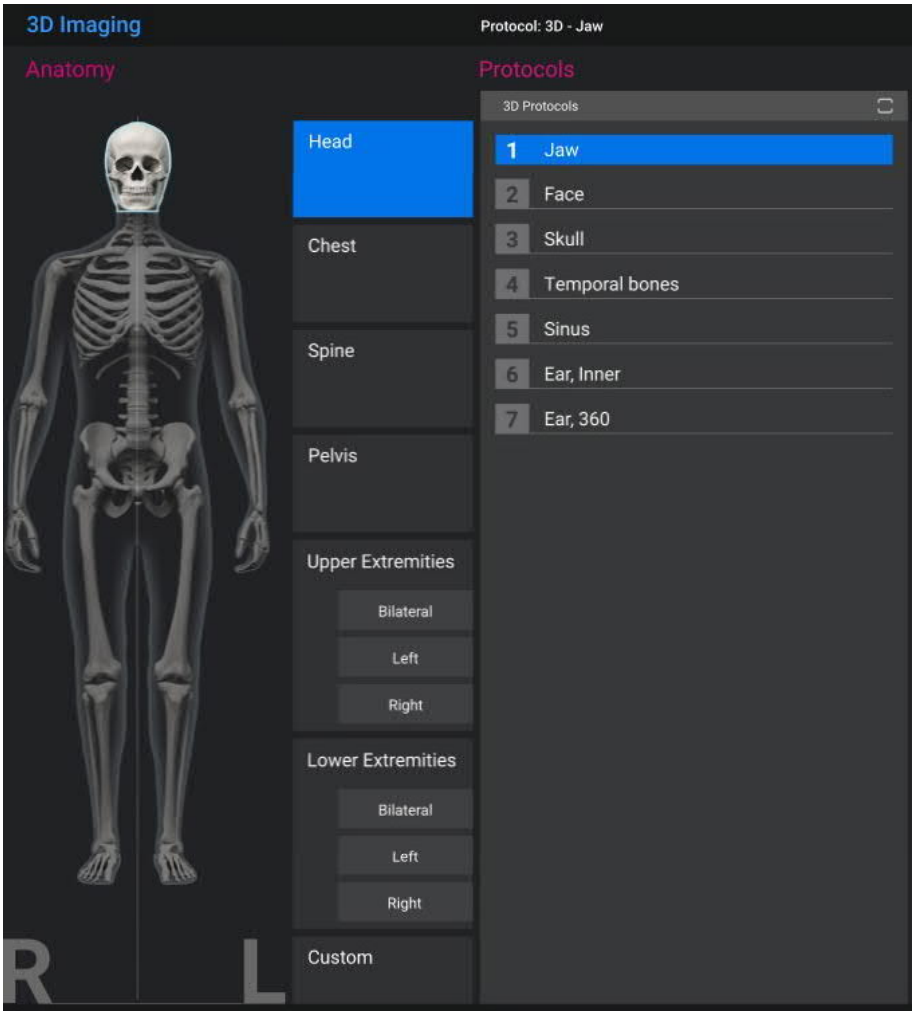
X0162458/B
11.3 Selecting protocol

About this task

Follow these instructions when selecting protocol.

Steps

1. Select the anatomy you want to use, for example **Head**.
2. Select protocol you want to use, for example **Jaw**.



What to do next

Proceed to selecting patient size, see section "Selecting patient size" on page 45.

X0173157/C
11.4 Selecting imaging parameters

NOTE
Always adjust the default parameters according to each patient.

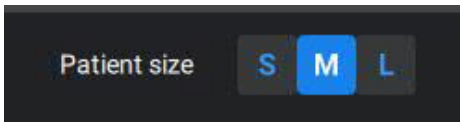
X0162450/C
11.4.1 Selecting patient size

About this task

Follow these instructions to select patient size on the workstation application.

Steps

1. Use these buttons to select the size.



- S = Child, small adult
- M = Medium-sized adult
- L = Large adult

The preset exposure values are shown in the *Exposure values* column on the right side of the *Parameters* screen.

NOTE

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

NOTE

Be sure to select size S for paediatric patients.

X0175664/B

11.4.2 Adjusting orientation and direction

X0162452/B

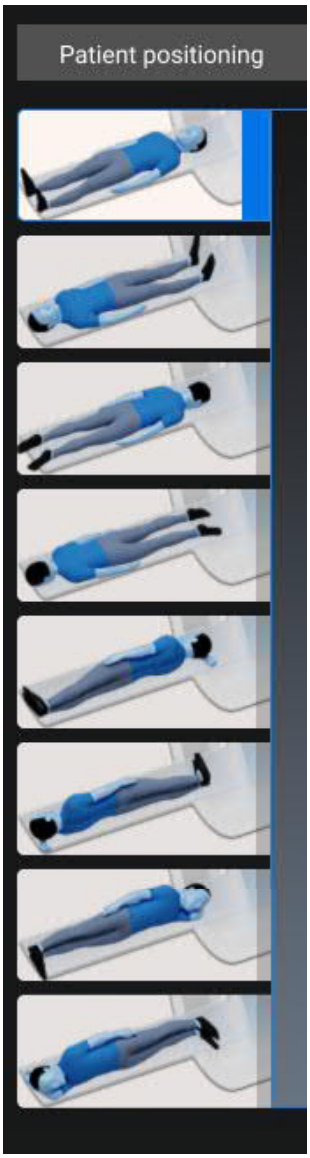
11.4.2.1 X-ray unit in horizontal mode

About this task

Follow these instructions if you need to change imaging orientation or direction.

Steps

1. Use these buttons to select orientation and direction.



X0175665/B

11.4.2.2 X-ray unit in vertical mode

About this task

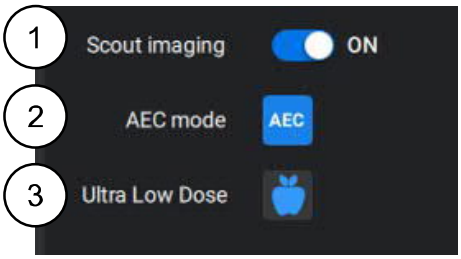
Follow these instructions if you need to change imaging orientation or direction .

Steps

1. Use these buttons to select orientation.

X0168600/C

11.4.3 Selecting scout imaging, Ultra Low Dose and AEC



1. Select scout imaging on/off. Scout imaging needs to be enabled if AEC is used.
2. If AEC (Automatic Exposure Control) mode is selected mAs value cannot be adjusted manually. When selected, the exposure values will change to preselected kV and mAs values chosen for each anatomy and patient size. The changed values are visible before taking exposure.

3. Select the Ultra Low Dose button if you want to take an exposure with a very low dose.

X0162456/C

11.4.4 Adjusting resolution and exposure values for current exposure

About this task

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

NOTE

Always try to minimise the radiation dose to the patient.

The preset exposure values are shown in section "Factory presets for 3D exposures" on page 49.

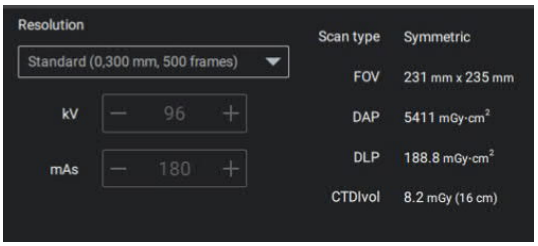
Follow these steps if you need to adjust the preset exposure values for current exposure:

Steps

1. Select imaging resolution from the drop-down menu.
2. If AEC is not selected, use the minus or plus signs to set the exposure values you wish to use.

