

proxeo^{AURA}

EN

Air Polishing Handpiece

USE AND MAINTENANCE MANUAL



PF-60, PF-60 M, PF-60 N, PF-60 S

SUMMARY

EN

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01 INTRODUCTION

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Carefully read this manual before proceeding with the installation, use, maintenance, or other operations on the device. Always keep this manual within reach.

IMPORTANT: To prevent harm to persons or damages to objects, read all the "Safety precautions" present in the manual with special care. Depending on their degree of seriousness, the safety precautions are classified with the following indications:

 **WARNING**
(always refers to personal injury)

 **CAUTION**
(refers to possible damage to property)

The purpose of this manual is for the operator knowledge regarding the safety precautions, the installation procedures, and the instructions for correct use and maintenance of the device and its accessories. Use of this manual for purposes other than those strictly tied to the installation, use and maintenance of the device is forbidden. The information and illustrations in this manual are updated as of the date of issue reported on the last page. Mectron is committed to continually updating its products with possible modifications to device components. In the event you uncover discrepancies between what is described in this manual and the device in your possession, contact your retailer or authorised W&H service partner for clarification and support.

01.1 INTENDED USE

The air polisher is intended for specific use depending on the type of powder being used (whether it be bicarbonate or glycine based).

Bicarbonate powder air polisher. Indications:

- Removal of bacterial plaque;
- Removal of stains from the tooth surface, due to tobacco, coffee, tea and chlorhexidine;
- Cavity preparation for a better adhesion between enamel and filling material;
- Polishing of the enamel's surface;

Glycine powder air polisher. Indications:

- Removal of bacterial plaque supra- and subgingival;
- Removal of biofilm in the prevention of periimplantitis;
- Prophylaxis on patients in orthodontic therapy.

01.2 DESCRIPTION OF THE DEVICE

The air polishing handpiece is a compact Bicarbonate or Glycine based powder compact whitening system with a quick-fit connection to the turbine coupling. The air polishing handpiece offers all the main advantages of the best-known table-top devices:

- a steady and efficient stream of powder
- simplicity of use and reliability.

The operating principle of the air polishing handpiece is based on the mechanical action, obtained with a jet of powder crystals accelerated by a stream of compressed air.

The kinetic energy impressed in this way on the particles is almost entirely dissipated as they strike the surface of the enamel, giving rise to a gentle but effective cleaning effect. This action is completed by a jet of water that exploits the depression created around the nozzle to form a bell shape around the main stream, producing two effects: it prevents to a great extent the cloud of powder from splashing and spilling out and performs continuous rinsing of the treated area.

01.3 DISCLAIMER

Mectron will not accept any liability for direct or incidental personal injury or damage to property in the following cases:

- 1 If the equipment is used for purposes other than those for which it is intended.
- 2 If the equipment is not used in accordance with all the instructions and requirements described in this manual.
- 3 If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements.
- 4 If any assembly operations, extensions, settings, alterations or repairs have been carried out by personnel not authorised by Mectron or W&H.
- 5 If the environmental conditions in which the device is kept and stored does not comply with the requirements indicated in the chapter on technical specifications.

01.4 SAFETY REGULATIONS

⚠ WARNING: No alterations to this device are permitted.

⚠ WARNING: The device must be used in a dental practice or ambulatory facility.

⚠ WARNING: Qualified and specialized personnel. The device must be used exclusively by specialized personnel with proper medical education; no particular training activities are intended for the use of the device. The use of the device does not cause side effects if applied correctly. Improper use may injure soft tissues and can cause emphysema tissues.

⚠ WARNING: Use the device solely for the purpose for which it is intended (see paragraph 01.1 and 01.2). Failure to comply with this requirement could lead to serious harm to the patient and/or to the operator and/or damage/failure of the equipment.

⚠ WARNING: Contraindications. Patients wearing contact lenses should remove them prior to receiving treatment with the air polishing handpiece.

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

⚠ WARNING: Contraindications. Do not direct the stream of air/bicarbonate-based powder/water towards eyes. Failure to observe this requirement can cause serious eye damage. It is advisable for everyone involved (patient, dentist and dental personnel) to wear goggles.

⚠ WARNING: Contraindications. Do not direct the stream of air/bicarbonate-based powder/water onto composites, fillings or bridges. Failure to observe this requirement may cause them to be damaged.

⚠ WARNING: Contraindications. Do not direct the stream of air/powder/water onto soft tissues or inside the gingival sulcus. Failure to comply with this direction can cause gingival tissue emphysema (emphysema of the mucosa and/or subcutaneous). Use only Prophylaxis Powder SENSITIVE – Glycine Powder and the setting "PERIO" for this

kind of treatments.

⚠ WARNING: Contraindications.

Dentists and other dental personnel are advised to use protective masks in order to avoid inhalation of the powder.

⚠ WARNING: Cleaning, disinfection and sterilisation of new or repaired accessories.

All new and repaired accessories are supplied in non-sterile condition. Before use, and after each treatment, they must be cleaned and sterilized in strict compliance with the instructions given in chapter 06 - Cleaning, disinfection and sterilisation.

⚠ WARNING: Infection control.

To ensure maximum safety of patient and operator, before using all the reusable parts and accessories, they should first be cleaned and sterilized, following the

instructions in Chapter 06 - Cleaning, disinfection and sterilisation.
















⚠ WARNING: Contraindications. After sterilizing the spray heads and any other accessory that can be sterilized in the autoclave, allow to cool down completely before reuse.

⚠ WARNING: Check the condition of the device before treatment.

Before each treatment, always check that the equipment is in proper working order and that the accessories are efficient. Do not carry out the treatment if any problems are encountered in operating the device. If the problems concern the equipment contact an authorised W&H service partner.

⚠ WARNING: Use genuine W&H accessories only.

01.5 SYMBOLS

	Serial number
	Lot number
	Product code
	Warning: read the instructions for use
	Operating instructions
	Temperature limitation - transport and storage conditions
	Humidity limitation - transport and storage conditions
	Atmospheric pressure limitation - transport and storage conditions
	It indicates compliance with the CE 93/42 CEE. Notified body: KIWA CERMET ITALIA
	Use-by date
	Manufacturer
	Date of manufacture
	Can be sterilized in autoclave up to a maximum temperature of 135 °C
	Non-sterile
Rx only	For US market only CAUTION US Federal law restricts this device to sale by or on the order of a dentist
	Thermo washer disinfectable

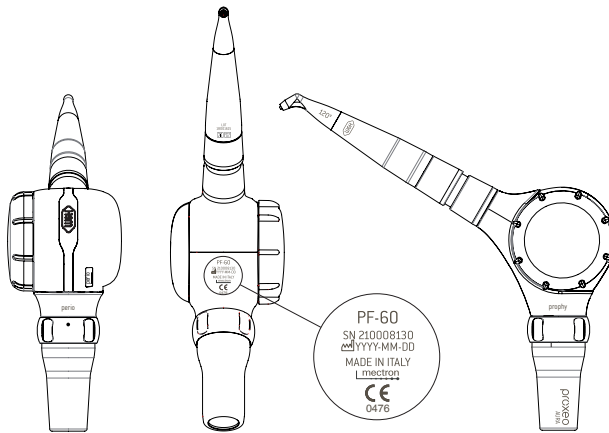
02 IDENTIFICATION DATA

An exact description of the model and serial number of the device will enable our After-Sales Service to provide fast and efficient support. Always provide this information whenever you contact an authorized W&H service partner.

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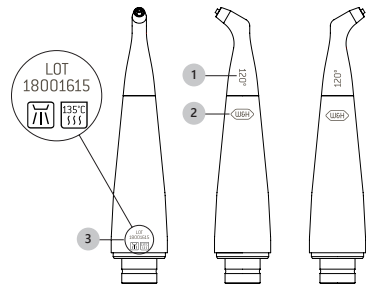
02.1 DEVICE IDENTIFICATION DATA

The device name, serial number and other relevant information is laser-marked on the device. The remaining data is included in this manual (see chapter 09 - TECHNICAL DATA).



02.2 SPRAY HEAD IDENTIFICATION DATA

The following data is laser-marked on each spray head: the name of the spray head (ref. 1), the W&H logo (ref. 2) and the lot number to which the spray head belongs (ref. 3).



