

TIVIS 300 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.

User's Manual - TMS300 Technix S.p.A. (This page is intentionally left blank)

TABLE OF CONTENTS

1.		Y AND COMPLIANCE	
		Electrical safety	2
		Mechanical safety	
	1.3.	Electromagnetic compatibility (EMC)	(
	1.4.	Protection against ionizing radiation	(
		General disposal	
		Application & final destination	
		Interfaceability	
		Classification	
		Compliance	
	1.10.	Copyright	5
2.	СОМ	PONENT IDENTIFICATION	6
	2.1.	Overview	(
	2.2.	Collimator	(
	2.3.	Control panel	7
		Audible signals	
	2.5.	Signals and error messages	9
3.	MESS	AGES ON THE DISPLAY	. 10
4.		TIONING	
٦.		Transport	
		Positioning	
		Collimator adjustment	
		Start up and checks at the ignition	
		Exposures	
	4.5.1.		
	4.5.2.		17
	4.5.3.		
	4.5.4.		
	4.5.5.		
	4.5.6.		
		Shutdown procedure	
5.		TENANCE	
٥.		General Warnings	
		Checks and inspection by the user	
		Cleaning	
		Disinfection	
,			
6.		NICAL DATA	
		Electrical data	
		Functioning features	
		Radiological data Environmental data	
	6.5.1.	Mechanical data	
		Unit sizes	
	6.6.1.	·	
	6.6.2.		
	6.6.3.	9 ,	
	6.6.4.		
	6.6.5. 6.7.	Printer for DAP (optional)	
		Accessories and opinons	
		Labels and symbols	
	6.9.1.		
	6.9.1.		
	6.9.3.	,	
D		-	
1)($\mathcal{L}\cup MFN$	T STATUS	

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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. Technix S.p.A. 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 <u>must not</u> 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 Technix S.p.A. for information.



- Technix S.p.A. is responsible for the safety of its products only when maintenance, repairs, or modifications have been performed by Technix S.p.A. or by personnel authorized by Technix S.p.A. 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 <u>must not</u>, for any reason, be moved, modified, or omitted.

Technix S.p.A. 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





- 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 <u>must be avoided</u> 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

Technix S.p.A. 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.



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. 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 <u>must not</u> 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 Technix S.p.A. in writing, is of the operator and/or the person who has performed the interface.

1.8. Classification

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.

Information concerning the compliance can be required to Technix S.p.A.

The manufacturer (according to the European Directive 93/42/EEC) of the unit TMS300 is:

Technix S.p.A.

Via E. Fermi, 45 24050 Grassobbio, BG - ITALY Tel: +39 035 38 466 11 Fax: +39 035 33 56 75

1.10. Copyright

The original release of this manual is in Italian language (file: AD3001_E00RXX.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
- 2. Goniometer
- 3. Monobloc handle
- 4. Collimator
- 5. Supply cable-winding
- 6. Equipotential node
- 7. Connector for Potter
- 8. X-ray handswitch
- 9. Foot brake
- 10. Cassette holder
- 11. Magneto-thermic switch

- 12. Supply cable
- 13. Handle for unit movement
- 14. Control panel
- 15. Arm safety lock for transport
- 16. Monobloc support arm
- 17. Safety lock for monobloc rotation
- 18. Selector of HAND-SWITCH CORDLESS mode
- 19. IR receiver (optional)
- 20. X-ray remote control (optional)
- 21. Printer for Dose Meter (optional)
- 22. Hook for radio protective apron (optional)
- 23. Tilting pedal (optional)

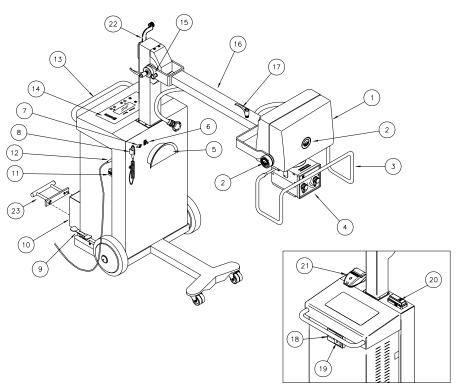


Figure 1

2.2. Collimator

- 1. Longitudinal collimation
- 2. Extensible meter for focus-skin distance check.
- 3. Transversal collimation

- 4. Lamp switching ON for the luminous irradiation field indication
- Guides for the accessories positioning (filters or DAP dosimeter)

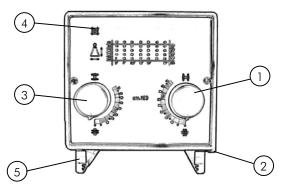


Figure 2

2.3. Control panel

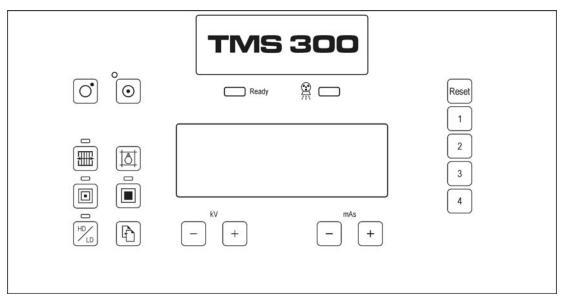


Figure 3

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

o*	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)
	SMALL FOCUS	Small focus selection. The lit led indicates that the selection has been done.
	LARGE FOCUS	Large focus selection. The lit led indicates that the selection has been done.
HD/LD	DOSE	Allows to select HIGH DOSE or LOW DOSE. The led indicates the selection of HIGH DOSE.
	MENU	Allows scrolling through pages in systems with more than one page.

