ARCOMA

Operation Manual

ARCOMA PRECISION i5

CE 0413

Doc.No.: 1000-095-051-EN Rev. 1.1

Manufacturer:
ARCOMA AB
Annavägen 1, 352 46 Växjö, Sweden
Printed in Sweden

ARCOMA PRECISION i5

INTENDED USE

The System is a stationary X-ray system intended for obtaining radiographic images of various portions of the human body in a clinical environment.
The System is not intended for mammography.

CAUTION: US Federal Law restricts this device to sale by or on order of a physician.

Revision

Revision history	Update	Chapter/ Pages	Rev	Date
New Release			1.1	2020-06

Revision

Contents

Contents

Contents

Contents

1 Introduction

1.1 Document information

- It is important to keep this document for the life of the equipment, and pass the document on to any subsequent holder or user of the equipment.
- The original version of this manual is written in English.
- Training is provided by or via Arcoma. Training material consists of the Operation manual and the Installation and service manual.

1.1.1 System documentation

The following documentation is available for the system:

- Installation and service manual
- Operation manual
- Planning guide

1.1.2 Stylistic conventions

All warning label texts are shown in *italic* style in this manual.

All references are shown in *italic* style in this manual.

1.1.3 Document producer

This document has been produced by:

Arcoma AB
Annavägen 1
S–352 46 VÄXJÖ,
Sweden

www.arcoma.se

1.1.4 Copyright © 2020 Arcoma Corporation all rights reserved

1.1.5 Text emphasis

WARNING!

All texts labelled with "WARNING" call attention to potential risk to health or life.

CAUTION!

All texts labelled with "CAUTION" contain information about dangerous situations and measures to avoid risk.

Note!

All texts labelled with “NOTE” contain additional information regarding the work step, and is provided for a better understanding or as a warning about unnecessary and avoidable difficulties.

1.2 Identification Labels

The figure shows the location of the identification labels on the equipment.

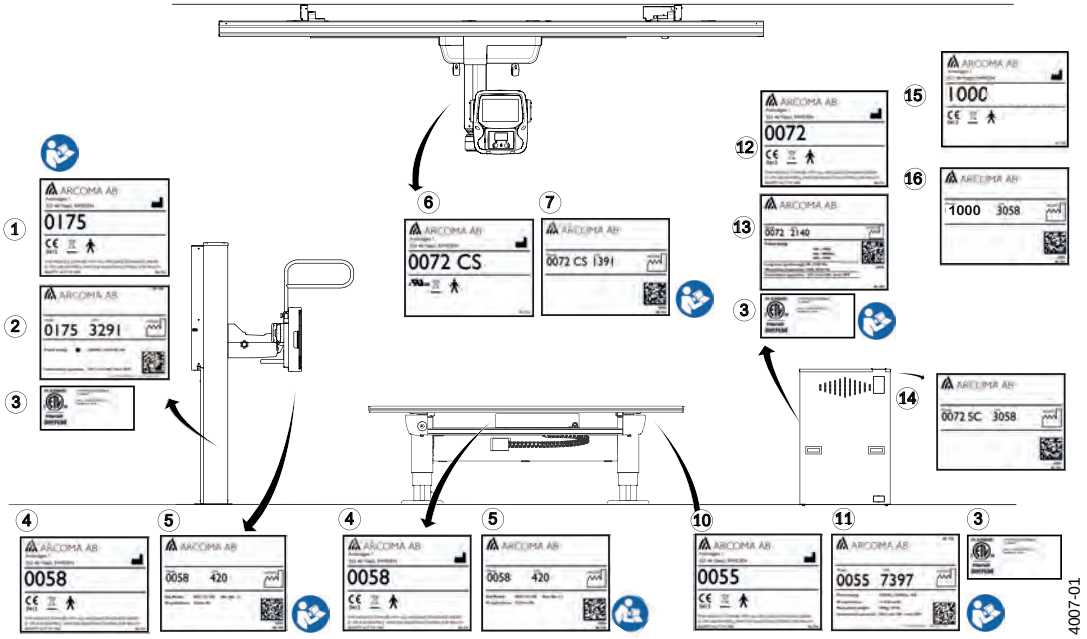
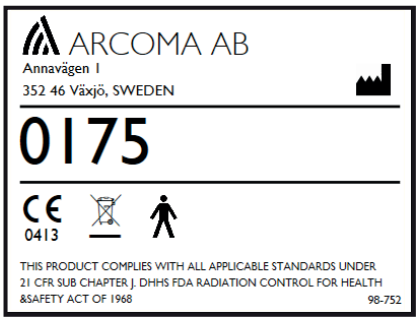
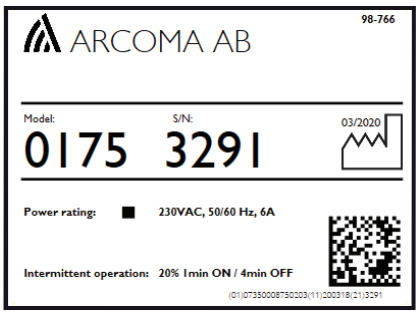


Fig. 1-1

1

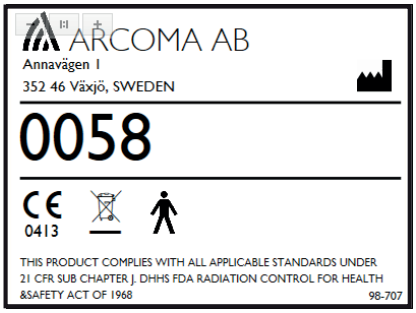


2

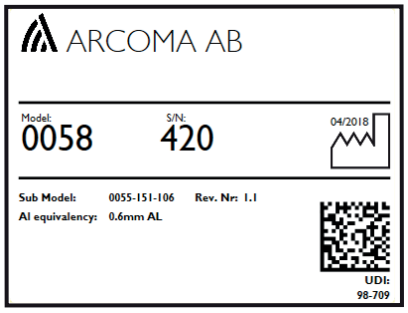


3

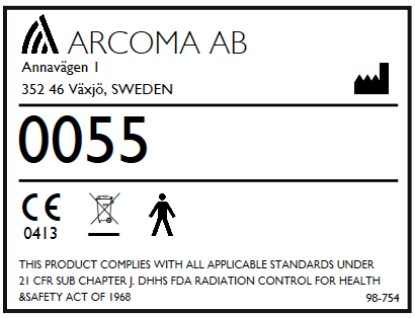
4



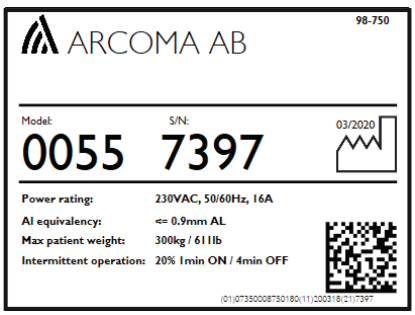
5



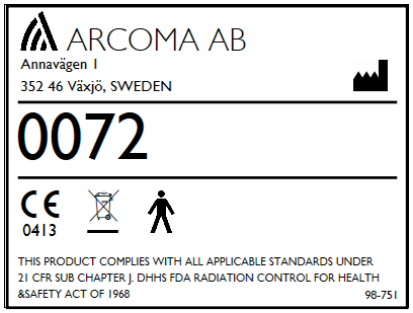
10



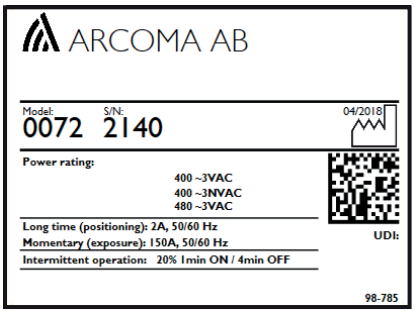
11



12

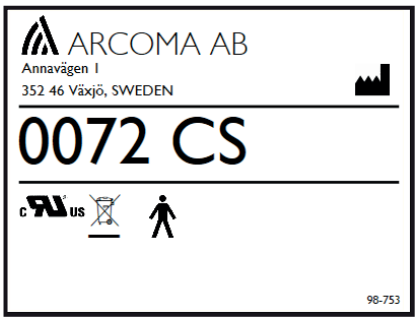


13

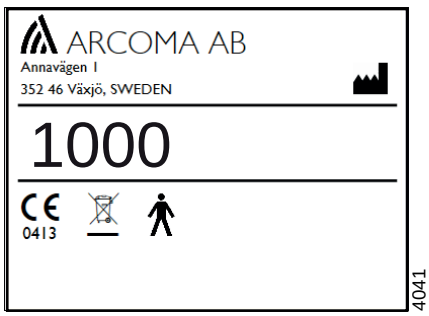


14

6


ARCOMA AB
Annavägen 1
352 46 Växjö, SWEDEN
0072 CS
98-753

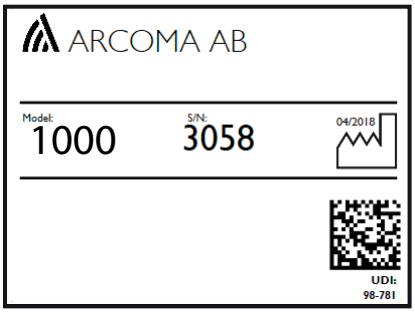
15


ARCOMA AB
Annavägen 1
352 46 Växjö, SWEDEN
1000
CE
0413
4041

7


ARCOMA AB
Model:
0072 CS
S/N:
1391
04/2018
UDI:
98-782

16


ARCOMA AB
Model:
1000
S/N:
3058
04/2018
UDI:
98-781

1.3 System Description

1.3.1 General

Arcoma Precision includes:

- Overhead tube crane (OTC) with x-ray tube and collimator
- Table
- Wall stand
- System cabinet with a high voltage generator
- Image Acquisition system
- Flat panel detectors

1.3.2 Intended Use

The system is a stationary X-ray system intended for obtaining radiographic images of various portions of the human body in a clinical environment.

The system is not intended for mammography.

1.3.3 Configuration

The basic system consists of system Cabinet (including generator), Image acquisition system, Flat panel detectors, and Overhead tube crane. The basic system can be equipped with one of the following three configurations:

- Table and Wall Stand
- Wall Stand
- Table

1.3.4 System Overview

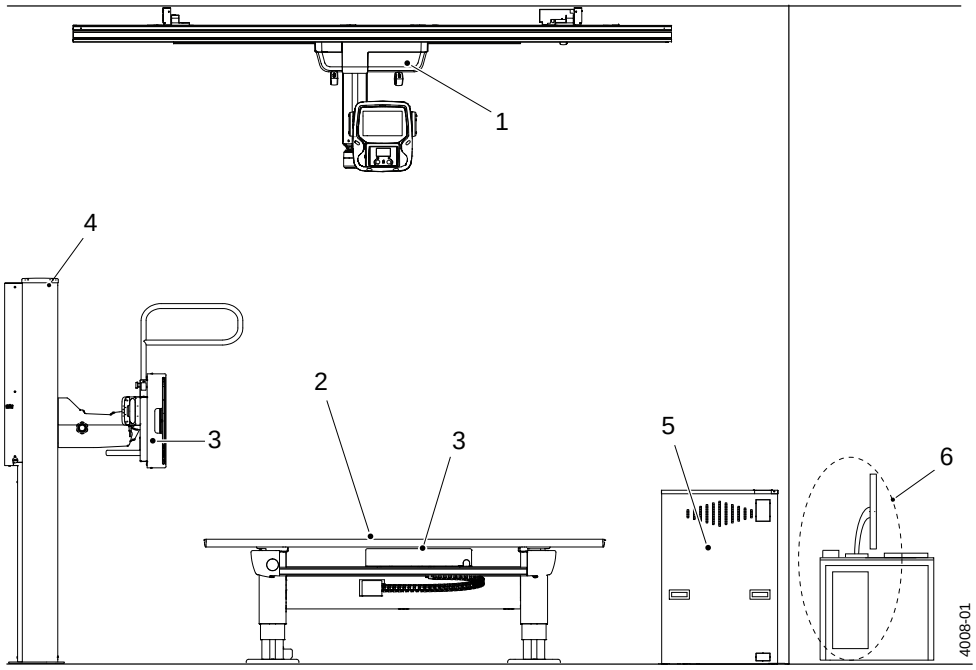


Fig. 1-2 System Overview

1. Overhead tube crane, OTC
2. Table
3. Detector holder
4. Wall stand
5. System cabinet
6. Computer and monitor

1.3.5 Overhead Tube Crane, overview

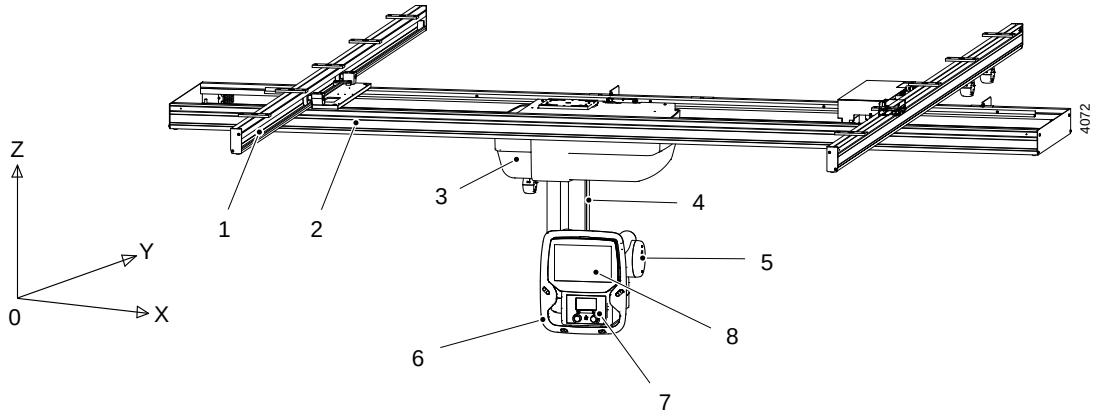


Fig. 1-3 Overhead Tube Crane, OTC

1. Ceiling rail (Y)
2. Traverse rail (X)
3. Ceiling wagon
4. Column (Z)
5. X-ray tube
6. Manoeuvre handle
7. Collimator
8. Display

1.3.6 Table overview

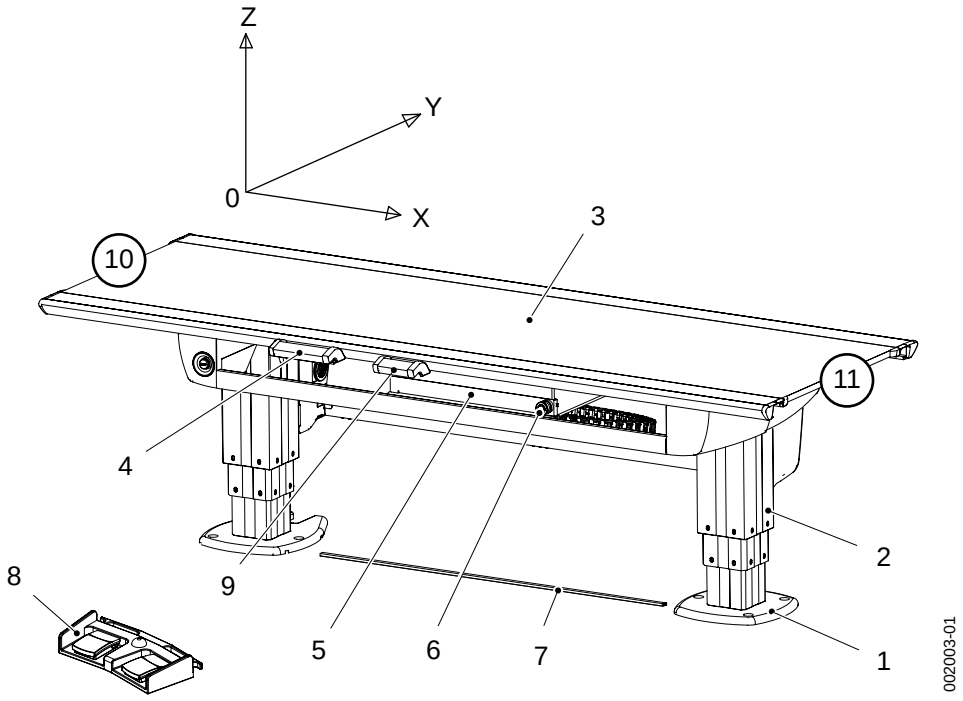


Fig. 1-4 Table overview

1. Foot plate
2. Column
3. Table top
4. Table hand control (X/Y/Z, Ceiling tube pendulum movement)
5. Detector holder
6. Brake release for detector holder
7. XY foot control strip type (Option)
8. Foot control table top (X/Y/Z) (Option)
9. Collimator hand control (option)
10. Head end
11. Foot end

1.3.7 Wall stand Overview

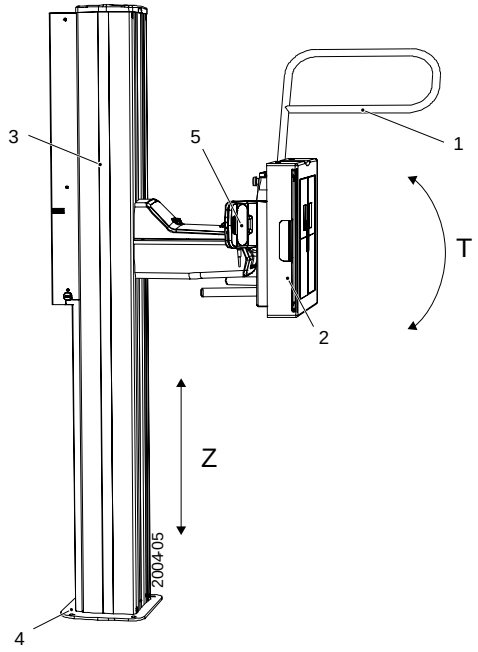


Fig. 1-5 Wall stand overview, T = Tilt

1. Lateral armrest
2. Detector holder
3. Column
4. Foot plate
5. Hand control (Collimator and movement adjustments)

2 Safety

2.1 Modification of equipment

WARNING!

No modification of this equipment is allowed.

2.2 Compliance

External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950–1 for IT equipment and the IEC 60601–series for medical electrical equipment.

In addition, all such combinations — Systems — shall comply with the safety requirements stated in the collateral standard IEC 60601–1–1 or the general standard IEC 60601–1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601–1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support.

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.

If in doubt, contact qualified medical technician or your local representative.

If external equipment is connected, an isolation device is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirements on the Separation Device is defined in IEC 60601–1–1 and in IEC 60601–1, edition 3, clause 16.

2.3 Qualifications of Personnel

CAUTION!

Federal law restricts this device to sale by, or on the order of a physician.

CAUTION!

This equipment is intended for use in radiographic examinations under the guidance of trained health care professionals.

2.3.1 Operating Personnel

Before using the product it is required that the operating personnel is thoroughly familiar with the product and its operating instructions, in particular:

- Safety
- Function and Safety Checks

2.3.2 Service Personnel

WARNING!

Before working with service and maintenance, always turn off the power and make sure to lock it, so it cannot be mistakenly turned on.

The equipment shall be serviced only by qualified personnel who:

- is completely familiar with the System
- has read and understood *Operation Manual* and *Installation and Service Manual*.
- knows how to remove power to the unit in case of an emergency
- is trained in the use of equipment and procedures of this type.

Failure to follow the instructions given in this Manual could result in serious injury to the service person, patient and operator.

Note!

It is the responsibility of the owner to ensure that the technicians have the right training and knowledge to perform service and maintenance.

Note!

It is the responsibility of the owner to ensure that the product is operated only by trained radiologist, service technicians or product specialists.

2.4 Service and Maintenance

WARNING!

When service or maintenance will be performed the technician shall lock the equipment from all energy sources.

Be aware of that there will be live parts even some time after having switched off the mains.

Due to remaining energy, always wait at least 5 minutes before working on the System.

WARNING!

There will still be live parts even when the System is switched off.

WARNING!

The equipment must not be serviced or maintained while in use with the patient.

- ***Risk for personal injury.***

Service and maintenance shall only be performed when patient is not present.

The equipment must be checked according to the 7 *Function and safety checks* to maintain reliability and serviceability, and to ensure the safety of the patients, the operator and third parties.

If national rules or regulations specify more frequent checks and/or maintenance, such regulations must be observed.

2.4.1 Operation, Installation and Repair

WARNING!

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

WARNING!

Only medical-approved products shall be in the X-ray room

Risk of electric shock to patient or user

- ***No non-medical electrical devices shall be used in the x-ray room.***
- ***Note that the monitor and the PC for the Image system, are none-medical approved products.***

WARNING!

The Manufacturer can not assume responsibility for the safety features or for the reliability and performance of the equipment, if:

- ***installation of equipment expansions or modification are not approved by the Manufacturer.***
- ***installation of equipment expansions or modification are not carried out by persons authorized by the Manufacturer.***
- ***components are not replaced by original spare parts in case of a malfunction.***
- ***the electrical installation of the room concerned does not meet the requirements or the corresponding national regulations.***
- ***the product is not used in accordance with the operating instructions.***

CAUTION!

Only service engineers are allowed to open the covers.

CAUTION!

When installing this equipment in a different location, contact us or our designated dealer.

CAUTION!

Do not remove, disassemble, change, modify, repair, or add any part.

2.5 Safety and Warning Symbols

The following symbols are used for the product.

	Attention consult accompanying documents.
	To signify a general warning. This symbol is used in various places throughout the Manual where special precaution shall be observed.
	Type B applied part.
	Protective earth terminal.
	Earth terminal.
N	Connection point for the neutral conductor on permanently installed equipment.
	Squeezing hazard.
	This symbol indicates compliance of the equipment with Directive 93/42/EEC.
	Separate collection for electrical and electronic equipment.
	Manufacturer
	Manufacture date producer
	To indicate the emission or the imminent emission of X-radiation.
	Marking on the emergency stop button. Activation of the actuator interrupts all mechanical movements and prohibits exposures.

2.6 Safety and Warning Labels on the Equipment

The figure shows the location of the safety and warning labels.

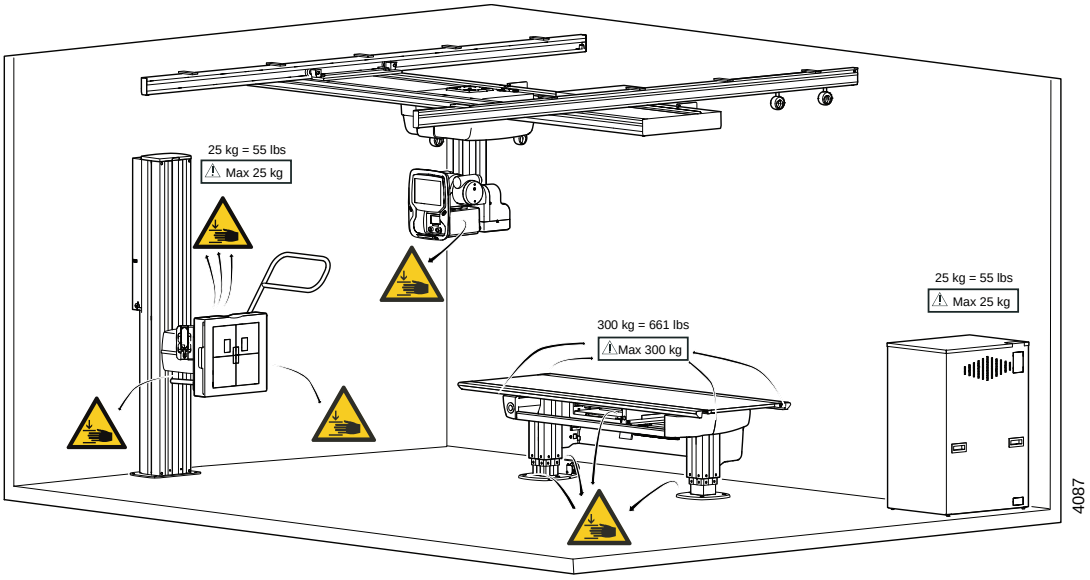


Fig. 2-1 Locations of safety and warning labels

2.7 Emergency stop

Note!

It is recommended to train the operator regularly in the use of the emergency stop function so the operator feels confident in using it.

The System has six internal emergency stops; one connected to the OTC and one on the servo button, one on each side of the table (at the head end) and two on the wall stand.

Pressing one of the emergency stop buttons immediately cuts the power to all motorized movements. The emergency stop is also connected to the generator. The emergency stop prevents a new exposure and terminates an ongoing exposure.

A system message is displayed in OTC display when the button is activated.

To reset the emergency stop position, turn the emergency stop button clockwise. The button is released and the system is ready for use again.

When the emergency stop is activated, it is possible to change the position of the tube/collimator manually, by lifting the overhead tube crane upwards and pushing or pulling sideways if needed.

There are additional external emergency stops as option.

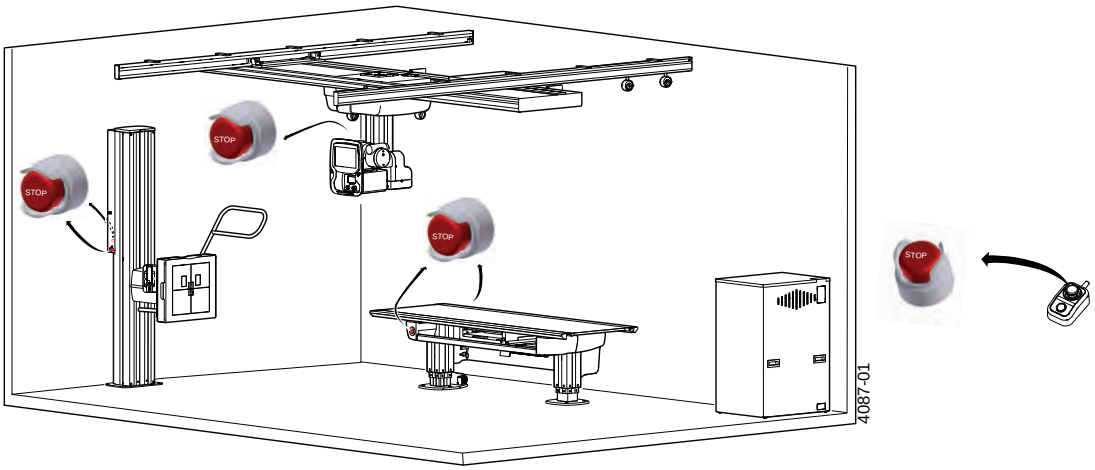


Fig. 2-2 Emergency stop buttons

2.8 Radiation and X-ray Tube

WARNING!

The patients, the operators and third parties must be protected against unnecessary X-ray radiation according to the local regulations.

WARNING!

The surfaces on the Collimator and the X-ray tube can be warm. The collimator temperature will not reach 60 degrees Celsius, but the X-ray tube may be up to 85 degrees Celsius.

WARNING!

The collimator filter must be verified so that correct filter is used during exposure.

CAUTION!

Audio and visual communication must be possible between the operator and the patient when performing an exposure.

CAUTION!

No exposure outside the active area of the imaging unit is allowed. Make sure that the x-ray beam is not outside the active area of the imaging unit in order to prevent unnecessary dose to the patient.

CAUTION!

To minimize the x-ray dose:

- keep the distance between the focal spot and patient as large as possible.

- and the beam size as small as possible.

2.9 Mechanical Safety

WARNING!

Motorized movements are only allowed under supervision of personnel.

WARNING!

Squeezing hazard can occur between column segments and beta rotational assembly interface.

WARNING!

No modification of the equipment is allowed.

Note!

Surrounding equipment are not subject of the collision warning.

2.9.1 General

It is the operators duty, before any movements are activated, to ensure that any danger to the patient and/or third person is prevented.

2.9.2 Overhead Tube Crane

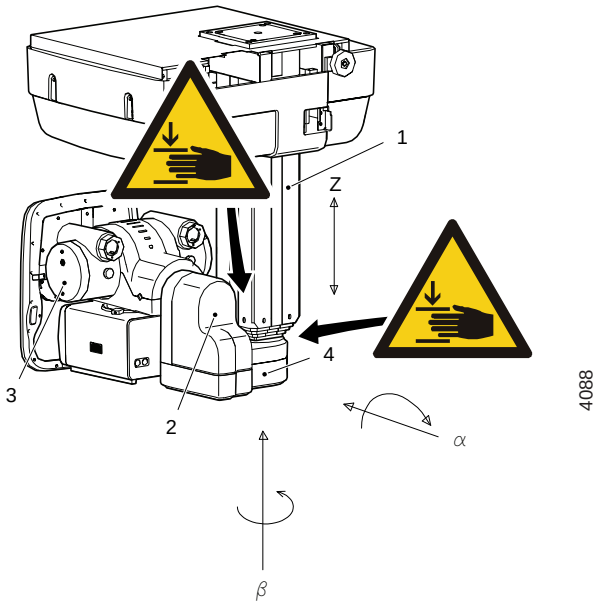


Fig. 2-3 Overhead Tube Crane, OTC

1. Column (Z)
2. Cover
3. X-ray tube
4. Column bottom plate

Possible squeeze hazard areas are indicated in the Fig. 2-3 *Overhead Tube Crane, OTC*.

