SIEMENS Healthineers

BN ProSpec System

Addendum to the Instruction Manual 1.4 (US)

Version: 1.4.3, Issue Date: 2020-09

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1 Introduction

This addendum supplements the BN ProSpec® System Instruction Manual, version 1.4.

The information in this addendum reflects the current status and supersedes other information in the instruction manual, if applicable.

1. File this addendum with your instruction manual.

2. Remove older versions of this addendum, since they are obsolete.

1.1 Trademarks

BN ProSpec is a trademark of Siemens Healthineers.

2 Manual version history

Manual			Software	
Version	**Date**	**Changes**	**Full version**	**Release version**
1.0	2003-11	First version	1.1	1
1.1	2008-09	Name change	1.1	1
1.2	2012-04	Update	1.4	1
1.2.1 (not published outside the USA)	2017-11	Update (US)	1.4.1	1
1.3 (not published in the USA)	2016-04	Update (zh-CN)	1.4.1	1
1.4 (not published in the USA)	2016-06	Update	1.4.2	1
1.4.1 (not published)	2017-11	Update	1.4.3	1
1.4.2 (not published in the USA)	2018-05	Update	1.4.3	1
1.4.3	2020-09	Update	1.4.1	1

Table 1 Manual version history

3 Changes since the last addendum (version 1.2.1)

The following chapters are introduced:

- page 9 Symbols
- page 12 Meaning of invalid control result
- page 13 Replacing the probe cleaner bottle

4 Environmental operating conditions

The BN ProSpec System may be operated under the following environmental conditions:

- Indoor use only
- Altitude up to 2000 m
- Temperature range 18 to 32° C
- Maximum relative humidity in the permissible temperature range: 85 %, non-condensing
- Voltage fluctuations in the supply network must not be any higher than ± 10 % of the nominal voltage
- Transient overvoltages, as are normal on the supply network

Note: The analyzer must be protected from direct sunlight.

Note: The protection type for the analyzer's housing corresponds to IP20 in accordance with IEC 60529.

5 Storage, transport, setup, and service

Note: The recommended storage temperature for the analyzer is between 5 and 45° C.

Note: The analyzer may only be transported by personnel who have been trained in its correct transport.

Note: The analyzer and the associated computer and monitor must be connected with cables that have been checked. On the analyzer side, a plug compliant with IEC 320 C13 must be used, while on the other side, a country-standard plug with ground contact must be used.

Note: The system's components must be set up so that the mains switch on each of the components is easily accessible.

Note: A space of at least 10 cm on all sides and 30 cm above must be left around the analyzer.

Note: With the device setup procedure, you will obtain information (hotline number, etc.) that will tell you how to contact Siemens Healthineers service.

Note: Only original Siemens Healthineers spare parts must be used. Please order these from your Siemens Healthineers representative.

6 Safety notes

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

- Disconnect the main plug immediately if liquid is spilled into the system.

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

- 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.
- Never bypass or remove safety devices.

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.

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.
- Ventilate the room.

7 Technical data

Weight

Analyzer: 115 kg

Computer: Approx. 20 kg, depending on the model

Footprint (L x W x H)

190 cm x 75 cm x 90 cm for analyzer, computer and external liquid containers

Note: The space required for ventilation on the rear of the analyzer of at least 10 cm must be ensured.

Sound pressure level

55 dB(A), measured value at operator’s position

8 Electromagnetic compatibility, interference suppression and immunity to interference

Test basis is EN 61326 or IEC 61326. The analyzer has been designed and tested according to EN 61326-1 Class A.

In a domestic environment, it may cause radio interference, in which case you may need to take measures to mitigate the interference.

The data cable(s) supplied must be used if the relevant requirements are to be met. Shielded cables and plugs must be used for connection to other components such as printers and modems.

Assess the electromagnetic environment prior to operating the analyzer.

Note: Do not use any strong electromagnetic transmitters (e.g. cellphones, walkie-talkies, door opening devices) in the vicinity of the analyzer.

9 Symbols

The following information supersedes the instruction manual, Chapter 1.5 Description of warning signs and Chapter 1.6 Meaning of symbols on the label of consumables.

This chapter describes symbols that may appear on the system and related products, except symbols in the software.

