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PLANMECA

Planmeca Viso® v2

EN

user's manual

The manufacturer, assembler and importer are responsible for the safety, reliability and performance of the unit only if:

- installation, calibration, modification and repairs are carried out by qualified authorised personnel
- electrical installations are carried out according to the appropriate requirements such as IEC 60364
- equipment is used according to the operating instructions.

Planmeca pursues a policy of continual product development. Although every effort is made to produce up-to-date product documentation this publication should not be regarded as an infallible guide to current specifications. We reserve the right to make changes without prior notice.

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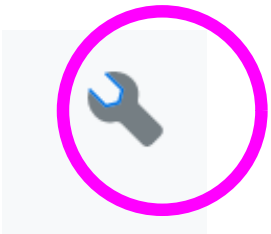
1 Introduction

The manual applies to Planmeca Viso G3, Viso G5 and Viso G7 X-ray units.



NOTE

This manual is valid for Planmeca Viso software version 2.1.0 or later. This software version is compatible with Romexis software version 6.4.4 or later. To check the software version of your X-ray unit, select Settings > About > 4100 Component Information > Viso ProTouch SW Version.

Make sure that you are fully acquainted with the appropriate radiation protection measures and these instructions before you use the X-ray unit. Note that your X-ray unit may not feature all the options described in these instructions. Refer to section "Licences (1700)" on page 86 for a list of available licences.

These instructions include options that may not be available in all countries.

NOTE

The X-ray unit may be used by health care professionals only.

NOTE

Cone beam imaging should not be used for routine (or screening) examinations. The imaging examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.

CE 0598

This X-ray unit fulfils the requirements of Medical Device Regulation (EU) 2017/745, Class IIB and RoHS, REACH and WEEE.

BASIC UDI-DI (Global Model Number): 6430035420145N (Viso G5), 6430035420155Q (Viso G7)

1.1 Device description

The X-ray unit uses cone beam computed tomography (CBCT) to produce three-dimensional (3D) images of the maxillofacial and ENT anatomies. Two-dimensional (2D) images are produced with the tomosynthesis method (panoramic imaging) as well as conventional 2D radiography (cephalometric imaging, 2D views). If the X-ray unit has an active ProFace licence, you can take a 3D photo of the patient's face.

In CBCT a cylindrical volume of data is captured in one imaging procedure. The data consists of several hundred sample images which are taken from different directions to cover a certain pre-programmed target area. These samples are used for 3D reconstruction (using a separate 3D reconstruction PC) that can be viewed in three dimensions using a separate workstation and the Planmeca Romexis software.

1.2 Intended use

The X-ray unit system is a system intended to produce two-dimensional (2D) and three-dimensional (3D) digital X-ray images as well as three-dimensional (3D) optical images of the dento-maxillo-facial, cervical spine and ENT (Ear, Nose and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

The 3D face photo can be used for patient education or in order to follow the results of medical treatments.

1.2.1 Indications for use

Specific recommended indications for use are:

Implantology, Endodontics, Dental and maxillofacial traumatology, Dental, oral and maxillofacial surgery, Orthodontics, Diagnosis and therapy of craniomandibular dysfunctions, Imaging of dentomaxillofacial and cervical spine regions, ENT imaging.

1.2.2 Usage environment

This X-ray unit is intended to be used in a professional healthcare environment such as dental offices, clinics and similar environments.

1.2.3 Intended user

The unit is intended to be used only under supervision of a dental/health care professional.

1.2.4 Intended patient population

Age	From infant to geriatric without any specific age limits
Sex	Not relevant
Weight	Not relevant
Height	Not relevant
Other	Patient must be in conscious state

1.3 Clinical benefits

Planmeca Viso is intended to provide clinically valuable diagnostic information for clinicians and radiologists in the diagnosis of possible injuries and diseases with regions specified in the intended use.

2 Associated documentation

The X-ray unit is supplied with the following manuals:

- User’s Manual
- Installation Manual
- Technical Manual

These manuals are intended to be used in conjunction with the documentation for the Planmeca Romexis program. The Romexis package contains the following manuals:

- User’s Manual
- Technical Manual

The original language of the manuals is English.

NOTE

The User's Manuals are available on Planmeca's website.

- For X-ray units, select Material Bank > Manuals > Imaging.
- For software products, select Material Bank > Manuals > Software.

3 Product registration

About this task

Follow these steps to register your X-ray unit on Planmeca's website.

Steps

1. Select **Settings > About > 4300 Product Registration**.
2. Do one of the following:
   - If you have a QR (Quick Response) code reader installed on your mobile device (e.g. smartphone), hold the device steady over the QR code shown on the screen.

     You are directed to Planmeca's product registration page.
   - Go to Planmeca's product registration page at https://www.planmeca.com/register.
3. Select the green check mark button.
4. Follow the instructions on the registration page.

NOTE

When you enter the X-ray unit serial number, you have to include any letters shown at the beginning of the number.

4 Symbols on product labels

Fulfils the requirements of Medical Device Regulation (EU) 2017/745.

SGS listing marking according to US and Canadian standards (ANSI/AAMI ES60601-1 and CAN/CSA C22.2 No. 60601- 1).

Manufacturer (Standard ISO 15223-1).

Date of manufacture (Standard ISO 15223-1).

Serial number (Standard ISO 15223-1).

Medical Device (Standard ISO 15223-1).

Consult electronic instructions for use (Standard ISO 15223-1).

Type B applied part (Standard IEC 60417).

Separate collection for electrical and electronic equipment according to Directive 2012/19/EU (WEEE).

Refer to instruction manual/booklet (Standard ISO 7010).

Emergency stop (Standard IEC 60417).

Warning: Electricity (Standard ISO 7010).

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Electrostatic sensitive device (Standard IEC 60417).

Warning, hot surface (Standard ISO 7010).

General warning (Standard ISO 7010).

5 Safety precautions

WARNING

The following safety precautions must be observed in order to avoid the risk of personal injury or damage to the X-ray unit.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the X-ray unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION

FOR US USERS:

Federal law restricts this device to sale by or on the order of a health care professional.

CAUTION

This X-ray unit may be dangerous to both patient and operator unless safe exposure values are used and correct operating procedures are observed.

CAUTION

It is very important that the place where the X-ray unit is to be used and the position from which the user is to operate the X-ray unit are correctly shielded.

Since radiation safety requirements vary from country to country and state to state it is the responsibility of the user to ensure that all local safety requirements are met.

CAUTION

The patient positioning lights are laser lights. Do not stare into the laser beam.

CAUTION

If an exposure is interrupted (e.g. exposure button is released or emergency stop button activated), the patient must be guided away from the X-ray unit before the C-arm is moved.

CAUTION

Do not connect items which are not specified as part of the system.

CAUTION

Do not touch an electrical connector and the patient at the same time.

CAUTION

If the X-ray unit shows any signs of oil leakage, switch the X-ray unit off and contact your service technician for help.

CAUTION

Do not use the X-ray unit in an oxygen rich environment or in the presence of flammable anesthetics.

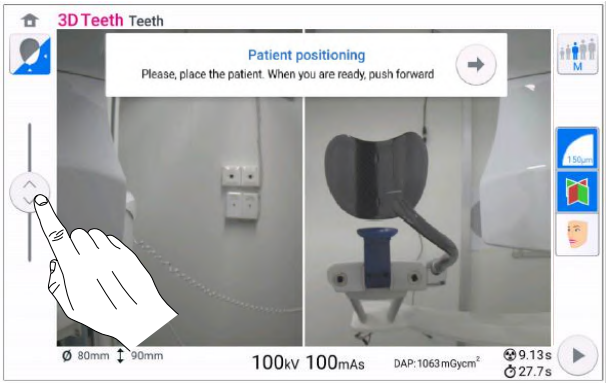
CAUTION

Never use a defective or damaged X-ray system. Contact your service technician for help.

CAUTION

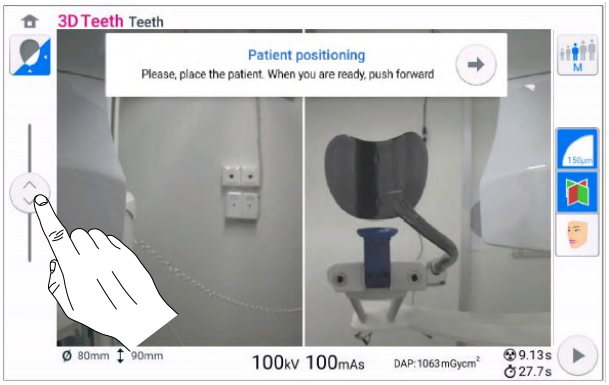
Do not modify the X-ray unit. The X-ray unit must be serviced by qualified personnel only.

CAUTION



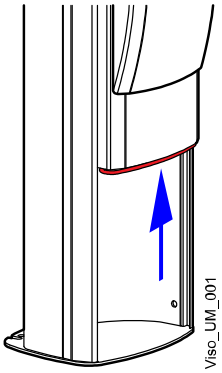
Be careful that the X-ray unit does not hit the ceiling when you move the X-ray unit up. The maximum height can be adjusted to suit offices with a low ceiling. Contact your service technician for help.

CAUTION



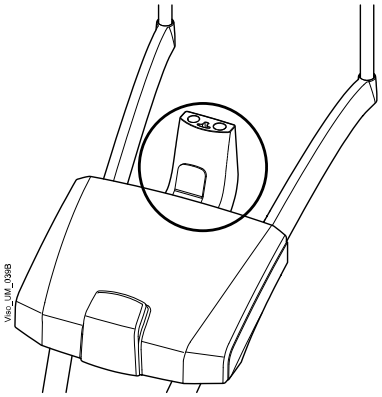
Make sure that there is no object under the X-ray unit when you move the X-ray unit down. If something is in danger of becoming trapped, release the height adjusting slider immediately to stop the movement. Clear any obstruction before moving the X-ray unit again.

NOTE



The column movement stops automatically if the emergency stop plate at the bottom is pressed upward. Clear any obstruction before moving the X-ray unit again.

NOTE



The adapter detaches itself from the patient support base if subjected to excessive load. This is a safety feature that ensures that the patient's head cannot get stuck if the patient faints or begins to fall when they are positioned in the X-ray unit.

NOTE

When positioning seated patients (e.g. in a wheelchair) always first move the X-ray unit down before you position the patient in the X-ray unit.

NOTE

Cone beam imaging should not be used for routine (or screening) examinations. The imaging examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.

NOTE

When it is likely that evaluation of soft tissues will be required as part of the patient’s radiological assessment, conventional CT or MR medical imaging should be used rather than CBCT.

NOTE

Before taking an exposure, ask any female patient of childbearing age whether she might be pregnant. Benefits of the examination should always outweigh the risks. Consult your local authorities for recommendations.

NOTE

FOR CANADIAN USERS:

All patients must be provided with a shielded apron for gonad protection and a thyroid shield. The use of a thyroid shield is especially important in children. The shielded apron and thyroid shield should have a lead equivalence of at least 0.25 mm on both sides (front and back of the patient).

NOTE

If the X-ray unit has been stored at temperatures under +10°C for more than a few hours, time must be allowed for the unit to reach room temperature before turning it on.

NOTE

Ensure efficient air conditioning in the X-ray room. It is recommended to keep the room temperature between +20°C and +25°C at all times.

NOTE

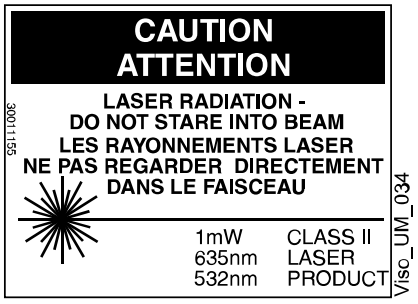
If exposures are taken in rapid succession, the X-ray tube may overheat and a cooling time will flash on the control panel. The cooling time indicates the delay before the next exposure can be taken.

NOTE

If the X-ray system is not connected to an Uninterruptible Power Supply (UPS), switch the X-ray unit off and disconnect the PCs from the mains during lightning storms.

NOTE

FOR US & CANADIAN USERS:



The laser lights are class II laser products (21 CFR § 1040.10).

NOTE

FOR EUROPEAN USERS:

The laser lights are class 1 laser products (Standard IEC / EN 60825-1: 2007).

NOTE

EMC requirements have to be considered, and the equipment must be installed and put into service according to the specific EMC information provided in the accompanying documents.

NOTE

External equipment intended for connection to signal input, signal output or other connectors, shall comply with relevant IEC standard (e.g. IEC 60950 for IT equipment and the IEC 60601 series for medical electrical equipment). In addition, all such combinations - systems - shall comply with the standard IEC 60601-1, Safety requirements for medical electrical systems. Equipment not complying to IEC 60601 shall be kept outside the patient area (more than 2m (79 in.) from the X-ray unit). Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements of IEC 60601-1. If in doubt, contact your service technician or local representative for help.

NOTE

Contact your service technician if you notice a decrease in image quality.

NOTE

Contact your service technician if you have taken an exposure but the image does not appear in the Planmeca Romexis program. You can import the last ten images manually into Planmeca Romexis.

NOTE

Do not handle liquids near or on the X-ray unit.

NOTE

Never place or hang any objects on any part of the X-ray unit.

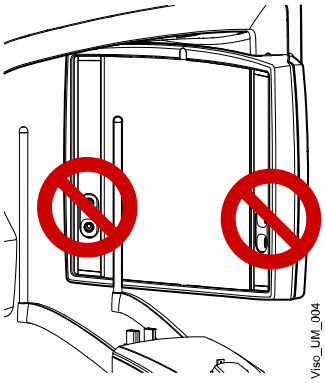
NOTE

Make sure that neither you nor your patient can get caught or hooked up on any part of the X-ray unit. Keep loose items of clothing, hair and jewellery tucked away safely.

NOTE

Do not touch the arm structures when the X-ray unit is moving.

NOTE



Do not touch the glass windows of the sensor. Fingerprints or other stains on the glass surface negatively affect image quality.

NOTE

Portable mobile devices and other high frequency electromagnetic energy emitting devices used close to the X-ray system may affect the system's performance. Diagnostic information of the X-ray image may be lost and unnecessary X-ray dose to the patient may result.

5.1 Reporting serious incidents

Serious incidents that have occurred in relation to the X-ray unit must be reported to the manufacturer and the local competent authority.

6 Pediatric use

6.1 Introduction

Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (typically children under the age of 13).

Exposure to ionising radiation is of particular concern in pediatric patients because:

1. For certain organs and tumor types, younger patients are more radiosensitive than adults (i.e. the cancer risk per unit dose of ionising radiation is higher for younger patients).
2. Use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients.
3. Younger patients have a longer expected lifetime over which the effects of radiation exposure may manifest as cancer.

To help reduce the risk of excessive radiation exposure, you should follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to obtain images that are adequate clinically.

6.2 References for pediatric dose optimisation

The following resources provide information about pediatric imaging radiation safety and / or radiation safety for cone beam computed tomography devices:

- Pediatric X-ray Imaging (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/ucm298899.htm)
- Medical X-ray Imaging (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm)

6.3 Device specific features and instructions

The X-ray unit provides the following specific design features and instructions that enable safer use with pediatric patients:

Design feature important to pediatric imaging (standard or optional)	Refer to section
Head support that can be adjusted for pediatric patients (standard)	"Patient positioning" on page 35 (2D panoramic exposure) and "Patient positioning" on page 52 (3D exposure)
Preset control settings which clearly specify the intended size range (standard)	"Selecting patient size" on page 41 (2D panoramic exposure) and "Selecting patient size" on page 56 (3D exposure)
Display and recording of patient dose or dose index and ability to record other patient information, e.g. age (standard)	"Control panel" on page 20 (Checking DAP values) Planmeca Romexis User's Manual (Entering date of birth and Generating X-ray log book)
ULD (Ultra Low Dose) setting (optional)	"Selecting image resolution, Ultra Low Dose (ULD) and ProFace" on page 58

Design feature important to pediatric imaging (standard or optional)	Refer to section
CALM (Correction Algorithm for Latent Movement) setting (optional)	"Selecting Artefact Removal Algorithm (ARA), patient movement correction (CALM) and resolution optimisation (PRO)" on page 61
Scout views (standard)	"Taking scout views" on page 62
User's manuals that consider the balance of radiation exposure and image quality (standard)	"Introduction" on page 1, "Adjusting exposure values for current exposure" on page 41 (2D panoramic exposure) and "Adjusting exposure values for current exposure" on page 59 (3D exposure)

The X-ray unit provides the following specific testing information and instructions.

Testing information	Refer to section
Estimated patient dosimetry covering pediatric size ranges (standard)	"Control panel" on page 20 (Checking DAP values) Planmeca Romexis User's Manual (Generating X-ray log book)
Quality control instructions including tests to ensure proper operation across a broad patient size range (standard)	"3D quality control" on page 74

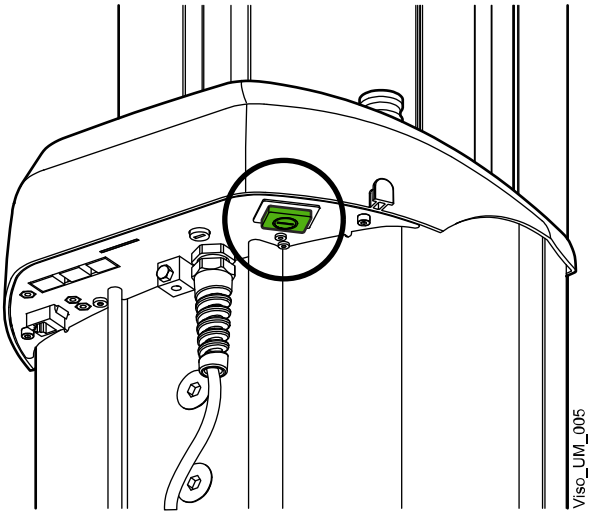
7 Switching X-ray system on

NOTE

To prolong the lifetime of your X-ray system, always switch the X-ray system off when it is not in active use.

7.1 Switching X-ray unit on

The on / off switch is located on the underside of the column top.

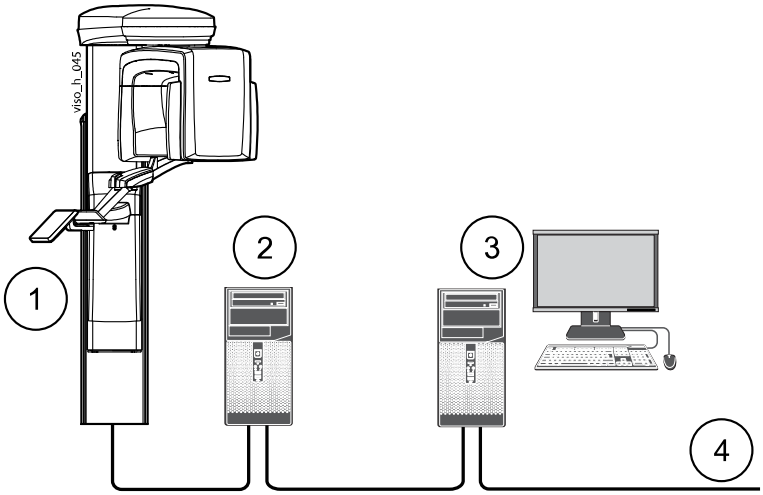


7.2 Switching 3D reconstruction PC on

The on / off switch is located at the top of the computer.

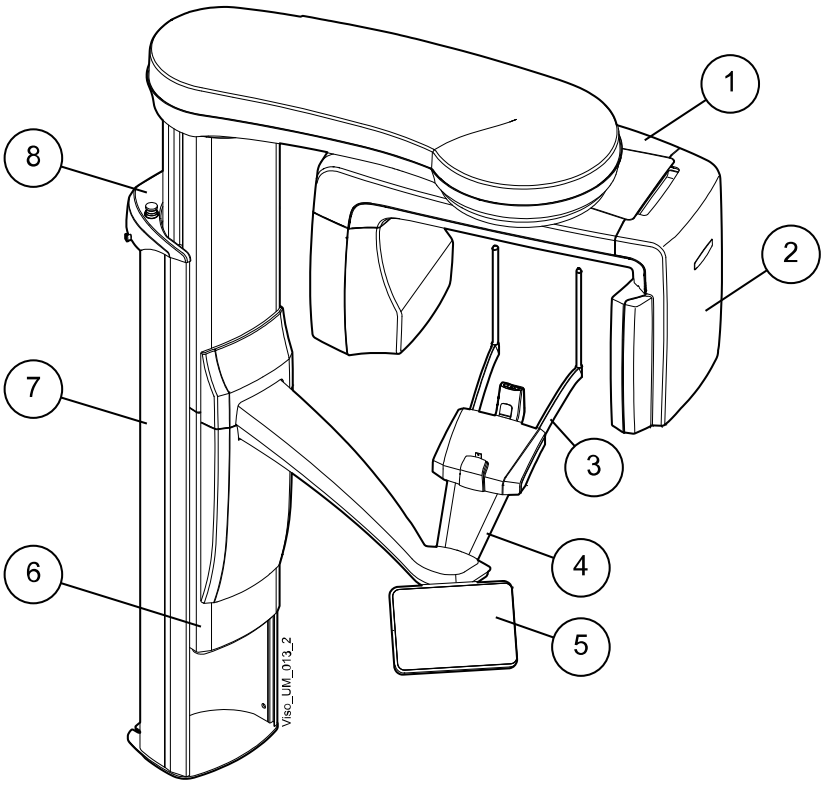
8 Main parts

8.1 General view of X-ray system



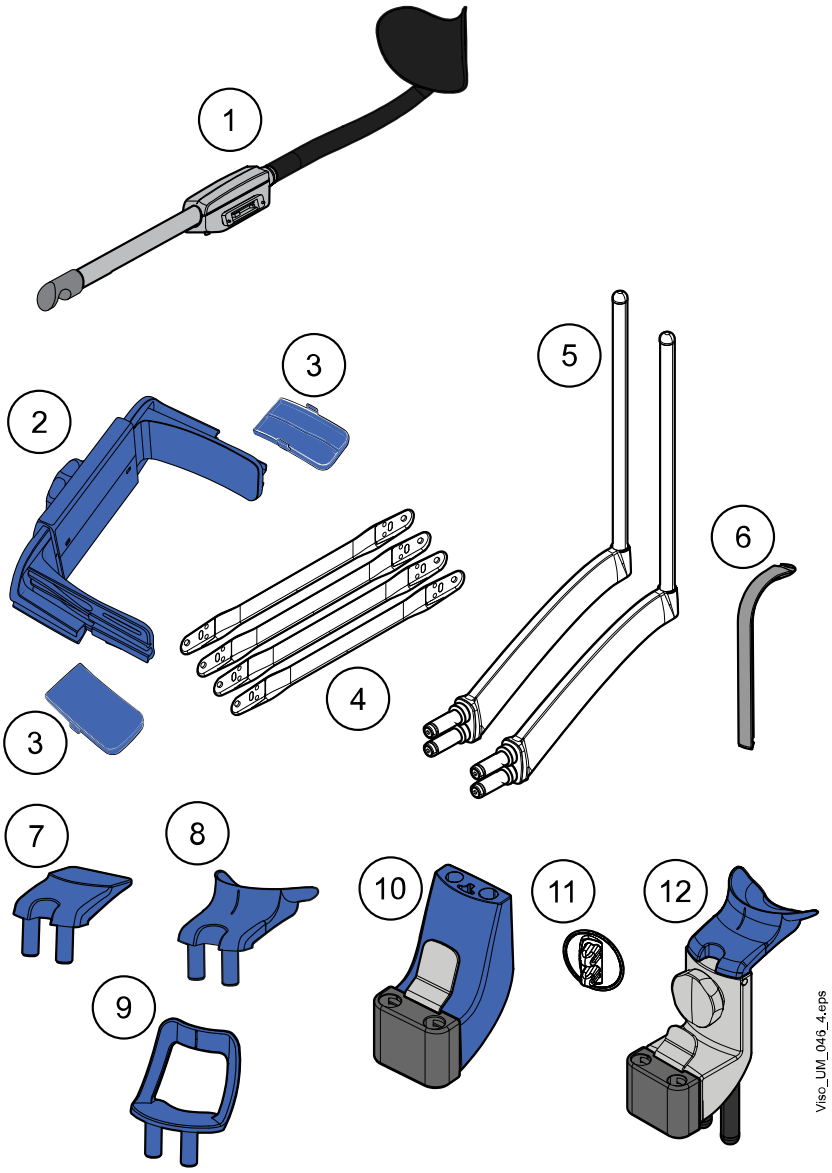
1 X-ray unit
2 3D reconstruction PC
3 Romexis workstation
4 Clinic network

8.2 General view of X-ray unit



1 C-arm
2 Sensor with digital cameras
3 Patient supports (see section "Patient supports" on page 18)
4 Patient handles
5 Touch screen (see section"Control panel" on page 20)
6 Moving column
7 Stationary column
8 Emergency stop button (see section "Emergency stop button" on page 19)

8.3 Patient supports



NOTE

Some of the optional patient supports are available for some market areas only.

