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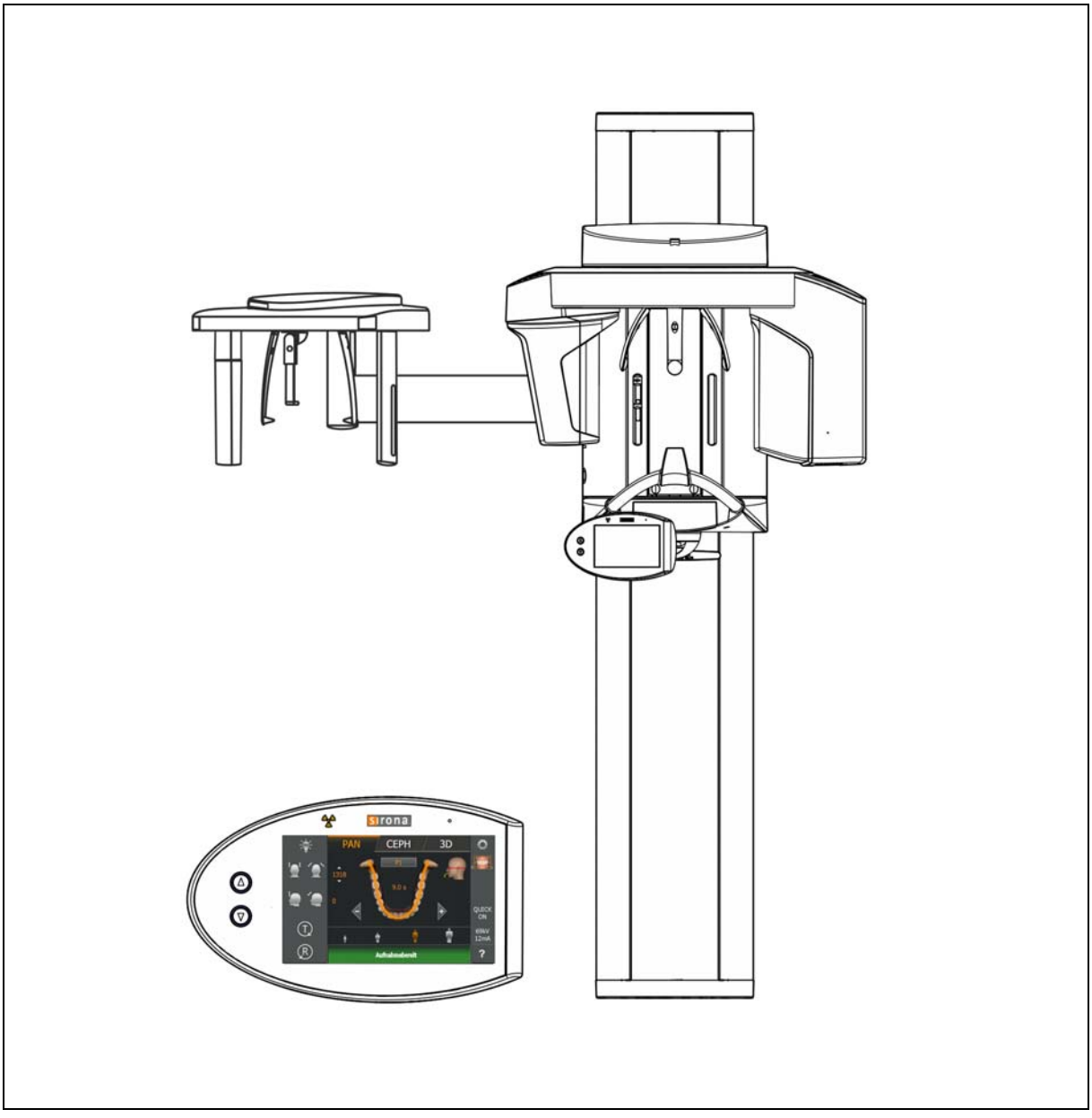
sirona
The Dental Company

ORTHOPHOS SL 2D / ORTHOPHOS SL 2D Ceph
ORTHOPHOS SL 3D / ORTHOPHOS SL 3D Ceph

Maintenance Instructions

English (US)



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1 Safety

NOTICE

Qualifications of service personnel

Installation and startup may be carried out only by personnel specifically authorized by Sirona.

⚠ WARNING

Perilous shock hazard!

You must switch off the unit and then wait at least 1 minute, for measurements at the tube assembly at least 4 minutes, before you start to connect test cables or remove a cover!
For measurements in the area of the power supply terminal, the unit must be disconnected from the junction box of the building installation before you start to connect test cables!

⚠ DANGER

X-rays

When performing the following tests, be sure to observe the radiation protection regulations applicable in your country (see Operating Instructions).

⚠ DANGER

X-rays

"Radiation" is signaled by the message "X-RAY active!", a beep, and an X-ray LED.

NOTICE

Risk of damage to boards

Please observe the usual precautionary measures for handling printed circuit boards (ESD). Touch a ground point to discharge static electricity before touching any boards.

IMPORTANT

It is essential that you also observe the notes about the operation of the unit in the Operating Instructions.

2 Operation notes

Nominal line voltage

The unit operates in the following nominal line voltage ranges:

- 200 – 240 V
- 50/60Hz

The permissible line voltage fluctuation is ±10%.

The internal line impedance must not exceed 0.8 Ω.

Only permanent electrical connection of the unit is allowed.

IMPORTANT
The regulation "Federal Performance Standard for Diagnostic X-ray Units, Code of Federal Regulations, Title 21 CFR, Subchapter J" requires a corresponding power supply connection.

Cooling period

The cooling period between two exposures is maintained by an automatic exposure blocking function according to the pulse/pause ratio (see Operating Instructions). The decrementing waiting time count is displayed on the control panel.

Measurements

Always switch the unit off before connecting a measuring instrument.

For safety reasons, the power supply should be switched off at the junction box of the building installation when performing measurements in the vicinity of the power supply unit.

Select the correct current/voltage type and adjust the measuring range to match the expected readings.

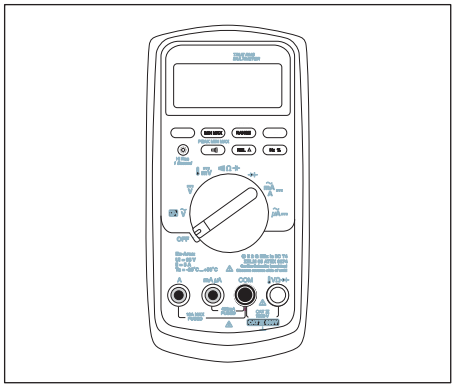
Perform continuity tests only on units which are switched off.

If several exposures with radiation must be taken to check a measurement, make sure that the prescribed cool-down intervals are observed. They are maintained by an automatic exposure blocking function (see Operating Instructions).

The pulse/pause ratio is 1:20, i.e. a 20-second pause is maintained for each second of radiation cycle. The pulse/pause ratio is automatically maintained (automatic exposure blocking).

It is essential that you observe the radiation protection regulations applicable in your country prior to radiation release.

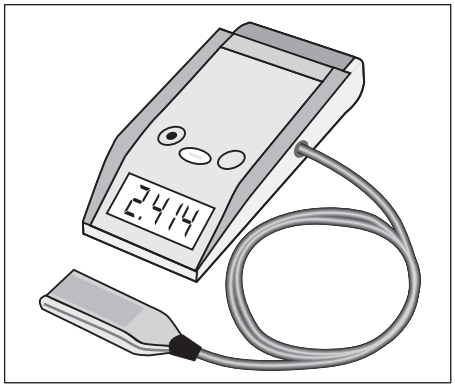
3 Auxiliary devices required



⚠ CAUTION

Only use a battery-operated digital multimeter with safety sockets.
It is essential that you observe the safety and operating notes provided in the operating instructions of the multimeter.

- Battery-operated digital multimeter of type:
  - Fluke 8000 A
  - Philips PM 2816 rms
  - or similar



⚠ CAUTION

It is essential that you observe the safety and operating notes provided in the operating instructions of the dosimeter.

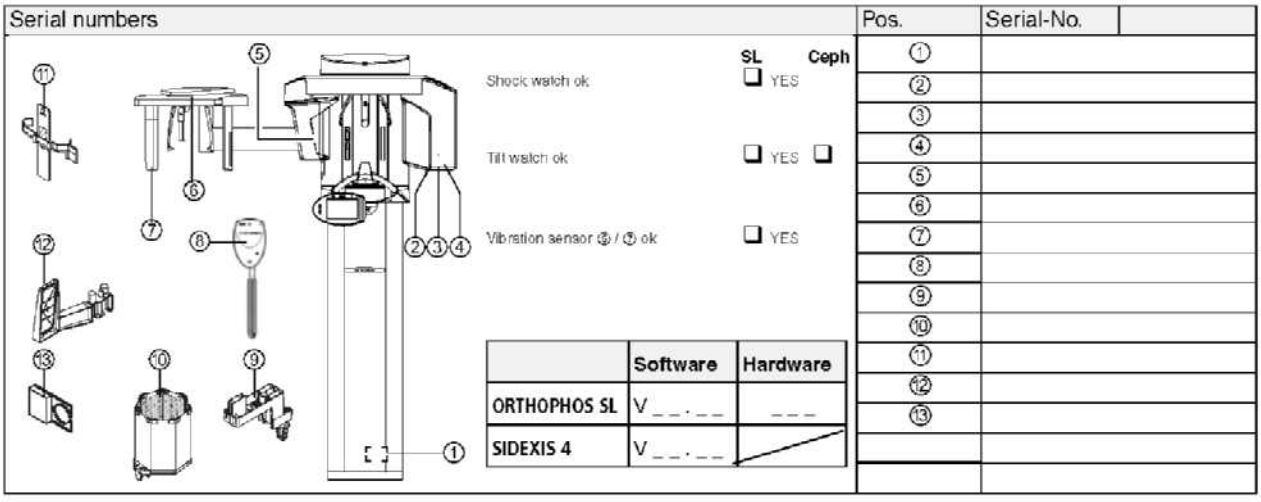
- Dosimeter for pulsed radiation of type:
  - Mult-O-Meter 512L
  - or similar

⚠ CAUTION

Use exclusively fully insulated measuring wires.
Check the measuring wires for damages before use.

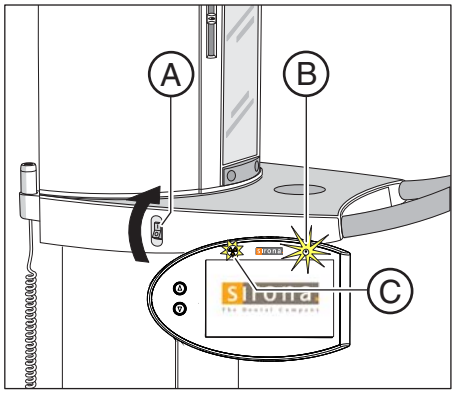
- Measuring wires with the following properties:
  - dielectric strength > 1000 V

4 Visual check

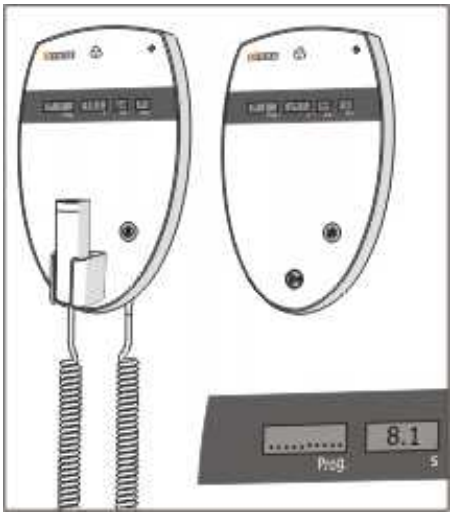


- Check for mechanical damage that could affect radiation protection.
- Check that all labels are attached and legible.
  - Damaged/imperfect labels must be replaced.
    You can order them in writing from Sirona (see back page for address),
    stating the following:
  - Customer's name
  - Customer's address
- Check to see whether all model numbers and serial numbers must still be legible on the unit so that it can be identified.

5 Optical and acoustic signals



1. Turn the main switch **(A)** to position I.
   - The X-Ray radiation indicator **C** lights up briefly.
   - After approx. 2 seconds, the green LED **B** in the upper part of the control panel lights up. This LED remains lit as long as the unit is on.
   - The start screen appears on the touchscreen of the Easypad and the initialization of the device starts running (for approx. 1 minute). The rotating element rotates briefly clockwise and counterclockwise. The diaphragm moves into position. The forehead and temple supports on the panoramic unit open and close and then stop moving in fully opened position.
2. Check the function of the keys.
   - Press a height-adjustment key. The movement of the height-adjustment motor is accompanied by an acoustic signal.
   - Press the keys for adjusting the forehead support and the temple support. If the keys are working correctly, the supports stop automatically when they come into contact with the patient's head.
   - If Remote has been installed, test the buttons and the display of the remote unit, too.
   - The release button must not be defective or damaged.



See also the Operating Instructions, in the Operation section.

5.1 Checking the function of keys and buttons

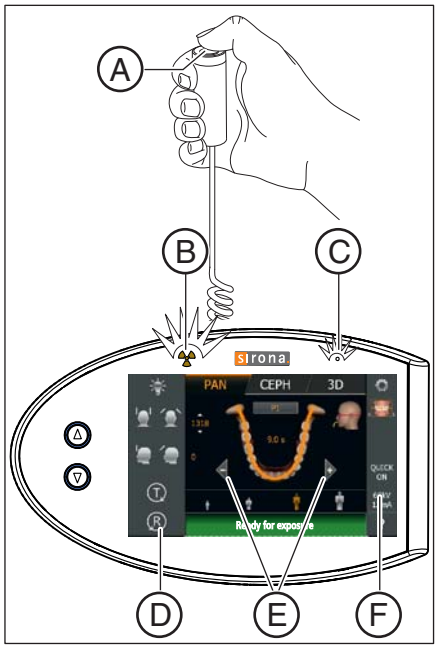
⚠ WARNING

The unit emits X-ray radiation.

Excess exposure to X-rays is detrimental to health.

➢ Use the prescribed accessories for radiation protection.

➢ Do not stay in the X-ray room during exposure. Move as far away from the unit as the coiled cable for the release button allows you to.



✓ "Unit ON" LED display **C** lights up. Press the R key **D** to move the unit to the starting position. As long as no connection has been made to SIDEXIS, the message is displayed in the comment line of the control panel on the *"Switch SIDEXIS to ready for exposure state"* touchscreen.

1. Switch on the PC.
2. Start SIDEXIS (see SIDEXIS user manual).
   For further information and possible error messages, see Operating Instructions.
3. Use the -/+ keys to select a program **E**.
4. In the sub menu **F**, select a kV/mA combination with the -/+ keys.
5. Check whether the patient symbols on the touchscreen can be selected in exactly the right position.
   If problems occur during selection, adjust the touchscreen).
6. Press release button **(A)** and hold it down until the end of the exposure.
   ↳ The exposure is released. *"Exposure is performed"* Appears in the comment line on the touchscreen.
   During radiation, the optical radiation indicator **(B)** lights up on the Easypad; during radiation, an acoustic signal is also emitted.
   Radiation can be triggered multiple times during exposure.
   When the rotation and radiation switch off automatically, the exposure is complete.
7. Let go of release button **(A)**.
   ↳ The exposure is completed.

8. **Cancel exposure - Check deadman function**
   Select the same exposure parameters.
   The operational readiness LED B flashes until the automatic cooling-off period of the X-ray tube assembly has expired (automatic exposure block).
9. Press the release button **A**.
10. Let go of the exposure release button.
    ↳ The exposure is immediately terminated.
    The confirmation of the exposure data is displayed on the touchscreen. The radiation time and the area dose product (the lower two values) flash. In this way, an exposure that has been triggered can be canceled again at any time.

⚠ CAUTION

Defective indicators and keys represent a risk to the safety of both the patient and the operator.

