mectron

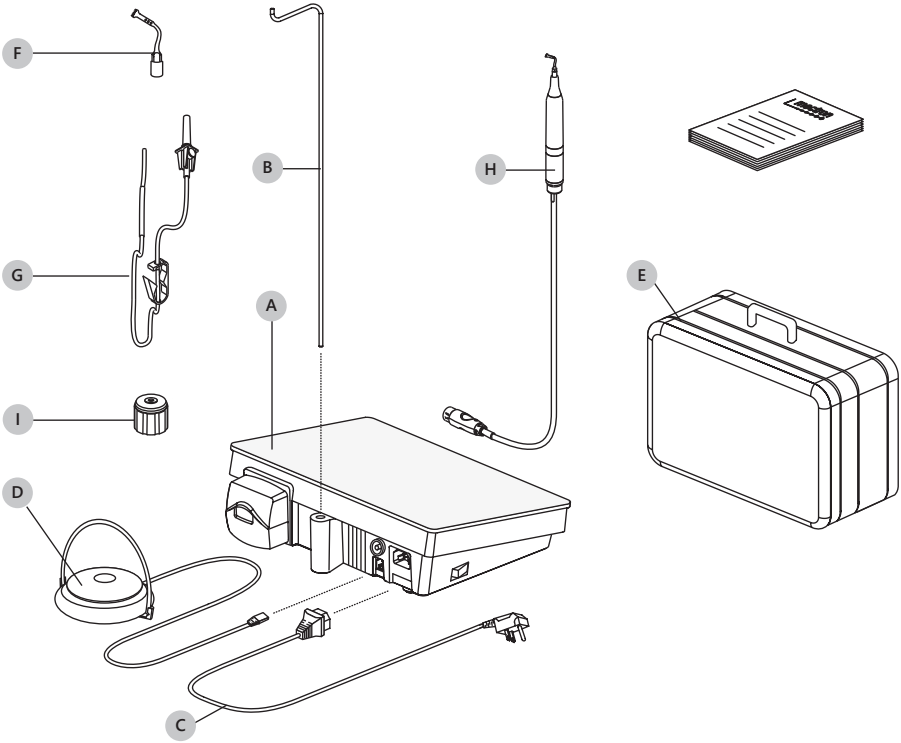
medical technology

USE AND MAINTENANCE MANUAL

PIEZOSURGERY® flex

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

CE 0051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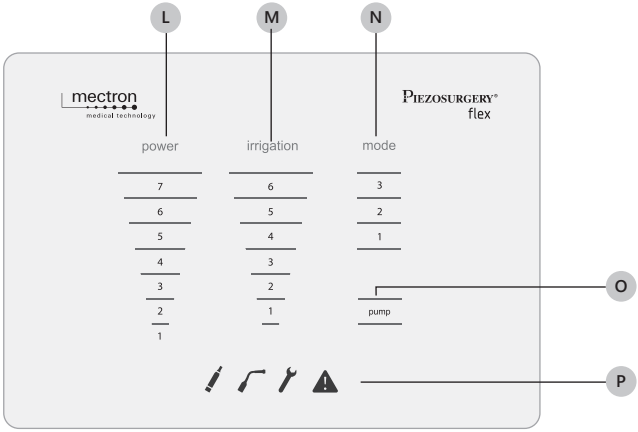
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1 INTRODUCTION

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 equipments, 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.
MECTRON is committed to the continuous updating of our 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 flex

PIEZOSURGERY flex is an ultrasonic surgical system consisting of handpieces and associated insert tips for cutting bone, osteotomy, osteoplasty and drilling in a variety of surgical procedures, including but not limited to:

- Hand and foot surgery;
- Oral/Maxillofacial surgery;
- Otolaryngology surgery;
- Plastic/Reconstructive Surgery;
- Neurosurgery;
- Spine surgery.

The device may also be used with endoscopic visual assistance to perform the above listed procedures.

⚠ **WARNING:** Use the device only for the intended use. Failure to meet these requirements may cause serious injuries to the patient, the operator, and damages/ breakdowns of the device.

⚠ **WARNING:** Carefully read this manual and follow its recommendations in order to avoid to compromise the patient and/ or the user safety. Failure to meet these requirements may cause serious injuries to the patient and/or the operator.

⚠ **WARNING: Qualified and specialized personnel.** The device must be used exclusively by specialized personnel such as Surgeon. To use the device no special training is requested. The use of the device does not cause side effects if it is used correctly. An improper use might cause tissues heating.

1 manuals.mectron.com

⚠ **WARNING:** The device must be used in a hospital environment, such as an operating theatre.

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

1.2 Description of the Device

The PIEZOSURGERY flex device is a piezoelectric ultrasonic bone cutting instrument: the device uses piezoelectric ultrasonic technology to generate mechanical micro-vibrations which allow the cutting of mineralized structures with minimal trauma to soft tissues.
The equipment has an automatic tuning circuit that offsets wear of the inserts, thus ensuring work in constant conditions of maximum efficiency.
The user interface has been optimized with PIEZOSURGERY flex making all the functions readily available by integrating them in the touch keyboard.

1.2.1 Users

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

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.).

⚠ **WARNING**: **Contraindications. Interference with other equipment.** The PIEZOSURGERY flex device complies with the standard IEC 60601-1-2. However, it may interfere with other devices in its vicinity. The user should take whatever steps are necessary to eliminate or reduce the source of interference. Install the PIEZOSURGERY flex at safety distance from life-support systems. The PIEZOSURGERY flex must not be used adjacent or stacked with other electrical equipments. If adjacent or stacked use of the device is necessary, normal operation of the equipment and the PIEZOSURGERY flex, in the configuration in which they will be used, should be verified prior their use.

⚠ **WARNING**: **Contraindications. Interference by other equipment.** An electro-surgical knife of other electro-surgical units near the PIEZOSURGERY flex device may interfere with its correct operation.

