Dimension®
Systems

Software Version 10.5.2 Release Notes with Installation Instructions

Siemens Healthineers is introducing system software version 10.5.2 for the Dimension® Systems. Dimension Systems software version 10.5.2 is installed by using the electronic Remote Update Handling system. This document presents the following information:

- Dimension software version 10.5.2 improvements
- Installation instructions for Dimension software version 10.5.2

Place this information with the operator's guide. Ensure that all users review and understand this document. If you have any questions or concerns regarding the information in this document, contact your local technical support provider.

NOTE: Siemens Healthineers recommends printing and retaining this document for reference during the installation.

doclib.siemens-healthineers.com

Search using keywords: Dimension 10.5.2

Ensure you have read and understood this document before performing any of the installation steps. A user must sign in with an Operator ID having Full control privileges. As the default setting, Lab Manager and Chief Technician Operator IDs have these privileges.

www.siemens-healthineers.com

Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Newark, DE 19714 USA
11349968 Rev. 01, 2021-10

Table of Contents

Installation Requirements

Software version 10.5.2 can be installed on the following systems currently running software version 10.4.1, 10.4.2,* 10.4.3, or 10.5.1.

*Software version 10.5.2 cannot be directly installed on systems running software version 10.4.2. Call your local technical support provider to install software version 10.5.2.

To verify the system's current software version, select **F6: SYSTEM CONFIG** from the Home Operating Menu and locate the Software Revision field.

- Dimension® RxL Max® clinical chemistry system
- Dimension® RxL clinical chemistry system
- Dimension® Xpand® clinical chemistry system
- Dimension® Xpand® Plus clinical chemistry system
- Dimension® EXL ™ with LM Integrated Chemistry system
- Dimension® EXL ™ 200 Integrated Chemistry system

Assay Updates

Reset assays to software defaults and calibrations required due to the installation of Dimension software version 10.5.2 are as follows:

Table 1. Software Version Installing From and Assays Updated

Software Version Installing From	Reset Assay to Software Default / Calibration Required
10.4.1	FT4L, CSA, CSAE, and BUN
10.4.2	FT4L, CSA, CSAE, BUN, and CV2T
10.4.3	FT4L, CSA, CSAE, BUN, and CV2G
10.5.1	CV2G

Table 2. Assay Updates

Assay	Change	IFU Updated	Resets Assay to Software Default	Calibration Required
FT4L	Updated the initial read cutoff for the LOCI® assay.	No	Yes	Yes
CSA	Improved error handling by updating result monitor.	No	Yes	Yes
CSAE	Improved error handling by updating result monitor.	No	Yes	Yes
BUN	Based on internal testing, it has been determined that the Result Monitor is no longer required.	No	Yes	Yes
CV2T	Reagent carryover mitigations have been implemented. Batch processing is no longer required. Upper Assay Value change to 30,000 QUAL Units from 2000 QUAL Units. Calibration interval change to 14 days from 7 days. Open Well stability change to 3 days from 2 days. Onboard unopened Flex® reagent cartridge stability change to 30 days from 14 days.	No	Yes	Yes
CV2G	Updated default lower limit of the Analytical Measurement Range from 0 Ind to 610 Ind.	Yes	Yes	Yes

NOTE: Refer to Table 1 for assays affected by software version installing from.

New Features

New Feature Descriptions and Configurability

Table 3 identifies and describes the new features for software version 10.5.2 and indicates if they are configurable. For customers installing software version 10.5.2 from software version 10.4.1, 10.4.2, or 10.4.3, new features are as follows:

Table 3. New and Improved Features, Descriptions, and Configurability

Feature	Description	Configurable Yes/No
VNC Password Authentication	Unique password required for remote control and screen sharing.	Yes
Continuous Cuvette Feature for User-Defined Methods	New feature for User-Defined Methods, if applicable in application sheets.	Yes
Weighted Calibrations Option for User-Defined Methods	New feature for User-Defined Methods, if applicable in application sheets.	Yes
LYTES QC Levels	LYTES QC levels now display in the Method Review Screen.	No
Updated Operating System	Updated operating system, including security patches.	No
New Compatible Printers	Lexmark MS312dn and Lexmark MS321dn printers are compatible for use.	No
Enhanced Conditioning Procedure	New conditioning procedure for X0, X1, and X2 tubing and the IMT sensor.	No

