Planmed

Planmed XFI™

EN

user's manual

DRAFT

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.

Planmed 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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X0104490/C

1 Introduction

This manual describes the Planmed XFI X-ray unit and how to use it. Depending on the configuration of your X-ray unit this manual may contain parts that do not apply to your X-ray unit. Please read this manual carefully before using the unit.

NOTE

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

NOTE

The values displayed in the pictures of this manual are only examples and should not be interpreted as recommended values unless otherwise stated.

NOTE

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.

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.

Conformity to standards

CE 0598

Cone Beam Computed Tomography scanner, Planmed XFI, IEC 60601-2-44:2009

X0173428/C

1.1 Device description

The Planmed XFI X-ray unit utilizes cone beam computed tomography (CBCT) to generate three dimensional images. In CBCT imaging, a cylindrical volume of data is acquired in a single imaging procedure. This data comprises several hundred 2D images taken from various angles to encompass a specific pre-programmed target area. These images are subsequently employed for 3D reconstruction, accomplished through a dedicated PC equipped with reconstruction algorithms. The resulting reconstructed images can be visualized in three dimensions using a separate PC workstation equipped with suitable image viewer software.

X000083/A

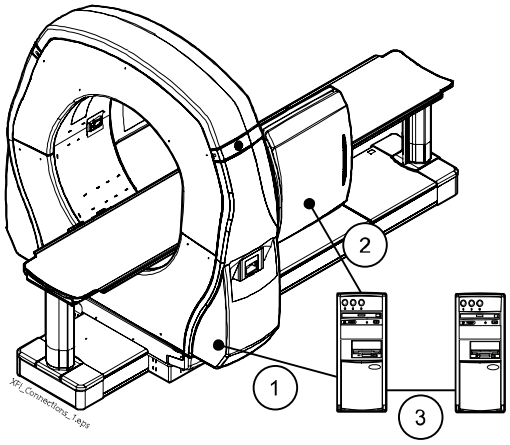
1.1.1 Device function

The X-ray unit is permanently installed and the room shall have radiation protection according to the regulations and laws in the market area. The unit is intended to be used only under supervision of a dental/health care professional. Imaging system is formed by the X-ray unit, 3D reconstruction PC and workstation PC with image viewer software as per image below. Image acquisition process can be started from X-ray unit by selecting suitable imaging protocol or from Romexis by selecting a patient and relevant imaging method.

The patient can be positioned in laying, seated or standing position. The patient support parts help the user in positioning the patient correctly and provide support for patient so that he / she can remain still during image acquisition process. Exposure starts when the user presses the exposure

button and continues until the selected imaging cycle has been completed. The exposure is stopped if the exposure button is released during the imaging cycle or the emergency switch is activated. User interfaces provide guidance for operator throughout the imaging process from positioning the patient to setting image parameters, performing the exposure and completion of image processing.

The figure below shows an example of an IP network specific setup used with the imaging system.



1 Ethernet XFI CPU to reconstruction PC connection
2 Optical 10Gbit detector to reconstruction PC connection
3 Reconstruction PC to workstation ethernet connection

X0173429/C
1.2 Intended use

XFI is intended to be used for cone beam computed tomography imaging of anatomies for lower extremities including hips, upper extremities, head and neck.

The device is to be managed and operated/used in a professional healthcare environment by healthcare professionals and other legally qualified professionals only.

X0183484/B
1.2.1 Contraindications

There are no known contraindications to use of Planmed XFI.

X0173430/B
1.3 Usage environment

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

X0256936/B
1.4 Intended patient population

Age	From a child that can stay put to geriatric without any specific age limits.
Sex	Unlimited, excluding pregnant persons
Weight	< 230 kg / 507 lb

X0227126/B
1.5 Medical purpose

The product is intended to provide clinically valuable information to healthcare professionals, including but not limited to orthopaedic surgeons,

radiologists, dentists and ENT-specialists, in the diagnosis and management of possible diseases, injuries and medical conditions.

X0104503/D

2 Associated documentation

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

- User's manual

  For health care professionals. Describes the X-ray unit and its different parts as well as instructs how to operate and clean the unit.

- Installation manual

  For service personnel. Describes how to install the X-ray unit.

- Technical manual

  For service personnel. Gives instructions for service situations.

- Wiring diagram (separately provided by the manufacturer)

  For service personnel. Gives additional instructions for service situations.

These manuals are intended to be used in conjunction with the documentation for Planmeca Romexis software. Planmeca Romexis software is delivered with the following manuals:

- Romexis user's manual

  For dental and health care professionals. Describes how to monitor and control the activities as well as gather data related to dental treatments.

- Romexis technical manual

  For service personnel. Gives instructions for service situations.

User's manuals are also available in the Planmed Material Bank:

Material bank

Installation and technical manuals and updating instructions are also available in the Planmed One:

https://one.planmed.com/

X0011269/E

3 Training

A hands-on user’s training is given in connection with the installation of this device.

X0104750/B

4 Product registration

About this task

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

Steps

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

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

NOTE

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

X0105289/C

5 Product labels

X0104753/D

5.1 Symbols on product labels

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

Medical Device (Standard ISO 15223-1).

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).

Type B applied part (Standard IEC 60417).

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

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.

Ionizing radiation (Standard ISO 7010).

Electrostatic sensitive device (Standard IEC 60417).

Warning, hot surface (Standard ISO 7010).

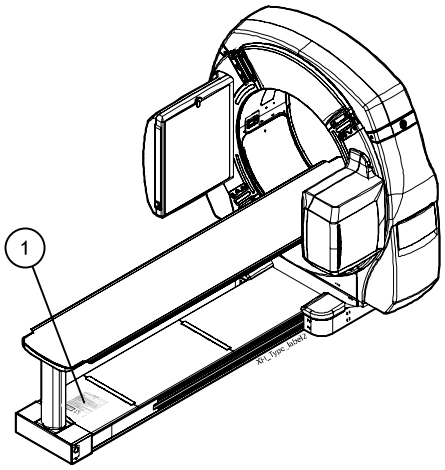
General warning (Standard ISO 7010).

CAUTION (Standard ISO 15223-1).

X0168547/E

5.2 Product labels

X-ray unit type label

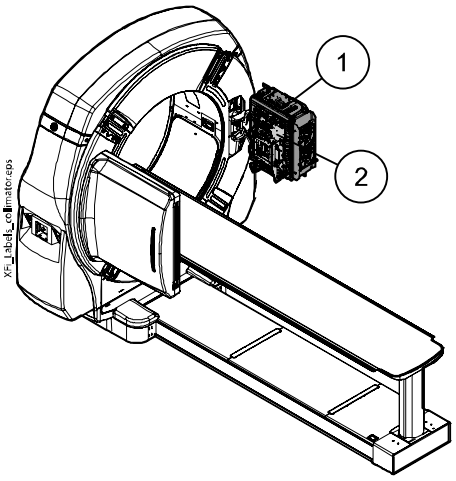


(1) X-ray unit type label

X-RAY UNIT
Trademark: Planmed XFI™
Model: Planmed XFI
SN :
200 - 240 V ~ 50-60Hz, 16 - 20 A
MINIMUM OVERCURRENT RELEASE 16AT
MAXIMUM APPARENT RESISTANCE OF SUPPLY MAINS 0.375 Ohm
CONTINUOUS OPERATION WITH INTERMITTENT LOADING 3600W Non continous operation:60 sec “ON”, 240 sec “OFF” 280VA Continuous
3D: 140 kV maximum, Total filtration 2.5 mm Al + 0.2 mm / 0.5 mm Cu 3D Bowtie: 140kV maximum: perm. filt. 2.5mm Al + Bowtie 0.3mm – 2mm (CuZn 37)
MOTOR OPERATION: Intermittent operation, 60 sec “ON”, 240 sec “OFF”
Manufactured by: PLANMED OY Sorvaajankatu 7, 00880 Helsinki, FINLAND
CLASS 1 LASER PRODUCT APPAREIL À LASER DE CLASSE 1 IEC 60825-1: 2014 EN 60825-1:2014 + A11:2021 CE 0598 30035017-B