⚠ **CAUTION**: In the case the hospital must subject the electro-medical equipment and systems to periodical inspections in order to adhere to imposed requirements in its own structure, 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 'Electro-medical devices - Periodical inspections and tests to be performed after repair interventions on electro-medical devices'. 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 make sure that there is no water underneath the device. Before each treatment, always make sure that the device and accessories are in proper working order. If anything unusual is noted during operation, do not carry out the treatment. If the problem concerns the device, contact Piezosurgery Inc. Customer Service.

⚠ **WARNING**: The electrical supply network to which the device is connected must comply with all the applicable standards and with electrical safety requirements.

⚠ **WARNING**: To avoid risk of electric shock, this device must be grounded. Only connect the console to hospital grade receptacle to ensure electrical grounding reliability.

⚠ **WARNING**: Do not operate the foot pedal of the PIEZOSURGERY flex when the peristaltic pump cover is open. Moving parts might pinch loose clothing or fingers. Personal injuries may result.

⚠ **WARNING**: **Personal injury.** Make sure that power cables do not interfere with free circulation of people in the area.

⚠ **CAUTION**: Federal Law (United States of America) restricts this device to sale by or on the order of a physician.

⚠ **WARNING**: Prior to any use, system components should be inspected for damage. Do not use if damage is apparent.

⚠ **WARNING**: Do not operate the device if the handpiece is defective, damaged or broken. Replace the handpiece immediately.

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

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

⚠ **WARNING**: **MR-UNSAFE** 
PIEZOSURGERY flex MUST NOT BE USED in a Magnetic Resonance (MR) environment.

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

⚠ **CAUTION**: **Contraindications.** Do not carry out any treatments on metal or ceramic prosthetic artifacts. The ultrasonic vibrations could cause decementation of such artifacts.

⚠ **WARNING**: **Single-use accessories.** Inserts and irrrigation kit are provided for single-use only and must be used on an individual patient during a single surgical procedure and then discarded.Do not attempt to reuse or re-sterilize these single-use items.

⚠ **WARNING**: **Control of infections - Reusable Accessories**
First Use The reusable accessories (brand new or returned by service) are delivered in NON-STERILE condition and must be cleaned and sterilized 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**: Allow reusable, autoclavable accessories to gradually return to room temperature after steam sterilization and prior to usage. The cooling process must not be accelerated.

⚠ **WARNING**: **Breakage and wear-out of the inserts.** In rare cases, high frequency oscillations and wear-out may lead to breakage of an insert.
Should an insert fracture during use, extreme care must be exercised to ensure that all the fragments of the insert are retrieved and removed from the surgical site and, at the same time, that an effective suction is applied. Unremoved fragments may cause tissue damage to the patient.
Do not modify the insert in any way, otherwise its performance could be diminished. Bending, prying or deforming the insert may cause it to fracture. These inserts must never be used.
Re-sharpening the insert damages it and is therefore forbidden. Always inspect the insert before and during the operation especially in its apical part for any damage. If damaged is observed replace with a new insert.
During surgery, avoid prolonged contact with retractors or other metal objects being used, otherwise the insert may break.
Do not exert excessive pressure on the inserts during their use, otherwise it may fracture resulting in harm to the patient or users.

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		MR-UNSAFE: The device must not be used in a Magnetic Resonance (MR) environment [b]
	Atmospheric pressure limitation		Humidity limitation
IP22	International Protection Code of the mechanical casing.	IP20	International Protection Code of the mechanical casing.
	Distributor		Do not use if package is damaged and consult instruction for use
Rx Only	For US market, only. **CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a licensed physician or dentist		

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

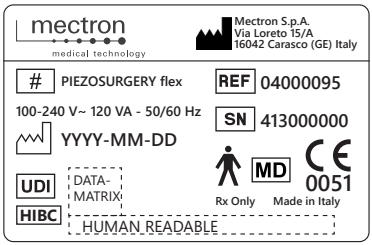
b) The symbol is represented by a red circle-with-slash and a black graphical symbol.

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.

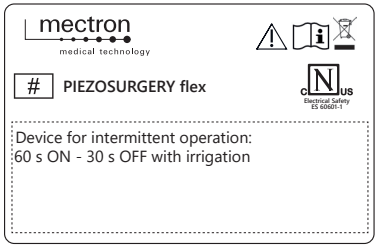
2.1 Device Identification Label

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.

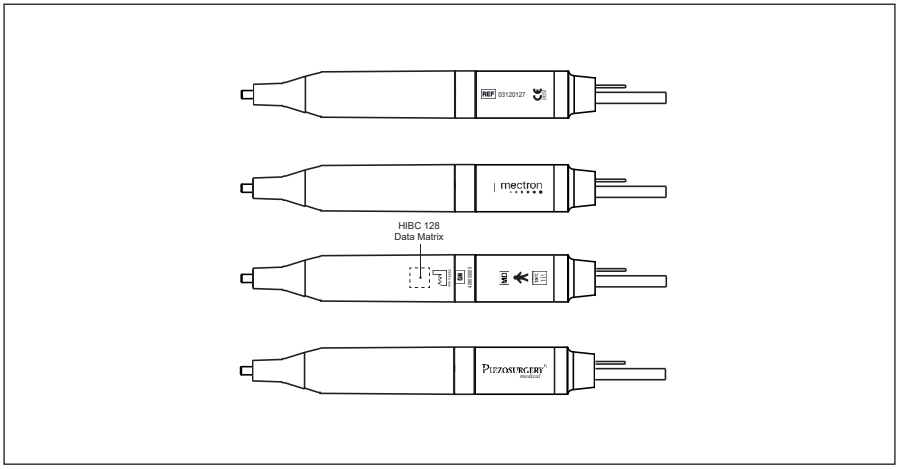
NOTE: The complete list of symbols and their description are shown in *Chapter 1.5 on page 5*.



