



# Visitor T15

MOBILE X-RAY SYSTEM



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## User's Manual

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

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# 1. SAFETY AND COMPLIANCE

The purpose of this user's manual is to provide a set of easy to use instructions for the proper use of the system. All of the information contained herein is based on the current version of the system. Villa Sistemi Medicali reserves the right to improve and implement changes to the information herein to reflect any changes necessitated by technological enhancements to the system.



- This x-ray unit must be used in strict compliance with the safety instructions contained in this manual and must not be used for purposes other those for which it was intended
- The x-ray unit may only be operated by skilled, properly trained personnel with the required knowledge of x-ray safety practices and the proper use of x-ray equipment.

**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 operated when electrical, mechanical, or radiological faults are present or when any of the indicators or alarm devices are malfunctioning.
- When used in conjunction with other apparatus, components, or modules, whose compatibility is uncertain, it is necessary to ensure the absence of any danger to the patient or operator. Consult Villa Sistemi Medicali for information.
- Villa Sistemi Medicali is responsible for the safety of its products only when maintenance, repairs, or modifications have been performed by Villa Sistemi Medicali or by personnel authorized by Villa Sistemi Medicali in writing.
- As with any technical apparatus, this x-ray unit must be used properly with periodic checks and maintenance as specified in the chapter "Programmed maintenance".
- The system safety circuits and devices must not, for any reason, be moved, modified, or omitted.

**Villa Sistemi Medicali cannot be held liable for any malfunction, damage, or danger resulting from improper use of the system or non-compliance with the rules for proper maintenance.**

## 1.1. Electrical safety



- Only trained service personnel authorized by Villa Sistemi Medicali may remove the unit covers and only in accordance with the instructions contained in the Service Manual.
- This X-ray unit may only be used in environments or medical rooms in compliance with the applicable IEC standards.
- The X-ray unit must not be used in areas where there exists a danger of explosion.
- Cleaning and disinfecting agents, including those used on patients, may create an explosive, gaseous mixture. Use only those products in compliance with the applicable rules.

## 1.2. Mechanical safety



- After positioning the unit, engage the parking brakes.
- Only use the proper handles to move the unit.
- Avoid collision with obstacles.

### 1.3. Electromagnetic compatibility (EMC)

This apparatus is in compliance with the applicable rule regarding EMC, Directive 89/336, that defines the max. allowed emission levels from electronic devices and the required immunity from interference caused by externally generated electromagnetic 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, the use of radio equipment proximity to electronically controlled systems must be avoided in order to eliminate any interference risk.

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



**Any transmissions by mobile radio equipment must be avoided.  
Mobile phones must be switched off in zones close to the unit.  
These rules must be applied when the unit is switched on (that is to say connected to the mains and ready for use).**

### 1.4. Protection against ionizing radiation



**Before any x-ray exposure, ensure that all the necessary protective 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:

- When necessary, use protective shielding against radiation in addition to the shielding already provided on the unit.
- Use protective aprons containing a material equivalent to 0,35mm of lead. Material of this nature reduces radiation at 50kV by 99,95% and at 100kV by 94,5%.
- The best protection against radiation is distance. It is therefore recommended that you stay as far as possible from the x-ray source and the exposure target. For this purpose, use all of the cable length provided for the foot-switch.
- Avoid walking or standing directly in the x-ray beam.
- Always use the smallest possible field of exposure by closing properly the collimator diaphragms. The scatter dose produced depends principally on the volume of the irradiated object.



**Never modify or disconnect the safety circuits or devices designed to prevent accidental exposures.**

### 1.5. General disposal

Villa Sistemi Medicali produces radiological systems that are advanced in terms of safety and environmental protection. Assuming that the unit is properly used, there is no risk to people or the environment.

In order to comply with applicable safety requirements, it is necessary to use materials that may be harmful to the environment (for example: monobloc oil, protective lead, boards and electronic components). Therefore, where necessary, proper disposal methods, according to the regulations of the country where the unit is installed, should be followed.



**For this reason, the unit may not be disposed of along with industrial or domestic waste and must be regarded as hazardous waste.**

For additional information, contact Villa Sistemi Medicali.

## 1.6. Application & final destination

This unit is a portable x-ray system aimed to fulfil a wide range of clinical applications; it must be operated exclusively by qualified, trained personnel who have been informed of the risks linked to the use of ionizing radiation.

The compactness and maneuverability of the unit enables the operator to navigate through obstacles such as doors, small rooms, narrow aisles and lifts with ease and allows accurate positioning between patient beds. The ergonomic design of the unit allows the operator excellent visibility during operation and movement.

The perfectly balanced monobloc arm allows free movement and positioning even in the more awkward positions. The shape of the base allows easy positioning and handling under the patient beds. The position and shape of the four antistatic wheels make the system easy to move even on coarse surfaces.

**The system does not belong to the category of equipment designed for continuous operation.**

**The system is not used in direct contact with the patient; however, accidental contact of some unit parts with the patient and operator is possible.**

**Contact with the patient is non-invasive.**

**Contact with the operator is strictly for reasons linked to the use of the equipment (normal operation).**

The unit is suitable to be used for x-ray examinations and diagnosis dedicated to:

- Operating theater
- Sport medicine
- Plaster room
- First aid
- Pediatrics
- Orthopaedics



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

## 1.7. Interfaceability

The device does not foresee any interaction with medicines; instead it's possible to apply to the unit the ionization chamber dosimeter as optional (mod. DIAMENTOR PX). It complies with the safety requirements foreseen by the 93/42/EEC Directive. However, the liability of the interface, if it has not been evaluated and authorized by Villa Sistemi Medicali in writing, is of the operator and/or the person who has performed the interface.

## 1.8. 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 (IPXO)  
 Use condition protection ..... Continuous use with intermittent load

## 1.9. Compliance



This x-ray unit is in compliance with the electromedical devices Directive 93/42 EEC and with the other national and international standards in force.

The distributor (according to the European Directive 93/42/EEC) of the unit Visitor T15 is:

### **Villa Sistemi Medicali**

Via delle Azalee, 3  
20090 - Buccinasco - (MI) - Italia  
Tel: +39-02-48.859.1  
Fax: +39-02-48.81.844  
E-mail: [vsmservice@villasm.com](mailto:vsmservice@villasm.com)

Information concerning the compliance can be required to Villa Sistemi Medicali.

The manufacturer (according to the European Directive 93/42/EEC) of the unit Visitor T15 is:

### **Technix S.p.A.**

Via E. Fermi, 26  
24050 Grassobbio, BG - ITALY  
Tel: +39 035 33 56 78  
Fax: +39 035 33 56 75

## 1.10. Copyright

The original release of this manual is in Italian language (file: AD30013100RXX.doc). For further information, please refer to the Italian version.

The software contained in the unit belongs to Technix S.p.A. Upon receipt of the unit, the user acquires the right to use the software in combination with the unit. **This right is neither exclusive nor transferable.**

Written authorization to Technix S.p.A. is mandatory prior to any modifications for the unit use with functions other than the ones foreseen.

## 2. COMPONENT IDENTIFICATION

### 2.1. Overview

- |                         |                                       |
|-------------------------|---------------------------------------|
| 1. Monobloc             | 10. Cassette holder                   |
| 2. Goniometer           | 11. Magneto-thermic switch            |
| 3. Monobloc handle      | 12. Supply cable                      |
| 4. Collimator           | 13. Handle for unit movement          |
| 5. Supply cable-winding | 14. Control panel                     |
| 6. Equipotential node   | 15. Arm safety lock for transport     |
| 7. Connector for Potter | 16. Monobloc support arm              |
| 8. X-ray handswitch     | 17. Safety lock for monobloc rotation |
| 9. Foot brake           |                                       |