DRAFT

X-ray tube assembly labels



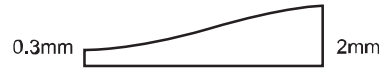
(1) X-ray tube assembly label (IAT RTM782HS)

X-RAY TUBE ASSEMBLY		
X-RAY TUBE ASSEMBLY TYPE: 140I001	**NOMINAL X-RAY TUBE VOLTAGE:** 140 kV	
X-RAY TUBE ASSEMBLY SN:		
X-RAY TUBE TYPE: IAE, RTM782HS		
X-RAY TUBE SN:		
FOCAL SPOT: 0.3 / 0.6 mm (IEC 60336)		
PERMANENT FILTRATION: 2,5 mm Al (IEC 60522)		
MANUFACTURING DATE:	**MANUFACTURED BY:** Planmeca Oy, 08800 Helsinki, FINLAND	30035018-A
Complies with DHHS radiation performance standards 21 CFR subchapter J		

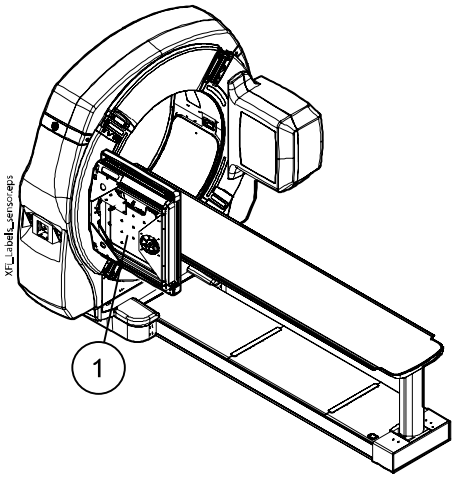
(1) X-ray tube assembly label (Varex, RAD-14mod)

X-RAY TUBE ASSEMBLY		
X-RAY TUBE ASSEMBLY TYPE: 140V001	**NOMINAL X-RAY TUBE VOLTAGE:** 140 kV	
X-RAY TUBE ASSEMBLY SN:		
X-RAY TUBE TYPE: Varex, RAD-14mod.		
X-RAY TUBE SN:		
FOCAL SPOT: 0.3 / 0.6 mm (IEC 60336)		
PERMANENT FILTRATION: 2,5 mm Al (IEC 60522)		
MANUFACTURING DATE:	**MANUFACTURED BY:** Planmeca Oy, 08800 Helsinki, FINLAND	30035019-A
Complies with DHHS radiation performance standards 21 CFR subchapter J		

(2) Beam limiting system label

BEAM LIMITING SYSTEM
TYPE: MX001
SN:
ADDITIONAL FILTRATION: 0.2mm / 0.5mm Cu
BOWTIE: 0.3mm 2mm CuZn 37 
MANUFACTURING DATE:
MANUFACTURED BY: Planmeca Oy, 08800 Helsinki,FINLAND
Complies with DHHS radiation performance standards 21 CFR subchapter J 30035020-A

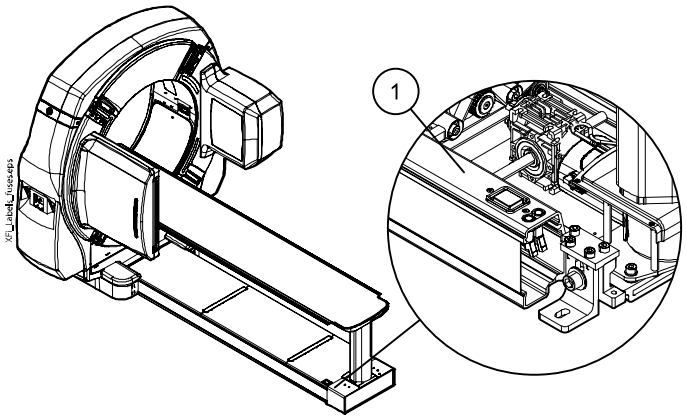
X-ray image receptor label



(1) X-ray image receptor label

X-ray image receptor		
TYPE: 4343		
S/N :	**Manufacturing Date:**	
Manufactured by: **Planmeca Oy Asentajankatu 6,** **00880 Helsinki, FINLAND**		30035055-A

Fuse label



<<< WILL BE ADDED LATER ON >>>

Remote control label

REMOTE CONTROLLER	30039935-A
S/N:	

Patient support stool label

PATIENT SUPPORT STOOL	30039934-A
S/N:	

Docking station label

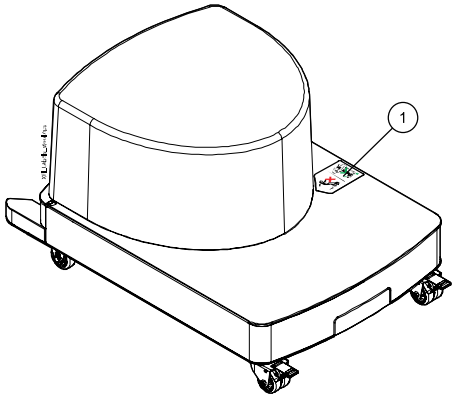
DOCKING STATION	30046319-A
S/N:	
FCC ID:YII-XFIRC2024	

X000241/A

5.3 Warning labels

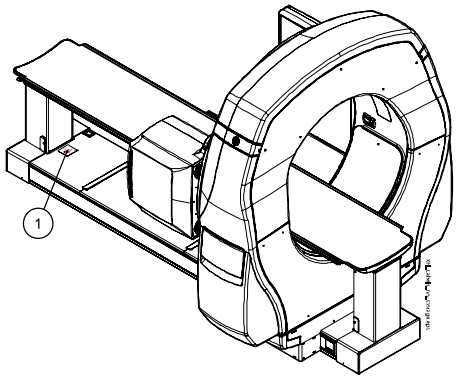
X-ray warning label

Stool warning label

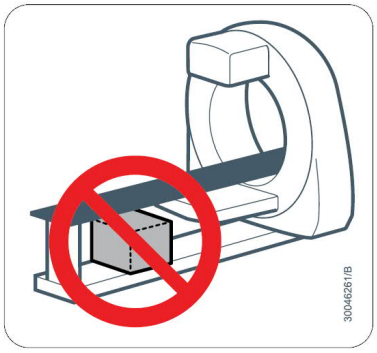


(1) Stool warning label

No storage warning label



(1) No storage warning label



X0104765/D

6 For your safety

X000135/A

6.1 Safety precautions

The following adverse events may be associated with the use of this X-ray unit:

- Excessive X-ray exposure
- Electric shock

WARNING

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

WARNING

Do not perform any maintenance when preparing or using the unit for imaging.

WARNING

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

WARNING

Do not connect a multiple portable socket outlet (MPSO) or an extension cord to the system.

WARNING

Maximum patient weight is 230 kg / 507 lb.

WARNING

All heavy components (>22 kg / 48.5 lb) must be handled and moved with appropriate safety aids, such as installation jigs and frames, lifts, hoists and handles.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING

Only accessories or exposure switch cables and Ethernet cables specified or provided by manufacturer must be used. Otherwise the risk of increased electromagnetic emissions or decreased electromagnetic immunity of this equipment could result in improper operation.

WARNING

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

CAUTION

Any use other than specified in Intended use is prohibited.

CAUTION

FOR US USERS:

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

CAUTION

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

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

Make sure that you are fully acquainted with the appropriate radiation protection measures and these instructions before using the system on patients. Even if not shown in the example pictures in this manual, always carry out appropriate radiation protection measures according to local requirements to protect yourself and the patient from radiation.

