



TMS 4



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User's Manual

WARNING: The information that is printed within this manual is vital for a correct use of the equipment; please carefully read it any time before use.

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1. SAFETIES AND CONFORMITIES

Purpose of the present User's Manual is to make the unit use friendly and safe. All the information herein contained represent the current know-how status. Technix S.p.A. reserves the right to improve and upgrade such information in function of the technological progresses.



- This X-ray unit has to be used exclusively according to the safety instructions herein contained and cannot be used for purposes other than those foreseen.
- The X-ray unit has to be exclusively operated by qualified personnel, aware of the radiation protections and precautions, properly trained about the use of X-ray units.

The operator is responsible for the use of the system in compliance with the applicable standards concerning installation and use.



- The unit must not be used when electrical, mechanical or radiological faults are present. Besides, the system must not be utilized in case of malfunctioning of any signaling or alarm device.
- In case of use jointly with other apparatus, components or modules whose compatibility is not certain, it is necessary to ensure the absence of any danger for patients or operators. For this purpose, contact Technix S.p.A.
- Technix S.p.A. is responsible for the safety of its own products only if their maintenance, repair or modification have been performed by Technix S.p.A. or by personnel expressly authorized by Technix S.p.A. itself by written notice.
- As with any technical apparatus, this x-ray unit must be used properly with periodic checks and maintenance as specified in the chapter "Planned maintenance".
- Circuits and safety devices must not, for any reason, be removed, modified or omitted.

Technix S.p.A. won't be held liable for any malfunctioning, damages due to an improper use of the system or non compliant with the maintenance rules.

1.1. Electrical safeties



- Only trained service personnel authorized by Technix S.p.A. may remove the unit covers and only in accordance with the instructions contained in the Service Manual.
- This X-ray unit can be only used in environments or medical rooms complying with the applicable IEC standards. The X-ray unit must not be utilized in areas where danger of explosion exists.
- The cleaning and disinfecting products, including the ones used for patients, may create explosive and gaseous mixtures. Therefore, use only products in compliance with the applying rules.

1.2. Mechanical safeties



- After positioning the unit, fix the stationary brakes.
- To move the unit, only operate with the predisposed handles.
- Avoid collisions with obstacles or similar.

1.3. **Electromagnetic compatibility (EMC)**

According to the use foreseen, this apparatus complies with the IEC 60601-1-2, which defines the max. allowed emission levels to the electronic devices and the required immunity against the electro-magnetic fields.

It is not, however, possible to exclude radio signals coming from transmitters such as mobile phones or similar mobile radio devices. These and other transmitting devices, including those in compliance with the EMC standards, may influence the proper functioning of medical apparatus when used in proximity and with a relatively high transmitting power. Therefore, in order to avoid any risk of interference, the use of these radio equipments **has to be avoided** in proximity of electronically controlled systems.

Explanation:

The electronic apparatus that meets the EMC standards has been designed so that, under normal conditions, any malfunctioning risk, caused by electromagnetic interferences, is avoided.

However, should radio signals be present, coming from high frequency transmitters with a relatively high transmitting power, used near the electronic apparatus, the risk of electromagnetic incompatibility, cannot be completely controlled.



Any transmission with mobile radio equipment should be avoided.

Mobile phones should be switched off in areas close to the unit.

These rules must be applied when the unit is switched on (that means when the unit is connected to the mains).

1.4. **Protection against ionizing radiation**



Before performing any exposure, ensure that all the necessary protections and precautions have been taken.

During the use of x-rays, personnel present in the room must comply with the following rules concerning protection against ionizing radiation. Therefore pay attention to the following:

- When necessary, use protective tools against radiation and in addition at the devices already foreseen on the unit.
- Use the dedicated radio protective aprons. A radio protective material equivalent to 0,35mm lead lowers of 99,95% a radiation of 50kV and of 94,5% one of 100kV.
- The best protection against radiation is the distance; keep the max. distance both from X-ray source and from exposure target. This is aimed to use all the length of the foot-switch controlling X-ray.
- Avoid walking or standing in the direct X-ray beam.
- Always use the smallest exposure field possible, properly closing the collimator diaphragms. The leaked radiation depends on the volume of the irradiated object.



In any case never modify or disconnect the safety circuits foreseen for accidental exposures.

1.5. **General disposal**

Technix S.p.A. produces X-ray systems advanced in terms of safety and environments protection. If the unit is properly utilized, then no risk exists for persons and environment.



Due to the above reasons, the unit cannot be disposed of along with industrial or domestic waste and it has to be regarded as special waste.



This symbol indicates that the wastes resulting from the electric and electronic units have not to be disposed as undifferentiated town wastes and they have to be picked up separately.

The proper differentiated collection for the following start of the unit disused to the recycle, treatment and disposal, compatible with the environment, aid to prevent possible negative effects on the environment and health and it favours the recycle of materials that compose the unit.

The abusive disposal of the product from the user implies the application of administrative sanctions according to the Standards in force of the unit installation country.

For information concerning the dismantling modes of the units out of use, stick to the local provisions or contact an representative authorized by the manufacturer.

For additional information, contact Technix S.p.A.

1.6. **Interfaceability**

The device does not foresee the interaction with medicines; with the possibility to interface a dosimeter, as optional. It complies with the safety requirements foreseen by the 93/42/EEC Directive. Liable is the operator and/or anyone performing any interface that has not been evaluated and authorized by Technix S.p.A. by prior written notice.

1.7. **Copyright**

The original release of this manual is in Italian language (file: 202363-00-00), for any further information please refer to the Italian version.

The software contained in the unit belongs to TTechnix S.p.A. When receiving the unit, the user acquires the right to use the software in connection to the unit: **this right is not exclusive and not transferable.**

For any modification of the unit operations other than those foreseen, the prior written notice authorization by Technix S.p.A. is required.

1.8. Applications & use destination

This is a mobile x-ray unit and it has been designed to satisfy a wide range of clinical applications; it must be operated exclusively by qualified, trained personnel who has been informed of the risks linked to the use of ionizing radiation.

Compactness and manoeuvrability make the unit movement fluent and accurate through doors, small rooms, narrow aisles and lifts permitting to move among obstacles with accuracy, in narrow curves and among the patients' beds. The ergonomic design of the unit allows the operator an excellent visibility during the motion and operations.

The monobloc arm, perfectly balanced, allows a free motion and positioning also in the more uncomfortable positions. The shape of the basement allows its positioning and handling under the patients' beds. The position and the shape of the four antistatic wheels make it ideal for an easy motion also on coarse surfaces.

For this system, no continuous use is required.

The accidental contact of some unit parts with the patient is possible and the contact with the operator is foreseen.

The contact with the patient is not invasive.

The contact with the operator is foreseen for reasons that are strictly linked to the use conditions. (Use operations).

The unit is suitable for X-ray exams and diagnostic investigations, such as:

- Operating theatre
- Sport medicine
- Plaster room
- First aid
- Pediatrics
- Orthopedics



This X-ray unit must not be used in areas where danger of explosion exists.

1.9. Classification

Protection against electrical hazards	Class I
Protection against direct and indirect contact	Unit, Type B with Type B applied part
Protection against water penetration	Common protection (IPX0)
Use condition protection	Continuous use with intermittent load

1.10. Regulations list for the evaluation of the product conformity

Reference	Description
MDD 93/42/EEC class IIB according to Annex IX rule 10.	Medical Device Directive (CE mark)
IEC 60601-1 2 nd edition	Medical devices safety
IEC 60601-1-2 2 nd edition	Electromagnetic compatibility
IEC 60601-1-3 1 st edition	Protection against ionizing radiation
IEC 60601-1-4 1 st edition	Programmable electromedical systems
IEC 60601-2-7 2 nd edition	High voltage generators
IEC 60601-2-28 1 st edition	Tube – housing groups
IEC 60601-2-32 1 st edition	Mechanical safety aspects
ISO 14971:2000 1 st edition	Risk analysis

1.11. Conformity



This x-ray unit is in compliance with the electromedical devices Directive 93/42 EEC class IIb and with the Annex IX rule 10.

