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INTENDED USE

The COMBI touch combines a multifunctional piezoelectric scaler and a water jet, air and sodium bicarbonate or glycine powder polisher in a unique device, intended for a complete supragingival and subgingival prophylaxis treatment.

Ultrasonic piezo scaler
Using the appropriate inserts, the following dental applications can be performed:
- scaling: all procedures for the removal of bacterial plaque deposits and supragingival, sub-gingival, and interdental calculus, and for the removal of stains;
- periodontology: periodontal treatment for scaling and root-planing/debridement, including cleaning and irrigation of periodontal pockets;
- cleaning of implant surfaces;
- endodontics: all treatments for root canals preparation, irrigation, filling, condensation of gutta-percha, endodontic revision and retrograde preparation;
- restoration and prosthesis: cavity preparation and removal of carious tissues, removal of restorations and of excess restoration material, condensation of the amalgam, finishing of the cervical margin;
- extraction techniques.

Polisher for prevention and dental hygiene.
Indications:
- Removal of bacterial plaque - using Mectron powder only (Prophylaxis powder);
- Removal of subgingival bacterial plaque, using glycine-based powder with specific intended use;
- Removal of biofilm in the implant patient for the purpose of preventing of periimplantitis, through the use of glycine-based powder with special specification of use;
- Removal of stains on the tooth surface due to tobacco, coffee, tea and chlorhexidine - use Mectron powder only (Prophylaxis powder);
- Prophylaxis on patients under going orthodontic treatment, using glycine-based powder with specific intended use;
- Preparation of cavities for better adhesion between enamel and filling material - use Mectron powder only (Prophylaxis powder);
- Polishing the surface of the enamel.
DANGER: In the presence of composite resin surfaces, the jet must be directed towards the part to be treated, on average 2-3 seconds per tooth.

WARNING: The device must be used in a dental practice or ambulatory facility. The device cannot be operated in environments where anesthetic or flammable mixtures are present.

WARNING: Qualified and specialized personnel. The device must be used exclusively by specialized and appropriately trained personnel. The use of the device does not cause side effects if applied correctly. An improper use might cause tissues heating.

WARNING: Use the device for intended use only. Failure to observe this precaution may cause serious injury to the patient, the operator, and damage/breakdown to the device.

01.2 DESCRIPTION OF THE DEVICE

The COMBI touch combines a multifunctional piezoelectric scaler and a water jet, air and a sodium bicarbonate and glycine powder polisher in a unique device, intended for a complete supragingival and subgingival prophylaxis treatment.

Concerning the various treatments possible using ultrasound, the COMBI touch allows work to be performed using the water supply of the dental practice and with independent irrigation through a dedicated liquid container, which can house different types of medicinal solutions.

The device is equipped with an automatic tuning circuit, which compensates for the wear of the inserts, thus always allowing operation in conditions of maximum efficiency.

The polishing side makes the use of two types of powder possible, depending on the type of treatment to be performed: Prophylaxis Powder dedicated to supragingival prophylaxis and glycine-based powder dedicated to subgingival treatment.

The operating principle of the polisher is based on the mechanical action obtained from a jet of various types of crystals accelerated by a flow of compressed air. The kinetic energy applied to the particles, dissipates almost completely due to impact against the surface of the enamel, producing a gentle yet effective cleaning action. The action is completed by a jet of water which, using the vacuum created around the nozzle, has a bell-shape around the main flow, thus producing a dual effect: to prevent much of the rebound and the leakage of the cloud of powder and perform continuous washing of the treated area, dissolving the powder.
The manufacturer, Mectron, disclaims any liability, expressed or implied, and shall have no responsibility for any direct, indirect or other damages and personal injury arising out of or in connection with any errors in the use of the device and its accessories.

The manufacturer, Mectron, shall be under no liability, expressed or implied, with respect to any damages (personal injury and/or damage to property) which might arise or be caused, whether by the customer or by any of the users of the product, and its accessories, as result of:

1. Use of or procedures not indicated other than those as specified in the intended use of the product;
2. Environmental conditions for the preservation and storage of the device not compliant with the precautions indicated in Chapter 11 - TECHNICAL DATA;
3. Device not being used in compliance with all instructions and precautions described in this manual;
4. Electrical system located in the premises in which the device is used not compliant with the electrical code compliance standard and to relative precautions;
5. Assembly operations, extensions, adjustments, updates, and repairs on the device performed by personnel not authorized by Mectron;
6. Improper use, mistreatments, and/or incorrect interventions;
7. Any and all attempts to tamper with or modify the device, under any circumstance;
8. Use of non-original Mectron inserts that cause a finite damage to the threading of the handpiece, thus compromising correct operation and causing risk of harm to the patient;
9. Use of inserts other than authentic Mectron inserts, used in accordance to the designed and tested settings of Mectron authentic inserts. The correct use of the settings is guaranteed only with original Mectron inserts;
10. Lack of backup components and accessories (handpiece, inserts, wrenches, scaler handpiece, polisher tips, subgingival perio tips) are to be used in the event of deviations from device proper use due to defects or other occurrences.
01.4 → SAFETY PRECAUTIONS

⚠️ WARNING: Contraindications. Do not use the COMBI touch on patients who carry heart stimulators (Pacemakers) or other implantable electronic devices. This precaution also applies to the operator.

⚠️ WARNING: Contraindications. Do not perform scaling treatments without irrigation to avoid insert over-heating, which may cause damage to the tooth. Treatments with no can be carried out only with "Irrigation Free" inserts which do not have the water passage.

⚠️ CAUTION: Contraindications. Ultrasonic scaler. Do not perform treatments on restorations made of metal or ceramics. As a result, the ultrasonic vibrations could lead to de-cementing of restorations.

⚠️ WARNING: Contraindications. Interference from other equipment. An electrical scalpel or other electro-surgical units near the COMBI touch device may interfere with its correct operation.

⚠️ WARNING: Contraindications. Interference with other equipment. Though compliant to the IEC 60601-1-2 standard, the COMBI touch may nonetheless interfere with other devices nearby. The COMBI touch must not be used near to or stacked on other devices. However, if this is necessary, you must check and monitor correct operation of the device in that configuration.

⚠️ CAUTION: In the case that the end user, when operating in his or her own dental facility or clinic, must subject the electro-medical equipment and systems to periodical inspections in order to adhere to imposed requirements, test procedures that must be applied to electro-medical equipment and systems to evaluate safety must be performed in conformance with standard EN 62353 ‘Electro-medical devices - Periodical inspections and tests to be performed after repair interventions on electro-medical devices’.

⚠️ WARNING: Checking device status before the treatment. Always check there is no water underneath the device. Before every treatment, always check that the device works perfectly and that the accessories are in efficient working order. In the event you uncover operating abnormalities, do not perform the treatment. Contact an Authorized Mectron Service Center if the abnormalities the device.

⚠️ CAUTION: The electrical system located on the premises in which the device is installed and used must be compliant with the electrical code compliance standards in force and to the relative electrical safety precautions.

⚠️ CAUTION: To avoid any risk of electric shock, this device must be grounded.

⚠️ WARNING: All of the accessories provided with new or repaired devices are not sterile. All new and repaired accessories are supplied in non-sterile conditions. Before use, and after each treatment, they must be cleaned and sterilized in strict compliance with the instructions given in the Chapter 08 - CLEANING AND STERILIZATION.

⚠️ WARNING: Infection control. To ensure maximum safety of patient and operator, before using all the reusable parts and accessories, they should first be cleaned and sterilized, following the instructions in Chapter 08 - CLEANING AND STERILIZATION.

⚠️ CAUTION: Contraindications. Prior to re-usage, allow reusable, autoclavable items (handpiece, inserts, torque wrench, and any other accessory that can be sterilized ) to gradually return to room temperature after steam sterilization. The cooling process must not be accelerated.

⚠️ WARNING: Insert breakage and wear. High frequency oscillations and wear and tear may, in rare circumstances, lead to insert breakage. Deformed or otherwise damaged inserts are susceptible to breakage during their use. These inserts must never be used. If an insert breaks, check that none of its fragments remain in the treated area and, at the same time, apply effective suction to remove them.
The patient must be instructed to breathe through their nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken inserts. When the nitride coating wears off of the insert, the cutting efficiency decreases; re-sharpening the insert damages it and is therefore forbidden. Always check that the insert is not worn out. During the treatment, frequently check that the insert is intact, especially in its apical part. During the treatment, avoid prolonged contact with retractors or with metallic instrumentation in use. Do not exert excessive pressure on the inserts during use.

⚠️ WARNING: Only use authentic Mectron inserts, accessories, and replacement parts.

⚠️ CAUTION: No modification of this equipment is allowed.

⚠️ CAUTION: Contraindications. Prior to re-usage, allow reusable, autoclavable items (handpiece, inserts, torque wrench, and any other accessory that can be sterilized) to gradually return to room temperature after steam sterilization. The cooling process must not be accelerated.

⚠️ WARNING: Contraindications - Jet polisher.
Patients that are on a low sodium diet or who suffer from serious respiratory problems, such as chronic bronchitis, asthma, emphysema, etc. must not undergo the prophylaxis treatment, until they have consulted with their doctor.

⚠️ WARNING: Contraindications - Jet polisher.
Patients wearing contact lenses should remove them prior to receiving treatment with the jet polisher.

⚠️ WARNING: Contraindications - Prophylaxis powder jet polisher.
Do not aim the jet of air/Prophylaxis powder/water onto soft tissues or inside the gingival sulcus. Failure to comply with this direction can cause gingival tissue emphysema (emphysema of the mucosa and/or subcutaneous). Use only Glycine-based powder for this kind of treatments.

⚠️ WARNING: Temperature of the water spray - Jet polisher.
This device is equipped with a double safety mechanism that controls the temperature of the water spray. Before treatment, it is however recommended to instruct the patient to inform the operator if they perceive an excessive increase in the temperature of the water.
INTRODUCTION

Warning: read the instructions for use

Operating instructions

Use-by date

Do not use if the packaging is not intact

Sterilized using ethylene oxide

Temperature limitation - transport and storage conditions

Humidity limitation - transport and storage conditions

Atmospheric pressure limitation - transport and storage conditions

It indicates compliance with the CE 93/42 CEE EN 60601-1 and EN 60601-1-2. Notified body: CERMET.

Nemko Mark
UL CSA conformity

Manufacturer
Date of Manufacture

Quantity of parts in the pack = 1

Do not re-use

Applied part of type “B” as per norm EN 60601-1

Can be sterilized in autoclave up to a maximum temperature of 135° C

Non-sterile

The device and its accessories must not be disposed of or treated as solid urban wastes

Biohazard

Activation switch “on”

Activation switch “off”

Alternating current

Connection of the foot pedal

For US market only

**CAUTION** US Federal Law restricts this device to sale by or on the order of a dentist.
COMBI touch

02 ➔ IDENTIFICATION DATA

An exact description of the model and serial number of the device will enable our After-Sales Service to provide fast and efficient support.
Always provide this information whenever you contact an Authorized Mectron Service Center.

02.1 ➔ DEVICE IDENTIFICATION PLATE

Every device has an identification plate that bears the technical characteristics and the serial number. The identification plate is located on the inferior panel of the device. Additional specifications are reported in this manual (See Chapter 11 - TECHNICAL DATA).

02.2 ➔ HANDPIECE IDENTIFICATION DATA

The handpiece is laser-marked with the Mectron logo (ref. 1) and with its serial number (ref. 2).
### 02.3 INSERT IDENTIFICATION DATA

The following data are laser-marked on each insert: the name of the insert (ref. 3), the Mectron logo (ref. 4) and the lot number to which the insert belongs (ref. 5).

