

Software Version 10.4.3 Release Notes with Installation Instructions

Siemens Healthineers introduces Dimension® Systems software version 10.4.3. Dimension Systems software version 10.4.3 is installed by a qualified Service Representative or via Remote Update Handling. This document presents the following information:

- Dimension software version 10.4.3 assay updates
- For future assays

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.

www.siemens-healthineers.com

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Installation

Software version 10.4.3 can be installed on the following systems currently running software version 10.4.1 or 10.4.2:

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

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

NOTE: Instruments with software version 10.4.1 or 10.4.2:

- Refer to the *Software Version 10.4.3 from Software Version 10.4.1* or *Software Version 10.4.3 from Software Version 10.4.2* section in this document.

Release Notes are located in the Laboratory Diagnostics Document Library:

www.siemens.com/document-library

Search using keywords: Dimension 10.4.3

Ensure you have read and understood all appropriate documents 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.

New Features

Assay Updates

NOTE: CV2T and CV2G* are LOCI® assays for the Dimension EXL 200 and Dimension EXL with LM systems only.

See the *Assay Installation Instructions Dimension® EXL™ SARS-CoV-2 IgG (CV2G) Assay* document, SMN 11536762, for specific instructions to install the new CV2G assay. The document is located in the Siemens Laboratory Diagnostics Document Library:

www.siemens.com/document-library

Search using keywords: Dimension CV2G

* Not commercially available in the US. Due to regulatory reasons, the future availability of this assay cannot be guaranteed.

See the *Assay Installation Instructions Dimension® EXL™ SARS-CoV-2 Total Antibody (CV2T) Assay* document, SMN 11536683, for specific instructions to install the CV2T assay. The Dimension EXL CV2T assay is released via Emergency Use Authorization. The document is located in the Siemens Laboratory Diagnostics Document Library:

www.siemens.com/document-library

Searching keywords: Dimension CV2T

Updated Features

Assay Updates

For customers installing software version 10.4.3 from software version 10.4.2 updates are as follows: Supplemental Operating Instructions

Assay	Change	IFU Updated	Calibration Required
CV2T	<ul style="list-style-type: none"> 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. 	Yes	Yes

Software Version 10.4.3 from Software Version 10.4.1

Software Installation by Service Representative

Pre-Installation

The following procedure provides customer instructions that are done in preparation of version 10.4.3 software installation from software version 10.4.1.

1. From the Operating Menu, select **F6: SYSTEM CONFIG** and locate the Software Revision field to verify the instrument's current software version is 10.4.1.

Post-Installation Check

1. Sign in with labmanager privileges.
2. Run system check. If either RFG HOT or CVT COLD displays, wait until the icon disappears before running the system check.
3. Run Quality Control on all methods in use. Review QC versus established ranges.
4. Document the installation of software version 10.4.3 in the Instrument Log for the system.

Software Installation by Remote Update Handling

NOTE: Remote Update Handling is only available for users connected to Smart Remote Services (SRS) via Atellica® Connectivity Manager (Atellica CM) or syngo® Laboratory Connectivity Manager (LCM).

Remote Update Handling Overview

When Dimension software version 10.4.3 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. If the Remote Update Handling icon is present but the system is not running software version 10.4.1, contact your local technical support provider.

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

The software version 10.4.3 Release Notes with installation instructions is located in the Laboratory Diagnostics Document Library:

www.siemens.com/document-library

Search using keywords: Dimension 10.4.3

Pre-Installation

Before beginning the installation, complete the following actions:

1. From the Operating Menu, select **F6: SYSTEM CONFIG** and locate the Software Revision field to verify the instrument's current software is version 10.4.1.
2. Proceed with the installation of software version 10.4.3 using the Remote Update Handling procedure.

Installation



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 recommends starting the installation process when the system will not be in use for approximately 1 hour.

When Dimension software version 10.4.3 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.



