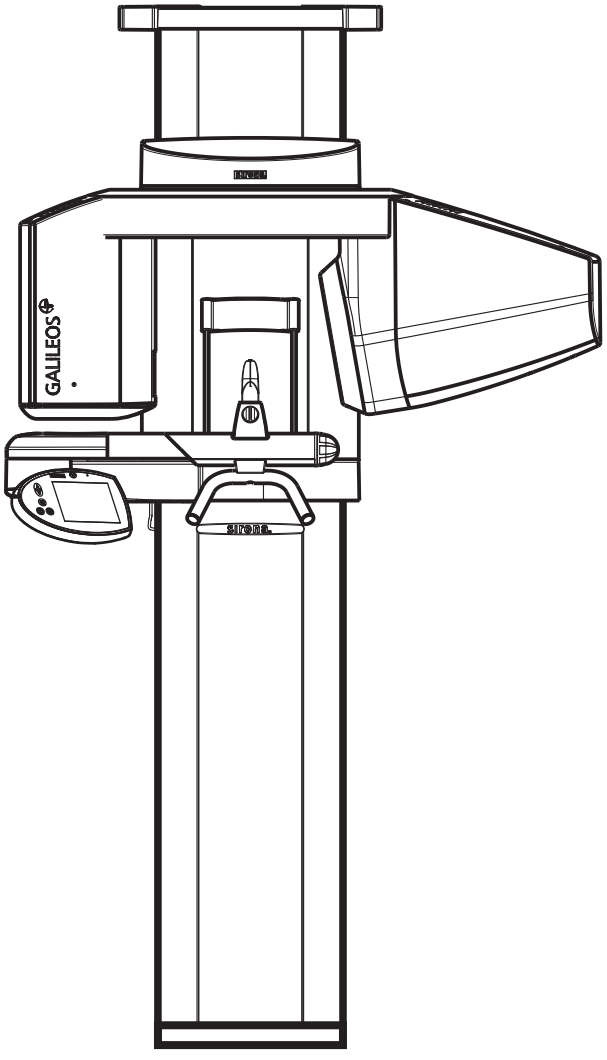
New as of: 06.2016

sirona
The Dental Company

GALILEOS

Quality inspection

English



Contents

1 Quality test

1.1 General

Explanation

SIRONA offers a quality test in order to ensure image quality.

Recommendation

The service engineer who performed the unit adjustment should enter the dose value measured during the unit adjustment in the chapter entitled TEST REPORT.

The user should see to it that a constancy test [→ 6] is performed once a month within the scope of quality assurance.

Prerequisites

A reference image for the constancy test [→ 13] must be taken first.

- The service engineer should create this image during the unit installation.
- Alternatively, it could also be taken by the responsible administrator in possession of the required password.

1.2 Structure of the document

1.2.1 Identification of the danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in these operating instructions. Such information is highlighted as follows:

⚠ DANGER

An imminent danger that could result in serious bodily injury or death.

⚠ WARNING

A possibly dangerous situation that could result in serious bodily injury or death.

⚠ CAUTION

A possibly dangerous situation that could result in slight bodily injury.

NOTICE

A possibly harmful situation which could lead to damage of the product or an object in its environment.

IMPORTANT

Application instructions and other important information.

Tip: Information on making work easier.

1.2.2 Formats and symbols used

The formats and symbols used in this document have the following meaning:

✓ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result ➢ Individual action step	Prompts you to do something.
See "Formats and symbols used [→ 4]"	Identifies a reference to another text passage and specifies its page number.
• List	Designates a list.
"Command / menu item"	Indicates commands, menu items or quotations.

2 Constancy test

2.1 Explanation

Contents

This chapter explains how to perform a constancy test.

Prerequisite

- Reference images must be available in order to perform a constancy test.
  - The reference images must be taken by a service engineer (password-protected area)
  - The chapter entitled "Reference images for the constancy test" describes how to take these reference images.
  - The work steps for taking the reference images are referred to as "Acceptance test" in the relevant document and in the software.

Test results

The **TEST RESULTS** form is used to document the results of the constancy test.

There are two ways to document test results.

- **Option 1**

  The test results are to be entered by hand on paper.

  They are attached to the end of this document.

- **Option 2**

  The test results can be entered by the constancy test program.

  This generates a PDF document, which then has to be printed out.

  For more information, refer to the section "Test results and TEST REPORT as a PDF document".

Test results of reference images

The test results of the reference images have to be compared to the test results of the constancy test, upon request.

2.2 Preparing the X-ray device

NOTICE
Observe Operating Instructions!

Make sure that no foreign particles are located in the beam path of the X-ray device and that the X-ray device is in its starting position.

