

TLX



Revision: 4

Date: September 2016
File: [AQ3001LE00R04.doc]

User's Manual

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

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

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TLX LITHO - User's Manual

TABLE OF CONTENTS

1.	SAFE	TY AND COMPLIANCE	
	1.1.	Electrical safety	2
	1.2.	Mechanical safety	
	1.3.	Electromagnetic compatibility (EMC)	
	1.4.	General disposal	3
	1.5.	Application & final destination	4
	1.6.	Classification	4
	1.7.	Compliance	4
	1.8.	Copyright	4
2.	INSTA	ALLATION	4
3.	COM	PONENT IDENTIFICATION	5
	3.1.	Overview	5
	3.2.	Connections and emergency push-buttons	
	3.3.	Accessories	
	3.4.	Control Hand-Switch	
	3.5.	Control Foot-Switch.	7
4.	FLINIC	CTIONING	
٦.	4.1.	Transport	
	4.2.	Positioning and setting at work	
	4.3.	Movements of the table	
	4.4.	"Positions 0" storage	
	4.4.1		10
	4.4.2	•	
	4.5.	Shutdown procedure	
_			
5.		ESSORIES ASSEMBLING	
	5.1.	Table extension assembling	
	5.2.	Assembly of lateral rests kit for lithotripsy	
	5.3.	Assembly of 450x250 mm lateral rests and extensions kit for lithotripsy	
		Assembling of the liquids tank	
	5.5.	Assembling of other accessories.	
6.	MAIN	TENANCE	
	6.1.	General warnings	
	6.2.	Checks and inspection by the user	
	6.3.	Cleaning	16
	6.4.	Disinfection	16
7.	TECH	NICAL DATA	17
	7.1.	Electrical data	
	7.2.	Radiological data	
	7.3.	Environmental data	
	7.4.	Mechanical data	
	7.4.1		19
	7.4.2		20
	7.5.	Labels and Symbols	
	7.5.1	,	
	7.5.2		
	7.5.3	0	
	7.5.4	,	
חכ		IT STATUS	
\sim	CONTILL	,, o,, ,, oo,,,,,,,,,,,,,,,,,,,,,,,,,,	

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 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 unit may only be operated by skilled, properly trained personnel with the required knowledge of x-ray safety practices and the proper use of 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

 Only trained service personnel authorized by Technix S.p.A. may remove the unit covers and only in accordance with the instructions contained in the Service Manual.



- This unit may only be used in environments or medical rooms in compliance with the applicable IEC standards.
- The unit <u>must not</u> 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



- Avoid collisions with obstacles or other frames.
- After positioning the unit, actuate the parking brakes that can be found on the wheels.

Pag. 2/22- Rev.2 [File: AQ3001LE00.doc]

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. General disposal

Technix S.p.A. produces medical and 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.

1.5. Application & final destination

The TLX LITHO is a multifunctional mobile and wheeled table suited to be used with Image Intensifiers with "C" arm, "U" arm and with any other fixed or mobile x-ray units. Its use must be absolutely reserved to qualified, skilled, trained personnel informed on the risks linked to its use. It's a table that is perfectly adaptable to most various applications in:

- Urology
- Lithotripsy

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

The system shall be used on contact with the patient. At every unit use, apply a sterile cloth before positioning the patient.

All contacts with the operator are required for reasons that are linked with the conditions of use (control operations).



For the use of the unit with systems for lithotripsy, it is necessary to use a footswitch type IP-X8.

1.6. Classification

1.7. Compliance



This unit is in compliance with the Directive for the Medical Devices 93/42 EEC Class IIb according to Annex IX Rule 10.

The manufacturer and distributor (according to the European Directive 93/42/EEC) of the unit TLX LITHO 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 Web: www.technix.it

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

1.8. Copyright

The original release of this manual is in Italian language (file: AQ3001_100RXX.doc). For further information, please refer to the Italian version.

2. INSTALLATION

For the installation of the unit, refer to the relative chapter in the Technical Manual of the unit.