For any further information concerning the compliance please contact:

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E-mail: technixd@technix.it

The manufacturer (according to the European Directive 93/42/EEC) of the unit TMS 4 is:

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Web: <http://www.technix.it>
E-mail: technixd@technix.it

2. LEGEND

2.1. Overview

- | | |
|-----------------------|---------------------------------------|
| 1. Monobloc | 10. Tilting pedal |
| 2. Goniometer | 11. Cassette holder |
| 3. Collimator | 12. Magneto-thermic switch |
| 4. Monobloc handle | 13. Handle for unit movement |
| 5. x-ray handswitch | 14. Control console |
| 6. Cable reel | 15. Arm safety lock for transport |
| 7. Equipotential node | 16. Monobloc support arm |
| 8. Power supply cable | 17. Safety lock for monobloc rotation |
| 9. Brake pedal | |

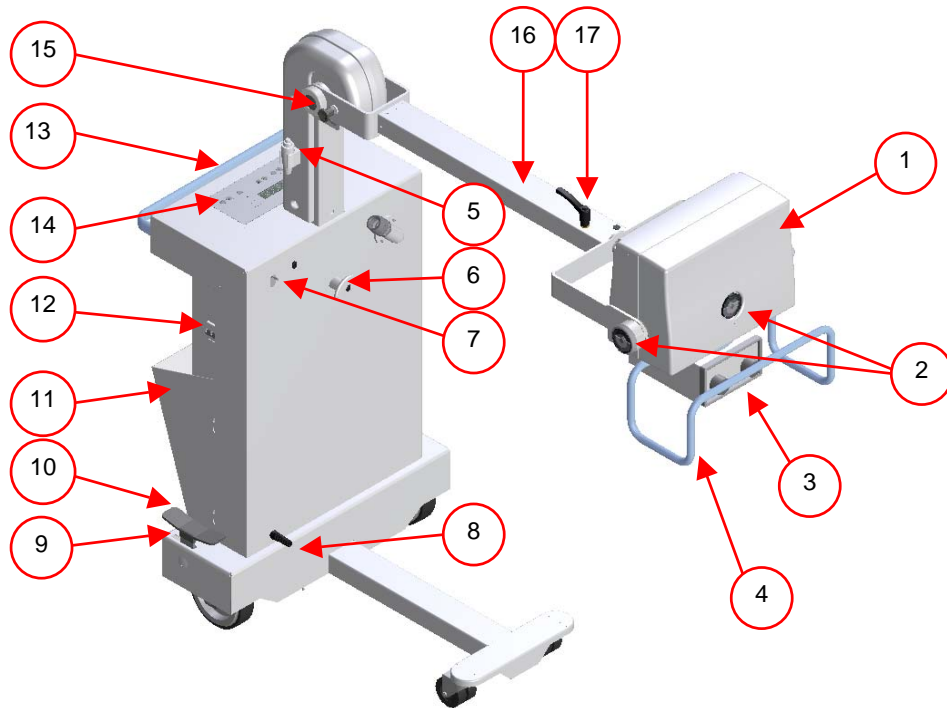


Figura 1

2.2. Collimator

- | | |
|---|--|
| 1. Lamp switching ON for the luminous irradiation on field indication | 4. Guides for the accessories or filters positioning |
| 2. Longitudinal collimation | 5. Retractable tape measure (placed on the collimator rear part) |
| 3. Trasversal collimation | |

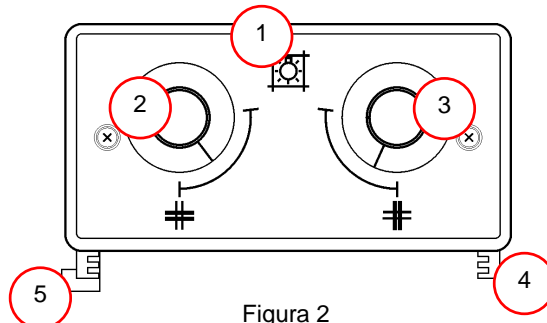


Figura 2

2.3. Control panel

All the keys are membrane type.

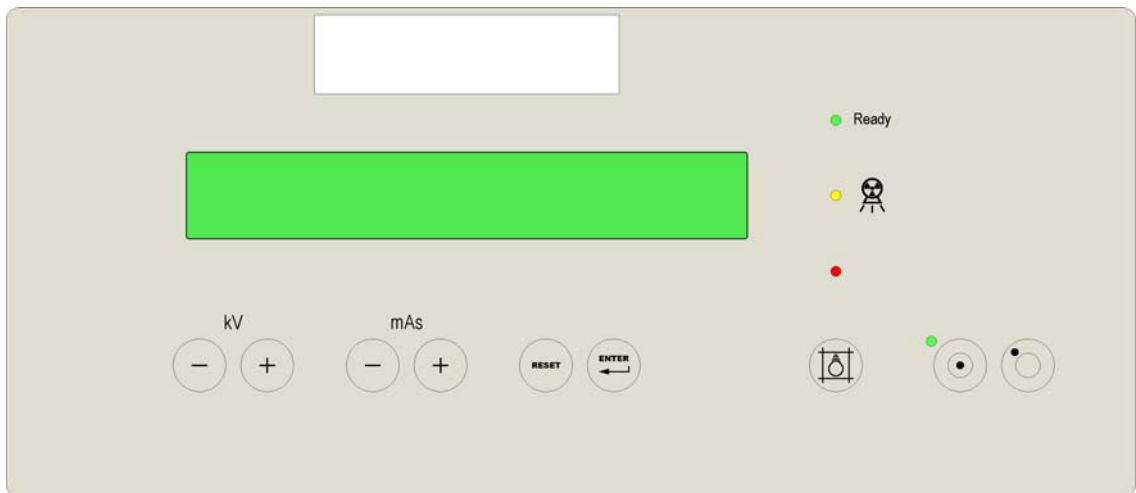
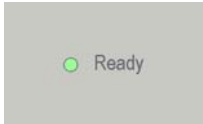




Figura 3

	ON	Unit ON, the yellow led indicates that the unit is connected and supplied
	OFF	Unit OFF
	COLLIMATOR	Collimator lamp ON (the lighting is timed for about 30s) <i><u>The key works only if the collimator is preset, instead the lamp lighting occurs only through the key on the collimator front.</u></i>
	kV+ kV-	Possibility to modify kV values
	mAs+ mAs-	Possibility to modify mAs values
	RESET	Reset the alarm. It cancels the configuration datum.
	ENTER	Confirm the configuration datum.

2.4. Luminous signals

	READY	Green led, lit all the time the unit is ready for radiography.
	X-RAY	Orange led, it means x-ray emission.
	ALARM	Red led, signal of alarm intervention.

It is not possible to deactivate the luminous signals.

2.5. Acoustical signals

- 3 BEEP Exposure ok
- 1 LONG BEEP Alarm, malfunctioning

It's not possible to disable the acoustical signals.

