PWR Air

Air Polisher

HuFriedyGroup
The Best In Practice

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1 INTRODUCTION

This manual applies to the following medical devices:

- PWR Air (referred to as “device” in the text)
- PWR Air Perio Handpiece (referred to as “accessory/ies” in the text)
- PWR Air 90° Handpiece (referred to as “accessory/ies” in the text)
- PWR Air 120° Handpiece (referred to as “accessory/ies” in the text)
- PWR Air Perio Subgingival Tips

Read this manual carefully before installing, operating, performing maintenance or otherwise working on the device and its accessories.
This manual must always be available to the user.

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

Depending on the level of severity, safety information is classified with the following indications:

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

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

The aim of this manual is to make users aware of the safety regulations, installation procedures, instructions for proper use and maintenance of the device and its associated items.
Do not use this manual for purposes other than those strictly related to the installation, operation, and maintenance of the device.
The information and illustrations in this manual were updated on the edition date shown on the last page.
HuFriedyGroup is committed to continuously updating its products, which may result in modifications to the device and its associated items.
If discrepancies are found between the content of this manual and the device in your possession, you may:

- check for any available updates in the MANUALS section of the HuFriedyGroup website[1];
- ask for clarifications Your Dealer;
- contact the HuFriedyGroup Service and Repair team.

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

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1.1 Indications for use

1.1.1 Indications for use for US Market Only:

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

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

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

1.1.2 Indications for use for Canada Market Only:

It is a device equipped with a dedicated handpiece that utilizes air-polishing technology for dental prophylaxis. Its purpose is to remove supragingival stains and both supra- and subgingival plaque from natural and prosthetic structures as well as orthodontic appliances in the oral cavity.

» **PWR AIR 90° HANDPIECE / PWR AIR 120° HANDPIECE**

It is a device used in conjunction with air-polishing technology for supra- and subgingival dental prophylaxis.

» **PWR AIR PERIO HANDPIECE**

It is a device used in conjunction with air-polishing technology for subgingival dental prophylaxis to be used in combination with PWR Air Perio Subgingival Tips.

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

⚠ **WARNING: Qualified and specialist personnel.** The device and its accessories must be used exclusively by specialized personnel with appropriate medical knowledge; No specific training is required for use of the device.
The device produces no side effects when used correctly.

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

⚠ **WARNING:** For composite resin surfaces, the jet should be directed exclusively at the part to be treated, for an average time of 2-3 seconds per tooth.

NOTE: For detailed information on PWR Air Perio Subgingival Tips, always refer to the relevant instructions for use.

1.2 Description of the Device

PWR Air is a table-top device, equipped with a polisher handpiece, which uses air-polishing technology to offer complete treatment in dental prophylaxis.
Its aim is to remove stains at supragingival level on natural teeth and restorations, as well as eliminate plaque at supra- and subgingival level on teeth, braces, restorations and implants.
The operating principle of the polisher is based on the mechanical action obtained from a jet of various abrasive agents accelerated by a flow of compressed air. The kinetic energy thus imprinted to the particles, dissipates almost completely due to impact against the surface of the enamel, producing a gentle but effective cleaning action. The action is completed by a jet of water which, using the vacuum created around the nozzle, has a bell-shape around the main flow, thus producing a double effect: to prevent much of the rebound and the leakage of the cloud of powder and perform continuous washing of the treated area, dissolving the powder.

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1.2.1 Eligible Patient Group

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

- Children;
- Adolescents;
- Adults;
- Seniors.

This medical device can be used on patients of any weight, height, sex or nationality, and who are over 2 years of age.

1.2.2 Patient Selection Criteria

It is not recommended to use the device and its relative handpiece in the following cases:

1. Upper respiratory tract infections, chronic bronchitis/asthma;
2. Pregnant and breastfeeding women;
3. Patients undergoing treatment (radiotherapy, chemotherapy, antibiotics);
4. Acute infectious oral lesions.

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

1. Allergy to the aroma of the powder;
2. Patients on a low-sodium diet or suffering from severe respiratory problems, such as chronic bronchitis, asthma, emphysema, etc. unless specifically indicated by the surgeon (for bicarbonate powders only).

All air-polishing devices are intended for professional use only. Therefore, it is up to the user to decide, based on his or her own experience, how and whether to treat patients.

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

1.2.3 Indications for Use

The use of PWR Air, equipped with a polisher handpiece, is indicated for all intended patients (see *Chapter 1.2.1 on page 3*) who require treatment within the scope of the intended use of the device (see *Chapter 1.1 on page 2*).

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1.2.4 Users

PWR Air and the polisher handpiece must be used exclusively by specialized and properly trained personnel, specifically a dentist or dental hygienist, who must be able-bodied, adult, of any weight, age, height, gender, and nationality.

1.2.5 Operating environment

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

1.3 Disclaimer

The manufacturer disclaims all liability, express or implied, and cannot be held liable for direct or indirect personal injury and/or property damage, occurring as a result of incorrect procedures related to use of the device and its associated items.
The manufacturer cannot be held liable, expressly or implicitly, for any type of personal injury and/or damage to property, inflicted by the user of the products and which occurs in the following cases, by way of example and not of limitation:

- Misuse or use during procedures other than those specified in the destination of use of the product;
- The environmental conditions for preservation and storage of the device are not complying with the requirements indicated in *Chapter 14 on page 67*;
- The device is not used in accordance with all the instructions and requirements outlined in this manual;
- The electrical system of the facilities where 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 HuFriedyGroup;
- Misuse, abuse, abnormal use, negligent use, intentional misconduct or use exceeding the limits of the device indicated and allowed and/or normal wear or deterioration, ill-treatment and/or incorrect interventions;
- Any attempt to tamper with or modify the device under any circumstances;
- Shortage of spare parts (handpiece, wrenches) to be used in case of a breakdown due to faults or problems;
- Use of non-original HuFriedyGroup subgingival nozzles.
- Incorrect/omitted maintenance compared to what is stated in *Chapter 12 on page 56* of this manual;
- Breach of the requirements and the information contained in *Chapter 5 on page 18* of this manual;
- Unauthorized repairs in accordance with the indications contained in *Chapter 15.4 on page 81* this manual.

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1.4 Safety Requirements

⚠ **WARNING: Interference from other equipment.**
An electrosurgical scalpel or other electrosurgical units positioned near the device PWR Air may interfere with the correct operation of the device.

⚠ **WARNING: Interference with other equipment.** Though compliant with standard IEC 60601-1-2, PWR Air and its accessories may nonetheless interfere with other devices nearby. PWR Air must not be used near to or stacked on other devices. However, 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 operate in environments where the atmosphere is saturated with flammable gases (anaesthetic mixtures, oxygen, etc.).

⚠ **CAUTION:** If the end user, operating in their dental practice or clinic, is required to conduct periodic equipment checks to comply with regulatory requirements, the testing procedures for evaluating the safety of medical equipment and systems must be carried out in accordance with the IEC 62353 standard: “Medical electrical equipment – periodic inspections and tests to be carried out after repair of medical electrical equipment”. The frequency of periodic inspections in the intended conditions of use described in this “Use and Maintenance” manual is once per year or every 2000 hours of use, whichever condition is satisfied first.

⚠ **CAUTION:** Maintenance and/or repair work must only be carried out by specialized personnel.

⚠ **WARNING: Checking the condition of the device and its accessories before treatment.**
Always check that there is no water under the device. Before each treatment, always check the perfect working order of the device and the efficiency of the accessories. If operation anomalies are observed do not carry out the treatment. If the faults concern the device, contact a HuFriedyGroup's Service and Repair team.

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

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

⚠ **WARNING: Sterile single-use material.** Before using a sterile disposable object, check the integrity of the packaging to ensure that it is sterile. The object will no longer be sterile if the packaging is broken or damaged.

⚠ **WARNING: Cleaning and sterilizing new or repaired instruments.** All new or repaired instruments, with the exception of PWR Air Perio Subgingival Tips, are not sterile. When first used and after each treatment, they must be cleaned and sterilized in strict accordance with the instructions in *Chapters 6, 7, 8, 9* of this manual.

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

⚠ **CAUTION:** After having autoclaved the handpiece, or any other sterilizable associated items, wait for them to completely cool down before reusing them.

⚠ **WARNING:** Use only original HuFriedyGroup associated items and replacement parts.

⚠ **CAUTION:** No modification of this device and its accessories/associated items is permitted.

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

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

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

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

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

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1.5 Symbols

Symbol	Description	Symbol	Description
	Consult instructions for use or consult electronic instructions for use		Nemko brand Compliance with UL - CSA regulations
	Caution		Country of manufacture
	Medical device		Unique device identifier
	Catalog Number		Batch number
	Serial number		Connection of the control pedal
	Sterilizable up to a max. temperature of 135 °C (275 °F)		Non-sterile
0	Power switch set to “off”	I	Power switch set to “on”
	Alternating current		Type B applied part
	Washer disinfector for thermal disinfection		Temperature limit
	Humidity limitation		Atmospheric pressure limitation
	Fragile		Keep dry
	General warning sign [a]		This side up
	Wear protective glasses [b]		Wear protective mask [b]
	Handpiece water flow		Handpiece air flow

Symbol	Description	Symbol	Description
	Warning: electricity		For US market only **CAUTION**: Federal (US) law restricts the marketing of this device to prescription or licensed practitioners

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

b) The symbol is represented by a blue warning circle and a white graphical symbol.

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The following table presents the additional symbols applicable to sterile devices and/or devices with an expiry date, used in combination with the PWR Air medical equipment and its associated accessories.

Symbol	Description	Symbol	Description
	Sterilized with Ethylene Oxide (EO)		Do not resterilize
	Do not re-use		Expiry date
	Single sterile barrier system		Non pyrogenic
	Do not use if the packaging is damaged and consult instruction for use		

NOTE: For other symbols, refer to
Chapter 15 on page 76

2 IDENTIFICATION DATA

A proper description of the model and serial number of the device and its accessories will enable the HuFriedyGroup's Service and Repair team to provide quick and effective answers.

Always provide this information every time you contact the HuFriedyGroup's Service and Repair team.

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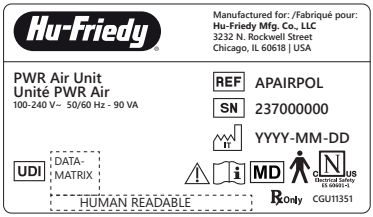
2.1 Device Nameplate

Each PWR Air comes with a nameplate indicating the main technical features and traceability data, including the UDI. This nameplate is located under the device. The complete technical specifications are provided in *Chapter 14 on page 67*.

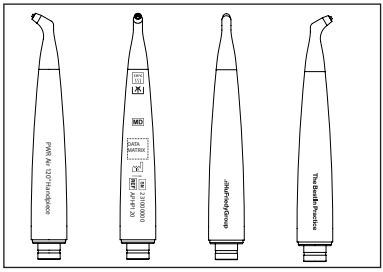
NOTE: The complete list of symbols and their description is provided in *Chapter 1.5 on page 8*.



2.2 Air-polishing Handpiece Identification Data

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

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



3 DELIVERY

3.1 List of Associated Items

Please refer to the figure on page 12.
PWR Air is supplied in a preset configuration; additional associated items may be ordered separately (see table on page 13).

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

The device's packaging must be handled with care to prevent strong impacts, as it contains sensitive electronic components. Both transport and storage should be conducted with caution.
Do not stack various boxes in order to avoid pinching the underlying packaging.
All material sent by HuFriedyGroup is checked at the time of dispatch.
The device and its associated items are shipped properly protected and packaged.
Upon receipt, check if the device was damaged during transport and, if damage/ defects are found, submit a claim to the carrier.
Keep the packaging for possible return to a HuFriedyGroup's Service and Repair team.

⚠ **WARNING:** Before starting the treatment, always make sure to have spare parts and materials (air-polishing handpieces, PWR Air Perio Subgingival Tips, PWR AIR K9 Tip Wrench) to use in the event of failures or drawbacks.