CAUTION

It is very important that the place where the device is to be used and the position from which the user is to operate it are correctly shielded from radiation.

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

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

The device is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

CAUTION

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

CAUTION

Do not handle liquids in proximity of the device to avoid spilling which may damage the system.

CAUTION

Do not place any weight on the X-ray unit's imaging arm by e.g. leaning, sitting or stepping on it.

CAUTION

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

CAUTION

The X-ray unit must not be used on patients with an IV catheter. The IV lines may become entangled in the rotating imaging arm.

CAUTION

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.

CAUTION

Pay attention to patient's condition such as being unconscious or anaesthetised or being connected to a catheter or other such device before starting the imaging procedure.

CAUTION

The remote control's lithium-ion battery pack must be handled with care to avoid risk of explosion. The lithium-ion battery pack must be replaced only by service personnel using a tool. Contact your service technician if the lithium-ion battery pack needs to be replaced.

CAUTION

Make sure that nothing obstructs the X-ray unit movement. Clear any obstruction before pressing the Preset button.

CAUTION

Be aware of potential detrimental interaction of CT X-ray imaging with active implantable medical devices and body worn active medical devices. Contact the manufacturer of such devices for more information.

CAUTION

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

CAUTION

The lasers on the X-ray unit are only allowed to be used with the unit's 40VDC power supply manufactured by Planmeca and compliant to IEC 60601.

CAUTION

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

CAUTION

Do not use hand-held devices (i.e. exposure switch or remote control) if their cover is ruptured or broken to avoid risk of electric shock. Contact your service technician for repair and replacement parts.

CAUTION

Contact your service technician if liquid is spilled on the device and it has entered the system from cover openings or seams. Service is required to clean and check the proper and safe operation of the system.

CAUTION

Keep the X-ray unit column surface clear of any objects.

CAUTION

Do not conduct any X-ray unit service or maintenance while in use with a patient.

CAUTION

The X-ray unit is not allowed to have any other electrical devices connected to it when operated.

CAUTION

Handle the capacitor banks and power supply unit (PSU) carefully during transport, installation and maintenance to avoid damage to the components, a fault in the components can cause a fire.

CAUTION

If a defibrillator is used to resuscitate a patient lying on the patient support, the X-ray unit must be checked before further use. The X-ray unit has not been tested for such an event. The manufacturer cannot guarantee its function after the use of defibrillator.

CAUTION

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE

Only use a computer specified by manufacturer.

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

After installation and when the X-ray unit has been stored at temperatures under +10°C / 50°F for more than a few hours, allow a minimum of six hours for the unit to reach room temperature before powering the system on.

NOTE

Ensure efficient air conditioning in the X-ray room. It is recommended to keep the room temperature between +20°C / 68°F and +25°C / 77°F at all times.

NOTE

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

NOTE

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

NOTE

FOR US & CANADIAN USERS:

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

NOTE

FOR EUROPEAN USERS:

The laser lights are class 1 laser products (Standard IEC 60825-1:2014 / EN 60825-1:2014/A11:2021).

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 section "EMC information" on page 76.

NOTE

Portable and mobile RF communications equipment can affect the device. Image quality may be affected due to RF interference of such equipment. If image quality is affected by RF interference a poor diagnostic value of the image may result.

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 2 m (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

If you notice a decrease in image quality, refer to instructions concerning image quality control. If necessary, contact your service technician.

NOTE

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

NOTE

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

NOTE

Use CT side marker to ensure correct image laterality.

NOTE

Scout images are suitable only for checking patient positioning, NOT for diagnosis.

NOTE

Should the imaging arm get stuck while the patient is in the X-ray device, carefully assist the patient to step over the imaging arm or to exit by ducking under it.

NOTE

The imaging arm can be manually moved and rotated (from the detector and tube head) if necessary.

NOTE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

NOTE

Only manufacturer provided PC is allowed to be used with the X-ray unit.

NOTE

Metallic surfaces opposite to the Time of Flight (ToF) sensors can cause interference.

Precautions for power and hardware failure

NOTE

It is recommended that an Uninterruptible Power Supply (UPS) be installed to support the Reco PC or both the Reco PC and the imaging workstation in the event of a power failure.

CAUTION

Due to uncontrollable events such as power and hardware failure the computer must not be the only image data storage location. Image data must be available from other locations such as an archive.

CAUTION

Image data can be lost if the computer is shut off abruptly while a study is being transferred to the hard drive (e.g., if there is a power failure or the device is accidentally unplugged).

Cyber security precautions

NOTE

Do not connect the device to the Internet.

NOTE

Do not install any other third party applications on the computer unless approved by the manufacturer.

NOTE

It is recommended to have an authorization process and establishing access control for the XFI workstation.

NOTE

Changes in the IT-network may result in previously unidentified risk. Be sure to identify, evaluate and control risks before making changes. Changes to the IT-network include:

- Changes in the IT-network configuration
- Connection of additional items to the IT-network
- Disconnecting items from the IT-network
- Update of equipment connected to the IT-network and upgrade of equipment connected to the IT-network

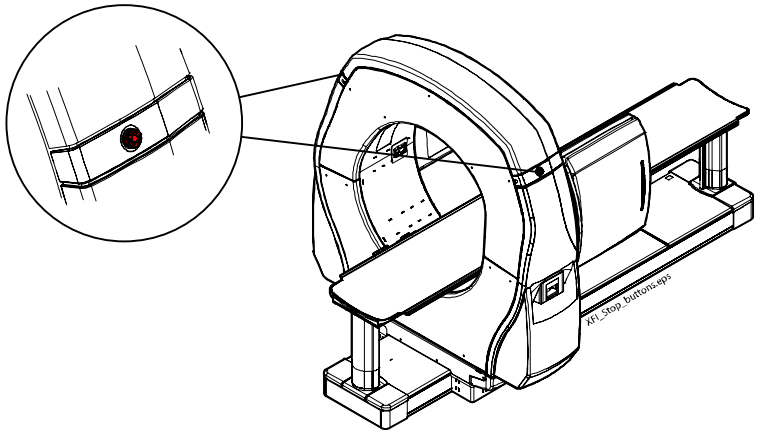
X0104767/B

6.2 Emergency stop buttons

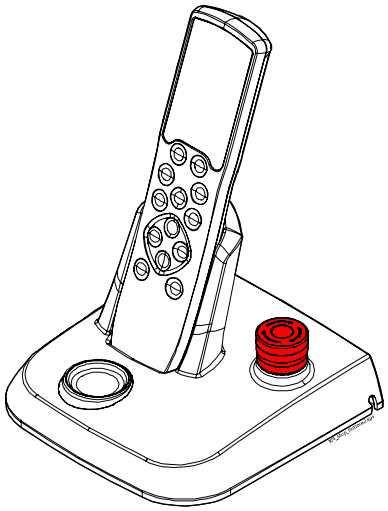
The X-ray unit has two emergency stop buttons. Press either of the emergency stop button to stop the X-ray unit operating in an emergency. All movements of the X-ray unit will be blocked and no radiation will be generated.

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

Emergency stop button in unit



Emergency stop button in remote control docking station



X0168629/D

6.3 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.