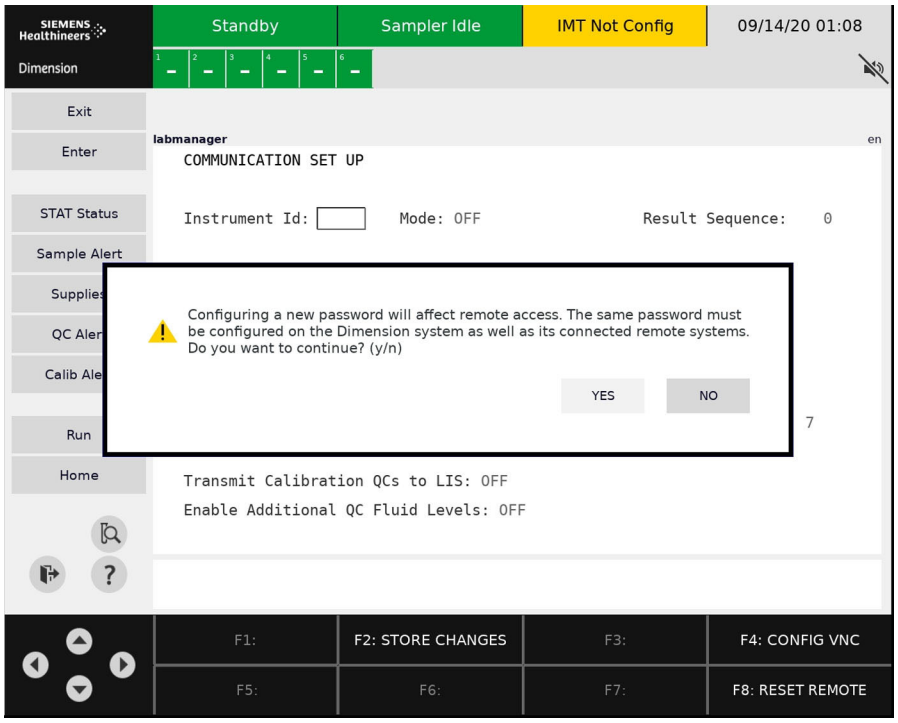
Cybersecurity Enhancement, Virtual Network Computing (VNC) Authentication

Cybersecurity is enhanced with required authentication for VNC remote control and screen sharing. A password must be configured and shared for both the Dimension System and all connected Atellica® Connectivity Manager (Atellica CM), Atellica® Process Manager (Atellica PM), *syngo*® Lab Connectivity Manager (sLCM), and VersaCell® X3 Systems. Contact your local technical support provider for assistance.

To configure the password on the Dimension System, perform the following steps:

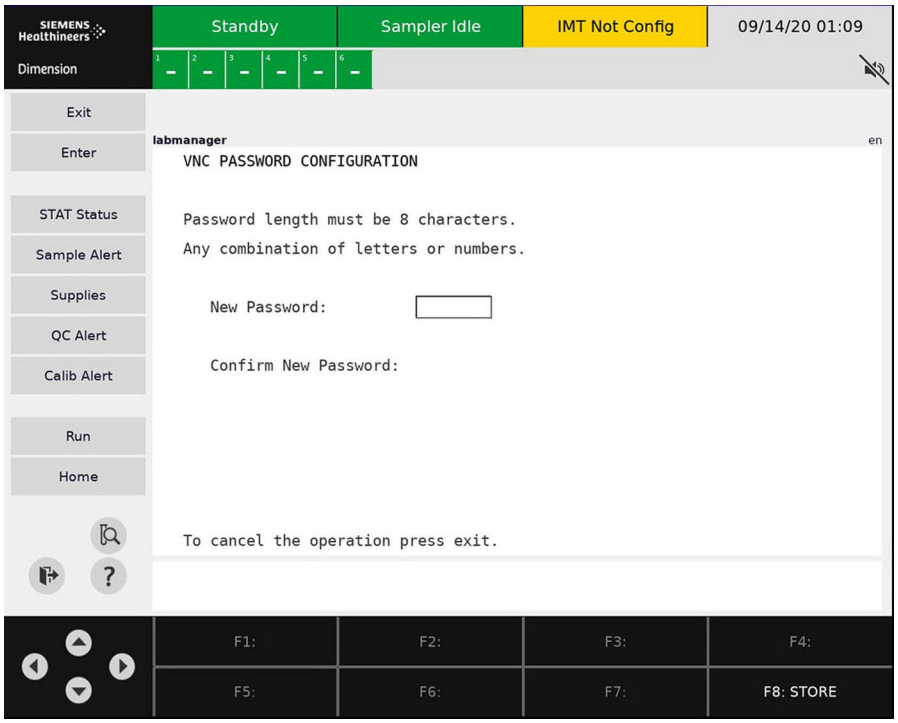
1. Sign in to the system as a labmanager.
2. From the Operating Menu, select **F6: SYSTEM CONFIG > F4: COMPUTER > F4: COMMUNICATIONS > F4: CONFIG VNC**. A pop-up message displays.

Figure 1. Configure New Password Pop-Up Message



3. Select **YES** to continue with the VNC Password Configuration password setup. Select **NO** to cancel the password setup. The VNC Password Configuration screen displays.

