PWR Pair

Piezoelectric Scaler & Air Polisher

HuFriedyGroup
The Best In Practice

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1 INTRODUCTION

Carefully read this manual before proceeding with installation operations, use, maintenance or other intervention operations on the device.
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 referred to damage to persons

⚠ **CAUTION**: Referring to possible damage to property

The aim of this manual is to make the operators aware of the safety regulations, installation procedures, instructions for proper use and maintenance of the device and its accessories.

Use of this manual for aims other than those strictly linked to the installation, use and maintenance of the device is prohibited.
The information and illustrations in this manual were updated on the edition date shown on the last page.
The Manufacturer is engaged in continuously updating its products with possible changes to the components of the apparatus.
In case you encounter discrepancies between the descriptions found in this manual and the equipment in your possession you can:

- check for any available updates in the *INSTRUCTIONS-FOR-USE section of the HuFriedyGroup website*[1];
- ask clarifications to your distributor;
- contact HuFriedyGroup Customer Care
- Phone: 1-800-Hu-Friedy (1-800-483-7433)
- Email: Care@Hu-Friedy.com.

1.1 Indications for use

PWR Pair combines, in a single device, a multi-purpose piezoelectric scaler and water jet, air, and powder polisher, distributed by HuFriedyGroup, intended for complete supra- and subgingival dental prophylaxis.
PWR Pair can be used on patients of any age and gender requiring a tooth polishing treatment. There are no contraindications for specific population segments.

⚠ **WARNING**: The device must be used in a dental practice or clinic, or in professional oral hygiene and preventive care centers. It cannot be operated in environments where the atmosphere is saturated with flammable gases (anesthetic mixtures, oxygen, etc.).

⚠ **WARNING**: **Qualified and specialized personnel.** The device should only be used by qualified personnel with adequate medical training; for the use of the device are not requested special training activities. Use of the device does not produce any side effects if used correctly. Improper use is manifested by the transfer of heat to the tissues.

⚠ **WARNING**: **Indications for use.** Use the device exclusively for the purpose for which it is intended. Failure to observe this regulation can cause serious injury to the patient, the operator, and damage/failure of the device.

1 https://HuFriedyGroup.com/compliance-sheets

1.1.1 Piezoelectric Scaler Function

The PWR Pair, by using the appropriate associated piezo tips and the piezoelectric handpiece, is intended for use in the following dental applications:

- Removing supra and subgingival calculus deposits and stains from teeth;
- Periodontal therapy and debridement for all types of periodontal desease, including periodontal pocket lavage with simultaneous ultrasonic tip movement;
- Scaling and root planning;
- Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha;
- Plugging for amalgam condensation;
- Amalgam burnishing;
- Preparing, cleaning and irrigating roots canals;
- Cavity preparation;
- Cleaning restorations and implant surfaces.

1.1.2 Air Polisher Function

By using the appropriate air polishing handpieces, the PWR Pair is intended for a complete supra-gingival and sub-gingival prophylaxis treatment.
The prophylaxis treatment is obtained by the projection of water, air and appropriate dental prophylaxis powders, onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.
The PWR Pair is intended for the following oral prophylaxis procedures:

- Plaque removal for placement of sealants;
- Surface preparation prior to bonding/ cementation of inlays, onlays, crowns and veneers;
- Surface preparation prior to placing composite restorations;
- Effective plaque and stain removal for orthodontic patients;
- Cleaning prior to bonding ortho brackets;
- Cleaning implant fixture prior to loading;
- Stain removal for shade determination;
- Plaque removal prior to fluoride treatment;
- Plaque and stain removal prior to whitening procedure.

The PWR Pair is also intended for use as an air-polisher in patients suffering from periodontal disease.
The PWR Pair is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

1.2 Description of the Device

PWR Pair combines, in a single device, a multi-purpose piezoelectric scaler and water jet, air, and powder polisher, intended for complete supra- and subgingival dental prophylaxis.
In regards to the various possible piezoelectric treatments, PWR Pair 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 solutions.
The device is equipped with an automatic tuning circuit which compensates the wear of the piezo tips, thus always allowing operation in conditions of maximum efficiency.
The operating principle of the polisher is

based on the mechanical action obtained from a jet of various prophylaxis powder types accelerated by a flow of compressed air. The kinetic energy thus imprinted at the particles, dissipates almost completely due to impact against the surface of the enamel, producing a gentle but effective cleaning action. The action is completed by a jet of water which, using the vacuum created around the air-polishing handpiece, 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.

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 age, weight, height, gender, and nationality, where applicable.
This medical device is not intended for use on patient populations younger than 2 years of age.
Use of the device is suitable for all eligible patients whose doctor has prescribed a treatment among those described in the indications for use of the device (see *Chapter 1.1.1 on page 2* for the piezoelectric scaler's functions and *Chapter 1.1.2 on page 2* for the air-polisher's functions).

1.2.2 Patient Selection Criteria

The use of the device is not recommended 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.

Piezoelectric scaler:

1. Patients with active implantable medical devices (for example: pacemakers, hearing aids, and/or other electromagnetic prostheses) without prior authorization from their doctor;
2. Patients with clinical conditions not suitable for treatment of the sites (for example: local anaesthesia).

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

1. Allergy to the aroma of the powder;
2. 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 scalers are intended for professional use only. The user is therefore the only person able to decide if and how to treat their patients.

1.2.3 Users

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

1.3 Disclaimer

The manufacturer disclaims all liability, express or implied, and cannot be held responsible for direct or indirect personal injury and/or property damage, occurring as a result of incorrect procedures linked to the use of the device and its accessories.
The manufacturer 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 accessories 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 18 on page 103*;
- The device is not used in accordance with all the instructions and requirements described in this manual;
- The electrical system located on the premises in which the device is used does not comply with the electrical code compliance standards in force and the relative electrical safety precautions;
- Assembly operations, extensions, re-adjustments, upgrades and repairs of the device are carried out by personnel not authorized by the Manufacturer;
- 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 modification of the device under every circumstance;
- Use of non original PWR Piezo Tips resulting in permanent damage to the thread of the handpiece with impaired functioning and risk of injury to the patient;
- Use of non original PWR Piezo Tips used in accordance with the settings designed and tested on the original PWR Piezo Tips. Correct use of the settings is only guaranteed with original PWR Piezo Tips;
- Shortage of stock material (handpiece, piezo tips, wrenches) to be used in case of a standstill due to faults or problems;
- Incorrect/omitted maintenance compared to what is stated in *Chapter 16 on page 90* of this manual;
- Breach of the requirements and the information contained in *Chapter 5.5 on page 31* of this manual;
- Breach of the requirements and the information contained in *Chapter 18 on page 103* of this manual;
- Unauthorized repairs in accordance with the indications contained in *Chapter 19.4 on page 120* this manual.

1.4 Safety Requirements

⚠ **WARNING**: **Contraindications.** Do not use PWR Pair on patients with Pacemakers or other implantable electronic devices. This precaution also applies to the operator.

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

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

⚠ **WARNING**: **Contraindications. Interference from other equipment.** An electrosurgical scalpel or other electrosurgical units near the device may interfere with its correct operation.

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

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

⚠ **CAUTION**: In case the final user, operating in their own medical room or surgery, in order to comply with mandatory requirements, must periodically inspect the equipment present in the surgery, the test procedures to apply to medical electrical equipment and medical electrical systems for the safety assessment must be carried out following the standard EN 62353 ‘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 before treatment.** Always check that there is no water under the device. Before every treatment always check the perfect operation of the device and efficiency of the accessories. If operation anomalies are observed do not carry out the treatment. If the faults concern the device, contact HuFriedyGroup Service & Repair.

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

⚠ **CAUTION**: To avoid any risk of electrical shocks this device must be grounded.

⚠ **WARNING**: **Cleaning and sterilizing new or repaired instruments.** All the new or repaired device accessories are not sterile. At first use and after each treatment they must be cleaned and sterilized by carefully following the instructions in *Chapter 10 on page 52*.

⚠ **WARNING**: **Infection control.**
For maximum patient and operator safety, before using all the parts and reusable accessories, make sure they have been previously cleaned and sterilized by following the instructions in *Chapter 10 on page 52*.

⚠ **CAUTION**: **Contraindications.**
After having autoclaved the handpiece, piezo tips, torque wrench or any other sterilizable accessory, wait for them to completely cool down before reusing them.

⚠ **WARNING**: **Piezo tip Breakage and Wear.** High frequency oscillations and wear can, in rare cases, lead to the breakage of the piezo tip. Deformed piezo tips or piezo tips that have been otherwise damaged are prone to breakage during use. Broken or worn piezo tips must not ever 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 piezo tips.

Check the state of wear of the piezo tip 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 piezo tips (S1, S1-S, S2, S5, P2, P4, P10) can be checked using the supplied Piezo Tip Wear Guide. To use the Piezo Tip Wear Guide correctly:

- Position the piezo tip on the "Piezo Tip Wear Guide" 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 piezo tip is shorter than the limit of wear, its performance will be significantly inferior compared to that of a new piezo tip, and should therefore be replaced.

If the layer of titanium nitride (gold-plated surface), where present, is visibly worn, the piezo tip must be replaced. The use of a worn piezo tip reduces its efficiency. When the nitriding is consumed, the cutting edge loses effectiveness; a possible regrinding harms the piezo tip, therefore it is prohibited. Verify that the piezo tip is not worn.
During the operation frequently check that the piezo tip 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 piezo tips during use.

Diamond Piezo Tips and Plastic Piezo Tips are SINGLE USE ONLY. The diamond coated Piezo Tips and the plastic Piezo Tips are intended to be used on an individual patient during a single treatment and then discarded. The diamond coated Piezo Tips and the plastic Piezo Tips must be sterilized only one time, prior first use.

⚠ **WARNING**: Exclusively use original PWR Piezo Tips, accessories and spare parts.

⚠ **CAUTION**: It is prohibited to make any changes to this device.

⚠ **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 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 during correct use and in accordance with the indications for use, a report must be made to the Competent Authority and to the company indicated on the product label.

⚠ **WARNING**: The device is classified for intermittent mode of operation (as reported in *Chapter 18 on page 103*). The continuous use of the device for a prolonged time and in any case exceeding the declared time limits can cause overheating, in particular, of the handpiece. In case of overheating, avoid contact of the handpiece with the operator and the patient.

1.5 Symbols

Symbol	Description	Symbol	Description
5.4.3 [*] 	Consult instructions for use or consult electronic instructions for use	5.1.5 [*] 	Batch number
5.4.4 [*] 	Caution	5.2.7 [*] 	Non-sterile
5.7.7 [*] 	Medical device	1844 [***] 	The sterilizable materials must be autoclaved and can resist up to a maximum temperature of 135°C
5.1.6 [*] 	Catalog Number	5.4.2 [*] 	Do not re-use
5.7.10 [*] 	Unique device identifier	5.2.6 [*] 	Do not resterilize
5.1.11 [*] 	Country of manufacture	5.6.3 [*] 	Non-pyrogenic
5.1.4 [*] 	Expiry date	5.2.3 [*] 	Sterilized with Ethylene Oxide (EO)
5.1.7 [*] 	Serial number	2785 [***] 	Washer disinfector for thermal disinfection
5144 [****] 	Connection of the control pedal		Nemko brand Compliance with UL - CSA regulations
13 [**] 0	Power switch set to “off”	12 [**] I	Power switch set to “on”

Symbol	Description	Symbol	Description
1 [**] 	Alternating current	5.3.9 [*] 	Atmospheric pressure limits for transport and storage
5.3.7 [*] 	Temperature limits for transport and storage	5.3.8 [*] 	Moisture limits for transport and storage
19 [**] 	“B” Part applied according to regulation IEC/EN 60601-1	5.2.8 [*] 	Do no use if the packaging is damaged and consult instructions for use
[*****] Rx Only	For US market only **CAUTION**: US federal law restricts sale to orders by licensed dentists or dental hygienists only.		

[*] ISO 15223-1:2021
[**] CEI EN 60601-1:2005, AMD1:2012
[***] ISO 7000:2019
[****] IEC 60417:2001
[*****] 21 CRF 801.109

NOTE: For other symbols, refer to *Chapter 19.1 on page 113*.

2 IDENTIFICATION DATA

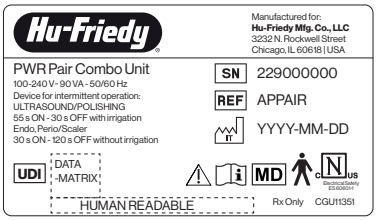
A correct description of the model and of the serial number of the device will allow HuFriedyGroup Customer Care to provide fast and effective answers.

Always provide this information every time that you contact HuFriedyGroup Customer Care.

2.1 Device ID Plate

Each device has its own identification label showing its main technical specifications and the traceability data, UDI code included. The identification plate is located under the device. The complete technical specifications are provided in *Chapter 18 on page 103*.

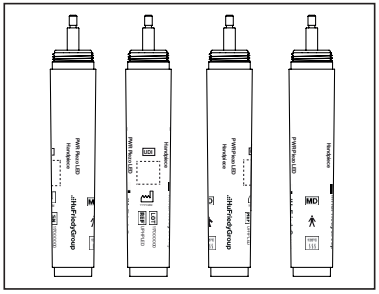
NOTE: The complete list of symbols and their description is provided in *Chapter 1.5 on page 8*.



2.2 Scaler Handpiece Identification Data

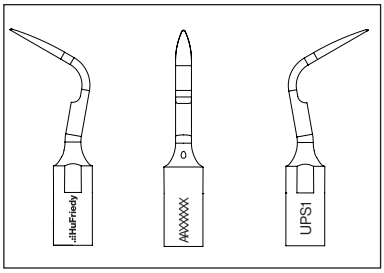
Each handpiece is laser-marked with the traceability data, UDI code included.

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



2.3 Piezo Tips Identification Data

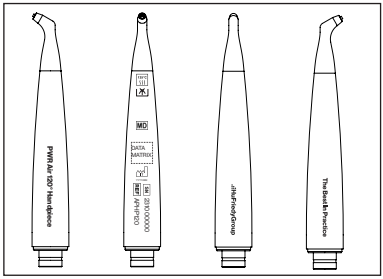
Each piezo tip is laser-marked with the traceability data. Their packaging contains traceability data including the UDI code.



2.4 Air-Polishing Handpiece Identification Data

Each handpiece is laser-marked with the traceability data, UDI code included.

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



3 DELIVERY

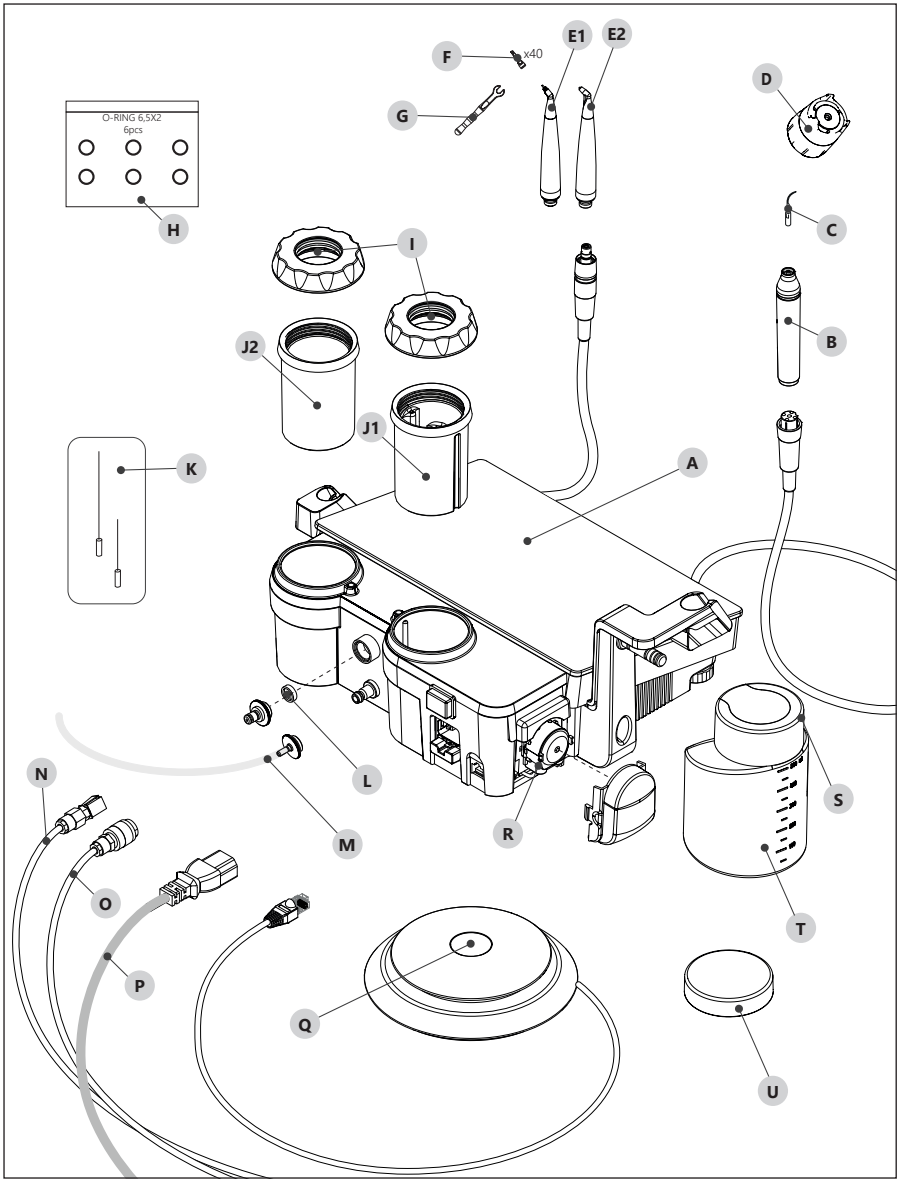
3.1 List of components

PWR Pair includes a basic equipment and a set of accessories that can be ordered separately, variable in relation to the configuration and customer requests (see Table on the following page).

NOTE: Both the items included in the standard supply and all accessories can be ordered separately by the client. Refer to the HuFriedyGroup website, or your local retailer, for the list of available and compatible accessories

The packaging of the device cannot undergo strong impacts as contains electronic components, therefore the transport and the storage must be carried out with particular care.
Do not stack various boxes in order to avoid pinching the underlying packaging.
All the material sent by HuFriedyGroup was controlled at the time of dispatch.
The device is shipped appropriately protected and packaged.
Upon receipt of the device, check for any possible damage caused during transport and in case any damage and/or defects is found, complain to the transporter.
Keep the packaging in case any items need to be sent to HuFriedyGroup Service & Repair 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 (piezo scaler handpiece, piezo tips, wrenches, air-polishing handpieces, and Subgingival Perio Tips) to use in the event of failures or drawbacks.


O-RING 6,5X2
6pcs
H
F
x40
G
E1
E2
D
C
I
B
J2
J1
K
A
L
M
N
O
P
R
S
T
Q
U

Basic equipment			
Ref.	**SKU**	**Item**	**Note**
A		Device core unit [a]	
B	UPHPLED	Piezo LED Handpiece [a]	
C		Piezo Tips [a]	Piezoelectric scaler tip
D	UPK10	K10 Tip wrench [a]	
E1	APHPPERIO	Air Perio Handpiece [a]	
E2	APHP120	Air 120° Handpiece [a]	
F	APPERIOTIPS	Perio Subgingival Tips [a]	40 pcs set
G	APK9	K9 Tip Wrench [a]	
H	APORINGS	PWR Pair O-ring Set [b]	
I	APPCCAP	Powder chamber cap [a]	
J1	APPCPROPHY	Powder chamber Prophy, without cap [a]	
J2	APPCPERIO	Powder chamber Perio, without cap [a]	
K	APNDLKIT	Cleaning needle kit [a]	Includes: Cleaning needle Ø 0.4 mm Cleaning needle Ø 0.8 mm
L	APFILTER	Unit Water filter [a]	
M	APICDKIT	Irrigation circuit disinfection kit [a]	
N	APH2OHOSE	Water supply hose with quick coupling [a]	
O	APAIRHOSE	Air supply hose with quick coupling [a]	
P		Power supply cable [b]	
Q	UPFTPEDAL	Foot Pedal [a]	
R	UPPUMP	Peristaltic water pump [b]	
S	UPBTLCAPGY	Bottle cap [a]	Grey
T	UPBTL	Plastic Bottle [a]	500ml
U		Bottle safety cap [a]	Grey

a) Produced by the Manufacturer.

b) Distributed by HuFriedyGroup.

4 INSTALLATION

4.1 First Installation

The device must be installed in a suitable place that is convenient for its use.

⚠ **WARNING:** The place where the device is installed must meet the requirements set out in *Chapter 4.2 on page 14*.

4.2 Safety Requirements During Installation

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

⚠ **WARNING**: **Contraindications. Interference from other equipment.** An electrosurgical scalpel or other electrosurgical units near the device may interfere with its correct operation.

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

⚠ **CAUTION**: To avoid any risk of electrical shocks this device must be grounded.