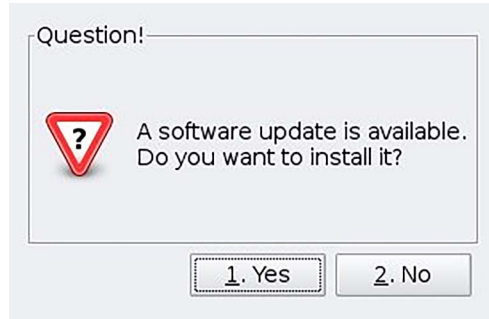
8. Select **SHUTDOWN** in the CHANGE OPERATOR pop-up window.
9. When the prompt `If you really want to shut down the application, type 'y'` displays, select **Yes** in the dialog box, or select **Y**.
10. Wait for the console menu to appear. Select the flashing **2. Update Software** button, or select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

Figure 1. Console Menu



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

Figure 2. 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. Verify Dimension system software version 10.4.3 is indicated on the System Configuration screen.

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

2. Sign in with labmanager privileges.

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. Run Quality Control on all methods in use. Review QC versus established ranges.

3. Document the installation of software version 10.4.3 in the Instrument Log for the system.

Software Version 10.4.3 from Software Version 10.4.2

Software Installation by Service Representative

Pre-Installation

The following procedure provides customer instructions that are done in preparation of version 10.4.3 from software version 10.4.2.

NOTE: Installation of software version 10.4.3 from software version 10.4.2 will reset the CV2T assay. Ensure that supplies are available to recalibrate the CV2T assay.

1. Sign in with labmanager privileges.
2. From the Operating Menu, select **F6: SYSTEM CONFIG** and locate the Software Revision field to verify the instrument's current software version is 10.4.2.
3. Remove and discard the onboard CV2T reagent cartridges.



CAUTION

Failure of the system to reset CV2T successfully may occur if the CV2T Flex cartridges are not removed before installing Dimension software version 10.4.3.

4. Record any key assignments for the CV2T assay. Navigate to **OPERATING MENU > F5: PROCESS CTRL > F8: MORE OPTIONS > F8: METHOD KEYS** to view key assignments.
5. Record customized CV2T method parameters. Navigate to **OPERATING MENU > F6: SYSTEM CONFIG > F1: METHOD PARAM.**
6. Select **CV2T**.

NOTE: Customized method parameters will reset to software defaults. These values will need to be reestablished if they have not been recorded.

7. Record Assay QC ranges. Navigate to **OPERATING MENU > F5: PROCESS CTRL > F4: QC RANGES**. Select **CV2T** and record QC values, or select **F5: PRINT ALL**.

NOTE: QC ranges will reset to software defaults. These values will need to be reestablished if they have not been recorded.

NOTE: All method QC values will print if **F5: PRINT ALL** is selected.

NOTE: Ensure that supplies are available to recalibrate the CV2T assay.

Post-Installation

The installation of software version 10.4.3 from software version 10.4.2 will reset the CV2T assay. The key assignment, method parameters, and QC ranges will be reset to software defaults.

Post-Installation Check

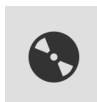
1. Sign in with labmanager privileges.
2. Perform the following steps for the CV2T assay:
 - Load new Flex cartridges
 - Restore the key assignment, customized assay method parameters, and assay QC ranges.
3. Run system check. If either RFG HOT or CVT COLD displays, wait until the icon disappears before running the system check.
4. Calibrate the CV2T assay.
5. Run Quality Control on all methods in use. Review QC versus established ranges.
6. Document the installation of software version 10.4.3 in the Instrument Log for the system.

Software Installation by Remote Update Handling

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

Remote Update Handling Overview

When Dimension Software Version 10.4.3 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 10.4.2. Ensure you have read and understood this document before performing any of the installation steps. If you have any questions or concerns regarding the information in this document, contact your local technical support provider.

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

Pre-Installation

The following procedure provides customer instructions that are done in preparation of version 10.4.3 from software version 10.4.2.

NOTE: Installation of software version 10.4.3 from software version 10.4.2 will reset the CV2T assay. Ensure that supplies are available to recalibrate the CV2T assay.

1. Sign in with labmanager privileges.
2. From the Operating Menu, select **F6: SYSTEM CONFIG** and locate the Software Revision field to verify the instrument's current software version is 10.4.2.
3. Remove and discard the onboard CV2T reagent cartridges.



CAUTION

Failure of the system to reset CV2T successfully may occur if the CV2T Flex cartridges are not removed before installing Dimension software version 10.4.3.

