

Anexa 102

Lot 102, Sistem de raze X 3D, dentar (CBCT) 210500, ProMax 3D, Planmeca

Nr. de inregistrare AMDM: DM000500216

Specificarea tehnică deplină solicitată, Standarde de referință	Specificarea tehnică deplină oferita, Standarde de referință
<p>Sistem de raze X 3D, dentar (CBCT) Cod 210500 Descriere CBCTeste o scanare 3D cu raze X. Afişează o vedere tridimensională a maxilarului superior, inferior, SIN și ATM. Parametrul Specificația Generator de raze X Tensiune 60-90 kV Curent diapazon minim 5-16 mA Tub raze X Tip staționar Filtrare totală (minimă), mm Al "în diapazon acceptabil 2.5-3.2" Înălțimea Minim ≥ 800mm Maxim ≥ 1800mm Punctul focal, maxim ≤ 0.5 mm SID, mm -500-650 Detector digital 2D & 3D Tip CdTe-CMOS/CdTe-CCD Rezoluție PANO, lp/mm ≥ 2.5 Dimensiune FOV, cm $\geq 10 \times 10$ VOXEL size, $\mu\text{m} \leq 100$ VOXEL size endo, $\mu\text{m} \leq 75$ Timpul de expunere în regim panoramic ≤ 14 sec Numărul punctelor de fixare a capului ≥ 4 Suport reglabil pentru bărbie obligatoriu Posibilitatea de deplasare suport barbă sus/jos și înainte/înapoi obligatoriu Protocol de scanare 2D și 3D PANO obligatoriu CBCT (3D) obligatoriu Serment obligatoriu ATM obligatoriu SIN obligatoriu DAP-metru obligatoriu Element de mușcare obligatoriu Mîner pacient 2 Fascicul laser de aliniere/pozitionare pacient Plan midsagittal obligatoriu Plan orizontal obligatoriu Canin obligatoriu Alimentarea 220-240V, 50 Hz Unghiul țintei, maxim ≤ 5 grade Monitor medical ≥ 19 inch Revenirea automată la poziția inițială obligatoriu Comanda de oprire urgentă obligatoriu Control multifuncțional obligatoriu Panou comandă Tehnologie Touchscreen obligatoriu Stație de achiziție Windows 10 OS obligatoriu CPU Quad core sau echivalent RAM ≥ 8GB HDD ≥ 1TB Network ≥ 1GB Monitor medical Accesorii PC Mouse Keyboard Modul software 2D Funcții de manipulare a imaginii 2D obligatoriu Măsurători, adnotări obligatoriu Importul/exportul imaginilor pe CD/DVD obligatoriu Salvare imagini în format DICOM, JPG obligatoriu Imprimare rezultat pe suport de hartie 1:1 obligatoriu Licență min 5 calculatoare Modul software 3D Funcții de manipulare a imaginii 3D obligatoriu Licență min 5 calculatoare Vizualizare/redactare și export imagini DICOM obligatoriu</p>	<p>Sistem de raze X 3D, dentar (CBCT) Cod 210500 Descriere CBCTeste o scanare 3D cu raze X. Afişează o vedere tridimensională a maxilarului superior, inferior, SIN și ATM. Parametrul Specificația Generator de raze X Tensiune 60-90 kV (pasaport tehnic, pagina 4) Curent diapazon minim 1-16 mA (pasaport tehnic, pagina 4) Tub raze X Tip staționar (pasaport tehnic, pagina 4) Filtrare totală (minimă), mm Al "în diapazon acceptabil 2.5mm (pasaport tehnic, pagina 4) Înălțimea Minim ≥ 800mm Maxim ≥ 1800mm Punctul focal, maxim 0.5 mm (pasaport tehnic, pagina 4) SID, mm -500 (pasaport tehnic, pagina 4) Detector digital 2D & 3D Tip CCD, (manual utilizator, pagina 106) Rezoluție PANO, lp/mm ≥ 2.5 Dimensiune FOV, cm 8x11 VOXEL size, $\mu\text{m} 100$ VOXEL size endo, $\mu\text{m} 75$ (manual utilizator, pagina 42) Timpul de expunere în regim panoramic 2,7-16 sec, pesetabil (manual utilizator, pagina 104) Numărul punctelor de fixare a capului 4 (manual utilizator, pagina 30) Suport reglabil pentru bărbie obligatoriu (manual utilizator, pagina 30-34) Posibilitatea de deplasare suport barbă sus/jos și înainte/înapoi obligatoriu Protocol de scanare 2D și 3D PANO obligatoriu CBCT (3D) obligatoriu Serment obligatoriu ATM obligatoriu SIN obligatoriu (manual utilizator, pagina 35,36,82) DAP-metru obligatoriu Element de mușcare obligatoriu Mîner pacient 2 Fascicul laser de aliniere/pozitionare pacient (manual utilizator, pagina 47) Plan midsagittal obligatoriu Plan orizontal obligatoriu Canin obligatoriu (manual utilizator, pagina 47-51) Alimentarea 220-240V, 50 Hz (manual utilizator, pagina 105) Unghiul țintei, maxim 5 grade Monitor medical 19 inch Revenirea automată la poziția inițială obligatoriu Comanda de oprire urgentă obligatoriu (manual utilizator, pagina 17) Control multifuncțional obligatoriu (manual utilizator, pagina 17) Panou comandă Tehnologie Touchscreen (manual utilizator, pagina 17) Stație de achiziție Windows 10 OS obligatoriu CPU</p>

Printer obligatoriu	Quad core sau echivalent RAM 8GB HDD 1TB Network 1GB Monitor medical Accesorii PC Mouse Keyboard Modul software 2D Funcții de manipulare a imaginii 2D obligatoriu Măsurători, adnotări obligatoriu Importul/exportul imaginilor pe CD/DVD obligatoriu Salvare imagini in format DICOM, JPG obligatoriu Imprimare rezultat pe suport de hartie 1:1 obligatoriu Licență 5 calculatoare Modul software 3D Funcții de manipulare a imaginii 3D obligatoriu Licență 5 calculatoare Vizualizare/redactare si export imagini DICOM obligatoriu Printer obligatoriu
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SPECIFICATION

1(5)

Planmeca ProMax 3D Classic CBCT unit

Introduction

The Planmeca ProMax 3D X-ray unit uses cone beam computerized tomography (CBCT) to produce three-dimensional X-ray images. Panoramic and cephalometric techniques are used for two-dimensional X-rays. The images can be used for examination of dentomaxillofacial anatomy.

Features

- Planmeca ProMax platform has patented SCARA3 construction. The movements enable the exact location of the image volume and thus the adjustment of the volume size
- Volume size and target area are selectable on the control panel to meet diagnostic needs without excess radiation outside the area of interest.
- Advanced stitching programs offer low dose, large volume imaging through the selection and targeting of up to 3 horizontal volumes. Once captures the targeted volumes are stitched together by Planmeca Romexis.
- Pulsed exposure, which is accurately synchronized to the image capturing, enables short effective exposure time and low dose.
- Proprietary Feldkamp based back projection reconstruction algorithm
- Planmeca AINO™ Adaptive Image Noise Optimizer removes noise from CBCT images without losing valuable details.
- Planmeca ARA™ Artefact Removal Algorithm reduces high contrast object artefacts.
- Automatically adjusting 4-blade collimator with beam hardening filter improves the radiation quality, reduces the patient dose and improves the visibility of the soft tissues.
- Ultra low dose mode reduces the patient dose to minimum



Imaging capabilities

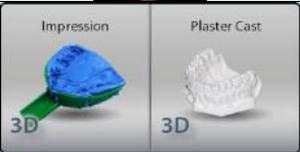
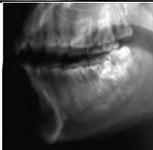
3D imaging:

Planmeca ProMax 3D provides high resolution volumetric 3D images of the mandible and maxilla and whole teeth area.



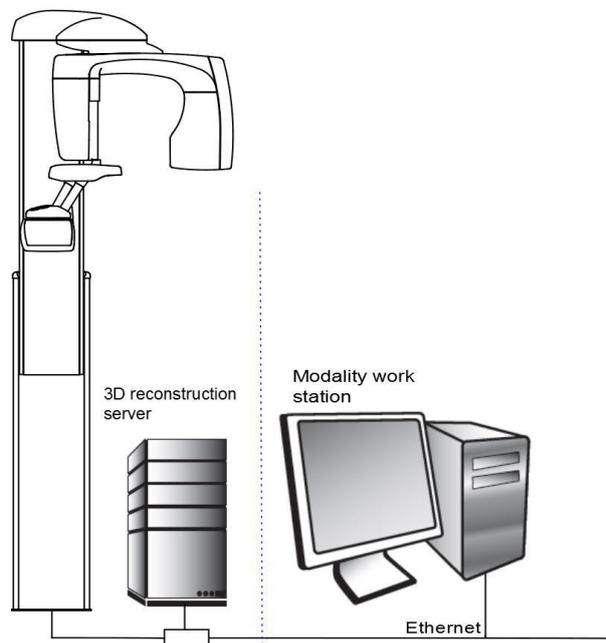
SPECIFICATION

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<p>Planmeca ProFace: 3D photograph capture in the same session with radiograph or separately.</p>	
<p>Model scan programs: Special programs produce very precise 3D images of impressions and plaster casts.</p>	
<p>Endodontic imaging mode.</p>	
<p>Braces Protocol: A special program optimised for imaging patients with brackets for braces design.</p>	
<p>2D imaging:</p>	
<p>Panoramic images can all be taken with the same X-ray. SmartPan system uses the same 3D sensor for 2D panoramic imaging. Planmeca Dimax sensor can be used as option. Available: Basic and Advanced programs, True bitewing program, Segmenting.</p>	
<p>Planmeca Dimax cephalostat or Planmeca ProCeph for cephalometric images</p>	
<p>2D view with 3D program provides 2D images with diagnostic quality taken with 3D sensor.</p>	

Planmeca ProMax 3D system components

- Planmeca ProMax 3D unit including 3D sensor
- 3D reconstruction computer
- Special 3D patient support with support points in forehead and chin
- Stool for patient



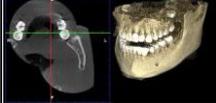
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Resolution modes

Mode					
	Endodontic (optional)	High resolution	HD (High Definition)	Normal	Low Dose
Voxel size μm	75	100	150	200	400

3D Imaging programs and volume sizes

Program	Height mm Adult (child)	$\varnothing 50$ mm ($\varnothing 42$ mm)	$\varnothing 80$ mm ($\varnothing 68$ mm)	Example	Mode / voxel
Tooth	Mand/Max 50 (Mand/Max 42)	$\varnothing 50 \times 50$ ($\varnothing 42 \times 42$)			Endo 75 μm HR 100 μm HD 150 μm N 200 μm d LD 400 μm
	80 (68)	$\varnothing 50 \times 80$ ($\varnothing 42 \times 68$)			HD 150 μm N 200 μm d LD 400 μm
Teeth	Mand/Max 50, 80 (Mand/Max 42, 68)		$\varnothing 80 \times 50$ $\varnothing 80 \times 80$ ($\varnothing 68 \times 42$ $\varnothing 68 \times 68$)		HD 150 μm N 200 μm d LD 400 μm
Double scan			2 x		N 400 μm d LD 400 μm
Triple scan			3 x		N 400 μm d LD 400 μm

Endo = endodontic, HR = high resolution, HD = High Definition, N = normal, LD = low dose, d = default

3D Model Scans

Models scan			$\varnothing 80 \times 40$		HD 100 μm
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HR = high resolution, HD = High Definition, N = normal, LD = low dose, d = default

Planmeca Romexis 3D Software

The Planmeca Romexis software modules

- Planmeca Romexis Patient management
- Planmeca Romexis 3D Explorer for image acquisition and viewing, printing and measurements
- Planmeca Romexis 2D Imaging
- Planmeca Romexis Report manager
- Planmeca Romexis 3D Viewer enabling viewing the studies without installed Planmeca Romexis
- DICOM Import/Export and DICOM DIR Media Storage

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Optional software modules:

- Planmeca Romexis 3D Cross Sections module (includes also reconstructed panoramic view)
- Planmeca Romexis 3D Implant Planning module (includes also panoramic view and Cross Sections module)
- Planmeca Romexis 3D TMJ module (includes also panoramic and Cross Section module)
- Planmeca Romexis DICOM Print
- Planmeca Romexis full DICOM licence (Includes DICOM Storage, DICOM Print, DICOM Worklist, DICOM Storage Commitment and DICOM Query/Retrieve, DICOM Modality Performed Procedure Step)
- Planmeca Romexis Ortho Studio
- Cephalometric Analysis module

Technical Specifications

Generator	Constant potential, microprocessor controlled, resonance mode, operating frequency 80 -160 kHz, Power Factor Corrector, complies with the standard IEC 60601-2-7
X-ray tube	Toshiba D-054SB
Focal spot size	0.5x0.5mm, according to IEC 6036
Total filtration	min. 2.5 mm Al + 0.5 mm Cu
Anode voltage	Panoramic: 60– 84 kV 3D: 60—90 kV
Anode current	Panoramic: 1 – 16 mA 3D: 1—14 mA
Exposure time	Pan: 2.7 – 16 s SmartPan: 3.3 – 19 s 3D: 3 – 15 s
Scan time	12– 26 s
Scan angle	200°
SID	Panoramic 500 mm 3D 527 mm
Focus to skin distance	min. 150 mm
Magnification	1.57
Line voltage	100—240 V~ ±10 %, 50 or 60 Hz, Power Factor Corrector
Line current	8 – 15 A
Electrical classification	Class I, type B
Weight	119 kg (263 lbs) 137 kg (304 lbs) with Cephalostat
Chin rest level	96 – 178 cm
Cooling period	Automatically controlled

Sensor specifications

Pixel size	127 µm
Active surface	13x13 cm

The 3D Reconstruction Server

3D reconstruction server is a zero maintenance Linux based high-performance computer, which captures images from imaging device and performs a 3D reconstruction routine. This automated routine converts the original image frames acquired into the 3D volume, which is then transmitted to the Modality Workstation (Planmeca Romexis Image Acquisition Workstation) and to Planmeca Romexis Server for storage.

SPECIFICATION

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3D Reconstruction Server is included in all deliveries.

--- EOF ---



Planmeca ProMax[®]

3D Classic

*user's manual
3D imaging*

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.

Planmecca 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

This manual describes how to take 3D exposures. The manual applies to Planmeca ProMax 3D Classic.



NOTE

This manual is valid for software version 3.9.14 or later. This software version is compatible with Romexis software version 6.4.2 or later.

To check the software version of your X-ray unit, select [Settings > About > 4100 Component Information > ProMax SW version](#).

The X-ray unit uses Cone Beam Computed Tomography (CBCT) to produce three-dimensional (3D) X-ray images. Panoramic, cephalometric and projection radiography techniques can be used for two-dimensional (2D) X-rays.

If the X-ray unit has a ProFace sensor, you can take a 3D photo of the patient's face.

The X-ray images can be used for examination of dentomaxillofacial anatomy. The 3D face photo can be used for patient education or in order to follow the results of medical treatments.

You need a PC with the Romexis program in order to save, view and modify the images.

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 (2300)" on page 87 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

You can register your X-ray unit online as described in section "Product registration (4300)" on page 90.



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): 6430035420105E

1.1 Intended use

The Planmeca ProMax X-ray unit uses Narrow Beam Tomography (NBT) to produce two-dimensional (2D) X-ray images and the Planmeca ProMax 3D X-ray units use Cone Beam Computed Tomography (CBCT) to produce three-dimensional (3D) X-ray images. Integrated optical cameras are used for 3D surface imaging (ProFace). Panoramic, cephalometric and projection radiography techniques are used for two-dimensional (2D) X-ray images. The images can be used for examination of dentomaxillofacial, ear, nose and throat, cervical spine, as well as other cranial anatomies. The X-ray unit is allowed to be used only under supervision of a health care professional.

1.1.1 Intended patient population

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

1.1.2 Intended users

Intended healthcare user

Education	Dental care professionals or radiographers
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Intended service user

Education	Planmeca authorised service and maintenance professionals
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1.2 Usage environment

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

2 Associated documentation

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

- User's Manual(s)
- Installation Quick Guide
- Installation Manual
- Technical Manual
- Planmeca Device Tool Manual

These manuals are intended to be used in conjunction with the documentation for the 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 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).

4 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.

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

Do not drop the sensor.

Planmeca limited warranty does not cover damage which is due to misuse, for example, dropping the sensor, neglect, or any cause other than ordinary use.

If you have any reason to believe that the sensor might be faulty, take a test exposure before taking a patient exposure.

CAUTION

If an exposure is interrupted (for example, if the exposure button is released or emergency stop button activated), guide the patient away from the X-ray unit before moving the C-arm.

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 anaesthetics.

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

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.

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. The X-ray unit is not intended for use on pregnant women.

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 touch screen. 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 60825-1:2014).

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

If you take an exposure but the image does not appear in the Romexis program, you can import the image manually into Romexis. Refer to the *Romexis user's manual* for details.

NOTE

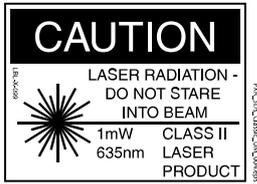
Do not handle liquids near or on the X-ray unit.

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

If you have any reason to believe that the C-arm might hit the patient during exposure (e.g. patients with wide shoulders), take a test exposure without radiation first. To switch radiation off, select Settings > User > 1300 Operational settings > 1310 Use Mode > 1311 Set Demo Mode.

Alternatively, use the 90° button at the bottom of the screen to test the C-arm rotation before you take a 3D exposure.

**NOTE**

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

NOTE

Patients are not allowed to hang on the patient handles.

NOTE

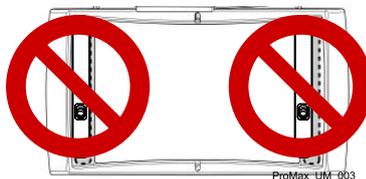
FOR X-RAY UNITS WITH ROTATING TUBE HEAD:



Do not touch the metal parts in the middle of the tube head. They might be hot.

NOTE

FOR PROFACE SENSOR:



Do not touch the glass windows. Fingerprints or other stains on the glass surface destroy 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.

4.1 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.

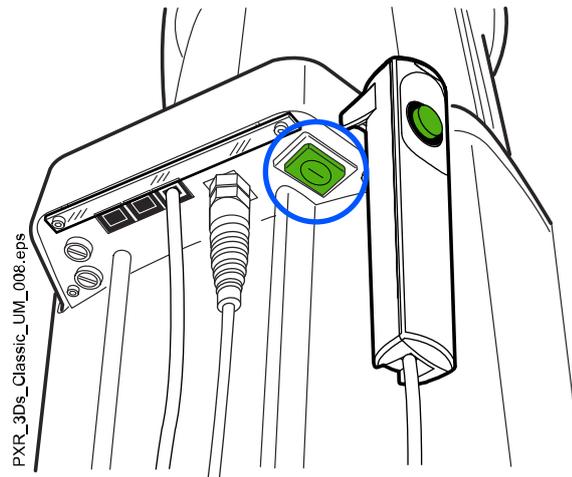
5 Switching X-ray system on

NOTE

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

5.1 Switching X-ray unit on

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



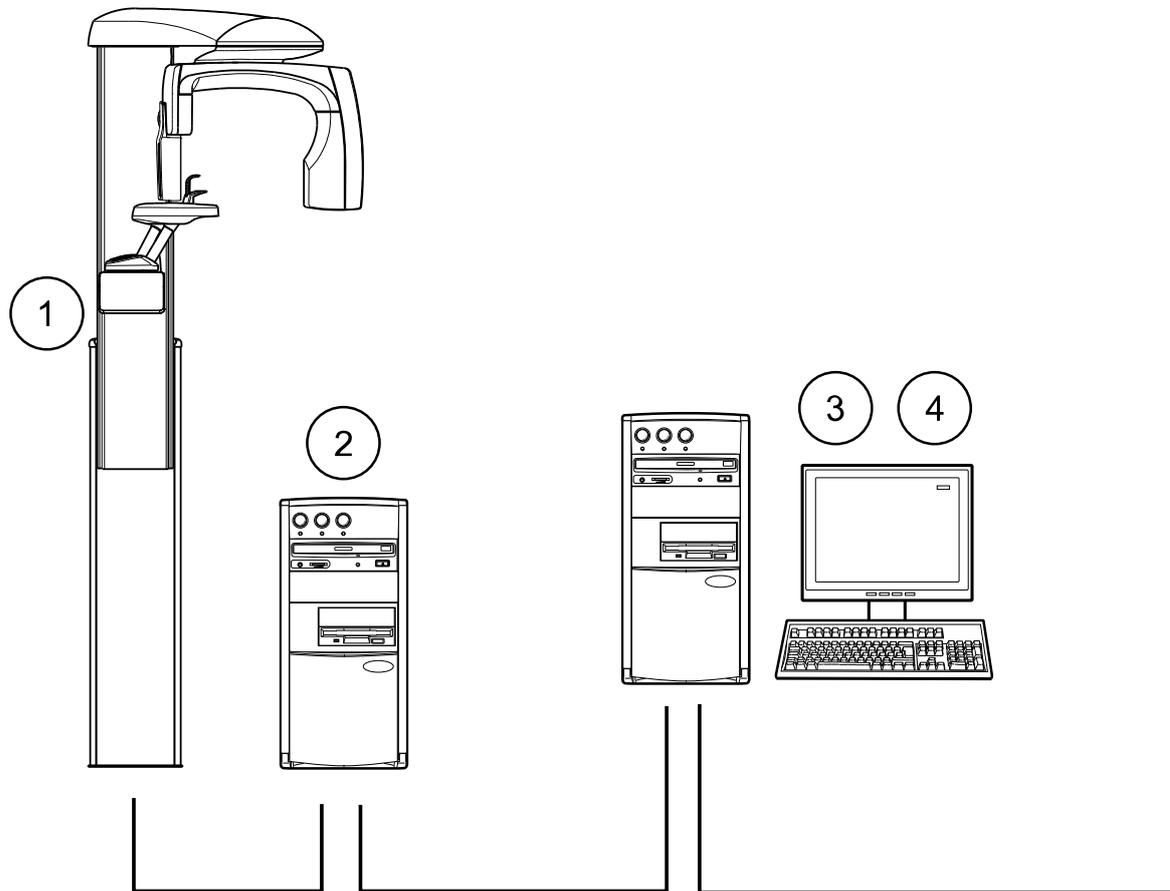
5.2 Switching 3D reconstruction PC on

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



6 Main parts

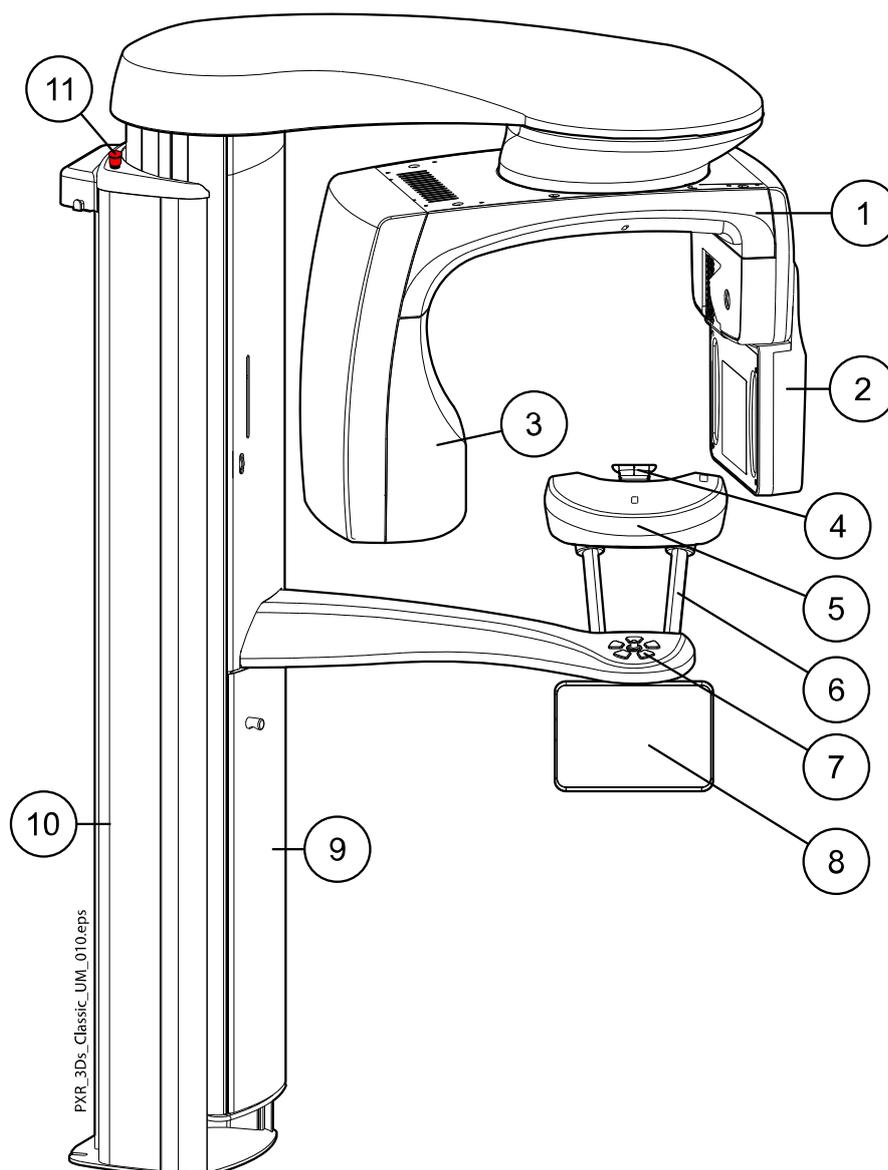
6.1 General view of X-ray system



PXR_3Ds_Classic_UM_009.eps

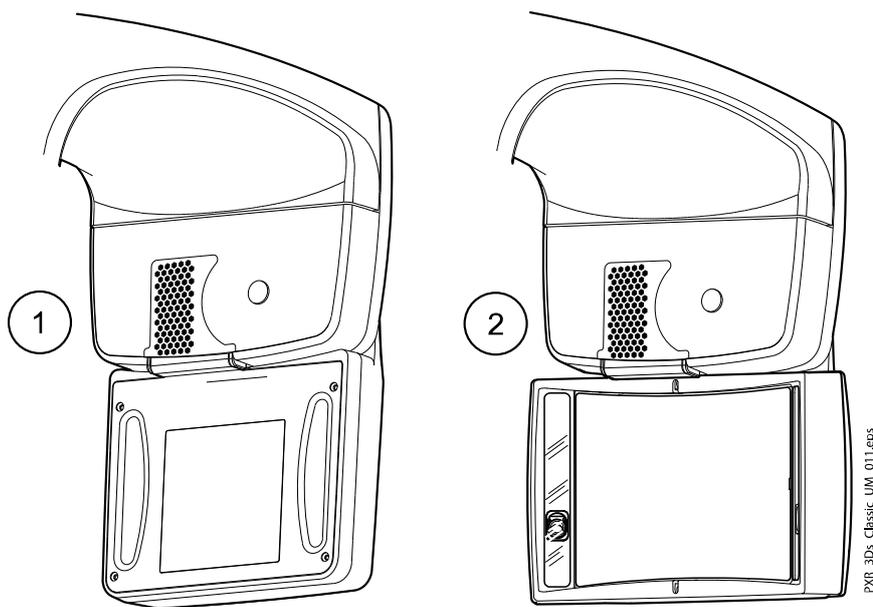
- 1 X-ray unit
- 2 3D reconstruction PC
- 3 Romexis program
- 4 ProTouch desktop application (optional, see section "ProTouch desktop application" on page 21)

