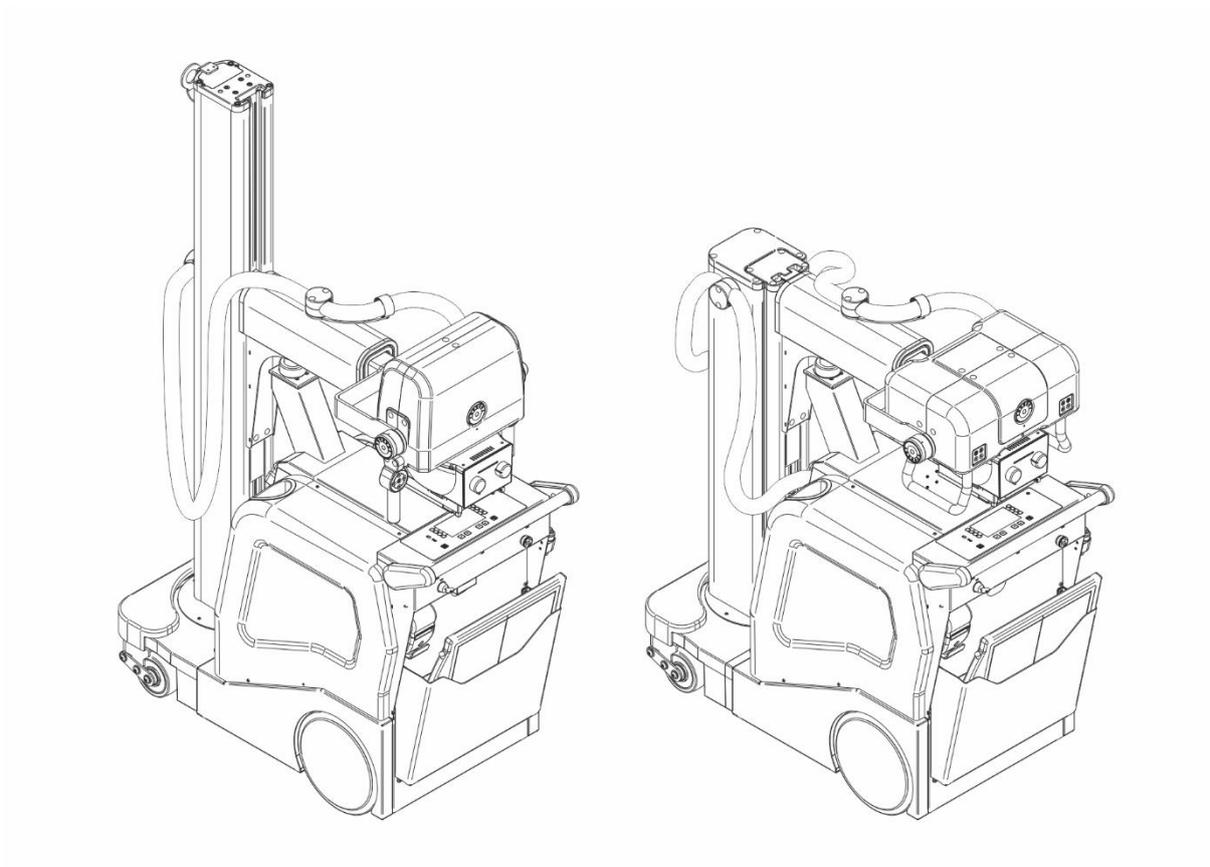


User's Manual



System: **PROSLIDE 32 B / PROSLIDE 40 B**

Version: **32 / 40 kW**

File: **228237-21-01**

Language: **EN**

Revision: **0**

Date: **08/2022**

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1 CREDITS

1.1 Compliance



This medical device is in compliance with the Medical Devices Regulation (UE) 2017/745 and its revised versions.

The medical device, hereafter called equipment, has been classified in class IIb according to annex VIII - item III Rule 10 of the directive mentioned above.

1.2 Manufacturer

The Manufacturer of the equipment is:

TECHNIX S.P.A.

via E. Fermi, 45

24050 Grassobbio, BG (Italy)

Tel.: +39 (0)35 3846611

Fax: +39 (0)35 335675

Web: <http://www.technix.it>

e-mail: technixd@technix.it

Information about the compliance can be required to the Manufacturer.

1.3 Distributor

The Distributor of the equipment is:

PROTEC GmbH & Co. KG

In den Dorfwiesen 14

71720 Oberstenfeld

Tel. +49(0)7062 / 9255-0

Fax +49(0)7062 / 22685

web: www.protec-med.com

e-mail: protec@protec-med.com

1.4 Publishing details

Published by the Manufacturer.

The Manufacturer reserves the right to modify this User's Manual and the equipment here described.

The equipment specifications are subject to variations without notice. Nothing written in this User's Manual can be considered as an offer, warranty, promise or contractual condition, nor should it be so.

1.5 Copyright

Translations from the original instructions in Italian language.

No part of this User's Manual may be reproduced or transmitted in any form without permission in writing from Manufacturer.

The software included in the equipment belongs to the Manufacturer. Upon receipt of the equipment, the user acquires only the right to use the software.

This right is neither exclusive nor transferable.

It is also necessary to seek a written permission to the Manufacturer before making changes for the use of the equipment for purposes other than those established.

1.6 Information about User's Manual

The purpose of this User's Manual is to provide a valid resource in order to ensure a safe and efficient use of the described equipment to the users.

Before starting up the equipment, it is necessary to read the User's Manual, note and strictly respect all the notices indicating Warning and Precaution messages.

Pay particular attention to information and procedures in the paragraph "Safety".

User's Manual is an integral part of the equipment. It must be kept near the equipment, so that it is possible to consult it at any minute.



A WARNING message indicates a potential serious outcome, critical event or safety risk a warning can cause death or serious injuries to the user and to the patient.



This equipment generates ionizing radiation. Before proceeding with x-ray exposure make sure that the necessary safety measures against radiation have been adopted



A PRECAUTION message indicates where it is necessary particular attention to ensure safe and efficient use of the equipment. The non-observance of a precaution message can cause slight or moderate personal injuries, damages to the equipment or to other goods, and expose to a possible remote risk of more serious injury and/or environmental pollution.



This indication signals particular suggestions, for example to help the user or to improve an operative sequence.

(A)

"EMERGENCY BUTTON PRESSED"

1. Perform visual checks
2. Switch on the unit
3. Switch on the collimator

Reference to position in the figure.

Display messages are formatted in double quotes and in capital letters.

In the figures/photos, the messages are displayed in English language, while in the text there is their translation in the language of the manual.

Operations that must be done step by step by following the logical numbering order.

Even a sequence consisting of a single step is numbered

The User's Manual describes the most complete equipment configuration with the highest number of options and accessories.

Depending on configuration, further use instructions can be supplied together with the equipment. These instructions must be consulted for information about safety, calibration, test procedures and maintenance.

The User's Manual respects the equipment specifications and it is in compliance with all safety norms applicable at the date of publication.

The Manufacturer reserves the right to make changes according to technical progress.

1.7 Compatibility

The equipment described in this User's Manual mustn't be used together with other products or components, except in case they are explicitly indicated as compatible by the Manufacturer.

Information concerning the compatibility with other products can be required by the Manufacturer.

Equipment changes and/or additions must be performed by the Manufacturer or by any third party explicitly authorized by the Manufacturer.

These changes and/or additions must be in compliance with all effective laws and local rules and must be performed with the highest technical capability.



Equipment changes and/or additions performed by skilled people and/or by people who use not approved spare parts, can nullify the equipment warranty.

As for all complicated technical products, maintenance performed by not qualified people and/or by people who use not approved spare parts can cause serious damages to the equipment and personal injuries risks.

1.8 Final destination

Motorized mobile device for X-ray image diagnostics with the exception of mammography examinations.

The battery power supply allows the movement and the emission of X-rays without connection to the mains.

The use of the equipment is reserved exclusively to qualified, trained personnel informed about the risks linked to the use of ionizing radiation.

Its use in professional health service, such as consulting rooms, clinics, hospitals (emergency, patients room, surgery rooms,...) is oriented to:

- Radiology
- Hospitalization
- Emergency ward
- Plaster room
- Pediatrics
- Orthopedics
- Operating theater
- Sports medicine

1.8.1 Indications/contraindications

The equipment is a mobile x-ray device designed for creating x-ray images in radiography.

The equipment must be used only by qualified, trained personnel informed about the risks linked to the use of ionizing radiation on patients both in adulthood and pediatric age.

Considering the x-ray nature, the trained personnel should select and perform the exam by taking care of observing the medical principles of justification and optimization ensuring that the patient advantages exceed the risks.

Specially pregnant women represent a category for which the trained personnel assumes responsibility for carrying out the exam by considering the advantages and the hazards. The exam should be performed by keeping the exposure at the lowest level reasonably achievable compatibly with the required diagnostic quality.

1.9 Training

Equipment users must be properly trained for a safety and effective use before trying to start up the equipment described in this User's Manual.

Contents of the training for this type of equipment are different in every country,

It is up to users to be sure to have received a proper training in compliance with effective laws and local norms.

2 SAFETY

2.1 Warnings and precautions



Expected use and compatibility

Do not use the equipment for purpose other than those for which it is intended. Do not use the equipment with other products than the ones whose compatibility has been recognized by the Manufacturer. The use of the equipment for purposes other than the ones expected or with an incompatible product, can cause serious or mortal physical injuries or wrong diagnosis or therapies.

This equipment must be used only in compliance with the safety instructions specified in this User's Manual and exclusively for intended purposes.

Proper training

Do not use the equipment for any application unless you have a proper and adequate training to a safe and efficient use.

If you aren't sure to be able to use this equipment in a safe and efficient way, don't use it. The use of this equipment without proper and adequate training can cause serious or mortal physical injuries or wrong diagnosis or therapies.

Do not use the equipment with the patients if there is no adequate understanding of its capabilities and functions. Using the equipment without an adequate knowledge of its functioning can compromise the efficacy and/or reduce the safety of the patient, the user and other people nearby.

Importance of safety

Do not use the equipment for any application before reading, understanding and assimilating all information about safety, safety and emergency procedures specified in this User's Manual. The use of the equipment without a proper knowledge of safety rules can cause serious or mortal physical injuries, or wrong diagnosis or therapies.

Safety systems

Never try to remove, modify, exclude or obstruct any safety device on the equipment. An intervention on safety devices can cause serious physical injuries or even death.

Maintenance and defects

The equipment should be subject to regular checks by the technical service support of the Manufacturer or by personnel expressly authorized by the Manufacturer, by following a preventive yearly maintenance plan prearranged by the Manufacturer.

If it is sure (or probable) that any part of the equipment is defective or wrong adjusted, don't use it before performing a check by the technical service support.

The use of an equipment with defective parts or adjusted in a wrong way, can expose the user or the patient to ionizing radiations or to other dangers concerning safety. This can cause serious or mortal physical injuries, or wrong diagnosis or therapies.



The user should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user is established

2.2 Electrical Safety

This equipment is in compliance with safety class I, Type B, in accordance with IEC 60601-1 norm.



Do not remove protections or cables from this equipment, unless it is expressly required in this User's Manual, because inside it there are dangerous electrical voltages. The removal of protections or cables can cause mortal injuries or serious damages to the people.

Protections or cables must be removed only by qualified and authorized technical personnel. Use the equipment only in rooms or areas comply with all applicable laws (or regulations having the force of law), referring to electrical safety of this type of medical device.

Always insulate the equipment from the power supply before proceeding with cleaning or disinfection operations in order to avoid electric shocks.

Equipotential earth connection

The equipment is supplied with an equipotential earth connection point.

The equipment can be used only in areas comply with local electrical safety norms and in environments suitable for medical activities. Besides IEC 60601-1 norm provides instructions about the equipotential earth connection point.

Additional equipotential earth connection

An additional equipotential earth connection is provided because the equipment is movable and the reliability of the main equipotential earth connection point can be insufficient.

It is possible to use this equipment only in rooms comply with IEC norm requirements.



The equipment described isn't protected against liquids seepage. Its classification is IPx0.

2.3 Mechanical safety



Be sure that parts of the body or clothes aren't stuck among moving components of the equipment.

Remove all objects from range of motion of the equipment.

Check that the unused hanging components (monitor and radiogenic complex) are positioned so as not to affect neither the user nor the patients.

It is not possible to transport this equipment while it is working. For a safety transport, switch off the equipment before transporting it and ensure that all system peripherals (monitor, mouse, keyboard, cables etc.) are disconnected.

Do not remove protections or cables from this equipment, unless this operation is expressly requested in this User's Manual.

The equipment includes moving parts. The removal of protections can cause serious or mortal physical injuries to people.

2.4 Protection against explosions



This device mustn't be used in presence of explosive gas or fumes. Do not use disinfectant spray flammable or potentially explosive. The use of this equipment in an unsuitable environment can cause fires or explosions.

2.5 Fire safety



Do not use this equipment in areas where there is a risk of fire.

Do not cover the ventilation openings while the equipment is turned on.

For electrical or chemical fires use only fire extinguisher marked as suitable for such uses. The use of water or other liquids in an electrical fire can cause physical injuries or even death.

Before trying to extinguish the fire, the safety measure to be taken is to separate the equipment from other electric power sources and from all other sources in order to reduce the risk of electrical shocks.

2.6 Electrostatic discharge (ESD)



Always resort to static procedures, protections and appropriate products before opening or during the handling of the equipment. This equipment includes electrostatically sensitive components.

Non-compliance with ESD procedures may cause damages to the components. Such damages to the components are not covered by any warranty.

The electrostatic discharge (ESD) can cause a remarkable voltage that could cause damages to printed circuit boards (PCB) or to other equipment components.

Electrostatic discharge (ESD) damages can accumulate and can initially not be visible, such as a hardware failure, but can reduce performances. Therefore, it is recommended to use proper ESD handling procedures. ESD can be due to low humidity or to the use of electrical equipment on carpets, bedding and clothes.

2.7 Electromagnetic compatibility (EMC)

This equipment complies with international and national laws and regulations relating to electromagnetic compatibility (EMC) in force for this type of product, if it is used for the intended purposes. Such laws and regulations define the electromagnetic emissions level coming from the product and the requested immunity against electromagnetic interferences from external sources. Other electronic products that exceed the limits defined by EMC standards can, in unusual situations, affect on the equipment working.

- Electromedical products request special precautions referring to electromagnetic compatibility (EMC) and must be installed and started up in compliance with EMC information provided in the documentation enclosed.
- The use of accessories and cables other than those specified can cause a higher emission or lowest immunity levels.
- The equipment mustn't be used in proximity of other products or stacked on them and, if this will be necessary, you must check the right functioning.



Mobile phones and laptops

Communications among RF portable and mobile equipments can affect medical equipments. It is recommended to use caution while using such communication devices within the specified radius of electromedical devices

2.7.1 Warning and Safety Precautions for Electromagnetic Compatibility



Increased emission or reduced interference immunity.

Use of unsuitable accessory or lines

- ▶ Exclusive use of the listed accessory or line with the exception of internal original spare part components.

Electric medical equipment is subject to special precautionary measures with regard to EMC and may only be installed and put into operation in compliance with the EMC information contained in the Operating Manual. Portable and mobile radiofrequency communication devices can influence electric medical devices.

Guide and declaration of the manufacturer - Electromagnetic emissions

The equipment is suitable to be used in the specified electromagnetic environment. The purchaser or the user of the equipment should ensure that it is used in an electromagnetic environment as described below:

Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	This equipment uses RF energy only for its internal operation. So the RF emission is very low and not probable cause of interferences in the closest electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable to be used in all environments, other than the domestic one and the ones directly connected to the public low voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage /flicker fluctuations emissions IEC 61000-3-3	Not applicable	

Guide and declaration of the manufacturer - Electromagnetic immunity

The equipment is suitable to be used in the specified electromagnetic environment. The purchaser or the user of the equipment should ensure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2/4/8/15 kV air	IEC 60601-1-2 Test Level	The floors must be by wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity should be at least equal to 30%.
Irradiated electromagnetic field IEC 61000-4-3	3 V/m 80 MHz at 2.7 GHz	IEC 60601-1-2 Test Level	The portable and mobile RF communication systems should be used not closed to the equipment parts included the cables. Min. distance 30 cm
Transistors/ rapid electric pulses sequence IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines > 3 m	IEC 60601-1-2 Test Level	Mains power quality should be the one of a typical commercial or hospital environment
Transitory overvoltage IEC 61000-4-5	0.5/1 kV differential mode 0.5/1/2 kV standard mode	IEC 60601-1-2 Test Level	Mains power quality should be the one of a typical commercial or hospital environment
Conducted noises caused by RF fields IEC 61000-4-6	3 V 150 kHz at 80 MHz 6V ISM frequencies	IEC 60601-1-2 Test Level	The portable and mobile RF communication systems should be used not closed to the equipment parts included the cables. Min. distance 30 cm
Voltage dips, short breaks and voltage variations on power supply input lines IEC 61000-4-11	0% U_n for 0.5 cycle 0 % U_n for 1 cycle 70 % U_n for 25 cycles 0 % U_n for 5 s	IEC 60601-1-2 Test Level	Mains power quality should be the one of a typical commercial or hospital environment. If the user of the equipment requires continuous operation during the electric power supply breaks, power the equipment with a continuity group or a battery.
Mains frequency (50/60 Hz) of the magnetic field IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test Level	The magnetic fields of the mains frequency should have specific levels of a commercial or hospital environment .



Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



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

2.8 Protection against ionizing radiations



This equipment generates ionizing radiations (hereinafter called radiations).

Before proceeding with x-ray exposure, be sure that all safety measures in protection against radiations have been taken.

While using the equipment, the examination room personnel have to respect all necessary protection rules. In this context, please observe the following rules:

- To protect patients from radiations, use tools suitable for protection against radiations, as well as the devices supplied together with the x-ray equipment (for example, diaphragm, spacer, filter)
- Always wear protective clothing. Anti-radiation clothing with an equivalent of 0,35 mm of lead can reduce the 99,84% of radiations at 50 kV and the 91,2% at 100 kV.
- If it is necessary to stay in the controlled area, please wear a personal dosimeter. The Manufacturer suggests to define the personal dose that occurs in the workplace under practical conditions and to use it as basis for precautions against radiations.
- Distance represents the more efficient protection against radiations. Please keep the largest possible distance from the exposed object and from x-ray complex.
- Avoid to work in the direct irradiation area; if it isn't possible, please protect yourself, Wear gloves for protection against radiations.
- Always use the lowest collimation of the x-ray area. Check that interested area is completely exposed. The diffused radiation depends largely on the volume of the object exposed.
- Always check that the x-ray field collimation completely covers the measurement range selected.
- Always select the largest possible distance between focal point and skin in order to minimize the dose absorbed by the patient.
- Always select the shortest examination time, in this way the radiation dose is considerably reduced.
- Move the interested area as close as possible to the image intensifier/ cassette / detector. Radiations exposure is reduced and even optimized.
- Always keep in mind that any material interposed along the path of radiation between the patient and the image receiver (for example film) reduces the images quality and increases the dose absorbed by the patient.
- Always check that there is visual and audible communication between the user and the patient during all the examination. If necessary keep the communication using technical means such as an intercom.
- Do not modify or remove safety circuits that under certain conditions prevent the x-ray emission.

2.9 Laser light source



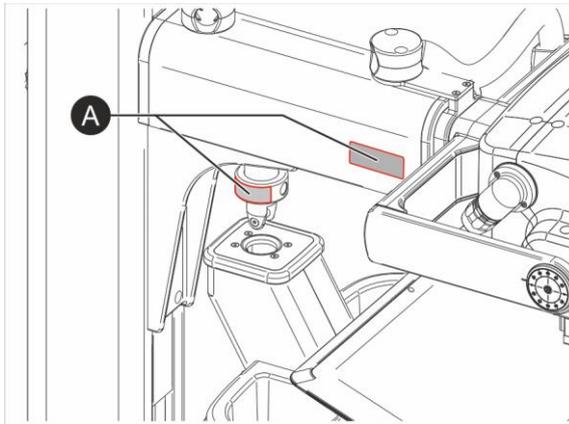
Laser radiation

Radiations potentially dangerous for skin and eyes.

- ▶ Do not stare directly or through optical instruments at the laser beam
- ▶ Do not point the laser beam on the face/eyes of the patient

2.10 Labeling

2.10.1 Equipment labels



(A) Warning label for the coupling/release of the rotating column:



Follow the instructions in the User's Manual



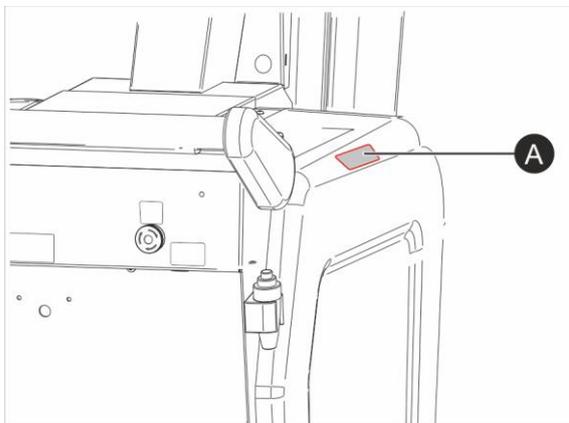
Warning / Hazard symbol



Hands crushing hazard



Label present also on the other side of the equipment.