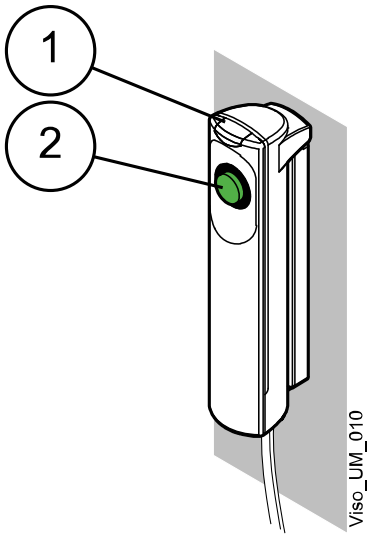
1 Rear head support (default for Viso G5 and Viso G7)
2 Top head support (default for Viso G3)
3 Temple pads for children (optional)
4 Fastening straps (optional)
5 Support bars
6 Bite piece (for panoramic exposures)
7 Chin rest (for panoramic exposures)
8 Chin cup
9 Chin support (for panoramic exposures)
10 Adapter
11 Connector plugs
12 Chiropractic patient support (optional)

8.4 Exposure switch

The exposure switch can be mounted on the wall, or it can be hung from the hook provided on the column top if a protected area is within reach.

A green light flashes on the exposure button when the X-ray system is getting ready for an exposure. The green light stops flashing and stays on continuously when the X-ray system is ready for an exposure.

During exposure a yellow radiation warning light illuminates on the exposure switch. It indicates that the X-ray unit is generating radiation.

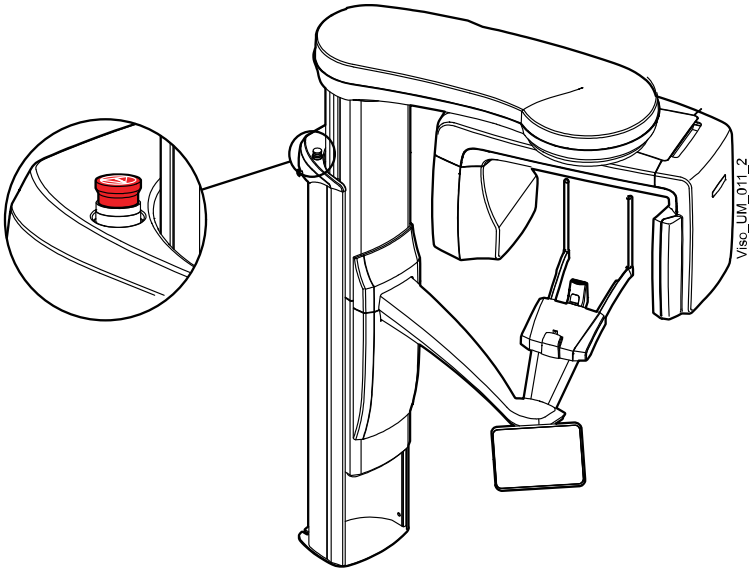


1 Exposure switch
2 Exposure button

8.5 Emergency stop button

Press the emergency stop button to stop the X-ray unit operating in an emergency. All movements of the X-ray unit will be blocked and no radiation will be generated.

A help message will appear on the control panel. Guide the patient away from the X-ray unit. Then release the emergency stop button. The X-ray unit will automatically restart.



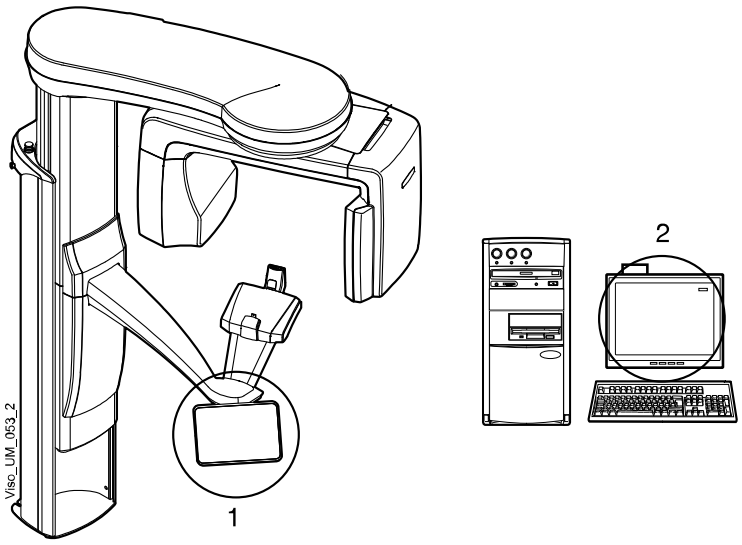
8.6 Control panel

You can use the control panel from:

1. The touch screen that is part of the X-ray unit
2. The virtual control panel that is integrated into the Romexis program

   The virtual control panel is shown on the computer screen when you have selected the patient and the exposure mode in Romexis.

The two control panels are synchronised, and you can use either or both of them. Note, however, that the height adjusting slider cannot be used on the virtual control panel (**2**).



NOTE

The options shown on the screen depend on the X-ray unit configuration. The views and values shown in this manual are only examples.

NOTE

The X-ray unit can be upgraded with new programs and features. Contact your dealer for further information.

NOTE

Never allow patients to touch the screen when they are positioned in the X-ray unit. Touching the screen during exposure will stop the imaging process.

Making selections

To make a selection on the touch screen, simply touch a button or a field with your finger or a soft stylus.

You hear an audible signal when you make a selection.

NOTE

Do not use sharp objects to operate the touch screen.

To make a selection on the virtual control panel in the Romexis program, simply click your mouse on the function that you wish to use.

The selected option is highlighted. To deselect an option, select the button or field again (or select another option if available).

Main screen

The main screen shows the name and the imaging programs of the X-ray unit.

NOTE

The control panel display varies depending on which Viso model is in use. The control panel pictures used in this manual are example images only and may not correspond to, for example, the Planmeca Viso G5 display.

Home button

To view up to five most recently used programs, select the home button. The most recently used program is shown first. This is the default view of the main screen.

Program group buttons

To view all the programs that are available for a program group, select the program group button.

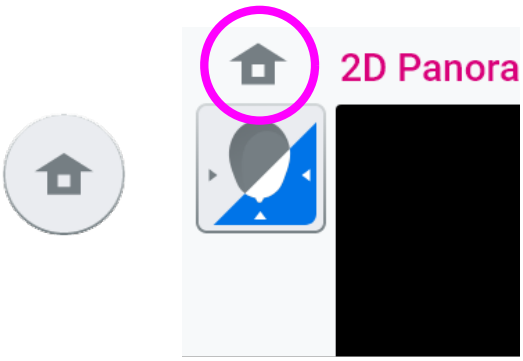
Accept button

To accept a selection, select the green check mark button.

Cancel button

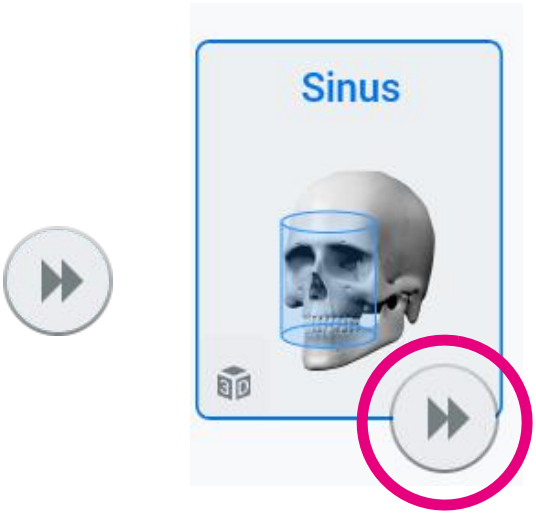
To cancel a selection and close a pop-up window, select the red cross button.

Home button



To go to the home screen from another screen, select the home button.

Fast forward button



To proceed directly to patient positioning, select the fast forward button.

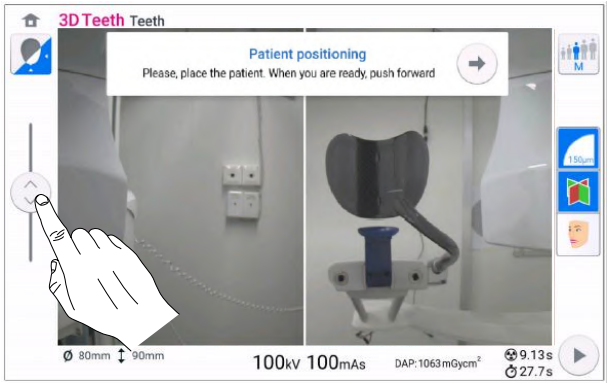
When the fast forward option is selected, the C-arm moves directly to patient positioning position instead of entry position.

Scrolling lists

To scroll a list up or down, slide your finger on the screen.

Height adjusting slider (touch screen only)

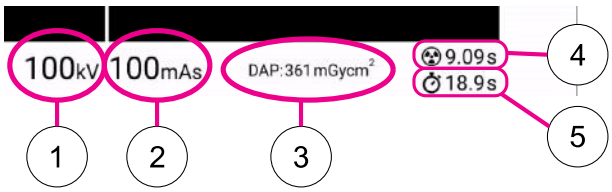
Use this slider on the touch screen to move the X-ray unit up or down.



- Move the slider up to move the X-ray unit up.
- Move the slider down to move the X-ray unit down.

The X-ray unit moves slowly at first, then faster.

Checking exposure and DAP values



1 kV = kilovolt setting

2 mAs = milliampere second setting

3 DAP = Dose Area Product

The DAP value shown on the screen before you take an exposure is an estimate. The actual DAP value is shown after the exposure.

4 Exposure time = Effective exposure time in seconds i.e. the time that the patient receives radiation

5 Scan time = Total scan time in seconds i.e. the time that you press the exposure button

Patient name

When a patient is selected in Planmeca Romexis, their name and date of birth is visible on the top right corner of on the control panel for the duration of the imaging. The date format depends on regional settings of your operating system.

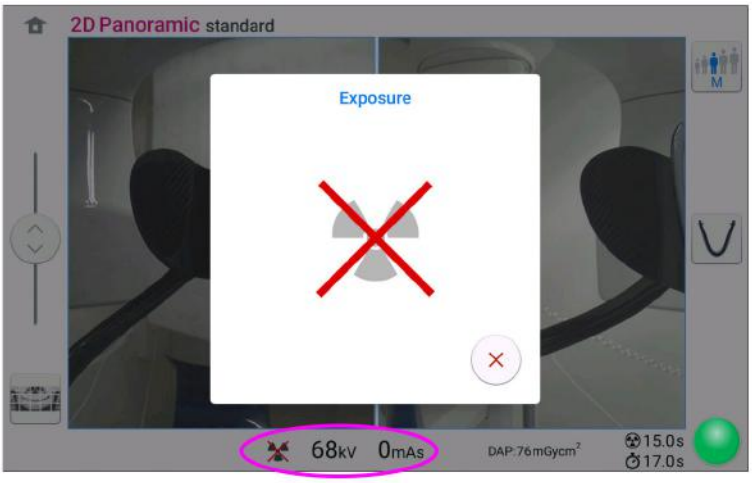
Changing settings

To change a setting, select the settings symbol on the main screen. This takes you to the settings menu where you can adjust the settings of the X-ray unit.

- **Selecting demo mode**

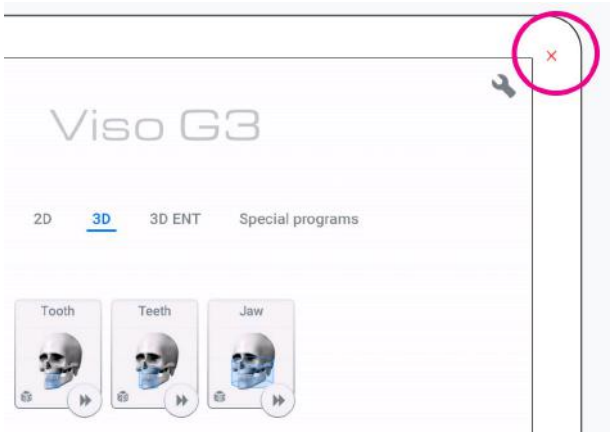
  You can switch the demo mode on if you wish to practice or demonstrate the functions of the X-ray unit without radiation and PC connection. For more information, see section "Operational Settings (1300)" on page 81 .

  You see these symbols in the bottom left corner of the screen when the demo mode is switched on. Additionally, a prohibition sign is shown on the top of the radiation symbol when you press the exposure button.



Closing virtual control panel

Click on this cross if you need to close the virtual control panel on the computer screen.



9 Before exposure

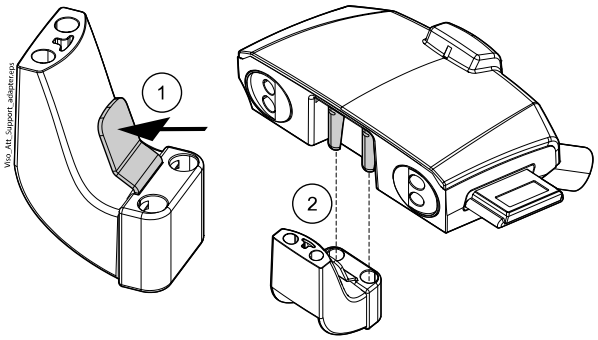
9.1 Preparing X-ray system

9.1.1 Attaching patient supports

9.1.1.1 Attaching adapter

About this task

Follow these instructions to attach the adapter to the patient support base.



Steps

1. Press the trigger down and hold.
2. Attach the adapter by sliding it into place in an upright position.
3. Release the trigger.

9.1.1.2 Removing adapter

About this task

Follow these instructions to remove the adapter.

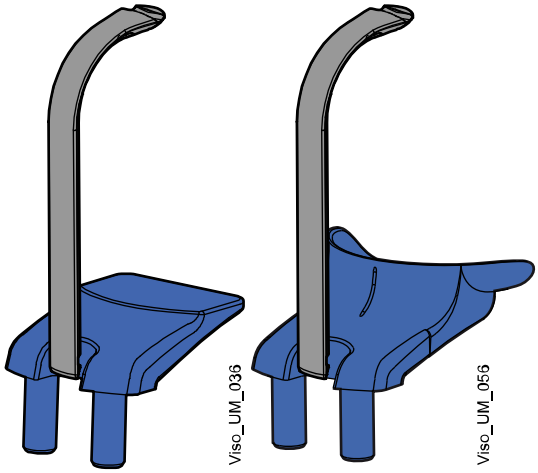
Steps

1. Press the trigger down and hold.
2. Remove the adapter by sliding it downwards in an upright position.

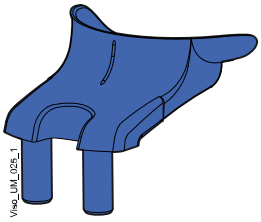
9.1.1.3 Attaching chin supports for 2D panoramic exposures

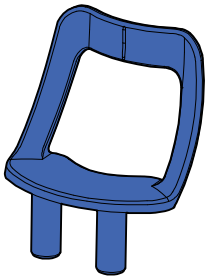
Steps

1. Attach either of the chin supports together with the bite piece to the adapter.



You can use the supports below for edentulous patients or for patients who are unable to bite.

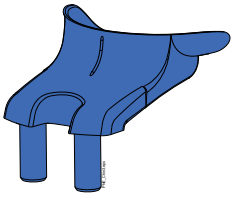




9.1.1.4 Attaching chin supports for 3D exposures

Steps

1. Attach the support shown below to the adapter.

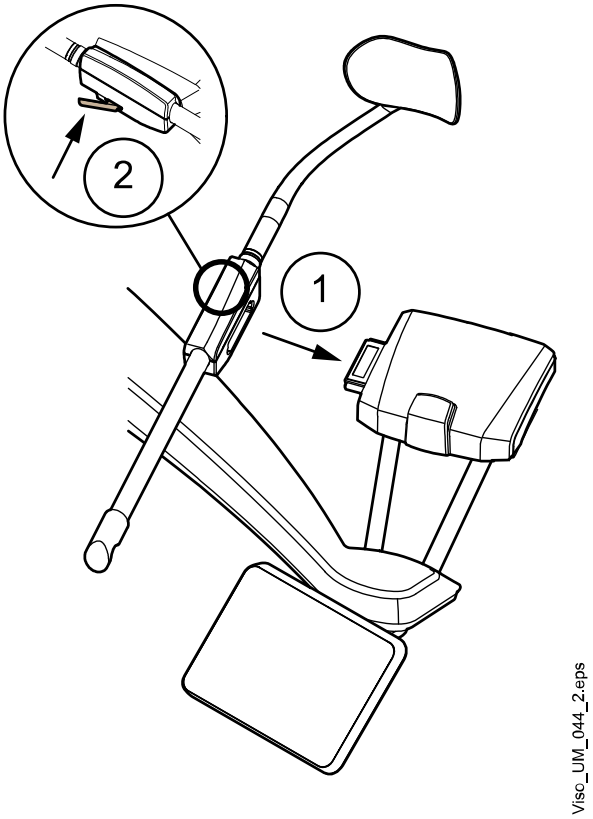


9.1.1.5 Attaching rear head support

Steps

1. Attach the rear head support to the connector on the patient support base.

2. Close the locking lever at the back.



9.1.1.6 Removing rear head support

Steps

1. Release the locking lever.
2. Pull out the head support.

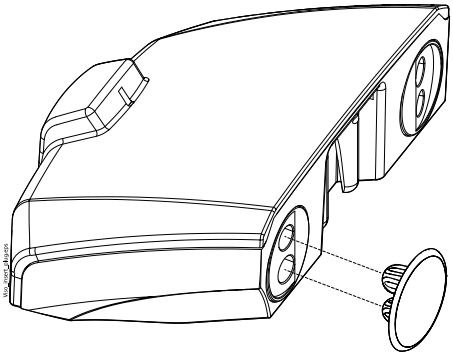
9.1.1.7 Attaching support bars

About this task

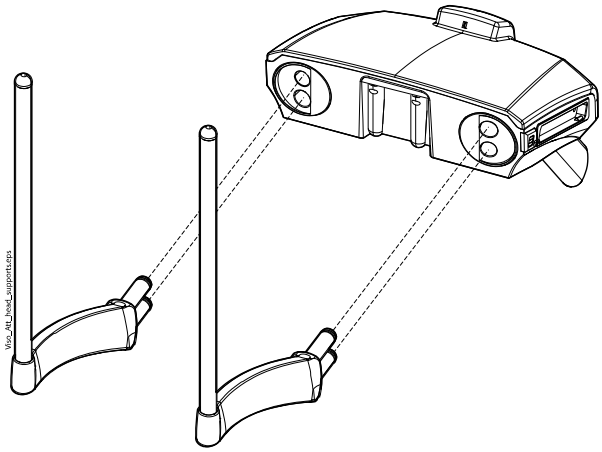
Follow these steps to attach the support bars to the patient support base.

Steps

1. Remove the plugs covering the connectors.

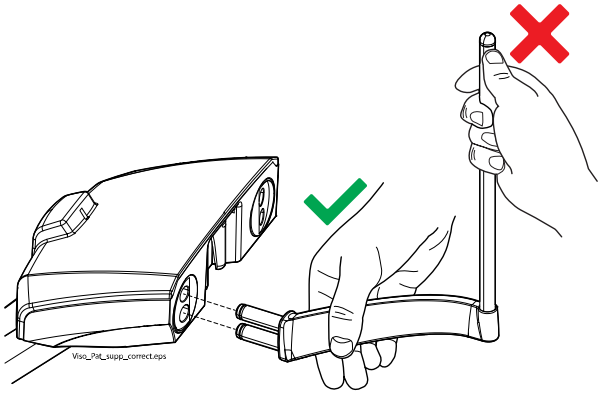


2. Insert the support bars into the connectors in the patient support base.



NOTE

Hold the support bar close to the connecting pins when inserting it into the patient support base to keep it steady.



Results

The support bar is locked into place when you hear a clicking sound.

