mectron
medical technology

USE AND MAINTENANCE MANUAL

PIEZOSURGERY® *touch*

Rx Only
CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed dentist.

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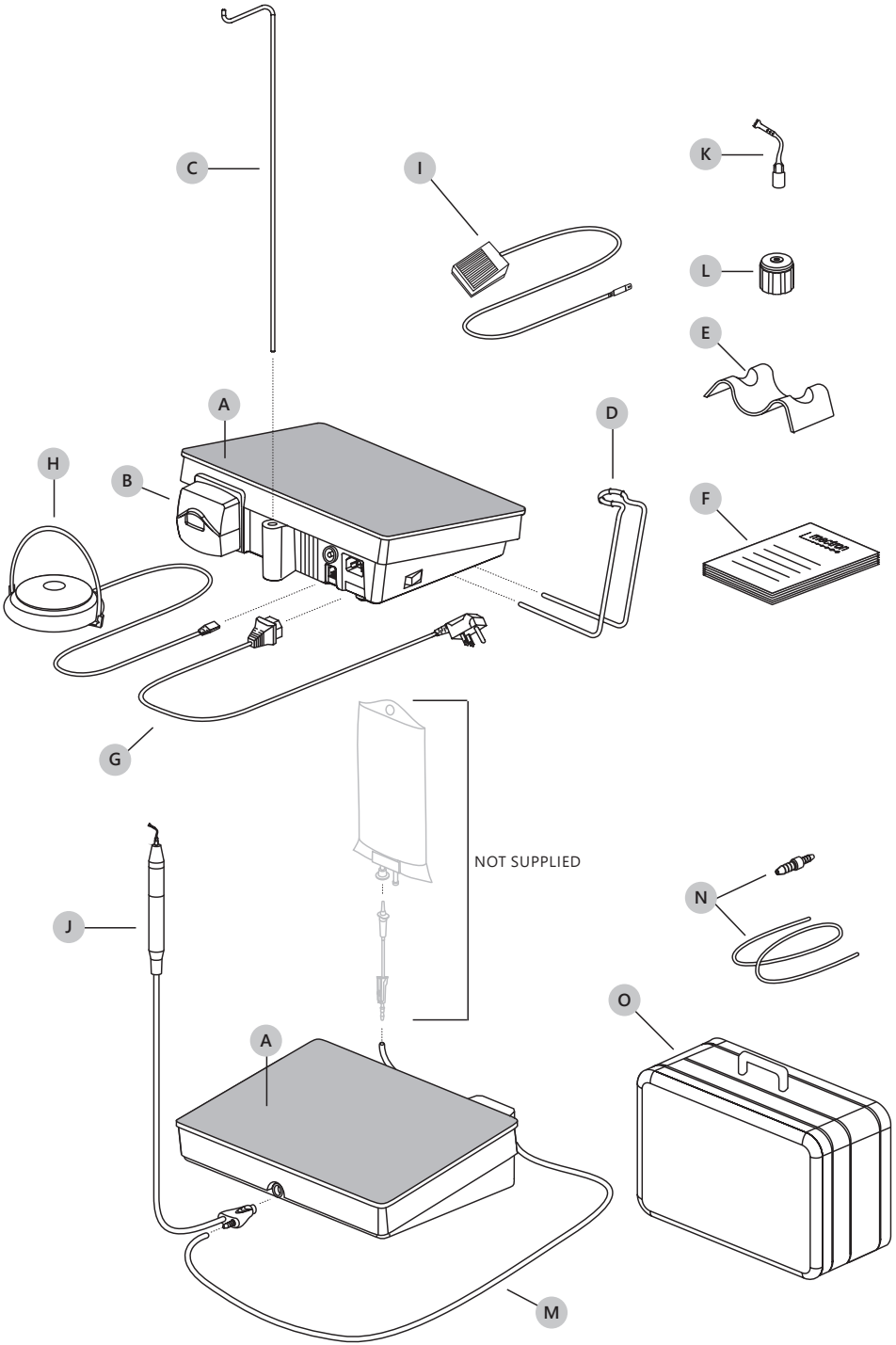
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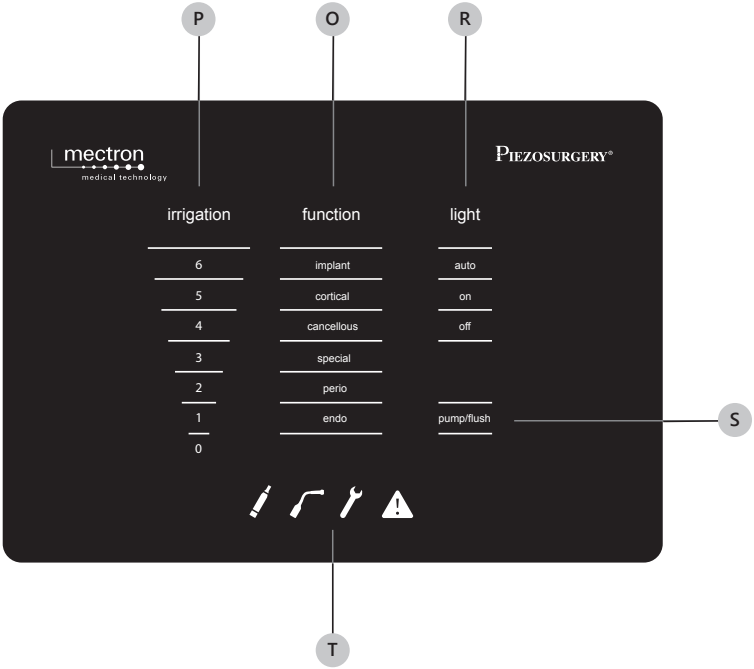
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1 INTRODUCTION

Carefully read this manual before proceeding with installation operations, use, maintenance or other intervention operations on the device. Always keep this manual at hand.

IMPORTANT: To avoid potential serious injury to the user and the patient and/or this device or other equipment, read all the "Safety precautions" present in the manual with particular attention.

The words **WARNING**, **CAUTION** and **NOTE** contained in this document, carry special meaning and must be carefully reviewed. Depending on their degree of seriousness, the safety precautions are classified as:

⚠ **WARNING:** Identifies conditions or practices that present a risk of serious injury or death to the patient and/or the user

⚠ **CAUTION:** Identifies conditions or practices that could result in minor injury or device damage

NOTE: Identifies special information to clarify or emphasize important instructions.

The purpose of this manual is to ensure that operators are aware of the safety requirements, installation procedures, and instructions for correct use and maintenance of the device and its accessories. Using this manual for purposes other than those relating to the installation, use and maintenance of the device, is strictly prohibited. The information and illustrations contained in this manual are updated as of the date of publication specified on the last page.
The manufacturer MECTRON S.p.A. is committed to the continuous updating of its products, which may entail changes to components of the device.
In case you encounter discrepancies between the descriptions found in this manual and the equipment in your possession you can:

- check for any available updates in the *section MANUALS of MECTRON website*[1];
- contact Piezosurgery Inc. Customer Service.

1.1 Intended Use of PIEZOSURGERY touch

PIEZOSURGERY touch is a piezoelectric ultrasonic device, consisting of handpiece/s and associated inserts intended for:

- Bone cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontics and surgical endodontics procedures;
- Scaling applications including:
  - Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits;
  - Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning;
  - Endodontics: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation;
  - Restorative and Prosthetics: Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.

⚠ **WARNING: Risk of explosion.**
The device cannot function in places where there is an atmosphere saturated with flammable gases (anaesthetic mixtures, oxygen, etc.).

1 manuals.mectron.com

⚠ **WARNING: Qualified and specialized personnel.** The device must be used exclusively by specialized and appropriately trained personnel such as a licensed dentist completely familiar with the required techniques and instructions for use of the equipment. The use of the device does not cause side effects if it is used correctly. An improper use might cause tissues heating.

⚠ **WARNING:** Use the device only for the intended use.
Failure to observe this precaution may cause serious injuries to the patient, the operator, and damages/breakdowns to the device.

1.2 Description of the Device

The user interface has been optimized with the PIEZOSURGERY touch making all the functions readily available by integrating them in the touch keyboard.
The PIEZOSURGERY touch is a device that uses ultrasonic piezoelectric technology to generate mechanical microvibrations of the inserts, to effectively cut mineralized tissues. This allows an efficient and safe cutting which preserves the integrity of the osteotomized surfaces.
The micrometric, ultrasonic vibrations of the inserts provide greater precision and a selective cutting action compared to traditional methods such as drills or oscillating saws (which act with macrovibrations), therefore minimizing traumatic effect on soft tissues.
The cavitation effect of the irrigating solution helps to keep the operatory field blood-free. This provides an optimal intra-operatory visual control thus increasing safety, even in areas that are anatomically most difficult to access.

1.2.1 Users

U.S. Federal law restricts this device to sale by or on the order of a licensed dentist.

