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Axeos

Constancy test 2D and 3D
(Dentsply Sirona / 21.CFR1020.33 / UK&IRL)

English



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1 About these instructions

These instructions describe the implementation of the 2D and 3D constancy tests for the *Axeos X-ray* unit with the Device Manager.

1.1 Other relevant documents

In addition to this document, you will also need the following documents for the constancy test:

- *Axeos Operating Instructions* (REF 67 30 548)
- *Sidexis 4 Operator's Manual* (REF 6447 028)
- Accompanying documents

2 General information about the constancy test (2D and 3D)

Dentsply Sirona provides the option of a quality inspection for the Axiom X-ray unit worldwide. The constancy test described here can be carried out by the operator and must be performed monthly.

The Device Manager is available for the constancy test.

Test report

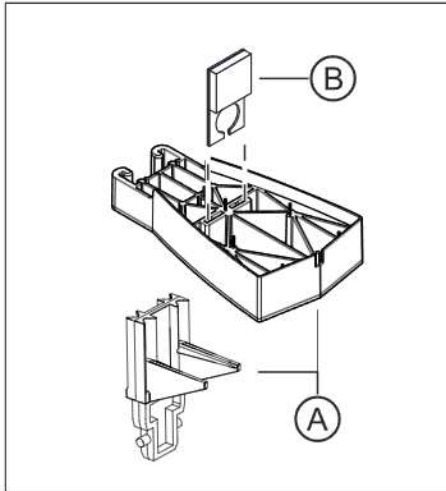
The test report of the constancy test is automatically filled out by the Device Manager and can be printed and saved.

2D and 3D acceptance tests

The constancy test is composed of a 2D (panorama/ceph) part and a 3D (DVT) part. These tests are performed separately and consecutively during the constancy test.

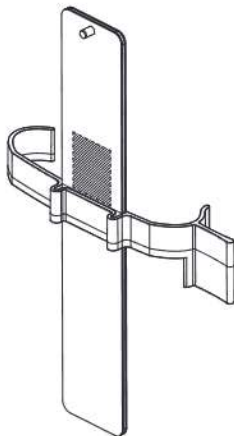
2.1 Devices and test phantoms for the constancy test

2D constancy test



Needle phantom with contrast element

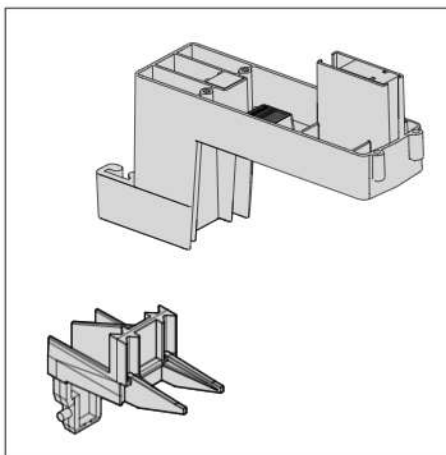
- Needle phantom (with short bite block holder) (A)
- Contrast element (B)
- *For pan:*
 - 6-mm thick aluminum plate (not included in the scope of supply)



Ceph test phantom

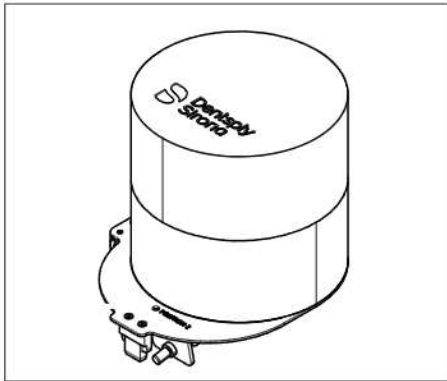
- *For cephalometer:*
 - Ceph test phantom with 0.8-mm thick copper plate (not included in the scope of supply for all countries)
 - 6-mm thick aluminum plate (8 cm x 8 cm) (not included in the scope of supply)

3D constancy test



3D constancy test phantom

- 3D constancy test phantom (with long bite block holder, gray)

3D constancy test
UK & IRL*CBCT test phantom - DIN 6868-161*

- CBCT test phantom - DIN 6868-161

NOTE**Possible incorrect positioning**

The CBCT test phantom is supplied pre-assembled for the Orthophos S/SL.

- Modify the test phantom as appropriate (see section Test phantom modification).
Position 2 = correct installation of the PMMA test phantom on the positioning plate for the Axeos

2.1.1 Modification of CBCT test phantom for Axeos

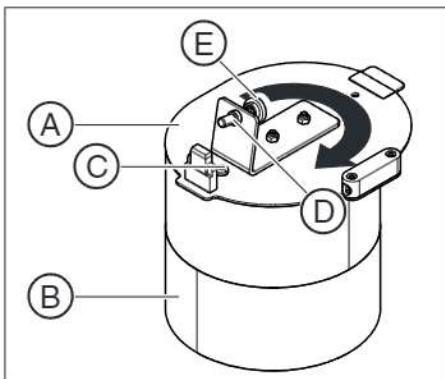
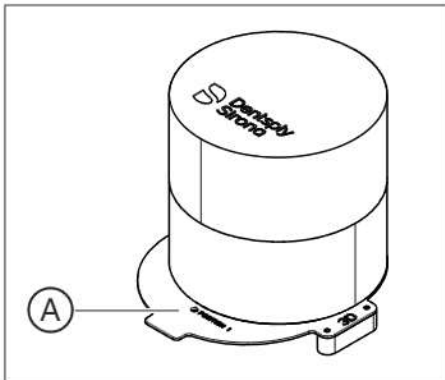
The test phantom was already modified in the course of the installation. If this is not the case, proceed as described in the next section.

Required tools

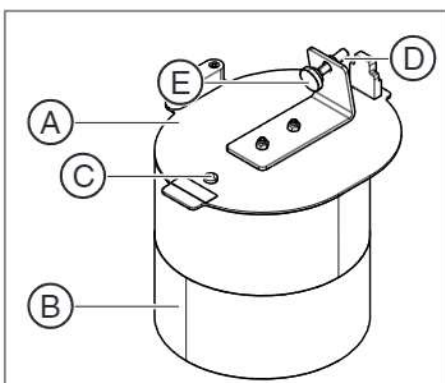
1x Torx® T25 screwdriver

Conversion

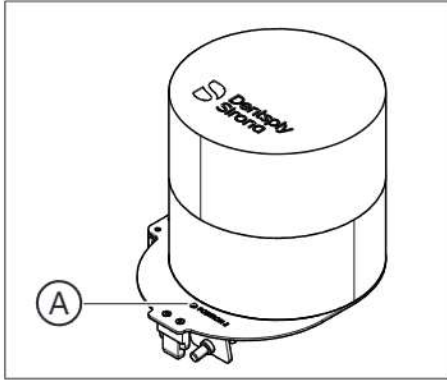
✓ The lettering Position 1 can be read on the positioning plate (A).



1. Place the test phantom with the top side made of PMMA (B) on a clean and sturdy surface.
2. Remove the protective cap (D) from the adjustment screw (E).
3. Screw the adjustment screw (E) back.
4. Unscrew and remove the screw (C).
5. Carefully lift the positioning plate (A) from the PMMA test phantom (B).
6. Rotate the positioning plate (A) by 180°.

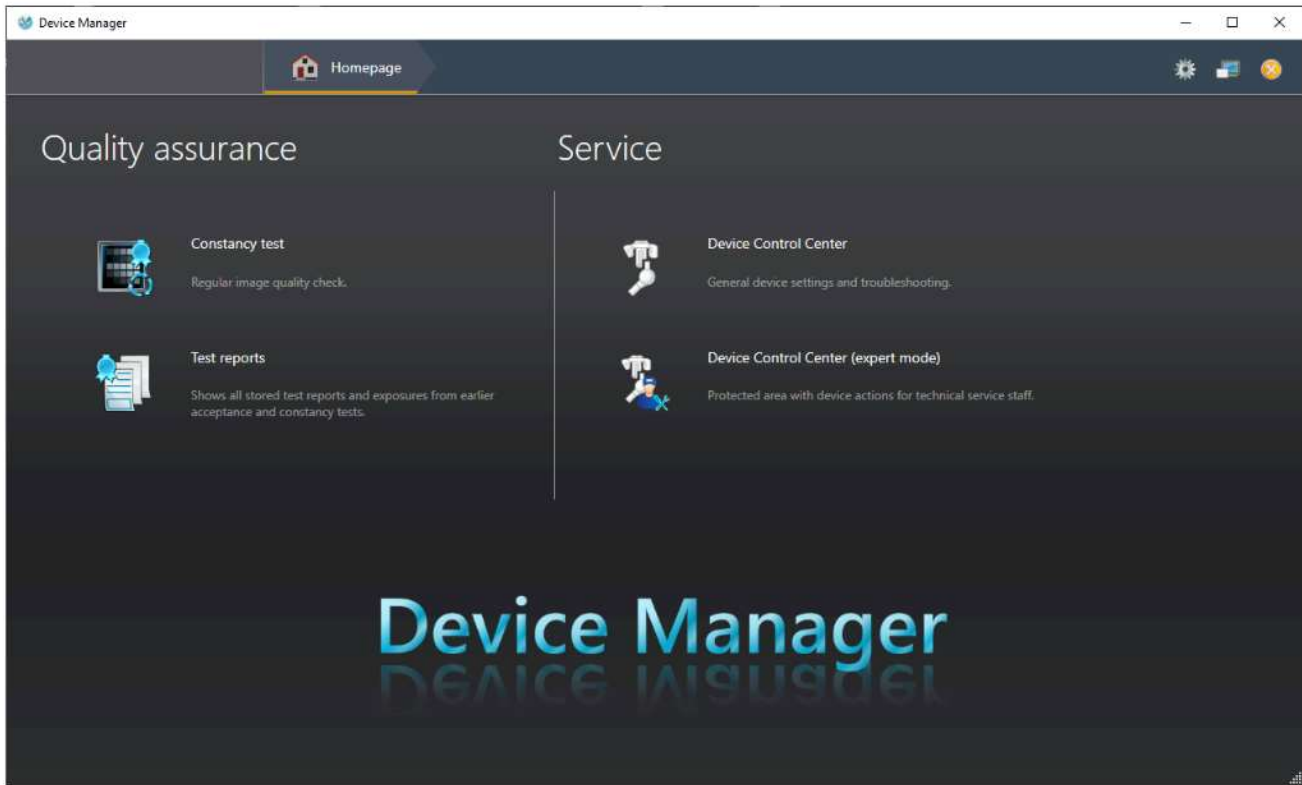


7. Snap the positioning plate (A) into the PMMA test phantom (B).
8. Screw the positioning plate (A) securely to the PMMA test phantom (B) again with the screw (C).
9. Screw the adjustment screw (E) on.
10. **IMPORTANT:** Place the protective cap (D) back onto the adjustment screw (E).

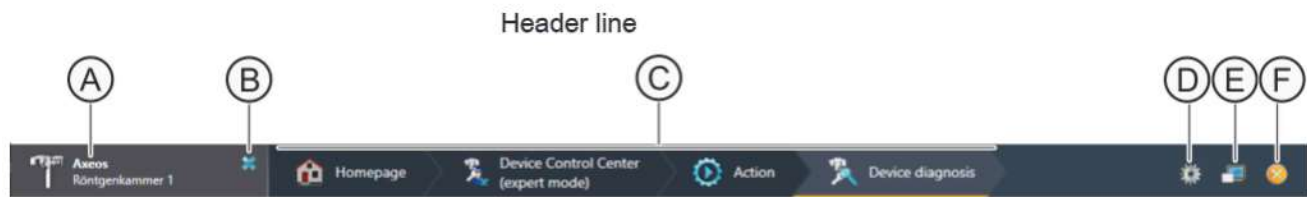


↙ The lettering Position 2 can now be read on the positioning plate (A).

3 Device Manager



Start screen of the Device Manager



Header line of the Device Manager

A	Name of the connected device (or acquisition server)
B	Log out of the X-ray equipment
C	Phase bar
D	Set up [→ 14] Device Manager
E	Configure full-screen/window mode
F	Close program [→ 12]

Phase bar

The phase bar indicates the navigation through the Device Manager. You can also return to the higher-level menus with the buttons in the phase bar.

Full-screen and window mode

When starting the Device Manager for the first time following installation, the program starts in full-screen mode as per the factory setting. Every time the Device Manager is restarted, it keeps the setting that was active when the program was last closed.

- Click on the screen icon in the system menu of the header line.
 - ↳ The display mode switches from full-screen mode to window mode and vice versa.

Switching display modes



3.1 Starting / closing the Device Manager



1. Double-click on the start program icon or the corresponding entry in the Start menu of your workstation.

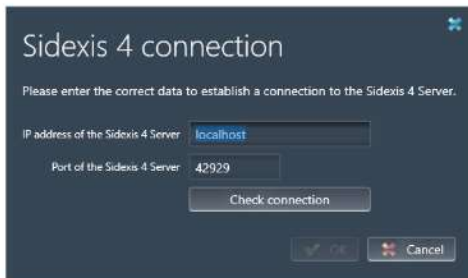
or

- Click on the Device Manager icon in the Start menu.

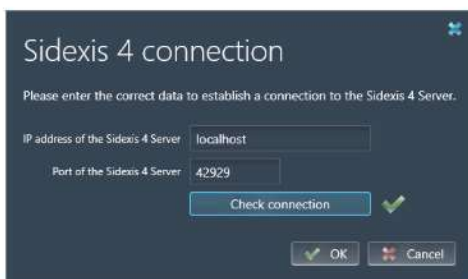
- ↪ When the Device Manager is started for the first time, a menu opens for selection of the region (see also section ""Language & Region" [-> 15]"). Select the desired region.



"Region selection"



Checking the Sidexis 4 connection



Sidexis 4 connection is okay

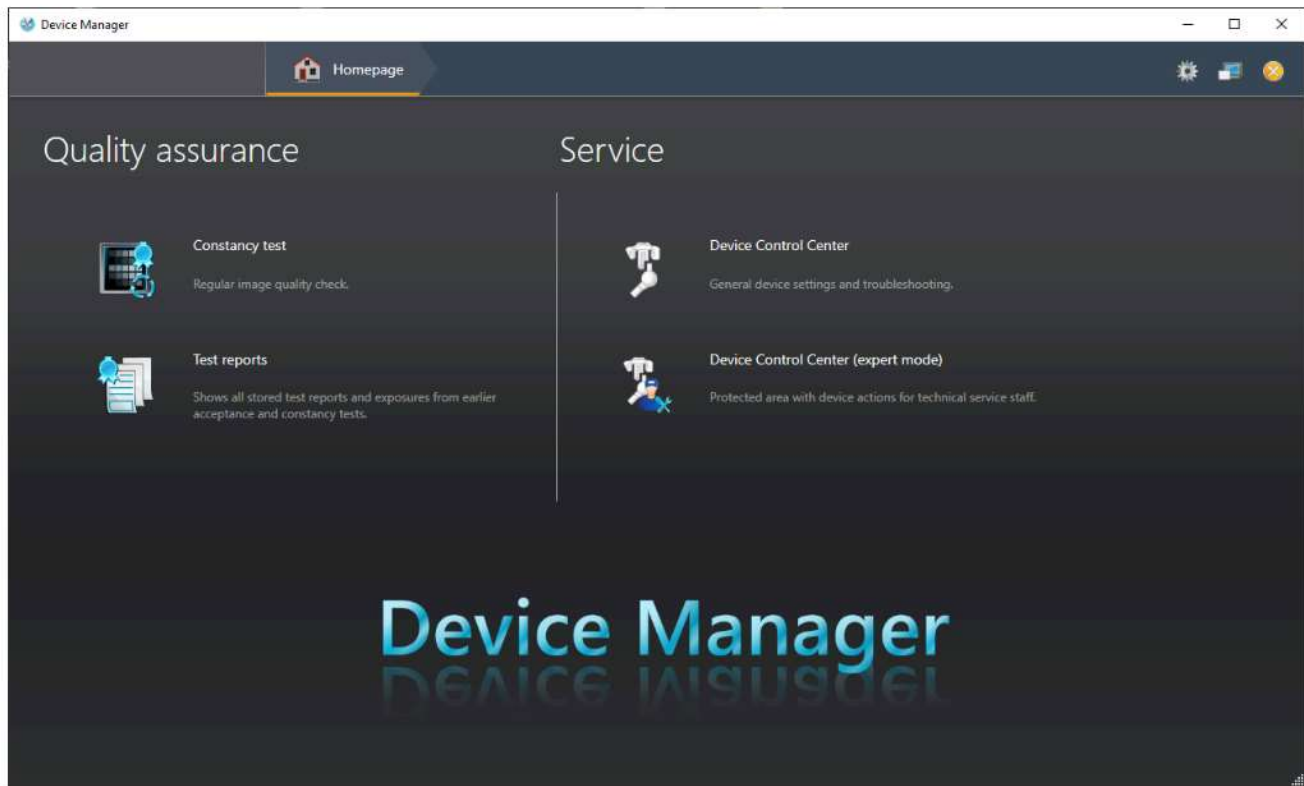
- ↪ When the Device Manager is started for the first time, a menu then opens for checking the Sidexis 4 connection.

2. Click on the *"Check connection"* button.

- ↪ A check is made to determine if the Sidexis 4 server is running and is accessible from the current PC.

- ↪ If the connection is okay, click on the *"OK"* button.

- ↪ If the connection is not okay, modify the entries in the text boxes and repeat the procedure.



Start screen of the Device Manager

☞ The Device Manager starts.

3. To close the Device Manager, click on the close program icon in the header line.



3.2 Setting up the Device Manager

You can use this menu to make the following settings for the Device Manager:

- *"Language & region"*:
Setting the program language [→ 15]
- *"Quality assurance"*:
Specifying schedules/reminders for the constancy test [→ 17]
- *"Sidexis 4"*:
Configuring/checking the connection to the Sidexis 4 server [→ 19]

The settings for the Device Manager have already been made in the course of the installation. If you want to change the settings, proceed as described in the following sections.

Opening the *"Settings"* menu

- ✓ The Device Manager is started.
- Click on the gear icon (D) in the header line.
 - ↪ The *"Settings"* menu opens.



D

Gear icon

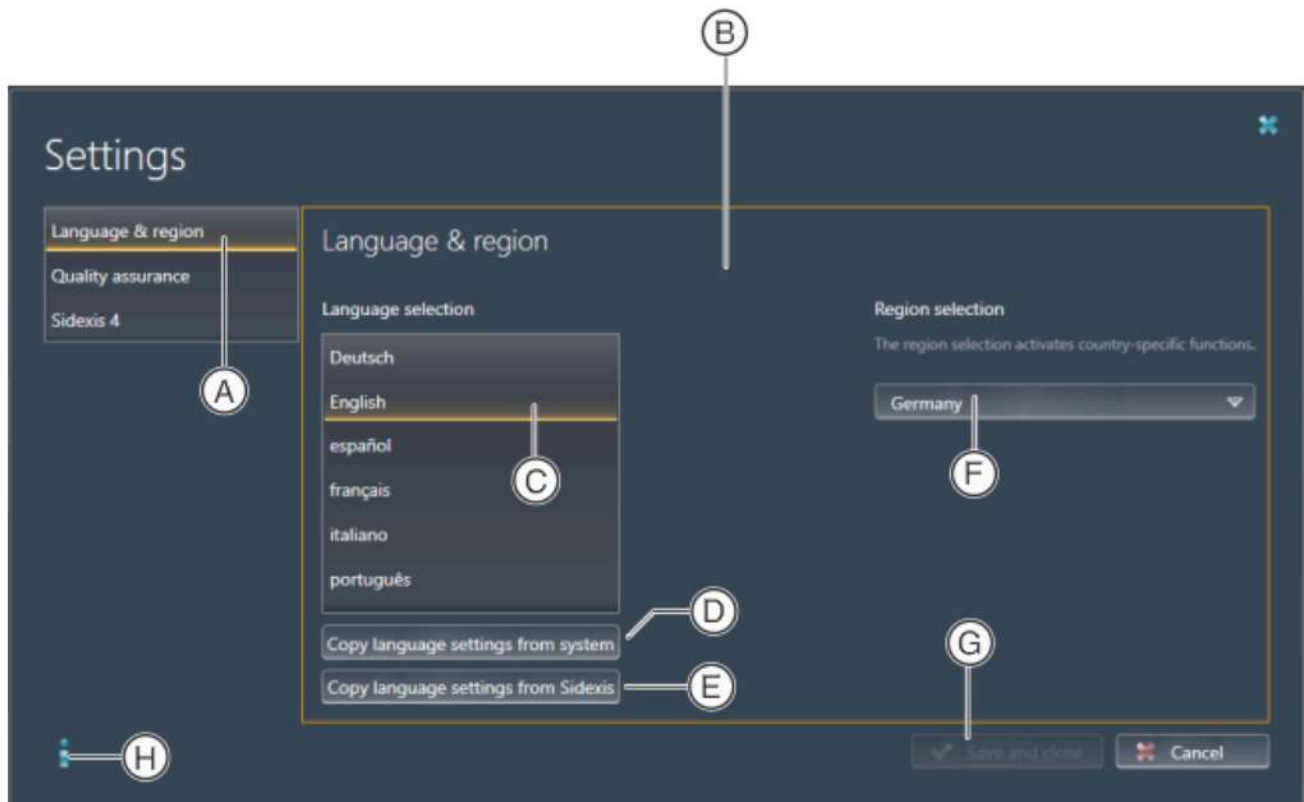
3.2.1 "Language & Region"

You can set the display language of the Device Manager in this menu.

If "German" is selected as the language, the test report will be created in German. If "French" is selected for the language, the test report will be created in "French". For all other language selections, the test report will be created in "English".

Country-specific functionalities for the acceptance and constancy tests are activated via the region setting.

For example, if "Germany" is selected for the language, the DIN standards (2D and 3D) applicable in Germany are automatically used for the acceptance and constancy tests.



Setting up "Language & region" in the Device Manager

- ✓ The Device Manager is started [-> 12].
- 1. In the menu tree, select the "Language & region" menu (A).
 - ↳ The "Language & region" menu (B) is displayed.
- 2. In the "Language selection" window (C), select the desired language.
- or
- > Click on the "Copy language settings from system" button (D) or "Copy language settings from Sidexis" button (E) below the list to apply the language setting from the operating system or Sidexis 4, respectively.
- 3. In the "Region selection" list box (F), select the desired region.
- 4. Click on the "Save and close" button (G) to accept the modified settings.

IMPORTANT: The changes will only take effect after a restart of the Device Manager.



Device Manager information

If you click on the information icon (H), information on the Device Manager will be displayed.

3.2.2 "Quality assurance"

In this menu, you can overwrite the specified intervals for the constancy test. The overwriting of an interval affects the date on which the message "A constancy test is necessary." is displayed on the workstation. The planned interval for constancy tests can vary depending on the quality control standard.



Setting up "Quality assurance" in the Device Manager

- ✓ The "Device Manager" is started [→ 12].
- 1. In the menu tree (A), select the "Quality assurance" menu.
 - ↳ The "Customized constancy test intervals" menu (B) is displayed.
- 2. Enter the desired intervals for the respective quality control standards in the text boxes (C) and select the desired time unit in the adjacent "Interval unit" list boxes (D).
The default value for the respective quality standard is indicated in the "Default value" column (E). You can reset all values back to their default values with the "Reset to default value" button (F).
- 3. Click on the "Save and close" button (G) to accept the modified settings.

IMPORTANT: The changes will only take effect after a restart of the Device Manager.

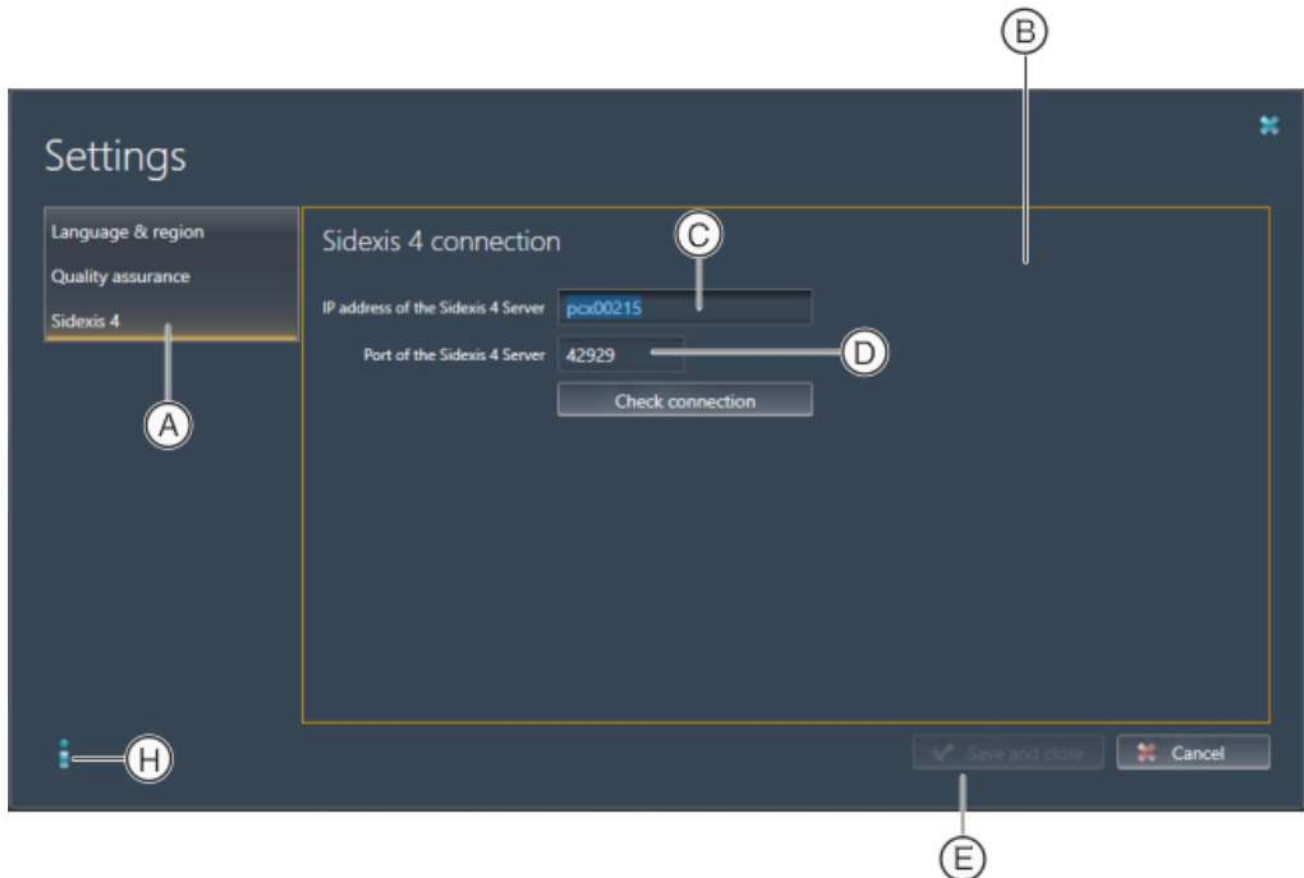


Device Manager information

If you click on the information icon (H), information on the Device Manager will be displayed.

3.2.3 "Sidexis 4"

In this menu, you can configure the connection to the Sidexis 4 server.



Configuring the "Sidexis 4" connection in the Device Manager

- ✓ The "Device Manager" is started [→ 12].
- 1. In the menu tree (A), select the "Sidexis 4" menu.
 - ↳ The "Sidexis 4 connection" menu (B) is displayed.
- 2. Enter the IP address of the Sidexis 4 Server and the Port of the Sidexis 4 Server in the corresponding text boxes (C+D) of the menu.
- 3. Click on the "Check connection" button to check the connection.
 - ↳ If the connection to the Sidexis 4 server is found, a green check mark appears next to the "Check connection" button.
- 4. Click on the "Save and close" button (E) to accept the modified settings.

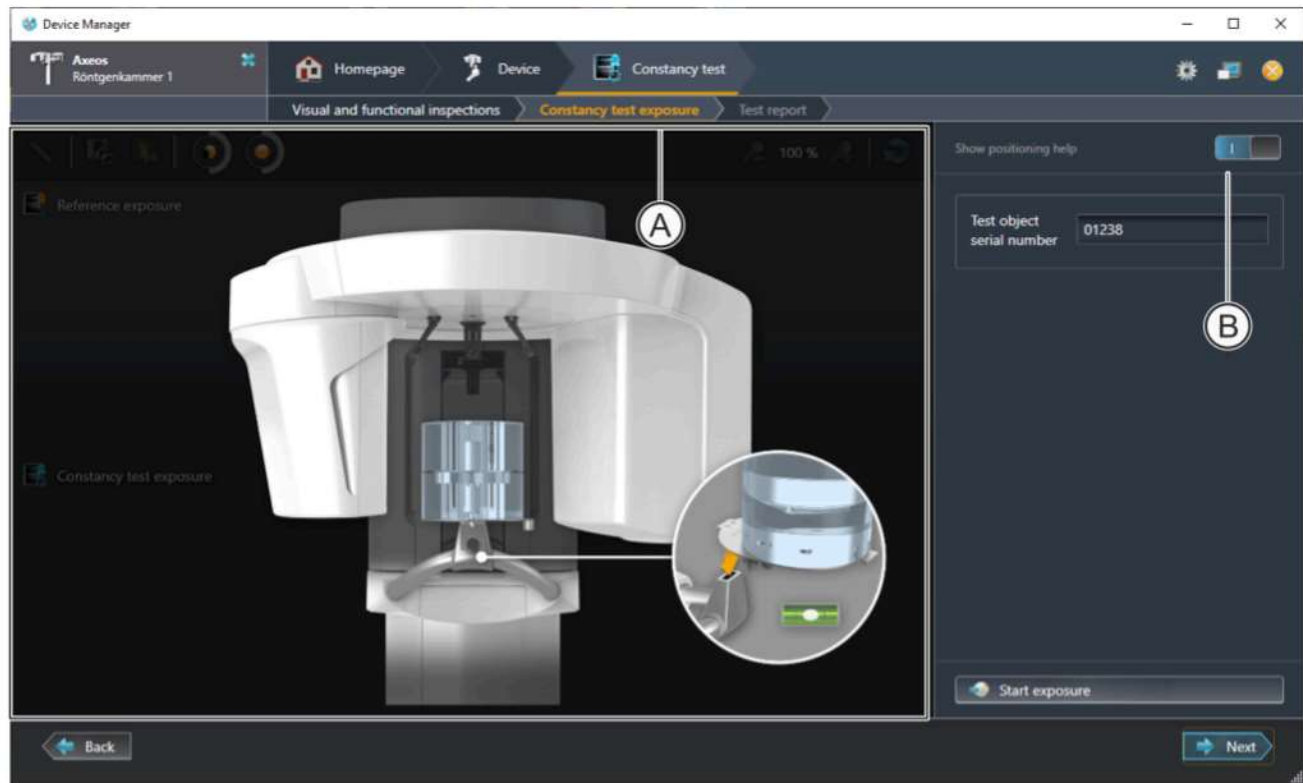
IMPORTANT: The changes will only take effect after a restart of the Device Manager.