3. MESSAGES ON THE DISPLAY

Text	Meaning	Action
READY	The unit is ready to perform an exposure.	---
BUSY	It appears after an exposure and shows the unit is preparing the next exposure; it's not possible to use the unit .	Wait for "READY" message.
*** FAULT	Absence of the power supply voltage +15Vcc (** = V2) o -15Vcc (** = V3).	Turn off and on again the unit. If the fault appears again, call Service.
FILAMENT	Absence of filament current.	Turn off and on again the unit. If the fault appears again, call Service.
HOT TUBE	The monobloc temperature is too high.	Wait for the monobloc cooling.
LACK OF X-RAY	The set voltage has not been achieved.	Turn off and on again the unit. If the fault appears again, call Service.
MAX TIME	The unit has interrupted the exposure because it has reached the max. allowed value; it's displayed the achieved mAs values.	If the fault appears again, call Service.
MAN STOP RX	The x-ray hand switch has been released before the end of exposure; it's displayed the achieved mAs values.	In order to repeat the exposure, it's necessary to press RESET.
INVERTER KV ERR.	Inverter malfunction.	Turn off and on again the unit. If the fault appears again, call Service.
INVERTER OVERLOAD	Inverter malfunction.	Turn off and on again the unit. If the fault appears again, call Service.
INVERTER FAULT	Inverter malfunction.	Turn off and on again the unit. If the fault appears again, call Service.
HAND SWITCH ERR.	Faulty x-ray handswitch.	Check the integrity of the x-ray handswitch. Turn OFF and ON again the unit. If the fault repeats, call Service.
TUBE SEASONING	After a long idle period (3 months or more) it is necessary to proceed with the x-ray tube seasoning, in order to avoid severe damages.	Press RESET to proceed, call Service for the tube seasoning.
Kv FAULT	During the exposure, the kV value is decreased under 75% of the set value.	Press RESET to repeat the exposure, if the fault appears again, call Service.
MIN mA	During the exposure, the min. mA value has not been reached.	Press RESET to repeat the exposure, if the fault appears again, call Service.

List of Messages on the display that can be set in five languages (the language setting has to be performed by Service personnel only).

 ITA	 ENG	 FRE	 GER	 SPA
PRONTA	READY	PRET	BEREIT	LISTO
ATTESA	BUSY	ATTENDRE	WARTEN	ESPERA
*** MANCANTE	*** FAULT	*** DEFECT.	*** DEFEKT	*** FALLO
FILAMENTO	FILAMENT	FILAMENT	HEIZKREIS-FEHLER	FILAMENTO
TUBO CALDO	HOT TUBE	TUBE CHAUD	ROHE HEISS	TEMPER.
ERRORE RAGGI	LACKING OF X-RAY	FAUTE RAYON	KEIN STRAHLUNG	SIN RADIACION
TEMPO MAX	MAX TIME	TEMPS MAX	MAX EXP ERREICHT	TIEMPO MAX
STOP MANUALE	MAN STOP RX	STOP MANUAL	EXP UNDERBROCHEN	INTERRUP. MANUAL
ERR. KV INVERTER	INVERTER KV ERR.	TRANSF. KV DEFECT	WANDLER KV FEHLER	FALLO KV TRANSF
SOVRACCARICO INV.	INVERTER OVERLOAD	TRANSF. SURCHARGE	WANDLER UBERLAST	SOBRECARGA TRANSF
ERRORE INVERTER	INVERTER FAULT	TRANSF. DEFECTUEUSE	WANDLER FEHLER	FALLO TRANSF
ERR. PULSANTE RX	HAND SWITCH ERR	BOUTON DEFECT.	HANDSCHALT. DEF	FALLO MANDO
FORMAZIONE TUBO	TUBE SEASONING	FORM. DU TUBE	ROHRE ENFAHREN	AJUSTE DEL TUBO
Kv FAULT	Kv FAULT	Kv FAULT	Kv FAULT	Kv FAULT
MIN mA	MIN mA	MIN mA	MIN mA	MIN mA

*** it can be V2 or V3.

4. FUNCTIONING

4.1. Transport

For the transport of the unit, consider the following instructions:

- The unit must be OFF, the supply plug must be removed from the socket outlet and the cable wound. (see Par. 4.6 Shutdown procedure).
- Place the monobloc – collimator group vertically and activate its rotation safety lock (see Figure 4).
- Pull the safety knob and rotate it till it is taken out (see Figure 5).
- Move downwards the arm by using the handles and by keeping in vertical position the monobloc-collimator; when the parking position is reached (see Figure 6) rotate and engage the safety lock.
- Release the stationary brake (see Figure 7)
- Move the unit by using only the proper handles for the transport.
- Never move the unit on surfaces with inclination higher than 10°.
- In order to overcome obstacles, push on the pedal with the foot and, at the same time, pull inward the transport handle (Figure 8).

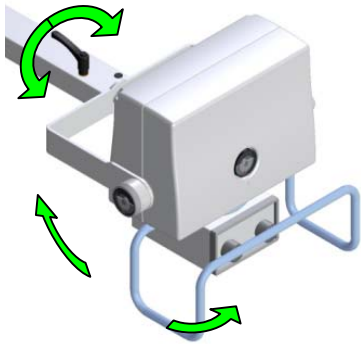


Figure 4
Movements of the monobloc-collimator group

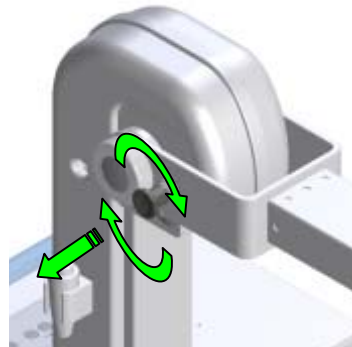


Figure 5
Safety knob

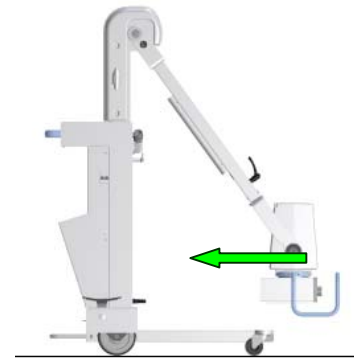


Figure 6
Parking position

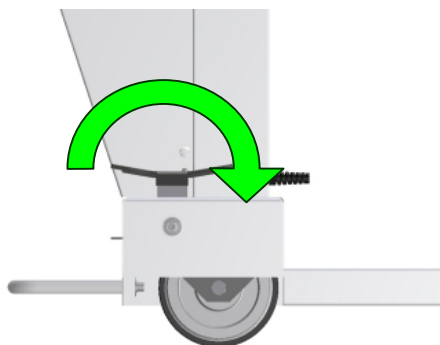


Figure 7
pos.1: disabled brake

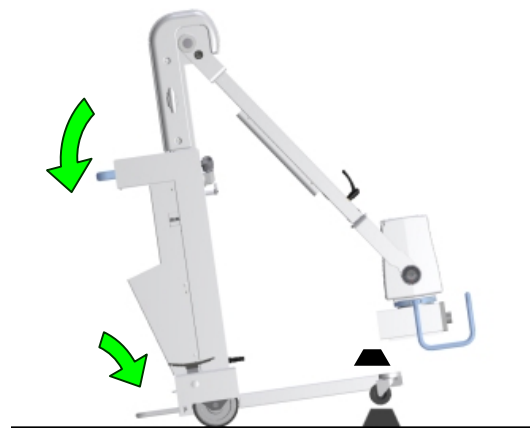


Figure 8

4.2. Positioning

For positioning the unit the following instructions should be considered:

Do not try to move the unit while braked. For the unit movements, use the proper handles.