1.3 Disclaimer

The manufacturer Mectron and the distributor, Piezosurgery Inc. disclaim any liability, expressed or implied, and shall have no responsibility for any direct, indirect or other damages and personal injury arising out in connection with any improper practice in the use of the device and its accessories. The manufacturer Mectron and the distributor, Piezosurgery Inc. shall be under no liability, expressed or implied, with respect to any damages (personal injury and/or damage to property) which might arise or be caused, whether by the customer or by any of the users of the product and its accessories, as result of:

1. Procedures different than those specified in the intended use of the product;
2. The environmental conditions for the preservation and storage of the device are not compliant with the precautions indicated in the Chapter 8 on page 26;
3. The device is not used in compliance with all the instructions and precautions described in this manual;
4. The electrical system of the relevant operating room is not compliant with the applicable regulations and with electrical safety requirements;
5. The assembly operations, extensions, adjustments, updates, and repairs on the device are performed by personnel not authorized by Piezosurgery Inc.;
6. Improper use, mistreatments, and/or incorrect interventions;
7. Any and all attempts to tamper with or modify the device, under any circumstance;

8. Use of non-original Piezosurgery/ Mectron inserts that damage the threading of the handpiece, thus compromising correct operation and causing risk of harm to the patient;
9. Use of non-original Piezosurgery/ Mectron inserts, even if they are used in accordance to designed and tested settings of Piezosurgery/Mectron original inserts. The correct use of the settings is guaranteed only with original Piezosurgery/Mectron inserts;
10. Lack of stock materials (handpiece, inserts, wrenches) to be used in the event of device stop due to fault or of inconveniences.

1.4 Safety Precautions

⚠ **WARNING**: **Risk of explosion.**
The device cannot operate in environments where the atmosphere is saturated with flammable gases (anaesthetic mixtures, oxygen, etc.).

⚠ **CAUTION**: In the case that the end user, when operating in his or her own medical study or clinic, must subject the electro-medical equipment and systems to periodical inspections in order to adhere to imposed requirements, the test procedures that must be applied to electro-medical equipment and systems to evaluate safety must be performed in line with norm EN 62353 'Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment'. The interval for periodic checks, in the intended operating conditions and described in this "Use and Maintenance" manual, is one year.

⚠ **WARNING**: **Checking device status before the treatment.**
Always check that there is no water underneath the device. Before every treatment, always check that the device works perfectly and that the accessories are efficient. In case you uncover operating abnormalities, do not perform the treatment. Contact Piezosurgery Inc. Customer Service if the abnormalities concern the device.

⚠ **CAUTION**: The electrical system of the premises in which the device is installed and used must be compliant to the norms in force and to the relative electrical safety precautions.

⚠ **CAUTION**: Only connect the console to hospital grade receptacles to ensure electrical grounding reliability. This device must be grounded.

⚠ **WARNING**: Do not operate the footswitch of the PIEZOSURGERY touch device when the pump head of the peristaltic pump is open. Moving parts could injure the operator.

⚠ **WARNING**: **Control of infections.**
First Use The reusable accessories (brand new or returned by service) and the single-use accessories (diamond coated inserts) are delivered in NON-STERILE conditions and must be prepared prior to use by applying the procedures described in the Cleaning and Sterilization manual provided with the device.
Every use Once used, each reusable accessory must be thoroughly reprocessed prior to reuse, according to the procedures described in the Cleaning and Sterilization manual provided with the device.

⚠ **WARNING**: **Breakage and wear-out of the inserts.** High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the insert.
Deformed or otherwise damaged inserts are susceptible to breakage during their use. These inserts must never be used.
If an insert breaks, check that none of its fragments remain in the treated part and, at the same time, apply effective suction to remove them.
The patient must be instructed to breathe through his nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken inserts.
When the nitride coating wears out, the cutting efficiency decreases; re-sharpening the insert damages it and is therefore forbidden. Check that the insert is not worn out. Use of a worn-out insert reduces the cutting performance and can cause necrosis of the bone surface treated.
During the intervention, frequently check that the insert is intact, especially in its apical part.
During the intervention, avoid prolonged contact with retractors or with metallic instrumentation in use. Do not exert excessive pressure on the inserts during their use.

⚠ **WARNING**: Diamond coated inserts are intended for single use only.

⚠ **WARNING**: Only use original Piezosurgery/Mectron inserts, accessories, and spare parts.

⚠ **WARNING**: **Contraindications.** Do not use the PIEZOSURGERY touch on patients who carry heart stimulators (Pace-makers) or other implantable electronic devices. This precaution also applies to the operator.

⚠ **WARNING**: **Contraindications. Interference from other equipment.** An electrical scalpel or other electro-surgical units near the PIEZOSURGERY touch device may interfere with its correct operation.

⚠ **CAUTION**: **Contraindications.** Do not perform treatments on metal or ceramic/porcelain prosthetic artifacts (unless otherwise specified). The ultrasonic vibration could cause decementation/loosening of such artifacts.

⚠ **WARNING**: **Contraindications. Interference with other equipment.** Although PIEZOSURGERY touch complies with standard IEC 60601-1-2, it may interfere with other equipment located nearby. PIEZOSURGERY touch must not be used near, or stacked on other devices.
If adjacent or stacked use is necessary, the PIEZOSURGERY touch and the other devices must be observed and checked to verify normal operation in the configuration in which they will be used.

⚠ **CAUTION**: **Contraindications.** Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage. The cooling process must not be accelerated.

⚠ **CAUTION**: No modification of this equipment is allowed.

1.5 Symbols

Symbol	Description	Symbol	Description
CE 0051	Class IIa device compliant with Regulation (EU) 2017/745. Notified body: IMQ S.p.A.	C N US Electrical Safety ES 60601-1	Nemko Mark UL CSA compliance
MD	Medical Device		Caution
	Consult instructions for use or consult electronic instruction for use		Manufacturer
	Date of manufacture	SN	Serial Number
LOT	Batch number	REF	Catalogue Number
#	Model number	HIBC	Health Industry Bar Code
UDI	Unique Device Identifier	QTY.1	Quantity of items in the package: 1
	Do not reuse	STERILIZE	Do not resterilize
	Use-by date	STERILE EO	Sterilized with Ethylene Oxide (EO)
NON STERILE	Non-sterile	135°C	Sterilizable up to a maximum temperature of 135° C
	Type “B” applied part		Equi-potentiality
	Alternating Current		Foot switch
I	Activation switch “on”	0	Activation switch “off”
	Earth (ground)		Dangerous voltage

Symbol	Description	Symbol	Description
	Biological risk		The device and its accessories must not be disposed of or treated as solid urban wastes
	General warning [a]		Do not touch moving parts [b]
	Temperature limit		Humidity limitation
	Atmospheric pressure limitation		Do not use if package is damaged and consult instruction for use
IP22	International Protection Code of the mechanical casing.	IP20	International Protection Code of the mechanical casing.
	Distributor	Rx Only	For US market, only. **CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a licensed dentist

a) The symbol is represented by a yellow warning triangle and a black graphical symbol.

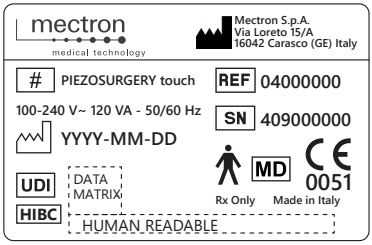
b) The symbol is represented by a red circle-with-slash and a black graphical symbol.

2 IDENTIFICATION DATA

A precise description of the model and device serial number will facilitate the After-Sales Service to answer the inquiries quickly and effectively.
Always provide this information when contacting Piezosurgery Inc. Customer Service.

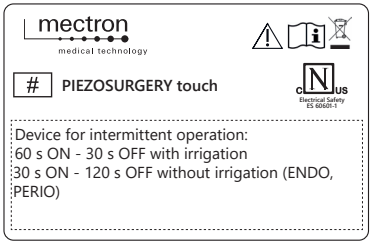
2.1 Device Identification Label

Each device has its own identification label showing its main technical specifications and the traceability data, UDI code included. The identification label is located under the device. The complete technical specifications are reported in *Chapter 8 on page 26*.



A separate label shows further symbols and characteristics of the device. This identification label is placed under the device.

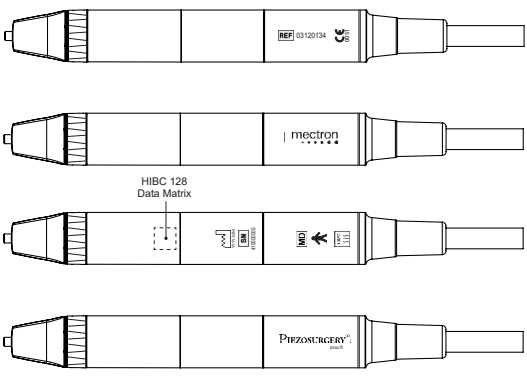
NOTE: The complete list of symbols and their description are shown in *Chapter 1.5 on page 5*.



2.2 Handpiece Identification Data

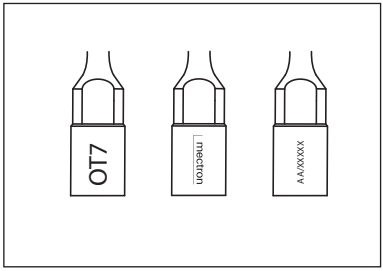
Each handpiece is laser-marked with the traceability data, UDI code included.

