

# PIEZOSURGERY //



MANUAL OF USE AND MAINTENANCE

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## 00.0 - INTRODUCTION

### 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 page 32.

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 to 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 inflammable 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.

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**⚠ 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”).

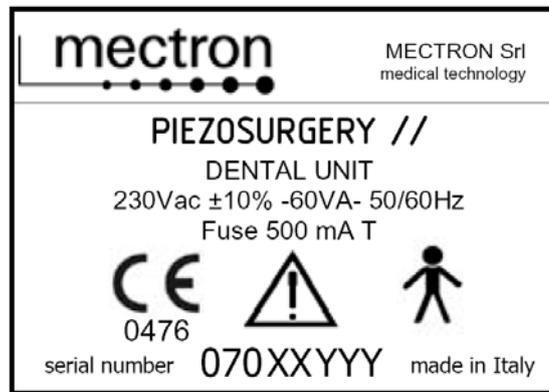


Fig. 1

### 01.3 - Data Plate of the Scaler Handpiece

The serial number of this Piezosurgery handpiece is engraved on the ringnut (Fig.2 - Ref.A).

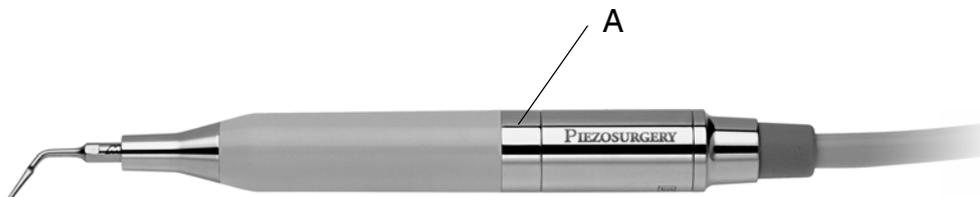


Fig. 2

## **02.0 - TESTING**

### **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.

## **03.0 - DELIVERY**

### **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 Materials included in the Standard Supply

- 1 Casing of the device (Fig.3 - Ref.B).
- 2 Piezosurgery handpieces complete with cords (Fig.3 - Ref.E).
- 2 K4 torque wrenches K4 (Fig.3 - Ref.D).
- 1 Footswitch with cable and plug (Fig.3 - Ref.G).
- 2 Connections for the cord and tube of the peristaltic pump (Fig.3 - Ref.F).
- 2 Drip system (Fig.3 - Ref.O).
- 1 Power-supply cable (Fig.3 - Ref.L).
- 8 Tube for the Piezosurgery peristaltic pump (Fig.3 - Ref.N).
- 1 Rod for supporting the bag (Fig.3 - Ref.Q).
- 1 Support for the Piezosurgery handpiece (Fig.3 - Ref.P).
- 1 Basic Insert Kit (Fig.3 - Ref.H) consisting of 5 inserts (Fig.3 - Ref.C).
- 1 Sinus Lift Insert Kit (Fig.3 - Ref.I) consisting of 5 inserts (Fig.3 - Ref.C).
- 1 Surgical Tray - Container for accessories to be sterilised (Fig.3 - Ref.M).

The items listed may vary during promotional campaigns.