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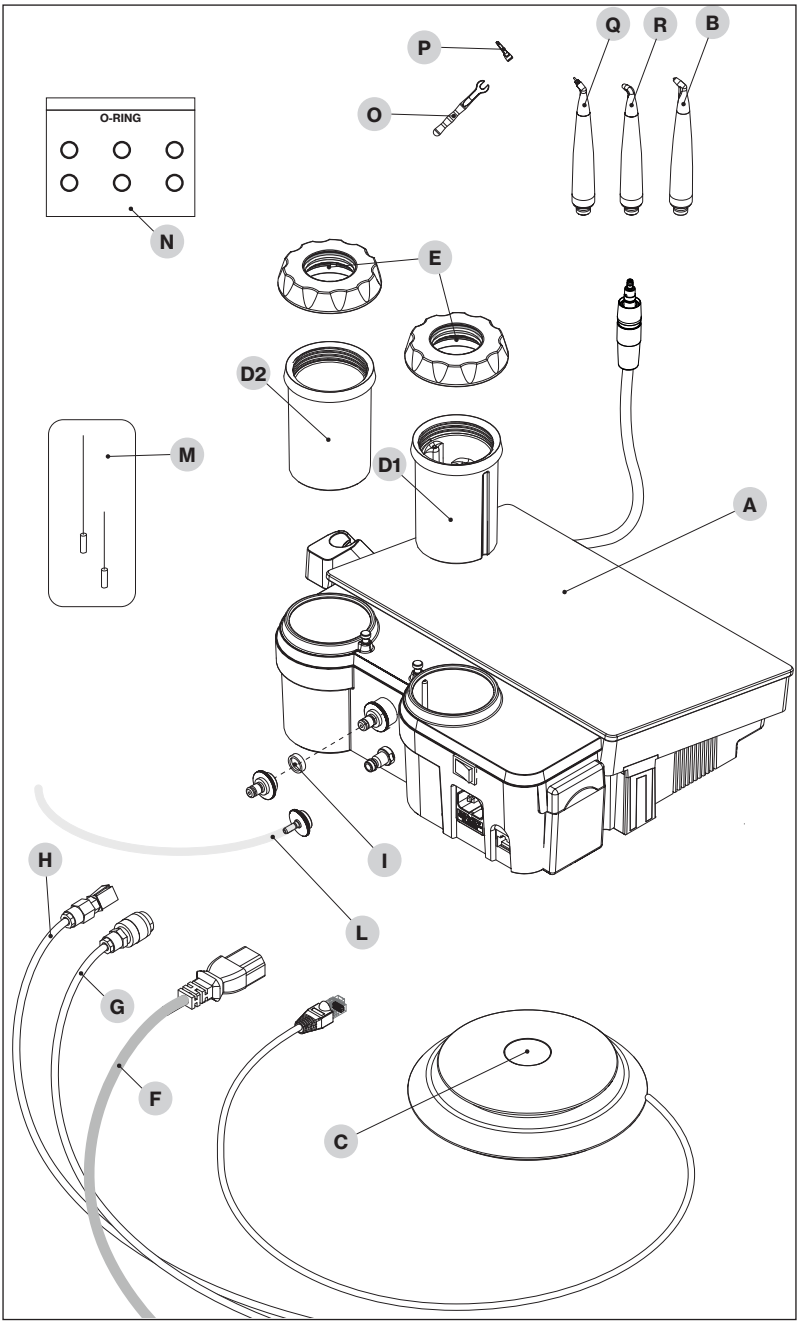

Accessories and Components of PWR Air			
Ref	**SKU**	**Item**	**Notes**
A	APAIRPOLB	Device core unit	
B	APHP120	Air 120° Handpiece	
C	UPFTPEDAL	Foot Pedal	
D1	APPCPROPHY	Powder chamber Prophy, without cap	
D2	APPCPERIO	Powder chamber Perio, without cap	
E	APPCCAP	Powder chamber cap	
F	-	Power supply cable	Plug compatible with destination country
G	APAIRHOSE	Air supply hose with quick coupling	
H	APH2OHOSE	Water supply hose with quick coupling	
I	APFILTER	Unit Water filter	
L	APICDKIT	Irrigation circuit disinfection kit	
M	APNDLKIT	Cleaning needle kit	Includes: Cleaning needle Ø 0.4 mm Cleaning needle Ø 0.8 mm
N	APAIRORINGS	O-ring set	
O	APK9	PWR Air K9 Tip Wrench	
P	APPERIOTIPS	Perio Subgingival Tips	40 pc set of PWR Air Perio Subgingival Tips
Q	APHPPERIO	Air Perio Handpiece	
R	APHP90	Air 90° Handpiece	Not included with the device, sold separately

4 INSTALLATION

4.1 First Installation

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

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

PWR Air can be purchased ready for use or may need to be enabled by entering an activation key.
If your device requires an activation key, the procedures may vary from country to country.
Always refer to your dealer and the leaflet included in the packaging for further details.

4.2 Safety Requirements During Installation

⚠ **WARNING: Contraindications. Interference with other equipment.** Though compliant with standard IEC 60601-1-2, PWR Air and its accessories may nonetheless interfere with other devices nearby. PWR Air must not be used near to or stacked on other devices. However, 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 positioned near the device PWR Air and/or its related accessories may interfere with the correct operation of the device.

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

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

⚠ **CAUTION:** The device shall be positioned such that the power plug remains readily accessible at all times, as it serves as the means of disconnection from the mains supply.

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

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

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

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

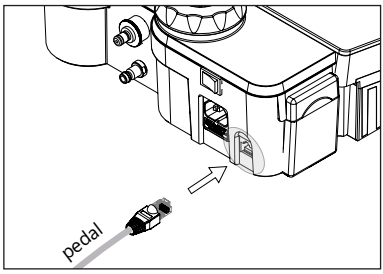
⚠ **CAUTION:** The device and its related accessories is portable but must be handled with care when moved. Position the foot pedal on the floor so that it can only be activated intentionally by the user.

4.3 Connecting the Associated Items

1

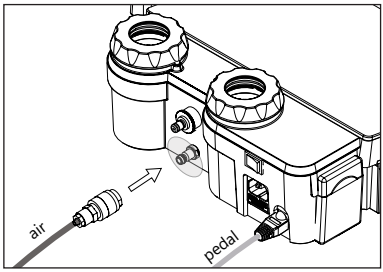
Connect the foot pedal to the back of the device in the socket marked with the symbol by inserting the foot pedal plug until you hear a 'click'.

⚠ **CAUTION:** Position the foot pedal carefully, ensuring it can only be activated intentionally by the user.



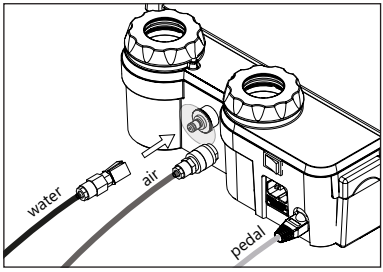
2

Drain the condensate from the compressed air system. Connect the supply hose to the compressed air circuit in the medical practice using a suitable reduction and shut-off valve (not included in the HuFriedyGroup supply).
Connect the quick coupling to the male coupling on the back of the device.
The device can be connected also with a 1/4" Quick Disconnect. The PWR Air Unit Supply Hose is supplied with the device.



3

Connect the water supply hose to the water circuit in the medical practice using a suitable reduction and shut-off valve (not included in the HuFriedyGroup supply).
Connect the quick coupling to the male coupling on the back of the device.
The device can be connected also with a 1/4" Quick Disconnect. The PWR Air Unit Water Supply Hose is supplied with the device.



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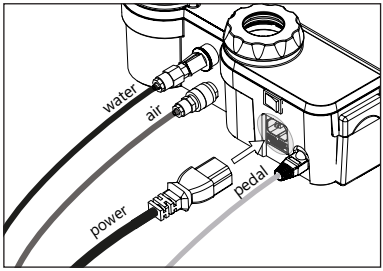
4

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

⚠ **CAUTION:** The device shall be positioned such that the power plug remains readily accessible at all times, as it serves as the means of disconnection from the mains supply.

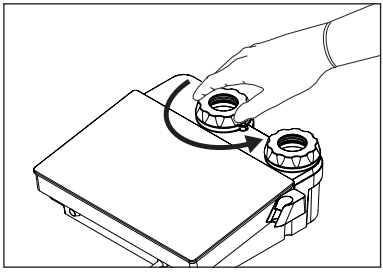


5

Unscrew the cap of the prophy powder container on the left.

⚠ **CAUTION:** The prophy powder container is marked “Prophy” and is positioned on the left.

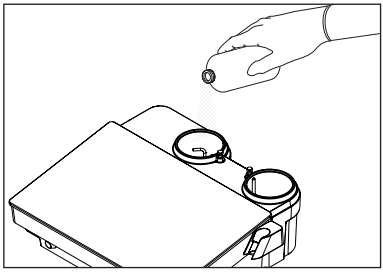
⚠ **CAUTION:** Before extracting the powder container or unscrewing the caps, check that “Refill” function has been performed and that the corresponding LED remains in pulsating mode or that the device is turned off (see *Chapter 5.5 on page 27*).



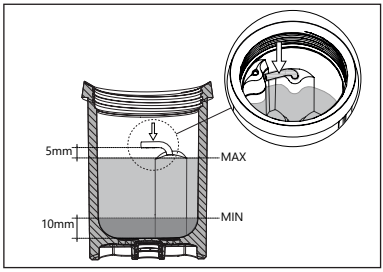
6

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

⚠ **WARNING:** Insert only specific supragingival powder distributed by HuFriedyGroup in the prophy powder container.



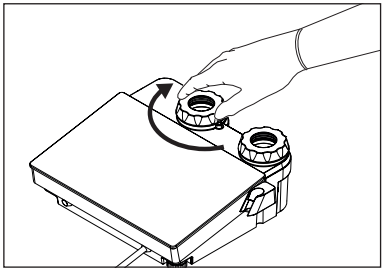
⚠ **CAUTION: Correct level of powder in the container.**
Minimum level: The level of powder in the container must not be lower than 10 mm to prevent cleaning performance from dropping.
Maximum level: The level of the powder in the container must remain below the diffuser (at least 5 mm).



7

Screw the cap onto the container as far as it will go.

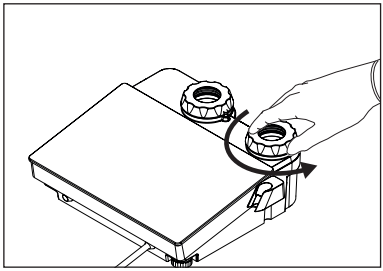
⚠ **CAUTION:** Always check that the threaded parts of the powder containers are perfectly clean.



8

Unscrew the cap of the perio powder container on the right.

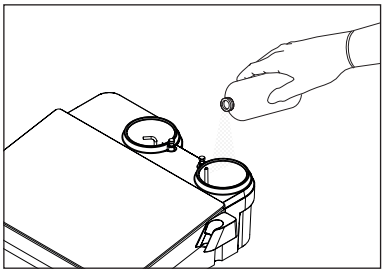
⚠ **CAUTION:** The perio powder container is marked "Perio" and is positioned on the right.



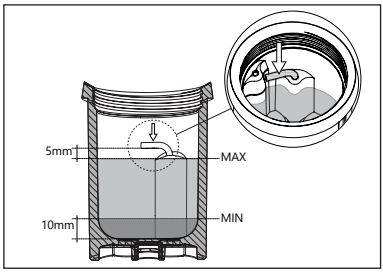
9

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

⚠ **WARNING:** Insert only specific subgingival powder distributed by HuFriedyGroup in the perio powder container.



⚠ **CAUTION: Correct level of powder in the container.**
Minimum level: The level of powder in the container must not be lower than 10 mm to prevent cleaning performance from dropping.
Maximum level: The level of the powder in the container must remain below the diffuser (at least 5 mm).



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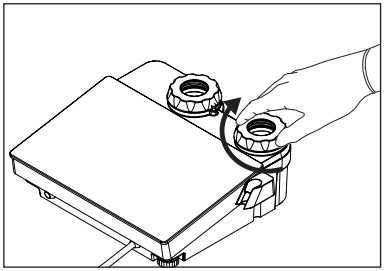
Close the tap on the container without tightening it excessively.

⚠ **CAUTION:** Always check that the threaded parts of the powder containers are perfectly clean.

10



5 USE

5.1 Power On/Off

Switching on the device

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

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

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

Preset configuration:

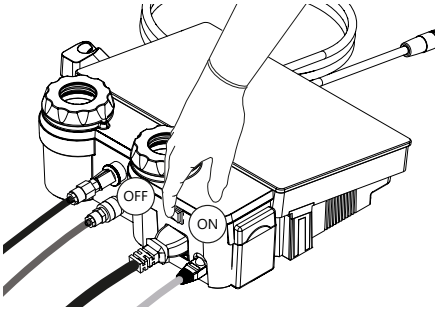
- “Perio” function,
- “Low” level

NOTE: The settings can only be changed when the foot pedal is released.

Switching off the device

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

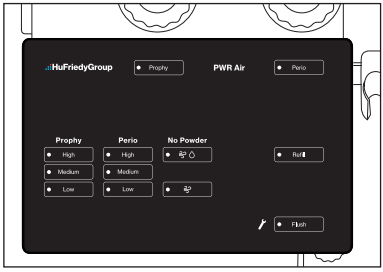
Flick the switch into the “O” position, taking care not to press the foot pedal.



⚠ **CAUTION:** The device shall be positioned such that the power plug remains readily accessible at all times, as it serves as the means of disconnection from the mains supply.

5.2 Description of the Touch Surface

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

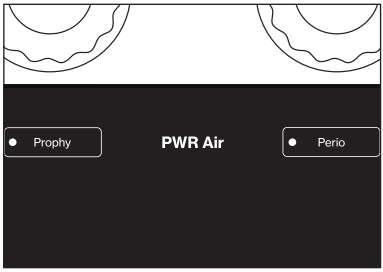


NOTE: An audible signal confirms the button selection. A short audible signal indicates that the button pressed cannot be selected in the current configuration.

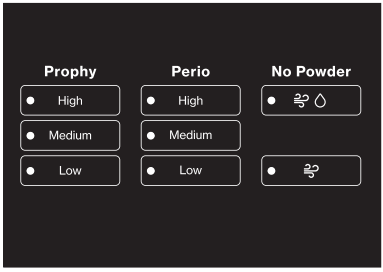
NOTE: All LEDs indicating the selection of different functions and power levels are green. Error notifications are represented by a wrench symbol with a yellow LED.

"Prophy" and "Perio" FUNCTIONS:
Depending on the type of application, one of two treatments can be selected as follows:

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



Different power levels can be selected for the two types of treatment using the dedicated buttons (High, Medium, Low).

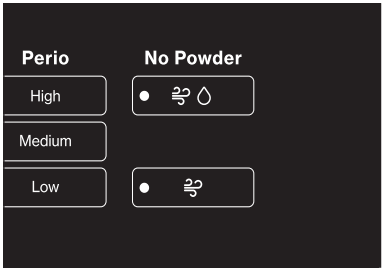


US

“No Powder” FUNCTIONS
The “No Powder” functions can be used to disable the emission of powder from the handpiece.

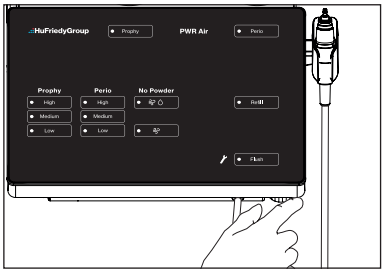
- The key marked with the symbols: disables the emission of powder from the handpiece, allowing only water and air to be dispensed.
- The key marked with the symbol: disables the emission of powder and water from the handpiece, allowing only air to be dispensed.

NOTE: Both functions disable the emission of powder from the handpiece.