1. Remove the bite block from the bite block holder.
2. Remove the forehead support.

2.3 Starting the constancy test program

2.3.1 Overview

Explanation

The start-up procedure differs depending on the version of SIDEXIS.

Description

- SIDEXIS XG [→ 7]
- SIDEXIS 4 [→ 7]

2.3.2 SIDEXIS XG

Reminder

If more than 30 days (configuration under *"Utilities"* / *"Configure system..."* / *"Constancy test"*) have elapsed since the acceptance test or the last constancy test, a dialog box reminding you that the constancy test is overdue may appear after the start of SIDEXIS XG.

➢ Acknowledge with *"OK"*.

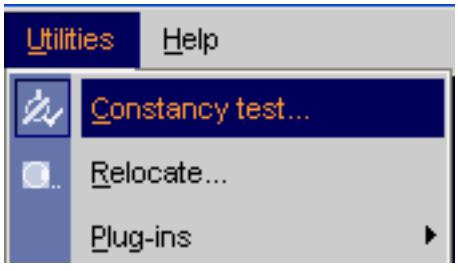
NOTICE

The time interval refers to the last constancy test that was performed on this PC.

The program makes no distinction between different X-ray devices.

The system owner is responsible for determining which X-ray device is due for a new constancy test.

Start

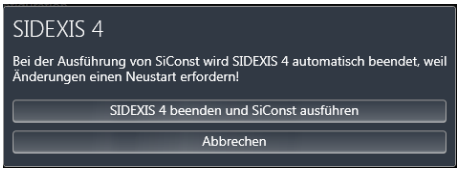


1. Start SIDEXIS XG.
2. Click the *"Constancy test"* menu option on the *"Utilities"* menu bar.

↳ The test program starts.

2.3.3 SIDEXIS 4

1. Start SIDEXIS 4.
2. In SIDEXIS 4, call the *"SIDEXIS Tools"* / *"Devices"* configuration menu.



3. Click on the *"SiConst / Constancy test "* button.
   ↳ A reconfirmation dialog box appears.
4. Confirm this dialog box.
   ↳ SIDEXIS 4 is closed.
   ↳ The *"SiConst"* program starts.

2.4 Selecting the X-ray device on the PC

Selection

1. Click the *"Select..."* menu option on the *"X-ray device"* menu bar.
   ↳ The *"Select X-ray device"* window opens.
2. Select the desired X-ray device from the list.
3. Acknowledge your selection with *"OK"*.
   ↳ The window closes.

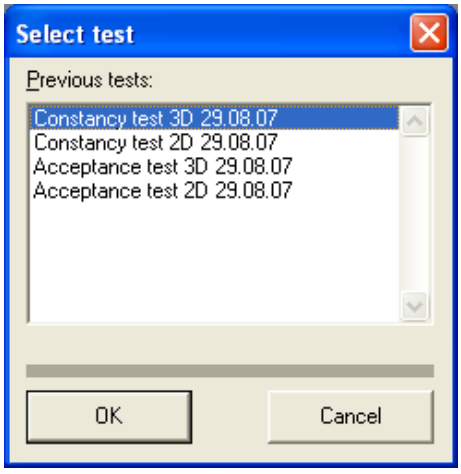
↳ The X-ray device is now selected.

2.5 Selecting the reference image for the constancy test

NOTICE

The image from the acceptance test is always used as the basis for the constancy test.

1. Click the *"Select image"* button in the left tool bar
   or
   Click the *"Select..."* menu option on the *"Test "* menu bar



2. Select *"Acceptance test 3D"*.
3. Acknowledge with *"OK"*.

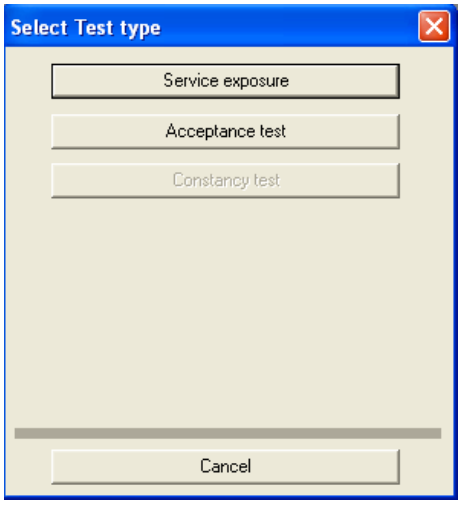
↳ The test phantom image of *"Acceptance test 3D"* appears

2.6 Making the PC ready for an exposure

Opening

1. Click the *"3D acquisition"* button in the left tool bar
   or
   Click the *"3D-Scan"* menu option on the *"Test "* menu bar.

