Use and maintenance manual

ΕN



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# 01 INTRODUCTION

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:

(!) 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 the After-Sales Service of Mectron for clarifications 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 Jet 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 Jet Polisher. Indications:

- Removal of bacterial plaque above and below the gums;
- Removal of the Biofilm in the prevention of Perimplantitis;
- Profilaxis on patients in ortodontics therapy.

#### 01.2 DESCRIPTION OF THE DEVICE

The Starjet is a Bicarbonate based or Glycine based powder compact whitening system with a quick-fit connection to the turbine. The Starjet has 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 Starjet is based on the mechanical action obtained with a jet of crystals of powder 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 cleansing 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 RESPONSIBILITY WAIVER

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.
- 5 If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications.

#### 01.4 SAFETY PRECAUTIONS

**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 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 to/ failure of the equipment.

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

#### ↑ 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: Controlndications.

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 protective goggles).

#### ↑ WARNING: Controlling Control Online Online

Do not direct the stream of air/Prophylaxis powder/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/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 Glycine based powder for this kind of treatments.

#### **↑** WARNING: Controindications.

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

# MARNING: Cleaning, disinfection and sterilisation of new or repaired accessories.

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 given in the 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.

① CAUTION: Controindications. After sterilizing the cleaner terminals 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 technical service centre.

⚠ **WARNING:** Use authentic Mectron accessories only.

### 01.5 SYMBOLS

SN

Serial number

LOT

Lot number

REF

Product code

Warning: read the instructions for use

 $\bigcap_{\mathbf{i}}$ 

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

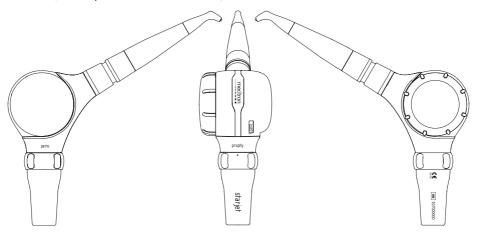
# 02 IDENTIFICATION DATA

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 Mectron Service Center.

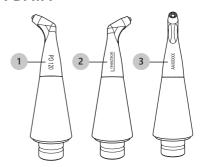
#### 02.1 DEVICE IDENTIFICATION DATA

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 POLISHER TIP IDENTIFICATION DATA

The following data are laser-marked on each insert: the name of the polisher tip (ref. 1), the Mectron logo (ref. 2) and the lot number to which the polisher tip belongs (ref. 3).



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# 03 DELIVERY

#### 03.1 LIST OF COMPONENTS

See inside cover

The Starjet consists of:

- A Starjet device
- **B** Ø 0.8 mm needle
- C Ø 0,4 mm needle
- **D** 3 polisher tips: 90° (PO 90) / 120° (PO 120) / PERIO
- E K9 wrench
- **F** subgingival perio tip
- **G** packet of "Glycine powder" (for European market only)
- H packet of "Prophylaxis powder"
- I use and maintenance manual
- L brush

Starjet 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 Mectron Service Center and for sto-ring 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 order, it is necessary to check the following:

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

Standard supplies from the dental unit for a turbine:

- water from 1 to 3 bars (from 1000 hPa to 3000 hPa), max. 40°C;
- air 2.0 3.0 bars (2000 hPa 3000 hPa).

The Starjet is supplied with a specific adaptor corresponding to the fitting of the turbine on your dental unit. Use the Starjet only for the fitting on your own turbine. Fitting the Starjet to a different connector could damage it. Use Starjet only with the possessed adaptor of the turbine.

Connect Starjet to another connector could damage it.

#### 04.2 SAFETY PRECAUTIONS DURING INSTALLATION

() **CAUTION:** Check that the connector of the turbine is clean and that the o-ring on it are in good conditions.

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

⚠ **WARNING:** Do not press thr turbine control pedal while connecting Starjet.

(!) **CAUTION:** If your turbine has a light, turn the light off.

(1) **CAUTION:** The front polisher terminal and the fitting of the turbine must be perfectly dry. The presence of moisture could cause clogging of the channels in which the air/powder circulate.

