Manual of use and maintenance
Summary

00.0 Introduction ................................................................. 3
00.1 Foreword ........................................................................ 3
00.2 Description of the Device ............................................ 3
00.3 Intended Use .................................................................. 4
00.4 Safety requirements .................................................... 4
01.0 Identification data .......................................................... 6
01.1 Identification data .......................................................... 6
01.2 Data plate of the device ................................................. 6
01.3 Data plate of the scaler handpiece .................................. 6
02.0 Testing ............................................................................. 7
02.1 Testing of the equipment ................................................ 7
03.0 Delivery .......................................................................... 7
03.1 Delivery of the apparatus ................................................. 7
03.2 List of material included in the supply ............................. 8
04.0 Installation ................................................................. 10
04.1 Safety requirements during Installation ....................... 10
04.2 Initial installation .......................................................... 10
04.3 Connecting the Accessories .......................................... 11
05.0 Use ............................................................................... 13
05.1 Controls ......................................................................... 13
05.2 Switching the device ON and OFF ................................. 13
05.3 Description of the display and functions ....................... 14
05.4 Safety requirements during use .................................... 16
05.5 Protection systems and alarms ...................................... 17
05.6 Instructions for use ....................................................... 18
05.7 Permissible settings on the basis of the type of insert ....... 19
05.8 Rules for keeping the device in proper working order ...... 19
06.0 Cleaning and sterilisation .............................................. 20
06.1 CLEAN function - Cleaning of the liquid circuit .......... 20
06.2 Cleaning and disinfecting the casing of the device ......... 20
06.3 Sterilisation procedure .................................................. 21
06.4 Cleaning and autoclave sterilisation of the handpiece ...... 21
06.5 Cleaning and autoclave sterilisation of the inserts .......... 22
06.6 Cleaning and autoclave sterilisation of the wrench for tightening the inserts .................................. 23
06.7 Autoclave sterilising of the tube of the peristaltic pump ... 23
06.8 Autoclave sterilising of the fitting between the cord and the tube of the peristaltic pump ............ 24
07.0 Regular maintenance ..................................................... 24
07.1 Shelf Storage ............................................................... 24
07.2 Power-supply cable ...................................................... 24
08.0 Replacement of the fuses .............................................. 25
09.0 Disposal procedures and precautions ............................. 25
10.0 The inserts ...................................................................... 26
11.0 Symbols .......................................................................... 26
12.0 Troubleshooting ............................................................ 27
13.0 Technical data .............................................................. 30
13.1 Electromagnetic compatibility EN 60601-1-2 .................. 31
14.0 Guarantee ...................................................................... 35

00.1 Foreword

Before proceeding with the installation, use, maintenance or any other activities on the equipment please read this manual carefully.
Always keep this manual within easy reach.

Important: To avoid causing personal injuries or damage to property, read all the points concerning “Safety requirements” contained in this manual with particular attention.
Depending on the level of risk involved, safety requirements are classed under the following indications:

⚠️ DANGER (always referred to personal injury)
⚠️ WARNING (referred to possible damage to property)

The purpose of this manual is to ensure that operators are aware of the safety requirements, of the installation procedures and of the instructions for correct use and maintenance of the apparatus.
The user is not authorised to tamper with the equipment under any circumstances.
If any problems are encountered, please contact a Mectron Service Centre.

Any attempts on the part of the user or any unauthorised personnel to tamper with or alter the apparatus will invalidate the warranty and release the Manufacturers from any liability in respect of any harm or damage to persons or property.
The information and illustrations contained in this manual are up-dated to the date of publication indicated on the last page.

MECTRON are committed to continuous up-dating of their products, which may entail changes to components of the equipment. If there are any discrepancies between the descriptions contained in this manual and your equipment, please contact your dealer or the MECTRON After-Sale service for explanations.

Using this manual for purposes other than those relating to the installation, use and maintenance of the equipment is strictly prohibited.

00.2 Description of the Device

Thanks to its controlled three-dimensional ultrasound oscillations, the original Piezosurgery technique rings in a new age for osteotomy and osteoplasty in Implantology, Periodontology, Endodontics and Orthodontic Surgery. Its main features are:
- Micrometric cutting: Maximum surgical precision and intra-operative sensibility;
- Selective cutting: Maximum safety for the soft tissues;
- Cavitation effect: Maximum intra-operative visibility (bloodless field).
The equipment has an automatic tuning circuit that offsets wear of the inserts, thus ensuring work in constant conditions of maximum efficiency.
00.3 Intended Use

The Piezosurgery is a piezoelectric device for bone surgery that enables osteotomy and osteoplasty techniques to be applied in almost any anatomical situation. This equipment can be used in the following fields:

- **Oral Surgery:**
  - Extraction - Apicectomy - Cystectomy - Osteogenic distraction.
- **Implantology:**
  - Bone window osteotomy - Crest expansion - Bone fragment removal - Monocortical bone removal - Osteoplasty - Final preparation of the implant site - Extraction for immediate implantation - Elevation of Schneider’s membrane.
- **Periodontal Surgery:**
  - Osteotomy and osteoplasty techniques - Removal of bone tissues in regeneration surgery - Root debridement - Root planing.
- **Surgical Orthodontics:**
  - Exposure or extraction of embedded teeth - Orthodontic corticotomy.

This equipment may be used only in a dentist’s surgery or out-patient’s department where there are no inflammmable gases (anaesthetic mixtures, oxygen, etc.).

00.4 Safety requirements

Mectron will not accept any liability for direct or incidental personal injury or damage to property in the following cases:

1. If the equipment is used for purposes other than that for which it is intended.
2. If the equipment is not used in accordance with all the instructions and requirements described in this manual.
3. If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements.
4. If any assembly operations, extensions, settings, alterations or repairs have been carried out by personnel not authorised by Mectron.
5. If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications.

⚠️ **DANGER:** Qualified and specialised personnel.

This equipment may be used only by specialised and suitably trained personnel such as surgeons. If correctly used, this equipment does not give rise to side effects. Improper use, on the other hand, will give rise to transmission of heat to the tissues.

⚠️ **DANGER:** Intended use.

Use the equipment solely for the purpose for which it is intended (see point “00.3”). Failure to comply with this requirement could lead to serious harm to the patient and/or to the operator and/or damage to/failure of the equipment.

⚠️ **DANGER:** Contraindications.

Do not use the Piezosurgery on patients with pace-makers or other implantable electronic devices. The same requirement applies also to the operator.