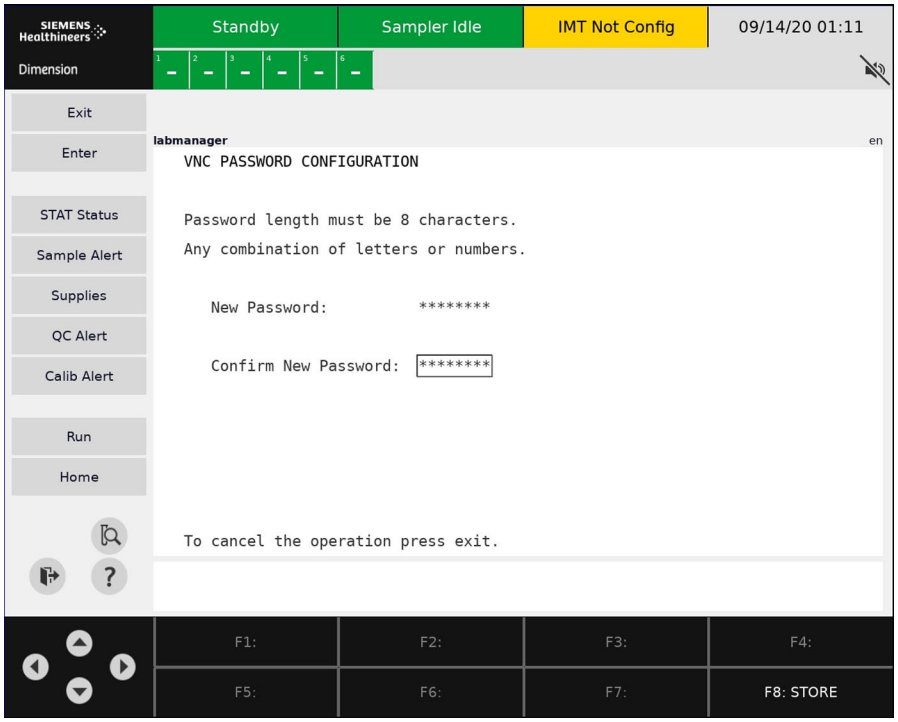
Figure 2. VNC Password Configuration Screen, Blank



4. Enter a new password in both the New Password and Confirm New Password fields.

   NOTE: Passwords must be 8 characters in length. Any letters or numbers are acceptable. The passwords must match in both fields to be accepted.

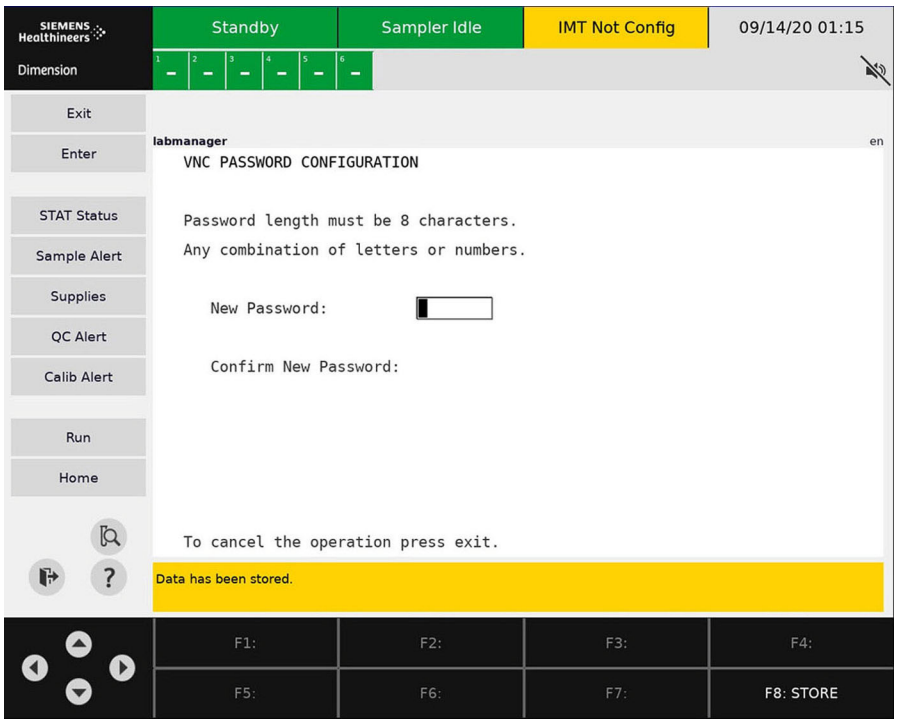
Figure 3. VNC Password Configuration Screen, Filled



5. Select **F8: STORE**. A message displays confirming that the password data has been stored.

NOTE: Once the password is successfully stored on the Dimension System, the Atellica CM, Atellica PM, sLCM, and VersaCell Systems need the same new password. Contact your local technical support provider for assistance.

Figure 4. VNC Password Configuration Screen, Password Stored



Continuous Cuvette Feature For User-Defined Methods

This feature ensures that reagent additions and photometer measurements occur in the same cuvette wheel positions for every patient sample test, which can improve precision. When the Continuous Cuvette feature is activated for a method, the system continues to make cuvettes and move the cuvette wheel while the test is processed.

NOTE: The Continuous Cuvette feature is defaulted to OFF. Toggle to ON if specified in the assay's application sheet.

Weighted Calibrations Option for User-Defined Methods

Calibration weighting can improve calibration curve fitting and reduce bias at important calibrator levels. Permissible values are 0–1000.