① **CAUTION:** Do not expose the apparatus to direct sunlight or to UV light sources.

(1) **CAUTION:** The apparatus is transportable, however it must be handled with care when it is moved.

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# 05 USE

Depending on the type of application required you need to choose the powder and the specific cleaner terminals.

- 1 For applications using bicarbonate-based powder you must:
  - Set the adjusting ring on Prophy;
  - Fill the powder container with Prophylaxis powder;
  - Insert one of the two available cleaner terminals for this type of applications (PO 90° and 120°) in the handpiece
- 2 For applications using glycine-based powder you must:
  - Set the adjusting ring on Perio;
  - Fill the powder container with glycinebased powder;
  - Insert the cleaner terminal required (PO 90°, PO 120° o PERIO) in the handpiece;
  - Should you wish to carry out a subgingival application, and as a result the PERIO cleaner terminal was inserted, you must insert the subgingival perio terminal on it.

- ① CAUTION: The subgingival perio tip can only be used with the PERIO polisher tip.
- ⚠ WARNING: The subgingival periotips 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 eliminated.

- (!) **CAUTION:** Use only Glycine-based powder with the PERIO polisher tip.
- ① **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 jet polisher.

#### **⚠ WARNING: Controlndications.**

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 protective goggles).

#### **↑** WARNING: Controindications.

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

#### **⚠ WARNING: Controindications.**

Do not direct the stream of air/Prophylaxis powder/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/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 Glycine based 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 technical service centre

⚠ **WARNING:** Use authentic Mectron 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 sterilization.

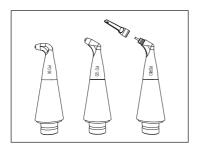
**Subsequent uses:** After every treatment, clean, disinfect and sterilize all the reusable parts and accessories, following the instructions provided in Chapter 06 - Cleaning, disinfection and sterilization.

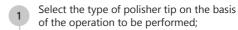
① **CAUTION:** Do not attempt to unscrew the cap of the powder container when it is under pressure.

(!) **CAUTION:** Make sure that the powder tank is perfectly dry.

The presence of moisture could case clogging of the channels.

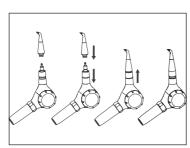
### 05.2 INSTRUCTIONS FOR USE





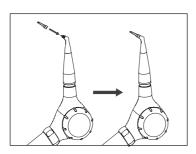
**CAUTION:** The subgingival perio tip can only be used with the perio polisher tip.





Take the Starjet, run the ferrule and maintain it in this position, insert the polisher tip fully to the home position and then release the handpiece ferrule;

⚠ WARNING: Before proceeding with successive operations, make sure that the polisher tip is inserted correctly, fully to the home position on the Starjet (the Starjet ferrule and the polisher tip must be in contact) and that the ferrule has returned to its initial position.



If the PERIO polisher tip has been chosen insert the subgingival perio tip in the front, pushing it until it stops.

⚠ **WARNING:** Make sure that the subgingival perio tip is correctly inserted fully home on the polisher tip; the two pieces must be in contact.

(!) **WARNING:** Use authentic Mectron accessories only.

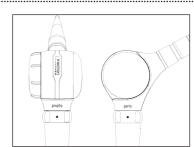
(!) **CAUTION:** Handle the front subgingival tip with care.

(!) **CAUTION:** Use only Glycine-based powder with the PERIO polisher tip.

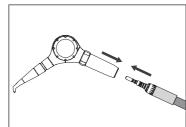
Select the desired "prophy" or "perio" function by turning the Starjet adjustment ring.

**"Prophy" function:** use Mectron Prophylaxis Powder;

**"Perio" function:** use specific glycine based powder.

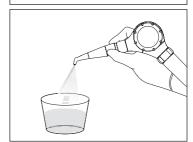


Connect Starjet to the turbine of the dental unit;



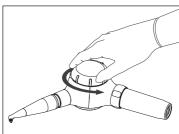
Adjust the water flow rate on your dental unit in order to obtain a steady stream of water. It is easier to adjust the flow rate without powder;





Unscrew the cap of the powder container;

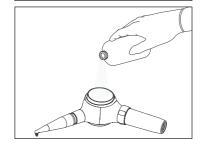


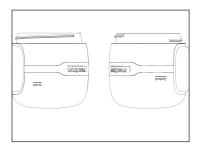


Pour the powder chosen for the particular application into the powder container.