2.2 Handpiece Identification Data

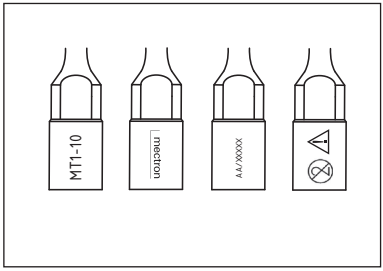
Each handpiece is laser-marked with the traceability data, UDI code included.

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 the PIEZOSURGERY flex

Refer to the front endpaper.
The PIEZOSURGERY flex device is supplied as of a set of equipment, as follows:

A. Console with an integrated peristaltic pump;
B. Drip stands for supporting the saline bags;
C. Power supply cable with hospital grade plug;
D. Foot Pedal with bracket, cord and connector;
E. Case;

- 1 x Instructions for Use manual;
- 1 x Instructions for cleaning and sterilizing manual.

The following accessories are sold separately from the PIEZOSURGERY flex device:

F. PIEZOSURGERY medical single-use inserts (supplied sterile);
G. PIEZOSURGERY medical single use irrigation kit (supplied sterile);
H. PIEZOSURGERY medical handpiece complete with cord and the connector protective cap (supplied NON sterile and reusable);

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

I. PIEZOSURGERY medical torque wrench (supplied NON sterile and reusable).

PIEZOSURGERY flex consists of accessories that can be ordered separately.
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. All material shipped by Piezosurgery Inc. have been inspected upon they delivery.
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, irrigation kit) available to use in case the device stops due to a fault or of inconveniences.

4 FIRST INSTALLATION

To ensure correct operation of the device, it must be installed by a person authorized by Piezosurgery Inc. The device must be installed in a suitable place that is handy for its use. The device must be installed in a comfortable place suitable for its use.

Position the device in way so that the power plug is always, easily reachable, since this plug is considered as a disconnecting means.
The installation form has to be filled and sent to Mectron S.p.A. to ensure traceability and the warranty activation.

4.1 Safety Requirements in the Installation Phase

⚠ **WARNING**: **Contraindications. Interference with other equipment.** The PIEZOSURGERY flex device complies with the standard IEC 60601-1-2. However, it may interfere with other devices in its vicinity. The user should take whatever steps are necessary to eliminate or reduce the source of interference. Install the PIEZOSURGERY flex at safety distance from life-support systems. The PIEZOSURGERY flex must not be used adjacent or stacked with other electrical equipments. If adjacent or stacked use of the device is necessary, normal operation of the equipment and PIEZOSURGERY flex, in the configuration in which they will be used, should be verified prior their use.

⚠ **WARNING**: **Contraindications. Interference by other equipment.** An electro-surgical knife of other electro-surgical units near the PIEZOSURGERY flex device may interfere with its correct functioning.

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

⚠ **WARNING**: The electrical supply network to which the device is connected must comply with all the applicable standards and with electrical safety requirements.

⚠ **WARNING**: To avoid any risk of electric shock this device must be grounded. Only connect the console to hospital grade receptacle to ensure electrical grounding reliability.

⚠ **WARNING**: Do not operate the foot pedal of the PIEZOSURGERY flex when the peristaltic pump cover is open. Moving parts might pinch loose clothing or fingers. Personal injuries may result.

⚠ **WARNING**: Install the device in a place protected against impacts or accidental splashes of water or other liquids.

⚠ **WARNING**: Do not install the device on top of or close to sources of heat. Adequate air circulation is needed to cool electronic components inside of the unit. Do not block the cooling fans at the console area and at the console bottom. Do not place the unit on a towel, foam or other soft surface since the material might block the air vent on the console bottom.

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

⚠ **CAUTION**: The device is transportable but must be handled with care when moved. Position the footswitch on the floor in such a way that it can only be activated intentionally by the operator.

⚠ **CAUTION**: **The electrical contacts inside the cord connector must be dry.** Upon completion of the sterilisation cycle and before connecting the handpiece cord to the console, make sure that the electrical contacts of the connector are perfectly dry. If necessary, dry the contacts by blowing air onto them with medical compressed air.

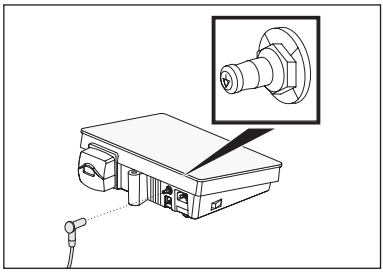
⚠ **CAUTION**: Do not allow the device console and the foot pedal to get wet. If liquid enters the console or footswitch, damage could occur.

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

4.2 Connecting the Accessories

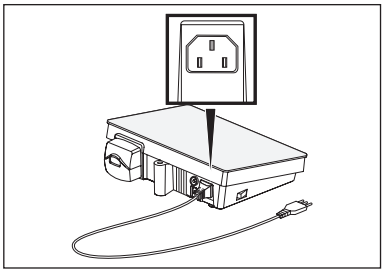
1

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;



2

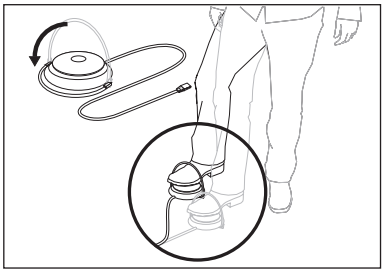
Plug the power supply cord into the power socket on the back of the device and then into the mains power outlet;



3

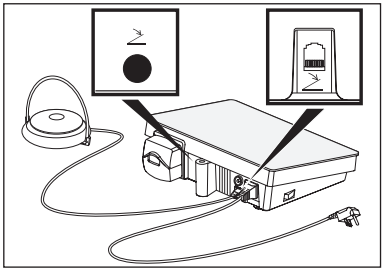
NOTE: The foot pedal comes equipped with a bracket that allows it to be moved to the place most suitable for the operation, without the need to use your hands to move it.