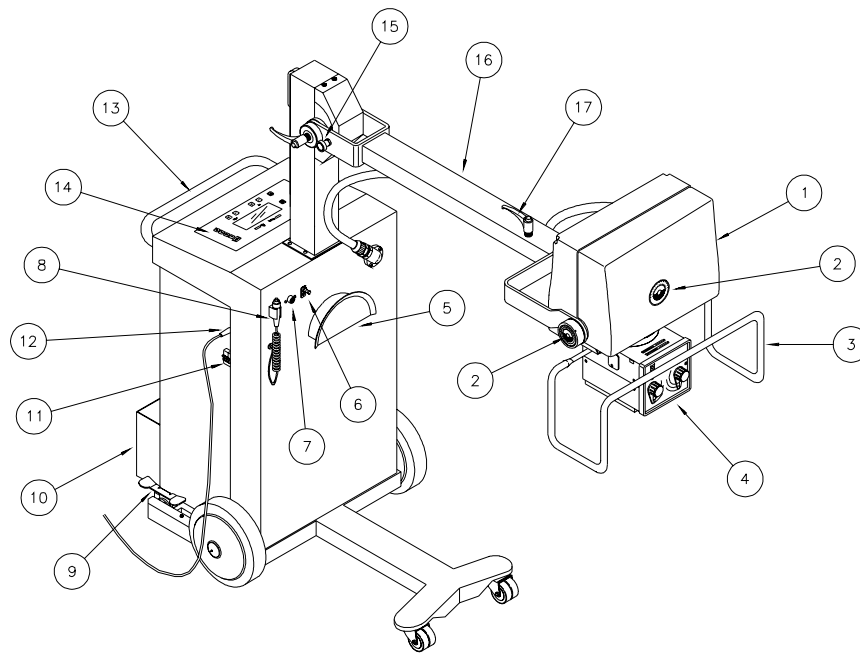


Figure 1

### 2.2. Collimator

- |  |  |
|--|--|
| 1. Longitudinal collimation                        | 4. Lamp switching ON for the luminous irradiation field indication   |
| 2. Extensible meter for focus-skin distance check. | 5. Guides for the accessories positioning (filters or DAP dosimeter) |
| 3. Transversal collimation                         |  |

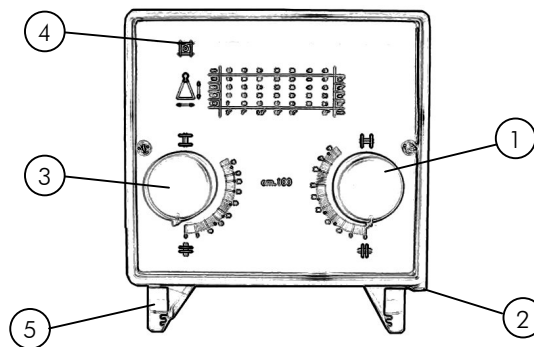


Figure 2



### 2.3. Control panel

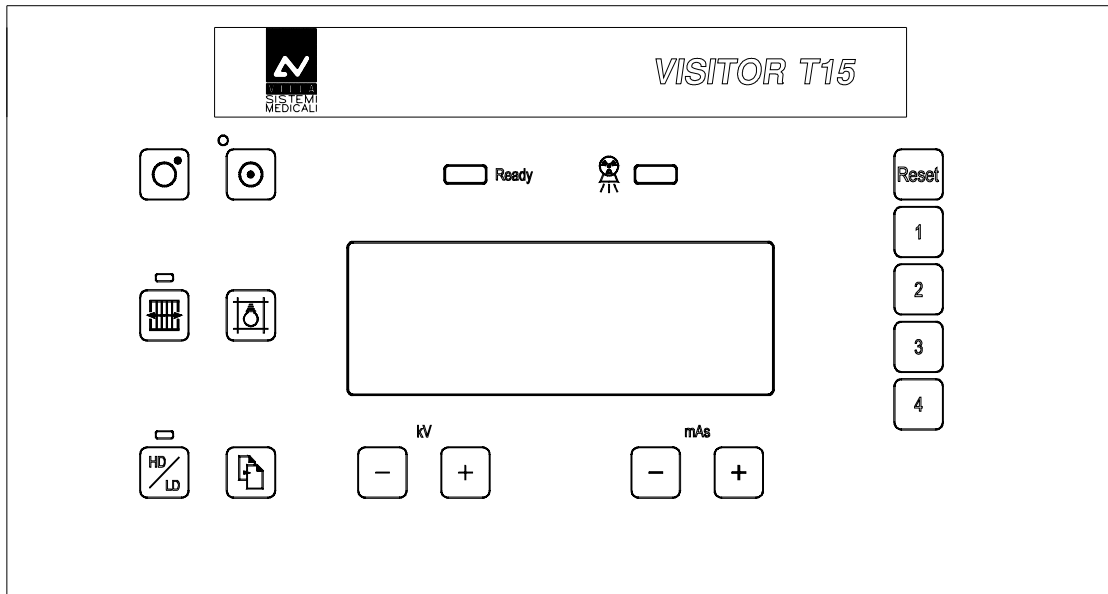
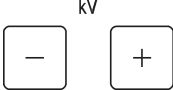


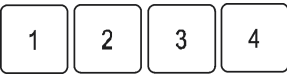




Figure 3

Here is a brief description of the keys function in standard use and the signals meaning.

	OFF	Unit OFF.
	ON	Unit ON, the green led indicates that the unit is connected to the mains and supplied.
	POTTER	External potter selection, only if the potter is inserted in the proper connector.
	COLLIMATOR	Collimator lamp ON. (the lighting is timed for about 30s)
	POWER	HIGH or LOW POWER selection. The led ON indicates the HIGH POWER selection.
	MENU	Allows scrolling through pages in systems with more than one page.

	kV+ kV-	To modify KV value
	mAs+ mAs-	To modify mAs value
	RESET	Return to the main menu.
	F#	Function keys: F1, F2, F3, F4 They refer to the display line number (4 lines display).
	READY	ON when the unit is ready for radiography.
	X-RAY	When this led is ON there is x-ray emission

## 2.4. Audible signals

Here is the list of the most important audible signals:

2 BEEPS	Storage ok
3 BEEPS	Exposure ok
A LONG BEEP	Alarm, malfunction

## 2.5. Signals and error messages

The unit foresees three types of alarm that can appear on the display:

- Warnings (WARN)
- Errors (ERR)
- Fatal Errors (FERR)

### Warnings (WARN)

When this alarm appears, after taking the proper precautions, it is enough to press RESET on the control panel to go on to work with the same modes set. In order to interpret the alarm, refer to the tables indicated successively.

### Errors (ERR)

When this alarm appears, after taking the proper precautions, it is enough to press RESET on the control panel to go on to work with the same modes set. In order to interpret the alarm, refer to the tables indicated successively. This type of alarm always leaves a trace, in fact the unit stores information about the error (date, time, kV and mAs) so that the service intervention is made easier.

### Fatal Error (FERR)

This alarm does not allow operations to continue on the unit. It's necessary to switch the unit OFF. This type of alarm always leaves a trace, in fact the unit stores information about the error (date, time, kV and mAs) so that the service intervention is made easier.

### For the unit operator

Every signal is displayed and appears in the language according to the unit configuration ("ITA", "ENG", "FRE", "GER", "SPA")

WARNING SIGNAL

E	R	R																	
M	A	N	U	A	L														
						6	3												4

The display shows error or warning messages on the first line, whilst the other lines show the unit status.  
In this condition press "RESET" on the keyboard (see Figure 3) to go on to work with the same set modes.

FATAL ERROR SIGNAL

F	A	T	A	L															
E	R	R	O	R															

The display shows the error message on the first line, whilst the other lines are blank.  
In this condition it is necessary to turn the unit off, wait for some minutes, turn the unit on again and repeat the operations performed previously.  
If the same error appears again, it is necessary to stop the unit use and call Service.

In order to interpret the unit messages, refer to the following pages.