Squeezing hazard can occur between the:

- column (1) and the column bottom plate (4) when the column is moving upwards (Z-direction).
- cover (2) and the column (1) when the X-ray tube is moving in Beta (β) direction

2.9.3 Table

Possible squeeze hazard areas are indicated in the Fig. 2-4 *Squeeze hazard*.

Squeezing hazard can occur between the:

- table top (1) and the top of the imaging unit (4); when the table top (1) is in the outer position (Y-direction) or moving in a longitudinal direction (X-direction).
- table top (1) and the imaging unit rail (6); when the table top (1) is in the outer position (Y-direction).
- imaging unit (4) and the cover (5); when the imaging unit is moving in a longitudinal direction (X-direction).
- column (7) and the footplate (8); when the column (7) is moving downwards (Z-direction).
- cover (2) and the column cover foot (3); when the column (7) is moving downwards (Z-direction).

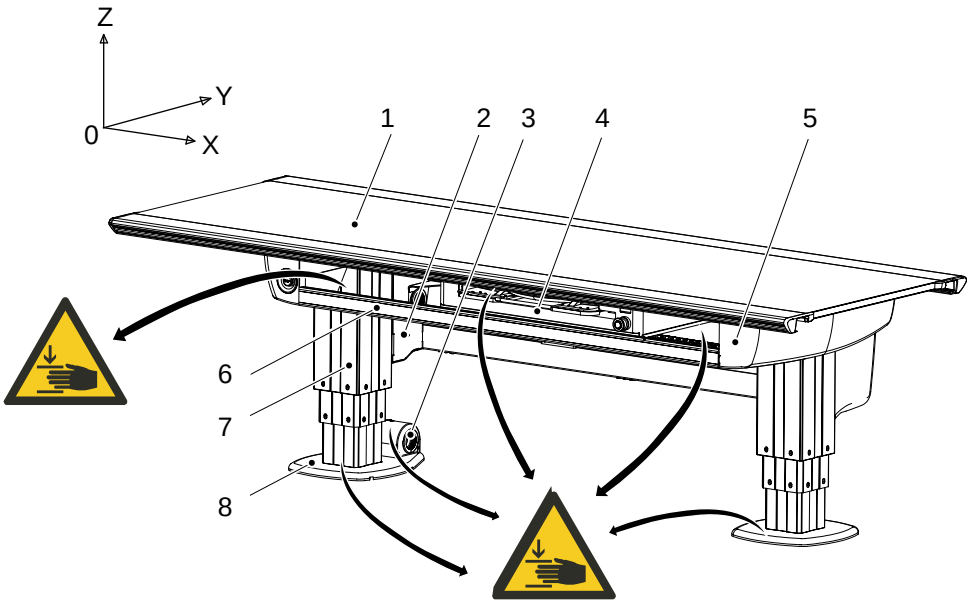


Fig. 2-4 Squeeze hazard

1. Table top (X/Y/Z)
2. Cover
3. Column cover foot
4. Imaging unit (X)
5. Cover
6. Imaging unit rail
7. Column (Z)
8. Footplate

WARNING!

Squeezing hazards may occur between the table top and the imaging unit or the imaging unit rail.

2.9.3.1 Detector Unit, Table

WARNING!

The detector must not be dropped.

Handle with care, to avoid detector malfunction causing delayed diagnostics.

The manoeuver control (2) controls the detector holder brake.

When the manoeuver control is activated the brakes are released in order to move the detector holder (1). Power loss will also release the brakes enabling moving the detector holder.

The brake is normally activated, at power loss the brake is released.

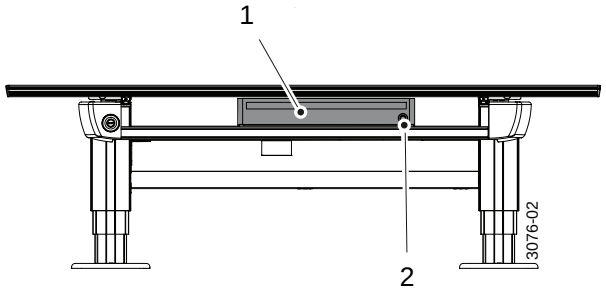


Fig. 2-5

1. Detector holder
2. Manoeuver control

2.9.4 Wallstand

Note!

*The patient or operator is allowed to lean against the Wallstand patient handle or armrest, but **not** to put any weight on it.*

2.9.4.1 Standard Version of Wallstand

Possible squeezing hazard areas are indicated in figure. Getting stuck in the imaging unit slide opening (1) causes squeezing hazard if the imaging unit is moving downwards (Z-direction).

CAUTION!

If the motorized movement is operated, it is not allowed to have patient sitting or standing in the surroundings of the Wallstand.

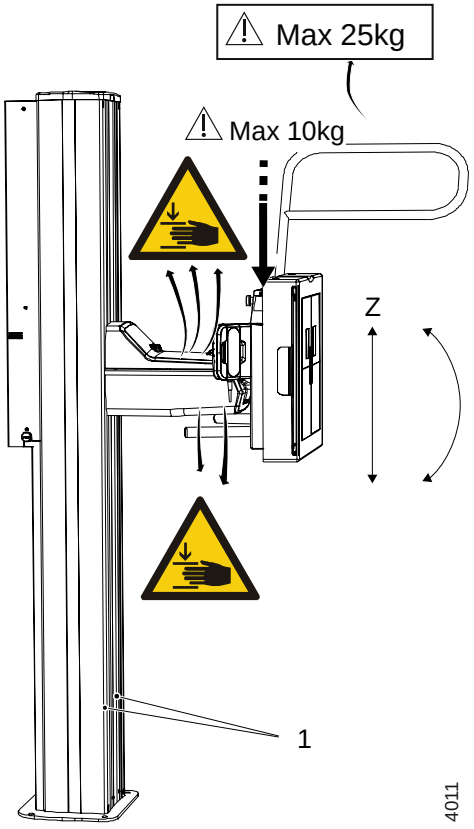


Fig. 2-6

1. Slide opening

Weight Restrictions

- The maximum weight to put on the Wallstand lateral armrest is restricted to 25 kg.
- For the Wallstand detector holder the maximum weight is set to 10 kg.

2.10 Safety issues when placing the patient

WARNING!

Wheelchair patients shall always be placed outside the working area, when operating any motorized movement.

WARNING!

The hospital bed shall be placed in direct contact with, and at the same height as, the table top to avoid any potential risk of injury during transfer of the patient between the bed and table.

WARNING!

Due to squeezing hazards, patients shall always have their extremities placed over the table top.

CAUTION!

When the table top switch is activated, the table top will be floating, therefore do not lean against the table top

When transferring the patient from the hospital bed to the X-ray table, the table top has to be locked and centered over the table.

The table shall always be operated from the front, i.e. the same side as the image receptor holder is operated. To reduce the lateral forces on the table, the operator should be placed on the opposite longitudinal side of the patient and the hospital bed. The operator should then drag the mattress with the patient from the hospital bed to the X-ray Table.

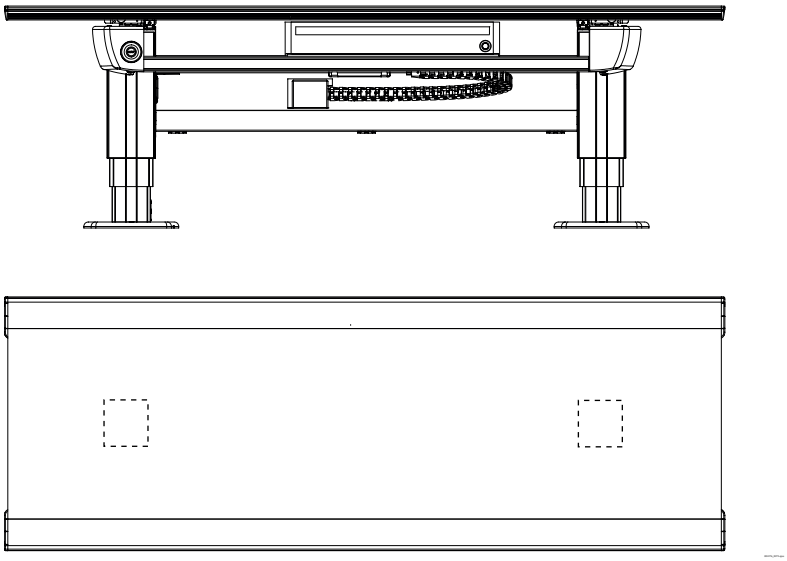


Fig. 2-7 Placement of the table top when loading the patient.

2.10.1 Working area

WARNING!

Due to squeezing hazard, when operating any motorized movement — when not placed on the table — patients shall always be outside the working area.

The working area is the size of the table top, including the length of stroke of the table top in the X- and Y-direction.

The measurements in Fig. 2-8 show the length of the stroke in the X- and Y-direction.

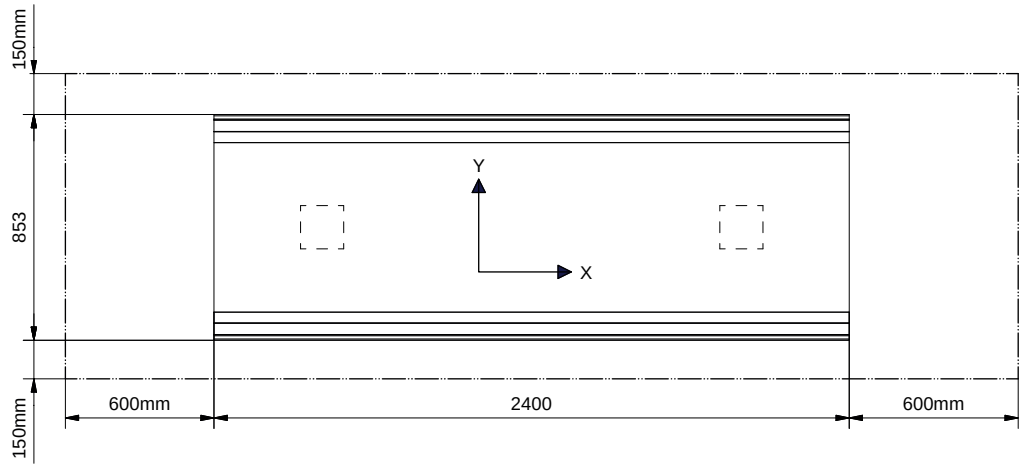


Fig. 2-8

The Fig. 2-9 shows the dimensions underneath the table

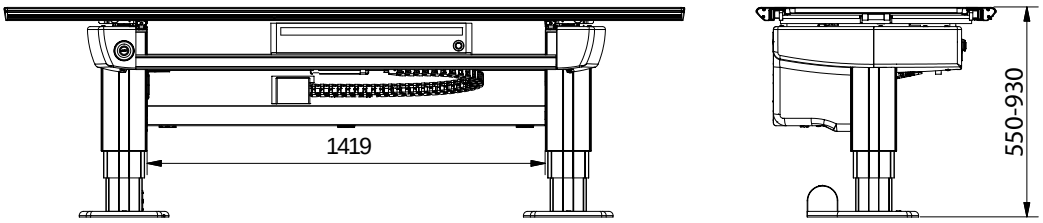


Fig. 2-9

2.10.2 Weight restrictions, table

The following figures show the maximum load at different positions of the table.

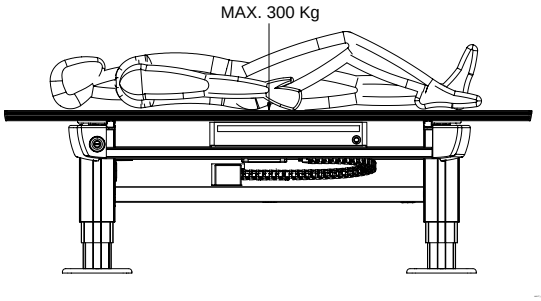


Fig. 2-10 Table top centered

Table top centered over the table frame

- Maximum load of a patient lying or sitting
  - 300 kg, see Fig. 2-10 *Table top centered*

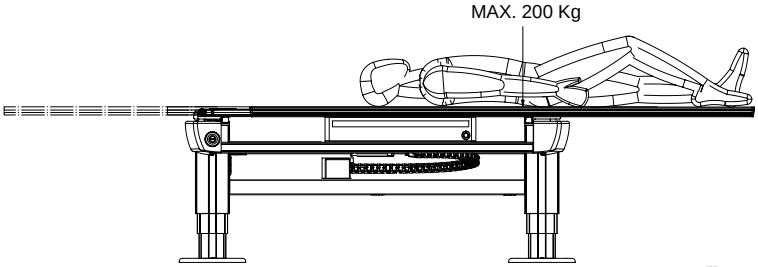


Fig. 2-11 Table top outside table frame

Table top positioned outside the table frame

- Maximum load of a patient lying on the table top:
  - 200 kg, see Fig. 2-11 *Table top outside table frame*
- Maximum load of at patient sitting on the table top:
  - 150 kg.

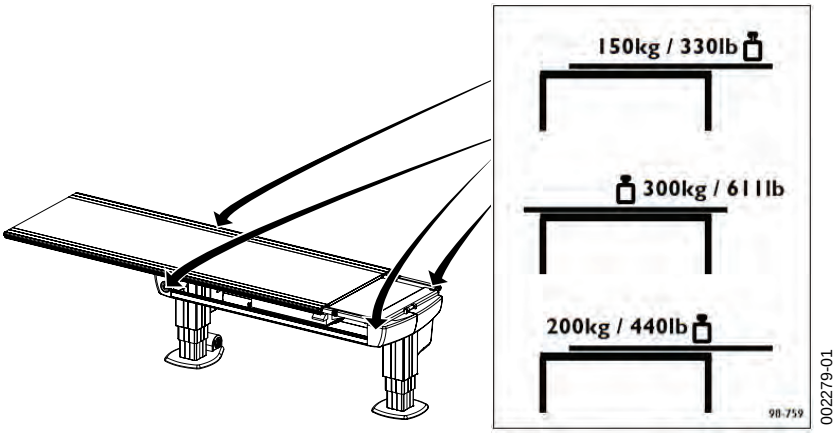


Fig. 2-12 Maximum patient weight label

The table frame is marked on the upper side with the maximum weight when positioning in outer positions, see Fig. 2-12 *Maximum patient weight label*.

2.11 Safety Functions

WARNING!

The operator must always have supervision of the System.

2.11.1 Table Safety Zone and OTC

There is a safety zone over and around the Table. The safety zone reaches from the table top surface and vertical up 500 mm and from the table top edge and horizontal out 120 mm.

Inside the zone the OTC moves vertically with reduced speed. Not until the OTC is outside the zone the vertical movements are performed with full speed.

WARNING!

When the stand has passed the table top level, on its way downward, the speed will increase to normal speed again.

Additionally, when the stand moves manually down into the zone, at a distance of 50 cm from the Table, the OTC stops the vertical movement and the movement has to be restarted by releasing and pressing the button again.

2.11.2 Wall stand Safety Zone

With consideration of detector tilting and the safety height of the tube, there is a collision validation when moving in Auto-position. The System validates if it is possible to move to the position, without any collision between tube and detector.

In *Wall Flexible mode*, when user activates the *Servo* button and Z reaches the transport interval zone, the System checks the Auto-position target with the detector tilting and the safety height of the tube to detect possible collision points. The System then moves, or stops moving and displays message.

2.11.3 Motorized tilt

On top of the detector wagon cover there is an IR sensor registering if an object interferes with the tilting movement. If an object is registered, the movement stops and cannot continue until the object is removed.

Below the detector wagon cover, there are three IR sensors:

- One sensor registering object between the detector holder and detector wagon.
- Two sensors registering objects close to the handles on detector holder. If an object is registered the movement stops and cannot continue until the object is removed.

2.11.4 Collision Detection

2.11.4.1 Motorized Movements

Every motorized movement has a collision detection.

All movements are stopped when the collision detection activates and the display shows an error message. When a collision in Z-direction is detected, the OTC has to be moved in the opposite direction before it can be moved in the original direction again.

2.11.4.2 Z Column

A guard plate installed on top of the column, registers vertical pressure on the column, for instance a vertical impact.

When the pressure exceeds the trig level vertically, all movements are stopped and a warning message is displayed. To be able to release the pressure, a movement in the opposite direction is allowed. When the pressure on the column has returned to normal, see Fig. 2-13 *Collision detection* the warning message is removed and motorized movements are allowed again.

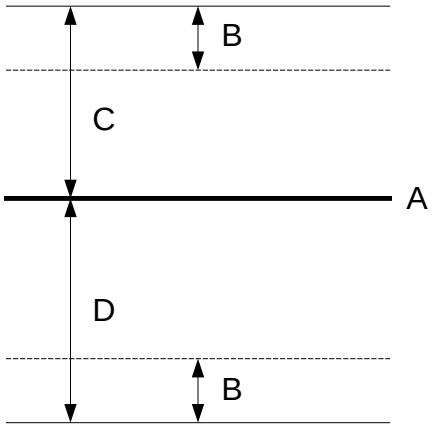


Fig. 2-13 Collision detection

A Zero force level
B Hysteresis
C Upper trig level
D Lower trig level

Note!

In some situations it is possible to force a false detection of a collision. This can occur if the column is affected by a pressure at the time the movement starts. This could be for example the case if the collimator rests on the Table, when the operator moves the column upward, a collision is detected.

The reason for the collision detection is that, when the movement starts, the zero force level is calculated based on the actual pressure affecting the column at that moment. As soon as the movement starts and the collimator is no longer resting on the Table, the guard plate catch a change in pressure and a collision is detected.

To solve the problem the operator must affect pressure on the column, for example manually pull the column up or down. The System will take this as a sign that the operator has removed the obstacle and that no collision exists any more. If the problem is yet not solved, the System must be restarted.

2.11.4.3 Motor Nodes

Every motor node has collision detection on its own movement. A collision can be detected in different ways, for instance if the control error in the motor node's regulator is too large, if the final position is not reached in time, or if the position transducer has not moved although the drive unit had an output voltage for a given time.

A detected collision stops all movements in that part of the System (e.g. OTC, Table or Wall-stand) where the collision is detected. An error message is displayed.

2.11.4.4 Malfunctioning Node

If any node stops functioning, all movements are stopped and the power to the motors in the System is removed.

2.11.5 Quick abortion of an auto positioning

When any of the buttons on the stand is pressed while the stand is moving toward its position, it has the same effect as when the servo button is released, all movements are stopped.

2.11.6 Opposite buttons pressed

If, at any time, two from each other opposite buttons are pressed, for example movements up and down, the movement is stopped. Both buttons must be released before any movement is allowed.

2.11.7 Dead man’s grip

All movements require constant activation of the chosen button.

If the operator releases one of the buttons/controls, the system will immediately stop or engage the brakes (manual movements). The exposure operator console has the same functionality.

2.12 Electromagnetic compatibility (EMC)

The system complies with the requirements of IEC 60601-1-2:2014 regarding electromagnetic compatibility. Surrounding equipment shall follow the standard IEC 60601-1-2:2014.

WARNING!

Do not use this equipment adjacent to or stacked with other equipment.

Such use could lead to improper operation.

Verify that the equipment is operating normally, if such use is necessary.

WARNING!

Do not use other accessories, transducers and cables than those specified or provided by the manufacturer.

Such use could lead to increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING!

Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer.

Such use could lead to degradation of the performance of this equipment.

CAUTION!

Do not place the system near MRI equipment or other equipment that generates a strong magnetic field.

CAUTION!

Mobile telephones and other radiating equipment can interfere with the function of the system and can therefore cause safety hazards.

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

Guidance and manufacturer's declaration - electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The system is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose. For information purpose the system complies with IEC61000-3-11 and is suitable for connection to public mains network if the impedance is 0.32 Ohm or lower
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

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

Guidance and manufacturer's declaration - electromagnetic emissions			
Emissions test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated emissions CISPR 16-2-3	30 MHz to 230 MHz: QP 40 230 MHz to 1 GHz: QP 47	30 MHz to 230 MHz: QP 40 230 MHz to 1 GHz: QP 47	
Conducted emissions CISPR 16-2-1	150 kHz to 500 kHz: QP 100+20, average 90 500 kHz to 5 MHz: QP 86+20, average 76 5 MHz to 30 MHz: QP 90+20 (at 5 MHz) decreasing linearly to 73+20 (at 30 MHz) average 80 (at 5 MHz) decreasing linearly to 60 (at 30 MHz)	150 kHz to 500 kHz: QP 100+20, average 90 500 kHz to 5 MHz: QP 86+20, average 76 5 MHz to 30 MHz: QP 90+20 (at 5 MHz) decreasing linearly to 73+20 (at 30 MHz) average 80 (at 5 MHz) decreasing linearly to 60 (at 30 MHz)	
	Note: These limits apply to equipment with a rated power > 20 kVA and intended to be connected to a dedicated power transformer or generator, and which is not connected to low voltage (LV) overhead power lines. 20 dB relaxation for Quasi-Peak (QP) is allowed for Radiography and pulsed Radiography (Intermittent Mode).		

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

Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharger (ESD) IEC 61000-4-2	± 8 kV contact ±15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines + 1 kV for input/ output lines 100 kHz repetitive frequency	± 2 kV for power supply lines + 1 kV for input/ output lines 100 kHz repetitive frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1.0 kV 1.2 kV 2.0 kV 0,90, 180, 270 degree phase angle	1.0 kV 1.2 kV 2.0 kV 0,90, 180, 270 degree phase angle	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle (0, 45, 90, 135, 180, 255, 270, and 315 degrees phase angle) <5% U_T (>95% dip in U_T for 1 cycle) 70% (30 % dip in U_T for 25/30 cycles) <5 % U_T (>95 % voltage dip in U_T for 250/300 cycles)	<5 % U_T (>95 % dip in U_T) for 0.5 cycle (0, 45, 90, 135, 180, 255, 270, and 315 degrees phase angle) <5% U_T (>95% dip in U_T for 1 cycle) 70% (30 % dip in U_T for 25/30 cycles) <5 % U_T (>95 % voltage dip in U_T for 250/300 cycles)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system should be powered from an uninterrupted power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Note! *U_T is the AC mains voltage prior to application of the test level.*			
			Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance, calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance;
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms (ISM and amateur radio bands)	3 Vrms 150 kHz to 80 MHz 6 Vrms (ISM and amateur radio bands)	$d = 1.2 \sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 10 V/m 80 MHz to 2.7 GHz	3 V/m 10 V/m 80 MHz to 2.7 GHz	$d = 1.2 \sqrt{p}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{p}$ 800 MHz to 2.7 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).
Proximity field from wireless transmitters 61000-4-3	9 V/m to 28 V/m 15 specific frequencies	9 V/m to 28 V/m 15 specific frequencies	
			Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.17 \sqrt{p}$	80 MHz to 800 MHz $d = 0.35 \sqrt{p}$	800 MHz to 2.7 GHz $d = 0.7 \sqrt{p}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.69	1.11	2.21
100	11.67	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption as reflection from structures, objects and people.

3 User Interface

3.1 Overhead Tube Crane

The overhead tube crane (OTC) can be moved to the correct position by autopositioning, motorized movements or manual movements.

The OTC has a display that shows patient information, information of the tube angulation and the selected workstation etc. The exposure parameters are shown and can easily be changed from the OTC.

3.1.1 Direction of Movement

The figure below shows the movements of the OTC.

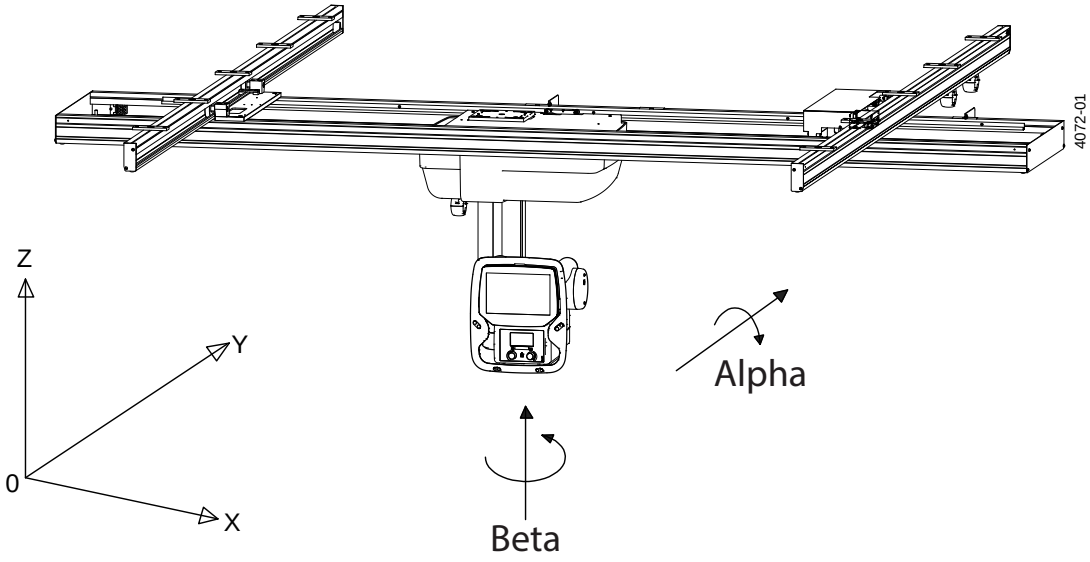


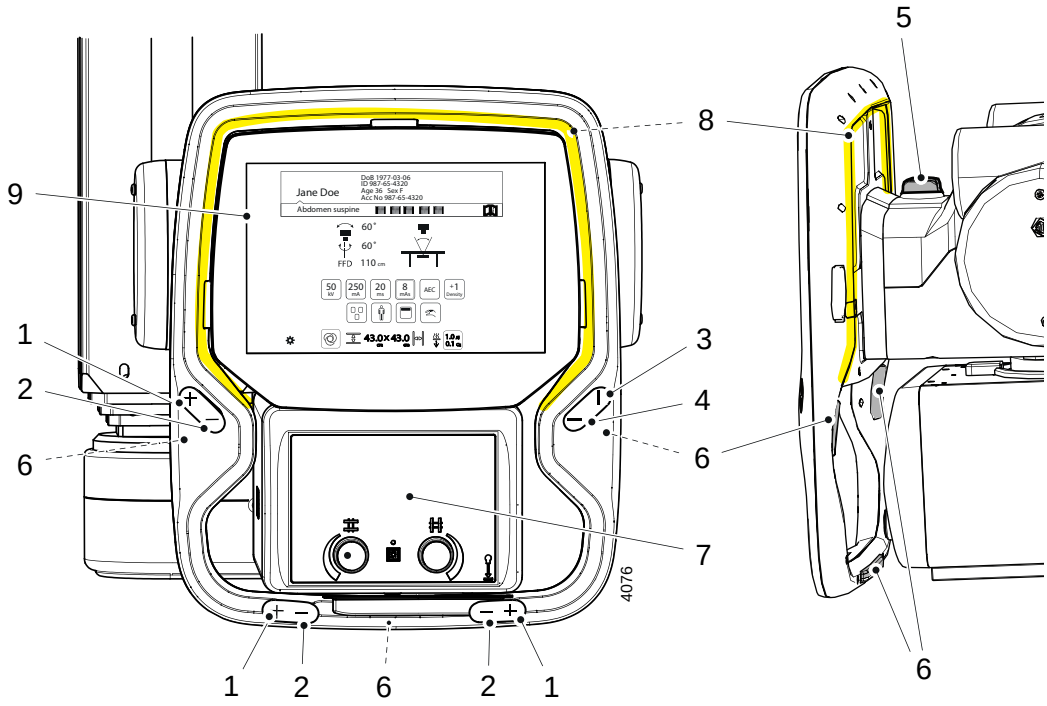
Fig. 3-1 OTC direction of movement

Z	Vertical movement	Motorized
Y	Lateral movement	Motorized and manual
X	Longitudinal movement	Motorized and manual

3.1.2 Sound Signal

- One sound signal, means that the OTC is in position and ready for exposure.
- Two sound signals, in rapid succession, indicates a fault and the display will show an error message, for example after a collision. The error message shows the corrective action.