- Pull the safety knob and turn it till it is taken out (see Figure 5).
- In order to adjust and position the arm height, use the handle on the monobloc (see Figure 9).
- Position the monobloc – collimator assembly over the relevant area of the patient (see Figure 10 - Figure 11).
- Turn the unit ON (see the paragraph 4.3 “Setting in and verifications upon ignition”).
- Turn the collimator lamp ON (the lamp will stay ON for about 30secs).
- Collimate the x-ray beam to the dimension of the cassette (see the next paragraph).
- If necessary, release the brake to perform this operation.
- When positioning has been completed, lock all the movements brakes handles and the parking brake.



Figure 9

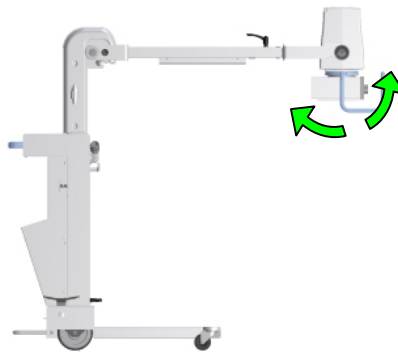


Figure 10

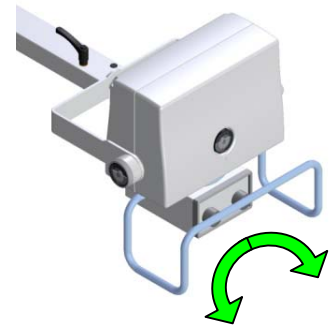


Figure 11

4.3. Setting in and verifications upon ignition

1. Unwind the cable from the cable reel and extend it completely. Connect the unit to the mains.
2. The presence of the power supply voltage is indicated by the switching ON of the yellow led, that is placed near the ON key (Fig.3). if, with the plug inserted, the led is off, check that the automatic switch lever (Fig.1 – pos.11), placed on the unit side, is up (ON position).
3. Turn the unit ON, by pressing ON key (Fig.3), follow step by step the Start up phase and check its performance by comparing it to the following one:
 - During the ignition, the microprocessor performs a visual check:
for 4 seconds it's displayed the writing,
for 2 seconds it switches on the READY, RX and ALARM led and control the buzzer.

U	N	I	T		-		V	e	r	.		Y	Y	.	X	X			

After the visual check, the microprocessor proposes the kV and mAs values

R	E	A	D	Y															
5	0					0	.	5											
kV					mAs														

4.4. Collimator adjustment

1. On the frontal panel of the collimator, two handles for the beam adjustment (width and length) are present, as well as the button to turn ON the collimator lamp (see Figure 12).

The extractable meter allows the correct measurement of the focus-film distance (DFF).

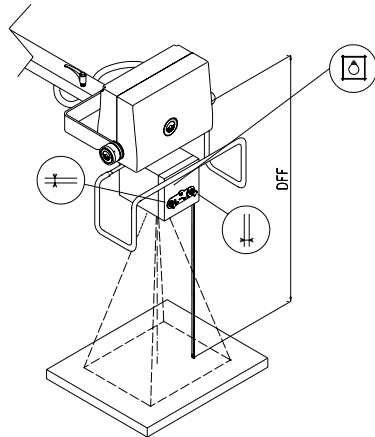


Figure 12

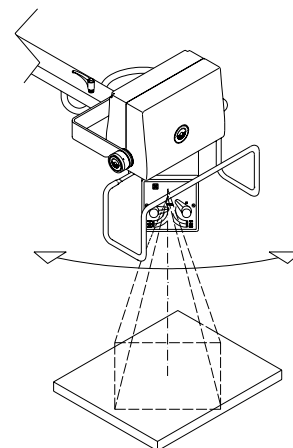


Figure 13

2. If needed, turn the collimator around its vertical axis. (see Figure 13).

4.5. Exposures



Before performing an exposure, make sure that all the necessary precautions against radiation have been taken.



After a long period of inactivity (3 months or more) it is very important to proceed with the XR TUBE SEASONING. This is necessary to avoid high voltage discharges that could be destructive for the XR tube. The seasoning procedure is described in the Service Manual.

In order to perform this operation, it's necessary to make intervene the Service.

Position, plug to mains and turn ON the unit.

Position the cassette..

Collimate the X-ray beam (use the collimator lamp to "see" the exposure area).

Set the exposure parameters (kV & mAs) using kV+ or kV-, mAs+ or mAs- buttons (i.e. kV=50 and mAs=0.2). The display shows the set exposure parameters.

- Keep away as much as possible from the x-ray source.
- If on the display "READY" appears and the READY led is ON, the exposure can be controlled.
- The emission control is made up of a two-steps switch.
 - 1°step: preparation (about 1 s)
 - 2°step: exposure control
- It is possible to press the exposure control immediately (second step). Then there is a delay of about 1.2s before the real exposure.
- Hold the x-ray control down till the exposure has been performed properly (3 beeps).

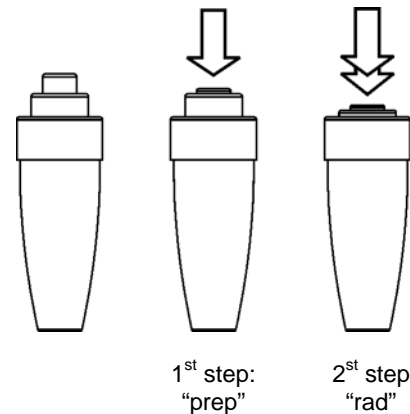


Figure 14

The x-ray handswitch allows to activate both the "prep" x-rays preparation phase and the "rad" emission phase. The Figure 14 shows how to operate the handswitch to activate the preparation and emission phases. It is not possible to activate the "rad" emission phase without preparation. On the contrary it is possible to perform preparation without activating the emission.

The most frequent alarms during the use of the x-ray handswitch are the following:

1. TIME OUT – The x-ray handswitch has been pressed at the "1st step" (preparation) for more than 15s. In order to perform radiography, it is necessary to release the handswitch and repeat the procedure.
2. MAN STOP RX - The x-ray handswitch has been released before the end of exposure. In this case, the display will show the radiological data obtained. In order to repeat the exposure, it is necessary to press RESET.

4.5.1. During the examination

Only if the display shows the writing "READY" and the READY led is ON, it is possible to perform an exposure.

The writing "READY" and the READY led switch off.

The X_RAY led blinks.

4.5.2. After the examination

3 beeps show the exposure has been correctly completed.

The display shows for 15s the exposure time (e.g. 0.01s).

	5	0						0	.	2							0	.	0	1	S
	kV							mAs													

The "READY" writing is substituted to the "BUSY" writing that shows the unit is preparing the next exposure. When the "READY" writing appears again, the unit is ready to perform another exposure.

	B	U	S	Y																	
	5	0						0	.	5											
	kV							mAs													

Replace or place the radiographic cassette in a different manner and perform eventually another exposition.

4.6. Shutdown procedure



Ensure unit is switched off before removing the connector from the mains outlet.

Upon the examination end, proceed as follows:

1. Turn the unit off by acting on the dedicated button OFF placed on the control console.
2. Disconnect the cable and wrap it on the wire-wrap.
3. Place the unit in parking position (lowered, with activated mechanical brakes).

5. MAINTENANCE

5.1. General Warnings

As any technical device, this system requires:

- Correct use;
- Regular checks by the user;
- Maintenance and repair by authorized staff.

Functioning and operational reliability of the unit are kept by following these precautions.

The radiological device user is obliged, under the accident-prevention directives, the laws concerning the medical equipment and other regulations, to adopt these precautions.



As users of x-ray units it is necessary to take these precautions in compliance with the prevention standards formulated by the laws concerning the medical equipment.

The unit needs regular checks and maintenances. The purpose of the following warnings is to keep a good operating and safety level.

The unit includes mechanical parts that are subjected to wear during normal use of the equipment. After a long period of use, it is possible that the safety of the system may decrease due to the parts wear.