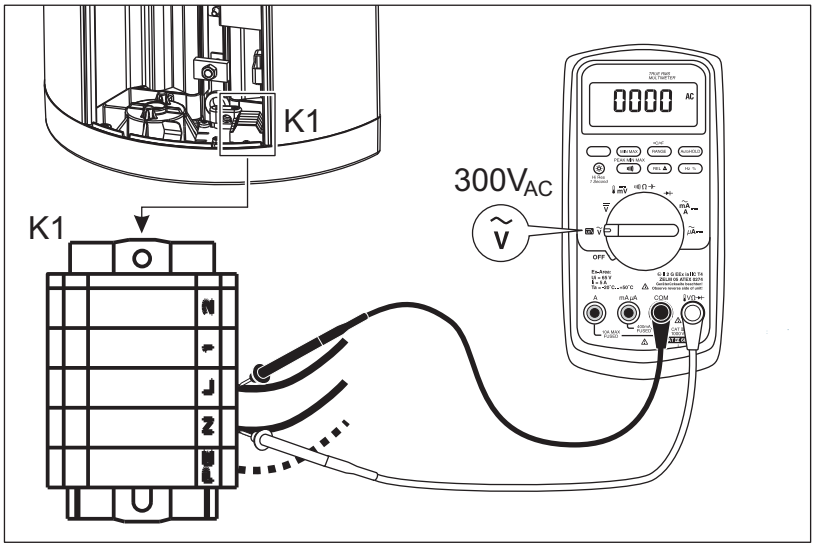
The user is not permitted to operate the unit until the necessary repairs have been made.

6 Checking the power supply connection

To check the line voltage, the *line voltage drop* must be determined while creating an X-ray. To do this, proceed as follows:

Preparing the measurement

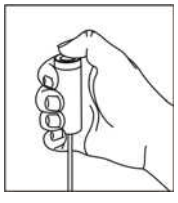
1. **DANGER! After disconnecting the unit from the junction box of the building installation, wait at least 1 minute before starting to check the line voltage!**
   Disconnect the unit from the junction box of the building installation.
2. Remove the "Bottom profile" cover (see Service Manual).



3. **CAUTION! Only use fully insulated measuring wires.**
   Connect the measuring wires as shown in the illustration to the connectors **L** and **N** of the power supply terminal **K1**.
4. On the multimeter, select the voltage measuring range "300 V_{AC}".
5. Re-attach the unit to the junction box of the building installation.
6. **DANGER! Do not touch any live components!**
   Set the main switch (A) to I (see also Operating Instructions).
7. Wait for approx. 1 minute.
8. Press the R key.
   ↳ The unit moves to its starting position.

Performing and analyzing a measurement

1. Set the highest kV/mA level, e.g. **90kV/12mA** (see Operating Instructions).
2. Make ready for exposure in SIDEXIS.
3. **CAUTION! Activating the release button triggers X-rays.**
   Activate the release button and take the voltage drop reading on the multimeter display.
   ↳ If the measured voltage drop does *not fall within the permissible tolerance range* (see the following table), notify the customer that a suitable line voltage (according to the notes listed in the Installation Requirements) must be installed.



IMPORTANT
In such a case, the unit must be switched off immediately and disconnected from the junction box of the building installation. It must not be placed in operation!

↳ If the measured voltage drop falls within the permissible tolerance range (see the following table), finalize the measurement.

Permissible voltage drop:

Line voltage, with zero load	Max. permissible line voltage drop
180-208 V	9 V
208-230 V	8 V
230-240 V	7.5 V
240-264 V	7 V

Concluding the measurement

1. Switch the unit on via switch (**A**) (see also Operating Instructions).
2. Disconnect the unit from the junction box of the building installation.
3. **DANGER! Wait at least 1 minute after disconnecting the unit from the junction box of the building installation before removing the measuring wires!**
   Remove the measuring units from the unit.
4. Re-attach the "Bottom profile" cover to the unit.

7 Checking the tube current

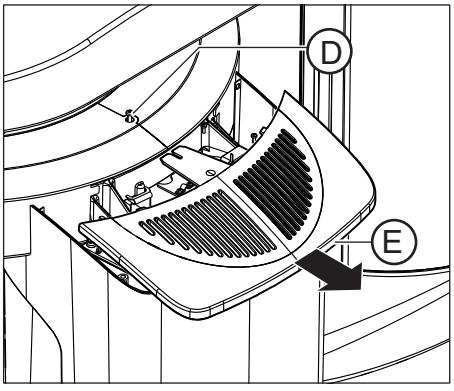
NOTICE

Damage to the measuring unit

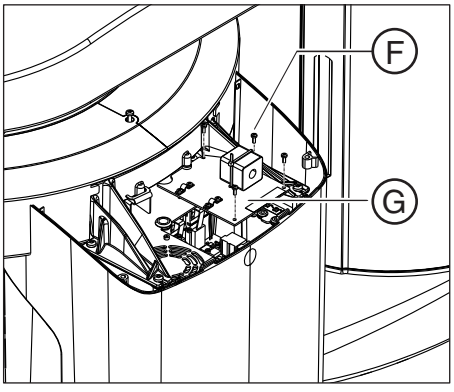
The ring assembly and the tube assembly move during the measurement.
Make sure that the measuring wires are sufficiently long to allow for the ring movement and that the measuring unit is in a secure position so that it will not fall down.

Preparing the measurement

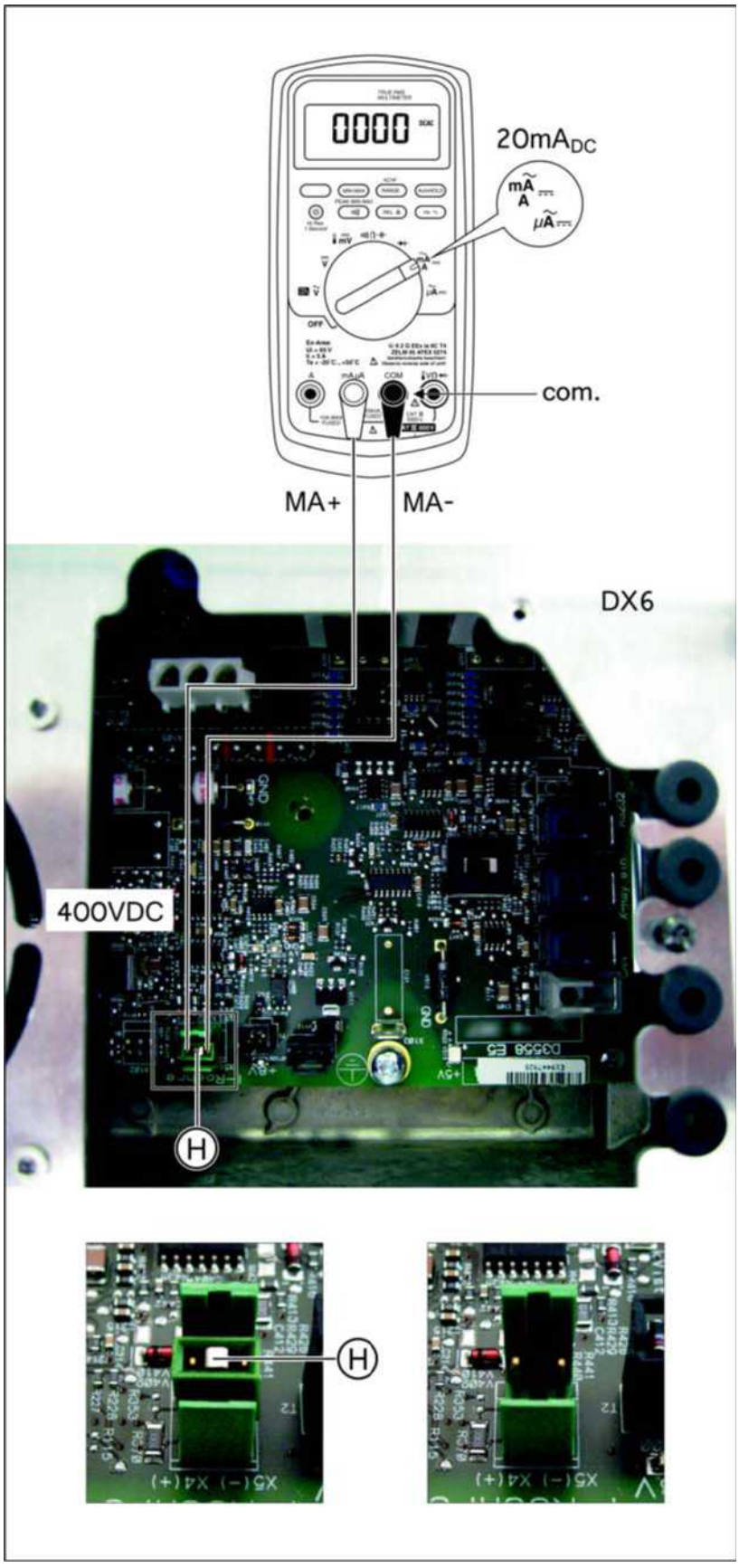
1. Switch off the unit (see Operating Instructions).
   DANGER! After switching off the unit, wait at least 4 minutes (LED V500 on the DX6 must no longer be on) before removing the cover on the tube assembly.



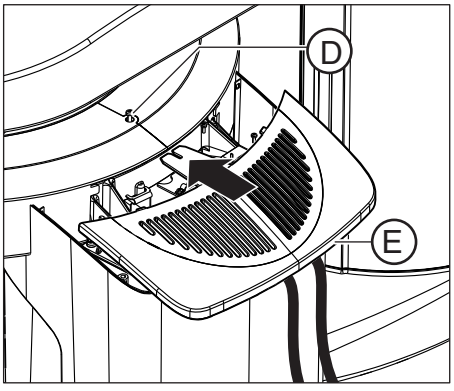
2. Loosen the screw (**D**) and remove the lid of the tube assembly cover (**E**).



3. Loosen the 4 screws (**F**) and remove the cover plate (**G**).


0000
20mA$_{DC}$
com.
MA+
MA-
DX6
400VDC
H
H

4. **DANGER! After switching off the unit, wait at least 4 minutes (LED V500 on the DX6 must no longer be on) before removing jumper H from the DX6 board.**
   Remove the jumper (**H**) from connector **X302** on the **DX6** board.
5. **DANGER! Only use fully insulated measuring wires.**
   Connect the digital multimeter with the measuring wires to test points **MA-** (X5-) and **MA+** (X4+) at connector **X302** on the **DX6** board.
6. On the multimeter, select the **current measuring range 20 mA DC**.

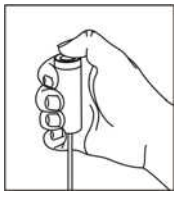


7. **NOTICE! If the lid of the tube assembly cover is not attached, the ring circulation is impeded and the unit can be damaged.**
   Temporarily install the lid of the tube assembly cover (**E**) on the unit using the screw (**D**).
8. **DANGER! Do not touch any live components!**
   Set the main switch (**A**) to **I** (see also Operating Instructions).
9. Wait for approx. 1 minute.

10. Touch the R key on the touchscreen.
    ↳ The unit moves to its starting position.

Performing measurements

1. Select the **P1** program (see Operating Instructions).
2. Set the highest kV/mA level, **66 kV/8 mA** (see Operating Instructions).
3. Establish readiness for exposure (see SIDEXIS 4 Operator´s Manual).



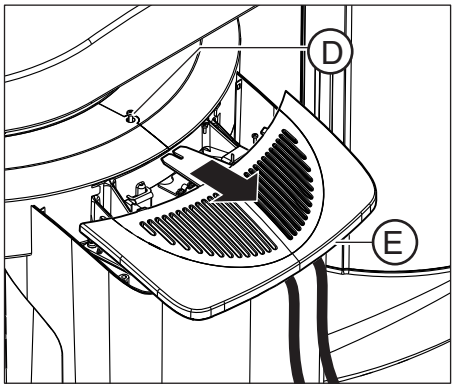
4. **CAUTION! Activating the release button triggers X-rays.**
   Start the exposure by pressing the release button. Hold down the release button until image acquisition is completed and the acoustic signal that indicates the end of the exposure can be heard.

IMPORTANT
1 mA corresponds to a tube current of 1 mA. The permissible tolerance is ± 20 %.

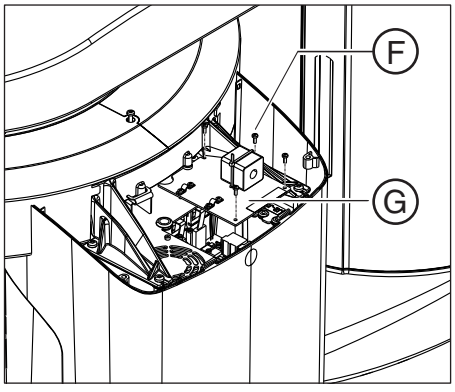
Analyzing measurements

➢ Read the voltage value on the display of the multimeter.
   ↳ The tube current must be **8 mA ± 1.6 mA**.
   ↳ If the measured value is *not* within the permissible tolerance, replace the *tube assembly*.
   ↳ If the measured value falls within the permissible tolerance, conclude the measurement.

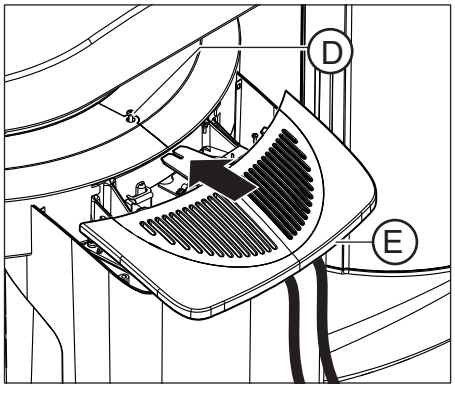
Concluding the measurement



1. Switch the unit on via switch (**A**) (see also Operating Instructions).
2. Loosen the screw (**D**) and remove the lid of the tube assembly cover (**E**).
3. **DANGER! After switching off the unit, wait at least 4 minutes before removing the measuring wires or reinserting the jumper!**
   Remove the measuring wires and bridge with the **test points MA+/ MA-** on the **DX6** board again with the jumper (**H**).



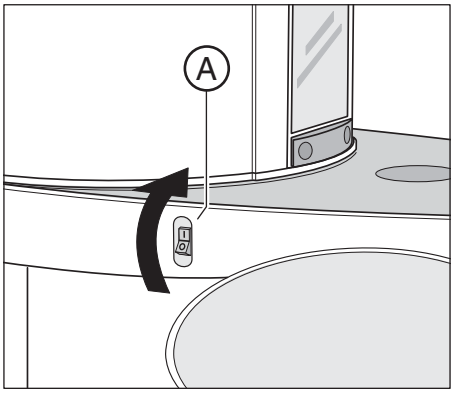
4. Reattach the cover plate (**G**) to the tube assembly with the 4 screws (**F**).



5. Reattach the lid of the tube assembly cover (**E**) to the unit and secure it with the screw (**D**).

8 Checking the tube voltage

Preparing the measurement

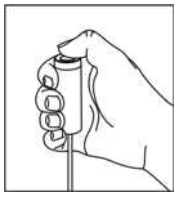


1. Attach the Mult-O-Meter sensor in the middle of the sensor (on 2D sensor side).
2. Set the main switch (**A**) to **I** (see also Operating Instructions).
3. Wait for approx. 1 minute.

4. Touch the R key on the touchscreen.
   ↳ The unit moves to its starting position.

Performing measurements

1. Select the **P1** program (see Operating Instructions).
2. Set the kV/mA level **63kV/8 mA** (see Operating Instructions).
3. Establish readiness for exposure (see SIDEXIS 4 Operator´s Manual).



4. **CAUTION! Activating the release button triggers X-rays.**
   Start the exposure by pressing the release button. Hold down the release button until image acquisition is completed and the acoustic signal that indicates the end of the exposure can be heard.

Analyzing measurements

➢ Read the voltage values on the display of the Mult-O-Meter.

IMPORTANT
The measured tube voltage must correspond with the tube voltage set of 63kV. The permissible tolerance is ± 10 %.

↳ If the measured values *are not within the permissible tolerance range*, replace the *tube assembly*.