3.1.3 System Display Overview



1. Up
2. Down
3. Y direction
4. X direction
5. Emergency brake (rear side)
6. Release all directions (rear side)
7. Automatic collimator, see 3.2.1 *Automatic collimator*
8. Light indication, see 3.2.15 *Light indication*
9. Display user interface, see 3.2.2 *Display user interface*

3.2 Automatic Collimator Control

The collimator is used to adjust the size of the x-ray field to cover the area of interest of the patient by adjusting the collimator light field size. The collimator light field size / x-ray field size and the collimator filtration can be predefined in the anatomical protocols and is then set automatically when the protocol is selected. The size of the light / x-ray field and the filtration can then be adjusted when needed to adapt to the patient.

The collimator can be operated from the collimator interface at the Overhead tube crane, from the hand control at the wall stand or from the control handle at the table (option).

The following figure shows the functions of the automatic collimator.

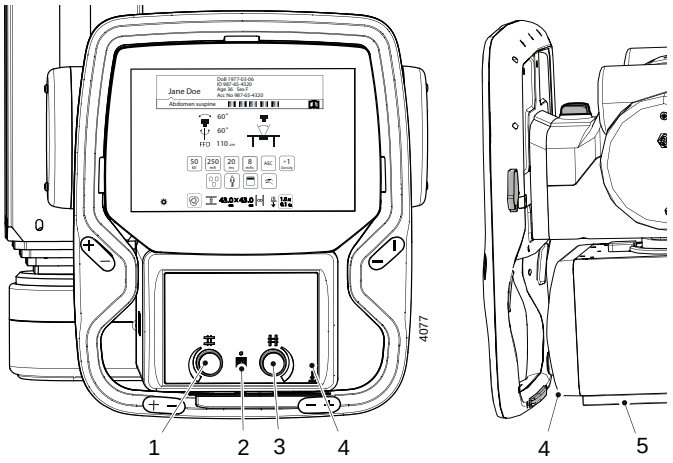
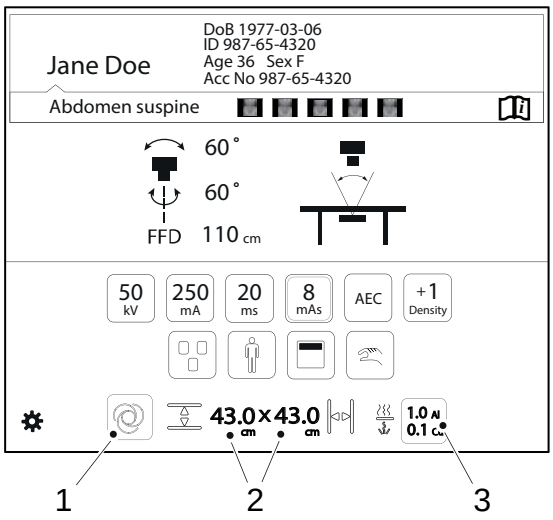


Fig. 3-2 Display, automatic collimator

1. Knob for adjusting collimator light/x-ray field height
2. Collimator light and laser light on/off.
   Automatic off after predefined time.
3. Knob for adjusting collimator light/x-ray field width
4. Measuring tape grip for SID measurement, graduation in cm/inch -
   Take reading at bottom edge of multi-leaf collimator.
5. Accessory rail

The collimator can rotate around the central beam axis +/-90°.

3.2.1 Automatic collimator



1. Select *Automatic* or *Manual* mode of the collimator.

   Note!

   If there is no new examination and the System is in a Manual mode, the collimator ignores the instructions of sent collimator area from the Imaging system. This can be useful if the collimator area is intended to be kept for the next examination.

2. Collimator light/x-ray field height x width
3. Collimator filter selection

3.2.1.1 Collimator mode

In automatic mode, the collimator light height and width is set from the anatomical program. The collimator light size can still be changed manually. In manual mode the collimator light height and width is not set from the anatomical program.

1. Automatic mode
2. Manual mode

Fig. 3-3 Collimator mode

When Automatic mode is selected the predefined values of the collimator light / x-ray field size and the filter selection will be set automatically when the anatomical protocol is selected. Both the light / x-ray field size and the filter can be changed when needed. In automatic mode the maximum light / x-ray field size is restricted to the maximum active area of the imaging unit.

When manual mode is selected the size of the collimator light / x-ray field size can be adjusted outside of the maximum active area of the imaging unit. When a new anatomical protocol is selected (for the same patient) the collimator light / x-ray field size or the filtration is not changed even if size and filtration is defined different in the protocol.

When changing from Manual mode to Automatic mode the collimator light / x-ray field size and filtration is restored to the values that were selected when changing from automatic to manual mode. Example:

- Automatic mode: Size: 30 cm x 10 cm; filter 1.
- Changes to Manual mode. Changes: Size: 30 cm x 20 cm, filter 2.
- Changes back to Automatic mode: Size 30 cm x 10 cm, filter 1.

When a new patient is selected Automatic mode is automatically activated.

3.2.1.2 Collimator filtration selection

The user can change the selected value from the display.

1. Collimator filtration selection icon
2. Collimator filtration selection values

3.2.1.3 Collimator filters

The collimator filter options are:

- No added filtration
- Filter 1 =1 mm Al + 0.1 mm Cu
- Filter 2 =1 mm Al + 0.2 mm Cu
- Combined: 2 mm Al + 0.3 mm Cu

The filters can be predefined in the anatomical protocol and also be changed if needed

3.2.1.4 Laser

The laser can be switched off by applying a mechanical cover over the laser. The cover is available underneath the collimator.

3.2.1.5 Collimator functionality - system

When the OTC moves in a direction that changes the SID, the collimator starts to compensate the field size. The collimator light field size on the imaging unit is held constant with changing SID.

When the OTC is tracking against the Wall stand or when the table top is released, the collimator light automatically will be turned on. This will make it easier to directly find the correct stand and patient position.

In *Free* mode/*Auto position* mode the position of the detector is unknown for the System. The indicated size of the light field is correct at the shown SID.

3.2.1.6 Collimator Control Handle, Table (option)

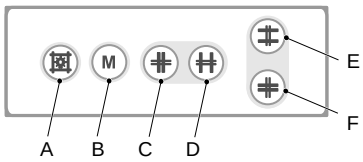
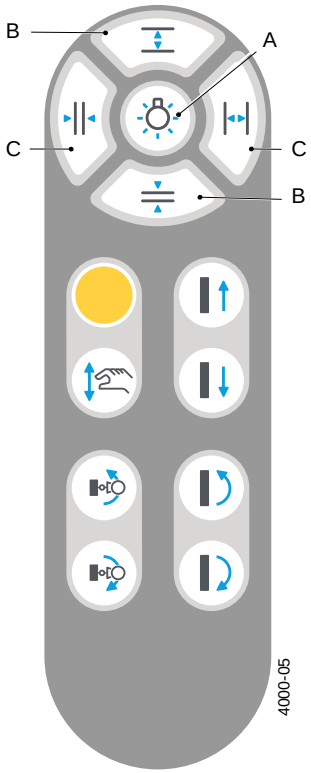


Fig. 3-4 Table collimator control handle

A. Button for switching the light and the laser line on/off. The light and laser line is automatically switched off via a time switch.
B. Button for changing between *Automatic mode* and *Manual mode*. A long activation of the *M button* set the light field to max image size, based on the pre-programmed SID value and the selected receptor.
C. Button for closing the format height collimation.
D. Button for opening the format height collimation.
E. Button for opening the format width collimation.
F. Button for closing the format width collimation.

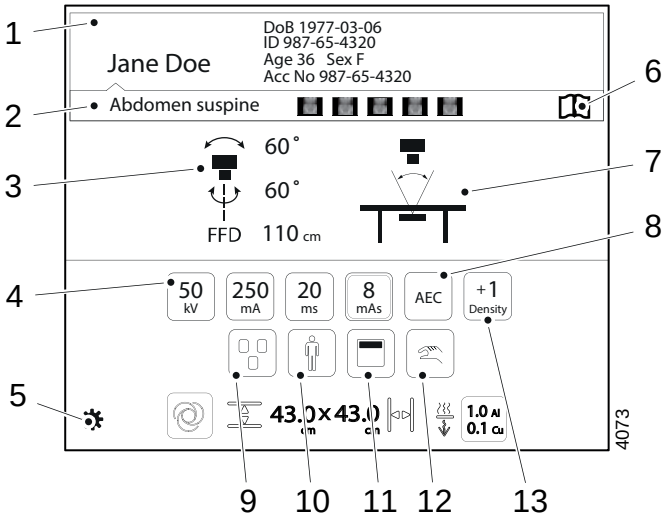
3.2.1.7 Hand control, Wall stand – collimator adjustment



A. Collimator light on/off
B. Adjustment height collimation
C. Adjustment width collimation

Fig. 3-5 Hand control

3.2.2 Display user interface



1. Patient information
2. Active protocol
3. Position information
4. Adjustment of generator parameters: kV, mA, ms, mAs
5. Select the settings menu
6. Hospital manual
7. Active System mode
8. Selection of Technique mode
9. Selection of active AEC field (AEC mode only)
10. Patient size
11. Collimator centering
12. Manual or Servo mode
13. Density

See the following pages for detailed description of the functions.

3.2.3 Patient Information

In this field the *Patient Name*, *Patient ID*, *Date of Birth*, *Age, Sex* and *Accession number* can be shown.

The information shown is defined in the *Setting menu*. In the *Setting menu* it is also possible to decide if the *Patient information* shall be shown always (picture 1), or on demand (picture 2).

When the button is shown on demand, the *Patient information* can be obtained by pushing the “i” on the black bar.

The *Patient information* closes automatically, or when the bar is pushed once again.

Picture 1 Picture 2

Fig. 3-6 Patient information display

3.2.4 Position Information

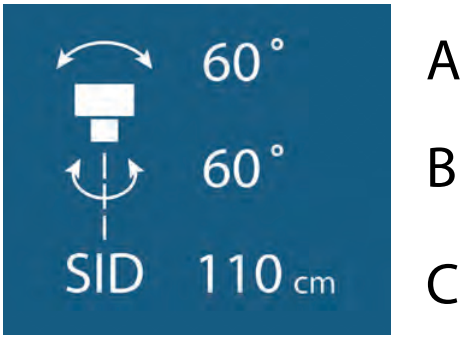


Fig. 3-7 Position information

A. Alpha angle (°)
B. Beta angle (°)
C. Source Image Distance (SID), or Height to floor (H) in Free or Auto Position Mode (cm/inch)

The height to floor (H) is shown in *Free mode* and *Auto position mode*. In all other modes the source image distance (SID) is shown. The unit for the distance can be either cm or inch, and is set in the *Setting menu* (Fig. 3-7 *Position information*).

3.2.5 Adjustment of Generator Parameters (kV, mA, ms, mAs, Density)

In order to change the exposure values, the button with the parameter that shall be changed, is pushed. Then the user may select to increase or decrease the value.

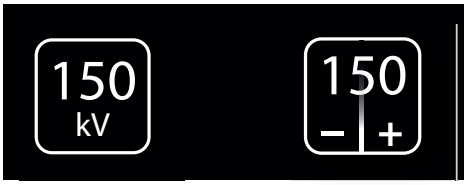


Fig. 3-8 Adjustment of generator parameters

Note!

The Operator/User is always responsible for checking and validating the exposure parameters in the Image system before performing exposure.

3.2.5.1 Exposure Index

The exposure index, EXI, is a measure of the amount of exposure received by the detector and depends on mAs, the total detector area irridiated respective the beam attenuation. It is indicative of the image quality.

3.2.6 Settings

The *Setting menu* is reached by a activating the *Setting* button for 1 second.

Fig. 3-9 Setting button

The *Setting menu* has the following tabs; *User Settings* and *Service*.

User settings has the following tabs: *Display*, *Settings* and *Themes*.

Service has the following tabs: *Log*, *Settings* and *Display*.

3.2.6.1 User settings

User settings – Display

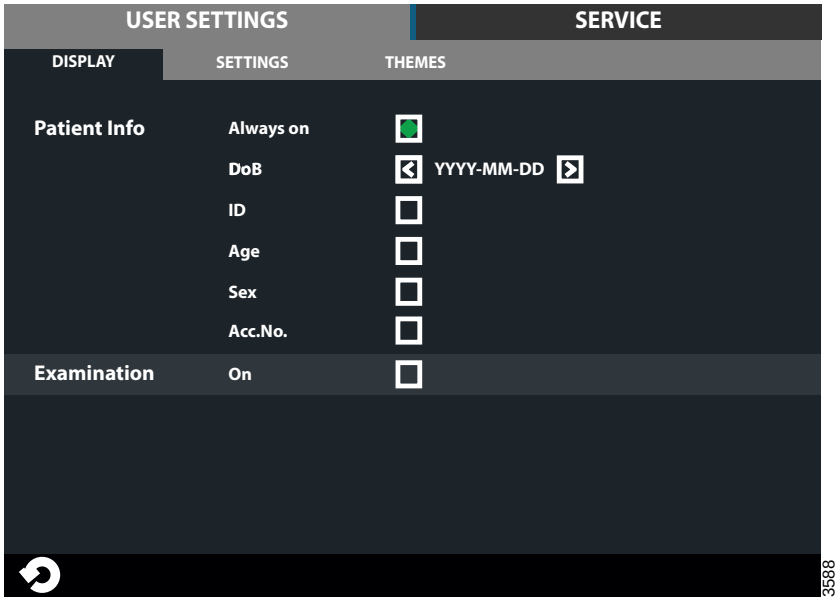


Fig. 3-10 User settings – Display

Patient Info

CAUTION!

The user shall always assure that the Patient info and the type of examination is corresponding to the one in HIS and RIS.

Fig. 3-11 "Always On" selected

When the *Always on* is marked, the *Patient information* is shown as soon as the information is selected in the imaging display.

Fig. 3-12 "Always On" not selected.

When the *Always on* is **not** marked, the *Patient information* is shown when pushing the black field where the *'i'* is.

The *Patient information* closes automatically.

It is also possible to select what patient information to show on the display. The following parameters can be selected:

- *Date of Birth (DoB)*, different formats selectable
  - YYYY-MM-DD
  - DD-MM-YYYY
  - MM-DD-YYYY
- ID
- Age
- Sex
- Accession number
- Examination/Active Protocol

User settings – Settings

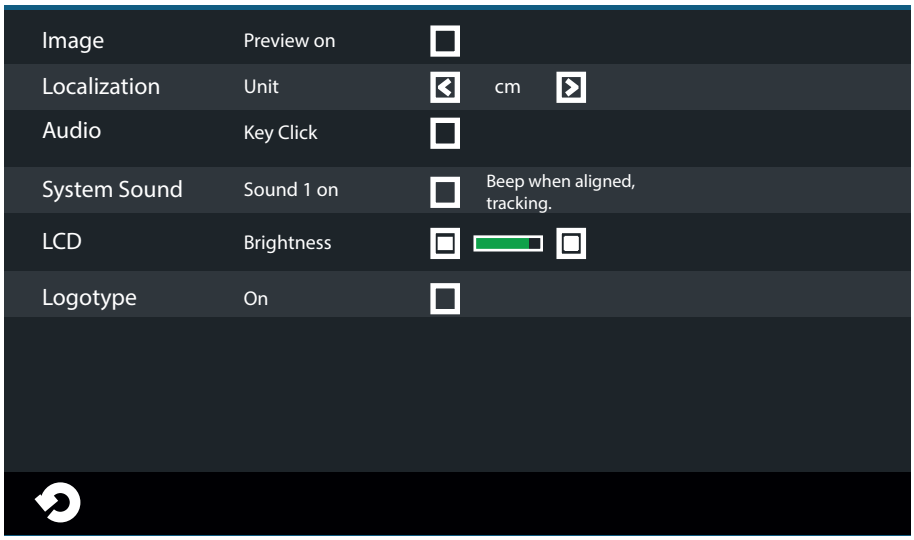


Fig. 3-13 User settings – Settings

In the *Settings* tab, it is possible to adjust the following:

- Preview Image (not applicable for CR systems)
- Localization unit selection
- Audio key click, On/Off
- System sound, On/Off
- LCD brightness, Plus/Minus
- Arcoma logotype in display, On/Off

– Image preview on	By selecting this, a small preview image will be shown next to the Active Protocol name (see figure on page).
– Localization	Changes between cm and inch, for collimator light width and height values and SID/H.
– Audio Key Click	By selecting this, a key click will be heard when touching the System display.
– Sound on	By selecting this, a beep will be heard when OTC is aligned with the detector, at tracking.

LCD

The display brightness can be adjusted. There is also a setting if the logo shall be shown or not.

Preview Image

WARNING!

The preview image must not be used for diagnostics or positioning

It is possible to select if a *Preview image* shall be shown on the touchscreen display or not.

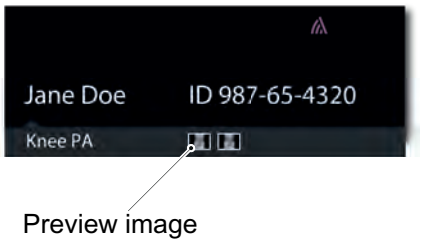


Fig. 3-14 Preview image displayed

If preview is selected, a small preview image, see Fig. 3-14 *Preview image displayed*, is shown on the touchscreen display when an exposure is performed.

Touch the small image on the display, and the image is shown as a large image.

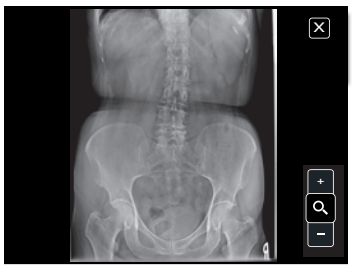


Fig. 3-15 Preview image enlarged

By touching the zoom button +/-, it is possible to zoom in and out, in the image.

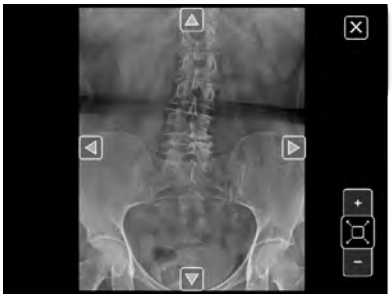


Fig. 3-16 Zooming In/Out

The arrows appearing in the image are used to pan in the image.

Themes

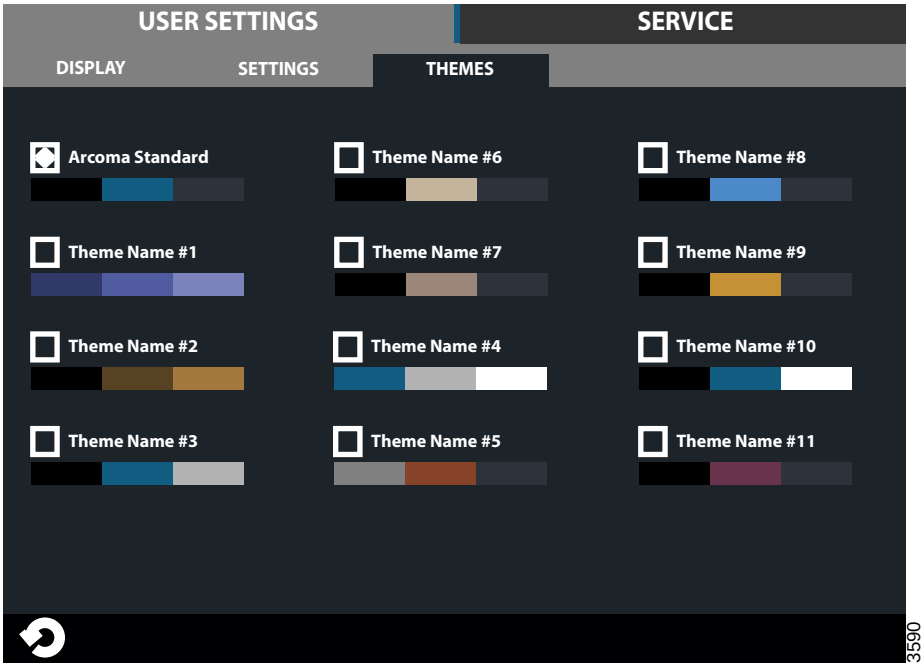


Fig. 3-17 Themes

Select a pre-set theme.

3.2.6.2 Service

The Service tag is meant to be used by the service technician.

Log

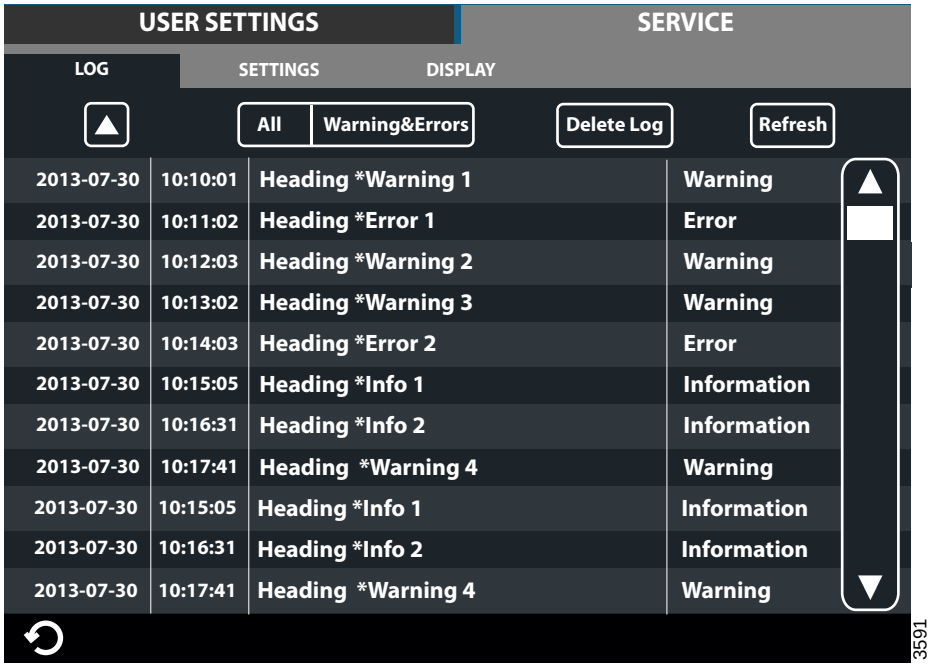


Fig. 3-18 Log

The log file shows warnings, errors and events that have occurred in the system. The log file can be filtered to show all information, or just warnings and errors. By selecting *Information*, *Warning* or *Error*, more information concerning the current issue will be shown.

The log file may be used for troubleshooting.

It is possible for service personnel to delete the log file which can be helpful when fault tracing. The refresh button retrieves the latest events.

Delete log file

Note!

This procedure shall only be performed by service personnel.

When selecting *Delete Log* a four digit access code is required before the log is deleted.

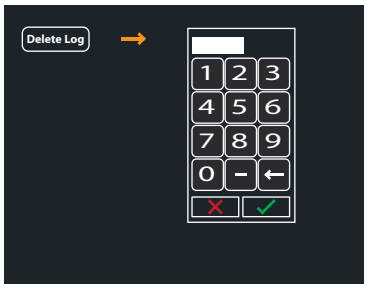


Fig. 3-19 Delete log file

Service – Settings

The Service menu shows system set up and system software versions. A more detailed description can be found in the Service and installation manual.

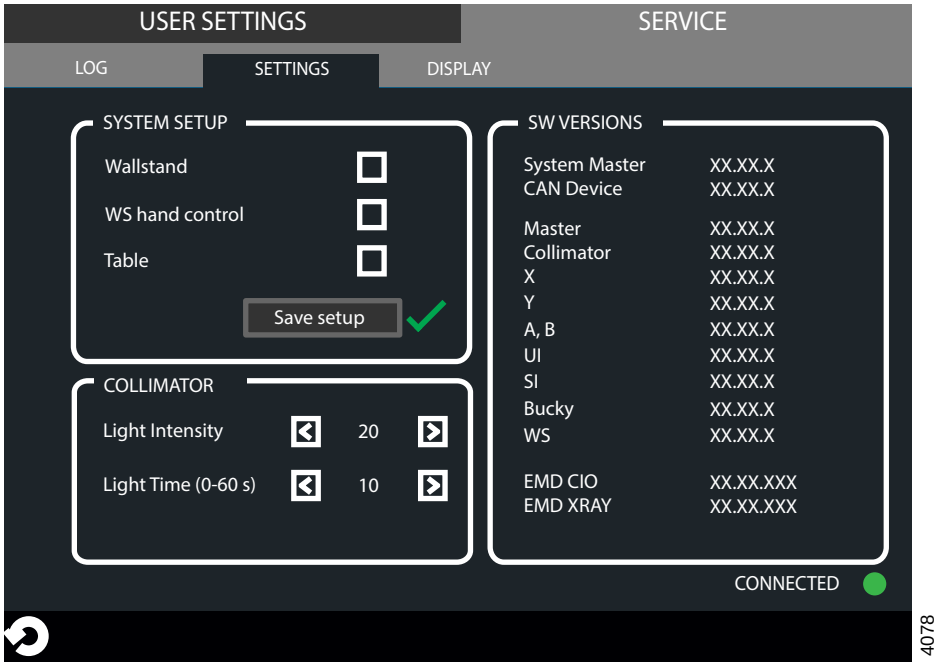


Fig. 3-20 Service – Settings

Service – Display

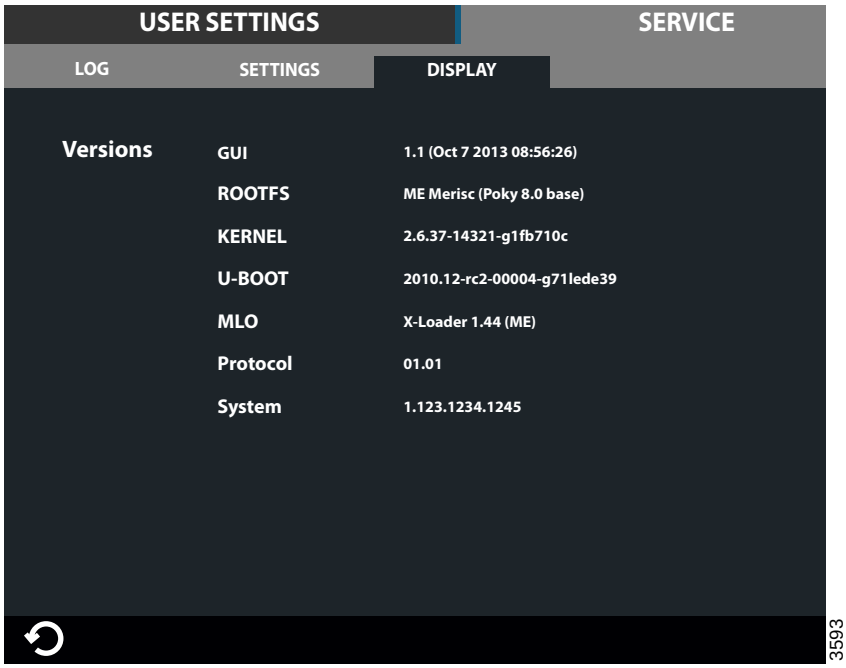


Fig. 3-21 Service – Display

Information of the display software versions.

3.2.7 System Mode

The System has a number of different modes. All modes are described below with their special functionalities and features.

Note that depending on the particular System, different modes and actual configurations are available.

- *Free mode*
- *Auto position mode*
- *Wall flexible mode*
- *Table flexible mode*
- *Film tracking mode*
- *Pendulum mode*, Table
- *Stitching mode* (toward the Table and Wall stand)

3.2.7.1 Free Mode

General Description

The *Free mode* is the most basic mode in the System.

The mode holds no special features or functionality. It is intended as a manual mode with a lot of freedom in positioning and exposure, e.g. for emergency examinations or examinations with the patient in a wheel chair or lying in a bed. This mode is available in all Systems.

The distance shown in display for *Free mode* is the distance to the floor.

Exposure Validation

Exposure is allowed if the stand is not moving and operating properly (not in an error state).

3.2.7.2 Auto Positioning Mode

General Description

The *Auto position mode* functions as the *Free mode* with the added functionality of automatic positioning in the room.

Automatic positions are a number of positions that can be programmed and saved into the System. The stand will upon activation of the servo button, move to the programmed position chosen from the imaging unit.

The mode is intended as a flexible, easy to use mode. The mode can also be used as a parking mode.

The distance (H) shown in display for *Auto position mode* is the distance to the floor.

Exposure Validation

Exposure is allowed if the stand is not moving and operating properly (not in an error state). The chosen position must have been reached successfully.

3.2.7.3 Wall Flexible Mode

General Description

The *Wall Flexible mode* is intended for examinations toward a Wallstand.

