stomdevice

mectron

medical technology

English

piezo smart



Manual of use and maintenance

CE 0476

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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 6
01.2 Equipment identification plate 6
01.3 Identification place 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 device 7
03.2 List of material included in the standard supply 8
04.0 Installation 8
04.1 Safety requirements during installation 8
04.2 Installation of the peristaltic pump 11
04.3 Connection of the device 11
04.4 Preparing the bottle 13
04.5 Installing the bottle on the equipment 13
04.6 Removing the bottle from the device 13
05.0 Use 14
05.1 Controls 14
05.2 Switching on and off 15
05.3 Description of the display and functions 15
05.4 Safety Requirements during use 16
05.5 Safety and alarm circuits 17
05.6 Instructions for use 18
05.7 Checking the inserts for wear 19
06.0 Cleaning, disinfection and sterilisation 19
06.1 CLEAN Function - Cleaning of the liquid circuit 19
06.2 Cleaning and disinfecting the housing of the device 19
06.3 Cleaning and disinfecting before sterilisation 20
06.4 Sterilisation procedure 20
06.5 Cleaning and Autoclave sterilisation of the scaler handpiece 21
06.6 Cleaning and Autoclave sterilisation of the inserts 21
06.9 Cleaning and Autoclave sterilisation of the torque wrench 22
07.0 Scheduled maintenance 22
07.1 Cleaning of the water circuit 22
07.2 External power supply unit 22
07.3 Replacement of the peristaltic pump 22
08.0 Procedures for disposal and precautions 23
09.0 Inserts for Mectron scaler and how to use them 23
10.0 Trouble-shooting 24
10.1 Suggestions on the delivery of device, inserts and accessories to the Service Centre 27
11.0 Symbols 27
12.0 Technical specifications 28
12.1 Electromagnetic compatibility EN 60601-1-2 29
13.0 Warranty 33

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00.0 Introduction

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 piezo smart is an extremely modern ultrasound piezoelectric scaler enabling application the US 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.

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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!**

⚠ **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.

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⚠ **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.).

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01.0 Identification data

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 12.0").

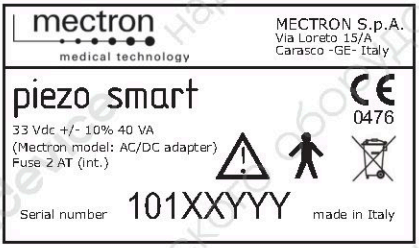


Fig. 1

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

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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.
To avoid crushing, do not pile cartons one on top of another.
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.

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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).
2 Bottles (Fig.3 - Ref.C)
1 K6 torque wrench (Fig.3 - Ref.D).
1 Kit of 4 inserts.(Fig.3 - Ref.E).
1 Pedal with cable and plug (Fig.3 - Ref.F).
1 Peristaltic pump (Fig.3 - Ref.G).
1 External power supply unit (Fig.3 - Ref.H).
2 Bottle caps (Fig.3 - Ref.I).