3. COMPONENT IDENTIFICATION

3.1. Overview

- 1. Control Hand-Switch
- 2. Control Foot-Switch
- 3. Patient table
- 4. Guides for accessory assembly
- 5. Direction pedal of the front wheels
- 6. Support for the control footswitch
- 7. Extension with cushion
- 8. Lateral rest
- 9. Lateral rest extension

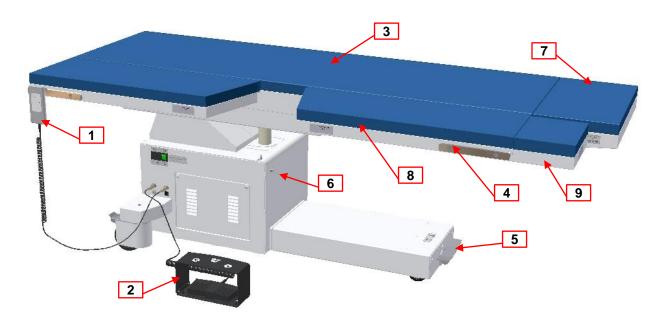
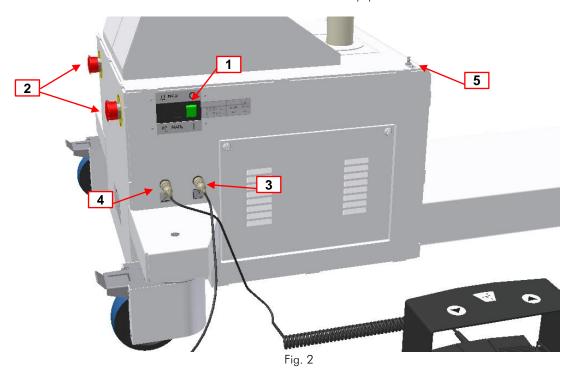


Fig. 1

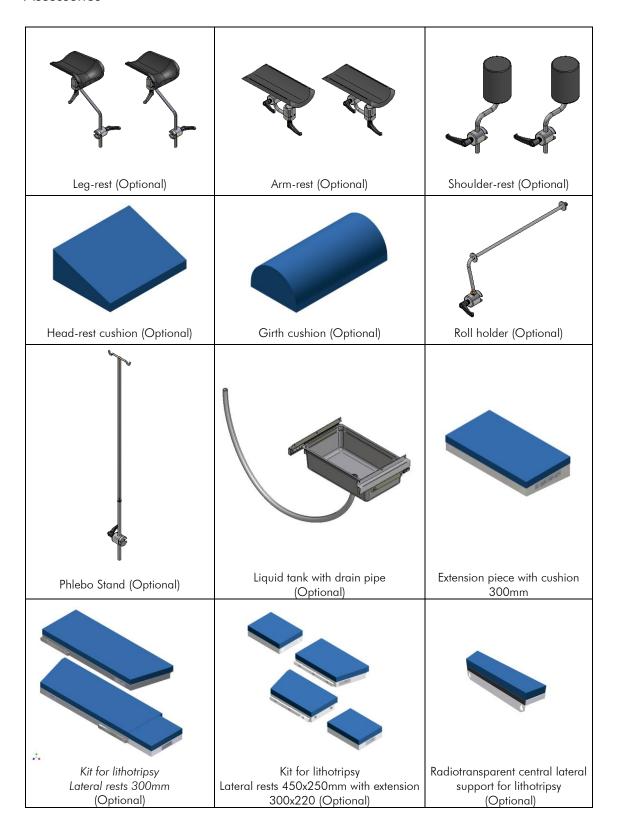
3.2. Connections and emergency push-buttons

- 1. Mains outlet with general switch
- Emergency push-buttons.
- 3.

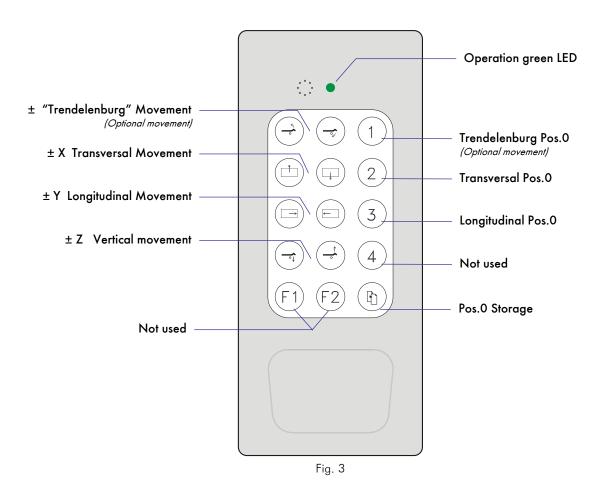
- 4. Control handswitch connector
- 5. Control footswitch connector
- 6. Equipotential node