⚠ **CAUTION**: Always position the device in way so that the power switch is easily reachable, since this switch is considered as a load-break switch.

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

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

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

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

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

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

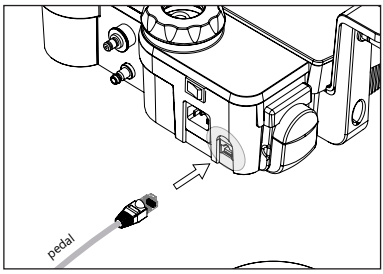
⚠ **CAUTION**: Each irrigation bottle has a maximum capacity of 500 ml.

4.3 Connecting the Accessories

1

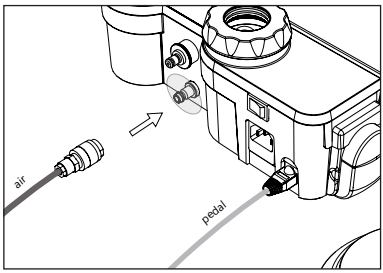
Connect the pedal to the back of the device in the socket marked with the symbol by inserting the pedal cord plug until you hear a 'click'.

⚠ **CAUTION**: Pay attention to the positioning of the pedal, which must be such that the pedal is only activated intentionally by the operator.



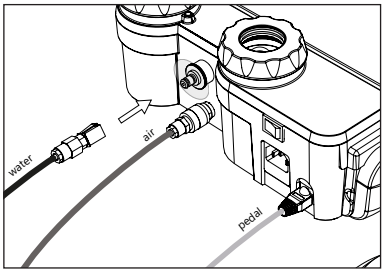
2

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 supply).
Connect the quick coupling to the male attachment on the rear of the device.



3

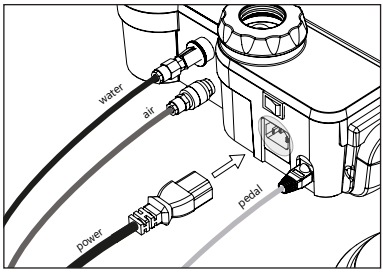
Connect the supply hose to the water circuit in the medical practice using a suitable reduction and shut-off valve (not included in the supply).
Connect the quick coupling to the male attachment on the rear of the device.



4

Insert the supply cable in its connection situated on the back of the device. Connect it to the socket in the wall.

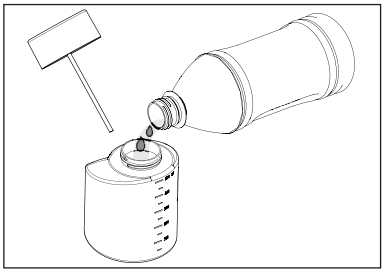
⚠ **CAUTION**: Position the device in a way that the power plug is easily accessible at all times; this is considered a means of isolation.



5

Unscrew the cap of the bottle and fill it with the desired liquid.

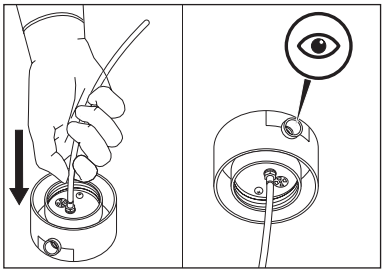
⚠ **CAUTION**: Each irrigation bottle has a maximum capacity of 500 ml.



6

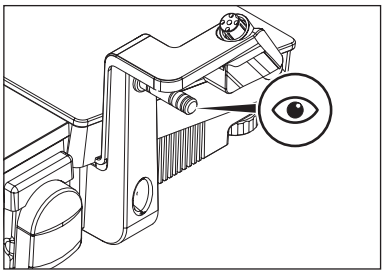
Check that the small tube inside the cap is properly installed, then screw the cap onto the bottle.

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



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

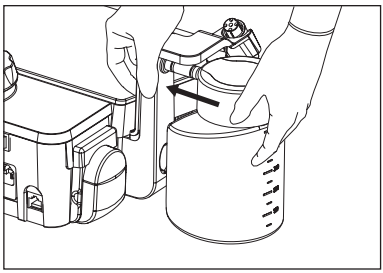
⚠ **CAUTION**: Use the support only to install the 500 ml bottle and to hold the handpiece. Do not use the support for other purposes.



7

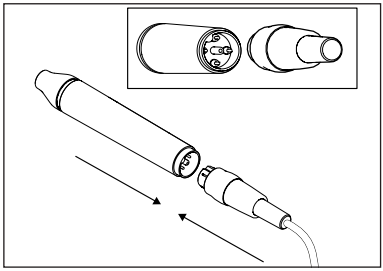
Keep the irrigation bottle in a vertical position and push it towards the device's body until it is firmly connected.

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



8

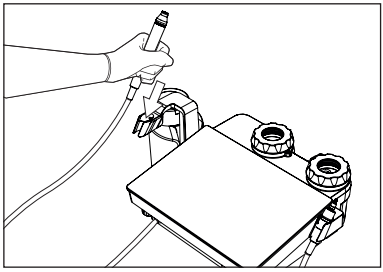
Correctly insert the scaler handpiece onto its cord by matching the alignment notch on the handpiece connector with the alignment key on the cord connector. Check that the electrical contacts of both are perfectly dry and if necessary dry them by blowing with compressed air.



9

Position the handpiece on its dedicated support.

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

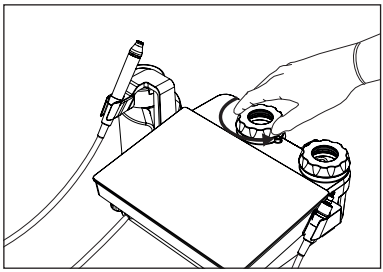


10

⚠ **CAUTION**: Before extracting the powder container or unscrewing the caps, check that the "Refill" function has been carried out and the corresponding LED stays lit (see *Chapter 5.2.2 on page 24*).

Unscrew the cap of the PROPHY white powder container on the left.

⚠ **CAUTION**: The PROPHY powder container is white colored and is positioned on the left.

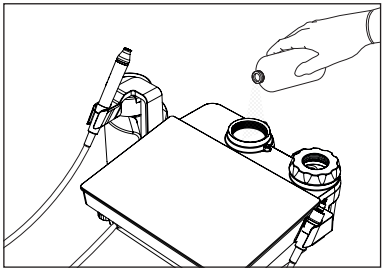


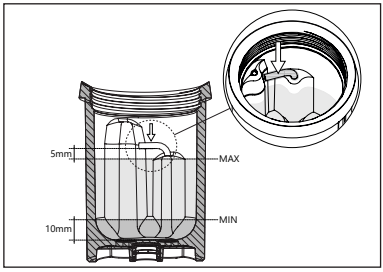
11

Pour the specific supragingival powder distributed by HuFriedyGroup (PWR Classic) into the container, making sure the level stays below the internal diffuser.

⚠ **WARNING**: Insert only specific supragingival powder distributed by HuFriedyGroup (PWR Classic) in the PROPHY container.

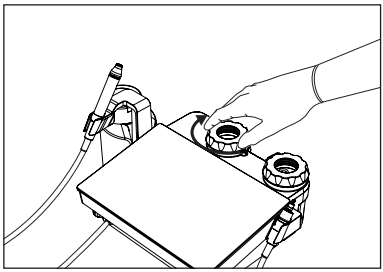
⚠ **CAUTION**: **Correct level of powder in the powder container. Minimum level:** The level of powder in the container must not be lower than one centimeter to prevent cleaning performance from dropping. **Maximum level:** The level of the powder in the container must remain below the diffuser (at least 5 mm).





12

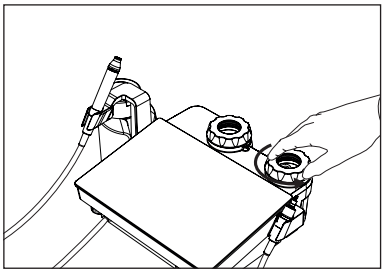
Close the tap on the container without tightening it excessively.



13

Unscrew the cap of the PERIO light blue powder container on the right.

⚠ **CAUTION**: The PERIO powder container is light blue colored and is positioned on the right.

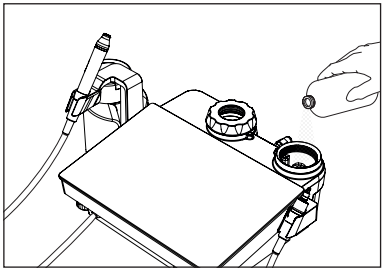


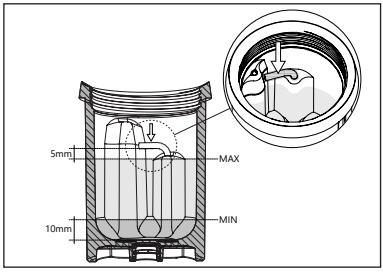
14

Pour the specific subgingival powder distributed by HuFriedyGroup (PWR Perio) into the container, making sure the level stays below the internal diffuser.

⚠ **WARNING**: Insert only specific subgingival powder distributed by HuFriedyGroup (PWR Perio) in the PERIO container.

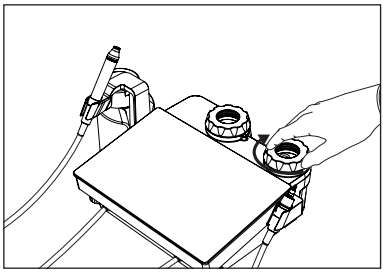
⚠ **CAUTION**: **Correct level of powder in the powder container.**
Minimum level: The level of powder in the container must not be lower than one centimeter to prevent cleaning performance from dropping.
Maximum level: The level of the powder in the container must remain below the diffuser (at least 5 mm).





15

Close the tap on the container without tightening it excessively.



5 USE

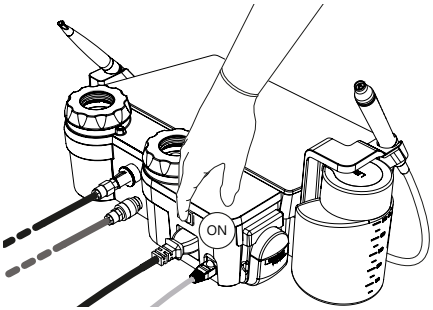
5.1 Power On/Off

Switching the device on
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 pedal.
All the warning lights on the device will turn on and off again. The keyboard 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.
- POLISHING part:
  - "Prophy" function.

NOTE: The settings of the scaler part and polisher part can both be modified only with the handpieces positioned in their housings. If one of the two handpieces is lifted, only the settings relative to the active function can be modified.

Switching the device off
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 pedal.

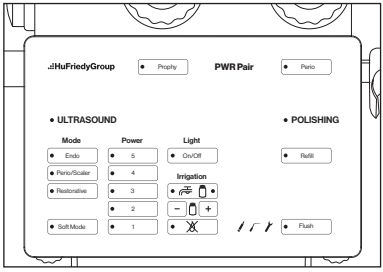


⚠ **CAUTION**: Always position the device in way so that the power switch is easily reachable, since this switch is considered as a load-break switch

5.2 Description of the Keyboard

TOUCH KEYBOARD
The user can configure the system by simply touching the touch keyboard.
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.

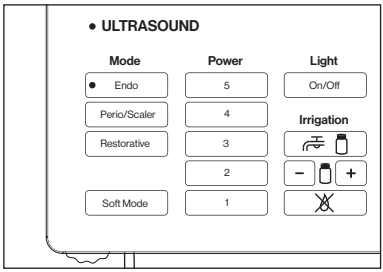


5.2.1 ULTRASOUND - Scaler Part

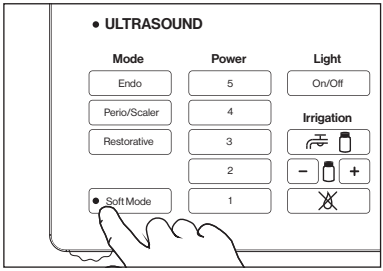
MODE
Depending on the type of operation, it is possible to select one of 3 options from the “Mode” list, as follows:

- **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 restoration and prosthesis.

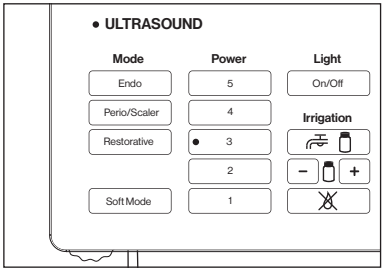
NOTE: when “**restorative”** is selected with power level 5, the PULSE function is activated.
It is used to optimise the tip’s performance in the prosthesis techniques.



SOFT MODE
The treatment can be made more delicate for sensitive patients, by activating "soft mode". This function. can only be activated with “**perio/ scaler**” and power levels from 1 to 5 and with “**restorative**” and power levels from 1 to 4.
In “endo” mode the function is not available.

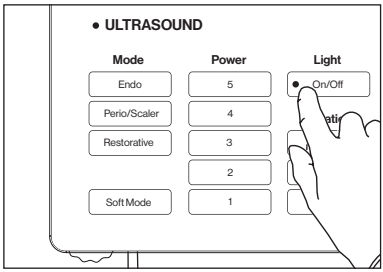


POWER
The operating power can be adjusted by selecting the numbers on the “power” scale, and this applies on all "mode" levels. There are 5 power levels, from 1 to 5. The operating power can be adjusted incrementally (1: minimum power, 5: maximum power).



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 front cone lights up when the 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 front cone stays off.



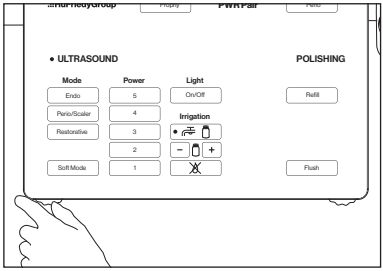
IRRIGATION

The device, for the scaler part, allows the use of two types of irrigation:

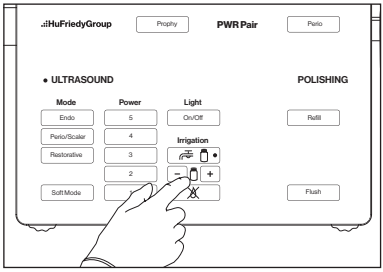
- the normal water circuit or
- the bottle circuit.

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

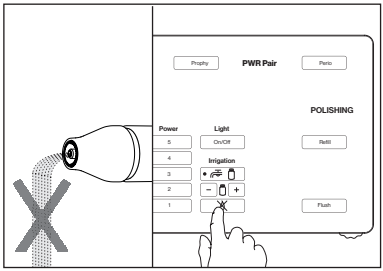
- for the normal water circuit, the flow can be continuously regulated using the left-hand knob.



- for the bottle circuit, the flow can be continuously regulated on 7 levels via touch screen using the “–“ and “+” keys.



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



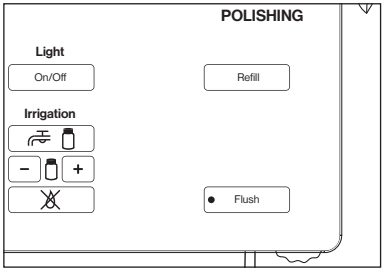
⚠ **CAUTION**: The exclusion of irrigation with non “Dry Work” piezo tips can cause overheating with consequent breakage of the handpiece.

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 pedal pressed).

"Flush" FUNCTION
The device has a "Flush" key, which allows the irrigation circuit to be filled and rinsed.
Filling the irrigation circuit: Before starting the treatment, the "Flush" function can be used to allow the liquid to reach the piezo tip, so as to start the treatment with the necessary irrigation.
Cleaning the hydraulic circuit:
The "Flush" function allows the irrigation circuit rinse cycle to be performed. This function must be used before the first treatment of the day, after every treatment and at the end of the day before starting the cleaning and reprocessing procedure.

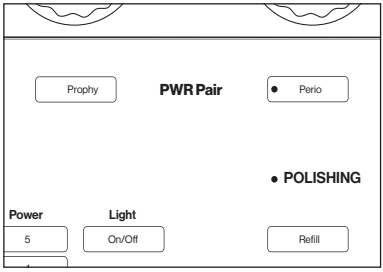
NOTE: If both handpieces are in their respective housings, the "Flush" function cannot be activated.



5.2.2 POLISHING - Polisher Part

FUNCTIONS
Depending on the type of application, one of the 2 types of powder can be selected as follows:

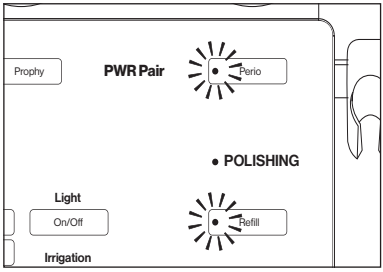
- "Prophy": dedicated to the clinical indications of the specific supragingival powder distributed by HuFriedyGroup (PWR Classic);
- "Perio": dedicated to the clinical indications of the specific subgingival powder distributed by HuFriedyGroup (PWR Perio).



“Refill” FUNCTION

The "Refill" function must be used to depressurize the powder containers in order to then be able to open and remove them from the device.

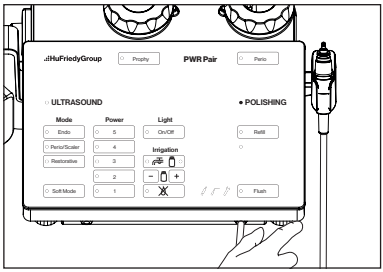
NOTE: The Refill procedure applies to both powder containers. Therefore, during this procedure, both LEDs associated with the powder containers flash alternately with the one of the Refill function.



IRRIGATION

The device uses just normal water for the polisher part.

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



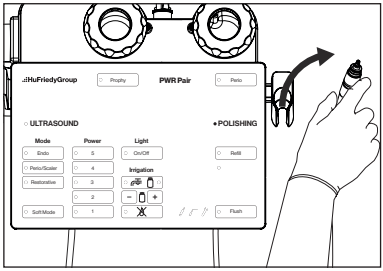
"Flush" FUNCTION

The "Flush" function can be used when the type of powder needs to be changed, to make sure the powder circuit has been properly cleaned of the previously used powder.

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

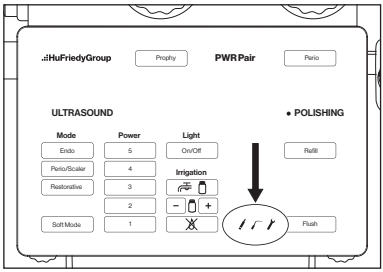
NOTE: Even if the process involves both powder containers at the same time, the user must first select one of them to start the process.

NOTE: As an effect of the Flush function, both powder containers will be depressurized.



5.2.3 Symbols

PWR Pair is provided with a diagnostic circuit that allows the detection of malfunctions and viewing of their type on the touch keyboard by means of a symbol.
To help the user identify the malfunctioning component, there are three symbols described in *Chapter 19.1 on page 113*.



5.3 Safety Requirements Before and During Use

⚠ **WARNING**: **Exclusively use original PWR Piezo Tips, accessories and replacement parts.**

⚠ **WARNING**: Before starting work always ensure that you have all replacement parts (handpiece, piezo tips, keys) to use should there be downtime due to a fault or problem.

⚠ **WARNING**: **Checking the condition of the device before treatment.** Always check that there is no water under the device. Before every treatment always check the perfect operation of the device and efficiency of the accessories. If operation anomalies are observed do not carry out the treatment. Contact HuFriedyGroup Service & Repair if the faults concern the device.

⚠ **WARNING**: **Infection control. First use:** All parts and reusable accessories (new or returned from HuFriedyGroup Service & Repair) are delivered in NON-STERILE conditions and must be treated before each use, according to the instructions provided in *Chapter 8 on page 46*. **Subsequent uses:** After each treatment, clean and sterilise all parts and reusable accessories according to the instructions in *Chapter 8 on page 46*.

⚠ **WARNING: Infection control.** Do not leave liquids in the bottle for long periods of time. The bottle must be filled after having cleaned and sterilized 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 accessories must be cleaned and sterilized.

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

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

5.3.1 Piezoelectric Scaler

⚠ **WARNING**: **Use of non-original piezo tips**: 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 prosthetics. Piezoelectric vibrations could lead to decementation of the dentures.

⚠ **WARNING**: **Contraindications.** Do not use PWR Pair on patients with Pacemakers or other implantable electronic devices. This precaution also applies to the operator.

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

⚠ **CAUTION**: In treatments requiring irrigation, use only piezo tips with a liquid passage.

⚠ **WARNING**: **Treatments that require irrigation.** Always check the operation of the irrigation before and during use. Make sure that the liquid exits from the piezo tip. Do not use the device if the irrigation does not work or if the pump is faulty.

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

⚠ **CAUTION**: For correct use of the device, the pedal must be pressed and the device started with the piezo tip 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 piezo tip without interference, thus allowing optimum performance.

⚠ **WARNING**: Before each treatment ensure that the piezo tip that is suitable for the treatment is inserted on the handpiece.
Use only the original torque wrench to secure the piezo tip to the handpiece.

⚠ **WARNING**: Do not change the piezo tip whilst the handpiece is in operation in order 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 6 on page 36*). If the tubes are not cleaned, the crystallisation of the salts may seriously damage the device.

