stomdevice

mectron

medical technology

English

combi



Manual of use and maintenance

CE
0476

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00.1 Foreword

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

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

The purpose of this manual is to ensure that operators are aware of safety requirements, installation procedures and instructions for correct use and maintenance of the device.
The user is not authorised to tamper with the equipment under any circumstances.
If any problems are encountered please contact a Mectron Service Centre.
Any attempts on the part of the user or any unauthorised personnel to tamper with or alter the 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 contained in this manual are up-dated to the date of publication indicated on the last page.
MECTRON is committed to continuous up-dating of its products, which may entail changes to components of the equipment. If there are any discrepancies between the descriptions contained in this manual and your equipment, please contact your dealer or the MECTRON After-Sale service for explanations.
Using this manual for purposes other than those relating to installation, use and maintenance of the equipment is strictly prohibited.

00.2 Description of the device

Combi combines into a single device a piezoelectric ultrasonic scaler and a polisher which uses a combination of water, air and prophylaxis powder to guarantee prophylaxis and dental cleaning.
The working principle on which the cleaner is based is the mechanical action obtained from a jet of sodium bicarbonate crystals accelerated by a stream of compressed air. The kinetic energy impressed in this way on the particles, is almost entirely dissipated as the jet strikes the surface of the enamel giving rise to a gentle but effective cleansing effect. This action is completed by a jet of water that exploits the depression created around the nozzle to form a bell shape around the main stream, producing two effects: it prevents to a great extent the cloud of bicarbonate from splashing and spilling and performs continuous rinsing of the area being treated, dissolving the bicarbonate.
The piezoelectric ultrasonic scaler enables the ultrasonic technique to be used in the field of dentistry. The device has an automatic tuning circuit that offsets the wear of the inserts so that it is always possible to work in conditions of maximum efficiency.

Combi can be used with the Starlight *p* (optional), a light-curing lamp for dental composites. The lamp is connected to the cord of the scaler. The device recognises the lamp automatically when it is connected.

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00.3 Intended use

Combi is a multi-purpose device which combines a piezoelectric ultrasonic scaler and a polisher which uses a combination of water, air and prophylaxis powder to guarantee prophylaxis and dental cleaning.
Piezoelectric ultrasonic scaler. Together with the suitable inserts the following treatments can be performed:

- **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

Polisher for prophylaxis and dental cleaning. Indications

- **Removal of bacterial plaque** - by using only Mectron powder (Prophylaxis powder).
- **Removal of subgingival bacterial plaque**, by using the appropriate powder.
- **Removal of Biofilm in the prevention of Peri implantitis**, by using the appropriate powder.
- **Removal of stains from the surface of teeth** due to tobacco, coffee, tea and chlorhexidine.
- **Prophylaxis on patients in orthodontic therapy.**
- **Preparation of cavities** for better adhesion between enamel and filling and implant material.
- **Polishing of the enamel surface**; ⚠ **DANGER:** Should composite resin surfaces be found, the jet should be directed towards the area requiring treatment for approximately 2-3 seconds for each tooth.

00.4 Safety requirements

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

1 If the equipment is used for purposes other than those for which it is intended.
2 If the equipment is not used in accordance with all the instructions and requirements described in this manual.
3 If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements .
4 If any assembly operations, extensions, settings, alterations or repairs have been carried out by personnel not authorised by Mectron.
5 If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the point 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.**
The equipment must be operated only by specialised or specifically trained personnel. The equipment does not produce any side effects when used correctly.

⚠ **DANGER: Intended use.**
Use the equipment only for the purpose for which it is intended (see point "00.3"). Failure to comply with this requirement could cause serious injury to the patient and/or to the operator and/or damage to/failure of the equipment.

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

⚠ **DANGER: Cleaning, disinfection, sterilisation of new or repaired products.**
All new or repaired products are delivered in non sterile conditions. Before being used for treatment all new or repaired products should be cleaned, disinfected and sterilised closely following the instructions under point “06.0”.

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

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

⚠ **WARNING: Contraindication - Ultrasonic scaler.**
Do not carry out tartar scaling treatments on metal or ceramic prostheses. The ultrasonic vibrations could cause decementation.

⚠ **DANGER: Contraindications - Ultrasonic scaler.**
To avoid overheating of the insert, which might cause damage to the tooth, do not carry out scaling treatments without the water spray .
Only treatment calling for dry-work inserts may be carried out without the water spray.

⚠ **DANGER: Breakage and wear of the inserts.**
The high-frequency vibrations as well as wear may, very occasionally, lead to breakage of the insert.
Inserts whose shape has changed or which are otherwise damaged, are liable to break during use. Any such inserts should definitely not be used.
The insert loses its efficiency if the nitride coating is worn out; check that the insert is in good working conditions.
During the intervention avoid all prolonged contact with metal instruments in use. Do not use excessive force on the inserts while using them.
It is necessary to instruct the patient to breathe through the nose during the treatment in order to avoid ingestion of the broken off fragment of the insert.

⚠ **DANGER: Check the condition of the device before treatment.**
Always make sure there is no water under the device. Before each treatment always check that the equipment is in proper working order and that the accessories are efficient. Should any problem be encountered in operating the device do not carry out the treatment. If the problems concern the equipment contact an authorised technical service centre.

⚠ **DANGER: Contraindications - Bicarbonate-jet polisher.**
Do not use the device on patients on a restricted sodium diet or with diseases of the respiratory device, such as chronic bronchitis, asthma, emphysema, etc., for prophylactic treatment, unless under strict doctor’s orders.

⚠ **DANGER: Contraindications - Bicarbonate-jet polisher.**
Patients using contact lenses should remove them before treatment with the bicarbonate-jet polisher.

⚠ **DANGER: Contraindications - Bicarbonate-jet polisher.**
Do not direct the jet of air/bicarbonate/water on soft tissue or into the dental pockets. Failure to comply with this requirement could cause a tissue emphysema of the gum (mucuous membrane and/or subcutaneous emphysema).