   To improve the image contrast, reduce the kV value.

   To reduce the radiation dose, reduce the mAs value.



   FOV, DAP, DLP and CTDIvol are calculated values and cannot be set manually.
3. Proceed to patient positioning.

X0174985/C

11.4.4.1 Factory presets for 3D exposures

Factory presets for 3D Head exposures

Patient size	kV value	mAs value
Child, small adult (S)		
Medium-sized adult (M)		
Large adult (L)		

Factory presets for 3D Chest exposures

Patient size	kV value	mAs value
Child, small adult (S)		
Medium-sized adult (M)		
Large adult (L)		

Factory presets for 3D Spine exposures

Patient size	kV value	mAs value
Child, small adult (S)		
Medium-sized adult (M)		
Large adult (L)		

Factory presets for 3D Pelvis exposures

Patient size	kV value	mAs value
Child, small adult (S)		
Medium-sized adult (M)		
Large adult (L)		

Factory presets for 3D Upper Extremities exposures

Patient size	kV value	mAs value
Child, small adult (S)		
Medium-sized adult (M)		
Large adult (L)		

Factory presets for 3D Lower Extremities exposures

Patient size	kV value	mAs value
Child, small adult (S)		
Medium-sized adult (M)		
Large adult (L)		

X0157187/C

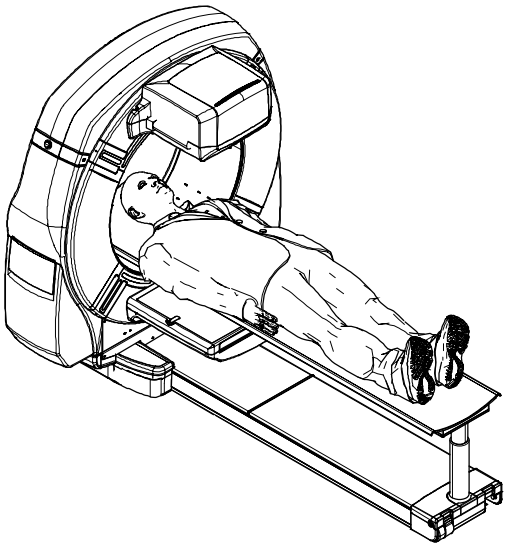
11.5 Patient positioning in horizontal position

About this task

Follow these instructions to position the patient.

Steps

1. Guide the patient to lie down on the patient support.



2. Fasten the necessary straps.
3. Select the **Preset** button.

CAUTION

Make sure that the patient or an object does not obstruct the X-ray unit movement. Clear any obstruction before pressing the Preset button.

CAUTION

If the patient wears an IV catheter, make sure that the IV lines are not positioned so that they can get caught in the rotating imaging arm.

The X-ray unit moves to the optimal position based on the patient size and selected protocol and parameters.

4. Make necessary adjustments.
   - Move the patient support by pressing the up/down buttons on the remote control so that the horizontal laser line is in the correct position.
5. Click on the forward button to proceed to the next phase.

NOTE

Make sure that patient positioning and parameter selection is complete before you proceed to Scout imaging. The remote control needs to be in the docking station during Scout imaging and thus patient positioning adjustments cannot be made at that stage.

X0174983/C

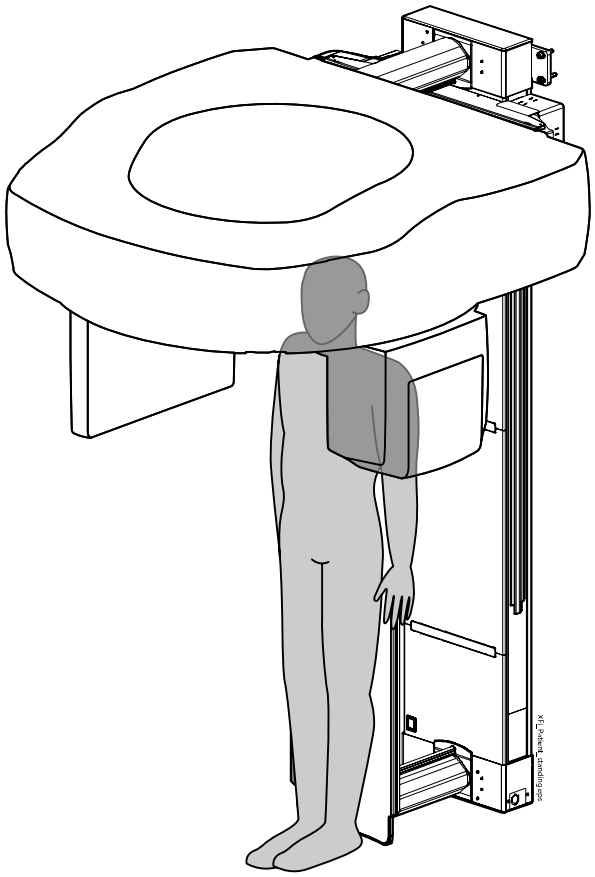
11.6 Patient positioning in vertical position

About this task

Follow these instructions to position the patient.

Steps

1. Guide the patient to stand or sit in the correct position.



Assist the patient in stepping on the patient support stool if it is required in imaging.

2. Place the necessary patient supports.
3. Select the **Preset** button.

CAUTION

Make sure that the patient or an object does not obstruct the X-ray unit movement. Clear any obstruction before pressing the Preset button.

CAUTION

If the patient wears an IV catheter, make sure that the IV lines are not positioned so that they can get caught in the rotating imaging arm.

The X-ray unit moves to the optimal position based on the patient size and selected protocol and parameters.

4. Make necessary adjustments.
   - Move the patient support by pressing the up/down buttons on the remote control so that the horizontal laser line is in the correct position.

5. Click on the forward button to proceed to the next phase.

NOTE

Make sure that patient positioning and parameter selection is complete before you proceed to Scout imaging. The remote control needs to be in the docking station during Scout imaging and thus patient positioning adjustments cannot be made at that stage.

X0175738/C

11.7 3D Exposure

NOTE

Confirm imaging parameters before each exposure.

NOTE

To avoid running out of battery life, it is recommended to always keep the remote control in the docking station when not in use.

X0160722/C

11.7.1 Taking scout views

Before you begin

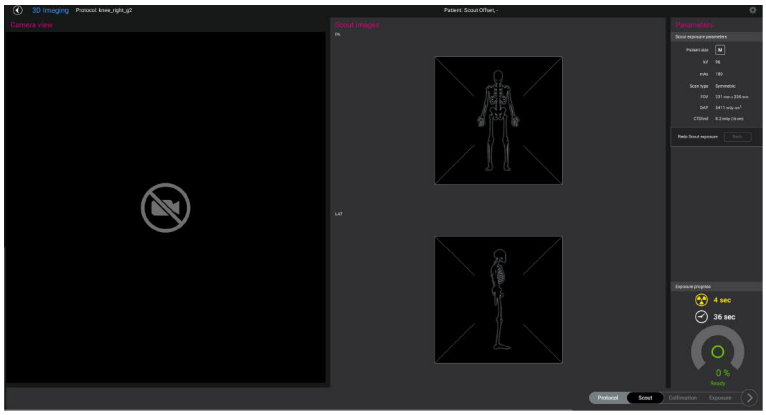
NOTE

To avoid patient movement during exposure, let the patient know that the X-ray unit will move before scout views are taken.