If you click on the information icon (H), information on the Device Manager will be displayed.



Device Manager information

3.3 Positioning aids in the menus



Positioning aids

When called up, some menus display positioning aids (A) in the display window of the menu. These aids provide you with important information for preparation of the device, e.g. use of test phantoms, mounting of measuring instruments.

After taking the exposure, the exposure will appear in the display window instead of the positioning aid.

If you want to display the positioning aid again, in order for example to check if you had prepared the device correctly, you can do so by clicking the "Show positioning help" switch (B). It will then be displayed again.

3.4 Toolbar in the exposure window



Editing and measuring of the exposures using functions in the toolbar (A)

The exposures can be edited and measured using the functions in the toolbar (A). For information on the meaning and functionality of the pictograms, refer to the technical document *"Sidexis 4 Operator's Manual"* (REF 6447 028).

Button	Function
	Set brightness and contrast with the mouse controller
	Reset brightness and contrast for the selected image
	Length measurement
	Invert image
	Color image with false colors
	Zoom out
	Zoom in
	Reset settings

Tip: The Zoom in and Zoom out functions can also be operated with the mouse wheel.

3.5 Entering the service password on the PC



Entering the service password

Some service functions in the software are password-protected.

For the password, enter the first four digits of the current system date (PC) in reverse order.

Example: On January 21, 2019, the service password is 1012.

If you click on the eye icon, the entered password will be displayed.

The service password only has to be entered once per Device Manager session.

4 Constancy test using the Device Manager

The constancy test is performed as a software-based test using the Device Manager, which guide guides you step by step through the constancy test.

IMPORTANT

For best performance of the device, Dentsply Sirona recommends switching on the device 30 minutes before the first exposure. This recommendation applies to patient exposures, exposures as part of acceptance and constancy tests and calibration exposures.

Prior to starting the constancy test

In order to perform a constancy test, a proper acceptance test of the device must have been performed by the technician in the Device Manager.

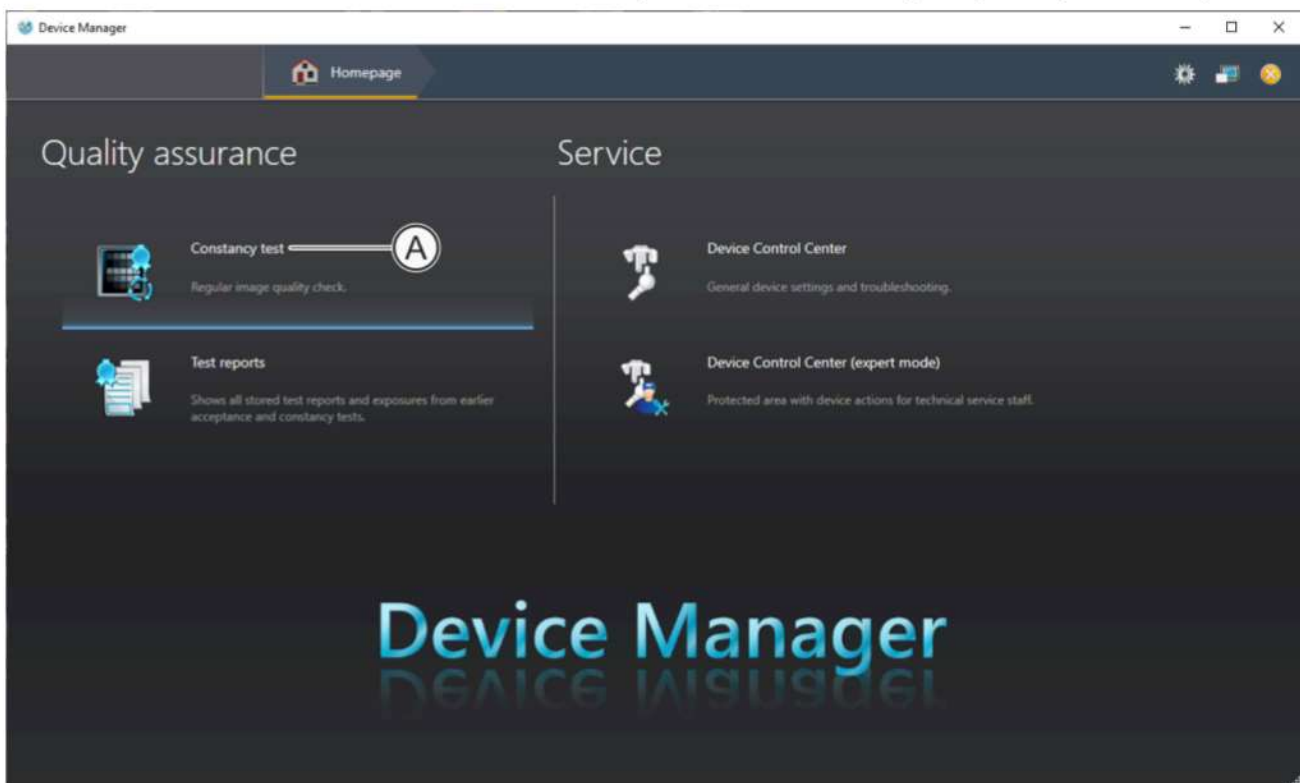
The constancy test phantom is necessary for the 3D constancy test.

Displaying the positioning aids

Ensure that the positioning aids are displayed in the menus of the constancy test, because they provide you with important information for preparation of your device for each exposure of the test.

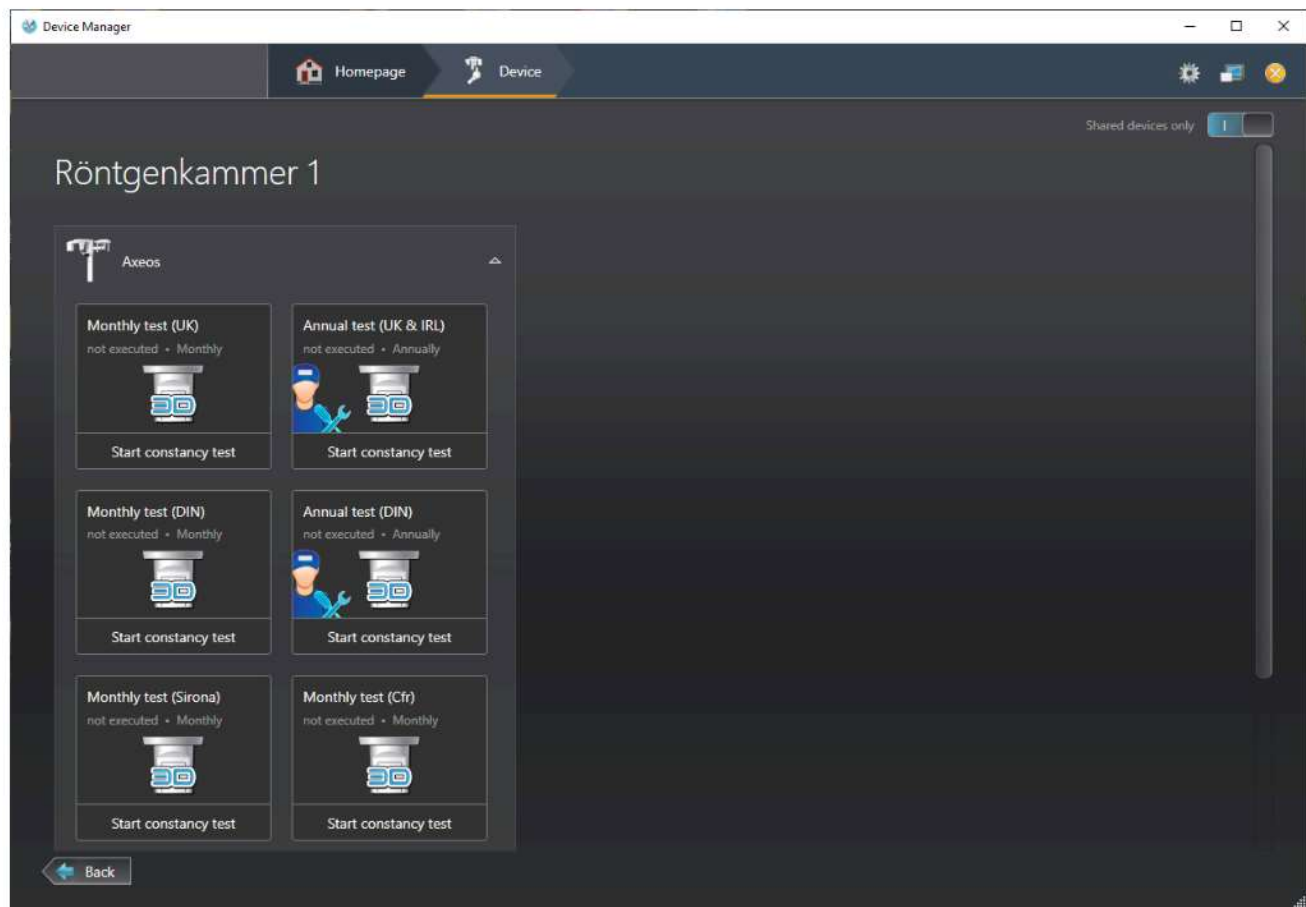
4.1 Opening the constancy test

- ✓ The Device Manager is started [→ 12].
- ✓ The X-ray device is switched on (see operating instructions).



Opening the "Constancy test" menu

1. Click on the "Constancy test" button (A).



"Constancy test" menu

- ☞ All constancy tests for which an acceptance or quality test has already been performed are displayed.
 - ☞ Constancy tests that are due are highlighted in orange.
2. To start a constancy test, click on the corresponding icon.

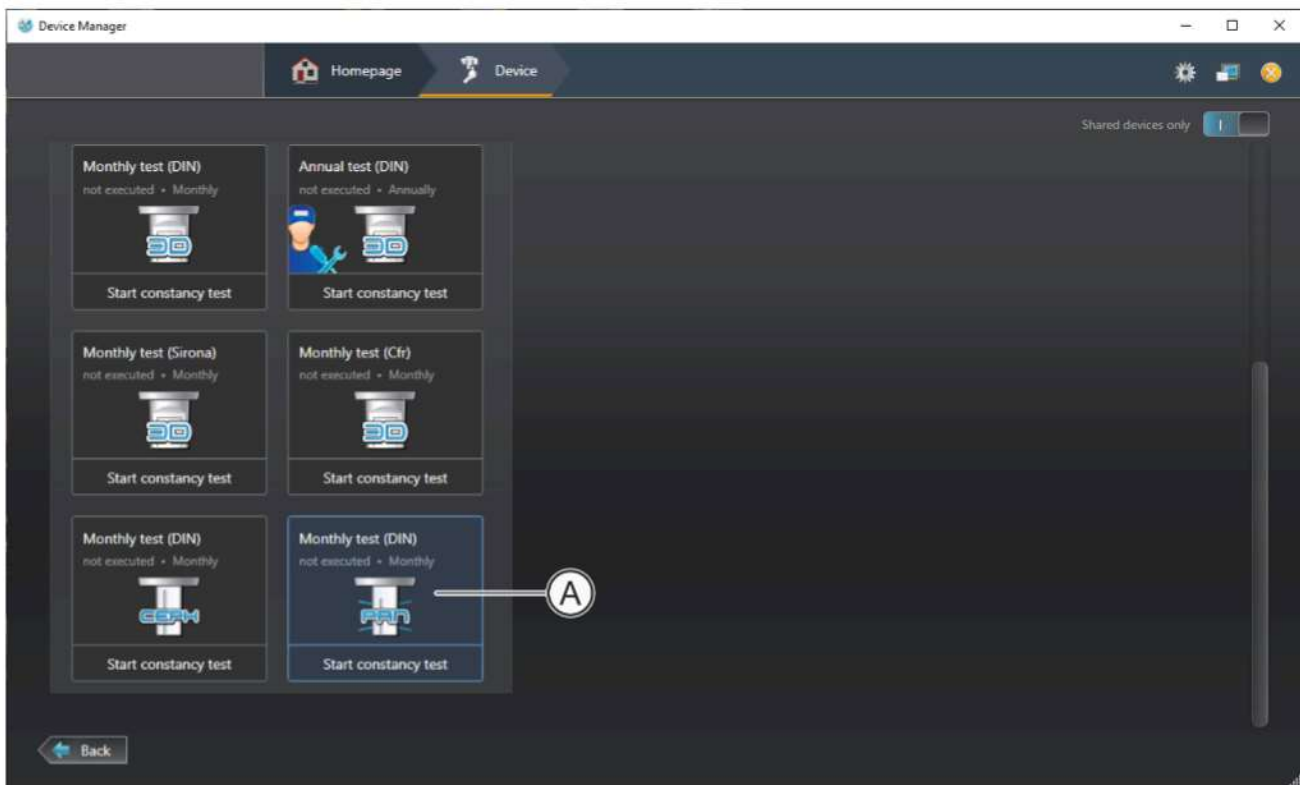
5 Monthly constancy test

5.1 Performing the 2D constancy test for pan (DIN 6868-5)

The 2D constancy test for pan is performed in accordance with DIN 6868-5.

Starting the monthly 2D constancy test for pan

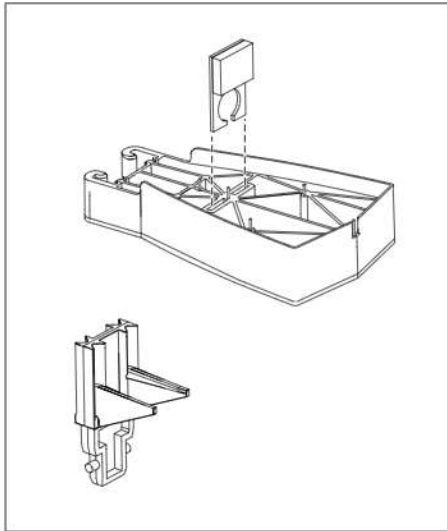
- ✓ The Device Manager is started [→ 12].
- ✓ The X-ray device is switched on (see operating instructions).
- ✓ The "Constancy test" menu is open [→ 24].



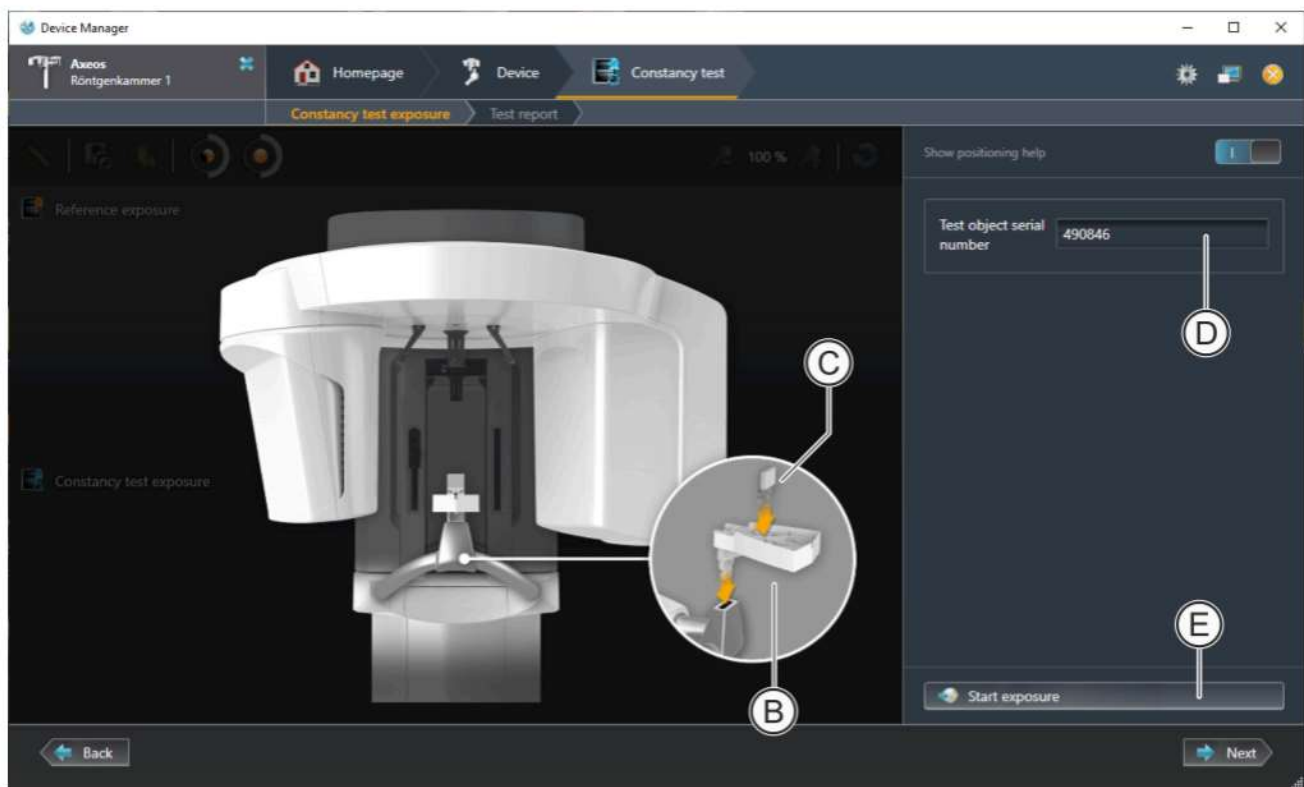
Starting the 2D constancy test for pan

- Click on the "Pan" icon (A).
 - ☞ The 2D constancy test for pan is started.

Preparing the device for the 2D constancy test exposure (pan)

**IMPORTANT**

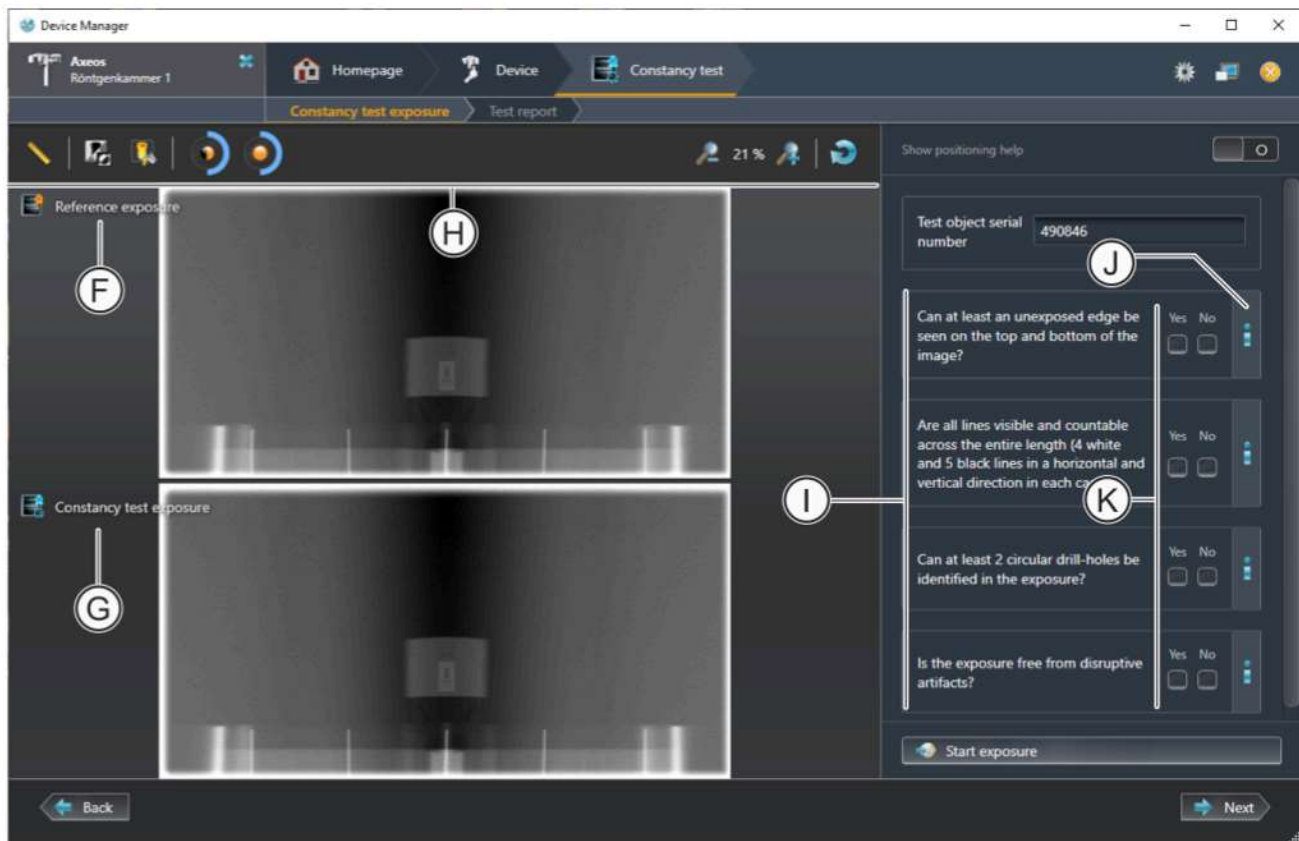
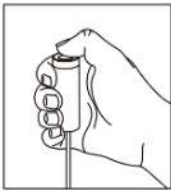
Ensure that you use the 2D constancy test phantom with the short bite block adapter (white) for the 2D constancy test.

*2D constancy test for pan*

1. Insert the needle phantom (B) into the bite block holder.
2. Insert the contrast element (C) into the slot on the needle phantom provided for that purpose.
Important: The aluminum plate of the contrast element must be facing away from the column of the unit (see positioning display). No additional aluminum plate may be attached to the device.

Performing the 2D constancy test exposure (pan)

1. Enter the serial number of the test phantom in the text box (D).
2. Click on the "Start exposure" button (E) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.56 with the exposure parameters 73 kV/8 mA, 14.1 s is displayed on the user interface.
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal indicating the end of the exposure (double beep) sounds.



2D reference exposure for pan and 2D constancy test exposure for pan are displayed for comparison

- ↳ The reference exposure created in the 2D acceptance test for pan is displayed (F).
 - ↳ The 2D constancy test exposure for pan (G) is stored in the archive (see section "") and displayed in the Device Manager.
5. If necessary, you can edit the exposures using the toolbar (H) [→ 22].

6. Evaluate the constancy test exposure (pan) using the questions in the menu (I). You will find help on evaluating via the corresponding information icon (J) and in section "Evaluating the 2D constancy test exposure for pan [-> 30]".
7. Compare the constancy test exposure with the reference exposure. No significant differences may be detected.
8. Click on the check boxes (K) in the menu corresponding to the results of your evaluation.
9. Click on the "Next" button.
 - ↳ The results are transferred to the test report.

2D TEST REPORT (2D X-ray)
on the Constancy Test of Dental X-ray Equipment as per DIN 6868 Part 5

Operator: Dr. Demo
Musterstrasse 1
12345 Musterstadt

Name of X-ray device: Axeos (Röntgenkammer 1)

Image display monitor test performed

Year: 2021 Month: 02

Constancy test

Useful beam: Is an unexposed edge visible on the exposure on at least two opposite sides? Yes No

Line pair resolution capacity: Are all lines over their complete length clearly visible and countable (4 white and 5 black lines in vertical as well as in horizontal orientation)? Yes No

Contrast resolution: Are sufficient holes visible? 2 holes 1 hole

Artefacts: Is the exposure free of disruptive artefacts? Yes No

Manufacturer: Test date: 26.02.2021

Serial number: 382
Complete unit
X-ray tube assembly: 341
X-ray tube: 98729
Panoramic sensor: 3371
Cephalometric sensor
Test phantom (Pan): 490648
Test phantom (Ceph):

Has the test been completed for the image display device and was the result in order? Yes No

Name of tester: John Dow

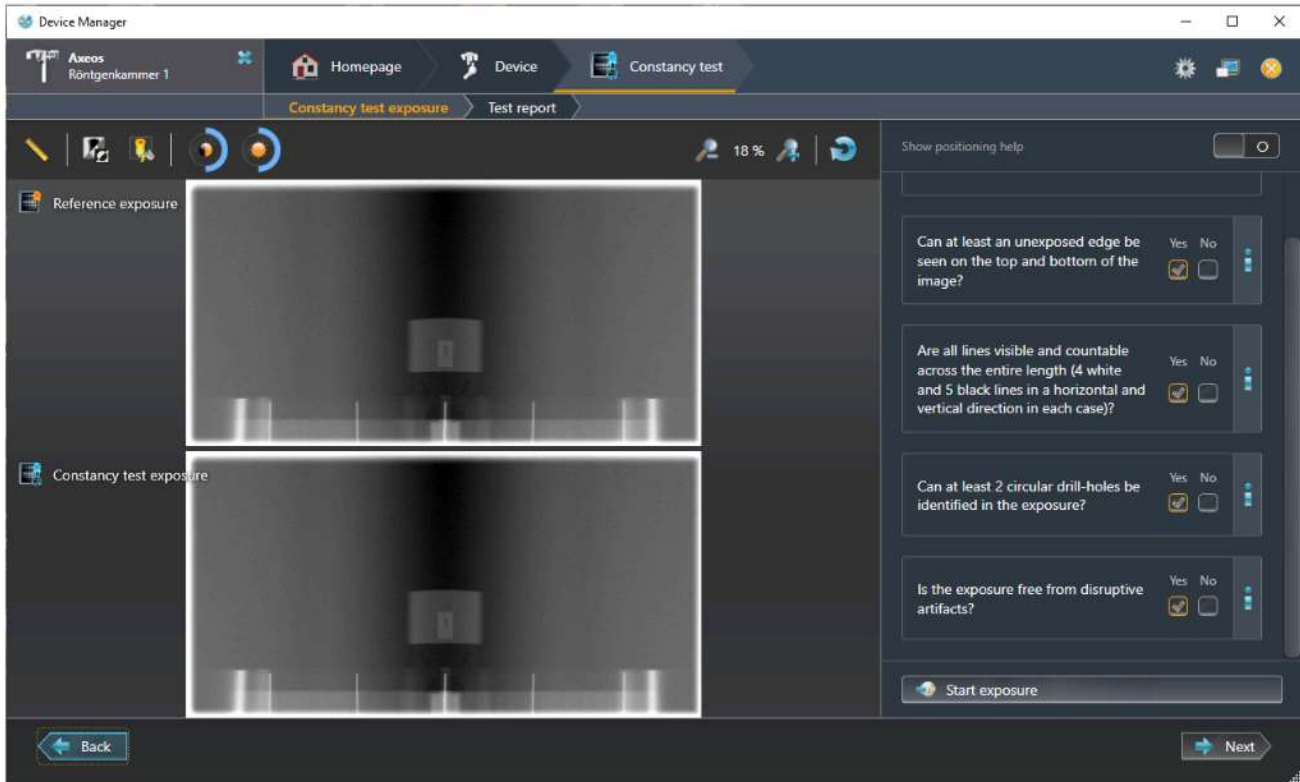
Notes

Test report of the 2D constancy test for pan

- ↳ The test report is displayed in the Device Manager.
10. Click on the check box (L) to confirm that the test of the image reproduction device was properly performed.
11. Enter the name of the tester and additional comments in the text boxes (M).
12. Click on the "Save" button.

5.1.1 Evaluating the 2D constancy test exposure for pan

Use of the functions in the toolbar may be useful for evaluating the constancy test exposure (see section "Toolbar in the exposure window [→ 22]").



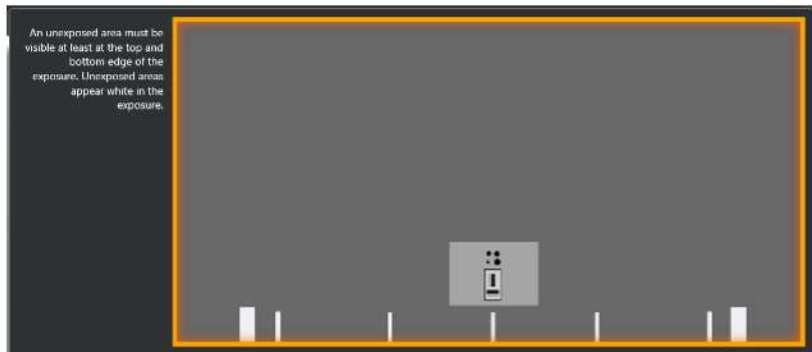
Example of a 2D constancy test exposure

Make the evaluation using the questions in the menu and select the corresponding check boxes next to the questions.

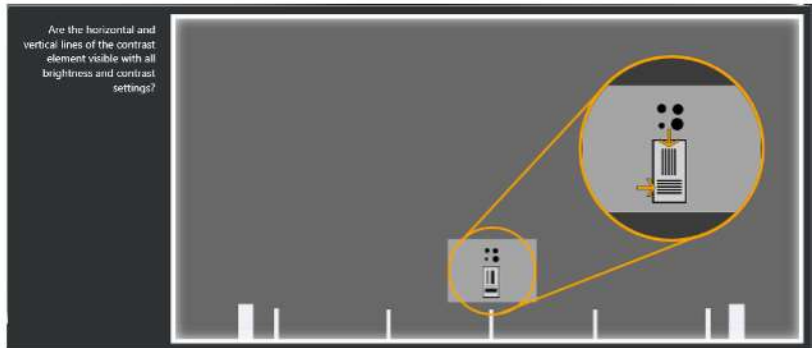
You will find help on answering the questions by hovering the mouse over the "i" icon. The points to be evaluated in the image are marked in orange.

Tip: For evaluating the exposure, zoom into/out from the exposure and move the constancy test exposure with the mouse button held down.