### 3. MESSAGES ON THE DISPLAY

F = fatal error      W = alarm      S = unit status

	Text	Meaning	Action	
S	READY	The unit is ready to perform an exposure		
S	BUSY	Preparation phase	Wait for "READY" message	
S	MANUAL			
W	CLOCK OFF	System clock error	Press RESET to proceed	
F	POWER FAULT	Charger or Chopper error Energy not available	Turn off, wait for some minutes, turn on and if the error appears again, call Service	
F	V3 FAULT	Absence of V3 power supply	Turn off, wait for some minutes, turn on and if the error appears again, call Service	
W	RESET APR	APR checksum error	Press RESET to proceed	
W	APR OUT OF RANGE	An APR value is out of range	Set differently the parameters	
W	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	
F	FILAMENT	Absence of filament current	Turn off, wait for some minutes, turn on and if the error appears again, call Service	
W	HOT TUBE	The monobloc temperature has achieved the max. allowed value	Wait for the monobloc cooling	
F	V2 FAULT	Absence of V2 power supply in the set mA and kV circuit	Turn off, wait for some minutes, turn on and if the error appears again, call Service	
F	STARTER INTERLOCK	Error during the start time	Press RESET to proceed and repeat exposure	
F	CHOPPER FAULT	Chopper error	Press RESET to proceed, repeat x-rays	
W	TIME OUT	The x-ray handswitch has been pressed at the 1 <sup>st</sup> step for more than 15 secs.	Release the handswitch and repeat radiography	
F	LACK OF X-RAY	kV don't reach the 75% of the set value within the first 10ms of exposure or lack of x-rays.	Press RESET to proceed and repeat exposure	
F	MAX TIME	The max. exposure time has been achieved (2s)	Press RESET to proceed and repeat exposure	
F	DATA ERR.	Memory error, data checksum error	Turn off, wait for some minutes, turn on and if the error appears again, call Service	
W	MAN STOP RX	The x-ray handswitch has been released before the end of exposure	Press RESET to proceed	
F	INVERTER KV ERROR	During x-ray emission kV decrease under 75% or increase over 110% of the set value or the H.V. circuit has unbalanced during exposure	Press RESET and repeat exposure	
F	INVERTER OVERLOAD	Inverter power out of range	Press RESET and proceed	
F	INVERTER FAULT	IGBT drivers error	Press RESET and proceed	
F	ERR. TUBE CALIB.	X-ray tube calibration error	Call Service	
F	HAND SWITCH ERR	Faulty x-ray handswitch	Check the x-ray handswitch integrity, turn off and on again the unit, then try again. If the error appears again, call Service	
W	Dosimeter	DAP INACTIVE	The dosimeter is not connected	-
-		MAX DOSE	The doses meter has reached the max.value that can be displayed	Press F1 + RESET to reset the value
S		DAP READY	The dosimeter is ready	-
W		DAP ERROR	The dosimeter is connected, but in fault	Press RESET and call Service
-		DAP RESET	The sum of the product-area doses have been reset	-

The table below shows all the messages and signals in the five languages that can be set.

 English (GB)	 Italian (I)	 French (F)	 German (D)	 Spanish (ES)
ENG	ITA	FRE	GER	SPA
CLOCK OFF	ERR. OROLOGIO	CHRONO DEF.	TAKTGEBER DEFEKT	FALLO RELOJ
POWER FAULT	POTENZA GUASTA	BAT. DEFECT.	STROMVERSORG. DEF	FALLO ACUMUL.
V3 FAULT	ERRORE V3	V3 DEFECT.	V3 DEFEKT	FALLO V3
RESET APR	INI. APR	INI. APR	APR-DATEN DEFEKT	INI. APR
APR OUT OF RANGE	ERRORE IN APR	APR DEFECT.	APR-WERT FALSCH	FALLO APR
TUBE SEASONING FILAMENT	FORM. DEL TUBO FILAMENTO	FORM. DU TUBE FILAMENT	RÖHRE ENFAHREN HEIZKREIS-FEHLER	AJUSTE DEL TUBO FILAMENTO
HOT TUBE	TUBO CALDO	TUBE CHAUD	RÖHRE HEISS	TEMPER.
V2 FAULT	ERRORE V2	V2 DEFECT.	V2 DEFEKT	FALLO V2
STARTER INTERLOOK	STARTER BLOCCATO	BLOCAGE DEMARREUR	ANLAUF-FEHLER	BLOQUEO CEBADOR
CHOPPER FAULT	CHOPPER GUASTO	HACHEUR DEFECT.	CHOPPER-FEHLER	FALLO PULSADOR
TIME OUT	TEMPO SCADUTO	TEMPS EXPIRE	PREP ZU LANG	FUERA TIEMPO
READY	PRONTO	PRET	BEREIT	LISTO
BUSY	ATTESA	ATTENDRE	WARTEN	ESPERA
LACK OF X-RAY	ERRORE RAGGI	FAUTE RAYON	KEINE STRAHLUNG	SIN RADIACION
MAX TIME	TEMPO MAX	TEMPS MAX	MAX EXP ERREICHT	TIEMPO MAX
DATA ERR.	ERR. DATI	FAULE DE VALEUR	DATEN-FEHLER	FALLO DATO
MAN STOP RX	STOP MANUALE	STOP MANUAL	EXP UNDERBROCHEN	INTERRUP. MANUAL
INVERTER KV ERR.	ERR. KV INVERTER	TRANSF. KV DEFECT	WANDLER KV FEHLER	FALLO KV TRANSF
INVERTER OVERLOAD	SOVRACCARICO INV.	TRANSF. SURCHAR GE	WANDLER ÜBERLAST	SOBRECARGA TRANSF
INVERTER FAULT	ERRORE INVERTER	TRANSF. DEFECTUE USE	WANDLER FEHLER	FALLO TRANSF
ERR. TUBE CALIBR.	ERR. CALIB. TUBO	CALIB. DEFECT.	RÖHRE KALIBRIEREN	FALLO CALIB.
MANUAL	MANUALE	MANUAL	MANUELL	MANUAL
HAND SWITCH ERR	ERR. PULSANTE RX	BOUTON DEFECT.	HANDSCHALT. DEF	FALLO MANDO
INACTIV	INATTIV	INACTIF	INAKTIV	INACTIV
ACTIV	ATTIVO	ACTIF	AKTIV	ACTIV
NOT OK	NON OK	NON OK	NOT OK	NO OK
MAXDOSE	MAXDOSE	MAXDOSE	MAXDOSE	MAXDOSE

## 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 group; when the parking position is reached (see Figure 6) rotate and engage the safety lock.
- Release the parking brake (see Figure 7 and Figure 8)
- Move the unit by using only the proper handles for the transport.
- Don't move the unit on surfaces with inclination higher than 10°.
- In order to overtake obstacles, it is possible to use the handle placed on the column.

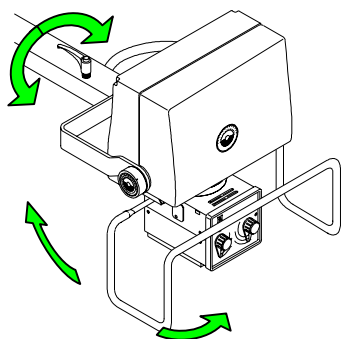


Figure 4  
Movements of the monobloc - collimator group

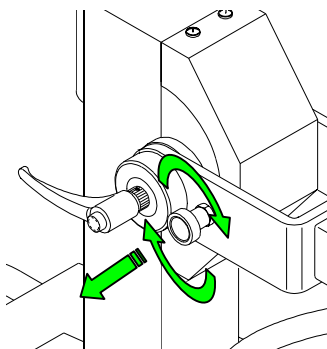


Figure 5  
Safety knob

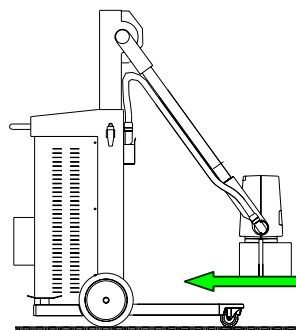


Figure 6  
Parking position

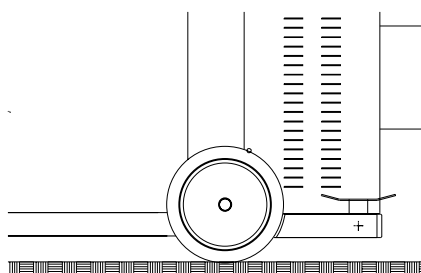


Figure 7  
pos.1: deactivated brake

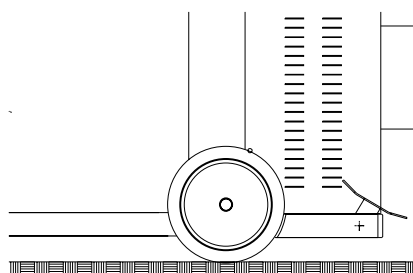


Figure 8  
pos.2: activated brake

## 4.2. Positioning

For positioning the unit the following instructions should be considered:

**Don't move the unit when the brakes are activated. For the movements use the proper handles.**

- Pull the safety knob and turn it till it is taken out (see Figure 5).
- For adjusting and positioning the arm height use the handle on the monobloc. (see Figure 8).
- Position the monobloc-collimator assembly over the relevant area of the patient (see Figure 10 - Figure 11).
- Turn the unit ON (see the paragraph "4.4 "Start up and checks at the 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 (don't forget to set it again!).
- When the positioning has been completed, lock all the movements braking handles and the parking brake.