About this task

When 3D protocol and parameters are selected, the *Scout view* opens.

Scout views of the selected image volume are taken before you can proceed to taking the actual 3D image. This allows you to check that the image volume is in the correct place.



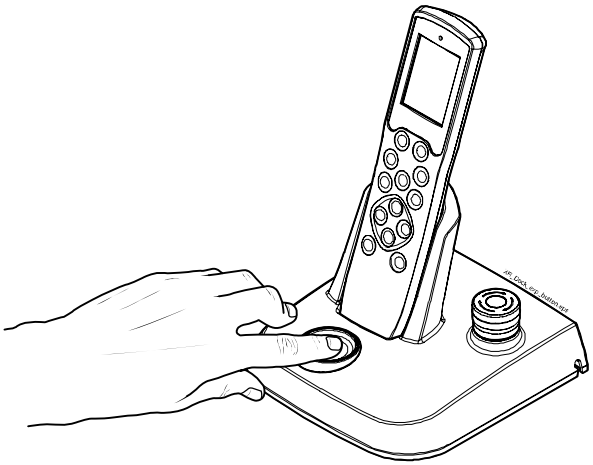
Exposure parameters section on the right shows the selected parameters affecting the exposure.

Steps

1. Move to a protected area.
2. Place the remote control in the docking station.

   Green light on the exposure button indicates that the X-ray system is ready for an exposure.

3. Ask the patient to stay as still as possible.
4. Press and hold down exposure button to take scout views.



During exposure yellow radiation warning light illuminates on the exposure button. You also hear a radiation warning tone and see a radiation warning symbol on the workstation application.

NOTE

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

NOTE

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

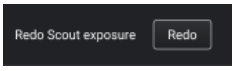
The progress can be seen from the **Exposure progress** section in the bottom right corner of the screen.

Results

The scout exposures appear in the **Scout Images** field.

What to do next

If the scout image is not satisfactory, click on the **Redo** button. This will restart the scout process.



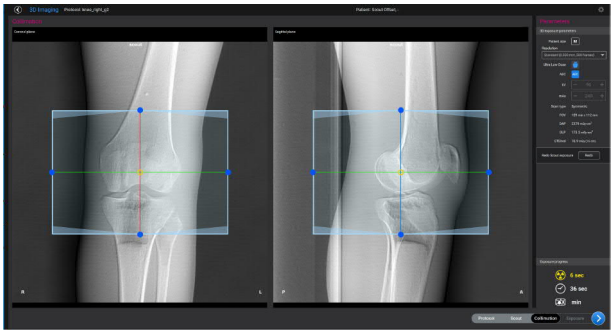
Click on the forward button to proceed to collimation.

X0168604/C

11.7.2 Adjusting image position and volume size

About this task

After scout images are taken, the **Collimation view** containing the two scout images opens.



The preset position and size of the image volume are shown with a blue area in both views. You can use either or both views to adjust the volume position and size.

NOTE

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

NOTE

Do not attempt to limit the volume very precisely and note that the shaded edges on the top and bottom of the blue area are not included in the exposure.

Follow these instructions to adjust image volume position and size.

Steps

1. To adjust the volume position, press and hold down the left mouse button and move the blue area to the anatomical region that you wish to expose.

   The blue area can be moved in any direction.
2. Adjust the volume size by selecting one of the blue handles with the left mouse button and dragging it while keeping the button pressed to enlarge or reduce the volume size.

   The volume size is adjusted in both image areas simultaneously.
3. Click on the forward button to proceed to taking the 3D exposure.

X0160723/C

11.7.3 Taking 3D exposure

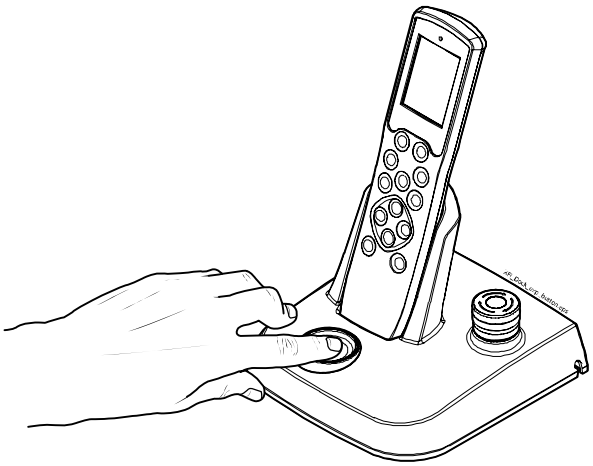
About this task

After scout views the X-ray unit is automatically ready for a 3D exposure. Follow these instructions to take a 3D exposure.

Steps

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

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



During exposure yellow radiation warning light illuminates on the exposure button. You also hear a radiation warning tone and see a radiation warning symbol on the workstation application.

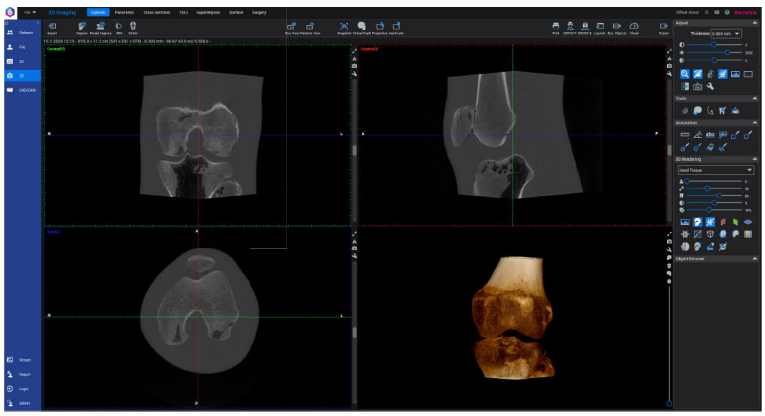
NOTE

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

NOTE

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

When ready, the image opens in Romexis.



3. Take the remote control from the docking station and return to the patient.
4. Press the **Entry/exit** button and use the control buttons to enable easy exit.

5. Remove the fastening straps (if used) and other patient supports.
6. Guide the patient away from the X-ray unit.
7. Return to the workstation application to confirm the image quality and to process the images and study.

X0173169/C

12 Quality control

Annual quality control test must be carried out on the X-ray unit in order to ensure consistent image quality. It is recommended to compare the test results to the results from the previous test to notice any significant changes that may have occurred. Contact your service technician for quality control test.

X0104774/D

13 Alert dialogs

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

Alert types

There are three types of alert dialogs: **Info**, **Warning** and **Error**.

Type	Icon	Description
Info		Information alert.
Warning		Warning alert. Requires user/technician to resolve the situation.
Error		Error alert. Resolving requires either system reset or maintenance call.