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.**

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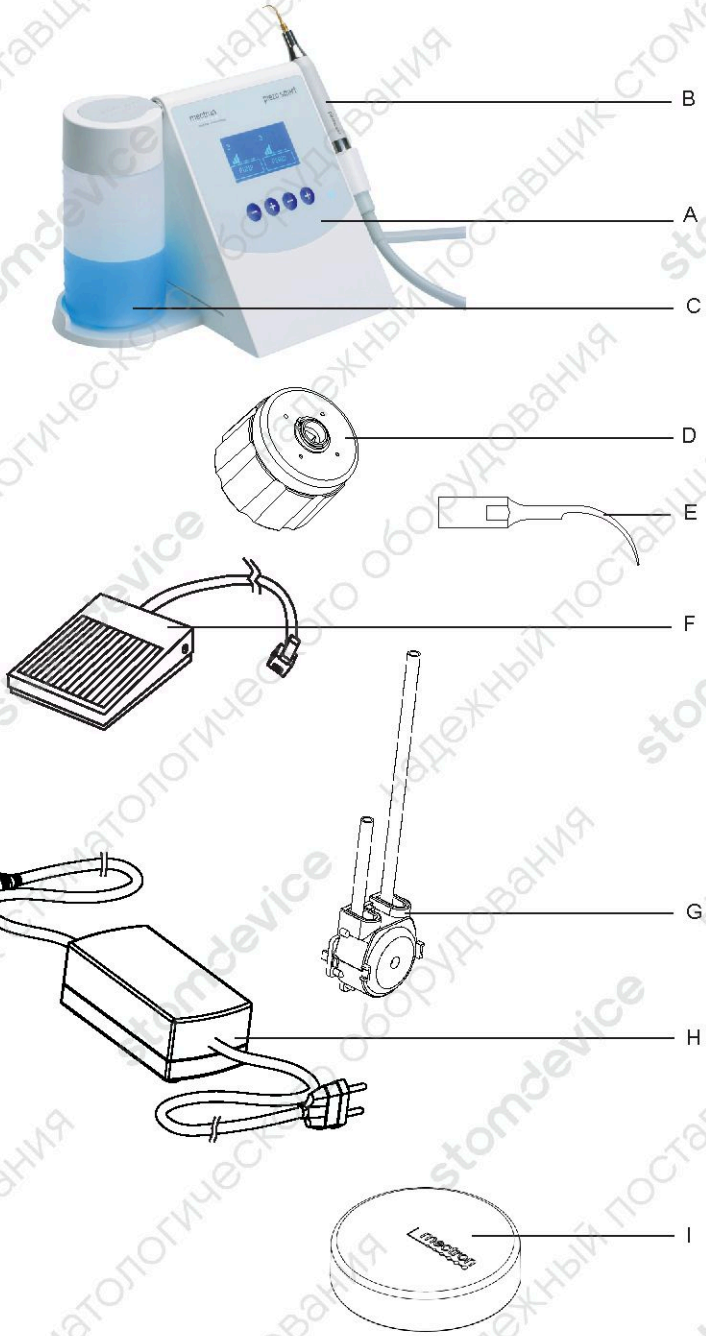


Fig. 3

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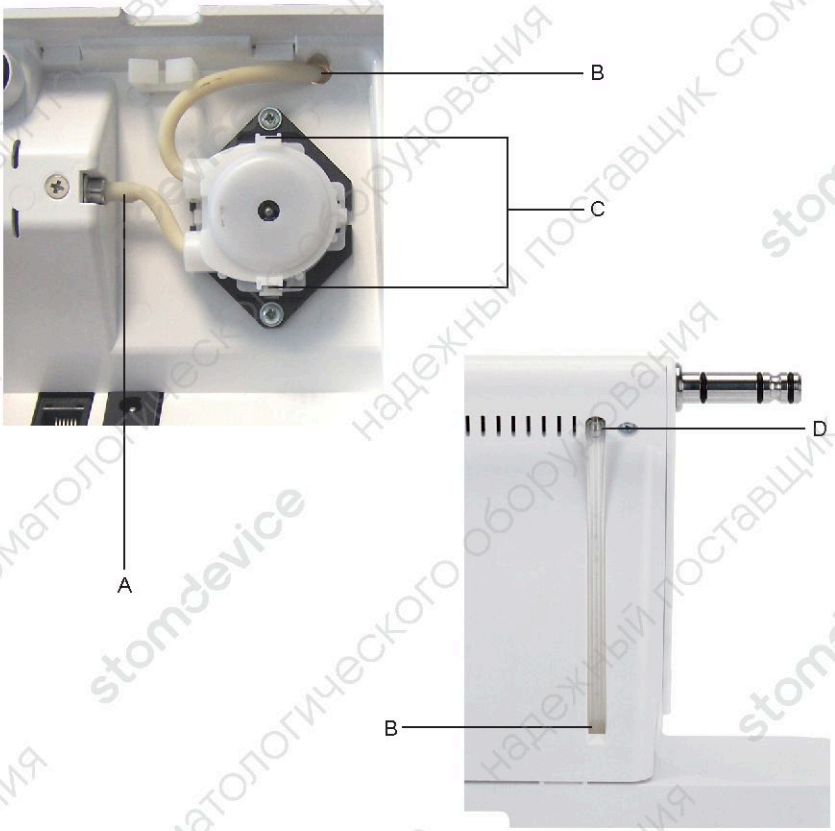