NOTE: The complete list of symbols and their description are shown in *Chapter 1.5 on page 5.*



2.3 Inserts Identification Data

Each insert is laser-marked with the traceability data. Their packaging contains traceability data including the UDI code



3 DELIVERY

3.1 List of the Components of PIEZOSURGERY touch

Refer to the front endpaper.
PIEZOSURGERY touch consists of:

A. Device core system;
B. Peristaltic pump;
C. Irrigation bag support rod;
D. PIEZOSURGERY touch handpiece fixed holder;
E. PIEZOSURGERY touch handpiece movable holder;
F. Use and Maintenance Manual, Cleaning and Sterilization Manual;
G. Power Cord;
H. Foot pedal with bracket, cable and connector;
I. Back-up foot pedal;
J. PIEZOSURGERY touch handpiece complete with cord and LED light front cone;

⚠ **CAUTION:** The handpiece and the cord cannot be separated.

NOTE: The stainless-steel box supplied with the PIEZOSURGERY handpiece is intended exclusively for transportation, from the working area to the decontamination area and **NOT** for the sterilization process.

K. Inserts/insert kit;

NOTE: Some inserts require specific accessories and tools for being correctly used (for example kits and / or dedicated torque wrenches). Always read and follow the assembly and cleaning instructions supplied with the insert.

L. K8 Mectron torque wrench;
M. Peristaltic pump tubing kit (The kit is composed by a set of 6 peristaltic pump tubing);
N. Bone grafting kit (optional);
O. Case.

PIEZOSURGERY touch consists of accessories that can be ordered separately. Refer to the "Packing List" included in your package, so that you may exactly know the quantity and type of the accessories supplied with the device you have purchased.
The packaging of the device cannot undergo strong impacts as contains electronic components, therefore the transport and the storage must be carried out with particular care. Do not stack more boxes in order to avoid damaging the underlying packaging.
All material shipped by Piezosurgery Inc. is controlled at the time of dispatch.
The device is shipped appropriately protected and packaged.
Upon receipt of the device, check for any possible damage caused during transport and in case any damage and/or defects is found, complain to the transporter.
Keep the packaging in case there is a necessity to send any item to Piezosurgery Inc. Customer Service and to store the device during long periods of inactivity.

⚠ **WARNING**: Before starting to operate with the device, make sure that you have stock material (handpiece, inserts, wrenches) available to use in case the device stops due to a fault or of inconveniences.

4 INSTALLATION

The device must be installed in a suitable and convenient place for its use.
Place the console on a sturdy, flat ,dry and horizontal surface.
Position the device in way so that the power plug is always, easily reachable, since this plug is considered as a disconnecting means.
Take care to ensure that cables do not hinder the free movement of personnel.

4.1 Safety Requirements in the Installation Phase

⚠ **WARNING**: **Contraindications. Interference with other equipment.** Although PIEZOSURGERY touch complies with standard IEC 60601-1-2, it may interfere with other equipment located nearby. PIEZOSURGERY touch must not be used near, or stacked on other devices.
If adjacent or stacked use is necessary, the PIEZOSURGERY touch and the other devices must be observed and checked to verify normal operation in the configuration in which they will be used.

⚠ **WARNING**: **Contraindications. Interference from other equipment.** An electrical scalpel or other electro-surgical units near the PIEZOSURGERY touch device may interfere with its correct operation.

⚠ **CAUTION**: The electrical system of the premises in which the device is installed and used must be compliant to the norms in force and to the relative electrical safety precautions.

⚠ **CAUTION**: Only connect the console to hospital grade receptacles to ensure electrical grounding reliability. This device must be grounded.

⚠ **WARNING**: **Do not install the device in places where there is a risk of explosion.** The device cannot operate in environments where anesthetic or flammable mixtures are present.

⚠ **WARNING**: Do not operate the footswitch of the PIEZOSURGERY touch device when the peristaltic pump cover is open. Moving parts could injure the operator.

⚠ **WARNING**: Install the device in a place protected against collisions or against accidental sprays of water or liquids.

⚠ **WARNING**: Do not install the device above or near heat sources. Foresee adequate air circulation around the device when installing it. Leave adequate space, especially near the fan placed on the back part of the device.

⚠ **CAUTION**: Do not expose the device to direct sunlight or to sources of UV light.

⚠ **CAUTION**: The device can be transported, but it must be handled with care when it is displaced. Position the foot pedal on ground, so that it can only be activated intentionally by the operator.

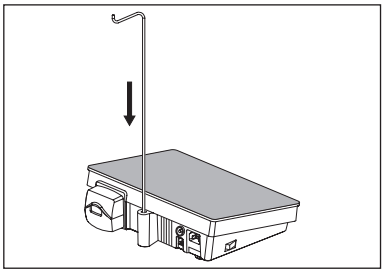
⚠ **CAUTION**: Before connecting the handpiece cord to the device, make sure that the electrical contacts are perfectly dry. If need be, dry them with compressed air.

⚠ **CAUTION**: No modification of this equipment is allowed.

4.2 Connecting the Accessories

1

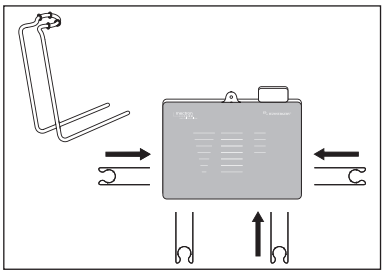
Insert the irrigation bag support rod in the dedicated hole;



2

Insert the handpiece fixed holder in its housing.
The handpiece fixed holder must be used only to hold the PIEZOSURGERY handpiece.

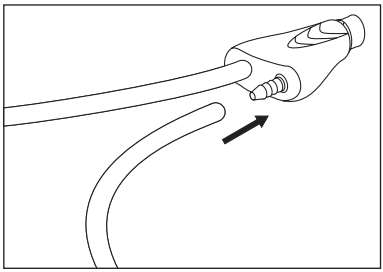
NOTE: The handpiece fixed holder can be placed in 4 different positions: right side, front right side, front left side and left side;



3

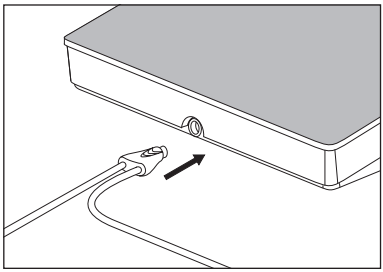
Insert the peristaltic pump tubing, supplied with the device, into the connector of the handpiece cord;

⚠ **CAUTION**: Use original PIEZOSURGERY/Mectron peristaltic pump tubing only, as damage or substandard performance could result.



4

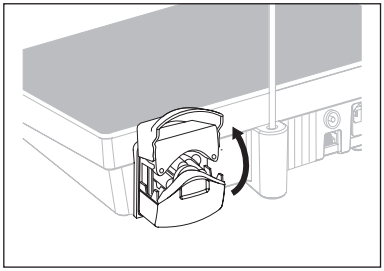
With the writing UP facing upward, insert the connector of the handpiece cord into the handpiece receptacle on the PIEZOSURGERY touch console;



5

Insert the peristaltic pump tubing into the peristaltic pump proceeding as follows:

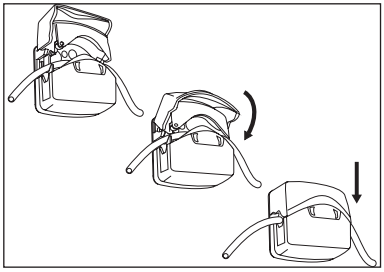
- Open the peristaltic pump cover completely;



6

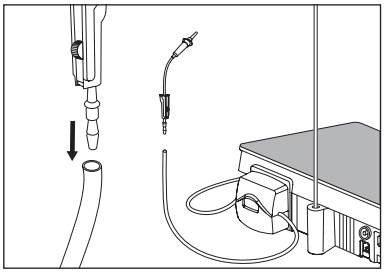
- Insert the tubing by placing it over the pump rollers;
- Close the peristaltic pump cover completely;

⚠ **WARNING:** Do not operate the footswitch of the PIEZOSURGERY touch device when the peristaltic pump cover is open. Moving parts could injure the operator.



7

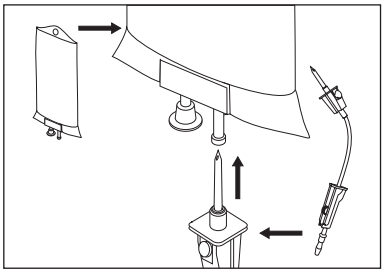
Connect the peristaltic pump tubing to the flow adjuster (not supplied);



8

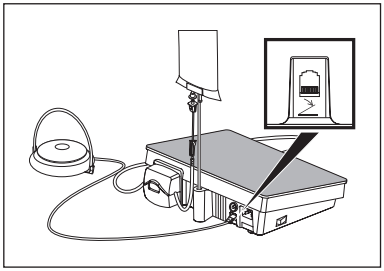
Connect the flow adjuster (not supplied) to the liquid bag used for the treatment (bag not supplied). Hang the bag to its specific support rod;

NOTE: The irrigation bag holder stand must be used with bags of up to a maximum of 1000 ml capacity.