03 DELIVERY

03.1 LIST OF COMPONENTS

See inside cover

The Proxeo Aura Prophy-Set consists of:

- A** air polishing handpiece
- B** Ø 0,8 mm needle
- C** Ø 0,4 mm needle
- D** spray head 120°
- H** bottle of "Prophylaxis Powder SOFT"
- I** use and maintenance manual
- L** brush

The Proxeo Aura Perio-Set* consists of:

- A** air polishing handpiece
- B** Ø 0,8 mm needle
- C** Ø 0,4 mm needle
- D** spray head 120°, spray head PERIO
- E** K9 wrench
- F** subgingival perio tips
- G** bottle of "Glycine Powder" (Prophylaxis Powder SENSITIVE)
- H** bottle of "Prophylaxis Powder SOFT"
- I** use and maintenance manual
- L** brush

* only available in EEA and CH

Air polishing handpiece has accessories available that can be ordered separately. The quantity and type of accessories supplied with the device you have purchased can vary according to promotional campaigns and to the country where the unit is sold. The package of the device is sensitive to strong collisions, therefore special precautions must be taken for transport and storage. All the materials shipped by Mectron have been inspected upon their delivery.

The device is delivered duly protected and packed. When receiving the device, check for the possible presence of damages incurred during the transport and, should that be the case, file a complaint with the transporter. Preserve the package in the event that you need to send the device to an authorized W&H service partner and for storing the device during prolonged periods of non-use.

04 INSTALLATION

04.1 FIRST INSTALLATION

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

To ensure that the device is in working condition, it is necessary to check the following:

- 1 Supply of water to the turbine coupling;
- 2 Supply of air to the turbine coupling;
- 3 Presence of powder.

Standard supplies from the dental unit for a turbine coupling:

- water from 1 to 3 bars (from 1,000 hPa to 3,000 hPa), max. 40 °C;

- air 2.2–3.0 bar (2,200 hPa - 3,000 hPa).
The air polishing handpiece is supplied with a specific connection corresponding to the fitting of the turbine coupling on your dental unit. Use the air polishing handpiece only with a connection fitting to the turbine coupling. Connecting the air polishing handpiece to a different turbine coupling could damage it.

04.2 SAFETY PRECAUTIONS DURING INSTALLATION

⚠ **CAUTION:** Check that the turbine coupling is clean and that the o-rings on it are in good condition.

⚠ **WARNING:** Do not press the pedal while checking the connector.

⚠ **WARNING:** Do not press the pedal while connecting the air polishing handpiece.

⚠ **CAUTION:** If the turbine coupling provides a light connection, turn it off.

⚠ **CAUTION:** The spray head and the turbine coupling must be perfectly dry. The presence of moisture could cause clogging of the channels in which the air/powder circulates.


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

⚠ **CAUTION:** The device is transportable, however it must be handled with care when it is moved.

05 USE


Depending on the type of application required, you need to choose the powder and the specific spray heads.


- 1 For applications using bicarbonate-based powder you must:
 - Set the adjustment ring to PROPHY;
 - Fill the powder container with Prophylaxis Powder SOFT;
 - Insert spray heads 120° or 90° for this type of application in the handpiece.
- 2 For applications using glycine-based powder you must:
 - Set the adjustment ring to PERIO;
 - Fill the powder container with Prophylaxis Powder SENSITIVE – Glycine Powder;
 - Insert the spray head required (90°, 120° or PERIO) in the handpiece;
 - Should you wish to carry out a subgingival application and the spray head PERIO was inserted, you must attach the subgingival perio tip on it.

 **CAUTION:** The subgingival perio tip can only be used with the spray head PERIO.

 **WARNING: The subgingival perio tips are sterile disposable.**

The subgingival perio tips are supplied sterile and disposable. They must be used on a single patient during a single application and must then be disposed of.

 **CAUTION:** Use only Prophylaxis Powder SENSITIVE – Glycine Powder with the spray head PERIO.

 **CAUTION:** Before filling the powder container with the chosen powder, make sure it is clean and free of powder residues.

05.1 SAFETY PRECAUTIONS BEFORE AND DURING USE

⚠ WARNING: Contraindications.

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

⚠ WARNING: Contraindications.

Patients wearing contact lenses should remove them prior to receiving treatment with the air polishing handpiece.

⚠ WARNING: Contraindications.

Do not direct the stream of air/powder/water in towards eyes.

Failure to observe this requirement can cause serious eye damage. It is advisable for everyone involved (patient, dentist and dental personnel) to wear goggles.

⚠ WARNING: Contraindications.

Dentists and other dental personnel are advised to use protective masks in order to avoid inhalation of the powder.

⚠ WARNING: Contraindications.

Do not direct the stream of air/Prophylaxis Powder SOFT/water onto composites, fillings or bridges. Failure to observe this requirement may cause them to be damaged.

⚠ WARNING: Contraindications.

Do not aim the jet of air/Prophylaxis powder SOFT or SMOOTH/water onto soft tissues or inside the gingival sulcus. Failure to comply with this direction can cause gingival tissue emphysema (emphysema of the mucosa and/or subcutaneous). Use only Prophylaxis Powder SENSITIVE – Glycine Powder for this kind of treatments.

⚠ WARNING: Check the condition of the device before treatment.

Before each treatment always check that the equipment is in proper working order and that the accessories are efficient. Do not carry out the treatment if any problems are encountered in operating the device. If the problems concern the equipment contact an authorised W&H service partner.

⚠ WARNING: Use genuine W&H accessories only.

⚠ WARNING: Infection control and cleaning of the water and air circuits.

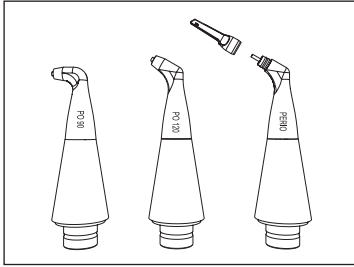
First use: All new and repaired accessories are supplied in NON STERILE conditions. Before use, and after each treatment, they must be cleaned and sterilized in strict compliance with the instructions provided in Chapter 06 - Cleaning, disinfection and sterilisation.

Subsequent uses: After every treatment, clean, disinfect and sterilize all the reusable parts and accessories, following the instructions provided in Chapter 06 - Cleaning, disinfection and sterilisation.

⚠ CAUTION: Do not attempt to unscrew the cap of the powder container when it is under pressure.

⚠ CAUTION: Make sure that the powder container is perfectly dry. The presence of moisture could cause clogging of the channels.

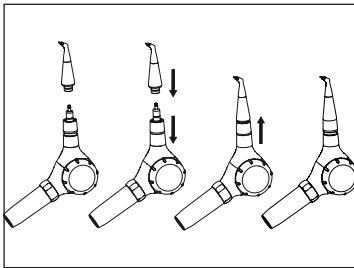
05.2 INSTRUCTIONS FOR USE



1

Select the type of spray head on the basis of the operation to be performed;

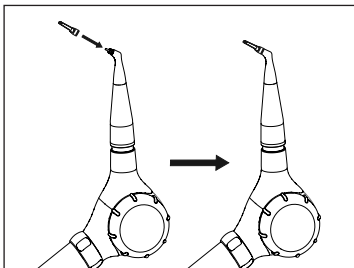
⚠ **CAUTION:** The subgingival perio tip can only be used with the spray head PERIO.



2

Take the air polishing handpiece, slide down the locking ring and keep it in this position, insert completely the spray head and then release the locking ring;

⚠ **WARNING:** Before proceeding with successive operations, make sure that the spray head is inserted correctly, until it reaches the limit stop on the air polishing handpiece (the locking ring and the spray head must be in contact) and that the locking ring has returned to its initial position.



3

If the spray head PERIO has been chosen, attach the subgingival perio tip in the front, pushing it until it stops.

⚠ **WARNING:** Make sure that the subgingival perio tip is completely attached onto the spray head; the two pieces must be in good contact.

⚠ **WARNING:** Use genuine W&H accessories only.

⚠ **CAUTION:** Handle the subgingival perio tip with care.