Fig. 4

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04.2 Installation of the peristaltic pump

⚠ **WARNING:** All activities involving the peristaltic pump must be carried out only after disconnecting the device from the mains power supply and without installing the bottle of liquid.

1 Turn the device upside down;
2 Plug the short end of the tube of the pump into the connector shown in Fig. 4, Ref.A;
3 Secure the pump to the black base as shown in Fig. 4. It must click audibly into place;
4 Pass the longer end of the tube of the pump through the hole shown in Fig. 4, Ref.B;
5 Plug the tube into the connector shown in Fig. 4, Ref.D.

04.3 Connection of the device

1 Plug the pedal into its socket on the housing of the device (Fig.4 - Ref.F).
2 Plug the power cable into its connector on the housing of the device (Fig.4 - Ref.G), then plug the other end into the power outlet.
⚠ **WARNING:** Make sure that the voltage and frequency of the mains power supply match those indicated on the data plate of the external power supply unit.
3 Fasten the pedal and power cables in the cable gland as shown in Fig.4 - Ref.H

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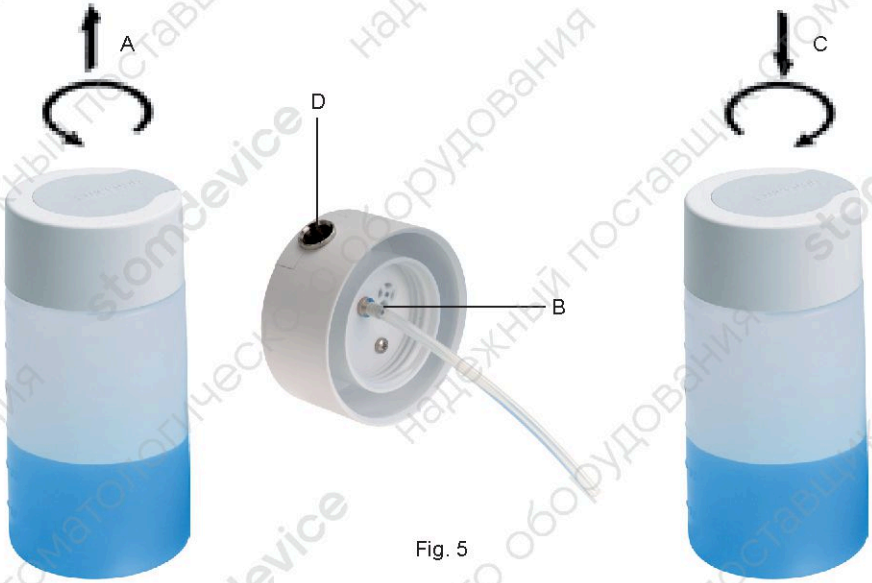


Fig. 5



Fig. 6

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04.4 Preparing the bottle

⚠ **WARNING:** Each bottle can contain up to a maximum of 300 ml.

1 Unscrew the cap from the bottle (Fig.5 - Ref.A);
2 Fill the bottle with the required liquid;
3 Check that the tube on the back of the cap is connected (Fig.5 - Ref.B);
4 Screw the cap onto the bottle (Fig.5 - Ref.C).

04.5 Installing the bottle on the equipment

⚠ **WARNING:** Make sure that the connection on the bottle is clean and not clogged (Fig.5 - Ref.D).

⚠ **WARNING:** Make sure that the connection for the bottle on the device is clean (Fig.6 - Ref.E).

⚠ **WARNING:** Make sure that the O-rings on the connection are not damaged (Fig.6 - Ref.E).