(A) Label for information:



Follow the instructions in the User's Manual



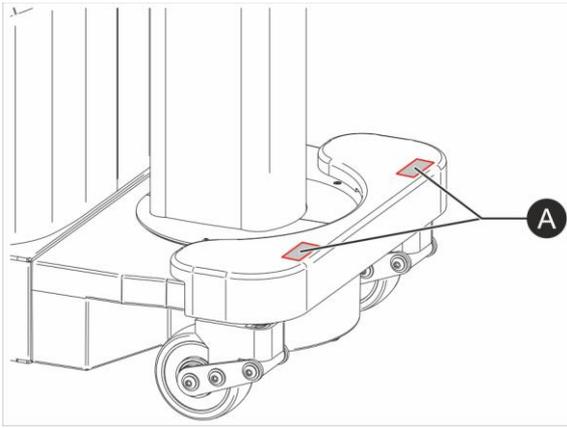
The operator, the patient or any other person should not sit down on the shelf of the equipment.



Do not place any object on the top of the equipment.



Label present also on the other side of the equipment.



(A) Label for information for the front bumper:



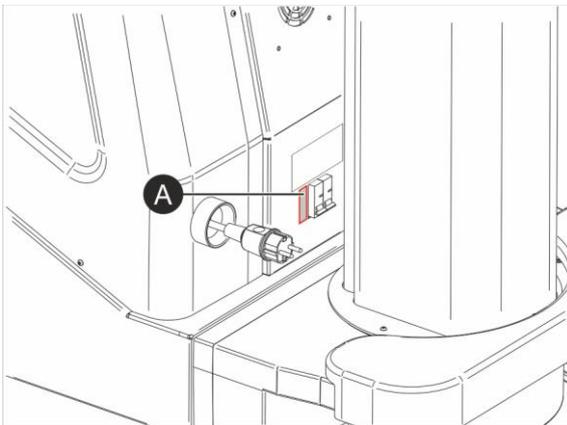
Follow the instructions in the User's Manual



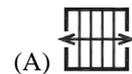
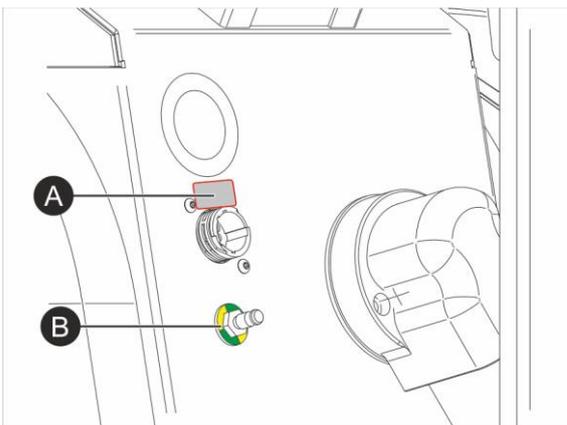
Do not climb



Do not place any object on the bumper.

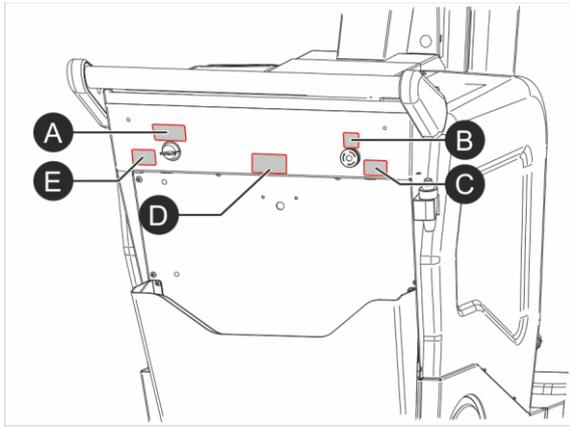


(A) Circuit breaker switch



(A) Potter connection

(B) Equipotential node



(A) Switching ON/ OFF of the equipment



(B) Emergency pushbutton



(C) Connection of the wired x-ray handswitch

(D) Warning label of metal rope for the manual moving of the equipment:



Follow the instructions in the User's Manual



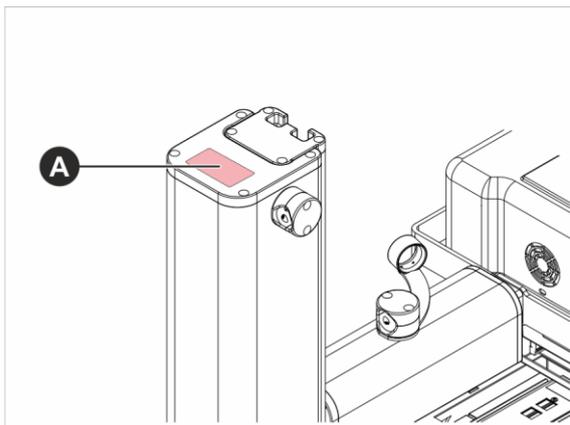
Warning/Hazard symbol



(E) DAP printer connection

Only for equipment with telescopic column

(A) Warning label on telescopic column



Warning/Hazard symbol



Observe the instructions in the User's manual



Don't touch

2.10.2 Packaging labels

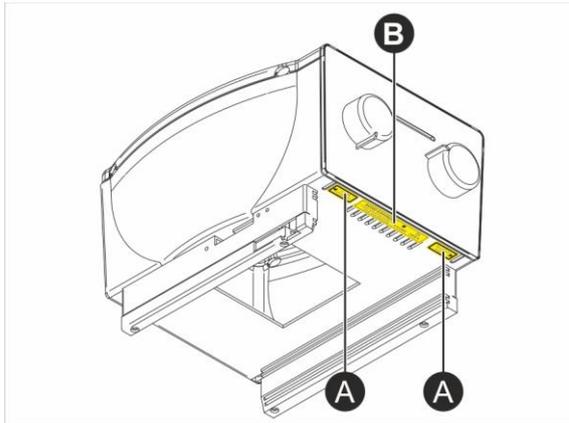
			
 <input type="text"/>			
Trade Name:		# <input type="text"/>	
SN	NN-_-_-_-		YYYY-MM
Peso Netto / Net Weight / Reingewicht:		kg <input type="text"/>	
Peso Lordo / Gross Weight / Rohgewicht:		kg <input type="text"/>	
MD	 CE 0051	UDI	

Packaging content identification label.

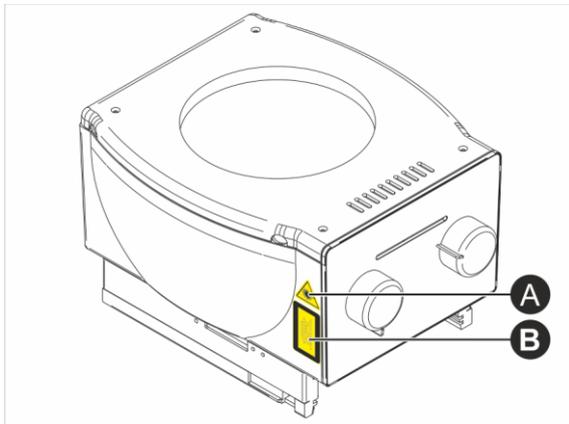


For more information about symbols, refer to the legend of the equipment serial number in par. 2.10.4.

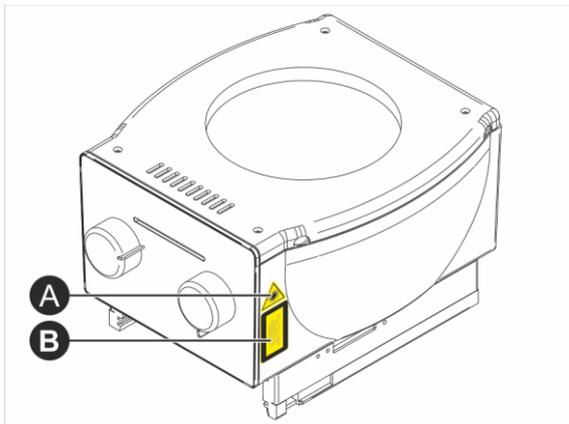
2.10.3 Collimator labels



- (A) Laser openings
 - (B) Warning labels
- Avoid the exposure
Radiations are emitted
from this opening



- (A)  Laser radiation symbol
- (B) Warning label:
LED Radiation
Risk group 2 IEC 62471:2006
CAUTION: Do not stare at operating light source.
May be harmful to the eyes.

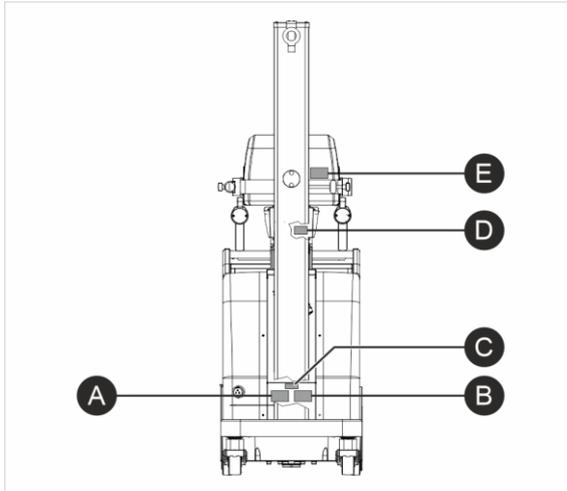


- (A)  Laser radiation symbol
- (B) Warning label:
Laser Radiation
Do not stare into beam
Class 2 LASER product
IEC 60825-1:2007
 $P_o \leq 1\text{mW}; \lambda = 645 \pm 10\text{nm}$

2.10.4 Serial Number Labels

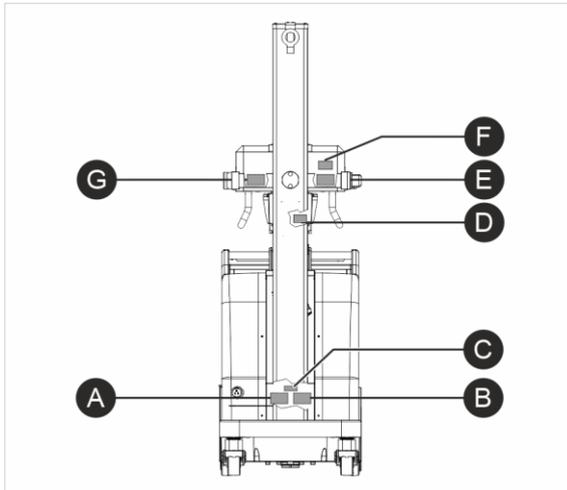
Labels position

32 kW version



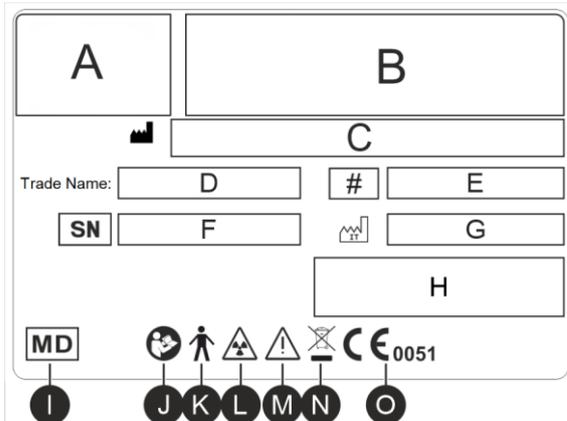
- A - Equipment serial number
- B - UDI label
- C - Equipment weight label
- D - Collimator serial number
- E - Monobloc serial number

40 kW version



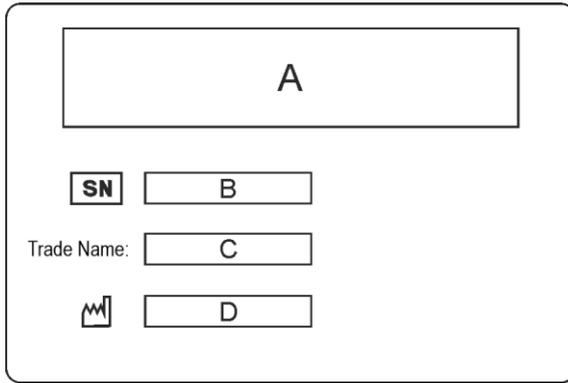
- A - Equipment serial number
- B - UDI label
- C - Equipment weight label
- D - Collimator serial number
- E - Tube serial number
- F - DHHS label
- G - Housing serial number

A - Equipment serial number



- Equipment s/n legend:
- A - Distributor's logo
 - B - Name and address of the Distributor
 - C - Name and address of the Manufacturer
 - D - Equipment model
 - E - Equipment version
 - F - Equipment serial number
 - G - Manufacturing date
 - H - Electrical data
 - I - Medical Device
 - J - Interventionist standard certification
 - K - Classification
 - L - Ionizing radiation
 - M - Warning symbol
 - N - WEEE
 - O - CE Marking

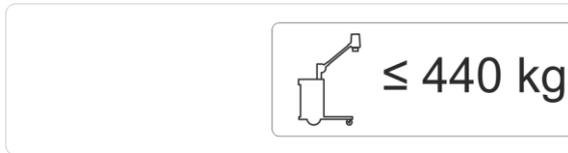
B - UDI label



Legend:

- A - Bar code
- B - Equipment serial number
- C - Equipment name
- D - Manufacturing date

C - Equipment weight label



Legend:

- A - Figure of the equipment
- B - Weight (in kg)



The indicated weight is only for example

D - Collimator serial number

A	B
C	D
E	

Legend:

- A - Manufacturer's logo
- B - Manufacturer's name and address, manufacturing date
- C - Model and s/n of the collimator
- D - Filtration data, max. voltage, power supply voltage
- E - Certification logo, warning symbols, classification

E - Monobloc serial number (only for 32 kW version)

A	B	C
D	E	
F	G	
H	I	
J		K

Legend of x-ray group serial number:

- A - Manufacturer's logo
- B - Manufacturer's address
- C - EC certification
- D - Monobloc code
- E - Manufacturing date
- F - Monobloc model
- G - Monobloc s/n
- H - XR tube type
- I - X-ray tube s/n
- J - Electric data, foci dimensions and filtration data
- K - WEEE, consult the attached documentation, ionizing radiation

E - X-Ray tube serial number (only for 40 kW version)

A	B	C
D		
E		
F		

Legend of x-ray group serial number:
 A - Manufacturer's logo
 B -Manufacturer's address
 C - EC certification and classification
 D - Date and place of manufacturing
 E - S/N and type
 F - Foci dimensions, anode speed, max. voltage

F - DHHS label

Caution
 it is restricted this device to sale or on an order of the user of the tube-assembly.
 This product conforms to DHHS radiation Standards of 21 CFR subchapter J.

G - Housing label (only for 40 kW version)

A	B	C
D		
E		
F		

Legend of housing serial number:
 A - Manufacturer's Logo
 B - Manufacturer's Address
 C - EC certification and classification
 D - Date and place of manufacturing
 E - S/N and type
 F - Filtration data, max. voltage

3 MAINTENANCE, CLEANING AND DISPOSAL

3.1 Checks by the user

Before every equipment use, the operator must be sure of its correct operation.

In case of malfunction or fault messages, both during the switching-ON phase and during the standard use, the equipment must be switched OFF, parked in a safe place and the technical service support must be informed.

3.1.1 Battery check

The equipment is provided with batteries for movement that are considered as "maintenance free" because they don't need to be refilled with water.

However they require regular checks by trained and competent service personnel, in order to ensure a correct functioning of the equipment and a long lasting of batteries, as described in the Service documentations.

3.1.2 Batteries maintenance

Actions for a correct maintenance of batteries:

- Keep the equipment connected to mains each time it is possible, so that the batteries are kept under continuous charge. It increases the useful duration.
- The batteries have not to discharge fully because in this way they lose the charge capacity and they will not be able to regain the 100% of their original capacity any more.
- Recharge completely the batteries when it is foreseen to let the equipment unplugged for more than 3 weeks.
- Recharge completely the batteries when the equipment is remained unplugged for more than 3 weeks.

3.2 Cleaning the equipment



Short-circuit or damage to electronic elements.

Liquids seepage inside the equipment.

- ▶ Always disconnect the equipment from the mains
- ▶ Don't use disinfectants in spray directly on equipment.
- ▶ Before cleaning and disinfecting, switch off the system and unplug all devices that can be connected to the equipment

Enameled parts and aluminium surfaces must be cleaned only with a damp cloth and a mild detergent and then with a dry woolen cloth.

Never use scouring powders, solvents, abrasives detergents or polishing abrasive.

Do not use a special detergent if its properties are not sure.

Chromed parts must be cleaned only with a dry woolen cloth.

Do not use polishing abrasives.

To protect the finish, use a non-abrasive wax.

Plastic surfaces must be cleaned only with soap and water. When using other cleaning agents (for example with a high alcohol content), the material can become opaque or can break.

3.3 Disinfection



Cross infections/ contaminations.

Missing observance of the hygiene standards.

- ▶ Follow all the policies concerning the control of the personnel infections and equipment.



The cleaning and disinfection techniques both for the equipment and for the environment where it is used must be in compliance with all laws and standards in force in the country where the equipment is installed.

Only personnel trained in the management of cleaning and disinfection of medical devices is authorized to conduct such activities.

Perform regularly cleaning and disinfection operations of the equipment.

The disinfection method used must be in compliance with all laws and norms in force for disinfection and protection against explosions in force in the country where the equipment is installed.

All parts of the equipment suitable for this type of treatment, accessories and connection cables included, can be disinfected with a damp cloth and a proper detergent. Never use disinfecting agents or corrosive sterilizers or solvents.

Do not use a special disinfecting or sterilizing agent if its properties are not sure.

If it is necessary to use non-inflammable and non-explosive sprays, first of all switch off and cool down the equipment.

In this way the vaporized spray can't be attracted by convention currents inside the equipment. Before starting spraying, it is necessary to cover carefully the product with plastic sheeting.

Once all traces of disinfecting spray disappear, it is possible to remove the protective plastic and directly disinfect or sterilize the equipment following the recommended instructions.

After using a spray the user must be sure that every single trace of gas has disappeared before starting up the equipment again.

3.4 Periodic maintenance



Injuries or damages risk

Technical interventions performed by non-authorized personnel.

- ▶ Only skilled and qualified service personnel is authorized to perform technical interventions on the equipment.

The correct working, safety and life of the equipment depend on a correct use from the user and from a plan of technical interventions and periodic maintenance programmed and performed regularly.

The user must agree with the technical service support a yearly plan of maintenance and technical interventions.

3.4.1 Repairs



Injuries or damages risk

Technical interventions performed by non-authorized personnel.

- ▶ Only skilled and qualified service personnel is authorized to perform technical interventions on the equipment.

The equipment includes mechanical parts subjected to wear because of working.

The correct adjustment of electromechanical and electronic complexes affects the working, image quality, electrical safety and the exposure of the patient and the medical personnel to radiations.

3.5 Disposal

The manufacturer wants to make a contribution to environment defense and wants to guarantee a constantly safe and efficient use of this equipment by using a proper support, maintenance and training program.

If the equipment is used correctly and always subjected to proper maintenance, it doesn't represent an environmental risk. However it can include materials that can be potentially harmful for the environment if they are not properly disposed.

The use of such materials is essential for carrying out the equipment functions in compliance with legal requirements and so on.

Final disposal of the equipment

The final disposal is effected when the equipment has been used so that it is no longer usable for the intended purposes.

The return, proper disposal or recovery of this medical equipment must be done in compliance with the European WEEE (Waste Electrical and Electronic Equipment) and / or national requirements.



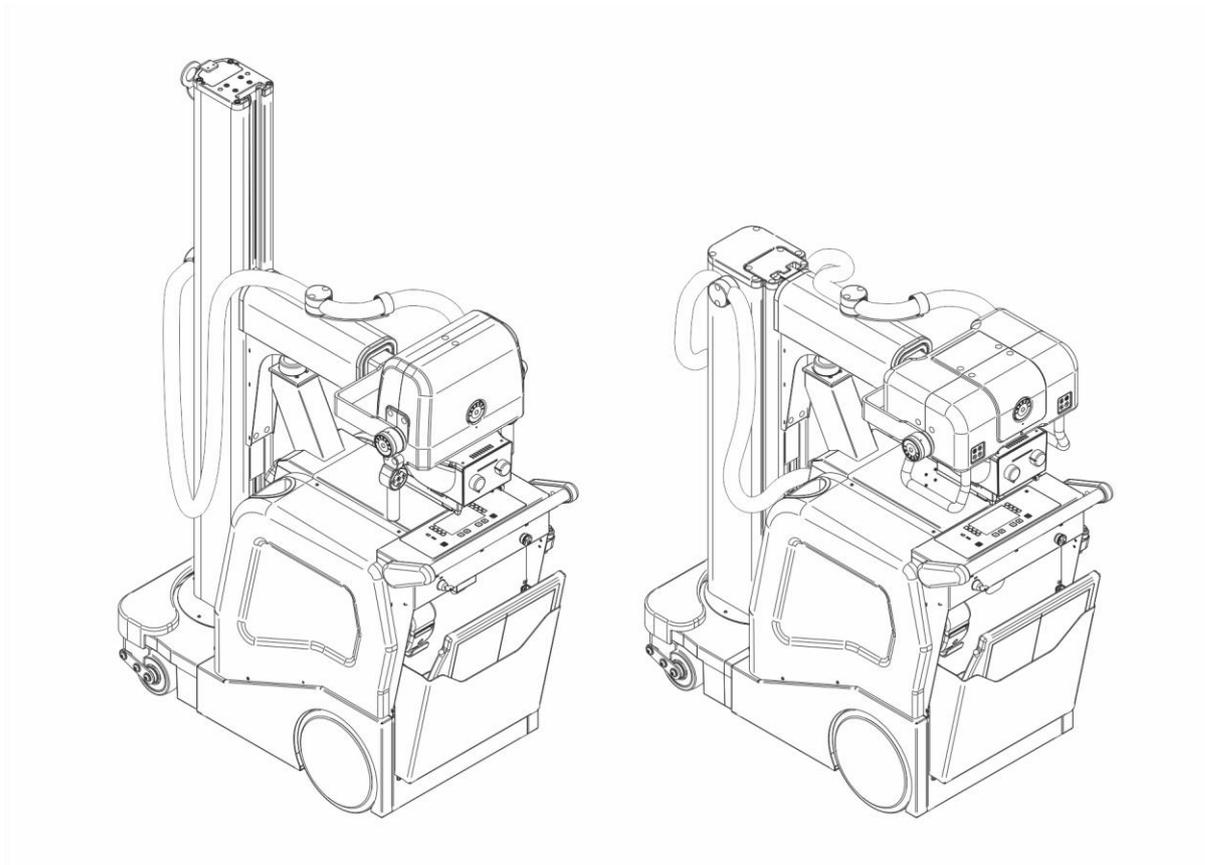
The equipment or parts of it mustn't be disposed as industrial or domestic waste, but they must be collected separately as special waste. The separate collection for the subsequent forwarding for recycling, treatment and environmentally compatible disposal, helps to avoid possible negative environmental and health effects and to promote recycling of the parts included in the equipment.