NOTE: The Weighted Calibration values are defaulted to 1. Change the values if specified in the assay's application sheet.

Configuration of the Continuous Cuvette and Weighted Calibration Features

From the Operating Menu:

1. Sign in to the system as a member of any user group with Open Channel configuration privileges.
2. Select **F7: DIAGNOSTICS > F8: OPEN CHANNELS**.

   NOTE: For new User-Defined Methods, see *User-Defined Assays* in the Operator's Guide to configure a new open channel method in the User-Defined Method screen.

   NOTE: Current User-Defined Methods have not been validated for these new options.
3. Select **F2: SETUP**. The User-Defined Method Secondary Menu screen displays.
4. Toggle the **Continuous Cuvette option** feature ON or OFF, as required.

   NOTE: The continuous cuvette feature is defaulted to OFF. Toggle to ON if specified in the assay's application sheet.
5. Enter the **Calibration Weights** presented in your application sheet.

   NOTE: If there are no **Calibration Weights** specified in the application sheet, use the default of 1 for all fields.
6. Select **F4: ACCEPT** to accept the new values. A message displays:

   ```
   The parameters have been accepted.
   ```
7. Select **EXIT.**
8. Select **F4: STORE**.

LYTES QC Levels Display In Method Review Screen

New QC levels introduced in software version 10.4.1 also display in the Method Review screen for LYTES assays.

Cybersecurity Enhancement, Upgraded Operating System

Due to end-of-life of the previous operating system, the operating system is upgraded from Debian 8 to Debian 10.2, including security patches.

New Compatible Printers

Two new printers are now compatible for use: Lexmark MS312dn and Lexmark MS321dn.

Enhanced Conditioning Procedure for X0, X1, and X2 Tubing and the IMT Sensor

This procedure must be performed every time the X0, X1, and X2 tubing is replaced. The procedure can also be performed when experiencing IMT errors that are not resolved using the standard troubleshooting steps listed in the Operator's Guide.

NOTE: These steps can be completed in approximately 40 minutes. The instrument is not available to run patient samples during this time.

NOTE: Complete this procedure using paper towels, fresh serum or plasma free of hemolysis, icterus, or lipemia (HIL), disposable pipettes, water, and the QuikLYTE Integrated multisensor.

To condition the X0, X1, and X2 tubing or the IMT Sensor, perform the following steps:

1. From the Operating Menu, and with the instrument in standby, select **F7: DIAGNOSTICS > F1: ELECTRO/MECH > F3: IMT > F8: ADVANCED DIAG**.
2. In the IMT Rotary Valve area, select **<ENTER>** to change the field from NONE to SAMPLE.
3. Manually fill the IMT port with serum or plasma free of HIL.
4. Select **F3: PUMP JOG** 10 times, with 1 second in between, to fill the X0, X1, and X2 tubing.

   NOTE: Ensure that the fluid is flowing up to the X tubing. The pump can be heard, and the fluid level in the IMT port will drop.
5. Fill the IMT port again with serum or plasma free of HIL. Select **F3: PUMP JOG** 10 times, with 1 second in between, to fill the X0, X1, and X2 tubing, ensuring the entire tubings are filled with serum or plasma.
6. Leave the serum or plasma sitting inside the tubing for 30 minutes of conditioning. The system does not display a countdown.

   NOTE: Wait for 30 minutes before proceeding to Step 7. Do not exit the IMT Advanced Diagnostics screen during the 30-minute conditioning period.
7. From the home screen, select **F4: SYSTEM PREP > F3: IMT > F2: CALIBRATION > F1: CALIBRATE**. The system primes and calibrates.

Software Security Updates

The following updates are included in this release. For additional information on these updates, visit the manufacturer's website and search by the description and version or ID number.

Table 4. Software Updates

	Manufacturer	Description	Version or ID
1	Debian Linux distribution.	Latest security updates for the Debian Buster release.	Debian 10.10

Supplemental Operating Instructions

Diluted Test Report Message Clarification

If the diluted assay result is printed, the assay range was not exceeded when rerun and the result is considered valid for reporting. If no assay result is printed, the rerun assay result did exceed the assay range. If an actual value is desired, see *Understanding Test Report Messages, Assay Range Diluted (assy rng/dilu)* in the Operator's Guide for additional instructions.

Alignment and Adjustment Measuring Feeler Gauge Tools

Two new feeler gauge tools can be used instead of using printer paper for maintenance adjustment. The ordering part number for the feeler gauge tool kit is SMN 11349508

Figure 5. Feeler Gauges.