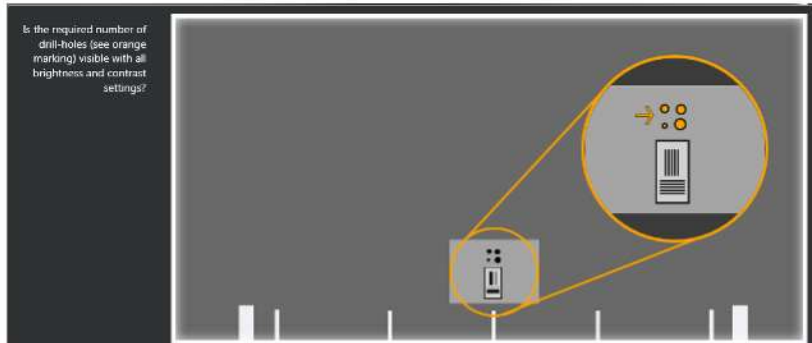
"An unexposed area must be visible at least at the top and bottom edge of the exposure. Unexposed areas appear white in the exposure."



"Are the horizontal and vertical lines of the contrast element visible with all brightness and contrast settings?"



"Is the required number of drill-holes (see orange marking) visible with all brightness and contrast settings?"



"Perform a visual inspection of the image for any unwanted artifacts. Unwanted artifacts may include: – Phantom images – Row and pixel failures – Row misalignment – etc..."

Perform a visual inspection of the image for any unwanted artifacts.
Unwanted artifacts may include:

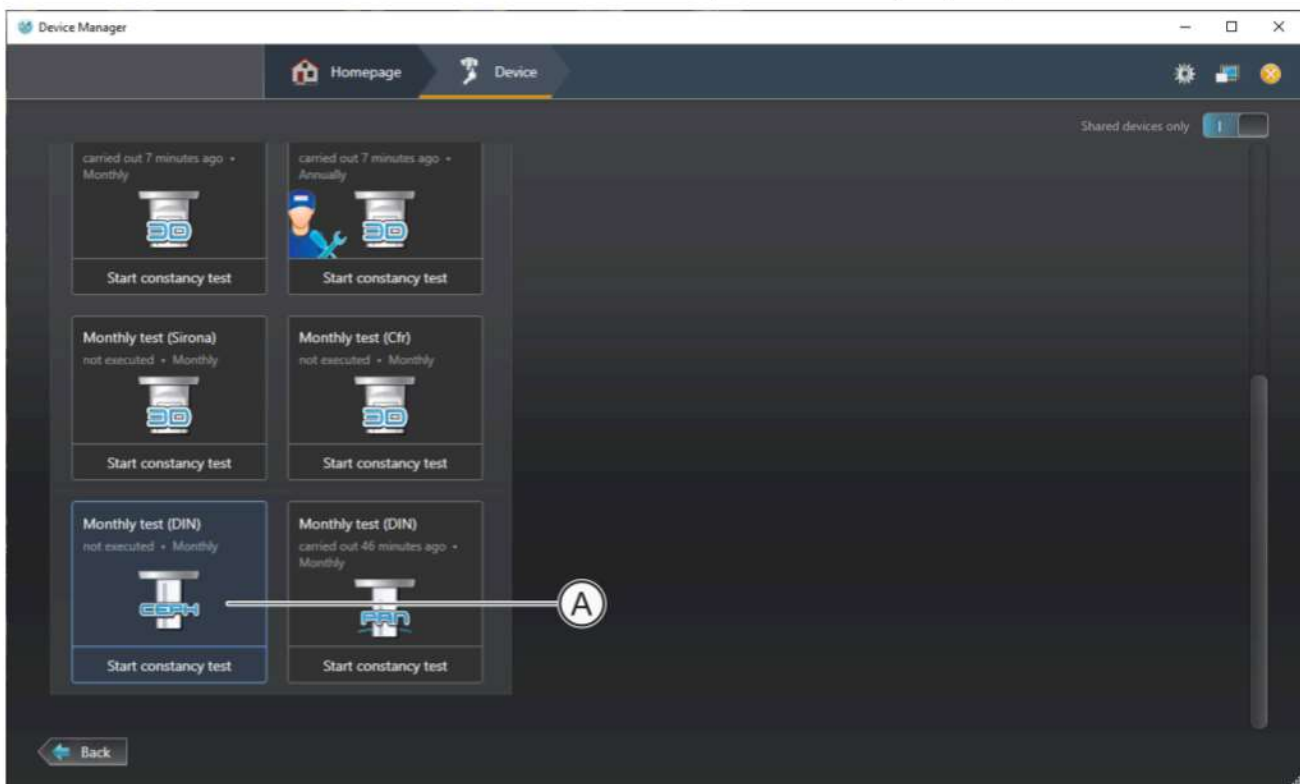
- Phantom images
- Row and pixel failures
- Row misalignment
- etc...

5.2 Performing the 2D constancy test for ceph (DIN 6868-5)

The 2D constancy test for ceph is performed in accordance with DIN 6868-5.

Starting the monthly 2D constancy test for ceph

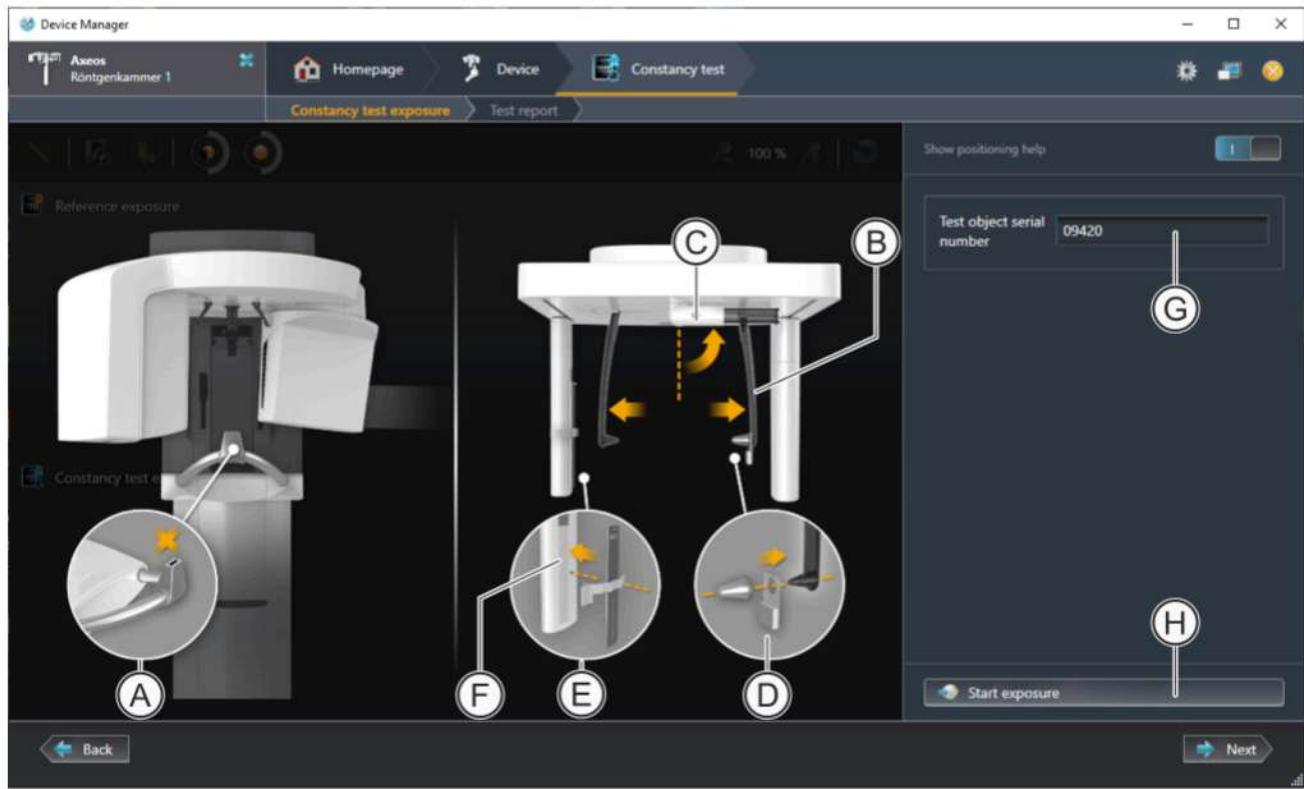
- ✓ The Device Manager is started [→ 12].
- ✓ The X-ray device is switched on (see operating instructions).
- ✓ The "Constancy test" menu is open [→ 24].



Starting the 2D constancy test for ceph

- Click on the "Ceph" icon (A).
- ↳ The 2D constancy test for ceph is started.

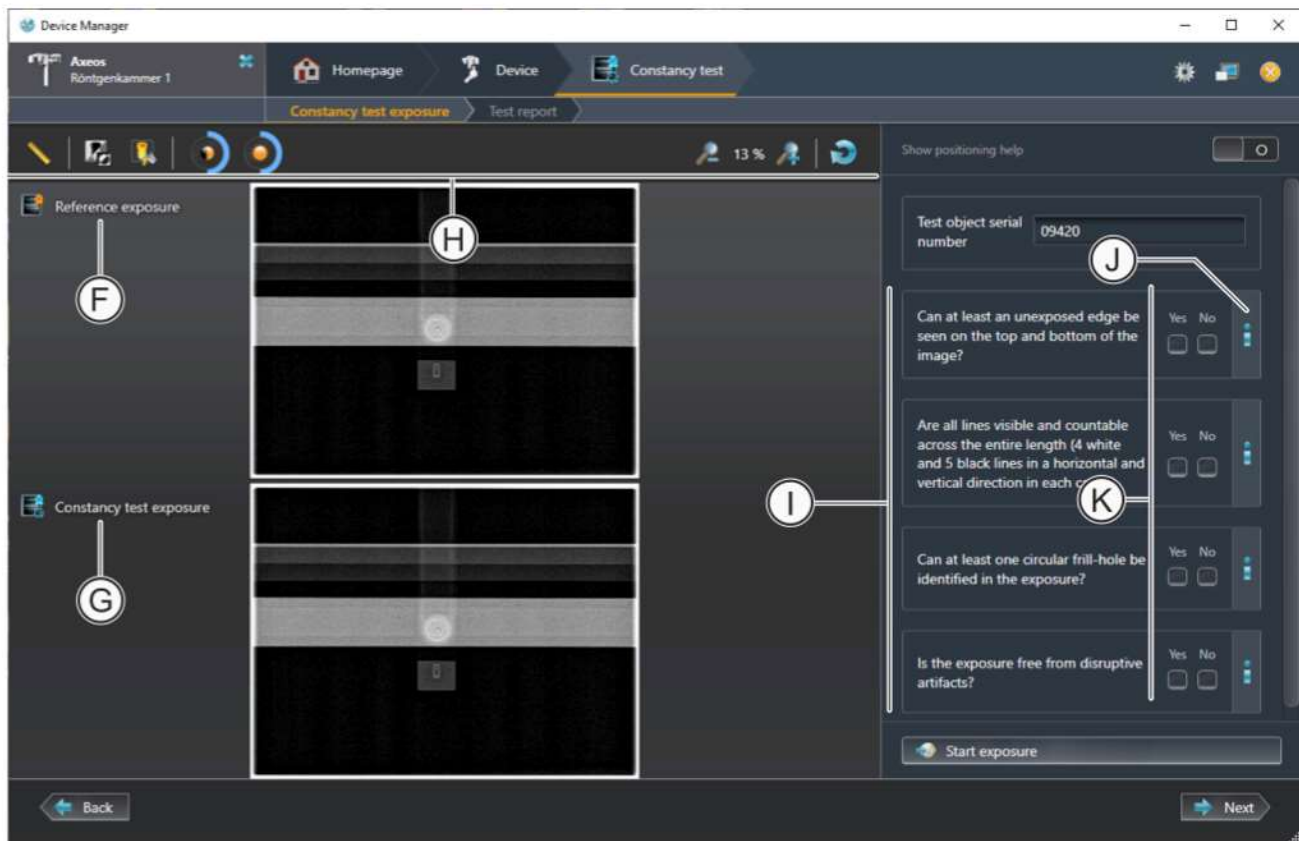
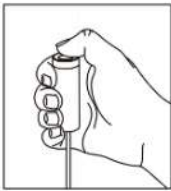
Preparing the device for the 2D constancy test exposure (ceph)

*2D constancy test for ceph*

- ✓ No test phantoms or bite blocks are inserted in the bite block holder of the device (A).
- 1. Open the ear plug holders completely, and turn the ear plug holders so that one ear plug is directly in front of the image receptor (B).
- 2. Fold up the nose support (C).
- 3. Fit the contrast element with its hole onto the ear plug and secure the position of the contrast element by fitting the protective cap onto the ear plug (D).
IMPORTANT: The aluminum plate of the contrast element must face the X-ray tube assembly.
- 4. If necessary, secure the protective cap of the ear plug with adhesive tape.
- 5. Attach the ceph test phantom to the clip provided for that purpose (E).
The clip must engage into the opening (F) on the secondary diaphragm provided for that purpose.

Performing the 2D constancy test exposure (ceph)

1. Enter the serial number of the test phantom in the text box (G).
2. Click on the "Start exposure" button (H) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.59 with the exposure parameters 80 kV/14mA, 14.9s is displayed on the user interface.
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal indicating the end of the exposure (double beep) sounds.



2D reference exposure for ceph and 2D constancy test exposure for ceph are displayed for comparison.

- ↳ The reference exposure created in the 2D acceptance test for ceph is displayed (F).
- ↳ The 2D constancy test exposure for ceph is stored in the archive (see section "") and displayed in the Device Manager (G).

5. If necessary, you can edit the exposures using the toolbar (H) [→ 22].
6. Evaluate the constancy test exposure (ceph) using the questions in the menu (I). You will find help on evaluating via the corresponding information icon (J) and in section "Evaluating the 2D constancy test exposure for ceph [→ 36]".
7. Compare the constancy test exposure with the reference exposure. No significant differences may be detected.
8. Click on the check boxes (K) in the menu corresponding to the results of your evaluation.
9. Click on the "Next" button.
 ↳ The results are transferred to the test report.

2D TEST REPORT (2D X-ray)
on the Constancy Test of Dental X-ray Equipment as per DIN 6868 Part 5

Operator: Dr. Demo Musterstrasse 1 12345 Musterstadt	Panorama unit: Axeos <input checked="" type="checkbox"/> With Cephalostat	Serial number: Complete unit: 382 X-ray tube assembly: 341 X-ray tube: 96729 Panoramic sensor: Cephalometric sensor: 195 Test phantom (Pan): Test phantom (Ceph): 09420
--	--	---

Name of X-ray device: Axeos (Röntgenkammer 1)
 Image display monitor test performed

Year: 2021 Month: 02

	Panoramic exposure		Cephalometric exposure	
	Yes	No	Yes	No
Useful beam: Is an unexposed edge visible on the exposure on at least two opposite sides?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Line pair resolution capacity: Are all lines over their complete length clearly visible and countable (4 white and 5 black lines in vertical as well as in horizontal orientation)?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Contrast resolution: Are sufficient holes visible?	2 holes		1 hole	
	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Artefacts: Is the exposure free of disruptive artefacts?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Manufacturer: Test date: 12.02.2021

Has the test been completed for the image display device and was the result in order? Yes No
 (L)

Name of tester: John Dow

Notes

Notes

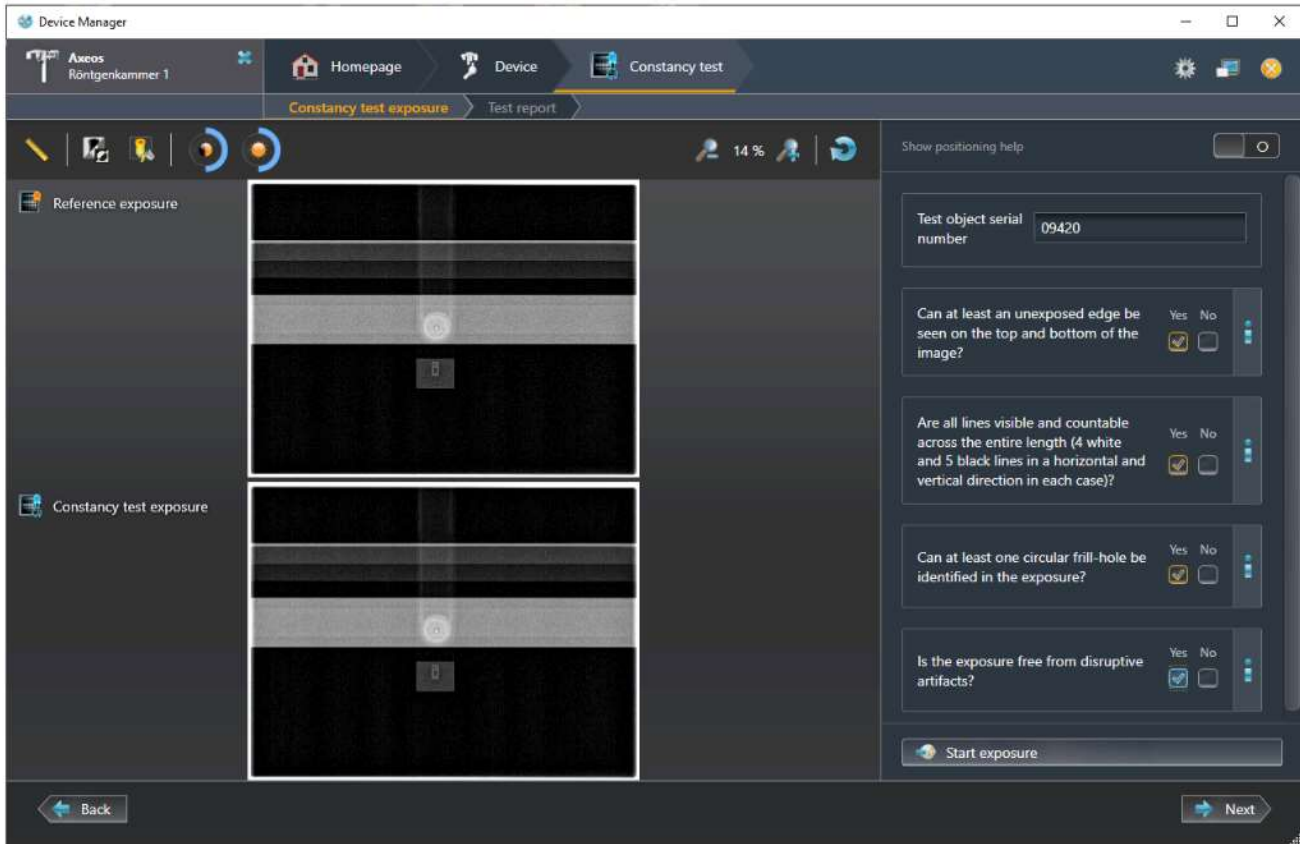
Back Save

Test report of the 2D constancy test for ceph

- ↳ The test report is displayed in the Device Manager.
10. Click on the check box (L) to confirm that the test of the image reproduction device was properly performed.
11. Enter the name of the tester and, if desired, additional comments in the text boxes (M).
12. Click on the "Save" button.

5.2.1 Evaluating the 2D constancy test exposure for ceph

Use of the functions in the toolbar may be useful for evaluating the constancy test exposure (see section "Toolbar in the exposure window [-> 22]").

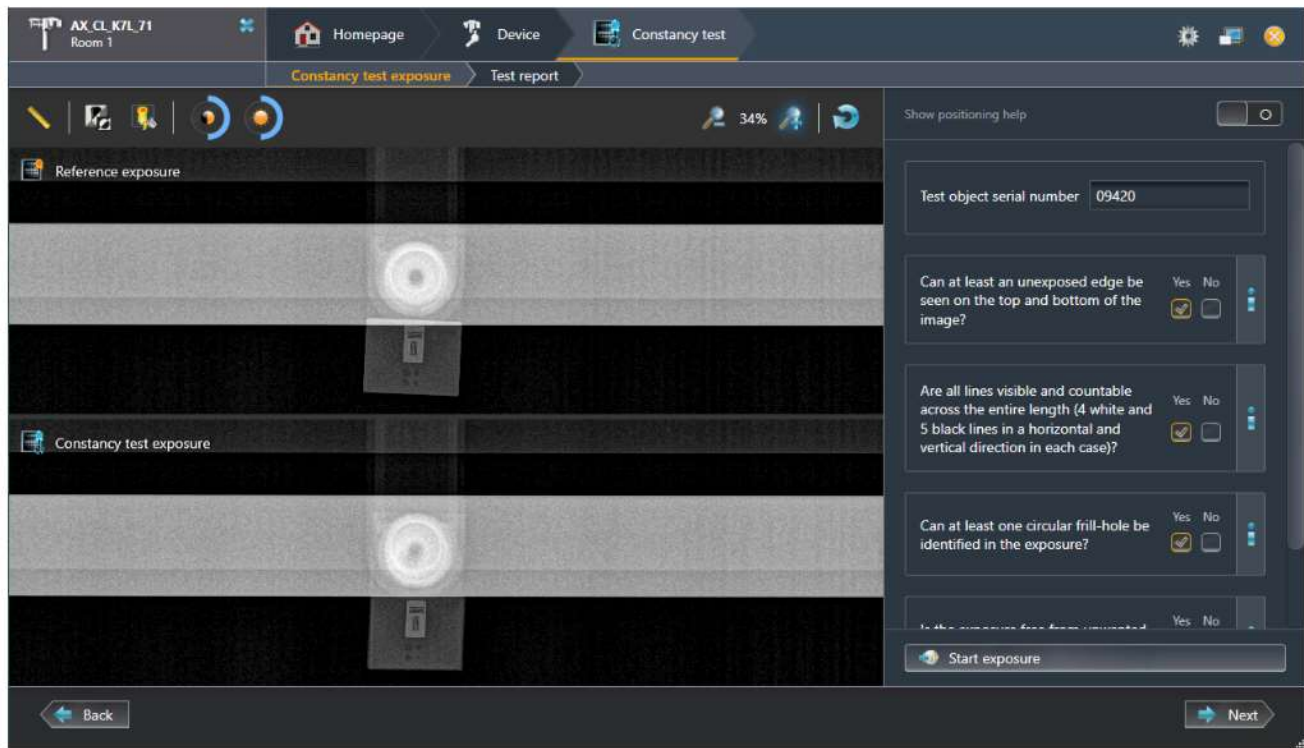


Example of a constancy test exposure for ceph

Make the evaluation using the questions in the menu and select the corresponding check boxes next to the questions.

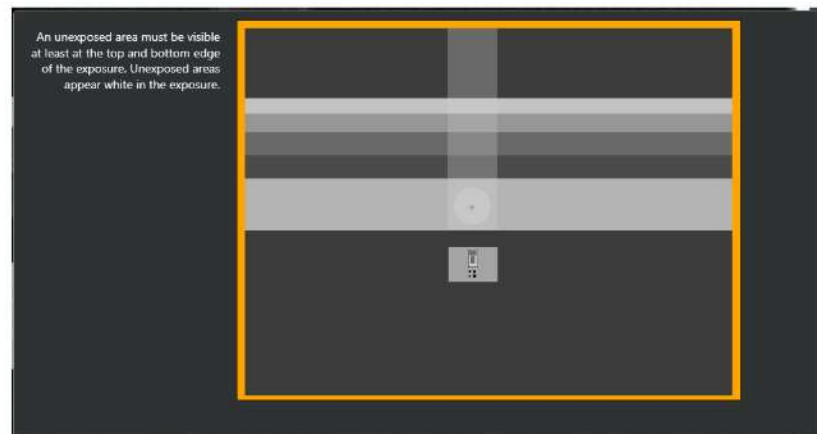
You will find help on answering the questions by hovering the mouse over the "i" icon. The points to be evaluated in the image are marked in orange.

Tip: For evaluating the exposure, zoom into/out from the exposure and move the constancy test exposure with the mouse button held down.

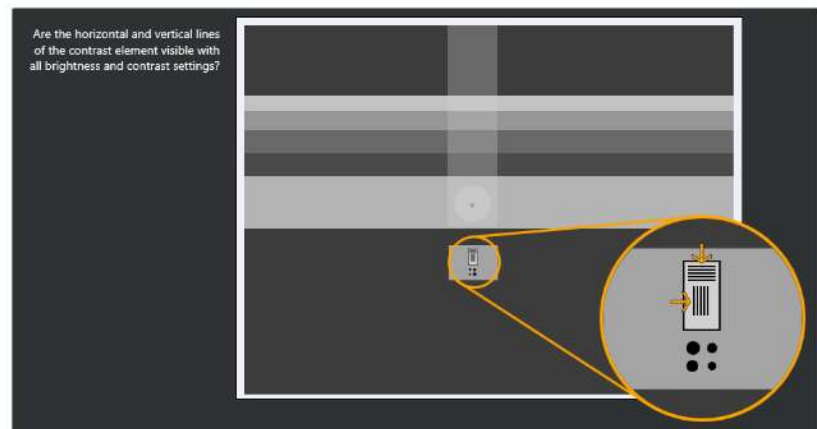


Zoomed-in exposure

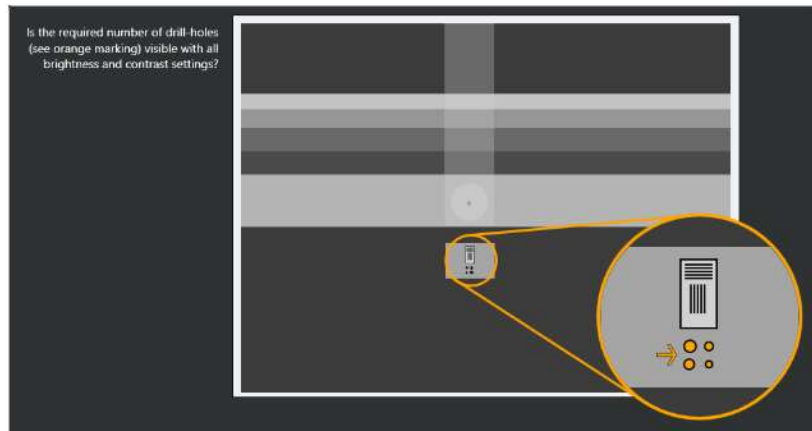
"An unexposed area must be visible at least at the top and bottom edge of the exposure. Unexposed areas appear white in the exposure."



"Are the horizontal and vertical lines of the contrast element visible with all brightness and contrast settings?"



"Is the required number of drill-holes (see orange marking) visible with all brightness and contrast settings?"



"Perform a visual inspection of the image for any unwanted artifacts. Unwanted artifacts may include: – Phantom images – Row and pixel failures – Row misalignment – etc..."

Perform a visual inspection of the image for any unwanted artifacts.

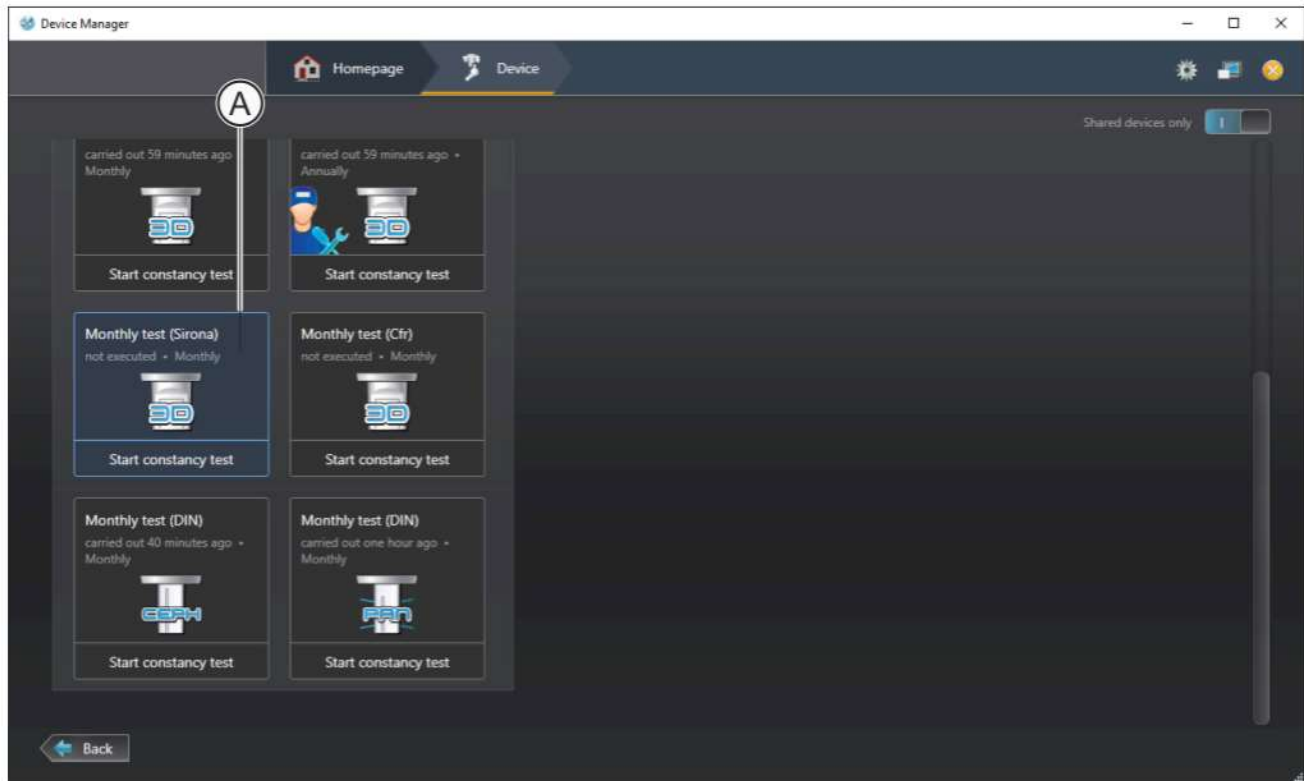
Unwanted artifacts may include:

- Phantom images
- Row and pixel failures
- Row misalignment
- etc...

5.3 Performing the 3D constancy test (Dentsply Sirona)

Starting the monthly 3D constancy test for Dentsply Sirona

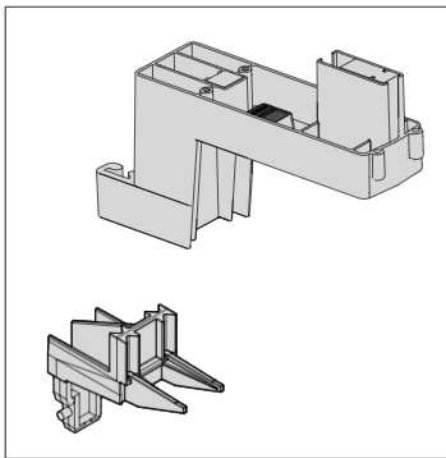
- ✓ The Device Manager is started [→ 12].
- ✓ The X-ray device is switched on (see operating instructions).
- ✓ The "Constancy test" menu is open [→ 24].