Illegal disposal of the equipment involves the application of administrative sanctions according to the current regulations of the country where the equipment is installed.

For information on how to dismantle the inoperative equipments comply with local legislation or contact an authorized representative of the Manufacturer.

4 LEGEND

4.1 Usability



The equipment is used in hospital to perform x-ray examinations, in particular in cases when the transport of the patient in a ward with fixed equipment is uncomfortable or not possible.

The equipment allows to perform x-rays, by setting the most suitable radiological data based on the interested anatomic area. In fact, the programmed anatomics and radiological data can be customized (typically during installation) according to requests and operation mode of the hospital.

The motorizing, in addition of the wide view provided by the low size of the telescopic column, allows easy and safe movements on the ward, narrow aisles and spaces, without requiring particular operator efforts.



The hardware shown in the User Manual corresponds to the equipment status at the moment of the delivery.

The Manufacturer reserves the right to make changes based on technical progress.

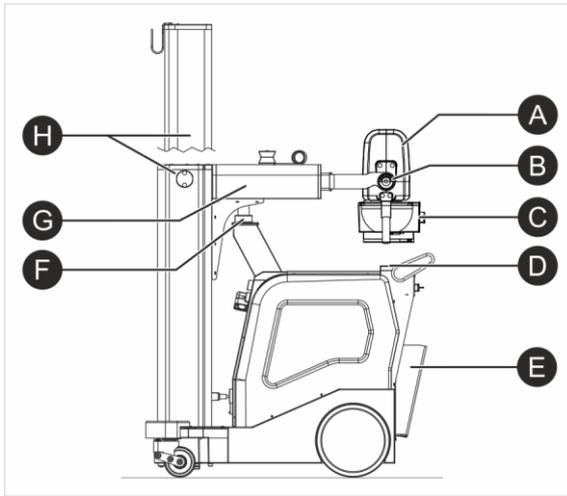
Design changes (for example of the covers) don't affect neither the functions nor the use of the equipment.



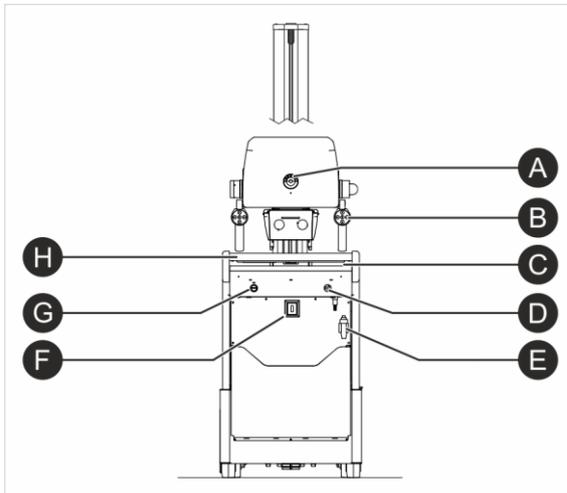
In some figures the equipment is represented with fixed column, in other ones with telescopic column. The difference of representation does not take off validity to the relative instructions.

4.2 General Overview

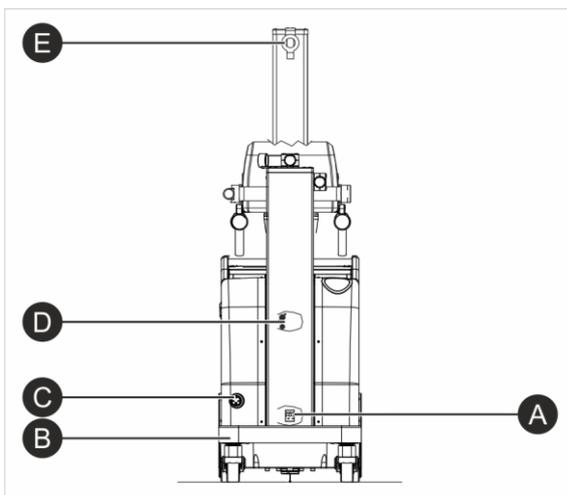
4.2.1 32 kW analogic version



- A - Monobloc
- B - Goniometer
- C - Collimator
- D - Control panel for x-ray generator
- E - Cassette holder
- F - Safety Lock for column
- G - Telescopic arm
- H - Rotating column

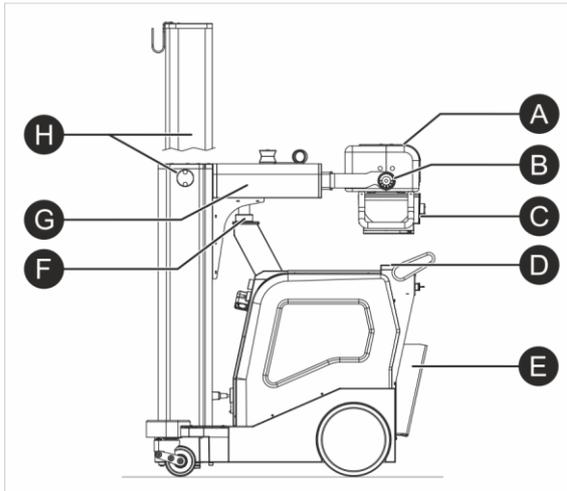


- A - Goniometer
- B - Remote controls
- C - Exposures remote control (optional)
- D - Emergency pushbutton
- E - X-ray emission handswitch
- F - Remote exposure control receiver (optional)
- G - Ignition key
- H - Transport handle with activation bar

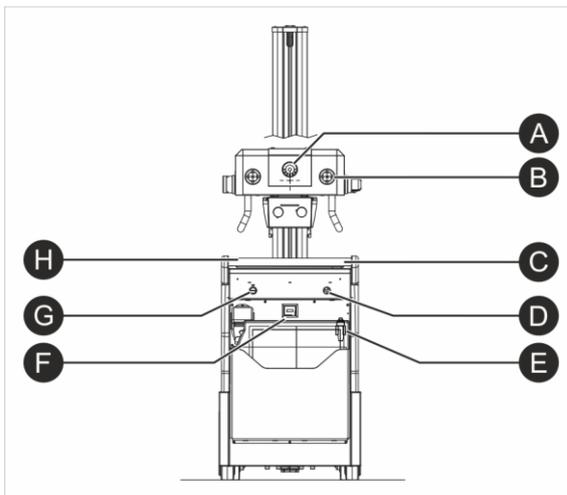


- A - Circuit breaker switch
- B - Bumper
- C - Retractable power cable
- D - Potter interface / Equipotential node
- E - Apron-hanger (present only with fixed column)

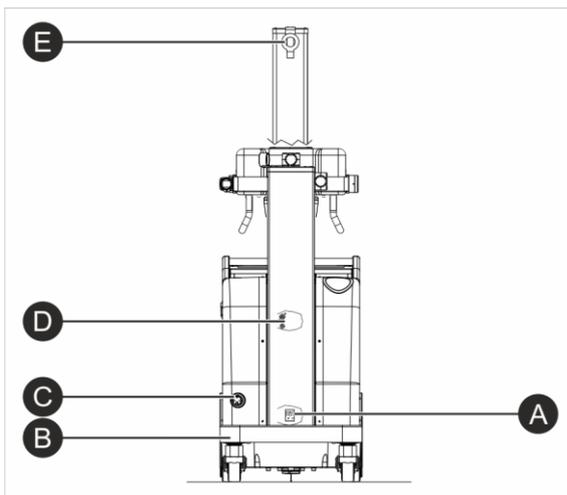
4.2.2 40 kW analogic version



- A - X-ray tube housing
- B - Goniometer
- C - Collimator
- D - Control panel for x-ray generator
- E - Cassette holder
- F - Safety Lock for column
- G - Telescopic arm
- H - Rotating column



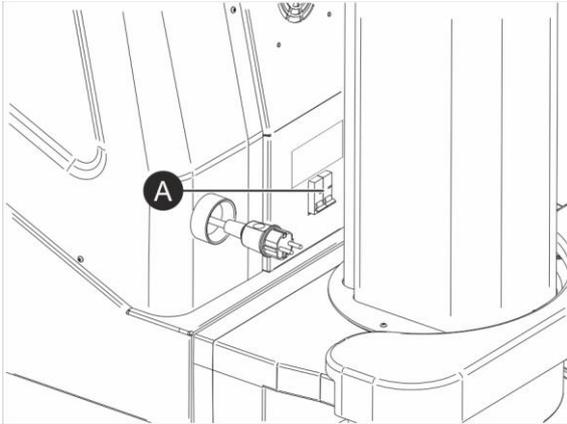
- A - Goniometer
- B - Remote controls
- C - Exposures remote control (optional)
- D - Emergency pushbutton
- E - X-ray emission handswitch
- F - Remote exposure control receiver (optional)
- G - Ignition key
- H - Transport handle with activation bar



- A - Circuit breaker switch
- B - Bumper
- C - Retractable power cable
- D - Potter interface / Equipotential node
- E - Apron-hanger (present only with fixed column)

4.3 Safety devices

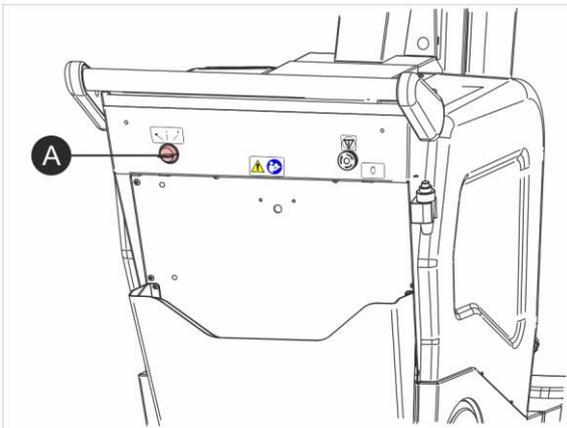
Circuit breaker switch



A circuit breaker switch (A) protects the equipment against excessive fluctuations of the mains during the batteries charging phase.

In case of intervention of the circuit breaker switch, in order to restore the functioning of the equipment it is enough to put back the control of the circuit breaker switch in "I" position.

Ignition key



A removable enabling key (A) prevents the use of the equipment from unauthorized personnel.

For the switching-ON:

1. Insert the key and turn it in "I" position.
2. Turn the key in "II" position and release it. The equipment switches ON.

For the switching-OFF:

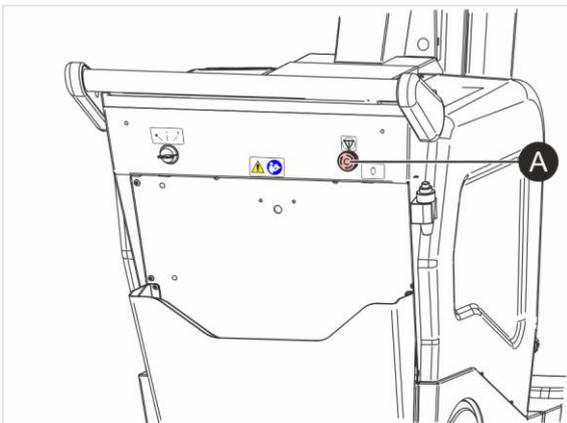
1. Turn the key in "II" position and release it. The equipment switches OFF.
2. Turn the key in "0" position.

Take away and keep the key in a safe place.



It is possible to remove the key only in "0" position.

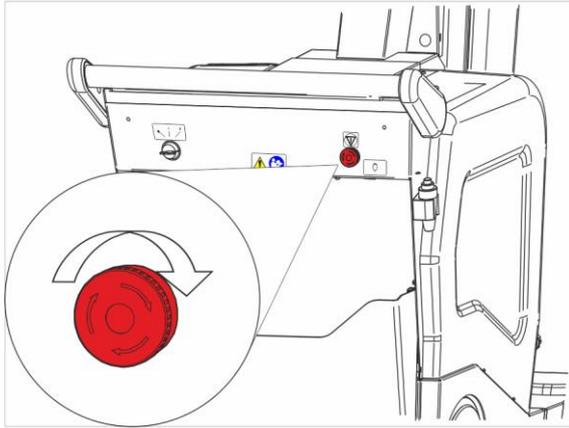
Emergency pushbutton



A Mushroom-head emergency pushbutton (A) placed under the control panel of the x-ray generator, stops the motion and use of the equipment in case of danger.

The use and motorized movement of the equipment are inhibited until the alarm is reset and the emergency pushbutton is activated.

Emergency pushbutton activation



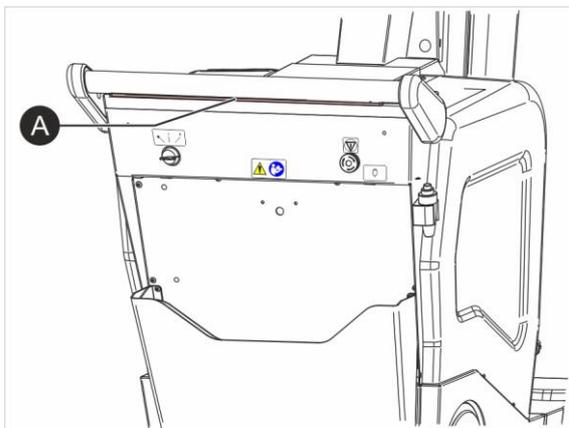
1. Press the pushbutton to stop the motion.

The display of the x-ray generator shows "STOP PRESSED"

2. Turn clockwise the pushbutton body to restore the motion and use of the equipment.

3. Press the reset key to cancel the message.

Activation bar



Under the transport handle there is a bar for brakes releasing and motors activation.

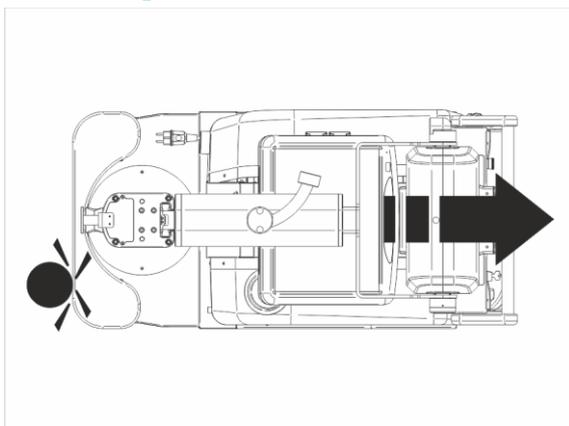
(1) Hold the transport handle with both hands and push the activation bar to move the equipment.

(2) Release the activation bar. The equipment stops.



Hold the transport handle with both hands.

Front bumper



The front bumper stops the equipment in case of collision against obstacles.

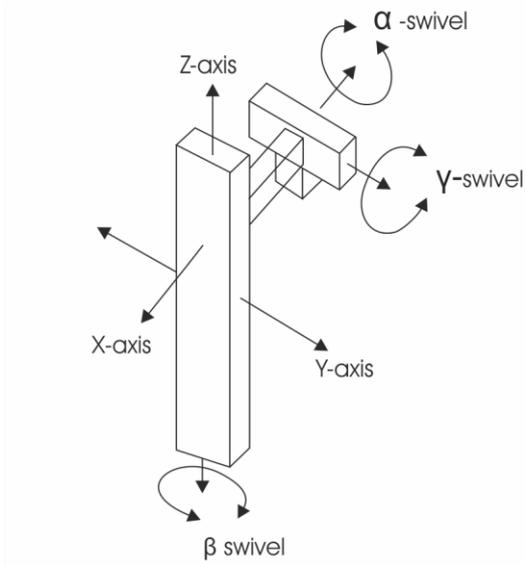
In case of bumper intervention, the x-ray generator display shows "BUMPER ACTIVE".

Until this bumper is activated, it is possible to use the equipment only into reverse, in this case the speed is reduced of 50%.

When the bumper is disabled, the equipment functions normally again.

Press the reset key to reset the alarm.

4.4 Movements



X-axis = Movement of the telescopic arm

Y-axis = n.a.

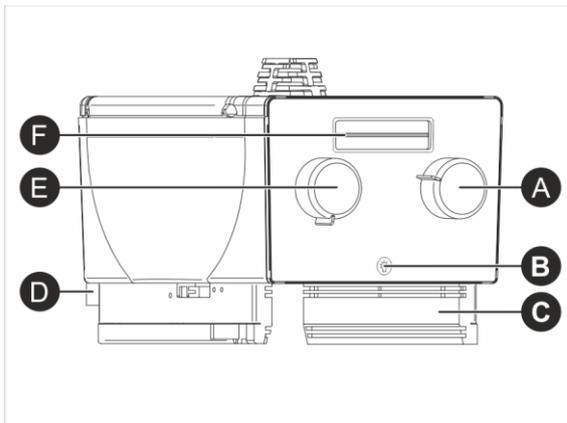
Z-axis = Vertical movement of the x-ray group

α-swivel = Rotation of x-ray group around X-axis

β-swivel = Rotation of x-ray group around Z-axis

γ-swivel = Rotation of x-ray group around its axis

4.5 Collimator



A - Longitudinal collimation

B - Lamp ignition pushbutton and laser pushbutton (optional)

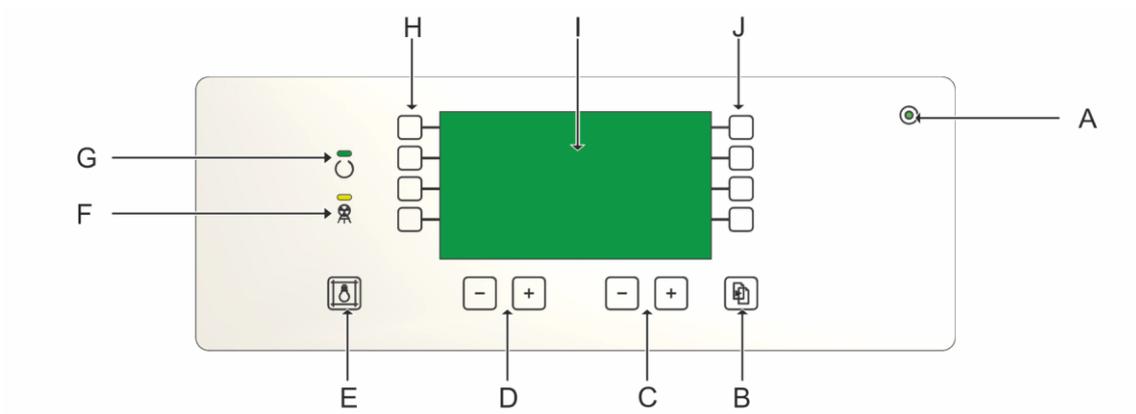
C - Guides for accessories positioning (filters or DAP meter)

D - Tape measure for the measurement of focus-image receptor distance

E - Transversal collimation

F - Disc for filters insertion

4.6 X-ray generator control panel



- A - Voltage indicator
- B - Scrolling of menu items
- C - Pushbuttons for mAs value selection
- D - Pushbuttons for kV value selection
- E - Collimator lamp switching ON
- F - X-ray emission signaling
- G - Equipment Ready/Busy signal
- H - Function keys (F1 ÷ F4)
- I - Alphanumeric display for x-ray parameters and warning/error messages visualization
- J - Function keys (F5 ÷ F8)

4.7 Light signals

	ON	green	ON: equipment ON and functioning. Flashing light of the equipment connected to the mains and in battery recharge phase.
	STAND-BY	green	ON: equipment ready for x-ray emission
	X-RAY	yellow	Performance of an exposure with x-ray emission

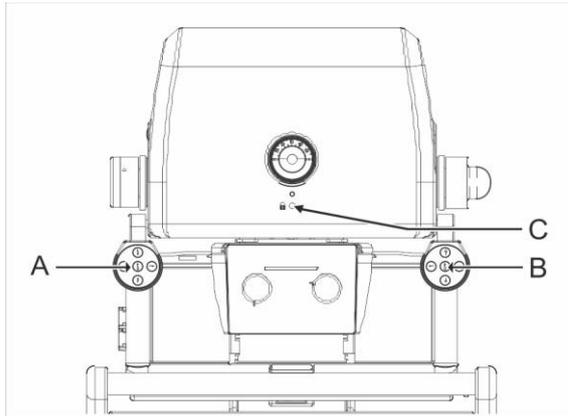
Light signals can't be disabled

4.8 Acoustic signals

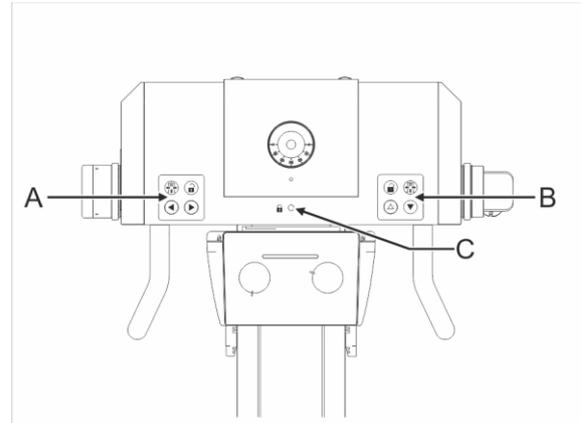
2 BEEP	Signal of storage complete
3 BEEPS	Successful x-ray emission
1 LONG BEEP	Alarm or malfunction signal (about 1 sec)

It is not possible to disable the acoustic signals.

