mectron
medical technology

English

micropiezo s

Manual of use and maintenance

CE
0476

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00.1 Foreword

Read this manual carefully before installing the equipment, using it or carrying out maintenance or any other activities on it.
Always keep this manual within easy reach.

Important: To avoid causing injuries or damage to property, read all the points concerning “Safety Requirements” contained in this manual particularly carefully. Depending on the level of risk involved, safety requirements are classed under the following headings:
⚠ **DANGER (always referred to personal injury)**
⚠ **WARNING (referred to possible damage to property)**

The purpose of this manual is to bring the safety requirements, the installation procedures and the instructions for correct use and maintenance of the device to the knowledge of operators.
The user is not authorised to camper with the equipment under any circumstances.
If any problems are encountered, please contact a Mectron Service Centre.
Anny attempts on the part of the user or of any unauthorised personnel to tamper with or alter the device will invalidate the warranty and release the manufacturer from any liability in respect of any harm or damage to persons or property.
The information and illustrations container 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 device. If any discrepancies are found between the descriptions container in the manual and your device, please contact your dealer of the MECTRON Afer-Sale Service.
Using this manual for purposes other to those relating to the installation, use and maintenance of the equipment is strictly prohibited.

00.2 Description of the device

The micropiezo s is an extremely modern ultrasound piezoelectric scaler enabling application the ultrasound technique to dentistry and is manufactured using state-of-the-art technology. The device has an automatic tuning circuit that offsets wear of the inserts, so that maximum efficiency is ensured at all times. The handpiece, which can be autoclave sterilised at 135 °C, has a titanium resonator and Is unbreakable.
The piezosmart can use the (optional) Starlight p curing lamp for dental composites. The lamp is connected to the scaler cord. The device recognises attachment of the lamp automatically.

00.3 Intended use

With the appropriate inserts, the following treatments can be carried out:
- **Scaling:** all procedures of removal of bacterial plaque deposits and supragingival, subgingival and interdental plaque and the removal of stains;
- **Periodontology:** periodontal therapy for scaling and root-planing/debridement without causing damage to the periodontium and including cleaning and irrigation of the periodontal pocket;
- **Endodontics:** all treatments for the preparation of canals, irrigation, filling, condensation of the guttapercha and retrograde preparation;
- **Repair and prosthetic activities:** preparation of the cavities, removal of prosthesis, condensation of the amalgam, trimming the prosthetic stump

00.4 Safety Requirements

Mectron cannot accept any liability for direct or incidental damage to property or personal injury 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 in which the equipment is used does not comply with the applicable standard 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 to not comply with the requirements indicated in the charter on technical specifications.
6 ⚠ **DANGER Using non original Mectron inserts:** this causes definitive damage to the handpiece thread impairing its proper functioning and risking to harm the patient. **In such case the manufacturer's warranty and the type-approval of the device are no longer valid!**

⚠ **WARNING:** No alterations to this device are permitted.

⚠ **WARNING:** The wiring system of the premises on which this device is used must comply with the applicable standards and requirements.

⚠ **DANGER: Qualified and specialised personnel.**
This equipment should be used only by specialised personnel having the appropriate training, The equipment does not produce any side effects if it is correctly used.

⚠ **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 or failure of the equipment.

⚠ **DANGER: Contraindications.**
To not use the ultrasonic scaler on patients fitted with pace-makers or other implantable electronic devices. This warning also applies to the operator.

⚠ **DANGER: Cleaning, disinfection and sterilisation of new or repaired products.**
All new or repaired products are delivered in non-sterile conditions. All new or repaired products should therefore be cleaned, disinfected and sterilised before being used for any treatments, following the instructions provided under point "06.0" closely.

⚠ **DANGER: Infection control.**
In order to censure 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.**

⚠ **WARNING: Contraindication.**
Do not carry out scaling on metal or ceramic prosthetic artefacts. The ultrasonic vibrations could cause decementation of the artefacts.

⚠ **DANGER: Contraindications.**
Do not carry out scaling treatments without spraying water as this could cause overheating of the insert with consequent injury of the tooth.
The only treatments that can be carried out without spraying water are those envisaged for “Dry Work” inserts, which are not cannulated.

⚠ **DANGER: Check the condition of the device before starting the treatment.**
Always make sure that there is no water underneath the device. 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 Service Centre.

⚠ **DANGER: Breakage and wear of the inserts.**
In rare cases the high-frequency oscillations and wear can lead to breakage of an insert. Inserts of which the shape has been altered or that are damaged in any way are liable to break during use. Any such inserts should not be used under any circumstances. The patient should be instructed to breathe through his nose during the treatment so as to avoid ingestion of a fragment of a broken insert.