3.3. Accessories



3.4. Control Hand-Switch



3.5. Control Foot-Switch

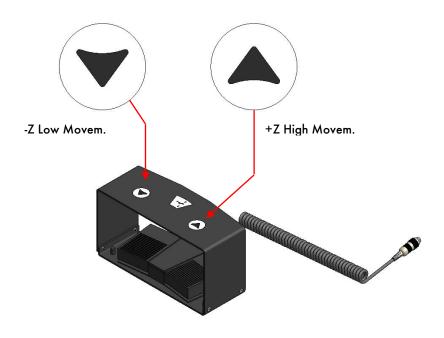


Fig. 4

4. FUNCTIONING

4.1. Transport

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

 Check that the unit is disconnected from the mains, the supply cable and the control devices are lodged in the proper spaces and/or supports.

- Check that the direction pedal of the front wheels is in horizontal position.
- Move the unit only after releasing the parking brakes placed on the wheels.
- Don't move the unit on surfaces with an inclination higher than 10°.
- Move the unit by using only the proper handles for the movement.

4.2. Positioning and setting at work

For the positioning and the setting at work of the unit, consider the following:

1. Don't move the unit with the brakes activated. For the movements, use the proper handles and the direction pedal of the front wheels (see Fig. 5).

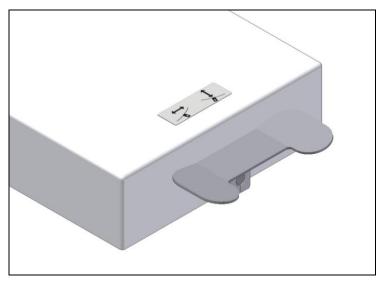


Fig. 5

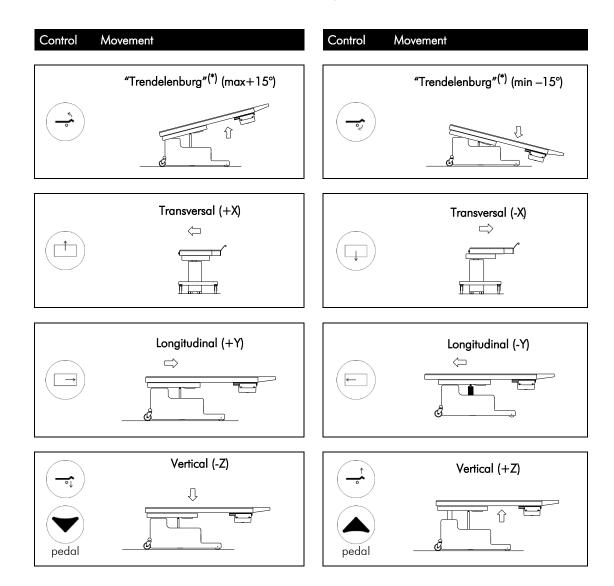
- 2. Place the unit in the intended position.
- 3. Activate the parking brakes on the wheels.
- 4. Check that the unit is connected to the mains.
- 5. Check that the emergency push-buttons are not activated.
- 6. Press the push-button "unit ON" in position "I". The green led on the switch will light ON in order to indicate the presence of the mains voltage.
- 7. Move the table in the "all low" position to ease the patient loading. The patient must go up near the central area of the table. The lateral rests and the extension parts, if present, cannot be used for the patient loading.
- 8. Move the table according to the requirements by activating the handswitch and/or footswitch.



Whenever you want it is possible to stop the unit working by pressing one of the two red emergency push-buttons on the lateral panel.

4.3. Movements of the table

The controls for the movement of the table are the following:



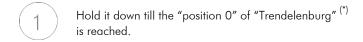
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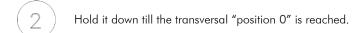
^(*)Optional movement

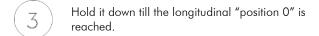
4.4. "Positions 0" storage

The storage function allows the user to store the favourite "Trendelenburg" (*), transversal, longitudinal "position "0" or the most used position of the table.