X0250491/C

6.4 Radiation safety

Conditions to achieve 1 Gy

Conditions to exceed 1 Gy shown in the table.

kVp	mAs	Cu filter	Scan mode	CTDI	Number of scans to exceed 1 Gy
140	800	0.2 mm + BOWTIE	Offset	32 cm	41
140	800	0.5 mm	32 cm Symmetric, 210 mm FOV	32 cm	21

X0173170/B

7 Pediatric use

X0173171/B

7.1 Introduction

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

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

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

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

X0173172/B

7.2 References for paediatric dose optimisation

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

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

X0173173/B

7.3 Device specific features and instructions

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

Design feature important to paediatric imaging (standard or optional)	Refer to section
Preset control settings which clearly specify the intended size range	"Selecting patient size" on page 45
Display and recording of patient dose or dose index and ability to record other patient information, e.g. age (standard)	"Checking exposure and DAP values" on page 35 Romexis user's manual (Entering date of birth and Generating X-ray log book)
Ultra Low Dose, AEC (Automatic Exposure Control) and CALM (Correction Algorithm for Latent Movement) setting (optional)	"Selecting scout imaging, Ultra Low Dose and AEC" on page 48
Scout views (standard)	"Taking scout views" on page 53

Design feature important to paediatric imaging (standard or optional)	Refer to section
User's manuals that consider the balance of radiation exposure and image quality (standard)	"Introduction" on page 1, "Adjusting resolution and exposure values for current exposure" on page 49

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

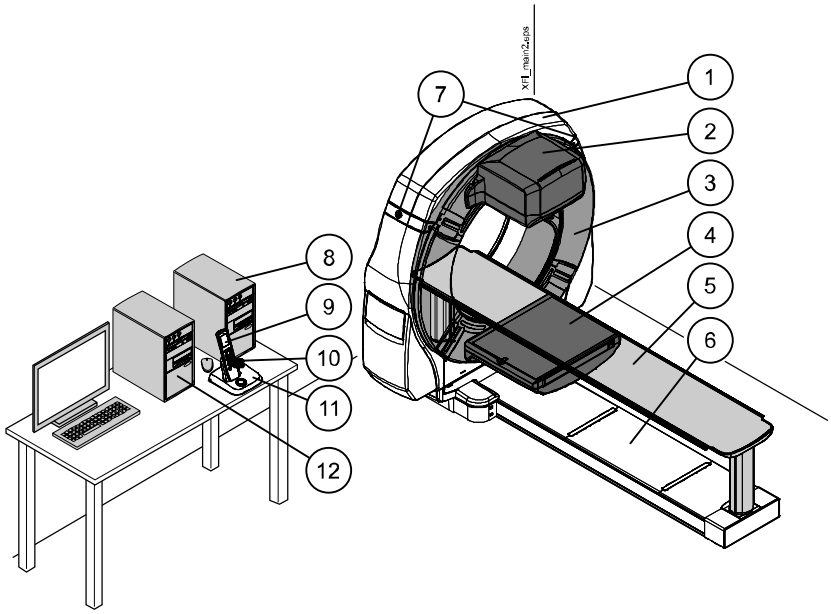
Testing information	Refer to section
Estimated patient dosimetry covering pediatric size ranges (standard)	"Checking exposure and DAP values" on page 35 Romexis user's manual (Generating X-ray log book)
Quality control instructions including tests to ensure proper operation across a broad patient size range (standard)	"Quality control" on page 57

X0104757/D

8 X-ray unit

X0104758/D

8.1 Main parts



1 Stationary arm*
2 X-ray tube assembly*
3 Rotating arm*
4 X-ray detector assembly*
5 Patient support
6 Column
7 Emergency stop buttons in unit
8 Reconstruction PC (Reco PC)
9 Remote control
10 Emergency stop button in remote control docking station
11 Remote control docking station
12 Imaging workstation

* The X-ray unit's **Imaging arm** consist of stationary arm, X-ray tube assembly, rotating arm and X-ray detector assembly.

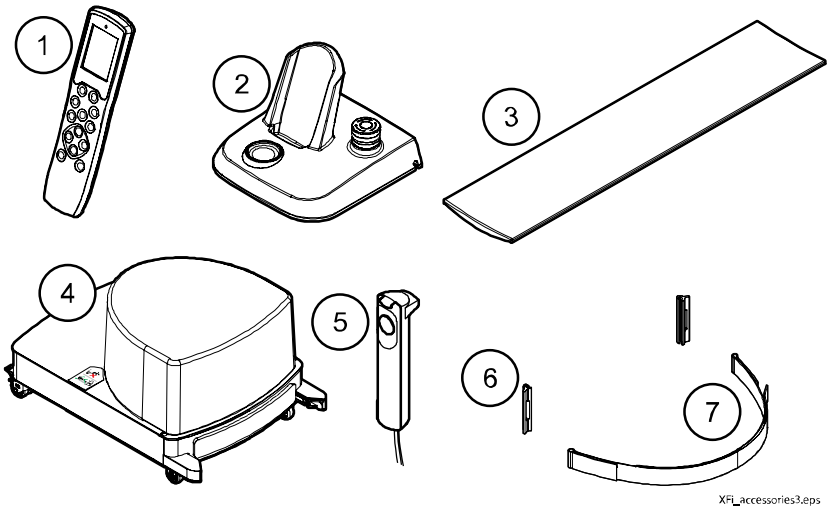
Cabling

Manufacturer type reference given in brackets.

1 Mains cable (30047635)
2 Dock cable (30046017)
3 Optical cable, detector (30047857)
4 Ethernet cable, XFI - Reco PC (10027515)
5 Exposure switch cable (10001193)

X0183481/C

8.2 Accessories

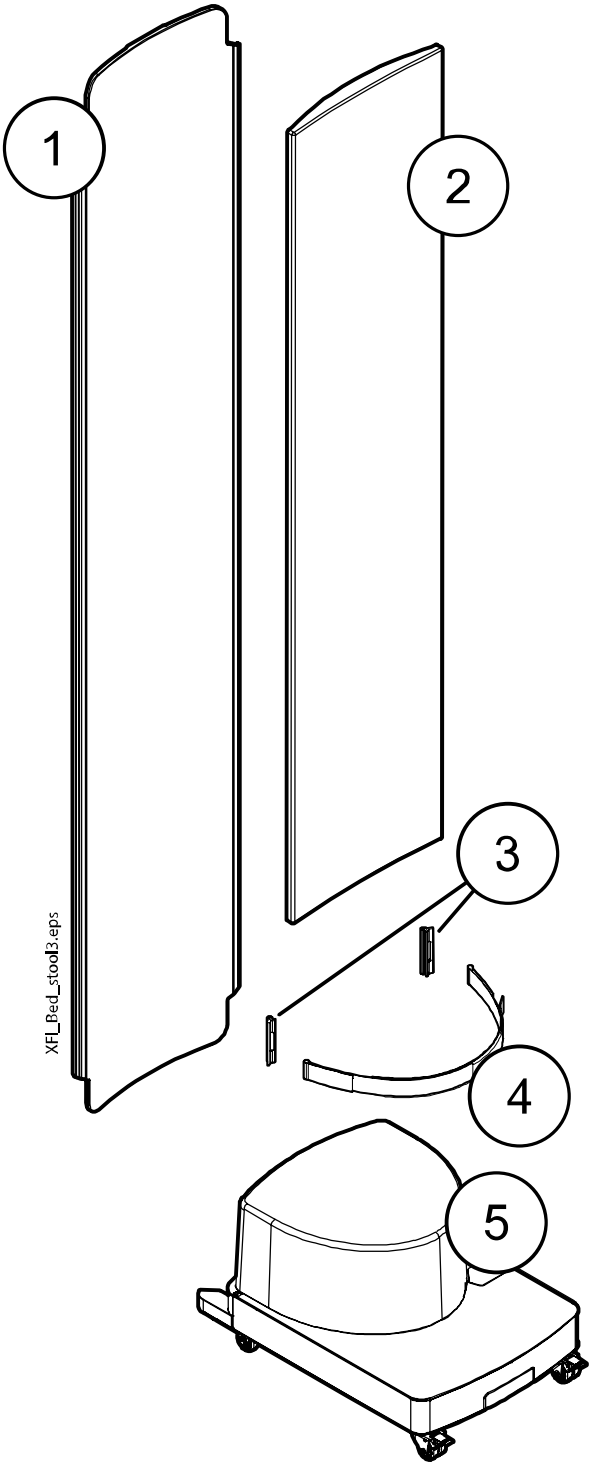


1. Remote control
2. Remote control docking station
3. Pad for patient support
4. Patient support stool
5. Exposure switch
6. Strap locks
7. Strap

X0104763/C

8.3 Patient contacting components

Patient contacting components are the parts of the X-ray unit that in normal treatment situations come into contact with the patient.