⚠ **WARNING**: **Piezo tip breakage and wear.** High frequency oscillations and wear can, in rare cases, lead to the breakage of the piezo tip.
Do not bend, change shape or sharpen an piezo tip in no way.
Folding an piezo tip or levering on it can cause the piezo tip to break.
Deformed or otherwise damaged piezo tips, are susceptible to breakage during use. These piezo tips should never be used.
Excessive pressure on the piezo tips 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 piezo tips.

Check the state of wear of the piezo tip 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 piezo tips (S1, S1-S, S2, S5, P2, P4, P10) can be checked using the supplied Piezo Tip Wear Guide. To use the Piezo Tip Wear Guide correctly:

- Position the piezo tip on the "Piezo Tip Wear Guide" 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 piezo tip is shorter than the limit of wear, its performance will be significantly inferior compared to that of a new piezo tip, and should therefore be replaced.

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

When the nitriding is consumed, the cutting edge loses effectiveness; a possible regrinding harms the piezo tip, therefore it is prohibited. Verify that the piezo tip is not worn.
During the operation, frequently check that the piezo tip is intact, especially in the apical part.
During the operation avoid prolonged contact with the retractor or with metal instruments in use.

Diamond Piezo Tips and Plastic Piezo Tips are SINGLE USE ONLY. The diamond coated Piezo Tips and the plastic Piezo Tips are intended to be used on an individual patient during a single treatment and then discarded. The diamond coated Piezo Tips and the plastic Piezo Tips must be sterilized only one time, prior first use.

⚠ **CAUTION**: **Contraindications.** After autoclaving the handpiece, the piezo tips, the torque wrench, or any other sterilizable accessory, wait until it has completely cooled before reuse.

⚠ **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 sterilization 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 Jet Polisher

⚠ **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.

⚠ **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.** To ensure utmost patient and operator safety, after each treatment follow the indications provided in *Chapter 14 on page 74*.

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

⚠ **CAUTION**: Do not attempt to unscrew the cap of the powder container before having performed the "Refill" cycle.

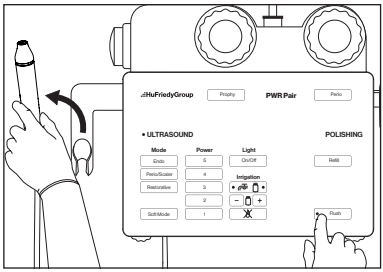
5.4 Instructions for Use - Scaler Part

After having connected all the accessories as described in *Chapter 4.3 on page 15* proceed as follows:

1

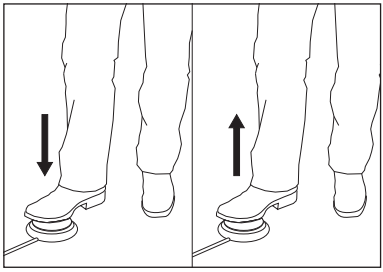
Lift the scaler handpiece, with or without piezo tip, fill the irrigation circuit by selecting "Flush" on the keyboard.
The "Flush" function LED flashes.
The device allows the use of two types of irrigation: the normal water circuit or the bottle circuit.

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



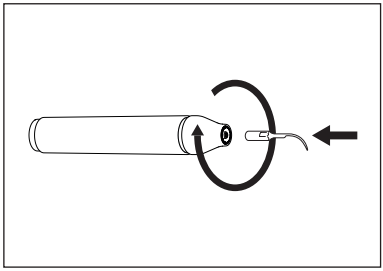
2

Press the pedal for a moment to start the cycle. The "Flush" function and selected irrigation type LEDs will flash. The performance of the cycle is indicated with brief sequence acoustic signals.
The cycle lasts 23 seconds, but can be interrupted by pressing the pedal as soon as the liquid starts coming out of the handpiece.
At the end of the "Flush" cycle, the device becomes available again with the most recently used configuration.



3

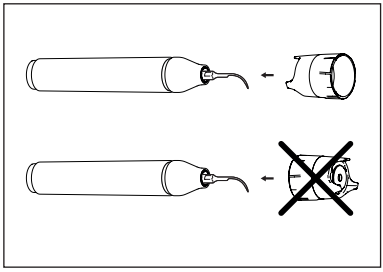
Screw in the preselected piezo tip on the PWR Piezo LED handpiece all the way down.



4

Tighten the piezo tip using the original torque wrench.
For correct use of the original torque wrench, proceed as follows:

- Place the piezo tip inside the torque wrench, as shown.

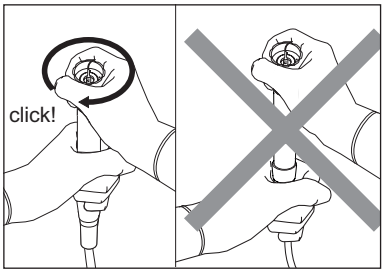


5

Hold the handpiece body firmly.

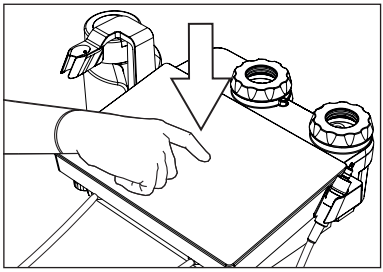
⚠ **CAUTION**: Do not grab the handpiece on the end and/or on the cord, but only on the body. Do not turn the handpiece, rather it must be held steady turning only the wrench.

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 piezo tip is now optimally locked.



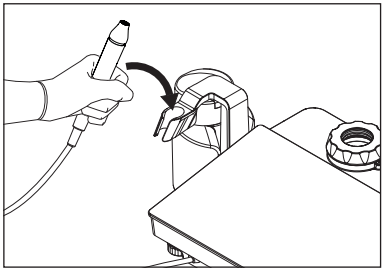
6

Select the mode, power, and irrigation necessary, and the light if desired, on the keyboard.
Lift the handpiece and press the pedal to start treatment.



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

7



5.5 Important information on the Piezo Tips

⚠ **WARNING**:

- Before using the sterilized piezo tip, check the integrity of the sterile packaging and inspect the product to ensure there is no damage. The piezo tip will no longer be sterile if the packaging is broken or damaged. If the packaging is damaged, the piezo tip MUST be sterilized again before use.
- When the layer of titanium nitride is visibly consumed the piezo tip must be replaced. The use of an piezo tip too worn decreases its efficiency.
- **Diamond Piezo Tips and Plastic Piezo Tips** are SINGLE USE ONLY. The diamond coated Piezo Tips and the plastic Piezo Tips are intended to be used on an individual patient during a single treatment and then discarded. The diamond coated Piezo Tips and the plastic Piezo Tips must be sterilized only one time, prior first use.
- Do not activate the handpiece while the piezo tip is in contact with the part to be treated so that the electronic circuit can recognise the best point of resonance of the piezo tip allowing optimum performance.
- Check the state of wear of the piezo tip and its integrity before and during each use. If you experience a loss of performance provide for its replacement.
- Use only original PWR Piezo Tips. The use of non-original piezo tips will void the warranty and damage the thread of the PWR Piezo LED handpiece, with the risk of no longer being able to correctly screw in the original piezo tips for subsequent use. In addition, the device settings are tested and guaranteed for correct operation using only original PWR Piezo Tips.
- Do not change in any way the shape of the piezo tip, by bending it or filing it. This could cause it to break.
- Do not use an piezo tip that has undergone deformation of any type.
- Do not attempt to sharpen an piezo tip used.
- Always check that the threaded parts of the piezo tip and the handpiece are perfectly clean - See *Chapter 10 on page 52* - Cleaning and sterilization.
- Excessive pressure applied to the piezo tip can cause it to break and potentially injure the patient.
- The PWR Piezo Tips 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 piezo tip must be held in constant movement. If the piezo tip 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 level of irrigation as the power level increases.
- Leave the piezoelectric vibrations to work, do not exert excessive pressure on the piezo tips during use. Apply slight force on the piezo tip for optimum performance.
- When the piezo tip is used in interproximal spaces, do not block the instrument or leverage on the operating part. The piezo tips 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 piezo tip. 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 piezo tip in an axial direction.

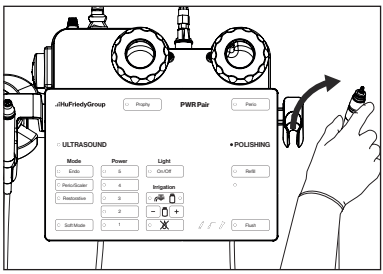
5.6 Instructions for Use - Polisher Part

After having connected all the accessories as described in *Chapter 4.3 on page 15* proceed as follows:

1

Lift the quick coupling on the air-polishing handpiece cord. The POLISHING function is activated.

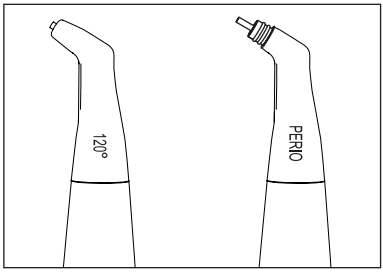
⚠ **CAUTION**: Make sure the scaler handpiece is in its housing, otherwise the system will remain inactive.



2

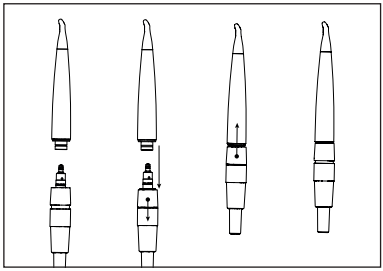
Choose the type of air-polishing handpiece depending on the operation that needs to be performed.

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



3

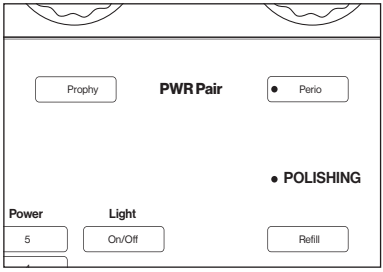
On the quick coupling of the cord, slide the ring and hold it in position, then insert the air-polishing handpiece until it comes into contact, and finally release the ring again.



4

Select the desired “Prophy” or “Perio” function.

- “Prophy” function: use the specific supragingival powder distributed by HuFriedyGroup (PWR Classic);
- “Perio” function: use the specific subgingival powder distributed by HuFriedyGroup (PWR Perio).



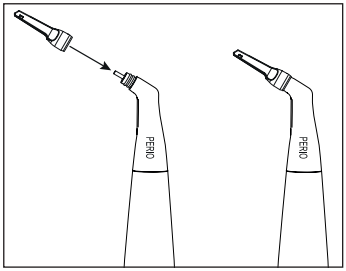
⚠ **WARNING**: Before performing any other operations, make sure the air-polishing handpiece is properly and completely inserted in the quick coupling (the quick coupling ring and air-polishing handpiece must be in contact) and that the ring has been returned to the initial position.

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

⚠ **CAUTION**: Handle the Subgingival Perio Tips with care.

⚠ **CAUTION**: With the PERIO air-polishing handpiece, only specific subgingival powder distributed by HuFriedyGroup (PWR Perio) must be used.

5



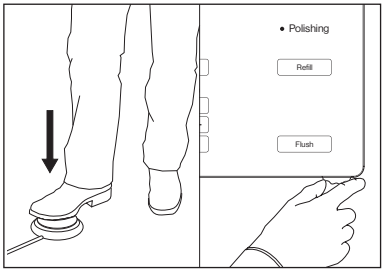
Insert the Subgingival Perio Tips on the PERIO air-polishing handpiece, pushing it in until it comes into contact.

⚠ **WARNING**: Make sure the Subgingival Perio Tips is properly inserted on the air-polishing handpiece; the two pieces must be in contact.

⚠ **CAUTION**: Use only original HuFriedyGroup accessories.

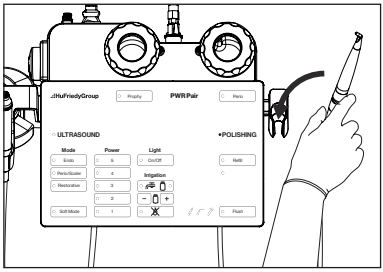
6

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



7

At the end of the treatment, put the polisher handpiece back in its seat.



5.6.1 “Refill” function

The "Refill" function allows the powder containers to be depressurized, enabling their opening or removal and preventing powder from escaping. This function must be used whenever a container is to be reloaded or cleaned.

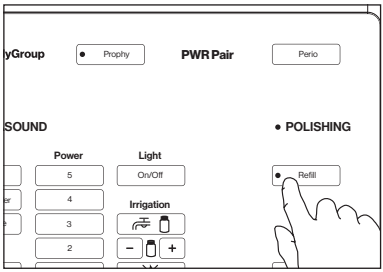
NOTE: The powder containers are only pressurized when, after being selected, the pedal is pressed.

⚠ **CAUTION**: During the "Refill" cycle, air and powder escape from the polisher handpiece.

To activate the "Refill" function, proceed as follows:

1

Press the "Refill" button.

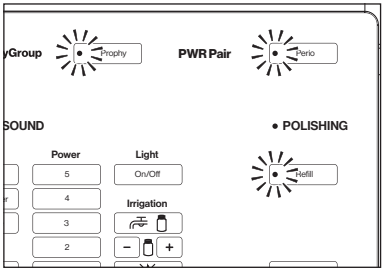


2

Wait for completion of the cycle, during which the LED of the "Refill" key will flash together with that of the pressurized powder container, emitting an acoustic signal.

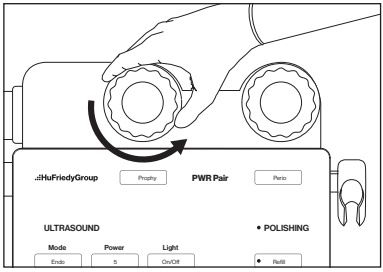
NOTE: If both the powder containers are pressurized, the "Refill" cycle will depressurize both.

NOTE: The duration of the "Refill" cycle varies depending on whether one or both pressurized powder containers are present.



3

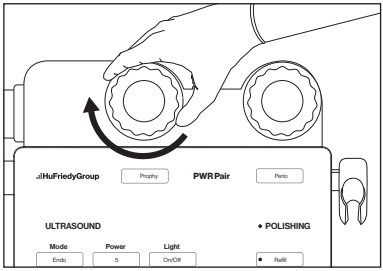
At the end of the cycle, the "Refill" key LED will remain lit and it will therefore be possible to open or remove the containers.



At this point simply close or re-insert the containers to continue using the device.

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

4



6 FLUSH FUNCTION

Using the "Flush" function it is possible to refill or rinse the irrigation circuit.

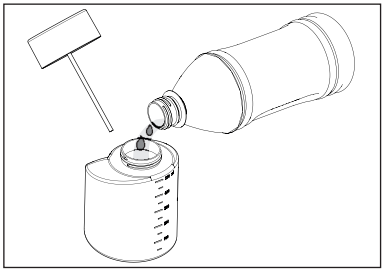
⚠ **CAUTION**: **Flush function.**
The "Flush" function must be used for each circuit and for all the used type of irrigations. It has to be used before the first treatment of the day; after every treatment and before starting the cleaning and sterilization procedures; at the end of the day and before starting the cleaning and reprocessing. In the latter case the "Flush" on the polishing side has to be performed with empty powder .chambers in order to remove any powder residuals from the internal circuits.

⚠ **CAUTION**: If the tubes are not rinsed, the crystallisation of the salts may seriously damage the device.

6.1 Ultrasound - Scaler Part

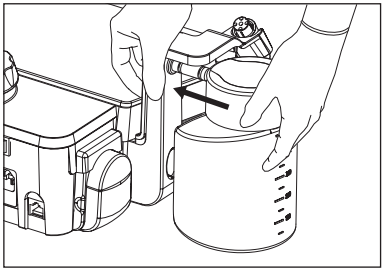
Fill the bottle with the appropriate liquid.

1



2

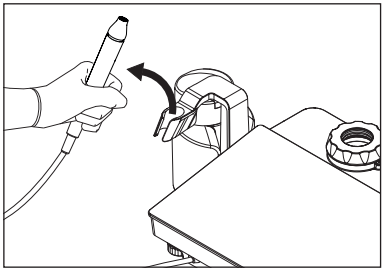
Connect the bottle to the device.



3

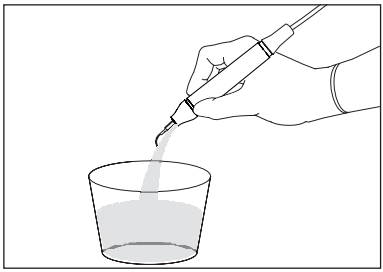
Extract the scaler handpiece from its housing.

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



4

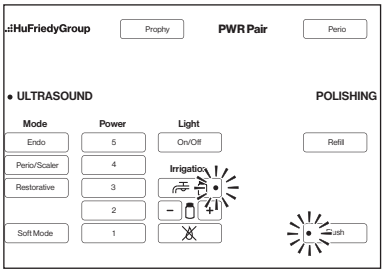
Place the scaler handpiece, with or without piezo tip, over a container to catch the liquid released during the rinse cycle.



5

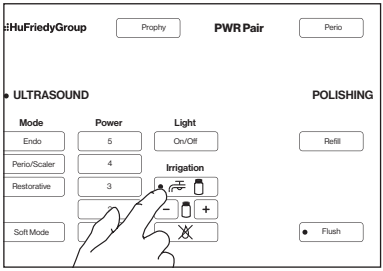
To enter "Flush" mode, select "Flush" on the touch keyboard.
The previously selected irrigation type will remain active and the corresponding LED will flash (faded out).
All the other selectable options on the keyboard will be disabled.

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



6

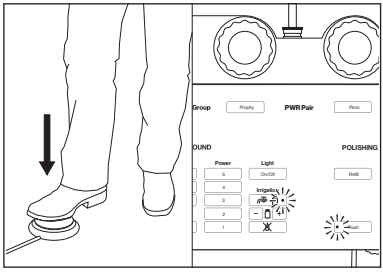
The irrigation circuit used to carry out the "Flush" cycle can be changed by pressing the key showing a tap and bottle.



7

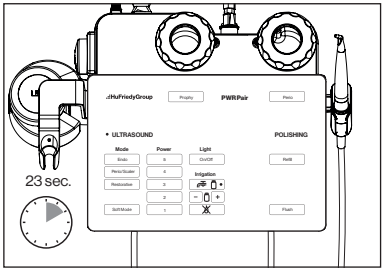
Press the pedal once and release it to start the cycle.
The function and selected irrigation type LEDs will flash. A sequence of short acoustic signals indicates that the cycle is running.

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



8

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



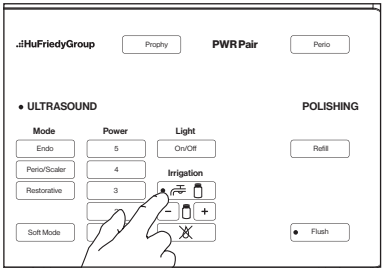
If the "Flush" cycle is to be performed on the water circuit, repeat the steps from point 4 selecting irrigation with water.
At the end of the selected function time or at the end of the "Flush" cycle, the system will be reactivated and configured in the last setting used.

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

⚠ **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.

9



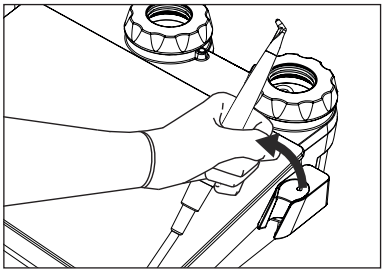
6.2 Polishing - Polisher Part

Lift the air-polishing handpiece or quick coupling on the cord of the air-polishing handpiece.

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

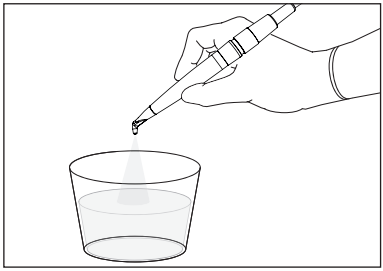
⚠ **CAUTION**: Make sure that both powder containers are inserted in the device before activating the "Flush" function.

1



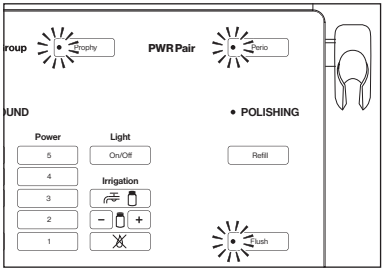
2

Position the quick coupling on the cord of the air-polishing handpiece, with or without the air-polishing handpiece, over a container or sink to catch the liquid and powder that will be released during the "Flush" cycle.



3

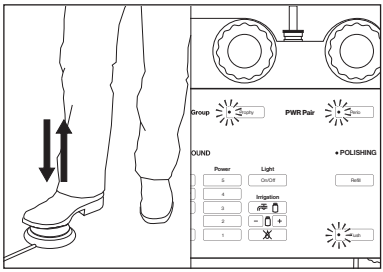
To enter "Flush" mode, select "Flush" on the touch keyboard: both the powder containers and corresponding LEDs will flash (faded out).
All the other selectable options on the keyboard will be disabled.