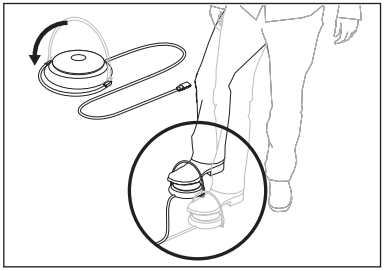
9

Connect the foot pedal to the back of the device in the socket marked with the symbol ⊿, using the foot pedal cable plug, ensuring it clicks into place;



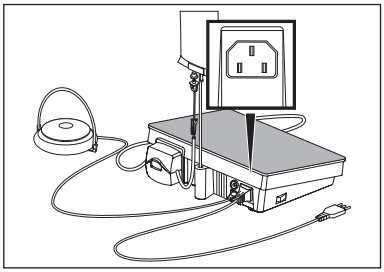
NOTE: The foot pedal is provided with a bracket that, if positioned vertically, enables it to be moved to the most appropriate place for use, with no need to touch it with hands.

The bracket can also be positioned horizontally, if not in use;



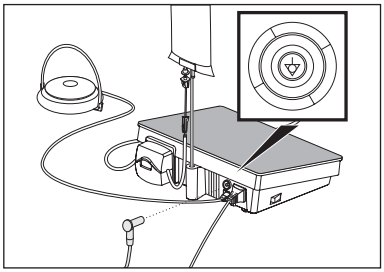
10

Connect the power supply cord into the receptacle on the back of the console. Connect it only to hospital grade receptacles;



11

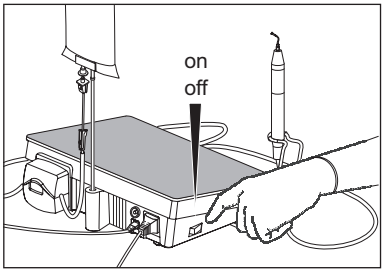
Equipotential plug: The device is equipped with an additional equipotential plug located on the rear of the console.
This plug is in accordance with DIN 42801. Insert the connector of the equipotential cord (optional) to the plug on the rear of the device's console.
The purpose of additional potential equalization is to reduce differences of potential which can occur during operation between the device's body and conductive parts of other objects within the medical environment.



5 USE

5.1 Switching the Device On and Off

Switching the Device On
To switch the device on, turn the switch button located on the left side of the device to position "I", taking care not to press the foot pedal down during this stage.
Four symbols light up on the device (ref. T inside the cover) and progressively switch off. When this sequence is completed, the device is set to default parameters and it is ready to use.

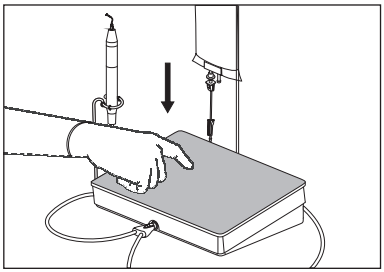


Switching the Device Off
To switch the device off, turn the switch button located on the left side of the device to position "0", taking care not to press the foot pedal down during this stage. The device turns off.

NOTE: When the PIEZOSURGERY touch is switched on, the following default settings are applied: "function" ENDO, "irrigation" 3, "light" OFF.

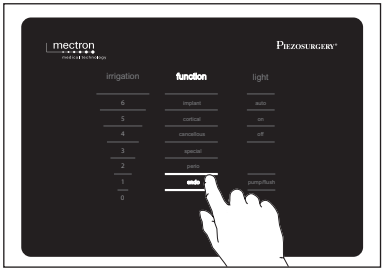
5.2 Description of the Keyboard

TOUCH KEYBOARD
The user can configure the device by simply touching on the touch keyboard. Depending on the selected setting, the electronic feedback system automatically adjusts the correct operating frequency.

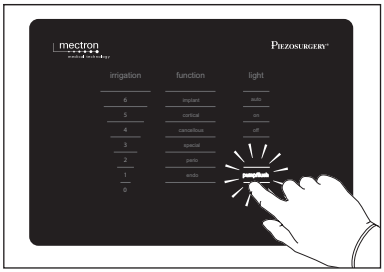


FUNCTIONS (Ref. O front endpaper)
Depending on the type of clinical application, it is possible to choose one of the 6 options available from the "function" list:

- **ENDO**: dedicated to endodontic surgery, to Schneider's membrane detachment and conventional endodontic treatments;
- **PERIO**: dedicated to periodontal surgery and conventional scaling and periodontal treatments;
- **SPECIAL**: dedicated only to the inserts for osteotomies with thickness of 0.35 mm and for prosthetic applications;
- **CANCELLOUS**: dedicated to the cutting and removal of poorly mineralized bone;
- **CORTICAL**: dedicated to the cutting and removal of highly mineralized bone;
- **IMPLANT**: dedicated to bone perforation in the technique of the implant site preparation.



FILLING AND FLUSHING THE IRRIGATION CIRCUIT (Ref. S front endpaper)
The device is equipped with the "pump/flush" key which, depending on the mode of use, allows to perform the PUMP function or the FLUSH function.
The PUMP function can be used at the beginning of the treatment, to flush the entire irrigation line up to the insert, so that the surgery can be started with the necessary irrigation (see Chapter 5.4 on page 21).
The FLUSH function allows to run a flushing cycle of the irrigation circuit of the handpiece(s) used during the treatment.



⚠ **CAUTION**: The FLUSH function must be used after every patient treatment, before starting the cleaning and sterilization procedures. Failure to carry out flushing of the handpiece tubing will lead to salt crystallisation that can seriously damage the device.

⚠ **WARNING:** The "FLUSH" function does not substitute for the cleaning and sterilization procedures described in the Cleaning and Sterilization manual. After having carried out the "FLUSH" function, the cleaning and sterilization procedures must be followed meticulously in order to prepare the device accessories ready for the next patient and minimize any risk of patient-to-patient contamination.

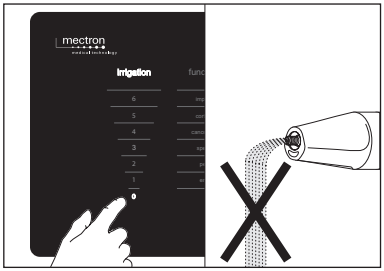
IRRIGATION (Ref. P front endpaper)
The capacity of the peristaltic pump can be adjusted by selecting the numbers on the touch keyboard in the "irrigation" column.
7 capacity levels are available:

- 0 = no operation of the pump: no irrigation outflows from the insert
- From 1 to 6= the pump flow ranges from 8 ml/min to approximately 75 ml/min.

The irrigation levels available depends on the type of function selected, in the particular:

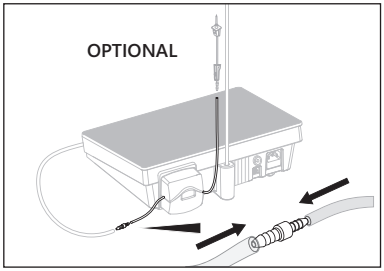
- ENDO - 7 flow levels: from 0 to 6 (from 0 to approximately 75ml/min)
- PERIO - 7 flow levels: from 0 to 6 (from 0 to approximately 75ml/min)
- SPECIAL - 6 flow levels: from 1 to 6 (from 8 to approximately 75ml/min)
- CANCELLOUS - 6 flow levels: from 1 to 6 (from 8 to approximately 75ml/min)
- CORTICAL - 6 flow levels: from 1 to 6 (from 8 to approximately 75ml/min)
- IMPLANT - 6 flow levels: from 1 to 6 (from 8 to approximately 75ml/min)

NOTE: treatment without irrigation is possible only with the ENDO and PERIO functions, setting the irrigation capacity level on "0".



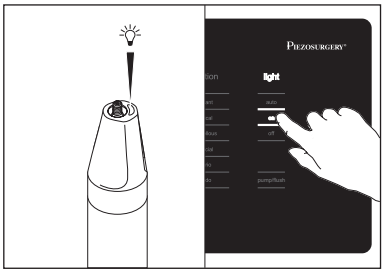
In the event that an irrigation capacity lower than 8 ml/min is required, use the "bone grafting kit" (accessory that can be ordered separately), inserting it between the irrigation set and the tube in silicon of the handpiece, making it pass through the peristaltic pump, and selecting 1 as the level of irrigation.

⚠ **WARNING:** If the "bone grafting kit" tube is kept inserted for the entire duration of the intervention, the capacity of the pump on all its levels is limited, independently of which insert is used.