1 Patient support
2 Pad for patient support
3 Strap locks
4 Strap
5 Patient support stool

Used materials in patient contacting components can be wiped with wet cloth. See section "Cleaning and disinfection" on page 66 for approved disinfectants.

Used materials in patient contacting components are meant for short term skin contact and are biocompatible in accordance with ISO 10993 standard.

NOTE

The patient support stool is used when taking images of ankles and feet. It can also be used as a chair when taking head images of tall patients. Before patient positioning make sure the patient support stool is in correct position with the notches on the back locked to the X-ray unit base.

X0160730/C

8.4 Remote control

The remote control is used in device cleaning, device set-up and patient set-up phases.

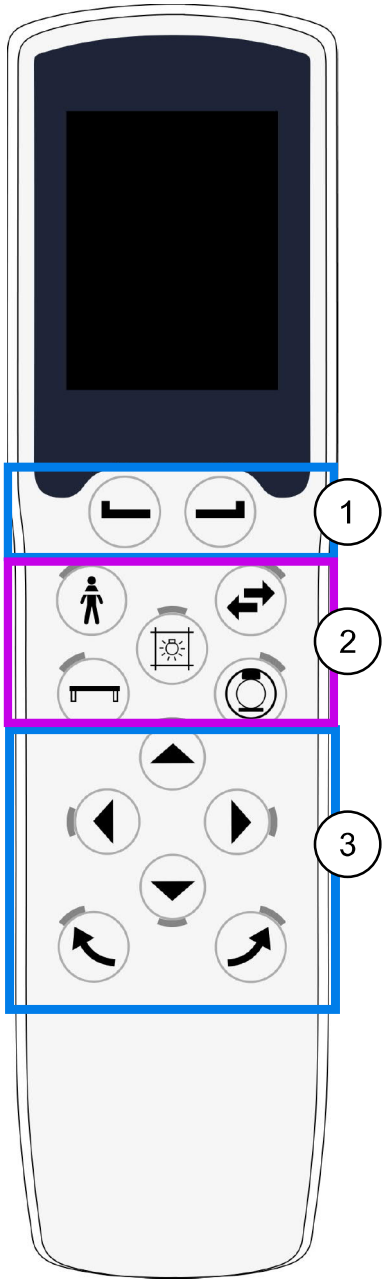
Remote control consists of buttons, display and indicator lights. It connects to the XFI system with a wireless connection. Internal battery is charged wirelessly by the charging pad in the docking station.

Light indicators on buttons show which options are available for each mode. Blue light indicates available button. Red light indicates unavailable option in a warning situation.

If needed, an alarm can be triggered from the workstation to assist in locating the remote control.

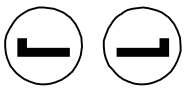
The remote control has three different button groups:

1. Softkey buttons
2. Operation mode buttons
3. Direction buttons



X0168593/C

8.4.1 Softkey buttons



Softkey buttons are used to acknowledge patient ID.

All available actions are shown on the display above the button.

X0168595/C

8.4.2 Operation mode buttons

Operation mode buttons are used to control different parts of the device. These buttons work in co-operation with the **direction buttons**. First the desired operation mode is activated and then **direction buttons** are used to drive that operation movement.

Preset mode

The **preset mode** drives the patient support, imaging arm and X-ray assembly at the same time to the location of interest that is defined by chosen protocol and patient size.

Once the patient set-up is done with patient position and orientation as defined in the chosen protocol, the preset drive functionality moves all device parts simultaneously to the correct location to enable minimal need for manual drive.

Exit/entry mode

The **exit/entry mode** drives the patient support, imaging arm and X-ray assembly simultaneously to predefined location that offers best access for patient positioning. It is used to enable patient entry and exit from the device.

XFI horizontal mode exit/entry position

Patient support is driven to the lowest point.

Imaging arm is driven to farthest head-side position.

Rotating arm is rotated so that X-ray assembly is vertical and the sensor is under the patient support.

XFI vertical mode exit/entry position

Patient support is driven close to the medium size preset position to minimize the need for patient support movement when patient is standing in the X-ray unit.

Imaging arm is driven to farthest head-side position.

Rotating arm is rotated so that the X-ray assembly is on sides of the patient support.

Laser light on/off

The light button is used to turn the laser light on and off.

Patient support

XFI horizontal mode

Patient support can be driven up/down

XFI vertical mode

Patient support can be driven forward/backward

X-ray assembly

Offset movement

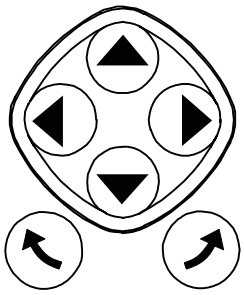
X-ray assembly can be driven to offset positions with left/right buttons.

Rotation movement

X-ray assembly rotation can be driven using clockwise/counter-clockwise buttons.

X0168594/C

8.4.3 Direction buttons



The movements of the X-ray unit and its different moving parts are controlled with the up, down, left, right, clockwise and counter-clockwise **direction buttons**.

X0179916/C

8.4.4 Pairing remote control with X-ray unit

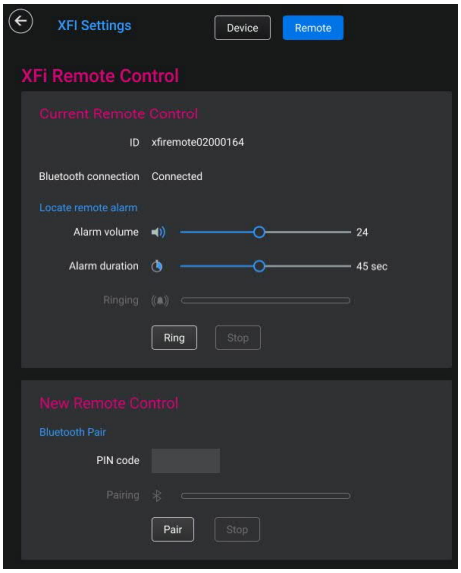
About this task

At any given time, there can be only one XFI Remote Control connected to the X-ray unit. In case of malfunction, you can initiate wireless pairing with a new XFI Remote Control from the Workstation application. During the pairing process the old remote control pairing with the system is disconnected as a safety precaution.

Follow these instructions to pair the remote control with the X-ray unit.

Steps

1. Go to XFI settings and select the **Remote** tab.



2. Click **Pair**.

   The workstation application shows PIN code and the status of the pairing process.

3. The remote control asks you to confirm the pairing.

The icon in the top-right corner indicates that the pairing is complete. Red symbol means that the pairing was unsuccessful.

X0168596/B

8.5 Docking station

The exposure process is controlled from the docking station. The docking station also functions as a charging station for the remote control.

For safety reasons the remote control must be in the docking station when the exposure process is initiated.

If the remote control is dislodged from the docking station during exposure process, the process is immediately halted. When the remote control is placed on the docking station, it shuts off to preserve battery life and to indicate that remote control use is not possible at that moment.

X0168597/B

8.5.1 Exposure button

Exposure button indicates exposure process phases by colours.

Exposure states are also indicated by audio signal.

A green light indicates that the X-ray system is ready for an exposure.