6.2 General view of X-ray unit



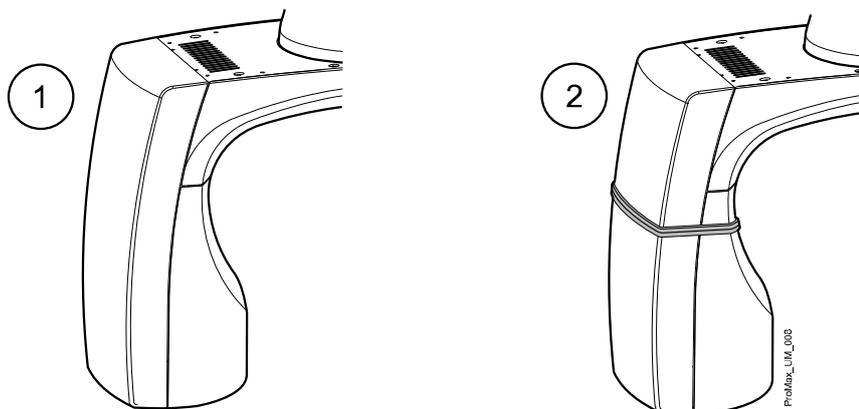
- 1 C-arm
- 2 Sensor (see section "Sensor" on page 14)
- 3 Tube head (see section "Tube head" on page 14)
- 4 Patient supports (see section "Patient supports" on page 15)
- 5 Patient support table
- 6 Patient handles
- 7 Patient positioning controls (see section "Patient positioning controls" on page 23)
- 8 Touch screen (see section "Touch screen" on page 17)
- 9 Telescopic column
- 10 Stationary column
- 11 Emergency stop button (see section "Emergency stop button" on page 17)

6.3 Sensor



- 1 3D sensor for Planmeca ProMax 3D Classic
- 2 ProFace sensor for Planmeca ProMax 3D Classic

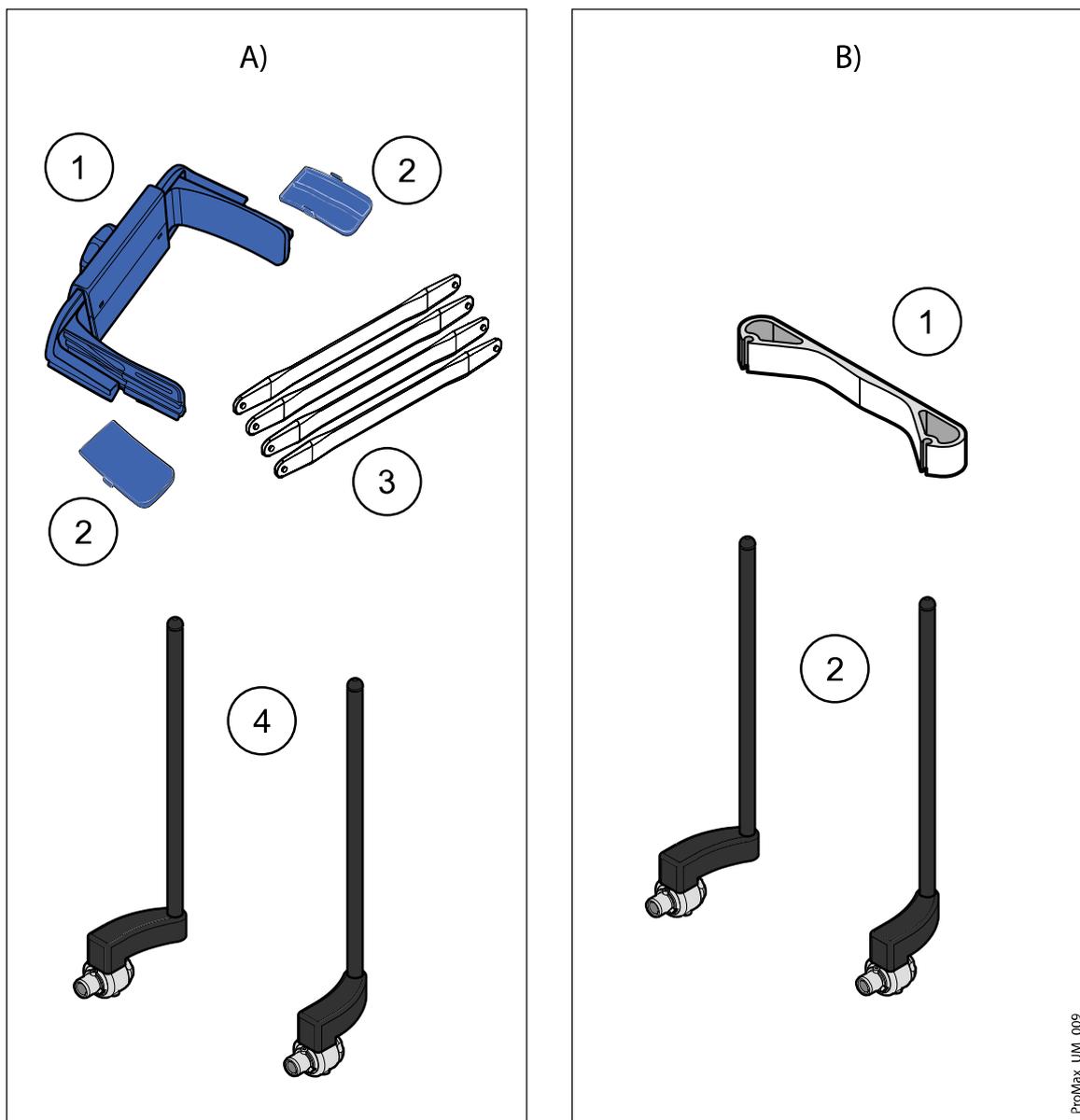
6.4 Tube head



- 1 Non-rotating tube head
- 2 Rotating tube head

6.5 Patient supports

6.5.1 Head supports (option A or B)



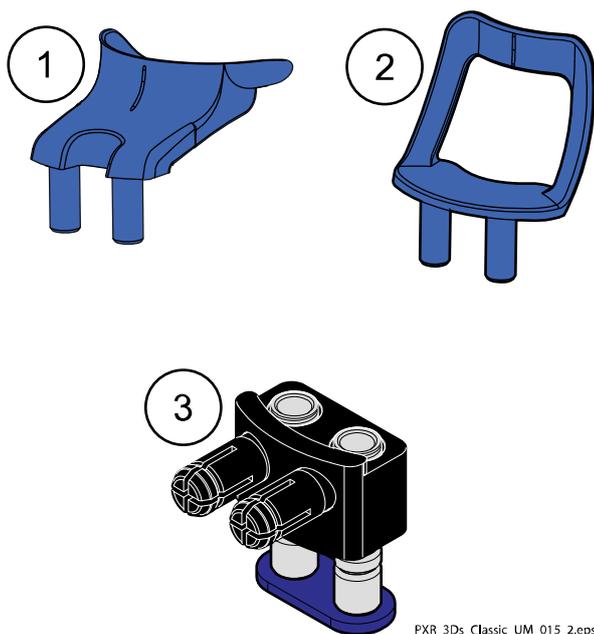
Option A

- 1 Adjustable head support
- 2 Temple pads for children
- 3 Fastening straps
- 4 Support bars

Option B

- 1 Head band 25
- 2 Support bars

6.5.2 Chin supports



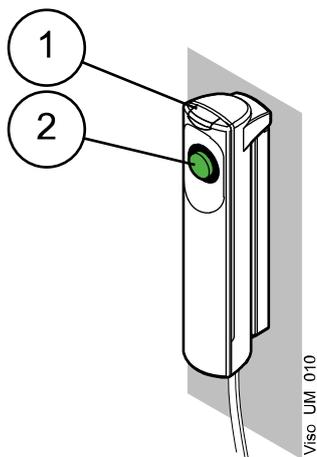
- 1 Chin cup
- 2 Chin support
- 3 Adjustable adapter

6.6 Exposure switch

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

Green lights flash on the exposure button and on the touch screen when the X-ray system is getting ready for an exposure. The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure.

During exposure yellow radiation warning lights illuminate on the exposure switch and on the touch screen. They indicate that the X-ray unit is generating radiation.



- 1 Exposure switch
- 2 Exposure button

6.7 Emergency stop button

The emergency stop button is located on the top of the stationary column. Press the button to stop the X-ray unit operating in an emergency. When the emergency stop button is pressed down, all movements of the X-ray unit are blocked and the unit will not generate radiation. The up / down movement will stop within a distance of 10 mm (0.4 in.).

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



6.8 Touch screen

NOTE

The X-ray unit may be delivered with physical or virtual control panel (or both). This manual is valid for all set-ups.

NOTE

The options shown on the touch screen depend on the unit configuration. The X-ray unit can be upgraded with new programs and features, contact your dealer for further information. The views and values shown in this manual are only examples.



NOTE

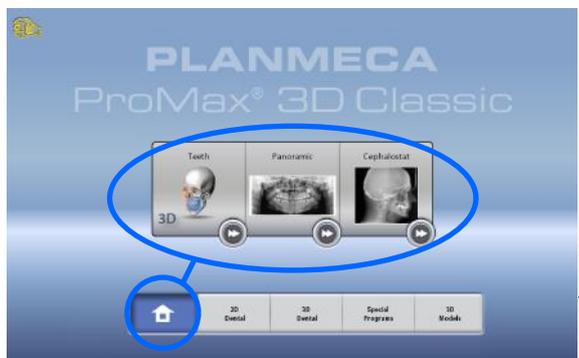
The illustrations shown on the touch screen are based on approximate patient anatomy. The actual exposure area depends on the individual anatomy of the patient.

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.

Main screen

The main screen shows the name and the imaging programs of the X-ray unit. You can use the buttons at the bottom of the main screen to change the appearance of the main view.



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.



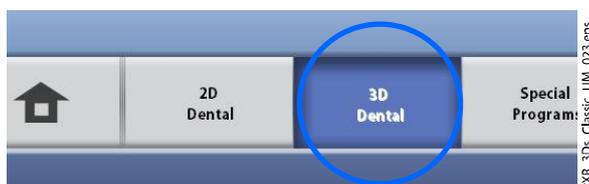
ProMax_UM_014

NOTE

If you wish to use fast forward buttons on this view, select **Settings > Program > 2200 Program Features > 2240 General > Fast Forward ON**. Using a fast forward button takes you directly to the screen where you can take an exposure.

Program group button(s)

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



Making selections



To make a selection on the touch screen, touch a button or a field with your finger or a soft stylus. The selected option is highlighted. To deselect an option, touch the button or field again (or select another option if available).

You hear an audible signal when you make a selection. If you wish to adjust the volume of the signal, select **Settings > User > 1300 Operational Settings > 1320 Audio Settings > Touch Volume**.

NOTE

Do not use sharp objects to operate the touch screen.

Accept button



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

Cancel button



To cancel a selection and close the screen, select the red cross button.

Pause button

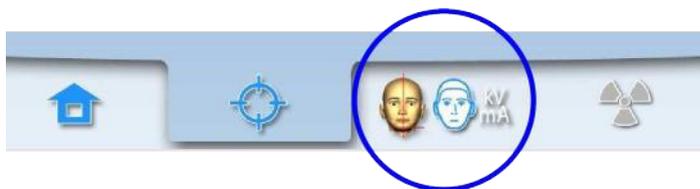


To pause a function (instead of cancelling it), select the pause button.

Moving forward

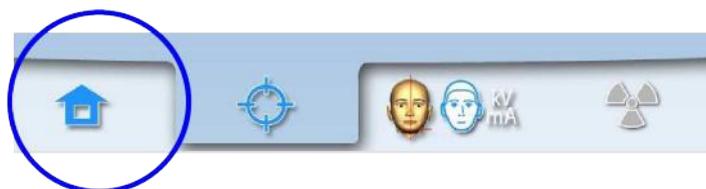


To go to the next screen, select either the forward button, or the **next** symbol at the bottom of the screen.



Moving backward

To go back to a previous screen, select a previous symbol at the bottom of the screen.

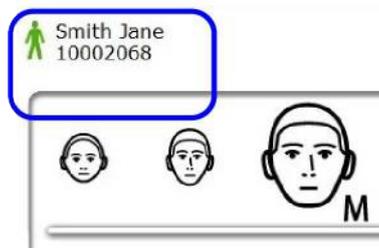


Scrolling lists

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

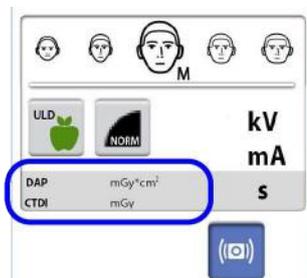
Checking patient's name and ID number

The patient's name and ID number are shown in the top right corner of the touch screen. The patient and exposure mode have to be selected in Romexis.



Checking DAP and CTDI values

The estimated values for DAP (Dose Area Product) and CTDI (Computed Tomography Dose Index) display in black text on the touch screen before you take an exposure. The actual values display in green text after the exposure.



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. For more information, see section "Settings" on page 75.

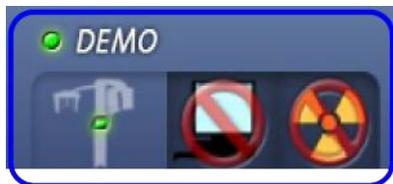


About stand-by mode

The touch screen automatically switches to stand-by mode if you do not touch the screen or the exposure button for more than thirty minutes. In stand-by mode the green light on the on / off switch indicates that the X-ray unit is switched on even though the screen is dark. The screen switches on as soon as you touch it again.

Selecting demo mode

You can switch demo mode on if you wish to practice or demonstrate the functions of the X-ray unit without radiation and PC connection. To do this, select **Settings > User > 1300 Operational settings > 1310 Use Mode > 1311 Set Demo Mode**. The selection displays in the bottom left corner of the touch screen.



6.9 ProTouch desktop application

If the ProTouch desktop application is installed on your computer, you can use a virtual control panel on your computer screen.

The application is identical to the touch screen that may be integrated to your X-ray unit depending on your set-up. If you have both the physical and the virtual control panel, you can use either. Alternatively, you can synchronize and use both of them.



NOTE

You need a licence if you wish to use the application for moving to the ready status. Contact your dealer for help.

To use the virtual control panel, double-click the ProTouch icon on your computer screen. Then click your mouse on the function that you wish to use.



NOTE

A help message appears if you use the settings menu before opening the application. The application automatically closes when you accept the help message. You can reopen the application by double-clicking the icon again.

The small icon in the bottom left corner of the screen indicates when the application is connected to the X-ray unit.

- A green icon indicates that the connection is working:

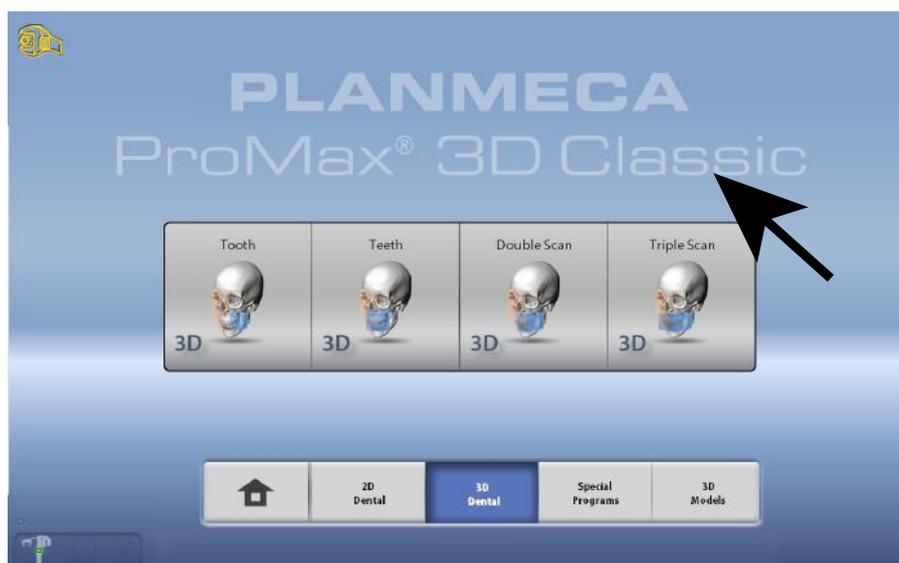


- A red icon indicates that the connection is not working:



Restart the X-ray unit if the icon is red.

To move the control panel screen, drag it with your mouse.



To close the application, click on the small red cross in the top right corner of the screen.



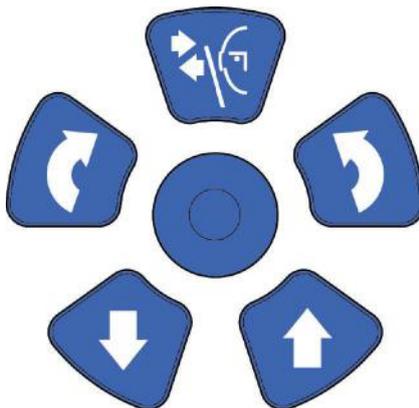
6.10 Patient positioning controls

NOTE

Never allow patients to press the positioning controls when they are positioned in the X-ray unit.

NOTE

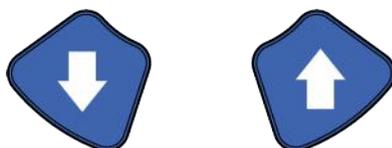
Pressing any of the positioning controls (button or joystick) switches the patient positioning lights on. The lights automatically switch off after two minutes. To switch them off earlier, press the positioning joystick.



6.10.1 X-ray unit up / down

Use the X-ray unit up and down buttons to adjust the X-ray unit to suit the height of the patient.

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



NOTE

If for some reason either of the buttons gets stuck during operation, you can stop the up / down movement by pressing any of the other control buttons or the positioning joystick. This is a safety measure that guarantees that the up / down movement can be stopped in an emergency.

NOTE

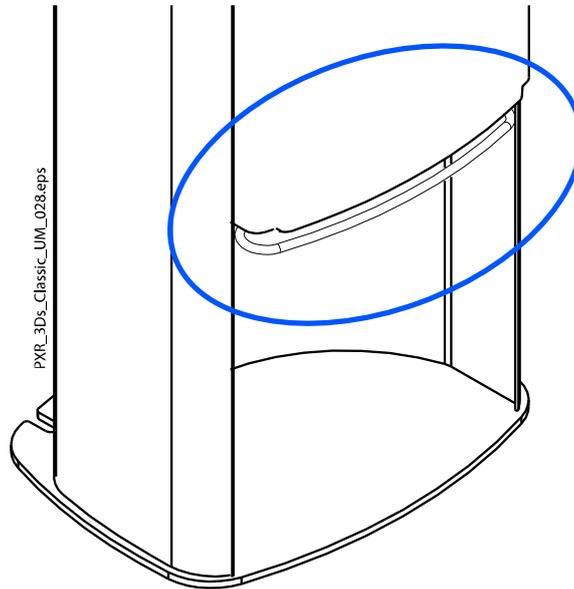
Be careful that the X-ray unit does not hit the ceiling when you press the up button. The maximum height can be adjusted to suit offices with a low ceiling. Contact your service technician for help.

NOTE

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

NOTE

The column movement stops automatically if the emergency stop plate at the bottom is pressed upwards. Clear any obstruction before moving the column again.

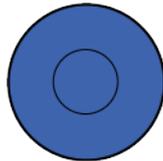


NOTE

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

6.10.2 Positioning joystick

The positioning joystick is used for adjusting the positioning lights. It is used when the patient is positioned in the X-ray unit.



6.10.3 Open / close temple supports

Press the temple support button to open the temple supports in 2D imaging. Close the temple supports by pressing the temple support button again.



7 Planmeca ProMax 3D Classic programs

7.1 3D Dental

NOTE

The values in parentheses represent the child size volumes.

Program	Planmeca ProMax 3D Classic
Tooth	Ø50 x 50 mm (Ø42 x 42 mm) Ø50 x 80 mm (Ø42 x 68 mm)
Teeth	Ø80 x 50 mm (Ø68 x 42 mm) Ø80 x 80 mm (Ø68 x 68 mm)
Double scan	2x Ø80 x 50 mm (Ø68 x 42 mm) 2x Ø80 x 80 mm (Ø68 x 68 mm)
Triple scan	3x Ø80 x 50 mm (Ø68 x 42 mm) 3x Ø80 x 80 mm (Ø68 x 68 mm)

7.2 3D Models

Program	Ø80 mm
Impression	Ø80 x H40 mm
Plaster cast	Ø80 x H40 mm

8 3D patient exposure

8.1 Preparing X-ray system

8.1.1 Attaching and removing sensor

CAUTION

Do not drop the sensor. Planmeca limited warranty does not cover damage which is due to misuse, e.g. dropping the sensor, neglect, or any cause other than ordinary use.

If you have any reason to believe that the sensor might be faulty, take a test exposure before taking a patient exposure.

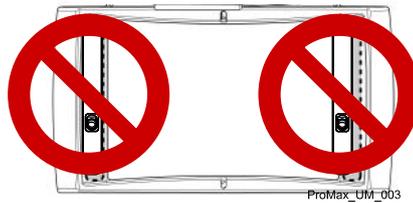
NOTE

The available sensors are shown in section "Sensor" on page 14.

NOTE

FOR PROFACE SENSOR:

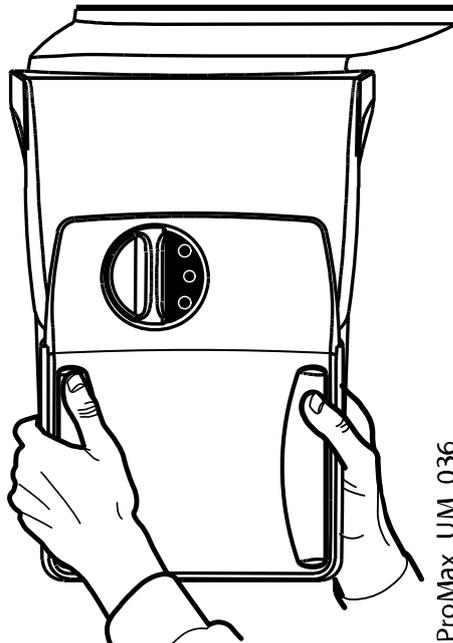
Do not touch the glass windows. Fingerprints or other stains on the glass surface destroy image quality.



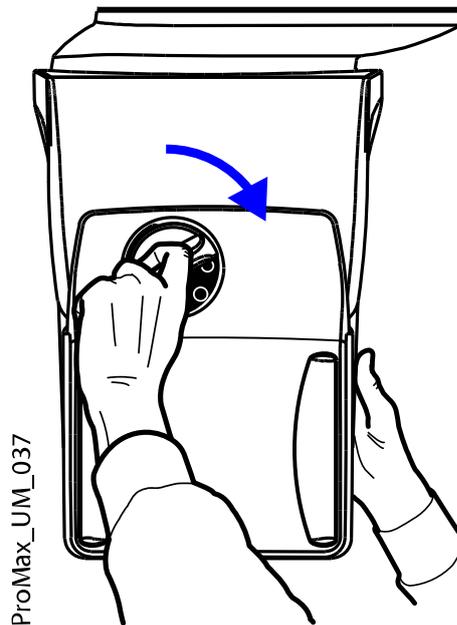
8.1.1.1 Attaching sensor to C-arm

Steps

1. Push the sensor onto the connector on the C-arm.

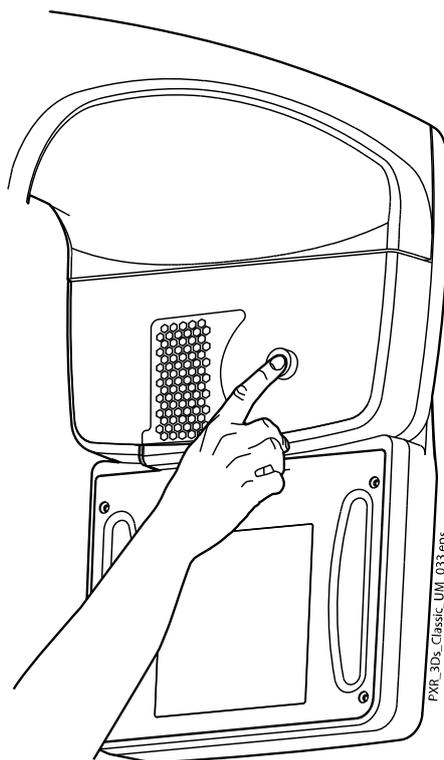


2. Turn the locking knob over the fastening mechanism.



This will secure the sensor in position.

3. Push in the C-arm electrical connector button on the other side.



This will make the electrical connection between the sensor and C-arm.

8.1.1.2 Detaching sensor from C-arm

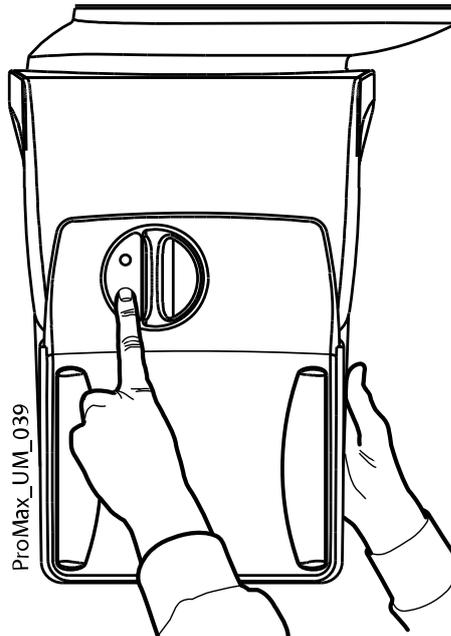
About this task

NOTE

Do not remove the sensor during imaging process.