### 02.4 POLISHER TIP IDENTIFICATION DATA

The following data are laser-marked on each insert: the name of the polisher tip (ref. 6), the Mectron logo (ref. 7) and the lot number to which the insert belongs (ref. 8).
The COMBI touch consists of:

A device body
B peristaltic pump
C foot pedal with cord and connector
D electrical power supply cable
E mectron torque wrench
F manual of use and maintenance
G 2 polisher containers complete with cap
H 3 polisher tips: 90° (PO 90) / 120° (PO 120) / PERIO
I polisher handpiece
J inserts/insert kit
K scaler handpiece complete with LED light front cone
L irrigation solution containers complete with caps
M water supply tubing with quick coupling
N air supply tubing with quick coupling
O accessories:
   O1 metal front cone without light
   O2 replacement filter for water circuit
   O3 Ø 0.8 mm needle
   O4 Ø 0.4 mm needle
   O5 screw-on lids for the irrigation solution containers
   O6 packet of Glycine Powder (for European market only)
   O7 packet of Prophylaxis Powder
   O8 subgingival perio tip
   O9 K9 wrench

The COMBI touch has accessories available that can be ordered separately. The quantity and type of accessories supplied with the device you have purchased can vary according to promotional campaigns and to the country where the unit is sold. The package of the device is sensitive to strong collisions, because it contains electronic components. Therefore, special precautions must be taken for transport and storage. Do not stack multiple boxes, in order not to damage the packages underneath. All the materials shipped by Mectron have been inspected upon their delivery. The device is delivered duly protected and packed.

When receiving the device, check for the possible presence of damages incurred during the transport and, should that be the case, file a complaint with the transporter. Preserve the package in the event that you need to send the device to an Authorized Mectron Service Center and for storing the device during prolonged periods of non-use.

⚠️ WARNING: Before commencing operation of the device, make sure that you have additional accessories, such as, scaler handpiece, inserts, wrenches, polisher tips, subgingival perio tips, available to use in case of deviations from device proper use due to defects or other occurrences.
04 INSTALLATION

04.1 FIRST INSTALLATION

The device must be installed in a comfortable and suitable place for its use. The COMBI touch can be purchased ready for instant use or may have to be enabled by typing an activation key. In the event that your device requires an activation key, the procedures to follow may vary from country to country. Always refer to your retailer to obtain information on the above.

04.2 SAFETY PRECAUTIONS DURING INSTALLATION

⚠️ WARNING: Contraindications. Interference with other equipment. Though compliant with the standard IEC 60601-1-2, the COMBI touch may nonetheless interfere with other devices nearby. The COMBI touch must not be used near to or stacked on other devices. However, if this were to prove necessary, you must check and monitor correct operation of the device in that configuration.

⚠️ WARNING: Contraindications. Interference from other equipment. An electrical scalpel or other electro-surgical units near the COMBI touch device may interfere with its correct operation.

⚠️ CAUTION: The electrical system located on the premises in which the device is installed and used must be compliant to the electrical code compliance standards in force and to the relative electrical safety precautions.

⚠️ CAUTION: To avoid any risk of electric shock this device must be grounded.

⚠️ WARNING: Risk of explosion. The device cannot operate in environments where there are saturated atmospheres of flammable gases (aesthetic mixtures, oxygen, etc.).

⚠️ WARNING: Install and use the device in a place protected against collisions or against accidental sprays of water or liquids.

⚠️ WARNING: Do not install the device above or near heat sources. Adequate air circulation around the device when installing it is necessary.

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

⚠️ CAUTION: The device can be transported, but it must be handled with care. Position the foot pedal on the ground, so that it can only be activated intentionally by the operator.

⚠️ CAUTION: Before connecting the handpiece to its cord, make sure that the electrical contacts are entirely dry, on both sides. If need be, dry them with compressed air.

⚠️ CAUTION: Position the device in a way that the power plug is easily accessible at all times; this is considered a insulation means.

⚠️ CAUTION: Each irrigation solution container has a maximum capacity of 500 ml.
04.3 CONNECTION OF THE ACCESSORIES

Connect the foot pedal to the back of the device in the socket marked with the symbol with the plug of the pedal cable, until you hear a “click” sound.

⚠️ CAUTION: Pay attention to the positioning of the pedal, so that the pedal is only activated intentionally by the operator.

Discharge any condensation from the compressed air supply - connect the air supply tubing to the practice’s air supply using the relative reduction and cut-off valve (not provided by Mectron).

Connect the quick coupling to the male attachment on the rear of the device;

Connect the supply tubing to the practice’s water circuit using the relative reduction and cut-off valve (not by Mectron).

Connect the quick coupling to the male attachment on the rear of the device;

Insert the power supply cable in its connection located at the back of the device. Connect it to the power outlet;

⚠️ CAUTION: Position the device in such a way that the power plug is easily accessible at all times; this is considered an insulation means.
Unscrew the cap from the irrigation solution container and fill in the irrigation solution container with the needed solution;

1 CAUTION: each irrigation solution container can contain liquids up to a maximum of 500 ml.

Check that the hose connected to the irrigation solution container’s cap is correctly installed, then screw the cap back on the irrigation solution container;

1 CAUTION: check that the female coupling of the cap is clean and free from impediments.

1 CAUTION: check that the male coupling on the unit is clean and that its o-rings are not worn.

Keep the irrigation solution container in a vertical position and push it towards the unit’s body until it is firmly connected;

1 CAUTION: Do not capsize the irrigation solution container as its cap is not watertight. The leaking of the physiological solution or of aggressive liquids can damage the surfaces.

Correctly connect the handpiece to its cord making sure to match the dot on the handpiece connector with the groove on the cord connector. Make sure that the electrical contacts of both handpiece and cord are entirely dry; if need be, dry them by blowing compressed air;
Position the handpiece on its support.

**CAUTION:** Before extracting the powder containers or unscrewing the caps, make sure that the device is off and disconnected from the main electricity or the “refill” function has been selected and the corresponding LED is on with a fixed light (see paragraph 05.2.2 - FILLING THE POWDER CONTAINERS).

Loosen the cap of the white PROPHY powder container.

**CAUTION:** The PROPHY powder container is identified due to by means of its white color.

Pour the Prophylaxis Powder into the container, making sure that the level reaches the diffuser inside.

**WARNING:** Introduce only Prophylaxis Powder into the PROPHY container.

**CAUTION:** Correct level of powder in the tank.

**Minimum level:** The level of powder in the container must not be lower than one centimeter to prevent cleaning performance from dropping.

**Maximum level:** The level of the powder in the container must remain below the diffuser (at least 5 mm).

Close the cap on the container without tightening it excessively.
Loosen the cap of the blue PERIO powder container.

**CAUTION:** The PERIO powder container is identified by means of its **blue** color.

---

Pour the Glycine-based powder into the container, making sure that the level reaches the diffuser inside.

**WARNING:** Introduce only glycine-based powder into the PERIO container.

**CAUTION:** Correct level of powder in the tank.

**Minimum level:** The level of powder in the container must not be lower than one centimeter to prevent cleaning performance from dropping.

**Maximum level:** The level of the powder in the container must remain below the diffuser (at least 5 mm).

---

Close the cap on the container without tightening it excessively.
05 USE

05.1 SWITCHING THE DEVICE ON AND OFF

Turning the device on
With the device in view from its front side, position the switch on the left of the device body on position “I”, being careful not to press the foot pedal. On the device, all of the signals switch on and switch off successively. The keyboard remains off for a few seconds until an acoustic signal, which indicates the end of the diagnostics cycle. At this point, the device positions itself on the default setting and is ready for use.

Default setting:
ULTRASOUND side
“endo” mode
power “1”
light “Off”
Jar symbol irrigation - average flow rate
POLISHING side
“prophy” function

NOTE: The setting operations for the scaler part and the polisher part can be performed simultaneously only with the handpieces at rest. If one of the two handpieces is lifted, only the settings of the active function can be changed.

Turning the device off
With the device in view from its front side, position the switch on the left of the device body on position “O”, being careful not to press the foot pedal. The device turns off.

CAUTION: Position the device in a way that the power plug is easily accessible at all times; this is considered an insulation means.
05.2 → DESCRIPTION OF THE KEYBOARD

Touch keyboard
The user can configure the device by simply touching on the touch surface. Depending on the selected setting, the electronic feedback system automatically adjusts the correct operating frequency.

PLEASE NOTE: A brief acoustic signal is emitted to indicate the selection of a key. A prolonged acoustic signal is emitted to indicate that the key cannot be selected for said setting.

05.2.1 → ULTRASOUND - Scaler side

FUNCTIONS
(ref. P inside cover)
Depending upon the type of treatment, it is possible to choose one of the 3 options available from the mode list, as follows:

- “endo”: dedicated to endodontic treatments such as cleaning of root canals and retro grade approach.
- “perio/scaler”: dedicated to supra- and sub-gingival prophylaxis procedures, to root planing and to implant cleaning.
- “restorative”: dedicated to restoration, prosthesis and extraction techniques.

PLEASE NOTE: by selecting “restorative” and power on 6 the PULSE mode is activated. It is used to optimize the insert’s performance in the extraction and prosthesis techniques.

“soft mode”
(ref. Q inside cover)
The treatment can be made more delicate for sensitive patients, by activating the “soft mode” function.
“Soft mode” can only be activated in the “perio/scaler” functions with powers from 1 to 5 and “restorative” with powers from 1 to 4.
In “endo” mode the function is not available.
POWER
(ref. R inside cover)
For all functions previously described, the power for use can be adjusted by selecting the numbers on the power scale. Five power levels are available, from 1 to 5: the work power can be adjusted in an incremental manner (1 → minimum power, 5 → maximum power).

LIGHT
(ref. S inside cover)
Depending on the front tip of the scaler handpiece and the type of treatment to be performed, the light function can be activated:
- by activating the “on/off” key; the LED light on the scaler handpiece front tip switches on when the pedal is pressed and switches off automatically after 3 seconds from pedal release;
- by deactivating the “on/off” key, the LED light of the scaler handpiece front tip is always off.

The position of the LED light on the front terminal of the handpiece can be adjusted in the following way:
- Hold the body of the handpiece and lightly unscrew the metal ring nut located at the base of the front terminal, rotating it counter-clockwise;
- Rotate the front terminal so that the LED light goes into the desired and necessary position;
- To fasten it into position, screw the metal ring nut, rotating it clockwise.
IRRIGATION
(rif. T inside cover)
For the scaler side, the device allows the use of two types of irrigation: the normal water circuit or the jar circuit.
The flow rate of the two circuits can be regulated as follows:
- for the normal water circuit, it can be regulated continuously through the left hand knob;
- for the jar circuit it can be continuously regulated on 7 levels via the touch surface using the “–” and “+” keys.
Irrigation can be excluded in “endo”, “perio/scaler” modes with power levels from 1 to 5 and “restorative” with power levels from 1 to 4.

⚠️ CAUTION: The exclusion of irrigation with non “irrigation free” inserts can cause overheating with consequent breakage of the handpiece.

PLEASE NOTE: On regulation of the irrigation flow rate (“–” and “+”) a prolonged acoustic signal is emitted when high full scale is reached.

PLEASE NOTE: The irrigation flow rate can be changed by pressing the “–” and “+” keys also during the treatment (maintaining the pedal pressed).
COMBI touch

“Flush” FUNCTION
(ref. U inside cover)
The device has a “flush” key, which allows the irrigation circuit to be filled and rinsed.

Filling the irrigation circuit: Before starting the treatment, the “flush” function can be used, which allows:
the liquid to reach the insert in order to start the treatment with the necessary irrigation.

