PWR Piezo

Piezoelectric Scaler

HuFriedyGroup
The Best In Practice

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1 INTRODUCTION

Read this manual and follow its instructions carefully before proceeding with the installation, use, maintenance, or other operations on the device. Please always keep this manual within easy reach.

IMPORTANT: to avoid potential serious injury to the user and the patient and/or this device or other equipments, read all the “Safety precautions” present in the manual with particular attention.

The words **WARNING**, **CAUTION** and **NOTE** contained in this document, carry special meaning and must be carefully reviewed. Depending on their degree of seriousness, the safety precautions are classified:

⚠ **WARNING**: Identifies conditions or practices that present a risk of serious injury or death to the patient and/or the user.

⚠ **CAUTION**: Identifies conditions or practices that could result in minor injury or device damage.

NOTE: Identifies special information to clarify or emphasize important instructions.

The purpose of this manual is to make the operator knowledgeable of the safety precautions, the installation procedures, and the instructions for a correct use and maintenance of the device and its accessories.
Use of this manual for purposes other than those strictly tied to the installation, use and maintenance of the device is forbidden.
The information and illustrations in this manual are updated as of the date of issue reported on the last page.
The Manufacturer is committed to continuously update its products with possible modifications to device components.
In case you encounter discrepancies between the descriptions found in this manual and the device 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 Piezo is a piezoelectric dental scaler intended for use, with the appropriate associated piezo tips, in the following dental applications:

- **Scaling**: all general procedures for removal of supragingival/subgingival and interdental calculus/ plaque deposits;
- **Periodontology**: periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning;
- **Endodontics**: all treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation;
- **Restorative and prosthetics**: all general restorative procedures including cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations, inlay/onlay condensation, implants/restorations cleaning.

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

⚠ **WARNING**: The device must be used in a dental practice, in a clinic, or in a professional oral hygiene and preventive care centers. The device 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**: **Intended use.** Use the device exclusively for the use for which it is intended. Failure to observe this regulation can cause serious injury to the patient, the operator, and damages/ breakdowns to the device.

1.2 Description of the Device

PWR Piezo is a multifunctiona piezoelectric scaler. It has been designed in order to offer a product with innovative design and exclusive technical characteristics to the operator, and maximum comfort during the treatment to the patient.
The user interface has been optimized making all the functions readily available by integrating them in the touch keyboard. The handpiece has a circular LED light and can be autoclaved at 275°F (135°C). The device has an automatic sync circuit which optimizes frequency and power for each available tip, so that the best performance is always assured.

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 on page 1*).

1.2.2 Patient Selection Criteria

The use of the device is not recommended in the following cases.

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).

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 any liability, expressed or implied, and shall have no responsibility for any direct or indirect personal injury and/or property damage, occurring as a result of incorrect procedures in the use of the device and its accessories. The manufacturer shall be under no liability, expressed or implied, for any type of personal injury and/or property damage, which might arise or be caused, whether by the customer or by any of the users of the product and its accessories, as results of the following conditions, by way of example and not limitated to:

- Misuse or use during procedures other than those specified in the intended use of the product;
- The environmental conditions for preservation and storage of the device are not complying with the requirements indicated in *Chapter 16 on page 53*;
- The device is not used in compliance with all the instructions and precautions 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 any 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, 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 14 on page 49* of this manual;
- Breach of the requirements and the information contained in *Chapter 5.5 on page 25* of this manual;
- Breach of the requirements and the information contained in *Chapter 8 on page 32* of this manual;
- Unauthorized repairs in accordance with the indications contained in *Chapter 17.4 on page 67* this manual.

1.4 Safety Requirements

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

⚠ **WARNING**: **Contraindications.** Do notperform scaling treatments without water spray in order to avoid the tip overheating which may cause damages to the tooth. Treatments with no water spray can be carried out only with “Dry Work” tips which do not have the water passage.

⚠ **CAUTION**: **Contraindications. Piezoelectric scaler.** Do not perform treatments on metal or ceramic/porcelain prosthetic artifacts (unless otherwise specified). The piezoelectric vibration could cause decementation/loosening of such artifacts.

⚠ **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. Install the device at safety distance from life-support systems. 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 device status before the treatment.** Always make sure that there is no water underneath the device. Before each treatment, always make sure that the device and accessories are in proper working order. If anything unusual is noted during operation, do not carry out the treatment. If the problem concerns the device, contact HuFriedyGroup.

⚠ **WARNING**: 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.

⚠ **WARNING**: To avoid any risk of electrical shock this device must be grounded. Only connect the console to hospital grade receptacle to ensure electrical grounding reliability.

⚠ **WARNING**: **Control of Infections.**

First Use. The reusable accessories(brand new or returned by service) and the single use accessories (diamond coated tips and plastic piezo tips) are delivered in NO-STERILE conditions and must be prepared prior to use by applying the procedures described in the *Chapter 8 on page 32*.

Every use. Once used, each reusable accessory must be thoroughly reprocessed prior to reuse, according to the procedures described in the *Chapter 8 on page 32*.

⚠ **WARNING**: **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.** Allow autoclavable items (the handpiece, the tips, the torque wrench, and any other accessory that can be sterilized) to gradually return to room temperature after steam sterilization and prior to usage. The cooling process must not be accelerated.

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

⚠ **CAUTION**: No modification of this equipment is allowed.

⚠ **WARNING**: Prior to any use, system components must be inspected for damage.
Do not use if damage is apparent.

⚠ **WARNING**: Do not operate the device if handpiece is defective, damaged or broken. Immediately replace the handpiece.

⚠ **WARNING**: Personal Injury. Make sure that power cable do not interfere with free circulation of people in the area.

⚠ **WARNING: Breakage and wear-out of the tips.** High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the PWR Piezo Tip.
Deformed or otherwise damaged tips are susceptible to breakage during their use. These tips must never be used.
Should an tip fracture, during use, check that none of its fragments remain in the treated part and, at the same time, apply effective suction to remove them.
The patient must be instructed to breathe through his nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken tips.
Check the state of wear of the 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 tips (S1, S1-S, S2, S5, P2, P4, P10) can be checked using the supplied Tip Wear Guide. To use the Tip Wear Guide correctly:

Position the tip on the 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 tip is shorter than the limit of wear, its performance will be significantly inferior compared to that of a new tip, and should therefore be replaced.

If the layer of titanium nitride (gold-plated surface), where present, is visibly worn, the tip must be replaced. The use of a worn tip reduces its efficiency.
When the nitride coating wears out, the efficiency decreases; re-sharpening the tip damages it and is therefore forbidden. Check that the tip is not worn out. During the intervention, frequently check that the tip is intact, especially in its apical part. During the intervention, avoid prolonged contact with retractors or with metallic instrumentation in use. Do not exert excessive pressure on the tips during their use.

⚠ **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.

1.5 Symbols

Symbol	Description	Symbol	Description
5.7.7 [*] 	Medical device		Nemko brand Compliance with UL - CSA regulations
5.4.3 [*] 	Consult instructions for use or consult electronic instruction for use	5.4.4 [*] 	Caution
5.1.11 [*] 	Country of manufacture	5.1.7 [*] 	Serial Number
5.1.5 [*] 	Batch Number	5.1.6 [*] 	Catalogue number
5.7.10 [*] 	Unique Device Identifier	18.4.4 [***] 	Sterilizable up to a max. temperature of 275°F (135°C)
5.1.4.4 [****] 	Connection of the control pedal	1 [**] 	Alternating current
5.2.7 [*] 	Non-sterile	19 [**] 	Type B applied part
12 [**] I	Power switch “on”	13 [**] 0	Power switch “off”
5.3.8 [*] 	Moisture limits for transport and storage	5.3.9 [*] 	Atmospheric pressure limits for transport and storage
QTY.1	Quantity of items in the package: 1	5.3.7 [*] 	Temperature limits for transport and storage

Symbol	Description	Symbol	Description
5.3.4 [*] 	Fragile	5.3.4 [*] 	Keep dry
W001 [*******] 	Generic warning signal [a]	[*****] Rx Only	For US market only **CAUTION**: U.S. Federal law restricts this device to sale by or on the order of a licensed dentist or dental hygienist.

[*] ISO 15223-1:2021
[**] CEI EN 60601-1:2005, AMD1:2012
[***] ISO 7000:2019
[****] IEC 60417:2001
[*****] 21 CRF 801.109
[*******] ISO 7010

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

NOTE: For other symbols, refer to *Chapter 17.1 on page 62*.

2 IDENTIFICATION DATA

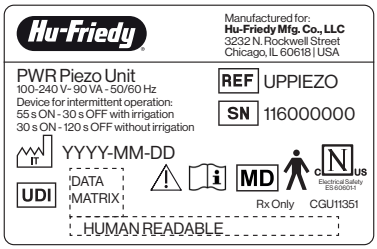
A correct description of the model and of the serial number of the device will allow HuFriedyGroup Customer Care to provide fast and efficient support.

Always provide this information every time that you contact HuFriedyGroup Service & Repair.

2.1 Identification Plate of the Device

Each device is equipped with an identification plate indicating the main technical characteristics and traceability data, UDI code included. The identification plate is located on the bottom of the device's console. The complete technical specifications are provided in *Chapter 16 on page 53*.

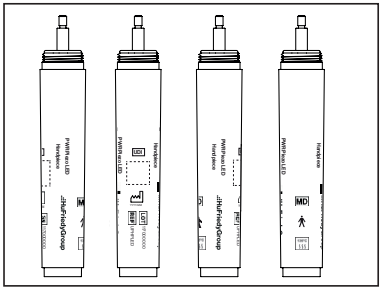
NOTE: The complete list of symbols is provided in *Chapter 1.5 on page 7.*



2.2 Handpiece Identification Data

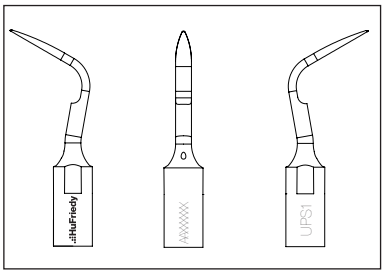
On the scaler handpiece are lasermarked the traceability data, UDI code included.