   ↳ The *"Select Test type "* dialog box appears.



2. Click the *"Constancy test"* button.

   ↳ The *"Constancy test"* dialog box appears.
3. In the *"Konstanzpruefung 3D Sirona Standard"* section, select the option *"Constancy test 3D "*.
4. Press the *"Image acquisition"* button.

↳ The exposure readiness dialog box opens.

2.7 Taking and evaluating exposures

Explanation

The constancy test is performed through the *"Constancy test"* dialog.

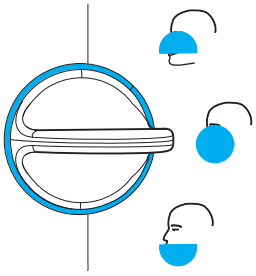
A 3D X-ray exposure is performed with a test phantom.

Prerequisite

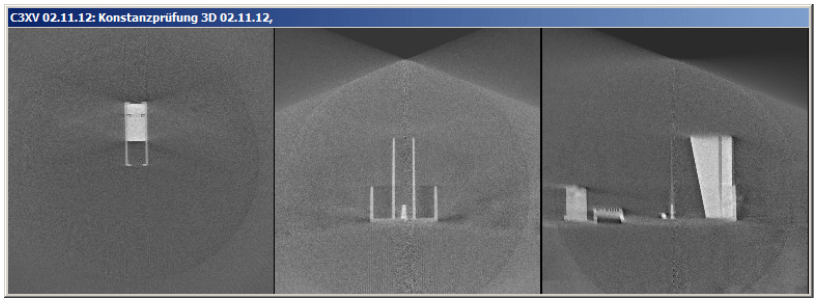
The *"Constancy test"* dialog box opens.

2.7.1 Exposure

1. Insert the test phantom in the bite block holder.



2. Move the GALILEOS unit to its starting position (Press Return key **R** on the user interface).
3. Check locking of the mechanical diaphragm. It has to be locked to the "open diaphragm" position.
4. Release an exposure.
   ↳ The X-ray exposure of the 3D constancy test is displayed on the user interface.

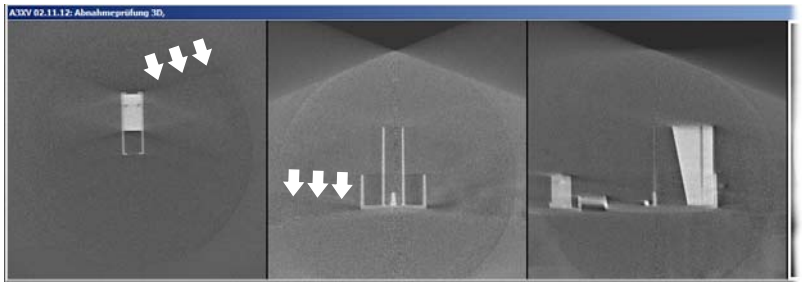


   ↳ On completion of the exposure, the program performs measurements. If these measurements check out OK, the results are displayed in the test field.
5. Enter the result of the gray level measurement (*"Result GW:"*) and the value of the *"Gray Val:"* field in the **TEST RESULTS 3D (DVT)** form.
6. Enter the result of the pixel noise measurement (*"Result SNR:"*) and the value of the *"SNR:"* field in the **TEST RESULTS 3D (DVT)** form.
7. Enter the result of the low contrast measurement (*"Low Contrast"*) in the **TEST RESULTS 3D (DVT)** form.
8. Enter the result of the modulation transfer function measurement (*"Result MTF:"*) in the **TEST RESULTS 3D (DVT)** form.

2.7.2 Visual check

Artifacts

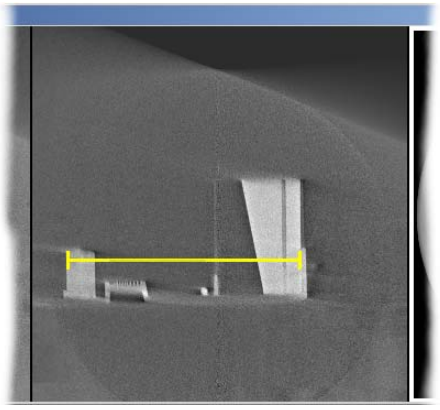
IMPORTANT
Artifacts resulting from the edges of the test phantom are system-related and are not considered (see arrows in example image)!



✓ The X-ray images of the 3D acceptance test and the 3D constancy test are open.

1. Compare the X-ray images of the 3D constancy test with those of the 3D acceptance test. No new or stronger artifacts should occur in the X-ray exposures of the constancy test in comparison to the acceptance test.
2. Acknowledge a positive result via the *"No/few artifacts visible"* check box and enter the result in the **TEST RESULTS 3D (DVT)** form.