⚠ **DANGER: Do not install the equipment anywhere where there is a risk of explosions.**
The equipment must not be used in places where there is an inflammable atmosphere (anaesthetic mixtures, oxygen, etc.).

01.1 Identification

An exact description of the model and 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 Equipment identification plate

Each device has its own identification plate (Fig.1) on which the technical specifications and the serial number are indicated. The identification place is on the bottom of the device. The remaining data are indicated in this manual (see Section 11.0").

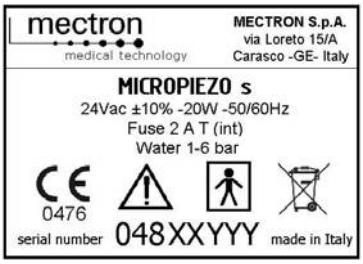

Fig. 1

01.3 Identification place of the scaler handpiece

The serial number of the scaler handpiece is engraved on the grey connector of the handpiece (Fig.2 - Ref.A).

Fig. 2

02.0 Testing

02.1 Testing of the equipment

Each component of all equipment manufactured by MECTRON is thoroughly checked and tested.
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 device

The equipment contains electronic components that may be damaged by impacts even inside the packaging. Special care must therefore be taken during both transport and storage.
All material shipped by MECTRON is checked at the time of shipment.
The equipment is delivered properly protected and packaged.
Check the equipment upon receipt for possible transport damage. If any damage is found make a complaint to the carrier.

03.2 List of material included in the standard supply

1 Housing of the device (Fig.3 - Ref.A).
1 Scaler handpiece (Fig.3 - Ref.B).
1 K6 torque wrench (Fig.3 - Ref.C).
2 Inserts for scaling (Fig.3 - Ref.D).
1 Footswitch with cable and plug (Fig.3 - Ref.E).
1 Spare filter for the water circuit (Fig.3 - Ref.F).
1 Water supply pipe with quick coupling (Fig.3 - Ref.G).
1 Power supply with cable and plug. (Fig.3 - Ref.H).

This equipment may vary at the time of promotional campaigns.

04.0 Installation

04.1 Safety requirements during installation

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

⚠ DANGER: Do not install the equipment anywhere where there is a risk of explosions. The equipment must not be used in places where there is an inflammable atmosphere (anaesthetic mixtures, oxygen, etc.).

⚠ DANGER: Install the device 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 above or in the vicinity of sources of heat. Make sure that there is sufficient air circulation around the device.

⚠ WARNING: The device is transportable, however it must be handled with care when it is moved.

