

Planmed



Planmed Verity<sup>®</sup>  
*extremity scanner*

*user's manual*

EN

20007788

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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# Table of contents

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<b>1</b>	<b>Introduction.....</b>	<b>1</b>
1.1	Intended use.....	1
1.1.1	Usage environment.....	1
1.1.2	Intended user.....	2
1.1.3	Intended patient population.....	2
1.2	Medical purpose.....	2
1.3	Conformity to standards.....	2
1.4	Software versions.....	2
<b>2</b>	<b>Associated documentation.....</b>	<b>3</b>
<b>3</b>	<b>Symbols on product labels.....</b>	<b>4</b>
<b>4</b>	<b>Safety precautions.....</b>	<b>6</b>
4.1	Potential residual risks.....	10
4.2	Reporting serious incidents.....	10
<b>5</b>	<b>Checklist before operation.....</b>	<b>11</b>
<b>6</b>	<b>In case of emergency.....</b>	<b>12</b>
6.1	Emergency stop button.....	12
6.2	Unlocking tray mechanism.....	12
<b>7</b>	<b>X-ray system.....</b>	<b>14</b>
7.1	Characteristics of use.....	14
7.2	System setup.....	14
7.2.1	Switching on system.....	16
7.2.2	Switching off system.....	17
7.2.3	Disconnecting X-ray unit.....	18
7.2.4	Connecting power cable.....	18
<b>8</b>	<b>Main parts.....</b>	<b>19</b>
8.1	Gantry.....	20
8.2	Touch screen control panel.....	21
8.2.1	Screen controls.....	22
8.2.2	Adjusting touch screen control panel height.....	22
8.2.3	Adjusting touch screen control panel tilt angle.....	22
8.3	On/off switch and computer On/Off button.....	23
8.4	USB ports.....	23
8.5	Patient positioning trays and supports.....	24
8.5.1	Patient positioning trays usage suggestions.....	25
8.5.2	Attaching and removing patient positioning trays.....	26
8.6	Positioning joysticks.....	26
8.7	Exposure switch and indicator lights.....	27
<b>9</b>	<b>Accessories.....</b>	<b>29</b>
9.1	Scattered radiation shield.....	29
9.2	Stack Rack (optional).....	30
9.2.1	Setting up Stack Rack.....	30
9.2.2	Stack Rack placement.....	31
9.2.3	Placing accessories on Stack Rack.....	32

	9.2.4	Cleaning Stack Rack.....	33
<b>10</b>		<b>Verity Manager.....</b>	<b>34</b>
	10.1	Login.....	34
	10.1.1	Changing password for Windows account.....	34
	10.1.2	Creating new Windows user.....	34
	10.2	Modality worklist.....	36
	10.2.1	Searching patients.....	36
	10.2.2	List.....	37
	10.2.3	Acquisition.....	37
	10.3	Local patient registry.....	37
	10.3.1	Searching patients in database.....	38
	10.3.2	Sorting patient list.....	39
	10.3.3	Creating new patients.....	39
	10.3.4	Editing patients.....	40
	10.3.5	Deleting patients.....	40
	10.3.6	Clearing patient list.....	41
	10.3.7	Continuing previous study.....	41
	10.4	Local study archive.....	42
	10.4.1	Searching studies.....	42
	10.4.2	Query/Retrieve images.....	42
	10.4.3	Opening studies.....	43
	10.4.4	Exporting studies.....	43
	10.4.5	Importing studies.....	47
	10.4.6	Clearing search results.....	47
	10.4.7	Deleting studies.....	47
	10.4.8	Sending studies to archive.....	48
	10.4.9	Verifying storage status.....	48
	10.4.10	Lock/unlock studies.....	48
	10.4.11	Recovering studies.....	48
<b>11</b>		<b>Patient positioning.....</b>	<b>51</b>
	11.1	Pre-set drive.....	51
	11.1.1	Pre-set positions for different body parts.....	53
	11.2	Patient positioning controls.....	56
	11.2.1	Joystick controls.....	56
	11.2.2	Field of view and positioning lasers.....	57
	11.2.3	Positioning camera and display (optional).....	58
	11.3	Positioning with scattered radiation shield.....	59
	11.3.1	Wrist and hand.....	59
	11.3.2	Knee, ankle, foot and toes.....	60
	11.3.3	Weight-bearing imaging of knee and ankle.....	61
	11.3.4	Weight-bearing imaging of foot and toes.....	61
<b>12</b>		<b>Imaging workflow.....</b>	<b>63</b>
	12.1	Preparing patient.....	63
	12.2	Starting study.....	63
	12.3	Selecting imaging target.....	64
	12.4	Pre-set drive.....	65
	12.5	Selecting imaging values.....	66
	12.6	Positioning patient.....	67
	12.7	Scout exposure.....	67
	12.8	3D exposure.....	69
<b>13</b>		<b>Imaging examples.....</b>	<b>71</b>
	13.1	Right elbow.....	71
	13.2	Weight-bearing imaging.....	72

13.2.1	Weight-bearing imaging of right knee.....	73
13.2.2	Weight-bearing imaging of right foot (metatarsus).....	76
13.3	MaxScan imaging.....	79
13.4	Head & neck imaging.....	82
13.5	Hover tray imaging.....	86
13.6	Imaging with eFOV.....	87
13.6.1	Patient positioning with eFOV.....	88
13.6.2	Weight-bearing imaging of foot with eFOV.....	88
13.6.3	Imaging wrists with eFOV.....	90
13.6.4	Reconstructing eFOV after imaging.....	93
<b>14</b>	<b>Stitching volumes.....</b>	<b>94</b>
14.1	Before stitching.....	94
14.1.1	Stitching requirements.....	94
14.2	Stitching workflows.....	95
14.2.1	Foot-stitching with vertical tray.....	95
14.2.2	Weight-bearing foot stitching (small <24 cm).....	99
14.2.3	Weight-bearing foot stitching (large >24 cm).....	104
14.2.4	Hand and wrist stitching.....	112
<b>15</b>	<b>Dose notifications.....</b>	<b>117</b>
<b>16</b>	<b>Scout exposure.....</b>	<b>118</b>
16.1	Acquiring scout images.....	118
16.2	Adjusting FOV.....	121
<b>17</b>	<b>3D exposure.....</b>	<b>124</b>
<b>18</b>	<b>Special consideration for pediatric imaging.....</b>	<b>127</b>
18.1	Pediatric Use: Summary.....	127
18.2	Patient positioning.....	127
18.3	Radiation protection.....	128
18.4	Exposure parameter recommendations for pediatric imaging.....	128
<b>19</b>	<b>Viewing and processing images.....</b>	<b>132</b>
19.1	Using viewing modes.....	132
19.2	Using processing tools.....	132
19.2.1	2D adjustment.....	132
19.2.2	Scroll slices.....	133
19.2.3	Slicer.....	136
19.2.4	3D adjustment.....	138
19.3	DICOM storage.....	139
19.4	Image properties.....	140
19.5	DICOM print.....	142
19.6	Reconstruction.....	143
<b>20</b>	<b>Quality Control.....</b>	<b>145</b>
20.1	Summary of QC tests.....	145
20.2	Accessing Quality Control mode.....	147
20.3	Phantoms.....	147
20.4	Quality Control (QC) tests.....	148
20.4.1	Visual checklist.....	149
20.4.2	Weekly / monthly QC test.....	149
20.4.3	HU accuracy test.....	154
20.4.4	Modulation transfer function (MTF) test.....	159
20.4.5	Geometry test.....	163
20.4.6	Slice thickness test.....	168
20.4.7	AEC reproducibility test.....	172

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<b>21</b>	<b>Calibration.....</b>	<b>177</b>
21.1	Summary of calibration procedures.....	177
21.2	Flat field calibration.....	178
21.2.1	Performing Flat-Field calibration.....	179
21.3	Geometry calibration.....	180
21.3.1	Performing geometry calibration.....	181
21.4	HU calibration.....	182
21.4.1	Performing HU calibration.....	183
21.5	Preheat calibration.....	187
21.5.1	Performing preheat calibration.....	187
<b>22</b>	<b>Support.....</b>	<b>189</b>
22.1	Notification and error messages.....	191
22.2	List of abbreviations.....	196
22.3	Printing audit trail.....	197
<b>23</b>	<b>Service.....</b>	<b>198</b>
<b>24</b>	<b>Cleaning and disinfection.....</b>	<b>199</b>
<b>25</b>	<b>Transportation.....</b>	<b>200</b>
25.1	Preparing device for transportation.....	200
25.2	Raising device onto its wheels.....	202
25.3	Returning device from transportation position to operating position.....	204
<b>26</b>	<b>Disposal.....</b>	<b>206</b>
<b>27</b>	<b>Default exposure values.....</b>	<b>208</b>
<b>28</b>	<b>Automatic / manual exposure mode.....</b>	<b>212</b>
28.1	Extremity scanner AEC principles.....	213
<b>29</b>	<b>Technical specifications.....</b>	<b>214</b>
29.1	Dosimetric information.....	215
29.1.1	Reference air kerma.....	215
29.1.2	Dose area product.....	216
29.1.3	CTDIvol.....	217
29.2	Environmental requirements.....	217
29.3	Original manufacturer.....	217
29.4	Dimensions.....	217
29.5	Device label.....	218
<b>30</b>	<b>QC test &amp; calibration forms.....</b>	<b>219</b>

# 1 Introduction

This manual describes how to set up and use the **Planned Verity extremity scanner** and the respective system, which are further in the text referred to as **Planned Verity**, the system or, where the unit alone is expressly concerned, just the device.

## 1.1 Intended use

Planned Verity is intended to be used for X-ray cone beam computed tomography imaging of anatomies within upper and lower extremities, neck and head.

There are no known contraindications to use of Planned Verity.

### NOTE

Please read this manual carefully before using the system.

### NOTE

The use of Planned Verity X-ray unit is allowed only under supervision of a health care professional.

### NOTE

This manual may contain descriptions or pictures of optional elements not included in the standard delivery.

### NOTE

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



### WARNING

Skin irritation may result with prolonged excessive imaging.

### CAUTION

Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, appropriate conventional medical imaging should be used such as computed tomography or magnetic resonance imaging.

### 1.1.1 Usage environment

This X-ray unit is intended to be used in a professional healthcare environment such as hospitals, clinics, multiple treatment and intensive care facilities and similar environments.

#### Space requirements

The absolute minimum dimensions for the operating space are presented in the following table.

Minimum space requirements		
Height	Width	Depth
1.8 m (5.9 ft)	2.4 m (7.9 ft)	2.0 m (6.6 ft)

### 1.1.2 Intended user

Radiographer

### 1.1.3 Intended patient population

Age From a child that can stay put to geriatric without any specific age limits.  
Sex Unlimited  
Weight < 135 kg  
Height Patients standing in weight-bearing imaging: 122,6...190,1 cm

## 1.2 Medical purpose

This product is intended to provide clinically valuable diagnostic information for orthopedists and radiologists in the diagnosis of injuries and diseases within the extremities, head and neck. The key clinical applications will include but is not limited to skeletal injuries (e.g. fractures), malformation (e.g. growth malformations) and diseases (e.g. rheumatoid arthritis). With MaxScan imaging option the clinical application is extended to cover sinuses and maxillofacial anatomies, and with Head & Neck imaging option head and neck area. The unit provides high resolution volumetric image data from the target of imaging that can be viewed as cross-sectional slice images or 3D renderings.

## 1.3 Conformity to standards



The extremity scanner fulfils the requirements of Medical Device Regulation (EU) 2017/745, Class IIB and RoHS, REACH and WEEE.

## 1.4 Software versions

This manual is valid provided that the following software versions are installed in the extremity scanner:

- Verity AWS SW 3.3.0
- Verity Embedded SW 3.3.0



## 2 Associated documentation

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

- User's Manual  
For health care professionals. Describes the X-ray unit and its different parts as well as gives instruction for operating, quality control, calibration and cleaning the X-ray unit.
- Installation Manual  
For service personnel. Describes how to install the X-ray unit.
- Technical Manual  
For service personnel. Gives instructions for service situations.

### 3 Symbols on product labels



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



Consult electronic instructions for use (Standard ISO 7000-1641).



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



Type B applied part (Standard IEC 60417).



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



Medical Device



Class 1 laser product (Standard EN 60825-1: 2007)



Consult accompanying documentation for moving the device.



Do not step on gantry ring.



Ionizing radiation (Standard ISO 7010)



General warning (Standard ISO 7010).



Safe working load (IEC 60601-1)

## 4 Safety precautions

The following adverse events may be associated with the use of this X-ray unit for imaging extremities and the maxillofacial area:

- Excessive X-ray exposure
- Electric shock
- Infection



### **WARNING**

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

### **CAUTION**

Make sure to position the unit so that the mains cable is easy to unplug.



### **WARNING**

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

### **CAUTION**

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

### **CAUTION**

X-ray unit must only be used for scanning of upper and lower extremities and, if approved by local authorities, imaging of the maxillofacial area and head and neck.

### **CAUTION**

The use of X-ray unit is only allowed under supervision of a health care professional.

### **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**

If the device shows any signs of oil leakage, disconnect it from mains 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 device. 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**

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

**CAUTION**

Do not step on gantry ring.

**CAUTION**

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

**CAUTION**

When driving the gantry with joysticks make sure there is enough space for the gantry to move freely without causing any hazard to the patient, to yourself or the surrounding property, and, especially, that there is no danger of anything colliding or squeezing under the gantry or between the gantry and the base support.

**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**

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**

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**

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.

**NOTE**

Some LED lights may interrupt the extremity sensor and should not be used.

**NOTE**

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

**NOTE**

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

**NOTE**

If the device is not connected to an Uninterruptible Power Supply (UPS), disconnect the device from mains during lightning storms.



**NOTE**

**FOR EUROPEAN USERS:** Class 1 laser product (Standard EN 60825-1:2007).

**NOTE**

EMC requirements have to be considered, and the equipment must be installed and put into service according to the specific EMC information provided in X-ray unit Technical Manual.

**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**

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.

**NOTE**

Only use a computer specified by manufacturer.

**NOTE**

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

**NOTE**

Check the condition of the positioning trays regularly. If you notice any signs of cracks or breakage on the tray discontinue use.

**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). Equipment not complying to IEC 60601 shall be kept outside the patient area (more than 2m (79 in.) from the system). 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**

Never place or hang any objects on any part of the system.

**NOTE**

Use CT side marker to ensure correct image laterality.

**NOTE**

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

**Precautions for power and hardware failure****NOTE**

It is recommended to install an Uninterrupted Power Supply (UPS) to support the computer in case of 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****CAUTION**

Do not make any changes to your computer's security settings.

**CAUTION**

Do not connect the device to the Internet.

**CAUTION**

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

**CAUTION**

Windows Defender should be used to scan the workstation for computer viruses on weekly basis. However, Windows Defender's real-time scanning should not be enabled so that it does not interfere with imaging.

## 4.1 Potential residual risks

The following is a list of potential residual hazards that remain when using the Planmed Verity, although mitigation efforts have been implemented:

### Injuries

Potential for physical injuries exists in following cases:

- Patient may have challenges to maintain stability and fall in weight-bearing mode.
- Potential device collisions during transportation of the device in challenging environment (e.g. Inclined floors).
- Movement of the device parts may potentially cause injuries in case of system failure.

### Irradiation

During the exams, patients receive X-ray dose to allow the detection and diagnosis of the injuries in the extremities and head and neck. Images may be repeated and patients may receive additional dose in the following cases:

- Degraded image quality due to inadequate patient positioning, patient motion drift of calibration or Invalid material in the field of view.
- Abort or failure of the system.

### False diagnosis

Potential for false diagnosis exists in following cases:

- Diagnosis of a patient may potentially be performed on images belonging to another patient if the wrong patient was selected at acquisition.
- Wrong image presentation due error in patient positioning, body part selection or on anatomy laterality selection.
- Inadequate diagnosis is based on degraded image quality due to drift of calibration.
- Misdiagnosis if extended Field Of View (eFOV) area is expected to provide same image quality as Field Of View (FOV).

### Excessive leakage current

Potential for electric shock exists in following cases:

- A USB device with external power is connected to the USB port intended for an USB stick.
- Workstation Ethernet cable connected to the Plancan port.

## 4.2 Reporting serious incidents

Serious incidents that have occurred in relation to the device must be reported to the manufacturer and the local competent authority.



## 5 Checklist before operation

### CAUTION

It is very important that the place where the system is to be used and the position from which the user operates the device 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.

Before using the system make sure that:

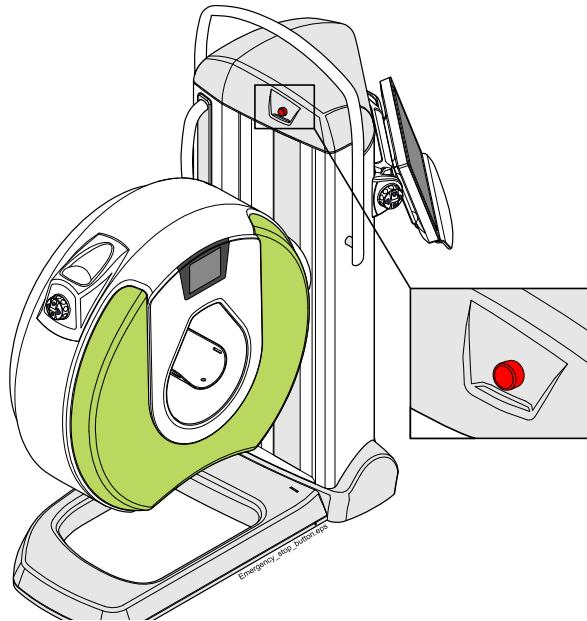
- You are fully acquainted with the appropriate radiation protection measures and these operating instructions.
- The exposure switch is installed in an area shielded from radiation.
- The exposure button and holder will be installed at a safe distance from the X-ray unit. The distance will depend on the local radiation safety regulations.
- The power supply you intend to use is suitable for the device (if the X-ray unit is being used in a new location for the first time): The X-ray unit is designed to operate using a line voltage between 100 V~, 115 V~ / 50-60 Hz and 200 - 240 V~ / 50/60 Hz and a line current between 8 and 17 A.
- The viewing facilities for the digital imaging are available and that the viewing conditions are optimal for the soft copy reading.
- The unit and the PC have had time to warm up for at least 20 minutes before starting. Insufficient warm-up time may result in lower image quality.

## 6 In case of emergency

### 6.1 Emergency stop button

The red emergency stop button is located on the hood cover of the vertical column

1. Stop the system from operating by pushing in the red emergency stop button located on the hood cover of the vertical column.



When the emergency stop button is pushed in, all movements of the system are blocked and no radiation is generated.

2. Guide the patient away from the system.
3. Release the emergency stop button by turning it.

### 6.2 Unlocking tray mechanism

If pushing in the emergency button is not sufficient for release (e.g. due to mechanical failure) proceed as follows:

Push the positioning tray mechanism downwards using force of approximately 15 kg mass.

### CAUTION

Do not push the tray when the device is switched on.



### NOTE

Do not push the tray in normal use. The positioning tray should be pushed downwards only in case of malfunction and when the tray is stuck in upper position.

When the tray is positioned for example for weight-bearing imaging the mechanism can also be pushed in from the front of the device by pulling/pushing it manually. In such case, however, more force is required.

## 7 X-ray system

### 7.1 Characteristics of use

#### Selecting patient and imaging parameters

Patient, target and exposure parameters are selected from the touch screen (1).

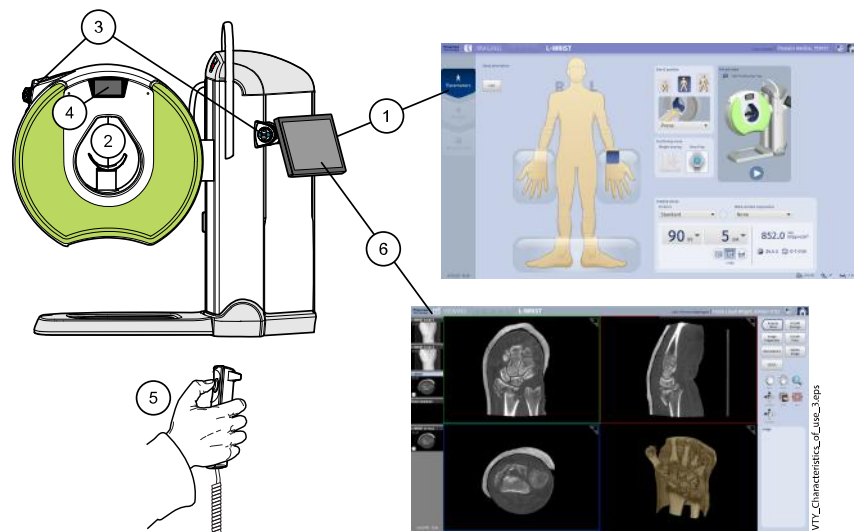
#### Positioning

The target is positioned by attaching the appropriate positioning tray (2) using the positioning controls of the touch screen control panel (pre-set drive), the joysticks (3) and the positioning lasers with an optional positioning display (4) (see sections "Touch screen control panel" on page 21 and "Positioning joysticks" on page 26). The gantry can be driven up and down, tilted backwards up to 90 degrees (gantry ring is horizontal) and forwards up to 15 degrees from vertical position.

#### Exposure

The exposure switch (5) is used to acquire images.

The acquired images are also displayed and manipulated from the touch screen control panel (6).



A general system setup is shown in section "System setup" on page 14.

Typically, the following components are required to generate digital X-ray images of high diagnostic value:

- Extremity scanner
- Radiation Shield (optional); the required protection can also be provided by other means.

### 7.2 System setup

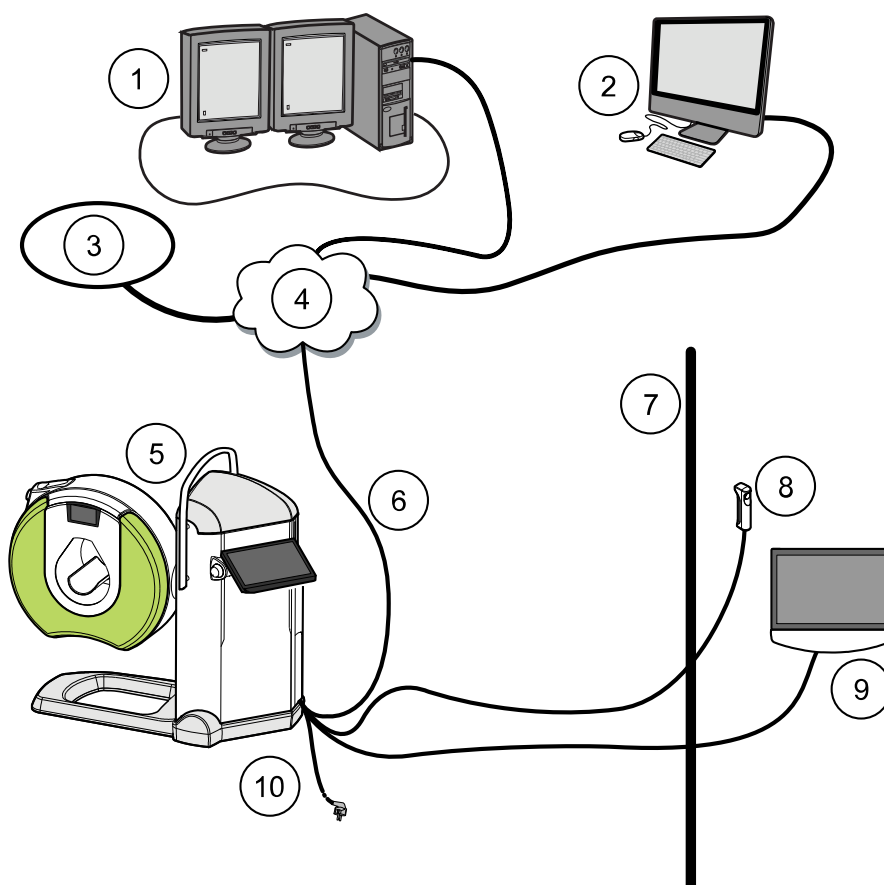
#### CAUTION

Do not connect to the device any items not specified as part of the system.

**CAUTION**

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

The functioning setup is illustrated below.



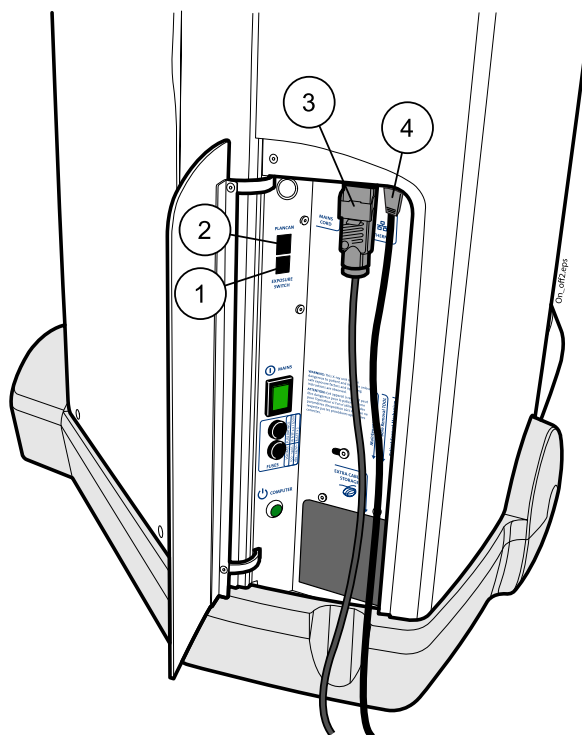
- |   |                            |
|---|----------------------------|
| 1 PACS workstation                                | 2 Review workstation (RWS) |
| 3 HIS/RIS   | 4 Private network          |
| 5 Extremity scanner                               | 6 Ethernet cable           |
| 7 Radiation protection screen                     | 8 Exposure switch          |
| 9 Secondary touch screen control panel (optional) | 10 Power cord              |

1. To start the setup, connect the power cord of the device to mains voltage.
2. Connect the Ethernet cable to the facility information system (Ethernet isolator Baaske MI 1005 (20006446) inside the unit).
3. Connect the exposure switch cable to the device.
4. Carry out appropriate radiation protection measures.

**NOTE**

Only wall socket exposure lamp cable is allowed to be connected to Plancan socket.

Do NOT connect the Ethernet cable to the Plancan socket.



- 1 Exposure switch
- 2 Plancan socket
- 3 Power cord
- 4 Ethernet cable

The following cables are allowed to be used.

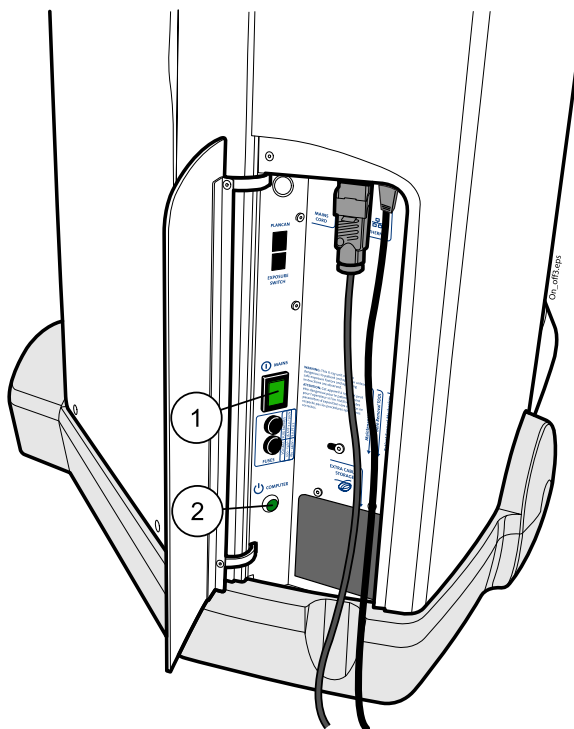
Name	Length	Type	Code
Exposure Switch Cable, Cross Connected	10 m	RJ12 Telephone Cable	30020103
Exposure Extension Cable	1.8 m	RJ12 Telephone Cable	20008287
Exposure Extension Cable	3 m	RJ12 Telephone Cable	20008462
Exposure Extension Cable	5 m	RJ12 Telephone Cable	20008456
Ethernet Cable	30 m	CAT 6 Unshielded	20002642

### 7.2.1 Switching on system

1. Open the small door at the backside of the vertical column.
2. Press the square mains On/Off switch (1).

The computer switches on automatically.

If the computer does not start automatically, press the round computer On/Off button (2).



- 1 Mains On/Off switch
- 2 Computer On/Off button

### 7.2.2 Switching off system

#### NOTE

Always switch off the system when it is not in use to minimise environmental impact by saving energy.

1. Go to *Home* screen by tapping the **Home** button.



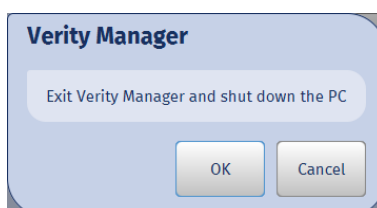
2. Tap the **Log off** button.



3. Tap **Exit and Shut down** button.



4. Tap **OK**.



5. Wait until the indicator light in the computer On/Off button has switched off.

6. Switch off the unit from the mains On/Off switch.

### **7.2.3 Disconnecting X-ray unit**

1. Disconnect the mains.
2. Disconnect the Ethernet cable from the device.
3. Disconnect the exposure switch from the device.

### **7.2.4 Connecting power cable**

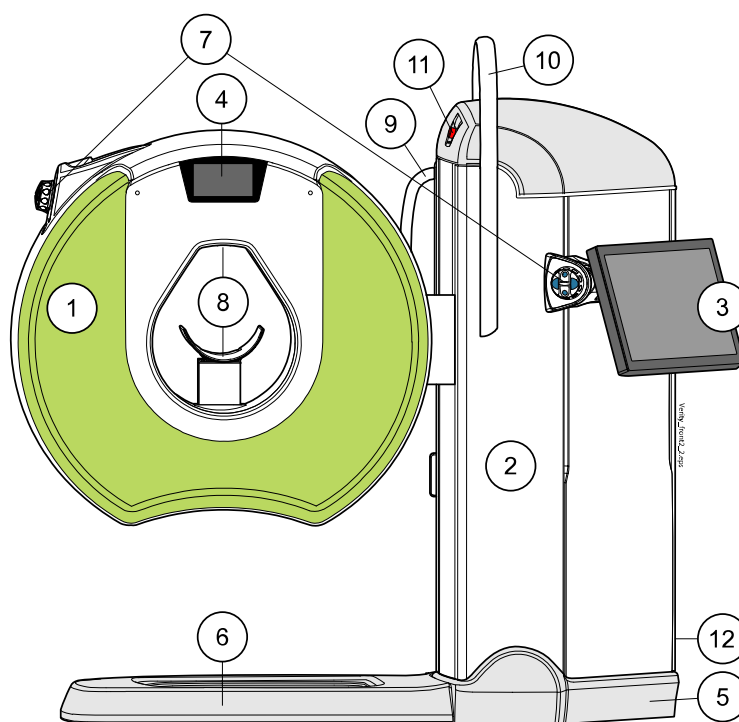
Before connecting detachable mains cord of the X-ray unit to the mains, make sure that the mains voltage and frequency correspond to the device plate.

Ensure that the X-ray unit is switched off before connecting to the mains.

The X-ray unit must always be connected to a grounded outlet to fulfill the safety directives stated.



## 8 Main parts

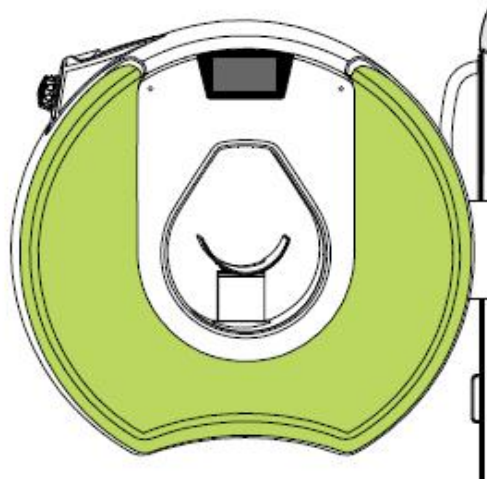


- |                              |                                    |
|------------------------------|------------------------------------|
| 1 Gantry                     | 2 Vertical column                  |
| 3 Touch screen control panel | 4 Information screen               |
| 5 Base                       | 6 Base support                     |
| 7 Joysticks                  | 8 Positioning lasers and trays     |
| 9 Support handle             | 10 Multi-purpose handle            |
| 11 Emergency stop button     | 12 On/Off switch (behind the door) |

## 8.1 Gantry

The adaptable gantry houses the X-ray tube and the digital flat panel detector. It has a drop-shaped bore in which the imaging area is located.

The body part to be exposed is positioned into the bore while the patient is sitting in the patient positioning chair, laying in bed, or, as in weight-bearing imaging, standing up in the middle of the gantry ring previously driven into horizontal position.



The gantry movements are controlled from the touch screen control panel (pre-set drive) and / or from the positioning joysticks (see sections "Touch screen control panel" on page 21 and "Positioning joysticks" on page 26).

The gantry can be driven up and down, tilted backwards up to 90 degrees (gantry ring is horizontal) and forwards up to 15 degrees from the vertical position.

The gantry can be driven faster when empty.

### CAUTION

Before driving the gantry make sure there is enough space for the gantry to move freely without causing any hazard to the patient, to yourself or the surrounding property.

### NOTE

If there is something under the gantry preventing it from moving, the anti-collision sensor in the gantry detects the object, automatically drives the gantry slightly upwards limiting colliding force approximately to 150 N (15 kg).

### NOTE

When a target is positioned into the gantry bore the system recognizes it, automatically turns on the laser lights and prevents the pre-set movements.

### NOTE

When the support handle is pulled out the movement range of the gantry is limited to prevent collision with the handle. To freely drive the gantry push the handle in.

### NOTE

If there is anything pressing the base support the sensor in the base support detects it and disables all downward movements.

**NOTE**

In case of collision when the gantry is tilted, the force of the movement is limited to 150 N (15 kg) by slip clutch to prevent damages. If the force exceeds 150 N (15 kg), the gantry will not move. To stop the gantry, release the joystick.

**NOTE**

The system is set to maintain a 12 cm space between the floor and the gantry at all times.

## 8.2 Touch screen control panel

The touch screen control panel is used to control all functions of the device such as adjusting exposure values, patient positioning, image acquisition, managing patient data as well as viewing and processing of images (see chapters "Imaging workflow" on page 63, "3D exposure" on page 124, "Modality worklist" on page 36, "Local patient registry" on page 37 and "Viewing and processing images" on page 132.)

To make a selection on the touch screen control panel, simply tap a text field or an icon with your finger or a touch screen stylus.

**NOTE**

Do not use sharp objects to operate the touch screen.

**TIP**

You can also control the device with a USB mouse connected to the device.

**NOTE**

The touch screen control panel is not intended for diagnostic use. To diagnose images use a suitable review workstation (RWS).

If exposures are taken from a separate shielded room an optional touch screen control panel and exposure switch can be used. The optional touch screen control panel is identical to the main touch screen control panel.

### 8.2.1 Screen controls

The screen controls can be found on the bottom side of the screen.

To open the monitor adjustment menu push the **Menu** button.

The following controls open at the bottom right corner of the screen.



1 Menu      2 Mute      3 Volume      4 Sleep mode      On/Off

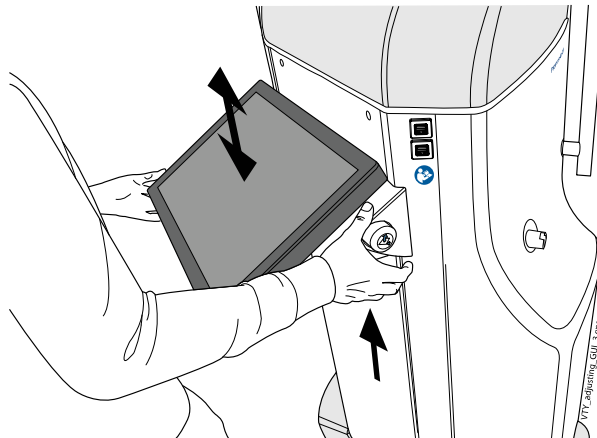
To turn off the screen push the **On/Off** button twice. When the screen is turned on the indicator light at the bottom of the screen turns from red to green.

**Green indicator light** screen is on

**Red indicator light** screen is off

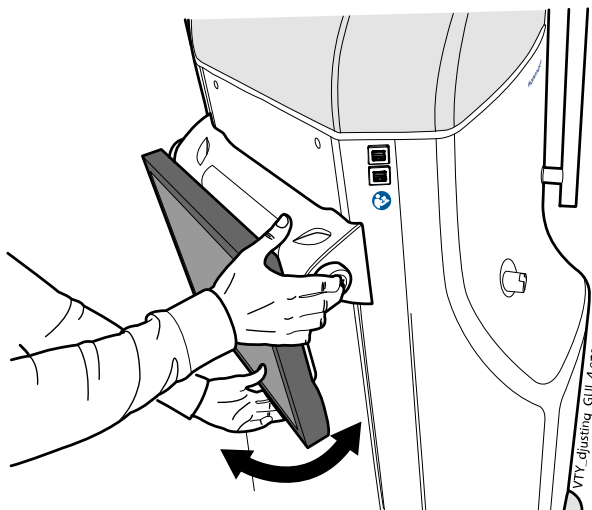
### 8.2.2 Adjusting touch screen control panel height

1. Push up the wedged lever under the adjusting knob with your right hand fingers.
2. Slide the touch screen control panel up or down using both hands while pushing up the lever.



### 8.2.3 Adjusting touch screen control panel tilt angle

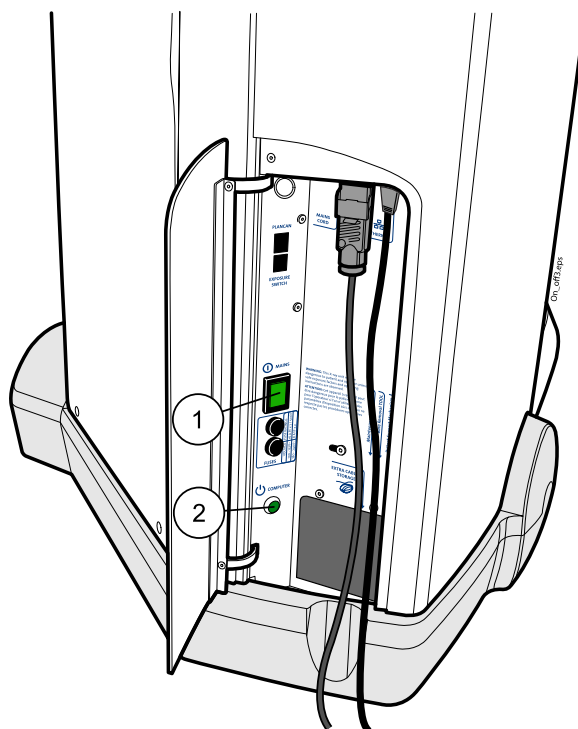
1. Push down the adjusting knob with your right hand.
2. Turn the touch screen control panel to an angle convenient for you.



### 8.3 On/off switch and computer On/Off button

The mains On/Off switch and the computer On/Off button are located under a metal plate in the lower zone of the vertical column, on the right hand side of the touch screen control panel.

The computer is hidden under the vertical column covers and requires no measures in normal operation of the system. If the computer does not start automatically when switching the system on from the mains On/Off switch, press the computer On/Off button.



- 1 Mains On/Off switch
- 2 Computer On/Off button

### 8.4 USB ports

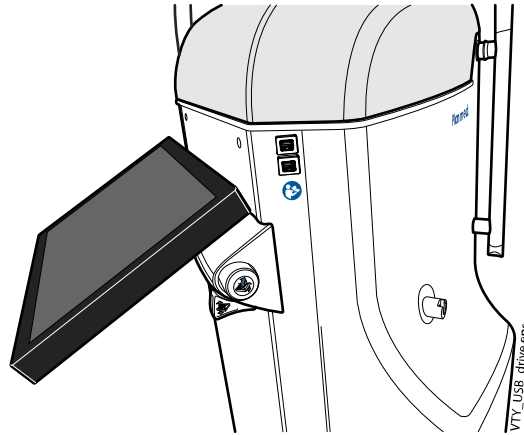
On the vertical column there are four USB ports. They can be used to export studies.

**CAUTION**

Do not touch the USB and Ethernet ports while touching the patient.

**CAUTION**

Do not connect any USB systems with an external power supply (e.g. an external hard disc) to the USB port.



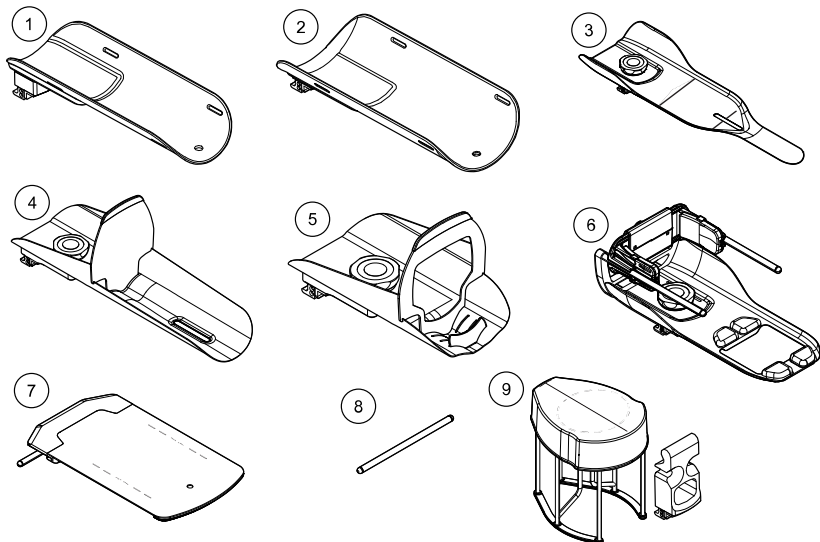
**8.5 Patient positioning trays and supports**

**CAUTION**

Always use an appropriate patient positioning tray when taking patient images. Imaging without a tray may lead to inferior image quality and expose to unnecessary doses of radiation due to re-takes.

**NOTE**

The Head and the Head & Neck positioning trays can only be used in countries where local regulations are met.



VTY\_trays\_and\_supports3.sps

1 Small PT

2 Large PT

3 Flat PT

4 Vertical PT

5 Head PT

6 Head & Neck PT

7 Wide PT

8 Grip bar for wrist imaging

9 Weight-bearing stool and adapter

### 8.5.1 Patient positioning trays usage suggestions

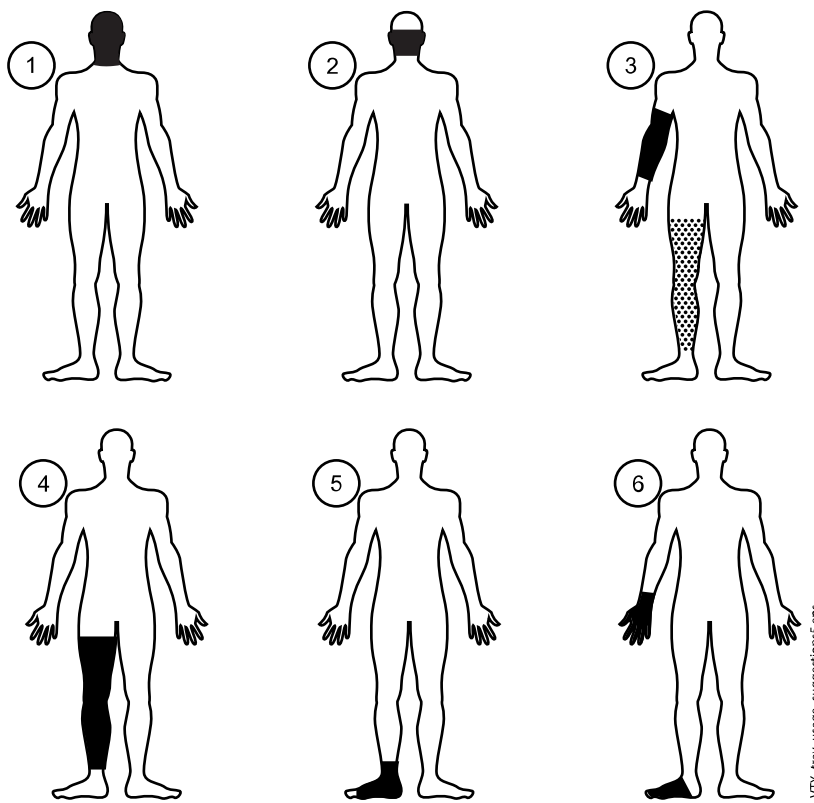
The following instructions are suggestions. Always select a suitable positioning tray according to the type of patient and imaging situation.

**NOTE**

Targets in the head and neck area require an appropriate head positioning tray.

**CAUTION**

Never use vertical positioning tray in weight-bearing mode or when driving the gantry to the weight-bearing imaging position.



- 1 Head & Neck positioning tray
- 2 Head positioning tray
- 3 Small positioning tray
- 4 Large positioning tray
- 5 Vertical positioning tray
- 6 Flat positioning tray

Target	Head (MaxScan)	Face	Jaw	Ears	Neck	Sinus	Teeth
Small	Head PT	Head & Neck PT					
Medium							
Large							

Target	Elbow	Arm	Wrist	Hand	Finger
Small	Small PT		Flat PT	Flat PT	Flat PT
Medium					
Large					

Target	Knee	Leg	Ankle	Foot	Toe
Small	Small PT		Vertical PT	Flat PT	
Medium	Large PT				
Large					

Target	WB knee	WB leg	WB ankle	WB foot	WB toe
Small	Small PT		Weight-bearing adapter and stool		
Medium	Large PT				
Large					

### 8.5.2 Attaching and removing patient positioning trays

#### Attaching tray to gantry bore

1. Attach the tray by inserting it into the holder in the gantry bore tilting the free end upwards.
2. Push down the tray to lock it in place.

#### Removing tray from gantry bore

To remove the tray tilt it up and lift off.

## 8.6 Positioning joysticks

The positioning joysticks are used for adjusting and fine-tuning the position of the gantry and the patient positioning tray to suit the patient's individual anatomy.

On how to use the joysticks in patient positioning, see "Joystick controls" on page 56.

There is one positioning joystick on both sides of the gantry, one on the vertical column and another on the outer surface of the gantry.

The functions of the two joysticks are basically the same. However the one on the gantry surface moves together with the gantry and changes coordinate systems depending on the gantry tilting angle. The other joystick on the vertical column is stationary.

#### NOTE

Only one joystick function can be used at any one time, for example, the gantry can be first tilted and then lifted or vice versa, but not tilted and lifted at the same time. The movement will stop when the joystick is released.

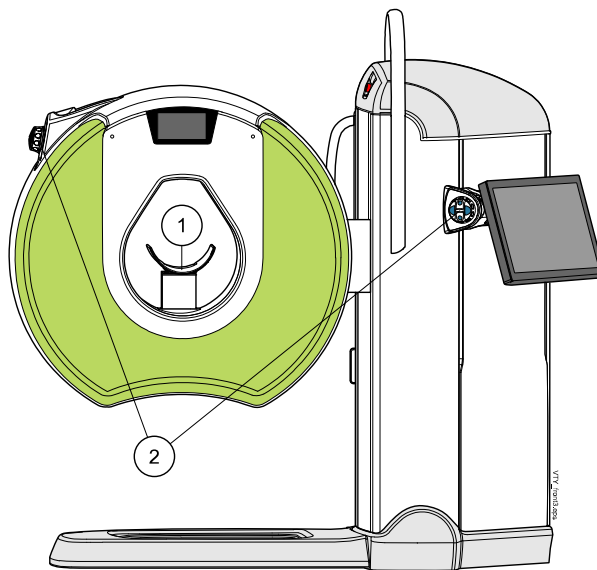
#### NOTE

During exposure all movements of the gantry are blocked and the positioning joysticks disabled.



**NOTE**

Do not touch the joystick controls when starting the system as it disables the joystick.



- 1 Patient positioning tray
- 2 Joysticks

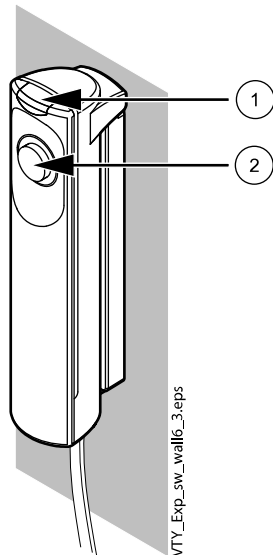
## 8.7 Exposure switch and indicator lights

**CAUTION**

The exposure switch must be operated from an area protected from radiation.

When the system is correctly set up and ready to take an exposure a green indicator light on the exposure button and on the touch screen control panel will come on and the message *Ready for exposure* appears on the touch screen control panel.

When taking an exposure a yellow indicator light on the exposure switch and on the touch screen control panel will come on. It indicates that the system is generating radiation. Additionally, you will hear a radiation warning signal.



- 1 Exposure indicator light
- 2 Exposure button with indicator light

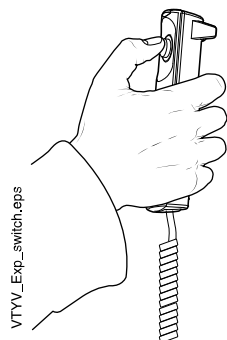
**Green** Ready for exposure

**Yellow** Exposure

To take an exposure press and **hold down** the exposure button for the whole duration of the exposure cycle.

If you remove your finger from the exposure button before the exposure cycle is completed radiation is interrupted and a help message will appear on the touch screen control panel display. To clear the message and continue using system tap **OK**.