Length measurement



1. Select the *"Measure Distance"* menu item on the *"Analysis"* menu bar.
2. Determine the starting point of the length measurement with the mouse pointer.
3. While holding the left mouse button down, drag the mouse pointer to the end point of the length measurement.
4. The distance between the two points in millimeters is displayed in the status bar at the bottom edge of the program window.
5. Enter this value in the *"Length measurement"* text box.
6. Enter the value measured in millimeters in the **TEST RESULTS 3D (DTV)** form.
7. Enter the serial number of the test phantom used in the *"Serial number test body"* text box.
8. Press the *"Check and save values"* button.

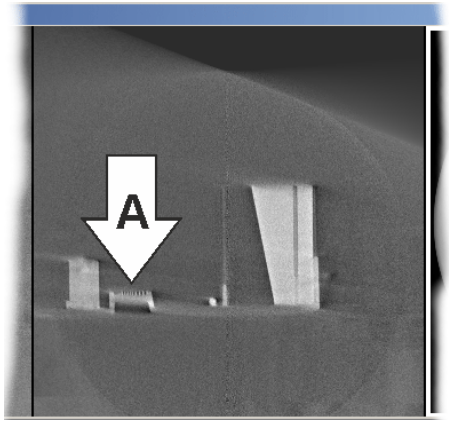
2.7.3 Checking the high contrast resolution

Explanation

In addition to the electronic measurement value logging of the constancy test, the X-ray image must be checked visually.

Check

- High contrast resolution:
  - The lines in the middle segment of the 3D test phantom (**A**) must be visible (1.4 Lp/mm).



✓ The part to be examined (see illustration) is sufficiently magnified in the software user interface.

✓ The center lines of the comb-shaped test element (**A**) must be visible (1.4 Lp/mm).

1. Check the high contrast resolution of the comb-shaped test element (**A**).
2. Enter the result of the high contrast resolution in the **TEST RESULTS 3D (DVT)** form.

Completion

1. Quit the *"Constancy test"* dialog box by clicking the *"Close"* button.

2. Remove the test phantom from the bite block holder.

2.8 Exiting the constancy test program

NOTICE

You must terminate all test programs before exiting the constancy test program.

NOTICE

Exiting SIDEXIS

Before exiting SIDEXIS, you must exit the constancy test program.

➢ To exit the constancy test program, click *"Utilities"* on the menu bar, followed by *"Constancy test"* in the menu window.

NOTICE

For constancy tests only: If the values required for the constancy test are not achieved, please contact a service engineer.

3 Reference images for the constancy test

3.1 Explanation

Contents

This chapter explains how to produce reference images.

The production of reference images is subsequently referred to as "Acceptance test" in the software and in the present document.

Prerequisite

- The reference image must be taken by a service engineer (password-protected area)!

Recommendation

The acceptance test should be performed by the service engineer immediately after the installation of the GALILEOS unit.

Documentation

➢ Note the data and measured values of the GALILEOS unit concerned in the test report [→ 23].

TEST REPORT

There are two ways to fill out the test report.

- **Option 1**

  The TEST REPORT in paper format can be handwritten.

  This form is found in the last chapter of this document.

- **Option 2**

  The TEST REPORT can be created and completed automatically using the constancy program.

  This generates a PDF document, which can then be printed out.

  For more information, see the section: “Test results and TEST REPORT as a PDF document”.

3.2 Preparing the X-ray device

NOTICE
Observe Operating Instructions!

Make sure that no foreign particles are located in the beam path of the X-ray device and that the X-ray device is in its starting position.

1. Remove the bite block from the bite block holder.
2. Remove the forehead support.

3.3 Starting the constancy test program

3.3.1 Overview

Explanation

The start-up procedure differs depending on the version of SIDEXIS.

Description

- SIDEXIS XG [→ 14]
- SIDEXIS 4 [→ 14]

3.3.2 SIDEXIS XG

Reminder

If more than 30 days (configuration under *"Utilities"* / *"Configure system..."* / *"Constancy test"*) have elapsed since the acceptance test or the last constancy test, a dialog box reminding you that the constancy test is overdue may appear after the start of SIDEXIS XG.

➢ Acknowledge with *"OK"*.

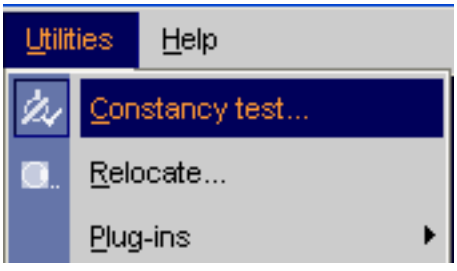
NOTICE

The time interval refers to the last constancy test that was performed on this PC.