⚠️ **DANGER:** Contraindications.

An electrosurgical knife could interfere with correct functioning of the device.

⚠️ **DANGER:** Cleaning, disinfection and sterilisation of new or repaired products.

All new or repaired products are delivered in non sterile conditions. Before being used for treatments, all new or repaired products should be cleaned, disinfected and sterilised following the instructions provided under point “06.0” strictly.

⚠️ **DANGER:** Infection control.

In order to ensure maximum safety for both the patient and the operator, use only accessories that have been cleaned, disinfected and sterilised. Follow the instructions provided under point “06.0” closely.

⚠️ **DANGER:** Use only original Mectron accessories and spare parts.

⚠️ **DANGER:** Check the condition of the device before treatment.

Always make sure that there is no water under the apparatus. Before each treatment always check that the equipment is in proper working order and that the accessories are efficient. Do not carry out the treatment if any problems are encountered in operating the device. If the problems concern the equipment contact an authorised technical service centre.

⚠️ **DANGER:** Breakage and wear of the Inserts.

The high-frequency vibrations and wear may, very occasionally, lead to breakage of the insert. Inserts of which the shape has been changed or which are otherwise damaged are liable to break during use. Any such inserts should definitely not be used. It is necessary to instruct the patient to breathe through his nose during the treatment in order to avoid ingestion of the broken off fragment of the insert.

⚠️ **DANGER:** Do not install the equipment anywhere where there is a risk of explosions.

The equipment cannot function in places where there is an inflammable atmosphere (anaesthetic mixtures, oxygen, etc.).

⚠️ **DANGER:** Personal injury.

The footswitch of the Piezosurgery must not be activated with the door of the peristaltic pump open (Fig.4 - Ref.B). Moving parts could injure the operator.

⚠️ **WARNING:** Contraindication.

Do not carry out this treatment on metal or ceramic prosthetic artefacts. The ultrasonic vibrations could lead to decementing of such artefacts.

⚠️ **WARNING:** Contraindication.

After autoclave sterilising of the handpiece, wait for it to cool down completely before using it.
01.0 Identification data

01.1 Identification data
An exact description of the model including the serial number of the equipment will make it easier for our After-Sale Service to respond quickly and efficiently to your queries. Always provide the above information whenever you contact a Mectron Service Centre.

01.2 Data plate of the device
Each device has its own data plate (Fig.1), on which its technical specifications and serial number are indicated. The data plate is on the rear of the device. The remaining data are included in this manual (see Section "13.0").

02.1 Testing of the equipment
All equipment manufactured by MECTRON is thoroughly checked and tested, including all components. During the testing procedure the components are subjected to a number of work cycles. The tests highlight any malfunctioning due to faulty components. This procedure ensures proper functioning and reliability of all components.

03.1 Delivery of the apparatus
The equipment contains electronic components that may be damaged by impacts even inside the packaging. Special care must therefore be taken for both transport and storage. In order to avoid crushing, do not place cartons on top of one. All material shipped by MECTRON is checked at the time of shipment. The equipment is delivered properly protected and packaged. At the time of receipt of the equipment check it for possible transport damage. If any damage is found, make a complaint to the carrier.
03.2 List of material included in the supply

The material included in the supply may vary in case of promotional campaigns.

⚠️ WARNING: Handpiece and cord can’t be detached.

“Starter” configuration

1. Casing of the device (Fig.3 - Ref.B).
2. Piezosurgery handpiece complete with cord (Fig.3 - Ref.E).
3. K5 torque wrench (Fig.3 - Ref.D).
4. Footswitch with cable and plug (Fig.3 - Ref.G).
5. Connection for the cord and tube of the peristaltic pump (Fig.3 - Ref.F).
6. Drip system (Fig.3 - Ref.L).
7. Power-supply cable (Fig.3 - Ref.H).
8. Tube for the Piezosurgery peristaltic pump (Fig.3 - Ref.I).
9. Rod for supporting the bag (Fig.3 - Ref.N).
10. Support for the Piezosurgery handpiece (Fig.3 - Ref.M).
11. Inserts (Fig.3 - Ref.C).

“Professional” configuration

1. Casing of the device (Fig.3 - Ref.B).
2. Piezosurgery handpieces complete with cords (Fig.3 - Ref.E).
3. K5 torque wrenches (Fig.3 - Ref.D).
4. Footswitch with cable and plug (Fig.3 - Ref.G).
5. Connections for the cord and tube of the peristaltic pump (Fig.3 - Ref.F).
6. Drip system (Fig.3 - Ref.L).
7. Power-supply cable (Fig.3 - Ref.H).
8. Tube for the Piezosurgery peristaltic pump (Fig.3 - Ref.I).
9. Rod for supporting the bag (Fig.3 - Ref.N).
10. Support for the Piezosurgery handpiece (Fig.3 - Ref.M).
11. Inserts (Fig.3 - Ref.C).

Fig. 3
04.0 Installation

04.1 Safety requirements during Installation

⚠️ DANGER: The wiring system of the premises where the apparatus is installed and used must comply with the applicable standards and the relevant electrical safety requirements.

⚠️ DANGER: Do not install the apparatus in places where there is a risk of explosion. The apparatus may not be used in areas where there are inflammable atmospheres (anaesthetic mixtures, oxygen, etc.).

⚠️ DANGER: Install the apparatus in a place where it will be protected from blows and from accidental sprays of water or other liquids.

⚠️ DANGER: Do not install the device on or in the vicinity of sources of heat. Install it in such a way that there is an adequate circulation of air around it. Leave sufficient free space around it, in particular with reference to the fan on the rear (Fig. 5 - Ref.G).

⚠️ DANGER: Personal injury. The footswitch of the Piezosurgery must not be activated when the door of the peristaltic pump is open (Fig. 4 - Ref.B). Moving parts could cause personal injury of the operator.

⚠️ WARNING: Do not expose the apparatus to direct sunlight or to sources of UV light.

⚠️ WARNING: The apparatus is transportable, however it must be handled with care when it is moved. Position the pedal on the floor in such a way that it can only be activated intentionally by the operator.

⚠️ WARNING: Before connecting the cord to the device, make sure that the electrical contacts are perfectly dry. If necessary, dry them with the air syringe.

04.2 Initial installation

To ensure perfect operation of the equipment, it is installed by technical personnel authorised by Mectron. The equipment will be installed in a suitable and handy place for it to be used, and is enabled by entering an activating password.