NOTE: The complete list of symbols is provided in *Chapter 1.5 on page 7.*



2.3 Piezo Tips Identification Data

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



3 DELIVERY

3.1 List of Components

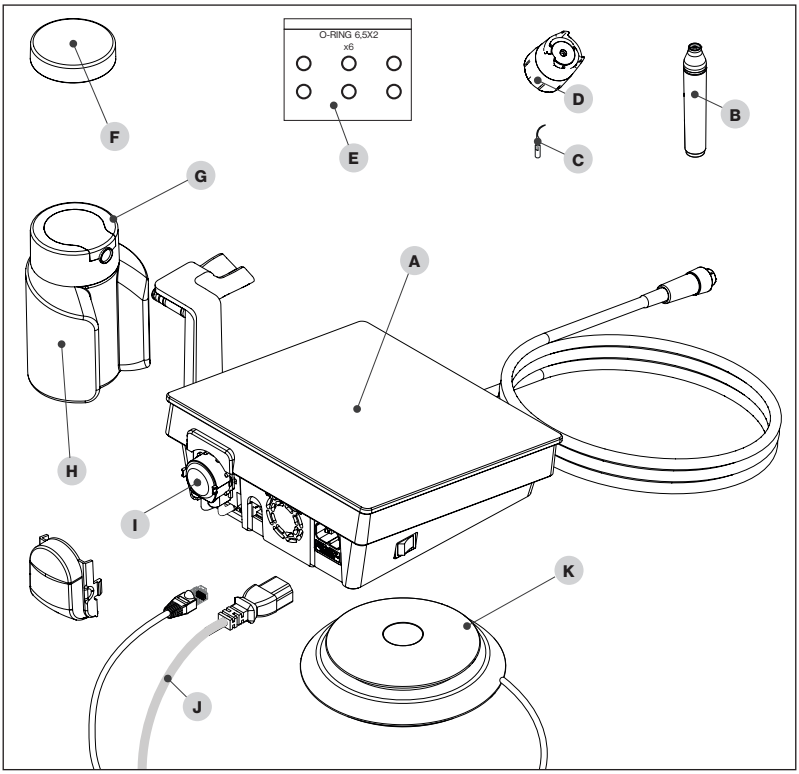
PWR Piezo includes a basic equipment and a set of accessories that can be ordered separately, variable in relation to the configuration and customer requests (see Table on the following page).

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 multiple boxes in order to avoid compressing the underlying packaging.
All the material shipped by HuFriedyGroup have been inspected upon their delivery.
The device is shipped duly protected and packed.
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 inactivity.

⚠ **WARNING:** Before starting the treatment, always make sure to have a stock of material (handpiece, tips, wrenches) to use in the event of failures or drawbacks.



Ref.	SKU	Item	Note
A		Device core unit [b]	
B	UPHPLED	Piezo LED Handpiece [b]	
C		Piezo tips [b]	
D	UPK10	K10 Tip wrench [b]	
E	UPORING	PWR Piezo Bottle Connection O-ring set [c]	
F		Bottle safety cap [c]	Grey
G	UPBTLCAPGY	Bottle cap [b]	Grey
H	UPBTL	Plastic bottle [b]	500ml
I	UPPUMP	Peristaltic water pump [c]	
J		Power supply cable [c]	
K	UPFTPEDAL	Foot Pedal [b]	

b) Produced by the Manufacturer.

c) Distributed by HuFriedyGroup.

4 INSTALLATION

4.1 First Installation

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

Place the console on a sturdy, flat ,dry and horizontal surface.

NOTE: The place where the device is installed must meet the requirements reported in *Chapter 4.2 on page 12*.

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. Install the device at safety distance from life-support systems. 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.

⚠ **WARNING**: The electrical supply network to which the device is connected must comply with all the applicable standards and with electrical safety requirements.

⚠ **WARNING**: To avoid any risk of electrical shock this device must be grounded. Only connect the console to hospital grade receptacle to ensure electrical grounding reliability.

⚠ **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 sides. If necessary dry them with compressed air.

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

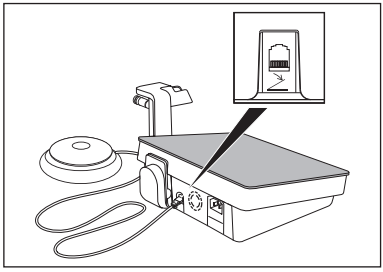
⚠ **CAUTION**: Always position the device in way so that the power switch is easily reachable, since this switch is considered as a load-break switch.

4.3 Connecting the Accessories

1

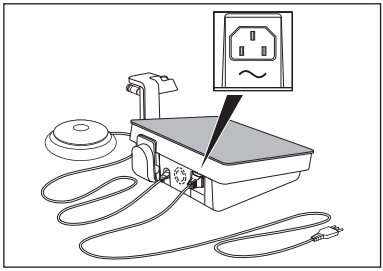
Connect the pedal to the back of the device, on the right-hand side, in the socket marked with the symbol ⇗ by inserting the pedal cord plug until you hear a 'click'.

⚠ **WARNING**: Pay attention to the positioning of the pedal, which must be positioned on the floor so that it can only be activated intentionally by the operator.



2

Plug the power supply cord into the power socket on the back of the device's console.
Plug the other end of the power cord into a hospital-grade wall outlet.

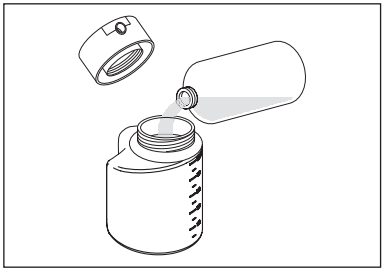


3

Unscrew the cap of the bottle and fill it with the needed solution.

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

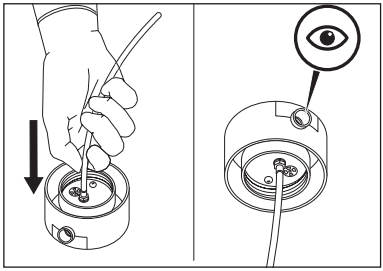
NOTE: Do not leave liquids in the bottle for long periods of time. The bottle must be filled after having cleaned and sterilized all parts, and before a treatment. If the bottle has been filled without having used the device, it must be emptied at the end of the day, and all parts and accessories must be cleaned and sterilized.



4

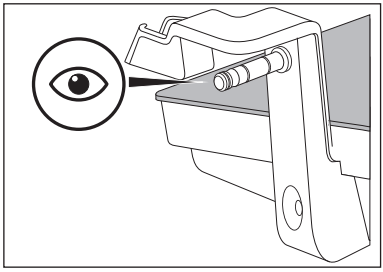
Check that the hose connected to the bottle's cap is correctly installed, then screw the cap back on its bottle.

⚠ **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.

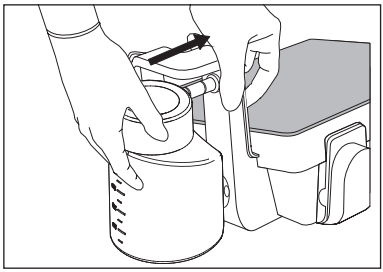
NOTE: Use the support only to install the 500 ml bottle and to house the handpiece. Do not use the support for other purposes.



5

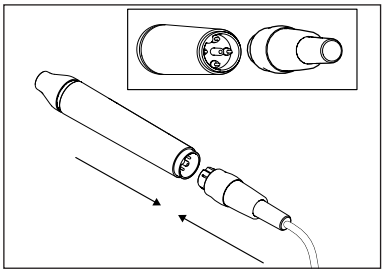
Keep the bottle in a vertical position and push it towards the device's body until it is firmly connected.

⚠ **CAUTION**: Do not capsize the bottle as its cap is not watertight. The leaking of the physiological solution or of aggressive liquids can damage the sufaces.



6

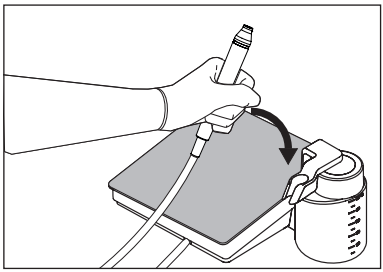
Correctly connect the scaler handpiece onto its cord by matching the alignment notch on the handpiece connector with the alignment key on the cord connector. Check that the electrical contacts of both are perfectly dry and if necessary dry them by blowing with compressed air.



Position the handpiece on its support.

NOTE Use the support only to install the 500 ml bottle and to house the handpiece. Do not use the support for other purposes.

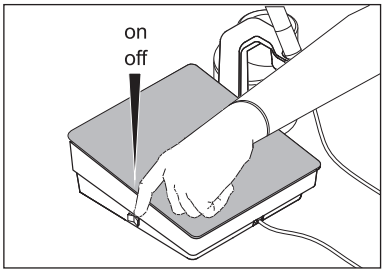
7



5 USE

5.1 Power On/Off

Switching the device on
The switch is located on the left-hand side of the console.
Flick the switch into the “I” position, taking care not to press the pedal.
On start-up, 4 symbols appear which will progressively turn off.
The system will then show the preset configuration and be ready for use.
Switching the device off
The switch is located on the left-hand side of the console.
Flick the switch into the “O” position, taking care not to press the pedal.
The system will turn off.



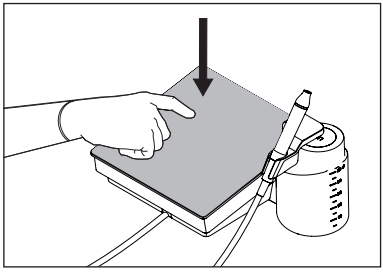
⚠ **CAUTION**: Always position the device in way so that the power switch is easily reachable, since this switch is considered as a load-break switch.

NOTE: By default, when the console is turned on the device is programmed on the following settings:

- “power”: 1;
- “light”: AUTO;
- “function”: ENDO;
- “irrigation”: 3.

5.2 Description of the Keyboard

TOUCH KEYBOARD
The user can configure the device by simply touching the touch keyboard.
Depending on the selected setting, the electronic feedback system will automatically adjust the correct operating frequency.

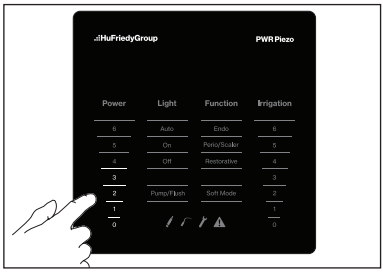


POWER
The operating power can be adjusted by selecting the numbers on the touch keyboard in the “power” column. There are 7 power levels:

- 0: the handpiece has no power: only the irrigation outflows from the handpiece;
- From 1 to 6: the operating power can be adjusted incrementally.

The power level can be regulated in each function, as indicated here below:

- **ENDO**: 7 power levels: from 0 to 6;
- **PERIO/SCALER**: 7 power levels: from 0 to 6;
- **RESTORATIVE**: 7 power levels: from 0 to 6.



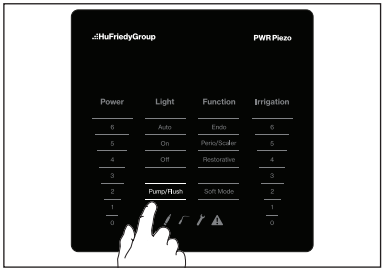
FILLING AND FLUSHING THE IRRIGATION CIRCUIT

The device is equipped with the “pump/flush” key, which depending on the operating mode allows running either the PUMP or the FLUSH function.

The PUMP function can be used at the beginning of the treatment, to prime the entire irrigation line up to the tip, so that the treatment can be started with the necessary irrigation (See *Chapter 5.4 on page 23*).