9.1.1.8 Removing support bars

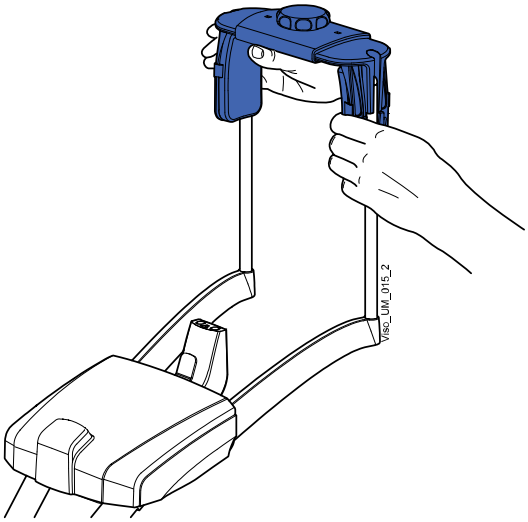
Steps

1. Pull the support bar out.
2. Cover the connectors with the silicone plugs.

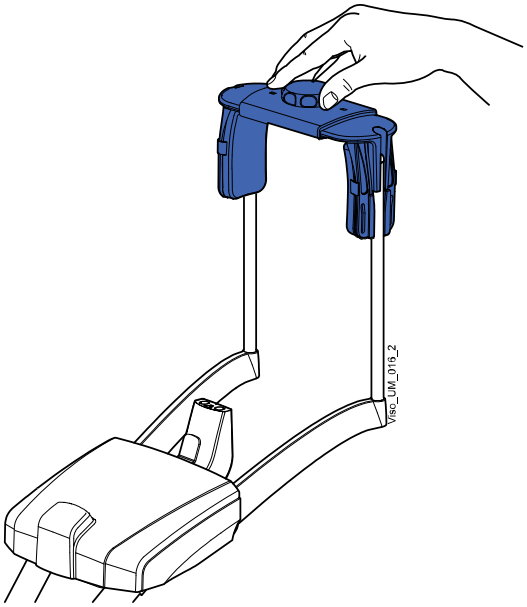
9.1.1.9 Attaching top head support

Steps

1. Slide the top head support onto the support bars.

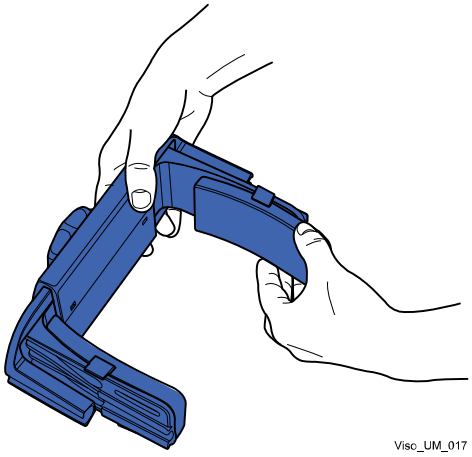


2. You can turn the adjusting knob to adjust the head support to suit the size of the patient's head.



3. You can use temple pads when you take exposures of children or patients with a small head.

   Slide the temple pads onto the head support as shown. Ensure that you slide the temple pads as far up as they will go.

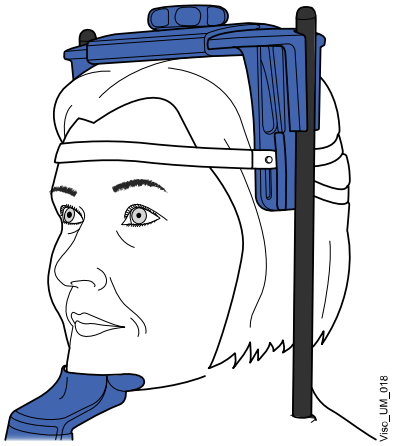


NOTE

Use temple pads on both sides (not on one side only).

4. You can use fastening straps for additional head support.

   Attach one strap in front of the forehead and two at the back of the head as shown.



NOTE

Be careful when you handle the straps. Do not let the straps hit the patient in the eye or face.

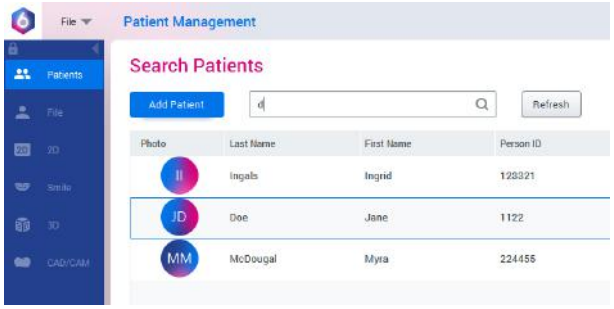
NOTE

Do not overstretch the straps. The straps lose their elasticity if you pull them more than 50 mm (2 in.). Straps with a free length (i.e. when they are not stretched) of over 255 mm (10 in.) do not support the patient's head firmly.

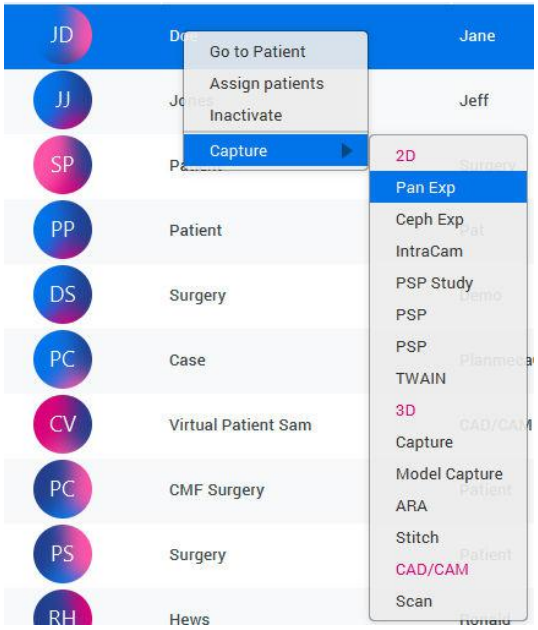
9.1.2 Preparing Planmeca Romexis

Steps

1. Select the patient.



2. Right-click on the patient and select **Capture** followed by **Pan Exp** for 2D exposure or **Capture** for 3D exposure.



Refer to the *Romexis user's manual* for details on Romexis functions.

9.2 Preparing patient

Ask the patient to remove any spectacles, hearing aids, dentures, hairpins, and personal jewellery such as earrings, necklaces and piercings as these can produce shadows or reflections in the image. The patient should also remove any loose items of clothing (e.g. scarf, tie) that might get caught in the arm structures of the X-ray unit.

NOTE

High contrast objects, such as gold teeth or amalgam, may cause artefacts in the image.

Place a protective lead apron over the patient's back if required.

10 2D exposure

10.1 2D dental programs

Panoramic

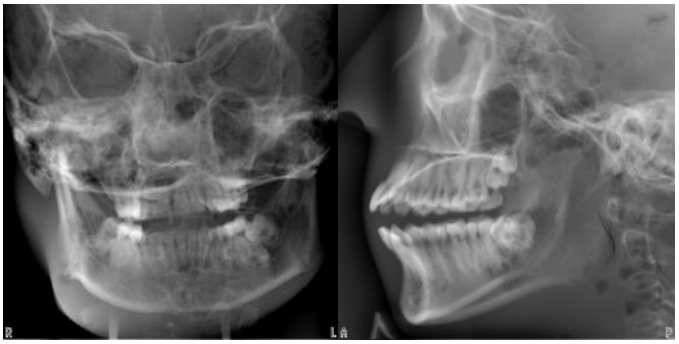
The **Panoramic** program is the standard 2D imaging program for dental imaging, and provides a wide exposure that shows the entire exposure area on a single plane.

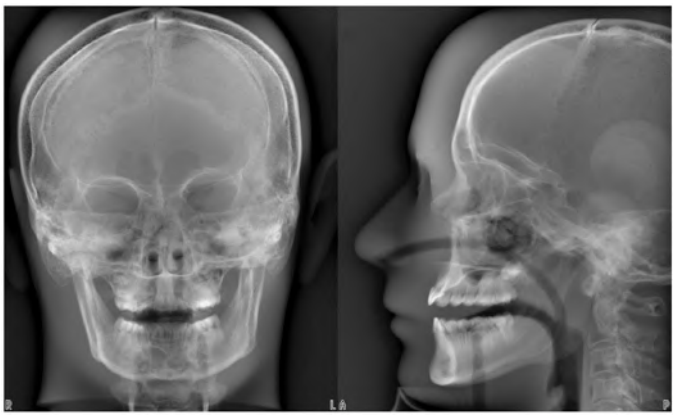
Bitewing

The **Bitewing** program produces bitewing images from premolar and molar areas including parts of maxilla, mandible and rami. The bottom of the maxillary sinus as well as the mandibular canal and the mental foramen are also visible.

2D View

The **2D View** program enables a large single-shot 2D exposure taken with the imaging arm, generating clear 2D projections of the maxillofacial region as shown in the example below.

1


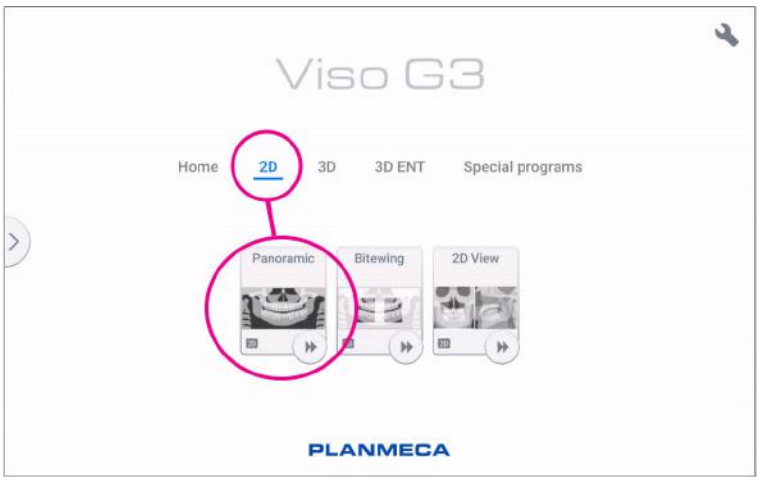
2


1 Planmeca Viso G5 projection example results
2 Planmeca Viso G7 projection example results

10.2 Selecting imaging program

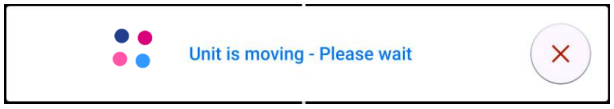
Steps

1. Select the 2D imaging program you want to use, for example **2D > Panoramic**.

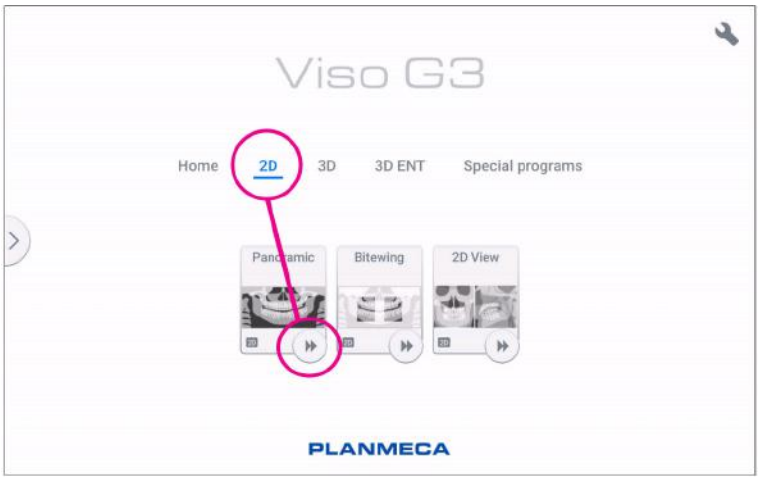


Results

The sensor moves to entry position if not already there. You see this message.



If you want to proceed directly to patient positioning, select the fast forward button in the lower right corner of the imaging program option.

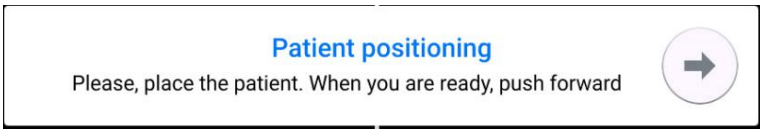


10.3 Patient positioning

Steps

1. Guide the patient to the X-ray unit when you see this message.

   NOTE
   The message does not display if the fast forward option is selected.

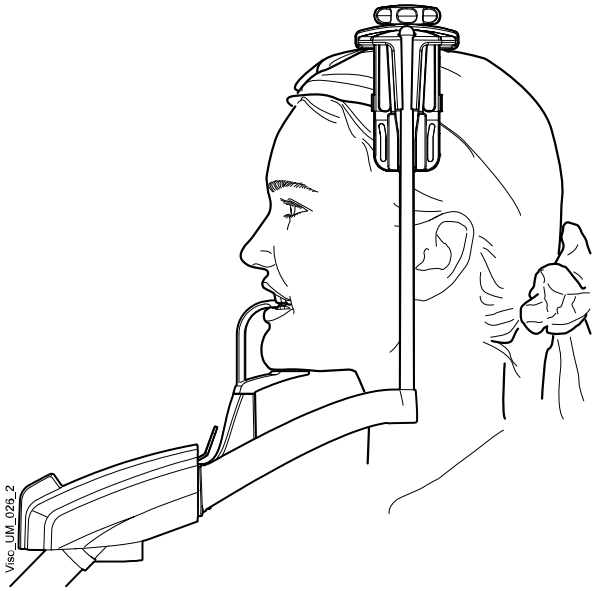
   The patient can sit or stand during the exposure.

   NOTE
   We recommend that you image patients with poor health in a sitting position.

2. Use the height adjusting slider on the touch screen to move the X-ray unit up or down until the chin rest is approximately level with the patient's lower jaw.

3. Ask the patient to step forward, grasp the patient handles, stretch and straighten their back and neck, and bite the bite piece.

   The upper and lower incisors must be in the groove in the bite piece.



NOTE

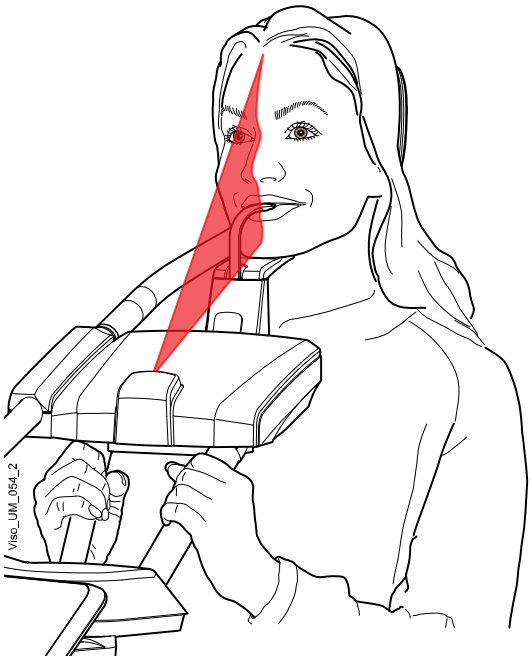
If you are using the chin support, position the patient so that the chin touches the top bar as shown.

NOTE

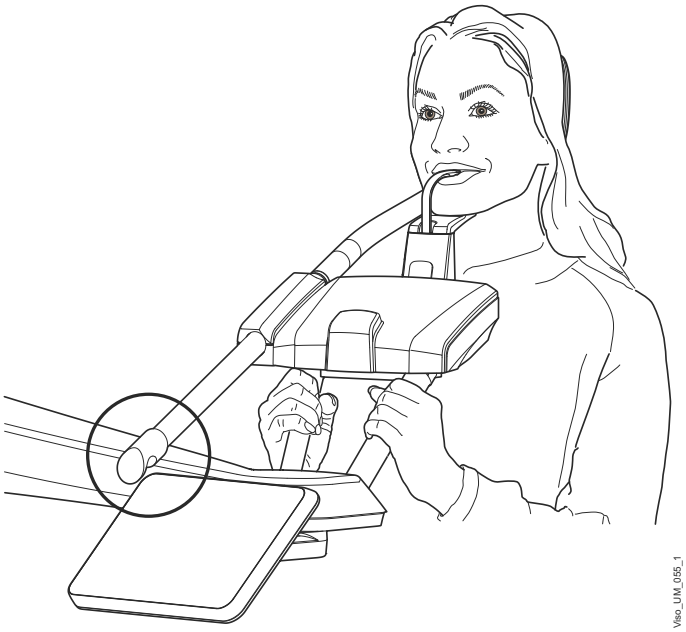
If you are using the chin support or chin cup, use for example a cotton roll between the patient's teeth to ensure that the upper and lower incisors do not make contact.

4. Position the patient’s head so that the patient’s midsagittal plane coincides with the midsagittal plane laser light.

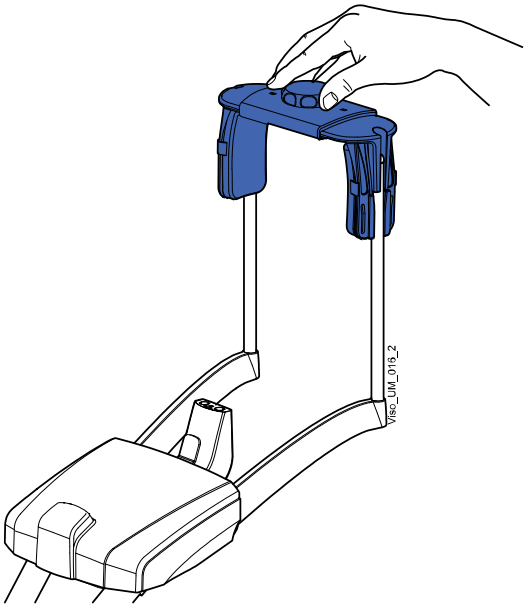
   The midsagittal plane laser light is shown in the middle of the patient’s face.



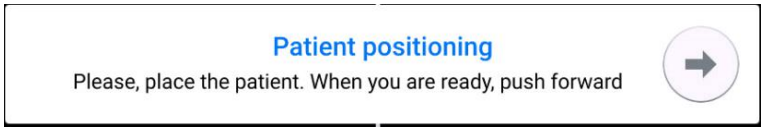
5. If you use the rear head support, you can slide it up or down for optimal support of the patient's head.



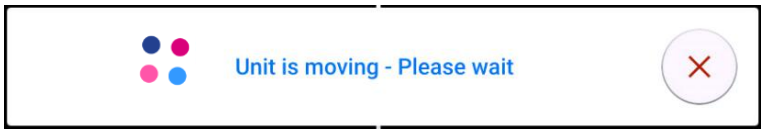
6. If you use the top head support, you can adjust it by turning the adjusting knob at the top.



7. Select the forward button.



The sensor moves to the front. You see this message.



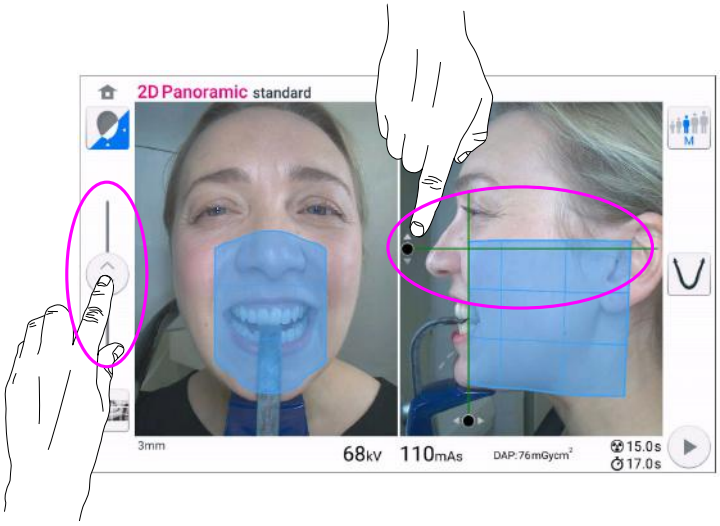
The sensor contains digital cameras which stream live video of the patient's head.

8. You see two camera images of the patient's head on the control panel: a front view and a side view.

   The preset position of the panoramic image layer is shown with a blue area in both views.

   - Carefully position the patient's Frankfort plane so that it is parallel to the Frankfort plane reference line.

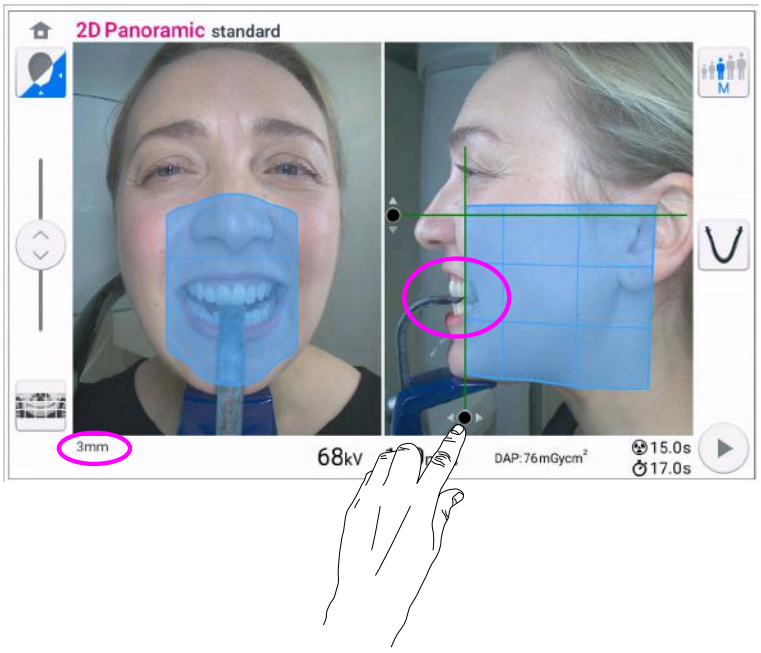
     Use the height adjusting slider on the touch screen to adjust the tilt of the patient's head. The patient's back and neck must be straight.