The program makes no distinction between different X-ray devices.

The system owner is responsible for determining which X-ray device is due for a new constancy test.

Start



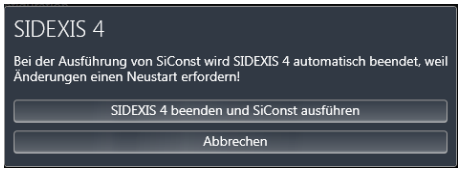
1. Start SIDEXIS XG.
2. Click the *"Constancy test"* menu option on the *"Utilities"* menu bar.

↳ The test program starts.

3.3.3 SIDEXIS 4

1. Start SIDEXIS 4.
2. In SIDEXIS 4, call the *"SIDEXIS Tools"* / *"Devices"* configuration menu.

3. Click on the *"SiConst / Constancy test "* button.



↳ A reconfirmation dialog box appears.

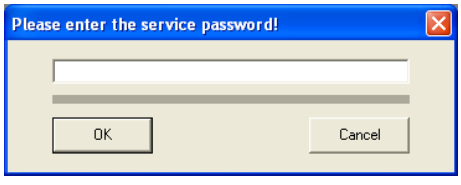
4. Confirm this dialog box.
   ↳ SIDEXIS 4 is closed.
   ↳ The *"SiConst"* program starts.

3.4 Registering the X-ray device on the PC

Registering

➢ Click the *"New"* menu option on the *"X-ray device"* menu bar.

Entering the service password



1. Enter the service password.
   ↳ Your input appears hidden behind placeholders.

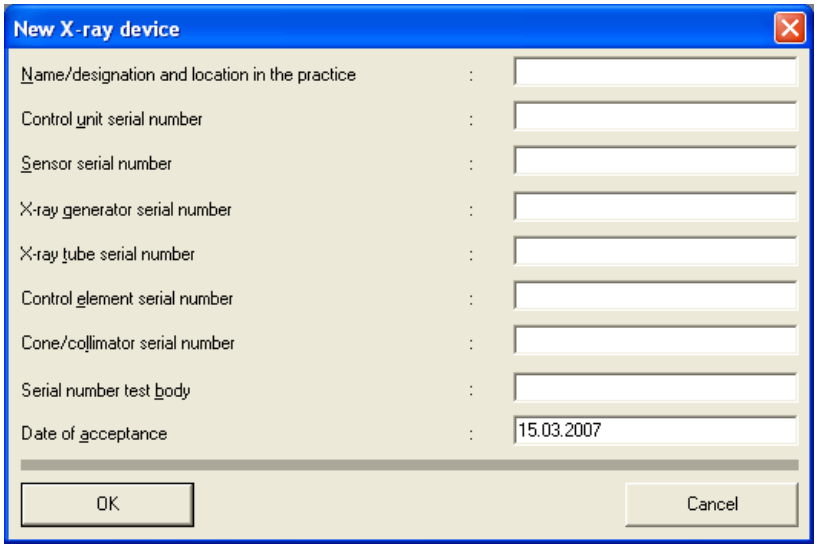
NOTICE

To obtain the service password, please refer to the SIDEXIS Service Manual.

2. Confirm with “OK”.
   ↳ If you have entered a wrong password, you may repeat your input.

Entering data

The *"New X-ray device"* window opens.



The current date automatically appears in the *"Date of &acceptance"* text box.

➢ Make sure to fill in all the text boxes.

- To jump from one text box to the next, press the *"Enter"* key.
- Please enter a "-" (hyphen) for any missing data.

➢ Acknowledge with *"OK"*.

↳ The window closes.

↳ The name/designation, location within the practice, several serial numbers and the date are displayed on the title bar.

↳ The unit is now registered.

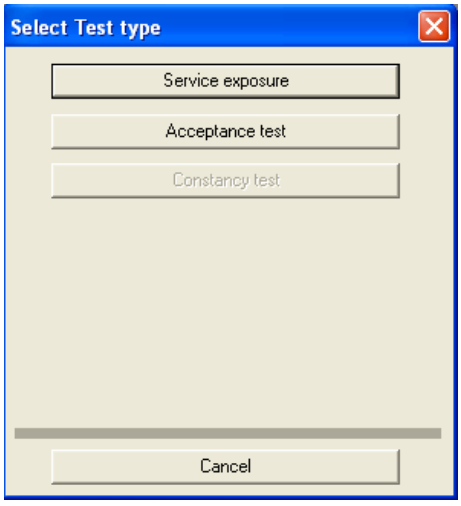
For the test report:

This data must be entered in the **TEST REPORT** form (upper box).