⚠ **DANGER: Temperature of the water spray - Bicarbonate-jet polisher.**
The device is equipped with a double safety system that controls the temperature of the spray of water. It is in any case recommended that the patient is instructed before starting the treatment, to warn the operator if he/she feels that the water temperature has risen excessively.

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

⚠ **WARNING:** End users will have to comply with law EN 62353 Electromedical devices – periodical inspections and tests to be performed after repair process – in case the devices they use within their medical surgeries and practices undergo periodical inspections and security tests, according to the relevant requirements in this field.

01.0 Identification data

01.1 Identification data

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

01.2 Equipment identification plate

Each device has an identification plate (Fig.1) on which the technical specifications and the serial number are indicated. The identification label is on the bottom of the device. The remaining data are indicated in this manual (see section “13.0”).

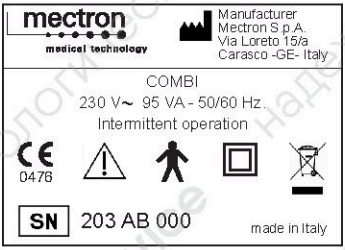


Fig. 1

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01.3 Identification plate of scaler handpiece

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



Fig. 2

02.0 Testing

02.1 Testing the equipment

All equipment manufactured by MECTRON is thoroughly checked and tested.
During the testing procedure the components are subjected to a number of work cycles.
These 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 device contains electronic components that may be damaged by impacts even inside the packaging. Special care must therefore be taken in transport and storage.
Do not stack cartons on top of each other to avoid crushing.
All goods shipped by MECTRON are carefully checked at the time of delivery.
The equipment is delivered properly protected and packaged.
When receiving the device check for any transport damage and should any be found, file a complaint with the carrier.

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03.2 List of material included in the standard supply

1 Body of the device (Fig.3 - Ref.A).
1 Polisher handpiece (Fig.3 - Ref.B).
1 Scaler handpiece (Fig.3 - Ref.C).
2 Polisher front terminal (Fig.3 - Ref.D).
2 Needles for cleaning the polisher front terminal (Fig.3 - Ref.E).
1 Prophylaxis powder bottle (Fig.3 - Ref.F).
1 Insert kit consisting of 4 inserts (Fig.3 - Ref.G).
1 Torque wrench K6 (Fig.3 - Ref.H).
1 Spare filter for water circuit (Fig.3 - Ref.I).
1 Black water hose with quick- coupling connector (Fig.3 - Ref.L).
1 Gray air hose with quick- coupling connector (Fig.3 - Ref.M).
1 Pedal with cable and plug (Fig.3 - Ref.N).
1 Power supply cable (Fig.3 - Ref.O).

This equipment set may vary at the time of promotional campaigns.

04.0 Installation

04.1 Safety requirements during installation

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

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

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

⚠ **DANGER:** Do not install the device on top or close to sources of heat. Make sure that adequate air circulates around the device.

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

⚠ **WARNING:** The device can be transported, yet it should be handled with care when moved. Position the pedal on the floor in such a way that it can only be activated by the operator intentionally.

In order to operate the device, these are the first steps:
1 Connect it to the cold water supply - Working pressure 1 to max. 6 bars;
2 Connect to the compressed air supply fitted with a dryer - Working pressure 4 to max. 8 bars;
3 Connect to power supply;
⚠ **WARNING:** Make sure that the voltage and the frequency of the power outlet match the values indicated on the identification label under the device.

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Fig. 3

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04.2 Connection of the device

1 Empty any condensation from the compressed air system.
2 Connect the air gray hose to the pneumatic circuit using a suitable adaptor and an on/off valve (Not included in the MECTRON supply).
3 Connect the water black hose to the water circuit using a suitable adaptor and an on/off valve (Not included in the MECTRON supply).
4 Connect the quick-fit connector of the air hose to the male coupling on the rear of the device (Fig.4 - Ref.A).
5 Connect the quick-fit connector of the water hose to the male coupling on the rear of the device (Fig.4 - Ref.B).
6 Insert the connector of the foot pedal into the socket on the rear of the device (Fig.4 - Ref.C).
7 Plug the power-supply cable into the socket on the rear of the device (Fig.4 - Ref.D) and then into the mains power outlet.
8 Clean the water and air circuits by pushing the clean button (See point “06.1” for more information).

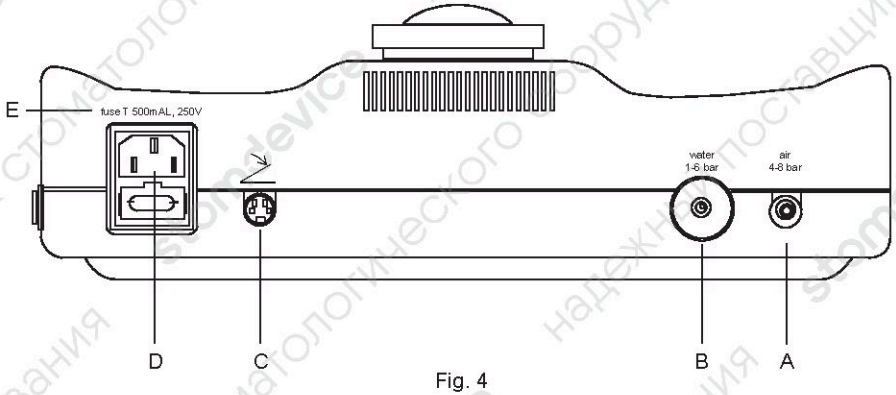


Fig. 4

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05.1 Controls

This section illustrates the front panel (Fig.5) of the Combi, so that the controls described in the manual can be immediately identified.

Description of the controls

Ref. A	- ON/OFF switch	I / O
Function	Supplies power to the device.	
Ref. B	- Set of 4 indicators of the power level selected for the ultrasonic scaler.	Green LED
Ref. C	- Set of 4 push buttons.	1 - 2 - 3 - 4
Function	Selection of the power level chosen for the ultrasonic scaler.	
Ref. D	- Water push button, with LED indicating when active	Green LED
Function	Selection of treatment with or without water (for the ultrasonic scaler).	
Ref. E	- “prophy” push button with LED indicating when active	Green LED
Function	Selects “prophy” function (for the jet polisher).	
Ref. F	- “perio” push button with LED indicating when active	Green LED
Function	Selects “perio” function (for the jet polisher).	
Ref. G	- “check” warning light.	Yellow LED
Function	Indicates errors and/or APC intervention for ultrasonic scaler	
Ref. H	- Polisher water control knob.	
Function	Controls the water flow to the polisher.	
Ref. I	- Scaler water control knob.	
Function	Controls the water flow to the scaler.	
Ref. L	- “clean” push button with LED indicating when active	Green LED
Function	Water and air circuit cleaning cycle.	