 **WARNING: Handpiece and cord can't be detached.**

## 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.

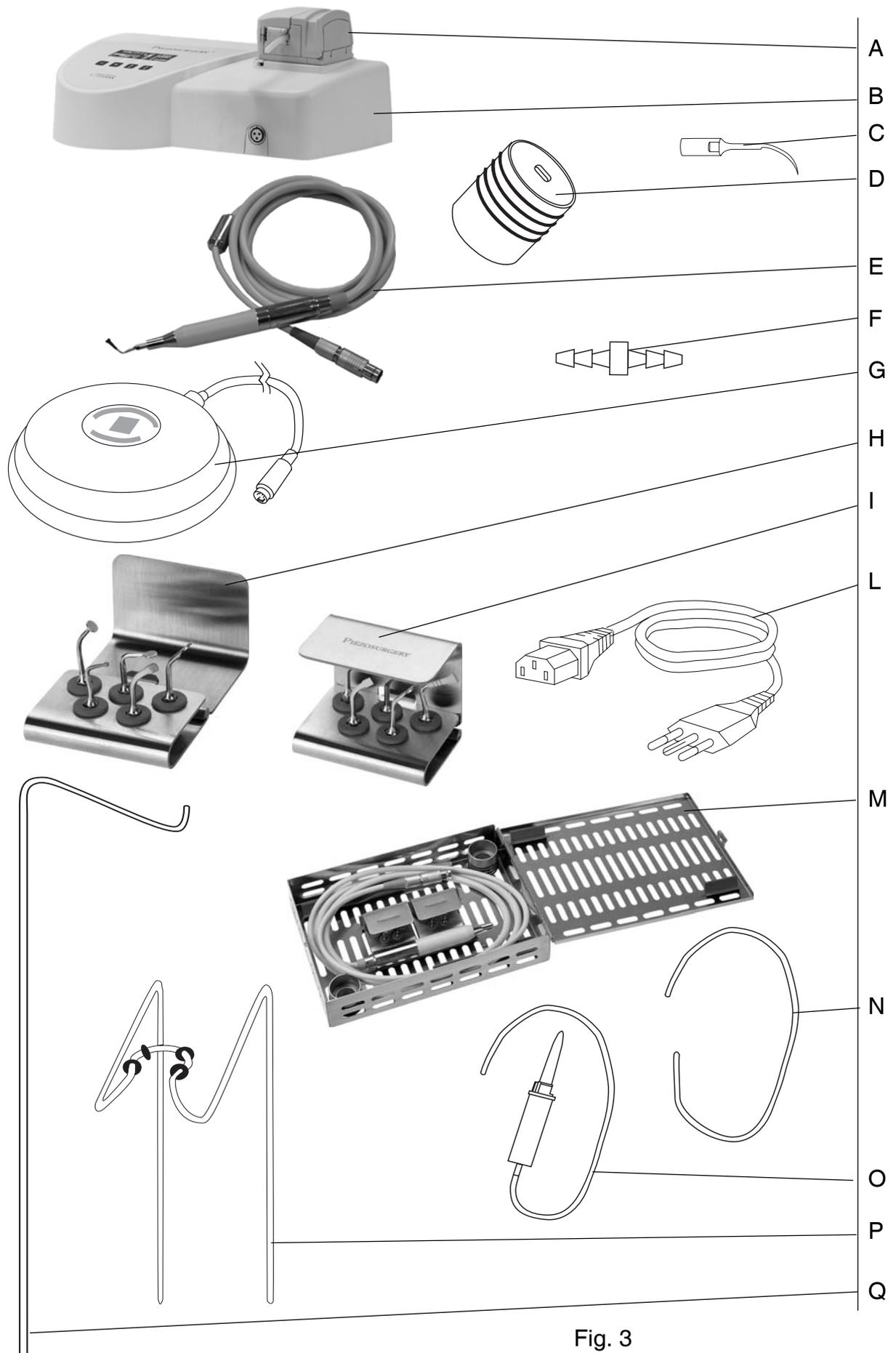


Fig. 3

**⚠ 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 Insert 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.

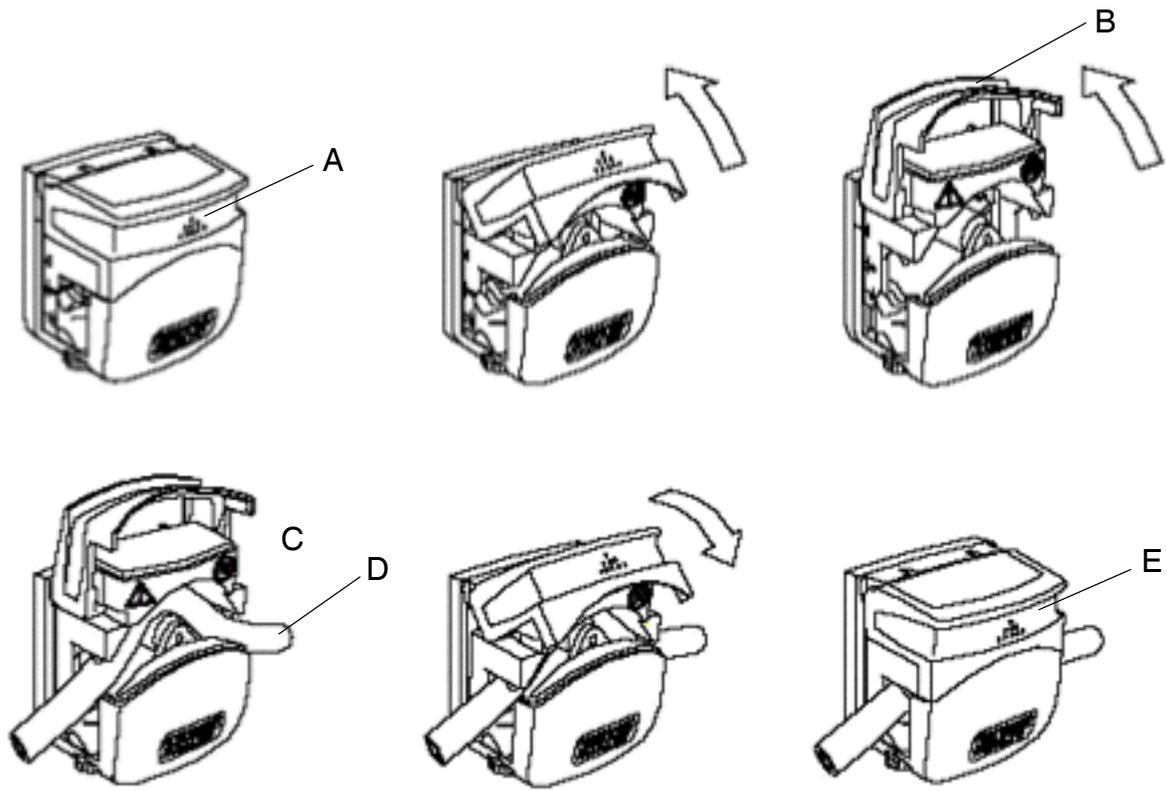


Fig. 4

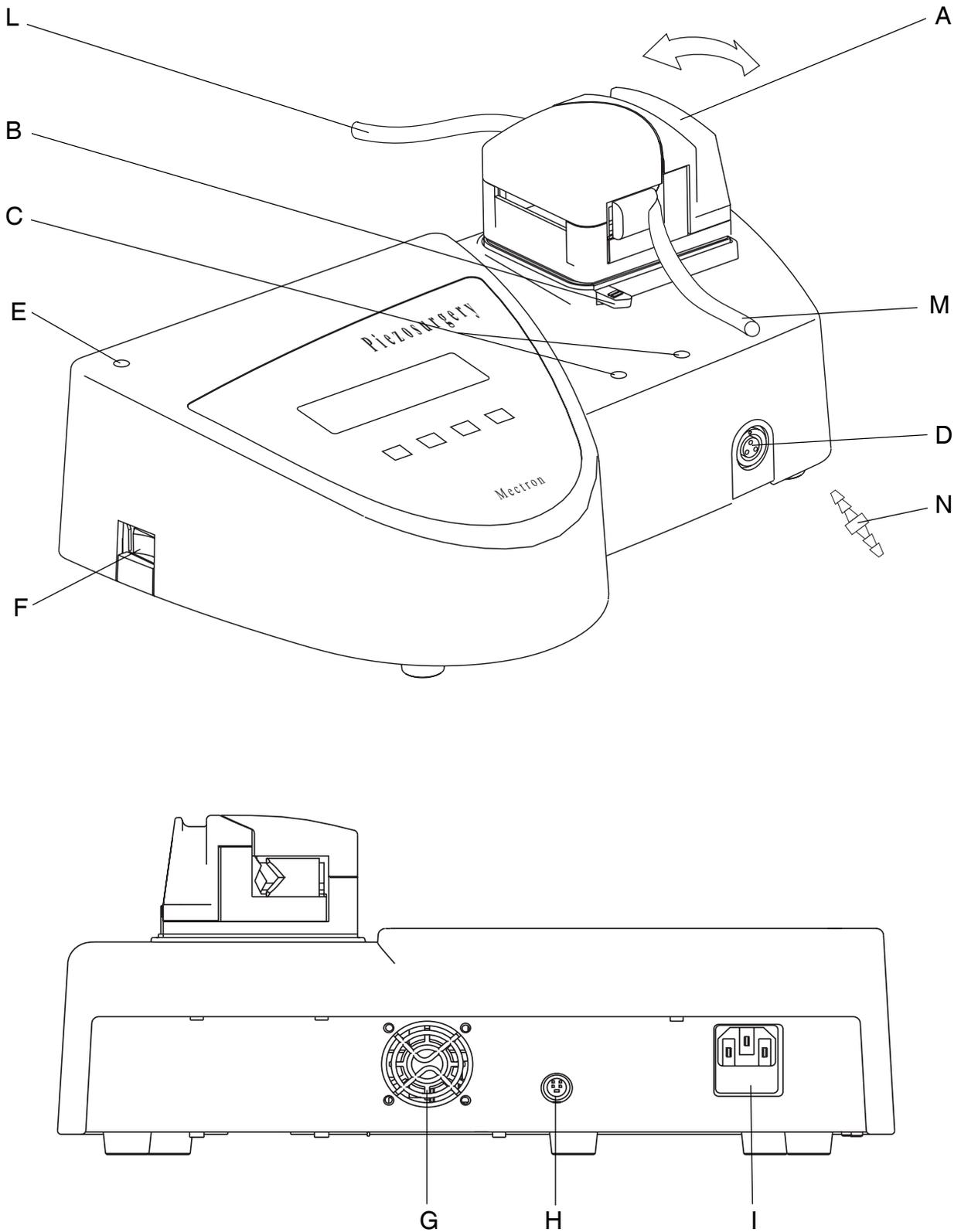


Fig. 5

## 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.	<b>ROOT/BONE ENDO/PERIO QUALITY 1/2/3 and SPECIAL PUMP: 5 Levels CLEAN</b>
	The delivery rate of the pump. The cleaning cycle for the liquid circuit.	
Ref. B	- Pair of 2 keys: <b>PUMP +</b> and <b>-</b> .	<b>+ -</b>
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: <b>ROOT/BONE</b> ; This key is used to set the <b>CLEAN</b> 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.