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

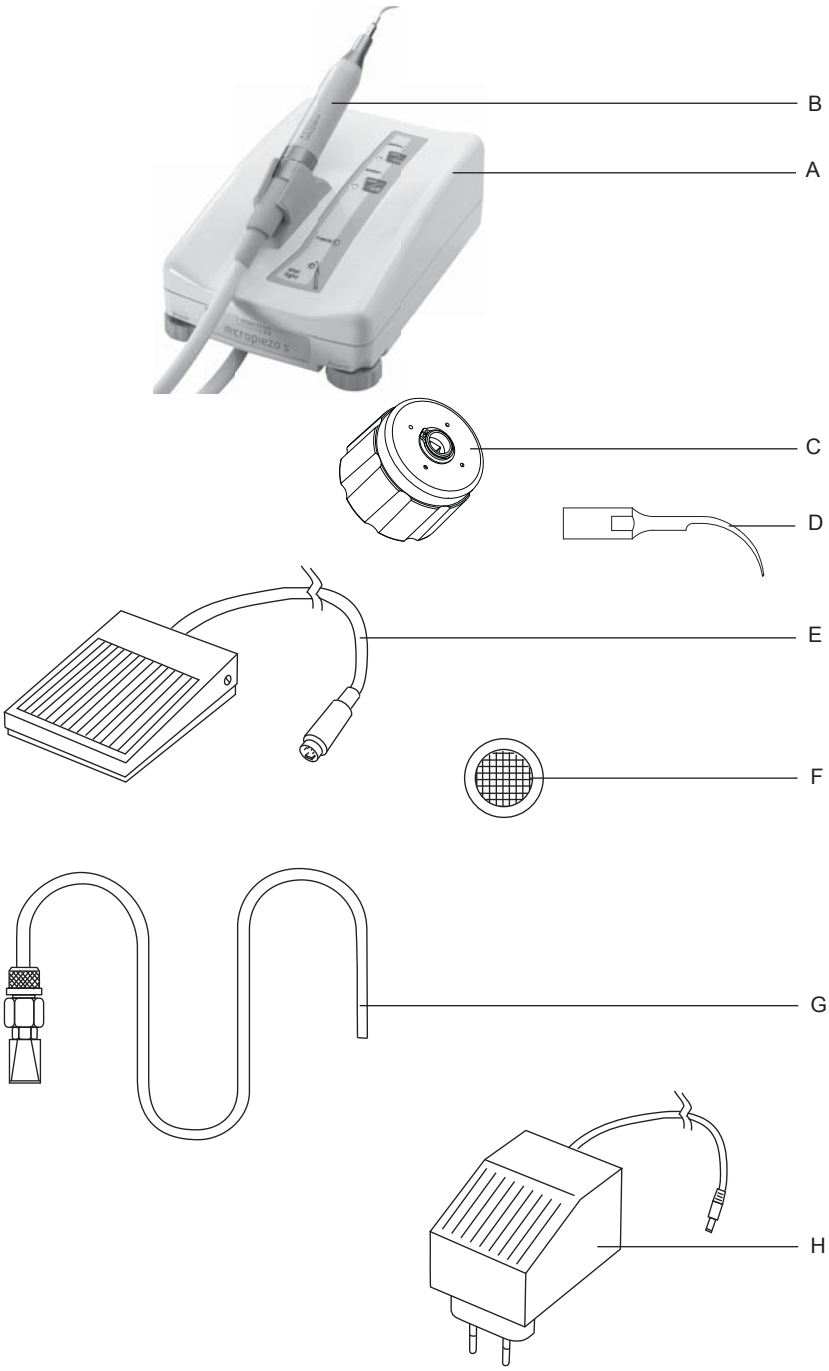

Fig. 3

04.2 Connecting the device

1 Connect the water pipe to the water mains using a suitable reduction and an on-off valve (not included in the MECTRON supply).
2 Connect the water supply pipe's quick coupling to the male connection at the back of the device (Fig.4 - Ref.C).
3 Plug the footswitch into the footswitch socket on the body of the device (Fig.4 - Ref.B).
⚠ **WARNING:** Pay particular attention to where you put the footswitch: it should be in a position where only the operator can work it intentionally, when wanted.
4 Put the plug into the socket on the device (Fig.4 - Ref.A) and then plug the power supply into the wall socket.

⚠ **WARNING:**The line used to power the device must have the same voltage and frequency as that indicated on the plate.

Fig. 4

Fig. 5

05.1 Controls

Micropiezos' s front panel (Fig. 5) is shown in this paragraph to help you find the controls described in this manual immediately.

Description of the controls

Ref. A	- Power button **on/off**.	On / Off
Function	It electrically powers the device.	
Ref. B	- Indicator light.	Green LED
Function	It signals the device is on.	
Ref. C	- Water button **on/off**.	On / Off
Function	It selects treatment with or without water.	
Ref. D	- Indicator light.	Green LED
Function	It signals treatment with water, spray active.	
Ref. E	- **Check** indicator light.	Yellow LED
Function	It signals triggering of the automatic APC protection.	
Ref. F	- **Starlight** indicator light.	Blue LED
Function	Signal of photopolymerization cycle in progress.	
Ref. G	- Adjustment knob.	
Function	It adjusts water flow.	
Ref. H	-Adjustment knob.	From 1 to 6
Function	It adjusts power.	

Other controls on this device are:
The footswitch (Fig.3 - Ref.E) for consent.

05.2 Switching on and off

To switch on the device

1 Power the device by pressing the button on the device (Fig.5 - Ref.A) making sure not to keep the footswitch pressed down.
2 The device will turn on.

To switch off the device

1 Turn the device off by pressing the button on the device (Fig.5 - Ref.A).
2 The device will turn off.

05.3 Safety Requirements during use

⚠ **DANGER: Contraindications.**
Do not use the scaler on patients fitted with pace-makers or other implantable electronic devices. This warning also applies to the operator.

⚠ **DANGER: Contraindications.**
Do not carry out scaling treatments without a water spray as this could cause overheating of the insert with consequent injury of the tooth. The only treatments that can be carried out without a water spray are those for which the “Dry Work” inserts, which are not cannulated, are designed. Ask for a catalogue of Mectron inserts.

⚠ **DANGER: Breakage and wear of the inserts.**
In rare cases the high-frequency oscillations and wear can lead to breakage of an insert. Inserts of which the shape has been altered or that are damaged in any way are liable to break during use. Any such inserts should not be used under any circumstances. In order to avoid ingestion of a fragment of a broken insert, the patient should be instructed to breathe through his nose during the treatment.

⚠ **DANGER: Infection control.**
To ensure maximum safety of both the patient and the operator, clean, disinfect and sterilize the piezoelectric handpiece, the inserts and torque wrench after each treatment. Follow the instructions on this subject container in Section 06.0 “CLEANING, DISINFECTION AND STERILISATION”.

⚠ **WARNING: Contraindication.**
Do not carry out treatment for removing calculus on metal or ceramic prosthetic artefacts as the ultrasound vibrations could cause decementation of the artefacts.