The OTC will upon activation of the servo button move to the programmed position associated with *Wall mode*. The stand will stop at the transport height and wait for a change in position of the Wallstand (detector height). When a change in position is detected (the user moves/drives the Wallstand up or down) the OTC will move downward and start tracking the position of the detector.

The value is constantly updated as soon as the Wallstand/OTC is moved. It is possible for an operator to change the position so the value cannot be calculated or would be incorrect; in those situations the display will clear the field for the value.

No Wait

At the installation of the System it is possible to select, that the OTC shall not wait for the user to move the Wallstand before tracking starts. The OTC will then start the tracking as soon as it reaches its final position.

Exposure Validation

Exposure is allowed if the stand is not moving, operating properly (not in an error state) and the servo button is activated.

3.2.7.4 Table Flexible Mode

General Description

The *Table flexible mode* is equal to *Auto positioning mode* with functionality added for tracking the height of the Table (compare with Wall flexible mode). The mode is intended for Table examinations.

The stand will upon activation of the servo button, move to the programmed *Table mode* position and start tracking the Table height, thereby keeping the film focus distance constant. The *Film focus distance* shown in the display is the actual distance to the detector. The Table position in the room is set during the installation of the System.

Exposure Validation

Exposure is allowed if the stand is not moving, operating properly (not in an error state) and the servo button is activated. Movement is allowed in X and alpha direction.

3.2.7.5 Film Tracking Mode

General Description

The *Film Tracking mode* functions as the *Table mode* with added functionality for controlling the position of the detector in one direction. The mode is intended for fast and easy positioning with the X-ray tube always aimed at the center of the detector.

The motorized detector holder will move the detector to the right position. The stand will upon activation of the servo button move to the pre-programmed *Film-tracking position* and start tracking the Table height, thereby keeping the film focus distance constant. The film focus distance shown in the display is the actual distance to the detector. When *Film Tracking mode* is chosen all buttons except X and alpha-brake buttons will be deactivated. The tube stand is operated manually by releasing one or both of the brakes. The position of the detector is changed according to the change in X and or alpha position of the tube. That is the X and alpha positions can be changed independently.

Exposure Validation

Exposure is allowed if the stand is not moving, operating properly (not in an error state), the X-ray tube is aimed to the center of the detector and the servo button is activated.

3.2.7.6 Pendulum Mode, Table

General Description

The *Pendulum mode* can be seen as a variation of film tracking.

The X-ray tube is always aimed at the center of the detector. The alpha angle of the tube and the position of the detector changes according to the change in X-position of the tube stand. Also *Pendulum mode* incorporates all the functionality of the more simple Table mode. The mode is intended for fast and easy positioning with the X-ray tube always aimed at the center of the detector.

For moving and controlling the position of the detector, a motorized detector holder is required. The stand will upon activation of the servo button move to the programmed position associated with the *Pendulum mode* and start tracking the Table height, thereby keeping the film focus distance constant.

All table handle bar buttons, except (move left) and (move right) buttons, will be deactivated when the *Pendulum mode* is activated. The X-position of the stand is controlled by these two buttons and thereby also the detector and the alpha angle of the tube.

Exposure Validation

Exposure is allowed if the stand is not moving, operating properly (not in an error state), the X-ray tube is aimed to the center of the detector and the servo button is activated.

3.2.7.7 Stitching Mode

General Description

Stitching is the process of combining multiple images with overlapping fields of view to produce a larger image.

When imaging long parts of the human body, there is need for an image with extended length. In digital radiography the image size is limited due to the sensitive area of flat-panel detectors. In order to produce a large image, images are assembled from multiple exposures with a small, spatial overlap.

Stitching is possible at both Table and Wallstand.

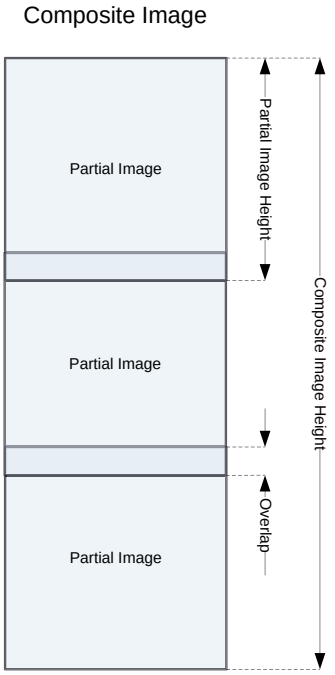


Fig. 3-22 Stitching, schematic description

Wallstand/Table Stitching

The user must define the area that shall be captured in the stitching sequence.

When choosing *Stitching mode*, new information will be present on the manoeuver handle; high (left) position, low (right) position, total length and number of exposures. The tube support moves to the pre-defined position for X, Y, Alpha, Beta and Wallstand (detector holder for TableStitching). Z moves to the position received from the Image system (*SID value for TableStitching*).

To start the stitching procedure, press *Start exam*.

The movement for stitching is:

- From head to foot, for booth Wallstand and Table.

The operator sets the size of the stitching area (the composite image) by positioning the light field.

Note!

A patient protection shall always be used at Wallstand examinations when performing stitching examinations.

For detailed information about the stitching operation, see the Operator's Manual.

Exposure Validation

It is only possible to perform an exposure when the System is ready;

- indication light is fixed
- generator is enabled.

The exposure will be blocked and the user needs to activate the start button once more if; a new parameter setting is received, the System is moved out from the start position, a collision when moving, patient position removed, or collimator size is changed.

3.2.8 Hospital manual

The hospital manual is reached by a activating the *Hospital manual* button for 1 second.

The hospital manual is selectable when a method book has been loaded to the display (performed by service engineer)

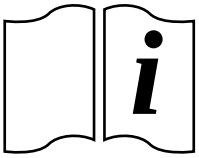


Fig. 3-23 Hospital manual button

3.2.9 Selection of Technique Mode

There are three different technique modes available that are selected by pushing the *Technique mode selection* button. The selected mode is highlighted and the pop-up window closes automatically.

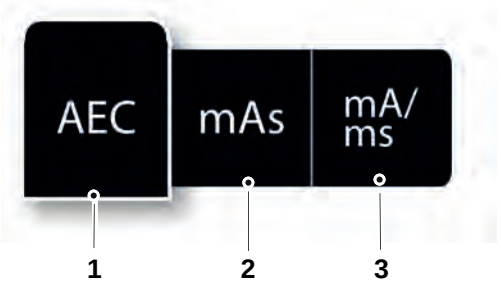


Fig. 3-24 Technique mode selection

1. AEC mode
2. mAs mode
3. mA/ms mode

Depending on what mode is active, different parameters will be available. Parameters not available for selection will be grayed out, see the *mAs selection* button in Fig. 3-25 *mAs selection button grayed out*, below.

In *AEC mode* the value that will be used as back-up value (ms, mAs or fixed), is indicated with the text *AEC Backup*.

CAUTION!

For avoiding unnecessary radiation, make sure that the AEC back-up values are properly defined.

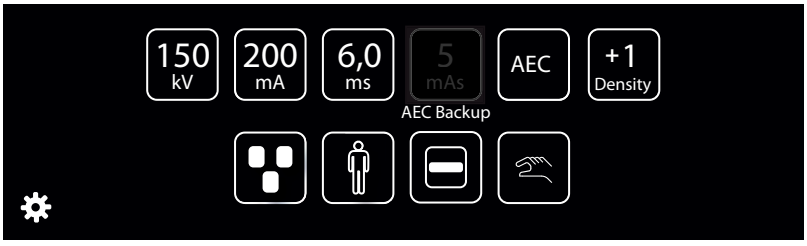


Fig. 3-25 mAs selection button grayed out

For more detailed information about the different technique modes, please see Operator's Manual for Canon single console CXDI NE.

3.2.9.1 Selection of Active AEC Field (AEC Mode Only)

The *AEC field selection* button is available in *AEC mode*.

When selecting the *AEC field* button, a pop-up-window with the different AEC fields according to Fig. 3-26 *AEC field selection*, will appear. The *AEC fields* are activated by a selection in the pop-up window to the right (2). All activated *AEC fields* will be shown in the left picture (1). *AEC fields* are deactivated by selecting them again in the pop-up window (2).

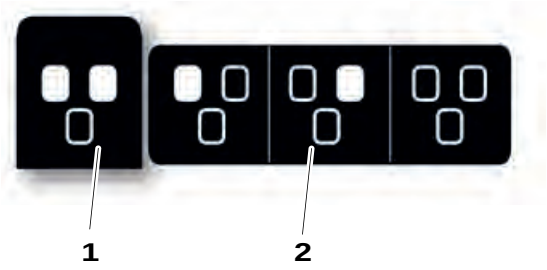


Fig. 3-26 AEC field selection

3.2.10 Patient Size

The *Patient size setting* is used for a quick setting of the generator parameters to suit the physique of the patient.

Patient size is adjusted by pressing the *Patient size selection* button. A pop-up window, according to Fig. 3-27 *Patient size selection*, will open and show available patient sizes.

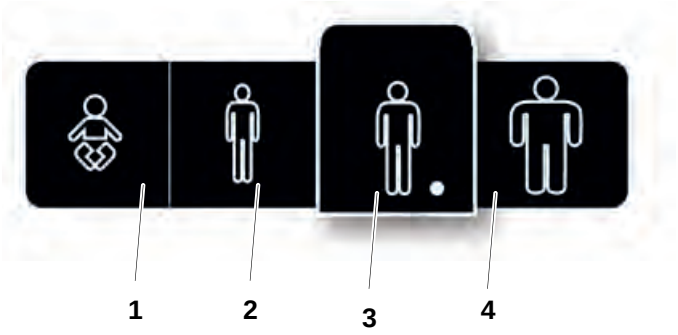


Fig. 3-27 Patient size selection

1. Paediatric
2. Small
3. Medium
4. Large

Select the desired *Patient size*. The pop-up window will automatically close shortly after the selection.

Note!

The generator parameters and the collimator settings (field size and filter) will change to the defined values for the new Patient size.

If no generator parameters or collimator settings are defined for the new Patient size (defined in APR), the current values will be kept.

Note!

At the stitching procedure, a change of the Patient size for the first included image in the sequence, will not be kept for the following included images.

3.2.11 Collimator Centering

The collimator light field size can be top or bottom centered against the maximum image area.

This means that the upper border of the collimator light field is aligned with the top of the maximum image area, or that the lower of the collimator light field is aligned with the bottom of the maximum image area. The stand will automatically move to keep the alignment of the top or bottom of the maximum image area when the collimator light field is increased or decreased.

The functionality of top and bottom centring is only available in *Wall mode* or *Wall Flexible mode*

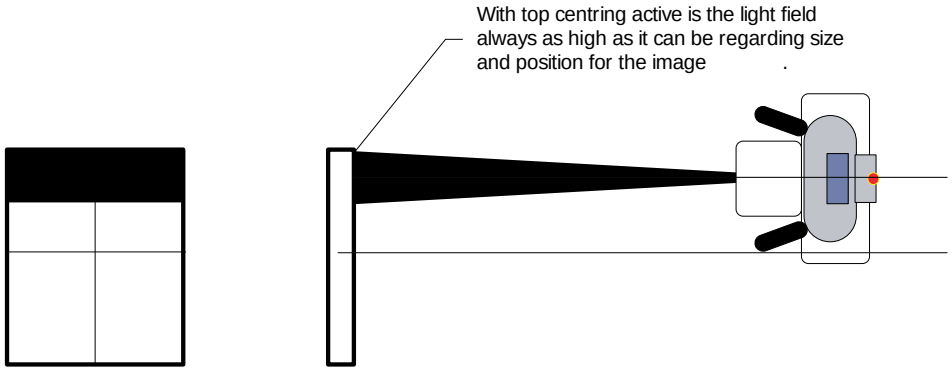
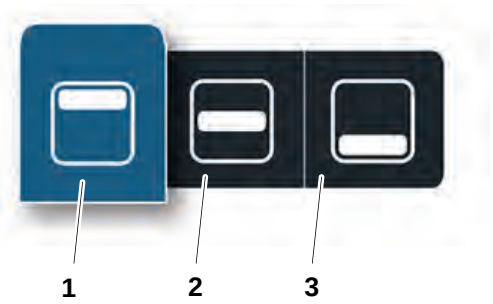


Fig. 3-28 Top and bottom centering of the collimator light field

The collimator centering is adjusted by pressing the *Collimator centering* button.

A pop-up window according to Fig. 3-29 *Collimator centering selection*, will appear with the alternatives *Top centering*, and *Bottom centering*. Select the desired collimator centering.

The pop-up window will automatically close shortly after the selection, and the light field will adjust accordingly.



1. *Top*
2. *Center*
3. *Bottom*

Fig. 3-29 Collimator centering selection

3.2.12 Servo State Mode

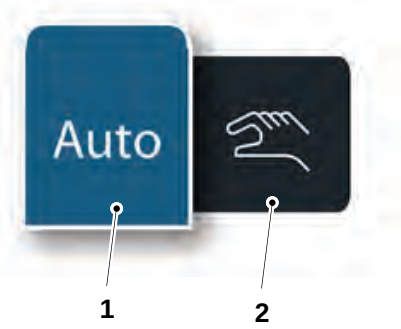


Fig. 3-30 Servo state mode

1. Automatic mode
2. Manual mode

The Servo state can be either *Automatic mode* (1) or *Manual mode* (2).

A pop-up window according to Fig. 3-30 *Servo state mode*, will appear with two alternatives. When the System is in *Manual mode* all movements are allowed and exposure can be performed in any position, also outside the detector.

For further information about *Manual mode*, see corresponding section.

3.2.13 Grid Status

The grid status is indicated in the OTC display and in the Canon NE user interface for guidance. There is also a pop-up window appearing in the Canon NE user interface if grid status needs to be adjusted.

It is possible to perform exposure without adjsuting the grid status according to the information in the pop up window. Please note that performing exposure with incorrect grid status might affect the image quality negative.

The grid status is shown in the upper right corner of the Canon NE user interface.

When the correct grid is attached the grid name is written with black letters, see Fig. 3-32.

When a grid is not needed for the examination "Removed" is shown with black letters in the same location, see Fig. 3-32.

When a correction of grid status is needed this is indicated with red text in the Canon interface, see detailed description in Table 3-1 *Grid status*

Fig. 3-31 Canon NE user interface. Grid data displayed.

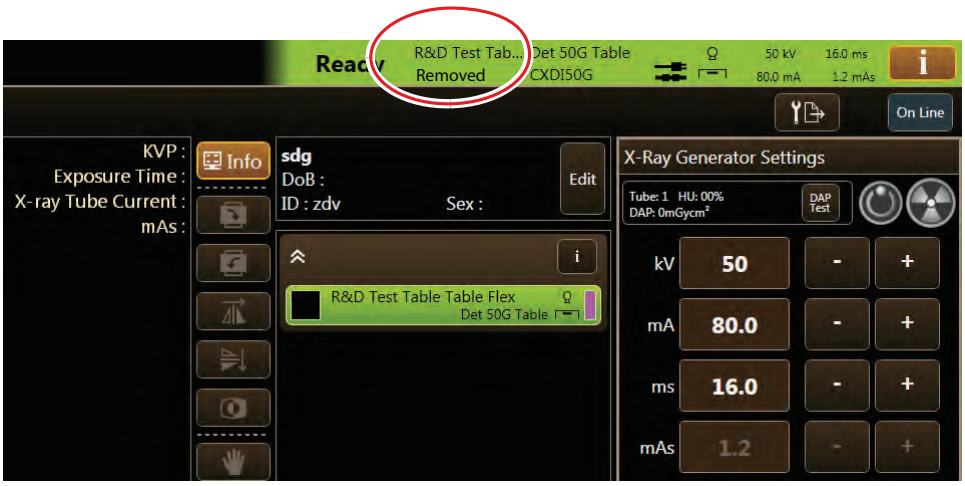


Fig. 3-32 Canon NE user interface. Grid removed.

Table 3-1 Grid status

OTC display	Message Canon NE user interface	Description	User Action
	Removed	INSERT GRID Pop up window in Canon will guide to insert the correct grid defined for the selected protocol.	Insert grid. Grid shall be used for this examination.
	Example: 180cm_10:1_52 lp/cm	REMOVE THE GRID Pop up window in Canon will guide to remove the grid.	Remove the grid. No grid shall be used for this examination.
	Example: 115cm_10:1_52 lp/cm	CHANGE GRID Pop up window in Canon will guide to exchange the grid inserted to the requested grid according to the protocol.	Wrong grid inserted (name of the attached grid shown in Canon). Change to the correct grid.

3.2.14 System Mode

The System has a number of different modes. All modes are described below with their special functionalities and features.

Note that depending on the particular System, different modes and actual configurations are available.

- *Free mode*
- *Auto position mode*
- *Wall flexible mode*
- *Table flexible mode*
- *Film tracking mode*
- *Pendulum mode*, Table
- *Stitching mode* (toward the Table and Wall stand)

3.2.14.1 Free Mode

General Description

The *Free mode* is the most basic mode in the System.

The mode holds no special features or functionality. It is intended as a manual mode with a lot of freedom in positioning and exposure, e.g. for emergency examinations or examinations with the patient in a wheel chair or lying in a bed. This mode is available in all Systems.

The distance shown in display for *Free mode* is the distance to the floor.

Exposure Validation

Exposure is allowed if the stand is not moving and operating properly (not in an error state).

3.2.14.2 Auto Positioning Mode

General Description

The *Auto position mode* functions as the *Free mode* with the added functionality of automatic positioning in the room.

Automatic positions are a number of positions that can be programmed and saved into the System. The stand will upon activation of the servo button, move to the programmed position chosen from the imaging unit.

The mode is intended as a flexible, easy to use mode. The mode can also be used as a parking mode.

The distance (H) shown in display for *Auto position mode* is the distance to the floor.

Exposure Validation

Exposure is allowed if the stand is not moving and operating properly (not in an error state). The chosen position must have been reached successfully.

3.2.14.3 Wall Flexible Mode

General Description

The *Wall Flexible mode* is intended for examinations toward a Wallstand.

The OTC will upon activation of the servo button move to the programmed position associated with *Wall mode*. The stand will stop at the transport height and wait for a change in position of the Wallstand (detector height). When a change in position is detected (the user moves/drives the Wallstand up or down) the OTC will move downward and start tracking the position of the detector.

The value is constantly updated as soon as the Wallstand/OTC is moved. It is possible for an operator to change the position so the value cannot be calculated or would be incorrect; in those situations the display will clear the field for the value.

No Wait

At the installation of the System it is possible to select, that the OTC shall not wait for the user to move the Wallstand before tracking starts. The OTC will then start the tracking as soon as it reaches its final position.

Exposure Validation

Exposure is allowed if the stand is not moving, operating properly (not in an error state) and the servo button is activated.

3.2.14.4 Table Flexible Mode

General Description

The *Table flexible mode* is equal to *Auto positioning mode* with functionality added for tracking the height of the Table (compare with Wall flexible mode). The mode is intended for Table examinations.

The stand will upon activation of the servo button, move to the programmed *Table mode* position and start tracking the Table height, thereby keeping the film focus distance constant. The *Film focus distance* shown in the display is the actual distance to the detector. The Table position in the room is set during the installation of the System.

Exposure Validation

Exposure is allowed if the stand is not moving, operating properly (not in an error state) and the servo button is activated. Movement is allowed in X and alpha direction.

3.2.14.5 Film Tracking Mode

General Description

The *Film Tracking mode* functions as the *Table mode* with added functionality for controlling the position of the detector in one direction. The mode is intended for fast and easy positioning with the X-ray tube always aimed at the center of the detector.

The motorized detector holder will move the detector to the right position. The stand will upon activation of the servo button move to the pre-programmed *Film-tracking position* and start tracking the Table height, thereby keeping the film focus distance constant. The film focus distance shown in the display is the actual distance to the detector. When *Film Tracking mode* is chosen all buttons except X and alpha-brake buttons will be deactivated. The tube stand is operated manually by releasing one or both of the brakes. The position of the detector is changed according to the change in X and or alpha position of the tube. That is the X and alpha positions can be changed independently.

Exposure Validation

Exposure is allowed if the stand is not moving, operating properly (not in an error state), the X-ray tube is aimed to the center of the detector and the servo button is activated.

3.2.14.6 Pendulum Mode, Table

General Description

The *Pendulum mode* can be seen as a variation of film tracking.

The X-ray tube is always aimed at the center of the detector. The alpha angle of the tube and the position of the detector changes according to the change in X-position of the tube stand. Also *Pendulum mode* incorporates all the functionality of the more simple Table mode. The mode is intended for fast and easy positioning with the X-ray tube always aimed at the center of the detector.

For moving and controlling the position of the detector, a motorized detector holder is required. The stand will upon activation of the servo button move to the programmed position associated with the *Pendulum mode* and start tracking the Table height, thereby keeping the film focus distance constant.

All table handle bar buttons, except (move left) and (move right) buttons, will be deactivated when the *Pendulum mode* is activated. The X-position of the stand is controlled by these two buttons and thereby also the detector and the alpha angle of the tube.

Exposure Validation

Exposure is allowed if the stand is not moving, operating properly (not in an error state), the X-ray tube is aimed to the center of the detector and the servo button is activated.

3.2.14.7 Stitching Mode

General Description

Stitching is the process of combining multiple images with overlapping fields of view to produce a larger image.

When imaging long parts of the human body, there is need for an image with extended length. In digital radiography the image size is limited due to the sensitive area of flat-panel detectors. In order to produce a large image, images are assembled from multiple exposures with a small, spatial overlap.

Stitching is possible at both Table and Wallstand.

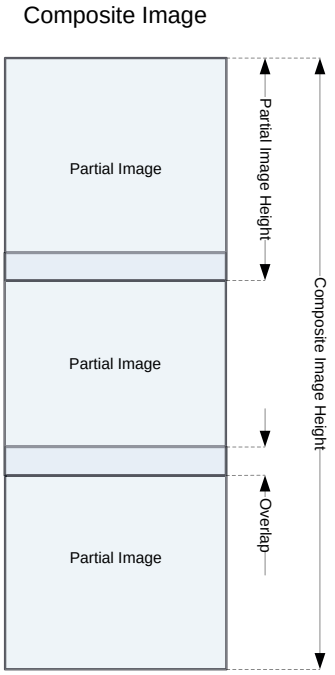


Fig. 3-33 Stitching, schematic description

Wallstand/Table Stitching

The user must define the area that shall be captured in the stitching sequence.

When choosing *Stitching mode*, new information will be present on the manoeuver handle; high (left) position, low (right) position, total length and number of exposures. The tube support moves to the pre-defined position for X, Y, Alpha, Beta and Wallstand (detector holder for TableStitching). Z moves to the position received from the Image system (*SID value for TableStitching*).

To start the stitching procedure, press *Start exam*.

The movement for stitching is:

- From head to foot, for booth Wallstand and Table.

The operator sets the size of the stitching area (the composite image) by positioning the light field.

Note!

A patient protection shall always be used at Wallstand examinations when performing stitching examinations.

For detailed information about the stitching operation, see the Operator's Manual.

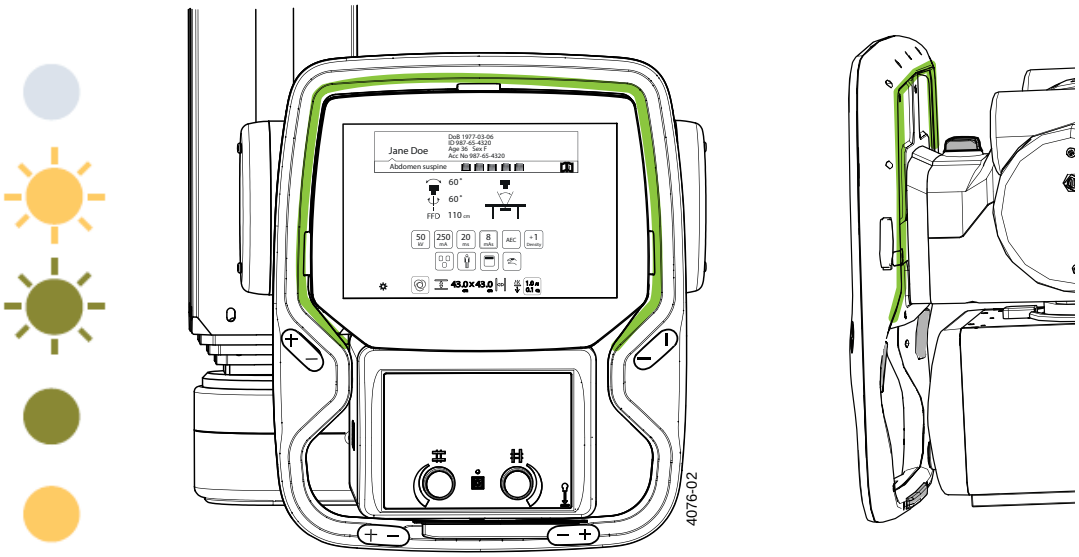
Exposure Validation

It is only possible to perform an exposure when the System is ready;

- indication light is fixed
- generator is enabled.

The exposure will be blocked and the user needs to activate the start button once more if; a new parameter setting is received, the System is moved out from the start position, a collision when moving, patient position removed, or collimator size is changed.

3.2.15 Light indication



There is a light indication available around the overhead tube display.

- No light — Between examinations
- Yellow flashing — Action needed by the user or system is moving
- Green flashing — System is ready for exposure
- Green fixed — Preparation (before exposure)
- Yellow fixed — Exposure

3.3 Exposure

CAUTION!

The operator is responsible for validation of the exposure parameters before performing an exposure.

3.3.1 Exposure Hand Control

A. Exposure control in normal position.
B. Exposure control in preparation position.
C. Exposure control in exposure position.

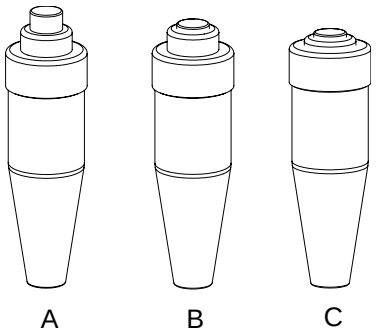


Fig. 3-34 Exposure hand control

3.3.2 Exposure Index

After exposure the Exposure Index (EXI) and Deviation Index (DI) will be shown in the image, in order to indicate the dose level. See further description of the indexes below.

The exposure index, is a measure of the amount of exposure received by the detector and depends on mAs, the total detector area irradiated respective the beam attenuation. It is indicative of the image quality.

3.3.3 Deviation Index

The deviation index, DI, gives an indication of the dose level used for capturing the image. The DI value compares the current standard EXI with the target EXI.

The target EXI is defined by the user. See Imaging system for further description.

3.4 Image System

For information about Image system functions, see the Image System Manual.

3.5 Remote control (option)

WARNING!

The System must always be supervised when activated.

Note!

The remote control shall only be used inside the examination room.

Note!

Always mark up the remote controls with, for example, the room number or the system number. Use the enclosed labels to distinguish different system remotes, from each other.

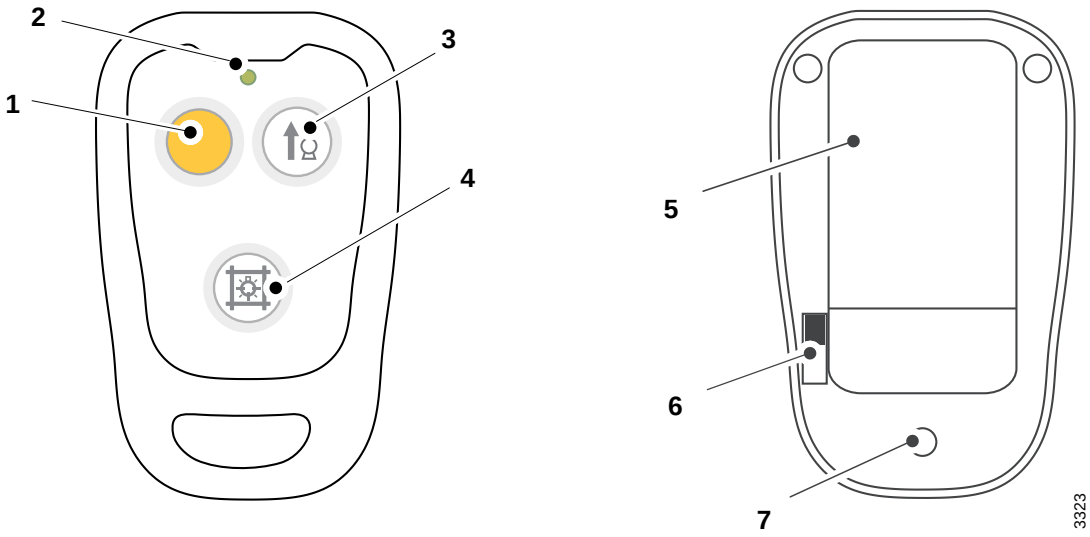


Fig. 3-35 Remote control, front and back

Front

1 Servo button – (yellow)

2 Indication diode (green)

3 Tube up

4 Switch On/Off Collimator light

Back

5 Fastening clip

6 On/Off switch

7 Battery changing slot

Servo button

The servo button is yellow with a little peg, making it easy to recognize the button.

