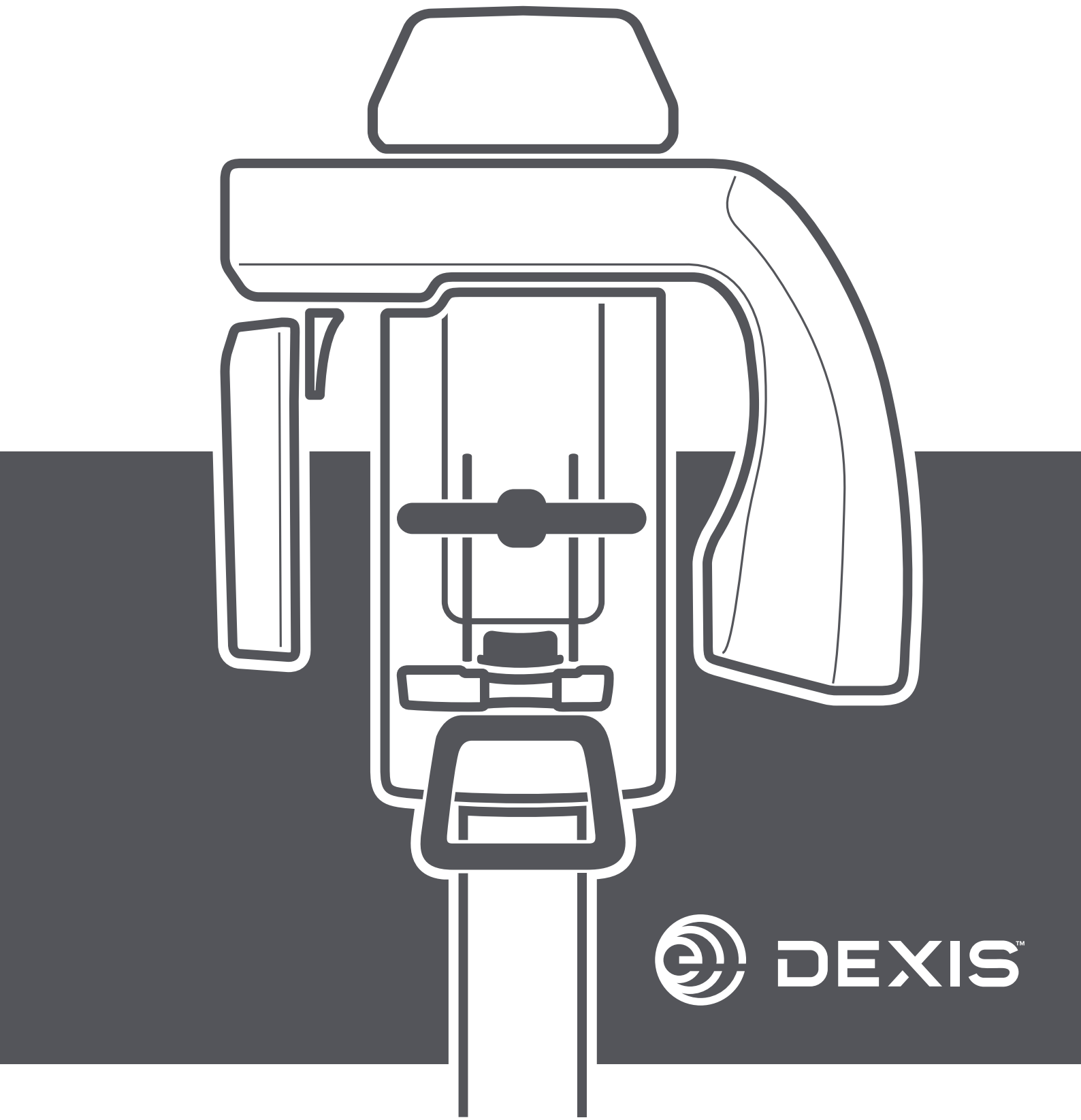
ORTHOPANTOMOGRAPH™ OP 3D EX

Instructions for Use

REF 225433-PTU rev. 10

ENGLISH



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1 Disclaimer and Legal Notices

Instructions for Use, 225433-PTU rev 10, 08-2024.

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www.dexis.com

Download this manual in digital format or order one in printed format for no additional cost from:

http://www.dexis.com

NOTICE! *Make sure to get the manual that applies to your device.*

For service, contact your local distributor.

2 Introduction

2.1 ORTHOPANTOMOGRAPH™ OP 3D™ EX

The ORTHOPANTOMOGRAPH OP 3D EX (later called device) is a dental X-ray device producing high quality digital images of dentition, TM-joints, head and neck area. To take images, you need a suitable workstation connected to the device and a dental imaging software to capture and manage the images.

The device is used as part of digital dental workflow, providing image data to diagnosis and treatment planning for the healthcare professionals. X-ray images reveal the targeted craniofacial anatomy, and condition and the position of anatomical structures inside field-of-view, such as teeth, mandibular joints and oral and nasal cavities. This helps dentists to prepare for various dental procedures such as implant placement, orthodontics and dental prosthetics and make possible to diagnose issues early, which enables early and less invasive treatment.

The device can be used for the following procedures depending on the device configuration and country-specific regulatory approvals:

Panoramic Imaging

- Standard panoramic
- Segmented panoramic
- Pediatric panoramic
- Bitewing
- TMJ, lateral projection

3D CBCT Imaging

- FOV (3D Volume **Height x Diameter** in centimeters)
  - 5 x 5
  - 6 x 9 *
  - 8 x 8
  - 10 x 10 *
  - 10 x 11 *
  - 10 x 15 **
- Resolution
  - Low (using LDT - Low Dose Technology™)
  - Standard
  - High
  - Endo (5 x 5 only)
- Scout images for FOV position and height verification
- Dental cast imaging

* In some countries/areas where 3D volume dimensions are limited by local regulations, FOV sizes 6 x 9 and 10 x 10 and 10 x 11 are replaced with FOV sizes 6 x 8 and 8 x 8.

** Optional FOV size available as separately purchasable feature.

NOTICE! *This manual describes the use of a device with all available functions and so may contain instructions to more functions than what are available with your device configuration.*

To function, the device requires a workstation with a dental imaging software. The device produces X-ray images in the industry standard image formats (e.g. DICOM and JPEG), depending on the dental imaging software used.

Any software used to capture and view X-ray images with the device (e.g. DTX Studio Clinic or a third party dental imaging software supporting TWAIN) must conform to the local regulatory standards, regulations and approval required to place the device on the market. Any workstation used with the device must conform to the connection and hardware requirements presented in chapters Connection requirements on page 10 and Workstation minimum requirements on page 99 as well as the dental imaging software system requirements.

2.2 Intended use and intended purpose

ORTHOPANTOMOGRAPH OP 3D EX is an X-ray device that is intended to be used for imaging of adult and pediatric patients. The device can be configured to take panoramic or 3D images of cranio-maxillofacial complex including the ear, nose and throat (ENT) and airway regions, and cervical spine.

The device is operated and used by qualified healthcare professionals.

2.3 Intended user profile

⚠ ***CAUTION!*** *Only for professionally qualified dental/medical personnel.*

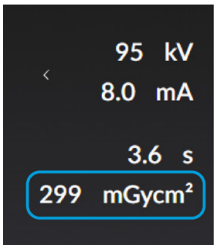
Typical user is a dental assistant with specific training for using dental X-ray devices.

2.4 Radiation guideline

The device produces X-ray beams to produce digital images. Reduce the risk of excessive radiation exposure by following the **As Low As Reasonably Achievable** (ALARA) principle and try to reduce the radiation dose to the level where obtained images are still clinically adequate.

The justification for X-ray exposure and the balance between intensity of radiation exposure and image quality should always be considered.

The X-ray beam intensity is a product of beam quality (kVp), beam quantity (mAs) and the distance between the X-ray tube and the exposed area. The radiation intensity is provided as **Dose Area Product** value (mGycm^2) on the GUI.



NOTICE! *An approximate DAP value is shown during the imaging program selection but the actual radiation dose amount is shown after the exposure.*

2.5 Contraindications

X-rays are known to be potentially harmful and the decision if the risk outweighs the benefit is always done by the professional user. No specific patient selection criteria are identified for this device. No contraindications are identified for this device.

2.6 Associated documentation

- Dental imaging software documentation
- Quick Guide

2.7 Abbreviations

3D	Three Dimensional
PAN	Panoramic
CBCT	Cone Beam Computed Tomography
L	Left
R	Right
H	Head
F	Foot
P	Posterior
A	Anterior
FOV	Field Of View. The cylindrical 3D volume that is reconstructed by the device. The FOV sizes are presented as the **Height x Diameter** of the 3D volume in centimeters.
ROI	Region Of Interest. The anatomical area or region that you are interested to examine.
TMJ	Temporomandibular joint
FH	Frankfort-Horizontal
GUI	Graphical User Interface
DAP	Dose Area Product
LDT	Low Dose Technology™ for low resolution 3D imaging
MAR	Metal Artifact Reduction. Reduces the effect of metal and other dense radiopaque objects, that typically create artifacts which are seen as stripes and shadows.
QC	Quality Control

ALARA	As Low As Reasonably Achievable
MDR	Medical Device Regulation (EU) 2017/745
SSD	Solid State Drive

2.8 Signal words

The following signal words and labels are used in this document:

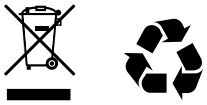
WARNING! *Indicates a hazardous situation which, if not avoided, could result in death or serious injury.*

CAUTION! *Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.*

NOTICE! *Highlights suggestions which will result in enhanced installation, reliability, or operation. Not used for safety related hazards.*

2.9 Disposal and recycling

The device and its components are lead-free, including its radiation protection components. The device meets the RoHS directives 2011/65/EU and EU 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Dispose of the device, accessories and consumables according to local requirements.



At least the following parts of the device should be recycled according to local and national regulations regarding disposal of non-environmentally friendly materials:

- Tubehead (oil)
- All electronic circuits and electronic boards
- Plastic parts

2.10 Warnings and requirements

2.10.1 Warnings and precautions for use

General:

- Before using the device for the first time, familiarize yourself with this manual to ensure the safe use of the device.
- Before using the device for the first time, ensure that it has been set up according to your requirements.
- The device must not be used for screening examinations.
- This device complies with the EMC (Electromagnetic Compatibility) according to IEC 60601-1-2. Radio transmitting equipment, cellular phones etc. **shall not be used** in proximity of the device as they could influence the performance of the device.

- Switch the device off after use.
- Do not move the upper shelf of the device by hand as it may hit a wall or cause the device to go to an error state.
- Report any incident, related to use of this device, having a serious effect on the health of a patient, user or other person to the manufacturer and to the local competent authority.
- **USA only:** Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.

Patient positioning accessories:

- ⚠ ***CAUTION!*** *Bite block and ear rods must always be used with new disposable covers and the patient contacting parts decontaminated according to guidance in chapter* *Cleaning and decontamination on page 68* *to prevent cross contamination.*
- Clean the patient positioning accessories before their first use.
- If patient positioning accessories show any signs of deterioration, replace them before use.

X-ray imaging:

- ⚠ ***CAUTION!*** *Make sure that the patient positioning is done correctly before you take X-ray images to decrease the risk of retakes.*
- ⚠ ***CAUTION!*** *When you take 3D X-ray images, take a scout image to make sure that the ROI is set correctly to decrease the risk of retakes.*
- When you take an X-ray image, protect yourself from radiation or stay at least 3 meters (9.8 ft) away from the device.
- Make sure that you can see and hear the patient during the imaging process, while also maintaining visibility to the GUI.
- Instruct the patient to stay still for the duration of the exposure to decrease the risk of retakes.
- When you take X-ray images of pediatric patients, use the pediatric imaging programs and where feasible, adjust the radiation field size.
- When you take X-ray images of patients who are feeling insecure or have unusual anatomy (typically very tall or large patient), use the **Test**-mode first to demonstrate the device movements and to make sure that the rotator does not collide with the patient.
- If the patient is using a pacemaker, consult the manufacturer of the pacemaker before you take an X-ray image to make sure that the device will not interfere with the operation of the pacemaker.
- Avoid taking X-ray images of pregnant women.
- Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, the imaging should be done using conventional medical computed tomography or magnetic resonance, rather than 3D imaging using Cone Beam technology.

2.10.2 Connection requirements

2.10.2.1 Electrical connection requirements

ⓘ ***NOTICE!*** *Always follow local and national requirements regarding the connection of medical systems.*

- The device must be connected to a dedicated mains power outlet with protective earth. The workstation and any other external devices must NOT be connected to the same outlet as the device.
- The workstation and any other external device(s) connected to the device must meet the **IEC 62368-1 (previously IEC 60950)** standard (minimum requirements). Devices that do not meet these requirements must not be connected to the device as they may pose a threat to the operational safety.
- Electronic equipment (workstation, network connecting devices etc.) that **do not** fulfill medical safety standard **IEC 60601-1** must be located outside of the patient environment, at least 1.5 m from the device.
- The workstation and any other external devices must be connected to the device in accordance with IEC 60601-1.
- Additional multiple socket-outlets or extension cords shall not be connected to the system.

2.10.2.2 Network requirements

NOTICE! *The workstation firewall or anti-virus software may cause unexpected issues to IP traffic and system performance.*

- 1Gbit network connection between the device and the acquisition workstation is required for the device to be used. If the network is interrupted during the imaging process, the image data is saved to the device memory and is transferred to the acquisition workstation automatically after the connection is re-established.
- If device is connected to the IT-network, it is the responsibility of the IT-network organization to evaluate that 1Gbit Ethernet connection between device and acquisition workstation is adequate and no disturbance or high traffic peaks exist from other applications during image transfer. Other methods in IT-infrastructure like Virtual LAN (VLAN) configuration between acquisition workstation and device can be also used to secure bandwidth for image transfer.

NOTICE! *See also requirements listed in Cybersecurity guidelines and requirements on page 11.*

2.10.3 Cybersecurity guidelines and requirements

Protection against cybersecurity threats is a shared responsibility between the imaging device manufacturer and the healthcare provider. The imaging device manufacturer has taken precautions to make sure that the imaging system is protected against such threats.

However, **the protection of any networked system is always the responsibility of the healthcare provider**. It is highly recommended to have a qualified IT security professional check and maintain the office network system for proper protection against viruses, malware, and intrusions. It is recommended to always have active and up-to-date **antivirus** and **anti-malware** software, together with a correctly configured **firewall**, installed on the workstation where the image viewing and image acquisition software are used.

Failure to maintain cybersecurity can result in compromised imaging device functionality, loss of data (PHI or PII) availability or integrity, or exposure of other connected devices or networks to security threats.

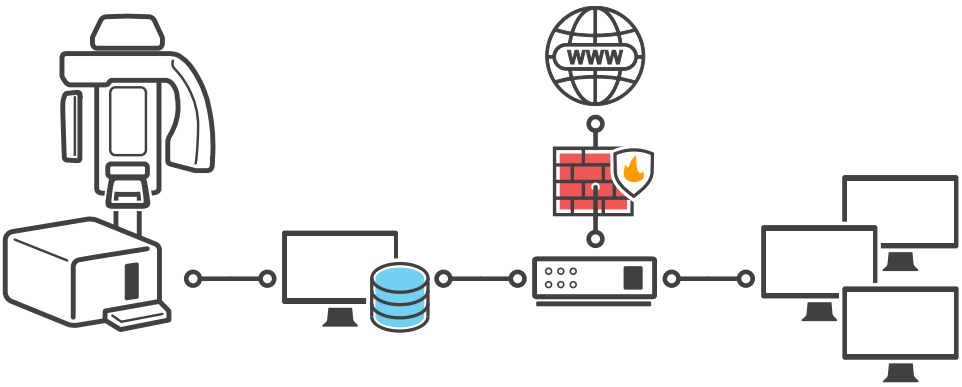
NOTICE! *Report any cybersecurity incident related to the use of the device to the manufacturer.*

Operating environment:

To function, the device requires a workstation with a dental imaging software. The device produces X-ray images in the industry standard image formats (e.g. DICOM and JPEG), depending on the dental imaging software used.

Any software used to capture and view X-ray images with the device (e.g. DTX Studio Clinic or a third party dental imaging software supporting TWAIN) must conform to the local regulatory standards, regulations and approval required to place the device on the market.

Any workstation used with the device must conform the **workstation minimum requirements** presented in the device documentation as well as the dental imaging software system requirements.



Example of system network infrastructure and security

Instructions for security configurations:

Authentication and authorization

- Take precautions to ensure unauthorized personnel cannot access the patient data or manipulate the image data on the PC workstation or the imaging device.
- Ensure the office network is protected from unauthorized access and separated from a guest network, if provided.
- Access to all workstations should be protected with strong passwords.
- Do not use default passwords in network equipment.
- Do not share or reuse passwords.
- Use individual user accounts for all authorized personnel.

Personal identifiable information

- Do not include PII (personally identifiable information) in computer host names.
- Do not include PII in Windows user account names.

Backup

- A suitable backup system is recommended to safeguard user-created data. Backup of user-created data is solely the responsibility of the healthcare provider.

Network

- The imaging device must be connected to a private, firewall-protected local area network to ensure proper security and protect against unauthorized access. All connections from outside the local area network to the imaging device must be blocked and unused ports in the firewall must be closed. Connections between the imaging device and workstation within the local area network must be allowed.

  NOTICE! *More detailed information on the firewall configuration is provided in DTX STUDIO™ DRIVER & DEXIS™ CONNECT software documentation.*
- Connecting the imaging device to a local area network that includes other equipment or modifying the local area network may cause unidentified safety or security risks to patients or operators. The IT organization or service provider is responsible for identifying, analyzing, evaluating, and controlling potential risks.
- Network equipment used in the local area network, including firewalls, must never use default passwords. Wireless communication (Wi-Fi), if used, must use strong encryption and be protected with a strong password.

Antivirus

- All workstations connected to the local area network should have active and up-to-date anti-virus software installed.
- The workstations connected to the imaging device must use anti-virus software and have individual password protected user accounts to prevent unauthorized access to patient data.

Software updates and decommissioning

- The workstation operating system and all software should be kept up-to-date with the latest updates. Failure to keep the operating system and software up-to-date may lead to unauthorized access. Only trained and authorized service personnel may install and service the imaging device and related software. Contact the manufacturer's representative for software updates.
- Decommissioning instructions are provided separately in the device and software documentation.

2.10.4 Device modification

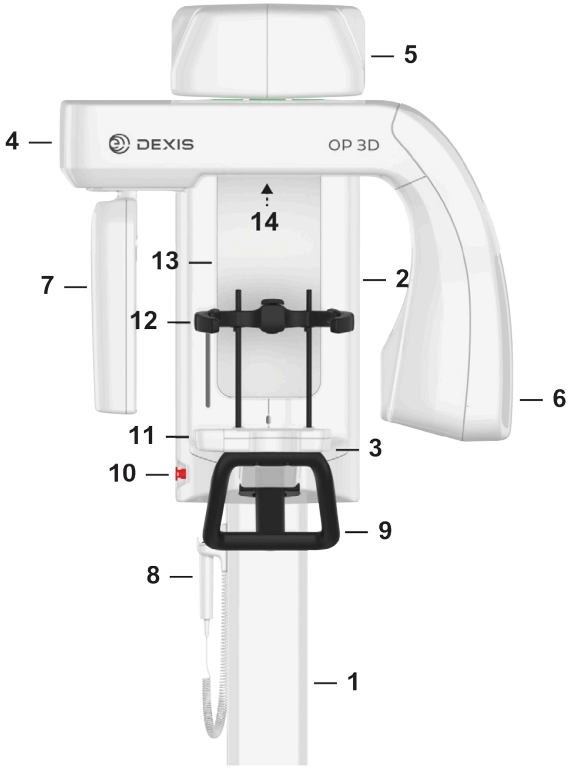
⚠ ***CAUTION!*** *The device does not contain user serviceable parts. Only authorized service technicians are allowed to service, install and replace parts of the device.*

⚠ ***CAUTION!*** *Only approved spare parts supplied by the manufacturer are allowed to be used in device service.*

- Never make unauthorized changes or modifications to the device or any of its parts.
- Never remove or re-manufacture any part of the tubehead assembly or beam limiting devices.
- Never adjust any part of the beam limiting devices unless under the direction of the manufacturer.
- All required information on the device service and part replacement is found in the Service Manual, which is available for authorized service technicians.
- Connect only items that have been specified as part of the ME system or specified as being compatible with ME system by the manufacturer of the device.