⚠ **WARNING: Contraindication.**
Wait for the handpiece to cool down completely before using it again after it has been autoclave sterilised.

⚠ **WARNING: The electric contacts inside the handpiece and cord connectors must be dry.**
Before connecting the handpiece to the cord make sure that the electric contacts of both connectors are perfectly dry. This is a particularly important check after an autoclave sterilisation cycle. If necessary, dry the contacts by blowing air onto them with the syringe.

⚠ **WARNING:** Use cannulated inserts only to carry out treatments requiring a spray.

⚠ **WARNING:** For a correct use of the device it is necessary to press the footswitch and start the device without placing the insert on the part to be treated. This will enable the electronic circuit to recognise the best point of resonance of the insert without interferences, so as to achieve optimum performance. Contact with the part to be treated or with other surfaces before starting the device could cause the tripping of the safety circuits.

05.4 Instructions for use

1 Connect the scaler handpiece to the cord, after checking that the electric contacts on both are perfectly dry. If necessary, dry the contacts by blowing air onto them with the syringe.
2 Screw the chosen insert onto the scaler handpiece until it fits closely (Fig.9 - Ref.A).

3 Tighten the insert by using the supplied wrench.
To use the torque wrench properly (Fig.6 - Ref.B) proceed as follows:
- Hold firmly the handpiece body;
⚠ **WARNING:** Do not grip the end part of the handpiece and/or the cord, but only the plastic casing (Fig.6 - Ref.C) and do not turn while fastening the insert in place.
- Tighten the insert by turning the torque wrench clockwise until the wrench clicks (the outer body of the wrench will slide against the body of the handpiece giving out a “CLICK” mechanical signal).
- The insert is now properly tightened in place.

4 Turn the device on by pressing the power button on/off. The green light will turn on (Fig.5 - Ref.B).

5 Select the power level wanted with the right knob (Fig.5 - Ref.H), which has a graduated scale going from 1 to 6.

6 If you want treatment with the spray, press the water button on/off (Fig.5 - Ref.C). The green light (Fig.5 - Ref.D) will turn on.

7 Press the footswitch and adjust the flow of water with the left knob (Fig.5 - Ref.G) turning it until you have the quantity required.

8 If you want treatment without the spray, press the water button on/off (Fig.5 - Ref.C). The green light (Fig.5 - Ref.D) will turn off.

9 The device has a sophisticated electronic circuit enabling the scaler to offset wear of the insert so as to keep the efficiency of the ultrasound generator constantly high.
NOTE: Whenever the protection triggers it is signalled by a yellow check light on the front (Fig.5 - Ref.E). Depending on the type of alarm there can be two different alarm signals: flashing or permanent. For more information see the Trouble-shooting chapter.

10 Upon completing the treatment place the scaler handpiece back in its holder.

11 With this device it is possible to use Starlight p (optional), a photopolymerizing curing light for dental composites. From power level 3 to 6 (Fig.5 - Ref.H) the device automatically recognizes the connection (Fig.5 - Ref.F). For a correct use refer to the manual of use and maintenance of Starlight p.

NOTE: When you stop using the micropiezo s, switch off the device as indicated under point 05.2.

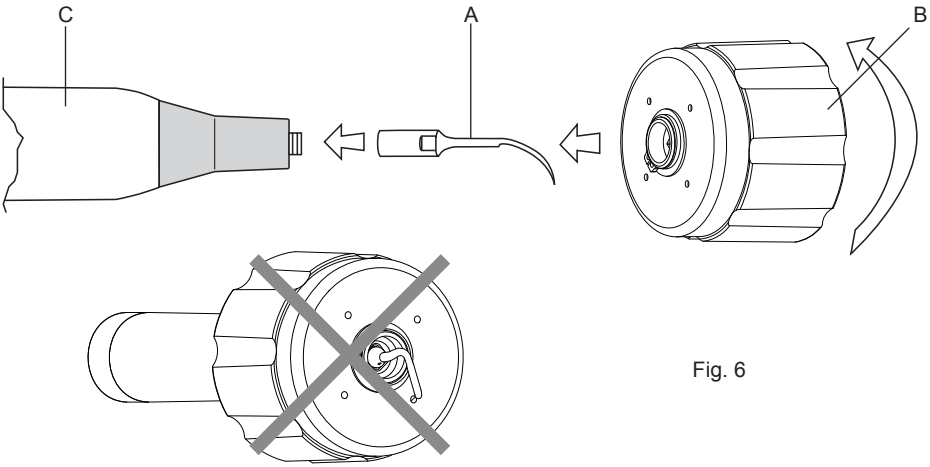

Fig. 6

05.5 Checking the inserts for wear

1 Check the insert regularly for wear and replace it if a drop in performance is noted.
2 Do not alter the shape of the insert in any way by bending or filing it.
3 Replace the insert if it has become deformed or received blows.