4.9 Remote controls



32 kW



40 kW

A - Remote controls. Direction keys + Release

B - Remote controls. Direction keys + Release

C - **Only for equipment with telescopic column:** activated brake signal (led ON) for the vertical movement of the column

The direction keys  allow to move the equipment without returning to the driving position, when it is placed next to the patient's bed and it needs small movements.

The key Release  releases the column and the arm from the parking position.

Only for equipment with telescopic column: when the column is in working position, it releases/connects the vertical movement brake.

5 MESSAGES

5.1 X-ray generator messages

The equipment displays three types of messages:

S = Equipment status

No influence on functioning

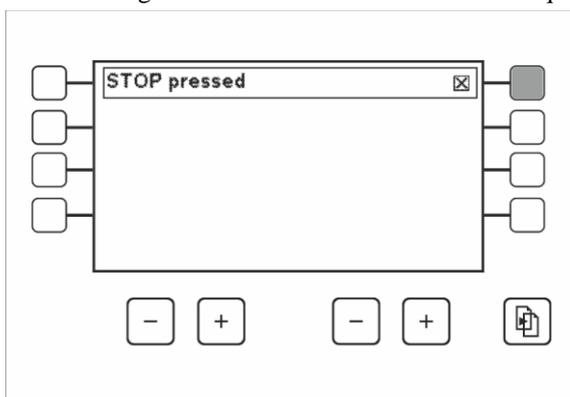
W = Warning

Press RESET key on the keyboard to cancel the warning and go on working.

E = Error

The equipment must be rebooted.

An error register is created to facilitate the subsequent work of Service personnel.



The display shows the warning or error message in a proper box.

The message is displayed in the configuration language of the equipment.

All warning messages should be reset by the operator by the RESET key next to the message.

Status messages

S-Code	Text	Meaning	Action
S	READY	The equipment is ready to perform an exposure	Perform the exposure
S	BUSY	Preparation / waiting phase	Wait for "READY" message
S	BUMPER ACTIVE	Bumper intervened against an obstacle	Release the handle, hold it again and, in reverse, move away from the obstacle. Press the RESET key
S	STOP PRESSED	STOP pushbutton pressed	Restore the correct functioning of the STOP pushbutton by turning it towards the sense of the arrows on the button. Press the RESET key.
S	TIMEOUT	It's been too long between the pressing of PREP key and pressing of RAD (>15s) key	Release the key, press RESET key and try again.
S	PLEASE CHANGE mAs	mAs not allowed for required focus.	Press RESET key, change mAs data and repeat the operation.
S	PLEASE CHANGE FOCUS	Tube focus not allowed for required data.	Press RESET key, change focus and repeat the operation.

Warning messages

S-Code	Text	Meaning	Action
W	SETUP ERROR	Lost setup data	It is possible to go on working carefully, radiological data are default values,
W	Batt. backed RAM	Battery of the memory exhausted	It is possible to go on working, but the data and time registration are not correct.
W	THERMIC ALARM	The monobloc temperature reached the max value allowed.	Switch OFF the equipment and wait for the tube cooling.
W	MAN. X-RAY STOP	The x-ray emission control has been released before the end of the exposure	Press the RESET key to continue.
W	HANDLE NOT FREE	At switching ON, the handle is pressed	Release the handle and try again. If the error still exists, call the Service.
W	RECHARGE NEEDED	Discharged batteries.	Press the RESET key, move the equipment in a place suitable for battery charging.
W	SEASONING REQUIRED	After a long period of inactivity (3 months or more), it is necessary to proceed to the tube seasoning, in order to avoid serious faults.	Press the RESET key to go on, call Service to perform the tube seasoning. It is possible to work but with caution
W	DAP TEST FAILED	Test not corresponding to the set value.	Press the RESET key to go on working without the DAP.
W	EXT XR ORDER	After a certain waiting time no x-ray consent is arrived from the Potter Bucky.	Press the RESET and call the Service
W	DRIVE TEMP.WARN	One of the motor is overheated	Switch OFF the equipment and let the drives to cool down.
W	DRIVE MAX TEMP.	One of the motor has reached the max temperature allowed.	Switch OFF the equipment and let the drives to cool down.
W	DRIVE OVER VOLT.	Too high voltage to one of the drives	Switch OFF the equipment. Call the Service
W	DRIVE UNDERVOLT.	Too low voltage to one of the drives.	Switch OFF the equipment. Call the Service
W	RECOMMENDED RECHARGE	The residual charge of the batteries is such that their recharge is allowed in five hours.	Press the RESET key to continue. In case you don't proceed with the recharge but you continue to work, the rechange of the batteries in five hours is not guaranteed.

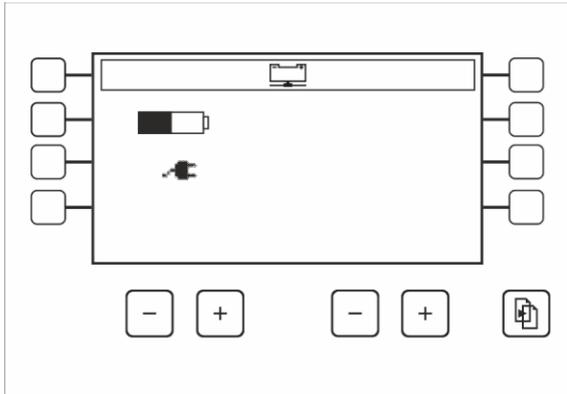
Error messages

S-Code	Text	Meaning	Action
E	GENERATOR OFFLINE	Communication with GSC board failed	Switch OFF the equipment, call Service.
E	CSB COMMUNICATION	Communication with CSB board failed	Switch OFF the equipment, call Service.
E	GENERATOR FAILURE	X-ray generator faulty	Switch OFF the equipment, try again, if the error persists, call Service.
E	FILAMENT ERROR	Filament current overload	Press RESET to continue, if the error appears again, call Service.
E	STEPUP ERROR	Stepup generator broken	Switch OFF the equipment, try again, if the error persists, call Service.
E	KV UNBALANCED	Unbalanced high voltage circuit during the exposure.	Press the RESET key to go on and repeat the exposure.
E	KV OVERLOAD	During exposure, kV increased over 110% of the max value.	Press the RESET key to go on and repeat the exposure.
E	LACKING OF X-RAY	kV didn't reach the 75% of set value within the first 5 ms of exposure.	Press the RESET key to go on and repeat the exposure.
E	KV FAULT	During the exposure, kV decreased under the 75%.	Press the RESET key to go on and repeat the exposure.
E	mA OVERLOAD	mA value out of range.	Press the RESET key to go on and repeat the exposure.
E	POWER SUPPLY ERR	Power supply circuit broken.	Switch OFF the equipment and call Service.
E	HANDSWITCH ERROR	X-ray pushbutton broken.	Switch OFF and ON the equipment, check the integrity of the x-ray handswitch, try again, if the error persists call Service.

Error messages

S-Code	Text	Meaning	Action
E	X-RAY MAX TIME	The max exposure time has been reached.	Press the RESET key to go on, repeat x-ray, if the error still exists call the Service.
E	STARTER FAULT	Error during x-ray tube launching.	Press the RESET key to go on, repeat the exposure, if the error still exists call the Service.
E	FILAMENTBROKEN	Filament circuit broken	Switch OFF the equipment, repeat the operation, if the error still exists call the Service
E	ANODIC CURR.FAULT	Lack of anodic current during exposure	Switch OFF the equipment, repeat the operation, if the error still exists call the Service
E	BATTERY TEST BROKEN	Batteries test circuit broken	Call the Service
E	BATTERY PACK ERR	During the batteries charging, an error occurs	It is possible to use the equipment with the charge made up to the occurrence of the fault. Call the Service.
E	CURRENT SENSOR FAULT	Error in the reading circuit of the current consumed.	It is possible to use the equipment in case of emergency and with caution. Call the Service.
E	GENERATOR OFFLINE	Communication error.	Switch OFF the equipment, call the Service.
E	L-DRIVE DISCONNECTED	Communication error with left drive.	It is possible to move the equipment. Call the Service
E	R-DRIVE DISCONNECTED	Communication error with right drive.	It is possible to move the equipment. Call the Service
E	CALIBRAT.MISSING	Calibration of the load curves of the missing x-ray tube	Switch OFF the equipment, repeat the operation. If the error still exist call the Service,

5.1.1 Visual messages



In case of alarm during the battery charge, the x-ray generator display shows the icons of the battery group with the graphic representation of their status.

Icon	Description
	Battery pack alarm disconnected from the communication net (charging of other batteries goes on)
	Battery pack temperature alarm
	Battery pack failure alarm
	Batteries ventilation alarm (fan stopped)

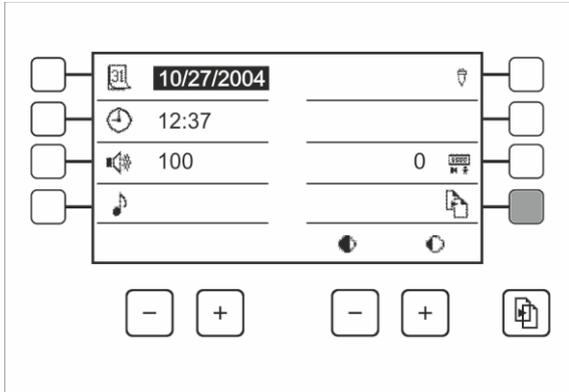
Other icons

Icon	Mnemonic	Description
	BATTERY	Charging status of batteries
	PARK	Equipment in transport position
	LF	Large Focus
	SF	Small Focus
	HS	Handswitch mode. X-ray emission is carried out through the wired x-ray handswitch
	WIRELESS	Wireless mode. The x-ray emission occurs through the infrared control (optional).

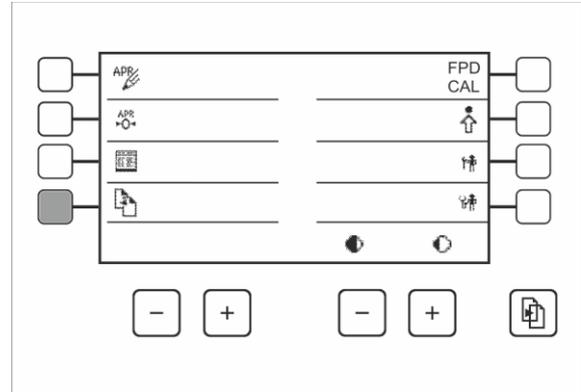
6 UTILITY MODE

The "UTILITY MODE" is a menu procedure that can be activated by the end user and that allows the setting of the unit parameters useful for daily operation.

The configuration voices are reported on several pages, press "NEXT PAGE" or "PREV PAGE" to move from a page to another.



Utility Mode page 1



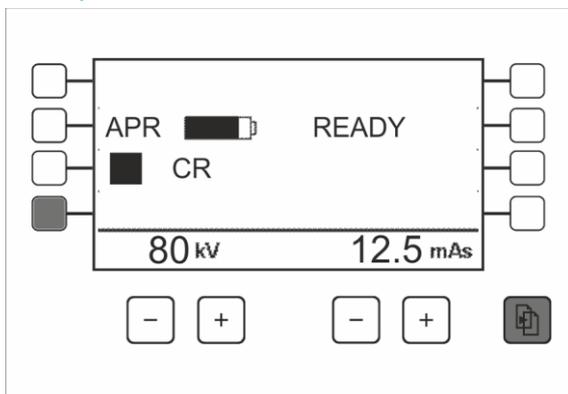
Utility Mode page 2

Icon	Mnemonic	Description	
	DATE	system date	format MM.DD.YYYY
	TIME	system hour	format hh.mm
	VOLUME	buzzer volume	1 ... 100
	KEY CLICK	acoustic signal at key pressing	0 ... 1
	X-RAY COMMAND	choice between HANDSWITCH and WIRELESS mode	
	TOT. EXPOSURES	counting of exposures made	0 ... 9999
	NEXT PAGE	Next page	
	CONTRAST	Brightness and contrast of the display	

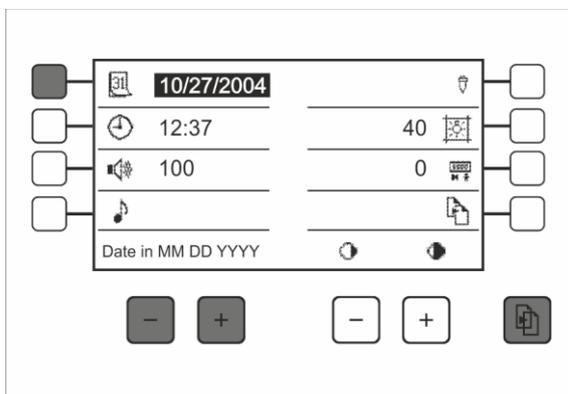
Icon	Mnemonic	Description
	APR EDIT	It modifies kV and mAs values associated to the exam
	EXPOS. HISTORY	Parameters of last 200 exposures
	PREV PAGE	Previous page
	RESET APR	It returns APR data to default values*.
	SETUP	Reserved to qualified service personnel.
	ADJUSTMENTS	Reserved to qualified service personnel.
	DIAGNOSTICS	Reserved to qualified service personnel.
FPD CAL.	FPD CALIBRATION	Reserved to qualified service personnel.
	Undo	Cancel the inserted data

* **WARNING! Data previously stored will be lost.**

Utility Mode activation



1. Press "MENU" key and, by holding it down, press F4 function key.

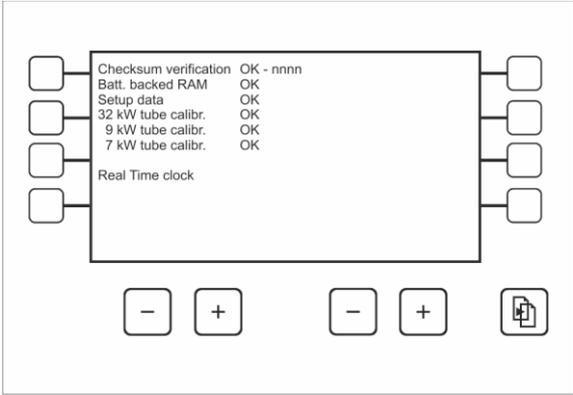


2. Press the key next to the item to be modified.
3. Modify the value by using kV- and kV+ keys.
4. Press "MENU" key to store the new data.
5. If necessary, modify other parameters by following the same procedure.
6. Press "MENU" key to go back to the Main Screen.

7 FUNCTIONING

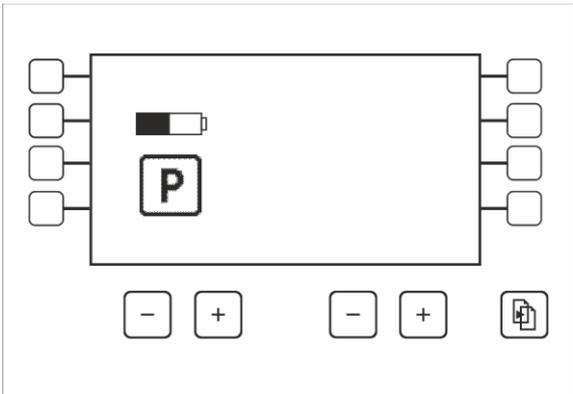
7.1 Switching ON

 It is possible to switch the equipment ON only if it is disconnected from the mains or if the circuit breaker switch is in "0" position.

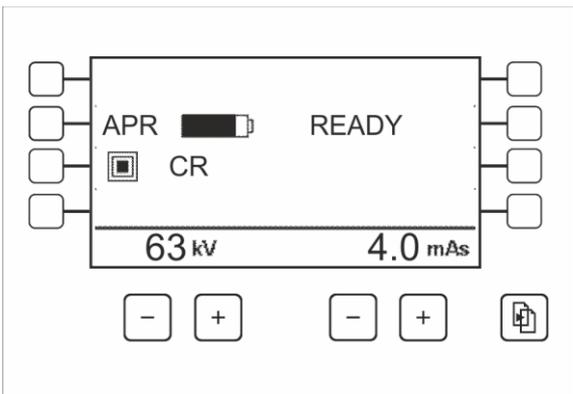


1. During the battery charge phase:
 - put the circuit breaker switch in "0" position
 - disconnect the power supply cable and wind it on the cable reel.
2. Put the ignition key in "II" position and release it.

The ON green led is fixed ON.
The system emits three beeps and goes on with checks and autotest.



3. If the rotating column is in transport position:
 - the ON green led is fixed ON
 - the display shows the battery charge symbol and the "transport condition" symbol
 - the x-ray generator is OFF.
 - the motion at standard speed (max. 5 km/h forwards, 2.5 km/h backwards) is allowed.

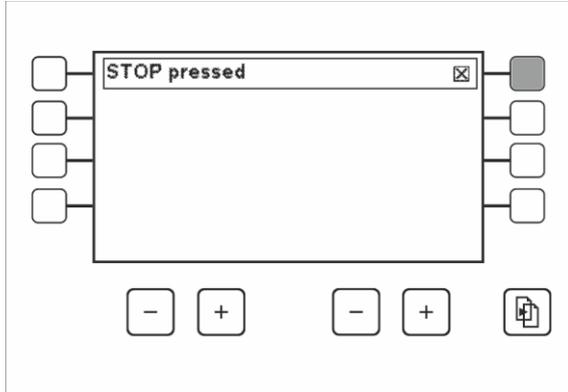


4. If the rotating column is in operating position:
 - the ON green led is ON and fixed
 - the display shows the Main screen
 - the battery symbol shows the charge level of the batteries
 - the x-ray generator is ON.
 - the motion at low speed (max. 2.5 km/h forwards, 2.5 km/h backwards) is allowed.

7.1.1 In fault condition

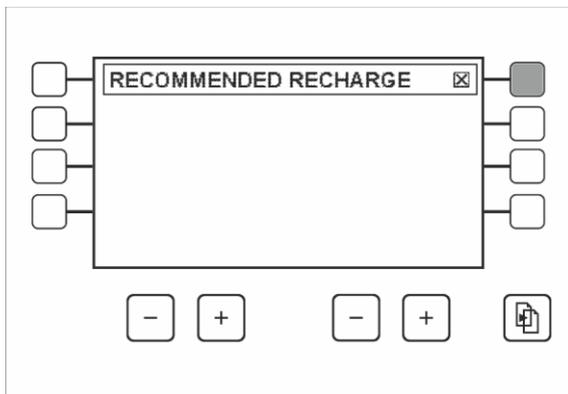


If on the first line of the display an error message appears, press the error reset key to go on.
 If the alarm persists, switch OFF and ON again the equipment.
 If the alarm goes on to persist, switch the equipment OFF and call Service.



If during the switching ON, the emergency pushbutton is pressed, the display emits a deep sound and it shows the message "STOP PRESSED" and all the equipment functions are inhibited.

Restore the emergency pushbutton
 Press the reset key of the error to continue.



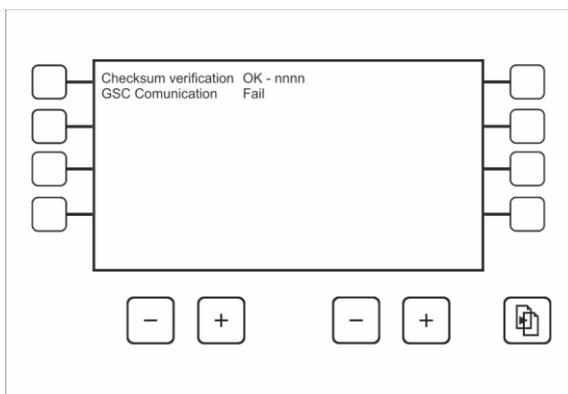
If during the switching ON the message "RECOMMENDED RECHARGE" appears, the residual charge of the batteries is such that a complete recharge in five hours is allowed.

In case you don't proceed with the recharge but you continue to work, the batteries recharge in five hours is not guaranteed.

Press the reset key of the error to continue.



The message appears even during the standard use of the equipment, when the batteries charge goes under the limit.



