference curves relating to this assay by using the buttons for master navigation in the top left corner, see (➔ Page 54 *Master navigation*).

Details on the reference curve are displayed above and below the graph, see the table below.

Above the graph	
Assay	Abbreviation of the assay and assay number
-	Date and time of the last measurement for the reference curve
-	Remark on the reference curve, for example, if the curve has been released automatically or manually
Mean deviation	Mean deviation of all supporting points of the reference curve

Below the graph	
Standard	Standard used for the measurement with its ID An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number.
Reagents	Abbreviation of the reagents and supplementary reagents used for the measurement and reagent IDs An ID comprises 6 digits, 4 digits for the identifier number and 2 digits for the lot number.
Table of supporting points	Information on the supporting points of the reference curve is given in the table below.

Details on the reference curve

Information	Explanation
No.	Running number of the supporting point
Dilution	Dilution at which the result was measured
Conc. [unit]	Concentration at which the result was measured
Prereact. [Bit]	Value of the pre-reaction
First value [Bit]	First value
Value [Bit]	Value at the supporting point
Dev. [%]	Deviation of the value at the supporting point from the calculated reference curve

Supporting points of the reference curve

Navigation between measurement curves

If an assay was selected in the dialog **Calibration**, the user can scroll through the reference curves relating to this assay by using the buttons for master navigation in the top left corner, see (➔ Page 54 *Master navigation*).

Action buttons

For special action buttons, see the table below.

Action button	Explanation
Repeat	Repeats the measurement of the reference curve for the displayed assay

Action button	Explanation
Release	Releases reference curves that deviate from the validity criteria Validity criteria are defined in the assay protocols.
Kinetics	Displays the dialog **Kinetics**, see (➔ Page 83 *Kinetics - Reference curve*)

Special action buttons

5.3.42 Special dilution

Paths to the dialog:

- **New > Special dilution**
- **Add request > Special dilution**

The dialog is used for the following:

- When accessed via the dialog **New**: Entering special dilutions for a job via a table
- When accessed via the dialog **Add request**: Entering special dilutions for a sample via a table

  In this case, in the top left corner, the sample ID is displayed.

Special dilutions cannot be assigned to jobs already requested.

The table heading lists all available assays. The left column lists all available dilution steps.

The colors and markings of the table cells are explained in the table below.

Color and marking	Explanation
Dark gray, no marking	Special dilution is not available for the assay.
White, no marking	Special dilution is available but not assigned to the job.
White, **X**	Special dilution is available and assigned to the job.
Yellow, no marking	Initial dilution for the assay, not assigned to the job The initial dilution is provided by Siemens Healthineers.
Yellow, **X**	Initial dilution for the assay, assigned to the job The initial dilution is provided by Siemens Healthineers.

Colors and markings of table cells

The user can enter special dilutions by clicking the corresponding field in the table. When the user places the mouse pointer over a field, a tool tip text with the corresponding measurement range is displayed.

Samples with a relatively low or higher concentration should be measured at a lower or higher dilution, different from the initial dilution.

5.3.43 Status

Path to the dialog:

- **Status**

The dialog is used to display the status of various parts of the system, see the figure below.



Details of the dialog Status (example)

(1) Background
(2) Dialog area (example)
(3) Buttons (examples)
(4) Estimated walk-away time (information only)

Colors of the background

The background is displayed in different colors representing the existence of problems and their seriousness. If multiple problems for a specific part of the system are detected, the color for the problem with the highest priority is displayed first. The colors are explained in the table below.

Color	Explanation
Red	The requested jobs cannot be processed. The system is not operating. Follow the directions given by the system to continue routine processing.
Yellow	The requested jobs cannot be completely processed. If the user does not resolve the problem, the color will change to red soon. – or – The system is warming up.
Blue	All material required is available and valid, operating conditions are ok, the system is operating. All requested jobs can be processed.

Colors of the background

Colors of the buttons

The buttons within the dialog areas are displayed in different colors, see the table below.

Dialog area	Button	Color	Explanation
All areas	All buttons	Blue	The material required is available and valid. Operating conditions are ok.
Samples and standards	**Not sufficient**	Red	Required samples are empty. Required standard are empty.
Samples and standards	**Not sufficient**	Yellow	Required samples are empty but the system can process other requested jobs. Required standards are empty but the system can process other requested jobs.
Samples and standards	**Missing**	Red	Required samples are missing. Required standards are missing.
Samples and standards	**Missing**	Yellow	Required samples are missing but the system can process other requested jobs. Required standards are missing but the system can process other requested jobs.
Reagents	**Not sufficient**	Red	Required reagents are empty.
Reagents	**Not sufficient**	Yellow	Required reagents are empty but the system can process other requested jobs.
Reagents	**Missing**	Red	Required reagents are missing.
Reagents	**Missing**	Yellow	Required reagents are missing but the system can process other requested jobs.
Controls	**Not sufficient**	Red	Required controls are empty.
Controls	**Not sufficient**	Yellow	Required controls are empty but the system can process other requested jobs.
Controls	**Missing**	Red	Required controls are missing.
Controls	**Missing**	Yellow	Required controls are missing but the system can process other requested jobs.
Cuvettes	**Used**	Red	All available cuvettes are used.
Cuvettes	**Used**	Yellow	More than 81 cuvettes are used and further jobs are requested.
Cuvettes	**Available**	Yellow	Less than 10 cuvettes are available and further jobs are requested.
Dilution cups	**Used**	Yellow	All dilution cups are used or spared for potential re-measurements and STAT samples.
Dilution cups	**Available**	Yellow	Less than 7 dilution cups are available and further jobs are requested.
Reference curves	**Missing**	Yellow	Reference curves for requested jobs are missing.
Reference curves	**Invalid**	Yellow	At least 1 reference curve for requested jobs is invalid, the mean deviation is outside the defined range.

Dialog area	Button	Color	Explanation
Information	**Temperatures**	Red	At least 1 monitored temperature is outside the defined temperature range. The defined temperature range was not reached within a defined period of time.
Information	**Temperatures**	Yellow	At least 1 monitored temperature is outside the defined temperature range. The system will resume operation when the defined temperature range is reached.
Information	**Covers**	Red	The covers have been opened during operation without access being requested via the software. – or – The covers have not been closed correctly. – or – The reagent rotor or cuvette rotor covers have not been inserted correctly. – or – The dilution frame has not been inserted correctly.
Information	**System liquids**	Red	Water, diluent, buffer, or probe cleaner is used up. – or – The level sensors have not been inserted properly into the corresponding containers.
Information	**System liquids**	Yellow	Water, diluent, buffer, or probe cleaner is almost used up. – or – Water, diluent, buffer, or probe cleaner is used up but no further jobs are requested.
Information	**Waste**	Red	The waste container is full and further jobs are requested.
Information	**Waste**	Yellow	The waste container is full but no further jobs are requested. – or – The waste container is almost full.
Information	**Analyzer status**	Red	An internal problem has occurred.

Colors of the buttons in dialog areas

When the user places the mouse pointer over a red or yellow button, a tool tip text specifying the problem is displayed.

When the user clicks a red or yellow button, there are 2 possibilities:

- The dialog where the problem can be resolved is displayed.
- The dialog **Logbook** providing detailed information on the problem is displayed.

Information on the buttons

The buttons within the dialog areas display varying information according to changing operating conditions, see the table below.

Dialog area	Button	Information	Explanation
Samples and standards	**On-board**	(Number)	The number of samples and standards loaded in the sample rotor is displayed.
Samples and standards	**Not sufficient**	(Number)	The system constantly calculates the required volumes of samples and standards for requested jobs. The number of samples and standards with insufficient volumes is displayed.
Samples and standards	**Missing**	(Number)	The system constantly checks the samples required to perform requested jobs. The number of missing samples is displayed. Missing standards are not displayed because a reference curve cannot be requested when the standard is missing.
Reagents	**On-board**	(Number)	The number of reagents loaded in the reagent rotor is displayed.
Reagents	**Not sufficient**	(Number)	The system constantly calculates the required volumes of reagents for requested jobs. The number of reagents with insufficient volumes is displayed.
Reagents	**Missing**	(Number)	The system constantly checks the reagents required to perform requested jobs. The number of missing reagents is displayed.
Controls	**On-board**	(Number)	The number of controls loaded in the reagent rotor is displayed.
Controls	**Not sufficient**	(Number)	The system constantly calculates the required volumes of controls for requested jobs. The number of controls with insufficient volumes is displayed.
Controls	**Missing**	(Number)	The system constantly checks the controls required to perform requested jobs. The number of missing controls is displayed.
Cuvettes	**Used**	(Number)	The system constantly tracks the use of cuvettes. The number of used cuvettes is displayed.
Cuvettes	**Available**	(Number)	The system constantly tracks the use of cuvettes. The number of available cuvettes is displayed.
Dilution cups	**Used**	(Number)	The system constantly tracks the use of dilution cups. The number of used dilution cups is displayed.
Dilution cups	**Available**	(Number)	The system constantly tracks the use of dilution cups. The number of available dilution cups is displayed. The system reserves dilution cups for possible re-measurements and for STAT samples. These cups are not shown as available.
Reference curves	**Missing**	(Number)	The number of missing reference curves is displayed. A reference curve is missing when it is not available or is being processed at the time a job is requested.

Dialog area	Button	Information	Explanation
Reference curves	**Invalid**	(Number)	The number of invalid reference curves is displayed. A reference curve is invalid when the value of at least 1 supporting point cannot be determined or when the mean deviation of the reference curve exceeds the defined deviation. Invalid reference curves are not used for the evaluation of results.
Information	**Temperatures**	**!**	At least 1 monitored temperature is outside the defined temperature range. The defined temperature range was not reached within a defined period of time
Information	**Temperatures**	**?**	At least 1 monitored temperature is outside the defined temperature range. The system will resume operation when the defined temperature range is reached.
Information	**Temperatures**	**ok**	All monitored temperatures are in the defined temperature range.
Information	**Covers**	**!**	The covers have been opened during operation without access being requested via the software. – or – The covers have not been closed correctly. – or – The reagent rotor or cuvette rotor covers have not been inserted correctly. – or – The dilution frame has not been inserted correctly.
Information	**Covers**	**ok**	All covers and lids are closed correctly. The dilution frame is inserted correctly.
Information	**System liquids**	**!**	Water, diluent, buffer, or probe cleaner is used up.
Information	**System liquids**	**?**	Water, diluent, buffer, or probe cleaner is almost used up. – or – Water, diluent, buffer, or probe cleaner is used up but no further jobs are requested.
Information	**System liquids**	**ok**	All system liquids required are available.
Information	**Waste**	**!**	The waste container is full and further jobs are requested.
Information	**Waste**	**?**	The waste container is full but no further jobs are requested. – or – The waste container is almost full.
Information	**Waste**	**ok**	The waste container can hold the estimated volume of liquid waste from the requested jobs.
Information	**Analyzer status**	**!**	An internal problem has occurred.

Dialog area	Button	Information	Explanation
Information	**Analyzer status**	**ok**	The system is operating.

Information on the buttons in dialog areas

Monitored temperatures

The following temperatures are monitored:

- Ambient temperature
- Temperature in the reagent rotor
- Temperature in the cuvette rotor
- Temperature in the probe

Walk-away time

In the dialog area **Information**, the field **Walk-away time**displays the estimated walk-away time.

Action buttons

For special action buttons, see the table below.

Action button	Explanation
Exit	Displays a confirmation dialog The buttons of the confirmation dialog are explained in the table below.

Special action buttons

Button	Explanation	Action
Yes	Aborts running jobs Rinses the system Switches off the reagent cooler Shuts down the system Closes the software	Click
No	Closes the software	Click
Cancel	Closes the confirmation dialog without shutting down the system	Click

Buttons of the confirmation dialog

5.3.44 System

Path to the dialog:

- **System**

The dialog is used to perform maintenance, to request access, to check and initialize hardware components, to update and backup the software, and to reset the system.

The dialog is divided into areas, see the table below.

Information	Explanation	Action
Maintenance	Starts maintenance on different parts of the system, see (➔ Page 125 *Buttons in the area*)	Click
Access	Requests access to different parts of the system, see (➔ Page 125 *Buttons in the area*)	Click
Hardware check	Requests a hardware check of the probe, see (➔ Page 81 *Hardware check - probe*)	Click
Initialization	Requests the initialization of different parts of the system, see (➔ Page 126 *Buttons in the area*)	Click
Update and back up software	Updates lot data, creates backups, and prints requested and available raw data, see (➔ Page 126 *Buttons in the area*)	Click
About	Displays the current versions of the software and its components, see (➔ Page 59 *About*)	Click
Reset analyzer	Requests a reset of the system	Click

Dialog System

Maintenance

Button	Explanation
Check probe	Displays the dialog **Check probe**, see (➔ Page 66 *Check probe*)
Clean probe	Displays the dialog **Clean probe**, see (➔ Page 66 *Clean probe*)
Replace syringe	Displays the dialog **Replace syringe**, see (➔ Page 112 *Replace syringe*)
Purge tubings	Displays the dialog **Purge tubings**, see (➔ Page 109 *Purge tubings*)
Rinse system	Displays the dialog **Rinse system**, see (➔ Page 114 *Rinse system*)

Buttons in the area

Access

Button	Explanation
System liquid & waste	Displays the dialog **Replace system liquids and empty waste container**, see (➔ Page 112 *Replace system liquids and empty waste container*)
Cuv. seg. & dil. strips	Displays the dialog **Access cuvette segments and dilution strips**, see (➔ Page 59 *Access cuvette segments and dilution strips*)
Samples	Displays the dialog **Access samples**, see (➔ Page 61 *Access samples*)
Reagents	Displays the dialog **Access reagents**, see (➔ Page 61 *Access reagents*)

Buttons in the area

Hardware check

Button	Explanation
Probe	Displays the dialog **Probe**.

Buttons in the area

Initialization

Button	Explanation
Probe	Initializes the probe
Syringe	Initializes the syringe
Reagent rotor	Initializes the reagent rotor
Sample rotor	Initializes the sample rotor
Cuvette rotor	Initializes the cuvette rotor
Dilution frame	Initializes the dilution frame
Hardware	Initializes all hardware components

Buttons in the area

Update and back up software

Button	Explanation
Lot data file	Displays the dialog **Open lot data file**, see (➔ Page 105 *Open lot data file*)
Backup	Displays the dialog **Select path for backup file**, see (➔ Page 115 *Select path for backup file*)
Print raw data	Prints raw data

Buttons in the area

About

Button	Explanation
About	Displays the dialog **About**.

Buttons in the area

Reset analyzer

Button	Explanation
Reset analyzer	Displays the dialog **Reset analyzer**.

Buttons in the area

Action buttons

For special action buttons, see the table below.

Action button	Explanation
Configuration	Displays the dialog **Configuration**, see (➔ Page 67 *Configuration*)
Logbook	Displays the dialog **Logbook**, see (➔ Page 101 *Logbook*)

Action button	Explanation
Definitions	Displays the dialog **Definitions**, see (➔ Page 74 *Definitions*)

Special action buttons

6 Configuring the system

This chapter describes how to configure the system.

6.1 Adding a standard lot

✓ Reference values for assays assigned to the standard are available.

✓ The system is in standby or routine mode.

To add a standard lot, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Standards lots**.

→ The tab **Standard lots** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 81 *Standard lots*).

3 Select the standard for which a lot is to be added.

→ The corresponding table row is highlighted dark blue. The action button **Lot ID** becomes active.

4 Click **Lot ID**.

→ A new table row is added to the table.

5 Enter the lot ID in the left table cell.

6 Enter the reference values for the corresponding assays. Reference values can be found in the instructions for use of the standard.

Reference values can only be entered in white table cells.

7 After entering all reference values, click outside of the table cells.

→ The action button **Save** becomes active.

8 Click the action button **Save**.

→ The dialog **System** is displayed. The standard lot is added.

→ Adding a standard lot is completed.

6.2 Configuring cyclic control measurements

✓ The system is in standby or routine mode.

To configure cyclic control measurements, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Controls**.

→ The tab **Controls** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 76 *Controls*).

3 Click a control name for which cyclic control measurements will be configured.

→ The corresponding table row is highlighted dark blue.

4 In the highlighted row, click an assay for which cyclic control measurements will be configured.

→ The dialog **Control details** is displayed.

Cyclic control measurements can only be defined for assays marked with an **X**.

5 Configure when control measurements will be performed.

6 Click the action button **Save**.

→ In the dialog **Definitions**, the tab **Controls** is displayed. Changes are saved.

7 Click the action button **Close**.

→ The dialog **System** is displayed.

Defining cyclic control measurements does not activate the cyclic control measurement automatically. Cyclic control measurement has to be requested manually in the dialog **Request controls** for each assay, see (➔ Page 113 *Request controls*). For more information on the dialog, click the action button **Help**.

→ Configuring cyclic control measurements is completed.

6.3 Deactivating cyclic control measurements for an assay

✓ The system is in standby or routine mode.

To deactivate cyclic control measurements for an assay of a control, proceed as follows:

1 Select a control result of the affected assay in the lab journal.

2 Click the action button **Delete**.

→ The control result is deleted from the lab journal. Cyclic control measurements for the assay are deactivated but settings for cyclic control measurements are retained by the system.

→ Deactivating cyclic control measurements for an assay is completed.

6.4 Adding a user-defined control

✓ The system is in standby or routine mode.

To add a user-defined control, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

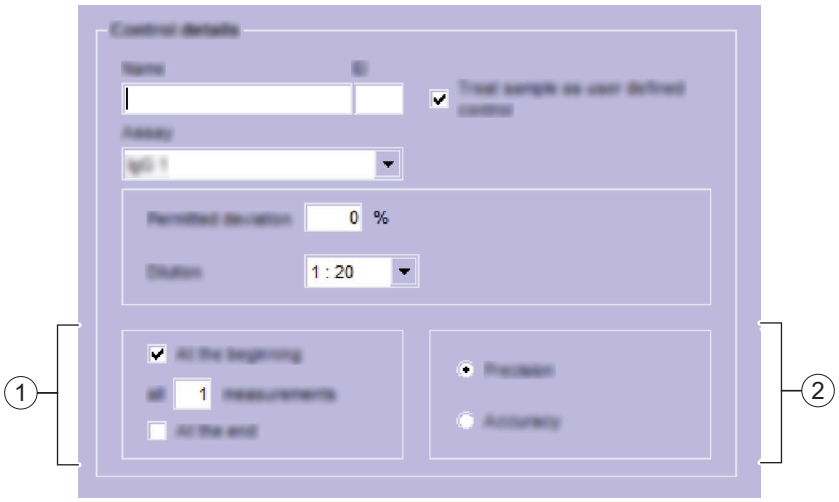
→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Controls**.

→ The tab **Controls** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 76 *Controls*).

3 Click the action button **New**.

→ The dialog **Control details** is displayed, see the figure below.



Areas of the dialog Control details

(1) Cyclic control measurement area
(2) Quality control area

4 In the input field **Name**, enter the name of the user-defined control.

5 In the input field **ID**, enter the 4-digit identifier number of the user-defined control.

The 4-digit identifier number of the user-defined control must not correspond to the identifier number of a reagent or standard. Otherwise the system will not accept the user-defined control.

Identifier numbers 9900–9999 are automatically specified as user-defined controls by the system.

6 Select the check box **Treat sample as user-defined control**.

7 In the list **Assay**, select an assay which will be assigned to the user-defined control.

8 In the input field **Permitted deviation**, enter the permitted deviation from the reference value.

9 In the list **Dilution**, select the dilution that will be used for the measurement of the assay.

Ensure that the selected dilution is appropriate for the assay.

10 Make other settings as required.

11 Click the action button **Apply**.

→ The user-defined control is saved.

An information dialog is displayed by the system

- Click **OK**.
- In the input field **ID**, enter a different 4-digit identifier number that does not correspond to the identifier number of a reagent or standard.
- Click the action button **Apply**.

12 Click the action button **Close**.

→ In the dialog **Definitions**, the tab **Controls** is displayed. In the left column, the new user-defined control is displayed.

13 To completely define the user-defined control, add a control lot, see (➔ Page 134 *Adding a control lot*).

14 Click the action button **Close**.

→ The dialog **System** is displayed.

→ Adding a user-defined control is completed.

6.5 Adding an assay to a user-defined control

✓ The system is in standby or routine mode.

To add an assay to a user-defined control, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Controls**.

→ The tab **Controls** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 76 *Controls*).

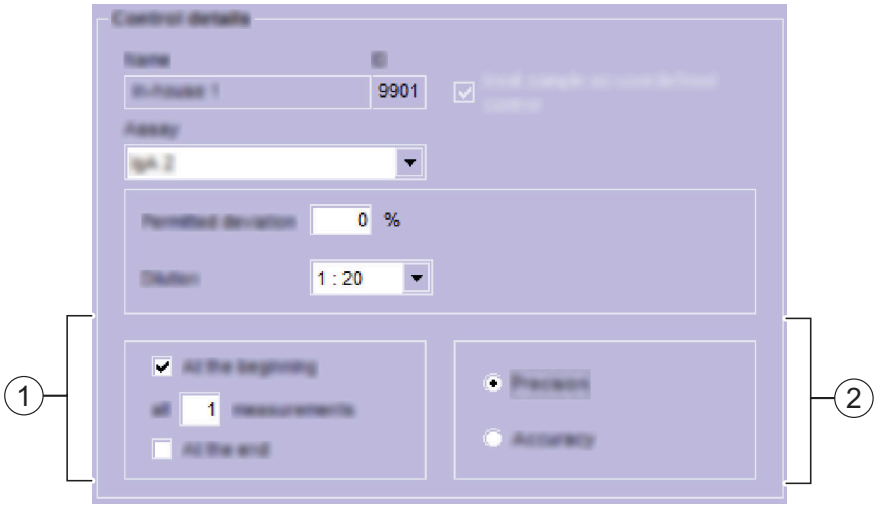
The names of user-defined controls are displayed in black.

3 Click the control name of the user-defined control.

→ The corresponding table row is highlighted dark blue.

4 Click the action button **New**.

→ The dialog **Control details** is displayed, see the figure below.



Areas of the dialog Control details

(1) Cyclic control measurement area
(2) Quality control area

5 In the list **Assay**, select an assay which will be assigned to the user-defined control.

6 In the input field **Permitted deviation**, enter the permitted deviation from the reference value.

7 In the list **Dilution**, select the dilution that will be used for the measurement of the assay.

Ensure that the selected dilution is appropriate for the assay.

8 Make other settings as required.

9 Click the action button **Apply**.

→ Changes are saved.

10 Click the action button **Close**.

→ In the dialog **Definitions**, the tab **Controls** is displayed. All assays assigned to the user-defined control are marked with an **X**.

11 Click the action button **Close**.

→ The dialog **System** is displayed.

Assays cannot be deleted from any control. If an assay is no longer required in a user-defined control, the user-defined control must be deleted, see (→ Page 134 *Deleting a user-defined control*). Then a new user-defined control must be created instead, see (→ Page 129 *Adding a user-defined control*).

→ Adding an assay to a user-defined control is completed.

6.6 Editing assay settings in a user-defined control

✓ The system is in standby or routine mode.

To edit assay settings in a user-defined control, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Controls**.

→ The tab **Controls** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 76 *Controls*).

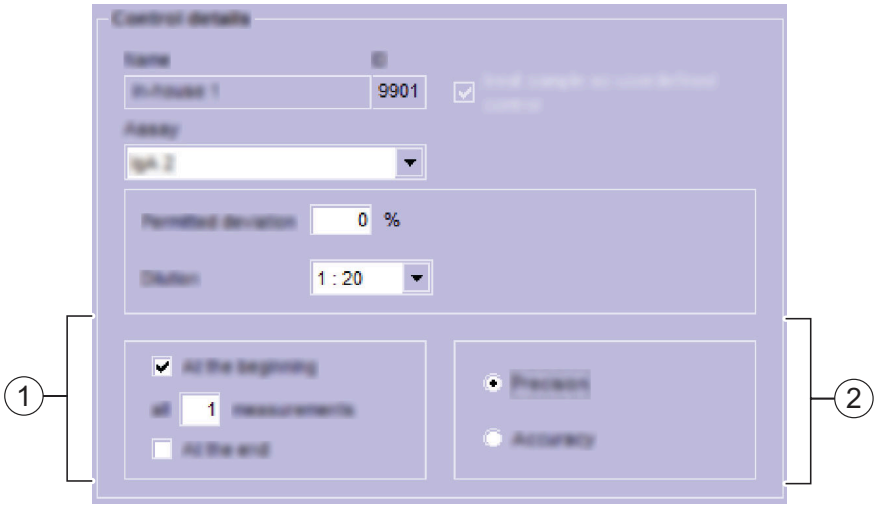
The names of user-defined controls are displayed in black.

3 Click the control name of the user-defined control.

→ The corresponding table row is highlighted dark blue.

4 Click the action button **New**.

→ The dialog **Control details** is displayed, see the figure below.



Areas of the dialog Control details

(1) Cyclic control measurement area
(2) Quality control area

5 In the list **Assay**, select the assay whose settings need to be edited.

6 Make other settings as required.

7 Click the action button **Apply**.

→ Changes are saved.

8 Click the action button **Close**.

→ In the dialog **Definitions**, the tab **Controls** is displayed.

9 Click the action button **Close**.

→ The dialog **System** is displayed.

Assays cannot be deleted from any control. If an assay is no longer required in a user-defined control, the user-defined control must be deleted, see (➔ Page 134 *Deleting a user-defined control*). Then a new user-defined control must be created instead, see (➔ Page 129 *Adding a user-defined control*)

→ Editing assay settings in a user-defined control is completed.

6.7 Deleting a user-defined control

✓ The user-defined control to be deleted is not on-board.

✓ The system is in standby or routine mode.

To delete a user-defined control, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Controls**.

→ The tab **Controls** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 76 *Controls*).

The names of user-defined controls are displayed in black.

3 Click the control name of the user-defined control.

→ The corresponding table row is highlighted dark blue.

4 Click the action button **Delete**.

→ A confirmation dialog is displayed.

5 Click **Yes**.

→ The user-defined control is deleted.

6 Click the action button **Close**.

→ The dialog **System** is displayed.

→ Deleting a user-defined control is completed.

6.8 Adding a control lot

✓ Reference values for assays assigned to the control are available.

✓ The system is in standby or routine mode.

To add a control lot, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Control lots**.

→ The tab **Control lots** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 80 *Control lots*).

3 Select a control for which a lot is to be added.

→ The corresponding table row is highlighted dark blue. The action button **Lot ID** becomes active.

4 Click **Lot ID**.

→ A new table row is added to the table.

5 Enter the lot ID in the left table cell.

6 Enter the reference values for the corresponding assays. Reference values for controls provided by Siemens Healthineers can be found in the instructions for use of the corresponding controls.

Reference values can only be entered in white table cells.

7 After entering all reference values, click outside of the table cells.

→ The action button **Save** becomes active.

8 Click the action button **Save**.

→ The dialog **System** is displayed. The control lot is added.

→ Adding a control lot is completed.

6.9 Deleting a control lot

Only control lots with a lot number can be deleted. If the lot number is replaced by --, no reference values have been defined for this control. This control cannot be deleted.

✓ The control lot to be deleted is not on-board.

✓ Reference values for assays assigned to the control are available.

✓ The system is in standby or routine mode.

To delete a control lot, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Control lots**.

→ The tab **Control lots** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 80 *Control lots*).

3 In the first column of the table, click the affected lot of the control.

→ The corresponding table row is highlighted dark blue.

4 Click the action button **Delete**.

→ A confirmation dialog is displayed.

5 Click **Yes**.

→ In the left column, the affected lot of the control is deleted.

6 Click the action button **Close**.

→ The dialog **System** is displayed.

→ Deleting a control lot is completed.

6.10 Adding a profile

✓ The system is in standby or routine mode.

To add a profile, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 76 *Profiles*).

2 Click the action button **New**.

→ An empty row is added to the table.

3 In the left table cell, enter the profile name.

4 In the table cells to the right of the profile name, select all assays required.

→ Selected assays are marked with an **X**.

5 Click the action button **Save**.

→ The dialog **System** is displayed. The new profile is added.

→ Adding a profile is completed.

6.11 Adding an assay to a profile

✓ The system is in standby or routine mode.

To add an assay to a profile, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 76 *Profiles*).

2 In the table cells to the right of the profile name, select all assays required.

→ Selected assays are marked with an **X**.

3 Click the action button **Save**.

→ The dialog **System** is displayed. Changes are saved.

→ Adding an assay to a profile is completed.

6.12 Removing an assay from a profile

✓ The system is in standby or routine mode.

To remove an assay from a profile, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 76 *Profiles*).

2 In the table cells to the right of the profile name, de-select all assays required.

→ The **X** is removed from de-selected assays.

3 Click the action button **Save**.

→ The dialog **System** is displayed. Changes are saved.

→ Removing an assay from a profile is completed.

6.13 Deleting a profile

✓ The system is in standby or routine mode.

To delete a profile, proceed as follows:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 76 *Profiles*).

2 In the left column, click the profile name.

3 Click the action button **Delete**.

→ A confirmation dialog is displayed.

4 Click **Yes**.

→ The profile is deleted from the table.

5 Click the action button **Save**.

→ The dialog **System** is displayed.

→ Deleting a profile is completed.

6.14 Adding a sample rotor segment ID

✓ The system is in standby or routine mode.

To add a sample rotor segment ID, proceed as follows:

1 In the dialog **System**, click the action button **Configuration**.

→ In the dialog **Configuration**, the tab **Language** is displayed.

2 Click the tab **Sample segments**.

→ The tab **Sample segments** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 71 *Sample segments*).

3 Make the settings as required.

4 Click the action button **Add**.

→ The sample rotor segment ID is added to the list **Segment list**.

5 Click the action button **Save**.

→ The dialog **System** is displayed.

→ Adding a sample rotor segment ID is completed.

6.15 Deleting a sample rotor segment ID

✓ The system is in standby or routine mode.

To delete a sample rotor segment ID, proceed as follows:

1 In the dialog **System**, click the action button **Configuration**.

→ In the dialog **Configuration**, the tab **Language** is displayed.

2 Click the tab **Sample segments**.

→ The tab **Sample segments** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 71 *Sample segments*).

3 In the list **Segment list**, select a sample rotor segment ID to be delete.

4 Click the action button **Delete**.

→ The sample rotor segment ID is deleted from the list **Segment list**.

5 Click the action button **Save**.

→ The dialog **System** is displayed.

→ Deleting a sample rotor segment ID is completed.

6.16 Configuring the immersion depth for cups used with a cup-in-tube segment

✓ A cup-in-tube segment is available.

✓ A tube of the type that will be used with the cup-in-tube segment is available.

✓ A cup of the type that will be used with the cup-in-tube segment is available.

✓ A folding rule or a tape measure is available.

✓ The system is in standby or routine mode.

To configure the immersion depth for cups used with a cup-in-tube segment, proceed as follows:

NOTICE

A default value for the variable Z is provided by Siemens Healthineers for all defined cup-in-tube segments. If the default value is not adapted to the cups used with a specific cup-in-tube segment, the probe can crash on the inner base of the cup.

Damage to the system can result.

- Adapt the default value to the cups used with a cup-in-tube segment before this cup-in-tube segment is loaded in the sample rotor.

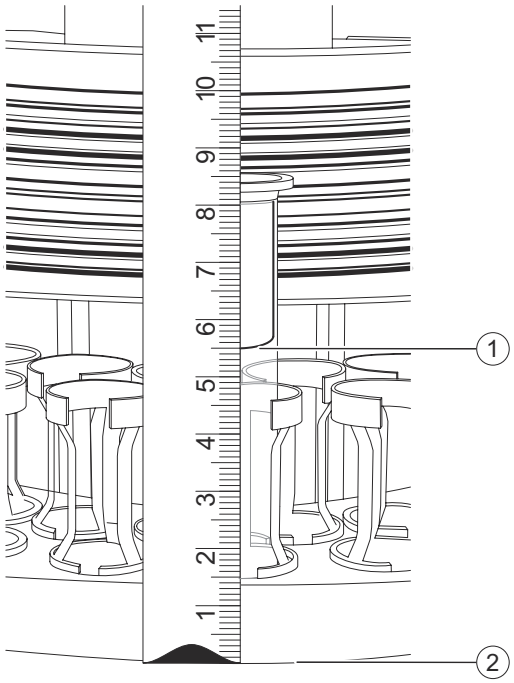
If the default value is not adapted to the cups used with a specific cup-in-tube segment, the probe cannot aspirate sample volume. Delay of results can occur.

1 Place the cup-in-tube segment on a level surface.

2 Place the tube in 1 of the adapters on the cup-in-tube segment.

3 Place the cup in the tube.

4 Hold the folding rule or tape measure in front of the cup, see the figure below.



Determining the immersion depth (example)

(1) Inner base or intermediate base of the cup
(2) Bottom edge of the cup-in-tube segment

Make sure that the zero mark of the folding rule or tape measure is aligned with the bottom edge of the cup-in-tube segment.

5 Measure the distance from the bottom edge of the cup-in-tube segment to the inner base or intermediate base of the cup.

6 Add 1 mm to the measured value as a safety allowance.

→ The calculated value corresponds to the value Z displayed in the dialog **Definitions**, on the tab **Immersing depth**.

Example:

The distance measured from the bottom edge of the cup-in-tube segment to the inner base of the cup is 55 mm.

Z = 55 mm + 1 mm = 56 mm

where Z is the calculated value.

7 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

8 Click the tab **Immersing depth**.

→ The tab **Immersing depth** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 79 *Immersing depth*).

9 Click the action button **Change depth**.

→ An information dialog is displayed.

The immersion depth can only be edited for defined cup-in-tube segments that are not on-board.

10 Click **Ok**.

→ A table and a graphic are displayed.

11 In the column **Z [mm]**, enter the previously calculated value for the corresponding cup-in-tube segment.

12 Click outside of the table cells.

→ The action buttons become active. The distance representing Z displayed in the graphic changes accordingly. The text in the corresponding table row is displayed in blue.

13 Click the action button **Save**.

→ In the dialog **Definitions**, the tab **Immersing depth** is displayed. The immersion depth is saved.

Siemens Healthineers recommends labeling the cup-in-tube segment to indicate what type of cup can be used with the cup-in-tube segment.

→ Configuring the immersion depth for cups used with a cup-in-tube segment is completed.

6.17 Configuring unit and reference range of an assay

✓ The system is in standby or routine mode.

To configure unit and reference range of an assay, proceed as follows:

WARNING

When the unit of an assay is changed, the values for the reference range are automatically converted to the new unit after saving. If the user has already entered the values for the reference range in the new unit, the values for the reference range will be wrong. False results can occur.

Death or serious injury to the patient can result.

- Change the unit of the assay first.
- Save the new unit before editing the reference range.

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Units**.

→ The tab **Units** is displayed. For more information on the tab, click the action button **Help** or see (→ Page 79 *Units*).

3 In the column **Unit** of the corresponding assay, select a unit, if required.

4 Click outside of the table cells.

→ The action button **Save** becomes active.

5 Click the action button **Save**.

→ The changes are saved. The dialog **System** is displayed.

6 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

7 Click the tab **Units**.

→ The tab **Units** is displayed.

8 In the column **Lower limit of reference range** and in the column **Upper limit of reference range** of the corresponding assay, enter a value, if required.

9 Click outside of the table cells.

→ The action button **Save** becomes active.

10 Click the action button **Save**.

→ The changes are saved. The dialog **System** is displayed.

→ Configuring unit and reference range of an assay is completed.

6.18 Setting automatic re-measurement and automatic release

✓ The system is in standby or routine mode.

To set automatic re-measurement and automatic release, proceed as follows:

1 In the dialog **System**, click the action button **Configuration**.

→ In the dialog **Configuration**, the tab **Language** is displayed.

2 Click the tab **Host**.

→ The tab **Host** is displayed. For more information on the tab, click the action button **Help** or see (→ Page 68 *Host*).

3 Select **Automatic re-measurement**, if required.

Re-measurements are done with the next higher or lower dilution for as long as the measurement result is outside the measurement range.

4 Select **Automatic release**, if required.

Results inside the reference range are automatically released and sent to the LIS, if available.

5 Click the action button **Save**.

→ The changes are saved. The dialog **System** is displayed.

→ Setting automatic re-measurement and automatic release is completed.

6.19 Configuring printouts

✓ The system is in standby or routine mode.

To configure printouts, proceed as follows:

1 In the dialog **System**, click the action button **Configuration**.

→ In the dialog **Configuration**, the tab **Language** is displayed.

2 Click the tab **Address / Analyzer**.

→ The tab **Address / Analyzer** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 72 *Address / Analyzer*).

3 Make the settings as required.

4 Click the action button **Save**.

→ The dialog **System** is displayed. Printouts are configured.

→ Configuring printouts is completed.

6.20 Setting the display of results in the lab journal

✓ The system is in standby or routine mode.

To set the display of results in the lab journal, proceed as follows:

1 In the dialog **System**, click the action button **Configuration**.

→ In the dialog **Configuration**, the tab **Language** is displayed.

2 Click the tab **User settings**.

→ The tab **User settings** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 72 *User settings*).

3 To the right of **Show results**, make the settings as required.

4 Click the action button **Save**.

→ The dialog **System** is displayed. The display of results in the lab journal is changed immediately.

→ Setting the display of results in the lab journal is completed.

6.21 Setting the default sort sequence in the lab journal

✓ The system is in standby or routine mode.

To set the default sort sequence in the lab journal, proceed as follows:

1 In the dialog **System**, click the action button **Configuration**.

→ In the dialog **Configuration**, the tab **Language** is displayed.

2 Click the tab **User settings**.

→ The tab **User settings** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 72 *User settings*).

3 To the right of **Sort sequence in the lab journal**, make the settings as required.

4 Click the action button **Save**.

→ The dialog **System** is displayed. The default sort sequence in the lab journal is changed immediately.

→ Setting the default sort sequence in the lab journal is completed.

6.22 Setting the language

✓ The system is in standby or routine mode.

To set the language, proceed as follows:

1 In the dialog **System**, click the action button **Configuration**.

→ In the dialog **Configuration**, the tab **Language** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 67 *Configuration*).

2 Select a language.

3 Click the action button **Save**.

→ The language is changed immediately. The dialog **System** is displayed in the selected language.

Entries already existing in the logbook are not translated.

→ Setting the language is completed.

6.23 Configuring significant digits of the sample ID

✓ The system is in standby or routine mode.

To configure significant digits of the sample ID, proceed as follows:

1 In the dialog **System**, click the action button **Configuration**.

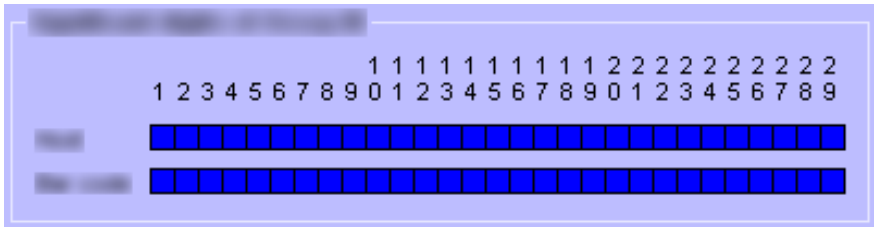
→ In the dialog **Configuration**, the tab **Language** is displayed.

2 Click the tab **Host**.

→ The tab **Host** is displayed. At the bottom of the tab, 2 rows of digits are displayed. For more information on the tab, click the action button **Help** or see (➔ Page 68 *Host*).

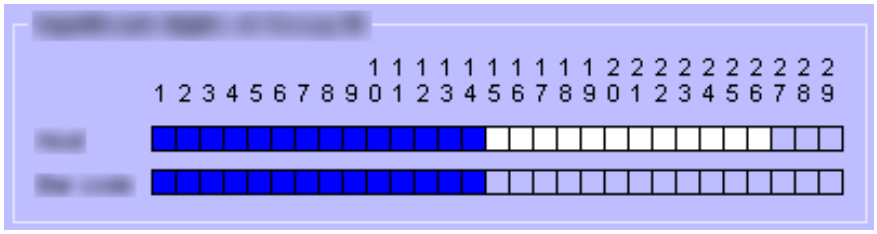
3 Make the settings in the 2 rows of digits as required.

Examples:



Significant digits of the sample ID (default setting)

In the default setting, the LIS sends the 29 digits of the barcode to the system together with the job list. The system sends the 29 digits of the barcode to the LIS together with the results.



Significant digits of the sample ID (example)

In the example, the LIS sends digits 1–14 of the barcode and digits 15–26 with additional information to the system together with the job list. The system sends digits 1–14 of the barcode to the LIS together with the results.

4 Click the action button **Save**.

→ The dialog **System** is displayed.

→ Configuring significant digits of the sample ID is completed.

6.24 Configuring the LIS connection

To configure the LIS connection, see the data interface manual of the system.

WARNING

False results due to incorrect LIS connection

Death or serious injury to the patient can result.

- Follow the instructions in the data interface manual of the system to configure the LIS connection correctly.
- LIS configuration needs to be validated by the laboratory organization.

7 Preparing for the analysis

This chapter describes how to prepare the system for the analysis.

7.1 Starting the system

✓ The system is off.

To start the system, proceed as follows:

NOTICE

Failure of electrical parts of the system can result if the system is re-started too soon after a shutdown.

Damage to the system can result.

◆ Wait at least 10 seconds before restarting the system after a shutdown.

1 Switch on the printer, if appropriate.

2 Make sure that the reagent rotor and cuvette rotor covers are inserted correctly and that the covers are closed correctly.

3 Check if the waste container is empty.

→ The waste container is empty.

The waste container is not empty.

◆ Empty the waste container, see (➔ Page 146 *Emptying the waste container*).

4 Make sure that the filling level of the system liquids is sufficient.

The filling level of at least 1 system liquid is low.

◆ Replace the system liquid, see (➔ Page 147 *Replacing system liquids*).

5 If the sensor of the buffer container is inserted into a container filled with water: Re-insert the level sensor into the buffer container. Otherwise skip this step.

6 Check that each level sensor is inserted properly in the corresponding container.

Make sure that the level sensor is inserted at an angle into the corresponding container. The free end of the level sensor inside the container must point away from the opening in the container so that the floater at the end of the level sensor can move up and down freely.

The tubing bears differently colored markings, see (➔ Page 47 *Liquid containers, level sensors, and tubing*).