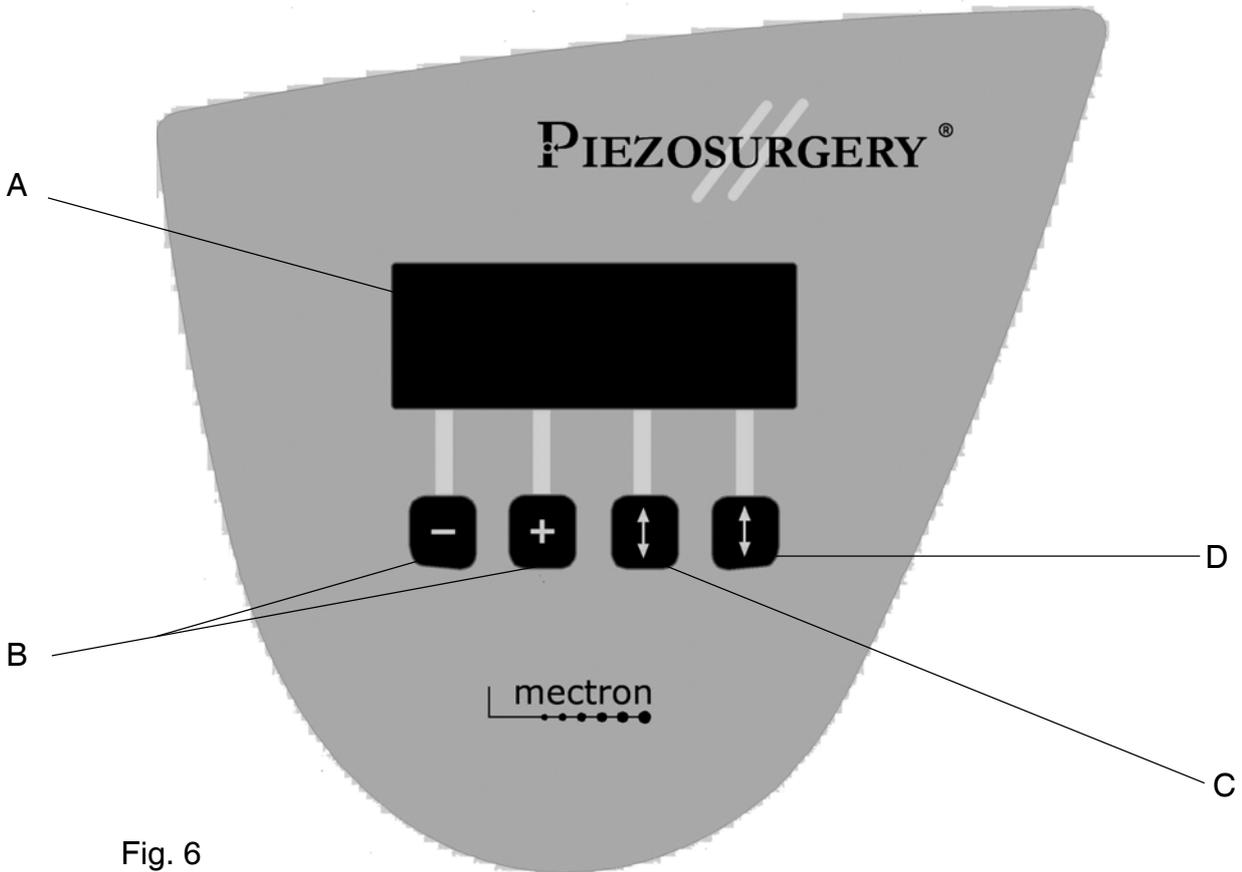


Fig. 6

### 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).

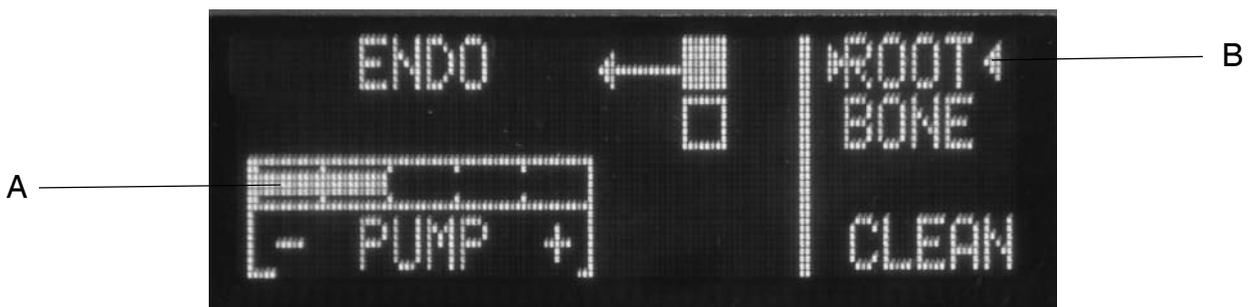


Fig. 7

**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).



Fig. 8

**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.

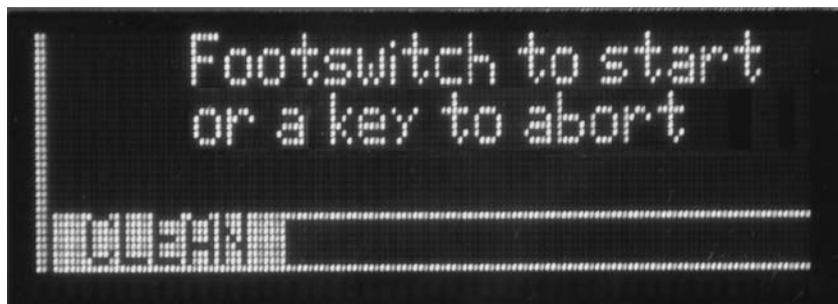


Fig. 9

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## 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 piezoelectric handpiece, the inserts and the torque wrench after each treatment. Follow the appropriate instructions for doing this provided in point 06.0 "CLEANING, DISINFECTATION 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:

- 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** For the manufacturer only - Contact the Mectron Service Centre.
- ERR 4** 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 Fit the required insert (Fig.10 - Ref.A) onto the Piezosurgery handpiece and lock it into place using one of the wrenches included in the supply.
  - 3 To use the torque wrench correctly (Fig.10 - Ref.B), proceed as follows:
    - screw the insert onto the handpiece as far as it will go
    - hold the wrench and the casing of the handpiece very firmly
    - turn the wrench in a clockwise direction until the clutch engages (the outer casing of the wrench slides against the casing of the handpiece). The insert is now locked properly into place.
  - 4 Make sure that the Piezosurgery handpiece is correctly connected to the handpiece connector (Fig.5 - Ref.D).
  - 5 Check the display to see the type of power that has been set (See point 05.3). If the type of power required differs from the type that has been set, use the **key for selecting the type of power** (Fig.6 - Ref.D). This can be pressed to toggle between the **ROOT** and **BONE** functions.