Cleaning the hydraulic circuit:
The “flush” function allows the irrigation circuit rinse cycle to be performed. This function must be used at the end of the treatment and before cleaning and sterilizing all parts.

NOTE: If both handpieces are at rest, the “flush” function cannot be activated.

05.2.2 → POLISHING - Polishing side

FUNCTIONS
(ref. V inside cover)
Depending on the type of application, one of the 2 types of powder can be selected as follows:

- “prophy”: dedicated to the clinical indications of the sodium carbonate-based powder;
- “perio”: dedicated to the clinical indications of the glycine-based powder;

“refill” FUNCTION
(ref. W inside cover)
The “refill” function must be used to depressurize the powder containers in order to then be able to open and remove them from the device.
The “flush” function can be used when you want to pass from the Prophylaxis powder to Glycine, and vice versa, in order to be sure that the powder circuit is clean from that previously used.

**NOTE:** If both handpieces are at rest, the “flush” function cannot be activated.

The device uses just normal water for polishing. The water circuit flow rate can be regulated continuously through the right hand knob.

The COMBI touch is equipped with a diagnostic circuit that allows for detection of operating abnormalities and to view their type on the touch surface via their relative symbol. To help the user identify the malfunctioning part, three symbols are visible which are described in paragraph 12.1.
**WARNING:** Only use authentic Mectron inserts, accessories, and replacement parts.

**WARNING:** Before starting to operate with the device, make sure that you have additional material (scaler handpiece, inserts, wrenches, polisher tips, subgingival perio tips) available to use in case of deviations from device proper use due to defects or other occurrences.

**WARNING:** Checking device status before the treatment. Always check that there is no water underneath the device. Before every treatment, always check that the device works perfectly and that the accessories are in working order. In the event you uncover operating abnormalities, do not perform the treatment. Contact an Authorized Mectron Service Center concerning device abnormalities.

**WARNING:** Infection control. **First use:** All new and repaired accessories are supplied in NON STERILE conditions. Before use, and after each treatment, they must be cleaned and sterilized in strict compliance with the instructions provided in Chapter 08 - CLEANING AND STERILIZATION. **Subsequent uses:** After every treatment, clean and sterilize all the reusable parts and accessories, following the instructions provided in Chapter 08 - CLEANING AND STERILIZATION.

**WARNING:** The patient must not come into contact with the device body or the foot pedal.

**CAUTION:** “flush” function. The “flush” function must be used after every treatment, before starting the cleaning and sterilization procedures.

**Ultrasonic scaler**

**WARNING:** Use of non-authentic Mectron inserts: this use will cause finite damage to the handpiece threading, thus compromising correct operation and risking harm to the patient.

**CAUTION:** Contraindication. Do not perform treatments on prosthetics made of metal or ceramics. The ultrasonic vibrations could lead to the de-cementing of the prosthetic dental work.

**WARNING:** Contraindications. Do not use the COMBI touch on patients who carry heart stimulators (Pace-makers) or other implantable electronic devices. This precaution also applies to the operator.

**WARNING:** Contraindications. Do not perform scaling treatments without water spray in order to avoid the insert over-heating which may cause damage to the tooth. Treatments with no water spray can be carried out only with “Irrigation free” inserts which do not have the water passage.

**CAUTION:** Only use inserts with water passage when performing treatments that require irrigation.

**WARNING:** Treatments that require irrigation. Always check the operation of the irrigation before and during use. Make sure the fluid outflows from the insert. Do not use the device if the irrigation does not work or if the pump is defective.

**WARNING:** To ensure that the handpiece cools down, always activate it with the irrigation circuit correctly installed and filled. To fill the irrigation circuit, always use the FLUSH function.

**CAUTION:** To correctly use the device, you must press the foot pedal and start it with the insert not making contact with the part to be treated, so that the electronic circuit can recognize the best point of resonance of the insert without interferences, allowing its optimal performance.

**WARNING:** Before every treatment, make sure that the insert appropriate for the treatment is inserted on the handpiece. Exclusively use the Mectron torque wrench to fasten the insert to the handpiece.
WARNING: Do not change the insert while the handpiece is operating, to prevent causing injury to the operator.

CAUTION: FLUSH function. After the device is used with aggressive and non-aggressive solutions, it is necessary to perform a cleaning cycle on the tubes and the handpiece with the FLUSH function (see Chapter 06 - FLUSH FUNCTION). If the tubes are not cleaned, the crystallization of the salts may seriously damage the device.

WARNING: Breakage and worn inserts. High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the insert. Do not bend, change the shape of, or re-sharpen an insert in any way. Bending an insert or applying leverage on it can lead to its breakage. Deformed or otherwise damaged inserts are susceptible to breakage during their use. If this occurs, these inserts must never be used again. Excessive pressure on the inserts during their use can lead to their breakage. If an insert breaks, check that none of its fragments remain in the treated area and, at the same time, apply effective suction to remove them. The patient must be instructed to breathe through their nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken inserts. When the nitride coating wears off, the cutting efficiency decreases; re-sharpening the insert damages it and is therefore forbidden. Check that the insert is not worn out. During the treatment, frequently check that the insert is intact, especially its top. During the treatment, avoid prolonged contact with retractors or with metallic instrumentation in use.

CAUTION: Contraindications. Prior to re-use, a reusable, autoclavable items (the handpiece, the inserts, the torque wrench, and any other accessory that can be sterilized) to gradually return to room temperature after steam sterilization. The cooling process must not be accelerated.

CAUTION: The electrical contacts of both handpiece and cord connectors must be dry. Before connecting the handpiece to its cord make sure that the electrical contacts of both connectors are entirely dry, especially after the sterilization cycle in the autoclave. If necessary, dry the contacts by blowing compressed air onto them.

CAUTION: Due to its configuration, the handpiece can rotate. When not in use, the handpiece must always be placed on its support.

Jet polisher:

WARNING: Contraindications. Patients that are on a low sodium diet or who suffer from serious respiratory problems, such as chronic bronchitis, asthma emphysema, etc. must not undergo the prophylaxis treatment, until they have consulted with their doctor.

WARNING: Contraindications. Patients wearing contact lenses should remove them prior to receiving treatment with the bicarbonate jet polisher.

WARNING: Contraindications - Prophylaxis powder jet polisher. Do not aim the jet of air/Prophylaxis powder/water onto the soft tissues or inside the gingival sulcus. Failure to comply with this instruction can cause a gingival tissue emphysema (emphysema of the mucous and/or subcutaneous). Use only Glycine-based powder for this kind of treatments.

WARNING: Temperature of the water spray. The device is equipped with a double safety device that controls the temperature of the water spray. Before the treatment, it is however recommended to instruct the patient to inform the operator if they perceives an excessive increase in the temperature of the water.
WARNING: Checking infections and cleaning the water and air circuits. For maximum safety of the patient and operator, after every treatment, follow the instructions provided in chapter 08 - CLEANING AND STERILIZATION.

WARNING: Do not use the device without water. Make sure that the device is connected to the water circuit and the water cap is open.

WARNING: Do not attempt to unscrew the cap of the powder container before having performed the “refill” cycle.

05.4 INSTRUCTIONS FOR USE - Scaler side

After having connected all the accessories as illustrated in Paragraph 04.3 proceed as follows:

1. Raise the scaler handpiece, with or without insert, load the irrigation circuit by selecting “flush” on the keyboard. The “flush” function LED flashes. The device allows the use of two types of irrigation: the normal water circuit or the jar circuit.

ATTENTION: Make sure that the polisher handpiece is in a resting position, otherwise the device remains inactive.

2. Press the pedal for a moment to start the cycle. The LEDs of the “flush” function and type of irrigation selected flash. The performance of the cycle is indicated with brief sequence of acoustic signals. The cycle lasts 23 seconds, but can be interrupted by pressing the pedal as soon as liquid is observed escaping from the handpiece. Upon completion of the “flush” cycle, the device goes back to being active and repositions itself at the last setting used;
Screw the chosen insert onto the COMBI touch handpiece, until it reaches its limit and can go no further;

Tighten the insert by using the Mectron torque wrench.
To correctly use the Mectron torque wrench, operate as follows:

Place the insert inside the wrench as shown;

Firmly hold the central body of the handpiece;

CAUTION: The handpiece must not be grabbed by its terminal part and/or cord, but only by its central body.
The handpiece must not be rotated, but must be grasped firmly, and you must only rotate the wrench.

Rotate the wrench clockwise until the friction snaps (the external body of the wrench rotates compared to the handpiece, emitting mechanical “CLICK” sounds).
The insert is now perfectly tightened;
COMBI touch

On the touch surface, select the type of function and irrigation necessary and the light, if desired;
Lift the handpiece and press the foot pedal in order to start the treatment;

At the end of the treatment, position the scaler handpiece on its support.

05.5 IMPORTANT INFORMATION ON THE INSERTS

⚠️ WARNING:
- When the titanium nitride coating is visibly worn, the insert must be replaced. Use of a worn insert reduces its efficiency.
- Diamond-coated inserts: the diamond inserts must be replaced when the titanium nitride coating is visibly worn and, at any rate, after a maximum of 10 treatments.
- Do not activate the handpiece while the insert is in contact with the treated area, so that the electronic circuit can recognize the best point of resonance of the insert and allow its optimal performance.
- Check the condition of wear of the insert and that it is intact before and during every use. In the event that a drop in performance becomes apparent, replace it.
- Use authentic Mectron inserts only. Use of non-authentic inserts, in addition to voiding the warranty, damages the threading of the COMBI touch handpiece, with the risk of no longer being able to screw the original inserts correctly during subsequent use. Moreover, the device settings are tested and guaranteed to operate correctly only when authentic Mectron inserts are used.
- Do not change the shape of the insert in any way by either bending or filing it. This could cause the insert to break.
- Do not use an insert that has suffered any type of deformation.
- Do not attempt to sharpen an insert.
- Always check that the threaded parts of the insert and of the handpiece are entirely clean – see Chapter 08 - CLEANING AND STERILIZATION.
- If excessive pressure is applied on the insert, it can cause the insert to break and possibly harm the patient.
After having connected all of the accessories as illustrated in Paragraph 04.3, proceed as follows:

1. Lift the polisher handpiece. The POLISHING function is activated.
   - **CAUTION:** Make sure that the scaler handpiece is in its resting position; otherwise the device remains inactive.

2. Select the type of polisher tip on the basis of the operation to be performed;
   - **CAUTION:** The subgingival perio tip can only be used with the PERIO polisher tip.

3. Take the polisher handpiece, run the ferrule and maintain it in this position, insert the polisher tip fully to the home position and then release the handpiece ferrule;
   - Select the desired “prophy” or “perio” function.
   - **“Prophy” function:** use Mectron Prophylaxis Powder;
   - **“Perio” function:** use specific glycine-based powder for subgingival use.
   - **WARNING:** Before proceeding with successive operations, make sure that the polisher tip is inserted correctly, fully to the home position on the polisher handpiece (the handpiece ferrule and the polisher tip must be in contact) and that the ferrule has returned to its initial position.
At the end of the treatment, put the polisher handpiece back in its seat.

**CAUTION:** If the PERIO polisher tip has been selected, the subgingival perio tip must be inserted onto the front.

**CAUTION:** Handle the front subgingival tip with care.

**CAUTION:** Use only Glycine-based powder with the PERIO polisher tip.

Insert the front subgingival tip onto the PERIO polisher tip, pushing it fully home.

**WARNING:** Make sure that the subgingival perio tip is correctly inserted fully home on the polisher tip; the two pieces must be in contact.