If during the initial tests the alarms "GSC COMMUNICATION FAULT" or "CSB COMMUNICATION FAULT" appear, move the key in "0" position to switch the equipment OFF.
 Call Service.



In case the key is not moved in "0" position, after a waiting time of two minutes, the equipment will switch OFF alone.

7.2 Sleep mode / Automatic switching OFF

After a programmed idle period (three minutes, not changeable) in which no key/pushbutton is pressed, the equipment enters in Sleep Mode, by lowering the brightness of the display.

After a further idle period, the equipment emits an audible signal, repeated after 20 seconds and then after further 10 s.

Once the waiting time is expired, the equipment switches OFF completely.

To restart it, it is enough to move the key in "II" position and release it.

If during Sleep mode or during the automatic switching OFF waiting time, one of the keys is pressed, the display switches ON again, the time interval resets and the counting starts again.

The idle time to enter Sleep mode cannot be modified.

The idle time for the automatic switching OFF can be programmed from 1 to 60 minutes (30 default minutes) and can be modified at any moment by qualified and trained Service personnel.



It is possible the auto-switching OFF due to technical reasons (discharged batteries or low battery power). In this case the equipment emits an only acoustic warning signal, then it switches OFF.

7.3 Transport



Risk of tilting.

Use and transportation on inclined floors.

- ▶ Don't use or move the equipment on floors with inclination more than 10°.

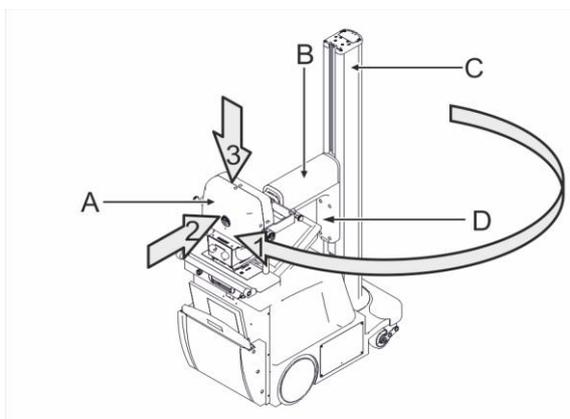


Danger of damages and injuries during the equipment movement.

The uncontrolled movement of the equipment could cause damages to the operator, patient and personnel in proximity of it.

- ▶ The equipment must be moved only in the condition called "transportation" and with all the blocks of the movements activated.

7.3.1 Preparation to transport



Move the equipment only if it is in transport position.

1. Monobloc group (A) on the equipment, by rotating the swiveling column (C).
2. Monobloc-collimator group (A) in vertical position.
Monobloc-collimator group (A) towards the swiveling column (C).
3. Arm (B) lowered until the safety lock for transport (D) clicks.



During the movement of the rotating column, pay attention to the position of the cables.
Check that all safety locks are correctly clicked and safe.

7.4 Movement of the equipment



Damages to people and things

During the movement, the equipment could pass on feet or objects located on the floor, by causing damages or injuries.

- ▶ Do not stand in front of the equipment
- ▶ Pay a lot of attention when moving the equipment



In starting phase the equipment could bend slightly according to the position of the wheels.



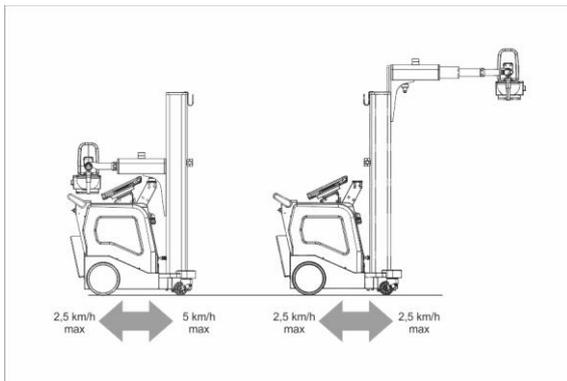
Hold always the handle for the transport with both hands and activate the bar integrated in the handle.

For stopping the equipment, push or pull the handle in reverse to the movement direction till it stops. Then release the activation bar.

By releasing the activation bar without decreasing the push on the handle, the equipment stops immediately.

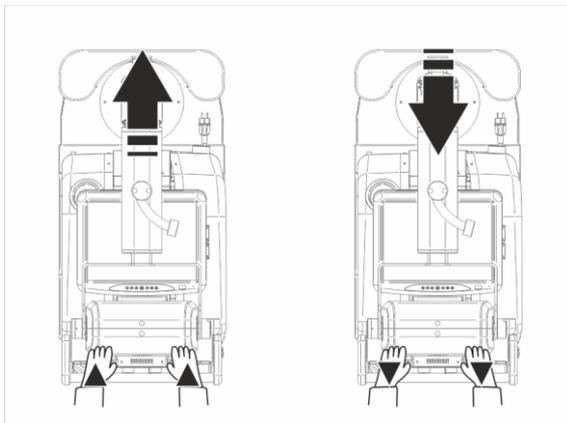
By reversing the movement, the equipment could turn a bit on a side, according to the position of the front wheels.

The speed is proportional to the stress on the handle for the transport.



In transport position, the equipment can be moved to a max speed of 5km/h forward and 2.5km/h backward.

In working position, the equipment can be moved to a max speed of 2.5km/h both forward and backward.



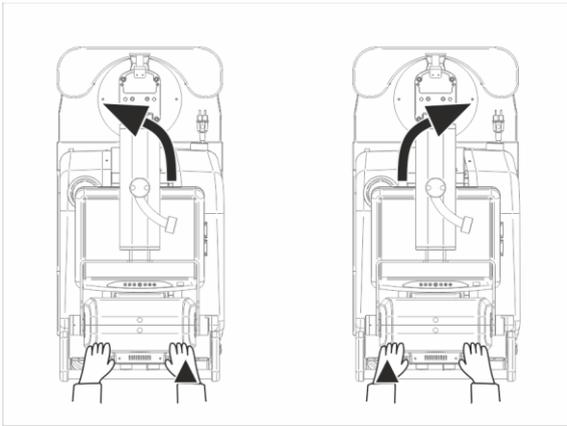
Forward-Backward

Hold the transport handle.

Press the activation bar under the handle.

Push a little bit the handle to move forward.

Pull a little bit the handle to move backward.



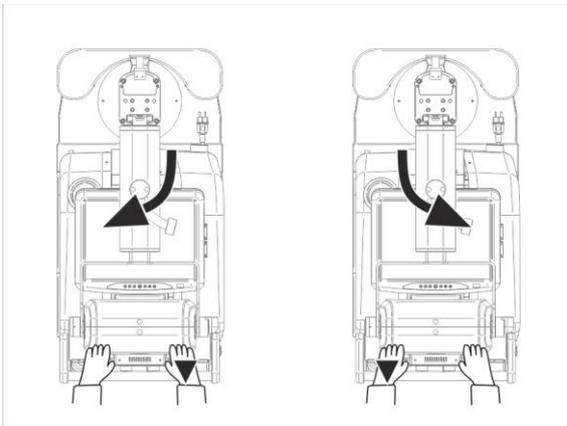
Turn on the left-right

Hold the handle for the transport.

Press the activation bar under the transport handle.

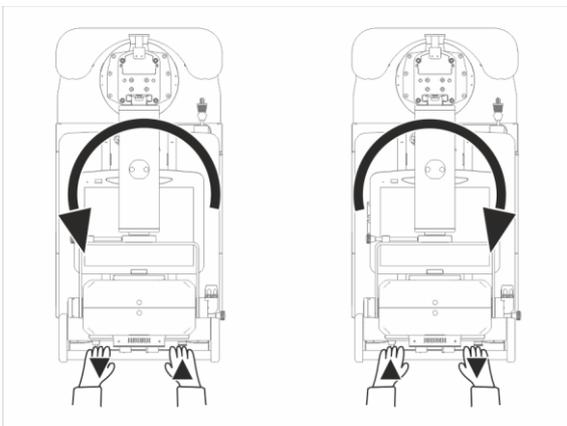
Push the right side of the handle to turn on the left

Push the left side of the handle to turn on the right



Pull the right side of the handle to turn on the left.

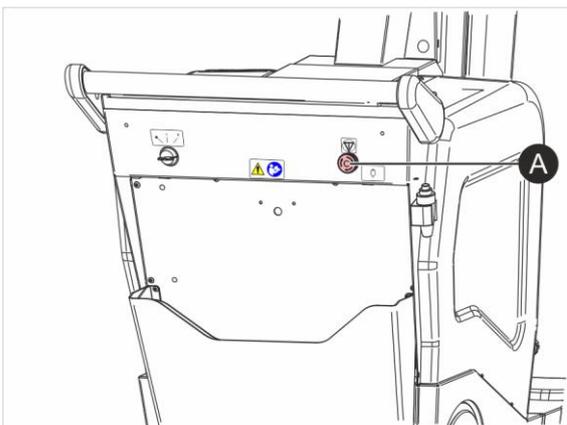
Pull the left side of the handle to turn on the right.



Rotation

Pull the left side and at the same time push the right side of the handle to turn counterclockwise

Push the left side and at the same time pull the right side of the handle to turn clockwise



In case of danger, press the emergency pushbutton located under the control panel of the x-ray generator.

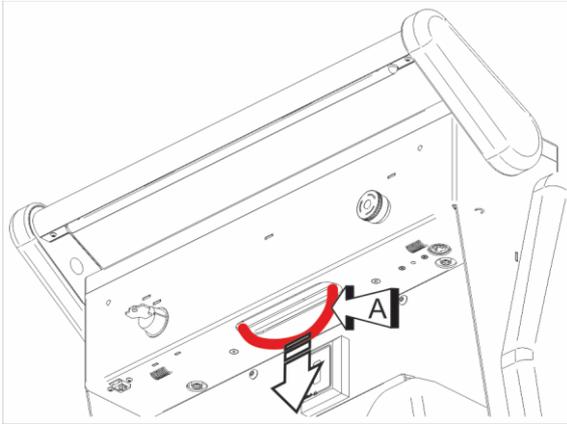
7.5 Emergency release



Impossibility to move the equipment

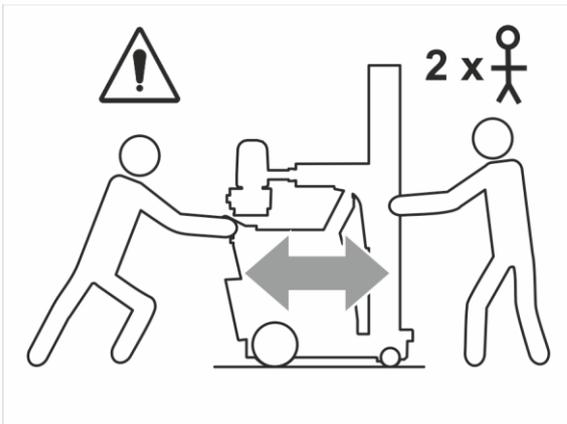
Motors and batteries failures or power too low to move the equipment.

- ▶ Never act on the transport handle to move the equipment
- ▶ Move the equipment in two people



1. Put the equipment in transport position.
2. Turn the key in OFF position, remove it and keep it in a safe place.
3. Find the red release metallic cable (A), placed under the control panel of the x-ray generator.

For the movement of the equipment, pull and keep pull downwards the metallic cable.

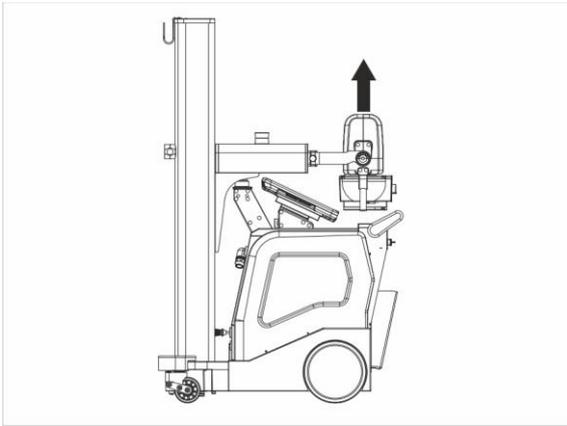


4. Move the equipment in two people. One person in the front pulls and drives the equipment, the other one in the back keeps the red metallic unlocking cable pulled and pushes the equipment.



Always keep the red metallic unlocking cable pulled. If it is released, the equipment immediately stops.

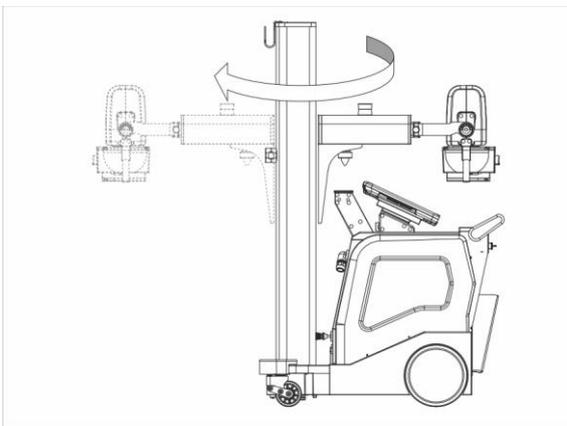
7.6 Positioning



1. Press the column release key

The x-ray generator switches ON and the x-ray generator display shows the x-ray default parameters.

2. Move the arm UP

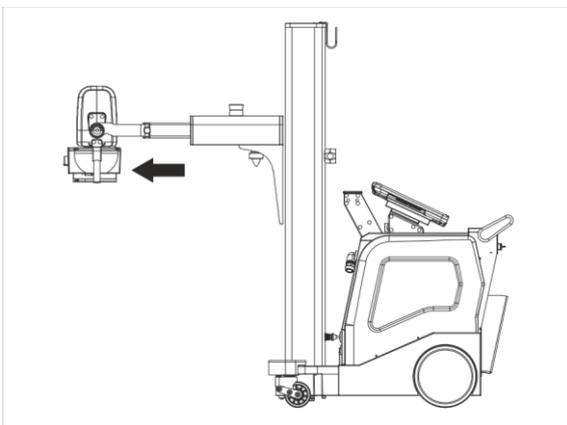


3. Rotate the column clockwise/counterclockwise by moving it in front position, according to the requirements of the exam to be performed.

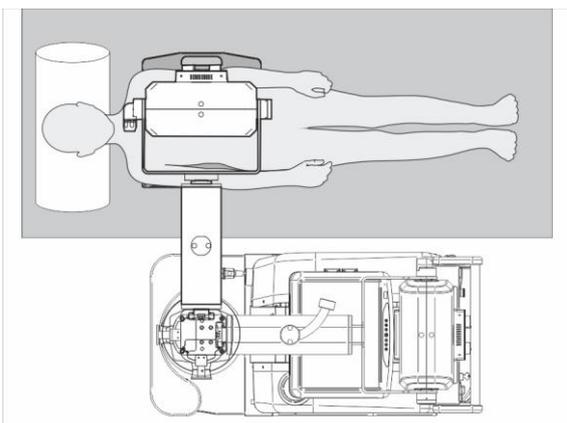
The rotation of the column around its vertical axis is of 320° both clockwise and counterclockwise.



Pay attention to the cables during the column rotation.



4. Pull the arm



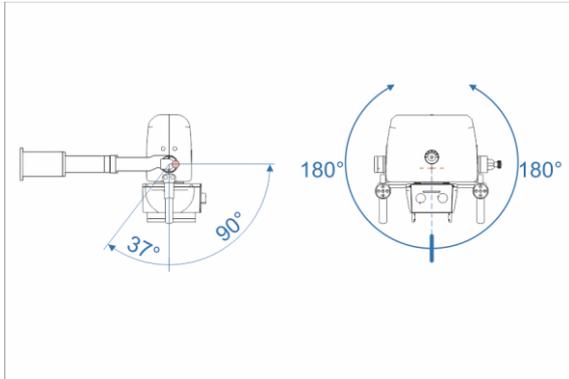
5. Move the x-ray group over the patient and over the images receptor, if possible in perpendicular position.



For additional information concerning the use of the provided detector, refer to the relative user's manual attached to the equipment.



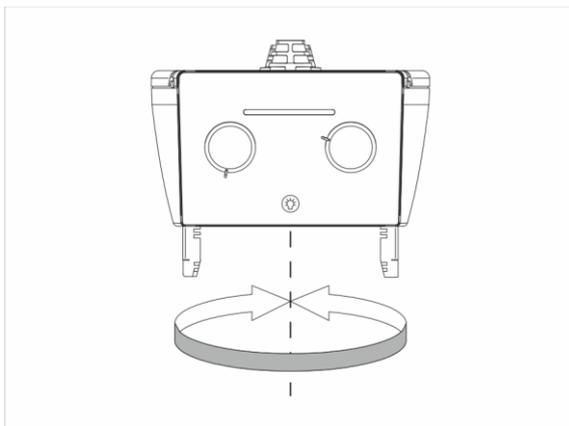
For additional information concerning the detector handling, refer to the instructions in the Safety Chapter of this manual and to the original detector documentation.



6. Move the system on the patient and on the image receptor, if possible in perpendicular position.

The monobloc-collimator group can rotate $+90^\circ$ and -37° in respect to the vertical one. The movement angle can be read on the lateral monobloc goniometer.

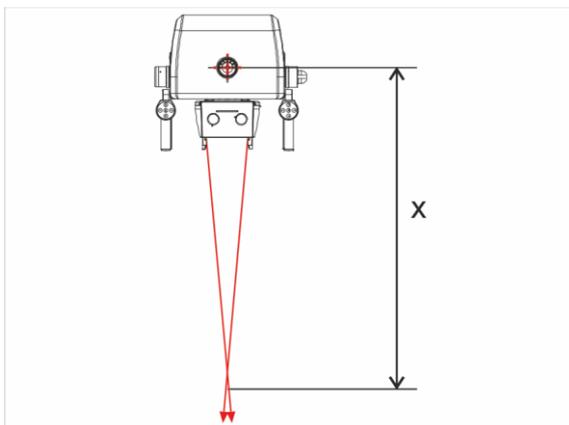
The monobloc-collimator group can rotate of $\pm 180^\circ$ around the tube axis. The moving angle can be read on the front goniometer of the monobloc.



7. If necessary, rotate the collimator.

The collimator can rotate around its axis of $\pm 120^\circ$.

To rotate it, simply hold it with both hands and rotate in the required direction.

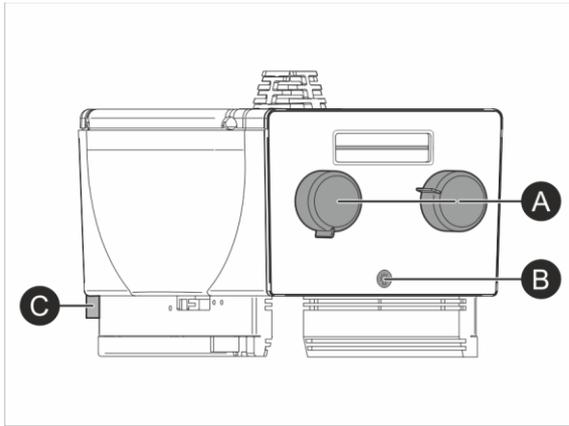


8. Set the focal distance.

9. Two laser beams are adjusted so that the FFD is defined from their intersection point at 1 mt.

10. The laser beam switches ON when the collimator lamp lights ON. It switches OFF automatically after 30 s.

11. For other FFD values (or if the laser accessory is not assembled) use the tape measure inside the collimator.



12. Light ON the collimator lamp.

13. Collimate the radiation beam to the dimension of the image receptor.

14. Measure the focal distance.

On the front panel of the collimator there are two knobs (A) to adjust the size of the beam (width and length); the pushbutton to light ON the collimator lamp (B) and the tape measure (C) to accurately measure the focus-film distance (FFD).



To the minimum inherent filtration of the collimator, it is possible to add a filtration obtained by means of a disk moved manually,

On the disk, in addition to a hole for the passage of x-ray beam without additional filtration, there are the following three filters:

“-“ 1mm Al + 0.1mm CU

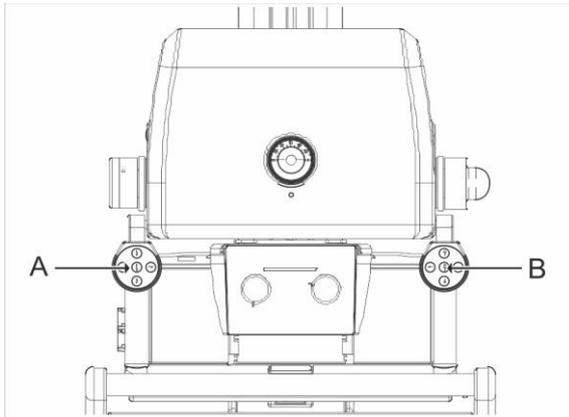
”-“ 1mm Al + 0.2mm CU

“- -“ 2mm Al

The lighting of a yellow LED on the front panel of the collimator indicates the insertion of the additional filtration.

7.7 Positioning through remote controls

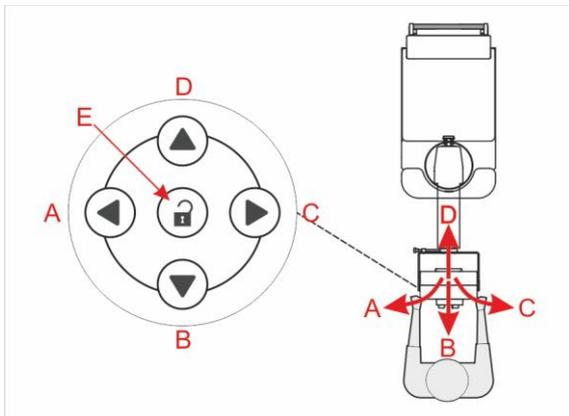
7.7.1 32 kW equipment version



Through remote controls (A, B) it is possible to perform displacements of the equipment when it is near the patient's bed.