Symbol	Meaning
LOT	Batch code
BUFFER	Buffer
SMN	Catalog number
CD	CD (compact disk)
CE	CE mark
	Consult instructions for use
	Content is fragile and must be handled with care
CONTENTS	Contents

Table 2 Symbols

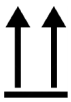
Symbol	Meaning
CUVETTES	Cuvettes
	Date of manufacture
DILUENT	Diluent
	Do not reuse
DOCUMENTATION	Documentation
DVD	DVD (digital versatile disk)
DO CD	Documentation CD
EVAP CAPS	Evaporation caps
	Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
STICK	Flash drive
	Handle with care
IVD	In vitro diagnostic medical device
	Indicates correct upright position of the transport package
	Keep dry
LOT DATA	Lot data
MANUALS	Manuals
	Manufacturer

Table 2 Symbols (continued)

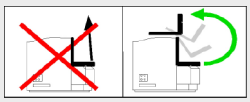
Symbol	Meaning
	Only open covers of the system as displayed
	Power off
	Power on
PREDIL WELLS	Predilution wells
REF	Reference number
	Remove caps from sample tubes before loading
SECURE D	Secure Download software
SN	Serial number
SW	Software
	Stacking of the transport package is not allowed and no load should be placed on the transport package.
SYSTEM	System
USB	USB flash drive
	Warning: Assembly is susceptible to electrostatic charge

Table 2 Symbols (continued)

Symbol	Meaning
	Warning: Biological risks The labeled area can come into contact with potentially infectious material. The safety instructions regarding infectious material must be observed, see page 7 Safety notes.
	Warning: Consult instructions for use for important cautionary information
	Warning: Laser beam
	Waste electrical and electronic equipment For more information, see the instruction manual of the system, version 1.4, chapter Legal Regulations.

Table 2 Symbols (continued)

10 Meaning of invalid control result

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

If in the dialog **Lab journal** the filter setting **Invalid controls** is activated, controls results will be displayed as invalid also, when their results lie outside the **reference range**. Despite that, they can be considered as valid, if they are **not** flagged with an **h** or **l**.

11 Yearly maintenance procedures

Replace the syringe

Replace the syringe as described in the instruction manual, Chapter 12.5 Replacing the Syringe.

Replace the container tubing

Replace the container tubing as described in the instruction manual, Chapter 12.6 Replacing the Tubing.

Record the maintenance procedures

Record every maintenance procedure that has been carried out in the maintenance log, see page 15 Maintenance log.

12 As needed tasks

12.1 Replacing the probe cleaner bottle

The following information supersedes the instruction manual, Chapter 8.3.8 Reloading cleaner.

You will need:

- 1 new probe cleaner bottle

System status:

- Standby mode
- Routine mode

To replace the probe cleaner bottle, proceed as follows:

Note: No processing of jobs when the right cover is opened without access being requested via the software. The stop function is triggered, the analyzer's operation is interrupted and existing pre-dilutions can be rejected. Delay of patient 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.

Note: When the probe cleaner bottle is stated as empty, it still contains a residual volume of approx. 3.9 mL, which cannot be used.

1. In the dialog **System**, in the area **Access**, click **System liquid & waste**.
   → In the dialog **System - Replace system liquids and empty waste container**, a progress bar is displayed. The system finishes current operations. This can take several minutes.
2. Wait until the dialog for replacing the system liquids is displayed.
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.
- If froth has formed, remove it using a cotton bud.

Note: Delay of patient 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.

Note: 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 button **Save** becomes active.
8. Click **Save**.
9. Wait until the message **Reloading of system liquids completed** is displayed.
10. Click **OK**. → The dialog **System** is displayed. The replacing of the probe cleaner bottle is complete.

BN ProSpec System maintenance log form

from _____ to _____

Day/month/year Day/month/year

Weekly maintenance procedures	Week 1	Week 2	Week 3	Week 4	Week 5
1. Probe operation checked					
2. Probe cleaned externally					
3. Surface of wet station and rhombus of dispensing area checked					
4. Fountain cleaned					
5. Syringe checked					
6. Distilled water container replaced					
7. Tubing checked					
8. Software ended, analyzer switched off					
9. Vessel of the reagent rotor cleaned					
10. Analyzer switched on and software started					
Remark:					
Signature:					

Monthly maintenance procedures	
1. Tubing purged	
2. Distilled water filter replaced	
3. Level sensors cleaned	
Remark:	
Signature:	

Yearly maintenance procedures	
1. Syringe replaced	
2. Tubing replaced	
Remark:	
Signature:	

13 Maintenance log

13 Maintenance log

This product is provided with a CE mark in accordance with the regulations stated in Council Directive 98/79/EC of October 27, 1998, concerning In-vitro Diagnostic Medical Devices and the Council Directive 2011/65/EU of June 08, 2011, on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The CE marking applies only to In-vitro Diagnostic Medical Devices which have been put on the market according to the above-mentioned EC Directives. Unauthorized changes to this product are not covered by the CE mark and the related Declaration of Conformity.

Siemens Healthcare Diagnostics Products GmbH 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 Healthcare Diagnostics Products GmbH as they may affect performance of the system and test results.

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

SMN 11211045

siemens-healthineers.com