

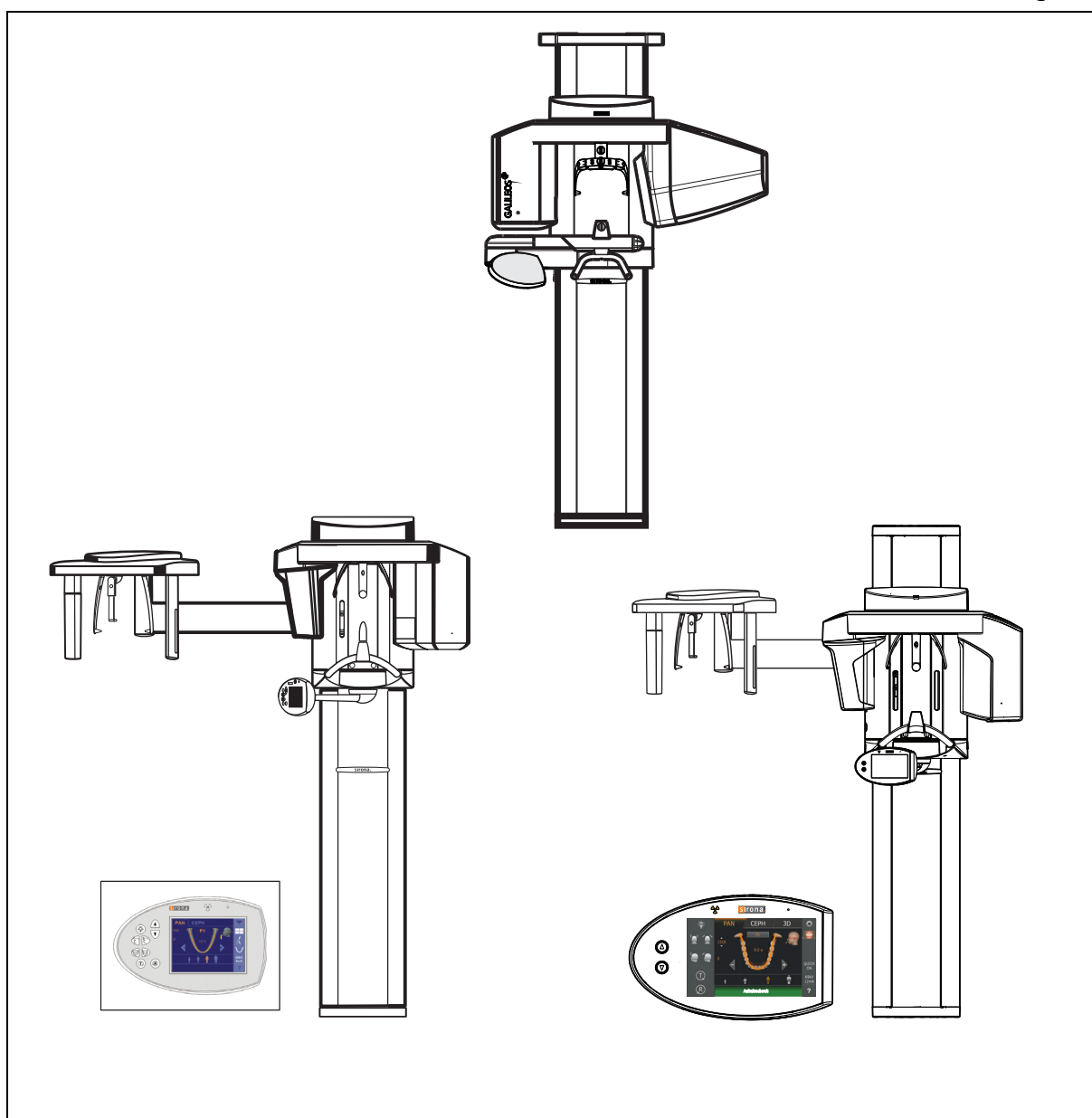
New as of:

01.2017

# ORTHOPHOS SL 3D ORTHOPHOS XG 3D GALILEOS Comfort Plus

Quality Assurance Tool Installation Instructions and Operating Instructions

English



# 1 Installing the Quality Assurance Tool

- ✓ You have access to the Sirona homepage.  
The Quality Assurance Tool and corresponding documentation can be downloaded from:  
<http://www.sironasupport.com> > imaging > USER DOCUMENTATION

- ✓ NOTE! This tool is only provided for installation on the RCU.