The movement occurs continuously and at low speed.

If the front wheels are in a difficult position and the equipment does not move, press at the same time the central key and the desired directional key.



A - Movement towards the left

B - Movement forwards

C - Movement towards the right

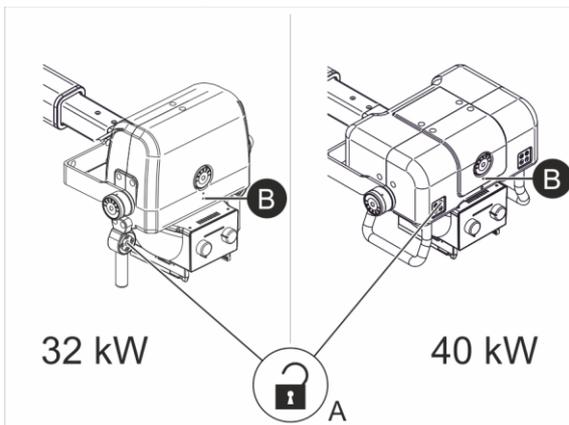
D - Movement backwards

E - Release of the vertical movement brake (*only for telescopic column*)



The movements refer to the position of the operator and equipment as indicated in figure.

Only for telescopic column



Once the position and the focal distance have been determined, press the key "Release" (A) on the Remote Controls to insert the parking brake of the vertical movement.

The red LED (B) lights UP.

In order to deactivate the parking brake and allow the vertical movement, press again the key "Release" (A).

The red LED (B) turns OFF.



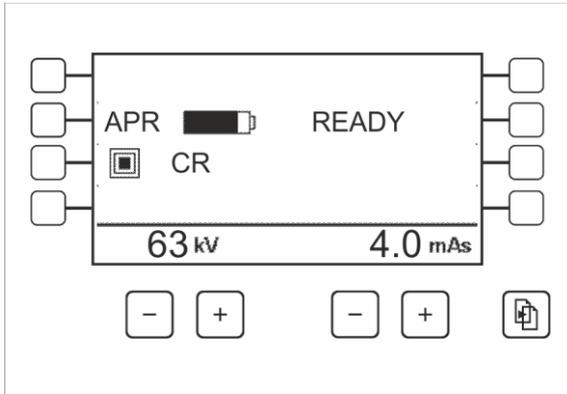
Don't move the X-ray group vertically if the brake is ON (red LED ON).

7.8 Exposures

 The values indicated in the following drawings are only indicative.

7.9 Exposures in AR mode

7.9.1 Free exposure



After the initial tests, the display shows the initial screen.

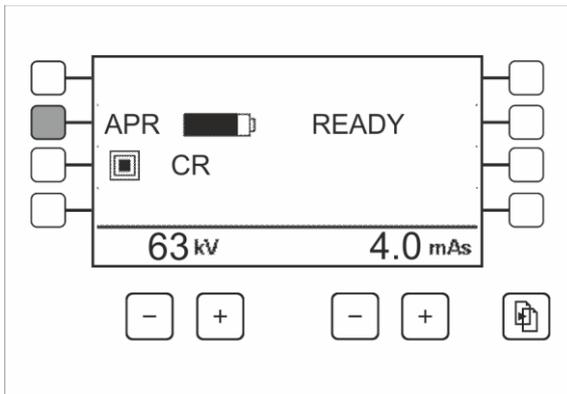
Default parameters of the equipment are displayed as they have been stored during configuration phase.

The kV, mAs, Focus parameters can be modified according to the need.

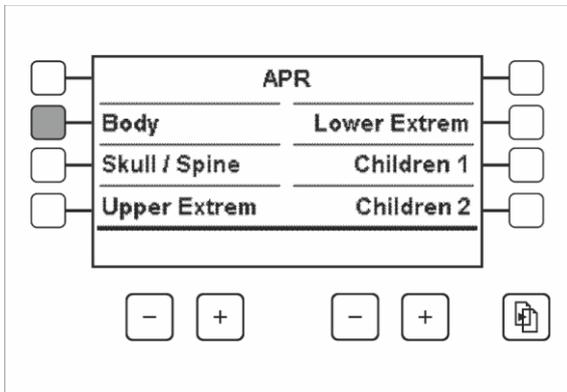
Perform the exposure.

The display shows the exposure time and, in case of error, the mAs value really released.

7.9.2 Exposure in Programmed Anatomic mode (APR)

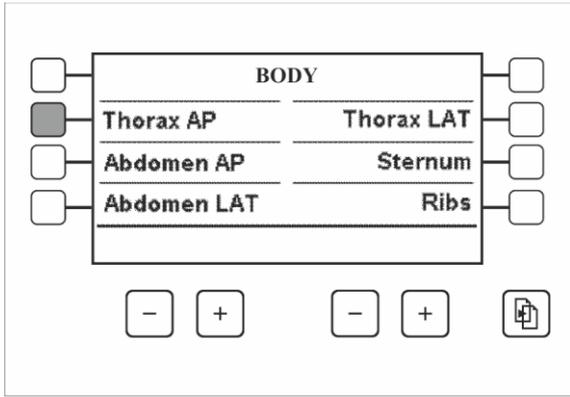


1. Press "APR" key.



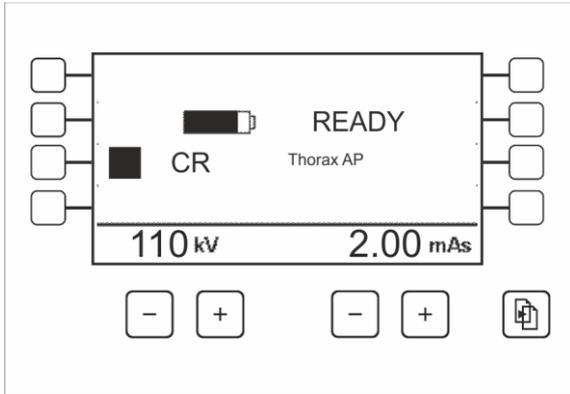
APR mode is divided into six groups of examinations.

2. Select one of the six suggested groups (eg "BODY").



Each examination group is divided into six APR programs.

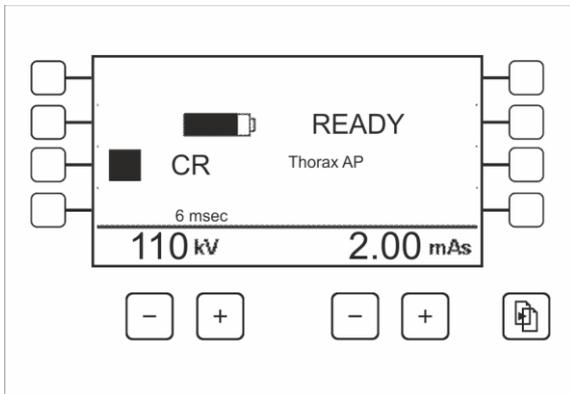
3. Choose one of the six suggested groups (eg "THORAX AP").



The display shows the exposure parameters of the APR program chosen (kV and mAs, Focus).

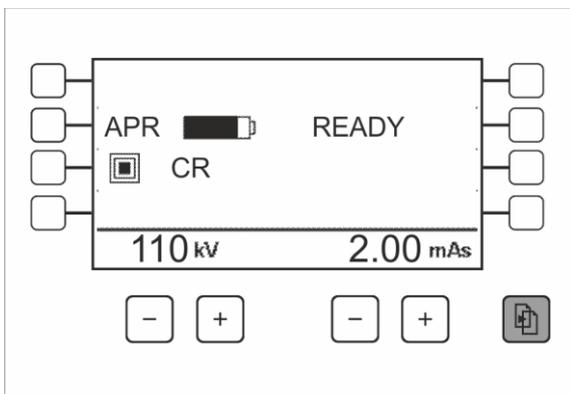
Parameters can be modified upon requirements.

The changes made apply only to the current examination.



4. Perform the exposure.

The display shows the exposure time and, in case of error, the mAs value effectively released.



To come back to Free exposure mode, press the "MENU" key until the main screen.

7.9.3 APR data table



APR programs suggested and preloaded by the manufacturer on the equipment, only represent recommendations to be applied to the patient in order to optimize the operation and result of the examination.

kV and mAs values set at the factory in APR programs can be modified at any moment by the user. They can be stored only if, during the equipment configuration, this possibility has been set (by authorized personnel only).

In the following table the dose values are expressed in μGym^2 (DAP Dose Area Product), the exposures are set with standard values for clinical investigations on the patient and performed with the x-ray tube with a SID (Source - Image receptor Distance) of 100 cm without grid.

The dose measurement has been performed according to IEC 60601-1-3 § 5.2.4.2 with dosimetric chamber supplied with the equipment and collimator with all shutters opened.

"BODY" folder

Name	Focus	kV	mAs	μGym^2
Thorax AP	LF	110	2	17.83
Abdomen AP	LF	81	16	76.37
Abdomen LAT	LF	90	20	118.94
Thorax LAT	LF	110	4	34.63
Breastbone	SF	85	4	22.84
Ribs	SF	70	6,3	24.12

"CRANIUM/vertebrae" folder

Name	Focus	kV	mAs	μGym^2
Cranium AP	SF	77	10	46.71
Vert. dors. AP	SF	77	20	93.97
Vert. lumb. AP	LF	81	20	104.10
Vert. cervic.	SF	66	8	27.07
Vert. dor. LAT	LF	81	16	76.39
Vert. lumb. LAT	LF	90	20	118.84

"UPPER EXTREMITY" folder

Name	Focus	kV	mAs	μGym^2
Clavicle	SF	66	5	16.81
Humerus	SF	60	3,2	8.56
Elbow	SF	55	4	8.53
Forearm	SF	55	2	4.27
Wrist	SF	50	2	3.25
Hand/Fingers	SF	46	1,6	1.99

"LOWER EXTREMITY" folder

Name	Focus	kV	mAs	μGym^2
Hip/Femur	SF	81	12,5	64.73
Knee	SF	63	5	15.07
Kneecap	SF	63	8	24.18
Leg/Ankle	SF	60	4	10.69
Foot	SF	48	2	2.85
Foot fingers	SF	44	2	2.12

"CHILDREN I" folder

Added Filter 1mmAl + 0,2mmCu (**)

Name	Focus	kV	mAs	μGym^2
Thorax 0,5 kg	SF	60	0,1	0.14
Thorax 1,0 kg	SF	60	0,2	0.24
Thorax 2,0 kg	SF	60	0,32	0.37
Thorax 3,0 kg	SF	62	0,4	0.54
Thorax 4,0 kg	SF	65	0,4	0.63
Thorax 5,0 kg	SF	68	0,4	0.75

"CHILDREN II" folder

Added Filter 1mmAl + 0,2mmCu (**)

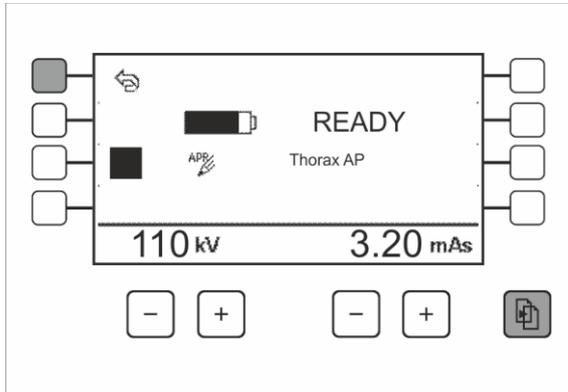
Name	Focus	kV	mAs	μGym^2
Thorax 8,0 kg	SF	76	0,4	1.08
Abdomen 4,5 kg	SF	65	2	3.19
Abdomen 8,0 kg	SF	65	3,2	5.13
Thorax 10 kg	SF	76	0,8	2.18
Abdomen 10 kg	SF	70	2	4.16
Abdomen 15 kg	SF	70	4	8.36

(**) The combination of filter 1 mm Al +0,1mm Cu is allowed too.

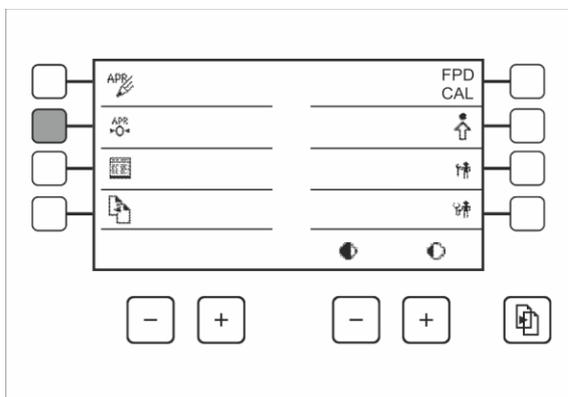
7.9.4 APR data modification



The procedure of anatomics adapting is valid only for the equipment used in analog mode.



1. Enter "UTILITY MODE" by pressing "MENU" and "F4" keys.
2. Press "NEXT" key to move to the next page.
3. Press "APR EDIT" key.
4. Choose the folder and the program to modify.
5. Modify the suggested kV, mAs Focus value as desired.
6. Press "MENU" key to store the data or press "UNDO CHANGES" to leave the changes and restore the data to previously stored values.
7. Press "MENU" key to exit and return to work.



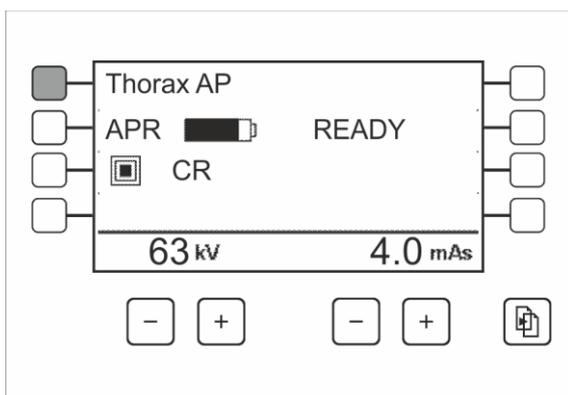
To return the APR values to the default values:

1. Enter "UTILITY MODE", by pressing "MENU" and "F4" keys,
2. Press "NEXT" to pass to the next page
3. Press "RESET APR" key.



By pressing the key "YES" in the confirmation page, all data previously saved in APR memory will be lost.

7.9.5 Rapid selection of APR program



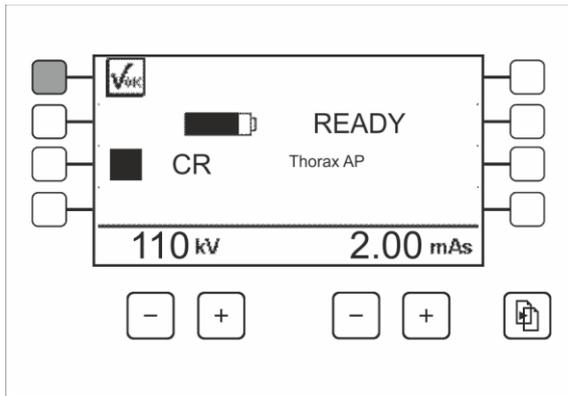
It is possible to assign the rapid choice mode to the APR program normally more used.

After the startup, on the display the name of the chosen APR program appears in the first line UP on the left.

1. To activate the chosen APR program, press the key near the name.



It is possible to choose one of any other APR program, by following the standard choice procedure.



To store the rapid choice APR program:

1. Select the desired APR program.
2. Press the key until an acoustic signal is emitted. Near the key the icon of occurred storage appears.

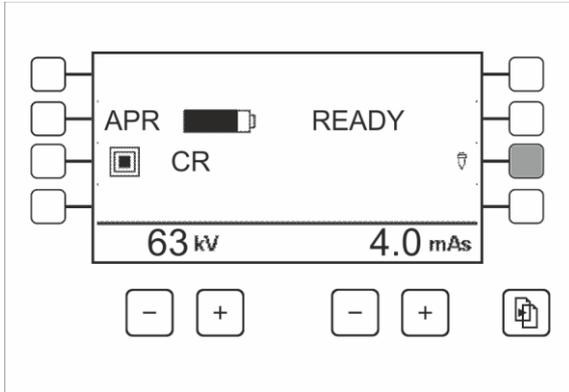
To delete the default APR program:

1. Press the key till an acoustic signal is emitted. The icon aside disappears.

7.10 Execution mode

The equipment has two execution modes of the exposure, that can be selected by the operator at any time:
HANDSWITCH: exposure performed by the wired control with extensible cable supplied with the equipment.
WIRELESS: the exposure is performed by the wired control or by remote infrared control (accessory) if installed.

An exposure mode excludes the other one.
 At starting up the mode is HANDSWITCH

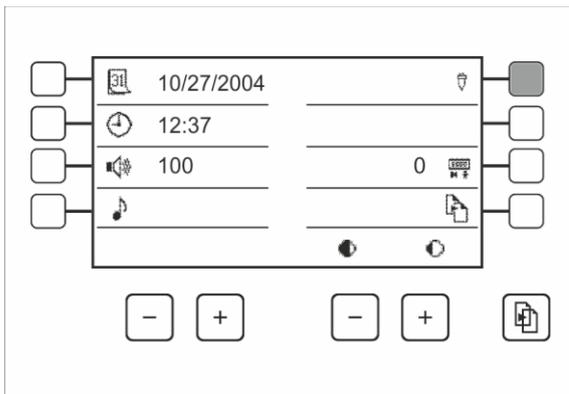


Operation by wired control (HANDSWITCH mode) is not indicated on the display.

Operation by wired control or by remote control (WIRELESS mode) is indicated by its icon next to the F7 function key.

To change the execution mode of the exposure, press the F7 function key.

Execution mode configuration



1. Enter Utility Mode.
2. Choose the exposure mode:



use with only wired control



use with wired control or remote control.

3. Press "MENU" key to store and exit from Utility Mode.



Use WIRELESS mode only if the remote infrared control is installed.

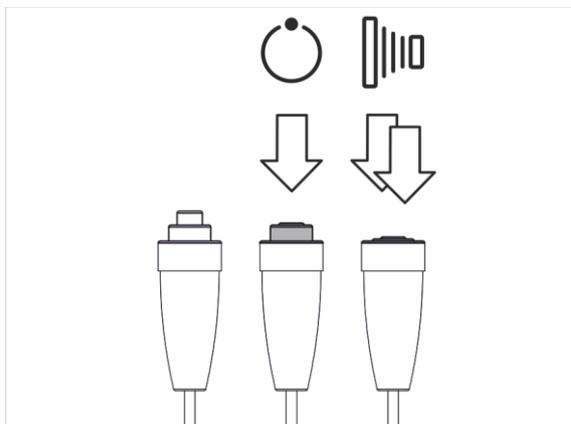
7.10.1 Handswitch mode



Ionizing radiations.

The operations described below require the emission of ionizing radiations.

- ▶ Take the proper measures to avoid exposing any part of the body to direct or indirect radiations.



1. Extend completely the x-ray control cable and keep as far away as possible from the x-ray source.

The x-ray control cable can be extended without deformations up to four meters. Over four meters the deformation becomes irreversible.

2. Press and hold down the exposures control at the first step to start the exposure preparation phase.

3. Press and hold down the exposures control at the second step to perform the exposure.

The end of the exposure is indicated through three beeps.

It is possible to press and hold down completely the x-ray control to perform the exposure immediately after the preparation phase.

7.10.2 REMOTE mode (optional)



Ionizing radiations.

The operations described below require the emission of ionizing radiations.

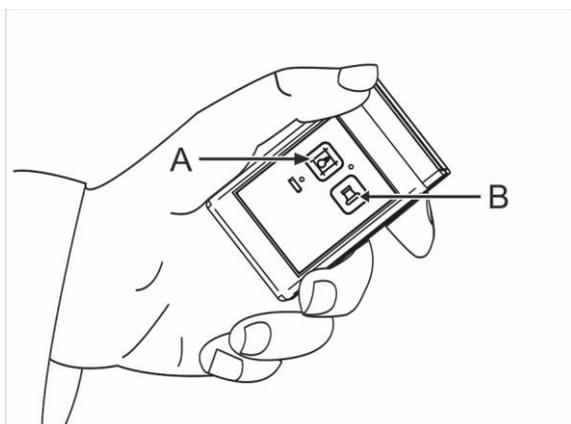
- ▶ Take the proper measures to avoid exposing any part of the body to direct or indirect radiations.



The wireless remote control works in visual mode up to 10 m with an operating angle of 360°, even through glass and leaded glass.

It doesn't work through doors or walls.

Activation



1. Remove the remote control IR from its support base, move away as much as possible from the x-ray source and address the remote control towards the receiver on the equipment.

2. Press the key "LAMP" (A) to turn the collimator lamp ON.

3. Press and release the key "RAD" (B) to start the exposure preparation phase.

4. Press and hold down the key "RAD" to perform the exposure.

5. After performing the exposure, put again the remote control in the support base on the equipment.

Deactivation

The light of the collimator deactivates automatically by pressing the key "RAD" or by pushing the key "LAMP".

The preparation cycle stops automatically and the stand-by condition returns if the exposure is not controlled within 15sec from its activation.