The exposure switch can also be mounted on the wall.



## 9 Accessories

### 9.1 Scattered radiation shield

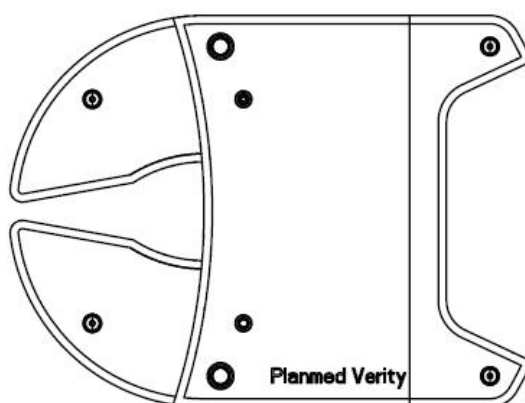
#### NOTE

It is recommended to always use the shield for scattered radiation when imaging patients. Local regulations regarding radiation protection must be considered.

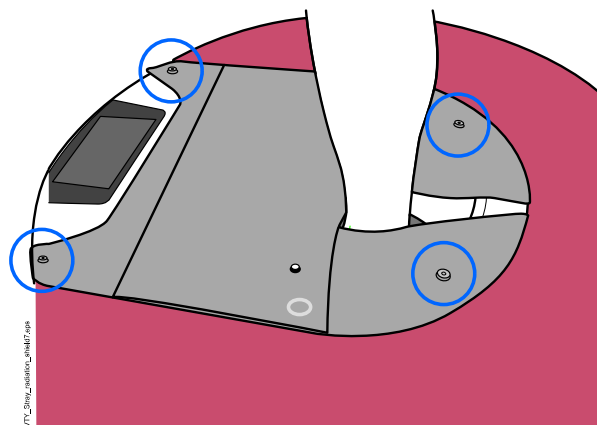
#### CAUTION

Never use damaged shield. Contact your Planned representative for replacement.

The shield lead equivalent is 0.25 mm Pb.



In the gantry there are four magnetic fixing points where the shield is attached.



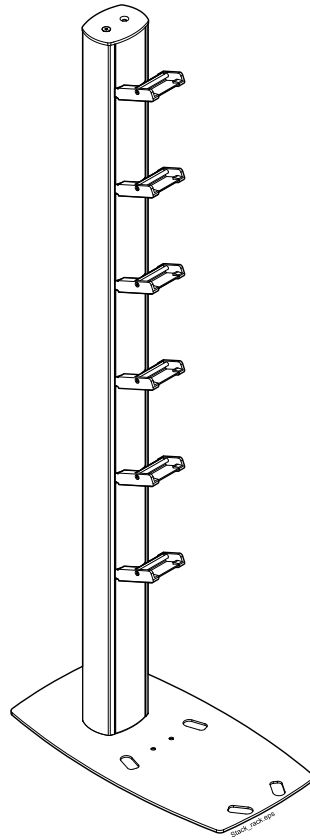
In the following sections the use of the shield with different targets and imaging modes is described.

#### TIP

On how to use the shield in different positionings, see section "Positioning with scattered radiation shield" on page 59.

## 9.2 Stack Rack (optional)

The Stack Rack is intended for storing the positioning trays and accessories. The positioning trays are not included in the delivery of the Stack Rack.



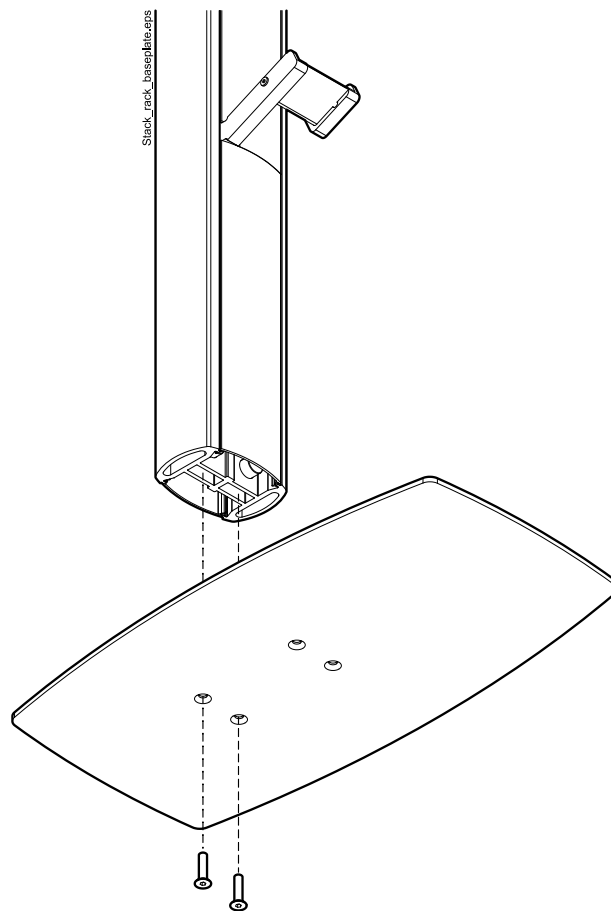
### 9.2.1 Setting up Stack Rack

1. Remove the packaging and place the Stack Rack on its side to the floor.
2. Insert the screws in the outer screw holes of the base plate and lift the stand to the holes level.

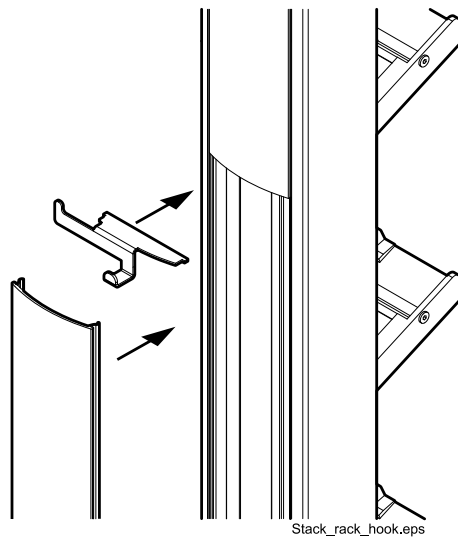
#### **NOTE**

The holes in the middle of the plate are for floor mounting.

3. Screw the DIN7991 M8x35 screws to the screw elements inside the profile.



4. Align the stand with the mid-line of the base plate and tighten the screws.
5. Attach the suspension hook for the scattered radiation shield and the upholstery panel to the Stack Rack.



### 9.2.2 Stack Rack placement

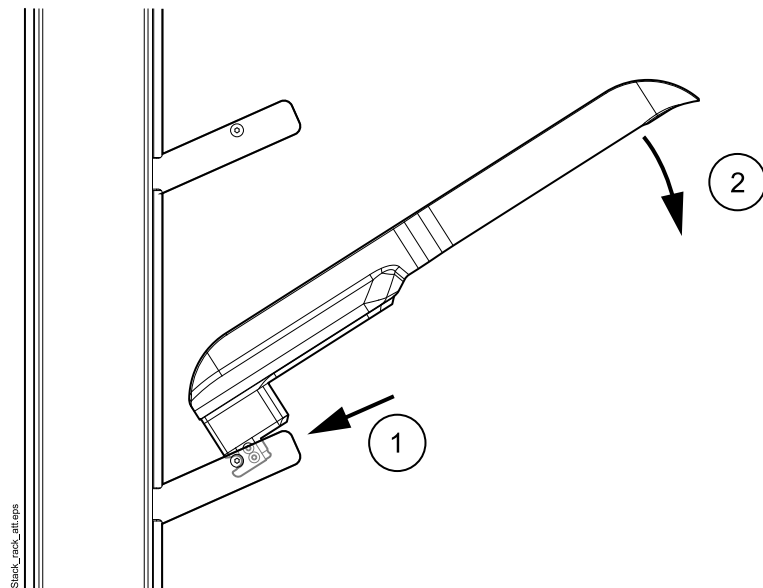
Place the Stack Rack in the closest proximity of the examination room while considering the following:

- It is preferable to place the Stack Rack next to a room wall. If this is not possible make sure it is not blocking the passage where other devices are transported.
- The Stack Rack is easily accessible.
- The Stack Rack can be placed in the corner of a room.
- The floor is level (maximum deviation 3 mm / 600 mm).
- The stand is stable and rests firmly on the adhesive felt bumpers.
- In the seismic hazard areas floor mounting is recommended. To mount the rack use two M6 screws and wall plugs (not included in the delivery)

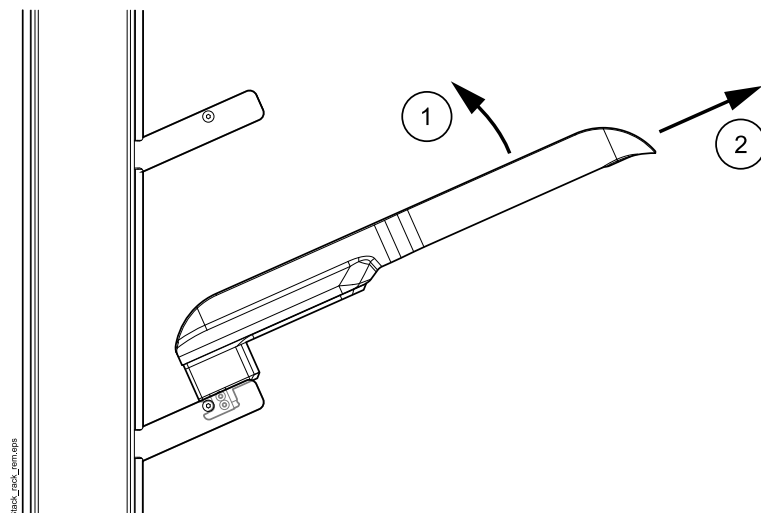
### 9.2.3 Placing accessories on Stack Rack

The positioning trays are placed on the Stack Rack in the same way as with X-ray unit.

1. Insert the tray into the holder tilting the free end of the tray upwards. (1)
2. Let the tray descent to storing position. (2)



The tray is removed from the Stack Rack by lifting it slightly (1) and pulling outwards (2).



3. Place the feet of the weight-bearing stool to the holes on the base plate.
4. Cover the stool with the protective fabric.
5. Insert the weight bearing stool adapter into the storage pocket of the protective fabric. When using the weight-bearing stool take the entire set (the stool, the protective fabric and the adapter) with you to the unit.

#### **9.2.4 Cleaning Stack Rack**

See section "Cleaning and disinfection" on page 199.

## 10 Verity Manager

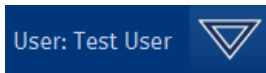
Patient information functionalities enable handling of patient information and reviewing of patient images in the local database. All the functions are controlled through touch screen user interface and Verity Manager.

### 10.1 Login



Double-tap this icon on your desktop:

- If you are registered in the database as a Windows user logging in is not required and the main window of the Verity Manager opens automatically.



The user name of the current user is shown on the top right corner of the window.

Also depending on the Service mode's security settings user name and/or password may or may not be required.

For more information see the X-ray unit technical manual.

- If you are not registered as Windows user fill in your username and password in the corresponding fields and tap **OK**.



#### 10.1.1 Changing password for Windows account

1. Sign in to Windows and exit Verity Manager.
2. Press **Ctrl + Alt + Del** combination on your keyboard.
3. Select **Change a password**.
4. Follow instructions given.
5. Check the recommendations for password policy in the *Cyber Security - Best Practices user's manual*.

#### 10.1.2 Creating new Windows user

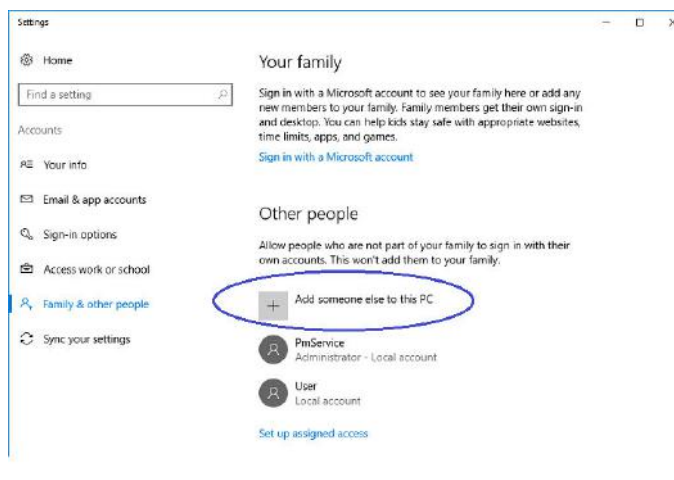
Each user shall have both Windows and Verity Manager user accounts.

For Verity Manager accounts, a new user is added and a password is changed from Verity Manager's service module. For detailed instructions, see *Planmed Verity technical manual*.

1. Sign in to Windows with credentials provided with unit.
2. Exit Verity Manager.
3. Select Windows Start menu.



4. Type *Control Panel* and open it.
5. Select *User accounts*.
6. The *Settings* windows opens up.  
Select *Add someone else to this PC*.



7. Fill in the fields.

 A screenshot of the 'Create an account for this PC' dialog box. The title is 'Create an account for this PC'. Below the title, there is a note: 'If you want to use a password, choose something that will be easy for you to remember but hard for others to guess.' The main section is 'Who's going to use this PC?' with a text input field containing 'User2'. Below this is the 'Make it secure.' section with three text input fields: 'Enter password', 'Re-enter password', and 'Password hint'. A blue 'Next' button is located at the bottom right.

- Enter username into the *Who's going to use this PC* field.

### NOTE

It is recommended to use the real names of the user e.g. "Jane Doe".

- Enter password.  
Check the password policy recommendations in the in *Cyber Security - Best Practices user's manual*.

## 10.2 Modality worklist

The purpose of the Modality worklist is to maintain a list of patients scheduled for an examination.

Typically, the Verity Manager application retrieves this worklist from a Hospital/Radiology Information Systems (HIS/RIS) using the Digital Imaging and Communication in Medicine (DICOM) Modality Worklist. Accessing Modality Worklist requires purchase of a licence.

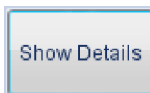
Use the *Modality Worklist* to select the patient whose images you want to acquire, and start a study.



### 10.2.1 Searching patients

The patients can be searched by the following criteria:

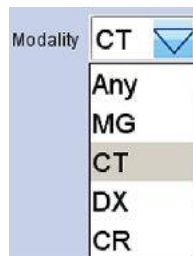
- Last name
- First name
- Patient ID
- Date of Birth
- Study date
- Accession number



To search patients by DICOM entries tap **Show details**. The following fields appear:

- Requested procedure ID
- Calling AE
- Scheduled ID
- Modality

Select the modality from the drop-down menu.



- Worklist AE

Select the Worklist AE from the list and tap **OK**.



After selecting / entering the search criteria in the corresponding field tap **Search**.

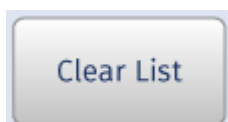


For situations where Verity Manager application is offline (i.e., not connected to a HIS/RIS system), see section "Local patient registry" on page 37 on how to enter patient records manually.

## NOTE

The Modality Worklist is an optional feature. If your application does not have this feature, it displays the Local Patient Registry view when you log in. (For more information see section "Local patient registry" on page 37.

### 10.2.2 List



To clear the patient listing tap **Clear List**.

### 10.2.3 Acquisition

For more information on image acquisition see section "Imaging workflow" on page 63.

## 10.3 Local patient registry

In the *Local Patient Registry* tab you can:

- **search** for patients registered in the database by their patient ID, first name, last name or date of birth.
- start a **new study** (see section "Starting study" on page 63 1).
- **continue** study (of which images were acquired earlier the same day)
- **create** new patients
- **edit** existing patients
- **delete** existing patients



### 10.3.1 Searching patients in database

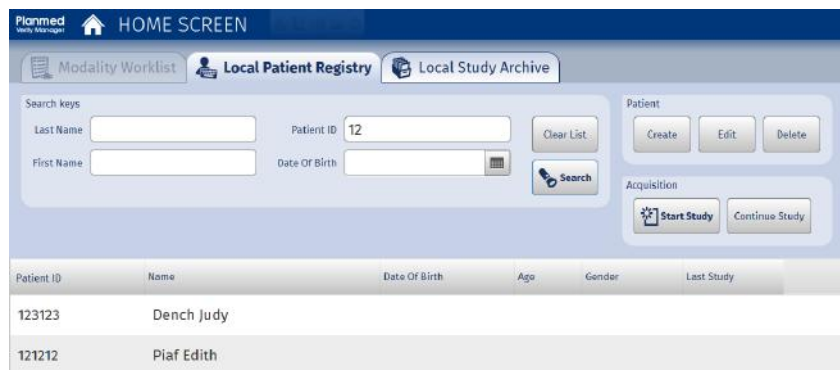
Patients can be searched in the database according to patient’s ID, last name, first name or date of birth.

To find patients in the database



1. Type the desired search criteria in the search field and tap the **Search** button.

2. The patient(s) matching the search criteria will appear on the patient list.



#### NOTE

By selecting *Search* without entering any search criteria the application will search and display all patients recorded in the database. This may take several minutes.

If a partial name is entered the software will return all patients whose last or first name begins with that partial string:

Examples:

*Last name searches*

**Doe:** all patients with the last name Doe

**S:** all patients whose last name starts with the letter S

**Smi:** all patients whose last name starts with ‘Smi’, e.g. Smith and Smiley.

*First name searches*

**Kim:** all patients whose first name is Kim

**A:** all patients whose first name starts with the letter A

**Jen:** all patients whose first name starts with “Jen”, e.g. Jenny, Jennifer

### 10.3.2 Sorting patient list

The Modality Worklist can be sorted in ascending or descending order.

To sort the patient list:

1. Tap the appropriate column heading in the list (e.g. **Name**).

The application sorts the list in ascending or descending order according to the information in the selected column (either alphabetically or numerically, depending on the type of information). It displays a single arrow in the column heading to indicate the column by which the list is sorted. For example, if the *Name* column heading appears with an up-arrow, the list is currently sorted by name in ascending alphabetical order (i.e. A to Z).

2. To reverse the order tap the column heading again (i.e. Z to A).

Patient ID	Name	Date Of Birth	Age	Gender	Last Study
789456	Smith Mary			Female	
123456	Doe Jane				11.2.2014

### 10.3.3 Creating new patients

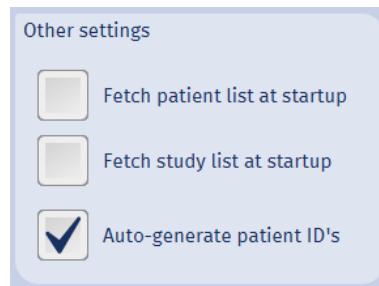


1. Tap **Create** in the *Patient* field.

2. Fill in the necessary information. fields.

*Patient ID*, *Last Name* and *First Name* are mandatory, all other information is optional.

In case you haven't manually entered a patient ID the software will automatically generate an ID if the option *Auto-generate patient ID's* is selected in the Database tab of *Service mode*.



To configure the automatic ID generation, contact your service representative.

**NOTE**

The *Auto-generate Patient ID's* option does not affect the view on the worklist, only on Local Patient registry.

When the *Auto-generate Patient ID's* option has been configured the entering patient ID is not mandatory and the Patient ID field does not show in bold.



3. Tap **OK**.

**10.3.4 Editing patients**



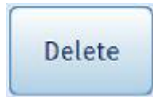
1. Select the patient you want to edit on the patient list and tap **Edit**.
2. Edit or add information as necessary.



3. Save the changes and to close the window by tapping **OK**.

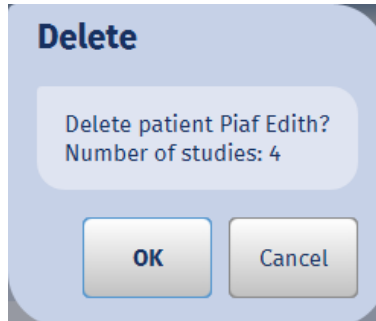
**10.3.5 Deleting patients**

1. Select the patient to delete on the list.



2. Tap **Delete**.

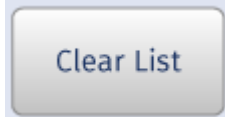
3. To delete the patient and the images from the database tap **OK**, otherwise tap **Cancel**.



4. Select **OK** to delete the patient from the database.

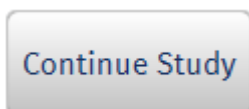


### 10.3.6 Clearing patient list



To clear the list of patients found in the database tap **Clear List**.

### 10.3.7 Continuing previous study

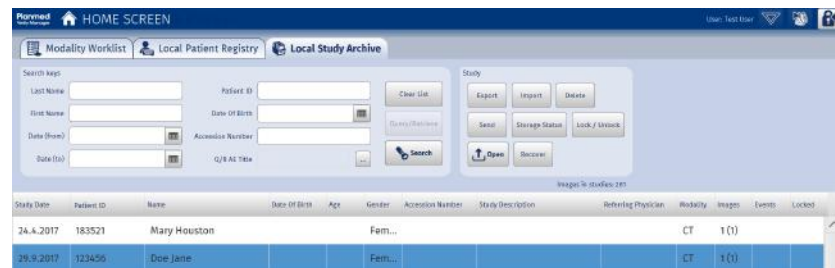


Select the study you would like to continue from the patient list in the *Local Patient Registry* or *Worklist* and tap **Continue Study**.

## 10.4 Local study archive

The local study archive can be used to:

- **search** studies in the database by patient ID, last name, first name, date of birth, accession number, date and Query/Retrieve AE Title.
- search studies with **rejected** images (view previous images and their exposure values)
- use **Query/Retrieve**: the purpose of the DICOM Query/ Retrieve is retrieving images from remote DICOM servers in order to store them locally. After the images have been received, they can be loaded and processed independent of the remote server.
- **open** studies stored in the *Local Study Archive*
- **recover** deleted studies
- **export** studies from database to local hard drive or USB flash drive
- **import** studies from files to database
- **send** studies to PACS (hospital network)
- check the **storage status**
- **delete** studies from database
- **lock / unlock** studies to prevent/allow modifications



### 10.4.1 Searching studies



To search studies in the database type the appropriate search criteria in the search field and tap **Search**.

The studies matching the search criteria will be listed in the study list window.

#### Study list events abbreviations key

- S** Storage
- SC** Storage commitment
- MS** Media Storage
- SSCP** Received via Storage
- Import** Imported from file

### 10.4.2 Query/Retrieve images

DICOM Query Retrieve (Q/R) Service Class User (SCU) service is used for retrieving images from DICOM PACS servers. Images can be first queried and then selected for retrieval to the local storage. Once retrieved they can be processed independent of the remote server. Use DICOM Storage function to send processed images back to the DICOM PACS server.



**NOTE**

Verity Manager information (application entity title, host name, port number) must be configured to PACS. Otherwise Query/Retrieve will not work.



To Query/Retrieve images from other locations tap **Query/ Retrieve**.

In the opening window select the studies you would like to retrieve and tap **OK**.



Study Date	Patient ID	Name	Date Of Birth	Gender	Accession Number	Study Description	Referring Physician	Modality
25.9.2014	4032049	Ewen Dora Mary, Mrs.	3.4.1950			KNEE		CT
23.5.2014	4032058	Nielsen Owen	5.7.1968			HAND		CT
23.5.2014	4032057	Adderley Lloyd	1.10.1990			ELBOW		CT
19.5.2014	4032062	Corkshire Deirdre		Female		FINGER		CT
20.5.2014	4032037	Brown Sara Lee Belle	29.2.1964	Female		ARM		CT
20.5.2014	4032042	Rockwell Peter	7.9.1467	Male		ELBOW		CT

If you tap Query/Retrieve without entering patient ID, name, date of birth or accession number the popup “Do you really want to make query without search criteria?” will appear.

To return to the previous screen and to enter patient information tap **Cancel** and enter information in the appropriate fields.

To Query/Retrieve images without any search criteria tap **OK**.

Retrieving of images is performed automatically. You may continue working normally.

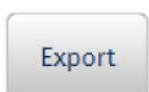
### 10.4.3 Opening studies



To open a found study displayed on the list tap **Open**.

The selected study will open showing the most recent images.

### 10.4.4 Exporting studies



1. Tap **Export**.

2. In the following window select the appropriate settings and the folder where you would like to export the study.

For detailed information on export settings see section "Export settings" on page 45.



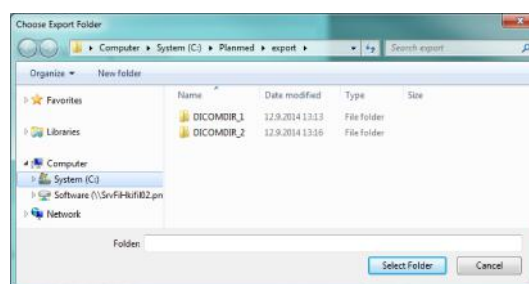
If you want to choose another folder for export tap the browsing button next to the *Folder* field.



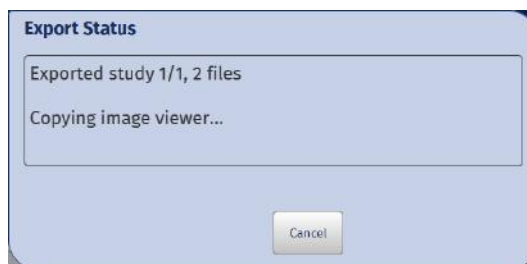
3. On the *Choose Export Folder* window select the appropriate folder and tap **Select Folder**.

**NOTE**

The default export folder is C:\Planned\export.



The export starts and the *Export Status* window appears.



To cancel the export tap Cancel.

4. When the export is complete the number of exported images is shown.



5. Tap **OK** to close the dialogue.

#### 10.4.4.1 Export settings



##### Image format

DICOM includes two ways of storing CT images: the new and more advanced Enhanced CT format and the so-called Standard CT format. Verity Manager uses internally only the Enhanced CT format but there are still several older systems that only support Standard CT and therefore Verity Manager also allows image export in Standard CT format.

**Enhanced CT**

Enable this option if you prefer to have 3D volumes sent to DICOM Storage in multi-frame format. For more information see your DICOM Storage server documentation.

The acquired images are in DICOM format. The following Service-Object Pair (SOP) Classes are supported:

- CT Image Storage: 1.2.840.10008.5.1.4.1.1.2
- Enhanced CT Image Storage: 1.2.840.10008.5.1.4.1.1.2.1

It is recommended to use Enhanced CT Image Storage SOP Class.

**Standard CT**

If this option is selected the images are exported as individual image files.

**Export**

**3D volumes**

Select this option to export only 3D volumes.

**Slice stacks**

Select this option to export only slice stacks.

**Scout images**

Select this option to export scout images together with the acquired 3D images.

**3D Raw data**

This option is intended mainly for trouble shooting purposes and therefore hidden by default. To show/hide the option click the *Show more/Hide* link.



The raw data of exported images is zipped to export folder and exported only when available.

**Remove patient data**

*Anonymize*

By selecting this option personally identifiable information is altered or removed from data sets, so that the people whom the data concern remain anonymous.

*Pseudonymize*

By selecting this option personally identifiable information is altered or removed as with Anonymize option, however, the study accession number is maintained.

## Export media

### Folder

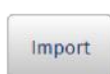
The folder where the DICOMDIR will be exported. The individual image files will be exported to the sub folders of that folder.

### Append to existing DICOMDIR

If this option is *not selected*, export fails in case there is an existing DICOMDIR (=DICOM Directory, a special DICOM file) in the *Export* folder.

If this option is *selected* the new images will be appended to it in case there is an existing DICOMDIR file in the *Export* folder. Otherwise a new DICOMDIR will be created normally.

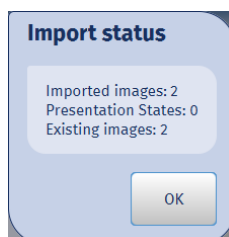
## 10.4.5 Importing studies



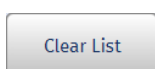
1. Tap **Import**.
2. On the appearing window, select the folder from where to import the study and tap **Open**.
3. When the import is completed the following window appears.  
Tap **OK**.

### NOTE

Only the recently imported studies are shown in the study list.

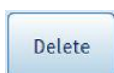


## 10.4.6 Clearing search results

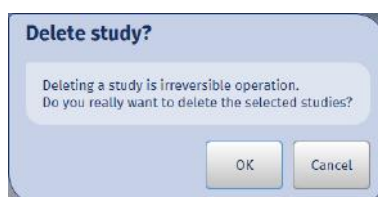


To clear the list of found studies and the search criteria from the screen tap **Clear List**.

## 10.4.7 Deleting studies



1. Select the study to delete on the list.
2. Tap **Delete**.
3. To *permanently* delete the study/studies from the database tap **OK**, otherwise tap **Cancel**.



4. Tap **OK**.



### 10.4.8 Sending studies to archive



1. On the patient list select the study you would like to send and tap **Send**.
2. Verify that the studies will be sent to the correct PACS. The study is set on queue to be automatically sent to PACS. You may continue working normally.

### 10.4.9 Verifying storage status

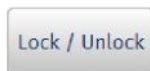


To check the status of storage transaction tap **Storage status**.

To exit the window tap **OK**



### 10.4.10 Lock/unlock studies



To prevent studies from being deleted they can be locked.

To lock a study, select it on the study list and tap **Lock / Unlock**.

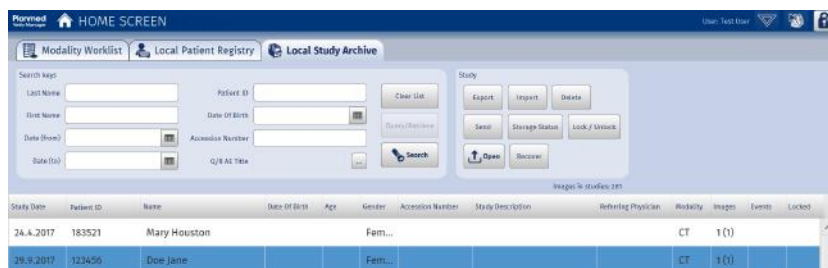
To unlock a study, select the study and retap the button. On the following window tap **OK**.



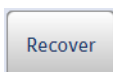
### 10.4.11 Recovering studies

If Verity Manager has crashed before 3D reconstruction is completed or downloaded to Verity Manager you can use the study recovery. Studies can be recovered as long as projection images and reconstruction configuration file is available.

1. Select the study containing the failed image in the study list.



- 2.

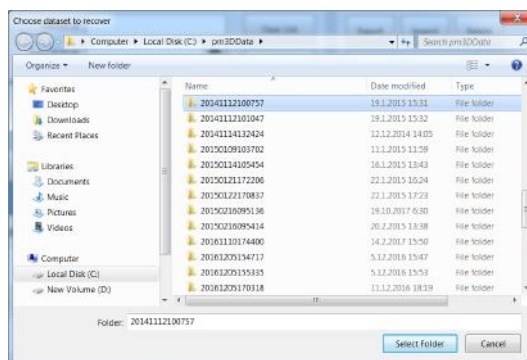


Tap **Recover**.

3. Select the folder in which the image is stored.

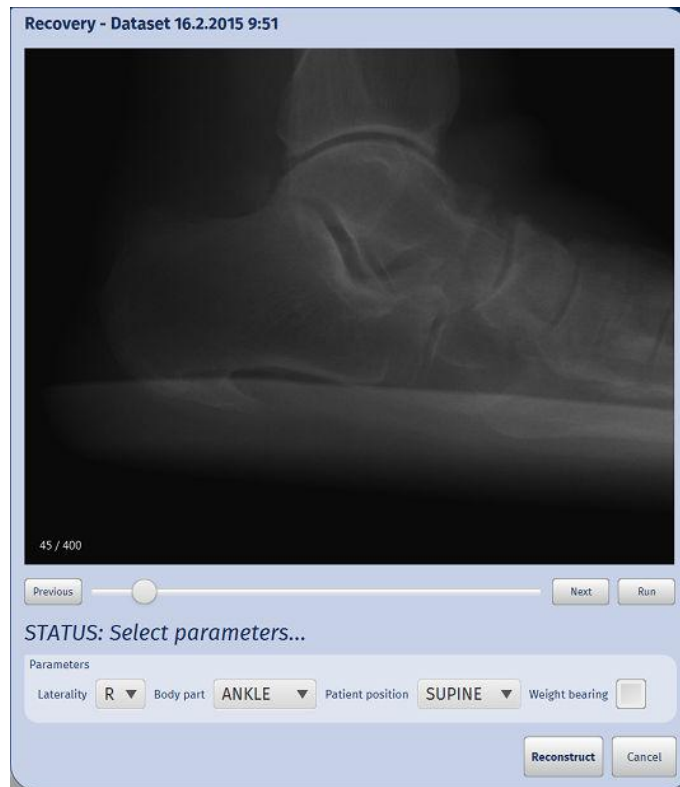
## NOTE

If the dataset folder does not contain reconstruction config file an error message appears and recovery process is ended. If the time stamp for the selected dataset is older than the selected study a warning message appears.



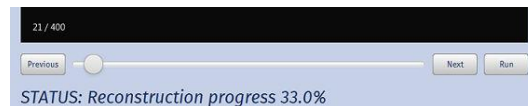
4. Select correct laterality, body part, patient position and, if applicable, weight bearing parameter.

To verify that the projection images belong to the right patient you can view them in a cine loop by tapping **Run**.

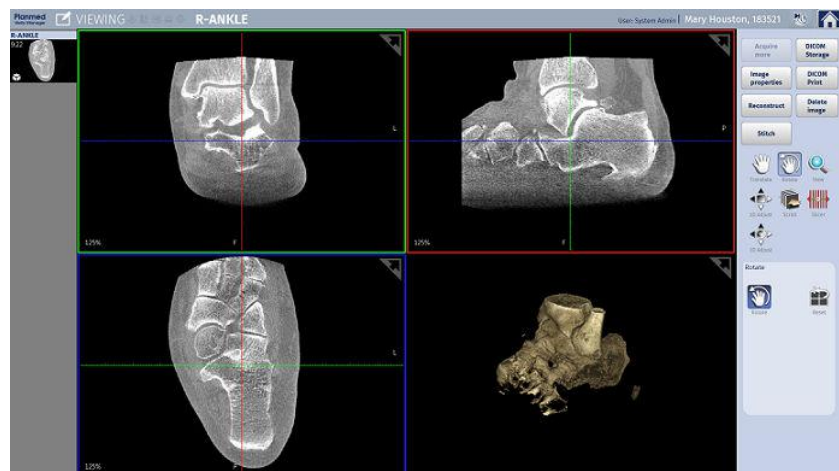


5. Tap **Reconstruct**.

The dataset is reconstructed with the voxel size indicated in the reconstruction configuration file **fdk.conf**. No post processing is applied. Progress of reconstruction is shown on the recovery dialog.



Once the recovery is completed the newly reconstructed image opens.





# 11 Patient positioning

## 11.1 Pre-set drive

The pre-set drive can be used for quicker and easier positioning. With preset drive the gantry is driven to a position with preset tilt, elevation, and tray height (see also section "Pre-set positions for different body parts" on page 53).

The pre-set positions are illustrated in section "Pre-set positions for different body parts" on page 53.

### NOTE

The pre-set drive is obligatory for enabling weight-bearing and Hover tray positioning.

### TIP

The pre-set positions can be customized in *Service* mode. Please contact your service technician for more information.

1. Select the body part, patient size and, if necessary, positioning mode (weight-bearing or HoverTray) (as instructed in section "Selecting imaging target" on page 64).

### NOTE

Start pre-set drive *before* selecting imaging values. Pre-set drive sets default values for the imaging target (patient position, kV, mA and FOV size).



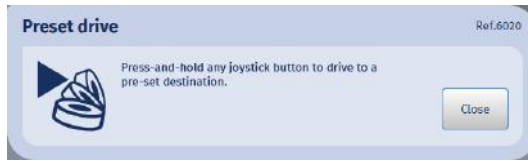
### 2. CAUTION

Make sure that the patient is NOT positioned in the gantry bore and that there are no objects obstructing the downward movement of the gantry. Remove any obstacles from under the gantry.

Tap to start pre-set drive.



- The joystick LEDs start to blink indicating a pre-set state.  
Press and hold down any joystick button to drive the gantry to pre-set destination.



- The gantry moves to the position with pre-set tilt, elevation and tray mechanism height (see also section "Pre-set positions for different body parts" on page 53).

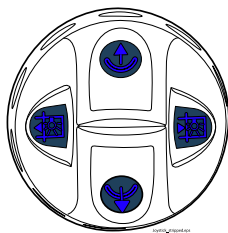
**NOTE**

In case of emergency see section "In case of emergency" on page 12.

Once the gantry has reached the pre-set position, the LEDs stop blinking and the pop-up window clears from the screen.

**TIP**

The pre-set drive can be stopped by releasing the joystick button. Close the popup to stop pre-set drive.



- If necessary fine-tune the positioning manually to suit the anatomy of individual patients.  
For detailed joystick functions description, see section "Positioning joysticks" on page 26.

- Position the patient into the gantry bore (see section "Positioning patient" on page 67 for instructions).



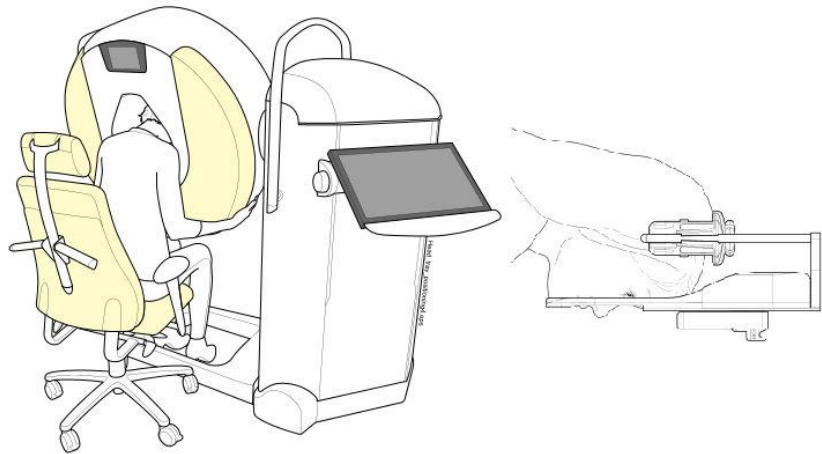
- Proceed to "Scout exposure" on page 118 or to "3D exposure" on page 124

## 11.1.1 Pre-set positions for different body parts

### 11.1.1.1 Head and neck

#### NOTE

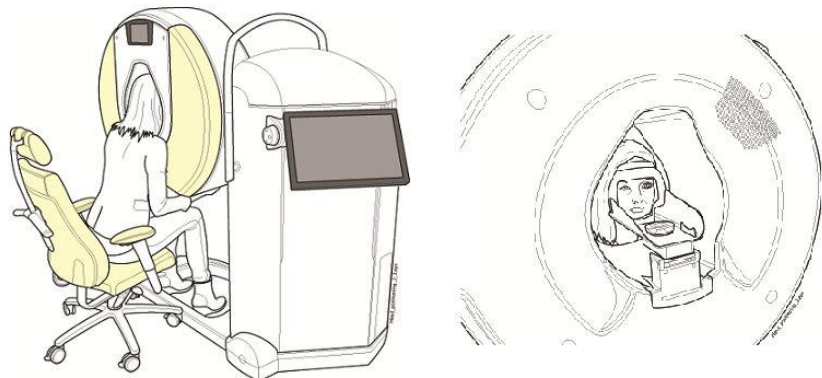
The Head & Neck positioning tray can only be used in countries where local regulations are met.



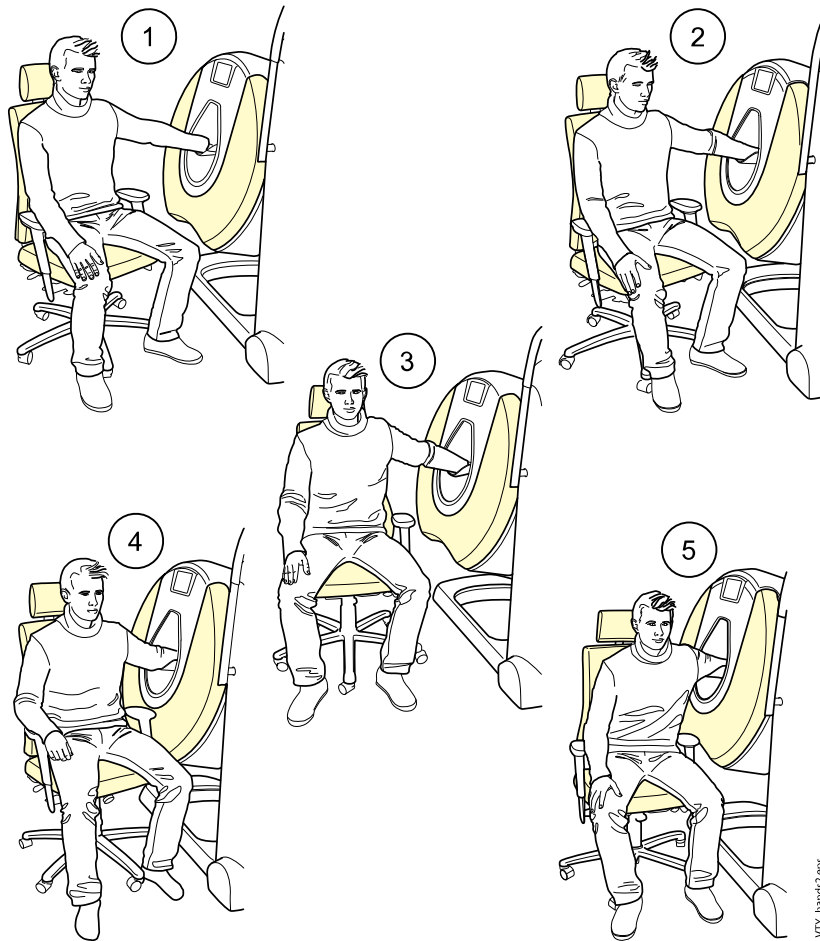
### 11.1.1.2 MaxScan imaging

#### NOTE

The head positioning tray can only be used in countries where local regulations are met.

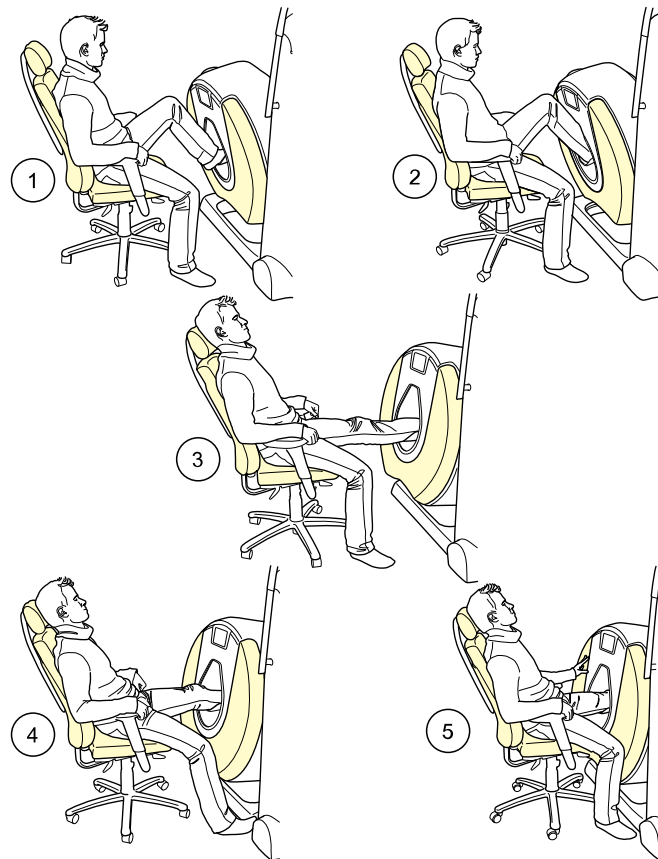


### 11.1.1.3 Upper extremities



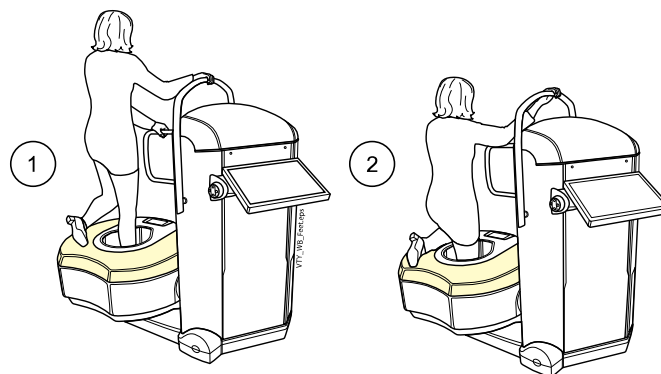
- 1 Fingers
- 2 Hand
- 3 Wrist
- 4 Arm
- 5 Elbow

### 11.1.1.4 Lower extremities



- 1 Toes
- 2 Foot
- 3 Ankle
- 4 Leg
- 5 Knee

### 11.1.1.5 Lower extremities for weight-bearing imaging



- 1 Toes, foot and ankle
- 2 Leg and knee

## 11.2 Patient positioning controls

### 11.2.1 Joystick controls

#### Gantry vertical adjustment

- **gantry down**: push the joystick downwards from above
- **gantry up**: push the joystick upwards from below

#### Tilting angle

- **tilt gantry forwards**: turn joystick in clockwise direction
- **tilt gantry backwards**: turn joystick in anti-clockwise direction.
- the LED lights indicate the direction of movement.

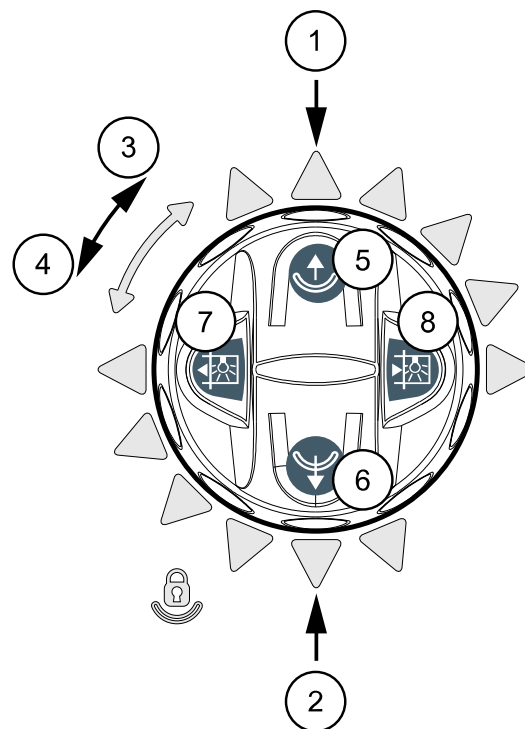
#### Vertical adjustment of the patient positioning tray

#### Vertical adjustment of the patient positioning tray

- patient positioning tray **up**: push the upper button
- patient positioning tray **down**: push the lower button

#### Volume size adjustment

- **increase volume size**: push increase volume size button
- **decrease volume size**: push decrease volume size button



VTY\_Joystick\_functions\_3eps

- 1 Gantry down
- 2 Gantry up
- 3 Tilt gantry forwards
- 4 Tilt gantry backwards
- 5 Tray up
- 6 Tray down
- 7 Large FOV
- 8 Small FOV

**CAUTION**

When driving the gantry make sure there is no danger of anything squeezing under the gantry or between the gantry and the column.

**11.2.2 Field of view and positioning lasers**

The scanner has three field of views (FOV): Large, small and extended (optional).

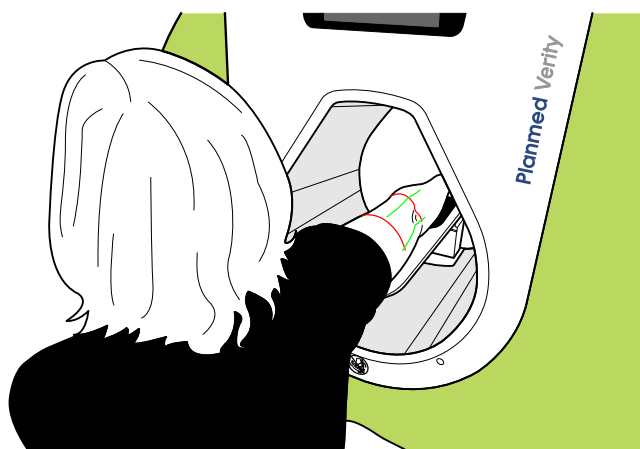
The size is selected by tapping the right field of view button (extended, large or small) in the *Imaging values* section or from joysticks (small and large only).



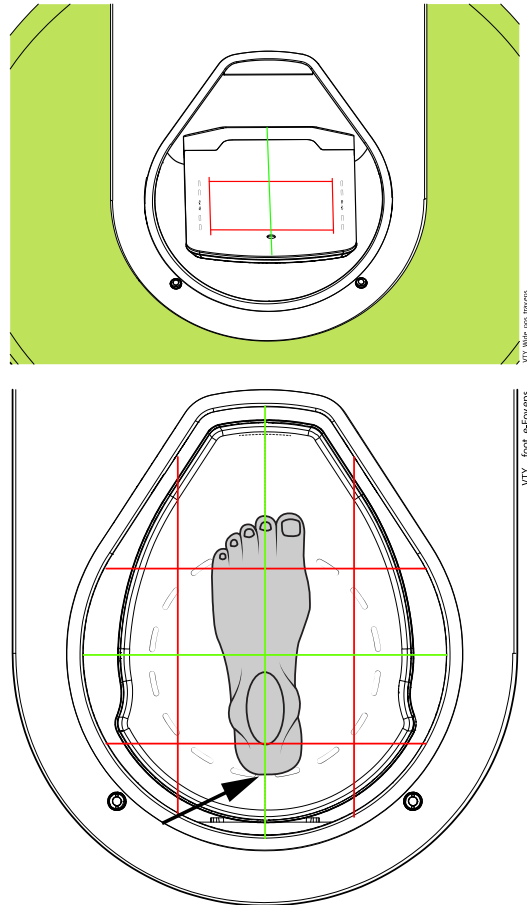
The positioning lasers indicate the large and small field of view: the red lasers indicate the boundaries of FOV and the green ones the centre line. The collimators inside the system communicate with the positioning lasers so that the X-ray beam sets within the limits of the field of view. When the field size is changed from small to large, the anterior vertical red laser moves deeper into the gantry bore.