3 Overview

3.1 Main parts of the device



1. Column

2. Carriage

3. Lower shelf

4. Rotator

5. Upper shelf

6. PAN/3D Tubehead

7. X-ray sensor

8. Exposure switch

9. Patient handles

10. Emergency stop switch

11. Control panel

12. Head support

13. Mirror

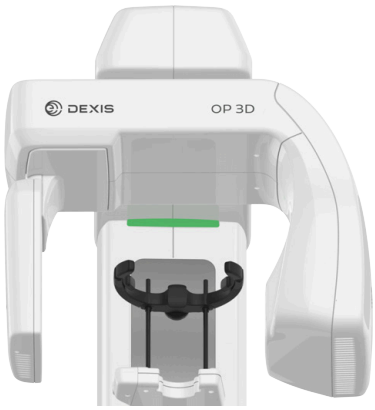
14. Status indication light

3.2 Exposure switch

The imaging programs and most of the device functions are done by pressing and holding down the exposure button. The device is supplied with a hand-held exposure switch that is used near the device. A remote exposure switch (separately available) can be used to operate the device from outside the patient area.

3.3 Status indicator light

Device status indicator light, located on the top of the carriage, illuminates according the device status:



- **GREEN**: Device is ready for imaging.
- **YELLOW**: Device is generating X-rays.
- **BLUE**: Device is in error state or pending user action. Check the GUI for details.

3.4 Patient positioning lights

NOTICE! *Appropriate lights are turned on automatically, based on the selected modality, program and FOV.*

3.4.1 Positioning light locations

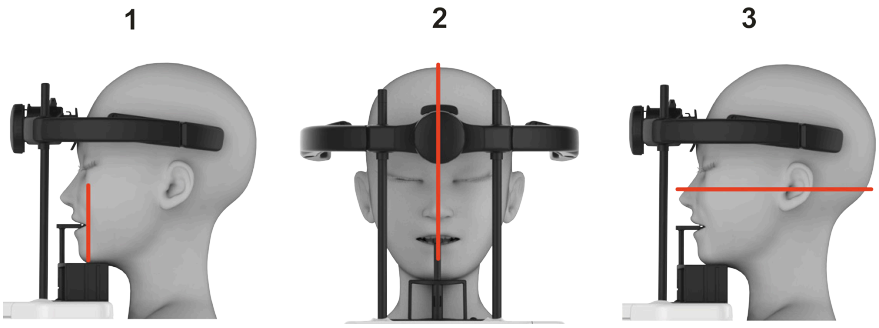
1. Tilt light

2. Midsagittal light

3. Horizontal light; top of FOV / FH light

4. Horizontal light; bottom of FOV

3.4.2 Panoramic lights



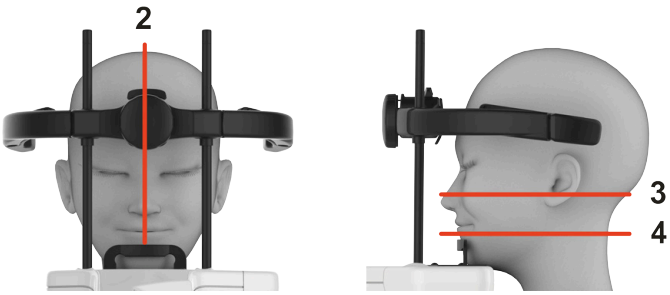
1 - Tilt light

2 - Midsagittal light

3 - FH (Frankfort-Horizontal) light

NOTICE! *The position of FH light is automatically adjusted according to the selected imaging program.*

3.4.3 3D lights



2 - Midsagittal light

3 - Horizontal light, top of FOV

4 - Horizontal light, bottom of FOV

NOTICE! *The position of the top of FOV light is automatically adjusted according to the selected FOV.*

3.5 Patient positioning accessories

Chin rest

Flat chin rest (available separately)

Bite block

Lip support

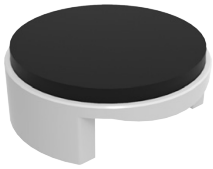
Head support

Disposable covers for patient positioning accessories:

- Disposable covers for bite block
- Disposable covers for lip support
- Disposable covers for chin rest

3.6 Other detachable parts

DENTAL CAST IMAGING TOOLS (AVAILABLE SEPARATELY):



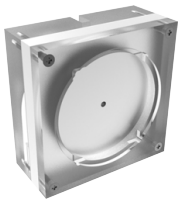
Dental cast holder

3D QUALITY CONTROL TOOLS:

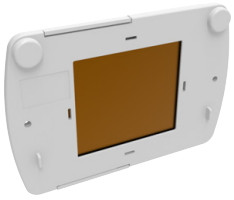
3D QC phantom

3D QC phantom holder

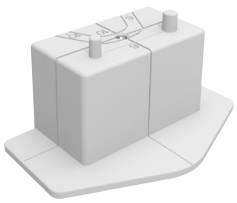
2D QUALITY CONTROL TOOLS (AVAILABLE SEPARATELY):



2D QC test phantom



Copper filter - 0.8 mm/1.8 mm



PAN QC phantom holder

CALIBRATION TOOLS:

Geometry calibration phantom

3.7 Emergency stop switch

An emergency stop switch is located on the left side of the carriage.

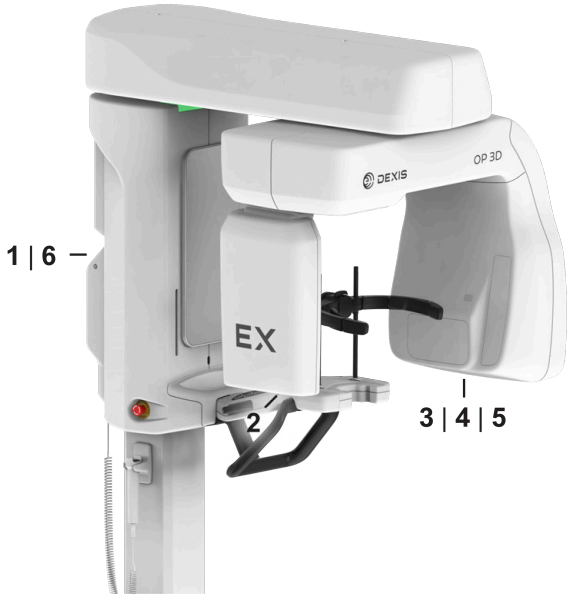
- Pressing the emergency stop switch immediately terminates the imaging and all device movements.
- To release the emergency stop switch, rotate it clockwise.
- The Graphical User Interface (GUI) has indication if the emergency stop is active and the device status indication lights are blue.

NOTICE! *An interrupted imaging process cannot be resumed. A new image needs to be taken.*

NOTICE! *Make sure that the emergency stop switch is not pressed down when you start the imaging process.*

NOTICE! *Activating the emergency stop causes the device to restart.*

3.8 Device label locations



1. Type label

2. Sensor label

3. Tubehead label

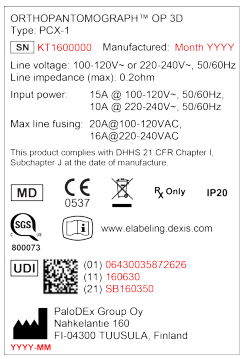
4. PAN/3D collimator label

5. Filtration label

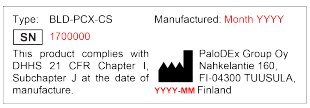
6. Warning label

Example illustrations of the device labels:

Device type label


ORTHOPANTOMOGRAPH™ OP 3D
Type: PCX-1
SN KT1600000 Manufactured: Month YYYY
Line voltage: 100-120V~ or 220-240V~, 50/60Hz
Line impedance (max): 0.2ohm
Input power: 15A @ 100-120V~, 50/60Hz, 10A @ 220-240V~, 50/60Hz
Max line fusing: 20A@100-120VAC, 16A@220-240VAC
This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture.
MD CE 0537 Rx Only IP20
800073
www.elabeling.dexis.com
UDI (01) 06430035872626 (11) 160630 (21) SB160350
PaloDEx Group Oy Nahkelantie 160 FI-04300 TUUSULA, Finland
YYYY-MM

Serial number labels


Type: BLD-PCX-CS Manufactured: Month YYYY
SN 1700000
This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture.
PaloDEx Group Oy Nahkelantie 160, FI-04300 TUUSULA, Finland
YYYY-MM

NOTICE! *These labels are for illustrative purposes only. Texts and images may vary.*

4 User interfaces

4.1 Graphical User Interface (GUI)

4.1.1 Overview

1. Patient name and identification.
2. Selection of imaging modality, **PAN**, **3D** or **CAST**.

   NOTICE! *The available imaging modalities vary depending on the device configuration.*
3. Selection of imaging program and imaging program settings.
4. Main view area. Shows a dental chart for the selected modality and previews of the taken images.
5. Selection of imaging parameters; kV and mA. These can be manually adjusted according to the patient size and skull anatomy if needed.
6. Exposure time and DAP estimation. Shows the estimated duration of X-ray radiation and the radiation dose with the selected imaging program and parameters. The actual imaging parameters and DAP are shown after imaging.
7. Sample image of the selected program or 3D FOV size and location illustration.
8. Status message bar and device status indicator.
9. Device settings and friendly name of the device. Pressing the cogwheel symbol opens a menu which is used to access the device settings, quality control and calibration programs and to show the device information, like serial number and software versions.

BASIC USE OF THE GUI:

Press on an icon to activate/inactivate imaging program or setting. Active selections are indicated with **GREEN** colour. Inactive selections are indicated with **GRAY** colour.

COMMON IMAGING PROGRAM SETTINGS:

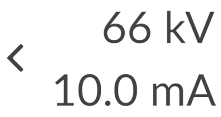
Test mode

Indicates if **Test** mode is active. Test mode disables device radiation production.

Test mode can be used for example to demonstrate the device movements.

You can also use the control panel to enable/disable the Test mode.

Imaging parameters



Indicates the currently selected kV and mA values. By default the selection is based on the imaging program and patient size selections.

- Press the Imaging parameters to open an adjustment menu.

- If needed, adjust the kV and mA values manually with the + and - buttons

STATUS MESSAGE BAR:

Message bar

The message bar provides messages and guidance to the user. Press on the bar to show messages if there are more than the ones shown.

Device status indicator

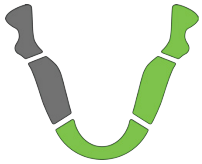
Status message bar shows the device status with a colored Device status indicator.

- **GREEN**: Device is ready for imaging.
- **GRAY**: Device is not ready for imaging, follow the instructions on the status message bar.
- **YELLOW**: Device is generating X-rays.
- **BLUE**: Device is in error state or pending user action. Details are shown on the status message bar.

4.1.2 Panoramic imaging

4.1.2.1 Panoramic imaging program settings

ORTHOselect™ panoramic dental chart



Dental chart shows which segments of the dentition are imaged with the selected imaging program.

You can also manually select which segments of the dentition are imaged. Press the segments to select (green) and deselect (gray) them.

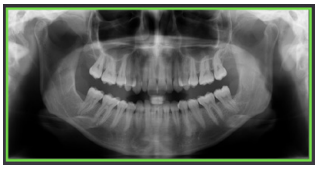
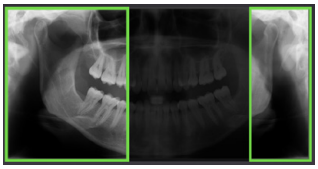
Panoramic imaging programs

Indicates which imaging program is selected.

Press the imaging program icons to change the active imaging program;

Standard Panoramic	Pediatric Panoramic	Bitewing	TMJ, lateral
			

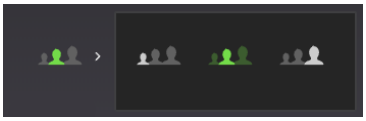
A sample image for the selected imaging program is shown on the GUI. If you take a segmented image, the unselected segments are grayed out in the sample image.

Standard Panoramic	Segmented Panoramic
	

Patient size

Indicates the currently selected patient size preset.

- Press the Patient size selection icon to open a list of patient sizes;



Small	Medium	Large
		

- Press on the patient size icon to activate the preset.

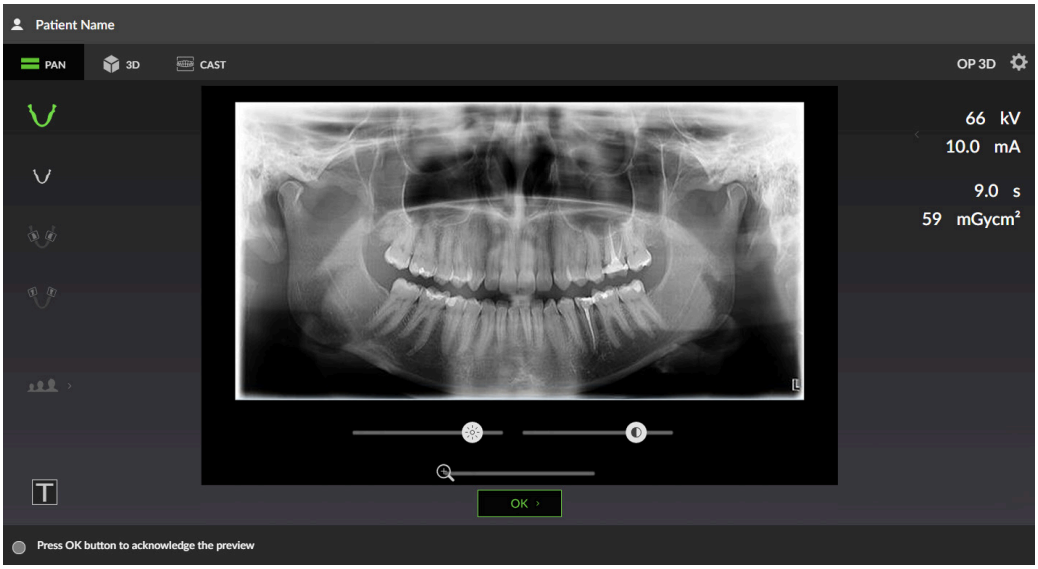
Select the patient size preset according to the patient to adjust the kV and mA to preset levels.

NOTICE! *Patient size presets can be adjusted from device settings.*

4.1.2.2 Panoramic image preview

QUICKcompose™ low resolution image preview is shown on the GUI after the image has been taken.

NOTICE! *Adjustments done in the preview are not saved to the image.*



Zoom slider

You can zoom the preview image in/out using the zoom slider.

While zoomed in, you can click and drag to scroll the image.

Brightness slider

You can adjust the brightness of the shown preview image using the brightness slider.

Contrast slider

You can adjust the contrast of the shown preview image using the contrast slider.

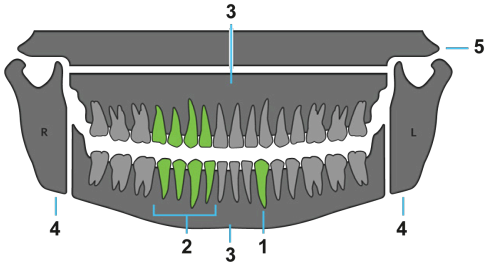
OK button

Press **OK** button to close the image preview.

4.1.3 3D imaging

4.1.3.1 3D imaging program settings

ORTHOselect™ dental chart

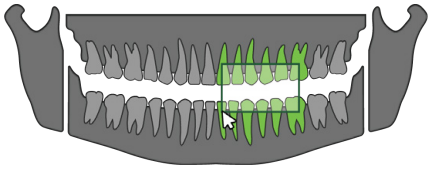


Dental chart is used to select the Region of Interest (ROI) for the 3D scan. The FOV changes automatically according to the selections made in the dental chart.

- To select the studied parts of dentition, click teeth, jaw and TMJ icons:
  - A single tooth (**1**)
  - Range of teeth (**2**).
  - Jaw with all teeth (**3**)
  - TMJ (**4**)
  - Maxillary Sinus (**5**)
  - Whole dentition

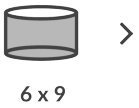
  NOTICE! *Both TMJs are selectable only if 10 x 15 FOV size is available.*

- To easily select multiple teeth (**2**) click and drag cursor to select all teeth icons within the area.



- To select **all parts of the dentition**, click **Select all** under the dental chart.
- To **clear all selections**, click **Clear Selection** under the dental chart.

FOV size



Indicates the currently selected FOV size (H x D).

The FOV changes automatically according to the selections made in the dental chart but can be changed manually also:

- Press the FOV size icon to open a list of the available 3D FOV sizes.

- Press on the listed FOV size icon to activate it.

The GUI illustrates an approximate coverage of the selected FOV.

NOTICE! *Use the ORTHOselect™ dental chart as primary method for FOV size selection.*

NOTICE! *The list of available FOV sizes depend on the device configuration and country specification.*

Image resolution

Indicates the currently selected resolution. The resolution affects the image quality and radiation dose to the patient.

- Press the image resolution selection icon to open a list of available image resolutions;

Low	Standard	High	Endo
L	S	H	E

- Press on the listed resolution icon to activate it.

For recommendations on resolution selection, see chapter 3D Resolutions on page 52.

NOTICE! *Endo resolution is available only for 5 x 5 FOV.*

Scout image program

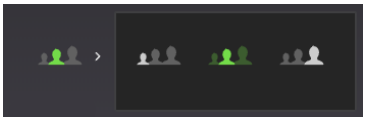
A Scout image is taken to verify and perform adjustment to the FOV position and height before initiating a full 3D scan. By default, the Scout image is always active when taking 3D images.

When the Scout image program is active, the FOV coverage illustration turns **green**.

Patient size

Indicates the currently selected patient size preset.

- Press the Patient size selection icon to open a list of patient sizes;



Small **Medium** **Large**

- Press on the patient size icon to activate the preset.

Select the patient size preset according to the patient to adjust the kV and mA to preset levels.

NOTICE! *Patient size presets can be adjusted from device settings.*

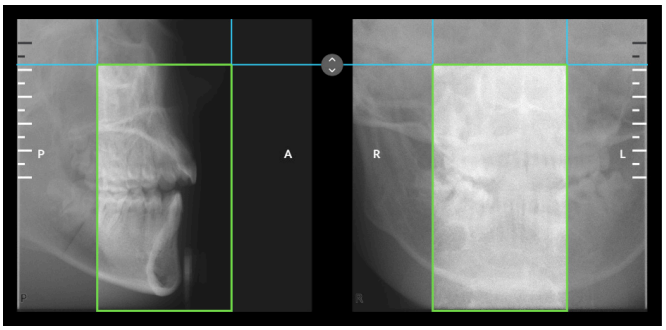
4.1.3.2 3D scout image

SMARTVIEW™ 2.0 scout image is shown on the GUI after the scout image has been taken. In this view you can fine-tune the FOV (green area) size and position for the actual 3D image.

FOV height adjustment

You can adjust the height of the FOV by sliding the height adjustment icon up or down.

The range how much FOV height can be adjusted is shown with the white marks on the image. The FOV size indicator shows the updated FOV size.



9 x 5

It's recommended to adjust the FOV size so that the **ROI is in the middle of the volume**.

FOV position adjustment

You can adjust the position of the FOV by clicking the Left / Right buttons.

- The buttons under the left projection adjust the FOV position in Posterior (**P**) - Anterior (**A**) direction.
- The buttons under the right projection adjust the FOV position in Left (**L**) - Right (**R**) direction.

You can also click and drag the images sideways to adjust the FOV position.

It's recommended to adjust the FOV location so that the **ROI is in the middle of the volume**.

NOTICE! *FOV position adjustment range varies between different FOV size selections.*

Brightness slider

You can adjust the brightness of the shown image preview using the brightness slider.