7 At the right side of the system, set the main switch to position I.

→ The system starts.

8 Switch on the monitor.

9 Switch on the computer.

→ The computer starts.

10 In the dialog for the log on to the operating system, enter user name and password, if appropriate.

11 Click **Ok**, if appropriate.

→ The operating system starts.

12 Wait until the 3 LEDs in the upper right corner at the front of the system are on.

13 In the desktop screen, click **Atellica NEPH 630 Viewer**.

→ The viewer software starts. The dialog **Initialize analyzer** is displayed. This can take up to 10 minutes.

14 Wait until the dialog **Status** is displayed.

→ The system is operating.

The dialog **Log on** is displayed.

- Enter user name and password.
- Click **Ok**.

→ Starting the system is completed.

7.2 Emptying the waste container

✓ The system is in standby or routine mode.

To empty the waste container, proceed as follows:

WARNING

Infection due to infectious waste

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle parts of the system that have come into contact with potentially infectious material in accordance with good laboratory practices.

NOTICE

If containers are placed on or above the system, system liquids can flow over or into the system.

Damage to the system can result.

- Place containers on the same level as or a lower level than the system.

1 In the dialog **System**, in the area **Access**, click **System liquid & waste**.

→ In the dialog **Replace system liquids and empty waste container**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 112 *Replace system liquids and empty waste container*).

2 Wait until the progress bar is no longer displayed.

3 Pull the level sensor 1–2 cm out of the waste container.

4 Unscrew the cap from the waste container. The level sensor remains in the cap.

5 Dispose of the liquid waste according to national and local standards and regulations.

6 Screw the cap back on to the waste container.

7 Push the level sensor back into the waste container.

8 Place the 2 pegs on the level sensor in the notches on the cap.

9 In the dialog **Replace system liquids and empty waste container**, in the area **Waste container**, select **Emptied**.

→ The action button **Save** becomes active.

10 Click the action button **Save**.

→ The dialog **System** is displayed.

→ Emptying the waste container is completed.

7.3 Replacing system liquids

✓ 1 new buffer container is available, if required.

✓ 1 new diluent container is available, if required.

✓ Water is available, if required.

✓ The system is in standby or routine mode.

To replace system liquids, proceed as follows:

NOTICE

If containers are placed on or above the system, system liquids can flow over or into the system.

Damage to the system can result.

◆ Place containers on the same level as or a lower level than the system.

1 In the dialog **System**, in the area **Access**, click **System liquid & waste**.

→ In the dialog **Replace system liquids and empty waste container**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 112 *Replace system liquids and empty waste container*).

2 Wait until the progress bar is no longer displayed.

3 Remove the sealing cap with the level sensor from the corresponding container.

4 Replace the container with the corresponding liquid.

5 Press the sealing cap with the inserted level sensor onto the opening of the container.

Make sure that the level sensor is inserted at an angle into the corresponding container. The free end of the level sensor inside the container must point away from the opening in the container so that the floater at the end of the level sensor can move up and down freely.

The tubing bears differently colored markings, see (➔ Page 47 *Liquid containers, level sensors, and tubing*).

WARNING

Air bubbles in the tubing can distort the mixing ratio in the cuvettes. False results can occur.

Death or serious injury to the patient can result.

- Carefully follow the instructions given below.

6 Check for air bubbles in the tubing.

7 In the dialog **Replace system liquids and empty waste container**, in the area **Replaced system liquid**, select the replaced system liquids and system liquids whose tubing contains air bubbles.

→ The action button **Save** becomes active.

8 Click the action button **Save**.

→ The tubing of the selected system liquids is rinsed.

9 Wait until the dialog **System** is displayed.

→ Rinsing is completed.

→ Replacing system liquids is completed.

7.4 Loading cuvette segments and dilution strips

✓ Unused cuvette segments, in original packaging, are available.

✓ Unused dilution strips are available.

✓ The system is in standby or routine mode.

To load cuvette segments and dilution strips, proceed as follows:

WARNING

Infection due to infectious material in used cuvette segments and dilution strips

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle used cuvette segments and dilution strips in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Cuv. seg. & dil. strips**.

→ The dialog **Access cuvette segments and dilution strips** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 59 *Access cuvette segments and dilution strips*).

2 Click the action button **Cuv. seg. & dil. strips**.

→ In the dialog **Access cuvette segments and dilution strips**, a progress bar is displayed. The system finishes current operations. This can take several minutes.

3 Wait until a message is displayed.

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

4 Open the right cover.

5 Remove the cuvette rotor cover.

6 Remove used cuvette segments from the cuvette rotor, if required.

7 Dispose of used cuvette segments according to national and local standards and regulations.

WARNING

The measurement signal can be misinterpreted due to polluted cuvette segments or dilution strips or due to re-use of cuvette segments or dilution strips. False results can occur.

Death or serious injury to the patient can result.

- Wear gloves when handling cuvette segments.
- Touch cuvette segments only by the grip.
- Make sure that cuvette segments are not scratched.
- Use cuvette segments only once.
- Do not use washed or recycled cuvette segments.
- Make sure that cuvette segments and dilution strips are free from dust and dirt particles.
- Store cuvette segments and dilution strips in the original packaging in a dust free place.

NOTICE

The probe can collide with cuvette segments that are inserted tilted.

Damage to the system can result.

- Make sure that the cuvette segments are inserted correctly.

8 Load unused cuvette segments into the cuvette rotor.

When removed from plastic bags, cuvette segments and dilution strips can carry a static charge. The system will not use electrically charged cuvette segments or dilution strips. A delay of results can occur. After removing cuvette segments and dilution strips from plastic bags, brush the cuvette segments and dilution strips with an anti-static brush with carbon fibers.

The cuvette rotor does not need to be fully loaded.

9 Replace the cuvette rotor cover.

10 Remove used dilution strips from the dilution frame, if required.

11 Dispose of used dilution strips according to national and local standards and regulations.

12 Load unused dilution strips in the dilution frame.

The dilution frame does not need to be fully loaded.

13 In the dialog **Access cuvette segments and dilution strips**, in the area **Cuvettes**, select the loaded cuvette segments.

14 In the area **Dilution strips**, select the loaded dilution strips.

15 Click the action button **Save**.

→ Another message is displayed.

16 Close the right cover.

→ The system detects the loaded dilution strips. The system measures the blank values of the loaded cuvette segments. The dialog **System** is displayed. Cuvette segments and dilution strips are available.

→ Loading cuvette segments and dilution strips is completed.

7.5 Loading lot data

To load lot data see the Secure Download software instruction manual of the system.

7.6 Preparing reagents and controls

✓ White evaporation caps for reagent vials with a capacity of 5 mL are available.

✓ Yellow evaporation caps for control vials with a capacity of 2.5 mL are available.

✓ Soft, lint-free cloth is available.

✓ Water is available.

✓ The system is in standby or routine mode.

To prepare reagents and controls provided by Siemens Healthineers in the reagent rotor, proceed as follows:

WARNING

Infection due to potentially infectious reagents and controls

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle reagents and controls in accordance with good laboratory practices.

WARNING

False results due to uncooled or expired reagents and controls can occur.

Death or serious injury to the patient can result.

- Do not leave reagents and controls uncooled.
- Make sure that reagents and controls are thoroughly cooled before preparing.
- If reagents and controls are warm before preparing, store them in the refrigerator for 15 minutes.
- Load reagents and controls in the reagent rotor immediately after preparing.
- Make sure that the reagents and controls have not expired.

Pooling of reagents or controls can cause overfilling of the vials. No liquid aspiration can be processed due to overfilled vials. Delay of results can occur. Do not pool any reagents or controls.

1 Prepare the reagents and controls according to the instructions for use of the product.

WARNING

False results due to sedimented reagents. False results due to froth or lamellae causing incorrect level detection. Accurate transfer of the reagent or control cannot be guaranteed.

Death or serious injury to the patient can result.

- Check reagents for sedimenting.
- Dispose of sedimented reagents according to national and local standards and regulations.
- Remove froth and lamellae before placing evaporation caps on reagent and control vials.

NOTICE

The probe cannot penetrate any seals, caps, or stoppers. The probe tip can be damaged after collision with seals, caps, or stoppers.

Damage to the system can result.

- Remove any seals, caps, or stoppers from reagent, standards, and control vials.

Delay of results can occur due to damaged probe tip after collision with caps or stoppers.

2 Check the outside of the reagent and control vials for adhering substances and clean them with a soft, lint-free cloth moistened with water, if required.

WARNING

Concentration of reagents and controls can increase due to evaporation out of open reagent or control vials. False results can occur.

Death or serious injury to the patient can result.

- Carefully follow the instructions given below.
- For more information on on-board stability of reagents and controls, see the separate document assay protocols and the instructions for use of the product.

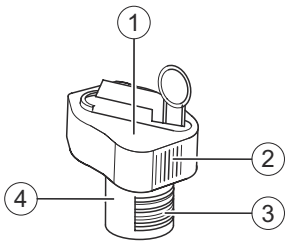
WARNING

False results due to re-use of evaporation caps

Death or serious injury to the patient can result.

- Use single-use evaporation caps only once.
- Do not use washed or recycled single-use evaporation caps.

3 Place evaporation caps on the reagent and control vials, see the figure below.



Placing evaporation caps

(1) Evaporation cap
(2) Vertical striation
(3) Barcode
(4) Reagent or control vial

The vertical striation on the evaporation cap and the barcode on the label of the vial must be aligned, see (➔ Page 153 *Placing evaporation caps*).

Do not tilt reagent and control vials with evaporation caps on. Evaporation caps do not prevent liquid from spilling.

→ Preparing reagents and controls is completed.

7.7 Loading reagents and controls

✓ Reagents are prepared, see (➔ Page 150 *Preparing reagents and controls*).

✓ Controls are prepared, see (➔ Page 150 *Preparing reagents and controls*).

✓ Reagent segments with white grips are available.

✓ Control segments with yellow grips are available.

✓ The system is in standby or routine mode.

To load reagents and controls provided by Siemens Healthineers in the reagent rotor, proceed as follows:

WARNING

Infection due to potentially infectious reagents and controls

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle reagents and controls in accordance with good laboratory practices.

1 Load reagent and control vials in the appropriate reagent rotor segments, see (➔ Page 307 *Reagent rotor segments*).

Alternatively, a reagent or control vial can be loaded in a free position of a reagent segment or control segment that is already on-board.

Take care to press the reagent and control vials down to the bottom of the reagent rotor segment.

2 In the dialog **System**, in the area **Access**, click **Reagents**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

3 Wait until a message is displayed.

4 Open the left and right covers.

→ Another message is displayed.

5 Remove the reagent rotor cover.

6 Place the small end of each reagent rotor segment over a free position of the reagent rotor.

7 Take care that the small end of the reagent rotor segment slides easily in the guide rails below the handwheel.

8 Carefully push down each reagent rotor segment next to the handwheel.

→ A clicking noise indicates that the reagent rotor segment is inserted correctly.

WARNING

False results due to uncooled reagents and controls

Death or serious injury to the patient can result.

- Do not leave reagents and controls uncooled.
- After placing reagents and controls in the reagent rotor, replace the reagent rotor cover immediately.

9 Close the left and right covers.

→ The action button **Close** is displayed.

10 Click the action button **Close**.

→ The dialog **System** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor. Reagents and controls are available.

No barcode on any vial of a reagent rotor segment can be scanned, the positions are displayed as empty in the dialog **Loading reagents**. The barcodes of the vials cannot be entered manually.

- Separate the vials on different reagent rotor segments.
- Enter the reagent or control information manually, see (➔ Page 158 *Identifying a reagent or control*).

→ Loading reagents and controls is completed.

7.8 Preparing a sample rotor segment for use

To prepare a sample segment, you will need:

- A new sample segment
- 15 black adapters or 15 white adapters from an adapter set for sample segments
- 1 plain text label with the number **01** for the first 2 digits from an adapter set for sample segments
- 1 barcode label corresponding to the plain text label from an adapter set for sample segments

To prepare a cup-in-tube segment, you will need:

- A new cup-in-tube segment
- 15 black adapters or 15 white adapters from an adapter set for sample segments
- 1 plain text label with the number **51** for the first 2 digits from a barcode sheet for cup-in-tube segments
- 1 barcode label corresponding to the plain text label from a barcode sheet for cup-in-tube segments

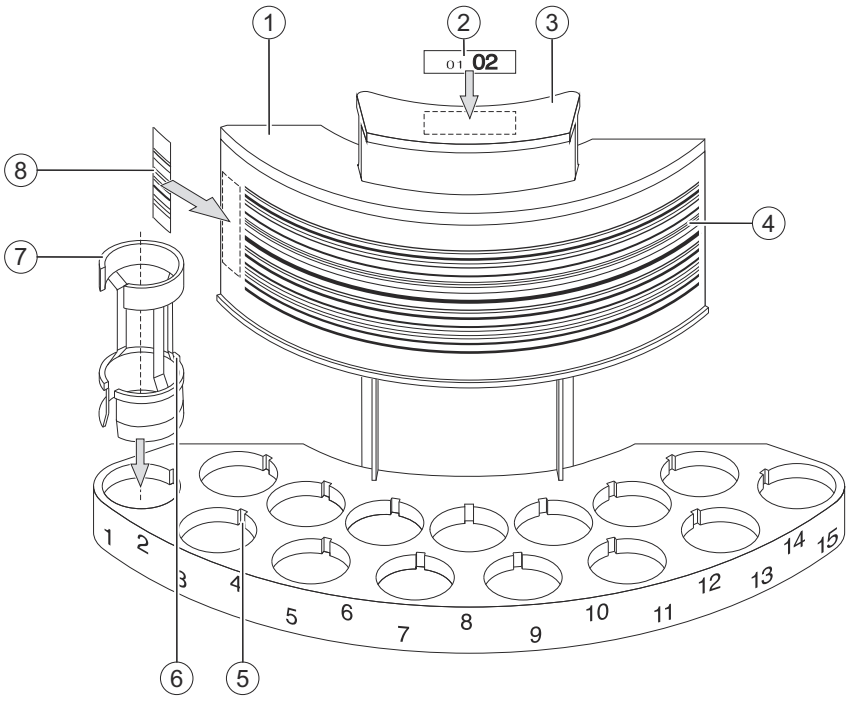
To prepare a cup-behind-tube segment, you will need:

- A new cup-behind-tube segment
- 7 black adapters or 7 white adapters, delivered with the cup-behind-tube segment
- 1 plain text label with the number **81** for the first 2 digits, delivered with the cup-behind-tube segment
- 1 barcode label corresponding to the plain text label, delivered with the cup-behind-tube segment

✓ The system is in standby or routine mode or is off.

To prepare a sample rotor segment for use, proceed as follows:

1 Attach the plain text label to the grip of the sample rotor segment, see the figure below.



Preparing a sample rotor segment for use (example)

(1) Sample rotor segment
(2) Plain text label
(3) Grip
(4) Barcode strip
(5) Groove
(6) Nose
(7) Adapter
(8) Barcode label

WARNING

If the plain text label and the barcode label do not match and if samples are manually identified, samples can be interchanged in the dialog **Loading samples**. Results will be assigned to the wrong patient.

Death or serious injury to the patient can result.

- The plain text label and the corresponding barcode label are delivered on barcode sheets in pairs. Always attach both labels as a pair.

2 Attach the corresponding barcode label vertically at the level of the barcode strip to the left side of the sample rotor segment, next to the left edge.

3 Carefully insert the corresponding adapters into the openings of the base plate of the sample rotor segment.

Align the nose at the back of each adapter with the groove in the openings of the base plate.

4 Push the adapters down until a clicking sound is heard.

→ Preparing a sample rotor segment for use is completed.

8 Performing the analysis

This chapter describes how to perform the analysis.

8.1 Identifying a reagent or control

✓ The system is in standby or routine mode.

To identify a reagent or control loaded in the reagent rotor, proceed as follows:

1 In the dialog **Loading**, click the action button **Reagents**.

→ In the dialog **Loading reagents**, the table view is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 89 *Loading reagents*).

2 In the list **Reagent status**, select **To be identified**.

→ In the table, the reagents and controls that need to be identified are displayed.

3 Click an entry in the table. The segment number and position are displayed in the table.

4 Click the action button **Access**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. The system moves the affected reagent rotor segment to the position below the access lid of the reagent rotor cover. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

---

5 Wait until a message is displayed.

6 Open the right cover.

→ Another message is displayed.

7 Open the access lid of the reagent rotor cover.

8 Remove the corresponding vial.

9 If a barcode is attached to the vial, align the vertical striation on the evaporation cap and the barcode on the label of the vial.

10 Re-load the vial at the same position.

11 Close the access lid of the reagent rotor cover.

12 Close the right cover.

→ The action button **Close** is displayed.

13 Click the action button **Close**.

→ The dialog **Loading reagents** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor.

14 Check the entries displayed in the table.

→ If the entry is no longer displayed, identifying the reagent or control is completed.

The entry is still displayed.

◆ Go to the next step.

15 Click an entry in the table.

16 Click the action button **Identify**.

→ In the dialog **Loading reagents**, a list of reagents and controls and a graphic of a reagent rotor segment is displayed. The position of the unidentified reagent or control is marked with a **?**. For more information on the dialog, click the action button **Help** or see (→ Page 93 *Loading reagents, identify reagents and controls*).

17 In the graphic, click the position that is marked with a **?**.

18 In the input field **Lot reference**, enter the identifier number and the lot number of the reagent or control.

19 Left of the graphic, select if the material is a reagent or a control.

20 Click the action button **Save**.

→ The dialog **Loading reagents** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor.

→ Identifying a reagent or control is completed.

8.2 Loading standards and user-defined controls

Pooling of standards and user-defined controls can cause overfilling of the vials. No liquid aspiration can be processed due to overfilled vials. Delay of results can occur. Do not pool any standards or user-defined controls.

✓ Standard segments are available.

✓ Sample segments are available.

✓ The system is in standby or routine mode.

To load standards and user-defined controls in the sample rotor, proceed as follows:

WARNING

Infection due to potentially infectious standards and user-defined controls

Death or serious injury to the user can result.

◆ Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.

◆ Handle standards and user-defined controls in accordance with good laboratory practices.

WARNING

False results due to expired standards and user-defined controls

Death or serious injury to the patient can result.

- Make sure that the standards and user-defined controls have not expired.

1 Prepare the standards and user-defined controls according to the instructions for use of the product.

WARNING

False results due to froth or lamellae causing incorrect level detection. Accurate transfer of the standard or user-defined control cannot be guaranteed.

Death or serious injury to the patient can result.

- Remove froth and lamellae before loading the standards and user-defined controls.

NOTICE

The probe cannot penetrate any stoppers. The probe tip can be damaged after collision with caps or stoppers.

Damage to the system can result.

- Remove caps from standard and user-defined control vials.
- Remove stoppers from standard and user-defined control vials.

The probe tip can be damaged after collision with caps or stoppers. Delay of patient result can occur.

After removing caps, Siemens Healthineers recommends marking standard caps with the respective abbreviation to prevent cross-contamination.

2 Load standards in a standard segment aligning the barcodes towards the outer edge of the standard segment. Alternatively, a standard vial can be loaded in an empty position of a standard segment that is already on-board.

3 Load user-defined controls in a suitable sample segment aligning the barcodes towards the outer edge of the sample segment. Alternatively, a user-defined control vial can be loaded in an empty position of a suitable sample segment that is already on-board.

The system identifies user-defined controls by the first 6 digits of the barcode. Further digits are not taken into account.

4 Load the sample rotor segments, see (➔ Page 171 *Loading sample rotor segments*).

→ The dialog **System** is displayed. The standards and user-defined controls are loaded. The barcode reader scans the barcodes in the sample rotor. The system adds the standard IDs and user-defined control IDs to the lab journal.

→ Loading standards and user-defined controls is completed.

8.3 Measuring a control

Siemens Healthineers recommends running assay-specific and lot-specific control measurements according to the valid instructions for use.

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls to be measured are on-board, see (➔ Page 153 *Loading reagents and controls*).

✓ Lot data for controls provided by Siemens Healthineers is loaded, see (➔ Page 150 *Loading lot data*).

✓ Lot data for user-defined controls is added to the system, if required, see (➔ Page 129 *Adding a user-defined control*).

✓ The system is in standby or routine mode.

To measure a control, proceed as follows:

1 In the dialog **Lab journal**, click the action button **Request control**.

→ The dialog **Request controls** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 113 *Request controls*).

The system identifies user-defined controls by the first 6 digits of the barcode. Further digits are not taken into account.

2 In the table, in the corresponding row, select the required assays.

→ The action button **Measure** becomes active.

An information dialog is displayed warning the user that the required control is not on-board.

◆ Load the appropriate control, see (➔ Page 153 *Loading reagents and controls*).

3 Click **OK**.

→ The dialog **Request controls** is displayed.

4 When a dialog is displayed in which you can select from different control lots or reagent lots: Click the required control lot or reagent lot and the action button **Save**.

→ The dialog **Request controls** is displayed.

5 If new dilutions have to be prepared for the control measurements: Below the table, select **New dilution series**.

If **New dilution series** is de-selected, the dilutions prepared previously are used for the control measurements.

6 Click the action button **Measure**.

→ The job is requested. The control is measured. In the dialog **Lab journal**, the control results are displayed.

7 Check the control results.

→ The control results are inside the confidence range.

At least 1 control result is outside the confidence range and therefore flagged h or I.

◆ Repeat the control measurement, see (➔ Page 162 *Repeating a control measurement*).

→ Measuring a control is completed.

8.4 Repeating a control measurement

✓ A control was measured and the control results are displayed in the dialog **Lab journal**.

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls to be measured are on-board, see (➔ Page 153 *Loading reagents and controls*).

✓ Lot data for controls provided by Siemens Healthineers is loaded, see (➔ Page 150 *Loading lot data*).

✓ Lot data for user-defined controls is available, if required.

✓ The system is in standby or routine mode.

To repeat a control measurement, proceed as follows:

1 In the dialog **Lab journal**, select the affected control result.

→ The action button **Repeat** becomes active.

2 Click the action button **Repeat**.

→ The dialog **Repeat** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 111 *Repeat*).

3 Make the settings as required.

4 Click the action button **Save**.

→ The job is requested. In the dialog **Lab journal**, the control result is displayed.

5 Check the control result.

→ If the control result is inside the confidence range, repeating the control measurement is completed.

The control result is outside the confidence range.

◆ Go to the next step.

---

6 Repeat the control measurement **twice** using a new control vial.

7 Check both control results.

→ If both control results are inside the confidence range, repeating the control measurement is completed.

1 or both control results are still outside the confidence range.

- Go to the next step.

8 Check if the affected reagents, the buffer, and diluent have expired and replace them, if required.

9 Measure a new reference curve for the affected assay, see (➔ Page 182 *Measuring the reference curve for an assay*).

10 Measure the control, see (➔ Page 161 *Measuring a control*).

11 Check the control result.

→ The control result is inside the confidence range.

The control result is still outside the confidence range.

- Contact Siemens Healthineers service.

→ Repeating a control measurement is completed.

8.5 Loading barcoded samples

Each laboratory should determine the acceptability of blood collection tubes and serum separation products used. Variations in these products exist between manufacturers and, at times, from lot to lot. For more information, contact Siemens Healthineers service.

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls for all requested assays have been measured, see (➔ Page 161 *Measuring a control*).

✓ Sample rotor segments suitable for the present sample tubes are available.

✓ The system is in standby or routine mode.

To load barcoded samples, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

WARNING

False results due to incorrect sample material or due to aspiration of packed cells from the sample tube.

Death or serious injury to the patient can result.

- Only use the required sample material, that is, serum, plasma, urine, or CSF.
- In the instructions for use of the product to be measured, check what kind of sample material must be used.
- If using centrifuged samples or tubes with separating gel, ensure that the volume of supernatant serum or plasma above the packed cells or separating gel is sufficient. Approximately 10 mm of supernatant serum or plasma above the packed cells or separating gel is required. If using 75 mm x 12 mm sample tubes, 450–500 µL plasma is required.

1 Check that the sample material is the required material and that it is of sufficient volume.

2 Slowly warm frozen samples up to room temperature, if applicable.

3 Mix frozen samples thoroughly after thawing, if required.

WARNING

Clogging of the probe can lead to interferences with the processing of assays and to contamination of assays. False results can occur.

Death or serious injury to the patient can result.

- Centrifuge thawed samples, turbid (lipemic) samples, urine and CSF samples, and serum and plasma samples that contain blood cells or fibrin strands. For more information, see the instructions for use of the assay to be measured.

4 Visually check centrifuged samples and repeat centrifugation, if required.

5 Prepare a manual pre-dilution using diluent, if required.

No processing of assays with duplicate sample IDs. Jobs for duplicate sample IDs will not be processed by the system. Delay of results can occur. Only use unique sample IDs.

6 Check the barcodes of the samples and replace barcode labels that are illegible or incorrectly placed, see (➔ Page 309 *Sample and user-defined control barcodes*).

WARNING

False results due to froth causing incorrect level detection. Accurate transfer of the sample cannot be guaranteed.

Death or serious injury to the patient can result.

- Remove froth before loading samples.

NOTICE

The probe cannot penetrate any stoppers. The probe tip can be damaged after collision with stoppers.

Damage to the system can result.

- Remove any stoppers from the sample tubes.

Delay of results can occur due to damaged probe tip after collision with stoppers.

7 Load the sample tubes in the sample rotor segment aligning the barcodes towards the outer edge of the sample rotor segment.

NOTICE

The probe can collide with sample tubes that are not completely pressed down.

Damage to the system can result.

- Make sure to press the sample tubes down to the bottom of the sample rotor segment.

8 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

In case of loading the job list for samples from the LIS, make sure that the job list is available before samples are loaded.

9 Wait until a message is displayed.

10 Open the left cover.

→ Another message is displayed.

11 Holding the sample rotor segment at its grip and with the sample tubes facing towards the outer edge, place the sample rotor segment over an empty position of the sample rotor.

12 Take care that the sample rotor segment slides easily in the guide rails below the handwheel.

13 Carefully push down the sample rotor segment next to the handwheel.

14 Close the left cover.

→ The action button **Close** is displayed.

15 Click the action button **Close**.

→ The dialog **System** is displayed. The samples are loaded. The barcode reader scans the barcodes in the sample rotor. The system adds the sample IDs to the lab journal.

When the system is connected to the LIS, requested jobs for the sample IDs are added to the lab journal. When the system is not connected to the LIS, the user can add jobs manually, see (➔ Page 173 *Requesting a job for a sample manually*).

→ Loading barcoded samples is completed.

8.6 Assigning STAT status to a barcoded sample

When the system is connected to the LIS, the user cannot assign STAT status to sample IDs with requested jobs.

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls for all requested assays have been measured, see (➔ Page 161 *Measuring a control*).

✓ The system is in standby or routine mode.

To assign STAT status to a barcoded sample, proceed as follows:

1 Load the STAT sample, see (➔ Page 163 *Loading barcoded samples*).

2 If the system is not connected to the LIS, in the dialog **Lab journal**, in the table, select the sample ID of the STAT sample.

3 Click the action button **Add request**.

→ The dialog **Add request** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Add request*).

4 At the top left, click **STAT**.

→ STAT status is assigned to the sample ID. The area **STAT** is highlighted.

5 Make other settings as required.

6 In the area **Assays**, select 1 or more assays or profiles.

7 Click the action button **Apply**.

→ The assays are assigned to the sample ID.

8 Click the action button **Close**.

→ The dialog **Lab journal** is displayed. STAT status is assigned to the sample ID. The assays are displayed in the lab journal. The system processes the requested jobs.

→ Assigning STAT status to a barcoded sample is completed.

8.7 Pre-identifying non-barcoded samples and non-barcoded STAT samples

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls for all requested assays have been measured, see (➔ Page 161 *Measuring a control*).

✓ The sample rotor segment to which the sample IDs will be assigned is not on-board.

✓ The system is in standby or routine mode.

To pre-identify non-barcoded samples and non-barcoded STAT samples, proceed as follows:

1 In the dialog **Lab journal**, click the action button **New**.

→ The dialog **New** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 103 *New*).

2 In the input field **Sample ID**, enter the sample ID.

No processing of assays with duplicate sample IDs. Jobs for duplicate sample IDs will not be processed by the system. Delay of results can occur. Only use unique sample IDs.

3 If the sample is a STAT sample: At the top left, click **STAT**.

→ STAT status is assigned to the sample ID. The area **STAT** is highlighted.

4 Fill in further required information.

5 Make other settings as required.

6 In the area **Assays**, select 1 or more assays or profiles.

7 Click the action button **Apply**.

→ The assays are assigned to the sample ID.

8 To add another sample ID, repeat these steps.

9 Click the action button **Close**.

→ The dialog **Lab journal** is displayed. The sample ID and assays are added to the lab journal and flagged.

WARNING

If sample IDs were manually assigned to a sample rotor segment, the assignments are not automatically removed. The system identifies newly loaded non-barcoded samples with the manually assigned sample IDs. Results are incorrectly assigned.

Death or serious injury to the patient can result.

◆ Remove previous assignments of sample IDs from the sample rotor segment.

10 In the navigation bar, click **Loading**.

→ The dialog **Loading samples** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 95 *Loading samples*).

11 In the bottom right area, right of **ID**, select all sample IDs to be assigned to a sample rotor segment.

12 Click the action button **Auto loading**.

→ The dialog **Pre-loading** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 106 *Pre-loading*).

13 In the table, select the segment ID of a suitable sample rotor segment.

If the number of positions on the sample rotor segment is not sufficient for the number of sample IDs, several segment IDs can be selected in the table, see (➔ Page 53 *Select*).

14 Click the action button **Save**.

→ The dialog **Loading samples** is displayed. The sample IDs are assigned to the positions on the sample rotor segment.

Alternatively, in the dialog **Loading samples**, single sample IDs can be dragged from the list at the bottom right and dropped on any unoccupied position in the graphic of a sample rotor segment that is not on-board.

15 At the top left, select the segment ID of the sample rotor segment with the assigned sample IDs.

16 Click the action button **Print**.

→ The data is printed. For more information, click the action button **Help** or see (➔ Page 72 *User settings*).

→ Pre-identifying non-barcoded samples and non-barcoded STAT samples is completed.

8.8 Loading non-barcoded samples and non-barcoded STAT samples

Each laboratory should determine the acceptability of blood collection tubes and serum separation products used. Variations in these products exist between manufacturers and, at times, from lot to lot. For more information, contact Siemens Healthineers service.

✓ Samples are pre-identified, see (➔ Page 167 *Pre-identifying non-barcoded samples and non-barcoded STAT samples*).

✓ Required sample rotor segments are not on-board.

✓ A sample rotor segment suitable for the present sample tubes is available.

✓ A print-out of the assignment of sample IDs to the positions on the sample rotor segment is available.

✓ The system is in standby or routine mode.

To load non-barcoded samples and non-barcoded STAT samples, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

WARNING

False results due to incorrect sample material or due to aspiration of packed cells from the sample tube.

Death or serious injury to the patient can result.

- Only use the required sample material, that is, serum, plasma, urine, or CSF.
- In the instructions for use of the product to be measured, check what kind of sample material must be used.
- If using centrifuged samples or tubes with separating gel, ensure that the volume of supernatant serum or plasma above the packed cells or separating gel is sufficient. Approximately 10 mm of supernatant serum or plasma above the packed cells or separating gel is required. If using 75 mm x 12 mm sample tubes, 450–500 µL plasma is required.

1 Check that the sample material is the required material and that it is of sufficient volume.

2 Slowly warm frozen samples up to room temperature, if applicable.

3 Mix frozen samples thoroughly after thawing, if required.

WARNING

Clogging of the probe can lead to interferences with the processing of assays and to contamination of assays. False results can occur.

Death or serious injury to the patient can result.

- Centrifuge thawed samples, turbid (lipemic) samples, urine and CSF samples, and serum and plasma samples that contain blood cells or fibrin strands. For more information, see the instructions for use of the assay to be measured.

4 Visually check centrifuged samples and repeat centrifugation, if required.

5 Prepare a manual pre-dilution using diluent, if required.

WARNING

False results due to froth causing incorrect level detection. Accurate transfer of the sample cannot be guaranteed. False results due to swapped samples.

Death or serious injury to the patient can result.

- Remove froth before loading samples.
- Load the sample tubes in the sample rotor segment to which the sample IDs are assigned exactly as they are displayed in the print-out.

NOTICE

The probe cannot penetrate any stoppers. The probe tip can be damaged after collision with stoppers.

Damage to the system can result.

- Remove any stoppers from the sample tubes.

Delay of results can occur due to damaged probe tip after collision with stoppers.

6 Load the sample tubes in the sample rotor segment to which the sample IDs are assigned.

NOTICE

The probe can collide with sample tubes that are not completely pressed down.

Damage to the system can result.

- Make sure to press the sample tubes down to the bottom of the sample rotor segment.

7 Carefully press the sample tubes down to the bottom of the sample rotor segment.

8 In the navigation bar, click **Loading**.

→ The dialog **Loading samples** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 95 *Loading samples*).

9 Click the action button **Access**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

10 Wait until a message is displayed.

11 Open the left cover.

→ Another message is displayed.

12 Holding the sample rotor segment at its grip and with the sample tubes facing towards the outer edge, place the sample rotor segment over an empty position of the sample rotor.

13 Take care that the sample rotor segment slides easily in the guide rails below the handwheel.

14 Carefully push down the sample rotor segment next to the handwheel.

15 Close the left cover.

→ The action button **Close** is displayed.

16 Click the action button **Close**.

→ The dialog **System** is displayed. The samples are loaded. The system processes the requested jobs.

→ Loading non-barcoded samples and non-barcoded STAT samples is completed.

8.9 Loading sample rotor segments

✓ Sample rotor segments suitable for the present sample tubes are available.

✓ The system is in standby or routine mode.

To load sample rotor segments, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

In case of loading the job list for samples from the LIS, make sure that the job list is available before samples are loaded.

2 Wait until a message is displayed.

3 Open the left cover.

→ Another message is displayed.

4 Holding the sample rotor segment at its grip and with the sample tubes or vials facing towards the outer edge, place the sample rotor segment over an empty position of the sample rotor.

5 Take care that the sample rotor segment slides easily in the guide rails below the handwheel.

6 Carefully push down the sample rotor segment next to the handwheel.

7 Close the left cover.

→ The action button **Close** is displayed.

8 Click the action button **Close**.

→ The dialog **System** is displayed. The barcode reader scans the barcodes in the sample rotor.

→ Loading sample rotor segments is completed.

8.10 Identifying a sample or standard with unreadable barcode

✓ The system is in standby or routine mode.

To identify a sample or standard with unreadable barcode, proceed as follows:

WARNING

Infection due to infectious samples and standards

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples and standards in accordance with good laboratory practices.

1 In the navigation bar, click **Loading**.

→ The dialog **Loading samples** is displayed. A schematic overview of the sample rotor is displayed. Sample rotor segments with unidentified samples and standards are colored green and yellow. For more information on the dialog, click the action button **Help** or see (➔ Page 95 *Loading samples*).

2 On the left, in the overview of the sample rotor, click the position of a sample rotor segment that is colored green and yellow.

→ A schematic overview of the sample rotor segment is displayed. Unidentified positions are displayed with a **?**.

3 Click the action button **Access**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

4 Wait until a message is displayed.

5 Open the left cover.

→ Another message is displayed.

6 Remove the sample tube or standard vial from the unidentified position.

7 Close the left cover.

8 Note the sample ID or standard ID.

9 In the dialog **Loading samples**, in the input field **Enter ID**, enter the sample ID or standard ID.

10 If a standard ID was entered: At the top right, select **Standards**. Otherwise skip this step.

11 Make other settings as required.

12 Drag the sample ID or standard ID from the input field and drop it on the corresponding position with the **?**.

13 Click the action button **Apply**.

→ The system assigns the sample ID or standard ID to the position. The system adds the sample ID or standard ID to the lab journal.

14 Open the left cover.

15 Load the sample tube or standard vial in the same position of the sample rotor segment.

16 Close the left cover.

→ The action button **Close** is displayed.

17 Click the action button Close.

→ The dialog **Loading samples** is displayed. The barcode reader scans the barcodes in the sample rotor. The sample ID or standard ID is assigned.

→ Identifying a sample or standard with unreadable barcode is completed.

8.11 Requesting a job for a sample manually

✓ Sample is loaded and identified, see (➔ Page 163 *Loading barcoded samples*) and (➔ Page 168 *Loading non-barcoded samples and non-barcoded STAT samples*).

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls for all requested assays have been measured, see (➔ Page 161 *Measuring a control*).

✓ The system is in standby or routine mode.

To request a job for a sample manually, proceed as follows:

1 In the navigation bar, click **Lab journal**.

→ The dialog **Lab journal** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 84 *Lab journal*).

2 In the table, select a sample ID.

WARNING

False results due to aspiration of packed cells from the sample tube

Death or serious injury to the patient can result.

- If using centrifuged samples or tubes with separating gel, ensure that the volume of supernatant serum or plasma above the packed cells or separating gel is sufficient. Approximately 10 mm of supernatant serum or plasma above the packed cells or separating gel is required. If using 75 mm x 12 mm sample tubes, 450–500 µL plasma is required.

3 Check that the sample material is the required material and that it is of sufficient volume.

4 Click the action button **Add request**.

→ The dialog **Add request** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Add request*).

5 In the area **Assays**, select the required profiles and assays.

6 Make other settings as required.

When the sample is manually pre-diluted 1 : 20 and the initial dilution for the assay is 1 : 5, the system rejects the job and a message is displayed.

7 Click the action button **Apply**.

→ The system applies the job to the sample ID. The system measures the assays applied to the job.

8 Click the action button **Close**.

→ The dialog **Lab journal** is displayed.

→ Requesting a job for a sample manually is completed.

8.12 Repeating a job for a sample manually

✓ Sample is loaded and identified, see (➔ Page 163 *Loading barcoded samples*) and (➔ Page 168 *Loading non-barcoded samples and non-barcoded STAT samples*).

✓ Results for the sample are displayed in the dialog **Lab journal**.

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls for all requested assays have been measured, see (➔ Page 161 *Measuring a control*).

✓ The system is in standby or routine mode.

To repeat a job for a sample manually, proceed as follows:

1 In the navigation bar, click **Lab journal**.

→ The dialog **Lab journal** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 84 *Lab journal*).

2 In the table, select a result.

WARNING

False results due to aspiration of packed cells from the sample tube

Death or serious injury to the patient can result.

- If using centrifuged samples or tubes with separating gel, ensure that the volume of supernatant serum or plasma above the packed cells or separating gel is sufficient. Approximately 10 mm of supernatant serum or plasma above the packed cells or separating gel is required. If using 75 mm x 12 mm sample tubes, 450–500 µL plasma is required.

3 Check that the sample material is the required material and that it is of sufficient volume.

4 Click the action button **Repeat**.

→ The dialog **Repeat** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 111 *Repeat*).

5 Make the settings as required.

Siemens Healthineers recommends repeating measurements from new dilution series.

To repeat a measurement previously measured at a special dilution, select the previous special dilution again in the table **Special dilution**.

6 Click the action button **Save**.

→ The dialog **Lab journal** is displayed. The system applies the job to the sample ID. The system re-measures the assay applied to the job.

→ Repeating a job for a sample manually is completed.

8.13 Refilling a sample tube

✓ The sample tube is on-board.

✓ Sample material of the same pre-dilution is available.

✓ The barcode reader is not scanning the barcodes in the sample rotor.

✓ The system is in standby or routine mode.

To refill a sample tube, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 In the dialog **Loading samples**, in the schematic overview of the sample rotor segment, click the position of the sample tube to be refilled, see (➔ Page 95 *Loading samples*).

→ The selected position is framed by blue lines. The action button **Level detection** becomes active. For more information on the dialog, click the action button **Help**.

2 Click the action button **Level detection**.

→ The probe detects the level in the sample tube. The position in the schematic overview of the sample rotor segment is colored and marked according to the level detected.

3 Click the action button **Access**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

4 Wait until a message is displayed.

5 Open the left cover.

→ Another message is displayed.

6 Remove the affected sample tube.

7 Refill the sample tube with an appropriate amount of the same sample material with the same pre-dilution.

8 Load the sample tube in the same position of the sample rotor segment.

9 Close the left cover.

→ The action button **Close** is displayed.

10 Click the action button **Close**.

→ The dialog **Loading samples** is displayed. The barcode reader scans the barcodes in the sample rotor.

→ Refilling a sample tube is completed.

8.14 Unloading samples

Do not unload a sample until all results of all requested jobs are available in the lab journal.

✓ The system is in standby or routine mode.

To unload samples, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

2 Wait until a message is displayed.

3 Open the left cover.

→ Another message is displayed.

4 Remove samples and sample rotor segments that are no longer required.

5 Dispose of samples and sample tubes according to national and local standards and regulations.

6 Close the left cover.

→ The action button **Close** is displayed.

7 Click the action button **Close**.

→ The dialog **System** is displayed.

→ Unloading samples is completed.

8.15 Unloading standards

✓ The system is in standby or routine mode.

To unload standards, proceed as follows:

WARNING

Infection due to infectious standards

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle standards in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

2 Wait until a message is displayed.

3 Open the left cover.

→ Another message is displayed.

4 Remove standards and sample rotor segments that are no longer required.

5 Replace stoppers and caps to the standard vials.

WARNING

False results due to uncooled standards

Death or serious injury to the patient can result.

- Do not leave standards uncooled.
- Store standards that are no longer used in the refrigerator immediately after unloading.

6 Dispose of empty standard vials according to national and local standards and regulations.

7 Close the left cover.

→ The action button **Close** is displayed.

8 Click the action button **Close**.

→ The dialog **System** is displayed.

→ Unloading standards is completed.

8.16 Unloading reagents and controls

✓ The system is in standby or routine mode.

To unload reagents and controls, proceed as follows:

WARNING

Infection due to potentially infectious reagents and controls

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle reagents and controls in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Reagents**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

2 Wait until a message is displayed.

3 Open the left and right covers.

→ Another message is displayed.

4 Remove the reagent rotor cover.

5 Remove reagent rotor segments and reagent or control vials that are no longer required.

WARNING

False results due to uncooled reagents and controls

Death or serious injury to the patient can result.

- Do not leave reagents and controls uncooled.