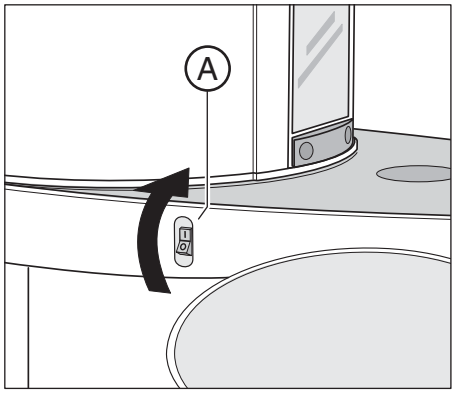
↳ If the measured values are within the permissible tolerance range, finalize the measurement.

Concluding the measurement

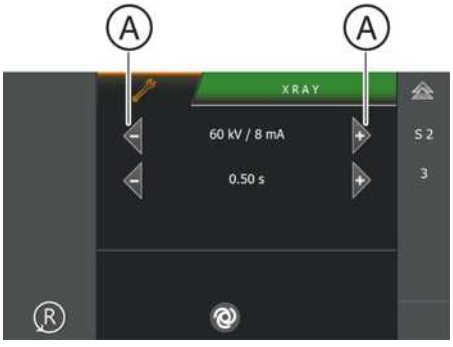
➢ Switch the unit on via switch (**A**) (see also Operating Instructions).

9 Checking the radiation time

Preparing the measurement

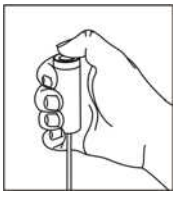


1. Attach the Mult-O-Meter sensor in the middle of the combisensor (on 2D sensor side).
2. Set the main switch (**A**) to **I** (see also Operating Instructions).
3. Wait for approx. 1 minute.
4. Press the R key.
   - ↳ The unit moves to its starting position.



5. Call the Service menu and the Service routine S002.3 (see Service Manual).
6. Use the arrow keys (**A**) in *selection field 1* to select the kV/mA level **60 kV/8 mA**.
7. Use the arrow keys (**A**) in *selection field 2* to select the radiation time **0.5 s**.

Performing measurements



➢ Initiate the radiation. Hold the release button pressed until the set radiation time has expired.

Analyzing measurements

➢ Read the radiation time on the Mult-O-Meter.
- ↳ The value for the radiation time displayed on the Mult-O-Meter must correspond to the radiation time of **0.5s** selected in the service routine. The permissible tolerance is ± 10 %.
- ↳ If the measured radiation time does *not* fall within the permissible tolerance, replace the *tube assembly* (see Service Manual).
- ↳ If the measured radiation time falls within the permissible tolerance, finalize the measurement.

Concluding the measurement

1. Exit the service routine.
2. Switch the unit on via switch (**A**) (see also Operating Instructions).

10 Checking the laser light localizers

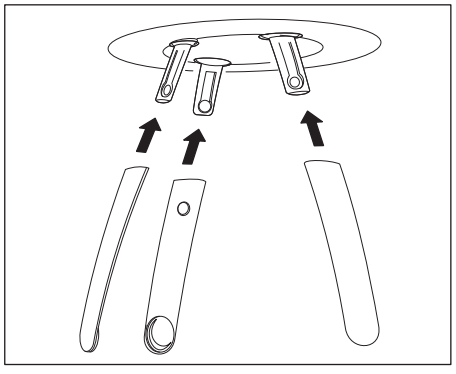
⚠ CAUTION

Risk of injury to eyes.

The unit contains lasers of Class 1.
Keep a distance of at least 4" (10 cm) between eye and laser. Do not look into the laser beam.

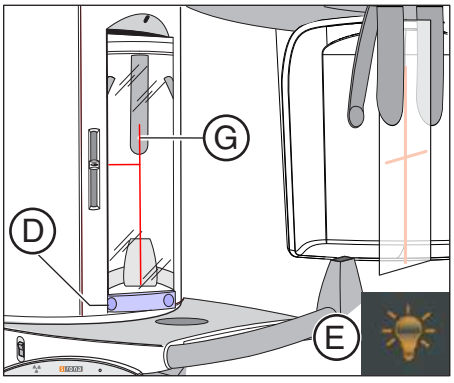
Checking the laser light localizers

Preparing the test



1. Insert the forehead and temple supports.
2. Set the main switch (A) to **I** (see also Operating Instructions).
3. Wait for approx. 1 minute.

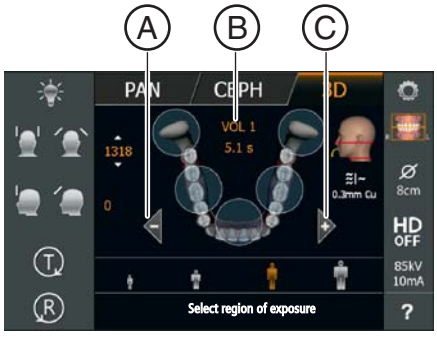
4. Touch the R key on the touchscreen.
   ↳ The unit moves to its starting position.



Checking the PAN laser beam

1. Affix a piece of white cardboard between the temple supports.
2. Rotate the mirror by pressing into the left depression (D) of the toolbar.
3. Touch the light localizer key (E) on the touchscreen.
   - ↳ The light localizers are switched on.
   - ↳ The laser beam is displayed on the cardboard by a red line.
   - ↳ The vertical laser beam (G) must be displayed in the center of the forehead support and the bite block holder. If this is not the case, adjust the laser light localizer.
   - ↳ The horizontal laser beam must be displayed horizontally. If this is not the case, adjust the laser light localizer.
4. Press on the light localizer key again.
   - ↳ The light localizer is switched back off again.

Checking the 3D laser beam



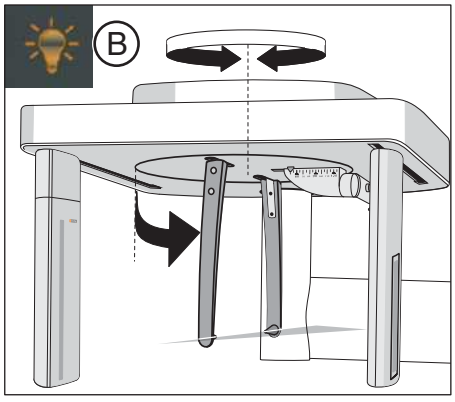
1. Touch the 3D symbol at the top of the touchscreen.
   - ↳ The 3D program group is selected.
2. Select the exposure program. Press the arrow keys **+** (C) and **-** (A).
   - ↳ The exposure program is displayed in the program display (B).
3. Touch the R key on the touchscreen.
   - ↳ The diaphragm and the sensor move into the starting position for volume exposures.
4. Touch the light localizer key on the touchscreen.
   - ↳ The light localizers are switched on.
   - ↳ Depending on a preselected program and collimation, the light beams show the upper and lower edges of the volume.

VOL1 VOL1 HD	Volume exposure with a diameter of approx. 8 cm and a height of approx. 8 cm or 5.5 cm collimated.
VOL2 VOL2 HD	Volume exposure with a diameter of about 5 cm and a height of about 5.5 cm for upper **or** lower mandible
VOL3 VOL3 HD	Volume exposure with a diameter of about 11 cm and a height of about 10 cm or selection of upper quadrant collimated to 7.5 cm and selection lower quadrant collimated to 8.0 cm

1. Select the different volume programs one after the other with different collimations and measure the distance of the light beams.
   - Minimum and maximum distances apply between the laser localizers.
   - Replace any light localizer that does not respond as desired.
2. Press on the light localizer key again.
   - The light localizer is switched back off again.

Checking the horizontal laser beam ceph (FH)

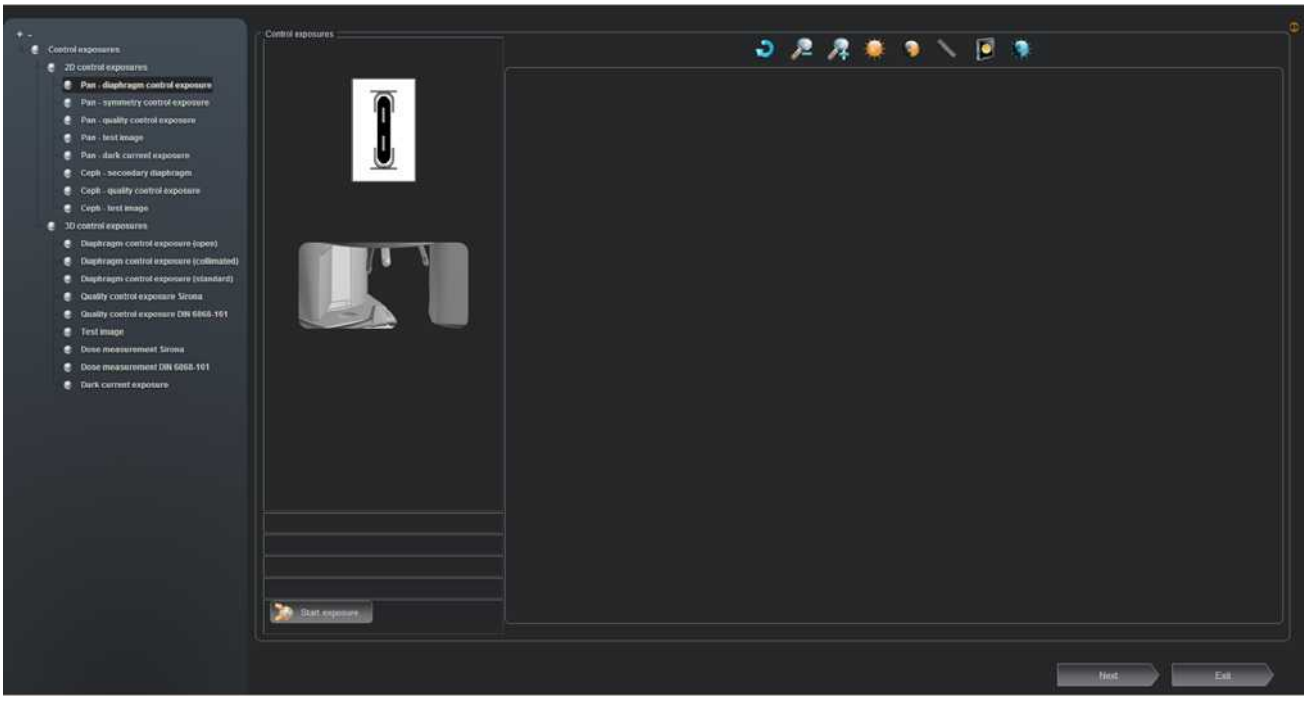
Tip: When checking or adjusting the light localizer, you may use a PA or AP position on the ear plugs to assess the light beam.



1. Touch the light localizer key (B) on the touchscreen.
   - The light localizers are switched on.
2. Check the position of the horizontal laser beam at the ceph.
   - The laser beam must run horizontally at the level of the ear plug position between the template supports. If this is not the case, adjust the laser localizer.
3. Press on the light localizer key again.
   - The light localizer is switched back off again.

11 Test exposures/Test images

The 2D/3D test exposures and test images are used for fast checking of the unit adjustment/calibration.



"Control exposures" menu

The following test exposures are available:

2D test exposures

- *"Pan - diaphragm control exposure"*
- *"Pan - symmetrie control exposure"*
- *"Pan - quality control exposure"*
- *"Pan - test image"*
- *"Pan - dark current exposure"*

Additionally for units with cephalometer:

- *"Ceph - secondary diaphragm"*
- *"Ceph - quality control exposure"*
- *"Ceph - test image"*

3D test exposures

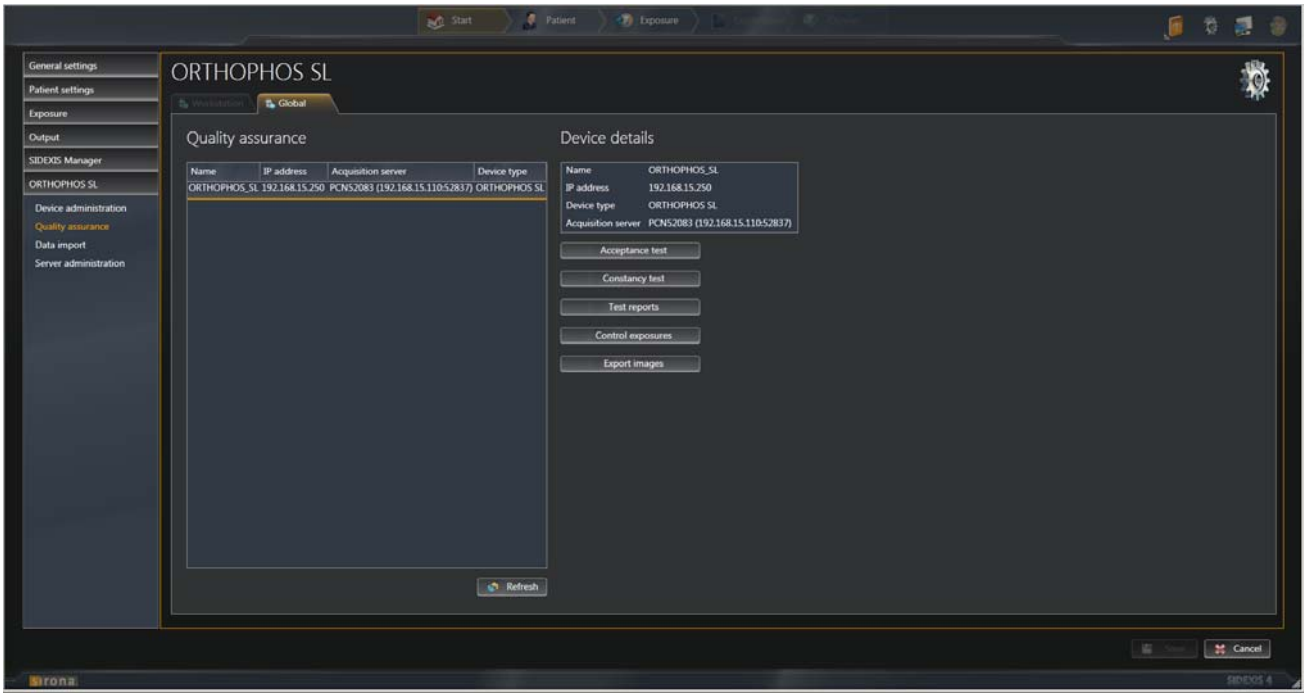
- *"Diaphragm control exposure (open)"*
- *"Diaphragm control exposure (standard)"*
- *"Quality control exposure Sirona"*
- *"Test image"*
- *"Dose measurement Sirona"*
- *"Quality control 21CFR 1020.33"*

The menu can be called up without a service password, so test exposures can thus be performed by the user as well.

11.1 Calling "Test exposures" menu

✓ SIDEXIS 4 is installed.