The bracket can also be positioned horizontally if it is not used;



4

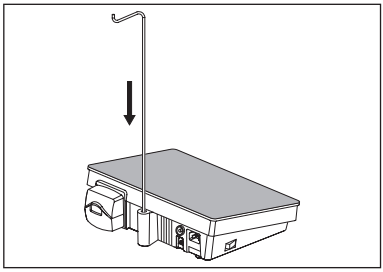
Connect the foot pedal to the back of the device in the socket marked with the symbol ⚓, by means of the plug of the pedal cable, until you hear a "click" sound.
In order to disconnect the foot pedal from the device grab the connector of the foot pedal, press the release flap and pull the connector back;



NOTE: MANUAL START STOP BUTTON
In the case of foot-pedal failure intraoperatively, the button allows the operative staff to manually turn handpiece operation on and off. The button is located on the back of the device's console, next to the peristaltic pump case, above the symbol marked ⚓. Refer to Chapter 5.3 on page 17.

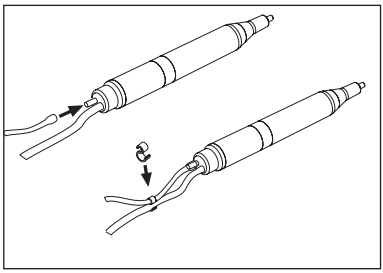
5

Fit the drip stand for supporting the solution bag into the dedicated hole;



6

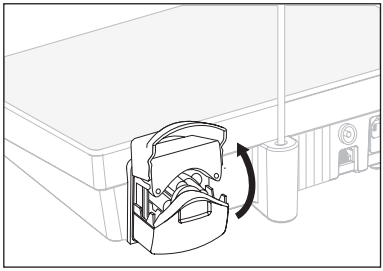
STEPS TO BE CARRIED OUT IN THE "STERILE AREA":
Open the sterile package of the handpiece and of the irrigation kit, remove the tube and the clips;
Connect the end of the irrigation tubing onto the dedicated handpiece irrigation nozzle;
Use the 6 clips provided in order to clip together the irrigation tubing and handpiece cable;



STEPS TO BE CARRIED OUT IN THE "NOT STERILE AREA":

7

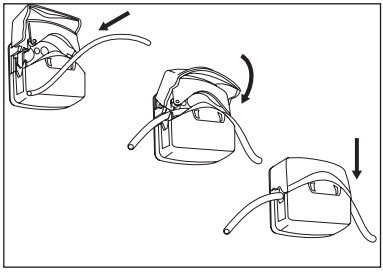
- Open the pump cover completely;



8

- Insert the part of the irrigation tube with a bigger diameter and with length of 15 cm into the peristaltic pump;

⚠ **WARNING:** Use only original Piezosurgery/Mectron accessories. Do not use irrigation tubings other than those supplied by Piezosurgery/Mectron.

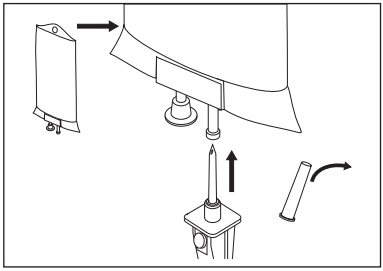


- Close the pump cover completely;

⚠ **WARNING:** Do not operate the foot pedal of the PIEZOSURGERY flex when the peristaltic pump cover is open. Moving parts might pinch loose clothing or fingers. Personal injuries may result.

9

Hang the saline bag to its specific drip stand;
Remove the protective cap from the spike and connect it to the irrigation bag;

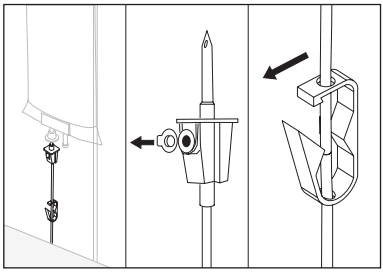


⚠ **WARNING:** The irrigation bag support rod must be used with bags of up to a maximum of 1000 ml.

⚠ **WARNING:** The PIEZOSURGERY Medical irrigation kit is provided in sterile packaging. Inspect the packaging to check its integrity. Whether it results damaged, DO NOT use the product and proceed with the proper disposal.

Open the air inlet on the tube before operating. Release the irrigation tube clamp, if this is closed;

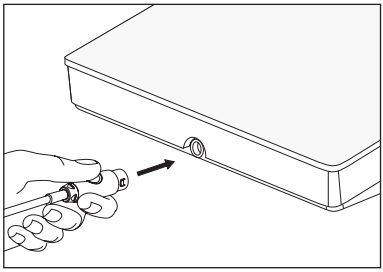
10



With the marked dot facing upward, insert the connector of the handpiece cord into the handpiece socket on the console. Gently push the handpiece-cord connector until it bottoms out.

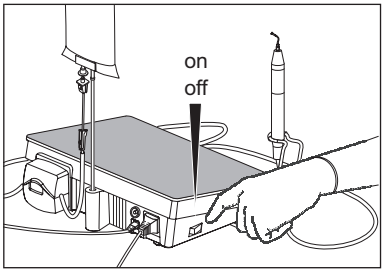
⚠ **CAUTION**: To avoid damaging the handpiece-cord, hold only the connector when disconneting the cord. Always hold the cord by its connector. Never pull on the cord itself.

11



5 USE

5.1 Switching the Device On and Off



Switching the Device On
Facing the front of the device, press the power switch on the left of the device body to the "I" position, being careful not to press the foot pedal. The device does a self-test and 4 symbols appear on the device (ref. P inside cover). At the end of the self-test the symbols turn off one by one, the device sets on the default setting and is ready to be used.

Switching the Device Off
Facing the front of the device, press the power switch on the left of the device body to the "O" position, being careful not to press the foot pedal. The device turns off.

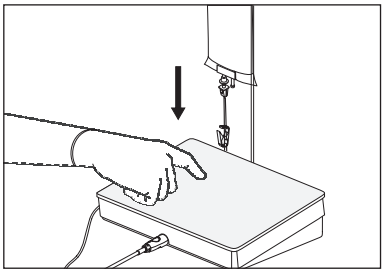
NOTE: whenever the device is started, the following default setting is programmed:

- "Power" 1;
- "irrigation" 1;
- "mode" 1.