4. Record any key assignments for the CV2T assay. Navigate to **OPERATING MENU > F5: PROCESS CTRL > F8:MORE OPTIONS > F8:METHOD KEYS** to view key assignments.
5. Record customized CV2T method parameters. Navigate to **OPERATING MENU > F6: SYSTEM CONFIG > F1: METHOD PARAM.**

6. Select **CV2T**.

NOTE: Customized method parameters will reset to software defaults. These values will need to be reestablished if they have not been recorded.

7. Record Assay QC ranges. Navigate to **OPERATING MENU > F5: PROCESS CTRL > F4: QC RANGES**. Select **CV2T** and record QC values, or select **F5: PRINT ALL**.

NOTE: QC ranges will reset to software defaults. These values will need to be reestablished if they have not been recorded.

NOTE: All method QC values will print if **F5: PRINT ALL** is selected.

Installation



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 recommends starting the installation process when the system will not be in use for approximately 1 hour.

When Dimension Software Version 10.4.3 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. Press **Shift+Alt** (on the left of the keyboard) **+Enter**. A dialog box appears 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 will appear 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 is displayed 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: Press **No** if the installation instructions have not been read and the instrument has not been properly prepared for the installation. The system will return to the initial dialog box which described 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.



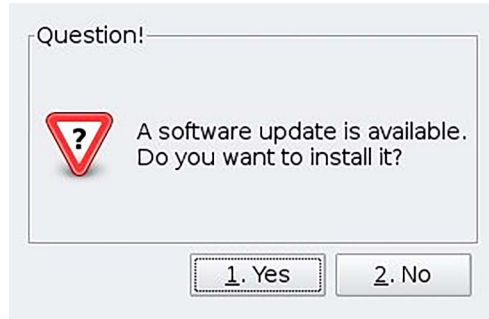
8. Select **SHUTDOWN** in the **CHANGE OPERATOR** pop-up window.
9. When the prompt `If you really want to shut down the application, type 'y'` displays, select **Y**.
10. Wait for the console menu to appear. Select the flashing **Update Software** button or press **Alt+2** to continue with the installation.

Figure 3. Console Menu



11. Select **1. Yes** or press **Alt+1** to begin installation.

Figure 4. 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. Press **ENTER** to select <OK>. The system restarts.

13. Select **1. Dimension®** or **Alt+1** on the keyboard to restart the Dimension application.

Post-Installation

1. Verify Dimension system software version 10.4.3 is indicated on the System Configuration screen.

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

2. Sign in with labmanager privileges.

3. Perform the following steps for the CV2T assay:

- Load new Flex cartridges
- Restore the key assignment, customized assay method parameters, and assay QC ranges.

4. Run system check. If either RFG HOT or CVT COLD displays, wait until the icon disappears before running the system check.

5. Calibrate the CV2T assay.

6. Run Quality Control on all methods in use. Review QC versus established ranges.

7. Document the installation of software version 10.4.3 in the Instrument Log for the system.

Troubleshooting

- If the Dimension software version 10.4.3 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 or distributor. 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.
 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 Remote Update Handling icon reappears after a successful installation, contact your local technical support provider to clear the icon.
- For customers installing software version 10.4.3 onto software version 10.4.2, if a system error is reported when the CV2T assays are run the Flex cartridges were not removed prior to installation of software version 10.4.3. Remove and discard the Flex cartridges, then replace them with new ones.

Software Certification Statement

The identified software was designed in accordance to 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 to the EU IVD Directive *Directive 98/79/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 to 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.

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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
- Debian Linux distribution V8.11 © 2016, 2018, 2019 Debian
- Linux Kernel V3.18.123 © Linux Kernel Developers
Modifications © 2017, 2018, 2019 Siemens Healthcare Diagnostics
- Linux Kernel Real-Time Patch V3.18.123-rt107 © 2016 Linux Kernel Real-Time Developers
- Kvaser Can Bus Driver, V5.15 © 2015 Kvaser
Modifications © 2017 Siemens Healthcare Diagnostics
- Control Rocketport Driver, V4.03, © 2014
- Control Rocketport Express driver, V2.10, © 2012
- Mono JIT compiler, V5.18, © 2002-2014
- x11vnc, V0.9.12, © 2002-2009

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