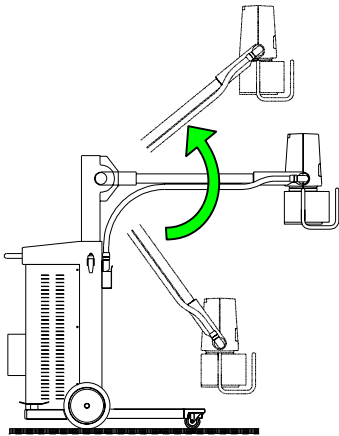


Figure 9

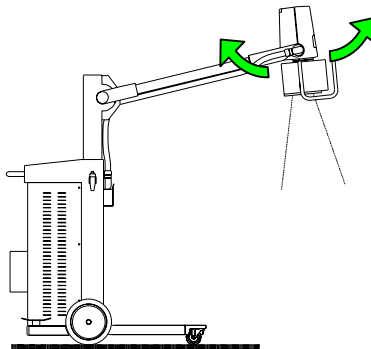


Figure 10

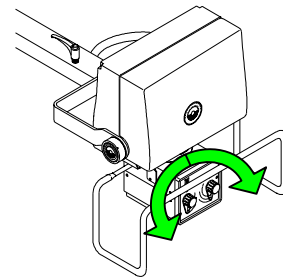
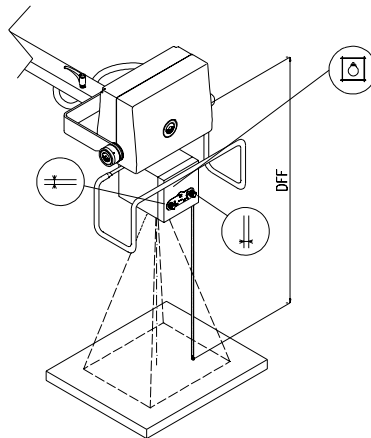


Figure 11

### 4.3. Collimator adjustment

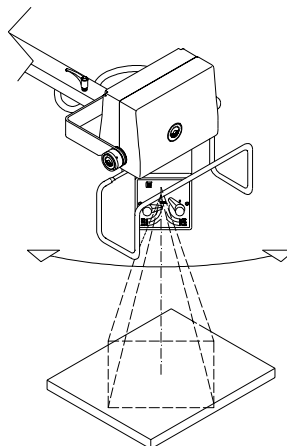
1. On the frontal panel of the collimator, there are two knobs for the beam adjustment (width and length) as well as the push-button to turn ON the collimator lamp (see Figure 12). It is possible to turn the lamp ON by pressing the COLLIMATOR push-button placed on the control panel.



**Figure 12**

The extensible meter allows to measure with accuracy the focus-film distance (FFD).

2. If necessary, rotate the collimator (see Figure 13).



**Figure 13**

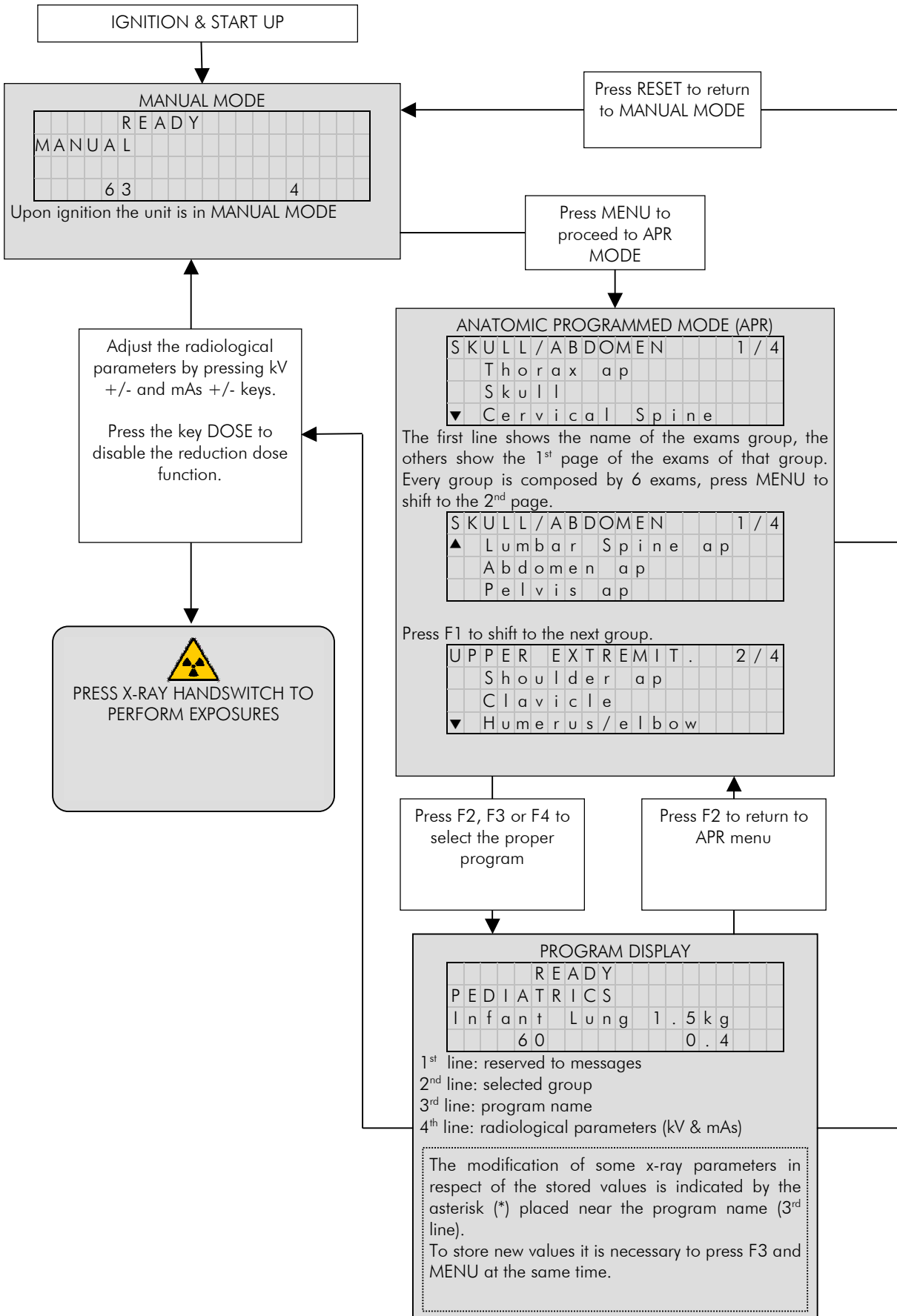




## 4.5. Exposures

### 4.5.1. Operative procedure

Set the exposure data by following the operative procedure here below.



#### 4.5.2. Programs for the Anatomical programming mode (APR MODE)

Here is a table with the APR default values. Consider that they are valid by placing the x-ray tube with a SID (Source-Image receptor Distance) of 100 cm without grid.

In case of cassettes with grid it is necessary to increase the mAs values by four increments.

Folder	Part of Body	kV	mAs	SC [DIN] <sup>1</sup>	Cartella	Part of Body	kV	mAs	SC [DIN] <sup>1</sup>
<b>1/4 SKULL / ABDOMEN</b>	Thorax ap	85	3.2	200	<b>3/4 LOWER EXTREMITIES</b>	Hip/Femur	74	5.0	400
	Skull	78	5.0	400		Knee	66	4.0	200
	Cervical Spine	66	6.3	400		Lower Leg	60	4.0	200
	Lumbar Spine ap	78	6.3	400		Ankle	55	4.0	200
	Abdomen ap	85	5.0	400		Calcaneus	52	3.2	200
	Pelvis ap	77	3.2	400		Foot	48	2.0	200
<b>2/4 UPPER EXTREMITIES</b>	Shoulder ap	66	16.0	200		<b>4/4 CHILDREN</b> <i>Added Filter 1mmAl + 0,2mmCu<sup>2</sup></i>	Thorax 1.0 Kg	60	0.2
	Clavicle	66	10.0	200	Thorax 2.0 Kg		62	0.4	400
	Humerus/elbow	60	4.0	200	Thorax 4.0 Kg		72	0.4	400
	Forearm	52	3.2	200	Thorax 6.0 Kg		74	0.4	400
	Wrist	48	2.5	200	Thorax 8.0 Kg		76	0.4	400
	Hand ap	46	2.5	200	Thorax 10 Kg		76	0.63	400

Here is the list of the APR programs and groups names in the five settable languages.