1 Holding the bottle at an angle of 45° (Fig.6 - Ref.F), fit it onto the device (Fig.6 - Ref.E) by means of the coupling on the cap (Fig.5 - Ref.D);
2 Fit the bottle snugly onto the coupling;
3 Turn the bottle downwards into a vertical position (Fig.6 - Ref.F).

04.6 Removing the bottle from the device

⚠ **WARNING:** Do not turn the bottle upside down as the cap is not watertight. Leaking physiological solution or aggressive liquid may damage surfaces.

1 Turn the bottle upwards until it is tilted by 45° (Fig.6 - Ref.F);
2 Pull off the bottle;
3 To preserve the liquid better, replace the cap fitted with a coupling with another cap that has no coupling.

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Fig. 7



Fig. 8

05.0 Use

05.1 Controls

This section illustrates the front panel (Fig.7) of the piezo smart, to as to enable immediate identification of the controls described in this manual.

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Description of the controls

Ref. A - Set of 2 keys, - and +
Function For setting the flow rate of the peristaltic pump (0-9).

Ref. B - Set of 2 keys, - and +
Function For setting the required power level (1-9).

Ref. C - Blue LED
Function The LED lights up to signal that the device is powered.

Ref. A/B - Set of 4 keys, - and +
Function When the device is off, press this key to switch it on.
When the device is on, hold this key down for at least 3 seconds to switch it off,

The other controls on the device are:
The pedal (Fig.3 - Ref. F) for enabling operation.

05.2 Switching on and off

To switch on the device

1 Press one of the 4 keys on the front panel;
2 The device will switch on.

To switch off the device

1 Press one of the 4 keys on the front panel and hold it down for at least 3 seconds;
2 The device will switch off.

NOTE: If the device is not used for at least 5 minutes i twill switch off automatically.

NOTE: If the device is not switched off correctly, when it is switched on again the message **WARNING 35** will appear on the display for a few seconds.

05.3 Description of the display and functions

The display shows the current settings of the instrument.
After the system check, two bars are shown, as follows:
- The part on the left indicates the output level of the peristaltic pump: “PUMP” (Fig.8 - Ref.A).
- The part on the right indicates the power level of the scaler and the associated level (Fig.8 - Ref.B).

The device can be used at different power levels for three different functions:
- Levels 1 to 2 **ENDO**
- Levels 3 to 5 **PERIO**
- Levels 6 to 9 **SCALER**

Use the - and + keys (Fig.7 - Ref.A) to lower or increase the output of the peristaltic pump. The indication on the display will change (Fig.8 - Ref.A).

Use the - and + keys (Fig.7 - Ref.B) to lower or increase the power of the scaler. The indication on the display will change (Fig.8 - Ref.B).

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05.4 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:** After using aggressive solutions it is necessary to carry out a cleaning cycle of the tube and of the handpiece with distilled water, using the Clean function (See point 06.1). If this is not done, the salts may crystallise and seriously damage the device.

⚠ **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 pedal 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.

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05.5 Safety and alarm circuits

The device has a diagnostic circuit enabling tripping of the safety and alarm systems to be recognised. They are signalled on the display.

WARNING 1 General safety circuit tripped:
- Scaler handpiece not connected to the device;
- Improper functioning of the tuning circuit;
- Handpiece failure.

WARNING 2 General safety circuit tripped:
- Scaler handpiece not connected to the device;
- Improper functioning of the tuning circuit;
- Handpiece failure.

WARNING 4 General safety circuit tripped:
- Improper functioning of the tuning circuit;
- Handpiece failure.

WARNING 5 Tuning scan failed:
- Insert not properly tightened onto the handpiece;
- Insert worn, broken or deformed;
- The electric contacts of the cord and/or of the handpiece are wet;
- Overheating of handipece.

WARNING 6 Power supply voltage out of range.

WARNING 16 Error in communications with the scaler module:
- The device switches off. Contact the Mectron Service Centre immediately.

