



Rotating Support for Laparoscopy side To side Evolution (sTs Evo)

Temporary non-invasive Class I medical device



USER MANUAL AND MAINTENANCE
ver.1.3 del 29/10/21



Read this user manual carefully before operating the device and keep it for future reference, along with the serial number located on the device's nameplate.



INTRODUCTION

- This manual is an integral part of the machine itself, providing the customer with all functional and safety information, as well as instructions for proper use and adequate maintenance.
- This booklet must be delivered to the personnel responsible for using and maintaining the machine and should be kept nearby the device for any future consultation.

TABLE OF CONTENTS

1 - MACHINE INFORMATION	Errore. Il segnalibro non è definito.
1.1 - Usage Precautions	Errore. Il segnalibro non è definito.
1.1.1 - General Precautions	Errore. Il segnalibro non è definito.
1.1.2 - Safety of Use	3
1.2 - Installed Safeguards	4
1.3 - Description of the Machine	4
1.3.1 - General Description	4
1.3.2 - Machine Composition	4
1.3.3 - Accessories	5
2 - TECHNICAL DATA	6
2.1 - Characteristic Plate	Errore. Il segnalibro non è definito.
2.2 - Technical Sheet	6
3 - MACHINE RECEPTION	6
3.1 - Composition and Packaging Check on Reception	6
3.2 - Packaging Disposal	6
4 - INSTALLATION	7
4.1 - Placement	7
4.2 - Securing on the Operating Table	7
4.2.1 - Mounting Bars for Recessed Fit	7
4.3 - Electrical Connection	8
4.3.1 - Electrical Diagram	8
5 - USE OF THE MACHINE	8
5.1 - Control Pedal	8
5.2 - Use of the Device	8
5.2.1 - Initial Verification Cycle	9
5.2.2 - Positioning and Securing the Animal in the Cradle	9
5.2.3 - Executing Rotation During Operation	9
5.2.4 - Restarting After a Sudden Stop.	10
6 - ROUTINE CLEANING	10
6.1 - Generalities	10
7 - MAINTENANCE	10

7.1 - Routine Maintenance	10
7.1.1 – Actuator	10
7.1.2 – Electrical System.	10
7.2 – Operating Anomalies	Errore. Il segnalibro non è definito.
7.3 – Spare Parts and Accessories List	Errore. Il segnalibro non è definito.
8 - DISASSEMBLY	Errore. Il segnalibro non è definito.1
8.1 - Decommissioning and Disposal	Errore. Il segnalibro non è definito.

1 - MACHINE INFORMATION

1.1 - Usage Precautions

1.1.1 - General Precautions

- The device can only be used by trained personnel who must fully understand the safety norms contained in the manual and the correct methods for performing laparoscopic operations.
- In the event of personnel turnover, timely provision of adequate training must be ensured.
- Before performing any cleaning operation, disconnect the power cable from the network.
- When performing maintenance or cleaning the device, focus on the ongoing operations and carefully assess any residual risks.
- Regularly check the condition of the power cables: a worn or otherwise compromised cable constitutes a serious electrical hazard.



WARNING: Do not remove any parts of the device, as such an operation can only be carried out by expert personnel.

- If the device appears to malfunction or demonstrate a fault, it is recommended not to use it or attempt to intervene, but rather to contact the manufacturer.
- The device is designed to optimally perform laparoscopic operations on anesthetized caniform and feliform animals weighing up to 100 kg. It is recommended not to use it for purposes other than those indicated.
 - Do not use the device for operating on animals other than those specified.
 - Do not use it for procedures other than laparoscopy.
 - Do not use it with unanesthetized animals or those not properly secured to the cradle.
 - Do not use it with objects or people.



WARNING: The rotating table can only be used if it is properly attached to a veterinary operating table using the provided vise system as an accessory or, alternatively, with vices or clamps to keep it secured.