kV	kV+ kV-	To modify KV value
mAs +	mAs+ mAs-	To modify mAs value
Reset	RESET	Return to the main menu.
1 2 3 4	F#	Function keys: F1, F2, F3, F4 They refer to the display line number (4 lines display). With dosimeter present and in working conditions (dose shown on the display), the F4 key allows to print the data concerning the dose released to the patient on a printer available as accessory.
Ready	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", "POR")

WARNING SIGNAL

Ε	R	R		0	r	W	Α	R	N					
M	Α	N	U	Α	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



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	READ		The unit is ready to perform an exposure	7 (6.101)
S	BUS	<u> </u>	Preparation phase	Wait for "READY" message
S	MAN			J
W	CLO	CK OFF	System clock error	Press RESET to proceed
				Turn off, wait for some minutes, turn on
F	POW	/ER FAULT	Charger or Chopper error	and if the error appears again, call
			Energy not available	Service
				Turn off, wait for some minutes, turn on
F	V3 F	AULT	Absence of V3 power supply	and if the error appears again, call
				Service
W	RESE	TAPR	APR checksum error	Press RESET to proceed
W	APR	OUT OF RANGE	An APR value is out of range	Set differently the parameters
			After a long idle period (3 months or more)	,
W	TUBE	E SEASONING	it is necessary to proceed with the x-ray tube	Press RESET to proceed, call Service for
			seasoning in order to avoid severe damages	the tube seasoning
				Turn off, wait for some minutes, turn on
F	FILA/	MENT	Absence of filament current	and if the error appears again, call
				Service
		TUDE	The monobloc temperature has achieved the	
W	HOI	TUBE	max. allowed value	Wait for the monobloc cooling
				Turn off, wait for some minutes, turn on
F	V2 F	AULT	Absence of V2 power supply in the set mA	and if the error appears again, call
			and kV circuit	Service
_				Press RESET to proceed and repeat
F	STAR	ter interlock	Error during the start time	exposure
F	CHC	OPPER FAULT	Chopper error	Press RESET to proceed, repeat x-rays
			The x-ray handswitch has been pressed at	Release the handswitch and repeat
W	TIME	OUT	the 1 st step for more than 15 secs.	radiography
			kV don't reach the 75% of the set value	
F	IACH	C OF X-RAY	within the first 10ms of exposure or lack of x-	Press RESET to proceed and repeat
	D (C)	() / () ()	rays.	exposure
			The max. exposure time has been achieved	Press RESET to proceed and repeat
F	MAX	TIME	(2s)	exposure
			()	Turn off, wait for some minutes, turn on
F	DATA	4 ERR.	Memory error, data checksum error	and if the error appears again, call
	D, (1)	· Liut.	Momenty direct, data effection of officer	Service
			The x-ray handswitch has been released	
W	MAN	I STOP XR	before the end of exposure	Press RESET to proceed
			During x-ray emission kV decrease under	
_			75% or increase over 110% of the set value	
F	INVE	RTER KV ERROR	or the H.V. circuit has unbalanced during	Press RESET and repeat exposure
			exposure	
F	INVF	RTER OVERLOAD	Inverter power out of range	Press RESET and proceed
F		RTER FAULT	IGBT drivers error	Press RESET and proceed
F		CALIB. ERR.	X-ray tube calibration error	Call Service
<u> </u>	. 000			Check the x-ray handswitch integrity, turn
F	HAN	D SWITCH ERR	Faulty x-ray handswitch	off and on again the unit, then try again.
'	, ., .,	2 Jim Cil Link	. asily king hamasimen	If the error appears again, call Service
W		DAP INACTIVE	The dosimeter is not connected	-
	1		The doses meter has reached the max, value	
-	ter	MAX DOSE	that can be displayed	Press F1 + RESET to reset the value
S	Dosimeter	DAP READY	The dosimeter is ready	-
W	osi	DAP ERROR	The dosimeter is connected, but in fault	Press RESET and call Service
- '			The sum of the product-area doses have	1.555 NEGET GITG GGT GOTTICO
-		DAP RESET	been reset	-
	l		The Bucky key has been pressed but no potter is	Press RESET to proceed and connect a
W	PLUC	G A BUCKY	connected to the unit.	Bucky.
	<u> </u>		After waiting for a short time, no x-ray consent is	,
W	EXT >	kr order	arrived from the Potter Bucky.	Press RESET and call Service
<u> </u>			a sa nom mo i onor bocky.	<u> </u>