1. Start the automatic installation of the Quality Assurance Tool (QA Tool) with the Autorun.exe.

↳ The start window appears.



2. Continue the installation by pressing the "Quality Assurance Tool" button.

↳ A Quality Assurance Tool 1.2. Installation window appears.

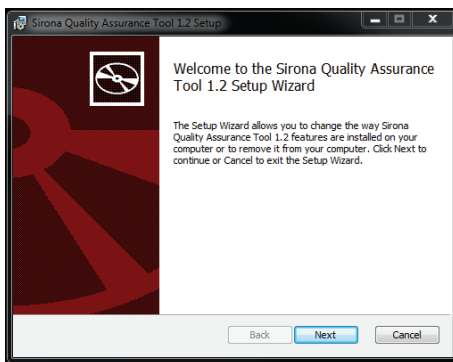


3. Click "Next".

↳ The installation starts.

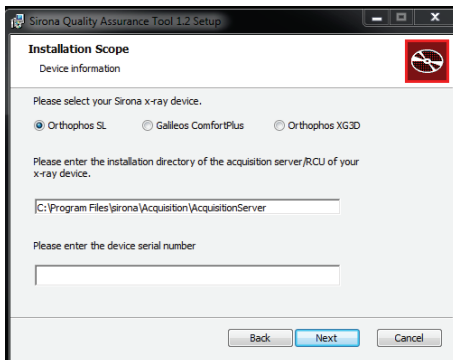
↳ The Setup Wizard window appears





4. Press "Next" to start.

↳ The "Installation Scope" window appears



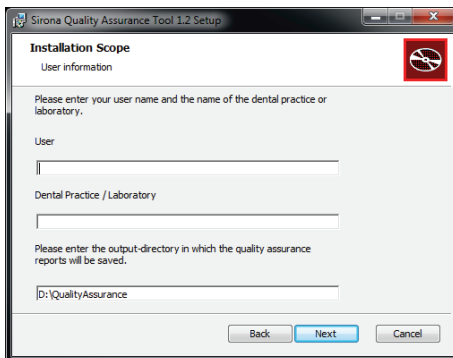
5. Select the corresponding X-ray device.
6. Enter the storage location for the acquisition server/RCU. Proceed as follows for the different X-ray units:  
For ORTHOPHOS SL: Specify the installation path for the acquisition server.  
**IMPORTANT:** The default installation path for the acquisition server is: C:\Program Files\Sirona\Acquisition\AcquisitionServer.

For ORTHOPHOS XG 3D/GALILEOS Comfort Plus: Specify the installation path for the NGImagingServer.

**IMPORTANT:** The default installation path for the NGImagingServer is: C:\Program Files (x86)\Sirona\GALILEOS

7. Note down the serial number of the X-ray unit and press the "Next" button
8. Enter the user and the name of the practice/the operator of the unit. This information appears later in the measurement protocol, the report.

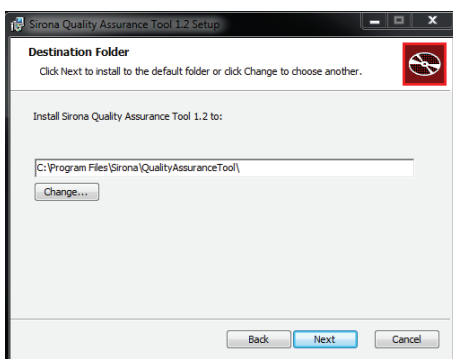
↳ The "Installation Scope - User Information" image appears.