When activating the yellow servo button, the OTC moves to auto-position.

Indication diode

The diode shows a green light, when the remote control button is activated. When the diode turns red, the batteries shall be exchanged.

Tube up

When the *Tube up* button is activated, the OTC will move upward. The movement will stop at button is release or when the highest possible position is reached.

Switch On/Off collimator light

The button turns the X-ray field illumination and linear light localizer on/off.

Automatic switch-off via a time switch.

On/Off switch

There is an On/Off switch for the remote control, at the back of the remote control. When the control is switched off, all buttons are disabled.

Battery changing slot

When the indication diode lights red, changing of battery is needed.

The remote control uses 2 pcs of LR03, 1.5V, AAA batteries. To change batteries, loosen the 3 screws and open the slot at the back of the remote control.

Note!

The batteries shall be recycled.

3.6 Servo Button

When the servo button is activated, the OTC and Wall stand detector (depending on system setup) automatically starts positioning (excluding *Free mode*). If the servo button is released, the movement stops and a manual movement of the stand is possible.

When a new protocol is chosen or if the OTC is manually moved from the position, the OTC automatically starts moving to a predefined position when the servo button is activated.

The servo button is available on the external servo button module, the Wall stand hand control, and on the remote control (option). The system status is indicated by indication light on the external servo module and at the OTC.

3.6.1 External Servo Button Module

The external servo button module holds a servo button and an emergency stop. The servo button is equipped with an indication light showing the system status. See Fig. 3-36.

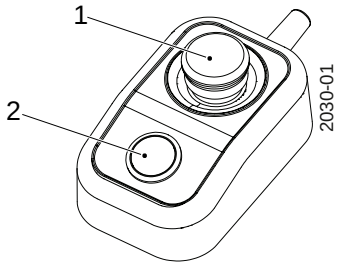


Fig. 3-36 External servo button module

1. Emergency stop
2. Servo button and Indication light

3.6.2 Indication Light

WARNING!

Due to the squeezing hazard, motorized movements are only allowed if patient and System are observed by personnel.

The Indicator light has 3 different modes:

- *Fixed light* - The System is in position and ready for exposure. Supervision of the patient and System is required.
- *Flashing light* - Attention. The System is performing an action, for instance manoeuvering to start position or waiting for action.
- *No light* - the chosen mode is not activated. No light is shown in *Free mode*.

See also 3.2.15 *Light indication*.

3.6.3 DAP

If a DAP meter is included the System, the Dose Area Product will be presented in the Imaging system.

Checks and settings can be done by the service software, see *'Installation and Service Manual'*, Chapter *5, Installation.*

3.7 Table Control elements

3.7.1 Directions of Movement

The figure below shows the directions of the table movement.

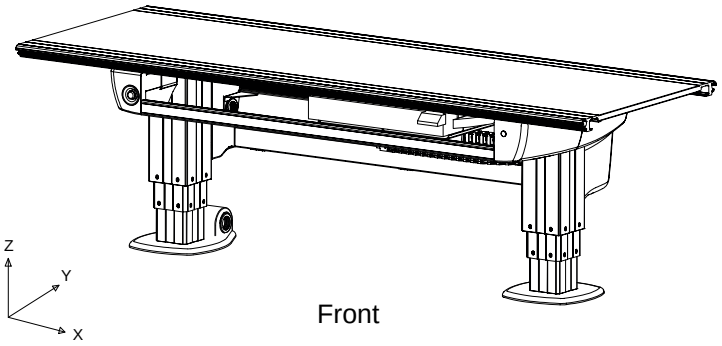


Fig. 3-37 Directions of movement, Table

Z Vertical movement

Y Lateral movement

X Longitudinal movement

3.7.2 Power Indication

The green light indicates that the System is active.

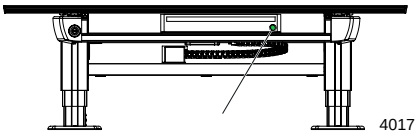


Fig. 3-38 Power indication light

3.7.3 Foot Control, Table X/Y/Z (option)

The foot control can be used for adjusting the table top height and for releasing the floating table top.

Consider the working area when the table top is manoeuvred.

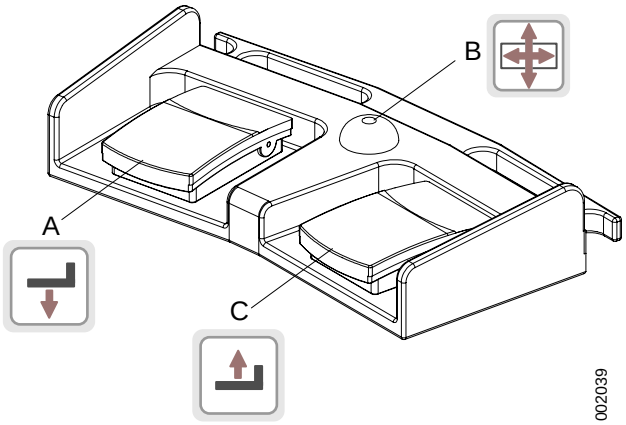


Fig. 3-39 Foot control

A. Z movement down
B. Unlock table top brakes (X/Y)
C. Z movement up

3.7.3.1 How to Manoeuver

A. Press button to move the table top downwards.
B. Press the button to release the brakes on the table top, Y and X. On activation, the table top can be moved manually.
   When the release button is activated, the collimator light will be lit.
C. Press button to move the table top upwards.

3.7.4 Foot control, wireless (option)

CAUTION!

It is important to assure that the correct control is activated, as there is one foot control for the table and one for the wallstand,

The foot control can be used for adjusting the table top height and for releasing the floating table top.

Consider the working area when the table top is manoeuvered.

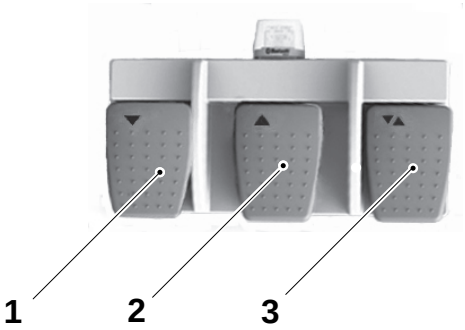
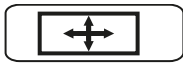


Fig. 3-40 Wireless foot control.

1. Z movement down 
2. Z movement up 
3. Release pedal:

 Unlocks wallstand detector brake. Manual movement is possible.

 Unlocks table top. Manual movement is possible, table top is floating.

3.7.4.1 How to Manoeuver

1. Press pedal to move downward.
2. Press pedal to move upward.
3. Press the pedal to release the brakes. On activation, the table top or the wallstand detector holder, can be moved manually.

   When the release pedal is activated, the collimator light will be lit.

Note!

The foot control must not be used outside the examination room.

The device has no applied parts and should not be accessible to patients.

3.7.4.2 Battery

The yellow battery indication LED will begin to flash once every two seconds, when the remaining battery capacity is approximately 1 week of constant use, or 168 hours. It will then change to 2 flashes per second when the capacity has been reduced to approximately 2 days, or 48 hours.

3.7.5 XY Foot Control, Strip Type (Option)

Press and hold the foot control strip type (1) to release the brakes (X, Y) on the table top (2). When activated, the table top can be moved manually (floating table top).

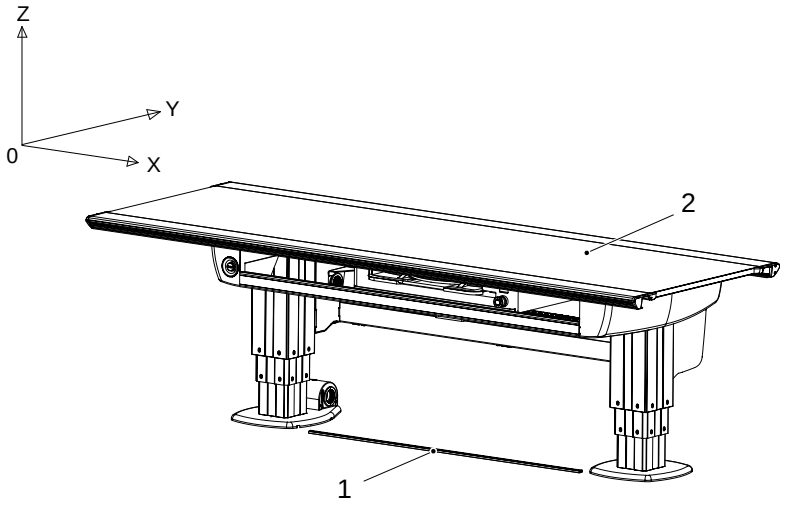


Fig. 3-41 Foot control strip type

1. XY foot control strip type (option)
2. Table top (X/Y)

3.7.6 Table Hand Control

Beside the functions for moving the table top, the hand control also has functions for; moving the imaging unit and performing a pendulum movement..

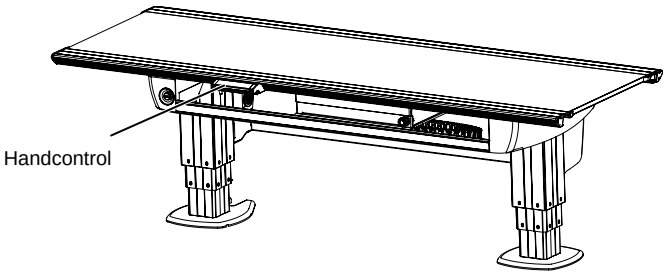


Fig. 3-42 Table hand control location

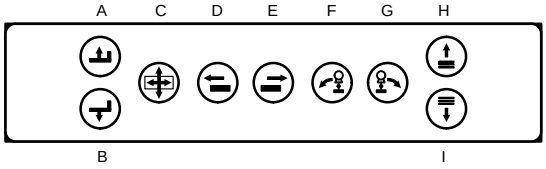


Fig. 3-43 Table hand control

3.7.6.1 How to Manoeuver

A. Press button to move the table top upwards.
B. Press button to move the table top downwards.
C. Press the button to release the brakes on the table top, Y and X. When activated, the table top can be moved manually.
D. Drive motorized image receptor holder to left.
E. Drive motorized image receptor holder to right.
F. Move the OTC to the left in *Pendulum mode*.
G. Move the OTC to the right in *Pendulum mode*.
H. Not used.
I. Not used.

3.7.7 Moving Table Top

To manually move the table top, release the brakes and use the hand grip rails located at the long sides of the table top.

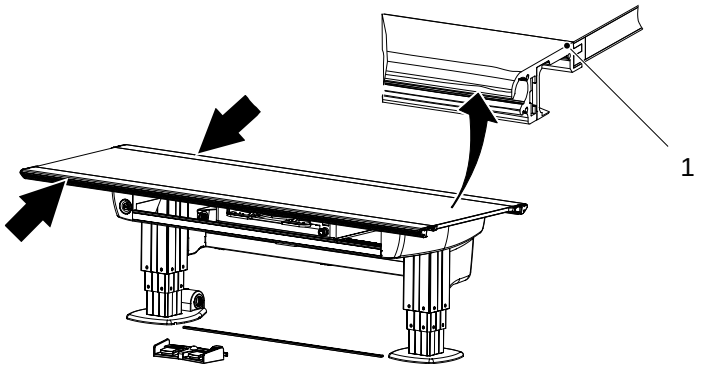


Fig. 3-44 Table hand grip rail

1. Hand grip rail

3.7.7.1 Directions of Movement

The figure below shows the directions of the table movement.

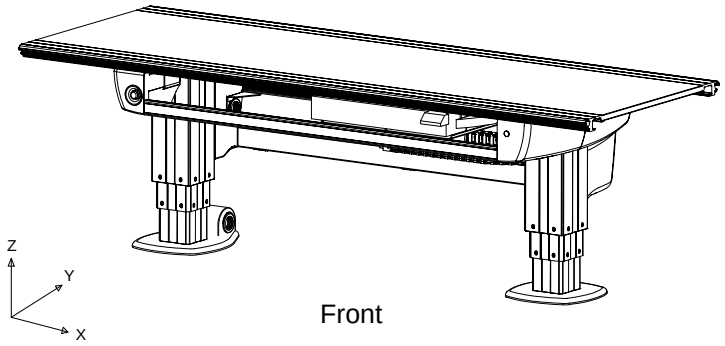


Fig. 3-45 Directions of movement, Table

Z Vertical movement

Y Lateral movement

X Longitudinal movement

3.7.8 Vertical Travel Safety (option)

The Table may, as an option, be equipped with a vertical travel safety system that protects the table top.

It activates if a collision is detected and the force exceeds 20 kg, all movements will be stopped.

3.7.9 Attach/Remove Accessories

Accessories are attached and removed as shown in the figures below. This instruction is valid for all accessories attached to the table top.

Attach

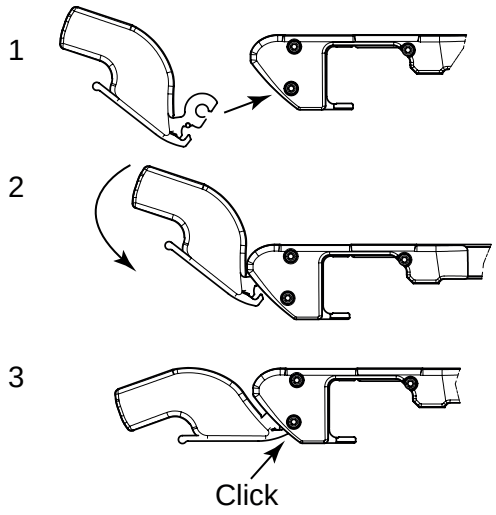


Fig. 3-46 Attaching accessories

Remove

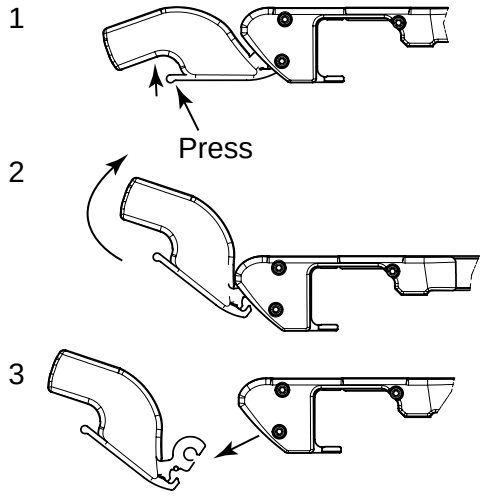


Fig. 3-47 Removing accessories

3.7.10 Motorized Imaging Unit Movement

The imaging unit can be moved in X direction motorized. The motorized movement is manoeuvred from the table hand control, see Fig. 1-4 *Table overview*.The function can synchronize the imaging unit and follow the movement of the ceiling unit.

3.7.10.1 Synchronization Function

In Auto position mode and in Table flexible mode, the detector holder may be moved in X-direction using the motor (via the table handle or manually by activating the green button at the detector holder). There is no synchronization between the tube and the table detector.

In Film tracking and Pendulum mode the detector holder may be moved manually in X-direction. If this is done, the servo button will be deactivated and exposure is no longer possible. To return to an activated servo button, the detector holder shall be moved to the correct position. The correct position will be indicated by the lightning of the green detector holder button.

Note!

It is the user's responsibility to verify that the detector is in position at exposure.

3.8 Wall stand Control Elements

3.8.1 Wall stand Controls

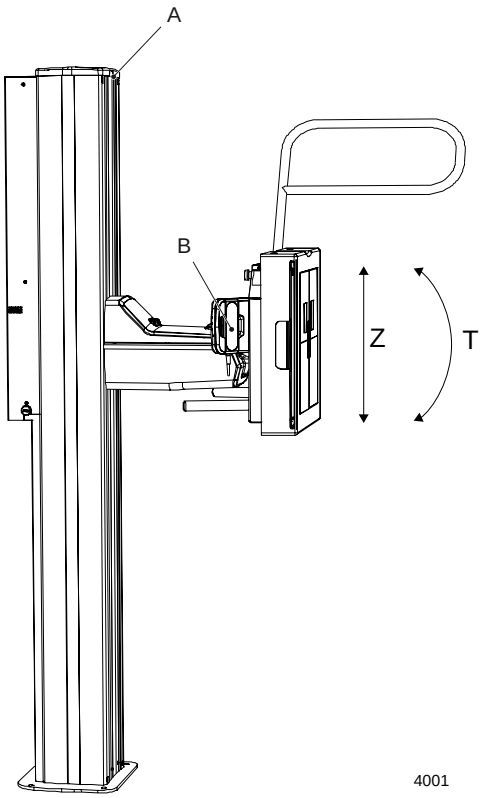


Fig. 3-48 Wall stand, direction of movement

Z Vertical movement

T Tilting movement

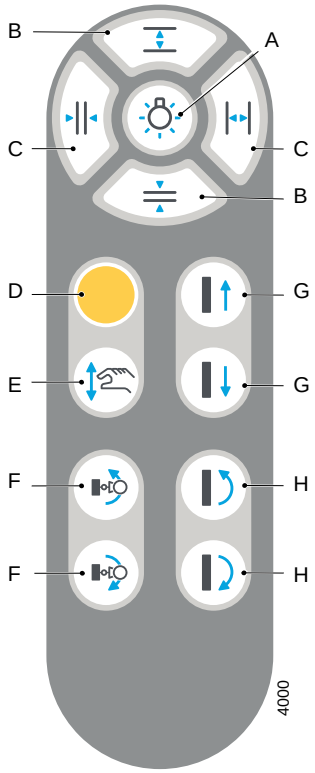
A Light indication (lit when the wallstand is selected as a work station)

B Hand control:
Adjustment of the automatic collimator, vertical movement of the detector, rotation of the detector and activation of pendulum mode.

The wall stand detector is tilted by activation of the hand control. The detector can be tilted -20 to + 90°.

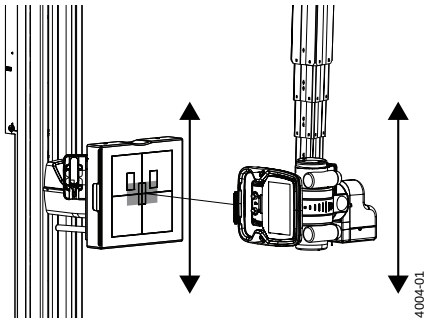
3.8.1.1 Wall Stand Hand Control Unit

Hand control



A. Collimator light on/off
B. Adjustment height collimation
C. Adjustment width collimation
D. Servo button, see 3.6 *Servo Button*
E. Break release for manual movement of detector
F. Pendulum mode wall stand
G. Detector up/down, Motorized
H. Detector tilt and OTC tracking, -20 to 90°

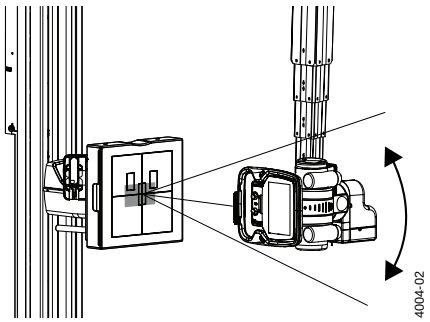
Fig. 3-49 Hand control



Up/down

- Button G, Motorized

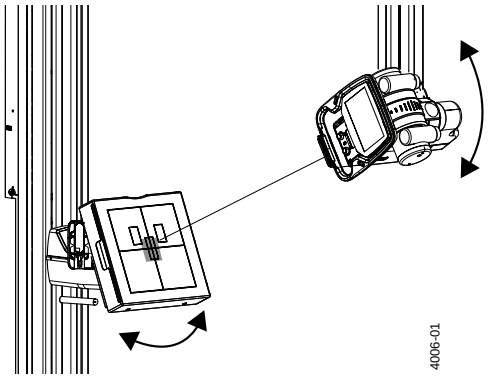
  OTC tracking wall stand detector when auto-position active
- Button E, Manual



Pendulum mode wall stand

- Button F

  The OTC performs a pendulum movement in order to find correct angulation of the central X-ray



Tilting -20° to 90°

- Button H, Motorized Tilt

  OTC tracking wall stand detector when auto-position active
- Button E, Manual

Note!

Armrest has to be removed to allow tilt movement.

3.8.1.2 Light Indication (A)

The selected Workstation is indicated in the imaging system and with a green light on the Wallstand.

3.8.1.3 Wall stand Foot Control for Vertical Movement

The Wall stand with motorized vertical movement is manoeuvred from the foot control. The foot control is a control unit for Wall stand with motorized vertical movement.

Consider the working area when the Wallstand detector is manoeuvred.

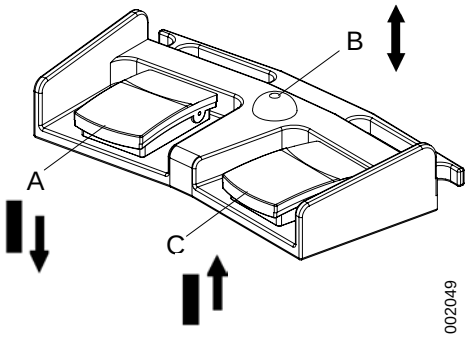


Fig. 3-50 Wallstand foot control manoeuvering

A Z movement down.

B Brake release manual movement

C Z movement up

How to Manoeuver

A. Press the pedal to move the detector downwards.

B. Press the pedal to release the brakes. When activated, the detector can be moved manually.

C. Press the pedal to move the detector upwards.

4 Operating the System

4.1 General

WARNING!

Always be aware of that there may still be power in the System and live parts accessible even though the system is turned off.

CAUTION!

The Detector should be powered up at least half an hour before intended use. If it is used sooner than half an hour after being powered up, image quality may be affected

4.1.1 Applied Parts

Applied parts are intended for the patient to touch.

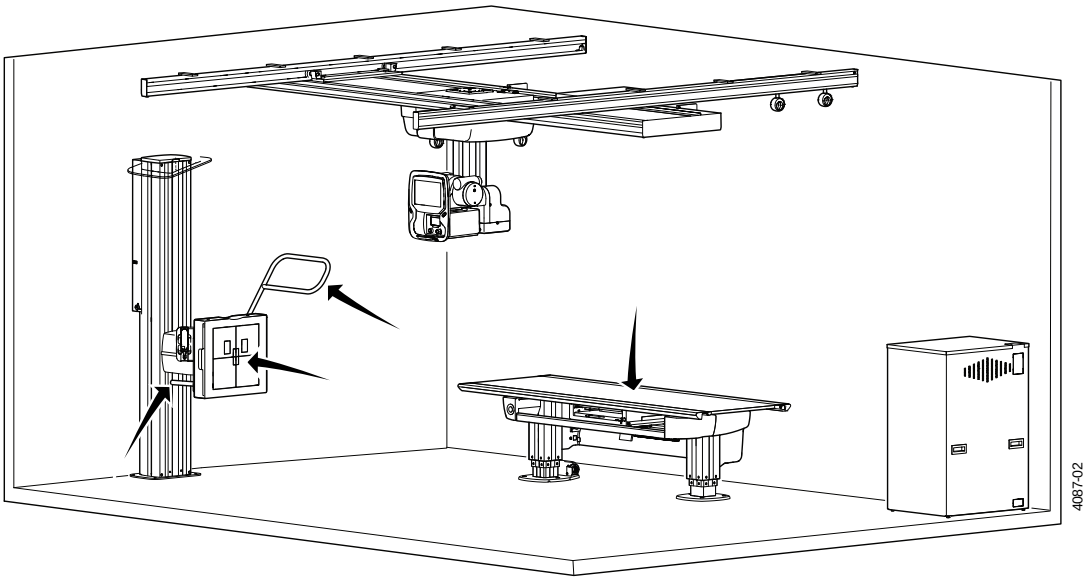


Fig. 4-1 Applied parts, System

4.2 Turn on the system

The system is ready for examination within two minutes after the system has been turned on.

- Before starting the system, check that the emergency stop is not activated.
  When the system starts up, light indications and displays are lit.
- Perform the following procedure when starting up the X-ray system:

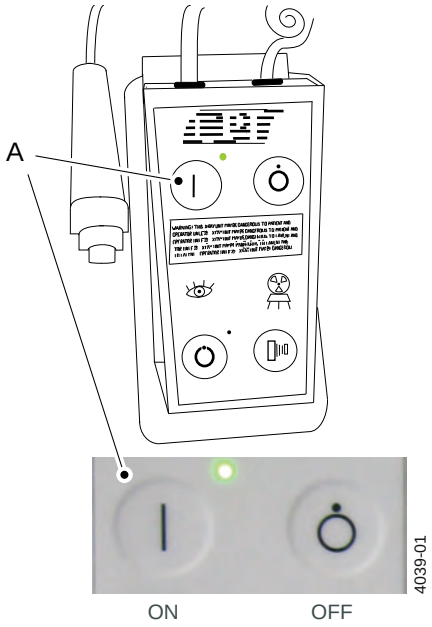


Fig. 4-2 Power on button – mini console

1. Press the power [ON] button (A) on the mini console.

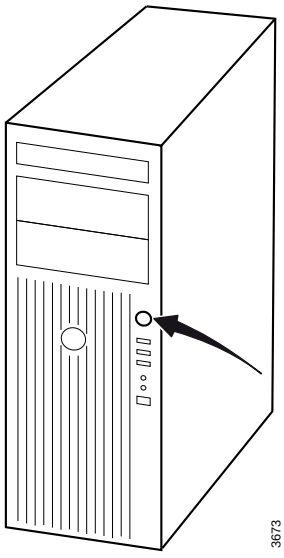


Fig. 4-3 Power button – image control unit

2. Press the power button on the computer.
3. Start the display.

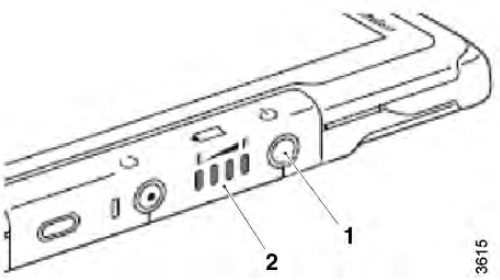


Fig. 4-4

4. Start the wireless detector (option), press the power button (1).
   The power-LED (2) lights with a fixed light.

Fig. 4-5

5. Log in on the computer.
6. Type user name and password, press Log in.

Fig. 4-6

7. Confirm that the image system has started normally by checking the status icons.

4.3 Turn off the system

Note!

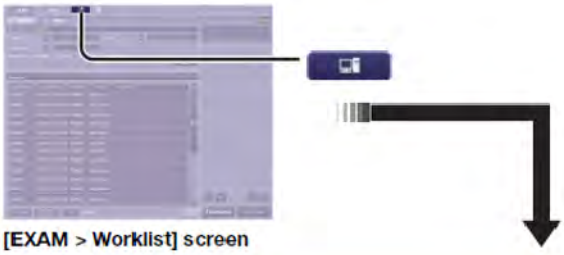
Wait for two minutes or longer after the examination is completed before turning OFF the power.

1. Move the OTC to a parking position, for example over the table.
2. Turn off the image system 

.

   Select 

.