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

				C (FC)	(07)
English (GB)	Italian (I)	French (F)	German (D)	Spanish (ES)	Portuguese (PT)
ENG	ITA	FRE	GER	SPA	POR
CLOCK OFF	ERR.OROLOGIO	ERR. HORLOGE	TAKTGEBER DEFEKT	FALLO RELOJ	ERRO RELOGIO
POWER FAULT	POTENZA GUASTA	ERR. BATTERIE	STROMVERSORG. DEF	FALLO ACUMUL.	POTENCIA FALHA
V3 FAULT	ERRORE V3	V3 DEFECT.	V3 DEFEKT	FALLO V3	ERRO V3
RESET APR	INI.APR	INI.APR	APR-DATEN DEFEKT	INI.APR	INI.APR
APR OUT OF RANGE	ERRORE IN APR	ERREUR APR	APR-WERT FALSCH	FALLO APR	ERRO APR
TUBE SEASONING	FORM.DEL TUBO	FORM. DU TUBE	ROEHRE ENFAHREN	AJUSTE DEL TUBO	FORMACAO TUBO
FILAMENT	FILAMENTO	FILAMENT	HEIZKREIS-FEHLER	FILAMENTO	FILAMENTO
HOT TUBE	TUBO CALDO	TUBE CHAUD	ROEHRE HEISS	TEMPER.	TUBO MORNO
V2 FAULT	ERRORE V2	ERREUR V2	V2 DEFEKT	FALLO V2	ERRO V2
STARTER INTERLOCK	STARTER BLOCCATO	BLOCAGE DEMARREUR	ANLAUF-FEHLER	BLOQUEO CEBADOR	STARTER OBSTRUIDO
CHOPPER FAULT	CHOPPER GUASTO	HACHEUR DEFECT.	CHOPPER-FEHLER	FALLO PULSADOR	ERRO CHOPPER
TIME OUT	TEMPO SCADUTO	TEMPS EXPIRE	PREP ZU LANG	FUERA TIEMPO	FORA TEMPO
READY	PRONTO	PRET	BEREIT	LISTO	PRONTO
BUSY	ATTESA	ATTENDRE	WARTEN	ESPERA	ATENDIDO
LACK OF X-RAY	ERRORE RAGGI	ERREUR RX	KEINE STRAHLUNG	SIN RADIACION	ERRO RAIOS
MAX TIME	TEMPO MAX	TEMPS MAX	MAX EXP ERREICHT	TIEMPO MAX	TEMPO MAXIMO
DATA ERR.	ERR. DATI	err. Donnée	DATEN-FEHLER	FALLO DATO	ERRO DADOS
MAN STOP XR	STOP MANUALE	ARRÊT UTILISAT.	EXP UNTERBROCHEN	INTERRUP. MANUAL	termino Manual
INVERTER KV ERR.	ERR.KV INVERTER	ERR.KV CONVERT.	WANDLER KV FEHLER	FALLO KV TRANSF	ERRO KV INVERTER
INVERTER OVERLOAD	SOVRACCARICO INV.	SURCHARGE CONVERT.	Wandler Ueberlast	SOBRECARGA TRANSF	SOBRECARGA INV.
INVERTER FAULT	ERRORE INVERTER	DEFAUT CONVERT.	WANDLER FEHLER	FALLO TRANSF	ERRO INVERTER
CALIB. TUBE ERR.	ERR. CALIB.TUBO	ERR. CALIBRAGE	ROEHRE Kalibrier.	FALLO CALIB.	ERRO CALIB.TUBO
MANUAL	MANUALE	MANUEL	MANUELL	MANUAL	MANUAL
HAND SWITCH ERR	ERR.PULSANTE RX	BOUTON DEFECT.	HANDSCHALT.DEF	FALLO MANDO	ERRO BOTAO RX
DAP READY	DAP PRONTO	DAP PRET	DAP BEREIT	DAP LISTO	DAP PRONTO
DAP INACTIVE	DAP INATTIVO	DAP INACTIF	DAP INAKTIV	DAP INACTIVO	DAP NAO ATIVO
DAP Reset	DAP AZZERATO	DAP a zero	DAP auf Null	DAP en cero	DAP ZERADO
DAP ERROR	DAP ERRORE	Dap erreur	DAP FEHLER	DAP ERROR	DAP ERRO
MAXDOSE	MAXDOSE	MAXDOSE	MAXDOSE	MAXDOSE	MAXDOSE
PLUG A BUCKY	COLLEGA BUCKY	RELIER BUCKY	VERBINDEN	CONECT.BUCKY	LIGAR. BUCKY
EXT XR ORDER	NO RX ESTERNO	EXT XR ORDRE	AUßENAMTRIEB	NO BUCKY	NO RX FORA

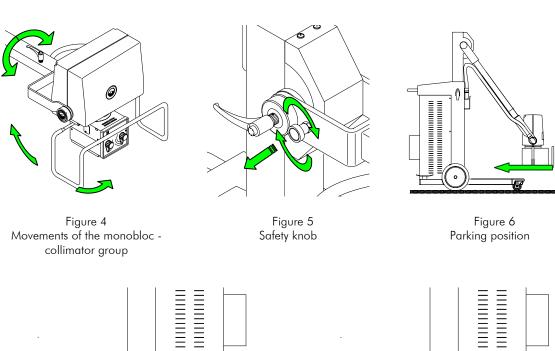
4. FUNCTIONING

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 monobloccollimator 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 overcome obstacles, pull downwards the transport handle and, at the same time, pull the handle placed on the column.
- In presence of the pedal for tilting (available as accessory on request) press with the foot on the pedal and, at the same time, pull the the handle placed on the column.