4

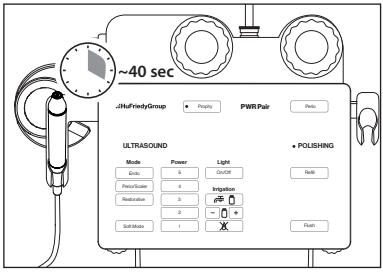
Press the pedal once and release it to start the cycle. The LEDs of the function and powder containers will flash. A sequence of short acoustic signals indicates that the cycle is running.

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

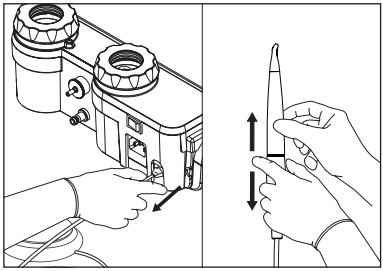


5

The "Flush" cycle is run on both powder containers simultaneously.
The cycle lasts about 40 seconds. Once ended, the keyboard will be reactivated and configured in the last setting used.



6



At the end of the irrigation circuit "Flush" cycle, disassemble the individual parts (see *Chapter 7 on page 42*) and proceed to clean and sterilise them (see *Chapter 8 on page 46*).

⚠ **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.

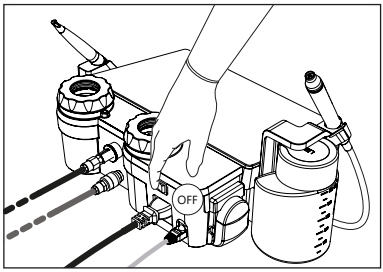
⚠ **CAUTION:** During the execution of the "Flush" cycle, do not remove the powder containers but wait for the end of the cycle.

7 DISASSEMBLING PARTS FOR CLEANING AND STERILIZATION

Before carrying out the cleaning procedures described in *Chapter 8 on page 46*, disconnect all accessories and components of the PWR Pair.

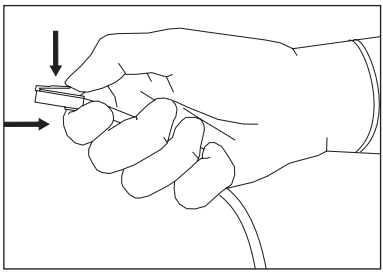
⚠ **WARNING**: Switch the device off. Always switch the device off using the switch and disconnect the power supply cable from the wall socket and device core unit before carrying out cleaning and sterilization tasks.

1



2

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

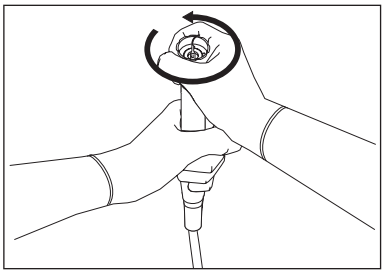


⚠ **CAUTION**: Do not try to unscrew or turn the connector during disconnection: this might damage the connector.

⚠ **CAUTION**: While disconnecting the cable from the pedal, keep always and only the connector of the cord. Never pull the cord itself.

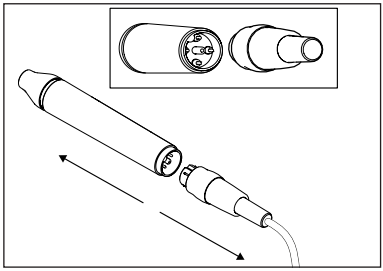
3

If present, unscrew the piezo tip from the handpiece using the torque wrench.

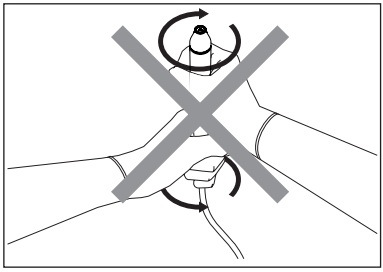


4

Disconnect the scaler handpiece from the cord.



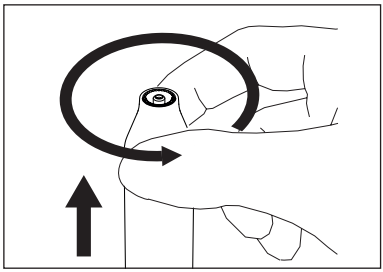
⚠ **CAUTION**: Do not try to unscrew or turn the connector when disconnecting the handpiece. The connector can be damaged.



5

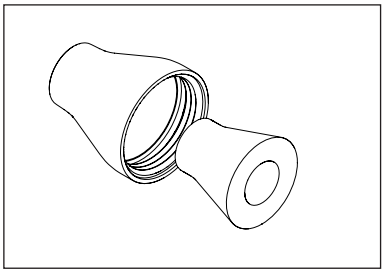
Unscrew the front cone from the scaler handpiece.

⚠ **CAUTION:** The front cone has a light guide. If the front 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.



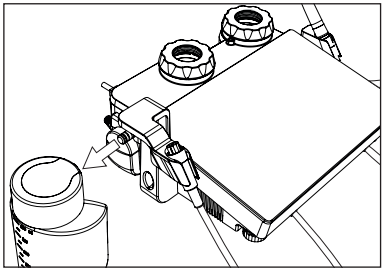
6

Remove the light guide from the front cone.



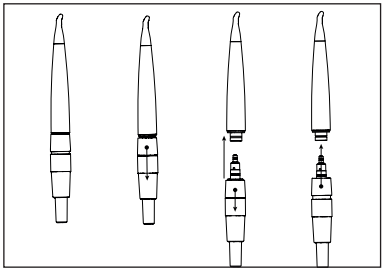
7

Disconnect the bottle from the device core unit, pulling it outwards.



8

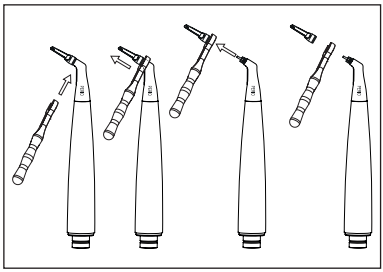
On the quick coupling of the cord, slide the ring and hold it in position, then extract the air-polishing handpiece, and finally release the ring of the handpiece.



9

If the PERIO air-polishing handpiece was used, remove the Subgingival Perio Tips using the supplied K9 wrench and proceed with disposal (see *Chapter 17 on page 102*).

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



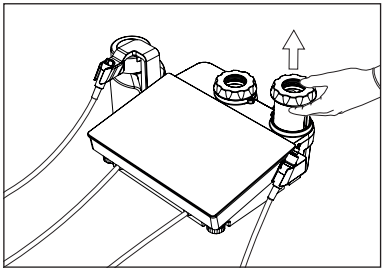
⚠ **CAUTION**: Before extracting the powder container or unscrewing the caps, check that the device is switched off and disconnected from the power mains, or run the "Refill" function (see *Chapter 5.6.1 on page 35*).

Extract the powder container from the device, remove the cap and empty it.
Proceed with their cleaning. (see *Chapter 16.8 on page 97*)
Repeat the operation on the second powder container of the device if both have been used.

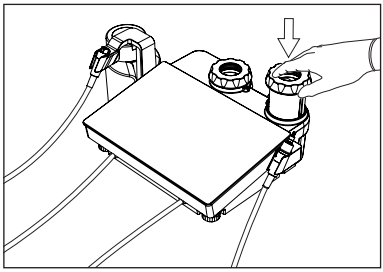
When the cleaning operation has been completed, reposition the containers in the device.

⚠ **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.

10



11



8 CLEANING AND STERILIZATION TABLE

This table is purely indicative. For the complete cleaning and sterilization procedures of the individual parts, refer to the paragraphs indicated in the table.

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

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

Device Core Unit, Pedal, Quick Coupling and Relative Cord of Polisher Handpiece and Scaler Handpiece, Bottle and Cap			
Phase	**Chapter**	**Procedure**	**Frequency**
I	*8.1*	Preparation	
II	*9*	Cleaning	Between each patient

Device Core Unit and Accessories (Scaler handpiece, Air polishing handpiece, K9 torque, Torque wrench, Piezo Tips, Irrigation kit)			
Phase	**Chapter**	**Procedure**	**Frequency**
III	*10.2*	Manual cleaning	- Prior the first use - After each treatment session
IV	*10.3*	Automatic cleaning	- Prior the first use - After each treatment session
V	*13*	Sterilization	- Prior the first use - After each treatment session
VI	*14*	Disinfection	- Prior the first use - Daily if the decontamination is not applied - Anytime is not use for longer than 72h consecutive
VII	*15*	Decontamination	- At the end of the day

NOTE: Repeated reconditioning has a minimal effect on the devices and their accessories. The end of the service life of the accessories is generally determined by wear or damage resulting from use. The Manufacturer guarantees the integrity of its sterilizable air-polishing and scaler handpieces for up to 250 reconditioning cycles.

8.1 Cleaning Preparation

1. Run the Flush function (see *Chapter 6 on page 36*);
2. Remove the following accessories from the device unit (see *Chapter 7 on page 42*):
   - Power supply cable;
   - Pedal;
   - Scaler handpiece;
   - Piezo tips;
   - Air-polishing handpiece;
   - Water and air hose.

⚠ **CAUTION**: The cleaning and sterilizing 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 piezo tip from the handpiece before cleaning and sterilizing 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 carry out the "Flush" function without the air-polishing handpiece.

9 CLEANING THE NON-STERILIZABLE PARTS

The following procedure must be performed on non-sterilizable parts of the device.
The parts in question are:

- Device core unit.
- Pedal and relative connection cable to the device.
- Quick coupling of polisher handpiece and relative cord.
- Quick coupling of scaler handpiece and relative cord.
- Bottle and cap.

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

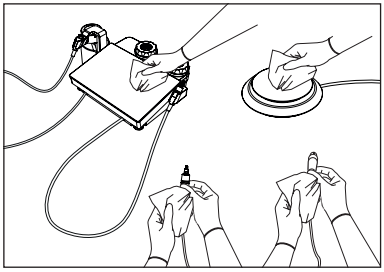
» **REQUIRED MATERIALS**

- Clean, soft, low-lint cloths;
- Use a cleaning and disinfecting aldehyde-free wipe (less than 35% alcohol) compatible EPA-registered intermediate-level surface disinfectant or that complies with the standards applicable in the country (e.g. Opti-Cide wipes).

» **CLEANING METHOD**

Clean the surface of the parts in question using a disinfecting wipe.
Dry the parts using a dry, non-abrasive, low-lint cloth.

1



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

⚠ **WARNING**: The device and its parts that cannot be sterilized are not protected against the penetration of liquids. Do not spray liquids directly on the surface of the device or its parts that cannot be sterilized.

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

⚠ **CAUTION**: Do not soak the non-sterilizable parts in liquids and/or various kinds of solutions.

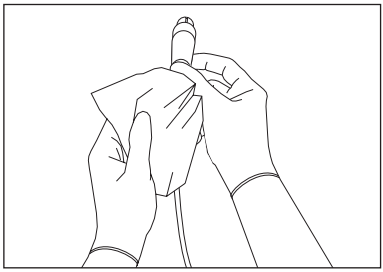
⚠ **CAUTION**: To disinfect the device and/or its accessories, it is recommended the use of water-based disinfectant solutions with a neutral pH (pH7).
DO NOT USE as disinfectants:

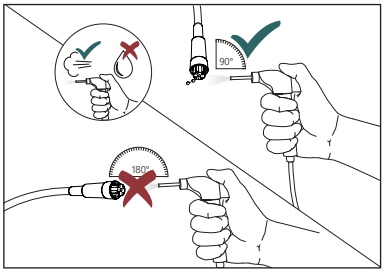
- Alcohol-based disinfectant solutions;
- Peracetic acid, Formaldehyde, Gluteraldehyde based products or other equivalent solutions/products;
- Very alkaline products (pH > 9);
- Products containing sodium hypochlorite;
- Products containing hydrogen peroxide;
- Products containing abrasive substances;
- Very acidic products (PH < 4);
- Products containing aldehyde, amine and/or phenols
- Acetone;
- Methylethylketone;

since they may discolor and/or damage the materials of the device and its accessories. 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.

⚠ **WARNING: Always dry scaler coupling electrical contacts**

After the cleaning and before connecting the scaler handpiece make sure that the scaler cord and the scaler coupling electrical contacts are perfectly dry. Dry the scaler coupling electrical contacts by using filtered compressed air. DO NOT blow the compressed air directly into the hose; keep the coupling upside down and direct the compressed air from its side (refer to figure on the right).





9.1 Cleaning the Bottle and Cap

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

» **PREPARATION**

1. Disconnect the bottle from the device core unit (see *Chapter 7 on page 42*);
2. Unscrew the cap from the bottle.

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

» **REQUIRED MATERIALS**

- Water;
- Use a cleaning and disinfecting wipe (less than 35% alcohol) compatible EPA-registered intermediate-level surface disinfectant or that complies with the standards applicable in the country (e.g. MICRO-KLEEN or Opti-Cide wipes)
- Clean, soft, low-lint cloth;
- Demineralised water.

⚠ **CAUTION**: To disinfect the device and/or its accessories, it is recommended the use of water-based disinfectant solutions with a neutral pH (pH7).
DO NOT USE as disinfectants:

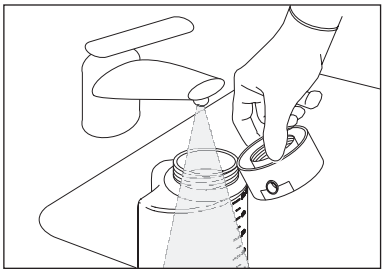
- Alcohol-based disinfectant solutions;
- Peracetic acid, Formaldehyde, Gluteraldehyde based products or other equivalent solutions/products;
- Very alkaline products (pH > 9);
- Products containing sodium hypochlorite;
- Products containing hydrogen peroxide;
- Products containing abrasive substances;
- Very acidic products (PH < 4);
- Products containing aldehyde, amine and/or phenols
- Acetone;
- Methylethylketone;

since they may discolor and/or damage the materials of the device and its accessories. 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.

» **CLEANING METHOD**

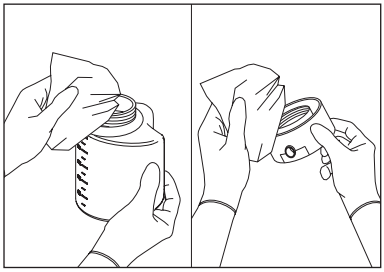
Thoroughly rinse the inside and outside of both the bottle and cap under running water.

1



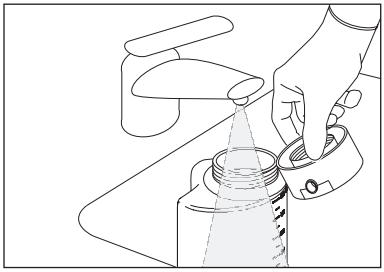
2

Clean the external and internal surfaces of the bottle and cap with a wipe.



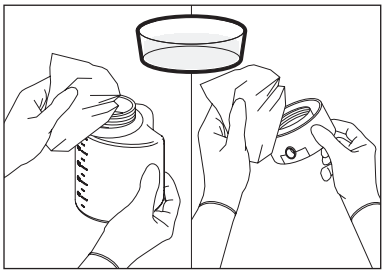
3

Thoroughly rinse the inside and outside of the bottle and cap under running water to eliminate all residue of the detergent solution.



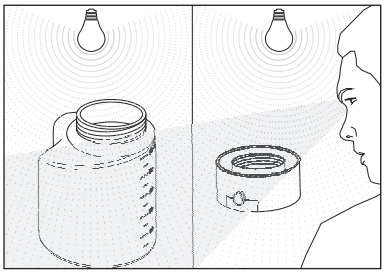
4

Remove any residue on the external or internal surfaces of the bottle and cap using a soft, low-lint cloth, dampened with demineralised 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.



10 CLEANING THE STERILIZABLE ACCESSORIES

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

The sterilizable parts of the device are:

- Scaler handpiece;
- Scaler front cone;
- Scaler light guide;
- Piezo tips;
- Piezo tips torque wrench;
- Air-polishing handpiece;
- K9 Wrench;
- Irrigation Circuit Cleaning Kit.

Before proceeding with cleaning check (*Chapter 11 on page 67*), drying and lubrication (*Chapter 12 on page 69*) and then sterilization (*Chapter 13 on page 71*), one of the two possible cleaning methods explained in detail in the following chapters must be selected (see *Chapter 10.2 on page 53* and *Chapter 10.3 on page 65*).

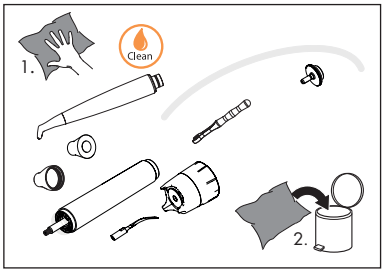
⚠ **CAUTION**: The instructions supplied below have been validated by the manufacturer of the medical device as ABLE to prepare a medical device for re-use. The process manager is responsible for ensuring that the processes repeated are effectively performed using the equipment, materials and staff in 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.

10.1 Pre-Cleaning

After having observed the indication provided in the *Chapter 8.1 on page 47*, proceed as follows:

1

Completely wipe down the external surfaces with aldehyde-free ready-to-use wipes (with less than 35% alcohol) until they are visually clean. Make sure that the surfaces are sufficiently moistened. Note the action time of the cleaning agent according the their Manufacturer.



10.2 Manual Cleaning

Manual cleaning can be carried out as an alternative to the automatic cleaning described in *Chapter 10.3 on page 65*.

» **REQUIRED MATERIALS**

- Enzymatic detergent at pH 6-9;
- Water;
- Container for immersion in the enzymatic liquid;
- Ultrasonic tank;
- Clean, soft, low-lint cloths;
- Brush with soft nylon bristles;
- Syringe;
- Demineralised water

⚠ **CAUTION**: **DO NOT USE** as disinfectants:

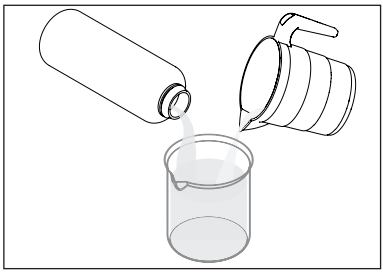
- Alcohol-based disinfectants solutions;
- Peracetic acid, Formaldehyde, Gluteraldehyde based products or other equivalent solutions/products;
- Very alkaline products (pH > 9);
- Products containing sodium hypochlorite;
- Products containing hydrogen peroxide;
- Products containing abrasive substances;
- Very acidic products (PH < 4);
- Products containing aldehyde, amine and/or phenols
- Acetone;
- Methylethylketone;

since they may discolor and/or damage the materials of the device and its accessories. 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.

1

Prepare a pH-neutral (6-9) enzymatic detergent solution, following the manufacturer's instructions.

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

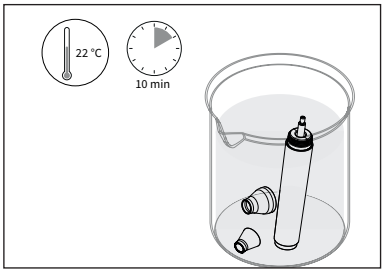


c) Process validated by independent bodies with ENZYMEC enzymatic detergent, 0.8% v/v.

10.2.1 Scaler Handpiece

2

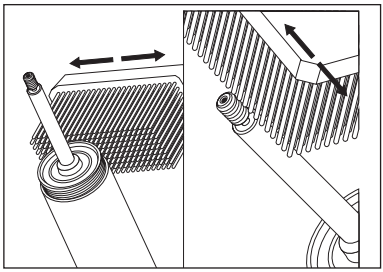
Completely immerse the scaler handpiece, front cone, and light guide in the enzymatic solution. Leave to soak for 10 minutes at 71.6°F ±3.6°F (22°C ±2°C).



3

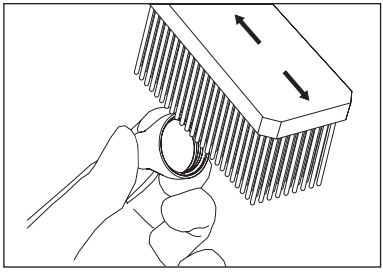
Gently brush the entire surface of the scaler handpiece, front cone, and light guide for at least 20 seconds using a brush with soft nylon bristles, paying particular attention to the following areas:

- thread of the scaler handpiece.
- titanium shaft.



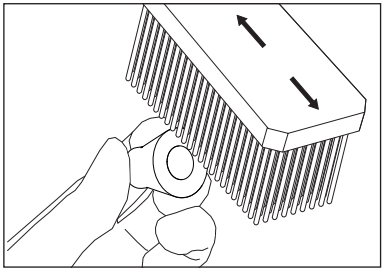
4

- external and internal parts of front cone.