The manufacturer is absolved of all responsibility for damages caused by:

- Unauthorized personnel tampering with the machine.
- Replacing parts with non-original components.
- Use not in accordance with the instructions in this manual.
- Treating the machine's surfaces with unsuitable products (corrosive chemicals, sharp objects, etc.).

1.1.2 - Safety of Use



WARNING: To greatly reduce the risk of injury to individuals, it is recommended to:




- Do not operate the machine if it is not functioning perfectly or if it has been damaged.
- Do not allow untrained personnel to use the machine.
- Follow all instructions and warnings placed on the machine.

To reduce the risk of falls:

- Do not install it near other fixed or movable objects.
- Ensure that no objects or anything else are placed on the device and that the animal to be operated on is anesthetized and adequately restrained.
- If abnormal noises or deformations are noticed, stop using the device and disconnect the power cable from the network.

1.2 - Installed Safeguards

This machine is equipped with all the safety devices, both electrical and mechanical, as required by the directives 2006/42/EC, 2007/47/EC, Legislative Decree No. 37 of 25/01/10, IEC601-1-2, EN 50082-2, and EN 61340. Nevertheless, there are residual risks mentioned in this manual that are not completely eliminable, concerning the probable incorrect use of the equipment. To minimize these risks, the following instructions and warnings are appropriately placed.

TARGHETTA	NOME	DESCRIZIONE	PERICOLO
	Danger of Moving Parts	The cradle is equipped with rotational movement relative to the fixed base.	Risk of objects falling if placed on it. Risk of collision and entanglement with objects in its path. Excessive motor strain.
	Maximum Load	Maximum load that can be applied on the cradle.	Risk of malfunction, excessive deformations, excessive motor strain.
	Disconnect Power During Maintenance	During maintenance, no unexpected movements of the parts should occur.	Risk of crushing, entanglement, and injury.
Maintenance and replacement of defective components must be carried out by qualified and authorized personnel.	Specialized Personnel	Maintenance and replacement of defective components must be carried out by qualified and authorized personnel.	Risk of malfunction, injury during maintenance.

1.3 - Description of the Machine

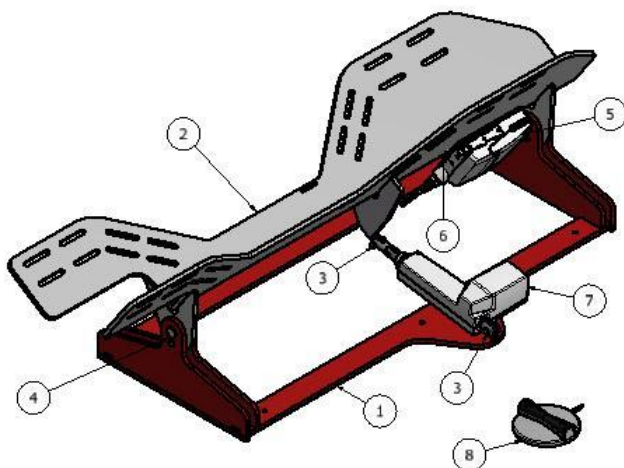
1.3.1 - General Description

The sTs Evo laparoscopic rotating support is a Class I non-invasive medical device comprising a motorized shaped platform. It's designed to maintain animals in the optimal position during laparoscopic procedures, allowing surgical access while ensuring space for the surgeon's operations. It includes various slots for securing anesthetized animals of any size (within specific guidelines). The device should be affixed to any veterinary operating table using suitable clamps, allowing 180° continuous and automatic rotation along its axis. It's pre-equipped for mounting on tables with a grooved frame, facilitating natural access to organs with minimized trauma by utilizing the relative natural movement of the organs, enhancing the visibility and accessibility of the area being operated on.

The machine is composed of a painted aluminum base on which a cradle is hinged that continuously rotates from -90° (left) to 90° (right). The rotational movement of the platform is pedal-controlled, allowing hands-free operation, and is performed by an electric actuator located beneath the rotating platform (see sec. 1.3.2).