06.0 Cleaning, disinfection and sterilisation

⚠ **WARNING:** After use with strong solutions, the tubes and the handpieces have to be cleaned with water for at least 60 seconds.
If the tubes are not cleaned, crystallisation of the salts can seriously damage the device.

NOTE: Water-based disinfectant solutions with a neutral pH are highly recommended. Some alcohol-based disinfectants may be harmful, discolour and/or damage plastic materials.

06.1 Cleaning and disinfecting the housing of the device

⚠ **DANGER: Switch off the device.**
Always switch off the device and unplug it from the power outlet before carrying out the following cleaning, disinfection and sterilisation activities.

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

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

After each treatment, proceed as follows:
1 Remove the insert from the scaler handpiece.
2 Clean and disinfect the surfaces of the housing, the cords and the connectors using a cloth moistened with a mild detergent or disinfectant solution with a neutral pH (pH7). Follow carefully the instructions provided by the manufacturer of the disinfectant solution. Allow the disinfectant solution to dry in air before using the device.

NOTE: Water-based disinfectant solutions with a neutral pH are highly recommended. Some alcohol-based disinfectants may be harmful, discolour and/or damage plastic materials.

06.2 Cleaning and disinfecting before sterilisation

⚠ **WARNING:** The cleaning procedure should be done with an enzymatic detergent (pH 6-9), following carefully the manufacturer's instructions.

⚠ **WARNING:** When using a disinfectant solution, make sure to use a mild disinfectant solution with a neutral pH (pH7); Follow carefully the manufacturer's instructions.

⚠ **WARNING:** Do not use hydrogen peroxide for disinfecting, but only neutral pH (pH7) disinfectants. If necessary, rinse with sterilized water.

⚠ **DANGER:** After cleaning and before sterilizing, accurately check all parts under a strong light, with particular attention to those parts which can hide residual dirt (threading, cavities, grooves) and, if necessary, repeat the washing cycle.
Check also the integrity of those parts and elements which could have deteriorated through use.

06.3 Sterilisation procedure

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

⚠ **WARNING: Do not exceed the permitted load of the steam steriliser.**

⚠ **DANGER: Infection control - Parts that can be sterilised - Remove thoroughly all residues before sterilisation.**
To avoid bacterial or viral infections, always clean and sterilise after each treatment the following components:
1 Scaler handpiece;
2 Inserts;
3 Wrench to tighten the inserts.

These components are made from materials able to withstand a maximum temperature of 135°C for a maximum of 20 minutes.
The steam autoclave sterilisation processes (SAL 10^{-6}) must be carried out using the parameters given below:
- 3 times pre-vacuum (min. pressure 60 mBar).
- Sterilisation temperature 132°C (interval 0°C ÷ +3°C).
- Sterilisation time 4 minutes.
- Minimum drying time 10 minutes.

All the stages of sterilisation must be carried out by the operator in accordance with UNI EN ISO 17665-1:2007, UNI EN ISO 556-1:2002 and ANSI/AAMI ST:46:2002.

N.B.: Do not used oxygenated water to disinfect. Only use neutral pH disinfectants. Always rinse with sterile water.

⚠ **DANGER:** Once clearing operations have been completed, before sterilisation check all objects under a suitable light source. Pay particular attention to parts that may hide residue dirt (threading, cavities, channelling). If necessary, repeat the cleaning cycle.
Finally, check that all parts and elements subject to wear and tear, are in good condition.

06.4 Cleaning and Autoclave sterilisation of the scaler handpiece

⚠ **WARNING: Do not allow the handpiece to be fully immersed in disinfectant solutions or liquids of any other type as this could damage it.**

⚠ **WARNING: Do not allow the handpiece to be fully immersed in an ultrasonic container.**

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

⚠ **WARNING:** Do not use hydrogen peroxide for disinfecting, but only neutral pH (pH7) disinfectants. If necessary, rinse with sterilized water.

Clean the handpiece carefully paying special attention to the threaded pin onto which the inserts are screwed (Fig.7 - Ref.B) and the adjacent ring-shaped cavity.