The positioning lasers are activated when an extremity is positioned in the bore.

The positioning lasers switch off when **Scouts** or **Acquire 3D** is selected from the touch screen control panel or if nothing is detected in the field of view for two minutes. You can reactivate the lasers with any joystick action.



The complete image data is acquired from the area inside the lasers. When using the extended field of view, additional although less accurate data is generated from the area between the red laser and the dashed line.



For detailed information, see section "Imaging with eFOV" on page 87

### 11.2.3 Positioning camera and display (optional)

The extremity scanner is equipped with positioning camera and display which aid in correct positioning of the extremity in the gantry bore.

The display and camera are automatically turned on when the device is in positioning mode. The LED positioning lights are activated when an extremity is inserted into the gantry bore.

By looking at the display you can check the correct positioning without having to look inside the gantry.

When imaging is started the camera is automatically turned off.

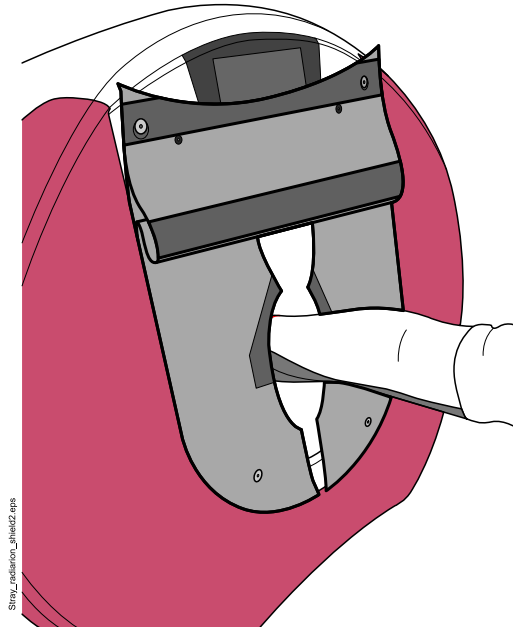




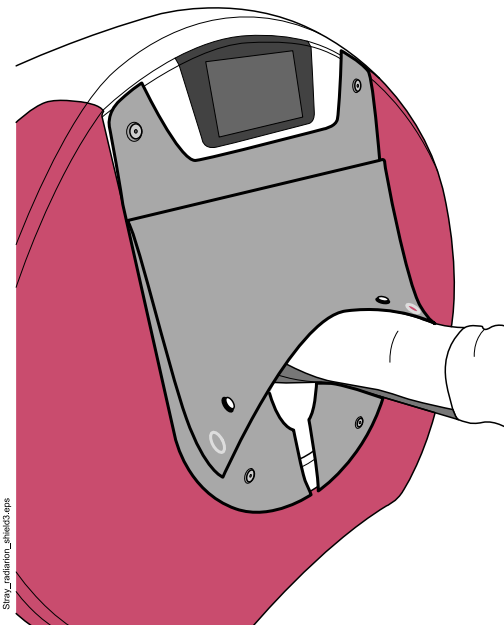
## 11.3 Positioning with scattered radiation shield

### 11.3.1 Wrist and hand

1. Position the extremity in the gantry bore (see section "Pre-set positions for different body parts" on page 53 ) for more information.
2. Attach the radiation shield to the front side of the gantry by aligning the four fixing knobs on the shield with the fixing points on the gantry.

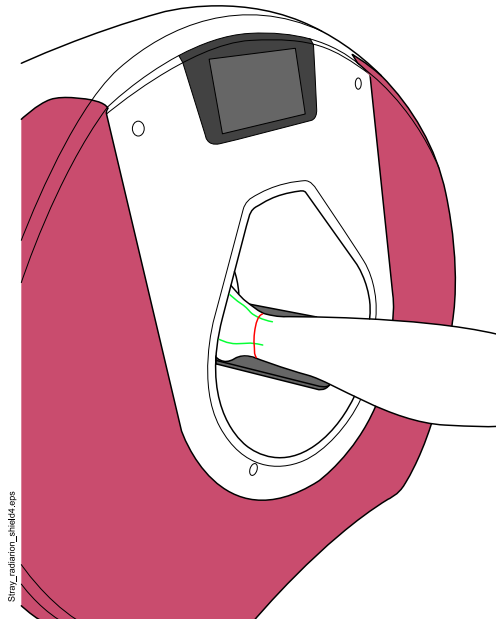


3. Let down the top cover for maximum protection.

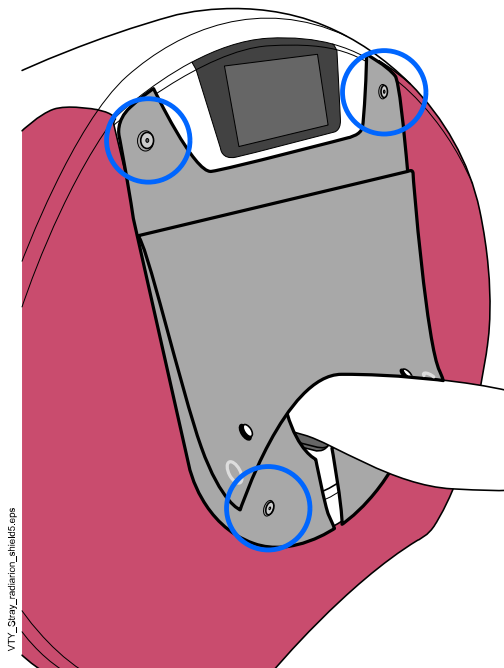


### 11.3.2 Knee, ankle, foot and toes

1. Position the extremity to the gantry bore (see section "Pre-set positions for different body parts" on page 53).

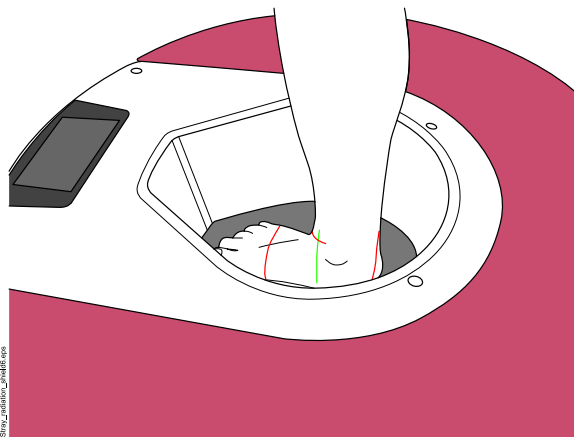


2. Attach the radiation shield to the front side of the gantry by aligning the four fixing knobs on the shield with the fixing points on the gantry.

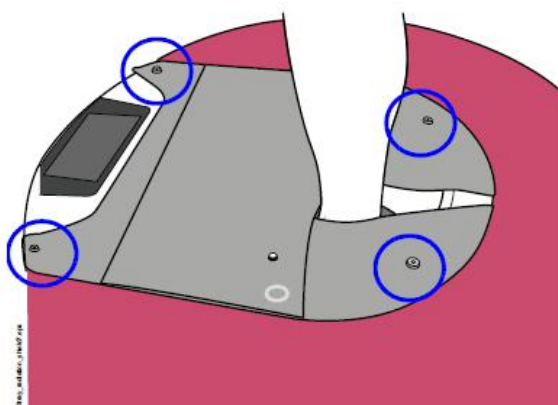


### 11.3.3 Weight-bearing imaging of knee and ankle

1. Position the extremity in the gantry bore (see section "Pre-set positions for different body parts" on page 53 ).

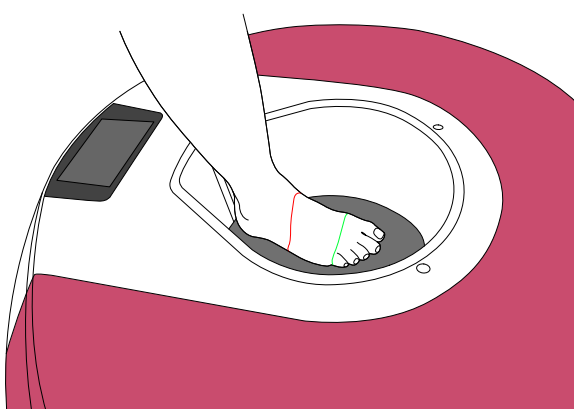


2. Attach the radiation shield to the front side of the gantry by aligning the four fixing knobs on the shield with the fixing points on the gantry.

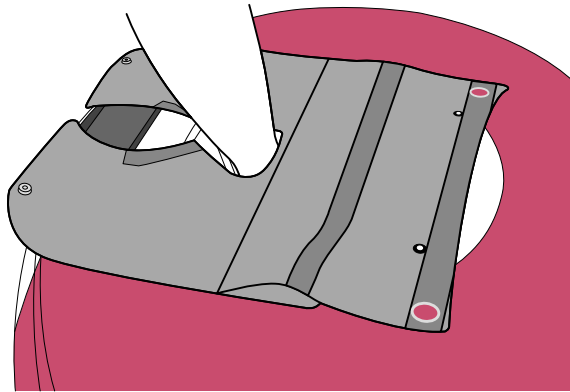


### 11.3.4 Weight-bearing imaging of foot and toes

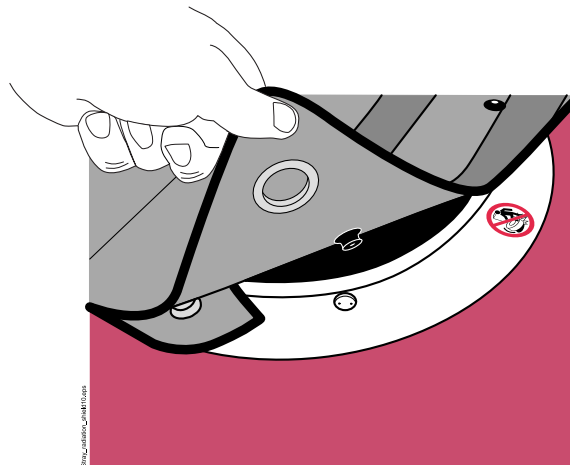
1. Position the extremity as instructed in section "Pre-set positions for different body parts" on page 53.



2. Attach the radiation shield by placing it upside down, aligning it with the lower fixing points.



3. Open the top cover and attach it by aligning the extra fixing knobs on the cover with the lower fixing points (2) on the gantry.



## 12 Imaging workflow

### 12.1 Preparing patient

1. Ask the patient to remove any jewellery and clothes from the imaging target.
2. Protect the patient from scattered radiation.



#### CAUTION

Frail or trembling patients may need additional support during exposure. Use cushions, straps or adhesives when necessary.

#### TIP

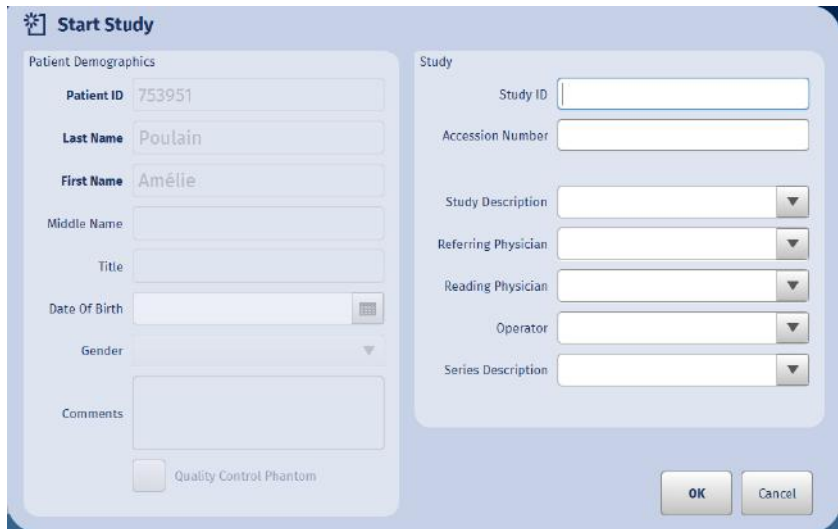
You may image a patient with a cast.

### 12.2 Starting study

1. Select the patient from *Worklist* or *Local Patient Registry* and tap **Start Study**.

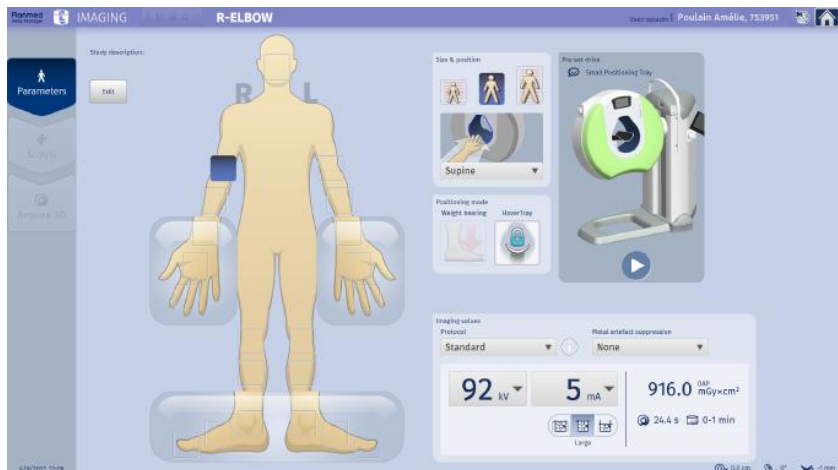
Patient ID	Name	Date Of Birth	Age	Gender	Last Study
444444	Binoche Juliette				
123123	Dench Judy				
121212	Piaf Edith				
753951	Poulain Amélie				
147896	Smith Maggie				

- Verify that the information is correct and tap **OK**.

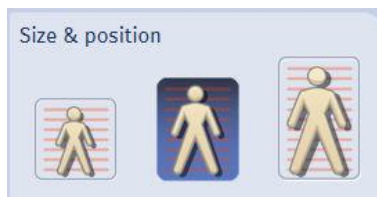


### 12.3 Selecting imaging target

- Select the imaging target and laterality by tapping on the body part.



- Verify the default patient size and adjust if necessary.



- Select positioning mode if necessary.



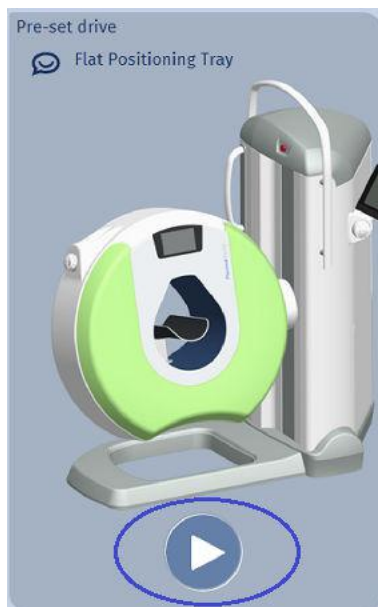
## 12.4 Pre-set drive

The system can be driven to a defined pre-set position by tapping the pre-set drive button. This is mandatory only to access weight-bearing or Hover tray positions.

### 1. CAUTION

Before driving the gantry make sure that the patient is NOT positioned in the gantry bore and that there is enough space for the gantry to move freely without causing any hazard to the patient, to yourself or the surrounding property. Remove any obstacles from under the gantry.

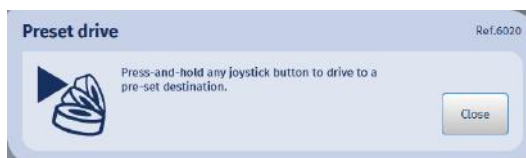
Tap the Start pre-set drive button.



The joystick LEDs start to blink indicating a pre-set state.

### 2. Press and hold down any joystick button.

When the gantry has reached the pre-set position, the LEDs stop blinking and the pop-up window clears from the screen.



For details, see section "Pre-set drive" on page 51.

### 3. Continue to "Positioning patient" on page 67.

## 12.5 Selecting imaging values

1. Verify the default imaging protocol.

The exposure values are automatically selected based on the selected body part, patient size and imaging protocol. If necessary change the values.



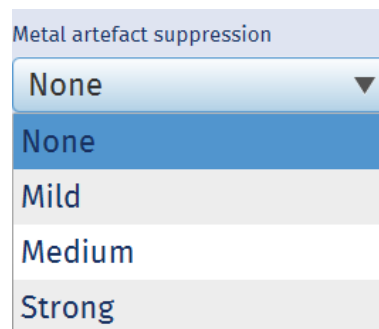
2. Check the Field of View (FOV) and adjust if necessary.

The FOV is automatically selected based on imaging target and protocol. (For more information, see section "Adjusting FOV" on page 121.)

Select the field of view size by tapping on the right button.



3. If necessary, enable metal artefact suppression by selecting artefact strength. A second corrected volume is automatically generated.



For detailed description on metal artefact suppression, see section "Reconstruction" on page 143.

### TIP

If hidden, this option can be enabled from the *Service* menu.

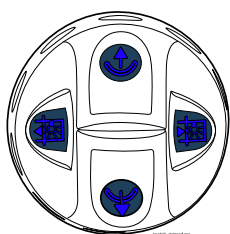


## 12.6 Positioning patient

1. Position the patient into the gantry bore.

The green lasers should be in the middle of the imaging target and the red lasers delimit the imaging area.

(See also section "Imaging examples" on page 71).



2. If necessary fine-tune the positioning manually to suit the anatomy of the patient.

Adjust the position and height of the gantry by moving and turning the joystick and the height of the tray by pressing the joystick buttons.

For detailed description on joystick functions, see section "Positioning joysticks" on page 26.

3. Verify orientation (prone or supine) and adjust if necessary.



## 12.7 Scout exposure

Scout images can be acquired to verify correct target positioning.

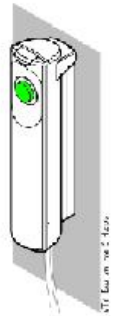
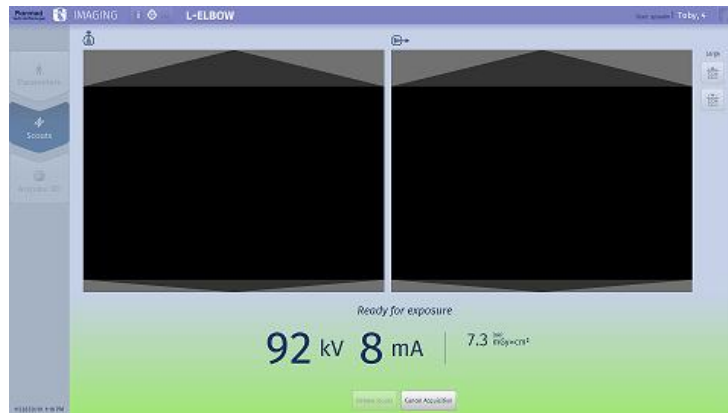
1. Tap **Scouts** on the left navigation bar.



2. **CAUTION**

**Protect the patient from raditation.**

Wait until the green indicator light on the screen comes on and the message *Ready for scout exposure* appears.



3. Ask the patient to remain still during the exposure cycle.

4. **CAUTION**

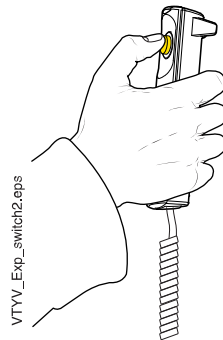
**Protect yourself from radiation and operate the exposure switch from the protected area.**

**NOTE**

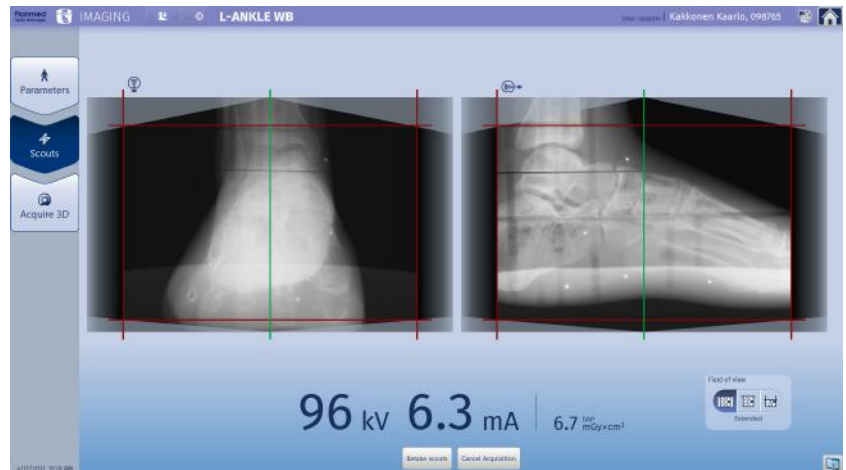
**Maintain auditory and visual contact with patient and the device during the entire exposure cycle.**

5. Press and hold down the exposure button for the whole duration of the exposure cycle.

A warning sound and a yellow light on the exposure button indicate the duration of exposure cycle. During the cycle radiation is generated.



- Verify the target positioning from AP and LAT scout images.



If necessary readjust the positioning and tap **Retake scouts**.



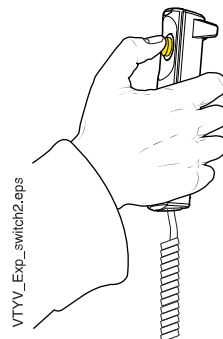
## 12.8 3D exposure

- At the touch screen tap **Acquire 3D**.



- Verify the positioning .
- CAUTION**  
Protect yourself from radiation and operate the switch from the protected area.
- Press and hold down the exposure button for the whole duration of the exposure cycle.

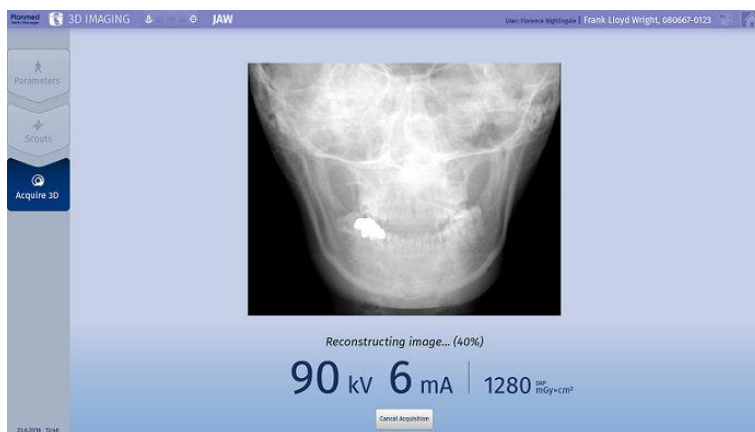
A warning sound and a yellow light on the exposure button indicate that radiation is being generated.



5. Inform the patient that the exposure cycle is completed.



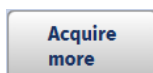
6. During reconstruction the original projections are shown. Reconstruction takes 30 to 120 s.



7. The ready image appears on the screen.

Verify the image:

- If more images are needed tap **Acquire more**.
- If the image is successful, release and help the patient out of the device.



8. The image(s) are automatically stored to *Local Study Archive*.

To return to Home screen, tap the **Home** icon.



To send images to **DICOM storage**, tap this button.



## 13 Imaging examples

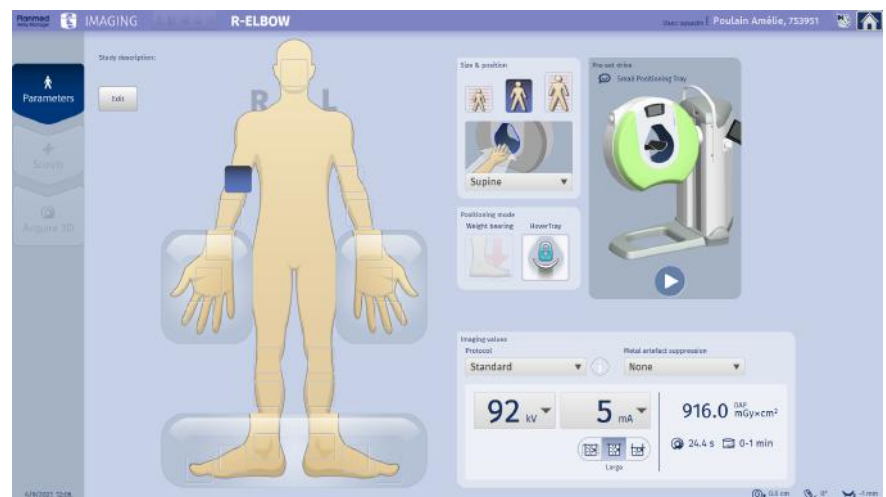
### NOTE

It is recommended to use a scattered radiation shield (see section "Scattered radiation shield" on page 29) or a lead apron.

### 13.1 Right elbow

1. In the *Imaging* screen select the **patient's** right elbow (R-ELBOW) and the correct patient size.

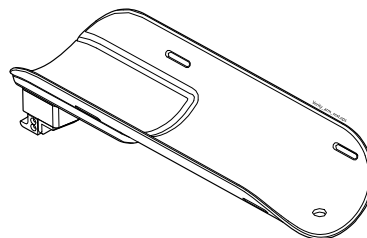
For detailed instructions, see section "Selecting imaging target" on page 64.



2. You can use pre-set drive to reach good starting position easily (see section "Pre-set drive" on page 51 for more information).

The gantry moves to the position with pre-set tilt, elevation and tray mechanism height (see also section "Pre-set positions for different body parts" on page 53).

3. **CAUTION**  
Do not touch, or allow the patient to touch, the gantry when it is moving.
4. Place the small positioning tray to the holder in the gantry bore tilting the free end upwards.



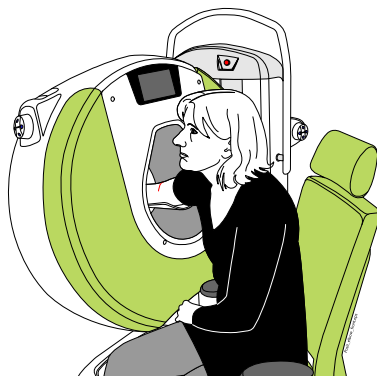
5. Push the tray down until it locks in place.

### NOTE

Never image a patient without an appropriate patient positioning tray installed in the gantry bore.

6. Place the patient positioning chair next to the gantry, to the right side of the gantry.

7. Guide the patient to sit on the patient positioning chair.  
Ask the patient to place the arm to be imaged in the gantry bore onto the tray.



8. Position the imaging target as accurately between the positioning lasers as possible.  
Adjust the position of the arm and / or move the chair in or out as necessary. Also ask the patient how they feel more comfortable.

**TIP**

The arm rests of the patient positioning chair can be removed by unscrewing the fastening screws from below the seat.



9. Fine-tune the positioning using joysticks if necessary (for instructions, see section "Joystick controls" on page 56 .

10. Verify orientation (prone or supine) and adjust if necessary.



11. To take exposure continue to section "Scout exposure" on page 118 or to section "3D exposure" on page 124)

## 13.2 Weight-bearing imaging

**NOTE**

The weight-bearing mode is optional.

**CAUTION**

In the weight-bearing imaging the patient is required to step into the gantry bore previously driven down into the horizontal position. Before using this mode always assess the patient's condition and provide them with support as necessary to ensure safe positioning.

**CAUTION**

Make sure the patient is in suitable condition to stand for the duration of the study.

**CAUTION**

Never use vertical positioning tray in weight-bearing mode.

### 13.2.1 Weight-bearing imaging of right knee

1. In the *Imaging* screen select the patient's right knee (R-KNEE).



2. Select **Weight-bearing** mode by tapping.



3. **CAUTION**

Do not touch or allow the patient to touch the gantry when it is moving and make sure that there is no danger of anything squeezing under or between the gantry and the column.

Activate the weight-bearing mode with *Pre-set drive*.



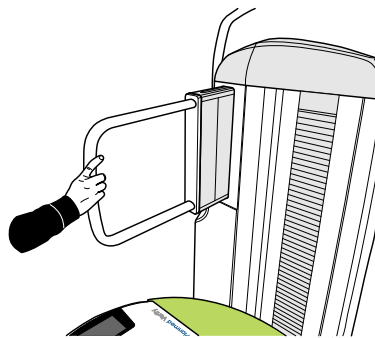
4. Press and hold down any joystick button.

When the gantry has moved and locked into pre-set horizontal position the LEDs stop blinking and the pop-up window clears from the screen.

5. Attach the large positioning tray into the gantry bore.



6. Pull out the support handle from the upper part of the vertical column.





7. Ask the patient to step **directly** into the gantry bore with the right leg and grab the handles with both hands as. Support the patient from the left side if necessary.

### CAUTION

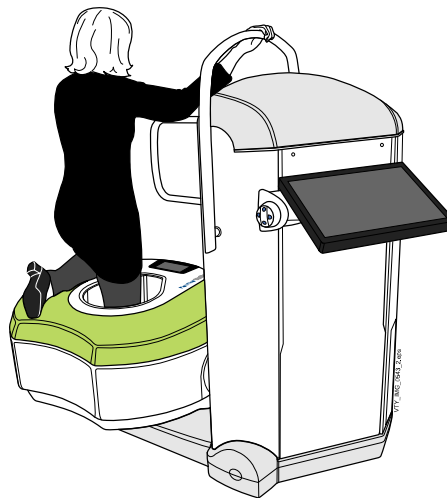
Make sure the patient does **NOT** step on the gantry ring.

### NOTE

When standing in the gantry bore the patient may lean the left knee on the gantry as the tilt mechanism is safely locked in place.

### TIP

Use the joysticks to drive the tray upwards (towards the patient's leg) for maximum support.



8. The program now proposes average kV and mA values based on your selections. If necessary, you can adjust them manually. For example, if you have a person of very light body build, you may want to decrease the exposure values accordingly.

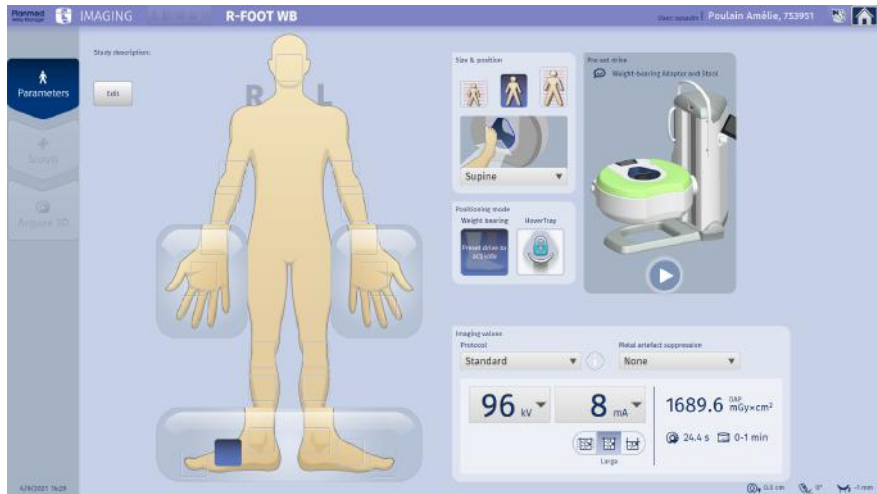


9. Position the area to be imaged as carefully between the positioning lasers as possible using the positioning joystick.
10. Provide the patient with appropriate radiation protection.
11. Ask the patient to remain still, keeping their weight on the leg being imaged.

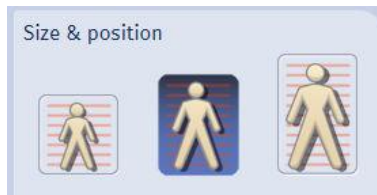
You may now proceed to the taking of a scout image (see section "Scout exposure" on page 118) or directly to the taking of the actual exposure, (see section "3D exposure" on page 124).

### 13.2.2 Weight-bearing imaging of right foot (metatarsus)

1. Select the patient's right foot (R-FOOT).



2. Verify the default patient size and adjust if necessary.



3. For detailed instructions, see section "Selecting imaging target" on page 64.
4. Select **Weight-bearing** mode by tapping.



5. **CAUTION**

**Do not touch or allow the patient to touch the gantry when it is moving.**

Activate weight-bearing mode with Pre-set drive.

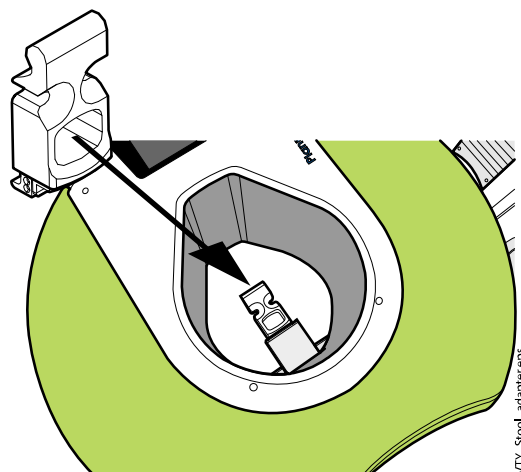


## 6. Press and hold down any joystick button.

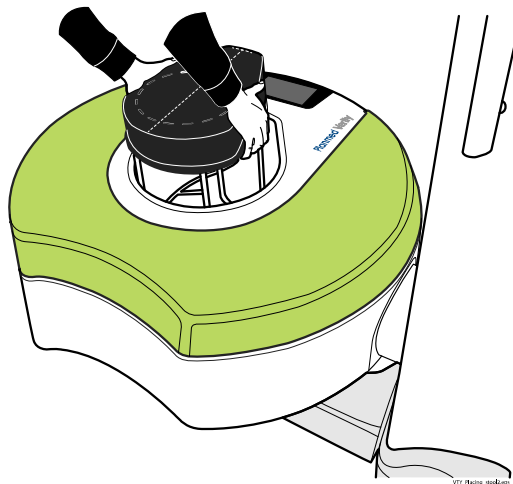
The joystick LEDs start to blink and the gantry moves and locks into pre-set horizontal position near the floor level.



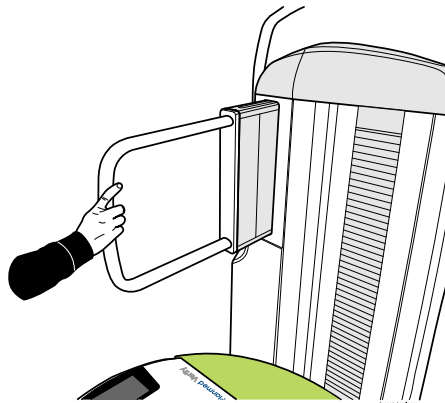
## 7. Attach the weight-bearing stool adapter into the gantry bore.



8. Insert the weight-bearing stool into the gantry bore down on the floor.



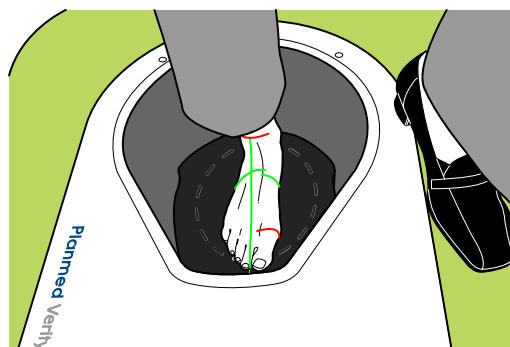
9. Pull out the support handle from the upper part of the vertical column.



10. **CAUTION**

Ask the patient to step directly onto the stool in the gantry bore, NOT on the gantry ring. The weight limit for both stool and gantry is 135 kg.

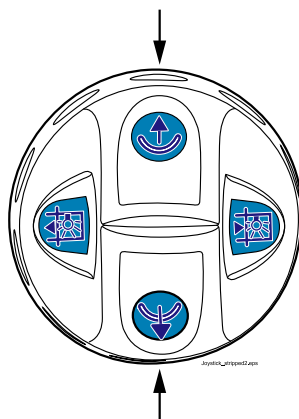
The patient may lean the other leg on the gantry which is locked in horizontal position.



11. Instruct the patient to grab the support handle. Provide additional support if necessary.

- Position the imaging target as carefully between the positioning lasers as possible. The FOV begins from the stool surface.

You can adjust the gantry upwards with joysticks if needed.



- Provide the patient with appropriate radiation protection.
- Ask the patient to remain still, keeping their weight on the leg being imaged.

You may now proceed to taking scout exposure (see section "Scout exposure" on page 118 or directly to taking 3D exposure (see section "3D exposure" on page 124).

### 13.3 MaxScan imaging

MaxScan imaging is an optional feature with limited availability.

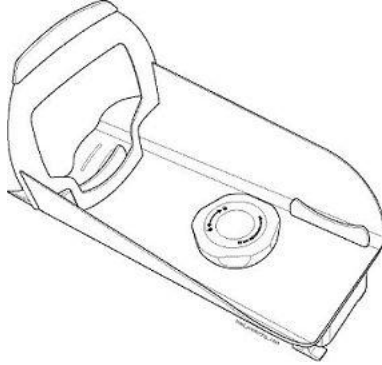
- In the *Imaging* screen select the maxillofacial area.



2. Place the head positioning tray to the holder in the gantry bore tilting the free end upwards.

**NOTE**

The head positioning tray can only be used in countries where local regulations are met.



3. Push the tray down until it locks in place.

**NOTE**

Never image a patient without an appropriate patient positioning tray installed in the gantry bore.

- 4.



Tap this button.

The gantry moves to the position with pre-set tilt, elevation, and tray mechanism height.

**CAUTION**

Do not touch or allow the patient to touch the gantry when it is moving.

5. You can use pre-set drive to reach good starting position easily (see section "Pre-set drive" on page 51 for more information.)
6. If necessary use the joysticks to manually fine-tune the positioning to suit the anatomy of individual patients.
7. Place the patient positioning chair next to the gantry.

**NOTE**

If necessary the arm rests of the patient positioning chair can be removed by unscrewing the fastening screws from below the seat.

**NOTE**

It is recommended to use a lead apron on a patient when taking exposures.

8. Guide the patient to sit on the chair and ask them to place the chin onto the positioning tray as illustrated.

### CAUTION

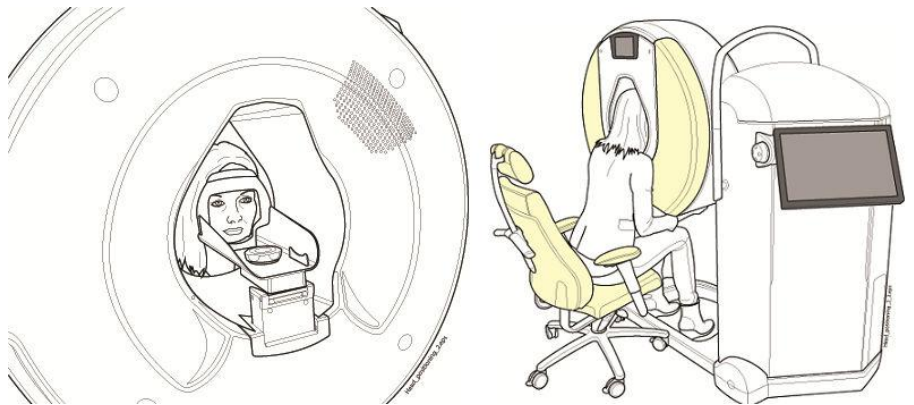
The maximum weight supported by the head positioning tray is 10 kg (22.05 lbs).

### CAUTION

Do NOT attach the patient's head to the positioning tray.

### CAUTION

Only image seated patients. Do NOT image patients in lied down position.

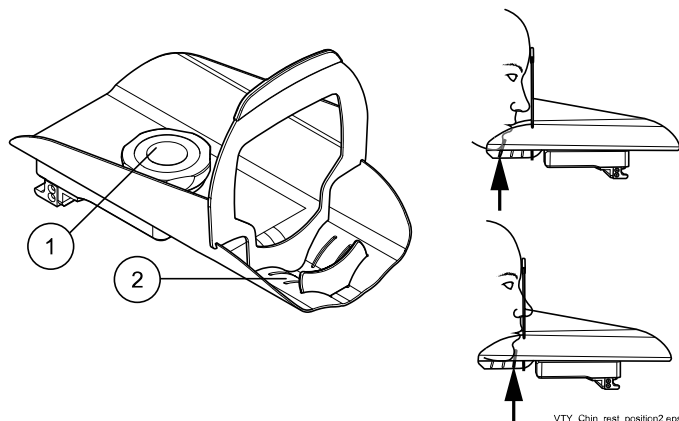


- 1 Forehead
- 2 Chin

9. Place the selected imaging area as accurately between the positioning lasers as possible:
- Adjust the position of the patient's head and / or move the chair in or out as necessary. Also ask the patient how they feel the most comfortable.
  - Fine-tune the height and tilting angle of the gantry, and the height of the patient positioning tray, from the nearest joystick, see section "Joystick controls" on page 56 for details.

The head position can also be adjusted by opening the tray adjustment knob (1) and gently sliding the tray towards or away from the patient.

The chin position can be fine-tuned by placing the chin support piece (2) to pre-selected locations.



10. Provide the patient with appropriate radiation protection.
11. Instruct the patient to remain still for the whole exposure cycle.

You may now proceed to scout imaging (see section "Scout exposure" on page 118 or continue to 3D imaging ("3D exposure" on page 124).

### 13.4 Head & neck imaging

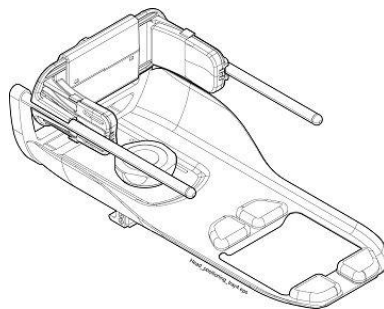
**NOTE**

Head & Neck imaging is an optional feature with limited availability.

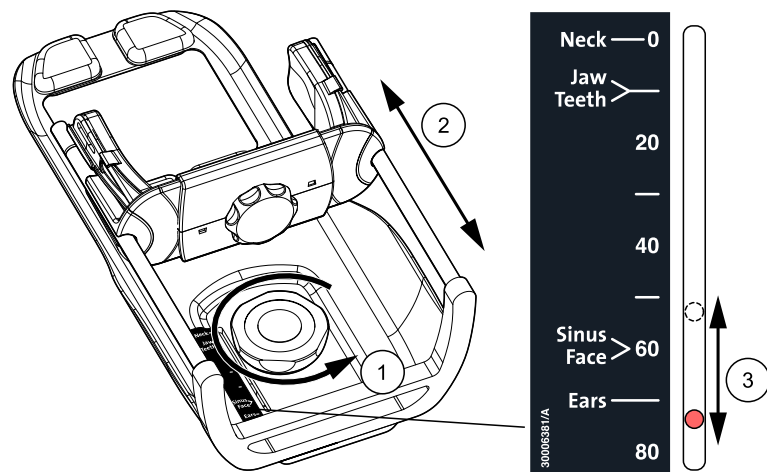
1. Attach the patient positioning tray to the holder in the gantry bore by tilting the free end upwards. Push the tray down until it locks in place.  
If the tray holder is too high in the gantry bore drive it down before attaching the tray.

**NOTE**

The Head & Neck positioning tray may only be used in countries where local regulations are met.



2. Adjust the head position by opening the tray adjustment knob (1) and gently sliding the tray towards or away from the patient. You can also adjust the tray in the depth direction (2) to fit to the selected target. Use the anatomy scale (3) to optimize positioning.

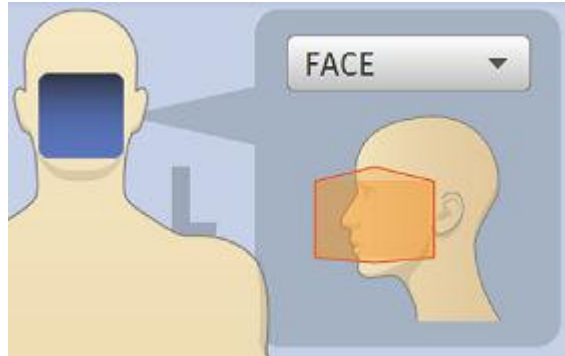




- In the *Imaging* screen select the face area.

### CAUTION

You are about to drive the gantry. Make sure that the patient is **NOT** positioned in the gantry and that there is no danger of anything squeezing under the gantry or between the gantry and the column.



- Select patient size.



- You can use pre-set drive to reach good starting position easily (see section "Pre-set drive" on page 51).



- If necessary use the joysticks to manually fine-tune the positioning to individual anatomy.
- Place the patient positioning chair next to the gantry.

### TIP

If necessary, remove the arm rests by loosening the fastening screws below the seat.

- Guide the patient to sit on the chair.

### NOTE

It is recommended to use a lead apron on a patient when taking exposures.

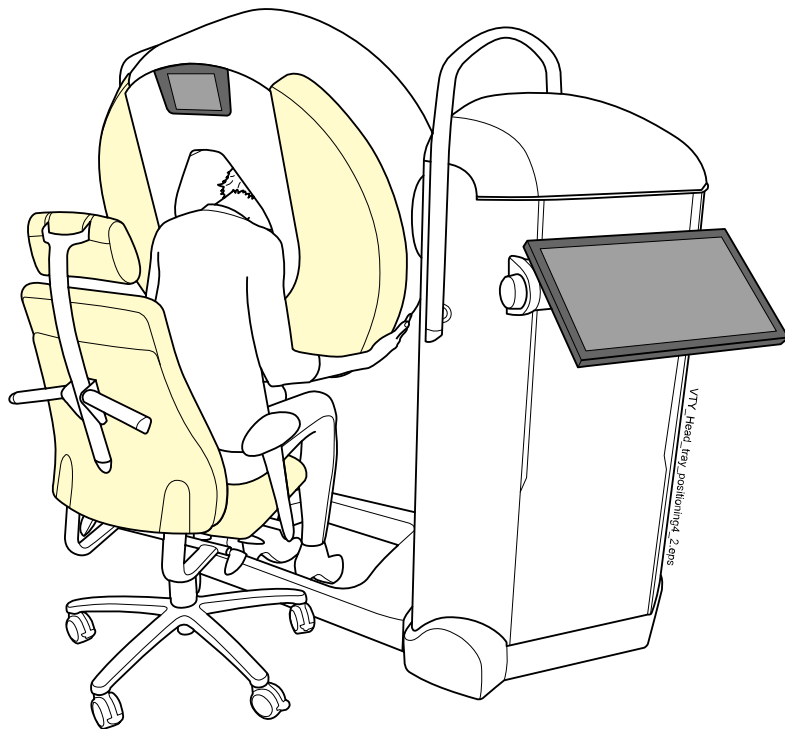
9. Ask the patient to place the feet on the floor through the base support hole. Make sure the patient does NOT step on the base support.

### CAUTION

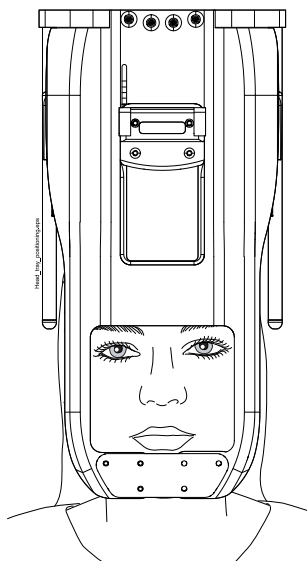
The maximum weight supported by the Head & Neck positioning tray is 10 kg (22.05 lbs).

### CAUTION

Only take exposures of seated patients. Do NOT take exposures of patients in lied down position.

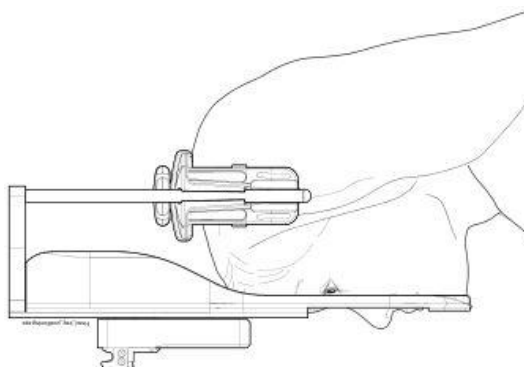


10. Ask the patient to place the chin and the forehead onto the positioning tray.

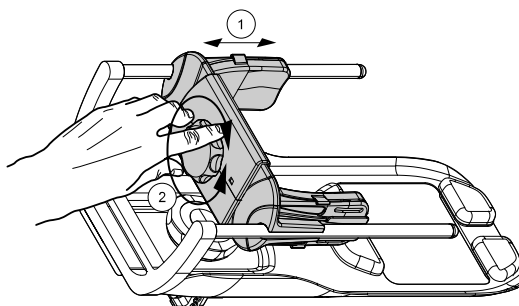


The camera starts driving to the side of the gantry.

11. Check that the target is in the imaging area and adjust the positioning if necessary.

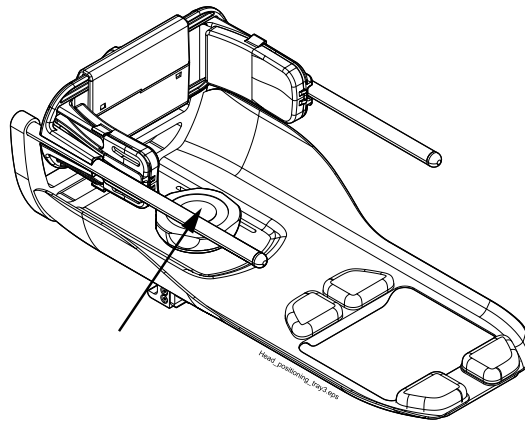


12. Stabilize the position by moving the side plates (1) and turning the knob of the head support adjustment mechanism (2).