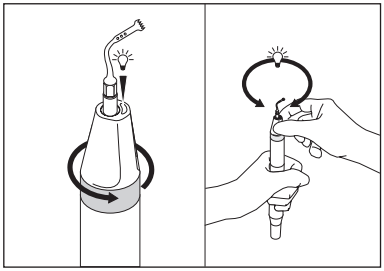
LIGHT (Ref. R front endpaper)
Depending on the type of handpiece and operation that needs to be performed, it is possible to choose 3 options from the "light" list:

- By choosing the AUTO option, the LED light on the front terminal of the handpiece is switched on by pressing the foot pedal, and automatically switches off 3 seconds after the pedal is released.
- By choosing the ON option, the LED light on the front terminal of the handpiece stays on permanently, regardless of whether pressure is applied on the foot pedal or not. The light switches off 100 seconds after the last pressure of the foot pedal and the option shifts from ON to AUTO.
- By choosing the OFF option, the LED light on the front terminal of the handpiece stays off permanently.

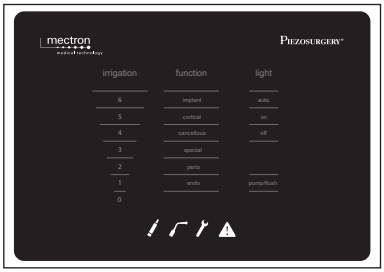


The position of the LED light on the front terminal of the handpiece can be adjusted in the following way:

16. Hold the body of the handpiece and lightly unscrew the metal ring nut located at the base of the front terminal, rotating it counter-clockwise.
17. Rotate the front terminal so that the LED light goes into the desired and necessary position.
18. To fasten it into position, screw the metal ring nut, rotating it clockwise.



SYMBOLS (Ref. T front endpaper)
PIEZOSURGERY touch is equipped with a diagnostic circuit that allows to detect operating abnormalities and to view their type on the keyboard via their relative symbol.
To help the user identify the malfunctioning part, four symbols are foreseen which are described in Chapter 9.1 on page 35.



5.3 Safety Requirements Before and During Use

⚠ **WARNING**: Before starting to operate with the device, make sure that you have stock material (handpiece, inserts, wrenches) available to use in case the device stops due to a fault or of inconveniences.

⚠ **CAUTION: Contraindication.** Do not perform treatments on metal or ceramic/porcelain prosthetic artifacts (unless otherwise specified). The ultrasonic vibration could cause decementation/loosening of such artifacts.

⚠ **WARNING**: **Contraindications.** Do not use PIEZOSURGERY touch on patients who carry heart stimulators (Pace-makers) or other implantable electronic devices. This precaution also applies to the operator.

⚠ **WARNING**: **Checking device status before the treatment.** Always check that there is no water underneath the device. Before every treatment, always check that the device works perfectly and that the accessories are efficient. In case you uncover operating abnormalities, do not perform the treatment. Contact Piezosurgery Inc. if the abnormalities concern the device.

⚠ **CAUTION: FLUSH function.** After the device is used with aggressive and non-aggressive solutions, it is necessary to perform a flushing cycle on the tubes and the handpiece with the FLUSH function (see Cleaning and Sterilization Manual). If the tubes are not cleaned, the crystallization of the salts may seriously damage the device.

⚠ **CAUTION: Contraindications.** Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage. The cooling process must not be accelerated.

⚠ **WARNING**: **Infections control.**
First Use The reusable accessories (brand new or returned by service) and the single-use accessories (diamond coated inserts) are delivered in NON-STERILE conditions and must be prepared prior to use by applying the procedures described in the Cleaning and Sterilization manual provided with the device.
Every use Once used, each reusable accessory must be thoroughly reprocessed prior to reuse, according to the procedures described in the Cleaning and Sterilization manual provided with the device.

⚠ **CAUTION: The electrical contacts inside the cord connector must be dry.** Before connecting the handpiece to the device, make sure that the electrical contacts of the connector are perfectly dry, especially after the sterilization cycle in autoclave. If need be, dry the contacts by blowing compressed air onto them.

⚠ **CAUTION: FLUSH function.** The FLUSH function must be used after every treatment, before starting the cleaning and sterilization procedures.

⚠ **WARNING**: To provide adequate cooling for the handpiece, always activate it with the irrigation circuit correctly installed and filled. To fill the irrigation circuit, always use the PUMP function.

⚠ **WARNING**: **Treatments that require irrigation.** Always check operation of the irrigation before and during use. Make sure the fluid outflows from the insert.
Do not use the device if the irrigation does not work or if the pump is defective.

⚠ **WARNING**: **Only use original PIEZOSURGERY/Mectron inserts, accessories, and spare parts.**

⚠ **WARNING**: **Use of non-original PIEZOSURGERY/Mectron inserts:** this use entails finite damage to the handpiece threading, thus compromising correct operation and risking to cause harm to the patient.

⚠ **CAUTION:** Do not activate the handpiece while the insert is in contact with the part to be treated. Doing so, will not allow the electronic control circuit of the console to recognize the best point of resonance of the insert, required for efficient and optimum performance.

⚠ **WARNING**: Before every treatment, make sure that the insert appropriate for the treatment is inserted on the handpiece. Exclusively use the PIEZOSURGERY/Mectron torque wrench to fasten the insert to the handpiece. Do not use any other tools, such as pliers, pincers, etc.

⚠ **WARNING**: The patient must not come into contact with the device body or the foot pedal.

⚠ **WARNING**: Do not change the insert or carry out any maintenance activities when the handpiece is operating; the operator may be injured.

⚠ **CAUTION**: Never force the cord-handpiece connector into its seat on the device as the cord-handpiece connector and/or the device can be damaged. If the connector cannot be easily fitted into its seat, probably the connector and its seat do not correctly match. Ensure that the connector index point of the cord-handpiece is placed upwards.

⚠ **CAUTION**: To avoid damaging the foot pedal cable, connect and/or disconnect it, holding it by the connector only. Never pull the cable.

⚠ **CAUTION**: Do not twist or rotate the foot pedal cable connector when inserting or removing it. Twisting can damage the connector.

⚠ **WARNING**: **Breakage and wear-out of the inserts.** High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the insert. Do not bend, change shape of, or re-sharpen an insert in any way. Bending an insert or applying leverage on it can lead to its breakage. Deformed or otherwise damaged inserts are susceptible to breakage during their use. These inserts must never be used.
Excessive pressure on the inserts during their use can lead to their breakage. If an insert breaks, check that none of its fragments remain in the treated part and, at the same time, apply effective suction to remove them.
The patient must be instructed to breathe through his nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken inserts. When the nitride coating wears out, the cutting efficiency decreases; re-sharpening the insert damages it and is therefore forbidden. Check that the insert is not worn out. Use of a worn-out insert reduces the cutting performance and can cause necrosis of the bone surface treated.
During the intervention, frequently check that the insert is intact, especially its top.
During the intervention, avoid prolonged contact with retractors or with metallic instrumentation in use.

⚠ **WARNING**: Before using the device, check that the irrigation tube clamps/roller are open. After surgery, close the clamps/roller before disconnecting the irrigation kit from the physiological irrigation bag.

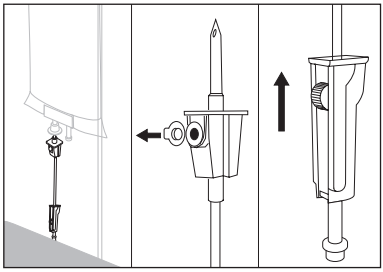
5.4 Instructions for Use

After having connected all the accessories as described in *Chapter 4.2 on page 11*, proceed as follows:

1

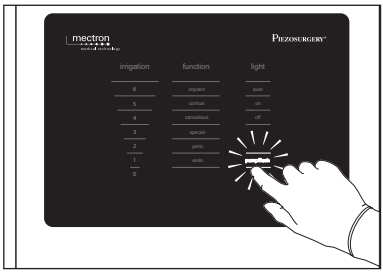
Open the air inlet on the spike, before proceeding with the operation.
Open the irrigation tube clamps/roller, if closed;

NOTE: Before using the device, check that the irrigation tube clamps/roller are open. After surgery, close the clamps/ roller before disconnecting the irrigation kit from the physiological irrigation bag.