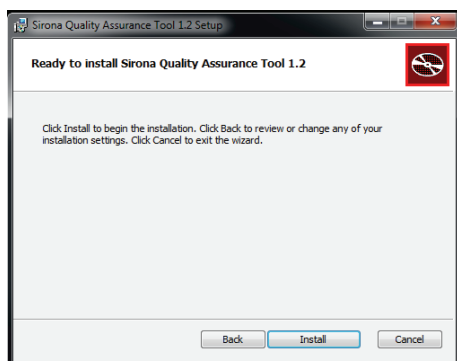
9. Specify the storage location for the Quality Assurance Report.  
**NOTE:** Make sure that the folder has the appropriate write authorization.  
↳ The program automatically generates a Quality Assurance Report and a cross section of the 3D exposure with the test phantom. This can be found in the output directory. Determine the storage location for this.

10. Press the "Next" button.

↳ The "Destination Folder" image appears. Accept the storage location or change it accordingly.

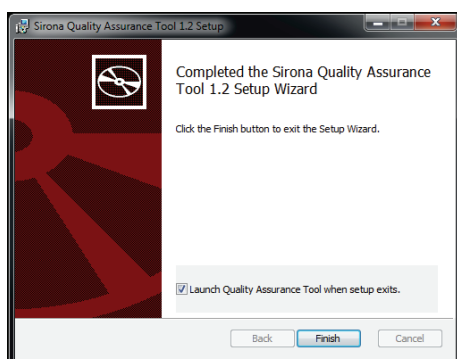


11. Press the "Next" button.



12. Then press the “Install” button.

→ The start window for installing the program opens.



→ The program is automatically installed.

Following successful installation of the QA Tool, the following image appears:

“Complete the Sirona Quality Assurance Tool 1.2 Setup Wizard”

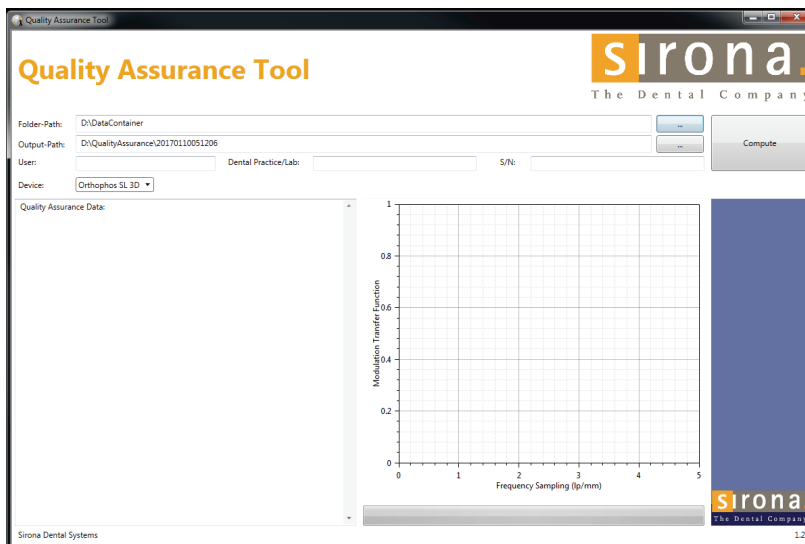
13. Press the “Finish” button and the installation is completed.

→ The start window appears.

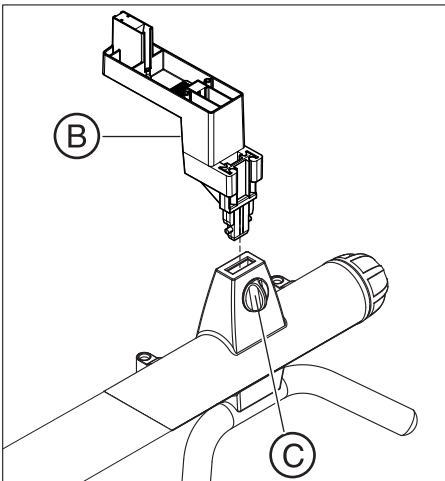
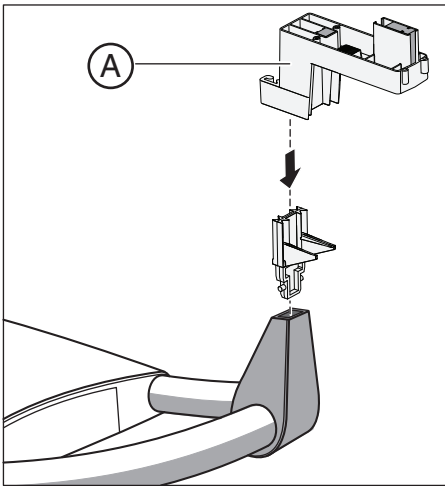