**CAUTION:** Use authentic Mectron accessories only.

Press the pedal to start treatment. The flow of water can be regulated by the right hand knob until the desired amount is reached.

At the end of the treatment, put the polisher handpiece back in its seat.
05.7 OPERATING INSTRUCTIONS - „refill” FUNCTION

The “refill” function allows removal of pressure from the powder containers, enabling opening or removal, and preventing powder from escaping. This function must be used whenever a container is to be reloaded or cleaned.

N.B.: The powder containers are only under pressure when, after being selected, the pedal is pressed.

ATTENTION: During the “refill” cycle, air and powder escape from the cleaner handpiece.

OPERATION:
To run the “refill” cycle, proceed as follows:

1. Press the “refill” button.

2. Wait for completion of the cycle, during which the LED of the “refill” button will flash together with that of the pressurised powder container emitting a beep.

N.B.: If both of the powder containers are pressurised the “refill” cycle will depressurise both.

N.B.: Duration of the “refill” cycle varies according to the presence of only one or both of the depressurised powder containers. With only one powder container pressurised the cycle lasts 7 seconds while with both powder containers pressurised it lasts 12 seconds.

3. At the end of the cycle the LED of the “refill” button will remain on and steady, and it will then be possible to open or remove the containers.
At this point simply close or re-insert the containers to continue using the device.

**N.B.**: If the powder containers are not opened or removed, simply press the “refill” button to return to the last program used.
The “flush” function allows the irrigation circuit to be filled and rinsed.

⚠️ CAUTION: FLUSH function. The FLUSH function must be used after every treatment, before starting the cleaning and sterilization procedures.

⚠️ CAUTION: Scaler side: If the tubing is not cleaned, crystallization of salts may seriously damage the device.

ULTRASOUND - Scaler part

1. Fill the liquid irrigation solution container on the basis of the cycle to be performed:
   - If the jar irrigation circuit must be filled, use the pre-selected liquid;
   - If the jar irrigation circuit rinse cycle is being performed, use water, preferably demineralised.
   - Connect the irrigation solution container to the device;

2. Lift the scaler handpiece.

   ⚠️ CAUTION: Make sure that the polisher handpiece is in the rest position otherwise the device remains inactive.

3. Position the scaler handpiece, with or without insert, above a container to contain the liquid that will outflow during the cleaning cycle;
To enter the flushing mode, select FLUSH menu on the touch surface; all the other selection options present on the display are disabled.

The type of irrigation previously selected remains active and the corresponding LED flashes (fading), the other selections present are deactivated.

**PLEASE NOTE:** You can exit the flushing mode at any time by pressing FLUSH menu, the touch surface is enabled again, and displays the last setting used;

It is possible to change the type of irrigation with which to perform the “flush” cycle, by pressing the key with image of the cap and the irrigation solution container;

To make the FLUSH function start while the FLUSH indicator is flashing, press the foot pedal once and release. The LEDs of the function and type of irrigation selected flash. The performance of the cycle is indicated with brief sequence acoustic signals;

**PLEASE NOTE:** the FLUSH function can be interrupted at any time by pressing the FLUSH indicator again or, alternatively, by pressing on foot pedal. The touch surface is enabled again, and displays the last setting used;

The cycle lasts 23 seconds. Once it has ended, the touch surface is enabled again, and displays the last setting used.
If the “flush” cycle is to be performed on the water circuit, repeat the steps from point 4 selecting irrigation with water. Upon conclusion of the function selection time or on completion of the “flush” cycle, the device returns to being active and repositions itself at the last setting used; **NOTE:** If the water circuit “flush” cycle is performed, remember to open the tap.

After the cleaning cycle of the irrigation circuit, proceed with disassembling the different parts (see Chapter 07 - DISASSEMBLY OF PARTS FOR CLEANING AND STERILIZATION) and to their cleaning and sterilization (see Chapter 08 - CLEANING AND STERILIZATION).

**CAUTION:** If the handpiece is placed back onto its support, with the “flush” function selected (flashing LED), but not running, the function is exited;

**CAUTION:** During execution of the “flush” cycle; i.e., when the function has been selected and activated by pressing the foot pedal, if the scaler handpiece is put back on the support, the cycle is not interrupted.
Lift the polisher handpiece.

**CAUTION:** Make sure that the scaler handpiece is in its resting position; otherwise the device remains inactive.

Position the polisher handpiece, with or without the polisher tip, on a receptacle that can contain the liquid and powder that will escape during the “flush” cycle;

To enter the “flush” function by selecting “flush” on the touch surface: the previously selected powder container remains active and the corresponding LED flashes (fading), the other selections present are deactivated.

**PLEASE NOTE:** The “flush” mode can be deactivated at any time by pressing the “flush” button again. The touch surface goes back to being active, repositioning itself at the last setting used;

It is possible to change the powder container on which the “flush” cycle is to be performed, if it is in place, by selecting the corresponding key on the touch surface;
Press the foot pedal once and release it to start the cycle. The LEDs of the function and powder container selected will flash. The performance of the cycle is indicated with a brief sequence of acoustic signals;

**PLEASE NOTE:** The execution of the “flush” cycle cannot be interrupted; before performing the “flush” cycle, check that the right-hand tap is open;

The cycle lasts 23 seconds. Once it has ended, the touch surface is enabled again, and displays the last setting used.

After the cleaning cycle of the irrigation circuit, disassemble the different parts (see Chapter 07 - DISASSEMBLY OF PARTS FOR CLEANING AND STERILIZATION) and proceed to their cleaning and sterilization (see Chapter 08 - CLEANING AND STERILIZATION).

**CAUTION:** If the handpiece is positioned on its support, with the “flush” function selected (flashing LED), but not running, the function is exited.

**CAUTION:** During execution of the “flush” cycle; i.e., when the function has been selected and activated by pressing the foot pedal, if the handpiece is put back on the support, the cycle is not interrupted.
Before proceeding to the cleaning procedures described in Chapter 08 - CLEANING AND STERILIZATION, disconnect all the accessories and components of the COMBI touch.

⚠️ **WARNING:** Switch the device off.
Always turn the device off by its switch, and disconnect the power supply cable from the power outlet and from the device body, before performing the cleaning and sterilization procedures.

1. Disconnect the foot pedal from the device:
   - Grab the connector of the foot pedal, press the release flap, and pull the connector back;

   ⚠️ **CAUTION:** Do not attempt to unscrew or twist the connector during the disconnection: the connector could become damaged.

   ⚠️ **CAUTION:** When disconnecting the foot pedal, always and only hold the connector of the cord. Never actually pull on the cord itself.

2. If an insert is connected to the handpiece, unscrew the insert from the handpiece by using the torque wrench;

3. Disconnect the handpiece from its cord;

4. 

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1. **CAUTION:** Do not attempt to unscrew or turn the connector when disconnecting the scaler handpiece. The connector could become damaged.

5. Unscrew the front cone of the handpiece;

   **PLEASE NOTE:** on the cone with LED light the metal ring cannot be separated from the cone in plastic;

6. Disconnect the irrigation solution container from the device body by pulling it outwards;

7. Take the polisher handpiece, slide the ferrule and maintain it in this position, extract the polisher tip and then release the handpiece ferrule;

   **CAUTION:** The polisher handpiece and its lead cannot be separated.

7b. Where the PERIO cleaner terminal has been used, remove the perio subgingival terminal using the K9 wrench supplied and then proceed to dismantling (Chapter 10);

   **PLEASE NOTE:** Introduce the K9 wrench exactly into the position indicated in the figure.
Extract the powder container from the device, remove the cap and empty it. Proceed with polishing. (See CLEANING POWDER CONTAINERS AND CAP 09.4) Repeat the operation on the second powder container of the device if both have been used.

When the cleaning operation has been completed, re-position the containers in the device.

**ATTENTION**: Insert the powder containers in such a way that the groove of the bottom of the device is aligned with the convexity of the powder container.
This table is purely indicative. For the complete cleaning and sterilization procedures of the individual parts, refer to the paragraphs indicated in the table.

⚠️ **CAUTION:** Methods not included in the table below must not be used.

### Device body, Pedal, Polisher handpiece, scaler handpiece end part

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### Irrigation solution container and cap

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### Accessories (Scaler handpiece scaler front tip, Inserts, Polisher tips, K9 wrench, Dynamometric wrench)

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⚠️ **WARNING:** Sterile disposable. The sterile disposable subgingival perio tips must be used in just one surgical treatment and dedicated to just one patient. The disposable subgingival perio tips must not be re-used. Separate and dispose of each disposable subgingival perio tip in compliance with the current regulations regarding hospital waste.

Particular information: Sterilization parameters, in steam autoclave, used in Great Britain: - temperature: 134° C, time: 3 minutes.
08.1 ➔ PREPARATION

PREPARATION
- Run the “flush” function (see chapter 02);
- Check that all of the following accessories have been removed/disconnected from the device body (see Chapter 07):
  • Electric power supply cable;
  • Pedal;
  • Scaler handpiece;
  • Inserts;
  • Polisher tip;
  • Water and air pipe.

⚠️ CAUTION: The cleaning and sterilizing operations described in the following paragraphs are to be performed upon initial use and prior to all successive uses.

⚠️ WARNING: Always turn the device off by its the switch and disconnect it from the electrical network before performing the cleaning and disinfection procedures.

⚠️ CAUTION: The polisher handpiece and the cable cannot be separated.

⚠️ CAUTION: Always disconnect the insert from the handpiece before cleaning and sterilizing it.

⚠️ CAUTION: Do not immerse the handpiece in disinfectant solutions or other liquids, because it could become damaged.

⚠️ CAUTION: Do not immerse the handpiece in an ultrasonic tank.

ATTENTION: Where the powder is excessively wet, remove/disconnect the cleaner terminal from the handpiece, remove powder residue from the channel of the cleaner handpiece using the Ø 0,8 mm cleaning needle supplied and then perform the “flush” function without the cleaner terminal.

08.2 ➔ POLISHING PARTS THAT CANNOT BE STERILIZED

The following procedure must be performed on all device parts that cannot be sterilized, except for the irrigation solution container and its cap. The parts in question are:
- Device body;
- Pedal and relative connection cable to the device;
- Polisher handpiece and relative lead;
- End part of the scaler handpiece and relative lead.

MATERIALS NECESSARY
- Clean, soft cloths with low fiber-release
- Detergent solution (pH 6-9).

CLEANING METHOD

Clean the surface of the parts using a clean, dry cloth with low fibre release, dampened with a detergent solution (pH 6-9);
08 → CLEANING AND STERILIZATION

⚠️ WARNING: Do not sterilize the scaler handpiece: it could stop working and cause harm to persons and/or damage to items.

⚠️ WARNING: Always turn the device off by its switch and disconnect it from the electrical network before performing the cleaning and disinfection procedures.

⚠️ WARNING: The device and the scaler handpiece are not protected against penetration of liquids. Do not spray liquids directly onto the touch surface of the device and the scaler handpiece (these cannot be sterilized).

⚠️ CAUTION: Do not clean the foot pedal under running tap water.

⚠️ CAUTION: Do not immerge the foot pedal in liquids and/or solutions of various nature.

⚠️ CAUTION: Do not immerge the handpiece in disinfectant solutions or other liquids, because it could become damaged.

⚠️ CAUTION: Do not immerge the handpiece in an ultrasonic tank.

08.3 → CLEANING THE IRRIGATION SOLUTION CONTAINER AND CAP

PREPARATION
- Disconnect the irrigation solution container from the device body (see Chapter 07);
- Un螺丝 the cap from the irrigation solution container.