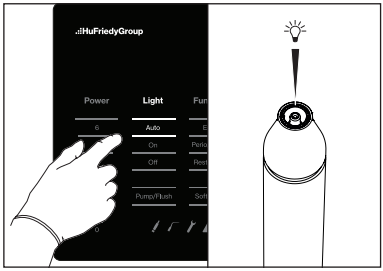
⚠ **CAUTION**: The FLUSH function (see *Chapter 6 on page 27*) must be used before the first treatment of the day, after every patient treatment, before starting the cleaning and sterilization procedures (See *Chapter 8 on page 32*). Failure to carry out flushing of the handpiece tubing will lead to salt crystallization that can seriously damage the device

⚠ **WARNING**: The “FLUSH” function does not substitute for the cleaning and sterilization procedures described in *Chapter 8 on page 32*. After having carried out the “FLUSH” function, the cleaning and sterilization procedures must be followed meticulously in order to prepare the device accessories ready for the next patient and minimize any risk of patient-to-patient contamination.



LIGHT
Depending on the type of treatment that needs to be carried out, 3 possible options can be selected from the “light” list:

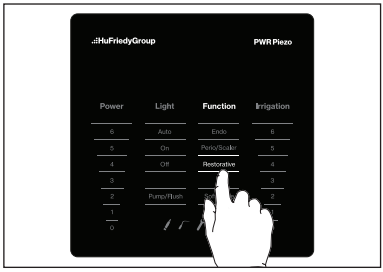
- If the **AUTO** option is selected, the LED light on the handpiece front cone lights up when the pedal is pressed and automatically switches off 3 seconds after the pedal is released;
- If the **ON** option is selected, the LED light on the handpiece front cone stays lit, regardless of the pedal. The light turns off 100 seconds after the last time the pedal is pressed, and the option switches from ON to AUTO;
- If the **OFF** option is selected, the LED light on the handpiece front cone stays off.



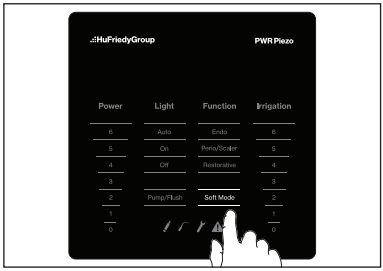
FUNCTIONS
Depending on the type of operation, it is possible to select one of 3 options from the “function” list, as follows:

- **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: by selecting RESTORATIVE and power on 6 the PULSE mode is activated. It is used to optimise the tip’s performance in the prosthesis techniques.

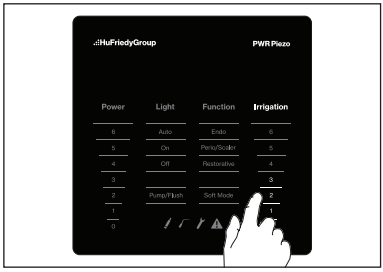


SOFT MODE
The treatment can be made more delicate for sensitive patients, by activating the "soft mode" function.
“Soft mode” can only be activated in the “PERIO/SCALER” functions with powers from 1 to 6 and “RESTORATIVE” with powers from 1 to 5.
In “ENDO” mode the function is not available.



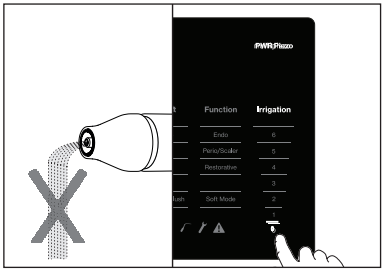
IRRIGATION
The irrigation flow rate can be adjusted by selecting the numbers on the touch keyboard in the “irrigation” column.
7 capacity levels are foreseen:

- **0**: operation of the pump is closed: no irrigation outflows from the tip.
- **From 1 to 6**: the pump flow goes from 6 ml/min to approximately 28 ml/min.

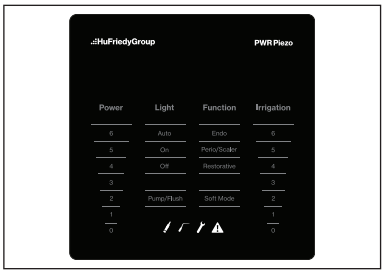


The possibility of choosing the irrigation capacity levels is tied to the type of function selected, in the following manner:

- **ENDO**: 7 flow levels: from 0 (Irrigation can be excluded) to 6;
- **PERIO/SCALER**: 7 flow levels: from 0 (Irrigation can be excluded) to 6;
- **RESTORATIVE**:
- With power set from 1 to 5:
  - 7 flow levels: from 0 (Irrigation can be excluded) to 6.
- With power set on 6:
  - 6 flow levels: from 1 to 6. The irrigation is compulsory.



SYMBOLS
PWR Piezo 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 identifying the part that is non-functioning there are four symbols described in *Chapter 17.1 on page 62*.



5.3 Safety Requirements Before and During Use

⚠ **WARNING**: Before starting to operate with the device, make sure that you have stock material (handpiece, tips, wrenches) available to use in case of downtime due to a fault or of inconveniences.

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

⚠ **WARNING**: **Use of non-original PWR 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 - Piezoelectric Scaler.** Do not perform treatments on metal or ceramic/porcelain prosthetic artifacts (unless otherwise specified). The piezoelectric vibration could cause decementation/loosening of such artifacts.

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

⚠ **WARNING**: **Contraindications.** Do not perform scaling treatments without water spray in order to avoid the tip over-heating which may cause damages to the tooth. Treatments with no water spray can be carried out only with “Dry Work” tips which do not have the water passage.

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

⚠ **WARNING**: **Treatments that require irrigation.** Always check irrigation delivery before and during use. Make sure the irrigation comes out from the tip tip. Use the PUMP button to prime the irrigation tubing line. Do not use the device if the irrigation does not work or if the pump is defective.

⚠ **WARNING**: **Checking the condition of the device before treatment.** Always check that there is no water underneath the device. Before every treatment, always check that the device works perfectly and that the accessories are efficient. If functional anomalies or damage are observed do not use the device. Contact HuFriedyGroup Service & Repair if the abnormalities concern the device.

⚠ **WARNING**: Control of Infections.

First Use. The reusable accessories(brand new or returned by service) and the single use accessories (diamond coated tips and plastic piezo tips) are delivered in NO-STERILE conditions and must be prepared prior to use by applying the procedures described in the *Chapter 8 on page 32*.

Every use. Once used, each reusable accessory must be thoroughly reprocessed prior to reuse, according to the procedures described in the *Chapter 8 on page 32*.

⚠ **WARNING**: Diamond coated tips are intended for single use only.

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

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

⚠ **WARNING**: Before every treatment, make sure that the tip appropriate for the the treatment is correctly screwed onto the handpiece. Only use the torque wrench, supplied with the device, to fasten the tip to the handpiece. Do not use any other instrument such as pliers, pincers, etc.

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

⚠ **WARNING**: Do not change the tip whilst the handpiece is in operation in order to avoid causing injury to the operator. During the intervention on the patient, do not perform any maintenance tasks on the system.

⚠ **CAUTION**: **FLUSH function**. After the device is used with aggressive and non-aggressive solutions, it is necessary to perform a flushing cycle on the tubes and the handpiece with the FLUSH function (see *Chapter 6 on page 27*). If the tubes are not flushed, the crystallization of the salts may seriously damage the device.

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

⚠ **WARNING: Breakage and wear-out of the tips.** High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the tip.
Deformed or otherwise damaged tips are susceptible to breakage during their use. These tips must never be used.
In the event of breakage check that no fragments remain in the treated part and at the same time use suction effectively to remove them.
The patient must be instructed to breathe through his nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken tips.

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

Position the tip on the 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 tip is shorter than the limit of wear, its performance will be significantly inferior compared to that of a new tip, and should therefore be replaced. If the layer of titanium nitride (gold-plated surface), where present, is visibly worn, the tip must be replaced. The use of a worn tip reduces its efficiency.

When the nitride coating wears out, the efficiency decreases; re-sharpening the tip damages it and is therefore forbidden. Check that the tip is not worn out. During the intervention, frequently check that the tip is intact, especially in its apical part. During the intervention, avoid prolonged contact with retractors or with metallic instrumentation in use. Do not exert excessive pressure on the tips during their use.

⚠ **CAUTION**: **Contraindications.** Allow autoclavable items (the handpiece, the tips, the torque wrench, and any other accessory that can be sterilized) to gradually return to room temperature after steam sterilization and prior to usage. The cooling process must not be accelerated.

⚠ **CAUTION**: **The electrical contacts inside the connectors on the handpiece and cord 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.

⚠ **WARNING**: Handle sharp-edged and pointed tips with particular care. During the tightening/untightening operations, the sharp-edged/pointed parts of the tip could cause harm.

⚠ **WARNING**: Pay attention to the positioning of the pedal, which must be positioned on the floor so that it can only be activated intentionally by the operator.

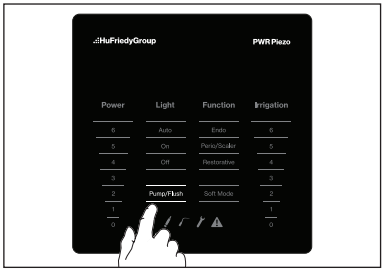
⚠ **WARNING:** Do not use the device in case of breaks or cracks on the casing.

5.4 Instructions for Use

After having connected all the accessories as described in *Chapter 4.3 on page 13* proceed as follows:

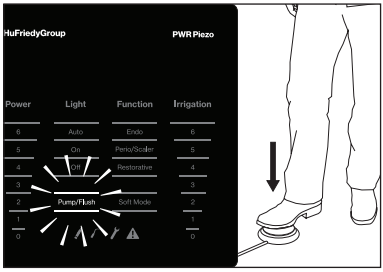
1

To fill the irrigation circuit, use the PUMP function by selecting PUMP/FLUSH on the touch keyboard: all the other selections will be deactivated and the writing PUMP/FLUSH will flash.



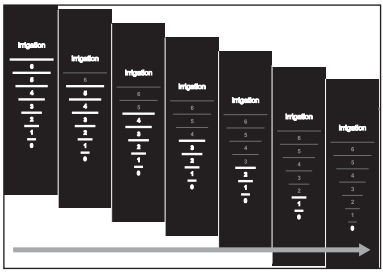
2

While the writing PUMP/FLUSH is flashing, press the pedal once and then release it, PUMP/FLUSH will stop flashing and the irrigation circuit will start to fill.



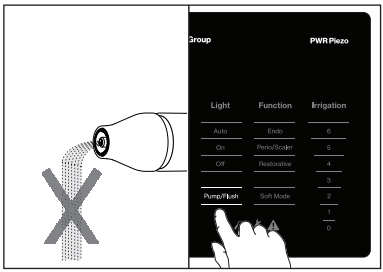
3

As soon as the peristaltic pump starts working, the entire scale of values in the “irrigation” section lights up, and during the passage of the liquid, the irrigation value switches from 6 to 0.