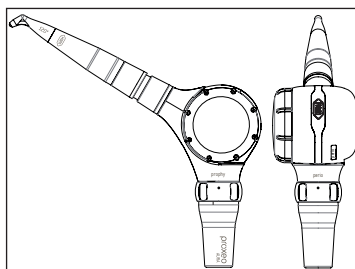
⚠ **CAUTION:** Use only Prophylaxis Powder SENSITIVE – Glycine Powder with the spray head PERIO.

Select the desired "PROPHY" or "PERIO" function by turning the adjustment ring on the air polishing handpiece.

"PROPHY" function: use Prophylaxis Powder SOFT or SMOOTH;

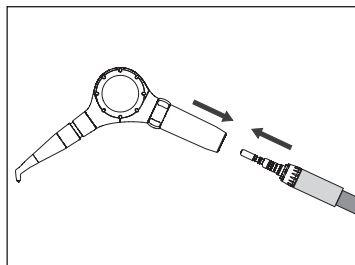
"PERIO" function: use Prophylaxis Powder SENSITIVE – Glycine Powder.

4



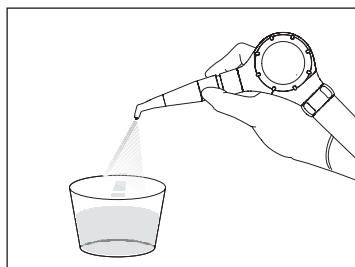
Connect air polishing handpiece to the turbine coupling of the dental unit;

5



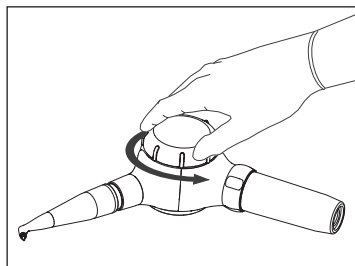
Adjust the water flow rate on your dental unit in order to obtain a steady stream of water. It is easier to adjust the flow rate without powder;

6



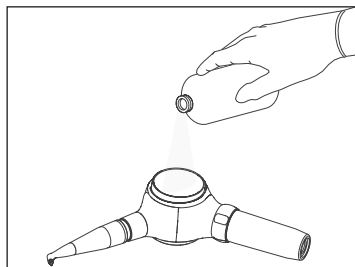
Unscrew the cap of the powder container;

7

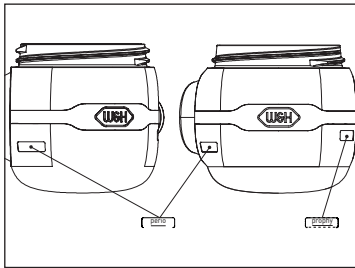


Pour the powder chosen for the particular application into the powder container.

8



⚠ CAUTION: Do not use the Prophylaxis Powder SOFT if the adjustment ring has been set to "PERIO".

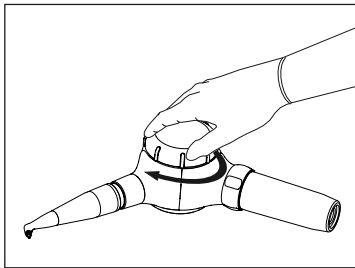


9

There are two maximum levels of powder shown on the powder container: one for Prophylaxis Powder SOFT or SMOOTH (PROPHY) and the other for Prophylaxis Powder SENSITIVE – Glycine Powder (PERIO).

⚠ **CAUTION:** When filling the powder container with Prophylaxis Powder SOFT or SMOOTH, do not exceed the "PROPHY" level indicated on the powder container.

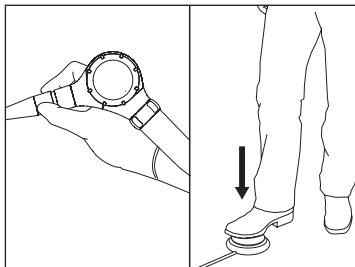
⚠ **CAUTION:** When filling the powder container with Prophylaxis Powder SENSITIVE – Glycine Powder do not exceed the "PERIO" level indicated on the powder container.



10

Screw the cap of the powder container back on;

⚠ **CAUTION:** Remove any residues of powder from the thread of the cap before screwing it on.



11

Press the pedal to carry out the treatment;

⚠ **CAUTION:** During the treatment use the suction cannula to evacuate the mixture of air/powder/water from the patient's mouth.

⚠ **CAUTION:** The stream of air/ powder/water will continue for several seconds after removing your foot from the pedal. Take these few extra seconds into account when finishing the treatment.

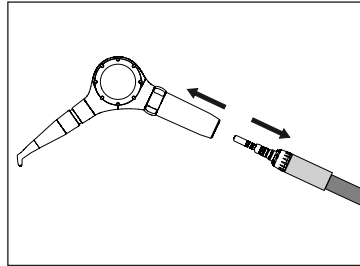
05.3 CLEANING THE POWDER CONTAINER

⚠ CAUTION: The instructions described in this paragraph must be carried out every time the powder is changed and before the cleaning, disinfection and sterilisation procedures.

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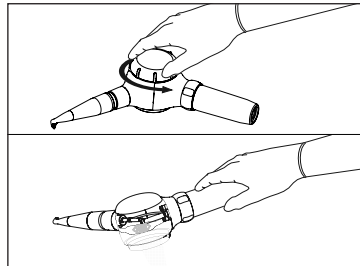
Disconnect the air polishing handpiece from the turbine coupling of the dental unit;

1



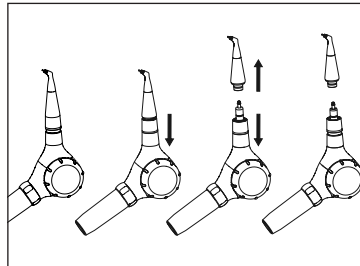
Unscrew the cap of the powder container and empty the powder container;

2



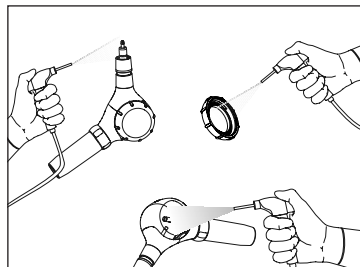
Take the air polishing handpiece, slide the locking ring down and maintain it in this position, extract the spray head and then release the locking ring;

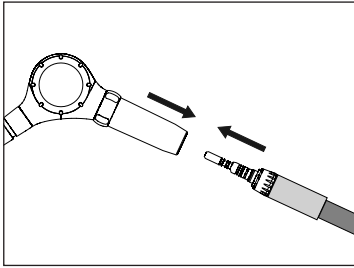
3



Blow compressed air into the powder container, on the cap and on the handpiece connector cavity, to remove all powder residues;

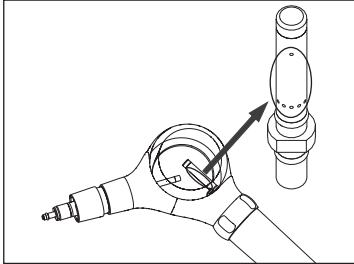
4





5

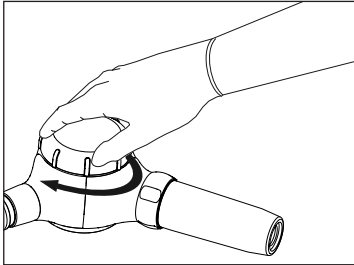
Connect the air polishing handpiece to the turbine coupling of the dental unit;



6

By using the brush supplied and while keeping the pedal pressed, brush the holes on the diffuser in the powder container.

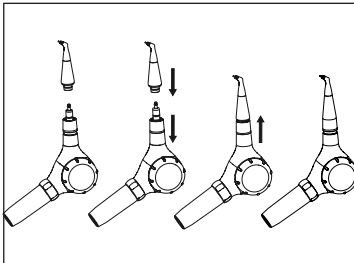
NOTE: Pay attention to the water released from the air polishing handpiece.



7

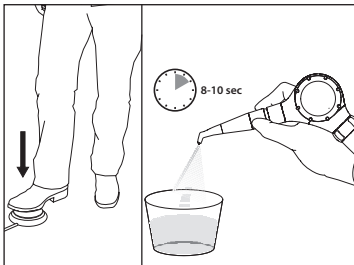
Screw the cap of the powder container back on;

⚠ CAUTION: Remove any residues of powder from the thread of the cap before screwing it on.