1. Start SIDEXIS 4.
2. In SIDEXIS 4, call the *"ORTHOPHOS SL" / "Quality assurance"* configuration menu.



Configuration menu "ORTHOPHOS SL" /"Quality assurance"

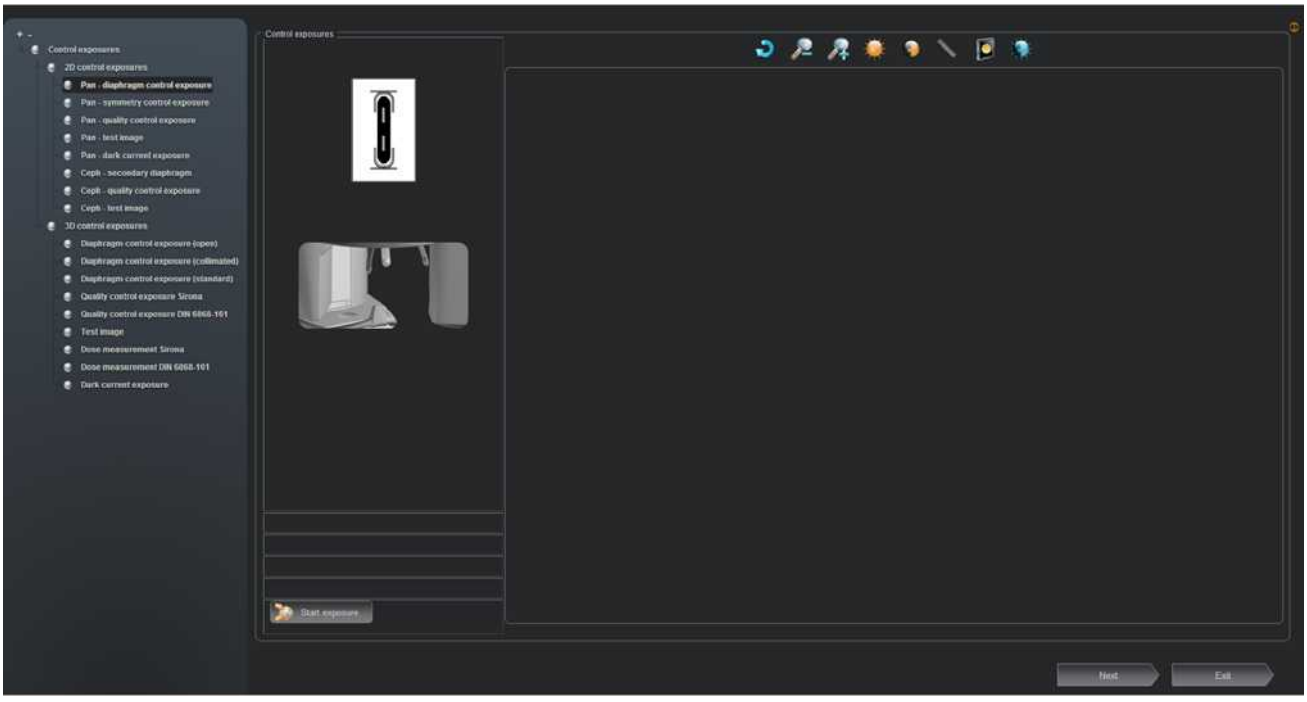
3. Select the desired X-ray component from the unit list.
4. Click on the *"Control exposures"* button.
   ↳ The *"Control exposures"* menu is started.

11.2 2D test exposures

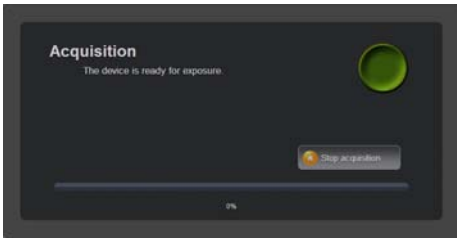
11.2.1 Pan - diaphragm test exposure (2D)

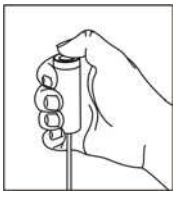
You can use the *"Pan - diaphragm control exposure"* to check the adjustment of the Pan - diaphragm adjustment.

1. Call up the *"Control exposures"* menu [→ 23].
2. Select the *"Pan - diaphragm control exposure"* element in the structure tree under *"2D control exposures"*.
   ↳ In the action area, the menu appears to create the *"Pan - diaphragm control exposure"*.



3. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.





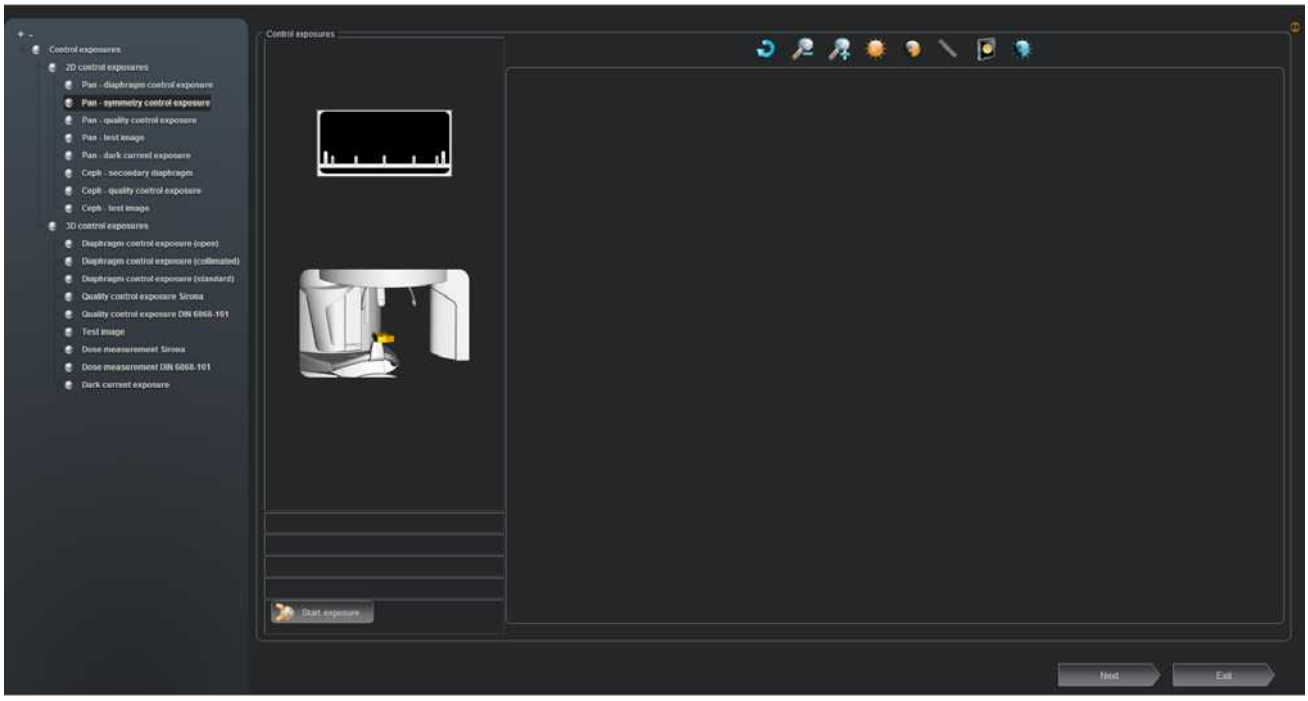
4. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   ↳ The exposure is displayed in the exposure window.
   For notes on evaluating the exposure, refer to the section "Unit adjustment and calibration"/"Pan aperture adjustment".

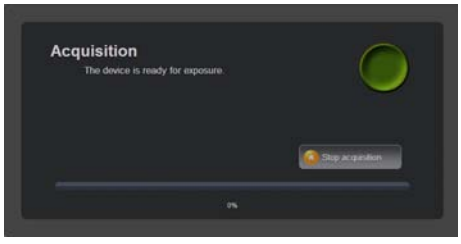
See service manual.

11.2.2 Pan - Symmetrical test exposure (2D)

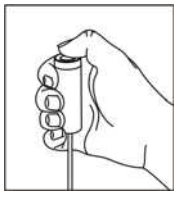
You can use the *"Pan - symmetrie control exposure"* to check the adjustment of the Pan - symmetry adjustment.

1. Insert the needle phantom into the bite block holder of the unit.
2. Call up the menu *"Control exposures"* [→ 23].
3. Select the *"Pan - symmetrie control exposure"* element in the structure tree under *"2D control exposures"*.
   - ↳ In the action area, the menu appears to create the *"Pan - symmetrie control exposure"*.





4. Click on the *"Start acquisition"* button.
   - ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   - ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.

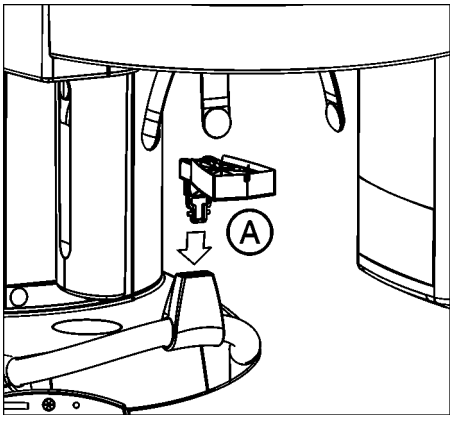


5. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   - ↳ The exposure is displayed in the exposure window.
     For notes on evaluating the exposure, refer to the section "Unit adjustment and calibration"/"Pan symmetry adjustment".
6. Remove the needle phantom again.

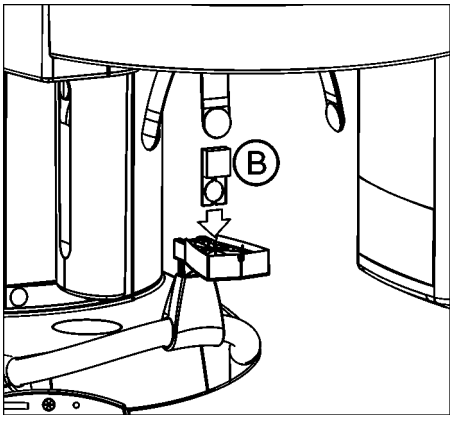
See service manual.

11.2.3 Pan - quality test exposure (2D)

You can use the *"Pan - quality control exposure"* to create a panoramic exposure with full rotation. This function enables you to simulate a quality test, for example, in a similar way to an acceptance/constancy test.



1. Insert the needle phantom (A) into the bite block holder.



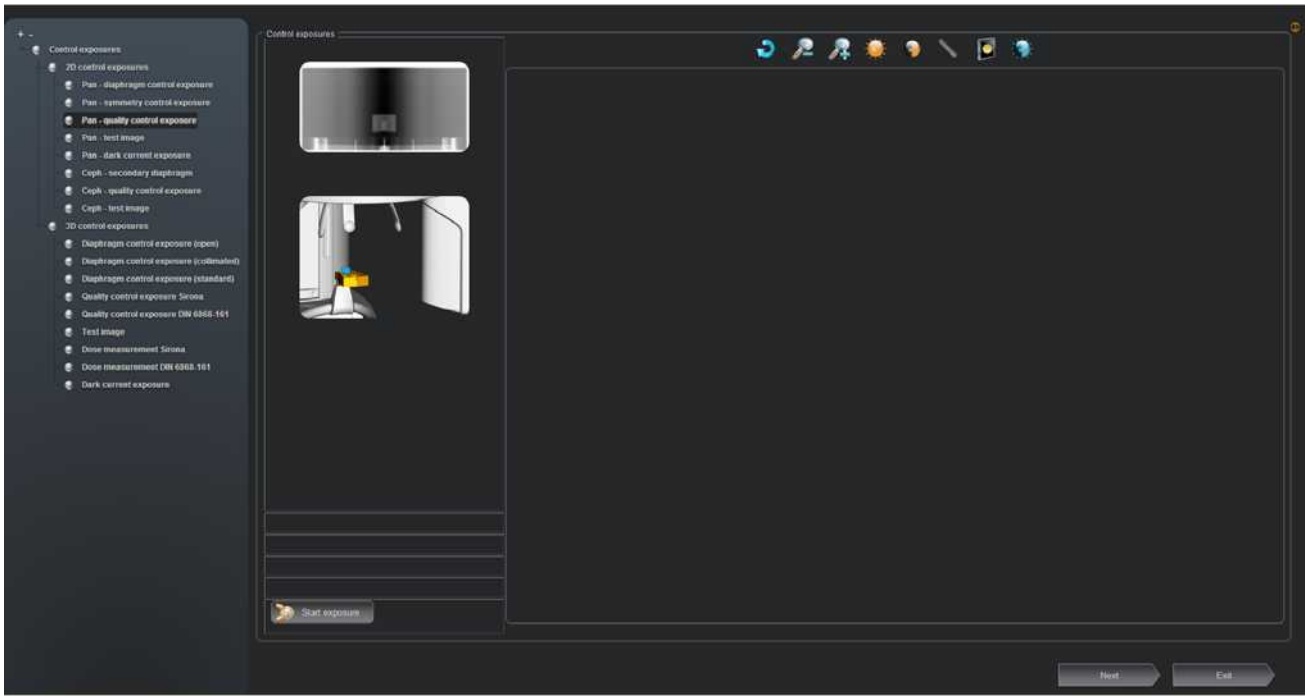
2. Plug the contrast element (B) into the slot on the needle phantom provided for that purpose.

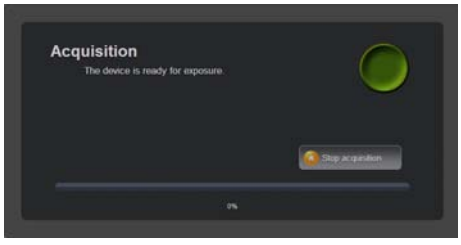
NOTICE

The aluminum plate of the contrast element must be facing away from the column of the unit.

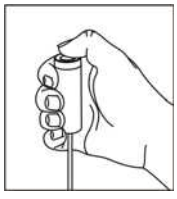
Do not attach any additional aluminum plate to the unit.

3. Press the R key.
   - The unit moves to its starting position.
4. Call the *"Control exposures"* menu [→ 23].
5. In the structure tree, under *"2D control exposures"*, select the *"Pan - quality control exposure"* element.
   - The menu for creating the *"Pan - quality control exposure"* appears in the action window.





6. Click on the *"Start acquisition"* button.
   - Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   - The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.

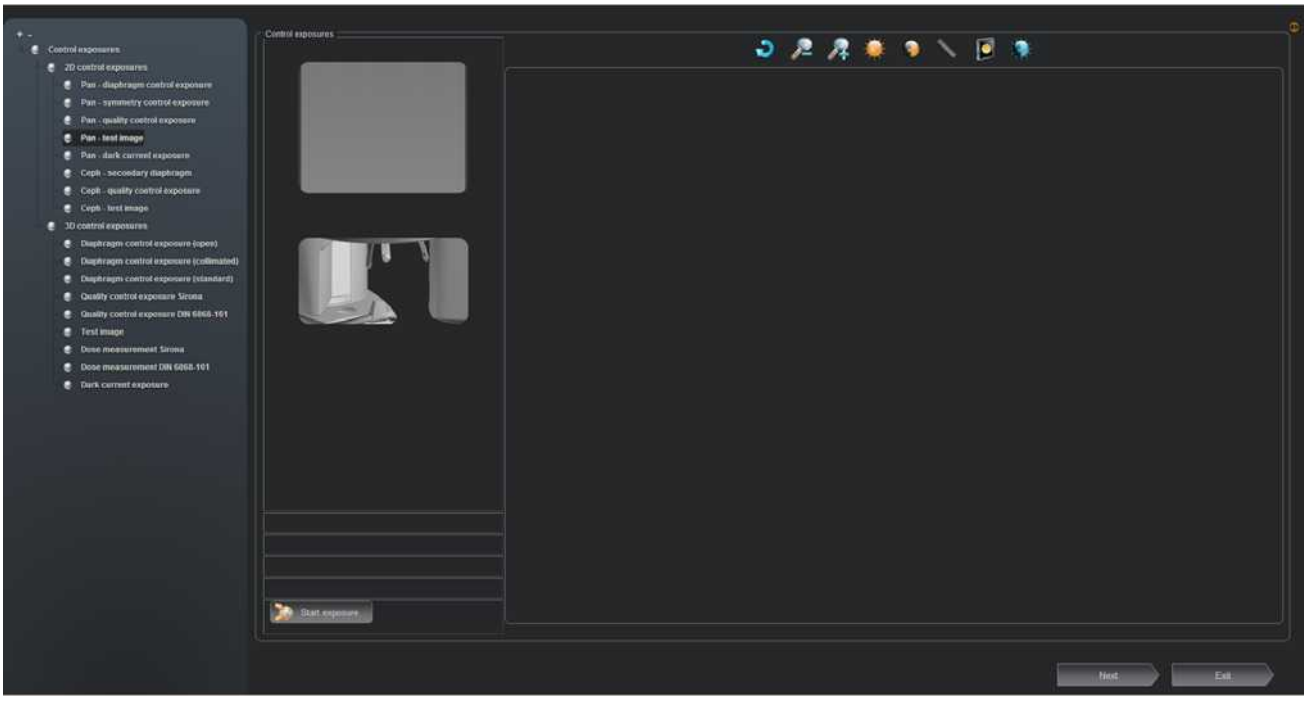


7. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if it has been configured).
   - The exposure is displayed in the exposure window.
     For notes on evaluating the exposure, refer to the technical documentation for acceptance/constancy testing.
8. Remove the needle phantom again with the constancy test phantom.