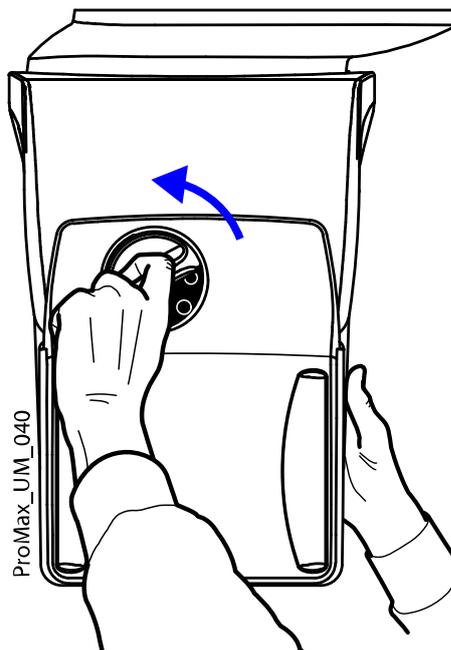
Steps

1. Push in the C-arm electrical connector.



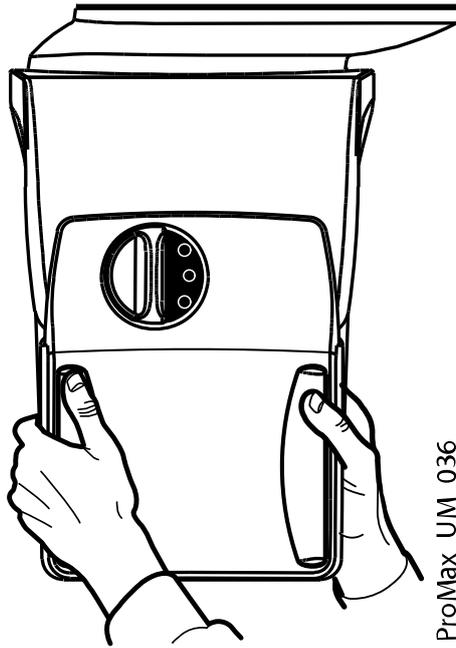
This will disconnect the electrical connection between the sensor and C-arm.

2. Turn the locking knob 180 degrees.



This will release the locking mechanism.

3. Carefully pull the sensor out.



What to do next

NOTE

For safety reasons, wait for at least ten seconds before you attach a sensor again. The blue indicator light under the locking knob has to switch off first.

8.1.2 Attaching patient supports

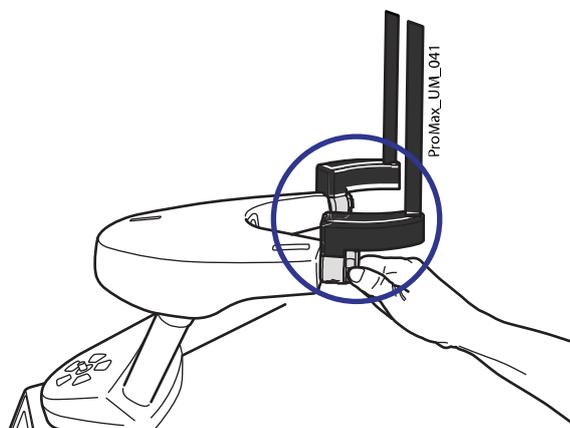
NOTE

The available head supports are shown in section "Head supports (option A or B)" on page 15.

8.1.2.1 Attaching support bars

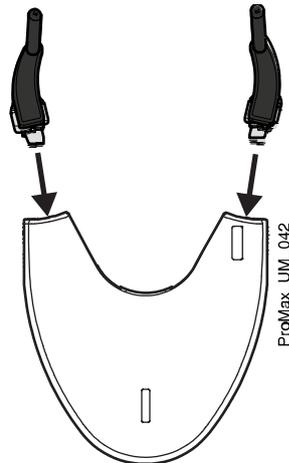
Steps

1. Insert the support bars into the holes in the patient support table.
2. Secure support bars in position by tightening the locking knobs.



NOTE

Ensure that you insert the support bars the right way around.



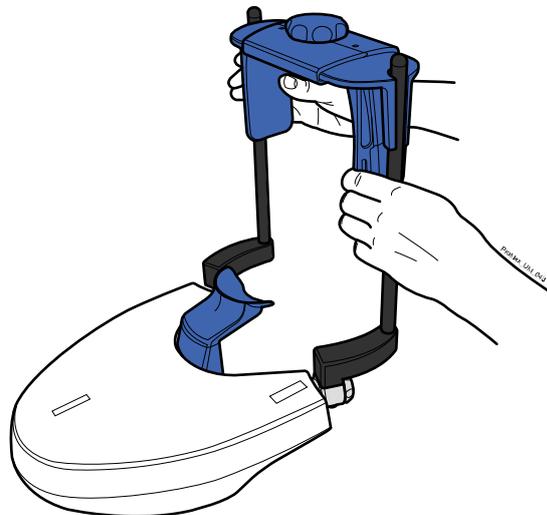
8.1.2.2 Head support A: Attaching adjustable head support

About this task

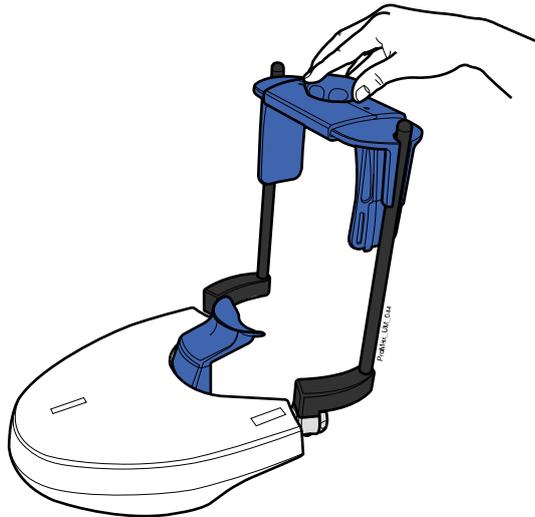
Follow these steps if you use the adjustable head support.

Steps

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



2. Turn the adjusting knob to adjust the head support to suit the size of the patient's head.

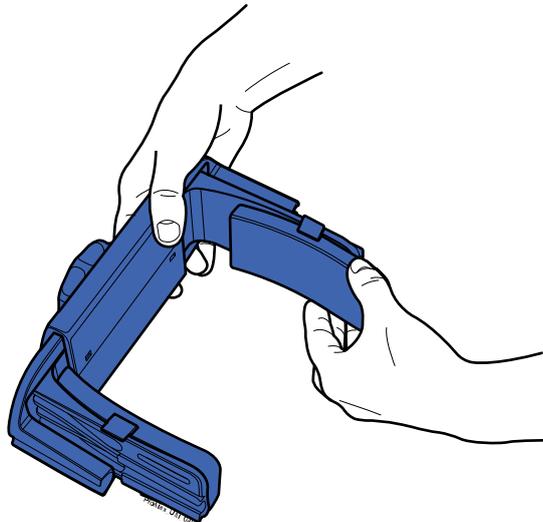


You can use temple pads if you take exposures of children, or patients with small heads.

Slide the temple pads onto the adjustable 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).



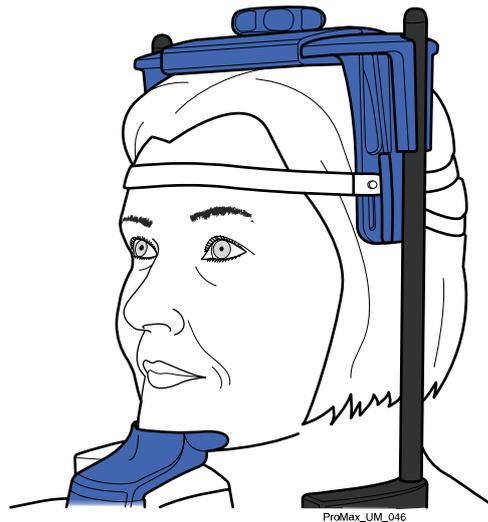
You can use fastening straps for additional head support if needed. Attach one strap in front of the forehead and two at the back of the head as shown.

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.



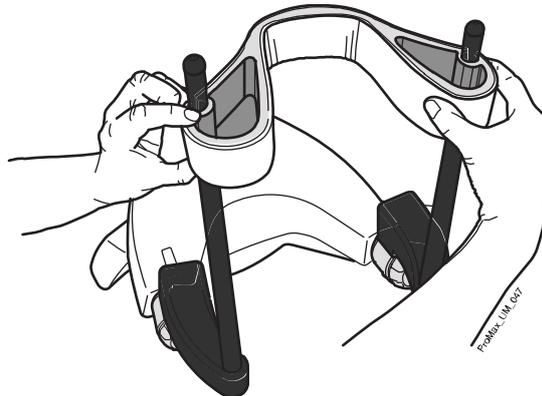
8.1.2.3 Head support B: Attaching head band

About this task

Follow these instructions if you use the head band.

Steps

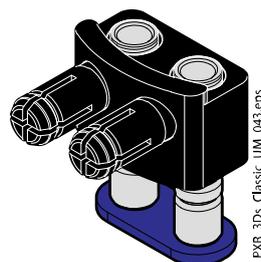
1. Attach the head band to the support bars as shown.
Set the side with the large openings against the patient's forehead.



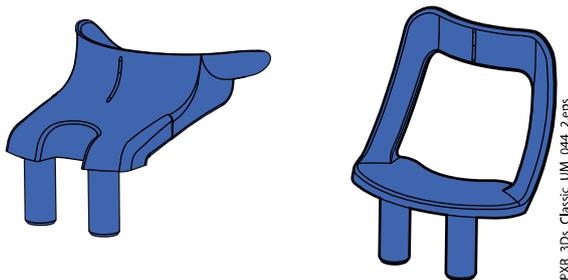
8.1.2.4 Adjusting adapter height

About this task

The adjustable adapter has five height positions. Position the patient's head at the correct height by lowering or raising the adapter as follows. The lower the patient is positioned, the higher the resulting image position.



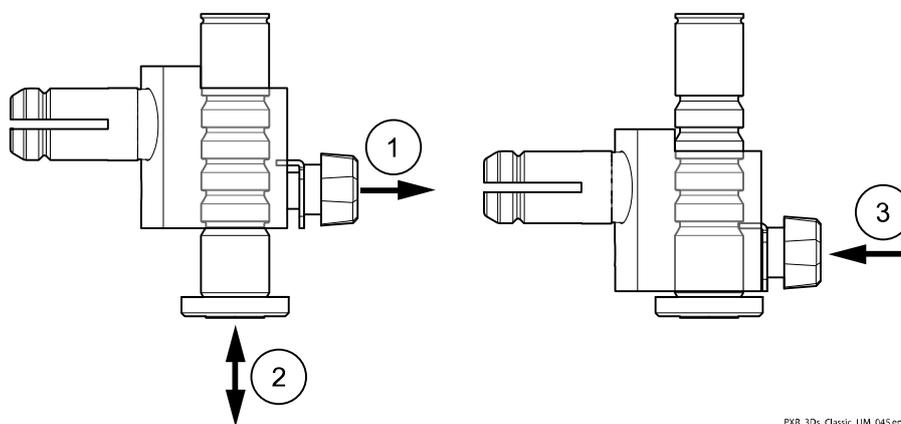
Use these patient supports.



Follow these steps to adjust the adapter height.

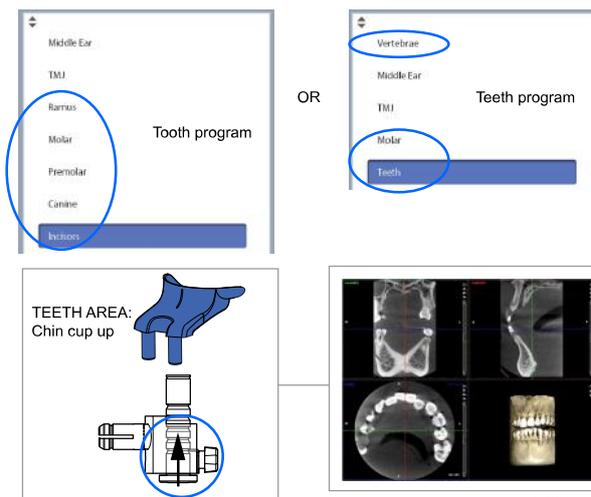
Steps

1. Pull the locking knob (1 in the figure below) and hold it out.
2. Raise or lower the adapter bars (2).
3. Release the locking knob (3) to lock the adapter into one of the five positions.



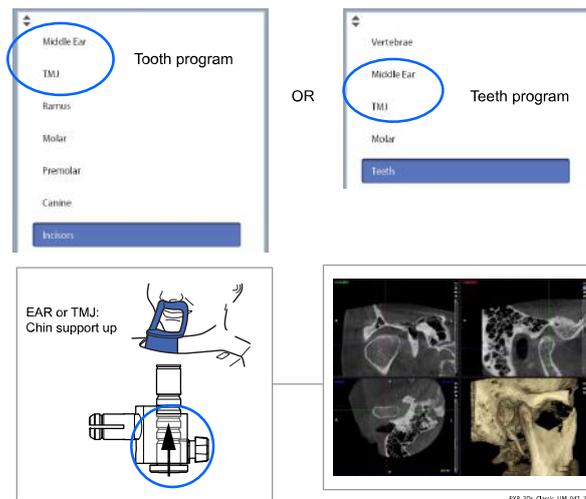
PXR_3Ds_Classic_UM_045.eps

- Use the highest position and a chin cup when taking exposures of the teeth area or other anatomical structures that are at this height.

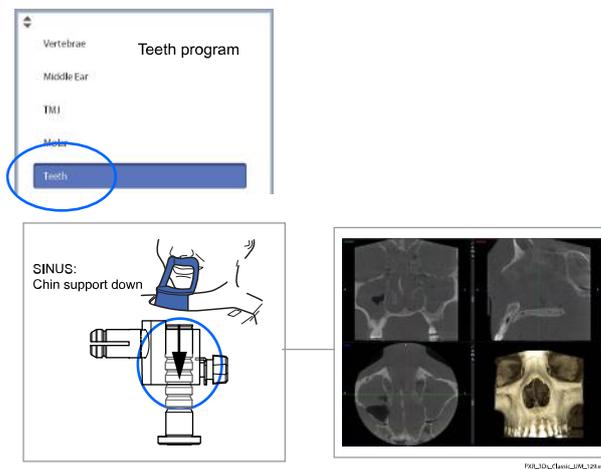


PXR_3Ds_Classic_UM_046.eps

- Use the highest position and a chin support under the nose when taking ear or temporomandibular joint (TMJ) exposures.



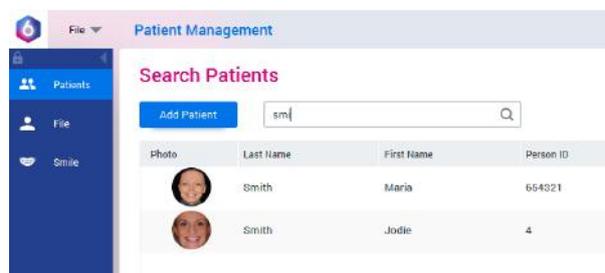
- Use the lowest position and a chin support under the nose when taking sinus exposures.



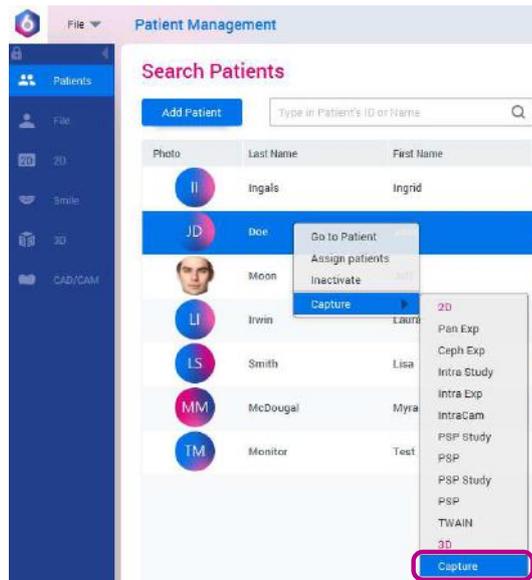
8.1.3 Preparing Romexis

Steps

- Select the patient.



- Right-click on the patient and select **Capture** followed by **3D Capture**.



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

8.2 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.

If you take a 3D face photo at the same time as you take an X-ray image, ask the patient to keep their hair away from their face and ears.

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

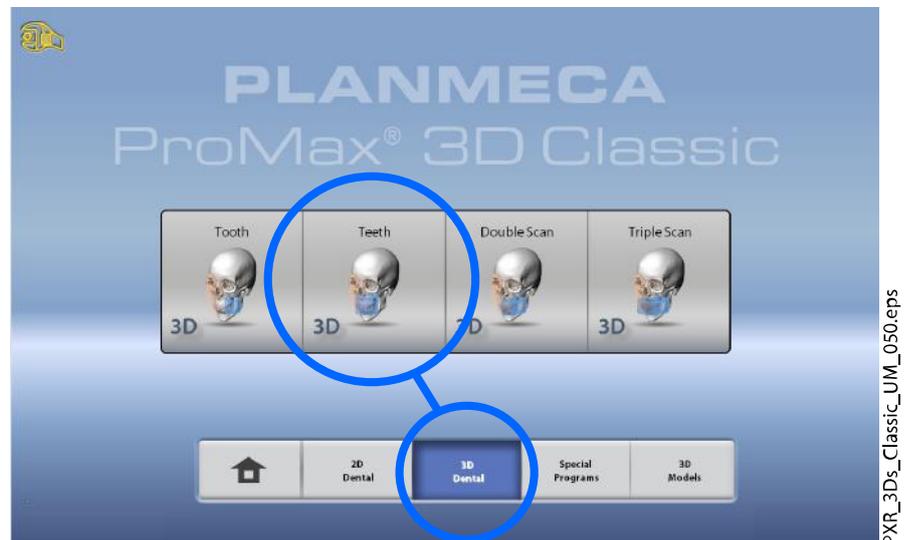
8.3 Selecting exposure settings

Refer to section "Touch screen" on page 17 for general information on how to make or cancel selections on the touch screen.

8.3.1 Selecting program

Steps

1. Select the 3D program you wish to use.

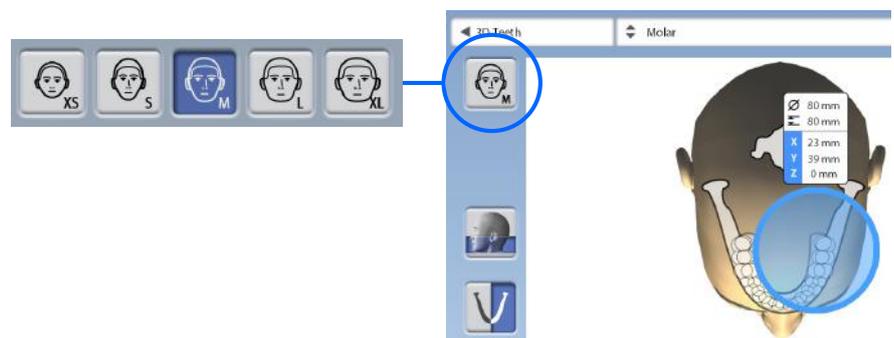


For more information on the available programs, see section "Planmeca ProMax 3D Classic programs" on page 25.

8.3.2 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



NOTE

Selecting child patient (XS) automatically reduces the volume size and patient dose.

NOTE

The exposure values automatically change according to the selected patient size, image resolution and ULD setting.

NOTE

The patient size can also be selected on the next screen.

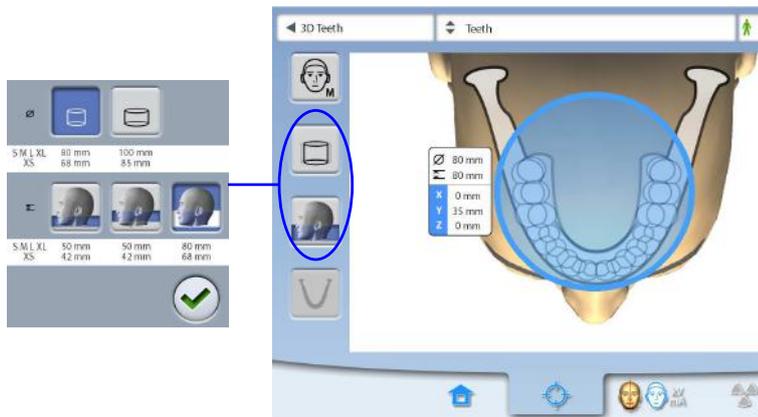
8.3.3 Selecting volume diameter and height

Steps

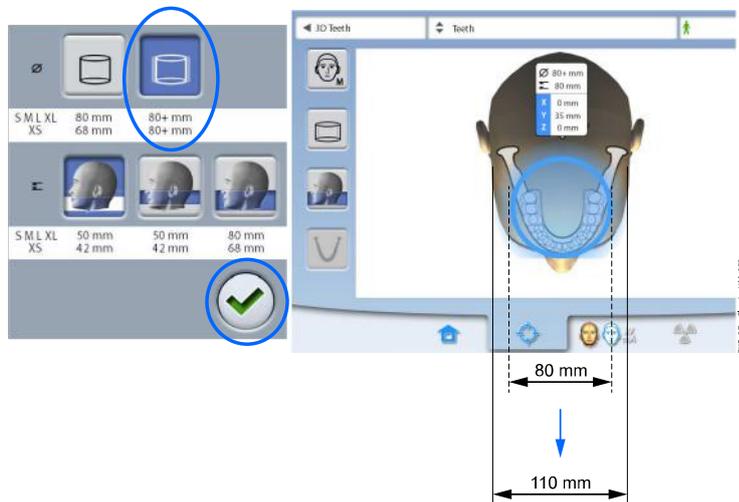
1. Select one of these buttons to set the diameter and height of the image volume.

NOTE

Depending on the program selected, only one of the options may be available.



Use this button to select the extended volume diameter. The extended volume diameter is 110 mm for all patient sizes. Selecting the extended volume diameter does not increase the patient radiation dose.



- Areas inside the volume diameter of 80 mm = sharp image
- Areas outside the volume diameter of 80 mm = less sharp image

NOTE

A slightly visible circular line between these two areas, as shown below, is normal.

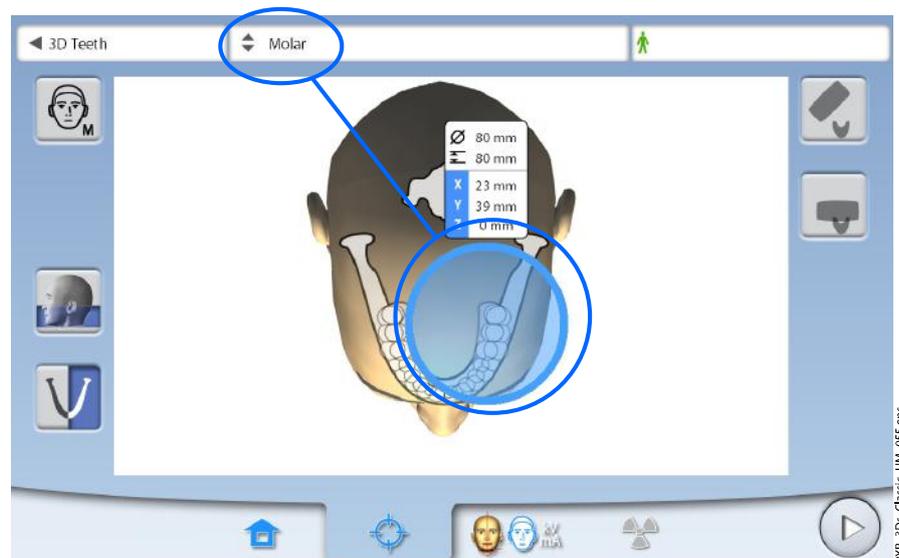


2. Press the green checkmark button to confirm selections.

8.3.4 Selecting volume position

Steps

1. Touch the area that you wish to expose.
Alternatively, select the volume position from the drop-down menu at the top.

**NOTE**

The available options depend on the selected program.

NOTE

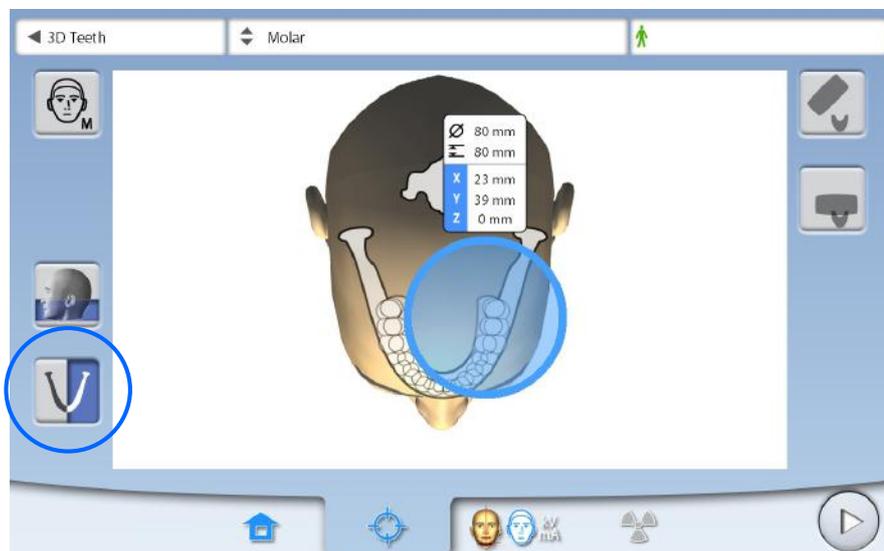
In 3D Double Scan and 3D Triple Scan programs the selected area is the primary image volume. The other image volume(s) adjoin(s) the primary image volume.

PXI_3D_Classic_LM_055.eps

8.3.5 Selecting jaw side

Steps

1. Use this button to select the jaw side (right / left / both sides) that you wish to expose.



NOTE

The available options depend on the selected program and image resolution.