8

Take the air polishing handpiece, slide the locking ring down and maintain it in this position, insert the spray head until it reaches the limit stop and then release the locking ring;



9

Activate the pedal for 8-10 seconds to remove possible powder residues from the handpiece;

06 CLEANING, DISINFECTION AND STERILISATION

This table is purely indicative.

For the complete cleaning, disinfection and sterilisation procedures of the individual parts, refer to the paragraphs indicated in the table.

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

⚠ **CAUTION:** The cleaning, disinfection and sterilisation procedures described in the following paragraphs are to be carried out after the first usage and all subsequent usages.

⚠ **WARNING: The subgingival perio tips are sterile and disposable.**

The subgingival perio tips are supplied sterile and disposable. They must be used on a single patient during a single application and must then be disposed of.

Proxeo Aura Air Polishing Handpiece

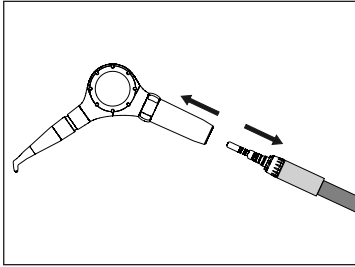
Phase	Paragraph	Procedure
I	06.1	Preparation
II	06.2	Cleaning and disinfecting

Accessories (spray heads, K9 wrench, needle for cleaning)

Phase	Paragraph	Procedure	Spray heads	K9 wrench	Needle for cleaning
IV	06.3.1	Manual cleaning	X	X	X
	06.3.2	Combined manual/automatic cleaning	X	X	
	06.3.3	Automatic cleaning	X	X	
V	06.4	Check cleaning	X	X	X
VI	06.5	Drying	X	X	X
VII	06.6	Sterilisation	X	X	X

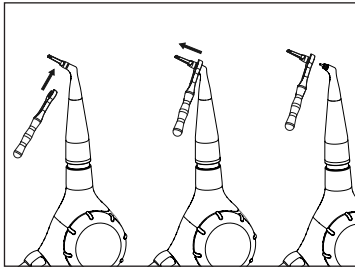
PLEASE NOTE: the steam autoclave sterilisation parameters used in Great Britain are different: temperature: 134 °C, time: 3 minutes

06.1 PREPARATION



1

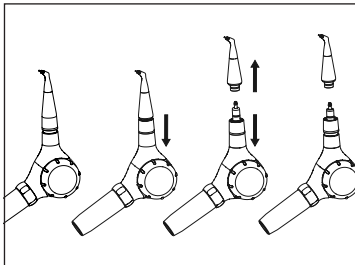
Disconnect the air polishing handpiece from the turbine coupling of the dental unit



2

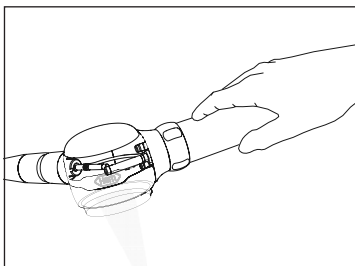
When the subgingival perio tip has been used, remove it by using the K9 wrench supplied and proceed with its disposal (chapter 08);

NOTE: Insert the K9 wrench exactly into the position indicated in the figure.



3

Take the air polishing handpiece, slide the locking ring down and maintain it in this position, extract the spray head and then release the handpiece locking ring;



4

Empty the air polishing handpiece powder container by following the instructions provided in paragraph 05.3.

06.2 CLEANING AND DISINFECTING

The following procedure must be carried out on the Air Polishing Handpiece.

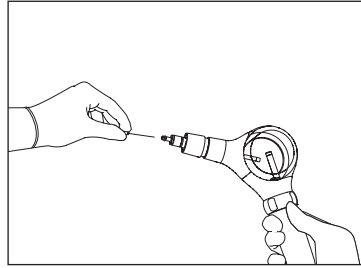
MATERIALS NECESSARY

- Clean, soft cloths with low fibre release;
- Detergent solution (pH 6-9);
- Demineralised water;
- Disinfectant agent (peracetic acid 2%).

CLEANING METHOD

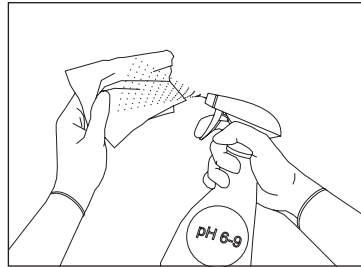
Free the channel of the air polishing handpiece from any powder residual by using the Ø 0,4 mm cleaning needle supplied.

1



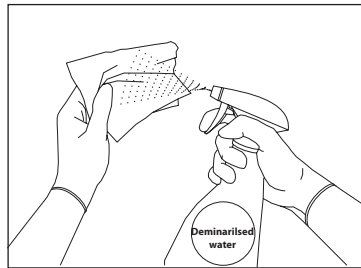
Clean the surface of the air polishing handpiece with a clean, soft and low fibre release cloth, dampened with a cleaning solution (pH 6-9) prepared according to the manufacturer's instructions;

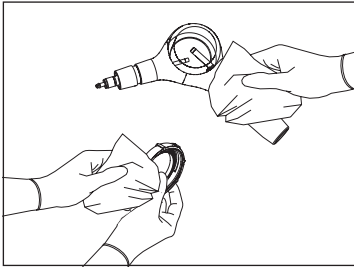
2



Clean the surface of the air polishing handpiece with a clean, soft and low fibre release cloth, dampened with demineralised water to remove all residues of the cleaning solution;

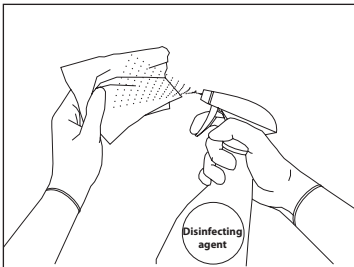
3





4

Dry the surface of the air polishing handpiece with a clean, soft and low fibre release cloth;



5

If you wish to disinfect the device, spray the disinfectant agent (prepared according to the manufacturer's instructions) on a clean and soft cloth with low fibre release and clean the surface of the air polishing handpiece.

⚠ **CAUTION:** Do not sterilize the air polishing handpiece. It may stop working and cause damage to people and/or property.

⚠ **CAUTION:** The air polishing handpiece is not protected against the penetration of liquids. Do not spray liquids directly onto the surface of the air polishing handpiece.

⚠ **CAUTION:** Do not immerse the air polishing handpiece in liquids and/or various kinds of solutions as it could get damaged.

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

⚠ **CAUTION:** Do not use running water to clean the air polishing handpiece.

⚠ **CAUTION:** Do not use as disinfecting agents:

- Very alkaline products (pH > 9);
- Products containing sodium hypochlorite;
- Products containing hydrogen peroxide;
- Products containing abrasive substances;
- Alcohol-based products;
- Products containing aldehyde, amines and/or phenols;
- Acetone;
- Methyl ethyl ketone.

as they can discolour and/or damage the plastic materials.

06.3 CLEANING ACCESSORIES THAT CAN BE STERILISED

PREPARATION

The following parts of the device can be sterilized:

- Spray heads;
- K9 wrench;
- Cleaning needle.

Before verifying the cleaning (paragraph 06.4), drying (paragraph 06.5) and then sterilisation (paragraph 06.6), depending on requirements, one of the three possible cleaning methods must be selected, which are explained in-depth in the following sub-paragraphs.

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

06.3.1 MANUAL CLEANING

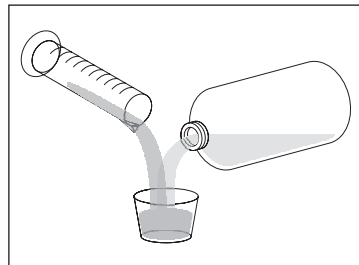
MATERIALS NECESSARY

- Enzymatic detergent at pH 6-9;
- Water;
- Container for immersion in the enzymatic liquid;
- Ultrasonic bath;
- Clean, soft cloths with low fibre release;
- Brush with soft nylon bristles;
- 25 ml syringe;
- Demineralised water.