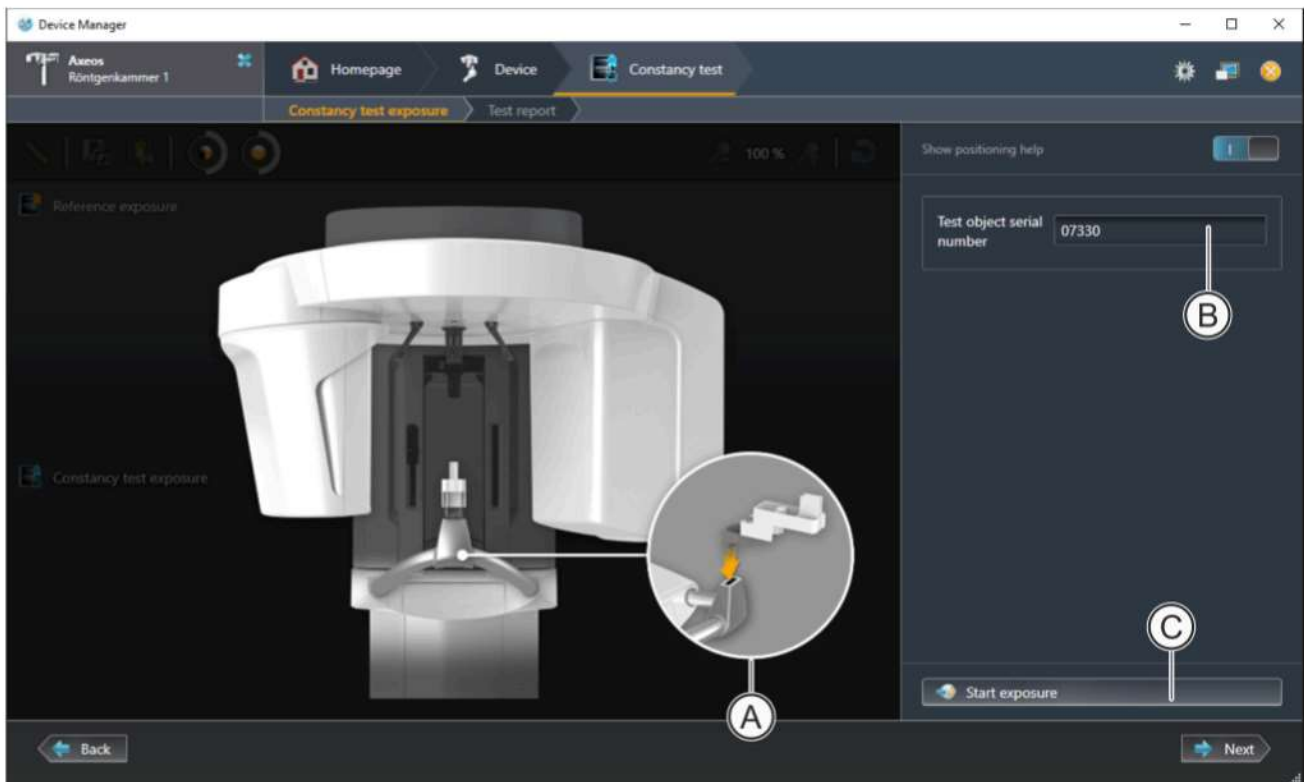
Starting the 3D constancy test for Dentsply Sirona

- Double-click on the "3D" icon (A).
 - ↳ The 3D constancy test for Dentsply Sirona is started.

Preparing the device for the 3D constancy test exposure for Dentsply Sirona



IMPORTANT
Ensure that you use the 3D constancy test phantom with the long bite block adapter (gray) for the 3D constancy test.

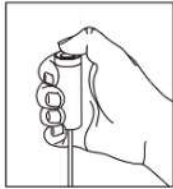


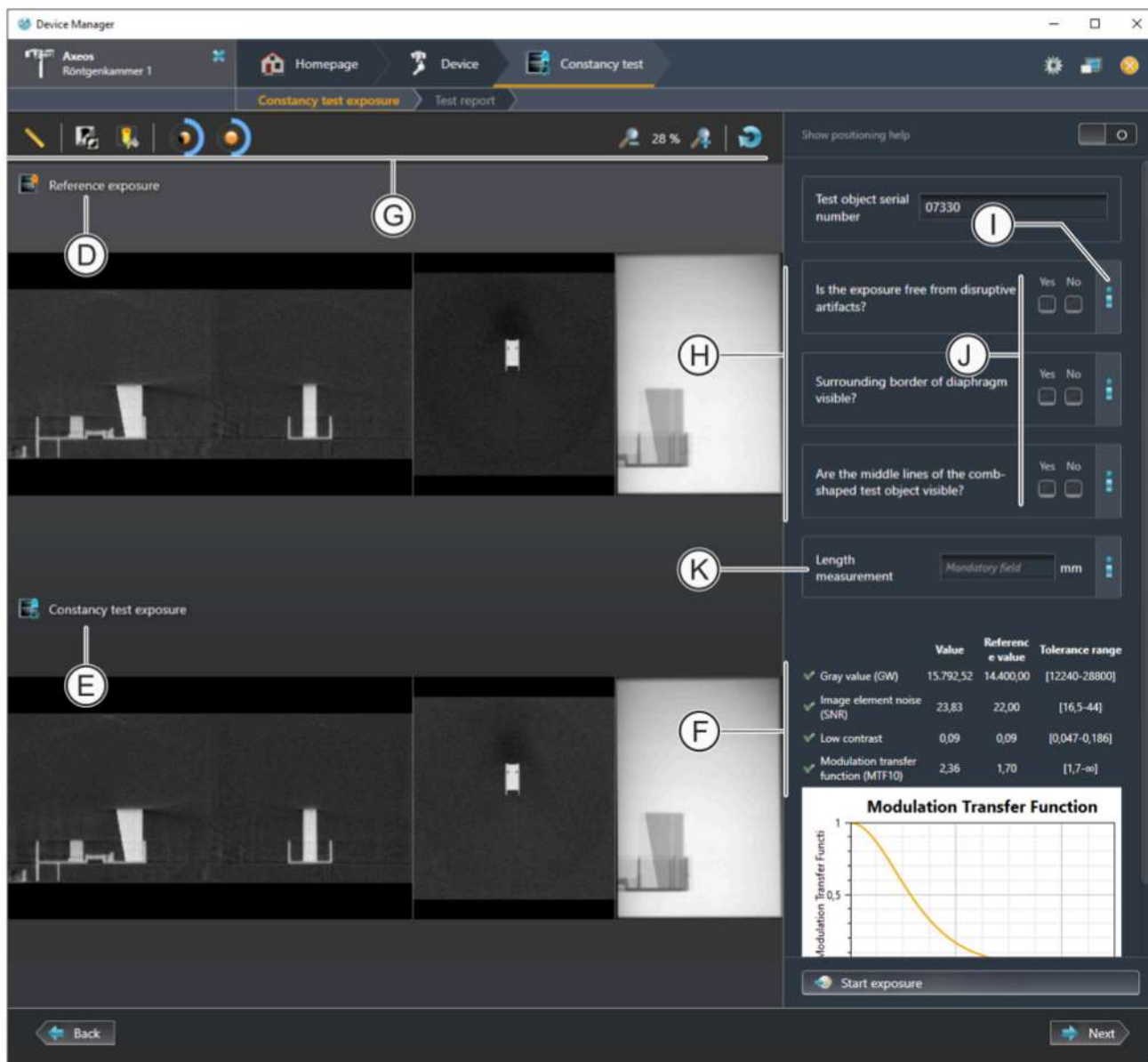
Performing the 3D constancy test for Dentsply Sirona

- Insert the constancy test phantom (A) in the bite block holder.

Performing the 3D constancy test exposure for Dentsply Sirona

1. Enter the serial number of the test phantom in the text box (B).
2. Click on the "Start exposure" button (C) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV/40 mAs is displayed on the user interface.
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal indicating the end of the exposure (double beep) sounds.





3D reference exposure for Dentsply Sirona and 3D constancy test exposure for Dentsply Sirona are displayed for comparison.

- ↪ The reference exposure created in the 3D acceptance test for Dentsply Sirona is displayed (D).
 - ↪ The 3D constancy test exposure for Dentsply Sirona (E) is stored in the archive (see section "") and displayed in the Device Manager.
 - ↪ On completion of the exposure, the Device Manager performs various measurements. The results are displayed in the form of a list (F). If the measurements are okay, all entries in the list have a green checkmark in front.
5. If necessary, you can edit the exposures using the toolbar (G) [→ 22].

6. Evaluate the 3D constancy test exposure for Dentsply Sirona using the questions in the menu (H). You will find help on evaluating via the corresponding information icon (K) and in section "Evaluating the 3D constancy test exposure for Dentsply Sirona [-> 45]".
7. Compare the constancy test exposure with the reference exposure. No significant differences may be detected.
8. Click on the check boxes (J) in the menu corresponding to the results of your evaluation.

The screenshot displays the software interface for a 3D constancy test. The main area shows two side-by-side X-ray images of a phantom. The top image is labeled 'Reference exposure' and the bottom image is 'Constancy test exposure'. A red horizontal line in the constancy test exposure is labeled '62,78 mm'. To the right, a control panel contains the following elements:

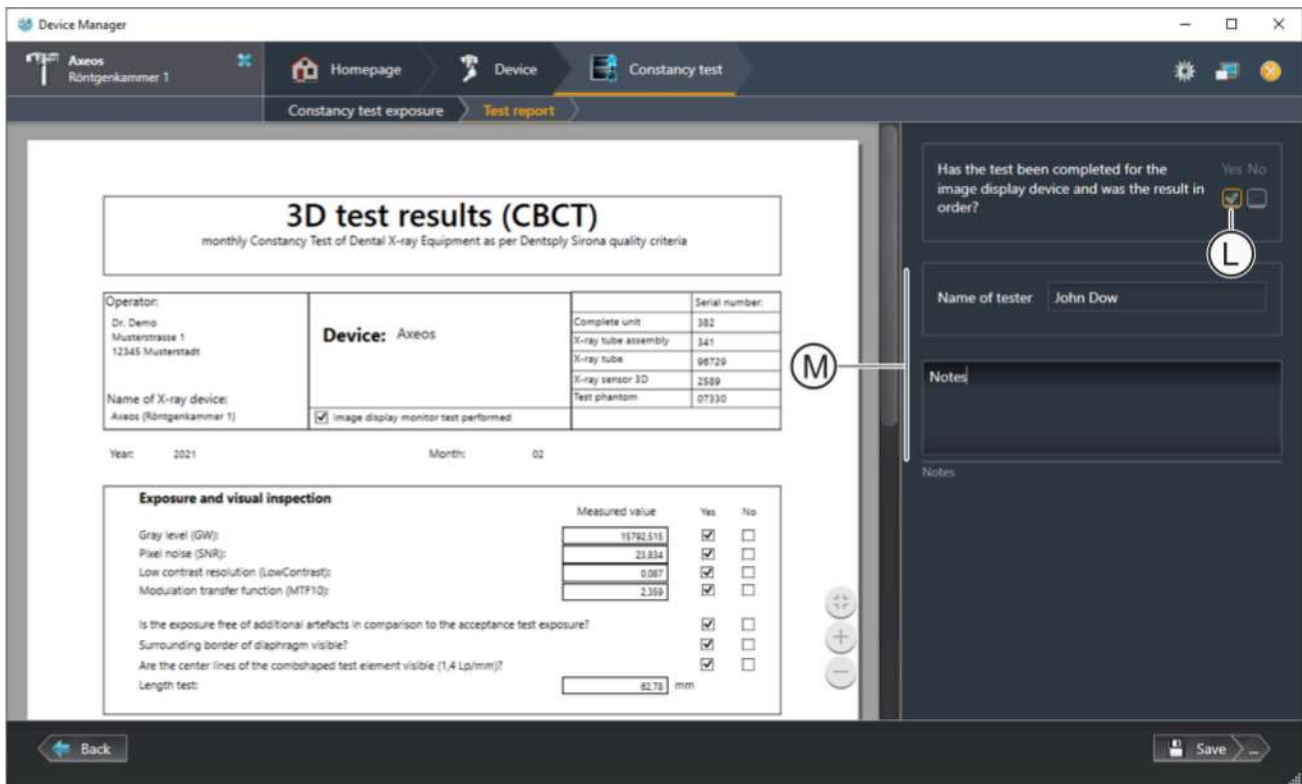
- 'Test object serial number' field with the value '07330'.
- Three evaluation questions, each with 'Yes' and 'No' radio buttons:
 - 'Is the exposure free from disruptive artifacts?' (Yes checked)
 - 'Surrounding border of diaphragm visible?' (Yes checked)
 - 'Are the middle lines of the comb-shaped test object visible?' (Yes checked)
- 'Length measurement' field with the value '62,78 mm'.
- A table of quality metrics:

	Value	Reference value	Tolerance range
✓ Gray value (GW)	15.792,52	14.400,00	[12240-28800]
✓ Image element noise (SNR)	23,83	22,00	[16,5-44]
✓ Low contrast	0,09	0,09	[0,047-0,186]
✓ Modulation transfer function (MTF10)	2,36	1,70	[1,7-∞]
- A 'Modulation Transfer Function' graph showing a curve starting at 1.0 and decreasing towards 0.0.
- 'Start exposure' button.

Navigation buttons 'Back' and 'Next' are visible at the bottom of the interface.

Length measurement

9. Measure the distance between the front and back edge of the constancy test phantom with the measuring ruler and enter the measured value in the text box (K).
10. Click on the "Next" button.
 - ↳ The results are transferred to the test report.

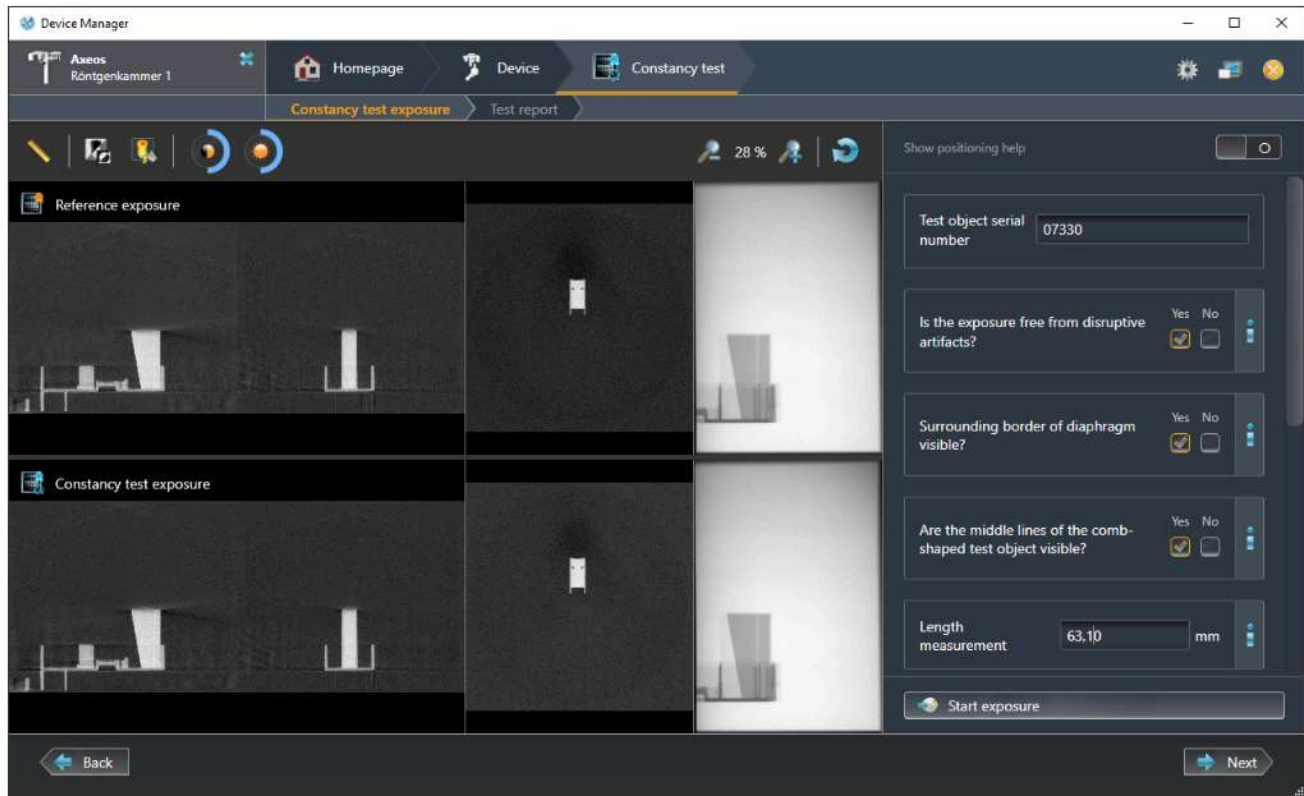


Test report of the 3D constancy test (Dentsply Sirona)

- 🖱️ The test report is displayed in the Device Manager.
11. Click on the check box (L) to confirm that the test of the image reproduction device was properly performed.
 12. Enter the name of the tester and, if desired, additional comments in the text boxes (M).
 13. Click on the "Save" button.

5.3.1 Evaluating the 3D constancy test exposure for Dentsply Sirona

Use of the functions in the toolbar may be useful for evaluating the constancy test exposure (see section "Toolbar in the exposure window [→ 22]").



Example of a 3D constancy test exposure for Dentsply Sirona

Make the evaluation using the questions in the menu and select the corresponding check boxes next to the questions.

You will find help on answering the questions by hovering the mouse over the "i" icon. The points to be evaluated in the image are marked in orange.

Tip: For evaluating the exposure, zoom into/out from the exposure and move the constancy test exposure with the mouse button held down.

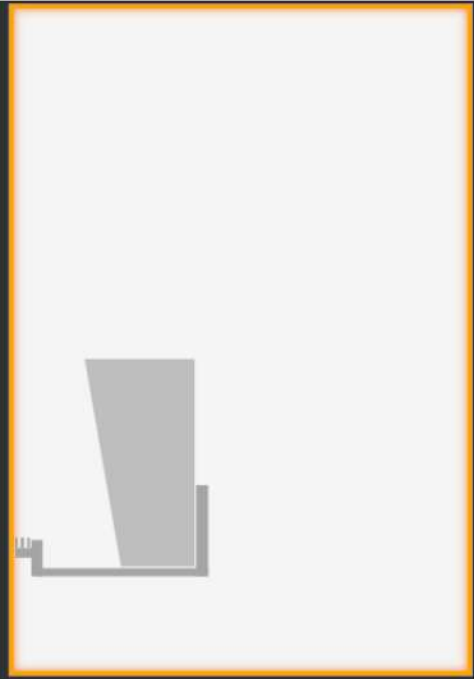
"Perform a visual inspection of the image for any unwanted artifacts. Unwanted artifacts may include: – Phantom images – Row and pixel failures – Row misalignment – etc..."

Perform a visual inspection of the image for any unwanted artifacts.
Unwanted artifacts may include:

- Phantom images
- Row and pixel failures
- Row misalignment
- etc...

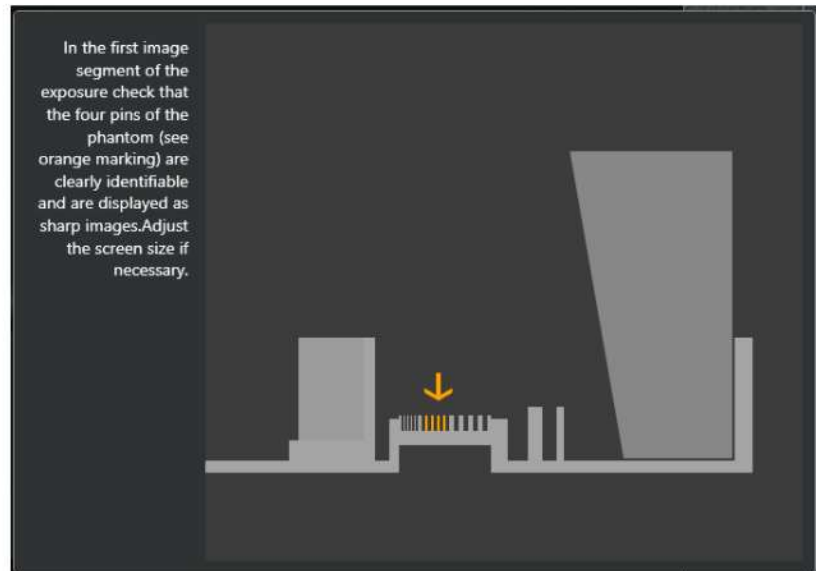
"Surrounding border of diaphragm visible?"

Check the diaphragm border of the control image. A depletion in gray tone must be visible (diaphragm border with soft transitions). The 'Pseudo color' filter can also be used to highlight the depletion in gray tone at the diaphragm borders.

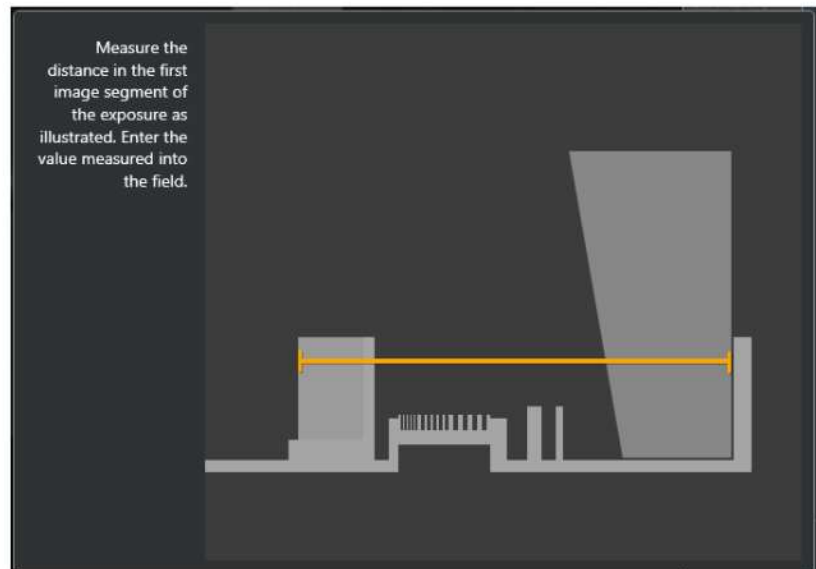


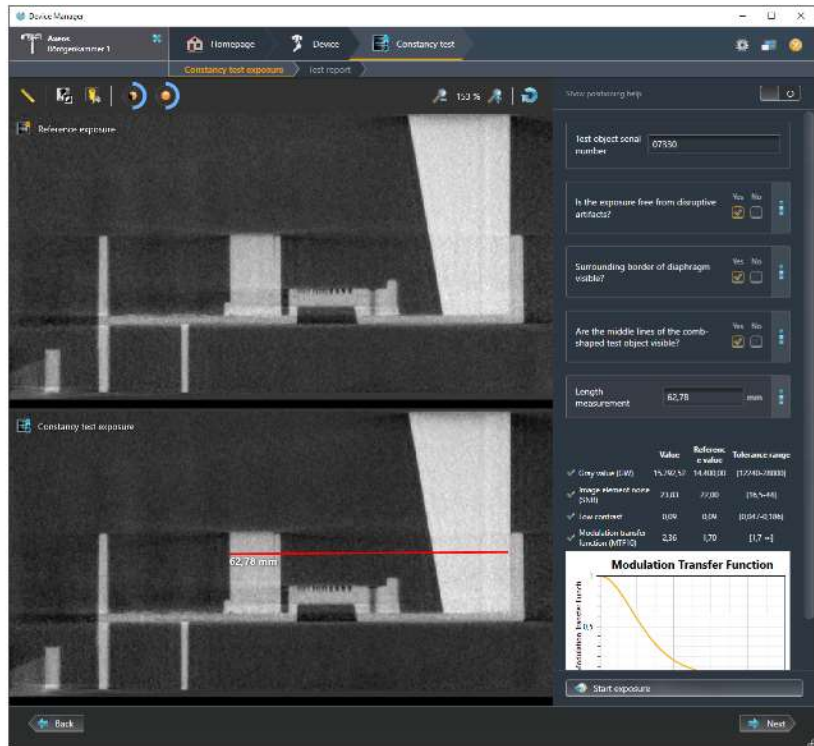
Tip: Use the false colors function for evaluating the diaphragm edge.

"In the first image segment of the exposure check that the four pins of the phantom (see orange marking) are clearly identifiable and are displayed as sharp images. Adjust the screen size if necessary."



"Length measurement (mm)"



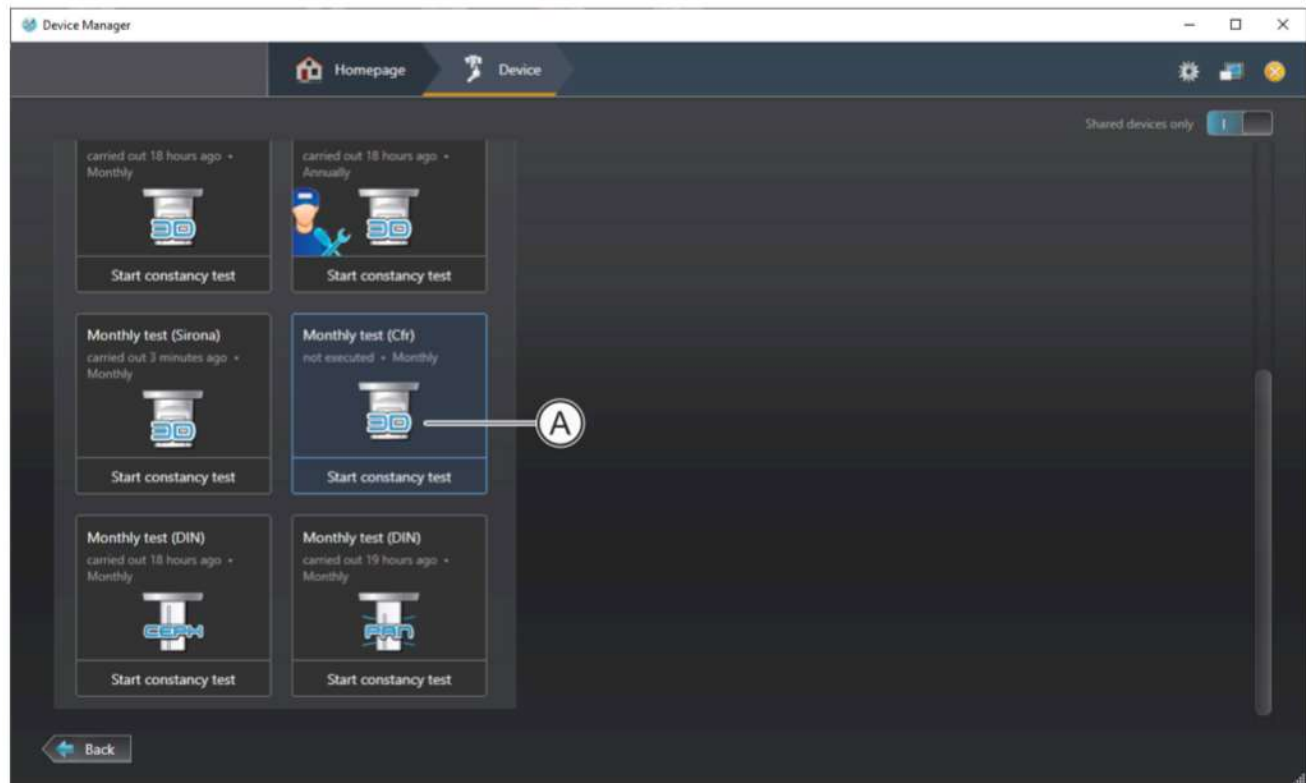


Length measurement

5.4 Performing the 3D constancy test (21 CFR 1020.33)

5.4.1 Starting the 3D constancy test for 21 CFR 1020.33

- ✓ The Device Manager is started [→ 12].
- ✓ The X-ray device is switched on (see operating instructions).
- ✓ The "Constancy test" menu is open [→ 24].



Starting the 3D constancy test for 21 CFR 1020.33

- Double-click on the "3D" icon (A).
- The 3D acceptance test for 21 CFR 1020.33 is started.

5.4.2 Performing visual and functional tests for 21 CFR 1020.33

The screenshot shows the 'Device Manager' application window. The top navigation bar includes 'Homepage', 'Device', and 'Constancy test'. Below this, a breadcrumb trail shows 'Visual and functional inspections' > 'Reference exposure' > 'Test report'. The main content area lists eight test steps:

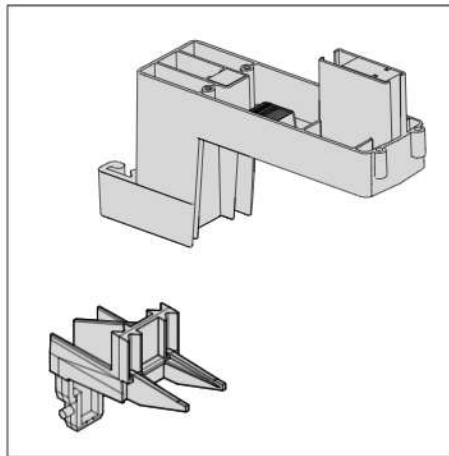
- 1.1 Unit assembled without error according to installation instructions?
- 1.2 Focal spot nominal size (IEC 60336): 0.5
- 1.3 Total filtration (target value: 2.5 mm Al)
read out: mm Al
- 1.4 Light localizer(s) in order?
- 1.5 Parameters (kV, mA, s) identifiable?
- 1.6 Are adjustment aids available (test object and geometric object)?
- 1.7 Adjustment of the (primary) diaphragm according to installation instructions in order?
- 1.8 Dose area product display legible?

To the right of these questions are 'Yes' and 'No' checkboxes. A vertical line of checkboxes is labeled with a circled 'A'. A circled 'B' points to the 'read out' text box for item 1.3. At the bottom, there are 'Back' and 'Next' buttons.