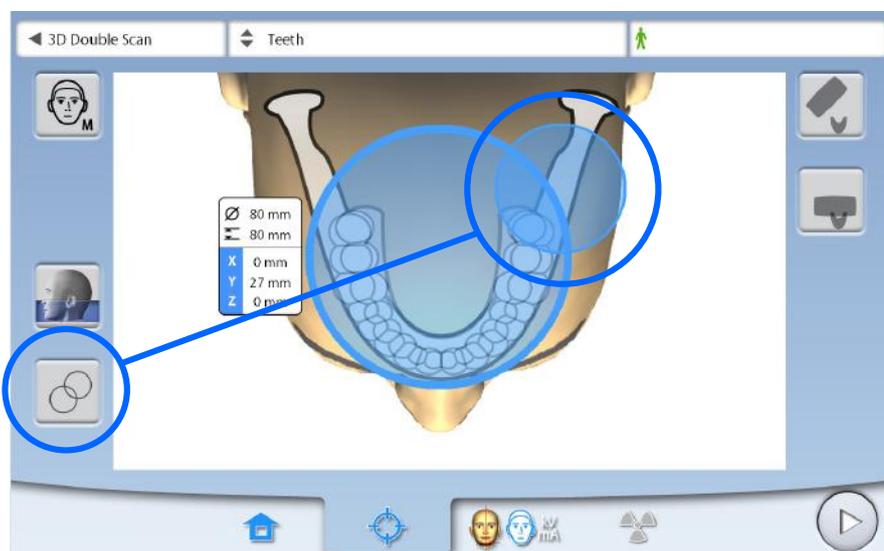
8.3.6 Reducing diameter of adjoining volume(s) (3D Double / Triple Scan only)

About this task

In 3D Double Scan and 3D Triple Scan programs all image volumes have the same diameter by default.

Steps

1. Use this button if you wish to reduce the diameter of the adjoining image volume(s).



NOTE

All image volumes are the same height.

8.4 Patient positioning**8.4.1 Selecting patient entry position****Steps**

1. Use the buttons on the right of the screen to select the patient entry position.
 - Select this button to move the C-arm to the back, away from the patient positioning area. This full view position allows you to monitor and adjust the patient's position freely from all directions.



- Select this button to position the C-arm around the patient support table. This is the traditional closed patient entry position.

**NOTE**

If needed, the full view position (top button) can be disabled (Settings > User > 1300 Operational settings > 1330 Patient positioning > Side entry OFF). This might be necessary if there is no space for the C-arm to move back.

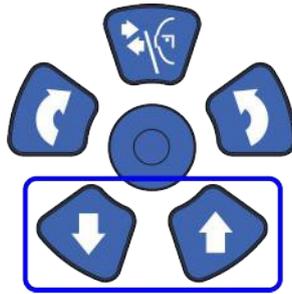
8.4.2 Positioning patient's head**Steps**

1. Guide the patient to the X-ray unit.
The patient can sit or stand during the exposure.

NOTE

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

2. Adjust the X-ray unit to suit the height of the patient.
To do this, press either of the height adjusting buttons until the chin cup / chin support is approximately level with the patient's lower jaw.

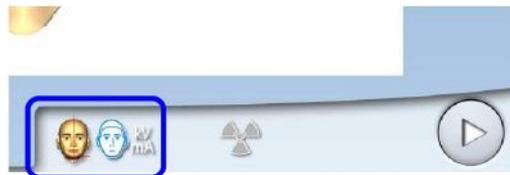


3. Ask the patient to grasp the patient handles.
4. Check that the patient's head is firmly positioned in the head support.
 - You can adjust the head support by turning the adjusting knob at the top.
 - You can use fastening straps for additional head support if needed. Refer to section "Attaching patient supports" on page 30 for details.

8.5 Selecting exposure values

To go to the next screen, select:

- This symbol



OR

- The forward button

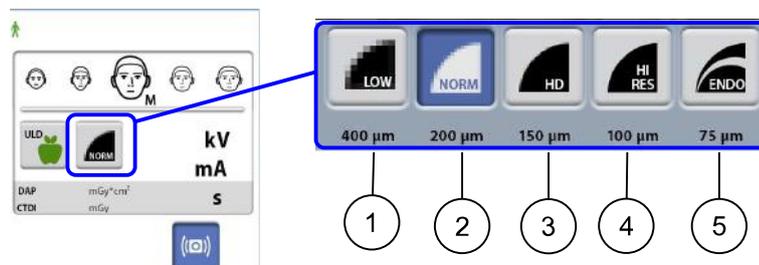


8.5.1 Selecting image resolution

Steps

1. Use this button to select the image resolution.

The voxel size is shown below the resolution button.



- 1 Low dose: Lower exposure values and reduced patient radiation dose
- 2 Normal resolution: Suitable for most targets
- 3 High definition: Better image quality for small targets, e.g. ear bones

- 4 High resolution: Sharp images
- 5 Endodontic: Very sharp images for endodontic applications and other small targets, for example, ear bones

NOTE

The available options depend on the selected program and X-ray unit model.

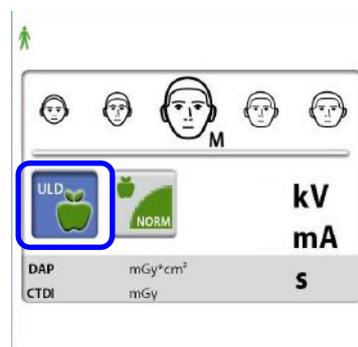
NOTE

The exposure values will automatically change according to the selected patient size, image resolution and ULD setting.

8.5.2 Selecting Ultra Low Dose (ULD)

Steps

1. Select the ULD button to take an exposure with a very low dose.
The function can be used to reduce patient radiation dose for example in orthodontic treatments, implant planning or follow-up studies.

**NOTE**

The exposure values will automatically change according to the selected patient size, image resolution and ULD setting.

8.5.3 Adjusting exposure values for current exposure

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.

Factory presets for image resolution Low dose

Patient size	kV value	mA value	mA value with ULD
Child (XS)	90	3.2	1.6
Small adult (S)	90	4.0	2
Medium-sized adult (M)	90	5	2.5
Large adult (L)	90	6.3	3.2

Factory presets for image resolution Low dose

Patient size	kV value	mA value	mA value with ULD
Extra large adult (XL)	90	8	4

Factory presets for image resolution Normal

Patient size	kV value	mA value	mA value with ULD
Child (XS)	90	4	2.8
Small adult (S)	90	5	3.6
Medium-sized adult (M)	90	6.3	4.5
Large adult (L)	90	8	5.6
Extra large adult (XL)	90	10	7.1

Factory presets for image resolution High definition (HD)

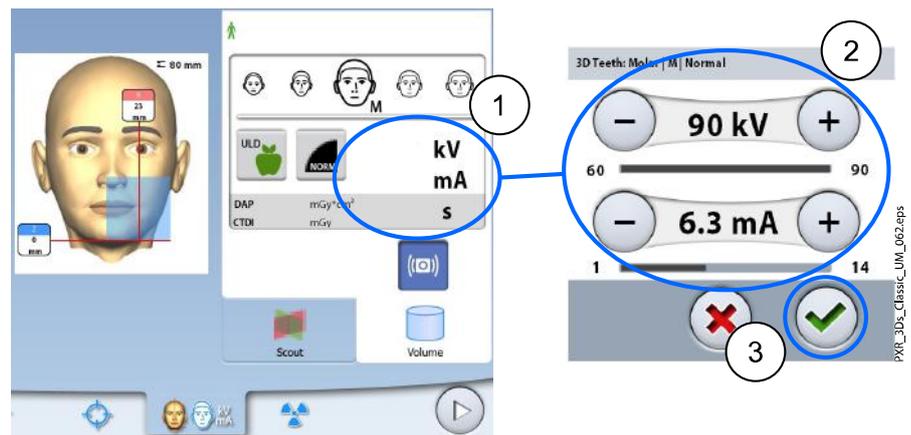
Patient size	kV value	mA value	mA value with ULD
Child (XS)	90	4	3.6
Small adult (S)	90	5	4.5
Medium-sized adult (M)	90	6.3	5.6
Large adult (L)	90	8	7.1
Extra large adult (XL)	90	10	9

Factory presets for image resolutions Hi Res and Endo

Patient size	kV value	mA value	mA value with ULD
Child (XS)	90	5	4.5
Small adult (S)	90	6.3	5.6
Medium-sized adult (M)	90	8	7.1
Large adult (L)	90	10	9
Extra large adult (XL)	90	11	11

If you need to adjust the preset exposure values for this exposure:

1. Select the kV / mA field.
2. Use the minus or plus buttons 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 mA value.
3. Select the green check mark button.



NOTE

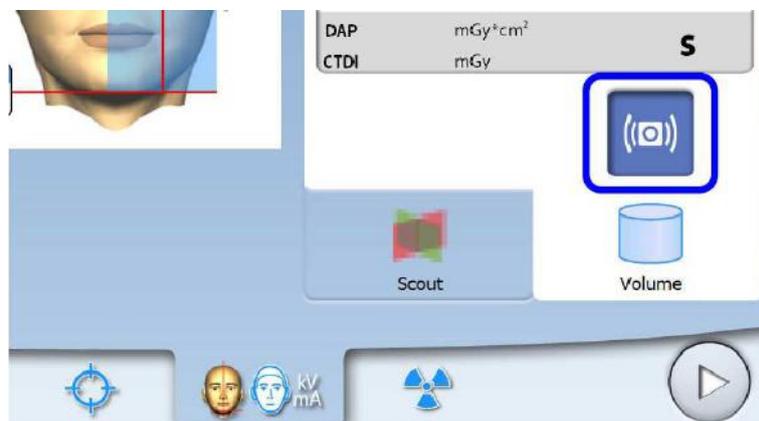
You can adjust the preset exposure values permanently as described in section "Programs (2100)" on page 85.

8.6 Selecting patient movement correction

Steps

1. Use this button to select the CALM patient movement correction function.

This is an algorithm that detects patient movement during exposure and then compensates for the effects of the movement during image reconstruction.



NOTE

The 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.

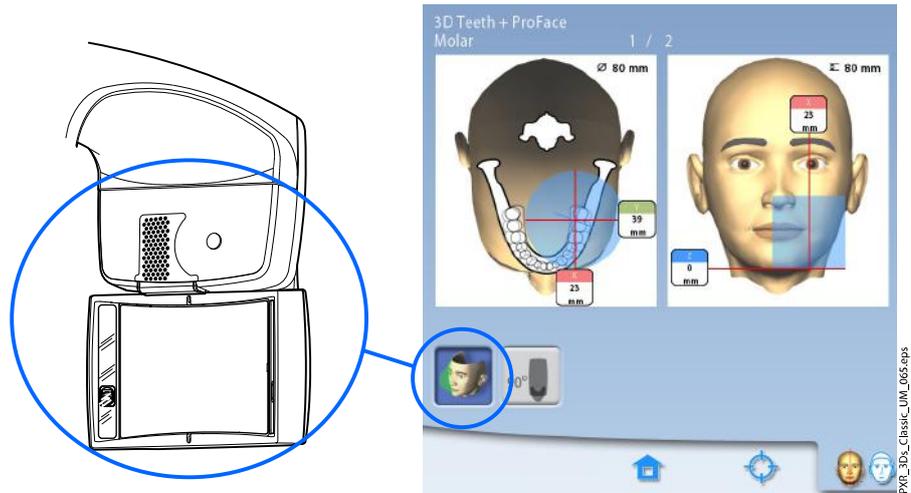
8.7 Selecting 3D face photo (X-ray units with ProFace sensor)

About this task

If the X-ray unit has a ProFace sensor, you can take a 3D photo of the patient's face at the same time as you take an X-ray image.

Steps

1. Select this button to take both images at the same time.



The button allows you to select the type of photo you wish to take. You can toggle between two photo options:

- Select this option if you wish to include the patient's ears in the photo:



The image is taken using a combined method of laser and optical scans.

- Select this option if you do not wish to include the patient's ears in the photo:



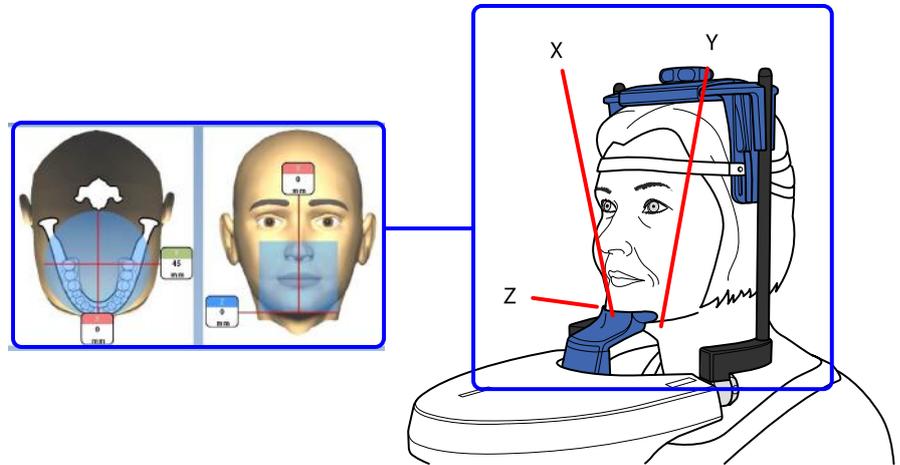
The image is taken with a laser scan. We recommend that you use this option if you need to take very sharp photos.

8.8 Adjusting volume position

The volume positions are preset at the factory for a standard patient. As all patients and their anatomical structures are different, however, you must check that the preset position covers the area of interest for this patient. If this is not the case, adjust the volume position according to the patient's anatomy. The positioning lights and the illustrations on the touch screen help you to do this.

NOTE

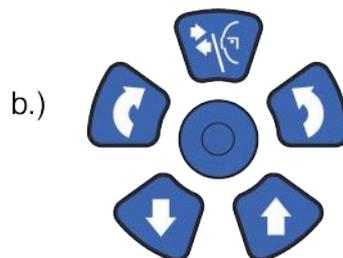
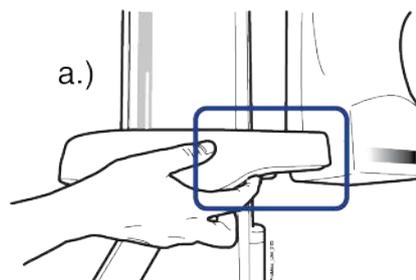
The following illustrations are guidelines only. When you adjust the volume position, the positioning lights move on your patient's face. The positioning lights on the illustrations show the preset volume position, and do not move according to your adjustments.



To switch the positioning lights on (if they are not already on), do one of the following:

- a.) Press the thumb wheel on the underside of the patient support table.
- b.) Press any of the positioning controls (button or joystick).

The lights automatically switch off after two minutes. To switch them off earlier, press the positioning joystick.



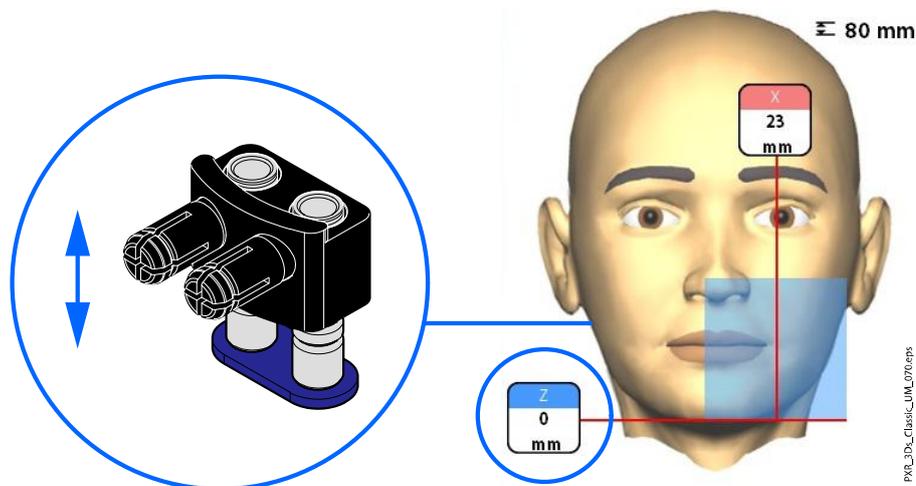
8.8.1 Moving image volume vertically (Z laser)

About this task

The volume bottom light (Z laser) indicates the position where the lower edge of the image volume is.

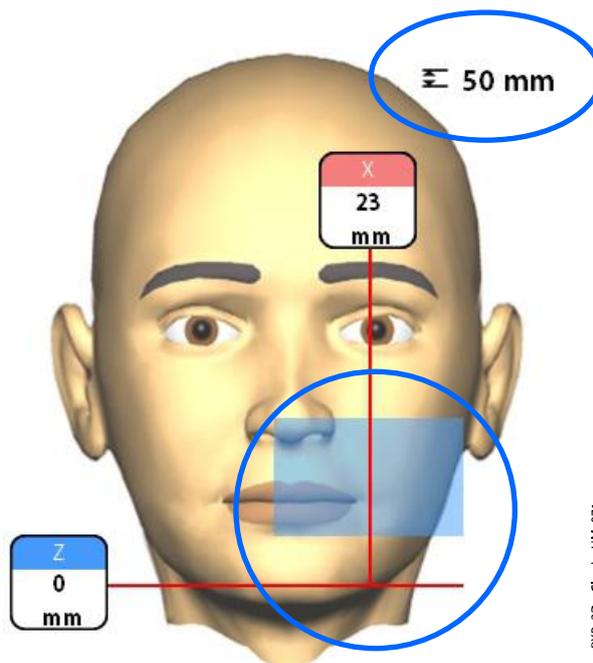
Steps

1. Check that the image volume is positioned at the correct height for your patient.



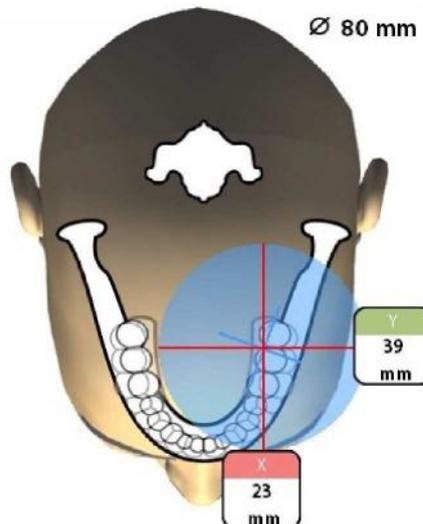
NOTE

If only the upper jaw half is selected, the lower edge of the image volume is positioned 30 mm (1.2 in.) above the volume bottom light.



8.8.2 Moving image volume horizontally (X and Y lasers)

The volume centre lights cross in the middle of the image volume. With the patient positioned in the unit, the volume centre lights form red lines on the front (front light = X laser) and on the left side (side light = Y laser) of your patient's head.

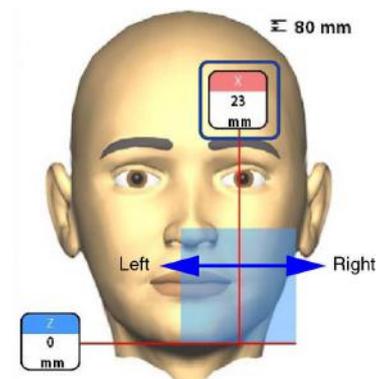
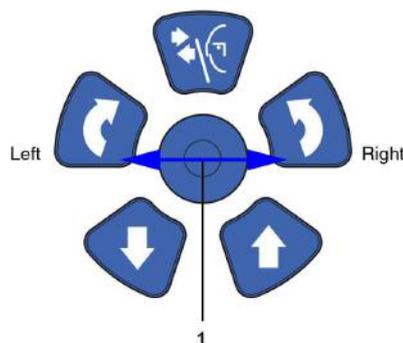


Check that the image volume is positioned correctly for your patient. If you need to adjust the volume position, proceed as follows.

8.8.2.1 Front light (X laser)

If you need to move the image volume to your left or right:

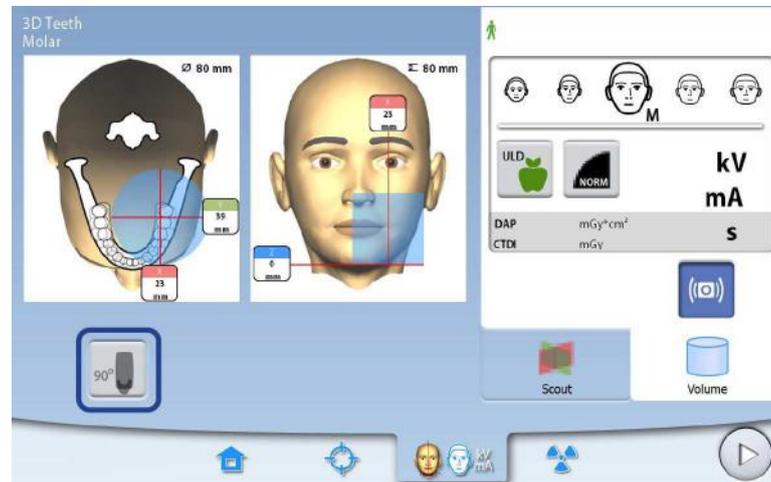
- Move the positioning joystick to your left or right. The front light (i.e. the image volume centre as seen from the front) moves accordingly on your patient's face.



8.8.2.2 Side light (Y laser)

First rotate the C-arm 90 degrees clockwise by selecting the 90° button at the bottom of the screen. This will give you a better view for checking the volume position.

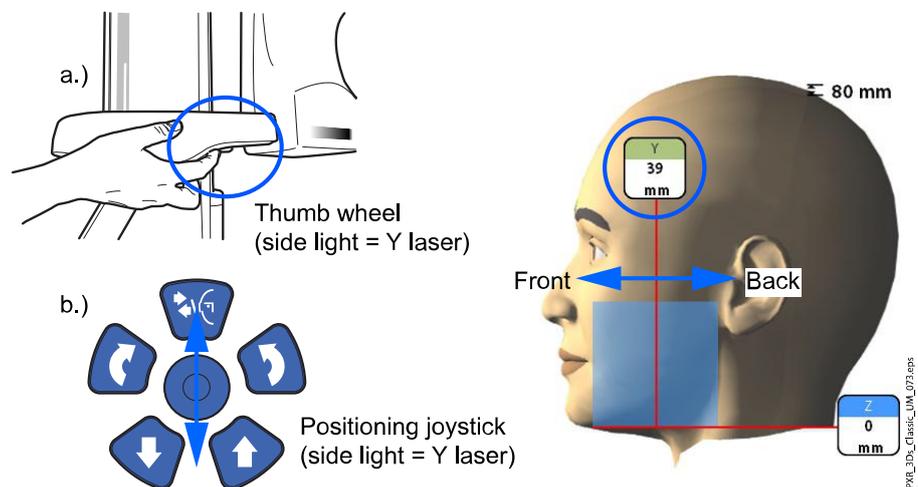
Select the button again if you wish to rotate the C-arm back to the original position.



If you need to move the image volume to the front or back, do one of the following:

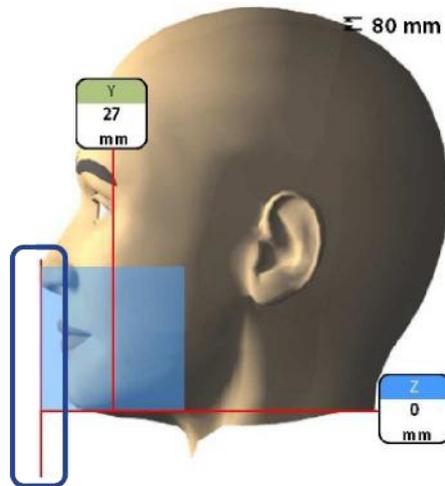
- Move the thumb wheel that is located on the underside of the patient support table
- Move the positioning joystick towards you or away from you

The side light (Y laser, i.e. the image volume centre as seen from the side) will move accordingly on your patient's face.



NOTE**FOR PROGRAMS TOOTH AND TEETH:**

The incisor light indicates the front edge of the image volume when the front position is selected.

**NOTE**

Moving the positioning joystick switches the incisor light off.

8.9 Taking scout image or 2D views (LAT, PA or LAT-PA)

About this task

NOTE

You can switch the functions on and adjust the preset exposure values as described in section "Programs (2100)" on page 85.

You can take a scout image or 2D views (LAT, PA or LAT-PA) of the selected image volume before you take the actual 3D image. This allows you to check the volume position or, if necessary, confirm the need for a 3D exposure.

NOTE

If the image consists of several volumes, scout imaging is available for the first image volume (1/2) only.

NOTE

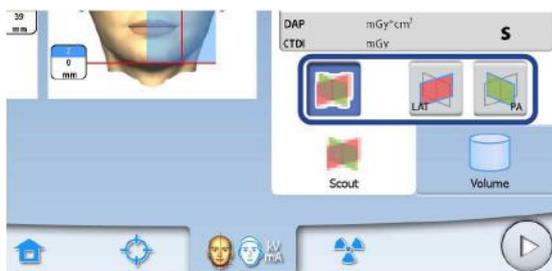
2D views are not available for all programs.

NOTE

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

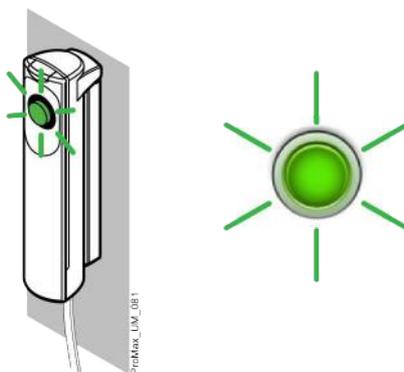
Steps

1. Select the view you wish to take.
To take LAT-PA views, select both buttons (LAT and PA).



2. Select the radiation symbol or the forward button.

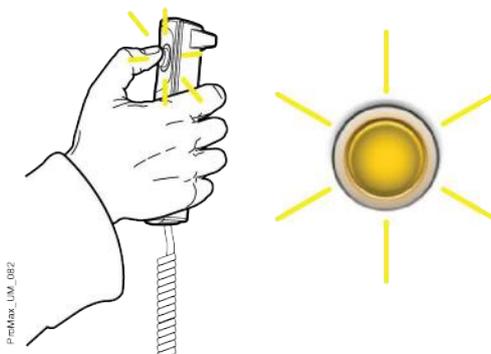
Green lights flash on the touch screen and exposure button when the X-ray system is getting ready for an exposure. The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure.



3. Ask the patient to stay as still as possible.
4. Move to a protected area.
5. Press and hold down the exposure button for the entire duration of the exposure.