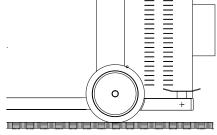


Figure 7 pos.1: deactivated brake

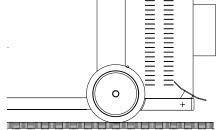


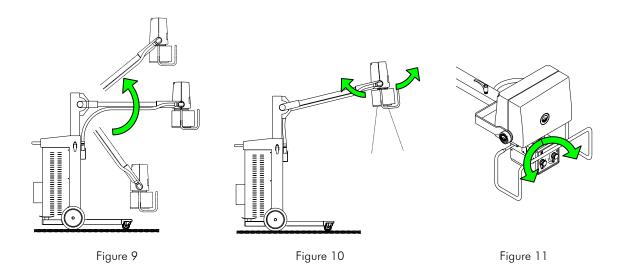
Figure 8 pos.2: activated brake

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 positioning has been completed, lock all the movements and the parking brakes.



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.

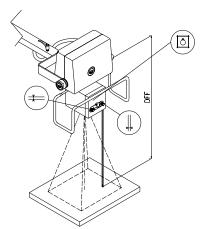


Figure 12

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

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

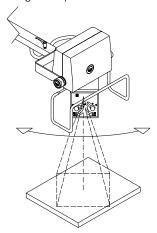
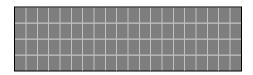


Figure 13

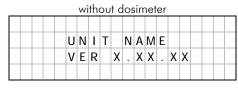
4.4. Start up and checks at the ignition

1. Connect the unit to the mains. Insert and turn the safety key in ON position (Fig.1 pos. 18), the presence of the power supply voltage is indicated by the switching ON of the yellow led 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).

- 2. 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 with the following one:
 - check of the display: every digit is completely ON (every pixel is dark);



- check of leds and beepers: all the leds of the keyboard turn ON and the beeper emits a prolonged sound;
- software version:



	with dosimeter																
Г	A	Р		Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ						
					U	N	ı	Т		N	Α	M	Ε				
					٧	Ε	R		Χ		Χ	Х		Χ	Χ		

XXXXXXX can have the following values:

READY: the reading of the chamber is enabled and it works properly

ERROR: the reading of the chamber is enabled but it does not work properly, it is not present or it is not connected.

INACTIVE: status displayed after ERROR signal and after pressing the key RESET.

If the DAP is accepted to the test, the writing READY appears and the system goes on.

If it is not accepted, the writing ERROR appears and the audible error alarm is activated.

At this point it is necessary that the operator intervenes; by pressing the key RESET it is possible to go on with the start up of the unit by indicating DAP INACTIVE.

• phase of capacitors battery charge:

<u>Start Up:</u> on the unit it is possible to set the radiological data, including the APR, but it is not possible to perform an exposure till the writing "READY" appears on the display

					В	U	S	Υ						ĺ
M	Α	N	U	Α	L									
				6	3							4		

When the Start up is finished, the writing "READY" will appear on the display, the unit is ready for use.

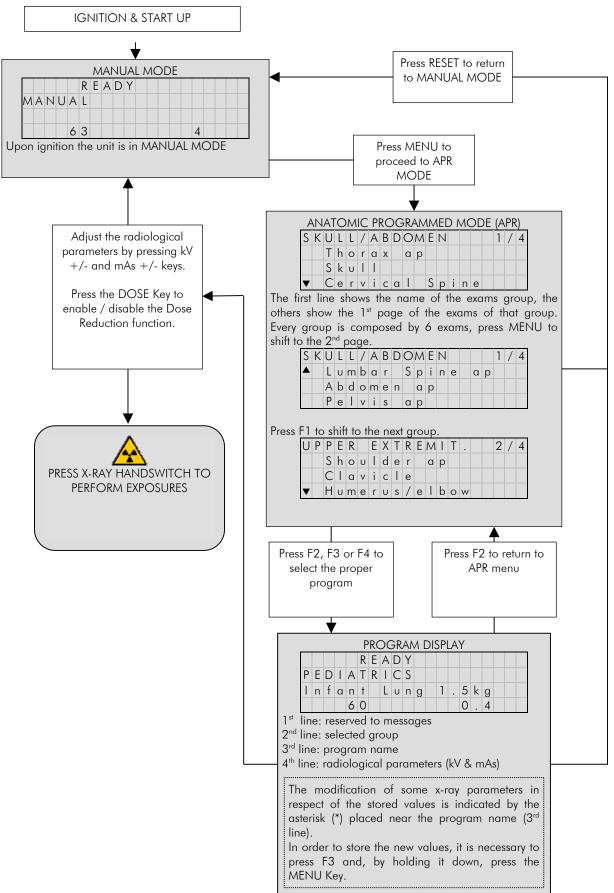
					R	Ε	Α	D	Υ					
M	Α	N	U	Α	L									
				6	3							4		

If it does not occur, it is probable that the unit is faulty or that there are some malfunctions, contact the authorized service personnel.