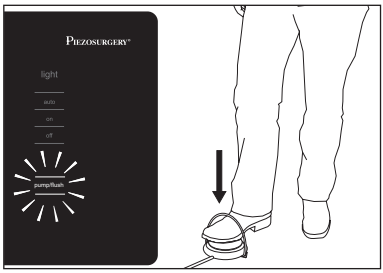
2

To fill the irrigation circuit, use the PUMP function by selecting PUMP/FLUSH on the touch keyboard: all the other selection options present on the display are disabled, and the PUMP/FLUSH writing flashes;



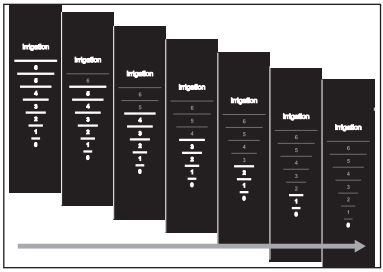
3

While the PUMP/FLUSH wording is flashing, press the foot pedal once and release it; the PUMP/FLUSH stops flashing and the irrigation circuit starts to fill up;



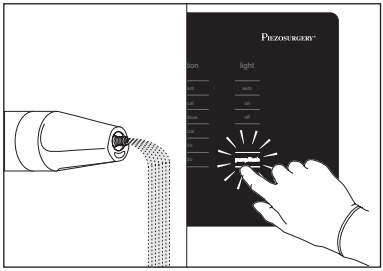
4

As soon as the peristaltic pump starts, the entire scale of values of the "irrigation" section lights up and during the liquid passage, the value of the irrigation shifts from 6 to 0;



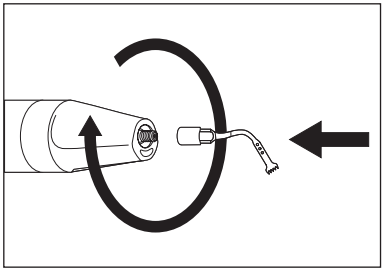
5

The cycle can be interrupted as soon you see liquid out-flowing from the PIEZOSURGERY touch handpiece, by pressing PUMP/FLUSH again or, alternatively, by pressing the foot pedal. The PUMP function is disabled and the keyboard is enabled again, and displays the last setting used;



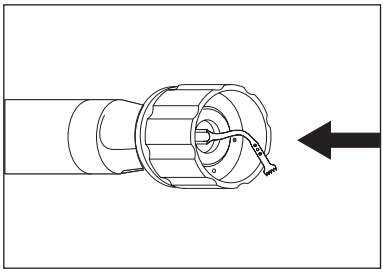
6

Screw the chosen insert onto the PIEZOSURGERY touch handpiece, till the end of the threading;



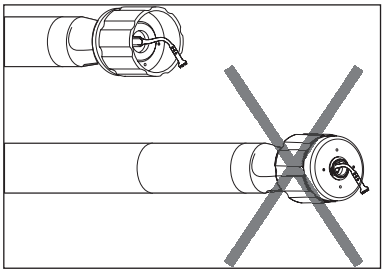
7

Tighten the insert by using the PIEZOSURGERY/Mectron torque wrench. To correctly use the PIEZOSURGERY/ Mectron torque wrench, operate as follows:



8

Place the insert into the wrench as shown;

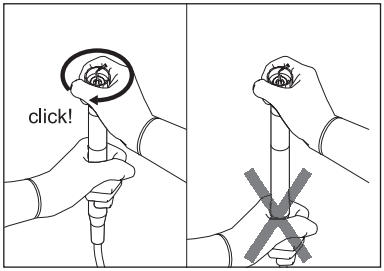


Hold the central body of the handpiece firmly.

⚠ **CAUTION:** The handpiece must not be grabbed by its terminal part and/ or cord, but only by its central body. The handpiece must not be rotated, but must be grasped firmly, and you must only rotate the wrench.

Turn the wrench in a clockwise direction until the clutch engages (the outer part of the wrench slips, compared to the handpiece, producing a mechanical "CLICK" sounds). The insert is now properly tightened;

9

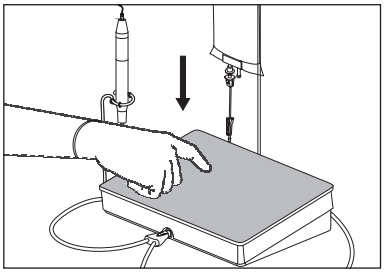


On the keyboard, select the type of function, the irrigation level and the light option, if required.

⚠ **CAUTION:** For the correct operating parameters to be adopted for a specific insert, refer to the Chart annexed to this manual titled "Appropriate settings for the inserts on the PIEZOSURGERY touch" or the illustrative leaflet of the purchased PIEZOSURGERY/Mectron insert.

NOTE: Check the level of physiological solution contained in the irrigation bag. Replace the irrigation bag with a new one before it is completely empty.

10



5.5 Important Information on Inserts

⚠ **WARNING:**

- **Diamond coated inserts**
  Diamond coated inserts are SINGLE USE. The diamond coated inserts are intended to be used on an individual patient during a single surgical procedure and then discarded.
  The diamond coated inserts cannot therefore be reprocessed since they cannot be cleaned properly.
  Bone and soil residues might remain adhered to the diamond coating even after cleaning and sterilization and enter into the oral cavity of another patient
- When the titanium nitride coating is visibly worn out, the insert must be replaced. Use of an overly worn out insert reduces its cutting efficiency.
- Do not activate the handpiece while the insert is in contact with the treated part, so that the electronic circuit can recognize the best point of resonance of the insert and allow its optimal performance.
- Check the condition of wear of the insert and that it is intact before and during every use. In the event that a drop in performance becomes apparent, proceed to replace it.
- Use original PIEZOSURGERY/Mectron inserts only. Use of non-original inserts, in addition to voiding the warranty, damages the threading of the PIEZOSURGERY touch handpiece, with the risk of no longer being able to screw the original inserts correctly during subsequent use. Moreover, the device settings are tested and guaranteed to operate correctly only when original PIEZOSURGERY/Mectron inserts are used.
- Do not change the shape of the insert in any way by either bending or filing it. This could cause it to break.
- Do not use an insert that has suffered any type of deformation.
- Do not attempt to sharpen the insert used.
- Always check that the threaded parts of the insert and of the handpiece are perfectly clean – see the Cleaning and Sterilization Manual.
- If excessive pressure is applied on the insert, it can cause the insert to break and possibly harm the patient.
- For information on how to correctly use the inserts, refer to the annexed sheet “Appropriate settings for the inserts on the PIEZOSURGERY touch” or the illustrative leaflet of the PIEZOSURGERY/ Mectron insert you’ve purchased.
- Before using PIEZOSURGERY touch, make sure you have prepared the operatory site by having first moved away the soft tissues, to avoid damaging them. It may happen that, while cutting the bone, accidental contact of certain parts of the insert with the soft tissues inflicts small traumas. To minimize this risk, use specific protective instruments.

6 MAINTENANCE

If the device is not used for a long time, observe the following recommendations:

1. Run a complete cleaning cycle on the irrigation circuit with the FLUSH function (see the Cleaning and Sterilization Manual);
2. Disconnect the device from the mains;
3. In case of a long period of inactivity, place the device back in its original packaging and store it in a safe area;
4. Before using the device again, clean and sterilise the handpiece and the wrench according to the instructions provided in the Cleaning and Sterilisation Manual;
5. Check that the inserts are not worn out, deformed, or broken, placing special attention to the integrity of their tip.

⚠ **WARNING:** Regularly check that the power supply cord is in good condition. If damaged, replace it with an original PIEZOSURGERY/Mectron spare part.

7 DISPOSAL METHOD AND PRECAUTIONS

⚠ **WARNING: Hospital waste.**
Treat the following items as hospital waste:

- Inserts: when they are worn out or broken;
- Irrigation set: at the end of each intervention;
- Peristaltic pump tube: after 8 sterilization cycles;
- Torque wrench for inserts: when worn out or broken.

Disposable materials and materials that imply a biological risk ☣ must be disposed of in accordance with current local regulations governing hospital waste.

The PIEZOSURGERY touch must be disposed of and treated as a waste requiring separate collection.
The customer is entitled to deliver the old device for disposal to the retailer supplying the new equipment. Instructions on correct disposal are available from Mectron.
Non-compliance with the previous points may produce a fine in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive.

8 TECHNICAL SPECIFICATIONS

Device compliant with Regulation (EU) 2017/745	Classe IIa
Classification as per IEC/EN 60601-1	I Applied part type B (insert) IP 20 (device) IP 22 (foot pedal - FS-01 model)
Essential performance	According to the standard IEC 80601-2-60 the device has no essential performance.
Device for intermittent operation	60sec. ON - 30sec. OFF with irrigation 30sec. ON - 120sec. OFF without irrigation (ENDO, PERIO)
Power supply voltage	100-240 V~ 50/60 Hz
Max. power consumption	120 VA
Fuses	Type 5 x 20 mm, T 2AL, 250V
Operating frequency	Automatic scan From 24 KHz to 36 KHz
Power settings	ENDO PERIO SPECIAL CANCELLOUS CORTICAL IMPLANT
Peristaltic pump capacity	Adjustable on the touch screen: ENDO / PERIO - 7 flow levels: from 0 to 6 (from 0 to approximately 75ml/min) SPECIAL / CANCELLOUS / CORTICAL / IMPLANT - 6 flow levels: from 1 to 6 (from 8 to approximately 75ml/min)
LED system of the handpiece	Light function on AUTO: LED system of the handpiece switches on as soon as the device starts to operate and switches off 3 seconds after the foot pedal is released. Light function on ON: The LED of the handpiece is always on; after 100 seconds of foot pedal disuse it switches off by itself and the light function moves into position AUTO. Light Function on OFF: The LED of the handpiece is always off. White LED light power risk free according to IEC/EN 62471.
APC circuit protections	No handpiece detected Cord interruption Insert not tightened correctly or broken

Operating conditions	from 10 °C to 40 °C Relative humidity from 30% to 75% Air pressure P: 800hPa/1060hPa
Transport and storage conditions	from -10 °C to 60 °C Relative humidity from 10% to 90% Air pressure P: 500hPa/1060hPa
Peristaltic pump tubing	It is advisable not to exceed 8 sterilization cycles
Altitude	Less than or equal to 2000 meters
Weight and size	3,2Kg 300 x 250 x 95 mm (L x l x H)[a)]

a) **W = width ; L = length ; H = height**

8.1 Electromagnetic Compatibility IEC/EN 60601-1-2

⚠ **WARNING: Contraindications. Interference with other equipment.** Though compliant with the standard IEC 60601-1-2, PIEZOSURGERY touch may nonetheless interfere with other devices nearby. PIEZOSURGERY touch must not be used near to or stacked on other devices. If adjacent or stacked use is necessary, PIEZOSURGERY touch and the other devices must be observed and checked to verify normal operation in the configuration in which they will be used.