Other controls on the device:
Foot pedal (Fig.3 - Ref.N) for enabling operation.

05.2 Switching on and off

To switch on the device

1 Set the switch on the right side of the device to the “I” position (Fig.5 - Ref.A - position I) taking care not to press the foot pedal.
2 The device will switch on

To select a function

The required function, polisher or scaler, is selected automatically by lifting the relative handpiece (Fig.3 - Ref.B Ref.C).

To switch off the device

1 Set the switch on the right side of the device to the “O” position (Fig.5 - Ref.A).
2 The device will switch off.

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Fig. 5

05.3 Instructions for use - Polisher function

Safety precautions during use:

⚠ DANGER: Contraindications.
Do not use the device on patients on a restricted sodium diet or with diseases of the respiratory device, such as chronic bronchitis, asthma, emphysema, etc., for prophylactic treatment, unless under strict doctor's orders.

⚠ DANGER: Contraindications.
Patients using contact lenses should remove them before treatment with the bicarbonate-jet polisher.

⚠ DANGER: Contraindications.
Do not direct the jet of air/bicarbonate/water on soft tissue or into the dental pockets. Failure to comply with this requirement could cause a tissue emphysema of the gum (mucuous membrane and/or subcutaneous emphysema).

⚠ DANGER: Temperatura dello spray dell'acqua.
The device is equipped with a double safety system that controls the temperature of the spray of water. It is in any case recommended that the patient is instructed before starting the treatment, to warn the operator if he/she feels that the water temperature has risen excessively.

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⚠ **DANGER: Infection control and cleaning of the water and air circuits.**
In order to ensure maximum safety for both patient and operator, after each treatment, follow the instructions indicated under point “06.0”.

⚠ **DANGER: Do not use the device without water.**
Make sure that the device is connected to the water supply system (see point “04.2”) and that the water tap is open (Fig.5 - Ref.I).

⚠ **WARNING: Do not try unscrewing the powder container cap before the device has been switched off.**
Switching off the device depressurises the powder container.

NOTE: It is normal for air to flow out of the front terminal of the polisher when the device is switched on and without pressing the pedal. It is intended to keep the nozzle free during the various stages of the treatment.

⚠ **WARNING: Correct level of powder in the container.**
Minimum level: The powder level in the container should never be lower than 1 cm as this would decrease the cleaning performance.
Maximum level: The powder level in the container must remain at least one centimetre below the internal chromium-plated diffuser.
NOTE: Use the Prophylaxis powder container measuring cap to fill the container properly.

1 Insert the front head of the polisher onto the relative handpiece (Fig.3 - Ref.B).
2 Make sure that the combi is switched off and unscrew the powder container cap (Fig.5 - Ref.M).
3 Pour the powder into the container, so that it remains at least one centimetre below the internal chromium-plated diffuser.
4 Screw the cap back into place without tightening too much.
5 Turn on the combi by mean of the right hand side switch (Fig.5 - Ref.A) without pressing the foot pedal.
6 Lift the polisher handpiece in order to select the polisher function (Fig.3 - Ref.B).
The green LED of the prophy or perio function will light up (Fig.5 - Ref.E Ref.F).
7 Select the prophy or perio function according to the need.
⚠ **WARNING: make sure that the selected function and the powder used comply, as follows:**
Prophy function: use Mectron Prophylaxis powder;
Perio function: use powder for specific subgingival use.
8 Press the foot pedal and adjust the water flow using the knob on the left (Fig.4 - Ref.F) until the required quantity is obtained.
NOTE: The device has a built-in heater to warm the water and a set of sensors checking its temperature at all times, in order to keep it close to body temperature.
9 When the treatment is ended put back the polisher handpiece in its standby position.

IMPORTANT NOTE: Clogged front head (powder fails to come out).
1 Remove the front head from the polisher handpiece (Fig.7).
2 Free the channel from powder residues by using the supplied needle (Fig.3 - Ref.E) and following the indicated movements(Fig.8). Blow compressed air through the syringe into the central hole of the terminal from both sides.
⚠ **WARNING: The nozzle channel should only be cleaned by using the cleaning needle supplied with the device (Fig.3 - Ref.E).**
3 ⚠ **WARNING:** Also clean the threaded part of the front cavity in the polisher handpiece carefully. If so required, remove any powder residues by blowing compressed air through the syringe.
On completing this operation, fit the front terminal back onto the handpiece.

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05.4 Instructions for use - Scaler function

Safety precautions during use:
⚠ DANGER: Contraindications.
Do not use the ultrasonic scaler on patients with pace-makers or any other implantable electronic devices. This also applies to the operator

⚠ DANGER: Contraindications.
To avoid overheating of the insert, which might cause damage to the tooth, do not carry out scaling treatments without the water spray .
Only treatment calling for dry-work inserts may be carried out without the water spray. Ask for a Mectron catalogue on inserts.

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

⚠ DANGER: Infection control.
In order to ensure maximum safety for both patient and operator after each treatment clean, disinfect and sterilise the piezoelectric handpiece, the inserts and the dynamometric wrench. Follow instructions on this topic given under points “06.6” - “06.7” - “06.8”.

⚠ WARNING: Contraindication.
Do not carry out tartar scaling treatments on metal or ceramic prostheses. The ultrasound vibrations could cause decementation.

⚠ WARNING: The electric contacts inside the handpiece and cord connectors have to be dry.
Before connecting the handpiece to the cord, make sure that the electric contacts of both connectors are completely dry, particularly after each autoclave sterilisation cycle. If necessary, dry the contacts by blowing air onto them with the compressed air of the syringe.