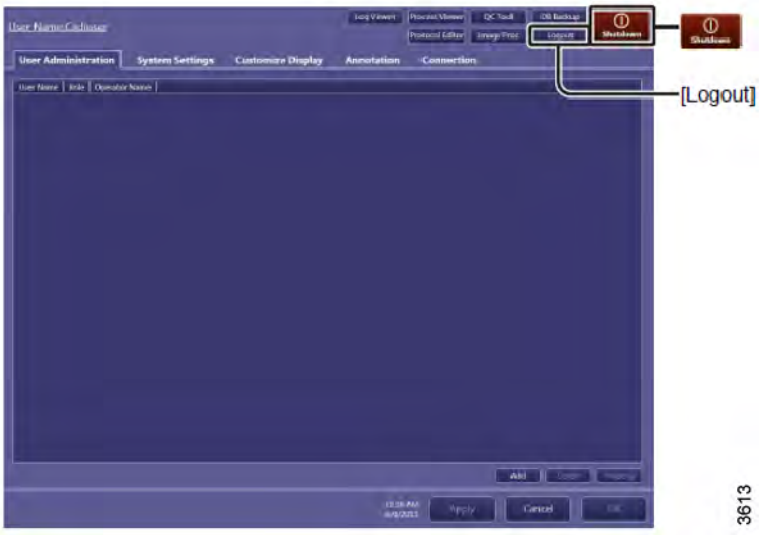


Fig. 4-7

Fig. 4-8

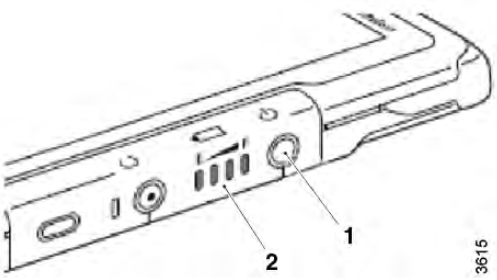


Fig. 4-9

3. Turn off the wireless detector (1).

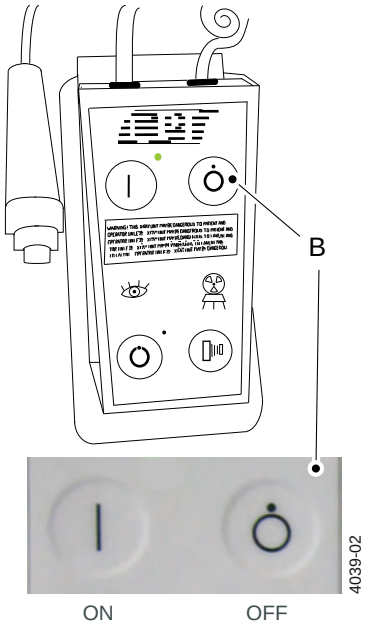


Fig. 4-10 Power button off – mini console

4. Press the power [OFF] button (B) on the mini console.

   It is possible to turn off the power to the X-ray system while the power to the image system is still on.

4.4 Perform examination

4.4.1 Select patient

1. Select [Exam] and [Worklist].

Fig. 4-11

2. Sort the list in [Search For Study List] and select patient.

4.4.2 Start examination

1. Select [Start Exam].
   Predefined protocols are activated automatically.
   Patient data can also be added manually, see Canon Operation Manual.

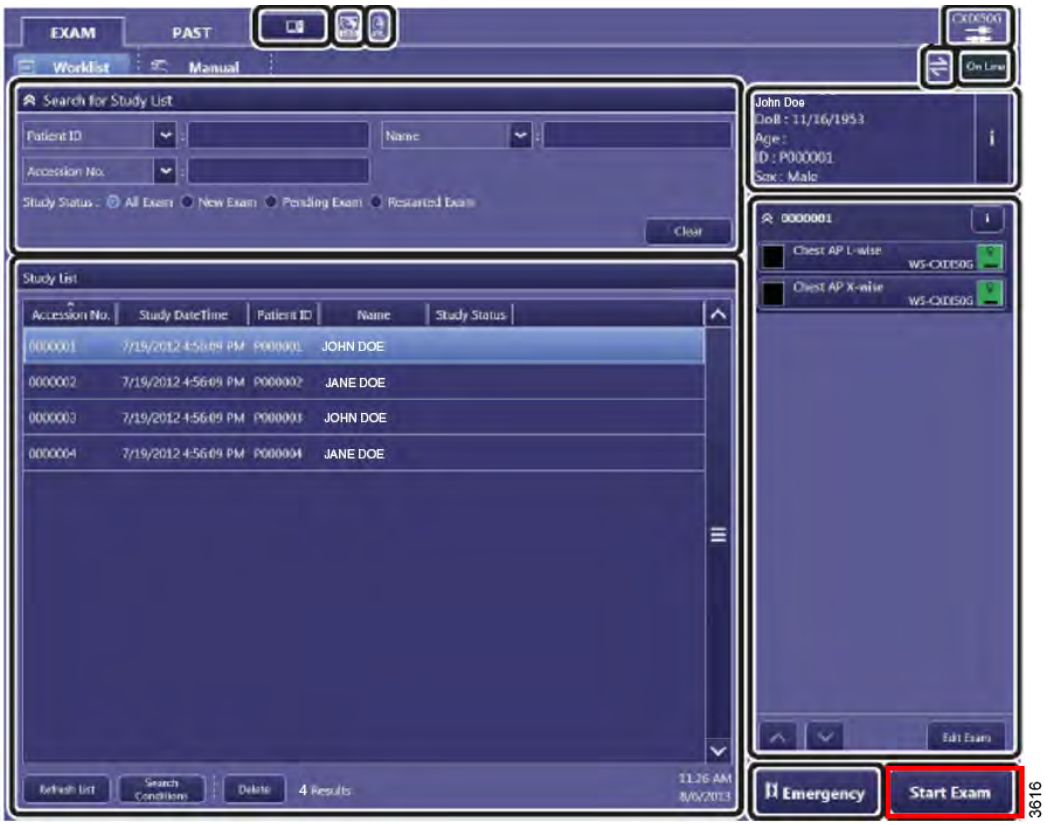
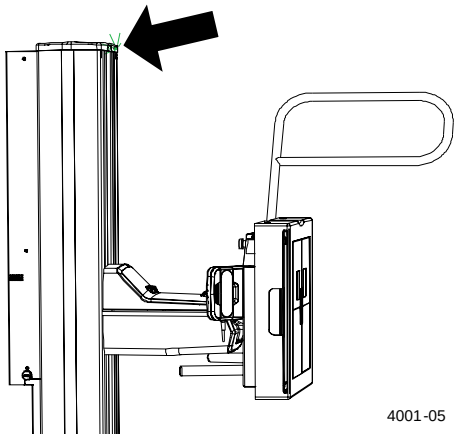


Fig. 4-12

2. The indication light will be lit on the selected workstation.



Wall stand indication light

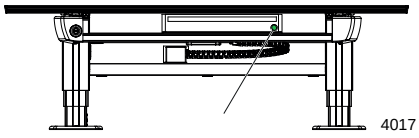


Table indication light

4.4.3 Position the system

1. Activate the servo button to position the system.

   The servo button is activated on the console, the remote control, or wall stand hand control.
2. The indication light around the OTC display indicates with a green flashing light that the sytem reached correct position.

Fig. 4-13 Indication light

4.4.4 Adjust position and collimator for chosen examination and patient

Adjust the position of the OTC, table top or wall stand according to:

- 3.1.1 *Direction of Movement*, Page 39
- 3.7 *Table Control elements*, Page 79
- 3.8 *Wall stand Control Elements*, Page 87

The light field should be reduced to the examination area. Adjust the collimator according to:

- 3.2 *Automatic Collimator Control*, Page 42

4.4.5 Exposure

WARNING!

Check that the settings of the SID (Source Image Distance) are accurate before the exposure.

WARNING!

Check that the selected workstation (wall stand, table) is connected and linked properly at the Examination Check screen of the image system before the exposure.

WARNING!

Check that the X-ray tube is set at correct position before the exposure.

CAUTION!

It is the responsibility of the user to ensure that the X-ray field is within the active detector area when exposing.

Note!

The operator is responsible for verifying the exposure parameters before exposure.

Check that the examination conditions are displayed on the image system without failure.

Exposures are done using either the hand control or the prep. and X-ray buttons on the operator console.

Exposure operator console in

A. normal position
B. preparation position
C. exposure position

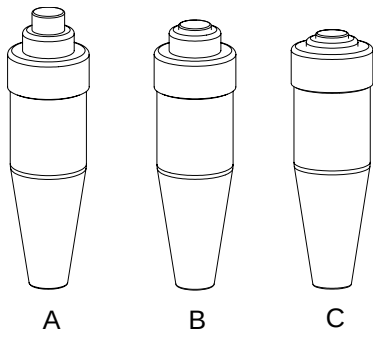


Fig. 4-14 Exposure operator console

Exposure operator console:

A. preparation exposure
B. exposure position
C. light indicating exposure

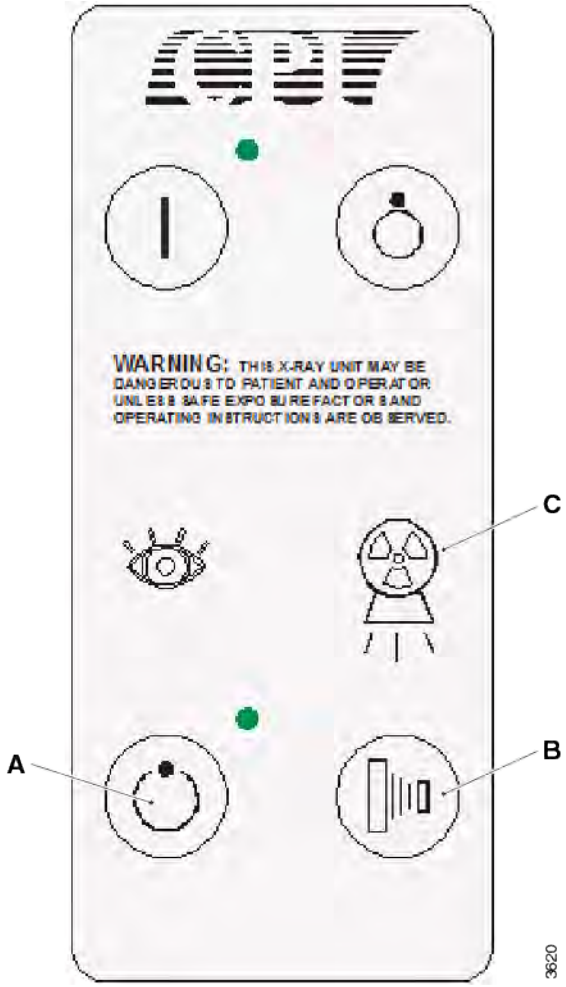


Fig. 4-15 Operator console

4.4.6 Review image

1. If the image is correct, select [End Exam] or continue examination if more images are planned.
2. If the image is not correct, select [Retake].
3. Type reject reason and retake image.

4.4.7 Change work space

1. Select [Protocol].

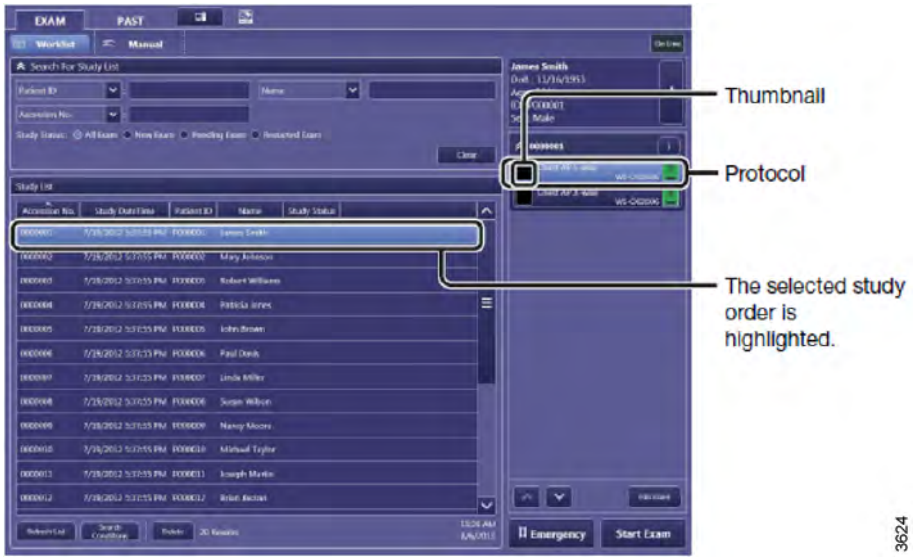


Fig. 4-16

2. Select detector or workspace.

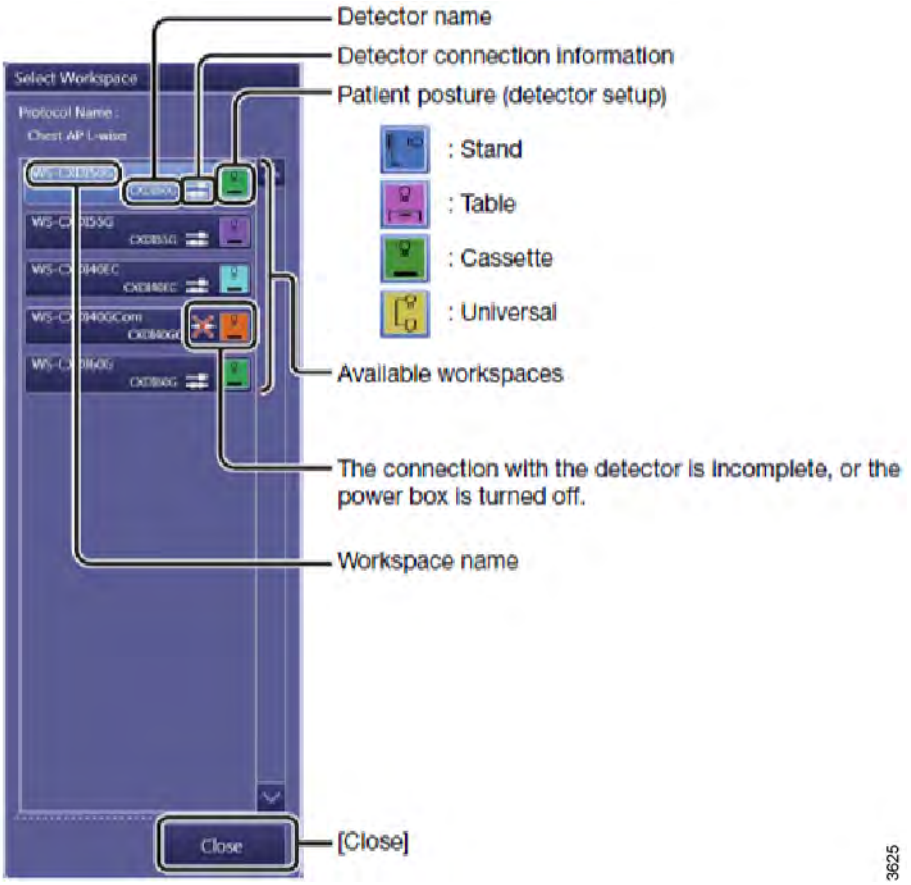

Detector name
Detector connection information
Patient posture (detector setup)
: Stand
: Table
: Cassette
: Universal
Available workspaces
The connection with the detector is incomplete, or the power box is turned off.
Workspace name
[Close]
Select Workspace
Protocol Name :
Chest AP L-wise
Close
3625

Fig. 4-17

4.4.8 Basic exposure error handling

Exposure not possible	Check	Measure
The small detector is selected (Green)	Is the small detector in the docking station?	Remove the small detector from the docking station.
Table examination	If the table is equipped with a wireless detector and charging the detector in the holder - check if the connector is correctly connected to the detector.	Connect the connector correctly to the wireless detector.
Table or wall stand	Is the indication light lit (yellow LED in the control room or green light on the OTC)?	Position the system correct by pressing the servo button on the remote control, the operators console or on the OTC. or Change from Auto to Manual on the OTC display if the patient/light field is in position (and you don´t want to reposition the OTC).
Table examination	Is the detector in the table detector holder?	Place the detector in the table detector holder, make sure to connect the connector correctly.
Wall stand examination	Is the detector in the wall stand detector holder?	Place the detector in the wall stand detector holder, make sure to connect the connector correctly.

4.5 Movement Short-cut Zones

A short-cut movement is defined as, when the OTC moves directly to the intended position, without first moving up into the transport interval zone.

Movement short-cut zones are defined both for the Table and the Wallstand, as rectangular cubes. (Short-cut zones can be defined by a servcie engineer)

To perform a short-cut movement, the following conditions must be fulfilled;

- The System shall be positioned above the Table, or at the specified short-cut zone in front of the Wallstand.
- At least one of the OTC corners must be inside the short-cut zone at the start of the movement.

  Outside these short-cut zones, the OTC will first move in Z direction, to the transport interval zone, before moving to position.

4.5.1 Wallstand Short-cut Zone

The Wallstand short-cut zone is defined in front of the Wallstand.

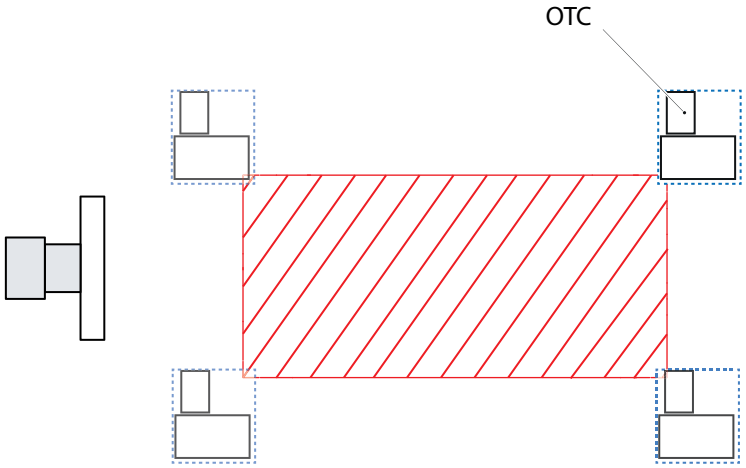


Fig. 4-18 Wallstand short-cut zone

4.5.2 Table Short-cut Zone

The Table short-cut zone is defined above the table top.

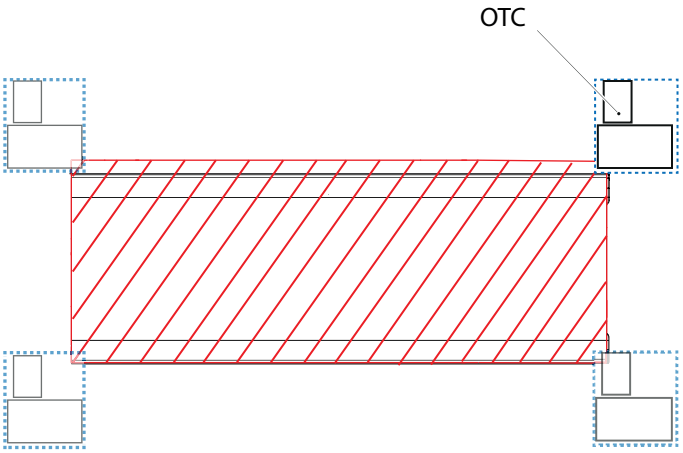


Fig. 4-19 Table short-cut zone

4.6 Transport Interval Zone

Outside the short-cut zones, movements between auto-positions are performed in a defined transport interval zone. The upper and lower limits are defined at System installation.

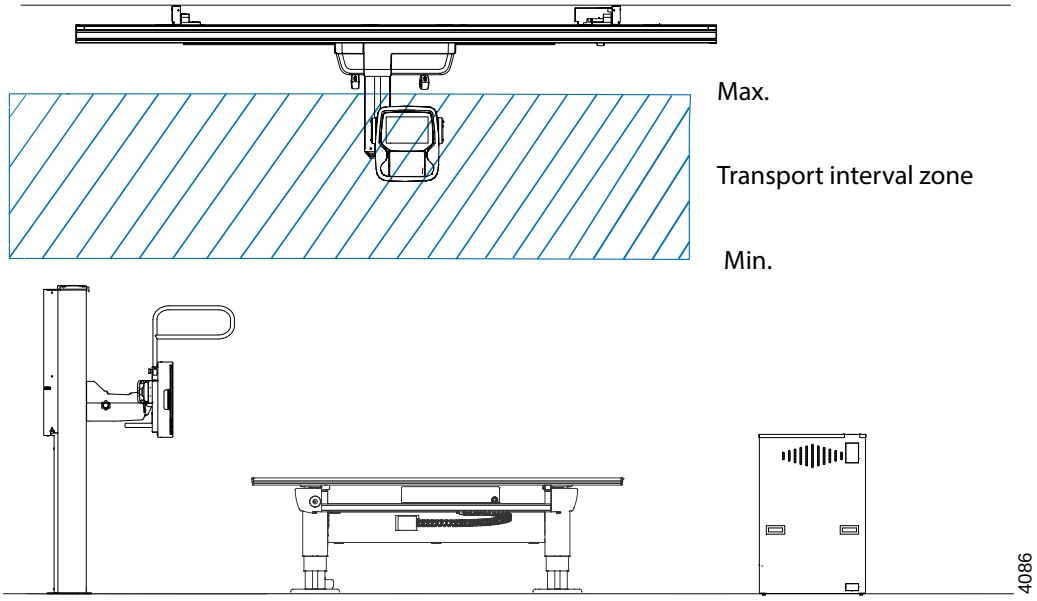


Fig. 4-20

When moving between positions outside the short-cut zones, the OTC will first move to the transport interval zone.

Inside the transport interval zone the OTC will move horizontally until it reaches the intended X, Y-position.

Then the OTC will move vertically, to the intended Z-position.

4.7 Manual Mode

CAUTION!

Be aware that there is no tracking between the x-ray tube and the detector when the System is in Manual mode. Therefore, take extra care that the x-ray beam is within the active area of the detector before performing an exposure.

The System can be set to a *Manual mode* from the display. In the *Manual mode* it is possible to move the System manually in the room and perform exposure. In *Manual mode* no tracking will be performed. The *Manual mode* can be selected when the System is in one of the following modes:

- *WallFlexible*
- *TableFlexible*
- *FilmTracking*
- *Pendulum table*

4.7.1 Activation of Manual Mode

The servo state can be either *Automatic mode* or *Manual mode*. A pop-up window according to Fig. 4-21 *Servo state selection pop-up window*, will appear with the two alternatives. When the System is in *Manual mode* all movements are allowed and exposure can be performed in any position.

Fig. 4-21 Servo state selection pop-up window

The *Manual mode* is activated by pressing the *Servo state* , see Fig. 4-21 *Servo state selection pop-up window*. If the System is in *TableFlexible*, *FilmTracking* or *Pendulum mode* the table and the OTC will be shown without connection when *Manual mode* is selected. In the same way, the Wallstand will be shown without connection to the OTC in *Manual mode*, see Fig. 4-22 *Wallstand and Table shown without connection to the OTC in Manual mode*

Fig. 4-22 Wallstand and Table shown without connection to the OTC in Manual mode

4.7.1.1 Deactivation of Manual Mode

The *Manual mode* is deactivated by selecting a new APR with a different auto-position. De-activation is also done by changing to *Automatic mode* .

If the same patient is examined and an APR with the same auto-position is selected, the *Manual mode* will be kept.

4.7.1.2 Restrictions in Manual Mode

In *Manual mode* the shown SID value is based on the assumption that the detector is positioned in the same way as it should have been in an active servo mode. Note that the SID value will not be able to be calculated is some positions. No SID value will be shown if the System is not in an active servo mode when *Manual mode* is activated.

Tracking or other mode movements are not possible when *Manual mode* is active.

4.8 Free Examination Procedures

4.8.1 Free Mode

4.8.1.1 General

The *Free mode* is designed for emergency examinations. The servo button cannot be activated in *Free mode*, consequently no automatic movement is available.

4.8.1.2 Flow of Operation

Select a *Free mode* examination.

The System display will display the following, see Fig. 4-23 *Free mode display*.

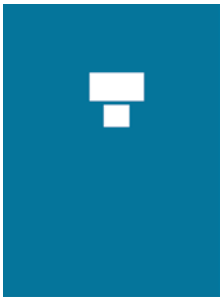


Fig. 4-23 Free mode display

- The stand will display H, distance to the floor.
- All movements are available.

4.8.1.3 Exposure

Exposure is possible when the OTC is not moving.

Note!

The OTC will automatically enter the “Free mode” at start-up.

4.8.2 Auto Position Mode

4.8.2.1 General

The *Auto position mode* is designed for emergency examinations or examination with a mobile detector.

4.8.2.2 Pre-defined Auto Positions

When the auto position mode is selected, the OTC will go to a predefined position in the room.

4.8.2.3 Flow of Operation

Select an *Auto position mode* examination.

The System display will display the following.

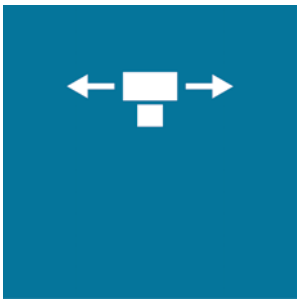


Fig. 4-24 Auto position mode display

- The OTC will display *"H"*, distance to the floor.

Activate the mode by pressing the servo button.

- When auto—positioning to a Wallstand, the Wallstand detector unit will move into a basic position.
- The OTC will automatically move to its programmed position.
- The servo mode button light indication will be switched off.

All movements are available.

4.8.2.4 Exposure

Exposure is possible when the OTC is not moving.

4.9 X-ray Table Examination Procedures

4.9.1 Table Flexible Mode

4.9.1.1 General

The *Table Flexible mode* is designed for examinations with the detector placed on the table top.

The OTC can be moved freely in all directions. When the height of the table top is adjusted, the OTC will track the height of the table top in order to keep the SID constant.

4.9.1.2 Flow of Operation

Select a *Table Flexible mode* examination.

The System display will show the following.

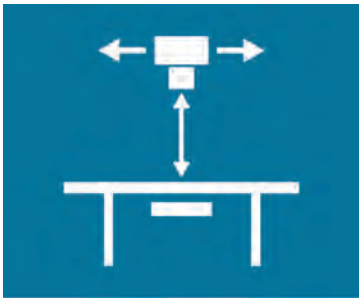


Fig. 4-25 Table Flexible mode display

- The SID will be displayed.

Activate the mode by pressing the servo button.

- The OTC will automatically move to its programmed position.
- The OTC will move to the programmed SID.
- Servo mode indication light fixed.

Adjust the table height.

- The OTC will follow the Table to maintain the programmed SID.

Adjust the tube position.

- The mode will stay activated (detector holder will not follow).
- Move the imaging unit manually, if needed, to assure that the x-ray field is inside the boundaries of the detector.

4.9.1.3 Exposure

Exposure is possible when the OTC is not moving, and the servo mode indication light is fixed.

CAUTION!

Materials located in the X-ray beam may cause adverse image effects.

Note!

In "Table Flexible mode" examinations exposure is possible outside the imaging unit.

The imaging unit does not follow the OTC.

4.9.2 Film Tracking Mode

4.9.2.1 General

The *Film Tracking mode* is designed for examinations of patients lying on the Table.

4.9.2.2 Flow of Operation

Select a *Film Tracking mode* examination.

The System display will display the following, see Fig. 4-26 *Film tracking mode display*.

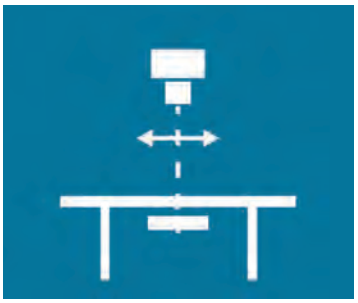


Fig. 4-26 Film tracking mode display

- The SID will be displayed.

Activate the mode by pressing the servo button.

- The OTC will automatically move to its programmed position.
- The OTC will move to the programmed SID.
- Servo mode indication light fixed.

Adjust the table height.

- The OTC will follow the Table to maintain the programmed SID.

Press the brake release button.

Move the OTC lengthwise the Table.

- The imaging unit will follow the movement to stay aligned with the tube.

Press the button to deactivate the alpha brake.

Turn the tube in alpha direction.

- The imaging unit will follow the movement to stay aligned with the tube.
- The SID value can be adjusted by moving the OTC, then all moving will be performed with the new SID.

4.9.2.3 Exposure

Exposure is possible when the OTC is not moving, and the servo mode indication light is fixed, and the x-ray beam covers the image unit

4.9.3 Pendulum Mode

4.9.3.1 General

The *Pendulum mode* is designed for non-vertical examinations of patients lying on the Table.

4.9.3.2 Flow of Operation

Select a *Pendulum mode* examination.

The System display will display the following, see Fig. 4-27 *Pendulum mode display*.

Fig. 4-27 Pendulum mode display

- The SID will be displayed.

Activate the mode by pressing the servo button.

- The OTC will automatically move to its programmed position.
- The OTC will move to the programmed SID.

Adjust the height of the Table stand.

- The OTC will follow the Table stand to maintain the programmed SID.

Press the arrow left or corresponding buttons on the table handle.

- Press the buttons for moving the OTC to the right or left, see item F and G at Fig. 3-43 *Table hand control*. The tube move in the desired direction and the imaging unit move to stay aligned with the tube.

4.9.3.3 Exposure

Exposure is possible when the OTC is not moving, and the servo button is activated.

4.9.4 Stitching Table Mode (Option)

Note!

Stitching Table Mode is not available according to the described procedure with CR systems.

Select a *Stitching Table mode* examination.