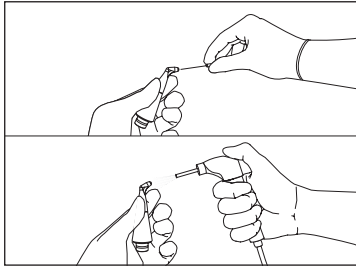
Prepare an enzymatic detergent solution* with pH 6-9, as per the instructions of the manufacturer;

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

1



SPRAY HEAD



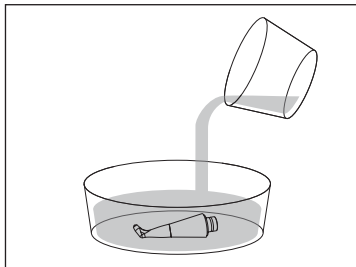
2

Free the spray head channel from any powder residual by using the supplied \varnothing 0,4 mm cleaning needle for the front side and the supplied \varnothing 0,8 mm cleaning needle for the rear side.

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

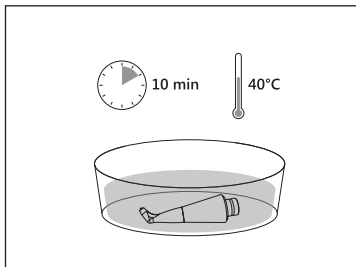
⚠ **CAUTION:** Clean the spray head channel exclusively using the cleaning needle supplied with the device.

⚠ **CAUTION:** In case the subgingival perio tip is still on the spray head, first remove it and then dispose it.



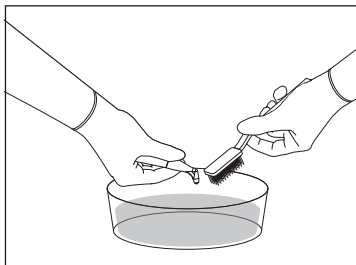
3

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



4

Let the spray head soak for 10 minutes at $40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$. This procedure reduces the amount of blood, protein and mucous present on the spray head;

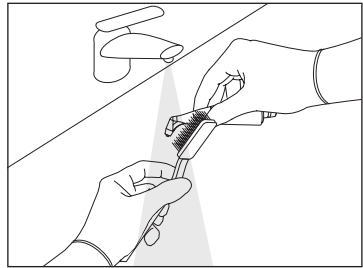


5

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

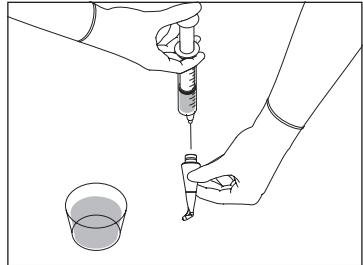
Delicately brush the surface of the spray head under running water using the brush with soft nylon bristles;

6



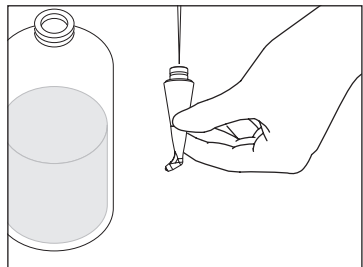
Using a syringe, inject the enzymatic detergent solution 3 times inside the cavity of the spray head to effectively remove the residues from the internal surface;

7



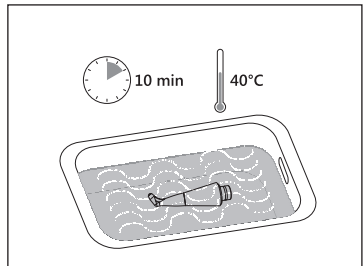
Using a disposable syringe (25 ml vol.) inject the demineralised water into the spray head cavity for at least 5 times in order to eliminate any detergent residue;

8



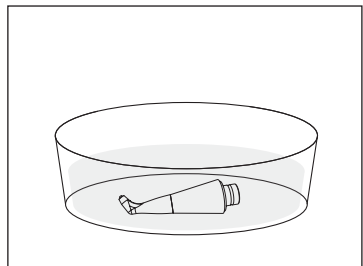
Place the spray head in the ultrasonic bath submerged by the enzymatic detergent solution at 40 °C \pm 2 °C, for at least 10 minutes;

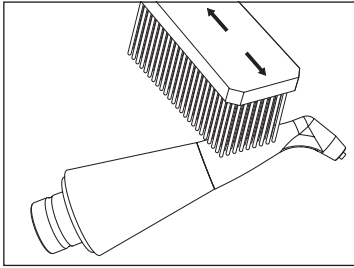
9



Remove the spray head from the ultrasonic bath and rinse with demineralised water;

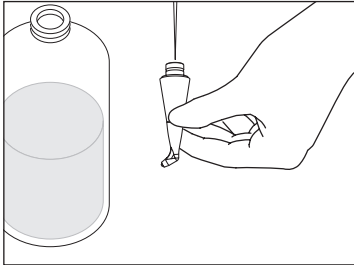
10





11

Delicately brush the surface of the spray head again, using the brush with soft nylon bristles;



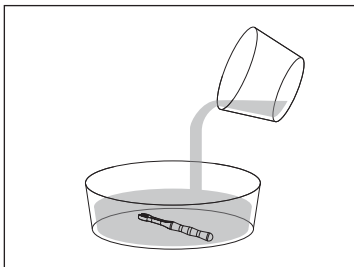
12

Using a disposable syringe (25 ml vol.) to inject the demineralised water into the spray head cavity for at least 5 times in order to eliminate any detergent residue;

Process validated by independent bodies with enzymatic detergent.

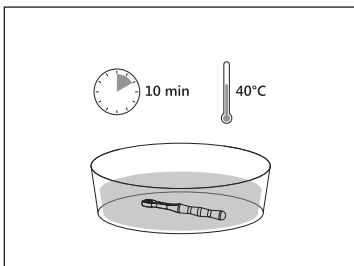
EN

K9 WRENCH



13

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

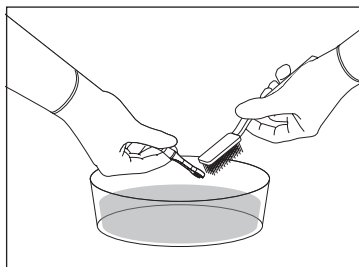


14

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

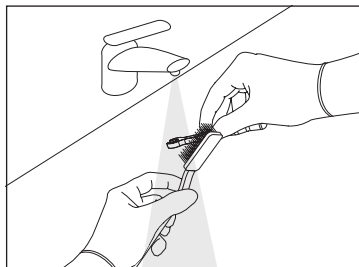
During immersion in the enzymatic solution, delicately brush the surface of the K9 wrench using the brush with soft nylon bristles to eliminate all traces of visible dirt. Thoroughly clean the difficult areas;

15



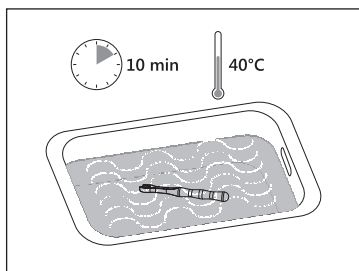
Delicately brush the surface of the K9 wrench under running water using the brush with soft nylon bristles;

16



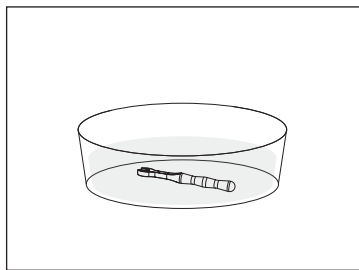
Place the K9 wrench in the ultrasonic bath submerged by the enzymatic detergent solution at 40 °C ±2 °C, for at least 10 minutes;

17



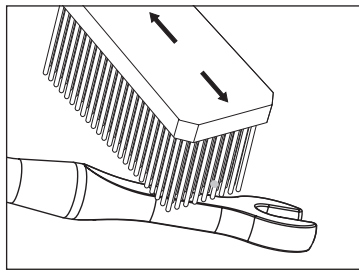
Remove the K9 wrench from the ultrasonic bath and rinse with demineralised water;