1.3.2 - Composition of the Machine

The sTs Evo rotating support is provided as shown in Figure 1, complete with a command foot pedal and extension bars for the feet frame, allowing for integration into the grooved frame of the operating table. The adjustable clamps (Fig.3) are optionally supplied.



- | | | |
|------------------|--------------------------|----------------|
| 1- Frame. | 4- Axis pin. | 7- Actuator. |
| 2- Cradle. | 5- Control unit. | 8- Pedalboard. |
| 3- Actuator pin. | 6- Control unit bracket. | |

Fig. 1 General view

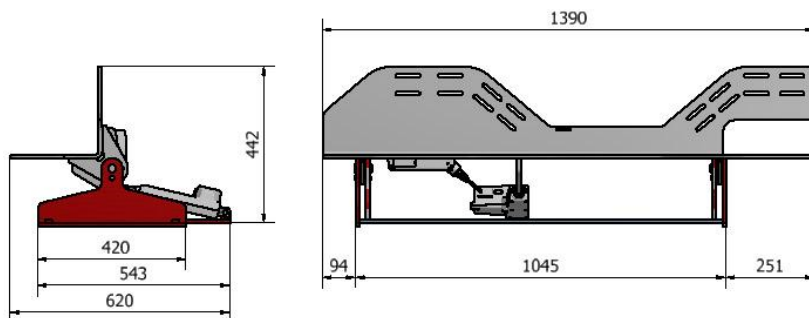
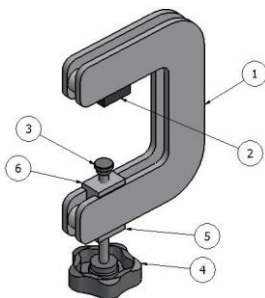


Fig. 2 Dimensions in millimeters

1.3.3 - Accessories

The sTs Evo rotating support must be secured to the veterinary operating table, and for this purpose, a system of 3 adjustable clamps is offered as an optional accessory, as described in the accompanying figure. Two extension bars are also supplied to connect to the frame in the case of using an operating table with a grooved frame (sec. 4.2.1).



1. Clamp body
2. Upper dowel
3. Tilting plate screw
4. Knob
5. Lower dowel cap
6. Lower dowel

Figure 3

2 - Technical Data

2.1 - Characteristic Plate

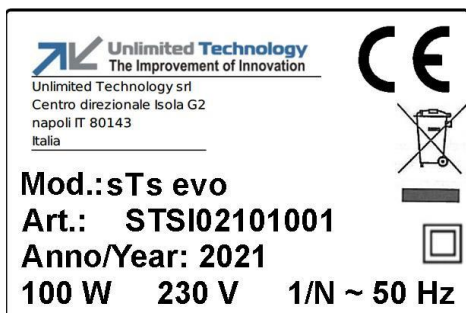


Figure 4 Nameplate

2.2 - Technical Sheet

Parameter	U.M.	sTs
Supply Voltage	V	230
Operating Voltage	V	24
Frequency	Hz	50/60
Power Consumption	W	100
No-load Rotation Speed	degrees/ sec	5.6
Full-load Rotation Speed	degrees/ sec	2.9
No-load Complete Rotation Time	sec	16
Full-load Complete Rotation Time	sec	31
Maximum Load Exercise Cycle	sec	2 minutes + 18 minutes rest
Cradle Dimensions	m	1.4 x 0.26 x 0.26
Maximum Dimensions	m	1.4 x 0.62 x 0.44
Cradle Height	cm	190
Cradle Angular Travel	°	180 (-90/90)
Maximum Load	Kg	100
Total Weight	kg	20

3 - MACHINE RECEPTION

3.1 – Composition and Package Inspection Upon Receipt

The packaging consists of a wooden pallet on which the machine is bolted, covered by a wooden crate. Accessories like the clamping system are packed separately. Ensure the packaging is intact upon receipt, showing no signs of damage or mishandling. Open the crate, remove the bolts securing the machine to the pallet, and check for all components. Report any damage immediately to the carrier and within 3 days of delivery. Keep the machine and components in a dry place. If stored for over three months, regularly check the packaging and parts.