13. Place the imaging target as accurately between the positioning lasers as possible:
- Adjust the position of the head and / or move the chair in or out as necessary. Also ask the patient how they feel the most comfortable.
  - Fine-tune the height and tilting angle of the gantry and the height of the tray from the nearest joystick (see section "Positioning joysticks" on page 26).

The position can also be adjusted by opening the tray adjustment knob and gently sliding the tray closer or further away from the patient.



14. Provide the patient with appropriate radiation protection.
15. Instruct the patient to remain still for the whole exposure cycle.

You may now proceed to the taking of a scout image (see section "Scout exposure" on page 118) or directly to the taking of the actual exposure (see section "3D exposure" on page 124).

## 13.5 Hover tray imaging

The Hover tray positioning mode can be used for example for imaging casted extremities or in other situations in which moving the extremity is difficult for the patient. In Hover tray mode the tray stays immobile in relation to the patient, while the joystick is being used to adjust gantry position and thus the field of view.

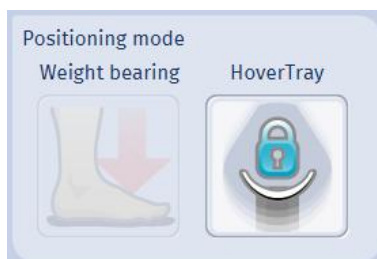
1. Select the body part and the patient size.

### NOTE

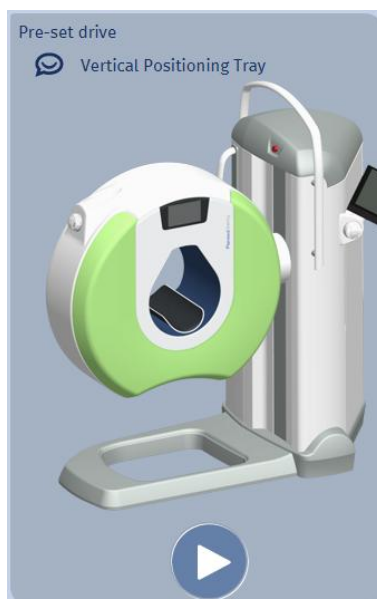
The head area is not supported



2. Select **HoverTray** mode.



3. Drive to pre-set destination as instructed in section "Pre-set drive" on page 65 to activate the mode.



4. The tray is now at the bottom of the gantry bore for easy positioning. Position the patient.



#### TIP

You can adjust the tray and the gantry to optimum height for the patient by pressing the tray height buttons while pushing the joystick up or down.

5. Finally, adjust the gantry downwards to position the target vertically into the FOV.
6. To take exposure, continue to section "Scout exposure" on page 118 or to section "3D exposure" on page 124)

## 13.6 Imaging with eFOV

The following section describes the use of extended field of view (eFOV) in detail.

EFOV increases the volume diameter to 20 cm from 16 cm that is used in large and small FOV. The extended volume area (here seen in lighter yellow) is reconstructed from less data lowering image quality.

#### NOTE

Limited angle reconstruction that is used to create the extended field of view (eFOV) offers visualization aid, not diagnostic value.

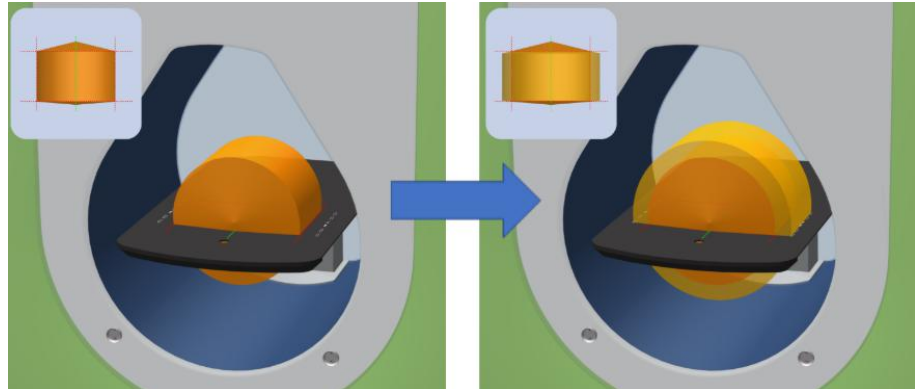
### 13.6.1 Patient positioning with eFOV

With eFOV, the extended target area is *not* displayed with the red laser lights. Instead, the extended area is indicated with the printed markings on the positioning equipment as instructed in the following examples.

**TIP**

**eFOV is not available for head imaging.**

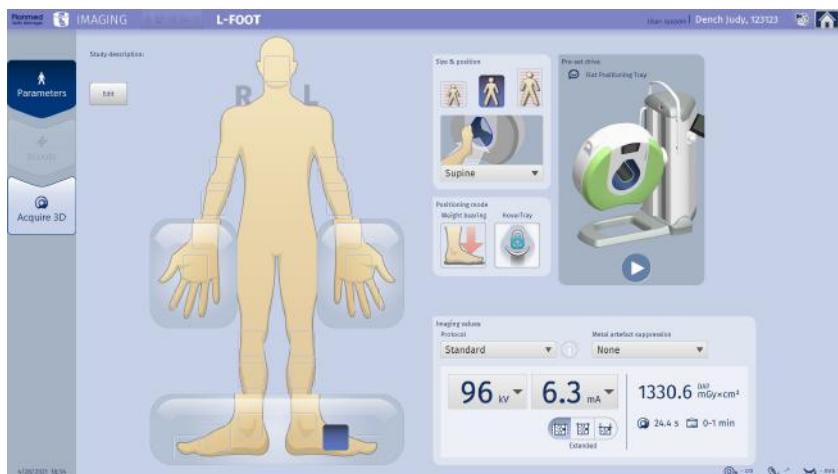
This image illustrates the extended field of view.



### 13.6.2 Weight-bearing imaging of foot with eFOV

1. Select **ANKLE** , **FOOT** or **TOE** as imaging target.

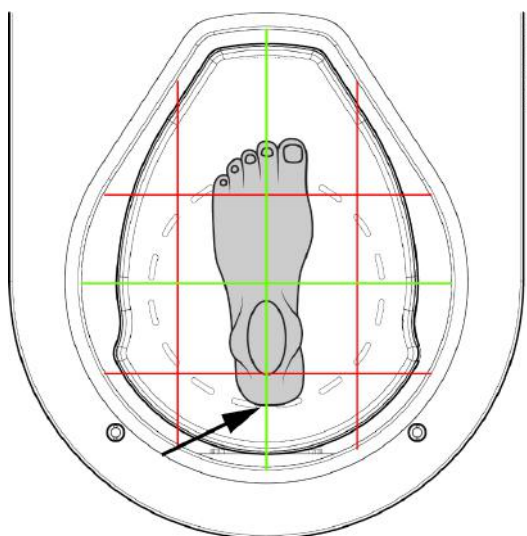
Drive the unit to weight bearing mode as described in section "Weight-bearing imaging of right foot (metatarsus)" on page 76.



2. Tap the extended field of view button.



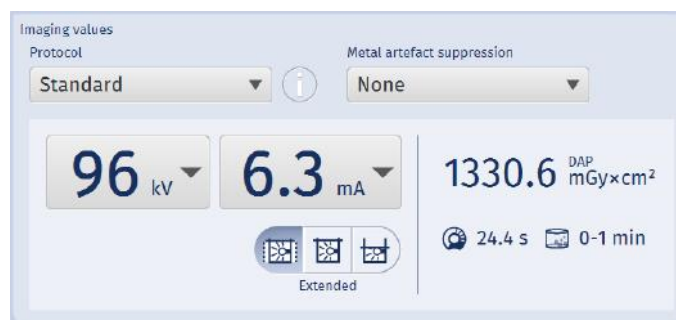
- Position the patient using the dashed lines that indicate eFOV area on the weight-bearing stool.



### TIP

Use the red lasers to keep the primary imaging target inside the full data FOV.

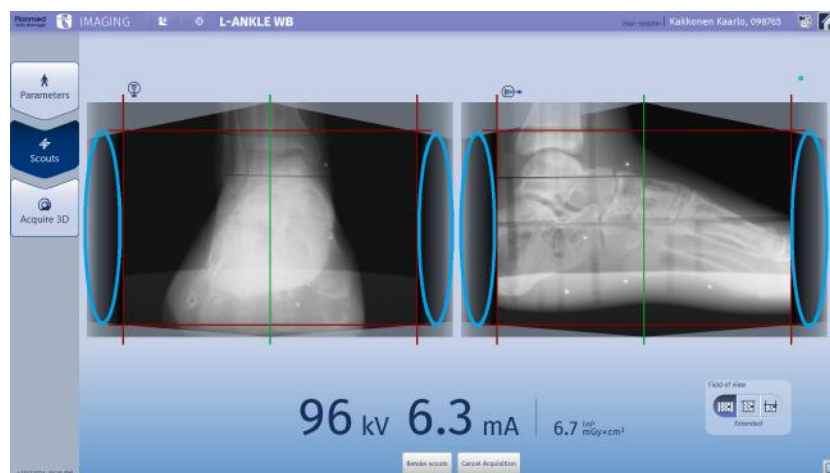
- Verify the default imaging values and adjust if necessary.



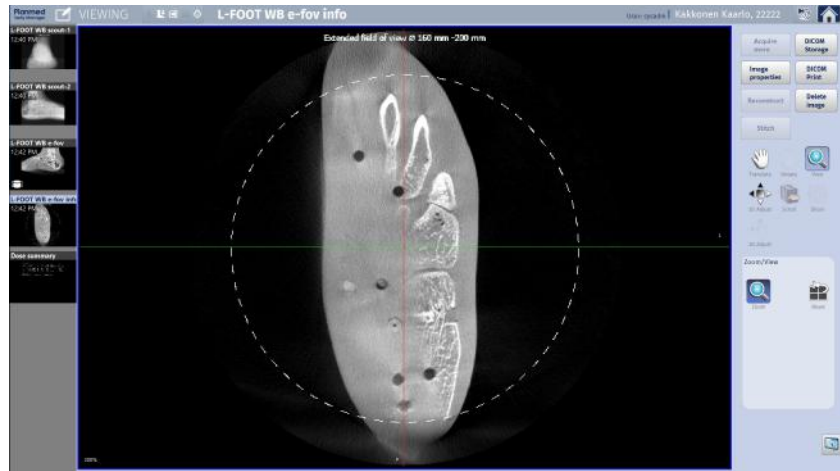
- Acquire images as usual ("3D exposure" on page 124).

### NOTE

The eFOV area is not shown in scout images. Instead, the blank areas (circled in blue in the image) on the outer sides of the images indicate the extended area available for 3D reconstruction.



EFOV images contain a separate annotated slice indicating the eFOV area for the clinician reading the image. The eFOV area starts outside the circular dashed line.



**TIP**

If you do not want the info slice to appear, the option can be deselected in Settings.

**13.6.3 Imaging wrists with eFOV**

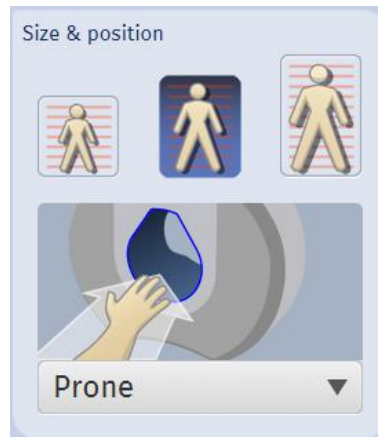
When imaging both hands (e.g. clenched fist images) with extended field of view the ulna becomes visible.

1. Select **WRIST**.





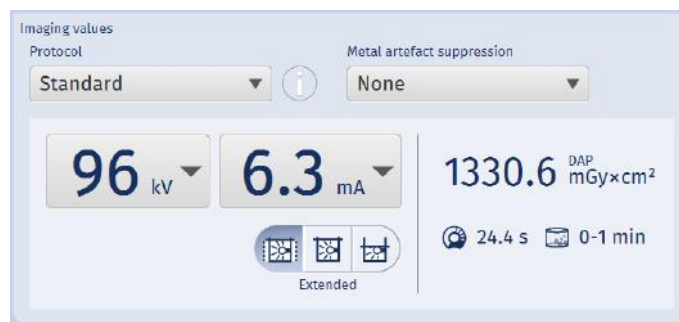
- Verify the default patient size and adjust if necessary.



- CAUTION**  
Do not touch or allow the patient to touch the gantry when it is moving.

You can use pre-set drive to reach good starting position easily (see section "Pre-set drive" on page 65 for more information.)

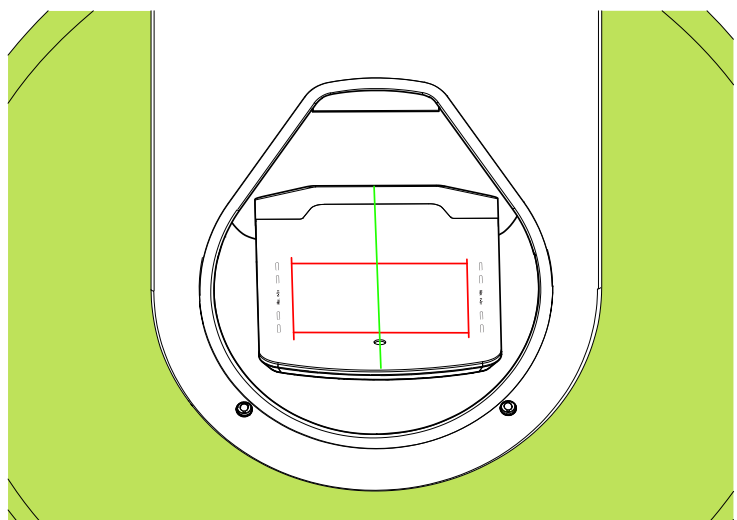
- Verify the default imaging values and adjust if necessary.



- Tap the eFOV (extended field of view) button.

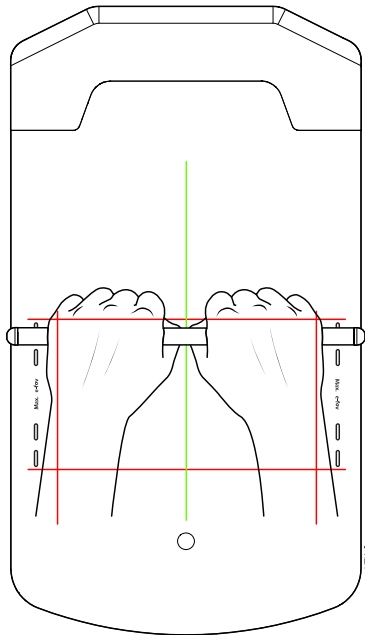


- Place the wide positioning tray to the holder in the gantry bore tilting the free end upwards.



- Push the patient positioning tray down until it locks in place.

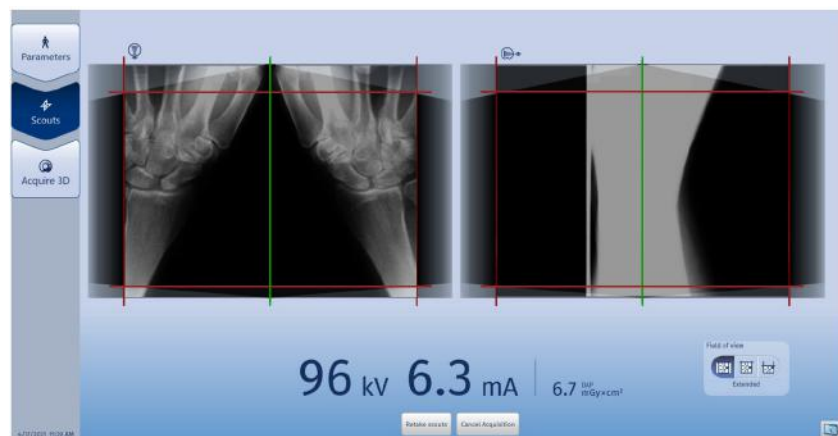
8. Ask the patient to hold the rod with both hands.  
Position the wrists so that the entire imaging target stays inside the red positioning lasers and the dashed eFOV lines.



9. If necessary, use the joysticks to manually fine-tune the positioning to suit the anatomy of individual patient.
10. Provide the patient with appropriate radiation protection.
11. Acquire images as usual ("3D exposure" on page 124).

**NOTE**

The eFOV area is not shown in scout images. Instead, the empty gradient bars indicate the extended area.



eFOV images contain a separate annotated slice indicating the eFOV area for the clinician reading the image.

**TIP**

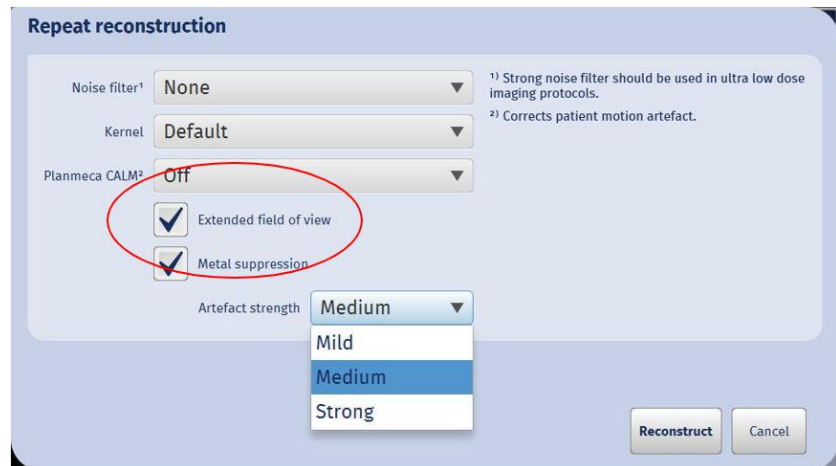
If you do not want the info slice to appear, the option can be deselected in Settings.

### 13.6.4 Reconstructing eFOV after imaging

eFOV can also be reconstructed after imaging when you have acquired an image using large or small field of view.

Tap **Reconstruct** in the *Viewing* screen.

Check the *Extended field of view* box and tap **Reconstruct**.



**Repeat reconstruction**

Noise filter<sup>1)</sup> **None** ▼ <sup>1)</sup> Strong noise filter should be used in ultra low dose imaging protocols.

Kernel **Default** ▼ <sup>2)</sup> Corrects patient motion artefact.

Planmeca CALM? **Off** ▼

Extended field of view

Metal suppression

Artefact strength **Medium** ▼

Mild

**Medium**

Strong

**Reconstruct** **Cancel**

## 14 Stitching volumes

The following section describes the procedure of taking two or three exposures and stitching them together.

### 14.1 Before stitching

For stitching, two or three volumes are acquired in the same study. The acquired volumes are then stitched together with stitching tool in a single image containing the data of the acquired images. The following section describes this procedure.

#### 14.1.1 Stitching requirements

Before stitching check that the following criteria is met:

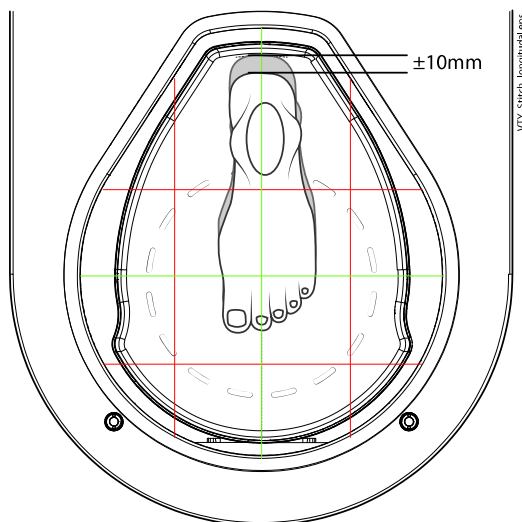
- Resolution is 0.4
- Body part is supported
- FoV is large (eFoV / small FoV not supported)
- Patient position is correct

#### NOTE

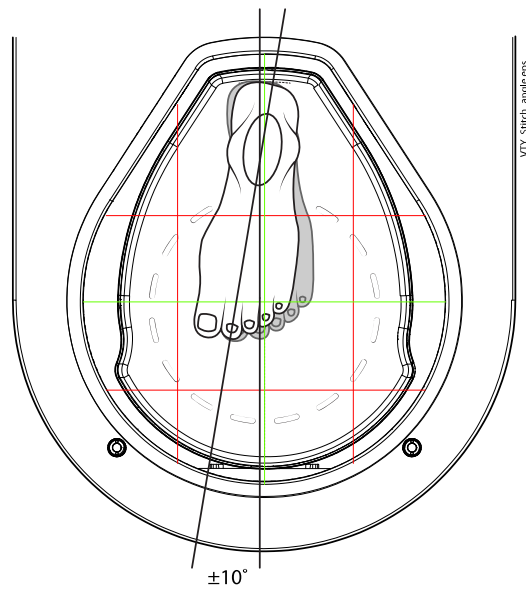
Re-reconstructed images (CALM, metal artefact suppression, different kernel) are suitable for stitching.

The required positioning accuracy for stitching is:

- Combined longitudinal displacement  $\pm 10\text{mm}$



- Combined angular displacement  $\pm 10^\circ$

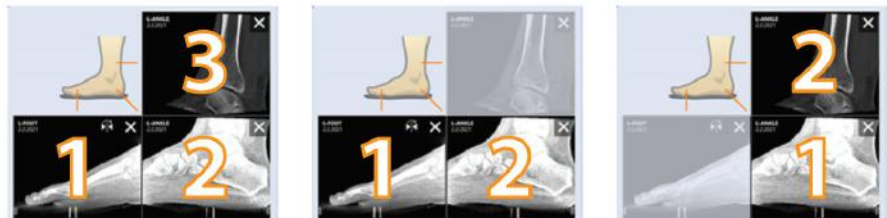


## 14.2 Stitching workflows

The following sections describe the full three-volume workflows for acquiring forefoot, distal ankle and proximal ankle images.

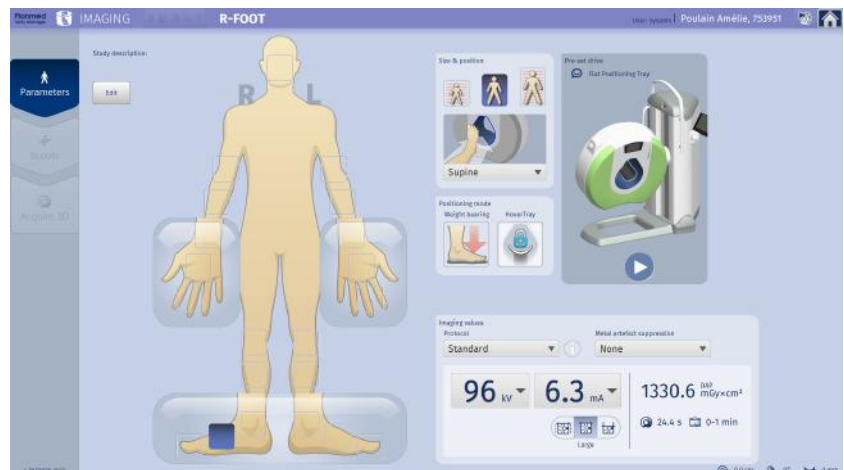
### TIP

Foot stitching can also be done with two connected vertical or horizontal volumes.



### 14.2.1 Foot-stitching with vertical tray

1. Select **FOOT** or **TOE** as imaging target.

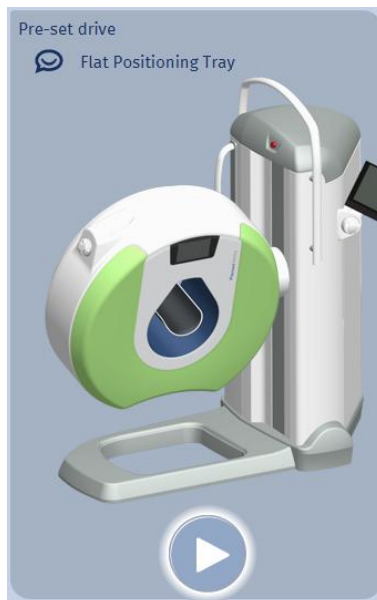


2. Verify the default patient size and adjust if necessary.

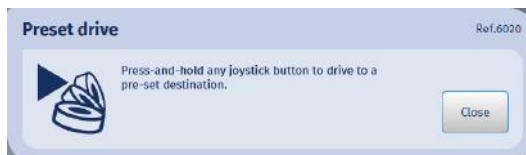


3. **CAUTION**  
Do not touch or allow the patient to touch the gantry when it is moving.

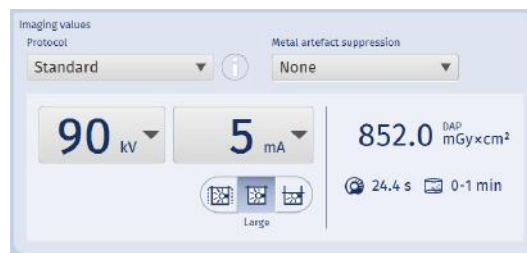
You can use pre-set drive to reach good starting position easily.  
(For more information, see section "Pre-set drive" on page 65)



4. Press and hold down any joystick button.  
When the gantry has reached the pre-set position, the LEDs stop blinking and the pop-up window clears from the screen.



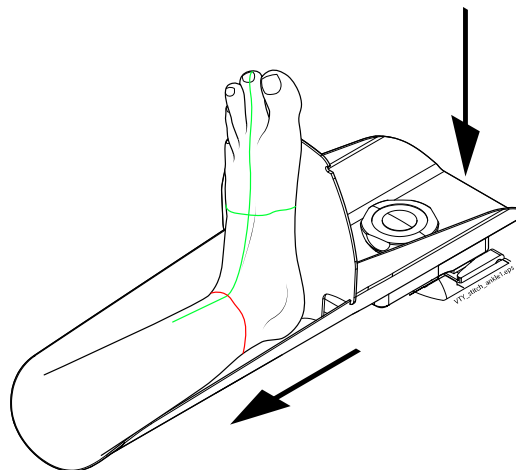
- Use imaging protocol that has 0.4 mm resolution, such as *Standard* protocol.



- Verify that the large FOV is selected and adjust if necessary.

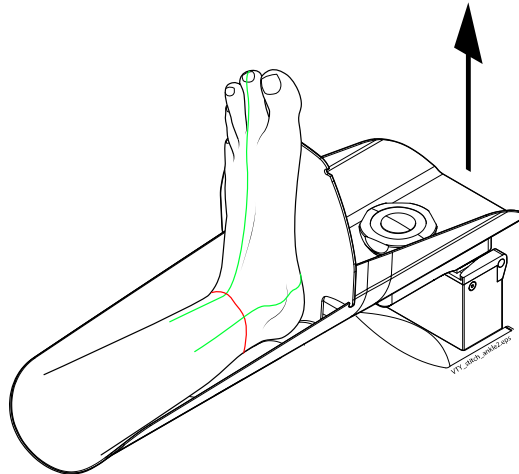


- Place the vertical positioning tray to the holder in the gantry bore tilting the free end upwards. Slide the tray to the front and lock it.
- For the first exposure drive the tray to the lowest position. If necessary, loosen the hand screw on the tray and slide the tray to forward position and lock it.

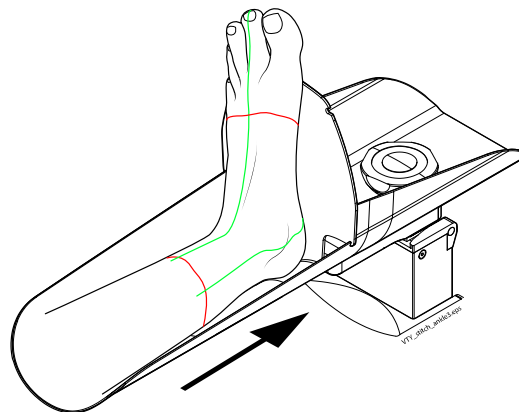


- Ask the patient to sit down and to place the foot to be imaged onto the patient positioning tray into the gantry bore.
- Provide the patient with appropriate radiation protection.
- Continue to "Scout exposure" on page 118 or directly to "3D exposure" on page 124.
- Verify that the image is ok and tap **Acquire more**.

13. For the second exposure, drive the patient positioning tray all the way up to acquire image from the distal ankle.



14. Select ANKLE as imaging target.
15. Acquire the second image. Verify image quality and tap **Acquire more**.
16. Loosen the hand screw on the tray and slide the tray to backward position and lock it to acquire image from the proximal ankle.



17. Keep ANKLE as imaging target.
18. Acquire the third image. Verify image quality and tap **Acquire more**.
19. Continue to "Stitching foot volumes together" on page 109.

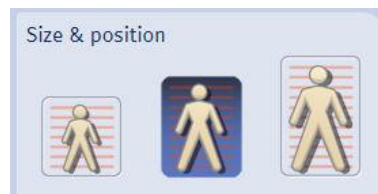


## 14.2.2 Weight-bearing foot stitching (small <24 cm)

1. Select **FOOT** or **TOE**.



2. Verify the default patient size and adjust if necessary.



3. Select **Weight-bearing** mode by tapping.



4. **CAUTION**

Do not touch or allow the patient to touch the gantry when it is moving.

Activate the weight-bearing mode with *Pre-set drive*.

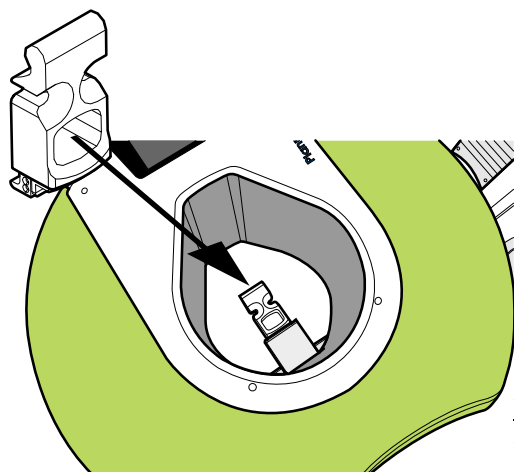


5. Press and hold down any joystick button.

When the gantry has reached the pre-set position, the LEDs stop blinking and the pop-up window clears from the screen.

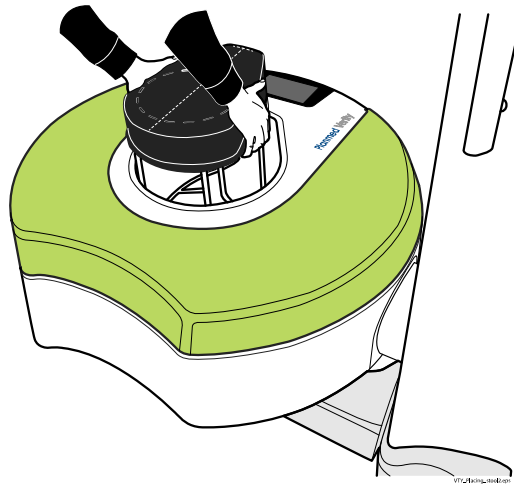


6. Attach the weight-bearing stool adapter into the gantry bore.

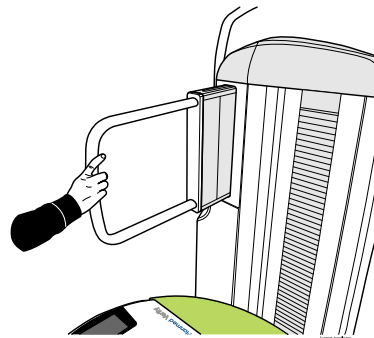


7. Insert the weight-bearing positioning stool into the gantry bore over the adapter.

Press the stool down on the floor.



8. Pull out the support handle from the upper part of the vertical column.



9. Use imaging protocol that has 0.4 mm resolution, such as Standard protocol.



10. Verify that the large FOV is selected and adjust if necessary.

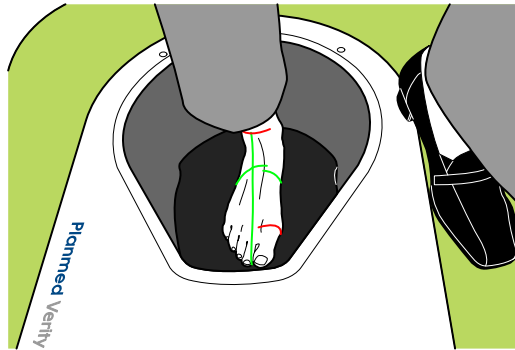


- Instruct the patient to step on the stool inside the gantry bore and use the support handles.

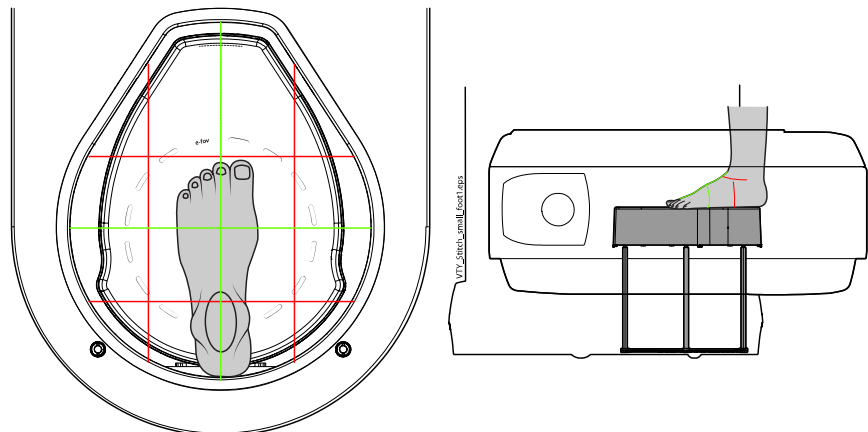
The patient may lean the other leg on the gantry locked in horizontal position.

**CAUTION**

Instruct the patient to step *directly* into the gantry bore, NOT on the gantry ring. The weight limit for both the stool and the gantry is 135 kg.



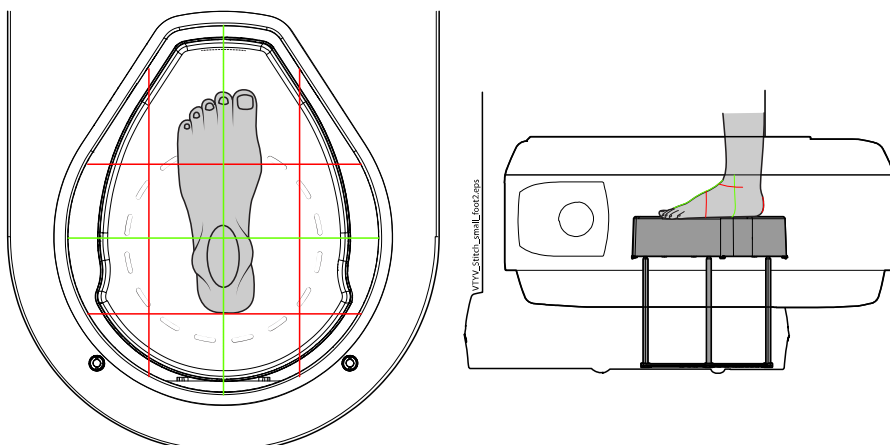
- Position the foot so that the heel touches the bottom edge of the gantry bore and the green laser goes along the foot.



- Provide the patient with appropriate radiation protection.
- Continue to "Scout exposure" on page 118 or directly to "3D exposure" on page 124).
- Verify that the image is ok and tap **Acquire more**.
- For the second volume, select ANKLE as imaging target.



17. Position the foot so that the heel edge touches the lower horizontal red laser.

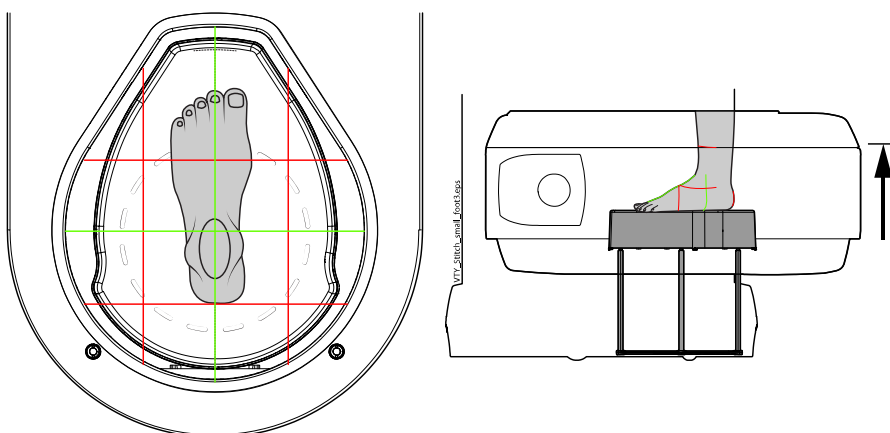


**Acquire  
more**

18. Acquire second image. Verify image quality and select **Acquire more**.

19. For the third volume, select ANKLE as imaging target.

20. Drive the gantry upwards to the limit and take exposure from the proximal ankle.



21. Take exposure as instructed in section "Scout exposure" on page 118 or "3D exposure" on page 124).

22. When finished, continue to "Stitching foot volumes together" on page 109.

### 14.2.3 Weight-bearing foot stitching (large >24 cm)

1. Select **FOOT** or **TOE**.



2. Verify the default patient size.



3. Select **Weight-bearing** mode by tapping.



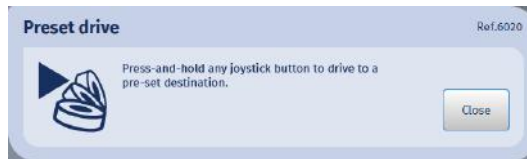
4. **CAUTION**

**Do not touch or allow the patient to touch the gantry when it is moving.**

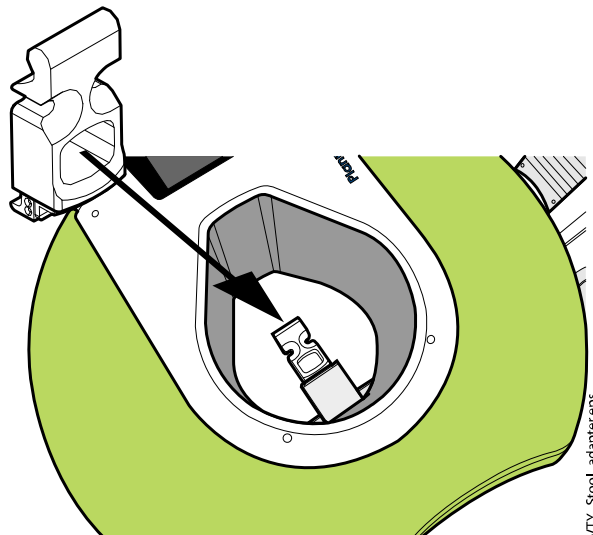
Activate weight-bearing mode with Pre-set drive.



5. Press and hold down any joystick button. When the gantry has reached the pre-set position, the LEDs stop blinking and the pop-up window clears from the screen.



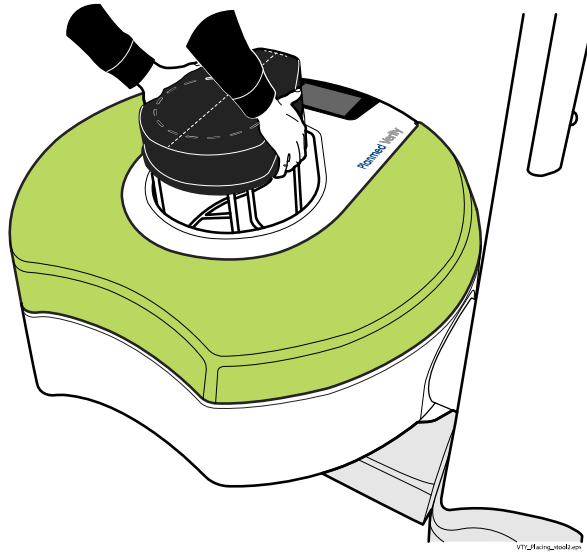
6. Attach the weight-bearing stool adapter into the gantry bore.



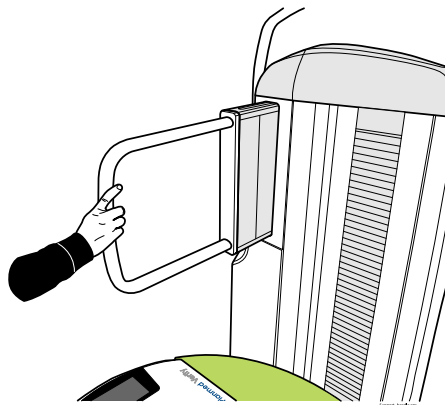
VTY\_Stool\_adapter.eps

7. Insert the weight-bearing positioning stool into the gantry bore over the adapter.

Press the stool down on the floor.



8. Pull out the support handle from the upper part of the vertical column.



9. Use imaging protocol that has 0.4 mm resolution, such as Standard protocol.



10. Verify that the large FOV is selected and adjust if necessary.





11. Change position parameter to **Prone**.

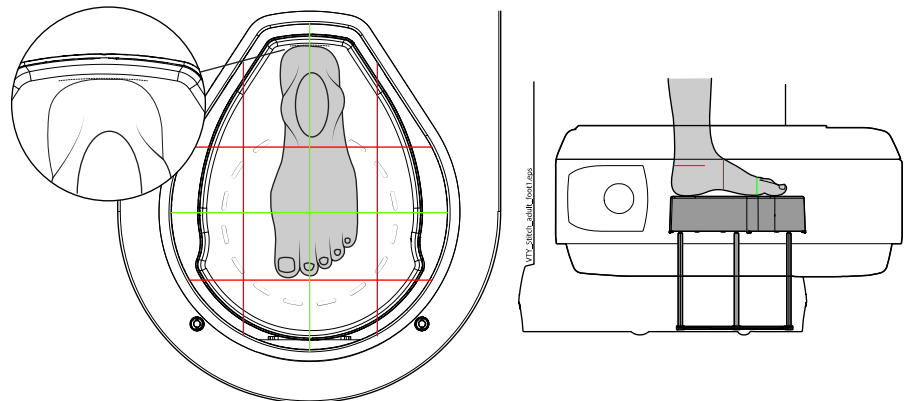


12. **CAUTION**

Instruct the patient to step directly into the stool, **NOT** on the gantry ring. The weight limit for both stool and gantry is 135 kg.

The patient may lean the other leg on the gantry locked in horizontal position.

13. Position the foot so that the heel touches the marking on the narrow end of the weight-bearing stool.



14. Provide the patient with appropriate radiation protection.
15. Take exposure as instructed in section "Scout exposure" on page 118 or in section "3D exposure" on page 124).
16. Verify that the image is ok and tap **Acquire more**.

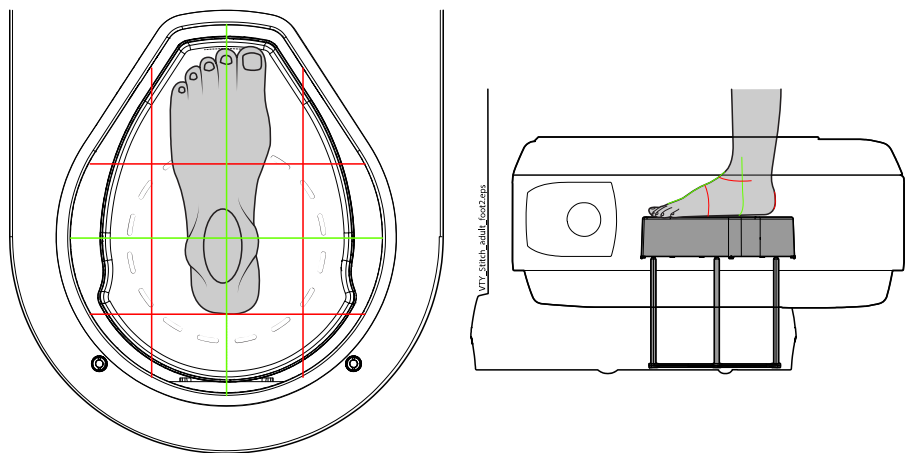


17. For the second volume, select ANKLE.



18. Turn the patient by 180°.

Make sure that the heel touches the lower red laser.



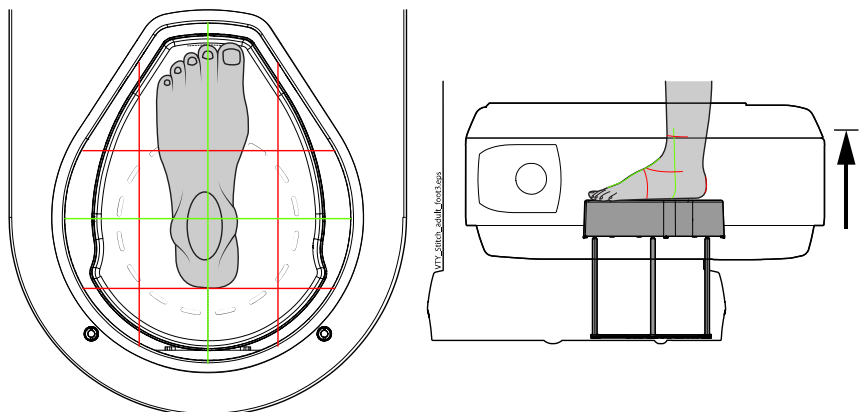
19. Take exposure as instructed in section "Scout exposure" on page 118 or in section "3D exposure" on page 124).

20. Verify that the image is ok and tap **Acquire more**.



21. For the third volume keep ANKLE as imaging target.

22. Drive the gantry to the upmost position to take exposure from the proximal ankle.



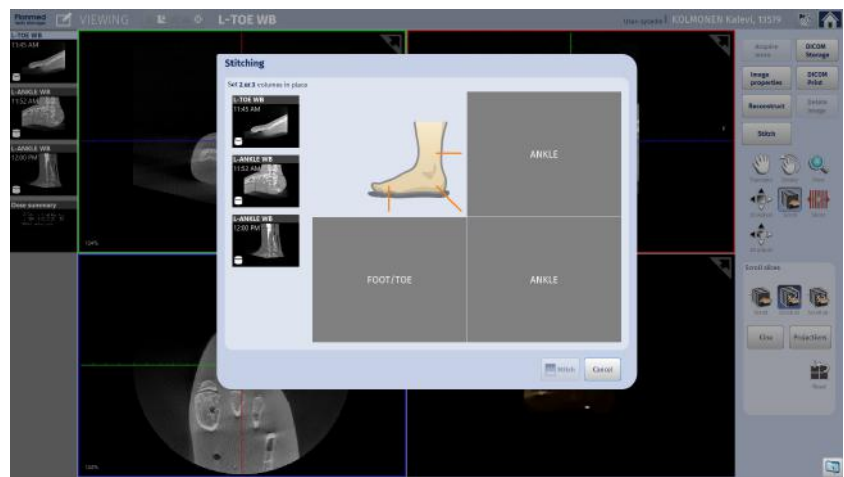
23. Take exposure as instructed in "3D exposure" on page 124 or in "Scout exposure" on page 118.
24. Verify that image is ok.
25. When finished, continue to "Stitching foot volumes together" on page 109.

### 14.2.3.1 Stitching foot volumes together

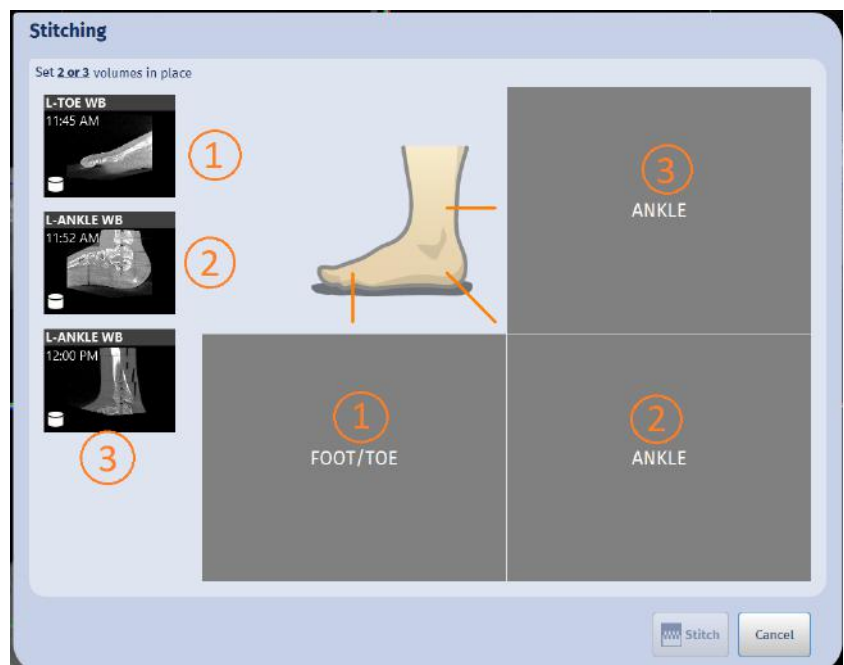


1. When all images have been acquired, click **Stitch** on the *Viewing* screen.

The stitching dialogue opens.



2. Set the images in place one by one by first clicking on the image thumbnail and then on the box with corresponding anatomy.