6 Store reagents and controls in the refrigerator immediately after unloading.

7 Dispose of empty reagent and control vials and of evaporation caps that are no longer required according to national and local standards and regulations.

WARNING

If reagents or controls were manually identified, the assignments to a reagent rotor segment are not automatically removed. In case of the same number of occupied positions in the reagent rotor segment, the system identifies non-barcoded reagents or controls with the previous IDs. False results can occur.

Death or serious injury to the patient can result.

- Delete manual identifications before loading reagent and control vials in the reagent rotor segment the next time.

8 Replace the reagent rotor cover.

9 Close the left and right covers.

→ The action button **Close** is displayed.

10 Click the action button **Close**.

→ The dialog **System** is displayed.

→ Unloading reagents and controls is completed.

8.17 Displaying data in the lab journal

✓ The system is in standby or routine mode.

To display data in the lab journal, proceed as follows:

1 In the navigation bar, click **Lab journal**.

→ The dialog **Lab journal** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 84 *Lab journal*).

2 To filter entries: Above the table, select a setting in 1 or more of the 3 filters, see the figure below.



Filtering and sorting entries in the lab journal

(1) Filter **Selection**
(2) Filter **View by**
(3) List **Sorted by**
(4) Filter **Date**

→ In the filters, the selected settings are displayed. In the lab journal, only the entries that match the settings are displayed.

3 To sort entries: Above the table, in the list **Sorted by**, select a sort sequence.

→ In the list, the selected sort sequence is displayed. In the lab journal, entries are displayed according to the selected sort sequence.

4 To scroll, use scroll functions, see (➔ Page 54 *Scroll*).

→ Displaying data in the lab journal is completed.

8.18 Displaying sample and control details

✓ The system is in standby or routine mode.

To display sample and control details, proceed as follows:

1 To display patient data and information on all sample results of a specific sample: In the dialog **Lab journal**, in the table, double-click a line that belongs to the sample ID.

→ The dialog **Sample details** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 114 *Sample details*).

2 To display details of a control measurement: In the dialog **Lab journal**, in the table, double-click a line that belongs to the control ID.

→ The dialog **Control details** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 73 *Control details*).

→ Displaying sample and control details is completed.

8.19 Displaying measurement curves

✓ The system is in standby or routine mode.

To display measurement curves, proceed as follows:

1 In the dialog **Lab journal**, in the table, double-click a line that belongs to the sample ID or control ID.

→ For samples, the dialog **Sample details** is displayed, see (➔ Page 114 *Sample details*). For controls, the dialog **Control details** is displayed, see (➔ Page 73 *Control details*). For more information on the respective dialog, click the action button **Help**.

2 In the table, select 1 or more results.

→ The action button **Kinetics** becomes active.

3 Click the action button **Kinetics**.

→ The measurement curve of the first selected result is displayed.

4 To navigate between the measurement curves of the selected results, use the navigation buttons at the top left, see (➔ Page 54 *Master navigation*).

→ Displaying measurement curves is completed.

8.20 Releasing results

✓ The system is in standby or routine mode.

To release results, proceed as follows:

WARNING

Unintended release of results by the user

Death or serious injury to the patient can result.

- Make sure to select only the results to be released.
- Results flagged  or  must be checked and validated separately, if required.

1 In the dialog **Lab journal**, in the table, select 1 or more unreleased results.

→ The action button **Release** becomes active.

2 Click the action button **Release**.

→ In the column **Status**, the symbol  is displayed with sample results and the symbol  is displayed with control results. The selected results are released.

3 If the system is connected to an LIS: Released results are sent to the LIS.

→ In the column **Status**, the symbol  is displayed with sample results and the symbol  is displayed with control results.

→ Releasing results is completed.

8.21 Printing results

✓ The system is in standby or routine mode.

To print results, proceed as follows:

1 In the dialog **Lab journal**, in the table, select those results that will be printed. If no result is selected, all results will be printed

2 Click the action button **Print**.

→ The results are printed directly.

If no result was selected, all results are printed directly.

In the dialog **Configuration**, on the tab **Address / Analyzer**, the header of the printed pages can be configured, see (➔ Page 72 *Address / Analyzer*).

→ Printing results is completed.

8.22 Sending control results for evaluation

✓ Controls have been measured, see (➔ Page 161 *Measuring a control*).

✓ The system is in standby or routine mode.

To send control results for evaluation, proceed as follows:

1 In the dialog **Lab journal**, above the table, set the filter **Selection** to **Controls**.

→ In the lab journal, only controls are displayed. Control results outside the confidence range are flagged.

2 In the table, select control results to be evaluated.

3 In the navigation bar, click **QC**, if available, see (➔ Page 110 *QC*). For more information on the dialog, click the action button **Help**.

→ Control results are sent to the quality control software and can be evaluated there.

Control results of deleted controls are not sent to the quality control software.

– or –

In the action bar, click the action button **Release**.

→ Control results are sent to the LIS software and can be evaluated there.

→ Sending control results for evaluation is completed.

8.23 Measuring the reference curve for an assay

✓ Required reagents are on-board, see (➔ Page 153 *Loading reagents and controls*).

✓ Required standards are on-board, see (➔ Page 159 *Loading standards and user-defined controls*).

✓ No reference curve is available for the selected reagent lot.

✓ The system is in standby or routine mode.

To measure the reference curve for an assay, proceed as follows:

1 In the dialog **Calibration**, in the area **Assays**, select an assay.

2 In the area **Reagents**, select the appropriate reagent lot.

3 Click the action button **Measure**.

→ In the table **Assays**, the affected assay is flagged . The system measures the reference curve, see (➔ Page 55 *Flags and symbols*).

The action button **Measure** is inactive.

- If the action button **Repeat** is active, repeat the measurement of the reference curve, see (➔ Page 183 *Repeating the measurement of a reference curve*).
- If neither the action button **Measure** nor the action button **Repeat** is active, select another reagent lot.

  Then click the action button **Measure**.

An information dialog is displayed warning the user that a required standard is not on-board.

- Load the appropriate standard, see (➔ Page 159 *Loading standards and user-defined controls*).
- Re-start this procedure.

An information dialog is displayed warning the user that the required reagent is not on-board.

- Load the appropriate reagent, see (➔ Page 153 *Loading reagents and controls*).
- Re-start this procedure.

4 In the navigation bar, click any other routine button as displayed data is not updated automatically.

5 In the navigation bar, click **Calibration**.

→ Calibration data is updated. The assay is flagged by a different symbol. A valid reference curve is activated automatically by the system. The affected reagent lot is flagged  .

→ Measuring the reference curve for an assay is completed.

8.24 Repeating the measurement of a reference curve

✓ Required reagents are on-board, see (➔ Page 153 *Loading reagents and controls*).

✓ Required standards are on-board, see (➔ Page 159 *Loading standards and user-defined controls*).

✓ A reference curve for the selected reagent lot is available.

✓ The system is in standby or routine mode.

To repeat the measurement of a reference curve, proceed as follows:

1 In the dialog **Calibration**, in the area **Assays**, select an assay.

2 In the area **Reagents**, select the appropriate reagent lot.

3 Click the action button **Repeat**.

→ A confirmation dialog is displayed warning the user that all jobs using the reference curve will be deleted.

The action button **Repeat** is inactive.

- If the action button **Measure** is active, measure the reference curve, see (➔ Page 182 *Measuring the reference curve for an assay*).
- If neither the action button **Measure** nor the action button **Repeat** is active, select another reagent lot.

  Then click the action button **Repeat**.

An information dialog is displayed warning the user that a required standard is not on-board.

- Load the appropriate standard, see (➔ Page 159 *Loading standards and user-defined controls*).
- Re-start this procedure.

4 To cancel the measurement of the reference curve, click **Cancel**.

→ The measurement of the reference curve is canceled.

– or –

To continue, click **OK**.

→ Another confirmation dialog is displayed.

Canceled jobs must be requested again, see (➔ Page 173 *Requesting a job for a sample manually*).

5 If new dilutions have to be prepared for the measurement, click **Yes**.

→ The measurement of the reference curve is repeated with new dilutions. In the table **Assays**, the affected assay is flagged . The system measures the reference curve, see (➔ Page 55 *Flags and symbols*).

– or –

If dilutions prepared previously should be used for the measurement, click **No**.

→ The measurement of the reference curve is repeated with dilutions prepared previously. In the table **Assays**, the affected assay is flagged . The system measures the reference curve, see (➔ Page 55 *Flags and symbols*).

An information dialog is displayed warning the user that the required reagent is not on-board.

- Load the appropriate reagent, see (➔ Page 153 *Loading reagents and controls*).
- Re-start this procedure.

6 In the navigation bar, click any other routine button as displayed data is not updated automatically.

7 In the navigation bar, click **Calibration**.

→ Calibration data is updated. The assay is flagged by a different symbol. A valid reference curve is activated automatically by the system. The affected reagent lot is flagged .

→ Repeating the measurement of a reference curve is completed.

8.25 Displaying a reference curve

✓ A reference curve for the selected assay is available.

✓ The system is in standby or routine mode.

To display a reference curve, proceed as follows:

1 In the dialog **Calibration**, in the area **Assays**, select an assay.

2 If more than 1 reagent lot is displayed in the area **Reagents**, select the appropriate reagent lot.

3 Click the action button **Show curve**.

→ The dialog **Show curve** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 116 *Show curve*).

If the reference curve is invalid and should not be activated, do not delete the invalid reference curve but repeat the measurement with a new dilution series, see (➔ Page 183 *Repeating the measurement of a reference curve*).

If the reference curve is invalid because the mean deviation is outside the defined range but the reference curve should be used nevertheless, activate the invalid reference curve, see (➔ Page 185 *Activating an invalid reference curve*).

→ Displaying a reference curve is completed.

8.26 Activating an invalid reference curve

All reference curves with a mean deviation within the permissible range are accepted automatically.

In case a reference curve is not accepted automatically, it can still be accepted manually by the user. The decision to use such reference curves is the sole responsibility of the user.

✓ The system is in standby or routine mode.

To activate an invalid reference curve, proceed as follows:

1 Display the affected reference curve, see (➔ Page 184 *Displaying a reference curve*).

2 Click the action button **Release**.

→ The reference curve is activated. The affected reagent lot is flagged  , see (➔ Page 55 *Flags and symbols*).

→ Activating an invalid reference curve is completed.

8.27 Deleting a sample ID from the lab journal

✓ The system is in standby or routine mode.

To delete a sample ID from the lab journal, proceed as follows:

1 In the dialog **Lab journal**, in the table, select all requested jobs and all results belonging to the affected sample ID.

2 Click the action button **Delete**.

→ A confirmation dialog is displayed.

3 Click **Yes**.

→ The sample ID, all requested jobs, and all results belonging to the sample ID are deleted.

The sample ID is not deleted from the lab journal.

As long as the sample is on-board, the sample ID cannot be deleted.

◆ Unload the sample, see (➔ Page 176 *Unloading samples*).

→ Deleting a sample ID from the lab journal is completed.

8.28 Removing previous assignments of sample IDs

✓ The system is in standby or routine mode.

To remove previous assignments of sample IDs from a sample rotor segment, proceed as follows:

1 In the dialog **Loading samples**, in the left area, below **Segment ID**, select the segment ID of the affected sample rotor segment, see (➔ Page 95 *Loading samples*). For more information on the dialog, click the action button **Help**.

→ A diagram of the sample rotor segment is displayed. The status **Not placed** is displayed for the sample rotor segment.

The status **On-board** is displayed.

◆ Unload the sample rotor segment, see (➔ Page 176 *Unloading samples*).
◆ Re-start this procedure.

2 In the diagram of the sample rotor segment, double-click an assigned position with the **right** mouse button.

→ An information dialog is displayed.

3 Click **Yes**.

→ All previous assignments of sample IDs are removed from the affected sample rotor segment. In the bottom right area, right of **ID**, the affected sample IDs are displayed.

Double-clicking an assigned position with the **left** mouse button removes the assignment of only this sample ID from the sample rotor segment.

After the affected sample IDs are removed from the lab journal, they are no longer displayed in the bottom right area.

→ Removing previous assignments of sample IDs is completed.

8.29 Using cup-in-tube segments

Each laboratory should determine the acceptability of blood collection tubes, see (➔ Page 308 *Sample tubes*), and cups used, see (➔ Page 308 *Special cups and vials*). Variations in these products exist, at times, from lot to lot. For more information, contact Siemens Healthineers service.

- ✓ Immersion depth for the cups used is defined, see (➔ Page 138 *Configuring the immersion depth for cups used with a cup-in-tube segment*).
- ✓ Only 1 type of cups is used with the specific cup-in-tube segment.
- ✓ Tubes used are barcoded.
- ✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).
- ✓ Controls for all requested assays have been measured, see (➔ Page 161 *Measuring a control*).
- ✓ A cup-in-tube segment suitable for the present cup type is available but not on-board.
- ✓ Suitable tubes are available.
- ✓ The system is in standby or routine mode.

To use cup-in-tube segments, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- ◆ Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- ◆ Handle samples in accordance with good laboratory practices.

WARNING

False results due to incorrect sample material or due to aspiration of packed cells from the sample tube

Death or serious injury to the patient can result.

- ◆ Only use the required sample material, that is, serum, plasma, urine, or CSF.
- ◆ In the instructions for use of the product to be measured, check what kind of sample material must be used.
- ◆ If using centrifuged samples, ensure that the volume of supernatant serum or plasma above the packed cells is sufficient. Approximately 10 mm of supernatant serum or plasma above the packed cells is required.

NOTICE

If the immersion depth is not defined for the cups used, the probe can collide with the bottom of the cups.

Damage to the system can result.

- Define the immersion depth for the cups used before working with cup-in-tube segments, see (→ Page 138 *Configuring the immersion depth for cups used with a cup-in-tube segment*).

1 Check that the sample material is the required material and that it is of sufficient volume.

2 Slowly warm frozen samples up to room temperature, if applicable.

3 Mix frozen samples thoroughly after thawing, if required.

WARNING

Clogging of the probe can lead to interferences with the processing of assays and to contamination of assays. False results can occur.

Death or serious injury to the patient can result.

- Centrifuge thawed samples, turbid (lipemic) samples, urine and CSF samples, and serum and plasma samples that contain blood cells or fibrin strands. For more information, see the instructions for use of the assay to be measured.

4 Visually check centrifuged samples and repeat centrifugation, if required.

5 Prepare a manual pre-dilution using diluent, if required.

NOTICE

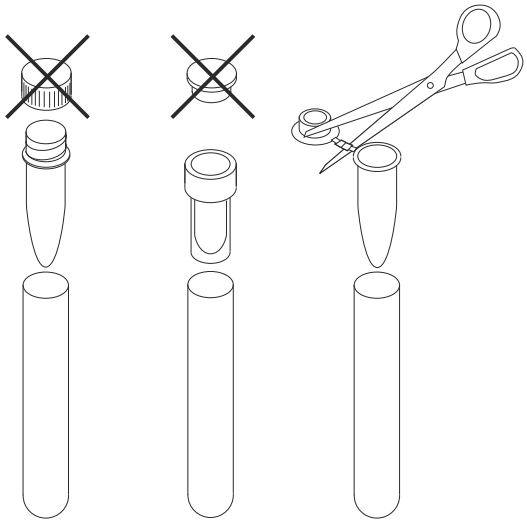
The probe cannot penetrate any caps or stoppers. The probe tip can be damaged after collision with caps or stoppers.

Damage to the system can result.

- Remove any caps or stoppers from the cups.

Delay of results can occur due to damaged probe tip after collision with caps or stoppers.

No processing of assays with duplicate sample IDs. Jobs for duplicate sample IDs will not be processed by the system. Delay of results can occur. Only use unique sample IDs.



Removing any caps and stoppers from cups (example)

6 Check the barcodes on the tubes and replace barcode labels that are illegible or incorrectly placed, see (➔ Page 309 *Sample and user-defined control barcodes*).

WARNING

False results due to froth causing incorrect level detection. Accurate transfer of the sample cannot be guaranteed. False results due to swapped samples. When loading cups in a cup-in-tube segment, cups can easily be mixed up and thus misplaced in a tube with the wrong barcode. Results will be assigned to the wrong patient.

Death or serious injury to the patient can result.

- Remove froth before loading cups.
- Take special care to load the correct cup in the barcoded tube in the cup-in-tube segment.

NOTICE

The probe can collide with cups that are inserted tilted or not completely pressed down.

Damage to the system can result.

- Make sure that the cups are completely pressed down and centered when inserted into the barcoded tubes.
- Make sure to press the barcoded tubes down to the bottom of the cup-in-tube segment.

7 Load the barcoded tubes in the cup-in-tube segment aligning the barcodes towards the outer edge of the cup-in-tube segment.

8 Load the cup-in-tube segments in the sample rotor, see (➔ Page 171 *Loading sample rotor segments*).

Measurements from a cup-in-tube segment cannot be repeated automatically. Re-measurements must be requested manually, see (➔ Page 173 *Requesting a job for a sample manually*).

→ Using cup-in-tube segments is completed.

8.30 Using Eppendorf cup segments

Each laboratory should determine the acceptability of blood collection cups used, see (➔ Page 308 *Special cups and vials*). Variations in these products exist, at times, from lot to lot. For more information, contact Siemens Healthineers service.

✓ Only 1 type of Eppendorf cups is used with the Eppendorf cup segment.

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls for all requested assays have been measured, see (➔ Page 161 *Measuring a control*).

✓ An Eppendorf cup segment is available but not on-board.

✓ The system is in standby or routine mode.

To use Eppendorf cup segments, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 Pre-identify the sample IDs of the Eppendorf cups, see (➔ Page 167 *Pre-identifying non-barcoded samples and non-barcoded STAT samples*).

WARNING

False results due to incorrect sample material or due to aspiration of packed cells from the sample tube

Death or serious injury to the patient can result.

- Only use the required sample material, that is, serum, plasma, urine, or CSF.
- In the instructions for use of the product to be measured, check what kind of sample material must be used.
- If using centrifuged samples, ensure that the volume of supernatant serum or plasma above the packed cells is sufficient. Approximately 10 mm of supernatant serum or plasma above the packed cells is required.

2 Check that the sample material is the required material and that it is of sufficient volume.

3 Slowly warm frozen samples up to room temperature, if applicable.

4 Mix frozen samples thoroughly after thawing, if required.

WARNING

Clogging of the probe can lead to interferences with the processing of assays and to contamination of assays. False results can occur.

Death or serious injury to the patient can result.

- Centrifuge thawed samples, turbid (lipemic) samples, urine and CSF samples, and serum and plasma samples that contain blood cells or fibrin strands. For more information, see the instructions for use of the assay to be measured.

5 Visually check centrifuged samples and repeat centrifugation, if required.

6 Prepare a manual pre-dilution using diluent, if required.

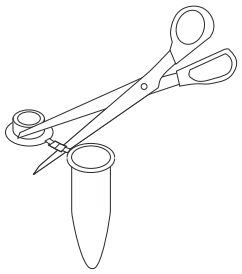
NOTICE

The probe cannot penetrate any caps or stoppers. The probe tip can be damaged after collision with caps or stoppers. The probe can collide with cups that are inserted tilted.

Damage to the system can result.

- Remove any caps or stoppers from the cups.

Delay of results can occur due to damaged probe tip after collision with caps or stoppers.



Removing any caps and stoppers from Eppendorf cups (example)

WARNING

False results due to froth causing incorrect level detection. Accurate transfer of the sample cannot be guaranteed. False results due to swapped samples.

Death or serious injury to the patient can result.

- Remove froth before loading cups.
- Load the cups in the Eppendorf cup segment to which the sample IDs are assigned exactly as they are displayed in the print-out.

NOTICE

The probe can collide with cups that are inserted tilted or not completely pressed down.

Damage to the system can result.

- Make sure to press the cups completely down.

7 Load the Eppendorf cup segment in the sample rotor, see (➔ Page 171 *Loading sample rotor segments*).

Measurements from an Eppendorf cup segment cannot be repeated automatically. Re-measurements must be requested manually, see (➔ Page 173 *Requesting a job for a sample manually*).

→ Using Eppendorf cup segments is completed.

8.31 Using Hitachi cup segments

Each laboratory should determine the acceptability of blood collection cups used, see (➔ Page 308 *Special cups and vials*). Variations in these products exist, at times, from lot to lot. For more information, contact Siemens Healthineers service.

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls for all requested assays have been measured, see (➔ Page 161 *Measuring a control*).

✓ A Hitachi cup segment is available but not on-board.

✓ The system is in standby or routine mode.

To use Hitachi cup segments, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

WARNING

False results due to incorrect sample material or due to aspiration of packed cells from the sample tube

Death or serious injury to the patient can result.

- Only use the required sample material, that is, serum, plasma, urine, or CSF.
- In the instructions for use of the product to be measured, check what kind of sample material must be used.
- If using centrifuged samples, ensure that the volume of supernatant serum or plasma above the packed cells is sufficient. Approximately 10 mm of supernatant serum or plasma above the packed cells is required.

1 Check that the sample material is the required material and that it is of sufficient volume.

2 Slowly warm frozen samples up to room temperature, if applicable.

3 Mix frozen samples thoroughly after thawing, if required.

WARNING

Clogging of the probe can lead to interferences with the processing of assays and to contamination of assays. False results can occur.

Death or serious injury to the patient can result.

- Centrifuge thawed samples, turbid (lipemic) samples, urine and CSF samples, and serum and plasma samples that contain blood cells or fibrin strands. For more information, see the instructions for use of the assay to be measured.

4 Visually check centrifuged samples and repeat centrifugation, if required.

5 Prepare a manual pre-dilution using diluent, if required.

6 Check the barcodes on the cups and replace barcode labels that are illegible or incorrectly placed, see (→ Page 309 *Sample and user-defined control barcodes*).

No processing of assays with duplicate sample IDs. Jobs for duplicate sample IDs will not be processed by the system. Delay of results can occur. Only use unique sample IDs.

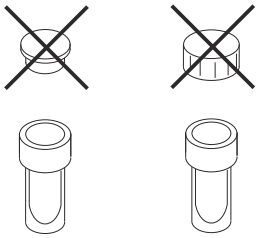
NOTICE

The probe cannot penetrate any caps or stoppers. The probe tip can be damaged after collision with caps or stoppers. The probe can collide with cups that are inserted tilted.

Damage to the system can result.

- Remove any caps or stoppers from the cups.

Delay of results can occur due to damaged probe tip after collision with caps or stoppers.



Removing any caps and stoppers from cups (example)

WARNING

False results due to froth causing incorrect level detection. Accurate transfer of the sample cannot be guaranteed.

Death or serious injury to the patient can result.

- Remove froth before loading cups.

NOTICE

The probe can collide with cups that are inserted tilted or not completely pressed down.

Damage to the system can result.

- Make sure to press the cups completely down.

7 Load the barcoded cups in the Hitachi cup segment. Align the barcodes towards the outer edge of the Hitachi cup segment so the barcodes can be scanned through the opening in the adapters.

8 Load the Hitachi cup segment in the sample rotor, see (➔ Page 171 *Loading sample rotor segments*).

Measurements from a Hitachi cup segment cannot be repeated automatically. Re-measurements must be requested manually, see (➔ Page 173 *Requesting a job for a sample manually*).

→ Using Hitachi cup segments is completed.

8.32 Using cup-behind-tube segments

Each laboratory should determine the acceptability of blood collection tubes, see (➔ Page 308 *Sample tubes*), and cups used, see (➔ Page 308 *Special cups and vials*). Variations in these products exist, at times, from lot to lot. For more information, contact Siemens Healthineers service.

✓ Tubes used are barcoded.

✓ Valid reference curves for all requested assays are available, see (➔ Page 182 *Measuring the reference curve for an assay*).

✓ Controls for all requested assays have been measured, see (➔ Page 161 *Measuring a control*).

✓ A cup-behind-tube segment is available but not on-board.

✓ Suitable tubes are available.

✓ The system is in standby or routine mode.

To use cup-behind-tube segments, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

WARNING

False results due to incorrect sample material or due to aspiration of packed cells from the sample tube

Death or serious injury to the patient can result.

- Only use the required sample material, that is, serum, plasma, urine, or CSF.
- In the instructions for use of the product to be measured, check what kind of sample material must be used.
- If using centrifuged samples, ensure that the volume of supernatant serum or plasma above the packed cells is sufficient. Approximately 10 mm of supernatant serum or plasma above the packed cells is required.

1 Check that the sample material is the required material and that it is of sufficient volume.

2 Slowly warm frozen samples up to room temperature, if applicable.

3 Mix frozen samples thoroughly after thawing, if required.

WARNING

Clogging of the probe can lead to interferences with the processing of assays and to contamination of assays. False results can occur.

Death or serious injury to the patient can result.

- Centrifuge thawed samples, turbid (lipemic) samples, urine and CSF samples, and serum and plasma samples that contain blood cells or fibrin strands. For more information, see the instructions for use of the assay to be measured.

4 Visually check centrifuged samples and repeat centrifugation, if required.

5 Prepare a manual pre-dilution using diluent, if required.

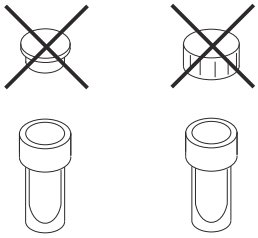
NOTICE

The probe cannot penetrate any caps or stoppers. The probe tip can be damaged after collision with caps or stoppers.

Damage to the system can result.

- Remove any caps or stoppers from the cups.

Delay of results can occur due to damaged probe tip after collision with caps or stoppers.



Removing any caps and stoppers from cups (example)

No processing of assays with duplicate sample IDs. Jobs for duplicate sample IDs will not be processed by the system. Delay of results can occur. Only use unique sample IDs.

6 Check the barcodes on the tubes and replace barcode labels that are illegible or incorrectly placed, see (➔ Page 309 *Sample and user-defined control barcodes*).

WARNING

False results due to froth causing incorrect level detection. Accurate transfer of the sample cannot be guaranteed. False results due to swapped samples. When loading cups in a cup-behind-tube segment, cups can easily be mixed up and thus misplaced behind a tube with the wrong barcode. Results will be assigned to the wrong patient.

Death or serious injury to the patient can result.

- Remove froth before loading cups.
- Take special care to load the correct cup behind the barcoded tube in the cup-behind-tube segment.

7 Load the barcoded tubes in the lower row of the cup-behind-tube segment.

8 Align the barcodes towards the outer edge of the cup-behind-tube segment.

NOTICE

The probe can collide with cups that are inserted tilted or not completely pressed down.

Damage to the system can result.

- Make sure that the cups are completely pressed down.
- Make sure to press the barcoded tubes down to the bottom of the cup-behind-tube segment.

9 Load the cups in the upper row behind the appropriate barcoded tubes.

10 Load the cup-behind-tube segment in the sample rotor, see (➔ Page 171 *Loading sample rotor segments*).

Measurements from a cup-behind-tube segment cannot be repeated automatically. Re-measurements must be requested manually, see (➔ Page 173 *Requesting a job for a sample manually*).

→ Using cup-behind-tube segments is completed.

9 Finishing the analysis

This chapter describes how to finish the analysis.

9.1 Rinsing the system

✓ The system is in standby or routine mode.

To rinse the system, proceed as follows:

WARNING

The filling level of the waste container is not checked by the system before the rinsing starts. Potentially infectious material in the waste container can overflow during rinsing. Potentially infectious material can be released.

Death or serious injury to the user can result. Property damage and damage to the surroundings can result.

◆ Empty the waste container before rinsing the system.

1 In the dialog **System**, in the area **Maintenance**, click **Rinse system**.

→ In the dialog **Rinse system**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Add request*).

2 Wait until the progress bar is no longer displayed.

3 Select the system liquids for rinsing, usually buffer, diluent, and water (washing liquid).

4 Enter the number of rinsing cycles for each selected system liquid.

5 Click the action button **Save**.

→ The system starts rinsing.

6 Wait until an information dialog is displayed.

7 Click **Ok**.

→ Rinsing the system is completed.

9.2 Creating a backup

After the backup is created, the system is shut down automatically.

Backup data can only be restored by Siemens Healthineers service.

✓ The system is in standby or routine mode.

To create a backup, proceed as follows:

1 In the dialog **System**, in the area **Update and back up software**, click **Backup**.

→ In the dialog **System**, the area **Select path for backup file** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 115 *Select path for backup file*).

NOTICE

Backup data will be added to an already existing backup file. Frequent backups can thus create a backup file of a size that cannot be restored.

Loss of data can result.

- Create a new folder for each backup via the operating system of the computer.
- Delete the backup file frequently via the operating system of the computer before creating a new backup.

2 Select the drive and path where the backup will be created.

3 Click the action button **Save**.

→ A confirmation dialog is displayed.

4 Click **Ok**.

→ The system creates a backup in the selected folder. Another confirmation dialog is displayed.

5 Click **Ok**.

→ Another confirmation dialog is displayed.

6 Click **Ok**.

→ The system is shut down.

7 At the right side of the system, set the main switch to position **O**.

→ The system is off.

8 Shut down the computer.

9 Switch off the monitor.

10 Switch off the printer.

→ Creating a backup is completed.

9.3 Shutting down the system

Siemens Healthineers recommends:

- Not shutting down the system for an extended period, for example, over night or over the weekend.
- Shutting down and restarting the system at least once a week.

✓ 1 container with at least 1 L of water is available if the system is shut down for more than 2 hours.

✓ The system is in standby or routine mode.

To shut down the system, proceed as follows:

WARNING

When the system shuts down, the reagent cooler is switched off. False results can occur due to uncooled reagents and controls. When the system is shut down for more than 2 hours, the buffer in the tubing and in the buffer reservoir can crystallize. The concentration of the buffer can change. False results can occur.

Death or serious injury to the patient can result.

- If the system is shut down for more than 2 hours, remove reagent and control vials, including evaporation caps, from the system and return them to the refrigerator.
- Before the system is shut down for more than 2 hours, rinse the system with water, see (➔ Page 199 *Rinsing the system*).
- If the system is shut down for more than 2 hours, insert the level sensor of the buffer container into a container with at least 1 L of water.

Delay of results can occur due to changed concentration of buffer.

1. If the system is shut down for more than 2 hours: Remove the level sensor of the buffer container.
2. If the system is shut down for more than 2 hours: Insert the level sensor of the buffer container into a container with at least 1 L of water.
3. If the system is shut down for more than 2 hours: Rinse the system with buffer. Enter **3** as the **Number of rinsing cycles**, see (➔ Page 199 *Rinsing the system*).
4. In the dialog **Status**, click the action button **Exit**.

   → A confirmation dialog is displayed.
5. Click **Yes**.

   → The system is rinsed with water. The system is shut down. The viewer software closes.
6. Wait until the 3 LEDs in the upper right corner at the front of the system are off.
7. Unload reagent and control vials from the system and return them to the refrigerator, if required, see (➔ Page 178 *Unloading reagents and controls*).
8. Empty the waste container, see (➔ Page 202 *Emptying the waste container*).
9. At the right side of the system, set the main switch to position **O**.

   → The system is off.
10. Shut down the computer.
11. Switch off the monitor.
12. Switch off the printer.

→ Shutting down the system is completed.

9.4 Emptying the waste container

✓ The system is in standby or routine mode or is off.

To empty the waste container, proceed as follows:

WARNING

Infection due to infectious waste

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle parts of the system that have come into contact with potentially infectious material in accordance with good laboratory practices.

NOTICE

If containers are placed on or above the system, system liquids can flow over or into the system.

Damage to the system can result.

- Place containers on the same level as or a lower level than the system.

1 If the system is in standby or routine mode: In the dialog **System**, in the area **Access**, click **System liquid & waste**.

→ In the dialog **Replace system liquids and empty waste container**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 112 *Replace system liquids and empty waste container*).

2 If the system is in standby or routine mode: Wait until the progress bar is no longer displayed.

3 Pull the level sensor 1–2 cm out of the waste container.

4 Unscrew the cap from the waste container. The level sensor remains in the cap.

5 Dispose of the liquid waste according to national and local standards and regulations.

6 Screw the cap back on to the waste container.

7 Push the level sensor back into the waste container.

8 Place the 2 pegs on the level sensor in the notches on the cap.

9 If the system is in standby or routine mode: In the area **Waste container**, select **Emptied**.

→ The action button **Save** becomes active.

10 If the system is in standby or routine mode: Click the action button **Save**.

→ The dialog **System** is displayed.

→ Emptying the waste container is completed.

10 Performing maintenance and cleaning

This chapter describes how to perform maintenance and how to clean the system.

WARNING

Risk of burns by combustion of highly flammable liquid and vapour. 70% ethanol and 70% isopropanol are highly flammable.

Death or serious injury can result.

- Keep 70% ethanol and 70% isopropanol away from sources of ignition, for example, heat or open flame.
- Due to no claim of completeness of these measures, follow all instructions from the product manufacturer and observe the material safety data sheet.

WARNING

Risk of serious eye irritation through contact with 70% isopropanol. Risk of drowsiness or dizziness through inhalation of 70% isopropanol.

Serious injury can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the information from the manufacturer regarding the compatibility of the gloves with the materials and liquids used.
- Due to no claim of completeness of these measures, follow all instructions from the product manufacturer and observe the material safety data sheet.

NOTICE

Purging agents, purging solutions, and alcohol dissolve the film of oil on ball bearings, guides, and tracks. Purging agents and purging solutions can cause short-circuits.

Damage to the system can result.

- Do not use purging agents, purging solutions, or alcohol on ball bearings, guides, and tracks.
- Do not use purging agents or purging solutions near printed circuit boards and light barriers.

NOTICE

Pollution by improper waste disposal.

Damage to the environment can result.

- Dispose of ethanol, isopropanol, and containers according to laboratory standards and national and local standards and regulations.
- Due to no claim of completeness of these measures, follow all instructions from the product manufacturer and observe the material safety data sheet.

10.1 List of tasks

Maintenance and cleaning tasks are listed in the table below.

Weekly task	See
Checking the functioning of the probe	(→ Page 205 *Checking the functioning of the probe*)
Cleaning the probe	(→ Page 206 *Cleaning the probe*)
Cleaning the wet station	(→ Page 208 *Cleaning the wet station*)
Cleaning the reagent rotor and the reagent rotor housing	(→ Page 210 *Cleaning the reagent rotor and the reagent rotor housing*)
Checking the syringe for leaks	(→ Page 211 *Checking the syringe for leaks*)
Cleaning the water container	(→ Page 212 *Cleaning the water container*)
Checking the tubing of the containers	(→ Page 213 *Checking the tubing of the containers*)
Checking the tubing of the probe	(→ Page 213 *Checking the tubing of the probe*)
Shutting down the system	(→ Page 200 *Shutting down the system*)
Starting the system	(→ Page 145 *Starting the system*)
Monthly task	**See**
Purging the tubing	(→ Page 215 *Purging the tubing*)
Replacing the water filter	(→ Page 217 *Replacing the water filter*)
Cleaning the level sensors	(→ Page 218 *Cleaning the level sensors*)
Yearly task	**See**
Replacing the syringe	(→ Page 221 *Replacing the syringe*)
Replacing the tubing of the containers	(→ Page 225 *Replacing the tubing of the containers*)
As needed task	**See**
Rinsing the system	(→ Page 199 *Rinsing the system*)
Cleaning the surface of the system	(→ Page 229 *Cleaning the surface of the system*)

As needed task	See
Cleaning the sample rotor and the sample rotor housing	(→ Page 229 *Cleaning the sample rotor and the sample rotor housing*)
Cleaning the segments	(→ Page 231 *Cleaning the segments*)
Cleaning the dilution station, the cuvette rotor, and the cuvette rotor housing	(→ Page 231 *Cleaning the dilution station, the cuvette rotor, and the cuvette rotor housing*)
Cleaning the waste container	(→ Page 234 *Cleaning the waste container*)
Cleaning the peripheral devices	(→ Page 234 *Cleaning the peripheral devices*)
Replacing the probe cleaner bottle	(→ Page 235 *Replacing the probe cleaner bottle*)
Preparing the purging solution	(→ Page 236 *Preparing the purging solution*)
Preparing the hypochlorite solution	(→ Page 236 *Preparing the hypochlorite solution*)

Have Siemens Healthineers service carry out maintenance tasks defined in the maintenance contract.

10.2 Weekly tasks

This section describes the maintenance and cleaning tasks that must be performed once a week.

10.2.1 Checking the functioning of the probe

✓ The system is in standby or routine mode.

To check the functioning of the probe, proceed as follows:

1 In the dialog **System**, in the area **Initialization**, click **Probe**.

→ A confirmation dialog is displayed.

2 Click **Yes**.

→ The system initializes the probe.

3 Wait until the information dialog **Initialization of probe completed** is displayed.

4 Click **Ok**.

→ The dialog **System** is displayed.

5 In the area **Maintenance**, click **Check probe**.

→ In the dialog **Check probe**, a progress bar is displayed. The system finishes current operations. This can take several minutes.

6 Wait until a message is displayed.

7 Click the action button **Check**.

→ The probe emits diluent straight into the dispensing area.

The jet of diluent exits diagonally, is split or fanned, or the probe drips.

- Click the action button **Close**.
- Click **Ok**.
- Rinse the system, see (➔ Page 199 *Rinsing the system*).

8 If the system was rinsed: In the dialog **System**, in the area **Maintenance**, click **Check probe**.

→ In the dialog **Check probe**, a progress bar is displayed. The system finishes current operations. This can take several minutes.

9 If the system was rinsed: Wait until a message is displayed.

10 If the system was rinsed: Click the action button **Check**.

→ The probe emits diluent straight into the dispensing area.

The jet of diluent exits diagonally, is split or fanned, or the probe drips.

- Click the action button **Close**.
- Click **Ok**.
- Replace the probe assembly, see (➔ Page 250 *Replacing the probe assembly*).

11 If the probe assembly was replaced: In the dialog **System**, in the area **Maintenance**, click **Check probe**.

→ In the dialog **Check probe**, a progress bar is displayed. The system finishes current operations. This can take several minutes.

12 If the probe assembly was replaced: Wait until a message is displayed.

13 If the probe assembly was replaced: Click the action button **Check**.

→ The probe emits diluent straight into the dispensing area.

The jet of diluent exits diagonally, is split or fanned, or the probe drips.

- Contact Siemens Healthineers service.

14 Click the action button **Close**.

→ A confirmation dialog is displayed.

15 Click **Ok**.

→ Checking the functioning of the probe is completed.

10.2.2 Cleaning the probe

✓ Soft, lint-free cloth is available.

✓ 70 % ethanol or 70 % isopropyl alcohol is available.

✓ The system is in standby or routine mode.

To clean the probe, proceed as follows:

WARNING

Infection due to contaminated material and injury to hands due to sharp edges.

Death or serious injury to the user can result.

- Be especially careful of the sharp probe tip and other sharp edges.
- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle parts of the system that have come into contact with potentially infectious material in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Maintenance**, click **Clean probe**.

→ In the dialog **Clean probe**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 66 *Clean probe*).

2 Wait until a message is displayed.

3 Click the action button **Park probe for cleaning**.

→ The probe moves to the parking position.

4 Wait until another message is displayed.

→ The probe is in the parking position.

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

5 Open the right cover.

NOTICE

Sharp edges can damage the inside of the probe.

Damage to the system can result.

- Do not use cleaning wires to clean the inside of the probe.

6 Wipe the probe from top to bottom with a soft, lint-free cloth moistened with the specified alcohol.

7 Close the right cover.

→ The action button **Close** becomes active.

8 Click the action button **Close**.

→ An information dialog is displayed.

9 Click **Ok**.

→ Cleaning the probe is completed.

10.2.3 Cleaning the wet station

✓ Soft, lint-free cloth is available.

✓ 70 % ethanol or 70 % isopropyl alcohol is available.

✓ The system is in standby or routine mode.

To clean the wet station, proceed as follows:

WARNING

Infection due to contaminated material and injury to hands due to sharp edges.

Death or serious injury to the user can result.

- Be especially careful of the sharp probe tip and other sharp edges.
- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle parts of the system that have come into contact with potentially infectious material in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Maintenance**, click **Clean probe**.

→ In the dialog **Clean probe**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 66 *Clean probe*).

2 Wait until a message is displayed.

3 Click the action button **Park probe for cleaning**.

→ The probe moves to the parking position.

4 Wait until another message is displayed.

→ The probe is in the parking position.

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

5 Open the right cover.

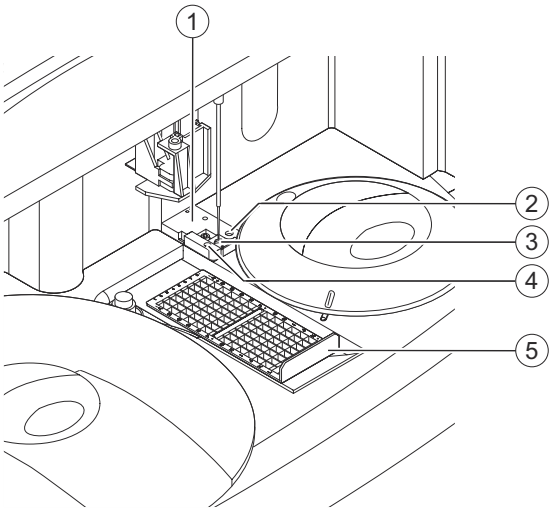
WARNING

Contamination of the buffer reservoir can cause dilution of the buffer used for measurement. Buffer can become unusable. False results can occur.

Death or serious injury to the patient can result.

- Do not contaminate the buffer reservoir during cleaning.

6 Wipe the surface of the wet station with a soft, lint-free cloth moistened with the specified alcohol, see the figure below.



Cleaning the wet station

(1) Wet station
(2) Fountain area
(3) Dispensing area
(4) Buffer reservoir
(5) Dilution frame

7 Remove the dilution frame.

8 Wipe the dispensing area, including the inside, with a soft, lint-free cloth moistened with the specified alcohol.

9 Insert the dilution frame.

10 Moisten a cotton bud with the specified alcohol.

11 Clean the internal upper section of the fountain area using circular downwards movements (approx. 8 mm deep).

12 Close the right cover.

→ The action button **Close** becomes active.

13 Click the action button **Close**.

→ An information dialog is displayed.

14 Click **Ok**.

15 Rinse the system with buffer only, see (➔ Page 199 *Rinsing the system*).

→ Cleaning the wet station is completed.

10.2.4 Cleaning the reagent rotor and the reagent rotor housing

✓ Soft, lint-free cloth is available.