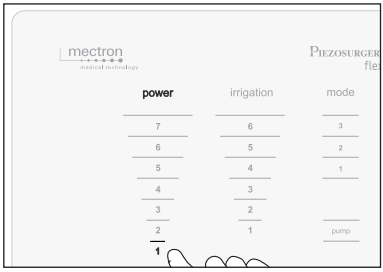
⚠ **CAUTION**: Once turned off, It is necessary to wait 5 seconds before switching the device on again. The device can give an error message.

5.2 Description of the Keyboard

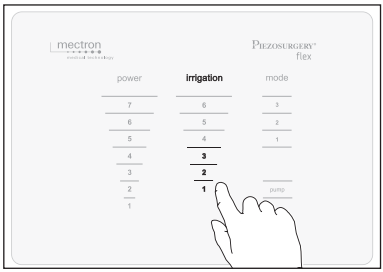
TOUCH KEYBOARD
The user can configure the device by simply touching on the touch keyboard.
Depending on the selected setting, the electronic feedback system automatically adjusts the correct operating frequency.



POWER (Ref. L front endpaper)
The desired level of power is adjustable from 7 levels, from 1 to 7, by selecting the numbers on the touch keyboard in the "power" column.

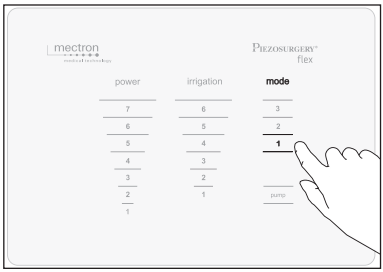


IRRIGATION (Ref. M front endpaper)
The delivery rate of the peristaltic pump is adjustable from 6 levels, by selecting the numbers on the touch keyboard in the "irrigation" column:
From 1 to 6= the pump flow goes from 8 ml/min to approximately 65 ml/min.

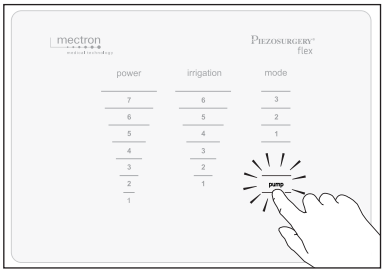


MODE (Ref. N front endpaper)
Depending on the type of surgery, it is possible to choose one of the 3 options available from the "mode" list:

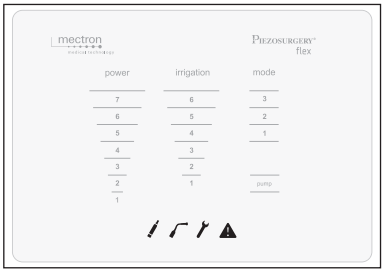
1. Dedicated to the most delicate surgeries and to the lift of the sinus membrane;
2. Dedicated to the cut and to the removal of the mineralized bone;
3. Dedicated to the cut and to the removal of very thick mineralized bone.



FILLING THE IRRIGATION TUBING KIT (Ref. O front endpaper)
The device is equipped with the "pump" key which allows to perform the PUMP function.
The PUMP function can be used at the beginning of the treatment, to fill the entire irrigation tubing up to the insert, so that the surgery can be started with the necessary irrigation (see Chapter 5.5 on page 21).

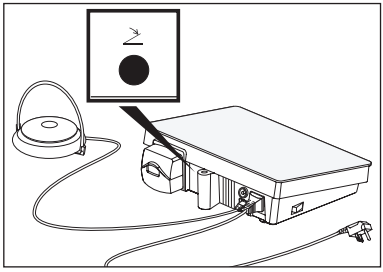


SYMBOLS (Ref. P front endpaper)
PIEZOSURGERY flex is equipped with a diagnostic system able to detect operating anomalies. Icons are displayed on the touchpanel according to the detected operating anomalies.
To help the user identify the malfunctioning part, four symbols are foreseen which are described in Chapter 9.1 on page 34.



5.3 Foot Pedal Button

In case the foot pedal is not functioning, the button on the back of the device, left hand side, under the symbol ⚡, can be used to bring the treatment to its end.



⚠ **CAUTION:** In the event of foot-pedal malfunction, disconnect it from the socket on the back of the console and proceed with the surgical treatment by operating - press/depress - the manual start stop button.

⚠ **WARNING**: Use the foot pedal button only upon user request. The users must train their staff on how and when they have to use this button.

⚠ **WARNING**: The manual start-stop button must be used only in case of malfunction of the foot pedal supplied with the device. The manual start-stop button allows completing the surgical treatment in the event of a foot pedal malfunction.

5.4 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.

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

⚠ **WARNING**: **Use of non-original Piezosurgery/Mectron inserts:** this can completely damage the threading of the handpiece, affecting the proper operation and causing injury to the patient.

⚠ **CAUTION: Contraindications.** Do not perform treatments on prosthetic artifacts made of metal or ceramics. The ultrasonic vibrations could lead to the de-cementing of the artifacts.

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

⚠ **WARNING**: **Checking device status before the treatment.** The system check must be always done in advance of preparing patiet for surgery to minimize risk to patient in case of system malfunction. Set up the entire system and verify each function before introducing the handpiece to the surgical site. System components should be operated and inspected for damage prior to use. If functional anomalies or damage are observed do not use the system.

⚠ **WARNING**: **Control of infections - Reusable Accessories (handpiece and torque wrench).**
First Use The reusable accessories (brand new or returned by service) are delivered in NON-STERILE condition and must be cleaned and sterilized 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. Before every surgery verify if they were cleaned and sterilized. If not cleaned and sterilized, do not use them.

⚠ **WARNING**: **Single-use accessories - Before the surgery.** Inspect the sterile package of the insert and irrigation kit for any damage. Do not use these accessories if package is opened or damaged. In case of broken or damaged packaging they lose sterility. Dispose of the items and do not attempt to sterilize or re-use them.