Performing visual inspections and functional tests

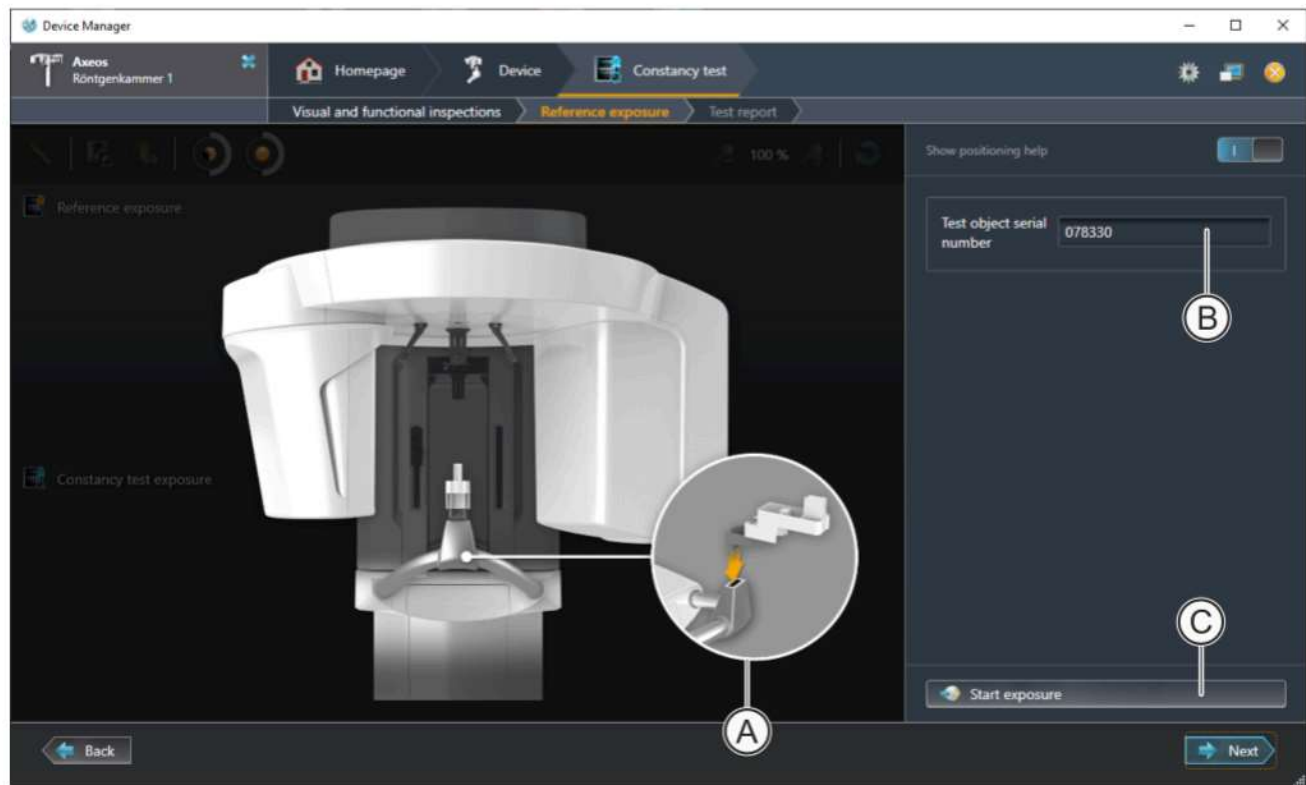
1. Perform the visual and functional tests according to test steps 1.1 to 1.8 requested in the menu.
2. Click on the check boxes (A) in the menu corresponding to the results of your test.
3. Read the actual value for the total filtration from the rating plate of the X-ray tube assembly and enter the value in the text box (B).
4. Click on the "Next" button.
 - ↳ The results are transferred to the test report.
 - ↳ The "Reference exposure" menu opens.
5. Continue with the "Reference exposure" for the constancy test [→ 51].

5.4.3 Performing the 3D constancy test exposure for 21 CFR 1020.33



IMPORTANT

Ensure that you use the 3D constancy test phantom with the long bite block adapter (gray) for the 3D constancy test.



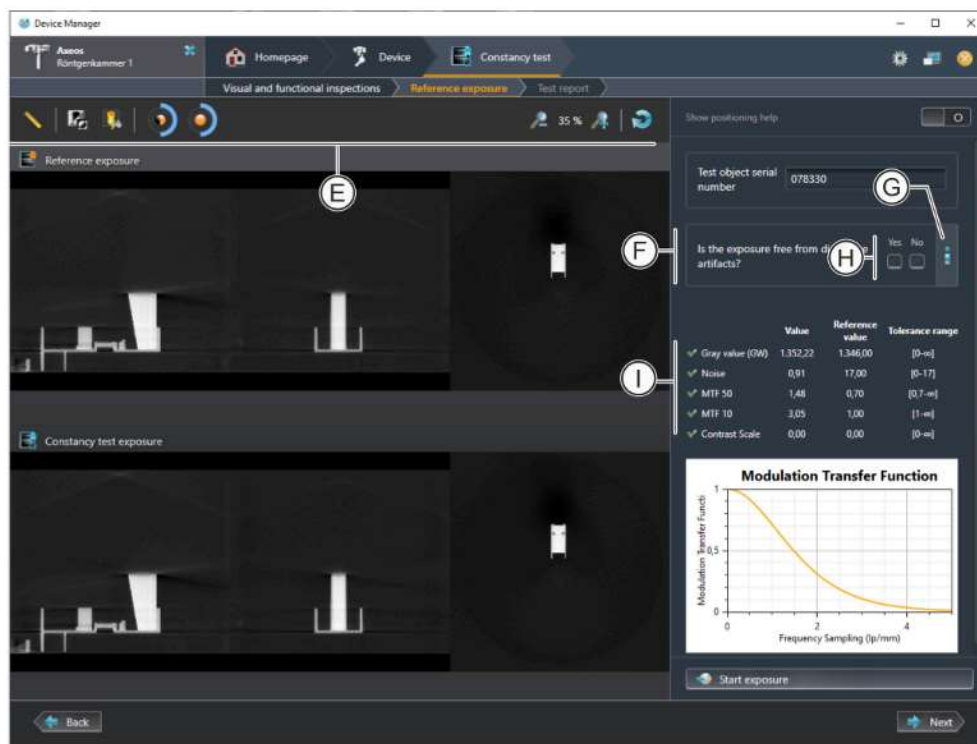
Constancy test exposure (3D)

Preparing the device for the constancy test exposure (3D)

- > Insert the constancy test phantom (A) in the bite block holder.

Performing the constancy test exposure (3D)

1. Enter the serial number of the test phantom in the text box (B).
2. Click on the "Start exposure" button (C) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the EasyPad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV/40 mAs is displayed on the user interface.
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal indicating the end of the exposure (double beep) sounds.



Constancy test exposure (3D)

- ↳ The constancy test exposure (3D) is stored in the archive (see section """) and displayed in the Device Manager.
 - ↳ On completion of the exposure, the Device Manager performs various measurements. The results are displayed in the form of a list (I) and a graph. If the measurements are okay, all entries in the list have a green checkmark in front.
5. If necessary, you can edit the reference exposure using the toolbar (E) [→ 22].

6. Evaluate the constancy test exposure (3D) using the questions in the menu (F). You will find help on evaluating via the corresponding information icon (G).
7. Click on the check boxes (H) in the menu corresponding to the results of your evaluation.
8. Click on the "Next" button.
 - ↳ The results are transferred to the test report.

3D TEST REPORT (CBCT)
about the quality check of dental X-ray equipment as per 21.CFR1020.33

Operator:
Dr. Demo
Musterstrasse 1
12345 Musterstadt

Device: Axiex

Name of X-ray device:
Axiex (Röntgenkammer 1)

Image display monitor test performed

Serial number:	
Complete unit	382
X-ray tube assembly	341
X-ray tube	96729
X-ray sensor 3D	2589
Test phantom	078330

1. Visual and function tests (optional)

	Yes	No
1.1 Unit assembled without error according to installation instructions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1.2 Focal spot nominal size (IEC 60336): 0.5	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1.3 Total filtration (target value: 2.5 mm Al) read out 2.5 mm Al	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1.4 Light localizer(s) in order?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1.5 Parameters (kV, mA, s) identifiable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1.6 Setup aids (test specimen and geometric phantom) available?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1.7 Adjustment of the (primary) diaphragm according to installation instructions in order?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1.8 Dose area product display legible?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

2. Measuring variables (optional)

Nominal value or conditions (limit value)	According to measurement	Test equipment for measured values
2.1 Reproducibility of image receptor dose Nominal values: 85 kV, 7 mA, 0 s Avg. deviation for measurement max ±10%	CBCT 1. <input type="text"/> %/A mGy 2. <input type="text"/> %/A mGy 3. <input type="text"/> %/A mGy	Measuring instrument:

Has the test been completed for the image display device and was the result in order? Yes No (J)

Name of tester: John Dow

Notes

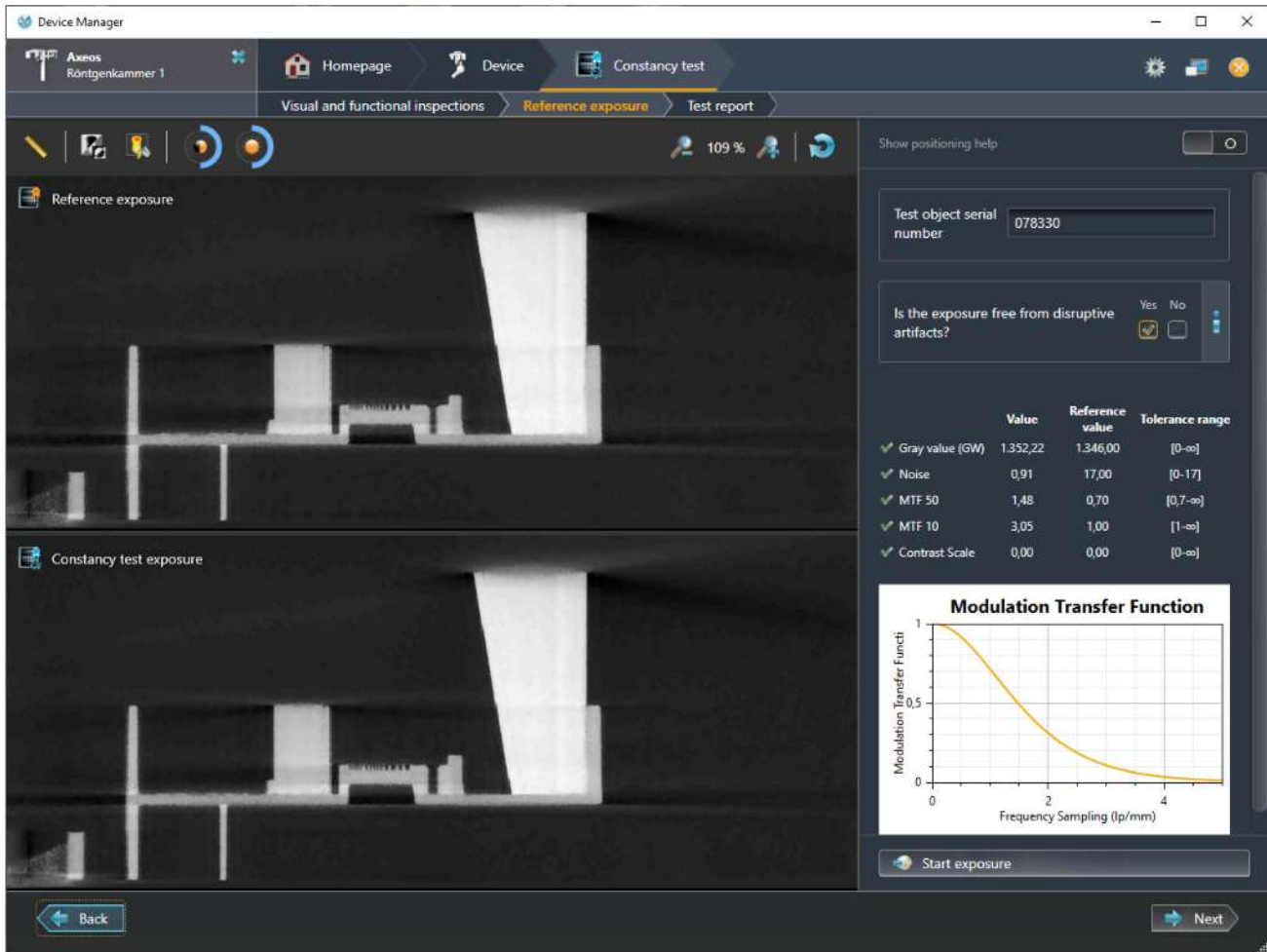
Back Save

Test report of the 3D constancy test (21.CFR1020.33)

9. Click on the check box (J) to confirm that the test of the image reproduction device was properly performed.
10. Enter the name of the tester and, if desired, additional comments in the text boxes (K).
11. Click on the "Save" button.

5.4.3.1 Evaluating the 3D constancy test exposure (21 CFR 1020.33)

Use of the functions in the toolbar may be useful for evaluating the constancy test exposure (see section "Toolbar in the exposure window [-> 22]").



Example of a 3D constancy test exposure for 21 CFR 1020.33

Make the evaluation using the questions in the menu and select the corresponding check boxes next to the questions.

You will find help on answering the questions by hovering the mouse over the "i" icon. The points to be evaluated in the image are marked in orange.

Tip: For evaluating the exposure, zoom into/out from the exposure and move the reference exposure with the mouse button held down.

"Perform a visual inspection of the image for any unwanted artifacts. Unwanted artifacts may include: – Phantom images – Row and pixel failures – Row misalignment – etc..."

Perform a visual inspection of the image for any unwanted artifacts.

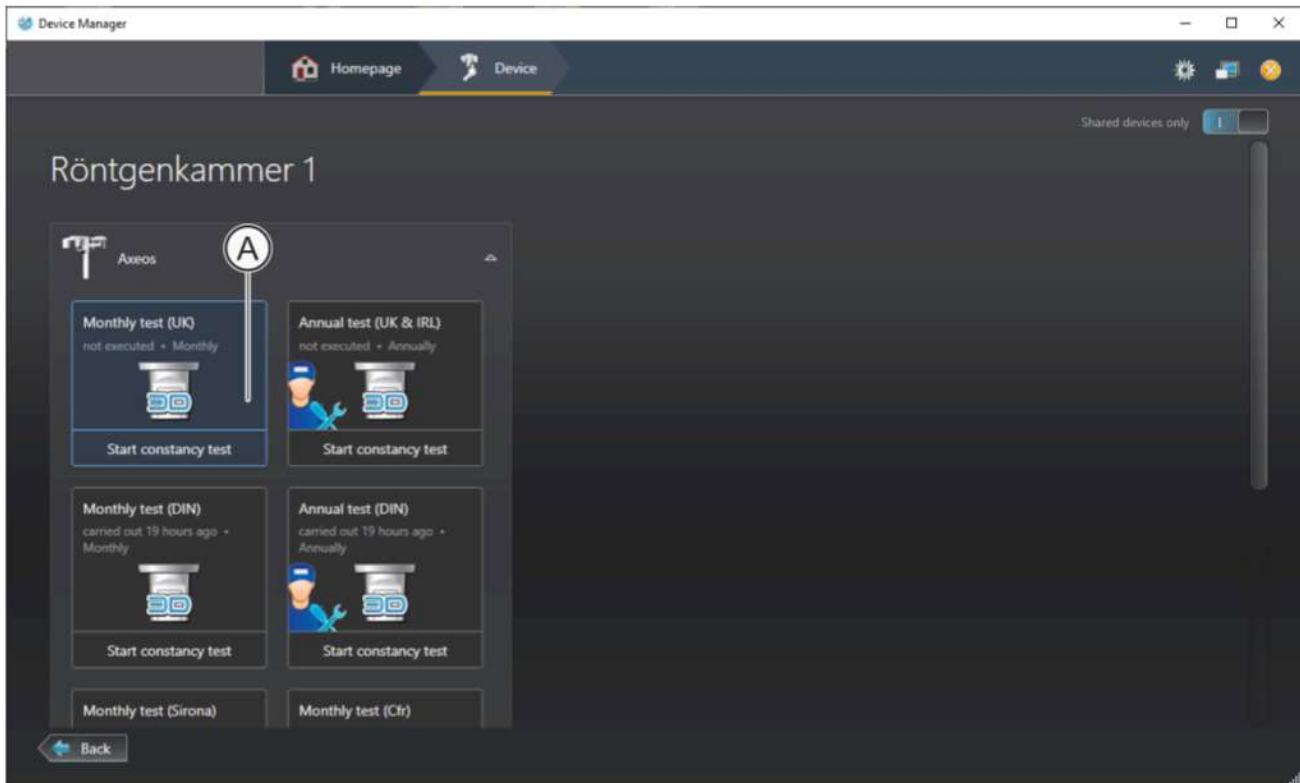
Unwanted artifacts may include:

- Phantom images
- Row and pixel failures
- Row misalignment
- etc...

5.5 Performing the 3D constancy test (UK & IRL)

5.5.1 Starting the 3D constancy test UK & IRL

- ✓ The Device Manager is started [→ 12].
- ✓ The X-ray device is switched on (see operating instructions).
- ✓ The "Constancy test" menu is open [→ 24].



Starting the 3D constancy test UK & IRL

- Double-click on the "3D" icon (A).
- ↳ The 3D constancy test UK & IRL starts.

5.5.2 Performing the visual inspections and functional tests UK & IRL

The screenshot shows the 'Device Manager' software interface. The top navigation bar includes 'Homepage', 'Device', and 'Constancy test'. Below this, a breadcrumb trail shows 'Visual and functional inspections' > 'Constancy test exposure' > 'Test report'. The main area contains four inspection questions, each with 'Yes' and 'No' radio button options:

- Safety and warning systems (lights, audible warnings, etc.) in order? Yes No
- Is the release button working as expected? Yes No
- Is the rotational or scanning motion during an exposure smooth and unobstructed? Yes No
- Is the overall general condition of the tube head and any other relevant physical attributes of the device in order? Yes No

A circled 'A' points to the 'No' option for the second question. At the bottom, there are 'Back' and 'Next' buttons.

Performing visual inspections and functional tests

1. Perform the visual inspection and functional test by following the test step prompts in the menu. Use the information given in the installation instructions (hardware and software) for this.
2. Click on the check boxes (A) in the menu corresponding to the results of your test.
3. Click on the "Next" button.
 - ↳ The results are transferred to the test report.
 - ↳ The "Reference exposure" menu opens.
4. Continue with the constancy test exposure [→ 56].

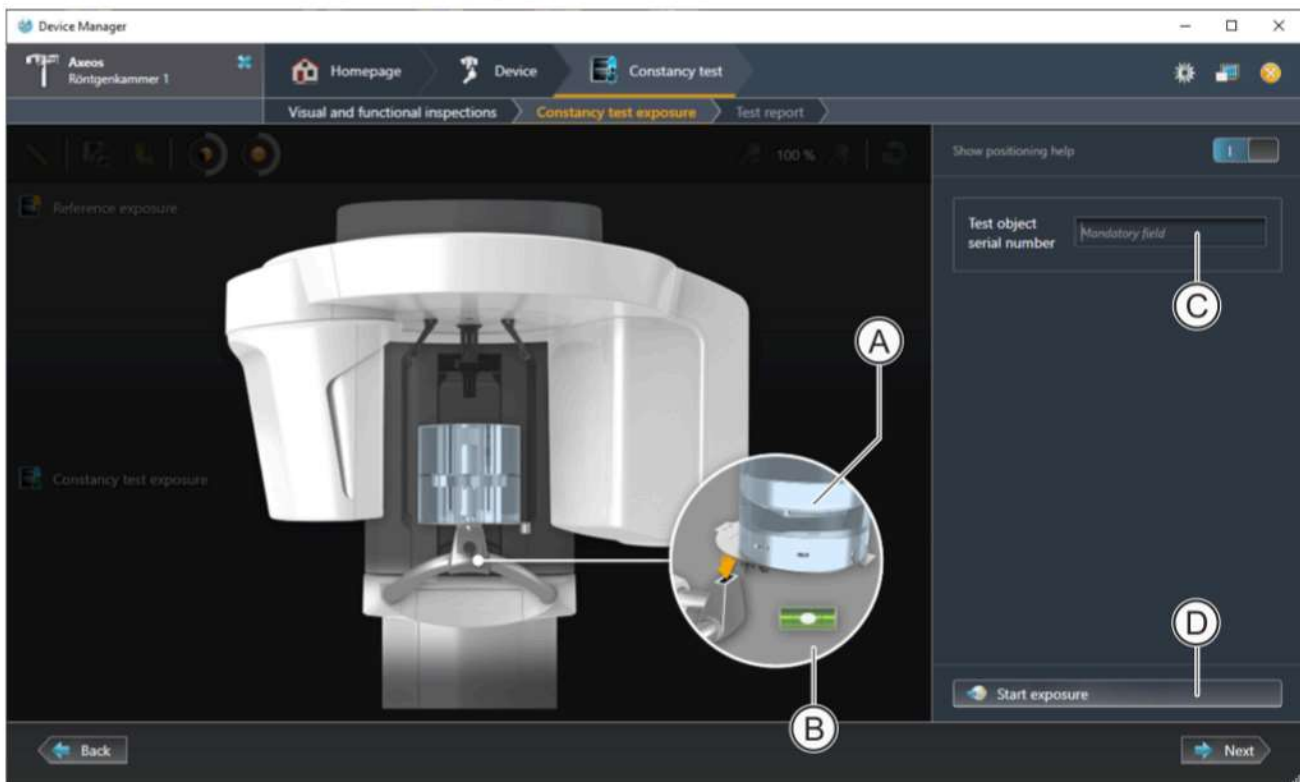
5.5.3 Performing the 3D constancy test exposure UK & IRL

NOTE

Possible incorrect positioning

The CBCT test phantom is supplied pre-assembled for the Orthophos S/SL.

- > Modify the test phantom as appropriate (see section Test phantom modification).
Position 2 = correct installation of the PMMA test phantom on the positioning plate for the Axeos



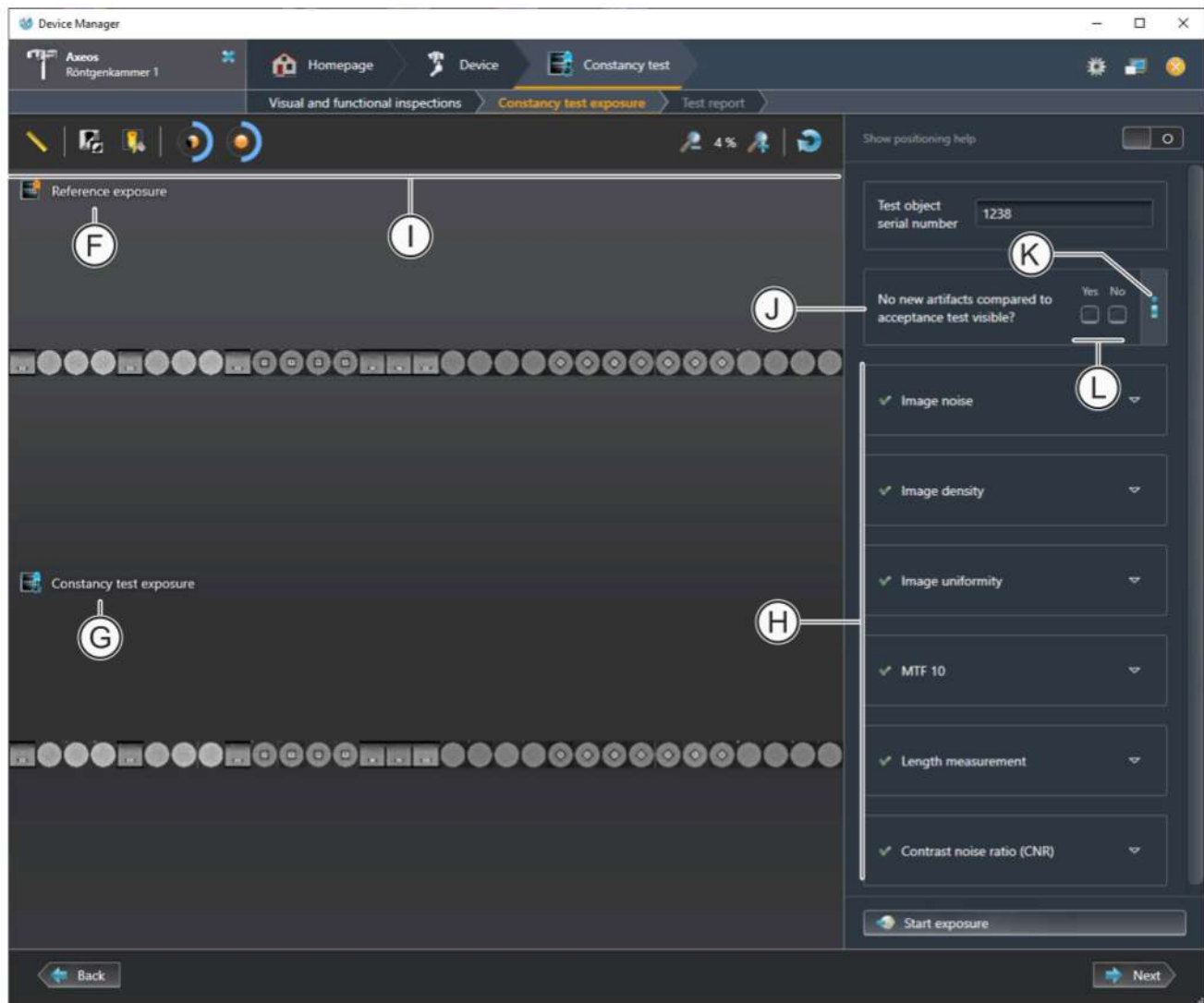
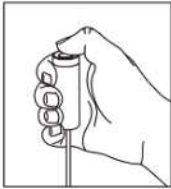
Constancy test exposure (3D)

Preparing the device for the constancy test exposure (3D)

1. Insert the CBCT test phantom (A) into the bite block holder.
2. Align the test phantom horizontally using the adjustment screw on the test phantom (B).

Performing the constancy test exposure (3D)

1. Enter the serial number of the test phantom in the text box (B).
2. Click on the "Start exposure" button (C) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV/51 mAs is displayed on the user interface.
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal indicating the end of the exposure (double beep) sounds.

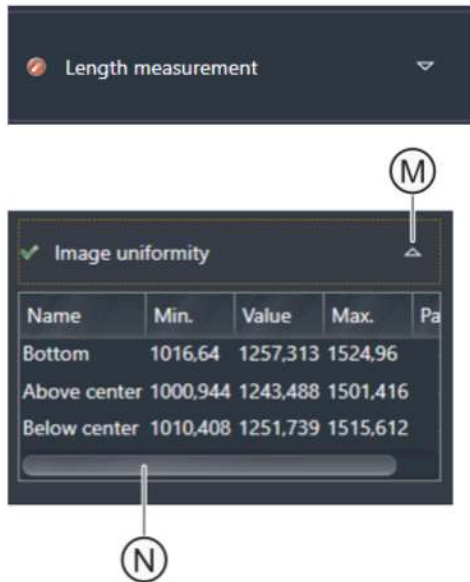


Constancy test exposure (3D)

On completion of the exposure, the Device Manager performs various measurements. The results are displayed in the form of a list (H). If the measurements are okay, all entries in the list have a green checkmark in front.

If a measurement is not okay, it is marked with a red symbol.

The measurement can be displayed by clicking the arrow icon (M). The scrollbar (N) can be used to move the content of the window horizontally.



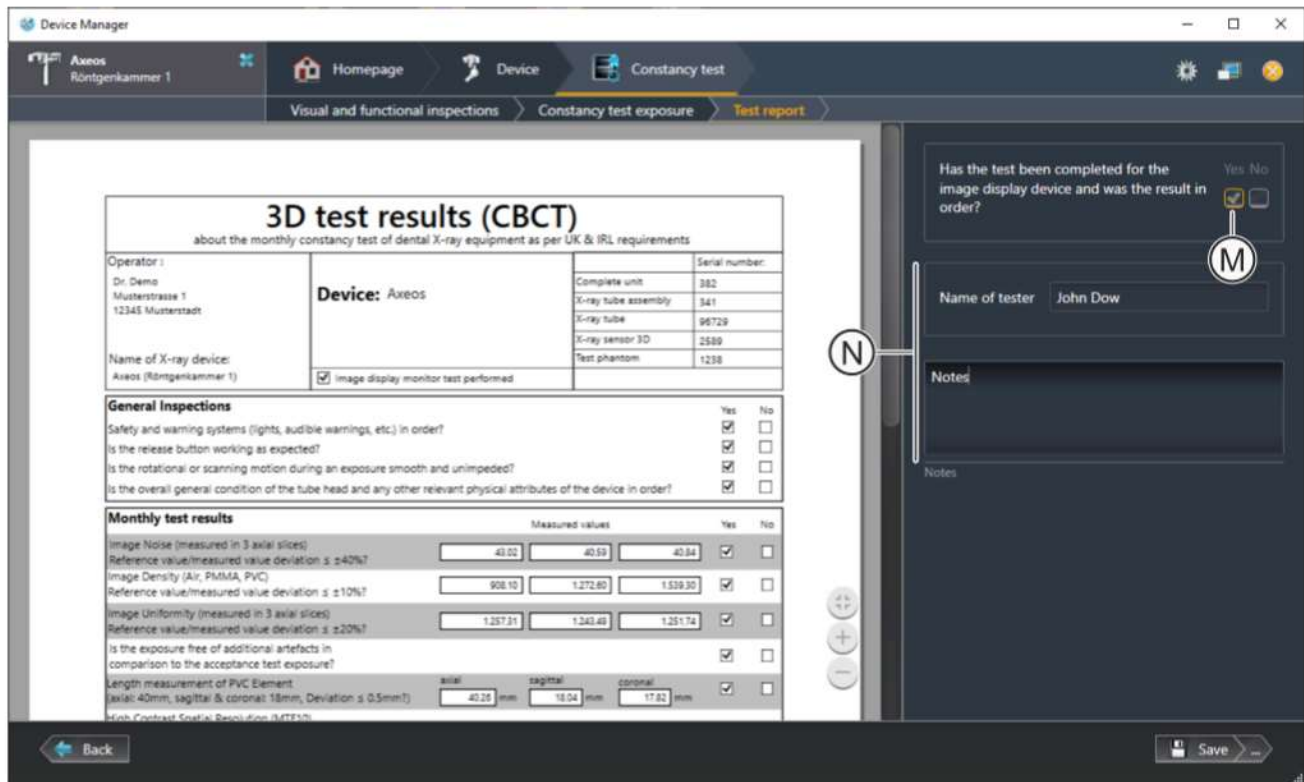
If necessary, you can edit the reference exposure using the toolbar (E) [→ 22].