The activating password is given to the technician responsible for installation and is not indicated inside the package containing the device. The purpose of this is to ensure immediate traceability of the device, as required according to current legislation.

The technician must:
- Install the device in a suitable place;
- Explain the main aspects of correct installation to the user;
- Fill in the installation form, including the purchaser’s data;
- Send the installation form to Mectron to ensure traceability and activation of the warranty;
- Enter the activating password to enable the device.

04.3 Connecting the Accessories

The accessories listed below have to be connected to the Piezosurgery device:

1. Insert the silicone tube into the peristaltic pump, proceeding as follows:
   - Open the door (Fig. 4 - Ref.A) as far as it will go (Fig. 4 - Ref.B).
   - Position the tube in the impeller (Fig. 4 - Ref.C).
   - Close the door completely (Fig. 4 - Ref.E).

   ⚠️ DANGER: Personal injury.
   The footswitch of the Piezosurgery must not be activated when the door of the peristaltic pump is open (Fig. 4 - Ref.B). Moving parts could cause personal injury of the operator.

2. Insert the rod for supporting the bag into the hole provided for it (Fig. 5 - Ref.E).

3. Insert the handpiece support into the two holes provided for it (Fig. 5 - Ref.C).

4. Connect the footswitch to the casing of the device by inserting the plug into the footswitch socket (Fig. 5 - Ref.H).

5. Plug the power cable into the connector on the casing of the device (Fig. 5 - Ref.I) and then into the power outlet.

6. Connect the Piezosurgery cord to the cord connector on the device (Fig. 5 - Ref.D).

7. Connect the tube of the Piezosurgery into the pump fitting (Fig. 5 - Ref.N). Insert the pump fitting into the tube of the peristaltic pump (Fig. 5 - Ref.M).

8. Connect end of the tube of the peristaltic pump (Fig. 5 - Ref.L) to the flow-control system.

9. Connect the flow-control system to the bag containing the appropriate liquid for the treatment.
05.0 Use

05.1 Controls

This section illustrates the parts of the front panel (Fig.6) of the Piezosurgery unit, enabling the controls described in this manual to be located immediately.

Description of the controls

Ref. A - Graphic display.
Function The display shows the following information:
- The type of power setting
- The output power level set in the ROOT mode.
- The output power level set in the BONE mode.
- The delivery rate of the pump.
- The cleaning cycle for the liquid circuit.

Ref. B - Pair of 2 keys: PUMP + and -.
Function These can be used to set the delivery rate of the peristaltic pump.

Ref. C - Power-level key
Function This key is used to set the output power level required.

Ref. D - Power-type key
Function This key is used to set the type of output power required: ROOT/BONE;
This key is used to set the CLEAN function by holding down the key for 5 seconds.

Other controls for operating the device are:

Ref. F (Fig.5) - The ON/OFF switch.
Function For supplying electricity to the device.

Ref. G (Fig.3) - The enabling footswitch.
Function For activating operation of the device.

05.2 Switching the device ON and OFF

Switching the device on
1  Power up the device by turning on the MAIN SWITCH (Fig.5 - Ref.F) situated on the casing of the device, taking care not to press the footswitch.
2  The device will switch on.

Switching the device off
1  Power down the device by turning off the MAIN SWITCH (Fig.5 - Ref.F) situated on the casing of the device.
2  The device will switch off.
05.3 Description of the display and functions

This point describes the three “screens” shown on the Piezosurgery display and their functions. With the Piezosurgery device, two different power modes can be used. These are ROOT and BONE. Press the arrow key (Fig.6 - Ref.D) to set the required power mode. The type of power that has been chosen will be indicated between two pointers (Fig.7 - Ref.B).

**Device in the ROOT mode Fig. 7** - In the ROOT mode, press the power-level key (Fig.6 - Ref.C) to set the following functions:
- ENDO
- PERIO
To adjust the delivery rate of the pump, press the + and – keys (Fig.6 - Ref.B). In the ROOT mode, the speed can be set to between nought and five. The display will show the speed that has been selected (Fig.7 - Ref.A).

**Device in the BONE mode Fig. 8** - In the BONE mode, press the power-level key (Fig.6 - Ref.C) to set the following functions:
- QUALITY 1
- QUALITY 2
- QUALITY 3
- SPECIAL
To adjust the delivery rate of the pump press the + and – keys (Fig.6 - Rif.B). In the BONE mode, the speed can be set to between one and five. The display will show the speed that has been selected (Fig.8 - Ref.A).

**Device in the CLEAN mode: Fig. 9** - The device has a CLEAN function, which can be used to carry out a cleaning cycle of the hydraulic circuit. This function must be carried out after using the device, before cleaning, disinfecting and sterilising all the parts (See Section 06.0).
To activate the CLEAN function, press the power selection key and hold it down for 5 seconds (Fig.6 - Ref. D). The following message will appear on the display “**Footswitch to start or a key to abort**”. This tells the operator to press the footswitch to start the cleaning cycle or to press any of the four keys below the display to exit from the CLEAN function. For further indications concerning the CLEAN function, see point 06.1.
05.4 Safety requirements during use

⚠️ **DANGER: Contraindications.**
Do not use the Piezosurgery on patients with pacemakers or other implantable electronic devices. This requirement also applies to the operator.

⚠️ **DANGER: Breakage and wear of the inserts.**
High frequency oscillations and wear may, on rare occasions, lead to breakage of an insert. If the shape of an insert has been altered or if it is otherwise damaged, it is liable to break while it is being used. Inserts in these conditions should not be used under any circumstances. In order to avoid ingestion by the patient of a fragment of a broken insert, he/she should be instructed to breathe through his/her nose during the treatment.

⚠️ **DANGER: Control of infections.**
For maximum safety of both the patient and the operator, clean, disinfect and sterilise the piezo-electric handpiece, the inserts and the torque wrench after each treatment. Follow the appropriate instructions for doing this provided in point 06.0 “CLEANING AND STERILISATION”.

⚠️ **WARNING: Contraindication.**
Do not carry out treatments on metal or ceramic prosthetic artefacts. The ultrasonic vibrations could cause decementing of such artefacts.

⚠️ **WARNING: Contraindication.**
After autoclave sterilising of the handpiece, wait for it to cool down completely before using it.

⚠️ **WARNING: 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, in particular after the autoclave sterilisation cycle. If necessary, dry the contacts by blowing air onto them with the syringe.