NOTICE! *Adjustment is not saved to the image.*

Contrast slider

You can adjust the contrast of the shown image preview using the contrast slider.

NOTICE! *Adjustment is not saved to the image.*

OK button

Press OK button to approve the changes made to the FOV location and size using the Scout image and to proceed to the 3D exposure.

4.1.3.3 3D image preview

QUICKcompose™ low resolution image preview is shown on the GUI after the image has been taken.

NOTICE! *Adjustments done in the preview are not saved to the image.*

NOTICE! *The image has indications from which direction the image is shown;* ***A/P*** *(Anterior/Posterior),* ***L/R*** *(Left/Right) and* ***H/F*** *(Head/Foot).*

Slice preview projection

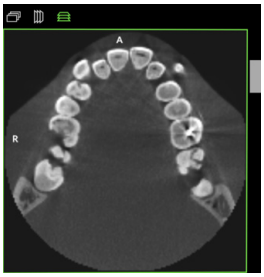
Indicates which preview projection is selected.

3D preview image is shown as a slice preview (left) and a rendered volume (right) on the GUI.

Press the preview projection icons to change the projection of the shown preview.

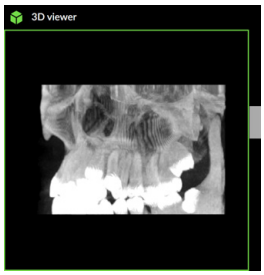
Coronal	Sagittal	Axial
		

Slice preview



Shows a preview of 3D slices. You can scroll through the preview using the slider on the right side of the image.

Volume preview



Shows a preview of the 3D volume. You can rotate the preview using the slider on the right side of the image.

Brightness slider

You can adjust the brightness of the shown image preview using the brightness slider.

NOTICE! *Adjustment is not saved to the image.*

Contrast slider

You can adjust the contrast of the shown image preview using the contrast slider.

NOTICE! *Adjustment is not saved to the image.*

OK button

Press OK button to close the image preview.

4.1.4 Dental cast view

NOTICE! *This is an optional, separately activated imaging modality.*

4.1.4.1 Dental cast program selection

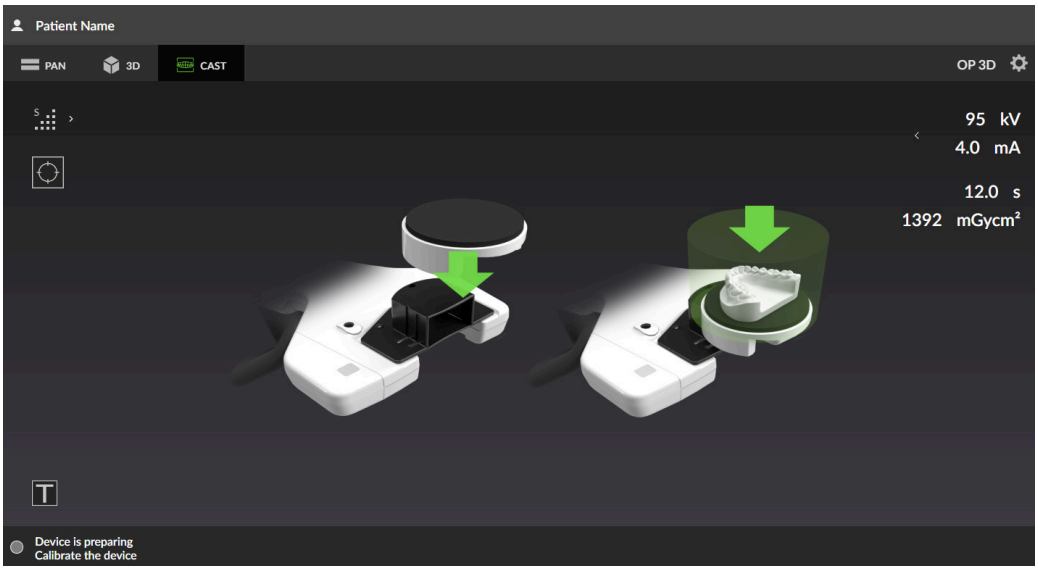


Image resolution

Indicates the currently selected resolution. The resolution affects the image quality and the amount of image layers.

- Press the image resolution selection icon to open a list of available image resolutions;

Low	Standard	High
		

Press on the listed resolution icon to activate it.

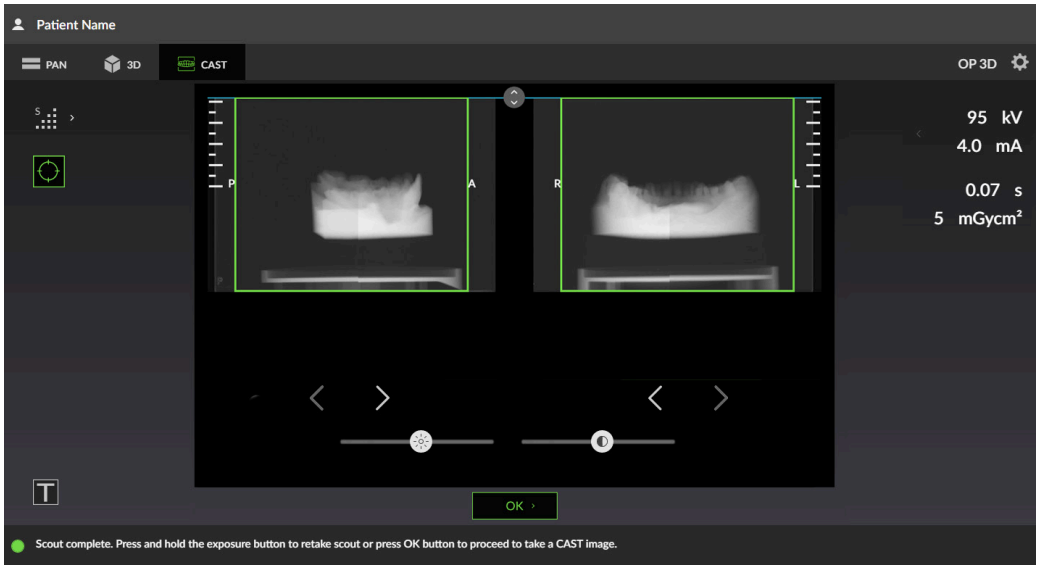
Scout image program

Indicates if the Scout image program is active.

A Scout image is taken to verify and perform adjustment to the FOV position and height before initiating a full 3D scan.

Press the Scout image icon to deactivate/activate it.

4.1.4.2 Dental cast scout image view



FOV height adjustment

You can adjust the height of the FOV by sliding the height adjustment icon up or down.

It's recommended to adjust the FOV size so that the **ROI is in the middle of the volume**.

FOV position adjustment

You can adjust the position of the FOV by clicking the Left / Right buttons.

- The buttons under the left projection adjust the FOV position in Posterior (**P**) - Anterior (**A**) direction.
- The buttons under the right projection adjust the FOV position in Left (**L**) - Right (**R**) direction.

You can also click and drag the images sideways to adjust the FOV position.

It's recommended to adjust the FOV location so that the **ROI is in the middle of the volume**.

Brightness slider

You can adjust the brightness of the shown image preview using the brightness slider.

NOTICE! *Adjustment is not saved to the image.*

Contrast slider

You can adjust the contrast of the shown image preview using the contrast slider.

NOTICE! *Adjustment is not saved to the image.*

OK button

Press OK button to approve the changes made to the FOV location and size using the Scout image and to proceed to the 3D exposure.

4.1.4.3 Dental cast image preview

NOTICE! *Image previews are not shown in full resolution on GUI.*

NOTICE! *The image has indications from which direction the image is shown;* ***A/P*** *(Anterior/Posterior),* ***L/R*** *(Left/Right) and* ***H/F*** *(Head/Foot).*

Slice preview projection

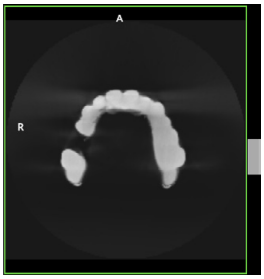
Indicates which preview projection is selected.

3D preview image is shown as a slice preview (left) and a rendered volume (right) on the GUI.

Press the preview projection icons to change the projection of the shown preview.

Coronal	Sagittal	Axial
		

Slice preview



Shows a preview of 3D slices. You can scroll through the preview using the slider on the right side of the image.

Volume preview

Shows a preview of the 3D volume. You can rotate the preview using the slider on the right side of the image.

Brightness slider

You can adjust the brightness of the shown image preview using the brightness slider.

NOTICE! *Adjustment is not saved to the image.*

Contrast slider

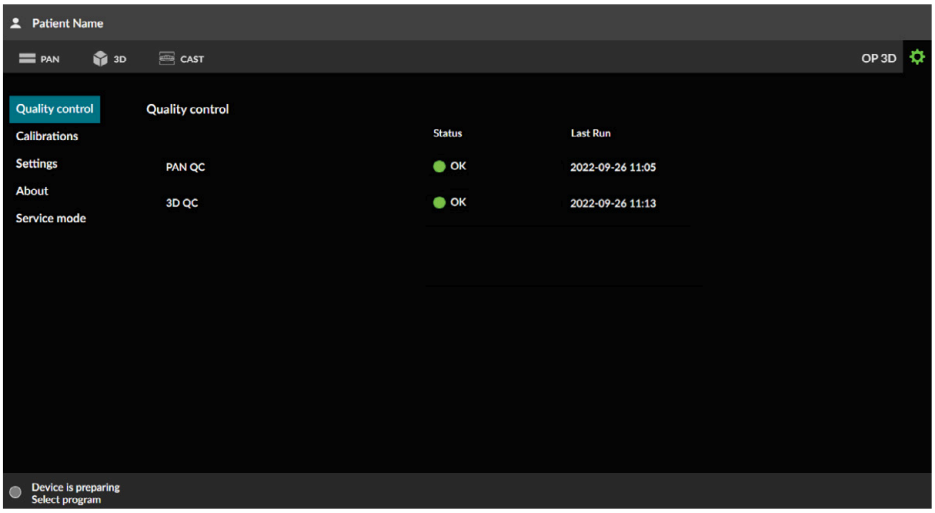
You can adjust the contrast of the shown image preview using the contrast slider.

NOTICE! *Adjustment is not saved to the image.*

OK button

Press OK button to close the image preview.

4.1.5 Device settings



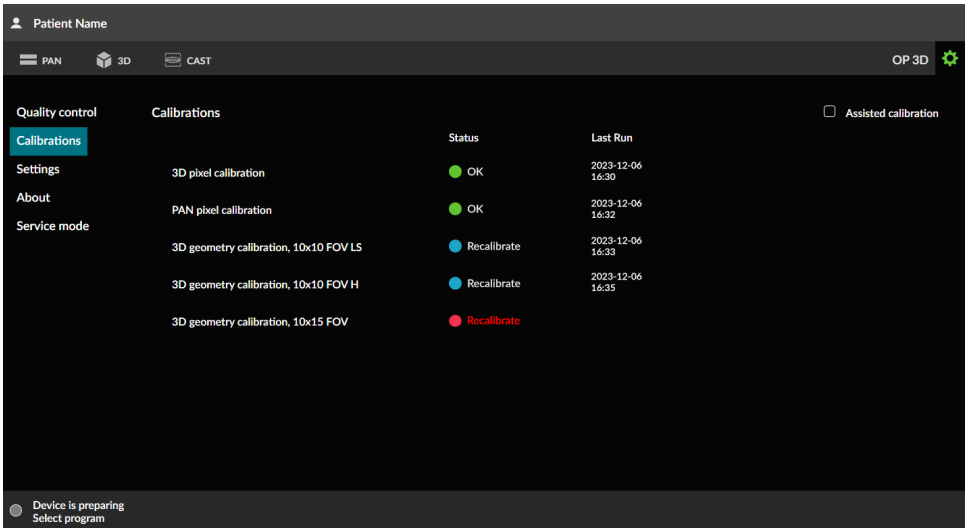
1. **QUALITY CONTROL**

   Shows a list of Quality Control (QC) programs, their completion status and last completion date.

   The Quality Control (QC) programs are used to ensure that the technical performance and the image quality of the device remains constant and valid for clinical use. Quality Control should be performed at regular intervals, preferably at least once a month and always after calibration.

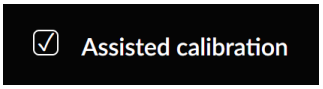
   See chapter Quality control on page 74 for more information on how to take quality control images.

2. CALIBRATIONS



Shows a list of user performable device calibrations, their completion status and last completion date. The calibrations are carried out through this menu.

Enabling **Assisted calibration** selection allows the device to automatically continue to the next required calibration program after the calibration result is passed.

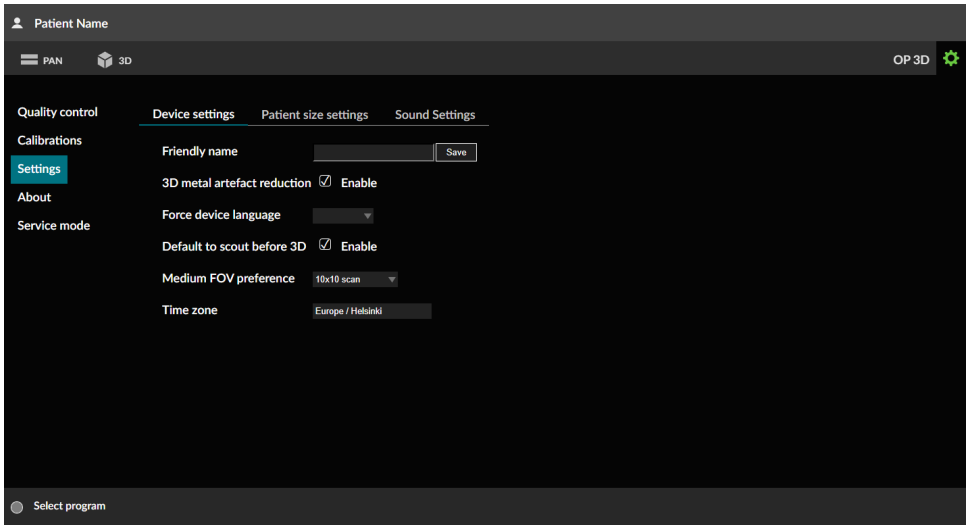


See chapter Calibrations for the user on page 69 for more detailed information on calibration programs and how to perform them.

NOTICE! *The available calibration programs depend on the device configuration.*

3. SETTINGS

Device settings:



Friendly name

Set a name for the device, which is shown next to the device settings icon and on the imaging software.

3D Metal Artefact Reduction

Enable or disable MAR, Metal Artefact Reduction. MAR is used to reduce the effect of metals and other dense radiopaque objects on the 3D image.

It is recommended to keep MAR activated.

Force device language

Change the language of the device GUI if needed.

It is recommended not to force the language of the GUI but change the language profile of the workstation.

Default to Scout before 3D

Enable or disable automatic Scout image activation when a 3D imaging modality is selected. It is recommended to have the Scout image taking enabled.

NOTICE! *If the selection is set to "disabled", a Scout image mode can still be activated manually in the 3D imaging program selection view.*

Medium FOV preference

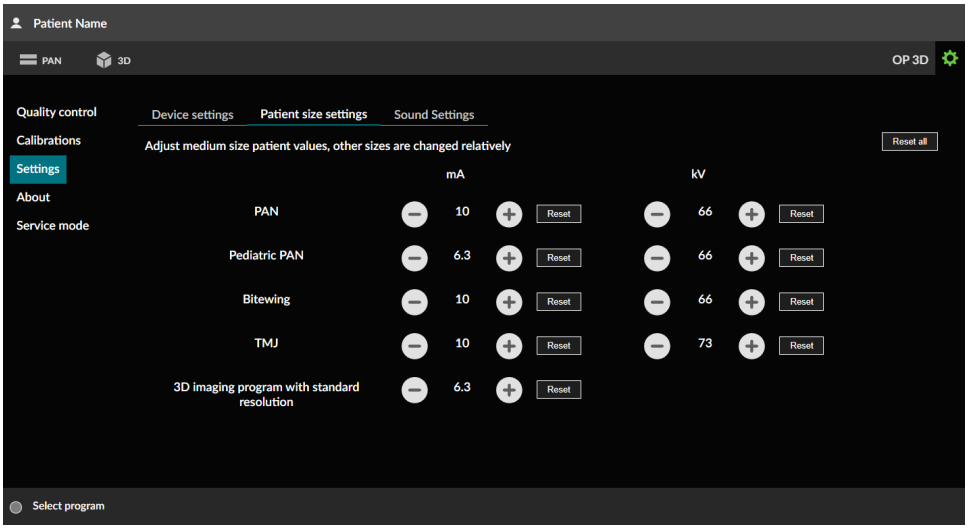
Select which FOV size is selected by default when selecting both jaws on the ORTHOselect™ dental chart.

- 10x10 for faster imaging
- 10x11 for larger area coverage

Time zone

Set the timezone to match the installation location. To change the time zone, start to write the continent, capitol or state (US) and select the correct selection from the drop down list.

Patient size settings:



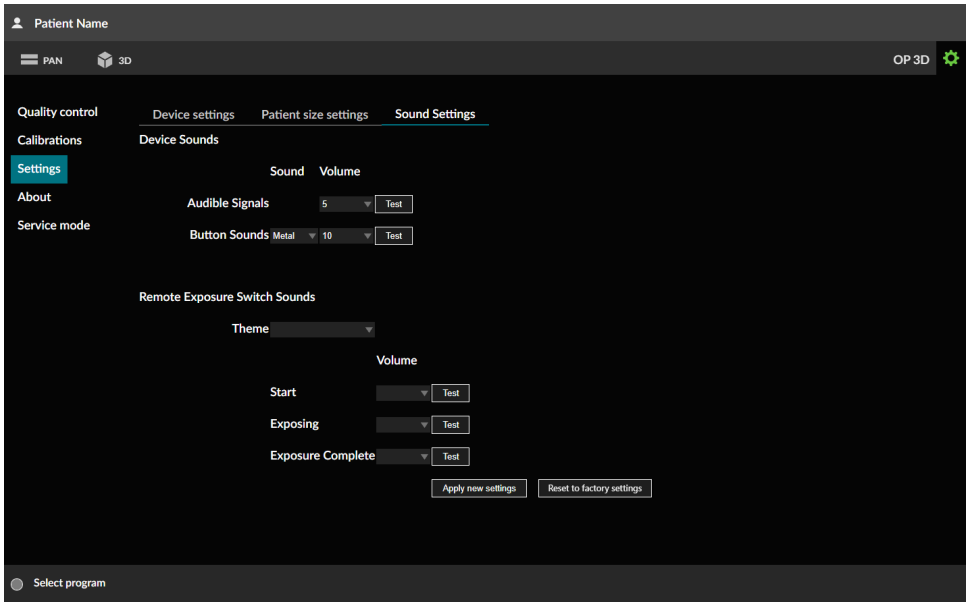
Adjust the default mA and kV values for **medium size patient** preset. Other patient size selections are changed relatively to the adjustment made.

Adjustments made to the 3D imaging program with standard resolution are applied relatively to other resolution selections as well.

Click **Reset** buttons to reset the patient size settings to their default values. The default values for each program are listed in chapter Patient size setting default values on page 87.

NOTICE! *The available programs and patient size presets depend on the device configuration.*

Sound settings:



Device sounds

Audible signals:

Adjust the volume level of the audible signals, such as program end sound.

NOTICE! *Does not affect exposure warning signal.*

Button sounds:

Select the sound theme and volume level of the signal when **HOME**, **Test mode** or **Patient positioning lights** buttons are pressed.