Evaluate the constancy test exposure (3D) using the questions in the menu (J). You will find help on making the evaluation via the corresponding info icon (K) and in section "Evaluating the constancy test exposure for 3D (UK & IRL) [→ 62]".

Click on the check boxes (L) in the menu corresponding to the results of your evaluation.

Click on the "Next" button.

The results are transferred to the test report.



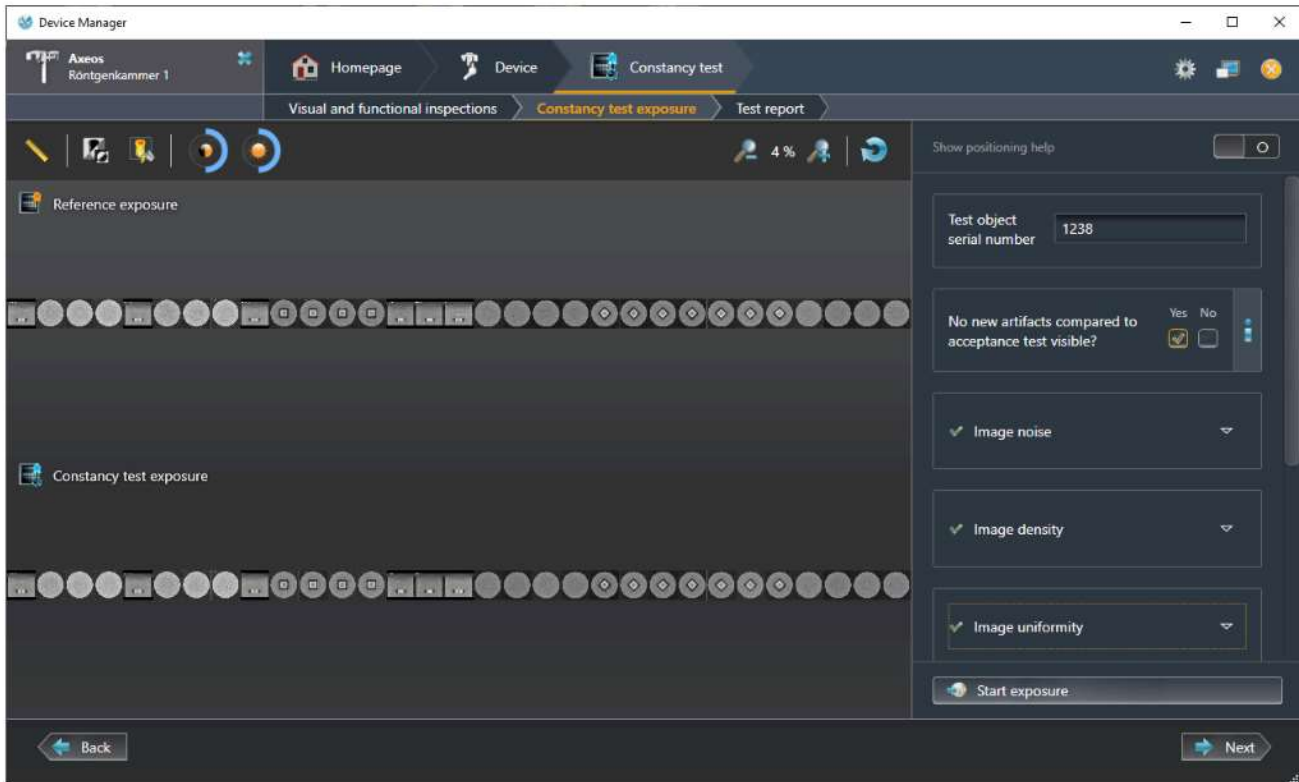
Test report of the 3D constancy test (UK & IRL)

The test report is displayed in the Device Manager.

9. Click on the check box (M) to confirm that the test of the image reproduction device was properly performed.
10. Enter the name of the tester and, if desired, additional comments in the text boxes (N).
11. Click on the "Save" button.

5.5.3.1 Evaluating the constancy test exposure for 3D (UK & IRL)

Use of the functions in the toolbar may be useful for evaluating the constancy test exposure (see section "Toolbar in the exposure window [-> 22]").



Example of a 3D constancy test exposure UK & IRL

Make the evaluation using the questions in the menu and select the corresponding check boxes next to the questions.

You will find help on answering the questions by hovering the mouse over the "i" icon. The points to be evaluated in the image are marked in orange.

Tip: For evaluating the exposure, zoom into/out from the exposure and move the reference exposure with the mouse button held down.

"Perform a visual inspection of the image for any unwanted artifacts. Unwanted artifacts may include: – Phantom images – Row and pixel failures – Row misalignment – etc..."

Perform a visual inspection of the image for any unwanted artifacts.
Unwanted artifacts may include:
– Phantom images
– Row and pixel failures
– Row misalignment
– etc...

5.6 Test report of the constancy test

3D test results (CBCT)
about the monthly constancy test of dental X-ray equipment as per UK & IRL requirements

Operator : Dr. Demo Musterstrasse 1 12345 Musterstadt	Device: Axelos	Complete unit X-ray tube assembly X-ray tube X-ray sensor 3D Test phantom	Serial number: 282 341 96729 2589 1238
--	-----------------------	---	---

Name of X-ray device:
Axelos (Röntgenkammer 1)
 Image display monitor test performed

General Inspections

	Yes	No
Safety and warning systems (lights, audible warnings, etc.) in order?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the release button working as expected?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the rotational or scanning motion during an exposure smooth and unimpeded?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the overall general condition of the tube head and any other relevant physical attributes of the device in order?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Monthly test results

	Measured values			Yes	No
Image Noise (measured in 3 axial slices) Reference value/measured value deviation $\leq \pm 40\%$?	43.02	40.59	40.94	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Image Density (Air, PMMA, PVC) Reference value/measured value deviation $\leq \pm 10\%$?	908.10	1.272.60	1.539.30	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Image Uniformity (measured in 3 axial slices) Reference value/measured value deviation $\leq \pm 20\%$?	1.257.31	1.243.49	1.251.74	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the exposure free of additional artefacts in comparison to the acceptance test exposure?				<input checked="" type="checkbox"/>	<input type="checkbox"/>
Length measurement of PVC Element (axial: 40mm, sagittal & coronal: 15mm, Deviation $\leq 0.5\text{mm}$)	axial 40.24 mm	sagittal 15.04 mm	coronal 17.82 mm	<input checked="" type="checkbox"/>	<input type="checkbox"/>

High Contrast Spatial Resolution (MTF10)

Has the test been completed for the image display device and was the result in order? Yes No

Name of tester: John Dow

Notes

Notes

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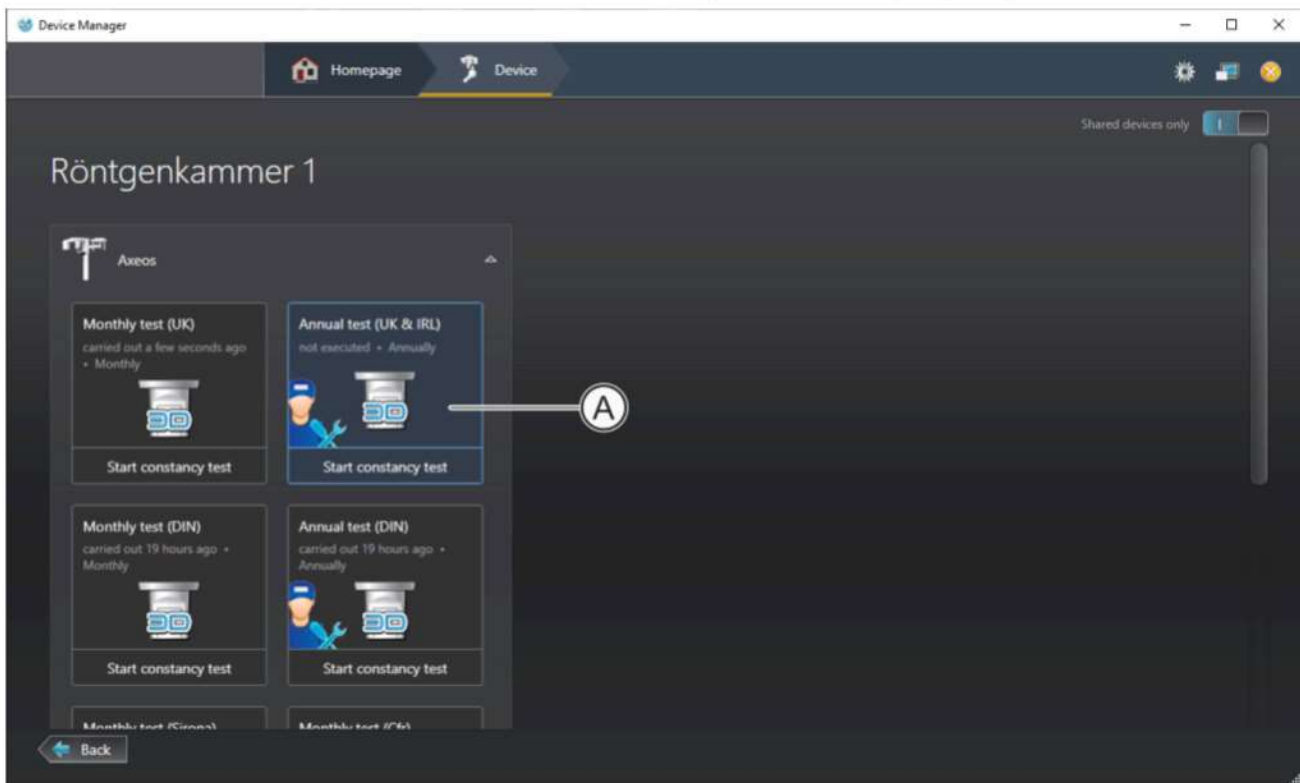
Example of a test report for the constancy test

1. Click on the check box (A) to confirm that the test of the image reproduction device was properly performed.
2. Enter the name of the tester, the address of the dental depot and, if desired, additional comments in the text boxes (B).
3. Click on the "Save" button.
 - ↳ The constancy test is saved on the Sidexis 4 server and can be displayed and printed out at any time.

6 Annual constancy test (UK & IRL)

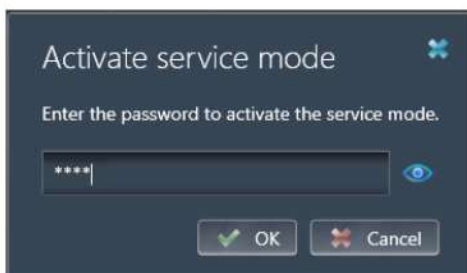
6.1 Starting the annual 3D constancy test UK & IRL

- ✓ The Device Manager is started [-> 12].
- ✓ The X-ray device is switched on (see operating instructions).
- ✓ The "Constancy test" menu is open [-> 24].



Starting the annual 3D constancy test UK & IRL

1. Click on the "3D" icon (A).
 - ↳ If you are not already in service mode, you will be prompted to enter the service password.
2. Enter the service password in the text box of the dialog window.
 - ↳ For the password, enter the first four digits of the current system date (PC) in reverse order. For example, on 21.01.2019, the service password is "1012".
 - ↳ The annual 3D constancy test UK & IRL starts.



Entering the service password

6.2 Performing visual and functional tests (3D)

Device Manager

Axeos
Röntgenkammer 1

Homepage Device Constancy test

Visual and functional inspections Repeatability Reproducibility Voltage DAP Constancy test exposure Test report

Exposure timer within $\pm 10\%$ of set time? Yes No

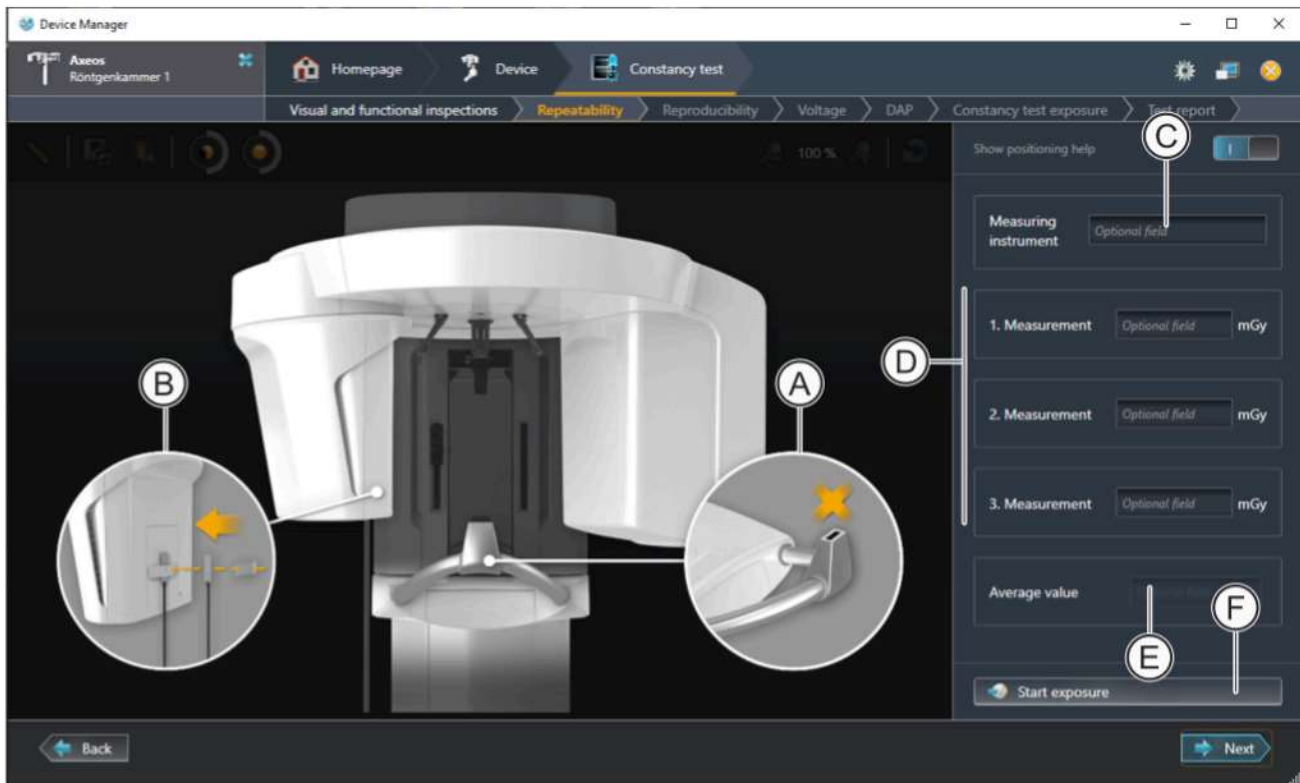
Radiation field size ≤ 10 mm or 10% expected field size or detector (depending on which value is smaller)? Yes No

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Performing visual inspections and functional tests

1. Perform the visual inspection and functional test by following the test step prompts in the menu. Use information provided in the technical documents of the X-ray device and the utilized measuring instrument (e.g. dosimeter) for this.
2. Click on the check boxes (A) in the menu corresponding to the results of your test.
3. Click on the "Next" button.
 - ↳ The results are transferred to the test report.
 - ↳ The "Repeatability" menu opens.
4. Continue with the "Repeatability" test [→ 66].

6.3 Testing repeatability (3D)



Repeatability (3D)

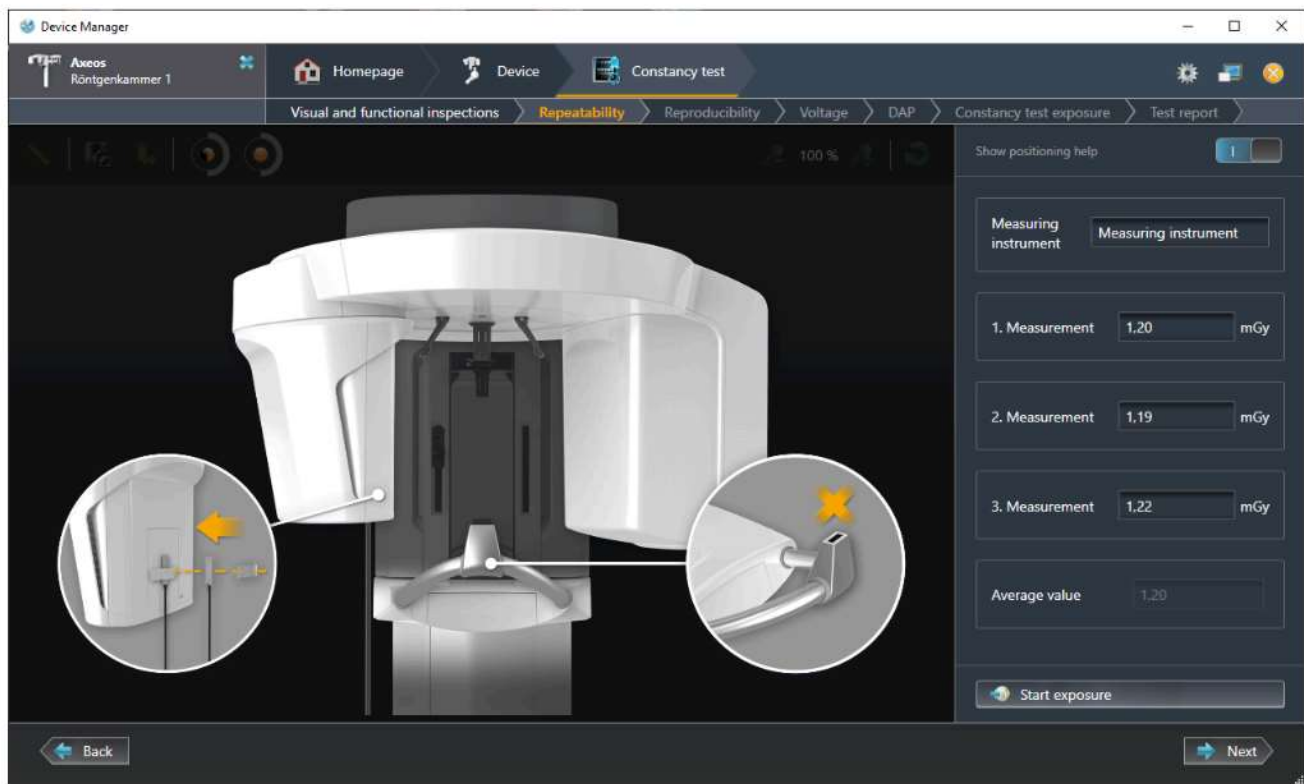
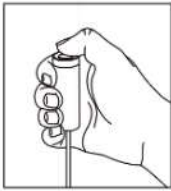
Preparing devices for the dosimetry

- ✓ No test phantoms or bite blocks are inserted in the bite block holder of the device (A).
- ✓ The forehead and temple supports must be removed.
- 1. Attach the dosimetry probe to the 3D sensor (B) with adhesive tape as shown in the positioning aid of the menu. Ensure that the dosimetry probe is centered exactly on the 3D sensor cover.
- 2. Switch on the dosimeter.
Observe the operating instructions of the measuring instrument.
- 3. Select the measurement range for the dose (mGy) on the measuring instrument.

Performing the dosimetry

1. Enter the type of dosimeter used in the "Measurement instrument" text box (C).
2. Click on the "Start exposure" button (F) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV / 51 mAs is displayed on the user interface.
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal that indicates the end of the exposure (double beep) sounds. No exposure is displayed in the Device Manager.
5. Read the dose value on the dosimeter and enter it in the text box (D) (Measurement 1).
6. Repeat the dosimetry two more times and enter the values of the second and third measurements in the corresponding text boxes (D).
 - ↳ The mean value of the dose is calculated and displayed in the box (E).

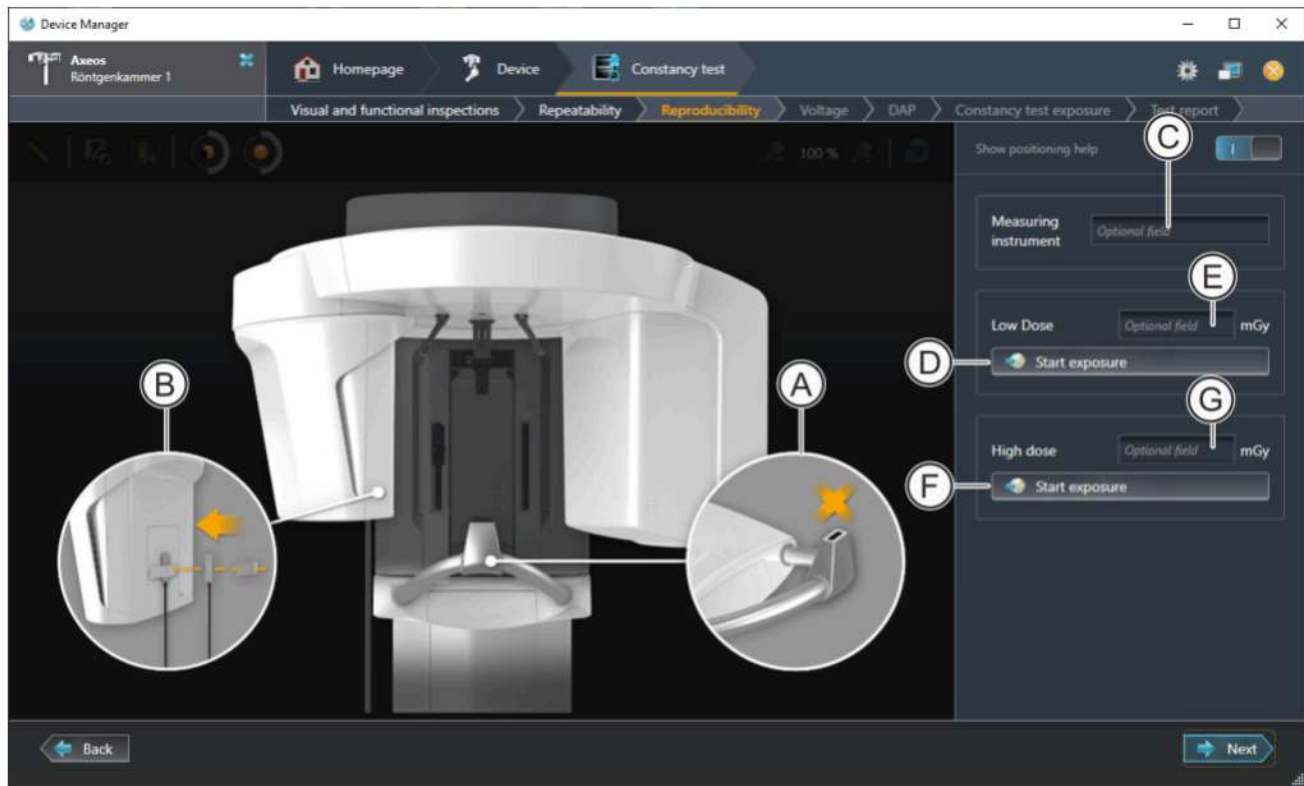
Expert guideline: The averaged dose value K_B must be between 0.9 and 1.7 mGy. The deviation of the comparison values from the mean value must not exceed $\pm 10\%$.



Completed dosimetry

7. Click on the "Next" button.
 - ↳ The results are transferred to the test report.
 - ↳ The "Reproducibility" menu opens.
8. Continue with the check of the "Reproducibility" of the dosimetry [→ 69].

6.4 Testing reproducibility (3D)



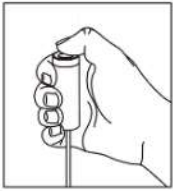
Reproducibility (3D)

Preparing devices for the dosimetry

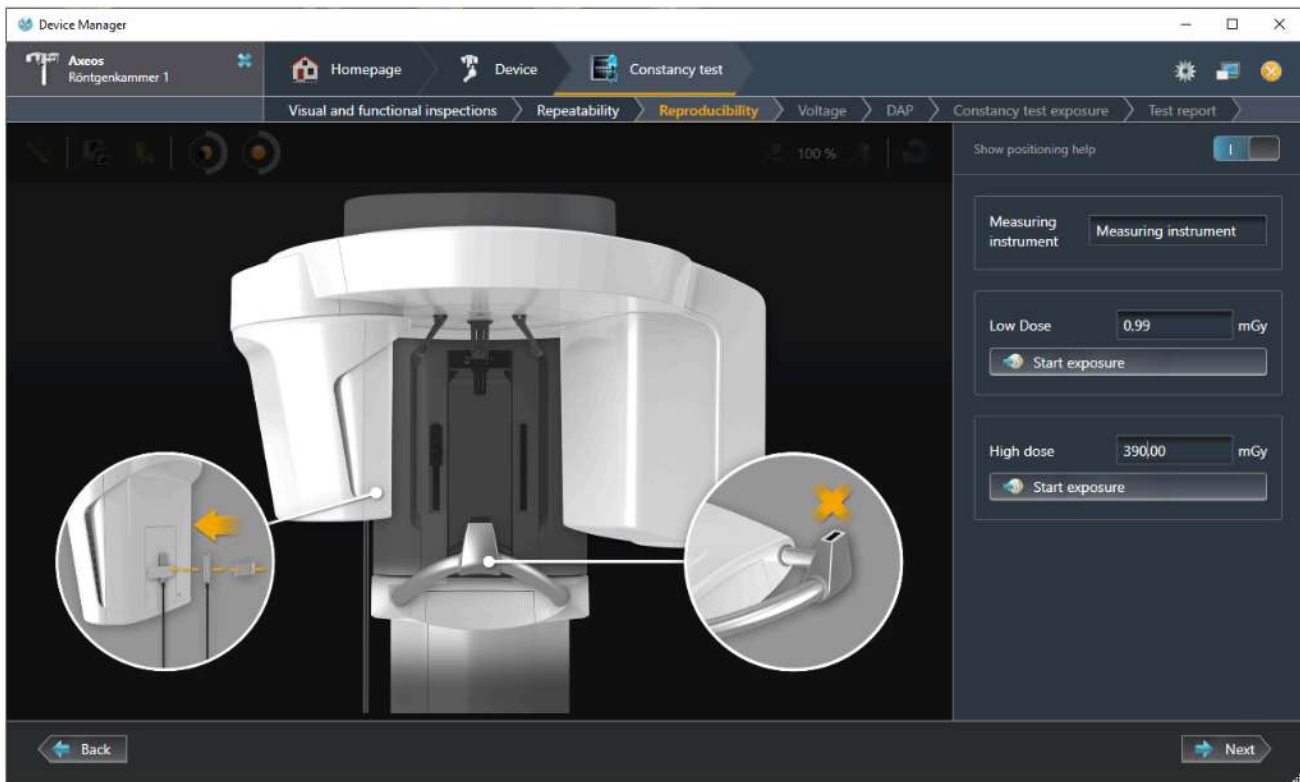
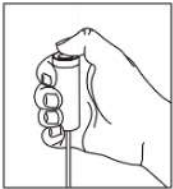
- ✓ No test phantoms or bite blocks are inserted in the bite block holder of the device (A).
- ✓ The forehead and temple supports must be removed.
- 1. The dosimetry probe must be attached to the cover of the 3D sensor, see section "Testing repeatability (3D) [→ 66]".
- 2. Switch on the dosimeter.
Observe the operating instructions of the measuring instrument.
- 3. Select the measurement range for the dose (mGy) on the measuring instrument.

Performing the dosimetry

1. Enter the type of dosimeter used in the "Measurement instrument" text box (C).
2. Click on the "Start exposure" button (D) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV / 40 mAs is displayed on the user interface.



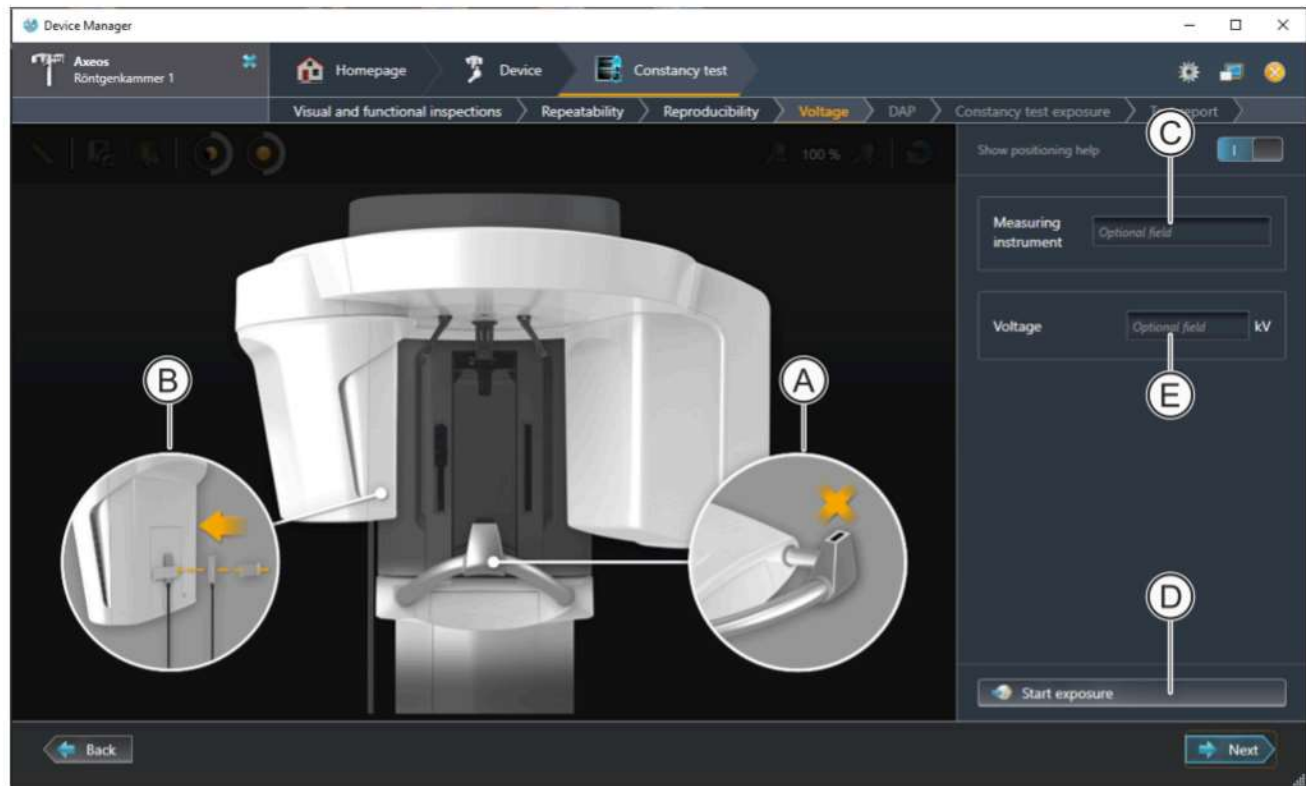
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal that indicates the end of the exposure (double beep) sounds.
No exposure is displayed in the Device Manager.
5. Read the dose value on the dosimeter and enter it in the text box (E) (Low dose).
6. Click on the "Start exposure" button (F) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
7. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV / 7 mAs is displayed on the user interface.
8. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal that indicates the end of the exposure (double beep) sounds.
No exposure is displayed in the Device Manager.
9. Read the dose value on the dosimeter and enter it in the text box (G) (High dose).