⚠ **WARNING**: **Single-use.** The insert tips and irrigation tubing kit are supplied sterile by prior exposure to ethylene oxide gas (ETO). They are single-use only, intended to be used on an individual patient during a single surgical procedure and then discarded. Do not attempt to reuse, reprocess or re-sterilize these items. The reuse of these accessories is an hazard to the patient and to the surgeon. Remove and discard the used inserts and irrigation kit following local regulations for proper disposal of contaminated surgical materials.

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

⚠ **CAUTION: The electrical contacts inside the cord connector must be dry.** Upon completion of the sterilization cycle and before connecting the handpiece cord to the console, make sure that the electrical contacts of the connector are perfectly dry. If necessary, dry the contacts by blowing air onto them with medical compressed air.

⚠ **WARNING**: Check delivery of water before and during use. Make sure the irrigation comes out from the insert tip. Do not operate the device or the handpiece if the water is not delivered or the pump is defective. Adequate cooling for the handpiece is needed. To ensure effective energy dissipation, use the PUMP button to prime the irrigation tubing line. Check the level of physiological solution in the saline bag. Replace it with a new irrigation bag before it is empty.

⚠ **WARNING**: The irrigation pump is not indicated for the administration of parental fluids, infusion of drugs or for any life sustaining purposes. The peristaltic pump is exclusively intended for provide sterile physiologicsl irrigant to the surgical site during the use.

⚠ **WARNING**: Verify that the irrigation clamp is in the 'Open' position before operation, and that it is closed before disconnecting the irrigation tubing from the bag at the end of the procedure.

⚠ **CAUTION**: Never force the connector into the console port as this may damage the connector and/or console. If the connector and the port do not join with reasonable ease, they probably don't match. Make sure that the marked dot on the handpiece-cord connector is facing upwards.

⚠ **WARNING**: Make sure that power cables do not interfere with free circulation of people in the area.

⚠ **CAUTION**: To avoid damaging the footswitch cord, hold only the connector when connecting or disconnecting the cord. Always hold the cord by its connector and never pull on the cord itself.

⚠ **CAUTION**: Do not screw or twist the footswitch cord connector during insertion or removal - it is a push/pull connector and can be damaged by twisting.

⚠ **CAUTION:** The foot pedal is specifically designed to be used only in connection with the PIEZOSURGERY flex device. Only use an original foot pedal otherwise damages or malfunctions can happen.

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

⚠ **WARNING**: The PIEZOSURGERY Medical device is intended for bone cutting. However, prolonged contact and/or excessive force of the instrument tip on soft tissues should be avoided as this may cause thermal and/or blunt injury. Particular care should be exercized when sharp tip inserts are used. Prolonged mechanical action of a sharp insert may also result in the soft tissue being cut. In close proximity to soft tissues/nerves (e.g. the perinevrium of the peripheral nerve system, or dura mater of central nerve system), it is recommended to complete the cut with a blunt tip diamond coated insert, to minimize the potential for soft tissue damage.

⚠ **WARNING**: Carefully check that the PIEZOSURGERY Medical handpiece is correctly working in all its parts before using it on the patient.

⚠ **CAUTION: Intermittent operation.** Long operational periods could cause overheating of the handpiece body. Refer to the Chapter 8 on page 26 for the recommended duty cycle.

⚠ **WARNING**: When not operating the handpiece, eliminate accidental footpedal activation.

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

⚠ **WARNING**: Handle sharp-edged and pointed inserts with particular care. During the tightening/untightening operations, the sharp -edged / pointed parts of the insert could cause harm.

⚠ **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 recognise the best point of resonance of the insert required for efficient, optimum performance.

⚠ **CAUTION:** Check that the PIEZOSURGERY Medical handpiece is correctly connected to the console before operating.

⚠ **WARNING**: Before every treatment, make sure that the insert appropriate for the treatment is securely attached to the handpiece. Use exclusively the PIEZOSURGERY Medical torque wrench to securing the insert to the handpiece. Do not use any other tool such as pliers, pincers, etc.

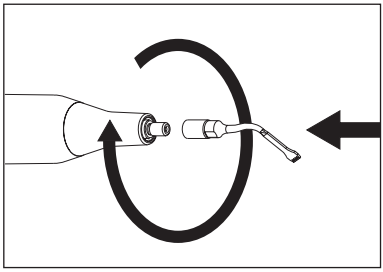
⚠ **WARNING**: Before every treatment, make sure that the selected insert has been correctly screwed onto the handpiece. This happens when the PIEZOSURGERY Medical torque wrench used to tighten the insert emits a mechanical “CLICK” sound.

5.5 Instructions for Use

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

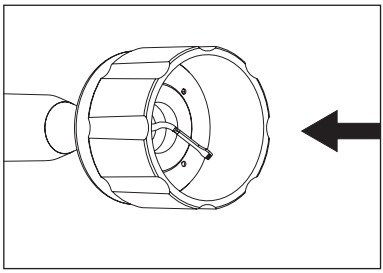
1

Screw the chosen insert onto the Piezosurgery Medical handpiece till it bottoms out;



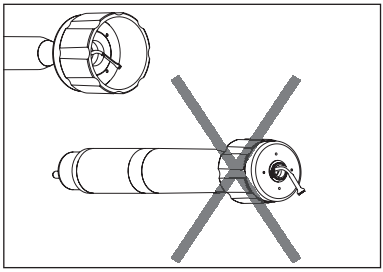
2

Use the Mectron torque wrench to secure the insert;
To use the Mectron torque wrench correctly, operate as follows:



3

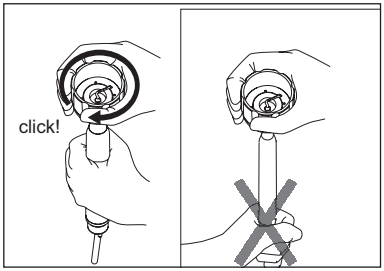
Fit the insert into the wrench as shown;



4

Firmly hold the central body of the handpiece;

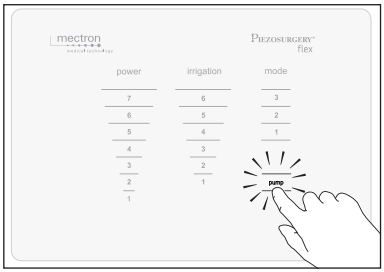
⚠ **CAUTION:** Do not grasp the handpiece by its terminal part and/or cord, but only by its central body.
The handpiece must not be rotated, but must be grasped firmly, and you must only rotate the wrench.