NOTE: APC activation.
The device is equipped with an APC (automatic protection circuit), which is activated when any upset occurs during operations. APC activation is indicated by the yellow LED on the front of the device (Fig.5 - Ref.G). According to the reason of the upset, two kind of alarms are possible: flashing or fixed light, as follows:

flashing check LED:
- Insert not properly fitted in/screwed onto handpiece;
- Insert worn out, broken or deformed;
- Handpiece electric contacts and/or cord connectors are wet.

fixed check LED:
- Handpiece not connected to the cord;
- Interruption of a wire inside the cord;
- Handpiece fault;
- Tuning circuit malfunctioning.

For further information refer to ”Troubleshooting” section.

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1 Make sure that the polisher handpiece is in place, the scaler function can only be enabled in this way.
2 Connect properly the scaler handpiece to the cord, checking that electric contacts of both are completely dry. In case they are not, dry them by blowing air through the syringe.
3 Screw the chosen insert onto the scaler handpiece until it bottoms out (Fig.6 - Ref.A).
4 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.
5 Select the required power level by pressing one of the 4 push buttons (Fig.5 - Ref.C) marked **Ultrasound**. The green LED (Fig.5 - Ref.B) corresponding to the selected power will light up.
6 If the treatment requires a water spray, check that the LED corresponding to the push button **water** (Fig.5 - Ref.D) is on. In case it is not, push the **water** button to activate it.
7 Press the foot pedal and adjust the water flow through the right-hand knob (Fig.5 - Ref.I) until the required flow of water is obtained.
8 Start the treatment. The device is fitted with a sophisticated electronic circuit enabling the scaler to offset the insert’s wear, thus always keeping a high level of efficiency of the ultrasound generator.
9 When the treatment is ended put the scaler handpiece back to its place.
10 This device enables the use of Starlight p (optional), which is a light-curing lamp for dental composites. By setting the device at a power level between 2 and 4 (Fig.5 - Ref.C) the insertion of the “Starlight *p*” handpiece is automatically recognised. For a correct use refer to the Starlight *p* user and maintenance manual.

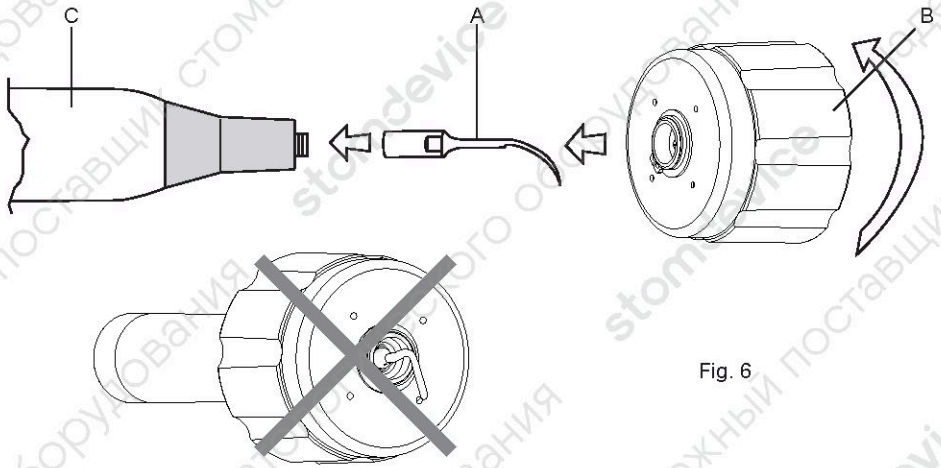


Fig. 6

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05.5 Checking the wear of the inserts

1 Always inspect the insert before and during operation in order to check its wear. In case the insert is worn, the performance drops. The insert needs to be replaced.
2 Do not alter the shape of the insert by bending or filing it.
3 Replace any insert which has been deformed, impacted, broken or worn out.
4 Should the wear of the insert be very high, the scaler will stop working thanks to the intervention of APC (see point "05.4" scaler function).

06.0 Cleaning, disinfection, sterilisation

06.1 Cleaning water and air circuits

The combi has a **clean** function which enables cleaning cycles to be carried out in the water and air circuits. The use of this function is recommended at the beginning of the day and between each treatment on the different patients.

Here below are the steps to be followed:
1 Push the **clean** button. The circuit-cleaning function is now open. **All LEDs on the cover will light up.**
2 Lift the scaler handpiece and press the foot pedal as long as necessary in order to complete the cleaning cycle. **The green LED of the last "ultrasound" power setting used will flash.**
3 Release the foot pedal and place the scaler handpiece in its holder. **The green LED of the last "Air-Polishing" setting used will flash.**
4 Lift the polisher handpiece and press the foot pedal until the following cleaning cycle is ended:
- 5 seconds to clean the polisher's water circuit.
- 13 seconds to clean the polisher's air circuit.
When the cleaning cycle is completed **all LEDs on the cover will flash**.
5 Release the foot pedal and place the polisher handpiece back on its holder. The combi is now ready to be used again.

NOTE: The cleaning cycle can be stopped at any time by releasing the foot pedal.
In this case, the combi will be ready to work again after:
- 10 seconds if you interrupted the scaler cleaning cycle
- Immediately if you stopped the water circuit cleaning cycle (polisher mode)
- After depressurising the powder container, if you stopped the air circuit cleaning cycle (polisher mode).

NOTE: It is possible to choose to carry out the cleaning cycle on the scaler circuit only or on the polisher circuit only. In case the cleaning cycle is done only on the scaler circuit, 10 seconds must pass before the combi can be used again.

⚠ **WARNING:** The cleaning cycle of the scaler part can be carried out with or without the handpiece mounted on the scaler cord. In case the cleaning has been carried out without the handpiece, make sure that the electric contacts of the cord connector are perfectly dry by blowing air with the syringe before starting any application.

⚠ **WARNING:** The cleaning cycle of the cleaner part can be carried out with or without the front terminal mounted on the handpiece. In case the cleaning has been carried out without the terminal, make sure that the internal part of the handpiece connector are perfectly dry by blowing air with the syringe before starting any application.