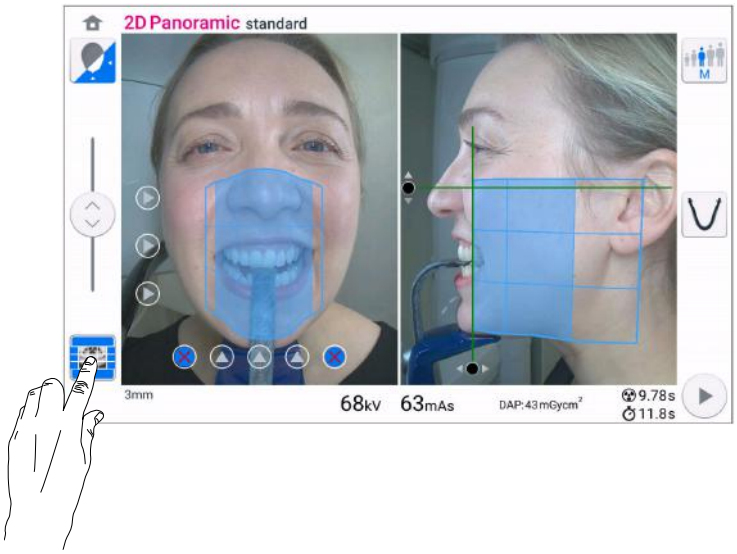
- A virtual layer light is shown with a green line on the screen. Use your mouse cursor (virtual control panel) or finger (touch screen) to move the blue area forwards or backwards so that the green line is positioned between the patient's second incisor and the canine.

  The selected position is shown in the bottom left corner (e.g. -1 mm).

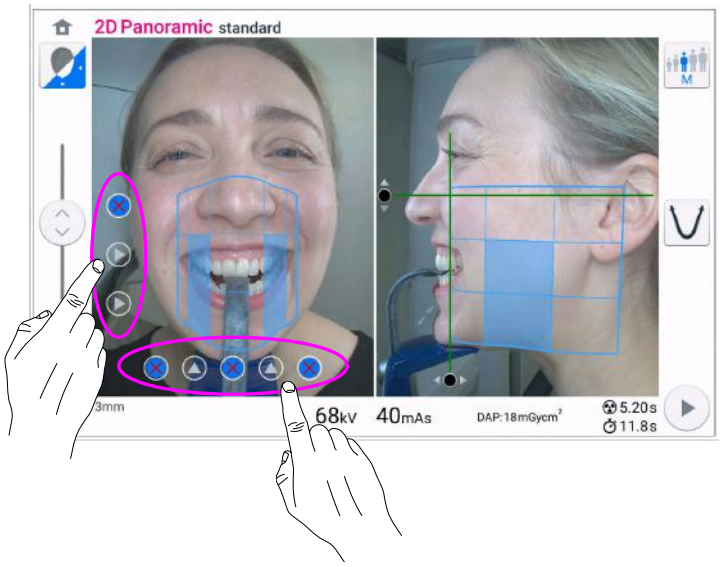
  Position the apices of the patient's upper central incisors within the image layer of the X-ray unit:



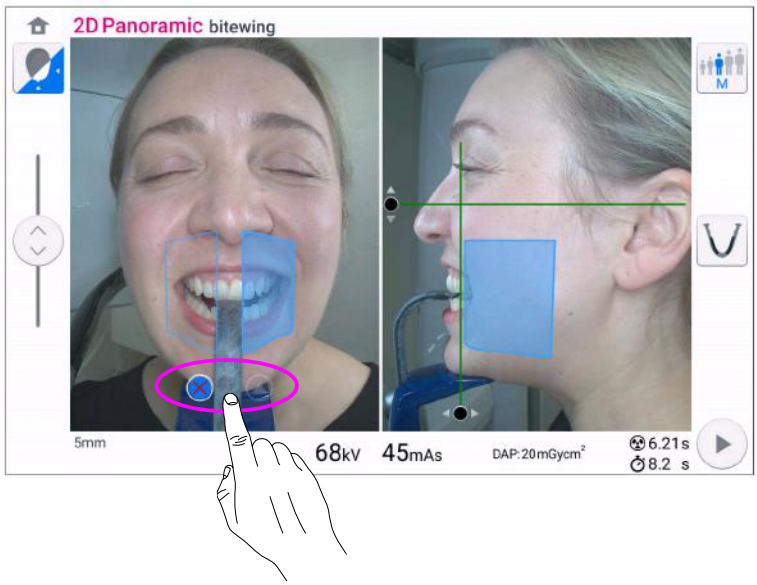
9. Optionally, activate the Panoramic segmentation and select the segments for exposure.
   - Select the **Segmentation** button from the left bottom corner.



- Use the segmentation buttons to select the active exposure areas.



10. If **2D Panoramic Bitewing** program is used, select the active exposure areas by using the buttons on the touch screen.



11. Check that the midsagittal plane light and the Frankfort plane reference line are still correctly positioned.

    Reposition them if necessary.

10.4 Selecting patient size

Steps

1. Use this button to select the patient size:

- XS = Child
- S = Small adult
- M = Medium-sized adult
- L = Large adult
- XL = Extra large adult

The preset exposure values are shown below the patient sizes.

NOTE

Selecting child patient (XS) will automatically reduce the exposure area.

NOTE

The exposure values will automatically change according to the selected patient size.

10.5 Adjusting exposure values for current exposure

About this task

The exposure values have been preset at the factory for each patient size. The preset exposure values are average values and they are only meant to guide the user.

NOTE

Always try to minimise the radiation dose to the patient.

The preset exposure values are shown in the following table.

Factory presets for panoramic exposures

Patient size	kV value	mAs value
Child (XS)	64	110
Small adult (S)	66	125
Medium-sized adult (M)	68	140

Factory presets for panoramic exposures

Patient size	kV value	mAs value
Large adult (L)	70	160
Extra large adult (XL)	72	180

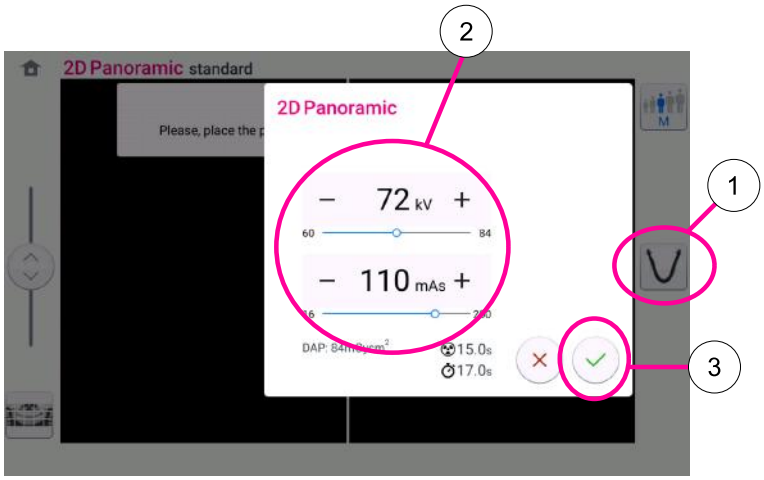
Follow these steps if you need to adjust the preset exposure values for current exposure:

Steps

1. Select this field (1) to open a pop-up window.
2. Use the minus or plus signs or the slider (2) to set the exposure values you wish to use.

   To improve the image contrast, reduce the kV value.

   To reduce the radiation dose, reduce the mAs value.
3. Select the green check mark button.



10.6 Taking 2D exposure

10.6.1 2D Panoramic exposure

Before you begin

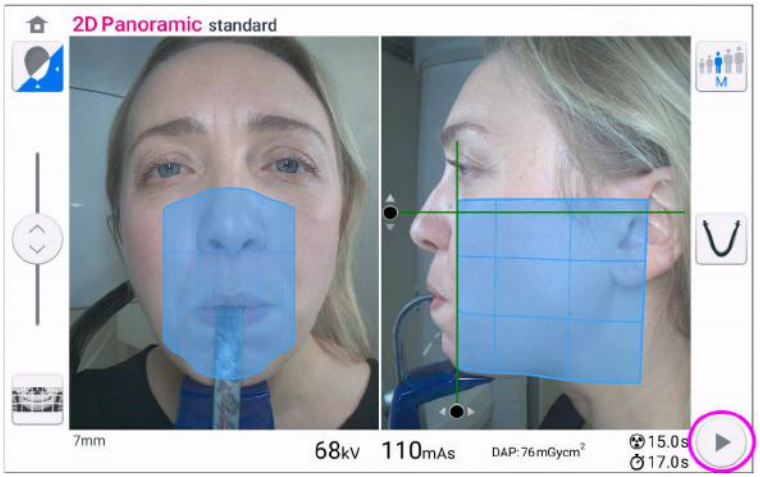
Make sure that you have selected the correct patient in the Planmeca Romexis program.

About this task

Follow these steps to take a 2D Panoramic exposure .

Steps

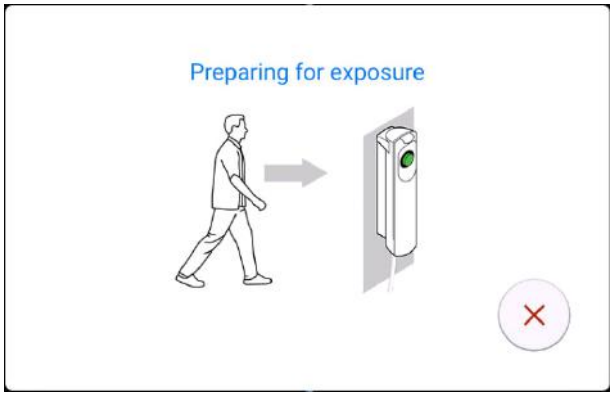
1. Select the forward button.



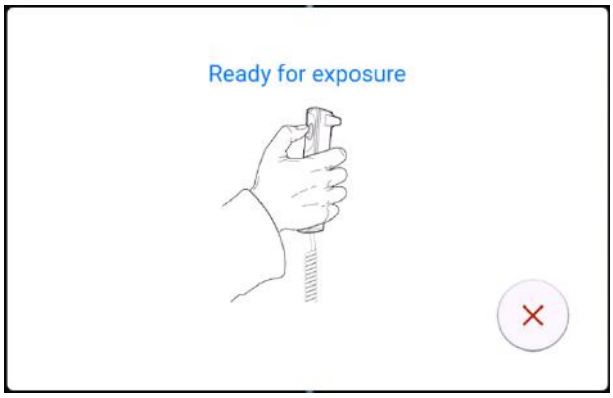
Green lights flash on the control panel and exposure button when the X-ray system is getting ready for an exposure. You see this message.

NOTE

Move to a protected area.

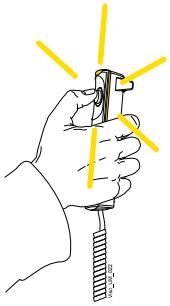


The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure. You see this message.



2. Ask the patient to swallow, place their tongue flat against the roof of the mouth and stay as still as possible.

3. Press and hold down the exposure button for the duration of the exposure.



The C-arm moves around the patient's head.

During exposure yellow radiation warning lights illuminate on the exposure switch and on the control panel. Additionally, you hear a radiation warning tone and see a radiation warning symbol on the control panel.

You can follow the imaging process on the virtual control panel.

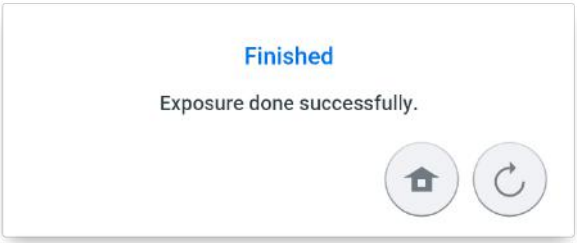
NOTE

Do not release the exposure button before the end of the exposure.

NOTE

Maintain audio and visual contact with the patient and X-ray unit during exposure. If the C-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately.

4. You see this message on the touch screen.



Select the home button if you want to return to the home screen.

Select this button if you want to retake the exposure with the same settings.

5. Release the patient from the head support.
6. Guide the patient away from the X-ray unit.

Results

The image is shown on the computer screen.

10.6.2 2D View exposure

Before you begin

Make sure that you have selected the correct patient in the Planmeca Romexis program.

About this task

Follow these steps to take a 2D View exposure.

Steps

1. Make the necessary selections on the 2D View screen, for example **PA** image, **LAT** image or both.
2. Select the forward button.

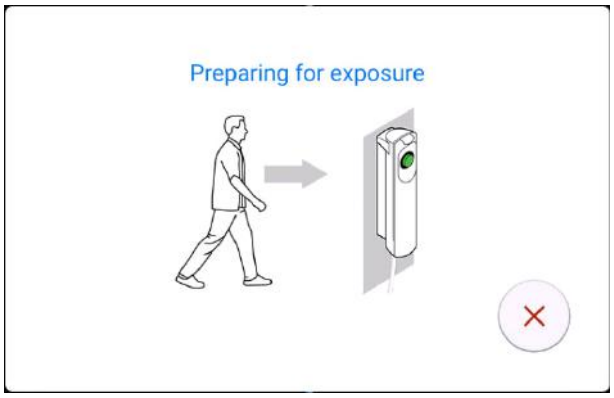
3. Place the patient as shown in the image below.

Green lights flash on the control panel and exposure button when the X-ray system is getting ready for an exposure.

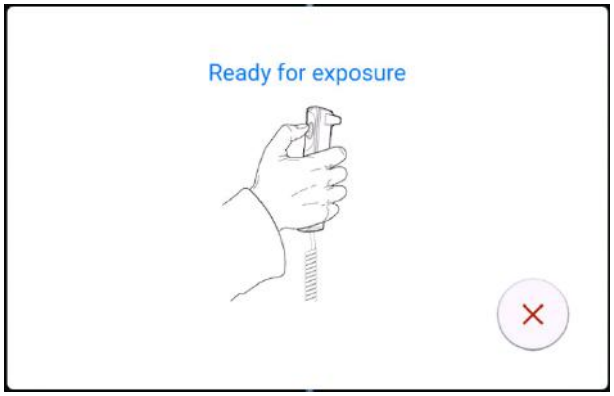
You see this message.

NOTE

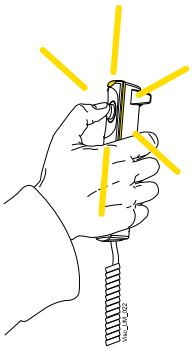
Move to a protected area.



The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure. You see this message.



4. Ask the patient to swallow, place their tongue flat against the roof of the mouth and stay as still as possible.
5. Press and hold down the exposure button for the duration of the exposure.



The C-arm moves around the patient’s head.

During exposure yellow radiation warning lights illuminate on the exposure switch and on the control panel. Additionally, you hear a radiation warning tone and see a radiation warning symbol on the control panel.

You can follow the imaging process on the virtual control panel.

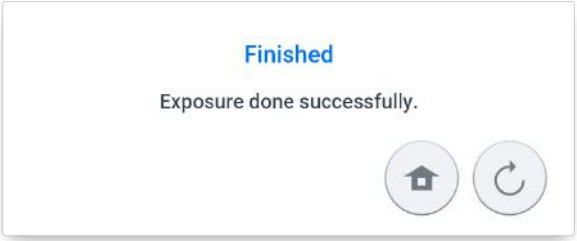
NOTE

Do not release the exposure button before the end of the exposure.

NOTE

Maintain audio and visual contact with the patient and X-ray unit during exposure. If the C-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately.

6. You see this message on the touch screen.



Select the home button if you want to return to the home screen.

Select this button if you want to retake the exposure with the same settings.

7. Release the patient from the head support.
8. Guide the patient away from the X-ray unit.

Results

The image displays on the computer screen.

11 3D exposure

11.1 3D dental programs

3D dental programs include:

- 3D programs
- 3D ENT programs
- Special programs

3D programs

3D ENT programs

Special programs

11.1.1 Preset volume sizes

When a program is selected, the device selects the following settings for the volume.

NOTE

If the volume size has been adjusted (is different than default), patient size change (adult > XS, child) does not change the volume size.

NOTE

When using 75 um voxel size, the AI based NOA denoising algorithm is applied to the resulting image. NOA is using neural network (a.k.a Artificial Intelligence, AI) for denoising and the network has been trained using machine learning methods.

3D programs, Planmeca Viso G7

Program	Preset volume size	Volume range	Note
Tooth	Ø50 × 50 mm	Ø30 × 30 mm – Ø60 × 60 mm 5 mm steps	75 µm voxel possible only with volumes smaller than 70 x 70 mm
TMJ	Ø50 × 50 mm	Ø30 × 30 mm – Ø60 × 60 mm 5 mm steps	
Teeth	Ø100 × 100 mm	Ø70 × 30 mm – Ø120 × 100 mm 10 mm steps	
Jaw	Ø140 × 100 mm	Ø130 × 30 mm – Ø170 × 170 mm 10 mm steps	Center line only 150 µm possible up to size 160 x 160 mm
Face	Ø160 × 160 mm	Ø140 × 120 – Ø300 × 200 mm 10 - 20 mm steps	Center line only 200 µm possible up to size 200 x 170 mm
Skull	Ø260 × 300 mm	Ø260 × 300 mm – Ø300 × 300 mm	Center line only

3D ENT programs, Planmeca Viso G7

Program	Preset volume size	Volume range	Note
Nose	Ø80 × 80 mm	Ø70 × 50 mm – Ø120 × 100 mm 10 mm steps	
Sinus	Ø130 × 130 mm	Ø100 × 100 mm – Ø170 × 200 mm 10 mm steps	
Middle Ear	Ø50 × 50 mm	Ø30 × 30 mm – Ø60 × 60 mm 5 mm steps	75 µm voxel possible only with volumes smaller than 70 x 70 mm
Temporal bone	Ø80 × 80 mm	Ø70 × 50 mm – Ø120 × 100 mm 10 mm steps	
Airways	Ø90 × 100 mm	Ø80 × 80 mm – Ø100 × 140 mm 10 mm steps	

Program	Preset volume size	Volume range	Note
Vertebrae	Ø100 × 140 mm	Ø80 × 80 mm – Ø140 × 140 mm 10 mm steps	

3D programs, Planmeca Viso G5

Program	Preset volume size	Volume range	Note
Tooth	Ø50 × 50 mm	Ø30 × 30 mm – Ø60 × 60 mm 5 mm steps	75 µm voxel possible only with volumes smaller than 70 x 70 mm
TMJ	Ø50 × 50 mm	Ø30 × 30 mm – Ø60 × 60 mm 5 mm steps	
Teeth	Ø90 × 90 mm	Ø70 × 30 mm – Ø90 × 90 mm 10 mm steps	
Jaw	Ø140 × 100 mm	Ø100 × 30 mm – Ø200 × 100 mm 10 mm steps	Center line only
Face	Ø160 × 160 mm	Ø140 × 130 mm – Ø200 × 170 mm 10 mm steps	Center line only

3D ENT programs, Planmeca Viso G5

Program	Preset volume size	Volume range	Note
Nose	Ø80 × 80 mm	Ø70 × 50 mm – Ø90 × 90 mm 10 mm steps	
Sinus	Ø130 × 130 mm	Ø100 × 110 mm – Ø200 × 150 mm 10 mm steps	Center line only
Middle Ear	Ø50 × 50 mm	Ø30 × 30 mm – Ø60 × 60 mm 5 mm steps	75 µm voxel possible only with volumes smaller than 70 x 70 mm
Temporal bone	Ø80 × 80 mm	Ø70 × 50 mm – Ø90 × 90 mm 10 mm steps	
Airways	Ø90 × 100 mm	Ø90 × 80 mm – Ø110 × 100 mm 10 mm steps	Center line only
Vertebrae	Ø90 × 100 mm	Ø90 × 80 mm – Ø110 × 100 mm 10 mm steps	Center line only

3D programs, Planmeca Viso G3

Program	Preset volume size	Volume range	Note
Tooth	Ø50 × 50 mm	Ø30 × 30 mm – Ø60 × 60 mm 5 mm steps	75 µm voxel possible only with volumes smaller than 70x70 mm

Program	Preset volume size	Volume range	Note
TMJ	Ø50 × 50 mm	Ø30 × 30 mm – Ø60 × 60 mm 5 mm steps	
Teeth	Ø90 × 90 mm	Ø70 × 30 mm – Ø90 × 90 mm 10 mm steps	
Jaw	Ø140 × 100 mm	Ø100 × 30 mm – Ø200 × 100 mm 10 mm steps	Center line only

3D ENT programs, Planmeca Viso G3

Program	Preset volume size	Volume range	Note
Nose	Ø80 × 80 mm	Ø70 × 50 mm – Ø90 × 90 mm 10 mm steps	
Sinus	Ø130 × 100 mm	Ø100 × 100 mm – Ø200 × 100 mm 10 mm steps	Center line only
Middle Ear	Ø50 × 50 mm	Ø30 × 30 mm – Ø60 × 60 mm 5 mm steps	75 µm voxel possible only with volumes smaller than 70x70 mm
Temporal bone	Ø80 × 80 mm	Ø70 × 50 mm – Ø90 × 90 mm 10 mm steps	
Airways	Ø90 × 100 mm	Ø90 × 80 mm – Ø110 × 100 mm 10 mm steps	Center line only
Vertebrae	Ø90 × 100 mm	Ø90 × 80 mm – Ø110 × 100 mm 10 mm steps	Center line only

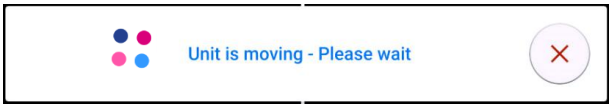
11.2 Selecting imaging program

Steps

1. Select the 3D program you want to use, for example **3D > 3D Teeth**.

Results

The sensor moves to the entry position if not already there. You see this message.



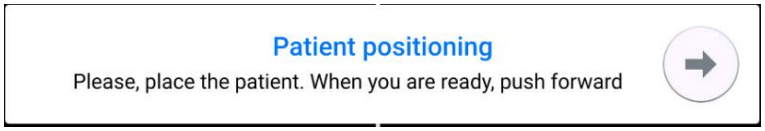
If you want to proceed directly to patient positioning, select the fast forward button in the lower right corner of the imaging program option.