At the end of the exposure the equipment returns in stand-by even if the key "RAD" is held down. In order to perform a new exposure, it is necessary to release the key.

The exposure in progress can be stopped by releasing the key "RAD" ("*dead man*" control).

In case the receiver should lose the received signal because of insufficient intensity or interference of a body or an object that inhibits the IR signal to arrive to the receiver, therefore the active controls are immediately removed. For performing a new control, it is necessary to release the key and then press it again.

Remote anti-loss research

In case the remote control has not been put into its support base for 2 minutes from the last press of a key, an audible signal, a series of two "beeps" every 5 seconds, is emitted.

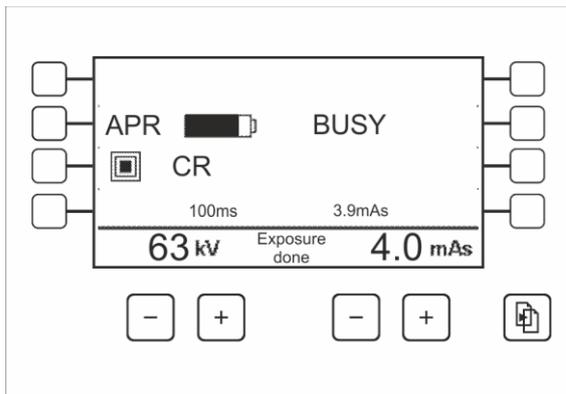
In order to stop the audible signal, put the remote control again in its support base, or press one of the two keys. This press does not imply any control, in order to perform a control it is necessary to press it twice.

When the remote control is in its support base, it switches OFF and there is no batteries consumption any more. In this condition no control is released by pressing the keys.

Indication of discharged batteries

The indicator of discharged batteries (red LED) flashes with 1 flash per second when the batteries have a limited autonomy (recommended replacement) and with 2 close flashes every second when the batteries are discharged (mandatory replacement).

7.11 After the exposure



An acoustic signal (three beeps) indicates the correct performance of the exposure.

The performed exposure time is displayed in ms.

The word "BUSY" replaces "READY" until the system is ready for the following exposure.

The word "Exposure done" flashes for about 15s between kV and mAs data.



If the x-ray button is held down at "1" click (preparation phase) for more than fifteen seconds without pressing the "2" click (X-ray releasing phase), the message "OVERTIME" is displayed. Release the pushbutton, press the key RESET and repeat the exposure.



If the x-ray emission control is released before the end of the exposure, the message "X-RAY MANUAL STOP" is displayed and the exposure is interrupted. The radiological data effectively released are displayed. Press the key "RESET" and repeat the exposure.

7.12 Radiography with examination table or Potter Bucky grid

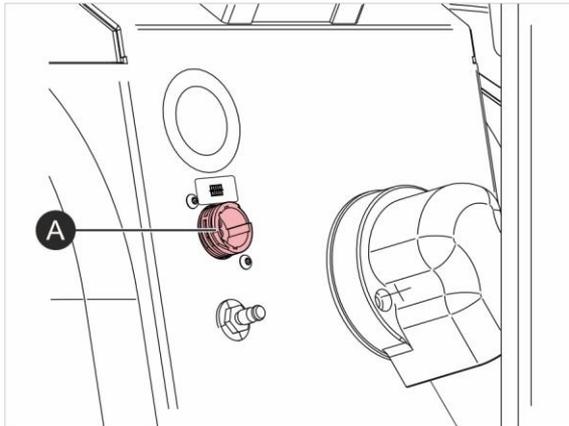


In HandSwitch mode: fully extend the extensible cable of the x-ray control and stay as far as possible from the radiation source.

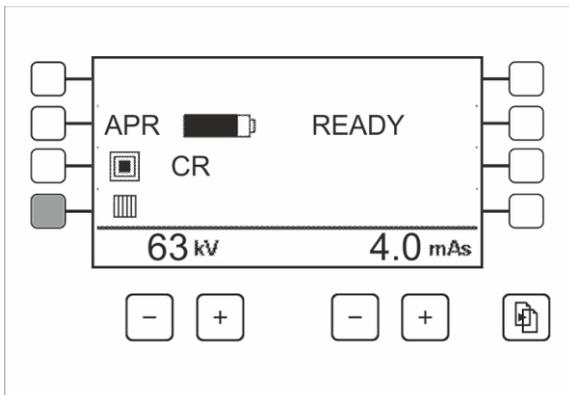
In Wireless mode: stay as far as possible from the radiation source.



The mode "Radiography with examination table or Potter Bucky grid" is active in CR mode or with Digital Imaging System off.



1. Connect the examination table or the Potter Bucky grid to the connector (A) on the front part of the equipment.



If the connection with the examination table or with the Potter Bucky is right, the display shows the icon.



connection not active

2. Press the F4 function pushbutton to activate the Potter Bucky.

On the display the icon appears



active connection

3. Grab the wired x-ray emission control or the remote control (optional) and keep as far away as possible from the x-ray source.

4. Perform a preparation

5. Perform the exposure. The equipment emits three beeps for confirming that the operation is successful.

In case of mistake, check the error type that appears on the display and the connections of the mobile grid.

7.13 Optional : DAP meter



The installation and maintenance of the DAP meter should be performed only by authorized service personnel.

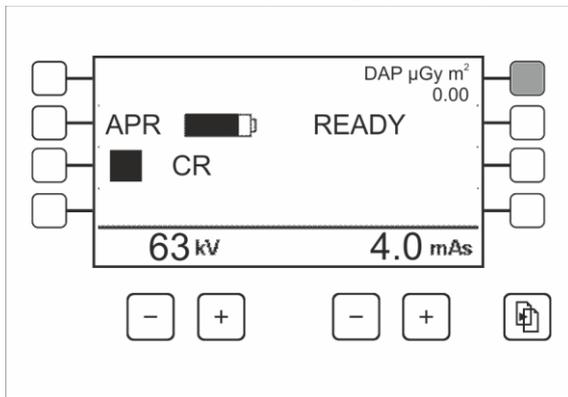


In order to determine the proper dose value to which the patient has been exposed, it is necessary to reset the dose value before starting the exam.

The function of the DAP meter is to measure the dose-area product (μGym^2) that is going out towards the patient as sum of all exposures:

$$\sum_{i=1}^n dose_i \cdot area_i$$

"n" is the number of exposures performed after the last pressing of F5-RESET pushbutton.



1. Before starting an exam, reset the dose value
Press the pushbutton F5 with the following confirmation request.
2. Perform all exposures concerning the patient under examination
3. Read the dose value accumulated by the patient
4. Reset the dose value
Press the pushbutton F5 with the following confirmation request

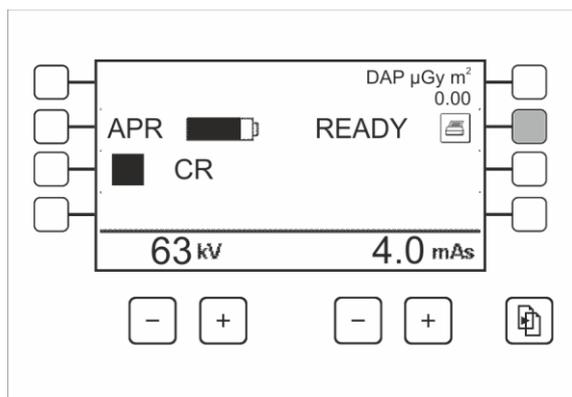
7.14 Optional: data printing

With DAP meter installed and in working condition, the data concerning the total dose released to the patient can be printed on an adhesive label and attached to the exam.

In the printing there are the values concerning:

Data	Description
Name/Id	Patient's name (*)
Day of birth	Patient's date of birth (*)
xxxx.xx μGym^2	Dose released to the patient (0000.00 μGym^2)
Operator	Operator's signature (*)
Date	Date and time of the exam (format dd-mm-yy hh:mm)

(*) data to be entered by hand by the operator



1. Before starting an examination, reset the dose value

Press the pushbutton F5, with the following confirmation request

Press the function key F5 to print the dose value.

2. Perform all the exposures concerning the patient under examination

3. Read the dose value absorbed by the patient

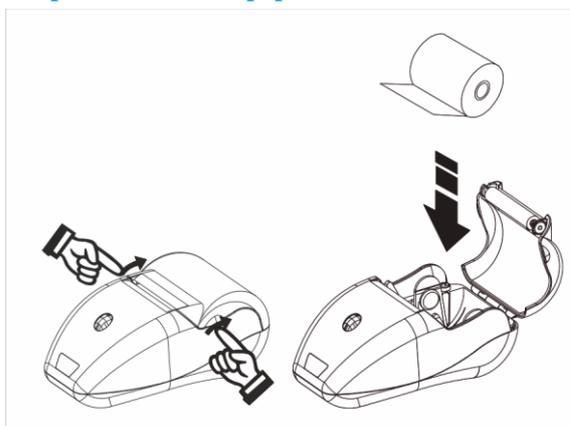
4. Reset the dose value

Press the pushbutton F5, with the following confirmation request

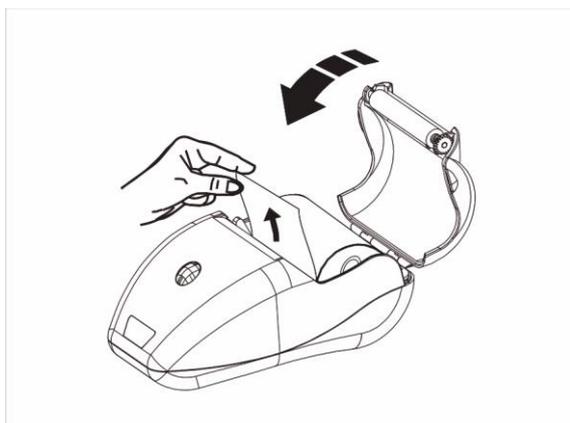


The printing function of the dose value is active only in analog mode or in CR mode.

Replacement of the paper roll



1. Open printer cover, relying on the side slabs of the cover and place the roll paper by respecting the direction of the paper rotation.



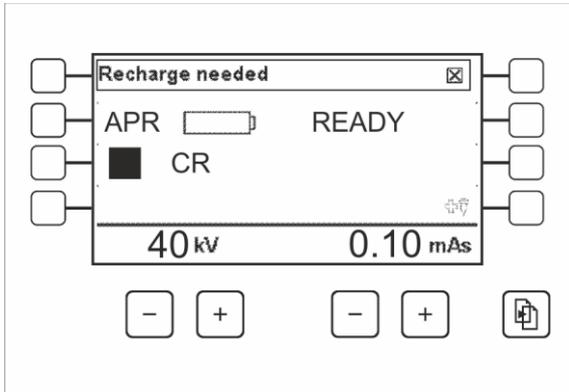
2. Pull upwards the paper and close the cover.

3. Tear off the paper. The printer is ready.

The right printing position is automatically determined by the printer.

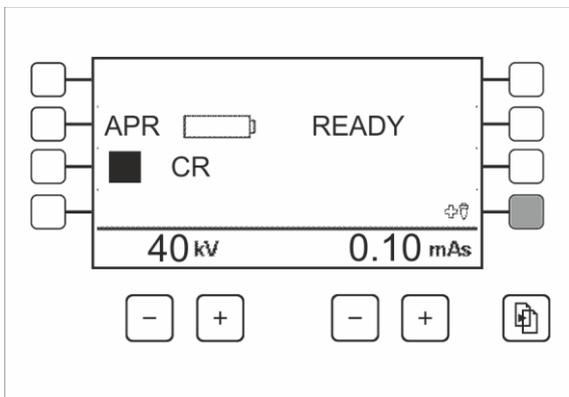
7.15 Emergency exposure

With discharged batteries it is possible to perform an exposure to close the exam in progress, move the equipment in a place suitable to proceed with the battery charging.



1. Press the pushbutton for the preparation to the exposure.

If the battery charge doesn't allow the exposure, the display emits an alarm sound, it shows the message "RECHARGE NEEDED" and the icon .



2. Reset the alarm.

3. Press the F8 function key.

The icon  is displayed.

4. Press the x-ray handswitch and perform the exposure.

After this exposure only the displacement of the equipment and the battery charge are possible.

 It is not possible to perform further x-ray exposures.

8 USE END



Damages to people or things

Use of the equipment by non authorized personnel.

- ▶ Never leave the equipment unguarded with ignition key inserted.
 - ▶ Remove and keep the ignition key in a suitable and safe place.
-

8.1.1 Equipment parking

1. At the end of the exams, put the equipment in transport position.
2. Move the equipment in a place suitable for parking.
3. Turn the ignition key in "II" position and release it.
4. Turn the ignition key in "0" position, remove it and keep it in a safe and suitable place.
5. Connect the equipment to a standard socket outlet for the battery recharge.

9 BATTERY RECHARGE

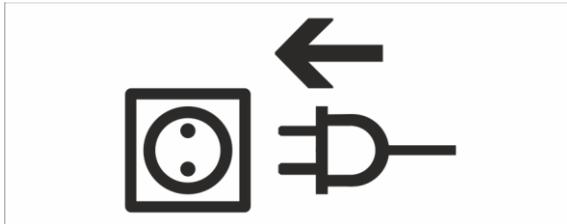


To recharge the batteries, place the equipment in a well-airy area.

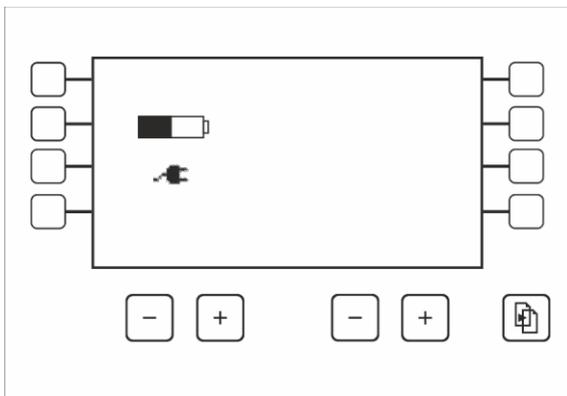
During the battery charge, all functions of the equipment are disabled.

The battery charge automatically starts when the equipment is connected to a single-phase AC mains with protective earth.

The battery charge can start in any moment with equipment ON or OFF.



1. Extract the retractable power supply cable from its housing and fully extend it.
2. Connect the cable to a standard power supply plug by keeping the cable extended.
3. Put the circuit breaker switch in "I" position.



The green led "voltage indicator" flashes.

The display switches ON.

The symbol of the batteries changes from 0% to 100% by indicating the charging phase of the battery.

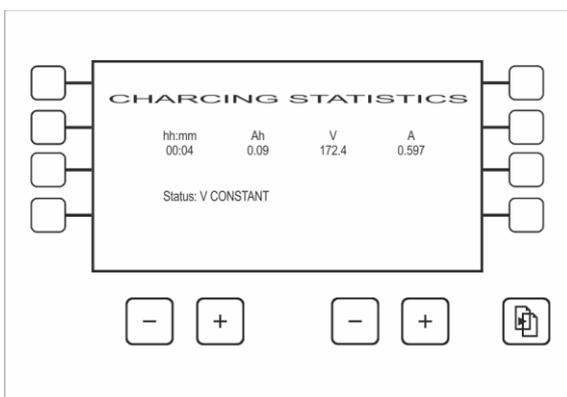
When the complete charge is reached, the symbol of the batteries is shown fix at 100%.

Once the batteries charge has been completed, the equipment can be let in charge.

In case of use:

1. Turn the circuit breaker switch in "0" position
2. Remove the power supply cable from the outlet.
2. Roll-up again the cable in the cable reel.

The equipment returns to the condition it was at the beginning of the recharge.



During the charge, it is possible to control the batteries charge status.

Press the keys MENU and F4 to enter the charge statistics page.

“status” can assume the following values:

Charge status: IDLE, I RAMP, I COSTANT, V COSTANT, MAINTENANCE

Error during the charge: TEMPERATURE, OVERVOLT, FAN ERROR, LOW VOLTAGE, HI CURRENT, OVER LOAD, FUSE, OFF LINE, FAULT



Even with the batteries completely charged, the equipment can be let in charge.

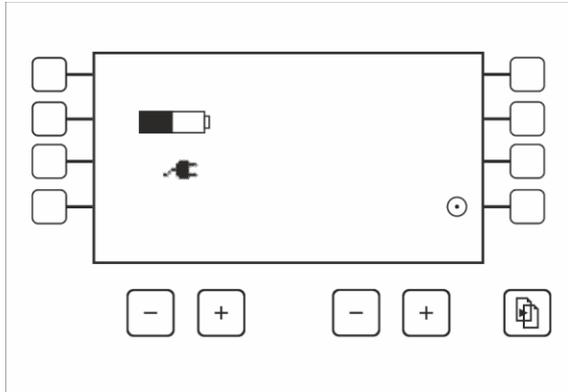
In order to keep the level of the batteries efficiency high, ensure that a complete recharge is performed at least once a month.

9.1 Working during the batteries recharge

During the batteries recharge, it is possible to use the equipment in exposures mode by holding the power supply cable connected to the electrical socket.



It is not possible any motorized movement.

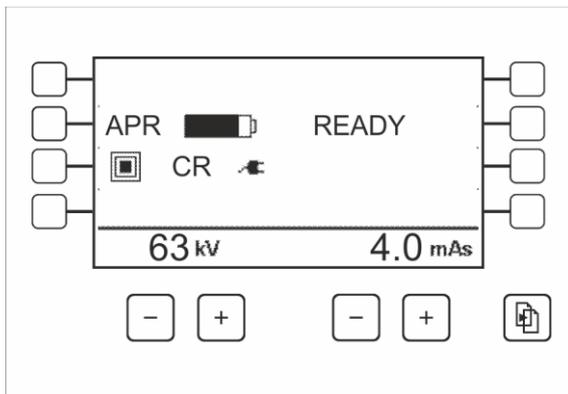


1. Turn the ignition key in "II" position.
2. Next to the key function F8 the icon "Standby" appears. Press the key function F8. The recharge phase stops. The x-ray generator switches ON and it is possible to perform exposures in all foreseen modes.

3. Switch the equipment OFF or wait for the planned idle time to enter Sleep Mode.

The x-ray generator switches OFF and the batteries charge starts again automatically.

The icon "Standby" remains visible.



The functioning with connected mains cable is indicated by the icon.