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06.2 Cleaning and disinfecting the casing of the device

⚠ **DANGER: Switch off the device.**
Always switch off the device by means of the right side switch (Fig.5 - Ref.A) and disconnect it from the power source, before carrying out the following cleaning, disinfection and sterilisation procedures.

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

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

After each treatment carry out the following steps:
1 Remove the insert from the scaler handpiece.
2 Remove the front terminal from the polisher handpiece (Fig 7).
3 Clean and disinfect the casing surfaces, the cords and their connectors using a cloth moistened with a mild detergent or disinfectant solution with a neutral pH (pH7).
Follow carefully the instructions given by the manufacturer of the disinfectant solution.
Allow the disinfectant solution to dry in the air before using the device.

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

06.3 Cleaning and disinfecting the polisher handpiece

⚠ **WARNING: The polisher handpiece cannot be sterilised.**

After each treatment carry out the following steps:
1 Remove the front terminal from the polisher handpiece (Fig 7).
2 Clean the polisher handpiece thoroughly paying special attention to the part of the front cavity.
If necessary, remove any powder residues by blowing compressed air with the syringe.
3 Disinfect the handpiece using a cloth moistened with a mild disinfectant solution with a neutral pH.

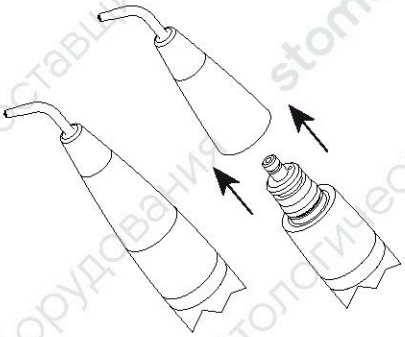


Fig. 7



Fig. 8

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06.4 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.

06.5 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;
4 Front terminal of the polisher;
5 Needle to clean the front terminal of the polisher.

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.

06.6 Autoclave sterilisation of the front terminal of the polisher

⚠ **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 Remove the front terminal from the polisher handpiece (Fig.7).
2 Free the channel from powder residues using the supplied needle (Fig.3 - Ref.E) and following the movements indicated in Fig.8. Blow compressed air through the syringe into the central hole of the terminal from both sides.
⚠ **WARNING:** Use only the cleaning needle supplied with the device to clean the nozzle channel (Fig.3 - Ref.E).

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3 A very hard water may cause a weak water spray. To eliminate this problem, it is recommended to dip the front terminal cleaner for a few minutes in a 2 % solution of hydrochloric acid.
⚠ **WARNING:** Rinse the terminal thoroughly in distilled water in order to eliminate all hydrochloric acid solution residues. Dry by blowing compressed air through the syringe into the central hole of the terminal from both sides.
4 Clean and disinfect the front terminal with an enzymatic detergent solution (pH 6-9) and in case also with a mild disinfectant solution with a neutral pH (pH7). Dry by blowing compressed air through the syringe into the central hole of the terminal from both sides.
5 Insert the cleaning needle in the channel in the front terminal and seal it in a disposable bag.
6 Sterilise the front terminal in a steam autoclave as described on point 06.5.

⚠ **WARNING: Before using the front terminal, blow compressed air with the syringe to eliminate any residual moisture left inside.**

06.7 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.9 - Ref.B) and the adjacent ring-shaped cavity.

1 Unscrew the insert;
2 Unscrew the front metal cone (Fig.9 - 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.9 - Ref.B);
- Titanium support (Fig.9 - Ref.C);
- Front cone (Fig.9 - 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.9 - 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 06.5.

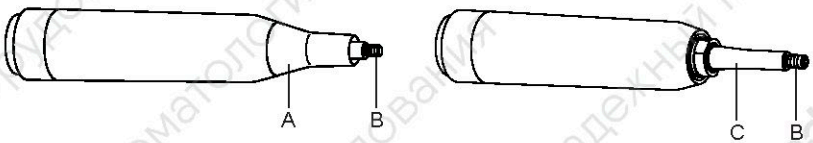


Fig. 9

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⚠ **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.

06.8 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 06.5.

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.10;
⚠ **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 06.5.

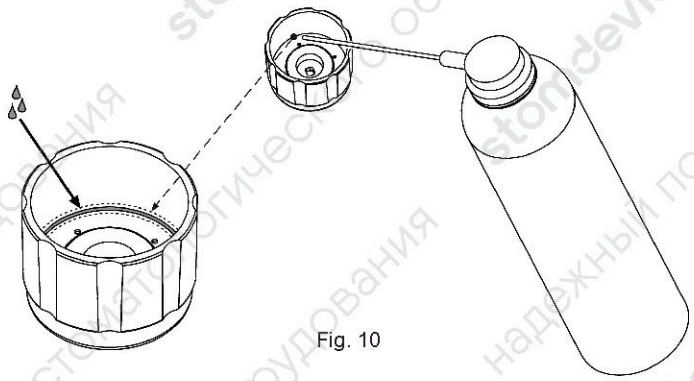


Fig. 10

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07.0 Regular maintenance

07.1 Cleaning and replacement of the water filter

⚠ **DANGER: Switch off the device.**
Always switch off the device by means of the right side switch (Fig.5 - Ref.A) and disconnect it from the power source, before carrying out the following maintenance activity

Check and clean the water filter monthly, as follows:
1 Disconnect the water supply hose from the male coupling (Fig.4 - Ref.B).
2 Unscrew the male coupling milled ring-nut (Fig.11 - Ref.B).
3 Take out the filter (Fig.11 - Ref.A), wash it under running water to eliminate any impurities and/ or clogs.
4 Replace the filter back into place and firmly screw the milled ring-nut back until it bottoms out.

NOTE: a damaged water filter or a filter that cannot be cleaned anymore, has to be replaced with a new one.

07.2 Elimination of condensation water

NOTE: This operation has to be carried on while the device is switched on.

The device has an air filter that retains any impurities and the formation of condensation in the pneumatic circuit.
To prevent the condensation from circulating inside the device, check the air filter and empty it weekly, as follows:

1 With the device switched on and in a perfectly horizontal working position, press the relief valve of the air filter (Fig.12 - Ref.A) at the bottom of the device until there is only air coming out.