3.5 Making the PC ready for an exposure

Opening

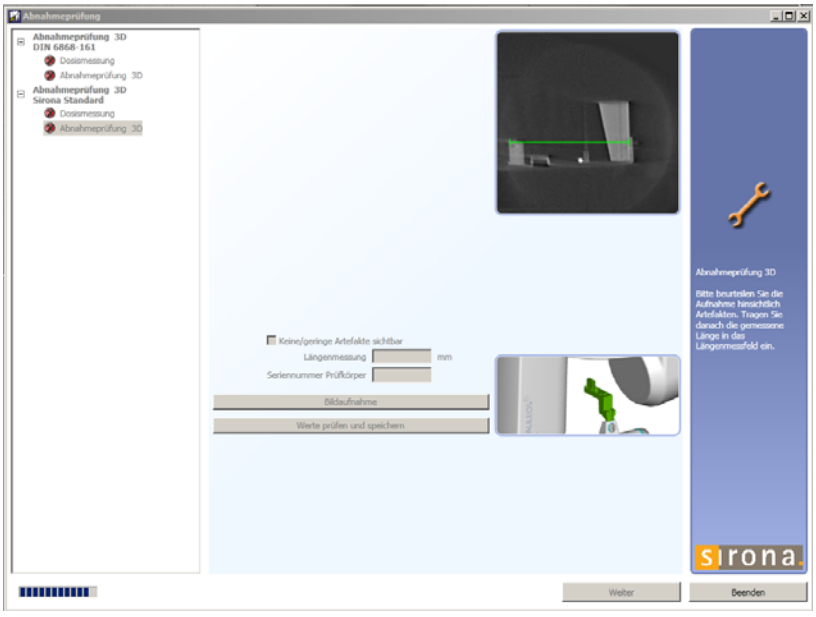
1. Click the *"3D acquisition"* button in the left tool bar
   or
   Click the *"3D-Scan"* menu option on the *"Test "* menu bar.
   ↳ The *"Select Test type "* dialog box appears.



2. Click the *"Acceptance test "* button.

↳ The acceptance test window appears.

Example screen



3.6 Taking and evaluating exposures

Explanation

The acceptance test is performed through the *"Acceptance test "* dialog.

A 3D X-ray exposure is performed with a test phantom.

Prerequisite

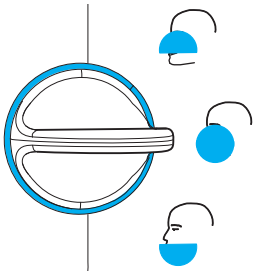
The *"Acceptance test "* dialog box opens.

3.6.1 Exposure

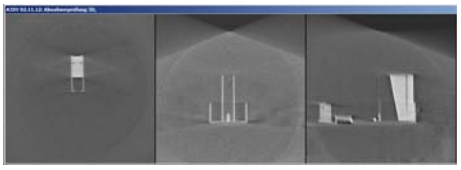
1. Insert the test phantom in the bite block holder.
2. In the *"Acceptance test"* dialog box, select the option *"Acceptance test 3D"* in section *"Constancy test 3D Sirona Standard"*.
3. Press the *"Image acquisition"* button.

↳ The exposure readiness dialog box opens.

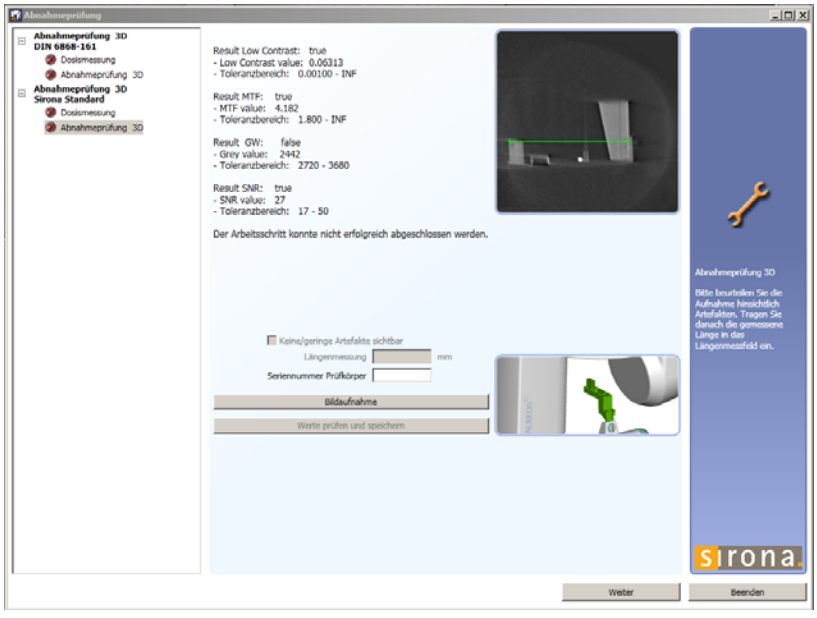
4. Move the GALILEOS unit to its starting position (Press Return key **R** on the user interface).