Regular checks and maintenance are necessary to protect the patient and the operator from damage as a result of the breakage of any mechanical parts.

The correct adjustment of the electro-mechanical and electronic modules is essential, as this has a direct influence on the unit operation, the image quality, the electrical safety and the exposure level of radiation to which the medical personnel and patients are subjected.

The maintenance plan includes checks and prevention measures to be done by expressly authorized personnel and at the unit owner's charge.



In case of parts replacement linked to the unit safety, use only original spare parts.

5.2. Checks and inspections by the user

The user must check the x-ray unit as indicated in the table below. In the event of operational faults or other deviations in respect of the standard operative behaviour, the user must turn off the unit and call the Service. The unit may only be operated after repairs have been made. The employment of faulty parts can increase risks for the security or an high radiations exposure.



If a faulty or malfunctioning unit is used, risks to the operators and patients can increase.

Summary of the periodical checks

Interval	Object	Method
Daily	Stability test	
Daily	Faulty lights, damaged components, nameplates and indicators.	Checking
Weekly	All the cables and terminals (damages/breakings). Oil leakage and unusual noises in the high voltage generator.	Checking
Every 6 months	Check the brakes tightness and the directional handle functionality.	Checking
Yearly	Contact the technical after-sale service to perform the constancy and reproducibility tests, as indicated by IEC 61223-1 and IEC 61223-2-11 standards, as well as the other operating tests of the unit, as instructed in the programmed maintenance plan.	Checking

5.3. **Cleaning**

Please take the following information into consideration before choosing a detergent:

To clean plastic surfaces, simply use water and soap, and nothing else. If other detergents are used (e.g. with a high alcoholic content), the material will tend to break or opacify. Never use corrosive solvents, or abrasive detergents.

Before cleaning the unit, please take the following actions:

Turn off the unit and unplug the mains power supply cable.

Ensure that neither water nor other liquids seeps into the unit, so as to avoid short-circuiting or corroding the electrical and electromechanical parts.

Clean enameled parts and aluminium surfaces simply with a wet cloth soaked in delicate detergent, then dry with a dry wool cloth.

As regards, chromium-plated surfaces, only rub them using dry wool clothes.



Don't use for the cleaning water or detergent direct jets. The unit protection rank for the liquids is IPX0.

5.4. **Disinfection**

Disinfection modality has to be in compliance with the current regulations and directives concerning disinfection and safekeeping against explosions.

Never use caustic substances, solvents or abrasive detergents.



In cases where there is a danger that disinfection products may form inflammable or explosive gaseous mixtures, always ensure that gases have dispersed before re-using the equipment.

Before disinfecting the unit, unplug the mains power supply cable.

Disinfect the equipment parts, including the accessories and connection cables, by using only a wet cloth with a disinfecting substance.

It's advisable to use vaporizers because the disinfectant may penetrate the system.

To disinfect by a vaporizer, the room where is placed the unit, turn it off, let it cool and cover it carefully with plastic cloths. Once the disinfecting gases have dispersed, remove the plastic cloths and proceed with the disinfection by a cloth.

6. TECHNICAL CHARACTERISTICS

6.1. Electrical data

Description	Dati		
Voltage	230Vac \pm 10% monophase standard 115Vac \pm 10% monophase		
Frequency	50/60Hz standard		
Absorbed current	Values of current absorbed by the unit in the different operative conditions and in the two power supply values:		
	<i>Operative condition</i>	115 Vac / 50Hz	230 Vac / 50Hz
	Stand By	0,5A	0,5A
	Radiographie	32A	20A
Line compensation	Automatic		
Line resistance	<0,8 Ω @230Vac <0,4 Ω @115Vac		
Standard mains plug	16A @230Vac		
Isolation class	Class I with applied part type B		
Use conditions	Continuous functioning with intermittent load		
The unit is not suitable to the use where danger of inflammable mixtures with air or nitrous oxide exists.			

6.2. Functioning features

Description	Data
User's interface	Keyboard with LCD alphanumeric display, 2 lines X 20 characters for all the operative parameters and messages of possible faulty status. Service program for faults finding. Microprocessor management.
Languages	Italian, English, French, German, Spanish Selection by means of configuration programme (accessible by Service personnel only).
Radiography control	By hand-switch with extendible cable. Upon the ignition, the unit is in manual mode with default values.
Safeties	Filament current Monobloc temperature Overload Max kV or H.V. fault Microcontroller auto test

6.3. Radiological data

Description	Data
Working technique	At 2 points with setting of kV and mAs
Focus in all the working conditions	1,5mm
Generator power in DC current (IEC 60601-1)	4kW @100kV @230Vac 1,5kW @100kV @115Vac
Inverter frequency	22kHz
Max. frequency in high voltage	44kHz
Max. ripple	<2% @100kV
Rise time	<2ms @100kV
kV variation range	40 ÷ 110kV in step of 1kV
mA variation range @230Vac	30 ÷ 80mA
mA variation range @115Vac	12 ÷ 37mA
mAs variation range @230Vac	0,2 ÷ 250mAs in steps with increases of 12,5% (R'20 curve)
mAs variation range @115Vac	0,2 ÷ 160mAs in steps with increases of 12,5% (R'20 curve)
Times range @115/230Vac	0,002 ÷ 5s in function of the set mAs
Use coefficient (duty cycle)	Ton: Toff = 1:40 Example 1: Ton = 0,002s Toff = 0,08s Example 2: Ton = 5s Toff = 200s

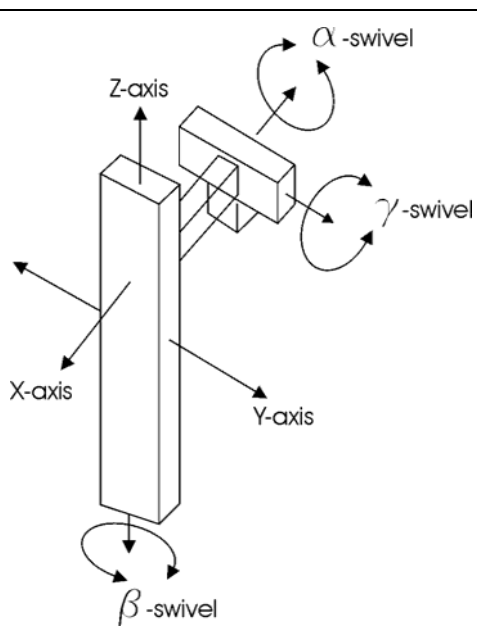
MA values @115 / 230Vac	kV	mA			
		@230Vac		@115Vac	
		t < 01,s	t > 0,1s	t < 01,s	t > 0,1s
	40	80	61	37	33
	50	70	53	30	27
	60	60	46	25	22
	70	51	42	22	19
	80	45	38	19	17
	90	42	36	16	15
	100	40	32	15	13
	110	36	30	13	12

MAs values in function of the kV	mAs			
	kV	@230Vac	kV	@115Vac
40 ÷ 44	0,2 ÷ 250	40 ÷ 41	0,2 ÷ 160	
45 ÷ 49	0,2 ÷ 200	42 ÷ 46	0,2 ÷ 140	
50 ÷ 54	0,2 ÷ 160	47 ÷ 52	0,2 ÷ 125	
55 ÷ 59	0,2 ÷ 125	53 ÷ 59	0,2 ÷ 110	
60 ÷ 64	0,2 ÷ 110	60 ÷ 64	0,2 ÷ 100	
65 ÷ 69	0,2 ÷ 90	75 ÷ 72	0,2 ÷ 90	
70 ÷ 74	0,2 ÷ 80	73 ÷ 80	0,2 ÷ 80	
75 ÷ 79	0,2 ÷ 56	81 ÷ 92	0,2 ÷ 71	
80 ÷ 84	0,2 ÷ 50	93 ÷ 107	0,2 ÷ 63	
85 ÷ 89	0,2 ÷ 45	108 ÷ 110	0,2 ÷ 56	
90 ÷ 94	0,2 ÷ 40	---	---	
95 ÷ 104	0,2 ÷ 36	---	---	
105 ÷ 110	0,2 ÷ 32	---	---	