① CAUTION: Do not use bicarbonatebased powder if the adjustment ring has been set to "perio".



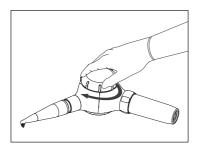




There are two maximum levels of powder shown on the powder container: one for the bicarbonate-based powder (prophy) and the other for the glycine-based powder (perio).

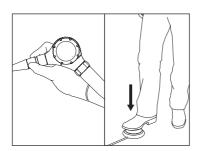
CAUTION: When filling the powder container with a bicarbonate-based powder do not exceed the "prophy" level indicated on the powder container.

① CAUTION: When filling the powder container with a glycine-based powder do not exceed the "perio" level indicated on the powder container.



Screw the cap of the powder container back on;

① **CAUTION:** Remove any residues of powder from the thread of the cap before screwing it on.



Press the turbine pedal to carry out the treatment:

(!) CAUTION: During the treatment use the suction cannula to evacuate the mixture of air/powder/water and water from the patient's mouth.

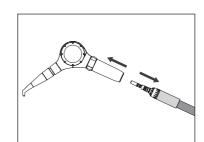
powder/water will continue for several seconds after removing your foot from the control pedal. Take these few extra seconds into account when finishing the treatment.

## 05.3 CLEANING THE POWDER CONTAINER

① **CAUTION:** The instructions described in this paragraph must be carried out every time the powder is changed from bicarbonate to glycine and before the cleaning, disinfection and sterilization procedures.

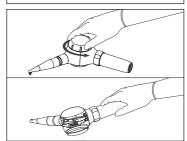
Disconnect Starjet from the turbine of the dental unit;





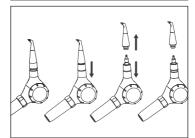
Unscrew the cap of the powder container and empty the powder container;





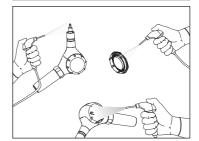
Take the Starjet, slide the ferrule and maintain it in this position, extract the polisher tip and then release the Starjet ferrule;

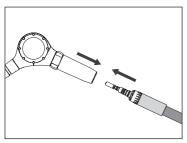


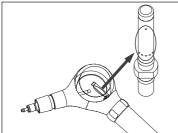


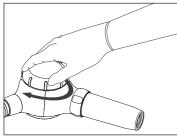
Blow compressed air into the powder container, on the cap and the handpiece connector cavity, so as to remove all powder residues;

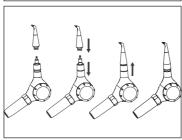


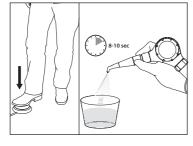












Connect Starjet to the turbine of the dental unit;

6 By using the brush supplied and while keeping the footpedal pressed, brush the 6 holes on the diffuser in the powder container.

**NOTE:** Pay attention to the water coming out of the Starjet.

Screw the cap of the powder container back on;

① **CAUTION:** Remove any residues of powder from the thread of the cap before screwing it on.

8 Take the Starjet, run the ferrule and maintain it in this position, insert the polisher tip fully to the home position and then release the handpiece ferrule;

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

# 06 CLEANING, DISINFECTION AND STERILISATION

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

① **CAUTION:** Methods not included in the table below must not be used.

① CAUTION: The cleaning, disinfection and sterilization 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 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 eliminated.