Remote exposure switch sounds

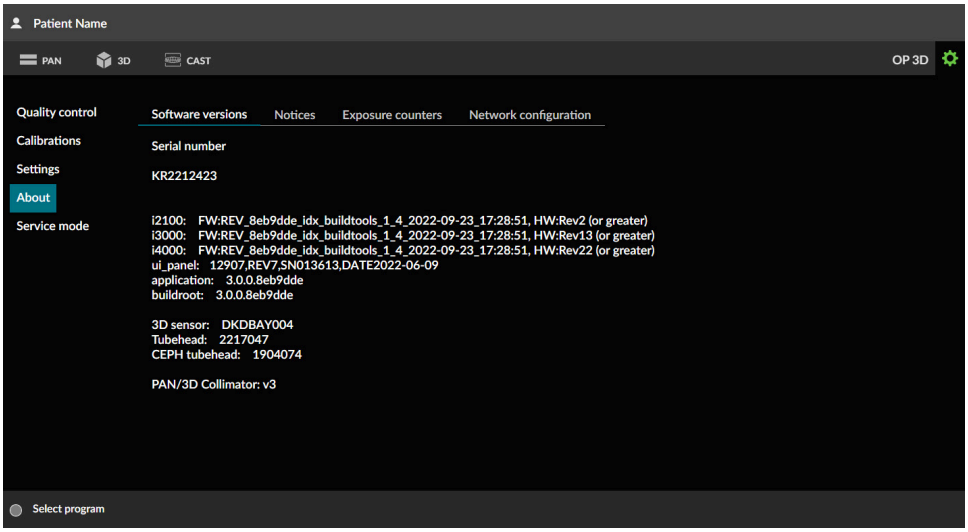
IMPORTANT! *These settings are applicable only to optional, new generation, remote exposure switches.*

Select sound theme and volume for each signal played through the remote exposure switch when it, or an exposure switch connected to it, is used to take X-ray images.

Press **Apply new settings** to upload the sound theme and volume selections to the remote exposure switch for them to take effect.

Press **Reset to factory settings** to set and upload the default values for the sound theme and volume selections to the remote exposure switch.

4. ABOUT



Software versions — Shows the serial numbers of:

- The main device
- Sensors
- Tubehead assemblies

Shows also the versions of the installed firmware and hardware.

Notices — Legal information and terms and conditions for use.

Exposure counters — Shows the amount of exposures taken with the device.

Network configuration — Shows the current network configuration of the device:

- IP address
- Subnet mask
- Default gateway
- IP address allocation
- MAC address
- NTP server

5. SERVICE MODE

NOTICE! *This menu is intended for authorized service personnel only.*

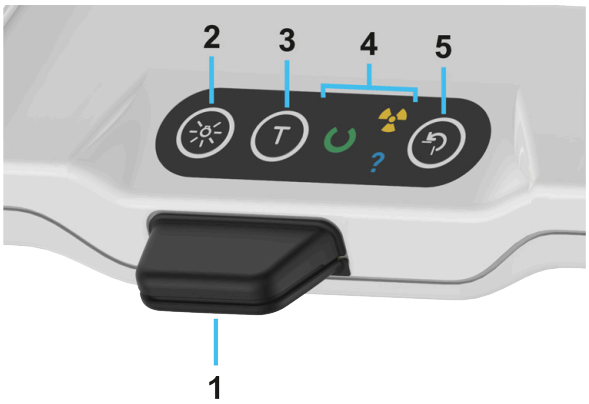
This menu is used to unlock Installation and Service specific functions on the GUI.

- Additional device settings
- Calibrations for installation and service of the device
- Optional imaging programs activation
- Demonstration mode activation for exhibition use
- Verification programs for radiation related testing

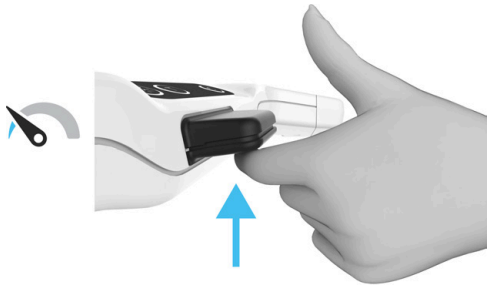
To access these functions, a PIN code is required.

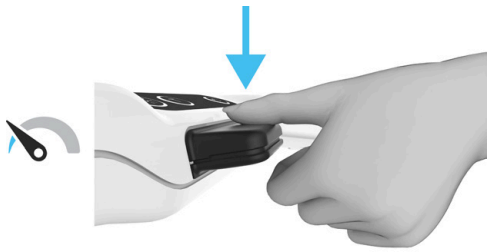
NOTICE! *The functions unlocked by the PIN code are highlighted with coloured indicators.*

4.2 Control panel



1. **Device height controller**. Move the device up/down by pressing on the device height controller. The device can move in two speeds, **slow** and **fast**.

MOVE DEVICE UP	
1. Press the **underside** of the controller to move **slowly**.	**2.** Press also the **top** of the controller to move **faster**.
	

MOVE DEVICE DOWN	
1. Press the **top** of the controller to move **slowly**.	**2.** Press also the **underside** of the controller to move **faster**.
	

2. **Patient positioning lights button**. Turn the patient positioning lights on/off.

3. **Test mode button**. Disable radiation production of the device. You can also use the GUI to activate the Test mode.

4. **Device status indicators**. Device status indicators light up according to the device status.

Ready

Device is ready for imaging.

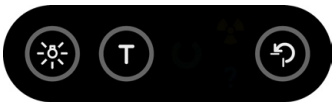
Error state

Device is in error state or pending user action. Check the GUI for details.

Exposure

Device is generating X-rays.

5. **HOME button**. Move the device to HOME (Patient-In) and scan start positions.

CONTROL PANEL STATUSES		
Status	**Explanation**	
	**Device power off**	Control panel lights are off.
	**Device in power save mode**	All button lights are "breathing" slowly. Press any button or the height controller to wake up the device.
	**Device requests a button to be pressed.**	HOME button light is flashing. Press the HOME button to complete action.
	**Button/Function is enabled**	Button light is dim but visible. Press the button to activate the function.
	**Button/Function is active**	Button light is on. The function is active as long as the light is on.

5 Imaging programs

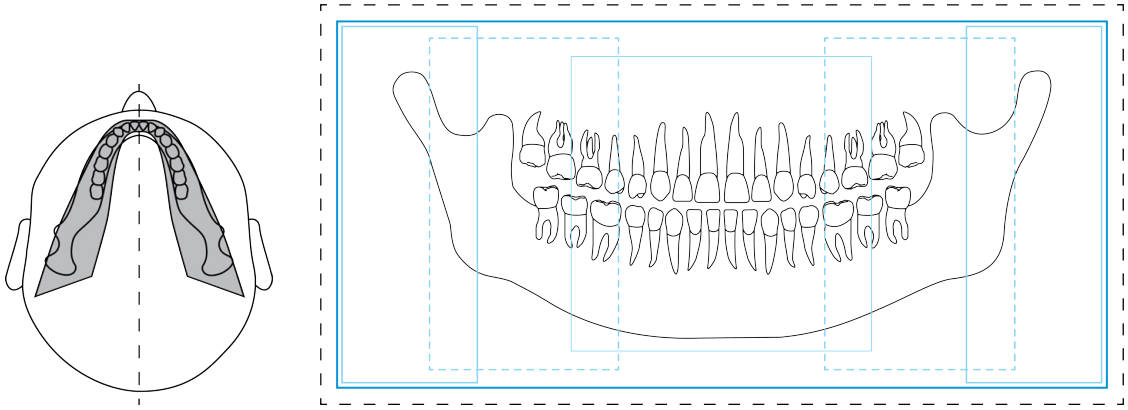
5.1 Panoramic programs

NOTICE! *The image field dimensions and segment widths and height differences shown here are for illustrative purposes only.*

Standard Panoramic imaging program

The Standard Panoramic imaging program provides general view of dental and facial anatomy based on panoramic imaging technique.

You can choose which segments of the dentition are imaged if imaging of the whole dentition is not required. Press the segments on the dental chart to deselect and select them.

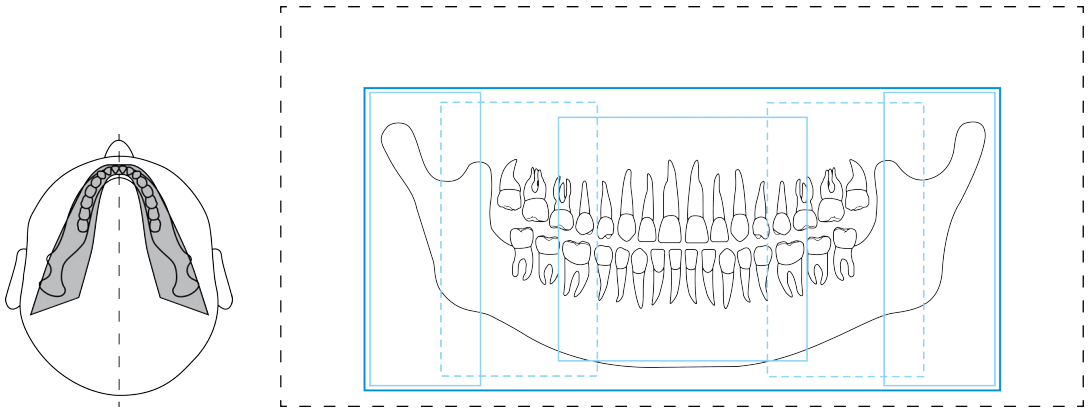


Pediatric Panoramic imaging program

The Pediatric Panoramic imaging program provides a general view of the dental and facial anatomy based on panoramic imaging technique for pediatric patients while using smaller radiation dose and smaller imaging area.

Adult patients with exceptionally narrow jaw can also be imaged with this program but note that the image height is limited.

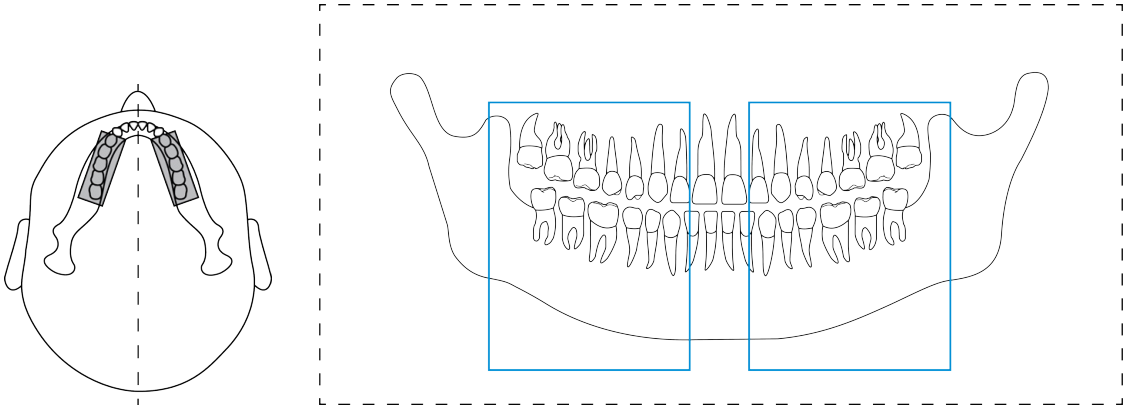
You can choose which segments of the dentition are imaged if imaging of the whole dentition is not required. Press the segments on the dental chart to deselect and select them.



Bitewing program

A bitewing view of the patient's Premolar-Molar region dentition.

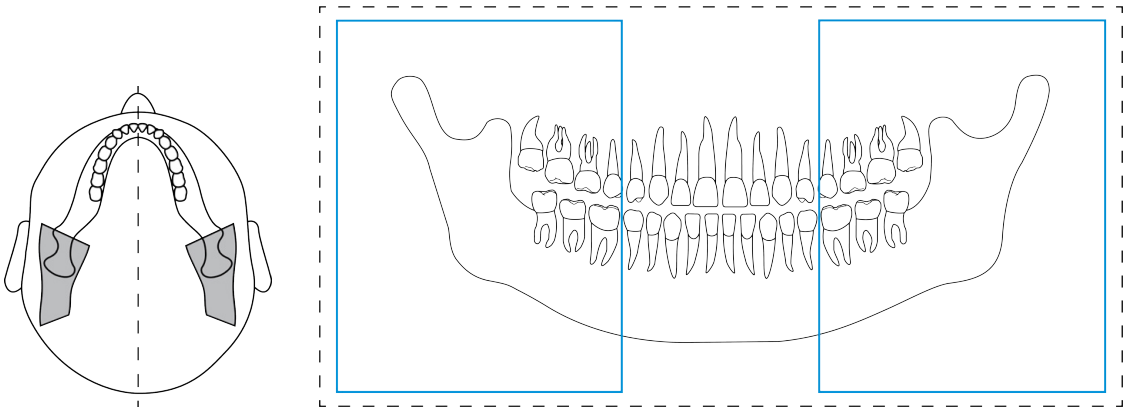
You can choose to image both or only other segment in single scan. Press the segments on the dental chart to deselect and select them.



TMJ, lateral projection

Lateral TMJ program provides a lateral view of the patient's left and right temporomandibular joints.

You can choose to image both or only other segment in single scan. Press the segments on the dental chart to deselect and select them.



5.2 3D programs

NOTICE! *These programs are available only for 3D devices.*

Always select the smallest feasible FOV size, resolution and imaging parameters for the 3D image in order to follow the ALARA (As Low As Reasonably Achievable) principle.

NOTICE! *It is always up to the dental professional to select the appropriate FOV, resolution and imaging parameters.*

5.2.1 FOV Sizes

The FOV sizes are presented as the **Height x Diameter** of the 3D volume in centimeters. For example FOV 5 x 5 corresponds to a cylindrical volume with diameter of 5 cm and height of 5 cm.

NOTICE! *Fine adjustment of the FOV location and FOV height can be done using the scout images. The location of the FOV is determined by the selected ROI.*

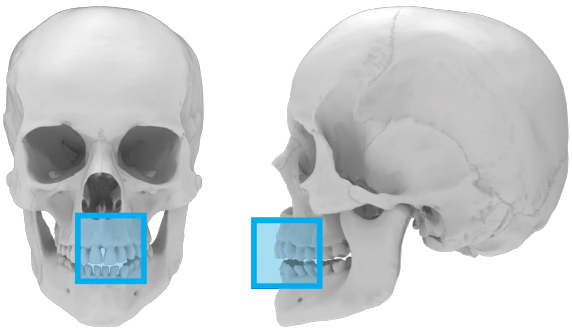
NOTICE! *Available FOV sizes depend on the device configuration and country specification.*

NOTICE! *FOV size 10 x 15 is an optional program and available only with a separately purchased license.*

FOV 5 x 5

Optimized for single site implants or localized diagnostics, for example, 3rd molar extractions, impacted teeth, periodontal cases, root fractures, single TMJ analysis, endodontics and for pediatric imaging.

5 x 5



Available resolutions:

L — Low (LDT)

S — Standard

H — High

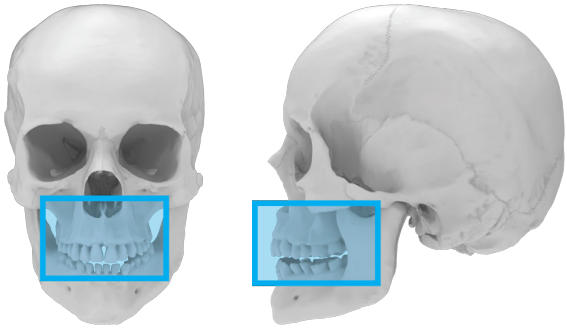
Resolution optimized for endodontic imaging:

E — Endo

FOV 6 x 9 / 6 x 8

6 x 9 6 x 8

Optimized for multiple implant placement using surgical guides, imaging the whole dental arc of one jaw, 3rd molar visualization, pathology (bilateral analysis) and periodontal cases.



Available resolutions:

Low (LDT)

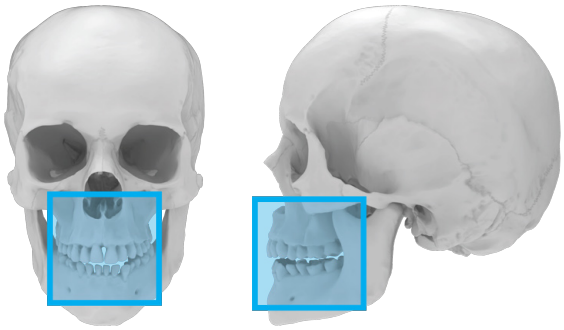
Standard

High

FOV 8 x 8

8 x 8

Optimized for imaging the entire dentition, both mandibula and maxilla with portion of maxillary sinuses.



Available resolutions:

Low (LDT)

Standard

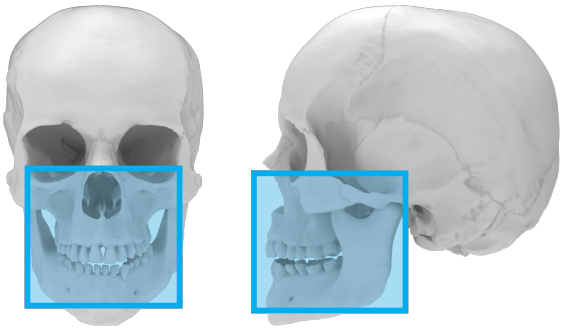
High

FOV 10x 10 / 10 x 11

10 x 10 10 x 11

Optimized for imaging the entire dentition, both mandibula and maxilla with portion of maxillary sinuses and one TMJ.

10 x 11 FOV size is useful to use with larger patients to make sure that third molars are included in the image.



Available resolutions:

Low (LDT)

Standard

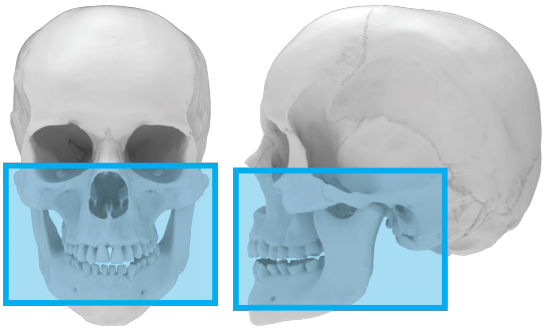
High

NOTICE! *You can change which FOV size is selected by default when both jaws are selected on the dental chart. See chapter Device settings on page 39 for more information.*

FOV 10 x 15

10 x 15

Optimized for imaging the entire dentition, both mandibula and maxilla, including airway and upper cervical spine or the sinus, maxillary sinuses, jaws with bilateral joints, jaws with airways, analyses of both TMJs and for maxillofacial surgeries.



Available resolutions:

Low (LDT)

Standard

High

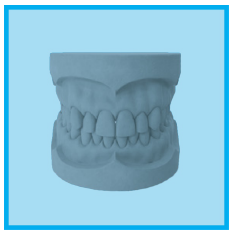
5.2.2 3D Resolutions

The resolution affects the image quality and radiation dose to the patient. For example, high resolution will produce more details than standard resolution, but the radiation dose is also higher. The unit offers a LDT (Low Dose Technology™) resolution which can be used for example in treatment follow-up cases. The LDT resolution will result in images proportional to the low dose and it is up to the healthcare professional to decide when it is sufficient to be utilized.

Resolution setting		General recommendations for the use
Low (LDT) resolution	L	Implants, treatment follow up, children
Standard resolution	S	Implants, 3rd molars, TMJ, impacted teeth, resorptions
High resolution	H	Pathologies, alveolar bone defects, root fractures
Endo resolution	E	Endodontic cases (periapical infections, root canals, fractures, etc.). Available only for 5x5 FOV.

5.3 Dental cast program

The dental cast program is initially taken with **FOV 10 x 10**. The height of the FOV can be adjusted after scout image.