.006 inch (.152 mm) Feeler Gauge

Measures the four-sheet paper thickness gap. Use this feeler gauge for the following procedures:

Replacing a Pump Syringe	For all Dimension Systems
Replacing a Pump Limit Sensor or Switch	For Dimension RxL, Dimension RxL Max, Dimension Xpand, and Dimension Xpand Plus Systems
Replacing a Pump Optical Sensor	For Dimension EXL 200 and Dimension EXL with LM Systems
Replacing The RMS R3 Reagent Pump Optical Sensor	For Dimension Reagent Management System (RMS) Module

.002 inch (.051 mm) Feeler Gauge

Measures the one-sheet paper thickness gap. Use this feeler gauge for the following procedures:

R1 Reagent Arm to Target (Cuvette) Alignments	For all Dimension Systems
R2 Reagent Arm to Reagent Tray Alignment	For all Dimension Systems
R2 Reagent Arm to Target (Cuvette) Alignment	For all Dimension Systems
Reagent Tray Alignment	For all Dimension Systems
Sample Probe to Cup Alignment	For all Dimension Systems
Sample Probe to Cuvette Alignment	For all Dimension Systems
Sample Probe to HM Incubate Wheel Alignment	For all Dimension Systems
IMT Probe Alignments	For Dimension EXL 200, Dimension EXL with LM, Dimension RxL, and Dimension RxL Max Systems
R2 Reagent Arm to HM Incubate Wheel Alignment	For Dimension EXL 200 and Dimension EXL with LM Systems
Sample Probe Maximum Depth Alignment	For Dimension RxL, Dimension RxL Max, Dimension Xpand, and Dimension Xpand Plus Systems
R2 Reagent Arm to Incubate Wheel Alignment	For Dimension RxL and Dimension RxL Max Systems
Sample Probe to Aliquot Wheel Alignment (non-HM)	For Dimension RxL and Dimension RxL Max Systems

R1 Reagent Arm to Reagent Tray Alignment	For Dimension RxL and Dimension RxL Max Systems
Reagent Arm to Cartridge Alignment	For Dimension Reagent Management System (RMS) Module
Aligning Sample Probe to Aliquot Segment Outer/Inner Holes	For Sample Transfer Module (STM)
Aligning the Pipette Tip to the Aliquot Segment Inner Hole	For STM
Aligning the Pipette Tip to the Aliquot Segment Outer Hole	For STM
Aligning the Pipette Tip to the Tip Tray	For STM
Aligning the IMT Probe to Aliquot Segment Outer/Inner Holes	For STM

Software Installation by Remote Update Handling or Field Service Representative

Ensure you have read and understood this document before performing any of the installation steps. Discuss any questions or concerns regarding the information in this document with your local technical support provider.

NOTE: Print and retain this document for reference during the installation.

NOTE: Remote Update Handling is only available for systems connected to Smart Remote Services (SRS) via Atellica Connectivity Manager (Atellica CM) or *syngo* Lab Connectivity Manager (sLCM).

NOTE: For systems with software version 10.4.2, call your local technical support provider to install software version 10.5.2.

Remote Update Handling Overview for Systems Running Software Version 10.4.1, 10.4.3, or 10.5.1

Remote Update Handling is used for the following situations:

- New versions of Dimension Systems software
- Security updates and configuration changes

When Dimension software version 10.5.2 is ready to be installed, a blinking icon displays in the Operating Conditions Status Area alerting the operator.

NOTE: Do not proceed with the Remote Update Handling installation procedure if the system is NOT running software version 10.4.1, 10.4.3, or 10.5.1. Software version 10.5.2 will not install on versions of Dimension software prior to 10.4.1 and may cause unnecessary downtime. If the Remote Update Handling icon is present but the system is not running software version 10.4.1 or later, contact your local technical support provider.

NOTE: Call your local technical support provider to install software version 10.5.2 if your system is currently running software version 10.4.2.

The software version 10.5.2 Release Notes with Installation Instructions is located in the Laboratory Diagnostics Document Library:

doclib.siemens-healthineers.com

Search using keywords: Dimension 10.5.2

Pre-Installation

CAUTION

To perform pre- and post-installation instructions, a user must sign in with an Operator ID having Full Control privileges for the following screens: Calibration, Correlation, and QC Ranges. As the default setting, Lab Manager and Chief Technician Operator IDs have these privileges.

Before beginning the installation, complete the following actions:

1. From the Operating Menu, select **F6: SYSTEM CONFIG**.
2. Ensure the system is running software version 10.4.1, 10.4.2, 10.4.3, or 10.5.1.

   Assay resets due to the installation of Dimension software version 10.5.2 are as follows:

Table 5. Assays Affected due to Software Installing From

Software Version Installing From	Reset Assay to Software Default / Calibration Required
10.4.1	FT4L, CSA, CSAE, and BUN
10.4.2	FT4L, CSA, CSAE, BUN, and CV2T
10.4.3	FT4L, CSA, CSAE, BUN, and CV2G
10.5.1	CV2G

NOTE: Assay key assignments, customized method parameters, and QC ranges reset to software defaults. Ensure that supplies are available to recalibrate the assays according to Table 5.

CAUTION

Do not install Dimension software version 10.5.2 without removing and discarding the Flex cartridges according to Table 5. Neglecting to do so may result in failure of the system to successfully reset the assays.