6.4. Environmental data

Description	Normal use	Transport and storage
Temperature	From +10°C (50°F) to +40°C (104°F)	From -25°C (-13°F) to +70°C (158°F)
Relative humidity	From 30% to 75% non condensing	From 10% to 90% non condensing
Pressure	From 700 to 1060hPa	From 500 to 1060hPa

6.5. Mechanical data

Description	Data
Weight	143 kg approx.
Max. width	680 mm (26,77 inch)
Lenght in transport position	1226 mm (48,26 inch)
Max lenght in working position	1687 mm (66,47 inch)
Max height in transport position	1450 mm (57,08 inch)
Max height with the arm at the max extension	2245 mm (88,38 inch)
Control panel height	971mm (38,22 inch)
Focus-floor distance	433 ÷ 2041 mm (17 ÷ 80 inch)
Monobloc rotation around the column axis (β swivel)	n.d.
Arm rotation around the vertical axis (α swivel)	$\pm 180^\circ$
Monobloc rotation around its axis (γ swivel)	151° (+133° onward, -18° back)
Max height of the unit front leg	107mm (4,21 inch)
Cassette holder	4 cassettes 35 x 43cm format (13,78x16,93in.)
Movement	Manual. Double front casters. Stationary brake. Handle and Pedal for tilting (obstacles overcoming)
Wheels diameter	Rear: wheel $\varnothing 160$ mm wigth 40mm (6,29 x 1,57 inch) Front: double wheel $\varnothing 80$ mm width 20mm (3,14 x 0,78 inch)
	

6.5.1. Unit sizes

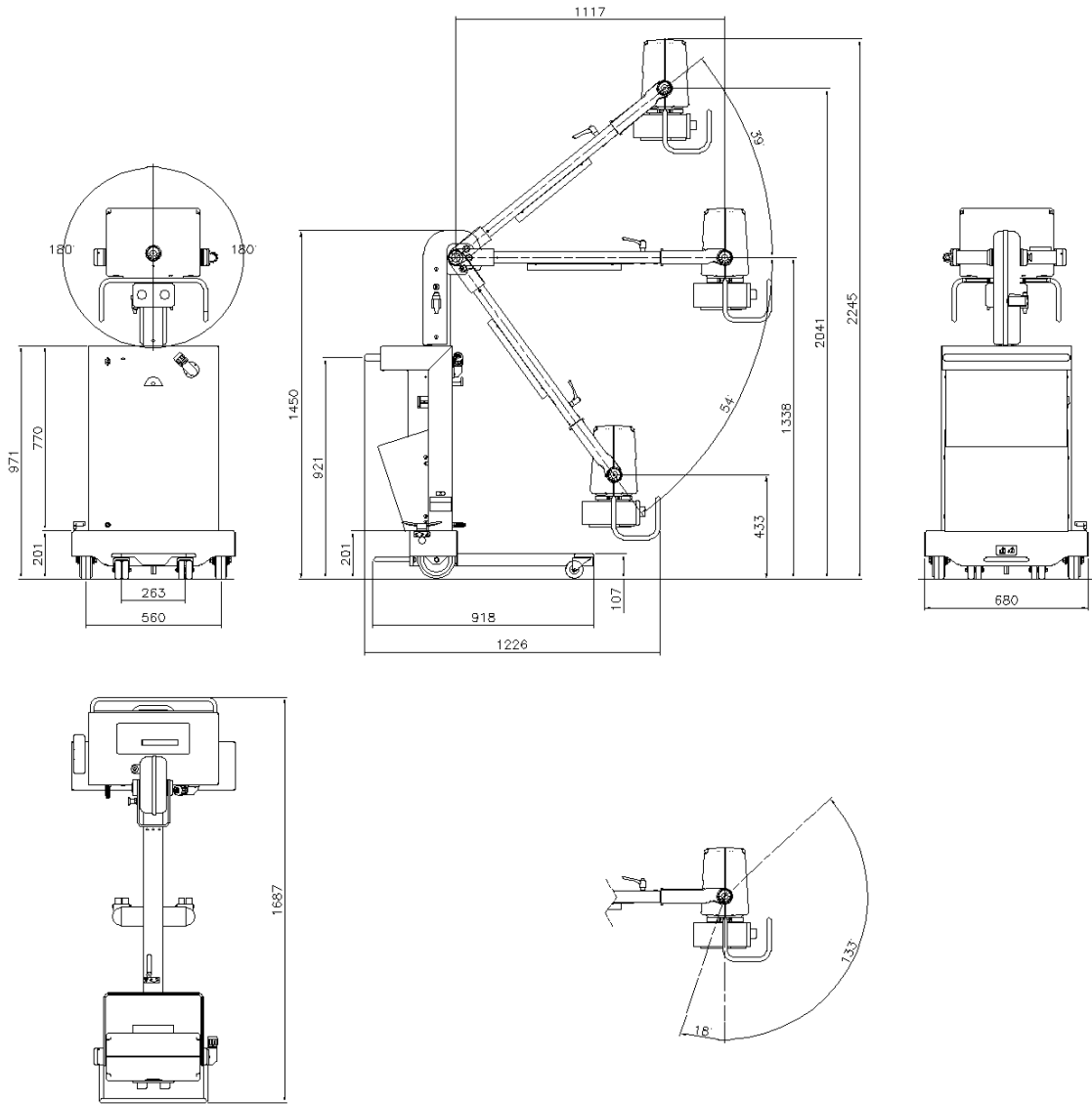


Figure 15

All the measures are in millimetres.

6.6. Components specifications

6.6.1. Generator

Description	Data
<i>Inverter model</i>	IHF 2205
<i>Working frequency</i>	22kHz max
<i>Power supply</i>	350Vdc max
<i>Dimensions</i>	220 x 160 x 160mm (8,66 x 6,30 x 6,30 in.)
<i>Technology</i>	IGBT
<i>Protection</i>	Over current primary and secondary over voltage malfunction of IGBT control
<i>Generator power in constant DC current (IEC 601-1)</i>	5kW (50mA @ 100kV per 0.1s)
<i>Max. voltage to the tube</i>	115kVp
<i>Max. ripple at 100kVp</i>	<2%
<i>Rise time at 100kVp</i>	<2 ms

6.6.2. Tube-Housing Assembly

X-Ray Tube

Description	Data
Type	OX/110-5
Nominal anode power (IEC 613, EN 60613)	800W/4000W
Focuses nominal Dim. (IEC 336, EN 60336)	0,6 (small Focus) - 1,5mm (large Focus)
Speed of rotation	Stationary
Anod material	Tungsten
Anode angle	15°
Min. inherent filtration (IEC 522)	0.5mmAl
Anod thermic capacity	40kJ (55kHU)
Max. continuous anode dissipation	400W – 536 HU/sec
Max anode cooling speed	19kJ/min (24.4 kHU/min)
Nominal high-voltage	110kV
Max. filament current	5.2A

Tube seasoning

After a long idle period (3 months or more), it is necessary to proceed to the X-RAY TUBE SEASONING. The procedure and the tube seasoning modes are described in the Service Manual.