4.4.1. Move the table in the "positions 0"







Note:

The unit is set in factory with:

"Trendelenburg" (*) Position 0 0°

Transversal Position 0 0 mm

Longitudinal Position 0 100 mm

4.4.2. How to store the "positions 0"

- 1. Move the multifunctional table in the intended position through the available movements.
- 2. Press the storage push-button and then press the relative push-button of "position 0" in order to store the intended position.
- 3. The occurred storage is confirmed by an audible signal emitted by the handswitch.
- 4. In order to move the table in the stored "positions 0", refer to par. 4.4.1.



Storage of longitudinal "position 0"

Pag. 10/22- Rev.2

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^(*)Optional movement

4.5. Shutdown procedure



Don't take the connector out of the socket outlet if the unit is not OFF

After use, in order to guarantee the operator's safety and a long life of the unit, proceed as follows:

- 1. Place the unit in parking position, that is to say with the table DOWN and the "Trendelenburg" (*) position at approx. 0°.
- 2. Turn the unit OFF by acting on the prearranged switch.
- 3. Disconnect the supply cable from the mains and lodge the control devices in the proper spaces and/or supports.
- 4. Activate the parking brakes on the wheels.

5. ACCESSORIES ASSEMBLING

The table TLX LITHO is a multifunctional unit equipped with several accessories. Here below their assembly and the lay-out are described.

5.1. Table extension assembling

(Standard accessory)

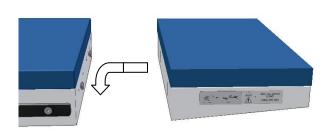
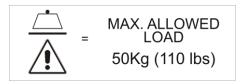


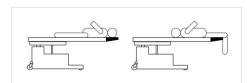
Fig. 6

For the extension part assembly, fit its connection holes in the fixing pivots on the multifunctional table and then push downwards as indicated in Fig. 6
For more safety, check under the extension part if the pivots are properly hitched.

The extension part of the table can be mounted indifferently in both sides.

Note: pay attention to the use of the extension part





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^(*)Optional movement

5.2. Assembly of lateral rests kit for lithotripsy

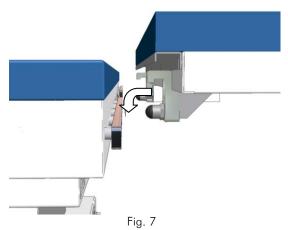
(Optional accessory)

Mount the left and right lateral rests by taking care to place properly the fixing hooks and the safety lock as indicated in Fig. 7 and Fig. 8.

Mount the extension by fitting its connection holes in the connecting pins on the lateral rest and then push downwards.

The lateral rests can be mounted indifferently both on right and left side.

Note: pay attention to the use of the lateral rest.

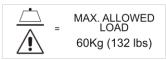


Disassembly of the lateral supports:

In order to remove the lateral left and right supports with a hand, pull the handle placed under the support (as indicated in Fig. 8) and at the same time lift it.

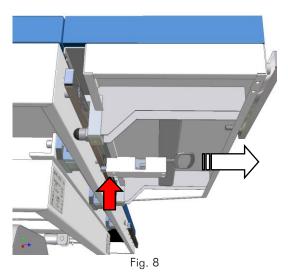
It is advisable that the disassembly operation is performed by two people.

Max allowed load of lateral rests:



Max allowed load of lateral rest extension





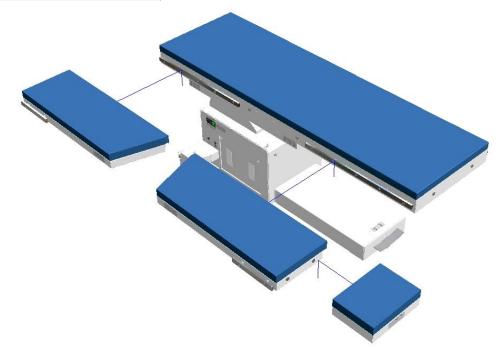


Fig. 9

Pag. 12/22- Rev.2

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5.3. Assembly of 450x250 mm lateral rests and extensions kit for lithotripsy

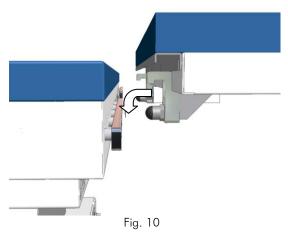
(Optional accessory)

Mount the left and right lateral rests by taking care to place properly the fixing hooks and the safety lock as indicated in Fig. 7, Fig. 11 and Fig. 12.