3. Remove and discard the onboard Flex reagent cartridges for the assays according to Table 5.
4. Record any key assignments for the assays according to Table 5. Navigate to **OPERATING MENU > F5: PROCESS CTRL > F8:MORE OPTIONS > F8:METHOD KEYS > F5: PRINT ALL** to print all key assignments.
5. Record customized method parameters according to Table 5. Navigate to **OPERATING MENU > F6: SYSTEM CONFIG > F1: METHOD PARAM**.

6. Select the assays according to Table 5.

   NOTE: ALT + P prints the Method Parameters screen.

   NOTE: Customized method parameters reset to software defaults. These values need to be reestablished if they have not been recorded. A delay in patient results can occur.

7. Record Assay QC ranges. Navigate to **OPERATING MENU > F5: PROCESS CTRL > F4: QC RANGES.**

   NOTE: QC ranges reset to software defaults. These values need to be reestablished if they have not been recorded. A delay in patient results can occur.

8. Select the assays according to Table 5. Then, select **ALT + P** to print each method screen.

   NOTE: F5: PRINT ALL prints the QC ranges for all methods.

9. Record any additional custom changes that may be affected due to assay resets for the assays in the screens listed in Table 6, as applicable.

Table 6. Custom Screens and Navigation

Screen	Navigation from the Operating Menu
Calculated Results	**F6: SYSTEM CONFIG > F6: SELECT PRINTER > F8: CALCULATED RES**
Define Inventory/ Hydration Setups	**F4: SYSTEM PREP > F2: REAGENT PREP > F6: REAGENT SETUP > F5: DEFINE SETUPS**
Reagent Cartridge Alert Setup	**SUPPLIES (Alert Keys Area) > F1: CONFIG ALERTS**
HIL Setup	**F5: PROCESS CTRL > F8: MORE OPTIONS > F6: HIL SETUP**
Correlation Entry	**F5: PROCESS CTRL > F2: CORRELATION**
Quality Control Status List	**F5: PROCESS CTRL > F3: QC STATUS**
Calibration Auto Acceptance Parameters	**F5: PROCESS CTRL > F1: CALIBRATION > F4: AUTO-ACCEPT**

10. Proceed to installation of software version 10.5.2 using the Remote Update Handling procedure.

Installation by Remote Update Handling Systems Running Software Version 10.4.1, 10.4.3, or 10.5.1

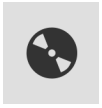
NOTE: Software version 10.5.2 cannot be directly installed on systems running software version 10.4.2. Call your local technical support provider to install software version 10.5.2 if your system is currently running software version 10.4.2. Installation by Remote Update Handling is not available for systems running software version 10.4.2.

NOTE: Remote Update Handling is only available for instruments connected to SRS via Atellica CM or *syngo* Lab Connectivity Manager. Please review these instructions with the laboratory manager.

NOTE: Field Service Representatives perform installations for Dimension Systems not connected to SRS.

CAUTION
Do not start the installation process when the system is in use. Ensure all results have been reported. A delay in reporting of patient results can occur if the installation is performed when the system is in use. Siemens Healthineers recommends starting the installation process when the system will not be in use for approximately 2 hours.

When Dimension software version 10.5.2 is ready to be installed, a blinking icon displays in the Operating Conditions Status Area alerting the operator.



1. Ensure all samples have completed processing, all results have been reported, and the system is in Standby.

   NOTE: All results will be deleted from the system when software is updated. Ensure that all results have been reported before updating.

2. Select **SHIFT+ALT** (on the left of the keyboard) **+ Enter**. A dialog box displays that informs the user how to obtain the installation instructions (this document).

   NOTE: If the software has already been prepared for installation, the dialog box appears without the Install button. Select **OK** and skip to Step 7.

3. Select **Install**.

   NOTE: Select **Close Window** to install at a later time.

4. `Preparing to Install` displays on the screen.

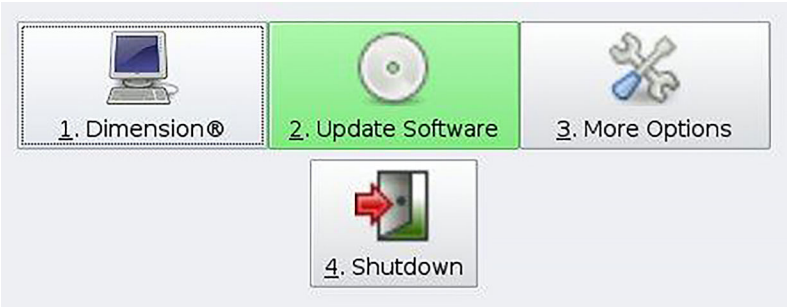
5. Select **Yes** in the dialog box to confirm that the release notes have been read and that all pre-installation steps described in these instructions have been performed.

NOTE: Select **No** if the installation instructions have not been read and the instrument has not been properly prepared for the installation. The system returns to the initial dialog box which describes where to obtain the software release notes and installation instructions.

6. Select **OK** after reading the instructions.
7. Select the SIGNOUT icon from the Quick Links Area or select **ALT+EXIT** on the keyboard.