#### Starjet device

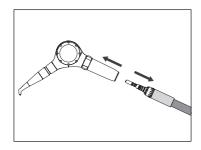
Phase	Paragraph	Procedure	
I	08.1	Preparation	
п	08.2	Manual cleaning with detergent solution and disinfecting	

## Accessories (Polisher tips, K9 wrench, needle for cleaning)

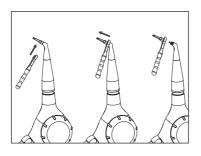
Phase	Paragraph	Procedure	Polisher tips	K9 wrench	Needle for cleaning
	08.4.1	Manual cleaning	Х	X	Х
IV	08.4.2	Combined cleaning manual/automatic	X	Х	
	08.4.3	Automatic cleaning	Х	Х	
V	08.5	Check cleaning	Х	X	Х
VI	08.6	Drying	Х	Х	Х
VII	08.7	Sterilisation	Х	X	Х

Particular information: Sterilization parameters, in steam autoclave, used in Great Britain: - temperature: 134° C , time: 3 minutes

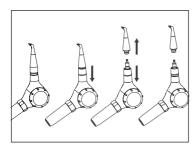
### **06.1 PREPARATION**



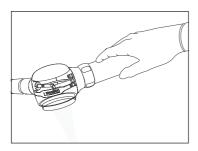
Disconnect Starjet from the turbine of the dental unit



Where the PERIO cleaner terminal has been used, remove the perio subgingival terminal using the K9 wrench supplied and then proceed to dismantling (Chapter 08); NOTE: Introduce the K9 wrench exactly into the position indicated in the figure.



Take the Starjet, slide the ferrule and maintain it in this position, extract the polisher tip and then release the Starjet ferrule;



Empty the Starjet device powder container by following the instructions provided in paragraph 05.3.

#### 06.2 CLEANING AND DISINFECTING STARJET DEVICE

The following procedure must be carried out on the Starjet device.

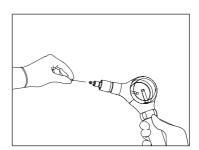
#### **MATERIALS NECESSARY**

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

#### **CLEANING METHOD**

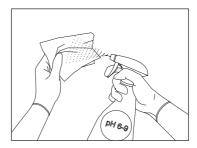
Free the channel of the Starjet from any powder residual by using the cleaning needle Ø 0,4 mm supplied.





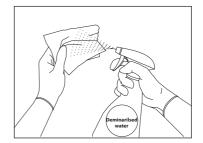
Clean the surface of the Starjet device with a clean, soft and low fibre release cloth, dampened with a cleaning solution (pH 6-9) prepared according to the manufacturer's instructions;

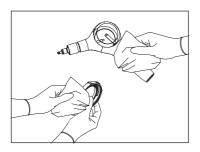




Clean the surface of the Starjet device with a clean, soft and low fibre release cloth, dampened with demineralised water to remove all residues of the cleaning solution;



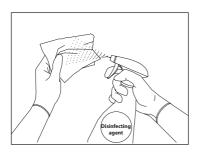






Dry the surface of the Starjet device with a clean, soft and low fibre release cloth;





If you wish to disinfect the device, vaporize the disinfectant agent (prepared according to the manufacturer's instructions) on a clean and soft cloth with low fiber release and clean the surface of the Starjet device.

- (!) CAUTION: Do not sterilize the Starjet device. It may stop working and cause damage to people and/or property.
- (I) CAUTION: The Starjet device is not protected against the penetration of liquids. Do not spray liquids directly on the surface of the Starjet device.
- (!) **CAUTION:** Do not immerse the Starjet device in liquids and/or various kinds of solutions as it could be damaged.
- (!) **CAUTION:** Do not immerse the handpiece in an ultrasonic basin.
- (!) **CAUTION:** Do not use running water to clean the Starjet device.

- (!) **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;
- Methylethylketone.

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:

- Polisher tips;
- · K9 wrench;
- · Cleaning needle.

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

(!) **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 monito-ring 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 tank;
- Clean, soft cloths with low fibre release;
- Brush with soft nylon bristles;
- 25 ml syringe;
- Demineralised water.

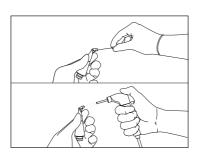
Prepare an enzymatic detergent solution\* with pH 6-9, as per the instructions of the manufacturer;

① **CAUTION:** Once used, dispose of the enzymatic detergent correctly, do not recycle it.