APR Groups and programs				
 English (GB)	 Italian (I)	 French (F)	 German (D)	 Spanish (ES)
SKULL/ABDOMEN	CRANIO/ADDOME	CRANE/ABDOMEN	SCHÄDEL/ABDOMEN	CRANEO/ABDOMEN
Thorax ap	Torace ap	Thorax ap	Thorax ap	Thorax ap
Skull	Cranio	Crane	Schädel	Craneo
Cervical Spine	Spina Dorsale	Col.Cervical	HWS	Vertebras Cerv.
Lumbar Spine ap	Spina Lombare	Col.Luminaire	LWS ap	Vertebras Lumb.
Abdomen ap	Addome ap	Abdomen ap	Abdomen ap	Abdomen ap
Pelvis ap	Bacino ap	Bassin ap	Becken ap	Pelvis ap
UPPER EXTREMIT.	ESTREMITÀ SUP.	EXTREMITES SUP.	OBERE EXTREMIT.	EXTREM. SUPERIOR
Shoulder ap	Spalla ap	Epaule ap	Schulter ap	Hombro
Clavicle	Clavicola	Clavicule	Schlueselbein	Clavicula
Humerus/elbow	Omero/Gomito	Humerus/Coude	OA/Ellenbogen	Humero/Codo
Forearm	Avambraccio	Bras inf.	Unterarn	Antebrazo
Wrist	Polso	Poignet	Handgelenk	Muneca
Hand ap	Mano ap	Main ap	Hand ap	Mano ap
LOWER EXTREMIT.	ESTREMITÀ INF.	EXTREMITES INF.	UNTERE EXTREMIT.	EXTREM. INFERIOR
Hip/Femur	Fianco/Femore	Hanche/Femur	Huefte/OS	Coxal/Femur
Knee	Ginocchio	Genou	Knie	Rodilla
Lower Leg	Gamba inf.	Jamb inf.	US	Pierna inf.
Ankle	Anca	Art.Tibio Tors.	Fussgelenk	Tobillo
Calcaneus	Calcagno	Calcaneum	Fersenbein	Calcaneus
Foot	Piede	Pied	Fuss	Pie
CHILDREN	BAMBINI	ENFANTS	KINDER	NINOS
Thorax 1.0 Kg	Torace 1.0 Kg	Thorax 1.0 Kg	Thorax 1.0 Kg	Thorax 1.0 Kg
Thorax 2.0 Kg	Torace 2.0 Kg	Thorax 2.0 Kg	Thorax 2.0 Kg	Thorax 2.0 Kg
Thorax 4.0 Kg	Torace 4.0 Kg	Thorax 4.0 Kg	Thorax 4.0 Kg	Thorax 4.0 Kg
Thorax 6.0 Kg	Torace 6.0 Kg	Thorax 6.0 Kg	Thorax 6.0 Kg	Thorax 6.0 Kg
Thorax 8.0 Kg	Torace 8.0 Kg	Thorax 8.0 Kg	Thorax 8.0 Kg	Thorax 8.0 Kg
Thorax 10 Kg	Torace 10 Kg	Thorax 10 Kg	Thorax 10 Kg	Thorax 10 Kg

<sup>1</sup> SC is the sensitivity class. According to DIN 6867-10, a class 400 film/screen system (SC = 400) can cover a sensitivity range of S<sub>min</sub>=320 DIN to S<sub>max</sub>=560 DIN. From the derived dose value Ks the tolerance for S will be approx. ±30%.

<sup>2</sup> The filter combination of 1 mmAl + 0,1 mmCu is also permissible

### 4.5.3. Perform an exposure



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



After a long idle period (3 months or more) it is very important to proceed with the X-RAY TUBE SEASONING. It is necessary to avoid high voltage discharges that could be destructive for the X-ray tube. The seasoning procedure is described in the Service Manual.

- 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 at once (second step). Then there is a delay of about 1.2 s before the real exposure.
- Hold the x-ray control down till the exposure has been performed properly (3 beeps).



1° step "prep"                      2° step "rad"  
Figure 14

The x-ray handswitch activates both the x-ray preparation phase "prep" and the emission phase "rad". The Figure 14 shows how to operate the handswitch to activate the preparation and the emission phases. It is not possible to activate the emission phase "rad" without preparation; however, 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 "1<sup>st</sup> 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.

### 4.5.4. Useful information

- Only if the display shows the writing "READY" and the READY led is ON, it is possible to perform an exposure.
- The 1<sup>st</sup> line of the display shows the use messages and the error signals.
- The 4<sup>th</sup> line of the display shows the radiological parameters.
- After every exposure, the 4<sup>th</sup> line shows the radiological parameters and, in the middle, the exposure time.
- While shifting from APR MODE (Anatomical programming) to the MANUAL MODE, radiological parameters do not change.

**4.5.5. Optional: dosimeter (DAPmeter)**

The unit can be supplied, on request, with a ionizing chamber dosimeter (dose-area product meter, DAP meter) installed. The DAPmeter function is to measure the dose-area product [cGgcm<sup>2</sup>] in output towards the patient.

The device that can be installed is type PTW-Freiburg DIAMENTOR PX - T11020-00011.

Only authorized service personnel can perform the installation and the maintenance of the dosimeter.

If DAPmeter has been installed and it works properly, the first line of the display shows alternatively the *measures summation* and the measurement unit [cGy cm<sup>2</sup>]:

				R	E	A	D	Y				0	0	0	0	.	0
--	--	--	--	---	---	---	---	---	--	--	--	---	---	---	---	---	---

				R	E	A	D	Y				c	G	y	c	m	2
--	--	--	--	---	---	---	---	---	--	--	--	---	---	---	---	---	---

The *measures summation* is the sum of all the dose-area products read by the chamber. By pressing F1 +RESET, the value resets.

$$\sum_{i=1}^n \text{dose}_i \cdot \text{area}_i$$

“n” is the number of exposures performed after the last time that F1 +RESET has been pressed.

In order to determine the correct Dose Area Product to which the patient has been exposed, it is necessary to press F1 +RESET before performing any exposures.

The possible measuring range is included between 00000.0cGy cm<sup>2</sup> and 99999.9cGy cm<sup>2</sup>. When the measures summation exceeds 99999.9cGy cm<sup>2</sup>, the message “MAXDOSE” will appear. The presence of this message does not exclude the possibility to perform exposures.

#### 4.5.6. Optional: Radiography with examination table and Potter Bucky grid



**The examination table or the Potter Bucky that can be connected to the unit must be according to the Medical Devices Directive EEC 93/42.**

After positioning the cassette and the patient, follow these instructions:

1. connect the Potter Bucky grid or the table for the examination to the socket outlet placed on the frontal unit part;
2. press the push-button for the Potter Bucky selection, if the potter works properly the led of the key turns on;
3. place monobloc and collimator, set the exposure field as shown previously;
4. lock the parking brake;
5. select manually the values of kV and mAs or in APR mode, by choosing the data about the examination that you need to perform;
6. pick up the x-ray handswitch;
7. keep away at least 2m from the x-ray tube;
8. press and hold down the handswitch in "prep" position for the preparation (about 1.2s);
9. press the x-ray handswitch in "rad" position;
10. hold down the x-ray handswitch till the exposure time is finished. The end of the exposure is indicated by three Beeps emitted by the audible signal of the unit.

Note: occasionally when the potter grid has been selected "non consent to proceed" may appear, in this case check the connection.

Note: it is possible to press the x-ray handswitch fully ("rad" position) from the beginning. In this case the x-ray exposure will be performed automatically after the preparation.

#### 4.6. Shutdown procedure



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

When finished the examination, do the following:

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

Villa Sistemi Medicali can supply, on request, a programmed maintenance plan to be performed on the unit.


### 5.1. General Warnings

As with any medical device, this system requires:

- proper use;
- regular checks by the user;
- maintenance and repairs by the authorized personnel.

Operational reliability of the unit is kept by following these precautions.

Villa Sistemi Medicali can provide, on request, circuit drawings, parts list, adjustment instructions or further information for the unit repair.



**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 the replacement of any parts that can affect the units safe operation, use only original spare parts.**

### 5.2. Checks and inspection 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. The unit may only be operated after repairs have been made.