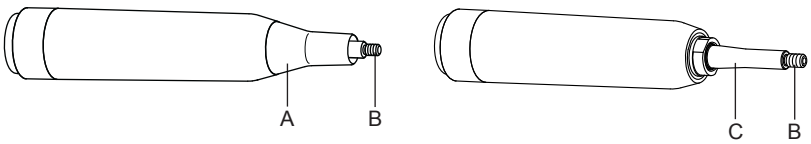

Fig. 7

1 Unscrew the insert;
2 Unscrew the front metal cone (Fig.7 - Ref.A);
3 Clean and disinfect the handpiece using a cloth moistened with a mild enzymatic detergent solution (pH 6-9) and in case also with a mild disinfectant solution with a neutral pH (pH7);
4 Delicately brush the handpiece surface with a soft nylon brush with particular attention to the following parts:
- Handpiece thread (Fig.7 - Ref.B);
- Titanium support (Fig.7 - Ref.C);
- Front cone (Fig.7 - Ref.A) in its external and internal parts.
5 Rinse thoroughly the front end and the surfaces of the external body of the handpiece under running water to eliminate any residual detergent;
6 Dry and reassemble the front cone on the handpiece (Fig.7 - Ref.A);
7 Dry the electric contacts by blowing compressed air with the syringe;
8 Seal the handpiece (without inserts) in a single disposable bag;
9 Sterilise the handpiece in a steam autoclave as described under paragraph 06.3.

⚠ **WARNING: At the end of the sterilisation cycle the handpiece must cool down to room temperature before it can be used again.**

⚠ **WARNING: The electric contacts of the cord connector must be dry.**
At the end of the sterilisation cycle, before connecting the cord to the device, make sure that the electrical contacts of the connector are completely dry, if necessary dry the contacts by blowing compressed air with the syringe.

06.5 Cleaning and Autoclave sterilisation of the inserts

⚠ **WARNING:** The cleaning procedure should be done with an enzymatic detergent (pH 6-9), following carefully the manufacturer's instructions.

⚠ **WARNING:** Do not use hydrogen peroxide for disinfecting, but only neutral pH (pH7) disinfectants. If necessary, rinse with sterilized water.

1 Clean the insert (preferably in an ultrasonic cleaner) and rinse with distilled water.
2 Dry the insert.
3 Disinfect the insert with a mild disinfectant solution with a neutral pH (pH7) and dry it completely by blowing compressed air with the syringe. This will prevent the appearance of stains or patches on the surface of the insert.
⚠ **WARNING:** Make sure that the insert is completely dry also internally before starting the sterilisation cycle by blowing air with the syringe through the internal hole.
4 Seal the insert alone in a disposable bag.
5 Sterilise the inserts in autoclave as described under paragraph 06.3.

06.6 Cleaning and Autoclave sterilisation of the torque wrench

⚠ **WARNING:** The cleaning procedure should be done with an enzymatic detergent (pH 6-9), following carefully the manufacturer's instructions

1 Clean the wrench.
2 Disinfect the wrench with a mild disinfectant solution with a neutral pH (pH7) and dry it carefully.
3 Lubricate with a commercial surgical grade instrument lubricant on the points shown in Fig.8;
⚠ **WARNING:** do not use any grease with an oil or silicon base.
4 Seal the wrench alone in a disposable bag.
5 Sterilise the wrench in autoclave as described under paragraph 06.3.

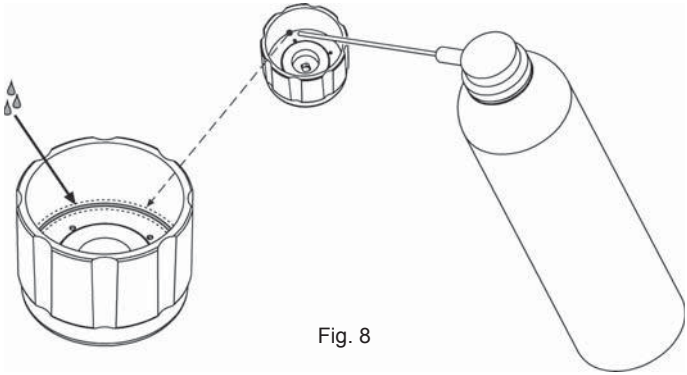

Fig. 8

07.0 Scheduled maintenance

1 The device must be switched off (switch in Fig.5 - Ref.A) prior to any servicing.
2 Pull the power cable out of the socket located at the back of the device.

07.1 Changing the water filter

1 Disconnect the water supply pipe from the male coupling (Fig.4 - Ref.C).
2 Unscrew the male coupling's knurled ring nut (Fig.9 - Ref.B).
3 Extract the filter (Fig.9 - Ref.A), change it or wash it, removing all impurities from the filtering mesh.
4 Put the filter back into place and firmly screw the knurled ring nut back down until it will go no further.