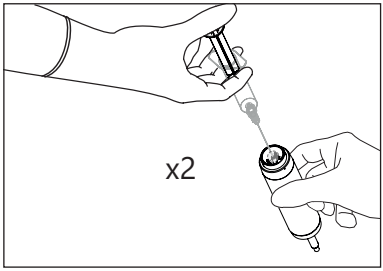
5

- external and internal parts of light guide.



6

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

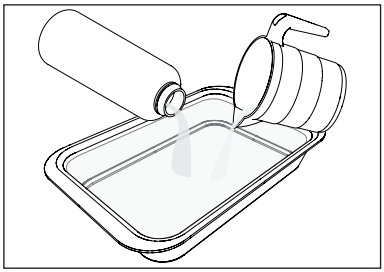


7

Remove the handpiece, front cone, and light guide from the enzymatic solution and gently brush their surfaces using a brush with soft nylon bristles under hot (104°F ±9°F (40°C ±5°C)) running water, for at least 10 minutes.

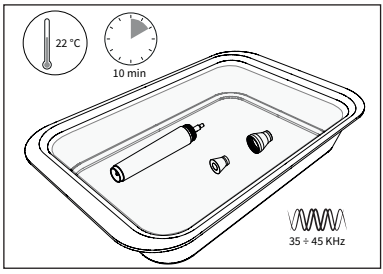
8

Fill the ultrasonic tank with the enzymatic detergent solution prepared according to the manufacturer's instructions.
Use water at ambient temperature 71.6°F ±3.6°F (22°C ±2°C).



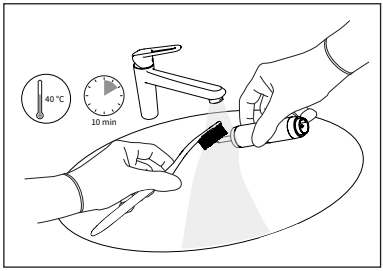
9

Place the scaler handpiece, front cone, and light guide in the ultrasonic tank immersed in the enzymatic detergent solution at 71.6°F ±3.6°F (22°C ±2°C) and run a cycle for at least 10 minutes.



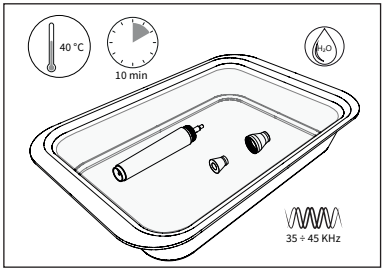
10

Remove the handpiece, front cone, and light guide from the enzymatic solution and gently brush their surfaces using a brush with soft nylon bristles under hot (104°F ±9°F (40°C ±5°C)) running water, for at least 10 minutes.



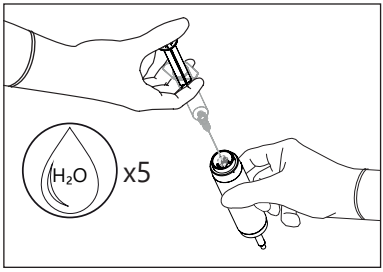
11

Place the scaler handpiece, front cone, and light guide in the ultrasonic tank immersed in demineralised water at 104°F ±9°F (40°C ±5°C) and run a cycle for at least 10 minutes.



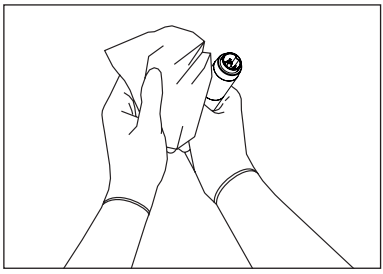
12

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



13

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

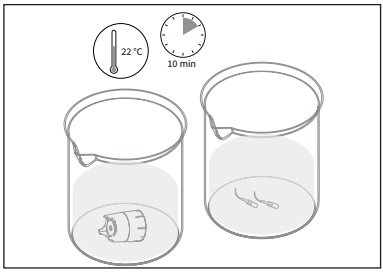


Process validated by independent bodies with enzymatic detergent

10.2.2 Piezo Tips and Torque wrench

14

Place the piezo tip or the torque wrench in a clean container, in a horizontal position. Add an adequate amount of enzymatic solution to fully cover the device to be cleaned.
Leave the device to soak in the enzymatic detergent solution for 10 minutes at ambient temperature 71.6°F ±3.6°F (22°C ±2°C).



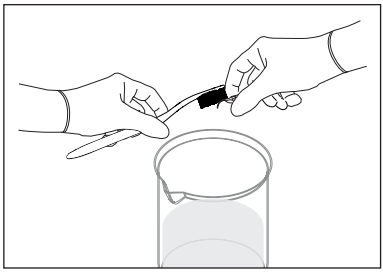
15

After 10 minutes of immersion in the enzymatic solution, gently scrub the device's internal and external surfaces with a soft-bristled brush until any visible dirt is removed.
For each part to be cleaned use a brush that is suitable to its dimension. Use different brushes for piezo tip and for torque wrench.

NOTE - Piezo tip: Thoroughly clean hard-to-reach areas such as sharp edges and in particular, the interstices between the cutting cusps.

NOTE - Wrench: Thoroughly brush for about 20 seconds:

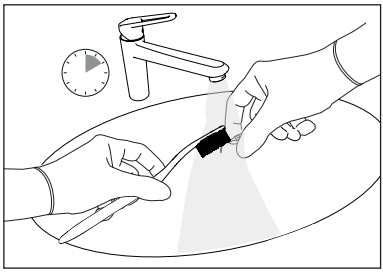
- Through-holes and internal channels;
- External metal ring;
- Internal cavities, grooves and fissures.



16

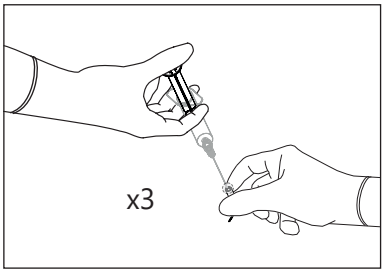
Remove the device from the enzymatic detergent solution.
Thoroughly rinse and brush all the surfaces of the device (see previous point) under running water for:

- at least 10 minutes for the wrench;
- at least 1 minute for the piezo tip.



17

PIEZO TIP: Use a 20ml disposable syringe to flush the enzymatic detergent solution into the hard-to-reach areas (inner channels and through-holes/ cannulae). Repeat this step three times to ensure the effective removal of dirt from the internal surfaces. Each time use freshly prepared solution.

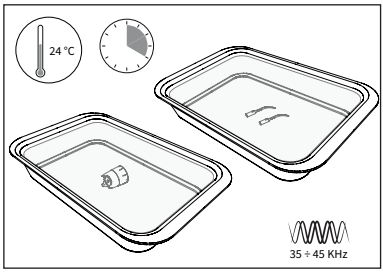


18

Place the device in the ultrasonic tank immersed in the enzymatic detergent solution at 75.2 °F ±35.6 °F (24 °C ±2 °C) and run a cycle for:

- at least 20 minutes for the wrench;
- at least 10 minutes for the piezo tip.

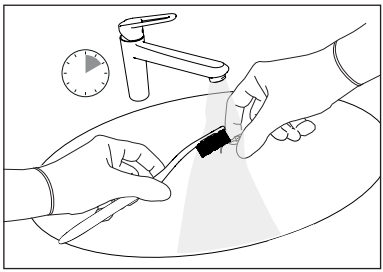
or as instructed by the Enzymatic detergent manufacturer or by the manufacturer of the ultrasonic tank.



19

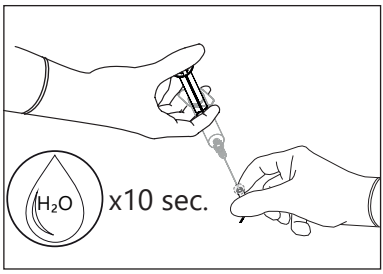
Remove the device from the enzymatic detergent solution.
Thoroughly rinse and brush all the surfaces of the device (see previous point) under running water for:

- at least 10 minutes for the wrench;
- at least 1 minute for the piezo tip.



20

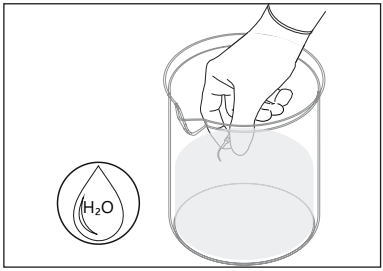
PIEZO TIP: Use a 20ml disposable syringe to inject demineralized water into the inner channel of the tip(s). Repeat this step three times to ensure the effective removal of any dirt from the internal surfaces.



Soak the device in demineralized water for:

- at least 5 minutes for the wrench;
- at least 1 minute for the piezo tip

21



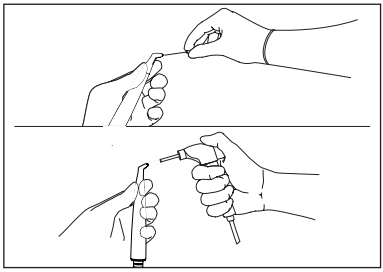
10.2.3 Air Polishing Handpiece

Free the channel of the air-polishing handpiece of any powder residue 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 air-polishing handpiece using only the Ø 0.4 mm cleaning needle supplied with the device.

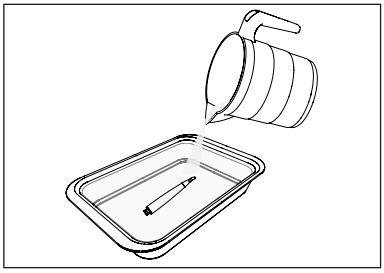
⚠ **CAUTION:** If the single-use Subgingival Perio Tips is on the air-polishing handpiece, remove and dispose of it.

22



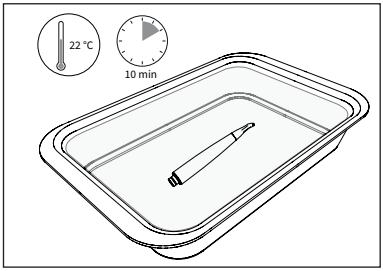
Place the air-polishing handpiece in a clean container, in a horizontal position, and add enough enzymatic detergent solution to completely cover the handpiece.

23



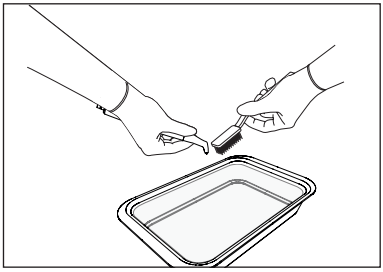
24

Leave to soak for 10 minutes at 71.6°F ±3.6°F (22°C ±2°C). This procedure reduces the amount of blood, protein and mucous present on the air-polishing handpiece.



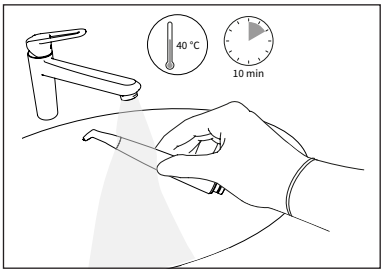
25

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.



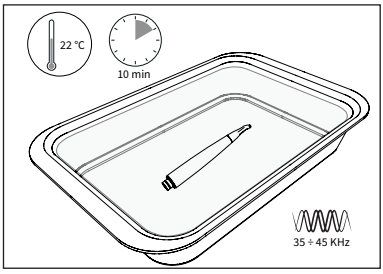
26

Brush with soft bristled nylon brush and rinse the air-polishing handpiece under hot running water (104°F ±9°F (40°C ±5°C)) for about 10 minutes, moving it slightly to allow the water to reach the entire surface.



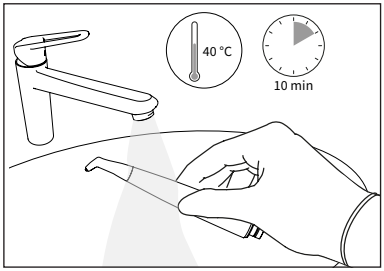
27

Place the air-polishing handpiece in the ultrasonic tank immersed in the enzymatic detergent solution for at least 10 minutes at 71.6°F ±3.6°F (22°C ±2°C).



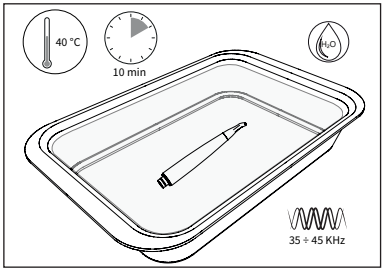
28

Brush with soft bristled nylon brush and rinse the air-polishing handpiece under hot running water (104°F ±9°F (40°C ±5°C)) for about 10 minutes, moving it slightly to allow the water to reach the entire surface.



29

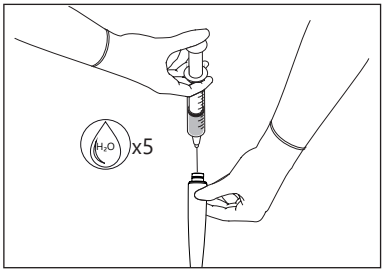
Place the air-polishing handpiece in the ultrasonic tank immersed in demineralised water for at least 10 minutes at 104°F ±9°F (40°C ±5°C).



30

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 deionised water at ambient temperature 68°F - 77°F (20°C – 25°C) using a syringe with needle, five times in a row.

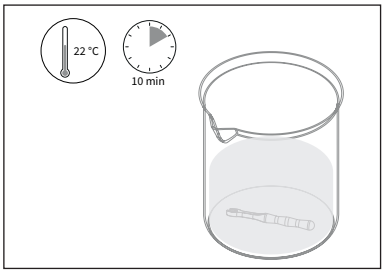
Process validated by independent bodies with enzymatic detergent.



10.2.4 K9 Wrench and Irrigation Kit

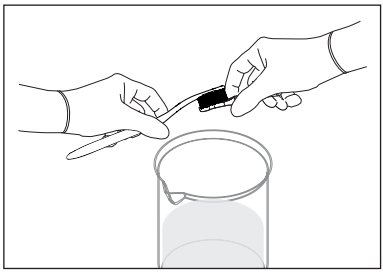
(31)

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 71.6°F ±3.6°F (22°C ±2°C).



(32)

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.

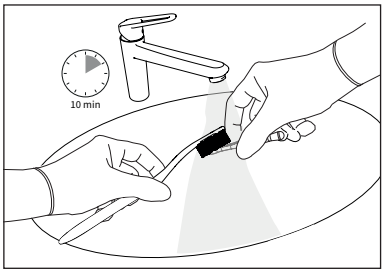


NOTE: Thoroughly brush all the following parts of the K9 wrench for about 20 seconds:

- Through-holes and internal channels;
- Hard-to-clean areas such as sharp edges and in particular, the interstices between the cutting cusps;
- External metal ring;
- Internal cavities, grooves and fissures.

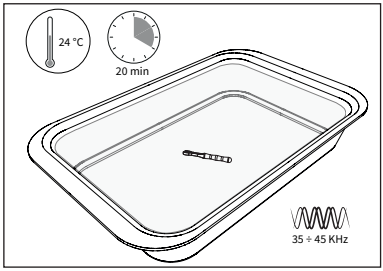
(33)

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.



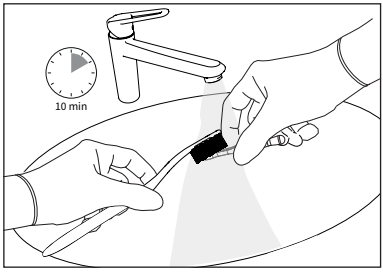
34

Place the K9 wrench in an ultrasonic tank immersed in the enzymatic detergent solution at 75.2°F ±3.6°F (24°C ±2°C) and run a cycle for at least 20 minutes.



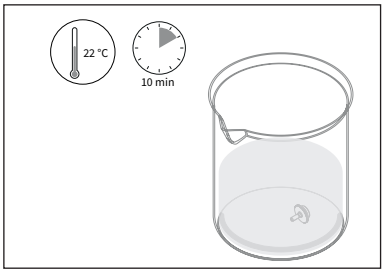
35

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 external surfaces of the K9 wrench with a clean brush with soft nylon bristles, under running water.



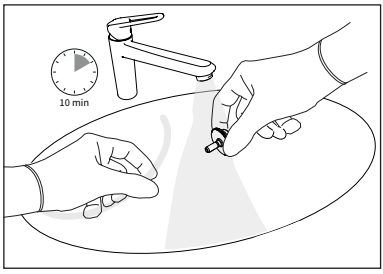
36

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 71.6°F ±3.6°F (22°C ±2°C).



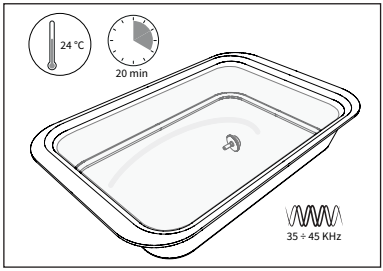
37

Remove the hose and the coupling from the enzymatic detergent solution.
Thoroughly rinse all surfaces under running water for at least 10 minutes.



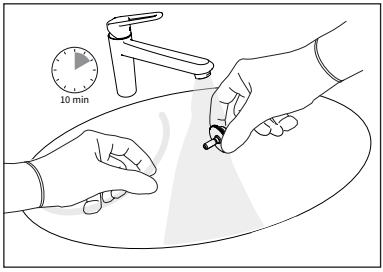
38

Place the Irrigation kit in the ultrasonic tank, submerged in the enzymatic detergent solution at 24 °C ± 2 °C (71.6 °F ±35.6 °F) and run a cycle of at least 10 minutes.



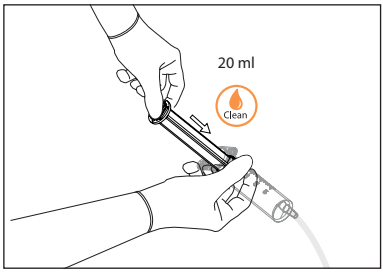
39

Remove the Irrigation kit from the enzymatic solution and rinse them under running hot (104 °F ±41 °F (40 °C ± 5 °C)) water for at least 10 minutes.



40

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



NOTE: Once all the cleaning steps have been performed, pass to the sterilization of all parts.

10.3 Automatic Cleaning

Automatic cleaning can be carried out as an alternative to the manual cleaning described in *Chapter 10.2 on page 53*.

NOTE: Procedure validated with:

- Miele PG8536 washer/disinfector;
- Miele DES-VAR-TD program;

» **REQUIRED MATERIALS**

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

NOTE: Make sure that the accessories are appropriately blocked 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.

- Alkaline detergent: neodisher® FA (0.2 % v/v);
- Neutralizing liquid: neodisher® Z (0.1 % v/v)

⚠ **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.

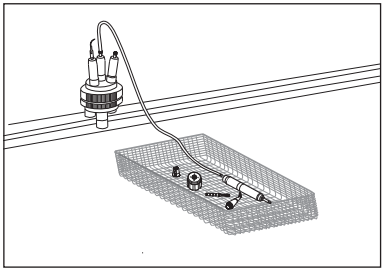
Position the accessories in a metal basket. Connect the relevant adapter (supplied as an optional) to the scaler handpiece connector and then to the water jet cleaning connections of the thermal-disinfector.
Repeat the same operation for the piezo tips by connecting them to the appropriate adapters supplied as optionals.
Sequence and parameters applicable to the cycle:

- 1 min, Rinse with cold water;
- 5 min, Wash with alkaline detergent at 131°F ±3.6°F (55°C ±2°C).
- 1 min, Neutralisation with suitable solution (1/3 cold water, 2/3 hot water);
- 1 min, Rinse with water (1/3 cold water, 2/3 hot water);
- 5 min, Thermal disinfection at 199.4°F (93°C) with demineralised water.

Thermal disinfection has not been tested experimentally. In compliance with ISO 15883-1, Table B.1 [4] thermal disinfection at a temperature di 194°F (90°C) for 5 min determines a value A0 3000.

NOTE: Once all the cleaning steps have been performed, pass to the sterilization of all parts.

1



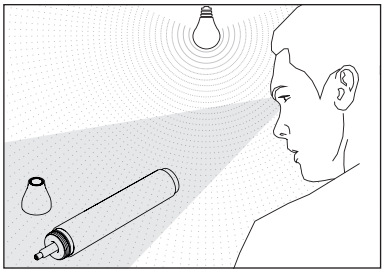
11 CLEANING CHECK

» **REQUIRED MATERIALS**

- Light source;
- 2.5X Magnifier.