14. Press the “Quit” button.

→ The following completion screen appears:



## 2 Operating the Quality Assurance Tool



- ✓ An exposure must be performed with the 3D constancy test phantom in patient mode.

1. Insert the correct constancy test phantom for the unit into the bite block of the unit.  
**ATTENTION!** The constancy test phantoms for GALILEOS Comfort Plus and ORTHOPHOS XG 3D/SL differ in size.

For ORTHOPHOS XG 3D/SL: Insert the constancy test phantom (A) into the bite block of the unit.

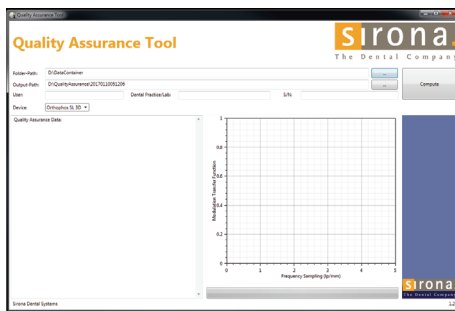
For GALILEOS Comfort Plus: Insert the constancy test phantom (B) into the bite block of the unit and lock it in place with the rotary knob (C).

2. Set the exposure parameters on the Easypad for the X-ray unit.  
 For ORTHOPHOS SL 3D:  
 Patient 1, front tooth volume 8x8, HDOff (85 kV, 23 mAs, 7 mA)

For ORTHOPHOS XG 3D:  
 Patient 1, 8x8, HDOff (85 kV, 23 mAs, 7 mA)

For GALILEOS Comfort Plus:  
 Patient 3, HCOFF, HDOff (98 kV, 10 mAs 5 mA)

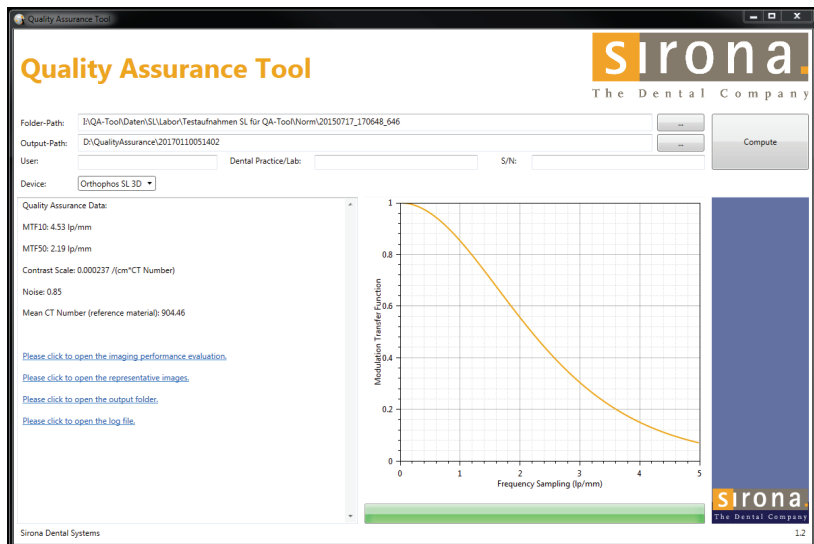
3. Make ready for exposure in SIDEXIS (see Sidexis 4 Operator's Manual).
4. **CAUTION! Activating the release button triggers X-rays.**  
 Start the exposure by pressing the release button. Hold down the release button until image acquisition is completed and the acoustic signal that indicates the end of the exposure can be heard.  
 ☞ The data container is automatically stored in the path set up by you in SIDEXIS 4.