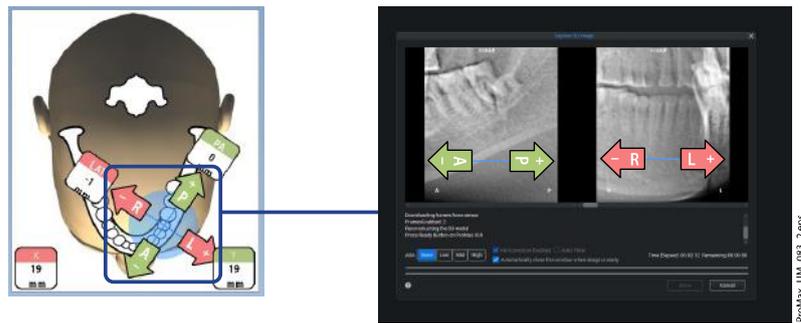
During exposure yellow radiation warning lights illuminate on the exposure switch and on the touch screen, and you hear a radiation warning tone.

Additionally, a radiation warning symbol is shown on the touch screen.



The image is shown on the computer screen. If needed, you can readjust the position of small volumes as shown below.

- Use the plus and minus signs that appear on the touch screen.



- Take a new exposure as described above.
Repeat the procedure until the image volume is in the correct place.

8.10 Taking 3D exposure

About this task

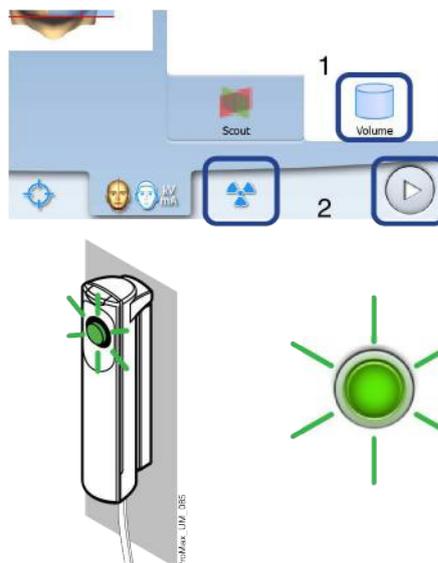
NOTE

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

Steps

- Make sure that the **Volume** tab is selected.
- Select the radiation symbol or the forward button.

Green lights flash on the touch screen and exposure button when the X-ray system is getting ready for an exposure. The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure.



- Ask the patient to stay as still as possible.

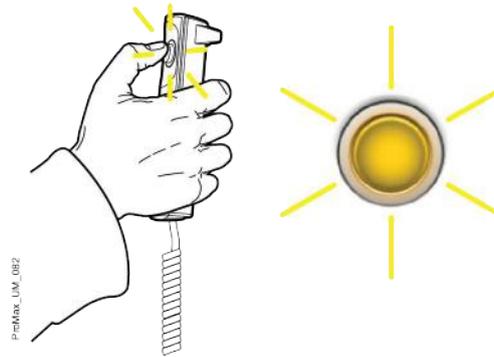
If you take a 3D face photo at the same time, tell the patient that a bright light will come on during the exposure but the patient should not be startled and move. Ask the patient to either keep their eyes shut or to

focus them on a fixed point in the distance so that the eyes will point in their natural direction in the resulting image.

4. Move to a protected area.
5. Press and hold down the exposure button for the entire duration of the exposure.

During exposure yellow radiation warning lights illuminate on the exposure switch and on the touch screen, and you hear a radiation warning tone.

Additionally, a radiation warning symbol displays on the touch screen.



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

- If you take two horizontal image volumes, the patient's left side is imaged first and the right side last.
- If you take one image volume and a 3D face photo, the X-ray image is taken first and the photo last. You hear a fast ticking sound when the photo is taken.

NOTE

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

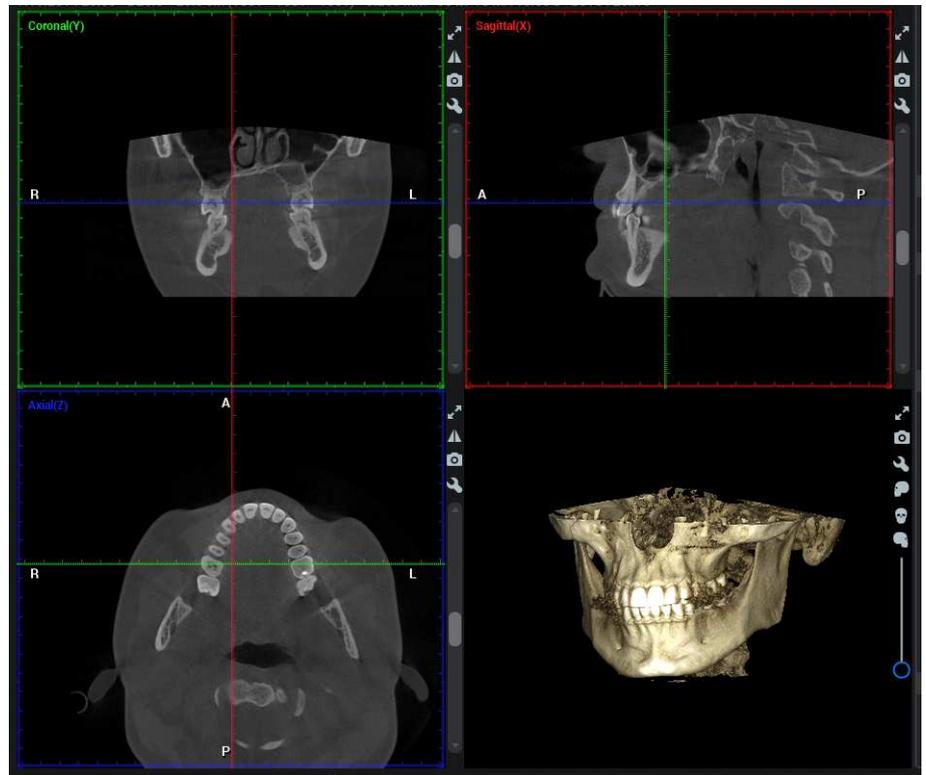
NOTE

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.

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) function, you have to wait longer before the image appears.
- If you took two image volumes, you must accept the image stitching function in the Romexis program.



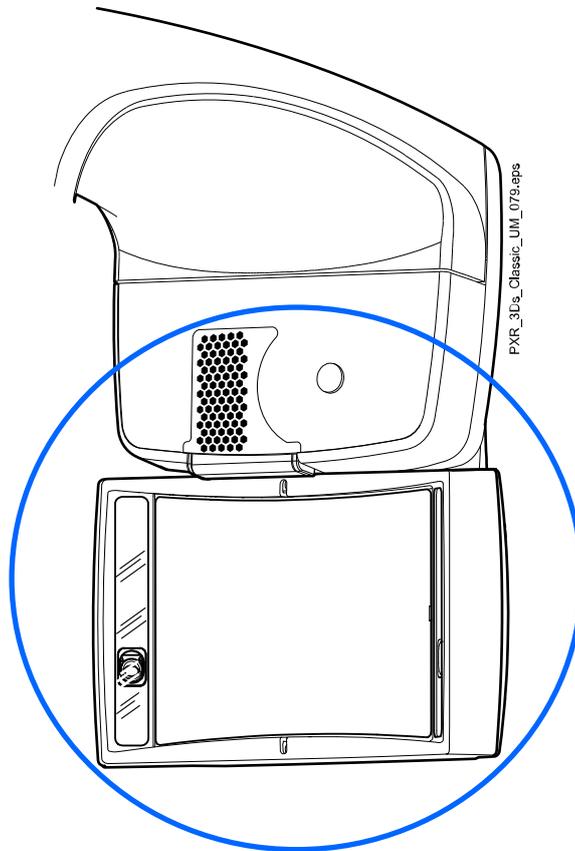
What to do next

Remove the fastening straps (if used). Release the patient from the head support by turning the adjusting knob at the top.

Guide the patient away from the X-ray unit.

9 3D face photo

If the X-ray unit has a ProFace sensor, you can take a 3D photo of the patient's face.



NOTE

If you wish to take an X-ray image and a 3D face photo at the same time, refer to section "Adjusting volume position" on page 46.

9.1 Before exposure

Steps

1. Attach the support bars and the adjustable head support.
See section "Attaching patient supports" on page 30 for more information.

NOTE

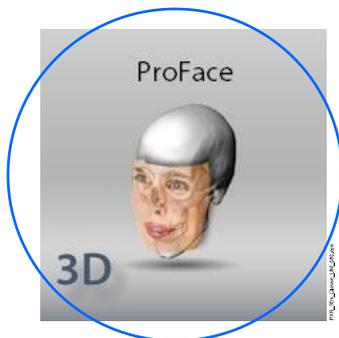
To get a realistic image of the patient's face, do not use the chin cup or the fastening straps when taking 3D face photos.

2. Select the patient and the 3D exposure in Romexis.
See section "Preparing Romexis" on page 35 for more information.

9.2 Patient positioning

Steps

1. Select the ProFace program (Special Programs > ProFace).



2. Select the patient entry position.
See section "Selecting patient entry position" on page 41 for more information.
3. Guide the patient to the X-ray unit.
The patient can sit or stand during the exposure. Ask the patient to keep their hair away from their face and ears.

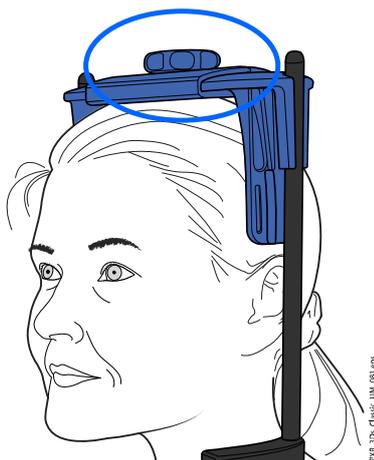
NOTE

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

4. Adjust the X-ray unit to suit the height of the patient.
To do this, press either of the height adjusting buttons until the patient support table is approximately level with the patient's lower jaw.

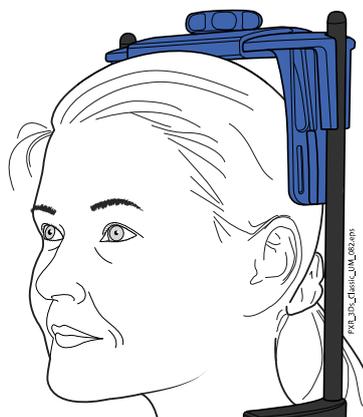


5. Position the patient's head in the head support.
You can adjust the head support by turning the adjusting knob at the top.



NOTE

If you wish to see the patient's ears clearly in the photo, position the patient's head so that the head support is at the back of the head as shown here.



6. Ask the patient to grasp the patient handles.

9.3 Selecting exposure settings

Steps

1. To go to the next screen, select:

- This symbol



OR

- The forward button



2. Use this button to select the type of photo you wish to take.

You can toggle between two options:

- Select this option if you wish to include the patient's ears in the photo:



The image is taken using a combined method of laser and optical scans.

- Select this option if you do not wish to include the patient's ears in the photo:



The image is taken with a laser scan. We recommend that you use this option if you need to take very sharp photos.

The positioning lights show on the patient's face.



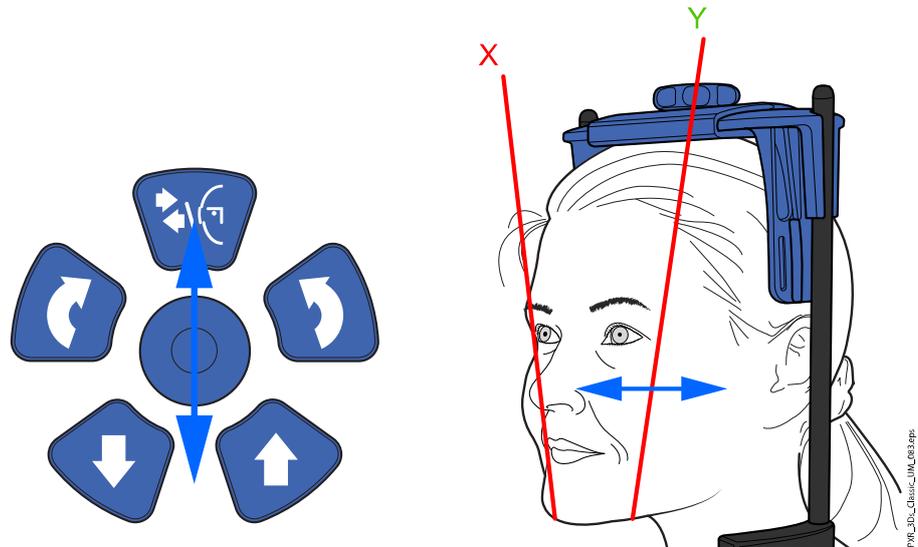
3. Rotate the C-arm 90 degrees clockwise by selecting the 90° button at the bottom of the screen.

This will give you a better view for checking the position of the side light (Y laser).

Select the button again if you wish to rotate the C-arm back to the original position.

4. Check that the side light (Y laser) is positioned 1 - 3 cm (0.4 - 1.2 in.) behind the patient's eye corner.

If you need to adjust the side light, move the positioning joystick towards you (laser to the front) or away from you (laser to the back).

**NOTE**

When you adjust the light position the positioning light moves on your patient's face. The positioning light on the touch screen illustration does not move according to your adjustment.

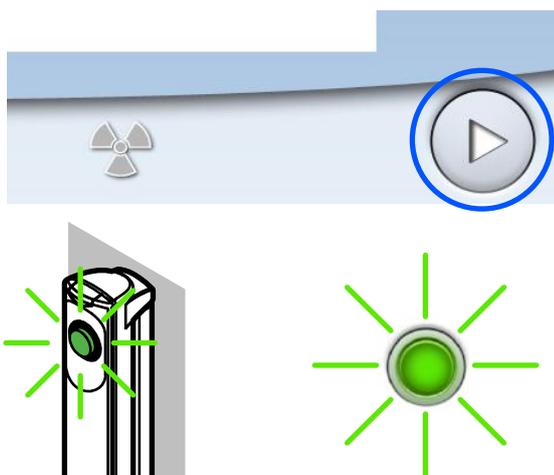
9.4 Taking a 3D face photo**About this task**

Follow the steps below to take a 3D face photo.

Steps

1. Select the forward button.

Green lights flash on the touch screen and exposure button when the X-ray system is getting ready for an exposure. The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure.



2. Ask the patient to stay as still as possible.

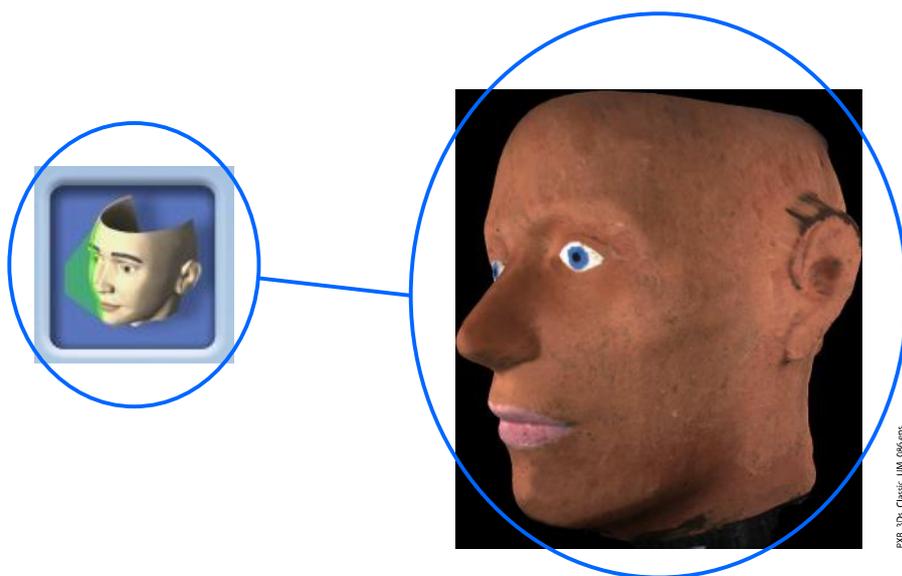
Tell the patient that a bright light will come on during the exposure but the patient should not be startled and move. Ask the patient to either keep their eyes shut or to focus them on a fixed point in the distance so that the eyes will point in their natural direction in the resulting image.

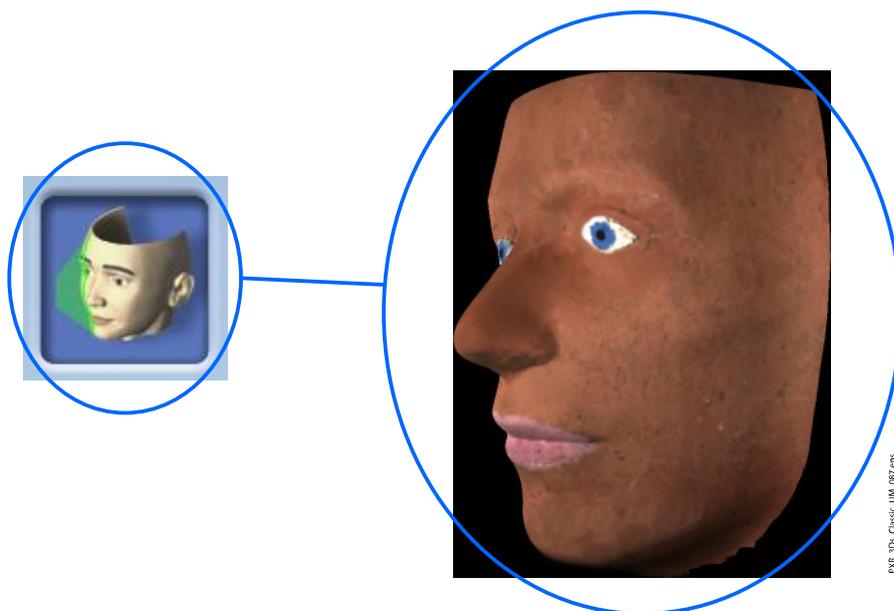
3. Press and hold down the exposure button for the entire duration of the exposure.

You hear a fast ticking sound when the photo is taken.



The photo is shown on the computer screen.





4. Release the patient from the head support by turning the adjusting knob at the top.
5. Guide the patient away from the X-ray unit.

10 3D model exposure



CAUTION

The 3D Model programs must not be used for patient imaging. The programs are intended for taking exposures of impressions and plaster casts only.

10.1 Calibrating X-ray unit for impression or plaster material

NOTE

The X-ray unit has to be calibrated for each new material that is used. The X-ray unit needs to be calibrated only once for each material.

NOTE

FOR IMPRESSIONS:

Only monophasic impression materials can be used.

NOTE

FOR PLASTER CASTS:

If the plaster cast consists of two materials, the X-ray unit has to be calibrated for the teeth material.

10.1.1 Preparing calibration material

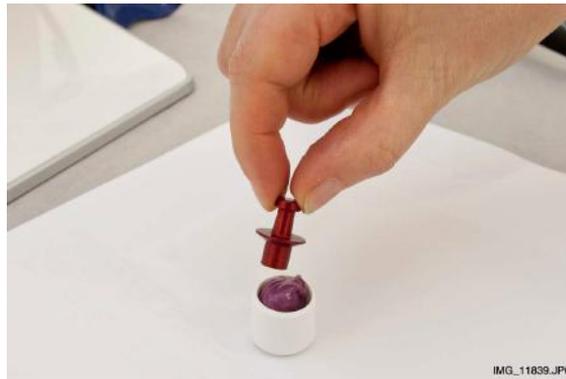
Steps

1. Insert impression material (1) into the calibration cup (2) provided (part number 10031325), until the calibration cup is full.



2. Place the calibration pin provided (part number 10031265) in the material.

Note that the calibration pin has to be pushed in thicker end first. The middle rim has to be flush with the top edge of the calibration cup.



3. Let the material set.

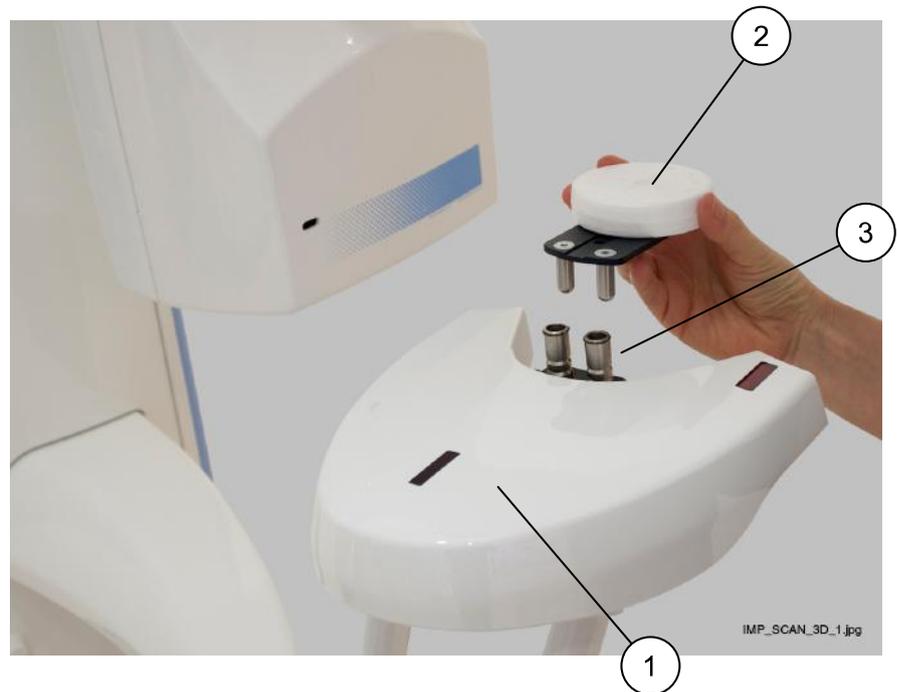
The setting time depends on the material used. Wait slightly longer than recommended in the instructions supplied by the manufacturer to ensure proper hardening.

4. Remove all excess material from the top of the calibration cup.



5. Gently pull the calibration pin out and ensure that the surfaces of the hole formed by the calibration pin are even (no air bubbles in inside walls).
6. Remove any patient supports attached to the X-ray unit patient support table (1).

7. Insert the polystyrene disc provided (2, part number) into the adjustable adapter (3).

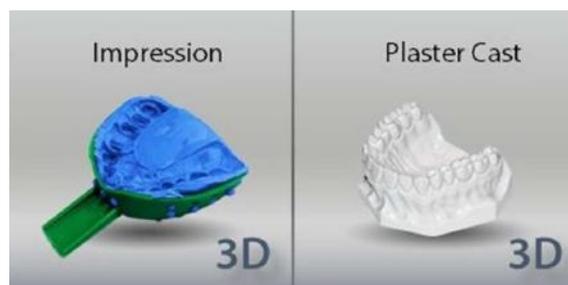


Position the adjustable adapter so that it is in the highest position. Refer to section "Adjusting adapter height" on page 33 for details.

10.1.2 Selecting settings

Steps

1. On the X-ray unit, select the program.
 - For impression material select **3D Models > Impression**
 - For plaster material select **3D Models > Plaster Cast**



2. To go to the next screen, select:

- This symbol



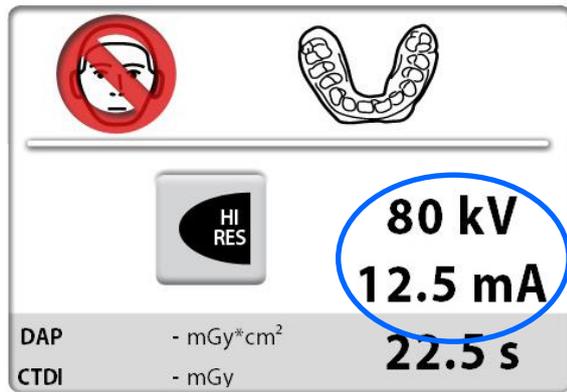
OR

- The forward button

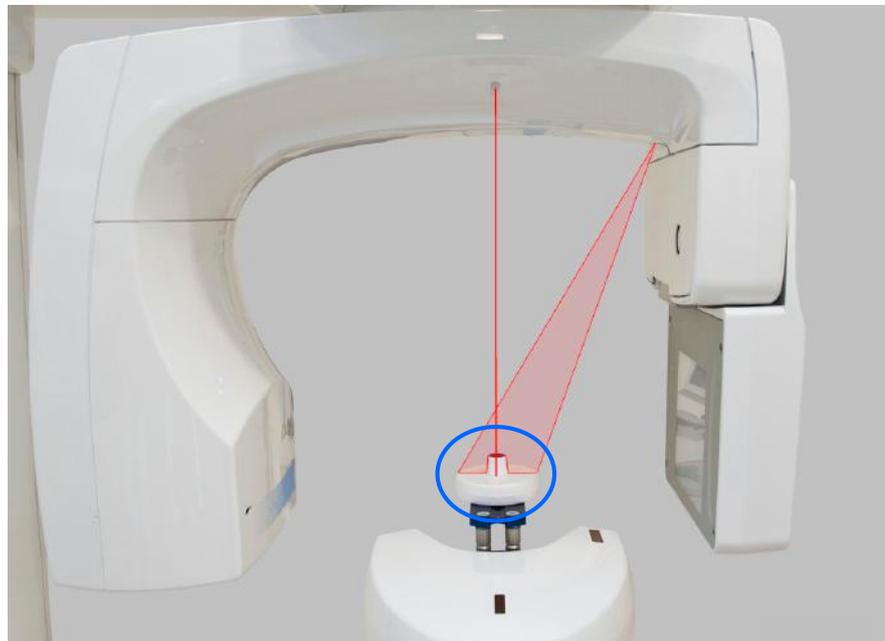


The positioning lights (volume centre lights and volume bottom light) come on. The volume centre lights cross in the middle of the image volume.

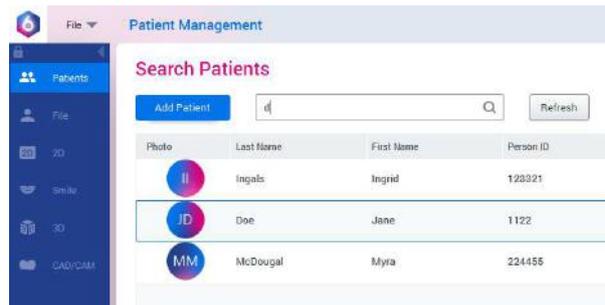
3. The required exposure values depend on the material and X-ray unit (X-ray tube and sensor) used. If you need to adjust the preset exposure values (80 kV / 12.5 mA), proceed as described in section "Adjusting exposure values for current exposure" on page 43. You can use either image resolution (Fast or High resolution) for the calibration process.