NOTE: It is in any case recommended to use a dry compressor and to add a dehumidifier in the surgery's pneumatic circuit.

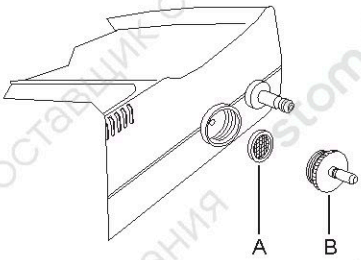


Fig. 11

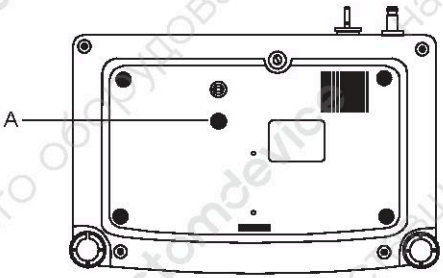


Fig. 12

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07.3 Cleaning the cap

⚠ **DANGER: Switch off the device.**
Always switch off the device by means of the right side switch (Fig.5 - Ref.A) and disconnect it from the power source, before carrying out the following maintenance activity

It is recommended to check weekly the thread of the container cap and make sure that it is clean and that no powder residues are left, these would otherwise make it difficult to open and close the cap.

07.4 When the device is not being used

If the device is not being used for several days, proceed according to the following instructions:
1 Empty the powder container.
2 Carry out the water and air circuit cleaning cycles by means of the clean function (see point "06.1").
3 Eliminate the condensation water from the air filter (see point "07.2").
4 Disconnect the device from the power source and from the water and air circuits.
5 Clean and dry the water filter (see point "07.1").
6 Carry out the cleaning, disinfection and sterilisation operations (see point "06.0").

07.5 Power cable

⚠ **DANGER:** Check the power cable regularly to make sure that it is in good conditions. If found to be damaged, replace it with an original Mectron spare cable.

08.0 Replacement of the fuses

⚠ **DANGER: Switch off the device.**
Always switch off the device by means of the right side switch (Fig.5 - Ref.A) and disconnect it from the power source, before carrying out the following maintenance activity.

1 Use as a lever the flat tip of a screwdriver, by inserting it into the housing of the fuse-holder compartment, under the power supply socket (Fig.13 - Ref.A).
2 Pull out the fuse-holder compartment (Fig.13 - Ref.B).
3 ⚠ **DANGER:** Replace the fuses complying with the indications found on the data place on the rear of the device, above the power supply socket (Fig.4 - Ref.E). According to the different power supplies, the following values may be obtained

230 Vac - Type 5 X 20 mm	T 500 mAL, 250V
120 Vac - Type 5 X 20 mm	T 800 mAL, 250V
115 Vac - Type 5 X 20 mm	T 800 mAL, 250V
100 Vac - Type 5 X 20 mm	T 800 mAL, 250V

4 Put the fuse-holder into place in its housing (Fig.13 - Ref.B).

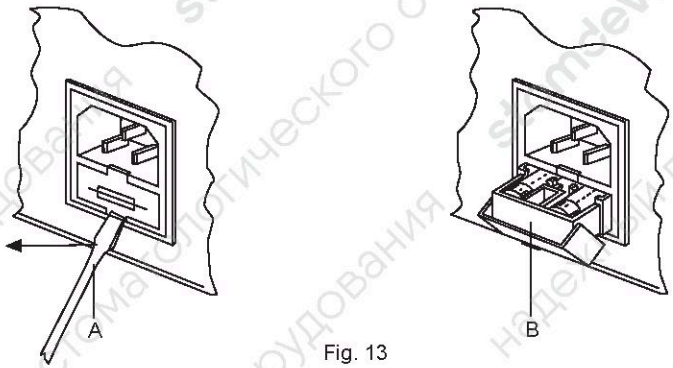


Fig. 13

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09.0 Disposal procedures and precautions

- The device should be disposed of and treated as separate waste;
- **Users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take these items for environmentally safe recycling**; Mectron S.p.A. can provide you with the correct instructions on separate waste disposal;
- Failure to comply with the above mentioned rules can bring to penalties, according to the European Directive 2002/96/EC.

⚠ **DANGER: Hospital waste.**
Treat the following articles as hospital waste:
- Inserts, when worn or broken;
- Torque wrench, when worn or broken;
- Polisher front head, when worn or broken;
- Cleaning needle for the front terminal of the polisher, when worn or broken.

10.0 Mectron scaling inserts and their use

S1 - S2 - S3 - S4 - S5: For general use in scaling and root planing interventions;
S6 - S7 - S8: High efficiency, for general use in scaling and root planing interventions for considerable tartar removal;
P1 - P2 - P3 - P4: For general use in removal interventions of concretions in root surfaces;
P10 - P11 - P12 - P13 - P14: For concrements and biofilm removal from root surfaces;
R1 - R2 - R3 - R4 - R5: For general use in the retrograde treatment of root canals;
D1 - D2 - D3 - D4: For general use of amalgam condensation – gold filling burnishing - lateral condensation of guttapercha - removal of crowns, bridges and pins;
CM1 - CM2 - CM3 - CM4: For preparation of the crown core and crown margin;
ER1 - ER2 - ER3 - ER4 - ER5: For general use in orthograde endodontic treatment;
E1 - E2: Endo file holder at 120° or 90° for endo files.

11.0 Symbols


WARNING Read the instructions for use


Type “B” applied part


The device and its accessories should not be disposed of or treated as solid urban waste.



Sterilizable in autoclave at a maximum temperature of 135° C.