✓ Water is available.

✓ Purging solution is available.

✓ The system is in standby or routine mode.

To clean the reagent rotor and the reagent rotor housing, proceed as follows:

1 Prepare the purging solution according to the instruction manual of the purging agent or contact Siemens Healthineers service.

2 In the dialog **System**, in the area **Access**, click **Reagents**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

3 Wait until a message is displayed.

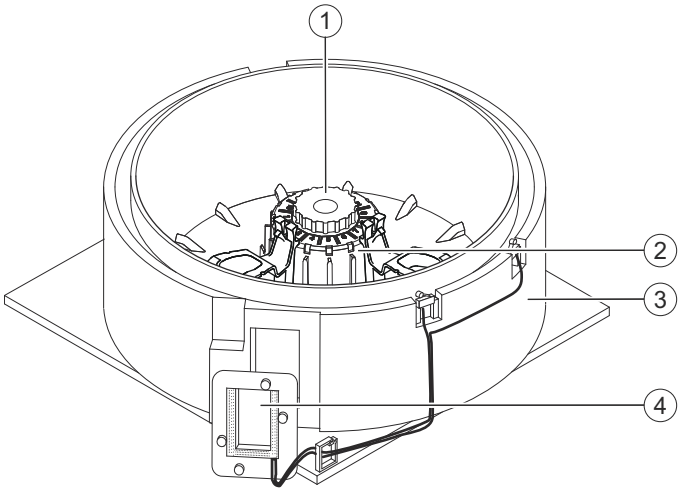
4 Open the left and right covers.

→ Another message is displayed.

5 Remove the reagent rotor cover.

6 Remove all reagent segments and control segments.

7 Loosen the handwheel of the reagent rotor, see the figure below. The handwheel cannot be completely unscrewed.



Cleaning the reagent rotor

(1) Handwheel
(2) Reagent rotor
(3) Reagent rotor housing
(4) Window of the barcode reader

8 Remove the reagent rotor by the handwheel.

9 Wipe the reagent rotor and the reagent rotor housing, especially the window of the barcode reader, with a soft, lint-free cloth moistened with water.

Do not use any purging agent or purging solution to clean the reagent rotor and the reagent rotor housing.

10 Wipe the reagent rotor cover with a soft, lint-free cloth moistened with purging solution.

11 Allow the purging solution to take effect, according to the instructions from the manufacturer.

12 Place the reagent rotor back. Turn the reagent rotor slightly in both directions until it locks in place.

13 Tighten the handwheel.

14 Clean the segments, see (➔ Page 231 *Cleaning the segments*).

15 Load reagent segments and control segments on the reagent rotor as required.

16 Replace the reagent rotor cover.

17 Close the left and right covers.

→ The action button **Close** is displayed.

18 Click the action button **Close**.

→ The dialog **System** is displayed.

→ Cleaning the reagent rotor and the reagent rotor housing is completed.

10.2.5 Checking the syringe for leaks

✓ Soft, lint-free cloth is available.

✓ The system is in standby or routine mode.

To check the syringe for leaks, proceed as follows:

1 In the dialog **System**, in the area **Maintenance**, click **Replace syringe**.

→ In the dialog **Replace syringe**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 112 *Replace syringe*).

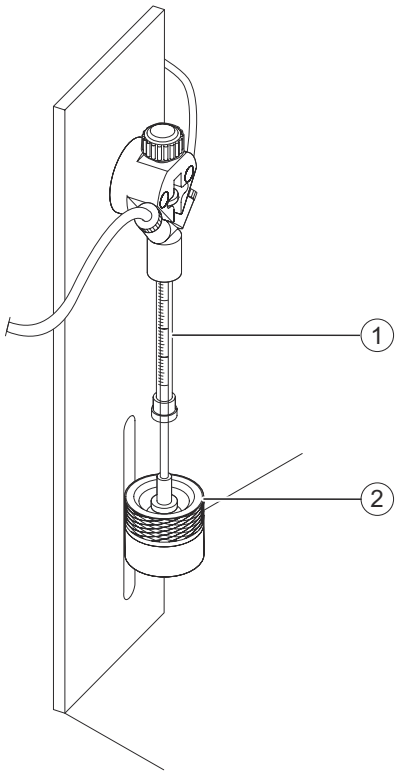
2 Wait until a confirmation dialog is displayed.

3 Click **Yes**.

4 Wait until a message is displayed.

5 Open the left cover.

6 Check if there is liquid in the straining ring, see the figure below.



Checking the syringe for leaks

(1) Syringe
(2) Straining ring

→ No liquid is in the straining ring

There is liquid in the straining ring.

◆ Troubleshoot the syringe, see (➔ Page 266 *Troubleshooting the syringe*).

→ Checking the syringe for leaks is completed.

10.2.6 Cleaning the water container

✓ 70 % ethanol or 70 % isopropyl alcohol is available.

✓ Water is available.

✓ The system is in standby or routine mode.

To clean the water container, proceed as follows:

1 Remove the sealing cap with the level sensor from the water container.

2 Empty the water container.

3 Fill 1/10 of the water container with the specified alcohol.

4 Slew the water container until the entire inner surface has been wetted.

5 Allow the alcohol to take effect, according to the instructions from the manufacturer.

6 Dispose of the alcohol according to national and local standards and regulations.

7 Rinse the water container thoroughly with water.

8 Refill the water container with water.

9 Press the sealing cap with the inserted level sensor onto the opening of the container.

Make sure that the level sensor is inserted at an angle into the corresponding container. The free end of the level sensor inside the container must point away from the opening in the container so that the floater at the end of the level sensor can move up and down freely.

The tubing bears differently colored markings, see (➔ Page 47 *Liquid containers, level sensors, and tubing*).

10 If the system is in standby mode: Rinse the system with water (washing liquid), see (➔ Page 199 *Rinsing the system*).

→ Cleaning the water container is completed.

10.2.7 Checking the tubing of the containers

✓ The system is in standby or routine mode.

To check the tubing of the containers, proceed as follows:

◆ Check if the tubing between the system and the containers is bent or contains any debris.

→ The tubing between the system and the containers is not bent and does not contain any debris.

The tubing between the system and the containers is bent.

◆ Replace the tubing, see (➔ Page 225 *Replacing the tubing of the containers*).

The tubing between the system and the containers contains any debris.

◆ Purge the tubing, see (➔ Page 215 *Purging the tubing*).

→ Checking the tubing of the containers is completed.

10.2.8 Checking the tubing of the probe

✓ The system is in standby or routine mode.

To check the tubing of the probe, proceed as follows:

1 In the dialog **System**, in the area **Maintenance**, click **Clean probe**.

→ In the dialog **Clean probe**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 66 *Clean probe*).

2 Wait until a message is displayed.

3 Click the action button **Park probe for cleaning**.

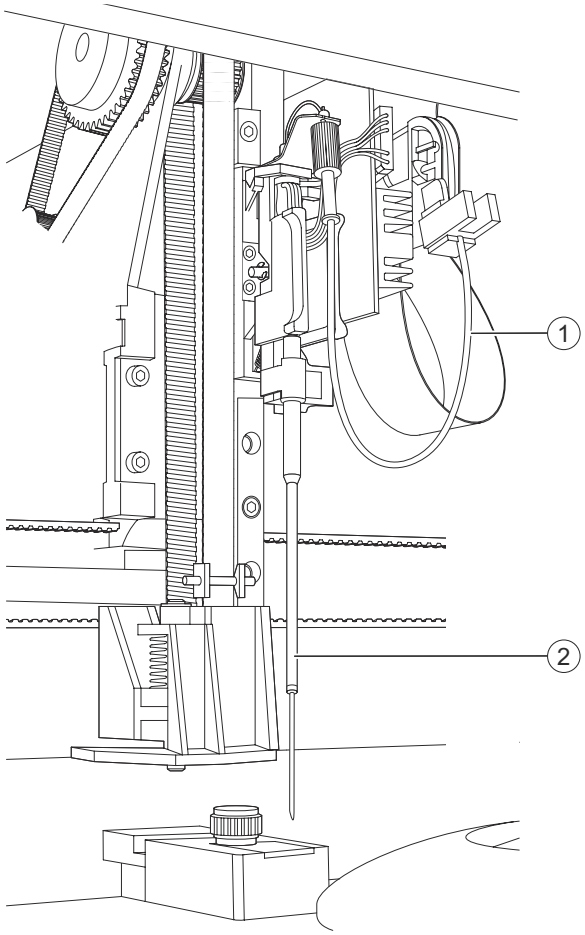
→ The probe moves to the parking position.

4 Wait until another message is displayed.

→ The probe is in the parking position.

5 Open the right cover.

6 Visually check if the tubing of the probe is bent or damaged, see the figure below.



Checking the tubing of the probe

(1) Tubing of the probe
(2) Probe

→ The tubing of the probe is not bent or damaged.

The tubing of the probe is bent or damaged.

◆ Contact Siemens Healthineers service.

---

7 Close the right cover.

→ The action button **Close** becomes active.

8 Click the action button **Close**.

→ An information dialog is displayed.

9 Click **Ok**.

→ The dialog **System** is displayed.

→ Checking the tubing of the probe is completed.

10.3 Monthly tasks

This section describes the maintenance and cleaning tasks that must be performed once a month.

10.3.1 Purging the tubing

Depending on the kind of container used to hold the 2–3 % hypochlorite solution, variable volumes are required to purge the tubing, see the table below.

Container	Design	Required volume
Small bottle, 500 mL	Narrow bottom	250 mL
Container, 5000 mL	Wide bottom	1000 mL

Examples for the required volume of hypochlorite solution

✓ 2–3 % hypochlorite solution is available.

✓ 1 empty container with a capacity of 500–5000 mL to hold the 2–3 % hypochlorite solution is available.

✓ Water is available.

✓ 1 empty, unused container with a capacity of 5–10 L to hold the water is available.

✓ The system is in standby or routine mode.

To purge the tubing, proceed as follows:

WARNING

Hypochlorite solution can cause damage to the respiratory system through inhalation. Hypochlorite solution can cause severe skin burns and eye damage if it comes into contact with skin and eyes.

Death or serious injury to the user and bystanders can result.

- Wear appropriate personal protective equipment; that is, gloves, protective clothing, safety glasses and mask.
- Pay attention to the information from the manufacturer regarding the compatibility of the gloves with the materials and liquids used.
- Observe the instructions from the manufacturer regarding handling of hypochlorite solution.
- Store and handle in a well ventilated area.
- Avoid breathing fume.
- Avoid contact with eyes and skin.
- Wash thoroughly after handling.
- In case of contact with eyes or skin, immediately rinse the affected area with plenty of water for several minutes.
- In the event of an accident or if you feel unwell, seek medical advice immediately and show the label if possible.

NOTICE

Hypochlorite solution is very toxic to aquatic life when released.

Environmental damage can result.

- Dispose of sodium hypochlorite solution and containers according to national and local standards and regulations.

1 Fill an empty container with the required volume of the 2–3 % hypochlorite solution.

WARNING

False results due to hypochlorite solution contaminating the water container and entering the tubing

Death or serious injury to the patient can result.

- Do not use the routinely installed water container to purge the tubing.

2 Fill an empty, unused 5 L or 10 L container with at least 2 L of water.

3 In the dialog **System**, in the area **Maintenance**, click **Purge tubings**.

→ In the dialog **Purge tubings**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or , see (➔ Page 109 *Purge tubings*).

4 Wait until a confirmation dialog is displayed.

5 Click **Yes**.

→ A message is displayed.

6 Remove the level sensor from the routinely installed water container.

7 Place the level sensor in the extra container holding the hypochlorite solution.

8 Click the action button **Start purging**.

→ In the status line, the process steps are displayed.

9 Wait until an information dialog is displayed.

10 Click **Ok**.

→ A progress bar is displayed. The purging time is 15 minutes. During countdown the remaining time is displayed in seconds starting at **900**.

11 Wait until a message is displayed.

12 Remove the level sensor from the extra container holding the hypochlorite solution.

13 Rinse the outside of the level sensor thoroughly with water.

WARNING

False results can occur due to hypochlorite solution contaminating the water container and entering the tubing.

Death or serious injury to the patient can result.

◆ Do not use the routinely installed water container to rinse the tubing.

14 Place the level sensor in the extra container holding water.

15 Click the action button **Start rinsing**.

→ The system rinses the tubing.

16 Wait until the information dialog **Rinsing process completed** is displayed.

17 Click **Ok**.

→ Another information dialog is displayed.

18 Rinse the routinely installed water container with water.

19 Remove the level sensor from the extra container holding water.

20 Place the level sensor in the routinely installed water container.

21 Click **Ok**.

→ The dialog **System** is displayed.

22 Rinse the system with buffer, diluent, and water (washing liquid), see (➔ Page 199 *Rinsing the system*).

→ Purging the tubing is completed.

10.3.2 Replacing the water filter

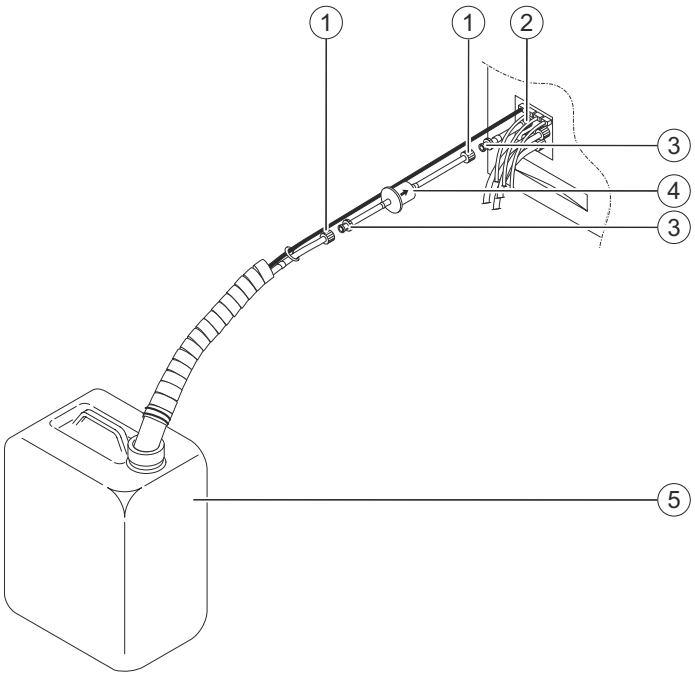
✓ Soft, lint-free cloth is available.

✓ 1 new water filter is available.

✓ The system is in standby or routine mode or is off.

To replace the water filter, proceed as follows:

1 Disconnect the Luer lock fittings from the water filter, see the figure below.



Replacing the water filter

(1) Female Luer lock fittings
(2) Connection fitting of the system
(3) Male Luer lock fittings
(4) Water filter
(5) Water container

2 Dispose of the used water filter according to national and local standards and regulations.

3 Insert the new water filter between the female and the male Luer lock fittings such that the arrow points in the direction of flow of the water.

4 If the system is off: Start the system, see (➔ Page 145 *Starting the system*).

5 Rinse the system with water, see (➔ Page 199 *Rinsing the system*).

→ No air bubbles appear in the water tubing.

Air bubbles appear in the water tubing.

◆ Repeat rinsing until no more air bubbles appear in the water tubing.

→ Replacing the water filter is completed.

10.3.3 Cleaning the level sensors

To clean the level sensors, proceed as follows:

1 Clean the level sensors of the buffer, diluent, and water container, see (➔ Page 219 *Clean level sensors of buffer, diluent, and water containers*).

2 Clean the level sensor of the waste container (green marking), see (➔ Page 220 *Clean level sensor of waste container*).

→ Cleaning the level sensors is completed.

Clean level sensors of buffer, diluent, and water containers

Clean the level sensors 1 at a time.

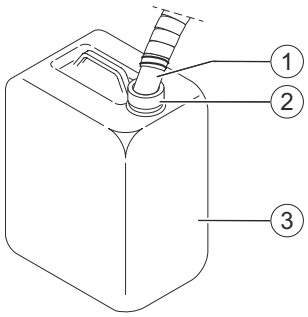
✓ Soft, lint-free cloth is available.

✓ 70 % ethanol or 70 % isopropyl alcohol is available.

✓ The system is in standby mode or is off.

To clean the level sensors of the buffer, diluent, and water containers, proceed as follows:

1 Pull the level sensor out of the cap, see the figure below.



Removing the cap

(1) Level sensor
(2) Cap
(3) Container

2 Pull the cap from the container.

3 Wipe the surface of the level sensor with a soft, lint-free cloth moistened with the specified alcohol.

4 Allow the alcohol to take effect, according to the instructions from the manufacturer.

5 Over a sink, rinse the level sensor with clean water.

6 Wipe the surface of the cap with a soft, lint-free cloth moistened with the specified alcohol.

7 Allow the alcohol to take effect, according to the instructions from the manufacturer.

8 Press the cap onto the opening of the container.

9 Insert the level sensor back into the container.

Make sure that the level sensor is inserted at an angle into the corresponding container. The free end of the level sensor inside the container must point away from the opening in the container so that the floater at the end of the level sensor can move up and down freely.

The tubing bears differently colored markings, see (➔ Page 47 *Liquid containers, level sensors, and tubing*).

10 Repeat the procedure for the level sensors of the buffer, diluent, and water containers.

11 Clean the level sensor of the waste container, see (➔ Page 220 *Clean level sensor of waste container*).

→ Cleaning the level sensors of the buffer, diluent, and water containers is completed.

Clean level sensor of waste container

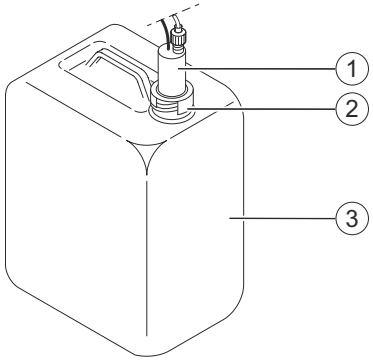
✓ Soft, lint-free cloth is available.

✓ 70 % ethanol or 70 % isopropyl alcohol is available.

✓ The system is in standby mode or is off.

To clean the level sensor of the waste container, proceed as follows:

1 Pull the level sensor out of the cap, see the figure below.



Removing the cap

(1) Level sensor
(2) Cap
(3) Container

2 Unscrew the cap from the container.

3 Wipe the surface of the level sensor with a soft, lint-free cloth moistened with the specified alcohol.

4 Allow the alcohol to take effect, according to the instructions from the manufacturer.

5 Over a sink, rinse the level sensor with clean water.

6 Wipe the surface of the cap with a soft, lint-free cloth moistened with the specified alcohol.

7 Allow the alcohol to take effect, according to the instructions from the manufacturer.

8 Screw the cap back onto the waste container.

9 Place the 2 pegs on the level sensor of the waste container in the notches of the cap.

10 Lower the level sensor back into the waste container.

11 Rinse the system with buffer, diluent, and water (washing liquid), see (➔ Page 199 *Rinsing the system*).

→ Cleaning the level sensor of the waste container is completed.

10.4 Yearly tasks

This section describes the maintenance and cleaning tasks that must be performed once a year.

10.4.1 Replacing the syringe

Besides the yearly maintenance, it may be required to replace the syringe due to leaking. This can be caused by dirt or deposits at low temperatures or the creep characteristics of Teflon causing parts of the plunger to shrink.

✓ Disposable, absorbent cloth is available.

✓ 1 new syringe is available.

✓ The system is in standby or routine mode.

To replace the syringe, proceed as follows:

1 In the dialog **System**, in the area **Maintenance**, click **Replace syringe**.

→ In the dialog **Replace syringe**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 112 *Replace syringe*).

2 Wait until a confirmation dialog is displayed.

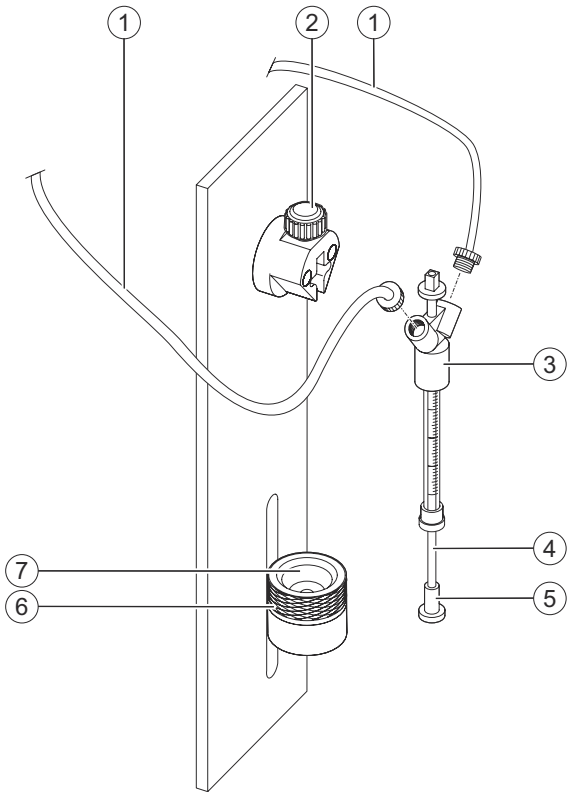
3 Click **Yes**.

→ The plunger of the syringe moves to a position that enables replacing of the syringe.

4 Wait until a message is displayed.

5 Open the left cover.

6 Hold the used syringe by the handle, see the figure below.



Removing the used syringe

(1) Tubing
(2) Screw
(3) Handle
(4) Plunger
(5) Head of plunger
(6) Knurled nut
(7) Straining ring

7 Loosen the knurled nut.

8 Push the plunger upward until the head of the plunger is above the straining ring.

9 Loosen the screw.

10 Have disposable, absorbent cloth available to absorb spilled liquid.

11 Remove the used syringe from the straining ring.

12 Unscrew the tubing from the handle.

13 Dispose of the used syringe according to national and local standards and regulations.

14 Fill the new syringe with diluent to moisten the inside.

15 Empty the new syringe again.

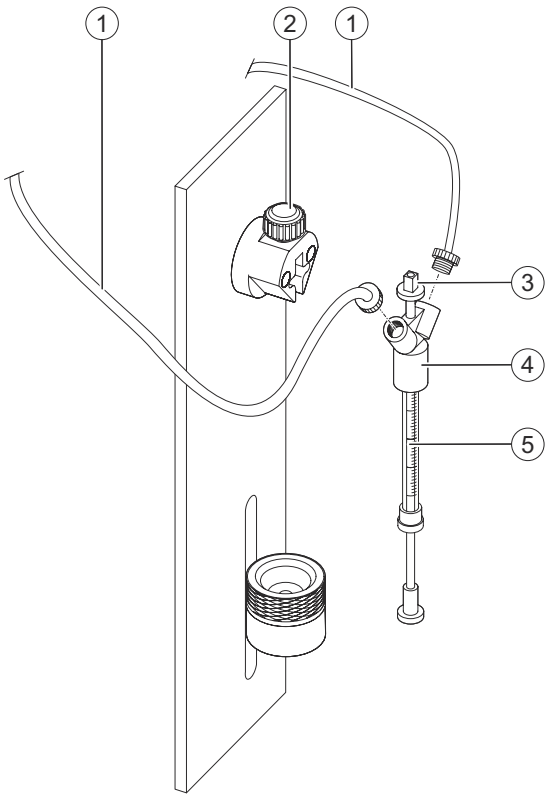
WARNING

False results due to bent tubing can occur. Measurements must be repeated.

Death or serious injury to the patient can result.

- Check that the tubing of the new syringe is not bent.

16 With the scale facing away from the screw, screw the tubing to the handle of the new syringe, see the figure below.



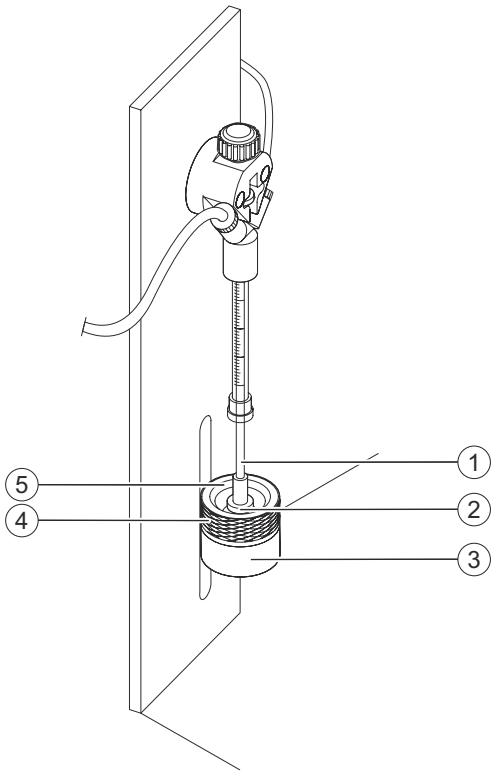
Screwing the tubing to the new syringe

(1) Tubing
(2) Screw
(3) Square
(4) Handle
(5) Scale

17 Insert the square of the new syringe below the screw.

18 Tighten the screw.

19 Position the head of the plunger in the straining ring, see the figure below.



Installing the new syringe

(1) Plunger
(2) Head of the plunger
(3) Syringe platform
(4) Knurled nut
(5) Straining ring

20 Push the plunger slightly downward while screwing the knurled nut tight to secure the head of the plunger.

21 Check the amount of play between the head of the plunger and the syringe platform.

→ There is no play between the head of the plunger and the syringe platform.

There is any amount of play between the head of the plunger and the syringe platform.

- Loosen the knurled nut a little.
- Push the plunger slightly more downward while screwing the knurled nut tight.
- Repeat this step.

---

22 Click the action button **Close**.

→ The system rinses the tubing.

23 Wait until an information dialog is displayed.

24 Click **Ok**.

WARNING

Air bubbles in the tubing can distort the mixing ratio in the cuvettes. False results can occur.

Death or serious injury to the patient can result.

- Carefully follow the instructions given below.

25 Rinse the system with diluent and water (washing liquid), see (➔ Page 199 *Rinsing the system*).

→ No air bubbles appear in the syringe or in the tubing.

Air bubbles appear in the syringe or in the tubing.

- Repeat this step.

26 Close the left cover.

→ A confirmation dialog is displayed.

27 Click **Ok**.

→ The dialog **System** is displayed.

→ Replacing the syringe is completed.

10.4.2 Replacing the tubing of the containers

Siemens Healthineers recommends replacement of the tubing of the containers by Siemens Healthineers service.

With the tubing set, the tubing of the containers is supplied in 1 piece. The current tubing to each container bears a colored marking that is assigned to a specific liquid, see the table below.

Liquid	Color
Diluent	Blue
Buffer	Red
Water	White
Waste	Green

Color assignment of the tubing of the containers

The current tubing of the water container contains a filter in addition.

✓ Disposable, absorbent cloth is available.

✓ 1 new tubing set is available.

✓ 1 side cutter is available.

✓ 1 folding rule or tape measure is available.

✓ 1 new water filter is available.

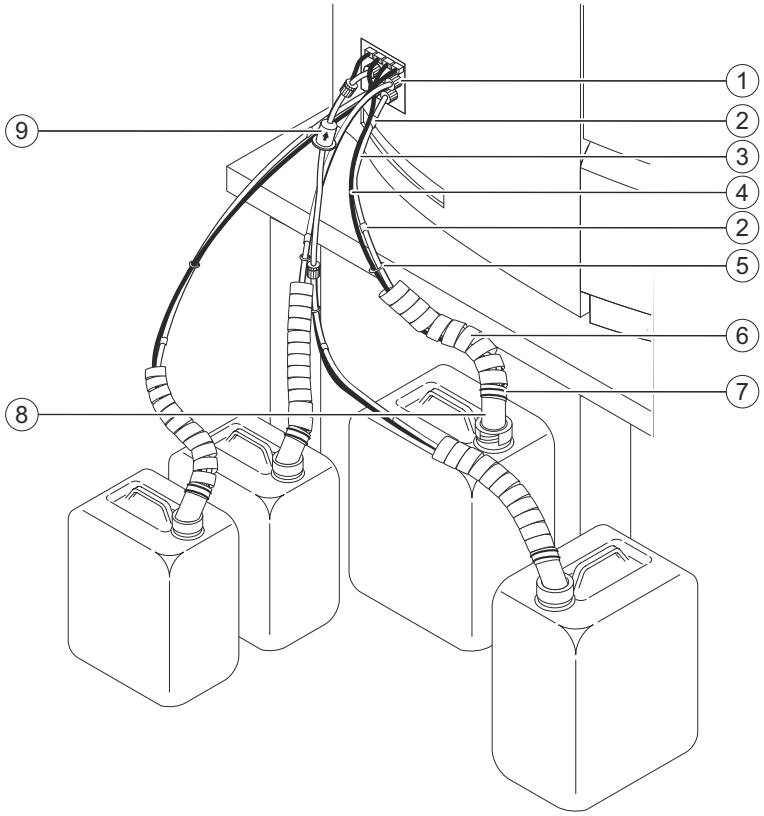
✓ The system is off.

To replace the tubing of the containers, proceed as follows:

Replace the tubing of each container 1 at a time.

1 Have disposable, absorbent cloth available to absorb spilled liquid.

2 Cut the new tubing according to the lengths of the current, used tubing, see the figure below.



Replacing the tubing

(1) Knurled screw with sealing ring
(2) Colored marking
(3) Tubing
(4) Cable
(5) Connector
(6) Spiral tube
(7) Cable ties
(8) Level sensor
(9) Water filter

3 Slide the new colored markings over both sides of the cut, new tubing according to the colored markings of the used tubing.

4 With the side cutter, cut the cable ties fastening the spiral tube to the level sensor.

5 Push the spiral tube away from the level sensor.

6 Loosen the used tubing from the connectors between tubing and cable.

7 Unscrew the knurled screw at both ends of the used tubing and pull it back.

8 Carefully pull off the used tubing from the system and the level sensor so it cannot drip.

9 Remove the knurled screws and the sealing rings from the used tubing and set them aside.

10 Remove the spiral tube from the used tubing and the cable.

11 Hold the new tubing in such a way that the openings do not touch the floor.

12 Slide the spiral tube over the new tubing and the cable.

13 Dispose of the used tubing according to national and local standards and regulations.

14 Fit a knurled screw and then a sealing ring to the end of the new tubing near the system. The wider end of the sealing ring must face in the direction of the tubing end. Approximately 1 mm of the tubing end should be visible.

15 Put this end of the tubing into the connection fitting of the system.

Make sure to put the tubing in the similarly colored connection fitting. When fitting the water tubing, take care to fit the tubing end with the water filter into the connection fitting of the system.

16 Tighten the knurled screw.

17 Fit the other knurled screw and then the sealing ring to the other end of the tubing. The wider end of the sealing ring must face in the direction of the tubing end. Approximately 1 mm of the tubing end should be visible.

18 Put this end of the tubing into the connection fitting of the level sensor.

Make sure to put the tubing in the connection fitting of the correct level sensor.

19 Tighten the knurled screw.

20 Insert the tubing into the connectors of the tubing and cable.

WARNING

Bends in the tubing can distort the mixing ratio in the cuvettes. False results can occur.

Death or serious injury to the patient can result.

- Take care that the tubing is not bent.
- Fit a spiral tube around the tubing and cable to prevent bends in the tubing.

21 Fit the spiral tube around the upper part of the level sensor.

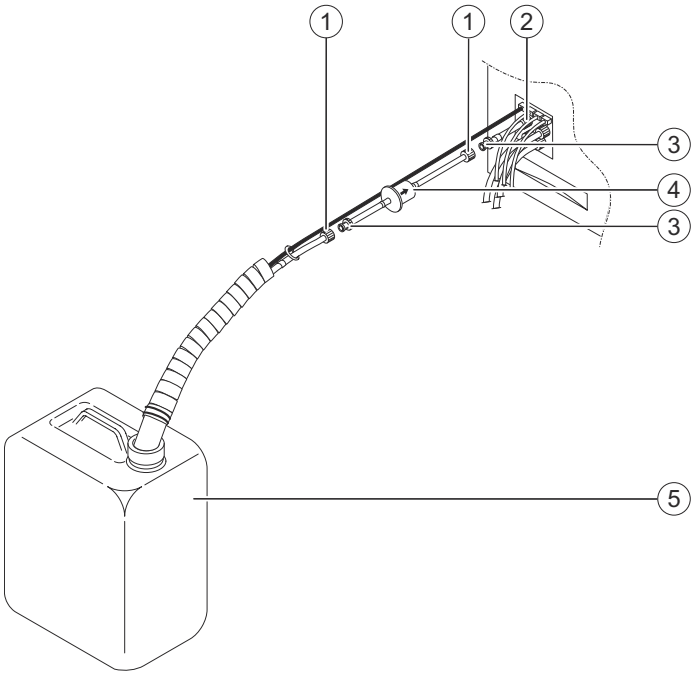
22 Fasten the spiral tube to the level sensor with 2 cable ties.

23 Check that the tubing is connected properly.

24 Repeat the procedure up to this step for each tubing.

→ The tubing is replaced. A new water filter has to be inserted.

25 Cut the tubing of the water container (white markings) approximately 10 cm from the connection fitting of the system, see the figure below.



Inserting the water filter

(1) Female Luer lock fittings
(2) Connection fitting of the system
(3) Male Luer lock fittings
(4) Water filter
(5) Water container

26 Fit the conical part of a female Luer lock fitting up to the flange in the tubing that leads to the water container.

27 Fit the conical part of a male Luer lock fitting up to the flange in the tubing that leads to the connection fitting of the system.

28 Insert the new water filter between the female and the male Luer lock fittings such that the arrow points in the direction of flow of the water.

29 Start the system, see (➔ Page 145 *Starting the system*).

30 Rinse the system with buffer, diluent, and water (washing liquid), see (➔ Page 199 *Rinsing the system*).

→ No air bubbles appear in the buffer, diluent, and water tubing.

Air bubbles appear in the buffer, diluent, or water tubing.

◆ Repeat rinsing until no more air bubbles appear in the buffer, diluent, and water tubing.

→ Replacing the tubing of the containers is completed.

10.5 As needed tasks

This section describes the maintenance and cleaning tasks that must be performed as needed.

10.5.1 Shutting down the system for maintenance

✓ The system is in standby or routine mode.

To shut down the system for maintenance, proceed as follows:

1 In the dialog **Status**, click the action button **Exit**.

→ A confirmation dialog is displayed.

2 Click **Yes**.

→ The system is rinsed with water. The system is shut down. The viewer software closes.

3 Wait until the 3 LEDs in the upper right corner at the front of the system are off.

→ The system is shut down.

→ Shutting down the system for maintenance is completed.

10.5.2 Cleaning the surface of the system

Purging agents that contain alcohol affect acrylic glass surfaces, for example, the cover windows. Do not use purging agents or purging solutions that contain alcohol to clean acrylic glass surfaces.

✓ Soft, lint-free cloth is available.

✓ Purging solution is available.

✓ The system is in standby or routine mode or is off.

To clean the surface of the system, proceed as follows:

1 Prepare the purging solution according to the instruction manual of the purging agent or contact Siemens Healthineers service.

2 Wipe the surface of the system with a soft, lint-free cloth moistened with purging solution.

3 Allow the purging solution to take effect, according to the instructions from the manufacturer.

→ Cleaning the surface of the system is completed.

10.5.3 Cleaning the sample rotor and the sample rotor housing

✓ Soft, lint-free cloth is available.

✓ Purging solution is available.

✓ The system is in standby or routine mode.

To clean the sample rotor and the sample rotor housing, proceed as follows:

1 Prepare the purging solution according to the instruction manual of the purging agent or contact Siemens Healthineers service.

2 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

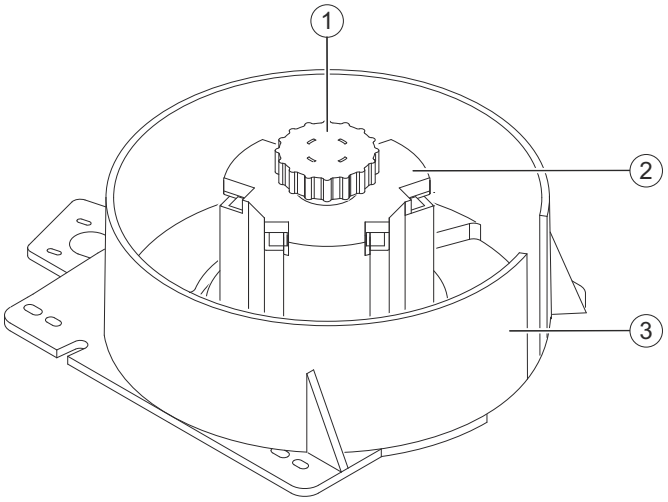
3 Wait until a message is displayed.

4 Open the left cover.

→ Another message is displayed.

5 Remove all sample rotor segments.

6 Loosen the handwheel of the sample rotor, see the figure below. The handwheel cannot be completely unscrewed.



Cleaning the sample rotor

(1) Handwheel
(2) Sample rotor
(3) Sample rotor housing

7 Remove the sample rotor by the handwheel.

8 Wipe the sample rotor and the sample rotor housing with a soft, lint-free cloth moistened with purging solution.

9 Allow the purging solution to take effect, according to the instructions from the manufacturer.

10 Place the sample rotor back. Turn the sample rotor slightly in both directions until it locks in place.

11 Tighten the handwheel.

12 Clean the segments, see (➔ Page 231 *Cleaning the segments*).

13 Load sample rotor segments on the sample rotor as required, see (➔ Page 171 *Loading sample rotor segments*).

14 Close the left cover.

→ The action button **Close** is displayed.

15 Click the action button **Close**.

→ The dialog **System** is displayed.

→ Cleaning the sample rotor and the sample rotor housing is completed.

10.5.4 Cleaning the segments

✓ Soft, lint-free cloth is available.

✓ Purging solution is available.

✓ The system is in standby or routine mode or is off.

To clean the segments, proceed as follows:

1 Prepare the purging solution according to the instruction manual of the purging agent or contact Siemens Healthineers service.

2 Wipe the segments with a soft, lint-free cloth moistened with purging solution.

– or –

Spray the segments with purging solution and wash them in a dishwasher.

3 Allow the purging solution to take effect, according to the instructions from the manufacturer.

→ Cleaning the segments is completed.

10.5.5 Cleaning the dilution station, the cuvette rotor, and the cuvette rotor housing

During cleaning, dilution strips and cuvette segments have to be replaced. Existing pre-dilutions in dilution strips and sample dilutions in cuvette segments are lost. No assays for those pre-dilutions and sample dilutions will be processed. A delay of results can occur. Only clean the dilution station, the cuvette rotor and the cuvette rotor housing after all jobs have been processed.

✓ Soft, lint-free cloth is available.

✓ Purging solution is available.

✓ Unused dilution strips are available.

✓ Unused cuvette segments in original packaging are available.

✓ The system is in standby or routine mode.

To clean the dilution station, the cuvette rotor, and the cuvette rotor housing, proceed as follows:

1 Prepare the purging solution according to the instruction manual of the purging agent or contact Siemens Healthineers service.

2 In the dialog **System**, in the area **Access**, click **Cuv. seg. & dil. strips**.

→ The dialog **Access cuvette segments and dilution strips** is displayed. For more information on the dialog, click the action button **Help** or see (→ Page 59 *Access cuvette segments and dilution strips*).

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

3 Click the action button **Cuv. seg. & dil. strips**.

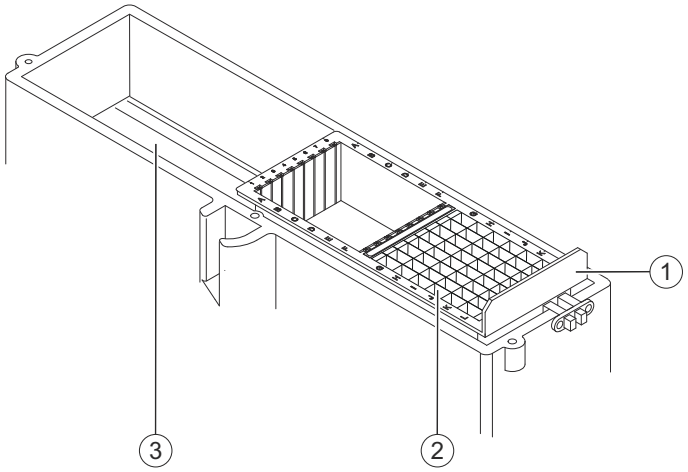
→ A progress bar is displayed. The system finishes current operations. This can take several minutes.

4 Wait until a message is displayed.

5 Open the right cover.

→ Another message is displayed.

6 Remove the dilution frame, see the figure below.



Cleaning the dilution station

(1) Dilution frame
(2) Dilution strips
(3) Base plate

7 Remove the dilution strips from the dilution frame.

8 Wipe the base plate and the dilution frame with a soft, lint-free cloth moistened with purging solution.

9 Allow the purging solution to take effect, according to the manufacturer's instructions.

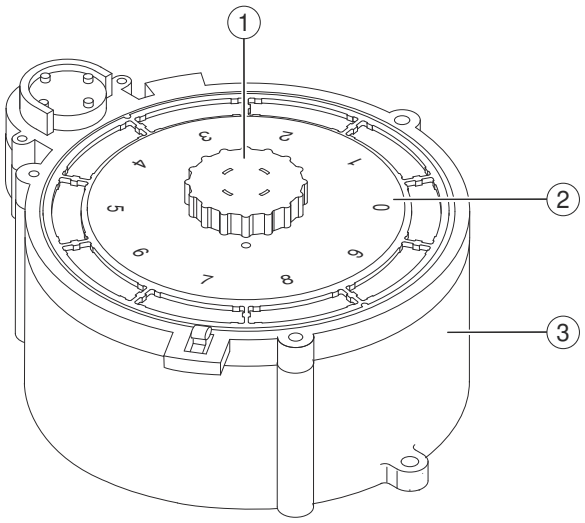
10 Load unused dilution strips in the dilution frame.

11 Place the dilution frame back on the system.

12 Remove the cuvette rotor cover.

13 Remove all cuvette segments.

14 Loosen the handwheel of the cuvette rotor, see the figure below. The handwheel cannot be completely unscrewed.



Cleaning the cuvette rotor

(1) Handwheel
(2) Cuvette rotor
(3) Cuvette rotor housing

15 Remove the cuvette rotor by the handwheel.

16 Wipe the cuvette rotor and the cuvette rotor housing with a soft, lint-free cloth moistened with purging solution.

17 Allow the purging solution to take effect, according to the manufacturer's instructions.

18 Place the cuvette rotor back. Turn the cuvette rotor slightly in both directions until it locks in place.

19 Tighten the handwheel.

20 Load unused cuvette segments in the cuvette rotor.

21 Replace the cuvette rotor cover.

22 Click the action button **Select all**.

23 Click the action button **Save**.

→ A message is displayed.