Tighten the insert by turning the torque wrench clockwise until it clicks (the wrench turns with respect to the body of the handpiece, producing clicking sounds).
The insert is now properly tightened;

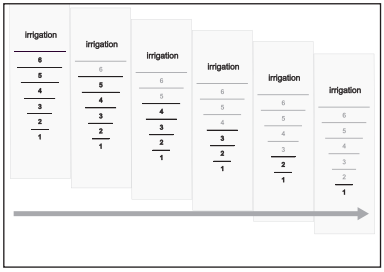
5

Fill the irrigation tubing by selecting the PUMP function on the touch keyboard. The irrigation circuit starts to fill up;



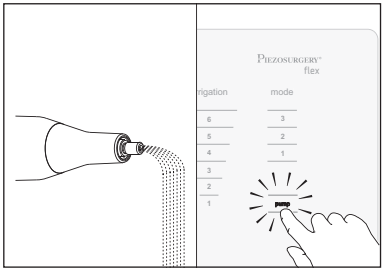
6

As soon as the peristaltic pump starts, the entire scale of values of the "irrigation" column lights up and during the liquid passage the value of the irrigation shifts from 6 to 1;



7

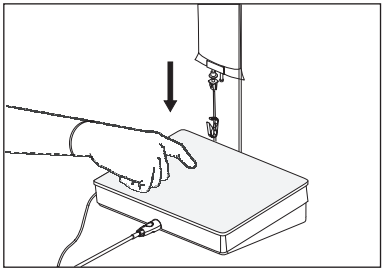
As soon as the irrigation comes out from the Piezosurgery Medical handpiece, the cycle can be stopped by pressing PUMP again or, alternatively, by pressing the foot pedal. The Pump function is disabled and the keyboard is enabled again, and displays the last setting used;



8

On the keyboard, select the necessary power, irrigation and mode;

⚠ **CAUTION:** According to the selected insert, for the correct setting of the parameters consult the Chart annexed to this manual titled “Recommended settings for the inserts” on the PIEZOSURGERY flex or the illustrative leaflet of the Piezosurgery Medical insert you’ve purchased.



5.6 Important Information on Inserts

⚠ **WARNING:**

- Excessive pressure applied to insert may cause insert fracture which may cause harm to the patient and operating-room staff. Bending and/or prying an insert reduces its structural integrity and can result in an insert breakage during use.
- During surgery, avoid contacting the insert with retractors or other metal objects. If insert contacts metal objects, it may break, leaving pieces in the surgical site.
- Always check that the threaded parts of the insert and of the handpiece are perfectly clean – see the Cleaning and Sterilization Manual.
- Do not modify the shape of the insert. Do not attempt to re-sharpen used inserts. In use, the insert might break. Do not use deformed insert in any way.
- High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the insert. Should an insert fracture during the use, extreme care must be exercised to ensure that all fragments of the insert are retrieved and removed from the surgical site. Unremoved insert fragments may cause injury to the patient.
- Always inspect the insert before and during the operation for any damage.
- If damaged is observed replace with a new insert. Insert showing signs of deformation or cracking must be replaced immediately.
- Do not activate the handpiece while the insert is in contact with the part to be treated. Doing so, will not allow the electronic circuit of the console to recognise the best point of resonance of the insert, required for efficient, optimum performance.
- Use the insert/s according to the working settings reported in the Chart annexed to this manual titled "Recommended settings for the inserts" on the PIEZOSURGERY flex or the illustrative leaflet of the Piezosurgery Medical insert you've purchased.
- During the cutting action of mineralized tissues, the accidental contact of some parts of the insert with surrounding soft tissues might cause small traumas. To minimize the risk, before using the PIEZOSURGERY flex, the surgical site must be prepared by moving away the soft tissues and by using specific protective instruments.
- Use only Piezosurgery Medical/Mectron inserts. Only Piezosurgery Medical/ Mectron inserts can fit properly in the PIEZOSURGERY flex handpiece. The use of non-original Piezosurgery Medical insert/s damages the threades pin of the handpiece with the risk of poor fastening of the original insert/s during subsequent use. The device settings are tested and guaranteed to operate only when original Piezosurgery Medical/Mectron inserts are used. The PIEZOSURGERY flex device is not compatible with other systems tips. Use of non-original Piezosurgery Medical/ Mectron inserts may result in patient or operator injury or system malfunction and will void any applicable warranty.

6 MAINTENANCE

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

1. Disconnect the device from the mains;
2. In case of a long period of inactivity, place the device in its original packaging and in a safe area;
3. Before using the device again, clean and sterilise the handpiece and the wrench according to the instructions provided in the Cleaning and Sterilisation Manual;

⚠ **WARNING:** Periodically check that the electrical power supply is intact; if it is 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 at the end of each surgery;
- Irrigation kit at the end of each surgery;
- Torque wrench: 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 flex 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 X8 (foot pedal model FS-06)
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
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	Adjustable on the touch screen: 7 power levels, from 1 to 7
Modes	Adjustable on the touch screen: from 1 to 3
Peristaltic pump capacity	Adjustable on the touch screen: 6 flow levels, from 1 to 6 (from 8 ml/min to approximately 65ml/min)
APC circuit protections	No handpiece detected Cord interruption Insert not tightened correctly or broken
Operating conditions	from 10 °C to 35 °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
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)]

Table 1 – Technical Specifications

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

8.1 Electromagnetic Compatibility IEC/EN 60601-1-2

⚠ **WARNING: Contraindications. Interference with other devices.** The PIEZOSURGERY flex device complies with the standard IEC 60601-1-2. However, it may interfere with other devices in its vicinity. The user should take whatever steps are necessary to eliminate or reduce the source of interference. Install the Piezosurgery Flex at safety distance from life-support systems. The Piezosurgery flex must not be used adjacent or stacked with other electrical equipments. If adjacent or stacked use of the device is necessary, normal operation of the equipment and the Piezosurgery Flex, in the configuration in which they will be used, should be verified prior their use.