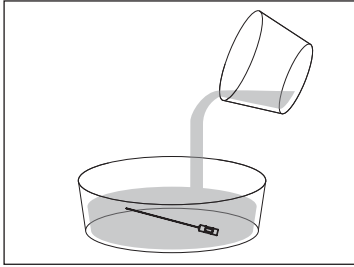
18



Delicately brush the surface of the K9 wrench again using the brush with soft nylon bristles;

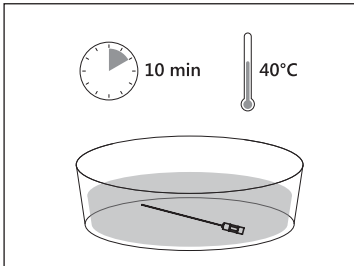
19



CLEANING NEEDLES

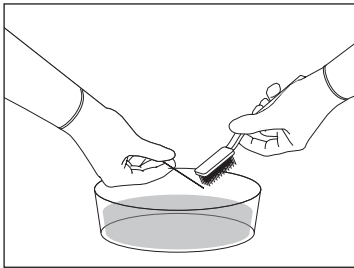
20

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



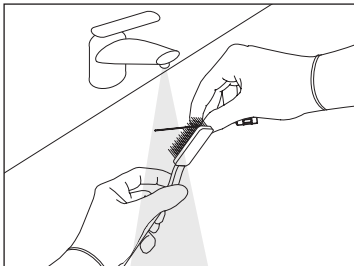
21

Let the cleaning needle soak for 10 minutes at 40 °C \pm 2 °C. This procedure reduces the amount of blood, protein and mucous present on the cleaning needle;



22

During immersion in the enzymatic solution, delicately brush the surface of the cleaning needle using the brush with soft nylon bristles to eliminate all traces of visible dirt. Thoroughly clean the difficult areas;



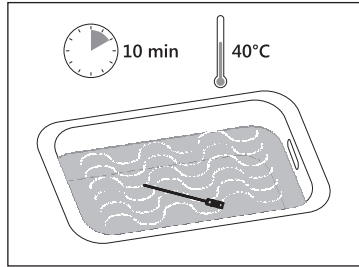
23

Delicately brush the surface of the cleaning needle under running water using the brush with soft nylon bristles;

EN

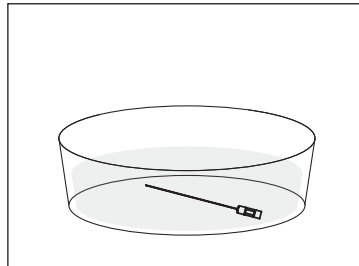
Place the cleaning needle in the ultrasonic bath submerged by the enzymatic detergent solution at 40 °C ± 2 °C, for at least 10 minutes;

24



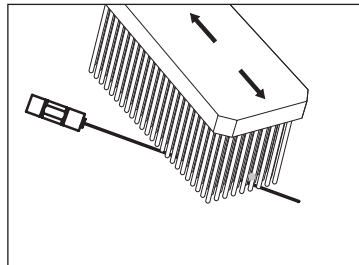
Remove the cleaning needle from the ultrasonic bath and rinse with demineralised water;

25



Delicately brush the surface of the cleaning needle again using the brush with soft nylon bristles;

26



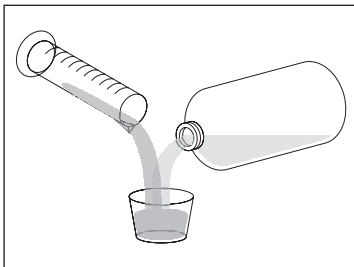
06.3.2 COMBINED MANUAL/AUTOMATIC CLEANING

MATERIALS NECESSARY

- Enzymatic detergent*;
- Water;
- Container for immersion in the enzymatic liquid;
- Brush with soft nylon bristles;
- Disposable syringe 25 ml;
- Demineralised water;
- Alkaline detergent**;
- Neutralising liquid**;
- Metal basket;
- Thermal disinfectant**.

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

06.3.2.1 MANUAL PRE-WASH



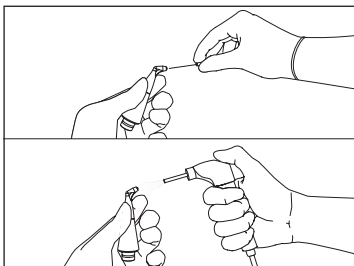
1

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

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

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

SPRAY HEAD



2

Free the spray head channel from any powder residual by using the supplied Ø 0,4 mm cleaning needle for the front side and the supplied Ø 0,8 mm cleaning needle for the rear side.

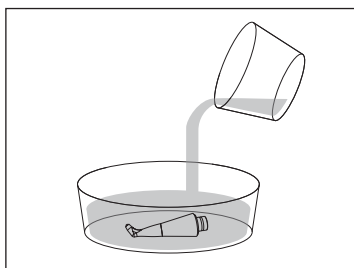
Blow compressed air into the central hole of the spray head, from both ends;

⚠ CAUTION: Clean the spray head channel exclusively using the cleaning needle supplied with the device.

⚠ CAUTION: In case the subgingival perio tip is still on the spray head, first remove it and then dispose it.

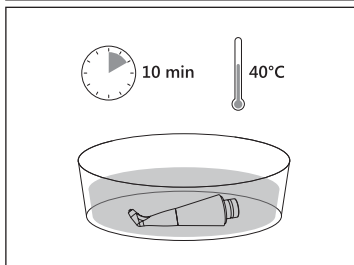
Place the spray head horizontally in a clean container and add enzymatic detergent solution until the spray head is covered completely;

3



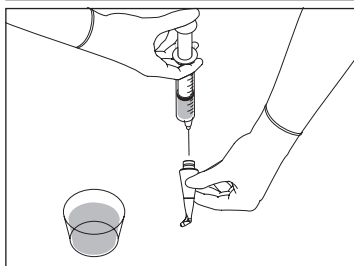
Let the spray head soak for 10 minutes at $40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$. This procedure reduces the amount of blood, protein and mucous present on the spray head

4



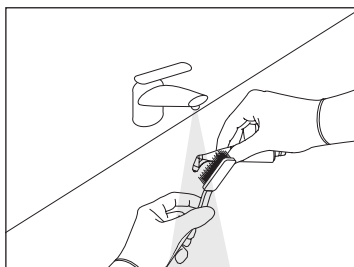
Using a disposable syringe (25 ml vol.) inject the enzymatic detergent solution into the spray head cavity for at least 5 times;

5



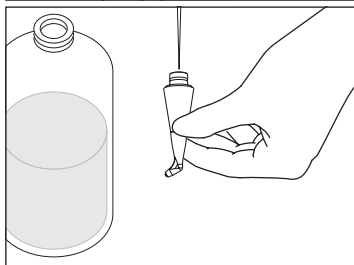
Delicately brush the surface of the spray head under running water (drinking water, temperature $20\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$), in particular the parts that are difficult to access (cavities, structured surfaces, etc.) using a brush with soft nylon bristles; The spray head must be brushed until no residues can be seen (at least 30 seconds);

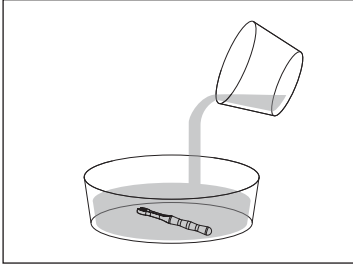
6



Using a disposable syringe (25 ml vol.) inject the cold demineralised water into the spray head cavity for at least 5 times;

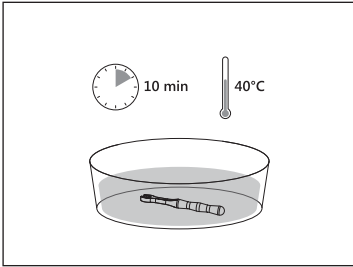
7



K9 WRENCH

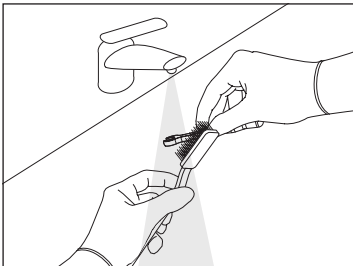
8

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



9

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



10

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

06.3.2.2 MECHANICAL CLEANING

⚠ **CAUTION:** The following mechanical cycle must always be preceded by the pre-washing phase with enzymatic detergent.