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] ¹
1/4	Thorax ap	85	3.2	200
SKULL /	Skull	78	5.0	400
ABDOMEN	Cervical Spine	66	6.3	400
	Lumbar Spine ap	78	6.3	400
	Abdomen ap	85	5.0	400
	Pelvis ap	77	3.2	400
2/4	Shoulder ap	66	16.0	200
2/4 UPPER	Clavicle	66	10.0	200
EXTREMITIES	Humerus/elbow	60	4.0	200
EXTREMITIES	Forearm	52	3.2	200
	Wrist	48	2.5	200
	Hand ap	46	2.5	200

Cartella	Part of Body	kV	mAs	SC [DIN] ¹
3/4	Hip/Femur	74	5.0	400
LOWER	Knee	66	4.0	200
EXTREMITIES	Lower Leg	60	4.0	200
	Ankle	55	4.0	200
	Calcaneus	52	3.2	200
	Foot	48	2.0	200
4/4	Thorax 1.0 Kg	60	0.2	400
CHILDREN	Thorax 2.0 Kg	62	0.4	400
Added Filter	Thorax 4.0 Kg	72	0.4	400
1 mmAl +	Thorax 6.0 Kg	74	0.4	400
0,2mmCu ²	Thorax 8.0 Kg	76	0.4	400
	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)	Portuguese (PT)
SKULL/ABDOMEN	CRANIO/ADDOME	CRANE/ABDOMEN	SCHÄDEL/ABDOMEN	CRÁNEO/ ABDOMEN	SKULL/ABDOMEN
Thorax ap	Torace ap	Thorax ap	Thorax ap	Tórax ap	Thorax ap
Skull	Cranio	Crane	Schädel	Cráneo	Skull
Cervical Spine	Spina Dorsale	Col.Cervical	HWS	Columna Cerv.	Espinho Dorsal
Lumbar Spine ap	Spina Lombare	Col.Lumbaire	LWS ap	Columna Lumb.	Espinho Lumbar
Abdomen ap	Addome ap	Abdomen ap	Abdomen ap	Abdomen ap	Abdomen
Pelvis ap	Bacino ap	Bassin ap	Becken ap	Pelvis ap	Pelvis
UPPER EXTREMIT.	ESTREMITÁ SUP.	EXTREMITES SUP.	OBERE EXTREMIT.	EXTREM. SUPERIOR	EXTREM.AVANCADA
Shoulder ap	Spalla ap	Epaule ap	Schulter ap	Hombro	Hombro
Clavicle	Clavicola	Clavicule	Schluesselbein	Clavícula	Clavicola
Humerus/elbow	Omero/Gomito	Humerus/Coude	OA/Ellenbogen	Húmero/Codo	Omero/Cotovelo
Forearm	Avambraccio	Bras inf.	Unterarm	Antebrazo	Forearm
Wrist	Polso	Poignet	Handgelenk	Muñeca	Pulso
Hand ap	Mano ap	Main ap	Hand ap	Mano ap	Мао ар
LOWER EXTREMIT.	ESTREMITÁ INF.	EXTREMITES INF.	Untere extremit.	extrem. Inferior	extrem.inferior
Hip/Femur	Fianco/Femore	Hanche/Femur	Huefte/OS	Cadera/Fémur	Flanco/Femore
Knee	Ginocchio	Genou	Knie	Rodilla	Joelho
Lower Leg	Gamba inf.	Jamb inf.	US	Tibia/Peroné	Pe' inferior
Ankle	Anca	Art.Tibio Tors.	Fussgelenk	Tobillo	Hip
Calcaneus	Calcagno	Calcaneum	Fersenbein	Calcáneo	Salto
Foot	Piede	Pied	Fuss	Pie	Pe'
CHILDREN	BAMBINI	ENFANTS	KINDER	NIÑOS	CRIANCAS
Thorax 1.0 Kg	Torace 1.0 Kg	Thorax 1.0 Kg	Thorax 1.0 Kg	Tórax 1.0 Kg	Thorax 1.0 Kg
Thorax 2.0 Kg	Torace 2.0 Kg	Thorax 2.0 Kg	Thorax 2.0 Kg	Tórax 2.0 Kg	Thorax 2.0 Kg
Thorax 4.0 Kg	Torace 4.0 Kg	Thorax 4.0 Kg	Thorax 4.0 Kg	Tórax 4.0 Kg	Thorax 4.0 Kg
Thorax 6.0 Kg	Torace 6.0 Kg	Thorax 6.0 Kg	Thorax 6.0 Kg	Tórax 6.0 Kg	Thorax 6.0 Kg
Thorax 8.0 Kg	Torace 8.0 Kg	Thorax 8.0 Kg	Thorax 8.0 Kg	Tórax 8.0 Kg	Thorax 8.0 Kg
Thorax 10 Kg	Torace 10 Kg	Thorax 10 Kg	Thorax 10 Kg	Tórax 10 Kg	Thorax 10 Kg

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

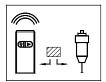
 $^{^{2}}$ The filter combination of 1 mmAl + 0,1 mmCu is also permissible

4.5.3. Perform an exposure

TMS300 provides for two different modes to perform an exposure:

- HANDSWITCH mode: the exposure is performed with the x-ray control supplied with the unit.
- CORDLESS mode: the exposure is performed with the infrared remote control available as accessory.

In order to change the x-ray control mode, it is enough to bring the choice switch on the mode fitter for use.



HANDSWITCH Mode



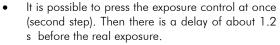
Before performing an exposure, make sure that all the necessary precautions against radiation have been taken.



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



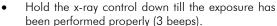




Figure 14

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 "1st step" (preparation) for more than 15s. In order to perform radiography, it is necessary to release the handswitch and repeat the procedure.
- 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.