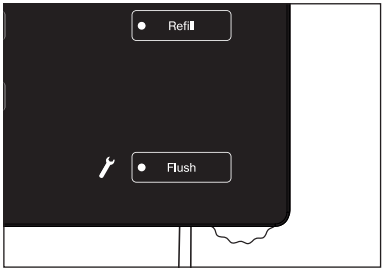
“Refill” FUNCTION
The “Refill” function must be used to depressurize the powder containers, in order that they can be opened or removed from the device (see *Chapter 5.5 on page 27).*

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

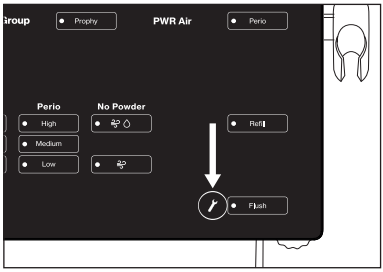


“Flush” FUNCTION
The “Flush” function allows a rinsing cycle of the irrigation circuit and empties both channels simultaneously. The “Flush” function can be used to change the type of powder, cleaning the circuit of the previously used type. (See *Chapter 5.6 on page 29)*

NOTE: The “Flush” function can be activated by lifting the handpiece and checking that the powder containers are correctly inserted into the device.



SYMBOLS
PWR Air is equipped with a diagnostic circuit allowing the detection and display of any errors on the touch surface via a wrench-shaped symbol (see *Chapter 15.1 on page 76*).



5.3 Safety Requirements Before and During Use

⚠ **WARNING: Use only original HuFriedyGroup associated items and replacement parts.**

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

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

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

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

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

US

⚠ **WARNING:** Personal injury. Ensure the cables do not obstruct the free movement of personnel.

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

⚠ **WARNING: Contraindications.** Patients suffering from severe respiratory problems, such as chronic bronchitis, asthma, emphysema, etc. must not receive prophylaxis treatment, unless otherwise specified by the treating dentist.

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

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

⚠ **WARNING: Patient Preparation** During treatment, patients are required to wear protective glasses.

⚠ **WARNING: User Preparation** During treatment, the user is required to wear protective glasses and a protective mask.

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

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

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

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

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

⚠ **WARNING**:**Treatment preparation.** High Volume Evacuator (HVE) and saliva ejector are recommended during treatment. They evacuate the powder deviated by the treated tooth.

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

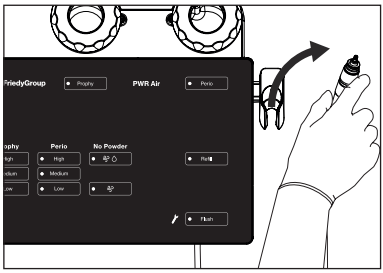
US

5.4 Using the Handpiece

Before using the handpiece, ensure that all associated items are connected as described in *Chapter 4.3 on page 15*.

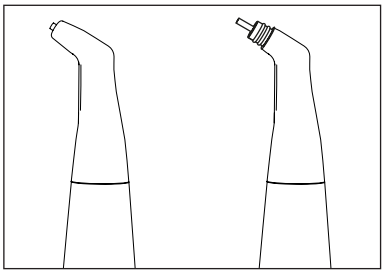
» **PROCEDURE**

1 Lift the handpiece cord;

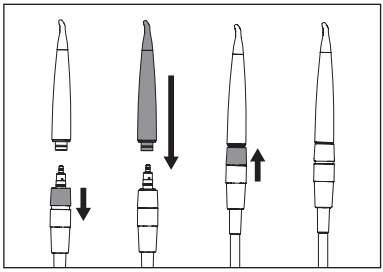


2 Choose the type of air-polishing handpiece depending on the operation that needs to be performed;

⚠ **CAUTION:** The PWR Air Perio Subgingival Tips can only be used with the PWR Air Perio Handpiece.



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



US

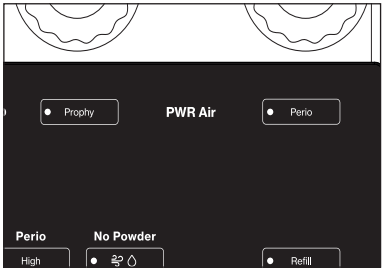
Select the desired “Prophy” or “Perio” function.

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

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

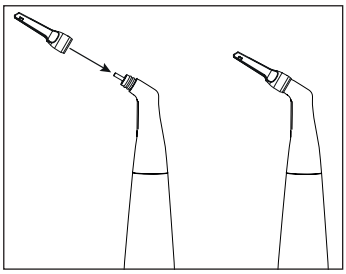
⚠ **WARNING**:**Treatment preparation.** High Volume Evacuator (HVE) and saliva ejector are recommended during treatment. They evacuate the powder deviated by the treated tooth.

4



5

Insert the PWR Air Perio Subgingival Tips on the PWR Air Perio Handpiece, pushing it in until it comes into contact.



⚠ **CAUTION:** If the PWR Air Perio Handpiece has been selected, the PWR Air Perio Subgingival Tips must be inserted on the front part.

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

⚠ **WARNING:** Before using the PWR Air Perio Subgingival Tips (supplied sterile), check the integrity of the packaging and inspect the product to ensure there is no damage. Do not use the PWR Air Perio Subgingival Tips if the packaging is open or damaged. The PWR Air Perio Subgingival Tips loses sterility if the packaging is broken or compromised. If the packaging is damaged, dispose of the tip properly. Do not re-sterilize or reuse the tip.

⚠ **CAUTION:** With the PWR Air Perio Handpiece, only specific subgingival powder distributed by HuFriedyGroup must be used.

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

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

US

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

WARNING: Patient Preparation During treatment, patients are required to wear protective glasses.

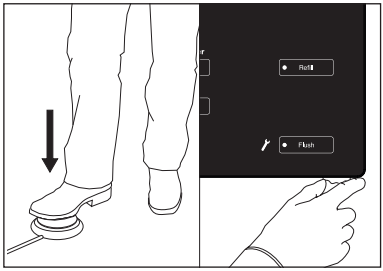
WARNING: User Preparation During treatment, the user is required to wear protective glasses and a protective mask.

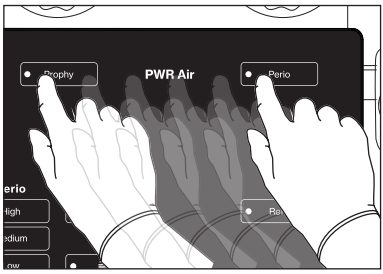
If the user switches from “Perio” to “Prophy” or vice versa, the device automatically performs the circuit emptying process, which lasts for about 3 seconds

NOTE: During the transition from the “Perio” function to “Prophy” or vice versa, do not point the handpiece toward the patient or the operator.

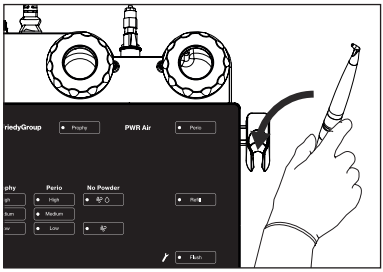
At the end of the treatment, stow the air-polishing handpiece in its housing.

6





7



5.5 “Refill” function

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

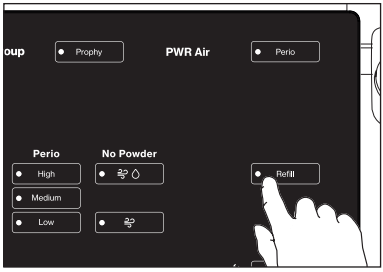
NOTE: The powder containers are only pressurized when, after being selected, the foot pedal is pressed.

⚠ **CAUTION:** During the “Refill” cycle, air and powder are expelled from the air-polishing handpiece.

» **PROCEDURE**

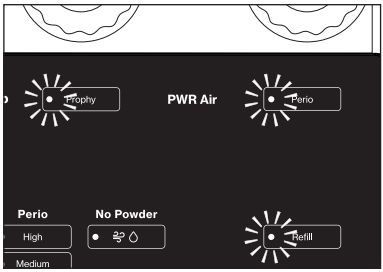
1

Press the “Refill” button.



2

Wait for the end of the cycle, during which the “Refill” key LED will flash together with that of the relative powder container, emitting an audible signal.



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

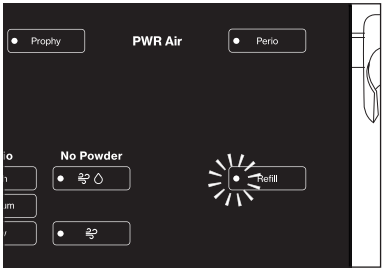
The “Refill” function will depressurize the containers one at a time, and not simultaneously.

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

US

3

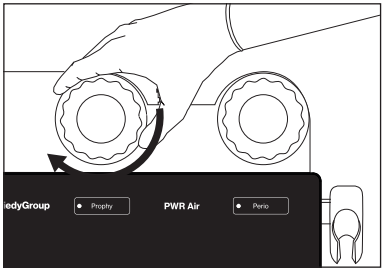
At the end of the cycle, the “Refill” key LED will be lit and will start to pulse rather than blink, indicating that the containers can now be opened or removed.



4

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

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



5.6 "Flush" function

The “Flush” function is used to perform the irrigation circuit rinse cycle and to empty both channels simultaneously.

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

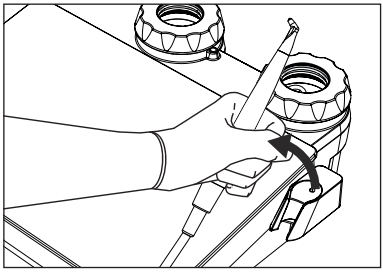
US

» **PROCEDURE**

1

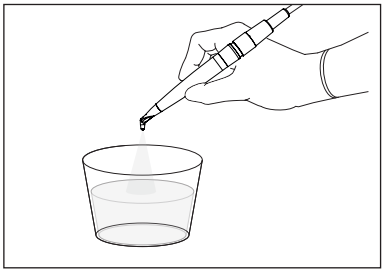
Lift the air-polishing handpiece;

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



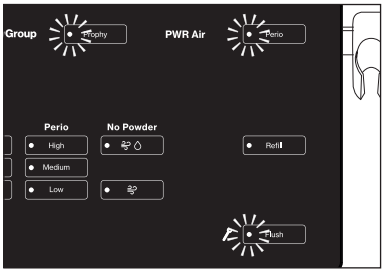
2

Place the cord and/or handpiece over a container or sink to catch the liquid and powder expelled during the “Flush” cycle;



3

To enter “Flush” mode, select “Flush” on the touch surface: the corresponding LED will blink.
All the other selectable options on the touch surface will be disabled.

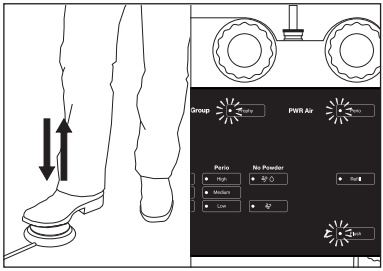


US

4

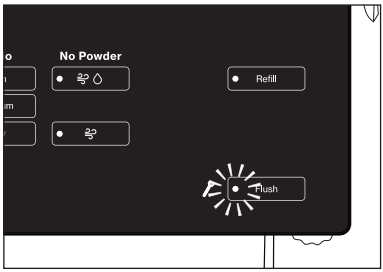
Press the foot pedal once and release it to start the cycle. The LEDs of the function and powder containers will flash. A sequence of short acoustic signals indicates that the cycle is running;

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



5

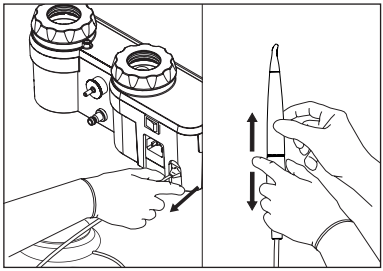
The “Flush” cycle is run on both powder containers simultaneously.



6

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

⚠ **CAUTION:** During the “Flush” cycle, i.e. when the function is activated by pressing the foot pedal, the cycle is not interrupted if the handpiece is stowed.



6 CLEANING

⚠ **CAUTION:** To disinfect the device and/or its associated items, it is recommended to use water-based disinfectant solutions with neutral pH (pH 7).
DO NOT USE the following as disinfectants:

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

as they may discolor and/or damage the materials of the device and its associated items.

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

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

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

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

US

6.1 Disassembling Parts for Cleaning and Sterilization

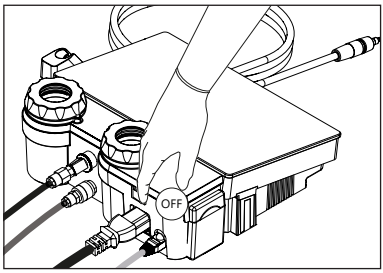
Before performing the cleaning procedures outlined in the following sections, disconnect all accessories and associated items of PWR Air.

» **PROCEDURE**

US

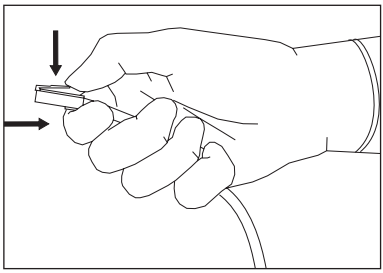
⚠ **WARNING: Switch the device off.** Always switch the device off using the switch and disconnect the power cable from the wall socket and device core unit before carrying out cleaning and sterilization tasks.

1



2

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

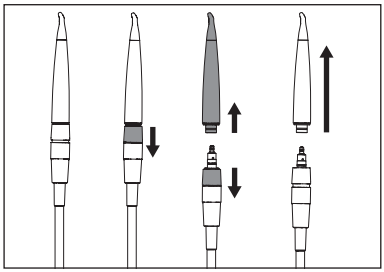


⚠ **CAUTION:** Do not try to unscrew or turn the connector during disconnection: this might damage the connector.