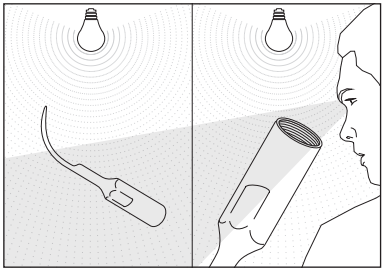
1

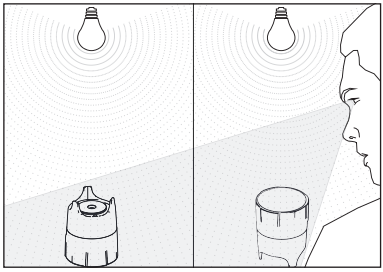
Once the cleaning operations have been completed, check the scaler handpiece and scaler front cone under an adequate source of light, if necessary using a magnifying glass 2.5X, paying attention to any parts that may conceal soil residue (threading, cavities, grooves) and, if need be, repeat the cleaning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

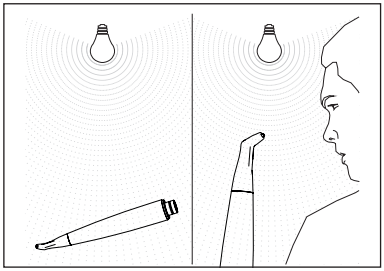


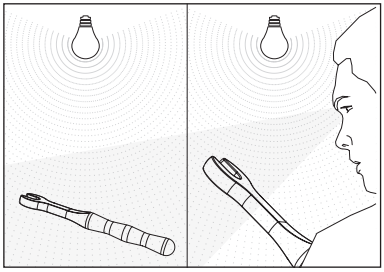
2

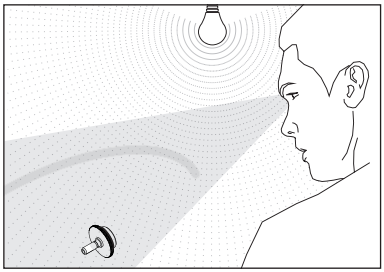
Repeat the checking operations for the other accessories (piezo tips, piezo tips tightening wrenches, air-polishing handpieces, K9 wrench, irrigation circuit cleaning kit), repeating the cleaning cycle if necessary.











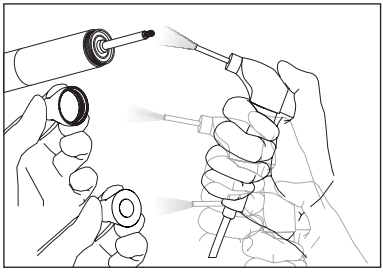
12 DRYING AND LUBRICATION

» **REQUIRED MATERIALS**

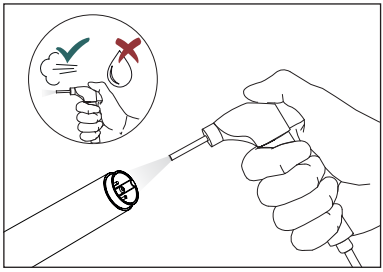
- Compressed air;
- Soft, low-lint cloth;
- Medical grade lubricant.

1

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

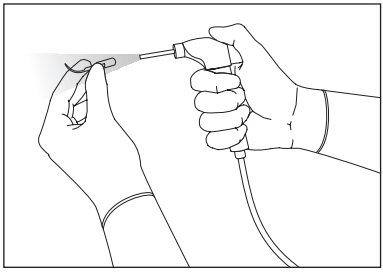


⚠ **CAUTION**: The scaler handpiece electrical contacts must be dry at the start and end of the sterilization cycle, before the cord is connected to the device. Always make sure that the electrical contacts of the connector are perfectly dry, if necessary dry them blowing with compressed air.



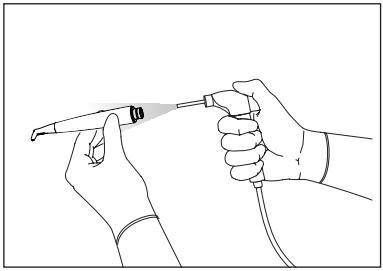
2

⚠ **CAUTION**: Before starting the sterilization cycle, make sure that the piezo tip 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 piezo tip.



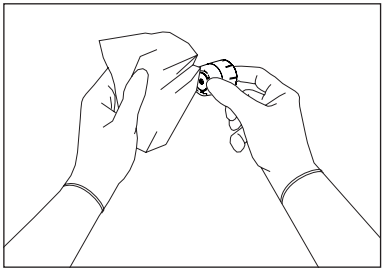
⚠ **CAUTION**: Before starting the sterilization cycle, make sure that the air-polishing handpiece is thoroughly dry both internally and externally.
To do so, blow compressed air both externally and through the internal through-holes. This will prevent the appearance of stains, streaks on the surface,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

3



4

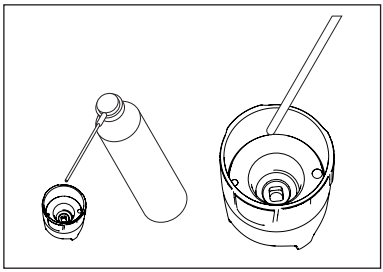
Dry the piezo tips tightening wrench using a soft, low-lint cloth.



5

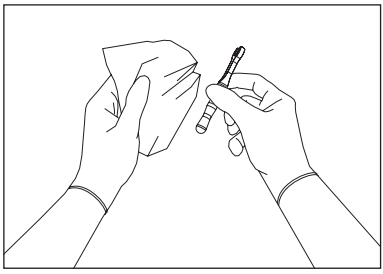
Lubricate the piezo tips tightening wrench with medical-grade lubricants in the indicated point.

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



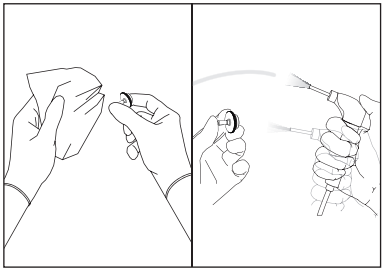
6

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



7

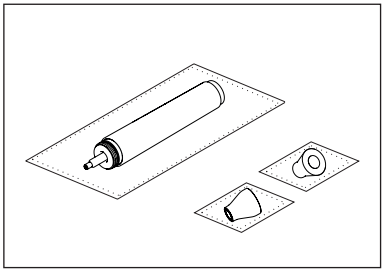
Dry the hose and the coupling surfaces with a clean, non-abrasive, low fiber release cloth.
Dry the internal surfaces with a jet of compressed air until the water is completely eliminated.



13 STERILIZATION

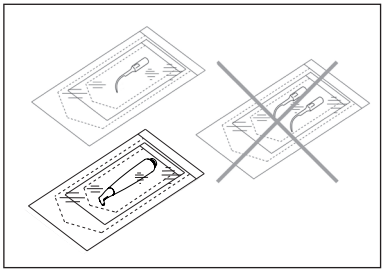
1

Seal the scaler handpiece (without piezo tips), scaler front cone, and light guide individually and separately in disposable legally marketed steam sterilization pouch.



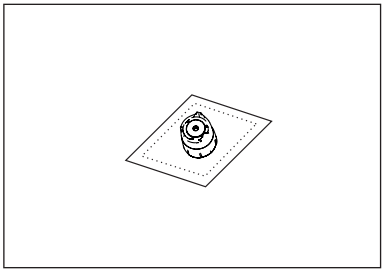
2

Seal the piezo tips individually in disposable legally marketed steam sterilization pouch.
Seal the air-polishing handpieces individually in disposable legally marketed steam sterilization pouch.



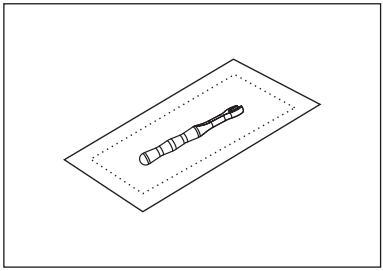
3

Seal the wrench individually in disposable legally marketed steam sterilization pouch.



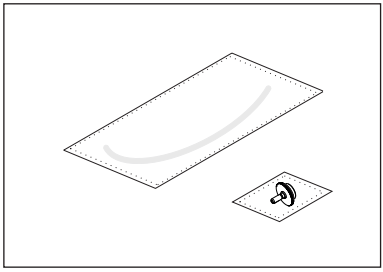
4

Seal the K9 wrench individually in disposable legally marketed steam sterilization pouch.



5

Individually seal the hose and the coupling, separately, in disposable legally marketed steam sterilization pouch.



13.1 Sterilization Method

The sterilizable parts of the device are:

- Scaler handpiece;
- Scaler front cone;
- Scaler light guide;
- Piezo tips;
- Piezo tips torque wrench;
- Air-polishing handpiece;
- K9 Wrench;
- Irrigation Circuit Cleaning Kit.

They are manufactured with materials resistant to a maximum temperature of 275°F (135°C) for a maximum time of 20 minutes.
Once the scaler handpiece and the other sterilizable accessories have been put in individually disposable legally marketed pouch, perform the steam sterilization process in the autoclave.

⚠ **CAUTION:** Use sterilization pouch compliant with standard UNI EN ISO 11607-1.

The sterilization process validated by the Manufacturer 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 (0.87 psi)).
- **Minimum sterilization temperature:** 270°F (132°C) (interval 270°F (132°C) ÷ 275°F (135°C).
- **Minimum sterilization time:** 4 minutes.
- **Minimum drying time:** 20 minutes.

All stages of sterilization 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 piezo tip screwed in.

⚠ **WARNING**: **Infection control - Sterilizable parts.** Thoroughly remove all residual organic matter before sterilization.

⚠ **CAUTION**: Carry out the sterilization by using only an autoclave with steam from water. Do not use any other sterilization 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 sterilization cycle in autoclave, the scaler handpiece remains at the sterilization temperature for a long time. Use appropriate precautions when extracting the scaler handpiece from the autoclave to prevent injury to the operator.

⚠ **CAUTION**: Wait for the scaler handpiece to cool down completely before use.

⚠ **WARNING**: Diamond coated Piezo Tips and the plastic Piezo Tips are inteded for single use only.

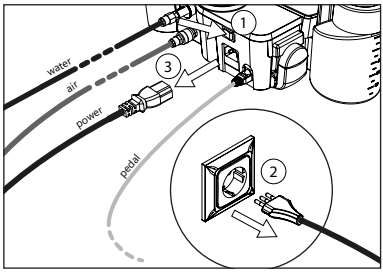
14 DISINFECTING THE IRRIGATION CIRCUIT

Before carrying out the following steps run the Flush function (see *Chapter 6 on page 36*).

NOTE: before starting the disinfection procedure make sure that both scaler and polisher handpieces have been disconnected from the device (see *Chapter 7 on page 42*)

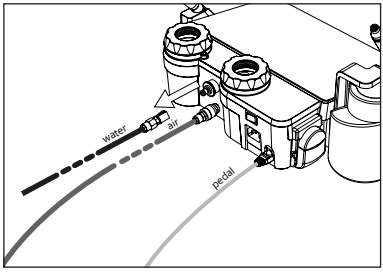
⚠ **WARNING**: **Switch the device off.** Turn the device off using the switch (Ref. 1), disconnect the power cord from the wall socket (Ref. 2) and device core unit (Ref. 3) before cleaning and sterilizing.

1



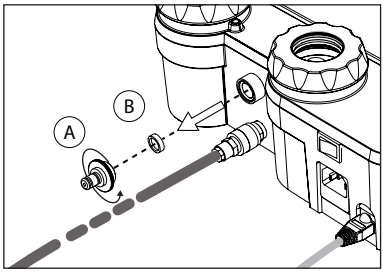
2

Disconnect the quick coupling connector of the external water supply from the device.



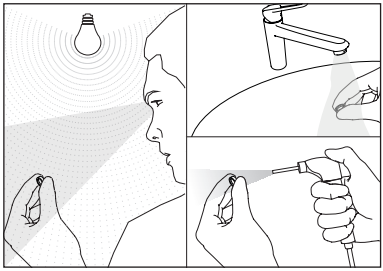
3

Unscrew the knurled bush of the male coupling for the connection to the water supply (Ref. A).
Remove the water filter (Ref. B); use tweezers, if necessary.



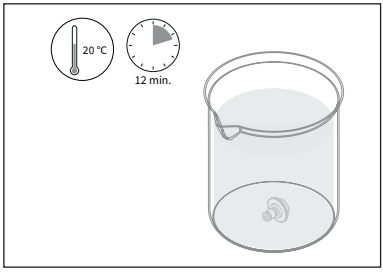
4

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



5

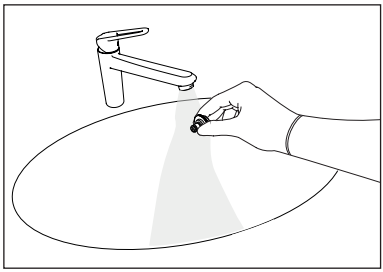
Completely immerse the male coupling for connection to the external water circuit in the disinfectant solution (CIDEX® OPA). Soak for 12 minutes at 68°F ±3.6°F. (20°C ±2°C).



6

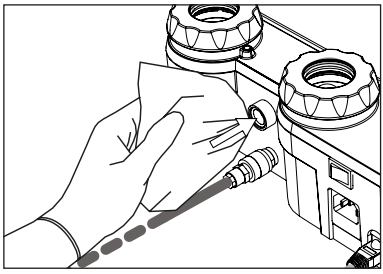
Remove the male coupling from the disinfectant solution (CIDEX® OPA) and rinse it under running water.

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



7

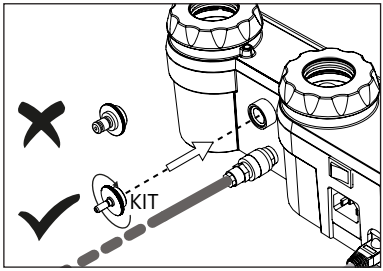
Disinfect the internal surfaces of the seat where the male coupling will be isnerted with a clean, soft, low-lint cloth dampened with the disinfectant solution (CIDEX® OPA).



8

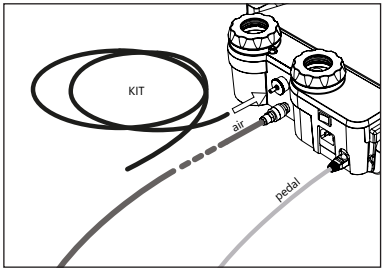
Screw in the male coupling supplied with the "Irrigation Circuit Cleaning Kit" into the housing until it reaches the stop.

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



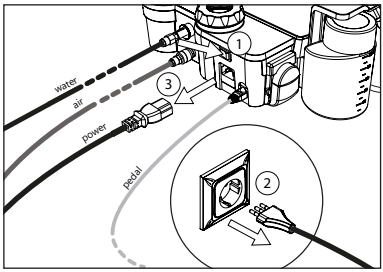
9

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



10

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).



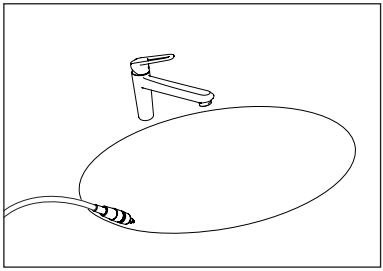
14.1 Air Polisher Side

11

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

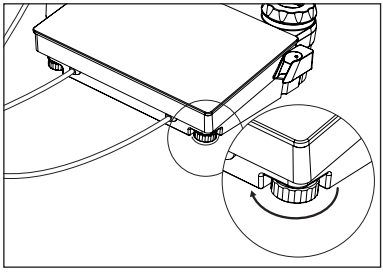
12

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



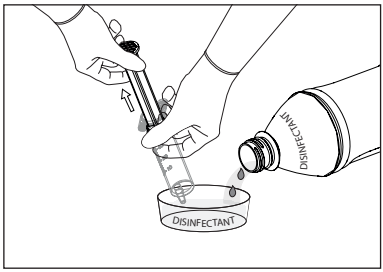
13

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



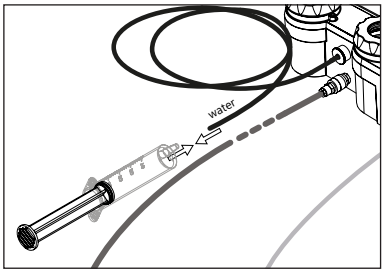
14

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



15

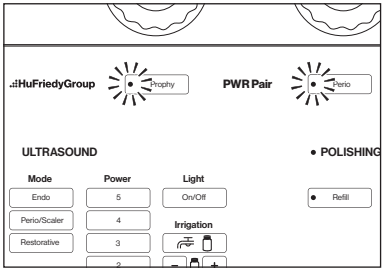
Connect the syringe to the end of the hose previously connected to the male water connection.



16

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

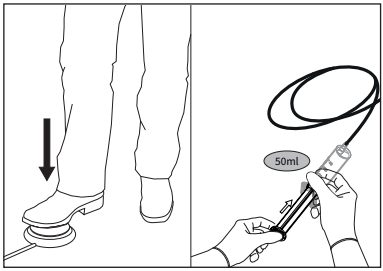
NOTE: Make sure that both powder containers are present and correctly positioned in their seats, otherwise it will not be possible to activate the "Flush" function.



17

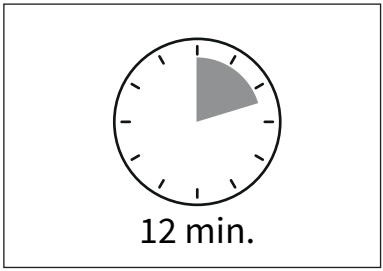
Press the pedal until 50 ml of disinfectant have been injected, leaving the remaining 10ml in the syringe.

⚠ **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



18

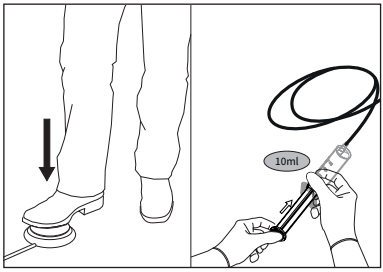
Wait 12 minutes.



19

Press the pedal and inject the last 10ml of remaining disinfectant.

⚠ **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.

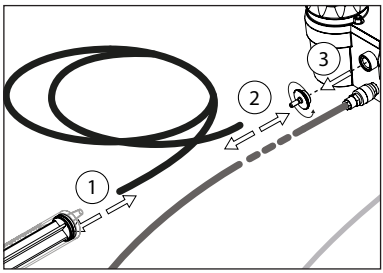


20

Disconnect the syringe and repeat points from 14 to 19.

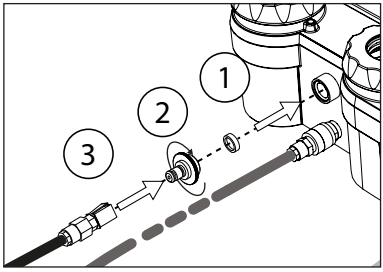
21

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



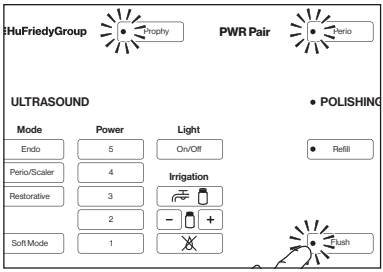
22

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.



23

Run 3 consecutive "Flush" cycles (see *Chapter 6 on page 36)*.



14.2 Ultrasound - scaler part

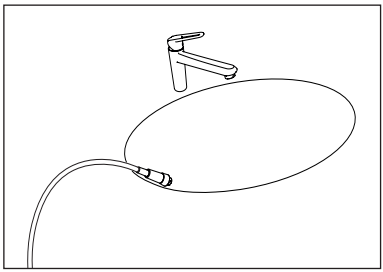
24

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

25

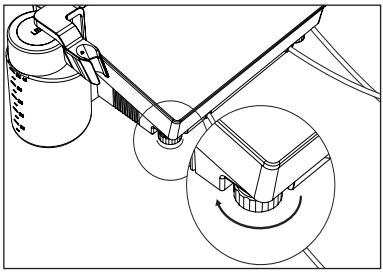
Lift the scaler hose and place it over a container or sink to contain the liquid that will flow outduring the procedure.

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



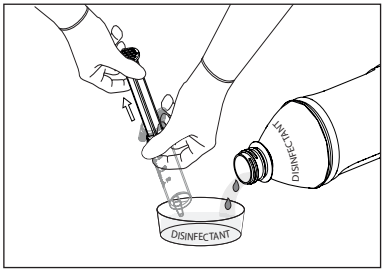
26

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



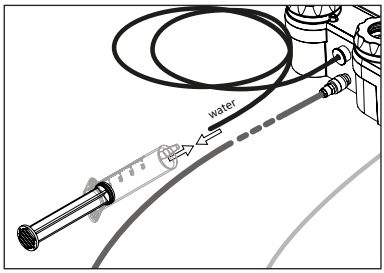
27

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



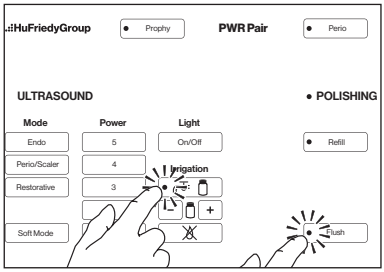
28

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



29

Select "Flush" on the touch keyboard (Ref. 1) and select the external irrigation circuit (Ref. 2).



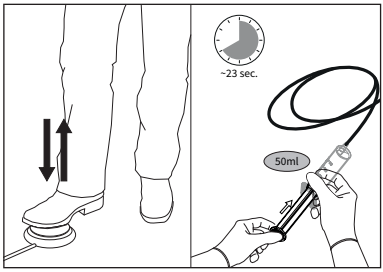
30

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.