**NOTE**

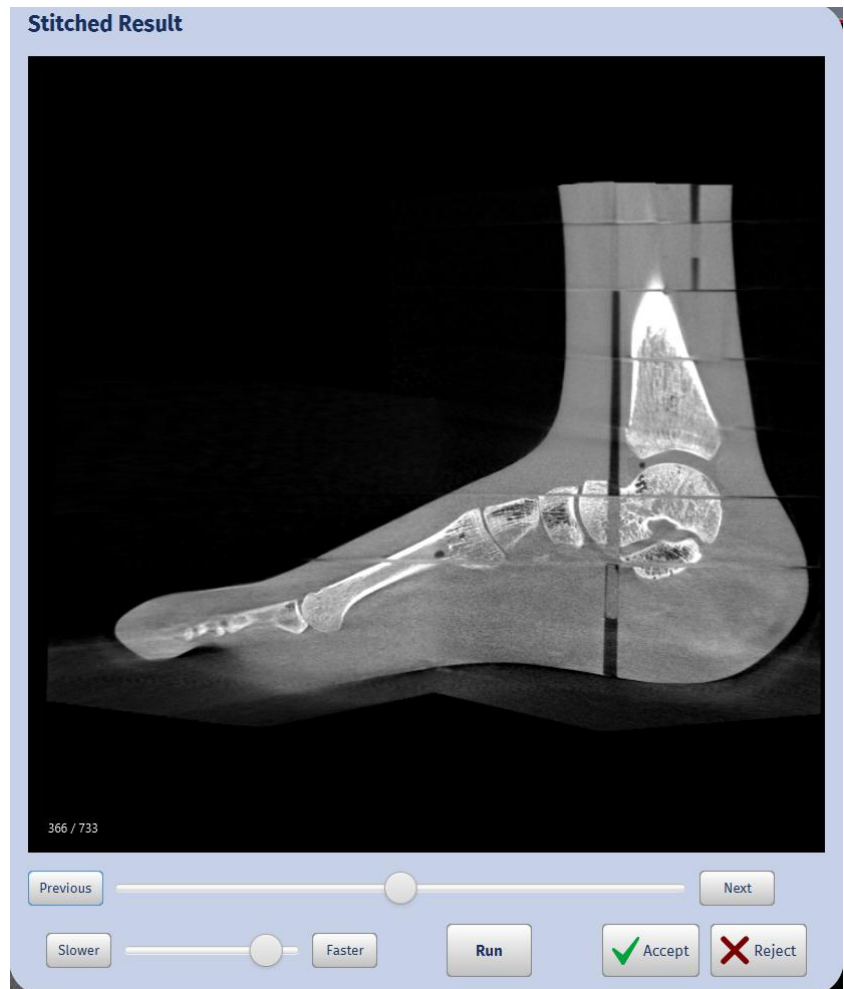
**TIP**

If patient position was incorrect during acquisition, the foot or toe image can be flipped by tapping the arrow button. Remember also to change the position of the original image from image properties.

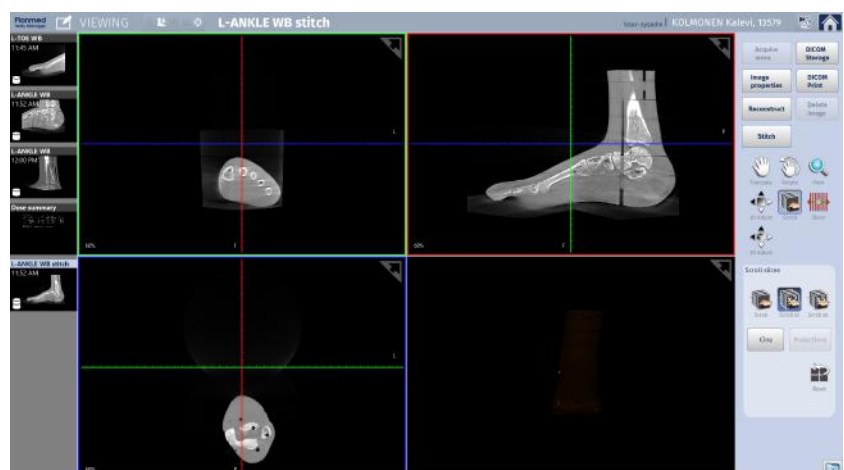


3. After having placed the images in the correct boxes, click **Stitch**.  
The stitching starts automatically.

- The stitching result opens.  
You can browse the image slices using the upper slide bar.  
Check the quality of the stitched image and click **Accept**.



- The stitched image opens in the *Viewing* screen.



### 14.2.4 Hand and wrist stitching

1. In the *Imaging* screen select WRIST, HAND or FINGER.



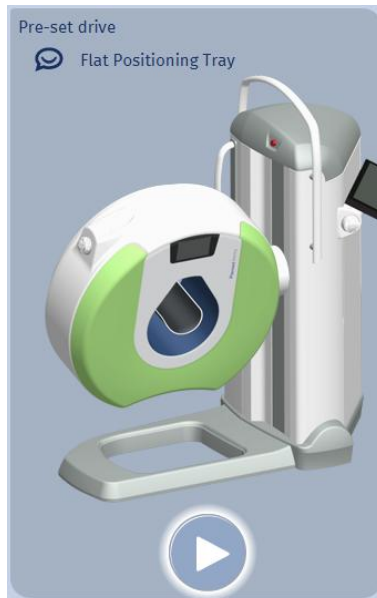
2. Verify the default patient size and adjust if necessary.



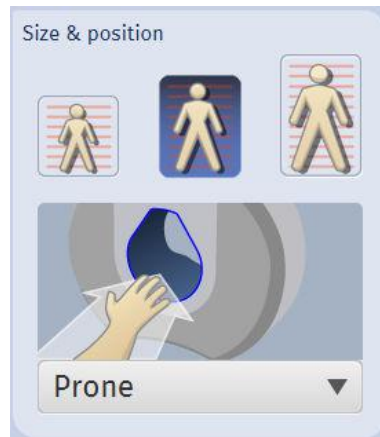
3. **CAUTION**

**You are about to drive the gantry. Do not touch or allow the patient to touch the gantry when it is moving.**

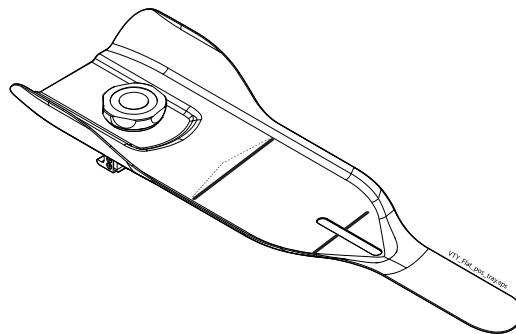
You can use pre-set drive to reach good starting position easily (see section "Pre-set drive" on page 65 for more information.)



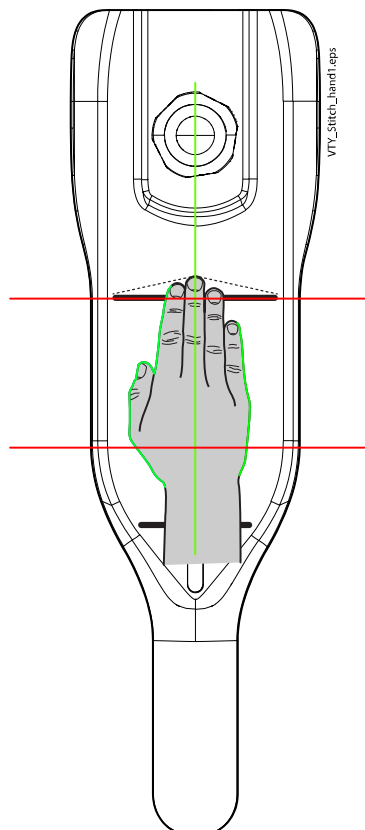
4. Verify the default patient position and adjust if necessary.



5. Place the flat positioning tray to the holder in the gantry bore tilting the free end upwards. If necessary, loosen the hand screw on the tray and slide the tray to forward position and lock it.

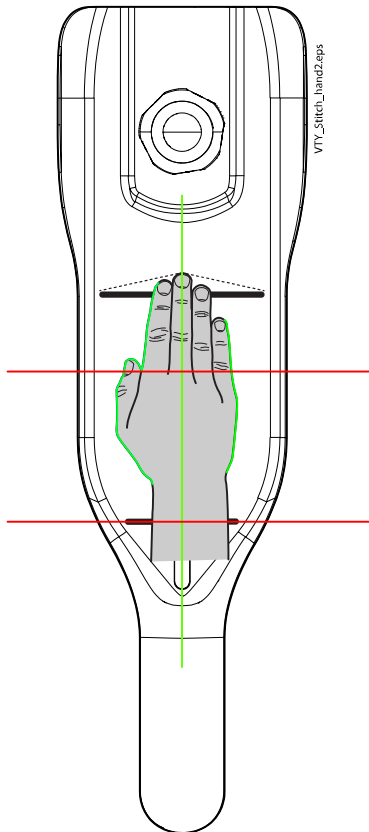


6. Position the imaging target between the positioning lasers as accurately as possible.





7. Continue to "Scout exposure" on page 67 or to "3D exposure" on page 69.
8. Verify image quality and select **Acquire more**.
9. Select WRIST or HAND for the second exposure.
10. Loosen the hand screw and slide the tray to the back. Tighten to re-lock. Make sure that the target area does not move on the tray and that the patient stays still for the second image.



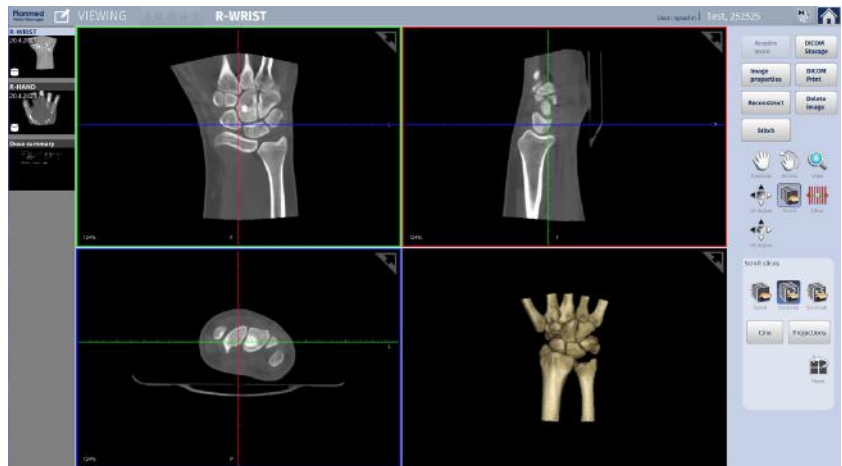
11. Continue to "3D exposure" on page 69
12. Verify image quality.
13. For stitching continue to "Stitching hand volumes together" on page 114.

#### 14.2.4.1 Stitching hand volumes together

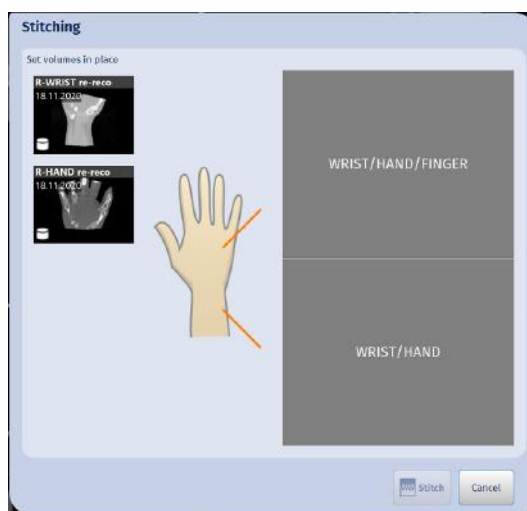


1. When all images have been acquired, click **Stitch** on the *Viewing* screen.

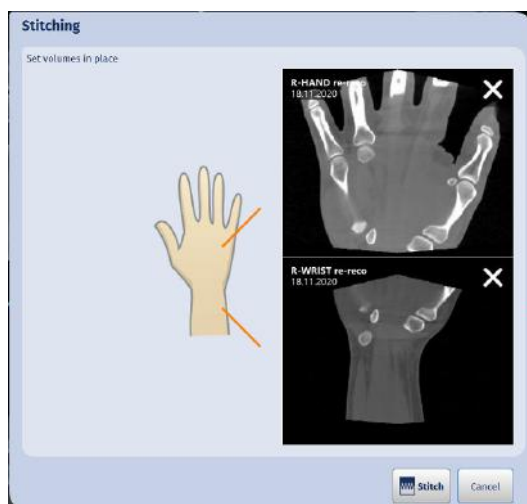




2. Set the images in place by first clicking on the image thumbnail and then on the box with corresponding anatomy.



3. After having placed the images in the correct boxes, click **Stitch**. The stitching starts automatically.



- The stitched result opens.  
You can browse the image slices using the upper slide bar.  
Check the quality of the stitched image and click **Accept**.



- The stitched image opens in the *Viewing* screen.

## 15 Dose notifications

If the selected imaging values exceed the set dose limit a dose notification or an alert is displayed.

Carefully assess the situation:

- If you want to reduce the dose select **Return to Imaging Parameters** to adjust the parameters.
- If you decide to continue imaging:
  - Check the *Continue imaging* check-box.
  - Enter password (for dose alert).
  - Select operator from the drop-down menu or enter it freely.
  - Enter diagnostic reason (optional).
  - Select **Continue**.

The image displays two side-by-side screenshots of a software interface for dose notifications and alerts. The left screenshot, titled "DOSE NOTIFICATION" (Ref. 0000), has a blue background and contains the text: "The patient dose XX mGy for the study will exceed the notification limit YY mGy (CTDivol). Carefully assess the situation." It features a checked "Continue imaging" checkbox, an "Operator" dropdown menu, and a "Diagnostic reason (optional)" text box. At the bottom are "Return to Imaging Parameters" and "Continue" buttons. The right screenshot, titled "DOSE ALERT" (Ref. 000) with the sub-header "A dose alert value will be exceeded!", has a red background and contains the text: "The patient dose XX mGy for the study will exceed the alert limit YY mGy (CTDivol). Carefully assess the situation." It features a checked "Continue imaging" checkbox, an "Operator" dropdown menu with "FlorenceN" selected, a "Password" text box, and a "Diagnostic reason (optional)" text box. At the bottom are "Return to Imaging Parameters" and "Continue" buttons.

## 16 Scout exposure

### 16.1 Acquiring scout images

To verify the correct patient positioning you can take a low-dose scout image.

#### NOTE

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

#### NOTE

Make sure the unit and the PC have had time to warm up for at least 20 minutes before taking exposures. Taking exposures after insufficient warm-up time may result in lower image quality.

1. Carry out appropriate radiation protection measures.

#### CAUTION

Always carry out appropriate radiation protection measures according to local requirements and use a proper shielding to protect yourself and the patient from radiation.

#### NOTE

Maintain auditory and visual contact with patient and the device during the entire exposure cycle.

#### NOTE

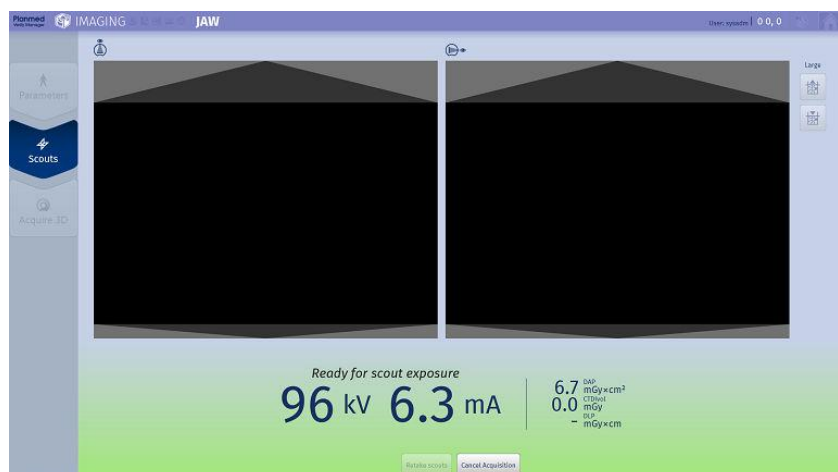
When taking weight-bearing images also ask the patient to keep their weight on the foot being imaged.

2. Tap **Scouts** from the left navigation bar.



The program starts to prepare for scout acquisition.

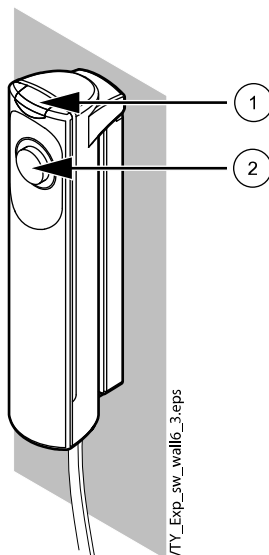
When the program is ready for imaging the green indicator light in the screen and in the exposure switch comes on.



- Go behind an appropriate radiation shield or to a separate shielded area where the exposure switch is located.

### CAUTION

When exposure is taken, radiation will be generated. Protect yourself from radiation and operate the exposure switch from the protected area.



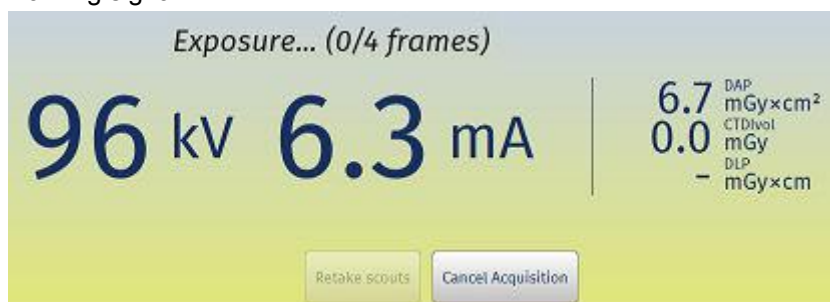
- Exposure indicator light
- Exposure button with indicator light

**Green** Ready for exposure

**Yellow** Exposure

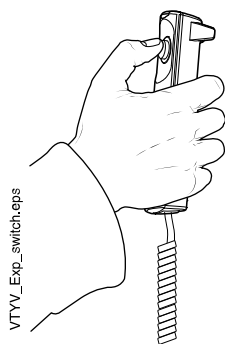
When the system is correctly set up and ready to take an exposure a green indicator light on the exposure button and on the touch screen control panel will come on and the message *Ready for exposure* will appear on the touch screen control panel.

When taking an exposure a yellow indicator light on the exposure switch and on the touch screen control panel will come on. It indicates that the system is generating radiation. Additionally, you will hear a radiation warning signal.



- Take an exposure by pressing and **holding down** the exposure button for the whole duration of the exposure cycle.

If you remove your finger from the exposure button before the exposure cycle is completed radiation is interrupted and a help message will appear on the touch screen control panel display. To clear the message and continue using the system tap **OK**.



The following image shows on the screen during the exposure cycle.



When the scout image is ready it opens in the screen in coronal and sagittal views.



If necessary you may now readjust the positioning. To retake scouts tap **Retake scouts**.

### NOTE

Since the extremity scanner offers versatile positioning possibilities, the patient positioning procedure is explained in the light of example cases in section "Pre-set positions for different body parts" on page 53.

To proceed to image acquisition refer to see section "3D exposure" on page 124.

## 16.2 Adjusting FOV

### TIP

FOV can also be adjusted from joysticks when positioning patient, see section "Field of view and positioning lasers" on page 57.

An extended, large or small FOV can be selected according to the size of the target to be imaged. If the area to be imaged is known in details, select small FOV to minimize patient dose. The extended volume size can be used to fit more data on a single image.

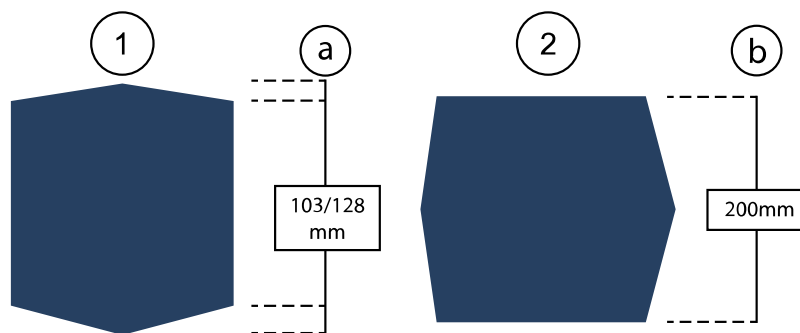
### Extended field of view (optional)

#### NOTE

eFOV is available on license.

#### NOTE

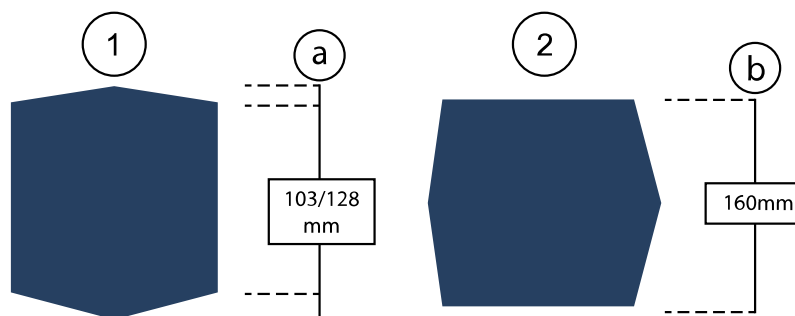
eFOV is not available for head imaging.



VTY\_FOV\_extended2.eps

- 1 Top view
- a Length
- 2 Side view
- b Diameter

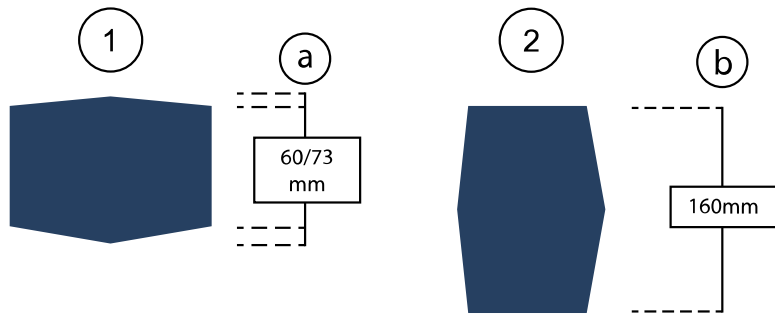
### Large field of view



VTY\_FOV\_Large2.eps

- 1 Top view
- a Length
- 2 Side view
- b Diameter

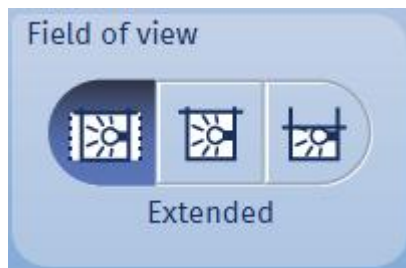
**Small field of view**



VTY\_FOV\_small3.eps

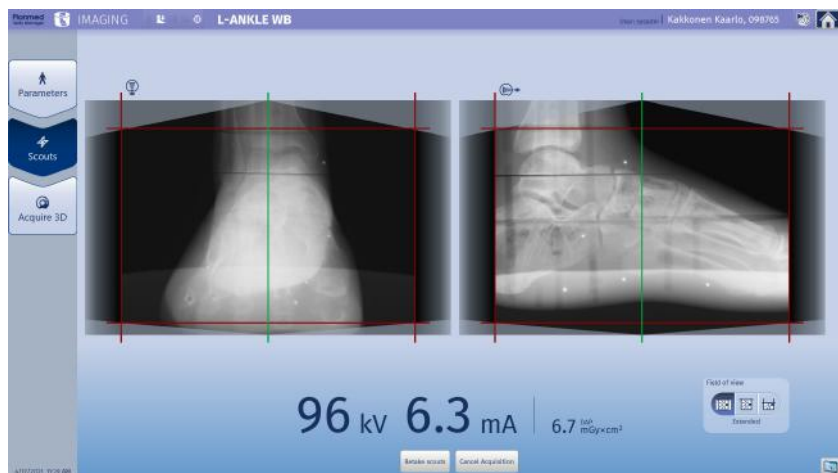
- 1 Top view
- a Length
- 2 Side view
- b Diameter

Select the suitable field of view by tapping these buttons.



**NOTE**

The eFOV area is not shown in scout images. Instead, the empty black areas indicate the extended area available in 3D reconstruction.



- **View icons**  
Image viewed from above.







- Image viewed from the side

## 17 3D exposure

After appropriate preparations (see section "Imaging workflow" on page 63 have been performed you may proceed to taking exposures.

### NOTE

Make sure the unit has had time to warm up for at least 20 minutes before taking exposures. Taking exposures after insufficient warm-up time may result in lower image quality.

1. Verify the positioning once more.

If OK, ask the patient to remain in position as still as possible for the whole exposure cycle.

### CAUTION

Always carry out appropriate radiation protection measures according to local requirements and use a proper shielding to protect yourself and the patient from radiation.

### NOTE

Maintain auditory and visual contact with patient and the device during the entire exposure cycle.

### NOTE

When taking weight-bearing images also ask the patient to keep their weight on the foot being imaged.

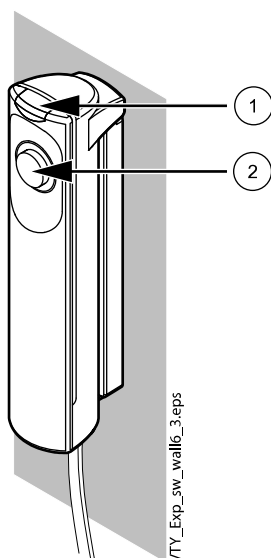


2. At the touch screen control panel tap **Acquire 3D**.

3. Go behind an appropriate radiation shield or to a separate shielded area where the exposure switch is located.

### CAUTION

When the exposure is taken, radiation will be generated. Protect yourself from radiation and operate the switch from the protected area.



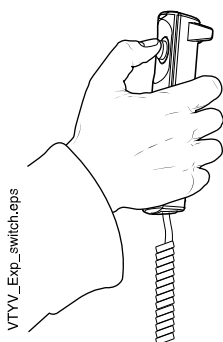
- 1 Exposure indicator light
  - 2 Exposure button with indicator light
- Green** Ready for exposure  
**Yellow** Exposure

When the system is correctly set up and ready to take an exposure, a green indicator light on the exposure button and on the touch screen control panel will come on and the message *Waiting for exposure* will appear on the touch screen control panel.

When you take an exposure, there is a yellow indicator light on the exposure switch and on the touch screen control panel. It indicates that the system is generating radiation. Additionally, you will hear a radiation warning signal.

4. Take an exposure by pressing and **holding down** the exposure button for the whole duration of the exposure cycle.

If you remove your finger from the exposure button before the exposure cycle is completed radiation is interrupted and a help message will appear on the touch screen control panel display. To clear the message and continue using the system tap **OK**.



The following image shows on the screen during the exposure cycle.



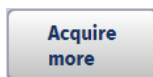
- When the exposure cycle is completed, inform the patient of this but do NOT release the patient yet.



After the exposure has been taken, reconstructing of the image will take from 30 to 120 s.

During reconstruction the original projections will be shown on the screen. This allows for the user to evaluate whether the image was taken from the correct area. If the image is successful the patient can now be released.

When the image is ready, it appears on the screen.



- Verify that the volumes contain the necessary information.  
If you need more images tap **Acquire more**. The *Imaging* window opens. For detailed instructions see section "3D exposure" on page 124.

- Release and guide the patient away from the device.  
Provide additional support to the patient when necessary.



- To send the images to DICOM storage, tap **DICOM storage** in the upper right corner of the touch screen control panel.

## 18 Special consideration for pediatric imaging

In general there is no limit how young or small children can be studied with extremity scanner. It is up to the end user to determine whether the extremity scanner is the most suitable imaging modality to be used in particular case. The child should be able to be still (alone or with help from parent) for 20 seconds to ensure optimal image quality.

### 18.1 Pediatric Use: Summary

#### Introduction:

#### CAUTION

**Take special care when imaging patients outside the typical adult size range.**

Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50 kg (110 lb) in weight and 150 cm (59 in) in height, measurements, which approximately correspond to that of an average 12 year old or a 5th percentile U.S. adult female.<sup>1)</sup>

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

- 1) for certain organs and tumor types, younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing 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; and
- 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.

#### A. References for pediatric dose optimization:

The following resources provide information about pediatric imaging radiation safety and/or radiation safety for CBCT devices:

- Image Gently Alliance: <https://www.imagegently.org/>

To develop user defined protocols for pediatric imaging see the technical manual for the extremity scanner.

<sup>1</sup>McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal. 2008. Anthropomorphic Reference Data for Children and Adults, United States, 2003-2006. National Health Statistics Reports, 10, 1-48.

### 18.2 Patient positioning

It is recommended that the small children are held by their parent / caregiver to encourage the child to stay still during imaging.

Otherwise the recommended patient positioning and tray selection is normal according to user instructions. Explain to the child and parent what is going to happen during imaging and how long the procedure takes.

In general patient positioning in pediatric imaging relies in the professional approach of educated personnel but the following hints might be helpful:

- Approach the child slowly and calmly.
- Observe the level of consciousness, the activity level and the respiratory rate/effort of the child before touching.
- Be honest with the child and the parent/caregiver about the imaging procedure.
- Explain all procedures to older children and adolescents directly.
- Allow the child to hold a familiar security object during imaging.
- Use distraction techniques to help gain the cooperation of the child.

### 18.3 Radiation protection

It is recommended to always use the scattered radiation shield, see section "Scattered radiation shield" on page 29 for more information and in head imaging thyroid shield. The parent holding the child during imaging should also wear the lead shield to protect from radiation. In case child is alone during examination it is recommended to use both the stray radiation shield and the lead shield.

### 18.4 Exposure parameter recommendations for pediatric imaging

The following values are valid for children up to 10 years (33 kg body mass).

- The values for large child delivers same dose than the values for small adult
- The values for medium child delivers 50% smaller dose (CTDIvol [mGy]) compared to medium adult
- The values for small child delivers 70% smaller dose (CTDIvol [mGy]) compared to medium adult.

For older children the factory default values can be used. In case the area to be imaged is known in details, the field of view is to be collimated to small in order to minimize patient dose.

The following values are factory recommendations. However, the radiologist should work closely with the medical physicist to reduce patient dose to as low as reasonably possible and to ensure that image quality is not compromised.

Child protocols	Anatomy	Protocol	Small (30% M adult)			Medium (50% M adult)			Large (S adult)		
			kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]
Jaw	ULD		90	2	0,7	92	3	1,1	96	4	1,7
	standard		90	3,2	1,9	92	4	2,6	96	4	3,1
	high definition		90	3,2	2,4	92	4	3,3	96	4	3,9

Face	ULD	90	1	0,3	92	2	0,7	96	2	0,9
	standard	90	3,2	1,9	92	4	2,6	96	4	3,1
	high definition	90	3,2	2,4	92	4	3,3	96	4	3,9
Sinus	ULD	90	1	0,3	92	2	0,7	96	2	0,9
	standard	90	3,2	1,9	92	4	2,6	96	4	3,1
	high definition	90	3,2	2,4	92	4	3,3	96	4	3,9
Nose	ULD	90	1	0,3	92	2	0,7	96	2	0,9
	high definition	90	3,2	2,4	92	4	3,3	96	4	3,9
	standard	90	3,2	1,9	92	4	2,6	96	4	3,1
Ear	ULD	90	1	0,3	92	2	0,7	96	2	0,9
	high definition	90	4	3,0	92	5	4,1	96	6,3	6,1
Neck	ULD	90	1	0,3	92	2	0,7	96	2	0,9
	standard	90	4	2,4	92	5	3,3	96	6,3	4,9
	high definition	90	4	3,0	92	5	4,1	96	6,3	6,1
Elbow	ULD	84	4	1,0	88	4	1,2	90	5	1,7
	standard	84	4	1,8	88	4	2,2	90	5	3,0
	high definition	84	4	2,3	88	4	2,8	90	5	3,8
Arm	ULD	80	4	0,8	84	5	1,3	88	5	1,6
	standard	80	4	1,5	84	4	1,8	88	5	2,8
	high definition	80	4	1,9	84	5	2,9	88	5	3,5
Wrist	ULD	80	4	0,8	84	5	1,3	88	5	1,6
	standard	80	4	1,5	84	4	1,8	88	5	2,8
	high definition	80	4	1,9	84	5	2,9	88	5	3,5

Hand	ULD	80	4	0,8	84	5	1,3	88	5	1,6
	standard	80	4	1,5	84	4	1,8	88	5	2,8
	high definition	80	4	1,9	84	5	2,9	88	5	3,5
Finger	ULD	80	2	0,4	84	3,2	0,8	88	3,2	1,0
	standard	80	3,2	1,2	84	4	1,8	88	4	2,2
	high definition	80	3,2	1,5	84	4	2,3	88	4	2,8
Knee	ULD	88	4	1,2	90	4	1,4	92	6,3	2,3
	standard	88	4	2,2	90	5	3,0	92	6,3	4,2
	high definition	88	4	2,8	90	5	3,8	92	6,3	5,2
Knee wb	ULD	88	4	1,2	90	4	1,4	92	6,3	2,3
	standard	88	4	2,2	90	5	3,0	92	6,3	4,2
	high definition	88	4	2,8	90	5	3,8	92	6,3	5,2
Leg	ULD	84	4	1,0	88	4	1,2	90	5	1,7
	standard	84	4	1,8	88	4	2,2	90	5	3,0
	high definition	84	4	2,3	88	4	2,8	90	5	3,8
Leg wb	ULD	84	4	1,0	88	4	1,2	90	5	1,7
	standard	84	4	1,8	88	4	2,2	90	5	3,0
	high definition	84	4	2,3	88	4	2,8	90	5	3,8
Ankle	ULD	84	4	1,0	88	5	1,6	92	6,3	2,3
	standard	84	5	2,3	88	6,3	3,5	92	6,3	4,2
	high definition	84	5	2,9	88	5	3,5	92	6,3	5,2
Ankle wb	ULD	84	4	1,0	88	5	1,6	92	6,3	2,3
	standard	84	5	2,3	88	5	2,8	92	6,3	4,2
	high definition	84	5	2,9	88	5	3,5	92	6,3	5,2



Foot	ULD	84	3,2	0,8	88	4	1,2	92	5	1,9
	standard	84	4	1,8	88	5	2,8	92	6,3	4,2
	high definition	84	4	2,3	88	5	3,5	92	6,3	5,2
Foot wb	ULD	84	4	1,0	88	5	1,6	92	6,3	2,3
	standard	84	5	2,3	88	6,3	3,5	92	6,3	4,2
	high definition	84	5	2,9	88	6,3	4,4	92	6,3	5,2
Toe	ULD	80	4	0,8	84	4	1,0	88	5	1,6
	standard	80	4	1,5	84	5	2,3	88	6,3	3,5
	high definition	80	5	2,3	84	5	2,9	88	6,3	4,4
Toe wb	ULD	80	5	1,0	84	5	1,3	88	6,3	2,0
	standard	80	6,3	2,3	84	6,3	2,9	88	6,3	3,5
	high definition	80	6,3	2,9	84	6,3	3,6	88	6,3	4,4
MaxScan	ULD	90	2	0,7	90	3,2	1,1	92	4	1,5
	standard	90	2	1,2	90	3,2	1,9	92	4	2,6
	high definition	90	3,2	2,4	90	4	3,0	92	5	4,1

# 19 Viewing and processing images



## 19.1 Using viewing modes

To activate the desired viewing mode tap it with your finger.

### Move



In the Move mode you can pan, rotate and zoom the image.

Use the tool to move the image on the screen by tapping and dragging the image.

### Rotate



In the Rotate mode you can use one or two fingers to rotate the image and two fingers zoom the image using the pinch to zoom feature.

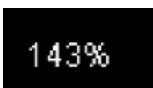
### View



In the View mode you can zoom in/out using the following two methods:

- Place a finger on the screen and move it up/down on the screen.
- Use the pinch to zoom feature by placing two fingers on the screen and moving them apart / towards each other.

The zoom percentage is shown in the lower left corner of each image.



## 19.2 Using processing tools

### 19.2.1 2D adjustment

#### NOTE

This tool can only be used with 2D images.

Use the **2D Adjust** tool to increase or decrease brightness and contrast of 2D slices.



Tap the icon and move your finger over the image.

Slice thickness can be selected from the Slice thickness (mm) menu.

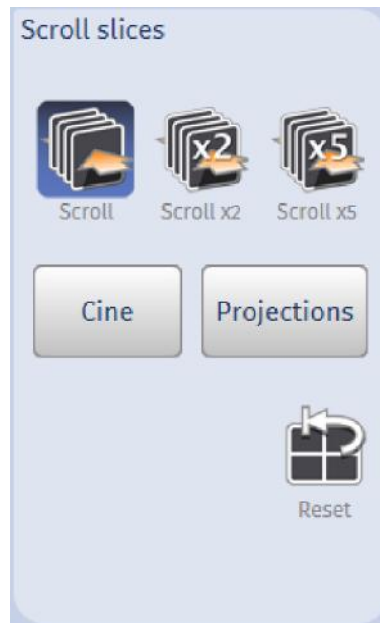
To reset images to their original state select **Reset**. The orientation, position, image size brightness, contrast, threshold and transparency settings will be reset.



### 19.2.2 Scroll slices

Scrolling through slices can be done by moving your finger on the screen up and down.

- Use the **Scroll x2** tool to scroll through slices two times faster than with the regular scroll icon.
- Use the **Scroll x5** tool to scroll through slices five times faster than with the regular scroll icon.

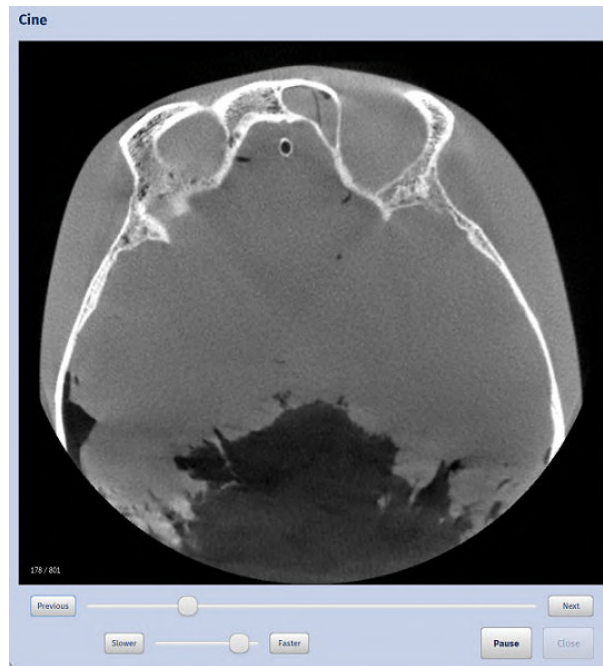


To reset the view to original tap **Reset**.

### Cine

The **Cine** tool starts a video presentation for viewing slices of reconstructed data one by one in axial direction.

The Cine tool can also be used for viewing slice stacks.

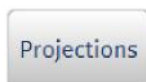


- To pause the video tap **Pause**. To restart the video tap **Run**.
- To view the image slice by slice use the **Previous** and **Next** buttons.
- To adjust the speed of the video use the **Slower** and **Faster** buttons and the slider.
- Tap **Close** to close the window

## Projections

### NOTE

The projection images are for additional information only. Clinical diagnosis should be based on 3D data.



Start a video presentation for viewing 2D raw projections one by one by clicking the **Projections** button.



- To pause the video tap **Pause**. To restart the video tap **Run**.
- To save single projections for viewing or later adjustments tap **Save**.
- To export all projections in a zip file to another workstation for reconstruction tap **Export**.
- Tap **Close** to close the window.

### 19.2.3 Slicer

The slicer tool can be used to create a new set of cross- section slices which can then be sent to DICOM storage as a 3D slice stack.

#### NOTE

Tap the position and angle of the image *before* creating slices. In case you change these settings afterwards the slices will disappear.

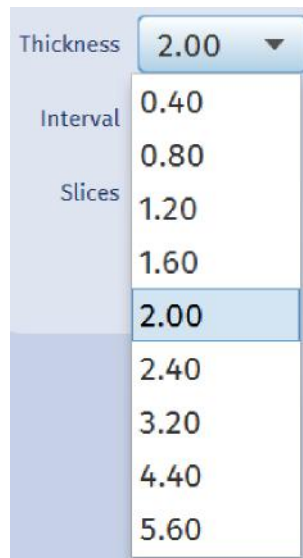
1. Tap the slicer tool



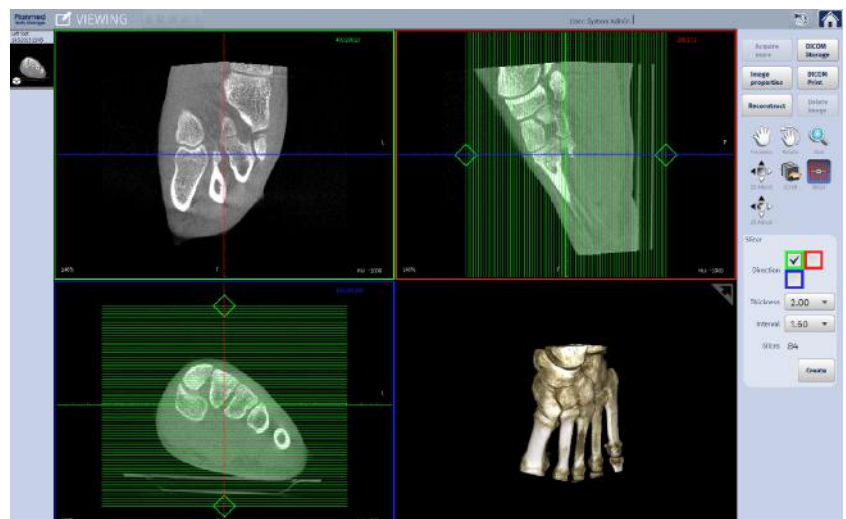
2. Select the direction for slices. The slicer tool appears on top of the image.



3. If necessary select the slice thickness and interval from the respective drop-down menus.



4. Set the area of which you want to create slices from by dragging the slicer from the diamond shape squares situated at both edges of the slicer.



5. Set the slice thickness and interval by selecting appropriate values from the corresponding drop-down menus.
6. Create a new slice stack by tapping **Create**.  
The new slice stack is shown
7. The number of the slice is shown on the lower left corner of the image in the following window.

Enter the name for the new slice stack in the *Series description* field and tap **OK**.



The original image and the created slice stack are shown as thumbnails in the *Viewing* window.

To differentiate the original image from the created slice stacks they are marked with different symbols:



The original image is marked with a small white cube in the lower left corner of the thumbnail.



The slice stack is marked with a small white stack in the lower right corner of the thumbnail.

8. To store and send the slice stacks to remote DICOM application tap **DICOM storage**. For more information on DICOM storage see section "DICOM storage" on page 139.

### 19.2.4 3D adjustment

Use this tool to increase or decrease brightness and contrast in 3D image.

Tap the **3D Adjust** icon and move your finger over the image.



#### NOTE

This tool can only be used with 3D images.

#### Brightness/contrast

To adjust **contrast** of the image tap the Bright./Contr. icon and move your finger on the image **up and down**.

To adjust **brightness** of the image tap the Bright./Contr. icon and move your finger on the image **left and right**.

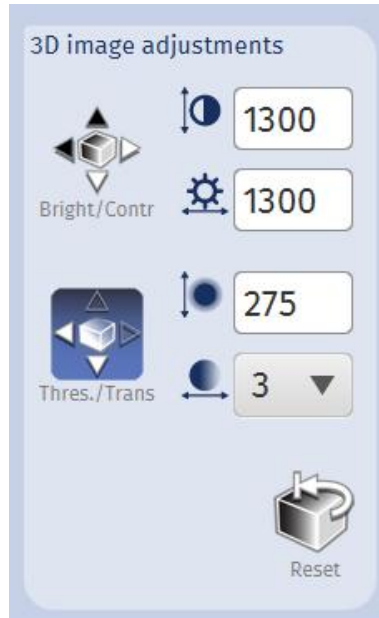
Brightness and contrast can also be fine-adjusted by entering an appropriate value in the corresponding field.



### Threshold / transparency

To adjust **threshold** of the image tap the Thres./Trans. icon and move your finger on the image **up and down** or enter an appropriate value in the corresponding field..

To adjust **transparency** of the image tap the Thres./Trans. icon and move your finger on the image **left and right** or select the transparency value (0, 3, 6, 9, 12, 15, 18, 21, 24, 27) from the drop-down menu.



### Reset



Use this tool to reset images to their original state. The orientation, position, image size, brightness, contrast, threshold and transparency settings will be reset.

## 19.3 DICOM storage

Using *DICOM storage* images can be sent to a remote DICOM application, i.e. DICOM image archive PACS.

### NOTE

**DICOM Storage needs to be configured in the *Service* section for detailed description see the *Planned Verity technical manual*.**



After you have acquired all necessary images tap **DICOM Storage**.

In the following window select the volumes and slice stacks you want to send.

Select the destination where you would like the images to be sent from the *Destination* drop-down menu.

When finished tap **Send**.



**NOTE**

If the *Autosend* option is configured in *Service* mode all images are automatically sent to the selected destination (e.g. PACS, DICOM storage). For more information contact your manufacturer's local representative.



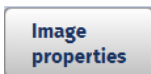
To check whether the images and stacks of the selected study have been successfully sent, tap **Storage status** see section "Verifying storage status" on page 48.

**NOTE**

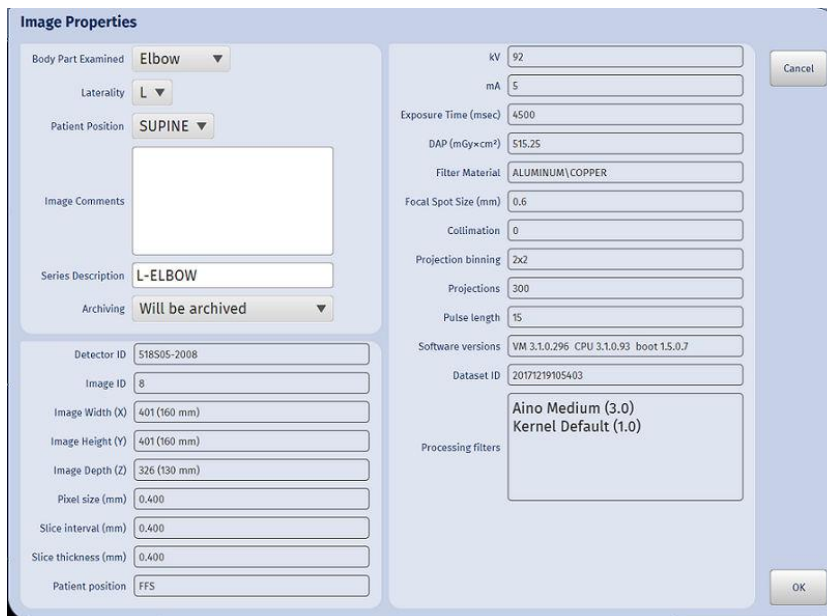
If the *Autosend* option has been selected in *Service* mode you do not need to check the storage status.

### 19.4 Image properties

To open the *Image Properties* window tap the **Image properties** button.



The properties are shown in the following dialog.



The description of properties are detailed below.

**Editable properties**

The following image properties can be edited after exposure.

- **Body Part Examined**

You can change the body part selected from the user interface afterwards by selecting the correct body part from the *Body part examined* drop-down menu.

- **Laterality**

You can change the laterality (from which side the image was taken, L=left, R=right) afterwards by tapping the arrow in the *Laterality* field drop-down menu.

- **Patient position**

To change the orientation (Patient Position) of the image after acquisition, select the correct orientation (Prone or Supine) from the *Patient Position* drop-down menu.

### NOTE

If you change the orientation the creation of slice stacks and stitching of images must be redone.

- **Image Comments**

You can add comments concerning the acquired images.

- **Series Description**

You can add a free description of the series.

- **Archiving**

Select whether the image is archived or not.

By selecting *Will not be archived* from the *Archiving* drop-down menu you can select image(s) not to be sent using DICOM storage.

### Displayed properties

- **Detector ID**
- **Image ID**
- **Dimensions**
  - Image width (x)**
  - Image height (y)**
  - Image depth (z)**
  - Pixel size (mm)**
- **Slice interval (mm)**
- **Slice thickness (mm)**
- **Patient position**
- **Used exposure values**
  - kV**
  - mA**
  - Exposure Time (msec)**
- **DAP (mGy $\times$ cm<sup>2</sup>)**
- **CTDI and DLP values**
- **Filter material**
- **Focal spot size (mm)**
- **Projection binning**

Describes how many detector pixels are combined to create one single pixel in a projection image used for image reconstruction.

- **Projections**

The number of projections taken in acquisition.

- **Pulse length**

- **Software versions**

You can verify the following version information from the *Software versions* field:

- CPU version
- Verity Manager version

The version of the following options is linked to currently installed Verity Manager software version:

- PmFDK reconstruction
- Metal artefact removal
- HU correction
- Planmeca AINO noise filtering
- Planmeca CALM movement artefact correction

- **Dataset ID**

- **Processing filters**

You can verify all filters used on the original data from the *Processing filters* field:

- AINO noise filter value: **None**, **Light**, **Medium** or **Strong**
- Metal artefact removal: for individual studies, **Metal artefact removal** can be set as an optional processing feature.
- Kernel value: **Default**, **Soft** or **Sharp**
- HU correction: **On** or **Off**
- Planmeca CALM movement artefact correction: **On** or **Off**

## 19.5 DICOM print

In case a DICOM Print license is purchased and installed, images can be printed with DICOM compatible printers. DICOM Print needs to be configured in the *Service*

section before DICOM printer can be used.

Tap **DICOM Print**.



From the following dialogue you can select the printer AE title, calling AE title, magnification ratio, film orientation and film size.

To print one image per film select the option *Crop image to fit to film if needed*.

Tap **OK**.



