

mectron

medical technology

USE AND MAINTENANCE MANUAL

EN

combi touch



CE
0051

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1 INTRODUCTION

This manual applies to the following medical devices:


- combi touch (referred to as "device" in the text)
- SCALER HANDPIECE (referred to as "accessories" in the text)
- PERIO AIR-POLISHING HANDPIECE (referred to as "accessories" in the text)
- 90° AIR-POLISHING HANDPIECE (referred to as "accessories" in the text)
- 120° AIR-POLISHING HANDPIECE (referred to as "accessories" in the text)
- Instruments
- Subgingival Perio Tip
- K9 Wrench
- Torque wrench
- Irrigation circuit disinfection kit


Read this manual carefully before installing, operating, performing maintenance or otherwise working on the device and its accessories.

This manual must always be available to the operator.

Important: To avoid damages to persons or property, carefully read all the "Safety Requirements" in the manual.

Depending on the level of severity, the safety requirements are classified with the following indications:

 **WARNING:** always refers to personal injury.

 **CAUTION:** refers to possible damage to property.

The aim of this manual is to make operators aware of the safety regulations, installation procedures, instructions for proper use and maintenance of the device and its components. Do not use this manual for purposes other than those strictly related to the installation, operation and maintenance of the device and its accessories.

The information and illustrations in this manual were updated on the edition date shown on the last page.

MECTRON is committed to continuously updating its products, which may result in modifications to the device and its components/accessories.

If discrepancies are found between the content of this manual and the devices in your possession, you may:

- check for any available updates in the *MANUALS* section of the *MECTRON website*;
- ask clarifications to Your Dealer;
- contact MECTRON After Sales Service.

1.1 Intended Use

⚠ WARNING: Intended use. Only use the device and its accessories for their intended purpose. Failure to observe this regulation can cause serious injury to the patient, the operator, and damage/failure of the device.

» PIEZOELECTRIC ULTRASONIC SCALER

With the appropriate inserts it is possible to perform the following treatments:

- **Scaling:** all procedures for the removal of bacterial plaque deposits and supragingival, subgingival, and interdental stones, and removal of stains;
- **Periodontology:** periodontal root planing and debridement therapy, including cleaning and irrigation of the periodontal pocket;
- **Cleaning treatment of the implant surface;**
- **Endodontics:** all treatments for root canal preparation, irrigation, filling, gutta-percha condensation, endodontic reprocessing and retrograde cavity preparation;
- **Restorative and prosthetics:** cavity preparation and removal of carious tissue, removal of prosthetics and excess restoration materials, amalgam condensation, finishing of prosthetic stump;
- **Extraction techniques.**

» SLIM SCALER HANDPIECE / COMBI TOUCH LED SCALER HANDPIECE

This device is a accessory for a piezoelectric ultrasonic scaler.

With the appropriate inserts it is possible to perform the following treatments:

- **Scaling:** all procedures for the removal of bacterial plaque deposits and supragingival, subgingival, and interdental stones, and removal of stains;
- **Periodontology:** periodontal root planing and debridement therapy, including cleaning and irrigation of the periodontal pocket;
- **Cleaning treatment of the implant surface;**
- **Endodontics:** all treatments for root canal preparation, irrigation, filling, gutta-percha condensation, endodontic reprocessing and retrograde cavity preparation;
- **Restorative and prosthetics:** cavity preparation and removal of carious tissue, removal of prosthetics and excess restoration materials, amalgam condensation, finishing of prosthetic stump;

» POLISHER FOR DENTAL PROPHYLAXIS AND HYGIENE

combi touch features a water jet, air, and prophylaxis powder polisher handpiece for dental use, designed for a complete supra- and subgingival prophylaxis treatment, with a specific intended use depending on the type of powder distributed by Mectron.

Air-polisher for supragingival use:

- Removal of supragingival bacterial plaque;
- Removal of stains on the surface of teeth;
- Preparation of cavity for better adhesion between enamel and filling material;
- Prophylaxis on patients undergoing orthodontic therapy.

Air-polisher for subgingival use:

- Removal of subgingival bacterial plaque;
- Removal of Biofilm in the prevention of Peri-implantitis.

» AIR POLISHING HANDPIECE PERIO/120°/90°

The Air Polishing handpieces are medical devices accessories for combi touch. Their Intended Use is the one reported in the Section "Polisher for Dental Prophylaxis and Hygiene".

1.2 Description of the Device

combi touch combines, in a single device, a multi-purpose piezoelectric scaler and water jet, air, and prophylaxis powder polisher, intended for complete supra- and subgingival dental prophylaxis.

In regards to the various possible ultrasonic treatments, combi touch can be used either connected directly to the main water supply in the dental practice, or with independent irrigation through the special liquid container, which can hold different types of medical solutions.

The device features an automatic tuning circuit that compensates for instrument wear, ensuring consistent optimal efficiency during operation.

The operating principle of the polisher is based on the mechanical action obtained from a jet of various crystal types accelerated by a flow of compressed air. The kinetic energy imparted to the particles is almost entirely dissipated upon impact with the treated surface area, resulting in 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 double 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.

⚠ WARNING: The device and its accessories must be used in a dental practice or clinic, or in professional oral hygiene and preventive care centres. Do not use the device and its accessories in environments where the atmosphere is saturated with flammable gases (anaesthetic mixtures, oxygen, etc.).

⚠ WARNING: Qualified and specialist personnel. The device and its accessories must be used exclusively by specialised personnel with appropriate medical knowledge. No specific training is required for the use of the device. The device and its accessories produce no side effects when used correctly. Improper use is manifested by the transfer of heat to the tissues.

1.2.1 Eligible Patient Group

This medical device is designed to be used with the following patient groups:

- Children;
 - Adolescents;
 - Adults;
 - Seniors.
- This medical device can be used on patients of any weight, height, sex or nationality, where applicable.

1.2.2 Patient Selection Criteria / Contraindications

It is not recommended to use the device in the following cases.

Air-polisher for supra- and subgingival use:

1. Upper respiratory tract infections, chronic bronchitis/asthma;
2. Pregnant and breastfeeding women;
3. Patients undergoing treatment (radiotherapy, chemotherapy, antibiotics);
4. Acute infectious oral lesions.
5. Patients with active implantable medical devices (for example: pacemakers, hearing aids, and/or other electromagnetic prostheses) without prior authorisation from their doctor;
6. Patients with clinical conditions not suitable for treatment of the sites (for example: local anaesthesia).

Piezoelectric ultrasonic scaler:

It is not recommended to use the powders in the following cases:

7. Allergy to the aroma of the powder;
8. Patients on a sodium restricted diet or who suffer from serious respiratory problems, such as chronic bronchitis, asthma, emphysema, etc., unless otherwise specified by their doctor.

All air-polishing devices and piezoelectric ultrasonic scalers are intended for professional use only. The user is therefore the only person able to decide if and how to treat their patients.

NOTE: It is recommended to consult the Instructions for Use of the powders before operation to check for any contraindications or specific indications.

1.2.3 Indications for Use

Use of combi touch equipped with both a scaler and polisher handpiece, is suitable for all indicated patients (see *Chapter 1.2.1 on page 4*) requiring treatment, within the scope of the intended use of the device (see *Chapter 1.1 on page 2*).

1.2.4 Users

The device and its accessories must be used exclusively by specialised and properly trained personnel, specifically the dental surgeon/dentist or dental hygienist, who must be able-bodied, adult, of any weight, age, height, gender, and nationality.

1.2.5 Operating Environment

The device is portable. It is intended for use in outpatient, private or hospital settings; in the absence of flammable mixtures, liquids, powders; far from other devices and/or electro-medical equipment.

1.3 Disclaimer

The manufacturer MECTRON disclaims all liability, express or implied, and cannot be held liable for direct or indirect personal injury and/or property damage, occurring as a result of incorrect procedures related to use of the device and its components.

The manufacturer MECTRON cannot be held liable, expressly or implicitly, for any type of personal injury and/or property damage, inflicted by the user of the product and its components and which occurs in the following cases, by way of example and not of limitation:

- Misuse or use during procedures other than those specified in the destination of use of the product;
- The environmental conditions for preservation and storage of the device are not complying with the requirements indicated in *Chapter 14 on page 103*;
- The device is not used in accordance with all the instructions and requirements outlined in this manual;
- The electrical system of the places where the device is used does not comply with the laws in force and relative requirements;
- Assembly operations, extensions, re-adjustments, upgrades and repairs of the device are carried out by personnel not authorised by MECTRON;
- Misuse, abuse, abnormal use, negligent use, intentional misconduct or use exceeding the limits of the device indicated and allowed and/or normal wear or deterioration, ill-treatment and/or incorrect interventions;
- Any attempt to tamper with or modify the device under any circumstances;
- Use of non original MECTRON instruments resulting in permanent damage to the thread of the handpiece with impaired functioning and risk of injury to the patient;
- Use of non original MECTRON instruments used in accordance with the settings designed and tested on the original MECTRON inserts. Correct use of the settings is only guaranteed with original MECTRON instruments;
- Shortage of stock material (handpiece, instruments, wrenches) to be used in case of a standstill due to faults or problems;
- Incorrect/omitted maintenance compared to what is stated in *Chapter 12 on page 91* of this manual;
- Breach of the requirements and the information contained in *Chapter 5.5 on page 33* of this manual;
- Breach of the requirements and the information contained in *Chapters 6, 7, 8, 9* of this manual;
- Unauthorised repairs in accordance with the indications contained in *Chapter 15.4 on page 121* this manual.

1.4 Safety Requirements

⚠ WARNING: Contraindications.

Do not use combi touch on patients with Pacemakers or other implantable electronic devices. This regulation also stands for the operator.

⚠ WARNING: Contraindications. Do not perform scaling treatments without water spray in order to avoid an overheating of the instrument that can cause damage to the tooth. Treatments without water spray can only be those performed with the "Dry Work" instruments without water passage.

⚠ CAUTION: Contraindications. Ultrasonic scaler. Do not perform treatments on metal or ceramic prosthetics. Ultrasonic vibrations could lead to decementation of the dentures.

⚠ WARNING: Contraindications. Interference from other equipment. An electrosurgical scalpel or other electrosurgical units positioned near the device combi touch may interfere with the correct operation of the device.

⚠ WARNING: Contraindications. Interference with other equipment. Even if compliant with standard IEC/EN 60601-1-2, combi touch and related accessories may interfere with other devices in the vicinity. combi touch must not be used near or stacked with other appliances. However, if deemed necessary, the proper functioning of the device in that configuration must be checked and monitored.

⚠ WARNING: Risk of explosion. The device cannot operate in environments where the atmosphere is saturated with flammable gases (anaesthetic mixtures, oxygen, etc.).

⚠ CAUTION: If the end user, operating in their dental practice or clinic, is required to conduct periodic checks to comply with regulatory requirements, the testing procedures for evaluating the safety of medical equipment and systems must be carried out in accordance with the IEC/EN 62353 standard: "Medical electrical equipment – Periodic inspections and tests to be carried out after repair of medical

electrical equipment". The frequency of periodic inspections in the intended conditions of use described in this "Use and Maintenance" manual is once per year or every 2000 hours of use, whichever condition is satisfied first.

⚠ WARNING: Checking the condition of the device and its accessories before treatment.

Always check that there is no water under the device. Before each treatment, always check the perfect working order of the device and the efficiency of the components. If operation anomalies are observed do not carry out the treatment. If there are errors concerning the device, contact a MECTRON Authorised Service Centre.

⚠ CAUTION: The electrical system of the places where the device is installed and used must comply with the laws in force and the relative electrical safety requirements.

⚠ CAUTION: To avoid the risk of electrical shocks, this device must be strictly connected to an earthed power supply.

⚠ WARNING: Cleaning and sterilising new or repaired instruments. All the components of new or repaired devices are not sterile, except for the Subgingival Perio Tips. When first used and after each treatment, they must be cleaned and sterilised in strict accordance with the instructions in *Chapters 6, 7, 8, 9* of this manual.

⚠ WARNING: Infection control. For maximum patient and operator safety, before using all reusable parts and components/accessories, make sure they are previously cleaned and sterilised according to the instructions in *Chapters 6, 7, 8, 9* of this manual.

⚠ CAUTION: Contraindications. After having autoclaved the handpiece, instruments, torque wrench or any other sterilisable component/accessory, wait for them to completely cool down before reusing them.

⚠ WARNING: Instrument Breakage and Wear. High frequency oscillations and wear can, in rare cases, lead to the breakage of the instrument. Deformed instruments or instruments that have been otherwise damaged are prone to breakage during use. Broken or worn instruments must never be used.

In the event of breakage check that no fragments remain in the treated part and at the same time use suction effectively to remove them.

The patient must be instructed to breathe through the nose during the treatment, or use a dental dam, so as to avoid ingesting fragments of broken instruments.

Check the state of wear of the instrument and its integrity before and during each use. If a drop in performance occurs, see to its replacement.

The state of wear of the most common instruments (S1, S1-S, S2, S5, P2, P4, P10) can be checked using the supplied INSERT-CARD. To use the INSERT-CARD correctly:

- Position the instrument on the INSERT-CARD so that the profile corresponds to the one printed on the card. The printed profile on the card has a red line indicating the limit of wear;
- If the instrument is shorter than the limit of wear, its performance will be significantly inferior compared to that of a new instrument, and should therefore be replaced.

If the layer of titanium nitride (gold-plated surface), where present, is visibly worn, the instrument must be replaced. The use of a worn instrument reduces its efficiency.

Diamond Instruments: diamond instruments must be replaced when the layer of titanium nitride is visibly worn and in any case after a maximum of 10 treatments.

When the nitriding is consumed, the cutting edge loses effectiveness; a possible regrinding harms the instrument, therefore it is prohibited. Verify that the instrument is not worn.

During the operation frequently check that the instrument is intact, especially in the apical part.

During the operation avoid prolonged contact with the retractor or with metal instruments in use. Do not exert excessive pressure on the instruments during use.

⚠ WARNING: Exclusively use original MECTRON instruments, components and replacement parts.

⚠ CAUTION: No modification of this device and its accessories/components is permitted.

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


























⚠ WARNING: Contraindications - Supragingival powder jet polisher. Do not aim the air, supragingival powder, or water jet onto the soft tissues or inside the gingival sulcus. Failure to comply with this prescription can cause a gingival tissue emphysema (emphysema of the mucous and/or subcutaneous). For this type of application, use only subgingival powder.
















⚠ WARNING: Contraindications - Jet polisher. Do not use the device and its accessories near areas subject to recent dental extraction and in traumatised/damaged areas (or areas nearby) due to the risk of emphysema.

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

⚠ WARNING: In case of an adverse event and/or accident attributable to the device and/or related accessory during correct use and in accordance with the intended use, a report must be made to the Competent Authority and manufacturer indicated on the product label.

1.5 Symbols

Symbol	Description	Symbol	Description
	Class IIa device compliant with Regulation (EU) 2017/745. Notified body: IMQ S.p.A.		Nemko brand Compliance with UL - CSA regulations
	Importer		Distributor
	Authorised representative in the United Kingdom		Authorised representative in Switzerland
	Manufacturer		Date of manufacture
	Type B applied part		Medical device
	Unique Device Identifier		Health Industry Bar Code
	Batch number		Serial Number
	Model number		Catalogue number
	Caution		Consult instructions for use or consult electronic instruction for use
	Sterilised with Ethylene Oxide (EO)		Non-sterile
	Sterilisable up to a max. temperature of 135°C		Do not re-sterilise
	Do not reuse		Use by date
	Alternating current	QTY.1	Quantity in package: 1
I	Power switch set to "on"	0	Power switch set to "off"

Symbol	Description	Symbol	Description
	General warning signal ^{a)}		Warning: electricity
	Temperature limit		Foot switch connection
	Humidity limitation		Atmospheric pressure limitation
	Irrigation		Do not use irrigation
	Clock, time switch, timer.		Do not use if the packaging is damaged and consult instruction for use
	Fragile		Keep dry
	Keep out of sunlight		This side up
	Separate collection for waste of electrical and electronic equipment.	<p>For US market only</p> <p>Rx only</p> <p>CAUTION: Federal (US) law restricts the marketing of this device to prescription or licensed practitioner.</p>	

a) The symbol is represented by a yellow warning triangle and a black graphical symbol.

NOTE: For other symbols, refer to *Chapter 15.1* on page 114

2 IDENTIFICATION DATA

A proper description of the model and serial number of the device and its accessories will enable the After-Sales Service to provide quick and effective answers.

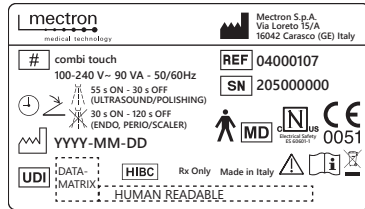
Always provide this information every time that you contact MECTRON After Sales Service.

EN

2.1 Device Nameplate

Each device is equipped with a nameplate indicating the main technical features and traceability data, including the UDI. This nameplate is located under the device. The complete technical specifications are provided in *Chapter 14 on page 103*.

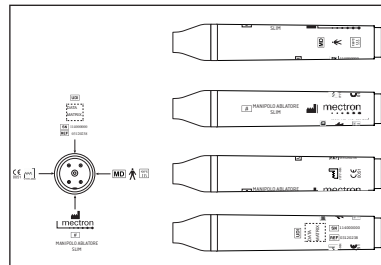
NOTE: The complete list of symbols and their description is provided in *Chapter 1.5 on page 8*.



2.2 Scaler Handpiece Identification Data

The traceability data, including the UDI code, are laser-engraved on the scaler handpiece.

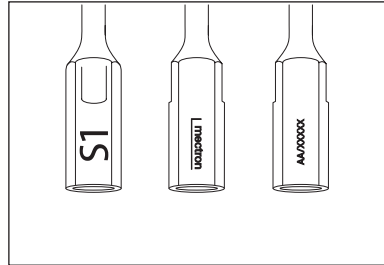
NOTE: The complete list of symbols and their description is provided in *Chapter 1.5 on page 8*.



2.3 Instruments Identification Data

Traceability data are laser-engraved on each instrument.

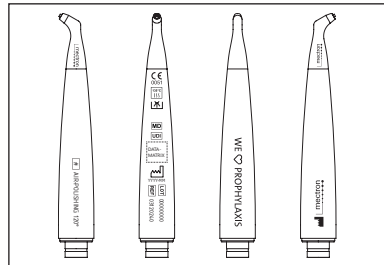
The traceability data, including the UDI code, is indicated on their packaging.



2.4 Air-Polishing Handpiece Identification Data

Traceability data, including the UDI code, are laser-engraved on each air-polishing handpiece.

NOTE: The complete list of symbols and their description is provided in Chapter 1.5 on page 8.



3 DELIVERY

3.1 List of Components

Please refer to the figure below.

combi touch comes with a standard supply and set of components that can be ordered separately, which vary depending on the configuration and client requests (see Tables on page 13 and page 14).

NOTE: Both items included in the standard supply and all components can be ordered separately by the client.

The device's packaging must be handled with care to prevent strong impacts, as it contains sensitive electronic components. Both transport and storage should be conducted with caution.

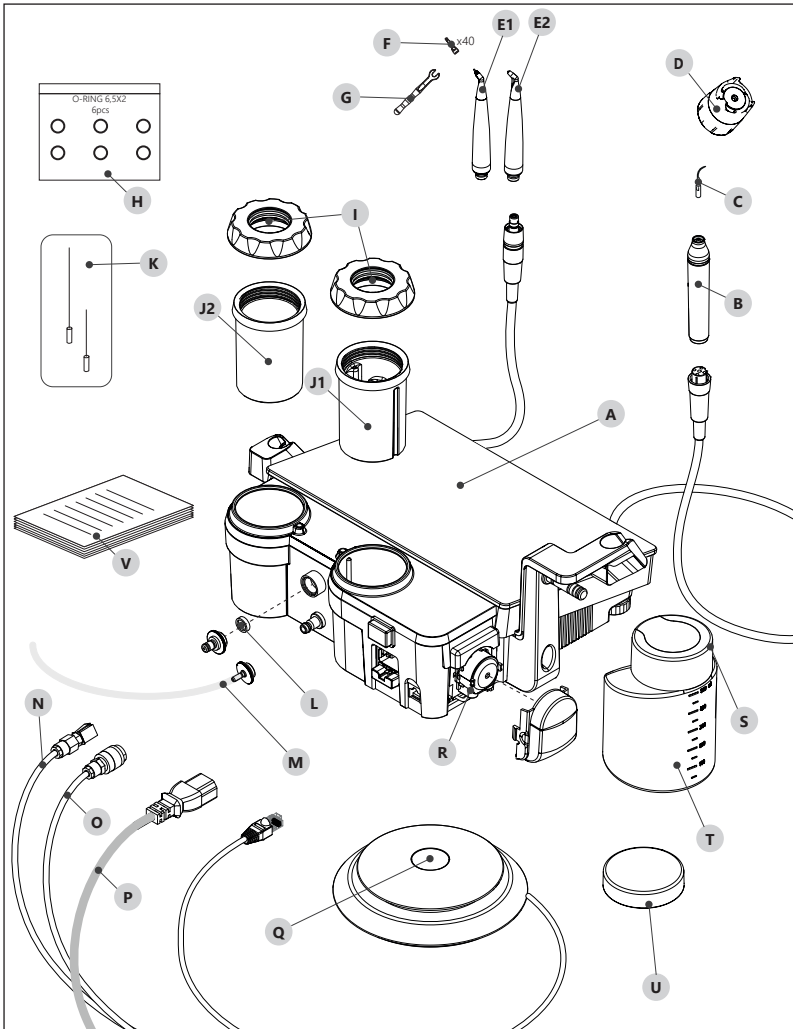
Do not stack various boxes in order to avoid pinching the underlying packaging.

All the material sent by MECTRON was controlled at the time of dispatch.

The device is dispatched with suitable protection and packaging.

Upon receiving the device, check if it was damaged during transport and, if damage/defects are found, submit a claim to the carrier. Keep the packaging for any returns to a MECTRON Authorised Service Centre and to store the device during long periods of non-use.

⚠ WARNING: Before starting the treatment, always make sure to have a stock of material (scaler handpiece, instruments, wrenches, air-polishing handpieces, Subgingival Perio Tips) to use in the event of failures or drawbacks.



Standard supply		
Ref.	Item	Notes
A	Device Body	
B	MANIPOLO ABLATORE SLIM	Slim Scaler Handpiece
C	Instruments	
D	Torque wrench	
E2	MANIPOLO AIR-POLISHING 120°	120° Air-Polishing Handpiece
H	O-ring kit combi touch	
J1	Prophy Polisher Container	
J2	Perio Polisher Container	
K	Cleaning needle kit	
L	Water filter	
M	Irrigation circuit disinfection kit	
N	Water supply tubing with quick coupling	
O	Air supply tubing with quick coupling	
Q	Foot pedal FS-05	
R	Peristaltic Pump	
S	Complete bottle cap	grey
T	Irrigation bottle	
U	Bottle safety cap	grey
V	Use and Maintenance Manual	
X	Power cable	Plug compatible with destination country

Components available for separate order		
Ref.	Item	Notes
E1	MANIPOLO AIR-POLISHING PERIO	Perio Air-Polishing Handpiece
F	Subgingival Perio Tips	40 pc set of Subgingival Perio Tips
G	K9 Wrench	
I	Polisher container cap	
S	Complete bottle cap	blue
U	Bottle safety cap	blue
	Light guide kit	Front cone, light guide and decorative ring for the SLIM SCALER HANDPIECE

4 INSTALLATION

4.1 First Installation

The device and its accessories must be installed in a suitable place allowing its comfortable use.

⚠ WARNING: The place where the device is installed must meet the requirements set out in *Chapter 4.2 on page 15*.

combi touch can be purchased ready for use or may need to be enabled by typing in an activation key.

If your device requires an activation key, the procedures may vary from country to country. Always refer to your dealer for details.

4.2 Safety Requirements During Installation

⚠ WARNING: Contraindications. Interference with other equipment. Even if compliant with standard IEC/EN 60601-1-2, combi touch and related accessories may interfere with other devices in the vicinity. combi touch must not be used near or stacked with other appliances. However, if deemed necessary, the proper functioning of the device in that configuration must be checked and monitored.

⚠ WARNING: Contraindications. Interference from other equipment. An electrosurgical scalpel or other electrosurgical units positioned near the device combi touch and/or its related accessories may interfere with the correct operation of the device.

⚠ CAUTION: The electrical system of the places where the device will be installed and used must comply with the laws in force and the relative electrical safety requirements.

⚠ CAUTION: To avoid the risk of electrical shocks, this device must be strictly connected to an earthed power supply.

⚠ CAUTION: Place the device in such a way that the power plug is easily accessible as it is considered a disconnection device.

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

⚠ WARNING: Install the device in a place protected against impact or accidental splashing of water or liquids.

⚠ WARNING: Do not install the device above or near heat sources. Ensure the installation allows adequate air circulation around the device.


⚠ CAUTION: Do not expose the device and/or its related accessories to direct sunlight or UV light sources.

⚠ CAUTION: The device and its related accessories is portable but must be handled with care when moved. Position the foot pedal on the floor so that it can only be activated intentionally by the operator.