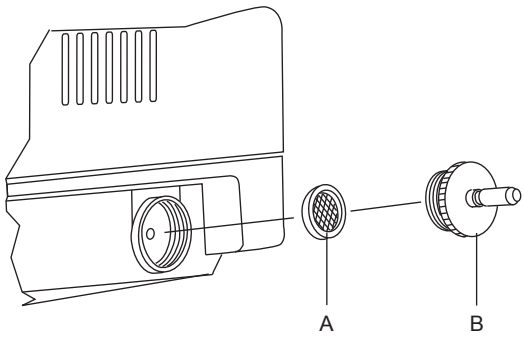

Fig. 9

08.0 Procedures for disposal and precautions

- The device must be disposed of and treated as waste for separate collection;
- The purchaser may return the device at the end of its working life to the dealer supplying a new device. Instructions for disposal are available from Mectron S.p.A.;
- Failure to comply with the above instructions could lead to application of a penalty in accordance with Directive 2002/96/EC.

⚠ **DANGER: Hospital waste.**
The following must be treated as hospital waste:
- Inserts, when worn or broken;
- Wrench for tightening the inserts, if worn or broken.

09.0 Symbols

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

Type “BF” 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

Manufacturer

CE 0476

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

10.0 Trouble-shooting

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

PROBLEM	POSSIBLE CAUSE	SOLUTION
The device will not turn after having pressed the power button **on/off**.	The electric power supply is not connected properly.	Check that all couplings are connected properly. Check that the socket is in proper working order.
	The electric power supply is faulty.	Contact your nearest authorised MECTRON technical assistance centre.
	The inside fuse is unusable.	Check that the red light, visible through the slits under the device, is on. In this case contact your nearest authorised MECTRON technical assistance centre. The device is switched on but will not work.
The device is on but not working. The yellow **check** indicator light stays off.	The footswitch plug is not firmly in the socket. The footswitch is not working.	Put the footswitch plug in properly. Contact your nearest authorised MECTRON technical assistance centre.
When the device is working you can hear a slight whistling noise coming from the scaler handpiece.	The insert has not been tightened properly on the scaler handpiece.	Loosen the insert and then tighten it again properly.
The device is on but not working. The yellow **check** indicator light is flashing (the automatic APC protection circuit has triggered).	The insert has not been fitted correctly on the handpiece. The insert is worn, broken or deformed. The connector of the handpiece or of the cord is wet.	Loosen the insert and then tighten it again properly. Change the insert. Dry the connectors.

PROBLEM	POSSIBLE CAUSE	SOLUTION
The device is on but not working. The yellow **check** indicator light is on permanently (the automatic APC protection circuit has triggered).	The handpiece is not connected to the cord.	Connect the handpiece to the cord.
	One of the wires in the cord is broken.	Contact your nearest authorised MECTRON technical assistance centre.
	Handpiece broken.	Contact your nearest authorised MECTRON technical assistance centre.
	The tuning circuit is malfunctioning.	Contact your nearest authorised MECTRON technical assistance centre.
When the device is working water is not coming through the insert.	This type of insert does not have a water channel.	Use an insert with a water channel.
	The water function is not active.	Press the water button on/off.
	The insert is clogged.	Free the insert's water channel.
	The handpiece is clogged.	Contact your nearest authorised MECTRON technical assistance centre.

10.1 Suggestions on the delivery of device, inserts and accessories to the Service Centre

If you encounter a problem that requires servicing or repair, and need to send the device, the inserts and/or the accessories to and authorized Mectron Service Centre, please respect the following rules:

1 Clean device, inserts and all accessories according to instructions at point “06.0 Cleaning disinfection and sterilisation”;
2 Sterilise the parts that can be sterilised according to instructions at point “06.0 Cleaning disinfection and sterilisation”:
   - Handpiece;
   - Insert/s;
   - Dynamometric wrench.
3 Leave the sterilised parts in the sterilisation bag in order to demonstrate that they have passed through the sterilisation process;
4 Should the device still be within the warranty period, attach a copy of the purchase document;
5 Pack the equipments in its original packaging to ensure it is not damaged during shipment.

The above mentioned requirements (points 1 and 2) comply with binding requirements on the safeguarding of health and safety at work places Leg. Dec. 626/94 and Leg. Dec. 81/08 and subsequent amendments, laws of Italy.
Mectron reserves the right not to accept the return of goods which do not respect the conformity with these requirements (points 1 and 2) and to return the non conform products at your expenses, for cleaning and sterilization.

11.0 Technical specifications

This device complies with Directive 93/42/EEC: Class IIa

Classification in accordance with EN 60601-1: II
Type BF
IP 20 (device)
IP 22 (Footswitch)

Device for intermittent operation: 60” ON 30” OFF with irrigation.
30” ON 120” OFF without irrigation.

Supply voltage of the external power supply:

230 Vac	± 10 %	50/60 Hz
115 Vac	± 10 %	50/60 Hz (optional).
100 Vac	± 10 %	50/60 Hz (optional).

Supply voltage of the device: 24 Vac ± 10 %

Max. input: 20 W

Internal fuse: Type 5 X 20 mm 2 A T

Working frequency: Automatic scanning.
from 24 to 36 KHz

Power: Continuously adjustable

Water supply: Continuously adjustable
Connection with the pipe supplied with quick coupling by means of a built-in removable filter.
Working pressure from 1 to 6 bar.