5. Check locking of the mechanical diaphragm. It has to be locked to the "open diaphragm" position.
6. Release an exposure.



↳ The X-ray exposure of the 3D acceptance test is displayed on the user interface.



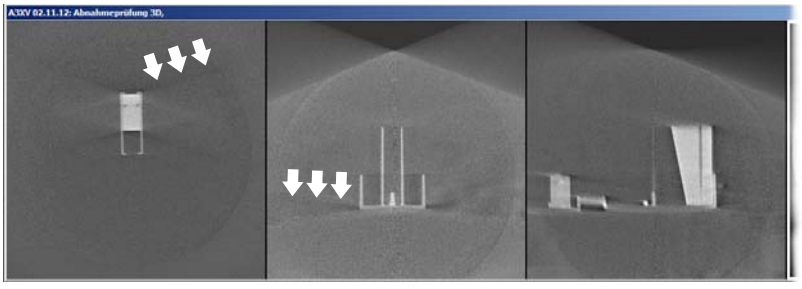
↳ On completion of the exposure, the program performs measurements. If these measurements check out OK, the results are displayed in the test field.

7. Enter the result of the gray level measurement (*"Result GW:"*) and the value of the *"Gray Val:"* field in the **TEST REPORT** under **Item 3.1**.
8. Enter the result of the pixel noise measurement (*"Result SNR:"*) and the value displayed in the *"SNR:"* field in the **TEST REPORT** under **Item 3.2**.
9. Enter the result of the low contrast (*"Low Contrast"*) measurement in the **TEST REPORT** under **Item 3.3**.
10. Enter the result of the modulation transfer function measurement (*"Result MTF:"*) in the **TEST REPORT** under **Item 3.4**.

3.6.2 Visual check

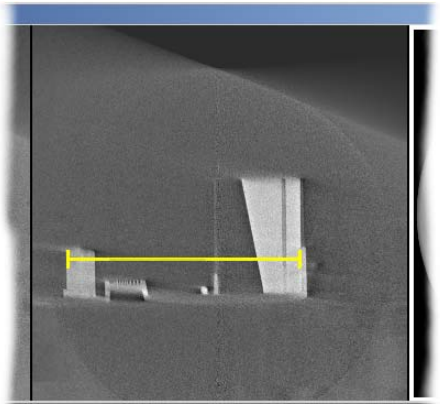
Artifacts

IMPORTANT
Artifacts that originate from the edges of the test phantom are system-related and are not taken into consideration (see arrows in sample image!)



1. Check the X-ray images of the 3D acceptance test. No strong artifacts should be evident.
2. If the result is positive, activate the *"No/few artifacts visible"* check box and enter the result in the **TEST REPORT** under **Item 3.5**.

Length measurement



1. Select the *"Measure Distance"* menu item on the *"Analysis"* menu bar.
2. Determine the starting point of the length measurement with the mouse pointer.
3. While holding the left mouse button down, drag the mouse pointer to the end point of the length measurement.
4. The distance between the two points in millimeters is displayed in the status bar at the bottom edge of the program window.
5. Enter this value in the *"Length measurement"* text box.
6. Enter the value measured in millimeters in the **TEST REPORT** under **Item 3.6**.
7. Enter the serial number of the test phantom used in the *"Serial number test body"* text box.
8. Press the *"Check and save values"* button.

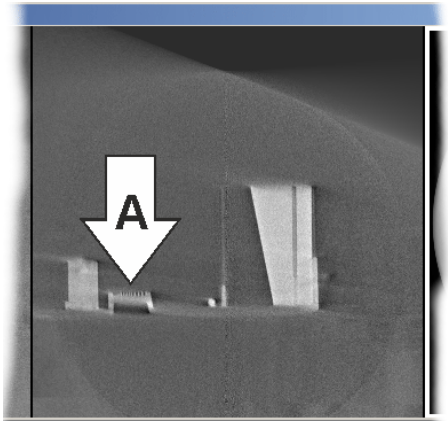
3.6.3 Checking the high contrast resolution

Explanation

For the TEST REPORT, Item 4.1

In addition to the electronic measurement value logging of the acceptance test, the high contrast resolution of the generated X-ray image also must be checked visually.