Available resolutions:

NOTICE! *The resolution selection affects the amount of image layers produced. Dose production is not affected.*

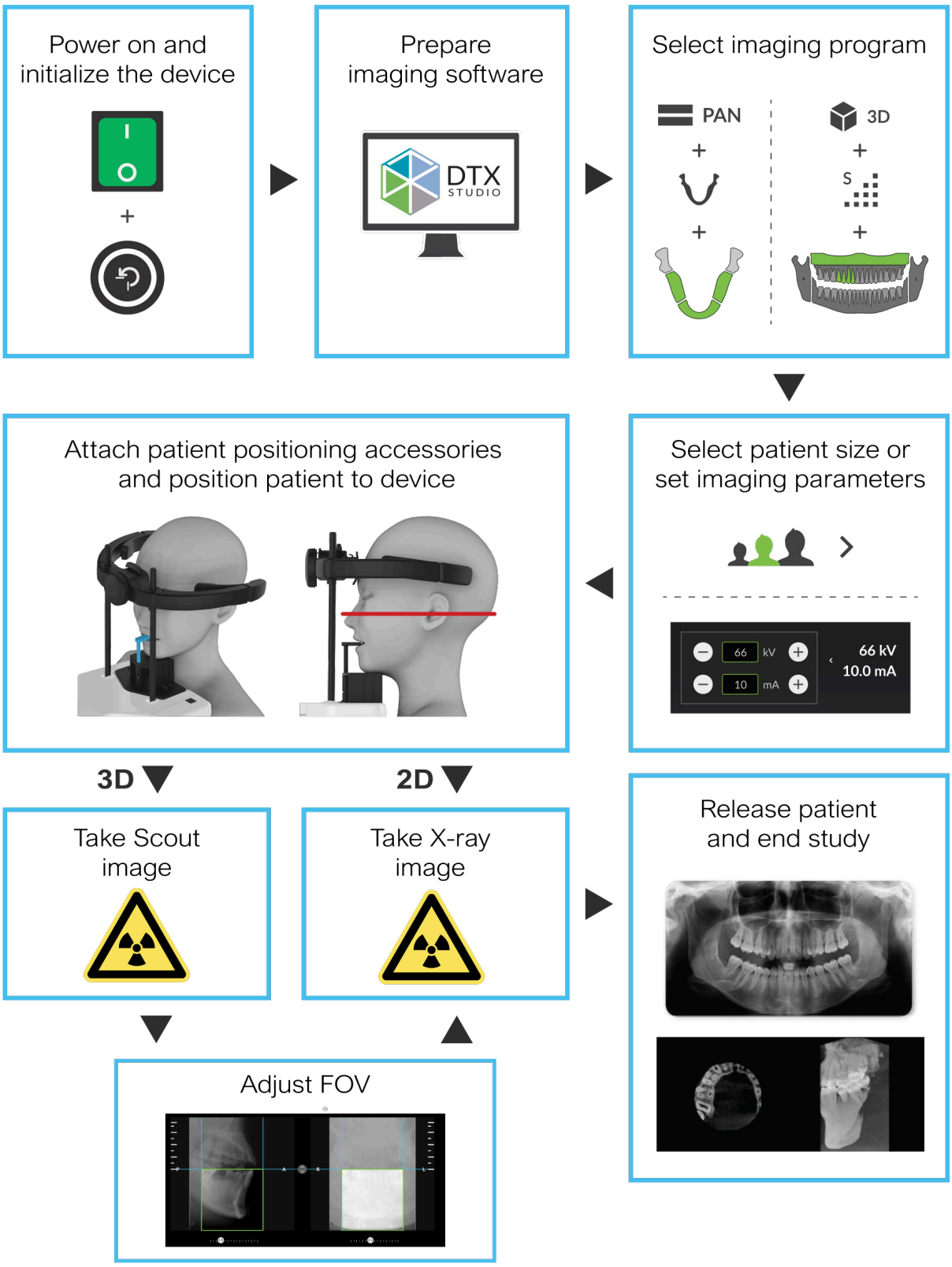
L — Low resolution

S — Standard resolution

H — High resolution

6 Using the device

6.1 General imaging workflow



6.2 Powering on/off the device

POWERING ON THE DEVICE

1. Push the power switch to ON (**I**) position. Power switch is located at the rear of the carriage.

2. The device starts the initialization process.
3. Press **HOME** button on the control panel when the indicator light starts blinking in blue. The device GUI also indicates when HOME button can be pressed.

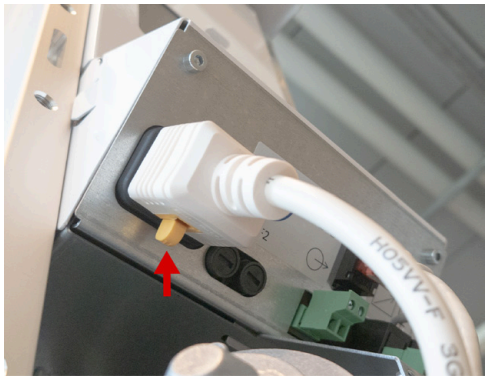
NOTICE! *The device moves up or down when HOME button is pressed.*

NOTICE! *The device enters a power save mode after 30 minutes of inactivity. While in the power save mode, the device cooling fan is not active, but the control panel lights are lit. The device wakes up from the power save mode when connection to it is established or when the HOME button is pressed.*

POWERING OFF THE DEVICE

1. Push the power switch to OFF (**O**) position. The device should be powered off when not in use.
2. Device can be isolated from the mains by detaching the mains cable plug from the rear of the device (under a cover, below the power switch) or cutting off the power supply from an external mains isolation switch (not supplied with the device).

NOTICE! *Press the yellow locking piece in to release the mains cable plug.*



6.3 Preparing the device for imaging

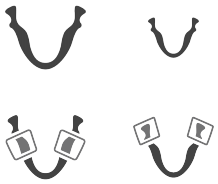
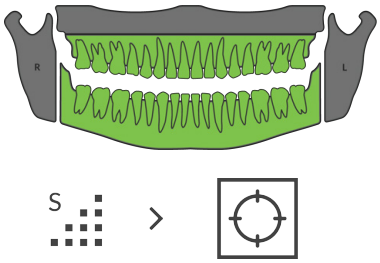
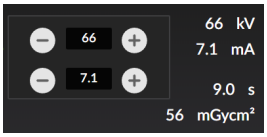
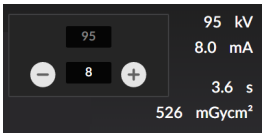
1. Power up the workstation.
2. Launch the dental imaging software.
3. **Imaging SW:** Select the patient for examination.
4. **Imaging SW:** Select the device to establish a connection.

   NOTICE! *Refer to the dental imaging software documentation for more details.*

5. The device GUI opens on the workstation when the connection to the device is established.

   NOTICE! *The device must be powered on and initialized before the connection is established.*

6. **GUI:** Select the **imaging modality**, **imaging program** and **patient size** to set up the device. If the preset selections are not suitable for the patient in question, adjust the **imaging parameters** manually.

Imaging modality	PAN	3D
Imaging program		
Patient size		
Imaging parameters		

NOTICE! *Exercise special care when imaging patients outside the typical adult size range, especially smaller pediatric patients. When imaging pediatric patients follow the **ALARA** (As Low As Reasonably Achievable) principle and seek to reduce the radiation dose to the amount necessary to acquire images that are clinically adequate. This can be achieved for example through utilizing the pediatric imaging programs and adjusting the imaging parameters for the patient in question.*

6.4 Patient positioning

6.4.1 Patient positioning for Panoramic imaging

NOTICE! *The device can be used to take images of both standing and seated patients. It is recommended to have very tall patients seated for easier positioning.*

1. Press **HOME** button. The device moves to HOME (Patient-In) position.

NOTICE! *Make sure that the device is set up correctly for the intended examination.*

2. The device goes to ready state and the status indicator light turns green.

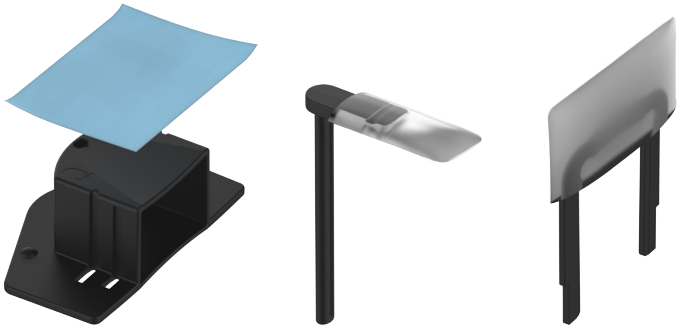
NOTICE! *If the status indicator light does not turn green, look for more information on the GUI.*

3. Select the patient positioning accessory according to the image to be taken, attach it to the chin rest and place them on the lower shelf of the device, as shown below.

STANDARD, PEDIATRIC AND BITEWING IMAGING		TMJ IMAGING
Dentate patients	**Edentulous patients**	**All patients**
• Bite block • Chin rest in lower jaw position 	• Lip support • Chin rest in lower jaw position 	• Lip support • Chin rest in upper jaw position 

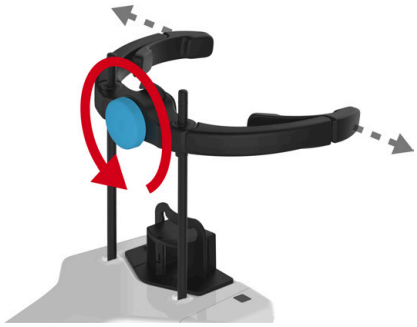
NOTICE! *The Chin Rest needs to be attached to the device in the correct orientation for the selected imaging program before the device allows images to be taken.*

4. Place disposable covers on the patient positioning accessories.



5. Adjust the device's height to approximately match the patient's height.

6. Open the head support.



7. Tell the patient to remove their glasses, hearing aids, removable dentures, jewellery, hair clips and all other things that can cause artifacts to the image.
8. Protect the patient from radiation according to the local regulations.
9. Guide the patient to the device and instruct to stand as straight and as tall as possible.
10. Ask the patient to grab the patient handles, place their chin on the chin rest and to bite the notches on the bite block or to push their lip against the lip support.

⚠ ***CAUTION!*** *Evaluate the condition of the patient's dentition before using the Bite Block. If the patient's teeth are more fragile than a normal healthy patient's, use the Lip Support and a cotton roll between the front teeth instead.*

ⓘ ***NOTICE!*** *If the patient has wide shoulders that could collide with the rotating unit, ask the patient to cross their arms when holding the handles in order to contract the shoulders.*

11. Ask the patient to take a step forward to straighten their spine.

12. Fine adjust the device height and adjust patient's head position/orientation using the patient positioning lights as guides.

NOTICE! *To ensure optimal image quality, pay attention to the correct patient positioning.*

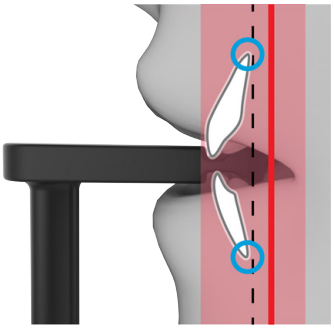
NOTICE! *You can open the mirror and use it to help in positioning the patient. Close the mirror before you start the imaging.*

STANDARD AND PEDIATRIC PANORAMIC IMAGING:

- Align the patient so that the root tips of lower and upper incisors are vertically aligned and parallel to the Tilt light. The ORTHOfocus™ feature automatically finds the optimum panoramic image layer, enabling forgiving patient positioning.

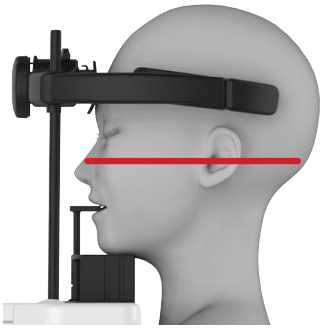
  NOTICE! *When you align the incisors to the same vertical level, the patient's Frankfort-Horizontal plane is also in the necessary orientation and close to parallel to the FH light.*

  NOTICE! *In rare cases, typically caused by abnormal anatomy, if the ORTHOfocus™ feature cannot find the optimal image layer, the device provides 5 different image layers to use in diagnosis.*



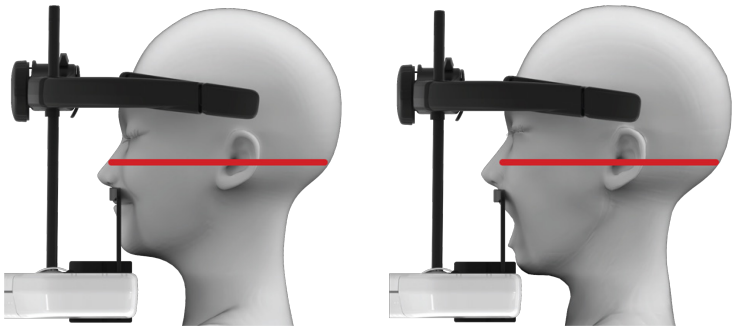
BITEWING IMAGING:

- The patient’s occlusal plane should be horizontal and parallel to the FH light.

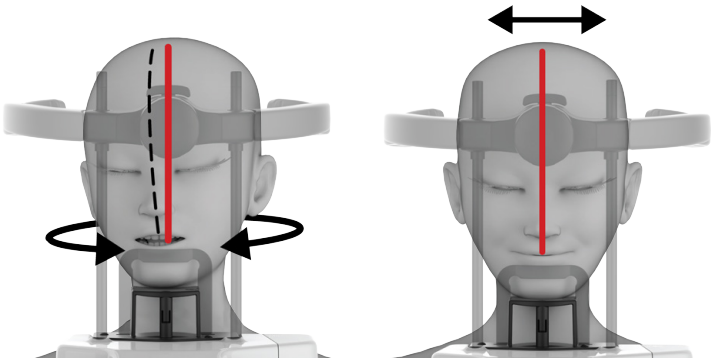


TMJ IMAGING:

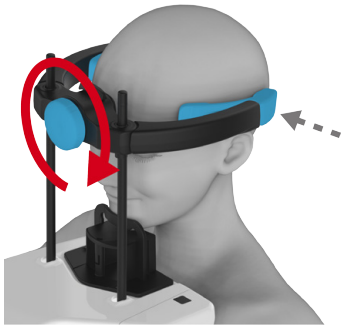
- The patient’s Frankfort-Horizontal plane should be close to parallel to the horizontal light. The FH light indicates the center of the field. You can take a TMJ image with the patient's mouth closed or open.



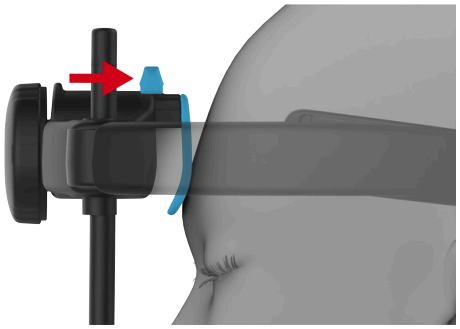
13. Check that the patient’s head is straight and not rotated and the patient’s mid-line coincides with the midsagittal light.



14. Close the head support.



15. Adjust the forehead support against the patient's forehead.

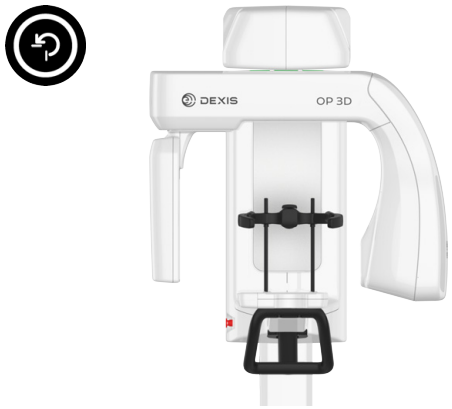


16. Ask the patient to close their lips and press their tongue against the palate if possible.

6.4.2 Patient positioning for 3D imaging

NOTICE! *The device can be used to take images of both standing and seated patients. In 3D imaging, having patient seated can decrease unwanted patient movement.*

1. Press **HOME** button. The device moves to HOME (Patient-In) position.



NOTICE! *Make sure that the device is set up correctly for the intended examination.*

2. The device goes to ready state and the status indicator light turns green.

NOTICE! *If the status indicator light does not turn green, look for more information on the GUI.*

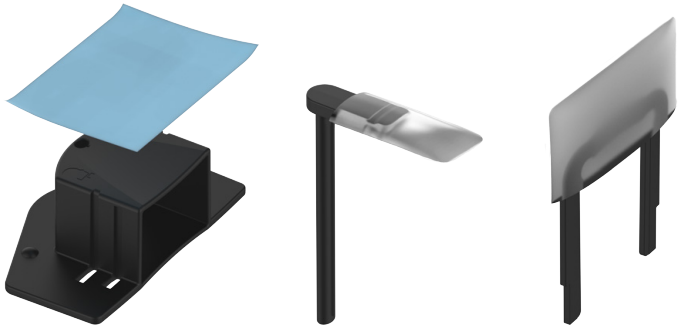
3. Select the patient positioning accessory according to the image to be taken, attach it to the chin rest and attach them on the lower shelf of the device, as shown below.

3D IMAGING WITH TEETH TOGETHER		
Lower jaw or both jaws	**Upper jaw**	**Upper jaw with emphasis on sinuses**
• Lip support • Chin rest in lower jaw position	• Lip support • Chin rest in upper jaw position	• Lip support • Flat chin rest in upper jaw position
		

3D IMAGING WITH TEETH SEPARATED		
Lower jaw or both jaws	**Upper jaw**	**Upper jaw with emphasis on sinuses**
• Bite block • Chin rest in lower jaw position	• Bite block • Chin rest in upper jaw position	• Bite block • Flat chin rest in upper jaw position
		
		

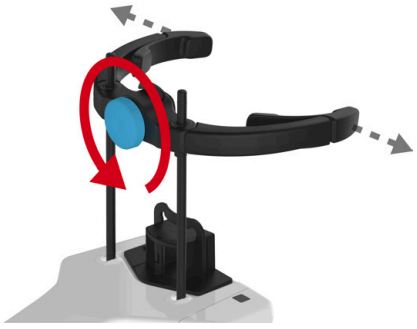
NOTICE! *It is possible to take 3D images with* ***FOV 10 x 15 FOV size without using a chin rest*** *if diagnostic need requires it and reduced patient support is justified.*

4. Place disposable covers on the patient positioning accessories.

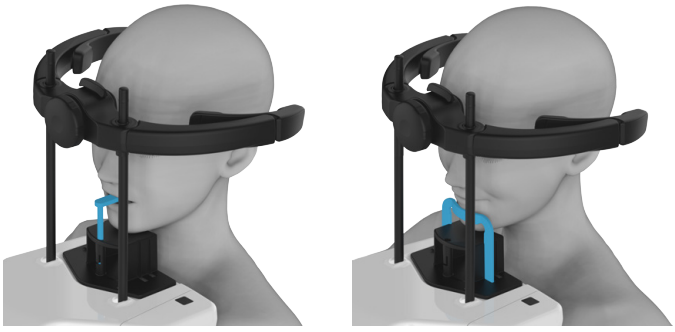


5. Adjust the device's height to approximately match the patient's height.

6. Open the head support.



7. Tell the patient to remove their glasses, hearing aids, removable dentures, jewellery, hair clips and all other things that can cause artifacts to the image.
8. Protect the patient from radiation according to the local regulations.
9. Guide the patient to the device and instruct to stand as straight and as tall as possible.
10. Ask the patient to grab the patient handles, place their chin on the chin rest and to bite the notches on the bite block or to push their lip against the lip support.



NOTICE! *If the patient has wide shoulders that could collide with the rotating unit, ask the patient to cross their arms when holding the handles in order to contract the shoulders.*

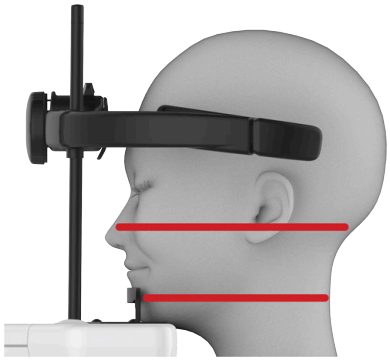
11. Ask the patient to take a step forward to straighten their spine.

12. Fine adjust the device height and adjust patient's head position/orientation using the patient positioning lights as guides.