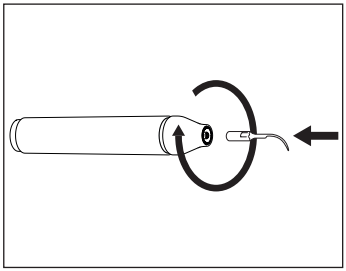
4

The cycle can be stopped as soon as liquid is seen flowing out from the PWR Piezo, handpiece by pressing PUMP/FLUSH or alternatively by pressing on the pedal. The PUMP function is deactivated, and the keyboard becomes active again in the last setting used.



5

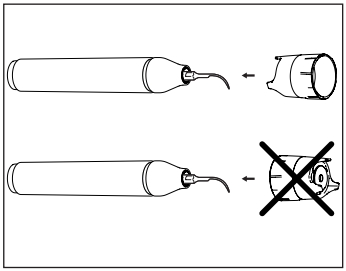
Screw in the preselected tip on the PWR Piezo handpiece all the way down.



6

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

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

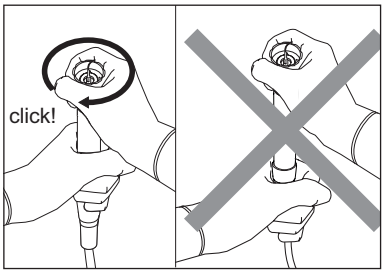


7

Hold the handpiece body firmly.

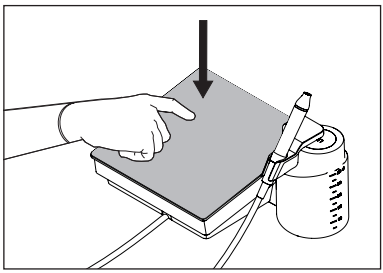
⚠ **CAUTION**: Do not grab the handpiece on the end and/or on the cord, but only on the body. Do not turn the handpiece, rather it must be held steady turning only the wrench.

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 tip is now optimally locked.



8

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

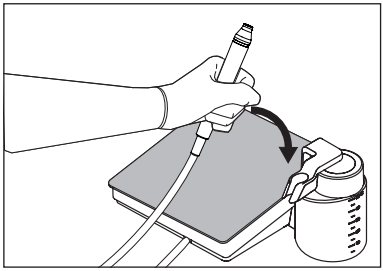


At the end of treatment stow the scaler handpiece on its support.

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

NOTE: Remember to empty the bottle.

9



5.5 Important Information on the Tips

⚠ **WARNING**:

- **Diamond coated Piezo Tips and plastic Piezo Tips are SINGLE USE.** The diamond coated Piezo Tips and the plastic Piezo Tips are intended to be used on an individual patient during a single treatment procedure and then discarded. The diamond coated Piezo Tips and the plastic Piezo Tips cannot therefore be reprocessed since they cannot be cleaned properly.Soil residues might remain adhered to the diamond coating even after cleaning and sterilization and enter into the oral cavity of another patient.
- Before the treatment, check that the tip is firmly secured to the handpiece. Properly secure the tip onto the handpiece using the torque wrench.
- When the titanium nitride coating is visibly worn out, the tip must be replaced. Use of an worn out tip reduces its efficiency.
- Do not activate the handpiece while the tip is in contact with the part to be treated. Doing so, will not allow the electronic control circuit of the piezoelectric generator to recognize the best point of resonance of the tip, required for efficient and optimum performance.
- Use the tip/s according to the working settings reported in the annexed sheet “Appropriate settings for the tips”.
- Always inspect the tip before and during the operation for any damage. If a damage or drop in performance is noted replace it with a new one. Tips showing signs of deformation or cracking must be replaced immediately.
- Use original PWR Piezo Tips only. Only PWR Piezo Tips can fit properly in the PWR Piezo handpiece. The use of non-original PWR Piezo Tips damages the threaded pin of the handpiece with the risk of poor fastening of the original tip/s during subsequent use. The device settings are tested and guaranteed to operate only when PWR Piezo Tips are used. Use of non-original PWR Piezo Tips may result in patient or operator injury or system malfunction and will void any applicable warranty.
- Do not modify the shape of the tip in any way. Bending or prying the tip may cause it to fracture.
- Do not use an tip that has suffered any type of deformation.
- Do not attempt to re-sharpen used tips. In use, the tip might break.
- Always check that the threaded parts of the tip and of the handpiece are perfectly clean - see *Chapter 8 on page 32*.
- Let the piezoelectric vibrations work, do not exert excessive pressure on the

tips during use. Apply a light force on the tip to obtain the best efficiency.

- The PWR Piezo Tips vibrate with a longitudinal oscillation, with forward and backward movement. During treatment, always keep the instrument tangential to the tooth surface. Move the handpiece back and forth while applying light lateral pressure.
- Do not aim the instrument directly on the surface of the enamel or implant. Position the tip/operative part only tangentially to the surface of the tooth or implant.
- When the tip is used in the interproximal spaces, do not block the instrument or leverage the operative part. The tips must be left free to vibrate.
- In the treatment of endodontic root canal therapy, never operate the files when they are outside the root canal to avoid breaking them. To prevent breakage, create a smooth path with a manual endo file and plan an access as straight as possible to limit creases in the tip. Use a light movement. Check the file often for signs of wear. In the case of a broken file inside the canal, do not allow contact between the instrument and the broken file to avoid pushing it deeper. Do not apply pressure to the tip in the axial direction.
- Excessive pressure applied to tip may cause tip fracture which may cause harm to the patient and user. Bending and/or prying an tip reduces its structural integrity and can result in an tip breakage during use.
- Breakage and wear-out of the tips. High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the tip.
- Deformed or otherwise damaged tips are susceptible to breakage during their use. These tips must never be used.
- Should an tip fracture, during use, check that none of its fragments remain in the treated part and, at the same time, apply effective suction to remove them.
- The patient must be instructed to breathe through his nose during the treatment,
  or a dental dam must be used to prevent the patient from ingesting fragments of broken tips.

6 FLUSH FUNCTION

The FLUSH function allows to run a flushing cycle on the irrigation circuit of the handpiece used during the treatment, by following the steps described in this chapter.

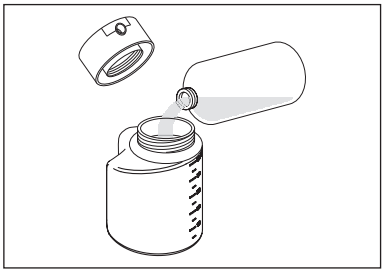
⚠ **CAUTION**: **FLUSH function.** The FLUSH function must be used before the first treatment of the day, after every treatment, before starting the cleaning and sterilization procedures.

⚠ **WARNING**: The “FLUSH” function does not substitute for the cleaning and sterilization procedure described in this manual. After having carried out the “FLUSH” function, the cleaning and sterilization procedures must be followed meticulously in order to prepare the device accessories ready for the next patient and minimize any risk of patient-to-patient contamination.

⚠ **CAUTION**: Failure to carry out flushing of the handpiece tubing will lead to salt crystallization that can seriously damage the device.

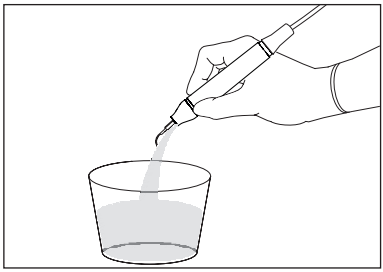
1

Fill the bottle with water, preferably demineralised water. Connect the bottle to the device.



2

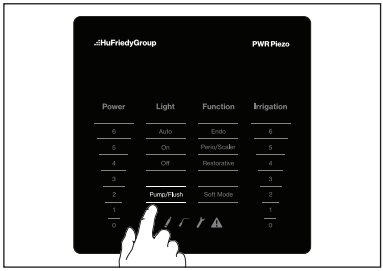
Position the handpiice, with or without tip, above a container to contain the liquid that will outflow during the flushing cycle.



3

To enter the flushing mode, select “pump/flush” menu on the touch keyboard: all the other selection options present on the display are disabled.

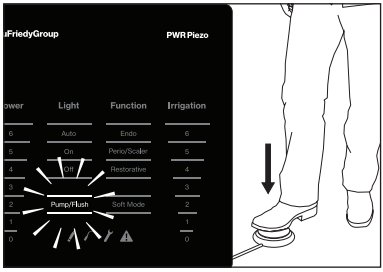
NOTE: The “flush” mode can be interrupted at any time by pressing the “pump/flush” key again. The keyboard will be reactivated and configured with the last setting used.



4

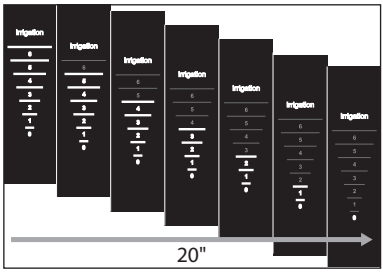
To start the “pump/flush” function while the writing “pump/flush” is flashing, press the pedal once and release it: the keyboard will stop flashing and the cleaning cycle will start.

NOTE: The function can be stopped at any time by pressing “pump/flush” again or alternatively by pressing the pedal briefly. The keyboard will be reactivated and configured with the last setting used.



5

As soon as the peristaltic pump starts, the entire scale of values in the “irrigation” section lights up, and during the passage of the liquid, the irrigation value shifts from 6 to 0. The cycle lasts 20 seconds. Once ended, the keyboard will be reactivated and configured with the last setting used.



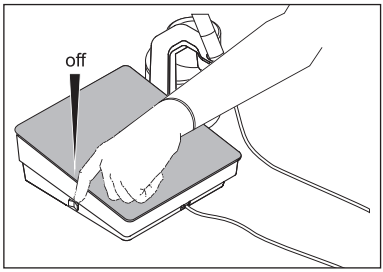
After the flushing cycle of the irrigation circuit move on to disassembling the different parts (see *Chapter 7 on page 29*) and to their cleaning and sterilization (see *Chapter 8 on page 32*).

7 DISASSEMBLING PARTS FOR CLEANING AND STERILIZATION

Before carrying out the cleaning procedures described in *Chapter 8 on page 32*, disconnect all accessories and components of PWR Piezo.

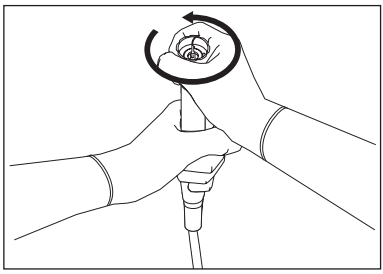
⚠ **WARNING**: **Switch the device off.** Always switch the device off using the switch and disconnect the power supply cable from the wall socket and from the device core unit before carrying out cleaning and sterilization tasks.

1



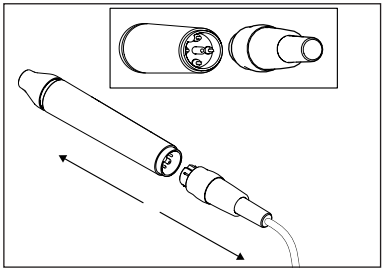
2

If present, remove the tip from the handpiece using the torque wrench.