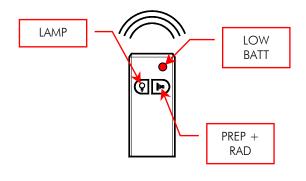
CORDLESS Mode

The x-ray infrared control has got two push-buttons, one for the lighting-ON of the collimator lamp and one for activating both the x-ray preparation phase "prep" and the emission phase "rad".

Lamp lighting-ON – For lighting ON the collimator lamp press the relative key, the lamp will light OFF after the lighting-ON time of 30sec.

Preparation phase "prep" – press and release the push-button "prep + rad".

Emission phase "rad" – Press twice the x-ray push- button "prep + rad" within 15sec. and hold it down till the exposure is finished. When the exposure has been completed, the unit emits three beeps. Put the remote control in its seat on the unit again.



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 1st line of the display shows the use messages and the error signals.
- The 4th line of the display shows the radiological parameters.
- After every exposure, the 4th 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 [cGgcm²] in output towards the patient.

The device that can be installed is type PTW-Freiburg DIAMENTOR CI-P.

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 [cGycm²]:



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

$$\sum_{i=1}^{n} dose_{i} \cdot area_{i}$$

"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 between each patient.

The possible measuring range is included between 0000,00cGycm² and 9999,99cGycm². When the measures summation exceeds 9999,99cGycm², the message "MAXDOSE" will appear. The presence of this message <u>does not exclude</u> the possibility to perform exposures.

Data printing

If the DAP meter is installed and works properly (dose shown on the display), by pressing the F4 key it is possible to print the data concerning the dose released on a dedicated printer, available as accessory on request.

The final printing relates the data concerning:

Datum	Description
Name/Id	Patient's name (*)
Born on	Birth date of the patient (*)
xxxx.xx cGycm2	Dose to which the patient has been exposed (0000.00 cGycm2)
Operator	Operator's signature (*)
Date	Date and time of the exam (format dd-mm-yy hh:mm)
	/*\

(*) datum to be inserted by hand from the operator.

Connect the printer to the connector placed on the front of the unit; Switch ON the printer; press the F4 key, on the display the "Print" writing appears.

For more details and / or explanations on the printer, refer to the User's Manual of the printer.

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;
- 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 operating the OFF key located on the control panel
- 2. Disconnect the supply cable and wrap it on the proper support.
- 3. Place the unit in parking position (down, with mechanical brakes activated).

5. MAINTENANCE

Technix S.p.A. 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.

Technix S.p.A. 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

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	$115/230$ Vac $\pm 10\%$ 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 d	ifferent operative o	conditions and in
	the two power supply values:		
	Operative condition	115 Vac / 50Hz	230 Vac / 50Hz
	Charger On	5,5 A _{MAX}	$3,4A_{MAX}$
	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 _{PK}	3A _{PK}
Line compensation	Automatic		
Line resistance	<1Ω @115/230Vac		
Standard socket outlet	16A @230Vac		
Isolation class	Class I with applied parts type B		
Use conditions	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, Português, 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

Data	Dati
Working technique	2 points with kV and mAs setting
APR technique	24 exams storage (4 folders each of 6 exams) available in
	the 5 different selectable languages.
Exposure control	Constant kV and mA during all the exposure
Dose	A 50% reduction (LD)
Small focus (IEC 60336)	0,8mm
Large focus (IEC 60336)	1,3mm
Generator power in DC current	30kW@100kV
Inverter frequency	20kHz
Inverter frequency in high voltage	40kHz
Max.ripple	<2% @100kV,
	(100kV,100ms, 300mA)
Rise time	<2ms @100kV
kV range	40 ÷ 125kV in step of 1kV
mA range @115/230Vac	50 ÷ 300mA automatically associated to kV
mAs range @115/230Vac	0,2 ÷ 220mAs steps with increases of 12,5%
Times range @115/230Vac	0,002 ÷ 2,2s
	in function of the set mAs
Use coefficient (duty cycle)	1:40

			mA values @	115/230Vac		
kV		Small	Small focus Large focus		focus	
		H.P.	L.P.	H.P.	L.P.	
		(t<100ms)	(t>100ms)	(t<100ms)	(t>100ms)	
	40	200mA	100mA	200mA	200mA	
	50	200mA	100mA	250mA	200mA	
	60	190mA	95mA	300mA	190mA	
	70	180mA	90mA	300mA	180mA	
	80	170mA	85mA	300mA	170mA	
	90	160mA	80mA	300mA	160mA	
	100	150mA	75mA	300mA	150mA	
	110	130mA	65mA	260mA	130mA	
	120	115mA	55mA	220mA	110mA	
	125	110mA	50mA	200mA	100mA	

mAs value in function of kV @115/230Vac			
mAs (HD)	mAs (HD) mAs (LD) kV		
0.2-220	0.2-110	40	
0.2-200	0.2-100	41-45	
0.2-180	0.2-90	46-52	
0.2-160	0.2-80	53-62	
0.2-140	0.2-70	63-72	
0.2-110	0.2-55	73-92	
0.2-100	0.2-50	93-112	
0.2-90	0.2-45	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	$151^{\circ} (+133^{\circ} \div -18^{\circ} \text{ in respect of the vertical axis})$
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