⚠ **CAUTION:** Avoid overloading the thermal disinfector as this could compromise the cleaning effectiveness.

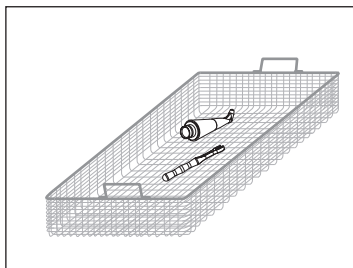
⚠ **CAUTION:** Do not place the air polishing handpiece in a thermal disinfector.

⚠ **CAUTION:** Do not place the cleaning needle in a thermal disinfector.

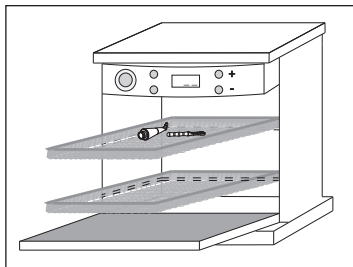
NOTE: Make sure that the accessories are appropriately blocked in the basket and cannot move during washing. Any movement during washing could damage them. Position the instruments in a way that the water can flow through all the surfaces, even internally.

Place the accessories in a metal basket and place the basket in the thermal disinfector;

1



2



Sequence and parameters applicable to the cycle:

- 1 min, rinse with cold water;
- 5 min, wash with alkaline detergent at 55 °C ± 2 °C;
- 1 min, neutralisation with neutralising liquid, 1/3 cold water and 2/3 hot water;
- 1 min, rinse with water (1/3 cold water, 2/3 hot water);
- 5 min, thermal disinfection at 93 °C with demineralised water.

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

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

06.3.3 AUTOMATIC CLEANING

MATERIALS NECESSARY

- Alkaline detergent**;
- Neutralising liquid**;
- Water;
- Metal basket;
- Adapters;
- Thermal disinfectant**.

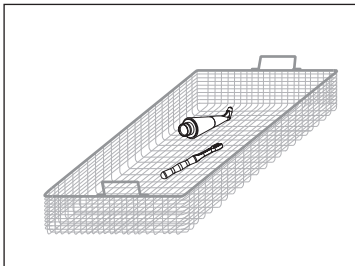
⚠ CAUTION: Before starting to use the thermal disinfectant, assess the entity of dirt and, if necessary, perform a pre-wash (paragraph 6.3.2.1) to avoid repeating the entire cleaning cycle.

⚠ CAUTION: Do not place the air polishing handpiece in a thermal disinfectant.

⚠ CAUTION: Do not place the cleaning needle in a thermal disinfectant.

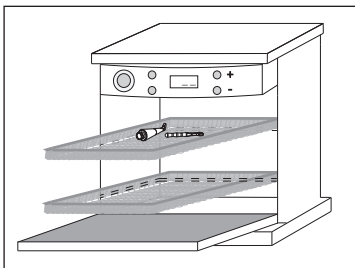
⚠ CAUTION: Avoid overloading the thermal disinfectant as this could compromise the cleaning effectiveness.

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



1

Place the accessories in a metal basket and place the basket in the thermal disinfectant;



2

Sequence and parameters applicable to the cycle:

- 1 min, rinse with cold water;
- 5 min, wash with alkaline detergent at 55 °C ± 2 °C;
- 1 min, neutralisation with neutralising liquid, 1/3 cold water, and 2/3 hot water;
- 1 min, rinse with water (1/3 cold water, 2/3 hot water);
- 5 min, thermal disinfection at 93 °C with demineralised water.

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

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

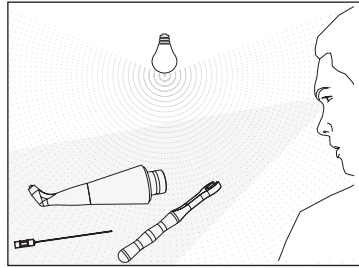
06.4 CLEANING VERIFICATION

MATERIALS NECESSARY

- Light source;
- Magnifying glass 2.5X.

Once the cleaning operations have been completed, visually inspect the spray head, the K9 wrench and the cleaning needle under an adequate source of light, if necessary using a magnifying glass 2.5X, paying attention to the details that could conceal dirt residue (threading, cavities, grooves) and, if necessary, repeat the cleaning cycle if dirt is still visible; Finally, check the integrity of those parts and those elements that could have deteriorated during use.

1



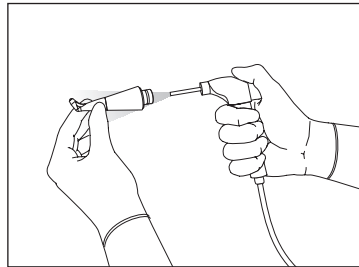
06.5 DRYING

MATERIALS NECESSARY

- Compressed air;
- Soft cloth with low fibre release.

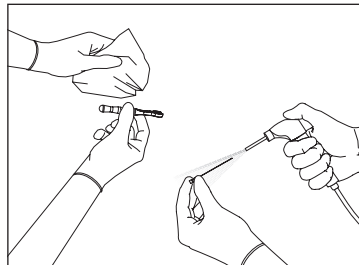
Thoroughly dry all the spray head parts, both internally and externally. To do this, blow compressed air both externally and through the internal channels. This will prevent the appearance of stains, streaks on the surface or oxidation inside the spray head;

1



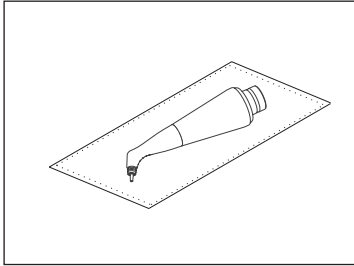
Dry the K9 wrench using a soft cloth with low fibre release. Thoroughly dry all the cleaning needle parts by blowing compressed air on it.

2



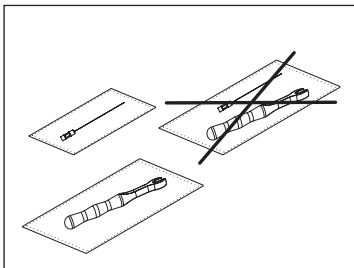
06.6 STERILISATION

PREPARATION



1

Seal the spray heads individually, separately in disposable sterilisation pouches.



2

Seal the the K9 wrench and the cleaning needle individually, separately in disposable sterilisation pouches.

STERILISATION METHOD

The parts that can be sterilized are made of material that can resist up to a maximum of 135 °C for maximum 20 minutes.

Once the parts that can be sterilized are individually wrapped, carry out the sterilisation process in a steam autoclave.

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

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

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

Minimum sterilisation time: 4 minutes.

Minimum drying time: 10 minutes.

All the stages of sterilisation must be performed by the operator in compliance with ISO 17665-1:2007, ISO 556-1:2002 and ANSI/AAMI ST 46:2002.

⚠ **CAUTION:** Do not sterilize the air polishing handpiece.

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

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

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

07 MAINTENANCE

- 1 If the air duct in the spray head connector gets clogged, it is sufficient to switch on the device for a few seconds and to use the needles supplied with the product to free the channel from any residues of powder.
- 2 If the spray head gets clogged due to excessively hard water, it is recommended to dip it in a 2 % solution of hydrochloric acid for a few minutes.
- 3 To avoid clogging, it is advisable to empty the powder container of the air polishing handpiece at least once a day.
- 4 Whenever the spray head is removed, it

07.1 CHECK SPRAY HEAD CONNECTOR

Periodically check o-rings' conditions on the spray head connector.

O-rings are useful to keep the outsourcings of powder and water separated.

O-rings must always be in good condition without the presence of powder residues or damages.

⚠ WARNING: Contraindications.

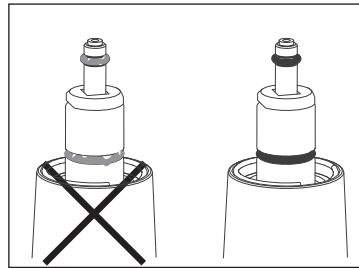
The spray head connector can clog in case of broken, worn o-rings or powder residues.