5. Start the “Quality Assurance Tool” program via the start menu by selecting the shortcut.
6. In the “Folder Path”, select the corresponding data container of the previously generated X-ray exposure and start checking the quality exposure with “Compute”.
  - ↳ Following a brief calculation time, the results of the quality check appear.

## IMPORTANT

Ensure that you always evaluate the test phantom exposure in the same way. If a patient exposure interferes, the simplest solution is to create a new test phantom exposure.



## Evaluation of results

The MTF curve is graphically represented and values are calculated for the MTF10, MTF50, Contrast Scale, Noise and Mean CT number. The MTF10 value must be greater than 1 lp/mm. The MTF50 value must be greater than 0 lp/mm. Contrast Scale must be greater than 0 and should be in the scale of 0.0002 (+/- fluctuation). The Noise value should be greater than 0.



### Report - Imaging Performance Evaluation

Sirona Dental Systems

This report documents the system performance according the FDA federal regulations  
21CFR2020.33.

Date: 2015/07/14 09:01:26 AM, QA-Tool Version: 1.0

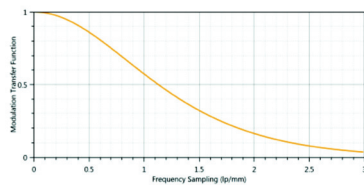
#### User Information

User	Lab/Dental Practice	Device Serial Number
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#### Quality Assurance Data

Quantities	MTF <sub>50</sub>	MTF <sub>10</sub>	Contrast Scale	Noise	Mean CT No.
Values	2.33	1.13	0.000236	2.31	1065.78
Limits	>3	—	—	<18	—

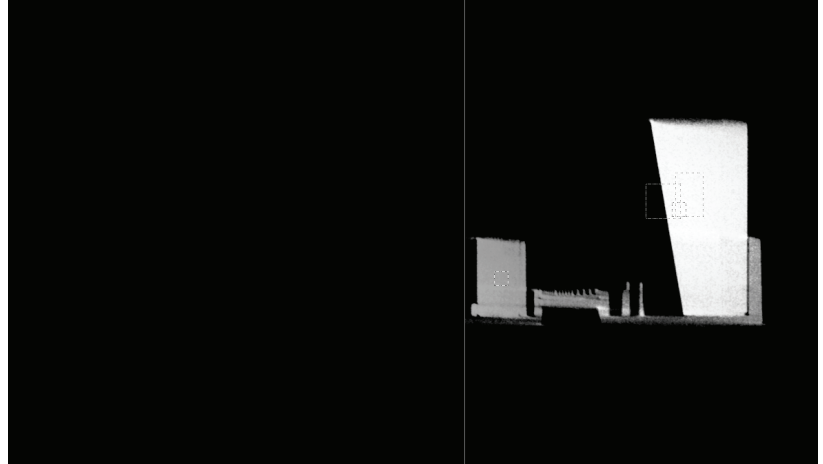
#### Modulation Transfer Function



Performance Evaluation: passed  
© 2015, Sirona Dental Systems

Sign:

- A measured data protocol is created in the output path as a PDF file with the user and unit data entered in the setup. A TIF file with the cross-sectional image of the test phantom reconstruction is also saved in the same directory; see Installing the Quality Assurance Tool [ → 2] .



Close the exposures and the Quality Assurance program.

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We reserve the right to make any alterations which may be required due to technical improvements.

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D3632.031.03.03.02 01.2017

Sprache: englisch  
Ä.-Nr.: 123 331

Printed in Germany

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**Sirona Dental Systems GmbH**



Fabrikstraße 31  
D-64625 Bensheim  
Germany  
[www.sirona.com](http://www.sirona.com)

**Contact in the USA:**

Sirona Dental, Inc.  
4835 Sirona Drive  
Charlotte, NC 28273  
USA

Order No

**65 63 576 D3632**