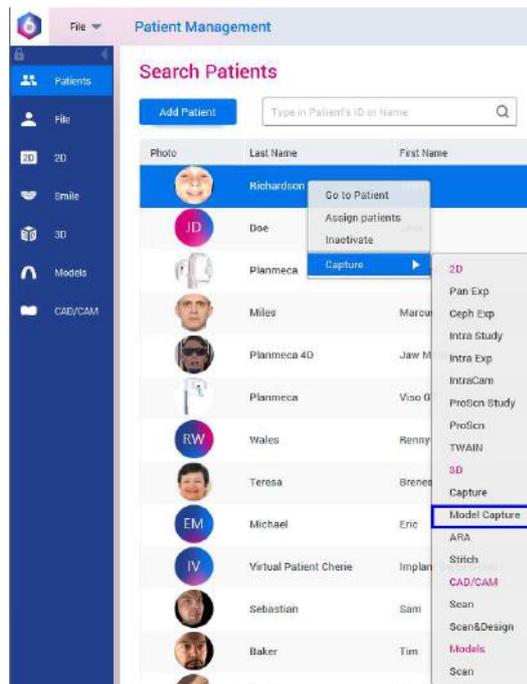
4. Place the calibration cup on the polystyrene disc so that the volume centre lights cross in the middle of the cup.



- In the Romexis program, select the patient.



- Select **Model Capture** as shown in the image.



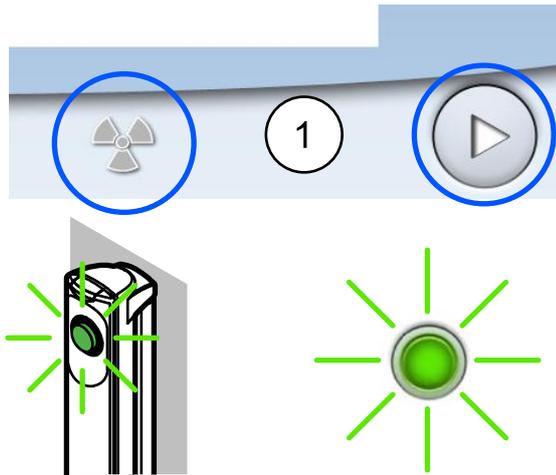
- Select the option **Add Material** in the window that displays.



10.1.3 Taking a calibration exposure

Steps

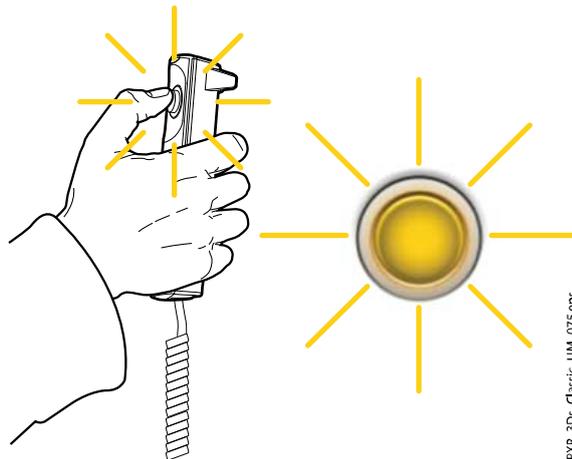
- Select the radiation symbol or the forward button.
Green lights flash on the touch screen and exposure button when the X-ray system is getting ready for an exposure. The green lights stop flashing and stay on continuously when the X-ray system is ready for an exposure.



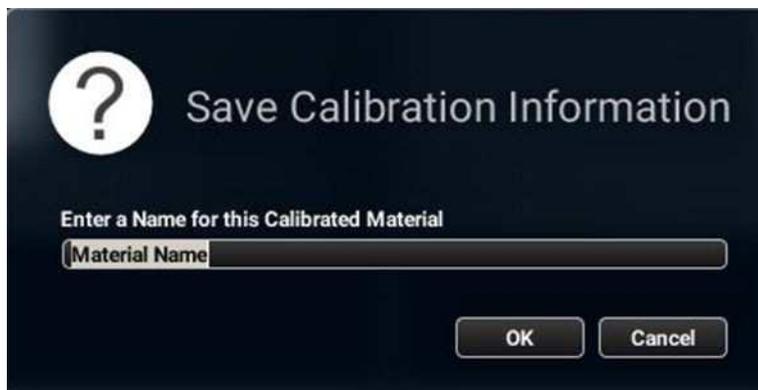
2. Move to a protected area.
3. Press and hold down the exposure button for the entire duration of the exposure.

During exposure yellow radiation warning lights illuminate on the exposure switch and on the touch screen, and you hear a radiation warning tone.

Additionally, a radiation warning symbol is shown on the touch screen.



4. In the Romexis program, enter a name for this material and select OK.



NOTE

The calibration exposure values are automatically included at the beginning of the name.

10.2 Taking an exposure of an impression or plaster cast

NOTE

The X-ray unit has to be calibrated for each new material that is used. Refer to the previous section for details.

NOTE

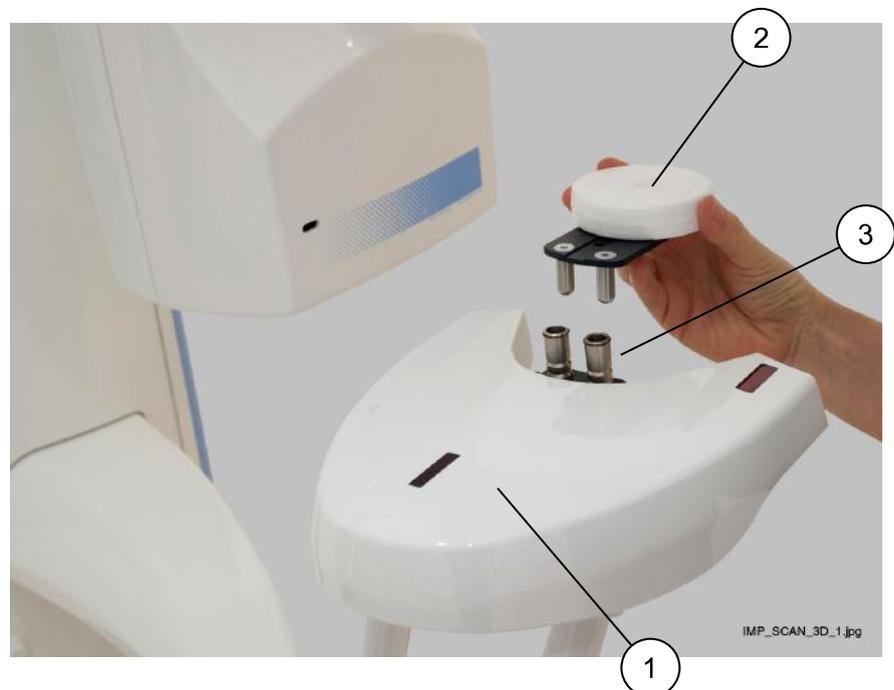
FOR IMPRESSIONS:

Do not use impression trays made of metal.

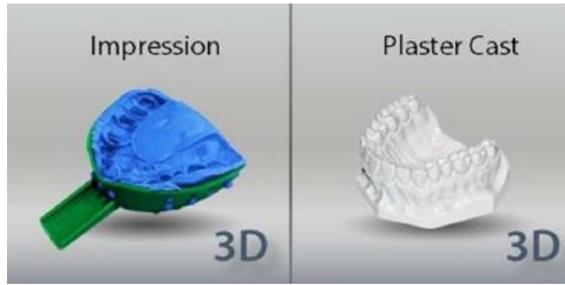
10.2.1 Selecting settings

Steps

1. Remove any patient supports attached to the X-ray unit patient support table (1). Insert the polystyrene disc (2) provided (part number) into the adjustable adapter (3) if it is not already in place.



2. Position the adjustable adapter:
 - For impressions so that the adapter is in the highest position
 - For plaster casts so that the adapter is in the second highest position
 Refer to section "Adjusting adapter height" on page 33 for details.
3. On the X-ray unit, select the program.
 - For impressions select **3D Models > Impression**
 - For plaster casts select **3D Models > Plaster Cast**



4. To go to the next screen, select:

- This symbol



OR

- The forward button

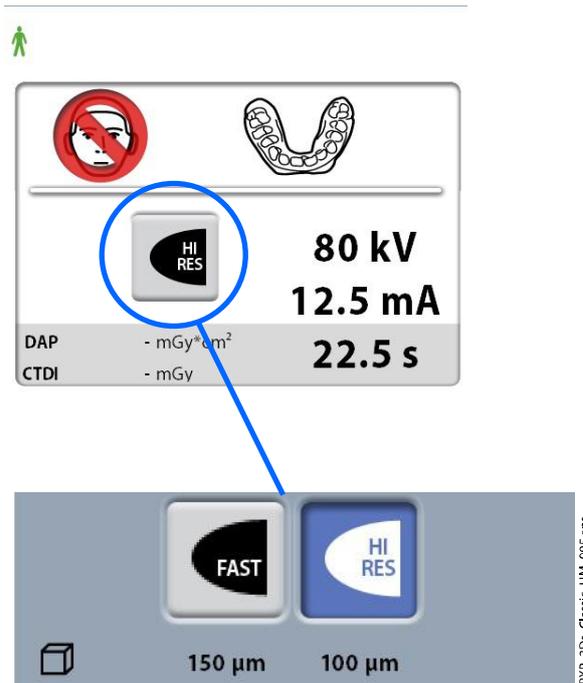


The positioning lights (volume centre lights and volume bottom light) come on. The volume centre lights cross in the middle of the image volume.

5. Select the image resolution you wish to use.

The voxel size is shown below the resolution button.

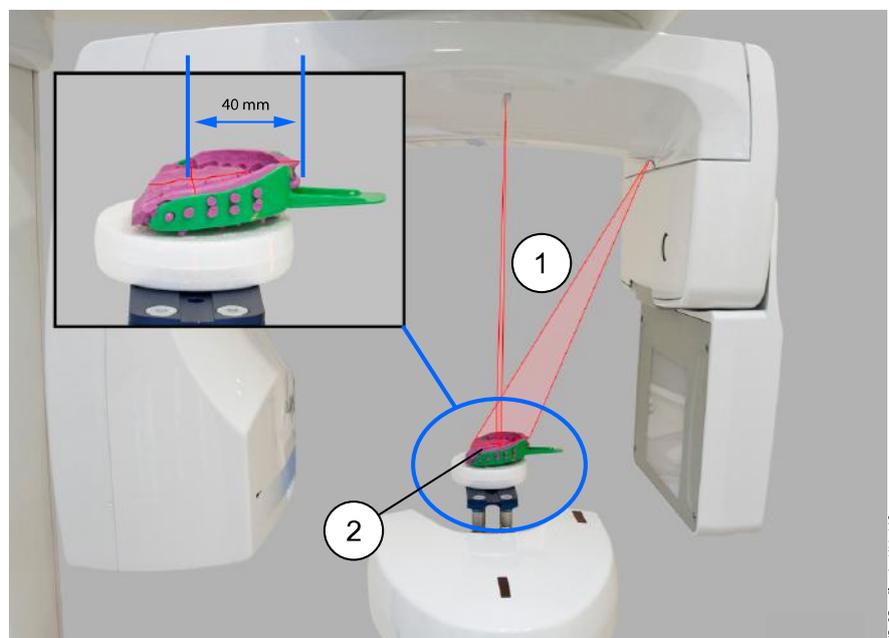
- Fast: Short exposure time and lower resolution for archiving purposes
- High resolution: Long exposure time and higher resolution for best results



6. Select the exposure values that you used in the calibration process for this material.

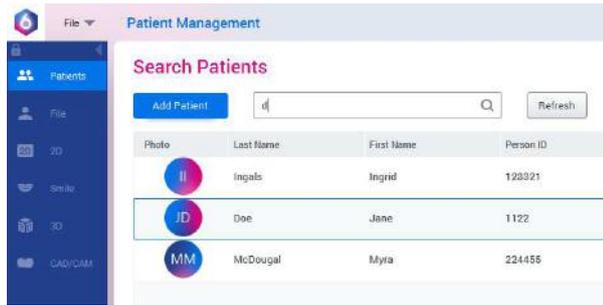
Refer to section "Adjusting exposure values for current exposure" on page 43 if you need to adjust the preset exposure values.

7. Place the model (impression or plaster cast) on the polystyrene disc so that the model faces the sensor and position the model so that the distance between the front edge of the model and the volume center cross is 40 mm (1.6 in.).

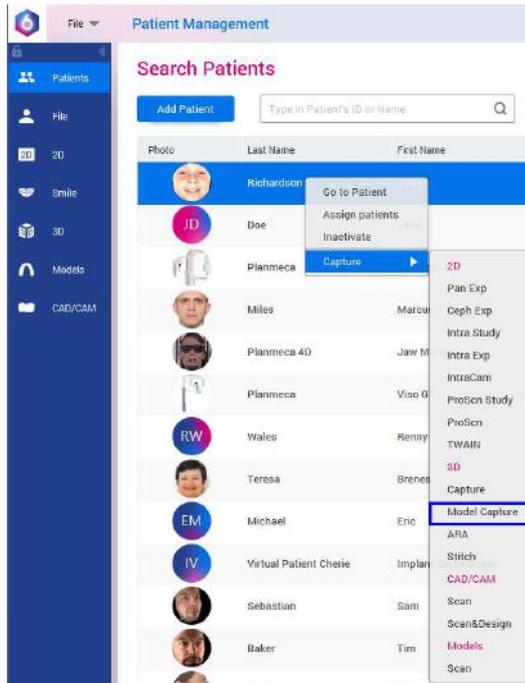


- 1 Volume centre lights
- 2 Impression on polystyrene disc

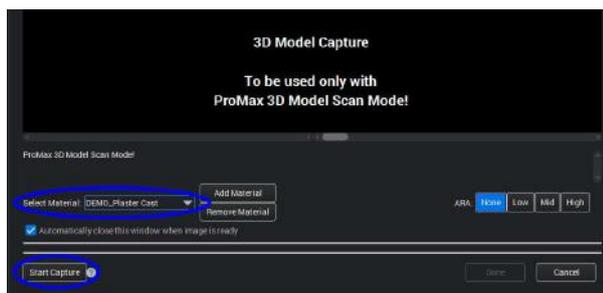
- If not done yet, in the Romexis program, select the patient.



- Select **Model Capture** as shown in the image.



- In the window that appears, first select the material you are exposing. Then select the option **Start Capture**.



NOTE

Ensure that you have selected the correct exposure values on the X-ray unit. The exposure values shown here are only examples.

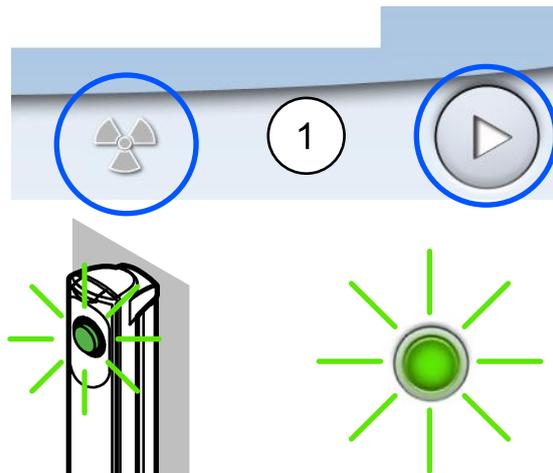
10.2.2 Taking an exposure

Steps

- Select the radiation symbol or the forward button.

Green lights flash on the touch screen and exposure button when the X-ray system is getting ready for an exposure. The green lights stop

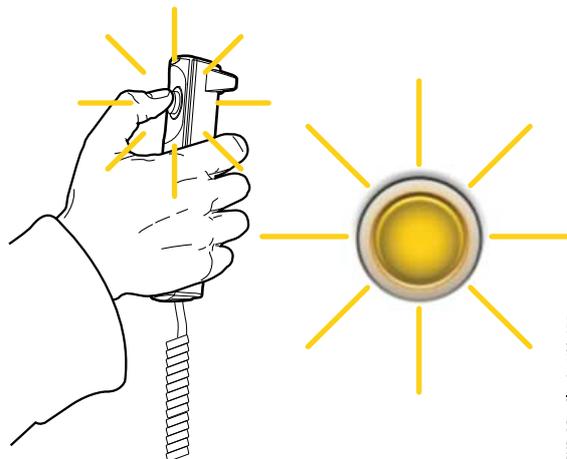
flashing and stay on continuously when the X-ray system is ready for an exposure.



2. Move to a protected area.
3. Press and hold down the exposure button for the entire duration of the exposure.

During exposure yellow radiation warning lights illuminate on the exposure switch and on the touch screen, and you hear a radiation warning tone.

Additionally, a radiation warning symbol is shown on the touch screen.



Results

The image is shown on the computer screen.



NOTE

The Romexis function Model Capture creates surface models (instead of voxel data images).

11 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.



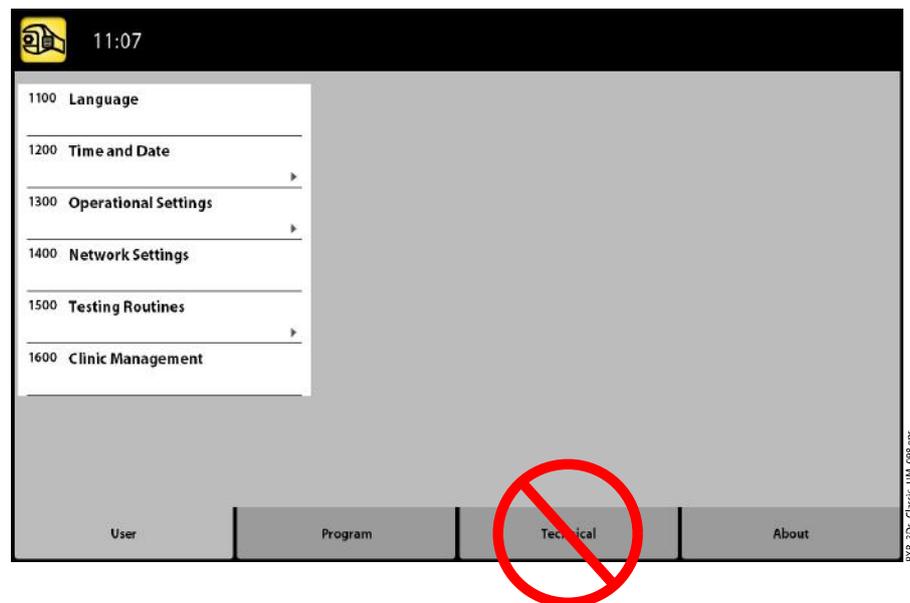
Select the settings symbol on the main screen to enter the settings menu.

Settings that can be entered by the user:

- User
- Program
- 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 left corner.

11.1 User settings

11.1.1 Language (1100)

About this task

Follow these steps to change language on the X-ray unit.

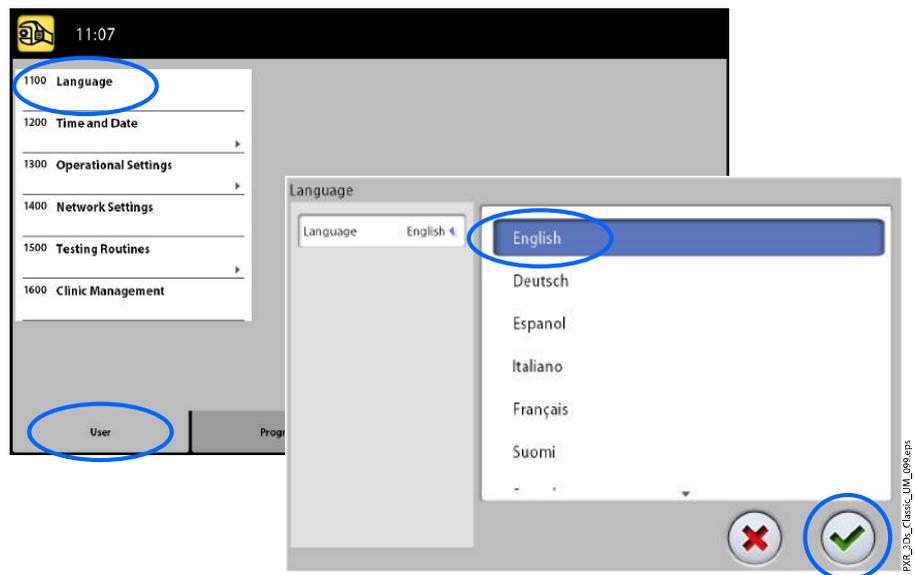
Steps

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.



11.1.2 Time and date (1200)

11.1.2.1 Time display format

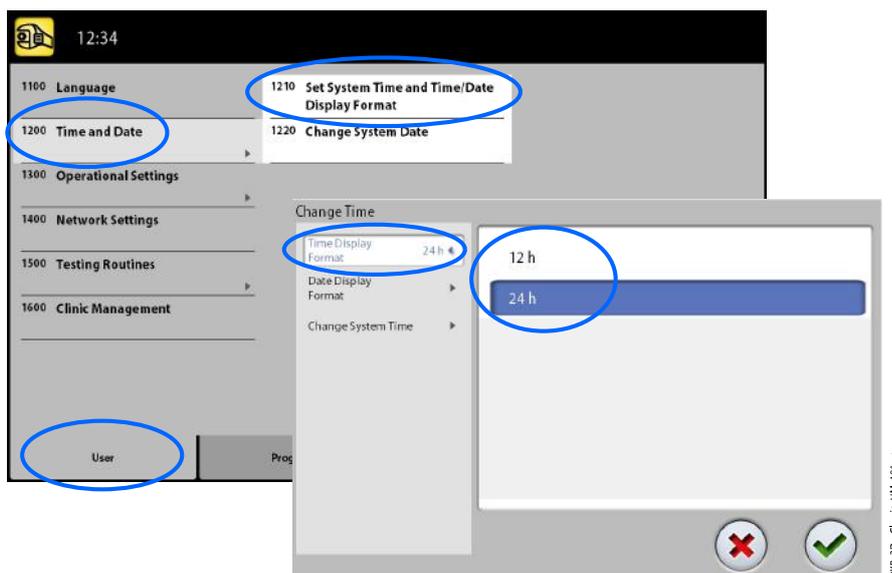
About this task

Follow these steps to set time display format.

Steps

1. Select **User > 1200 Time and Date > 1210 Set System Time and Time / Date Display Format > Time Display Format.**
2. Select the display format you wish to use.

3. Select the green check mark button.



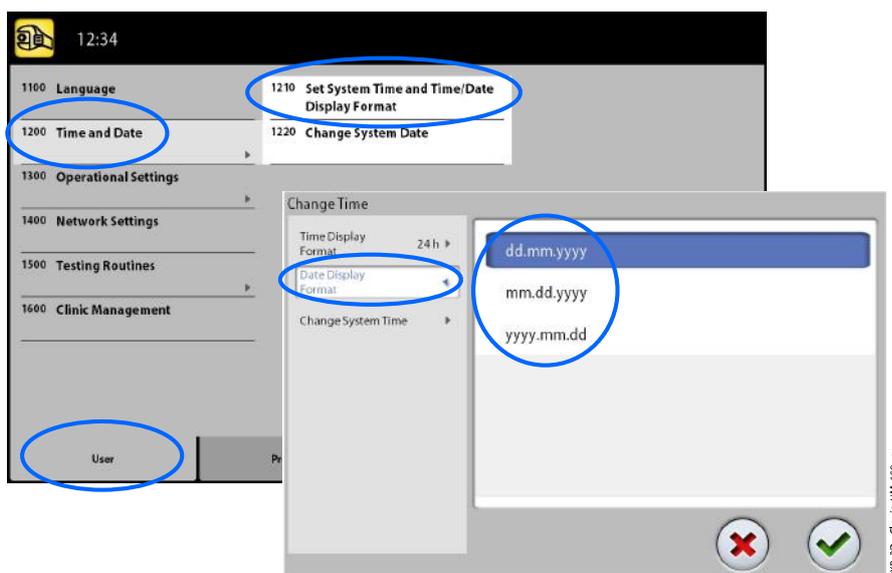
11.1.2.2 Date display format

About this task

Follow these steps to set date display format.

Steps

1. Select **User > 1200 Time and Date > 1210 Set System Time and Time / Date Display Format > Date Display Format**.
2. Select the display format you wish to use.
3. Select the green check mark button.



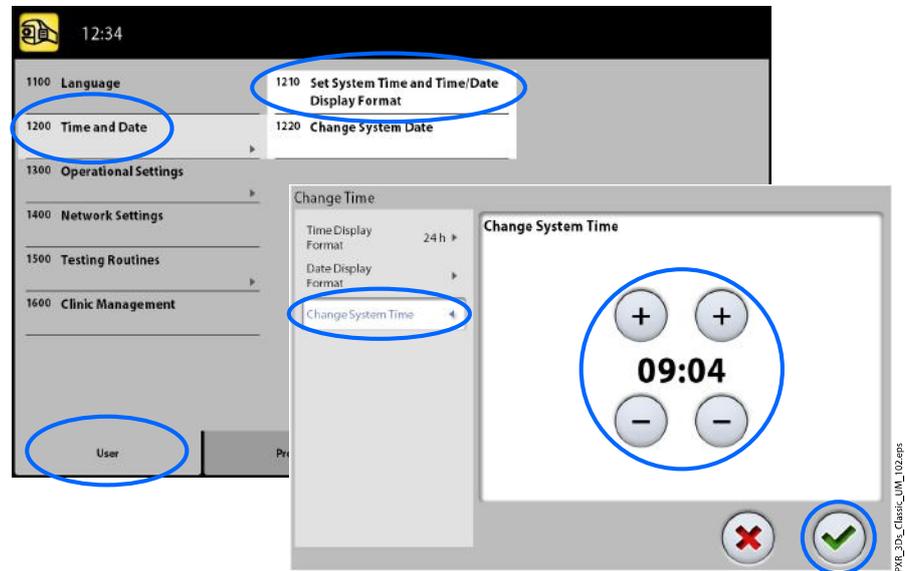
11.1.2.3 Setting time

About this task

Follow these steps to set time.

Steps

1. Select **User > 1200 Time and Date > 1210 Set System Time and Time / Date Display Format > Change System Time**.
2. Use the plus and minus buttons to change the time.
3. Select the green check mark button.