List of alerts

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

Type	Code	XFI App Alert dialog - Title	XFI App Alert dialog - Message	Technical explanation
H1xx HELPS				
Warning	101	Exposure stopped	Exposure button released too early. Take new exposure.	Exposure switch released before end of exposure.
Error	102	Exposure switch malfunction	Docking station malfunction. Please contact service.	Exposure switch continuously depressed or cable short-circuited.
Warning	105	Emergency stop activated	Emergency stop button activated. Release stop button and check cable connection. Restart XFI system.	Emergency stop button pressed.
Error	121	Calibration	Perform flat field calibration. Please contact service.	Flat field calibration not done.
Error	122	Calibration	Perform geometry calibration. Please contact service.	Geometry calibration not done.
Error	124	Workstation memory problem	PC Workstation memory is low. Please contact service.	Not enough memory on workstation for this imaging.
Warning	131	Movement restricted	Movement for selected direction blocked. Remove obstacle.	Y motor gantry cover stop switch.
Warning	132	Movement restricted	Movement for selected direction blocked.	Y movement minimum limit exceeded.

Warning	133	Movement restricted	Movement for selected direction blocked.	Y movement maximum limit exceeded.
Info	134	Rotating arm limit	Movement limit reached. Drive to opposite direction.	Rotating arm sensor low limit.
Info	135	Rotating arm limit	Movement limit reached. Drive to opposite direction.	Rotating arm sensor high limit.
Info	136	Rotating arm limit	Movement limit reached. Drive to opposite direction.	X movement maximum limit exceeded.
Info	137	Rotating arm limit	Movement limit reached. Drive to opposite direction.	X movement fell below the minimum limit.
Warning	138	Motor overheated	Rotating arm motor overheated. Wait for cooldown. If problem persist please contact service.	Rotating arm motor overheated.
Warning	139	Motor overheated	Stationary arm motor overheated. Wait for cooldown. If problem persist please contact service.	X motor overheated.
Error	140	System malfunction	Sensor malfunction. Please contact service.	Z motor sensor failure.
Info	142	Movement restricted	Movement for selected direction blocked. Remove obstacle.	Column bottom safety switch activated. Only upward movement possible.
Info	143	Movement restricted	Movement for selected direction blocked. Remove obstacle.	Column top safety switch activated. Only downward movement possible.
Info	144	Movement restricted	Movement for selected direction blocked. Remove obstacle.	X motor detector cover stop switch.
Info	145	Movement restricted	Movement for selected direction blocked. Remove obstacle.	X motor gantry cover stop switch.
Info	146	Movement restricted	Movement for selected direction blocked. Remove obstacle.	X motor gantry cover stop switch2.
Error	147	Motor overheated	Imaging arm motor overheated. Wait for cooldown. If problem persist please contact service.	Z motor overheated.
Info	149	Movement restricted	Rotating arm movement blocked. Remove obstacle.	Rotating arm movement stopped due to TOF sensor.
Error	151	System malfunction	XFI system malfunction. Please contact service.	Line voltage dropped too low during exposure. Please, drop mA settings and try again.
Error	152	System malfunction	XFI system malfunction. Please contact service.	Line voltage is too low.
Info	153	Movement restricted	Movement limit reached. Drive to opposite direction.	Z column is too high.

Info	154	Movement restricted	Movement limit reached. Drive to opposite direction.	Z column is too low.
Error	160	Directional error	Imaging equipment is moving to wrong direction, check sensors and cables.	Tubehead or panel is moving to wrong direction
Info	161	X-ray source overheated	X-ray source overheated. Wait for cooldown.	Temperature of tubehead too high.
Error	162	Motor overheated	Anode motor overheated. Wait for cooldown. If problem persists, please contact service.	Anode motor overheated.
Error	163	Motor sensor malfunction	Sensor malfunction. Please contact service.	Rotating arm motor sensor failure.
Error	164	Motor sensor malfunction	Sensor malfunction. Please contact service.	X motor sensor failure.
Error	169	Motor overheated	Patient lift motor overheated. Wait for cooldown. If problem persists, please contact service.	Y motor overheated.
Info	166	Anode heat too high	Maximum anode heat unit capacity reached, please wait. (Include cooling progress timer into dialog)	Maximum tubehead energy exceeded. Lower exposure parameters.
Error	182	System malfunction	XFI system malfunction. Restart XFI System. If problem persists, please contact service.	Timeout in image data transmission. Check panel connection.
Error	187	System malfunction	XFI system malfunction. Restart XFI System. If problem persists, please contact service.	Exposure interrupted by the reconstruction PC due to data transmission fault.
Error	188	System malfunction	XFI system malfunction. Please contact service.	Reconstruction PC error.
Error	190	System malfunction	XFI system malfunction. Please contact service.	GUI-CPU communication failure.
Error	192	System malfunction	Please power up or restart XFI system and check ethernet cables.	Workstation communication failure.
Error	193	System malfunction	XFI system malfunction. Please contact service.	Invalid scan settings.
Error	194	Connection failure	Please check ethernet cable connection on workstation.	CPU connection not established.
Error	195	System malfunction	Please restart XFI system.	Request timed out while waiting for CPU to respond.
Error	196	System malfunction	XFI system malfunction. Please contact service.	Version mismatch in communication interfaces.
Error	200	System malfunction	XFI system malfunction. Please contact service.	Temperature of tube head too low or sensor malfunction.

Error	201	System malfunction	XFI system malfunction. Please contact service.	X-ray source linear motor or position sensor failed.
Error	202	System malfunction	XFI system malfunction. Please contact service.	X-ray detector linear motor or position sensor failed.
Error	203	System malfunction	XFI system malfunction. Please contact service.	Timeout in rotating arm automatic movement.
Error	204	System malfunction	XFI system malfunction. Please contact service.	Rotating arm motor speed feedback collision.
Error	205	System malfunction	XFI system malfunction. Please contact service.	X motor speed feedback collision.
Error	206	System malfunction	XFI system malfunction. Please contact service.	Z motor speed feedback collision.
Error	215	System malfunction	XFI system malfunction. Please contact service.	Open circuit in anode drive motor, which is connected to SMDU PCB J2.
Error	230	System malfunction	XFI system malfunction. Please contact service.	Overcurrent detected in lift motor, which is connected to MMDU Z PCB J2.
Error	233	System malfunction	XFI system malfunction. Please contact service.	Overcurrent detected in Anode motor, which is connected to SMDU Andode PCB J1.
Error	234	System malfunction	XFI system malfunction. Please contact service.	Overcurrent detected in Gantry motor, which is connected to MMDU XO PCB J1.
Error	235	System malfunction	XFI system malfunction. Please contact service.	Overcurrent detected in patient support motors, which are connected to DCMDU PCB J1 and J2.
Error	236	System malfunction	XFI system malfunction. Please contact service.	Overcurrent detected in X motor, which is connected to MMDU gantry PCB J2.
Error	256	System malfunction	XFI system malfunction. Please contact service.	Direction rotating arm.
Error	272	System malfunction	XFI system malfunction. Please contact service.	Z motor not ready / not responding.
Error	273	System malfunction	XFI system malfunction. Please contact service.	Anode motor not ready / not responding.
Error	274	System malfunction	XFI system malfunction. Please contact service.	Gantry motor not ready / not responding.
Error	275	System malfunction	XFI system malfunction. Please contact service.	Patient lift motor not ready / not responding.
Error	276	System malfunction	XFI system malfunction. Please contact service.	X motor not ready / not responding.
Error	277	System malfunction	XFI system malfunction. Please contact service.	Timeout in collimator Y1 upper motor, which is connected to CMCM PCB.