⚠️ **WARNING: After using aggressive solutions, it is necessary to carry out a cleaning cycle of the tubes and handpiece with distilled water, using the clean function (See point 06.1). If the tubes are not cleaned, crystallisation of the salts could seriously damage the device.**

⚠️ **WARNING: To use the device correctly, it is necessary to press the footswitch and start it up without letting the insert rest on the part to be treated. This will allow the electronic circuit to detect the point where resonance of the insert is best without any interference, thus enabling optimum performance. If this is not done, contact with the part to be treated or with other surfaces before start-up could cause tripping of the protection systems.**

⚠️ **WARNING: For spray treatment, use only inserts through which liquid is passed.**

05.5 Protection systems and alarms

The device has a diagnostics circuit that is used to recognize tripping of the protection systems and of the alarms. These are shown on the display, as follows:

- **ERR0** Switch the device off and then on again. If the problem persists contact the Mectron Service Centre
- **ERR1** Signal that the general protection system has been activated:
  - Piezosurgery handpiece not connected to the device.
  - Tuning circuit not working correctly.
  - Handpiece failure.
- **ERR 2** Signal that the general protection system has been activated:
  - Piezosurgery handpiece not connected to the device.
  - Tuning circuit not working properly.
  - Handpiece failure.
- **ERR 3** Signal that the general protection system has been activated:
  - Tuning circuit not working properly.
  - Handpiece failure.
- **ERR 5** Signal that the tuning scan has failed:
  - Insert not correctly secured to the handpiece.
  - Insert worn, broken or deformed.
  - Electrical contacts of cord wet
- **ERR 6** Signal that the “power supply out of range” protection system has been tripped.
- **ERR 8** Signal indicating an error in communications with the scaler module.
- **ERR 9** Signal indicating an error in pump operation:
  - Check whether the pump and tube are correctly installed.
  - Check whether the pump is prevented from turning
- **ERR CKS** Error signal. Firmware. Firmware checksum incorrect:
  - If the equipment is working properly, call as soon as possible.
  - If the equipment is not working correctly, stop using it and call the Mectron Service Centre immediately.
05.6 Instructions for use

1. Open the air intake on the drip system.
2. Screw the chosen insert onto the Piezosurgery handpiece until it is flush against it (Fig. 10 - Ref. A).
3. Use the wrench included with the device to tighten the insert.

To use the torque wrench correctly (Fig. 10 - Ref. B) proceed as follows:

**WARNING:** Do not grip the end part of the handpiece or the cord, only the plastic casing (Fig. 10 - Ref. C), and do not turn it while fastening the insert in place;
- Turn the wrench in a clockwise direction until the clutch engages (the outer body of the key turns in relation to the casing of the handpiece, making clicking sounds);
- The insert is now properly tightened in place.

4. Make sure that the Piezosurgery handpiece is correctly connected to the device connector (Fig. 5 - Ref. D).

**WARNING:** To set the Mode and Power parameters correctly on the basis of the type of insert to be used, consult Table 1 or the leaflet accompanying the Mectron insert you have purchased.

5. Check the display to see the power mode that has been set (See point 05.3). Use the power mode selection key (Fig. 6 - Ref. D) to choose between the ROOT and BONE modes.

6. Check the display to see the level of power that has been set (See point 05.3), then use the power level selection key (Fig. 6 - Ref. C) to make your choice depending on the power mode:
- ROOT; ENDO; PERIO;
- BONE; QUALITY 1; QUALITY 2; QUALITY 3; SPECIAL

7. Check the display to see the delivery rate of the peristaltic pump (see point 05.3). If the delivery rate required is other than the level that has been set, use the PUMP + and – keys (Fig. 6 - Ref. B) to choose between the following, depending on the type of power that has been set:
- ROOT; 6 delivery rate levels From 0 to 5;
- BONE; 5 delivery rate levels From 1 to 5

**NOTE:** Sprayless treatment is only possible in the ROOT function, setting the delivery rate of the peristaltic pump PUMP to nought (Fig. 7 - Ref. A). No notches should be shown on the display.

05.7 Permissible settings on the basis of the type of insert

Table 1 shows the Mode and Power level settings permissible for correct use of the instrument.

<table>
<thead>
<tr>
<th>Insert</th>
<th>Mode</th>
<th>Power level</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL1 - EL2 - EL3</td>
<td>ROOT</td>
<td>ENDOD**</td>
</tr>
<tr>
<td>EN1 - EN2</td>
<td>ROOT</td>
<td>ENDOD**</td>
</tr>
<tr>
<td>EN3 - EN4</td>
<td>ROOT</td>
<td>ENDOD**</td>
</tr>
<tr>
<td>EX1 - EX2 - EX3</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>IM2A</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>IM2P</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>IM3A</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>IM3P</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OP1 - OP2</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OP3 - OP3A</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OP4</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OP6 - OP6A</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OP7</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OT1 - OT1A</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OT2 - OT3 - OT4</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OT5 - OT5A - OT5B</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OT6</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OT7 - OT7A</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>OT7S-3 - OT7S-4</td>
<td>BONE</td>
<td>SPECIAL**</td>
</tr>
<tr>
<td>OT8L - OT8R</td>
<td>BONE</td>
<td>1* ÷ 2* ÷ 3*</td>
</tr>
<tr>
<td>PP1</td>
<td>ROOT</td>
<td>PERIO</td>
</tr>
<tr>
<td>PS1 - PS2 - PS6</td>
<td>ROOT</td>
<td>PERIO</td>
</tr>
<tr>
<td>OP5</td>
<td>ROOT</td>
<td>PERIO</td>
</tr>
</tbody>
</table>

* *Quality 1 = Maximum power - Quality 2 = Medium power - Quality 3 = Minimum power
** Maximum permissible power

05.8 Rules for keeping the device in proper working order

1. Check the state of wear of the inserts periodically and replace any for which a drop in performance is noted.
2. Do not alter the shape of the inserts by bending or filing them.
3. Replace any insert that has become deformed or damaged by impacts.
4. Always make sure that any threaded parts and their contact surfaces are perfectly clean.
5. If an insert becomes too worn, the device will stop working.
06.0 Cleaning and sterilisation

06.1 CLEAN function - Cleaning of the liquid circuit

⚠️ WARNING: Failure to carry out cleaning of the tubes will lead to crystallisation of salts that can seriously damage the equipment.

⚠️ WARNING: The cord cannot be detached from the handpiece.

The device has a CLEAN function (See point 05.3) that can be used to run a cleaning cycle to clean the hydraulic circuit. This function must be carried out after using the device, before cleaning and sterilising all the parts (see following points).