NOTE

The time is set to the local time at the factory. Change the time setting to show the correct time before you start using the X-ray unit.

11.1.2.4 Setting date

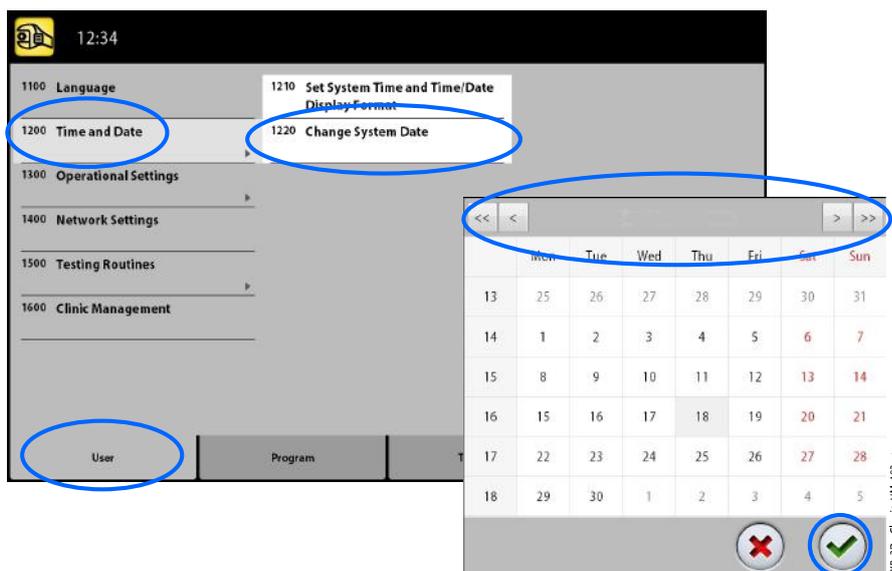
About this task

Follow these steps to set date.

Steps

1. Select **User > 1200 Time and Date > 1220 Change System Date**.
2. Select the day or use the arrow buttons to change the month (single arrow) or year (double arrow).

3. Select the green check mark button.



11.1.3 Operational settings (1300)

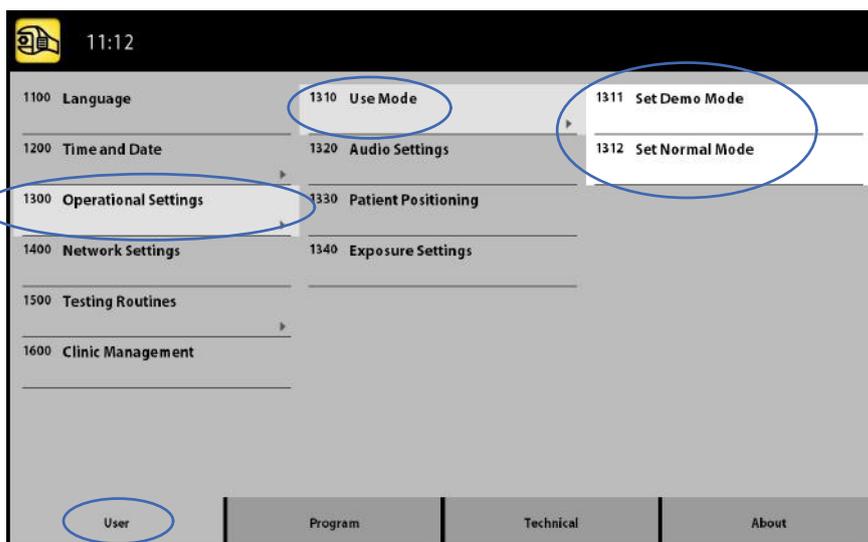
11.1.3.1 Mode

About this task

Follow these steps to select mode.

Steps

1. Select **User > 1300 Operational Settings > 1310 Use Mode**.
2. Select the mode you wish to use.
In demo mode you can practice or demonstrate the functions of the X-ray unit without radiation and PC connection.
3. Select the green check mark button.



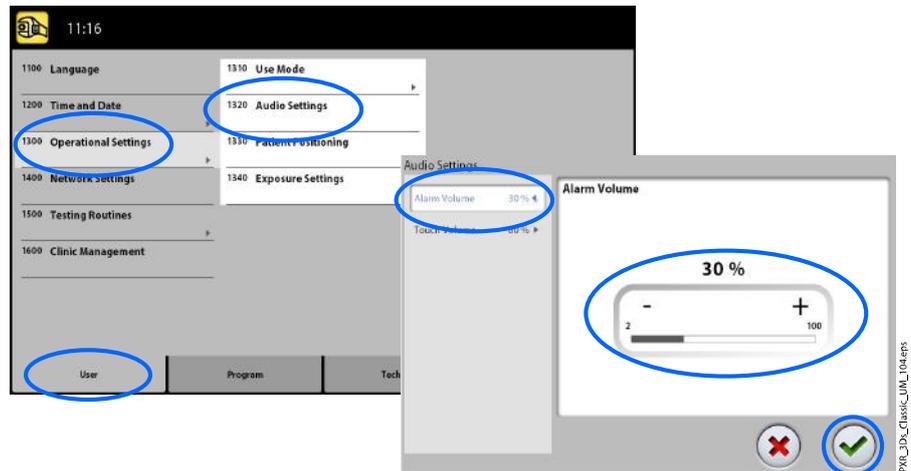
11.1.3.2 Audio settings

About this task

Follow these steps to control audio settings.

Steps

1. Select **User > 1300 Operational Settings > 1320 Audio Settings**.
2. Select:
 - **Alarm Volume**
This setting adjusts the volume of the radiation warning tone. Use the minus or plus button to reduce or increase the volume.
 - **Touch Volume**
This setting adjusts the volume of the audible signal that you hear when you make a selection on the touch screen. Use the minus or plus button to reduce or increase the volume. Set the volume level to 0% if you do not wish to use this function.
3. Select the green check mark button.



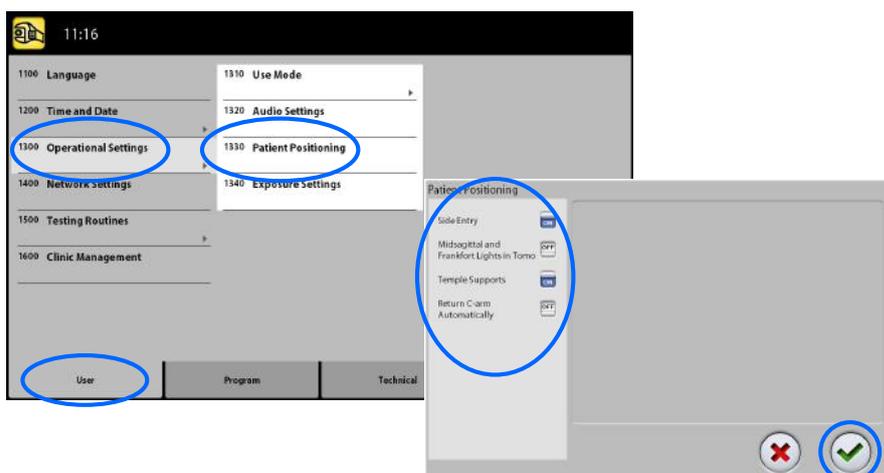
11.1.3.3 Patient positioning

About this task

Follow these steps to manage settings for patient positioning.

Steps

1. Select **User > 1300 Operational Settings > 1330 Patient Positioning**.



2. Turn an option(s) ON or OFF:



- **Side Entry**

Turn this option OFF if you do not wish to use the open (full view) patient entry position. This might be necessary if there is no space for the C-arm to move back.

- **Midsagittal and Frankfort Lights in Tomo**

Turn this option ON if you wish to use the midsagittal and Frankfort plane lights when you take 2D tomographic or 3D exposures.

- **Temple Supports**

Turn this option OFF if you do not wish to use the temple supports.

- **Return C-arm Automatically**

Turn this option ON if you wish to set the X-ray unit so that the C-arm will automatically return to the starting position at the end of an exposure cycle. Note, however, that the automatic function works only if the exposure button is pressed and held down for the entire duration of the exposure.

3. Select the green check mark button.

11.1.3.4 Exposure settings

About this task

Follow these steps to control exposure settings.

Steps

1. Select **User > 1300 Operational Settings > 1340 Exposure Settings**.



2. Select:

- **Panoramic System**

On 3D X-ray units you can use either the Dimax sensor or the 3D sensor for taking 2D exposures. Select the Dimax or SmartPan (3D sensor) system and change the sensor as described in section "Attaching and removing sensor" on page 26.

- **Continuous Exposure Indicator**

Turn this option ON if you wish to set the X-ray unit so that the yellow radiation warning light stays on continuously (instead of flashing) 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).

- **Scout Settings**

Select the default angle (anatomical or LAT-PA) for scout images in 3D Tooth Program.

3. Select the green check mark button.

11.1.4 Network settings (1400)

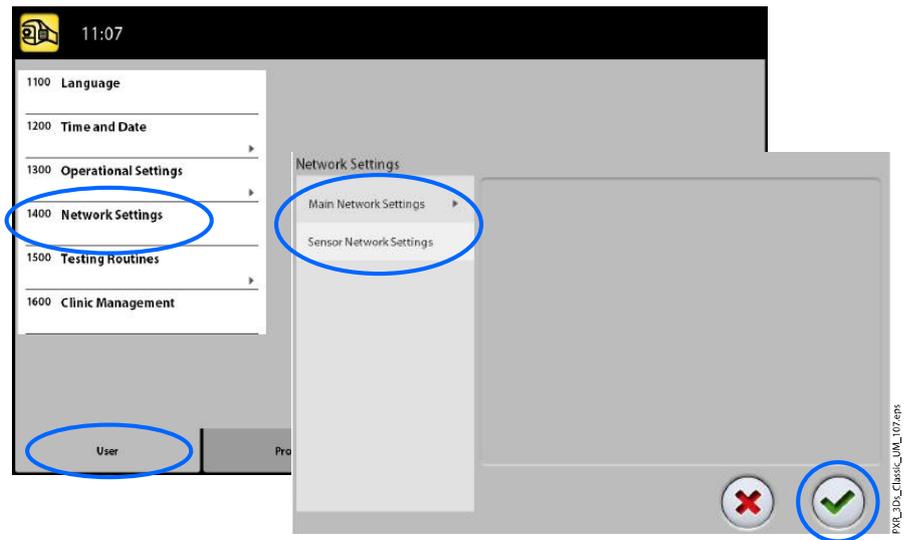
About this task

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.

11.1.5 Testing routines (1500)

11.1.5.1 Test exposure

About this task

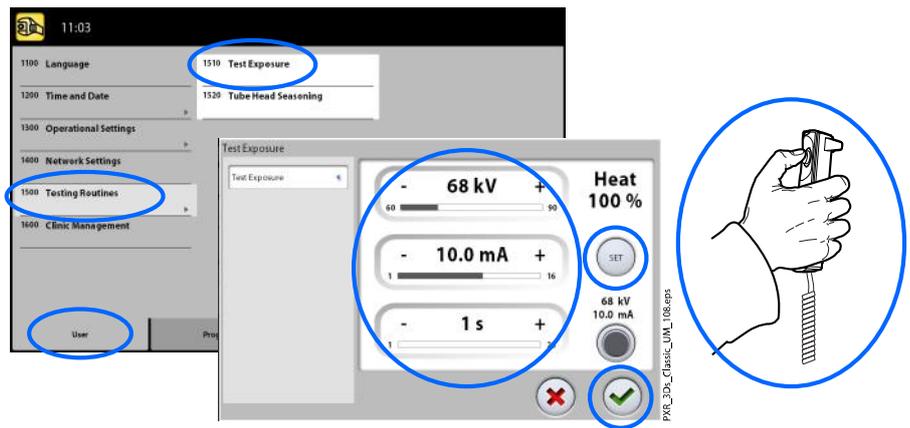
Follow these steps to take a test exposure.

Steps

1. Select **User > 1500 Testing Routines > 1510 Test Exposure**.
2. Use the minus or plus buttons 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 will not move when you take a test exposure.

6. Select the green check mark button.



11.1.5.2 Tube head seasoning

About this task

Follow these steps to perform tube head seasoning.

Steps

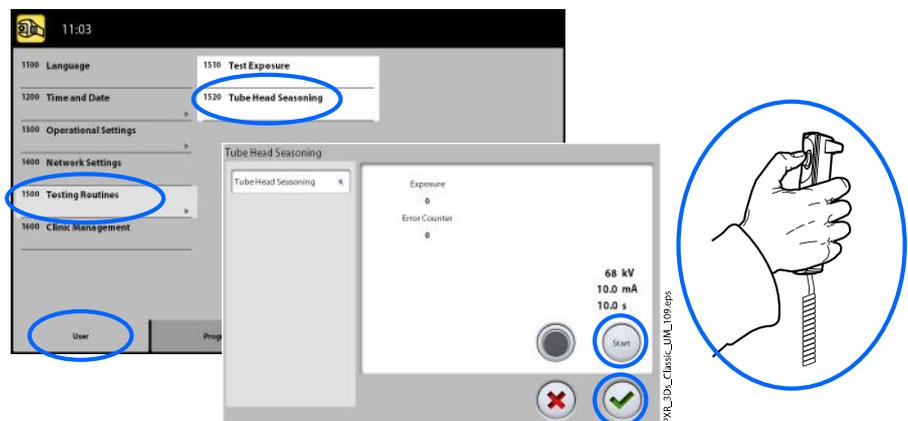
1. Select **User > 1500 Testing Routines > 1520 Tube Head Seasoning**.

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 remove your thumb from the exposure button when the word *Wait* appears. Note that the seasoning process will take several minutes. After a successful process, the message **OK** is shown.

5. Select the green check mark button.



NOTE

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

11.1.6 Clinic management (1600)

About this task

Follow these steps to view network settings for Clinic Management.

Steps

1. Select **User > 1600 Clinic Management** to view the network settings for the Romexis Clinic Management module.

NOTE

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

11.2 Program settings

11.2.1 Programs (2100)

11.2.1.1 Turning programs ON or OFF

About this task

Follow these steps to turn a program(s) ON or OFF.

Steps

1. Select **Program > 2100 Programs**.
2. Select a program group (e.g. 2D Panoramic).
3. Turn a program type(s) (e.g. Interproximal) ON or OFF.
4. Select the green check mark button.

NOTE

The function is available for programs that have been activated in menu 2300 Licences.

11.2.1.2 Permanently adjusting preset exposure values

About this task

Follow these steps to permanently adjust preset exposure values.

Steps

1. Select **Program > 2100 Programs**.
2. Select a program group (e.g. 2110 2D Panoramic).
3. Select a program type (e.g. Interproximal).
4. Select the exposure values you wish to adjust (e.g. 66kV / 10 mA for patient size M).



- If you use both sensors (Dimax and 3D) for taking 2D exposures, make sure that the panoramic system in menu 1340 is set to the option (Dimax or SmartPan) you wish to adjust.



- In 2D panoramic programs with a 3D sensor (2D Panoramic / SmartPan /) select also the MultiView button if you wish to adjust the presets for the MultiView imaging mode.
 - In 3D programs the exposure values are given separately for each image resolution. The image resolutions that are not available are shown with faded buttons. Select also the ULD (Ultra Low Dose) button if you wish to adjust the presets for the ULD function.
5. Use the minus or plus buttons to set the exposure values you wish to use.
 6. Select the green check mark button.
 7. Repeat for an other program type, patient size or image resolution (3D) if needed.
 8. Select the green check mark button.

NOTE

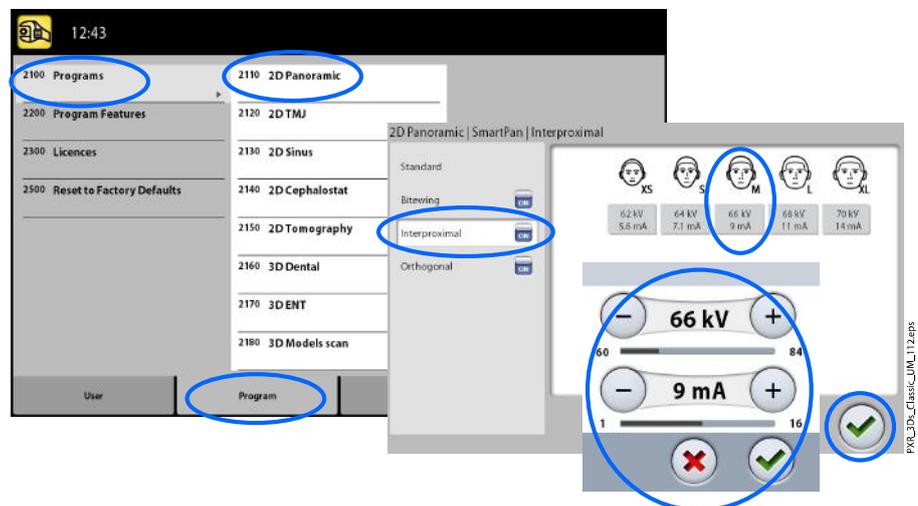
Always try to minimise the radiation dose to the patient.

NOTE

You can restore the exposure values that have been preset at the factory (i.e. overrule your own settings) by selecting Program > 2500 Reset to Factory Defaults.

NOTE

You can adjust the preset exposure values temporarily as described in section "Adjusting exposure values for current exposure" on page 43.



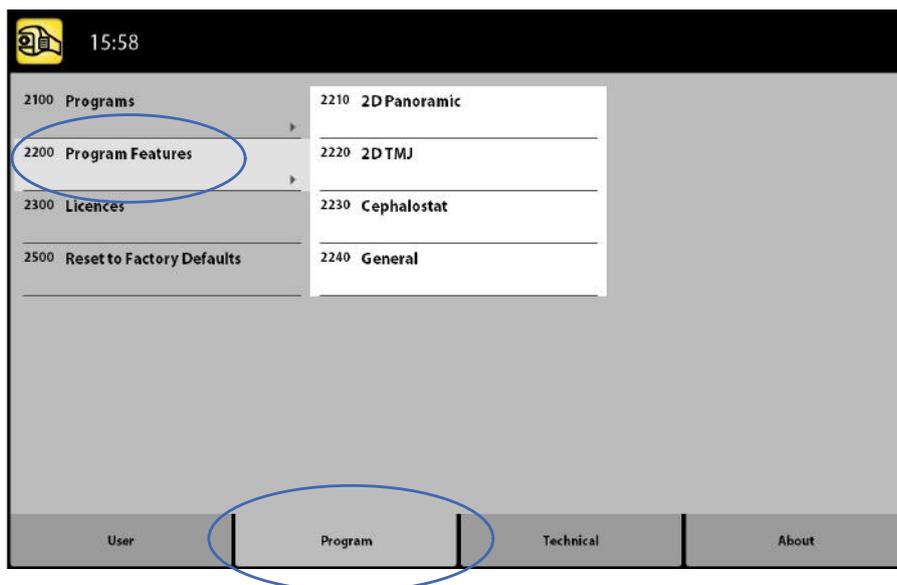
11.2.2 Program features (2200)

About this task

Follow these steps to manage program settings.

Steps

1. Select **Program > 2200 Program Features** to manage program settings.
For details on a specific setting, refer to the manual section that contains the corresponding function.



11.2.3 Licences (2300)

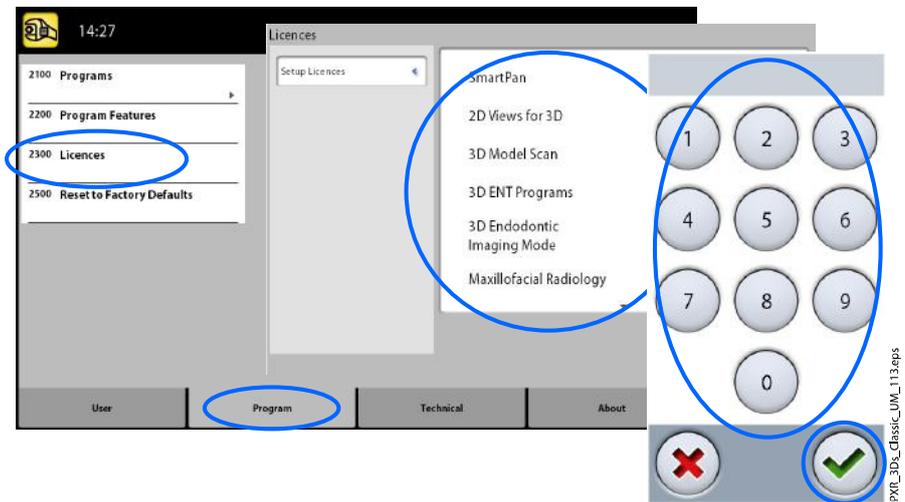
About this task

Follow these steps to activate a program licence.

Steps

1. Select **Program > 2300 Licences**.
2. Select the licence you wish to activate:
 - Subscription licence (Allows any licence to be activated for a given period of time. After expiration, the subscription licence may be reactivated with a code.)
 - Trial licence (Available to activate once. Activates all licences for a three-month period. Trial licence expires when expiration date passes or imaging count exceeds. A reactivation is possible with subscription licence.)
 - SmartPan (Basic 2D panoramic, TMJ and sinus programs with 3D sensor)
 - Horizontal and Vertical Segmenting (Reduced exposure area for 2D panoramic programs)
 - Bitewing Panoramic Program (True extraoral bitewing program)
 - Advanced Panoramic Programs (Additional 2D panoramic, TMJ and sinus programs)
 - Panoramic DEC (Dynamic Exposure Control for 2D panoramic programs with Dimax sensor)
 - Cephalometric DEC (Dynamic Exposure Control for 2D cephalometric programs with Dimax sensor)
 - 2D Views for 3D (LAT, PA and LAT-PA views for 3D programs)
 - 3D Model Scan (3D Impression and 3D Plaster Cast programs)
 - 3D Endodontic Imaging Mode (Endodontic image resolution for small 3D image volumes)
 - Braces Protocol (3D Braces program, for Planmeca ProMax 3D Classic only)

- ProTouch Desktop (Virtual control panel that allows you to take exposures)
 - CALM (Patient movement correction for 3D programs)
 - 3D Classic Extended Volume (Extended 3D image volume for 3D Teeth program, for Planmeca ProMax 3D Classic only)
 - ULD (Ultra Low Dose for 3D programs, licence available for Planmeca ProMax 3D Classic only)
 - Autofocus (Autofocus for 2D panoramic programs, licence available for Planmeca ProMax 3D Classic only)
 - 3D Advanced FOVs (Additional 3D programs and volume heights, licence available for Planmeca ProMax 3D Classic only)
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 other program licences if needed.
 6. Select the green check mark button.



11.2.4 Reset to Factory Defaults (2500)

About this task

Follow these steps to reset to factory defaults.

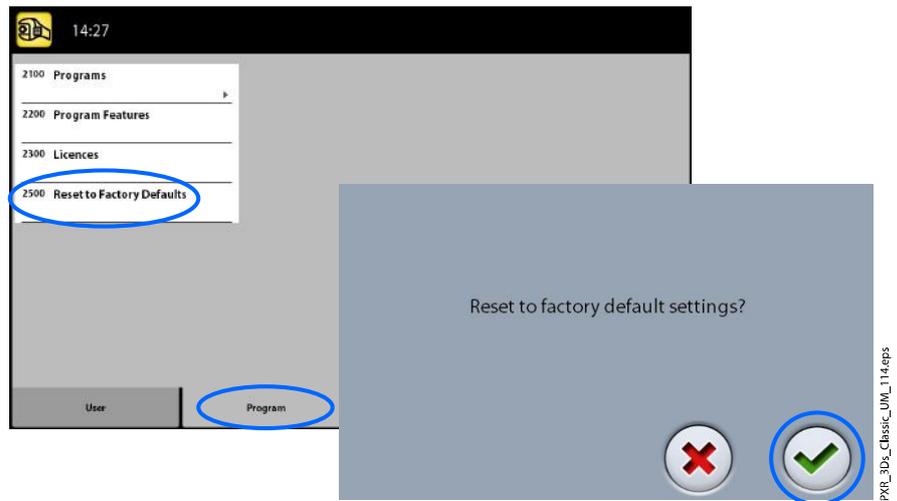
Steps

1. Select **Program > 2500 Reset to Factory Defaults**.

The function will restore the exposure values that have been preset at the factory (i.e. overrule your own settings in menu **Programs (2100)**).

The preset exposure values for 3D patient exposures are shown in section "Adjusting exposure values for current exposure" on page 43 and for 3D model exposures in section "Selecting settings" on page 65.

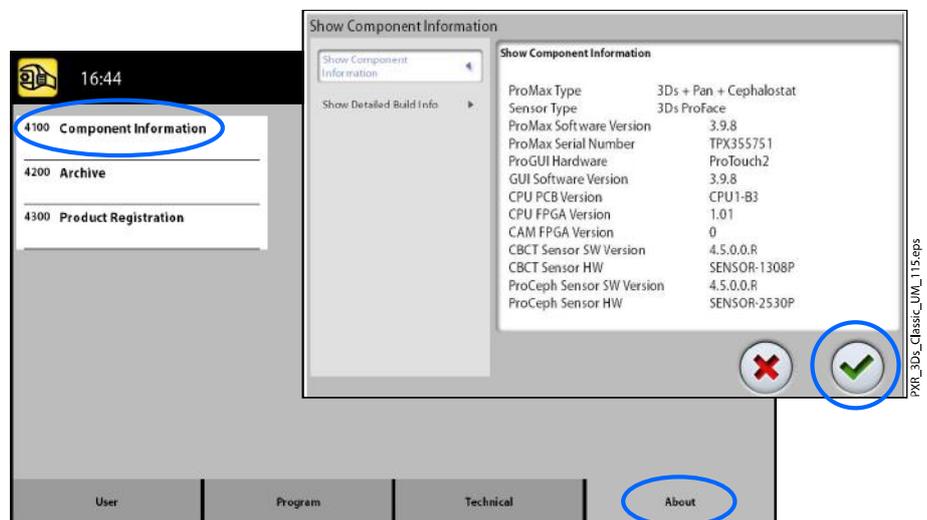
2. Select the green check mark button.



11.3 About tab

11.3.1 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.



11.3.2 Archive (4200)

- **To view error history:**
Select **About > 4200 Archive > 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 > Exposure Statistics** to view statistical data about the X-ray unit.