11.3 Patient positioning

Steps

1. Guide the patient to the X-ray unit when you see this message.

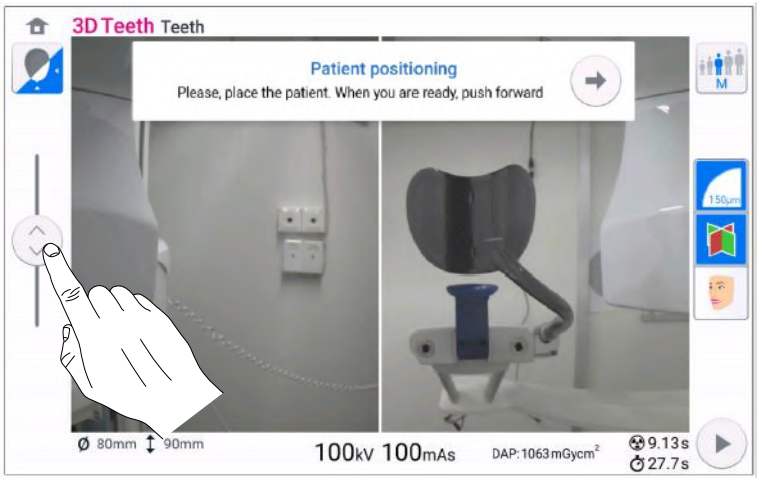
   NOTE
   The message does not display if the fast forward option is selected.

   The patient can sit or stand during the exposure.

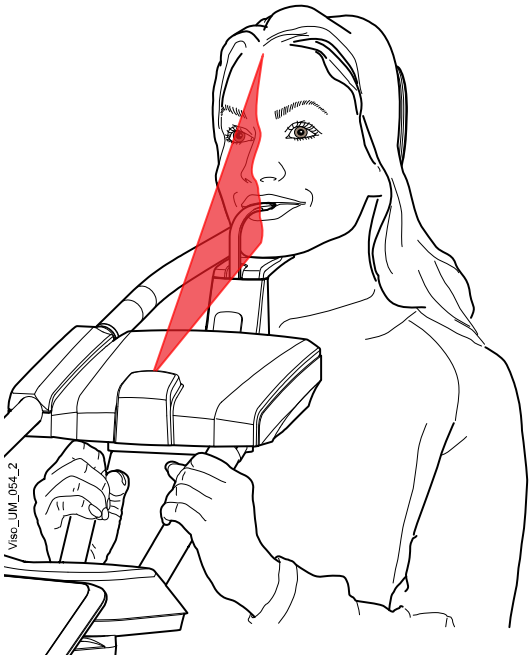
   NOTE
   We recommend that you image patients with poor health in a sitting position.

2. Use the height adjusting slider on the touch screen to move the X-ray unit up or down until the chin cup is approximately level with the patient's lower jaw.

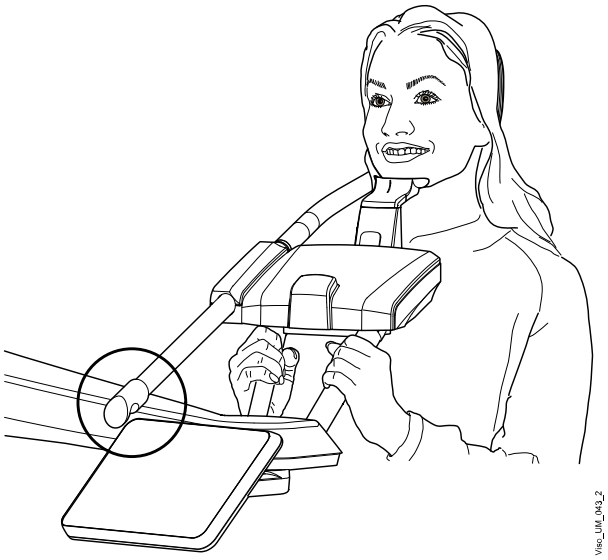


3. Ask the patient to grasp the patient handles.
4. Position the patient's head so that the patient's midsagittal plane coincides with the midsagittal plane laser light.

   The midsagittal plane laser light is shown in the middle of the patient's face.



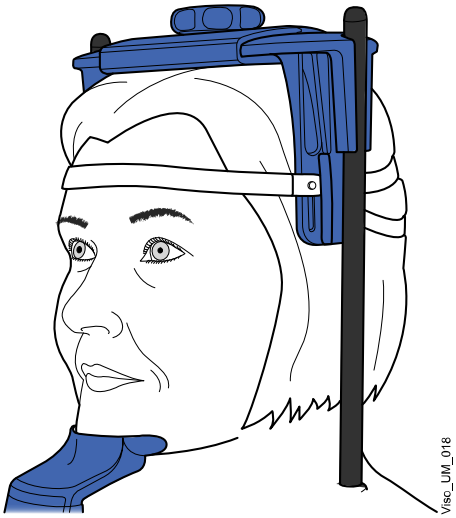
5. If you use the rear head support, you can slide the rear head support up or down for optimal support of the patient's head.



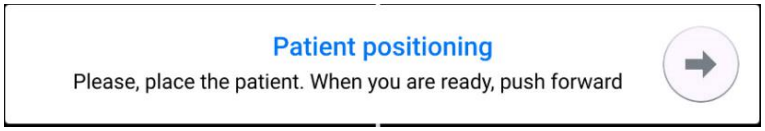
NOTE

When using the chiropractic patient support, the patient is positioned higher than with the standard patient support.

6. If you use the top head support:
   - You can adjust the head support by turning the adjusting knob at the top.
   - You can use fastening straps for additional head support if needed. Refer to section "Attaching top head support" on page 30 for details.

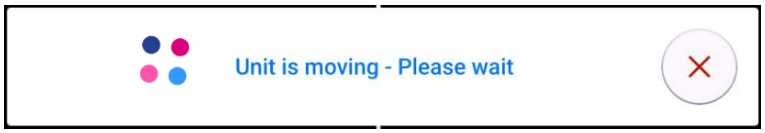


7. Select the forward button.



Results

The sensor moves to the front. You see this message.



11.4 Selecting patient's left or right side

About this task

Follow these instructions to select the patient's left or right side.

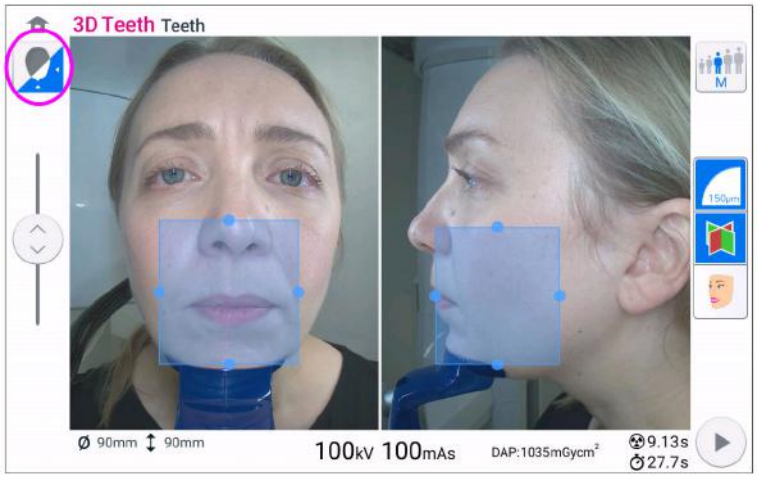
NOTE

This function is not available for the Skull program.

The sensor contains digital cameras which stream live video of the patient's head.

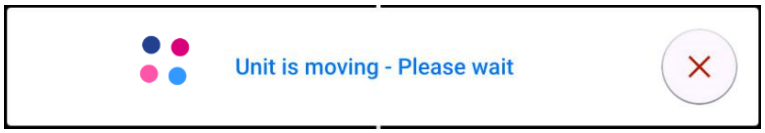
Steps

1. Use the button shown to select the side that you wish to expose.



Results

The sensor moves to the selected side and an image of that side is shown on the screen. You see this message.



Patient's left side selected

Patient's right side selected

11.5 Selecting patient size

Steps

1. Use the button shown below to select the patient size.

- XS = Child
- S = Small adult
- M = Medium-sized adult
- L = Large adult
- XL = Extra large adult

The preset exposure values are shown below the patient sizes.

NOTE

The exposure values will automatically change according to the selected patient size, image resolution and ULD setting. The preset exposure values are shown in section "Adjusting exposure values for current exposure" on page 59.

11.6 Adjusting image volume position and size

About this task

Follow these instructions to adjust image volume position and size.

NOTE

This function is not available for the Skull program.

You see two camera images of the patient's head on the control panel: a front view and a side view. The preset position and size of the image volume are shown with a blue area in both views. You can use either or both views to adjust the volume position and size.

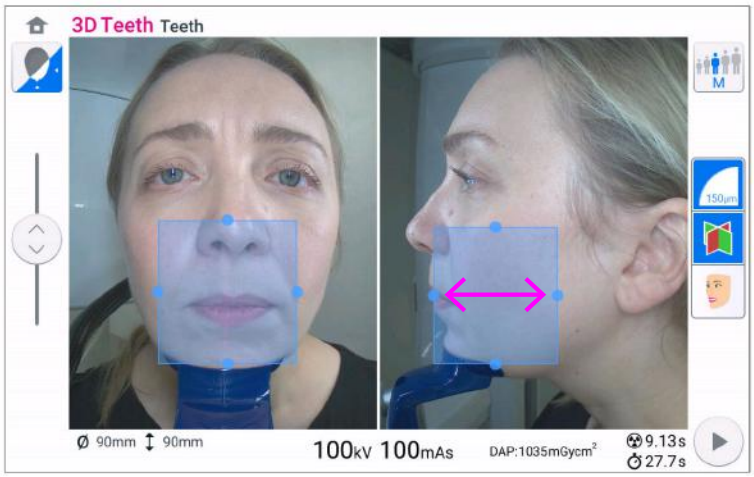
NOTE

The blue area is not an exact representation of the image volume. It is intended for visualization purposes only.

Steps

1. To adjust the volume position, use your mouse cursor (virtual control panel) or finger (touch screen) to move the blue area to the anatomical region that you wish to expose.

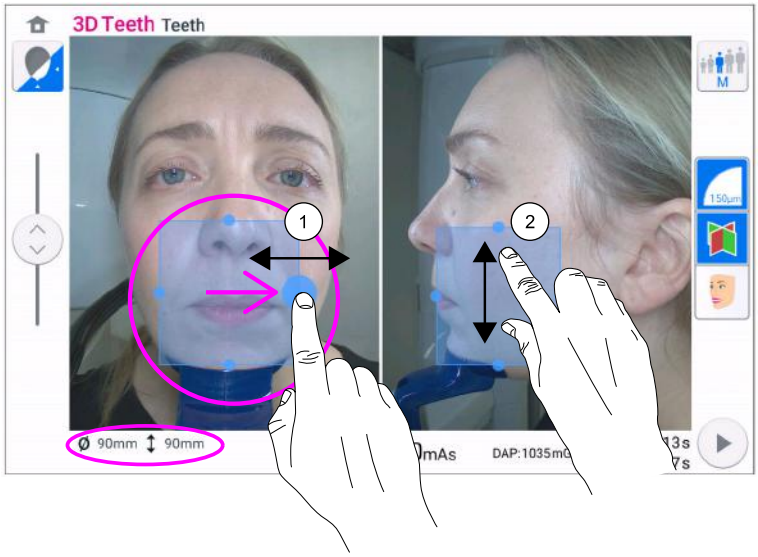
   The blue area can be moved in any direction.



2. Adjust the volume size on the touch screen smaller or larger by finger (touch screen) on one of the small blue balls and moving the ball to enlarge or reduce the volume size (**1**) or by using pinch gestures (**2**).

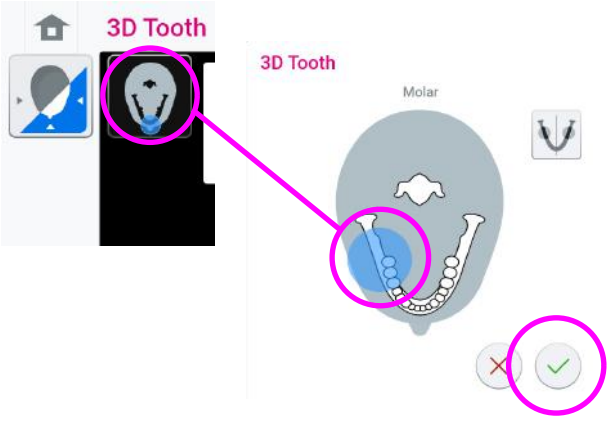
   The ball turns red when you reach the limit value, i.e. when the volume diameter or height cannot be further adjusted in that direction.

   The selected volume size (diameter and height) is shown in the bottom right corner of the screen.



NOTE

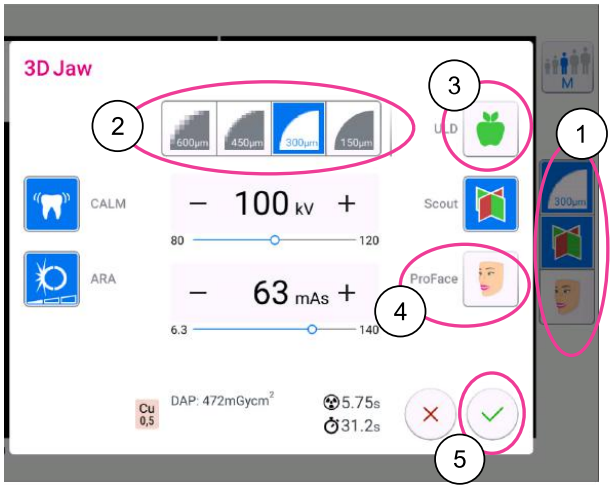
With Tooth program you can alternatively use the button shown below when you select the image volume position. Select the position from the pop-up window that appears and confirm by selecting the green check mark button.



11.7 Selecting image resolution, Ultra Low Dose (ULD) and ProFace

Steps

1. Select field (1) to open a pop-up window.
2. Select the image resolution you wish to use (2). The voxel size options are 600 / 450, 300, 200, 150 and 75 micrometres, depending on the selected program.
3. Select the ULD (Ultra Low Dose) button (3) if you want to take an exposure with a very low dose. The voxel size buttons turn green and show a small apple.
4. Select the ProFace (optional feature) button (4) to add the 3D photo to the exposure.
5. Select the green check mark button (5).



NOTE

The available options depend on the selected program.

NOTE

The exposure values will automatically change according to the selected patient size, image resolution and ULD setting. The preset exposure values are shown in section"Adjusting exposure values for current exposure" on page 59 .

11.8 Adjusting exposure values for current exposure

About this task

NOTE

Always try to minimise the radiation dose to the patient.

The exposure values have been preset at the factory for each patient size, image resolution and ULD (Ultra Low Dose) setting. The preset exposure values are average values and they are only meant to guide the user.

The preset exposure values are shown in the following tables.

NOTE

The D-059SBR X-ray tube's maximum mAs value is 110 mAs. If the mAs value shown in the table exceeds this, 110 mAs is used instead.

NOTE

Be aware of AI processing

When using 75 um voxel size, the AI based NOA denoising algorithm is applied to the resulting image. NOA is using neural network (a.k.a Artificial Intelligence, AI) for denoising and the network has been trained using machine learning methods.

Factory presets for Tooth, Teeth, Jaw, Face, Skull, Ear, Temporal Bone and Vertebrae programs

	Child (XS)		Small adult (S)		Medium-sized adult (M)		Large adult (L)		Extra-large adult (XL)	
Voxel size	kV	mAs	kV	mAs	kV	mAs	kV	mAs	kV	mAs
0.5 mm Cu filter										
600	90	32	90	36	100	28	110	25	120	22
450	90	56	90	63	100	50	110	45	120	40
300	90	71	90	80	100	63	110	56	120	50
200	90	90	90	100	100	80	110	71	120	63
150	90	110	90	125	100	100	110	90	120	80
75	90	160	90	160	100	160	110	140	120	125
0.2 mm Cu filter										
600	90	16	90	18	100	14	110	12.5	120	11
450	90	28	90	32	100	25	110	22	120	20
300	90	36	90	40	100	32	110	28	120	25
200	90	45	90	50	100	40	110	36	120	32
150	90	56	90	63	100	50	110	45	120	40

Factory presets for Tooth, Teeth, Jaw, Face, Skull, Ear, Temporal Bone and Vertebrae programs

	Child (XS)		Small adult (S)		Medium-sized adult (M)		Large adult (L)		Extra-large adult (XL)	
Voxel size	kV	mAs	kV	mAs	kV	mAs	kV	mAs	kV	mAs
75	90	90	90	100	100	80	110	71	120	63
ULD										
600	90	8	90	9	100	7.1	110	6.3	120	5.6
450	90	14	90	16	100	12.5	110	11	120	10
300	90	18	90	20	100	16	110	14	120	12.5
200	90	22	90	25	100	20	110	18	120	16
150	90	28	90	32	100	25	110	22	120	20
75	90	45	90	50	100	40	110	36	120	32

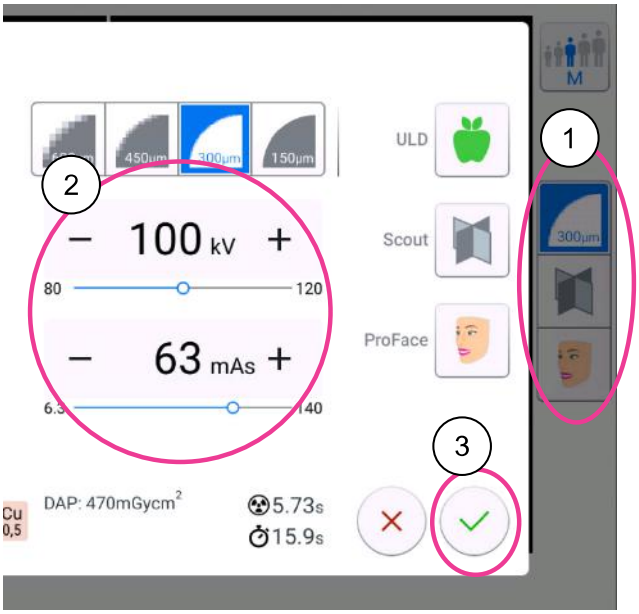
Factory presets for Sinus, Nose and Airways programs

	Child (XS)		Small adult (S)		Medium-sized adult (M)		Large adult (L)		Extra-large adult (XL)	
Voxel size	kV	mAs	kV	mAs	kV	mAs	kV	mAs	kV	mAs
0.5 mm Cu filter										
600	90	25	90	28	100	22	110	20	120	18
450	90	45	90	50	100	40	110	36	120	32
300	90	56	90	63	100	50	110	45	120	40
200	90	71	90	80	100	63	110	56	120	50
150	90	90	90	100	100	80	110	71	120	63
75	90	140	90	160	100	125	110	110	120	100
0.2 mm Cu filter										
600	90	12.5	90	14	100	11	110	10	120	9
450	90	22	90	25	100	20	110	18	120	16
300	90	28	90	32	100	25	110	22	120	20
200	90	36	90	40	100	32	110	28	120	25
150	90	45	90	50	100	40	110	36	120	32
75	90	71	90	80	100	63	110	56	120	50
ULD										
600	90	6.3	90	7.1	100	5.6	110	5	120	4.5
450	90	11	90	12.5	100	10	110	9	120	8
300	90	14	90	16	100	12.5	110	11	120	10
200	90	18	90	20	100	16	110	14	120	12.5
150	90	22	90	25	100	20	110	18	120	16
75	90	36	90	40	100	32	110	28	120	25

Follow these steps if you need to adjust the preset exposure values for current exposure:

Steps

1. Select this field (**1**) to open a pop-up window.
2. Use the minus or plus signs (**2**) to set the exposure values you wish to use. To improve the image contrast, reduce the kV value. To reduce the radiation dose, reduce the mAs value.
3. Select the green check mark button (**3**).



The selected default filter option (Cu 0.2 or Cu 0.5) is shown in the exposure settings pop-up window. Contact you service technician if you want to change the default filter.

11.9 Selecting Artefact Removal Algorithm (ARA), patient movement correction (CALM) and resolution optimisation (PRO)

Steps

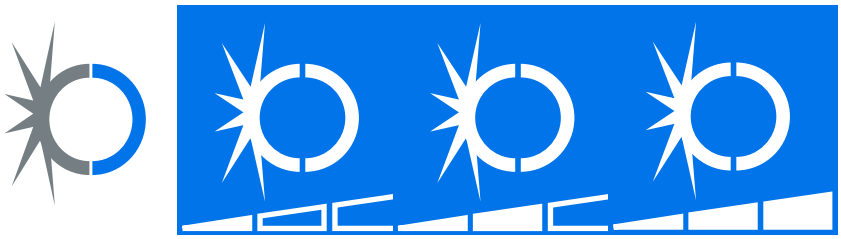
1. Select this field (**1**) to open a pop-up window.
2. Select the CALM (patient movement correction) button (**2**) if you wish to minimise the effects of movements on the image.

   The Planmeca CALM function is an algorithm that detects patient movement during exposure and then compensates for the effects of the movement during image reconstruction. We recommend that you use this setting when taking exposures of children (patient size XS) or restless patients.

   NOTE

   The Planmeca CALM algorithm is for use only on live patients and is not recommended for use, for example, in imaging involving an inorganic sample or QA phantom attachment.

3. Toggle the ARA (Artefact Removal Algorithm) button (**3**) to select the setting you wish to use:



No artefact removal | Low | Medium | High

4. Select the PRO button (**4**) if you want to use resolution optimisation to further enhance image quality.

   The PRO option is available for the following 3D programs:

   Viso G7: tooth, teeth, nose, middle ear, temporal bone, airways

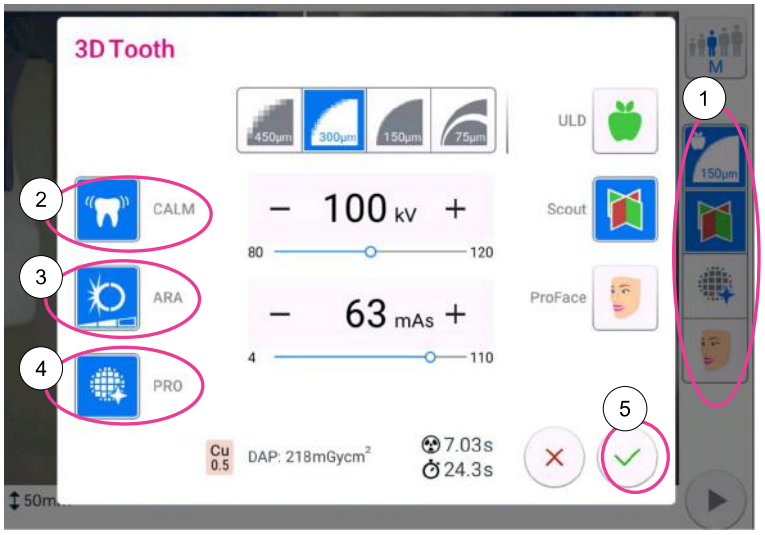
   Viso G5: tooth, middle ear

   Viso G3: tooth, middle ear

   NOTE

   The PRO selection is made for each exposure separately. The button does not remain selected if you click away from the exposure screen for any reason.