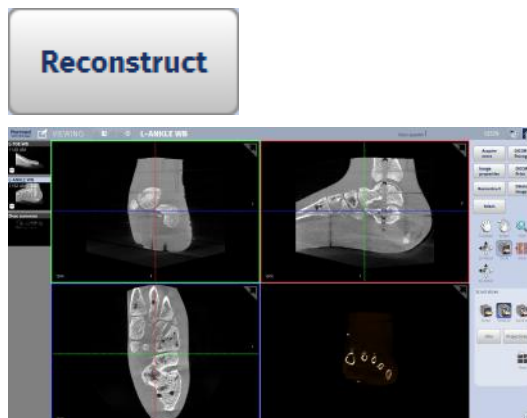
The image shows a 'DICOM Print' dialog box with the following fields and options:

- AE** section:
  - Printer AE Title: PRINT\_SCP
  - Calling AE Title: PLANMED\_AWS\_2
- Parameters** section:
  - Magnification: 1.0 (range 0.5 ... 3.0)
  - Film Orientation: PORTRAIT
  - Film Size: (dropdown menu)
  - Crop image to fit to film if needed
- Buttons: OK and Cancel

## 19.6 Reconstruction

After exposure image reconstruction can be repeated with different parameters if necessary.

1. In the viewing screen tap **Reconstruct**.



2. Select the *Noise filter*, *Kernel* and *Planmeca CALM* values.
3. Check the metal suppression and the resolution conversion options.

### NOTE

The Planmeca CALM patient movement correction algorithm requires a separate license.

**NOTE**

If the parameters are disabled or hidden contact your service technician.

- 4. To reconstruct image with extended field of view, check the box.
- 5. Tap **Reconstruct**.



## 20 Quality Control

This section describes the recommended Quality Control (QC) procedures to ensure optimal operation and image quality of the scanner. Its purpose is to assist the operator in the testing and maintenance of the system and to make a recording of the test results. It includes a detailed description on how to perform the QC tests.

The goal of Quality Control is to provide an effective means to discover and identify any image quality problems.

### 20.1 Summary of QC tests

Imaging performance metric	Performance	Exposure values	Phantom
MTF	MTF 10 $\geq$ 1.25 lp/mm	96 kV, 4 mA	MTF Phantom
HU Accuracy	-1100 < Air < 900 -65 < PMMA < 135 1800 < Al < 2000	90 kV, 9 mA	Quality Control Phantom
Noise level expressed as standard deviation	$\sigma$ < 100 HU	90 kV, 9 mA	Quality Control Phantom

For detailed description on phantoms see section "Phantoms" on page 147.

#### Summary of QC tests

QC test	Medical equipment evaluation	Minimum test frequency	Performance criteria	Corrective action	Section in the manual
Visual checklist	RT or MP (or according to local regulations)	Daily	Each of the items listed in the visual checklist should pass the visual check and receive a check mark.	Items not passing the visual check should be replaced or corrected immediately.	"Visual checklist" on page 149
Weekly / Monthly QC test	RT or MP (or according to local regulations)	Weekly / Monthly (User) Annual maintenance (Service technician)	HU Accuracy: PMMA $>$ -65 and $<$ 135 HU Uniformity: deviation $<$ 50 Noise: standard deviation $<$ 100.0 Artefacts: No visible artefacts	Perform Flat field (FF) calibration(see section "Flat field calibration" on page 178. If the test still fails contact your local representative.	"Weekly / monthly QC test" on page 149

## Summary of QC tests

QC test	Medical equipment evaluation	Minimum test frequency	Performance criteria	Corrective action	Section in the manual
HU Accuracy test	RT or MP (or according to local regulations)	Annual maintenance	-1100 < Air < -900 -65 < PMMA < 135 1800 < Al < 2000	Perform HU calibration (section "HU calibration" on page 182). If the test still fails contact your local representative.	"HU accuracy test" on page 154
MTF test	RT or MP (or according to local regulations)	Annual maintenance	MTF 10 $\geq$ 1.25 lp/mm	Perform Flat Field (FF) calibration (section "Flat field calibration" on page 178 ). If the test still fails contact your local representative.	"Modulation transfer function (MTF) test" on page 159
Geometry test	RT or MP (or according to local regulations)	Annual maintenance	The circles and their edges show as even in the image.	Perform geometry calibration (section "Geometry calibration" on page 180 ). If the test still fails contact your local representative.	"Geometry test" on page 163
Slice thickness	RT or MP (or according to local regulations)	Annual maintenance	The calculated slice thickness is within +/- 5% of the indicated slice thickness.	Perform geometry calibration (section "Geometry calibration" on page 180 ). If the test still fails contact your local representative.	"Slice thickness test" on page 168



### Summary of QC tests

QC test	Medical equipment evaluation	Minimum test frequency	Performance criteria	Corrective action	Section in the manual
AEC Reproducibility	RT or MP (or according to local regulations)	Annual maintenance	The AEC reproducibility is < 20 %.	Perform geometry calibration (section "Geometry calibration" on page 180 ). If the test still fails contact your local representative.	"AEC reproducibility test" on page 172

## 20.2 Accessing Quality Control mode



1. Tap the *Options* arrow on top of the window.

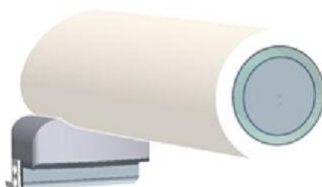


2. Select **Quality**.

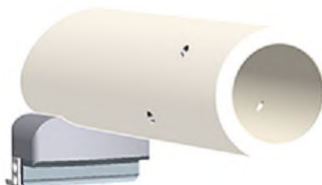
## 20.3 Phantoms

The following phantoms are delivered with the device:

- MTF phantom



- Geometry phantom



- Quality Control phantom



The following rods are supplied with the Quality Control phantom:

- 5 PMMA rods
- 1 aluminium rod
- 1 short aluminium center rod

The rods are inserted into the phantom for quality control testing and calibration in a specific manner depending on the test/calibration to be performed. For more information, see the sections instructing how to perform the specific test/calibration.

## 20.4 Quality Control (QC) tests

The test results are stored into the folder *C:/planmed/qc\_results*.

The quality control images are stored into the Local Study Archive with the following information:

- Patient ID: QC
- Name: QUALITY CONTROL [QC Phantom]
- Study Description: name of the QC test

### CAUTION

Quality control is essential part of the system maintenance, and neglecting to perform the necessary tests at regular interval as instructed in this manual might affect harmfully the performance of the device resulting in unnecessary doses of radiation and poor diagnostic value of the image.

### CAUTION

Local regulations regarding the viewing conditions in the viewing room (e.g. lighting) have to be taken into account.

### CAUTION

The quality of monitors used in viewing the images have to be assured according to the quality control instructions given by the monitor manufacturer.

### CAUTION

The touch screen control panel is not suitable for diagnostic applications. Image interpretation requires an appropriate review workstation.

### CAUTION

During QC tests radiation will be generated. Protect yourself from radiation.

### 20.4.1 Visual checklist

**Objective**

To ensure that the system indicator lights, displays, mechanical locks and detents are working properly and that the mechanical rigidity and stability of the equipment is optimum.

**Test equipment**

N/A

**Medical equipment evaluation**

RT or MP (or according to local regulations)

**Performance frequency**

Daily or after any service or maintenance on the X-ray system.

**Procedure**

- Check that the positioning trays are clean and intact.
- Check that the monitor is clean.
- Make sure there are no errors or cautions in the software.
- Check that the positioning lasers function properly.
- To make sure they move freely, drive the gantry and the positioning trays in all directions as you would for patient imaging.

Some of the items on the visual checklist are operator convenience features. Many of them, however, are essential for ensuring patient safety and high-quality of diagnostic images. If necessary, other visual checks can be added to the list. Make sure to perform all the checks at the same time.

**Performance criteria**

Each of the items listed in the visual checklist should pass the visual check and receive a check mark.

**Corrective action**

Items not passing the visual check should be replaced or corrected immediately.

Items missing from the room should be replaced immediately. Malfunctioning equipment should be reported to the X-ray service engineer for repair or replacement as soon as possible.

### 20.4.2 Weekly / monthly QC test

**Objective**

To ensure Hounsfield Unit (HU) value accuracy and uniformity.

To define the image noise level and to visually check that there are no artefacts in the images.

### Test equipment

- Image quality phantom
- PMMA (Polymethyl methacrylate ) rods (5)



### Exposure values

90 kV, 9 mA.

### Medical equipment evaluation

RT or MP (or according to local regulations)

### Performance frequency

- Weekly / Monthly (User)
- Annual maintenance (Service technician)

#### 20.4.2.1 Performing weekly/monthly QC test

1. Go to the *Weekly QC* tab.
2. Insert the PMMA rods (5) into the phantom.

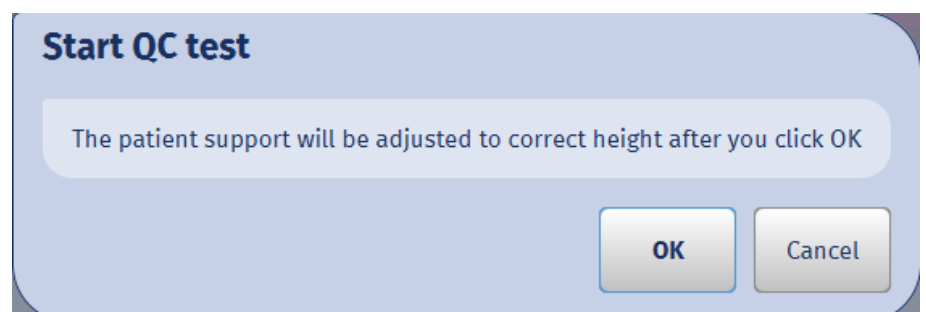
3. Attach the phantom into the tray holder in the gantry bore in the middle of the imaging area.



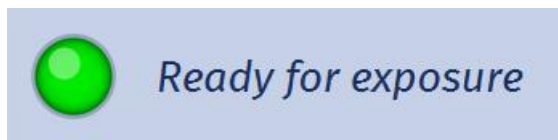
4. Tap **Start QC test**.



The device automatically drives the phantom to correct height and the software automatically selects the correct exposure values: 90 kV, 9 mA.



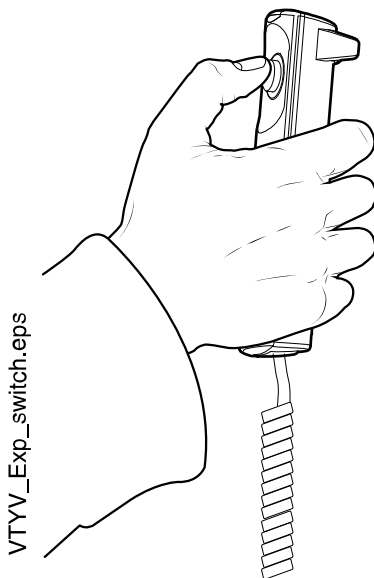
The exposure can be taken when the green indicator lights come on.



### CAUTION

When the exposure is taken, radiation will be generated. Protect yourself from radiation.

5. Press the exposure button to take an exposure.

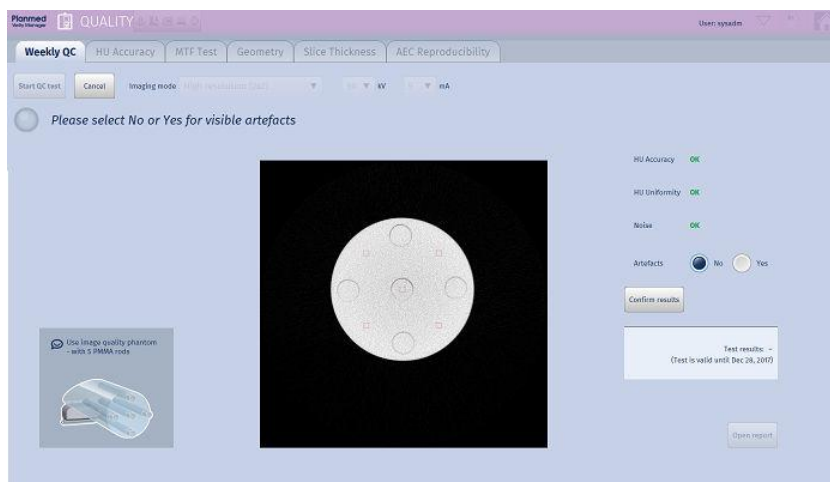


6. Visually check the test image to detect visible artefacts e.g. ring artefacts and check the corresponding box (No / Yes).

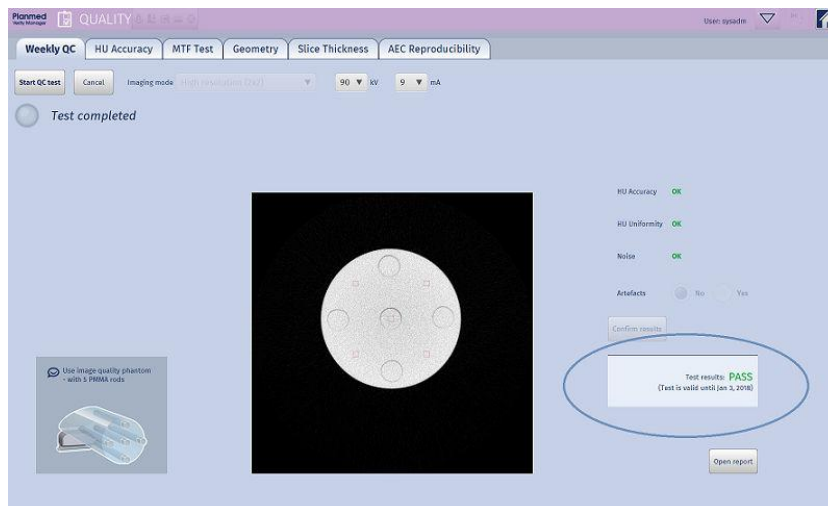
Also check that the squares are correctly placed.

The software automatically analyses the average HU value and image noise in the ROI areas. The analysis is repeated in three axial slices selected automatically from the front, middle and back of the phantom.

7. Approve the results by clicking **Confirm results**.



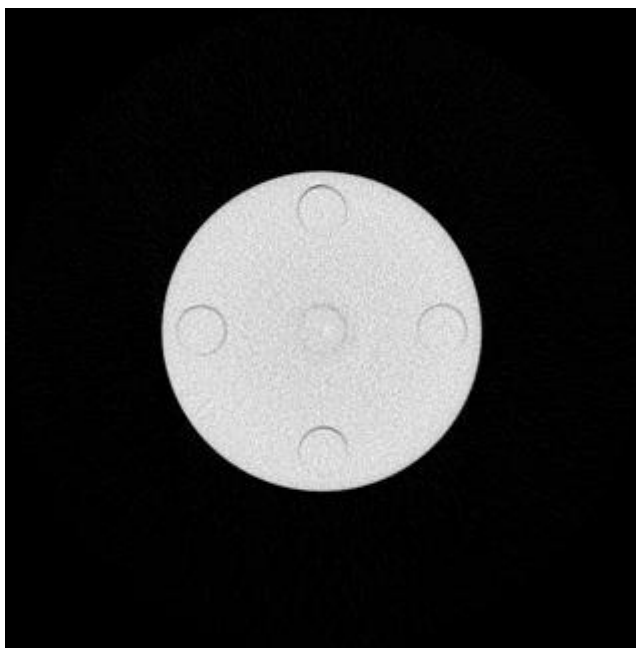
The test results are shown in the window.



The test results are stored into the folder *C:/planmed/qc\_results*.

The quality control images are stored into the Local Study Archive with the following information:

- Patient ID: QC
- Name: QUALITY CONTROL [QC Phantom]
- Study Description: name of the QC test



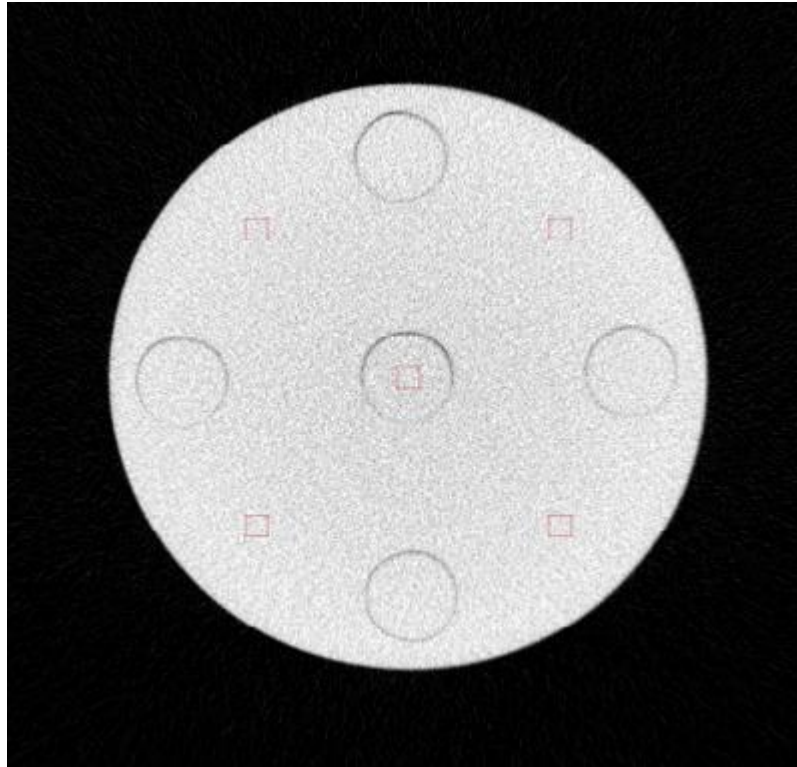
## Methods

The results are calculated of three slices perpendicular to the phantom axis:

1. location of the 1st slice: total number of slices/4
2. location of the 2nd slice: total number of slices/2
3. location of the 3rd slice: total number of slices\* (3/4)

For HU accuracy and noise analysis all 5 ROI:s in each test slice are used.

The locations of ROI:s are presented below.



#### Performance criteria

*HU Accuracy:* PMMA  $> -65$  and  $< 135$ . The HU value of each ROI's average value must be within the lower and upper limits.

*HU Uniformity:* deviation  $< 50$ . The HU value of each ROI's average must not deviate from the average HU value of all ROI's more than allowed.

*Noise:* standard deviation  $< 100.0$

*Artefacts:* No visible artefacts

#### Corrective action

Perform Flat field calibration. If the test still fails contact your local representative.

### 20.4.3 HU accuracy test

#### Objective

To ensure correct HU values by using the test phantom containing reference materials (PMMA, Aluminum (Al), air).

#### Test equipment

- Image quality phantom (20008121)
- Aluminum center rod (1)
- PMMA rods (4)



**Exposure values**

90 kV, 9 mA

**Medical equipment evaluation**

RT or MP (or according to local regulations) Annual maintenance

**Performance frequency**

Annual maintenance

**20.4.3.1 Performing HU accuracy test**

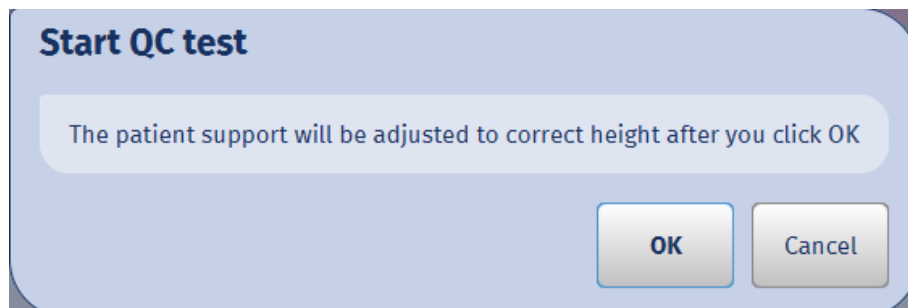
1. From the *Quality* section tap **HU Accuracy**.
2. Insert the Aluminum center rod in the middle insert of the phantom.
3. Insert the PMMA rods in the other four inserts of the phantom.

4. Attach the phantom into the tray holder in the gantry bore.

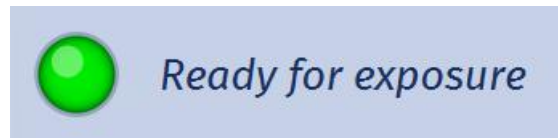


5. Tap **Start QC test**.

The device automatically drives the phantom to correct height and the software automatically selects the correct exposure values: 90 kV, 9 mA.



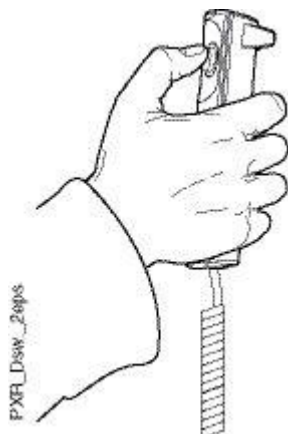
The exposure can be taken when the green indicator lights come on.



### CAUTION

When the exposure is taken, radiation will be generated. Protect yourself from radiation.

- Press the exposure button to take an exposure.



The software defines the Al insert, air (space outside the phantom) and the average HU value of PMMA.

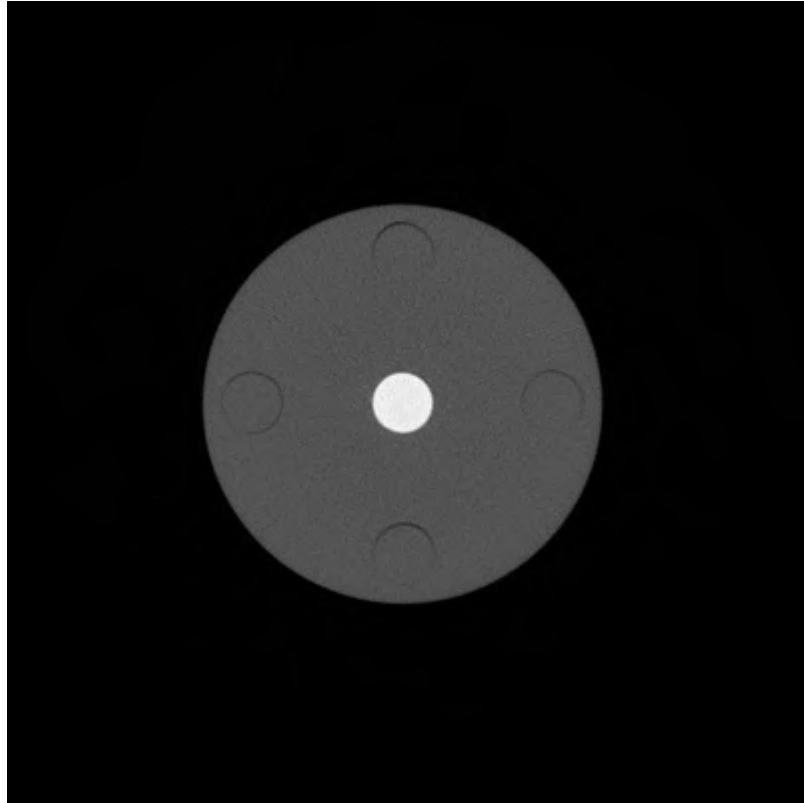
- Check that the HU values are inside the limits of the reference value and adjust if necessary.

The screenshot displays the Planmed Quality Manager interface. At the top, it shows 'Planmed Quality Manager' and 'QUALITY' with navigation icons. The user is identified as 'System Admin'. The main menu includes 'Weekly QC', 'HU Accuracy', 'MTF Test', 'Geometry', 'Slice Thickness', and 'AEC Reproducibility'. The 'HU Accuracy' tab is active, showing 'Start QC test' and 'Cancel' buttons. The imaging mode is set to 'High resolution (2x2)', with 90 kV and 9 mA parameters. A status indicator shows 'Test completed'. The central image is a circular phantom with four PMMA rods and one aluminum center rod. To the right, the test results are listed: Air (OK), PMMA (OK), and Aluminum (OK). A summary box indicates 'Test results: PASS (Test is valid until 17.9.2015)'. An 'Open report' button is located at the bottom right. A note in the bottom left corner states: 'Use image quality phantom - with 4 PMMA rods - and aluminum center rod'.

The test results are stored into the folder *C:/planmed/qc\_results*.

The quality control images are stored into the Local Study Archive with the following information:

- Patient ID: QC
- Name: QUALITY CONTROL [QC Phantom]
- Study Description: name of the QC test



### Methods

The results are calculated of three slices perpendicular to the phantom axis:

1. location of the 1st slice: total number of slices/4
2. location of the 2nd slice: total number of slices/2
3. location of the 3rd slice: total number of slices\* (3/4)

The HU values are calculated of three ROI's whose locations in the image correspond to the different materials (Aluminium, PMMA and air).

### Performance criteria

HU value for Air > -1100 and < -900

HU value for PMMA > -65 and < 135

HU value for Aluminum > 1800 and < 2000

The HU value of each ROI's average value must be within the lower and upper limits.

### Corrective action

Perform HU calibration. If the test still fails contact your local representative.

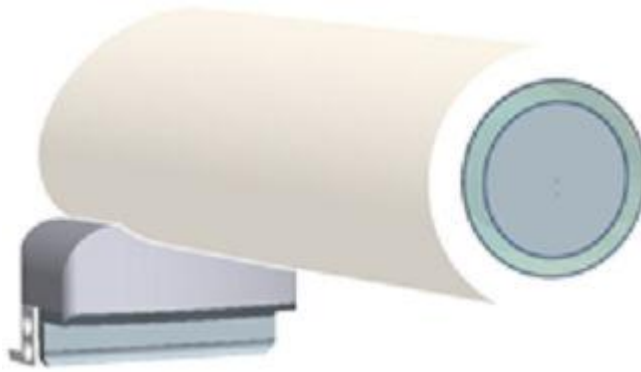
## 20.4.4 Modulation transfer function (MTF) test

### Objective

To define high contrast differentiation capacity of the device.

### Test equipment

MTF phantom (20008120)



### Exposure values

96 kV, 4 mA

### Medical equipment evaluation

RT or MP (or according to local regulations)

### Performance frequency

Annual maintenance

### 20.4.4.1 Performing modulation transfer function (MTF) test

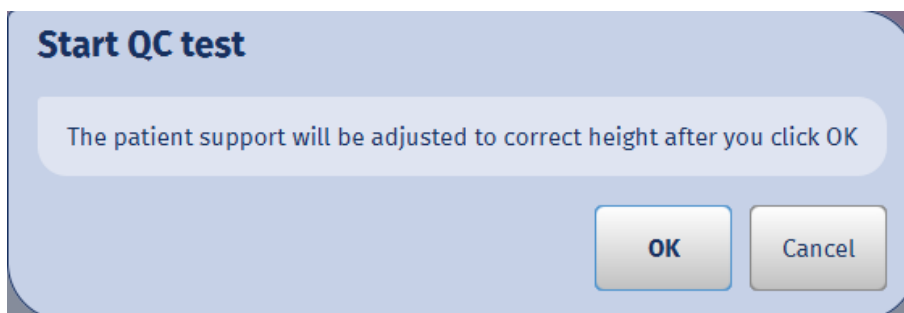
1. From the Quality control section tap **MTF test**.
2. Attach the image quality phantom into the tray holder in the gantry bore.





3. Tap **Start QC test**.

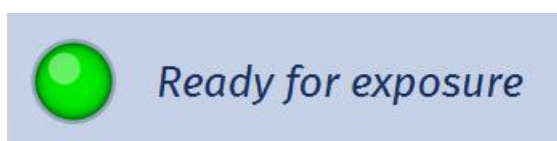
The device automatically drives the phantom to correct height and the software automatically selects the correct exposure values: 96 kV, 4 mA.



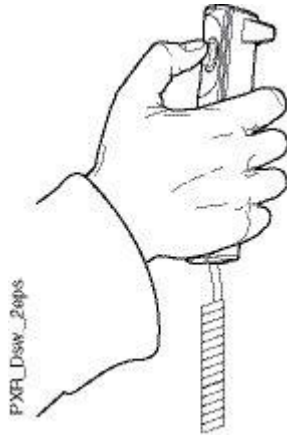
**CAUTION**

When the exposure is taken, radiation will be generated. Protect yourself from radiation.

The exposure can be taken when the green indicator lights come on.



4. Press the exposure button to take an exposure.



The software automatically calculates the modulation transfer function value.

When the test is completed the message *Test completed* appears and the results appear in the window.

Planmed Verity Manager QUALITY User: System Admin

Weekly QC HU Accuracy **MTF Test** Geometry Slice Thickness AEC Reproducibility

Start QC test Cancel Imaging mode High resolution (2x2) 96 kV 4 mA

Test completed

Use MTF phantom

MTF Curve

MTF10 0.43 lp/mm

Criteria MTF10 > 125

Test results: **PASS**  
(Test is valid until 17.9.2015)

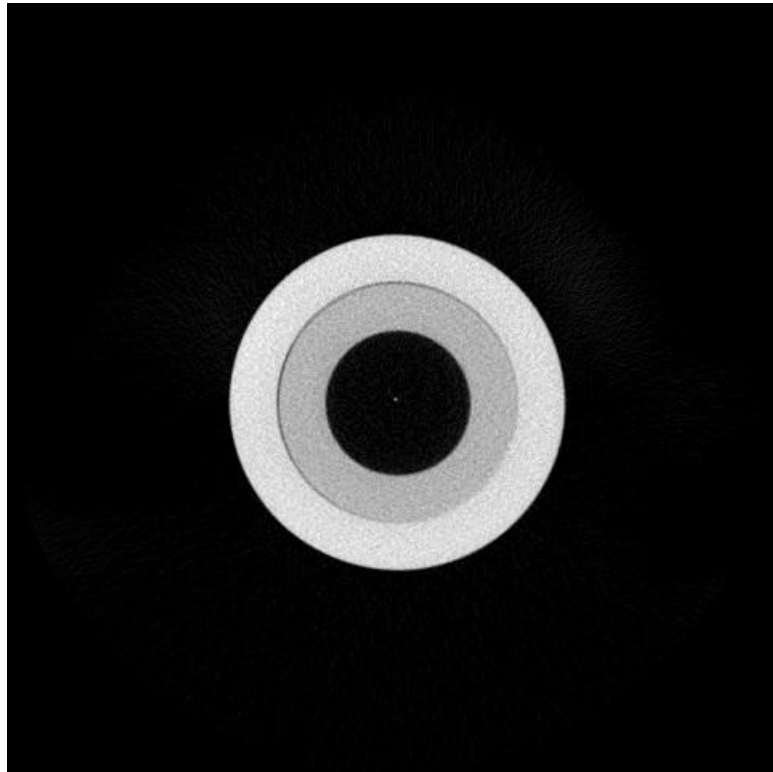
Open report

VTY\_MTF\_test\_21.psd

The test results are stored into the folder *C:/planmed/qc\_results*.

The quality control images are stored into the Local Study Archive with the following information:

- Patient ID: QC
- Name: QUALITY CONTROL [QC Phantom]
- Study Description: name of the QC test



### Methods

- The MTF phantom is a POM tube.
- In the middle of the tube there is a 0,1 mm thick and 30 mm long copper wire.
- The wire is at a 7-degree angle to the central axis of the phantom.
- The wire is examined about 1 cm away from the first axial slice where the wire shows for the first time.
- The MTF values are calculated in X- and Y-direction in the axial slice with the highest voxel value for the copper wire.
- The MTF is obtained from the Fourier transformation of the copper wire's LSF (Line Spread Function). The LSF is formed by averaging the neighborhood of the three slices.

### Performance criteria

MTF 10 > 1.25 lp/mm

### Corrective action

Perform Flat Field (see section "Flat field calibration" on page 178) and Geometry calibration (see section "Geometry calibration" on page 180).

If the test still fails contact your local representative.



## 20.4.5 Geometry test

### Objective

To check that the geometry calibration is successfully completed.

### Test equipment

- Image quality phantom (20008121)
- 4 PMMA rods



### Exposure values

90 kV, 9 mA

### Medical equipment evaluation

RT or MP (or according to local regulations)

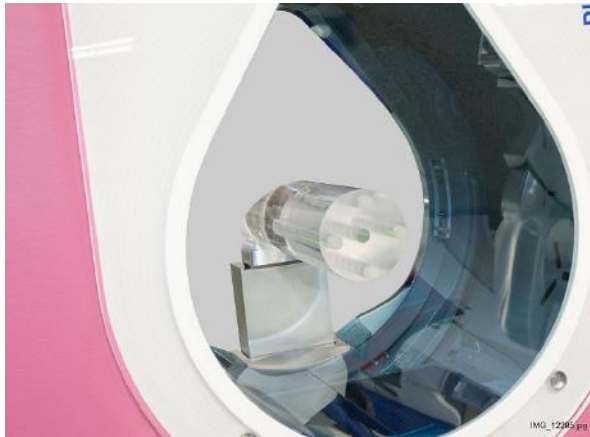
### Performance frequency

Annual maintenance

### 20.4.5.1 Performing Geometry test

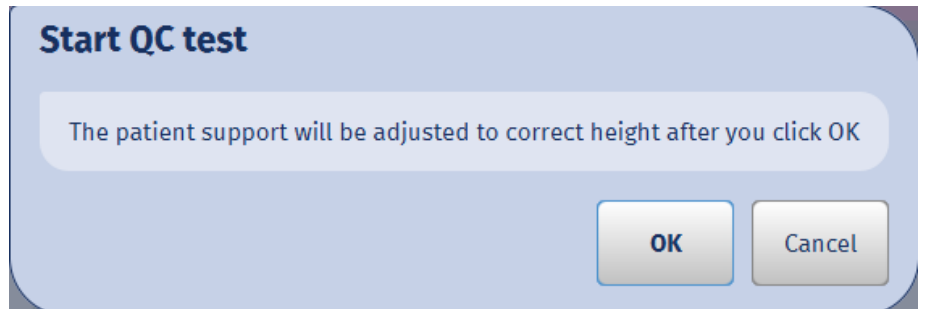
1. From the *Quality* section tap **Geometry** tab.

- Place the image quality phantom into the gantry bore.



- Tap **Start QC test**.

If the height of the patient support needs to be adjusted the following message appears.



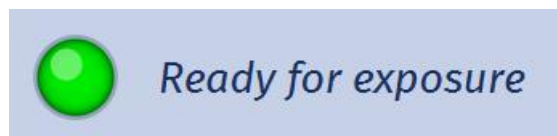
- Tap **OK**

The device automatically drives the phantom to correct height and the software automatically selects the correct exposure values: 90 kV, 9 mA.

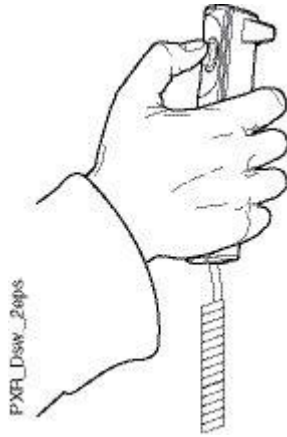
### CAUTION

When the exposure is taken, radiation will be generated. Protect yourself from radiation.

The exposure can be taken when the green indicator lights come on.

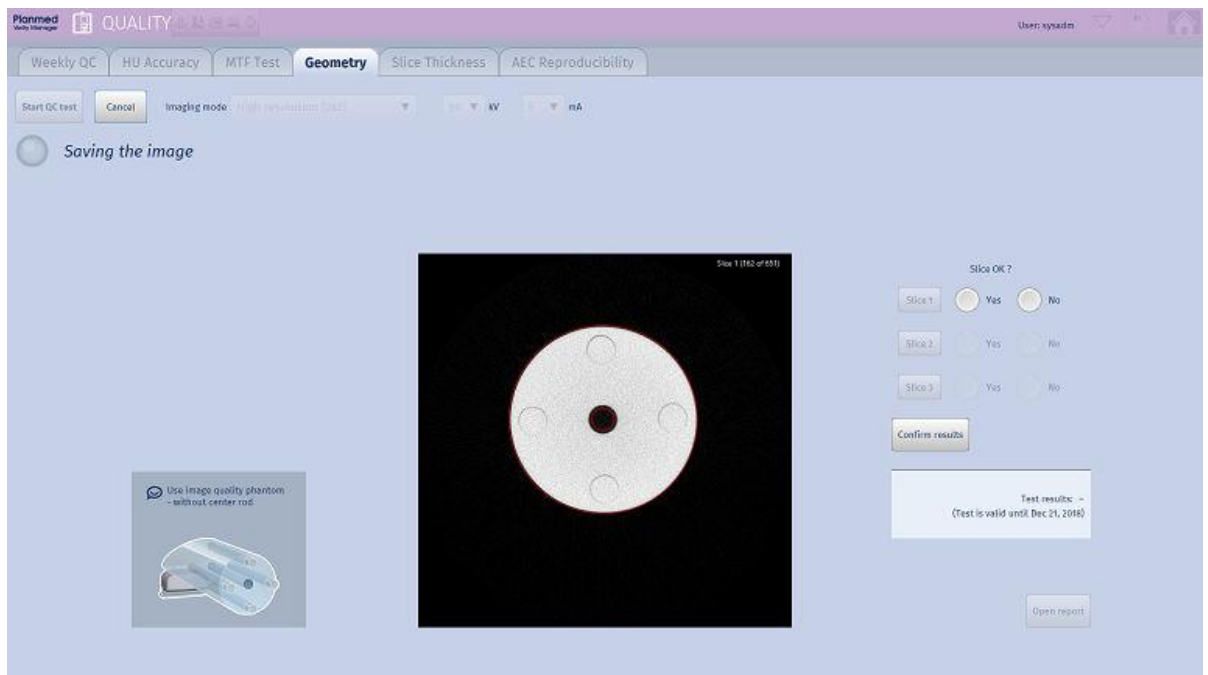


5. Press the exposure button.

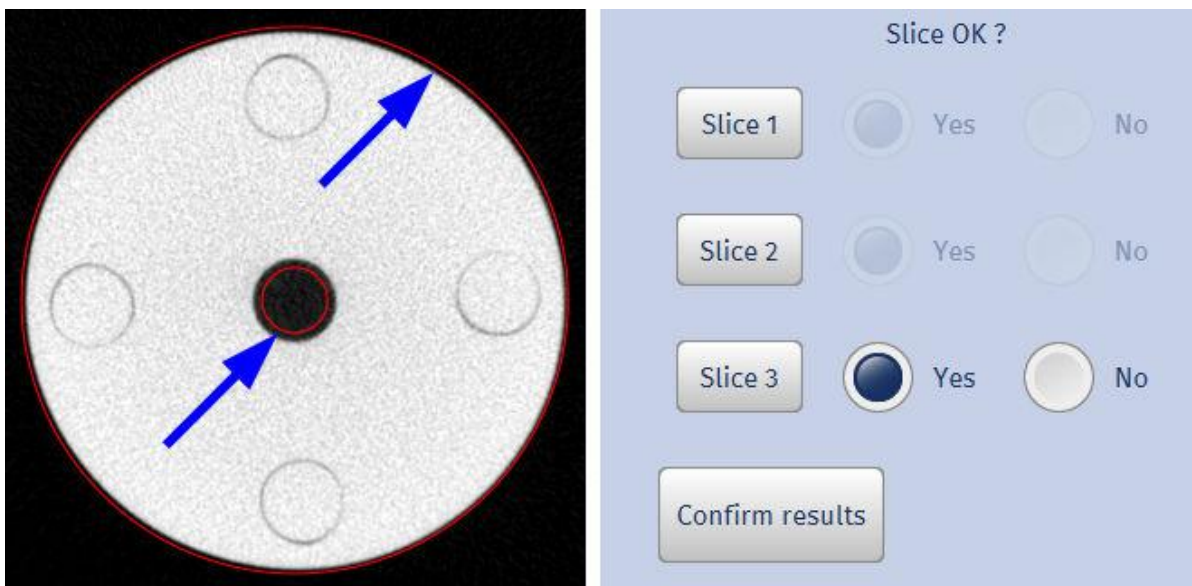


After the exposure has been taken the image reconstruction takes between 30 to 120 seconds.

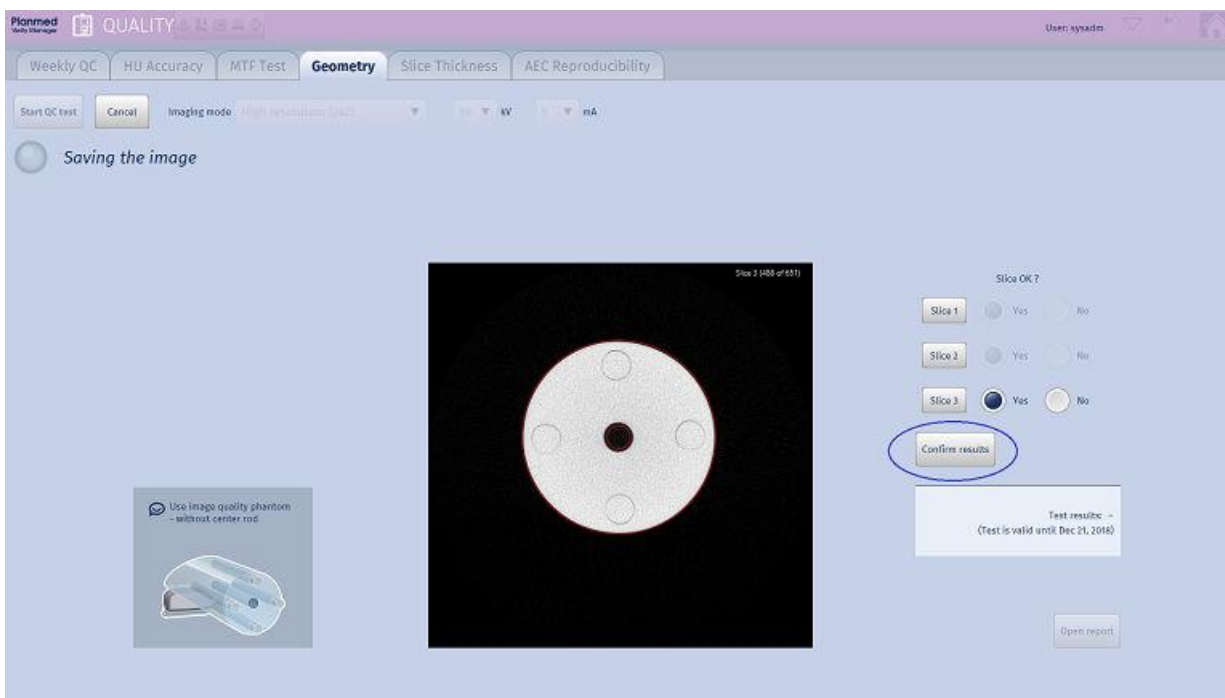
The image is presented from three different areas: slice 1, slice 2 and slice 3.



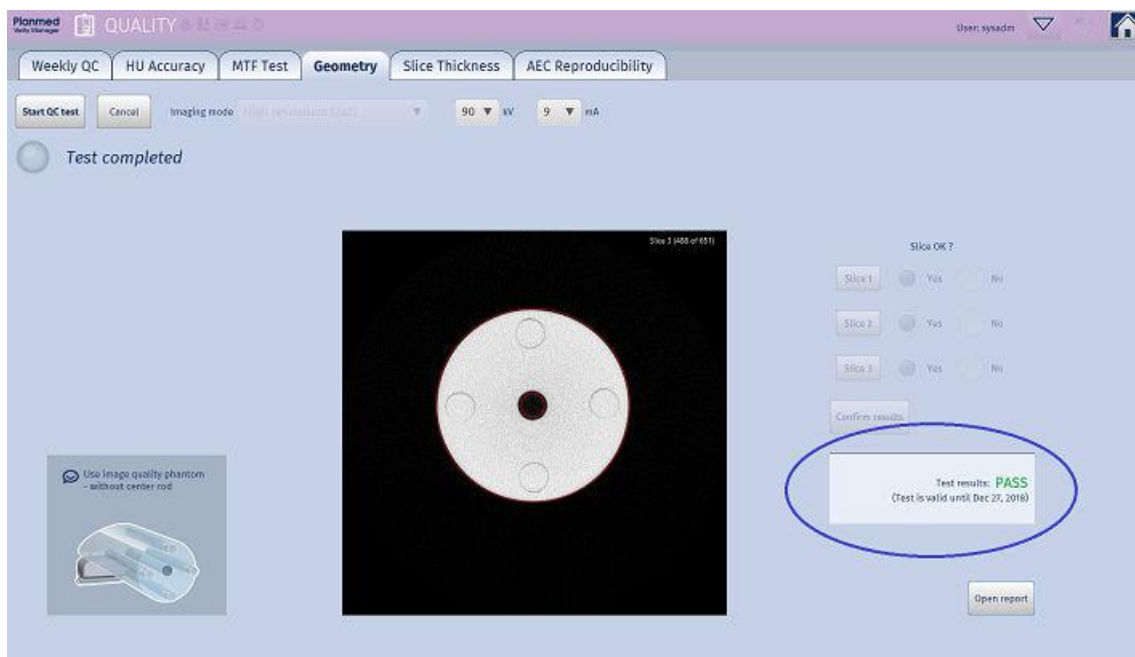
6. Check that the insert holes and the outer edge of the phantom show as even (not distorted) and if so tap **Yes** next to *Slice 1*, *Slice 2* and *Slice 3*.



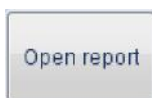
7. Approve the results by clicking **Confirm results**.



The test is completed when the results appear in the window.



8. When the test is completed the test report can be opened by tapping **Open report**.



```

20120329_geometry.txt - Notepad
File Edit Format View Help
Planmed Verity - Geometry test 29.3.2012

Detector ID: C782-10B
90 kV 9.5 mA

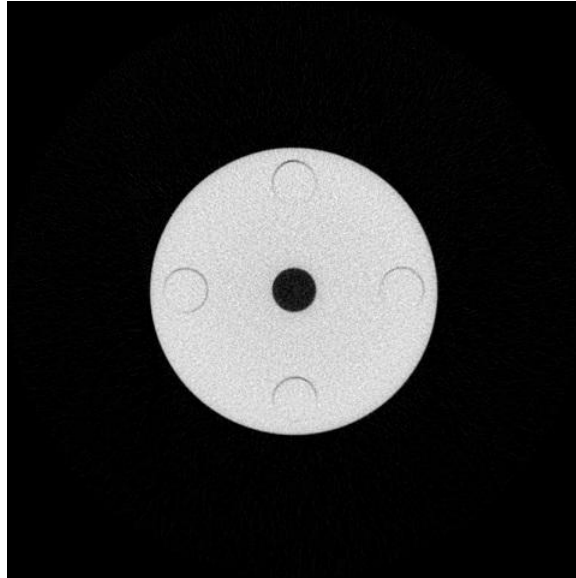
Volume size X: 401 Y: 401 Z: 326, voxel size: 0.400 mm

Test result: PASS
  
```

The test results are stored into the folder *C:/planmed/qc\_results*.

The quality control images are stored into the Local Study Archive with the following information:

- Patient ID: QC
- Name: QUALITY CONTROL [QC Phantom]
- Study Description: name of the QC test



### Methods

- The boundaries of the phantom are traced in the reconstruction slice. Around the phantom inside these boundaries is fitted a rectangle which contains all data of the phantom. The red circles appearing in the geometry calibration are focused according to the central point of the rectangle. The values of the circles' radii are constant.
- The geometry is examined in three axial slices (the slices perpendicular to the phantom axis.)
  1. location of the 1st slice: total number of slices/4
  2. location of the 2nd slice: total number of slices/2
  3. location of the 3rd slice: total number of slices\* (3/4)

### Performance criteria

The phantom circles show as even (not distorted) in the image.

### Corrective action

Perform geometry calibration. If the test still fails contact your local representative.

## 20.4.6 Slice thickness test

### Objective

To measure the actual slice thickness produced by the device.

### Test equipment

- Image quality phantom (20008121)
- Short aluminium center rod (1)
- PMMA rods (4)



### Exposure values

90 kV, 9 mA

### Medical equipment evaluation

RT or MP (or according to local regulations)

### Performance frequency

Annual maintenance

#### 20.4.6.1 Performing slice thickness test

1. From the Quality section tap **Slice Thickness** tab.
2. Place the inserts in the Image quality phantom.

#### NOTE

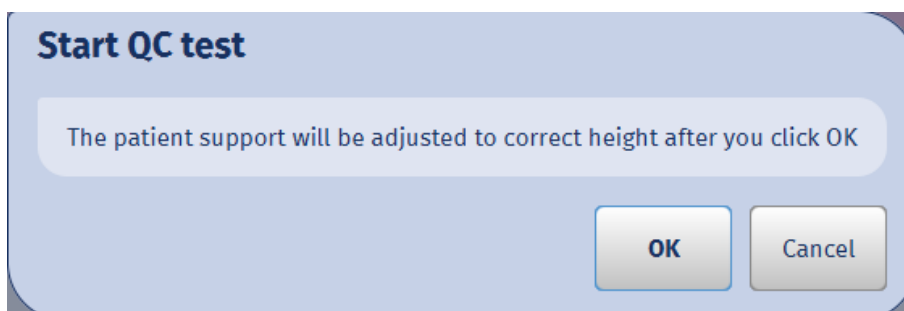
Make sure that the notch of the center rod is on top.

3. Place the phantom into the tray holder in the gantry bore.



4. Tap **Start QC test**.

If the height of the patient support needs to be adjusted the following window appears.



5. Tap **OK**.

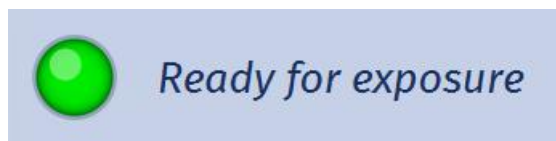
The device automatically drives the phantom to correct height and the software automatically selects the correct exposure values: 90 kV, 9 mA.