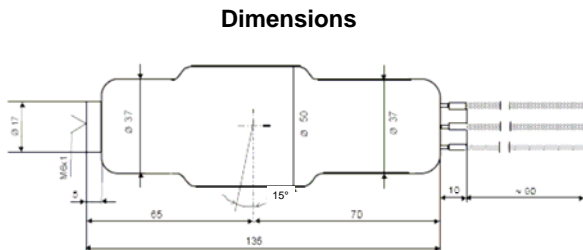


Figure 16

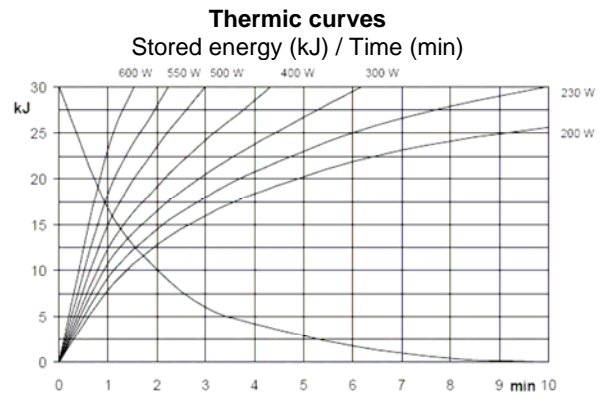


Figure 17

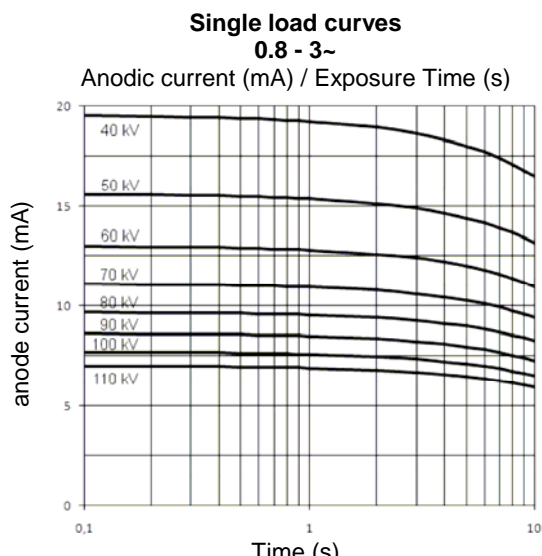


Figure 18

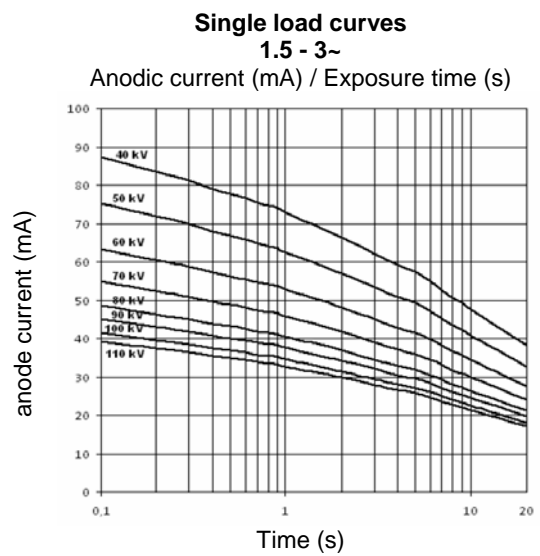


Figure 19

Monobloc

Description	Data
Monobloc	MHF20K3
Weight	19 Kg
Dimensions	320x140x255mm (12,60x5,51x10,04in.)
x-rays tube model	CEI OX 110-5
Anode	Fixed
External thermostat	57°
Thermal monobloc capacity	500kJ (665kJHU)
Max continuous thermal dissipation of monobloc	55W
Total filtration	2,7mmAl equ.
Leakage radiation	<1mGy/h according to IEC 601-1-3
Loading, heating and cooling curves	See the diagram here attached
H.V. transformer insulation	In oil bath

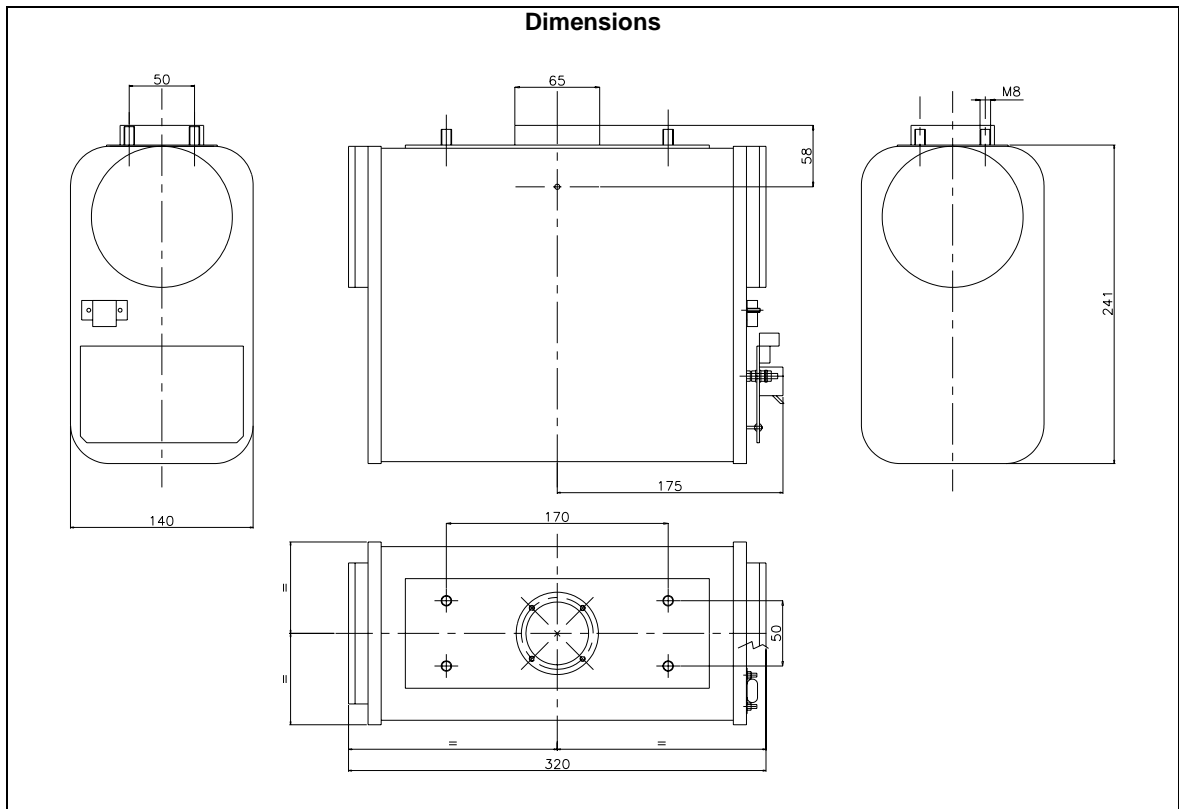


Figure 20

Thermic curves
Stored energy (kJ) / Time (min)