3.2 - Disposal of Packaging

Packaging materials are classified as urban solid waste and can be disposed of according to the regulations in the country of installation.

4 - INSTALLATION

4.1 - Placement

The room designated for the machine's installation must comply with the current safety and hygiene standards of the country where it's being installed. The device must be securely fastened to an operating table that is:

- Wide enough to accommodate the machine.
- Strong enough to support the weight of the machine, the animal to be operated on, and the force exerted by the actuator.
- Level, dry, smooth, robust, and stable to ensure safe operation.

The machine should be installed as close as possible to an electrical power supply.

- Ensure that all packaging material has been removed.
- **WARNING:** Inspect the machine for visible damage such as a damaged platform, dents, or significant breaks, as well as damaged or cracked accessories. If any such damage is found, **DO NOT USE** the machine and contact qualified personnel.
- The machine and all its components must be kept away from sources of heat, steam, or flammable products.

4.2 – Securing to the Operating Table.

After performing all the checks described in section 4.1 for each component, clear the operating table of any obstacles and objects. Place the sTs Evo rotating support on the operating table and lay the foot pedal on the floor, making sure to route the cable underneath the rods and over the reinforcement plates of the frame (1 fig.1). Center the sTs Evo rotating support on the operating table both horizontally and vertically, ensuring that both the feet and the frame reinforcement plates (1 fig.1) are resting on the table surface.

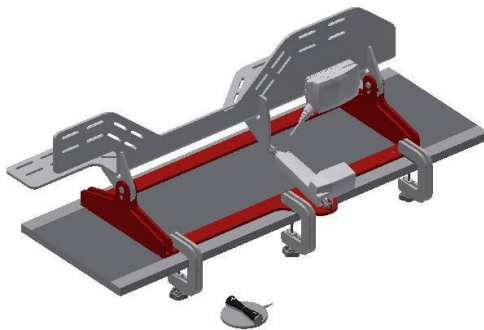


Figure 5 Securing to the Operating Table.

Secure the sTs Evo rotating support to the operating table using the clamp system provided as an optional accessory or any suitable clamp system. This may require using plates, bars, or appropriate reinforcements. Attach the sTs Evo rotating support to the operating table at a minimum of three points on the side of the actuator, as indicated in Figure 5.

⚠️ WARNING: The attachment must be secure and stable. Securing the sTs Evo table with straps, adhesives, movable weights, etc., is strictly prohibited.

4.2.1– Mounting Bars for Recessed Fit

Attach the two painted aluminum bars using the supplied screws as shown in Figure 6.

Place the sTs Evo rotating support ensuring that the frame reinforcement plates rest on the surface of the operating table and that the feet fit into the grooved profile of the operating table's frame.

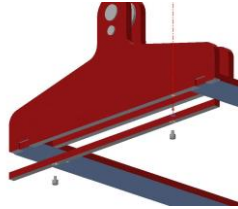


Figure 6 Securing bars for recessed fit.

4.3 - Electrical Connection

The connecting cables for the various electronic components are supplied and are of adequate size. Connect the foot pedal cable to the control unit (5 in fig.1).

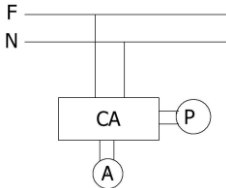
The power cable must be connected to an adequately specified power outlet (see fig. 4; sec 2.2). Any extension cords used should have cables with a cross-sectional area suitable for the power rating.

When connecting the machine to the electrical power supply, it's crucial to use a protection switch (magnetothermic differential circuit breaker) that's appropriately rated for the machine.