Error	278	System malfunction	XFI system malfunction. Please contact service.	Timeout in collimator X motor, which is connected to CMCM PCB.
Error	279	System malfunction	XFI system malfunction. Please contact service.	Timeout in collimator X1 right motor, which is connected to CMCM PCB.
Error	280	System malfunction	XFI system malfunction. Please contact service.	Timeout in collimator Y motor, which is connected to CMCM PCB.
Error	281	System malfunction	XFI system malfunction. Please contact service.	Timeout in tube head rotation motor, which is connected to CMCM PCB.
Error	282	System malfunction	XFI system malfunction. Please contact service.	Timeout in collimator filter revolver motor, which is connected to CMCM PCB.
Error	283	System malfunction	XFI system malfunction. Please contact service.	Timeout in collimator filter motor, which is connected to CMCM PCB.
Error	284	System malfunction	XFI system malfunction. Please contact service.	Timeout in collimator X2 left motor, which is connected to CMCM PCB.
Error	285	System malfunction	XFI system malfunction. Please contact service.	Timeout in collimator Y2 lower motor, which is connected to CMCM PCB.
Error	286	System malfunction	XFI system malfunction. Please contact service.	Timeout in tube head rotation motor, which is connected to CMCM PCB.
Error	291	System malfunction	XFI system malfunction. Please contact service.	Collimator right X self test failed.
Error	292	System malfunction	XFI system malfunction. Please contact service.	Collimator left X self test failed.
Error	293	System malfunction	XFI system malfunction. Please contact service.	Collimator upper Y self test failed.
Error	294	System malfunction	XFI system malfunction. Please contact service.	Collimator lower Y self test failed.
Error	295	System malfunction	XFI system malfunction. Please contact service.	Collimator filter revolver self test failed.
E3xx X-RAY GENERATION RELATED ERRORS		Seasoning Process To Be Implemented - Change these when done!		
Error	301	System malfunction	XFI system malfunction. Please contact service.	Filament voltage missing completely.
Error	302	System malfunction	XFI system malfunction. Please contact service.	Filament voltage too low during preheat.
Error	303	System malfunction	XFI system malfunction. Please contact service.	Filament voltage too high during preheat.
Error	311	System malfunction	XFI system malfunction. Please contact service.	Tube voltage missing completely.

Error	312	System malfunction	XFI system malfunction. Please contact service.	Tube voltage too low.
Error	313	System malfunction	XFI system malfunction. Please contact service.	Tube voltage too high.
Error	317	System malfunction	XFI system malfunction. Please contact service.	Tube voltage overshooted suddenly without arching.
Error	318	System malfunction	XFI system malfunction. Please contact service.	Tube mA overshooted suddenly without arching.
Error	319	System malfunction	XFI system malfunction. Please contact service.	Xray pulse length exceeded the requested value.
Error	321	System malfunction	XFI system malfunction. Please contact service.	Tube current missing completely.
Error	322	System malfunction	XFI system malfunction. Please contact service.	Tube current too low.
Error	323	System malfunction	XFI system malfunction. Please contact service.	Tube current too high.
Error	332	System malfunction	XFI system malfunction. Please contact service.	Severe arcing across x-ray tube.
Error	334	System malfunction	XFI system malfunction. Please contact service.	Severe arcing at tube head anode end.
Error	336	System malfunction	XFI system malfunction. Please contact service.	Severe arcing at tube head cathode end.
Error	342	System malfunction	XFI system malfunction. Please contact service.	Exposure pulsing fault.
E4xx FEEDBACK ERRORS		Seasoning Process To Be Implemented - Change these when done!		
Error	401	System malfunction	XFI system malfunction. Please contact service.	Tube head KVPOS offset failure, short-circuited.
Error	402	System malfunction	XFI system malfunction. Please contact service.	Tube head KVPOS offset failure, out of bounds.
Error	403	System malfunction	XFI system malfunction. Please contact service.	Tube head offset KVNEG failure, short-circuited.
Error	404	System malfunction	XFI system malfunction. Please contact service.	Tube head KVNEG offset failure, out of bounds.
Error	405	System malfunction	XFI system malfunction. Please contact service.	Tube head MAPOS offset failure, short-circuited.
Error	406	System malfunction	XFI system malfunction. Please contact service.	Tube head MAPOS offset failure, out of bounds.
Error	407	System malfunction	XFI system malfunction. Please contact service.	Tube head MANEG offset failure, short-circuited.
Error	408	System malfunction	XFI system malfunction. Please contact service.	Tube head MANEG offset failure, out of bounds.
Error	409	System malfunction	XFI system malfunction. Please contact service.	Tube head filament offset failure, out of bounds.
Error	411	System malfunction	XFI system malfunction. Please contact service.	Tube head kV-feedback imbalance.

Error	412	System malfunction	XFI system malfunction. Please contact service.	Tube head mA-feedback imbalance.
Error	414	System malfunction	XFI system malfunction. Please contact service.	Tube head temperature measurement error (signal out of bounds).
Error	415	System malfunction	XFI system malfunction. Please contact service.	Tube head electronics supply voltage error.
Error	416	System malfunction	XFI system malfunction. Please contact service.	Tube head not calibrated.
Error	417	System malfunction	XFI system malfunction. Please contact service.	Tube head type not supported.
Error	428	System malfunction	XFI system malfunction. Please contact service.	Failure in patient support height potentiometer.
E5xx POWER SUPPLY RELATED ERRORS				
Error	500	System malfunction	XFI system malfunction. Please contact service.	MMDU XO 400 VDC supply undervoltage.
Error	501	System malfunction	XFI system malfunction. Please contact service.	MMDU Z 400 VDC supply undervoltage.
Error	502	System malfunction	XFI system malfunction. Please contact service.	DCMDU Y 40 VDC supply undervoltage.
Error	503	System malfunction	XFI system malfunction. Please contact service.	SMDU Anode 400 VDC supply undervoltage.
Error	506	System malfunction	XFI system malfunction. Please contact service.	MMDU XO 400 VDC supply overvoltage.
Error	507	System malfunction	XFI system malfunction. Please contact service.	MMDU Z 400 VDC supply overvoltage.
Error	508	System malfunction	XFI system malfunction. Please contact service.	DCMDU Y 40 VDC supply overvoltage.
Error	509	System malfunction	XFI system malfunction. Please contact service.	SMDU Anode 400 VDC supply overvoltage.
E6xx COMMUNICATION ERRORS				
Error	628	System malfunction	XFI system malfunction. Please contact service.	Error in communication with 3D sensor.
Error	630	Connection lost	XFI device was shut down.	Error in GUI - CPU communication.
Error	631	System malfunction	XFI system malfunction. Please contact service.	MMDU X / O communication failure. Problem with CAN bus.
Error	632	System malfunction	XFI system malfunction. Please contact service.	MMDU Z communication failure. Problem with CAN bus.
Error	633	System malfunction	XFI system malfunction. Please contact service.	DCMDU Y communication failure. Problem with CAN bus.
Error	634	System malfunction	XFI system malfunction. Please contact service.	SMDU Anode communication failure. Problem with CAN bus.
E8xx SYSTEM CONFLICTS				