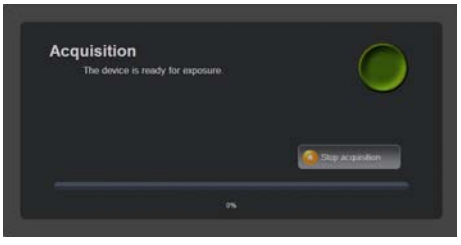
11.2.4 Pan - test image (2D)

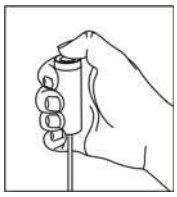
You can use the *"Pan - test image"* menu to check the 2D data path of the unit and the operability of the DCS sensor.

1. Call up the menu *"Control exposures"* [→ 23].
2. Select the *"Pan - test image"* element in the structure tree under *"2D control exposures"*.
   ↳ The menu for creating the test image appears in the action window.

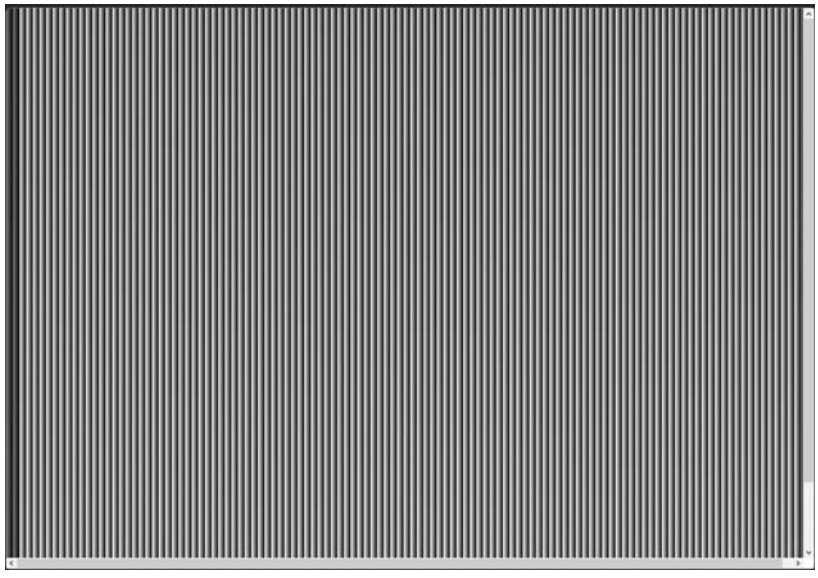


3. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.





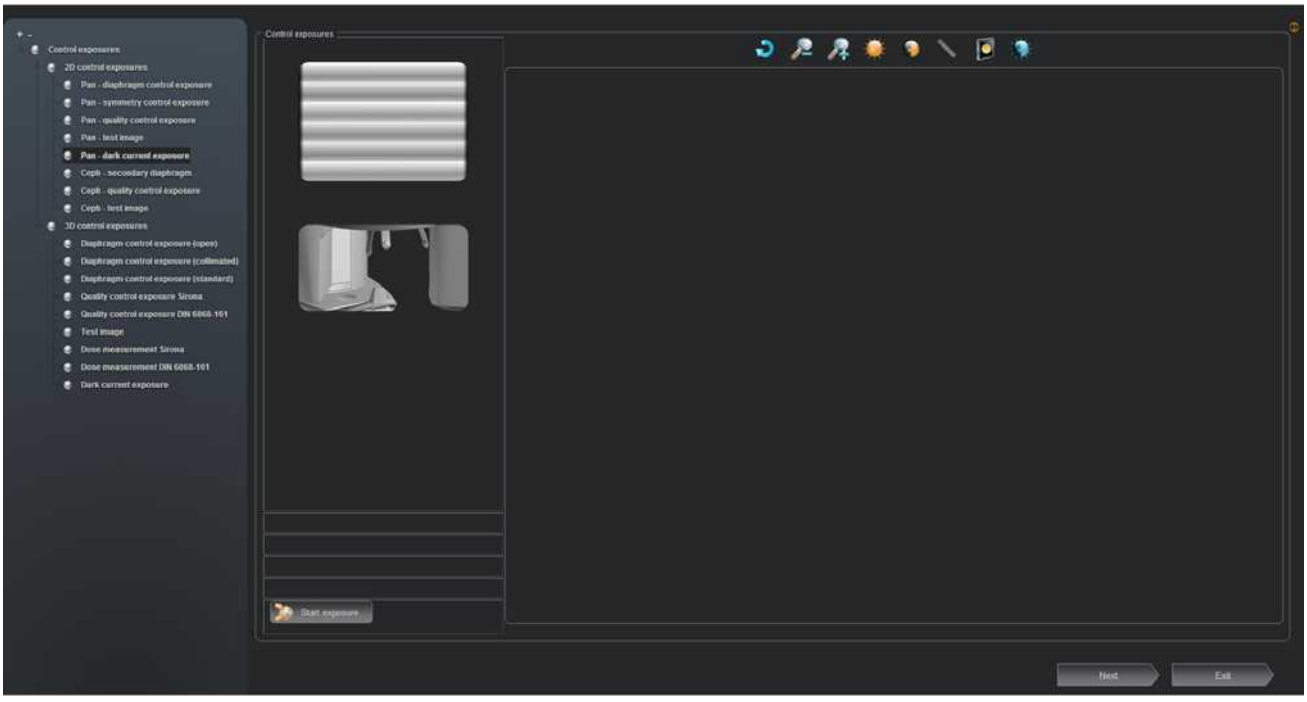
4. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   ↳ The exposure is displayed in the exposure window.
   See below for reference image.



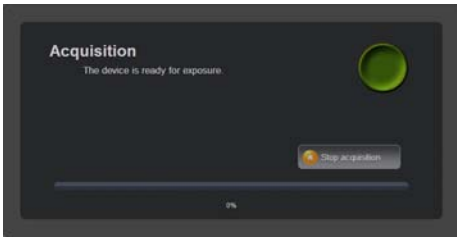
11.2.5 Pan - dark current exposure (2D)

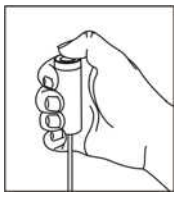
You can use the *"Pan - dark current exposure"* menu to check the DCS sensor and the data path.

1. Call up the menu *"Control exposures"* [→ 23].
2. Select the *"Pan - dark current exposure"* element in the structure tree under *"2D control exposures"*.
   ↳ The menu for creating the *"Pan - dark current exposure"* appears in the action window.

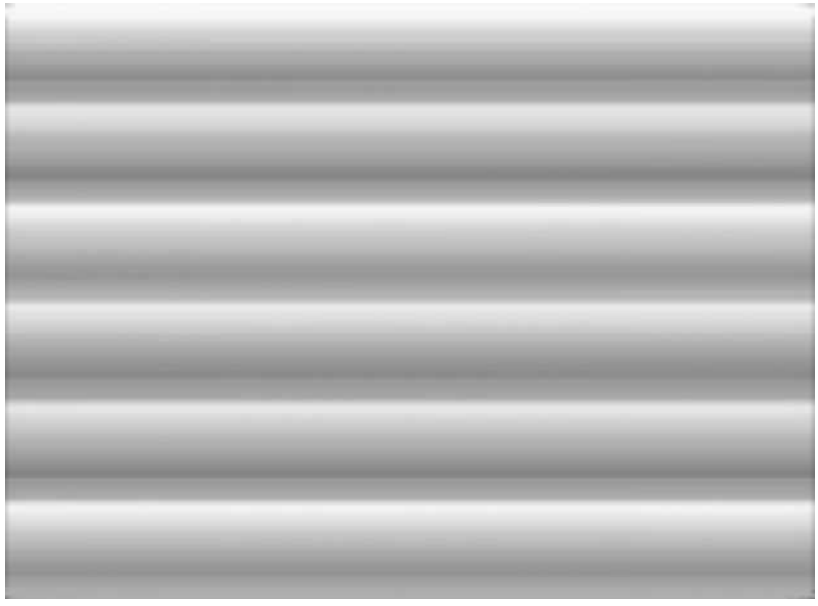


3. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.





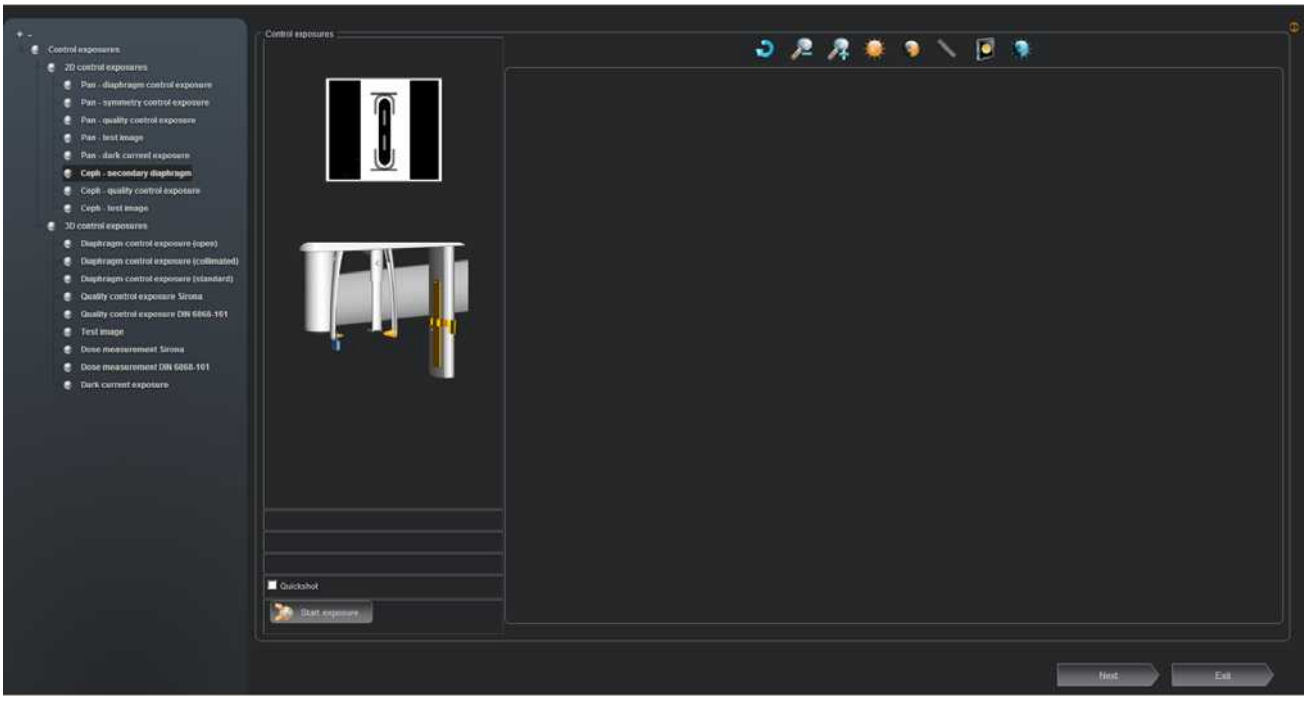
4. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   ↳ The exposure is displayed in the exposure window.
   See below for reference image.



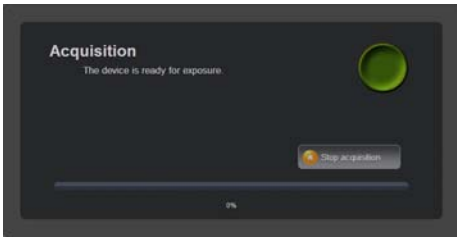
11.2.6 Ceph - secondary diaphragm (2D)

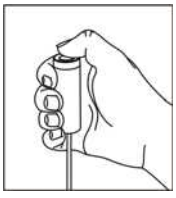
You can use the *"Ceph - secondary diaphragm"* menu to check the adjustment of the Ceph secondary diaphragm.

1. Call up the menu *"Control exposures"* [→ 23].
2. Select the *"Ceph - secondary diaphragm"* element in the structure tree under *"2D control exposures"*.
   ↳ In the action area, the menu appears to create the exposure for the *"Ceph - secondary diaphragm"*.



3. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.





4. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   ↳ The exposure is displayed in the exposure window.
   For notes on evaluating the exposure, refer to the section "Unit adjustment and calibration"/"Adjustment of the ceph secondary diaphragm".

See service manual.

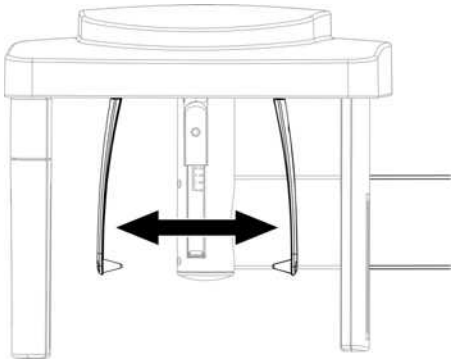
11.2.7 Ceph - quality test exposure (2D)

You can use the *"Ceph - quality control exposure"* to create a Ceph exposure with full rotation. This function enables you to simulate a quality test, for example, in a similar way to an acceptance/constancy test.

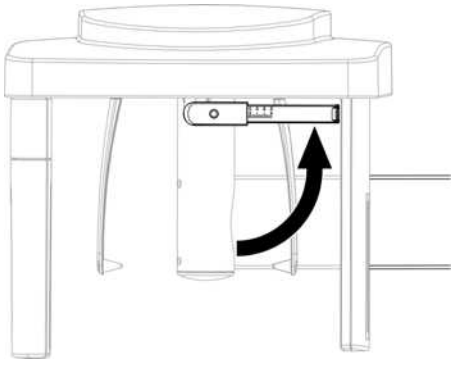
✓ **No** needle phantom is inserted into the bite block of the unit.

✓ The Ceph sensor is inserted in the sensor holder of the cephalometer.

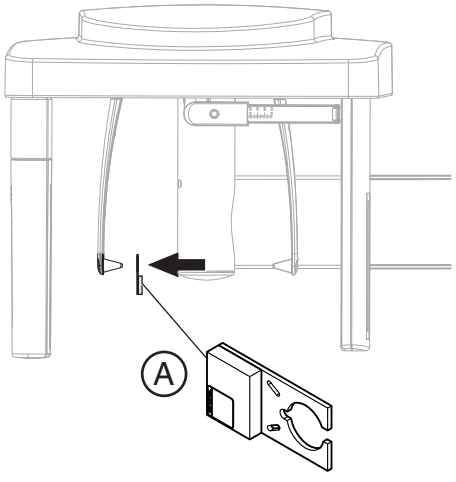
1. Open the ear plug holders completely.
2. Turn the ear plug holders so that one ear plug is directly in front of the image receptor.



3. Fold up the nose support.

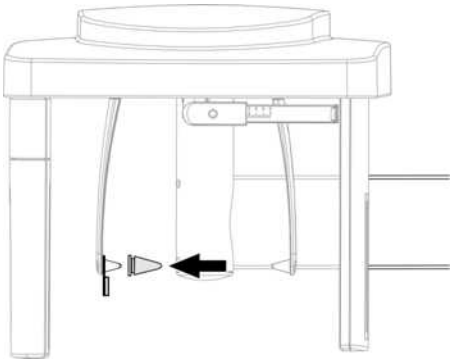


4. Fit the contrast element (A) with its hole onto the ear plug.

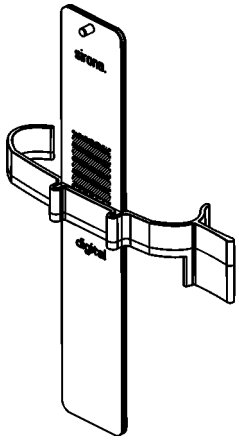


NOTICE

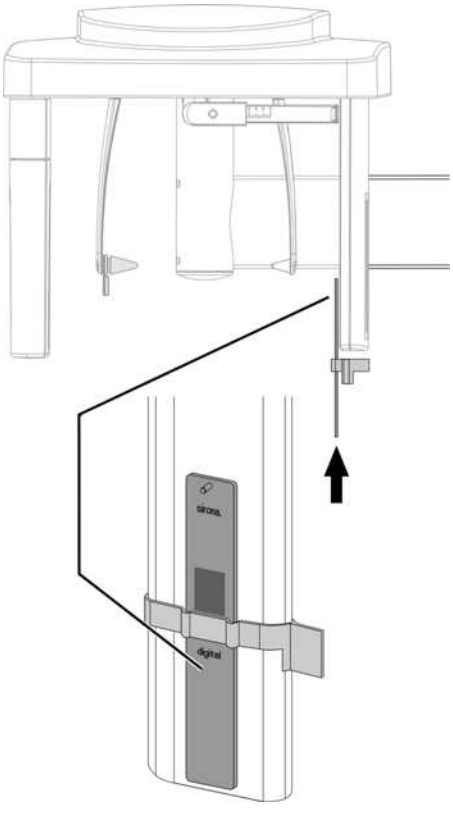
The aluminum plate of the contrast element must face the X-ray tube assembly.