Using a larger circuit breaker is not a good solution, as it can lead to inadequate circuit protection and make the installation hazardous. Such modification nullifies any previous certification of the installation and may incur criminal liability in case of damage. Before connecting the power cable, check the nameplate (sec. 2.1) to ensure compatibility with the power supply.

1. Neither the manufacturer nor the dealer can be held responsible for damage to the device or personal injury resulting from incorrect application of the electrical connection procedures.
2. Ensure that the cables are not damaged, not placed under the machine, nor come into contact with hot, sharp, or abrasive surfaces.
3. The protection switch must be easily accessible.

4.3.1 - Electrical Diagram



- A – Actuator
- CA – Actuator Control Unit
- P – Pedal
- F – Phase
- N – Neutral

Figure 7 Electrical Diagram

5 - USE OF THE MACHINE

5.1 - Control Pedal

The control pedal is used to operate the rotational movement of the cradle. The motion is only activated by continuous pressing of the button corresponding to the desired direction, and releasing the buttons stops the movement.



- + button for piston extension
- button for piston retraction

Fig. 8 Control Pedal for Cradle Rotation

5.2 - Use of the Device

Before using the device, ensure that the external protective film has been completely removed without leaving any adhesive residues. If necessary, remove any residues without using sharp tools or abrasive or flammable substances.

Before starting operations, ensure that:

- No one is near the machine.
- The machine is perfectly clean.
- There are no objects or anything that may obstruct the movement of the platform.
- All components and cables are mounted and securely attached.
- The sTs Evo rotating support is securely attached to the operating table (sec. 4.2).
- Check that the connectors of the power cables, control unit, and pedal are firmly inserted into their sockets and that the electrical connection is made as described in sec. 4.3.

5.2.1 – Initial Verification Cycle

Perform the following no-load verification cycle at least once:

- 1- Ensure all general precautions outlined in the previous section (5.2) are met.
- 2- Verify the plug is inserted into an adequate power supply.
- 3- Press and hold the (+) button of the pedal (Fig. 8) to extend the piston, ensuring the cradle rotates at a consistent speed without vibrations. If it moves irregularly, stops, or doesn't start, turn off the machine, disconnect the power, don't use it, and call for service.
- 4- Hold the (+) button until the cradle automatically stops at its limit.
- 5- Press and hold the (-) button of the pedal to retract the piston, checking the cradle's rotation speed and smoothness. If it moves irregularly, stops, or doesn't start, turn off the machine, disconnect the power, don't use it, and call for service.
- 6- Hold the (-) button until the cradle automatically stops at its limit.

5.2.2 – Positioning and Securing the Animal on the Cradle

- 1- Perform steps 1 to 3 from the initial verification cycle (sec. 5.2.1).
- 2- Execute either step 4 or 6 from sec. 5.2.1, depending on the desired access side to the table.
- 3- Place the already anesthetized animal on the cradle in a supine position, with the head towards the head side and the hind legs towards the tail side.
- 4- Secure the animal to the cradle with at least two straps through the designated slots. CAUTION: Avoid passing straps under the cradle or inadvertently blocking the cradle's rotation by attaching the strap to fixed elements of the table. The fastening should be secure and stable, but not overly tight on the animal.



WARNING: Avoid passing straps under the cradle or inadvertently blocking the cradle's rotation by attaching the strap to fixed elements of the table. The fastening should be secure and stable, but not overly tight on the animal.

- 5- Perform steps 4 to 6 from the initial verification cycle, ensuring the sTs Evo table is properly secured to the operating table and the animal is adequately fixed to the sTs Evo table.
- 6- Rotate the cradle using the + or - buttons (Fig. 8) to position it in the preferred configuration for the start of the operation.

5.2.3 – Executing Rotation During Operation

- 1- Verify compliance with general precautions outlined in sec. 5.2.
- 2- Follow procedures described in sec. 5.2.1 and 5.2.2.
- 3- Rotate the cradle using the + or - buttons (Fig. 8) to the necessary configuration for optimal operation continuation.
- 4- Upon completion, execute step 4 or 6 from sec. 5.2.1, depending on the desired access side to the table.
- 5- Unfasten the animal by releasing the securing straps and place it on a stretcher.