MATERIALS NECESSARY
- Water
- Detergent solution (pH 6-9).
- Clean and soft cloth with low fiber-release
- Sterile water

⚠️ CAUTION: If you intend to disinfect the irrigation solution container and its cap, we recommend that you use water-based disinfectant solutions with a neutral pH (pH7). Alcohol-based disinfectant solutions and hydrogen peroxide are contra-indicated, because they can fade the color and/or damage the plastic materials. This also holds true for chemical products such as acetone and alcohol. Always rinse with sterile water to preserve the disinfection.
CLEANING METHOD - Irrigation solution container and cap

1. Carefully rinse under running water the internal and the external surfaces of the irrigation solution container and of the cap;

2. Clean the external surfaces of the irrigation solution container and of the cap with a clean, soft cloth with low fiber-release, dampened with a detergent solution (pH 6-9);

3. Thoroughly rinse the inside and outside of the irrigation solution container under running water to eliminate all residues of the detergent solution;

4. Remove any detergent remaining with a soft cloth with low fiber-release dampened with sterile water in order to maintain the disinfection;

5. Once you’ve finished the cleaning procedure, check the irrigation solution container and the cap under an adequate source of light, paying attention to the areas that could conceal dirt residues (cavities, grooves) and, if need be, repeat the cleaning cycle.
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08.4 CLEANING ACCESSORIES THAT CAN BE STERILIZED

PREPARATION
The following parts of the device can be sterilized:
- Scaler handpiece;
- Scaler front tip;
- Inserts;
- Inserts torque wrench;
- Polisher tips;
- K9 wrench.

Before verifying the cleaning (paragraph 08.5), drying and lubrication (paragraph 08.6) and then sterilization (paragraph 08.7), depending on requirements, one of the three possible cleaning methods must be selected, which are explained in-depth in the following sub-paragraphs.

08.4.1 MANUAL CLEANING

MATERIALS NECESSARY
- Enzymatic detergent at pH 6-9;
- Ø 0,4 mm polishing needle;
- Water;
- Container for immersion in the enzymatic liquid;
- Ultrasonic tank;
- Clean, soft cloths with low fibre release;
- Brush with soft nylon bristles;
- Syringe;
- Demineralised water.

CAUTION: The instructions provided below have been validated by the manufacturer of the medical device as ABLE to prepare a medical device for re-use. The person in charge of the process is responsible for ensuring that the processes repeated are effectively performed using the equipment, materials and staff in the reprocessing structure in order to obtain the desired result. This generally requires the validation and systematic monitoring of the process. Similarly, all deviations from the instructions provided by the process manager must be adequately assessed to judge their efficiency and potential undesired consequences.

CAUTION: If you intend to disinfect, we recommend that you use water-based disinfectant solutions with a neutral pH (pH7). Alcohol-based disinfectant solutions and hydrogen peroxide are contraindicated, because they can fade the color and/or damage the plastic materials. This also holds true for chemical products such as acetone and alcohol. Always rinse with sterile water to preserve the disinfection.

CAUTION: Do not use hydrogen peroxide. If you intend to disinfect the accessories, do not use hydrogen peroxide, but only disinfectants with neutral pH (pH7); always rinse with sterile water to preserve the disinfection.

Prepare an enzymatic detergent solution with pH 6-9, as per the instructions of the manufacturer;

CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.
Clean the surface of the scaler handpiece and of its connector with a clean, soft cloth with low fiber-release, dampened with a detergent solution (pH 6-9).

Delicately clean the surface of the scaler handpiece using the enzymatic detergent solution with the aid of a brush with soft nylon bristles, placing special care to the following areas:
- threading of the handpiece
- titanium stem
- front terminal in its external and internal parts

Accurately rinse with tap water to eliminate any detergent residues and perform the last rinse with distilled water;

Process validated by independent bodies with enzymatic detergent.
INSERTS

5. Place the insert horizontally in a clean container and add enzymatic detergent solution until the insert is covered completely;

6. Let the insert soak for 10 minutes at 40°C ±2°C. This procedure reduces the amount of blood, protein and mucous present on the insert;

7. During immersion in the enzymatic solution, delicately brush the surface of the insert using the brush with soft nylon bristles to eliminate all traces of visible dirt. Thoroughly clean the difficult areas such as sharp edges;

8. Delicately brush the surface of the insert under running water using the brush with soft nylon bristles;

9. Using a syringe, inject the enzymatic detergent solution 3 times inside the cavity of the insert to effectively remove the residues from the internal surface;
Delicately brush the surface of the insert again using the brush with soft nylon bristles;

Rinse the internal canal of the insert with distilled water injected under pressure (3.8 bar) for at least 10 seconds to eliminate all residues;

Place the insert in the ultrasound tank submerged by the enzymatic detergent solution at 40°C ±2°C, for at least 10 minutes;

Remove the insert from the ultrasonic tank and rinse with distilled water;

Rinse the internal canal of the insert with distilled water injected under pressure (3.8 bar) for at least 10 seconds to eliminate all residues;

Process validated by independent bodies with enzymatic detergent.
15. Soak the wrench in the enzymatic detergent solution for 10 minutes at 40°C ±2°C;

16. During immersion in the enzymatic solution, delicately brush the surface of the wrench using the brush with soft nylon bristles to eliminate all traces of visible dirt both in the internal and external part;

17. Delicately brush the surface of the wrench with a brush with soft nylon bristles under running water;

18. Rinse the wrench with demineralised water until all contaminants have been visually removed;
POLISHER TIPS

Free the channel of the polisher tip from residues of powder using the Ø 0,4 mm cleaning needle supplied.
Blow compressed air into the central hole in the tip, from both ends;

⚠️ CAUTION: Clean the nozzle channel exclusively using the Ø 0,4 mm cleaning needle supplied with the device.
⚠️ CAUTION: If the subgingival perio tip is present on the polisher tip, remove it and dispose of it.
PLACE THE POLISHER TIP HORIZONTALLY IN A CLEAN CONTAINER AND ADD ENZYMATIC DETERGENT SOLUTION UNTIL THE POLISHER TIP IS COVERED COMPLETELY;

LET THE POLISHER TIP SOAK FOR 10 MINUTES AT 40°C ±2°C. THIS PROCEDURE REDUCES THE AMOUNT OF BLOOD, PROTEIN AND MUCOUS PRESENT ON THE POLISHER TIP;

DURING IMMERSION IN THE ENZYMATIC SOLUTION, DELICATELY BRUSH THE SURFACE OF THE POLISHER TIP USING THE BRUSH WITH SOFT NYLON BRISTLES TO ELIMINATE ALL TRACES OF VISIBLE DIRT. THOROUGHLY CLEAN THE DIFFICULT AREAS SUCH AS EDGES AND, IN PARTICULAR, THE GAPS;

DELICATELY BRUSH THE SURFACE OF THE POLISHER TIP UNDER RUNNING WATER USING THE BRUSH WITH SOFT NYLON BRISTLES;

USING A SYRINGE, INJECT THE ENZYMATIC DETERGENT SOLUTION THREE TIMES INSIDE THE CAVITY OF THE POLISHER TIP TO EFFECTIVELY REMOVE THE RESIDUES FROM THE INTERNAL SURFACE;
Rinse the cavity of the polisher tip using demineralised water injected under pressure (3.8 bar) for at least 10 seconds, to eliminate all residues of detergent;

Place the polisher tip in an ultrasonic tank in an enzymatic detergent solution at 40°C ±2°C, for at least 10 minutes;

Remove the polisher tip from the ultrasonic tank and rinse with demineralised water;

Delicately brush the surface of the polisher tip again using the brush with soft nylon bristles;

Rinse the internal channel of the polisher tip using demineralised water injected under pressure (3.8 bar) for at least 10 seconds, to eliminate all residues;
Place the K9 wrench in a clean container and add enzymatic detergent solution until the K9 wrench is covered completely;

Let the wrench soak for 10 minutes at 40°C ±2°C. This procedure reduces the amount of blood, protein and mucous present on the K9 wrench;

During immersion in the enzymatic solution, delicately brush the surface of the K9 wrench using the brush with soft nylon bristles to eliminate all traces of visible dirt. Thoroughly clean the difficult areas such as edges and, in particular, the gaps;

Delicately brush the surface of the K9 wrench under running water using the brush with soft nylon bristles;
Place the K9 wrench in an ultrasonic tank in an enzymatic detergent solution at 40°C ±2°C, for at least 10 minutes;

Remove the K9 wrench from the ultrasonic tank and rinse with demineralised water;

Delicately brush the surface of the K9 wrench again using the brush with soft nylon bristles;
08.4.2 COMBINED MANUAL/AUTOMATIC CLEANING

MATERIALS NECESSARY

- Enzymatic detergent (Mectron ENZYMEC, 0.8% v/v);
- Ø 0.4 mm polishing needle;
- Water;
- Container for immersion in the enzymatic liquid;
- Brush with soft nylon bristles;
- Disposable syringe 20 ml;
- Demineralised water;
- Alkaline detergent: neodisher® FA (0.2 % v/v);
- Neutralising liquid: neodisher® FA (0.1 % v/v);
- Metal basket;
- Thermal disinfecter.

CAUTION: If you intend to disinfect the accessories, it is recommended to use water-based disinfectants with neutral pH (pH7). Alcohol-based disinfectant solutions and hydrogen peroxide are contraindicated, because they can fade the color and/or damage the plastic materials. This is also valid for chemical products such as acetone and alcohol. Always rinse with sterile water to maintain disinfection.

CAUTION: Do not use hydrogen peroxide. If you intend to disinfect the accessories, do not use hydrogen peroxide, but only disinfectants with neutral pH (pH7); always rinse with sterile water to preserve the disinfection.

08.4.2.1 MANUAL PRE-WASH

1. Prepare an enzymatic detergent* solution with pH 6-9, as per the instructions of the manufacturer;

   CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.

SCALER HANDPIECE

2. Clean the surface of the scaler handpiece and of its connector with a clean, soft cloth with low fiber-release, dampened with a detergent solution (pH 6-9);
Delicately clean the surface of the handpiece using the enzymatic detergent solution with the aid of a brush with soft nylon bristles, placing special care to the following areas:
- threading of the handpiece
- titanium stem
- front terminal in its external and internal parts

Completely rinse with tap water to eliminate any detergent residues and perform the last rinse with distilled water;

Process validated by independent bodies with enzymatic detergent Enzymec (Mectron).