⚠ **WARNING:** Portable and mobile radio communication devices may influence the correct functioning of the device.

⚠ **WARNING: Contraindications. Interference from other devices.** An electro-surgical knife or other electro-surgical units placed in the vicinity of the PIEZOSURGERY flex device may interfere with its correct functioning.

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

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	PIEZOSURGERY flex 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 flex 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	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliant	

8.1.2 Accessible Parts of the Casing

PIEZOSURGERY flex is designed to operate in the electromagnetic environment specified below. The customer or user of PIEZOSURGERY flex should ensure that it is used in such an 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 33*	
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 34*	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 flex shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the PIEZOSURGERY flex.

b) PIEZOSURGERY flex 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 flex is designed to operate in the electromagnetic environment specified below. The customer or user of PIEZOSURGERY flex 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 flex 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 flex 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 flex 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 flex.

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 EQUIPMENT 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 flex is designed to operate in the electromagnetic environment specified below. The customer or user of PIEZOSURGERY flex 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 flex is designed to operate in the electromagnetic environment specified below. The customer or user of PIEZOSURGERY flex 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 flex is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The customer or the user of PIEZOSURGERY flex can help prevent electromagnetic interference by ensuring a minimum distance between the mobile and portable RF (transmitters) communication devices and PIEZOSURGERY flex, 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 flex 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 flex, 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 flex is equipped with a diagnostic system able to detect operating anomalies. Icons are displayed on the touchpanel according to the detected operating anomalies.
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 Medical handpiece not connected to the device.	Connect the handpiece.
	Faulty Handpiece.	Replace the handpiece.
	Malfunction of the tuning circuit.	Contact Piezosurgery Inc. Customer 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 5.5 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.
	Irrigation kit not positioned correctly inside the 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. Customer Service.
	Turn-on procedure incorrect: the device has been turned on with the foot pedal pressed.	Check that during system start-up the pedal is not pressed. If the problem persists, disconnect the pedal and contact Piezosurgery Inc. Customer Service.

NOTE: For any error message not listed in the table, contact Piezosurgery Inc. Customer 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 38*)
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.	During the surgery: disconnect the foot pedal from the console and use the button replacing the pedal (see Chapter 5.3 on page 17). At the end of the intervention contact Piezosurgery Inc. Customer Service
The device is switched on but not working. One of the following symbols appears on the screen: 	See *Chapter 9.1 on page 34* for the possible cause, according to the symbol that has been displayed.	See *Chapter 9.1 on page 34* for the action to undertake, according to the symbol that has been displayed
When operating, the Piezosurgery Medical 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 5.5 on page 21*)
	The irrigation circuit has not been completely filled.	Fill the irrigation circuit by using the "pump" function (Refer to *Chapter 5.5 on page 21*)

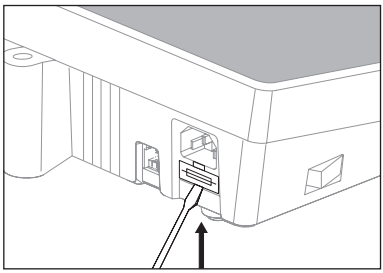
Problem	Possible Cause	Solution
During operation, no irrigation flows out from the insert.	The insert is clogged.	Unscrew the insert from the handpiece and unclog the insert water passage by blowing compressed air through it. If the problem persists, replace the insert with a new one.
	The handpiece is clogged.	Contact Piezosurgery Inc. Customer Service.
	The liquid irrigation bag is empty	Replace the empty bag with a new one full.
	The air inlet on the spike has not been opened.	Open the air inlet on the spike/roller.
	Irrigation kit not positioned correctly inside the pump.	Check that the Irrigation kit is properly connected.
The device works properly but the pump strains/ is stressed.	Excessive pressure of the impeller on the peristaltic pump tube.	Check that the tube inside the peristaltic pump is properly positioned (Refer to *Chapter 4.2 on page 11*)
The pump turns correctly, but when it stops, irrigation flows out from the handpiece.	The lid of the peristaltic pump is not closed correctly.	Check that the lid of the peristaltic pump is perfectly closed (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 5.5 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 with the main switch and disconnect it from the electrical power socket before performing the following intervention.

1

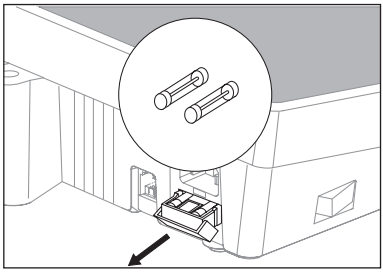
Use a flat tool, if necessary, to open the fuse-holder drawer located under the power supply socket;



2

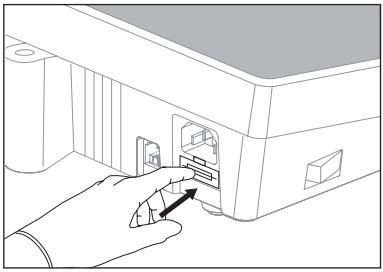
Pull out the fuse-holder drawer;

⚠ **WARNING:** Replace the fuses, complying to 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 flex 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 39
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:

- Insert tips (all kinds) are not warranted;
- Irrigation kit is not warranted.

mectron
medical technology

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