⚠ **WARNING:** Portable and mobile radio communication appliances may affect proper device operation.

⚠ **WARNING: Contraindications. Interference from other equipment.** An electrical scalpel or other electro-surgical units near the PIEZOSURGERY touch device may interfere with its correct operation.

⚠ **WARNING:** The device requires specific EMC precautions and must be installed and commissioned according to the EMC information provided in this chapter.

⚠ **WARNING:** Only use original PIEZOSURGERY/Mectron accessories and spare parts. The use of cables and accessories not supplied by PIEZOSURGERY/ Mectron might negatively affect the EMC performances.

8.1.1 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

PIEZOSURGERY touch is intended for use in the electromagnetic environment specified below. The customer or the user of PIEZOSURGERY touch should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	PIEZOSURGERY touch only uses RF energy for internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF Emissions CISPR 11	Class B	PIEZOSURGERY touch is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions of fluctuations voltage/flicker IEC 61000-3-3	Compliant	

8.1.2 Accessible Parts of the Casing

PIEZOSURGERY touch is designed to operate in the electromagnetic environment specified below.
The customer or the user of PIEZOSURGERY touch should ensure that it is used in such environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30 %.
Radiated RF EM fields [a)]	IEC 61000-4-3	3 V/m [f)] 80 MHz - 2,7 GHz [b)] 80 % AM a 1 kHz [c)]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See *Chapter 8.1.4 on page 34*	
RATED power frequency magnetic fields [d)]	IEC 61000-4-8	30 A/m 50 Hz o 60 Hz	The magnetic fields at the mains frequency should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See *Chapter 8.1.5 on page 35*	Portable and mobile RF communication devices shall be used with a separation distance of at least 0,15 m from the field sources.

a) The interface between the PATIENT physiological signal simulation, if used, and the PIEZOSURGERY touch shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the PIEZOSURGERY touch.

b) PIEZOSURGERY touch that intentionally receives RF electromagnetic energy for the purpose of its operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) Void

f) Before modulation is applied.

8.1.3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

8.1.3.1 Power Connection A.C. Input

PIEZOSURGERY touch is designed to operate in the electromagnetic environment specified below.
The customer or the user of PIEZOSURGERY touch should ensure that it is used in such an environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrical fast transients / bursts [l) o)]	IEC 61000-4-4	±2 kV on contact 100 KHz repetition frequency	The quality of the network voltage should be that of a typical commercial or hospital environment.
Surges [b) j) o)] Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Surges [b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V [m)] 0.15 MHz - 80 MHz 6 V [m)] in the ISM bands between 0.15 MHz and 80 MHz [n)] 80 % AM at 1 KHz [e)]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.
Voltage dips [f) p) r)]	IEC 61000-4-11	0% UT; 0,5 cycle [g)] At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)]	The quality of the network voltage should be that of a typical commercial or hospital environment.
		0 % UT; 1 cycle e 70 % UT; 25/30 cycle [h)] Single phase: at 0°	
Voltage interruptions [f) i) o)]	IEC 61000-4-11	0% UT; 250/300 cycle [h)]	The quality of the network voltage should be that of a typical commercial or hospital environment.

a) Void.

b) All PIEZOSURGERY touch cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150 Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEMS. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.

g) Applicable only to PIEZOSURGERY touch connected to single-phase a.c. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). PIEZOSURGERY touch with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j) ME EQUIPMENT and ME SYSTEMS that does not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).

k) Not applicable to CLASS II PIEZOSURGERY touch.

l) Direct coupling shall be used.

m) r.m.s. , before modulation is applied.

n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.

p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.

q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT shall provide BASIC SAFETY during and after the test.

r) For ME E QUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the power input voltage specified in Table 1 - “Power input voltages and frequencies during the tests” of the IEC 60601-1-2:2014/AMD1:2020.

8.1.3.2 Points of Contact with the Patient

PIEZOSURGERY touch is designed to operate in the electromagnetic environment specified below.
The customer or the user of PIEZOSURGERY touch should ensure that it is used in such an environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) [c]	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30 %.
Conducted disturbances induced by RF fields [a]	IEC 61000-4-6	3 V [b] 0.15 MHz - 80 MHz 6 V [b] in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 KHz	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.

a) The following apply:

- All PATIENT-COUPLED cables shall be tested, either individually or bundled
- PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0, 15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18, 17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29, 7 MHz and 50,0 MHz to 54,0 MHz.

b) R.M.S., before modulation is applied.

c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

8.1.3.3 Parts Accessible to the Input / Output Signals

PIEZOSURGERY touch is designed to operate in the electromagnetic environment specified below.
The customer or the user of PIEZOSURGERY touch should ensure that it is used in such an environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) [e]	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30%.
Electrical fast transients / bursts [b] [f]	IEC 61000-4-4	±1 kV on contact 100 KHz repetition frequency	The quality of the network voltage should be that of a typical commercial or hospital environment.
Surges Line-to-ground [a]	IEC 61000-4-5	± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields [d] [g] [j] [k]	IEC 61000-4-6	3 V [h] 0.15 MHz - 80 MHz 6 V [h] in the ISM bands between 0.15 MHz and 80 MHz [i] 80 % AM a 1 KHz [c]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.

a) This test applies only to output lines intended to connect directly to outdoor cables.

b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Calibration for current injection clamps shall be performed in a 150 Ω system.

e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

f) Capacitive coupling shall be used.

g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

h) R.M.S., before modulation os applied.

i) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0, 15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18, 17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29, 7 MHz and 50,0 MHz to 54,0 MHz.

j) See IEC 61000-4-6:2013, Annex B, for modified start frequency versus cable length and equipment size.

k) SIP/SOPS whose maximum cable length is less than 1 m are excluded.

8.1.4 Specifications of the tests for the Immunity of the Accessible Parts of the Casing to the Wireless RF Communications Device

PIEZOSURGERY touch is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The customer or the user of PIEZOSURGERY touch can help prevent electromagnetic interference by ensuring a minimum distance between the mobile and portable RF (transmitters) communication devices and PIEZOSURGERY touch, as recommended, in relation to the maximum output power of radiocommunications equipment.

Test Freq. (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Max power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 Band LTE 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 Band LTE 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulateci using a 50 % duty cycle square wave signal at 18 Hz. While it does noi represent actual modulation, it would be worst case.

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the PIEZOSURGERY touch may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

⚠ **WARNING:** Portable RF communication equipment (including peripheral devices as antenna cables and external antennas) must not be used closer than 30 cm (12 inches) to any part of the device PIEZOSURGERY touch, including the cables specified by the manufacturer. Otherwise, there may be a performance degradation of these devices.

8.1.5 Immunity to Proximity Magnetic Fields in the Frequency Range 9 kHz to 13,56 MHz

The following table reports the test specifications tor ENCLOSURE PORT IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz.

Test Frequency	Modulation	Immunity test level (A/m)
30kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

a) This test is applicable only to devices intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.

9 TROUBLESHOOTING

9.1 Diagnostic System and Symbols on Keyboard

PIEZOSURGERY touch is equipped with a diagnostic circuit that allows to detect operating abnormalities and to view their type on the keyboard via their relative symbol.

By using the following chart, the user is guided toward the identification and possible solution of the malfunction detected.

Symbol on the Keyboard	Possible Cause	Solution
	Handpiece electric contacts/ lead wet.	Thoroughly dry the contacts with compressed air.
	PIEZOSURGERY handpiece not connected to the device.	Connect the handpiece.
	Faulty Handpiece.	Replace the handpiece.
	Malfunction of the tuning circuit.	Contact Piezosurgery Inc.'s Service.

Symbol on the Keyboard	Possible Cause	Solution
	Insert not properly tightened on the handpiece.	Unscrew the insert and screw it back correctly using the torque wrench (see *Chapter 5.4 on page 21*).
	Insert broken, worn or deformed.	Replace the insert.
	Handpiece electric contacts/ lead wet.	Thoroughly dry the contacts with compressed air.
	Peristaltic pump malfunction.	Check that there are no impediments to pump rotation.
	Tubing not correctly positioned in the peristaltic pump.	Correctly reposition the silicon tubing inside the pump (see *Chapter 4.2 on page 11*).
	The device has been turned off and on again without waiting 5 seconds.	Turn device off and wait 5 seconds before turning it on again.
	Abnormalities in the power distribution network, excessive electrostatic discharges or internal anomalies.	Turn the device off and wait 5 seconds before turning it on again. If the message persists, contact Piezosurgery Inc.'s Service.
	The system was started with the pedal pressed.	Check that during system start-up the pedal is not pressed. If the problem persists, disconnect the pedal and contact Piezosurgery Inc.'s Service.