#### **POLISHER TIP**

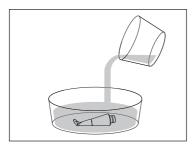


Free the polisher tip channel from any powder residual by using the supplied cleaning needle Ø 0,4mm for the front side and the supplied cleaning needle Ø 0,8mm for the rear side Blow compressed air into the central hole

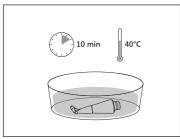
of the tip, from both ends;

(!) **CAUTION:** Clean the polisher tip channel exclusively using the cleaning needle supplied with the device.

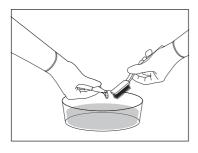
(I) CAUTION: If the subgingival perio tip is present on the polisher tip, remove it and dispose of it.



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



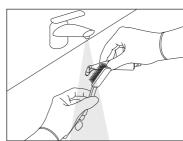
Let the polisher tip soak for 10 minutes at 40°C ±2°C. This procedure reduces the amount of blood, protein and mucous present on the polisher tip;



During immersion in the enzymatic solution, delicately brush the surface of the polisher tip 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 polisher tip under running water using the brush with soft nylon bristles;





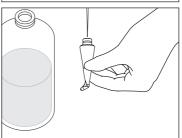
Using a syringe, inject the enzymatic detergent solution 3 times inside the cavity of the polisher tip to effectively remove the residues from the internal surface;





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





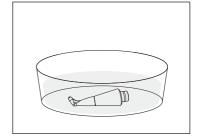
Place the polisher tip in the ultrasound tank submerged by the enzymatic detergent solution at 40°C ±2°C, for at least 10 minutes;

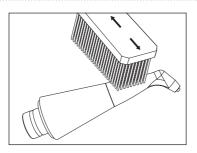




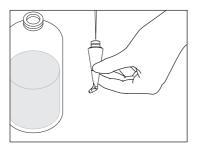
Remove the polisher tip from the ultrasonic tank and rinse with demineralised water;







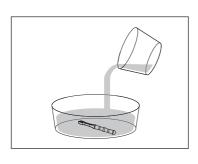
Delicately brush the surface of the polisher tip again using the brush with soft nylon bristles;



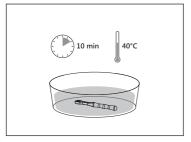
Using a disposable syringe (25 ml vol.) inject the demineralized water into the polisher tip cavity for at least 5 times in order to eliminate any detergent residue;

Process validated by independent bodies with enzymatic detergent.

#### **K9 WRENCH**



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



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;

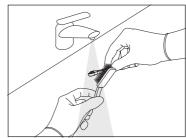
During immersion in the enzymatic solution, delicately brush the surface of the K9 wrench using the brush with soft nylon bristles to eliminate all traces of visible dirt. Thoroughly clean the difficult areas;





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





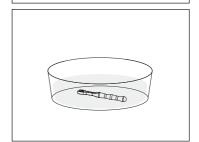
Place the K9 wrench in the ultrasound tank submerged by the enzymatic detergent solution at  $40^{\circ}\text{C}\ \pm 2^{\circ}\text{C}$ , for at least 10 minutes;





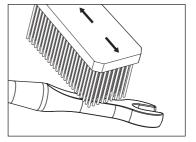
Remove the K9 wrench from the ultrasonic tank and rinse with demineralised water;



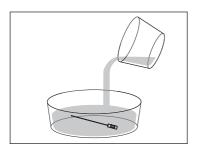


Delicately brush the surface of the K9 wrench again using the brush with soft nylon bristles;





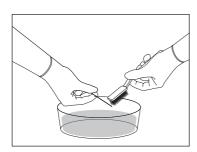
#### **CLEANING NEEDLES**



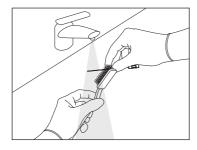
Place the cleaning needle horizontally in a clean container and add enzymatic detergent solution until the cleaning needle is covered completely;