Place the insert horizontally in a clean container and add enzymatic detergent solution until the insert is covered completely;
Let the insert soak for 10 minutes at 40°C ±2°C. This procedure reduces the amount of blood, protein and mucous present on the insert;

Using a 20 ml disposable syringe, inject 20 ml of enzymatic detergent solution 3 times inside the cavity of the insert;

Delicately brush the surface of the insert under running water (drinking water, temperature 20°C+/- 2°C), in particular the parts that are difficult to access (cavities, structured surfaces, etc.) using a brush with soft nylon bristles;

The insert must be brushed until no residues can be seen (at least 30 seconds);

Using a 20 ml disposable syringe, inject 20 ml of cold demineralised water 3 times inside the cavity of the insert;

Process validated by independent bodies with enzymatic detergent Enzymec (Mectron).
Soak the wrench in the enzymatic detergent solution for 10 minutes at 40°C ± 2°C;

Using a 20 ml disposable syringe, flush the surface of the wrench three times with 20 ml of enzymatic detergent solution;

Delicately brush the surface of the wrench under running water (drinking water, temperature 20°C +/- 2°C), in particular the parts that are difficult to access (cavities, structured surfaces, etc.) using a brush with soft nylon bristles; The wrench must be brushed until no residues can be seen (at least 30 seconds);

Using a 20 ml disposable syringe, flush the surface of the wrench 3 times with 20 ml of enzymatic detergent solution;

Process validated by independent bodies with enzymatic detergent Enzymec (Mectron).
Free the channel of the polisher tip from residues of powder using the relevant Ø 0,4 mm cleaning needle supplied. Blow compressed air into the central hole in the tip, from both ends;

**CAUTION:** Clean the nozzle channel exclusively using the Ø 0,4 mm cleaning needle supplied with the device.

**CAUTION:** If the subgingival perio tip is present on the polisher tip, remove it and dispose of it.

Place the polisher tip horizontally in a clean container and add enzymatic detergent solution until the polisher tip is covered completely;

Let the polisher tip soak for 10 minutes at 40°C ±2°C. This procedure reduces the amount of blood, protein and mucous present on the polisher tip;

Using a 20 ml disposable syringe, inject 20 ml of enzymatic detergent solution 3 times inside the cavity of the polisher tip;
Delicately brush the surface of the polisher tip under running water (drinking water, temperature 20°C +/- 2°C), in particular the parts that are difficult to access (cavities, structured surfaces, etc.) using a brush with soft nylon bristles; The polisher tip must be brushed until no residues can be seen (at least 30 seconds);

Using a 20 ml disposable syringe, inject 20 ml of cold demineralised water 3 times inside the cavity of the polisher tip;
**K9 WRENCH**

20. Place the K9 wrench in a clean container and add enzymatic detergent solution until the K9 wrench is covered completely;

21. Let the K9 wrench soak for 10 minutes at 40°C ±2°C. This procedure reduces the amount of blood, protein and mucous present on the K9 wrench;

22. Delicately brush the surface of the K9 wrench under running water (drinking water, temperature 20°C +/- 2°C), in particular the parts that are difficult to access (joint) using a brush with soft nylon bristles; The K9 wrench must be brushed until no residues can be seen (at least 30 seconds);
Place the accessories in a metal basket and place the basket in the thermal disinfector;

Sequence and parameters applicable to the cycle:
- 1 min, rinse with cold water;
- 5 min, wash with alkaline detergent at 55°C ±2°C;
- 1 min, neutralisation with suitable solution (1/3 cold water, 2/3 hot water);
- 1 min, rinse with water (1/3 cold water, 2/3 hot water);
- 5 min, thermal disinfection at 93°C with demineralised water.

Thermal disinfection has not been tested experimentally. In compliance with ISO 15883-1, Table B.1 [4] thermal disinfection at a temperature of 90°C for 5 min determines a value A0 3000.

Procedure validated with Miele PG8535 instrument washer/disinfector.
Miele DES-VAR-TD program.
Alkaline detergent: neodisher® FA (0.2 % v/v);
Neutralising liquid: neodisher® Z (0.1 % v/v);

**CAUTION:** Due to its shape, the scaler handpiece can rotate. When not in use, the scaler handpiece must always be placed on its support.
08.4.3  AUTOMATIC CLEANING

MATERIALS NECESSARY

- Alkaline detergent: neodisher® FA (0.2 % v/v);
- Neutralising liquid: neodisher® FA (0.1 % v/v);
- Water;
- Metal basket;
- Adaptors;
- Thermal disinfector.

**NOTE:** Make sure that the accessories are appropriately blocked in the basket and cannot move during washing. Any contact could damage them. Position the instruments in a way that the water can flow through all the surfaces, even internal.

**WARNING:** Avoid overloading the thermal disinfector, as this could compromise cleaning effectiveness.

**WARNING:** Upon completion of the cleaning cycle in the thermal disinfector, the scaler handpiece remains at the heated washing temperature. Use appropriate precautions when extracting the scaler handpiece from the thermal disinfector to prevent injury to the operator.

**CAUTION:** Due to its shape, the scaler handpiece can rotate. When not in use, the scaler handpiece must always be placed on its support.

1. Position the accessories in a metal basket. Connect the relevant adapter (supplied as an option) to the scaler handpiece connector and then to the water jet cleaning connections of the thermal disinfector. Repeat the same operation for the inserts and polisher tips, connecting them to the relevant adapters supplied as an optional.

2. Sequence and parameters applicable to the cycle:
   - 1 min, rinse with cold water;
   - 5 min, wash with alkaline detergent at 55°C ±2°C;
   - 1 min, neutralisation with suitable solution (1/3 cold water, 2/3 hot water);
   - 1 min, rinse with water (1/3 cold water, 2/3 hot water);
   - 5 min, thermal disinfection at 93°C with demineralised water.

Thermal disinfection has not been tested experimentally. In compliance with ISO 15883-1, Table B.1 [4] thermal disinfection at a temperature of 90°C for 5 min determines a value of A0 3000.
08.5 → CLEANING VERIFICATION

MATERIALS NECESSARY

- Light source;
- Magnifying glass 2.5X.

Once the cleaning operations have been completed, visually inspect the scaler handpiece and scaler front tip under an adequate source of light, if necessary using a magnifying glass 2.5X, paying attention to the details that could conceal dirt residue (threading, cavities, grooves) and, if necessary, repeat the cleaning cycle if dirt is still visible; Finally, check the integrity of those parts and those elements that could have deteriorated during use:

Repeat the checks on the other accessories (inserts, insert torque wrenches, polisher tips, K9 wrench), repeating the cleaning cycle if necessary.
08 → CLEANING AND STERILIZATION
08.6 **DRYING AND LUBRICATION**

**MATERIALS NECESSARY**

- Compressed air;
- Soft cloth with low fibre release;
- Medical grade lubricant.

Dry all parts of the scaler handpiece and the scaler front tip well, in particular the electric contacts, by blowing compressed air;

1️⃣ **CAUTION:** The scaler handpiece electric contacts must be dry before the end of the sterilization cycle, before connection of the device lead. Always make sure that the connector electric contacts are entirely dry; dry them by blowing compressed air if necessary.

2️⃣ **CAUTION:** Before starting the sterilization cycle, make sure that the insert is thoroughly dry both internally and externally. To do this, blow compressed air both externally and through the internal passage hole. This will prevent the appearance of stains, streaks on the surface or oxidation inside the insert.
CAUTION: Before starting the sterilization cycle, make sure that the polisher tip is thoroughly dry both internally and externally. To do this, blow compressed air both externally and through the internal passage holes. This will prevent the appearance of stains, streaks on the surface or oxidation inside the polisher tip.

Dry the inserts torque wrench using a soft cloth with low fibre release.

Lubricate the inserts torque wrench with medical-grade lubricants at the point indicated;

CAUTION: Do not use oil or silicone-based lubricants.

Dry the K9 wrench using a soft cloth with low fiber release.
08.7 → STERILIZATION

PREPARATION

Seal the scaler handpiece (without inserts) and the scaler front tip individually, separately in disposable sterilization bags.

Seal the inserts individually inside a disposable bag for sterilization. Seal the polisher tips individually inside a disposable bag for sterilization.

Seal the wrench individually inside a disposable bag for sterilization.

Seal the K9 wrench individually inside a disposable bag for sterilization.
STERILIZATION METHOD

The scaler handpiece and the other accessories that can be sterilized are manufactured with materials that resist a maximum temperature of 135°C for a maximum time of 20 minutes. Once the scaler handpiece and the other accessories that are able to be sterilized have been put into bags individually, perform the sterilization process in the steam autoclave.

The sterilization process validated by Mectron S.p.A., in a steam autoclave, guarantees SAL 10^-6 by setting the parameters indicated below:

**Type of cycle:** 3 times Pre-vacuum (min. pressure 60 mBar).

**Minimum sterilization temperature:** 132°C (interval 0°C÷ +3°C).

**Minimum sterilization time:** 4 minutes.

**Minimum drying time:** 20 minutes.


⚠️ **CAUTION:** Do not sterilize the handpiece with the insert screwed onto it.

⚠️ **WARNING:** Infection control - Parts that can be sterilized - Diligently remove all residues of organic dirt before the sterilization.

⚠️ **CAUTION:** Perform the sterilization using a water steam autoclave only. Do not use any other sterilization procedure (dry heat, irradiation, ethylene oxide, gas, low temperature plasma, etc.).

⚠️ **CAUTION:** Do not exceed the allowed load of the steam sterilizer.

⚠️ **WARNING:** On completion of the sterilization cycle in autoclave, the scaler handpiece remains at the sterilization temperature for a long time. Use appropriate precautions when extracting the scaler handpiece from the autoclave to prevent injury to the operator.

⚠️ **CAUTION:** Wait for the scaler handpiece to cool down completely before use.
If the device is not used for a prolonged time, observe the following recommendations:
1. Empty the powder containers;
2. Perform a complete cleaning cycle of the irrigation circuit using the “flush” function (see chapter 06 - “flush” function) both on the ULTRASOUND side and the POLISHING side;
3. Empty the irrigation solution container irrigation circuits, removing the irrigation solution container and performing the “flush” cycle of the ULTRASOUND side;
4. Eliminate any condensation from the air filter (see paragraph 09.3);
5. Disconnect the device from the mains electricity and the water and air circuits;
6. Clean and dry the water filter (see paragraph 09.2);
7. Before using the device again, clean and sterilize the handpiece and the accessories, following the instructions given in chapter 08 - CLEANING AND STERILIZATION;
8. Check that the inserts are not worn out, deformed, or broken, placing special attention to the integrity of their tip.

WARNING: Periodically check that the electrical power cable is intact; if it is damaged, replace it with an authentic Mectron spare part.

09.1 REPLACEMENT OF THE PERISTALTIC PUMP

There is a plastic protection on the left side of the device, which covers the peristaltic pump housing. Remove this protection by pressing on the sides and pulling towards yourself;

⚠️ CAUTION: Before performing any kind of service on the peristaltic pump, make sure that the device is disconnected from the power outlet and that the liquid container is not connected.

Disconnect the two silicon tubes of the peristaltic pump from their respective couplings, which are positioned beneath the pump;
Extract the peristaltic pump from its base, pulling it towards yourself. Pay close attention, as pieces may detach;

Connect the new peristaltic pump to its seat until a “click” sound is heard and then connect the two pump tubings to their respective couplings positioned beneath the pump;

**WARNING:** Only use authentic Mectron parts.

Re-position the plastic cover on the peristaltic pump.
09.2  CLEANING AND/OR REPLACING THE WATER FILTER

Check and clean the water filter monthly, performing the following operations:

Disconnect the water supply pipe from the male coupling. Unscrew the knurled bush of the male coupling;

⚠️ **CAUTION:** Before cleaning and/or replacing the water filter, make sure that the device is disconnected from the main electricity and that the liquid container is not connected.

Extract the filter and wash it under running water to eliminate the impurities that obstruct it.

Re-introduce the filter into its seat and screw the knurled bush back into its housing tightly until it is fully in position.

**NOTE:** Replace the filter with a new one if it is damaged or washing is not effective.
09.3 → ELIMINATING CONDENSATION

The device has an air filter, which intercepts any impurities and the condensate present in the pneumatic circuit. To prevent the condensation from entering into circulation in the device, check and empty the air filter weekly by performing the following operations:

1. Position an absorbent cloth underneath the device to collect the condensate;

   CAUTION: This maintenance operation must be performed with the appliance on in order for the air circuit to be pressurised.

2. With the device on and in an exact horizontal position, press the air filter vent valve positioned on the bottom of the device, just until air escapes.

   NOTE: However, it is recommended to use dry compressors and introduce a dehumidifier into the practice's pneumatic circuit.
09.4 ➔ CLEANING POWDER CONTAINERS AND CAPS

Check cleanliness of the powder container and, in particular, the cap as powder residues in the presence of moisture could solidify and make opening and closing operations difficult.