WARNING 17 Pump operational error:
- Check that the pump and the tube are properly installed;
- Make sure that there is nothing preventing the pump from turning.

WARNING 18 Pump operational error:
- Contact the Mectron Service Centre.

WARNING 19 Scaler module initialisation error:
- The device switches off. Contact the Mectron Service Centre immediately.

WARNING 21 Checksum error, modification of scaler module firmware:
- The device is working properly. Contact the Mectron Sertice Centre as soon as possible;
- The device is not working properly. Contact the Mectron Service Centre immediately and in the meantime do not use the device.

WARNING 22 Checksum error, modification of mainboard firmware:
- The device is working properly. Contact the Mectron Sertice Centre as soon as possible;
- The device is not working properly. Contact the Mectron Service Centre immediately and in the meantime do not use the device.

WARNING 26 Voltage low safety circuit tripped:
- The device switches off. Disconnect the power supply unit from the power outlet and contact the Mectron Service Centre immediately.

WARNING 27 Voltage high safety circuit tripped:
- The device switches off. Disconnect the power supply unit from the power outlet and contact the Mectron Service Centre immediately.

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WARNING 35 Abnormal switching off procedure:
- The switching off procedure was not carried out correctly the last time the device was used;
- The device switched off during use due to outside interference.

05.6 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).
4 Tighten the insert by using the supplied wrench.
To use the torque wrench properly (Fig.9 - 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.9 - 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 Select the required power level by means of the two - and + keys (Fig.7 - Ref.B):
- From 1 to 2 ENDO
- From 3 to 5 PERIO
- From 6 to 9 SCALER.
5 Select the required speed of the peristaltic pump by means of the two - and + keys (Fig.7 - Ref.A):
- 0 treatment without liquid;
- from 1 to 9 treatment with liquid.
6 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.
7 Upon completing the treatment place the scaler handpiece back in its holder.
8 With this device it is possible to use the Starlight p (optional), a curing lamp for dental composites. The device recognised insertion of the “Starlight p” automatically when it is set to a power level between 3 and 9 (Fig.7 - Ref.C). For correct use, consult the User and Maintenance manual of the “Starlight p”.

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

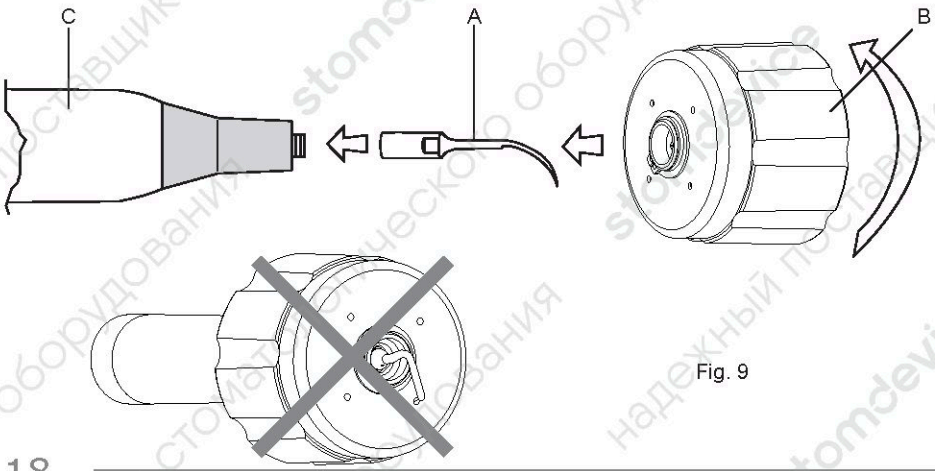


Fig. 9

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05.7 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.
4 If the insert becomes excessively worn, the scaler will stop working as the APC circuit will be tripped (see Section"05.3").

06.0 Cleaning, disinfection and sterilisation

06.1 CLEAN Function - Cleaning of the liquid circuit

The device has a CLEAN function (See Section 05.3) that enables a cleaning cycle to be carried out on the hydraulic circuit. This function should be used after using the device, before cleaning, disinfecting and sterilising all the parts (see below).
⚠ **WARNING:** If the circuit is not cleaned, salts may crystallise in it and could seriously damage the device.