⚠ CAUTION: Before connecting the handpiece to its cord, check that the electrical contacts are perfectly dry, on both parts. If necessary dry them with compressed air.

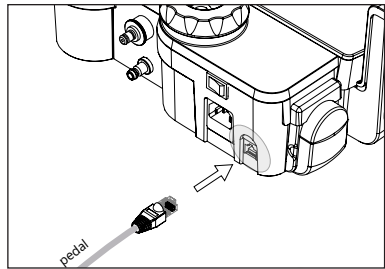
⚠ CAUTION: Every bottle can contain up to max. 500 ml of liquid.

4.3 Connecting the Components

Connect the foot pedal to the back of the device in the socket marked with the symbol  by inserting the foot pedal plug until you hear a 'click'.

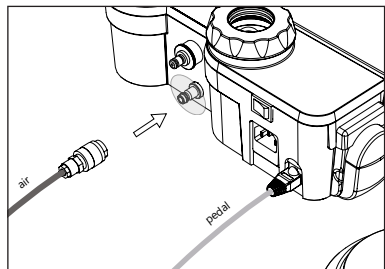
CAUTION: Exercise caution when positioning the foot pedal, ensuring it can only be activated intentionally by the operator.

1



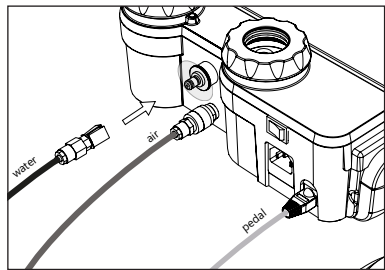
Drain the condensate from the compressed air system. Connect the supply hose to the compressed air circuit in the medical practice using a suitable reduction and shut-off valve (not included in the Mectron supply). Connect the quick coupling to the male coupling on the back of the device;

2



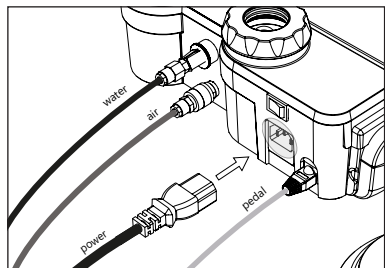
Connect the supply hose to the water circuit in the medical practice using a suitable reduction and shut-off valve (not included in the Mectron supply). Connect the quick coupling to the male coupling on the back of the device;

3



Plug the power cable into its socket at the back of the device. Connect it to the socket in the wall;

4



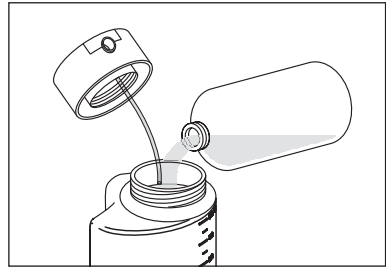
CAUTION: Place the device in such a way that the power plug is easily accessible as it is considered a disconnection device.

EN

Unscrew the bottle cap and fill it with the desired liquid;

⚠ CAUTION: Every bottle can contain up to max. 500 ml of liquids

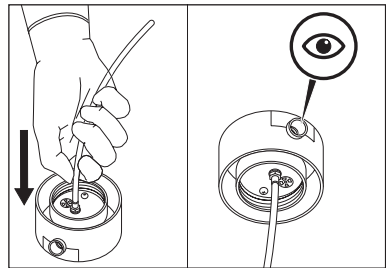
5



Check that the small tube inside the cap is properly installed, then screw the cap onto the bottle;

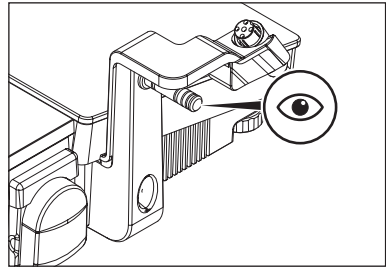
⚠ CAUTION: Check that the female coupling of the bottle cap is clean and free from obstructions.

6



⚠ CAUTION: Check that the male coupling on the device core unit is clean and that its O-rings are not worn.

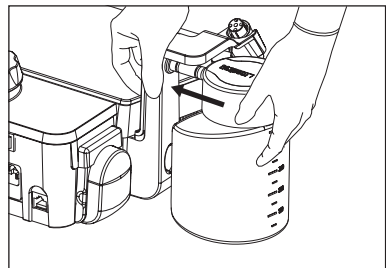
⚠ CAUTION: Use the support only to install the Mectron 500 ml bottle and to stow the handpiece. Do not use the support for other purposes.



Holding the bottle in a vertical position, insert it on the core unit of the device until it reaches the stop;

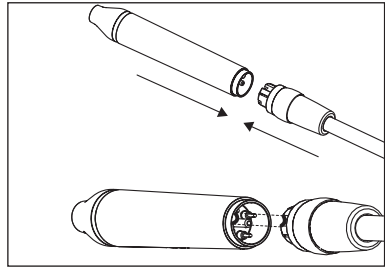
⚠ CAUTION: Do not overturn the bottle, the cap is not watertight. The outflow of physiological solution or aggressive liquids may cause damage to the surfaces.

7



Correctly insert the scaler handpiece on its cord by aligning the notch on the handpiece connector with the groove on the cord connector. Check that the electrical contacts of both are perfectly dry and if necessary dry them by blowing with compressed air;

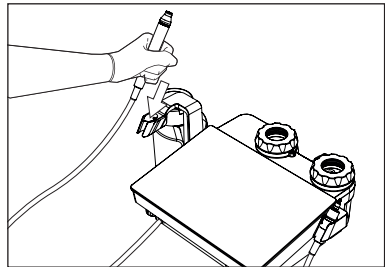
8



Position the handpiece on its dedicated support.

⚠ CAUTION: Use the support only to install the Mectron 500 ml bottle and to stow the handpiece. Do not use the support for other purposes.

9

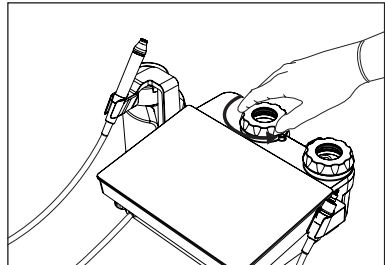


Unscrew the cap of the PROPHY polisher container on the left.

⚠ CAUTION: The PROPHY polisher container is marked "PROPHY" and is positioned on the left.

⚠ CAUTION: Before extracting the polisher container or unscrewing the caps, check that the device is switched off and disconnected from the power mains, or that the "refill" function has been run and the corresponding LED stays lit (see *Chapter 5.6.1 on page 36*).

10



Pour the specific supragingival powder distributed by Mectron into the container, making sure the level stays below the diffuser located inside.

⚠ WARNING: Insert only specific supragingival powder distributed by Mectron in the PROPHY polisher container.

⚠ CAUTION: Correct level of powder in the container.

Minimum level: The level of powder in the container must not be lower than 10 mm to prevent a decline in cleaning performance.

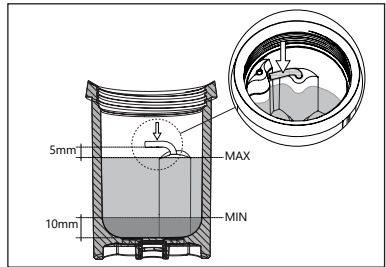
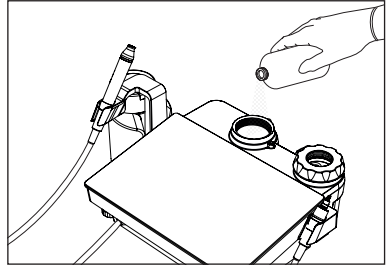
Maximum level: The level of the powder in the container must remain below the diffuser (at least 5 mm).

Close the tap on the container without tightening it excessively.

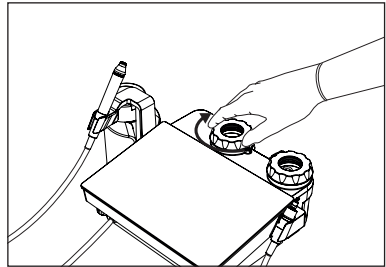
Unscrew the cap of the PERIO polisher container on the right.

⚠ CAUTION: The PERIO polisher container is marked "PERIO" and is positioned on the right.

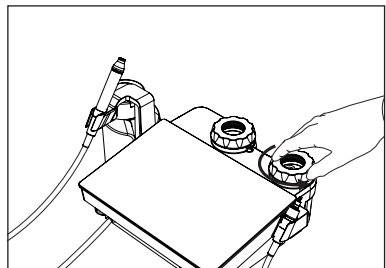
11



12



13



Pour the specific subgingival powder distributed by Mectron into the container, making sure the level stays below the diffuser located inside.

⚠ WARNING: Insert only specific subgingival powder distributed by Mectron in the PERIO polisher container.

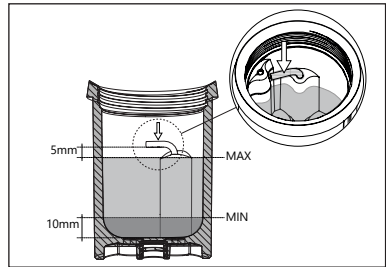
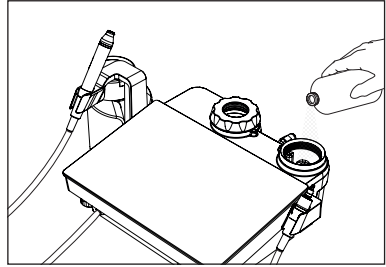
⚠ CAUTION: Correct level of powder in the container.

Minimum level: The level of powder in the container must not be lower than 10 mm to prevent cleaning performance from dropping.

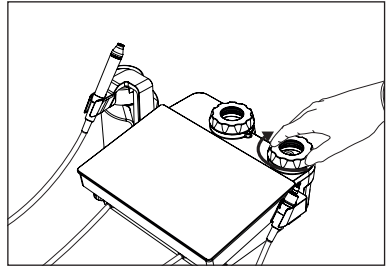
Maximum level: The level of powder in the container must remain below the diffuser (at least 5 mm).

Close the tap on the container without tightening it excessively.

14



15



5 USE

5.1 Power On/Off

Switching on the device

The switch is positioned at the rear of the device, on the left.

Flick the switch into the "I" position, taking care not to press the foot pedal.

All the warning lights on the device will turn on and off again. The touch surface stays off for a few moments until an acoustic signal indicates the end of the diagnostic cycle. At the end of the diagnostic cycle, the system loads the preset configuration and is ready for use.

Preset configuration:

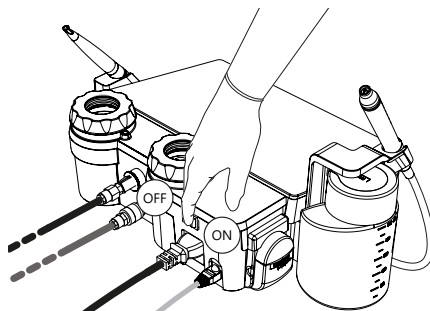
- ULTRASOUND part:
 - mode: "endo";
 - power: "1";
 - light: "off";
 - irrigation: bottle - medium flow.
- AIR-POLISHING starts:
 - "Prophy" function.

NOTE: The settings of the scaler part and polisher part can both be modified only with the handpieces stowed in their housings. If either of the two handpieces are extracted, only the settings relative to the active function can be modified.

Switching off the device

The switch is positioned at the rear of the device, on the left.

Flick the switch into the "O" position, taking care not to press the foot pedal.



CAUTION: Place the device in such a way that the power plug is easily accessible as it is considered a disconnection device.

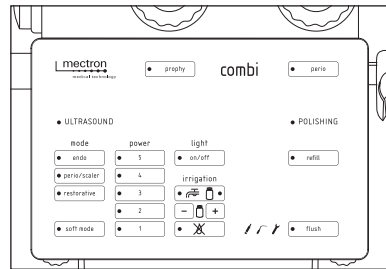
5.2 Description of the Touch Surface

TOUCH SURFACE

The user can configure the system by simply touching the touch surface.

Depending on the configuration, the electronic feedback system will automatically adjust the correct working frequency.

NOTE: A brief acoustic signal is emitted to confirm a key selection. A prolonged acoustic signal indicates that the current configuration does not allow the selection of the pressed key.



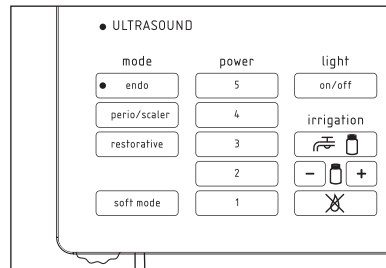
5.2.1 ULTRASOUND - Scaler Part

FUNCTIONS

Depending on the type of operation, it is possible to select one of 3 options from the "mode" list, as follows:

- **"endo"**: dedicated to endodontic treatments such as root canal cleaning and the retrograde approach.
- **"perio/scaler"**: dedicated to all supra- and subgingival dental prophylaxis, root planing and implant surface cleaning procedures.
- **"restorative"**: dedicated to preservative techniques, implants and extractions.

NOTE: when **"restorative"** is selected with power level 5, the PULSE function is activated, which is used to optimise the performance of instruments used in extraction and prosthetic techniques.

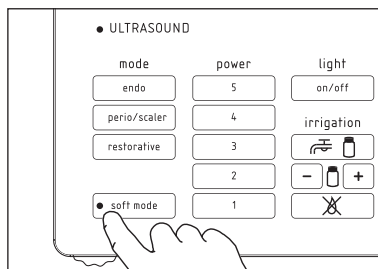


SOFT MODE

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" function with power levels from 1 to 5 and "restorative" function with power levels from 1 to 4.

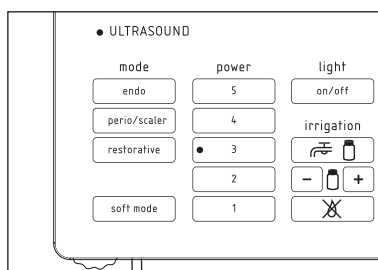
In "endo" mode the function is not available.



EN

POWER

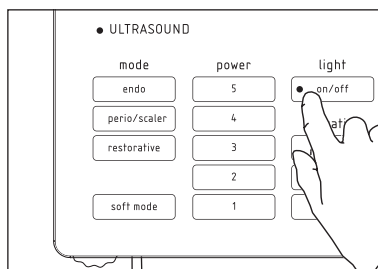
For all "mode" functions, the operating power can be adjusted by selecting the numbers on the "power" scale. There are 5 power levels, from 1 to 5. The operating power can be adjusted incrementally (1: minimum power, 5: maximum power).



LIGHT

Depending on the type of treatment to be performed, the "light" function can be activated:

- When the "on/off" key is activated, the LED light on the scaler handpiece metal cone lights up when the foot pedal is pressed and automatically switches off 3 seconds after the pedal is released;
- When the "on/off" key is deactivated, the LED light on the scaler handpiece metal cone stays off.



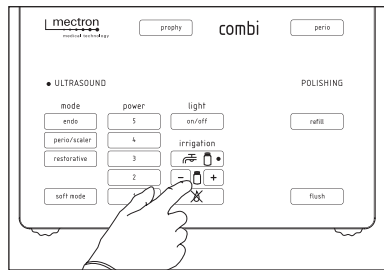
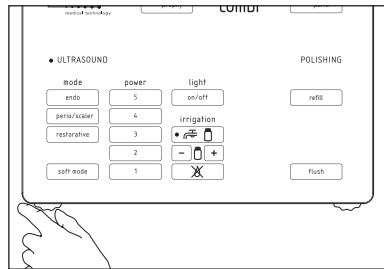
IRRIGATION

For the scaler part, the device allows two types of irrigation (via the "irrigation" keys):

- the mains water circuit or
- the bottle circuit.

The flow rate of the two circuits can be regulated as follows:

- the mains water flow can be continuously regulated using the left knob;
- the bottle circuit flow can be continuously regulated across 7 levels via the touch screen, using the "-" and "+" keys.

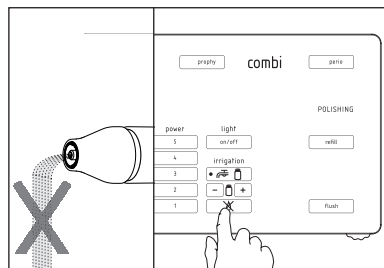


Irrigation can be excluded in "endo" and "perio/scalar" modes with power levels from 1 to 5 and in "restorative" mode with power levels from 1 to 4.

CAUTION: The exclusion of irrigation with non "Dry Work" instruments can cause overheating with consequent breakage of the handpiece.

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

NOTE: the irrigation flow rate can be adjusted using the "-" and "+" keys also during the treatment (holding the foot pedal pressed).



"Flush" FUNCTION

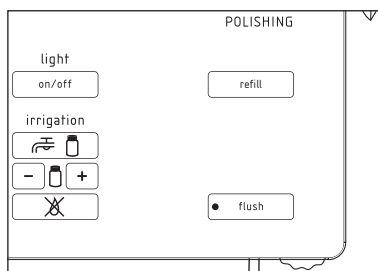
The device has a "flush" key to fill and flush the irrigation circuit.

Filling the irrigation circuit: Before starting the treatment, the "flush" function can be used to deliver the liquid to the instrument, so as to start the treatment with the necessary irrigation.

Cleaning the water circuit:

The "flush" function is used to perform the irrigation circuit rinse cycle. This function must be used at the end of the intervention and before cleaning and sterilising all parts.

NOTE: If both handpieces are stowed in their housings, the "flush" function cannot be activated.



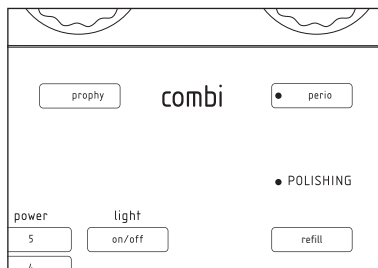
EN

5.2.2 AIR-POLISHING - Polisher Part

FUNCTIONS

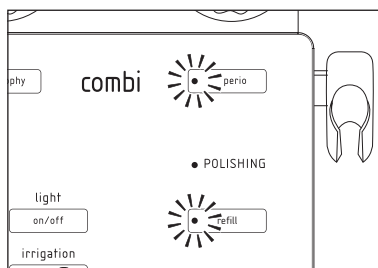
Depending on the type of application, one of two treatments can be selected as follows:

- "prophy": dedicated to the clinical indications of the specific supragingival powder distributed by Mectron;
- "perio": dedicated to the clinical indications of the specific subgingival powder distributed by Mectron.



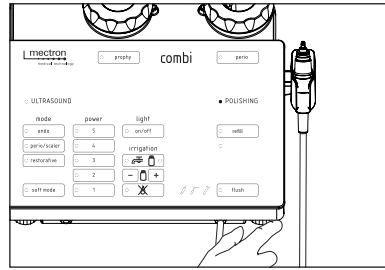
"Refill" FUNCTION

The "refill" function must be used to depressurise the polisher containers, in order that they can be opened or removed from the device.



IRRIGATION

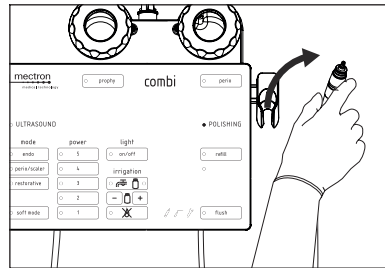
The water circuit flow rate can be regulated continuously through the right hand knob;



“Flush” function

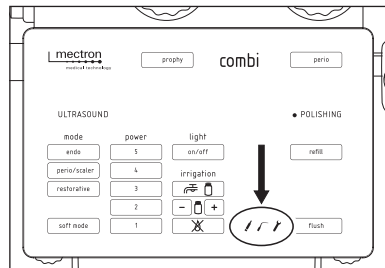
The “flush” function can be used to change the type of powder, cleaning the circuit of the previously used type (see Chapter 5.7 on page 38).

NOTE: If both handpieces are stowed in their housings, the “flush” function cannot be activated.



5.2.3 Symbols

combi touch is provided with a diagnostic circuit that allows the detection of malfunctions and viewing of their type on the touch surface by means of a symbol. To help the user identify the malfunctioning component, there are three symbols described in Chapter 15.1 on page 114.



5.3 Safety Requirements Before and During Use

⚠ WARNING: Use only original Mectron instruments, components and replacement parts.

⚠ WARNING: Before starting work, always ensure you have spare materials (handpiece, instruments, wrenches) available for use in case of a breakdown or other issues.

⚠ WARNING: Checking the device and its accessories before treatment. Always check that there is no water under the device. Before each treatment, always check the perfect working order of the device and the efficiency of the components. If operation anomalies are observed do not carry out the treatment. Contact a Mectron Authorised Service Centre with regard to errors concerning the device and/or its accessories.

⚠ WARNING: Infection control. First use: All reusable parts and components (new or returned from a Mectron Authorised Service Centre) are delivered in NON-STERILE conditions and must be treated before each use, according to the instructions provided in *Chapters 6, 7, 8, 9* of this manual. **Subsequent uses:** After each treatment, clean and sterilise all reusable parts and components according to the instructions in *Chapters 6, 7, 8, 9* of this manual.

⚠ WARNING: Infection control. Do not leave liquids in the bottle for long periods of time. The bottle must be filled after cleaning and sterilising all parts, and before a treatment. If the bottle has been filled without having used the device, it must be emptied at the end of the day, and all parts and components must be cleaned and sterilised.

⚠ WARNING: The patient must not come into contact with the device core unit or with the foot pedal.

⚠ WARNING: During the intervention on the patient, do not perform any maintenance tasks on the system.

5.3.1 ULTRASOUND - Scaler Part

⚠ WARNING: Use of non-original instruments not produced by Mectron:

this entails permanent damage to the thread of the handpiece and compromises correct operation with the risk of causing harm to the patient.

⚠ CAUTION: Contraindications. Do not perform treatments on metal or ceramic prostheses. Ultrasonic vibrations could lead to decementation of the dentures.

⚠ WARNING: Contraindications. Do not use combi touch on patients with Pacemakers or other implantable electronic devices. This regulation also stands for the operator.

⚠ WARNING: Do not perform scaling treatments without water spray in order to avoid an overheating of the instrument that can cause damage to the tooth. Treatments without water spray can only be those performed with the "Dry Work" instruments without water passage.

⚠ CAUTION: In treatments requiring irrigation, use only instruments with a liquid passage.

⚠ WARNING: Treatments that require irrigation. Always check the operation of the irrigation before and during use. Ensure the liquid flows out from the instrument. Do not use the device and/or its accessories if irrigation is not working or the pump is faulty.

⚠ WARNING: To ensure that the handpiece cools down activate it always with irrigation circuit installed and properly filled. Always use the "flush" function to fill the irrigation circuit.

⚠ CAUTION: For correct use of the device and its related accessories, the foot pedal must be pressed and the device started with the instrument not in contact with the part to be treated, so that the electronic circuit is able to recognise the best point of resonance of the instrument without

interference, thus allowing optimum performance.

⚠ WARNING: Before each treatment ensure that the proper instrument suited to the treatment is inserted on the handpiece. Use only the Mectron torque wrench to secure the instrument to the handpiece.

⚠ WARNING: Do not change the instrument while the handpiece is in operation to avoid causing injury to the operator.

⚠ CAUTION: "Flush" function. After use with aggressive and non-aggressive solutions, the tubes and handpiece must be cleaned using the "flush" function (see *Chapter 5.7 on page 38*). Failure to clean the tube may result in salt crystallisation, causing serious damage to the device and its related accessories.

⚠ WARNING: Instrument breakage and wear. High frequency oscillations and wear can, in rare cases, lead to the breakage of the instrument.

Do not bend, change shape or sharpen an instrument in no way.

Folding an instrument or levering on it can cause the instrument to break.

Deformed or otherwise damaged instruments, are susceptible to breakage during use. These instruments should never be used.

Excessive pressure on the instruments during use can lead to breakage. In the event of breakage check that no fragments remain in the treated part and at the same time use suction effectively to remove them. The patient must be instructed to breathe through the nose during the treatment, or use a dental dam, so as to avoid ingesting fragments of broken instruments.

Check the state of wear of the instrument and its integrity before and during each use. If a drop in performance occurs, see to its replacement.

The state of wear of the most common instruments (S1, S1-S, S2, S5, P2, P4, P10) can be checked using the supplied INSERT-CARD. To use the INSERT-CARD correctly:

- Position the instrument on the INSERT-CARD so that the profile corresponds to the one printed on the card. The printed profile on the card has a red line indicating the limit of wear.
- If the instrument is shorter than the limit of wear, its performance will be significantly inferior compared to that of a new instrument, and should therefore be replaced.

If the layer of titanium nitride (gold-plated surface), where present, is visibly worn, the instrument must be replaced. The use of a worn instrument reduces its efficiency.

Diamond Instruments: diamond instruments must be replaced when the layer of titanium nitride is visibly worn and in any case after a maximum of 10 treatments.

When the nitriding is consumed, the cutting edge loses effectiveness; a possible regrinding harms the instrument, therefore it is prohibited. Verify that the instrument is

not worn.

During the operation, frequently check that the instrument is intact, especially in the apical part.