NOTE: For any error message not listed in the table, contact Piezosurgery Inc.'s Service.

9.2 Troubleshooting Quick Guide

Problem	Possible Cause	Solution
The device does not turn on after having brought the switch into position "I"	The power supply connector is not properly plugged into the socket on the back of the device.	Check that the power supply cord is firmly connected.
	The power supply cord is faulty.	Check that the power supply socket is functioning. Replace the power supply cord.
	The fuses are out-of-order.	Replace the fuses (refer to *Chapter 9.3 on page 39*)
The device is switched on but not working. The display does not show any error.	The foot pedal plug is not correctly inserted into the device socket.	Correctly insert the foot pedal plug into the socket on the back of the device.
	The foot pedal is not working properly.	Contact Piezosurgery Inc.'s Service.
The device is switched on but not working. One of the following symbols appears on the screen: 	See *Chapter 9.1 on page 35* for the possible cause, according to the symbol that has been displayed.	See *Chapter 9.1 on page 35* for the action to undertake, according to the symbol that has been displayed
When operating, the PIEZOSURGERY handpiece emits a slight whistle.	The insert is not properly tightened into the handpiece.	Unscrew the insert and screw it back correctly by using the Mectron torque wrench. (Refer to *Chapter 5.4 on page 21*)
	The irrigation circuit has not been completely filled.	Fill the irrigation circuit by using the "pump" function (Refer to *Chapter 5.4 on page 21*)

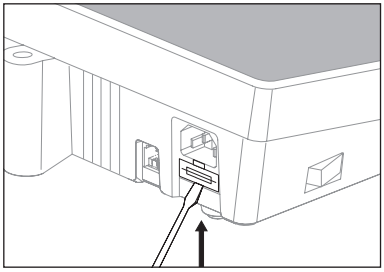
Problem	Possible Cause	Solution
During operation, no liquid flows out from the insert.	The insert is of the type which does not provide the passage of liquids.	Use an insert of the type with the passage of liquids.
	The insert is clogged.	Unscrew the insert from the handpiece and unclog the insert water passage by blowing compressed air through it. If the problem persists, replace the insert with a new one.
	The handpiece is clogged.	Contact Piezosurgery Inc.'s Service.
	The irrigation level on the screen is set to "0".	Adjust the irrigation level
	The liquid irrigation bag is empty	Replace the empty bag with a new one full.
	The air inlet on the spike/ roller has not been opened.	Open the air inlet on the spike/roller.
	The silicon tubing are incorrectly installed.	Check the irrigation kit connections.
The device is working properly but the pump works with difficulty.	Excessive pressure of the peristaltic pump impeller on the tube.	Check that the tube in the peristaltic pump has been correctly inserted. (Refer to *Chapter 4.2 on page 11*)
The pump is working properly, but when it stops, liquid flows out from the handpiece.	The peristaltic pump cover is not closed properly.	Check that the peristaltic pump cover is closed properly. (Refer to *Chapter 4.2 on page 11*)
Poor performance	The insert is not correctly tightened on the handpiece	Unscrew the insert and screw it back correctly by using the Mectron torque wrench. (Refer to *Chapter 5.4 on page 21*)
	Broken, worn-out or deformed insert.	Replace the insert with a new one.

9.3 Fuses Replacement

⚠ **WARNING: Switch the device off.**
Always turn the device off by means of the main switch and disconnect it from the electrical power socket before proceeding.

1

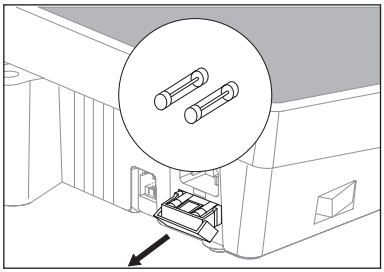
Use a flat tool, if necessary, to open the fuse-holder drawer located under the power supply socket;



2

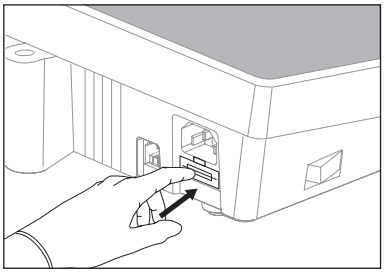
Pull out the fuse-holder drawer;

⚠ **WARNING:** Replace the fuses with others respecting the characteristics indicated in *Chapter 8 on page 26*.



3

Reinsert the drawer in its housing.



9.4 Customer Service - Returns and/or Repairs

If you need technical assistance regarding the use, or you encounter a problem that requires servicing or repair, contact Piezosurgery Inc. Customer Service at (1.888.87-PIEZO).
Returning products for any reason, requires a return authorization number that can be obtained by contacting Piezosurgery Inc. Customer Service.

Please provide the following information:

- Data of the owner with telephone number;
- Product name;
- Serial number and/or lot number;
- Reason for goods returned / description of the malfunction;
- Photocopy of delivery note or purchase invoice of the device.

9.4.1 Repairs

Products returned for repair must have a return authorization number that must be included on all paperwork and clearly visible on the package sent to Piezosurgery Inc.
Contact Piezosurgery Inc. Customer Service and provide the following information to obtain a return authorization number prior to returning any product for repairing. Make reference to this number for inquiries regarding the repair status.

- Data of the owner with telephone number;
- Product name;
- Serial number and/or lot number;
- Reason for goods returned / description of the malfunction;
- Photocopy of delivery note or purchase invoice of the device.

If you require a quote – Notify Customer Service, when requesting the return authorization number that a quote is required. If a quote is not requested the repair will be processed and your account billed accordingly – provided the repair is not covered under warranty.

9.4.2 Returned Goods

All returns must have a return authorization number that must be included in all the shipping documents and clearly visible on the package sent to Piezosurgery Inc. All returns must be shipped prepaid freight, otherwise they will not be accepted.

⚠ **CAUTION: Packaging**
Pack the device in its original packaging to prevent damages during transport.

⚠ **WARNING:** All the products must be cleaned and sterilized before returning. Piezosurgery Inc. will not accept and process potentially bio-contaminated products which do not meet this requirement. Contaminated products will be immediately returned to you, at your expense, for decontamination and sterilization.

This warranty gives you specific legal rights and you may have other rights which vary by state and municipality.
The foregoing limited warranty is in lieu of all other warranties, expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.
Except claims for personal injury, in no case shall the company be liable for any special, incidental or consequential damages based upon breach of warranty or any other legal theory.
Some jurisdictions do not allow limits on warranties, or on remedies, and, in such jurisdictions, the limit in this and the preceding paragraphs may not apply.

10 WARRANTY

For all PIEZOSURGERY products unless otherwise specified.
Any non-approved usage of the PIEZOSURGERY touch will void the warranty.
Any usage of non-PIEZOSURGERY parts, tips, components or procedures will void the warranty.
The manufacturer, Mectron S.p.A., warrants to the first original purchaser (customer) that their products have been tested, inspected and shipped in proper working order.
All PIEZOSURGERY products, with exceptions noted below, are covered by warranty for a period of one year from the date of purchase. Products are warranted to be free from defects in material and workmanship.
This limited warranty is extended only to the first customer purchasing the PIEZOSURGERY products directly from Piezosurgery Inc. or from its authorized distributor or representative.
This limited warranty does not apply to any unit/accessory which has been subject to abnormal wear and tear, misuse, abuse, neglect, improper installation or operation or that has been altered, adjusted or tampered with by any person other that Piezosurgery Inc. authorized service personnel.
The warranty is valid only if Piezosurgery Inc. is notified within thirty (30) days following discovery of a defect. For returning procedure make reference to the Chapter 9.4 on page 40.
Returns must be authorized by Piezosurgery Inc.
Piezosurgery Inc. cannot accept responsibility for returns which have not been authorized.
Contact Piezosurgery Inc. Customer Service at 1.888.87-PIEZO for return authorization.
This warranty is valid only if the product is returned to Piezosurgery Inc. service within thirty (30) days of Piezosurgery Inc. receiving notice of such defect, as described above.
The customer is responsible for returning the defective equipment to the Piezosurgery Inc., service location at his or her own expense.
Within a reasonable time after receipt of product/s, Piezosurgery Inc., service will investigate and shall correct any defect covered by warranty by providing , at its option, one of the following: service or repair of the product, or a replacement of the product.
If upon examination by Piezosurgery Inc. service personnel it is determined that the malfunction is caused by abnormal wear and tear or by damage caused by misuse, abuse, tamper with, or by failure to perform normal and routine maintenance as set out in the instruction for use and instruction for cleaning and sterilizing manuals, warranty provisions will not apply.
In this case an estimate for the cost of repair will be given to the customer prior servicing and repairing the product.
The repair will be billed to the customer in the same manner as out of warranty repair.
For selected products:

- Diamond coated inserts are not warranted.

mectron
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