1 Replace the bottle with one containing water (demineralised water is recommended).
2 Place the handpiece over a bowl to collect the liquid that will come out during the cleaning cycle.
3 To activate the CLEAN function, use the "-" key to set the power level to less than 1 (Fig.7 - Ref.B). The wording "clean" and the associated status bar will appear on the display (Fig.8 - Ref.C).
NOTE: If you have selected the Clean function by mistake, press the "+" key below the wording "esc".
4 Fit one of the inserts used during treatment onto the handpiece.
5 Press the pedal briefly to start the cleaning cycle. As soon as the peristaltic pump starts, a status bar will appear on the display, and will increase to indicate the time to completion of the CLEAN cycle. You can stop the cycle by pressing the pedal again or the "+" key below the wording "esc".
6 When the Clean cycle has been completed, the device exits the CLEAN function and returns to the function that was set previously.
7 Repeat the above steps from point 2 to carry out a cleaning cycle on the tubes and all the accessories used, such as:
- handpieces (check that the electric contacts of the connector on the cord of accessory to be subjected to the cleaning cycle are dry);
- inserts.
8 After the cleaning operations, empty the tubes and dry the accessories that have undergone cleaning.

06.2 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.

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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.

06.3 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.

06.4 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 of materials that can resist to a maximum temperature of 135°C for a maximum period of 20 minutes.
The sterilisation process (SAL 10^{-6}) in a steam autoclave must be carried out following the parameters indicated below:
- sterilisation temperature 134°C (0°C ÷ +3°C interval) - Sterilisation time 4 minutes.
- sterilisation temperature 121°C (0°C ÷ +3°C interval) - Sterilisation time 16 minutes.

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

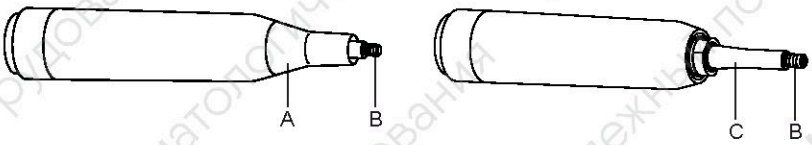


Fig. 10

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06.5 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.10 - Ref.B) and the adjacent ring-shaped cavity.

1 Unscrew the insert;
2 Unscrew the front metal cone (Fig.10 - 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.10 - Ref.B);
   - Titanium support (Fig.10 - Ref.C);
   - Front cone (Fig.10 - 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.10 - 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 06.4.

⚠ **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.

06.6 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 06.4.

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06.9 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.11;
⚠ **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 06.4.

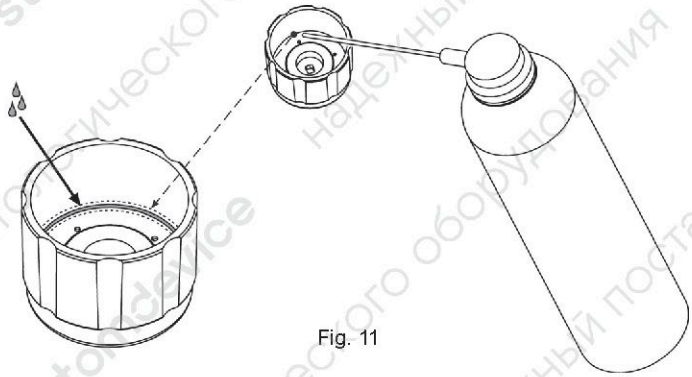


Fig. 11

07.0 Scheduled maintenance

07.1 Cleaning of the water circuit

1 The device has a Clean function for cleaning the water circuit (see point 06.1).
Press the pedal and hold it down for the time considered most suitable for completing the cleaning cycle.
2 The cleaning cycle can be carried out with or without the handpiece and the insert fitted.
3 Empty the residual water from the circuits by removing the bottle and operating the device for a few seconds.
4 If the cleaning cycle has been carried out without the handpiece, it is important to dry the electric contacts of the cord by blowing air onto them with the syringe before starting any application.