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



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;



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

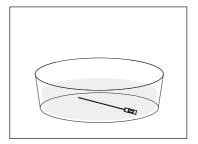
Place the cleaning needle in the ultrasound tank submerged by the enzymatic detergent solution at 40°C ±2°C, for at least 10 minutes;





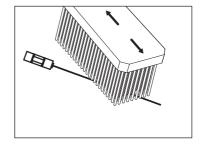
Remove the cleaning needle from the ultrasonic tank and rinse with demineralised water;





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



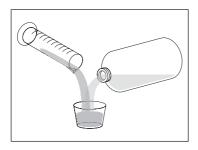


#### 06.3.2 COMBINED MANUAL/AUTOMATIC CLEANING

#### **MATERIALS NECESSARY**

- Enzymatic detergent (Mectron ENZYMEC, 0.8% v/v);
- Water:
- Container for immersion in the enzymatic
- Brush with soft nylon bristles;
- Disposable syringe 25 ml;
- Demineralised water;
- Alkaline detergent: neodisher® FA (0.2 % v/v);
- Neutralising liquid: neodisher® FA (0.1 % v/v):
- Metal basket;
- Thermal disinfector.

#### 06.3.2.1 MANUAL PRE-WASH

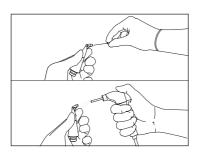




Prepare an enzymatic detergent solution\* with pH 6-9, as per the instructions of the manufacturer:

(!) **CAUTION:** Once used, dispose of the enzymatic detergent correctly, do not recycle it.

#### **POLISHER TIP**



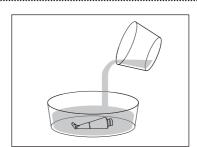
Free the polisher tip channel from any powder residual by using the supplied cleaning needle Ø 0,4mm for the front side and the supplied cleaning needle Ø 0.8mm for the rear side Blow compressed air into the central hole of the tip, from both ends;

(!) **CAUTION:** Clean the polisher tip channel exclusively using the cleaning needle supplied with the device.

(!) **CAUTION:** If the subgingival perio tip is present on the polisher tip, remove it and dispose of it.

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





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





Using a disposable syringe (25 ml vol.) inject the enzymatic detergent solution into the polisher tip cavity for at least 5 times:





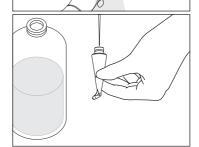
Delicately brush the surface of the polisher tip under running water (drinking water, temperature 20°C+/- 2°C), in particular the parts that are difficult to access (cavities, structured surfaces, etc.) using a brush with soft nylon bristles;

The polisher tip must be brushed until no residues can be seen (at least 30 seconds);



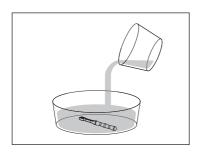
Using a disposable syringe (25 ml vol.) inject the cold demineralized water into the polisher tip cavity for at least 5 times;





Process validated by independent bodies with enzymatic detergent Enzymec (Mectron).

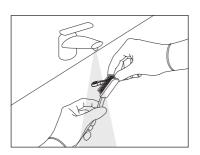
#### **K9 WRENCH**



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



21 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;



22 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);

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① **CAUTION:** The following mechanical cycle must always be preceded by the prewashing phase with enzymatic detergent.

① **CAUTION:** Avoid overloading the thermal disinfector as this could compromise cleaning effectiveness.

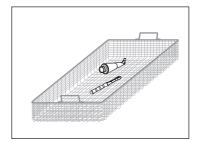
(!) **CAUTION:** Do not place the Starjet device in a thermal disinfector.