24 Close the right cover.

→ The action button **Close** is displayed.

25 Click the action button **Close**.

→ The dialog **System** is displayed. The system detects the dilution strips and cuvette segments. The system measures the blank values of the cuvette segments.

→ Cleaning the dilution station, the cuvette rotor, and the cuvette rotor housing is completed.

10.5.6 Cleaning the waste container

✓ 70 % ethanol or 70 % isopropyl alcohol is available.

✓ Optional: Purging agent is available.

✓ The system is off.

To clean the waste container, proceed as follows:

WARNING

Infection due to infectious waste

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle parts of the system that have come into contact with potentially infectious material in accordance with good laboratory practices.

1 Pull the level sensor of the waste container 1–2 cm out of the waste container.

2 Unscrew the cap from the waste container. The level sensor remains in the cap.

3 Dispose of liquid waste according to national and local standards and regulations.

4 Fill 1/10 of the waste container with the specified alcohol.

5 Slew the waste container until the entire inner surface has been wetted.

6 Allow the alcohol to take effect, according to the instructions from the manufacturer.

7 Dispose of the alcohol according to national and local standards and regulations.

Siemens Healthineers recommends filling the waste container with some purging agent to prevent unpleasant odors. Handle the purging agent according to the instructions from the manufacturer.

8 Screw the cap back onto the waste container.

9 Push the level sensor back into the waste container.

10 Place the 2 pegs on the level sensor in the notches of the cap.

→ Cleaning the waste container is completed.

10.5.7 Cleaning the peripheral devices

Peripheral devices are, for example, the computer, the monitor, the keyboard, the mouse, or a printer.

✓ Soft, lint-free cloth is available.

✓ Purging solution is available.

✓ The system is in standby or routine mode or is off.

To clean the peripheral devices, proceed as follows:

1 Prepare the purging solution according to the instruction manual of the purging agent or contact Siemens Healthineers service.

2 Close the viewer software, see (➔ Page 300 *Closing viewer software*).

3 Wipe the peripheral devices with a soft, lint-free cloth moistened with purging solution.

4 Allow the purging solution to take effect, according to the manufacturer's instructions.

5 Start the viewer software, see (➔ Page 299 *Starting viewer software*).

→ Cleaning the peripheral devices is completed.

10.5.8 Replacing the probe cleaner bottle

The residual volume in the probe cleaner bottle is 3.9 mL.

✓ 1 new probe cleaner bottle is available.

✓ The system is in standby or routine mode.

To replace the probe cleaner bottle, proceed as follows:

1 In the dialog **System**, in the area **Access**, click **System liquid & waste**.

→ In the dialog **Replace system liquids and empty waste container**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 112 *Replace system liquids and empty waste container*).

2 Wait until the progress bar is no longer displayed.

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

3 Open the right cover.

WARNING

Hardware problem due to froth on the probe cleaner. The probe may not be sufficiently cleaned. False results can occur.

Death or serious injury to the patient can result.

- Do not shake the probe cleaner bottle.
- Do not pool probe cleaner bottles.
- If froth has formed, remove it.

Delay of results can occur due to froth on the probe cleaner.

4 Remove the cap from the new probe cleaner bottle.

5 Replace the empty probe cleaner bottle with the new probe cleaner bottle.

Do not replace dilution strips or cuvette segments while loading probe cleaner, as the system would not update the status of the dilution strips or cuvette segments.

6 Close the right cover.

7 In the area **Replaced system liquid**, select **Cleaner bottle replaced**.

→ The action button **Save** becomes active.

8 Click the action button **Save**.

9 Wait until the dialog **System** is displayed.

→ Replacing the probe cleaner bottle is completed.

10.5.9 Preparing the purging solution

Prepare the purging solution according to the instruction manual of the purging agent or contact Siemens Healthineers service.

10.5.10 Preparing the hypochlorite solution

✓ Sodium hypochlorite solution is available.

✓ Water is available.

✓ An alkali-resistant container is available.

✓ The system is in standby or routine mode or is off.

To prepare the hypochlorite solution, proceed as follows:

WARNING

Hypochlorite solution can cause damage to the respiratory system through inhalation. Hypochlorite solution can cause severe skin burns and eye damage if it comes into contact with skin and eyes.

Death or serious injury to the user and bystanders can result.

- Wear appropriate personal protective equipment; that is, gloves, protective clothing, safety glasses and mask.
- Pay attention to the information from the manufacturer regarding the compatibility of the gloves with the materials and liquids used.
- Observe the instructions from the manufacturer regarding handling of hypochlorite solution.
- Store and handle in a well ventilated area.
- Avoid breathing fume.
- Avoid contact with eyes and skin.
- Wash thoroughly after handling.
- In case of contact with eyes or skin, immediately rinse the affected area with plenty of water for several minutes.
- In the event of an accident or if you feel unwell, seek medical advice immediately and show the label if possible.

NOTICE

Hypochlorite solution is very toxic to aquatic life when released.

Environmental damage can result.

- Dispose of sodium hypochlorite solution and containers according to national and local standards and regulations.

1 Calculate the required amount of the initial sodium hypochlorite solution depending on the required amount of the 2–3 % hypochlorite solution.

$V_1 = (V_2 \cdot c_2) / c_1$

With:

V_1: Required amount of the initial sodium hypochlorite solution

c_1: Concentration of the initial sodium hypochlorite solution

V_2: Final volume of the 2–3 % hypochlorite solution

c_2: Final concentration of the 2–3 % hypochlorite solution

2 Calculate the required amount of purified water to make up the final volume of the 2–3 % hypochlorite solution.

$V_W = V_2 - V_1$

With:

V_W: Required amount of water

V_2: Final volume of the 2–3 % hypochlorite solution

V_1: Required amount of the initial sodium hypochlorite solution

3 Fill the required amount of water into an alkali-resistant container.

4 Add the required amount of the initial sodium hypochlorite solution to the water.

→ Preparing the hypochlorite solution is completed.

Example The initial sodium hypochlorite solution is concentrated to 14 %. The required amount of a 2 % hypochlorite solution is 1000 mL.

The required amount of the initial sodium hypochlorite solution is calculated as follows:

$V_1 = (V_2 \cdot c_2) / c_1 = (1000\ mL \cdot 2\ \%) / 14\ \% = 143\ mL$

The required amount of water is calculated as follows:

$V_W = V_2 - V_1 = 1000\ mL - 143\ mL = 857\ mL$

1 Fill an alkali-resistant container with 857 mL of water.

2 Add 143 mL of the 14 % initial sodium hypochlorite solution to make up 1000 mL of a 2 % hypochlorite solution.

10.6 Atellica® NEPH 630 System maintenance log

Analyzer ID:

Weekly maintenance		Week 1	Week 2	Week 3	Week 4	Week 5
1.	Functioning of the probe checked					
2.	Probe cleaned					
3.	Wet station cleaned					
4.	Reagent rotor and reagent rotor housing cleaned					
5.	Syringe checked for leaks					
6.	Water container cleaned					
7.	Tubing of the containers checked					
8.	Tubing of the probe checked					
9.	System shut down					
10.	System started					
Remark:						
Date:						
Signature:						

Monthly maintenance		
1.	Tubing purged	
2.	Water filter replaced	
3.	Level sensors cleaned	
Remark:		
Date:		
Signature:		

Yearly maintenance		
1.	Syringe replaced	
2.	Tubing replaced	
Remark:		
Date:		
Signature:		

11 Troubleshooting

This chapter describes the troubleshooting of the system.

11.1 Carrying out troubleshooting

To carry out troubleshooting, proceed as follows:

1 Check if the problem is a hardware problem.

The problem is a hardware problem.

- Check if the problem is described in the hardware troubleshooting chart, see (➔ Page 242 *Hardware troubleshooting chart*).

The problem is not a hardware problem.

- Go to the next step.

2 Check if a **Message window** is displayed.

A **Message window** is displayed.

- Follow the instructions given in the **Message window**, below **Explanation**.
- In the **Message window**, click **OK**.
- If the problem is not solved, check if a description and appropriate corrective measures to the problem is available, see (➔ Page 267 *Software troubleshooting*).

No **Message window** is displayed.

- Go to the next step.

3 Check if a status button is highlighted.

A status button is highlighted.

- Place the mouse pointer over the highlighted status button.
- Register the displayed tool tip text that specifies the problem.
- Click the highlighted status button.
- If the dialog **Logbook** is displayed, click the most recent entry that corresponds to the tool tip text and follow the instructions on how to solve the problem, see (➔ Page 101 *Logbook*). For more information on the dialog, click the action button **Help**.
- If the dialog where the problem can be solved is displayed, solve the problem that was specified in the tool tip text.

No status button is highlighted.

- Check if a description and appropriate corrective measures to the problem is available, see (➔ Page 267 *Software troubleshooting*).

4 If none of the above mentioned corrective measures solves the problem, contact Siemens Healthineers service.

→ Troubleshooting is completed.

11.2 Hardware troubleshooting

This chapter lists possible hardware problems that could occur during operation of the system together with probable causes and corrective measures. If the recommended measures do not solve the problem, contact Siemens Healthineers service.

11.2.1 Hardware troubleshooting chart

The chart below describes possible hardware problems and probable causes. To solve a problem, follow the instructions described in the right column of the chart.

Problem	Probable cause	Corrective measure
System does not start when the main switch is set to position **I**.	Supply cable is not plugged into the power module at the right side of the system.	Plug the supply cable into the power module at the right side of the system.
	Supply cable is not plugged into a wall outlet meeting the electrical conditions.	Plug the supply cable into a wall outlet meeting the electrical conditions, see (➔ Page 304 *Electrical conditions*).
	Supply cable is damaged.	At the right side of the system, set the main switch to position **O** and replace the supply cable.
	Circuit breaker in electrical circuit of building is tripped.	Reset the circuit breaker.
	Fuses are blown.	Replace the fuses, see (➔ Page 247 *Replacing the fuses*).
	Electrical failure of the system.	Contact Siemens Healthineers service.
3 LEDs in the upper right corner at the front of the system do not light up after the main switch has been set to position **I**.	Electrical failure of the system.	Re-start the system. If the 3 LEDs still do not light up, contact Siemens Healthineers service.
Computer, monitor, or printer does not start when switched on.	Supply cable is not plugged into the power module of the computer, monitor, or printer.	Plug the supply cable into the power module of the computer, monitor, or printer.
	Supply cable of the computer, monitor, or printer is not plugged into a wall outlet meeting the electrical conditions.	Plug the supply cable of the computer, monitor, or printer into a wall outlet meeting the electrical conditions, see (➔ Page 304 *Electrical conditions*).
	Supply cable of the computer, monitor, or printer is damaged.	Switch off the computer, monitor, or printer and replace the supply cable.
	Circuit breaker in electrical circuit of building is tripped.	Reset the circuit breaker.
	Electrical failure of the computer, monitor, or printer.	Contact Siemens Healthineers service.

Problem	Probable cause	Corrective measure
Probe is bent.	Probe has collided with a solid object.	Replace the probe assembly, see (➔ Page 250 *Replacing the probe assembly*).
Air bubbles appear in the tubing.	Valve is leaking or tubing is bent or leaking.	• Check if the external tubing is bent and ensure that the tubing is connected properly. • Rinse the system, see (➔ Page 199 *Rinsing the system*). • If air bubbles still appear, contact Siemens Healthineers service.
Liquid accumulates within the system.	Tubing of the probe or syringe has not been tightened correctly.	Re-tighten the tubing of the probe and syringe.
	Probe leaks.	Replace the syringe, see (➔ Page 221 *Replacing the syringe*).
	Tubing leading to the waste container is bent.	Replace the tubing, see (➔ Page 225 *Replacing the tubing of the containers*).
Liquid accumulates under the system.	-	Contact Siemens Healthineers service.
Reagent rotor makes scratching noises.	1 or more reagent rotor segments have not been inserted correctly.	Insert the reagent rotor segments correctly, see (➔ Page 243 *Inserting reagent rotor segments*).
	Too much ice has built up in the reagent rotor.	• Shut down the system, see (➔ Page 200 *Shutting down the system*). • Wait until the ice has melted completely. • Re-start the system, see (➔ Page 145 *Starting the system*).
Dilution cups or cuvettes remain empty even though the system processes jobs.	Probe is blocked, for example, by a clot that has been aspirated.	Check the functioning of the probe, see (➔ Page 205 *Checking the functioning of the probe*).
Other hardware problem with the system, computer, monitor, or printer has occurred.	Electrical or mechanical failure has occured.	Contact Siemens Healthineers service.

Hardware troubleshooting chart

11.2.2 Inserting reagent rotor segments

When the reagent rotor makes scratching noises, reagent rotor segments may not be inserted correctly. In this case, reagent rotor segments have to be inserted correctly.

✓ The system is in standby or routine mode.

To insert reagent rotor segments, proceed as follows:

1 In the dialog **System**, in the area **Access**, click **Reagents**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

2 Wait until a message is displayed.

3 Open the left and right covers.

→ Another message is displayed.

4 Remove the reagent rotor cover.

5 Push down the white and yellow parts of all reagent rotor segments next to the handwheel.

→ A clicking noise indicates that a reagent rotor segment was not inserted correctly but is now in the correct position.

6 Replace the reagent rotor cover.

7 Close the left and right covers.

→ The action button **Close** is displayed.

8 Click the action button **Close**.

→ The dialog **System** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor. The reagent rotor segments have been inserted correctly if no more scratching noises occur.

→ Inserting reagent rotor segments is completed.

11.2.3 Checking the level of samples visually

✓ The system is in standby or routine mode.

To check the level of samples visually, proceed as follows:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

2 Wait until a message is displayed.

3 Open the left cover.

→ Another message is displayed.

4 Remove the affected sample tube.

5 Check that the sample material is of sufficient volume.

Approximately 10 mm of supernatant serum or plasma above the packed cells or separating gel is required. If using 75 mm x 12 mm sample tubes, 450–500 µL plasma is required.

6 Refill the sample tube with an appropriate amount of the same sample material, if required.

WARNING

False results due to froth causing incorrect level detection. Accurate transfer of the sample cannot be guaranteed.

Death or serious injury to the patient can result.

- Remove froth before loading samples.

7 Load the sample tube in the same position of the sample rotor segment. Carefully push down the sample tube until it touches the base of the sample rotor segment.

8 Close the left cover.

→ The action button **Close** is displayed.

9 Click the action button **Close**.

→ The dialog **System** is displayed. The samples are loaded. The barcode reader scans the barcodes in the sample rotor.

→ Checking the level of samples visually is completed.

11.2.4 Checking the level of reagents or controls

✓ The system is in standby or routine mode.

To check the level of reagents or controls, proceed as follows:

WARNING

Infection due to potentially infectious reagents and controls

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle reagents and controls in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Reagents**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

2 Wait until a message is displayed.

3 Open the left and right covers.

→ Another message is displayed.

4 Remove the reagent rotor cover.

5 Remove the affected reagent or control vial.

6 Remove the evaporation cap from the reagent or control vial.

7 Check that the reagent or control material is of sufficient volume.

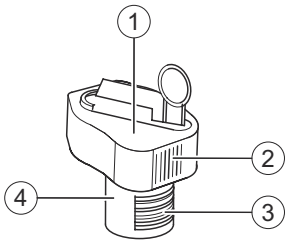
WARNING

False results due to froth or lamellae causing incorrect level detection. Accurate transfer of the reagent or control cannot be guaranteed. False results due to increased concentration of reagents and controls. Concentration can increase due to evaporation out of open reagent or control vials.

Death or serious injury to the patient can result.

- Remove froth and lamellae before placing evaporation caps on reagent and control vials.
- Carefully follow the instructions given below.
- For more information on on-board stability of reagents and controls, see the separate document assay protocols and the instructions for use of the product.

8 Replace evaporation caps on the reagent and control vials, see the figure below.



Placing evaporation caps

(1) Evaporation cap
(2) Vertical striation
(3) Barcode
(4) Reagent or control vial

The vertical striation on the evaporation cap and the barcode on the label of the vial must be aligned.

Do not tilt reagent and control vials with evaporation caps on. Evaporation caps do not prevent liquid from spilling.

9 Reload the reagent or control vial in the same position of the reagent rotor segment.

10 Replace the reagent rotor cover.

11 Close the left and right covers.

→ The action button **Close** is displayed.

12 Click the action button **Close**.

→ The dialog **System** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor.

→ Checking the level of reagents or controls is completed.

11.2.5 Checking the geometry of the probe

When the probe has collided with a solid object, for example, an evaporation cap, the geometry of the probe must be checked.

✓ The system is in standby or routine mode.

To check the geometry of the probe, proceed as follows:

1 In the dialog **System**, in the area **Initialization**, click **Probe**.

→ A confirmation dialog is displayed.

2 Click **Yes**.

→ The system initializes the probe.

3 Wait until the information dialog **Initialization of probe completed** is displayed.

4 Click **Ok**.

→ The dialog **System** is displayed.

5 In the area **Hardware check**, click **Probe**.

→ In the dialog **Hardware check - probe**, a progress bar is displayed. The system finishes current operations. This can take several minutes.

6 Wait until a confirmation dialog is displayed.

7 Click **Yes**.

→ The geometry of the probe is checked. The probe moves in a predefined track along the inside of the dispensing area. An information dialog is displayed saying that the checking is complete.

An information dialog is displayed saying that the checking has been canceled.

If the probe is bent, it will touch the inside of the dispensing area. The system will display an information dialog accordingly.

- Click **Ok**.
- Replace the probe assembly, see (➔ Page 250 *Replacing the probe assembly*).

8 Click **Ok**.

→ The dialog **System** is displayed

→ Checking the geometry of the probe is completed.

11.2.6 Replacing the fuses

If the fuses are blown, replace the fuses with the same type, see (➔ Page 304 *Electrical conditions*).

✓ 1 set of replacement fuses is available.

✓ 1 small, blade-type screwdriver is available.

✓ The system is off.

To replace the fuses, proceed as follows:

WARNING

Electric shock due to contact with live parts. Even when the system is shut down, some components, for example, capacitors, can be live as they can still be electrically charged.

Death or serious injury to the user can result.

- Unplug the supply cable from the power supply socket before replacing the fuses.

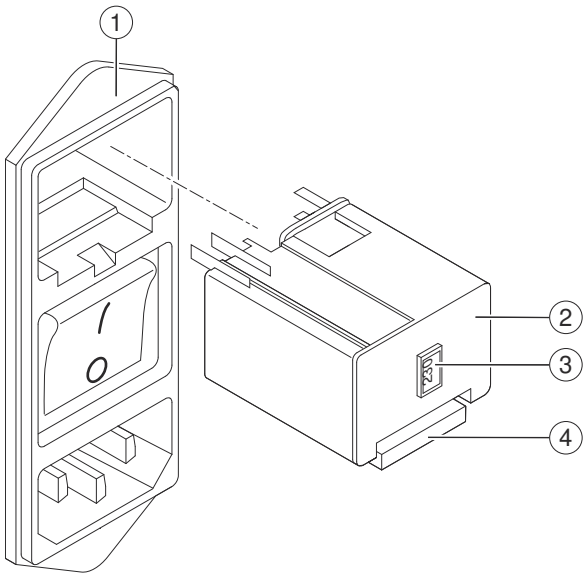
WARNING

When the fuses are blown, the reagent cooler is off. False results can occur due to uncooled reagents and controls.

Death or serious injury to the patient can result.

- If the system is not re-started immediately, remove reagent and control vials, including evaporation caps, from the system and return them to the refrigerator.

1 Pry open the fuse holder by lifting the clip at the bottom using a small, blade-type screwdriver, see the figure below.



Removing the fuse holder

(1) Power module
(2) Fuse holder
(3) Window
(4) Clip

2 Pull the fuse holder out of the power module.

NOTICE

Malfunctions and electrical failure due to inadequate fuses

Damage to the system can result.

- Only use fuses whose electrical rating matches the number displayed in the window of the fuse holder.

3 Check the electrical rating of the replacement fuses.

→ The electrical rating of the replacement fuses matches the number displayed in the window of the fuse holder. For example, the electrical rating of 230 V of the replacement fuses matches **230** in the window.

The electrical rating of the replacement fuses does not match the number displayed in the window of the fuse holder.

- Provide replacement fuses that match the number displayed in the window of the fuse holder, see (➔ Page 304 *Electrical conditions*).

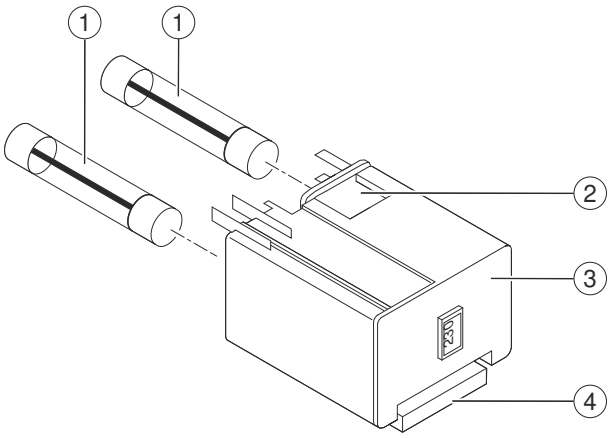
NOTICE

Malfunctions and electrical failure due to incorrectly inserted gray inset

Damage to the system can result.

- Do not remove the gray inset from the fuse holder.

4 Remove the used fuses from the gray inset within the fuse holder, see the figure below.



Removing the fuses

(1) Fuses
(2) Gray inset
(3) Fuse holder
(4) Clip

5 Insert replacement fuses with the appropriate electrical rating into the gray inset.

6 With the clip facing downward, push the fuse holder into the power module until a clicking sound is heard.

→ The fuse holder is inserted correctly.

7 At the right side of the system, plug the supply cable in the power supply socket.

8 Start the system, see (➔ Page 145 *Starting the system*).

→ Replacing the fuses is completed.

11.2.7 Replacing the probe assembly

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

✓ Disposable, absorbent cloth is available.

✓ 70 % ethanol or 70 % isopropyl alcohol is available.

✓ 1 new probe assembly is available.

✓ The system is in standby or routine mode.

To replace the probe assembly, perform the following tasks:

WARNING

Infection due to contaminated material and injury to hands due to sharp edges

Death or serious injury to the user can result.

- Only trained users are allowed to replace the probe assembly.
- Be especially careful of the sharp probe tip and other sharp edges.
- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle parts of the system that have come into contact with potentially infectious material in accordance with good laboratory practices.

1 Clean the dispensing area, see (➔ Page 251 *Clean dispensing area*).

2 Shut down the system, see (➔ Page 252 *Shut down system*).

3 Re-start the system, see (➔ Page 253 *Re-start system*).

4 Prepare the de-installation of the used probe assembly, see (➔ Page 254 *Prepare de-installation of used probe assembly*).

5 De-install the used probe assembly, see (➔ Page 255 *De-install used probe assembly*).

6 Install the new probe assembly, see (➔ Page 259 *Install new probe assembly*).

7 Shut down the system, see (➔ Page 265 *Shut down system*).

8 Re-start the system, see (➔ Page 265 *Re-start system*).

→ Replacing the probe assembly is completed.

Clean dispensing area

To clean the dispensing area, proceed as follows:

> ***NOTICE***
>
> Crystals in the dispensing area can cause the failure of the automatic adjustment of the probe
>
> **Damage to the system can result.**
>
> ◆ Thoroughly follow the instructions given below.

1 In the dialog **System**, in the area **Maintenance**, click **Clean probe**.

→ In the dialog **Clean probe**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 66 *Clean probe*).

2 Wait until a message is displayed.

3 Click the action button **Park probe for cleaning**.

→ The probe moves to the parking position.

4 Wait until another message is displayed.

→ The probe is in the parking position.

5 Open the right cover.

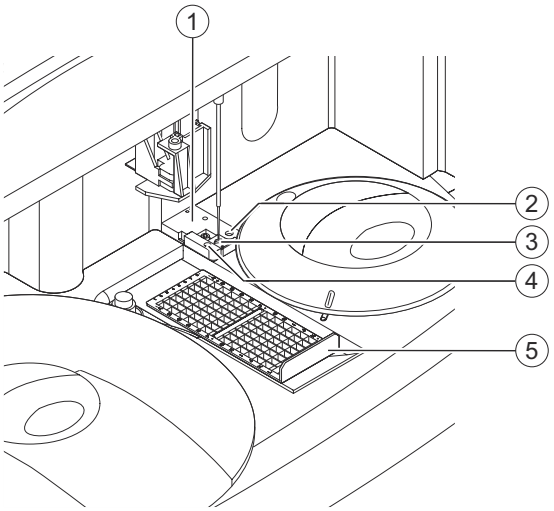
WARNING

Contamination of the buffer reservoir can cause dilution of the buffer used for measurement. Buffer can become unusable. False results can occur.

Death or serious injury to the patient can result.

- Do not contaminate the buffer reservoir during cleaning.

6 Wipe the surface of the wet station with a soft, lint-free cloth moistened with the specified alcohol, see the figure below.



Cleaning the wet station

(1) Wet station
(2) Fountain area
(3) Dispensing area
(4) Buffer reservoir
(5) Dilution frame

7 Remove the dilution frame.

8 Wipe the dispensing area, including the inside, with a soft, lint-free cloth moistened with the specified alcohol.

9 Close the right cover.

→ The action button **Close** becomes active.

10 Click the action button **Close**.

→ An information dialog is displayed.

11 Click **Ok**.

12 Shut down the system, see (➔ Page 252 *Shut down system*).

→ Cleaning the dispensing area is completed.

Shut down system

To shut down the system, proceed as follows:

1 In the dialog **Status**, click the action button **Exit**.

→ A confirmation dialog is displayed.

2 Click **Yes**.

→ The system is rinsed with water. The system is shut down. The viewer software closes.

3 Wait until the 3 LEDs in the upper right corner at the front of the system are off.

WARNING

When the system shuts down, the reagent cooler is switched off. False results can occur due to uncooled reagents and controls.

Death or serious injury to the patient can result.

- If the system is shut down for more than 2 hours, remove reagent and control vials, including evaporation caps, from the system and return them to the refrigerator.

4 At the right side of the system, set the main switch to position **O**.

→ The system is off.

5 Pull the level sensor of the waste container 1–2 cm out of the waste container.

6 Unscrew the cap from the waste container. The level sensor remains in the cap.

7 Dispose of the liquid waste according to national and local standards and regulations.

8 Screw the cap back on to the waste container.

9 Push the level sensor back into the waste container.

10 Place the 2 pegs on the level sensor in the notches on the cap.

11 Re-start the system, see (→ Page 253 *Re-start system*).

→ Shutting down the system is completed.

Re-start system

To re-start the system, proceed as follows:

NOTICE

If the system is re-started too soon after a shutdown, failure of electrical parts of the system can result.

Damage to the system can result.

- Wait at least 10 sbefore re-starting the system after a shutdown.

1 Make sure that the reagent rotor and cuvette rotor covers are inserted correctly and that the covers are closed correctly.

2 Check that the filling level of the system liquids is sufficient.

→ The filling level of the system liquids is sufficient.

The filling level of at least 1 system liquid is low.

- Replace the affected system liquids, see (→ Page 147 *Replacing system liquids*).

3 Check that each level sensor is inserted properly in the corresponding container.

Make sure that the level sensor is inserted at an angle into the corresponding container. The free end of the level sensor inside the container must point away from the opening in the container so that the floater at the end of the level sensor can move up and down freely.

The tubing bears differently colored markings, see (➔ Page 47 *Liquid containers, level sensors, and tubing*).

4 At the right side of the system, set the main switch to position **I**.

→ The system starts.

5 Wait until the 3 LEDs in the upper right corner at the front of the system are on.

6 At the bottom left of the desktop screen, click > **All Programs > ANEPH630 > ANEPH 630 ISP**.

→ The instrument support program starts. The dialog **Log on** is displayed.

7 Enter user name and password.

8 Click **Login**.

→ The dialog **Instrument Support Program** is displayed. An information dialog is displayed.

9 Click **Ok**.

10 Prepare the de-installation of the used probe assembly, see (➔ Page 254 *Prepare de-installation of used probe assembly*).

→ Re-starting the system is completed.

Prepare de-installation of used probe assembly

To prepare the de-installation of the used probe assembly, proceed as follows:

1 At the bottom of the instrument support program, in the area **BASIC**, click **Probe exchange**.

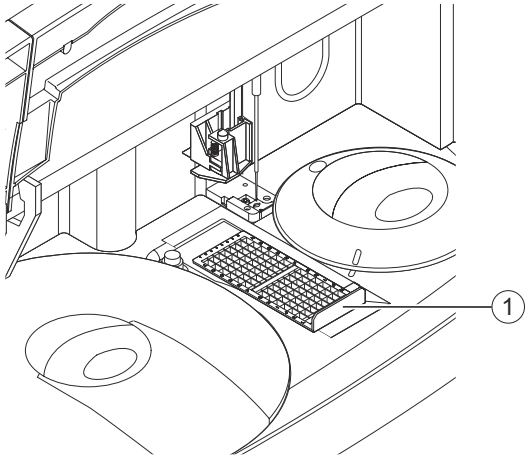
→ The dialog **Probe Exchange** is displayed.

2 On the left, click **Exchange probe**.

→ An information dialog is displayed. The probe moves to the wash station.

3 Open the right cover.

4 Remove the dilution frame, see the figure below.



Removing the dilution frame

(1) Dilution frame

5 Close the right cover.

6 Click **Ok**.

→ Another information dialog is displayed. The probe moves to the parking position.

Do not select **OK** again until the new probe assembly is installed.

---

7 De-install the used probe assembly, see (➔ Page 255 *De-install used probe assembly*).

→ Preparing the de-installation of the used probe assembly is completed.

De-install used probe assembly

To de-install the used probe assembly, proceed as follows:

WARNING

During the time the instrument support program is running, protective guards can be switched off and the probe can start moving even though the covers are open. Infection due to contaminated material can occur. Injury to hands due to sharp edges can occur.

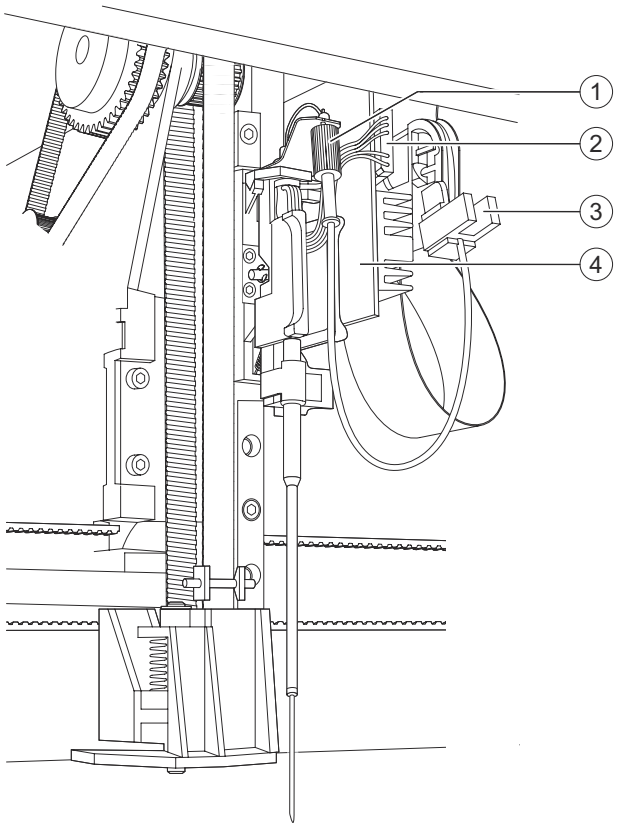
Death or serious injury to the user can result.

- Be especially careful of the sharp probe tip and other sharp edges.
- Secure the probe tip of the used and the new probe assembly while handling probe assemblies. A protective sleeve is delivered with the new probe assembly.

1 Open the right cover.

2 Place a disposable, absorbent cloth beneath the used probe assembly so that spilled liquid will be absorbed.

3 Loosen the knurled nut, see the figure below.



Disconnecting the used probe assembly

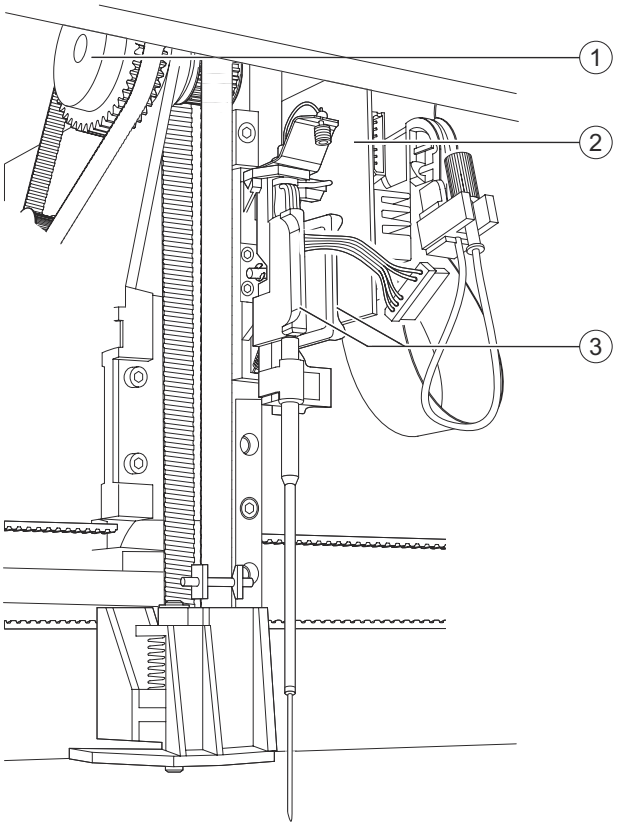
(1) Knurled nut
(2) Electrical connector
(3) Bracket
(4) Printed circuit board

4 Position the knurled nut in the bracket with the opening pointing upward.

5 Wipe the probe with an absorbent cloth to remove liquid from the tip of the probe.

6 Carefully pull the electrical connector out of the socket on the printed circuit board.

7 With 1 hand, hold the gearwheel left of the probe assembly, see the figure below.



Loosening the used probe assembly

(1) Gearwheel
(2) Printed circuit board
(3) Holder

8 With the other hand, grasp the holder on both sides of the probe.

NOTICE

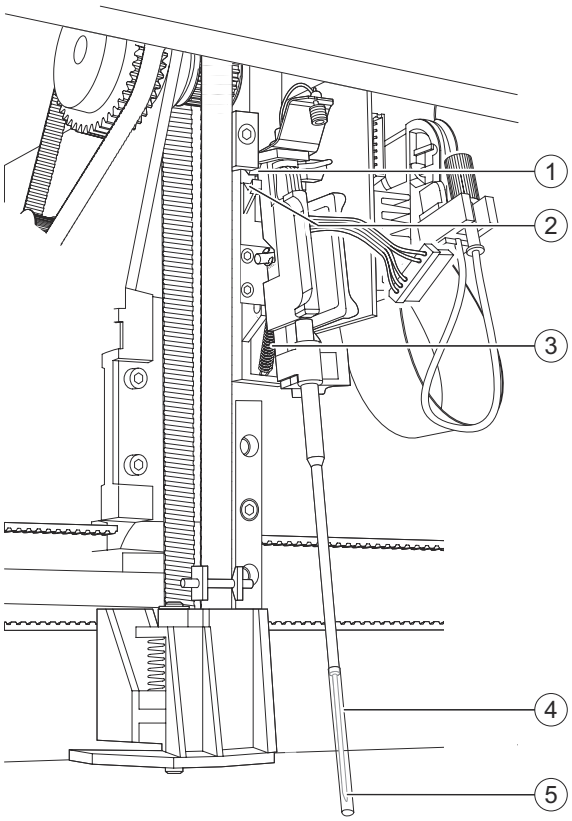
System failure due to damaged printed circuit board

Damage to the system can result.

- Take special care not to scratch the printed circuit board with any part of the used probe assembly during de-installation.

9 Hold the gearwheel steady and carefully pull the used probe assembly a little toward you.

10 Secure the probe tip of the used probe assembly with the protective sleeve.



Securing the probe tip

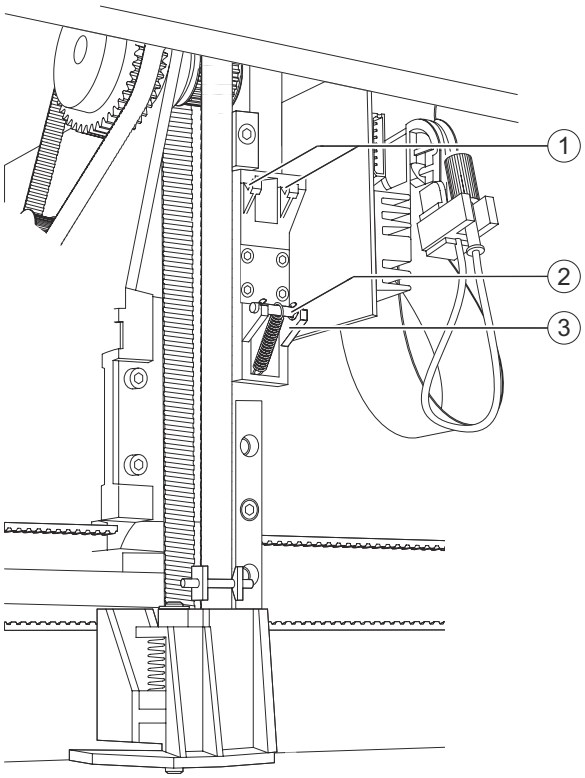
(1) Wedge
(2) Notch
(3) Spring
(4) Protective sleeve
(5) Probe tip

11 Carefully push the used probe assembly upward, against the force of the spring.

→ The wedges come free of the notches.

12 Carefully pull the used probe assembly forward and tilt it slightly, if required.

13 Still holding the used probe assembly, place the bolt on the bolt tray, see the figure below.



Placing the bolt on the bolt tray

(1) Notches
(2) Bolt
(3) Bolt tray

14 Carefully remove the used probe assembly from the system.

15 Remove the protective sleeve from the used probe assembly and set it aside for further use.

16 Dispose of the used probe assembly according to national and local standards and regulations.

17 Install the new probe assembly, see (➔ Page 259 *Install new probe assembly*).

→ De-installing the used probe assembly is completed.

Install new probe assembly

To install the new probe assembly proceed as follows:

WARNING

During the time the instrument support program is running, protective guards can be switched off and the probe can start moving even though the covers are open. Infection due to contaminated material can occur. Injury to hands due to sharp edges can occur.

Death or serious injury to the user can result.

- Be especially careful of the sharp probe tip and other sharp edges.
- Secure the probe tip of the used and the new probe assembly while handling probe assemblies. A protective sleeve is delivered with the new probe assembly.

NOTICE

System failure due to damaged probe assembly

Damage to the system can result.

- Grasp the new probe assembly only at the holder on both sides of the probe.

1 Secure the probe tip of the new probe assembly with the protective sleeve.

2 With 1 hand, hold the gearwheel steady throughout the installation of the new probe assembly.

3 With the other hand, grasp the new probe assembly at the holder on both sides of the probe, see the figure below.

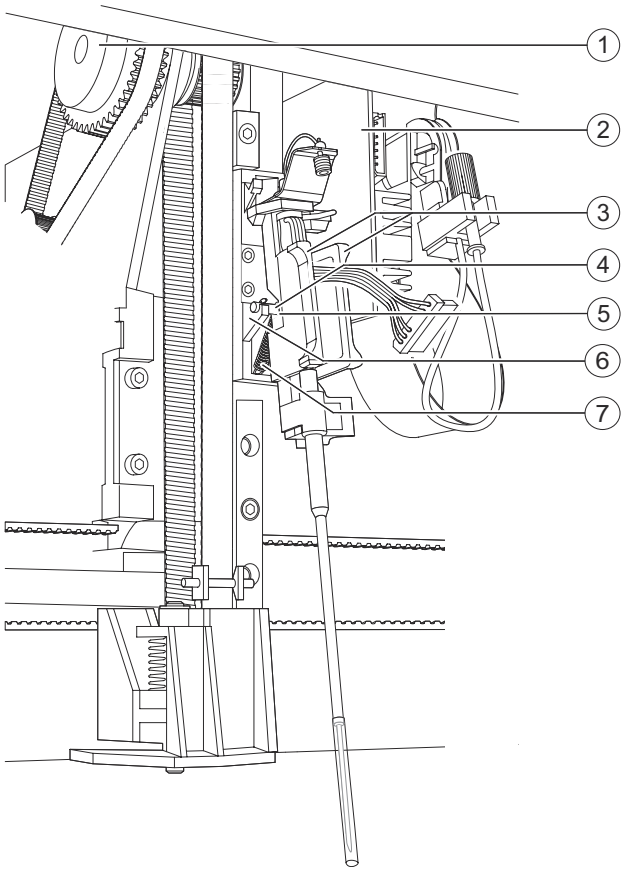
NOTICE

System failure due to damaged printed circuit board

Damage to the system can result.

- Take special care not to scratch the printed circuit board with any part of the used probe assembly during installation.

4 Hold the new probe assembly vertically and tilt it slightly, if required, to avoid collision with the wet station, see the figure below.