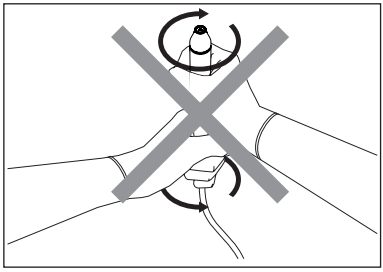


3

Disconnect the handpiece from its cord.



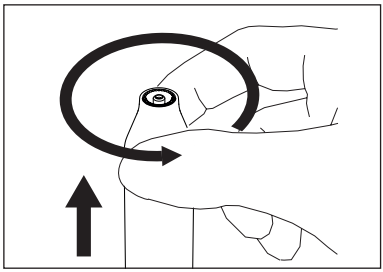
⚠ **CAUTION**: Do not attempt to unscrew or turn the connector when disconnecting the handpiece.
The connector could get damaged.



4

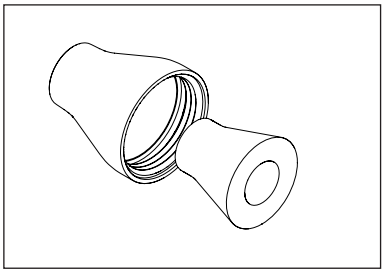
Unscrew the front cone from the handpiece.

NOTE: 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.



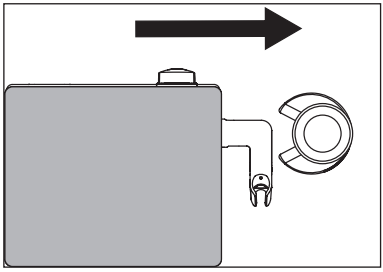
5

Remove the light guide from the front cone.



6

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

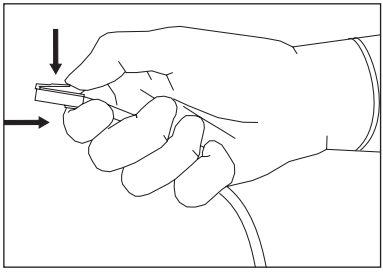


7

Disconnect the pedal from the device: grab the pedal connector, press the release clip and pull the connector back.

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

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



8 CLEANING AND STERILIZATION

⚠ **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.

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.

Device Core Unit, Pedal, Scaler Cord, Bottle and Cap			
Phase	**Chapter**	**Procedure**	**Frequency**
I	*8.1*	Preparation	
II	*10.1*	Manual Cleaning	Between each patient

Accessories (Scaler handpiece, Torque wrench, Piezo Tips, Irrigation kit)			
Phase	**Chapter**	**Procedure**	**Frequency**
II	*10.1*	Manual cleaning	- Prior the first use - After each treatment session
IV	*13*	Sterilization	- Prior the first use - After each treatment session

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 scaler handpieces for up to 250 reconditioning cycles.

8.1 Cleaning Preparation

- Run the flush function (see *Chapter 6 on page 27*);
- Remove the following accessories from the device (see *Chapter 7 on page 29*):
  - Power supply cable;
  - Pedal;
  - Scaler handpiece;
  - Tips.

⚠ **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 cleaning tasks.

⚠ **CAUTION**: Always disconnect the 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**: Do not immerse the handpiece in the ultrasonic tank.

9 CLEANING THE NON-STERILIZABLE PARTS

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

- Device core unit;
- Pedal and relative connection cable to the device;
- End part of the scaler handpiece and relative cord.

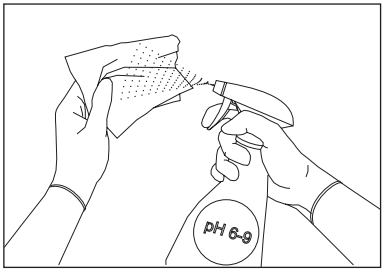
» REQUIRED MATERIALS

- Clean, soft, low-lint cloths;
- Cleaning solution (pH 6-9).

» CLEANING METHOD

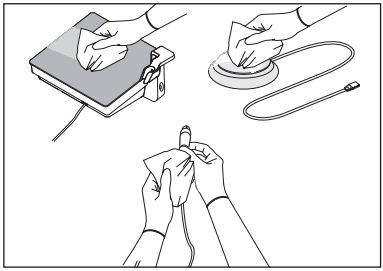
Clean the surface of the parts in question using a clean, dry, low-lint cloth, dampened with a detergent solution (pH 6-9).

1



2

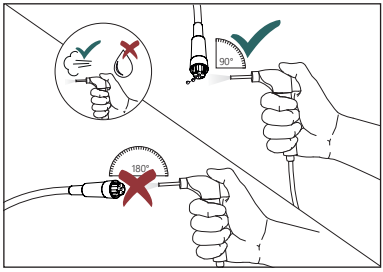
Dry the parts using a dry, non-abrasive, low-lint cloth.



3

⚠ **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).



⚠ **CAUTION**: Do not sterilize the parts in question. They may stop working and cause damage to people and/or property.

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

⚠ **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 parts in question.

⚠ **CAUTION**: Do not soak these parts in liquid and/or various kinds of solutions.

⚠ **CAUTION**: If disinfection is required, water-based disinfectant solutions must be used with neutral pH (pH7). Alcohol-based disinfectant solutions and hydrogen peroxide are contraindicated, because they can fade the color and/or damage the plastic materials. This is also valid for chemical products such as acetone and alcohol.

9.1 Cleaning the Bottle and Cap

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

» PREPARATION

- Disconnect the bottle from the device core unit (see *Chapter 7 on page 29*);
- Unscrew the cap from the bottle.

» REQUIRED MATERIALS

- Water;
- Cleaning solution (pH 6-9);
- 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 aneutral pH (pH7).

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

DO NOT USE as disinfectants:

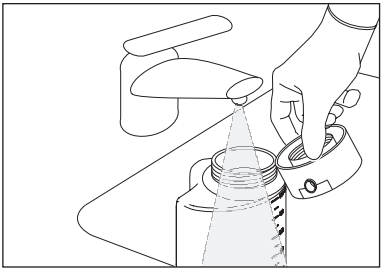
- Alcohol-based disinfectant solutions;
- Peracetic acid, Formaldehyde,
- Gluteraldehyde based products or other equivalent solutions/products;
- Very alkaline products (pH > 9);
- Products containing sodium hypochlorite;
- Products containing hydrogen peroxide;
- Products containing abrasive substances;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

since they may discolor and/or damage the plastic materials.
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

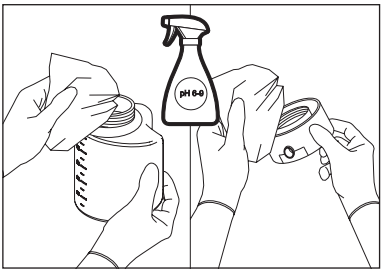
1

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



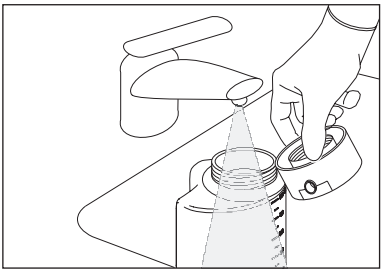
2

Clean the external and internal surfaces of the bottle and cap with a clean, soft, low-lint cloth, dampened with a mild detergent solution (pH 6-9).



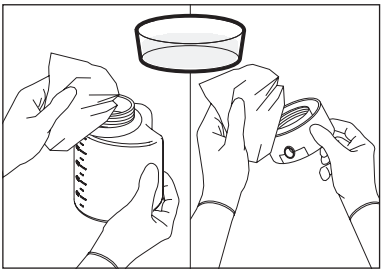
3

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



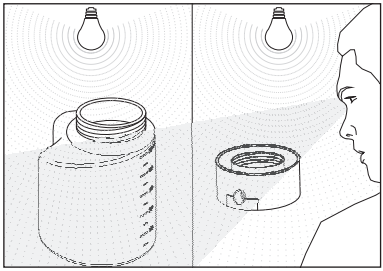
4

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



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.

5



10 CLEANING THE STERILIZABLE ACCESSORIES

NOTE: The cleaning procedures must be performed immediately after each use. Immerse the 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 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;
- Tips;
- Tips torque wrench.

Proceed with the cleanin procedure (see *Chapter 10.1 on page 37*) before proceeding with the cleaning check (see *Chapter 11 on page 44*), drying, lubrication (see *Chapter 12 on page 45*) and then sterilization (see *Chapter 13 on page 46)*

⚠ **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 Manual Cleaning

» 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**: To disinfect the device and/or its accessories, it is recommended the use of water-based disinfectant solutions with aneutral 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;

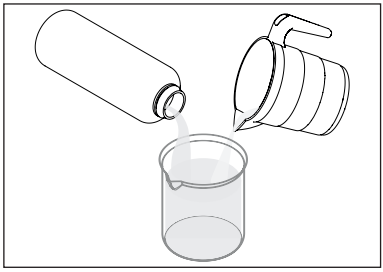
since they may discolor and/or damage the plastic materials.
The manufacturer disclaims all liability for any damage caused by the substances mentioned above. In case of damage caused by those substances, the Warranty will be void.

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.

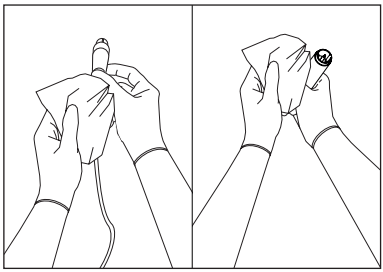
Process validated by independent bodies with ENZYMEC enzymatic detergent, 0.8% v/v.



10.1.1 Scaler Handpiece

2

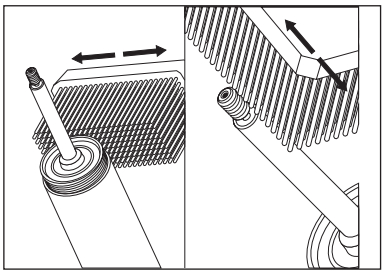
Clean the surface of the handpiece and of its connector using a clean, soft, lint free, cloth moistened with the prepared enzymatic detergent solution and, if need be, disinfect with no-aggressive disinfectant solution with neutral pH (pH7), according to the disinfectant's manufacturer.



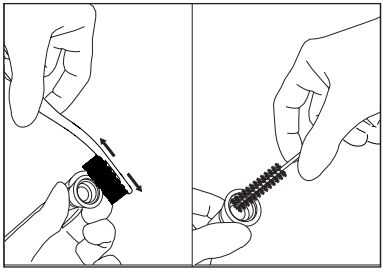
3

Use the enzymatic detergent solution and a clean soft bristled, nylon brush to gently scrub the external surface of the handpiece and the front terminal until all visible soil has been removed.
The following parts must be brushed meticulously:

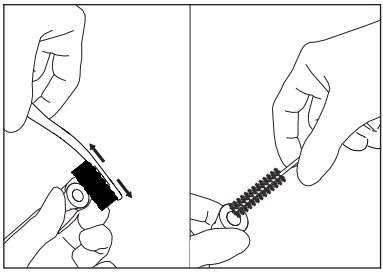
- threaded pin onto which the tips are screwed;
- the visible parts adjacent to the threaded pin;
- threaded part of the handpiece onto which the front cone is screwed;



- external and internal parts of front cone;



- external and internal parts of light guide.