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

X0175722/C

8.6 XFI workstation application

X0175725/C

8.6.1 Making selections

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

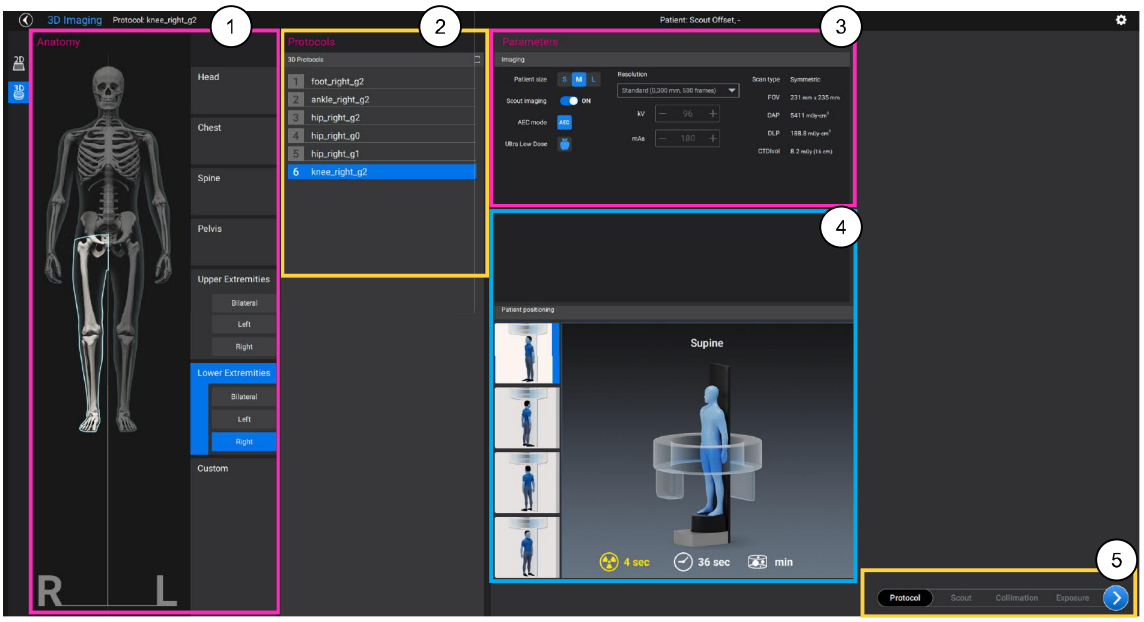
The selected option is highlighted. To deselect an option, reselect the button or field (or select another option if available).

X0175727/C

8.6.2 Main views 3D imaging

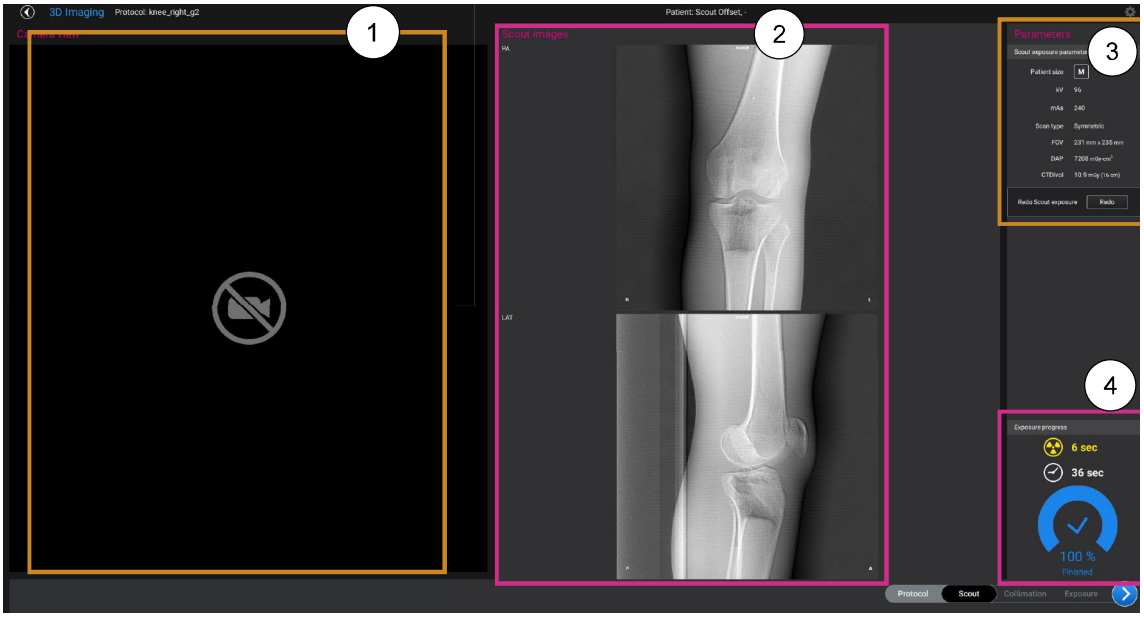
Protocol view

In Protocol view user has five focus areas:



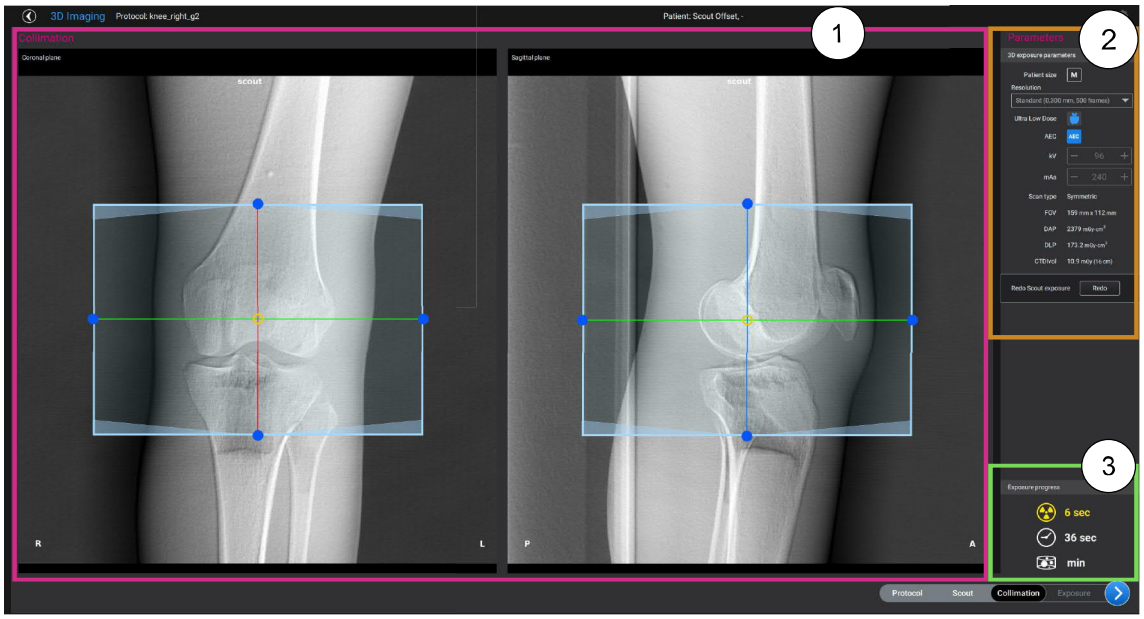
1. Anatomy selection
2. Protocol selection
3. Parameter selection
4. Patient positioning selection
5. Forward selection