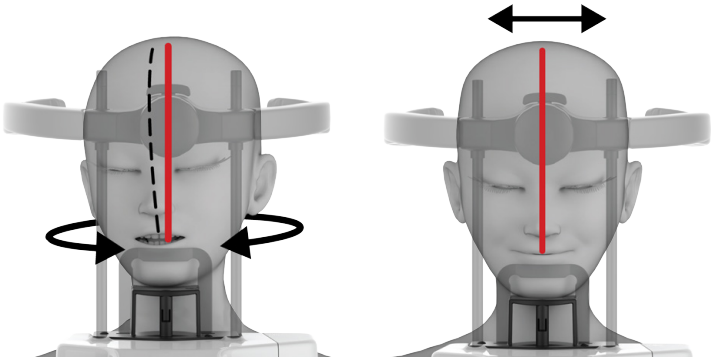
NOTICE! *To ensure optimal image quality, pay attention to the correct patient positioning.*

NOTICE! *You can open the mirror and use it to help in positioning the patient. Close the mirror before you start the imaging.*

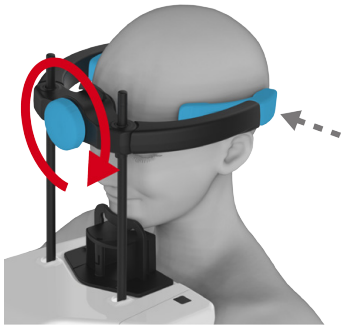
- The patient's occlusal plane should be horizontal and the ROI is between the top and bottom FOV lights.



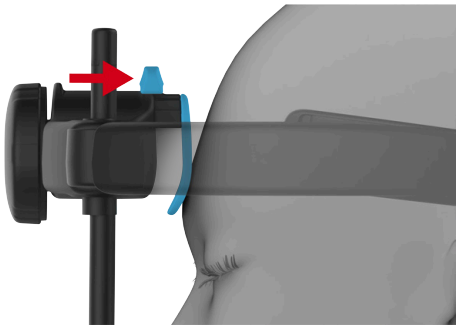
13. Check that the patient’s head is straight and not rotated and the patient’s mid-line coincides with the midsagittal light.



14. Close the head support.



15. Adjust the forehead support against the patient's forehead.



6.5 Taking an image

The exposure button is used to operate the device movements and X-ray generation during the imaging process.

The exposure button must be pressed down for the whole duration of the imaging process.

If device movements and exposure must be stopped prematurely, release the exposure button or activate the emergency stop switch.

NOTICE! *If the patient is feeling insecure or has an exceptional anatomy, use the Test mode to demonstrate the unit movements and to make sure that the rotating unit does not collide with the patient during the imaging process. Activate the Test mode from the GUI or the control panel and then press and hold the exposure button. The unit will complete the imaging movements without generating X-rays.*

6.5.1 Taking Panoramic images

1. Ensure the correct patient positioning, imaging program selection, imaging parameters and that the device is in Ready state with the indicator light turned green.
2. Press **HOME** button. The device moves to IMAGING START position and locks the device in place to prevent unwanted movement.

   NOTICE! *This is an optional step but decreases the imaging process time and the time that the patient must stay still.*

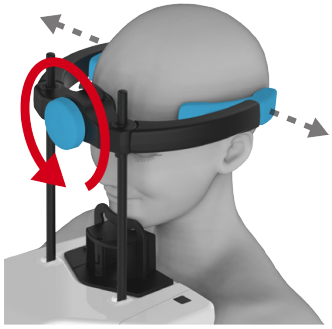
   NOTICE! *The device stays in the IMAGING START position for **1 minute**.*
3. Ask the patient to stay still during the whole imaging process.
4. Protect yourself from radiation.
5. Press and **hold** the exposure button down to take the image. The device starts to move and plays an audible exposure warning signal.

   
6. Release the exposure button after all device movements stop and the device plays an audible program end sound.
7. A preview image appears on the GUI for a quick review (no visible artifacts etc.).
8. Acknowledge the preview by pressing the **OK** button.

9. Continue to take the next image, if multiple images need to be taken.

10. Release the patient from the device.



11. Remove all disposable covers and decontaminate the device and the patient positioning accessories.

6.5.2 Taking 3D images

⚠ ***CAUTION! It's recommended to have Scout mode enabled by default.*** *If you do not wish to take a Scout image, deactivate the selection from the GUI.*

Taking a Scout image

1. Ensure the correct patient positioning, imaging program selection and that the device is in Ready state with the indicator light turned green.
2. Ask the patient to stay still during the whole imaging process.
3. Protect yourself from radiation.
4. Press and hold the exposure button down.
5. The device starts to move and an audible exposure warning signal is played.
6. Hold the exposure button down until all movements have stopped.

ⓘ ***NOTICE!*** *The device also plays a program end tune when the imaging process is complete.*

7. The Scout image appears on the GUI.
8. **GUI:** Adjust the FOV height, diameter and location using the Scout image, if needed.

   ⓘ ***NOTICE!*** *You can verify the adjustments by pressing the exposure button to take another scout image. Scout images produce only a small radiation dose so taking additional scout images won't produce excessive radiation dose to the patient.*

9. **GUI:** Approve the scout image and proceed to the 3D imaging phase by pressing **OK** button.

Taking a 3D image

10. Press **HOME** button. The device moves to IMAGING START position and locks the device in place to prevent unwanted movement.

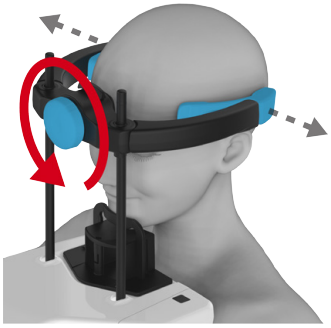
NOTICE! *This is an optional step but decreases the imaging process time and the time that the patient must stay still.*

NOTICE! *The device stays in the IMAGING START position for **1 minute**.*

11. Ask the patient to stay still until the 3D image has been taken.
12. Protect yourself from radiation.
13. Press and **hold** the exposure button down to take the image. The device starts to move and plays an audible exposure warning signal.

14. Release the exposure button after all device movements stop and the device plays an audible program end sound.
15. Image preview appears on the GUI for a quick review (no visible artifacts etc.).
16. Acknowledge the preview by pressing the **OK** button.

17. Continue to take the next image, if multiple images need to be taken.
18. Release the patient from the device.



19. Remove all disposable covers and decontaminate the device and the patient positioning accessories.

6.5.3 Taking Dental cast images

NOTICE! *You can take a Scout image of the dental cast before the actual 3D image by activating the Scout selection from the GUI.*

1. Attach Chin rest to the lower shelf of the device.

2. Attach the Dental cast holder over the Chin rest.

3. Place the dental cast on the holder as shown on the GUI.
4. Protect yourself from radiation.
5. Press and **hold** the exposure button down to take the image. The device starts to move and plays an audible exposure warning signal.

6. Release the exposure button after all device movements stop and the device plays an audible program end sound.
7. A preview image appears on the GUI for a quick review (no visible artifacts etc.).
8. Acknowledge the preview by pressing the **OK** button.

7 Maintenance

The maintenance and calibration procedure intervals described here are minimum requirements and recommendations. The maintenance and calibration procedures can be made more frequent and stringent to comply with local regulations regarding the use and maintenance of dental X-ray devices.

7.1 Cleaning and decontamination

CAUTION! *Bite block and ear rods must always be used with new disposable covers.*

NOTICE! *Decontamination techniques for the device, its accessories and the room must comply with all laws and regulations within the local jurisdiction.*

NOTICE! *Clean the patient positioning accessories before their first use.*

CLEANING THE SURFACES THAT THE PATIENT TOUCHES:

All surfaces and parts that the patient touches or comes into contact with, must be decontaminated after each patient. Use a de-contaminant that is formulated specifically for decontaminating dental equipment and use it in accordance with the instructions supplied with it. Wipe all items and surfaces dry after the decontamination.

WARNING! *Do not use any disinfecting aerosols, since the vapors could ignite causing injuries.*

NOTICE! *Wear gloves and other protective equipment during the decontamination process.*

CLEANING THE DEVICE:

The device should be cleaned regularly.

CAUTION! *Switch the device off or isolate it from mains before cleaning the device.*

CAUTION! *Do not allow water or other cleaning liquids to enter the device's interior since it might cause short-circuits or corrosion. If you use a spray cleaner do not spray into any ventilation grills.*

CAUTION! *Clean the dust off the device regularly. The device might overheat if excess dust is gathered on the ventilation grills.*

Device surfaces

All device surfaces can be wiped clean with a soft cloth dampened with a mild detergent, for example soapy water. DO NOT use abrasive cleaning agents or polishes.

Control panel

Wait for the control panel to dry or wipe it dry before use. Moisture can affect the usability of the panel.

Allowed cleaning agents for cleaning and decontamination of the device:

- Distilled water
- Ethanol 96%
- Isopropyl alcohol
- Soapy water
- CaviCide™, CaviWipes™ or Metasys™ disinfectant

7.2 Calibrations for the user

7.2.1 When to calibrate the device

The device must be calibrated and, if necessary, adjusted at regular intervals in accordance with the national regulations regarding the use, maintenance and service of dental X-ray devices.

NOTICE! *The device has multiple calibration programs, but only the ones listed in this chapter are meant to be performed by the user.*

NOTICE! *Some of the calibrations shown in this chapter may not be applicable to all device configurations. Only the applicable and required calibration programs are shown on the GUI.*

Minimum calibration frequency	Recommended calibration frequency
2 times / year	4 times / year

NOTICE! *The device will automatically remind of the re-calibrations (2 times a year for User calibrations and once a year for service calibrations by default). If you want to change the frequency of the recalibration reminders, contact service for assistance.*

DEVICE CALIBRATION BASIC GUIDELINE:

1. The device must be **fully recalibrated** at least **once a year**, by a service technician. The last calibration date for each program is listed in the calibration menu on the GUI. The complete calibration program is available only for service technicians. The user calibration programs, visible on the GUI, can be performed as often as preferred.
2. The device must be fully calibrated after the first installation.
3. The device must be recalibrated when parts are replaced.
4. Take QC images always after calibration to ensure good and consistent image quality.

7.2.2 Preparation for calibration

The calibration programs help you to maintain the image quality and correct operation of the device. Calibration data is stored in the device memory and is used for later calibrations and image processing.

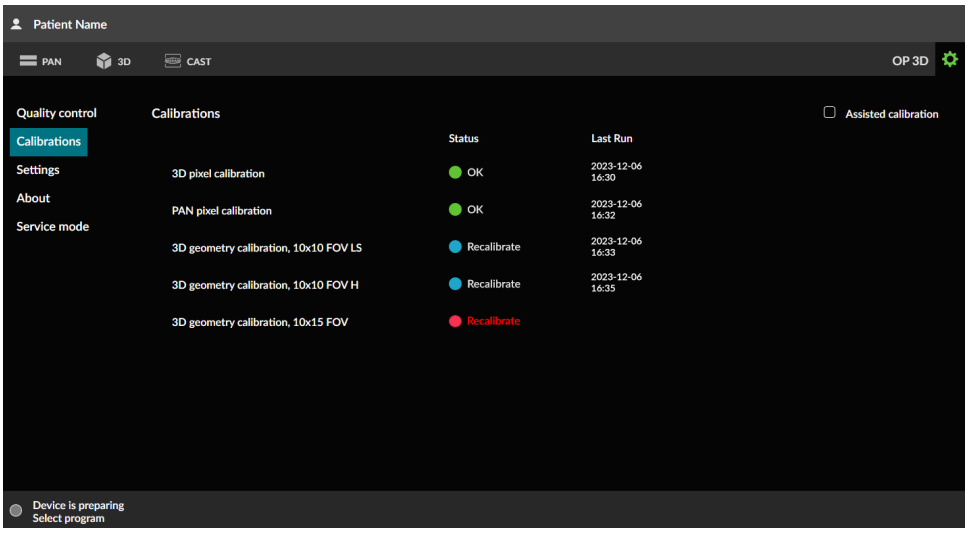
NOTICE! *Perform the calibrations in the exact order they are listed on the GUI.*

1. **GUI:** Go to device settings.

2. **GUI:** Select **Calibrations** menu.

3. A list of available device calibrations is shown with the status of the calibration.

NOTICE! *The calibration programs listed on the GUI depend on the device configuration.*



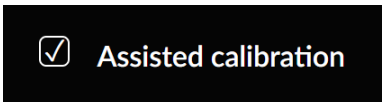
Calibration status indications:

Calibration not performed or failed.

Recalibration is required.

Calibration performed successfully.

4. Enable **Assisted calibration** selection if you want the device to automatically continue to the next required calibration when the calibration result is **PASSED**, without showing the calibration result images. This makes the calibration process faster.



NOTICE! *Calibration images are saved to the selected patient even if they are not shown on the GUI.*

5. Select the calibration program and follow the instructions on the GUI.

NOTICE! *Performed calibrations are indicated with green colour and the completion date of the calibration. All calibrations need to be successfully performed before using the device.*

NOTICE! *If calibration program fails, follow the instructions on the GUI (if any) and run the failed program again.*

NOTICE! *Calibration images are shown on the GUI as viewed from the sensor.*

7.2.3 Calibration procedure

NOTICE! *Some calibrations in this chapter are not available with all device configurations. Perform the calibrations in the exact order as shown on the GUI.*

After you have run all available calibrations successfully, take quality control images as instructed in chapter Quality control on page 74.

NOTICE! *Calibration result images may show some artefacts without them having an effect on the image quality. Always verify the image quality from the QC images.*

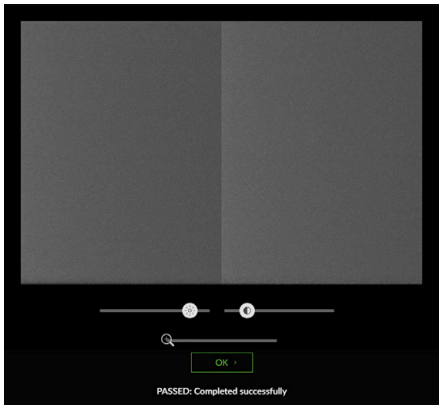
7.2.3.1 3D pixel calibration

This program calibrates the sensor for 3D imaging.

NOTICE! *Make sure that PAN/3D tubehead front cover and sensor covers are installed. Calibrating without the covers may have an effect on the image quality.*

1. Select **3D pixel calibration** from the Calibrations menu.
2. Protect yourself from radiation.
3. Press and hold the exposure button down to take the calibration image.

4. When the exposure warning stops and the program end sound is played, the program is complete.
5. The calibration image appears on the GUI.



6. Acknowledge the calibration result by pressing the **OK** button.

7.2.3.2 PAN pixel calibration

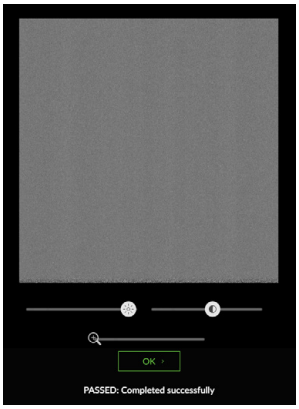
This program calibrates the sensor for Panoramic imaging.

NOTICE! *Make sure that PAN/3D tubehead front cover and sensor covers are installed. Calibrating without the covers may have an effect on the image quality.*

1. Select **PAN pixel calibration** from the Calibrations menu.
2. Protect yourself from radiation.

3. Press and hold the exposure button down to take the calibration image.

4. When the exposure warning stops and the program end sound is played, the program is complete.
5. The calibration image appears on the GUI.



6. Acknowledge the calibration result by pressing the **OK** button.

7.2.3.3 3D geometry calibrations

These programs create the calibration data for reconstructing 3D images.

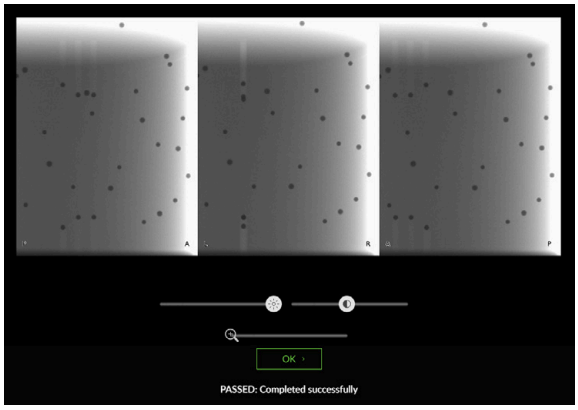
NOTICE! *The list of available calibrations depend on the device configuration and country specification.*

The device has multiple 3D geometry calibration programs. Perform each 3D geometry calibration in the exact order they are listed on the GUI. The same instructions apply for all programs.

1. Attach the Geometry Calibration Phantom to the lower shelf.

2. Select a **3D geometry calibration** from the Calibrations menu.
3. Protect yourself from radiation.
4. Press and hold the exposure button down to take the calibration image.

5. The calibration results appear on the GUI.



NOTICE! *This will take several minutes.*

6. Acknowledge the calibration by pressing the **OK** button.

7. Repeat the calibration for the remaining FOV sizes.
8. Remove the calibration phantom.

7.3 Quality control

The Quality Control (QC) programs are used to ensure that the technical performance and the image quality of the device remains constant and valid for clinical use. Quality Control should be performed at regular intervals, preferably at least once a month and always after calibration.

NOTICE! *The device will automatically remind of retaking the QC images. If you want the change the frequency of the reminders, contact your service for assistance.*

NOTICE! *QC programs produce X-rays. Protect yourself from radiation.*

7.3.1 PAN QC

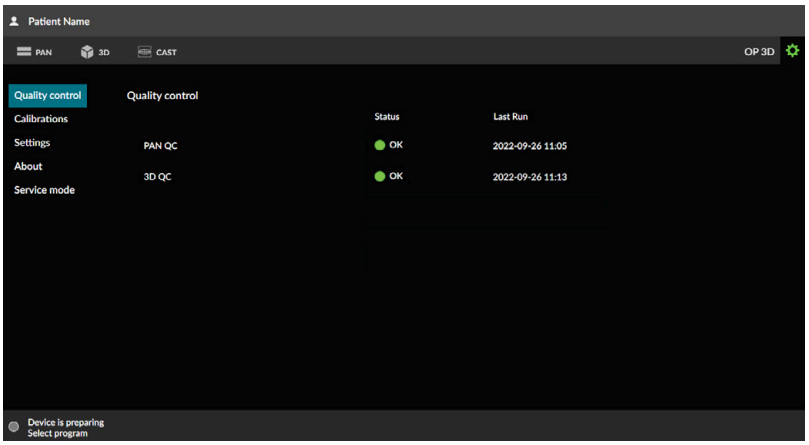
NOTICE! *The PAN QC is a recommended procedure but some local regulations/authorities may require it to be performed.*

NOTICE! *The PAN QC requires separately purchasable **2D Quality Control tools**.*

NOTICE! *The device can select the correct QC program automatically after a QC phantom has been attached to the device.*

1. **GUI:** Go to device settings.

2. **GUI:** Select **PAN QC** program from the **Quality control** menu.



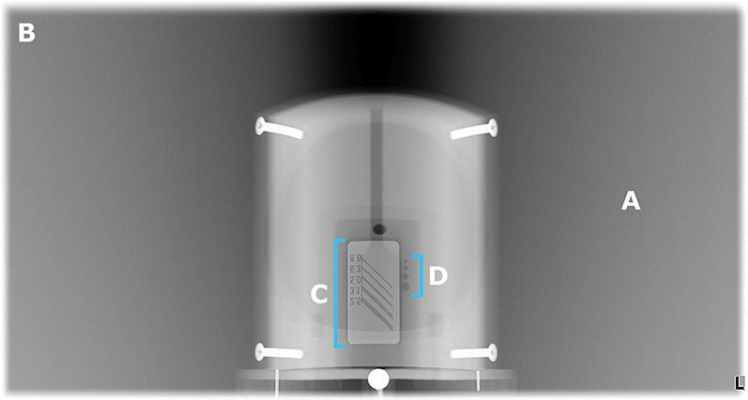
3. Attach the PAN QC phantom holder and 2D QC test phantom to the lower shelf.

4. Attach the copper filter in front of the radiation window on the tubehead. The filter attaches in place with magnets.

5. Protect yourself from radiation.
6. Press and hold the exposure button down to take the QC image.

7. The QC image preview appears on the GUI.
8. Acknowledge the preview by pressing the **OK** button on the GUI.

9. **Workstation:** Visually evaluate the image using the dental imaging software:



A: Smoothness of the exposed area.