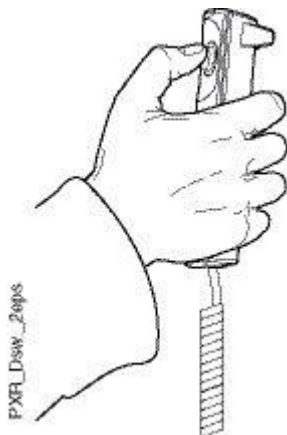
**CAUTION**

When the exposure is taken, radiation will be generated. Protect yourself from radiation.

The exposure can be taken when the green indicator lights come on.

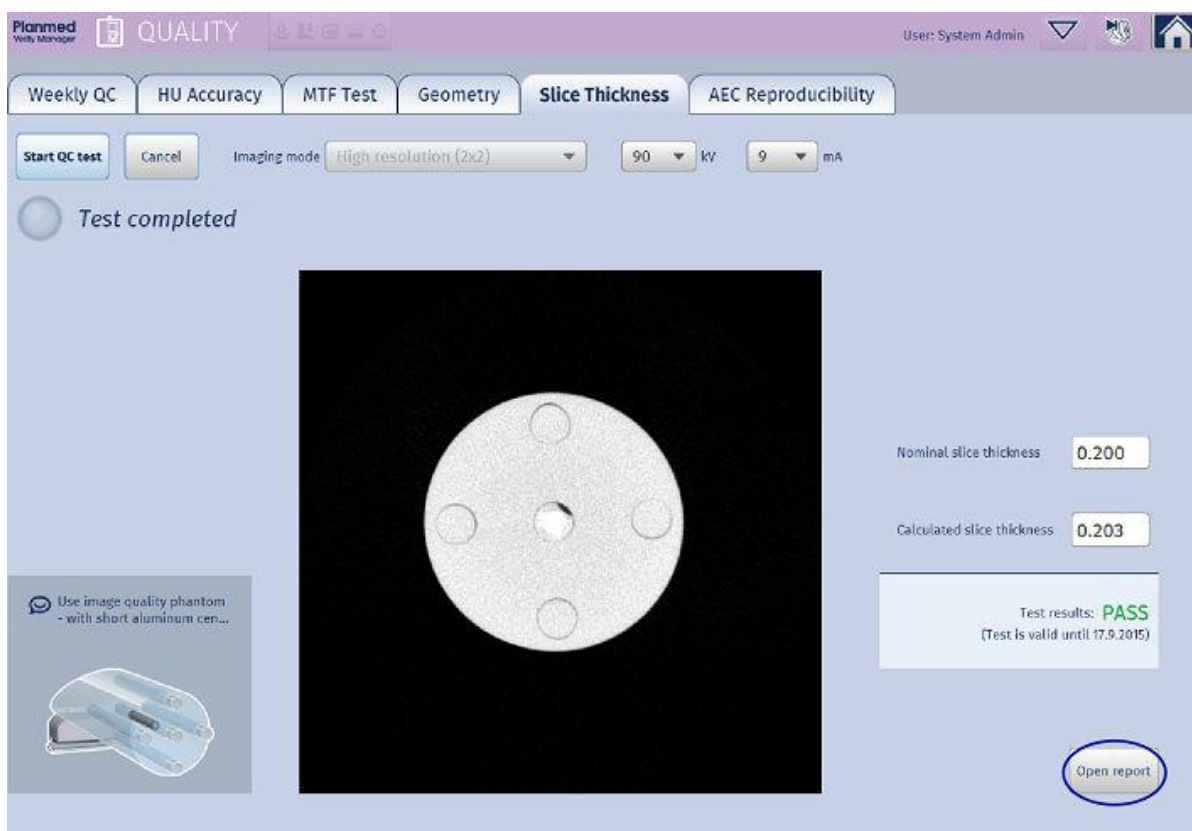


6. Press the exposure button to take an exposure.



When the test is completed the following window appears.

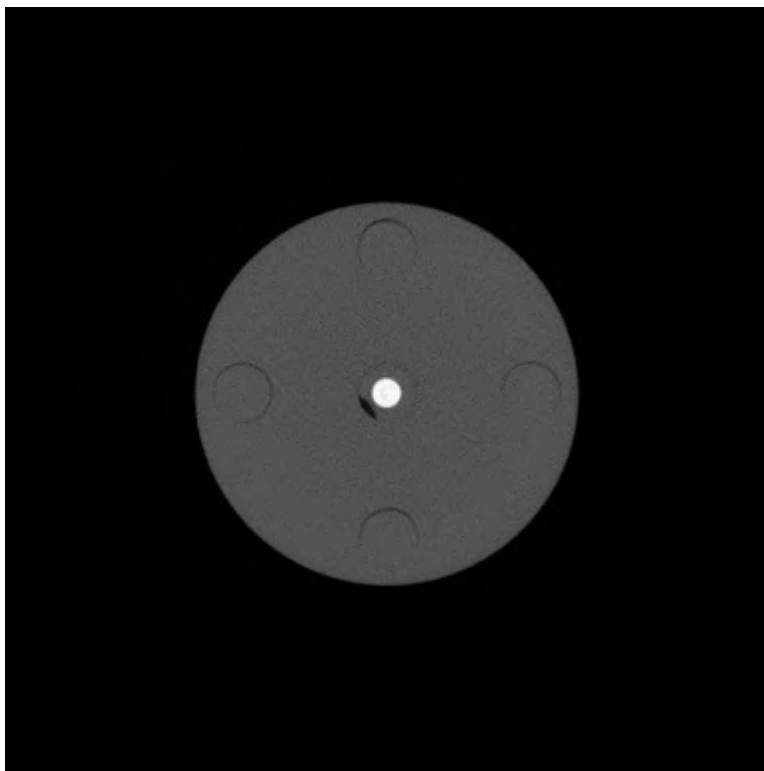
To open the test report tap **Open report**.



The test results are stored into the folder *C:/planmed/qc\_results*.

The quality control images are stored into the Local Study Archive with the following information:

- Patient ID: QC
- Name: QUALITY CONTROL [QC Phantom]
- Study Description: name of the QC test



### Methods

In the reconstruction image the first and the last axial slices where the Aluminium rod is visible, is detected. The difference of the index of the slices is multiplied by the size of the voxel and the obtained value is compared to the length (40 mm) of the Aluminium rod.

### Performance criteria

The calculated slice thickness is within +/- 5 % of the indicated slice thickness.

### Corrective action

Perform geometry calibration (see section "Geometry calibration" on page 180). If the test still fails contact your local representative.

## 20.4.7 AEC reproducibility test

### Objective

To verify the reproducibility of the AEC with quality control phantom.

### Test equipment

- Image quality phantom (20008121)
- PMMA rods (5)

**Exposure values**

90 kV, 5 mA (automatically selected)

**Medical equipment evaluation**

RT or MP (or according to local regulations)

**Performance frequency**

Annual maintenance

**20.4.7.1 Performing AEC reproducibility test**

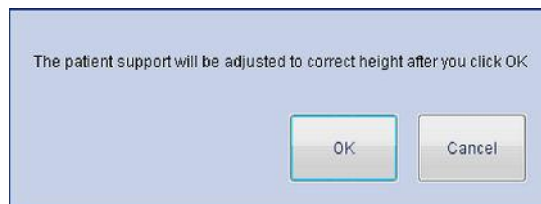
1. From the Quality section tap **AEC Reproducibility** tab.
2. Insert the rods into the Image quality phantom.
3. Place the phantom into the tray holder in the gantry bore.





4. Tap **Start QC test**.

If the height of the patient support needs to be adjusted the following window appears.



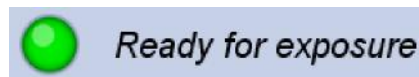
5. Tap **OK**

The device automatically drives the phantom to correct height and the software automatically selects the correct exposure values: 90 kV, 5 mA.

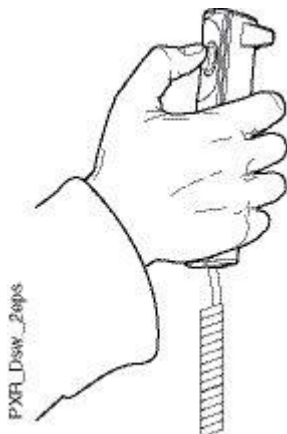
**CAUTION**

**When the exposure is taken, radiation will be generated. Protect yourself from radiation.**

The exposure can be taken when the green indicator lights come on.

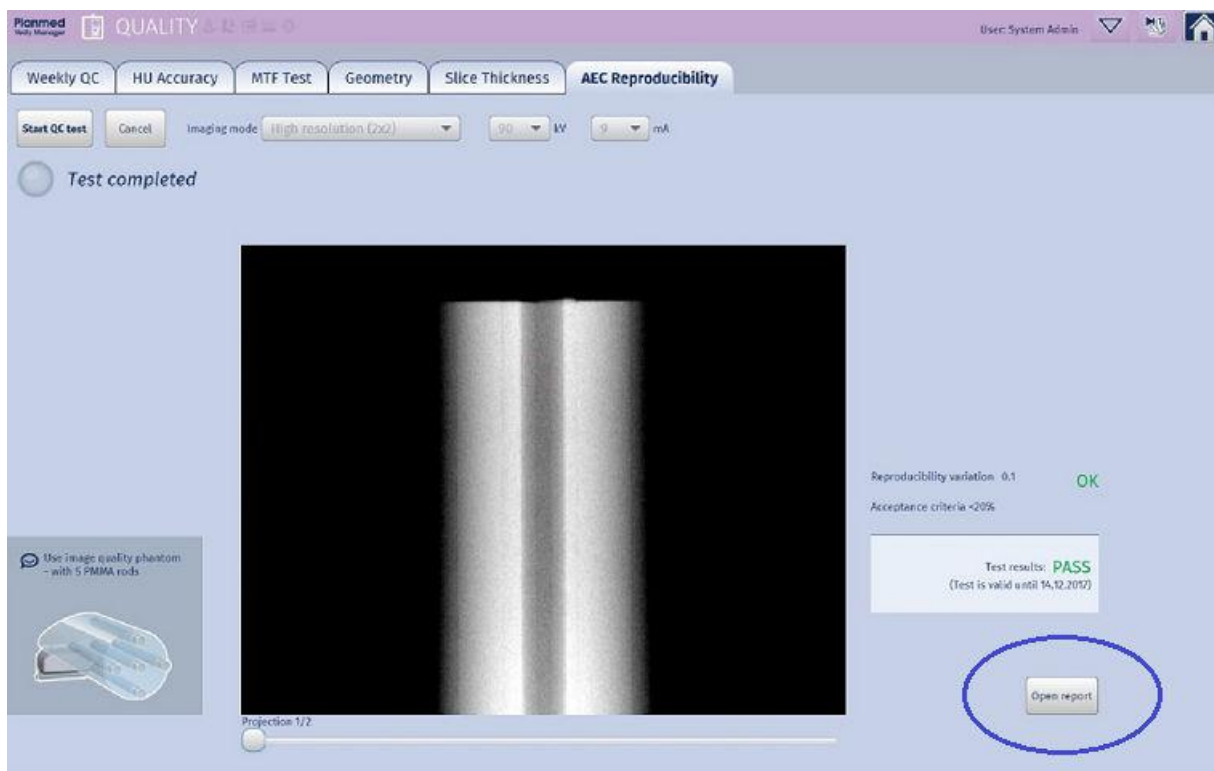


6. Press the exposure button to take an exposure.



When the test is completed the following window with the test result (pass/fail) appears.

To open the test report tap **Open report**.



The test results are stored into the folder *C:/planmed/qc\_results*.

The quality control images are stored into the Local Study Archive with the following information:

- Patient ID: QC
- Name: QUALITY CONTROL [QC Phantom]
- Study Description: name of the QC test

## Methods

10 images are acquired and the voxel values in the specific areas in the images are compared.

**Performance criteria**

The AEC reproducibility is < 20 %.

**Corrective action**

Perform Flat Field calibration, see section "Flat field calibration" on page 178.  
If the test still fails contact your local representative.

## 21 Calibration

### CAUTION

During calibration exposures are taken and radiation is emitted. Always use a proper shielding to protect from radiation. It is prohibited to stay in the calibration room during exposure. Before taking exposures make sure there is no one in the room.

### CAUTION

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

### CAUTION

The calibrations must be performed at regular intervals as instructed in this manual and after every 10000 exposures. Neglecting to perform the calibrations may result in unnecessary doses of radiation and poor diagnostic value of the image.

### NOTE

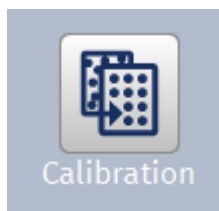
The Dose Area Product, CTDIvol and Dose Length Product must be measured regularly to ensure that the displayed values correspond to the indicated values.

#### Accessing calibration application



1. Tap the *Options* arrow on top of the window.

2. Select **Calibration**.



### 21.1 Summary of calibration procedures

Calibration	Medical equipment evaluation	Minimum calibration frequency	Performance criteria	Corrective actions	Section in the manual
Flat field calibration	RT or MP (Europe) MP (USA)	During annual maintenance or when needed	Defective single pixels < 1500 Dead rows and columns < 8 Correctable defect clusters < 90 Uncorrectable defect clusters 0	Check that the gantry bore is empty. Check the exposure values and repeat calibration. If the problem persists contact your service technician.	"Flat field calibration" on page 178

Calibration	Medical equipment evaluation	Minimum calibration frequency	Performance criteria	Corrective actions	Section in the manual
Geometry calibration	RT or MP (Europe) MP (USA)	During annual maintenance or when needed	None	Check that you are using the correct phantom and place it in the middle of the imaging field. Check that the exposure values are correct. Repeat the calibration. If the calibration still fails contact your service technician.	"Geometry calibration" on page 180
HU calibration	RT or MP	During annual maintenance or when needed	None	Make sure the test was performed using the right phantom and phantom rods. Repeat calibration.	"HU calibration" on page 182
Preheat calibration	RT or MP	During annual maintenance or when needed	At minimum 10 values are required. If less than 15 values are obtained calibration can be re-performed to increase accuracy.	If calibration fails repeat the test a few times. If calibration continues to fail contact your service technician.	"Preheat calibration" on page 187

## 21.2 Flat field calibration

### NOTE

Flat field calibration takes approximately 10 minutes.

#### Objective

To ensure uniform image quality in the entire exposure area.  
To identify and fix potential dead pixels.

#### Test equipment

None.



**CAUTION**

Do not use positioning tray.

**Exposure values**

The system will select exposure values automatically.

If necessary the mA values can be configured in *Service* mode.

Default mA values:

- mA for 2 x 2: 7
- mA for 4 x 4: 6

**Medical equipment evaluation**

RT or MP (Europe) MP (in the USA)

**NOTE**

The user is required to perform the calibration only in case the image quality tests fail.

**Performance frequency**

During annual maintenance or when needed.

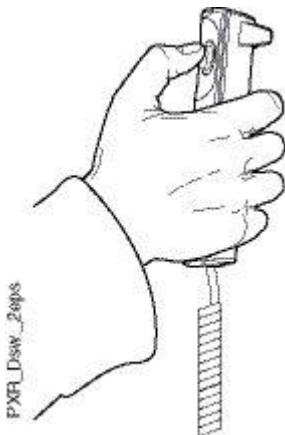
**21.2.1 Performing Flat-Field calibration**

1. Tap **Flat Field Calibration** tab.
2. Remove possible positioning trays or phantoms from the gantry bore.  
The system will select exposure values automatically.
3. Tap **Start Calibration**.
4. The exposure can be taken when the green indicator lights come on.

**CAUTION**

When the exposure is taken, radiation will be generated. Protect yourself from radiation.

Press the exposure button to take an exposure.



When the test is completed the results appear in the screen.

5. Check that all values are inside the limits.

6. Note the results and then tap **OK**.

Defect Acceptance Test Results		
Criterion	Count	Limit
Defective single pixels	10	<1500
Dead rows and columns	2	<8
Correctable defect clusters	2	<90
Uncorrectable defect clusters	0	0

**Result: PASSED**

OK

#### Performance criteria

- Defective single pixels < 1500
- Dead rows and columns < 8
- Correctable defect clusters < 90
- Uncorrectable defect clusters 0

#### Corrective action

Check that the gantry bore is empty. Check the exposure values and take a new exposure. If the problem persists contact your local representative.

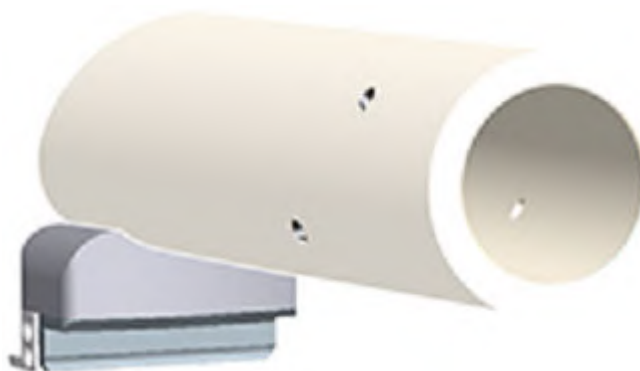
## 21.3 Geometry calibration

#### Objective

To calibrate the imaging geometry of the device.

#### Test equipment

- Geometry Phantom (20008119)



#### Exposure values

The system will select exposure values automatically. If necessary the mA values can be configured in the *Service* section.

The default values are 92 kV, 8 mA.

### Medical equipment evaluation

RT (in Europe) MP (in the USA)

#### NOTE

The user is required to perform the calibration only in case the image quality tests fail.

### Performance frequency

During annual maintenance or when needed.

## 21.3.1 Performing geometry calibration

The test will take approximately 5 minutes.

1. Attach the Image quality phantom to the tray holder in the gantry bore.

#### NOTE

Handle the phantom with care.

The system will select exposure values automatically.

2. Tap **Start Geometry Calibration**.



A rectangular button with rounded corners, a light blue gradient, and a dark blue border. The text "Start geometry calibration" is centered in a dark blue, sans-serif font.

The device automatically drives to correct position.

The exposure can be taken when the green indicator lights come on.

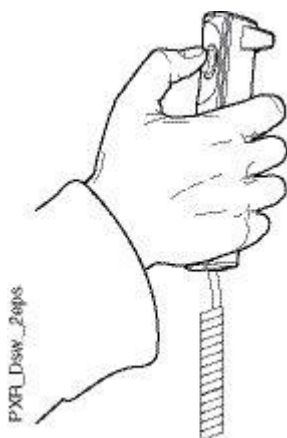


*Ready for exposure*

3. **CAUTION**

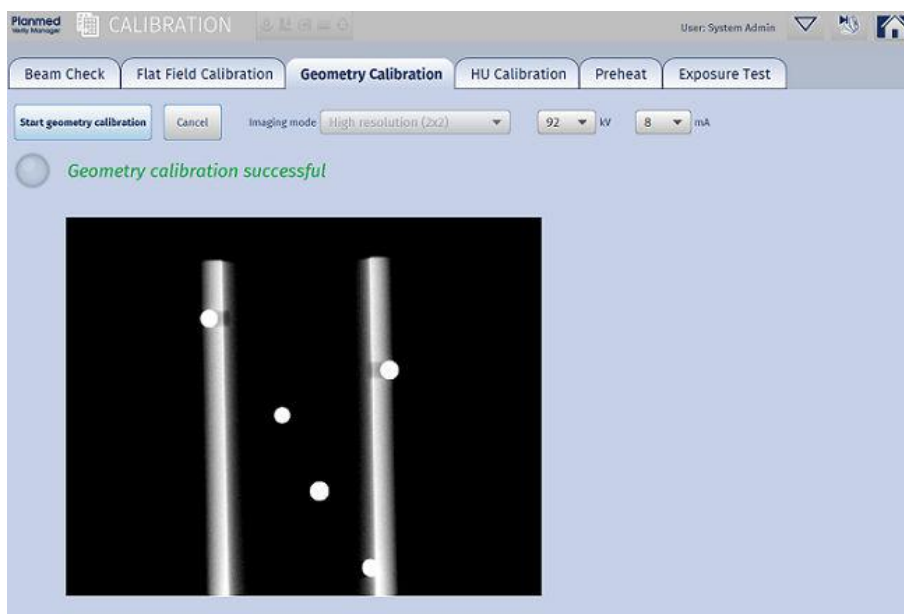
When the exposure is taken, radiation will be generated. Protect yourself from radiation.

Press the exposure button to take an exposure.



The calibration starts and the message *Geometry calibration in progress* appears.

4. When the calibration is successfully completed the message *Geometry calibration successful* appears.

**Performance criteria**

None

**Corrective action**

Check that you are using the correct phantom and place it in the middle of the imaging field.

Check that the exposure values are correct.

Repeat the test. If the test fails contact your service technician.

## 21.4 HU calibration

**Objective**

To ensure the image brightness values comply with standardized HU-scale.

### Test equipment

- Image quality phantom (20008121),
- Aluminum center rod,
- PMMA rods (4)



### Exposure values

The system will select exposure values automatically. Default starting values: 80 kV, 7 mA

### Medical equipment evaluation

RT or MP

### Performance frequency

Annually or as needed.

## 21.4.1 Performing HU calibration

### NOTE

The calibration takes approximately 15 minutes.

1. Insert the Aluminum center rod in the middle insert of the phantom.
2. Insert the acrylic rods in the other four inserts of the phantom.

3. Attach the phantom into the tray holder in the gantry bore. The system will set the exposure values automatically.

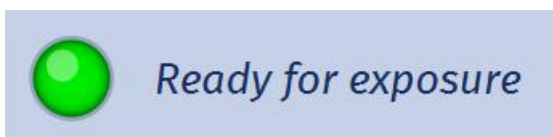


4. Tap **Start HU calibration**.  
The unit automatically drives to correct position.

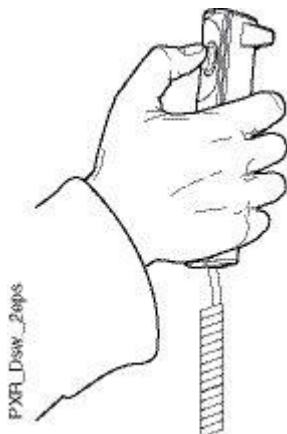
**CAUTION**

When the exposure is taken, radiation will be generated. Protect yourself from radiation.

The exposure can be taken when the green indicator lights come on.



5. Press the exposure button to take an exposure.

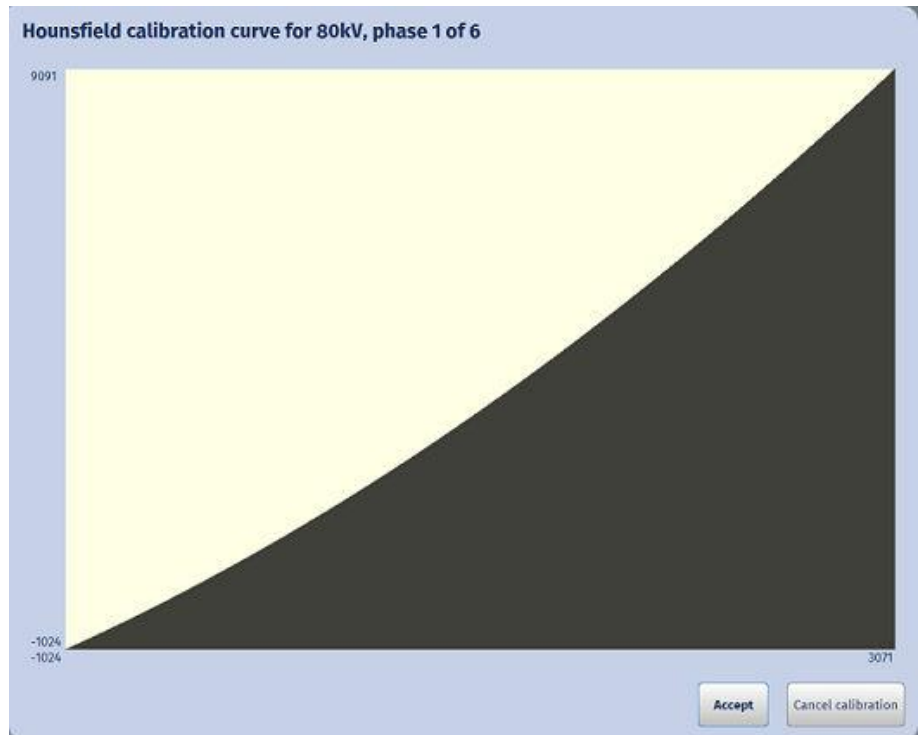


6. The device performs automatic reconstruction and presents an image of the phantom. Aluminum, acrylic and air parts in the phantom have been automatically calculated.

Check that the squares are in the right places and tap **Calibrate**.



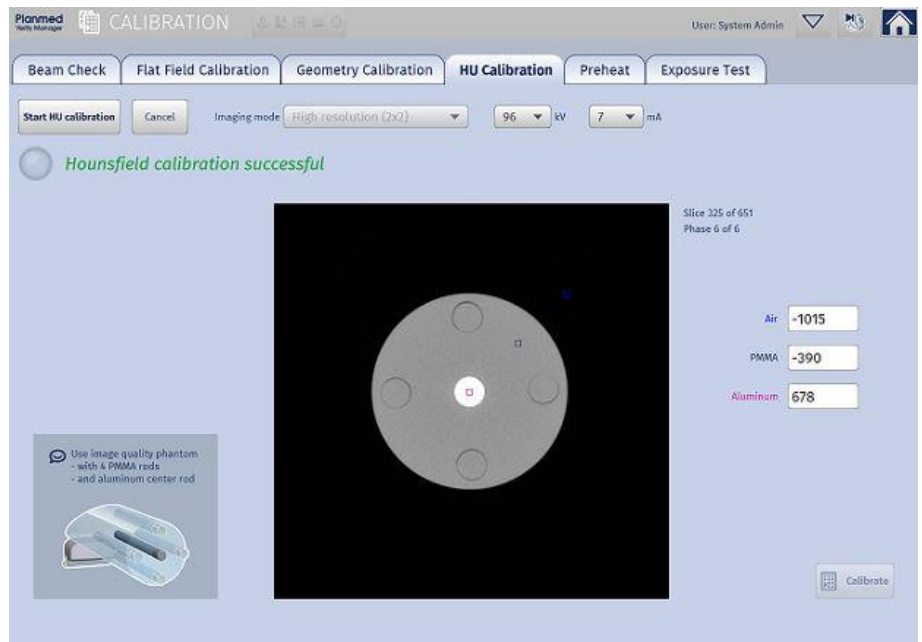
- In the following window tap **Accept**.



The device automatically modifies the exposure values and drives to the correct position for a new exposure.

- Take an exposure.
- Repeat the above procedure starting from step 6 for each kV value.

When calibration is successfully completed the following window and the message *Hounsfield calibration successful* appears.



**Performance criteria**

None



**Corrective action**

Make sure the test was performed using the right phantom and phantom rods. When performing another calibration sequence make sure the squares are in the right places, one in the middle, second anywhere on the phantom and the third outside the phantom but in the exposure area.

**21.5 Preheat calibration****Objective**

To measure the filament voltage induced filament current curve and save it for selecting proper filament voltage values. The obtained values are used as starting values for filament voltage preheat stage.

**Test equipment**

None

**Medical equipment evaluation**

RT or MP

**Performance frequency**

Annually or as needed.

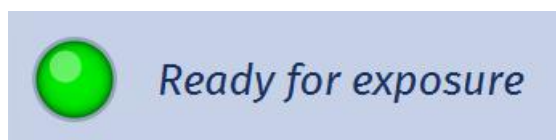
**21.5.1 Performing preheat calibration**

1. Tap **Start preheat calibration**.

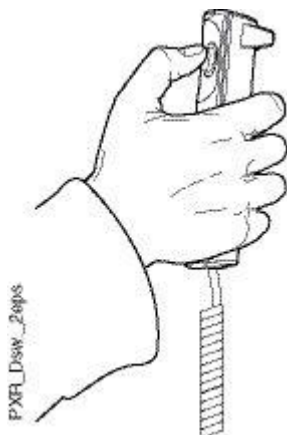
**CAUTION**

**When the exposure is taken, radiation will be generated. Protect yourself from radiation.**

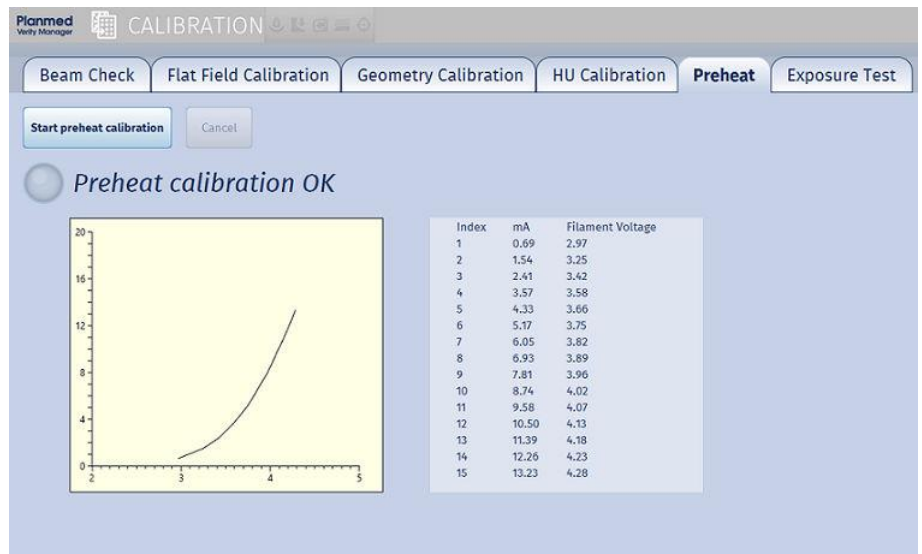
The exposure can be taken when the green indicator lights come on.



2. Press the exposure button to take an exposure.



When calibration is successfully completed the following window and the message *Preheat calibration OK* appears.



### Performance criteria

At minimum 10 values are required to pass calibration. If more than 10 but less than 15 values are obtained calibration can be re-performed to increase accuracy.

### Corrective action

If calibration fails repeat the test a few times. If calibration continues to fail contact your service technician.

## 22 Support

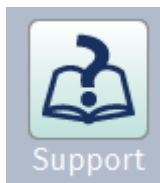
### NOTE

DICOM logs may contain patient information.



To access support application tap the *Options* arrow on top of the window.

Select **Support**.



The following window opens.



### Collect logs

The AWS related errors and other messages are recorded in log files. The files are stored in the folder `C:\Planned\logs`.

The main log files are named in format:

`Verity_Manager_YYYYMMDD.log`

where YYYY = year, MM = month and DD = day.

In the same folder there are other log files for recording detector temperatures. These log files are named in format:

`Temperatures_YYYYMMDD.log`

New log files are created during Verity Manager startup. The existing log files are moved into the folder `C:\Planned\logs\old`.

The latest log files can be collected into a compressed zip file by tapping the Collect Logs button in the Tools window of Verity Manager application.

The zip file is stored on the desktop. You can copy the zip file and send it to Planned representatives upon request.

The zip files are named in format:

`VerityManagerDump_YYYYMMDD_HHMMSS.zip`

### Open log file

1. Tap this button to open the log file.
2. The log file currently in use opens.

### Clear log

Tap this button to clear the log.

**Delete old logs**

Tap this button to delete old logs.

**Open error history**

Tap this button to open error history.

**Install license**

The following functions require license:

- DICOM Print
- DICOM Worklist
- DICOM MPPS
- DICOM Media Export
- Weight Bearing
- Maxillofacial imaging
- Head & Neck imaging
- Image stitching
- Automatic Exposure Control

To install the latest license tap this button.

By default the license is located in the E:\ folder (USB memory).

The `VerityManager.lic` license file will be copied to the folder `C:\Planmed\license`.

**About**

To open the information window containing version and license information tap this button. The application versions and licence information is shown.

**User's manual**

To open the User's manual in PDF format tap this button.

## Technical manual

To open the Technical manual in PDF format tap this button.

### 22.1 Notification and error messages

Code	Description
5000	<p><b>Lost connection to Verity CPU</b></p> <p>Cause: Verity Manager is not able to communicate with Verity CPU.</p> <p>Corrective action: Check the connection cable between Workstation PC and Verity CPU. Restart Verity X-ray unit.</p>
5001	<p><b>Detector connection time-out. Imaging cancelled.</b></p> <p>Cause: Verity Manager is not able to communicate with detector.</p> <p>Corrective action: Check the connection cable between Workstation PC and detector. Restart Verity X-ray unit.</p>
5002	<p><b>Detector serial number is not configured. Image acquisition is not possible.</b></p> <p>Cause: Verity Manager is not able to communicate with the detector.</p> <p>Corrective action: Configure the detector serial number in Service/Device.</p>
5003	<p><b>Data folder for the detector is missing. Image acquisition is not possible.</b></p> <p>Cause: Verity Manager is not able to communicate with detector.</p> <p>Corrective action: Check that the configured detector serial number in Service/Device is correct and that the data folder exists. If data folder is missing, re-install detector software on Workstation PC.</p>
5010	<p><b>Flat-field calibration is missing.</b></p> <p>Cause: Flat-field calibration files are missing. Image acquisition is disabled.</p> <p>Corrective action: Perform flat-field calibration before acquiring patient images</p>
5011	<p><b>Geometry calibration has not been performed.</b></p> <p>Cause: Geometry calibration files are missing. Image acquisition is disabled.</p> <p>Corrective action: Perform geometry calibration before acquiring patient images</p>
5012	<p><b>Hounsfield (HU) calibration has not been performed.</b></p> <p>Cause: Hounsfield calibration files are missing. Image acquisition is disabled.</p> <p>Corrective action: Perform HU calibration before acquiring patient images</p>
5020	<p><b>Requested position could not be reached.</b></p> <p>Cause: The X-ray unit was not able to drive to the requested pre-set position. Pre-set position is out of operation range.</p> <p>Corrective action: Retry the pre-set drive or drive the gantry back to the operating range to resume normal use. If problem persists check the pre-set position adjustments.</p>
5021	<p><b>Weight bearing position could not be reached. Gantry is not locked.</b></p> <p>Cause: Gantry was moving to weight bearing position but the drive was interrupted before Gantry reached correct weight-bearing angle. Gantry is in unsafe area and weight bearing lock is open.</p> <p>Corrective action: Use joystick to move the gantry back to angle larger than 15 degrees or re-activate weight bearing drive.</p>

Code	Description
5022	<b>DOSE ALERT! The patient dose for the study will exceed the alert limit.</b> Cause: for detailed description see section "3D exposure" on page 124. Corrective action: -
5024	<b>Please attach the Head positioning tray to continue.</b> Cause: Head target anatomy requires Head positioning tray. Corrective action: Attach Head positioning tray to continue.
5025	<b>DOSE ALERT! The patient dose for the selected protocol will exceed the alert limit.</b> Cause: for detailed description see section "3D exposure" on page 124. Corrective action:-

Code	Description
6000	<b>Activated weight-bearing mode requires that you use weight-bearing stool.</b> Cause(s): Activated weight-bearing mode requires that you use weight-bearing stool and adapter. Error in patient support recognition. Corrective action(s): To continue attach the weight-bearing adapter before placing the stool to the gantry bore. Check the Patient Support Sensor PCB. Check the cabling between patient support mechanism - Interface PCB - CPU Connector PCB - CPU PCB.
6001	<b>Unable to drive to selected pre-set destination because weight-bearing adapter is attached.</b> Cause(s): Weight-bearing stool adapter cannot be used while driving selected pre-set drive. Corrective action(s): Remove the weight-bearing stool and adapter to resume normal use.
6002	<b>The weight-bearing stool cannot be used in this imaging mode.</b> Cause(s): Error in patient support recognition. Corrective action(s): Remove the stool and adapter to resume normal use. Check the Patient Support Sensor PCB. Check the cabling between patient support mechanism - Interface PCB - CPU Connector PCB - CPU PCB.
6003	<b>Unable to drive the tray mechanism without a tray in weight-bearing mode.</b> Cause(s): Pre-set drive or patient position. Corrective action(s): Please attach correct tray to be used in weight-bearing mode to continue to drive the tray mechanism. Check the Patient Positioning Sensor PCB. Check the cabling between patient positioning mechanism - Interface PCB - CPU Connector PCB - CPU PCB.
6004	<b>Vertical tray may not be used in weight bearing mode.</b> Corrective action(s): Remove the tray.
6011	<b>All downward movements are disabled due to pressure on base cover.</b> Cause(s): Base cover safety switch is activated. Corrective action(s): Remove pressure from the base cover and retry pre-set drive. Remove any weighing object from the top of base cover. Check microswitches and cabling.

Code	Description
6012	<p><b>Pre-set drive was halted because an object was detected inside the gantry.</b></p> <p>Cause(s): Limb recognition sensor activated.</p> <p>Corrective action(s): Remove any object inside the gantry and retry pre-set drive. If the problem persists, ensure that recognition sensor transmitter and receiver are correctly placed and nothing is obstructing the signal.</p>
6013	<p><b>All downwards movements disabled due to an object between gantry and floor.</b></p> <p>Cause(s): Base cover safety switch is activated.</p> <p>Corrective action(s): Make sure that nothing is squeezed under the gantry while driving it downwards. Check microswitches and cabling.</p>
6014	<p><b>Moving the unit is allowed only in transportation mode.</b></p> <p>Cause(s): Transportation handle activated without first driving the unit in transportation mode.</p> <p>Corrective action(s): Lower the unit carefully back on ground and lock the handle in place to resume. If the warning appears but transportation handle seems to be correctly in place Check microswitches and cabling from patient support mechanism to the CPU PCB.</p>
6015	<p><b>Automatic pre-set drive was stopped due to manually operating joysticks.</b></p> <p>Corrective action(s): Drive the pre-set again to reach pre-set destination.</p>
6016	<p><b>Support handle can only be used in weight-bearing imaging.</b></p> <p>Cause(s): Weight-bearing handle or handle recognition activated.</p> <p>Corrective action(s): Push the handle in to resume. Check the microswitches and the cabling to the CPU Connector PCB.</p>
6017	<p><b>Weight-bearing mode activated. Rotation with joystick disabled.</b></p>
6018	<p><b>Hover tray mode activated</b></p> <p>Cause: Hover tray mode is ready for use.</p> <p>Corrective action: -</p>
6020	<p><b>Manual pre-set drive Press-and-hold down any joystick button to drive to a pre-set destination.</b></p>
6021	<p><b>Do not switch off the unit before the computer is powered off. Verify computer status from the indicator light in the device panel.</b></p>
6022	<p><b>The computer will automatically shut down after the pre-set drive to packaging mode is completed.</b></p>
6023	<p><b>The computer will automatically shut down after the pre-set drive to transportation mode is completed.</b></p>
6024	<p><b>The patient dose for the study will exceed the notification limit.</b></p> <p>Cause: see section "3D exposure" on page 124 for detailed description.</p> <p>Corrective action: -</p>
6025	<p><b>Acquisition software is not compatible with the software installed on the device. &gt; Please update latest software.</b></p> <p>Cause(s): Old or invalid software version installed on CPU or no connection to CPU.</p> <p>Corrective action(s): Verify CPU connection and update correct CPU software version if necessary.</p>

Code	Description
6026	<p><b>The patient dose for the selected protocol will exceed the notification limit.</b></p> <p>Cause: The selected protocol is configured to exceed notification limit.</p> <p>Corrective action:</p>
6030	<p><b>Software checksum error &gt; Please verify or re-run PC software installation.</b></p> <p>Cause(s): Corrupted Verity Manager software installation.</p> <p>Corrective action(s): Check Verity Manager installation package version and re-run PC software installation.</p>
6055	<p><b>Selected imaging mode does not support AEC. Manual imaging values are in use. &gt; Carefully assess the situation.</b></p> <p>Cause(s): Selected imaging protocol does not support AEC. AEC imaging mode is disabled and imaging values must be selected manually.</p> <p>Corrective action(s): Use imaging protocol that supports AEC or select imaging values manually.</p>
6056	<p><b>Collimation cannot be changed during AEC exposure. &gt; Please return previous collimation.</b></p> <p>Cause(s): Collimation has changed after acquiring AEC scout images.</p> <p>Corrective action(s): Use the same collimation for scout images and 3D image in AEC mode.</p>
6057	<p><b>No human tissue detected &gt; Please make sure that anatomy is correctly positioned.</b></p> <p>Cause(s): Dose measured at X-ray detector is too low and is not indicative of real anatomy.</p> <p>Corrective action(s): Run quality control tests and verify that nothing is blocking the X-ray beam and that the X-ray detector is working properly.</p>
6058	<p><b>AEC scouts not found.</b></p> <p>Cause(s): Not enough scout images found in study before AEC 3D imaging. AEC imaging requires four scout images.</p> <p>Corrective action(s): Acquire scout images in AEC mode before AEC 3D imaging to ensure correct amount of scout images.</p>
6059	<p><b>Invalid protocol configuration.</b></p> <p>Cause: Exposure parameters for selected anatomy were not found.</p> <p>Corrective action: Configure exposure parameters for the selected anatomy in Service\Imaging Protocols page.</p>
6060	<p><b>Saving preset parameters without any positioning equipment is not possible. &gt; Use suitable positioning equipment to save.</b></p> <p>Cause(s): No positioning equipment was attached to gantry while adjusting preset values.</p> <p>Corrective action(s): Attach positioning equipment to gantry before saving the adjustments.</p>
6061	<p><b>It is not recommended to acquire images without a tray.</b></p> <p>Cause: Positioning tray is missing or not detected.</p> <p>Corrective action: Attach positioning tray or ensure the patient is sufficiently supported before acquiring images.</p>



Code	Description
6062	<p><b>Not licensed for clinical use.</b></p> <p>Cause(s): Verity Manager has no connection to the detector or not able to find the license file.</p> <p>Corrective action(s): Check the connection between workstation and the detector and whether a license is correctly installed.</p>
6063	<p><b>Verity Manager license is expired on x</b></p> <p>Cause(s): Verity Manager license has expired.</p> <p>Corrective action(s): Install new Verity Manager license file.</p>
6064	<p><b>X days to license expiration. Imaging is not possible after the license expires.</b></p> <p>Cause(s): Verity Manager license is about to expire.</p> <p>Corrective action(s): Install new license.</p>
6065	<p><b>Demo mode -&gt; Demo mode activated</b></p> <p>Cause(s): Verity Manager is configured to work in demo mode or Verity Manager license has expired.</p> <p>Corrective action(s): Change demo mode configuration on Service/Device tab or install new Verity Manager license file.</p>
6066	<p><b>License is for detector</b></p> <p>Cause(s): Verity Manager has no connection to the detector or the configured detector serial number does not match the license file.</p> <p>Corrective action(s): Check the connection to the detector and the configured detector serial number in Service/Device. Correct the serial number or change the Verity Manager license file if necessary.</p>
6068	<p>The factory imaging protocol is in use and cannot be disabled. To disable the protocol its setting as default protocol must be removed. By checking the box to disable a default configured protocol for any anatomy, the pop-up opens and the deselect checkbox is disabled.</p>
6073	<p>This factory imaging protocol is in use and cannot be disabled. Remove it's use as a default protocol first. When user clicks a check box to disable a protocol that is configured as default for any anatomy, this pop-up opens and the deselecting the checkbox is prevented.</p>
6074	<p>Cannot repeat reconstruction for stitched image. Reconstruct individual volumes before stitching. When user selects stitched image and clicks reconstruct button.</p>
6075	<p>Cannot stitch 0.2 resolution images. Use stitching for 0.4 mm resolution images. Shown when user selects image with 0.2 resolution and clicks stitch button. Corrective action: Reconstruct image to standard resolution.</p>
6076	<p>Cannot stitch small field of view (FOV) images. Use stitching for large FOV images. Shown when user selects image acquired with small FOV and clicks stitch button. Corrective action: Acquire image with large fov.</p>
6077	<p>Cannot stitch extended field of view (FOV) images. Use stitching for large FOV images. Shown when user selects image with extended FOV and clicks stitch button. Corrective action: Reconstruct image without EFOV</p>
6078	<p>Cannot stitch this body part. Use stitching with ANKLE, FOOT and TOE or WRIST, HAND and FINGER images. Shown when user selects image of invalid body part for stitching and clicks stitch button.</p>
6079	<p>Cannot stitch image without a suitable pair. Use stitching for images with same laterality. Shown when user clicks stitch button and study does not contain another image with the same laterality status as the selected image.</p>

Code	Description
6080	Cannot stitch image without a suitable pair. Use stitching for images with or without weight bearing. Shown when user clicks stitch button and study does not contain another image with the same weight bearing status as the selected image.
6081	Cannot stitch an already stitched image. Use stitching for individual images. Shown when user selects stitched image and clicks stitch button. Corrective action: Select individual image and click Stitch button.
6082	Cannot stitch image without a suitable pair. Stitch FOOT or TOE images to ANKLE images. Shown when user selects foot image, clicks stitch button and the study does not contain ankle images.
6083	Cannot repeat reconstruction for already re-reconstructed volume. Reconstruct original volume. Shown when user selects re-reco image and clicks Reconstruct button. Corrective action: Select original image and click Reconstruct button.
6084	Cannot stitch image without a suitable pair. Use stitching for large FOV images. Shown when user clicks stitch button and study does not contain another image with large fov status.
6085	Cannot stitch image without a suitable pair. Use stitching for 0.4 mm resolution images. Shown when user clicks stitch button and study does not contain another image with large standard resolution.
6086	Cannot stitch image without a suitable pair. Use stitching for individual images. Shown when user clicks stitch button and study does not contain another individual image that could be stitched with the selected image. It is not possible to stitch already stitched images.
6087	Cannot stitch PRONE ankle images. Use stitching for SUPINE ankle images. Shown when user selects ANKLE image with PRONE patient position and clicks stitch button. It is not possible to stitch prone ankle images.
6088	Cannot stitch image without a suitable pair. Use stitching for SUPINE ankle images. Shown when all ANKLE images in study have PRONE patient position, user selects FOOT/TOE image and clicks stitch button.
6089	Cannot stitch image without a suitable pair. Stitch FINGER image to HAND or WRIST images. Shown when user selects FINGER/HAND or WRIST image, clicks stitch button and the study does not contain other FINGER/HAND or WRIST image.
6090	Cannot stitch image without a suitable pair. Use stitching for FINGER, HAND and WRIST images with same patient position. Shown when user selects FINGER/HAND or WRIST image, clicks stitch button and the study does not contain other FINGER/HAND or WRIST image with same patient position.

## 22.2 List of abbreviations

ABBREVIATION	DEFINITION
AE	Application Entity
Al	Aluminum
APR	Acoustic Pulse Recognition
a-Si	Amorphous silicon
CBCT	Cone Beam Computed Tomography
CsI	Caesium Iodide
CTDI	Computed Tomography Dose Index
DICOM	Digital Imaging and Communications in Medicine

EC	European Community
EEC	European Economic Community
EMC	Electromagnetic Compatibility
FF	Flat Field
FPD	Flat panel detector
HIS	Hospital Information System
HU	Hounsfield Unit
IEC	International Electrotechnical Commission
MP	Medical Physicist
MTF	Modulation Transfer Function
PACS	Picture Archiving and Communication System
PMMA	Polymethyl Meth Acrylate
PT	Positioning Tray
QC	Quality Control
Q/R	Query/Retrieve
RF	Radio Frequency
RIS	Radiology Information System
RT	Radiologic Technologist
SCU	Service Class User
SID	Source to Image Distance
SOP	Service-Object Pair
RT	Radiologic Technologist
USB	Universal Serial Bus
WEEE	Waste Electrical and Electronic Equipment
WB	Weight-bearing

## 22.3 Printing audit trail

To print out all dose alert and notification events, double tap the **AuditTrail.bat** file in the *C:\Planmed\config* folder.

The **DoseAlertReport.txt** file appears in the same folder listing the events.

The following is an example of the .txt file output.

id	event_time	event_date	event	username	study_id	limit_value	value	description
1	140824550	20170928	0	HRZW7J2	666 1		3.0	
2	141048703	20170928	1	HRZW7J2	666 1		3.0	

### NOTE

The number 0 in the event column indicates a dose notification event. The number 1 indicates a dose alert event.

## 23 Service

To guarantee user and patient safety and to ensure consistent image quality, the scanner 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 *Planmed Verity technical manual* for complete servicing information.

## 24 Cleaning and disinfection

The Planned Verity and its accessories including the patient position trays has been designed considering high hygienic requirements set for medical equipment. The surfaces are easy to keep clean and disinfect.

When necessary clean the surfaces with a soft, lint-free cloth damped in mild soap solution and water.

For disinfection the manufacturer recommends the following disinfection agents tested and found to be harmless to the surfaces:

- CaviWipes (Metrex Research, USA)
- Dax Extra (CCS HealthCare AB, Sweden)
- MinutenSpray Classic (Alpro, Germany)
- Minuten Wipes (Alpro, Germany)
- Optim Blue Wipes (SciCAN, Canada)
- Orbis (Plandent, Finland)

### NOTE

Observe the instructions for use of the cleaning and disinfecting agents exactly.

### NOTE

Do not use abrasive cleaning agents, mechanical cleaning methods or cleaning equipment.

### NOTE

Do not use any cleaning agents in aerosol or spray form directly on device surfaces as the moisture can enter into the system and damage the electronic components.

### NOTE

The cleaning solution must not flow or run.

### NOTE

To avoid damage or stains, any cleaning solution must be wiped immediately from the surfaces of the device.

### NOTE

Do not immerse the parts in the cleaning agent.

### CAUTION

If liquid enters the system, disconnect the electrical supply and schedule inspection by service personnel before the system is returned to use.

### CAUTION

Unclean and broken surfaces in the X-ray field have a negative effect on image quality.

### CAUTION

All patient contacting surfaces must be disinfected before each patient.

## 25 Transportation

### 25.1 Preparing device for transportation

#### CAUTION

The unit must be transported only on even surfaces. Minimum two persons are required to move the device.