Picking up the bolt from the bolt tray

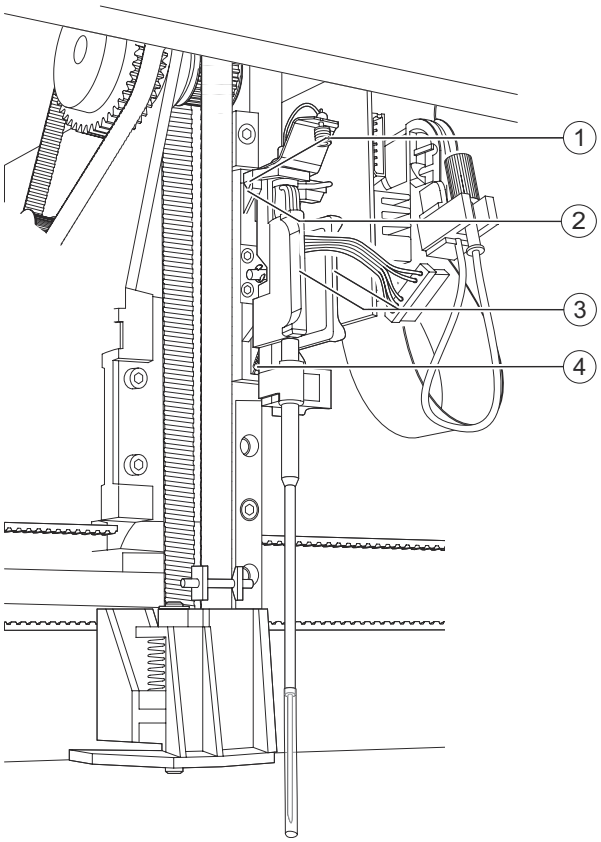
(1) Gearwheel
(2) Printed circuit board
(3) Holder
(4) Bolt
(5) Recess
(6) Bolt tray
(7) Spring

5 Pick up the bolt from the bolt tray using the recess at the back of the holder.

→ The spring attached to the bolt is extended.

6 Carefully push the new probe assembly upward, against the force of the spring.

7 Carefully place the wedges at the back of the new probe assembly in the notches, see the figure below.



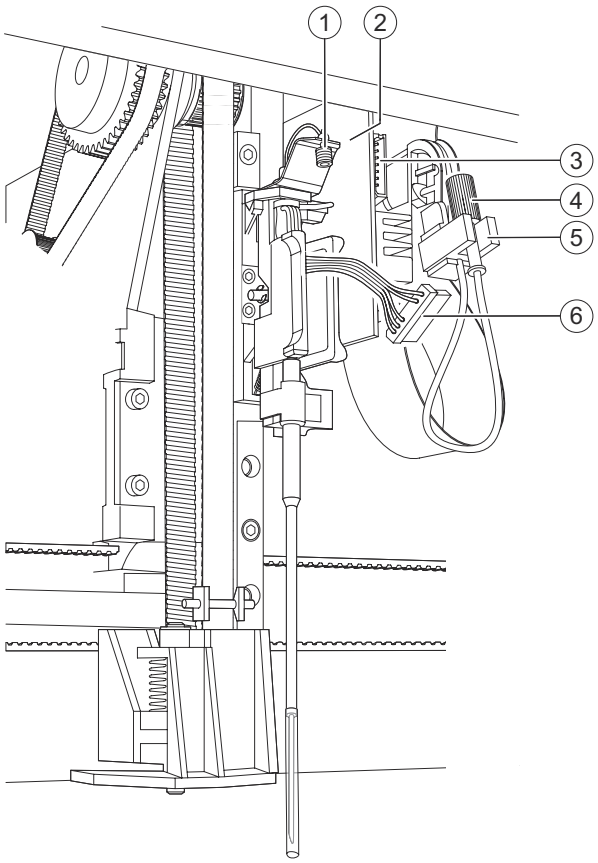
Mounting the new probe assembly

(1) Wedge
(2) Notch
(3) Holder
(4) Spring

8 Slowly let go of the holder.

→ The spring brings the new probe assembly into the correct position.

9 Carefully plug the electrical connector into the socket on the printed circuit board, see the figure below.



Connecting the new probe assembly

(1) Threaded connector
(2) Printed circuit board
(3) Socket
(4) Knurled nut
(5) Bracket
(6) Electrical connector

The electrical connector is shaped in such a way that it is not possible to plug it into the socket the wrong way. If the electrical connector cannot be plugged into the socket, turn it 180° and try again.

Ensure that the cable routing of the electrical connector is correct. First the cable runs down, then it turns up 180°. The cable must run behind the knurled nut.

10 Remove the knurled nut from the bracket.

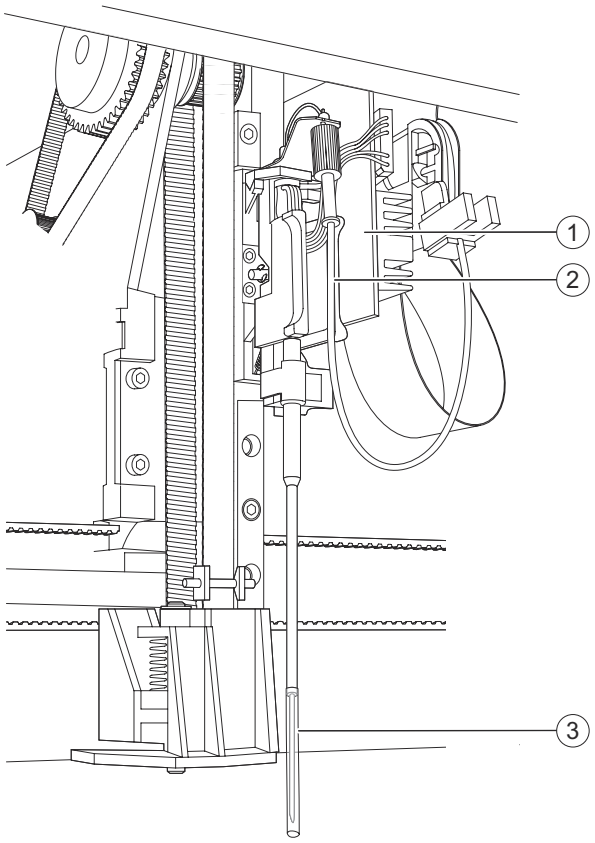
WARNING

If the knurled nut is incorrectly screwed to the threaded connector, liquids can leak from the tubing. False results can occur. Spilled liquids can come into contact with live parts. System failure due to short-circuit can occur.

Death or serious injury to the patient can result. Damage to the system can result

- Screw the knurled nut hand-tight to the threaded connector.

11 If the tubing of the probe is stuck, for example, on the edge of the printed circuit board, carefully free it, see the figure below.



Freeing the tubing

(1) Printed circuit board
(2) Tubing
(3) Protective sleeve

12 Remove the disposable, absorbent cloth beneath the new probe assembly.

13 Carefully remove the protective sleeve from the new probe assembly.

14 Close the right cover.

15 In the information dialog, click **OK**.

→ The dialog **Probe Exchange** is displayed. Adjustment of the probe starts automatically. Different checks are carried out successively. At the right of the dialog, check boxes are checked off successively. This can take up to 20 minutes.

16 Wait until all check boxes are checked off.

→ On the right, the button **Close** becomes active.

Not all check boxes are checked off and an information dialog is displayed.

◆ Contact Siemens Healthineers service immediately.

---

17 On the right, click **Close**.

→ A confirmation dialog is displayed.

18 Click **Yes**.

→ The dialog **Instrument Support Program** is displayed.

19 On the left, click **Exit**.

→ A confirmation dialog is displayed.

20 Click **Ok**.

→ An information dialog is displayed.

21 Click **Ok**.

→ The instrument support program is closed. The desktop screen is displayed.

22 Shut down the system, see (➔ Page 265 *Shut down system*).

→ Installing the new probe assembly is completed.

Shut down system

To shut down the system, proceed as follows:

1 At the right side of the system, set the main switch to position **O**.

→ The system is off.

2 Open the right cover.

3 Replace the dilution frame.

4 Close the right cover.

5 Re-start the system, see (➔ Page 265 *Re-start system*).

→ Shutting down the system is completed.

Re-start system

To re-start the system, proceed as follows:

NOTICE

If the system is re-started too soon after a shutdown, failure of electrical parts of the system can result.

Damage to the system can result.

◆ Wait at least 10 sbefore re-starting the system after a shutdown.

1 Make sure that the reagent rotor and cuvette rotor covers are inserted correctly and that the covers are closed correctly.

2 Check that the filling level of the system liquids is sufficient.

→ The filling level of the system liquids is sufficient.

The filling level of at least 1 system liquid is low.

◆ Replace the affected system liquids, see (➔ Page 147 *Replacing system liquids*).

3 Check that each level sensor is inserted properly in the corresponding container.

Make sure that the level sensor is inserted at an angle into the corresponding container. The free end of the level sensor inside the container must point away from the opening in the container so that the floater at the end of the level sensor can move up and down freely.

The tubing bears differently colored markings, see (➔ Page 47 *Liquid containers, level sensors, and tubing*).

4 At the right side of the system, set the main switch to position **I**.

→ The system starts.

5 Wait until the 3 LEDs in the upper right corner at the front of the system are on.

6 Start the viewer software, see (➔ Page 299 *Starting viewer software*).

→ Re-starting the system is completed.

11.2.8 Troubleshooting the syringe

✓ Soft, lint-free cloth is available.

✓ The system is in standby or routine mode.

To troubleshoot the syringe, for example, if there is liquid in the straining ring, proceed as follows:

1 In the dialog **System**, in the area **Maintenance**, click **Replace syringe**.

→ In the dialog **Replace syringe**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 112 *Replace syringe*).

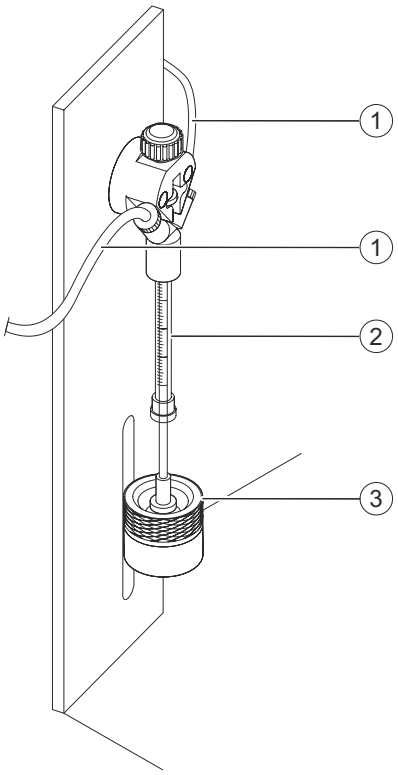
2 Wait until a confirmation dialog is displayed.

3 Click **Yes**.

4 Wait until a message is displayed.

5 Open the left cover.

6 If there is liquid in the straining ring, dry the straining ring with a soft, lint-free cloth, see the figure below.



Troubleshooting the syringe

(1) Tubing
(2) Syringe
(3) Straining ring

7 Re-tighten the tubing on both sides of the syringe.

8 Rinse the system with diluent only, see (➔ Page 199 *Rinsing the system*).

→ No liquid is in the straining ring

There is liquid in the straining ring.

◆ Replace the syringe, see (➔ Page 221 *Replacing the syringe*).

→ Troubleshooting the syringe is completed.

11.3 Software troubleshooting

This chapter lists possible software problems that could occur during system operation together with probable causes and corrective measures. If the recommended measures do not solve the problem, contact Siemens Healthineers service.

11.3.1 Message window

This chapter describes software problems displayed in the **Message window**.

Position without barcode detected on sample rotor

Probable cause:

- A sample that was identified manually has been removed. Another sample is loaded in the same position and the barcode cannot be read. The **Message window** displays that a position without barcode has been detected and that the previous assignment will be used.

Corrective measure:

1 In the **Message window**, click **OK**.

→ The previous assignment is applied to the affected position.

2 Remove the previous assignment of the sample ID from the affected position of the sample rotor segment, see (➔ Page 186 *Removing previous assignments of sample IDs*).

3 In the navigation bar, click **Loading**.

→ The dialog **Loading samples** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 95 *Loading samples*).

4 Click the action button **Access**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

5 Wait until a message is displayed.

6 Open the left cover.

→ Another message is displayed.

7 Holding the sample rotor segment at its grip and with the sample tubes facing towards the outer edge, place the sample rotor segment over an empty position of the sample rotor.

8 Take care that the sample rotor segment slides easily in the guide rails below the handwheel.

9 Carefully push down the sample rotor segment next to the handwheel.

10 Close the left cover.

→ The action button **Close** is displayed.

11 Click the action button **Close**.

→ The dialog **System** is displayed.

12 Identify the sample manually, see (➔ Page 172 *Identifying a sample or standard with unreadable barcode*).

→ The sample is identified.

The problem is not solved.

◆ Contact Siemens Healthineers service.

→ Troubleshooting is completed.

Position without barcode detected on reagent rotor

Probable cause:

- A reagent or control that was identified manually is empty. Another reagent or control is loaded in the same position and the barcode cannot be read. The **Message window** displays that a position without barcode has been detected and that the previous assignment will be used.

Corrective measure:

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

---

1 In the **Message window**, click **OK**.

→ The previous assignment is applied to the affected position.

2 In the dialog **Loading**, click the action button **Reagents**.

→ In the dialog **Loading reagents**, the table view is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 89 *Loading reagents*).

3 Click the action button **Graphic**.

→ In the dialog **Loading reagents**, the graphic overview is displayed.

4 In the diagram of the reagent rotor, click the affected reagent rotor segment.

→ A diagram of the reagent rotor segment is displayed on the right. The action button **Access** becomes active.

5 Click the action button **Access**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. The system moves the affected reagent rotor segment to the position below the access lid of the reagent rotor cover. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

6 Wait until a message is displayed.

7 Open the right cover.

→ Another message is displayed.

8 Open the access lid of the reagent rotor cover.

9 Remove the affected reagent rotor segment.

10 Close the access lid of the reagent rotor cover.

11 Close the right cover.

→ The action button **Close** is displayed.

12 Click the action button **Close**.

→ In the dialog **Loading reagents**, the table view is displayed. The previous assignment to the reagent rotor segment is deleted.

13 Click the action button **Graphic**.

→ In the dialog **Loading reagents**, the graphic overview is displayed.

14 In the diagram of the reagent rotor, click the affected reagent rotor segment.

→ The action button **Access** becomes active.

15 Click the action button **Access**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. The system moves the affected reagent rotor segment to the position below the access lid of the reagent rotor cover. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

16 Wait until a message is displayed.

17 Open the right cover.

→ Another message is displayed.

18 Open the access lid of the reagent rotor cover.

19 Replace the affected reagent rotor segment.

20 Close the access lid of the reagent rotor cover.

21 Close the right cover.

→ The action button **Close** is displayed.

22 Click the action button **Close**.

→ The dialog **Loading reagents** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor.

23 In the list **Reagent status**, select **To be identified**.

→ In the table, the reagent or control that needs to be identified is displayed.

24 Click the action button **Identify**.

→ In the dialog **Loading reagents**, a list of reagents and controls and a graphic of a reagent rotor segment is displayed. The position of the unidentified reagent or control is marked with a **?**. For more information on the dialog, click the action button **Help** or see (➔ Page 93 *Loading reagents, identify reagents and controls*).

25 In the graphic, click the position that is marked with a **?**.

26 In the input field **Lot reference**, enter the identifier number and the lot number of the reagent or control.

27 Left of the graphic, select if the material is a reagent or a control.

28 Click the action button **Save**.

→ The dialog **Loading reagents** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor. The reagent or control is identified.



The problem is not solved.

◆ Contact Siemens Healthineers service.

→ Troubleshooting is completed.

11.3.2 Status bar

This chapter describes software problems related to the buttons in the status bar.

Status button Samples & Standards is yellow or red

Check first:

- In the dialog **Loading samples**, in the schematic overview of the sample rotor segment, at least 1 position is marked with a **?**.

Probable cause:

- A sample tube carries a static charge. The level of the affected sample cannot be measured.

Corrective measure:

1 In the dialog **Loading samples**, in the schematic overview of the sample rotor segment, click the position of the affected sample tube, see (➔ Page 95 *Loading samples*).

→ The selected position is framed by blue lines. The action button **Level detection** becomes active. For more information on the dialog, click the action button **Help**.

2 Click the action button **Level detection**.

→ The probe detects the level in the sample tube. The affected position is no longer marked with a **?**. The static charge has dissipated. Troubleshooting is completed.

The affected position is still marked with a **?**.

- ◆ Check the level of the sample visually, see (➔ Page 244 *Checking the level of samples visually*).
- ◆ In the dialog **Loading samples**, in the schematic overview of the sample rotor segment, click the position of the affected sample tube.

  The selected position is framed by blue lines. The action button **Level detection** becomes active.
- ◆ Click the action button **Level detection**.

  The probe detects the level in the sample tube. The affected position is no longer marked with a **?**.

The affected position is still marked with a **?**.

- ◆ Contact Siemens Healthineers service.

→ Troubleshooting is completed.

Status button Ref. curves & Contr. results remains yellow

Probable cause:

- An invalid control result is present. Deleting the invalid control result is not sufficient to solve the problem. The status button remains yellow until a valid result has been measured with the control lot.

Corrective measure:

1 In the dialog **Lab journal**, delete the invalid control result, see (➔ Page 84 *Lab journal*). For more information on the dialog, click the action button **Help**.

2 Close the viewer software, see (➔ Page 300 *Closing viewer software*).

3 Re-start the viewer software, see (➔ Page 299 *Starting viewer software*).

→ The status button **Ref. curves & Contr. results** is blue.

4 Re-measure the control, see (➔ Page 161 *Measuring a control*).

The problem is not solved.

◆ Contact Siemens Healthineers service.

→ Troubleshooting is completed.

Status button Information is red directly after starting viewer software

Probable cause:

• A problem occurred during the start of the system.

Corrective measure:

1 Place the mouse pointer over the status button **Information**.

→ A tool tip text that specifies the problem is displayed.

2 Register the displayed tool tip text that specifies the problem.

3 Click the status button **Information**.

→ The dialog where the problem can be solved is displayed.

The dialog **Logbook** is displayed.

For more information on the dialog, see (➔ Page 101 *Logbook*) or click the action button **Help**.

◆ Click the most recent entry that corresponds to the tool tip text.
◆ Follow the instructions on how to solve the problem.
◆ If the problem is not solved, in the dialog **System**, on the bottom right, click **Reset analyzer**.
◆ In the confirmation dialog, click **Ok**.

During reset, the mouse pointer is changed.

◆ Wait until the mouse pointer has changed back to an arrow.
◆ If the problem is not solved, contact Siemens Healthineers service.

4 In the dialog, solve the problem that was specified in the tool tip text.

→ The status button **Information** is blue.

The status button **Information** is still red.

◆ In the dialog **System**, on the bottom right, click **Reset analyzer**.
◆ In the confirmation dialog, click **Ok**.

During reset, the mouse pointer is changed.

◆ Wait until the mouse pointer has changed back to an arrow.
◆ If the problem is not solved, contact Siemens Healthineers service.

→ Troubleshooting is completed.

Status button Information is red

There are multiple probable causes for the problem.

1 Decide which of the following causes would be the most probable and follow the appropriate link.
   - A cover is not properly closed, see (➔ Page 273 *Cover not properly closed*).
   - Right cover was open too long, see (➔ Page 273 *Right cover open too long*).
   - The heating of the probe has stopped, see (➔ Page 274 *Heating of probe has stopped*).
   - The cooling of the reagent rotor has stopped, see (➔ Page 275 *Cooling of reagent rotor has stopped*).
   - A level sensor is not inserted properly, see (➔ Page 276 *Level sensor not inserted properly*).
   - The water filter is blocked, see (➔ Page 276 *Water filter blocked*).
   - The probe is blocked, see (➔ Page 277 *Probe blocked*).
2 If the problem is not solved, follow the link to the next probable cause until the problem is solved.
3 If the problem is not solved with the linked procedures, contact Siemens Healthineers service.

→ Troubleshooting is completed.

Cover not properly closed

Check first:

- In the dialog **Status**, in the area **Information**, the button **Covers** is red.

Probable cause:

- When 1 cover was opened, the other cover was slightly opened with it unintentionally. After closing 1 cover, the other cover stays slightly open.

Corrective measure:

◆ Make sure that both covers are completely closed.

→ The system is operating. The status button **Information** is blue.

→ Troubleshooting is completed.

Right cover open too long

Check first:

- In the dialog **Status**, in the area **Information**, the button **Covers** is red. The tool tip text displays **The right cover is open**. The system does not resume working although the right cover is properly closed.

Probable cause:

- The right cover was open for more than 30 minutes.

Corrective measure:

1 In the dialog **System**, on the bottom right, click **Reset analyzer**.

→ A confirmation dialog is displayed.

2 Click **Ok**.

→ The mouse pointer changes. The system is reset. This can take several minutes.

3 Wait until the mouse pointer has changed back to an arrow.

→ The system is operating. The status button **Information** is blue.

→ Troubleshooting is completed.

Heating of probe has stopped

Check first:

- In the dialog **Status**, in the area **Information**, the button **Temperatures** is red.

Probable cause:

- The heating of the probe has stopped. The temperature of the probe is too low.

Corrective measure:

WARNING

Infection due to contaminated material and injury to hands due to sharp edges.

Death or serious injury to the user can result.

- Be especially careful of the sharp probe tip and other sharp edges.
- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle parts of the system that have come into contact with potentially infectious material in accordance with good laboratory practices.

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

1 In the dialog **System**, in the area **Maintenance**, click **Clean probe**.

→ In the dialog **Clean probe**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 66 *Clean probe*).

2 Wait until a message is displayed.

3 Click the action button **Park probe for cleaning**.

→ The probe moves to the parking position.

4 Wait until another message is displayed.

→ The probe is in the parking position.

5 Open the right cover.

6 Carefully touch the probe in the upper half.

→ The probe is warm to the touch.

The probe is cold to the touch.

- Close the right cover.
- Click the action button **Close**.
- In the information dialog displayed then, click **Ok**.
- Replace the probe assembly, see (➔ Page 250 *Replacing the probe assembly*).

---

7 Close the right cover.

→ The action button **Close** is displayed.

8 Click the action button **Close**.

→ An information dialog is displayed.

9 Click **Ok**.

→ The dialog **System** is displayed. The status button **Information** is blue.

→ Troubleshooting is completed.

Cooling of reagent rotor has stopped

Check first:

- In the dialog **Status**, in the area **Information**, the button **Temperatures** is red.

Probable cause:

- The reagent cooler has stopped working because the opening time of the access lid of the reagent rotor cover has exceeded 10 minutes. The temperature in the reagent rotor is too high.

Corrective measure:

No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the system's operation is interrupted, and existing pre-dilutions may be rejected by the system. Delay of results can occur.

- Always request access through the right cover via the software.
- If the right cover was opened without access being requested, immediately close the right cover.

---

1 In the dialog **System**, in the area **Maintenance**, click **Reagents**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

2 Wait until a message is displayed.

3 Open the right cover.

4 Check that the access lid of the reagent rotor cover is closed correctly.

5 Close the right cover.

→ The action button **Close** is displayed.

6 Click the action button **Close**.

→ An information dialog is displayed.

7 Click **Ok**.

→ The dialog **System** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor. The reagent cooler starts working. The status button **Information** stays red for some time.

8 If the button **Temperatures** is still red after 45 minutes, contact Siemens Healthineers service.

If the ambient temperature is above 25 °C, the system can take longer to cool down the reagent rotor.

→ Troubleshooting is completed.

Level sensor not inserted properly

Check first:

- In the dialog **Status**, in the area **Information**, the button **System liquids** is red although the filling levels of the system liquids are not too low.

Probable cause:

- The level sensors are not inserted properly into the corresponding containers.

Corrective measure:

1 Remove the level sensors 1 after another from the containers.

2 Check that the floater at the end of each level sensor can move up and down freely.

3 Insert each level sensor into the corresponding container.

→ The system is operating. The status button **Information** is blue.

Make sure that the level sensor is inserted at an angle into the corresponding container. The free end of the level sensor inside the container must point away from the opening in the container so that the floater at the end of the level sensor can move up and down freely.

The tubing bears differently colored markings, see (➔ Page 47 *Liquid containers, level sensors, and tubing*).

→ Troubleshooting is completed.

Water filter blocked

Check first:

- In the dialog **Status**, in the area **Information**, the button **System liquids** is red although the filling levels of the system liquids are not too low and the level sensors are inserted properly into the corresponding containers.

Probable cause:

- The water filter is blocked.

Corrective measure:

◆ Replace the water filter, see (➔ Page 217 *Replacing the water filter*).

→ The system is operating. The status button **Information** is blue.

→ Troubleshooting is completed.

Probe blocked

Check first:

- In the dialog **Status**, in the area **Information**, the button **System liquids** is red although the filling levels of the system liquids are not too low and the level sensors are inserted properly into the corresponding containers. The water filter has been replaced recently.

Probable cause:

- The probe is blocked, for example, by a clot that has been aspirated.

Corrective measure:

◆ Check the functioning of the probe, see (➔ Page 205 *Checking the functioning of the probe*).

→ The system is operating. The status button **Information** is blue.

→ Troubleshooting is completed.

Status button Information is yellow

Check first:

- In the dialog **Status**, in the area **Information**, the button **Temperatures** is yellow.

Probable cause:

- The system had been idle for more than 20 minutes and changed to standby mode. The heating of the cuvette rotor was turned off. The system automatically changes back to routine mode when new jobs are requested. The heating is then switched on again, and the status button **Information** turns blue after a maximum of 5 minutes. Then the requested jobs are processed.

◆ A corrective measure is not required.

→ Troubleshooting is completed.

Status button Information is frequently yellow

Check first:

- In the dialog **Status**, in the area **Information**, the button **System liquids** is frequently yellow although the filling levels of the system liquids are not too low and the level sensors are inserted properly into the corresponding containers.

Probable cause:

- The conductivity of the water is too low. The system cannot always detect the correct filling level in the wet station. Error numbers 3046 and 3053 are displayed frequently.



The water used must meet the water specifications, see (➔ Page 305 *Water specifications*).

Corrective measure:

◆ Replace the water, see (➔ Page 147 *Replacing system liquids*).

→ The status button **Information** is blue.

→ Troubleshooting is completed.

11.3.3 Dialog Status

This chapter describes software problems related to the dialog **Status**.

Dialog Status displays incorrect numbers

Probable cause:

- Updating of the dialog **Status** can take up to 10 minutes.

Corrective measure:

◆ Wait a few minutes until the dialog has been updated.

→ Correct numbers are displayed.

→ Troubleshooting is completed.

11.3.4 Dialog Lab journal

This chapter describes software problems related to the dialog **Lab journal**.

Lab journal empty

Probable cause:

- The entries in the lab journal are filtered.

Corrective measure:

◆ Reset the 3 filters above the table. For more information on the dialog **Lab journal**, see (➔ Page 84 *Lab journal*) or click the action button **Help**.

→ Lab journal data is displayed.

→ Troubleshooting is completed.

Lab journal data not updated

Probable cause:

- If the entries in the lab journal are filtered, data is not updated automatically.

Corrective measure:

1 In the navigation bar, click any other routine button.

2 In the navigation bar, click **Lab journal**.

→ Lab journal data is updated.

→ Troubleshooting is completed.

Unknown character string as sample ID

Probable cause:

- A sample tube without a label was loaded. Through the sample tube, the barcode reader scans parts of the barcode strip attached to the sample rotor segment, see (➔ Page 41 *Sample rotor segments*).

  The system interprets the fragmentary barcode as a character string, for example, **mpty** or **xty**. The correct sample ID cannot be identified manually.

Corrective measure:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

2 Wait until a message is displayed.

3 Open the left cover.

→ Another message is displayed.

4 Remove the affected sample tube.

5 Attach a blank label to the sample tube.

6 Re-load the sample tube.

7 Close the left cover.

→ The action button **Close** is displayed.

8 Click the action button **Close**.

→ The dialog **System** is displayed.

9 Identify the sample manually, see (➔ Page 172 *Identifying a sample or standard with unreadable barcode*).

→ The correct sample ID is displayed in the lab journal.

The problem is not solved.

- Contact Siemens Healthineers service.

→ Troubleshooting is completed.

Jobs not displayed when job list is imported from LIS

There are multiple probable causes for the problem.

1 Decide which of the following causes would be the most probable and follow the appropriate link.

- The lab journal was not updated, see (➔ Page 280 *Lab journal not updated*).
- The job list was not sent by the LIS, see (➔ Page 280 *Job list not sent by LIS*).

2 If the problem is not solved, follow the link to the next probable cause until the problem is solved.

3 If the problem is not solved with the linked procedures, contact Siemens Healthineers service.

→ Troubleshooting is completed.

Lab journal not updated

Probable cause:

- When the job list is imported from the LIS, the lab journal is not updated automatically.

Corrective measure:

1 In the navigation bar, click any other routine button.

2 In the navigation bar, click **Lab journal**.

→ Lab journal data is updated.

→ Troubleshooting is completed.

Job list not sent by LIS

Probable cause:

- The LIS has not sent the job list.

Corrective measure:

1 In the dialog **Lab journal**, in the table, select all sample IDs without requested jobs.

→ The action button **Add request** becomes active.

2 Click the action button **Add request**.

→ The dialog **Add request** is displayed. For more information on the dialog, click the action button **Help** or see (→ Page 61 *Add request*).

3 Click the action button **Host job list**.

→ The job list is requested from the LIS for the samples selected.

4 In the navigation bar, click any other routine button.

5 In the navigation bar, click **Lab journal**.

→ Lab journal data is updated. Requested jobs are displayed.

No requested jobs are displayed.

◆ Repeat the complete procedure.

Requested jobs are not sent simultaneously by the LIS but little by little.

→ Troubleshooting is completed.

Jobs not processed after reference curve has been re-measured

Probable cause:

- If the reference curve for an assay is re-measured with a different lot while jobs are requested for this assay, these jobs are not evaluated. The new reference curve is not used.

Corrective measure:

1 Delete the affected jobs in the lab journal.

2 Request the affected assays again, see (➔ Page 173 *Requesting a job for a sample manually*).

→ The jobs are processed.

→ Troubleshooting is completed.

Results marked with a technical flag

Probable cause:

- If a hardware problem has occurred or if a resource was low during processing of a sample, the measurement cannot be processed. The result is flagged  .

  If a hardware problem has occurred or if a resource was low during processing of a control, the measurement cannot be processed. The result is flagged  .

Probable hardware problems are:

- The right cover was opened during measurement.
- The cuvette rotor cover opened unintentionally during measurement.
- The temperature in the reagent rotor was too high during measurement.
- The temperature in the cuvette rotor was too low during measurement.

Corrective measure:

1 In the dialog **Logbook**, click the most recent entry that corresponds to the probable hardware problems listed above, see (➔ Page 101 *Logbook*). For more information on the dialog, click the action button **Help**.

2 Follow the instructions on how to solve the problem.

3 Request the affected assays again, see (➔ Page 173 *Requesting a job for a sample manually*).

→ The jobs are processed.

→ Troubleshooting is completed.

Results of a cup-in-tube sample marked with a Y flag

Probable cause:

- The system could not detect the level in the cup of a cup-in-tube segment when aspirating the sample. The results are flagged **Y**.

Corrective measure:

1 Check whether there was a sufficient amount of sample material in the cup.

2 If required, refill the cup with a sufficient amount of sample material, approximately 100–350 µL and request the affected assays again.

→ The jobs are processed.

3 If the results are still marked with a **Y** flag, check if the results are outside the measurement range.

→ If the results are not outside the measurement range, the results can be released.

The results are outside the measurement range.

◆ Go to the next step.

4 Check if the remaining sample volume is still sufficient.

5 If required, refill the cup with a sufficient amount of sample material, approximately 100–350 µL.

No more sample is available.

◆ The result is doubtful.

6 Request the affected assays again from a new dilution.

→ The jobs are processed. Results are no longer flagged with a **Y** flag.

→ Troubleshooting is completed.

Requested job for a control not processed

There are multiple probable causes for the problem.

1 Decide which of the following causes would be the most probable and follow the appropriate link.

- A reference value is missing, see (➔ Page 282 *Missing reference value*).
- Cyclic control measurements are defined, see (➔ Page 283 *Cyclic control measurements defined*).

2 If the problem is not solved, follow the link to the next probable cause until the problem is solved.

3 If the problem is not solved with the linked procedures, contact Siemens Healthineers service.

→ Troubleshooting is completed.

Missing reference value

Probable cause:

- If a requested job for a control is not processed even though a reference curve for the affected assay is available, the reference value for the assay is missing.

Corrective measure:

1 In the dialog **System**, click the action button **Definitions**.

→ In the dialog **Definitions**, the tab **Profiles** is displayed.

2 Click the tab **Control lots**.

→ The tab **Control lots** is displayed. For more information on the tab, click the action button **Help** or see (➔ Page 80 *Control lots*).

3 Select the control and the lot ID for which the reference value is to be entered.

→ The corresponding table row is highlighted dark blue. The action button **Lot ID** becomes active.

4 Enter the reference values for the corresponding assays. Reference values for controls provided by Siemens Healthineers can be found in the instructions for use of the corresponding controls.

Reference values can only be entered in white table cells.

5 Click outside of the table cells.

→ The action button **Save** becomes active.

6 Click the action button **Save**.

→ The changes are saved. The dialog **System** is displayed.

7 Request the affected assays again, see (➔ Page 173 *Requesting a job for a sample manually*).

→ The jobs are processed.

→ Troubleshooting is completed.

Cyclic control measurements defined

Probable cause:

- Cyclic control measurements are defined. As long as there are cyclic control measurements to be carried out, no manually requested control measurements will be processed, see (➔ Page 128 *Configuring cyclic control measurements*).

Corrective measure:

1 Delete the request for cyclic control measurements in the lab journal, see (➔ Page 129 *Deactivating cyclic control measurements for an assay*).

2 Request the affected assays again, see (➔ Page 173 *Requesting a job for a sample manually*).

→ The jobs are processed.

→ Troubleshooting is completed.

Assay not displayed for control measurement

Probable cause:

- No valid reference curve is available for the assay.

Corrective measure:

1 Measure the reference curve for the assay, see (➔ Page 182 *Measuring the reference curve for an assay*).

2 In the dialog **Lab journal**, measure the control again, see (➔ Page 161 *Measuring a control*).

→ Troubleshooting is completed.

All results of dilution series deleted

Probable cause:

- A measurement was repeated from the same dilution series but at a higher dilution. When the result of this re-measurement is deleted, all results of the same dilution series are deleted.

Corrective measure:

◆ Repeat the measurement at an appropriate dilution, see (➔ Page 173 *Requesting a job for a sample manually*).

→ The result is displayed in the lab journal.

→ Troubleshooting is completed.

11.3.5 Dialog Loading

This chapter describes software problems related to the dialog **Loading**.

Sample barcode cannot be scanned

There are multiple probable causes for the problem.

1 Decide which of the following causes would be the most probable and follow the appropriate link.

- The sample barcode is not visible, see (➔ Page 284 *Sample barcode not visible*).
- The barcode label is damaged, see (➔ Page 285 *Barcode label damaged*).
- The quiet zone on the barcode label is too small, see (➔ Page 285 *Quiet zone on the barcode label too small*).
- The barcode label is incorrectly placed, see (➔ Page 286 *Barcode label incorrectly placed*).
- The barcode type used is not specified, see (➔ Page 286 *Barcode type used not specified*).
- The left cover was closed too early, see (➔ Page 286 *Left cover closed too early*).
- The barcode reader is incorrectly adjusted, see (➔ Page 286 *Barcode reader incorrectly adjusted*).

2 If the problem is not solved, follow the link to the next probable cause until the problem is solved.

3 If the problem is not solved with the linked procedures, contact Siemens Healthineers service.

→ Troubleshooting is completed.

Sample barcode not visible

Probable cause:

- The barcodes of sample tubes must be aligned towards the outer edge of the sample rotor segment. If this is not the case, the barcode reader cannot scan the barcode.

Corrective measure:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

2 Wait until a message is displayed.

3 Open the left cover.

→ Another message is displayed.

4 Make sure that the barcodes of all sample tubes are aligned towards the outer edge of the sample rotor segment.

5 Close the left cover.

→ The action button **Close** is displayed.

6 Click the action button **Close**.

→ The dialog **System** is displayed. The barcode reader scans the barcodes in the sample rotor. The system adds the sample IDs to the lab journal.

→ Troubleshooting is completed.

Barcode label damaged

Probable cause:

- The barcode label is damaged or the barcode is scratched. The barcode reader cannot scan the barcode.

Corrective measure:

- Identify the sample manually, see (➔ Page 172 *Identifying a sample or standard with unreadable barcode*).

→ Troubleshooting is completed.

Quiet zone on the barcode label too small

Probable cause:

- The quiet zone on the barcode label is too small. The barcode reader cannot scan the barcode, see (➔ Page 309 *Sample and user-defined control barcodes*).

Corrective measure:

- Identify the sample manually, see (➔ Page 172 *Identifying a sample or standard with unreadable barcode*).

→ The system adds the sample ID to the lab journal.

→ Troubleshooting is completed.

Barcode label incorrectly placed

Probable cause:

- The barcode reader can only scan a specified area of the sample tube. If the barcode label is incorrectly placed or if the barcode is tilted, the barcode reader cannot scan the barcode.

Corrective measure:

◆ Place the barcode according to the specifications, see (➔ Page 309 *Sample and user-defined control barcodes*).

→ The barcode reader scans the barcodes in the sample rotor. The system adds the sample ID to the lab journal.

The sample ID is not added to the lab journal.

◆ Identify the sample manually, see (➔ Page 172 *Identifying a sample or standard with unreadable barcode*).

→ Troubleshooting is completed.

Barcode type used not specified

Probable cause:

- The barcode reader can only interpret specified barcode types. If the barcode type used is not specified, the barcode reader cannot scan the barcode, see (➔ Page 309 *Sample and user-defined control barcodes*).

Corrective measure:

1 Identify the sample manually, see (➔ Page 172 *Identifying a sample or standard with unreadable barcode*).

→ The system adds the sample ID to the lab journal.

2 In the future, use only specified barcode types.

→ Troubleshooting is completed.

Left cover closed too early

Probable cause:

- If the left cover is open for less than 6 seconds, the barcode reader does not scan the sample barcodes.

Corrective measure:

1 Open the left cover.

2 Wait at least 6 seconds.

3 Close the left cover.

→ The barcode reader scans the barcodes in the sample rotor. The system adds the sample IDs to the lab journal.

→ Troubleshooting is completed.

Barcode reader incorrectly adjusted

Probable cause:

- The barcode reader can only scan a specified area of the sample tube. If the barcode reader is incorrectly adjusted, the barcode reader cannot scan the barcode.

Corrective measure:

- Contact Siemens Healthineers service.

→ Troubleshooting is completed.

Reagent or control barcode cannot be scanned

There are multiple probable causes for the problem.

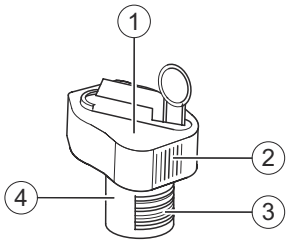
1 Decide which of the following causes would be the most probable and follow the appropriate link.
   - The barcode is not visible, see (➔ Page 287 *Barcode not visible*).
   - The barcode label is damaged, see (➔ Page 288 *Barcode label damaged*).
2 If the problem is not solved, follow the link to the next probable cause.
3 If the problem is not solved with the linked procedures, contact Siemens Healthineers service.

→ Troubleshooting is completed.

Barcode not visible

Probable cause:

- The barcode reader scans reagent and control barcodes through an opening in the reagent rotor segment. To ensure that the barcode is visible through the opening, the vertical striation on the evaporation cap and the barcode on the label of the vial must be aligned, see the figure below. If this is not the case, the barcode reader cannot scan the barcode.



Placing evaporation caps

(1) Evaporation cap
(2) Vertical striation
(3) Barcode
(4) Reagent or control vial

Corrective measure:

1 In the dialog **System**, in the area **Access**, click **Reagents**.

   → In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).
2 Wait until a message is displayed.
3 Open the left and right covers.

   → Another message is displayed.

4 Remove the reagent rotor cover.

5 Remove the reagent or control vial from the reagent rotor segment.

Do not tilt reagent and control vials with evaporation caps on. Evaporation caps do not prevent liquid from spilling.

6 Align the vertical striation on the evaporation cap and the barcode on the label of the vial.

7 Load the reagent or control vial correctly in the reagent rotor segment.

8 Replace the reagent rotor cover.

9 Close the left and right covers.

→ The action button **Close** is displayed.

10 Click the action button **Close**.

→ The dialog **System** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor. Reagents and controls are available.

→ Troubleshooting is completed.

Barcode label damaged

Probable cause:

- The barcode label is damaged or the barcode is scratched. The barcode reader cannot scan the barcode.

Corrective measure:

1 In the dialog **Loading**, click the action button **Reagents**.

→ In the dialog **Loading reagents**, the table view is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 89 *Loading reagents*).

2 In the list **Reagent status**, select **To be identified**.

→ In the table, the reagents and controls that need to be identified are displayed.

3 Click an entry in the table.

→ The segment number and position are displayed in the table.

4 Click the action button **Identify**.

→ In the dialog **Loading reagents**, a list of reagents and controls and a graphic of a reagent rotor segment is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 93 *Loading reagents, identify reagents and controls*).

5 In the graphic, click the position that is marked with a **?**.

6 In the input field **Lot number**, enter the identifier number and the lot number of the reagent or control.

7 Left of the graphic, select if the material is a reagent or a control.

8 Click the action button **Save**.

→ The dialog **Loading reagents** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor. The reagent or control is identified.

→ Troubleshooting is completed.

Reagent or control in the reagent rotor not used

Probable cause:

- During preparing of the reagent or control, the evaporation cap was placed incorrectly on the reagent or control vial or the reagent or control vial was loaded incorrectly in the reagent rotor segment. Therefore, the probe collided with the evaporation cap or with the reagent or control vial. The system cannot detect the level of the reagent or control. The assay is flagged in the lab journal.

Corrective measure:

1 In the dialog **System**, in the area **Access**, click **Reagents**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

2 Wait until a message is displayed.

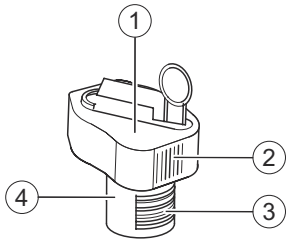
3 Open the left and right covers.

→ Another message is displayed.

4 Remove the reagent rotor cover.

5 Remove the reagent or control vial from the reagent rotor segment.

6 Place the evaporation cap correctly on the reagent or control vial.



Placing evaporation caps

(1) Evaporation cap
(2) Vertical striation
(3) Barcode
(4) Vial

Do not tilt reagent and control vials with evaporation caps on. Evaporation caps do not prevent liquid from spilling.

The vertical striation on the evaporation cap and the barcode on the label of the vial must be aligned, see the figure above.