Scout view



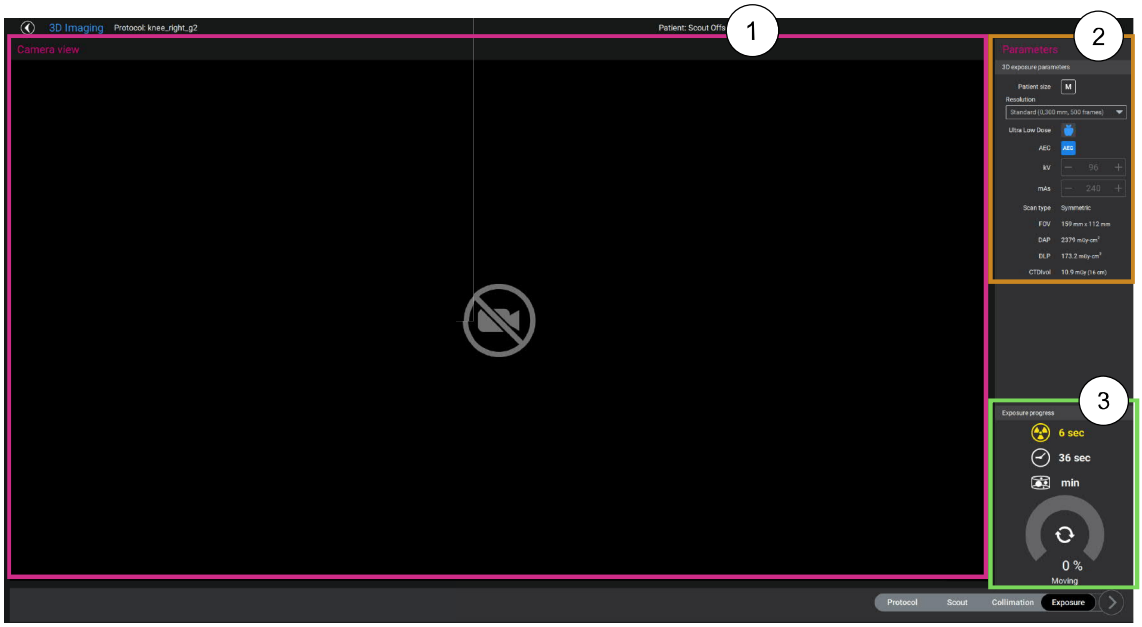
1. Patient camera (video)
2. Scout images
3. Scout exposure parameters
4. Exposure progress information

Collimation view



1. Collimation
2. Main exposure parameters
3. Exposure progress information

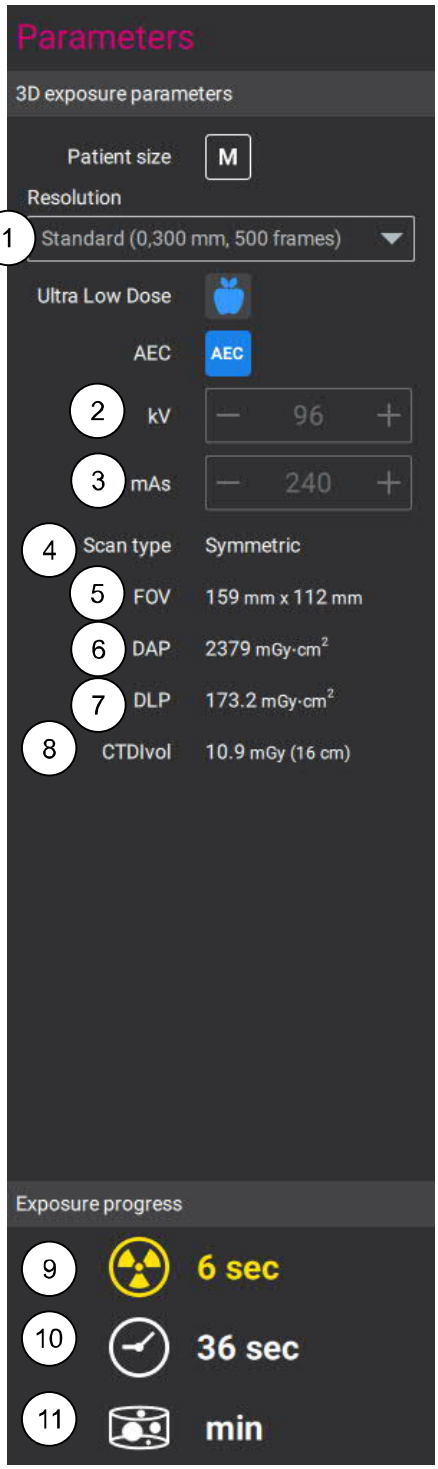
Exposure view



1. Patient camera (video)
2. Main exposure parameters
3. Exposure progress information

X0175732/B

8.6.3 Checking exposure and DAP values



1 Resolution setting
2 kV = kilovolt setting Volume
3 mAs = milliampere second setting
4 Scan type: Symmetric/Offset
5 Volume
6 DAP = Dose Area Product
7 DLP = Dose length product
8 CTDIvol = CT dose index

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

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

11 Image reconstruction time

X0175734/C

8.6.4 Patient name

When a patient is selected in Romexis, their name and ID number are shown on the top right corner of the workstation application view for the duration of the imaging.

X0175735/C

8.6.5 Changing settings

The XFI device and remote control settings can be accessed by selecting the **settings** icon on the top right corner of the screen.

X0104769/D

9 Switching X-ray system on/off

NOTE

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

NOTE

When switched ON/OFF allow up to 20s for the device to turn ON/OFF, this is due to power supply unit startup / shutdown time.

X0183478/C

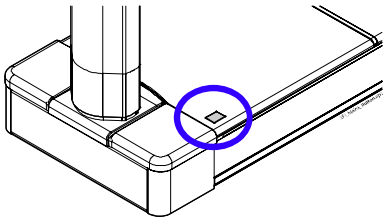
9.1 Switching X-ray unit on/off

About this task

The on/off switch is located on the X-ray unit's column.

Steps

1. Press the switch to turn the XFI on/off.



NOTE

When the mains power is cut off from the main switch or emergency stop buttons, all movements will stop in less than 1 second. The imaging arm rotation will stop within 10 degrees, and other movements with maximum of 5 mm (0.20 inch) travel.

X0104771/C

9.2 Switching reconstruction PC on/off

The on/off switch is located on the at the top of the computer. Press the switch to turn the reconstruction PC on/off.

X0183479/B

9.3 Closing XFI workstation application

About this task

Follow these instructions if you want to leave the XFI workstation application and terminate current session at any stage.

Steps

1. Press the *F12* key on your keyboard for 5 seconds.

Results

The XFI workstation closes and you will return to Romexis.

X0104772/C
10 Before exposure

X0156832/C
10.1 Preparing X-ray system

X000130/A
10.1.1 X-ray source warm-up and seasoning

It is highly recommended by the X-ray tube manufacturer, that when the tube has been idle, a warm-up procedure is conducted prior use. The warm-up and seasoning procedures cure the X-ray tube's vacuum conditions and produce more stable tube that is less prone to arcing.

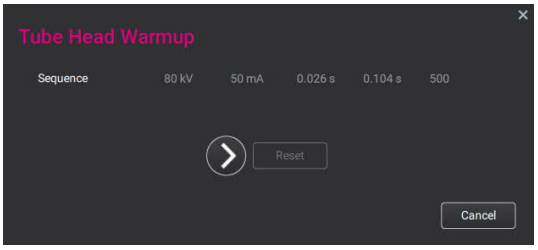
X000132/A
10.1.1.1 X-ray source warm-up procedure

About this task

The warm-up procedure should be performed daily prior to use with patients. Follow the steps below to perform warm-up for the X-ray unit.

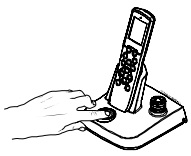
Steps

1. Go to **Settings**.
2. Select Select **User > Testing Routines > Tube Head Warmup**.



3. Click the start arrow.

4. Move to a protected area.
5. Press and hold down the exposure switch until the series of exposures ends.



CAUTION

Radiation is generated when the exposure button is pressed. Take adequate protection measures.

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

NOTE

The seasoning process takes several minutes.

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

6. Exit the window.

X000133/A
10.1.1.2 Tube head seasoning

About this task

The tube head seasoning process is necessary if the X-ray unit has not been used for a week or more.