5.2.4 – Restarting After a Sudden Stop

- 1- Check for compliance with general warnings outlined in sec. 5.2.
- 2- Ensure the obstacle causing the stop has been removed.
- 3- Perform steps 2 to 6 from the initial verification cycle (sec. 5.2.1).
- 4- Resume the previously interrupted operation.

6 - ROUTINE CLEANING

6.1 – General Information

Regular cleaning of the machine should be done at the end of each work cycle. This primarily involves removing and drying any organic residues or medicinal substances to prevent the growth and spread of molds or viruses.

- 1) Turn off the machine and unplug the power supply.
- 2) Remove the sTs Evo table from the operating table by loosening and removing all clamps.
- 3) Wash and clean the table and all its components using a clean cloth, non-abrasive cleaners, and appropriate disinfectants.

7 - MAINTENANCE

7.1 - Routine Maintenance

Routine maintenance should only be performed by skilled personnel and involves the procedures listed in the following table.



WARNING: Before performing any maintenance, turn off the machine and disconnect the power cable from the network.

COMPONENT	MAINTENANCE	OPERATION	FREQUENCY
Structure and Cradle	Cleaning	See Chapter 6	Each cycle
	Checking of Fixing Elements	See sec. 5.2.1	Semi-annual
Actuator	Checking	See sec. 7.1.1	Annual
Electrical System	Cables, Control Unit, Pedal	See sec. 7.1.2	Annual

7.1.1 – Actuator.



WARNING: The inspection of the actuator must be performed exclusively by personnel skilled in electromechanical maintenance.

The inspection involves verifying the correct functioning and power consumption of the actuator.

1. Perform the initial verification cycle (see sec. 5.2.1).
2. Electrically check the actuator's operation and visually inspect, with care, that the fixings and their supports are secure and not rusted.
3. If an anomaly is detected, disconnect the machine from the power supply and contact a qualified and authorized service center for repair.

7.1.2 – Electrical System.



WARNING: This inspection must be carried out exclusively by personnel experienced in electrical and electronic maintenance.

1. Visually inspect, with care, that the cables, electrical components, and control buttons are intact, not deteriorated, and functioning properly.
2. If any anomalies are detected, do not use the machine and contact a qualified and authorized service center for repair.

7.2 – Operating Anomalies

This chapter lists the main possible operating anomalies and some guidelines to understand and solve the problem.

IF NONE OF THESE ACTIONS CHANGE THE SITUATION, CONTACT THE NEAREST AUTHORIZED SERVICE CENTER WITH QUALIFIED PERSONNEL. NEVER ATTEMPT TO REPAIR THE MACHINE ON YOUR OWN.



WARNING: Extraordinary maintenance must be carried out exclusively by skilled and authorized personnel.

Before performing any maintenance operation, turn off the machine and disconnect the power cable from the network.

PROBLEMA	PROBABILE CAUSA	SOLUZIONE
The cradle does not rotate.	<ul style="list-style-type: none"> ● The machine is not connected to the power network. ● The transformer, control unit, pedal, or sensors are not functioning. ● The cradle has reached the right or left end of travel. 	<ul style="list-style-type: none"> ● Check the power network and protection switches. ● Perform the operations outlined in sec. 5.2.4. ● Check the connection of the pedal and actuator cables to the control unit. ● Inspect or replace the faulty component. ● Press the other button on the pedal board.
The cradle locks up or does not move smoothly.	<ul style="list-style-type: none"> ● There are obstacles in the path. ● The cradle has reached the right or left limit switch. ● The rotation structure is defective. 	<ul style="list-style-type: none"> ● Remove the obstacle. ● Press the other button on the pedal board. ● Clean the machine and check the structure and the actuator (see sec. 7.1).
Excessive noise.	<ul style="list-style-type: none"> ● The actuator is under strain. ● The rotation structure is not well secured. 	<ul style="list-style-type: none"> ● Verify that the weight of the animal is below the maximum load capacity. ● If there is any obstacle present, it should be addressed. ● Inspect the structure and actuator as outlined in section 7.1 of the manual.