7 Load the reagent or control vial correctly in the reagent rotor segment.

8 Replace the reagent rotor cover.

9 Close the left and right covers.

→ The action button **Close** is displayed.

10 Click the action button **Close**.

→ The dialog **System** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor. The reagent or control can be used.

→ Troubleshooting is completed.

Segment ID of sample rotor segment not displayed in the dialog Loading samples

Each type of sample rotor segment is identified by a colored plain text label with a number located on the grip of the sample rotor segment. This number corresponds to the barcode label located at the left side of the sample rotor segment, see (➔ Page 41 *Sample rotor segments*).

✓ 1 new plain text label corresponding to the sample rotor segment is available.

✓ 1 new barcode label corresponding to the plain text label is available.

Probable cause:

- The barcode label at the left side of the sample rotor segment is damaged or the barcode is scratched. The barcode reader cannot scan the barcode.

Corrective measure:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

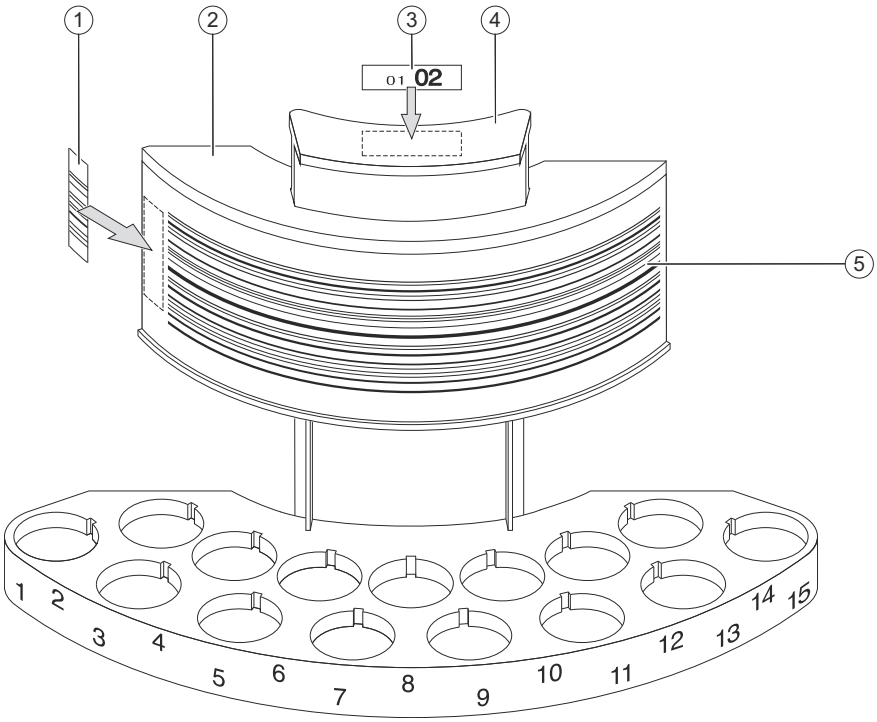
2 Wait until a message is displayed.

3 Open the left cover.

→ Another message is displayed.

4 Remove the sample rotor segment.

5 Remove the current plain text label and barcode label from the sample rotor segment, see the figure below.



Replacing the barcode of a sample rotor segment (example)

(1) Barcode label
(2) Sample rotor segment
(3) Plain text label
(4) Grip
(5) Barcode strip

WARNING

If the plain text label and the barcode label do not match and if samples are manually identified, samples can be interchanged in the dialog **Loading samples**. Results will be assigned to the wrong patient.

Death or serious injury to the patient can result.

- The plain text label and the corresponding barcode label are delivered on barcode sheets in pairs. Always attach both labels as a pair.

6 Attach the plain text label to the grip of the sample rotor segment.

7 Attach the corresponding barcode label vertically at the level of the barcode strip to the left side of the sample rotor segment, next to the left edge.

8 Replace the sample rotor segment.

9 Close the left cover.

→ The action button **Close** is displayed.

10 Click the action button **Close**.

→ The dialog **System** is displayed.

→ Troubleshooting is completed.

Segment ID of sample rotor segment not displayed in the dialog Pre-loading

Probable cause:

- Non-barcoded samples were pre-identified and loaded using the dialog **Pre-loading**. In the dialog, only segment IDs of sample rotor segments that are not on-board are displayed and can be selected.

Corrective measure:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 In the dialog **Pre-loading**, select the segment ID of a suitable sample rotor segment that is not on-board.

– or –

If this is not possible, click the action button **Access**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

2 Wait until a message is displayed.

3 Open the left cover.

→ Another message is displayed.

4 Remove the sample rotor segment.

5 Close the left cover.

→ The action button **Close** is displayed.

6 Click the action button **Close**.

→ The dialog **Loading samples** is displayed. The segment ID of the sample rotor segment is displayed.

→ Troubleshooting is completed.

Segment ID of reagent segment not displayed in the dialog Loading reagents

Probable cause:

- When reagent vials are loaded in both positions of a reagent segment, the barcode reader scans both reagent barcodes. If neither reagent barcode can be scanned, for example, because they are damaged, the system assumes that no vials are loaded. As the barcode labels attached to the back of every position of the reagent segment cannot be scanned through the reagent vials, the system assumes that no reagent segment is loaded in this position. Therefore, the reagent segment is not displayed in the dialog **Loading reagents**.

Corrective measure:

1 In the dialog **System**, in the area **Access**, click **Reagents**.

→ In the dialog **Access reagents**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access reagents*).

2 Wait until a message is displayed.

3 Open the left and right covers.

→ Another message is displayed.

4 Remove the reagent rotor cover.

5 Remove 1 reagent vial from the affected reagent segment.

6 Load the reagent vial in another reagent segment.

7 Load a reagent vial with a readable barcode in the affected reagent segment.

8 Replace the reagent rotor cover.

9 Close the left and right covers.

→ The action button **Close** is displayed.

10 Click the action button **Close**.

→ The dialog **System** is displayed. The barcode reader scans the barcodes of the vials in the reagent rotor. The segment ID of the reagent segment is displayed.

→ Troubleshooting is completed.

11.3.6 Dialog Calibration

This chapter describes software problems related to the dialog **Calibration**.

Valid reference curve cannot be displayed

Probable cause:

- For some assays, negative bit values are possible and valid at the lowest dilution step. Negative bit values cannot be displayed in the double-logarithmic representation of the reference curve. The assay or reagent is flagged as valid but cannot be displayed or printed. The affected reference curve is only used for evaluation.

Corrective measure:

- No corrective measure is possible.

11.3.7 Dialog System

This chapter describes software problems related to the dialog **System**.

Unknown character string in raw data

Probable cause:

- If a technical problem or a problem with a reagent occurred during measurement, a specific character string, for example, **1E+30** is displayed in the raw data. In the lab journal, **–** is displayed instead of a result.

Corrective measure:

1 In the dialog **Lab journal**, in the table, select the respective row.

→ The action button **Repeat** becomes active.

2 Click the action button **Repeat**.

→ The dialog **Repeat** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 111 *Repeat*).

3 Make the settings as required.

4 Click the action button **Save**.

→ The dialog **Lab journal** is displayed. The result is displayed in the table.

– is still displayed in the table instead of a result.

◆ Contact Siemens Healthineers service.

→ Troubleshooting is completed.

Logbook entry not displayed completely

Probable cause:

- The logbook entry is longer than the available space in the column of the logbook table.

Corrective measure:

1 In the dialog **Logbook**, select the logbook entry.

2 Click the action button **Print**.

→ The logbook entry is printed and can be read completely.

→ Troubleshooting is completed.

Logbook entry displays a level outside limits

Probable cause:

- The level in a part of the system was detected incorrectly due to impurities, froth, or lamellae.

Corrective measure:

1 In the dialog **Logbook**, read the entries immediately following.

2 If the following entries mention **samples**, check the samples visually, see (➔ Page 244 *Checking the level of samples visually*).

– or –

If the following entries mention **reagents or controls**, check the level of the reagents and controls, see (➔ Page 245 *Checking the level of reagents or controls*).

– or –

If the following entries mention **cuvettes or dilution cups**, replace the affected cuvette segments or dilution strips, see (➔ Page 148 *Loading cuvette segments and dilution strips*).

– or –

If the following entries mention the **buffer**, clean the wet station. Afterwards clean the level sensor of the buffer container, see (➔ Page 208 *Cleaning the wet station*) and (➔ Page 219 *Clean level sensors of buffer, diluent, and water containers*).

– or –

If the following entries mention **wash station or wet station**, clean the wet station. Afterwards replace the water filter, see (➔ Page 208 *Cleaning the wet station*) and (➔ Page 217 *Replacing the water filter*).

→ Troubleshooting is completed.

Immersion depth for cup-in-tube segment cannot be defined

Probable cause:

- The immersion depth for a cup-in-tube segment cannot be defined while the affected cup-in-tube segment is on-board.

Corrective measure:

WARNING

Infection due to infectious samples.

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Handle samples in accordance with good laboratory practices.

1 In the dialog **System**, in the area **Access**, click **Samples**.

→ In the dialog **Access samples**, a progress bar is displayed. The system finishes current operations. This can take several minutes. For more information on the dialog, click the action button **Help** or see (➔ Page 61 *Access samples*).

2 Wait until a message is displayed.

3 Open the left cover.

→ Another message is displayed.

4 Remove the cup-in-tube segment.

5 Define the immersion depth, see (➔ Page 138 *Configuring the immersion depth for cups used with a cup-in-tube segment*).

6 Replace the cup-in-tube segment.

7 Close the left cover.

→ The action button **Close** is displayed.

8 Click the action button **Close**.

→ The dialog **System** is displayed. The immersion depth is defined.

→ Troubleshooting is completed.

Progress bar of purging of tubing stops at 0:00

Avoid purging of the tubing after 10:00 PM.

Probable cause:

- If purging of the tubing is started before midnight, the progress bar stops at **0:00** and the remaining time is no longer visible. No message is displayed in the dialog **Purge tubings**. The purging of the tubing cannot be continued automatically.

Corrective measure:

1 Shut down the system, see (➔ Page 200 *Shutting down the system*).

2 Wait at least 10 seconds.

3 Start the system, see (➔ Page 145 *Starting the system*).

4 Purge the tubing, see (➔ Page 215 *Purging the tubing*).

→ Troubleshooting is completed.

11.3.8 General software problems

This chapter describes general software problems not related to a specific area or dialog.

Password cannot be entered when starting system

Probable cause:

- A technical problem may have occurred.

Corrective measure:

1 Shut down the computer.

2 Wait at least 5 seconds.

3 Re-start the computer.

→ The password can be entered.

The password cannot be entered.

◆ Contact Siemens Healthineers service.

→ Troubleshooting is completed.

System does not respond

Probable cause:

- A technical problem may have occurred.

Corrective measure:

WARNING

When the system shuts down, the reagent cooler is switched off. False results can occur due to uncooled reagents and controls.

Death or serious injury to the patient can result.

◆ If the system is not re-started immediately, remove reagent and control vials, including evaporation caps, from the system and return them to the refrigerator.

1 In the dialog **Status**, click the action button **Exit**.

→ A confirmation dialog is displayed.

2 Click **Yes**.

→ The system is rinsed with water. The system is shut down. The viewer software closes.

3 Wait until all LEDs are off.

4 At the right side of the system, set the main switch to position **O**.

→ The system is off.

NOTICE

Failure of electrical parts of the system can result if the system is re-started too soon after a shutdown.

Damage to the system can result.

◆ Wait at least 10 seconds before restarting the system after a shutdown.

5 At the right side of the system, set the main switch to position **I**.

→ The system starts.

6 Wait until the 3 LEDs in the upper right corner at the front of the system are on.

7 Start the viewer software, see (➔ Page 299 *Starting viewer software*).

→ The system is operating.

The system does not respond.

◆ Contact Siemens Healthineers service.

→ Troubleshooting is completed.

System does not continue working after standby mode

Probable cause:

- The ambient temperature has fallen significantly.

Corrective measure:

1 In the dialog **System**, on the bottom right, click **Reset analyzer**.

→ A confirmation dialog is displayed.

2 Click **Ok**.

→ The system is reset. The mouse pointer changes. In the status line, **Resetting analyzer** is displayed. This can take several minutes.

3 Wait until the mouse pointer has changed back.

→ The system is operating.

→ Troubleshooting is completed.

Viewer software does not respond

Probable cause:

- If the viewer software does not respond to the click of buttons, the viewer software may have crashed.

Corrective measure:

1 On the keyboard, press **Ctrl + Alt + Del**.

→ An operating system screen is displayed.

2 Click **Start Task Manager**.

→ The dialog **Windows Task Manager** is displayed.

3 Click the tab **Applications**.

→ All programs that are currently running are displayed.

4 In the list, select **Siemens ANEPH 630 - <dialog>**.

5 At the bottom, click **End Task**.

6 Close the dialog **Windows Task Manager**.

7 Close all open programs.

8 In the desktop screen, click **Atellica NEPH 630 Viewer**.

→ The viewer software starts.

The viewer software does not start.

- Switch off the computer.
- Wait at least 10 seconds.
- Switch on the computer.
- In the dialog for the log on to the operating system, enter user name and password.
- Click **Ok**.
- In the desktop screen, click **Atellica NEPH 630 Viewer**.
- If the viewer software does not start, contact Siemens Healthineers service.

---

9 Enter user name and password, if required.

10 Click **Ok**, if required.

11 Wait until the dialog **Status** is displayed.

→ The viewer software is running.

→ Troubleshooting is completed.

Incorrect context in a dialog

There are multiple probable causes for the problem.

1 Decide which of the following causes would be the most probable and follow the appropriate link.
   - Dialogs are not updated automatically, see (➔ Page 299 *No automatic update of dialogs*).
   - Dialogs were changed too fast, see (➔ Page 299 *Dialogs changed too fast*).

2 If the problem is not solved, follow the link to the next probable cause until the problem is solved.

3 If the problem is not solved with the linked procedures, contact Siemens Healthineers service.

→ Troubleshooting is completed.

No automatic update of dialogs

Probable cause:

- The system only updates data in a dialog when opening the dialog.

Corrective measure:

1 In the navigation bar, click any other routine button.

2 In the navigation bar, click the routine button for the required dialog.

   → Data in the required dialog is updated.

→ Troubleshooting is completed.

Dialogs changed too fast

Probable cause:

- When the user changes between dialogs too fast, the display may not be updated correctly.

Corrective measure:

1 In the navigation bar, click **Status**.

2 Wait at least 3 seconds.

3 In the navigation bar, click the routine button for the required dialog.

   → Data in the required dialog is updated.

→ Troubleshooting is completed.

Starting viewer software

✓ The system is on.

✓ The computer is on.

To start the viewer software, proceed as follows:

1 In the desktop screen, click **Atellica NEPH 630 Viewer**.

   → The viewer software starts. The dialog **Initialize analyzer** is displayed. This can take up to 10 minutes.

2 Wait until the dialog **Status** is displayed.

→ The system is operating.

The dialog **Log on** is displayed.

- Enter user name and password.
- Click **Ok**.

→ Starting the viewer software is completed.

Closing viewer software

Results measured while the viewer software is closed are stored in the system's memory. Capacity of the system's memory is low. Results can be lost. Do not close the viewer software while jobs are still processing.

✓ The system is in standby or routine mode.

To close the viewer software, proceed as follows:

1 In the dialog **Status**, click the action button **Exit**.

→ A confirmation dialog is displayed.

2 Click **No**.

→ The viewer software closes and the desktop is displayed. The system is still running.

Do not switch off the system in this condition. Results stored in the system's memory will be lost. The system will not be rinsed.

→ Closing the viewer software is completed.

Printing problem during print preview

Probable cause:

- Printer settings may be incorrect.

Corrective measure:

1 On the keyboard, press **Alt + Tab** to bring the dialog **Save As** in front of the screen.

2 If the problem is not solved, contact Siemens Healthineers service.

→ Troubleshooting is completed.

11.4 Entering a logbook entry

To enter a logbook entry, proceed as follows:

1 In the dialog **System**, click the action button **Logbook**.

→ The dialog **Logbook** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 101 *Logbook*).

2 Click the action button **Manual entry**.

→ The dialog **Entry** is displayed.

3 In the text box, enter text.

4 Click **Ok**.

→ The entry is stored in the logbook.

5 To view the entry, set the filter **Gravity** to **(All)**.

→ The entry is displayed in the logbook.

→ Entering a logbook entry is completed.

11.5 Exporting logbook entries

To export logbook entries, proceed as follows:

1 In the dialog **System**, click the action button **Logbook**.

→ The dialog **Logbook** is displayed. For more information on the dialog, click the action button **Help** or see (➔ Page 101 *Logbook*).

2 Above the table, set the filters **Period** and **Gravity** as required.

→ Entries in the logbook are filtered.

3 Click the action button **Export**.

→ Displayed logbook entries are exported to the file **LogBook.asc**.

→ Exporting logbook entries is completed.

12 Technical specifications

This chapter describes the specifications of the system and the environmental conditions.

12.1 Analyzer

Dimensions (W x H x D)	1070 mm x 600 mm x 630 mm (42.1 in x 23.6 in x 24.8 in), closed 1070 mm x 880 mm x 630 mm (42.1 in x 34.7 in x 24.8 in), open
Required space for ventilation	100 mm (4 in) on all sides
Required working space	300 mm (12 in) above
Footprint (W x H x D)	1070 mm x 900 mm x 750 mm (67 in x 36 in x 30 in) for analyzer, computer, and liquid containers
Required space for service (W x H x D) (may overlap with other working spaces)	1 m (39.4 in) on all sides
Weight	115 kg (254 lbs)

Dimensions and weight

Sample types	Serum Plasma Urine CSF
Types of sample tubes, cups, and vials	For more information on sample tubes, see (➔ Page 308 *Sample tubes*). For more information on cups and vials, see (➔ Page 308 *Special cups and vials*).
Capacity	3 segment positions for a maximum of 45 samples
Temperature	Room temperature

Sample rotor

Vial types	2.5 mL 5 mL
Capacity	15 segment positions for a maximum of 30 reagents or 45 controls
Temperature	• If the room temperature is ≤ 28 °C, the temperature in the reagent rotor is 8 °C. • If the room temperature is > 28 °C, the temperature in the reagent rotor is 20 °C lower than the actual room temperature.

Reagent rotor

Capacity	16 dilution strips with 6 dilution cups each for a maximum of 96 pre-dilutions

Dilution station

Rinse volumes per washing cycle (depending on assay)	Inside rinse with system liquids: Approximately 1500–4000 µL Outside rinse with water: Approximately 8 mL

Wet station

Capacity	10 segments with 9 cuvettes each for a maximum of 90 dilutions
Temperature	Approximately 37 °C

Cuvette rotor

Light source	LED
Wavelength	840 nm ± 10 nm
Detector	Hybrid diode (silicon photo diode with integrated pre-amplifier)
Angle of measurement	13°–24°

Optics

Syringe volume	500 µL
Valves	2-way and 3-way valves

Syringe

Light source	For single barcode reader: class 2 laser (according to IEC 60825-1:2007) For overall classification of the system: class 1 laser (according to IEC 61010-1:2001 (second edition)
Wavelength	655 nm

Barcode reader

Assays	Up to 15 different assays at the same time

Performance data

12.1.1 Operating conditions

Operating voltage	100 V rating: 90–110 V, AC 120 V rating: 108–132 V, AC 230 V rating: 207–253 V, AC
Main frequency	50/60 Hz
Fuses	100 V rating: 100/120 V, 5.0 AT, 5 mm x 20 mm 120 V rating: 100/120 V, 5.0 AT, 5 mm x 20 mm 230 V rating: 230 V, 5.0 AT, 5 mm x 20 mm
Power consumption	500 VA
Degree of ingress protection	IP20
Surge voltage protection	Class II
Voltage fluctuations in the supply network	Not higher than ± 10 % of the nominal voltage
Transient overvoltage	As normal in the supply network
Supply cables	Type H 03 VV-F, country-specific, for example, VDE, CSA C22.2 No. 21, CSA C22.2 No. 49 Length: 1.5 m Minimum cross-section: 3 x 0.75 mm^2 Analyzer: Plug according to IEC 60320 C13

Electrical conditions

Altitude	0–2000 m
Ambient temperature	18–32 °C
Ambient humidity	< 85 % (non-condensing)
Sound level	55 dB(A), at operator's position
Pollution degree	2
Angle of installation	± 1° (horizontal)

Distance between liquid containers and table edge	80 cm
Other environmental conditions	Only indoor use No direct light and sunlight

Environmental conditions

Water with a low microbial content, for example, purified water	≤ 100 CFU/mL
Conductivity	> 30 µS/cm
Water consumption	Dependent on the selected job list

Water specifications

12.1.2 Storage conditions

Ambient temperature	5–45 °C
Ambient humidity	< 85 % (non-condensing)

Environmental conditions

12.1.3 I/O ports

1 AC input socket	Power supply
1 Ethernet port	Computer
2 RS-232 ports	LIS, for example

Specifications of I/O ports

12.2 Computer

Operating system	Windows operating system
Weight	Approximately 20 kg (44 lbs), depending on the computer type

Specifications of the computer

12.3 Consumables

This chapter describes the specifications of consumables.

12.3.1 Sample rotor segments

Specifications of sample segments:

- White plain text label
- Numbers 01 or 02 for the first 2 digits on the plain text label
- 15 positions

Specifications of standard segments:

- Orange plain text label
- Number 20 for the first 2 digits on the plain text label
- 6 positions

Specifications of cup-in-tube segments:

- Identical in construction to sample segment
- Gray plain text label
- Number 51 for the first 2 digits on the plain text label
- 15 positions
- For use with all common cups, including Dimension cups from Siemens Healthineers
- Maximum total height of cup and tube: 110 mm

Specifications of cup-behind-tube segments (optional):

- Green plain text label
- Number 81 for the first 2 digits on the plain text label
- 7 positions

Specifications of Eppendorf cup segments (optional):

- Yellow plain text label
- Number 61 for the first 2 digits on the plain text label
- 15 positions

Specifications of Hitachi cup segments (optional):

- Green plain text label
- Number 81 for the first 2 digits on the plain text label
- 15 positions

Specifications of False bottom tube segments (optional):

- Green plain text label
- Number 81 for the first 2 digits on the plain text label
- 15 positions

12.3.2 Reagent rotor segments

Specifications of reagent segments:

- White grip
- Letter R on the barcode labels
- 2 positions for reagent vials

Specifications of control segments:

- Yellow grip
- Letter C on the barcode labels
- 3–positions for control vials

12.3.3 Cuvette segments

Storage conditions (ambient temperature)	2–25 °C
Shelf life	Unlimited

Specifications of cuvette segments

12.3.4 Dilution strips

Storage conditions (ambient temperature)	2–25 °C
Shelf life	Unlimited

Specifications of dilution strips

12.3.5 Evaporation caps

Types of evaporation caps	White evaporation caps for reagent vials with a capacity of 5 mL Yellow evaporation caps for control vials with a capacity of 2.5 mL
Storage conditions (ambient temperature)	2–25 °C
Shelf life	Unlimited

Specifications of evaporation caps

12.4 Sample tubes, cups, and vials

This chapter describes the specifications of sample tubes, cups, and vials to be used with sample rotor segments.

12.4.1 Sample tubes

Sample tubes must have the following dimensions:

- 65–100 mm height
- 11–16 mm outer diameter

Sample tubes must be used with differently colored adapters:

- Sample tubes of 11–13 mm outer diameter must be used with white adapters.
- Sample tubes of 13–16 mm outer diameter must be used with black adapters.

12.4.2 Special cups and vials

The following special cups and vials can be used with the specified sample rotor segments:

- 0.5 mL or 1.0 mL standard vials can be used with a standard segment.
- All common cups, including Dimension cups from Siemens Healthineers, can be used together with empty sample tubes with a cup-in-tube segment. The total height of sample tube and inserted cup must not exceed 110 mm.
- Standard Eppendorf cups, 1.5 mL, with conical shaped bottom, can be used with an Eppendorf cup segment.
- Advia cups, Sample cup 16 mm Ezee-Nest, can be used with a Hitachi cup segment.
- Advia cups, Sample cup 16 mm Ezee-Nest, can be used with a cup-behind-tube segment.
- Hitachi cups, can be used with a Hitachi cup segment.
- Hitachi cups, can be used with a cup-behind-tube segment.
- False bottom tubes, like the Sarstedt Screw cap tube, working volume: 3.5 ml, (LxØ): 92 x 13 mm, rounded base shape can be used with a false bottom tube segment.

12.5 Adapters

Adapters for sample tubes have different colors depending on the outer diameter of the sample tubes

- White adapters must be used for sample tubes of 11–13 mm outer diameter.
- Black adapters must be used for sample tubes of 13–16 mm outer diameter.

Standard segments are fitted with black adapters to hold 0.5 mL or 1 mL standard vials.

Control segments are fitted with black adapters to hold 0.5 mL or 1 mL control vials.

12.6 Barcodes

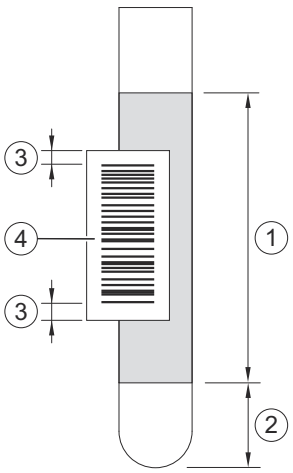
This chapter describes the specifications of barcodes.

12.6.1 Sample and user-defined control barcodes

Barcode types	• Interleaved 2 of 5 • Codabar • Code 39 • Code 93 • Code 128
Required quality of barcodes	According to ISO/IEC 15416:2000 (ANSI X3.182-1990): • Grade 4 (ANSI grade A) • Grade 3 (ANSI grade B) • Grade 2 (ANSI grade C)
Barcode size	Height ≤ 72 mm
Module width (width of the smallest element within the barcode type)	≥ 0.2 mm
Number of digits	4–29
Barcode orientation	Vertically

Specifications of sample and user-defined control barcodes

Barcodes must be attached to sample tubes as displayed in the figure below.



Attaching barcodes to sample tubes

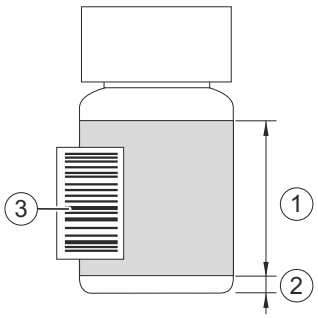
(1) Barcode placement area: 16–98 mm from bottom of sample tube
(2) Distance from bottom of sample tube to barcode placement area: 16 mm
(3) Quiet zones on the barcode label: ≥3 mm of blank area
(4) Barcode label (example)

12.6.2 Reagent barcodes

Barcode types	Interleaved 2 of 5
Required quality of barcodes	According to ISO/IEC 15416:2000 (ANSI X3.182-1990): • Grade 4 (ANSI grade A) • Grade 3 (ANSI grade B) • Grade 2 (ANSI grade C)
Barcode size	Height ≤ 12.9 mm Width ≤ 8 mm
Module width (width of the smallest element within the barcode type)	≥ 0.19 mm
Number of digits	8 Digits 1–6 from the left represent the lot number. The lot number can contain zeros. Digit 7 represents the vial size. Digit 8 is a check digit.
Barcode orientation	Vertically

Specifications of reagent barcodes

Barcodes must be attached to reagent vials as displayed in the figure below.



Attaching barcodes to reagent vials

(1) Barcode placement area: 3–16 mm from bottom of reagent vial
(2) Distance from bottom of reagent vial to barcode placement area: 3 mm
(3) Barcode label (example)

13 Appendix

This chapter describes the principle of operation, the principles of measurement, and the calculation of results.

13.1 Principle of operation

The system provides a quantitative determination of plasma proteins by means of nephelometric analysis of serum, plasma, urine, and CSF, see (➔ Page 322 *Principle of measurement*).

The system can perform precipitation and agglutination reactions (latex).

13.1.1 Handling of samples

The system processes jobs sample-oriented. This means that all requested jobs for a sample are started before the system moves on to process jobs for the next sample.

The barcode reader scans every position of the sample rotor segments every time the left cover has been closed after being open for more than 6 seconds. If a barcode is missing or unreadable, a message window is displayed. The ID of the unidentified sample must be checked and any missing information must be entered in the dialog **New**, see (➔ Page 103 *New*).

Based on the sample barcode and information from the LIS, sample dilution starts. The level in the sample tube is detected. If an assay is to be measured at a specific dilution, the sample is pre-diluted. Further pre-dilutions are prepared from the first pre-dilution in additional dilution cups. If an assay is to be measured undiluted, the sample remains in the sample tube unprocessed.

The usual sequence is as follows:

- The required amount of diluent is aspirated by the syringe and supplied to the probe.
- The required amount of sample is aspirated by the probe.
- Sample and diluent are dispensed into a dilution cup.
- The pre-dilution is mixed by the probe.
- The probe is cleaned inside and outside.

Controls are processed in the same way.

13.1.2 Handling of reagents

The barcode reader scans every position of the reagent rotor segments after system start and every time the reagent rotor cover or the access lid of the reagent rotor cover are closed. If a barcode is missing or unreadable, a message window is displayed. The ID of the unidentified reagent must be checked and any missing information must be entered in the dialog **Loading reagents** via a list of reagents and controls, see (➔ Page 93 *Loading reagents, identify reagents and controls*).

When a reagent lot is identified, the system reads the lot data. The system checks if additional information for the reagent lot is available in the database. If not, the information is requested from a special lot information file which is frequently provided by Siemens Healthineers.

Based on the requested job, reagent processing starts.

If an assay requires only 1 reagent, the sequence can be as follows:

- The required amount of reagent is aspirated by the probe.
- The required amount of sample is aspirated by the probe, either from the sample tube or from the dilution cup.
- Sample and reagent are dispensed into a cuvette in the cuvette rotor.
- Sample and reagent are mixed, the reaction starts.

If an assay requires the addition of a supplementary reagent or buffer, the sequence can be as follows:

- The required amount of supplementary reagent or buffer is aspirated by the probe.
- The required amount of sample is aspirated by the probe, either from the sample tube or from the dilution cup.
- Sample and supplementary reagent or buffer are dispensed into a cuvette in the cuvette rotor.
- The required amount of reagent is aspirated by the probe.
- The reagent is dispensed into the cuvette.
- Sample, supplementary reagent or buffer, and reagent are mixed, the reaction starts.



As the processing sequence of an assay depends on the assay definition provided by Siemens Healthineers, sequences described above are only example sequences.

While the reagent is being transferred, it is heated in the probe to approximately 37 °C so that a constant temperature is maintained in the cuvette directly after pipetting. The temperature is kept constant by the heated cuvette rotor during the entire reaction time.

13.1.3 Handling of standards

Calibrations are performed following the pre-sets in the assay definition using standards. Required dilutions of standards are calculated and performed automatically. The dilutions depend on the standard concentration and the required support points of the curve.



Missing reference curves should be measured for the assays before samples are processed.

The sample rotor turns the standard into the pipetting position. The level of the required standard is checked. Standard is pipetted into the dilution cups. The probe is cleaned after each pipetting.

The dilution cups are brought into the pipetting position. A level detection of each cup is performed. If the cup is empty, the pre-dilution is created and then mixed. The next empty cuvette is turned to the pipetting position.

The standard dilution is pipetted into the cuvette. The reagent rotor turns the required reagent into the pipetting position. The probe pipettes the reagent into the cuvette that contains the standard.

In the case of an assay that is prepared with supplementary reagent or buffer, first supplementary reagent or buffer is aspirated and then the diluted standard is aspirated and dispensed into the cuvette and mixed. Then the next pre-dilution is created, dispensed into a cuvette, and reagent is added.

If you require a different lot for a kit reagent, delete the old reference curve. Request a new reference curve with the required lots of, for example, reagent and supplementary reagent.

13.1.4 Handling of controls

Controls serve to validate sample results and calibration curves. Controls need to be assigned to assays before control measurements can be requested. Control measurements are requested automatically or manually.

The sample or reagent rotor turns the control into the pipetting position. The probe pipettes the control into the dilution cups. The required pre-dilutions are created and mixed. The probe is cleaned after each pipetting. The diluted control is dispensed into the cuvette. Reagent is added and mixed.

In the case of an assay that is prepared with supplementary reagent or buffer, first supplementary reagent or buffer is aspirated and then the diluted control is aspirated and dispensed into the cuvette and mixed.

The system performs accuracy checks and precision controls. If the quality control software is installed, other evaluations of the control results can be performed on the system. For more information, see the documentation of the quality control software.

If the system is connected to an LIS system, the control results can also be sent to the LIS for evaluations of the control results.

13.1.5 Dilutions

The system dilutes standards, samples, and controls.

Sample dilution

Sample dilutions are automatically created with diluent, in multiple dilution steps if required. Sample dilutions are 1 : 5, 1 : 20, 1 : 100, 1 : 400, 1 : 2,000, 1 : 8,000, and 1 : 32,000.

Samples can also be manually pre-diluted 1 : 5 or 1 : 20. This can be required, for example, in the case of pediatric samples with only little serum volumes available. The manual pre-dilution factor must be entered in the software. When processing this sample, the manual pre-dilution for creating the required sample dilution (initial dilution) is taken into account, and the results will not need to be subsequently converted manually. Manually pre-diluted samples are flagged in the job list.

Dilution of standards

The system is able to create a dilution series of the standard serum with a maximum of 15 dilution steps, from 1 : 2.5 up to 1 : 20,480, including 1 : 1. Dilutions are made with diluent. The number of dilution steps depends on the protein to be determined.

A basic dilution is created, from which the required dilutions will be created, each in a new dilution cup. Basic dilutions of 1 : 2.5, 1 : 5, 1 : 10, 1 : 20, 1 : 40, and 1 : 80 can be created. The number of dilutions required for a calibration is specified according to the assay.

Dilution of controls

Controls are diluted in the same way as samples.

13.1.6 Handling of lot data and calibration data

Lot data contains lot numbers and assigned values for Siemens Healthineers standards and controls within shelf life. Lot data is regularly updated by Siemens Healthineers. They can either be downloaded from the Document Library or can be loaded from a CD ROM sent by Siemens Healthineers. Lot data is stored on the hard drive after loading and are retrieved as required. Missing lot data can also be entered manually from the table of assigned values.

The reagent lots are read automatically via the barcode on the reagent vial and stored. Up to 3 lots of a reagent for an assay can be stored. 1 reference curve can be evaluated for each reagent lot of an assay. That means that a maximum of 3 valid reference curves for 3 different reagent lots can be stored for an assay. With the third valid reference curve measured for an assay, the action button **Measure** is deactivated until at least 1 of the stored reference curves has been deleted.

The system stores lot data for only 1 lot of supplementary reagents.

If a valid reference curve for a reagent lot is repeated, the original reference curve is retained in the background. If the newly measured reference curve is also valid, it is automatically used by the system. If the system shall continue to use the original reference curve, the newly measured reference curve has to be deleted.

13.1.7 Calibration

In order to evaluate an immunonephelometric measurement quantitatively, a reference curve is required for each assay. The reference curve is obtained with the help of standards.

Multiple point calibration

Since there is no proportional relationship between the measurement signal and the protein concentration, several measurement points of a standard at different dilutions with a known antigen concentration must be measured. The reference curve is calculated by fitting the theoretical curve to the measured supporting points. The measurement signals of samples with unknown antigen concentrations are compared with those of the standard dilutions, and the relevant concentration is read from the reference curve.

The reference curves measured by multiple point calibration are stored by the system. They remain stored until they are replaced by new reference curves. Depending on the assay definition, a reference curve can be measured with a minimum of 5 and a maximum of 8 dilution steps. A new reference curve can be measured any time as required.

Reference curves are valid until the reagent lot changes, as long as the control results measured with the respective reagent lot are within the confidence range. If 2 or more of the controls measured are outside the confidence range, a new reference curve has to be measured or fresh reagent has to be used, because the reagent may have expired or may be spoiled. If only 1 control is outside the confidence range, this control has to be measured again. If the result of the repeat measurement is also outside the confidence range, a new reference curve has to be measured or fresh reagent has to be used.

The validity of the reference curves is stated in the corresponding instruction for use.

Siemens Healthineers recommends to measure multilevel controls several times a day.

Methods for reference curve calculation

The relationship of the scattered light signal or the rate of the reaction to the protein concentration is described by the so-called logit log function. The system stores calibration data and evaluates the measurement signals of the samples on the basis of the corresponding reference curves.

A reference curve shows the relationship between the measured scattered light intensity or rate of reaction Y and the diluted standard concentration C specific to the assay. A double logarithmic representation is chosen. This function has a mathematically continuous progression, which fits the signal progression of the individual assays.

The following applies:

$$\ln(C) = a \cdot \ln\left(\frac{R - y_0}{y_{max} - R}\right) + b$$

With:

R ... Raw value (measured scattered light or rate of reaction)

C ... Concentration

y_0 ... Lowest calculated signal

y_{max} ... Highest calculated signal

a ... Gradient

b ... Intersection of the axis

y_0, y_{max}, a, and b are parameters that are calculated by the system. The course of the reference curve is described by these 4 parameters.

Logit log function

The logit log function ensures a reliable, quick, and compact calculation of the concentration. The calculation method is therefore superior to other evaluation methods. A short section of the course of the reference curve changes to a straight line when the following expression is applied to the Y axis instead of Y:

$$\ln\left(\frac{R - y_0}{y_{max} - R}\right)$$

With:

R ... Raw value (measured scattered light or rate of reaction)

y_0 ... Lowest calculated signal

y_{max} ... Highest calculated signal

The parameters a and b describe the gradient or the intersection of the axis. The fitting of the reference curve to the measured values is optimized by determining the 4 parameters of the reference curve calculation using a stepwise approximation method.

In order to determine the validity of the reference curve, the percentage deviation of the mathematically fitted curve from the actually measured signals of the standard dilutions is calculated. If the mean value of this percentage deviation lies above a maximum value as defined in the assay definition the reference curve is invalid and must be repeated. The maximum value for Siemens Healthineers assays is usually 5 %.

The percentage deviation of the individual points is displayed on the screen. Reference curves whose percentage deviation is above 5 % can be released manually via the software.

13.1.8 Processing of assays

Before processing any assays, all required preparations have to be completed, see (➔ Page 145 *Preparing for the analysis*).

Verification of lot data

After reagents, controls, and standards were loaded, the barcode reader scans the barcodes in the reagent rotor and in the sample rotor. The scanned identifier numbers and lot numbers of reagents, controls, and standards are compared with those stored in the system's memory and thus verified. If a reagent with a new lot is loaded, lot data is read and stored automatically.

Loading samples

After samples were loaded and the left and right covers are closed, the barcode reader scans the barcodes in the sample rotor. Opening the left cover does not trigger the stop function and the system continues operation. Samples can be re-loaded any time. Sample rotor segments that are no longer required can be removed or can be re-loaded with new samples. STAT status can be assigned to samples to process emergency analyses. STAT samples are flagged **STAT** and are given priority processing.

Processing of job list

A job list containing the assays to be measured can be entered manually or can be received from an LIS. At a minimum, the job list requires a sample ID and a requested job for 1 assay. If the system is connected to an LIS, the requests for the relevant samples are transferred between system and LIS. If the LIS driver is operating in auto host mode, the system requests the job list from the LIS and automatically sends the results back to the LIS. If the system is not connected to an LIS, sample IDs are entered automatically in the lab journal after the sample barcodes have been scanned. Jobs have to be entered manually in the lab journal. Processing of the job list starts. The system is in routine mode.

While the job list is being processed, reagent lots can be changed if a valid reference curve is available for all lots.

Checking of liquid levels

To check liquid levels, the probe employs capacitive resistance to determine the level of liquid in a sample tube or cup, in a standard, control, or reagent vial, in the cuvettes, the dilution cups, the probe cleaner bottle, and the buffer reservoir. When the probe enters the liquid, the capacitance between the probe and bottom of the sample rotor or reagent rotor, which constitutes the counter electrode, changes. The system determines whether or not there is sufficient volume of liquid in the containers to process requests.

Before the first job is processed, the system checks the liquid levels in the reagent vials. If the quantities of reagents loaded are insufficient for the current job list, this is indicated in the status bar. The level in standard or control vials is not checked until the standard or control is pipetted.

Aspirating of volumes

A maximum volume of 450 µL, including diluent, can be aspirated per transfer. The probe dips into the sample tube or reagent vial until it reaches a depth at which it can aspirate the required amount of liquid.

Aspirating volumes:

- Sample: ≥ 5 µL
- Reagent: ≥ 5–400 µL

All required pre-dilutions are prepared in the dilution cups and then pipetted into the cuvettes.

The required amount of sample is aspirated by the syringe from a sample tube or from a dilution cup and dispensed into a cuvette. When a reagent is required, the relevant reagent vial is moved to the pipetting position. The system opens the evaporation cap, the probe aspirates the reagent, and the system closes the evaporation cap. The probe dispenses the liquid into the cuvettes.

When a reference curve is measured, the required amount of diluent is aspirated by the syringe, then the standard is aspirated from the vial and the liquid is pipetted into the dilution cups. It is then pipetted into a cuvette.

The cuvettes in the cuvette rotor are used consecutively. If a cuvette is not usable due to high blank value, the system automatically rejects it. The reaction solutions are measured while the rotor is turning. The measurement results are saved by the system and sent to the LIS.

Documentation of measurement results

The measurement usually takes about 6 minutes, depending on the assay. After a measurement is complete, the result is displayed in the lab journal. Measurement results are continually transferred from the system to the computer and displayed in the lab journal. Measurement results can be printed or sent to the LIS. Additional requests are possible at any time. When the processing of the job list has finished, the system goes into standby mode.

Example: processing of 1 sample

All reference curves are available. Assays are processed 1 after the other.

Example:

- IgA and CRP are requested for a sample.

Processing in detail is as follows:

- The probe determines the filling level of the sample. If the volume of the sample is not sufficient for the pending job list, no sample is aspirated.
- The outside and the inside of the probe are cleaned.

  Processing of IgA starts.

- The probe is filled with the amount of diluens required to create the sample dilution required for IgA.
- The probe aspirates the amount of sample required to create the sample dilution required for IgA.