Completed reproducibility test

10. Click on the "Next" button.
 - ↳ The results are transferred to the test report.
 - ↳ The "Voltage" menu opens.
11. Remove the dosimeter from the X-ray device again.
12. Continue with the "Voltage" test [→ 71].

6.5 Voltage (3D)



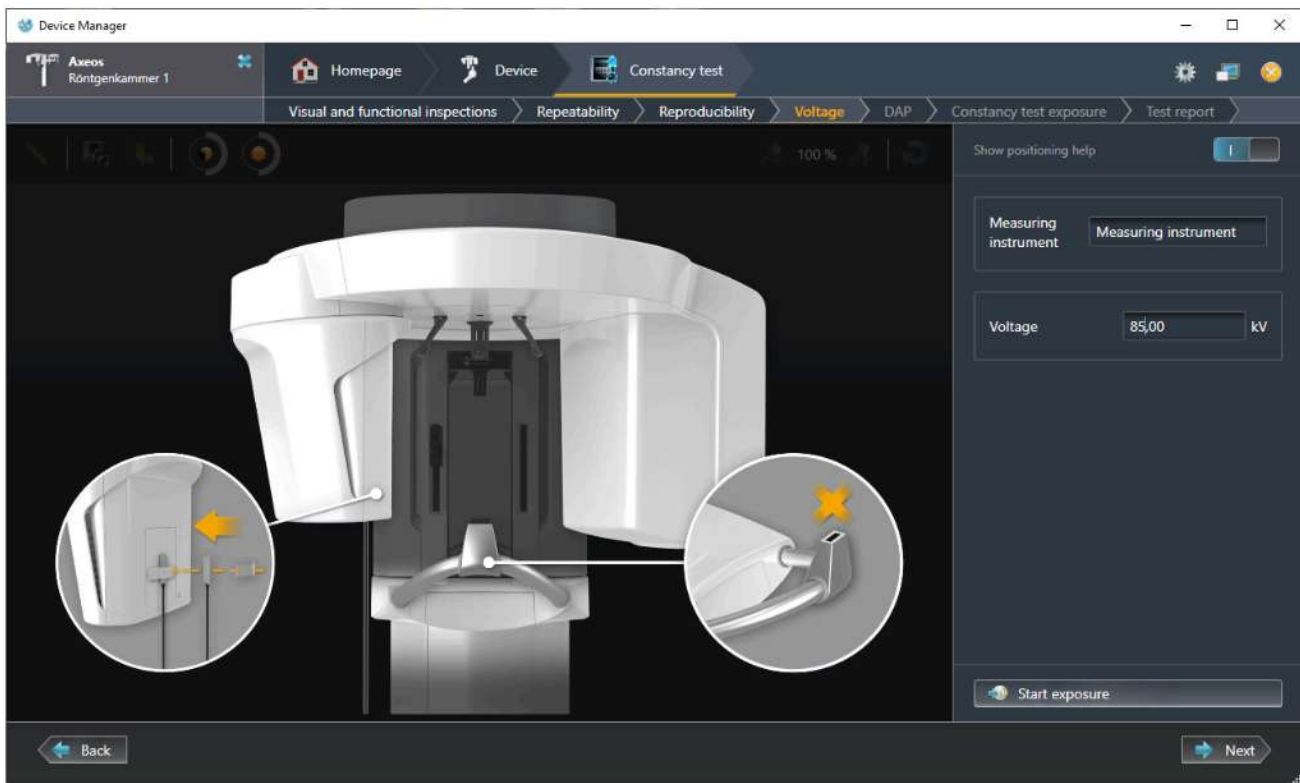
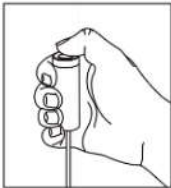
Voltage (3D)

Preparing devices for the voltage measurement

- ✓ No test phantoms or bite blocks are inserted in the bite block holder of the device (A).
 - ✓ The forehead and temple supports must be removed.
1. The dosimetry probe must be attached to the cover of the 3D sensor, see section "Testing repeatability (3D) [→ 66]".
 2. Switch on the dosimeter.
Observe the operating instructions of the measuring instrument.
 3. Configure the measuring instrument for the voltage measurement.

Performing the voltage measurement

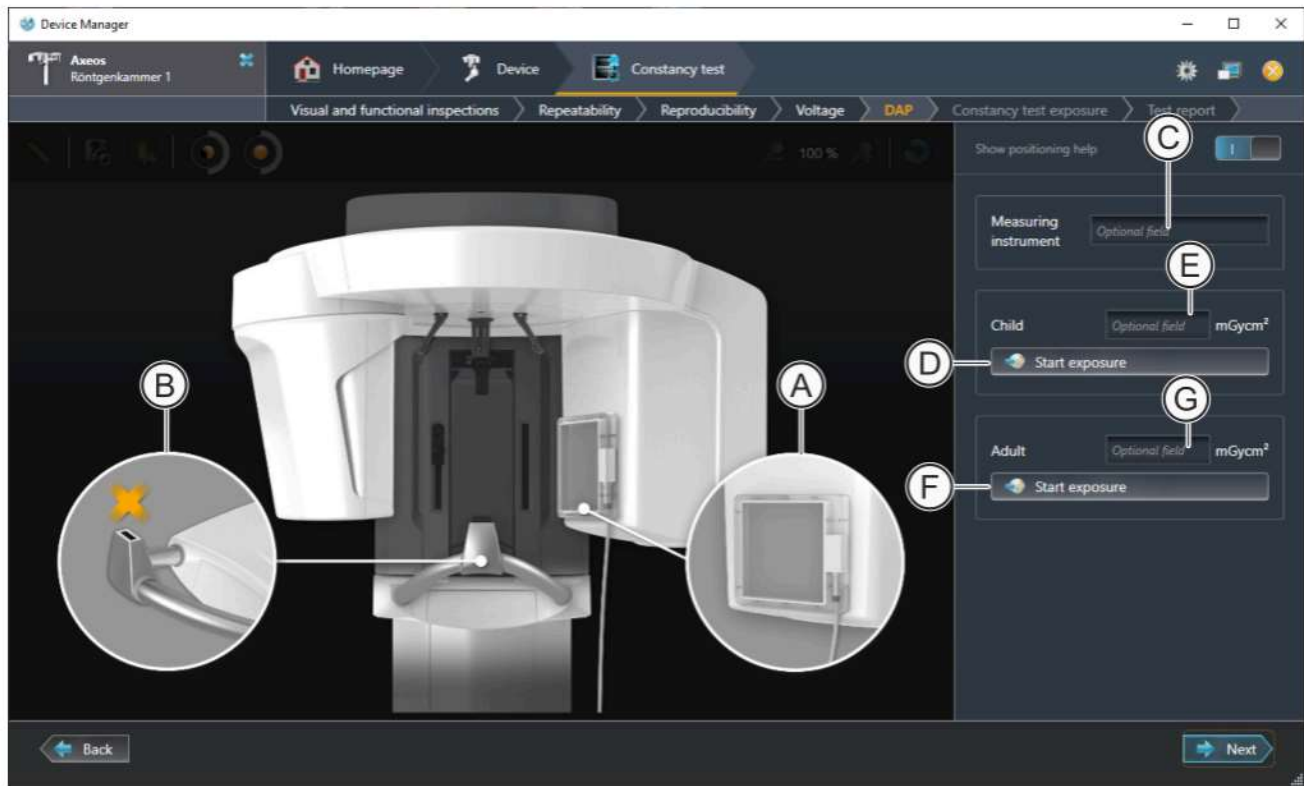
1. Enter the type of measuring instrument used in the text box (C) ("*Measurement instrument*").
2. Click on the "*Start exposure*" button (D) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV / 51 mAs is displayed on the user interface.
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal that indicates the end of the exposure (double beep) sounds.
No exposure is displayed in the Device Manager.
5. Read the voltage value on the measuring instrument and enter it in the text box (E).



Completed voltage test

6. Click on the "*Next*" button.
 - ↳ The results are transferred to the test report.
 - ↳ The DAP menu opens.
7. Remove the dosimeter from the X-ray device again.
8. Continue with the DAP test.

6.6 DAP (3D)

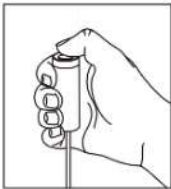
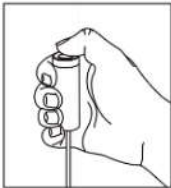
*Dose area product (3D)*

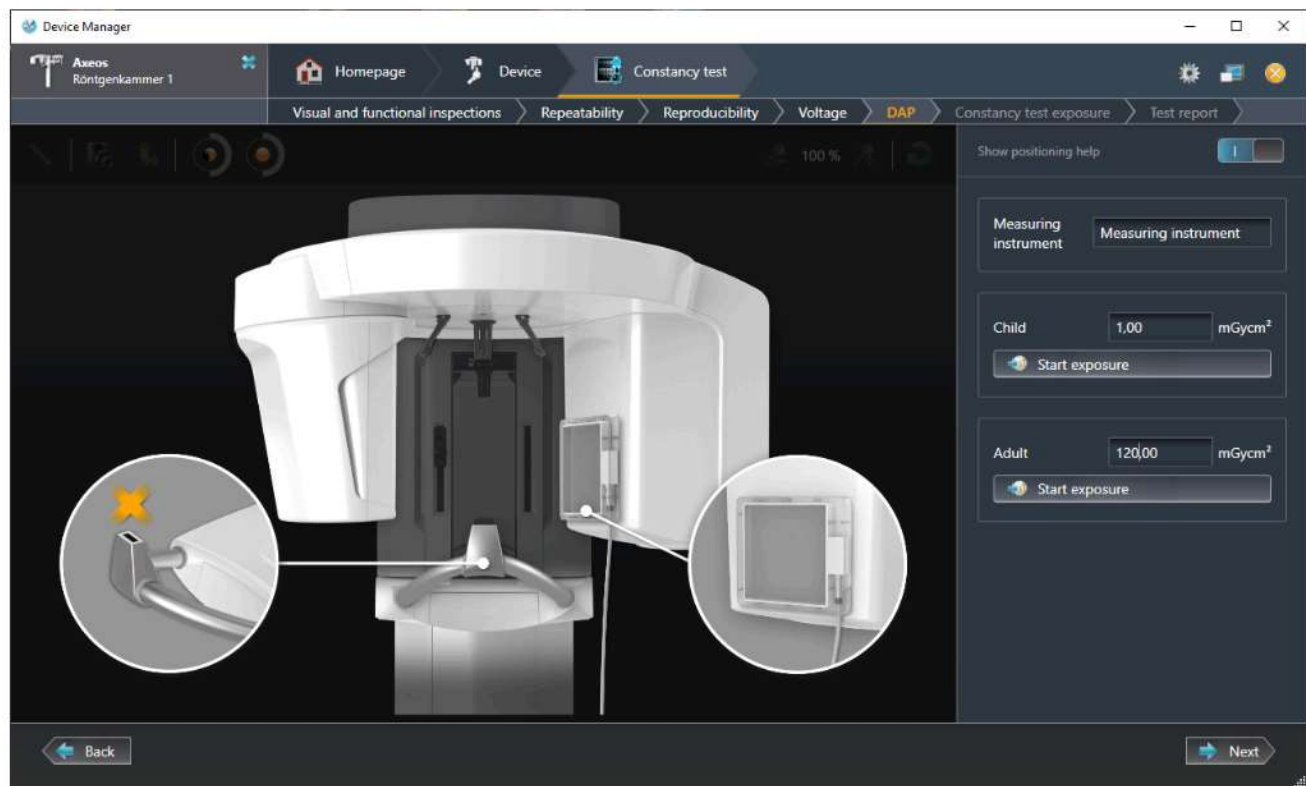
Preparing devices for measuring the dose area product

- ✓ No test phantoms or bite blocks are inserted in the bite block holder of the device (B).
 - ✓ The forehead and temple supports must be removed.
1. Attach the ionization chamber (A) to the cover of the tube assembly (centrally in the beam path).
Observe the information provided on this subject in the operating instructions of the ionization chamber.
 2. Switch on the ionization chamber.
Observe the information provided on this subject in the operating instructions of the ionization chamber.
 3. Select the measurement range for dose area product (mGycm^2) on the measuring instrument.

Performing the measurement of the dose area product

1. Enter the type of ionization chamber used in the text box (C) ("*Measurement instrument*").
2. Click on the "*Start exposure*" button (D) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV / 22 mAs is displayed on the user interface.
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal that indicates the end of the exposure (double beep) sounds.
No exposure is displayed in the Device Manager.
5. Read the dose area product on the ionization chamber and enter it in the text box (E) (Child).
6. Click on the "*Start exposure*" button (F) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
7. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV / 40 mAs is displayed on the user interface.
8. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal that indicates the end of the exposure (double beep) sounds.
No exposure is displayed in the Device Manager.
9. Read the dose area product on the ionization chamber and enter it in the text box (G) (Adult).





Completed test of dose area product

10. Click on the "Next" button.
 - ↳ The results are transferred to the test report.
 - ↳ The "Reference exposure" menu opens.
11. Remove the ionization chamber from the X-ray device again.
12. Continue with the "Constancy test exposure".

6.7 Performing the reference exposure for the constancy test (3D)

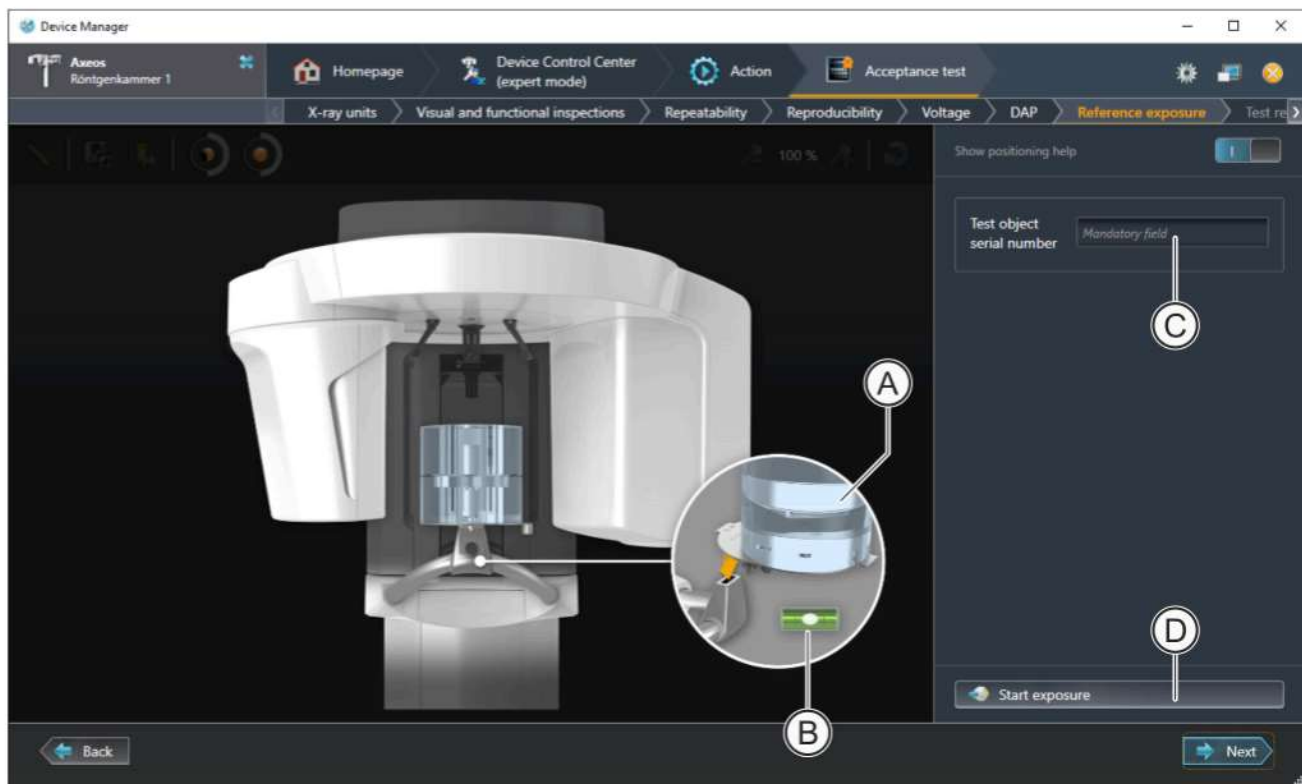
NOTE

Possible incorrect positioning

The CBCT test phantom is supplied pre-assembled for the Orthophos S/SL.

- > Modify the test phantom as appropriate (see section Test phantom modification).
Position 2 = correct installation of the PMMA test phantom on the positioning plate for the Axeos

This menu guides you through the creation of the reference exposure for the later constancy test for 3D.



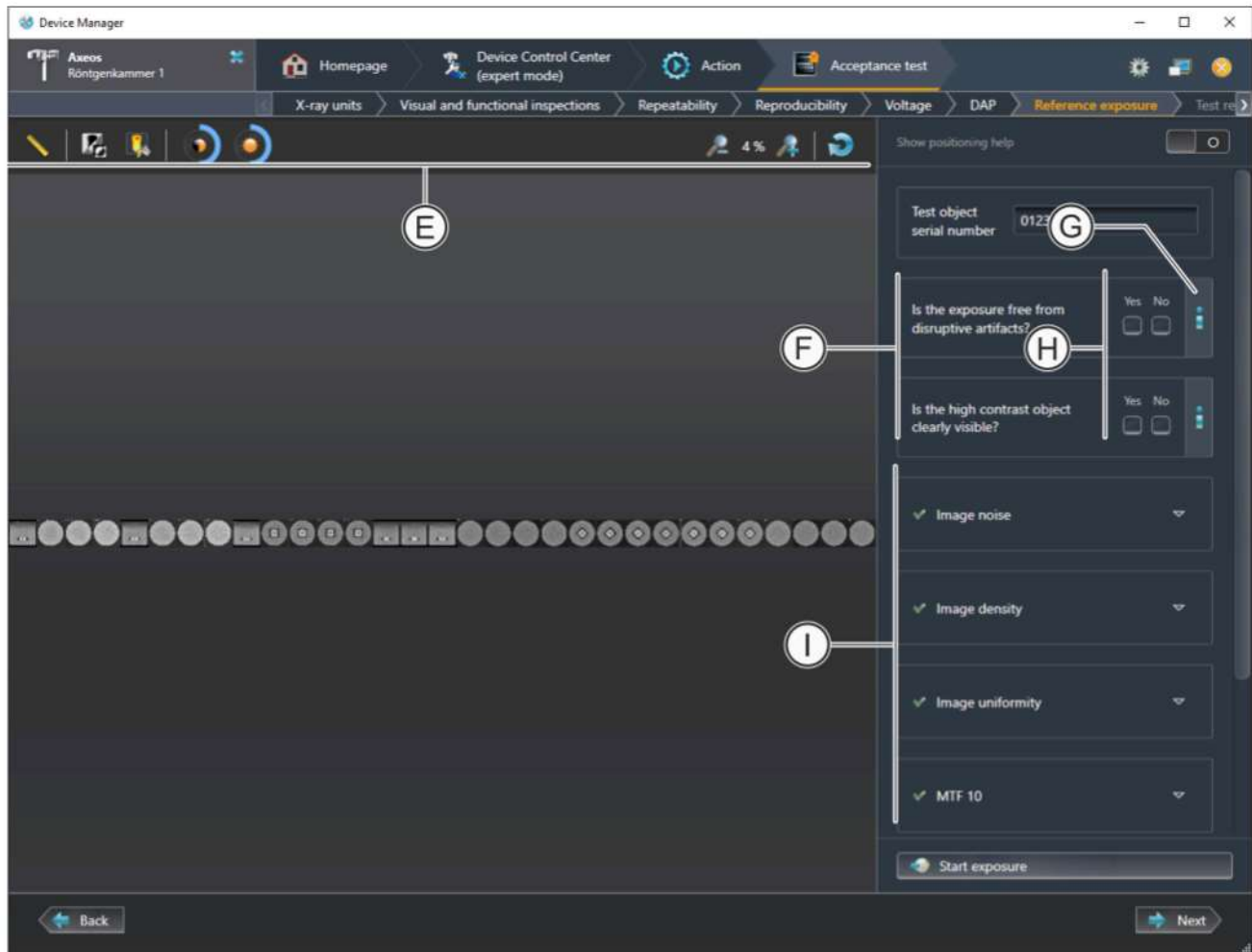
Reference exposure (3D) for the constancy test

Preparing the device for the reference exposure (3D)

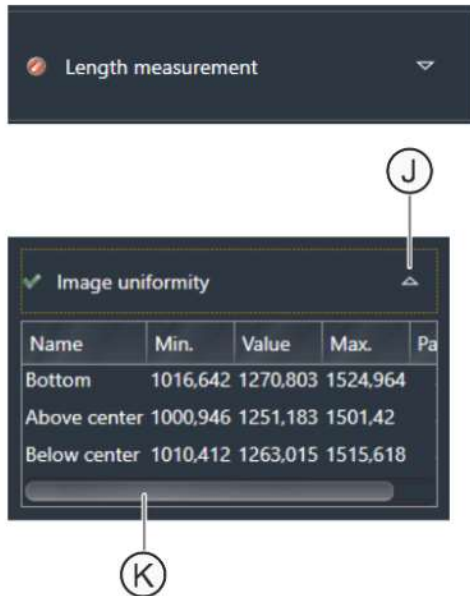
1. Insert the constancy test phantom (A) in the bite block holder.
2. Align the test phantom horizontally using the adjustment screw on the test phantom (B).

Performing the reference exposure (3D)

1. Enter the serial number of the test phantom in the text box (B).
2. Click on the "Start exposure" button (C) in order to establish the exposure readiness of the device.
 - ↳ The help message "H3 01" (unit is not set to its starting position) appears on the Easypad (or the remote control).
3. Press the R key to move the unit back to the starting position.
 - ↳ As soon as the device has reached the starting position, it is ready to take an exposure.
 - ↳ The service routine S32.55 with the exposure parameters 85 kV/51 mAs is displayed on the user interface.
4. Press the release button. Hold down the release button until the exposure is complete and the acoustic signal indicating the end of the exposure (double beep) sounds.



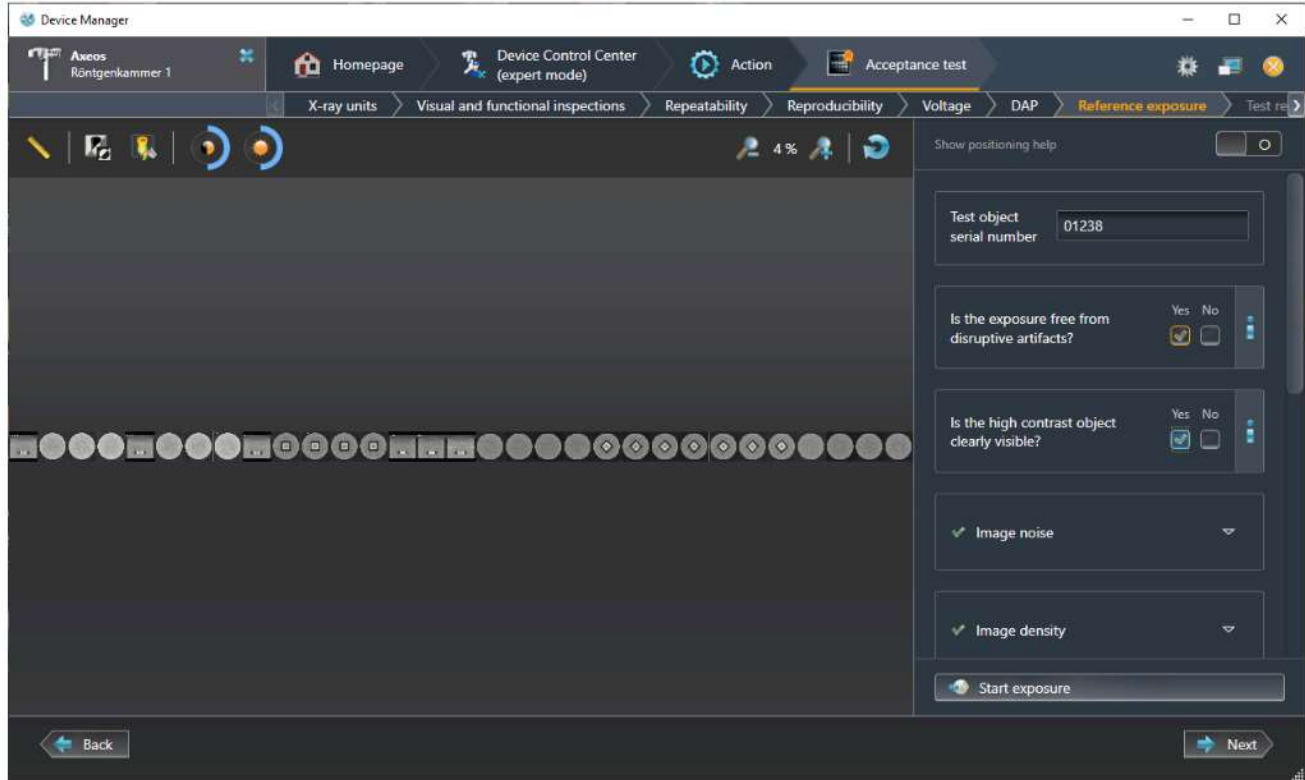
Reference exposure (3D) for the constancy test



- ↪ The diaphragm test exposure (3D) is stored in the archive (see section "") and displayed in the Device Manager.
 - ↪ On completion of the exposure, various measurements are taken. The results are displayed in the form of a list (I). If the measurements are okay, all entries in the list have a green checkmark in front.
 - ↪ If a measurement is not okay, it is marked with a red symbol.
 - ↪ The measurement can be displayed by clicking the arrow icon (J). The scrollbar (K) can be used to move the content of the window horizontally.
5. If necessary, you can edit the reference exposure using the toolbar (E) [→ 22].
 6. Evaluate the reference exposure (3D) using the questions in the menu (F). You will find help on making the evaluation via the corresponding info icon (G) and in section "Evaluating the reference exposure for 3D (UK & IRL) [→ 79]".
 7. After you have completed the evaluation, click on the check boxes (H) in the menu corresponding to the results of your evaluation.
 8. Then click the "Next" button.
 - ↪ The results are transferred to the test report.
 - ↪ The test report is displayed in the Device Manager.

6.7.1 Evaluating the reference exposure for 3D (UK & IRL)

Use of the functions in the toolbar may be useful for evaluating the reference exposure (see section "Toolbar in the exposure window [→ 22]").



Example of a 3D reference exposure UK & IRL

Make the evaluation using the questions in the menu and select the corresponding check boxes next to the questions.

You will find help on answering the questions by hovering the mouse over the "i" icon. The points to be evaluated in the image are marked in orange.

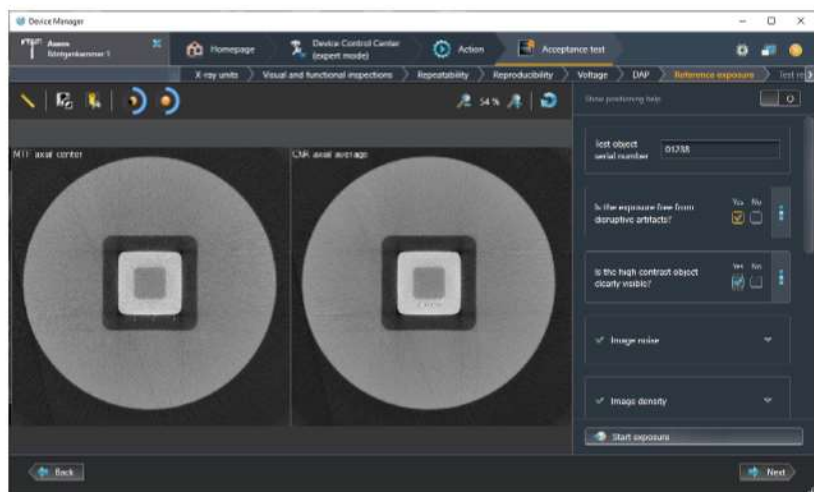
Tip: For evaluating the exposure, zoom into/out from the exposure and move the reference exposure with the mouse button held down.

"Is the exposure free from disruptive artifacts?"

Perform a visual inspection of the image for any unwanted artifacts.
Unwanted artifacts may include:

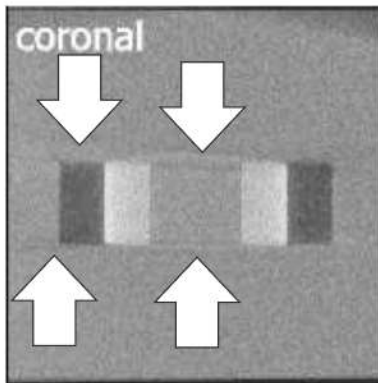
- Phantom images
- Row and pixel failures
- Row misalignment
- etc...

Tip: For evaluating the artifacts, zoom in on the exposure and move the reference exposure with the mouse button held down, as required.



Zoomed-in reference exposure

Tip: For evaluating the artifacts, zoom into/out from the exposure and move the reference exposure with the mouse button held down.