10 TECHNICAL SPECIFICATIONS

10.1 Electrical Specifications

Specifications	Data
Power supply	115 Vac or 230Vac \pm 10%, standard single phase and earth
Frequency	50/60 Hz \pm 5 Hz
Absorbed current	10 A
Line compensation	Automatic
Line resistance	<1 Ω @ 115/230Vac
Standard socket	16 A @ 230Vac
Power supply cable	2.9 mt, retractable
Isolation Class	Class I with B type applied parts
Use conditions	Continuous operation with intermittent load
Classification with respect to the liquid penetration	IPx0
Safety if anaesthetic inflammable gas is present	Equipment is either AP nor APG type

10.2 Environmental conditions

Environmental Factor	In normal use	Warehouse and transport
Temperature	from 10 °C to 40 °C	from -25°C to 70°C
Relative humidity	from 30 % to 75 % non-condensing	from 10% to 90% non-condensing
Pressure	from 700 hPa to 1060 hPa	from 500 hPa to 1060 hPa

10.3 Total filtration of the equipment

Description	Data 32 kW	Data 40 kW
Filtration of x-ray group	1.4 mmAl @75kV	1.5 mmAl @75kV
Inamovable additional filter	0	0
Collimator	2 mmAl @75kV	2 mmAl @75kV
Total filtration of x-ray group	3.4 mmAL @75kV	3.5 mmAL @75kV
Additional DAPMeter filtration	0.3 mmAl @75kV	0.3 mmAl @75kV
Total filtration of the equipment	3.7 mmAl @75kV	3.8 mmAl @75kV

10.4 Mechanical Specifications

10.4.1 32 kW analogic version

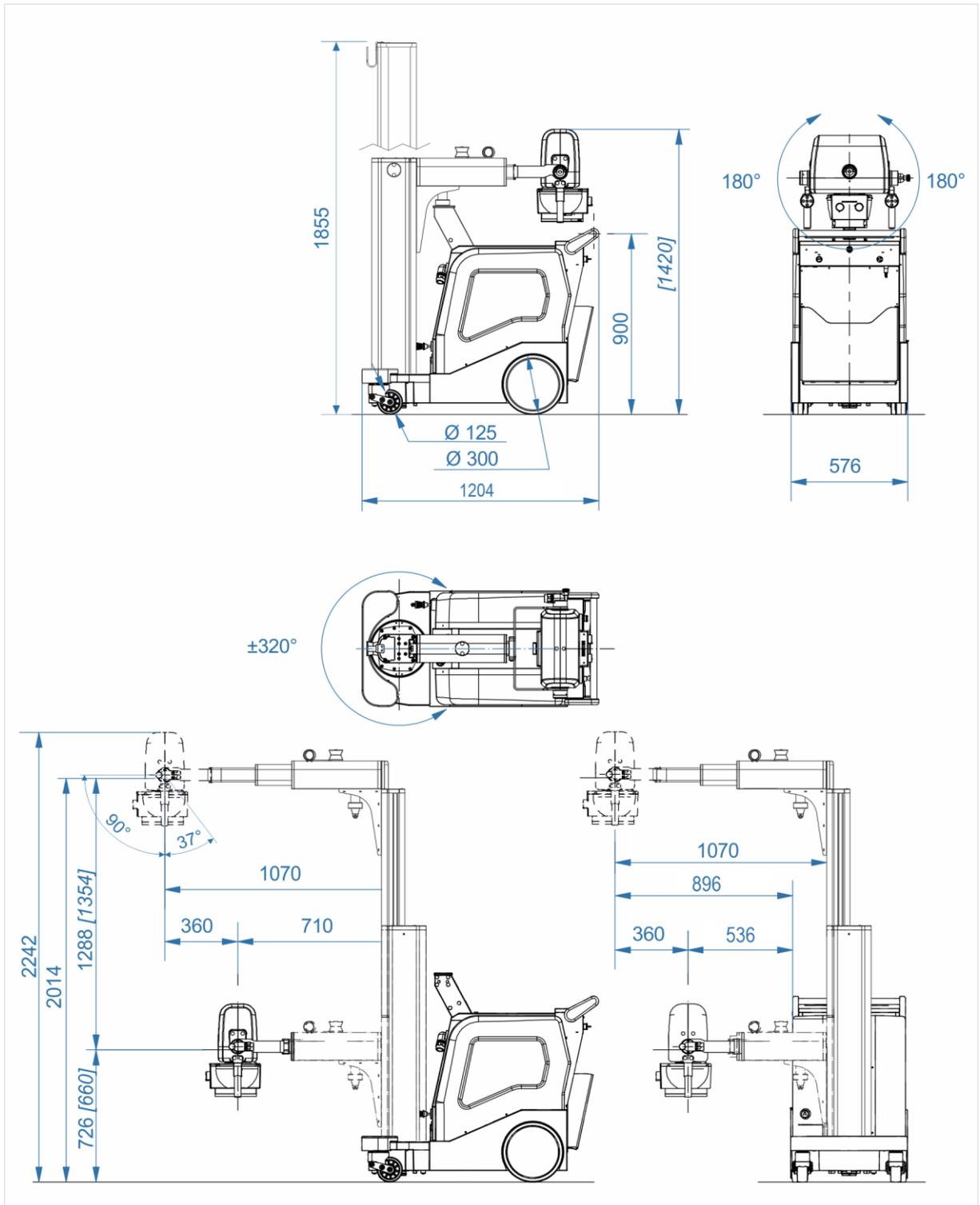
Description	Data	
Width (in transport position)	576 mm	576 mm
Length (in transport position)	1204 mm	1204 mm
Height (in transport position)	1855 mm	1420 mm
Transport handle height	900 mm	900 mm

Description	Data
Focus-ground distance (Z-axis)	726 mm ÷ 2013 mm (Fixed column) 660 ÷ 2014 mm (Telescopic column)
Max. height	2242 mm
Arm extension (X-axis)	360 mm
Front range	710 ÷ 1070 mm
Lateral range	536 ÷ 896 mm
Rotation of the monobloc around the arm axis (α swivel)	$\pm 180^\circ$
Rotation of the monobloc around the column axis (β swivel)	$\pm 320^\circ$ from transport position
Rotation of the monobloc around its axis (γ swivel)	127° (90° forward, 37° backward)

Description	Data
Movement	Motorized, speed proportional to the force impressed on the transport handle.
Speed forwards (transport position)	0 ÷ 1,4 m/s
Speed forwards in working position	0 ÷ 0,7 m/s
Speed backwards	0 ÷ 0,7 m/s
Max. superable inclination	10° (18%)
Max. height of a superable obstacle	40 mm

Description	Data
Diameter of the wheels	Front: 125 mm, damped Rear; 300 mm.

Description	Data
Weight	397 kg, batteries included



All dimensions are in mm. Linear tolerances ± 5 mm, angular $\pm 1^\circ$.
 Dimensions for telescopic column version in brackets.

10.4.2 40 kW analogic version

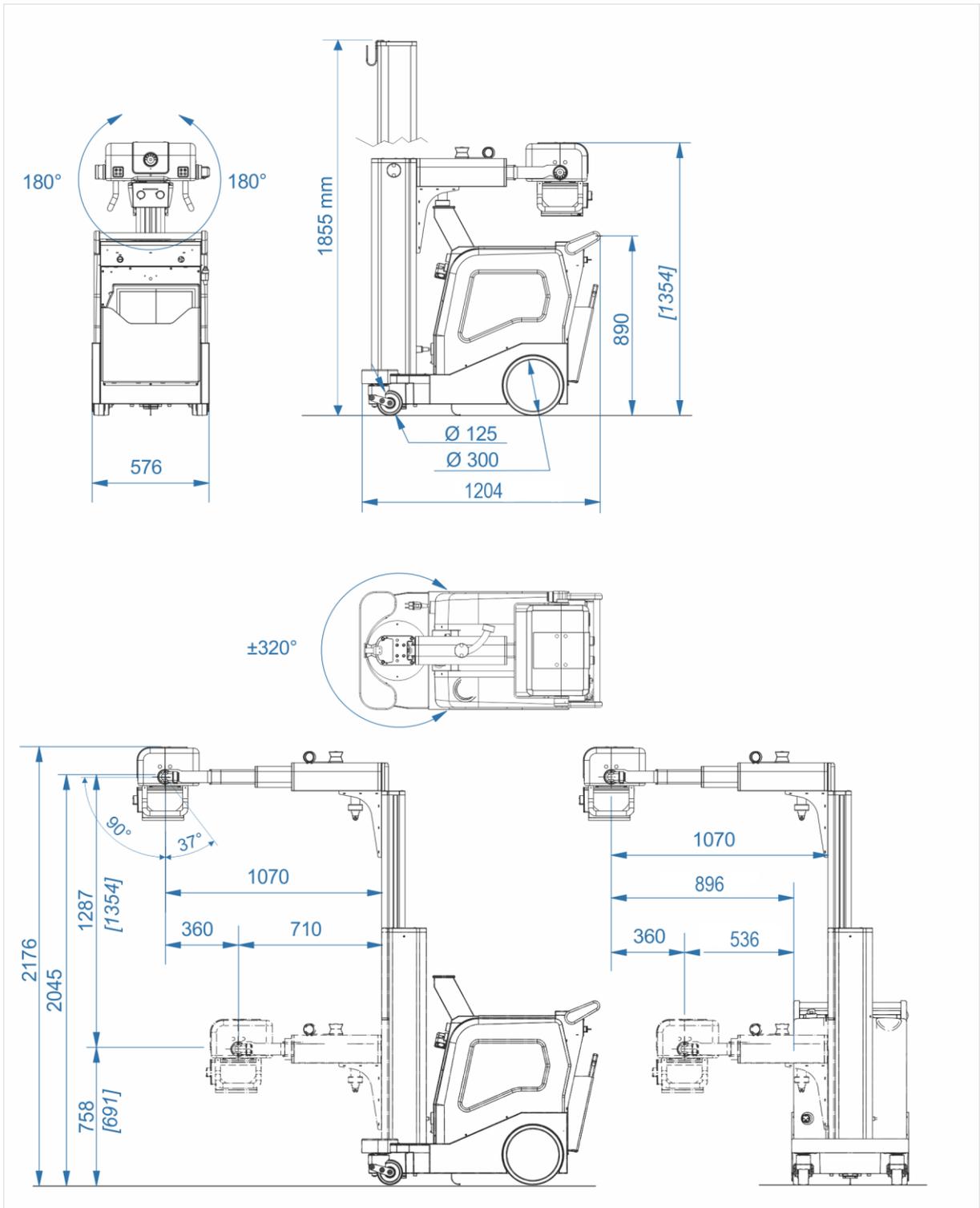
Description	Fixed column	Telescopic column
Width (in transport position)	576 mm	576 mm
Length (in transport position)	1204 mm	1204 mm
Height (in transport position)	1855 mm	1354 mm
Transport handle height	890 mm	890 mm

Description	Data
Focus-ground distance (Z-axis)	758 mm ÷ 2045 mm (Fixed Column) 691 ÷ 2045 mm (Telescopic column)
Max. height	2176 mm
Arm extension (X-axis)	360 mm
Front range	710 ÷ 1070 mm
Lateral range	536 ÷ 896 mm
Rotation of the monobloc around the arm axis (α swivel)	$\pm 180^\circ$
Rotation of the monobloc around the column axis (β swivel)	$\pm 320^\circ$ from transport position
Rotation of the monobloc around its axis (γ swivel)	127° (90° forward, 37° backward)

Description	Data
Movement	Motorized, speed proportional to the force impressed on the transport handle.
Speed forwards (transport position)	0 ÷ 1,4 m/s
Speed forwards in working position	0 ÷ 0,7 m/s
Speed backwards	0 ÷ 0,7 m/s
Max. superable inclination	10° (18%)
Max. heigth of a superable obstacle	40 mm

Description	Data
Diameter of the wheels	Front: 125 mm, damped Rear; 300 mm.

Description	Data
Weight	420 kg, batteries included



All dimensions are in mm. Linear tolerances ± 5 mm, angular $\pm 1^\circ$.
 Dimensions for telescopic column version in brackets.

10.5 Batteries and battery charger

Batteries	
Battery type	VRLA (Valve regulated lead acid batteries)
Battery pack	32 kW: 12 batteries x 12V, 18 Ah, Pb 40 kW: 13 batteries x 12V, 18 Ah, Pb
Vacuum nominal voltage	32 kW: 144 Vdc 40 kW: 156 Vdc
Low battery charge indicator	Yes

Battery charger	
Power supply	115Vac / 230Vac \pm 10% single-phase, 50/60 Hz
Absorption by mains	10 A max
Charge indicator	Yes
Charge characteristics	IUoU
Standard charge time	5 h
Safeties	Overtemperature, overvoltage, charge timeout

10.6 Operating specifications

Description	Data
User's interface	Keyboard with graphic LCD display 5,7" (240x128 dots), to display the operating parameters and possible unusual message or condition.
User's interface languages (set only by authorized service personnel)	English, Italian, German, French, Spanish, Portuguese, Hungarian.
X-ray handswitch	Local handswitch with extensible cable. Wireless remote control (optional)
Safeties	Filament current Monobloc temperature Overloading Max kV or fault in HV. Check of stored data. Microcontrollers auto test . Battery overvoltage
Use coefficient (duty cycle) according to the applied power	Waiting t (s) = kV * mAs / 100

Description	Data
External interfaces	X-ray interface with examination table or Potter Bucky grid. Interface for the dose data printing on dedicated printer.

Description	Data
Programmed Anatomics Mode (APR)	Storage of 36 exams (6 APR groups, each one of 6 exams)

10.7 X-ray specifications

10.7.1 32 kW version

Description	Data
Max power of the generator	32kW (320mA @ 100kV)
Inverter frequency in high voltage	40kHz
Max ripple	<2% @100kV
Climbing time	<1ms @100kV
kV variation range	40 ÷ 125kV in steps of 1kV
kV accuracy	±5% (IEC 60601-2-54)
mA variation range	70 ÷ 320mA automatically associated to kV
mA accuracy	±10% (IEC 60601-2-54)
mAs variation range	0,1 ÷ 320mAs with increases of 12,5%
mAs precision	±10% (IEC 60601-2-54)
Exposure times range	0,001 ÷ 3sec according to set mAs
Exposure times accuracy	±10% (IEC 60601-2-54)
Continuous thermal dissipation	60 W

mA Range

kV	7kW (1)	9kW (1)	12kW	20kW (3)	32kW (2)(4)
40	70	200	240	310	310
50	70	180	240	310	310
60	70	150	200	310	310
70	70	128	170	285	310
80	70	112	150	250	310
90	70	100	133	222	310
100	70	90	120	200	320
110	70	81	109	181	260
120	70	75	100	166	220
125	70	72	96	160	200

(1) Calibration curves for Small Focus

(2) Calibration curve for Large Focus

(3) 20 ms < t(RX) < 80 ms

(4) t(RX) < 20 ms

mAs range according to kV

kV	mAs
Small focus	
40 ÷ 100	0,1 ÷ 200
Large focus	
40 ÷ 100	0,63 ÷ 320
101 ÷ 125	0,63 ÷ 250

10.7.2 40 kW version

Description	Data
Max power of the generator	40kW (400mA @ 100kV)
Inverter frequency in high voltage	40kHz
Max ripple	<2% @ 100kV
Climbing time	<1ms @ 100kV
kV variation range	40 ÷ 130kV in steps of 1kV
kV accuracy	±5% (IEC 60601-2-54)
mA variation range	70 ÷ 400mA automatically associated to kV
mA accuracy	±10% (IEC 60601-2-54)
mAs variation range	0,1 ÷ 320mAs with increases of 12,5%
mAs precision	±10% (IEC 60601-2-54)
Exposure times range	0,001 ÷ 3sec according to set mAs
Exposure times accuracy	±10% (IEC 60601-2-54)
Continuous thermal dissipation	120 W

mA Range

kV	7kW (1)	9kW (1)	12kW (2)	20kW (2)(3)	40kW (2)(4)
40	70	200	240	310	400
50	70	180	240	310	400
60	70	150	200	310	400
70	70	130	170	280	400
80	70	110	150	250	400
90	70	100	130	220	400
100	70	90	120	200	390
110	70	80	110	180	330
120	70	75	100	160	290
130	70	70	90	150	250

(1) Calibration curves for Small Focus

(2) Calibration curve for Large Focus

(3) 20 ms < t(RX) < 100 ms

(4) t(RX) < 20 ms

mAs range according to kV

kV	mAs
Small focus	
40 ÷ 130	0,1 ÷ 200
Large focus	
40 ÷ 130	0,63 ÷ 320

10.8 X-ray group

10.8.1 32 kW version

Monobloc

Description	Data
Monobloc	HF1 R/7
Nominal power (100kV – 320mA) 0.1 s	32 kW
Max voltage at the tube	125 kV
Max current at the tube	350 mA
Ripple to max power	< 2 %
kV increasing time at max power	< 1 ms
Half-value layer @ 75kV	2 mmAl
Min. inherent filtration @75kV	1.4 mmAl
Weight	19.0 kg
Thermal capacity available	600 kJ
Total thermal safety	900 kJ
Thermal safety (n.c. thermal switch)	60 °C ± 5°C
Compensation lung volume	0.2 dm ³
Continuous thermal dissipation	60 W
Leakage radiation (EN 60601-1-3)	< 1 mGy/h

X-ray tube

Description	Data
X-ray tube	X22
Rotation speed	3000 min ⁻¹
Nominal High voltage	130 kVp
Nominal focus dim. (IEC 60336)	0,8 mm small focus 1,3 mm large focus
Nominal anodic power (IEC 60613)	16 kW small focus 32 kW large focus
Anodic material	RT (Focus track: Tungsten-Rhenium), TZM (Anode mass: molybdenum+ titanium+zirconium)
Anodic diameter	64 mm (2,52in.)
Anodic angle	15°
Thermal capacity of the anode	80 kJ (107kHU)
Max continuous anode dissipation	300 W
Min. inherent filtration (IEC 522)	0,7 mmAl eq.
Tube material	glass

10.8.2 40 kW version**HT generator**

Description	Data
Model	HF1 G/29
Nominal power	40kW (100kV 400mA)
Max. output voltage	150 KV
Max. output current	450mA
Ripple at the max. power	< 2%
kV Rise time at max. power	<1ms
Thermal safety	60°C ±5°C
Compensation lung	0.20 dm ³ (12.2 cubic inch)
High voltage output connectors	Standard Claymount Mini 75 type receptacles
Weight	17 kg (37,48 lbs)

X-ray housing

Description	Data
Tube assembly	C31
Weight	15.0 kg
Max voltage at the tube	150 kV
Maximum tube assembly heat content	500 kJ
Maximum continuous heat dissipation	120 W
Min. tube assembly inherent filtration	1.2 mmAl @75kV
Additional filtration	0.3 mm Al
Min. total filtration	1.5 mmAl @75kV
Maximum leakage radiation at 1 m	20 mR/h
Thermal safety	67 °C ± 3°C

X-ray tube

Description	Data
X-ray tube	RTM 72 HS
Nominal focus dim. (IEC 60336)	0.6 mm small focus 1.2 mm large focus
Rotation speed	3000 rpm (f=50Hz), 3600 rpm (f=60Hz)
Nominal anodic power (IEC 60613)	17 kW small focus 43 kW large focus
Anodic diameter	73 mm (2,9 in.)
Anodic material	RT-TZM
Anodic angle	12.5°
Min. inherent filtration (IEC 522)	0,7mmAl eq.
Thermal capacity of the anode	225 kJ (300 kWh)
Max continuous anode dissipation	500 W
Nominal High voltage	150 kVp

10.9 Collimator

Description	Data
Model	R108 F
Collimation	Manual with internal light source, multilayer, squared field.
Assembly plan from focus	80 mm (3.14")
Coverage of the field at 100cm FFD (SID)	min 0 x 0 cm, max 43 x 43 cm
Lighting source	Clusters of high-brightness LED power.
Lamp lighting time	30 s.
Light intensity (IEC 60601-2-54)	> 160 lux
Minimum contrast ratio (IEC 60601-2-54)	4:1
Focal distance measurement	Retractable tape measure (max extension 3 mt)
Inherent filtration	2 mm equivalent Al/75kV
Additional filtration	Manual section 0 mm Al 1 mm Al + 0,1 mm Cu 1 mm Al + 0,2 mm Cu 2 mm Al
Rotation	$\pm 120^\circ$
Weight	5,5 Kg
Optional	Laser field to determine the focal distance at 1 m

10.10 Optional: Dose Meter

Description	Data
Model	Diamentor CI-P
Type	Device for the area-dose product measurement in x-ray diagnostics according to IEC 60580 standard.
Principle of measurement	Radiation measure with ionization chamber
Measured quantity	Area-dose product
Digital resolution	0,01 μGym^2
Max linearity error	< 2.5%
Nominal range of dose-area product rate	(0,01 ÷ 2500) $\mu\text{Gym}^2 / \text{s}$
Equivalent filtration of the chamber @75kV	0.3 mm Al
Max measurement field	118 x 118mm
Dimensions (W x D x H)	152 x 234 x 23 mm
Weight	455g

10.10.1 Thermal Dose Meter Printer

Description	Data
Type	Movable printer
Model	Custom Print's
Printing method	Thermal printing line
Resolution	203 dpi
Printing speed	50mm/sec*
Paper width (mm)	58 mm
Roll dimensions (mm)	57.5 \pm 1
Print area	48 mm
Interface	RS-232
Power Supply	9/50 Vdc / 0,6 A
Operating temperature	0 \pm 50 $^{\circ}\text{C}$
Humidity storage	10 \pm 85 %, there must be no condensation
Dimensions (WxDxH)	146 x 88 x 65 mm
Weight	340 gr
Safety	EN60950

* it depends on the printing typology and the environment temperature

10.11 Optional: Remote exposures control

Description	Data
Type	Infrared x-ray control device (IR)

Transmitter

Description	Data
Construction	ABS case with matt surfaces Durable fireproof, high resistance to bad use or falls, resistance to water, oils, organic acids and alcohol
Technology	Infrared light (940 nm) with carrier 38kHz. It operates through glass or leaded glass. Don't operate through doors or walls.
Identification signature	Controls with proprietary safety coding at 11 bit - non standard Non compatible with commercial receivers
Power supply	2 alkaline "AA" batteries (LR6) - 1,5 V / 2500mAh. Autonomy > 25.000 exposures.
Operative distance	10 mt (33 feet)
Operative angle	>180°
Remote anti-loss research	Repetition of a series of beeps if the transmitter, after the use, has not been put again for two minutes into its support base.
Light indicators	Yellow LED indicates that the transmission is active Red LED indicates the batteries status: - 1 flash/sec -> recommended replacement - 2 flash/sec necessary replacement

Receptor and Decoder

Description	Data
Construction	Plexiglass®
Power supply	12... 24 Vdc - 50mA
Consumption	1.2W
Identification signature	Controls with proprietary safety coding at 11 bit - non standard Non compatible with commercial transmitters
Commands towards generator	Power supply voltage Vcc – 1V (11 ... 23Vdc) 100mA max per channel

11 CONFIGURATION AND ACCESSORIES

11.1 Accessories

Description	
X-ray emission control with extensible cable	Standard
Apron hanger	Fixed column: standard; Telescopic column: not available
Interface for examination table or Potter Bucky	Standard
Dosimeter with ionization chamber	Optional
Remote control of x-ray emission	Optional
Double laser line on collimator for the definition of the reference distance at 1m	Optional

Description	
DAP Printer	Optional

12 ABBREVIATIONS LIST

AP	Equipment or part of it, protected by the ignition of a mix of inflammable anaesthetic with air
APG	Equipment or part of it, designed to avoid any flames in a mix of inflammable anaesthetic with oxygen and nitrous oxide.
APR	Programmed anatomic radiography
CR	Computer Radiography - Displaying system of the primary radiological image based on a phosphors detector
DAP	Dose-area product
DIS	Digital images acquisition system
EMC	Electromagnetic compatibility
ESD	Electrostatic discharge
IP	Protection degree of the electric and electronic devices housings against the penetration of external agent both solid or liquid.
LED	Light-emitting diode
LF	Large focus
PCB	Printed Circuit Board – printed circuit for electronic board.
RF	Radiofrequency
SF	Small focus
SID / DF	Focus-image receptor distance
WEEE	Electric and electronic equipments waste

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13 DOCUMENT STATUS

Rev.	Date	Description
0	10/2019	Document approval
A	05/2021	General update for the adaptation to the new EU regulation 2017/745