⚠ WARNING: Exclusively use W&H original accessories and spare parts.

In case of o-rings' wear or damage, exclusively use the kit supplied by W&H.

is necessary to blow compressed air with the syringe, both into the cavity of the handpiece connector and into the rear central hole of the spray head to avoid accumulation of powder residues.

- 5 If the airway duct of the air polishing handpiece gets clogged, use the cleaning needle supplied to clear the duct from powder residue.



07.2 CHECK TURBINE QUICK COUPLING

Periodically check o-rings' conditions on the turbine quick coupling.

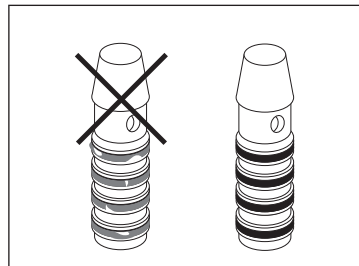
O-rings are useful to keep the outsourcings of powder and water separated.

O-rings must always be in good conditions without the presence of soil or cuts.

⚠ WARNING: Contraindications.

The air polishing handpiece can clog in case of broken, worn o-rings or powder residues.

⚠ WARNING: Exclusively use original accessories and spare parts supplied by turbine's manufacturer.



08 DISPOSAL MODES AND PRECAUTIONS

⚠ WARNING: Hospital wastes.

Treat the following items as hospital waste:

- Spray heads, when they are worn out or broken;
- Subgingival perio tip at the end of each treatment.

The use and disposal of materials, and materials that entail a biological risk, must be disposed in accordance to the local regulations concerning hospital wastes. The air polishing handpiece must be disposed and treated as a waste for separate collection. It is up to the purchaser to hand over the device for its disposal to the retailer who supplies them with new equipment; the instructions for proper disposal are available from Mectron.

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09 TECHNICAL DATA

Device in accordance with EEC Directive 93/42:	Class IIa
Device for intermittent operation:	60 sec. ON - 10 sec. OFF
Standard water pressure provided by the dental unit for a turbine coupling:	from 1 to 3 bar (from 1,000 hPa to 3,000 hPa) max 40 °C.
Standard air pressure provided by the dental unit for a turbine coupling:	2,2 - 3,0 bar (2,200 hPa - 3,000 hPa).
Operating conditions:	From +10 °C to +35 °C Relative humidity from 30% to 75% Air pressure P: 800 hPa/1060 hPa
Transport and storage conditions: (Powder included)	from +15 °C to +25 °C Relative humidity from 10% to 70% Air pressure P: 500 hPa/1060 hPa
Weights and sizes:	~ 155 g (air polishing handpiece) L x w x h ~ 200 x 90 x 50 mm Weight and sizes may vary depending on the various configurations

10 TROUBLESHOOTING

10.1 QUICK SOLUTION TO PROBLEMS

If the device doesn't appear to be functioning properly, read the instructions once again and check the following users guide table in order to identify and solve the relevant malfunction.

Problem	Possible cause	Solution
The cap of the powder container cannot be unscrewed	The air polishing handpiece is connected to the turbine coupling and the powder container is pressurised	Disconnect the air polishing handpiece from the turbine coupling to depressurise the internal circuit
Leakage of powder from the cap of the container	Cap not correctly screwed in place	Screw the cap on correctly
	The cap seal is not properly positioned in its place	Check the positioning of the cap seal
	Residues of powder in the thread	Read point "05.3"
No powder comes out of the spray head of the polisher during operation	Dental unit not connected to the air circuit	Check the connection between the dental unit and the air circuit
	The tank of the air polishing handpiece is empty	Read point "05.2"
	Spray head clogged due to excessive moisture in the powder or insufficient cleaning/maintenance	Read point "05.3", "06.1", "06.3", and "07". Remove the powder from the container and clean it with a dry cloth.
	The air polishing handpiece duct is clogged due to an excessive amount of humidity in the powder or insufficient cleaning/maintenance	Read paragraph "06.2" and "07"
	The level of powder inside the container is higher than permitted	Restore the correct level of powder in the container (see point "05.2")
No water comes out of the spray head of the polisher during operation	Dental unit not connected to the water circuit	Check the connection between the dental unit and the water circuit
	Water too hard	Read point "06.3 - 07"
	Water filter of dental unit clogged	Check the connection to the water circuit of the dental unit

Problem	Possible cause	Solution
Treatment ineffective	Insufficient pressure of the air-supply circuit	Check the pressure in the air circuit of the dental unit
	Level of powder inside the container too low or too high	Restore the correct level of the powder inside the container (see point "05.2")
	Spray head is clogged by too much moisture in the powder or insufficient cleaning/maintenance	Read point "05.3" "06.1", "06.3", and "07". Remove the powder from the container and clean it with a dry cloth.
	Water/powder flow is irregular and/or intermittent	Check the o-rings on the coupling for the spray head on the air polishing handpiece (see paragraph 07.1)

10.2 SENDING THE DEVICE TO AN AUTHORISED W&H SERVICE PARTNER

In the event that technical assistance is needed on the device, contact one of the authorised W&H service partners or your retailers. Do not attempt to repair or modify the device and its accessories.

Clean and sterilize all the parts that need to be sent to an authorised W&H service partner, following the instructions provided in Chapter 06 - Cleaning, disinfection and sterilisation.

Return all parts in sterilisation pouches to provide evidence that the sterilisation process has been performed.

The cleaning and sterilisation requirements are in line with those in force concerning the safeguarding of health and safety in the workplace, as per DLgs 81/08 and its subsequent amendments, that is a law of the Italian State.

In the event that customer does not fulfil the requirements, W&H reserves the right to charge him or her for the cleaning and sterilisation expenses, or to reject the goods received in unsuitable conditions, returning them to the customer, at the customer's expense, for them to be correctly cleaned and sterilized.

The device must be returned properly packaged, accompanied by all the accessories, and by a document including:

- Owner information including complete address and telephone number
- Product name
- Serial number and/or lot number
- Reason for goods returned / description of the malfunction
- Photocopy of packing list or purchase invoice of the device

⚠ CAUTION: Package

Pack the device in its original packaging to prevent damages during transport.

Once the material has been received by the authorised W&H service partner, qualified technical personnel will provide an evaluation based on the given circumstances. The repair work will be performed only upon the prior acceptance by the customer. For further details, contact the closest authorised W&H service partner or your retailer.

Unauthorised repair works may damage the system and make the warranty void, and will absolve Mectron of any responsibility for direct or indirect harm to persons or damages to anything else.

11 WARRANTY

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All Mectron devices are subjected to an accurate final inspection that ascertains their full functionality before they are placed on the market.

Mectron provides a warranty on all new Proxeo Aura air polishing handpieces purchased from a retailer or a W&H importer to cover material or manufacturing defects for 1 YEAR (ONE) from the date of purchase.

The accessories are not included in the warranty.

During the period in which the warranty is valid, W&H commits itself to repair (or at its own free choice, replace) those product parts that were to proved defective according to its judgement, free of charge.

Entire replacement of the products is excluded.

The warranty of the manufacturer and the certification of the device are not valid in the following cases:

- The device is not used in accordance to its intended use.
- The device is not used in compliance with all the instructions and precautions described and outlined in this manual.

- The assembly operations, extensions, adjustments, updates, and repair works are performed by personnel not authorized by Mectron/W&H.
- The environmental conditions for the preservation and storage of the device are not compliant to the precautions indicated in the Chapter 09 - TECHNICAL DATA.
- Use of non genuine W&H inserts, accessories, and spare parts that can compromise correct device operation and cause harm to the patient.
- Accidental breakage due to transport
- Warranty expiration

NOTE: The warranty starts from the date of purchase, which is the date that appears on the packing list/purchase invoice issued by the retailer/importer.

To benefit from the warranty service, the customer must return, at its own expense, the device to be repaired to the retailer/W&H importer from whom the customer purchased the product.

See paragraph 10.2 for the details relative to the procedure to send the device to an authorised W&H service partner.

The indications that appear in this publication can be modified without fore-notice. The Italian version of this manual is the original document from which its translations have been obtained. In case of any discrepancy, the Italian version will have pertinence.

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