During the operation avoid prolonged contact with the retractor or with metal instruments in use.

⚠ **CAUTION: Contraindications.**

After having autoclaved the handpiece, instruments, torque wrench or any other sterilisable component/accessory, wait for them to completely cool down before reusing them.

⚠ **CAUTION: The electrical contacts inside the handpiece and cord connectors must be dry.** Before connecting the

handpiece to its cord, make sure that the electrical contacts of the connector on both sides are perfectly dry, especially after the sterilisation cycle in an autoclave. If necessary dry the contacts by blowing them with compressed air.

⚠ **CAUTION:** Owing to its conformation, the handpiece can rotate. When not used the handpiece must always be put back on its support stand.

5.3.2 AIR-POLISHING - Polisher Part

⚠ WARNING: Contraindications. Patients on a sodium restricted diet must not receive treatment with sodium bicarbonate powders.

⚠ WARNING: Contraindications. Patients who suffer from serious respiratory problems such as chronic bronchitis, asthma, emphysema, etc., must not receive prophylaxis treatment unless otherwise indicated by their doctor.

⚠ CAUTION: Before using powders, always refer to the Instructions for Use specific to the product in use. Carefully follow the manufacturer's instructions to ensure safe and effective use.

⚠ WARNING: Contraindications. Patients wearing contact lenses or glasses must remove them prior to receiving treatment with the jet polisher.

⚠ WARNING: Contraindications - Jet polisher. Do not aim the air, supragingival powder, or water jet onto the soft tissues or inside the gingival sulcus. Failure to comply with this prescription can cause a gingival tissue emphysema (emphysema of the mucous and/or subcutaneous). For this type of application, use only subgingival powder.

⚠ WARNING: Contraindications. Do not use the device near areas subject to recent dental extraction and in traumatised/damaged areas (or areas nearby) due to the risk of emphysema.

⚠ 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 he perceives an excessive increase in the temperature of the water.

⚠ WARNING: Infection control and cleaning the water and air circuits. For maximum patient and operator safety, after each treatment, follow all the instructions outlined in *Chapters 6, 7, 8, 9* of this Manual.

⚠ WARNING: Do not use the device without water. Check that the device is connected to the water circuit and that the water tap is open.

⚠ CAUTION: Do not attempt to unscrew the cap of the polisher container before having performed the "refill" cycle.

5.4 Operating Instructions - ULTRASOUND - Scaler Part

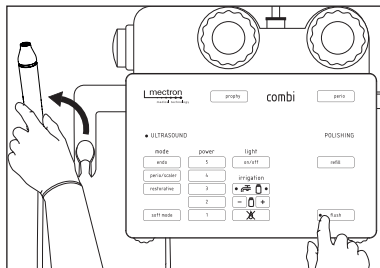
Before using the handpiece, ensure that all components are connected as described in *Chapter 4.3 on page 16*.

» PROCEDURE

Lift the scaler handpiece, with or without instrument, fill the irrigation circuit by selecting "flush" on the touch surface. The "flush" function LED flashes. The device allows two types of irrigation: via the mains water circuit or the bottle circuit.

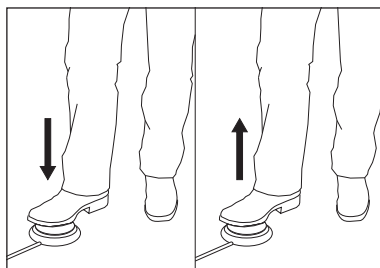
⚠ CAUTION: Make sure the polisher handpiece is stowed in its housing, otherwise the system will remain inactive.

1



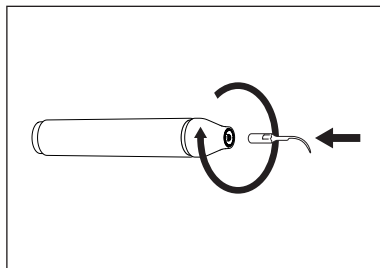
2

To start the cycle, press the foot pedal briefly. The "flush" function LEDs and the selected irrigation type will start flashing. The cycle is indicated by short sequential beeps. The cycle lasts for 23 seconds, but can be interrupted as soon as the liquid is seen coming out of the handpiece, simply by pressing the foot pedal. At the end of the "flush" cycle, the device becomes available again, maintaining the last set configuration.



3

Screw in the preselected instrument on the combi touch handpiece until it comes into contact;

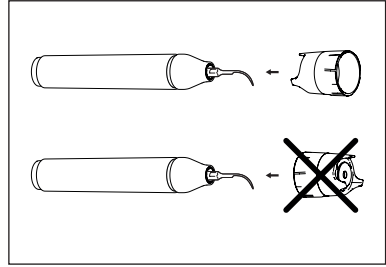


Tighten the instrument using the Mectron torque wrench.

For correct use of the Mectron torque wrench, proceed as follows:

- Place the instrument inside the torque wrench, as shown;

4

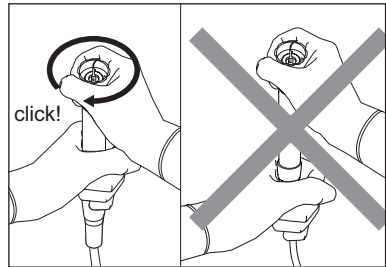


- Firmly grip the body of the handpiece.

⚠ CAUTION: Do not grab the handpiece by the nozzle and/or by the cord, but only by the core unit. Do not rotate the body during tightening. Firmly hold the body of the handpiece and rotate only the torque wrench.

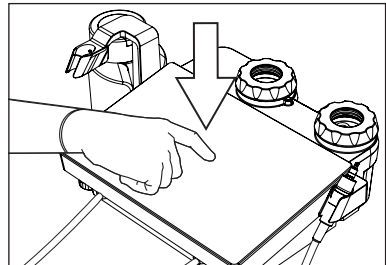
- Turn the torque wrench in a clockwise direction until the notch clicks (the external body of the torque wrench turns with respect to the body of the handpiece, emitting mechanical "CLICK" sounds).
- The instrument is now optimally locked;

5



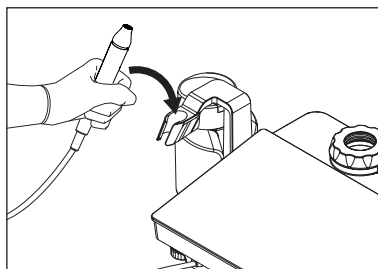
Select the type of function, power, and irrigation necessary, and the light if desired, on the touch surface; Lift the handpiece and press the foot pedal to start treatment;

6



At the end of treatment, stow the scaler handpiece in its housing.

7



EN

5.5 Important Information on the Instruments

⚠ WARNING:

- Before using the sterilised instrument, check the integrity of the sterile packaging and inspect the product to ensure there is no damage. The instrument will no longer be sterile if the packaging is broken or damaged. If the packaging is damaged, the instrument **MUST** be sterilised again before use.
- When the layer of titanium nitride is visibly consumed the instrument must be replaced. The use of an instrument too worn decreases its efficiency.
- **Diamond Instruments:** diamond instruments must be replaced when the layer of titanium nitride is visibly worn and in any case after a maximum of 10 treatments.
- Do not activate the handpiece while the instrument is in contact with the part to be treated so that the electronic circuit can recognise the best point of resonance of the instrument allowing optimum performance.
- Check the state of wear of the instrument and its integrity before and during each use. If you experience a loss of performance provide for its replacement.
- Use only original Mectron instruments. The use of non-original instruments will void the warranty and damage the thread of the combi touch handpiece, with the risk of no longer being able to correctly screw in the original instruments for subsequent use. In addition, the machine

settings are tested and guaranteed for correct operation using only original Mectron instruments.

- Do not change in any way the shape of the instrument, by bending it or filing it. This could cause it to break.
- Do not use an instrument that has undergone deformation of any type.
- Do not attempt to sharpen a used instrument.
- Always check that the threaded parts of the instrument and handpiece are perfectly clean - See *Chapters 6, 7, 8, 9* of this manual.
- Excessive pressure applied to the instrument can cause it to break and potentially injure the patient.
- The Mectron instruments vibrate with longitudinal oscillation, with a back and forward movement. During the treatment, always keep the instrument in a tangential direction with respect to the surface of the tooth. Move the handpiece back and forward, applying slight side pressure.
- Do not point the instrument directly onto the surface of the enamel or implant. Position the tip/operating part only in a tangential direction with respect to the surface of the tooth or implant.
- The instrument must be held in constant movement. If the instrument is blocked it may cause overheating of the treated part. It is recommended to use continuous motions to minimise contact between the tip and the part. Do not

block them against the tissues so as not to cause their overheating. It is advisable to increase the flow rate as the power level increases.

- Leave the ultrasonic vibrations to work, do not exert excessive pressure on the instruments during use. Apply slight force on the instrument for optimum performance.
- When the instrument is used in interproximal spaces, do not block the instrument or leverage on the operating part. The instruments must be left free to vibrate.

- In endodontic root canal therapy, never operate the files outside of the root canal to prevent them from breaking. To prevent breakages, create a smooth path with a manual endo file and plan the most direct possible path of access to minimise any bending of the instrument. Make delicate movements. Examine the file often for signs of wear. If the file breaks inside the canal, avoid contact between the instrument and the broken file to stop it from being pushed further it. Do not apply pressure on the instrument in an axial direction.

5.6 Operating Instructions - AIR-Polishing - Polisher Part

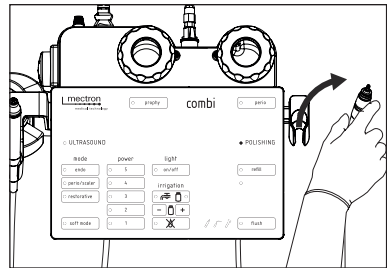
Before using the handpiece, ensure that all components are connected as described in *Chapter 4.3 on page 16*.

» PROCEDURE

Lift the cord of the air-polishing handpiece. The "POLISHING" function is activated.

CAUTION: Make sure the scaler handpiece is stowed in its housing, otherwise the system will remain inactive.

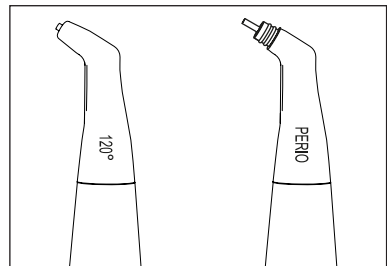
1



Choose the type of air-polishing handpiece depending on the operation that needs to be performed;

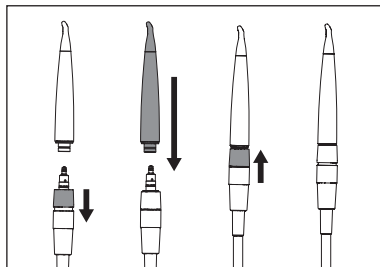
CAUTION: The Subgingival Perio Tip can only be used with the perio air-polishing handpiece.

2



On the quick coupling of the cord, slide the ring and hold it in position, then instrument the air-polishing handpiece until it comes into contact, and finally release the ring again;

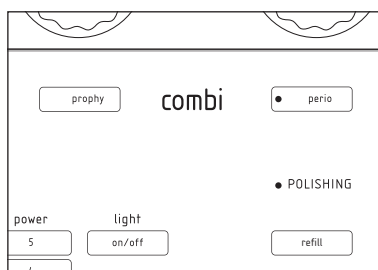
3



Select the desired "prophy" or "perio" function.

- "Prophy" function: use the specific supragingival powder distributed by Mectron;
- "Perio" function: use the specific subgingival powder distributed by.

4



⚠ WARNING: Before performing any other operations, make sure the air-polishing handpiece is properly and completely inserted in the quick coupling (the quick coupling ring and air-polishing handpiece must be in contact) and that the ring has been returned to the initial position.

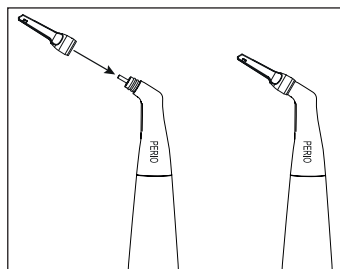
⚠ CAUTION: If the perio air-polishing handpiece has been selected, the Subgingival Perio Tip must be inserted on the front part.

⚠ CAUTION: Handle the Subgingival Perio Tip with care.

⚠ CAUTION: With the perio air-polishing handpiece, only specific subgingival powder distributed by Mectron must be used.

Insert the Subgingival Perio Tip on the perio air-polishing handpiece, pushing it in until it reaches the stop.

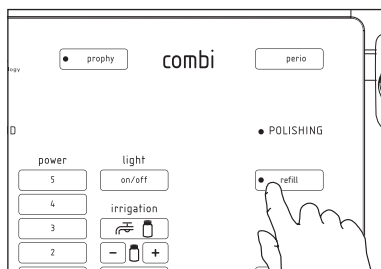
5



» PROCEDURE

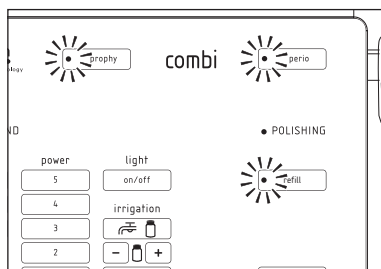
Press the "refill" button.

1



Wait for the end of the cycle, during which the "refill" key LED will flash together with that of the relative polisher container, emitting an audible signal.

2

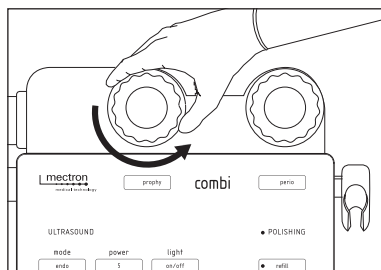


NOTE: If both the polisher containers are pressurised, the "refill" cycle will depressurise both.

NOTE: The duration of the "refill" cycle varies depending on whether one or both pressurised polisher containers are present.

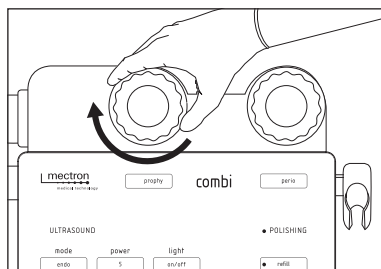
At the end of the cycle, the "refill" key LED will be steadily lit, indicating that the containers can now be opened or removed.

3



At this point the containers can simply be closed or re-inserted to continue using the device.

4



NOTE: If the polisher containers are neither opened nor removed, suffice it to simply press the "refill" key to return to the last used program.

5.7 “Flush” Function

Using the “flush” function it is possible to refill or rinse the irrigation circuit.

⚠ CAUTION: “Flush” function.
The “flush” function must be used after each treatment, before starting the cleaning and sterilisation procedures.

⚠ CAUTION: Failure to rinse the tubes leads to salt crystallisation. This can seriously damage the device.

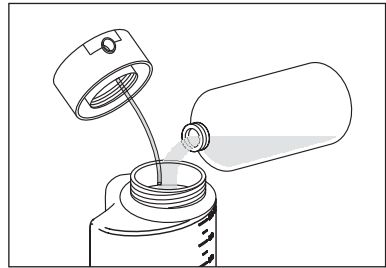
5.7.1 ULTRASOUND - Scaler Part

» PROCEDURE

Fill the bottle with the appropriate liquid. Depending on the aim of the “flush”, different liquids can be used:

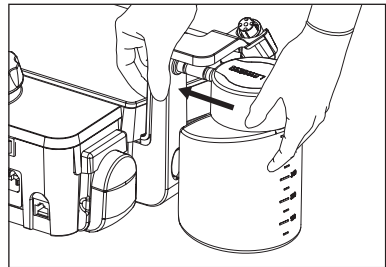
- If the bottle irrigation circuit needs to be filled, use the solution suited to the treatment;
- If the bottle irrigation circuit needs a rinse cycle, use water, preferably demineralised.

1



Connect the bottle to the device;

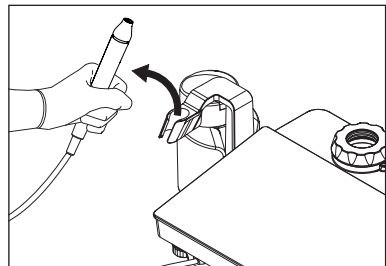
2



Extract the scaler handpiece from its housing;

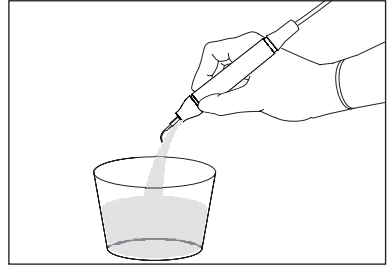
3

⚠ CAUTION: Make sure the polisher handpiece is stowed in its housing, otherwise the system will remain inactive.



4 Place the scaler handpiece, with or without instrument, over a container to catch the liquid released during the rinse cycle;

4



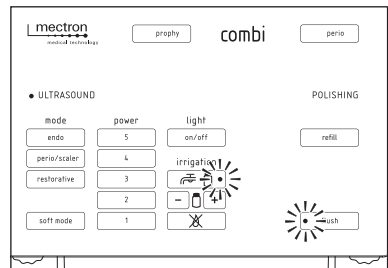
5 To enter "flush" mode, select "flush" on the touch surface.

5

The previously selected irrigation type will remain active and the corresponding LED will flash (faded out).

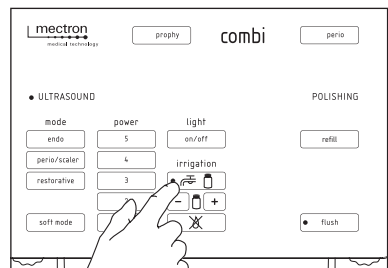
All the other selectable options on the touch surface will be disabled.

NOTE: The "flush" mode can be deactivated at any time by pressing the "flush" key again. The touch surface will be reactivated and configured in the last setting used.



6 The irrigation circuit used to carry out the "flush" cycle can be changed by pressing the key showing a tap and bottle;

6

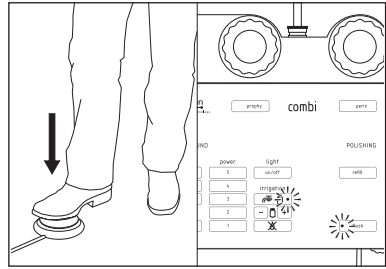


7

Press the foot pedal once and release it to start the cycle.

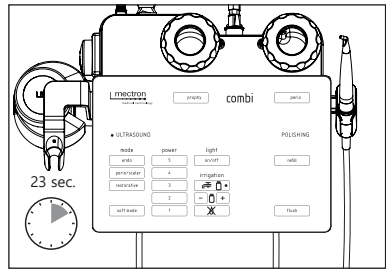
The function and selected irrigation type LEDs will flash. A sequence of short acoustic signals indicates that the cycle is running;

NOTE: The function can be interrupted at any time by briefly pressing the foot pedal. The touch surface will be reactivated and configured in the last setting used.



8

The cycle lasts 23 seconds. Once ended, the touch surface will be reactivated and configured in the last setting used;

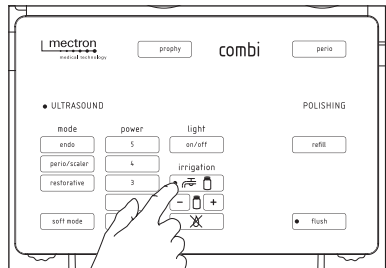


9

If the "flush" cycle is to be performed on the water circuit, repeat the steps from point 4 selecting irrigation with water.

At the end of the selected function time or at the end of the "flush" cycle, the system will be reactivated and configured in the last setting used.

NOTE: If running a water circuit "flush" cycle, remember to open the tap.

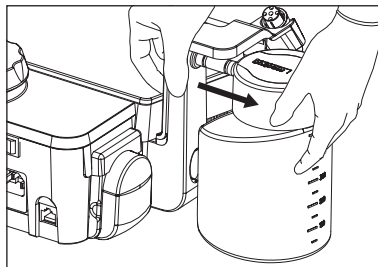


Once the irrigation circuit has been rinsed, proceed to disassemble (see Chapter 6.1 on page 44), clean and sterilise the individual parts (see Chapters 6, 7, 8, 9 of this manual).

⚠ CAUTION: If the handpiece is stowed back in its support with the "flush" function selected (LED flashing), the function will be deactivated.

⚠ CAUTION: During the "flush" cycle, i.e. if the function has been selected and activated by pressing the foot pedal, the cycle will continue if the handpiece is stowed back in the support.

10



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5.7.2 AIR-POLISHING - Polisher Part

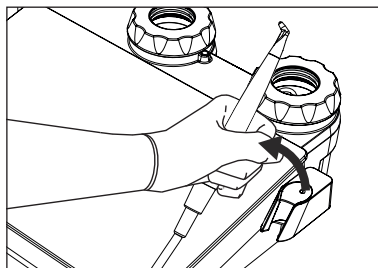
» PROCEDURE

Lift the air-polishing handpiece or its cord;

⚠ CAUTION: Make sure the scaler handpiece is stowed in its housing, otherwise the system will remain inactive.

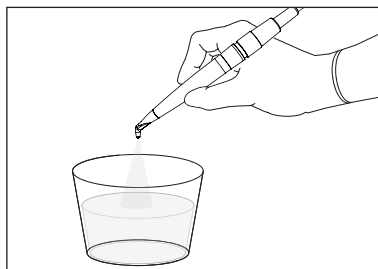
⚠ CAUTION: Make sure that both polisher containers are inserted in the device before activating the "flush" function.

1



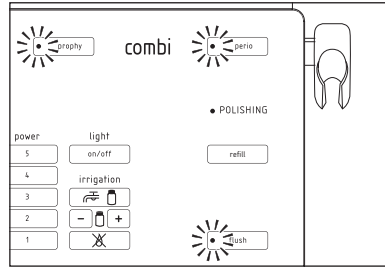
2

Place the cord and/or handpiece over a container or sink to catch the liquid and powder expelled during the "flush" cycle;



3

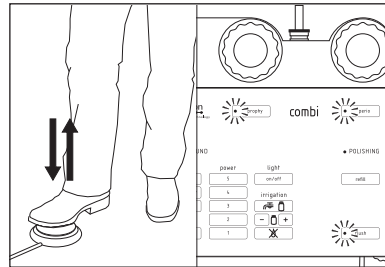
To enter "flush" mode, select "flush" on the touch surface: both the polisher containers and corresponding LEDs will flash (faded out). All the other selectable options on the touch surface will be disabled.



4

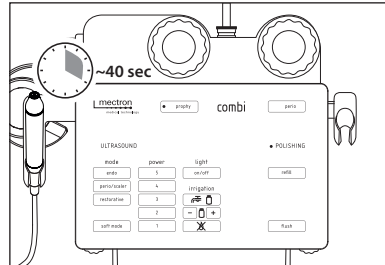
Press the foot pedal once and release it to start the cycle. The LEDs of the function and polisher containers will flash. A sequence of short acoustic signals indicates that the cycle is running;

NOTE: The "flush" cycle cannot be interrupted. Before running the "flush" cycle, check that the right-hand tap is open.



5

The "flush" cycle is run on both polisher containers simultaneously. The cycle lasts about 40 seconds. Once ended, the touch surface will be reactivated and configured in the last setting used.



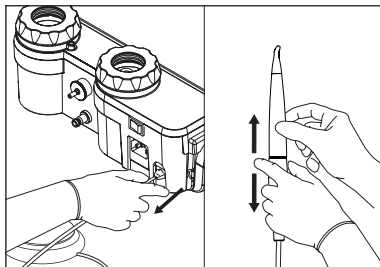
Once the irrigation circuit has been subjected to the "flush" cycle, proceed to disassemble, clean and sterilise the individual parts (see *Chapters 6, 7, 8, 9* of this manual).

⚠ CAUTION: If the handpiece is stowed back in its support with the "flush" function selected (LED flashing) but not running, the function will be deactivated;

⚠ CAUTION: During the "flush" cycle, i.e. if the function has been selected and activated by pressing the foot pedal, the cycle will continue if the handpiece is stowed back in the support.

⚠ CAUTION: When running the "flush" cycle, do not remove the polisher containers but rather wait for the cycle to end.

6



EN

6 CLEANING

⚠ CAUTION: To disinfect the device and/or its components, it is recommended to use water-based disinfectant solutions with neutral pH (pH 7).

DO NOT USE the following as disinfectants:

- Alcohol-based products above 70%;
- Products containing peracetic acid, formaldehyde, glutaraldehyde or other equivalent solutions;
- Very alkaline products (pH > 9);
- Products containing sodium hypochlorite;
- Products containing hydrogen peroxide;
- Products containing abrasive substances;
- Very acid products (pH < 4);
- Products containing aldehyde, amine and/or phenols;
- Acetone;
- Methylene ketone;

as they may discolour and/or damage the materials of the device and its components.

The manufacturer disclaims all liability for any damage caused by the substances mentioned above. In case of damage caused by those substances, the Warranty will be void.

⚠ CAUTION: Methods not covered in the following sections must not be used.

⚠ WARNING: The sterile, single-use Subgingival Perio Tips must be used for one treatment and one patient only. Single-use Subgingival Perio Tips must not be reused. Sort and dispose of each single-use Subgingival Perio Tip in accordance with current hospital waste disposal laws.