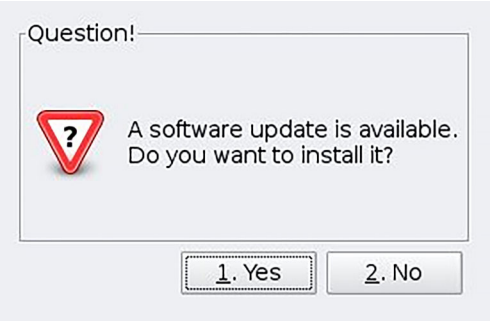
8. Select **SHUTDOWN** in the CHANGE OPERATOR pop-up window.
9. When the prompt `If you really want to shut down the application, type 'y'` displays, select **Y**.
10. Wait for the console menu to appear. Select the flashing **2. Update Software** button, or select **ALT+2** on the keyboard to continue with the installation.

Figure 6. Console Menu



11. Select **1. Yes**, or select **ALT+1** on the keyboard to begin installation.

Figure 7. Installation Pop-Up Window



The system reboots, and when installation is complete the system displays the message: `Successfully Installed Software`.

NOTE: If **2. No** is selected, see the Troubleshooting section.

12. Select **ENTER** on the keyboard to activate **<OK>** on the screen. The system restarts.
13. Select **1. Dimension®** or **ALT+1** on the keyboard to restart the Dimension application.

Post-Installation

To confirm the installation, perform the following steps:

1. Sign in with an Operator ID having Full Control privileges for the following screens: Calibration, Correlation, and QC Ranges. As the default setting, Lab Manager and Chief Technician Operator IDs have these privileges.
2. Verify Dimension System software version 10.5.2 is indicated on the System Configuration screen.

   NOTE: If the version is not correct, contact your local technical support provider.

3. Restore the assay key assignments according to Table 7, if applicable. Navigate to **OPERATING MENU > F5: PROCESS CTRL > F8: MORE OPTIONS > F8: METHOD KEYS > F1: VIEW BY METHOD**.

   Assay resets due to the installation of Dimension software version 10.5.2 are as follows:

Table 7. Software Version Installing From and Assays Updated

Software Version Installing From	Flex Cartridges To Be Restored
10.4.1	FT4L, CSA, CSAE, and BUN
10.4.2	FT4L, CSA, CSAE, BUN, and CV2T
10.4.3	FT4L, CSA, CSAE, BUN, and CV2G
10.5.1	CV2G

4. Assay key assignments, customized method parameters, and QC ranges reset to software defaults. Ensure that supplies are available to recalibrate the assays according to Table 7.
5. Move the cursor to the assays.
6. With the assay highlighted, select **F5: ASSIGN KEY**. Select the recorded key assigned to the assay.
7. Repeat Steps 5 and 6 for each assay in use.
8. Select **F8: STORE**.
9. Restore customized method parameters. Navigate to **OPERATING MENU > F6: SYSTEM CONFIG > F1: METHOD PARAM** and select the assays according to Table 7, if applicable. Then, enter the appropriate method parameters.
10. Select **F4: STORE PARAM's** for each assay.
11. Restore Assay QC ranges. Navigate to **OPERATING MENU > F5: PROCESS CTRL > F4: QC RANGES** and select the assays according to Table 7, if applicable. Then, enter the appropriate QC range information. See *Defining QC Ranges* in the Operator's Guide.
12. Select **F2: STORE CHANGES** after entering the range information for each assay.

13. Restore changes that may be affected by assay resets for the assays in the screens listed in Table 8, as applicable. Refer to the Operator's Guide for the procedures to enter values.

Table 8. Custom Screens and Navigations

Screen	Navigation from the Operating Menu
Calculated Results	**F6: SYSTEM CONFIG > F6: SELECT PRINTER > F8: CALCULATED RES**
Define Inventory/ Hydration Setups	**F4: SYSTEM PREP > F2: REAGENT PREP > F6: REAGENT SETUP > F5: DEFINE SETUPS**
Reagent Cartridge Alert Setup	**SUPPLIES (Alert Keys Area) > F1: CONFIG ALERTS**
HIL Setup	**F5: PROCESS CTRL > F8: MORE OPTIONS > F6: HIL SETUP**
Correlation Entry	**F5: PROCESS CTRL > F2: CORRELATION**
Quality Control Status List	**F5: PROCESS CTRL > F3: QC STATUS**
Calibration Auto Acceptance Parameters	**F5: PROCESS CTRL > F1: CALIBRATION > F4: AUTO-ACCEPT**

Post-Installation Check

1. Run system check. If either the RFG HOT or the CVT COLD icon displays, wait until it disappears before running the system check.
2. Recalibrate the assays according to Table 9.