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

Summary of the periodical checks	
Daily:	Check the functionality of alarms, displays and indicators. Check the warning and danger labels integrity.
Weekly:	Check for oil leakage from the monobloc. Check unusual noises in the monobloc during x-ray emission Check the x-ray tube and collimator centering
Every 6 months:	Check the brakes and the directional handle functionality.
Yearly:	Contact the technical after-sale service to perform the constancy and reproducibility tests, as indicated by IEC 1223-2 and IEC 1223-11 standards, as well as the other operating tests of the unit, as instructed in the programmed maintenance plan. (see Service Manual).

### 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, or corrosive solvents, or abrasive detergents), the material will tend to break or opacify.
- To clean enameled parts and aluminium surfaces, simply rub them with a wet cloth and a delicate detergent, after that rub them with a dry wool cloth.
- As regards, chromium-plated surfaces, only rub them using dry wool clothes; do not use any detergent.
- To clean the other surfaces of the equipment, never use highly alcoholic products, corrosive or abrasive detergents and solvents

**Before cleaning the unit, please take the following actions:**

- **Turn off the unit and unplug the mains power supply cable.**
- **Ensure that no liquid seeps into the unit, so as to avoid short-circuiting or corroding the electrical and electromechanical parts.**

### 5.4. *Disinfection*

To disinfect the equipment it's advisable to use a common liquid solution featuring an aldehyde base or disinfectants featuring an ampholytic surface-active agent base (e.g. Tego 103, Korsolin).

Substitute disinfectants releasing chlorine or based on phenols are likely to weaken the materials, hence they are much to be avoided. The same limitations apply to undiluted solutions featuring a high alcoholic content. Do not use disinfectant spray; it might penetrate the system, and its safety would not be guaranteed any longer (damages possibly affecting electrical and electromechanical parts, formation of flammable air mixtures and vapor solutions).



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



## 6. TECHNICAL DATA

### 6.1. Electrical data

Description	Data		
Voltage	115/230Vac $\pm$ 10% standard monophase with automatic unit prearrangement in function of the mains (plug & play).		
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:		
	Operative condition	115 Vac / 50Hz	230 Vac / 50Hz
	Charger On	5,5 A <sub>MAX</sub>	3,4A <sub>MAX</sub>
	Stand By	0,87A	0,58A
	Stand By + Collimator Lamp	2,3A	1,5A
	Stand By + Charger On	5,1A	3,0A
	Stand By + Collimator Lamp + Charger On	6,7A	3,8A
	Preparation	4,3A	5,5A
	Preparation + Collimator Lamp	5,5A	7,3A
X-ray emission + Collimator Lamp	3A <sub>PK</sub>	3A <sub>PK</sub>	
Line compensation	Automatic		
Line resistance	<1 $\Omega$ @115/230Vac		
Standard socket outlet	16A @230Vac		
Isolation class	Class I with applied parts type B		
Use conditions	Continuous functioning with intermitting 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, 4 lines X 20 characters for all the operative parameters and messages of possible faulty status. Service program for faults finding. Microprocessor management.
Settable languages	Italian, English, French, German, Spanish, through configuration program
Radiography control	By handswitch with extendible cable. It is proposed the use of the last kV value used in manual mode or APR. Upon the ignition, the unit is in manual mode with default values.
Safeties	Filament current Monobloc temperature Overload Max kV or H.V. fault Stored data check Microcontroller auto test

### 6.3. Radiological data

Characteristic	Performances				
Working technique	2 points technique with kV and mAs setting				
APR anatomic program	24 exams memorization (4 programs each of 6 exams) available in the 5 different selectable languages.				
Exposure control	Constant kV and mA during the whole exposure				
Power reduction	It can be selected of L.P. (50%) or H.P. (100%)				
Generator power in DC current	15kW @100kV				
Inverter frequency	20kHz				
Max. inverter frequency in high voltage	40kHz				
Max.ripple	<2% @100kV				
Rise time	<2ms @100kV				
mA variation range @115/230Vac	40 ÷ 200 mA automatically associated to kV				
mAs variation range @115/230Vac	0.2 ÷ 200 mAs in 61 steps with increases of 12,5%				
Range times @115/230Vac	0.002 ÷ 2s in function of the set mAs and dose select.				
kV Range	40 ÷ 125kVp in step of 1kV				
mA Range @115/230Vac	kV	mA			
		mAs>0,63		mAs<0,63	
		(t<100ms) MODE1	(t>100ms) MODE 1/2	MODE 1/2	
	40	200	100	100	
	50	200	100	100	
	60	190	95	95	
	70	180	90	90	
	80	170	85	85	
	90	160	80	80	
	100	160	80	80	
110	130	65	65		
120	110	55	55		
125	120	50	50		
mAs value in function of kV @115/230Vac	0,2 ÷ 200mAs in 61 steps with increases of 12,5%				
		mAs		kV	
		0,2 ÷ 200		40	
		0,2 ÷ 180		41 ÷ 45	
		0,2 ÷ 160		46 ÷ 52	
		0,2 ÷ 140		53 ÷ 62	
		0,2 ÷ 125		63 ÷ 72	
		0,2 ÷ 100		73 ÷ 92	
	0,2 ÷ 80		93 ÷ 112		
	0,2 ÷ 71		113 ÷ 125		

## 6.4. Environmental data

Description	Normal use	Transport and storage
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 to 1060hPa	From 500 to 1060hPa

## 6.5. Mechanical data

Description	Data
Weight	approx. 185 Kg (408 Lb)
Max. width	700mm (27,56in.)
Length in transport position	1338mm (52,68in.)
Max. height in transport position	1458mm (57,40in.)
Max. height with the arm at the max. extension	2258mm (88,90in.)
Control panel height	1000mm (39,37in.)
Focus-floor distance	456 ÷ 2018mm (17,95 ÷ 79,45in.)
Arm rotation around the vertical axis	n.a.
Monobloc rotation around the arm axis	±180°
Monobloc rotation around its axis	151° (+133° ÷ -18° in respect of the vertical axis)
Max. height of the front unit leg	105mm (4,13in.)
Cassette holder	5 cassettes format 35 x 43cm (12x15in.)
Movement	Manual. Double front swiveling wheel. Parking brake Handle for tilting (obstacles overcoming)
Wheels diameter	Rear: wheel Ø250mm (9,84in.) width 50mm (1,97in.) Front: double wheel Ø 80mm (3,15in.) width 22mm (0,87in.)