NOTE: Repeated reconditioning has a minimal effect on the devices and components. The end-of-life of the devices and components is generally determined by wear or damage resulting from use. Mectron guarantees the integrity of its sterilisable air polisher nozzles and scaler handpieces for up to 250 reconditioning cycles.

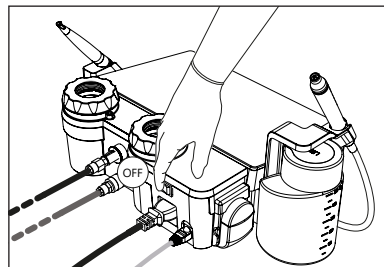
6.1 Disassembling Parts for Cleaning and Sterilisation

Before performing the cleaning procedures outlined in the following sections, disconnect all components of combi touch.

» PROCEDURE

⚠ WARNING: Switch off the device. Always switch off the device using the switch and disconnect the power cable from the wall socket and machine core unit before carrying out cleaning and sterilisation tasks.

1

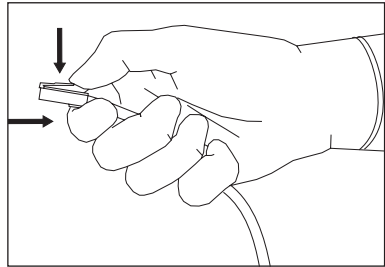


Disconnect the foot pedal from the device:
grasp the foot pedal connector, press the release tab and pull the connector back;

⚠ CAUTION: Do not try to unscrew or turn the connector during disconnection: this might damage the connector.

⚠ CAUTION: To disconnect the cable from the foot pedal, only ever grab the cable connector. Never pull the cable itself.

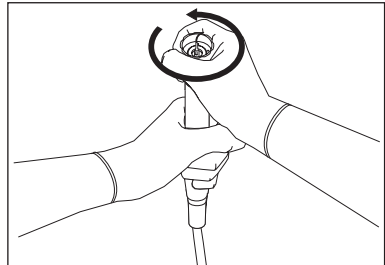
2



EN

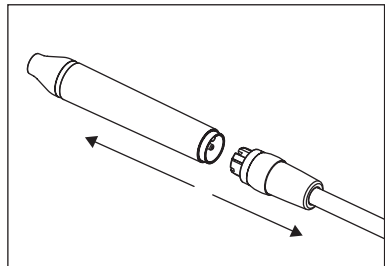
If present, unscrew the instrument from the handpiece using the torque wrench;

3

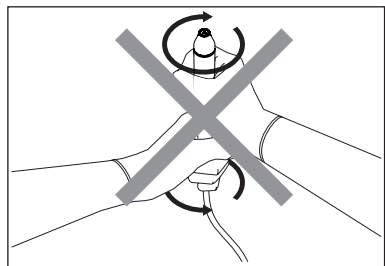


Disconnect the scaler handpiece from the cord;

4



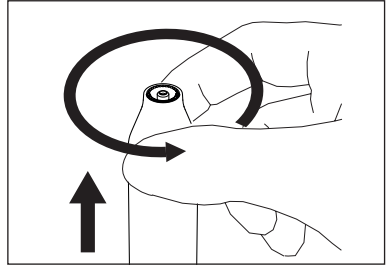
⚠ CAUTION: Do not try to unscrew or turn the connector when disconnecting the handpiece. The connector can be damaged.



Unscrew the metal cone from the scaler handpiece;

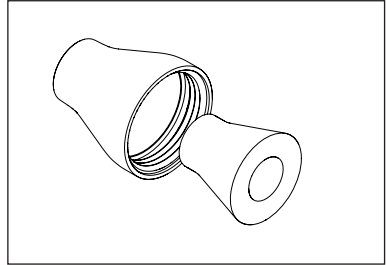
⚠ CAUTION: The metal cone has a light guide. If the metal cone is unscrewed, the light guide will no longer be held in place and may slide and be disconnected. Be careful not to lose the light guide.

5



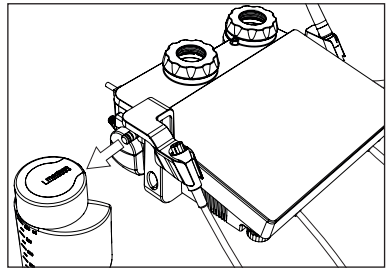
Remove the light guide from the metal cone;

6



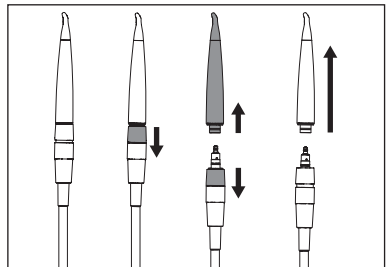
Disconnect the bottle from the machine core unit, pulling it outwards;

7



On the quick coupling of the air-polishing handpiece cord, slide the ring nut and hold it in that position, pull out the air-polishing handpiece, then release the handpiece ring nut;

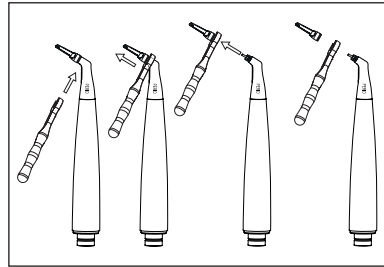
8



If the perio air-polishing handpiece was used, remove the Subgingival Perio Tip using the supplied K9 wrench and proceed with disposal (see *Chapter 10* on page 75);

NOTE: Insert the K9 wrench exactly in the position shown in the figure.

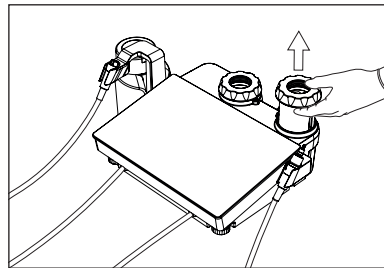
9



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CAUTION: Before extracting the polisher container or unscrewing the caps, check that the device is switched off and disconnected from the power mains, or start the "refill" function (see *Chapter 5.6.1* on page 36).

10



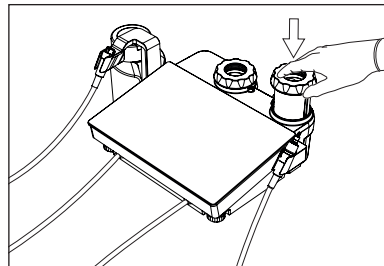
Extract the polisher container from the device, remove the cap and empty it. Proceed with polishing. (see *Chapter 12.8* on page 98).

Repeat the procedure on the device's second polisher container if both have been used;

11


Once cleaning is complete, place the containers back in the device.

CAUTION: Insert the polisher containers so that the groove in the bottom of the device coincides with the curvature of the polisher container.





6.2 Preparation


1. Run the "flush" function (see *Chapter 5.7 on page 38*);
2. Disinfect the external irrigation circuit as described in *Chapter 10.1 on page 75*.
3. Disinfect the bottle irrigation circuit as outlined in *Chapter 10.2 on page 86*.
4. Check that all of the following components have been removed/ disconnected from the machine core unit (see *Chapter 6.1 on page 44*):
 - Power supply cable;
 - Foot pedal;
 - Scaler handpiece;
 - Instruments;
 - Air-polishing handpiece;
 - Water and air hose.

 **CAUTION:** The cleaning and sterilising operations described in the following sections are to be performed at first use and at all subsequent uses.

WARNING: Always switch off the device using the O/I switch and disconnect it from the power mains before carrying out the post-preparation cleaning tasks.

 **CAUTION:** Always disconnect the instrument from the handpiece before cleaning and sterilising it.

 **CAUTION:** Do not immerse the handpiece in disinfecting solutions or other liquids as these could damage it.

 **CAUTION:** In case of excessive powder humidity, remove/disconnect the air-polishing handpiece from the quick coupling on the cord, free the air-polishing handpiece channel of any powder residue using the supplied Ø 0.8 mm cleaning needle, then run the "flush" function without the air-polishing handpiece.

6.3 Cleaning the Non-Sterilisable Parts

6.3.1 Cleaning the Machine Core Unit, Foot Pedal and Cords

The following procedure must be performed on non-sterilisable parts of the device, except for the bottle and its cap. The parts in question are:

- Machine core unit;
- Foot pedal and relative connection cable to the machine;

- Polisher handpiece cord;
- Scaler handpiece cord.

⚠ WARNING: Always switch off the device using the O/I switch and disconnect it from the power mains before cleaning.

» REQUIRED MATERIALS

- Clean, soft, low-lint cloths
- Cleaning solution (pH 4-9).

» PROCEDURE

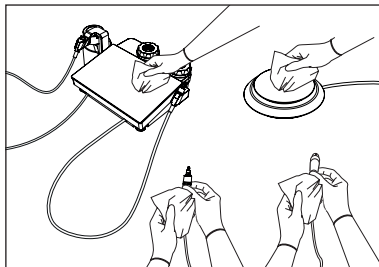
Clean the surface of the parts in question using a clean, dry, low-lint cloth, dampened with a detergent solution (pH 4-9);

1



Dry the parts using a dry, non-abrasive, low-lint cloth.

2



⚠ CAUTION: Do not sterilise the non-sterilisable parts. They may stop working and cause damage to people and/or property.

⚠ WARNING: The device and its non-sterilisable parts are not protected against the penetration of liquids. Do not spray liquids directly onto the

surface of the device and its parts sold as non-sterilisable.

⚠ CAUTION: Do not use running water to clean the non-sterilisable parts.

⚠ CAUTION: Do not use solutions other than those recommended as they may damage non-sterilisable parts.

6.3.2 Cleaning the Bottle and Cap

The following procedure should be carried out on the bottle and cap of the device.

» PREPARATION

1. Disconnect the bottle from the machine body (see *Chapter 6.1 on page 44*);
2. Unscrew the cap from the bottle.

⚠ CAUTION: Do not sterilise the bottle and cap in the autoclave. They could be damaged.

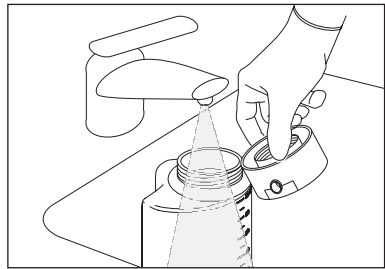
» REQUIRED MATERIALS

- Water;
- Cleaning solution (pH 4-9);
- Clean, soft, low-lint cloth;
- Demineralised water.

» PROCEDURE

Rinse thoroughly the inside and the outside of both the bottle and the cap under running water;

1



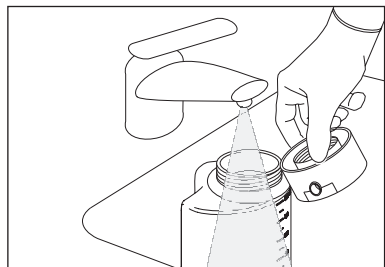
Clean the external and internal surfaces of the bottle and of the cap with a clean cloth, soft and with low fibres release, dampened with a mild detergent solution (pH 4-9);

2

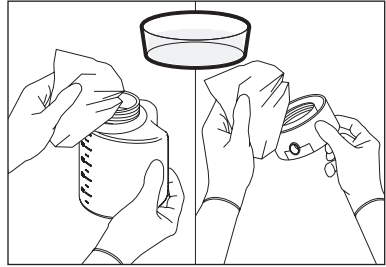


Thoroughly rinse the inside and outside of the bottle under running water to eliminate all residues of the detergent solution;

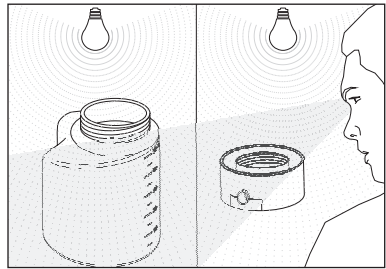
3



4 Remove any residues on the external or internal surfaces of the bottle and of the cap using a soft cloth with low fibres release moistened with demineralized water;



5 When cleaning operations are over, check the pieces under an appropriate light source, paying attention to any soil residue and, if necessary, repeat the cleaning cycle.



6.4 Cleaning Sterilisable Components

The sterilisable parts of the device are:

- Scaler handpiece;
- Scaler metal cone;
- Light guide
- Instruments;
- Torque wrench;
- Air-polishing handpiece;
- K9 Wrench;
- Irrigation circuit disinfection kit.

The Operator can choose between the following cleaning procedures:

- Manual cleaning;
- Automatic cleaning.

The procedures applicable to components combi touch have been validated by an independent body.

Before proceeding with operations to check cleanliness (*Chapter 7 on page 68*), drying and lubrication (*Chapter 8 on page 70*) and then sterilisation (*Chapter 9 on page 72*), one of the two possible cleaning methods explained in detail in the following chapters must be selected.

NOTE: The cleaning procedures must be performed immediately after each use. Immerse the instrument and/or instrument in demineralised water or in an enzymatic detergent solution immediately after use. Do not leave residue or blood deposits on the instruments, eliminate larger impurities with a disposable cloth or paper towel.

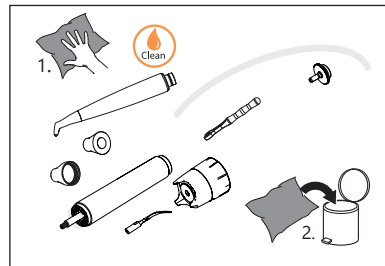
CAUTION: The instructions supplied below have been validated by the manufacturer of the medical device as ABLE to prepare a medical device for re-use. The process manager is responsible for ensuring that the processes repeated are effectively performed using the equipment, materials and staff in the 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 processes manager must be adequately assessed to judge their efficiency and potential undesired consequences.

6.4.1 Pre-Cleaning

The “pre-wash” cycle is optional and preparatory to the chosen cleaning method. After following the instructions provided in *Chapter 6.2 on page 48*, proceed as follows:

Thoroughly clean the outer surfaces with ready-to-use aldehyde-free wipes (with less than 35% alcohol) until visually clean. Ensure the surfaces are sufficiently damp. Note the action time of the detergent as indicated by the manufacturer.

1



6.4.2 Manual Cleaning

Manual cleaning can be carried out as an alternative to the automatic cleaning described in Chapter 6.4.3 on page 66.

» REQUIRED MATERIALS

- Enzymatic detergent at pH 4-9;
- Water;
- Container for immersion in the enzymatic liquid;
- Ultrasonic tank;
- Clean, soft, low-lint cloths;
- Brush with soft nylon bristles;
- Syringe;
- Demineralised water

PROCEDURE - SCALER HANDPIECE

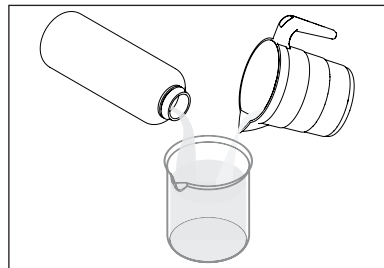
Prepare a solution of enzymatic detergent^{a)} with pH 4-9, according to the manufacturer's instructions;

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

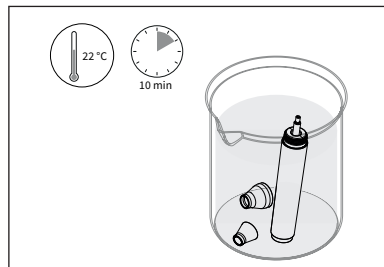
- a) Process validated by independent bodies with ENZYMEC enzymatic detergent, 0.8% v/v.

Completely immerse the scaler handpiece, metal cone and light guide in the enzymatic solution. Leave to soak for 10 minutes at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$;

1



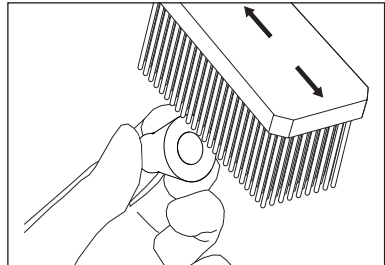
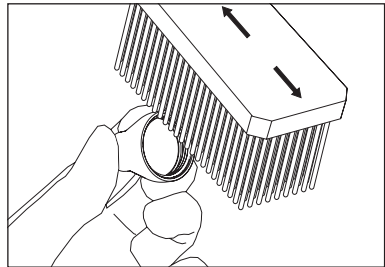
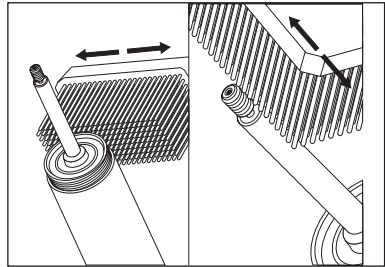
2



3

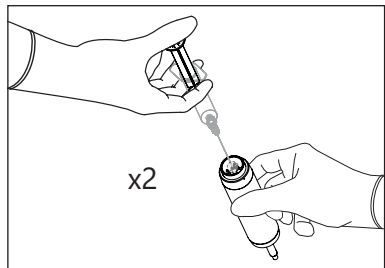
Gently brush the entire surface of the scaler handpiece, metal cone, and light guide for at least 20 seconds using a brush with soft nylon bristles, paying particular attention to the following areas:

- thread of the scaler handpiece;
- titanium shaft;
- external and internal parts of metal cone;
- external and internal parts of light guide.



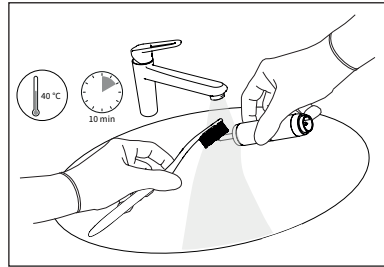
4

Rinse the inner channel of the scaler handpiece using a 20 ml syringe previously filled with a new enzymatic solution. Repeat twice;



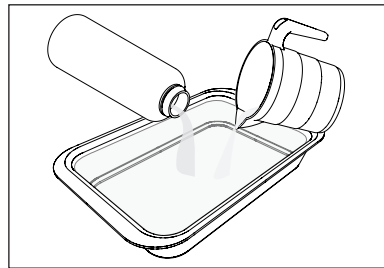
5

Remove the handpiece, metal cone and light guide from the enzymatic solution and gently brush their surfaces using a brush with soft nylon bristles under hot ($40^{\circ}\text{C} \pm 5^{\circ}\text{C}$) running water, for at least 10 minutes;



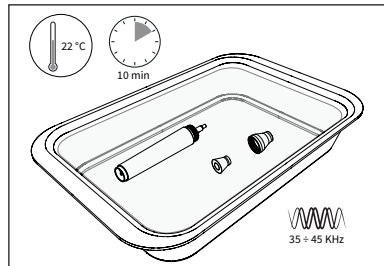
6

Fill the ultrasonic tank with the enzymatic detergent solution prepared according to the manufacturer's instructions. Use water at ambient temperature ($22^{\circ}\text{C} \pm 2^{\circ}\text{C}$);



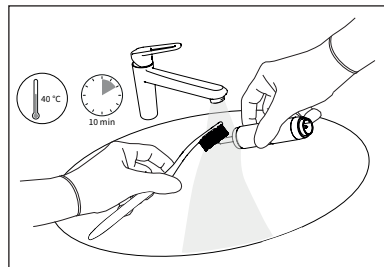
7

Place the scaler handpiece, metal cone and light guide in the ultrasonic tank immersed in the enzymatic detergent solution at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and run a cycle for at least 10 minutes;



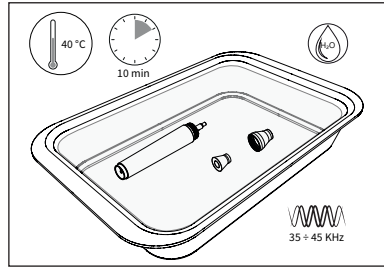
8

Remove the handpiece, metal cone and light guide from the enzymatic solution and gently brush their surfaces using a brush with soft nylon bristles under hot ($40^{\circ}\text{C} \pm 5^{\circ}\text{C}$) running water, for at least 10 minutes;



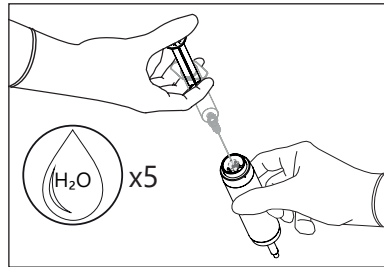
9

Place the scaler handpiece, metal cone and light guide in the ultrasonic tank immersed in demineralised water at 40°C ± 5°C and run a cycle for at least 10 minutes;



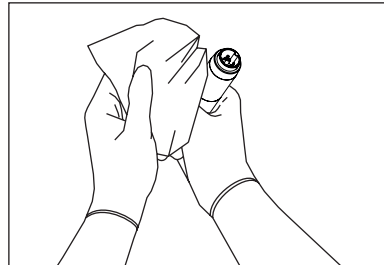
10

Rinse the inner channel of the scaler handpiece using a 20 ml syringe previously filled with demineralised water. Repeat five times;



11

Dry the surface of the scaler handpiece, metal cone, and light guide with a clean, non-abrasive, low-lint cloth.



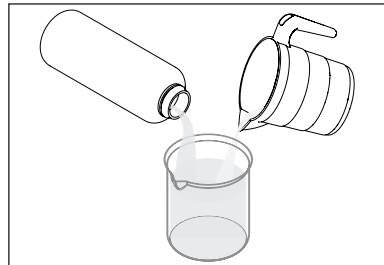
» **PROCEDURE - INSTRUMENTS AND TORQUE WRENCH**

1

Prepare a solution of enzymatic detergent^{a)} with pH 4-9, according to the manufacturer's instructions;

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

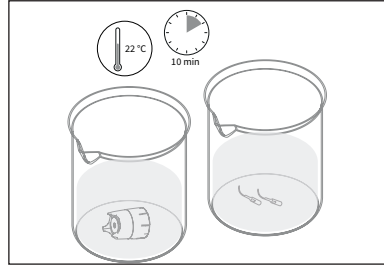
a) Process validated by independent bodies with ENZYMEC enzymatic detergent, 0.8% v/v.



2

Lay the instrument or torque wrench in a clean container, in a horizontal position. Add enough of the prepared solution to completely cover the device to be cleaned.

Leave the device to soak in the enzymatic detergent solution for 10 minutes at ambient temperature. ($22^{\circ}\text{C} \pm 2^{\circ}\text{C}$);



3

After 10 minutes of soaking in the enzymatic solution, gently brush all the surfaces until all visible soil has been removed.

For each part to be cleaned, use a brush appropriate to its size. Use different brushes for the instrument and torque wrench.

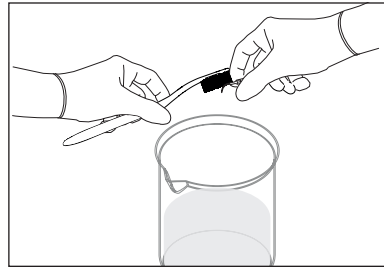
NOTE:

For the instrument: use a clean brush with soft nylon bristles for the outer surfaces, and a clean pipe cleaner with soft nylon bristles for the internal cavities and grooves. Thoroughly clean the hard-to-reach areas such as sharp edges and, in particular, the gaps between the shearing cusps.

For the wrench: use only a clean brush with soft nylon bristles.

Thoroughly brush all the following parts of the torque wrench for about 20 seconds:

- Through-holes and internal channels;
- External metal ring;
- Internal cavities, grooves and fissures.

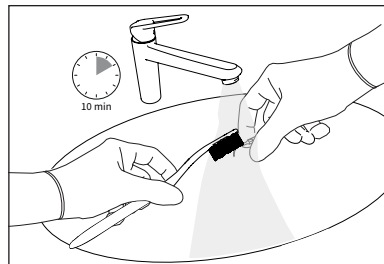


4

Remove the instrument or torque wrench from the enzymatic cleaning solution.

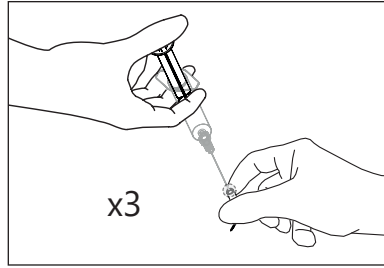
Thoroughly rinse and brush all the surfaces of the instrument(s) or torque wrench (see previous point) under running water for:

- at least 10 minutes for the wrench,
- at least 1 minute for the instrument.



Use a single-use 20 ml syringe to withdraw and inject the enzymatic detergent solution into the hard-to-reach areas (through-holes/cannulae). Repeat this procedure three times to ensure the effective removal of soil from inside the through-hole and inject fresh enzymatic detergent solution.

5

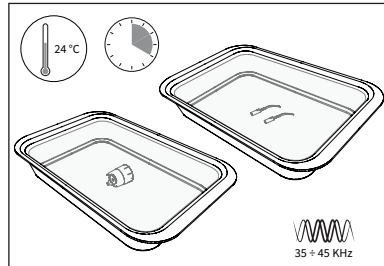


Place the instrument(s) or torque wrench in an ultrasonic tank, immersed in fresh enzyme solution 24°C ± 2°C.

Subject to ultrasonic cleaning for:

- at least 20 minutes for the torque wrench
- at least 10 minutes for the instruments or in accordance with the manufacturer's instructions for the enzymatic detergent and ultrasonic tank.