07.2 External power supply unit

⚠ **DANGER:** Check the housing and the cables of the external transformer periodically to make sure that they are intact. If it is damaged, replace it with a Mectron original spare.

07.3 Replacement of the peristaltic pump

⚠ **WARNING:** Before carrying out any activities on the peristaltic pump, it is necessary to:
- Remove the bottle (see point 04.6);
- Empty the water circuit by operating the device. Any residues of liquid could accidentally penetrate inside the device.

1 Disconnect the tubes of the peristaltic pumps from their couplings.
2 Press the two side tabs (Fig.4 - Ref. C) and pull out the body of the pump.
3 Insert the new pump following the instructions under point 04.2.

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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 Inserts for Mectron scaler and how to use them

S1 - S2 - S3 - S4 - S5: For general use in scaling;
S6 - S7 - S8: High-efficiency, for general use in scaling for removing large quantities of calculus;
P1 - P2 - P3 - P4: For general use in removing concretions from root surfaces;
P10 - P11 - P12 - P13 - P14: For general use in removing concretions from deep root surfaces;
R1 - R2 - R3 - R4 - R5: For general use in retrograde root canal treatment;
D1 - D2 - D3 - D4: For general use in condensing amalgam - burnishing fillings - lateral condensation of gutta-percha - removal of crowns, bridges and pins;
CM1 - CM2 - CM3 - CM4: For marginal finishing;
ER1 - ER2 - ER3 - ER4 - ER5: For general use in orthograde endodontics;
E1 - E2: Holder for 120° or 90° files, for endo files.

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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 switch on. The blue LED is off (Fig.7 - Rif.G).	The power supply unit is not properly connected to the mains outlet or to the device.	Make sure that the power supply unit is properly connected. Check that the power outlet is in proper working order.
	The power supply unit and/ or is out of use or 'the internal fuse is blown.	Contact an authorised MECTRON Service Centre.
The device is switched on but will not work.	The pedal is not properly plugged into its socket.	Plug the pedal in correctly.
	The pedal is out of order.	Contact an authorised MECTRON Service Centre.
A slight hissing noise is made by the scaler handpiece while it is working.	The insert is not properly tightened onto the scaler handpiece.	Unscrew the insert and screw it back into place correctly.
One of the following wordings appears in the display: **WARNING 1** **WARNING 2** **WARNING 4.**	Scaler handpiece not connected to the device.	Check whether the handpiece is properly connected to its cord.
	Improper functioning of the tuning circuit.	Contact an authorised MECTRON Service Centre.
	Handpiece failure.	Contact an authorised MECTRON Service Centre.
The message **WARNING 35** appears on the display for a few seconds.	The switching off procedure was not carried out correctly after the last time it was used.	Switch the device off correctly. See point 05.2.
	The device switched off during use due to an external interference.	Consult the tables under point 12.1.

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PROBLEM	POSSIBLE CAUSE	SOLUTION
The following wording appears on the display: **WARNING 5.**	The insert is not properly tightened onto the scaler handpiece.	Unscrew the insert and screw it back into place correctly.
	Insert worn, broken or deformed.	Replace the insert.
	The electric contacts of the cord or of the handpiece are wet.	Switch off the device, dry the contacts of the cord and of the handpiece with compressed air.
	Handpiece overheated.	Wait for it to cool down. To speed up cooling carry out a cleaning cycle (after removing the insert it is of the dry work type).
One of the following wordings appears on the display: **WARNING 6** **WARNING 26** **WARNING 27.**	Power supply voltage out-of-range safety circuit tripped.	Contact an authorised MECTRON Service Centre.
One of the following wordings appears on the display: **WARNING 16** **WARNING 19** **WARNING 26** **WARNING 27.**	The device switches off.	Contact an authorised MECTRON Service Centre.
The following wording appears on the display: **WARNING 17.**	Pump operational error.	Check whether the pump and the tube are correctly installed. Make sure there is nothing preventing the pump from turning.
The following wording appears on the display: **WARNING 18.**	Pump operational error.	Contact an authorised MECTRON Service Centre.
Checksum error. Modification of the firmware. One of the following wordings appears on the display: **WARNING 21** **WARNING 22.**	The device is in proper working order.	Contact an authorised MECTRON Service Centre as soon as possible.
	The device is not in proper working order.	Disconnect the power-supply unit from the mains outlet and contact an authorised MECTRON Service Centre immediately.