The system display will display the following, see Fig. 4-28 *a) Left position and b) Right position.*

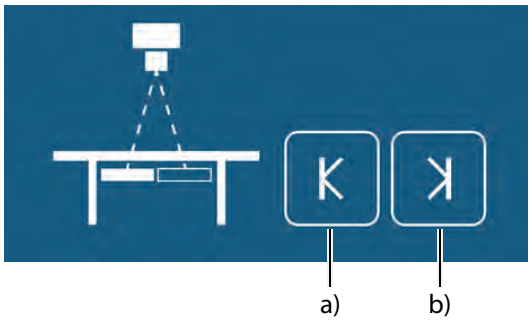


Fig. 4-28 a) Left position and b) Right position.

Activate the mode by pressing the servo button.

- The servo mode indication light will flash until the left and right positions are specified.
- The OTC will automatically move to its programmed position.
- The system will beep when position is reached.

Invite the patient and position the patient on the table.

Move the focus point to the middle of the planned composite image. This could be done either by moving the tabletop or by moving the column in X (or Y) direction.

Rotate the x-ray tube in order for the right edge of the collimator light field to indicate the right limit for the composite image.

Press the button (F1) to set the right limit, see Fig. 4-29 .

- The button turns green to indicate that the limit is set.

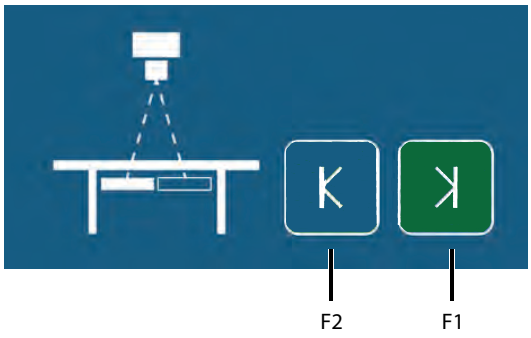


Fig. 4-29

Rotate the x-ray tube in order for the left edge of the collimator light field to indicate the left limit for the composite image.

Press the button (F2) to set the left limit, see Fig. 4-29 .

- The button turns green to indicate that the limit is set.
- Data is present on the right side of the display.
- When both limits have been defined, the total length of the composite image (c), see Fig. 4-30 *Left and Right Limits Set.*and the number of exposures (d) will be shown.

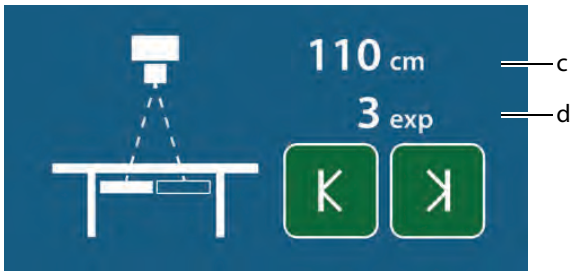


Fig. 4-30 Left and Right Limits Set.

- The servo mode indication light will be fixed.

Modify the exposure settings if necessary.

Activate the exposure button, and keep it activated during the procedure.

- The starting position is always at the left edge of the composite image. Activate the exposure button and keep it activated until the exposure procedure is completed. The system will move to the correct starting position.
- When the system is in the correct position for the first image, the first image is captured.
- After exposure, the system will move to the next correct position and the second image will be captured.

This is repeated until all images for the composite image has been captured.

- The system will beep when the sequence is finished.

4.10 Wallstand Examination Procedures

4.10.1 Wall Flexible Modes

4.10.1.1 General

The *Wall Flexible modes* are designed for examinations of patients standing up against a vertical moving imaging unit.

The movement up/down of the OTC, will only change the tube position, the Wallstand will not follow.

4.10.1.2 Wall Flexible Movements

There is 3 different Wall Flexible Modes, all accessible from the Arcoma Service program, *Adjust WallFlexible parameters*. The *Wall Flexible Movements* shall be set at the installation, and will thereafter be valid for all Auto positions using the *Wall Flexible mode*.

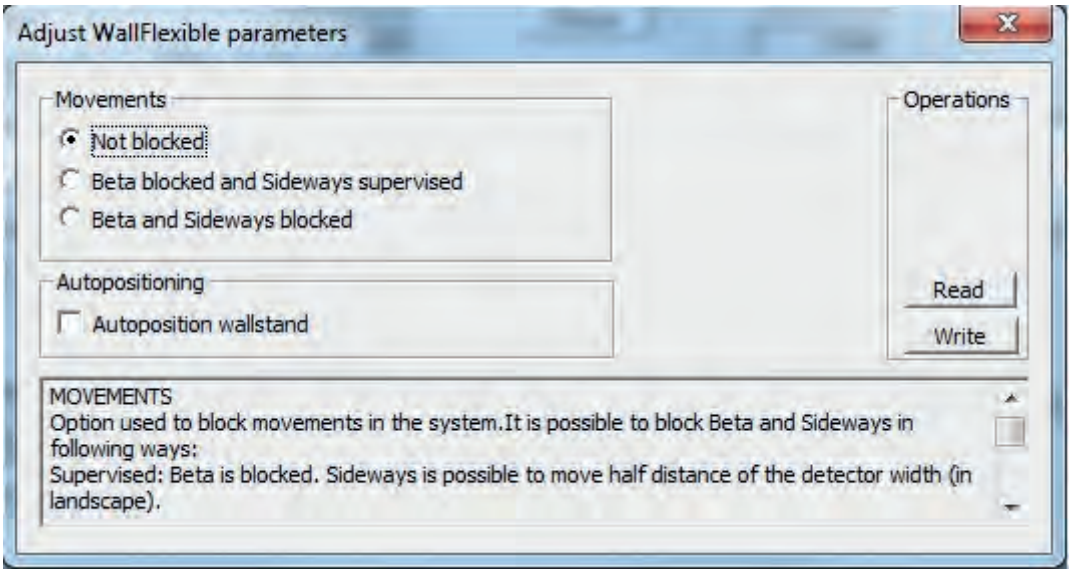


Fig. 4-31 Adjust WallFlexible parameters.

- *Not Blocked* — All OTC movements are allowed.
- *Beta blocked and Sideways supervised* — Blocked beta movement, movement will turn the servo off. It is possible to move a distance of half the detector length (landscape), before turning off the servo.
- *Beta and Sideways blocked* — It is only possible to move the OTC upwards and downwards. Blocked beta movement, movement will turn servo off. Blocked non-FFD directional (X/Y) movement, movement will turn servo off and block exposure.

4.10.1.3 Basic Flow

Select a *Wall Flexible mode* examination.

The System display will display the following.

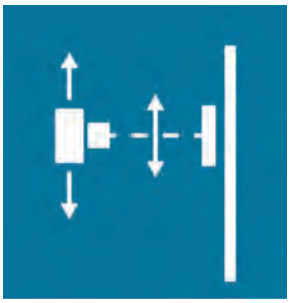


Fig. 4-32 Wall Flexible mode display

- The SID will be displayed.

Activate the mode by pressing the servo button.

- All movements are available.
- The OTC will automatically move to its programmed position.
- The OTC will either go direct to an aligned position to the detector or wait in the transportation height until detector is moved (wait or no wait selected).
- The mode will stay activated. The OTC beeps once and the servo mode indication light will flash.

Adjust the height of the Wallstand.

Move the detector holder at the Wallstand.

- The OTC will move down and align with the Wallstand.
- The OTC will follow the Wallstand to stay aligned.
- The OTC turns on the collimator light when the correct height is reached.

Adjust the position.

- The mode will stay activated.
- The *SID* value is changed to the new distance (if selected distance towards the Wallstand is changed).

4.10.2 NoWait Configuration

WARNING!

The Wallstand will immediately start tracking the height of the detector.

At the installation of the System, it is possible to select that the System shall not wait for the user to move the Wallstand.

The flow will then be as follow;

Select a *Wall Flexible mode* examination.

- The SID will be displayed.

Activate the mode by pressing the servo button.

- All movements are available.
- The OTC will automatically move to its programmed position.
- The OTC will move down and align with the Wallstand detector.
- The OTC will follow the Wallstand detector to stay aligned.
- The OTC reaches the correct height and stops.
- The *SID* value is changed to the new distance (if selected distance towards the Wallstand is changed).

4.10.2.1 Exposure

Exposure is possible when the OTC stands still, and the servo mode indication light is fixed.

4.10.3 Stitching Wallstand Mode

Note!

Stitching Wallstand Mode is not available according to the described procedure with CR systems.

WARNING!

The Wallstand detector holder will move during stitching. This may cause danger for the patient.

Select a *Stitching Wallstand mode* examination.

The System display will display the following.

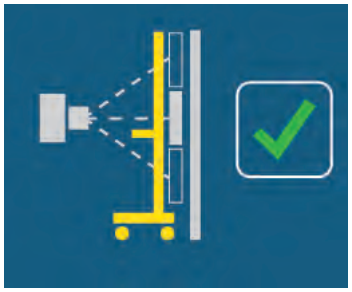


Fig. 4-33 Patient protection

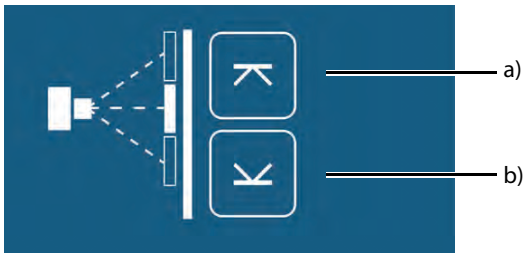


Fig. 4-34 Stitching Wallstand mode examination

The following buttons and information are located in the display, see Fig. 4-34 *Stitching Wallstand mode examination*

a *High position* , b *Low position*

1. Activate the mode by pressing the *servo* button.
   - The servo mode indication light will flash until both limits are defined.
   - The OTC will automatically move to its programmed position.
   - The System will beep when position is reached.
2. Install a patient protection in front of the Wallstand.
3. Invite the patient and position the patient in front of the Wallstand.
4. Verify that the patient protection is placed in front of the Wallstand by pressing the*green check* button on the display.
5. Move the focus point to the middle of the planned composite image. This could be done by moving the tube in Z direction.
6. Rotate the x-ray tube in order for the lower edge of the collimator light field to indicate the lower limit for the composite image.

7. Press the button to indicate the lower limit. The button turns green.

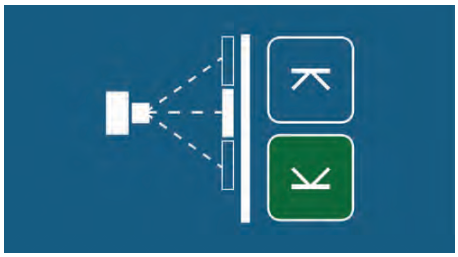


Fig. 4-35 Lower limit indication

8. Rotate the x-ray tube in order for the upper edge of the collimator light field to indicate the upper limit for the composite image.
9. Press the button to indicate the upper limit.
   - The button turns green to indicate that the limit is set.

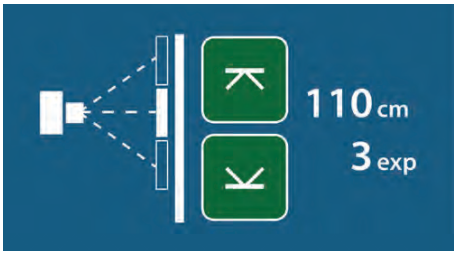


Fig. 4-36 Stitching mode — upper and lower limit set

   - When both limits have been defined the total length of the composite image and the number of exposures will be shown.
   - The servo mode indication light will be fixed.
10. Modify the exposure settings if necessary.

Note!

For a stitching procedure, a change of the patient size or change of exposure parameters for the first image included in the sequence, is not kept for the following included images.

11. Activate the *Exposure* button and keep it activated during the procedure.

- The starting position is always at the top edge of the composite image. Activate the *Exposure* button and keep it activated until the exposure procedure is completed.
- The System will move to the correct starting position.
- When the System is in the correct position for the first image, the first image is captured.
- After exposure, the System moves to the next, correct position and the second image will be captured.
- This is repeated until all images for the composite image has been captured.
- The System will beep when the sequence is finished. Release the button.

4.10.4 AEC Technique Setup

For information about the AEC Technique setup, see the *Generator Manual*.

4.11 Detector, Wallstand

WARNING!

- ***Before setting or adjusting the detector and other equipment, complete the setting of the counterweights.***
- ***Whenever any item is removed from the Wallstand, e.g. the lateral armrest, the detector holder will become highly unbalanced.***
- ***Whenever the brake is released, it will move upwards and may cause injury.***
- ***Make sure that the operation will be done by personnel who are trained in the use of the equipment.***
- ***Shutdown the power when changing a permanent detector.***
- ***Confirm that it is not possible to elevate. If the detector holder elevates accidentally while work is being carried out, it may fall against the worker and result in serious injury.***

CAUTION!

Do not put any load on the detector tray. It might be damaged.

CAUTION!

Always supervise movements of the detector to avoid collision with peripherals.

Note!

This instruction applies only to the portable image receptor.

Note!

- Depending on left or right operated Wallstand, the location of the detector tray and position of button and latches is different.

Note!

If the System includes more than one detector, assure that the active detector is used.

4.11.1 14x17 Detector, Wallstand

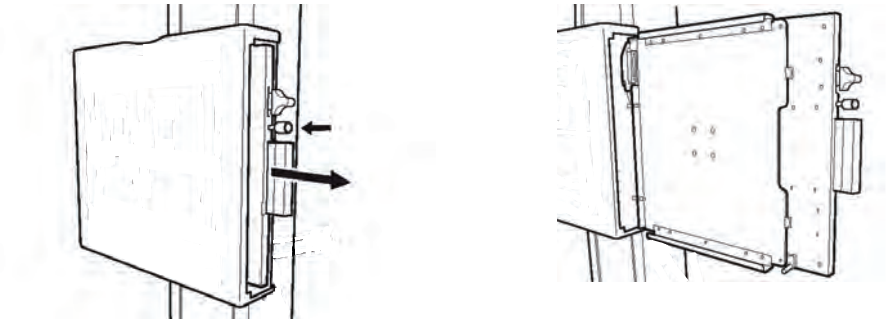
WARNING!

- ***Before setting or adjusting the detector and other equipment, complete the setting of the counterweights.***
- ***Whenever any item is removed from the Wallstand, e.g. detector, it will become highly unbalanced.***
- ***Whenever the brake is released, it will move upward and can cause injury. Make sure that the operation will be done by personnel who are trained in the use of the equipment.***
- ***Shut down the power when changing the detector. Confirm that the detector holder is not possible to elevate. If the detector holder elevates accidentally while work is being carried out, it may fall against the worker and result in serious injury.***

4.11.1.1 Method to Load the 14x17 Detector, Wallstand

The method of setting the detector to the detector holder is as follows:

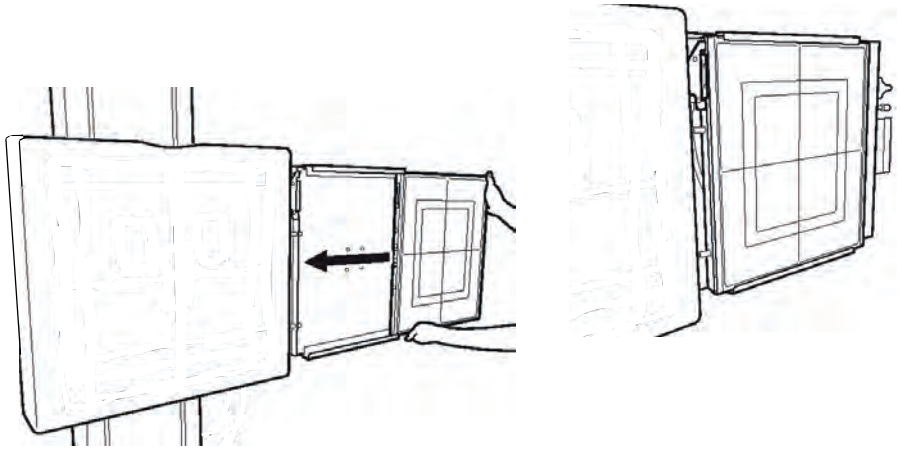
1. Pull the detector tray toward you until it locks.



Note!

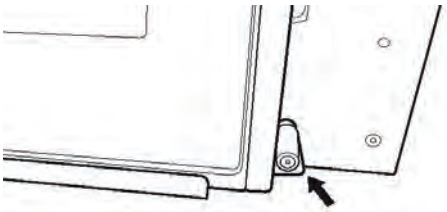
- Install the detector with the detector tray pulled into the locked position. When pulling the detector tray, the button on the side of the tray will first recede before snapping back into its original position when it locks.

2. Insert the detector into the detector holder, as shown below and set it by pushing it in, until it clicks.

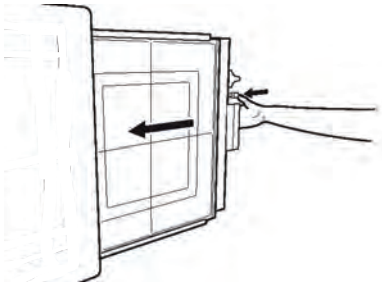


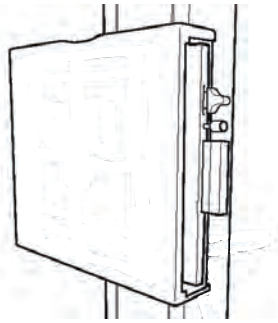
CAUTION!

- ***Confirm that the latch is going up firmly, as shown below.***



3. While pressing and holding the button of the detector tray, return it back to the inside of the detector holder.

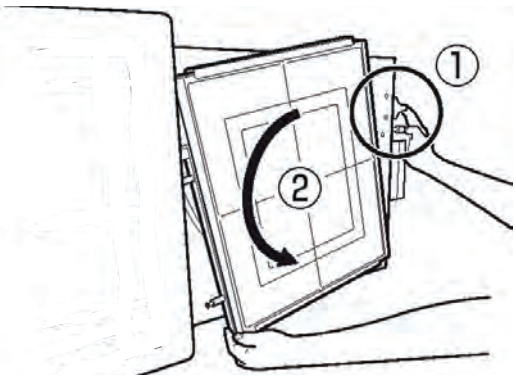


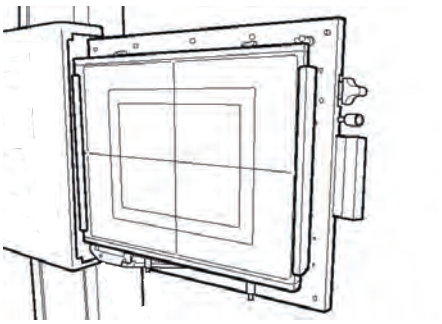


4.11.1.2 Change between Portrait and Landscape

The method of rotating the detector in the detector holder, is as follows:

1. To rotate the detector by 90°, , in the step 2 of “Method to set the detector”, hold the lower side of the detector and turn it from the below, clockwise or anti-clockwise (2) while pulling the latch upward or downward of the detector tray (1) in the direction of the arrow.





Note!

- To set the detector, pull the latch:
  - upward at upper position of the tray.
  - downward at the center of the tray.
- Depending on left— or right—operated Wallstand, the location of the detector tray and position of button and latches is different.

Centered or Top Rotation of the Detector

In the landscape position, there is a choice between having the detector rotated through the detector center or through the detector top.

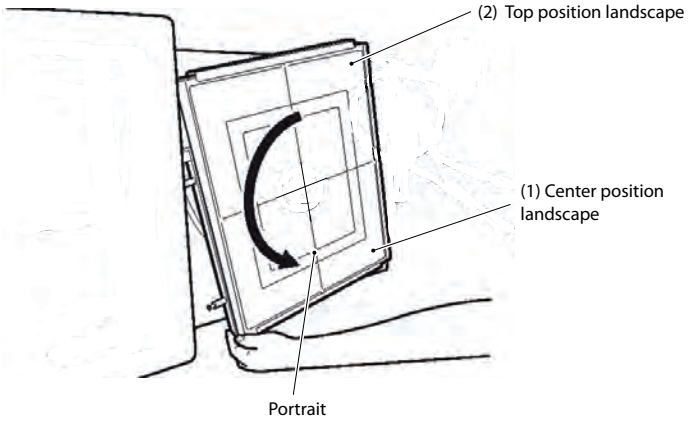


Fig. 4-37 Rotating the detector

4.11.1.3 Method to Remove the 14x17 Detector, Wallstand

The method of removing the detector from the detector tray is as follows.

1. To remove the detector, in the step 2 of “Method to set the detector”, unlock the connector by pulling the latch of the detector tray in the direction of the arrow.

Note!

- Depending on left or right operated Wallstand, the location of the detector tray and position of button and latches is different.

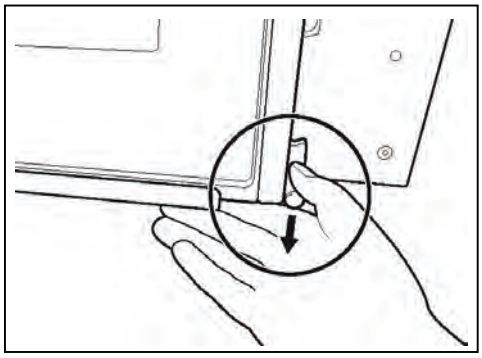


Fig. 4-38 Unlocking the detector latch

4.11.2 17x17 Detector, Wallstand

4.11.2.1 Method to load the 17x17 detector

WARNING!

- ***Before setting or adjusting the detector and other equipment, complete the setting of the counterweights.***
- ***Whenever any item is removed from the wallstand, e.g. detector, it will become highly unbalanced.***
- ***Whenever the brake is released, it will move upward and can cause injury. Make sure that the operation will be done by personnel who are trained in the use of the equipment.***
- ***Shut down the power when changing the detector. Confirm that the detector holder is not possible to elevate. If the detector holder elevates accidentally while work is being carried out, it may fall against the worker and result in serious injury.***

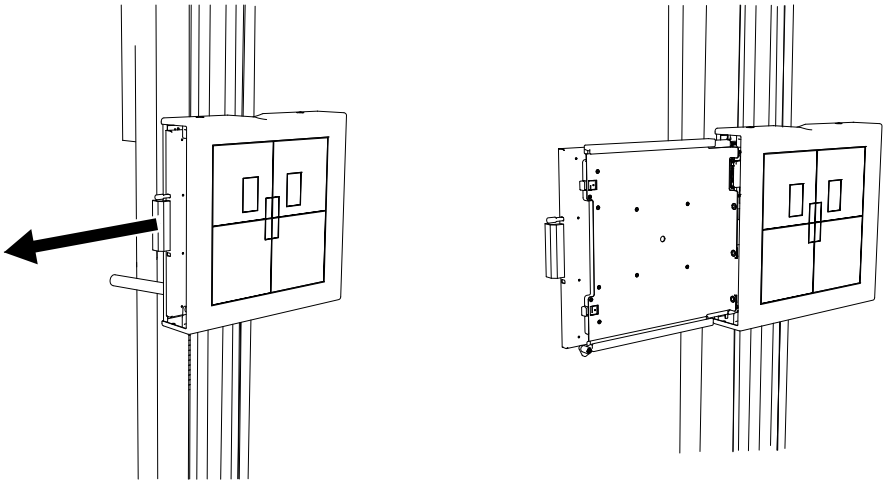
Note!

- Depending on left- or right-operated wallstand, the location of the detector tray and position of button and latches is different.

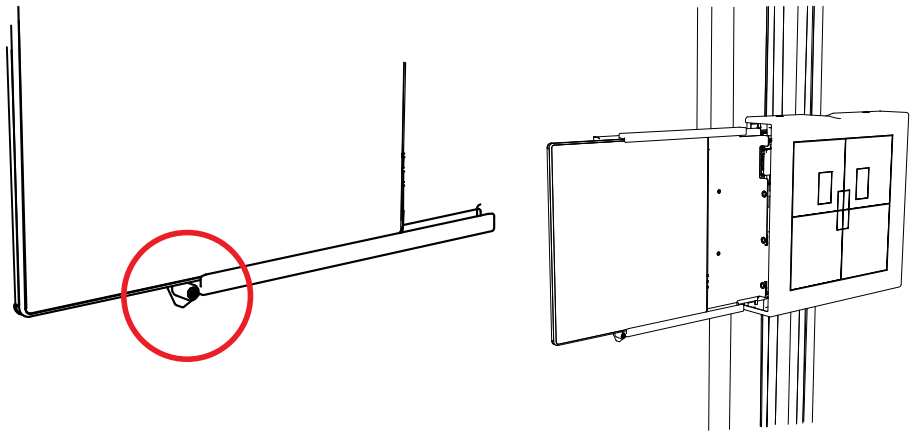
The method of setting the detector to the detector holder is as follows;

The following instruction describes the detector operated from the left side.

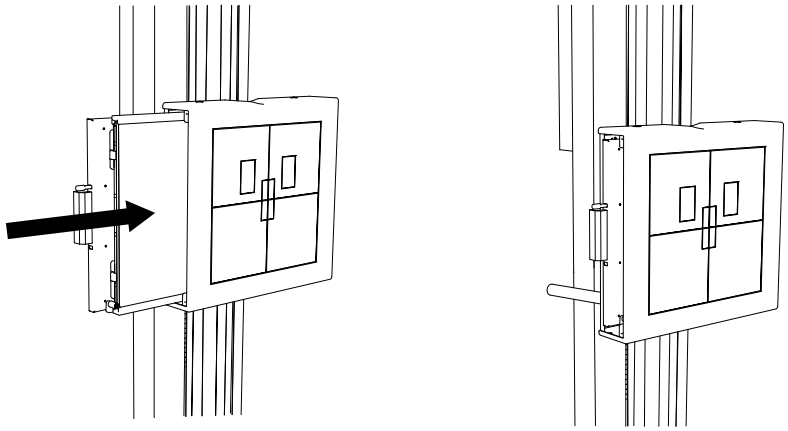
1. Pull the detector tray toward you. Make sure the detector tray is completely brought out.



2. Insert the detector into the detector tray as shown below and set it by pushing the detector, holding down the latch.



3. While pressing and holding the button of the detector tray, return it back to the inside of the detector holder.



4. Push the detector until the hold-backs are set. Then the detector is in the correct position. Chargeable detectors will start charging when set in this position.

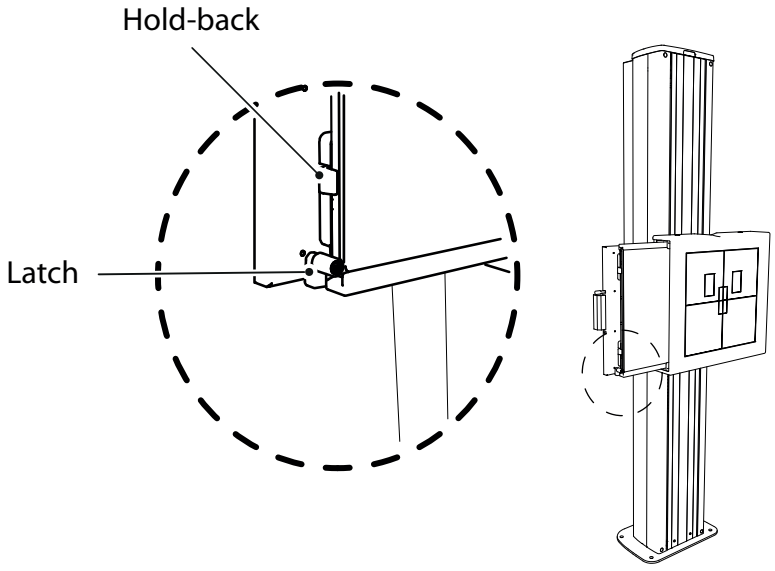


Fig. 4-39

CAUTION!

It is important that the hold-backs lock outside the detector end. Failure to position the detector in the proper position, will lead to incorrect images.

Note!

If the detector or the detector holder is not properly inserted, a warning symbol will be shown at the display.

4.12 Portable detector, table

Note!

This instruction applies only to a portable detector.

CAUTION!

Do not put any load on the detector tray. It might be damaged.

CAUTION!

Always supervise movements of the detector to avoid collision with peripherals.

Note!

If the System includes more than one detector, assure that the active detector is used.