1. Prepare a solution of enzymatic detergent with a pH of 6 to 9, in accordance with the manufacturer’s instructions.
2. Disconnect the tube of the peristaltic pump from the flow-control system.
3. Place the tube in a receptacle containing the enzymatic detergent.
4. To activate the CLEAN function, press the power level selection key and hold it down for 5 seconds (Fig. 6 - Ref.D). The following message will appear on the display: "Footswitch to start or a key to abort".
5. Fit one of the inserts used during the operation onto the handpiece.
6. Place the handpiece over a bowl to collect the water that pours out of it during the cleaning cycle.
7. Press the footswitch briefly to start the cleaning cycle. As soon as the peristaltic pump starts up a status bar will appear on the display to indicate progressively the time remaining to completion of the CLEAN cycle. The cycle lasts for 20 seconds and once it has started it cannot be stopped.
8. Upon completion of the cleaning cycle, the device exits from the CLEAN function and returns to whatever function had been set previously.
9. Repeat the operations described above from point 4 onwards to carry out a cleaning cycle for each of the tubes and for all of the accessories used, i.e.:
   - Handpieces;
   - Peristaltic pump tubes;
   - Fittings.
10. Carry out a CLEAN cycle using distilled water to remove any residual detergent.
11. After completion of the cleaning operations, empty the tubes and dry the accessories and dry the accessories that have been subjected to the cleaning cycle.

06.2 Cleaning and disinfecting the casing of the device

⚠️ DANGER: Switch off the device.
Always turn off the device by means of the switch (Fig. 5 - Ref. F) and disconnect it from the power outlet before carrying out the following cleaning and disinfection activities.

⚠️ DANGER: The casing of the device is not protected against the penetration of liquids. Do not spray liquids directly onto the surface of the casing of the device.

⚠️ DANGER: The device cannot be sterilised.

After each treatment carry out the following operations:
1. Remove the insert from the handpiece.
2. Clean and disinfect the surfaces of the casing, the cords and their connectors using a low-phasing cloth moistened with a mild detergent solution (pH 6 to 9) and/or non-aggressive disinfectant having a neutral pH (pH 7). Follow the instructions supplied by the manufacturer of the disinfectant solution carefully. Allow the disinfectant solution to dry in air before using the device.

NOTE: Water-based disinfectant solutions with a neutral pH are highly recommended. Alcohol-based disinfectants are not recommended as they could discolour and/or otherwise damage plastic materials.

06.3 Sterilisation procedure

⚠️ WARNING: Carry out sterilisation using only a steam autoclave.
Do not use any other type of sterilising procedure (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.).

⚠️ DANGER: Infection control - Parts that can be sterilised - Thoroughly remove all residues before sterilising.
In order to avoid bacterial or viral infections, always clean, disinfect and sterilise the following components after each treatment:
1. Handpiece (Fig. 3 - Ref.E);
2. Inserts (Fig. 3 - Ref.C);
3. Wrench for tightening the inserts (Fig. 3 - Ref.D);
4. Tube for peristaltic pump (Fig. 3 - Ref.I);
5. Fitting between the cord and the tube of the peristaltic pump (Fig. 3 - Ref.F).

These components are made of materials able to withstand a maximum temperature of 135°C for 20 minutes at most.
The steam autoclave sterilising process must be carried out using one of the following two parameters:
- Cycle at 121°C for 16 minutes.
- Cycle at 134°C for 4 minutes.

All the stages of sterilisation must be carried out by the operator in accordance with EN ISO 17665-1:2006, EN ISO 556-1:2001 and ANSI/AAMI ST:46:2002 standards.

NOTE: Do not use hydrogen peroxide for disinfecting. Use only disinfectants with a neutral pH. Always rinse with sterile water.

06.4 Cleaning and autoclave sterilisation of the handpiece

⚠️ WARNING: The cord cannot be detached from the handpiece.

⚠️ WARNING: Disconnect the handpiece from the device only by unplugging the connector.

⚠️ WARNING: Do not dip the handpiece into disinfectant solutions or liquids of any other kind since this could damage it.

⚠️ WARNING: Do not place the handpiece in an ultrasonic tank.

⚠️ WARNING: Do not sterilise the handpiece with an insert screwed onto it.
NOTE: Do not use hydrogen peroxide for disinfecting. Use only disinfectants with a neutral pH and always rinse with sterile water.

Clean the handpiece thoroughly, taking special care to clean the threaded pin onto which the inserts are screwed (Fig. 11 - Ref.B) and to the adjacent ring-shaped cavity.

1 Prepare a solution of enzymatic detergent* with a pH of between 6 and 9, following the manufacturer’s instructions.

⚠️ WARNING: Carry out the CLEAN function on the handpiece (Point 06.1).

2 Unscrew the insert.

3 Unscrew the metal front cone (Fig. 11 - Ref.A).

4 Clean the surfaces of the casing, the cords and the connectors using a low-linting cloth moistened with a detergent solution (pH between 6 and 9) and disinfect them with a mild disinfectant having a neutral pH (pH 7).

5 Brush the surface of the handpiece gently with a soft nylon brush, paying special attention to the following parts:
   - Thread of the handpiece (Fig. 11 - Ref.B);
   - Titanium stem (Fig. 11 - Ref.C);
   - Front cone (Fig. 11 - Ref.A), externally and internally.

6 Rinse thoroughly with distilled water to eliminate any residual detergent.

7 Re-assemble the front cone onto the handpiece (Fig. 11 - Ref.A).

8 Dry the electric contacts by blowing air onto them with the syringe.

9 Seal the handpiece in an individual disposable bag (without any inserts).

10 Sterilise the handpiece in a steam autoclave.

⚠️ WARNING: Allow the handpiece to cool down completely after the sterilisation cycle before using it.

⚠️ WARNING: The electric contacts of the connector must be dry.

At the end of the sterilisation cycle, make sure that the electric contacts of the connector are perfectly dry before connecting the cord to the device. If necessary, dry the contacts by blowing air onto them with the syringe.

06.5 Cleaning and autoclave sterilisation of the inserts

⚠️ WARNING: Do not use hydrogen peroxide.

Do not use hydrogen peroxide to sterilise the inserts. Use only disinfectants with a neutral pH. Always rinse with sterile water.