Mount the extension by fitting its connection holes in the connecting pins on the lateral rest and then push downwards.

The lateral rests can be mounted indifferently both on right and left side.

Note: pay attention to the use of the lateral rest.

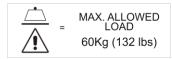


Disassembly of the lateral supports:

In order to remove the lateral left and right supports with a hand, pull the handle placed under the support (as indicated in Fig. 11) and at the same time lift it.

It is advisable that the disassembly operation is performed by two people.

Max allowed load of lateral rests:



Max allowed load of lateral rest extension



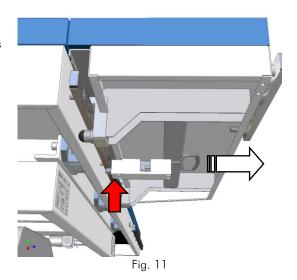




Fig. 12

5.4. Assembling of the liquids tank

(Optional accessory)

Take out the LEFT and RIGHT guides (see Fig. 13).

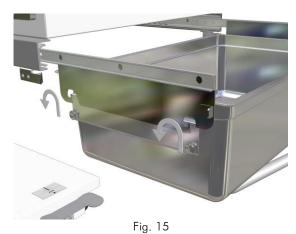
Before assembling the liquids tank on the guides, if it is foreseen, screw down the liquids draining pipe. (see Fig. 14).





Fig. 13





Assemble the tank starting under the guides, keeping it in horizontal position with two hands at the base and insert its pivots in the fixing slots as indicated in Fig. 15.

5.5. Assembling of other accessories

(Optional accessories)



Fig. 16

For fixing on the lateral guides the leg-rest, arm-rest, shoulder-rest, phlebo-stand and roll-holder, the block with handle indicated in Fig. 16 is used. Insert the block and, if it is necessary, rotate the cylinder so that the internal and external holes are aligned and the accessory rod can go through (see Fig. 17). Then fix the accessory in the intended position.

6. MAINTENANCE

Technix S.p.A. can supply, on request, a programmed maintenance plan to be performed on the unit

6.1. 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 parts.

6.2. 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 periodical checks		
Daily:	Check the functionality. Check the warning and danger labels integrity.	
Weekly:	Check unusual noises in the different parking positions of the table.	
Every 6 months:	Check the limit switches functionality of the table movement	
Yearly:	Contact the technical service to perform the checks described in the programmed maintenance plan	

6.3. 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 aluminum 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.

6.4. Disinfection

To disinfect the equipment it is 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 vapour 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.

Pag. 16/22- Rev.2 [File: AQ3001LE00.doc]

7. TECHNICAL DATA

7.1. Electrical data

Description	Data		
Voltage	monophase, 115/230Vac ±10%		
Frequency	50/60Hz standard		
Absorbed current	115 Vac / 50Hz 5A		
	230 Vac / 50Hz 2,5A		
Line resistance	<1Ω @115/230Vac		
Standard socket outlet	16A @230Vac		
Isolation class	Class I with applied parts type B		
Use conditions	Continuous operation with intermittent loading, 2' ON and 8' OFF		
Protecting fuses	The unit has got 2 line fuses F1 and F2 near the main switch and		
	they have the following values:		
	With mains at 115Vac ⇒ 5A		
	With mains at 230Vac \Rightarrow 2,5A		
The unit is not suitable to	the use where danger of inflammable mixtures with air or nitrous		
oxide exists.			

Control Unit

Description	Data
Power supply voltage	monophase, 115/230Vac ±10% 50/60Hz
Secondary rated voltage	25 Vdc
Max. power for single	180W
output	
Utilization factor	20% (2min on, 8min off)

CAFSx linear actuators

Description	Data
Power supply voltage	24 Vdc
Utilization factor	20%

7.2. Radiological data

Description	Data
Equivalent attenuation value of the patient table	0,3 mmAl / 75kV