5. Select the green check mark button (**5**).



11.10 Taking scout views

About this task

You can take scout views of the selected image volume before you take the actual 3D image. This allows you to check that the image volume is in the correct place.

The scout views are automatically saved in the Planmeca Romexis program under 2D images (CBCT tab).

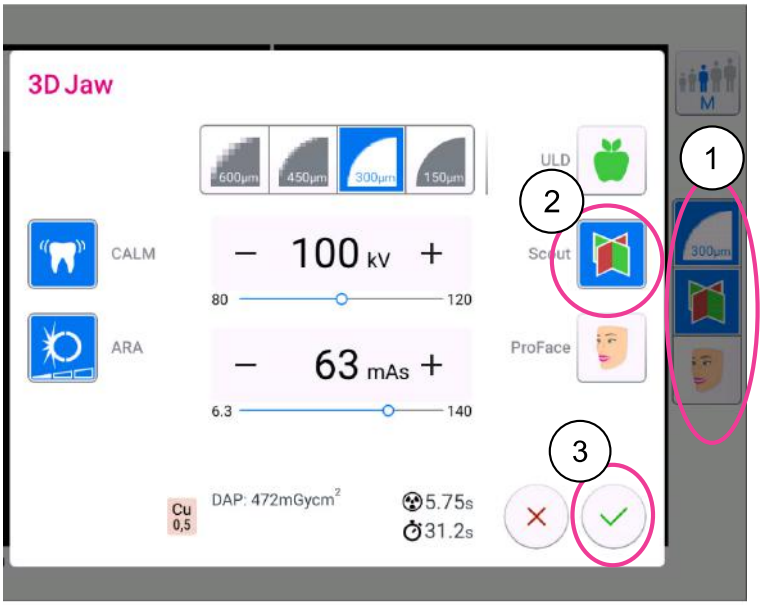
Make sure that you have selected the correct patient in the Planmeca Romexis program.

NOTE

The scout view function can yield results for Teeth, Tooth and Jaw programs that look different to the scouts for Face and Sinus programs.

Steps

1. Select field (1) to open a pop-up window.
2. Select the Scout (2) button.
3. Select the green check mark button (3).
4. Select the forward button.



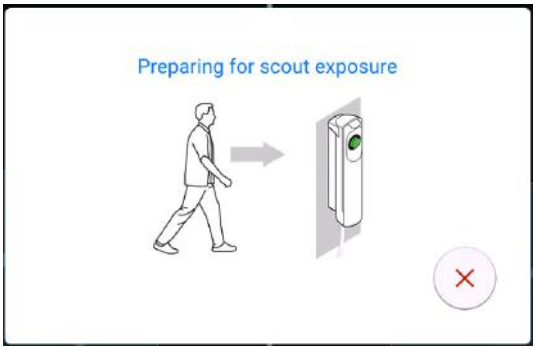
NOTE

The Scout button is already selected if you used it in the previous exposure. In this case you only need to select the forward button.

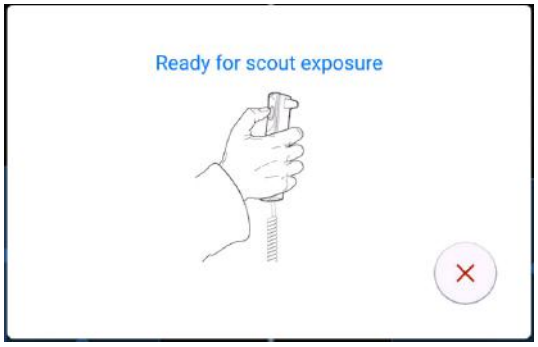
Green lights flash on the control panel and exposure button when the X-ray system is getting ready for an exposure. You see this message.

NOTE

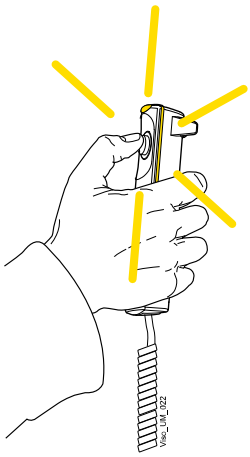
Move to a protected area.



The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure. The following message displays.

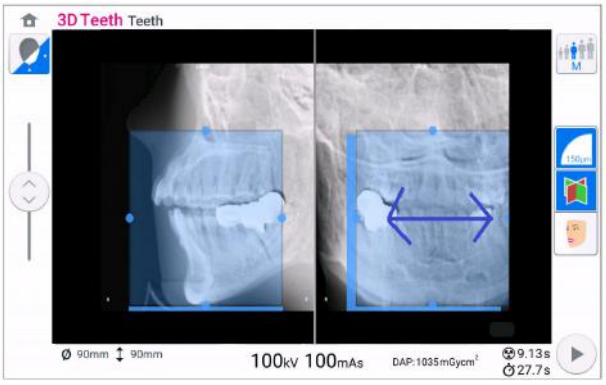


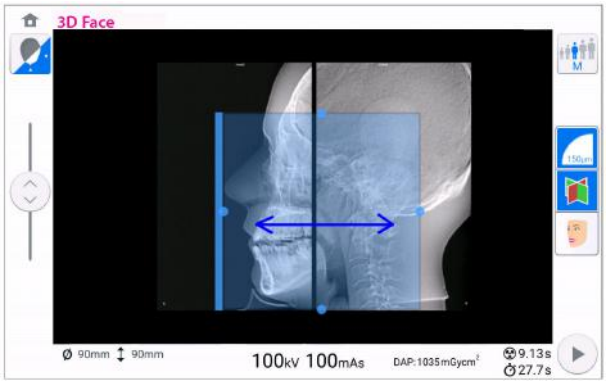
5. Ask the patient to stay as still as possible.
6. Press and hold down the exposure button for the duration of the exposure.



During exposure yellow radiation warning lights illuminate on the exposure switch and on the control panel. Additionally, you hear a radiation warning tone and see a radiation warning symbol on the control panel.

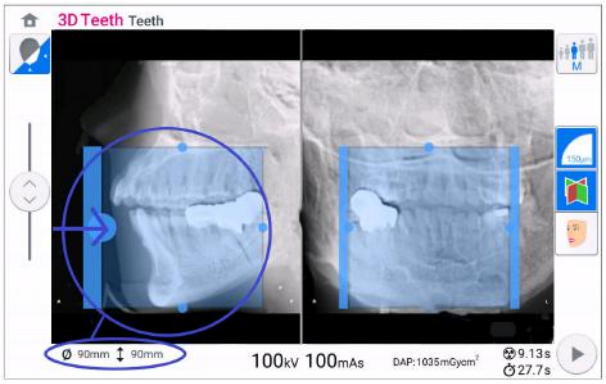
7. If needed, you can now fine-adjust the volume position and size.
   - To fine-adjust the volume position, use your mouse cursor (virtual control panel) or finger (touch screen) to move the blue area. The blue area can be moved in any direction.

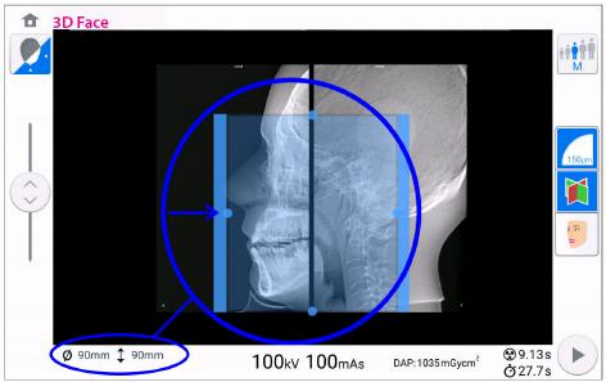




- To fine-adjust the volume size, hold your mouse cursor (virtual control panel) or finger (touch screen) on one of the small blue balls and move the ball to enlarge or reduce the volume size. The ball turns red when you reach the limit value, i.e. when the volume diameter or height cannot be further adjusted in that direction.

  The selected volume size (diameter and height) is shown in the bottom right corner of the screen.





The adjustment is indicated by different blue shades:

- Dark blue area = Volume position and size before adjustment
- Light blue area = Volume position and size after adjustment

8. If you want to take new scout views, select this button and take a new exposure as described above. Make new fine-adjustments until the image volume is in the correct place.

11.11 Taking 3D exposure

Before you begin

Make sure that you have selected the correct patient in the Romexis program.

NOTE

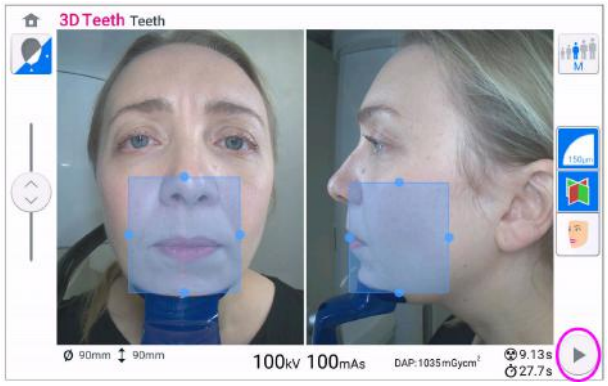
After scout views the X-ray system is automatically ready for a 3D exposure. Go directly to step 2.

NOTE

Make sure that the Scout button is switched off if you do not want to take scout views first.

Steps

1. Select the forward button.

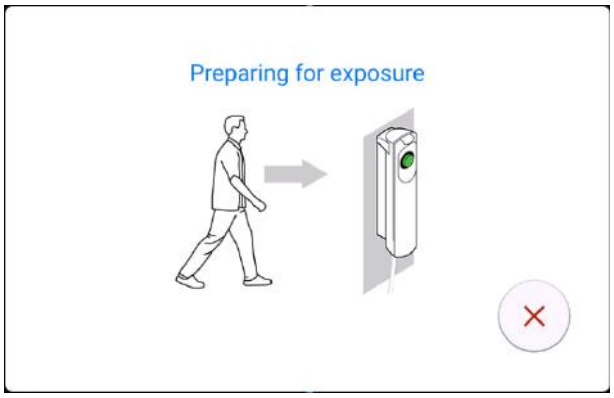


Green lights flash on the control panel and exposure button when the X-ray system is getting ready for an exposure.

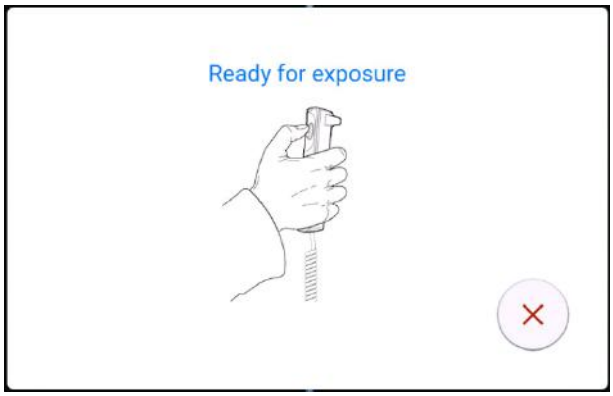
You see this message.

NOTE

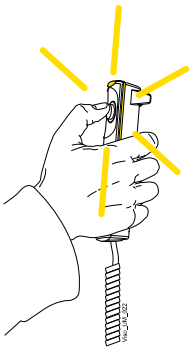
Move to a protected area.



The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure. You see this message.



2. Ask the patient to stay as still as possible.
3. Press and hold down the exposure button for the duration of the exposure(s).



The C-arm moves around the patient's head.

During exposure yellow radiation warning lights illuminate on the exposure switch and on the control panel. Additionally, you hear a radiation warning tone and see a radiation warning symbol on the control panel.

If you take a skull exposure with two image volumes, the lower volume (1 / 2) is imaged first and the upper volume (2 / 2) last. The C-arm is automatically moved up between the volumes.

You can follow the imaging process on the virtual control panel. You see two preview images: the progress bar below the first image (**1**) shows the capture progress and the slider below the second image (**2**) allows you to view the captured frames from different angles.

NOTE

Do not release the exposure button before the end of the exposure(s).

NOTE

Maintain audio and visual contact with the patient and X-ray unit during exposure. If the C-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately.

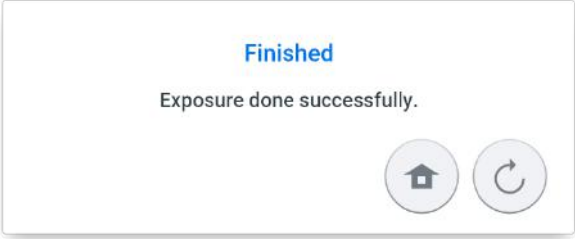
4. If the ProFace option was selected, the second phase of the exposure, i.e. the image of the selected exposure area is taken.

NOTE

In this phase no radiation is used.

The C-arm moves around the patient's head and the image is generated.

You see this message on the touch screen.



Select the home button if you want to return to the home screen.

Select this button if you want to retake the exposure with the same settings.

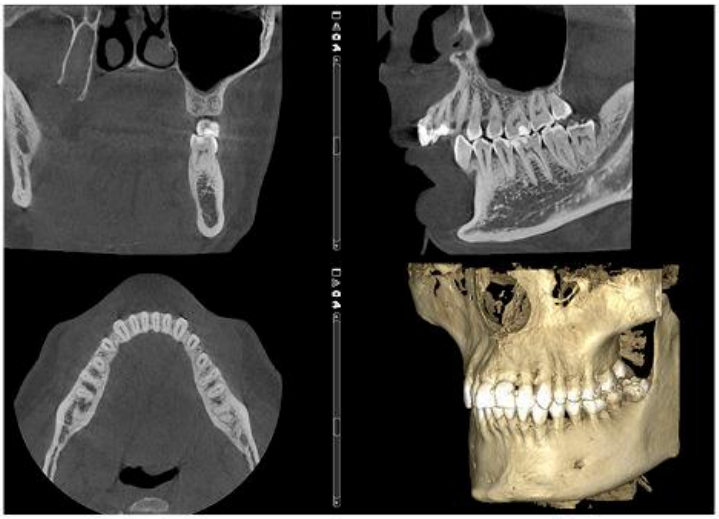
5. Remove the fastening straps (if used). Release the patient from the head support.
6. Guide the patient away from the X-ray unit.

Results

The image is shown on the computer screen.

The image processing time depends on the selected settings. For example, if you selected the ULD (Ultra Low Dose) button, you have to wait longer before the image appears.

If you took a skull exposure with two image volumes, you must accept the image stitching function in the Romexis program.



If the ProFace option was selected, the image processing takes some extra time.

11.12 Taking 3D face photo

Before you begin

Select the ProFace program from the main page by selecting **Special Programs > ProFace**. For more information, see section "3D dental programs" on page 48.

Make sure that you have selected the correct patient in the Planmeca Romexis program.

Steps

1. Position the patient as described in section "Patient positioning" on page 52.

   Adjust the patient position and the settings on the screen until the Frankfort line and the patient's eye are correctly positioned as shown in the image below.

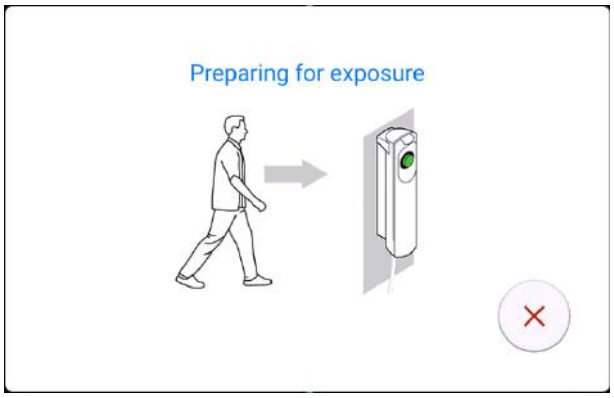
   NOTE

   You can move the Frankfort line and eye markers using a finger (touch screen) or the mouse cursor (virtual control panel).

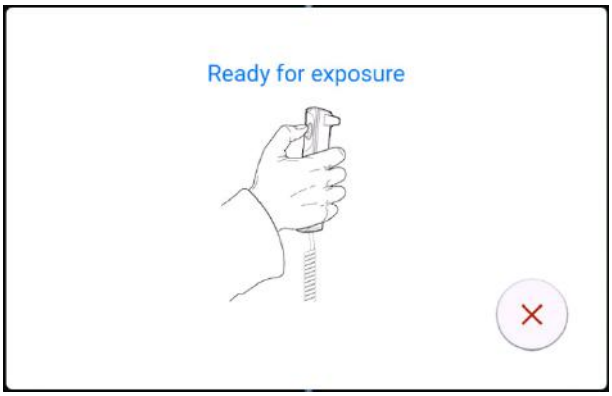
2. Select the forward button in the bottom right corner.

   Green lights flash on the control panel and exposure button when the X-ray system is getting ready for an exposure.

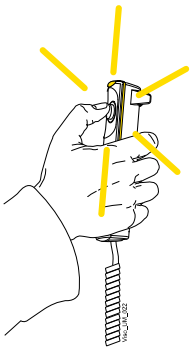
   The following screen displays.

   The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure. The following screen displays.



3. Ask the patient to stay as still as possible.
4. Press and hold down the exposure button for the duration of the exposure(s).



The C-arm moves around the patient's head.

NOTE

Do not release the exposure button before the end of the exposure(s).

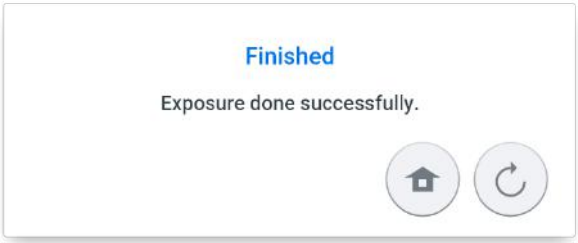
NOTE

Maintain audio and visual contact with the patient and X-ray unit during exposure. If the C-arm stops moving during exposure, or moves in an erratic way, release the exposure button immediately.

5. The image generates.

   This may take several minutes.

   You see this message on the touch screen.



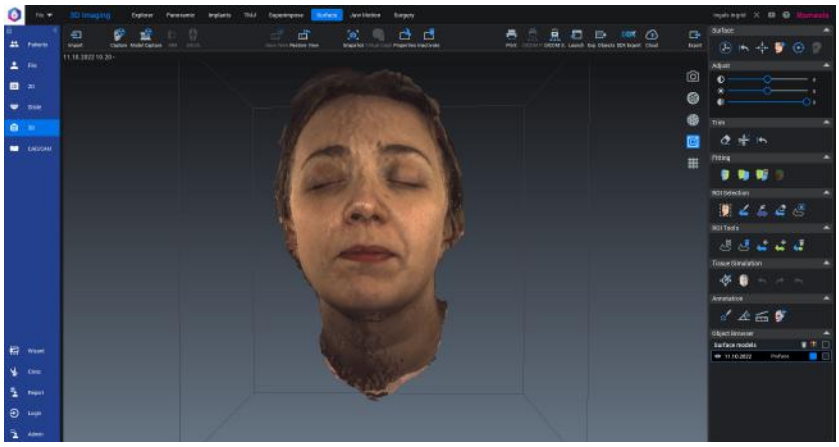
Select the home button if you want to return to the home screen.

Select this button if you want to retake the exposure with the same settings.

6. Remove the fastening straps (if used). Release the patient from the head support.
7. Guide the patient away from the X-ray unit.

Results

The image is shown on the computer screen.



12 3D quality control

A quality control test must be carried out on the X-ray unit once a month in order to ensure consistent image quality. It is recommended to compare the test results to the results from the previous month's test to notice any significant changes that may have occurred. Quality control tests are carried out using a separate software called **Device Tool QA**, that is installed on your computer for this purpose.

The following sections provide instructions on how to run 3D Quality Assurance (QA) tests for Planmeca Viso 3D X-ray units.

NOTE

The instructions in the following sections are valid only for Planmeca QA tests. The instructions for DIN 6868 based QA tests (used in Germany) are given in a separate manual.

NOTE

The Reconstruction PC must be switched on and the TCP/IP connection must work.

12.1 Safety notices and compatibility

CAUTION

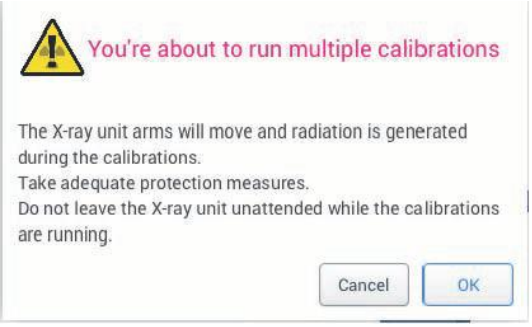
Only qualified service technicians may perform QA testing using the full Planmeca Device Tool installation. If performing the QA test using the Device Tool QA program, read this section carefully before proceeding.

CAUTION

In the Device Tool, for the Planmeca 3D QA, it is possible to run multiple calibrations, i.e. select all 3D QA calibrations to be run in a row. If the multiple calibration is used, be extra careful with the following issues:

- The X-ray unit arms will move and radiation is generated during the calibrations.
- Take adequate protection measures.
- Do not leave the X-ray unit unattended while the calibrations are running.

The Device Tool displays a confirmation when the grouped calibration is started.



NOTE

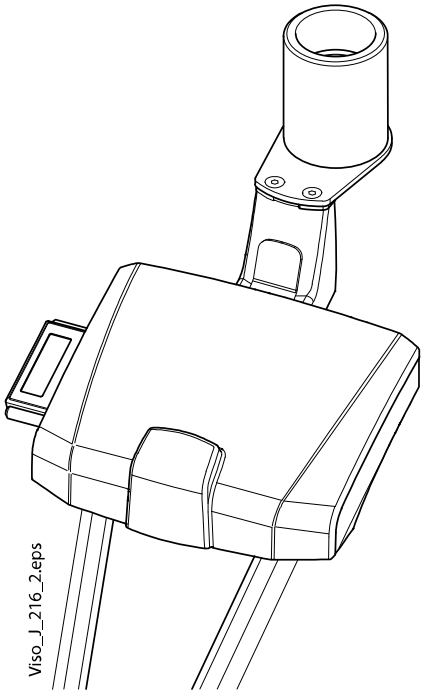
The display values and user interface images shown in this chapter are only examples and should not be interpreted as recommended values unless otherwise stated.