5. Secure the contrast element using a hygienic cap.



6. Attach the ceph test phantom to the clip provided for that purpose.

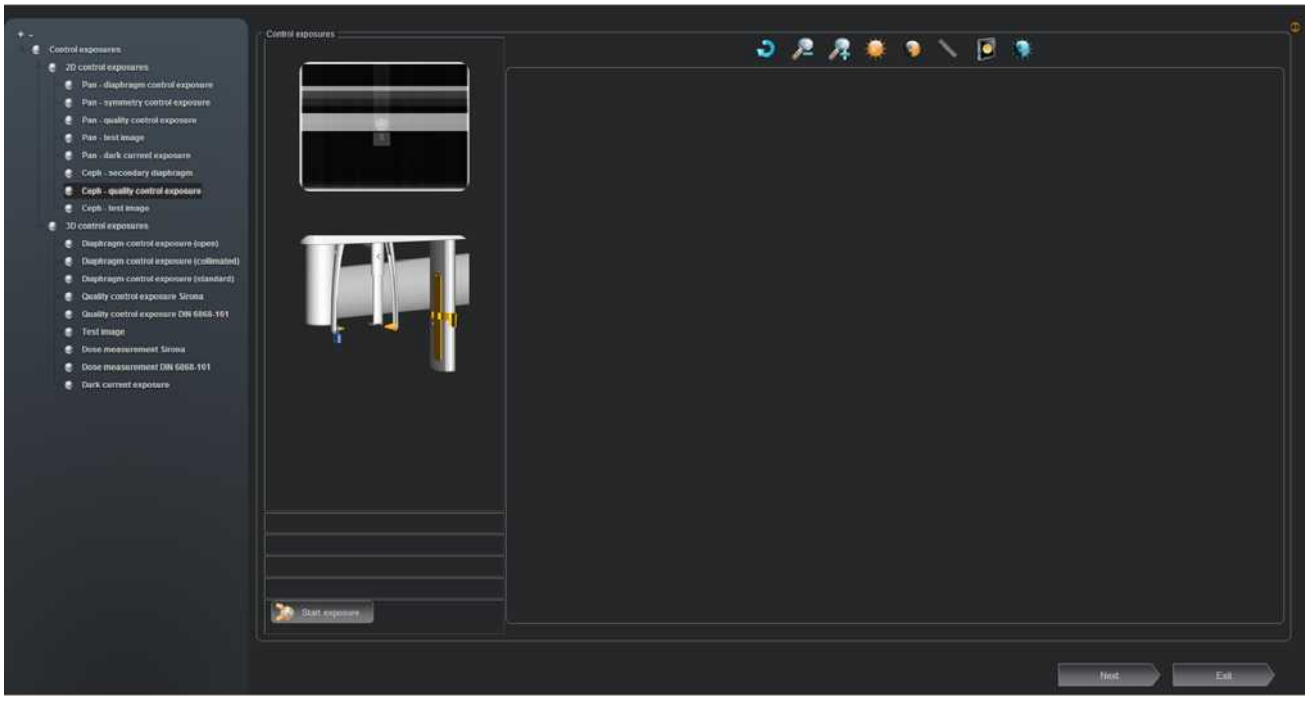


7. Push the ceph test phantom with the clip from **below** on to the secondary diaphragm of the ceph arm.

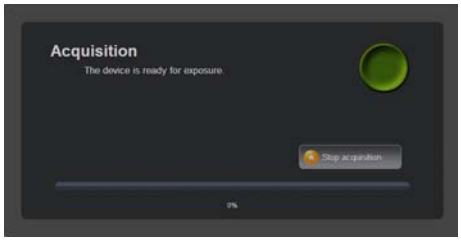
IMPORTANT
The clip must engage into the opening on the secondary diaphragm provided for that purpose.

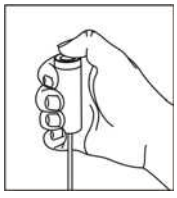
8. Press the R key.
   ↳ The unit moves to its starting position.

9. Call the *"Control exposures"* menu [→ 23].
10. In the structure tree, under *"2D control exposures"*, select the *"Ceph - quality control exposure"* element.
    - In the action area, the menu appears to create the *"Ceph - quality control exposure"*.



11. Click on the *"Start acquisition"* button.
    - Exposure readiness is established. A dialog window displays the status of readiness to exposure.
    - The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.



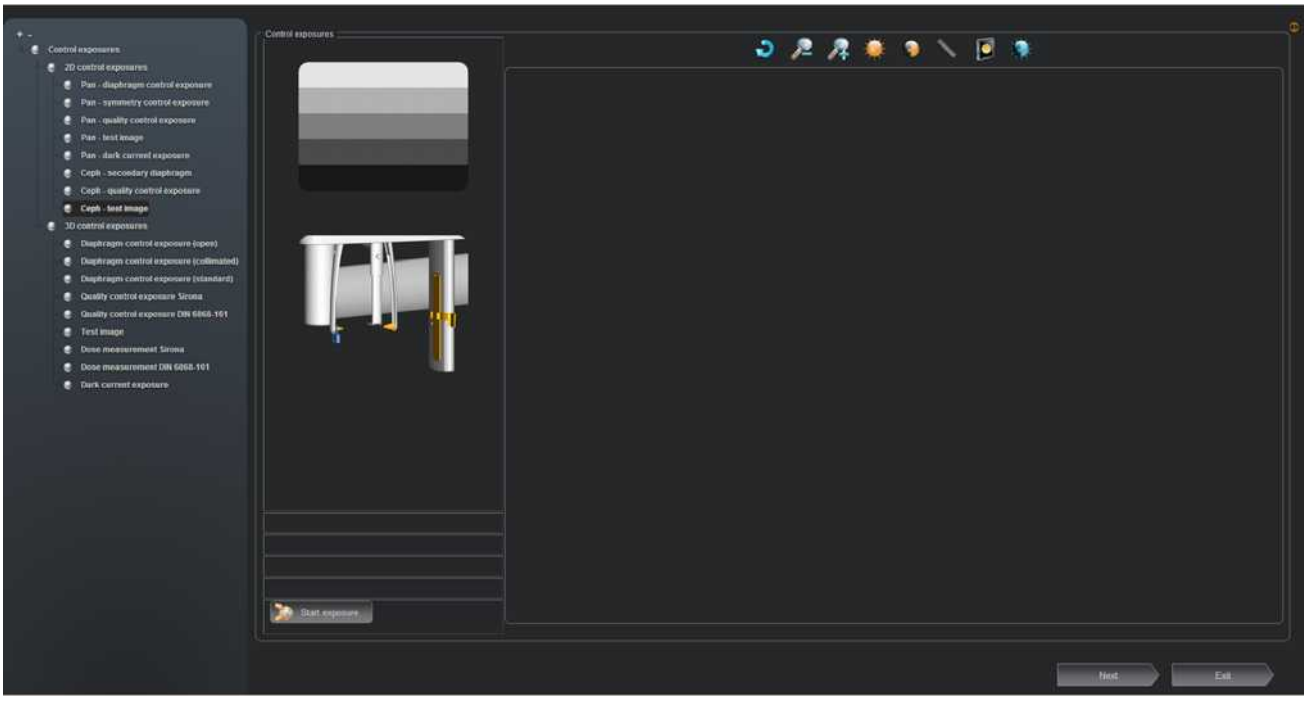


12. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if it has been configured).
    - The exposure is displayed in the exposure window.
      For notes on evaluating the exposure, refer to the technical documentation for acceptance/constancy testing.

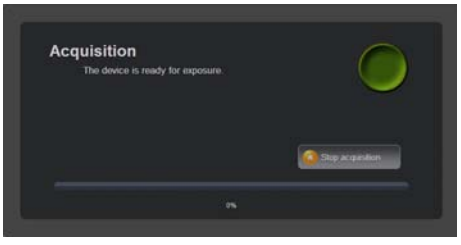
11.2.8 Ceph - test image (2D)

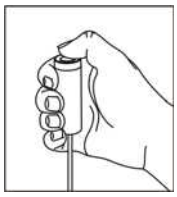
You can use the *"Ceph - test image"* menu to check the 2D data path of the unit and the operability of the Ceph sensor.

1. Call up the menu *"Control exposures"* [→ 23].
2. Select the *"Ceph - test image"* element in the structure tree under *"2D control exposures"*.
   ↳ The menu for creating the test image appears in the action area.

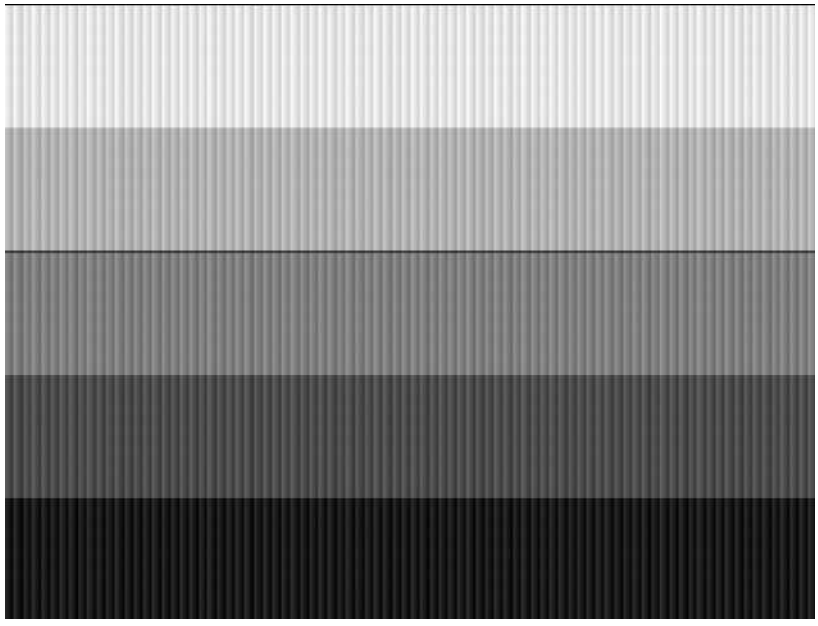


3. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.





4. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   ↳ The exposure is displayed in the exposure window.
   See below for reference image.

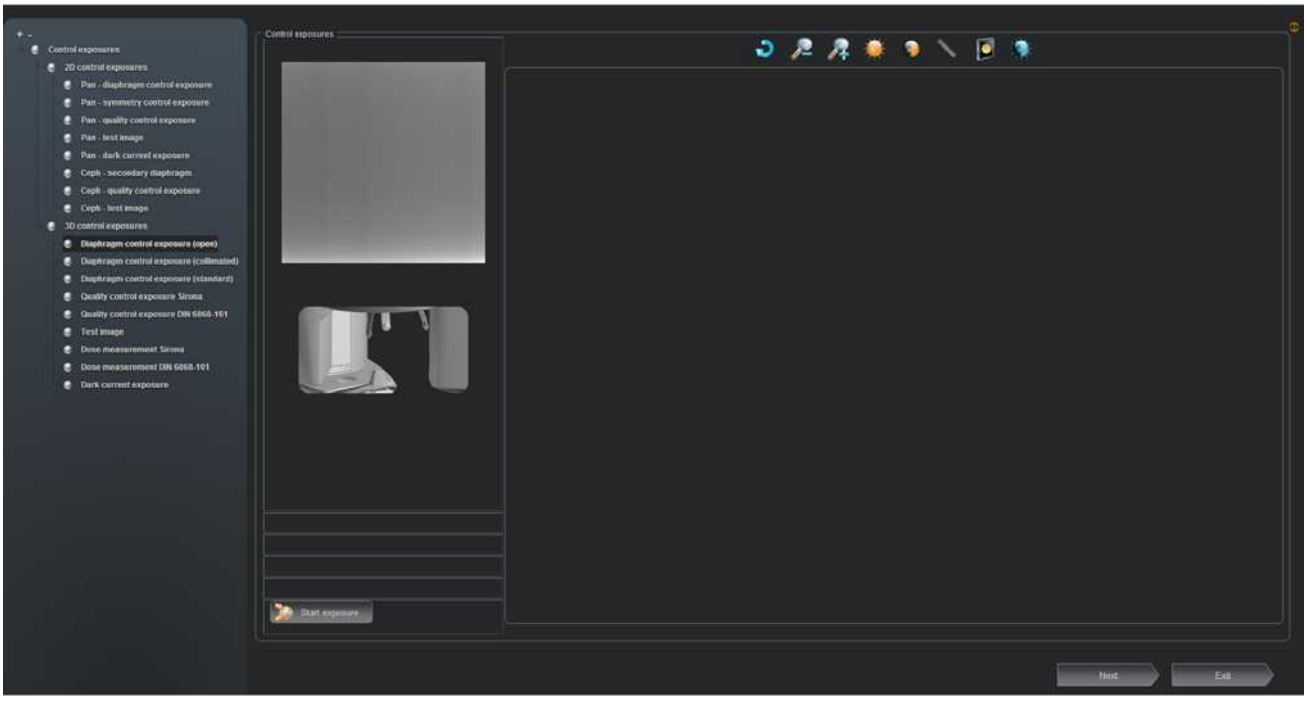


11.3 3D test exposures

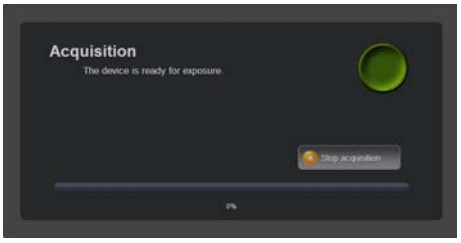
11.3.1 Diaphragm test exposure (open) (3D)

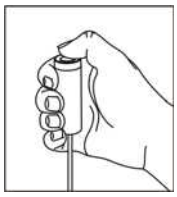
You can use the *"Diaphragm control exposure (open)"* to check the adjustment of the **3D diaphragm for overexposure when the diaphragm is open**.

1. Call up the menu *"Control exposures"* [→ 23].
2. Select the *"Diaphragm control exposure (open)"* element in the structure tree under *"3D control exposures"*.
   ↳ In the action area, the menu appears to create the *"Diaphragm control exposure (open)"*.

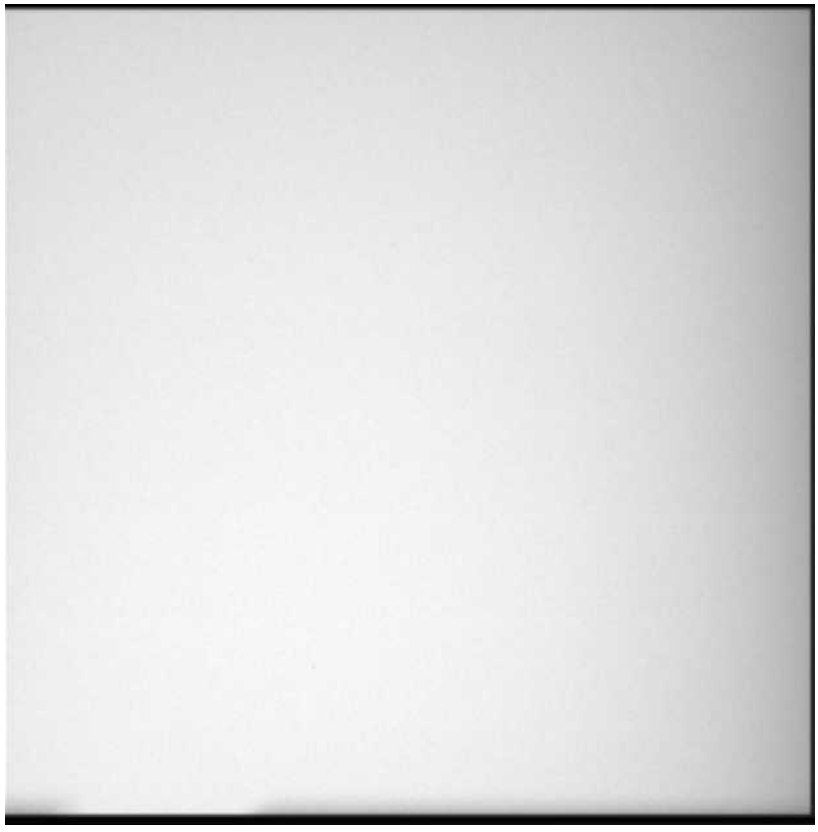


3. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.