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

3

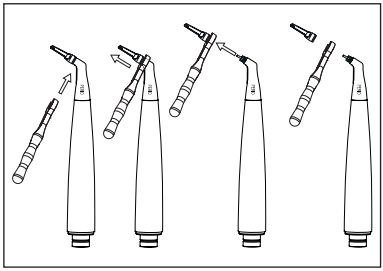
On the quick coupling of the air-polishing handpiece cord, slide the ring and hold it in place, pull out the air-polishing handpiece, then release the handpiece ring;



If the PWR Air Perio Handpiece was used, remove the PWR Air Perio Subgingival Tips using the PWR AIR K9 Tip Wrench and proceed with disposal (see *Chapter 13 on page 66*);

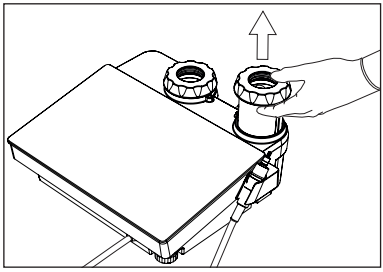
NOTE: Insert the PWR AIR K9 Tip Wrench exactly in the position shown in the figure.

4



⚠ **CAUTION:** Before extracting the powder container or unscrewing the caps, check that the device is switched off and disconnected from the power mains, or start the “Refill” function (see *Chapter 5.5 on page 27*).

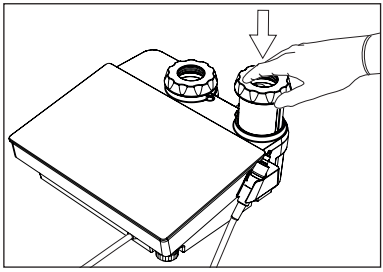
5



Extract the powder container from the device, remove the cap and empty it. Proceed with polishing. (see *Chapter 12.7 on page 62*)
Repeat the procedure on the device's second powder container if both have been used.

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

6



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

US

6.2 Preparation

1. Run the "Flush" function (see *Chapter 5. 6 on page 26*);
2. Disinfect the irrigation circuit as described in *Chapter 10 on page 49.*
3. Check that all of the following accessories and associated items have been removed/disconnected from the device core unit (see *Chapter 6.1 on page 32*):
   - Power supply cable;
   - Foot pedal;
   - Air-polishing handpiece;
   - Water and air hose.

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

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

⚠ **CAUTION:** Do not immerse the handpiece in non-recommended solutions as it may be damaged.

⚠ **CAUTION:** In case of excessive powder humidity, remove/disconnect the air-polishing handpiece from the quick coupling on the cord, free the air-polishing handpiece channel of any residual powder using the supplied Ø 0.4 mm cleaning needle, then run the “Flush” function without the air-polishing handpiece.

Device core unit and foot pedal:
The only applicable cleaning method is manual cleaning.
Handpiece, PWR AIR K9 Tip Wrench and irrigation circuit cleaning kit:
The user can choose between the following cleaning procedures:
Manual cleaning;
Automatic cleaning.
The procedures applicable to the PWR Air accessories and associated items in this manual have been independently validated.

6.3 Cleaning the Non-Sterilizable Parts

The following procedure must be performed on all non-sterilizable parts of the device The parts concerned are:

- Device core unit;
- Foot pedal and relative connection cable to the device
- Cleaning cord and its quick coupling for the handpiece

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

US

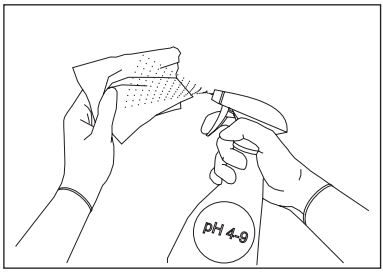
» **NECESSARY MATERIAL**

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

» **PROCEDURE**

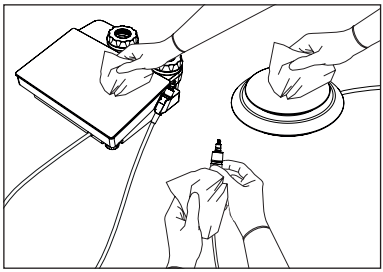
1

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



2

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



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

⚠ **WARNING:** The device and its non-sterilizable parts are not protected against the penetration of liquids. Do not spray liquids directly onto the surface of the device and its parts sold as non-sterilizable.

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

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

US

6.4 Cleaning Sterilizable Accessories and Associated Items

The user can choose between the following cleaning procedures:

- Manual cleaning;
- Automatic cleaning.

The procedures applicable to the PWR Air accessories and associated items have been validated by an independent body. The sterilizable parts of the device are:

- Air-polishing handpiece;
- PWR AIR K9 Tip Wrench;
- Irrigation Circuit Cleaning Kit.

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

⚠ **CAUTION:** The instructions supplied below have been validated by the manufacturer of the medical device as ABLE to prepare a medical device for re-use.

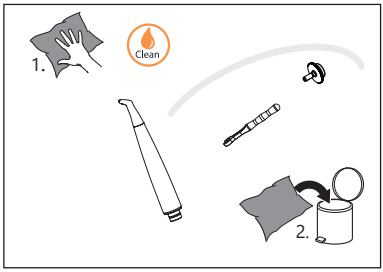
The user/operator is responsible for ensuring that the processes repeated are effectively performed using the equipment, materials and staff in the reprocessing structure in order to obtain the desired result. This generally requires the validation and systematic monitoring of the process. Similarly, all deviations from the instructions provided by the processes manager must be adequately assessed to judge their efficiency and potential undesired consequences.

6.4.1 Pre-Cleaning

The “pre-wash” cycle is optional and preparatory to the chosen cleaning method
After following the instructions provided in *Chapter 6.2 on page 34*, proceed as follows:

1

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



6.4.2 Manual Cleaning

Manual cleaning can be carried out as an alternative to the automatic cleaning described in *Chapter 6.4.3 on page 43*.

» **NECESSARY MATERIAL**

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

NOTE: Alternative enzymatic products intended for manual cleaning must be strictly used in accordance with the respective manufacturers' Instructions for Use.

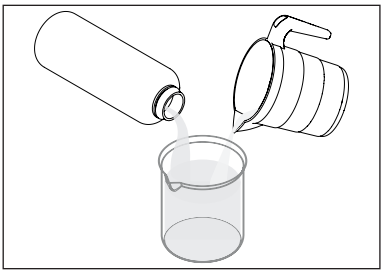
» **PROCEDURE - AIR-POLISHING HANDPIECES**

1

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

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

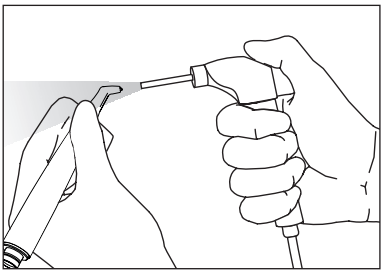
a) Process validated by an independent body with enzymatic ENZYMEC, 0.8% v/v.



2

Blow compressed air into the central hole of the handpiece front side as shown in the figure ;

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

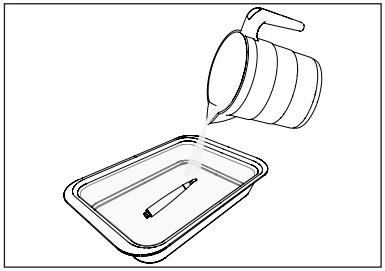


US

US

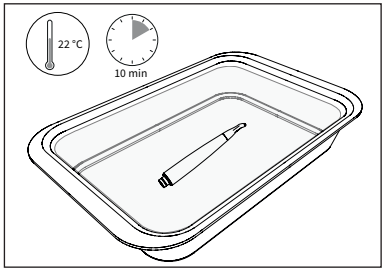
3

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



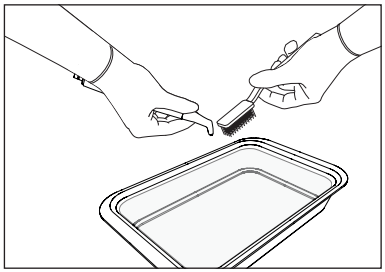
4

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



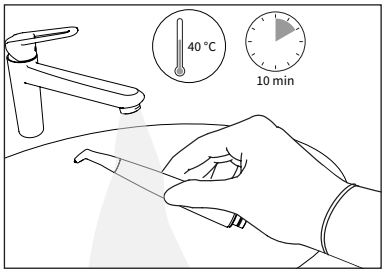
5

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



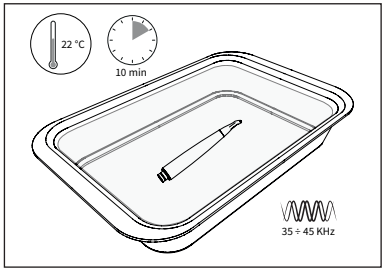
6

Rinse the air-polishing handpiece under hot running water (104 °F ± 9 °F (40 °C ± 5 °C)) for about 10 minutes, moving it slightly to allow the water to reach the entire surface;



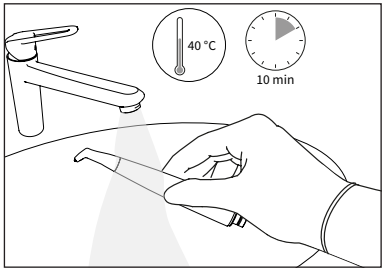
7

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



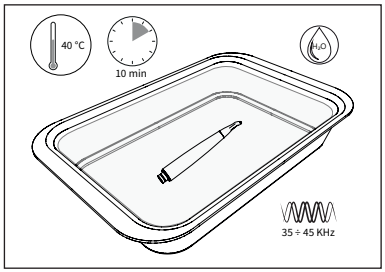
8

Gently brush the surface of the air-polishing handpiece using the brush with soft nylon bristles;
Rinse the air-polishing handpiece under hot running water (104 °F ± 9 °F (40 °C ± 5 °C)) for about 10 minutes, moving it slightly to allow the water to reach the entire surface;



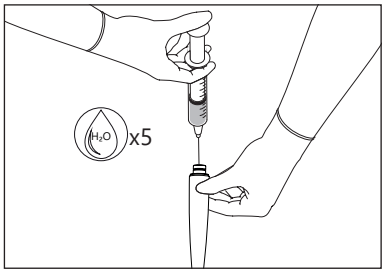
9

Place the air-polishing handpiece in the ultrasonic tank immersed in demineralized water for at least 10 minutes at 104 °F ± 3.6 °F (40 °C ± 2 °C);



10

After 10 minutes of immersion in the ultrasonic tank with demineralized water, rinse the internal channels of the air-polishing handpiece by injecting 20 ml of demineralized water at ambient temperature (68 °F - 77 °F (20 °C – 25 °C)) using a syringe with needle, five times in a row.



» **PROCEDURE - PWR AIR K9 TIP WRENCH AND IRRIGATION CIRCUIT CLEANING KIT**

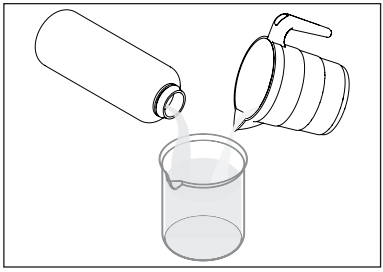
US

11

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

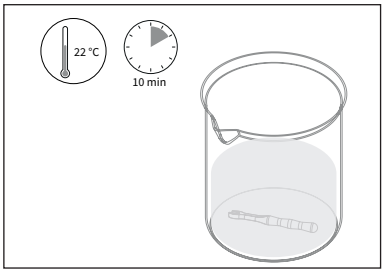
⚠ **CAUTION:** Once used, dispose of the enzymatic detergent correctly, do not reuse it.

a) Process validated by an independent body with enzymatic ENZYMEC, 0.8% v/v.



12

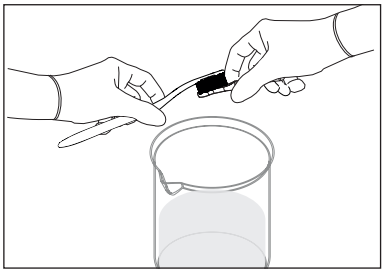
Place the PWR AIR K9 Tip Wrench in a clean container. Add enough enzymatic detergent solution to completely cover it.
Leave the PWR AIR K9 Tip Wrench to soak in the enzymatic detergent solution for 10 minutes at ambient temperature 71.6 °F ± 3.6 °F (22 °C ± 2 °C);



13

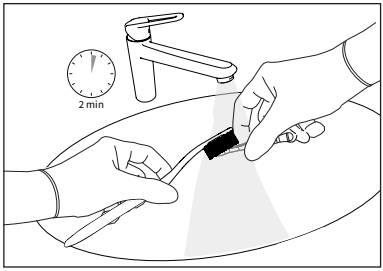
While soaking in the enzymatic solution, gently brush all the surfaces until all visible soil has been removed.
Use a clean brush with soft nylon bristles for the external surfaces, and a clean pipe cleaner with soft nylon bristles for the internal cavities and grooves.

NOTE: Thoroughly brush the PWR AIR K9 Tip Wrench for about 20 seconds.



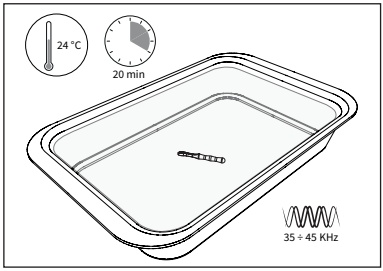
14

Remove the PWR AIR K9 Tip Wrench from the enzymatic detergent solution. Thoroughly rinse and brush all the surfaces of the PWR AIR K9 Tip Wrench (see previous point) under running water for at least 2 minutes;



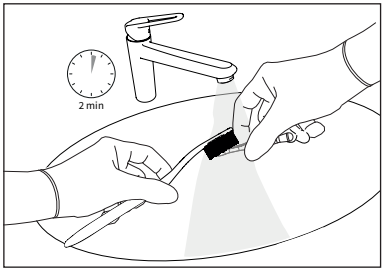
15

Place the PWR AIR K9 Tip Wrench 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;



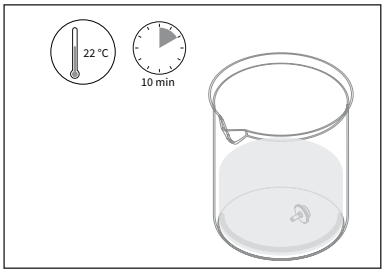
16

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



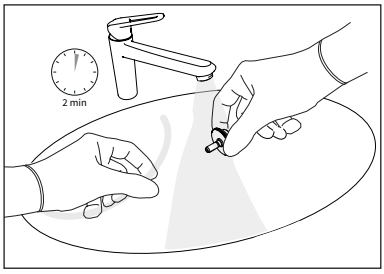
17

Place the cleaning kit in a clean container. Add enough enzymatic detergent solution to completely cover it.
Leave it to soak in the enzymatic detergent solution for 10 minutes at ambient temperature 71.6 °F ± 3.6 °F (22 °C ± 2 °C).