4.12.1 Set the detector

1. Pull out the detector tray.

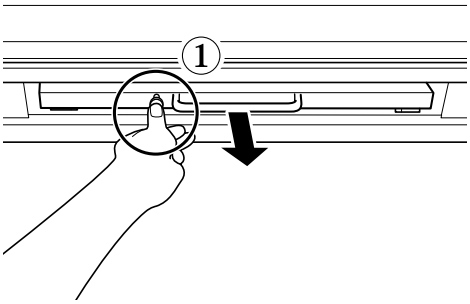


Fig. 4-40 Releasing the detector tray

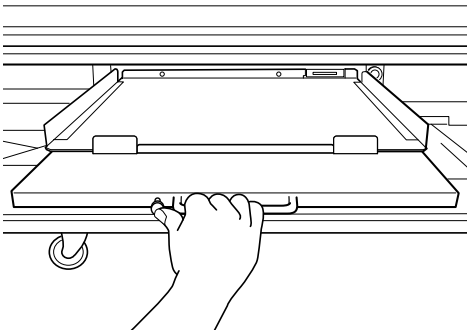


Fig. 4-41 Pulling out the detector tray

2. Insert the detector into the tray as shown below.

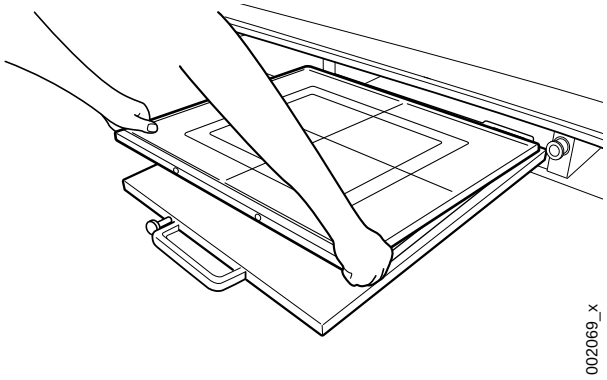


Fig. 4-42 Inserting the detector into the detector tray

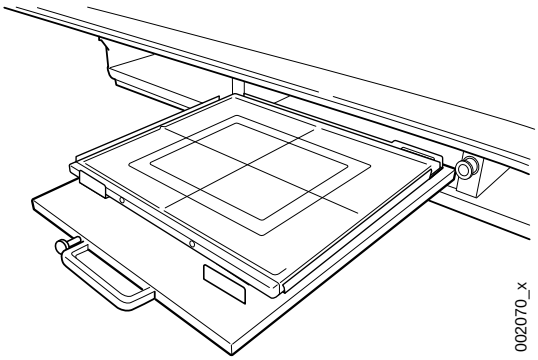


Fig. 4-43

3. In this position exposure is possible in *Free mode*, *Table Flexible mode* and *Auto position mode*.
4. Press and hold the button of the tray and push it in.

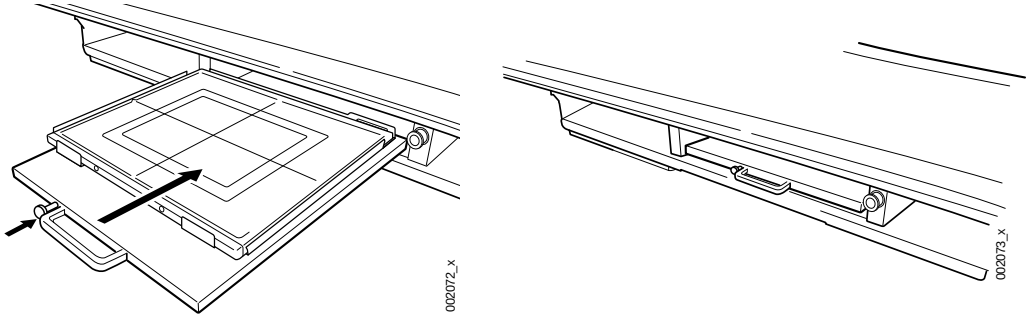


Fig. 4-44 Reinserting the detector tray

To check if the detector is in the right position, see the *"STATE" ; Detector position/ present/undefined* at the display.

4.12.2 Change between portrait and landscape

1. Rotate the detector 90°.
2. Hold as shown below and turn the detector, clockwise or anti-clockwise.

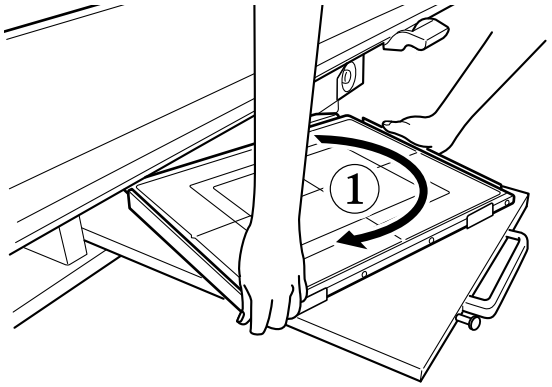


Fig. 4-45 Detector change between portrait and landscape

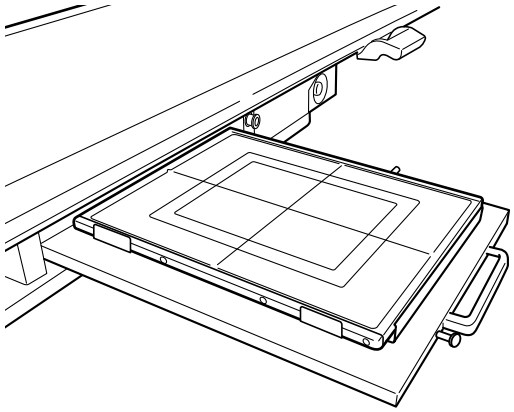


Fig. 4-46

4.12.3 Remove detector

1. Withdraw the detector holder and rotate the detector, if needed, to remove the detector.

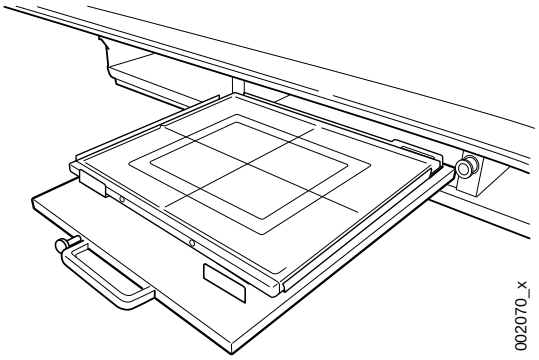


Fig. 4-47

2. Remove the detector by pulling it towards you according to Fig. 4-48 *Detector removal*.

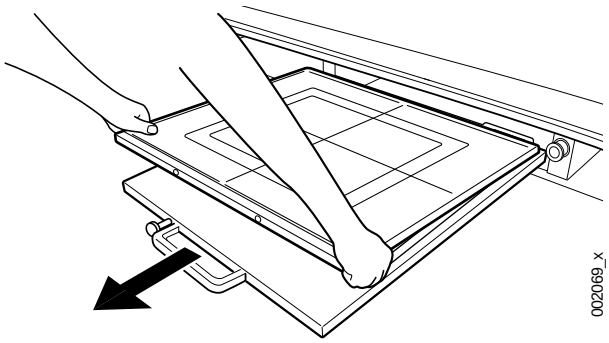


Fig. 4-48 Detector removal

4.12.4 Exchange grid

WARNING!

Failure to insert the grid in the correct orientation, with the tube side facing towards the X-ray source, can result in unsuccessful patient imaging.

Additional corrective patient imaging and additional ionising radiation exposure for the patient may be needed.

Ensure the grid is inserted in the correct way.

1. Pull out the grid.

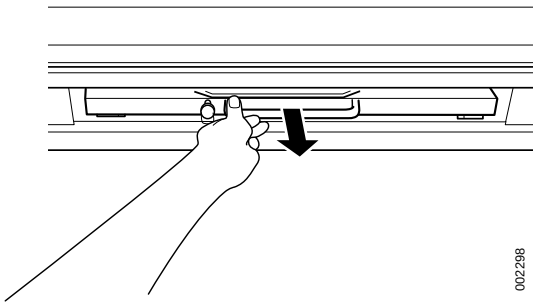


Fig. 4-49 Pull out the grid

2. Exchange the grid.
   Insert the grid with the tube side facing upwards, towards the X-ray source. The tube side of the grid has the specification label and the grid centre line identification.
3. Push in the grid, until it clicks.

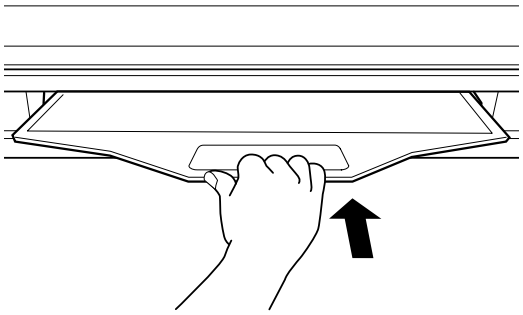


Fig. 4-50 Push in the grid

5 Error Handling

5.1 Fault Handling

There are three types of NOTIFICATIONS - Shows the present occurence. For example; collision. They are listed below in ranking order.

1. ERROR
   Information in the OTC display (red). Sound: two beeps.
2. WARNING
   Information in the OTC display (grey). Sound: one beep.
3. INFO
   No information in the OTC display but can be found in the setting menu.

5.1.1 Notifications

5.1.1.1 - 1) Error

When an error occurs, an Error pop-up window will appear in the display.

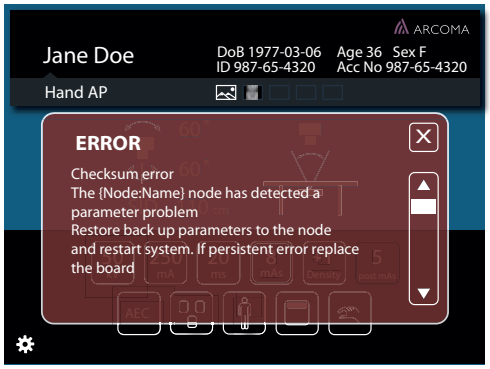


Fig. 5-1 Error pop-up window

The Error pop-up window will disappear when the user pushes the close button.

Fig. 5-2 Close button

When closing the Error pop-up window (Fig. 5-1 *Error pop-up window*), a red information bar will appear (see Fig. 5-3 *Error information bar, Table* and Fig. 5-4 *Error information bar, Wallstand*).

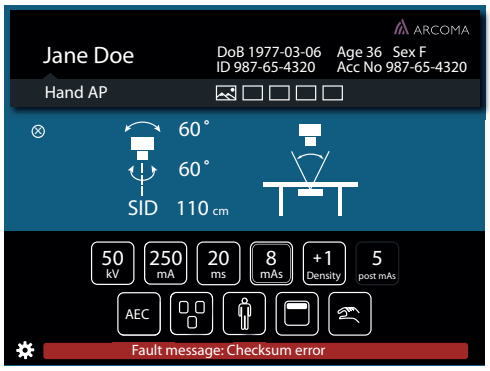


Fig. 5-3 Error information bar, Table

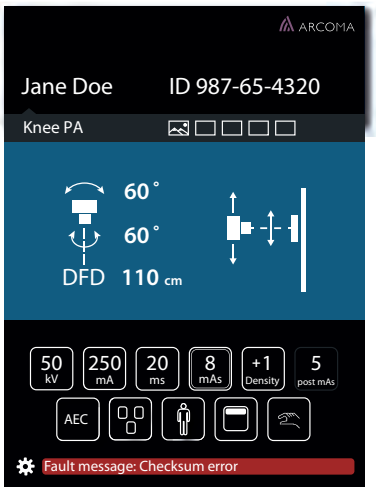


Fig. 5-4 Error information bar, Wallstand

When the user pushes the red information bar, the Error pop-up window will appear again.

The Error information bar (lower part of the window) is present until the error is fixed or the System is restarted.

5.1.1.2 2) Warning

A warning message will appear in a Warning information bar (lower part of the display), when the handling of the System justifies that.

The Warning information bar will be cleared if/when a new warning is displayed, or after time.

The latest sent warning is shown.

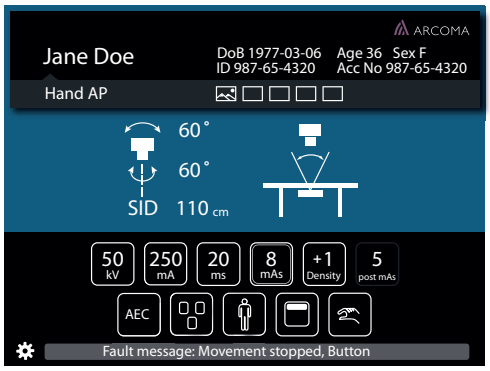


Fig. 5-5 Warning information bar, Table

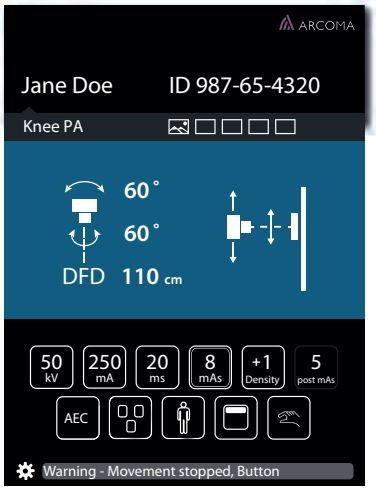


Fig. 5-6 Warning information bar, Wallstand

When pushing the Warning information bar, (see Fig. 5-5 *Warning information bar, Table* and Fig. 5-6 *Warning information bar, Wallstand*), a pop-up window will appear (see Fig. 5-7 *Pop-up window — Warning information bar* and Fig. 5-8 *Pop-up window — Information bar*).

Fig. 5-7 Pop-up window — Warning information bar

When the user closes the pop-up window, the Warning Information bar will appear again.

The Warning pop-up window will also appear again, when the user pushes the information bar.

Fig. 5-8 Pop-up window — Information bar

The *Warning pop-up window* disappears when the user pushes the close button.

Fig. 5-9 Close button

5.1.1.3 Log

The *Log file* is part of the *Setting menu* and reached by pressing the gear or the *Error/Warning messenger* bars.

5.2 Diagnostic

For System messages, error messages and error handling, see the System Installation and Service Manual.

6 Cleaning

6.1 General

CAUTION!

Be sure to clean the device so it will not affect the operation the next time it is being used.

Note!

Use a moderate amount of liquid, when cleaning the product!

- Surfaces that are in contact with the patient shall be cleaned with a lint-free cloth and a small amount of soap water or cleaning spirit.

6.2 Collimator

Follow local, national and organizational procedures regarding cleaning. The following agents are safety to use

- Isopropanol
- Ethyl alcohol

These cleaning agents may be diluted with water for cleaning purposes.

WARNING!

Use of other cleaning agents may result in damaging the collimator or possible injury to the user.

How to clean the collimator:

- Switch off the collimator.
- Use a damp soft cloth to clean the collimator. This reduces the possibility for liquids to enter the collimator.
  - Do not use abrasive cleaning products.

CAUTION!

Use of abrasive cleaning could result in deterioration of the collimator. E.g. the cross-hair window can be damaged, resulting in reduction of light field illumination.

–

CAUTION!

Do not spray, pour, or soak the collimator with liquids

- Use a dry soft cloth to remove any residuals form the collimator.

When there is a structural damage to the housing of the collimator, label the collimator as “out of order” and have have the collimator repaired prior to further use.

6.3 Wallstand, Table, OTC and X-ray Tube

Preferred cleaning agents for cleaning X-ray tube housing assemblies are:

- Alcohol
- Methanol
- Hospital grade disinfectant.

The X-ray tube assembly is not intended to come into contact with patients.

Cleaning
Wallstand, Table, OTC and X-ray Tube

7 Function and safety checks

7.1 Monthly Checks

7.1.1 General

If any malfunction is detected, the entire equipment must be taken out of use until the problem is eliminated by a service engineer from the supplier or by the local technical staff trained by the supplier.

Note!

Before performing any maintenance please read the Safety chapter.

Daily and monthly checks are normally performed by the user/operator.

Annual checks shall be performed either by local technical staff trained by the supplier or authorized service representatives.

Checks for all units.

OTC, table and Wallstand:

- ☐ 1. Check the cable hose for damage.
- ☐ 2. Check all outer cabling for damage.
- ☐ 3. Clean all outer surfaces, except for the lubricated column segments.
- ☐ 4. Make sure that the Instruction for use is available and up to date.
- ☐ 5. Check the emergency stop. By activating the emergency stop all motorized movements are inhibited. See *Safety Chapter* for information on how the Emergency stop should react on command.

7.1.2 OTC

- ☐ 6. Power up the OTC and check all functions.
- ☐ 7. Move the OTC around and observe any irregularities.

7.1.3 Table

- ☐ 8. Move the Table in X, Y and Z direction to make sure it runs smoothly and sounds OK.
- ☐ 9. Move the table top longitudinal and check that the mechanical end stops are not loose.

7.1.4 Wallstand

- ☐ 10. Move the Wallstand up and down in Z direction and make sure it runs smoothly and sounds OK.

8 Technical specification

8.1 Subsystem 0072

8.1.1 Electrical Characteristics

Mains voltage for the System	400 V 3N, 50/60 Hz 400 V 3~ 480 V 3~ Long-time (positioning) 2 A 50/60 Hz. Momentary (exposure):150 A, 50/60 Hz (Short term peak value), (recommended fuse 63 A, thermal breaker, B curve.) Class 1
Heat dissipation	1713 BTU/H

Generator Series and Mains Voltage	Minimum Recommended **Mains Disconnect to Generator (15 ft/5 m max)**	**Generator Momentary Line Current**	Minimum Recommended **Generator Service Rating**	Minimum Recommended **Distribution Transformer Rating**	Minimum Recommended **Ground Wire Size**	**Apparent Mains Resistance**
50kW 400 VAC, 3p.	(13.3 mm^2)	100 A	100 A	65 kVa	(13.3 mm^2)	0.17 Ω
65kW 400 VAC, 3p.	(13.3 mm^2)	125 A	100 A	85 kVa	(13.3 mm^2)	0.13 Ω
80kW 400 VAC, 3p.	(13.3 mm^2)	155 A	100 A	105 kVa	(13.3 mm^2)	0.10 Ω

8.1.2 Environmental Requirements

Ambient transport and storage temperature	-25°C - +70°C
Ambient operating temperature	+10°C- +40°C
Transport and storage humidity (relative)	10-90%, non-condensing
Operating humidity (relative)	30-75% RH, non-condensing
Maximum transport and storage altitude	3000 m
Maximum operating altitude	3000 m
Maximum air pressure	700–1060 hPa

8.2 Ceiling suspended X-ray tube support

8.2.1 General

Rotation range ceiling (beta)	>340°
Rotation range tube arm (alpha)	>±135°
Column (Z stroke)	1750 mm

8.2.2 Configuration

OTC	The OTC is a mechanical part of an X-ray system.

8.2.3 Weight

Total weight Overhead tube crane (4x4m traverse and rail) including cabling	372 kg
Overhead tube crane (including tube and collimator, ceiling wagon, column)	165 kg
Traverse (X-ray assembly, 4 m)	95 kg
Ceiling rail Y (4 m standard)	28 kg/each

8.2.4 Electrical Characteristics

Mains voltage	230 VAC, 50/60 Hz center tapped single phase 4 A

8.2.5 Classification

Classification according to IEC 60601-1.

Class	Class I equipment. All dead metal parts of the equipment are electrical connected to protective earth.
Applied part	Type B
Protection against ingress of water	IPXO
Mode of operation	Intermittent operation: 20%, maximum 1 min. ON / 4 min. OFF
Use of anaesthetic mixtures	The equipment is not suitable for use in the presence of flammable anaesthetic mixtures with air or with oxygen or with nitrous oxide.

8.2.6 Speed

	Low speed	Maximum speed
Z movement	60 mm/s	
X movement	250 mm/s	500 mm/s
Y movement	250 mm/s	500 mm/s
α movement	16°/s	
β movement	16°/s	
Image receptor holder movement (with 50 kg mass)	166 mm/s	350 mm/s

8.3 Cabinet

8.3.1 Dimensions

Dimensions (L x W x H) mm	750 x 600 x 1125 mm

8.3.2 Weight

Cabinet	Max 134 kg

8.4 Table

8.4.1 Column

Lowest table top position (from the floor to the table top surface)	550 mm
Column (Z stroke)	380 mm

8.4.2 Table Top

Table top dimensions	2424 mm x 850 mm
Table top transparent area	2400 mm x 613 mm
Table top thickness	21,5 mm
Length of stroke, X direction	± 600 mm
Length of stroke, Y direction	± 150 mm
Movement range of the imaging unit	>650 mm
Movement range of the detector	up to 850 mm

8.4.3 Weight

Table	Approximately 150 kg
Imaging unit	Approximately 21 kg
Table top	Approximately 47 kg
Maximum patient load	300 kg

8.4.4 Electrical Characteristics

Maximum power without external electronics	500 W

8.5 Wall stand

Column, Z stroke	1580 +10/-10

Rotation range detector holder wagon (Only the tiltable detector holder wagon).	-20° - 90°

8.5.1 Attenuation equivalent

Detector holder	<=0.6 mm

8.5.2 Weight

Wall stand	200 kg ±10

8.5.3 Speed

	Maximum speed
Z movement	200 mm/s

9 Waste Disposal

The Manufacturing company is responsible for disposal of the product.

To avoid environment pollution and human injury, we therefore request that you contact the Manufacturer or your dealer if you wish to cease operation of your product with the intention of disposal.

For disposal of other components, refer to corresponding documentation.

Follow the rules and regulations of your relevant authorities in the disposal of this product, accessories, options, consumables, media and their packing materials.

Waste Disposal

10 Accessories

10.1 General

WARNING!

Due to squeezing hazards from motorized movements, only accessories approved by the Manufacturer are allowed for the 0072.

Part no.	Description
0510–099–001	Cable carriage (1 pc)
0072–099–210	External servo button incl. emergency stop
0512–099–001	Unistruts for rails 4x4m
0512–099–002	Unistruts for rails 4x5m
0512–099–003	Mounting kit, unistruts for rails 4x4m
0512–099–004	Mounting kit, unistruts for rails 4x5m

10.1.1 Table

Part no.	Description
0072–095–170	Patient kit incl.;
	- Compression belt cost effective
	- Patient handgrip (2 pcs)
	- Mattress
0072-099-014	Patient handgrip
0055-099-001	Mattress, Comfort
0055-099-007	Mattress, 2200 mm
0055–099–009	Hand control for automatic collimator (1 pc)
0072-099-011	Lateral cassette holder
0072-099-004	X, Y, Z Foot control
0055-099-025	X, Y Foot control strip type
0072-099-028	Compression belt cost effective
0072-099-029	Compression belt high-end
0080-099-051	Form pad small- rectangle

Part no.	Description
0080-099-050	Form pad medium- wedge
0080-099-052	Form pad large- head

10.1.2 Wallstand

Part.no.	Description
0072-099-307	Stitching; patient protection shield
	Stitching removable footstep
0182–099–320	Wall brackets WS

10.1.3 Detector

Part.no.	Description
CXDI-401C, wireless 43x43 compact	Canon
CXDI-402C, wireless 43x43	
CXDI-410C, wireless 43x43	Canon
CXDI-701C, wireless 35x43	Canon
CXDI-702C, wireless 35x43	
CXDI-710C, wireless 35x43	Canon
CXDI-810C, wireless ~28x35	Canon

10.1.4 Grid

Part.no.	Description
0180-099-050	Grid 40 lp/cm, 10:1 Ratio, F115, Al type
0180-099-051	Grid 40 lp/cm, 10:1 Ratio, F150, Al type
0180-099-052	Grid 40 lp/cm, 10:1 Ratio, F180, Al type
0180-099-060	Grid 52 lp/cm, 10:1 Ratio, F110, Al type
0180-099-076	Grid 52 lp/cm, 10:1 Ratio, F140, Al type
0180-099-061	Grid 52 lp/cm, 10:1 Ratio, F180, Al type
0180-099-082	Grid 52 lp/cm, 10:1 Ratio, F115, Carbon cover
0180-099-083	Grid 52 lp/cm, 10:1 Ratio, F180, Carbon cover

11 Appendix A

11.1 Glossary

A

Accessories	Extra facilities to the product which easily can be mounted by the user.
AEC	Automatic Exposure Control
Alpha	A direction for a rotation movement.

B

Beta	A direction for a rotation movement. The tube turns around the Z-axis.
Btu/hr	British thermal unit/hour
BU/Back-up	A precautionary measure that shuts off the exposure, if the AEC chamber does not.
Bucky	See Detector holder.

C

CE	A CE-marked product verifies that the Manufacturer guarantees that the product fulfils the EU fundamental health, environment and security requirements.
Centering	The field of image is centered over the detector.
Collision	Either a physical collision with an obstacle or the node cannot reach its end position.
CR	Image plates.

D

DAP meter	Dose Area Product meter. The DAP-meter is placed next to the collimator and measures the amount of X-ray radiation that leaves the collimator.
Diode	Electrical component that leads voltage and current in one direction.
Dealer	See “Supplier”.
Detector	Image receptor for X-ray that does not require a cassette. The reception and transfer of an image is digital.

E

Appendix A
Glossary

EMC	Electromagnetic Compatibility.
End stop	See mechanical end stop and software end stop.
Exposure	An image is taken against an image receptor.

F

G

Guard function	Collision detection of the Z-movement (option).
Guard sensor	A sensor in the top of the Z-column that registers variations of force.

H

I

IEC	International Electrotechnical Commission.
Image receptor	Receptor for images; Film, CR, DR or Cassette.
Image receptor holder	Holder for the image receptor (Film, CR, DR or Cassette).
Index	Mechanical position markings, for instance alpha 0°, +90° and -90°.
Intermittence	The number of repetitions / unit of time. Recurrent cycles.
ISO	International Organization for Standardization.

J

K

L

M

Mechanical end stop	A physical device that stops an automatic or manual movement if the software end stop is out of order.
Motorized movement	A motor assisted movement.

N

Node	A control and supervision unit, consists of printed circuit board and node specific software.

O

O.D.	Optic Density.
Options	Extra facilities that demand updating of the System software and hardware before use. Options demand installation of an authorized service technician.

P

Position	A location in the room (X, Y and Z).

Q

R

S

SID	Source to image distance. The distance between the focus spot in the X-ray tube and the active image receptor surface. FFD is also used.
Software end stop	A non-physical device that stops an automatic or manual movement. The software end stop is placed before the mechanical end stop.
SSW	Service software.
Supplier	The company that sells the System to the user (hospital).

T

Table frame	The metallic frame that carries the Table top. The frame is attached to the bottom of the Table top.

U

V

W

Working area	The size of the Table top including X- and Y-stroke.

X

X-movement	The System moves in the X-direction.

Y

Y-movement	The System moves in the Y-direction.

Z

Appendix A
Glossary

Z-node	The Z-node controls the Z-movement.
Z-movement	The System moves in the Z-direction.

12 Appendix B

12.1 Monthly Checklist

Make a copy of this paper before filling in.

If there is any discrepancy please use the table to make a note.

Hospital:.....

Id no:..... Room:.....

Sign:..... Date:.....

12.1.1 OTC

- ☐ 1. Move the OTC manually to all positions in X, Y and Z direction and make sure it runs smoothly and sounds OK.
- ☐ 2. Check the emergency stop. By activating the emergency stop all motorized movements are inhibited.
- ☐ 3. Choose table position and make sure the tracking is activated.

  Measure between the X-ray tube focal spot and the active image receptor surface of the image receptor holder. The measured SID shall correspond with the displayed *SID*.

  Move the OTC in X or Y direction and measure between the X-ray tube focal spot and the active detector surface of the detector holder again. The SID is allowed to differ ±1%.
- ☐ 4. Check that the *SID*, shown on the display of both the Image system and the collimator, correspond with the measured SID.
- ☐ 5. Check the hoses for damage.
- ☐ 6. Check all outer cabling for damage.
- ☐ 7. Clean all outer surfaces, except for the lubricated column segments. See Chapter *“Cleaning”* at the *Instruction for use*

Appendix B
Monthly Checklist

12.1.1.1 General

Checks for All Units OTC, Table and Wallstand

- ☐ 1. Make sure that the *Operation Manual* is available and up to date
- ☐ 2. Check the hoses for damage.
- ☐ 3. Check all outer cabling for damage.
- ☐ 4. Clean all outer surfaces, except for the lubricated column segments. See *Operation Manual, Chapter 6 “Cleaning”*, for cleaning instructions.
- ☐ 5. Check the emergency stop.

  By activating the emergency stop, all motorized movements are inhibited. See *Chapter 2, “Safety”*, for information of how the Emergency stop should react on command.

12.1.1.2 OTC

- ☐ 6. Power up the Ceiling suspended unit and check all functions.
- ☐ 7. Move the Ceiling suspended unit around and observe any irregularities.

12.1.1.3 Table

- ☐ 8. Move the Table in X, Y and Z direction an make sure it runs smoothly and without any dissonance.
- ☐ 9. Move the Table top in longitudinal direction and check that the mechanical end stops are not loose.

12.1.1.4 Wallstand

- ☐ 10. Move the Wallstand up and down in Z direction and make sure it runs smoothly and sounds OK.

12.1.2 Remark

No.	Remark	Action	Int Note
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

12.2 Annual Checks

Refer to Service and Installation Manual.