1 Prepare a solution of enzymatic detergent* with a pH of between 6 and 9, following the manufacturer’s instructions.

2 Soak the insert in the enzymatic detergent solution for 10 minutes at 40°C.

3 Brush the surface of the insert gently with a soft nylon brush.

4 Use a syringe to inject the enzymatic detergent into the cavity of the insert. Repeat this operation three times in order to remove all the residues from the inner surface effectively.

5 Rinse with distilled water injected at a pressure of (3.8 bars) for at least 10 seconds so as to remove any residues.

6 Place the insert in an ultrasonic tank with the enzymatic solution at 40°C, leaving it for at least 10 minutes.

7 Rinse the insert with distilled water.

8 Brush the surface of the insert again gently with a soft nylon brush.

9 Rinse with distilled water injected at a pressure of 3.8 bars for at least 10 seconds so as to eliminate any residues.

⚠️ WARNING: Make sure that the insert is absolutely dry also internally before starting the sterilising cycle. To do this, blow air into it through the hole with the syringe. This will prevent the appearance of stains or patches on the surface of internal oxidising of the insert.

10 Seal the inserts individually in disposable bags.

11 Sterilise the inserts in a steam autoclave.

06.6 Cleaning and autoclave sterilisation of the wrench for tightening the inserts

⚠️ WARNING: Do not use hydrogen peroxide.

Do not use hydrogen peroxide to disinfect the wrench for tightening the inserts. Use only disinfectants with a neutral pH. Always rinse with sterile water.

1 Prepare a solution of enzymatic detergent* with a pH of between 6 and 9, following the manufacturer’s instructions.

2 Soak the wrench in the enzymatic detergent for 10 minutes at 40°C.

3 Brush both the internal and the external surfaces of the wrench gently with a soft nylon brush.

4 Rinse the wrench with distilled water until it can be seen that the contaminated parts have been removed.

5 Place the wrench in an ultrasonic tank with the enzymatic detergent solution at 40°C, leaving it there for at least 10 minutes.

6 Rinse with distilled water to eliminate any residues.

7 Seal the wrench in an individual disposable bag.

8 Sterilise the wrench in a steam autoclave.

06.7 Autoclave sterilising of the tube of the peristaltic pump

1 Prepare a solution of enzymatic detergent with a pH of between 6 and 9, following the manufacturer’s instructions.

⚠️ WARNING: Carry out the CLEAN function on the tube of the peristaltic pump (Point 06.1).

2 Clean the tube of the peristaltic pump with the enzymatic solution.

3 Rinse with distilled water and dry thoroughly.

Note: Do not use hydrogen peroxide to disinfect the tube. Use only disinfectants with a neutral pH. Always rinse with sterile water and dry thoroughly.

4 Seal the tube individually in a disposable bag.

5 Sterilise the tube in a steam autoclave.

* Process validated by an independent organisation using the enzymatic detergent Cidezime® (Enzol®).
06.8 Autoclave sterilising of the fitting between the cord and the tube of the peristaltic pump

1 Prepare a solution of enzymatic detergent with a pH of between 6 and 9, following the manufacturer’s instructions.

**WARNING:** Carry out the CLEAN function on the fitting of the peristaltic pump tube (Point 06.1).

2 Clean the fitting of the peristaltic pump tube with the enzymatic solution prepared as above.

3 Rinse with distilled water to eliminate any residues of detergent and dry thoroughly.

**NOTE:** Do not use hydrogen peroxide to disinfect the fitting. Use only disinfectants with a neutral pH. Always rinse with sterile water.

4 Seal the fitting individually in a a disposable bag.

5 Sterilise the fitting in a steam autoclave.

07.0 Regular maintenance

07.1 Shelf Storage

If the device is not used for several days running, follow the recommendations indicated below:

1 Carry out the cleaning cycles for the water circuits using the CLEAN function (see point "06.1").

2 Disconnect the device from the power mains.

3 Carry out cleaning, disinfection and sterilisation (see Section "06.0")

07.2 Power-supply cable

**DANGER:** Check regularly that the power cable is intact. If it is damaged, replace it with an original Mectron spare.

08.0 Replacement of the fuses

**DANGER:** Switch off the apparatus.

Always turn off the apparatus by means of the switch (Fig.5 - Ref.F) and disconnect it from the power outlet before carrying out the following maintenance activities.

1 Insert the flat tip of a screwdriver into the recess in the fuse compartment below the power socket and use it as a lever (Fig.12 - Ref.A).

2 Pull out the fuse compartment (Fig.12 - Ref.B).

3 **DANGER:** Replace the fuses, using fuses of the type indicated on the identification label on the bottom of the apparatus. Depending on the mains power supply, these fuses may be rated as follows:

- 230 VAC 500 mA T
- 115 VAC 1 mA T
- 100 VAC 1,2 mA T

4 Put the compartment back into place (Fig.12 - Ref.B).

09.0 Disposal procedures and precautions

- This equipment must be disposed of and treated as waste requiring separate collection;

- At the end of the life-cycle of this equipment, the purchaser is entitled to return the equipment to the dealer supplying new equipment. Instructions for disposal are available from Mectron;

- Failure to comply with the foregoing points may entail punishment in accordance with Directive 2002/96/EC.

**DANGER:** Hospital waste.

Treat the following items as hospital waste:

- Inserts, when worn or broken;
- Irrigator, after each treatment;
- Tube of the peristaltic pump, after 8 sterilising cycles;
- Torque wrench for tightening inserts, when worn or broken.
10.0 The inserts

Sharp inserts.

The sharp edges of these inserts can be used to treat bone structures efficiently and effectively. Sharp inserts are used in osteotomy and osteoplasty when a fine and well-defined cut in the bone structure concerned is required. There are also inserts with sharp edges for osteoplasty techniques and for removing bone fragments.

Smoothing inserts.

The smoothing inserts have surfaces shaped in such a way that they can be used to work the bone structures with precision and in a controlled manner. Smoothing inserts are used in osteotomy when it is necessary to prepare difficult and delicate structures such as those for preparing a maxillary sinus window or to complete preparation of the site of an implant.

Blunt inserts.

Blunt inserts are used for separating the soft tissues, for example for detaching Schneider’s membrane or for lateralis ing nerves. In periodontology, these inserts are used to smooth the root surfaces.

11.0 Symbols

N.B.: Please read carefully the instructions for use.

Type “B” applied part.

This device and its accessories shouldn’t be disposed or treated as solid urban waste.

The sterilisable materials must be autoclave sterilised and can withstand a maximum temperature of 135° C.


12.0 Troubleshooting

If the device does not seem to be working properly, read the instructions again and then check the following table.