   NOTE: Assay resets due to the installation of Dimension software version 10.5.2 are as follows:

Table 9. Recalibration Due To Assay Resets

Software Version Installing From	Assay Resets
10.4.1	FT4L, CSA, CSAE, and BUN
10.4.2	FT4L, CSA, CSAE, BUN, and CV2T
10.4.3	FT4L, CSA, CSAE, BUN, and CV2G
10.5.1	CV2G

3. Assay key assignments, customized method parameters, and QC ranges reset to software defaults. Ensure that supplies are available to recalibrate the assays according to Table 9.
4. Run Quality Control on all methods in use. Review QC versus established ranges.

5. Document the installation of software version 10.5.2 in the Instrument Log for the system.
6. For remote access and screen sharing, configure the VNC password. See *Cybersecurity Enhancement, Virtual Network Computing (VNC) Authentication* on page 6.

NOTE: Configure VNC password if installing software version 10.5.2 from software version 10.4.1. 10.4.2, or 10.4.3.

Troubleshooting

- If a System Error is reported when the FT4L, CSA, CSAE, BUN, CV2T, or CV2G assays are run, the FT4L, CSA, CSAE, BUN, CV2T, or CV2G Flex cartridges were not removed prior to installing the Dimension software version 10.5.2. Remove and discard the Flex cartridges, then load new Flex cartridges.
- If the Dimension software version 10.5.2 upgrade does not complete for any reason, the system attempts to automatically recover and return the Dimension system software to its existing software version. Depending on the error, the following message can display:

  ```
  A problem occurred while preparing the software for installation.
  Software installation has been canceled with no effect.
  ```

  If this message displays:

  1. Select **ENTER** to acknowledge the message.
  2. Select **1. Dimension®** or **ALT+1** on the keyboard to restart the Dimension system.

  NOTE: The system restarts at the existing software version.

  NOTE: If the installation fails and the system cannot automatically recover (for example, if there is a loss of power during the installation), the issue must be resolved by a technical support provider. The Dimension system is inoperable until the problem is resolved. Contact your local technical support provider.

- If **2. No** was inadvertently selected in Step 11 of the Installation by Remote Update Handling instructions, the installation will be aborted.

  1. A message displays: `Please insert the software installation media (CD/USB)`. Select **2. Cancel** or **ALT+2** on the keyboard.

  NOTE: The installation media CD/USB is for service use only.

  2. Select **1. OK** or **ALT+1** on the keyboard to abort the installation of the updated software.

  3. To install the software update, start at the beginning of the installation section of this procedure.
- If the RUH icon reappears after a successful installation, contact your local technical support provider to clear the icon.
- If remote control and screen sharing does not work, ensure that the passwords match on the Dimension and remote access systems. If the problem persists, contact your local technical support provider.

Software Certificate Statement

The identified software was designed in accordance with the Food and Drug Administration's (FDA) *Current Good Manufacturing Practice (CGMP) for Medical Devices and In Vitro Diagnostic Products, 21 CFR–Part 820.30 (Design Controls)*.

The identified software was also designed in accordance with the EU IVD Directive *Directive98/79/EC of the European Parliament* and of *The Council of 27 October 1998 on In Vitro Diagnostic Medical Devices*.

The identified software was also designed in accordance with an approved plan that addressed Configuration and Change Management, Requirements Definition, Software Safety Risk Management, Design, Implementation, Integration, Verification, and Validation.

Upon completion of the development process, the software proceeded through a design review in accordance to a defined procedure and was approved for release.

Copyright Information

The components of open source software included in this device are as follows:

- dwm (Dynamic Window Manager) V6.0 © 2011 suckless.org
  Modifications © 2017, 2018, 2019 Siemens Healthcare Diagnostics Inc.
- Debian Linux distribution V10.10 © 2021 Debian
- Linux Kernel V4.19.67 © Linux Kernel Developers
  Modifications © 2019 Siemens Healthcare Diagnostics Inc.
- Linux Kernel Real-Time Patch V4.19.67-rt24 © 2019 Linux Kernel Real-Time Developers
- Kvaser Can Bus Driver, V5.28 ©2017–2019 Kvaser
  Modifications © 2019 Siemens Healthcare Diagnostics Inc.
- Comtrol Rocketport Driver, V4.08, © 2014
- Comtrol Rocketport Express driver, V2.18, © 2012
- Mono JIT compiler, V5.18, © 2002–2014
- x11vnc, V0.9.12, © 2002–2009

Each component of open source software included in this device is licensed under at least one of the following licenses:

- License information is available at www.debian.org
- GNU General Public License (GPL) v1, v2
  (Versions of the GNU LGPL are available at www.gnu.org)
- GNU Lesser General Public License (LGPL) v1, v2, v2.1
  (Versions of the GNU LGPL are available at www.gnu.org)
- Artistic License v1.0
  (Versions of the Artistic License are available at www.perlfoundation.org)
- BSD License
  (The BSD License is available at www.opensource.org)
- MIT/X Consortium License

The copyright information for each component of open source software included in this device is embedded in its applicable source code.

Trademark Information

Atellica, Dimension, EXL, Flex, LOCI, RxL Max, VersaCell, and Xpand are trademarks of Siemens Healthineers.

syngo is a trademark of Siemens Healthcare GmbH.

All other trademarks and brands are the property of their respective owners.