The 3D QA testing described in this chapter is valid for Planmeca Viso X-ray units.

12.2 Running QA test

Steps

1. Attach the 3D QA phantom to the patient support base.



2. Switch on the X-ray unit.
3. Start the **Device Tool QA** in the clinic computer.
4. Select the test type **Planmeca QA** from the options.

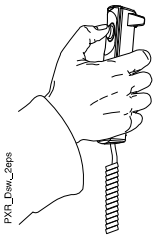
5. Click the **Start** button to continue.

   Planmeca QA tests consists of the following test:

   - QA 3D - C-Arm Center

- QA 3D - Middle Arm Center
- QA 3D - Middle Arm Offset

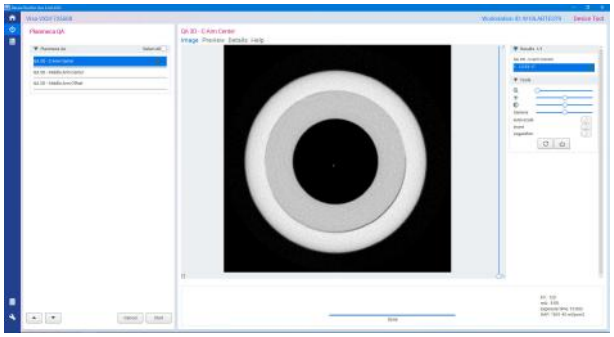
6. Select the **QA 3D - C-Arm Center** from the calibration task list (if not yet selected) and click the **Start** button.
7. Press the exposure button to take the exposure.



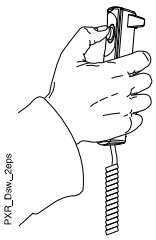
CAUTION

Protect yourself from radiation.

The following image view appears.



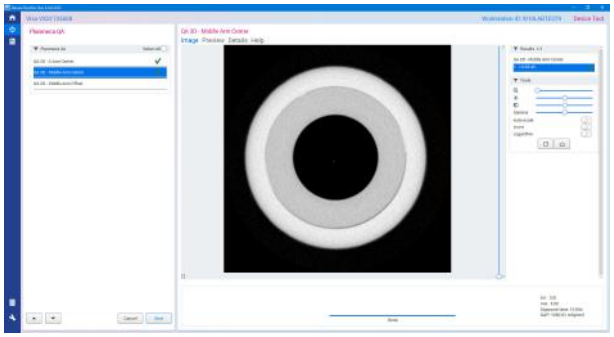
8. Select the **QA 3D - Middle Arm Center** from the calibration task list and click the **Start** button.
9. Press the exposure button to take the exposure.



CAUTION

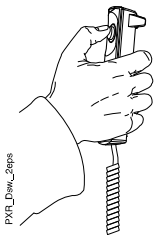
Protect yourself from radiation.

The following image view appears.



10. Select the **QA 3D - Middle Arm Offset** from the calibration task list and click the **Start** button.

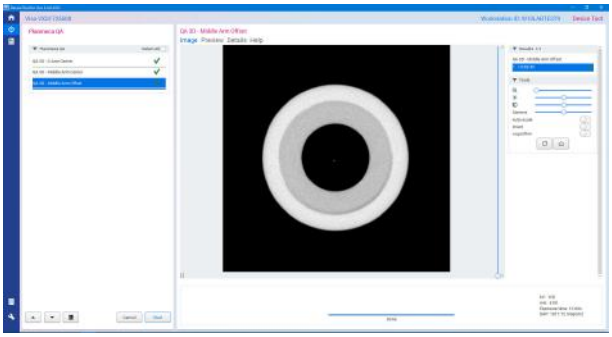
11. Press the exposure button to take the exposure.



CAUTION

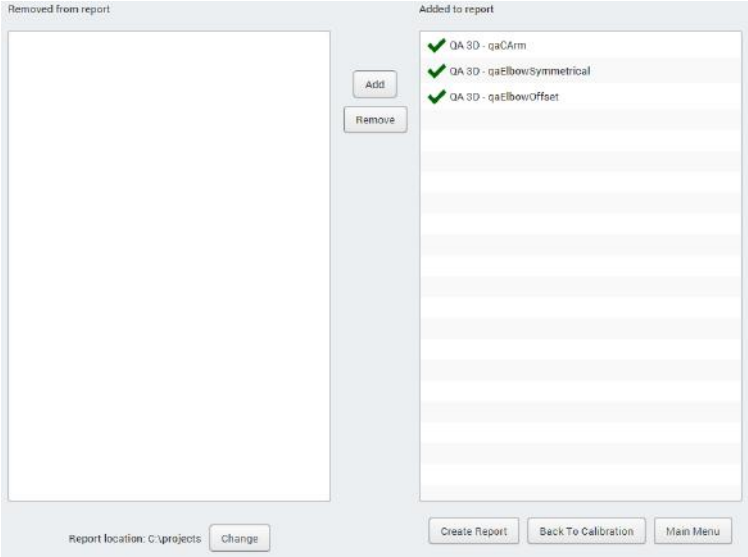
Protect yourself from radiation.

The following image view appears.



12. Click the **Open Report Editor** button.

The following window is displayed.



On the report page, you can select which of the QA tests you want to include in the report.

13. Once your selections are ready, click **Create Report**.

Results

The report opens in a new browser window.

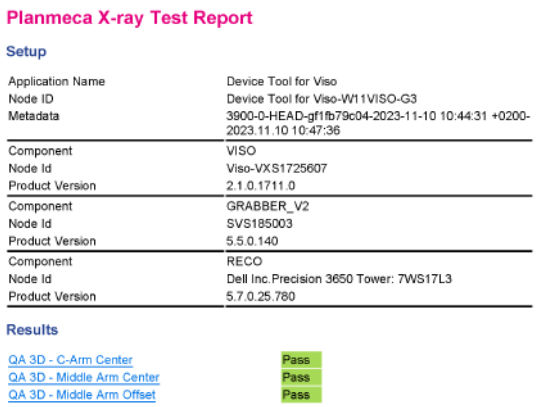
For more information on the test results, see section "Post-test process" on page 78.

The QA test will fail if the measurement tolerances are not met. The following table lists the expected 3D QA test results and tolerances.

X-ray unit model	Material	Expected/tolerance
Viso G5 and G7		
	Acrylic	Density (avg HU mean): 0 (±200)
		Signal to noice ratio (avg SNR): > 5
		Uniformity/homogeneity: < 40
	Aluminium	Density (Avg HU mean with 90kV): 3000 (±1000)
		Signal to noice ratio (avg SNR): > 5
		Uniformity/homogeneity: < 30
	Air	Density (avg HU mean): -1000 (-1000 - -900)
		Uniformity/homogeneity: < 20
	MTF	MTF ≥ 1.0 lp/mm, if voxel size ≤ 400 µm

12.3 Post-test process

If the QA tests were successful, the test results report shows each test with green highlighting and marked with **Pass**, example below.



Planmeca X-ray Test Report

Setup

Application Name	Device Tool for Viso
Node ID	Device Tool for Viso-W11VISO-G3
Metadata	3900-0-HEAD-gf1fb79c04-2023-11-10 10:44:31 +0200-2023.11.10 10:47:36
Component	VISO
Node Id	Viso-VXS1725607
Product Version	2.1.0.1711.0
Component	GRABBER_V2
Node Id	SVS185003
Product Version	5.5.0.140
Component	RECO
Node Id	Dell Inc.Precision 3650 Tower: 7WS17L3
Product Version	5.7.0.25.780

Results

QA 3D - C-Arm Center	Pass
QA 3D - Middle Arm Center	Pass
QA 3D - Middle Arm Offset	Pass

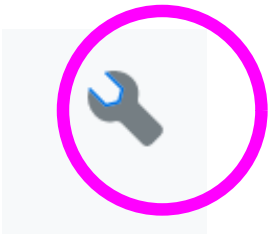
QA test passes

After successful QA test, remove the 3D QA phantom from the patient support table.

QA test fails

If the QA test fails, the unit is not correctly adjusted and calibrated. Contact your service technician for adjustment and calibration assistance.

13 Settings



NOTE

Some of the settings can be used to alter the operation of the X-ray unit. Never use functions that you are not familiar with.

NOTE

The contents of the displays depend on the unit configuration. The displays shown here are only examples.

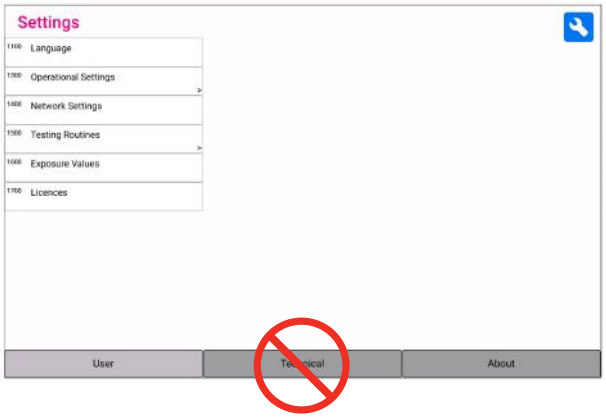
Select the settings symbol on the main screen to enter the settings menu.

Settings that can be entered by the user:

- User
- About

Settings that can be entered by service personnel only (password required):

- Technical



To return to the main screen, select the settings symbol at the top right corner.

13.1 User settings

13.1.1 Language (1100)

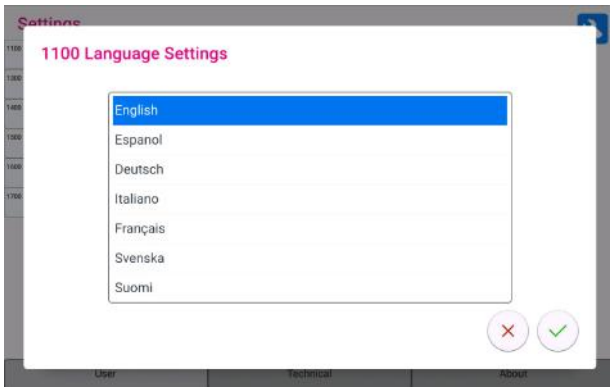
About this task

Follow these steps to change language.

Steps

1. Select **User > 1100 Language**.

2. Select the language you wish to use.



Available languages:

- English
- Chinese (Simplified)
- Chinese (Traditional)
- Danish
- Dutch
- Finnish
- French
- German
- Italian
- Japanese
- Korean
- Norwegian
- Polish
- Russian
- Spanish
- Swedish
- Turkish

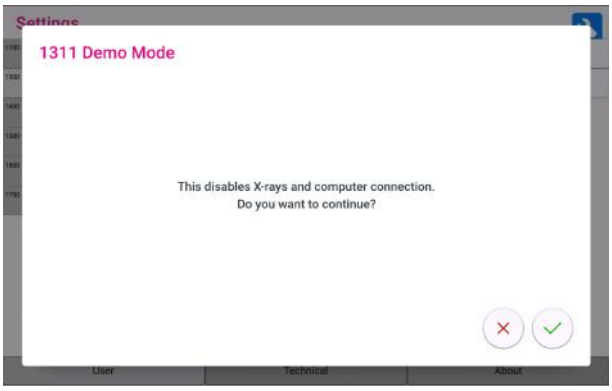
3. Select the green check mark button.

13.1.2 Operational Settings (1300)

13.1.2.1 Mode (1310)

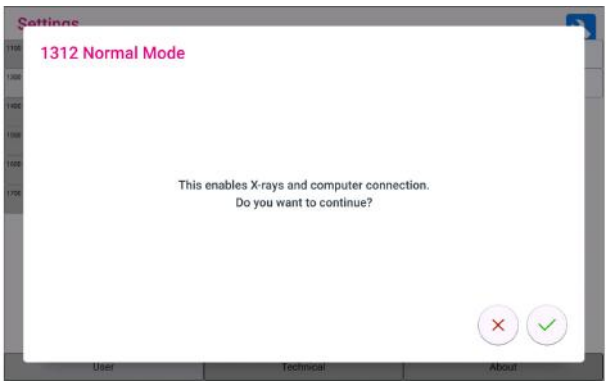
Steps

1. Select **User** > **1300 Operational Settings** > **1310 Mode**.
2. Select the mode you wish to use:
   - 1311 Demo Mode



   In demo mode you can practice or demonstrate the functions of the X-ray unit without radiation and PC connection.

   - 1312 Normal Mode



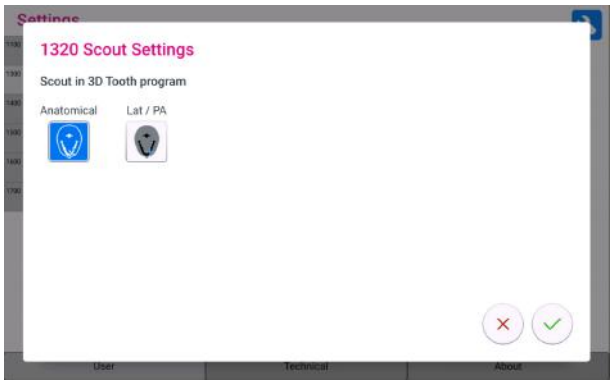
3. Select the green check mark button.

13.1.2.2 Scout Settings (1320)

Steps

1. Select **User** > **1300 Operational Settings** > **1320 Scout Settings**.

2. Select the default scout setting in the 3D Tooth program.



- Anatomical
- Lat/PA

3. Select the green check mark button.

13.1.2.3 Exposure settings (1330)

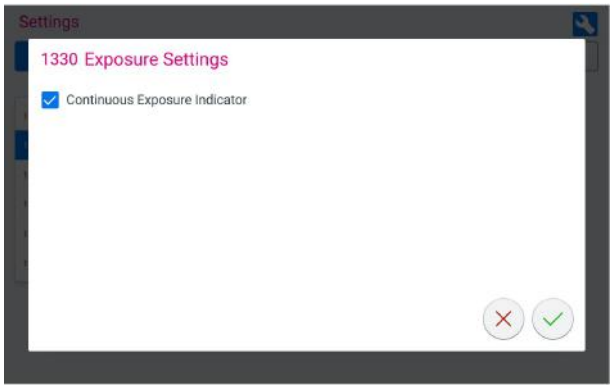
About this task

Turn the Continuous Exposure Indicator option ON if you wish to set the X-ray unit so that the yellow radiation warning light and radiation warning tone stay on continuously when you take an exposure.

Note that the setting affects all indicator lights that are connected to your X-ray system (indicator light on the hand-held exposure switch, wall exposure switch(es) and remote exposure lamp).

Steps

1. Select **User** > **1300 Operational Settings** > **1330 Exposure settings**.
2. Select/deselect **Continuous Exposure Indicator**.



3. Select the green check mark button.

13.1.2.4 Default kV / mA settings

For more information on setting the default kV / mA values, see section "Exposure Values (1600)" on page 85.

13.1.3 Network Settings (1400)

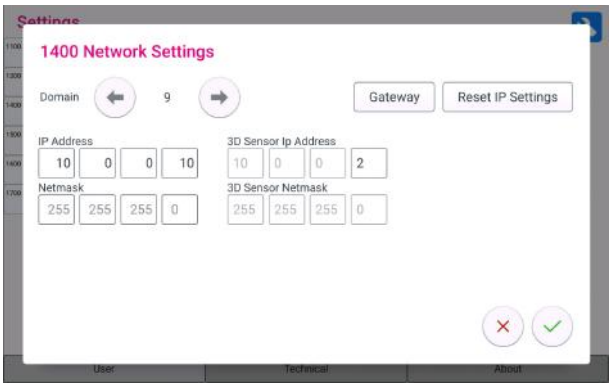
About this task

Follow these steps to view network settings.

Steps

1. Select **User > 1400 Network Settings**.

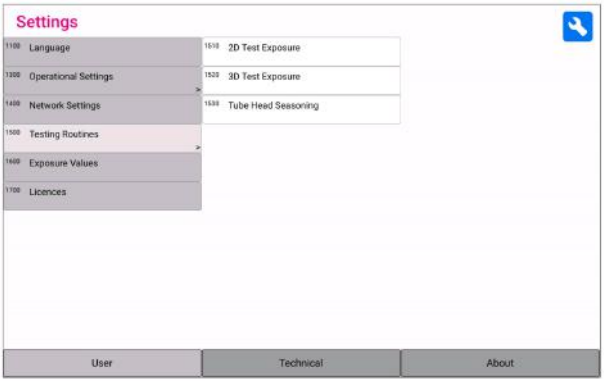
2. Select the network settings you wish to view.
3. Select the green check mark button.



NOTE

Only a service technician or local administrator may change the network settings.

13.1.4 Testing Routines (1500)



13.1.4.1 2D test exposure

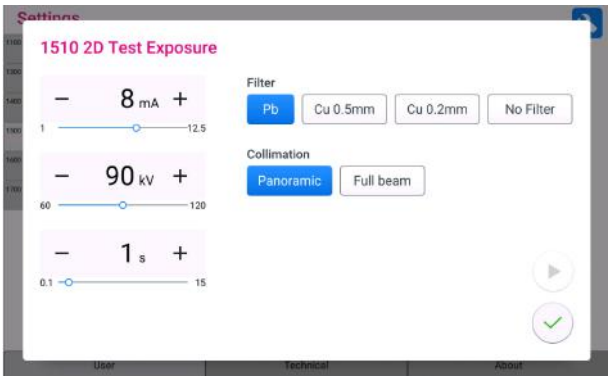
About this task

Follow the steps below to take a 2D test exposure.

Steps

1. Select **User > 1500 Testing Routines > 1510 2D Test Exposure**.

2. Use the **-** or **+** button to set the exposure values you wish to use.
3. Select the SET button.
4. Move to a protected area.
5. Press and hold down the exposure button for the duration of the exposure. The C-arm does not move when you take a test exposure.
6. Select the green check mark button.



13.1.4.2 3D test exposure

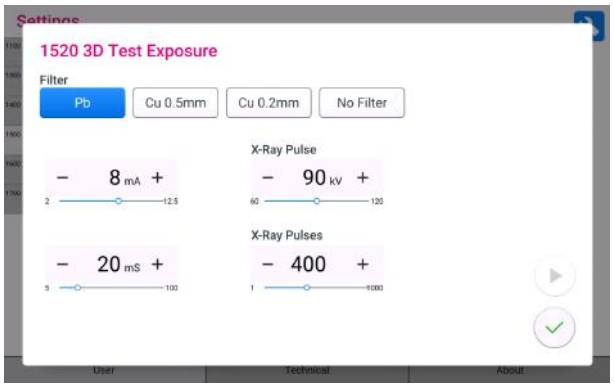
About this task

Follow the steps below to take a 3D test exposure.

Steps

1. Select **User > 1500 Testing Routines > 1520 3D Test Exposure**.
2. Use the **-** or **+** button to set the exposure values you wish to use.
3. Select the SET button.
4. Move to a protected area.
5. Press and hold down the exposure button for the duration of the exposure.

   The C-arm does not move when you take a test exposure.
6. Select the green check mark button.



13.1.4.3 Tube head seasoning

About this task

Follow the steps below to perform tube head seasoning.

Steps

1. Select **User > 1500 Testing Routines > 1530 Tube Head Seasoning**.

   This option allows you to warm up the X-ray tube, i.e. run a tube head seasoning process. This is necessary if the X-ray unit has not been used for a week or more and/or if you receive error message E332 (Severe arcing across X-ray tube).

2. Select the START button.

3. Move to a protected area.
4. Press the exposure button when the word **Ready** appears.

   You can press and hold down the exposure button for the whole duration of the process or lift your thumb from the exposure button when the word **Wait** appears.

   NOTE
   The seasoning process takes several minutes.

   After a successful process the message **OK** displays.

5. Select the green check mark button.

NOTE
Contact your service technician for help if error message E332 (Severe arcing across X-ray tube) reoccurs after a successful seasoning process.

13.1.5 Exposure Values (1600)

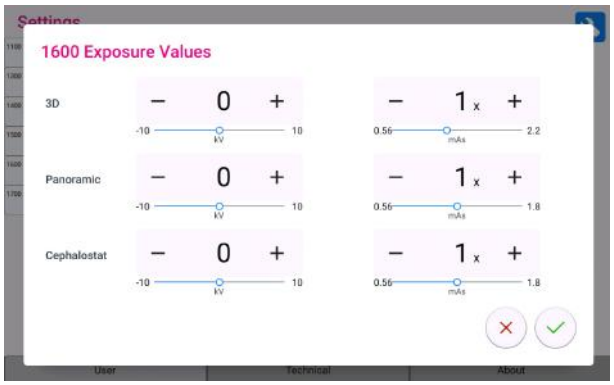
Steps

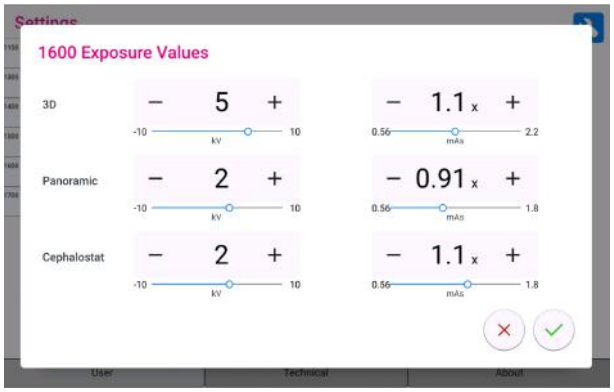
1. Go to **1600 Exposure Values** to check the default kV and mA settings for 3D or Panoramic imaging.

   The values can be adjusted as follows:

   - 5 kV increments for 3D
   - 2 kV increments for Panoramic

   NOTE
   The mA adjustment increments are measured according to a decimal scale with divisions proportioned to the relevant mA measures.





The revised exposure values are then used in performance of next exposure.

13.1.6 Licences (1700)

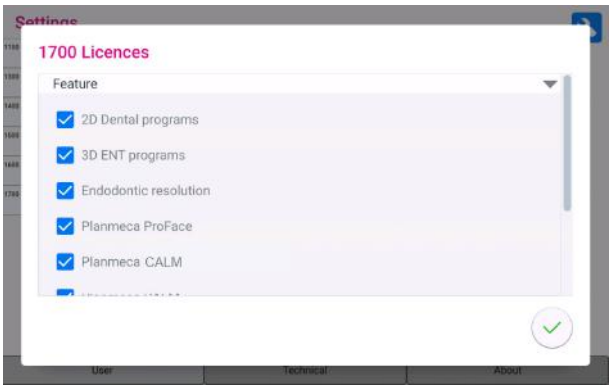
About this task

Follow the steps below to activate a program licence.