  - 6 Check the display to see the power level that has been set (See point 05.3). If the type of power required differs from the level that has been set, use the **key for selecting the power level** (Fig.6 - Ref.C). This can be used to choose between the following options, depending on the type of power that has been set:
    - 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 - 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.

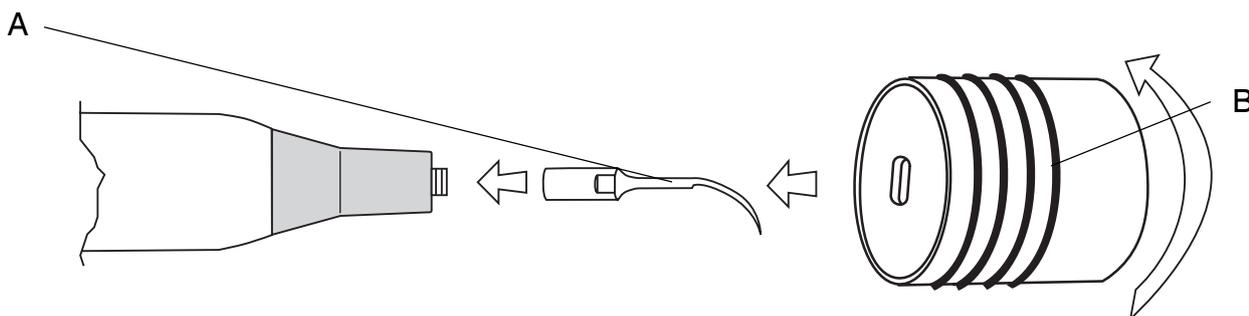


Fig. 10

- 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, DISINFECTION 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:** Handpiece and cord can't be detached.

The device has a **CLEAN** function (See point 05.3), which 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, disinfecting and sterilising all the parts (**See following points**).

- 1 Disconnect the tube of the peristaltic pump from the flow-control system.
- 2 Place the tube in a glass containing water (**demineralised water is recommended**).
- 3 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**".
- 4 Fit one of the inserts used during the operation onto the handpiece.
- 5 Place the handpiece over a bowl to collect the water that will be drained off during the cleaning cycle.
- 6 Press the footswitch 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 tempo **CLEAN** cycle. The cycle lasts for 20 seconds and cannot be stopped.
- 7 Once the cleaning cycle has been completed, the device exits from the **CLEAN** function and returns to the function that had been set previously.
- 8 Repeat the operations described from point 3 onwards to carry out the cleaning cycle of the tubes and of all the accessories used, i.e.:
  - **Handpieces** (Make sure that the electrical contacts of the cord connector to be subjected to the cleaning cycle are dry);
  - **Inserts;**
  - **Peristaltic pump tube;**
  - **Cord / peristaltic pump tube connection.**
- 9 On completion of the cleaning operations, empty the tubes and dry the accessories that have been through the cleaning cycle.