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>POSSIBLE CAUSE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device does not turn on when the switch is positioned on ON.</td>
<td>The connector on the end of the power cable is not plugged into the socket on the rear of the device properly.</td>
<td>Check that the power cable is firmly connected.</td>
</tr>
<tr>
<td>The device is switched on but will not work. No errors are shown on the display.</td>
<td>The connector of the footswitch is not properly plugged into the socket.</td>
<td>Insert the footswitch connector properly.</td>
</tr>
<tr>
<td>A faint whistle can be heard coming from the Piezosurgery handpiece during operation.</td>
<td>The insert is not correctly tightened onto the scaler handpiece.</td>
<td>Unscrew the insert and screw it back into place correctly.</td>
</tr>
<tr>
<td>The device is switched on but does not work. The message ERR appears on the display.</td>
<td>The insert is not fitted correctly into the handpiece.</td>
<td>Unscrew the insert and screw it back into place correctly.</td>
</tr>
<tr>
<td>The connector of the cord is wet.</td>
<td>The insert is worn, broken or deformed.</td>
<td>Replace the insert.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dry the connectors.</td>
</tr>
<tr>
<td>PROBLEM</td>
<td>POSSIBLE CAUSE</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>The device is switched on but will not work. The message ERR appears on the display.</td>
<td>Cord not connected to the device</td>
<td>Connect the cord to the device</td>
</tr>
<tr>
<td></td>
<td>Lack of continuity of a lead in the cord.</td>
<td>Contact the nearest authorised MECTRON Service Centre.</td>
</tr>
<tr>
<td></td>
<td>Handpiece failure.</td>
<td>Contact the nearest authorised MECTRON Service Centre.</td>
</tr>
<tr>
<td></td>
<td>Malfunctioning of the tuning circuit.</td>
<td>Contact the nearest authorised MECTRON Service Centre.</td>
</tr>
<tr>
<td>No liquid comes out of the insert during operation.</td>
<td>The insert is of the type with no through-flow of liquid.</td>
<td>Use an insert of the type with through-flow of liquid.</td>
</tr>
<tr>
<td></td>
<td>The PUMP function is set to nought.</td>
<td>Press the + key on the front panel of the device for the PUMP function.</td>
</tr>
<tr>
<td></td>
<td>The bag of liquid is empty.</td>
<td>Replace the bag with a full one.</td>
</tr>
<tr>
<td></td>
<td>The drip system air intake has not been opened.</td>
<td>Open the air intake of the drip system.</td>
</tr>
<tr>
<td></td>
<td>The tubes of the drip system and of the pump have not been correctly installed.</td>
<td>Check the connections of the tubes.</td>
</tr>
<tr>
<td></td>
<td>The insert is clogged.</td>
<td>Free the passage in the insert through which the water passes.</td>
</tr>
<tr>
<td></td>
<td>The handpiece is clogged.</td>
<td>Contact the nearest authorised MECTRON Service Centre.</td>
</tr>
<tr>
<td>The device is working properly, but the pump is being forced.</td>
<td>Too much pressure by the impeller on the tube in the peristaltic pump.</td>
<td>Check that the tube in the peristaltic pump has been correctly inserted (See page 10, point 04.3)</td>
</tr>
<tr>
<td>The pump is turning correctly but when it stops liquid comes out of the handpiece.</td>
<td>The door of the peristaltic pump is not closed properly.</td>
<td>Make sure that the door of the peristaltic pump is properly closed (see page 10, point 04.3).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>POSSIBLE CAUSE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient power.</td>
<td>The insert is not correctly fitted to the handpiece (the message ERR appears on the display).</td>
<td>Unscrew the insert and screw it back into place correctly.</td>
</tr>
<tr>
<td></td>
<td>The insert is worn, broken or deformed (the message ERR appears on the display).</td>
<td>Replace the insert.</td>
</tr>
<tr>
<td></td>
<td>Insufficient maintenance of the insert.</td>
<td>See point “Rules for Keeping the Device in Proper Working Order”.</td>
</tr>
</tbody>
</table>
13.0 Technical data

Device in accordance with Directive 93/42/EEC:  
Class II a.

Class according to EN 60601-1:

<table>
<thead>
<tr>
<th>Device</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td>IP 20</td>
<td></td>
</tr>
<tr>
<td>IP X8</td>
<td></td>
</tr>
</tbody>
</table>

Device for intermittent operation:  
60° ON 30° OFF.

Power-supply voltage:

<table>
<thead>
<tr>
<th>Voltage</th>
<th>Frequency</th>
<th>50/60 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>230 VAC</td>
<td>± 10 %</td>
<td>50/60 Hz</td>
</tr>
<tr>
<td>115 VAC</td>
<td>± 10 %</td>
<td>50/60 Hz (optional).</td>
</tr>
<tr>
<td>100 VAC</td>
<td>± 10 %</td>
<td>50/60 Hz (optional).</td>
</tr>
</tbody>
</table>

Max. power absorbed:  
70 VA.

Fuses:

<table>
<thead>
<tr>
<th>Type</th>
<th>Voltage</th>
<th>500 mA</th>
<th>1 A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 5 X 20 mm 230 VAC</td>
<td>2 X</td>
<td>500 mA T.</td>
<td></td>
</tr>
<tr>
<td>Type 5 X 20 mm 115 VAC</td>
<td>2 X</td>
<td>1 A T.</td>
<td></td>
</tr>
<tr>
<td>Type 5 X 20 mm 100 VAC</td>
<td>2 X</td>
<td>1,2 A T.</td>
<td></td>
</tr>
</tbody>
</table>

Working frequency:  
Automatic scan.  
From 24 to 29.5 KHz.

Average power applied to the handpiece:  
Adjustable to 6 power levels:

<table>
<thead>
<tr>
<th>Mode</th>
<th>Power (W)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROOT</td>
<td>ENDO: 2,8 W</td>
</tr>
<tr>
<td>BONE</td>
<td>QUALITY1: 16 W</td>
</tr>
<tr>
<td></td>
<td>QUALITY2: 16 W</td>
</tr>
<tr>
<td></td>
<td>QUALITY3: 16 W</td>
</tr>
<tr>
<td></td>
<td>SPECIAL: 4,6 W</td>
</tr>
</tbody>
</table>

Delivery rate of the peristaltic pump:  
Adjustable via the keypad.  
In the ROOT power mode: 6 delivery rates:  
From 0 to approx. 100 ml / min.  
In the BONE power mode: 5 delivery rates:  
From 15 to approx. 100 ml / min circa.