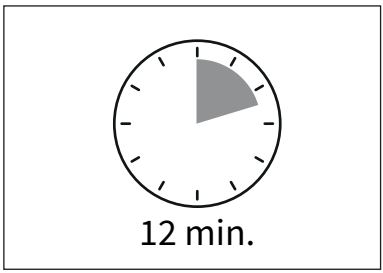
⚠ **CAUTION**: Do not exert excessive pressure on the syringe plunger. The size of the irrigation circuit pipes is small and it is normal that the injection proceeds slowly.

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.



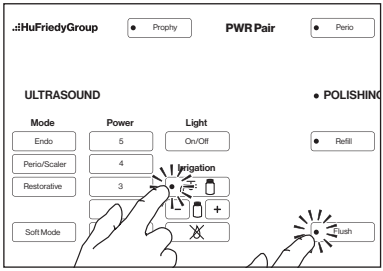
31

Wait 12 minutes.



32

Select "Flush" on the touch keyboard (Ref. 1) and select the external irrigation circuit (Ref. 2).



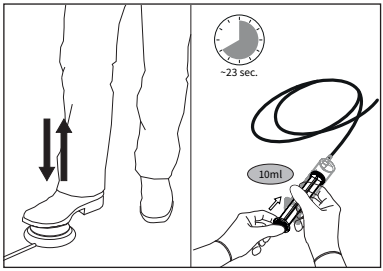
33

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.

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.

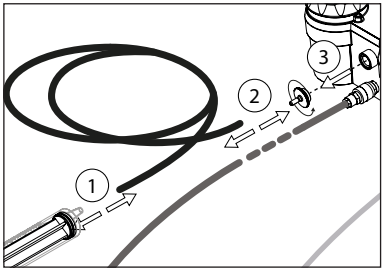


34

Disconnect the syringe and repeat points from 27 to 33.

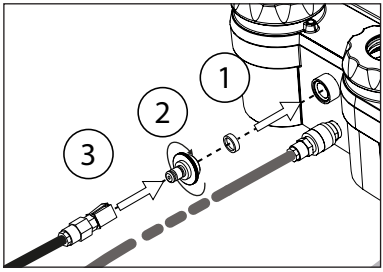
35

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



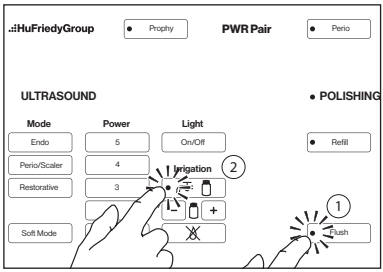
36

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 (Ref. 1 - see *Chapter 6 on page 36*) assuring to select the external irrigation circuit (Ref. 2).

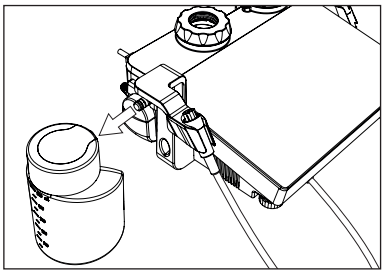


⚠ **CAUTION**: Before connecting and using the scaler handpiece, make sure that the electrical contacts on both the scaler handpiece and its cord are perfectly dry.

14.3 Irrigation Circuit from the Bottle

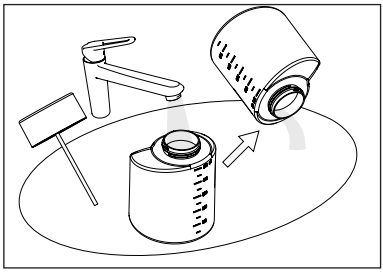
38

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



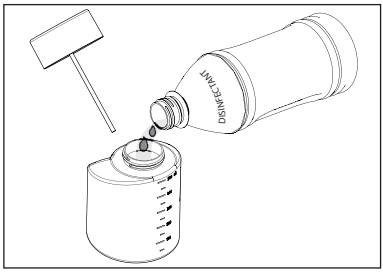
39

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



40

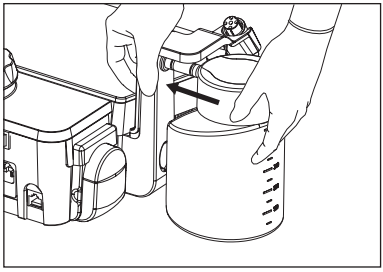
Fill the irrigation bottle with 200ml of disinfectant (CIDEX® OPA) and close the cap.



41

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

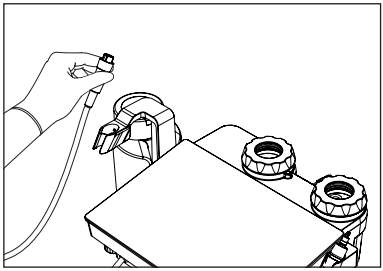
⚠ **CAUTION**: Do not capsize the Irrigation Bottle as its cap is not watertight. The leaking of potentially aggressive liquids can damage the surfaces.



Lift the scaler hose.

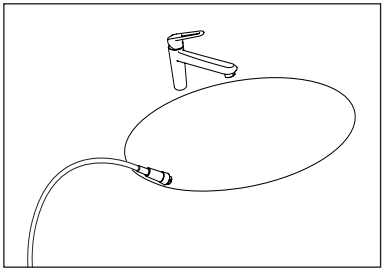
⚠ **CAUTION**: Make sure that the polisher hose is in its housing otherwise the device remains inactive.

42



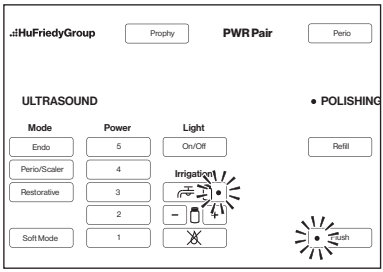
Place the hose over a container or sink to contain the liquid that will flow outduring the procedure.

43



Select the bottle irrigation circuit by pressing the “irrigation” key.
Select "Flush" on the touch surface (see *Chapter 6 on page 36)*.
All other selectable options on the touch surface will be disabled.

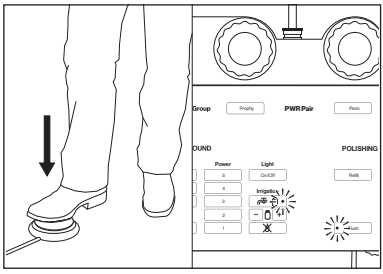
44



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.

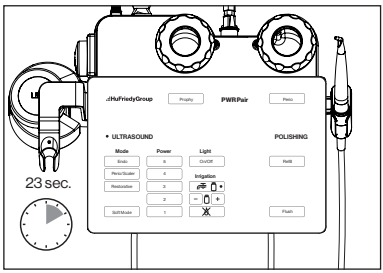
NOTE: You can exit the "Flush" mode at any time by pressing "Flush", the touch surface is enabled again, and displays the last setting used.

45



46

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

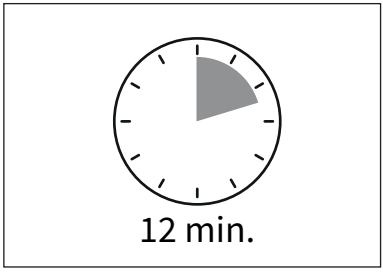


47

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

48

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

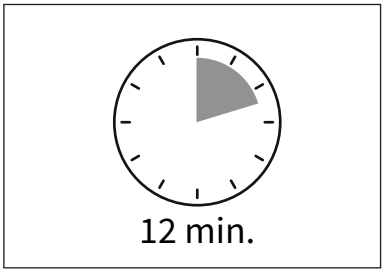


49

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

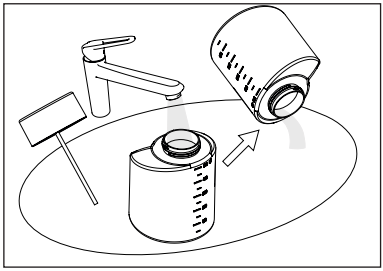
50

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



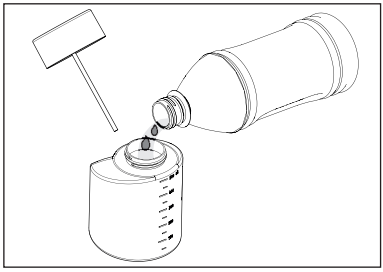
51

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.



52

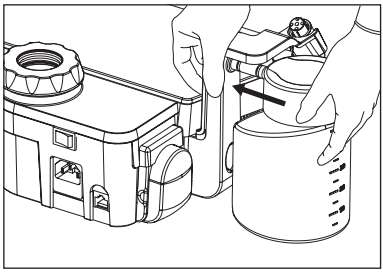
Fill the irrigation bottle with 100ml of demineralized water.



53

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

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



54

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

⚠ **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.

15 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 cleand and protect the dental unit's irrigation lines. The Manufacturer recommends using EPA-registered dental unit irrigation lines cleaners (for example MicroCLEAN).
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 (see *Chapter 6 on page 36*);
- Disconnect the device from the water sources (mains water supply; containers (see *Chapter 7 on page 42*));
- Inject chlorine dioxide into the connection of the mains water supply by means of a 60 cc syringe; (see *Chapter 14 on page 74*);
- 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.

16 MAINTENANCE

16.1 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 6 on page 36*) both on the Ultrasound side and the Polishing side for all types of irrigation;
Immediately disassemble the different parts (see *Chapter 7 on page 42*) and proceed to their cleaning and sterilization (see *Chapter 10 on page 52*).
Clean the not-sterilzable parts (see *Chapter 9 on page 48.*

16.2 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 7 on page 42*).

⚠ **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.

Polishing Side

3 Start the Refill function if the powder containers are still pressurized (see *Chapter 5.6.1 on page 35*).

4 Remove and empty both powder containers (see *Chapter 7 on page 42*).

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 16.8 on page 97*). Put the empty powder containers back into their correct position in the device.

7 Start "Flush" on Polishing side (see *Chapter 6.2 on page 39*).

8 Clean the parts of the device that cannot be sterilized (see *Chapter 9 on page 48*).

9 Reconnect the empty water bottle and perform the Decontamination or Disinfection of the Irrigation circuit.

16.3 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 6 on page 36*) for both the Ultrasound and Polishing parts.
3. Perform a complete disinfection of all the irrigation circuits (see *Chapter 14 on page 74*).
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 16.10 on page 100*).
6. Disconnect the device from the power mains and from the air and water circuits.
7. Clean and dry the water filter (see *Chapter 14 on page 74*).
8. Follow the steps outlined in Chapter 14, but this time the syring should be filled with air instead of disinfectant.
9. Repeat all the steps, there will be no need to wait for 12 minuts 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.

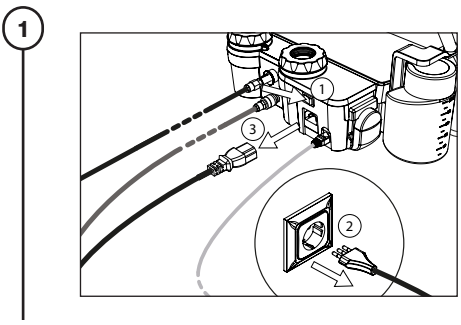
Before using the device again after a long inactivity period:

11. Perform a complete cleaning cycle of the irrigation circuit using the “Flush” function (see *Chapter 6 on page 36*) both on the Ultrasound side and the Polishing side.
12. Perform again a complete disinfection of all the irrigation circuits (see *Chapter 14 on page 74.*
13. Clean and sterilise the handpiece and accessories following the instructions in *Chapter 8 on page 46.*
14. 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 HuFriedyGroup spare part.

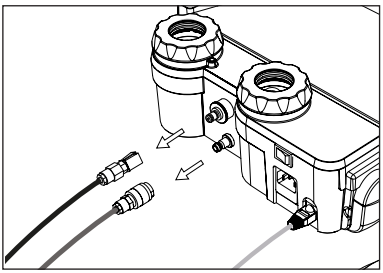
16.4 Unclogging the device polisher line

⚠ **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.



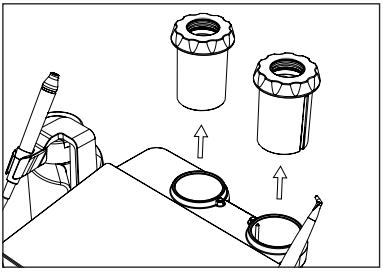
2

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



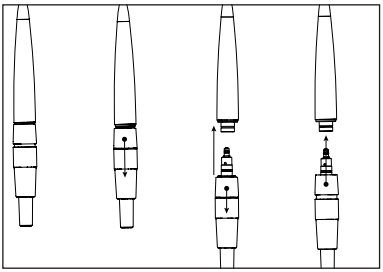
3

Remove both powder containers from their seat.



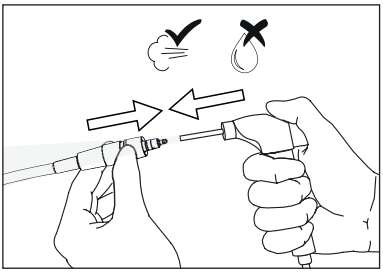
4

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.



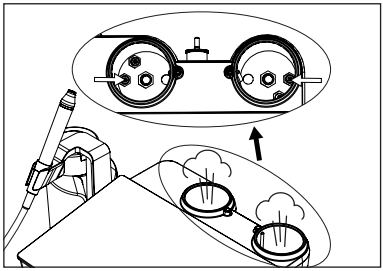
5

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



6

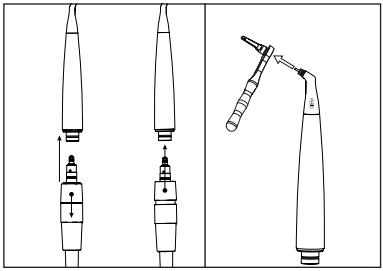
In case any clogging was present in the powder line inside the device, the air coming out from the powder container seats will free it.



16.5 Unclogging the air polisher handpiece

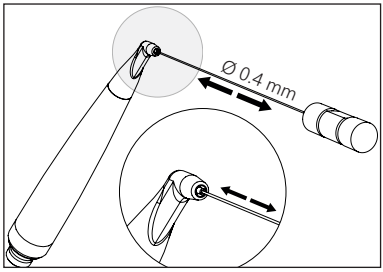
1

Disconnect the air polisher handpiece in use, and the Subgingival Perio Tips, if used (see *Chapter 7 on page 42 point 8 and 9*).



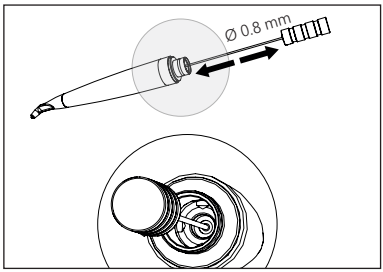
2

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



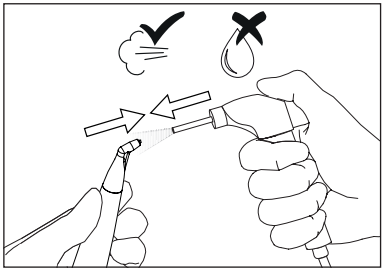
3

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



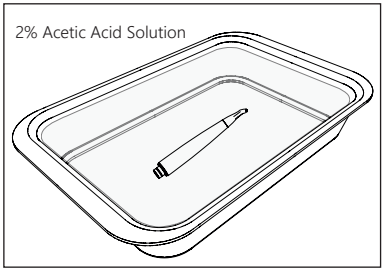
4

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



5

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

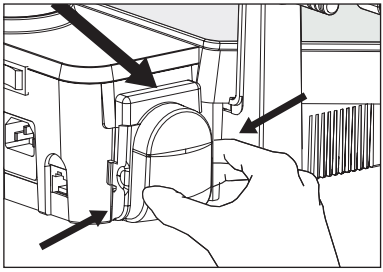


16.6 Replacing the Peristaltic Pump

1

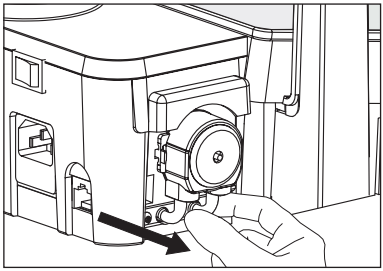
There is a plastic protection on the left side of the device, which covers the peristaltic pump housing. Remove this protection by pressing on the sides and pulling towards yourself.

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



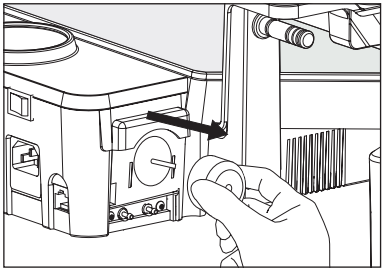
2

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



3

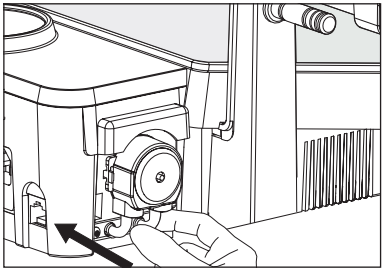
Extract the peristaltic pump from its seat, pulling it towards yourself. Use caution as pieces may detach.



4

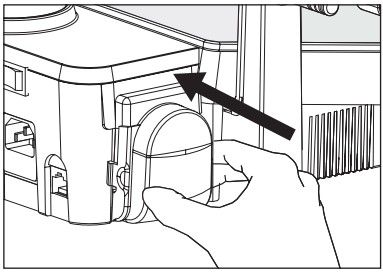
Attach the new peristaltic pump onto the base until you hear it click in, and connect the two pump tubes to the respective couplings underneath it.

⚠ **WARNING**: Only use original spare parts.



5

Refit the plastic protection onto the peristaltic pump.



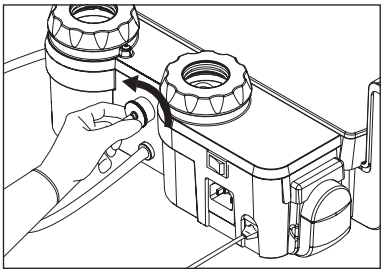
16.7 Cleaning and/or Replacing the Water Filter

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

1

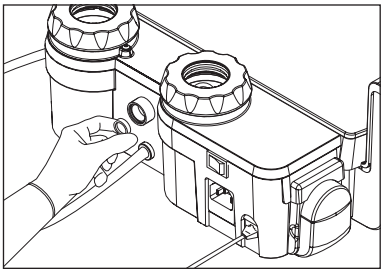
Disconnect the water supply hose from the male coupling.
Unscrew the knurled bush of the male coupling.

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



2

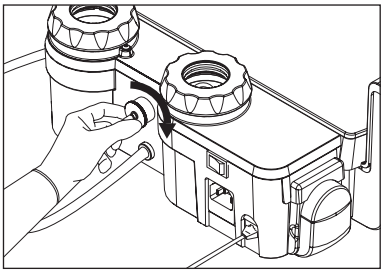
Extract the filter and wash it under running water to eliminate any impurities obstructing it (see *Chapter 14 on page 74* for the cleaning procedures).



3

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

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



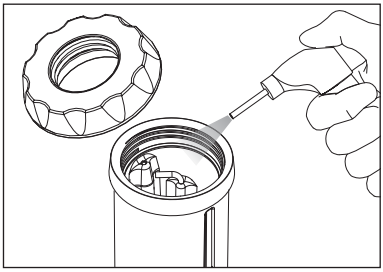
16.8 Powder Containers and Caps Maintenance

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**: 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.

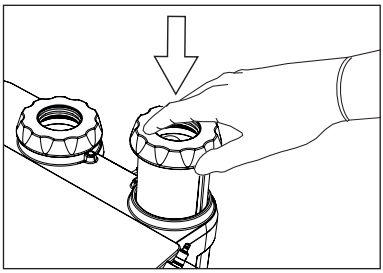
1



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.

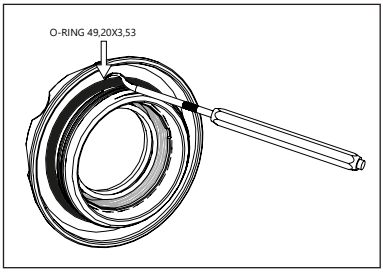
2



⚠ **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.

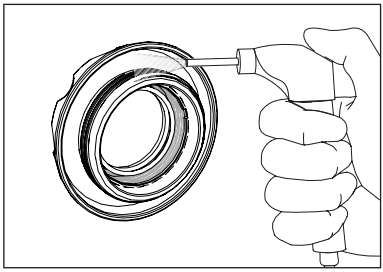
3



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.

4

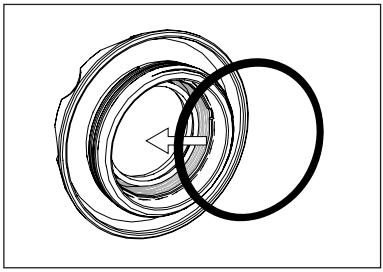
Clean accurately the o-ring seat from powder residues, by blowing compressed air.