Steps

1. Select **User > 1700 Licences**.

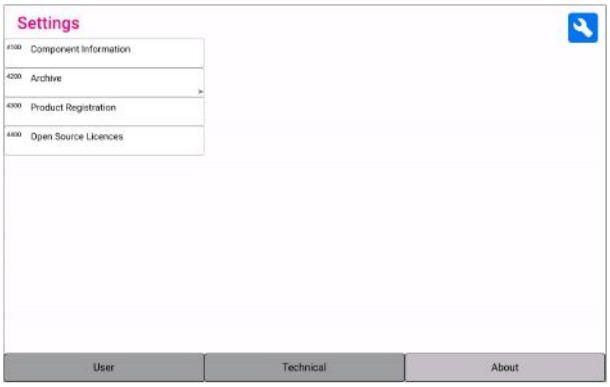
2. Select the licences you wish to activate.



- 2D Dental programs
- 3D ENT programs
- Endodontic resolution
- Planmeca ProFace
- Planmeca CALM
- TWAIN connection
- Planmeca PRO
- Planmeca Viso G5 Upgrade

3. Enter the licence code that you have received for this licence on this X-ray unit.
4. Select the green check mark button.
5. Repeat for another program licence if needed.
6. Select the green check mark button.

13.2 About



13.2.1 Component Information (4100)

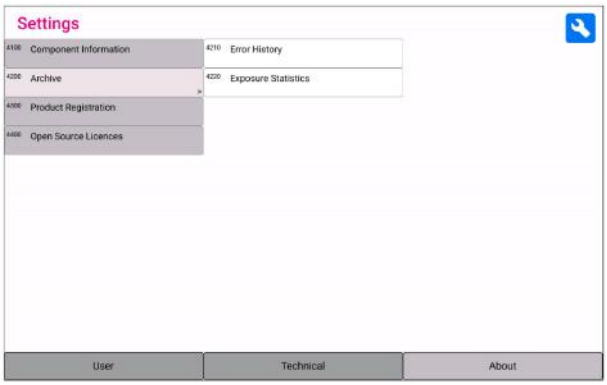
To view component information:

Select About > 4100 Component Information > Show Component Information to view the set-up or current software versions of the X-ray unit.

To view software build information:

Select About > 4100 Component Information > Show Detailed Build Info to view details about the software build.

13.2.2 Archive (4200)

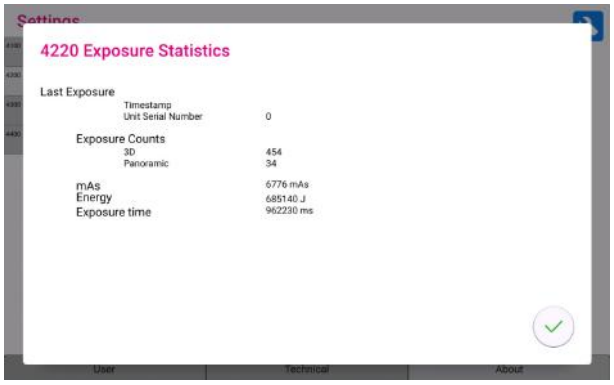


To view error history:

Select About > 4200 Archive > 4210 Error History to view a list of the error messages that have been generated by the X- ray unit. The errors are shown in chronological order with the latest error message on top.

To view exposure statistics:

Select About > 4200 Archive > 4220 Exposure Statistics to view statistical data about the X-ray unit.



13.2.3 Product Registration (4300)

For more information on product registration, see section "Product registration" on page 4.

14 Help messages

The X-ray unit incorporates a self-checking feature that monitors the operation of the unit. If the system detects an operating error, a help message (e.g. H101) appears on the control panel.

The X-ray unit will not accept any commands from the user until the help message is cleared. Clear the message by selecting the green check mark button.

The following list shows, in numerical order, all the help messages that can appear.

Code	Explanation		Comments
H101	Exposure switch	The exposure button was released before the end of the exposure.	Guide the patient away from the X-ray unit before moving the C-arm. Press and hold down the exposure button for the entire duration of the exposure.
H102		The exposure button is stuck or the cable is short circuited.	Release the exposure button. Contact your service technician if you need to replace the exposure switch.
H105	Emergency stop button	The emergency stop button has been activated.	All movements of the X-ray unit are blocked and no radiation is generated. Guide the patient away from the X-ray unit. Then release the emergency stop button to resume normal operation.
H124	Memory	Not enough memory on imaging workstation for this imaging.	There is not enough memory allocated in the imaging workstation (e.g. Planmeca Romexis) for the selected imaging program. E.g. the skull program with volume size 300x300 requires 32 GB memory in the imaging workstation. For more information on the Planmeca Romexis memory allocations, see *Planmeca Romexis technical manual*.
H130	Patient safety area	Patient safety area violation detected.	
H131	Rear head support	Rear head support movement detected.	
H132		Rear head support detached.	
H133		Remove the rear head support.	
H134		Adjust the rear head support.	

Code	Explanation		Comments
H141	Height movement	Movement stopped because the column is moving in wrong direction.	The column is moving in wrong direction, check sensors and cables.
H142		Height movement is not possible because the stop plate at the bottom of the column was activated.	Clear any obstruction before moving the column again.
H146		Motor safety switch in upper direction z drive	
H147		Motor safety switch in lower direction z drive	
H148		Height movement is not possible. The position of the patient support base is too high.	Use the height adjusting slider to move the patient support base down.
H149		Height movement was stopped because the C-arm cannot be moved higher.	Clear any obstruction before continuing.
H150		Height movement was stopped because the patient support base cannot be moved lower.	Clear any obstruction before continuing.
H151	Line voltage	The line voltage was too low during exposure.	Exposure was interrupted. Contact your service technician for help.
H152		The line voltage is too low.	Exposure is not possible. Contact your service technician for help.
H153	Height movement	Z column is too high.	
H154		Z column is too low.	
H155		Imaging equipment is too high.	
H156		Imaging equipment is too low.	
H157		Imaging equipment movement timeout.	
H158		Imaging equipment position sensor not working properly.	
H159		Z column position sensor not working properly.	
H160		Imaging equipment is moving in wrong direction, check sensors and cables.	

Code	Explanation		Comments
H161	Temperature	The temperature of the tube head is too high.	Wait for a few minutes for the tube head to cool down.
H162		The temperature of the lift motor is too high.	Wait for a few minutes for the lift motor to cool down.
H165		The temperature of the tube head is too high for the selected exposure values.	Wait for a few minutes for the tube head to cool down.
H166		The maximum tube head energy level was exceeded.	Wait for a few minutes for the tube head to cool down or use lower exposure values.
H170	User related messages	Wrong licence code.	Check the licence code.
H171		Timeout in production test.	
H181		The imaging process was cancelled in Planmeca Romexis.	
H182		Timeout in image data transmission.	Exposure was interrupted. Contact your service technician for help.
H186		No IP address defined for 3D sensor.	
H187		Problem during image data transmission.	Exposure was interrupted. Contact your service technician for help.
H188		Reconstruction PC error	Exposed image data exists in reconstruction PC with the dataset ID given in the error message. The image can be brought into the Planmeca Romexis with the Redo 3D reconstructions command.
H189		The screen was touched during exposure.	Exposure was interrupted.
H190		Protouch-CPU communication failure.	
H191		3D sensor communication failure.	
H192		Workstation communication failure.	
H193		Invalid scan settings.	
H194		CPU connection not established.	
H195		Request timed out while waiting for CPU to respond.	
H196		Version mismatch in communication interfaces.	
H197		Workstation communication disabled.	
H199		Video streaming failed.	

15 Error messages

NOTE

Contact your service technician for help if you receive an error message.

The X-ray unit incorporates a self-checking feature that monitors the operation of the unit. If the system detects a technical fault, an error message (e.g. E201) appears on the control panel.

An error message indicates that the X-ray unit has a problem that needs to be solved before further exposures can be taken. The X-ray unit will not accept any commands from the user until the error message is cleared. Guide the patient away from the X-ray unit. Then clear the message by selecting the green check mark button.

16 Cleaning and disinfection

For Planmeca approved cleaning agents and disinfectants, see document *Planmeca approved disinfectants* (30025870). The document can be found in the Planmeca Material bank.

NOTE

Switch the X-ray unit off before cleaning and disinfection.

NOTE

Use a Planmeca approved cleaning agent and surface disinfectant. The products are categorised as cleaning agents and / or disinfectants according to the information provided by the manufacturers.

NOTE

Follow the instructions provided by the manufacturer of the cleaning agent, disinfectant and autoclave.

NOTE

FOR SPRAYS, LIQUIDS AND FOAMS:

Do not apply sprays, liquids or foams directly on the surfaces. Apply sparingly to a clean soft cloth and wipe the surface with the cloth.

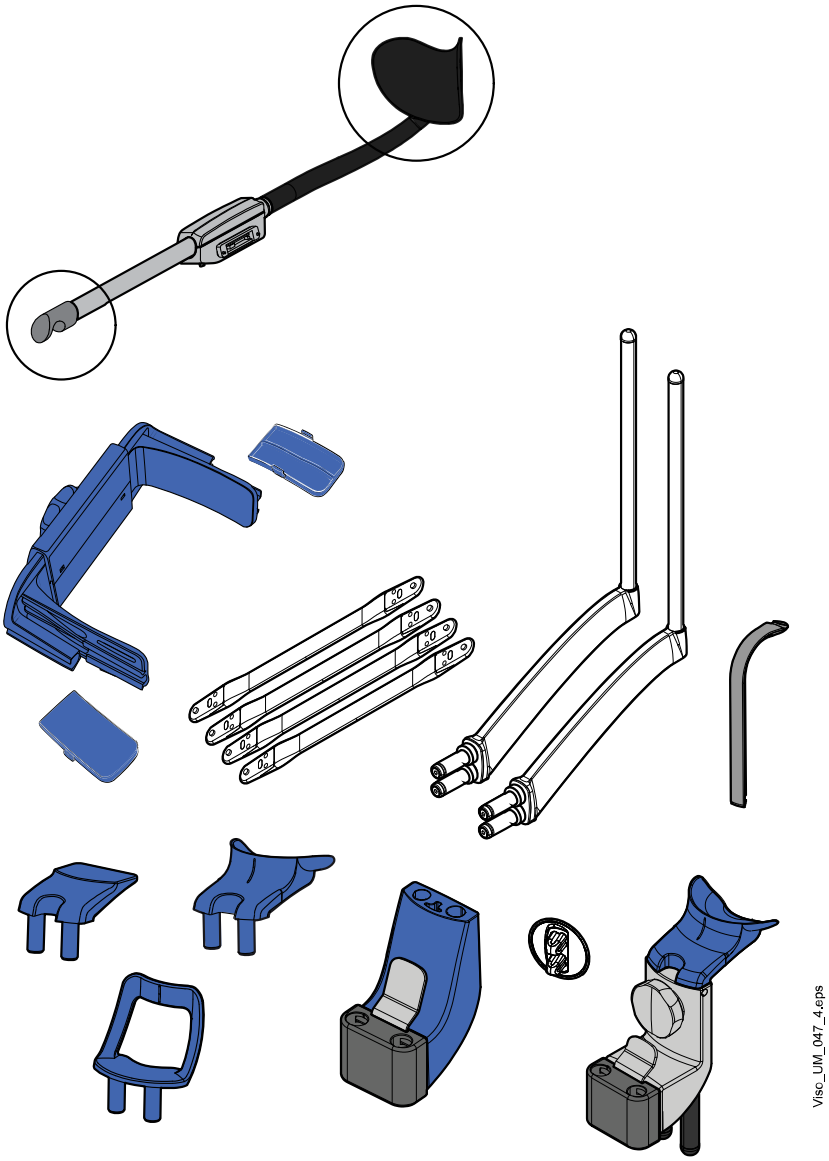
Contact your service technician for help if sprays, liquids or foams enter the system.

16.1 Patient supports, patient handles and touch screen

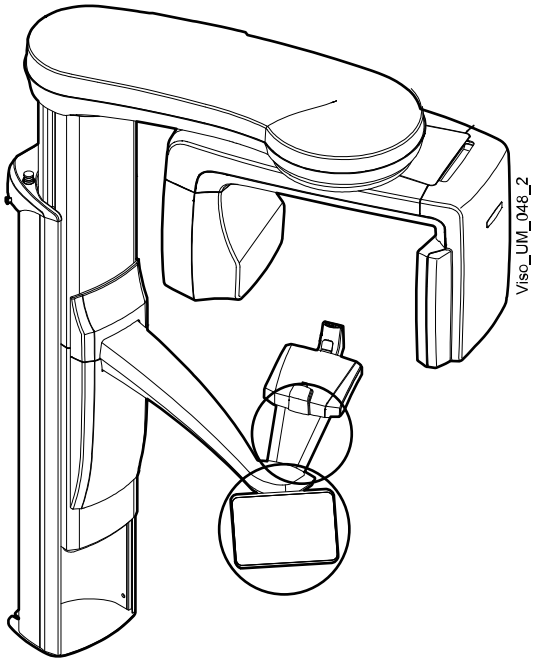
Wipe these parts after each patient using a Planmeca approved surface disinfectant.

Use a Planmeca approved cleaning agent for cleaning stains and dirt if needed.

Patient supports

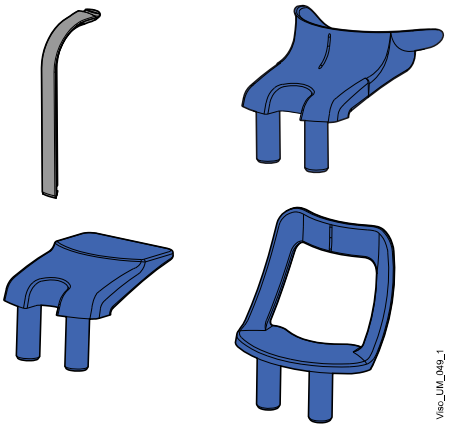


Patient handles and touch screen



NOTE

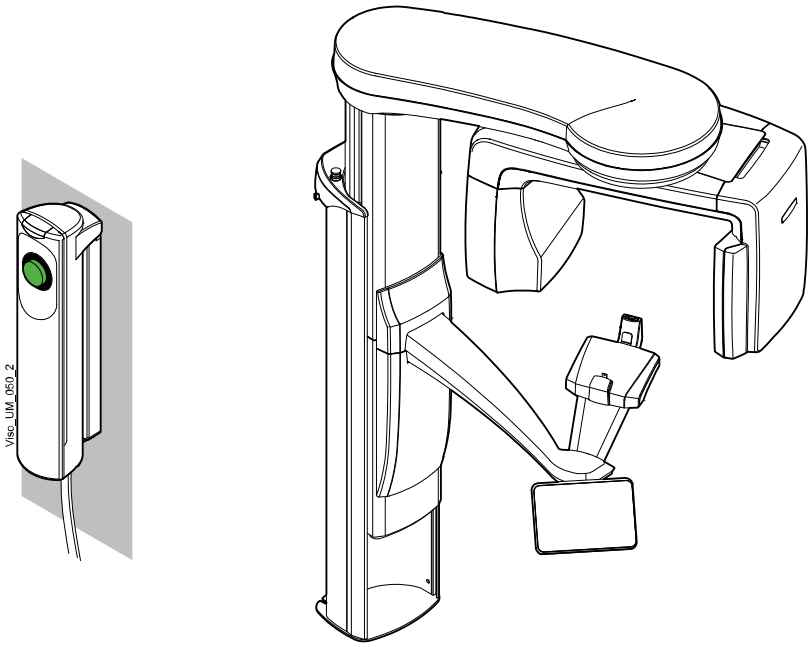
These parts can be autoclaved at 134°C (273°F).



16.2 Other surfaces

Wipe the other surfaces regularly using a Planmeca approved surface disinfectant.

Use a Planmeca approved cleaning agent for cleaning stains and dirt if needed.



17 Service

The X-ray unit must be checked by a Planmeca qualified service technician once a year or after every 10 000 exposures (if this is sooner). This will guarantee patient and user safety and ensure consistent image quality.

The annual maintenance service includes inspection of the following:

- X-ray unit adjustments and quality control checks
- Data security updates
- Exposure switch
- Exposure indicator lights and warning signals
- Emergency stop button
- Column motor nut
- Labels

18 Disposal

In order to reduce the environmental load over the product's entire lifecycle, our products are designed to be as safe as possible to dispose of. The products fulfil the requirements of directives RoHS, REACH and WEEE.

Disposal of obsolete units is the responsibility of the waste possessor. The risks involved and the necessary precautions must be taken into account when handling waste products.

Parts which can be recycled should always be taken to the appropriate processing centres, after hazardous waste has been removed. All parts and components containing hazardous materials must be disposed of in accordance with waste legislation and instructions issued by the local environmental authorities.

The following parts contain hazardous waste:

- X-ray tube assembly (lead, mineral oil)
- X-ray collimators (lead)
- Imaging sensors and sensor back covers (lead)

Batteries must be disposed of following the requirements of Directive 2006/66/EEC and in accordance with waste legislation and instructions issued by the local environmental authorities.

The following parts may contain batteries:

- Circuit boards

NOTE

FOR 3D RECONSTRUCTION PC

Delete all patient data from the hard drive before disposal. Use special sanitising software that cleans the media or physically destroy the hard drive.

19 Technical specifications

Classification	Class IIb
Medical Device Regulation	(EU) 2017/745
RoHS	2011/65/EU
IEC 60601-1	Class I, type B
CISPR 11	Class B
IP Classification	IPX0
Applied parts (according to IEC 60601-1: 2012)	
Patient supports	As shown in section *Patient supports* in user's manuals.
Patient handles	
Generator (according to IEC 60601-2-7: 1998)	
	Resonant-mode, DSP-controlled, 80 - 160 kHz
X-ray tube	
	OPX 105-10, D-059SBR or SXR 130-10-0.5 SC
Focal spot size (according to IEC 60336: 2005)	
	0.5 x 0.5 mm
Filtration	
3D	Total 2.5 mm Al + 0.2 mm / 0.5 mm Cu
Pan (SmartPan) / ProCeph	Total 2.5 mm Al
Tube housing front cover quality equivalent filtration (not included in the specified total filtration)	0.3 mm Al @ 70 kV / HVL 2.6 mm Al
Anode voltage	
3D	80 - 120 kV ±5%
Pan (SmartPan)	60 - 84 kV ±5%
ProCeph	60 - 84 kV ±5%
Anode current	
3D	OPX 105-10: 2 - 16 mA ±10% D-059SBR: 2 - 12.5 mA ±10% SXR 130-10-0.5 SC: 2 - 16 mA ±10%
Pan (SmartPan)	OPX 105-10: 2 - 16 mA ±10% D-059SBR: 2 - 14 mA ±10% SXR 130-10-0.5 SC: 2 - 16 mA ±10%
ProCeph	OPX 105-10: 14 mA ±10% D-059SBR: 14 mA ±10% SXR 130-10-0.5 SC: 16 mA ±10%
mAs range	
	min. / max. as indicated ±(10% + 0.2 mAs)
Dose range and accuracy	

	Dose range min. / max. as indicated on system user interface. Accuracy of dosimetric indication (DAP, CTDI): ±40%
Linearity of radiation output	
	< 0.1
Exposure time	
3D	Pulsed, effective 1.5 - 36 s as indicated ±10% Pulse range: 5 ms - 48.5 ms Time between pulses range: 24 ms - 108 ms
Pan (SmartPan)	2.5 – 15.6 s as indicated ±10%
ProCeph	0.1 – 1.6 s as indicated ±10%
SID	
3D / Pan (SmartPan)	700 mm
Ceph	1700 mm (66.9 in.)
Magnification	
3D	1.40 - 1.71
Pan (SmartPan)	1.40
Ceph	1.13
Duty cycle for height adjustment	
	25 s ON / 400 s OFF
Line voltage	
	100 - 220 V~ / 50 - 60 Hz 230 - 240 V~ / 50 Hz
Line current	
	8 - 17 A
Input power	
Stand by	150 VA
Exposure	1800 W
Line harmonics	
	Cos better than 0.9
Max. permissible apparent impedance of supply mains	
	0.5 ohm (100 VAC)
Max. continuous heat dissipation	
	250 W
Internal fuse(s)	
One user replaceable fuse	100 - 220 V~ / 16A FF H 500 V 230 - 240 V~ / 8A FF H 500 V
Type	195100 ELU
External fuse(s)	

	100 - 220 V ~ / 16A min. - 20A max. T 250 V 230 - 240 V ~ / 10A min. - 20A max. T 250 V
Battery	
	Lithium battery: 3V, CR2032, Panasonic / Varta
Max. weight	
Base unit	165 kg (364 lb)
ProCeph	20 kg (44 lb)
Environmental requirements	
Transport:	
Temperature	-20°C - +60°C (-4°F - +140°F)
Relative humidity	10 - 90% RH (non-condensing)
Air pressure	700 - 1060 hPa
Storage:	
Temperature	-10°C - +50°C (+14°F - +122°F)
Relative humidity	10 - 90% RH (non-condensing)
Air pressure	700 - 1060 hPa
Operating:	
Temperature	+10°C - +35°C (+50°F - +95°F)
Relative humidity	10 - 90% RH (non-condensing)
Air pressure	800 - 1060 hPa
Max. altitude	2000 m (1.25 miles)
Image properties	
ProCeph:	
Flat panel pixel size	131 µm
Flat panel active surface	301.82 x 248.9 mm (11,88 x 9,80 in.)
3D:	
Flat panel pixel size	Planmeca Viso G5: 105 µm Planmeca Viso G7: 139 µm
Flat panel active surface	Planmeca Viso G5: 161.28 x 161.28 mm (6,35 x 6,35 in.) Planmeca Viso G7: 247.7 x 301.1 mm (9,75 x 11,85 in.)
Pan (SmartPan):	
Flat panel pixel size	Planmeca Viso G5: 105 µm Planmeca Viso G7: 139 µm
Flat panel active surface	Planmeca Viso G5: 8.4 x 161.28 mm (0.33 x 6,35 in.) Planmeca Viso G7: 8.896 / 17.792 x 166.8 mm (0,35 / 0,70 x 6,57 in.)
Operating requirements for ProFace program	

Optimum colour temperature	Approx. 6500 Kelvin
Even and uniform lighting	
No bright lights	

Original manufacturer

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PLANMECA

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PLANMECA Oy's Quality System
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Certificate awarded in 1994 by Det Norske Veritas
fulfils the highest acknowledged international standards

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ISO 14001
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