#### CAUTION

Imaging is not allowed in transportation mode.

#### CAUTION

Exercise caution when transporting the device. Collision during transport may damage the detector.

1. Go to *Home* screen.
2. Tap the *Options* arrow on top of the window.



3. Tap **Transportation**.

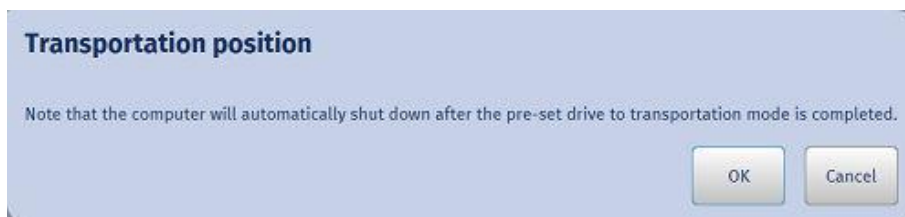


4. Tap the button circled in the image.



The gantry is automatically driven into transportation position (gantry positioned vertically in the lowest position) and the computer is shut down.

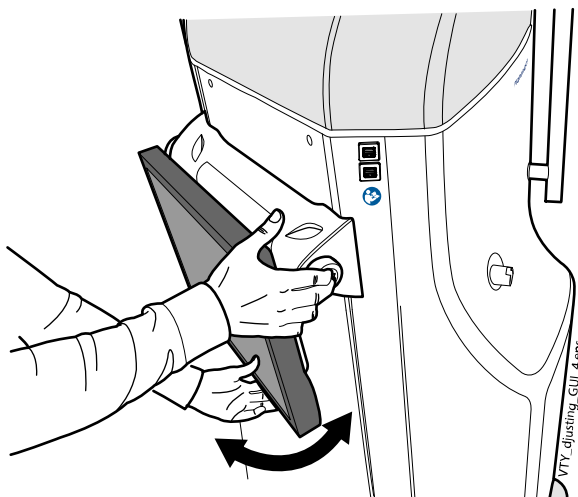
5. To proceed to transportation tap **OK**.



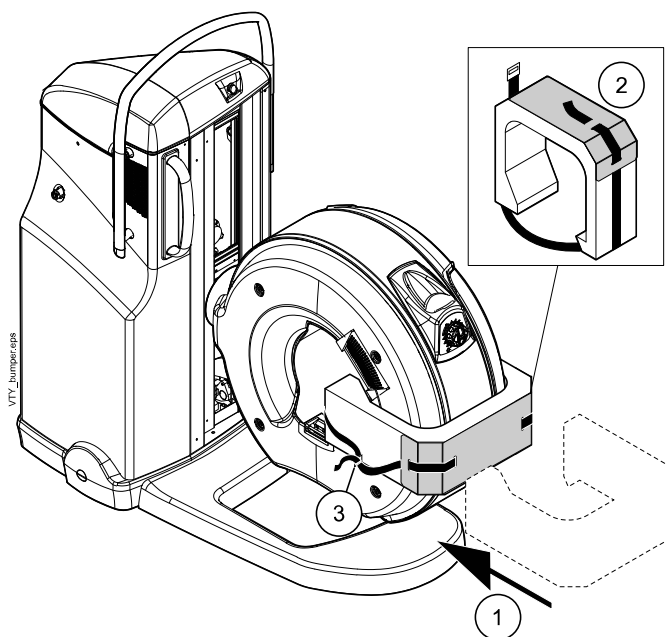
## NOTE

Turn off the device only after the computer has switched off.

6. Disconnect the device from the mains and hospital information system.
7. Reel up the cables and place them in the space reserved for them in the vertical column base. Close the lid.
8. Pushing the adjustment knob on the right side, bring the touch screen control panel down onto the vertical column surface.



- Attach the transportation bumper to the gantry (1), thread the belt through the bumper (2) and tighten the buckle (3).



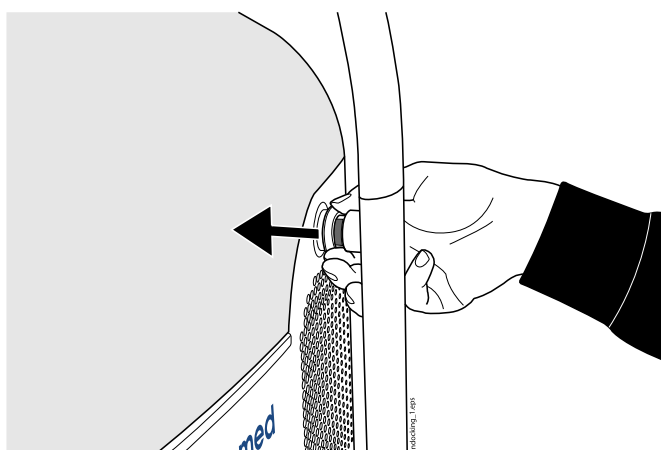
- After having transported the unit to the desired area remove the transportation bumper.

## 25.2 Raising device onto its wheels

- Release the multi-purpose handle by pushing the handle securing ring towards the vertical column with your fingers.

### NOTE

Make sure the touch screen control panel has been bent down and that there is enough space for the handle to move freely.





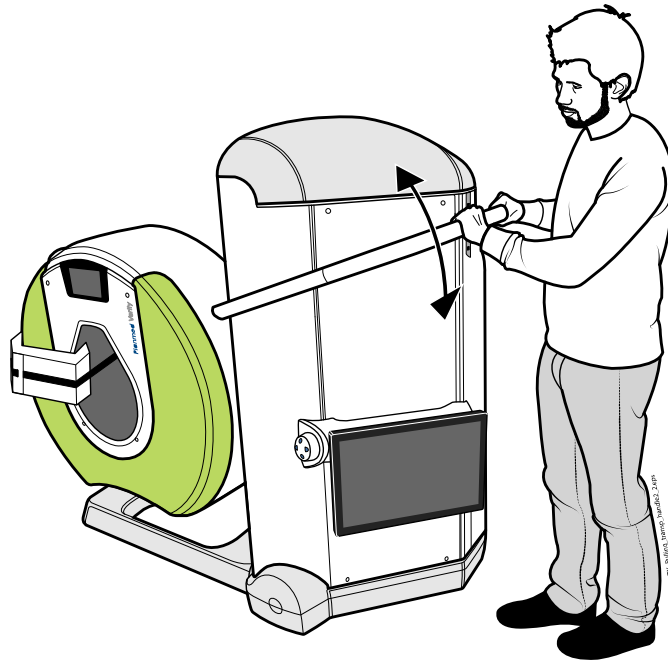
2. Pull the handle carefully down until horizontal. The vertical column raises on its wheels.

**NOTE**

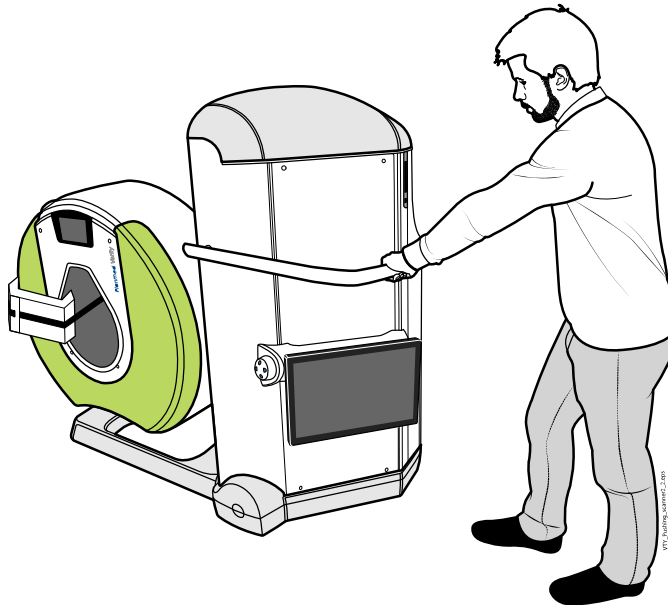
When the handle has been pulled down imaging is not allowed

**CAUTION**

When lowering the device down from the wheels be careful not to leave e.g. your toes or the cables under the vertical column.

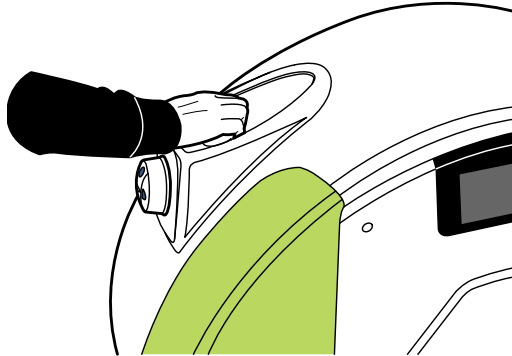


3. Push the device on its wheels to the location.



**NOTE**

Always ask another person to grab the device from the transportation handle at the other end of the device and steer it e.g. around corners. You can normally push it over thresholds max. 2 cm in height.



### 25.3 Returning device from transportation position to operating position

1. Make sure there is enough space to operate the device and to position the patient at the new site, allowing for the gantry movements from vertical all the way down to the horizontal position.
2. Slowly lift the multi-purpose handle upwards. At a certain point the handle releases and rises swiftly to the vertical position. Resist the movement with your hand.

**CAUTION**

Do not let go of the handle until it is vertical.

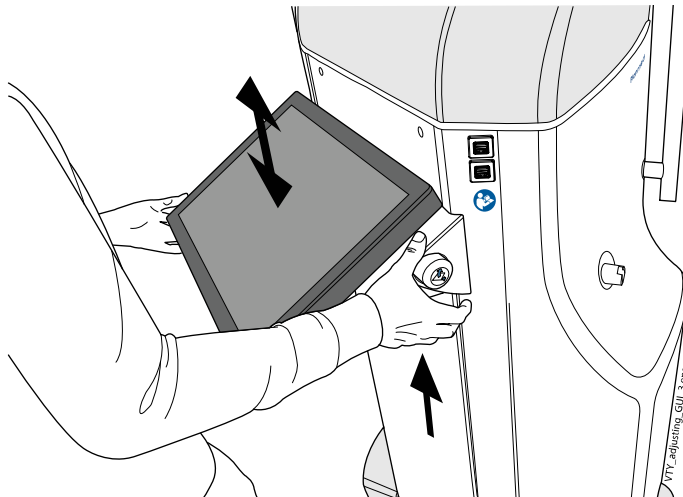
**CAUTION**

Lower the device down from its wheels before connecting it to mains voltage and/or the information system, and before switching it on.

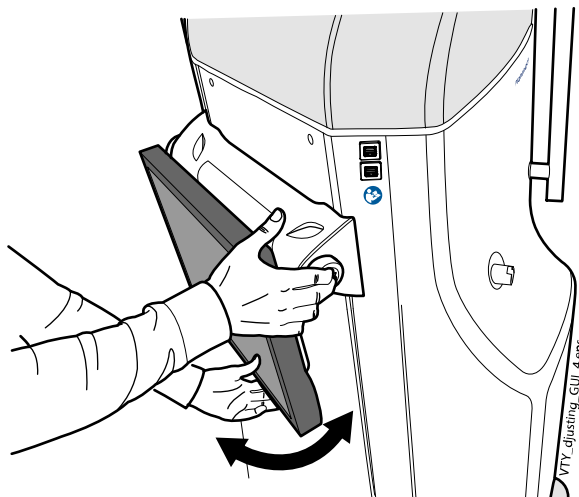
**CAUTION**

When lowering down the device from its wheels be careful not to leave your toes, the cables etc. under the vertical column.

3. Adjust the touch screen control panel to a suitable level by pushing up the wedged switch under the adjusting knob (see picture) with your right hand fingers.



4. Slide the touch screen control panel up or down using both hands while pushing up the switch.
5. Adjust the angle of the touch screen control panel by pushing down the adjusting knob with your right hand and turn the touch screen control panel to an angle convenient for you..



6. Connect the device to the mains and the hospital information system.
7. Connect the exposure switch cable to the device.
8. Carry out appropriate radiation protection measures.

### CAUTION

Always carry out appropriate radiation protection measures according to local requirements and use a proper shielding to protect yourself and the patient from radiation.

9. Switch the device on from the on/off switch.
10. Before using the system the Weekly / Monthly QC test (see section "Weekly / monthly QC test" on page 149 and the Geometry test (see section "Geometry test" on page 163 must be performed. The system is ready for imaging after passing the tests.

# 26 Disposal

In order to reduce the environmental load over the product's entire life cycle, manufacturer's products are designed to be as safe as possible to manufacture, use and dispose of.

Parts which can be recycled should always be taken to the appropriate processing centres, after hazardous waste has been removed. Disposal of obsolete device is the responsibility of the possessor.

All parts and components containing hazardous materials, such as oil and heavy metals, must be disposed of in accordance with local and national waste legislation and instructions issued by the environmental authorities. The risks involved and the necessary precautions must be taken into account when handling waste products. For more detailed information consult your local representative.

The X-ray tube contains beryllium in solid form. Inhaled Beryllium and its compounds are extremely poisonous and inhalation of beryllium containing dust or fumes can cause cancer. Avoid skin exposure!

The X-ray tube and its compounds must not be disposed of together with industrial or house hold waste. All waste material must be carefully transported and disposed in accordance with local and national regulations.

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

## Disposal

Part	Main materials for disposal	Recyclable material	Waste disposal site	Hazardous waste (separate collection)
<b>Frame and covers</b>				
<i>Metal</i>	Aluminum	X		
	Galvanized steel	X		
	Lead			X
<i>Plastic</i>	PUR, UP	X		
	Other plastics		X	
<i>Rubber</i>		X		
<i>Glass</i>			X	
<b>Motors</b>			(X)	
<b>Component boards</b>			(X)	
<b>Cables, transformers</b>	Copper	X		
	Steel	X		
	Transformer oil			X
	PVC			X
<b>X-ray tube</b>				X

**Disposal**

<b>Part</b>	<b>Main materials for disposal</b>	<b>Recyclable material</b>	<b>Waste disposal site</b>	<b>Hazardous waste (separate collection)</b>
<b>Packaging</b>	Wood	X		
	Cardboard	X		
	Paper	X		
	Polystyrene	X		
<b>Detector</b>	Return detector to original manufacturer.			
<b>Radiation shield</b>				X
<b>Other parts</b>			X	

X = action,

(X) = action in cases where processing is available.

## 27 Default exposure values

Adult protocols		Small			Medium			Large		
Anatomy	Protocol	kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]
Jaw	ULD	96	4	1,7	96	6,3	2,7	96	8	3,5
	standard	96	4	3,1	96	6,3	4,9	96	8	6,2
	high definition	96	4	3,9	96	6,3	6,1	96	8	7,7
Face	ULD	96	2	0,9	96	3,2	1,4	96	4	1,7
	standard	96	4	3,1	96	5	3,9	96	6,3	4,9
	high definition	96	4	3,9	96	6,3	6,1	96	8	7,7
Sinus	ULD	96	2	0,9	96	3,2	1,4	96	4	1,7
	standard	96	4	3,1	96	5	3,9	96	6,3	4,9
	high definition	96	4	3,9	96	6,3	6,1	96	8	7,7
Nose	ULD	96	2	0,9	96	3,2	1,4	96	4	1,7
	high definition	96	4	3,9	96	6,3	6,1	96	8	7,7
	standard	96	4	3,1	96	5	3,9	96	8	6,2
Ear	ULD	96	2	0,9	96	3,2	1,4	96	4	1,7
	high definition	96	6,3	6,1	96	8	7,7	96	12	11,6
Neck	ULD	96	2	0,9	96	3,2	1,4	96	4	1,7
	standard	96	6,3	4,9	96	8	6,2	96	12	9,3
	high definition	96	6,3	6,1	96	8	7,7	96	12	11,6
Elbow	ULD	90	5	1,7	92	5	1,9	96	6,3	2,7
	standard	90	5	3,0	92	5	3,3	96	6,3	4,9
	high definition	90	5	3,8	92	5	4,1	96	6,3	6,1

Adult protocols		Small			Medium			Large		
Anatomy	Protocol	kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]
Arm	ULD	88	5	1,6	90	5	1,7	90	6,3	2,1
	standard	88	5	2,8	90	5	3,0	90	6,3	3,8
	high definition	88	5	3,5	90	5	3,8	90	6,3	4,7
Wrist	ULD	88	5	1,6	90	5	1,7	90	6,3	2,1
	standard	88	5	2,8	90	5	3,0	90	6,3	3,8
	high definition	88	5	3,5	90	5	3,8	90	6,3	4,7
Hand	ULD	88	5	1,6	90	5	1,7	90	6,3	2,1
	standard	88	5	2,8	90	5	3,0	90	6,3	3,8
	high definition	88	5	3,5	90	5	3,8	90	6,3	4,7
Finger	ULD	88	3,2	1,0	90	3,2	1,1	90	5	1,7
	standard	88	4	2,2	90	4	2,4	90	5	3,0
	high definition	88	4	2,8	90	4	3,0	90	5	3,8
Knee	ULD	92	6,3	2,3	96	6,3	2,7	96	8	3,5
	standard	92	6,3	4,2	96	6,3	4,9	96	8	6,2
	high definition	92	6,3	5,2	96	6,3	6,1	96	8	7,7
Knee wb	ULD	92	6,3	2,3	96	6,3	2,7	96	8	3,5
	standard	92	6,3	4,2	96	6,3	4,9	96	8	6,2
	high definition	92	6,3	5,2	96	6,3	6,1	96	8	7,7
Leg	ULD	90	5	1,7	92	5	1,9	96	6,3	2,7
	standard	90	5	3,0	92	5	3,3	96	6,3	4,9
	high definition	90	5	3,8	92	5	4,1	96	6,3	6,1

Adult protocols		Small			Medium			Large		
Anatomy	Protocol	kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]
Leg wb	ULD	90	5	1,7	92	5	1,9	96	6,3	2,7
	standard	90	5	3,0	92	5	3,3	96	6,3	4,9
	high definition	90	5	3,8	92	5	4,1	96	6,3	6,1
Ankle	ULD	92	6,3	2,3	96	6,3	2,7	96	8	3,5
	standard	92	6,3	4,2	96	6,3	4,9	96	8	6,2
	high definition	92	6,3	5,2	96	6,3	6,1	96	8	7,7
Ankle wb	ULD	92	6,3	2,3	96	6,3	2,7	96	8	3,5
	standard	92	6,3	4,2	96	6,3	4,9	96	8	6,2
	high definition	92	6,3	5,2	96	6,3	6,1	96	8	7,7
Foot	ULD	92	5	1,9	96	5	2,2	96	6,3	2,7
	standard	92	6,3	4,2	96	6,3	4,9	96	8	6,2
	high definition	92	6,3	5,2	96	6,3	6,1	96	8	7,7
Foot wb	ULD	92	6,3	2,3	96	6,3	2,7	96	8	3,5
	standard	92	6,3	4,2	96	8	6,2	96	10	7,7
	high definition	92	6,3	5,2	96	8	7,7	96	10	9,6
Toe	ULD	88	5	1,6	90	5	1,7	90	6,3	2,1
	standard	88	6,3	3,5	90	6,3	3,8	90	8	4,8
	high definition	88	6,3	4,4	90	6,3	4,7	90	8	6,0
Toe wb	ULD	88	6,3	2,0	90	6,3	2,1	90	8	2,7
	standard	88	6,3	3,5	90	8	4,8	90	10	6,0
	high definition	88	6,3	4,4	90	8	6,0	90	10	7,5



Adult protocols		Small			Medium			Large		
Anatomy	Protocol	kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]	kV	mA	CTDIvol [mGy]
MaxScan	ULD	92	4	1,5	96	5	2,2	96	6,3	2,7
	standard	92	4	2,6	96	5	3,9	96	6,3	4,9
	high definition	92	5	4,1	96	6,3	6,1	96	8	7,7

## 28 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 mA value in order to optimize the patient dose. mA 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 mA 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 1000mGy 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.



### Enabling AEC

1. On the top toolbar tap the **Service** button.

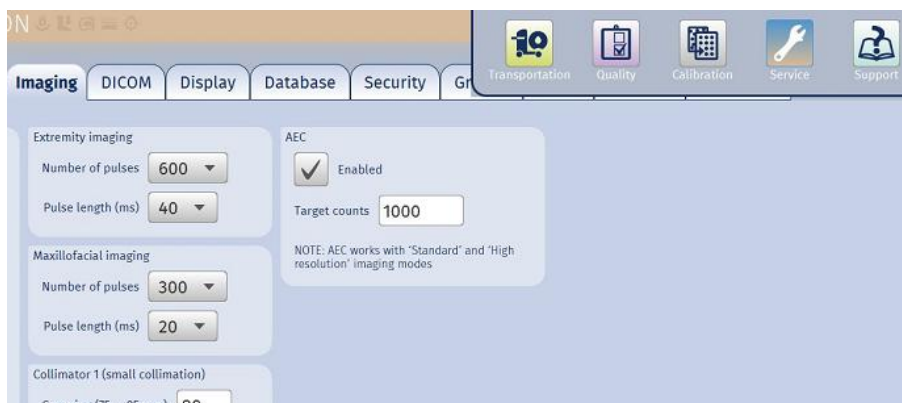


### NOTE

Access requires Service Mode permission.

2. Check the *Enabled* box in the AEC field.

Target count affects the sensitivity of the AEC adjustment as well as the desired dose and image quality level.



### AEC quality control

For detailed description of quality control procedures see section "AEC reproducibility test" on page 172.

## 28.1 Extremity scanner AEC principles

The AEC operation is based on a principle where preselected kV and mA 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 mA 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 96 kV and the mA range is 1 mA to 12 mA. The used mA 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 mA value and maximum correction is  $\pm 20\%$  compared to preselected initial value.

## 29 Technical specifications

<b>Generator</b>	Resonant-mode, DSP controlled, 80...160 kHz, complies with standard IEC 60601-2-7: 1998		
<b>X-ray tube</b>	D-067SB, P		
<b>Focal spot size</b>	0.6 x 0.6 mm (according to IEC 60336)		
<b>Focal spot to skin distance</b>	The focal spot to skin distance is limited by the plastic cover of the bore to a minimum distance FSD > 165 mm.		
<b>Total filtration</b>	0.5 mmCu + 3.9 mmAl		
<b>Inherent filtration</b>	1.0 mmAl		
<b>Anode voltage</b>	80 - 96 kV $\pm 5$ %		
<b>Anode current</b>	1 - 12 mA $\pm 10$ %		
<b>Linearity of radiation output</b>	< 0.1		
<b>Cooling period</b>	Automatically controlled		
<b>Exposure time</b>	Pulsed, effective 4.5 - 24 s, Scout 2 x 20 ms.		
<b>Focal spot to image receptor distance (SID)</b>	580 mm (22.83 in.), fixed		
<b>Flat panel pixel size</b>	127 mm		
<b>Flat panel active surface</b>			
<b>Extended field</b>			
<b>Large field</b>	190 x 239 mm (7.5 x 9.4 in.)		
<b>Small field (with 43% collimation)</b>	110 x 239 mm (4.3 x 9.4 in.)		
<b>Line voltage</b>	100 V~, 115 V~ / 50- 60 Hz,	200 - 240 V~ / 50/60 Hz	
<b>Line current</b>	8 - 17 A		
<b>Line harmonics</b>	cos better than 0.9		
<b>Max. permissible apparent impedance of supply mains</b>	0.5 W (100 VAC)		
<b>Maximum continuous heat dissipation</b>	< 600 W		
<b>Mode of operation</b>	Continuous operation with intermittent loading		
<b>Electrical classification</b>	Class I, type B		

FUSES	200-240 V~	100 V~, 115 V~	TYPE
2 user replaceable fuses	8 A FF	16 A FF /500 V	195100 ELU

<b>IP class</b>	20
<b>Weight</b>	355 kg (783 lbs)
<b>Colour</b>	White (RAL 9016)

## 29.1 Dosimetric information

### 29.1.1 Reference air kerma

#### Patient entrance reference point

The patient entrance reference point is located at 15 cm distance from the isocentre i.e. 32 cm from the gantry bottom.

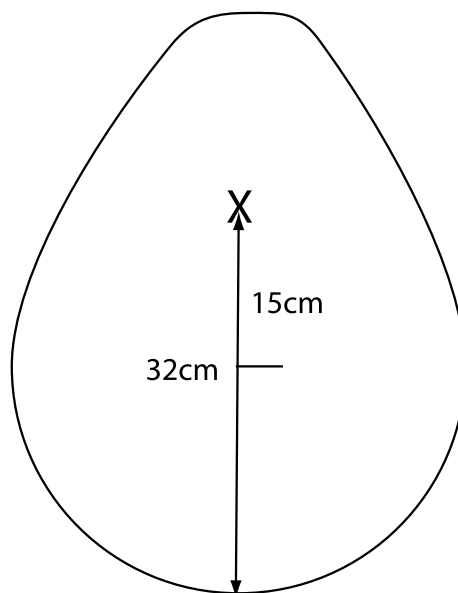
The highest available reference air kerma rate per frame is available with tube voltage of 96 kV, tube current of 12 mA and pulse length of 40 ms.

The following table defines skin dose levels at patient entrance reference point as a function of selectable exposure value for each factory protocol. The values are measured using dosimeter with solid state detector on patient entrance reference point.

The table is based on a set of measurements. Measurements are made using Quality control phantom as a test object representing an average patient. The measurements have been made in Service/Beam check mode i.e. when the tube head does not move during exposure sequence.

If you are using modified protocols you can scale air kerma value by equation  $\text{air kerma} = (\text{number of projection} * \text{pulse length in milliseconds}) / 8000 * \text{value in topmost table}$ .

Deviation of values is less than 50%.



#### Skin dose levels at patient entrance reference point as a function of selectable exposure value

Air kerma @ Standard [mGy]												
kV/m A	1	1.3	1.6	2	2.5	3.2	4	5	6.3	8	10	12
80	1.2	1.6	1.9	2.4	2.7	3.1	3.7	4.7	6.1	7.3	9.3	11.7
84	1.5	1.9	2.3	2.9	3.3	3.8	4.7	6.1	7.5	9.1	11.5	14.4
88	1.8	2.3	2.9	3.6	4.0	4.6	5.5	6.9	9.1	10.9	13.9	17.5
90	1.9	2.5	3.1	3.9	4.3	5.0	6.0	7.6	10.0	12.0	15.2	19.1
92	2.1	2.7	3.3	4.1	4.7	5.5	6.5	8.3	10.8	13.1	16.5	20.7

**Skin dose levels at patient entrance reference point as a function of selectable exposure value**

96	2.4	3.1	3.8	4.8	5.5	6.5	7.7	9.7	12.7	15.3	19.5	24.3
<b>Air kerma @ Ultra Low Dose [mGy]</b>												
<b>kV/m A</b>	1	1.3	1.6	2	2.5	3.2	4	5	6.3	8	10	12
80	0.7	0.9	1.1	1.4	1.5	1.7	2.1	2.6	3.4	4.1	5.3	6.6
84	0.8	1.1	1.3	1.7	1.8	2.1	2.6	3.2	4.2	5.1	6.5	8.1
88	1.0	1.3	1.6	2.0	2.3	2.6	3.1	3.9	5.1	6.2	7.8	9.8
90	1.1	1.4	1.7	2.2	2.4	2.8	3.4	4.3	5.6	6.8	8.6	10.7
92	1.2	1.5	1.9	2.3	2.6	3.1	3.7	4.7	6.1	7.4	9.3	11.6
96	1.4	1.8	2.2	2.7	3.1	3.6	4.4	5.5	7.2	8.6	11.0	13.7
<b>Air kerma @ High Definition [mGy]</b>												
<b>kV/m A</b>	1	1.3	1.6	2	2.5	3.2	4	5	6.3	8	10	12
80	1.5	2.0	2.4	3.0	3.3	3.9	4.7	5.8	7.6	9.2	11.7	14.7
84	1.8	2.4	2.9	3.7	4.1	4.7	5.7	7.2	9.4	11.3	14.3	18.0
88	2.3	2.9	3.6	4.5	5.0	5.8	6.8	8.7	11.4	13.7	17.3	21.8
90	2.4	3.1	3.9	4.8	5.4	6.3	7.5	9.5	12.5	15.0	19.0	23.8
92	2.6	3.4	4.1	5.2	5.8	6.8	8.2	10.3	13.5	16.3	20.7	25.8
96	3.0	3.9	4.8	6.0	6.8	8.1	9.7	12.2	15.9	19.2	24.3	30.3

### 29.1.2 Dose area product

The Dose Area Product (DAP) values shown on the user interface are based on the conversion factors presented in the table below:

- The DAP values were obtained using a KermaX plus. IBA Dosimetry DAP-meter.
- DAP values can be calculated from the following equation:  $\text{DAP [mGy}\cdot\text{cm}^2] = \text{tube current [mA]} * \text{number of projection} * \text{pulse length [ms]} * \text{conversion factor [mGy}\cdot\text{cm}^2/\text{mAs]} / 1000$
- Deviation of values is less than 35%.

#### Dose Area Product (DAP) conversion factors

kV	DAP/mAs [mGycm <sup>2</sup> ]	
	Large field	Small field
96	26.4	14.0
92	22.9	12.2
90	21.3	11.3
88	19.7	10.5
84	16.8	8.9
80	14.0	7.4

### 29.1.3 CTDIvol

For detailed information refer to technical manual chapter "CTDI VALUES".

## 29.2 Environmental requirements

Operating temperature	+10 °C to +35 °C
Transportation & storage temperature	±0 °C to +60 °C
Humidity	10 % - 90 %
Ambient pressure	700 - 1060 hPa
Cooling	Sufficient cooling / ventilation must be made available and operating to guarantee above ambient temperature.

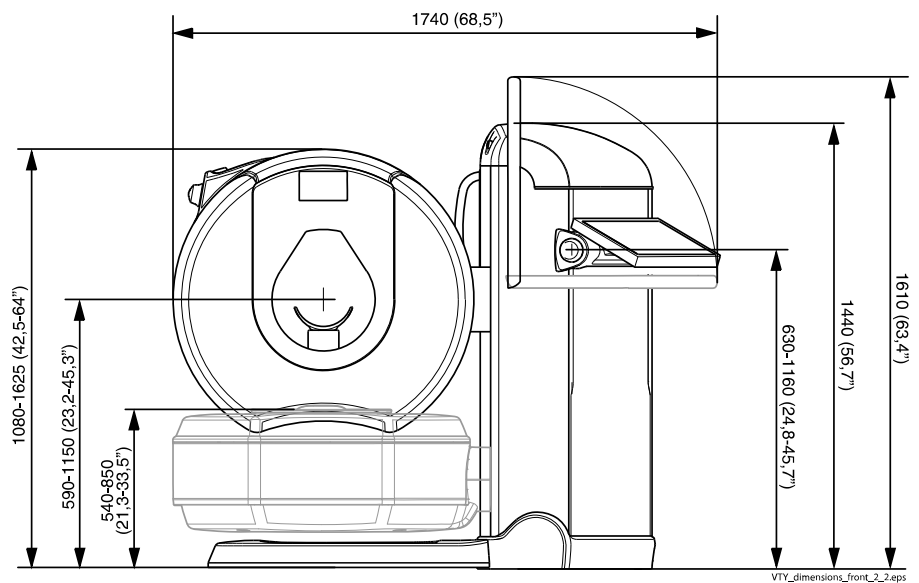
## 29.3 Original manufacturer

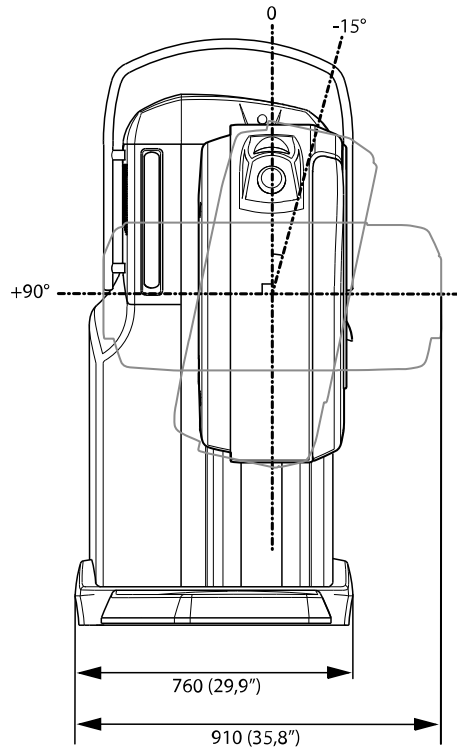
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Tel. +358 20 7795 300, fax +358 20 7795 664,

Web site: <http://www.planmed.com>

## 29.4 Dimensions





### 29.5 Device label

X-RAY UNIT	
TYPE: PLANMED VERITY	REF: <b>30010465</b>
SN: XXXXXXX	XX/20XX
<input type="checkbox"/> 100VAC/115VAC 50/60Hz <input type="checkbox"/> 200-240VAC 50/60Hz	
STANDBY 500VA/2kW 45s, MINIMUM OVERCURRENT RELEASE 16 AT	
MAXIMUM APPARENT RESISTANCE OF SUPPLY MAINS: 0.5 Ohm	
LIFT MOTOR OPERATION: Intermittent operation, ED 6%, 25 sec "ON", 400 sec "OFF"	TILT MOTOR OPERATION: Intermittent operation, ED 9%, 12 sec "ON", 120 sec "OFF"
96kV maximum	TOTAL FILTRATION 3.9 mmAl + 0.5 mmCu
MANUFACTURER: PLANMED OY SORVAAJANKATU 7, 00880 HELSINKI, FINLAND	Total weight: 355 kg
Complies with DHHS radiation performance standard 21 CFR subchapter J	

FED00730

NESP01006

CLASS 1 LASER PRODUCT  
APPAREIL À LASER DE CLASSE 1

EN/IEC 60825-1:2007



# 30 QC test & calibration forms

## Visual checklist

Visual checklist												Planned Verity																				
Medical equipment evaluation: RT or MP (or according to local regulations)				Frequency: Daily		Date:		Facility:		Site:		Room:		Unit:																		
<p><b>Procedure:</b></p> <ol style="list-style-type: none"> <li>1 Check that the positioning trays are clean and intact.</li> <li>2 Check that the monitor is clean.</li> <li>3 Make sure there are no errors or cautions in the software.</li> <li>4 Check that the positioning lasers function properly.</li> <li>5 Drive the gantry and the positioning trays in all directions as you would for patient imaging to make sure that they move freely.</li> </ol> <p>Some of the items on the visual checklist are operator convenience features. Many of the items, however, are essential for patient safety and high-quality diagnostic images. It may be necessary to add additional items to the list that are specific to no particular equipment or procedure. These should be included on the checklist and in each evaluation</p>																																
<p><b>Performance criteria:</b></p> <p>Each of the items listed in the Visual Checklist should pass the visual check and receive a check mark.</p>																																
Date	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Trays are clean and intact																																
Monitor is clean																																
No errors/cautions in software																																
Positioning lasers function properly																																
Gantry and trays move freely																																
<p><b>Corrective action:</b></p> <p>Items not passing the visual check should be replaced or corrected immediately. Items missing from the room should be replaced immediately. Malfunctioning equipment should be reported to the X-ray service engineer for repair or replacement as soon as possible.</p>																																

Weekly QC

Weekly QC										Planned Verity																	
Date:					Facility:					Site:					Room:					Unit:							
<b>Objective</b> To ensure HU value accuracy and uniformity.  To define the image noise level and to visually check that there are no artefacts in the images.					<b>Test equipment</b> Image quality phantom (20008121), Polymethyl methacrylate (PMMA) rods (5)					<b>Medical Equipment Evaluation</b> RT or MP (or according to local regulations)					<b>Performance frequency</b> Weekly					<b>Exposure values:</b> 90 kV, 9 mA							
<b>Procedure:</b> <ol style="list-style-type: none"> <li>1 Insert the PMMA rods (5) into the phantom.</li> <li>2 Attach the phantom into the tray holder in the gantry bore.</li> <li>3 Select the Start QC test button. The device automatically drives the phantom to correct height and performs the necessary measurements.</li> <li>4 Check that the ROI areas are correctly targeted (between the PMMA inserts at the edge of the phantom and in the middle of the middle insert so that no space is left in the ROI area between the insert and phantom. The software automatically performs the measurements.</li> <li>5 Visually check the test image to detect visible artefacts e.g. ring artefacts and tick the corresponding box (No / Yes).</li> <li>6 Check that the squares are correctly placed. If necessary move the squares manually by dragging them using your finger.</li> <li>7 Software automatically analyses the average HU value and image noise in the ROI areas. The analysis is repeated in three axial slices selected automatically from the front, middle and back of the phantom.</li> <li>8 When the test is completed the test result shows at the bottom of the window.</li> </ol>																											
<b>Performance criteria:</b> HU Accuracy: PMMA > -65 and < 135, HU Uniformity: deviation < 50, Noise: standard deviation < 100.0, Artefacts: No visible artefacts																											
Week		01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Week		27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52
Remarks: Initials = Passed																											
<b>Corrective action:</b> Perform Flat field and HU calibrations and repeat the test. If the test still fails contact your local representative.																											

## HU accuracy

HU accuracy test		Planned Verity		
Date:	Facility:	Site:	Room:	Unit:
<b>Objective</b> To ensure correct HU values by using the test phantom containing reference materials (PMMA, Aluminum (Al), air).	<b>Test equipment</b> Image quality phantom (20008121), Aluminum rod (1), PMMA rods (4)	<b>Medical Equipment Evaluation</b> RT or MP (or according to local regulations)	<b>Performance frequency</b> Annually	<b>Exposure values</b> 90 kV, 9 mA
<b>Procedure:</b>				
<ol style="list-style-type: none"> <li>1 From the Quality section select HU Accuracy.</li> <li>2 Insert the Aluminum rod in the middle insert of the phantom.</li> <li>3 Insert the acrylic rods in the other four inserts of the phantom.</li> <li>4 Attach the phantom into the tray holder in the gantry bore.</li> <li>5 Select Start QC test. The device automatically drives the phantom to correct height.</li> <li>6 The software automatically selects the correct exposure values: 90 kV, 9 mA.</li> <li>7 When the exposure is taken, radiation will be generated. Protect yourself from radiation.</li> <li>8 Press the exposure button. The software defines the Al insert, air (space outside the phantom) and the average HU value of PMMA.</li> <li>9 Check that the HU values are inside the limits of the reference value and adjust if necessary.</li> </ol>				
<b>Performance criteria:</b>				
HU value for Air > -1100 and < -900				
HU value for PMMA > -65 and < 135				
HU value for Aluminum > 1800 and < 2000				
PASS				
FAIL				
<b>Corrective action:</b>				
Perform Flat field and HU calibrations and repeat the test. If the test still fails contact your local representative.				

Modulation transfer function

<b>Modulation transfer function (MTF) test</b>					<b>Planned Verity</b>	
<b>Date:</b>	<b>Facility:</b>	<b>Site:</b>	<b>Room:</b>	<b>Unit:</b>		
<b>Objective</b> To define high contrast differentiation capacity of the device.	<b>Test equipment</b> MTF phantom (20008120)	<b>Medical Equipment Evaluation</b> RT or MP (or according to local regulations)	<b>Performance frequency</b> Annually	<b>Exposure values</b> 96 kV, 4 mA		
<b>Procedure:</b>						
<ol style="list-style-type: none"> <li>1 From the Quality control section select MTF test.</li> <li>2 Place the image quality phantom into the tray holder in the gantry bore.</li> <li>3 Select the Start QC test button.</li> <li>4 The device automatically drives the phantom into correct height.</li> <li>5 The software automatically selects the correct exposure values.</li> <li>6 Press the exposure button.</li> <li>7 The software automatically calculates the modulation transfer function value.</li> </ol>						
<b>Performance criteria:</b>						
MTF 10 > 1.25 lp/mm						
PASS						
FAIL						
<b>Corrective action:</b>						
Perform Flat Field and Geometry calibration.						

## Geometry

Geometry test		Planned Verity		
Date:	Facility:	Site:	Room:	Unit:
<b>Objective</b> To check that the geometry calibration is successfully completed.	<b>Test equipment</b> Image quality phantom (20008121)	<b>Medical Equipment Evaluation</b> RT or MP (or according to local regulations)	<b>Performance frequency</b> Annual maintenance	<b>Exposure values</b> 90 kV, 9 mA
<b>Procedure:</b>				
<ol style="list-style-type: none"> <li>1 From the Quality section select Geometry tab.</li> <li>2 Place the image quality phantom into the gantry bore.</li> <li>3 Select Start QC test. The device automatically drives the phantom to correct height.</li> <li>4 In the following window select OK.</li> <li>5 The software automatically selects the correct exposure values: 90 kV, 9 mAs.</li> <li>6 When the exposure is taken, radiation will be generated.</li> <li>7 Protect yourself from radiation. Press the exposure button.</li> <li>8 After the exposure has been taken the image reconstruction takes between 30 to 120 seconds.</li> <li>9 The image is taken from three different areas: slice 1, slice 2 and slice 3.</li> <li>10 Check that the circles are even (not distorted) and if so select Yes next to Slice 1, Slice 2 and Slice 3.</li> <li>11 Once an option (Yes or No) has been selected it can no longer be modified.</li> <li>12 When the test is completed the test report can be opened by touching the Open report button.</li> </ol>				
<b>Performance criteria:</b>				
The circles and their edges show as even in the image.				
PASS				
FAIL				
<b>Corrective action:</b>				
Perform geometry calibration.				

Slice thickness

Planned Verity			
Date:	Facility:	Site:	Room:
<b>Objective</b> To measure the actual slice thickness produced by the device. This is performed by measuring how many slices fit in the Aluminum area of the phantom rod. With 0,4 mm resolution the number of slices is 100.	<b>Test equipment</b> Image quality phantom (20008121), Slice thickness rod (1), PMMA rods (4)	<b>Medical Equipment Evaluation</b> RT or MP (or according to local regulations)	<b>Performance frequency</b> Annual maintenance
		<b>Unit:</b>	<b>Exposure values</b> 90 kV, 9 mA
<p><b>Procedure:</b></p> <ol style="list-style-type: none"> <li>1 From the Quality section select Slice Thickness tab.</li> <li>2 Place the inserts in the Image quality phantom. Make sure that the notch of the Aluminum rod is on top.</li> <li>3 Attach the phantom into the tray holder in the gantry bore.</li> <li>4 Select <b>Start QC test</b>.</li> <li>5 When the message <i>Ready for exposure</i> appears and the green indicator light on the exposure button and on the touch screen stay on continuously, take the exposure.</li> <li>6 Verify that the selected exposure values are: 90 kV, 9 mAs.</li> <li>7 Protect yourself from radiation. When the exposure is taken, radiation will be emitted.</li> <li>8 Press the exposure button.</li> <li>9 When the test is completed the message <i>Test completed</i> is shown.</li> <li>10 To open the test report touch the Open report button.</li> </ol>			
<p><b>Performance criteria:</b> The calculated slice thickness is within +/- 5% of the indicated slice thickness.</p>			
<b>PASS</b>			
<b>FAIL</b>			
<p><b>Corrective action:</b> Perform geometry calibration.</p>			

AEC reproducibility

Planned Verity					
AEC Reproducibility test		Facility:	Site:	Room:	Unit:
<b>Date:</b>		<b>Test equipment</b> Image quality phantom (20008121), PMMA rods (5)	<b>Medical Equipment Evaluation</b> RT or MP (or according to local regulations)	<b>Performance frequency</b> Annual maintenance	<b>Exposure values</b> 90 kV, 5 mA (automatically selected)
<b>Objective</b>	To verify the reproducibility of the AEC with quality control phantom.				
<b>Procedure:</b>	<ol style="list-style-type: none"> <li>1 From the Quality section select <i>AEC Reproducibility</i> tab.</li> <li>2 Place the inserts in the Image quality phantom.</li> <li>3 Attach the phantom into the tray holder in the gantry bore.</li> <li>4 Select <b>Start QC test</b>.</li> <li>5 When the message <i>Ready for exposure</i> appears and the green indicator light on the exposure button and on the touch screen stay on continuously, take the exposure.</li> <li>6 Verify that the selected exposure values are: 90 kV, 5 mA.</li> <li>7 Protect yourself from radiation. When the exposure is taken, radiation will be emitted.</li> <li>8 Press the exposure button.</li> <li>9 When the test is completed the message <i>Test completed</i> is shown.</li> <li>10 To open the test report touch the <b>Open report</b> button.</li> </ol>				
<b>Performance criteria:</b>	< 20%				
<b>PASS</b>					
<b>FAIL</b>					
<b>Corrective action:</b>	Perform Flat Field calibration.				

Flatfield calibration

<b>Planned Verity</b>						
<b>Flat field calibration</b>		<b>Date:</b>	<b>Facility:</b>	<b>Site:</b>	<b>Room:</b>	<b>Unit:</b>
<b>Objective</b> To ensure uniform image quality in the entire exposure area. To identify and fix potential dead pixels.	<b>Test equipment</b> None	<b>Medical Equipment Evaluation</b> RT or MP (Europe) MP (in the USA)	<b>Performance frequency</b> During annual maintenance or when needed.	<b>Exposure values</b> Can be configured in Service mode.		
<p><b>Procedure:</b>                  Select Flat Field Calibration tab.                  Remove possible positioning trays or phantoms from the gantry bore.                  The system will select the exposure values automatically.                  Select the Start Calibration button.                  Take an exposure.                  The test takes approximately 1 minute.                  When completed the results appear in the screen.                  Make sure that all values are inside the limits. Note the results.</p>						
<p><b>Performance criteria:</b>                  Defective single pixels &lt;150                  Dead rows and columns &lt;8                  Correctable defect clusters &lt;90                  Uncorrectable defect clusters 0</p>						
<b>PASS</b>						
<b>FAIL</b>						
<p><b>Corrective action:</b>                  Check that the gantry bore is empty. Check the exposure values and take a new exposure. If the problem persists contact your local representative.</p>						



## Geometry calibration

Planned Verity				
Geometry calibration		Site:	Room:	Unit:
<b>Date:</b>	<b>Facility:</b>	<b>Medical Equipment Evaluation</b> RT (in Europe) MP (in the USA) The user will perform the test only in case the image quality tests fail.	<b>Performance frequency</b> During annual maintenance or when needed.	<b>Exposure values</b> Can be configured in Service mode. The default values are 92 kV, 8 mA.
<b>Objective</b> To calibrate the imaging geometry of the device.	<b>Test equipment</b> Geometry calibration phantom (20008119)			
<b>Procedure:</b> The calibration will take approximately 5 minutes.  Attach the Image quality phantom to the tray holder in the gantry bore. Handle the phantom with care. From the opening window select OK. Select Start Geometry Calibration button. The device automatically drives to correct position. Using the lasers check that the phantom is in the middle of the imaging area. Take an exposure. Calibration starts and the message Geometry calibration in progress appears. When the calibration is successfully completed the message Geometry calibration OK appears.				
<b>Performance criteria:</b> None				
PASS				
FAIL				
<b>Corrective action:</b> Check that you are using the correct phantom and place it in the middle of the imaging field. Check that the exposure values are correct. Perform the test again. If the test fails contact your service technician.				

HU calibration

Planned Verity			
<b>HU calibration</b>		<b>Room:</b>	<b>Unit:</b>
<b>Date:</b>	<b>Facility:</b>	<b>Site:</b>	<b>Performance frequency</b> Annually or as needed.
<b>Objective</b> To ensure the image brightness values comply with standardized HU-scale.	<b>Test equipment</b> Image quality phantom (20008121), Aluminum rod, PMMA rods (4)	<b>Medical Equipment Evaluation</b> RT or MP	<b>Exposure values</b> 80 kV, 7 mA
<p><b>Procedure:</b> The calibration takes approximately 15 minutes.</p> <ol style="list-style-type: none"> <li>1 Insert the Aluminum rod in the middle insert of the phantom. Insert the acrylic rods in the other four inserts of the phantom.</li> <li>2 Attach the phantom into the tray holder in the gantry bore.</li> <li>3 The system will select exposure values automatically.</li> <li>4 Select Start HU calibration. The unit automatically drives to correct position.</li> <li>5 Take an exposure. The device performs automatic reconstruction and presents an image of the phantom.</li> <li>6 Aluminum, acrylic and air parts in the phantom have been automatically calculated: Check that the squares are in the right places and select Calibrate.</li> <li>7 In the opening window select Accept. The device automatically modifies the exposure values and drives to the correct position for a new exposure.</li> <li>8 Take an exposure. Repeat the above procedure starting from step 6 for each kV value.</li> <li>9 When calibration is successfully completed the message HU calibration OK appears.</li> </ol>			
<b>Performance criteria:</b>			
None			
PASS			
FAIL			
<b>Corrective action:</b>			
Make sure the test was performed using the right phantom and the right phantom rods. When performing another calibration sequence make sure the squares are in right places, one in the middle, second anywhere on the phantom and the third one outside the phantom but in the exposure area.			

## Preheat calibration

Preheat calibration				Planned Verity	
Date:	Facility:	Site:	Room:	Unit:	Exposure values
<b>Objective</b> To ensure the image brightness values comply with standardized HU-scale.	<b>Test equipment</b> None	<b>Medical Equipment Evaluation</b> RT or MP	<b>Performance frequency</b> Annually or as needed.		
<p><b>Procedure:</b> Tap Start preheat calibration. The exposure can be taken when the green indicator lights come on. When the exposure is taken, radiation will be generated. Protect yourself from radiation. Press the exposure button to take an exposure. When calibration is successfully completed the message Preheat calibration OK appears.</p>					
<p><b>Performance criteria:</b> At minimum 10 values are required to pass calibration. If more than 10 but less than 15 values are obtained calibration can be re-performed to increase accuracy.</p>					
PASS					
FAIL					
<p><b>Corrective action:</b> If the calibration fails repeat the calibration a few times. If the calibration continues to fail contact your service technician.</p>					





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