E9xx INFRASTRUCTURE ERRORS				
Error	905	System malfunction	XFI system malfunction. Please contact service.	Checksum error in tubehead EEPROM.
Error	906	System malfunction	XFI system malfunction. Please contact service.	Checksum error in collimation calibration data
Error	928	System malfunction	XFI system malfunction. Please contact service.	PathFinder cannot solve trajectory.
Error	960	System malfunction	XFI system malfunction. Please contact service.	CPU update failed
Error	961	System malfunction	XFI system malfunction. Please contact service.	Software update failed
Error	970	System malfunction	XFI system malfunction. Please contact service.	CPU watchdog timeout. System was reset, indicates software fault.
Error	972	System malfunction	XFI system malfunction. Please contact service.	MMDU Z watchdog timeout. System was reset, indicates software fault.
Error	973	System malfunction	XFI system malfunction. Please contact service.	MMDU X / O watchdog timeout. System was reset, indicates software fault.
Error	974	System malfunction	XFI system malfunction. Please contact service.	DCMDU Y watchdog timeout. System was reset, indicates software fault.
Error	975	System malfunction	XFI system malfunction. Please contact service.	SMDU anode watchdog timeout. System was reset, indicates software fault.

X0104776/C

14 Cleaning and disinfection

NOTE

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

NOTE

Use a Planmed approved cleaning agent and surface disinfectant.

NOTE

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

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.

Planmed approved cleaning agents/disinfectants

- Alpro IC 100
- Alpro Clean wipes
- Ecolab Incidin Oxywipe S
- Clinell Universal wipes

Patient supports and other surfaces

Wipe patient supports after each patient using a Planmed approved surface disinfectant.

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

X0249266/B

15 Automatic / manual exposure mode

The AEC (automatic exposure control / manual exposure button is used to select either automatic or manual mode of exposure. In AEC mode the kV value is based on the preselected value for each anatomy and patient size. AEC adjusts the preselected mAs value in order to optimize the patient dose. The mAs adjustment is based on the scout image analysis and thus taking scout images is compulsory when using AEC. In manual mode, however, it is possible to select higher mAs and kV values too high for appropriate normal imaging. This will result in excessive absorbed dose and could be harmful for the patient. However according to some references only a dose in the range of 1000 mGy may result in deterministic effects for the patient. Dose alert limit where user is informed about exceeding the set limits can be adjusted from the service settings.

NOTE

Do not use AEC if metal is present in the object to be imaged.

X0249267/B

15.1 XFI AEC principles

The AEC operation is based on a principle where preselected kV and mAs values are chosen for each anatomy and patient size. When scout images are acquired the system measures the signal levels at the detector in the whole area covered by the imaged object. In order to ensure high enough signal level the lowest signal levels dominate in the optimal mAs calculation. Signal measurement is based on the areas where the attenuation is highest. Thus, detector areas that receive direct radiation do not even partially deteriorate the image quality. The operation of AEC is strongly dependent on the human tissue like objects to be imaged and for this reason it is not recommended to use the AEC when metal is present in the object to be imaged as metal implants interfere with AEC functionality and may cause inferior images.

AEC operates in the kV range between 80 kV and 140 kV and the mAs range is 22-800 mAs. The used mAs is calculated based on the targeted detector signal level, patient size and selected anatomy. Signal target levels can be programmed from service settings.

AEC affects only the mAs value and maximum correction is ± 20 % compared to preselected initial value.

X0105302/D

16 Stray radiation measurements

The international standard IEC 60601-2-44 is applied in the stray radiation measurements. A CTDI (PMMA, West Physics 000138) phantom (Ø320 x 140 mm) has been used for the measurements. The values were measured at two planes (**XY** and **XZ** planes) the phantom being in the centre of the planes.

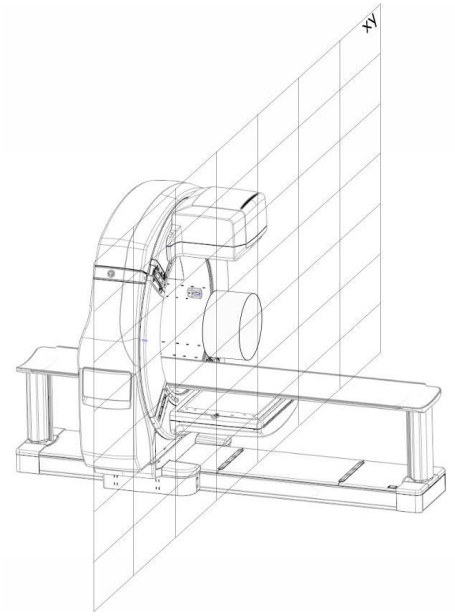
The unit of measurement was air kerma per mAs applied to the X-ray tube during normal use. The **Head 1 Jaw** protocol were used: FOV size 200x200 mm, 140 kV and 200 mAs. Values are presented in nGy/mAs.

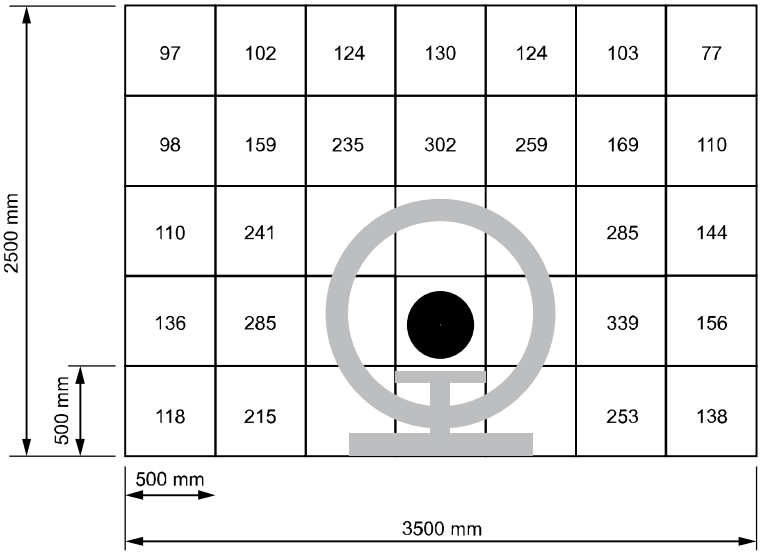
The actual stray radiation values are calculated with formula:

Stray Radiation = factor x mAs

where **mAs** is the milliampere second value in the protocol in question.