7.3. Environmental data

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

7.4. Mechanical data

Description	Data	
Weights		
Weight of unit without accessories	280 Kg	(617,29 Lb) approx
Weight of 300mm extension part	7 Kg	(15,43 Lb)
Weight of the 300x740mm two lateral rests	7 Kg x 2 = 14 Kg	$(15,43 \text{ Lb} \times 2 = 30,86 \text{ Lb})$
Weight of the 250x700mm two lateral rests	6 Kg x 2 = 12Kg	(26,46 Lb x 2 = 52,91 Lb)
Weight of the 250x450mm two lateral rests	5 Kg x 2 = 10 Kg	$(11,02Lb \times 2 = 22,04 Lb)$
Weight of the 270x200 lateral extension	1,5Kg	(3,31 Lb)
Weight of the 220x300 lateral extension	1,5Kg	(3,31 Lb)
Weight of the two leg-rest	7 Kg x 2 = 14 Kg	$(15,43 \text{ Lb} \times 2 = 30,86 \text{ Lb})$
Weight of liquid tank with drain pipe	3,5 Kg	(7,72 Lb)
Weight of phlebo stand	2 Kg	(4,41 Lb)
Weigh roll holder	2Kg	(4,41 Lb)
Weight of head-rest cushion and girth cushion	2Kg	(4,41 Lb)

Max loads

Max. load on carbon fiber patient plane	180 Kg	(396 Lb)
Max. load on iron patient plane	180 Kg	(396 Lb)
Max. load on table extension part	50 Kg	(110 Lb)
Max. allowed weight on the lateral supports	60 Kg	(132 Lb)
Max allowed weight for lateral rest 270 x 200 mm	12 Kg	(26 Lb)
Max. allowed weight on the 220x300mm lateral	12 Kg	(26 Lb)
extension		

Dim<u>ensions</u>

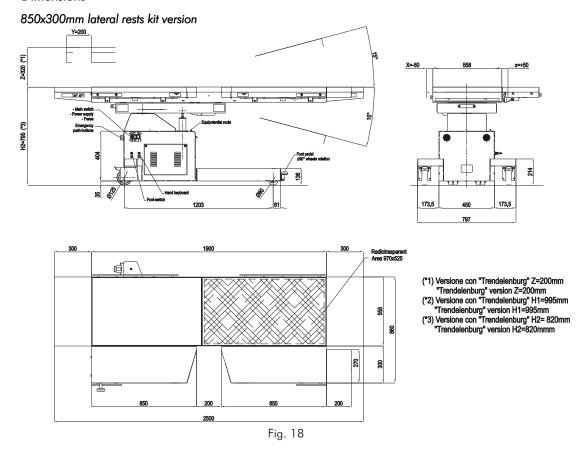
Table length without extension	1900 mm	(74,80 in.)
Table length with extension	2500 mm	(98,43 in.)
Table width	600 mm	(23,62 in.)
Min. cushion plane height	795 mm	(31,30 in.)
Min. cushion plane height	820 mm	(32,28 in.)
(Trendelenburg version)		
Max. cushion plane height	1115 mm	(43,90 in.)
Max. cushion plane height	995 mm	(39,17 in.)
(Trendelenburg version)		
Overall dimensions of the unit without extension	797x1900mm	(31,38 x 74,80 in.)
Overall dimensions of the unit with extension	1002x2500mn	n (39,45 x 98,43 in.)

Table movements	Travel	Speed
Up/Down "Z" axis movement	320 mm (12,60 in.)	9 mm/ sec
		0,35 in/sec
Up/Down "Z" axis movement	200 mm (7,90 in.)	9 mm/ sec
(Trendelenburg version)		0,35 in/sec
"Trendelenburg" ^(*) movement	± 15°	0,85°/sec
Longitudinal "Y" axis movement	200 mm (0 - 200 mm)	6,5 mm/sec
	7,87 in. (0 - 7,87 in.)	0,26 in/sec
Transversal "X" axis movement	100 mm (±60 mm)	6,5 mm/sec
	3,94 in $(\pm 1,97 \text{ in.})$	0,26 in/sec