18

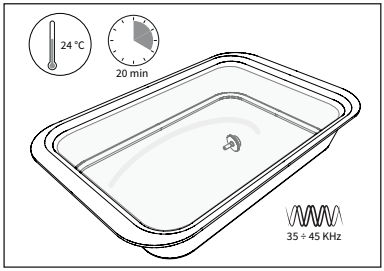
Remove the tube and fitting from the enzyme detergent solution.
Thoroughly rinse all the surfaces under running water for at least 2 minutes.



US

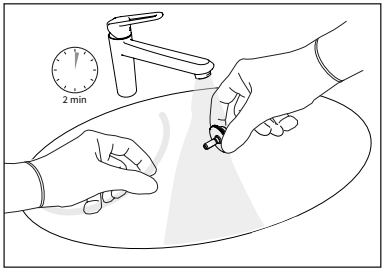
19

Place the cleaning kit 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 10 minutes.



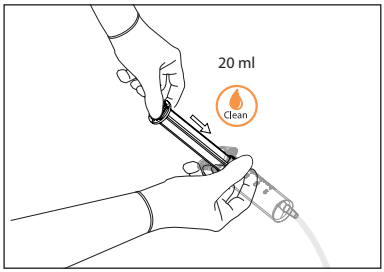
20

Remove the cleaning kit from the enzymatic solution and rinse it under warm running water (104 °F ± 9 °F (40 °C ± 5 °C)) for at least 2 minutes.



21

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



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

6.4.3 Automatic Cleaning

Automatic cleaning can be carried out as an alternative to the manual cleaning described in *Chapter 6.4.2 on page 37*.

NOTE: Procedure validated with:

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

» **NECESSARY MATERIAL**

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

NOTE: Ensure that the accessories and associated items are properly secured in the basket and cannot move during washing. Any blows could damage them. Position the instruments in a way that the water can flow through all the surfaces, even internal.

NOTE: Alternative alkaline/neutralizing products intended for automatic cleaning must be strictly used in accordance with the respective manufacturers' Instructions for Use.

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

⚠ **WARNING:** Avoid overloading the thermal-disinfector as this could compromise the effectiveness of cleaning.

⚠ **WARNING:** On completion of the cleaning cycle in the washer-disinfector, the handpiece and the K9 tip wrench remain at the wash temperature for a long time. Use appropriate precautions when extracting the handpiece and the K9 tip wrench from the washer-disinfector to prevent injury to the user.

⚠ **CAUTION:** Due to its form, the handpiece can roll. When not in use, the handpiece must always be placed on its support.

» **PROCEDURE**

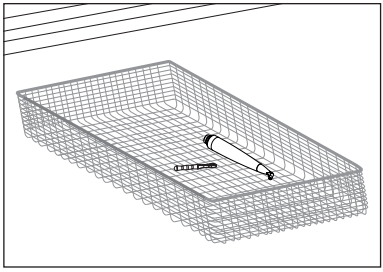
US

Place the accessories and associated items in a metal basket.
Sequence and parameters applicable to the cycle:

- 1 min, Rinse with cold water;
- 5 min, Wash with alkaline detergent at 131 °F ± 3.6 °F (55 °C ± 2 °C);
- 1 min, neutralizing with neutralizing liquid and water at 89.6 °F ± 3.6 °F (32 °C ± 2 °C);
- 1 min, Rinse with water at 89.6 °F ± 3.6 °F (32 °C ± 2 °C);
- 5 min, Thermal disinfection at 199.4 °F (93 °C) with demineralized water.

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

1



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

7 CLEANING CHECK

» **NECESSARY MATERIAL**

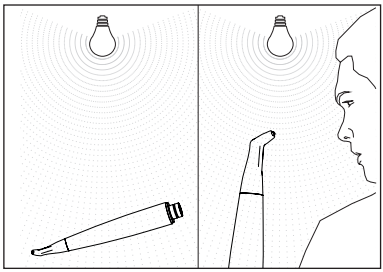
- Light source;
- 2, 5X Magnifier.

» **PROCEDURE**

US

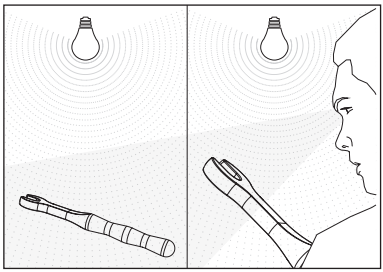
1

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



2

Repeat the checks for the other associated items, repeating the cleaning cycle if necessary.



8 DRYING

» **NECESSARY MATERIAL**

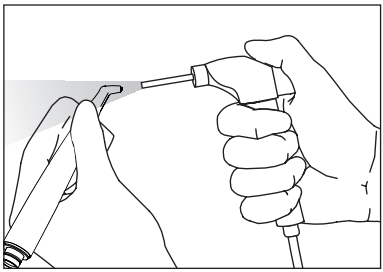
- Compressed air;
- Soft, low-lint cloth;

US

» **PROCEDURE**

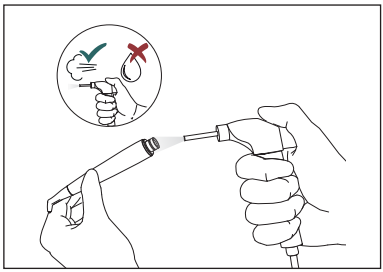
1

Dry all parts of the air-polishing handpiece thoroughly by blowing compressed air from the tip of the handpiece;



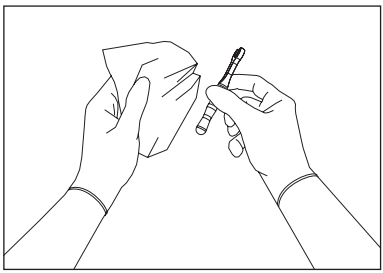
2

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



3

Dry the PWR AIR K9 Tip Wrench using a soft, low-lint cloth.



4

Dry the irrigation circuit cleaning kit.

9 STERILIZATION

The sterilizable parts of the device are:

- Air-polishing handpiece;
- PWR AIR K9 Tip Wrench;
- Irrigation circuit cleaning kit.

The sterilizable parts are manufactured with materials able to withstand a maximum temperature of 275 °F (135 °C) for a maximum time of 20 minutes.
After individually bagging the air-polishing handpiece and the other sterilizable associated items, proceed with the sterilization process in a steam autoclave.

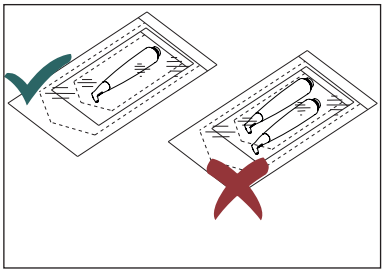
⚠ **CAUTION:** Use sterilization pouches compliant with standard FDA-approved ISO 11607-1.

⚠ **CAUTION:** Ensure that the pouch is large enough to hold the instrument without needing to force its closure/ sealing or tearing the packaging.

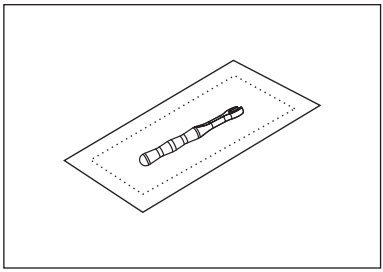
US

» **PREPARATION**

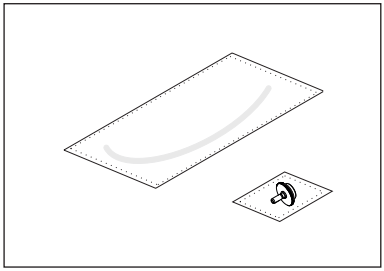
1 Seal the air-polishing handpieces individually inside a single-use sterilization pouch.



2 Seal the PWR AIR K9 Tip Wrench separately inside a single-use sterilization pouch.



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



» **PROCEDURE**

US

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

Procedure A:

- Cycle type: 3 times Pre-vacuum (minimum pressure 0.87 psi (60 mBar)).
- Minimum sterilization temperature: 269.6 °F (0 °F ÷ +5.4 °F) / 132 °C (0 °C ÷ +3 °C)
- Minimum sterilization time: 4 min.
- Drying time: 20 min.

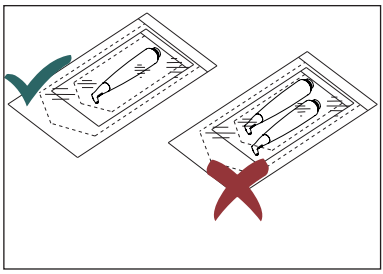
Or Procedure B:

- Cycle type: 3 times Pre-vacuum (minimum pressure 0.87 psi (60 mBar)).
- Minimum sterilization temperature: 273.2 °F (-1.8 °F ÷ +1.8 °F) / 134 °C (-1 °C ÷ +1 °C).
- Minimum sterilization time: 3 min.
- Drying time: 20 min.

For the sterilization of products with moist heat, follow the guidelines specified in ISO 17665 and comply with the legal requirements in your country.

⚠ **CAUTION:** The device core unit and foot pedal cannot be sterilized in an autoclave.

1



⚠ **WARNING: Infection control** – Sterilizable parts – Carefully remove any residual organic matter before sterilization.

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

⚠ **CAUTION:** Do not exceed the permissible load of the steam sterilizer as this could cause excess residual moisture that could impair sterilization.

⚠ **WARNING**: On completion of the autoclave sterilization cycle, the sterilized parts remain at the sterilization temperature for a long time. During the removal of the sterilized parts from the autoclave adopt suitable precautionary measures in order to prevent injury to the operator.

⚠ **CAUTION**: Wait until the sterilized parts have completely cooled down before use.

10 DISINFECTING THE IRRIGATION CIRCUIT

Before disinfecting the irrigation circuit, check that the “Flush” function has been performed (see *Chapter 5.6 on page 49*)

NOTE: Before starting the disinfection procedure, check that the air-polishing handpiece has been disconnected from the device (*Chapter 6.1 on page 32*).

US

To disinfect the irrigation circuit, proceed as follows:

» **NECESSARY MATERIAL**

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

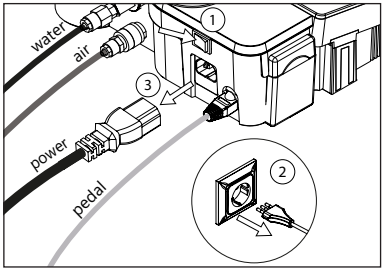
NOTE: Alternative product based on Aldehyde/Ortho-Phtaladehyde intended for internal circuit disinfection (for example RAPICIDE OPA-28) must be strictly used in accordance with the respective manufacturers’ Instructions for Use.

» **PROCEDURE**

validated with CIDEX OPA

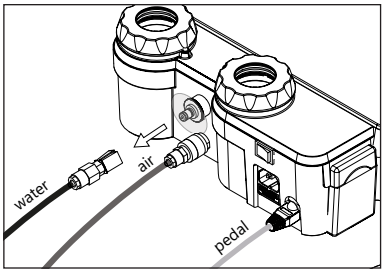
⚠ **WARNING: Switch the device off.** Turn the device off using the switch (Ref. 1) and disconnect the power cable from the wall socket (Ref. 2) and device console (Ref. 3) before carrying out cleaning and sterilization tasks.

1



2

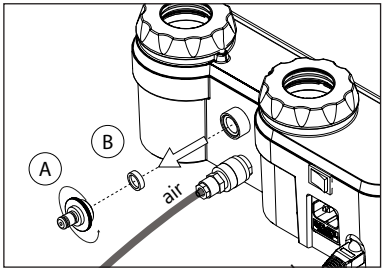
Disconnect the quick connector of the external water circuit from the device (see *Chapter 4.3 on page 15*);



US

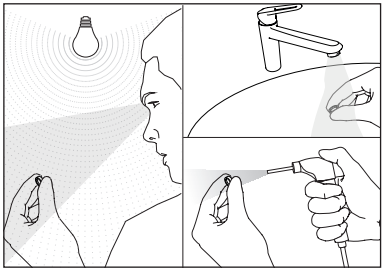
3

Unscrew the male coupling for the external water circuit connection (Ref. A); remove the water filter (Ref. B) - (see *Chapter 12.6 on page 60*);



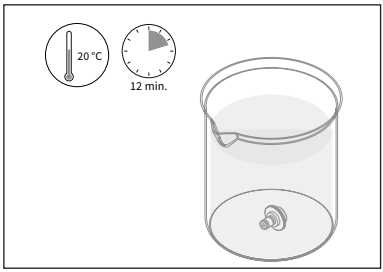
4

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



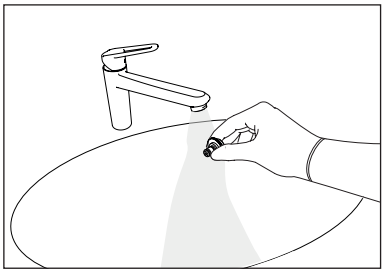
5

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



6

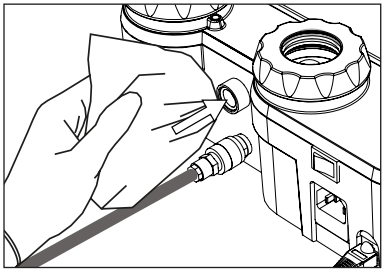
Remove the male coupling for the external water circuit connection from the disinfectant solution and rinse it under running water;
Place the male coupling for the external water circuit connection in a clean and safe place for later use.