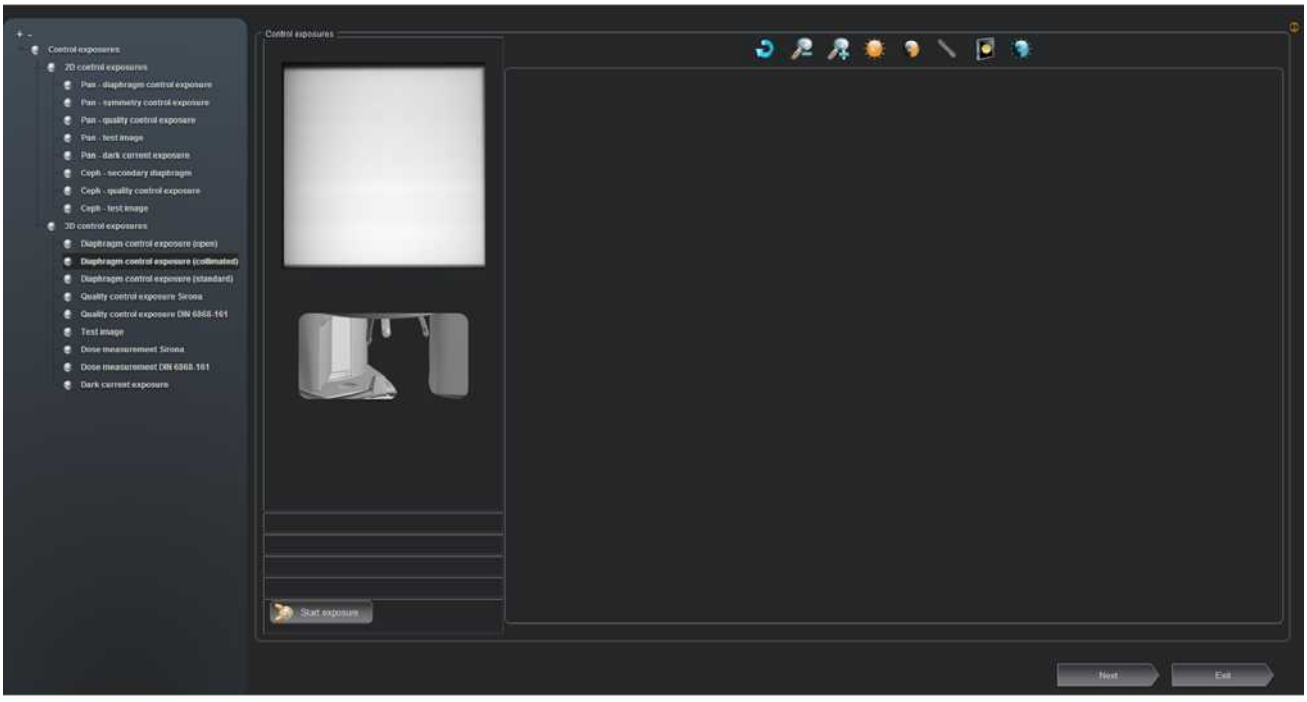
4. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   - The exposure is displayed in the exposure window.
     See below for reference image.
     No foreign bodies may appear on the image.



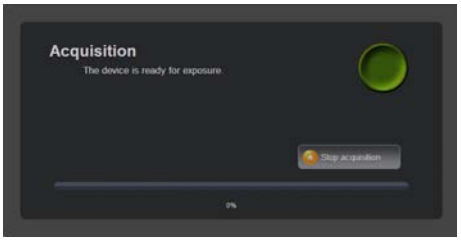
11.3.2 Diaphragm test exposure (collimated) (3D)

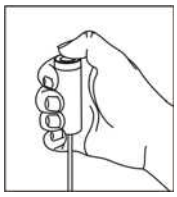
You can use the *"Diaphragm control exposure (collimated)"* to adjust the **Pan diaphragm with reduced diaphragm opening (to check dose waste on all sides)**.

1. Call up the menu *"Control exposures"* [→ 23].
2. Select the *"Diaphragm control exposure (collimated)"* element in the structure tree under *"3D control exposures"*.
   ↳ In the action area, the menu appears to create the *"Diaphragm control exposure (collimated)"*.

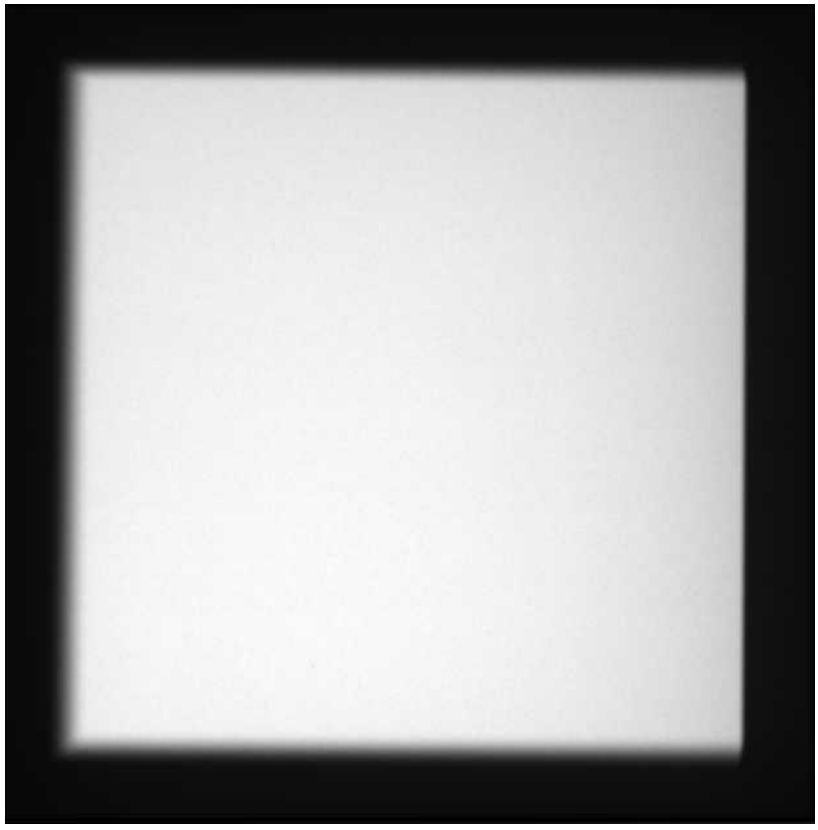


3. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.





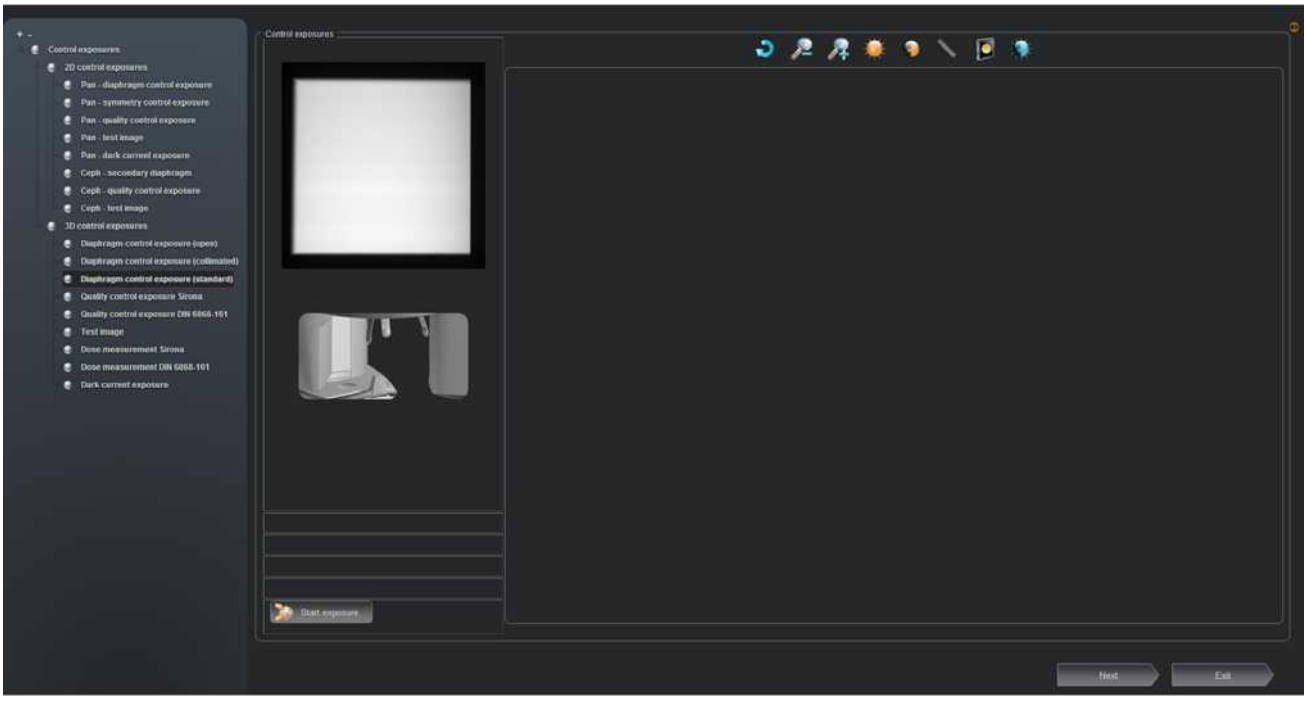
4. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   ↳ The exposure is displayed in the exposure window.
   See below for reference image.



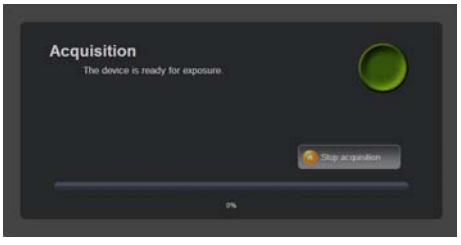
11.3.3 Diaphragm test exposure (standard) (3D)

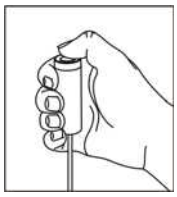
You can use the *"Diaphragm control exposure (standard)"* to check the adjustment of the **original 3D diaphragm to check the circulating edge**.

1. Call up the menu *"Control exposures"* [→ 23].
2. Select the *"Diaphragm control exposure (standard)"* element in the structure tree under *"3D control exposures"*.
   ↳ In the action area, the menu appears to create the *"Diaphragm control exposure (standard)"*.



3. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.



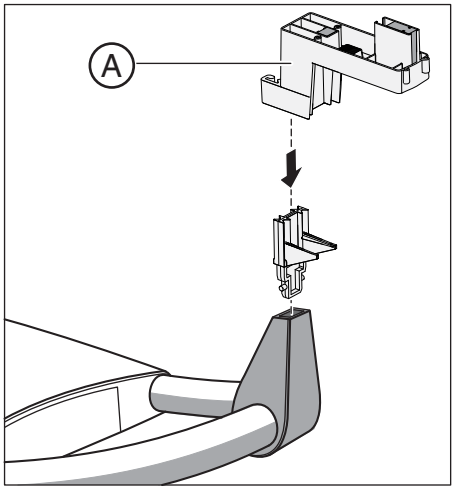


4. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   ↳ The exposure is displayed in the exposure window.
   See below for reference image.

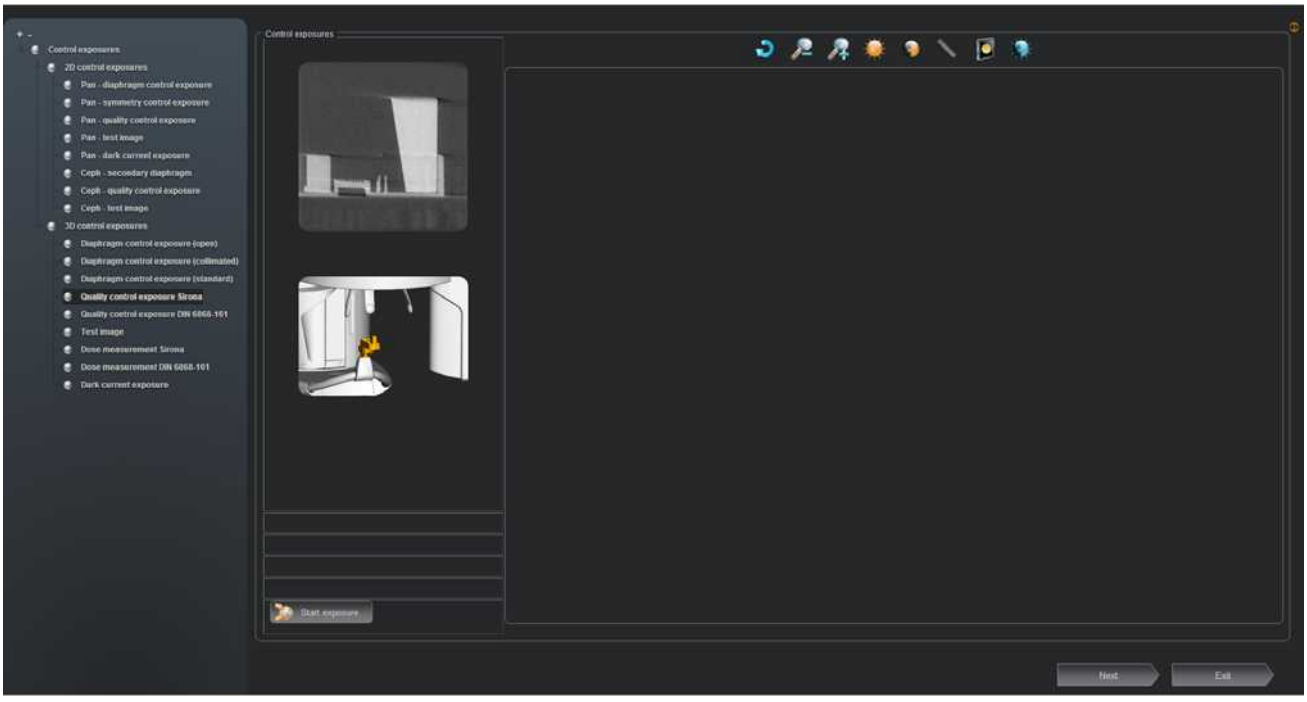
The diaphragm is correctly adjusted if a black surrounding edge can be detected.

11.3.4 Quality test exposure (3D)

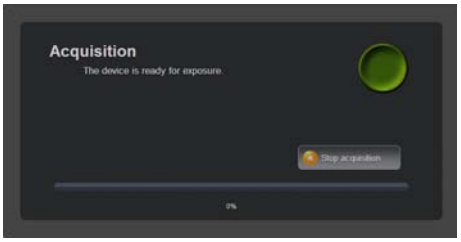
You can use the *"Quality control exposure Sirona"* to create a **volume exposure with a full rotation**. This function enables you to simulate a quality test, for example, in a similar way to an acceptance/constancy test.

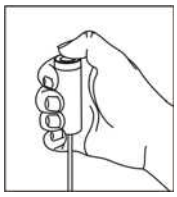


1. Insert the constancy test phantom (A) into the bite block of the unit.
2. Call menu *"Control exposures"* [→ 23].
3. In the structure tree, under *"3D control exposures"*, select the *"Quality control exposure Sirona"* element.
   - ↳ In the action area, the menu appears for creating the *"Quality control exposure Sirona"*.