### **06.2 - Cleaning and disinfecting the casing of the apparatus**

 **DANGER:** Switch off the apparatus.

Always turn off the apparatus by means of the switch (Fig.5 - Ref.L) and disconnect it from the power outlet before carrying out the following cleaning, disinfection and sterilisation activities.

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

**⚠ DANGER: The apparatus cannot be sterilised.**

After each treatment carry out the following operations:

- 1 Remove the insert from the scaler handpiece.
- 2 Clean and disinfect the surfaces of the casing, the cords and their connectors using a cloth moistened with a mild detergent or disinfectant solution with a neutral pH (pH 7). Follow carefully the instructions given by the manufacturer of the disinfectant solution. Allow the disinfectant solution to dry in the air before using the apparatus.

**NOTE:** Water-based disinfecting solutions with a neutral pH are highly recommended. Some alcohol-based disinfecting solutions may be harmful and discolour 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 sterilisation procedure (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.).

**⚠ DANGER: Infection control - Parts that can be sterilised.**

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 Peristaltic pump tube (Fig.3 - Ref.N);
- 5 Cord / peristaltic pump tube connection (Fig.3 - Ref.F).

The above components are made of materials that will withstand a maximum temperature of 135 °C for maximum of 20 minutes.

All the stages of sterilisation must be carried out by the operator in accordance with EN 554 and EN 556 standards.

### 06.4 - Autoclave sterilisation of the handpiece

**⚠ WARNING: Handpiece and cord can't be detached.**

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

**⚠ WARNING: Do not sterilise the handpiece with the insert screwed into it.**

**⚠ WARNING: The electric contacts of the connectors of the handpiece and of the cord must be dry.**

At the end of the sterilisation cycle and before connecting the handpiece to the cord, make sure that the electric contacts of both connectors are completely dry. If necessary, dry the contacts by blowing air onto them with the syringe.

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**⚠ WARNING:** After completing the sterilisation cycle, allow the handpiece to dry completely before using it.

**NOTE:** Water-based disinfecting solutions with a neutral pH are highly recommended. Some alcohol-based disinfecting solutions may be harmful and discolour or otherwise damage plastic materials.

- 1 Clean the handpiece carefully paying special attention to the threaded pin onto which the inserts are screwed and to the adjacent ring-shaped cavity.
- 2 Disinfect the handpiece using a cloth moistened with a mild disinfectant solution having a neutral pH.
- 3 Dry the electric contacts by blowing air onto them with the syringe.
- 4 Seal the handpiece in an individual disposable bag (without any inserts). If the number of bags available is insufficient, it is possible to use the surgical tray included in the supply.
- 5 Sterilise the handpiece in the autoclave.

**⚠ 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.

## 06.5 - Autoclave sterilisation of the inserts

- 1 Clean the insert (preferably in an ultrasonic tank) and rinse it in distilled water.
- 2 Dry the insert.
- 3 Disinfect the insert with a mild disinfectant solution having a neutral pH and dry it carefully.

**⚠ WARNING:** Before starting the sterilisation cycle make sure that the insert is completely dry also inside. To do this, blow air through the internal hole with the syringe.

This will prevent stains and patches from appearing on the surface of the insert.

- 4 Seal the inserts inside individual disposable bags. As an alternative it is possible to use the insert holder included in the supply.
- 5 Autoclave sterilise the inserts.

## 06.6 - Autoclave sterilisation of the wrench for tightening the inserts

- 1 Clean the wrench.
- 2 Disinfect the wrench with a mild disinfectant solution having a neutral pH and dry it thoroughly.
- 3 Seal the wrench inside an individual disposable bag. As an alternative it is possible to use the surgical tray included in the supply.
- 4 Autoclave sterilise the wrench.

## **06.7 - Autoclave sterilisation of the peristaltic pump tube**

- 1 Clean the peristaltic pump tube.
- 2 Disinfect with a mild disinfectant solution having a neutral pH and dry it thoroughly.
- 3 Seal the tube inside an individual disposable bag.
- 4 Autoclave sterilise the tube.

## **06.8 - Autoclave sterilisation of the connection between cord and peristaltic pump tube connection**

- 1 Clean the connection between cord and peristaltic pump tube connection.
- 2 Disinfect with a mild disinfectant solution having a neutral pH and dry it thoroughly.
- 3 Seal the connection inside an individual disposable bag.
- 4 Autoclave sterilise the connection.

## 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.11 - Ref.A).
- 2 Pull out the fuse compartment (Fig.11 - 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.11 - Ref.B).