6

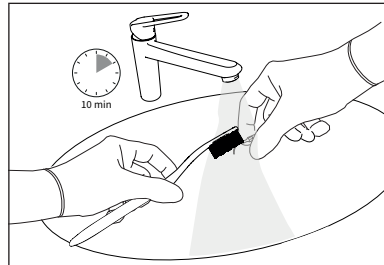


Remove the instrument or torque wrench from the enzymatic cleaning solution.

Thoroughly rinse and brush all the surfaces of the instrument(s) or torque wrench (see previous point) under running water for:

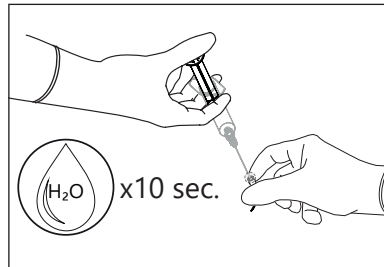
- at least 10 minutes for the wrench,
- at least 1 minute for the instrument.

7



Rinse the internal channel of the instrument with demineralised water at a pressure of 3.8 bar for at least 10 seconds so as to eliminate any soil residue.;

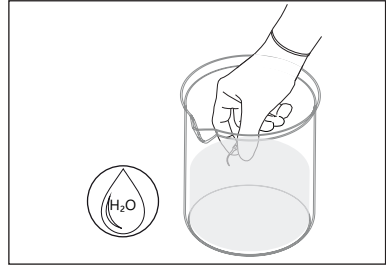
8



Rinse the device in demineralised water;

- at least 5 minutes for the wrench,
- at least 1 minute for the instrument.

9



EN

» PROCEDURE - AIR-POLISHING HANDPIECES

Prepare a solution of enzymatic detergent^{a)} with pH 4-9, according to the manufacturer's instructions;

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

a) Process validated by independent bodies with ENZYMEC enzymatic detergent, 0.8% v/v.

Clean any powder residue inside the channel of the air-polishing handpiece using the supplied Ø 0.4 mm cleaning needle, from both sides.

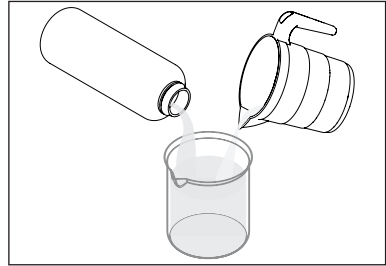
Blow compressed air into the central hole of the handpiece, from both ends;

⚠ CAUTION: Clean the channel of the nozzle using only the Ø 0.4 mm cleaning needle supplied with the device.

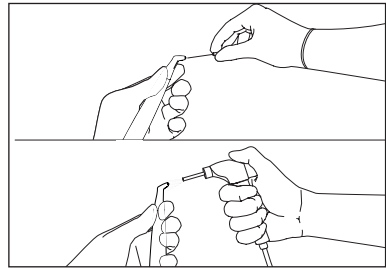
⚠ CAUTION: If the single-use Subgingival Perio Tip is on the air-polishing handpiece, remove and dispose of it.

Place the air-polishing handpiece in a clean container, in a horizontal position, and add enough enzymatic detergent solution to completely cover the handpiece;

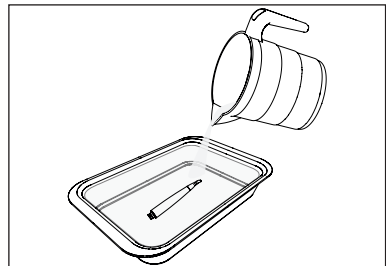
1



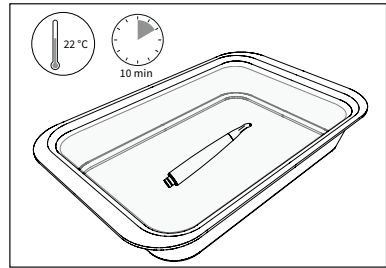
2



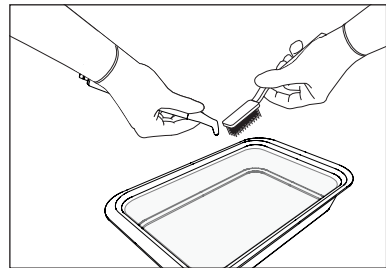
3



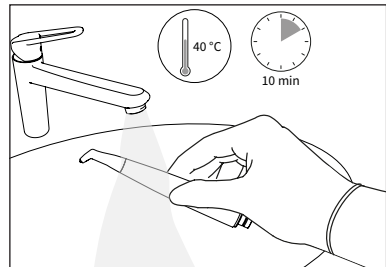
4 Leave to soak for 10 minutes at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$. This procedure reduces the amount of blood, protein and mucous present on the air-polishing handpiece;



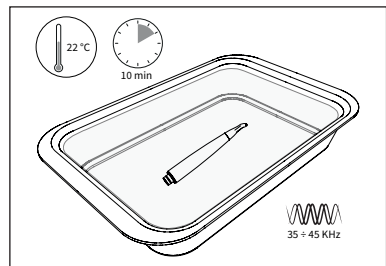
5 After 10 minutes of immersion in the enzymatic solution, gently brush the surface of the air-polishing handpiece using the brush with soft nylon bristles for at least 20 seconds, and eliminate all visible residue. Thoroughly clean the hard-to-reach areas such as the edges, recesses, and joints;



6 Rinse the air-polishing handpiece under hot running water ($40^{\circ}\text{C} \pm 5^{\circ}\text{C}$) for about 10 minutes, moving it slightly to allow the water to reach the entire surface;

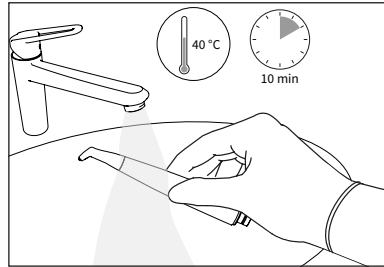


7 Place the air-polishing handpiece in the ultrasonic tank immersed in the enzymatic detergent solution for at least 10 minutes at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$;



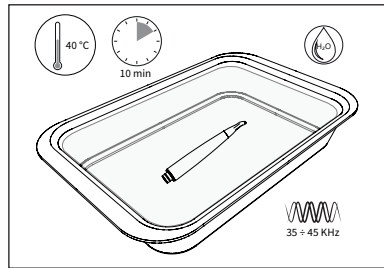
8

Gently brush the surface of the air-polishing handpiece using the brush with soft nylon bristles; Rinse the air-polishing handpiece under hot running water ($40^{\circ}\text{C} \pm 5^{\circ}\text{C}$) for about 10 minutes, moving it slightly to allow the water to reach the entire surface;



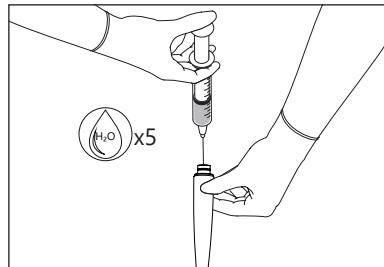
9

Place the air-polishing handpiece in the ultrasonic tank immersed in demineralised water for at least 10 minutes at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$;



10

After 10 minutes of immersion in the ultrasonic tank with demineralised water, rinse the internal channels of the air-polishing handpiece by injecting 20 ml of demineralized water at room temperature ($20^{\circ}\text{C} - 25^{\circ}\text{C}$) using a syringe with needle, five times in a row.



» **PROCEDURE - K9 WRENCH AND IRRIGATION CIRCUIT DISINFECTION KIT**

Prepare a solution of enzymatic detergent^{a)} with pH 4-9, according to the manufacturer's instructions;

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

a) Process validated by independent bodies with ENZYMEC enzymatic detergent, 0.8% v/v.

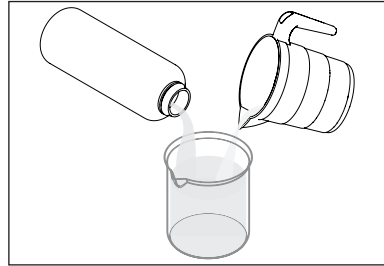
Place the K9 wrench in a clean container. Add enough enzymatic detergent solution to completely cover it. Leave the K9 wrench to soak in the enzymatic detergent solution for 10 minutes at ambient temperature (22 °C ± 2 °C);

While soaking in the enzymatic solution, gently brush all the surfaces until all visible soil has been removed. Use a clean brush with soft nylon bristles for the external surfaces, and a clean pipe cleaner with soft nylon bristles for the internal cavities and grooves.

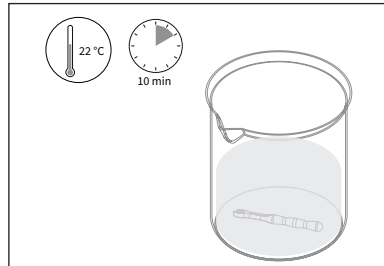
NOTE: Thoroughly brush all the following parts of the K9 wrench for about 20 seconds.

Remove the K9 wrench from the enzymatic detergent solution. Thoroughly rinse and brush all the surfaces of the K9 wrench (see previous point) under running water for at least 10 minutes;

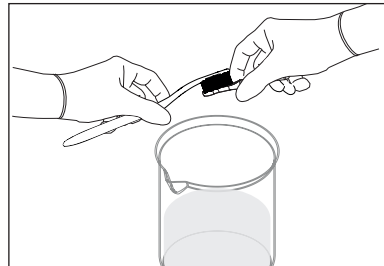
1



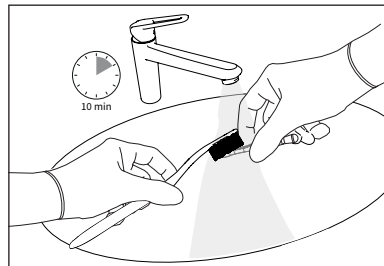
2



3

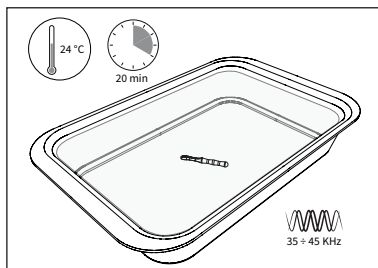


4



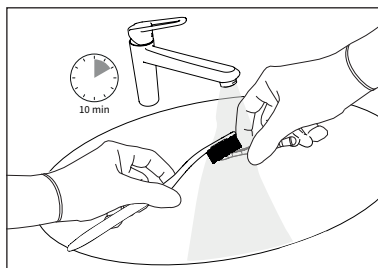
5

Place the K9 wrench in the ultrasonic tank immersed in the enzymatic detergent solution at 24 °C ± 2 °C and run a cycle for at least 20 minutes;



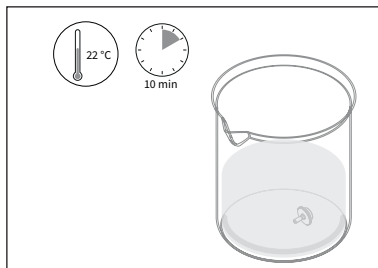
6

Remove the K9 wrench from the ultrasonic tank and rinse it under running water so as to eliminate all detergent residue. Brush the internal and outer surfaces of the K9 wrench with a clean brush with soft nylon bristles, under running water;



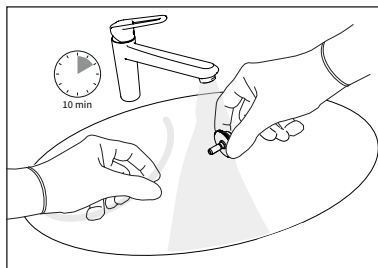
7

Place the irrigation kit in a clean container. Add enough enzymatic detergent solution to completely cover it. Leave it to soak in the enzymatic detergent solution for 10 minutes at ambient temperature 22°C ±2°C;



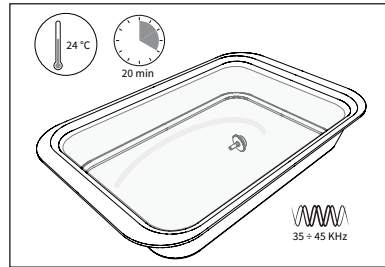
8

Remove the tube and fitting from the enzyme detergent solution. Thoroughly rinse all the surfaces under running water for at least 10 minutes;



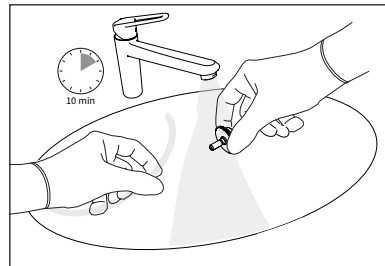
Place the irrigation kit in the ultrasonic tank immersed in the enzymatic detergent solution at $24^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and run a cycle for at least 10 minutes;

9



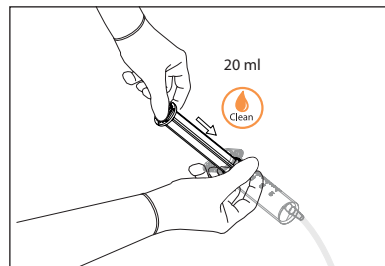
Remove the irrigation kit from the enzymatic solution and rinse it under warm running water ($40^{\circ}\text{C} \pm 5^{\circ}\text{C}$) for at least 10 minutes;

10



Rinse the inner channel with a 20 ml syringe (without needle) previously filled with demineralised water. Repeat three times;

11



6.4.3 Automatic Cleaning

Automatic cleaning can be carried out as an alternative to the manual cleaning described in Chapter 6.4.2 on page 53.


NOTE: Procedure validated with:

- Miele PG8536 washer/disinfector;
- Miele DES-VAR-TD program;
- Alkaline detergent: neodisher® FA (0.2 % v/v);
- Neutralising liquid: neodisher® Z (0.1 % v/v)


» REQUIRED MATERIALS


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

NOTE: Ensure that the components are properly secured in the basket and cannot move during washing. Any blows 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 the effectiveness of cleaning.

 **WARNING:** On completion of the cleaning cycle in the thermal-disinfector, the scaler handpiece remains at the wash temperature for a long time. Use appropriate precautions when extracting the scaler handpiece from the thermal-disinfector to prevent injury to the operator.

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

» **PROCEDURE**

Place the components/accessories in a metal basket. Connect the relevant adapter (supplied as an optional) to the scaler handpiece connector and then to the water jet cleaning connections of the thermal-disinfector.

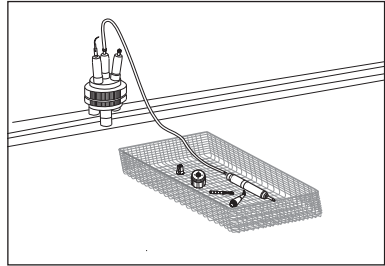
Repeat the same operation for the instruments by connecting them to the appropriate adapters supplied as optionals.

Sequence and parameters applicable to the cycle:

- 1 min, Rinse with cold water;
- 5 min, Wash with alkaline detergent at $55^{\circ}\text{C} \pm 2^{\circ}\text{C}$;
- 1 min, Neutralisation with neutralising liquid and water at $32^{\circ}\text{C} \pm 2^{\circ}\text{C}$;
- 1 min, Rinse with water at $32^{\circ}\text{C} \pm 2^{\circ}\text{C}$;
- 5 min, Thermal disinfection at 93°C with deionized water.

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

1



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7 CLEANING CHECK

» REQUIRED MATERIALS

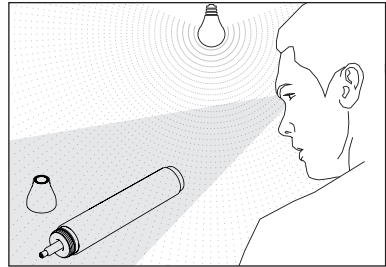
- Light source;
- 2.5X Magnifier.

» PROCEDURE

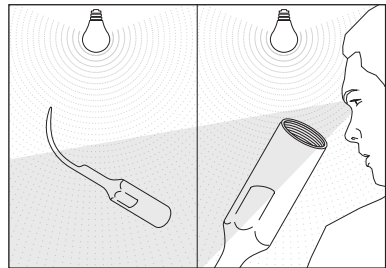
Once the cleaning operations have been completed, check the scaler handpiece and scaler metal cone under an adequate source of light, if necessary using a magnifying glass 2.5X, paying attention to any parts that may conceal soil residue (threading, cavities, grooves) and, if need be, repeat the cleaning cycle if soil is still visible. Finally, check the integrity of those parts and those elements that could have deteriorated during use;

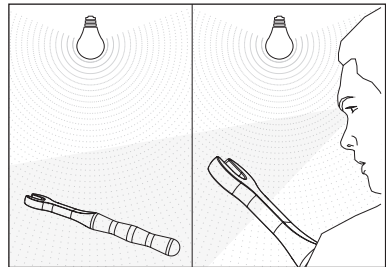
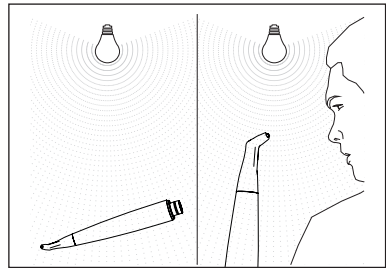
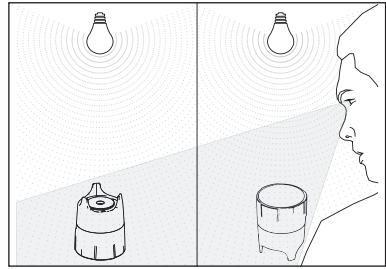
Repeat the checking procedures for the other components (instruments, instrument tightening wrenches, air-polishing handpieces, K9 wrench), repeating the cleaning cycle if necessary.

1



2





8 DRYING AND LUBRICATION

» REQUIRED MATERIALS

- Compressed air;
- Soft, low-lint cloth;
- Medical grade lubricant.

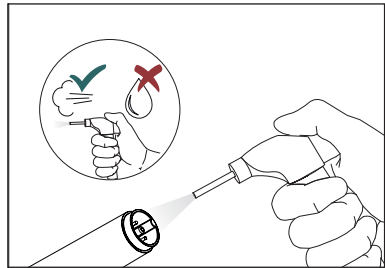
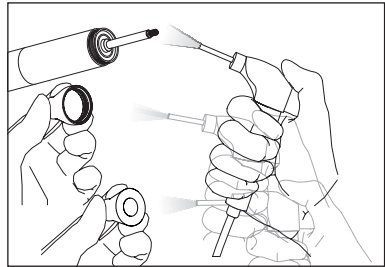
» PROCEDURE

Thoroughly dry all parts of the scaler handpiece, metal cone, and light guide by blowing them with compressed air;

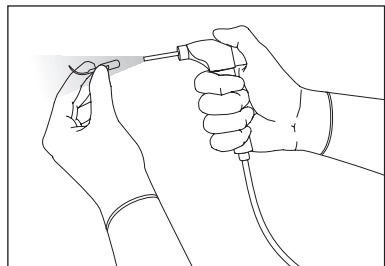
⚠ CAUTION: The scaler handpiece electrical contacts must be dry at the start and end of the sterilisation cycle, before the cord is connected to the device. Always make sure that the electrical contacts of the connector are perfectly dry, if necessary dry them blowing with compressed air.

⚠ CAUTION: Before starting the sterilisation cycle, make sure that the instrument is thoroughly dry both internally and externally. To do so, blow compressed air both externally and through the internal through-hole. This will prevent the appearance of stains, streaks on the surface, or oxidation inside the instrument.

1

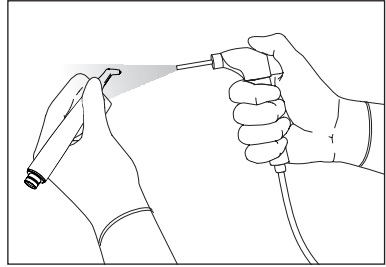


2



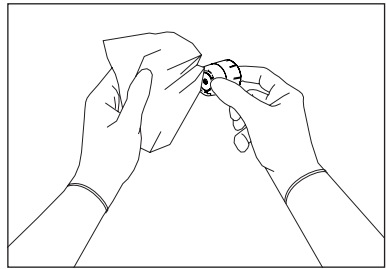
⚠ CAUTION: Before starting the sterilisation cycle, make sure that the air-polishing handpiece is thoroughly dry both inside and out. To do so, blow compressed air both externally and through the internal through-holes. This will prevent the appearance of stains, streaks on the surface, or oxidation inside the air-polishing handpiece.

3



Dry the instrument tightening wrench using a soft, low-lint cloth;

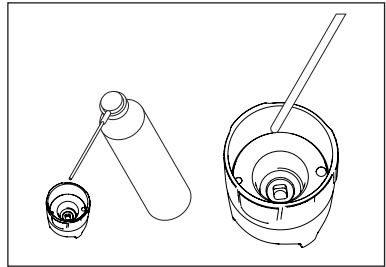
4



Lubricate the instrument tightening wrench with medical-grade lubricants in the indicated point.

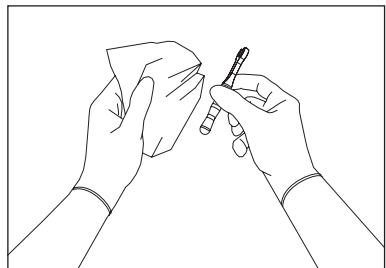
5

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



Dry the K9 wrench using a soft, low-lint cloth.

6



9 STERILISATION

» PREPARATION

The sterilisable parts of the device are:

- Scaler handpiece;
- Scaler metal cone;
- Light guide
- Instruments;
- Torque wrench;
- Air-polishing handpiece;
- K9 Wrench;
- Irrigation circuit disinfection kit.

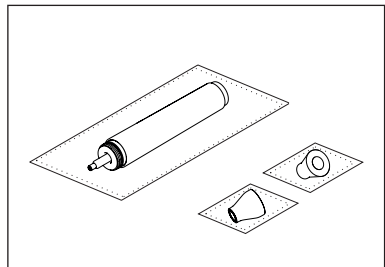
Seal the scaler handpiece (without instruments), metal cone, and light guide individually and separately in single-use sterilisation pouches.

Seal the instruments individually inside a single-use sterilisation pouch.
Seal the air-polishing handpieces individually inside a single-use sterilisation pouch.

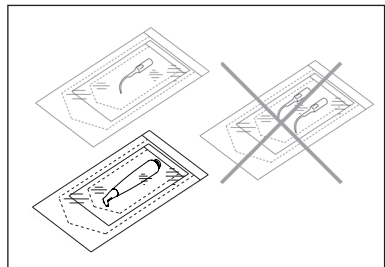
The sterilisable parts are manufactured with materials able to withstand a maximum temperature of 135°C for a maximum time of 20 minutes. After individually bagging both the scaler handpiece and the other sterilisable components, proceed with the sterilisation process in a steam autoclave.

⚠ CAUTION: Use sterilisation pouches compliant with standard UNI EN ISO 11607-1.

1

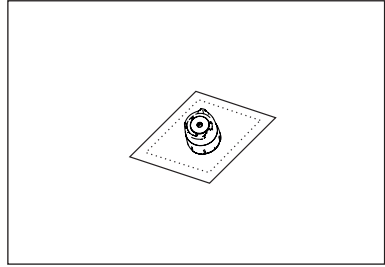


2



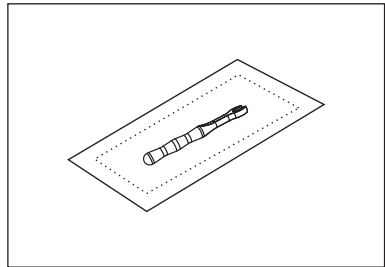
Seal the torque wrench separately inside a single-use sterilisation pouch.

3



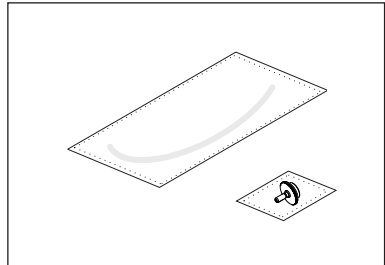
Seal the K9 wrench individually inside a single-use sterilisation pouch.

4



Individually seal the tube and the fitting separately in a single-use pouch legally marketed for steam sterilisation.

5



» PROCEDURE

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

- **Type of cycle:** 3 times Pre-vacuum (pressure min. 60 mBar).
- **Minimum sterilisation temperature:** 132°C (interval 0°C ÷ +3°C).
- **Minimum sterilisation time:** 4 minutes.
- **Minimum drying time:** 20 minutes.


All stages of sterilisation must be carried out by the operator in compliance with the most


current version of standards: UNI EN ISO 17665-1, UNI EN ISO 556-1 and ANSI/AAMI ST:46.

⚠ CAUTION: Do not sterilise the scaler handpiece with the instrument screwed in.


⚠ WARNING: Infection control - Sterilisable parts. Thoroughly remove all residual organic matter before sterilisation.

⚠ CAUTION: Carry out the sterilisation by using only an autoclave with steam from water. Do not use any other sterilisation procedure (dry heat, irradiation, ethylene oxide, gas, low temperature plasma, etc.).

 **CAUTION:** Do not exceed the permissible load of the steam-steriliser.

 **WARNING:** On completion of the sterilisation cycle in autoclave, the scaler handpiece remains at the sterilisation 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.