Indicates conformity to EC medical device directive 93/42 EEC, EN 60601-1 and EN 60601-1-2 included. Notified body: CERMET



Serial number


Manufacturer


Class II device


Alternating current

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12.0 Troubleshooting

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

PROBLEM	POSSIBLE CAUSE	SOLUTION
The device does not switch on (no LED is ON).	No power. The switch (Fig.5 - Ref.A) is positioned on “O”.	Switch on the device.
	The power supply cable is not properly connected to the device.	Connect the cable both to the device and to the power socket.
	The power cable is faulty.	Replace the power cable.
	The fuses are burnt.	Change the fuses (see point “08.0”).
The device is switched on but will not work.	The footswitch plug is not correctly plugged into the footswitch socket (Fig.4 - Ref.C).	Plug in the footswitch plug properly.
	The footswitch is out of order.	Contact the authorised MECTRON Service Centre.
The powder container cap cannot be unscrewed.	The device is switched on and the powder container is under pressure.	Switch off the device to depressurise the internal circuit.
	The device is switched off but the powder container is under pressure because the front terminal is clogged.	Read point “06.6”.
	The device is switched off but the powder container is under pressure because the handpiece cord is clogged.	Contact the authorised MECTRON Service Centre.

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PROBLEM	POSSIBLE CAUSE	SOLUTION
No powder comes out from the front terminal during operation.	The device is not connected to the air circuit.	Check the connection to the water circuit.
	Polisher front terminal clogged due to excessive moisture in the powder or insufficient cleaning/maintenance.	Read point “06.6”. Remove the powder from its container and clean with a dry cloth. Read point “07.2”
	The powder level in the container is higher than that allowed.	Restore the proper powder level inside the container (see point “05.3”).
	Unsuitable powder.	To ensure a correct functioning, make sure that the power used is a suitable one.
No water comes out of the polisher front terminal during operation.	The device is not connected to the water circuit.	Check connection to the water circuit.
	The water tap on the device is closed (Fig.5 - Ref.I).	Adjust the water flow by turning the left knob.
	Water is too hard.	Read point “06.5”.
	Water filter is clogged.	Read point “07.1”.
Powder leakage from the container cap.	The cap is not properly screwed on.	Screw the cap properly on.
	Powder residues in the thread.	Read point “07.3”
Insufficient cleaning	Insufficient pressure in the air-supply circuit.	Check the pressure in the air-supply circuit (4-8 bar max).
	Too low or too high powder level in the container.	Restore the proper powder level inside the container (see point “05.3”).
	Unsuitable powder.	To ensure a correct functioning, make sure that the power used is a suitable one. Read point “06.5”.
	Polisher front terminal clogged due to excessive moisture in the powder or insufficient cleaning/maintenance.	Remove the powder from its container and clean with a dry cloth. Read point “07.2”.

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PROBLEM	POSSIBLE CAUSE	SOLUTION
The device is switched on but will not work. the yellow **check** LED is flashing (APC activation).	The insert is not properly fitted on the handpiece.	Unscrew the insert and screw it back properly.
	The insert is worn, broken or deformed.	Replace the insert.
	The handpiece or cord connector is wet.	Dry the connectors.
The device is switched on but will not work. Yellow **check** LED is steady on (APC activation).	Handpiece not connected to the cord.	Connect the handpiece to the cord.
	Discontinuity of a wire inside the cord.	Contact the authorised MECTRON Service Centre.
	Handpiece fault.	Contact the authorised MECTRON Service Centre.
	Tuning circuit not working properly.	Contact the authorised MECTRON Service Centre.
A slight hissing sound from the scaler handpiece can be heard during the operation.	The insert is not properly tightened to the scaler handpiece.	Unscrew the insert and screw it back properly.
No water supply.	The device is not connected to the water circuit.	Check connection to the water circuit.
	The insert used is without liquid outake.	Use an insert having a liquid outake.
	The **water** function has not been activated.	Push the button **water** on the button pad, the green LED will light up.
	The water tap on the device is closed (Fig.5 - Ref.L).	Adjust the water flow by using the right knob.
	The insert is clogged.	Free the water channel of the insert.
	Water filter is clogged.	Read point “07.1”.
	The handpiece is clogged.	Contact the authorised MECTRON Service Centre.

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PROBLEM	POSSIBLE CAUSE	SOLUTION
Insufficient power	The insert is not properly fitted on the handpiece (yellow **check** LED flashing).	Unscrew the insert and screw it back properly.
	The insert is worn, broken or deformed (yellow **check** LED flashing).	Replace the insert.
	Handpiece fault (yellow **check** LED steady on).	Contact the authorised MECTRON Service Centre.

12.1 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 “05.0 Cleaning disinfection and sterilisation”;
2 Sterilise the parts that can be sterilised according to instructions at point “05.0 Cleaning disinfection and sterilisation”:
   - Handpiece;
   - Insert/s;
   - Dynamometric wrench;
   - Polisher front terminal;
   - Needle to clean the polisher front terminal.
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.

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13.0 Technical specifications

Device conforming with Dir. 93/42/EEC:	Class II a.
Class according to EN 60601-1:	II Type B IP 20 (device) IP 22 (footswitch)
Device for intermittent operation:	60” ON 30” OFF with irrigation. 30” ON 120” OFF without irrigation.
Power supply voltage:	230 Vac 50/60 Hz. 120 Vac 50/60 Hz (optional). 115 Vac 50/60 Hz (optional). 100 Vac 50/60 Hz (optional).
Max. power absorption:	95 VA.
Fuses:	230 Vac - Type 5 X 20 mm T 500 mAL, 250V 120 Vac - Type 5 X 20 mm T 800 mAL, 250V 115 Vac - Type 5 X 20 mm T 800 mAL, 250V 100 Vac - Type 5 X 20 mm T 800 mAL, 250V
Working frequency:	Automatic scanning. From 24 KHz. to 36 KHz.
Potenza:	Adjustable to 4 pre-set levels.
Alimentazione acqua:	Polisher function: - Stepless adjustment. - Water heated by built-in heater Scaler function: - Stepless adjustment. Water circuit cleaning function, polisher and scaler - See point “06.1”. Connection by hose supplied with quick-coupling connector through a built-in removable filter. Working pressure from 1 to 6 bars.
Air supply:	Air circuit cleaning function - See point “06.1”. Connection through supplied hose with quick- coupling connector through a built-in filter and pressure reducing valve. Input pressure between 4 and 8 bars. Working pressure: Prophy function = 3,5 bar Perio function = 2,7 bar

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APC activation:

- No handpiece
- Discontinuity of cord wire
- Insert not properly tightened or broken
- Intervention of the ground discharge protection system

Alarms:

Yellow **check** LED on front:
Steady on or flashing see "Troubleshooting" paragraph.