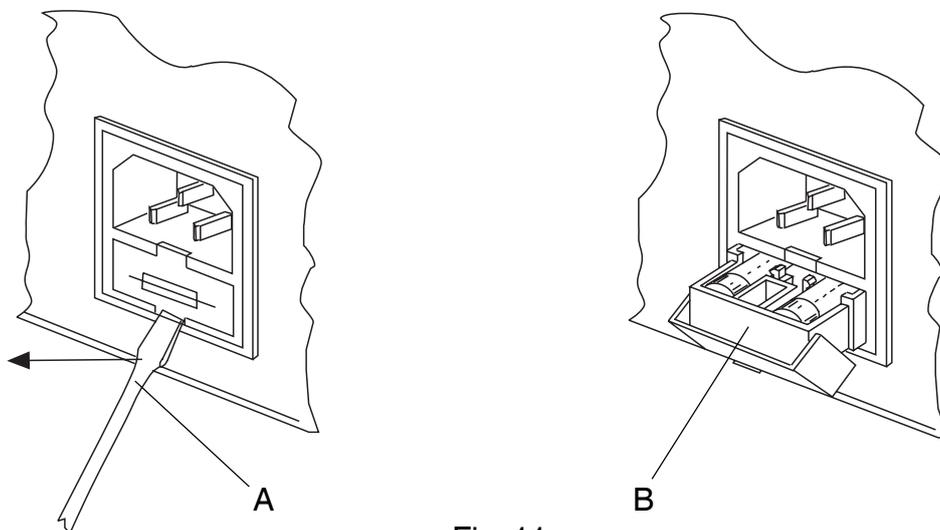


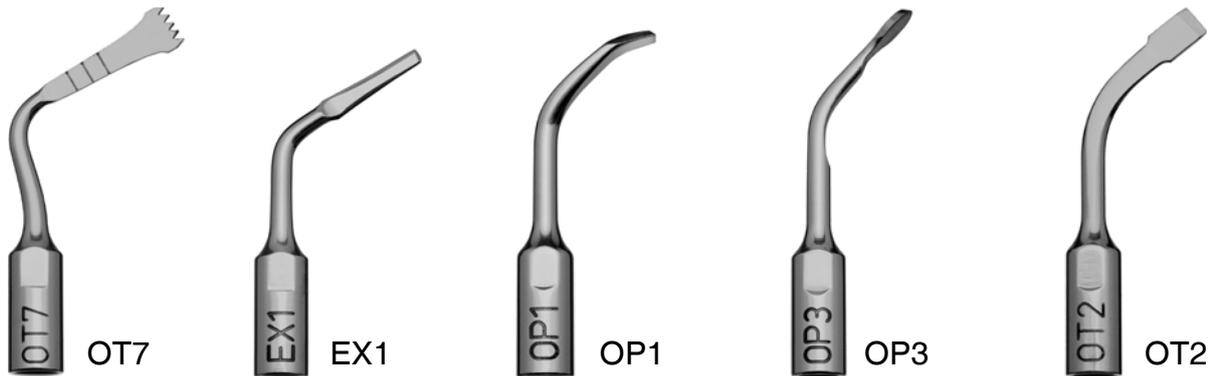
Fig. 11

## 09.0 - PROCEDURES AND PRECAUTIONS FOR DISPOSAL

The procedures and precautions to be observed for disposing of the apparatus are those indicated in the current regulations for any other electronic apparatus that is no longer in use.

## 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 lateralising 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.



Apparatus in accordance with EC Directive 93/42 EEC  
Including EN 60601-1 and EN 60601-1-2.  
Notified body: CERMET

## 12.0 - TROUBLESHOOTING

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

PROBLEM	POSSIBLE CAUSE	SOLUTION
<p>The device does not turn on when the switch is positioned on ON.</p>	<p>The connector on the end of the power cable is not plugged into the socket on the rear of the device properly.</p> <p>The power cable is faulty.</p> <p>The fuses are unserviceable.</p>	<p>Check that the power cable is firmly connected.</p> <p>Check that the power outlet is working properly. Replace the power cable.</p> <p>Replace the fuses (see point “Replacement of fuses”).</p>
<p>The device is switched on but will not work. No errors are shown on the display.</p>	<p>The connector of the footswitch is not properly plugged into the socket.</p> <p>The footswitch will not work.</p>	<p>Insert the footswitch connector properly.</p> <p>Contact the nearest authorised MECTRON Service Centre.</p>
<p>A faint whistle can be heard coming from the Piezosurgery handpiece during operation.</p>	<p>The insert is not correctly tightened onto the scaler handpiece.</p>	<p>Unscrew the insert and screw it back into place correctly.</p>
<p>The device is switched on but does not work. The message <b>ERR</b> appears on the display.</p>	<p>The insert is not fitted correctly into the handpiece.</p> <p>The insert is worn, broken or deformed.</p> <p>The connector of the cord is wet.</p>	<p>Unscrew the insert and screw it back into place correctly.</p> <p>Replace the insert.</p> <p>Dry the connectors.</p>