US

7

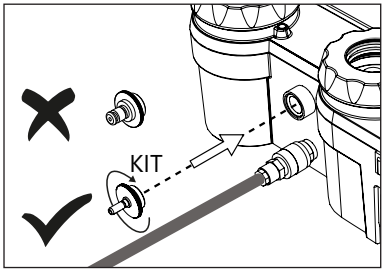
Disinfect the internal surfaces of the seat where the male coupling for the external water circuit connection will be inserted using a clean, soft, low-lint cloth dampened with the disinfectant solution .



8

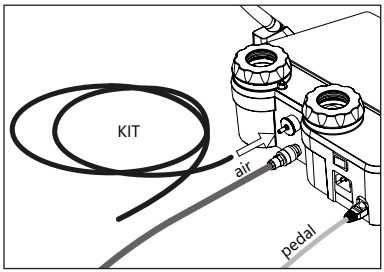
Screw in the male coupling supplied with the “Irrigation circuit disinfection kit” in its seat until it comes into contact;

⚠ **CAUTION:** Check the integrity of the “irrigation circuit disinfection kit”. Replace the “irrigation circuit disinfection kit” in case of wear or damage.



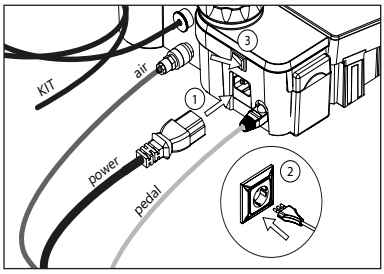
9

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



10

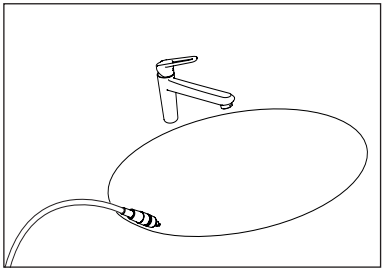
Connect the power supply cable to the device (Ref. 1) and to a wall socket (Ref. 2). Switch on the device using the switch located at the back (Ref. 3);



US

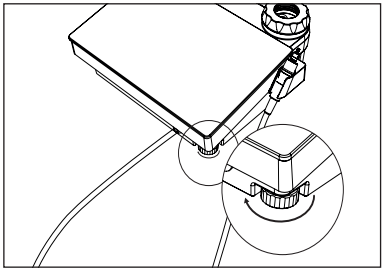
11

Lift the air-polishing cord and place it over a container or sink able to hold the liquid that will spill out during the procedure;



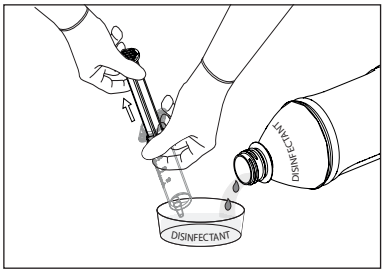
12

Fully open the knob at the front right of the device;



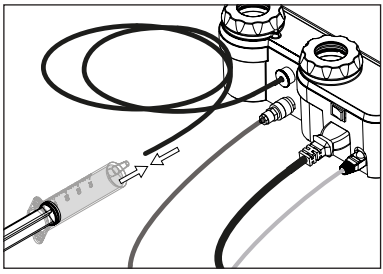
13

Using the syringe, aspirate 60ml of disinfectant , making sure there is no air inside;



14

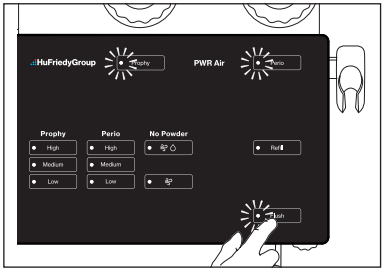
Connect the syringe to the end of the hose previously connected to the male water coupling (see point 9 of the procedure);



15

Select “Prophy” or “Perio” on the touch surface.

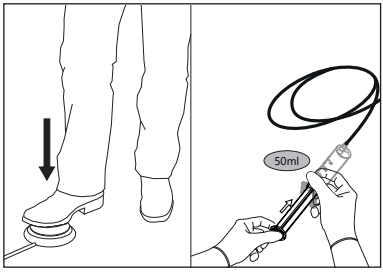
NOTE: Make sure that both powder containers are present and correctly stowed in their seats, otherwise it will not be possible to activate the “Flush” function.



16

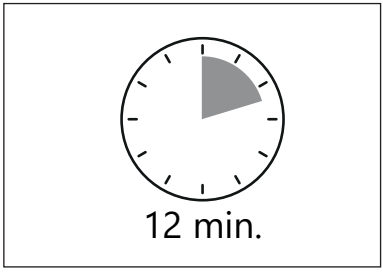
Press the foot pedal until 50 ml of disinfectant has been injected, leaving the remaining 10 ml inside the syringe.

⚠ **CAUTION:** Do not press too hard on the piston of the syringe. The irrigation circuit hoses are quite small and it is normal for injection to occur slowly.



17

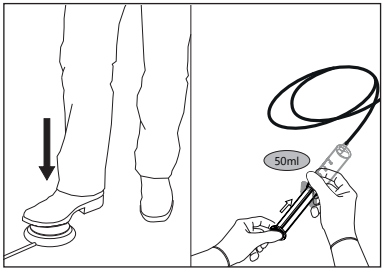
Wait 12 minutes;



18

Press the foot pedal and inject the remaining 10 ml into the syringe.

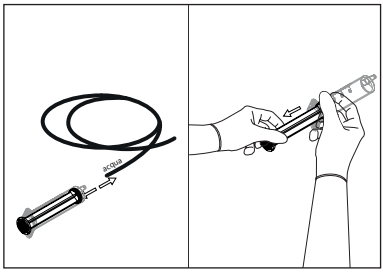
⚠ **CAUTION:** Do not press too hard on the piston of the syringe. The irrigation circuit hoses are quite small and it is normal for injection to occur slowly.



US

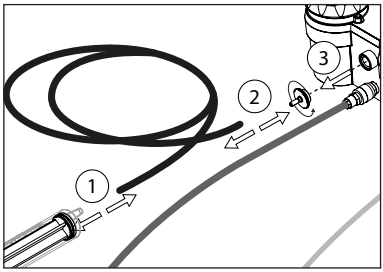
19

Disconnect the syringe and repeat points 13 to 18.



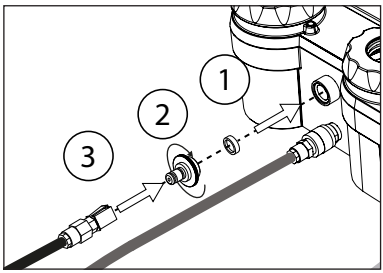
20

At the end of the disinfection procedure, remove the syringe (Ref. 1), the hose (Ref. 2) and unscrew the male coupling used (Ref. 3).



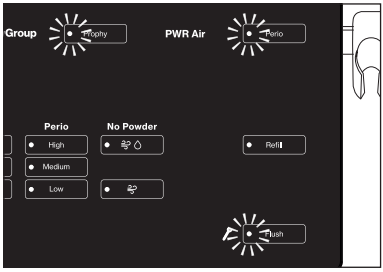
21

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



22

Perform the “Flush” function (see *Chapter 5.6 on page 29)* three times in a row.



11 DECONTAMINATION OF THE IRRIGATION CIRCUIT

The device's irrigation line should be kept clean to prevent any microbial contamination. A regular cleaning and maintenance protocol should be adopted to clean and protect the device's irrigation lines. The manufacturer recommends the use of EPA-registered dental device irrigation line detergents.
Irrigation line detergent decontamination must be carried out daily at the end of the working day, according to the following protocol:

- Perform “Flush” cycles with water to remove any residual traces before disconnecting the handpieces (*Chapter 5.6 on page 29*);
- Disconnect the device from the water supply (mains/bottles) (see *Chapter 4.3 on page 15*);
- Inject irrigation line detergent into the water mains connection using a 60 cc syringe; (*Chapter 10 on page 49*);
- Inject the irrigation line detergent into the additional bottle-fed water lines by filling the source bottle with a solution prepared according to the manufacturer's instructions and activating a “Flush” cycle, thus ensuring that the germicidal solution infuses the entire system;
- Leave the germicidal agent to act in the water hoses overnight and over the weekend;
- Before the first use on the next working day, reconnect the irrigation lines and run three “Flush” cycles to flush the water lines.

12 MAINTENANCE

US

12.1 Maintenance After Every Treatment

At the end of each treatment, proceed as follows:
Run a complete cleaning cycle on the irrigation circuits using the “Flush” function (see *Chapter 5. 6 on page 26*).

Immediately disassemble the various parts (see *Chapter 6.1 on page 32*) and proceed with their cleaning and sterilization (*Chapter 6.4 on page 36*).
Clean the non-sterilizable parts (*Chapter 6.3 on page 35*).

12.2 Daily Maintenance

Regardless of the time elapsed since the last treatment and use of the device, at the end of the day proceed as follows:

1. Start the “Refill” function if the powder containers are still pressurized (see *Chapter 5.5 on page 27*).
2. Remove and empty both powder containers (see *Chapter 6.1 on page 32*).
3. Blow compressed air into the powder container housings each time they are removed, to remove any powder residual. Do not use water or lubricants.
4. Clean the powder containers with compressed air (see *Chapter 12.7 on page 62*). Place the empty powder containers back in their position in the device.
5. Start “Flush” (see *Chapter 5.6 on page 29)*.
6. Clean the parts of the device that cannot be sterilized (see *Chapter 6.3 on page 35*).

12.3 Transport or Long Periods of Non-use

If the device is not used for more than 72 hours, proceed as follows:

1. Empty the powder containers;
2. Run a complete cleaning cycle on the irrigation circuit using the “Flush” function (see *Chapter 5.6 on page 29*)
3. Completely disinfect the irrigation circuit (see *Chapter 10 on page 49*).
4. Drain the irrigation circuit of any residual water.
5. Remove the condensate from the air filter (see *Chapter 12.9 on page 65*).
6. Disconnect the device from the power supply and the air and water circuits.
7. Clean and dry the water filter (see *Chapter 12.6 on page 60*).
8. Follow the steps described in Chapter 10 , filling the syringe with air instead of disinfectant this time.
9. Repeat all the steps again; it is not necessary to wait 12 minutes after the injection of air.
10. In case of long periods of non-use, store the device in its original packaging in a safe place.

Before using the device and its accessories again after a long period of non-use:

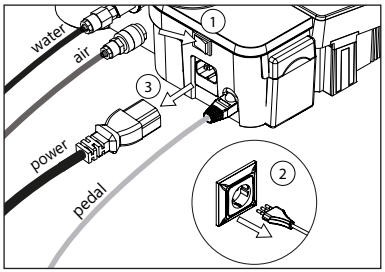
11. Run a complete cleaning cycle on the irrigation circuit using the “Flush” function (see *Chapter 5. 6 on page 26*).
12. Completely disinfect the irrigation circuit again (see *Chapter 10 on page 49*).
13. Clean and sterilize the handpiece and associated items according to the instructions in *Chapters 6, 7, 8, 9* of this manual.
14. Check that the Piezo Tips are not worn, deformed or broken, with particular attention to the integrity of the tip.

⚠ **WARNING:** periodically check the integrity of the power supply cable; when it appears to be damaged replace it with an original HuFriedyGroup spare part.

12.4 Unclogging the Air-polishing Circuit

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

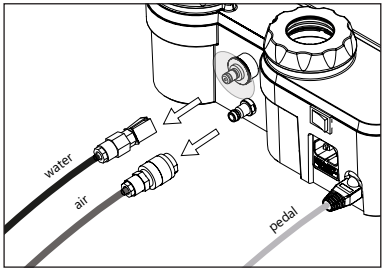
1



US

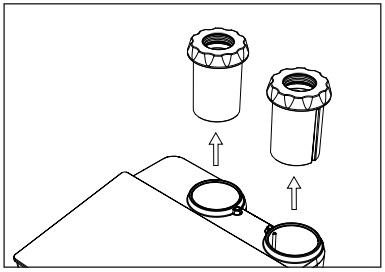
2

Disconnect the air supply and irrigation hoses from the device;



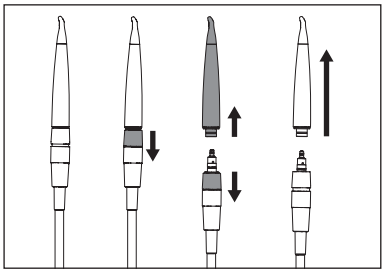
3

Remove both powder containers from their housing;



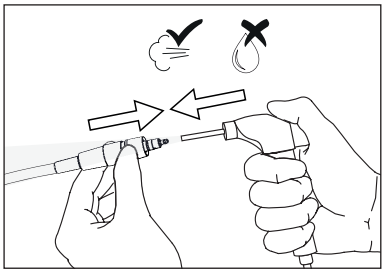
4

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



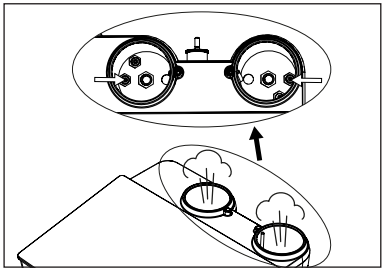
5

Take the air-polishing cord connected to the device and blow compressed air into the front of the cord connector;



6

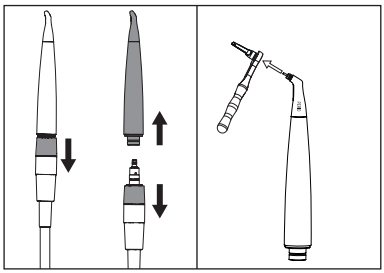
The air expelled from the powder container housings will clear the powder channel inside the device, in the event it is clogged.