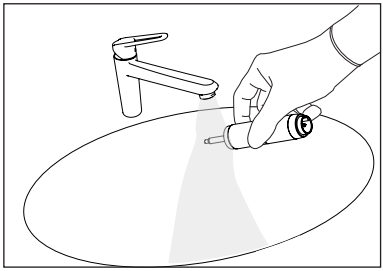
Thoroughly rinse the front terminal under running warm tap water and then under demineralized water to eliminate any residual detergent;
Hold the handpiece with its front end pointed downward;
Rinse thoroughly the front end and the surfaces of the external body of the handpiece under running warm tap water to eliminate any residual detergent.

» **FINAL RINSING**

Hold the handpiece with its front end pointed downward;
Rinse thoroughly the front end and the surfaces of the external body of the handpiece under demineralized water.

NOTE: Repeat steps 3 and 4 until rinse de-mineralized water runs clear.

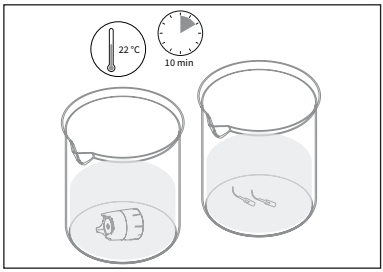
4



10.1.2 Piezo Tips and Torque Wrench

5

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)



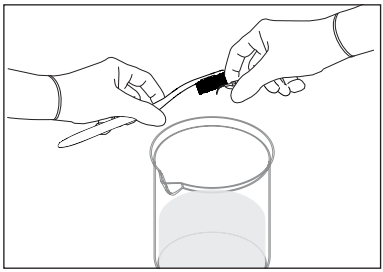
6

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:

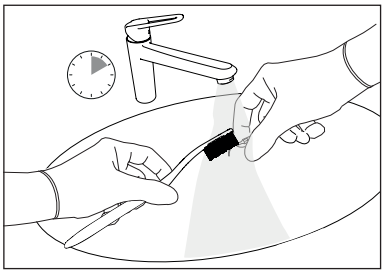
- Through-holes and internal channels;
- External metal ring;
- Internal cavities, grooves and fissures.



7

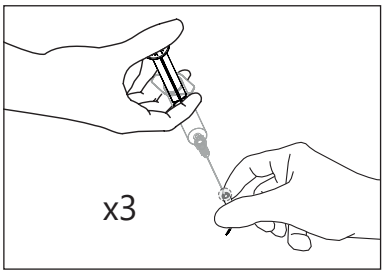
Remove the device from the enzymatic detergent solution.
Thoroughly rinse and brush all the surfaces of the device (see previous point) under running water for:

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



8

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.

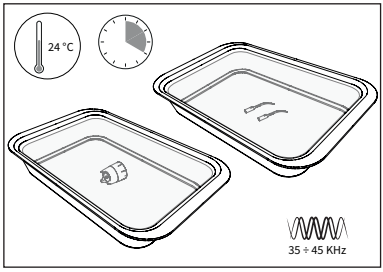


9

Place the device in the 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 for the wrench;
- at least 10 minutes for the piezo tip.

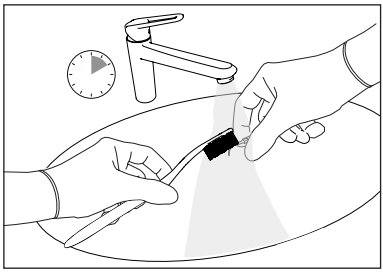
or as instructed by the Enzymatic detergent manufacturer or by the manufacturer of the ultrasonic tank.



10

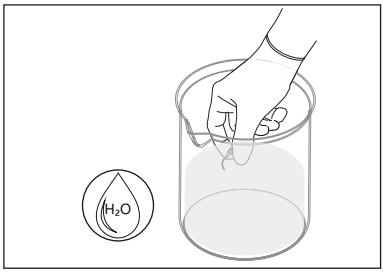
Remove the device from the enzymatic detergent solution.
Thoroughly rinse and brush all the surfaces of the device (see previous point) under running water for:

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



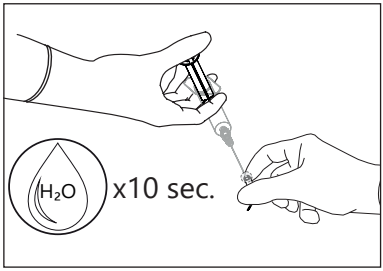
11

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



12

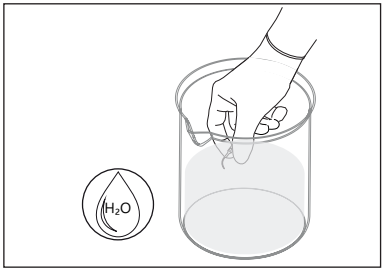
Brush the internal and external surfaces of the tip with a clean brush with soft nylon bristles, under running water.



13

Soak the device in demineralized water for:

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



11 CLEANING CHECK

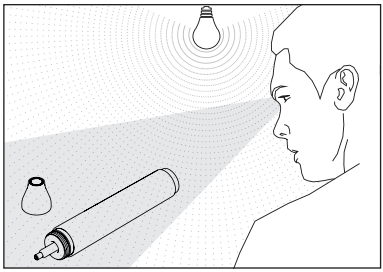
» REQUIRED MATERIALS

- Light source;
- 2.5X Magnifier.

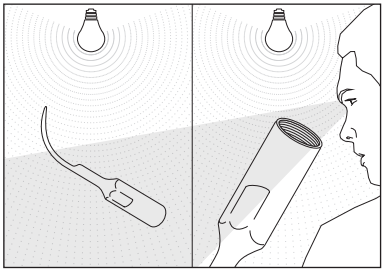
Once the cleaning operations have been completed, check the scaler handpiece and scaler front cone under an adequate source of light, if necessary using a magnifying glass 2.5X, paying attention to any parts that may conceal soil residue (threading, cavities, grooves) and, if need be, repeat the cleaning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

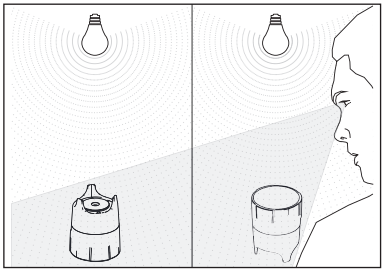
Repeat the control operations for the other accessories (tips, tightening wrenches), repeating if necessary the cleaning cycle.

1



2





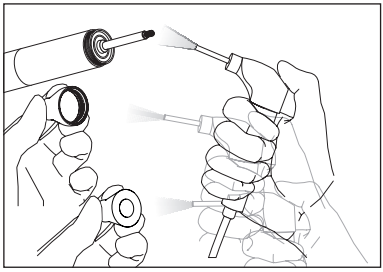
12 DRYING AND LUBRICATION

» REQUIRED MATERIALS

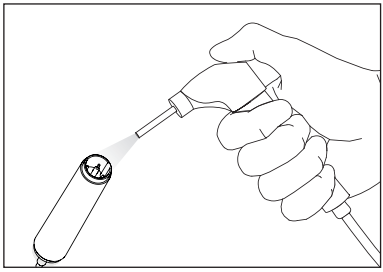
- Compressed air;
- Soft, low-lint cloth;
- FDA approved medical grade lubricant.

1

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

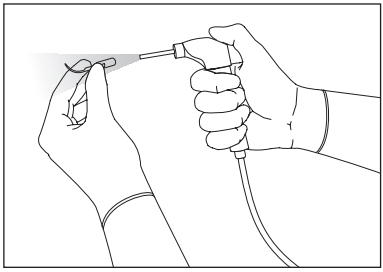


⚠ **CAUTION**: The scaler handpiece electrical contacts must be dry at the start and end of the sterilization cycle, before the cord is connected to the device. Always make sure that the electrical contacts of the connector are perfectly dry, if necessary dry them blowing with compressed air.



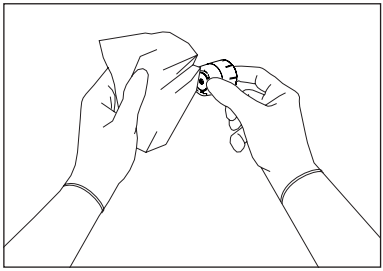
2

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



3

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

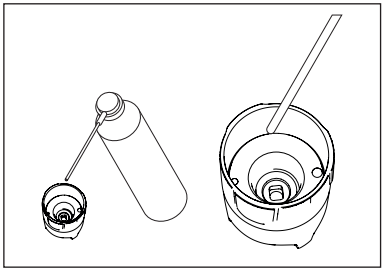


4

Lubricate the tips torque wrench with FDA approved medical-grade lubricants by spraying it directly onto the peripheral contact surface inside the torque wrench, as indicated in the figure.

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

After having applied the lubricant, remove any excess oil using a clean lint-free cloth.

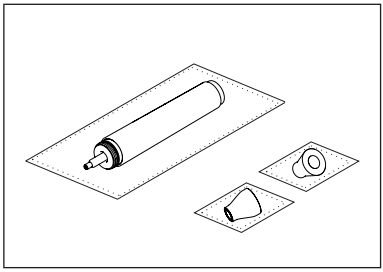


13 STERILIZATION

1

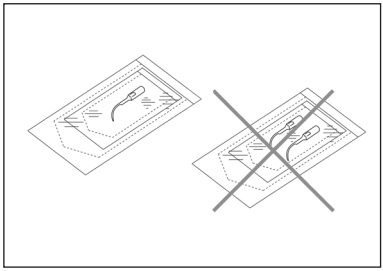
Seal the scaler handpiece (without tips), scaler front cone, and light guide individually and separately in disposable sterilization bags.

⚠ **CAUTION:** Use FDA approved, appropriately sized medical steam sterilization pouch compliant with standard UNI EN ISO 11607-1.



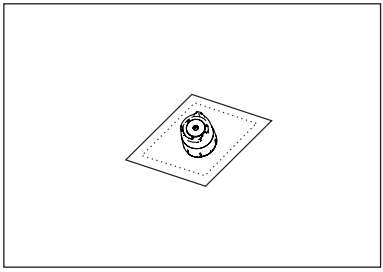
2

Seal the tips individually inside a disposable bag for sterilization.



3

Seal the wrench individually inside a disposable bag for sterilization.



13.1 Sterilization Method

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

⚠ **WARNING**: Diamond coated tips and the plastic Piezo Tips are **SINGLE USE ONLY**. The diamond coated 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 tips and the plastic Piezo Tips must be sterilized only one time, prior first use.