B: Non-exposed area surrounds the whole image.

C: High contrast resolution; the distinguishable line pair resolution should be:

- **3.1 LP/mm or better** when using 0.8mm Copper filter
- **2.5 LP/mm or better** when using 1.8mm Copper filter

D: Low contrast holes must be visible:

- **4 holes** when using 0.8mm Copper filter
- **2 holes** when using 1.8mm Copper filter

NOTICE! *You should also compare the new QC image to the reference image taken during the installation or the latest service. Doing this helps you ensure that the image quality has remained constant.*

NOTICE! *The line pair resolution depends also on the other factors than the device itself, for example the imaging Software configurations. According to the standards, the distinguishable line pair resolution must be* ***2.5 LP/mm*** *or better.*

10. If the image fails on any of the previously listed criteria, redo the QC program. If it fails again, recalibrate the device according to Calibration procedure on page 71 or contact service.
11. Detach the PAN QC phantom holder and 2D QC test phantom from the device.

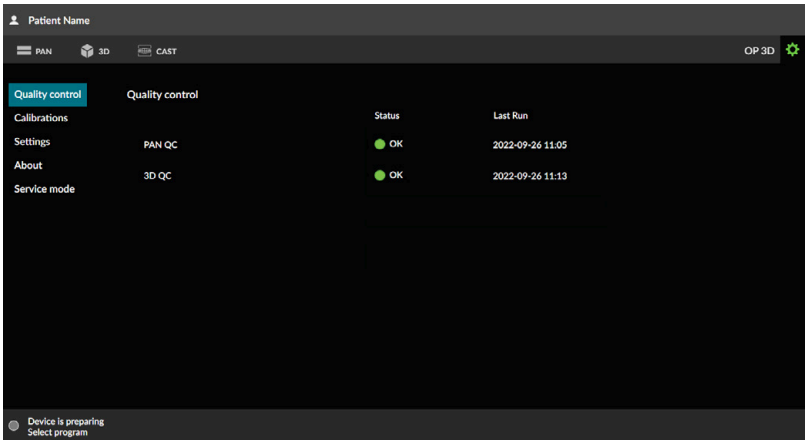
12. Detach the copper filter from the PAN/3D tubehead.

7.3.2 3D QC

NOTICE! *The device can select the correct QC program automatically after a QC phantom has been attached to the device.*

1. **GUI:** Go to device settings.

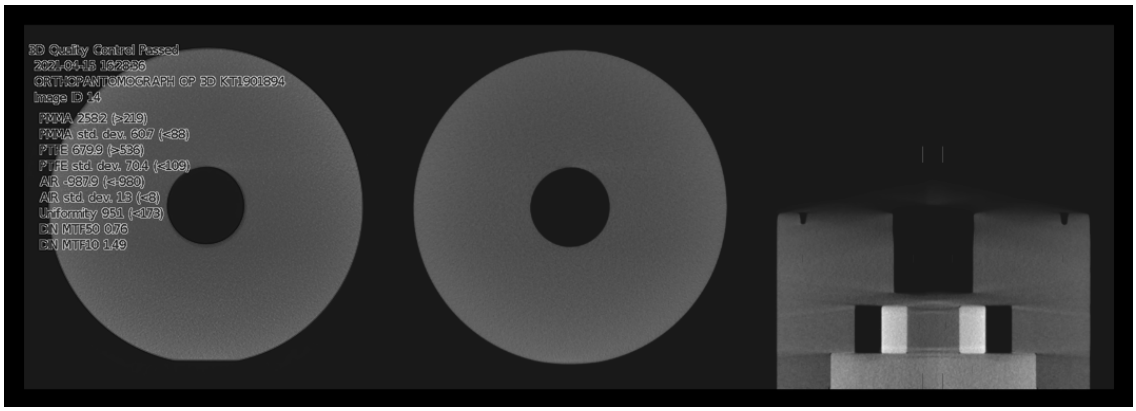
2. **GUI:** Select **3D QC** program from the **Quality control** menu.



3. Attach the 3D QC phantom holder and the 3D QC phantom to the lower shelf.

4. Protect yourself from radiation.
5. Press and hold the exposure button down to take the QC image.

6. The QC image preview appears on the GUI, showing the result of the check.



7. Acknowledge the preview by pressing the **OK** button on the GUI.

8. **Workstation:** Visually evaluate and inspect the 3D image for visual defects such as artifacts using the 3D imaging software.

   NOTICE! *The device determines if the QC image is PASSED or FAILED according to measured data, not based on the visible image quality.*

   NOTICE! *You should also compare the new QC image to the reference image taken during the installation or the latest service. Doing this helps you ensure that the image quality has remained constant.*

9. If the image fails or any visual defects are apparent, redo the QC program. If it fails again, recalibrate the device according to Calibration procedure on page 71 or contact service.

10. Detach the 3D QC phantom and the 3D QC phantom holder from the device.

7.4 Annual maintenance

An authorized service technician must carry out a full inspection of the device once a year.

The following checks must be carried out during the inspection:

- Check that the mains cord is not damaged in any way.
- Check that the protective earth is connected.
- Check that all fixing screws are tight.
- Check that the positioning lights operate correctly and are aligned correctly.
- Check that no oil is leaking from the tubehead.
- Check that all covers and mechanical parts are correctly secured and have not come loose.
- Check that any vents in the covers are not blocked with dust and that no dust has accumulated inside the device.
- Check the functionality of the power switch.
- Check the functionality of the Emergency stop switch.
- Check the Z-movement limits.
- Check that the exposure warning indicators work correctly.
- Check device movements and functionality of exposure button.

During the annual maintenance, all calibrations and QC programs must be performed according to the device installation manual.

The full maintenance procedure is described in detail in the device service manual.

8 Troubleshooting

Problem	Possible cause	Solution
Image is not transferred to the workstation.	Local network connection is disrupted, which causes loss of data.	The device stores the latest image until a confirmation of a successful transfer to the workstation is received. Re-establish the local network connection and the image data is transferred automatically. Do not power the device off or the image will be erased.
Message "Release control panel buttons" shows on the GUI.	• A button is pressed down during the during the device initialization. • Button mechanics in the control panel is stuck or broken.	**1.** Make sure that you are not pressing any button. The message should clear and the initialization continue. **2.** Contact service if the problem persists.
No connection to the device.	• The device is not powered on. • Problem with the local area network. • Check the device configuration.	**1.** Power the device on. **2.** Check the Ethernet cable connections on the workstation and the device. **3.** Restart the device and the workstation.
Device shows error message about disabled modalities.	Device has detected an issue with one or more of its functions and has disabled their use. After the next device boot the faulty functions are removed from the GUI.	Contact service. The device can be used normally with the enabled functions in the meantime.
Calibration and QC program date- and timestamps are incorrect.	The device receives the system time from the network it is connected to during start-up. If the time stamps in the Calibration and Quality control menus are incorrect, the system time has not been received correctly.	**1.** Restart the device and redo a calibration or QC program to check if the device receives the time correctly. **2.** Check that the system time is correct on the acquisition workstation, or any other computer that may operate as network time server in the local network. **3.** Check that the acquisition workstation has UDP port 123 opened in the firewall and the NetTime service installed and running.

9 Technical data

9.1 Technical specifications

General device information	
Manufacturer:	PaloDEx Group Oy Nahkelantie 160, FI–04300 Tuusula, FINLAND
Model:	PCX–1
Protection against electric shock	Class I
Degree of protection	Type B applied with no conductive connection to the patient
Protection against the ingress of liquids	IP20
Cleaning agents and protection against cross contamination	• Distilled water • Ethanol 96% • Isopropyl alcohol • Soapy water • Cavicide™ disinfectant • CaviWipes™ disinfectant • Metasys™ disinfectant • Disposable plastic covers for bite block, chin rest, lip support
Use environment	In environments where no flammable anesthetics nor flammable cleaning agents are present
Mode of operation	Continuous operation/intermittent loading
Source of power	Mains connection
EMC Classification	Class B
Conformity	This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture. The device is in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. RoHS directives 2011/65/EU and EU 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

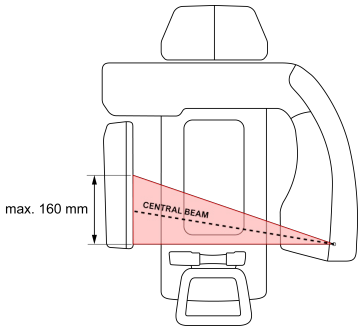
Tubehead assembly	
Tubehead assembly	THA/HVGEN PCX
Tube type	D–054S or equivalent Stationary anode
Tube voltage	60 – 95 kV
Max. tube current	16 mA
Target angle	5°
Focal spot	0.5 (IEC 60336/2020)
Total filtration	min. 3.4 mm Al @ 95 kV
Leakage technique factors	PAN: 4613 mAs/h @ 90 kV/12.5 mA 3D: 2880 mAs/h @ 95 kV/4 mA

NOTICE! *Leakage technique factors may be impacted by ambient temperature or used workstation.*

Electrical connections	
Nominal mains voltage	100 - 240 VAC Tolerance: ± 10%
Over-current release in the supply mains	220–240 VAC: 16A T 250V 100–120 VAC: 20A T 250V
Input power frequency	50 / 60 Hz
Nominal current	10 A @ 220–240 VAC, 15 A @ 100 – 120 VAC
Main fuses (F1 & F2)	220–240 VAC: Littelfuse 215 (Time–Lag) 10 A Cooper Bussman (Time Delay) S505H–10–R 100–120 VAC: Littelfuse 326 (SlowBlow) 15 A Cooper Bussman (Time Delay) MDA–15
External warning light fuse (F3)	Cooper Bussmann (Time Delay) S506–2–R 2 A
Power consumption	2.3 kVA @ 220–240 VAC, 1.65 kVA @ 100–120 VAC
Maximum impedance of mains	0.2 Ω
Mains cord	EU 230V: 16 A / 250 VAC; 50/60 Hz H05VV–F3G1.5 US 115V: 15 A / 125 VAC 50/60 Hz SJT 3 x AWG 14 US 230V: 15 A / 250 VAC 50/60 Hz SJT 3 x AWG 14
Exposure controller cable	Remote exposure switch: DINFLEX–YY 4 x AWG 26, max. 15 m
Data communication cable	CAT5e or higher UTP Ethernet cable

Positioning laser lights	
Panoramic laser lights (3) 3D laser lights (3)	IEC 60825–1/2014 (CLASS 1 LASER PRODUCT)

X–ray generator	
Generator	High frequency DC generator
Anode voltage	60 – 95 kV (± 5 kV)
Anode current	2 – 16 mA (± 20%)
Exposure time accuracy	± 5%
DAP display accuracy	± 25%
Spine compensation	kV / mA compensated
Accuracy of radiation output	> 95%
Air kerma reproducibility	> 95%

X-ray image detector	
Technology / Sensor type	IGZO TFT
Effective detector area	168,34 x 167,39 mm / 6.63 x 6.59 in 1772 x 1762 px
	

Device physical measures	
Source–Image distance (SID)	630 mm / 24.8 in
Dimensions (H x W x D)	1688–2443 x 770 x 1095 mm 66.5–96.2 x 30.3 x 43.1 in
Weight	120 kg / 265 lbs

Main device package	
Package dimensions (L x W x H)	1220 x 750 x 1100 mm 48 x 29.5 x 43.3 in
Package weight	179 kg / 395 lbs
Package material weight	Wood: 17 kg / 37 lbs Plywood: 10 kg / 22 lbs Cardboard: 10 kg / 22 lbs Plastic: 3.8 kg / 8.4 lbs Metal: 9.5 kg / 21 lbs

NOTICE! *The device package and packaging material weights may vary depending on the device configuration.*

Ambient temperatures	
Transportation and storage	-25 – +55°C RH 0 – 90% Atmospheric pressure 70 – 108 kPa
Operation Temperature	+10 – +35°C RH 30 – 80% Atmospheric pressure 70 – 106 kPa

9.2 Imaging program specifications

NOTICE! *The values given in this chapter are nominal values and apply to 220-240 VAC devices. The technical factors and their ranges are limited and may differ from the given values when using a device configured to 100 - 120 VAC.*

NOTICE! *Device's radiation dose production (DAP) varies from unit to unit. Radiation dose production, shown on the GUI, is calculated by scaling a measured reference dose production value with the selected imaging program technical factors and DAP correction factor.*

NOTICE! *Air KERMA production can be calculated by dividing the DAP value with the beam size at the sensor. The tables in this chapter contain approximate beam size at sensor level for determining the Air KERMA production.*

9.2.1 Panoramic programs

Panoramic programs & technical factors				
Magnification factor: 1.45 X-ray beam size at sensor: 8.1 cm^2 / 6.2 cm^2 (Pediatric)				
	Exposure time	**Image height**	**kV range**	**mA range**
Standard Panoramic	9.0 s	159.6 mm / 6.3 in 1680 px	60 - 70 kV 73 - 81 kV 85 - 90 kV	2.0 - 16.0 mA 2.0 - 14.0 mA 2.0 - 12.5 mA
Segmented Standard Panoramic	1.4 - 9.0 s			
Pediatric Panoramic	9.0 s	130.3 mm / 5.1 in 1372 px		
Segmented Pediatric Panoramic	1.4 - 9.0 s			
Bitewing	6.4 s (3.2 + 3.2 s)	116.7 mm / 4.6 in 1228 px		
TMJ, Lateral	4.0 s (2.0 + 2.0 s)	159.6 mm / 6.3 in 1680 px		

9.2.2 3D programs

NOTICE! *Available imaging programs and 3D FOV sizes depend on the device configuration and country specification.*

NOTICE! Voltage is always fixed to 95 kV in 3D imaging.

Scout programs & technical factors			
FOV	**Resolution**	**mA range**	**Exposure time**
5 x 5	Scout	2.0 - 12.5 mA	0.04 s
6 x 8	Scout		0.04 s
6 x 9	Scout		0.04 s
8 x 8	Scout		0.04 s
10 x 10	Scout		0.04 s
10 x 11	Scout		0.07 s
10 x 15	Scout		0.07 s

3D imaging programs & technical factors							
FOV	**Resolution**	**Voxel size**	**Beam size at sensor**	**mA range**	**Exposure time ***	**Exposure pulse**	**Duty cycle**
5 x 5	Low	280 µm	76 cm^2	2.0 - 12.5 mA	0.9 s	5 ms	5:24
	Standard	200 µm			2.7 s	10 ms	10:40
	High	125 µm		2.0 - 11.0 mA	11.5 s	Continuous	1:1
	Endo	80 µm		2.0 - 8.0 mA	19.4 s	Continuous	1:1
6 x 8	Low	320 µm	140 cm^2	2.0 - 12.5 mA	1.0 s	5 ms	5:24
	Standard	300 µm			2.9 s	10 ms	10:40
	High	200 µm		2.0 - 11.0 mA	11.9 s	Continuous	1:1
6 x 9	Low	320 µm	157 cm^2	2.0 - 12.5 mA	1.0 s	5 ms	5:24
	Standard	300 µm			2.9 s	10 ms	10:40
	High	200 µm		2.0 - 11.0 mA	11.9 s	Continuous	1:1
8 x 8	Low	320 µm	186 cm^2	2.0 - 12.5 mA	1.0 s	5 ms	5:24
	Standard	300 µm			2.9 s	10 ms	10:40
	High	200 µm		2.0 - 11.0 mA	11.8 s	Continuous	1:1
10 x 10	Low	320 µm	288 cm^2	2.0 - 12.5 mA	1.0 s	5 ms	5:24
	Standard	300 µm			2.9 s	10 ms	10:40
	High	200 µm		2.0 - 11.0 mA	12.0 s	Continuous	1:1
10 x 11	Low	320 µm	174 cm^2	2.0 - 12.5 mA	1.6 s	5 ms	5:40
	Standard	300 µm			3.0 s	5 ms	5:20
	High	200 µm			5.3 s	8 ms	8:20
10 x 15	Low	400 µm	229 cm^2	2.0 - 12.5 mA	1.3 s	5 ms	5:50
	Standard	350 µm			2.4 s	5 ms	5:25
	High	250 µm			4.9 s	9 ms	9:25

Voxel size tolerance: ±2%

* Exposure time with Medium size patient.

Dental cast program & technical factors			
FOV	**Resolution**	**Voxel size**	**Exposure time**
10 x 10	Low	320 µm	12.0 s
	Standard	300 µm	
	High	200 µm	
NOTICE! *Current is fixed to 4 mA*			

9.2.3 Patient size setting default values

Panoramic programs			
	Patient size		
	Small	Medium	Large
PAN	66 kV / 7.1 mA	66 kV / 10.0 mA	73 kV / 12.5 mA
Pediatric PAN	63 kV / 5.0 mA	66 kV / 6.3 mA	66 kV / 8.0 mA
Bitewing	66 kV / 7.1 mA	66 kV / 10.0 mA	73 kV / 12.5 mA
TMJ	73 kV / 8.0 mA	73 kV / 10.0 mA	73 kV / 12.5 mA

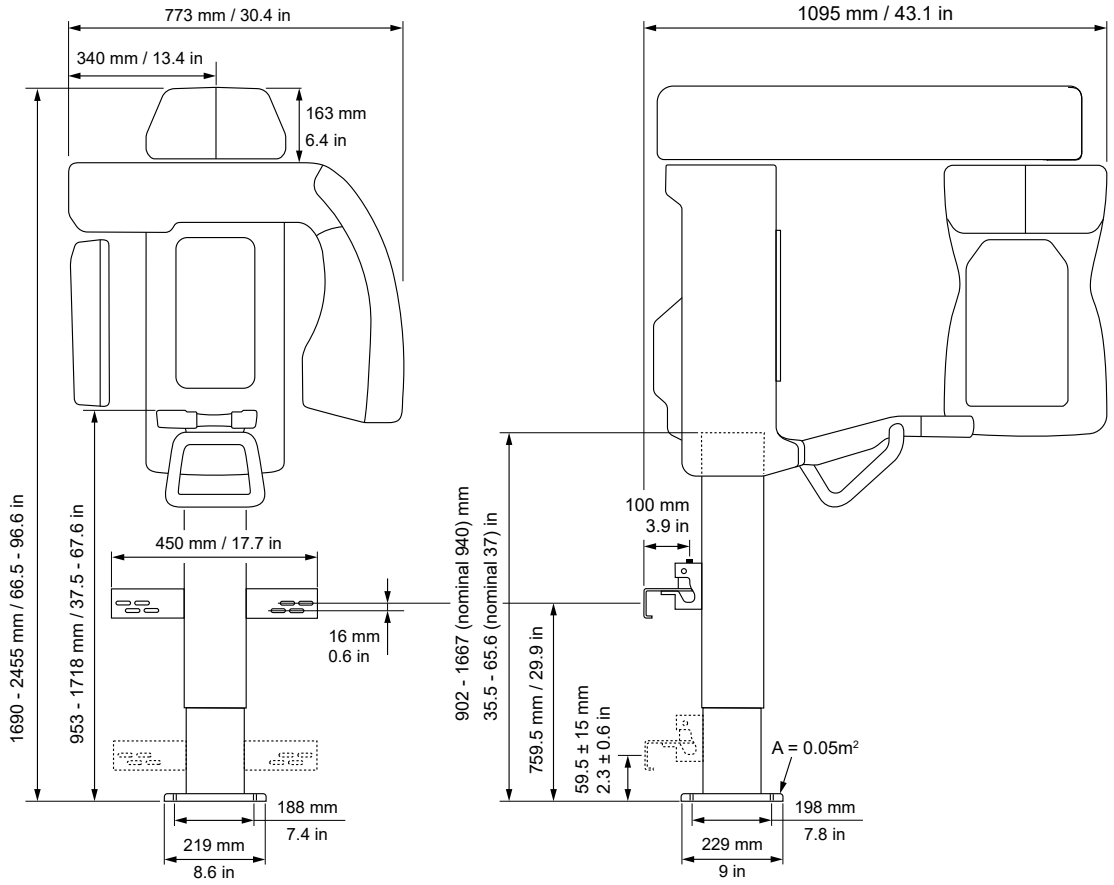
3D programs				
		Patient size		
FOV	**Resolution**	**Small**	**Medium**	**Large**
5 x 5	**Low**	4 mA	6.3 mA	8 mA
	Standard			
	High		5 mA	
	Endo		6.3 mA	
6 x 8	**Low**	2.8 mA	4 mA	6.3 mA
	Standard			
	High		3.2 mA	
6 x 9	**Low**	2.8 mA	4 mA	6.3 mA
	Standard			
	High		3.2 mA	
8 x 8	**Low**	2.8 mA	4 mA	6.3 mA
	Standard			
	High		3.2 mA	
10 x 10	**Low**	2.8 mA	4 mA	6.3 mA
	Standard			
	High		3.2 mA	
10 x 11	**Low**	4 mA	5 mA	8 mA
	Standard	6.3 mA	7.1 mA	10 mA
	High		8 mA	
10 x 15	**Low**	4 mA	5 mA	8 mA
	Standard	6.3 mA	7.1 mA	10 mA
	High		8 mA	
NOTICE! *Voltage is fixed to 95 kV*				

9.3 Patient contacting parts

Part type	Type of contact	Contact duration
Head Support	Skin	<5 min
Chin Rest with a disposable cover	Skin	<5 min
Bite Block with a disposable cover	Mucosal membrane	<5 min
Lip Support with a disposable cover	Skin	<5 min
Patient Handles	Skin	<5 min

9.4 Device dimensions

9.4.1 Main device dimensions



NOTICE! *The maximum height of the device is adjustable during the installation calibration.*

9.5 Symbols that may appear on the device or its parts


Manufacturer


Date of manufacture

Medical device

Serial number

Catalog or model number

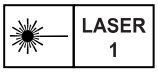
Lot number

Unique Device Identification


Caution


General warning


Radiation warning



Laser Class 1 warning


Radiation emitting device


Type B Applied part


Dangerous voltage

On or enabled


Off or disabled


External warning light


Exposure switch


Remote exposure switch


Ethernet

Protective earth (ground)

Focal spot

Total X-ray filtration

Do not reuse

Recyclable

Instructions for use

Refer to the instructions for use for more information. The instructions can be supplied electronically or in paper format.