- The probe dispenses sample and diluens into an empty dilution cup.
- The probe mixes sample and diluens in the dilution cup.
- The outside and the inside of the probe are cleaned.
- The probe aspirates the amount of buffer required for the diluted sample.
- The outside of the probe is cleaned.
- The probe aspirates the amount of diluted sample required for measurement.
- The probe dispenses diluted sample and buffer into an empty cuvette.
- The outside and the inside of the probe are cleaned.
- The probe aspirates the amount of buffer required for the reagent.
- The outside of the probe is cleaned.
- The probe aspirates the amount of IgA reagent required. Simultaneously, the probe determines the filling level of the IgA reagent.
- The probe dispenses buffer and IgA reagent into the cuvette.
- The probe mixes the content of the cuvette.

Reaction time starts.

- The outside and the inside of the probe are cleaned.

Processing of CRP starts.

- The probe is filled with the amount of diluens required to create the first sample dilution step required for CRP.
- The probe aspirates the amount of sample required to create the first sample dilution step required for CRP.
- The probe dispenses sample and diluens into an empty dilution cup.
- The probe mixes sample and diluens in the dilution cup.
- The outside and the inside of the probe are cleaned.
- The probe is filled with the amount of diluens required to create the second sample dilution step required for CRP.
- The probe aspirates the amount of diluted sample required to create the second sample dilution step required for CRP.
- The probe dispenses diluted sample and diluens into another empty dilution cup.
- The probe mixes diluted sample and diluens in the dilution cup.
- The outside and the inside of the probe are cleaned.
- The probe aspirates the amount of supplementary reagent required.
- The outside of the probe is cleaned.
- The probe aspirates the amount of diluted sample required for measurement.
- The probe dispenses supplementary reagent and diluted sample into an empty cuvette.
- The outside and the inside of the probe are cleaned.

- The probe is filled with the amount of diluens required for the CRP latex reagent.
- The probe aspirates the amount of CRP latex reagent required. Simultaneously, the probe determines the filling level of the CRP latex reagent.
- The probe dispenses diluens and CRP latex reagent into the cuvette.
- The probe mixes the content of the cuvette.

  Reaction time starts.
- The outside and the inside of the probe are cleaned.

The next requested job can be processed.

Example: routine processing

All reference curves are available. All requested jobs for a sample are started before the system moves on to process jobs for the next sample. Assays for a sample are processed 1 after the other.

Example:

- Sample 1: IgA and CRP are requested.
- Sample 2: IgG and IgA are requested.
- Sample 3: IgG is requested.

Processing in general is as follows:

- **IgA and CRP of sample 1** are processed as described above in detail, see (➔ Page 317 *Example: processing of 1 sample*).
- **IgG of sample 2** is processed. 2 dilution steps are created for IgG.
- **IgA of sample 2** is processed. The first dilution created for IgG of sample 2 is used for measurement.
- **IgG of sample 3** is processed. 2 dilution steps are created for IgG.

The next requested job can be processed.

13.1.9 Processing of reference curves

Processing in detail is as follows:

- The probe determines the filling level of the required standard.
- The outside and the inside of the probe are cleaned.

  Processing of the first standard dilution step starts.
- The probe is filled with the amount of diluens required to create the first standard dilution step.
- The probe aspirates the amount of standard required to create the first standard dilution step.
- The probe dispenses standard and diluens into an empty dilution cup.
- The probe mixes standard and diluens in the dilution cup.
- The outside and the inside of the probe are cleaned.

- Depending on the assay, the probe aspirates the amount of either buffer or supplementary reagent required.
- The outside of the probe is cleaned.
- The probe aspirates the amount of diluted standard required for measurement.
- The probe dispenses buffer or supplementary reagent and diluted standard into an empty cuvette.
- The outside and the inside of the probe are cleaned.
- Depending on the assay, the probe is filled with the amount of either buffer or diluens required.
- The probe aspirates the amount of reagent required. Simultaneously, the probe determines the filling level of the reagent.
- The probe dispenses buffer or diluens and reagent into the cuvette.
- The probe mixes the content of the cuvette.

  Reaction time for the first dilution step starts.
- The outside and the inside of the probe are cleaned.

  Processing of the second standard dilution step starts.
- The probe is filled with the amount of diluens required to create the second standard dilution step.
- The probe aspirates the amount of diluted standard required to create the second standard dilution step.
- The probe dispenses diluted standard and diluens into another dilution cup.
- The probe mixes diluted standard and diluens in the dilution cup.
- The outside and the inside of the probe are cleaned.
- Depending on the assay, the probe aspirates the amount of either buffer or supplementary reagent required.
- The outside of the probe is cleaned.
- The probe aspirates the amount of diluted standard required for measurement.
- The probe dispenses buffer or supplementary reagent and diluted standard into an empty cuvette.
- The outside and the inside of the probe are cleaned.
- Depending on the assay, the probe is filled with the amount of either buffer or diluens required.
- The probe aspirates the amount of reagent required. Simultaneously, the probe determines the filling level of the reagent.
- The probe dispenses buffer or diluens and reagent into the cuvette.
- The probe mixes the content of the cuvette.

  Reaction time for the first dilution step starts.

Further required standard dilution steps are processed in the same way.

13.1.10 Processing of control measurements

Processing in detail is as follows:

- The probe determines the filling level of the required control.
- The outside and the inside of the probe are cleaned.

  Processing of the control starts.

- The probe is filled with the amount of diluens required to create the control dilution.
- The probe aspirates the amount of control required to create the control dilution.
- The probe dispenses control and diluens into an empty dilution cup.
- The probe mixes control and diluens in the dilution cup.
- The outside and the inside of the probe are cleaned.
- Depending on the assay, further control dilution steps are created likewise.
- Depending on the assay, the probe aspirates the amount of either buffer or supplementary reagent required.
- The outside of the probe is cleaned.
- The probe aspirates the amount of diluted control required for measurement.
- The probe dispenses buffer or supplementary reagent and diluted control into an empty cuvette.
- The outside and the inside of the probe are cleaned.
- Depending on the assay, the probe is filled with the amount of either buffer or diluens required.
- The probe aspirates the amount of reagent required. Simultaneously, the probe determines the filling level of the reagent.
- The probe dispenses buffer or diluens and reagent into the cuvette.
- The probe mixes the content of the cuvette.

  Reaction time starts.

- The outside and the inside of the probe are cleaned.

The next requested job can be processed.

13.1.11 Plausibility check

If a result is below the measuring range, for example, < 0.46 g/L in the 1 : 20 dilution, the measurement is repeated from the 1 : 5 dilution if automatic re-measurement is configured. If the result of the 1 : 5 dilution deviates more than 15 % from the result of the 1 : 20 dilution, for example, 0.46 g/L + 15 %, the plausibility check causes the result of the 1 : 20 measurement to be displayed. That means that in the lab journal, the same result is shown for the 1 : 5 dilution and for the 1 : 20 dilution. No further re-measurement is started.

13.1.12 Formula test

A formula test is a combination of 2 assays. The measurement results of the 2 assays are determined first. If both measurement results are valid, the result of the formula test is calculated from these measurement results according to a defined formula. If 1 of the measurement results is invalid, this assay is re-measured until the result is valid. Manually repeated measurements of the 2 assays are not taken into account.

Example The user requests the formula test **kap_lam**.

The system processes the assays **kap** and **lam**. The result for **kap** is 0.0911 g/L, the result for **lam** is 0.0651 g/L. Both results are valid. The system calculates the result of the formula test **kap_lam** as follows:

kap_lam = **kap** / **lam** = 0.0911 g/L / 0.0651 g/L = 1.399

Changing the units of the 2 assays has no impact on the result of the formula test.

13.2 Principle of measurement

This section describes the physical principles of measurement.

13.2.1 Nephelometry

Nephelometry is the most commonly used measurement principle for the immunochemical determination of protein in serum, urine, and other body fluids. In this method, the light scattered by the antigen-antibody complexes is measured.

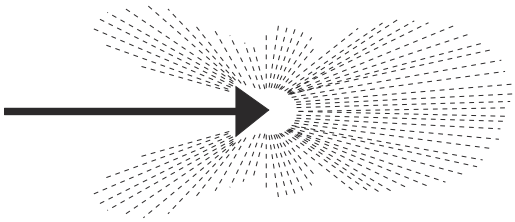
If a sample containing antigen and the corresponding antiserum are put into a cuvette, antigen-antibody complexes are formed. When the antibody is in excess, the intensity of the measured light scatter is proportional to the amount of the antigenantibody complex in the sample. At a constant antibody concentration, the signal is proportional to the antigen concentration. A reference curve is created from a standard with known antigen concentrations. The scattered light signal of the samples can then be read from this curve as an antigen concentration.

The scattered light signal is considerably amplified by the adherence of antibodies or antigens to latex particles. This makes sensitive measurements of trace proteins possible.

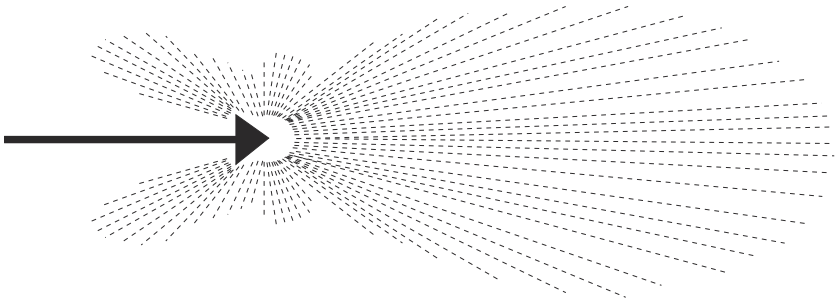
A light beam is generated by means of an LED and sent through the cuvette. The light is scattered by the antigen-antibody complexes that are present. The intensity distribution of the scattered light depends on the relationship of the particle size of the antigen-antibody complex to the wavelength.

Rayleigh or Mie scattering can occur:

- If the particle diameter is small in comparison to the wavelength of the light, Rayleigh scattering occurs. The light is scattered to all sides almost symmetrically. The light efficiency for the measurement is reduced, see below.
- If the particle diameter is large in comparison to the wavelength of the light, Mie scattering occurs. With increasing particle size, the light is mainly scattered in the forward direction. This allows improved light efficiency for the measurement, see below.



Rayleigh scattering

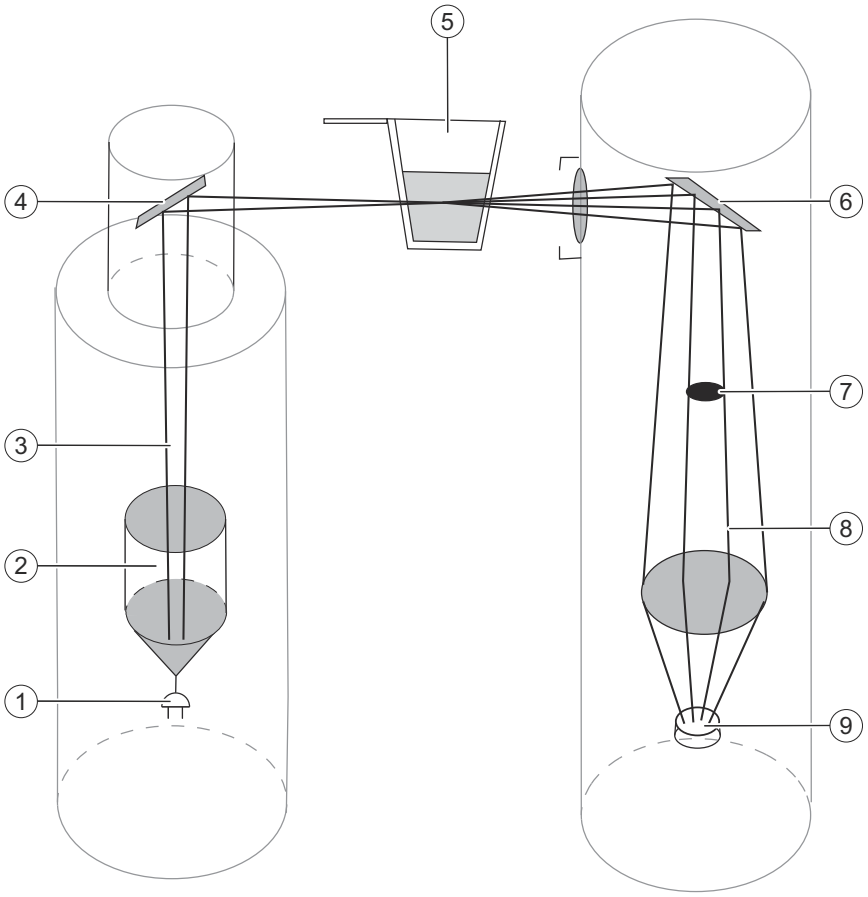


Mie scattering

Due to the use of latex particles, among other things, the diameter of the antigen-antibody complexes is of the order of magnitude d > 1000 nm. The diode used in the system radiates light with a wavelength of 840 nm ± 20 nm. The particles are generally larger than the wavelength and therefore Mie scattering occurs primarily, with a correspondingly higher signal yield.

13.2.2 Optical path of beam

The diode emits a beam with a wavelength of 840 nm. The beam of light is practically parallel and falls on the cuvette. The light is scattered by the particles in the cuvette. The scattered light is measured at an angle of 13°–24° with a hybrid diode (detector). The primary beam is filtered out. The primary beam is the light beam that was not scattered by the antigen-antibody complexes or latex aggregates. The scattered light is focused on a detector by means of a system of lenses. The optimum measurement angle is determined by the wavelength of the incident light of the diode and the particle size of the antigen-antibody complex at the time of measurement, see below.



Optical system

(1) Diode
(2) Microscope lens
(3) Primary beam
(4) Tilted mirror
(5) Cuvette
(6) Tilted mirror
(7) Primary beam mask
(8) Scattered light
(9) Detector

Due to the geometrical arrangement of the detector, only a part of the scattered light is detected. The detector converts the incident scattered light into an electrical signal. The protein concentration in the sample measured is derived from the difference between the signal before the start of the reaction and the signal after the start of the reaction, using a mathematical procedure and by means of comparison with the reference curve. Due to the intense, forwardly inclined scattered light signal, post-amplification with a photomultiplier is not required.

13.2.3 Principle of immunochemical protein determination

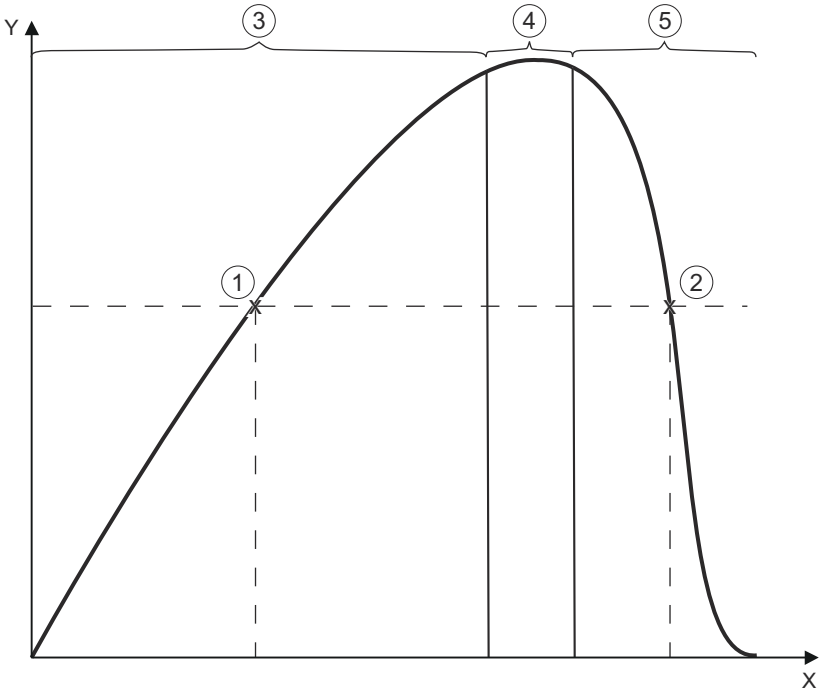
This chapter describes protein determination. This includes:

- Heidelberger-Kendall curve
- Pre-reaction
- Turbidity check

The determination of the protein concentration is achieved by means of the quantitative evaluation of an immunochemical reaction.

Heidelberger-Kendall curve

The Heidelberger-Kendall curve shows the relationship between the antigen concentration and the measurement signal at a constant antibody concentration, see the figure below.

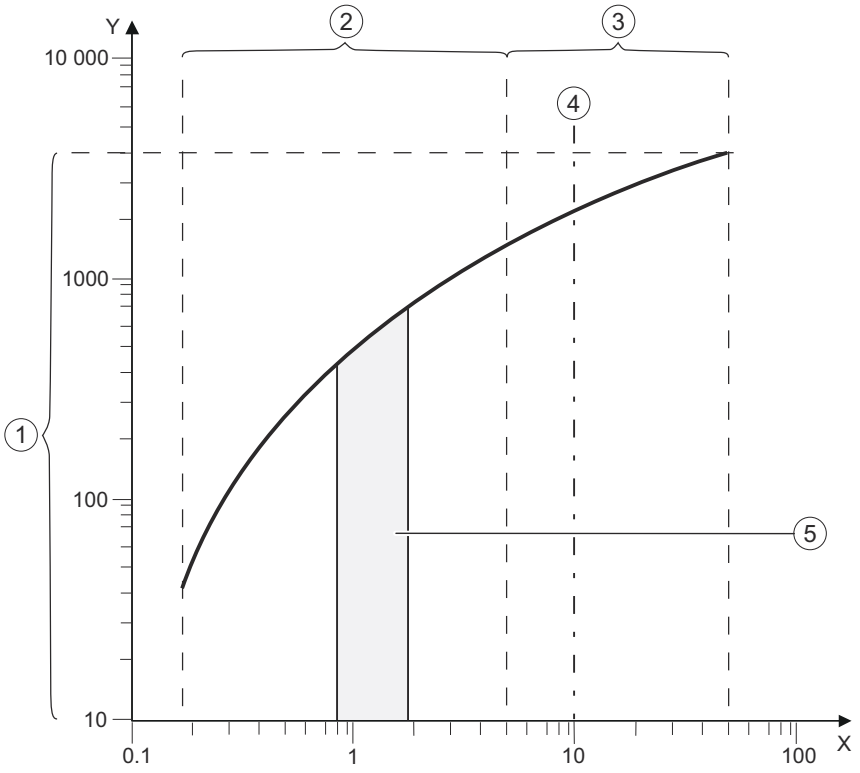


Heidelberger-Kendall curve

X Antigen concentration
Y Precipitation/measurement signal
1 Point 1
2 Point 2
3 Antibody excess
4 Equivalence range
5 Antigen excess

The Heidelberger-Kendall curve can be divided into 3 areas: antibody excess, equivalence range, and antigen excess. For an explanation of the 3 areas, see the table below.

Information	Explanation
Antibody excess	In this area there is an antibody excess, i.e. there are many free binding sites. Each antigen that is added is immediately bound and leads to a further cross-linking. The solubility decreases as the amount of crosslinking increases. In this area of the curve, the relationship between antigen concentration and measurement signal is proportional.
Equivalence range	At approximately equal concentrations of antigens and antibodies, this area of the curve is called the equivalence range. Here the cross-linking is strongest and the solubility of the antigen-antibody complex is at its lowest.
Antigen excess	In the case of an antigen excess, the solubility of the immune complex increases again because the number of antibodies no longer suffices to bind all antigens. This means that the measurement signal becomes less than in the equivalence range. In the evaluation on the Heidelberger-Kendall curve, 2 antigen concentrations could therefore be responsible for a particular measurement signal: • Point 1 lies on the ascending branch in the antibody excess range (low antigen concentration) • Point 2 lies on the descending branch in the antigen excess range (high antigen concentration) Through optimization of the reaction conditions on the system, the maximum of the Heidelberger-Kendall curve has been shifted in the direction of higher antigen concentrations to such an extent that the measurement signals still fall on the left branch of the curve, even at high protein concentrations, see the figure below.



Measurement range on the optimized Heidelberger-Kendall curve

X Concentration in g/L
Y Scattered light intensity
1 Maximum allowed signal range
2 Allowed concentration range
3 Safety margin
4 Pathological threshold
5 Normal range

In order to guarantee antigen excess reliability - even in the case of proteins that are present in high concentrations, or that display great biological variance, for example, urine proteins - certain assays have a pre-reaction performed.

Pre-reaction

In the pre-reaction, a fraction of the sample is prepared with the complete amount of reagent. If, during the pre-reaction, a defined threshold is not exceeded, the usual amount of sample is dispensed and the measurement is performed. The calculated raw value is evaluated on the reference curve.

If there is a significant increase in the signal that exceeds the defined threshold, this measurement is repeated automatically at the next higher dilution if automatic repeat measurement has been configured. A pre-reaction is also measured for this new dilution.

If there is again a significant increase, the sample is prepared at the next dilution and checked by means of a pre-reaction. This procedure is repeated until the result of the pre-reaction lies below the stated threshold or until the system has reached the limits of the permitted dilutions.

If a result cannot be obtained, it remains flagged **>** (value).

Pre-reaction measurement methods are available, for example, for the following assays:

- IgM/Serum
- Albumin/Urine
- Ig/L-chain type lambda in urine

For more information, see the respective assay definition.

Turbidity check

If a measurement signal exceeds the defined threshold, the result for a sample is flagged  , the result for a control is flagged  , the so-called turbidity flags. The turbidity check is performed on the basis of 2 criteria, see the table below.

Criterion	Explanation
1	The difference between the start value, that is, the first measured value, typically after 7.5 s, and the cuvette blank value is higher than typically 1800 bit. The 1800 bit value is called the general turbidity threshold. This criterion records samples with a very high intrinsic turbidity, for example, lipemic samples, or a fast reaction, for example, monoclonal immunoglobulins.
2	The difference between the start value, that is, the first measured value, typically after 7.5 s, and the cuvette blank value is higher than typically 800 bit plus 15 % of the difference between the second measured value and the start value. This criterion was developed in order to exclude non-specific turbidities, or atypical reaction courses with a small measurement signal difference between the second measured value and the start value.

Criteria of turbidity check

The 800 bit value is called the turbidity threshold, the 15 % is called the turbidity factor. Siemens Healthineers calculates the general turbidity threshold and general turbidity factor and provides them as standard values.

If non-specific reactions occur, the affected sample has to be removed from the system and centrifuged. Lipemic samples, for example, can be centrifuged for 10 minutes at 15,000 × g. After re-loading, the sample will be processed without a further check for a non-specific reaction.

13.2.4 Methods of determining the protein concentration at different times

The light scattered by the antigen-antibody complexes can be measured in different ways:

- After the reaction has finished: end point method
- As the difference between the signals at 2 defined points in time: fixed time kinetic method
- Across the whole course of the reaction: VLinIntegral

End point method

The end point method is only used for certain selected assays. The maximum turbidity of the reaction dilution is measured.

Fixed time kinetic method

With the fixed time kinetic method the measurement signal is calculated of the difference between 2 measured values that are obtained at different times.

After all components of the reaction have been pipetted into the cuvette, the first signal, that is, the start value, is measured after approximately 7.5 s, depending on the assay definition. The second value is measured after an incubation time of 6 minutes or longer, depending on the assay definition. The increase in scattered light calculated from these values is processed and can be output in different concentration units, for example, g/L or IU/mL.

The advantage of this measurement method lies in the calculation of the result from the signal difference. The fundamental scattering, which occurs when light is passed through the cuvette containing the reaction partners, even when no antigen-antibody complex is formed, is subtracted.

VLinIntegral

VLinIntegral is a mathematical algorithm for the evaluation of agglutination reactions such as particle enhanced immunoassays or precipitation tests via the maximum rate of reaction.

With the help of this algorithm, 1 or more of the following characteristics that vary depending on the particular assay can be influenced:

- The analytical sensitivity is increased.
- The measuring range is extended.
- The antigen excess reliability is improved.
- The measurement time is reduced.

With this method, the change in scattered light intensity per time interval is determined. In order to determine the maximum change in the rate of the reaction, both the width of the time window and its location are dynamically determined by means of the kinetics.

This evaluation method uses the kinetics to ascertain how many measuring points are to be included for the calculation of the line of regression.

The maximum rate of reaction (value/min) determined in this manner is proportional to the protein concentration and is evaluated, like the other methods, on the basis of a reference curve.

13.3 Communications

The viewer software is installed on the computer and gives the user access to the analyzer. The user can, for example, enter a job list in the viewer software. The job list is sent to the system with the help of a driver. The system processes the job list. The results are sent back to the computer.

With a modem, lot data or update versions can be downloaded. Remote service actions are also possible. Problems can be dealt with in this manner, for example, with remote accessing.

The LIS is the interface for the laboratory information system. The analyzer can be connected to a laboratory information system using communications drivers.

14 Revision Information

The revision information lists topics that have changed since the previously published version of this document.

Topic	Link
Identification	(➔ Page 9 *Identification*)
Trademarks	(➔ Page 13 *Trademarks*)
Manual version history	(➔ Page 13 *Manual version history*)
Intended use	(➔ Page 14 *Intended use*)
Operator qualification	(➔ Page 15 *Operator qualification*)
Mechanical safety	(➔ Page 16 *Mechanical safety*)
Statutory provisions	(➔ Page 25 *Statutory provisions*)

Updated topics

Topic	Link
–	–

Introduced topics

Topic	Link
Revision information	–

Removed topics

A

About, dialog 59

Access cuvette segments and dilution strips, dialog 59

Access reagents, dialog 61

Access samples, dialog 61

Accessories 41

Action buttons, common 55

Adapter, technical specifications 308

Add
- Sample ID to lab journal 167
- STAT sample ID to lab journal 167

Add request, dialog 61

Adjust column width, display function 54

Air bubble detector 38

Analyzer 29

Analyzer ID, configuration 72

As needed maintenance task 229

Assay
- Activate invalid reference curve 185
- Configure reference range 140
- Configure unit 140
- Display reference curve 184
- Measure a reference curve 182
- Processing by system 316
- Repeat a reference curve 183

Assign STAT status 166

Atellica Process Manager 110

Automatic re-measurement 141

Automatic release 141

B

Backup
- Create 199
- Select path for backup file, dialog 115

Barcode label
- Control vial 44
- Reagent rotor segment 44
- Reagent vial 44
- Sample rotor segment 41

Barcode reader 38
- Reagent rotor 31
- Sample rotor 31

Battery Directive 25

Bottle, probe cleaner 49

Buffer container 49

Buffer reservoir 33

Buffer, replace 147

C

Calibration
- Dialog 64
- Kinetic 83
- Show reference curve 116
- Valid reference curve cannot be displayed 293

Calibration data, handling by system 314

CE conformity 25
- see Declaration of Conformity

Check
- Control level 245
- Functioning of probe 205
- Probe geometry 247
- Reagent level 245
- Sample level, visually 244
- Syringe for leak 211
- Tubing of container 213
- Tubing of probe 213

Check probe, dialog 66

Clean
- Cuvette rotor and housing 231
- Dilution station 231
- Level sensor 218
- Peripheral device 234
- Probe 206
- Reagent rotor and housing 210
- Sample rotor and housing 229
- Segment 231
- Surface of system 229
- Waste container 234
- Water container 212
- Wet station 208

Clean probe, dialog 66

Close, viewer software 300

Color
- Buttons in dialog areas 119
- Container 47
- Dialog background 119
- Grip, control segment 45
- Grip, reagent segment 45
- LED 30
- Plain text label 41

Communication 329

Computer 40
- Technical specifications 305

Condensation, reagent rotor 31

Configuration
- Analyzer ID 72
- Connection 68
- Cyclic control measurement 128
- Dialog 67
- Host 68
- Laboratory address 72
- Language 67
- LIS connection 144
- Password 67
- Printout 142
- Result report 67
- Sample rotor segment 71
- User settings 72

Conformity 25

Connection, configuration 68

Consumable 41
- Safe handling 18
- Technical specifications 305

Contact information 9

Container
- Buffer 49
- Check tubing 213
- Diluent 49
- Replace tubing 225
- Waste 47
- Water 47

Control 50
- Check level 245
- Configure cyclic control measurement 128
- Deactivate cyclic measurement 129
- Definition 76
- Display details 180
- Display measurement curve 180
- Evaluate result 181
- Handling by system 313
- Identify 158
- Load 153
- Measure 161
- Prepare 150
- Repeat measurement 162
- Safe handling 18
- Unload 178

Control details, dialog 73

Control lot
- Add 134
- Definition 80
- Delete 135

Control measurement, processing by system 321

Control segment 45

Cover 30

Create backup 199

CSF (cerebrospinal fluid) 14

Cup
- Configure immersion depth 138
- Immersion depth, definition 79
- Special cups, technical specifications 308

Cup-behind-tube segment 44
- Use segment 195

Cup-in-tube segment 42
- Configure immersion depth 138
- Use segment 187

Cuvette rotor 34
- Clean 231
- Cover 34

Cuvette segment 34, 46
- Access cuvette segments and dilution strips, dialog 59
- Load 148
- Technical specifications 307

D

Data protection 20

Data, display in lab journal 179

De-installation 27

Declaration of Conformity 25

Definitions
- Control lots 80
- Controls 76
- Dialog 74
- Immersion depth 79

Profiles 76
Standard lots 81
Units 79
Delete sample ID from lab journal 185
Delivery 26
Diluent container 49
Diluent, replace 147
Dilution cup 32
Dilution frame 32
Dilution station 32
Clean 231
Dilution strip 32, 46
Access cuvette segments and dilution strips, dialog 59
Load 148
Technical specifications 307
Dilutor 39
Directive on restriction of hazardous substances 25
Directive on waste electrical and electronic equipment 25
Dispensing area 33
Display
Control details 180
Measurement curve 180
Sample details 180
Disposal 28
Distilled water 18

E

Electrical safety 15
Electromagnetic compatibility 25
Empty waste container 202
End point method 328
Eppendorf cup segment 43
Use segment 190
European directives 25
Evaluate control result 181
Evaporation cap 46
Technical specifications 307
External device 39

F

False-bottom-tube segment 44
Filter, display function 54
Fixed time kinetic method 329
Flag, symbol 55
Formula test 322
Fountain area 33
Function key 58
Fuse holder 37
Fuse, replace 247

H

Handwheel
Cuvette rotor 34
Reagent rotor 31
Sample rotor 31
Hardware check - probe, dialog 81
Hardware troubleshooting 242
Heidelberger-Kendall curve, principle 325
Help, dialog 81
Hitachi cup segment 43
Use segment 193
Host, configuration 68
Hypochlorite solution, prepare 236

I

I/O port 305
Identification
System 9
Identify
Control 158
Reagent 158
Sample with unreadable barcode 172
Standard with unreadable barcode 172
Immersion depth
Configure 138
Definition 79
Immunochemical protein determination, principle 325
In vitro diagnostic medical devices Regulation 25
Incorrect context in a dialog 299
Infection, safe handling 18
Initialize analyzer, dialog 82
Insert reagent rotor segment 243
Installation 26
Intended purpose
see Intended use
Intended use 14
Intended user 14
International standards 25
IT security 21
IVDR
see In vitro diagnostic medical devices Regulation

K

Kinetics, dialog
Measurement curve 82
Reference curve 83

L

Lab journal
Add request 61
Add sample ID 167
All results of dilution series deleted 283
Assay not displayed for control 283
Cup-in-tube result with Y flag 281
Data not updated 278
Delete sample ID 185
Dialog 84
Display data 179
Display result 142
Empty lab journal 278
Job for control not processed 282
Job list from LIS not displayed 279
Jobs not processed with re-measured reference curve 280
New 103
Result with technical flag 281
Set sort sequence 142
Unknown character string 278
Laboratory address, configuration 72
Language
Configuration 67
Set 143
LED 30
Level sensor 47
Clean 218
Limitations of nephelometry 20
Liquid container 47
LIS (laboratory information system) 40
Configure connection 144
Load
Barcoded sample 163
Control 153
Cuvette segment 148
Dilution strip 148
Non-barcoded sample 168
Non-barcoded STAT sample 168
Reagent 153
Sample rotor segment 171
Standard 159
User-defined control 159
Loading
Reagent or control barcode cannot be scanned 287
Reagent or control not used 289
Sample barcode cannot be scanned 284
Segment ID of reagent segment not displayed 292
Segment ID of sample rotor segment not displayed 290
Segment ID of sample rotor segment not displayed in dialog Pre-loading 292
Loading cuvette segments and dilution strips, dialog 87
Loading reagents, dialog 89
Graphic overview 90
Identify reagents and controls 93
Loading samples, dialog 95
Log on, dialog 100
Logbook
Dialog 101
Enter entry 300
Export entry 301
Logit log function 315

Lot data
Handling by system 314
Open lot data file, dialog 105
Verification 316

M

Main switch 37
Maintenance
As needed task 229
List of tasks 204
Monthly task 215
Weekly task 205
Yearly task 221
Maintenance log 238
Maintenance task 204
Measure control 161
Measurement curve
Details 82
Display 180
Mechanical safety 16
Message window 102
Position without barcode on reagent rotor 269
Position without barcode on sample rotor 268
Model number 9
Monthly maintenance task 215
Movement 27

N

Navigate, display function 54
Nephelometry 322
Nephelometry, limitations 20
New, dialog 103
Non-operation 26

O

Online help 81
Open lot data file, dialog 105
Operating conditions 304
Operational safety 17
Operator qualification 15
Optical path of beam 323
Ordering information 9
Overview
Analyzer 29
Software 51

P

Password cannot be entered 296
Password, configuration 67
Peripheral device 40
Clean 234
Personal data protection 20
Personal health information (PHI) 20
Personally identifiable information (PII) 20
PHI (Personal health information) 20
PII (Personally identifiable information) 20
Plain text label 41
Plausibility check 321
Port 39
Power module 37
Power supply socket 37
Pre-identify
Non-barcoded sample 167
Non-barcoded STAT sample 167
Pre-loading, dialog 106
Pre-reaction, principle 327
Prepare
Control 150
Hypochlorite solution 236
Purging solution 236
Reagent 150
Sample rotor segment 155
Principle
Control dilution 314
Heidelberger-Kendall curve 325
Immunochemical protein determination 325
Multiple point calibration 314
Pre-reaction 327
Sample dilution 313
Standard dilution 313
Turbidity check 328
Print preview for raw data, dialog 109
Print preview, dialog 107
Print result 181
Printing problem 300
Printout, configure 142
Probe 35
Check functioning 205
Check geometry 247
Check probe, dialog 66
Check tubing 213
Clean 206
Clean probe, dialog 66
Hardware check - probe, dialog 81
Replace probe assembly 250
Probe cleaner
Bottle 49
Replace bottle 235
Profile
Add 136
Add assay 136
Definition 76
Delete 137
Remove assay 136
Protection, personal data 20
Purge tubing 215
Purge tubings, dialog 109
Purging solution, prepare 236
Purified water 18

Q

QC, dialog 110
Qualification of the operator 15

R

Raw data, print preview for raw data, dialog 109
Re-measurement 111
Set 141
Reagent 50
Access reagents, dialog 61
Barcode, technical specifications 310
Check level 245
Handling by system 311
Identify 158
Load 153
Prepare 150
Unload 178
Reagent cooler 31
Reagent rotor 31
Access lid 31
Barcode reader 31
Clean 210
Cover 31
Insert segment 243
Position without barcode detected 269
Reagent cooler 31
Reagent rotor segment 44
Insert 243
Technical specifications 307
Reagent segment 45
Reagent, safe handling 18
Reference curve
Activate invalid reference curve 185
Calculation 315
Display 184
Kinetic 83
Measure 182
Processing by system 319
Repeat 183
Show curve 116
Reference range, configure 140
Refill sample tube 175
Release result 180
Release, set 141
Remote control, dialog 110
Repair 9
Repeat control measurement 162
Repeat job manually 174
Repeat, dialog 111
Replace
Fuse 247
Probe assembly 250
Probe cleaner bottle 235
Tubing of container 225
Water filter 217
Replace syringe 221
Dialog 112

Replace system liquids and empty waste container, dialog 112
Report serious incident 15
Request controls, dialog 113
Request job manually 173
Result
  Evaluate control result 181
  Print 181
  Release 180
  Set display in lab journal 142
Result report, configuration 67
Rinse system 199
  Dialog 114
RoHS
  see Directive on restriction of hazardous substances

S

Safety information
  CAUTION, meaning 22
  Consumable 18
  Control 18
  Electrical safety 15
  General 15
  Infection 18
  Mechanical safety 16
  Nephelometry, limitations 20
  NOTICE, meaning 22
  Operational safety 17
  Operator qualification 15
  Personal data 20
  Reagent 18
  Safety messages, structure 22
  Sample 18
  Standard 18
  Symbol 22
  WARNING, meaning 22
Sample
  Access samples, dialog 61
  Assign STAT status 166
  Check level visually 244
  Display details 180
  Display measurement curve 180
  Handling by system 311
  Identify 172
  Load barcoded sample 163
  Load non-barcoded sample 168
  Pre-identify non-barcoded sample 167
  Refill sample tube 175
  Repeat job manually 174
  Request job manually 173
  Safe handling 18
  Unload 176
Sample barcode, technical specifications 309
Sample details, dialog 114
Sample ID
  Delete from lab journal 185
  Remove previous assignment 186
  Significant digits 143
Sample rotor 31
  Barcode reader 31
  Clean 229
  Load standard 159
  Load user-defined control 159
  Position without barcode detected 268
Sample rotor segment 41
  Add segment ID 137
  Configuration 71
  Delete segment ID 138
  Load 171
  Prepare 155
  Technical specifications 306
  Use cup-behind-tube segment 195
  Use cup-in-tube segment 187
  Use Eppendorf cup segment 190
  Use Hitachi cup segment 193
Sample segment 41
Sample tube
  Refill 175
  Technical specifications 308
Scroll, display function 54
Security whitepaper 22
Segment
  Clean 231
  Control segment 45
  Cup-behind-tube segment 44, 195
  Cup-in-tube segment 42, 187
  Cuvette rotor 34
  Eppendorf cup segment 43, 190
  False-bottom-tube segment 44
  Hitachi cup segment 43, 193
  Reagent rotor segment 44
  Reagent segment 45
  Sample rotor segment 41
  Sample segment 41
  Standard segment 42
Select path for backup file, dialog 115
Select, display function 53
Serious incident 15
Service
  Contact information 9
Set
  Automatic re-measurement 141
  Automatic release 141
  Display result in lab journal 142
  Language 143
  Sort sequence in lab journal 142
Show curve, dialog 116
Shutdown 200
  Maintenance 229
Significant digits, sample ID 143
SMN, system 9
Software version, information 59
Software, troubleshooting 267
Sort, display function 54
Spare parts 9
Special dilution, dialog 118
Standard 50
  Handling by system 312
  Identify 172
  Load 159
  Unload 177
Standard lot
  Add 128
  Definition 81
Standard segment 42
Standard, safe handling 18
Standards, statutory requirements 25
Start
  System 145
  Viewer software 299
STAT sample
  Barcoded sample, assign status 166
  Load non-barcoded STAT sample 168
  Pre-identify non-barcoded STAT sample 167
Status
  Dialog 119
  Incorrect numbers 278
Status button 52
Status button Information
  Frequently yellow 277
  Red 273
  Red directly after start 272
  Yellow 277
Status button Ref. curves & Contr. results
  Remains yellow 271
Status button Samples & Standards
  Yellow or red 271
Statutory requirements
  CE conformity 25
  Electromagnetic compatibility 25
  European directives 25
  International standards 25
Storage 26
Storage conditions 305
Symbol
  Flag 55
  Meaning 22
Syringe 37
  Check for leak 211
  Replace 221
  Replace syringe, dialog 112
  Troubleshooting 266
System
  Clean surface 229
  Dialog 124
  Does not respond 297
  Does not work after standby 297
  Rinse 199
  Rinse system, dialog 114
  Shut down 200
  Start 145
System (dialog)
  Immersion depth cannot be defined 295
  Logbook entry displays level outside limits 294
  Logbook entry not displayed completely 294
  Progress bar of purging of the tubing stops at 0:00 296
  Unknown character string in raw data 293

System identification 9
System liquid
Replace 147
Replace system liquids and empty waste container, dialog 112

T

Technical safety 15
Technical specifications
Adapter 308
Analyzer 302
Barcode for user-defined control 309
Computer 305
Consumable 305
Cuvette segment 307
Dilution strip 307
Evaporation cap 307
I/O port 305
Operating conditions 304
Reagent barcode 310
Reagent rotor segment 307
Sample barcode 309
Sample rotor segment 306
Sample tube 308
Special cup 308
Storage conditions 305
Vial 308
Temperature, monitoring 124
Training
see Operator qualification
Transfer arm 35
Transport
see Movement
Troubleshooting 241
Hardware 242
Software 267
Syringe 266
Tubing 47
Check tubing of container 213
Check tubing of probe 213
Purge 215
Purge tubings, dialog 109
Replace tubing of container 225
Turbidity check, principle 328

U

Uninterruptible power supply 15
Units
Configure 140
Definition 79
Unload
Control 178
Reagent 178
Sample 176
Standard 177
UPS
see Uninterruptible power supply
User role 100
User settings, configuration 72
User-defined control
Add 129
Add assay 131
Barcode, technical specifications 309
Delete 134
Edit assay settings 132
Load 159

V

Vial, technical specifications 308
Viewer software
Close 300
Does not respond 298
Start 299
VLinIntegral, method 329

W

Walk-away time 124
Warranty 9
Waste container 47
Clean 234
Empty 146, 202
Replace system liquids and empty waste container, dialog 112
Water
Replace 147
Requirement 18
see Distilled water
see Purified water
Water container 47
Clean 212
Water filter, replace 217
WEEE
see Directive on waste electrical and electronic equipment
Weekly maintenance task 205
Wet station 33
Clean 208

Y

Yearly maintenance task 221

This document is maintained in electronic form through Siemens Healthineers distribution channels. Printed versions not provided by Siemens Healthineers and/or downloaded copies are considered uncontrolled.

CE

Siemens Healthineers has validated the provided instructions, reagents, instrument, software and customizable features for this system to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens Healthineers as they may affect performance of the system and test results.

Gender inclusivity

At Siemens Healthineers, we want to address all genders equally in our Instructions for Use. It is not our intention to exclude anyone. We continue to update our documentation with this in mind.

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Legal Manufacturer
Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Material No. 11212159
Published by Siemens Healthineers / Print No. DCSI-B04.621.01.02.02 / © Siemens Healthineers, 2016 - 2023
Date of first issue: 2016-10 / Revision date: 2023-02