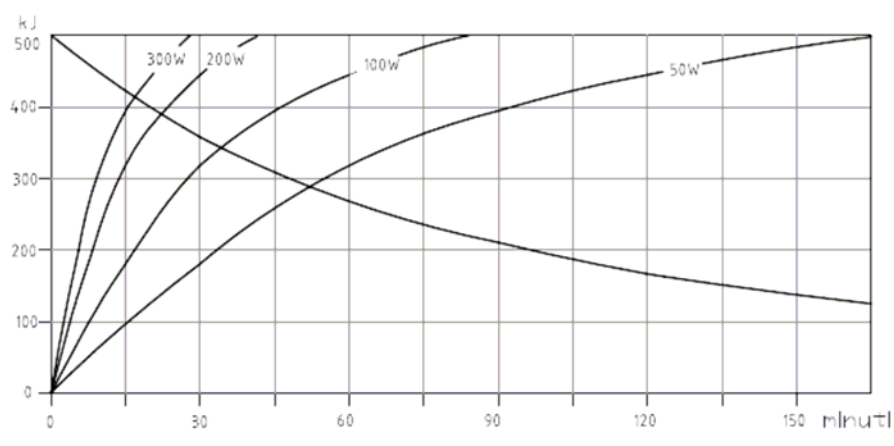


Figure 21

6.6.3. Collimator

Description	Data
Type, brand and model	Manual with internal light source (Ralco R105)
Collimator	Square field, multilayers
Light source	Halogen Lamp 12V 100W with 30sec timer
X-ray field	43x43cm (16,93x16,93in.) at 1m (39,37in.) DFF
Luminous intensity	160lux at 1m (39,37in.) DFF
Contrast ratio	3:1
Measurement of focus-film distance	Extractable meter
Rotation	±115°
Weight	4kg
Sizes	177 x 103 x 255 mm
Max protection against leaked radiation (EN60601-1-3 par.29.204.3)	110kV 4mA
Indicator accuracy (EN60601-1-3 par.29.202.8)	It corresponds to the x-ray fields with tolerance lower than 2% of used FFD
Inherent filtration (EN60601-1-3 par.29.201.2/29.201.6)	2.0mmAl eq.
Light field accuracy (EN60601-1-3 par.29.202.9)	It corresponds to the x-ray fields with tolerance lower than 2% of the used FFD.
Classification EN60601-1 par.5 Protection against electrical hazards Protection against direct and indirect contacts Protection against water penetration	Class I Unit with applied part Type B Common protection (IPXO)

6.7. Accessories and options

Description	
X-ray hand switch with extendible cable	Standard
Dosimeter	Optional

6.8. Labels and symbols

6.8.1. Labels of the unit

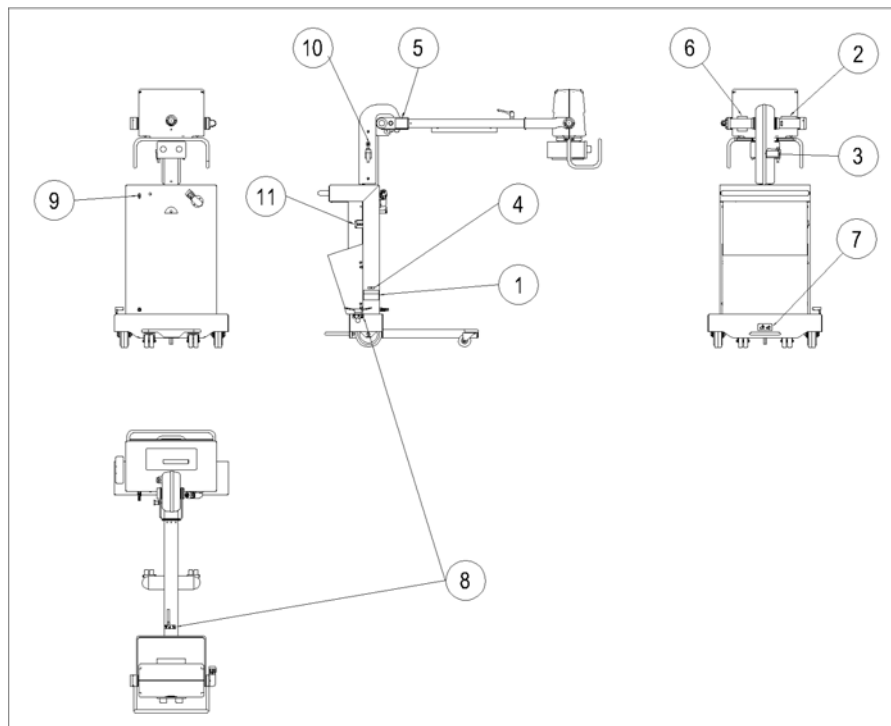









Figure 22






Pos.1 – Unit label

 TECHNIX TECHNIX S.p.A. - Via E.Fermi 45 - 24050 Grassobio - BG - ITALY MANUFACTURED ACCORDING TO THE MEDICAL DEVICE DIRECTIVE 93/42 EEC			
Model	TMS 4	Classification	 IEC 60601-1
Serial Number	81-XX-XX-XX	Ionizing radiation max	110kVp
Date mfg.	XX-XX	Physiological effects	
Supply	115/230V~	Mechanical stability	
Frequency	50/60Hz	Operational mode: continuous operation with intermittent loading	
Power	Stand-by: 0.5A Max absorption 115/230V~	Made in ITALY	 0061

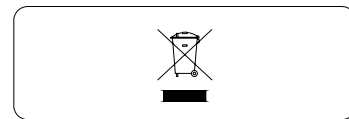
Pos.2 – Monobloc label

Tank Unit	MHF20K3	kVp max	110
Serial Number	XXXX	mA max	73
X-ray Tube	OX110-5	 Permanent filtration 2,7 Al/100 Total filtration >= 4,7 Al/100 <small>incl. beam limiting device</small>	
Serial Number	XXXXX		
Focus (IEC60336)	 1.5		

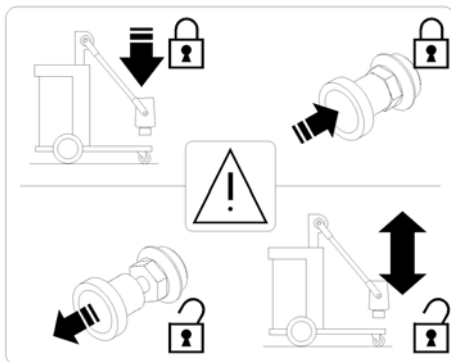
Pos.3 – Collimator label

 S.r.l.	via dei Tigli 13/G 20046 Biassono (MILAN) ITALY
	BEAM LIMITING DEVICE Collimator Type: R 105 s/n: 027A/12345
Date of manufacture: FEBRUARY 2008	
 0051   	

Pos.4 - WEEE label



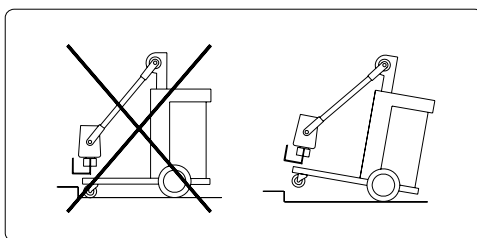
Pos.5 – Label for arm movement lock/release



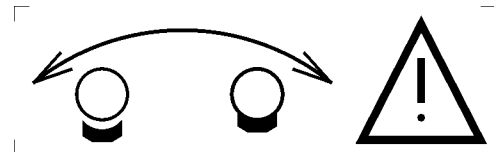
Pos.6 – Transport position label



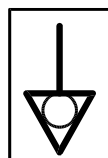
Pos.7 – Tilting label



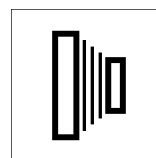
Pos.8 - Brakes label



Pos.9 - Equipotential node



Pos.10 – Graphy push button



Pos.11 – Mains label



Figure 23

DOCUMENT STATUS

<i>Rev.</i>	<i>Date</i>	<i>Pages</i>	<i>Modification description</i>
-	07-11-2008	-	Document approval
A	02/10/09	9, 10 19,23	Updated alarms list. Updated radiological data.
B	26/10/09	6, 26	Upgrading of manufacturer address and relative S/N labels
C			
D			
E			
F			