5

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

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



16.9 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.

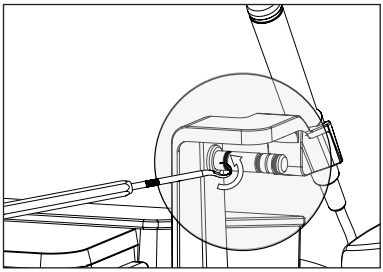
⚠ **CAUTION**: In case of no or difficult delivery of water from the bottle replace the O-rings even if they are not visually worn or damaged.

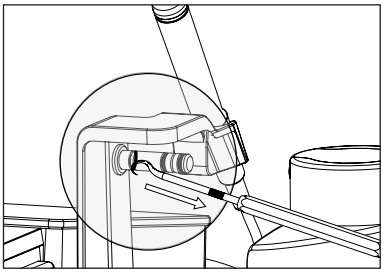
1

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.

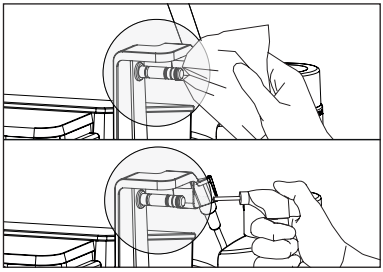
NOTE: If all 3 O-rings need to be replaced, remove and insert one O-ring at a time starting with the innermost one.





2

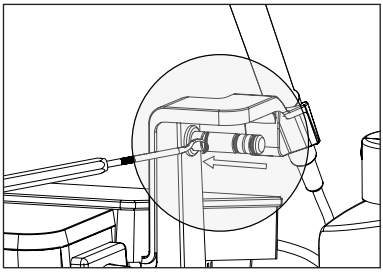
Clean and eventually dry accurately the o-ring seat, by blowing compressed air.



3

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.



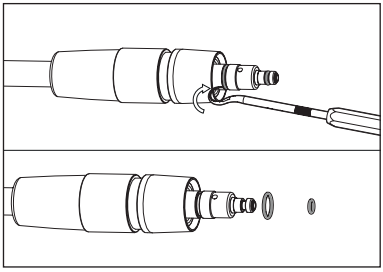
16.10 Replacing the polisher cord O-Rings

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

1

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

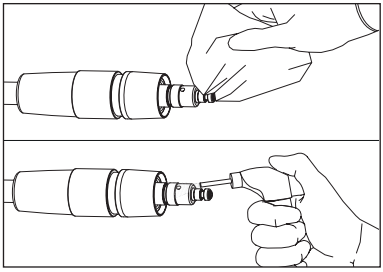
NOTE: The procedure requires the use of a tool to extract and insert the O-rings. This tool is not included in the standard supply.



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..



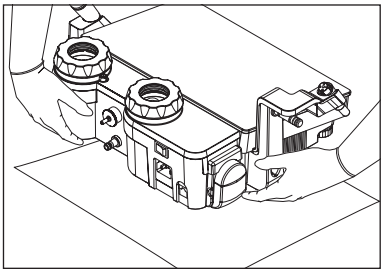
16.11 Eliminating the Condensation

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:

1

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

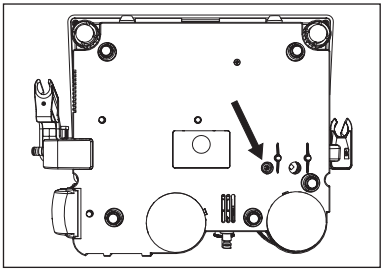
⚠ **CAUTION**: This maintenance operation must be performed with the device on in order for the air circuit to be pressurized.



2

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.



16.12 Maintenance Schedule

Maintenance schedule		
Description	**Q.ty each unit**	**Once every:**
Full device maintenance at approved HuFriedyGroup Service & Repair		1 year
6,5x2 O-ring (on Irrigation bottle connector)	3	1 year
49,2x3,53 O-ring (Powder cap)	2	1 year
Water filter	1	1 year
Prophy Powder container	1	18 months
Perio Powder container	1	18 months
Peristaltic pump	1	2 years
Scaler light conductor	1	2 years
Blue silicone ring(External Irrigation line)	1	2 years

17 METHODS AND PRECAUTIONS FOR DISPOSAL

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

- Piezo tips, when worn or broken;
- Piezo tips 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 Tips, after each use;
- Diamond coated Piezo Tips and plastic Piezo Tips, 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 piezo tips, pay particular attention to the sharp, pointed, irregular parts to avoid any wounds or injuries.

PWR Pair 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 purchaser is entitled to deliver the device to be disposed of to the distributor who supplies them with new equipment; at HuFriedyGroup instructions for proper disposal are available.

18 TECHNICAL DATA

Device compliant with Regulation (EU) 2017/745	Class IIa
Classification under the IEC/EN 60601-1	I Parts applied: type B (piezo tip) IP 20 (device) IP 22 (foot pedal)
Essential performance	According to the standard IEC 80601-2-60 the device has no essential performance
Device for intermittent operation	55 sec. ON - 30 sec. OFF with irrigation (ULTRASOUND function and POLISHING function) 30 sec. ON - 120 sec. 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 (14.5 to 87 psi). Polisher and scaler part water circuit cleaning function - See *Chapter 6 on page 36*. Connection via the supplied hose with quick coupling through an incorporated and removable filter.
Air supply:	Inlet pressure between 4 and 8 bar (58 to 116 psi). Air circuit cleaning function - See *Chapter 16.10 on page 100* Connection via the supplied hose with quick coupling through an incorporated filter and pressure reducer.
Operating Conditions	from 50°F (10°C) to +95°F (35°C) Relative humidity from 30% to 75% Air pressure P: 800hPa/1060hPa
Transport and Storage Conditions	from 14°F (-10°C) to 140°F (+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)[b)]

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

ULTRASOUND 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: 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 device starts working, and turns off 3 seconds after the 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; Breaking wire cord; Piezo tip not correctly tightened or broken;

POLISHING PART

Polisher functions	Can be selected via touch screen: “Prophy” function - “Perio” function
Irrigation	Continuous regulation via knob. Water heating via heating element. Water flow with inlet water pressure 1 bar (14.5 psi): approx. 33 ml/min Water flow with inlet water pressure 6 bar (87 psi): approx. 143 ml/min

18.1 Electromagnetic Compatibility IEC/EN 60601-1-2

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

⚠ **WARNING:** Portable and mobile radio communication equipment may influence the correct operation of the device.

⚠ **WARNING: Contraindications. Interference from other equipment**
An electrosurgical scalpel or other electrosurgical units near the device may interfere with its correct operation.

⚠ **WARNING:** The device requires particular EMC precautions and must be installed and put into service according to the EMC information provided in this chapter.

⚠ **WARNING:** The use of cables and accessories not supplied by HuFriedyGroup may adversely affect the EMC performances.

18.2 Guide and Manufacturer's Declaration - Electromagnetic Emissions

PWR Pair is designed to operate in the electromagnetic environment specified below. The purchaser or user of PWR Pair should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	PWR Pair 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	PWR Pair 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	

18.3 Accessible Parts of the Casing

PWR Pair is designed to operate in the electromagnetic environment specified below. The purchaser or user of PWR Pair 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 on 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 RF EM fields [a)]	IEC 61000-4-3	3 V/m [f)] 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.
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Chapter 18.5 on page 111	
RATED power frequency magnetic fields [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 18.6 on page 112	Portable and mobile RF communication devices shall be used with a separation distance of at least 0.15 m from the field sources.

e) The interface between the PATIENT physiological signal simulation, if used, and the device shall be located within 0.1 m of the vertical plane of the uniform field area in one orientation of the device.

f) The device that intentionally receives RF electromagnetic energy for the purpose of its operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

g) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

h) Applies only to devices with magnetically sensitive components or circuitry.

i) Void.

j) Before modulation is applied.

18.4 Guide and the Manufacturer's Declaration - Electromagnetic Immunity

18.4.1 Power Connection BC Input

PWR Pair is designed to operate in the electromagnetic environment specified below. The purchaser or user of PWR Pair 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 on 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 the 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)] at 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 and 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.

k) Void.

l) All device cables are attached during the test.

m) Calibration for current injection clamps shall be performed in a 150 Ω system.

n) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

o) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

p) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEMS. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.

q) Applicable only to the device connected to single-phase a.c. mains.

r) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

s) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). The device with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.ME EQUIPMENT and ME SYSTEMS that does not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).

t) Not applicable to CLASS II device.

u) Direct coupling shall be used.

v) R.M.S. , before modulation is applied.

w) The ISM (industrial, scientific and medical) bands 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.

x) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.

y) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.

z) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT shall provide BASIC SAFETY during and after the test.

aa) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the power input voltage specified in Table 1 - "Power input voltages and frequencies during the tests" of the IEC 60601-1-2:2014/AMD1:2020.

18.4.2 Points of Contact with the Patient

PWR Pair is designed to operate in the electromagnetic environment specified below. The purchaser or user of PWR Pair 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 on 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%.

Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
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 apply:

- All PATIENT-COUPLED cables shall be tested, either individually or bundled
- PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands 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., before modulation is applied.

c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

18.4.3 Parts Accessible to the Input / Output Signals

PWR Pair is designed to operate in the electromagnetic environment specified below. The purchaser or user of PWR Pair 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 on 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 on 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 intended to connect directly to outdoor cables.

b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Calibration for current injection clamps shall be performed in a 150 Ω system.

e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INDICATIONS FOR USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

f) Capacitive coupling shall be used.

g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

h) R.M.S., before modulation is applied.

i) The ISM (industrial, scientific and medical) bands 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 modified start frequency versus cable length and equipment size.

k) SIP/SOPS whose maximum cable length is less than 1 m are excluded.

18.5 Specifications of the tests for the Immunity of the Accessible Parts of the Casing to the Wireless RF Communications Device

PWR Pair is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The purchaser or operator of PWR Pair can help prevent electromagnetic interferences by guaranteeing a minimum distance between the mobile and portable RF communication devices (transmitters) and PWR Pair, 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 level (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460 FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 to 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 to 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 to 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 Band LTE 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 to 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 shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulateci using a 50 % duty cycle square wave signal at 18 Hz. While it does noi represent actual modulation, it would be worst case.

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the device may be reduced to 1 m. The 1 m test distance is permitted 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 PWR Pair device, including the cables specified by the manufacturer. Otherwise, there may be a performance degradation of these devices.

18.6 Immunity to Proximity Magnetic Fields in the Frequency Range 9 kHz to 13,56 MHz

The following table reports the test specifications tor ENCLOSURE PORT IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz.

Test Frequency	Modulation	Immunity test level (A/m)
30kHz [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 is applicable only to devices intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.

19 TROUBLESHOOTING

19.1 Diagnostic System and Symbols on the Keyboard

PWR Pair is provided with a diagnostic circuit that allows the detection of malfunctions and viewing of their type on the touch keyboard 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 keyboard	Possible cause	Solution
	Handpiece/cord electrical contacts wet	Thoroughly dry the contacts with compressed air (see *Chapter 12 on page 69*).
	Scaler handpiece PWR Pair not connected to the device	Connect the scaler handpiece (see *Chapter 4.3 on page 15*).
	Scaler handpiece failure	Replace the scaler handpiece
	Tuning circuit malfunction	Contact HuFriedyGroup Service & Repair
	Piezo tip not present or not properly tightened on the scaler handpiece	Unscrew the piezo tip and screw it back in correctly using the torque wrench (See *Chapter 5.4 on page 29*).
	Piezo tip broken, worn or deformed	Replace the piezo tip.
	Cord/handpiece electrical contacts wet	Thoroughly dry the contacts with compressed air (see *Chapter 12 on page 69*).

Symbol on keyboard	Possible cause	Solution
	Incorrect start-up procedure: the device was started with the pedal pressed.	Check that the pedal is not pressed down. If the problem persists, disconnect the pedal and potentially contact HuFriedyGroup Service & Repair.
	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 *Chapter 16.6 on page 94*).
	The device has been switched off and on again without waiting 5 seconds	Turn off and wait for 5 seconds before switching on the device 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 HuFriedyGroup Service & Repair.
	A powder container has been opened without performing the "Refill" cycle.	Before opening one of the powder containers, the "Refill" cycle must be run (See *Chapter 5.6.1 on page 35*).
	One of the powder containers has been removed from its seat without performing the "Refill" cycle.	Before removing one of the powder containers, the "Refill" cycle must be run (See *Chapter 5.6.1 on page 35*).
	The selected powder container is not correctly inserted in place.	Correctly insert the powder containers until they are in contact.

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

19.2 Quick Troubleshooting

Problem	Possible Cause	Solution
The device does not start after the switch has been moved to the “I” position.	The terminal of the electrical power supply 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 *Chapter 19.3 on page 119*)
The device is on but is not working. There are no anomalies signalled on the keyboard.	The pedal plug is not correctly inserted into the device socket	Properly insert the plug of the pedal in the connector on the back of the device (see *Chapter 4.3 on page 15).*
	The pedal does not work properly	Contact HuFriedyGroup Service & Repair
The device is on but is not working. One of the following symbols appears on the screen: 	See *Chapter 19.1 on page 113* for the possible cause depending on the symbol	See *Chapter 19.1 on page 113* 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 piezo tip is not correctly tightened on the handpiece	Unscrew the piezo tip and screw it back in correctly using the torque wrench (See *Chapter 5.4 on page 29*)
	The irrigation circuit has not been completely filled	Fill the irrigation circuit using the "Flush" function (See *Chapter 5.4 on page 29*)
The pump rotates properly, but liquid leaks from the handpiece when it is stopped.	The peristaltic pump is worn.	Replace the peristaltic pump (See *Chapter 16.6 on page 94).*
By pressing the pedal, a prolonged signal is emitted and the ULTRASOUND and POLISHING function LEDs flash.	The pedal has been pressed with both handpieces positioned in their housings.	Lift the handpiece to be used before pressing the pedal.

Problem	Possible Cause	Solution
Poor performance	The piezo tip is not correctly tightened on the handpiece	Unscrew the piezo tip and screw it back in correctly using the torque wrench (See *Chapter 5.4 on page 29*)
	Piezo tip broken, worn or deformed	Replace the piezo tip with a new one
	Insufficient or excessive powder level in the container.	Restore the correct level of powder in the container (See *Chapter 4 on page 14).*
No liquid flows out from the piezo tip or air-polishing handpiece during operation	Device not connected to the water circuit	Check the connection to the water circuit (See *Chapter 4.3 on page 15).*
	The piezo tip is the "Dry Work" type without a liquid passage	Use an piezo tip type with a liquid passage
	The piezo tip is clogged	Unscrew the piezo tip/air-polishing handpiece from the handpiece and free the water passage of the piezo tip/air-polishing handpiece by blowing compressed air through it. If the problem persists, replace the piezo tip/air-polishing handpiece with a new one.
	The quick coupling on the air-polishing handpiece cord is clogged	Contact HuFriedyGroup Service & Repair
	Irrigation is disabled	Activate irrigation and adjust the irrigation level (See *Chapter 5.2.1 on page 21).*
	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 *Chapter 16.7 on page 96.*
	The Irrigation bottle is empty	Fill the bottle
	The bottle is not properly installed	Properly connect the bottle to the device core unit
	The silicone tubes of the pump are not correctly installed	Check the tube connections (see *Chapter 16.6 on page 94).*
	The peristaltic pump is worn	Replace the peristaltic pump (See *Chapter 16.6 on page 94*)

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 *Chapter 4.3 on page 15*).
	Air-polishing handpiece clogged due to an excessive amount of moisture in the powder or insufficient cleaning/maintenance	See *Chapter 16.5 on page 93*
	Polisher handpiece channel clogged due to an excessive amount of moisture in the powder or insufficient cleaning.	See *Chapter 16.5 on page 93*
	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 *Chapter 4 on page 14*).
	Unsuitable powder	Use the correct powder for correct device operation.
Powder leak through the powder container cap	Cap not correctly tightened	Screw the cap correctly.
	Powder residue in the thread	Clean the powder container thread (See *Chapter 16.8 on page 97*).
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	Check the correct powder for correct device operation.
	Air-polishing handpiece clogged due to an excessive amount of moisture in the powder or insufficient cleaning/ maintenance	Remove the powder from the container and clean it using a dry cloth.

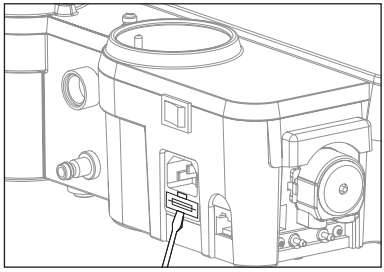
Problem	Possible Cause	Solution
One of the powder container caps does not unscrew	The device is on and the powder container is pressurized	Run the "Refill" cycle before opening one of the powder containers (See *Chapter 5.6.1 on page 35).*
	The "Refill" cycle has been performed but the powder containers have remained pressurized because the air-polishing handpiece is clogged	Read the section on cleaning the air-polishing handpiece (See *Chapter 8 on page 46).*
	The "Refill" cycle has been performed but the powder containers have remained pressurized because the polisher cord is clogged	Contact HuFriedyGroup Service & Repair.

19.3 Replacing the Fuses

⚠ **WARNING: Switch the device off.**
Always switch the device off using the main switch and disconnect it from the power supply socket before carrying out the next intervention.

1

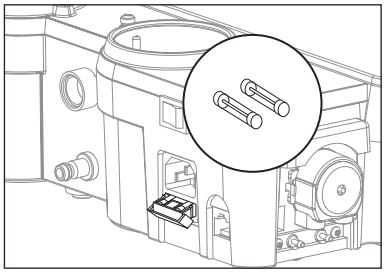
Use a flat tool, if necessary, to open the fuse-holder drawer located under the power supply socket.



2

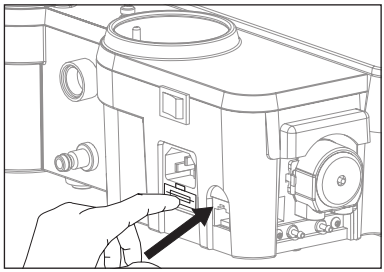
Extract the fuse holder compartment.

⚠ **WARNING:** Replace the fuses in respect of the characteristics indicated in *Chapter 8 on page 46*.



3

Reinsert the compartment in its place.



19.4 Shipping to HuFriedyGroup Service & Repair

If technical assistance is required on the device, please visit hufriedygroup.com/PWR/Support or you can contact Service & Repair or your distributor. Do not try to repair or modify the device and its accessories.
Clean and sterilise all parts that need to be sent to HuFriedyGroup Service & Repair, following the instructions in *Chapter 8 on page 46*.
Leave the sterilized parts in the pouch which certifies the sterilization process.
The cleaning and sterilization demands comply with the mandatory requirements for workplace health and safety protection laws.
If the client fails to comply with the requirements, HuFriedyGroup reserves the right to charge them the cost of cleaning and sterilization or to refuse goods that arrive in unsuitable conditions, returning them at the client's own expense for proper cleaning and sterilization.
The device must be returned suitably packaged and accompanied by all the accessories and a form including:

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

⚠ **CAUTION**: **Packaging**
Pack the device in its original packaging to prevent damage during transport.

Once the material is received by HuFriedyGroup Service & Repair, the qualified technical personnel will evaluate the problem. The repair will be made only upon acceptance by the end client. For further details, please contact HuFriedyGroup Service & Repair or your distributor.
Unauthorized 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.

20 WARRANTY

Before being marketed, PWR Pair is subjected to a thorough final check that verifies the full functionality.
The manufacturer provides a warranty for PWR Pair, purchased new from a HuFriedyGroup distributor 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 accessories are not covered by the warranty.
During the warranty period, HuFriedyGroup 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 HuFriedyGroup products is not covered by the warranty.
The manufacturer's warranty and the approval of the device are not valid in the following cases:

- The device is not used in accordance with the indications for use.
- The device is not used in accordance with all the instructions and requirements described in this manual.
- The electrical system located on the premises in which the device is used does not comply with the electrical code compliance standards in force and the relative electrical safety precautions
- Assembly operations, extensions, adjustments, updates and repairs are carried out by personnel not authorized by the MAnufacturer.
- The environmental conditions for

preservation and storage of the device do not comply with the requirements indicated in *Chapter 8 on page 46*.

- Use of non-original PWR Piezo Tips, accessories, and spare 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 indications for 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 distributor/importer or, in case of device with activation code, from the date of activation of the same.
In order to avail of the warranty service, the client must return the device, at their own expense, to the HuFriedyGroup distributor/importer from which they purchased the product.
The device must be returned together with the original packaging, accompanied by all the accessories and by a form containing:

- The data of the owner and telephone number;
- The data of the distributor/importer;
- Photocopy of the delivery note/purchase invoice of the device by the owner where are reported the date, the name of the device and the serial number;
- Description of the failure.

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

Manufactured for:
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Chicago, IL 60618 | USA
1-800-Hu-Friedy | HuFriedyGroup.com

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