⚠ **CAUTION**: **DO NOT** sterilize the console. The console will no longer function.

⚠ **CAUTION**: **DO NOT** sterilize the foot pedal. Foot pedal will no longer function.

⚠ **CAUTION**: When sterilizing multiple instruments in one autoclave cycle, ensure that the autoclave maximum load is not exceeded.

⚠ **WARNING**: **Risk of contamination. DO NOT** use a gravity displacement autoclave to sterilize the PWR Piezo sterilizable intruments. The operating cycle of a gravity displacement autoclave **DO NOT** ensure adequate sterilization of the lumens, cavities, recessed features of the instruments.

⚠ **WARNING**: Use exclusively a pre-vacuum autoclave to sterilize the PWR Piezo sterilizable instruments.

⚠ **CAUTION**: Never use any other sterilization method, because of potential incompatibility with the materials used in the construction of the components.

⚠ **CAUTION**: **DO NOT USE** the following sterilization methods:

- Ethylene oxide sterilization;
- Hot air sterilization;
- Flash Autoclaving;
- STERRAD sterilization;

- STERIS system;

or comparable sterilization systems.

⚠ **CAUTION**: **DO NOT** sterilize the instruments by using:

- Hydrogen peroxide;
- Peracetic acid system;
- Formaldehyde sterilization;
- Glutaraldehyde sterilization;

or comparable sterilization solutions/ system.

The sterilizable parts of the device are:

- Scaler handpiece;
- Scaler front cone;
- Scaler light guide;
- Piezo tips;
- Piezo tips torque wrench;.

They are manufacturedured with materials that resist a maximum temperature of 275°F (135°C) for a maximum time of 20 minutes.

⚠ **CAUTION**: **DO NOT** exceed 275°F (135°C).

Once the scaler handpiece and the other sterilizable accessories have been put into separate sterilization puches, perform the steam sterilization process in the autoclave.

⚠ **CAUTION**: Do not sterilize the scaler handpiece with the tip screwed in.

⚠ **CAUTION:** Use FDA approved, appropriately sized medical steam sterilization pouch compliant with standard UNI EN ISO 11607-1.

The sterilization process validated by the Manufacturer. in a pre-vacuum autoclave, guarantees a SAL 10^{-6} by setting the parameters indicated below:

- **Type of cycle**: 3 times Pre-vacuum (pressure min. 60 mBar).
- **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 operate or store the handpiece unless a drying cycle has been performed;
- Do not sterilize handpiece with an tip screwed on it;
- The handpiece and other accessories must not be assembled during sterilization;
- After sterilization, the handpiece should only be used again when it has cooled down to room temperature.
- The cooling process must not be accelerated;
- Never immerge the handpiece in a liquid to help it cool after sterilization, or product damage may result;
- After sterilization, verify functionality by operating the equipment prior to use;
- Remove the handpiece from the sterilizer immediately after the sterilization cycle is complete or product damage may result;
- Upon completion of the sterilization cycle, before connecting the handpiece to the cord, make sure that the electrical contacts of the connector are perfectly dry. If necessary, dry the contacts by blowing air onto them with medical compressed air.

14 MAINTENANCE

14.1 Maintenance after every treatment

At the end of each treatment, proceed with the activities described in the following.

Perform a complete cleaning cycle of the irrigation circuits using the “Flush” function (see *Chapter 6 on page 27*). Immediately disassemble the different parts (see *Chapter 7 on page 29*) and proceed to their cleaning and sterilization (see *Chapter 8 on page 32*).

Clean the not-sterilzable parts (see *Chapter 9 on page 33*

14.2 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:

1 Perform “Flush”

2 Remove and empty the water bottle (see *Chapter 7 on page 29*).

⚠ **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.

3 Lift scaler hose, select „Flush“ and press the foot pedal to empty the circuit (see *Chapter 6 on page 27*).

9 Clean the parts of the device that cannot be sterilized (see *Chapter 9 on page 33*).

10 Reconnect the empty water bottle.

14.3 Transport or long inactivity periods

If the device is not used for a long time observe the following recommendations:

- Run a complete flushing cycle on the irrigation circuit using the “pump/flush” function (see *Chapter 6 on page 27*);
- Empty the circuits of any residual water, removing the bottle and making the handpiece work for a few seconds;
- Disconnect the device from the mains;
- 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, clean and sterilize the handpiece, tips, and wrench following the instructions in *Chapter 8 on page 32*;
- Check that the tips are not worn, deformed or broken, with particular attention to the integrity of the tip.

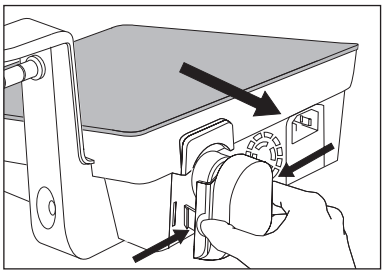
⚠ **WARNING**: Periodically check the integrity of the power supply cable; if damaged, replace it with an original spare part.

14.4 Replacing the Peristaltic Pump

1

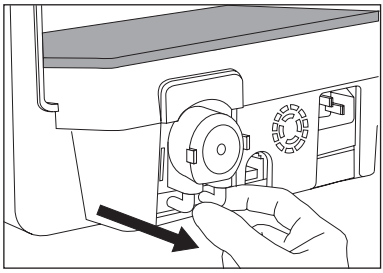
On the back of the device there is the plastic cover which covers the housing of the peristaltic pump. Remove this protection by pressing on the sides and pulling towards yourself.

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



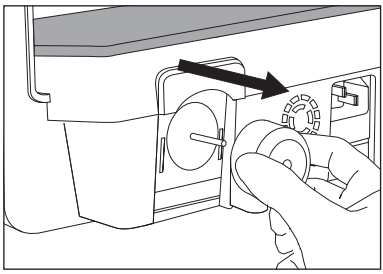
2

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



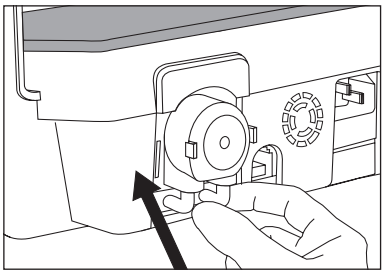
3

Extract the peristaltic pump from its base, pulling it towards yourself.



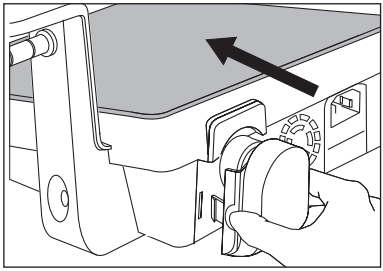
4

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.



Refit the plastic protection onto the peristaltic pump.

5



14.5 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.

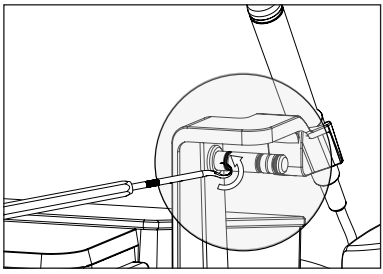
⚠ **CAUTION**: In case of no or difficult delivery of water from the bottle replace the O-rings even if they are not visually worn or damaged.

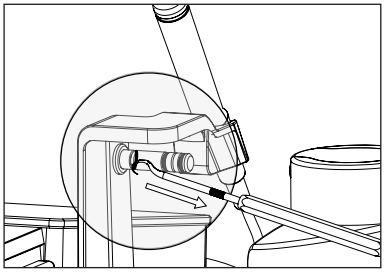
NOTE: If all 3 O-rings need to be replaced, remove and insert one O-ring at a time starting with the innermost one.

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.

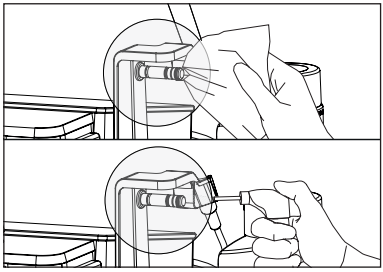
1





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

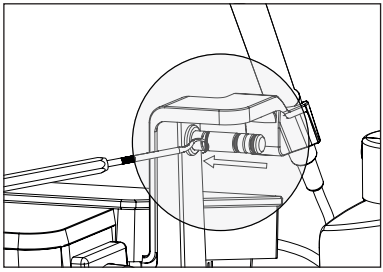
2



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

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

3



15 METHODS AND PRECAUTIONS FOR DISPOSAL

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

- Tips, when worn or broken;
- Tips tightening wrench, when worn or broken.
- 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 tips, pay particular attention to the sharp, pointed, irregular parts to avoid any wounds or injuries.

PWR Piezo 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.

16 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 30 sec. ON - 120 sec. OFF without irrigation
Power Supply	100-240 V~ 50/60 Hz
Max. Power Consumption	90 VA
Fuses	Type 5 x 20 mm, T 2AL, 250V
Working Frequency	Automatic Scan From 24 KHz to 36 KHz
Powers	”endo” “perio/scaler” “restorative” “soft mode”
Peristaltic pump flow rate	Adjustable using the touch screen 7 flow rate levels: from 0 (0 ml/min) to 6 (approx. 28 ml/min) (see *Chapter 5.2 on page 16*) Bottle capacity: 500 ml. Bottle lighting system: Blue LED light power risk free according to standard IEC/EN 62471.
Handpiece LED system:	Light function set to AUTO: The handpiece LED lights up as soon as the device starts working, and turns off 3 seconds after the pedal is released Light function set to ON: The handpiece LED is always lit; after 100 seconds of non-use of the pedal, it turns off by itself and the light function switches to AUTO The handpiece LED stays off when both the options (ON and AUTO) are off. White LED light power risk free according to standard IEC/EN 62471
Protections of the APC Circuit	Missing handpiece; Breaking wire cord; Tip not correctly tightened or broken;

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	2.4Kg 320 x 230 x 145 mm (L x W x H)[b)]

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

16.1 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. Install the device at safety distance from life-support systems. 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:** Only use original HuFriedyGroup accessories and spare parts. The use of cables and accessories not supplied by HuFriedyGroup might negatively affect the EMC performances.

16.2 Guide and Manufacturer's Declaration - Electromagnetic Emissions

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

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

16.3 Accessible Parts of the Casing

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

Phenomenon	Basic EMC standard or test method	Immunity test levels	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 the floor is covered with synthetic material, the relative humidity should be at least equal to 30%.
Radiated RF EM fields [a]	IEC 61000-4-3	3 V/m [f] 80 MHz - 2,7 GHz [b] 80% AM a 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.
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See *Chapter 16.5 on page 61*	
RATED power frequency magnetic fields [d]	IEC 61000-4-8	30 A/m 50 Hz o 60 Hz	The magnetic fields at the mains frequency should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See *Chapter 16.6 on page 62*	Portable and mobile RF communication devices shall be used with a separation distance of at least 0,15 m from the field sources.

a) The interface between the PATIENT physiological signal simulation, if used, and the PWR Piezo shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the PWR Piezo.

b) PWR Piezo 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 anambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

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

d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) Void.

f) Before modulation is applied.