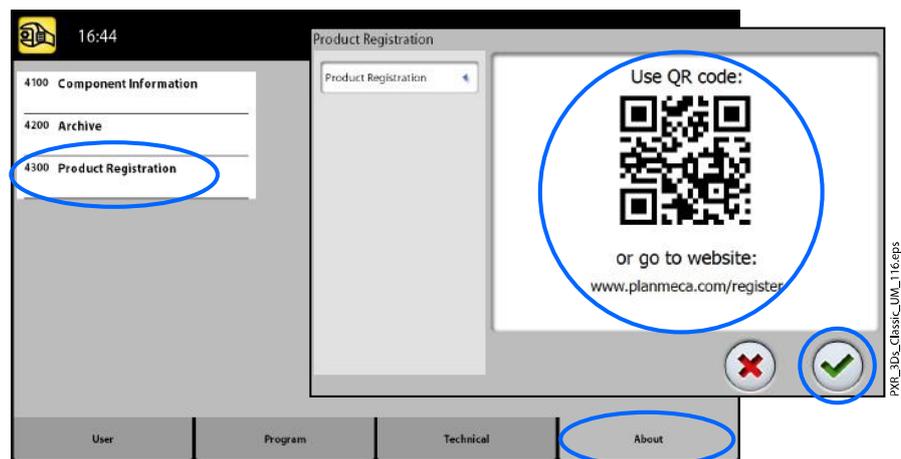
11.3.3 Product registration (4300)

About this task

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

Steps

1. Select **About > 4300 Product Registration**.
2. Do one of the following:
 - A QR (Quick Response) code is shown on the screen. If you have a QR code reader installed on your mobile device (e.g. smartphone), hold the device steady over the QR code. You will be directed to Planmeca's product registration page.
 - Go to Planmeca's product registration page at www.planmeca.com/register.
3. Select the green check mark button.



4. Follow the instructions on the registration page.

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

12 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 touch screen.

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

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.
H103	ProTouch desktop application	The ProTouch desktop application needs to be closed.	Restart the application.
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.
H110	Device Maintenance	The date for your next scheduled device maintenance is due.	Please contact your service technician to arrange a service visit.
H112	Collimator	Check panoramic X-collimator position setting.	Check collimator settings.
H113		Check panoramic X-collimator width setting.	Check collimator settings.
H114	DEC	DEC calibration initialization failed.	Check the sensor connection.
H115		DEC is receiving too much radiation.	Change the exposure values.
H116		DEC is receiving too little radiation.	Change the exposure values.
H120	Subscription	A subscription licence is expiring soon.	Please renew the subscription to avoid losing features.
H121		A subscription licence has expired.	Some features have been disabled.
H127	CEPH	Cephalometric DEC exposure too long.	
H130	Patient safety area	Patient safety area issue detected.	Check the scan and layer settings.

Code	Explanation		Comments
H131		Patient safety area issue in tomo slice 1.	Check the scan and layer settings.
H132		Patient safety area issue in tomo slice 2.	Check the scan and layer settings.
H133		Patient safety area issue in tomo slice 3.	Check the scan and layer settings.
H134		Patient safety area issue in tomo slice 4.	Check the scan and layer settings.
H142	Height movement	Height movement is not possible because one (or more) of the positioning control buttons or the positioning joystick is stuck	Clear any obstruction before moving the column again.
H144		Height movement is not possible because one (or more) of the positioning control buttons is stuck.	Release the button / joystick.
H148		Height movement is not possible. The position of the patient support table is too high.	Press the X-ray unit down button to move the patient support table down.
H149		Height movement was stopped because the C-arm cannot be moved lower.	Clear any obstruction before continuing.
H150		Height movement was stopped because the patient support table 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.
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.
H163		The temperature of the tube head is too high. Please wait for tube head to cool down for beam check.	Wait for tube head to cool down for beam check.
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		The sensor is not attached properly to the C-arm.	Attach and / or lock the sensor in position.

Code	Explanation	Comments
H172	The sensor is not attached properly to the cephalostat.	Attach and / or lock the sensor in position.
H175	Romexis program selection is in conflict with the selected X-ray unit program.	Select another exposure mode in the Romexis.
H180	PC program selection in conflict with selected X-ray program	
H181	The imaging process was cancelled in Romexis.	
H182	Timeout in image data transmission.	Exposure was interrupted. Contact your service technician for help.
H183	The attached sensor is not suitable for the selected program.	Change the sensor.
H184	Remove the 3D sensor.	
H185	The 3D sensor is not attached properly.	Attach and / or lock the sensor in position.
H186	No IP address defined for 3D sensor.	
H187	Problem during image data transmission.	Exposure was interrupted. Contact your service technician for help.
H189	The screen was touched during exposure.	Exposure was interrupted.
H190	Error in communication protocol UID!	Retry or contact technical support if problem persists.
H191	Error in communication protocol state!	Retry or contact technical support if problem persists.
H192	Command queue full!	Retry or contact technical support if problem persists.
H193	Invalid scan settings.	Retry or contact your service technician for help.
H194	X-ray connection not established!	Operating in standalone mode.
H195	Request timed out while waiting for X-ray unit to respond!	Retry or contact technical support if problem persists.
H196	Version mismatch in communication interfaces!	Please update X-ray unit software.
H197	Eeprom reading failed!	Retry or contact technical support if problem persists.
H198	Incompatible parts GPU-module not found in Reconstruction PC.	Restart reconstruction PC or contact technical support if problem persists.

Code	Explanation	Comments
H199	The 3D reconstruction PC does not support the CALM algorithm	Upgrade the 3D reconstruction PC or deactivate the CALM licence. Contact your service technician for help.

13 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 touch screen.

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 from the touch screen. Guide the patient away from the X-ray unit. Then clear the message by touching the green check mark.

14 Cleaning and disinfection

For cleaning agents and disinfectants approved by the manufacturer, 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 cleaning agent and surface disinfectant approved by the manufacturer. The products are categorised here 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.

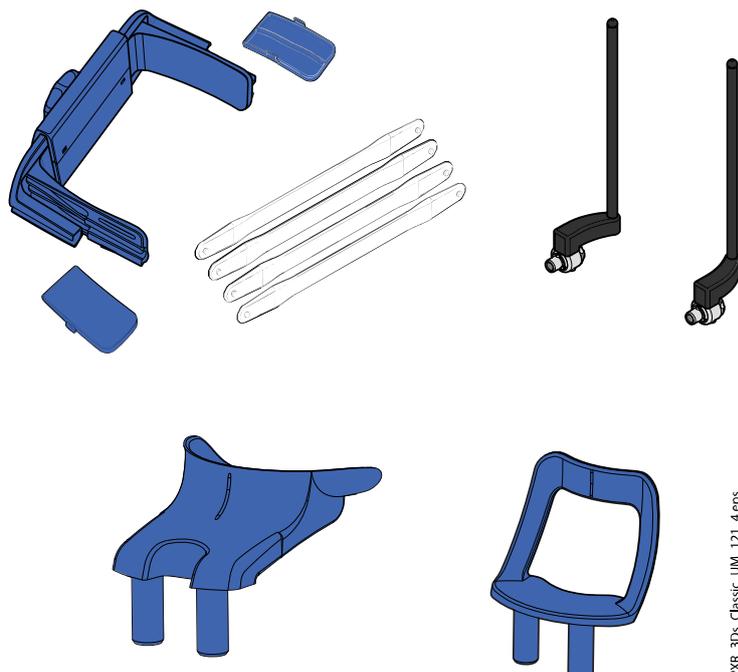
Contact your service technician for help if sprays, liquids or foams enter the system.

14.1 Patient supports, patient handles and touch screen

Wipe these parts after each patient using a surface disinfectant.

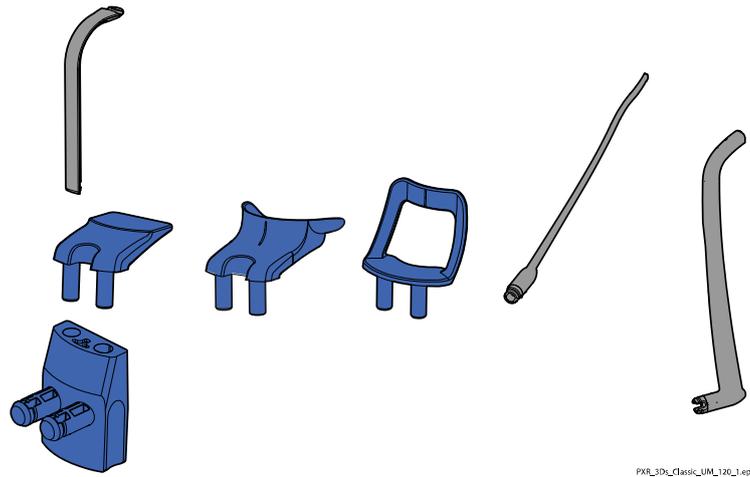
Use a agent approved by the manufacturer for cleaning stains and dirt if needed.

3D patient supports



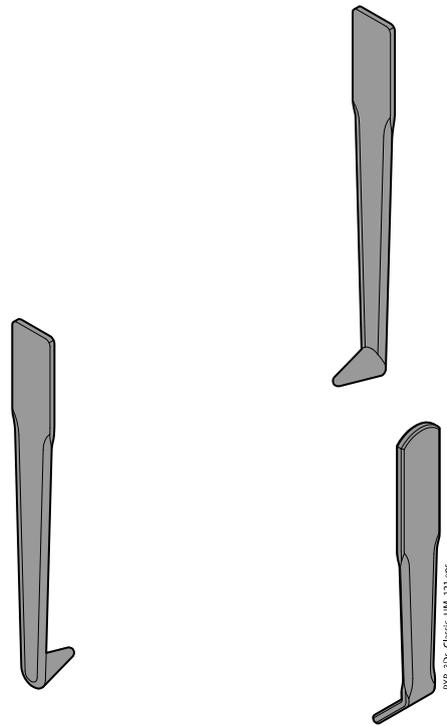
PXR_3Ds_Classic_UM_121_4.eps

Panoramic patient supports



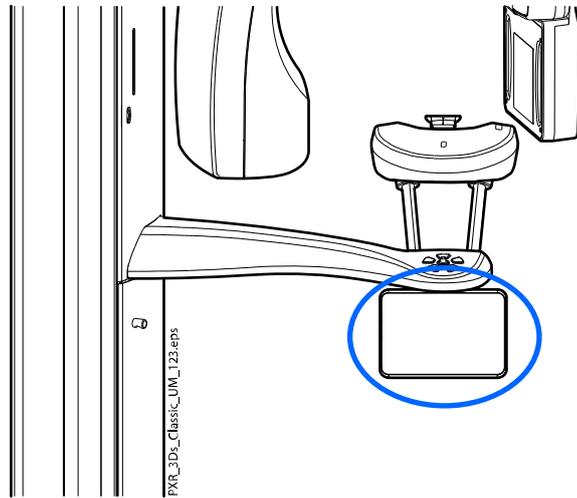
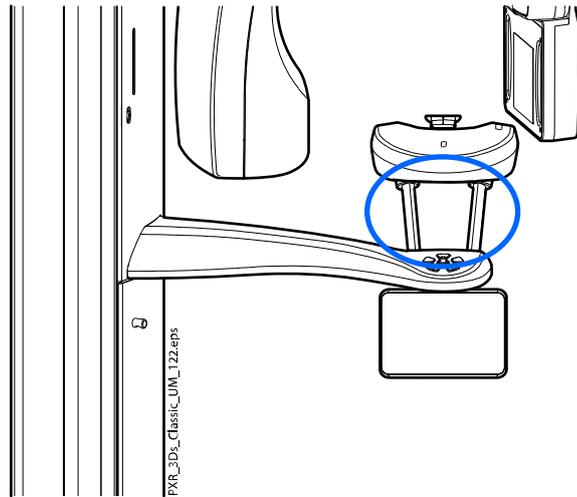
PXR_3Dx_Classic_UML_120_1.eps

Cephalometric patient supports



PXR_3Dx_Classic_UML_121.eps

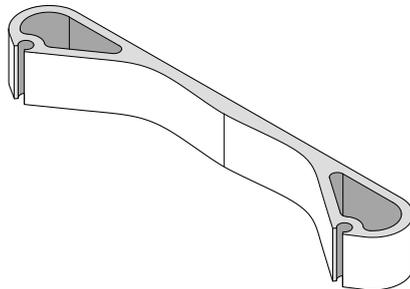
Patient handles and touch screen



NOTE

FOR HEAD BAND 25:

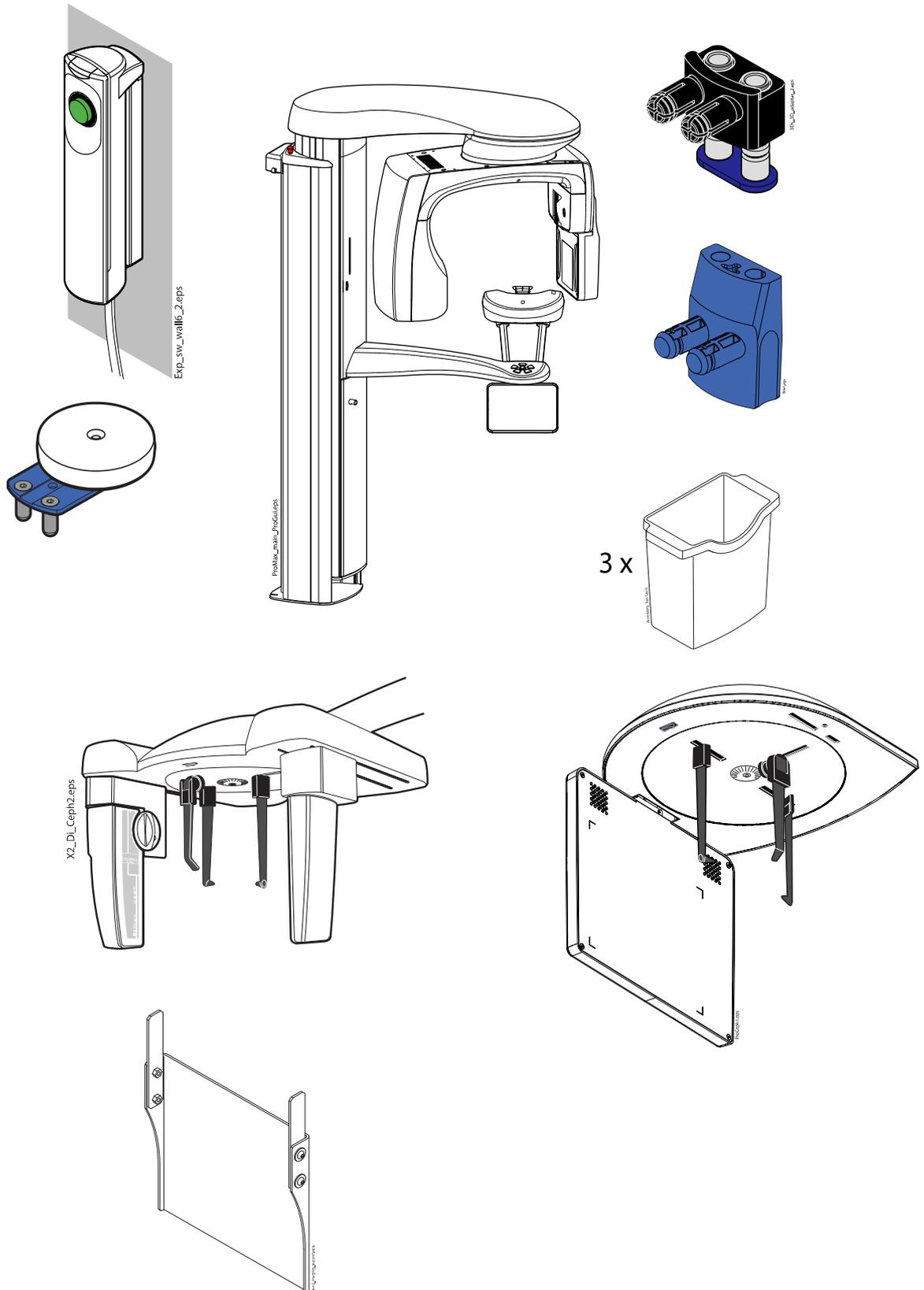
Wipe the head band after each patient using a mild cleaning agent and a clean soft cloth. Do not use disinfectants.



14.2 Other surfaces

Wipe the other surfaces regularly using a surface disinfectant approved by the manufacturer.

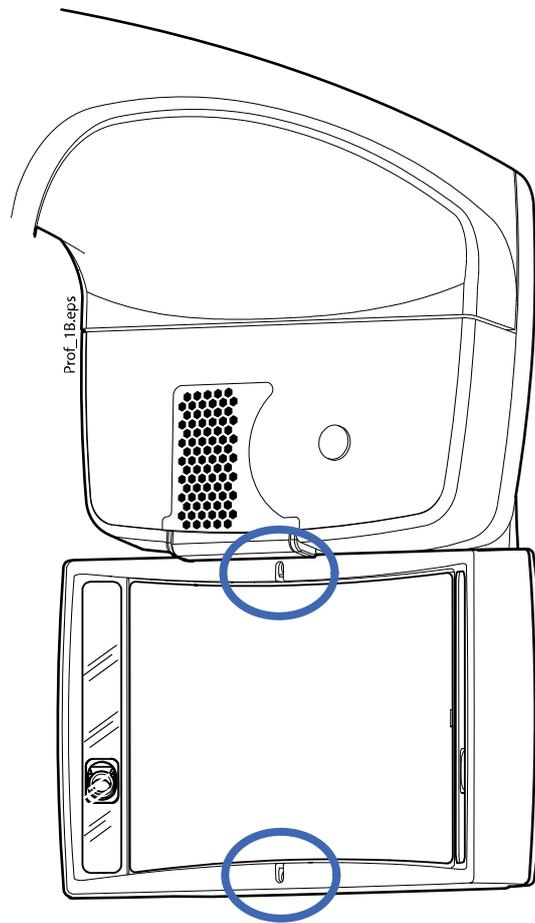
Use a cleaning agent approved by the manufacturer for cleaning stains and dirt if needed.



NOTE

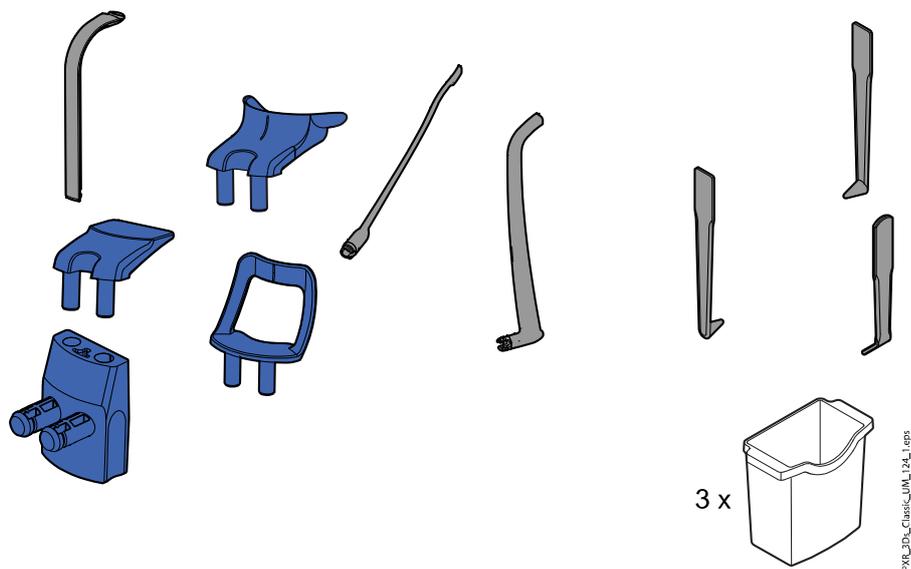
FOR PROFACE SENSOR:

Clean the laser windows regularly using compressed air.



NOTE

The parts in the figure below can be autoclaved at 134°C (273°F). The parts can be autoclaved up to 100 times.



15 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

16 Environmental aspects

16.1 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.

16.2 Energy efficiency

Energy consumption can be reduced by the following measures:

- Switching off the X-ray unit when not in use.
- Using the Ultra Low Dose (ULD) setting when possible.
- Using vertical segmentation in 2D panoramic and scanning cephalometric imaging.

17 Technical specifications

Classification	
Medical Device Regulation	(EU) 2017/745, Class IIb
RoHS	2011/65/EU, 2015/863 and (EC) No1907/2006.
IEC 60601-1	Class I, type B
CISPR 11	Class B
IP Classification	IP20
Applied parts (according to IEC 60601-1: 2012)	
Patient supports	As shown in section Patient supports in User Manuals
Patient handles	
Generator (according to IEC 60601-2-7: 1998)	
	Resonant-mode, DSP-controlled, 80 - 160 kHz
X-ray tube	
2D / 3D Classic	D-054SB
3D Plus / 3D Mid	D-054SB, D-059SBR or SXR 130-10-0.5 SC
Focal spot size (according to IEC 60336: 2005)	
2D / 3D Classic / 3D Plus / 3D Mid with X-ray tube D-054SB	0.5 x 0.5 mm
3D Plus / 3D Mid with X-ray tube D-059SBR or SXR 130-10-0.5 SC	0.5 x 0.5 mm
Filtration	
Pan / ceph	Total 2.5 mm Al
3D	Total 2.5 mm Al + 0.5 mm Cu
SmartPan	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	
Pan / SmartPan	60 - 84 kV \pm 5%
Ceph	60 - 84 kV \pm 5%
3D Classic / 3D Plus or 3D Mid with X-ray tube D-054SB	60 - 90 kV \pm 5%
3D Plus / 3D Mid with X-ray tube D-059SBR or SXR 130-10-0.5 SC	60 - 120 kV \pm 5%
Anode current	
Pan	1 - 16 mA \pm 10%
Ceph	1 - 16 mA \pm 10%
3D Classic / 3D Plus / 3D Mid with X-ray tube D-054SB	
	3D: 1 - 14 mA \pm 10%
	Pan / SmartPan: 1 - 16 mA \pm 10%

	Scanning ceph: 1 - 16 mA \pm 10%
	Planmeca ProCeph: 16 mA \pm 10%
3D Plus / 3D Mid with X-ray tube D-059SBR	
	3D: 1 - 14 mA \pm 10%
	Pan / SmartPan: 1 - 14 mA \pm 10%
	Scanning ceph: 1 - 14 mA \pm 10%
	Planmeca ProCeph: 11 mA \pm 10%
3D Plus / 3D Mid with X-ray tube SXR 130-10-0.5 SC	
	3D: 1 - 14 mA \pm 10%
	Pan / SmartPan: 1 - 16 mA \pm 10%
	Scanning ceph: 1 - 16 mA \pm 10%
	Planmeca ProCeph: 11 mA \pm 10%
mAs range	
	min. / max. as indicated \pm (10% + 0.2 mAs)
Dose range and accuracy	
	Dose range min. / max. as indicated on system user interface. Accuracy of dosimetric indication (DAP, CTDI): \pm 40%
Linearity of radiation output	
	< 0.1
DEC accuracy	
	\pm 10%
Cooling period	
	Automatically controlled
Exposure time	
Pan	2.7 - 16 s as indicated \pm 10%
SmartPan	2.5 - 15.6 s as indicated \pm 10%
Scanning ceph	6.7 - 10.5 s as indicated \pm 10%
Planmeca ProCeph	0.1 - 0.8 s as indicated \pm 10%
3D	Pulsed, effective 3 - 36 s as indicated \pm 10% Pulse range: 10 - 30 ms Time between pulses: 15 - 130 ms
SID	
Pan	<ul style="list-style-type: none"> • 2D / 3D Classic: 501 mm (19.7 in.) • 3D Plus / 3D Mid: 574 mm (22.6 in.)
Ceph	1700 mm (66.9 in.)

3D / SmartPan	<ul style="list-style-type: none"> • 3D Classic: 528 mm (20.7 in.) • 3D Plus or 3D Mid with X-ray tube D-054SB: 600 mm (23.6 in.) • 3D Plus / 3D Mid with X-ray tube D-059SBR or SXR 130-10-0.5 SC: 632 mm (23.8 in.)
Magnification	
Pan	<ul style="list-style-type: none"> • 2D / 3D Classic: 1.2-1.5 • 2D tomography: 1.5 • 3D Plus / 3D Mid: 1.4
SmartPan	<ul style="list-style-type: none"> • 3D Classic: 1.27 • 3D Plus / 3D Mid: 1.4
Ceph	1.13
3D	<ul style="list-style-type: none"> • 3D Classic: 1.58 • 3D Plus / 3D Mid: 1.38, 1.40, 1.42, 1.43 or 1.8
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
Line harmonics	
	Cos better than 0.9
Max. permissible apparent impedance of supply mains	
	0.5 Ω (100 VAC)
Max. continuous heat dissipation	
	250 W
Internal fuse(s)	
User replaceable	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: CR2032, Varta / Panasonic
Max. weight	
2D / 3D Classic	119 kg (262 lb)
3D Plus / 3D Mid	141 kg (311 lb)
Scanning ceph	26 kg (57 lb)

Planmeca 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	<ul style="list-style-type: none"> • Pan / scanning ceph: +10°C - +40°C (+50°F - +104°F) • 3D / ProCeph: +10°C - +35°C (+50°F - +96°F)
Relative humidity	10 - 90% RH (non-condensing)
Air pressure	800 - 1060 hPa
Max. altitude	2000 m (1.25 miles)
Image properties	
Pan / ceph CCD:	
Pixel size	48 µm
Pan active surface	6 x 146 mm (0.24 x 5.74 in.)
Ceph active surface	6 x 292 mm (0.24 x 11.15 in.)
Planmeca ProCeph:	
Flat panel pixel size	139 µm
Flat panel active surface	302 x 249 mm (11.89 x 9.80 in.)
3D:	
Flat panel pixel size	127 µm
Flat panel active surface	<ul style="list-style-type: none"> • 3D Classic: 130 x 130 mm (5.12 x 5.12 in.) • 3D Plus / 3D Mid: 146 x 146 mm (5.74 x 5.74 in.)
SmartPan:	
Flat panel pixel size	127 µm
Flat panel active surface	<ul style="list-style-type: none"> • 3D Classic: 8 - 25 x 130 mm (0.31 - 0.98 x 5.12 in.) • 3D Plus / 3D Mid: 8 - 25 x 146 mm (0.31 - 0.98 x 5.74 in.)
Operating conditions for X-ray units with ProFace sensor	
Optimum colour temperature	Approx. 6500 Kelvin
Frequency for fluorescent lamps	100 Hz
Even and uniform lighting	
No natural light	

Original manufacturer

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