Protection systems and tripping time of the APC:

- No handpiece connected  
  Tripping time 20 ms.
- Cord interrupted  
  Maximum tripping time 80 ms.
- Insert broken or not correctly tightened  
  Three scans, 150 ms each.
- Protection by discharge to earth  
  Tripping time 20 ms.

Alarms:  
The display on the front panel indicates error (see point "Problem-solving").

Operating conditions:  
From +10°C to +40°C.  
Relative humidity from 30% to 75%.

Transport and storage conditions:  
From -10°C to +70°C.  
Relative humidity from 10% to 90%.  
Air pressure P: 500hPa/1060hPa

Cord:  
It is recommended not to exceed 100 sterilisation cycles

Tube of peristaltic pump:  
It is recommended not to exceed 8 sterilisation cycles

Weight and size:  
3.5 Kg  
L - W - H 340 X 210 X 150 mm.

13.1 Electromagnetic compatibility EN 60601-1-2

<table>
<thead>
<tr>
<th>Guidance and manufacturer's declaration - Electromagnetic emissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The PIEZOSURGERY // is intended for use in the electromagnetic environment specified below. The customer or the user of the PIEZOSURGERY // should assure that it is used in such an environment.</td>
</tr>
<tr>
<td>Emissions test</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
</tr>
</tbody>
</table>

Guidance and manufacturer's declaration - Electromagnetic emissions  
The PIEZOSURGERY // is intended for use in the electromagnetic environment specified below. The customer or the user of the PIEZOSURGERY // should assure that it is used in such an environment.
### Guidance and manufacturer's declaration - Electromagnetic immunity

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5 % U&lt;sub&gt;r&lt;/sub&gt; (≥95 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 0,5 cycle</td>
<td>&lt;5 % U&lt;sub&gt;r&lt;/sub&gt; (≥95 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 0,5 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>40 % U&lt;sub&gt;r&lt;/sub&gt; (60 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 5 cycle</td>
<td>40 % U&lt;sub&gt;r&lt;/sub&gt; (60 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 5 cycle</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70 % U&lt;sub&gt;r&lt;/sub&gt; (30 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 25 cycle</td>
<td>70 % U&lt;sub&gt;r&lt;/sub&gt; (30 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 25 cycle</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5 % U&lt;sub&gt;r&lt;/sub&gt; (≥95 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 5 s</td>
<td>&lt;5 % U&lt;sub&gt;r&lt;/sub&gt; (≥95 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 5 s</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE: U<sub>r</sub> is the a.c. mains voltage prior to application of the test level.

---

### Guidance and manufacturer’s declaration - Electromagnetic immunity

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 V/eff 150 kHz to 80 MHz</td>
<td>3 Vrms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the disposal including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2,5 GHz</td>
<td>3 V/m</td>
<td>Recommended separation distance</td>
</tr>
<tr>
<td></td>
<td>d = 1,2 √P</td>
<td>d = 1,2 √P 80 MHz to 800 MHz</td>
<td>d = 2,3 √P 800 MHz to 2,5 GHz</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 2,5 GHz</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

![RF symbol](image)

Notes:
1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
   a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PIEZOSURGERY™ is used exceeds the applicable RF compliance level above, the PIEZOSURGERY™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PIEZOSURGERY™.
   b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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** Recommended separation distances between portable and mobile RF communications equipment and the PIEZOSURGERY // **

The PIEZOSURGERY // is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PIEZOSURGERY // can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PIEZOSURGERY // as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter “W”</th>
<th>Separation distance according to frequency of transmitter “m”</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>$d = 1,2 \sqrt{P}$</td>
</tr>
<tr>
<td>80 MHz to 800 MHz</td>
<td>$d = 1,2 \sqrt{P}$</td>
</tr>
<tr>
<td>800 MHz to 2.5 GHz</td>
<td>$d = 2,3 \sqrt{P}$</td>
</tr>
</tbody>
</table>

- 0.01 | 0.12 | 0.12 | 0.23
- 0.1 | 0.38 | 0.38 | 0.73
- 1   | 1.2  | 1.2  | 2.3
- 10  | 3.8  | 3.8  | 7.3
- 100 | 12   | 12   | 23

For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:
1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**14.0 Guarantee**

Before being placed on the market, all MECTRON equipment undergoes a thorough final check to ensure that it is are in proper working order.

MECTRON guarantees its products, purchased new from a MECTRON dealer or importer, to be free from manufacturing or material defects for:
- 2 (TWO) YEARS from the date of purchase for the device;
- 1 (ONE) YEAR from the date of purchase for the handpiece with its cord.

Throughout the warranty period, MECTRON undertake to repair (or, at their sole discretion, to replace) free of charge any parts that, in their opinion, are faulty. Complete replacement of MECTRON products is excluded.

Mectron cannot accept any liability for direct or incidental damage or personal injury in the following cases:
- If the equipment is used for purposes other than that for which it is intended.
- If the equipment is not used in accordance with all the instructions and requirements described in this manual.
- If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements.
- If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements.
- If any assembly operations, extensions, settings, alterations or repairs have been carried out by personnel not authorised by Mectron.
- If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications.

Accidental damages due to transport, incorrect use or carelessness or to connection to power supplies other than as envisaged and damage to the signalling lamps, handpieces and all accessories are excluded from the warranty.

The warranty will no longer apply if the apparatus has been tampered with or repaired by unauthorised personnel.

**WARNING**

The warranty is valid only if the warranty slip enclosed with the product has been completed in full and returned to us or, if appropriate, to your MECTRON dealer or importer within 20 (TWENTY) DAYS from the date of purchase, as proven by the consignment note/invoice issued by the dealer/importer.

In order to benefit from the warranty service, the customer must return the apparatus to be repaired to the MECTRON dealer/importer from which it was purchased, at his own expense.

The apparatus should be returned suitably packed (possibly in its original packing material), accompanied by all the accessories and by the following information:

a) Owner’s details, including his telephone number.

b) Details of the dealer/importer

c) Photocopy of the consignment note/purchase invoice of the apparatus issued to the owner and indicating, in addition to the date, also the name of the apparatus and its serial number.

d) A description of the problem.

Transport and any damages caused during transport are not covered by the warranty.

In the event of failures due to accidents or improper use, or if the warranty has lapsed, repairs to MECTRON products will be charged on the basis of the actual cost of the materials and labour required for such repairs.