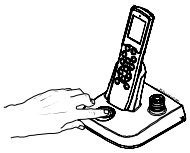
Follow the steps below to perform tube head seasoning.

Steps

1. Go to **Settings**.
2. Select **User > Testing Routines > Tube Head Seasoning**.

3. Click the start arrow.

4. Move to a protected area.
5. Press and hold down the exposure switch until the series of exposures ends.



CAUTION

Radiation is generated when the exposure button is pressed. Take adequate protection measures.

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

NOTE

The seasoning process takes several minutes.

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

6. Exit the window.

X0156834/C
10.1.2 Attaching patient supports

Attach separate patient supports and straps as necessary. Place a cushion on the patient support if needed in horizontal imaging.

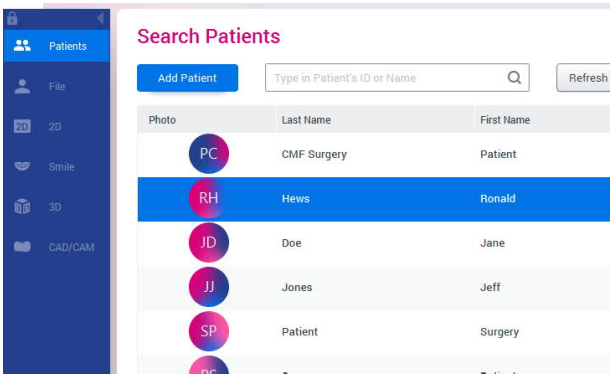
X0157191/C
10.1.3 Preparing Romexis

About this task

Follow the steps below to prepare Romexis.

Steps

1. Select the patient from the patient list.



2. Right-click on the patient and select **Capture.**

What to do next

See Romexis user's manual for information on other Romexis functions.

X0179561/C

10.1.4 Attaching and removing patient support stool

Before you begin

CAUTION

It important that you evaluate the patient's condition before examination. The patient stool can be dangerous to use for a patient that cannot properly move on it.

CAUTION

Before patient positioning make sure that the stool is locked correctly to the base of the X-ray unit. If not locked, the stool may slip from under the user causing injury.

CAUTION

Do not use the patient support stool for any purpose other than positioning the patient for imaging with the Planmed XFI X-ray unit.

CAUTION

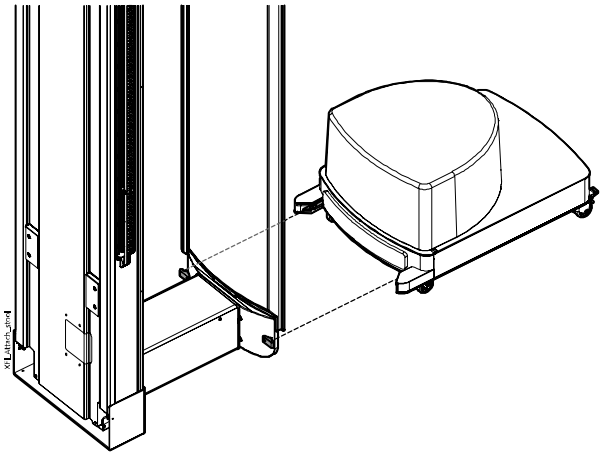
Do not use the patient support stool's own wheel locks when the patient support stool is locked on the X-ray unit.

About this task

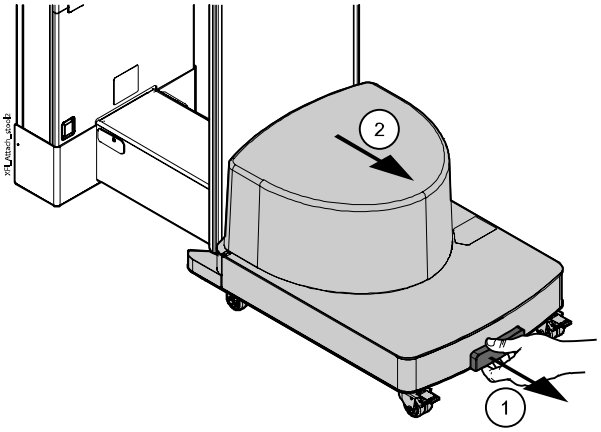
The patient support stool is used when taking images of ankles and feet. It can also be used as a chair when taking head images of tall patients. Follow these instructions to attach and remove the patient support stool.

Steps

1. Push the patient support stool towards the X-ray unit so that the notches on the back of the patient support stool lock to the base of the X-ray unit.



2. When no longer needed, release the patient support stool by pulling from the handle (1) and pulling the stool away from the X-ray unit (2).



X0156833/C

10.2 Preparing patient

Ask the patient to remove any spectacles, hearing aids, dentures, hairpins, watches, mobile devices and personal jewellery such as earrings, bracelets, necklaces and piercings as these can attenuate the X-ray beam or 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 structures of the X-ray unit. Long hair should be fastened.

NOTE

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

X0156966/C

11 Taking exposure

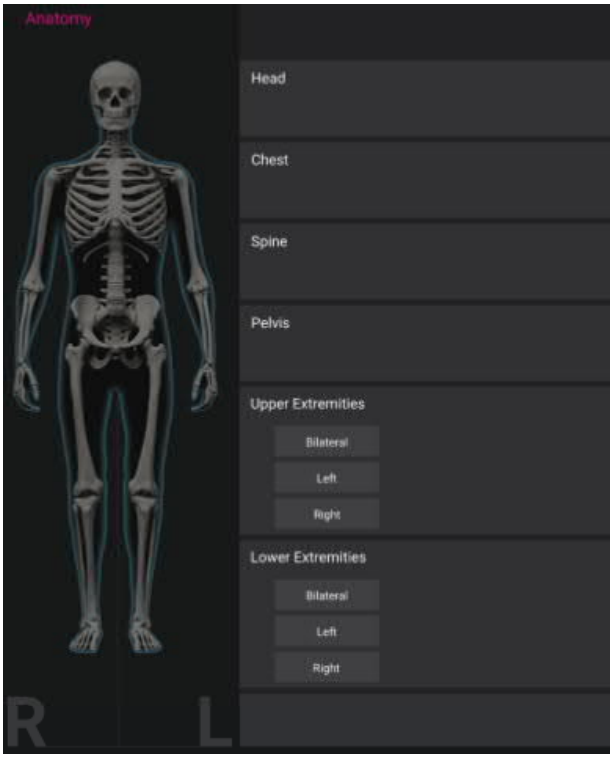
After you have selected the patient in Romexis XFI workstation application, the *Protocol view* opens. You will now be able to select imaging mode, anatomy, protocol and adjust parameters.

X0173155/C

11.1 Anatomies

The Anatomies include:

- Head
- Chest
- Spine
- Pelvis
- Upper Extremities
  - Bilateral
  - Left
  - Right
- Lower Extremities
  - Bilateral
  - Left
  - Right



X0173156/C

11.2 Protocols

After selecting anatomy, the imaging protocols are shown. Each individual protocol contains all relevant parameter settings for scout, exposure and reconstruction processes. The tables below list available protocols for each anatomy.

X0163473/C

11.2.1 3D protocols

Anatomy	Protocol
Head	• Jaw • Face • Skull • Temporal bones • Sinus • Ear, Inner • Ear, 360
Chest	• Chest
Spine	• Cervical Spine • Thoratic Spine • Lumbar Spine
Pelvis	• Pelvis
Upper Extremities	**Bilateral** • Shoulders • Wrists • Hands
	Left • Shoulder - Left • Wrist - Left • Hand - Left
	Right • Shoulder - Right • Wrist - Right • Hand - Right
Lower Extremities	**Bilateral** • Hips • Knees • Ankles • Feet
	Left • Knee - Left • Ankle - Left • Foot - Left
	Right • Knee - Right • Ankle - Right • Foot - Right