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PROBLEM	POSSIBLE CAUSE	SOLUTION
No water comes out of the insert during operation.	The insert is not of the cannuled type.	Use a cannulated insert.
	The pump output is on zero.	Increase the output of the pump.
	The bottle for the liquid is empty.	Replace the bottle with a full one.
	The bottle containing the liquid is not correctly installed.	See points 04.6 and 04.5.
	The tubes of the pump are not correctly installed.	Check the connections of the tubes.
	The insert is clogged.	Unstop the insert to allow the passage of water.
	The handpiece is clogged.	Contact an authorised MECTRON Service Centre.

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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 Symbols


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



Serial number


Type “B” applied part



Product code


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


Class II apparatus



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


Manufacturer



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

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12.0 Technical specifications

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

Classification in accordance with EN 60601-1: II
Type B
IP 20 (device)
IP 20 (power-supply unit)
IP 22 (pedal)

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

Voltage required by the external power-supply unit:
Mectron - Model AC/DC adapter
from 100 to 240 Vac ± 10 % 50/60 Hz

Voltage required by the device: 33 VDC ± 10 %

Max. power absorbed: 40 VA

Internal fuse: Type 5 X 20 mm 1 X 2 A T

Working frequency: Automatic scanning. From 24 to 29.5 KHz

Power: Adjustable in 9 pre-set steps:
From 1 to 2 ENDO
From 3 to 5 PERIO
From 6 to 9 SCALER

Output of the peristaltic pump: Adjustable in 10 steps from 0 to 9
From 25 to 55 ml/min approx.

Safety devices and time to tripping of the APC circuit:
- No handpiece connected
- Cord interrupted
- Insert broken or not correctly tightened
- Protection by discharge to earth

Alarms: A warning appears on the front-panel display.
Se sections:
"Safety and alarm circuits"
"Troubleshooting"

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

Weight and measurements: 0.92 Kg
L - W - H 228 x 146 x 146 mm

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12.1 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.

Guidance and manufacturer's declaration - Electromagnetic emissions		
The PIEZO SMART is intended for use in the electromagnetic environment specified below. The customer or the user of the PIEZO SMART should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - Guidance**
RF emissions CISPR 11	Group 1	The PIEZO SMART 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.
RF emissions CISPR 11	Class B	The PIEZO SMART is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

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Guidance and manufacturer's declaration - Electromagnetic immunity			
The PIEZO SMART is intended for use in the electromagnetic environment specified below. The customer or the user of the PIEZO SMART 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	±6 kV contact ±8 kV air	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	±2 kV for power supply lines ±1 kV for input/output lines	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	±1 kV differential mode ±2 kV common mode	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	<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	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	3 A/m	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.			

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Guidance and manufacturer's declaration - Electromagnetic immunity			
The PIEZO SMART is intended for use in the electromagnetic environment specified below. The customer or the user of the PIEZO SMART 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	3 Veff 150 kHz to 80 MHz	3 Vrms	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** $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 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 PIEZO SMART is used exceeds the applicable RF compliance level above, the PIEZO SMART should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PIEZO SMART.

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 PIEZO SMART

The PIEZO SMART is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PIEZO SMART can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PIEZO SMART 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.

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13.0 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.

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mectron

medical technology

Rivenditore - Reseller - Wiederverkäufer - Revendeur - Revendedor

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