⚠️ CAUTION: Always switch the device off using the I/O switch and disconnect it from the mains electricity before cleaning the powder containers and the caps.

⚠️ WARNING: Before blowing compressed air into the powder containers, make sure that they have been emptied.

Blow compressed air inside the container and on the threading of both the powder containers and the caps.

When the cleaning operation has been completed, re-position the containers on the device.

⚠️ CAUTION: Insert the powder containers in a way that the grooves on the bottom of the device are in line with the convexity of the powder containers.

10 ➔ DISPOSAL MODES AND PRECAUTIONS

⚠️ WARNING: Hospital wastes.

Treat the following items as hospital waste:
- Inserts: when they are worn out or broken;
- Torque wrench for inserts: when worn out or broken;
- Cleaner terminals, when worn or broken;
- Perio subgingival terminal, at the end of each treatment.

The COMBI touch must be disposed of and treated as a waste for separate collection. Disregarding the previous points may entail a fine, pursuant to Directive 2012/19/UE. It is up to the purchaser to hand over the device for its disposal to the retailer who supplies them with new equipment; the instructions for proper disposal are available from Mectron.

The use and disposal of materials, and materials that entail a biological risk, must be disposed of in accordance to the local regulations in force concerning hospital wastes.
### TECHNICAL DATA

<table>
<thead>
<tr>
<th>Device compliant to Dir. 93/42/CEE:</th>
<th>Class IIa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification as per EN 60601-1:</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Applied part type B (handpiece, insert)</td>
</tr>
<tr>
<td></td>
<td>IP 20 (device)</td>
</tr>
<tr>
<td></td>
<td>IP 22 (foot pedal)</td>
</tr>
<tr>
<td>Essential performance:</td>
<td>According to the standard IEC 80601-2-60 the device has no essential performance.</td>
</tr>
<tr>
<td>Apparecchio per funzionamento intermittente:</td>
<td>55sec. ON - 30sec. OFF with irrigation (ULTRASOUND function and POLISHING function)</td>
</tr>
<tr>
<td></td>
<td>30 sec. ON - 120sec. OFF without irrigation (mode: “endo” and “perio/scaler” power from 1 to 5, “restorative” power from 1 to 4).</td>
</tr>
<tr>
<td>Power supply voltage:</td>
<td>100-240 V ～ 50/60 Hz</td>
</tr>
<tr>
<td>Max. power absorbed:</td>
<td>90 VA</td>
</tr>
<tr>
<td>Fuses:</td>
<td>Type 5 x 20 mm T 2AL, 250V</td>
</tr>
<tr>
<td>Water supply:</td>
<td>Working pressure from 1 to 6 bar. Cleaning function of the polishing part and scaler water circuit - See Chapter 06. Connection via the pipe supplied with quick coupling through a built-in and removable filter.</td>
</tr>
<tr>
<td>Air supply:</td>
<td>Inlet pressure between 4 and 8 bar. Air circuit cleaning function - See 09.3 Connection via pipe supplied with quick coupling through a filter and built-in pressure reducer.</td>
</tr>
<tr>
<td>Operating conditions:</td>
<td>from +10°C to +35°C</td>
</tr>
<tr>
<td></td>
<td>Relative humidity from 30% to 75%</td>
</tr>
<tr>
<td></td>
<td>Pressure of air P: 800hPa/1060hPa</td>
</tr>
<tr>
<td>Transport and storage conditions:</td>
<td>from -10°C to +70°C</td>
</tr>
<tr>
<td></td>
<td>Relative humidity from 10% to 90%</td>
</tr>
<tr>
<td></td>
<td>Pressure of air P: 500hPa/1060hPa</td>
</tr>
<tr>
<td>Weights and sizes:</td>
<td>4.8 Kg</td>
</tr>
<tr>
<td></td>
<td>L - W - H 410 x 260 x 145 mm</td>
</tr>
</tbody>
</table>
### Parte ULTRASOUND

<table>
<thead>
<tr>
<th>Operating frequency:</th>
<th>Automatic scan</th>
</tr>
</thead>
<tbody>
<tr>
<td>From 24 KHz to 36 KHz</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tipi Potenze (mode):</th>
<th>“endo”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“perio/scaler”</td>
</tr>
<tr>
<td></td>
<td>“restorative”</td>
</tr>
<tr>
<td></td>
<td>“soft mode”</td>
</tr>
</tbody>
</table>

| Power Levels:                             | from 1 to 5                                        |

| Peristaltic pump capacity:                | Adjustable on the touch screen                     |
|                                          | 7 flow levels                                      |
|                                          | from 0 (0 ml/min) to 6 (circa 30 ml/min)           |
|                                          | (see Paragraph 05.2 - IRRIGATION)                  |

| LED system of the handpiece:              | Light function on AUTO: LED system of the handpiece switches on as soon as the device starts to operate and switches off 3 seconds after the foot pedal is released |
|                                          | Light function on ON: The LED of the handpiece is always on; after 100 seconds of foot pedal disuse, it switches off by itself and the light function moves into position AUTO |
|                                          | Light Function on OFF: The LED of the handpiece is always off |

| Protections of the APC circuit:            | No handpiece detected                              |
|                                          | Cord interruption                                  |
|                                          | Insert not tightened correctly or broken           |

### POLISHING part

| Polisher Function:                         | Can be selected via touch screen:                  |
|                                          | “Prophy” function - “Perio” function               |

| Irrigation:                                | Continuous regulation via knob.                    |
|                                          | Water heated via heating element.                  |
11.1 ELECTROMAGNETIC COMPATIBILITY EN 60601-1-2

⚠️ WARNING: Interference with other equipment. Though compliant with the standard IEC 60601-1-2, the COMBI touch may nonetheless interfere with other devices nearby. The COMBI touch must not be used near or stacked on other devices. However, if this is necessary, you must check and monitor the correct operation of the device in that configuration.

⚠️ WARNING: Portable and mobile radio communication devices may affect the correct functioning of the device.

⚠️ WARNING: Interference from other equipment. An electrical scalpel or other electro-surgical units near the COMBI touch device may interfere with its correct operation.

⚠️ WARNING: The device requires specific EMC precautions and must be installed and activated in accordance with the EMC information given in this paragraph.

Guidance and manufacturer’s declaration - Electromagnetic emissions

The COMBI touch is intended for use in the electromagnetic environment specified below. The customer or user of the COMBI touch should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The COMBI touch only uses RF energy for internal function. Therefore, its FR emissions are very low and are not likely to cause any interference with nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td>The COMBI touch is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations /</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>flicker emissions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Guidance and manufacturer’s declaration - Electromagnetic immunity

The COMBI touch is intended for use in the electromagnetic environment specified below. The customer or user of the COMBI touch should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level IEC 60601</th>
<th>Compliance level</th>
<th>Electromagnetic environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact ±8 kV air</td>
<td>The device continues to work regularly and in safety</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>The device continues to work regularly and in safety</td>
<td>Main power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>The device continues to work regularly and in safety</td>
<td>Main power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5 % ( U_T ) (&gt;95 % dip in ( U_T )) for 0,5 cycles 40 % ( U_T ) (60 % dip in ( U_T )) for 5 cycles 70 % ( U_T ) (30 % dip in ( U_T )) for 25 cycles &lt;5 % ( U_T ) (&gt;95 % dip in ( U_T )) for 5 s</td>
<td>The device can vary from the required levels of immunity with a duration of &lt;5% / &gt;95% / 5 s as long as the device remains in safety, no malfunctions have been detected and can be restored to pre-test status with the intervention of the operator</td>
<td>Main power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>The device continues to work regularly and in safety</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.</td>
</tr>
</tbody>
</table>

N.B.: \( U_T \) is the AC mains voltage prior to application of the test level.
## Guidance and manufacturer’s declaration - Electromagnetic immunity

The COMBI touch is intended for use in the electromagnetic environment specified below. The customer or user of the COMBI touch should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level IEC 60601</th>
<th>Compliance level</th>
<th>Electromagnetic environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Veff from 150 kHz to 80 MHz</td>
<td>The device continues to work regularly and in safety</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m from 80 MHz to 2,5 GHz</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
</tbody>
</table>

N.B.:
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 any reasonable 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 COMBI touch is used exceeds the applicable RF compliance level given above, the COMBI touch should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the COMBI touch.
   b. Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
The COMBI touch is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the COMBI touch can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the COMBI touch as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter ‘W’</th>
<th>Separation distance according to the frequency of transmitter ‘m’</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>from 150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>( d = 1,2 \sqrt{P} )</td>
</tr>
<tr>
<td>0,01</td>
<td>0,12</td>
</tr>
<tr>
<td>0,1</td>
<td>0,38</td>
</tr>
<tr>
<td>1</td>
<td>1,2</td>
</tr>
<tr>
<td>10</td>
<td>3,8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \( d \) in metres (m) can be calculated 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.

**N.B.:**
(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.
The COMBI touch is equipped with a diagnostic circuit that allows for the detection of operating abnormalities and to view their type on the touch surface via their relative symbol. By using the following chart, the user is guided toward the identification and possible solution of the malfunction detected.

<table>
<thead>
<tr>
<th>Symbols on keyboard</th>
<th>Possible cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece electric contacts/lead wet.</td>
<td>Thoroughly dry the contacts with compressed air (See paragraph 08.6).</td>
<td></td>
</tr>
<tr>
<td>COMBI touch handpiece not connected to device.</td>
<td>Connect the handpiece (See paragraph 04.3).</td>
<td></td>
</tr>
<tr>
<td>Scaler handpiece failure.</td>
<td>Replace the handpiece.</td>
<td></td>
</tr>
<tr>
<td>Sync circuit malfunction.</td>
<td>Contact an Authorized Mectron Service Center.</td>
<td></td>
</tr>
<tr>
<td>Insert not tightened correctly on handpiece.</td>
<td>Unscrew the insert and correctly screw it on again with the Mectron torque wrench (See paragraph 05.4).</td>
<td></td>
</tr>
<tr>
<td>Insert broken, worn-out or deformed.</td>
<td>Replace the insert.</td>
<td></td>
</tr>
<tr>
<td>Handpiece/cord contacts wet.</td>
<td>Thoroughly dry the contacts with compressed air (See paragraph 08.6).</td>
<td></td>
</tr>
<tr>
<td>Turn-on procedure incorrect: the device has been turned on with the foot pedal depressed.</td>
<td>Check that the foot pedal is not depressed. If the problem persists, disconnect the pedal and, if need be, contact an Authorized Mectron Service Center.</td>
<td></td>
</tr>
<tr>
<td>Peristaltic pump malfunction.</td>
<td>Check that there are no impediments to pump rotation. Check that the peristaltic pump and the pipes are installed correctly. (See paragraph 09.1).</td>
<td></td>
</tr>
<tr>
<td>The device has been turned off and on again without waiting 5 seconds.</td>
<td>Turn device off and wait 5 seconds before turning it on again.</td>
<td></td>
</tr>
<tr>
<td>Abnormalities on electrical network or excessive electrostatic discharges or internal abnormalities.</td>
<td>Turn device off and wait 5 seconds before turning it on again If the signal persists, contact an Authorized Mectron Service Center.</td>
<td></td>
</tr>
<tr>
<td>A powder container has been opened without performing the “refill” cycle.</td>
<td>Before opening one of the powder containers, the “refill” cycle must be performed (See paragraph 05.7).</td>
<td></td>
</tr>
<tr>
<td>One of the powder containers has been removed from its seat without performing the “refill” cycle.</td>
<td>Before removing one of the powder containers, the “refill” cycle must be performed (See paragraph 05.7).</td>
<td></td>
</tr>
<tr>
<td>The selected powder container is not correctly inserted in place.</td>
<td>Correctly insert the powder containers to the furthest point possible.</td>
<td></td>
</tr>
</tbody>
</table>
## 12.2 QUICK SOLUTION TO PROBLEMS