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 size:

3,5 Kg
L - l - h 280 X 185 X 100 mm.

13.1 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">Manufacturer's directory and statement - Electromagnetic emissions</th></tr>
<tr><td colspan="3">Combi is manufactured to work in the electromagnetic environment specified below.
The client or user of the Combi device should make sure that it is used in such environment.</td></tr>
<tr><th>Emissions trial</th><th>Conformity</th><th>Electromagnetic environment - Directory</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>Combi uses RF energy only for its internal functioning. So, its RF Emissions are very low and would most likely not cause any interference with electronic devices lying nearby.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class B</td><td rowspan="3">Combi is fit to be used in all buildings, including houses, and those directly connected to the public low voltage electricity network supplying buildings for household purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Emissions of voltage fluc-tuations/flicker
IEC 61000-3-3</td><td>Standard</td></tr>
</table>

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Manufacturer's directory and statement - Electromagnetic immunity			
Combi is manufactured to work in the electromagnetic environment specified below. The client or user of the Combi device should make sure that it is used in such environment.			
Immunity trial	**Trial level IEC 60601**	**Conformity level**	**Electromagnetic environment - Directory**
Electrostatic discharges (ESD) IEC 61000-4-2	±6 kV on contact ±8 kV in air	±6 kV on contact ±8 kV in air	Floorings should be in wood, concrete or ceramics. If the flooring is covered with synthetic material, the relative humidity should at least be 30 %
Tansients/fast electric trains 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	The quality of the voltage network should be that of a typical commercial or hospital environment.
Impulses IEC 61000-4-5	±1 kV in differential mode ±2 kV in common mode	±1 kV in differential mode ±2 kV in common mode	The quality of the voltage network should be that of a typical commercial or hospital environment.
Buchi di tensione, Voltage gaps, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % gap of U_T) for 0.5 cycles 40 % U_T (60 % gap of U_T) for 5 cycles 70 % U_T (30 % gap of U_T) for 25 cycles <5 % U_T (>95 % gap of U_T) for 5 s	<5 % U_T (>95 % gap of U_T) for 0.5 cycles 40 % U_T (60 % gap of U_T) for 5 cycles 70 % U_T (30 % gap of U_T) for 25 cycles <5 % U_T (>95 % gap of U_T) for 5 s	The quality of the voltage network should be that of a typical commercial or hospital environment.
Magnetic field at a network frequency of (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at network frequency should have the characteristic levels of a typical site in a commercial or hospital environment.
NOTE: U_T is the voltage network in c.a. before the trial level is applied			

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Manufacturer's directory and statement - Electromagnetic immunity			
Combi is manufactured to work in the electromagnetic environment specified below. The client or user of the Combi device should make sure that it is used in this environment.			
Immunity trial	**Trial level IEC 60601**	**Conformity level**	**Electromagnetic environment - Directory**
			Portable and mobile RF communication devices should not be used anywhere near the product, including wires, unless they conform to the recommended distances of separation estimated by the equation applicable to the transmitter's frequency.
Conducted RF IEC 61000-4-6	3 Veff from 150 kHz to 80 MHz	3 Veff	**Recommended distances of separation** $d = 1,2 \sqrt{P}$
Irradiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ *from 80 MHz to 800 MHz* $d = 2,3 \sqrt{P}$ *from 800 MHz to 2,5 GHz* where ***P*** is the transmitter's maximum nominal output power in Watt (W) according to the transmitter's manufacturer and ***d*** is the recommended distance of separation in metres (m). The field intensity of RF fixed transmitters, as established in an electromagnetic investigation of the site [a], could be less than the conformity level in each frequency interval [b]. An interference check could be made close to devices indicated by this sign: 

Notes:

(1) At 80 MHz and 800 MHz the highest frequency interval is applied.

(2) These guidelines may not apply in all cases. Electromagnetic propagation is influenced by the absorption and the reflection of structures, objects and persons.

a The field intensity for fixed transmitters such as base stations for radiophones (mobile and cordless) and land mobile radios, amateur radio operators' devices, AM and FM radio transmitters and TV transmitters could not be theoretically and precisely laid down. To establish the electromagnetic environment caused by RF fixed transmitters, an electromagnetic investigation should be made of the site. If the measured field intensity at the place where the Combi is used, exceeds the applicable conformity level referred to above, the normal functioning of the Combi should be kept under observation. Should it not be working well, further measures may be required such as a redirection or new positioning of the Combi.

b The field intensity on a frequency interval from 150 kHz to 80 MHz should be less than 3 V/m.

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Distances of separation recommended between portable and mobile radiocommunication devices and the Combi

Combi is manufactured to work in an electromagnetic environment where RF irradiated disturbances are under control. Combi's client or operator could contribute to prevent any electromagnetic interference by making sure there is a minimum distance between the portable and mobile communication RF devices (transmitters) and the Combi, as recommended here below, in relation to a maximum output power of the radiocommunication devices

Maximum nominal output power of the transmitter "W"	Distance of separation at transmitter frequency "m"		
	from 150 kHz to 80 MHz $d = 1,2\sqrt{P}$	from 80 MHz to 800 MHz $d = 1,2\sqrt{P}$	from 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 having a maximum nominal output power not shown above, the recommended distance of separation ***d*** in metres (m) could be estimated by using the equation applicable to the transmitter's frequency, where ***P*** is the maximum nominal output power of the transmitter in Watt (W) according to the transmitter's manufacturer.

Notes:

(1) At 80 MHz and 800 MHz the highest frequency interval is applied.

(2) These guidelines may not apply in all cases. Electromagnetic propagation is influenced by the absorption and the reflection of structures, objects and persons..

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14.0 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

manufacturer:
Mectron S.p.A.
Via Loreto 15/A
16042 Carasco (Ge) Italy
Tel. +39 0185 35361
Fax +39 0185 351374
www.mectron.com
e-mail: mectron@mectron.com

combi V. GB
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