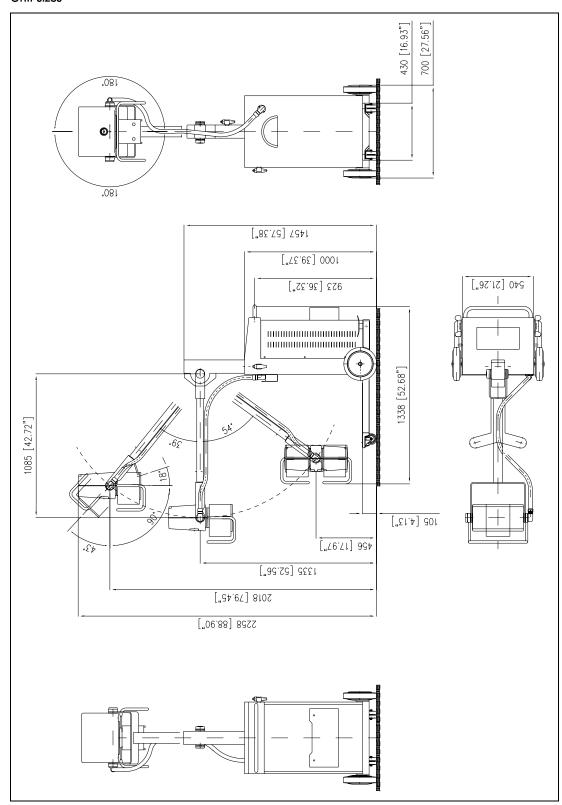


Figure 15

6.6. Components specifications

6.6.1. Generator

Description	Dati
Inverter	IHF 2030
Working frequency	20kHz max
Power supply	680Vdc max
Dimensions	240x210x140 mm
	9,45x8,27x5,51 in.
Max. absorbed current	75A
Technology	IGBT
Safeties	overcurrent
	overvoltage
	IGBT driver fault
Generator power in constant DC current (IEC 601-1)	30kW
	(300mA @ 100kV per 0.1s)
Max. voltage to the tube	125kVp
Max. ripple at 100kVp	<2%
Rise time at 100kVp	<2 ms
Max. current in radiography	300mA

6.6.2. Tube-Housing Assembly

X-Ray Tube

Description	Data
Туре	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.

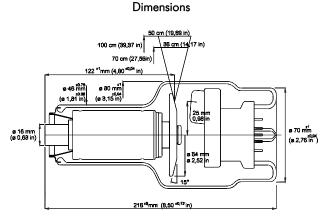


Figure 16

Single load curves

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

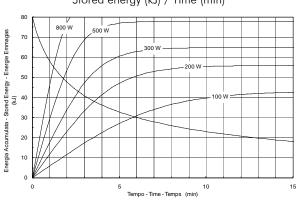
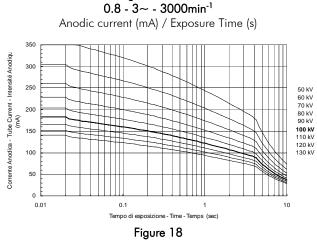


Figure 17

Single load curves

1.3 - 3~ - 3000min⁻¹



Anodic current (mA) / Exposure Time (s)

700

80 kV

100 kV

1

<u>Monobloc</u>

Description	Dati
Monobloc	MHF 2030
Weight	20kg (44,09Lb)
Dimensions	320x140x255mm (12,60x5,51x10,04in.)
X-ray tube	X22 0.8/1.3
Anode	Rotating (2850rpm at 50Hz)(3400rpm at 60Hz)
External thermostat	57°
Thermal monobloc capacity	600kJ (800kHU)
Max continuous thermal dissipation of monobloc	55W
Max. monobloc anode cooling speed	5,4kJ/min (7,2kHU/min)
Total filtration	1.1mm 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

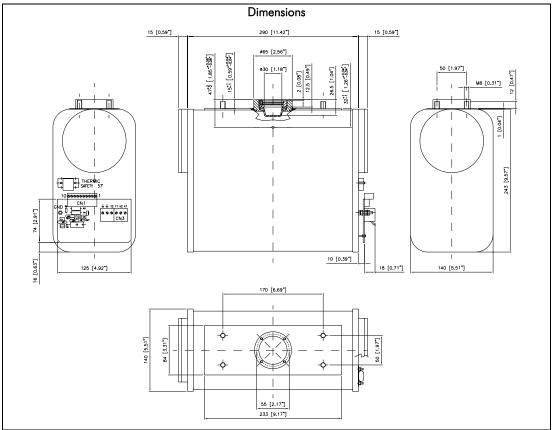
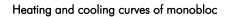


Figure 20



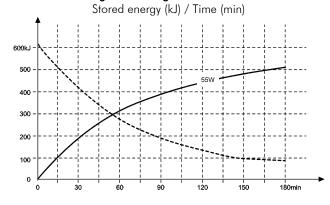


Figure 21

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	It corresponds to the x-ray fields with tolerance lower than
(EN60601-1-3 par.29.202.8)	2% of used FFD
Inherent filtration	2.0mmAl eq.
(EN60601-1-3 par.29.201.2/29.201.6)	
Light field accuracy	It corresponds to the x-ray fields with tolerance lower than
(EN60601-1-3 par.29.202.9)	2% of the used FFD.
Classification EN60601-1 par.5	
Protection against electrical hazards	Class I
Protection against direct and indirect contacts	Unit with applied part Type B
Protection against water penetration	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 CI-P
Measurement unit	cGycm ²
Resolution	0,01cGycm ²
Dose-area product summation range	0000,00 ÷ 9999,99 cGycm ²
Max. measuring range	118mm x 118mm (4,65x4,65in.)