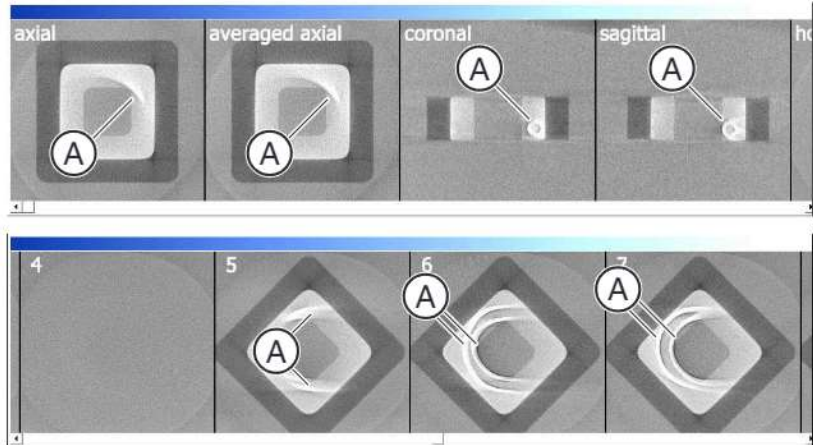


System-related artifacts

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!)

Atypical artifacts (A)



6.8 Test report of the constancy test

3D test results (CBCT)
 about the monthly constancy test of dental X-ray equipment as per UK & IRL requirements

Operator : Dr. Demo Musterstrasse 1 12345 Musterstadt:	Device: Axios	Complete unit: 282	Serial number:
Name of X-ray device: Axios (Röntgenkammer 1)	<input checked="" type="checkbox"/> Image display monitor test performed	X-ray tube assembly: 341	X-ray tube: 96729
		X-ray sensor 3D: 2589	Test phantom: 1238

General Inspections

	Yes	No
Safety and warning systems (lights, audible warnings, etc.) in order?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the release button working as expected?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the rotational or scanning motion during an exposure smooth and unimpeded?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the overall general condition of the tube head and any other relevant physical attributes of the device in order?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Monthly test results

	Measured values			Yes	No
Image Noise (measured in 3 axial slices) Reference value/measured value deviation $\leq \pm 40\%$?	43.02	40.59	40.84	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Image Density (Al _K , PMMA, PVC) Reference value/measured value deviation $\leq \pm 10\%$?	908.10	1.272.60	1.538.30	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Image Uniformity (measured in 3 axial slices) Reference value/measured value deviation $\leq \pm 20\%$?	1.257.31	1.249.49	1.251.74	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the exposure free of additional artefacts in comparison to the acceptance test exposure?				<input checked="" type="checkbox"/>	<input type="checkbox"/>
Length measurement of PVC Element (axial: 40mm; sagittal & coronal: 15mm; Deviation $\leq 0.5\text{mm}$)	axial: 40.28 mm	sagittal: 18.04 mm	coronal: 17.82 mm	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Has the test been completed for the image display device and was the result in order? Yes No

Name of tester: John Dow

Notes

Notes

Back Save

Example of a test report for the constancy test

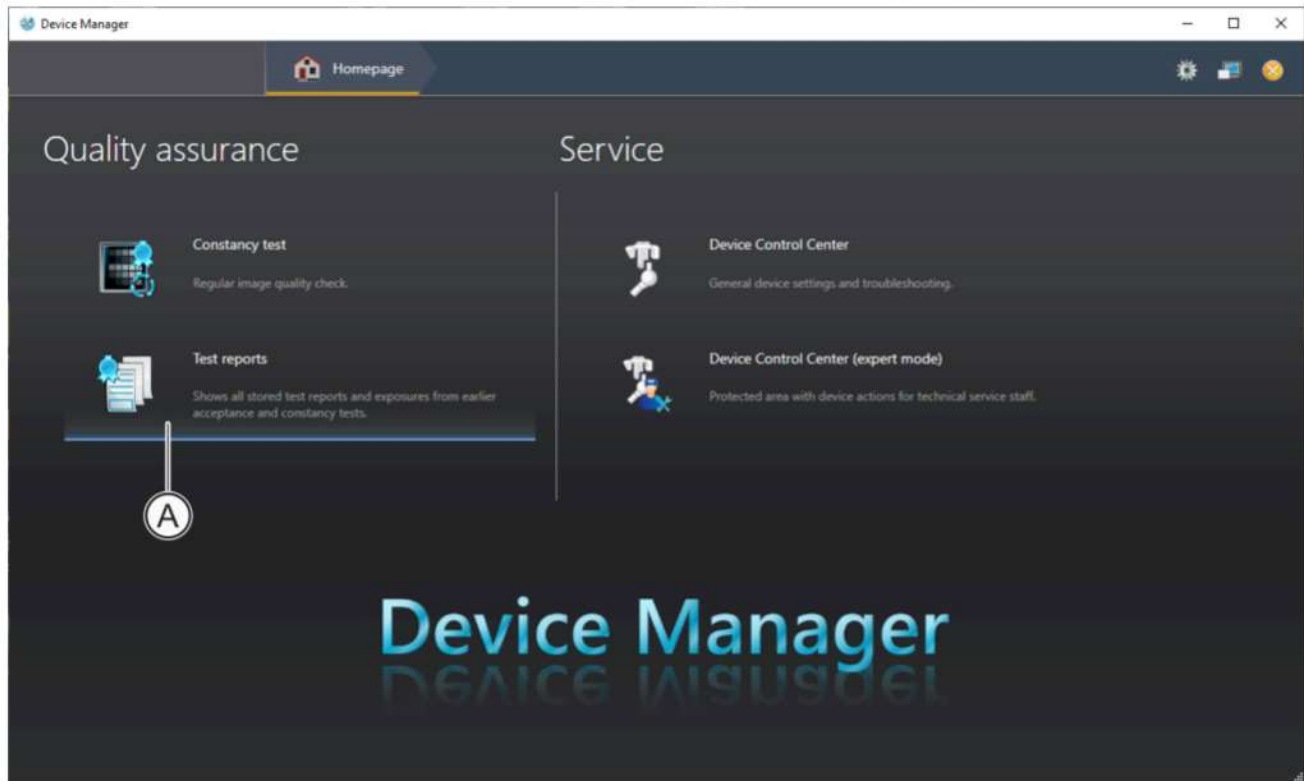
1. Click on the check box (A) to confirm that the test of the image reproduction device was properly performed.
2. Enter the name of the tester, the address of the dental depot and, if desired, additional comments in the text boxes (B).
3. Click on the "Save" button.
 - ↳ The constancy test is saved on the Sidexis 4 server and can be displayed and printed out at any time.

7 Displaying/printing/exporting test reports

7.1 Displaying / printing test reports

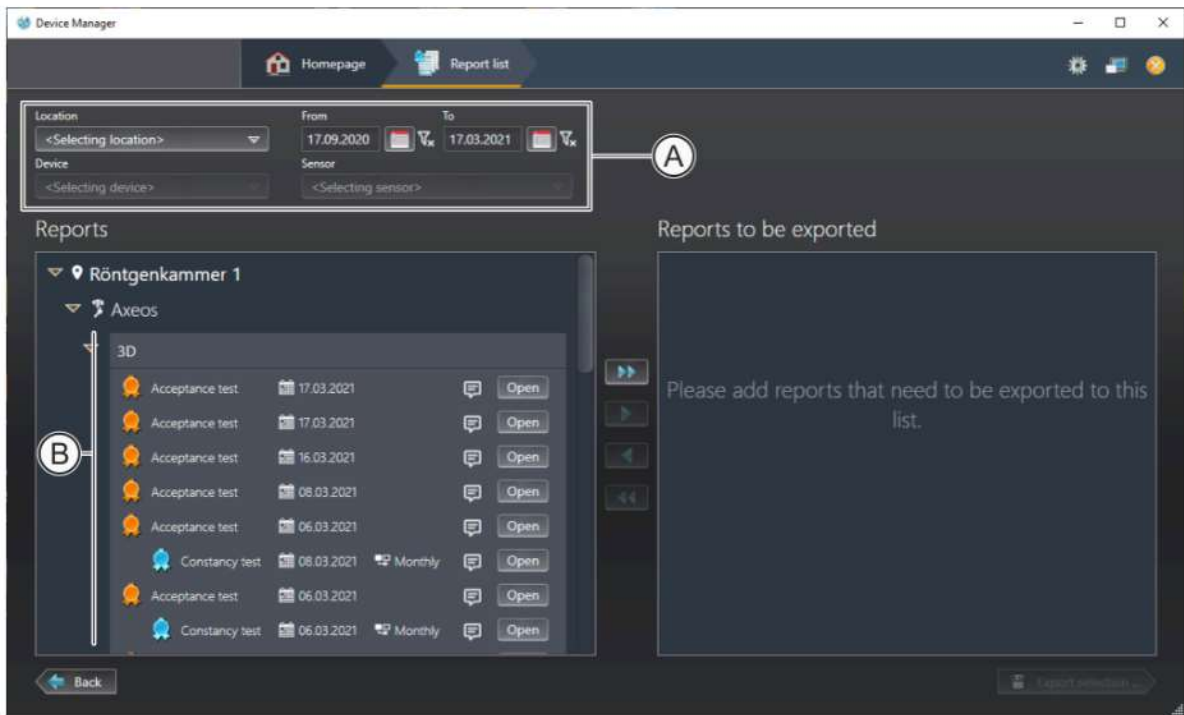
Once test reports have been created, you can display and print them again at any time. To do this, proceed as follows:

- ✓ The Device Manager is started [→ 12].



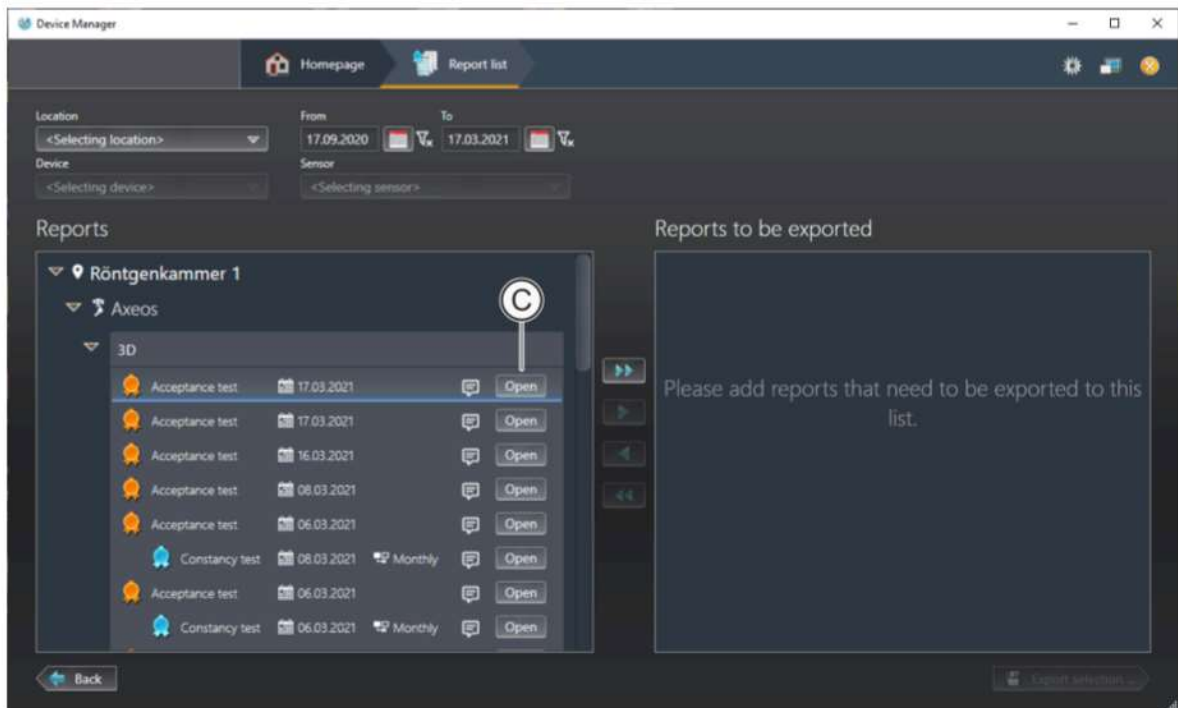
Opening the "Report list"

1. Click on the "Test reports" button.



"Report list"

- ✎ The "Report list" (B) is displayed.
- You can use the text and list boxes in the menu area (A) to filter the "Report list" by device location, device, sensor and creation date of test report.



Selecting and opening a test report

2. Select the desired test report and then click on the "Open" button (C).

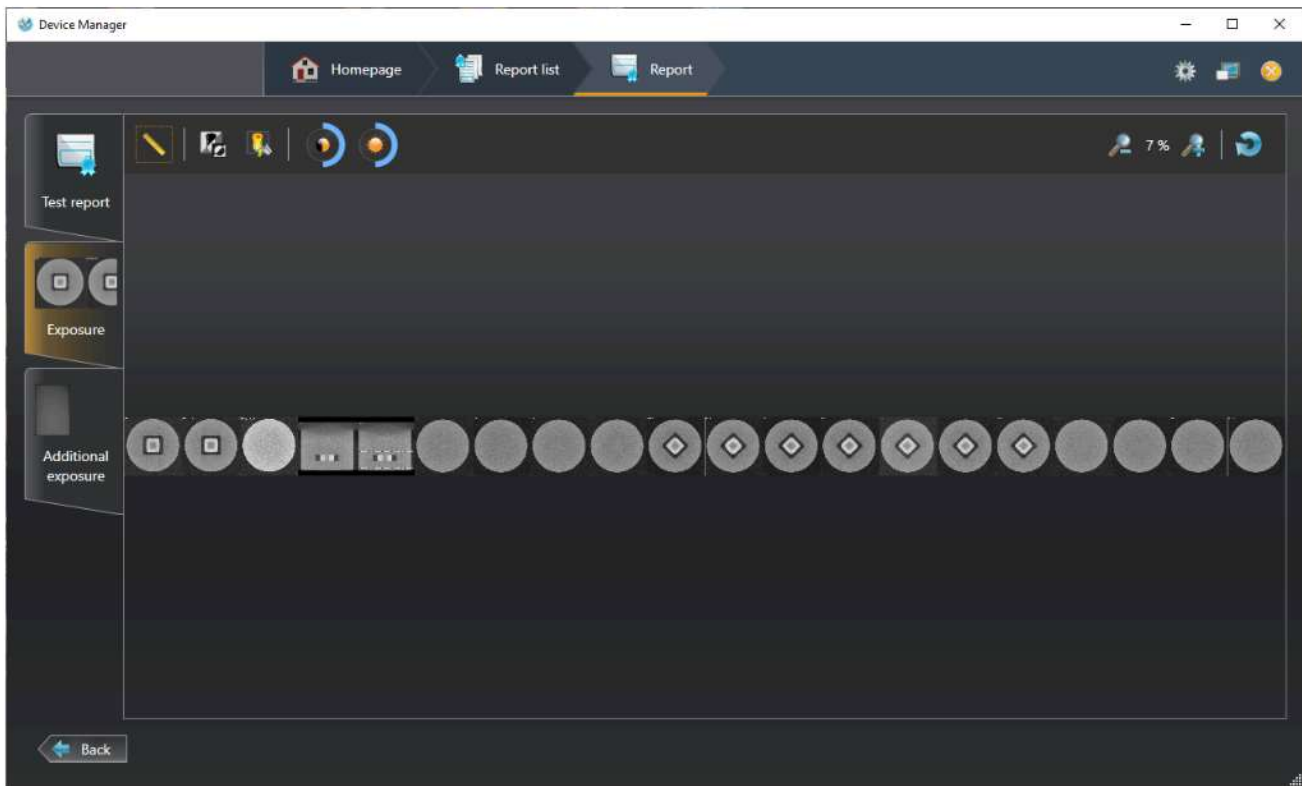
The screenshot shows the 'Device Manager' application window. The main content area displays a '3D TEST REPORT (CBCT)' for an 'Axeos' device. The report is titled 'about the acceptance test of dental X-ray equipment as per DIN 6868 Part 161'. It is divided into several sections:

- Operator:** Dr. Demo, Musterstrasse 1, 12345 Musterstadt.
- Device:** Axeos.
- Serial number:** A table listing components: Complete unit (382), X-ray tube assembly (341), X-ray tube (96729), X-ray sensor 3D (2589), and Test phantom (01238).
- Name of X-ray device:** Axeos (Röntgenkammer 1).
- Image display monitor test performed:**
- 1. Visual and function tests:** A table with 8 rows of tests, each with 'Yes' and 'No' checkboxes. All 'Yes' boxes are checked.

On the left side of the interface, there are three tabs: 'Test report', 'Exposure', and 'Additional exposure'. The 'Test report' tab is selected and highlighted with a circled 'E'. At the top right, there is a printer icon labeled with a circled 'F'. At the bottom left, there is a 'Back' button.

Test report

- ☞ The corresponding test report is opened. You can switch between the display of the test report, reference exposure and additional exposures, such as the diaphragm test exposure, by selecting the tabs (E).



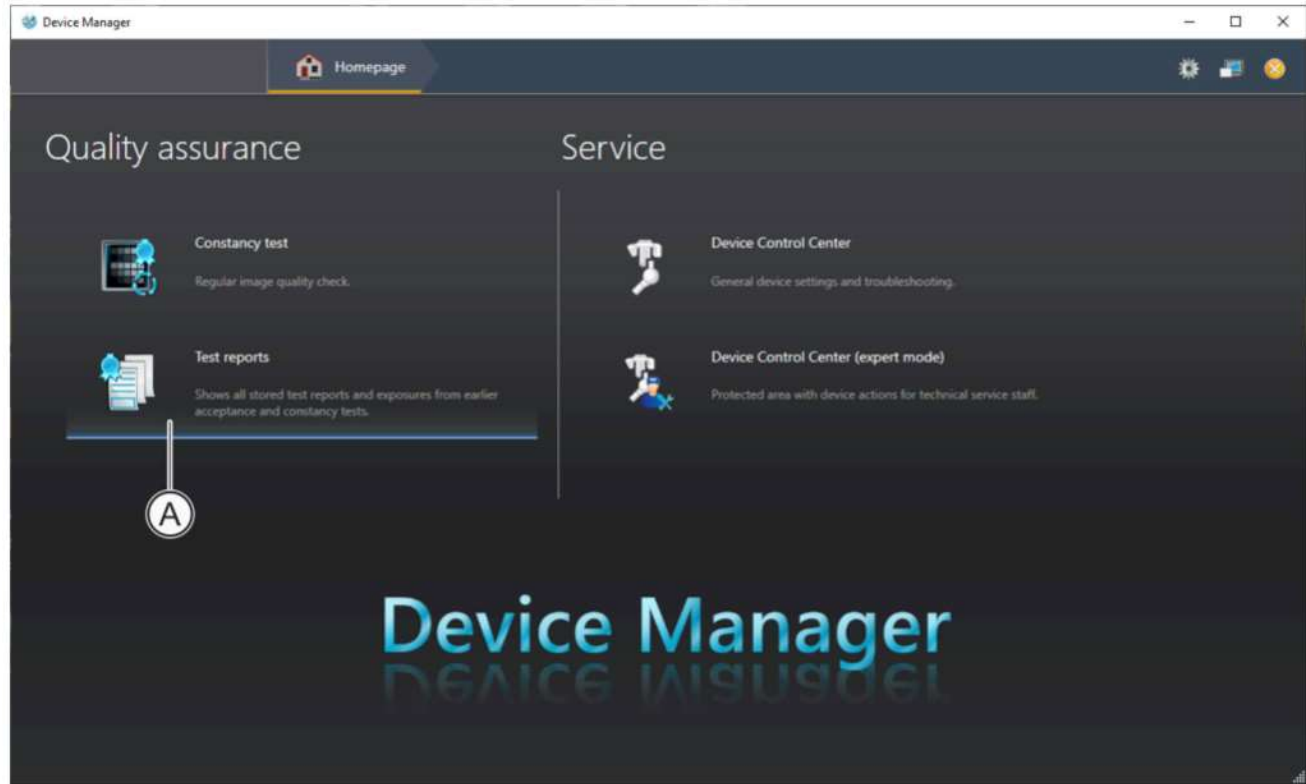
Example image of a reference exposure

3. To print out the test report, first select the "Test report" tab and then click on the printer icon (F).
 - ↳ The test report is printed out.

7.2 Exporting test reports

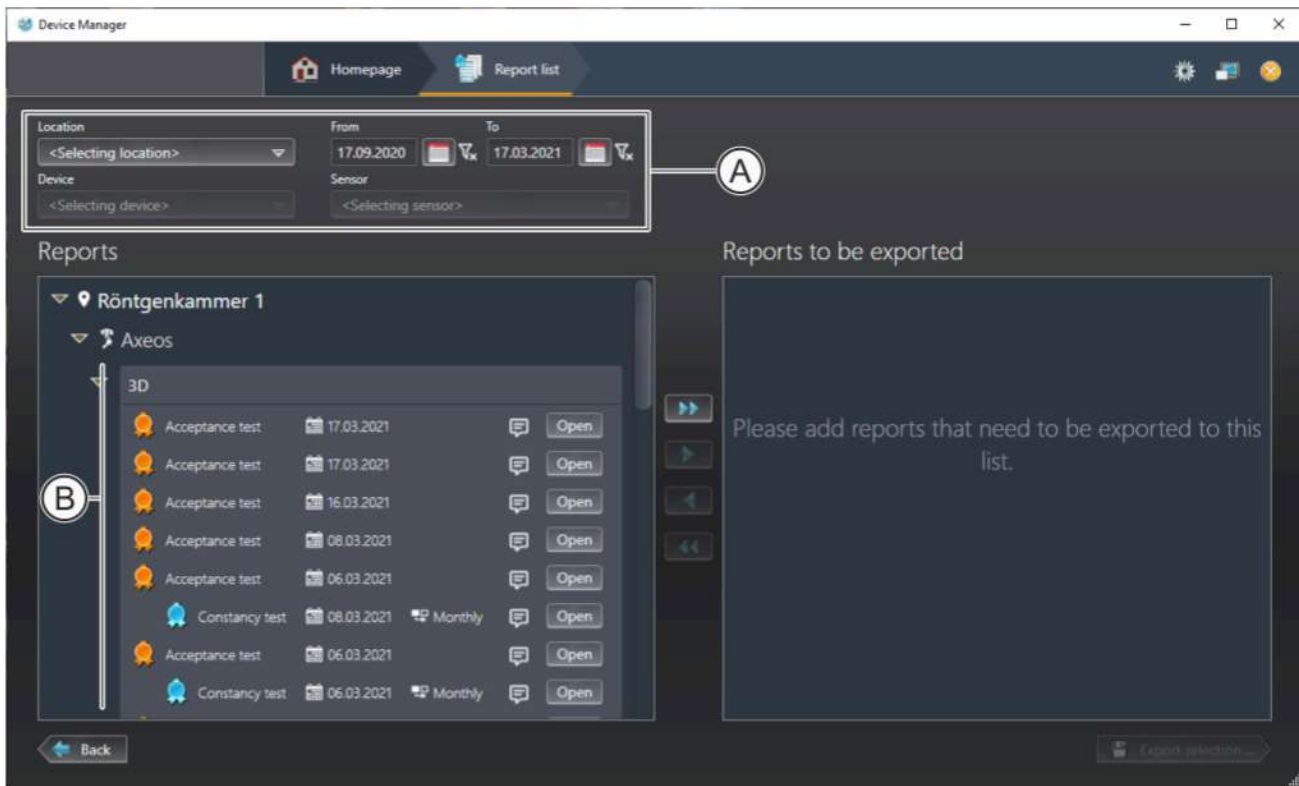
The test reports can be exported. To do this, proceed as follows:

- ✓ The Device Manager is started [→ 12].



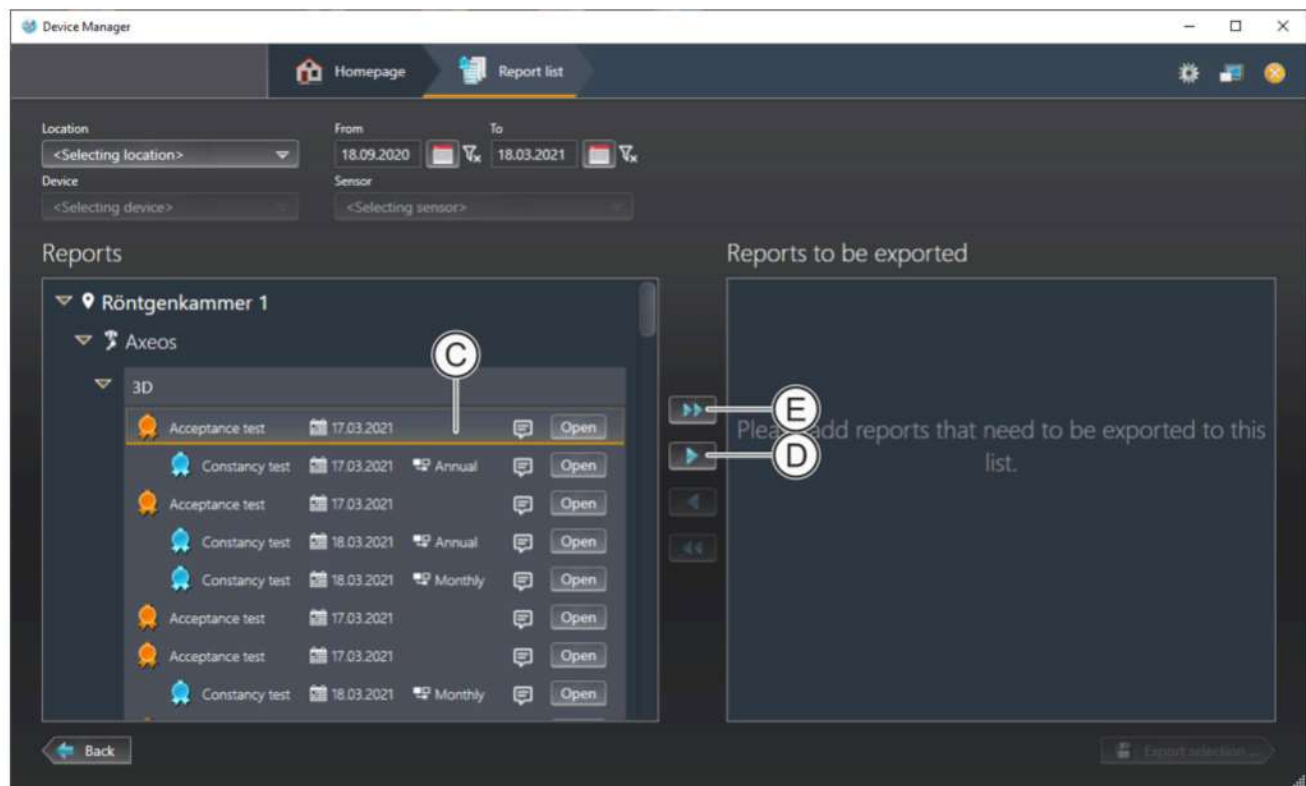
Opening the "Report list"

1. Click on the "Test reports" button.

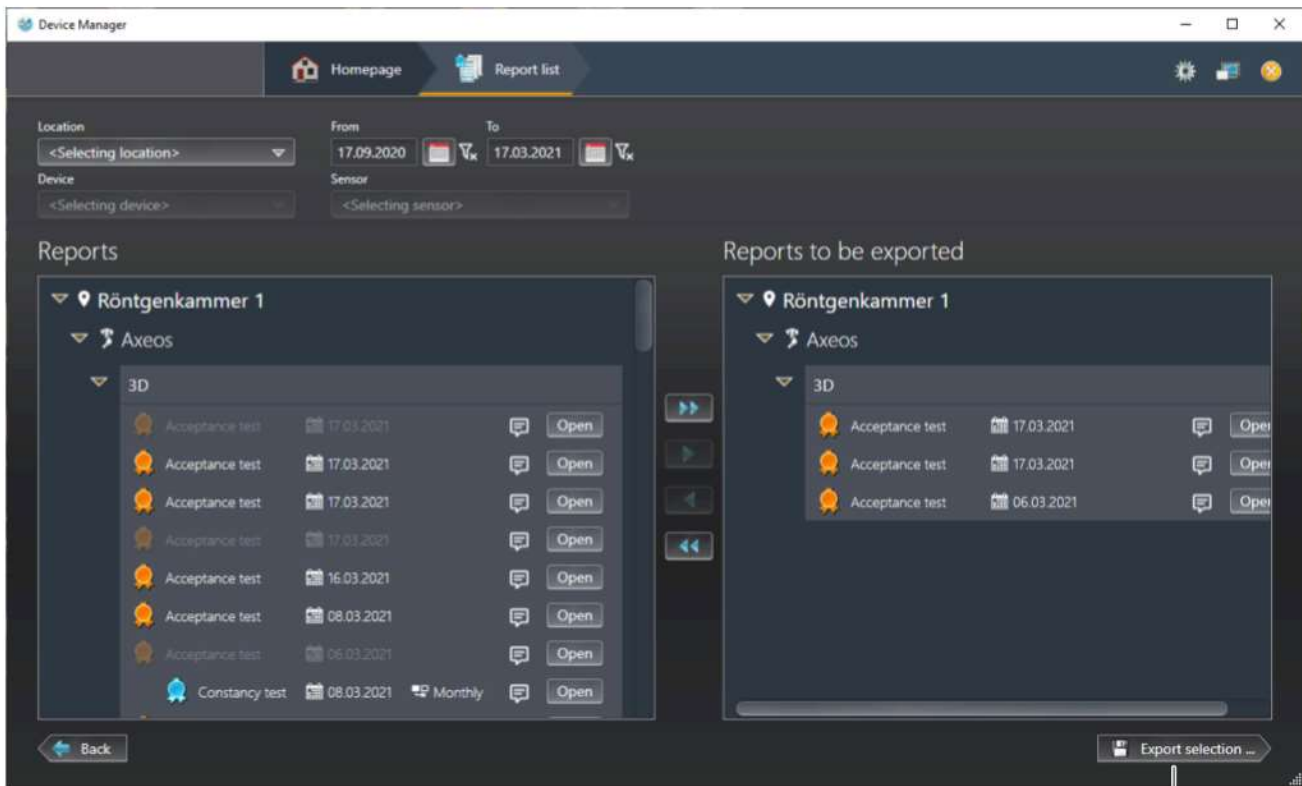


"Report list"

- ☞ The "Report list" (B) is displayed.
You can use the text and list boxes in the menu area (A) to filter the "Report list" by device location, device, sensor and creation date of test report.



2. Select the desired test report in the list (C) and click on the button with the arrow symbol (D).
To transfer all test reports (displayed in the list on the left) to the list of reports to be exported, click on the button with the double arrow (E).
↳ The reports are transferred to the list of reports to be exported.



Exporting reports

3. To export reports, click on the "Export selection ..." button (F).
↳ The test reports are exported.

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

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