Before calling for service assistance if the machine is not working:

Ensure that the device is securely connected to the electrical network. Check the fuses and the main circuit breaker to see if it has tripped.

7.3 – Spare Parts and Accessories List

The use of non-original spare parts, unless expressly authorized, voids the warranty terms and absolves the manufacturer of any damages caused by such components.

POSITION	DESCRIPTION	POSITION	DESCRIPTION	POSITION	DESCRIPTION
1 of Fig. 1	Frame support	2 of Fig.1	Cradle	3 of Fig.1	Actuator pin
4 of Fig. 1	Axis pin	5 of Fig.1	Control unit	6 of Fig.1	Control unit bracket
7 of Fig. 1	Actuator	8 of Fig.1	Pedal board	Fig. 3	Adjustable clamp
Fig. 6	Recessed fit bars				

8 - DISMANTLING

8.1 - Decommissioning and Disposal

When decommissioning the machine, ensure it becomes unusable to prevent potential harm. After disconnecting the machine from the power supply, it is recommended to detach or cut the electrical connections. For proper disposal of the device, consult local companies specialized in scrapping materials constituting the product.



Unlimited Technology srl
Centro direzionale Isola G2
napoli IT 80143
Italia

DECLARATION OF CONFORMITY

THE UNDERSIGNED Antonio Ferraro, LEGAL REPRESENTATIVE OF THE COMPANY
Unlimited Technology - Centro direzionale Isola G2 – 80143 Napoli (NA) - Italy
DECLARES THAT THE FOLLOWING MEDICAL DEVICE DISTRIBUTED BY THIS COMPANY:

Class I
Function Temporary non-invasive medical device for laparoscopic operations on animals.
Name Rotating Support.
Model sTs Evo.
Serial Number

IS IN CONFORMITY WITH THE PROVISIONS OF THE DIRECTIVES
"MACHINERY" (2006/42/EC and subsequent amendments)
"MEDICAL DEVICES" (2007/47/EC and subsequent amendments)
"ELECTROMAGNETIC COMPATIBILITY" (2004/108/EC and subsequent amendments)
AND WITH THE NATIONAL IMPLEMENTING PROVISIONS
D.Lgs 17/2010; D.lgs 37/2010; D.Lgs 194/2007

IS IN CONFORMITY WITH THE PROVISIONS OF THE FOLLOWING HARMONIZED STANDARDS:

UNI EN 60601-1: Electromedical equipment Part 1: General requirements for basic safety and essential performance
CEI EN 61557-8 1998-09 “Electrical safety in low-voltage distribution systems up to 1 kV AC and 1.5 kV DC -
Equipment for testing, measuring or monitoring the protection systems Part 8: Equipment for insulation monitoring
in IT systems”

CEI EN 61558-2-15 2001-10 “Safety of transformers for medical use”

CEI EN 60335-1: Safety of household and similar electrical appliances

UNI EN 292-1/-2/-2:A1 Safety of machinery. Basic concepts, general principles of design.

UNI EN 294 Safety of machinery. Safety distances to prevent hazard zones being reached by upper limbs.

UNI EN 953 Safety of machinery - Guards - General requirements for the design and construction of fixed and
movable guards

CEI EN 61340-5-1:2008 Protection of electronic devices from electrostatic phenomena - general requirements.

EN 50081-1 Electromagnetic compatibility: emissions

EN 50082-1 Electromagnetic compatibility: immunity

Montesarchio

Il 27/10/2021

Unlimited Technology
Legale rappresentante
Dr Antonio Ferraro