### 6.5.1. Unit sizes

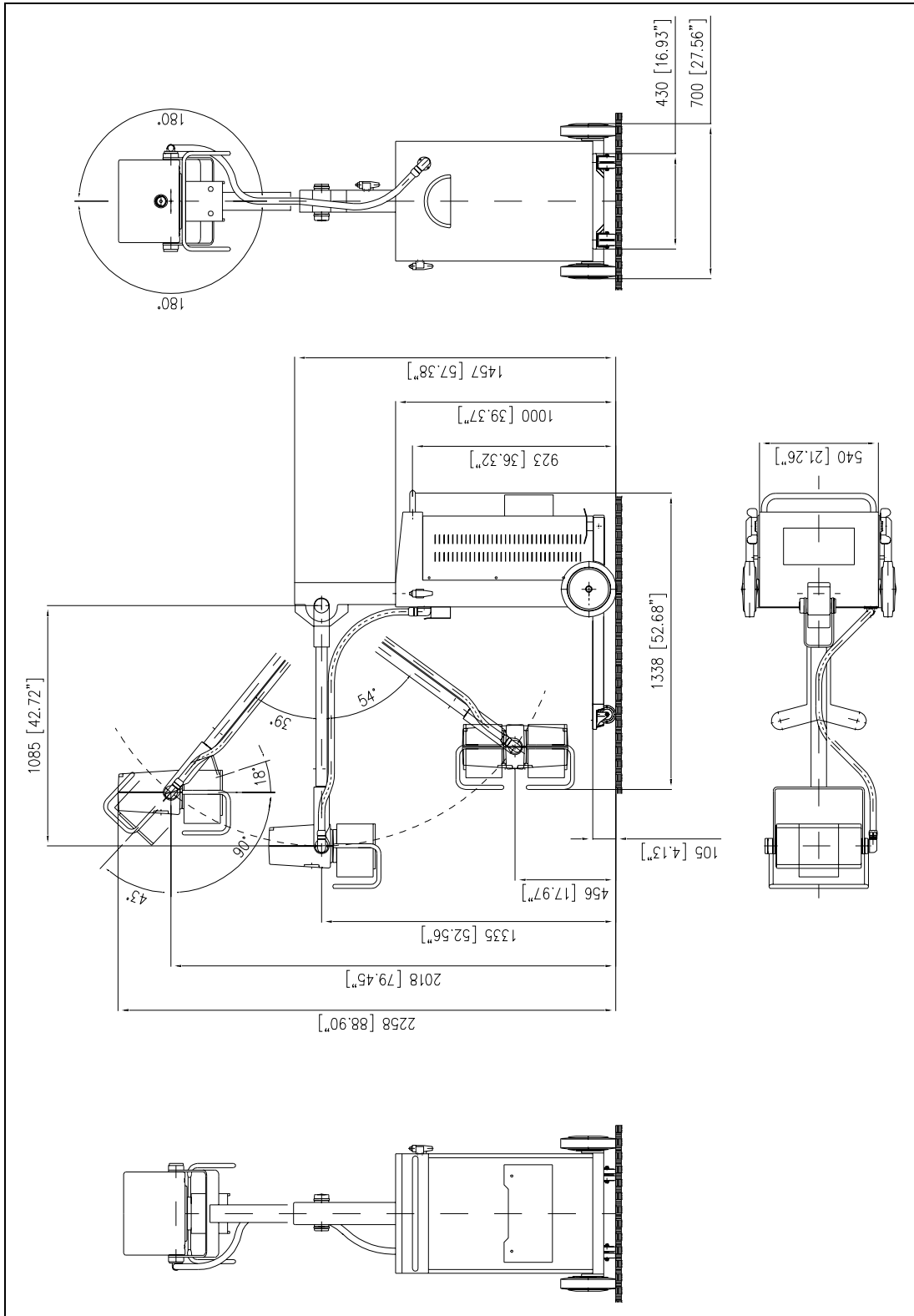


Figure 15

## 6.6. Components specifications

### 6.6.1. Generator

Description	Data
<i>Inverter</i>	IHF 2015
<i>Working frequency</i>	20kHz max
<i>Max. inverter frequency in high voltage</i>	40kHz
<i>Power supply</i>	350Vdc max
<i>Dimensions</i>	190x130x140 mm (7,48x5,12x5,51 in.)
<i>Max. absorbed current</i>	50A
<i>Technology</i>	IGBT
<i>Safeties</i>	overcurrent overvoltage IGBT driver fault
<i>Generator power in constant DC current (IEC 601-1)</i>	15kW (150mA @ 100kV per 0.1s)
<i>Max. voltage to the tube</i>	125kVp
<i>Max. ripple at 100kVp</i>	<2%
<i>Rise time at 100kVp</i>	<2 ms
<i>Max. current in radiography</i>	200mA

### 6.6.2. Tube-Housing Assembly

#### X-Ray Tube

Description	Data
Type	X22 0.8/1.3
Nominal anode power (IEC 613, EN 60613)	16kW/32kW
Nominal foci size (IEC 336, EN 60336)	0.8mm – 1.3 mm
Speed of rotation	2850 rpm @ 50Hz
Anode diameter	64mm (2,52in.)
Anode material	Tungsten
Anode angle	15°
Min. inherent filtration (IEC 522)	0.7mmAl eq.
Thermal anode capacity	80kJ (107kHU)
Max. continuous anode dissipation	300W
Max. anode cooling speed	22kJ/min (29.5kHU/min)
Nominal high-voltage	130kV
Max. filament current	5.4A

#### 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.

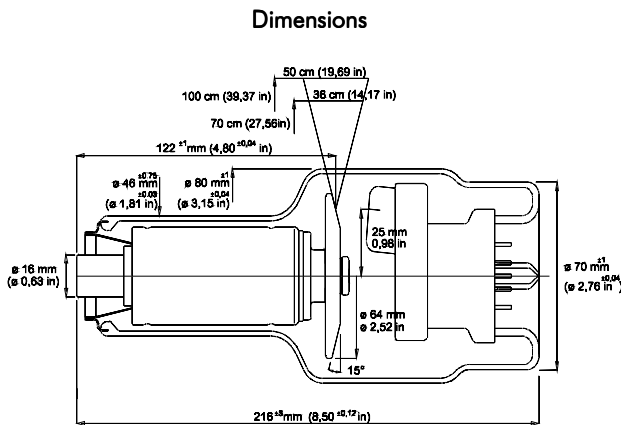


Figure 16

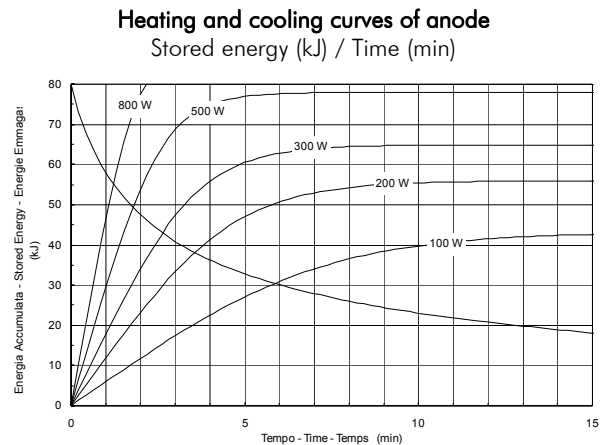


Figure 17

Single load curves  
0.8 - 3~ - 3000min<sup>-1</sup>  
Anodic current (mA) / Exposure Time (s)

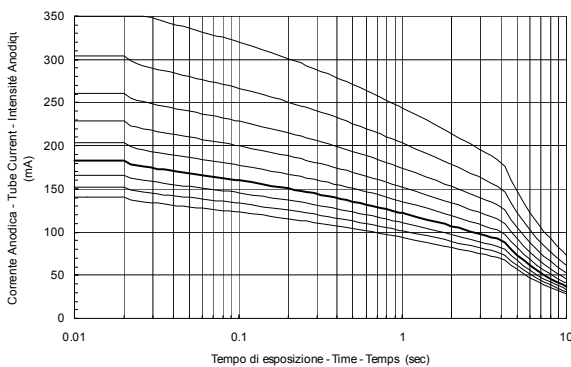


Figure 18

Single load curves  
1.3 - 3~ - 3000min<sup>-1</sup>  
Anodic current (mA) / Exposure Time (s)

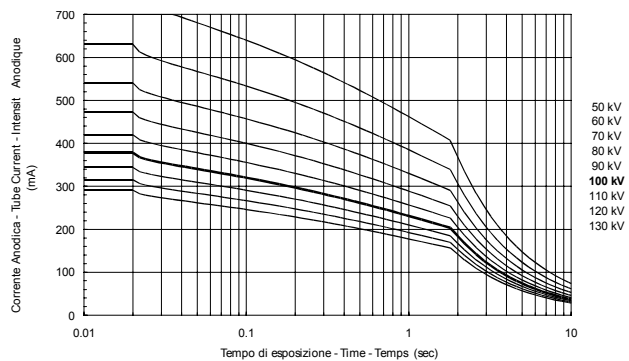


Figure 19

**Monobloc**

Description	Data
Monobloc	MHF 2015
Weight	19 Kg (41,89Lb)
Dimensions	320x140x255mm (12,60x5,51x10,04in.)
X-ray tube	X22 0.8/1.3 (Large focus not used)
Anode	Rotating (2850rpm at 50Hz)(3400rpm at 60Hz)
External thermostat	57°
Thermal monobloc capacity	600kJ (800kHU)
Max continuous thermal dissipation of monobloc	55W
Total filtration	2.7mm Al
Leakage radiation	<1mGy/h according to IEC 601-1-3
Loading, heating and cooling curves	See the enclosed diagrams
H.V. transformer insulation	Oil bath