4. Click on the *"Start acquisition"* button.
   - ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   - ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.



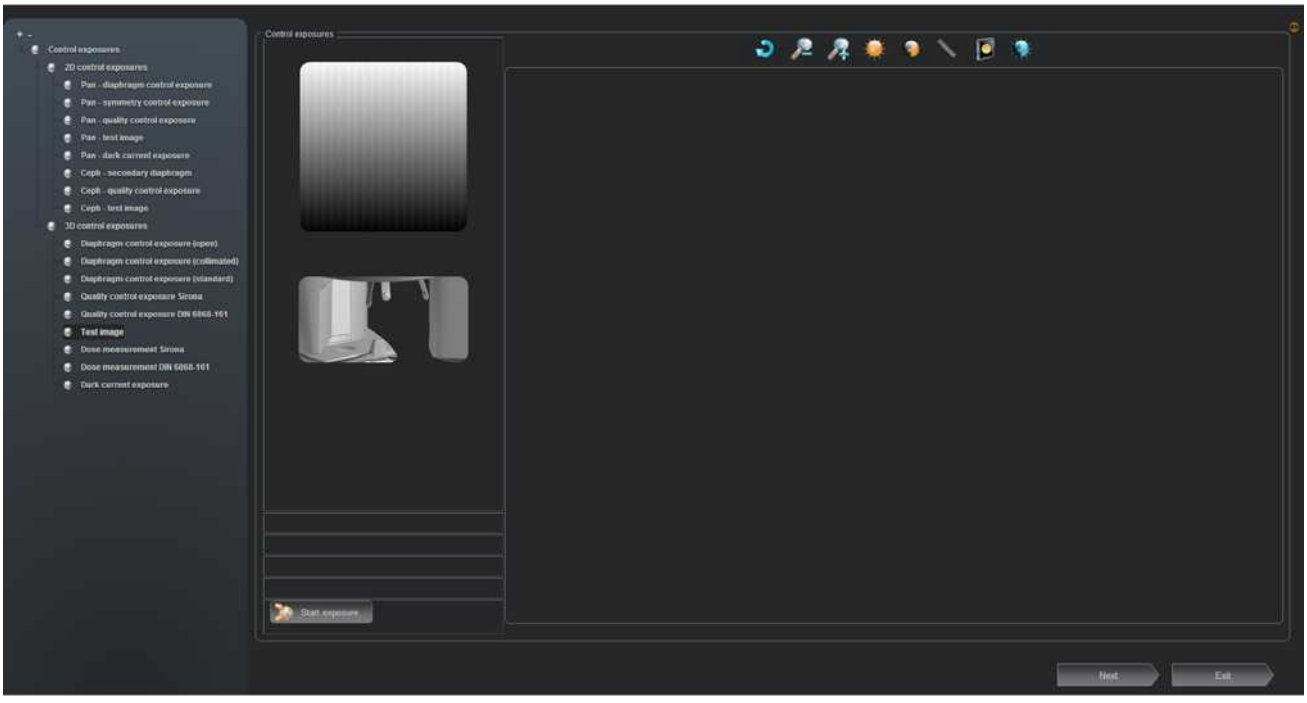


5. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if it has been configured).
   - The exposure is displayed in the exposure window.
     For notes on the evaluation of the exposure, refer to technical documentation for acceptance/constancy testing.
6. Remove the test phantom again.

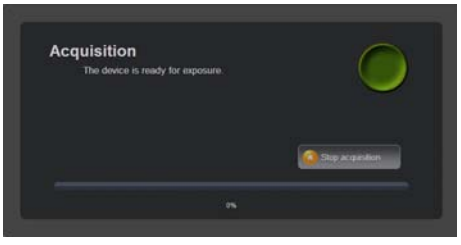
11.3.5 Test image (3D)

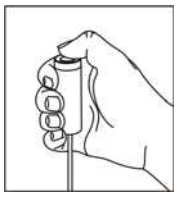
You can use the *"Test image"* menu to check the 3D data path of the unit and the operability of the flat panel detector.

1. Call up the menu *"Control exposures"* [→ 23].
2. Select the *"Test image"* element in the structure tree under *"3D control exposures"*.
   ↳ In the action area, the menu appears to create the *"Test image"*.

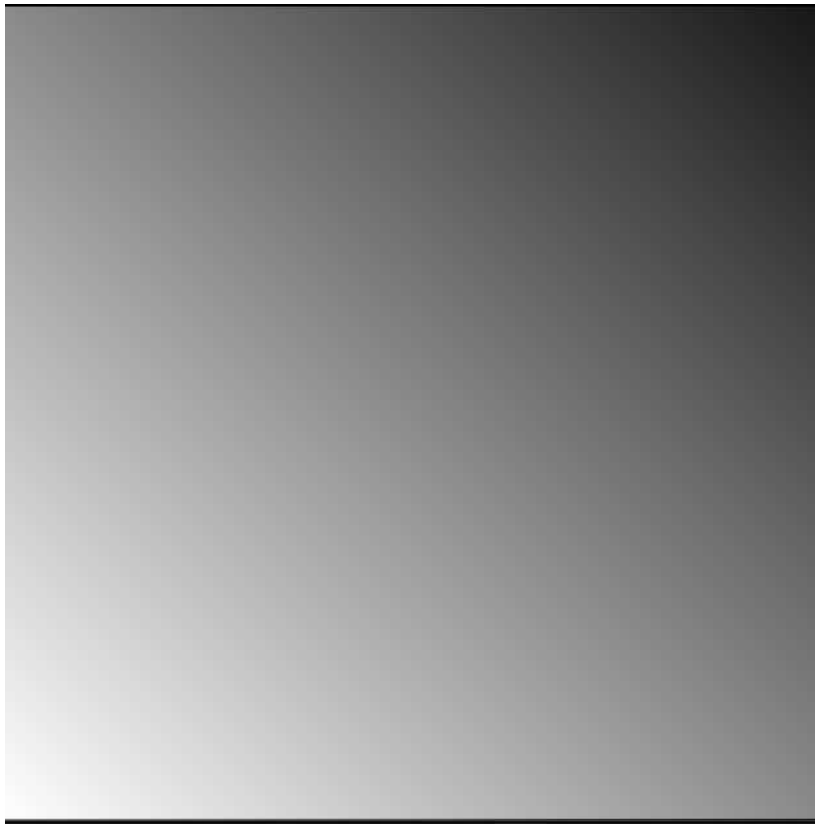


3. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.





4. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
   ↳ The exposure is displayed in the exposure window.
   See below for reference image.

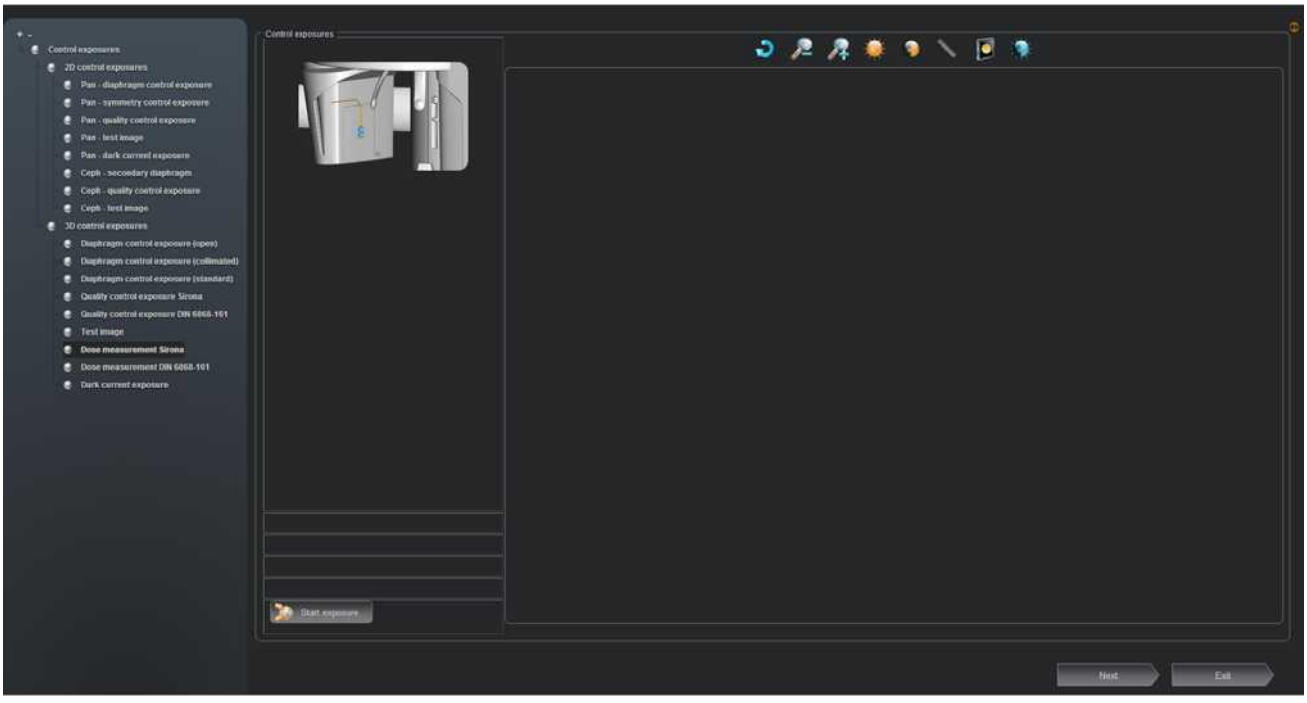


11.3.6 Dosimetry (3D)

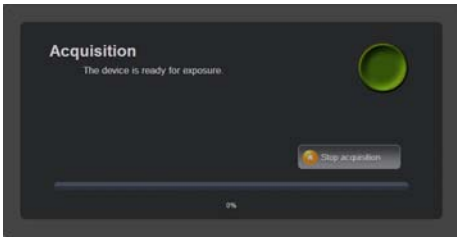
A dosimeter for pulsed radiation (e.g. Mult-O-Meter 512L) is required for dosimetry.

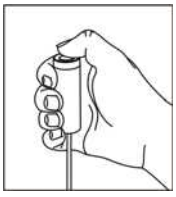
You can use the *"Dose measurement Sirona"* menu to perform dosimetry independently of the unit adjustment or calibration.

1. Attach the Mult-O-Meter sensor in the middle of the sensor unit.
2. Select a program from the 3D program group on the control panel.
   ↳ The unit moves to the 3D exposure position.
3. Call up the menu *"Control exposures"* [→ 23].
4. Select the *"Dose measurement Sirona"* element in the structure tree under *"3D control exposures"*.
   ↳ In the action area, the menu appears to create the *"Dose measurement Sirona"*.



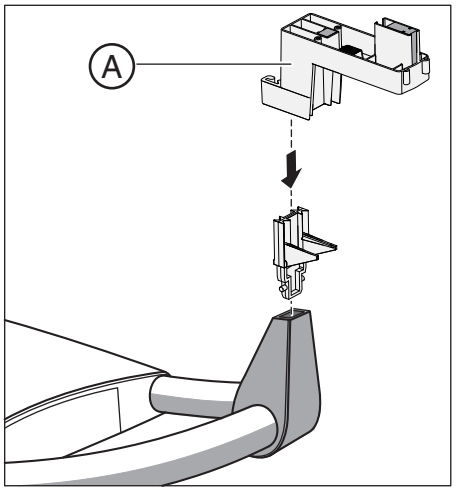
5. Click on the *"Start acquisition"* button.
   ↳ Exposure readiness is established. A dialog window displays the status of readiness to exposure.
   ↳ The service routine used for the corresponding exposure is displayed on the control panel, along with the specific exposure parameters.





6. Press the release button. Press and hold down the button until the exposure is complete, the preview image is displayed in the exposure window, and the acoustic signal that indicates the end of the exposure (double beep) sounds (if configured).
7. Read off the dose from the Mult-O-Meter. The dose value must be between 1.2 and 2.3 mGy.
8. Remove the Mult-O-Meter from the sensor unit again.

11.3.7 Quality control 21CFR 1020.33 (3D)



✓ The Quality Assurance Tool evaluates the performance of ORTHOPHOS SL as per 21CFR1020.33.

✓ The Quality Assurance Tool must be installed on the computer.

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

1. Insert the constancy test phantom (A) into the bite block of the unit.
2. Set the exposure parameters on the Easypad: Program VOL1, HDOFF, front tooth region, Patient 2 (85 kV/ 7 mA)
3. Establish exposure readiness in SIDEXIS (see SIDEXIS 4 Operator´s Manual).
4. **CAUTION! Activating the release button triggers X-rays.**
   Start the exposure by pressing the release button. Hold down the release button until image acquisition is completed and the acoustic signal that indicates the end of the exposure can be heard.
5. Start the Quality Assurance Tool as described in the installation instructions.
6. Select the folder in which the exposure with the constancy test phantom is saved.
7. Adapt the output directory as required.
8. Press Compute to start the performance evaluation.

↳ After the calculation, the quality values noise, contrast scale, MTF10, MTF50, mean CT number, and the modulation transfer function are displayed. Values which breach the limits are displayed in red. The results of the Quality Assurance Tool are saved in the output directory.

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ORTHOPHOS SL / Ceph

Yearly Maintenance Checklist

Customer: _____ Address: _____

Dealer: _____ Address: _____

Date of original installation: _____ Date of inspection: _____

Report of Assembly FD 2579 # _____

SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

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ORTHOPHOS SL / Ceph

Yearly Maintenance Checklist

Customer: _____ Address: _____

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Date of original installation: _____ Date of inspection: _____

Report of Assembly FD 2579 # _____

SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

ORTHOPHOS SL / Ceph

Yearly Maintenance Checklist

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Dealer: _____ Address: _____

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SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

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Yearly Maintenance Checklist

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Date of original installation: _____ Date of inspection: _____

Report of Assembly FD 2579 # _____

SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

ORTHOPHOS SL / Ceph

Yearly Maintenance Checklist

Customer: _____ Address: _____

Dealer: _____ Address: _____

Date of original installation: _____ Date of inspection: _____

Report of Assembly FD 2579 # _____

SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

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ORTHOPHOS SL / Ceph

Yearly Maintenance Checklist

Customer: _____ Address: _____

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Date of original installation: _____ Date of inspection: _____

Report of Assembly FD 2579 # _____

SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

ORTHOPHOS SL / Ceph

Yearly Maintenance Checklist

Customer: _____ Address: _____

Dealer: _____ Address: _____

Date of original installation: _____ Date of inspection: _____

Report of Assembly FD 2579 # _____

SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

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Yearly Maintenance Checklist

Customer: _____ Address: _____

Dealer: _____ Address: _____

Date of original installation: _____ Date of inspection: _____

Report of Assembly FD 2579 # _____

SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

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Yearly Maintenance Checklist

Customer: _____ Address: _____

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Date of original installation: _____ Date of inspection: _____

Report of Assembly FD 2579 # _____

SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

sirona
The Dental Company

ORTHOPHOS SL / Ceph

Yearly Maintenance Checklist

Customer: _____ Address: _____

Dealer: _____ Address: _____

Date of original installation: _____ Date of inspection: _____

Report of Assembly FD 2579 # _____

SCHEDULE	Yes	No	Remarks
All manuals are present	☐	☐	
Test instruments as required	☐	☐	

	Manufacturer	Model	Accuracy	Last calibrated
Voltmeter				
mAmeter				
Dosemeter				

Any mechanical damage noticed	☐	☐	
All labels are present and legible	☐	☐	
All indicator lights are OK	☐	☐	
Radiation indicator **X-ray** lights up, audible buzzer OK	☐	☐	
Deadman feature OK	☐	☐	
Power supply adequate	☐	☐	Line voltage: . . . . . .V Voltage drop: V
kV – Verification is OK	☐	☐	
Tube current is within specified limits	☐	☐	Measurement: . . . . . mA
Specified exposure time, (pulses) OK	☐	☐	Pulse count: . . . . .
X-ray beam position, panoramic OK	☐	☐	
X-ray beam position, ceph OK	☐	☐	
The unit is in compliance with MFG specified tests and safety	☐	☐	
IP-SW Check 21CFR1020.33 is OK	☐	☐	

Technician: Dealer:

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

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