16.4 Guide and the Manufacturer's Declaration - Electromagnetic Immunity

16.4.1 Power Connection BC Input

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

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrical fast transients / bursts [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.
Surges [b) j) o)] Line-to-line	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.
Surges [b) j) k) o)] Line-to-ground	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.
Conducted 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 distances, calculated 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 e 70% UT; 25/30 cycle [h)] Single phase: at 0°	
Voltage interruptions [f) i) o)]	IEC 61000-4-11	0% UT; 250/300 cycle [h)]	The quality of the network voltage should be that of a typical commercial or hospital environment.

a) Void.

b) All PWR Piezo cables are attached during the test.

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

d) 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.

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

f) 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.

g) Applicable only to PWR Piezo connected to single-phase a.c. mains.

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

i) 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). PWR Piezo 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.

j) 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).

k) Not applicable to CLASS II PWR Piezo.

l) Direct coupling shall be used.

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

n) 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.

o) 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.

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

q) 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.

r) 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 IEC60601-1-2:2014/AMD1:2020.

16.4.2 Points of Contact with the Patient

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

16.4.3 Parts Accessible to the Input / Output Signals

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

Phenomenon	Basic EMC standard or test method	Immunity test levels	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 the floor is covered with synthetic material, the relative humidity should be at least equal to 30%.
Electrical fast transients / bursts [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.
Surges Line-to-ground [a]	IEC 61000-4-5	± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conducted 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 a 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) **T**his 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 INTENDED 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 os 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.

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

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

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

a) For some services, only the 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 reach the immunity test level, the distance between the transmitter antenna and PWR Piezo can be reduced to 1 m. The test distance of 1 m is allowed by IEC 61000-4-3.

⚠ **WARNING**: Portable RF communication equipment (including peripheral devices such as antenna cables and external antennas) must not be used closer than 30 cm to any part of the PWR Piezo device, including the cables specified by the manufacturer. Otherwise, there may be a performance degradation of these devices.

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

The following table reports the test specifications for 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 [a)]

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.

17 TROUBLESHOOTING

17.1 Diagnostic System and Symbols on the Keyboard

PWR Piezo 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
	Cord electrical contacts wet	Thoroughly dry the contacts with compressed air. (see *Chapter 12 on page 45*)
	PWR Piezo handpiece not connected to the device	Connect the handpiece (see *Chapter 4.3 on page 13*).
	Faulty handpiece	Replace the handpiece
	Tuning circuit malfunction	Contact HuFriedyGroup Customer Care.

Symbol on keyboard	Possible cause	Solution
	Tip not present or not properly tightened on the handpiece	Unscrew the tip and screw it back in correctly using the torque wrench (See *Chapter 5.4 on page 23*).
	Tip broken, worn or deformed	Replace the tip.
	Cord electrical contacts wet	Thoroughly dry the contacts with compressed air (see *Chapter 12 on page 45*).
	Peristaltic pump malfunction	Check that there are no impediments for the rotation of the pump. Check that the pump and the two pipes are correctly installed.
	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 or excessive electrostatic discharges or internal faults	Turn off and wait 5 seconds before switching the device on again If the warning persists, contact HuFriedyGroup Customer Care.
	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 Customer Care.

NOTE: For diagnostic warnings not included in this list, contact HuFriedyGroup Customer Care.

17.2 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 power supply cable is inserted incorrectly into the rear plug 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 17.3 on page 66*)
The device is on but is not working. The display reports no errors.	The pedal plug is not correctly inserted into the device socket	Correctly insert the pedal plug in the socket on the back of the device (see *Chapter 4.3 on page 13*)
	The pedal does not work properly	Contact HuFriedyGroup Customer Care
The device is on but is not working. One of the following symbols appears on the screen: 	See *Chapter 17.1 on page 62* for the possible cause depending on the symbol	See *Chapter 17.1 on page 62* for the action to be taken depending on the symbol
During operation a faint whistling noise can be heard coming from the PWR Piezo handpiece.	The tip is not correctly tightened on the handpiece	Unscrew the tip and screw it back in correctly using the torque wrench (See *Chapter 5.4 on page 23*)
	The irrigation circuit has not been completely filled	Fill the irrigation circuit using the PUMP function (See *Chapter 5.4 on page 23*)

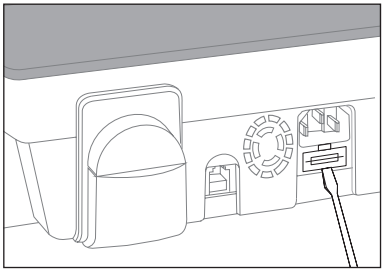
Problem	Possible Cause	Solution
No liquid flows out from the tip during operation	The tip is the type without a liquid passage	Use an tip type with a liquid passage
	The tip is clogged	Unscrew the tip from the handpiece and release the water passage of the tip by blowing compressed air through it. If the problem persists, replace the tip with a new one
	The handpiece is clogged	Contact HuFriedyGroup Customer Care
	The irrigation level on the screen is set to "0"	Adjust the irrigation level
	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 connections of the tubes
	The peristaltic pump is worn	Replace the peristaltic pump (See *Chapter 14.4 on page 50*)
Poor performance	The tip is not correctly tightened on the handpiece	Unscrew the tip and screw it back in correctly using the torque wrench (See *Chapter 5.4 on page 23*)
	Tip broken, worn or deformed	Replace the tip with a new one

17.3 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

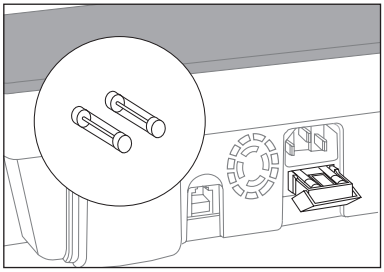
Use a flat tool, if necessary, to open the fuse-holder drawer located under the power supply socket;



2

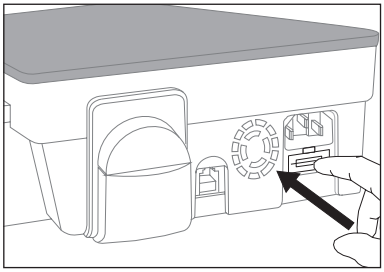
Extract the fuse holder compartment;

⚠ **WARNING:** Replace the fuses in respect of the characteristics indicated in *Chapter 8 on page 32*.



3

Reinsert the compartment in its place.



17.4 Customer Service - Returns and/or Repairs

If you need technical assistance regarding the use, or you encounter a problem that requires servicing or repair, please visit hufriedygroup.com/PWR/Support or you can contact HuFriedyGroup Customer Care at 1-800-Hu-Friedy (1-800-483-7433). Returning products for any reason, requires a return authorization number that can be obtained by contacting HuFriedyGroup Customer Service.

Please provide the following information:

- Data of the owner with telephone number;
- Product name;
- Serial number and/or lot number;
- Reason for goods returned / description of the malfunction;
- Photocopy of delivery note or purchase invoice of the device.

17.4.1 Repairs

Products returned for repair must have a return authorization number that must be included on all paperwork and clearly visible on the package sent to HuFriedyGroup.
Contact HuFriedyGroup Customer Care and provide the following information to obtain a return authorization number prior to returning any product for repairing. Make reference to this number for inquiries regarding the repair status.

- Data of the owner with telephone number;
- Product name;
- Serial number and/or lot number;
- Reason for goods returned / description of the malfunction;
- Photocopy of delivery note or purchase invoice of the device.

If you require a quote – Notify Customer Service, when requesting the return authorization number that a quote is required.
If a quote is not requested the repair will be processed and your account billed accordingly – provided the repair is not covered under warranty.

17.4.2 Returned Goods

All returns must have a return authorization number that must be included in all the shipping documents and clearly visible on the package sent to HuFriedyGroup. All returns must be shipped prepaid freight, otherwise they will not be accepted.

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

⚠ **WARNING:** All the products must be cleaned and sterilized before returning. HuFriedyGroup will not accept and process potentially bio-contaminated products which do not meet this requirement. Contaminated products will be immediately returned to you, at your expense, for decontamination and sterilization.

This warranty gives you specific legal rights and you may have other rights which vary by state and municipality.
The foregoing limited warranty is in lieu of all other warranties, expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.
Except claims for personal injury, in no case shall the company be liable for any special, incidental or consequential damages based upon breach of warranty or any other legal theory.
Some jurisdictions do not allow limits on warranties, or on remedies, and, in such jurisdictions, the limit in this and the preceding paragraphs may not apply.

18 WARRANTY

Any non-approved usage of the PWR Piezo will void the warranty.
Any usage of non-HuFriedyGroup parts, tips, components or procedures will void the warranty.
The manufacturer warrants to the first original purchaser (customer) that their products have been tested, inspected and shipped in proper working order.
All products, with exceptions noted below, are covered by warranty for a period of one year from the date of purchase. Products are warranted to be free from defects in material and workmanship.
This limited warranty is extended only to the first customer purchasing the HuFriedyGroup products directly from HuFriedyGroup or from its authorized distributor or representative.
This limited warranty does not apply to any unit/accessory which has been subject to abnormal wear and tear, misuse, abuse, neglect, improper installation or operation or that has been altered, adjusted or tampered with by any person other that HuFriedyGroup authorized service personnel.
The warranty is valid only if HuFriedyGroup is notified within thirty (30) days following discovery of a defect. For returning procedure make reference to the *Chapter 17.4 on page 67*
Returns must be authorized by HuFriedyGroup.
HuFriedyGroup cannot accept responsibility for returns which have not been authorized.
Contact HuFriedyGroup Customer Care at 1-800-Hu-Friedy (1-800-483-7433) for return authorization. This warranty is valid only if the product is returned to HuFriedyGroup service within thirty (30) days of HuFriedyGroup receiving notice of such defect, as described above.
The customer is responsible for returning the defective equipment to the HuFriedyGroup, service location at his or her own expense.
Within a reasonable time after receipt of product/s, HuFriedyGroup, service will investigate and shall correct any defect covered by warranty by providing , at its option, one of the following: service or repair of the product, or a replacement of the product.
If upon examination by HuFriedyGroup service personnel it is determined that the malfunction is caused by abnormal wear and tear or by damage caused by misuse, abuse, tamper with, or by failure to perform normal and routine maintenance as set out in the instruction for use and instruction for cleaning and sterilizing manuals, warranty provisions will not apply.
In this case an estimate for the cost of repair will be given to the customer prior servicing and repairing the product.
The repair will be billed to the customer in the same manner as out of warranty repair.
For selected products:

- **Diamond coated tips and/or accessories are not warranted.**

Manufactured for:
Hu-Friedy Mfg. Co., LLC
3232 N. Rockwell Street
Chicago, IL 60618 | USA
1-800-Hu-Friedy | HuFriedyGroup.com

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