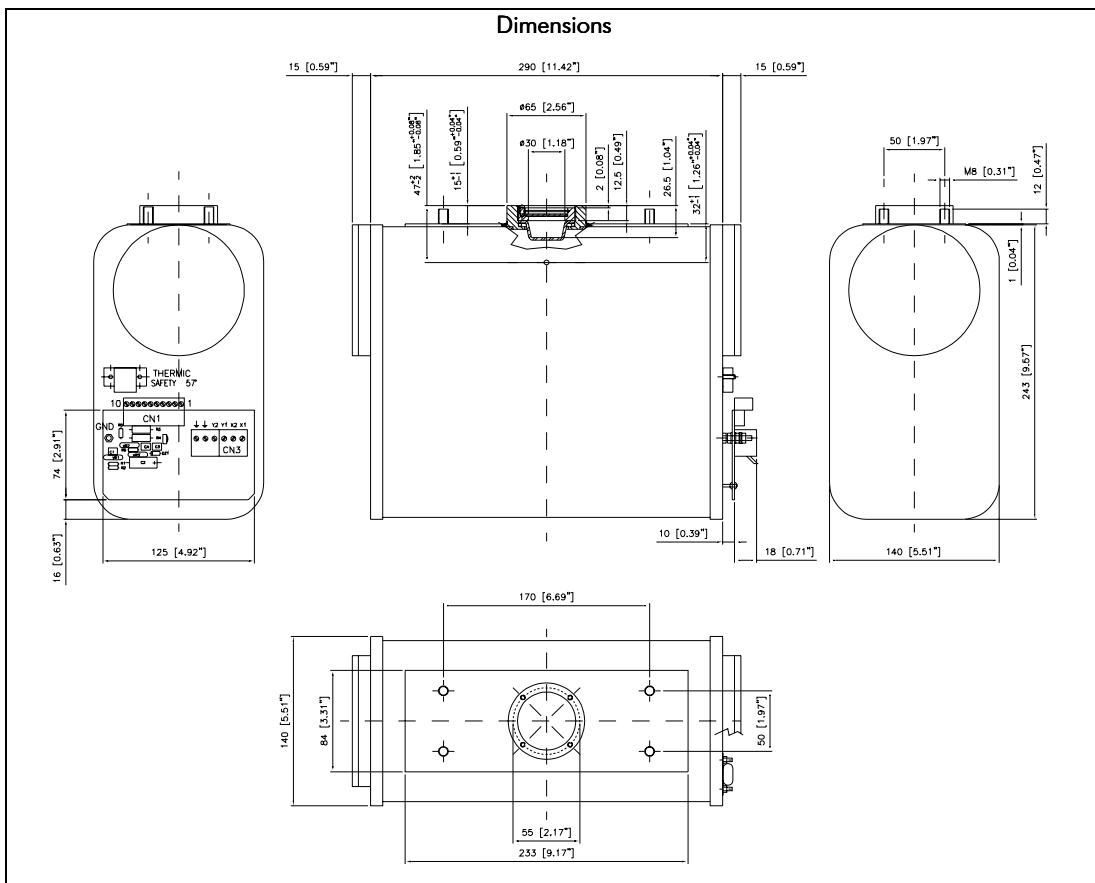


Figure 20

**Heating and cooling curves of monobloc**  
Stored energy (kJ) / Time (min)

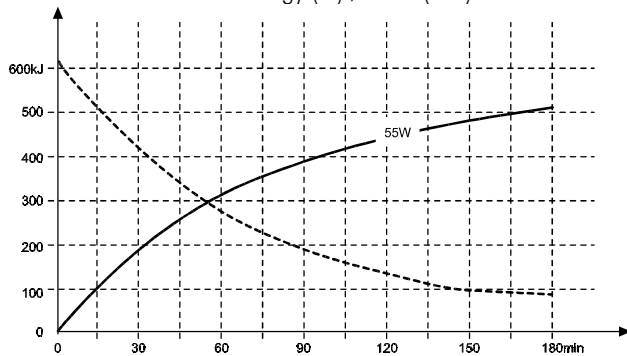


Figure 21

### 6.6.3. Collimator

Description	Data
Type, brand and model	Manual with internal light source (Ralco R221)
Collimator	Square field, multilayers
Light source	Halogen Lamp 12V 100W with timed switching-on at approx. 30s
X-ray field	43x43cm (16,93x16,93in.) at 1m (39,37in.) DFF
Luminous intensity	160lux at 1m (39,37in.) DFF
Contrast ratio	4:1
Measurement of focus-film distance	Extractable meter
Rotation	±115°
Weight	8,4kg (18,52Lb)
Sizes	183x168x256mm (7,20x6,61x10,08in.)
Accessories	Prearrangement to insert the dosimeter
Max protection against leaked radiation (EN60601-1-3 par.29.204.3)	125kV 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)

### 6.6.4. DAP meter (dose-area product meter) (optional)

This device is installed only on request.

Description	Data
Type, brand and model	Dosimeter with ionization chamber, PTW-Freiburg DIAMENTOR PX - T11020-00011
Measurement unit	cGycm <sup>2</sup>
Resolution	0.1 cGycm <sup>2</sup>
Dose-area product range	0.3 ÷ 15000 cGycm <sup>2</sup>
Dose-area product summation range	00000.0 ÷ 99999.9cGycm <sup>2</sup>
Max. measuring range	118mm x 118mm (4,65x4,65in.)

### 6.7. Accessories and options

Description	
X-ray handswitch with extendible cable	Standard
Ionization chamber dosimeter, mod. DIAMENTOR PX	Optional








### 6.8. Compliance with Directives and Technical Standards

Reference	Description
MDD 93/42/EEC	Medical Devices Directive (CE mark)
IEC 60601-1	Medical devices safety
IEC 60601-1-2	Electromagnetic compatibility
IEC 60601-1-3	Protection against ionizing radiation
IEC 60601-2-7 2nd edition	High voltage generators
IEC 60601-2-28	Tube – housing groups
IEC 60336	X-ray tubes focus






## 6.9. Labels and symbols


### 6.9.1. Labels of the unit

	Model :	VISITOR T15
	Code :	XXXXXXXXXX
	Serial Number :	XX-XX-XXXX
	Date mfg. :	XX-XX
Supply : 115/230V ~ Frequency : 50/60Hz		
Standby: 2A		POWER Radiography: 9A 
Classification : I  IEC 60601-1  0051		
Ionizing radiation : max 125 kVp Physiological effects : 		
Mechanical stability - Operational modes : 		
VILLA SISTEMI MEDICALI 20090 BUCCINASCO-MILANO-ITALY <small>MANUFACTURED ACCORDING TO THE MEDICAL DEVICE DIRECTIVE 93/42 EEC BY TECHNIX-GRASSOBBIO-BERGAMO-ITALY</small>		





unit label

	20090 BUCCINASCO - MILANO - ITALY	
	Tank unit :	MHF 2015
	Serial Number :	XXXX
X-ray Tube :	X22 0,8-1.3	 0051
Serial number :	XXXXX	
Focus :	<input type="checkbox"/> 0.8 <input checked="" type="checkbox"/> 1.3  2.7 Al/100kV	
U max :	125 kVp	I max : 200 mA
<small>MANUFACTURED ACCORDING TO THE MEDICAL DEVICE DIRECTIVE 93/42 EEC BY TECHNIX-GRASSOBBIO-BERGAMO-ITALY</small>		

external monobloc label

 TECHNIX TECHNIX S.p.A. - Via E.Fermi 26 - 24050 Grassobbio - BG - ITALY			
Inverter	IHF 2015	Mode	DC/AC
Serial N.	XXXXX	Date mfg.	XX-XX
Supply	350 VDC	Power	15kW
Made in ITALY			



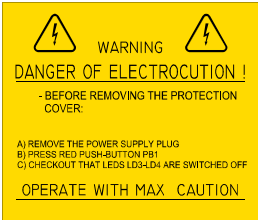
inverter label

	Via SCHIAPPARELLI 27/33 20035 - LISSONE (MI) ITALY	
	S.r.l.	
BEAM LIMITING DEVICE type: R 221/A s/n: Collimator	Min. inherent filtration Al. equiv.: 2mm Al. / 80 IEC 522/1976 X-ray rating up to: 125kVp Supply: 12V AC/DC 9A 50/60Hz	
Date of manufacture:	 0051  	










collimator label

Figure 22

### 6.9.2. Internal symbols

	Protective ground clamp
	Dangerous voltage
	Precautionary warning

### 6.9.3. Various symbols

	Unit OFF		Unit Type B
	Unit ON		Total filtration
	Ionizing radiation		Alternate voltage
	Large focus		Equipotential node
	Small focus		

### 6.9.4. Packing label

It is stuck outside the packing with red writings on white background.

		
Fragile	Protect from rain	Upper edge of the packing

## DOCUMENT STATUS

<i>Rev.</i>	<i>Date</i>	<i>Pages</i>	<i>Modification description</i>
0	26.08.03	-	Document approval
1	14.01.04	all	Documents general revision.
2	26.03.04	17	Performed modification of the APR values in the unit software.
3			
4			
5			