Refer to instruction manual

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

CE Mark

Marking for devices to be sold in European Economic Area with Notified Body number

UKCA (UK Conformity Assessed) marking

Swiss authorised representative

NRTL Mark

Conforms to U.S. and Canada national safety standards

Importer

Fragile, Handle with Care (Packaging)

This way up (Packaging)

Keep dry (Packaging)

Maximum number of boxes that can be stacked on the bottom box (Packaging)

9.6 Electromagnetic Compatibility (EMC) tables

NOTICE! *Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information.*

IEC 60601-1-2 ed4.1 testing has verified that electromagnetic interference stimulus has no effect on safety critical functionality of the device. This includes the device lifting movement, accuracy of loading factors and reproducibility of the radiation output.

If abnormal performance is observed, such as degradation of essential performance in form of changes in loading factors, additional measures may be necessary, such as reorienting or relocating the device. Suggested actions according to RF immunity of non-life-support equipment or system IEC 60601-1-2 ed4.1 on page 93.

The device is suitable for use in both professional healthcare (hospitals/large clinics) facility environment and home healthcare (clinics in domestic establishments and those directly connected to the public low-voltage power supply) environment.

Exceptions for professional healthcare facility environment: Not to be used or installed near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

Electromagnetic emissions IEC 60601-1-2 ed4.1

<table>
<tr><th colspan="3">PCX-1 is suitable for use in the specified electromagnetic environment. The purchaser or user of PCX-1 should assure that it is used in an electromagnetic environment as described below:</th></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment</th></tr>
<tr><td>Radio-Frequency Emissions CISPR11</td><td>Group 1</td><td>PCX-1 uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>Radio-Frequency Emissions CISPR11</td><td>Class B</td><td rowspan="3">PCX-1 is suitable for use in both at professional healthcare (hospitals/large clinics) facility environment and home healthcare (clinics in domestic establishments and those directly connected to the public low-voltage power supply) environment.

Exceptions for professional healthcare facility environment : Not to be used or installed near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.</td></tr>
<tr><td>Harmonic emissions
IEC61000-3-2</td><td>IEC61000-3-2
Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC61000-3-3</td><td>Complies</td></tr>
</table>

Electromagnetic immunity IEC 60601-1-2 ed4.1

PCX-1 is suitable for use in the specified electromagnetic environment. The purchaser or user of PCX-1 should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV for contact discharge ±2, 4, 8, 15 kV for air discharge	± 8 kV for contact discharge ±2, 4, 8,15 kV for air discharge	Floors are wood, concrete, or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines (100 kHz) ±1 kV for input/output lines (100kHz)	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality is that of a typical commercial and/or hospital environment
Surge IEC61000-4-5	± 0.5, 1 kV Line-to-line	± 0.5, 1 kV Line-to-line	Mains power quality is that of a typical commercial and/or hospital environment.
	± 0.5, 1, 2 kV Line-to-ground	± 0.5, 1, 2 kV Line-to-ground	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality is that of a typical commercial and/ or hospital environment. If the user of **PCX-1** requires continued operation during power mains interruptions, it is recommended that **PCX-1** be powered from an uninterruptible power supply.
	0 % U_T; 1 cycle At 0°	0 % U_T; 1 cycle At 0°	
	70 % U_T; 25/30 cycles At 0°	70 % U_T; 25/30 cycles At 0°	
	0 % U_T; 250/300 cycle	0 % U_T; 250/300 cycle	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/ or hospital environment. The device shall not be used closer than 15cm to sources of 50/60Hz magnetic field.
NOTICE! *U_T is the a.c. mains voltage prior to application of the test level.*			

RF immunity of non-life-support equipment or system IEC 60601-1-2 ed4.1

PCX-1 is suitable for use in the specified electromagnetic environment. The purchaser or user of PCX-1 should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Conducted RF IEC 61000-4-6	3V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment are used no closer to any part of PCX-1 including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = 2\sqrt{P}$ 150kHz-80MHz $d = 0,6\sqrt{P}$ 80MHz to 800 MHz $d = 0,6\sqrt{P}$ 800 MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* are less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz Immunity to proximity fields from RF wireless communication equipment, levels according to IEC 60601-1-2 table 9.	10 V/m 80 MHz to 2.7 GHz Immunity to proximity fields from RF wireless communication equipment, levels according to IEC 60601-1-2 table 9.	
Proximity magnetic fields IEC 61000-4-39	• 30 kHz: 8 A/m • 134.2 kHz: 65 A/m • 13.56 MHz: 7.5 A/m	• 30 kHz: 8 A/m • 134.2 kHz: 65 A/m • 13.56 MHz: 7.5 A/m	

*Field strengths from fixed transmitters, such as base stations for cellular telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be estimated accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be performed. If the measured field strength exceeds the RF compliance level above, observe **PCX-1** to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating **PCX-1**.

Guidance for actions taken can be found from AAMI TIR 18:2010, Guidance on electromagnetic compatibility of medical devices in healthcare facilities.

NOTICE! *Precautions to take if the use location is near (e.g. less than 1,5 km from) AM, FM or TV broadcast antennas.*

Over the frequency range 150 kHz to 80 MHz, field strengths are less than 3 V/m. **The Recommended Separation Distances are listed in the next table.

NOTICE! *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*

NOTICE! *RF communications equipment can affect medical electrical equipment.*

NOTICE! *If the network connection is disrupted momentarily because of electromagnetic disturbances, re-establish the local network connection. The latest image is stored in the device and transferred automatically to the workstation. Do not power off the device as the image will be erased.*

Test specifications for enclosure port immunity to RF wireless communications equipment IEC 60601-1-2 ed4.1 table 9

PCX-1 is suitable for use in the specified electromagnetic environment. The purchaser or user of PCX-1 should assure that it is used in an electromagnetic environment as described below:				
Test frequency (MHz)	**Band** * (MHz)	**Service** *	**Modulation**	**Immunity test level** (V/m)
385	380 to 390	TETRA 400	Pulse modulation ** 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM *** ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation ** 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ** 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ** 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ** 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation ** 217 Hz	9
5500				
5785				

If necessary to achieve the immunity test level, the distance between the transmitting antenna and the ME equipment or ME system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

* For some services, only the uplink frequencies are included.

** The carrier shall be modulated using a 50% duty cycle square wave signal.

*** As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

Separation distances

Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2			
The PCX-1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of PCX-1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PCX-1 as recommended below, according to the maximum output power of the communications equipment.			
Frequency of Transmitter Equation Rated Maximum Output Power of Transmitter (watts)	150 kHz to 80 MHz $d = 2\sqrt{P}$ Separation Distance (meters)	80 MHz to 800 MHz $d = 0,6\sqrt{P}$ Separation Distance (meters)	800 MHz to 2.7 GHz $d = 0,6\sqrt{P}$ Separation Distance(meters)
0,01	0,20***	0,06***	0,06***
0,1	0,63	0,19***	0,19***
1	2	0,6	0,6
10	6,32	1,90	1,90
100	20	6	6
For transmitters rated at maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. ***WARNING!*** **** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12") to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. See Separation distances on page 95.* ***NOTICE!*** *At 80 MHz, the separation distance for the higher frequency range applies.* ***NOTICE!*** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*			

USE LIMITATION:

External components

WARNING! *Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.*

INSTALLATION REQUIREMENTS & ENVIRONMENT CONTROL:

In order to minimize interference risks, the following requirements shall apply.

Cables shielding & grounding

All interconnect cables to peripheral devices must meet the requirements given in Technical specifications on page 80. Use of incorrect cables may result in the device causing radio frequency interference.

Electrostatic discharges environment & recommendations

In order to reduce electrostatic discharge interference, a charge dissipative floor should be installed to prevent charge accumulation.

- The dissipative floor material must be connected to the system reference ground, if applicable.
- Relative humidity must be maintained above 30 percent.

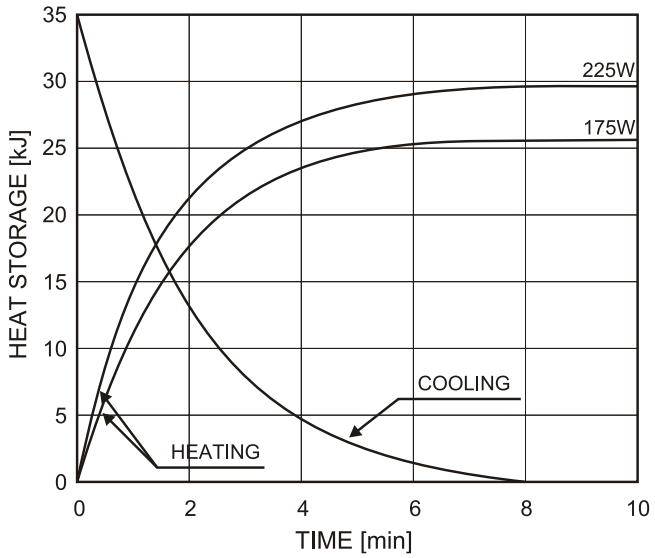
Stacked components & equipment

⚠ ***WARNING!*** *The PCX-1 should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the PCX-1 should be observed to verify normal operation in the configuration in which it will be used.*

Interference may occur in the vicinity of equipment marked with the following symbol:

9.7 X-ray tube assemblies

Anode Thermal Characteristics

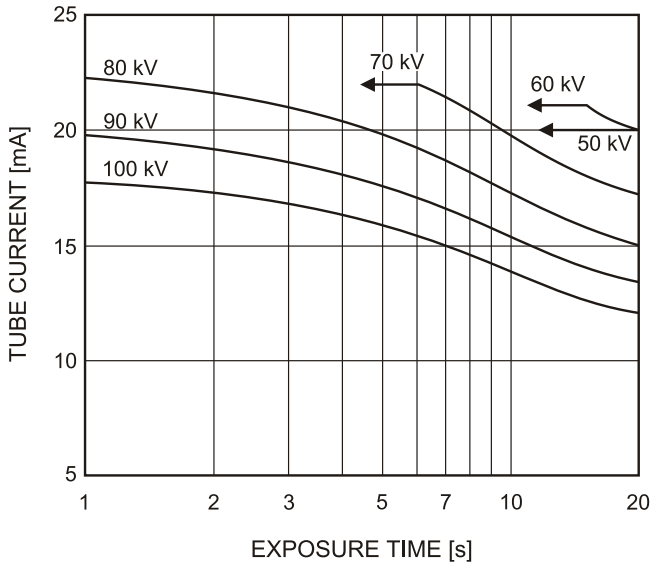


Maximum Rating Charts

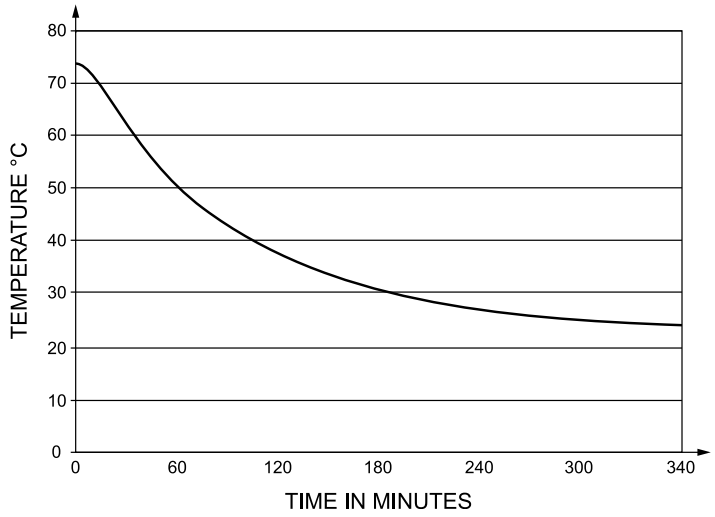
(Absolute maximum rating charts)

DC (Center-Grounded)

Focal Spot: 0.5 mm



TUBE HOUSING ASSEMBLY COOLING CHARACTERISTICS



9.8 Workstation minimum requirements

NOTICE! *For most up to date and more detailed system requirements and setup instructions, see the* ***dental imaging software*** *and* ***DTX Studio Driver*** *documentation.*

NOTICE! *A workstation used in a medical system must always meet the requirements in IEC 62368-1 (previously IEC 60950) standard.*

NOTICE! *A workstation that does not fulfill medical safety standard IEC 60601-1 must be located outside of the patient environment, at least 1.5 m / 4.9 ft from the device.*

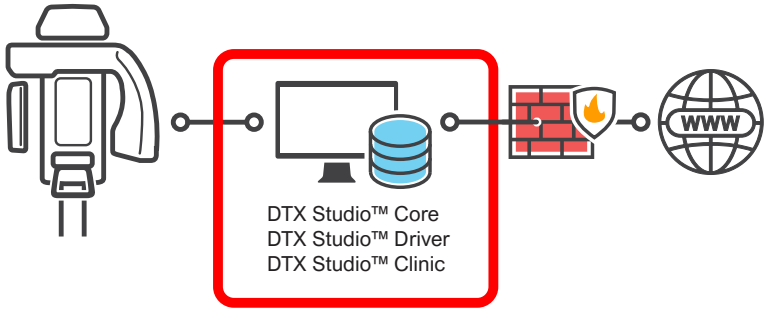
Image acquisition workstation with database and image data	
	
CPU	Intel Core i5, i7 or Xeon, 4-cores or more
RAM	16 GB, ECC (error correcting) recommended
GPU	• NVIDIA Quadro P1000, T1000, M2000, K2200 4GB • NVIDIA GeForce GTX 1650, 1050 Ti 4GB Only validated GPU's and WHQL certified driver versions may be used. GPU requirements and driver versions are dependent on the DTX Studio Driver version installed. ***NOTICE!*** *Additional GPU's may be certified for use with this device. Always refer to the DTX Studio Driver documentation for latest details on the supported GPU and driver versions. GPU requirements may change at any time when a new DTX Studio Driver is released.*
Storage space	• 1 TB or more for image data. • 256 GB SSD for the operating system and the imaging software is recommended. **Image sizes:** • PAN: 5 - 10 MB • 3D: 10 - 800 MB
Operating system	• Windows 11 Pro or Enterprise 64-bit • Windows 10 Pro or Enterprise 64-bit ***NOTICE!*** *32-bit Windows installations are not supported.*
Device Driver	DTX Studio Driver 24.2 (latest version is always preferred)

Image acquisition workstation with database and image data	
Network	• Supported interface chipsets: Intel i210, i219, i225 • Gigabit Ethernet 1000Base-T • The device must be connected to a private, firewall protected local area network to ensure proper data security. All connections from outside of the local area network to the device must be blocked. Connections between the device and the workstation in the local area network must be allowed.
Display	1920 x 1080 (Full HD) resolution or higher recommended.
Backup	A suitable backup system is required to safeguard user-created data. Backup of user-created data is solely the responsibility of the user. The manufacturer disclaims responsibility for backup of user-created data. Contact your IT provider regarding selection of a suitable backup system according to your data storage needs.
UPS	UPS (uninterruptible power supply) is recommended to prevent data corruption or loss in the event of a power failure.

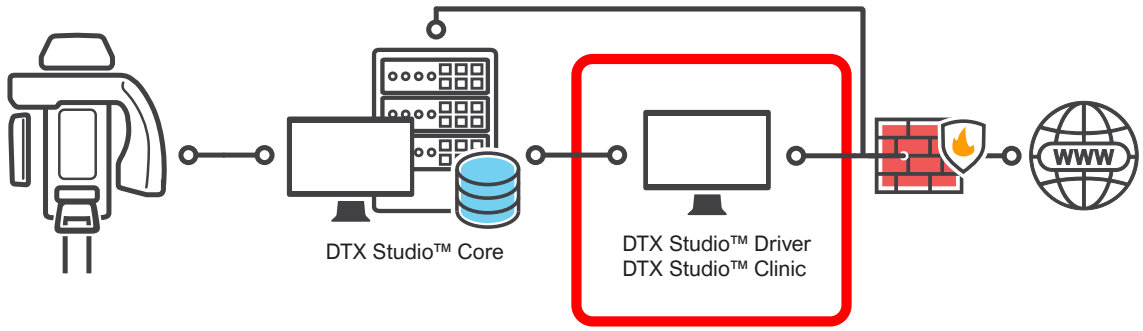
Image acquisition workstation	
	
CPU	Intel Core i5, i7 or Xeon, 4-cores or more
RAM	8 GB, ECC (error correcting) recommended
GPU	• NVIDIA Quadro P1000, T1000, M2000, K2200 4GB • NVIDIA GeForce GTX 1650, 1050 Ti 4GB Only validated GPU's and WHQL certified driver versions may be used. GPU requirements and driver versions are dependent on the DTX Studio Driver version installed. ***NOTICE!*** *Additional GPU's may be certified for use with this device. Always refer to the DTX Studio Driver documentation for latest details on the supported GPU and driver versions. GPU requirements may change at any time when a new DTX Studio Driver is released.*
Storage space	• 1 TB or more for image data. • 256 GB SSD for the operating system and the imaging software is recommended. **Image sizes:** • PAN: 5 - 10 MB • 3D: 10 - 800 MB

Image acquisition workstation	
Operating system	• Windows 11 Pro or Enterprise 64-bit • Windows 10 Pro or Enterprise 64-bit ***NOTICE!*** *32-bit Windows installations are not supported.*
Device Driver	DTX Studio Driver 24.2 (latest version is always preferred)
Network	• Supported interface chipsets: Intel i210, i219, i225 • Gigabit Ethernet 1000Base-T • The device must be connected to a private, firewall protected local area network to ensure proper data security. All connections from outside of the local area network to the device must be blocked. Connections between the device and the workstation in the local area network must be allowed.
Display	1920 x 1080 (Full HD) resolution or higher recommended.

2D/3D Viewing workstation
See dental imaging software requirements

Database server
See dental imaging software requirements

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