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device does not turn on after having brought the switch into position “I”</td>
<td>The electrical power cable terminal is poorly inserted in the rear plug of the device.</td>
<td>Check that the power supply cable is firmly connected.</td>
</tr>
<tr>
<td></td>
<td>The electrical power cable is defective.</td>
<td>Check that the power supply socket works properly. Replace the electrical power cable.</td>
</tr>
<tr>
<td></td>
<td>The fuses are out of order.</td>
<td>Replace the fuses (See paragraph 12.3).</td>
</tr>
<tr>
<td>The device is on but not working. There are no anomalies signalled on the keyboard</td>
<td>The foot pedal plug is incorrectly inserted in the device socket.</td>
<td>Correctly insert the pedal plug in the socket on the back of the device (See paragraph 04.3).</td>
</tr>
<tr>
<td></td>
<td>The foot pedal does not work.</td>
<td>Contact an Authorized Mectron Service Center.</td>
</tr>
<tr>
<td>The device is on but not working. One of the following symbols appears on the screen:</td>
<td>See paragraph 12.1 for the possible cause, according to the symbol that has been displayed.</td>
<td>See paragraph 12.1 for the action to be undertaken, according to the symbol that has been displayed.</td>
</tr>
<tr>
<td>A slight whistling sound coming from the COMBI touch handpiece is heard during operation</td>
<td>The insert is not correctly tightened on the handpiece.</td>
<td>Unscrew and correctly screw the insert on again with the Mectron torque wrench (See paragraph 05.4).</td>
</tr>
<tr>
<td></td>
<td>The irrigation circuit has not been completely filled.</td>
<td>Fill the irrigation circuit via the function “flush” (See paragraph 05.4).</td>
</tr>
<tr>
<td>The pump turns correctly but when it stops, liquid escapes from the handpiece</td>
<td>The peristaltic pump is worn.</td>
<td>Replace the peristaltic pump (See paragraph 09.1).</td>
</tr>
<tr>
<td>By pressing the foot pedal, a prolonged signal is emitted and the ULTRASOUND and POLISHING function LEDs flash</td>
<td>THE foot pedal has been depressed with both handpieces at rest.</td>
<td>Lift the handpiece to be used before depressing the pedal.</td>
</tr>
<tr>
<td>Problem</td>
<td>Possible cause</td>
<td>Solution</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Insufficient performance</td>
<td>The insert is not correctly tightened on the handpiece.</td>
<td>Unscrew and correctly screw the insert on again with the Mectron torque wrench (See paragraph 05.4).</td>
</tr>
<tr>
<td></td>
<td>Insert broken, worn-out or deformed.</td>
<td>Replace the insert with a new one.</td>
</tr>
<tr>
<td></td>
<td>Insufficient or excessive powder level in the container.</td>
<td>Correct level of powder in the container (See paragraph 04).</td>
</tr>
<tr>
<td>Device not connected to the water circuit.</td>
<td>Check the connection to the water circuit (See paragraph 04.3).</td>
<td></td>
</tr>
<tr>
<td>The insert is the “Irrigation free” type and does not envision the passage of liquid.</td>
<td>Use an insert that envisions the passage of liquid.</td>
<td></td>
</tr>
<tr>
<td>The insert is obstructed.</td>
<td>Unscrew the insert from the handpiece and free the insert water passage by blowing compressed through it. If the problem persists, replace the insert with a new one.</td>
<td></td>
</tr>
<tr>
<td>The handpiece is obstructed.</td>
<td>Contact an Authorized Mectron Service Center.</td>
<td></td>
</tr>
<tr>
<td>Irrigation is disabled.</td>
<td>Activate irrigation and regulate the level of irrigation (See paragraph 05.2.1).</td>
<td></td>
</tr>
<tr>
<td>The water tap on the device is closed.</td>
<td>Regulate the flow of water using the knob dedicated to the function used.</td>
<td></td>
</tr>
<tr>
<td>Water filter clogged.</td>
<td>See paragraph 09.2.</td>
<td></td>
</tr>
<tr>
<td>The irrigation solution container is empty.</td>
<td>Fill the irrigation solution container.</td>
<td></td>
</tr>
<tr>
<td>The irrigation solution container is not installed correctly.</td>
<td>Connect the irrigation solution container to the device body correctly.</td>
<td></td>
</tr>
<tr>
<td>The silicon tubings of the pump are incorrectly installed.</td>
<td>Unscrew and correctly screw the insert on again with the Mectron torque wrench (See paragraph 09.1).</td>
<td></td>
</tr>
<tr>
<td>The peristaltic pump is over-used.</td>
<td>Replace the insert with a new one (See paragraph 09.1).</td>
<td></td>
</tr>
</tbody>
</table>

No liquid outflows from the insert during operation
<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>During operation powder does not escape from the polisher tip</strong></td>
<td>Device not connected to the air circuit.</td>
<td>Check the connection to the air circuit (See paragraph 04.3).</td>
</tr>
<tr>
<td></td>
<td>Polisher tip blocked due an excessive amount of moisture in the powder or insufficient cleaning/maintenance.</td>
<td>See Chapter 09.</td>
</tr>
<tr>
<td></td>
<td>Cleaner handpiece channel clogged due to an excessive amount of moisture in the powder or insufficient cleaning.</td>
<td>See paragraph 08.1.</td>
</tr>
<tr>
<td></td>
<td>The level of powder in the container exceeds the maximum allowed.</td>
<td>Remove the powder from the container and clean it using a dry cloth. Correct level of powder in the container. (See Chapter 04).</td>
</tr>
<tr>
<td></td>
<td>Unsuitable powder.</td>
<td>Use the correct powder for correct device operation.</td>
</tr>
<tr>
<td><strong>Loss of powder through the powder container cap</strong></td>
<td>Cap not correctly tightened.</td>
<td>Screw the cap correctly.</td>
</tr>
<tr>
<td></td>
<td>Powder residues in the threading.</td>
<td>Clean the threading of the powder container (See paragraph 09.4).</td>
</tr>
<tr>
<td><strong>Insufficient cleanliness</strong></td>
<td>Insufficient pressure in the air supply circuit.</td>
<td>Check air supply circuit pressure (4-8 bar max).</td>
</tr>
<tr>
<td></td>
<td>Insufficient or excessive powder level in the container.</td>
<td>Correct level of powder in the container.</td>
</tr>
<tr>
<td></td>
<td>Unsuitable powder.</td>
<td>Check the correct powder for correct device operation.</td>
</tr>
<tr>
<td></td>
<td>Polisher tip blocked due an excessive amount of moisture in the powder or insufficient cleaning/maintenance.</td>
<td>Remove the powder from the container and clean it using a dry cloth.</td>
</tr>
<tr>
<td><strong>One of the powder container caps does not unscrew</strong></td>
<td>The device is on and the powder container is pressurised.</td>
<td>Perform the “refill” cycle before opening one of the powder containers (See paragraph 05.7).</td>
</tr>
<tr>
<td></td>
<td>The “refill” cycle has been performed but the powder containers have remained pressurised because the polisher tip is clogged.</td>
<td>Read the part concerning cleaning the polisher tip (See Chapter 08).</td>
</tr>
<tr>
<td></td>
<td>The “refill” cycle has been performed but the powder containers have remained pressurised because the polisher lead is clogged.</td>
<td>Contact a Mectron-Authorised After-sales Assistance Centre.</td>
</tr>
</tbody>
</table>
12.3 → REPLACEMENT OF THE FUSES

⚠️ **WARNING: Switch the device off.** Always turn the device off with the main switch and disconnect it from the electrical power socket before performing the following procedure.

1. Apply leverage with a flat screwdriver, inserting its tip in the seat of the fuse-holder drawer located under the power supply socket;

2. Pull out the fuse-holder drawer;

⚠️ **WARNING:** Replace the fuses, complying with the characteristics indicated in Chapter 11 - TECHNICAL DATA.

3. Reinsert the drawer in its housing.
12.4 ➔ SENDING THE DEVICE TO AN AUTHORISED MECTRON SERVICE CENTER

In the event that technical assistance is needed on the device, contact one of the Authorized Mectron Service Centers or your Retailer. Do not attempt to repair or modify the device and its accessories.

Clean and sterilize all the parts that need to be sent to an Authorized Mectron Service Center, following the instructions provided in the Chapter 08 - CLEANING AND STERILIZATION. Return all parts in sterilization pouches to provide evidence that the sterilization process has been performed.

The cleaning and sterilization requirements are in line with those in force concerning the safeguarding of health and safety in the workplace, as per Law Decree 626/94 and DLgs 81/08 and its subsequent amendments, both laws of the Italian State.

In the event that customer does not fulfill the requirements, Mectron reserves the right to charge him or her for the cleaning and sterilization expenses, or to reject the goods received in unsuitable conditions, returning them to the customer, at the customer’s expense, for them to be correctly cleaned and sterilized.

The device must be returned properly packaged, accompanied by all the accessories, and by a document bearing the:
- Owner information including complete address and telephone number
- Product name
- Serial number and/or lot number
- Reason for goods returned / description of the malfunction
- Photocopy of packing list or purchase invoice of the device

**CAUTION: Package**
Pack the device in its original packaging to prevent damages during transport.

Once the material has been received by the Authorized Mectron Service Center, qualified technical personnel will provide an evaluation based on the given circumstances. The repair work will be performed only upon the prior acceptance by the customer. For further details, contact the closest Authorized Mectron Service Center or your retailer.

Unauthorized repair works may damage the system and make the warranty void, and will absolve Mectron of any responsibility for direct or indirect harm to persons or damages to anything else.
All Mectron devices are subjected to an accurate end inspection that ascertains their full functionality before they are placed on the market. Mectron provides a warranty on all new COMBI touch purchased from a retailer or a Mectron importer to cover material or manufacturing defects for:
- 2 YEARS (TWO) on the device from the date of purchase;
- 1 YEAR (ONE) on the handpiece from the date of purchase.
The accessories are not included in the warranty.

During the period in which the warranty is valid, Mectron commits itself to repair (or at its own free choice, replace) those product parts that were to proved defective according to its judgment, free of charge. Entire replacement of the Mectron products is excluded.

The warranty of the manufacturer and the certification of the device are not valid in the following cases:
- The device is not used in accordance to its intended use.
- The device is not used in compliance with all of the instructions and precautions described and outlined in this manual.
- The electrical system located at the in which the device is used is not compliant to electrical code compliance standards and to the relative precautions.
- The assembly operations, extensions, adjustments, updates, and repair works are performed by personnel not authorized by Mectron.
- The environmental conditions for the preservation and storage of the device are not compliant to the precautions indicated in the Chapter 11 - TECHNICAL DATA.
- Use of non-authentic Mectron inserts, accessories, and spare parts that can compromise correct device operation and cause harm to the patient.
- Accidental breakage due to transport
- Damages due to incorrect use or negligence, or to connection to a power voltage other than the one required
- Warranty expiration

**PLEASE NOTE** The warranty is valid only if the warranty sheet annexed to the product has been filled out in all its parts, and sent to our offices or possibly to the retailer or Mectron importer within 20 (twenty) days from the date of purchase, which is the date that appears on the packing list/purchase invoice issued by the retailer/importer. To benefit from the warranty service, the customer must return, at its own expense, the device to be repaired to the retailer/Mectron importer from whom the customer purchased the product.

See paragraph 12.4 for the details relative to the procedure to send the device to an Authorized Mectron Service Center.