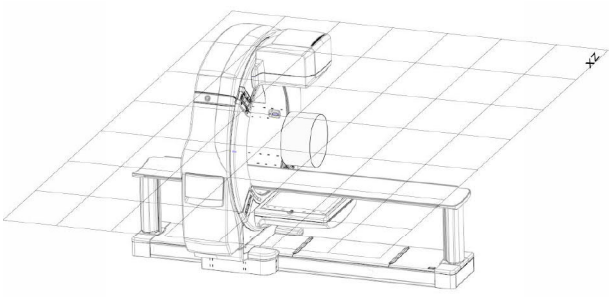
Stray radiation in XY-plane





factor	nGy/mAs
FOV size	Ø200x200 mm
tube voltage	140 kV
mAs	200

Stray radiation in XZ-plane



30	143	246	270	282	169	31
30	57	482	640	513	49	38
97	56				109	158
150	281				594	315
220	541	1460	2540	2220	606	380
193	323	590	711	745	417	303
156	223	337	357	352	263	190

3500 mm

500 mm

500 mm

3500 mm

factor	nGy/mAs
FOV size	Ø200x200 mm
tube voltage	140 kV
mAs	200

X0104752/C

17 Service

To guarantee user and patient safety and to ensure consistent image quality, the X-ray unit must be checked and recalibrated by the manufacturer's qualified service technician annually or after every 10 000 exposures if this is sooner. Refer to the X-ray unit's technical manual for complete servicing information.

All cyber security software updates listed in a technical bulletin must be installed on the X-ray unit.

X0104777/C

18 Disposal

In order to reduce the environmental load over the product's entire lifecycle, Planmed products are designed to be as safe as possible to dispose of. Planmed 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 XFI WORKSTATION

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

X0104779/E

19 Technical specifications

Classification	
Medical Device Directive	93/42/EEC (Class IIb)
RoHS	2011/65/EU
IEC 60601-1	Class I, type B
CISPR 11	Class A
IP Classification	IPX2,X0
Applied parts (according to IEC 60601-1: 2012)	
Patient couch and supports	As shown in section *Patient contacting components* in user's manual.
Generator (according to IEC 60601-2-7: 1998)	
	Resonant-mode, 60 - 100 kHz
X-ray tube	
	RTM782HS or RAD-14
Focal spot size (according to IEC 60336: 2005)	
	0.3 mm / 0.6 mm
Filtration	
3D	Total 2.5 mm Al + 0.2 mm / 0.5 mm Cu / variable thickness bowtie filter
2D projection radiography	Total 2.5 mm Al + selectable 0.2mm / 0.5mm Cu filter
Tube housing front cover quality equivalent filtration (not included in the specified total filtration)	0.3 mm Al @ 70 kV / HVL 2.6 mm Al
Anode voltage	
3D	80 - 140 kV ±5%
2D projection radiography	80 - 140 kV ±5%
Anode current	
3D	5 - 100 mA ±10%
2D projection radiography	5 - 100 mA ±10%
mAs range	
	min. / max. as indicated ±(10% + 0.2 mAs)
Dose range and accuracy	
	Dose range min. / max. as indicated on system user interface. Accuracy of dosimetric indication (DAP, CTDI): ±40%
Linearity of radiation output	
	< 0.1
Exposure time	
3D	2.8 s - 18 s
2D projection radiography	14 ms - 1000 ms

SID	
	1084 mm
Magnification	
3D	1.8
2D projection radiography	Variable
Line voltage	
	200 - 240 V~ / 50 - 60 Hz Single phase / Split phase
Line current	
	16 - 20 A
Input power	
Stand by	280 VA
Exposure	3600 W
Line harmonics	
	Cos better than 0.9
Max. permissible apparent impedance of supply mains	
	0.375 Ohms
Max. continuous heat dissipation	
	550 W
Internal fuse(s)	
User replaceable - 1 fuse on permanently installed X-ray units	200 - 240 V~ / 16A FF H 500 V
Type	195100 ELU
Batteries	
Device clock battery BTP (7056-26 PCB)	Lithium battery: 3V CR2032 Panasonic / Varta
Remote controller battery	Li-Ion Battery pack 3.7 V 600mAh Renata ICP622540PMT
Max. weight	
Base unit	approx. 500 kg (1102 lb)
Image properties	
Flat panel pixel size	148 µm
Flat panel active surface	432 x 432 mm (17.01 x 17.01 in.)
Mode of operation	
	Continuous operation with intermittent loading
Remote control and XFI unit	
Frequency bands	Bluetooth LE: 2402 - 2480 MHz
Output power	Bluetooth LE: 9.8 dBm (DSSS) / 19.6 dBm (FHSS) (E.I.R.P)
Antenna type and gain	Integral 1.0 dBi

Wireless charger for remote control	
Standard	WPC V1.2.4
Power	5 W
Frequency bandwidth	118 - 148 kHz

Original manufacturer

Planmed Oy, Sorvaajankatu 7, FIN-00880, Helsinki, Finland

Phone: +358 20 7795 300, Fax: +358 20 7795 664

http://www.planmed.com/

X0146102/C

19.1 Environmental requirements

Operating

Temperature	+20°C - +30°C (+68°F - +86°F)
Relative humidity	25 - 75% RH (non-condensing)
Air pressure	800 - 1060 hPa
Max. altitude	2000 m (1.25 miles)
Cooling	Sufficient cooling/ventilation must be made available and operating to guarantee above ambient temperature.

Storage

Temperature	-10°C - +50°C (+14°F - +122°F)
Relative humidity	10 - 90% RH (non-condensing)
Air pressure	700 - 1060 hPa

Transportation

Temperature	-20°C - +60°C (-4°F - +140°F)
Relative humidity	10 - 90% RH (non-condensing)
Air pressure	700 - 1060 hPa

X000077/A

19.2 Essential performance description

Planmed XFI device has two distinctive systems **Automatic Control System** and **Radiation Control System**

that automatically monitor for movement abnormalities and ensures that the X-ray output remains in specified limits.

If electromagnetic interference causes the loss of EP during the scanning process, resulting in the scanning being halted, all acquired data up to that point are stored in the reconstruction PC and can be manually retrieved if necessary.

Automatic Control System

The Planmed XFI device incorporates an advanced Automatic Control System primarily focused on motion control. This system ensures precise and consistent scanning during the imaging process. In event of unexpected patient movements or anomalies, the system can pause or abort the scan to prevent potential harm.

Radiation Control

The Planmed XFI device includes a sophisticated Radiation Control System dedicated to patient safety. Radiation Control System employs a beam collimation system to restrict the X-ray beam to the specific area of interest, minimizing exposure to surrounding tissues. Radiation Control System incorporates dose modulation algorithms that adapt the radiation dose based on the thickness and density of the imaged anatomy, optimizing image quality while minimizing the radiation exposure. Dose monitoring and recording features track and document the radiation dose delivered to each patient, ensuring compliance with recommended dose limits. The Planmed XFI device adheres to international radiation safety standards, with the Radiation Control System regularly undergoing quality assurance checks to maintain accurate and consistent dose delivery.

X000134/A

19.3 EMC information

WARNING

Use of any accessories and cables other than those specified in Planmed XFI accompanying documentation, with the exception of cables sold by Planmed as replacement parts for internal components, may result in increased emission or decreased immunity of the device.

WARNING

Planmed XFI should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify its normal operation in the configuration in which it is used.

CAUTION

To make sure electromagnetic emissions and immunity do not degrade over the lifetime of the equipment, do not modify the Planmed XFi system in any way. Only qualified Planmed service technicians may conduct service and maintenance procedures.

CAUTION

In the event of electromagnetic disturbance caused by a source that generates higher levels of transmission power than tested in immunity testing, the ME device might lose essential performance and cause the imaging process to halt. The operator will be presented with an error message.

Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
Emission / Radiated CISPR 11	Class A 30 - 1000 MHz	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emissions test	Compliance	Electromagnetic environment – guidance
Emission / Conducted CISPR 11	Class A 0.150 - 30 MHz	This X-ray unit is intended to be used in a professional healthcare environment such as hospitals, clinics and similar environments.
Emission / Harmonic distortion IEC 61000-3-2	Class A	
Ethernet / Conducted IT-port CISPR 32	Class A 0.150 - 30 MHz	

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	Test/compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2,4,8,15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions IEC 61000-4-11	0 % *UT*; 0,5 cycle (8/45° steps) 0 % *UT*; 1 cycle 70 % *UT*; 25 cycles 0 % *UT*; 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 15 cm safety distance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Immunity test	Test/compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** **d = 1.2 √P** **d = 1.2 √P (80 MHz to 800 MHz)** **d = 2.3 √P (800 MHz to 2.7 GHz)** where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
ISM band (industrial, scientific and medical)	6.765 to 6.795 MHz 13.553 to 13.567 MHz 26.957 to 27.283 MHz 40.66 to 40.70 MHz 6 Vrms	
RF- Radiated EM fields IEC 61000-4-3	80 MHz - 2.7 GHz 3 V/m, 80% AM at 1 kHz	
Radiated RF spot frequencies IEC 61000-4-3	385 MHz, 27 V/m 450 MHz, 28 V/m 710, 745, 780 MHz, 9 V/m 810, 870, 930 MHz, 28 V/m 1720, 1845, 1970 MHz, 28 V/m 2450 MHz, 28 V/m 5240, 5500, 5785 MHz, 9 V/m	
Immunity to proximity mg-fields IEC 61000-4-39	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 15 cm (6 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

At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.7 GHz d = 2.3 √P ()
0.01	0.2	0.2	0.3
0.1	0.4	0.4	0.7
1	1.2	1.2	2.4
10	4.0	4.0	8.0
100	12.0	12.0	24.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

X0153200/D

19.4 Imaging system network requirements

In this section the imaging system network architecture related requirements, recommendations and notes are listed.

Introduction

The imaging system is designed to be installed in a closed local area network (LAN) with static IP addresses. Data in the system is transferred by using both UPD and TCP protocols. Workstation PC firewall and antivirus scanner need to be properly configured to let both UPD and TCP traffic to pass to all X-ray unit imaging system applications: XFI workstation application, Device Tool and Imaging System Updater.

The imaging system supports auto-discovery so it does not require manual IP configuration. The device(s) found from the network are automatically displayed with the Device Tool and the Imaging System Updater.

The imaging system implements its internal communication with a standard connectivity framework from OMG Data Distribution Service (DDS).

General requirements

- The minimum requirement for the Ethernet cables used in the imaging system network is Category 6 (Cat 6).

  All cables delivered with the X-ray unit are Cat 6 cables.

- Each image acquisition workstation (i.e. Romexis workstation) in the network has to have an unique IP address.
- The X-ray unit, Reconstruction PC (Reco PC) and XFI workstation network should be configured as a standalone network.
- If the XFI workstation is connected to a common network, a second network card is necessary and a secure firewall and antivirus software must be installed.
- Connection of the imaging system to an IT-network that includes other equipment, or changes made to that network, could result in previously unidentified risks to patient, operators or third party that the responsible IT personnel should identify, analyse, evaluate and control.

Network security

Good computer and network security must be followed in any environment where the X-ray unit is installed and used. It is recommended to install industry standard firewall and virus protection on both client and servers.

All operating systems, as well as firewall and virus protection software, should be kept up to date. All security patches should be installed.

Place the required and trusted programs on a white list.

NOTE

Firewall that protects the network where the imaging system is located shall only have outbound HTTP access to whitelisted domains. The whitelisting prevents malware execution.

NOTE

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

NOTE

The Reconstruction PC should be installed in a restricted access area, for example, placed in a locked cabinet. Alternatively, secure the Reconstruction PC with a lock using the holes provided in the PC shell.

NOTE

It is recommended to change the Reconstruction PC (RecoPC) password during installation, see the XFI technical manual for more information. .

NOTE

It is recommended to switch on BIOS authentication during system setup. Refer to the Reco PC manufacturer's instructions.

Firewall settings

The firewall settings must be configured to let communication through to the XFI workstation application from the X-ray unit and the Reconstruction PC (Reco PC).

This requires inbound UDP traffic to be allowed for all X-ray unit imaging system executables: XFI workstation application, Device Tool and Capture Dialog.

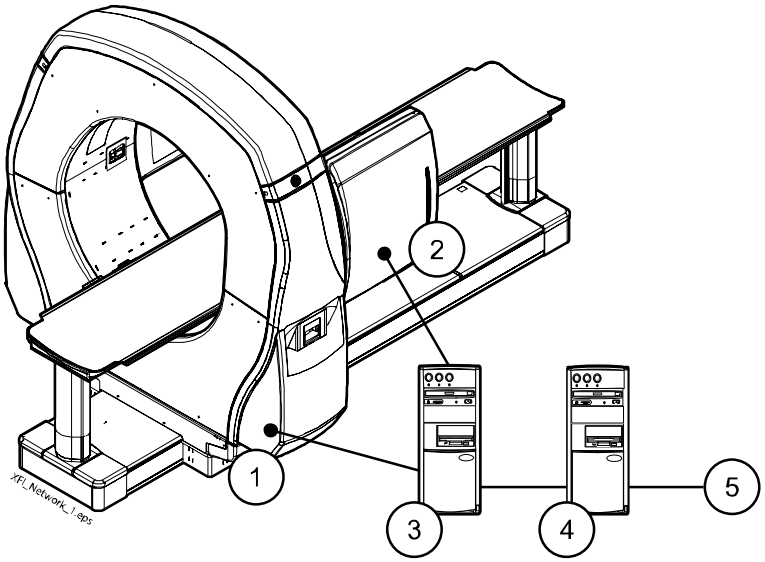
- The following UDP inbound ports must be open:

  9650, 9651, 9660-9699

- The following TCP inbound ports must be open:
  7401, 7402, 7411, 7413, 7431, 7433, 7501

IP addresses

The figure below shows the IP network setup used with the Planmed XFI imaging system.



1 Ethernet cable connection from X-ray unit to Reco PC
2 Optical cable connection from detector to Reco PC
3 Reconstruction PC (Reco PC)
4 Imaging workstation
5 Clinic network (optional)

In the following, the default network settings are listed.

Setting	Default value
Domain	9
X-ray unit	IP address: 223.255.255.1 Netmask: 255.255.255.0 Gateway: 0.0.0.0
Detector	IP address: 192.168.1.1 Netmask: 255.255.255.0
Reconstruction PC	IP addresses: eth0 (to X-ray unit): 223.255.255.10 eth1 (to detector): 192.168.1.2 eth1:0 (internal, to pixdyn host sw): 192.168.0.2 em1 (to Romexis workstation): 192.168.66.1
Imaging workstation	IP address: 192.168.66.X Netmask: 255.255.255.0 Gateway: 0.0.0.0

NOTE

The reconstruction PC IP address should not be changed.

Planmed

Planmed Oy | Sorvaajankatu 7 | 00880 Helsinki | Finland

tel. +358 20 7795 300 | fax +358 20 7795 664 | sales@planmed.com | www.planmed.com