12.5 Unclogging the Air-polishing handpiece

1

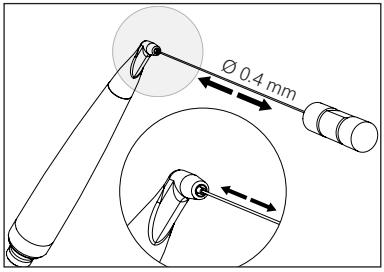
Disconnect the air-polishing handpiece if used (see *Chapter 5.4 on page 23*);



2

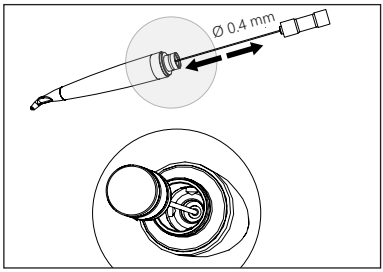
Remove the obstruction by inserting the 0.4 mm diameter needle from the front of the air-polishing handpiece;

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



3

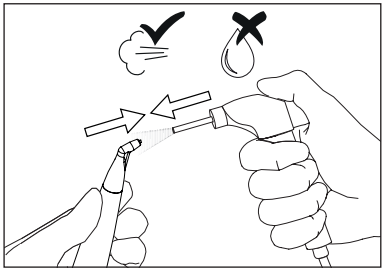
Remove the obstruction by inserting the 0.4 mm diameter needle from the back of the air-polishing handpiece;



US

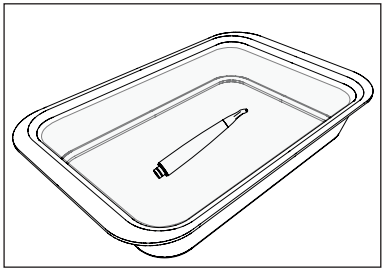
4

Now remove any residual powder by blowing compressed air into the air-polishing handpiece from the front side, as shown in the figure.



5

If the mechanical actions are not effective, leave the handpiece to soak in a 2% acetic acid solution;



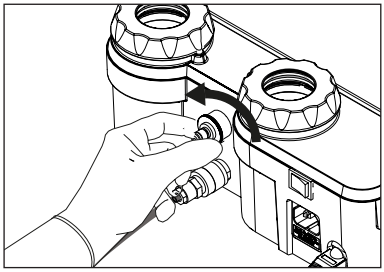
12.6 Cleaning and/or Replacing the Water Filter and the Water Inlet O-ring

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

1

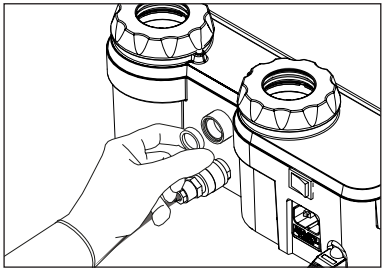
Disconnect the water supply hose from the male coupling.
Unscrew the knurled bush of the male coupling;

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



2

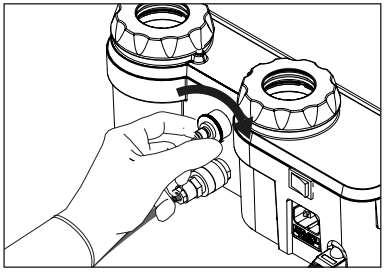
Extract the filter and wash it under running water to eliminate any impurities obstructing it;



3

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

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

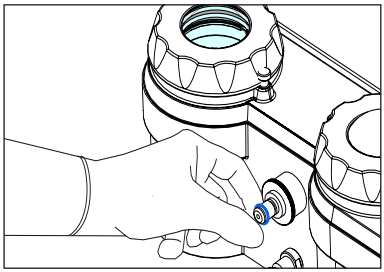


4

⚠ **CAUTION:** Regularly check the wear condition of the O-ring and replace it when necessary. Replacement must be carried out at least once every 2 years.

Replace the worn O-ring carefully, ensuring that the surface where it is positioned is not damaged or scratched. Place the new O-ring in its seat, taking care not to damage it.

⚠ **CAUTION:** Do not use sharp tools or instruments to insert the new O-ring into its seat.



12.7 Cleaning the Powder Containers and Caps

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

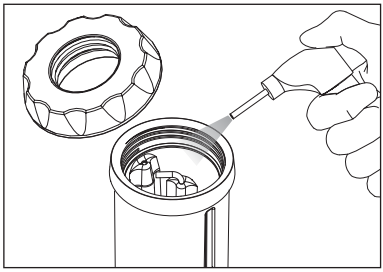
US

⚠ **CAUTION:** Do not clean the containers with cleaning solutions, use only compressed air.

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

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

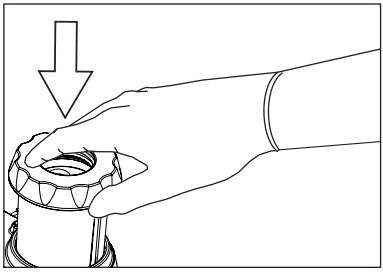
1



Blow compressed air into the container and onto the threads of both the powder containers and the caps;

2

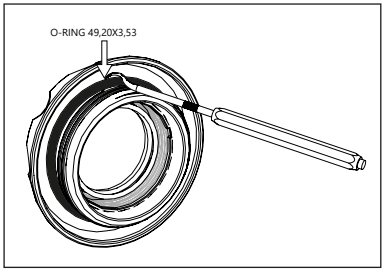
Once cleaning is complete, place the containers back on the device.



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

3

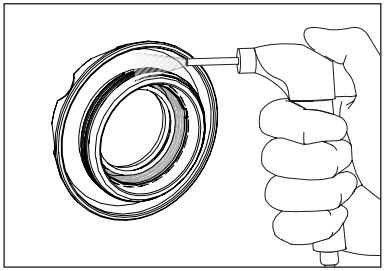
In case the O-ring of the cap is worn out, remove it being careful not to damage and/or scratch the surface where it is located.



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

4

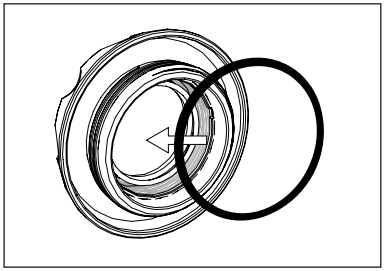
Clean accurately the O-ring seat from powder residues, by blowing compressed air.



5

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

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



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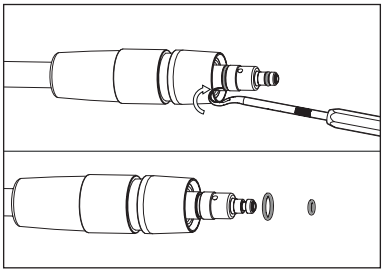
12.8 Replacing the Air-polishing Cord O-Rings

⚠ **CAUTION:** Regularly check the wear condition of the O-rings and replace them when necessary. Replacement must be carried out at least once every 6 months.

1

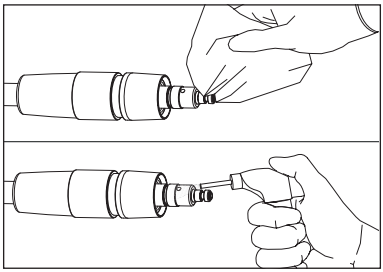
Remove worn O-rings, taking care not to damage and/or scratch the surface where they are located;

NOTE: A tool is required to extract and insert the O-rings. This tool is not included in the standard supply.



2

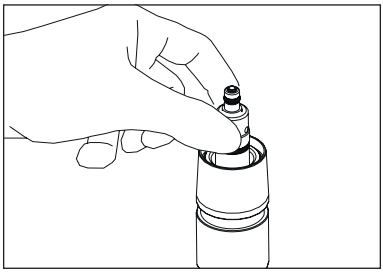
Thoroughly clean and, if necessary, dry the O-ring seats by blowing compressed air before inserting the new O-rings.



3

Place the new O-ring in its seat, taking care not to damage it.

⚠ **CAUTION:** Do not use sharp tools or instruments to place the new O-ring into its seat.



12.9 Eliminating the Condensate

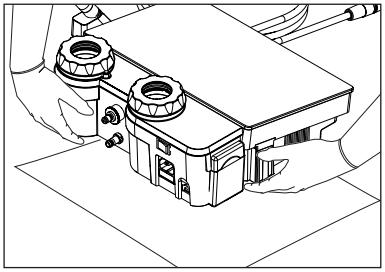
The device is equipped with an air filter that captures any impurities and condensate in the pneumatic circuit.
To prevent condensate from circulating in the device, check and empty the air filter weekly, proceeding as follows:

US

1

Place an absorbent cloth under the device to collect the condensate;

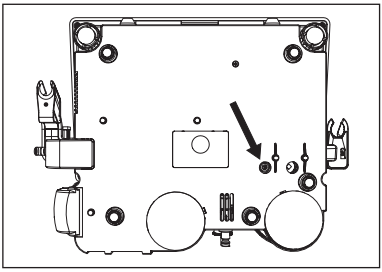
⚠ **CAUTION:** This task must be carried out with the device switched on to ensure proper pressurization of the air circuit.



2

With the device switched on, in the “No Powder” configuration (by selecting or), and in a perfectly horizontal position: press the air filter vent valve at the bottom of the device until only air is expelled.

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



12.10 Maintenance Table

Description	Qty. per unit	Replace every:
Air-polishing cord O-ring 2.5x1.0	1	6 months
Air-polishing cord O-ring 6.0x1.0	1	6 months
Water filter	1	1 year
Powder containers	2	18 months
O-ring in blue silicone (External irrigation line)	1	2 years

13 METHODS AND PRECAUTIONS FOR DISPOSAL

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

- Air-polishing handpiece, when worn or broken;
- Cleaning needles, when worn or broken;
- PWR AIR K9 Tip Wrench, when worn or broken;
- PWR Air Perio Subgingival Tips, after each use.

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

PWR Air and related accessories must be disposed of and treated as waste subject to separate collection.
Failure to comply with the previous points can result in a penalty pursuant to the directive on waste electrical and electronic equipment (WEEE).
The buyer has the option to return the device to the retailer when receiving a new one for disposal. Disposal instructions are available at HuFriedyGroup for proper waste management.

14 TECHNICAL DATA

Classification under the IEC 60601-1	Class I Applied part: Type B
Classification under the IEC 60529	IP20 (device) IP22 (foot pedal model UPFTPEDAL)
Essential performance	According to the standard IEC 80601-2-60, the device has no essential performance
Power Supply	100-240 V~ 50/60 Hz
Max. Power Consumption	90 VA
Fuses	Type 5 × 20 mm, T 2AL, 250V
Air-polishing functions	Can be selected via touch screen: “Prophy” function - “Perio” function
Irrigation	Continuous regulation via knob. Water heating via heating element.
Water supply:	Operating pressure from 14.5 to 72.5 psi (1.0 to 5.0 bar). Water circuit cleaning function, air-polishing part - (see *Chapter 5.6 on page 29*). Connection via the supplied hose with quick coupling through an incorporated and removable filter.
Air supply:	Inlet pressure between 65 and 116 Psi (4.5 to 8.0 bar). Air circuit cleaning function - See *Chapter 12.9 on page 65* Connection via the supplied hose with quick coupling through an incorporated filter and pressure reducer.
Operating Conditions	From 50 °F to 86 °F (10 °C to +30 °C) Relative humidity from 30% to 75% Air pressure P: 700hPa/1060hPa
Transport and Storage Conditions (Excluding Powders)	From 14 °F to 140 °F (-10 °C to +60 °C) Relative humidity from 10% to 90% Air pressure P: 500hPa/1060hPa
Altitude	Lower than or equal to 9843 feet (3000 metres)
Weights and dimensions	9.93 Lbs (4.2 kg) 12.20 × 10.24 × 5.71 in / 310 × 260 × 145 mm (L × W × H)[a)]

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

US

14.1 Electromagnetic Compatibility IEC 60601-1-2

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

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

⚠ **WARNING: Contraindications.**

Interference by other equipment
An electrosurgical scalpel or other electrosurgical units positioned near the PWR Air device and its related accessories may interfere with the correct operation of the device itself.

⚠ **WARNING:** PWR Air with its related accessories, requires special EMC precautions and must be installed and commissioned in compliance with the EMC information in this chapter.

⚠ **WARNING:** The use of cables and associated items not supplied by HuFriedyGroup may adversely affect EMC performance.

14.2 Guide and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	PWR Air 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 Air is suitable for use in all buildings, including domestic buildings, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions of fluctuations voltage/flicker IEC 61000-3-3	Compliant	

14.3 Accessible Parts of the Casing

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

Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated EM RF fields [a)]	IEC 61000-4-3	3 V/m [f)] 80 MHz - 2.7 GHz [b)] 80% AM at 1 kHz [c)]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended and calculated distances from the equation applicable at the frequency of the transmitter.
RF proximity fields from wireless communication equipment	IEC 61000-4-3	See *Chapter 14.5 on page 74*	
Magnetic field at network frequency [d)]	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Power supply frequency magnetic fields should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See *Chapter 14.6 on page 75*	Portable and mobile RF communication equipment must be used at a separation distance of at least 0.15 m from the field sources.

a) If used, the interface between the PATIENT'S physiological signal simulation and the device must be positioned within a 0.1 m radius of the vertical plane of the uniform field area in the same direction as the device.

b) The device, which intentionally receives RF electromagnetic energy for its operation, must be tested at the receiving frequency. The test can be performed with other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test evaluates the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an environmental signal is in the passband. It is understood that the receiver may not receive normally during the test.

c) The test can also be conducted at other modulation frequencies identified through the RISK MANAGEMENT PROCESS.

d) Only applicable to equipment and systems with magnetically sensitive components or circuits.

e) Empty.

f) Before applying the modulation.