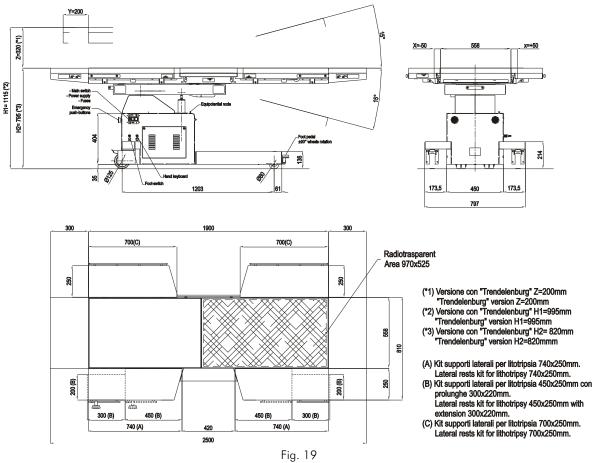
Unit movement	Manual
	Double front wheels with rotation 90° through
	footswitch.
	Rear casters with braking device.
Wheels diameter	Rear:
	wheel Ø125mm (4,92in.) width 30mm (1,18in.)
	Front:
	double wheel Ø80mm (3,15in.) width 30mm (1,18in.)

^(*) Optional movement

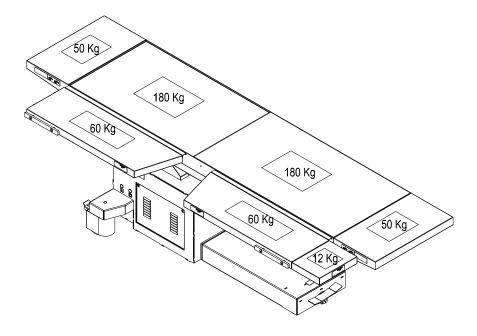
7.4.1. Dimensions



450x250mm lateral rests and 300x220mm extensions and 700x250mm lateral rests kit version

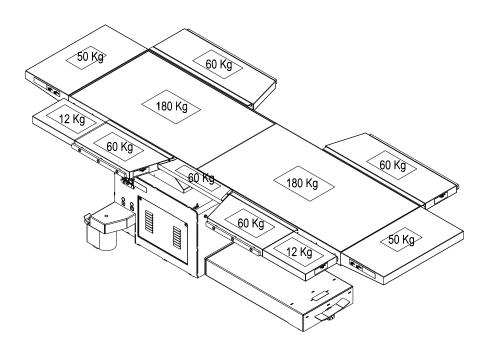


7.4.2. Max. loads



740x300mm lateral rests kit version

Fig. 20



450x250mm lateral rests and 300x220mm extensions and 700x250mm lateral rests kit version.

Fig. 21

7.5. Labels and Symbols

7.5.1. Unit labels

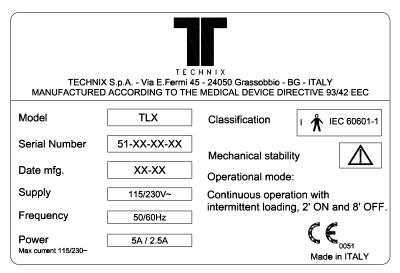


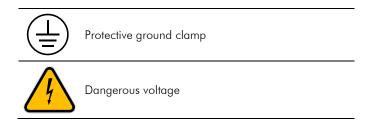
Fig. 22

7.5.2. Packing label

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



7.5.3. Internal symbols



7.5.4. Various symbols



Power ON (equipment ON) F2 line protection fuse



Warning, read the attached documents



Power OFF (equipment OFF) F1 line protection fuse



Equipotential node



Hand-switch outlet



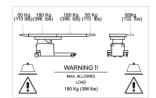
Class I equipment With applied parts Type B



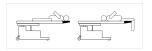
Foot-switch outlet



Alternate voltage



It indicates the max. allowed loads on the multifunctional table



It shows the positions the patient can take on the table



The max. load of the extension parts is indicated



MAX. ALLOWED LOAD 60Kg (132 lbs)

The max. load of the lateral rests is indicated



MAX. ALLOWED LOAD 12Kg (26 lbs) The max. load of the extension parts of lateral rest is indicated



WEEE label (see charter 1.4 General disposal)





It indicates how to activate the direction pedal of the front wheels

Document status

TLX LITHO – User's Manual

DOCUMENT STATUS

Rev.	Date	Pages	Modification description
0	29/06/06	-	Document approval
1	27/11/06	5-6-12-17- 18-20	Lateral rests with extension introduction and technical data updating.
2	27/01/09	all	Introduction of 450x250 lateral rests and 300x220 extensions lithotripsy kit.
3	26/10/09	4, 21	Upgrading of manufacturer address and relative S/N labels
4	09/2016	All	General revision