PROBLEM	POSSIBLE CAUSE	SOLUTION
<p>The device is switched on but will not work. The message <b>ERR</b> appears on the display.</p>	<p>Cord not connected to the device</p> <p>Lack of continuity of a lead in the cord.</p> <p>Handpiece failure.</p> <p>Malfunctioning of the tuning circuit.</p>	<p>Connect the cord to the device</p> <p>Contact the nearest authorised MECTRON Service Centre.</p> <p>Contact the nearest authorised MECTRON Service Centre.</p> <p>Contact the nearest authorised MECTRON Service Centre.</p>
<p>No liquid comes out of the insert during operation.</p>	<p>The insert is of the type with no through-flow of liquid.</p> <p>The <b>PUMP</b> function is set to nought.</p> <p>The bag of liquid is empty.</p> <p>The drip system air intake has not been opened.</p> <p>The tubes of the drip system and of the pump have not been correctly installed.</p> <p>The insert is clogged.</p> <p>The handpiece is clogged.</p>	<p>Use an insert of the type with through-flow of liquid.</p> <p>Press the <b>+</b> key on the front panel of the device for the <b>PUMP</b> function.</p> <p>Replace the bag with a full one.</p> <p>Open the air intake of the drip system.</p> <p>Check the connections of the tubes.</p> <p>Free the passage in the insert through which the water passes.</p> <p>Contact the nearest authorised MECTRON Service Centre.</p>

PROBLEM	POSSIBLE CAUSE	SOLUTION
<p>The device is working properly, but the pump is being forced.</p>	<p>Too much pressure by the impeller on the tube in the peristaltic pump.</p>	<p>Check that the tube in the peristaltic pump has been correctly inserted (See page 10, point 04.3)</p>
<p>The pump is turning correctly but when it stops liquid comes out of the handpiece.</p>	<p>The door of the peristaltic pump is not closed properly.</p>	<p>Make sure that the door of the peristaltic pump is properly closed (see page 10, point 04.3).</p>
<p>Insufficient power.</p>	<p>The insert is not correctly fitted to the handpiece (the message <b>ERR</b> appears on the display).</p> <p>The insert is worn, broken or deformed (the message <b>ERR</b> appears on the display).</p> <p>Insufficient maintenance of the insert.</p>	<p>Unscrew the insert and screw it back into place correctly.</p> <p>Replace the insert.</p> <p>See point “Rules for Keeping the Device in Proper Working Order”.</p>

## 13.0 - TECHNICAL DATA

<b>Device in accordance with Directive 93/42/EEC:</b>	Class II a.
<b>Class according to EN 60601-1:</b>	I Type B IP 20 (device) IP X8 (footswitch)
<b>Device for intermittent operation:</b>	60" ON 30" OFF.
<b>Power-supply voltage:</b>	230 VAC $\pm$ 10 % 50/60 Hz. 115 VAC $\pm$ 10 % 50/60 Hz (optional). 100 VAC $\pm$ 10 % 50/60 Hz (optional).
<b>Max. power absorbed:</b>	70 W.
<b>Fuses:</b>	Type 5 X 20 mm 230 VAC 2 X 500 mA T. Type 5 X 20 mm 115 VAC 2 X 1 A T. Type 5 X 20 mm 100 VAC 2 X 1,2 A T.
<b>Working frequency:</b>	Automatic scan. From 24 to 29 KHz.
<b>Average power applied to the handpiece:</b>	Adjustable to 6 power levels: ROOT mode Power: ENDO: 2,8 W Power: PERIO: 4,6 W BONE mode Power: QUALITY1: 16 W Power: QUALITY2: 16 W Power: QUALITY3: 16 W Power: SPECIAL: 4,6 W
<b>Delivery rate of the peristaltic pump:</b>	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.
<b>Protection systems and tripping time of the APC:</b>	No handpiece. Tripping time 20 ms. Discontinuity of cord lead. Tripping time 20 ms. Insert not correctly tightened or broken. Tripping time 80 ms.

<b>Alarms:</b>	The display on the front panel indicates <b>error</b> (see point “Problem-solving”).
<b>Operating conditions:</b>	From +10°C to +40°C. Relative humidity from 30% to 75%.
<b>Transport and storage conditions:</b>	From -10°C to +70°C. Relative humidity from 10% to 90%. Air pressure P: 500hPa/1060hPa
<b>Cord:</b>	It is recommended not to exceed 100 sterilisation cycles
<b>Tube of peristaltic pump:</b>	It is recommended not to exceed 8 sterilisation cycles
<b>Weight and size:</b>	3.5 Kg L – W - H      340 X 210 X 150 mm.

## 14.0 - GUARANTEE

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

MECTRON warrant their products, purchased brand-new from authorised MECTRON dealers or importers, free from material or manufacturing defects for a period of 2 (two) years from the date of purchase.

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.



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Reseller

The information given in this manual is not binding and can be modified without prior notice.