Protections and triggering times of the APC circuit: No handpiece connected
Cord interrupted
Insert broken or not correctly tightened

Alarms: Yellow **check** indicator light:
Flashing or permanent - See paragraph: “Trouble-shooting.”

Operating conditions: from 10 °C to 40 °C
Relative Humidity from 30% to 75%
Air pressure P: 800 hPa/1060 hPa

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

Weights and dimensions: 0.7 Kg
L - W - H 120 X 170 X 90 mm

11.1 Electromagnetic compatibility EN 60601-1-2

⚠ **DANGER: Contraindications. Interference from other devices**
Electroscalpels or other electrosurgical devices lying next to the combi could interfere with the proper functioning of the device itself.

⚠ **DANGER: Contraindications. Interference with other devices**
Even if conforming with standard IEC 60601-1-2, the scaler could interfere with other devices near it.

⚠ **DANGER:** The device follows specific EMC precautions and has to be installed and used in compliance with the EMC data described in this paragraph.

⚠ **DANGER:** portable and mobile radiocommunication devices could affect the proper functioning of the device.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - Electromagnetic emissions</th></tr>
<tr><td colspan="3">The Micropiezo s is intended for use in the electromagnetic environment specified below.
The customer or the user of the Micropiezo s should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - Guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Micropiezo s uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The Micropiezo s is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration - Electromagnetic immunity			
The Micropiezo s is intended for use in the electromagnetic environment specified below. The customer or the user of the Micropiezo s should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	The device continues to work regularly and in safety.	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	The device continues to work regularly and in safety.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	The device continues to work regularly and in safety.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 s	The device can vary from the required levels of immunity with a duration of <5% / > 95% / 5s as long as the device remains in safety, no malfunctions have been detected and can be restored to pre-test status with the intervention of the operator.	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	The device continues to work regularly and in safety.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - Electromagnetic immunity			
The Micropiezo s is intended for use in the electromagnetic environment specified below. The customer or the user of the Micropiezo s should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	The device continues to work regularly and in safety.	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. **Recommended separation distance** *d = 1,2 √P* *d = 1,2 √P 80 MHz to 800 MHz* *d = 2,3 √P 800 MHz to 2,5 GHz* 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,a should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

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 Micropiezo s is used exceeds the applicable RF compliance level above, the Micropiezo s should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Micropiezo s.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Micropiezo s

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

Rated maximum output power of transmitter "W"	**Separation distance according to frequency of transmitter "m"**		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2 \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3 \sqrt{P}$
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.

12.0 Warranty

All MECTRON devices, before being placed on the market, undergo a thorough final check to ensure that they are in proper working order.
MECTRON warrants to the first original customer, purchasing from authorised MECTRON dealers or importers, that the product is free from defects in material or workmanship:

- As to the equipment for 2 YEARS (TWO) from the date of purchase;
- As to the handpiece for 1 YEAR (ONE) from the date of purchase.

During the warranty period, MECTRON undertake to repair (or, at their sole discretion, to replace) free of charge any product parts which, in their opinion, are faulty.
Complete replacement of MECTRON products is excluded.
Mectron will not accept any liability for direct or incidental personal injury or damage to property 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 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 paragraph on technical specifications.
- Use of inserts, accessories and not original MECTRON spare parts which could compromise the proper functioning of the device and harm patients.
  The above mentioned cases void the manufacturer's warranty and the type-approval of the device.

The warranty do not include accidental damages caused by transport, improper use or carelessness, connection to a power supply different from the one prescribed, LEDs, knobs and any other accessory.
The warranty is voided if the device 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 filled in and returned to MECTRON, or to a MECTRON dealer or importer, within 20 (TWENTY) DAYS from the date of purchase, as proven by the invoice issued by the dealer/importer.
In order to benefit from the warranty service the customer must return, at his own expense, the device to be repaired to the MECTRON dealer/importer from which it was purchased, or to the nearest authorised MECTRON Service Centre.
The device has to be returned suitably packed (if possible in its original packaging), and equipped with all its accessories and supported by the following information:

a) Owner's details including telephone number and mail address;
b) Dealer/importer's details;
c) A copy of the purchase invoice related to this device indicating the owner's name, date of purchase, name of the device and its serial number;
d) A description of the problem.

Transport and damages caused during transport are not covered by warranty.
In the event of failures caused by accident or improper use, or if the warranty time is expired, repairs to MECTRON products will be charged on the basis of the current material cost and the labour required for such repairs.

mectron

medical technology

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