14.4 Guide and the Manufacturer's Declaration - Electromagnetic Immunity

14.4.1 Input A.C. Power Connection

US

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

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

a) Empty.

b) During the test, all the device cables must be connected.

c) The calibration of the current injection terminals must be performed in a system at 150 Ω.

d) If an ISM or amateur radio band is not present among the frequency samples, as appropriate, an additional test frequency has to be used in the ISM band or in the amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) The test can be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) Devices and systems with a Direct Current (DC) input power supply using AC to DC converters must be tested with a converter that complies with the MANUFACTURER'S specifications. Immunity test levels are applied to the AC power input of the converter.

g) Only applicable to devices and systems connected to a single-phase Alternating Current (AC) power supply.

h) For example, 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) Devices and systems with nominal input current above 16 A / phase must be disconnected from the power supply once every 250/300 cycles at any angle and from all phases simultaneously (if applicable). Devices and systems with battery backup, after the test, must resume operation using the power supply line. For devices and systems with a nominal input current lower than 16 A, all phases must be disconnected simultaneously.

j) Devices and systems that do not have a surge protection device in the primary power circuit can only be tested at ± 2 kV between the line(s) and the earth (common mode) and at ± 1 kV between line(s) and line(s) (differential mode).

k) Not applicable to CLASS II devices and systems.

l) Direct coupling must be used.

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

n) The ISM bands (industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

o) Applicable to devices and systems with NOMINAL input current less than or equal to 16 A / phase and devices and systems with NOMINAL input current greater than 16 A / phase.

p) Applicable to devices and systems with NOMINAL input current less than or equal to 16 A/ phase.

q) At some phase angles, the application of this test to devices with a transformer on the input power supply may cause the opening of an overcurrent protection device. This can occur due to the saturation of the magnetic flow of the transformer core after the voltage drop. If this happens, the device must ensure BASIC SAFETY during and after the test.

r) For equipment and systems that have multiple voltage settings or self-regulating voltage capacity, the test must be carried out at the input supply voltage specified in Table 1 - “Power input voltages and frequencies during the tests” of standard IEC 60601-1-2:2014/AMD1:2020.

US

14.4.2 Points of Contact with the Patient

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

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

a) The following applies:

- All connection cables with the patient must be tested, either individually or grouped together.
- The connection cables with the patient must be tested using a current clamp unless the current clamp is not suitable. If a current clamp is not suitable, an EM clamp must be used.
- In any case, no intentional decoupling device should be used between the injection site and POINT OF CONNECTION TO THE PATIENT.
- The tests can be performed with other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- The tubes that are intentionally filled with conductive liquids and intended to be placed in contact with the PATIENT must be considered connection cables with the patient.
- If an ISM or amateur radio band is not present among the frequency samples, as appropriate, an additional test frequency has to be used in the ISM band or in the amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM bands (industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The non-professional bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

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

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

14.4.3 Parts Accessible to the Input / Output Signals

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

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

a) This test applies only to output lines connected directly to the external cables.

b) SIP/SOPS with maximum cable length less than 3 m are excluded.

c) The tests can be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) The calibration of the current injection terminals must be performed in a system at 150 Ω.

e) The connectors must be tested in accordance with Section 8. 3. 2 and Table 4 of IEC 61000-4-2:2008. For insulated connector housings, perform the air discharge test on the connector housing and pins using the probe with the rounded tip of the ESD generator, with the exception that only the connector pins that are tested are those that can be reached or touched, under the conditions of INTENDED USE, by the standard probe shown in Figure 6 of the general standard, applied in a bent or straight position.

f) The capacitive coupling must be used.

g) If an ISM or amateur radio band is not present among the frequency samples, as appropriate, an additional test frequency has to be used in the ISM band or in the amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

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

i) The ISM bands (industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The non-professional bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

j) See IEC 61000-4-6:2013, Annex B, for the modified start frequency with respect to cable length and device size.

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

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

US

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

Test Freq. (MHz)	Band [a] (MHz)	Service [a]	Modulation	Max power (W)	Distance (m)	Immunity test value (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13.17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 Band LTE 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4.25 UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth WLAN 802. 11 b/g/n RFID 2450 Band LTE 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802. 11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

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

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

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

NOTE: If necessary to reach the immunity test level, the distance between the transmitter antenna PWR Air 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 Air device, including the cables specified by the manufacturer. Otherwise, there may be a performance degradation of these appliances.

US

14.6 Proximity Magnetic Field Immunity in the Frequency Range from 9 kHz to 13.56 MHz

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

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

a) This test applies only to devices intended for use in the HOME HEALTHCARE ENVIRONMENT.

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

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

15 TROUBLESHOOTING

15.1 Diagnostic System and Symbols on the Touch Surface

US

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

Symbol on touch surface	Possible cause	Solution
	Incorrect start-up procedure: the device was started with the foot pedal pressed.	Check that the foot pedal is not pressed down. If the problem persists, disconnect the foot pedal and potentially contact the HuFriedyGroup's Service and Repair team.
	Incorrect power-on procedure: the device was operated during the calibration phase	Switch off and wait 5 seconds before switching on the device again. Do not operate the foot pedal during the calibration phase. If the warning persists, contact the HuFriedyGroup's Service and Repair team.
	The self-diagnostic functions detected a fault or malfunction	Switch off and wait 5 seconds before switching on the device again. If the warning persists, contact the HuFriedyGroup's Service and Repair team.
	Mains faults, electrostatic discharges	Turn off and wait 5 seconds before switching the device on again If the warning persists, contact the HuFriedyGroup's Service and Repair team.
	A pressurized powder container was opened without running the “Refill” cycle.	Before opening one of the powder containers, the “Refill” cycle must be run (See *Chapter 5.5 on page 27*).
	The device fails to regulate the air pressure correctly	Check for compressed air in the system and check that the connector is correctly connected. Switch off and wait 5 seconds before switching on the device again. Do not operate the foot pedal during the calibration phase. If the warning persists, contact the HuFriedyGroup's Service and Repair team.
	Condensate drainage was attempted without activating one of the two “No Powder” functions.	Switch the device off and on again, set the “No Powder” function (by selecting  or ) and attempt to drain the condensate again.

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

15.2 Quick Troubleshooting

Problem	Possible Cause	Solution
The device does not start after the switch is set to “I”.	The terminal of the electrical power cable has not been properly inserted in the rear socket of the device	Check that power supply cable is firmly connected
	The power supply cable is faulty	Check that the supply socket is working. Replace the power supply cable
	The fuses are out of order	Replace the fuses (See *Chapter 15.3 on page 80*)
The device is on but not working. No errors are reported on the touch surface.	The foot pedal plug is not properly inserted in the device socket	Properly insert the foot pedal plug into the connector at the back of the device (see *Chapter 4.3 on page 15*).
	The foot pedal does not work properly	Contact the HuFriedyGroup's Service and Repair team
The device is on but not working. The following symbol appears on the touch surface: 	See *Chapter 15.1 on page 76* for the possible cause	See *Chapter 15.1 on page 76* for details of the necessary action
No liquid flows out from the air-polishing handpiece during operation	Device not connected to the water circuit	Check the connection to the water circuit (See *Chapter 4.3 on page 15*).
	The air-polishing handpiece is clogged	Disconnect the air-polishing handpiece and clear the water passage by blowing compressed air through it. See *Chapter 12 on page 56* See *Chapter 6.4 on page 36* If the problem persists, replace the air-polishing handpiece with a new one.
	The water tap on the device is closed	Adjust the water flow using the dedicated knob See *Chapter 5.2 on page 19*.
	The foot pedal connector is not properly inserted in the device socket	Properly insert the foot pedal connector at the back of the device (see *Chapter 4.3 on page 15*).

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Problem	Possible Cause	Solution
No powder flows out from the air-polishing handpiece during operation.	The air-polishing handpiece is clogged due to an excessive moisture content in the powder or insufficient cleaning/maintenance	Remove the powder from the container and clean it using a dry cloth. Disconnect the air-polishing handpiece and clear the water passage by blowing compressed air through it. See *Chapter 12 on page 56* See *Chapter 6.4 on page 36* If the problem persists, replace the air-polishing handpiece with a new one.
	The amount of powder in the container exceeds the maximum level	Remove the powder from the container and clean it using a dry cloth. Restore the correct level of powder in the container (See *Chapter 4 on page 14).*
	Unsuitable powder	Use the correct powder to ensure proper functioning of the device.
Powder leak through the powder container cap	Powder residue in the thread	Clean the powder container thread (See *Chapter 12.7 on page 62).*
Poor cleaning performance	Insufficient pressure in the air supply circuit	Check air supply circuit pressure (4-8 bar max).
	Insufficient or excessive powder level in the container	Restore the correct level of powder in the container See *Chapter 4.3 on page 15*.
	Unsuitable powder	Use the correct powder to ensure proper functioning of the device.
	The air-polishing handpiece is clogged due to an excessive moisture content in the powder or insufficient cleaning/maintenance	Remove the powder from the container and clean it using a dry cloth. Disconnect the air-polishing handpiece and clear the water passage by blowing compressed air through it. See *Chapter 12 on page 56* See *Chapter 6.4 on page 36* If the problem persists, replace the air-polishing handpiece with a new one.

Problem	Possible Cause	Solution
One of the powder container caps does not unscrew	The device is on and the powder container is pressurized	Run the “Refill” cycle before opening one of the powder containers (See *Chapter 5.5 on page 27).*
	The “Refill” cycle has been performed but the powder containers have remained pressurized because the air-polishing handpiece is clogged	Read the section on cleaning the air-polishing handpiece (See *Chapter 6.4 on page 36).*
	The “Refill” cycle has been performed but the powder containers have remained pressurized because the air-polishing cord is clogged	Contact a HuFriedyGroup's Service and Repair team.

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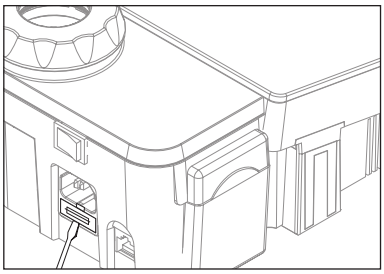
15.3 Replacing the Fuses

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

1

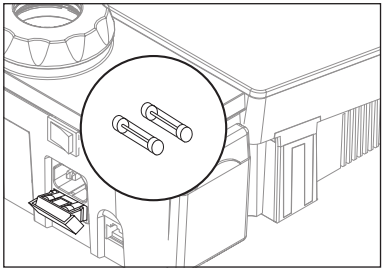
Use a flat tool, if necessary, to open the fuse box located below the power socket;



2

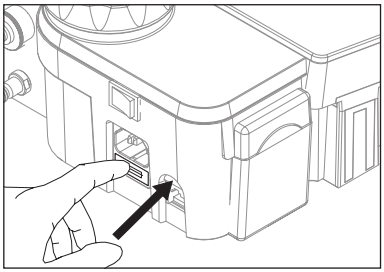
Extract the fuse holder compartment;

⚠ **WARNING:** Replace the fuses in respect of the characteristics indicated in *Chapter 14 on page 67*.



3

Reinsert the compartment in its place.



15.4 Shipping to HuFriedyGroup's Service and Repair

If technical assistance is required on the device, please visit hufriedygroup.com/PWR/Support or you can contact Service & Repair or your distributor. Do not try to repair or modify the device and its accessories.
Clean and sterilise all parts that need to be sent to HuFriedyGroup Service & Repair, following the instructions in *Chapters 6, 7, 8, 9* of this Manual.
Leave the sterilized parts in the pouch which certifies the sterilization process.
The cleaning and sterilization demands comply with the mandatory requirements for workplace health and safety protection laws.
If the client fails to comply with the requirements, HuFriedyGroup reserves the right to charge them the cost of cleaning and sterilization or to refuse goods that arrive in unsuitable conditions, returning them at the client's own expense for proper cleaning and sterilization.

The device must be returned suitably packaged and accompanied by all the accessories and a form including:

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

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

Once the material is received by HuFriedyGroup Service & Repair, the qualified technical personnel will evaluate the problem. The repair will be made only upon acceptance by the end client. For further details, please contact HuFriedyGroup Service & Repair or your distributor.
Unauthorized repairs can damage the system and void the guarantee and furthermore will disclaim the manufacturer from any liability for direct or indirect damage to persons or property.

16 WARRANTY

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Before being marketed, PWR Air is subjected to a thorough final check that verifies the full functionality.
The manufacturer provides a warranty for PWR Air, purchased new from a HuFriedyGroup distributor or importer, which covers defects in material and workmanship for a period of:

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

The other associated items are not covered by the warranty.
During the warranty period, HuFriedyGroup undertakes to repair (or, at its discretion, to replace) the parts of products free of charge, which, according to its judgement, are proven to be defective.
Full replacement of HuFriedyGroup products is not covered by the warranty.
The manufacturer's warranty and device approval are not valid in the following cases:

- The device is not used in accordance with the intended use.
- The device is not used in accordance with all the instructions and requirements outlined in this manual.
- The electrical system of the facilities where the device is used does not comply with the electrical code compliance standards in force and the relative electrical safety precautions.
- Assembly operations, extensions, adjustments, updates and repairs are carried out by personnel not authorized by the Manufacturer.
- The environmental conditions for preservation and storage of the device do not comply with the requirements indicated in *Chapter 14 on page 67*.
- Use of non-original HuFriedyGroup associated items and replacement parts that may compromise the correct operation of the device and cause injury to the patient.
- Accidental breakage during transport.
- Damage due to incorrect use or carelessness, or due to connection to a voltage other than that envisaged.
- Expired warranty.

The expected service life of the device is minimum 5 years.
The service life / duration does not establish a limit of use; the service life of the device defines the period of time after installation and/or commissioning, during which the original performance, or in any case performance suited to the intended use, is guaranteed without there being any degradation such as to compromise functionality and reliability.
The service life is a minimum qualitative objective of the design, therefore, individual parts or components may guarantee superior performance and reliability with respect to that declared by the manufacturer.
The service life assumes compliance with the maintenance schedules set out in this manual, does not include components normally subject to "wear", and is not linked to the warranty period: the service life does not establish any implicit or explicit extension of the warranty period.

CAUTION

The warranty starts from the date of purchase of the device, which evidence is given by the delivery note/purchase invoice issued by the Dealer / Importer or, in case of device with activation code, from the date of activation of the same.
In order to benefit from the warranty service, the client must return the device, at their own expense, to the HuFriedyGroup dealer/importer from which they purchased the product.
The device must be returned in its original packaging, accompanied by all associated items and following informations:

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

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

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

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