EN

» SPECIAL INFORMATION

Sterilisation parameters, in steam autoclave, used in Great Britain:

- Temperature: 134 °C;
- Time: 3 minutes.

10 DISINFECTION OF THE IRRIGATION CIRCUIT

Before carrying out the following steps run the Flush function (*Chapter 5.7 on page 38*)

NOTE: before starting the disinfection procedure make sure that both scaler

and polisher handpieces have been disconnected from the device (*Chapter 6.1 on page 44*)

EN

10.1 Irrigation Circuit Disinfection - Water Network

The procedure must be performed on both scaler and polisher circuits. Proceed as follows:

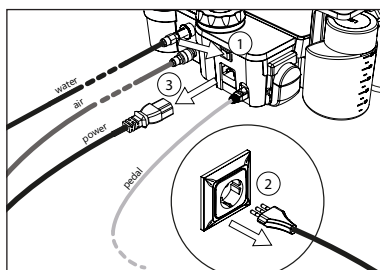
» REQUIRED MATERIALS

- CIDEX® OPA disinfectant solution
- Distilled water
- Irrigation circuit disinfection kit
- 60ml syringe with Luer Slip eccentric cone, without needle

» PREPARATION

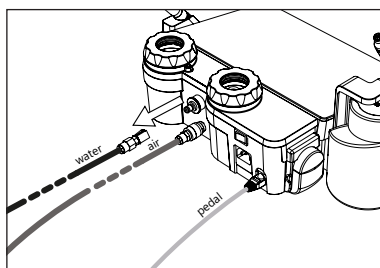
⚠ WARNING: Switch the device off. Turn the device off using the switch (Ref. 1), disconnect the power cord from the wall socket (Ref. 2) and device core unit (Ref. 3) before cleaning and sterilising.

1



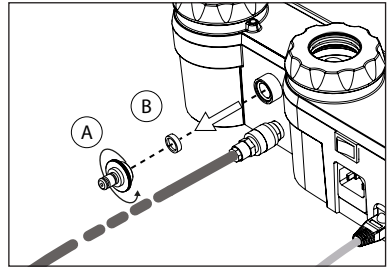
2

Disconnect the quick coupling connector of the external water supply from the device. (*Chapter 4.3 on page 16*);



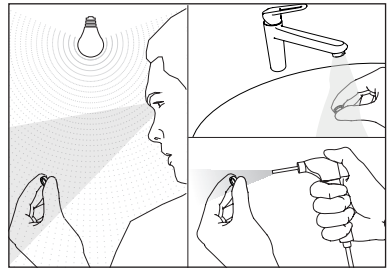
Unscrew the male connector for the external water circuit (Ref. A) and remove the water filter (Ref. B) (Chapter 12.7 on page 97);

3



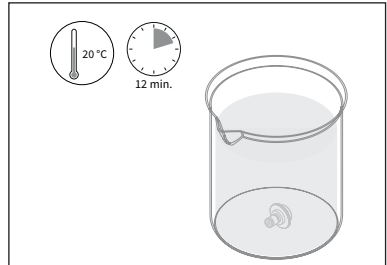
Check the integrity of the filter, rinse it, dry it with compressed air, making sure to remove any residual impurities.

4



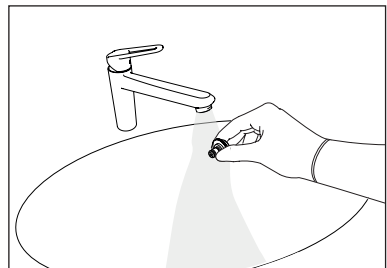
Completely immerse the male coupling for connection to the external water circuit in the disinfectant solution (CIDEX® OPA). Soak for 12 minutes at $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

5



Remove the male coupling from the disinfectant solution (CIDEX® OPA) and rinse it under running water.

6

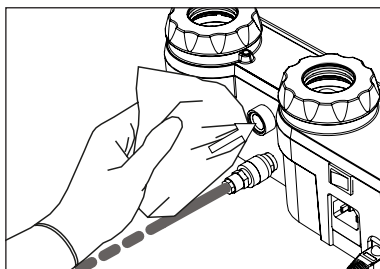


Store the filter and the male coupling in a clean and safe place for subsequent re-use.

DISINFECTION OF THE IRRIGATION CIRCUIT

Disinfect the internal surfaces of the seat where the male coupling will be inserted with a clean, soft, low-lint cloth dampened with the disinfectant solution (CIDEX® OPA).

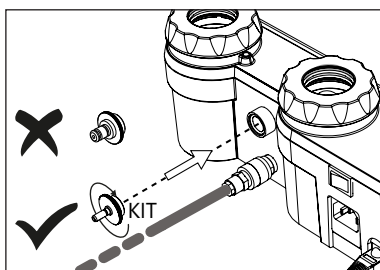
7



Screw in the male coupling supplied with the "Irrigation Circuit Cleaning Kit" into the housing until it reaches the stop.

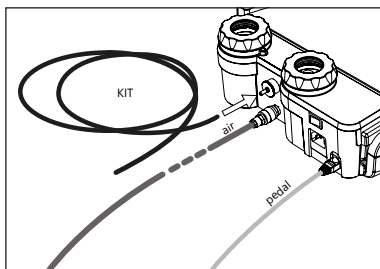
8

⚠ CAUTION: Check the integrity of the "Irrigation Circuit Cleaning Kit". Replace the "Irrigation Circuit Cleaning Kit" in case of wear or damage.



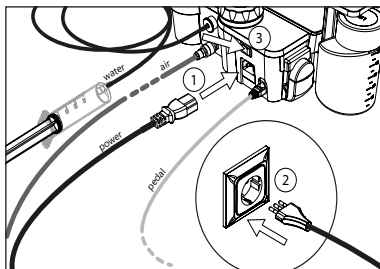
If previously disconnected (for example, for cleaning), connect the hose supplied with the kit to the male water coupling.

9



Connect the power cord to the device (Ref. 1) and to a wall socket (Ref. 2). Turn on the device on using the switch located at the back (Ref. 3).

10



EN

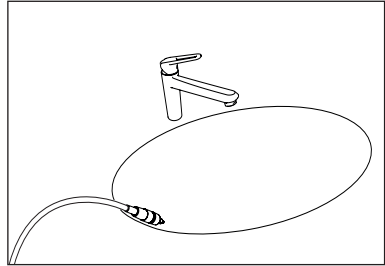
» PROCEDURE - AIR POLISHER SIDE

Make sure that all steps from point 1 to point 10 have been executed.

11

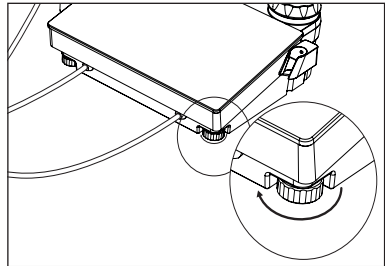
Lift the scaler hose and place it over a container or sink to contain the liquid that will flow out during the procedure.

12



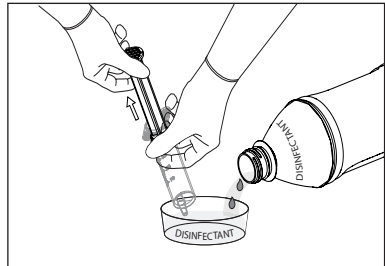
Completely open the right-hand knob on the front right of the device.

13



Aspirate with the syringe at least 60ml of disinfectant (CIDEX® OPA), making sure there is no air inside.

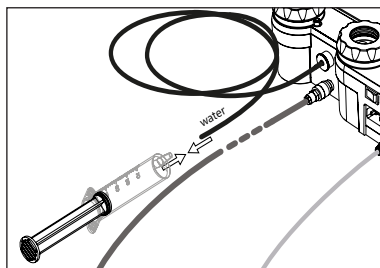
14



DISINFECTION OF THE IRRIGATION CIRCUIT

Connect the syringe to the end of the hose previously connected to the male water connection. (see point 9 of the procedure);

15

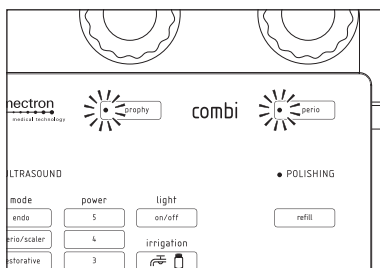


EN

Select "prophy" or "perio" on the touch keyboard.

16

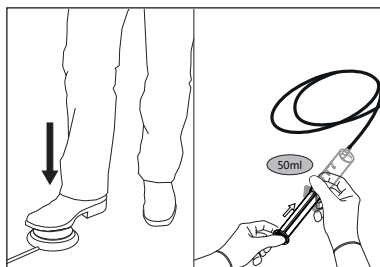
NOTE: Make sure that both powder containers are present and correctly positioned in their seats, otherwise it will not be possible to activate the "Flush" function.



Press the pedal until 50 ml of disinfectant have been injected, leaving the remaining 10ml in the syringe.

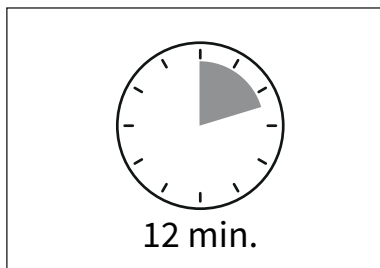
17

CAUTION: Do not apply excessive pressure to the syringe plunger. The size of the irrigation circuit tubes is small, and it is normal for the injection to be slow.



Wait for 12 minutes.

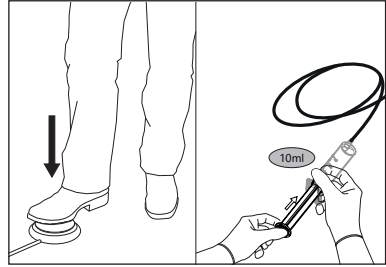
18



Press the pedal and inject the remaining 10 ml from the syringe.

⚠ CAUTION: Do not apply excessive pressure to the syringe plunger. The size of the irrigation circuit tubes is small, and it is normal for the injection to be slow.

19

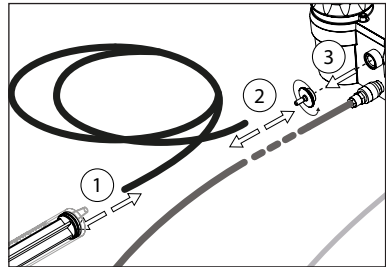


Disconnect the syringe and repeat points from 14 to 19.

20

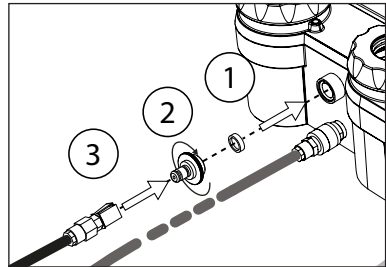
Remove the syringe (Ref. 1), the hose (Ref. 2) and unscrew the male coupling used (Ref. 3).

21



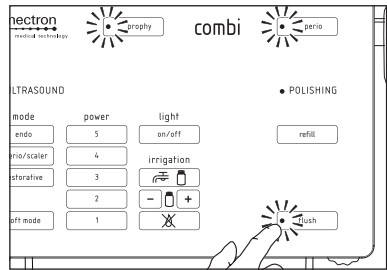
Re-insert the previously cleaned water filter (see point 4) in its seat - Ref. 1 -, screw in the original and previously disinfected male coupling (see points 5 and 6) - Ref. 2 - and reconnect the quick coupling of the external water circuit - Ref. 3.

22



Run 3 consecutive "Flush" cycles (see Chapter 5.7.2 on page 41).

23



EN

» PROCEDURE - ULTRASOUND - SCALER PART

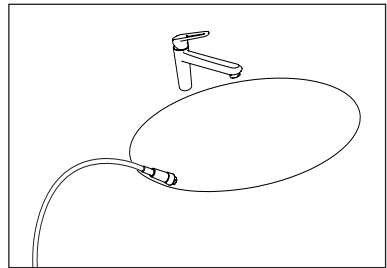
Make sure that all steps from point 1 to point 10 have been executed.

24

Lift the scaler hose and place it over a container or sink to contain the liquid that will flow out during the procedure.

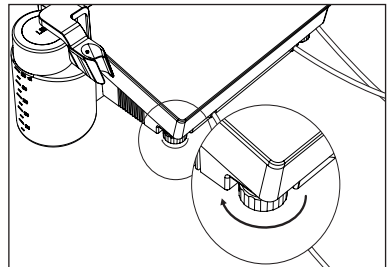
25

⚠ CAUTION: Make sure that the polisher hose is in its housing otherwise the device remains inactive.



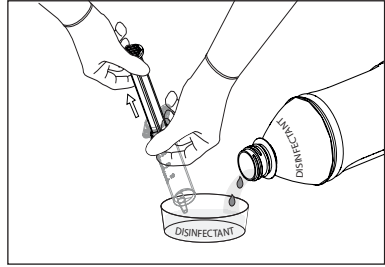
Completely open the left-hand knob in the front of the device.

26



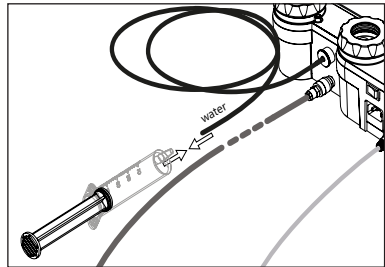
Using the syringe, aspirate 60ml of disinfectant (CIDEX® OPA), making sure there is no air inside.

27



Connect the syringe to the end of the hose previously connected to the male water connection.

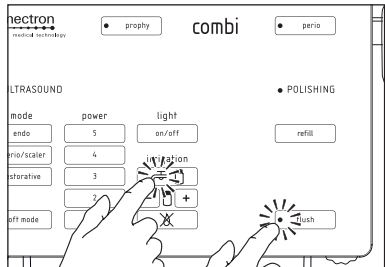
28



Press the "flush" button on the touch keyboard and select the external irrigation circuit (faucet symbol).

29

NOTE: Ensure both powder containers are present and properly inserted in their slots; otherwise, the "flush" function cannot be activated.



Press and release the pedal. When the "Flush" cycle begins, start injecting the disinfectant with the syringe.

During the "Flush" cycle, inject 50ml of disinfectant, leaving the remaining 10ml in the syringe.

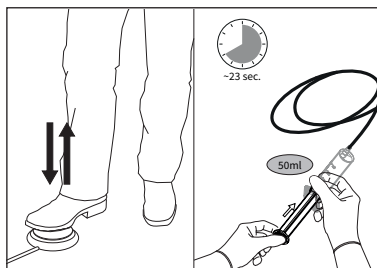
The "Flush" cycle on the "Ultrasound" part lasts about 23 seconds.

NOTE: The "Flush" cycle on the "Ultrasound" part can be interrupted at any time by pressing and releasing the pedal. Before running the "Flush" cycle on the "Ultrasound" part check that the left-hand knob in the front part of the device is open. At the end of the "Flush" cycle, stop injecting the liquid with the syringe.

CAUTION: Do not exert excessive pressure on the syringe plunger. The size of the irrigation circuit pipes is small and it is normal that the injection proceeds slowly.

NOTE: If the 50ml of disinfectant are injected before the Flush cycle is completed, wait for it to finish. If the cycle ends before the full 50ml have been injected, repeat the Flush cycle until the 50ml have been completely injected.

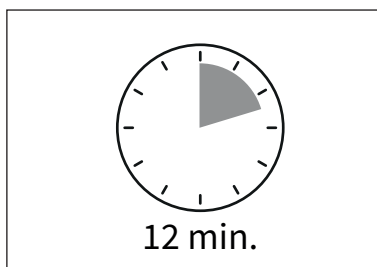
30



EN

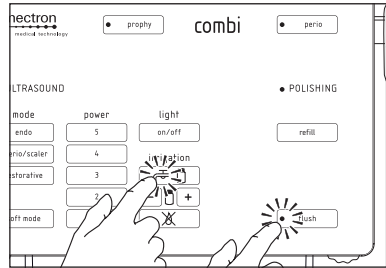
Wait for 12 minutes.

31



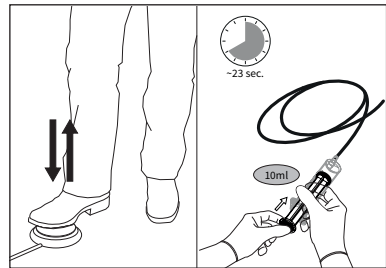
Press the "flush" button on the touch keyboard and select the external irrigation circuit (faucet symbol)

32



Press and release the pedal. When the "Flush" cycle begins, start injecting the remaining disinfectant with the syringe. **During the "Flush" cycle, inject the 10ml of remaining disinfectant.** The "Flush" cycle on the "Ultrasound" part lasts about 23 seconds.

33



NOTE: The "Flush" cycle on the "Ultrasound" part can be interrupted at any time by pressing and releasing the pedal. Before running the "Flush" cycle on the "Ultrasound" part check that the left-hand knob in the front part of the device is open. At the end of the "Flush" cycle, stop injecting the liquid with the syringe.

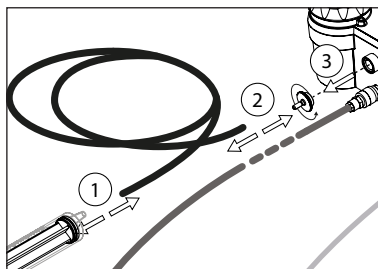
CAUTION: Do not exert excessive pressure on the syringe plunger. The size of the irrigation circuit pipes is small and it is normal that the injection proceeds slowly.

NOTE: If the 10ml of disinfectant are injected before the Flush cycle is completed, wait for it to finish. If the cycle ends before the full 10ml have been injected, repeat the Flush cycle until the 10ml have been completely injected.

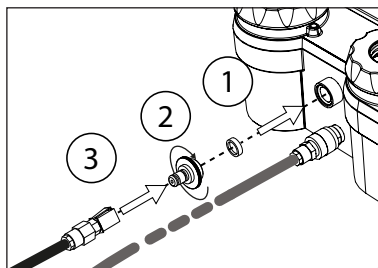
34

Disconnect the syringe and repeat points from 27 to 33.

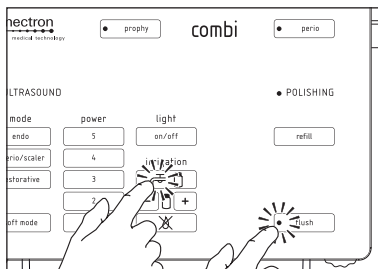
35 Remove the syringe (Ref. 1), the hose (Ref. 2) and unscrew the male coupling used (Ref. 3).



36 Re-insert the previously cleaned water filter in its seat - Ref. 1 -, screw in the original and previously disinfected male coupling - Ref. 2 - and reconnect the quick connector of the external water circuit - Ref. 3.



37 Run 3 consecutive "Flush" cycles (see Chapter 5.7.1 on page 38), assuring to select the external irrigation circuit (faucet symbol).



⚠ CAUTION: Before connecting and using the scaler handpiece, make sure that the electrical contacts on both the scaler handpiece and its cord are perfectly dry.

10.2 Disinfection of the Irrigation Circuit - Bottle

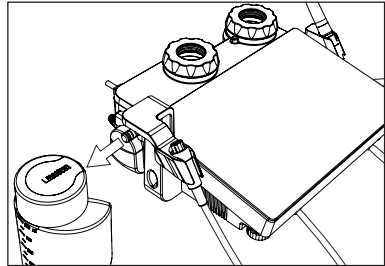
» REQUIRED MATERIAL

- CIDEX® OPA disinfectant solution
- Distilled water

» PROCEDURE

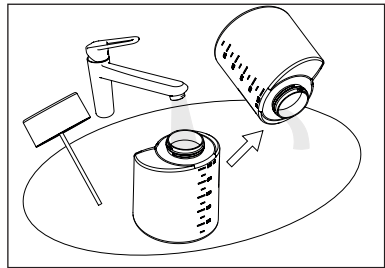
Disconnect the irrigation bottle from the device, pulling it outward.

38



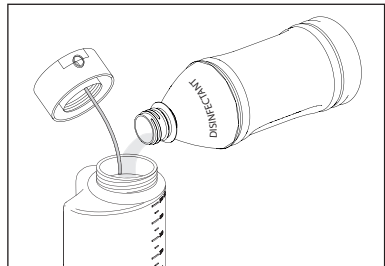
Unscrew the cap from the irrigation bottle and empty it.
Rinse the irrigation bottle with running water.

39



Fill the irrigation bottle with 200ml of disinfectant (CIDEX® OPA) and close the cap.

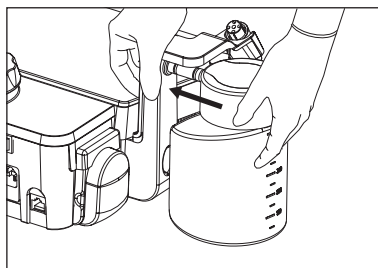
40



Keep the irrigation bottle in a vertical position and push it towards the device's body until it is firmly connected.

41

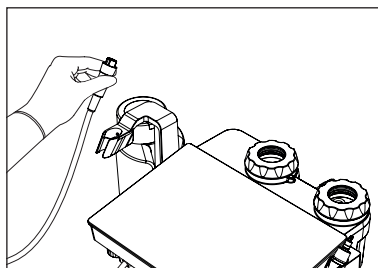
CAUTION: Do not invert the bottle as its cap is not airtight. Leakage of saline solution or aggressive liquids can damage surfaces.



Lift the scaler hose.

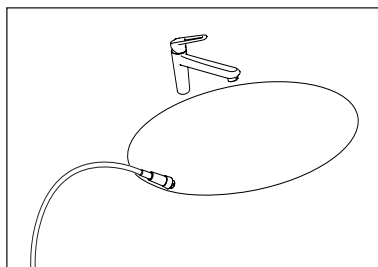
42

CAUTION: Make sure that the polisher hose is in its housing otherwise the device remains inactive.



Place the hose over a container or sink to contain the liquid that will flow out during the procedure.

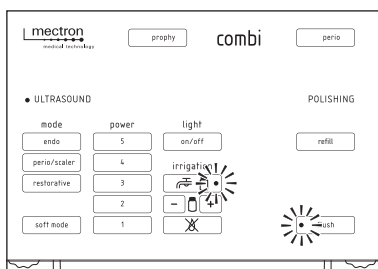
43



Select the bottle irrigation circuit by pressing the "irrigation" key. Select "Flush" on the touch keyboard

44

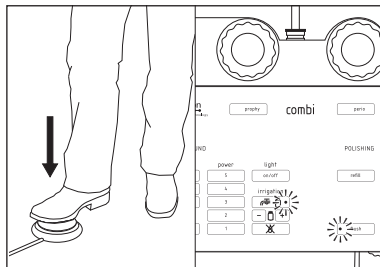
All other selectable options on the touch surface will be disabled.



To start the "Flush" function, press the foot pedal once and release it. The LEDs of the function and the type of irrigation selected will alternately flash. The progress of the cycle is indicated with brief sequence of acoustic signals.

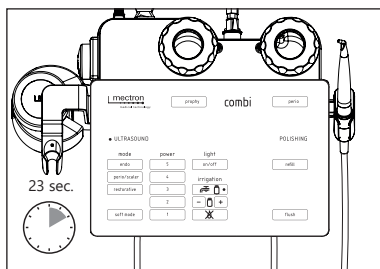
NOTE: You can exit the "Flush" mode at any time by pressing "Flush", the touch surface is enabled again, and displays the last setting used.

45



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

46

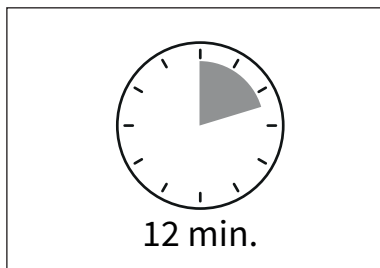


Repeat the "Flush" cycle (points 44 to 46) a second time.

47

At the end of the second "Flush" cycles, wait 12 minutes.

48

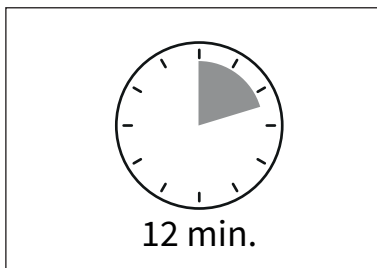


Repeat the "Flush" cycle (points 44 to 46) another 2 times.

49

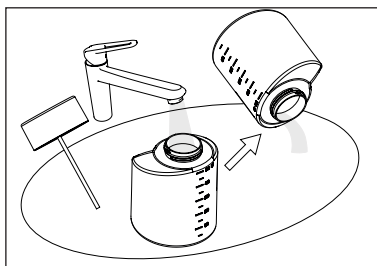
At the end of the "Flush" cycles, wait 12 minutes.

50



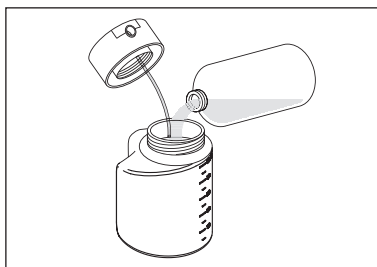
Disconnect the irrigation bottle from the device.
Unscrew the cap from the irrigation bottle and drain the remaining liquid;
Rinse the irrigation bottle with running water.