6.6.5. Printer for DAP (optional)

This device is installed only on request.

Description	Data
Туре	S'Print-S
Printing method	Thermal line printing
Resolution	203dpi
Printing speed	>50mm/sec (it depends on the printing typology and the
	environment temperature)
Paper width (mm)	58mm
Roll dimensions (mm)	57.5 ±1
Print area	48mm
Interface	RS-232
Power Supply	18±24VDC / 0,6A
Power consumption (print)	925mA
Temperature, Operatine, Storage	0±50°C
	-20±70°C, without paper roll
Humidity, Operating, Storage	10±85%, without condensation
	10±90%, without condensation, without paper roll
Dimensions (WxDxH)	146 x 88 x 65mm
Weight	370gr (without paper roll
Safety	EN60950+A1+A2+A3+A4

6.7. Accessories and options

Description	
X-ray handswitch with extendible cable	Standard
Ionization chamber dosimeter, mod. DIAMENTOR CI-P	Optional
X-ray infrared remote control, mod. TECH SWITCH	Optional
Printer for dose meter, mod. S'Print-S	Optional
Hook for radio protective apron	Optional
Tilting pedal	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 60601-1-8	General requirements, tests and guidance for alarm systems in medical	
	electrical equipment and medical electrical systems	
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

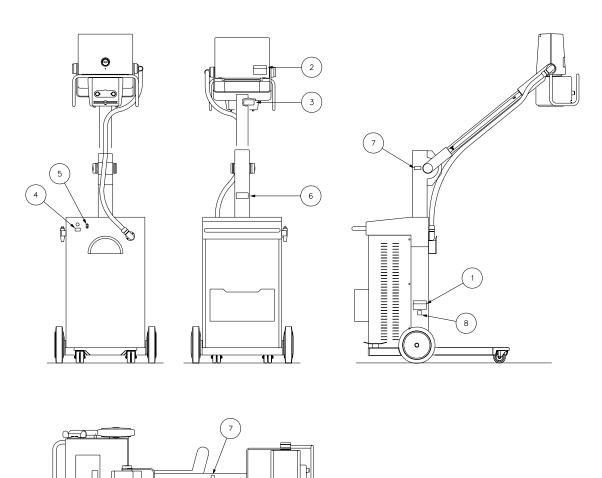
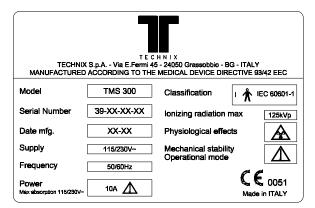


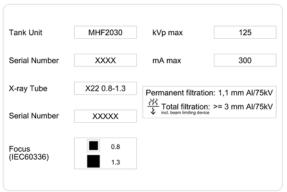
Figure 22

Reference Figure 22

Pos.1. - Unit label



Pos.2. - Monobloc label



Pos.3. - Collimator label



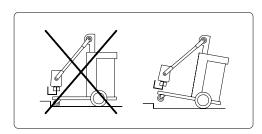
Pos.4. - Potter Bucky label



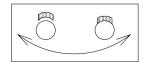
Pos.5. – Equipotential Node label



Pos.6. – Tilting label



Pos.7. – Braking indication label



Pos.8. – WEEE label



6.9.1. Internal symbols



Protective ground clamp

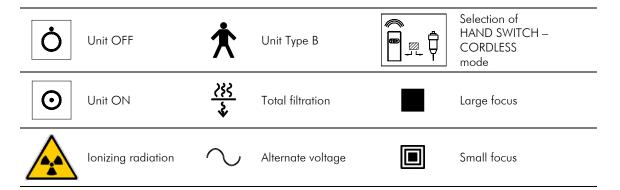


Dangerous voltage



Precautionary warning

6.9.2. Various symbols



6.9.3. Packing label

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



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Document status

TMS300 – User's Manual

DOCUMENT STATUS

Rev.	Date	Pages	Modification description
0	26.08.03	-	Document approval
1	25-07-02	4-34	Updated paragraph "Applications & use destination" Updated unit's labels
2	14-01-04	All	General revision
3	21.01.05	6, 18, 19, 30, 32	Introduction of the x-ray remote control accessory.
4	31.10.05	tutte	Introduced position of WEEE label. Introduced explanation note of the WEEE symbol (+repaging). Updating of the unit labels and symbols.
5	10/07/06	32	Updating of the monobloc and unit labels according to the standards in force.
6	05/12/06	5, 6, 7, 8, 9, 10, 11, 12, 16, 17, 19, 23, 24, 30	Introduced the function of the half dose. Introduced the new dose meter chamber, printer for dosimeter, tilting pedal, portuguese language on the display.
7	21/05/07	30, 31	Introduction of the technical data of the DAP printer and the standard with the general requirements of the electromedical systems
8	26/10/09	5, 32	Upgrading of manufacturer address and relative S/N labels