A comb-shaped test element (**A**) inside the test phantom is used for this purpose.



Check

✓ The part to be examined (see illustration) is sufficiently magnified in the software user interface.

✓ The center lines of the comb-shaped test element (**A**) must be visible (1.4 Lp/mm).

1. Check the high contrast resolution of the comb-shaped test element (**A**).
2. Enter the result for the high contrast resolution in the **TEST REPORT** under **Item 4.1**.

Completion

1. Quit the acceptance test dialog box by clicking the *"Close"* button.
2. Remove the test phantom from the bite block holder.

3.7 Describing the test

Explanation

You are free to enter the test results on the screen form. You **must**, however, enter all information and values in the “TEST REPORT” form in the X-ray System Logbook as described above.

Scope

This functionality is only available in the following languages:

- French
- Spanish
- Italian
- Russian
- Japanese

Activation

1. Click the *"Describe image"* button in the left tool bar
   or
   Click the *"Comment"* menu option on the *"Test "* menu bar
   ↳ The *"Describe test"* window is displayed.
2. Enter your name under *"Done by"*.
3. Enter any comments you wish to make in the *"Result"* box.
4. Once you have described your acceptance test, click *"OK"*.

↳ The *"Describe test"* window is closed.

3.8 Storing the image

➢ Click the *"Close image"* button on the left toolbar.

or

➢ Close the image by activating the *"Close"* option on the *"Test "* menu bar.

↳ The image is now stored.

⚠ CAUTION

If any test phantom images are not OK

If the test phantom exposure does not comply with the requirements specified, you must remedy the problem.

✓ E.g. check the unit adjustments.

➢ Subsequently you must repeat the acceptance test.

3.9 Exiting the constancy test program

NOTICE

You must terminate all test programs before exiting the constancy test program.

NOTICE

Exiting SIDEXIS

Before exiting SIDEXIS, you must exit the constancy test program.

➢ To exit the constancy test program, click *"Utilities"* on the menu bar, followed by *"Constancy test"* in the menu window.

NOTICE

For constancy tests only: If the values required for the constancy test are not achieved, please contact a service engineer.

4 General

4.1 Test results as a PDF document

Explanation

The constancy test program features an option to generate a form for test reports for the constancy test results and reference exposures for constancy tests in PDF format.

- Forms that have been retrieved from the system contain control fields and text boxes that can be filled in manually to record test results.

  These boxes are highlighted with a light-blue background.
- The form is filled out automatically where possible.
- Any missing information can be added electronically at a later time.
- Boxes that were filled in automatically can subsequently be edited.
- These forms are assigned to the respective exposure and saved.
- They can be printed out, exported, or sent via e-mail.

NOTICE

Restriction

Test report forms may only be created after creating the reference exposures for the constancy test (acceptance test).

The results of the visual inspection and function test and measurement quantities are to be entered in the PDF document later. These results are to be noted down in the meantime.

Opening

➢ Click the *"Describe image"* button in the left tool bar
or
Click the *"Describe"* menu option on the *"Test"* menu bar

↳ If a form does not already exist, a new one will be generated now.

↳ The form is opened in Acrobat Reader.

5 TEST REPORT

Explanation

The results of the reference image for the constancy test are recorded in the **test report**.

The results must be noted or checked ☒.

The production of the reference image is described in the chapter "Reference image for the constancy test".

5.1 Unit data

Serial numbers

Complete unit	
X-ray tube unit	
X-ray tube	
X-ray detector	
Test phantom	

5.2 Dosimetry

Nominal values

- 85 kV, 7 mA, 4 sec.
  - GALILEOS Comfort
  - GALILEOS Compact
- 98 kV, 28 mAs
  - GALILEOS Comfort Plus

Entry

Enter the dose reading taken during the GALILEOS adjustment here:

.....mGy

5.3 Results of reference image

X-ray image and visual check

Test item 3.1: Gray level (*"Result GW:"*) OK? *"Gray Val:"*:	☐ yes (true)	☐ no (false)
Test item 3.2: Pixel noise (*"Result SNR:"*) OK? *"SNR:"*	☐ yes (true)	☐ no (false)
Test item 3.3: Low contrast resolution (*"Low Contrast"*):?	☐ yes (true)	☐ no (false)
Test item 3.4: Modulation transfer function (*"Result MTF:"*)?	☐ yes (true)	☐ no (false)

	Test item 3.5: No/few artifacts?	☐ yes	☐ no
	Test item 3.6: Length test?	..... mm	
Checking the high contrast resolution	**Test item 4.1:** Are the center lines of the comb-shaped test element visible (1.4 Lp/mm)?	☐ yes	☐ no

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

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