51



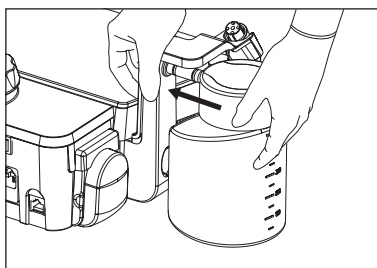
Fill the irrigation bottle with 100ml of demineralized water.

52



Keep the irrigation bottle in a vertical position and push it towards the device's body until it is firmly connected.

53



⚠ CAUTION: Do not capsize the Irrigation Bottle as its cap is not watertight. The leaking of potentially aggressive liquids can damage the surfaces.

Run 3 "Flush" cycles (points 44 to 46).

54

⚠ CAUTION: If the handpiece is positioned back in its support, with the "Flush" function selected (flashing LED) but not running, the function is deactivated;

⚠ CAUTION: During the "Flush" cycle, i.e. when the function has been selected and activated by pressing the pedal, if the

handpiece is positioned back in its support, the cycle is not interrupted.

⚠ CAUTION: Before connecting and using the scaler handpiece, make sure that the electrical contacts on both the scaler handpiece and its cord are perfectly dry.

EN

11 DECONTAMINATION OF THE IRRIGATION CIRCUIT

It is recommended to keep the device's irrigation line clean in order to prevent any microbial contamination. A regular cleaning and maintenance protocol should be adopted to clean and protect the dental unit's irrigation lines. The Manufacturer recommends using EPA-registered dental unit irrigation lines cleaners (for example MicroCLEAR). Decontamination by means of chlorine dioxide should be applied on a daily basis at the end of the workday, pursuant to the following protocol:

- Perform Flush cycles with water to eliminate any residual traces from the patients prior to disconnecting the handpieces (*Chapter 5.7 on page 38*);
- Disconnect the device from the water sources (mains water supply; containers (*Chapter 4.3 on page 16*);
- Inject chlorine dioxide into the connection of the mains water supply by means of a 60 cc syringe; (*Chapter 10 on page 75*);
- Inject chlorine dioxide in any additional bottle-fed waterlines by filling the source containers with a solution prepared according to the manufacturer's instructions and activating a Flush cycle, thus ensuring that the germicidal solution infuses the entire system;
- Leave the germicidal agent in the waterlines overnight and during the weekend;
- Prior to the first use the following workday, re-connect the water sources and perform 3 Flush cycles to rinse the waterlines

12 MAINTENANCE

12.1 Maintenance After Every Treatment

At the end of each treatment, proceed with the following activities:

- Perform a complete cleaning cycle of the irrigation circuits using the "Flush" function (see *Chapter 5.7 on page 38*) both on the Ultrasound side and the Polishing side for all types of irrigation;
- Immediately disassemble the different parts (see *Chapter 6.1 on page 44*) and proceed to their cleaning and sterilisation (see *Chapter 6.4 on page 52*).
- Clean the not-sterilizable parts (*Chapter 6.3 on page 49*).

12.2 Daily Maintenance

Regardless of the time elapsed since the last treatment and use of the device, at the end of the day, proceed with the activities described here below:

Ultrasound Side

1. Perform "Flush" by using both types of irrigations:
 - Bottle Water
 - External irrigation circuit.
2. Remove and empty the water bottle (see *Chapter 6 on page 44*).

⚠ WARNING: Infection control. Do not leave liquids in the bottle for long periods of time. The bottle must be filled just immediately before a treatment. If the bottle has been filled without having used the device, it must be emptied at the end of the day.

Air-polishing Side

3. Start the Refill function if the powder containers are still pressurized (see *Chapter 5.6.1 on page 36*).
4. Remove and empty both powder containers (see *Chapter 6.1 on page 44*).
5. Blow compressed air in the powder container housings, each time the containers are removed in order to eliminate any powder residual. Do not use water or lubricants.
6. Clean the powder containers with compressed air (see *Chapter 12.8 on page 98*). Put the empty powder containers back into their correct position in the device.
7. Start "Flush" on Air-polishing side (see *Chapter 5.7 on page 38*).


Both Sides

8. Clean the parts of the device that cannot be sterilised (see *Chapter 6.3 on page 49*).
9. Reconnect the empty water bottle and perform the Decontamination or Disinfection of the Irrigation circuit.

12.3 Transport or Long Inactivity Periods

In case the device is not used for more than 72h perform the following actions:

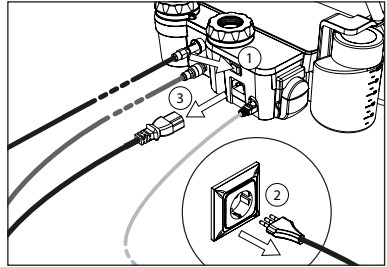
1. Empty the powder containers.
2. Run a complete cleaning cycle of the irrigation circuit using the "Flush" function (see *Chapter 5.7 on page 38*) for both the Ultrasound and Polishing parts.
3. Perform a complete disinfection of all the irrigation circuits (see *Chapter 10 on page 75*).
4. Drain the irrigation circuits of any residual water, removing the bottle and running the "Flush" cycle for the Ultrasound part.
5. Eliminate the condensate water from the air filter (see *Chapter 12.11 on page 102*).
6. Disconnect the device from the power mains and from the air and water circuits.
7. Clean and dry the water filter (see *Chapter 12.7 on page 97*).
8. Follow the steps outlined in *Chapter 10*, but this time the syringe should be filled with air instead of disinfectant.
9. Repeat all the steps, there will be no need to wait for 12 minutes after the air injection.
10. In case of long periods of non-use, place the device back in its original packaging, in a safe place.
11. Before using the device again after a long inactivity period:
12. Perform a complete cleaning cycle of the irrigation circuit using the "Flush" function (see *Chapter 5.7 on page 38*) both on the Ultrasound side and the Polishing side.
13. Perform again a complete disinfection of all the irrigation circuits (see *Chapter 10 on page 75*).
14. Clean and sterilise the handpiece and accessories following the instructions in *Chapter 6, 7, 8, 9*.
15. Check that the Piezo Tips are not worn, deformed or broken, with particular attention to the integrity of the tip.

 **WARNING:** Periodically check the integrity of the power supply cable; if damaged, replace it with an original Mectron spare part.

12.4 Unclogging the Device Polisher Line

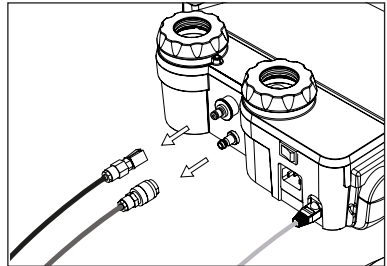
⚠ WARNING: Switch the device off. Switch the device off using the switch (Ref. 1), disconnect the power supply cable from the wall socket (Ref. 2) and device core unit (Ref. 3) before carrying out the cleaning and sterilisation tasks.

1



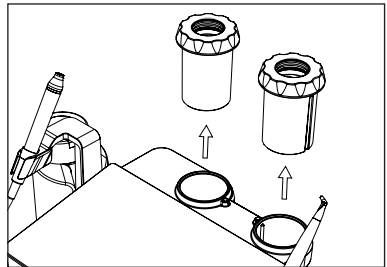
Disconnect the Air and the Irrigation supply hoses from the device.

2



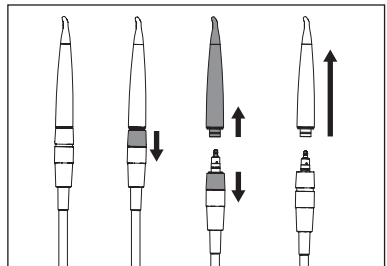
Remove both powder containers from their seat.

3



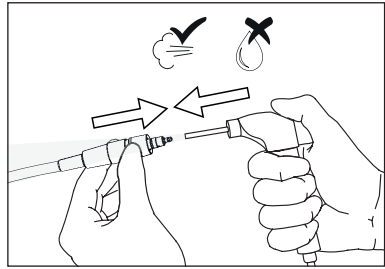
On the quick coupling of the cord, slide the ring and hold it in position, then extract the air-polishing handpiece, and finally release the ring of the handpiece.

4



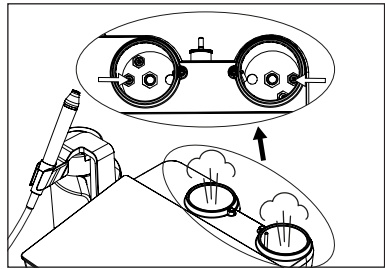
Take the polisher cord attached to the device and blow compressed air into the frontal part of the cord connector.

5



In case any clogging was present in the powder line inside the device, the air coming out from the powder container seats will free it.

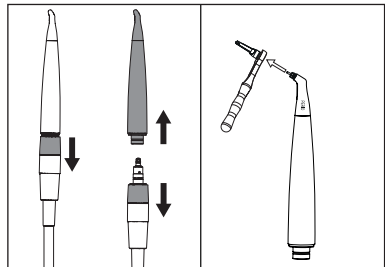
6



12.5 Unclogging the Air Polisher Handpiece

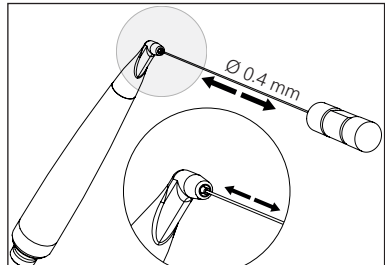
Disconnect the air polisher handpiece in use, and the Subgingival Perio Tips, if used (see Chapter 5.6 on page 34).

1



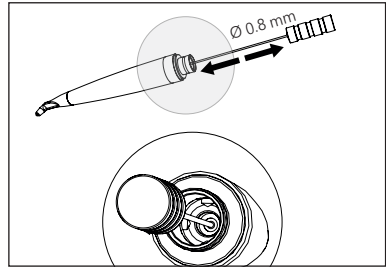
Remove the clogging by inserting the 0.4mm diameter needle from the front of the polisher handpiece.

2



Remove the clogging by inserting the 0.8mm diameter needle from the back of the polisher handpiece.

3



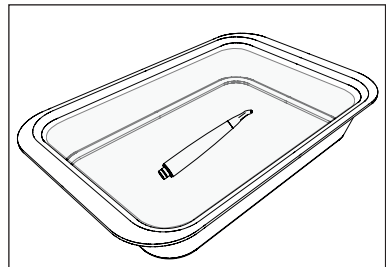
Remove now any powder residuals by blowing compressed air into the air polisher handpiece.

4



In case the mechanical actions has not been enough, leave the handpiece soaked in a 2% Acetic Acid Solution.

5

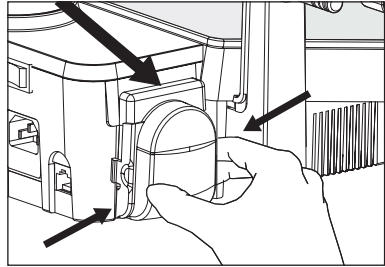


12.6 Replacing the Peristaltic Pump

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.

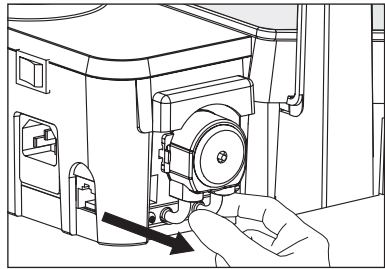
⚠ CAUTION: Before carrying out operations on the peristaltic pump, make sure the device is unplugged and that the liquids container is not connected.

1



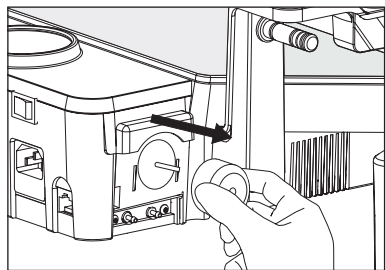
Remove the two tubes of the pump from the respective clutches positioned below it.

2



Extract the peristaltic pump from its seat, pulling it towards yourself. Use caution as pieces may detach.

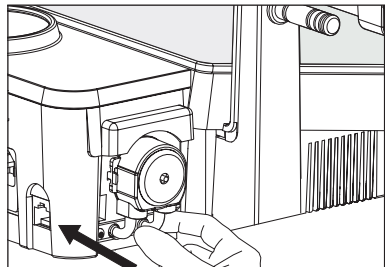
3



Attach the new peristaltic pump onto the base until you hear it click in, and connect the two pump tubes to the respective couplings underneath it.

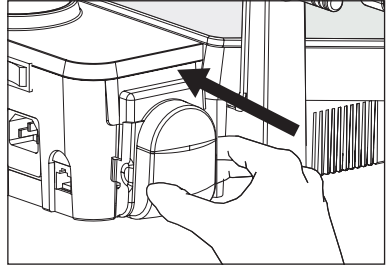
⚠ WARNING: Only use original spare parts.

4



Refit the plastic protection onto the peristaltic pump.

5



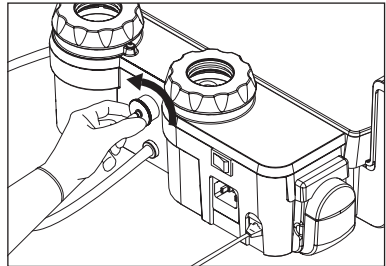
EN

12.7 Cleaning and/or Replacing the Water Filter

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

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

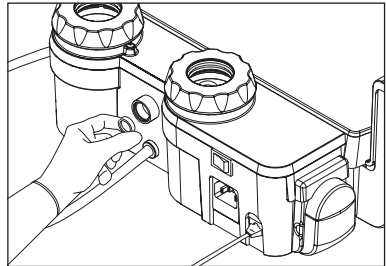
1



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

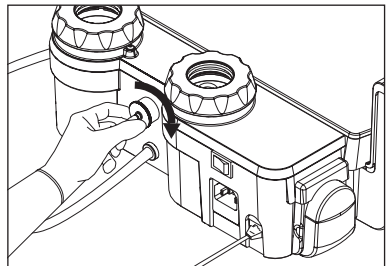
Extract the filter and wash it under running water to eliminate any impurities obstructing it.

2



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

3



NOTE: Replace the filter with a new one if it is damaged or washing is not effective.

12.8 Powder Containers and Caps Maintenance

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: Do not clean the powder containers with cleaning products, use compressed air only.

⚠ 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.

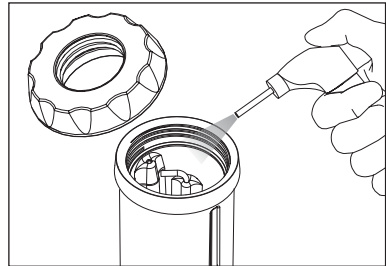
When the cleaning operation has been completed, reposition the containers on the device.

⚠ CAUTION: 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.

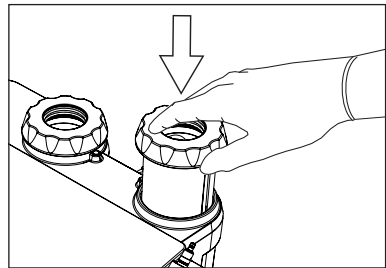
In case the o-ring of the cap is worn out, remove it being careful not to damage and/or scratch the surface where it is located.

NOTE: The procedure requires the use of a tool to extract and insert the O-rings. This tool is not included in the standard supply.

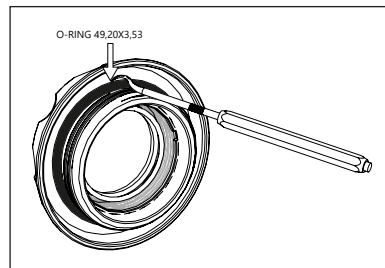
1



2

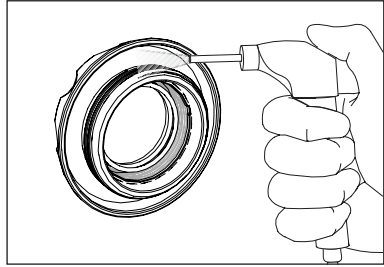


3



Clean accurately the o-ring seat from powder residues, by blowing compressed air.

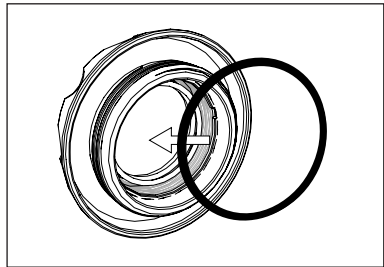
4



Place the new o-ring in its seat dilating it as little as possible during insertion.

5

⚠ CAUTION: Do not use sharp tools/utensils to position the new o-ring in its location.



EN

12.9 Replacing the Bottle O-Rings

⚠ CAUTION: Periodically check the O-ring state of wear and when necessary proceed to the replacement. It is suggested to replace the bottle O-rings once a year.

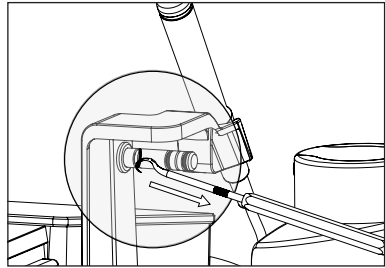
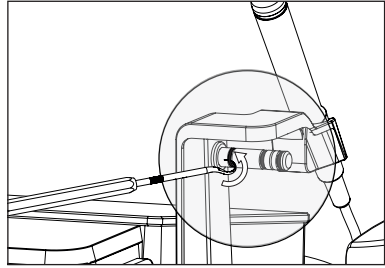
⚠ CAUTION: In case of no or difficult delivery of water from the bottle replace the O-rings even if they are not visually worn or damaged.

Remove the worn O-ring being careful not to damage and/or scratch the surface where it is located.

NOTE: The procedure requires the use of a tool to extract and insert the O-rings. This tool is not included in the standard supply.

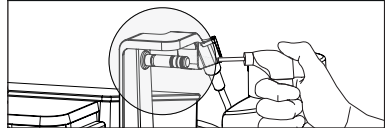
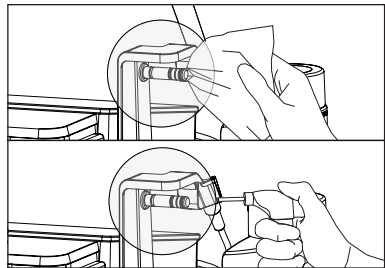
NOTE: If all 3 O-rings need to be replaced, remove and insert one O-ring at a time starting with the innermost one.

1



2

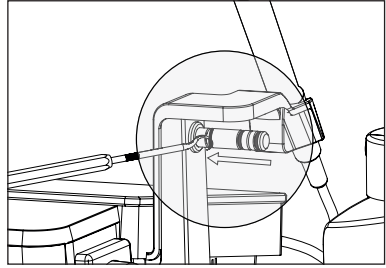
Clean and eventually dry accurately the o-ring seat, by blowing compressed air.



Place the new o-ring in its seat being careful not to damage it by drilling it with the removal tool and dilating it as little as possible during insertion.

NOTE: Do not use sharp tools/utensils to position the new o-ring in its location.

3



EN

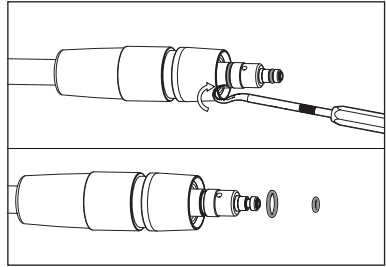
12.10 Replacing the Polisher Cord O-Rings

⚠ CAUTION: Periodically check the O-ring state of wear and when necessary proceed to the replacement.

Remove the worn O-rings being careful not to damage and/or scratch the surface where they are located.

NOTE: The procedure requires the use of a tool to extract and insert the O-rings. This tool is not included in the standard supply.

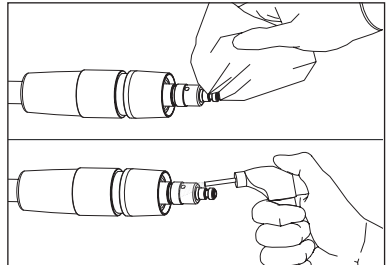
1



2

Clean and eventually dry accurately the o-ring seats, by blowing compressed air, before inserting the new o-rings.

NOTE: Do not use sharp tools/utensils to position the new o-ring in its location.



12.11 Eliminating the Condensation

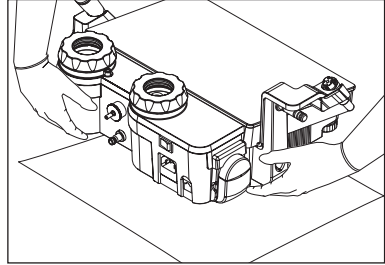
The device has an air filter, which intercepts any impurities and the condensation present in the pneumatic circuit.

To prevent the condensation entering into circulation in the device, check and empty the air filter weekly by performing the following operations:

Position an absorbent cloth underneath the device to collect the condensation.

⚠ CAUTION: This maintenance operation must be performed with the device on in order for the air circuit to be pressurized.

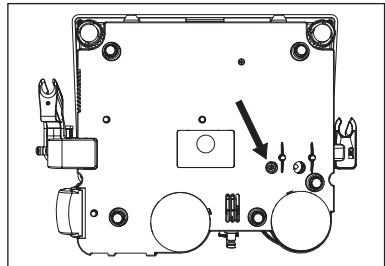
1



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

NOTE: However, it is recommended to use dry compressors and introduce a dehumidifier into the practice's pneumatic circuit.

2



12.12 Maintenance Schedule

Description	Q.ty each unit	Once every:
O-ring 6.5x2 (on the irrigation bottle connector)	3	1 year
O-ring 49.2x3.53 (Powder cap)	2	1 year
O-ring of the cleaner cord	2	1 year
Water filter	1	1 year
Powder containers	2	18 moths
Peristaltic pump	1	2 years
Light guide for the handpiece	1	2 years
Blue silicone O-ring (External irrigation line)	1	2 years

13 METHODS AND PRECAUTIONS FOR DISPOSAL

⚠ WARNING: Hospital waste. Treat the following objects as hospital waste:

- Instruments, when worn or broken;
- Instrument tightening wrench, when worn or broken;
- Air-polishing handpiece, when worn or broken;
- Cleaning needles, when worn or broken;
- K9 wrench, when worn or broken;
- Subgingival Perio Tip, after each use.

Disposable materials and materials that carry biological risk must be disposed of according to local regulations in force regarding hospital waste.

⚠ WARNING: When handling the

instruments, pay particular attention to the sharp, pointed, irregular parts to avoid any wounds or injuries.

combi touch and related accessories must be disposed of and treated as waste subject to separate collection.

Failure to comply with the previous points can result in a penalty pursuant to the directive on waste electrical and electronic equipment (WEEE).

The buyer has the option to return the device to the retailer when receiving a new one for disposal. Disposal instructions are available at Mectron for proper waste management.

EN

14 TECHNICAL DATA

Device compliant with Regulation (EU) 2017/745	Class IIa
Classification under the IEC/EN 60601-1	I Parts applied: type B (instrument) IP 20 (device) IP 22 (foot pedal model FS-05)
Essential performance	According to the standard IEC 80601-2-60 the device has no essential performance
Device for intermittent operation	55sec. ON - 30sec. OFF with irrigation ("ULTRASOUND" function and "POLISHING" function) 30sec. ON - 120sec. OFF without irrigation (mode: "endo" and "perio/scaler" power from 1 to 5, "restorative" power from 1 to 4).
Power Supply	100-240 V~ 50/60 Hz
Max. Power Consumption	90 VA
Fuses	Type 5 x 20 mm, T 2AL, 250V
Water supply:	Working pressure from 1 to 6 bar. Polisher and scaler part water circuit cleaning function - See <i>Chapter 5.7</i> on page 38. Connection via the supplied hose with quick coupling through an incorporated and removable filter.

Air supply:	Inlet pressure between 4 and 8 bar. Air circuit cleaning function - See <i>Chapter 12.11 on page 102</i> Connection via the supplied hose with quick coupling through an incorporated filter and pressure reducer.
Operating Conditions	from 10°C to +35°C Relative humidity from 30% to 75% Air pressure P: 800hPa/1060hPa
Transport and Storage Conditions (Excluding Powders)	from -10°C to +60°C Relative humidity from 10% to 90% Air pressure P: 500hPa/1060hPa
Altitude	lower than or equal to 2000 metres
Weights and dimensions	4.8Kg 410 x 260 x 145 mm (L x W x H) ^{a)}

a) W = width ; L = length ; H = height

14.1 ULTRASOUND - Scaler Part

Working Frequency	Automatic Scan From 24 KHz to 36 KHz
Power Level	"endo" "perio/scaler" "restorative" "soft mode"
Irrigation	Water circuit with continuous regulation. Peristaltic pump with continuous regulation via touch screen: <ul style="list-style-type: none"> • 7 flow rate levels, from 1 (approx. 5 ml/min) to 7 (approx. 30 ml/min). Possibility to exclude irrigation in "endo", "perio/scaler" and "restorative" powers, with power levels from 1 to 4.
Handpiece LED system:	ON/OFF function enabled: The handpiece LED lights up as soon as the machine starts working, and turns off 3 seconds after the foot pedal is released. ON/OFF function disabled: The handpiece LED is off. White LED light power risk free according to standard IEC/EN 62471.
Protections of the APC Circuit	Missing handpiece; Broken cord wire; Instrument not correctly tightened or broken;

14.2 AIR-POLISHING - Polisher Part

Polisher functions	Can be selected via touch screen: "Prophy" function - "Perio" function
Irrigation	Continuous regulation via knob. Water heating via heating element.

14.3 Electromagnetic Compatibility IEC/EN 60601-1-2

⚠ WARNING: Contraindications. Interference with other equipment
 Even if compliant with standard IEC/EN 60601-1-2, combi touch may interfere with other devices in the vicinity. combi touch must not be used near or stacked with other appliances. However, if this is necessary, the correct operation of the device in that configuration – and of all equipment – must be checked and monitored before starting the treatment.

⚠ WARNING: Portable and mobile radiocommunications equipment can influence the correct operation of the device.

⚠ WARNING: Contraindications. Interference from other equipment
 An electrosurgical scalpel or other electrosurgical units placed near the device **combi touch** may interfere with the proper functioning of the device.

⚠ WARNING: The device requires special EMC precautions and must be installed and commissioned in compliance with the EMC information in this chapter.

⚠ WARNING: The use of cables and components not supplied by MECTRON may adversely affect EMC performance.

14.4 Guide and Manufacturer’s Declaration - Electromagnetic Emissions

combi touch and related accessories, is designed to operate in the electromagnetic environment specified below. The purchaser or user of combi touch should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	combi touch uses RF energy only for its internal operation. Therefore, its RF emissions are very low and probably do not cause any interference with nearby electronic devices.
RF Emissions CISPR 11	Class B	combi touch is suitable for use in all buildings, including domestic buildings, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions of fluctuations voltage/flicker IEC 61000-3-3	Compliant	

14.5 Accessible Parts of the Casing

combi touch and related accessories, is designed to operate in the electromagnetic environment specified below.

The purchaser or user of combi touch should ensure that it is used in such an environment.

Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated EM RF fields ^{a)}	IEC 61000-4-3	3 V/m ^{d)} 80 MHz - 2.7 GHz ^{b)} 80 % AM at 1 kHz ^{c)}	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended and calculated distances from the equation applicable at the frequency of the transmitter.
RF proximity fields from wireless communication equipment	IEC 61000-4-3	See Chapter 14.7 on page 112	
Magnetic field at network frequency ^{d)}	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Power supply frequency magnetic fields should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See Chapter 14.8 on page 113	Portable and mobile RF communication equipment must be used at a separation distance of at least 0.15 m from the field sources.

- a) If used, the interface between the PATIENT'S physiological signal simulation and the device must be positioned within a 0.1 m radius of the vertical plane of the uniform field area in the same direction as the device.
- b) The device, which intentionally receives RF electromagnetic energy for its operation, must be tested at the receiving frequency. The test can be performed with other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test evaluates the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an environmental signal is within the passband. It is understood that the receiver may not function normally during the test.
- c) The test can also be conducted at other modulation frequencies identified through the RISK MANAGEMENT PROCESS.

- d) Only applicable to equipment and systems with magnetically sensitive components or circuits.
- e) Empty.
- f) Before applying the modulation.

14.6 Guide and the Manufacturer's Declaration - Electromagnetic Immunity

14.6.1 Power Connection BC Input

combi touch and related accessories, is designed to operate in the electromagnetic environment specified below.

The purchaser or user of combi touch should ensure that it is used in such an environment.

Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
Electrical fast transient/burst ^{l) o)}	IEC 61000-4-4	± 2 kV contact 100 KHz repetition frequency	The quality of the network voltage should be that of a typical commercial or hospital environment.
Pulses differential mode ^{b) j) o)}	IEC 61000-4-5	± 0.5 kV, ± 1 kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Pulses common mode ^{b) j) k) o)}	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conductive disturbances induced by RF fields ^{c) d) o)}	IEC 61000-4-6	3 V ^{m)} 0.15 MHz - 80 MHz 6 V ^{m)} in ISM bands between 0.15 MHz and 80 MHz ⁿ⁾ 80 % AM at 1 KHz ^{e)}	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended and calculated distances from the equation applicable at the frequency of the transmitter.
Voltage dips ^{f) p) r)}	IEC 61000-4-11	0% UT; 0.5 cycle ^{g)} A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° ^{q)}	The quality of the network voltage should be that of a typical commercial or hospital environment.
		0 % UT; 1 cycle ^{e)} 70 % UT; 25/30 cycle ^{h)} Single phase: at 0°	
Voltage interruptions ^{f) i) o)}	IEC 61000-4-11	0 % UT; 250/300 cycle ^{h)}	The quality of the network voltage should be that of a typical commercial or hospital environment.

- a) Empty.
- b) During the test, all the device cables must be connected.
- c) The calibration of the current injection terminals must be performed in a system at 150 Ω .
- d) If an ISM or amateur radio band is not present among the frequency samples, as appropriate, an additional test frequency has to be used in the ISM band or in the amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- e) The test can be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- f) Devices and systems with a Direct Current (DC) input power supply using AC to DC converters must be tested with a converter that complies with the MANUFACTURER'S specifications. Immunity test levels are applied to the AC power input of the converter.
- g) Only applicable to devices and systems connected to a single-phase Alternating Current (AC) power supply.
- h) For example, 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.
- i) Devices and systems with nominal input current above 16 A / phase must be disconnected from the power supply once every 250/300 cycles at any angle and from all phases simultaneously (if applicable). Devices and systems with battery backup, after the test, must resume operation using the power supply line. For devices and systems with a nominal input current lower than 16 A, all phases must be disconnected simultaneously.
- j) Devices and systems that do not have a surge protection device in the primary power circuit can only be tested at ± 2 kV between the line(s) and the earth (common mode) and at ± 1 kV between line(s) and line(s) (differential mode).
- k) Not applicable to CLASS II devices and systems.
- l) Direct coupling must be used.
- m) R.M.S., applied before modulation.
- n) The ISM bands (industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.
- o) Applicable to devices and systems with NOMINAL input current less than or equal to 16 A / phase and devices and systems with NOMINAL input current greater than 16 A / phase.
- p) Applicable to devices and systems with NOMINAL input current less than or equal to 16 A / phase.
- q) At some phase angles, the application of this test to devices with a transformer on the input power supply may cause the opening of an overcurrent protection device. This can occur due to the saturation of the magnetic flow of the transformer core after the voltage drop. If this happens, the device must ensure BASIC SAFETY during and after the test.
- r) For equipment and systems that have multiple voltage settings or self-regulating voltage capacity, the test must be carried out at the input supply voltage specified in Table 1 - "Power input voltages and frequencies during the tests" of standard IEC 60601-1-2:2014/AMD1:2020.

14.6.2 Points of Contact With the Patient

combi touch and related accessories, is designed to operate in the electromagnetic environment specified below.

The purchaser or user of combi touch should ensure that it is used in such an environment.

Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) ^{c)}	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Conductive disturbances induced by RF fields ^{a)}	IEC 61000-4-6	3 V ^{b)} 0.15 MHz - 80 MHz 6 V ^{b)} in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 KHz	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.

a) The following applies:

- All connection cables with the patient must be tested, either individually or grouped together.
- The connection cables with the patient must be tested using a current clamp unless the current clamp is not suitable. If a current clamp is not suitable, an EM clamp must be used.
- In any case, no intentional decoupling device should be used between the injection site and POINT OF CONNECTION TO THE PATIENT.
- The tests can be performed with other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- The tubes that are intentionally filled with conductive liquids and intended to be placed in contact with the PATIENT must be considered connection cables with the patient.

- If an ISM or amateur radio band is not present among the frequency samples, as appropriate, an additional test frequency has to be used in the ISM band or in the amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM bands (industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b) R.M.S., applied before modulation.

c) The discharges must be applied without connection to an artificial hand and without connection to the PATIENT simulation. The PATIENT simulation can be connected after the test, if necessary, to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

14.6.3 Parts Accessible to the Input / Output Signals

combi touch and related accessories, is designed to operate in the electromagnetic environment specified below.

The purchaser or user of combi touch should ensure that it is used in such an environment.

Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) ^{e)}	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst ^{b) f)}	IEC 61000-4-4	± 1 kV contact 100 KHz repetition frequency	The quality of the network voltage should be that of a typical commercial or hospital environment.
Pulses Common mode ^{a)}	IEC 61000-4-5	± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conductive disturbances induced by RF fields ^{d) g) j) k)}	IEC 61000-4-6	3 V ^{h)} 0.15 MHz - 80 MHz 6 V ^{h)} in the ISM bands between 0.15 MHz and 80 MHz ⁱ⁾ 80 % AM at 1 KHz ^{c)}	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.

- a) This test applies only to output lines connected directly to the external cables.
- b) SIP/SOPS with maximum cable length less than 3 m are excluded.
- c) The tests can be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- d) The calibration of the current injection terminals must be performed in a system at 150 Ω.
- e) The connectors must be tested in accordance with paragraph 8.3.2 and Table 4 of the standard IEC 61000-4-2:2008. For insulated connector housings, perform the air discharge test on the connector housing and pins using the probe with the rounded tip of the ESD generator, with the exception that only the connector pins that are tested are those that can be reached or touched, under the conditions of INTENDED USE, by the standard probe shown in Figure 6 of the general standard, applied in a bent or straight position.
- f) The capacitive coupling must be used.
- g) If an ISM or amateur radio band is not present among the frequency samples, as appropriate, an additional test frequency has to be used in the ISM band or in the amateur radio band. This applies to each ISM and amateur radio band within the specified frequency

- range.
- h) R.M.S., applied before modulation.
- i) The ISM bands (industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.
- j) See IEC 61000-4-6:2013, Annex B, for the modified start frequency with respect to cable length and device size.
- k) SIP/SOPS with maximum cable length less than 1 m are excluded.

14.7 Specifications of the Tests for the Immunity of the Accessible Parts of the Casing to the Wireless RF Communications Device

combi touch and related accessories, is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The purchaser or operator of combi touch can help prevent electromagnetic interferences by guaranteeing a minimum distance between the mobile and portable RF communication devices (transmitters) and combi touch, as recommended below, in relation to the maximum output power of the radio communication devices.

Test Freq. (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation	Max power (W)	Distance (m)	Immunity test value (V/m)
385	380 - 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 Band LTE 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 Band LTE 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only uplink frequencies are included.

b) The carrier must be modulated using a square-wave signal with a duty cycle of 50%.

- c) As an alternative to FM modulation, the carrier can be pulse-modulated using an 18 Hz square-wave signal with 50% duty cycle. Although this does not represent actual modulation, it would be worst case.

NOTE: If necessary to reach the immunity test level, the distance between the transmitter antenna and combi touch can be reduced to 1 m. The test distance of 1 m is allowed by IEC 61000-4-3.

⚠ WARNING: Portable RF communication

equipment (including peripheral devices such as antenna cables and external antennas) must not be used closer than 30 cm to any part of the combi touch device, including the cables specified by the manufacturer. Otherwise, there may be a performance degradation of these appliances.

14.8 Proximity Magnetic Field Immunity in the Frequency Range From 9 kHz to 13.56 MHz

The following table outlines the specifications of the test for IMMUNITY of the CASING to proximity magnetic fields in the frequency range from 9 kHz to 13.56 MHz.



Test frequency	Modulation	Immunity test level (A/m)
30 kHz ^{a)}	CW	8
134.2 kHz	Pulse modulation ^{b)} 2.1 kHz	65 ^{c)}
13.56 MHz	Pulse modulation ^{b)} 50 kHz	7.5 ^{c)}


- a) This test applies only to devices intended for use in the HOME HEALTHCARE ENVIRONMENT.
- b) The carrier must be modulated using a square-wave signal with 50% duty cycle.
- c) r.m.s., before modulation is applied.

15 TROUBLESHOOTING

15.1 Diagnostic System and Symbols on the Touch Surface


combi touch is provided with a diagnostic circuit that allows the detection of malfunctions and viewing of their type on the touch surface by means of a symbol. Users, by using the following table, are guided to identifying and the possible resolution of the malfunction detected.

Symbol on touch surface	Possible cause	Solution
	Handpiece/cord electrical contacts wet	Thoroughly dry the contacts with compressed air (see <i>Chapter 8 on page 70</i>).
	Scaler handpiece combi touch not connected to the device	Connect the scaler handpiece (see <i>Chapter 4.3 on page 16</i>).
	Scaler handpiece failure	Replace the scaler handpiece
	Tuning circuit malfunction	Contact an Authorised Mectron Service Centre.
	Instrument not present or not properly tightened on the scaler handpiece	Unscrew the instrument and screw it back in correctly using the torque wrench (See <i>Chapter 5.4 on page 31</i>).
	Instrument broken, worn or deformed	Replace the instrument.
	Cord/handpiece electrical contacts wet	Thoroughly dry the contacts with compressed air (see <i>Chapter 8 on page 70</i>).

Symbol on touch surface	Possible cause	Solution
	Incorrect start-up procedure: the device was started with the foot pedal pressed.	Check that the foot pedal is not pressed down. If the problem persists, disconnect the foot pedal and potentially contact a Mectron Authorised Service Centre.
	Peristaltic pump malfunction	Check that there are no impediments to the rotation of the peristaltic pump. Check that the peristaltic pump and two tubes are correctly installed (see <i>Chapter 12.6 on page 96</i>).
	The device has been switched off and on again without waiting 5 seconds	Switch off and wait 5 seconds before switching the device on again.
	Faults on the electrical network, excessive electrostatic discharges or internal faults	Turn off and wait 5 seconds before switching the device on again If the warning persists, contact a Mectron Authorised Service Centre.
	A pressurised polisher container was opened without running the "refill" cycle.	Before opening one of the polisher containers, the "refill" cycle must be run (See <i>Chapter 5.6.1 on page 36</i>).
	One of the polisher containers has been removed from its seat without performing the "refill" cycle.	Before removing one of the polisher containers, the "refill" cycle must be run (See <i>Chapter 5.6.1 on page 36</i>).
	The selected polisher container is not correctly inserted in place.	Correctly insert the polisher containers until they are in contact.

NOTE: For diagnostic warnings not included in this list, contact the technical service desk.

15.2 Quick Troubleshooting

Problem	Possible Cause	Solution
The device does not start after the switch is set to "I".	The terminal of the electrical power cable has not been properly inserted in the rear socket of the device	Check that power supply cable is firmly connected
	The power supply cable is faulty	Check that the supply socket is working. Replace the power supply cable
	The fuses are out of order	Replace the fuses (See <i>Chapter 15.3 on page 120</i>)
The device is on but not working. No errors are reported on the touch surface.	The foot pedal plug is not properly inserted in the device socket	Properly insert the foot pedal plug into the connector at the back of the device (see <i>Chapter 4.3 on page 16</i>).
	The foot pedal does not work properly	Contact an Authorised Mectron Service Centre
The device is on but not working. One of the following symbols appears on the screen: 	See <i>Chapter 15.1 on page 114</i> for the possible cause depending on the symbol	See <i>Chapter 15.1 on page 114</i> for the action to be taken depending on the symbol
During operation a faint whistling noise can be heard coming from the scaler handpiece.	The instrument is not correctly tightened on the handpiece	Unscrew the instrument and screw it back in correctly using the Mectron torque wrench (See <i>Chapter 5.4 on page 31</i>)
	The irrigation circuit has not been completely filled	Fill the irrigation circuit using the "flush" function (See <i>Chapter 5.7 on page 38</i>)
The pump rotates properly, but liquid leaks from the handpiece when it is stopped.	The peristaltic pump is worn.	Replace the peristaltic pump (See <i>Chapter 12.6 on page 96</i>).
When the foot pedal is pressed, a prolonged signal is emitted and the ULTRASOUND and AIR-POLISHING function LEDs start to flash.	The foot pedal has been pressed with both handpieces stowed in their housings.	Lift the handpiece to be used before pressing the foot pedal.

Problem	Possible Cause	Solution
Poor performance	The instrument is not correctly tightened on the handpiece	Unscrew the instrument and screw it back in correctly using the Mectron torque wrench (See <i>Chapter 5.4 on page 31</i>)
	Instrument broken, worn or deformed	Replace the instrument with a new one
	Insufficient or excessive powder level in the container.	Restore the correct level of powder in the container (See <i>Chapter 4.3 on page 16</i>).
No liquid flows out from the instrument or air-polishing handpiece during operation	Device not connected to the water circuit	Check the connection to the water circuit (See <i>Chapter 4.3 on page 16</i>).
	The instrument is the "Dry Work" type without a liquid passage	Use an instrument type with a liquid passage
	The instrument is clogged	Unscrew the instrument/air-polishing handpiece from the handpiece and free the water passage of the instrument/air-polishing handpiece by blowing compressed air through it. If the problem persists, replace the instrument/air-polishing handpiece with a new one.
	The quick coupling on the air-polishing handpiece cord is clogged	Contact an Authorised Mectron Service Centre
	Irrigation is disabled	Activate irrigation and adjust the flow rate (See <i>Chapter 5.2.1 on page 22</i>).
	The water tap on the device is closed	Regulate the flow of water using the knob dedicated to the function used.
	Water filter clogged	See <i>Chapter 12.7 on page 97</i> .
	The liquid bottle is empty	Fill the bottle
	The bottle is not installed correctly	Connect the bottle to the machine body correctly
	The silicone tubes of the pump are not correctly installed	Check the tube connections (see <i>Chapter 12.6 on page 96</i>).
The peristaltic pump is worn	Replace the peristaltic pump (See <i>Chapter 12.6 on page 96</i>)	

Problem	Possible Cause	Solution
No powder flows out from the air-polishing handpiece during operation.	Device not connected to the air circuit	Check the connection to the air circuit (See <i>Chapter 4.3 on page 16</i>).
	Air-polishing handpiece clogged due to an excessive moisture content in the powder or insufficient cleaning/maintenance	Remove the powder from the container and clean it using a dry cloth. Disconnect the air-polishing handpiece and clear the air passage by blowing compressed air through it. See <i>Chapter 12.4 on page 93</i> If the problem persists, replace the air-polishing handpiece with a new one.
	The amount of powder in the container exceeds the maximum level	Remove the powder from the container and clean it using a dry cloth. Restore the correct level of powder in the container (See <i>Chapter 4.3 on page 16</i>).
	Unsuitable powder	Use the correct powder to ensure proper functioning of the device.
Powder leak through the polisher container cap	Cap not correctly tightened	Screw the cap correctly.
	Powder residue in the thread	Clean the polisher container thread (See <i>Chapter 12.8 on page 98</i>).
Poor cleaning performance	Insufficient pressure in the air supply circuit	Check air supply circuit pressure (4-8 bar max).
	Insufficient or excessive powder level in the container	Correct level of powder in the container.
	Unsuitable powder	To ensure the proper functioning of the device, check that the correct powder is used.
	The air-polishing handpiece is clogged due to an excessive moisture content in the powder or insufficient cleaning/maintenance	Remove the powder from the container and clean it using a dry cloth. Disconnect the air-polishing handpiece and clear the air passage by blowing compressed air through it. See <i>Chapter 12.4 on page 93</i> If the problem persists, replace the air-polishing handpiece with a new one.

Problem	Possible Cause	Solution
One of the polisher container caps does not unscrew	The device is on and the polisher container is pressurised	Run the "refill" cycle before opening one of the polisher containers (See <i>Chapter 5.6.1 on page 36</i>).
	The "refill" cycle has been performed but the polisher containers have remained pressurised because the air-polishing handpiece is clogged	Read the section on cleaning the air-polishing handpiece (See <i>Chapter 12.5 on page 94</i>).
	The "refill" cycle has been performed but the polisher containers have remained pressurised because the polisher cord is clogged	Contact an Authorised Mectron Service Centre.

15.3 Replacing the Fuses

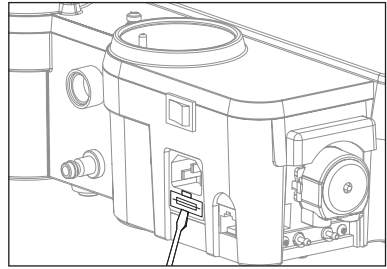
⚠ WARNING: Switch off the device.
Always switch the device off using the main switch and disconnect it from the

power socket before performing the next procedure.

EN

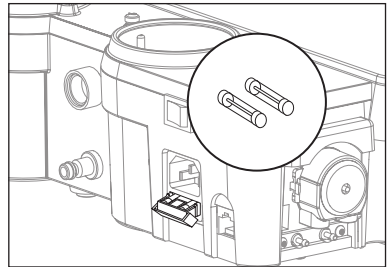
Use a flat tool, if necessary, to open the fuse box located below the power socket;

1



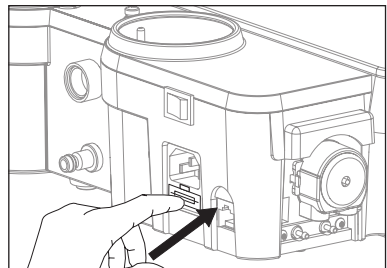
Extract the fuse holder compartment;
⚠ WARNING: Replace the fuses in respect of the characteristics indicated in Chapter 13 on page 103.

2



Reinsert the compartment in its place.

3



15.4 Shipping to an Authorised Mectron Service Centre

If technical assistance is required on the machine, contact an Authorised Mectron Service Centre or your Dealer. Do not try to repair or modify the device and its components.

Clean and sterilise all parts to be sent to a Mectron Authorised Service Centre following the instructions in *Chapters 6, 7, 8, 9* of this Manual.

Leave the sterilised parts in the bag which certifies the sterilisation process.

The cleaning and sterilisation demands comply with the mandatory requirements for workplace health and safety protection pursuant to Legislative Decree 81/08 and Italian laws.

If the client fails to comply with the requirements, Mectron reserves the right to charge them the cost of cleaning and sterilisation or to refuse goods that arrive in unsuitable conditions, returning them at the client's own expense for proper cleaning and sterilisation.

The device and its accessories must be returned properly packaged with all components and a slip stating:

- Details of owner and contact number;
- Product name;
- Serial number and/or batch number;
- Reason for return / description of failure;
- Photocopy of purchase bill or invoice for the device.

CAUTION: Packaging

Pack the device in its original packaging to avoid damage during transport.

Once the material is received at the Authorised Mectron Service Centre, the qualified technical personnel will evaluate the problem. The repair will be made only upon acceptance by the end client. For further details contact your nearest Authorised Mectron Service Centre or your dealer.

Unauthorised repairs can damage the system and void the guarantee and furthermore will disclaim Mectron from any liability for direct or indirect damage to persons or property.

16 WARRANTY

All Mectron devices undergo a thorough final inspection to ensure full functionality before being marketed.

Mectron provides a warranty for combi touch, purchased new from a Mectron dealer or importer, which covers defects in material and workmanship for a period of:

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

The other components are not covered by the warranty.

During the warranty period, Mectron undertakes to repair (or, at its discretion, to replace) the parts of products free of charge, which, according to its judgement, are proven to be defective.

Full replacement of Mectron products is not covered by the warranty.

The manufacturer's warranty and device approval are not valid in the following cases:

- The device is not used in accordance with the intended use.
- The device is not used in accordance with all the instructions and requirements outlined in this manual.
- The electrical system of the places where the device is used does not comply with the laws in force and relative requirements.
- Assembly operations, extensions, adjustments, updates and repairs are carried out by personnel not authorised by Mectron.
- The environmental conditions for preservation and storage of the device do not comply with the requirements indicated in *Chapter 14 on page 103*.
- Use of non-original Mectron instruments, components and replacement parts that may compromise the correct operation of the device and cause injury to the patient.
- Accidental breakage during transport.
- Damage due to incorrect use or carelessness, or due to connection to a voltage other than that envisaged.

- Expired warranty.

The expected service life of the device is minimum 5 years.

The service life / duration does not establish a limit of use; the service life of the device defines the period of time after installation and/or commissioning, during which the original performance, or in any case performance suited to the intended use, is guaranteed without there being any degradation such as to compromise functionality and reliability.

The service life is a minimum qualitative objective of the design, therefore, individual parts or components may guarantee superior performance and reliability with respect to that declared by the manufacturer.

The service life assumes compliance with the maintenance schedules set out in this manual, does not include components normally subject to "wear", and is not linked to the warranty period: the service life does not establish any implicit or explicit extension of the warranty period.

CAUTION

The warranty starts from the date of purchase of the device, which evidence is given by the delivery note/purchase invoice issued by the Dealer / Importer or, in case of device with activation code, from the date of activation of the same.

In order to benefit from the warranty service, the client must return the device, at their own expense, to the MECTRON dealer/importer from which they purchased the product.

The devices must be returned in their original packaging, accompanied by all components and a slip stating:

- The data of the owner and telephone number;
- The data of the Dealer / Importer;
- Photocopy of the purchase bill/invoice for the device issued to the owner, stating the purchase date, name of the device and serial number;
- Description of the failure.

The transport and the damage caused by transport are not covered by the warranty.

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

Reseller