(!) **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;



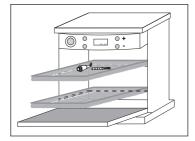


Sequence and parameters applicable to the cycle:

- 1 min, rinse with cold water;
- 5 min, wash with alkaline detergent at 55°C ±2°C;
- 2 min, neutralisation with suitable solution (1/3 cold water, 2/3 hot water);
- 1 min, rinse with water (1/3 cold water, 2/3 hot water);
- 5 min, thermal disinfection at 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 AO 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)

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#### 06.3.3 AUTOMATIC CLEANING

#### **MATERIALS NECESSARY**

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

() **CAUTION:** Do not place the Starjet device in a thermal disinfector.

(!) **CAUTION:** Do not place the cleaning needle in a thermal disinfector.

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

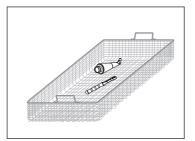
**NOTE:** Make sure that the accessories are appropriately blocked in the basket and cannot move during washing. Any movement during washing could damage them. Position the instruments in a way that the water can flow through all the surfaces, even internally.

(!) **CAUTION:** Before starting to clean

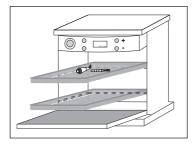
of dirt and, if necessary, perform a

pre-wash (paragraph 6.3.2.1) to avoid repeating the entire cleaning cycle.

the thermal disinfector, assess the entity



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



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)

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 suitable solution (1/3 cold water, 2/3 hot water);
- 1 min, rinse with water (1/3 cold water, 2/3 hot water);
- 5 min, thermal disinfection at 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 AO 3000.

### 06.4 CLEANING VERIFICATION

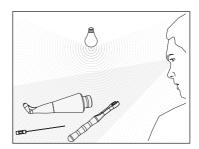
#### **MATERIALS NECESSARY**

- Light source;
- Magnifying glass 2.5X.

Once the cleaning operations have been completed, visually inspect the polisher tips, 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.





#### 06.5 DRYING

#### **MATERIALS NECESSARY**

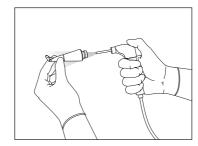
- Compressed air;
- Soft cloth with low fibre release.

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

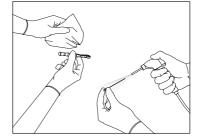
Dry the K9 wrench using a soft cloth with low fiber release.

Thoroughly dry all the cleaning needle parts by blowing compressed air on it.





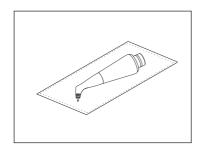


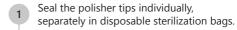


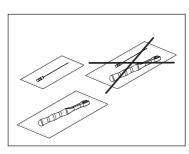
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#### 06.6 STERILISATION

#### **PREPARATION**







Seal the the K9 wrench and the cleaning needle individually, separately in disposable sterilization bags.

#### STERILISATION METHOD

The parts that can be sterilized are made with 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 sterilization process in a steam autoclave. The sterilization process validated by Mectron S.p.A., in a steam autoclave, guarantees SAL 10<sup>-6</sup> by setting the parameters indicated below:

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

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

**Minimum sterilization time:** 4 minutes

Minimum drying time: 10 minutes.

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

① **CAUTION:** Do not sterilize the Starjet device.

MARNING: Infection control Parts that can be sterilized - Diligently remove all residues of organic dirt before the sterilization.

① CAUTION: Perform the sterilization using a water steam autoclave only. Do not use any other sterilization procedure (dry heat, irradiation, ethylene oxide, gas, low temperature plasma, etc.).

(!) **CAUTION:** Do not exceed the allowed load of the steam steriliser.

## 07 MAINTENANCE

- If the air passage in the front terminal gets clogged, it is sufficient to switch on the device for a few seconds and to use the needles included in the supply (Fig. 5) to free the channel from any resides of powder.
- 2 If the front terminal gets clogged due to the 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 Starjet at least once a day.
- 4 Whenever the front terminal is removed, it 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 front terminal, so as to avoid the accumulation of residues of powder.
- 5 If the airway passage of the Starjet device gets clogged, use the cleaning needle supplied to clear the duct of powder residue.

#### 07.1 CHECK STARJET FRONT TERMINAL GRAFT

Periodically check o-rings' conditions on the front terminal graft.

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

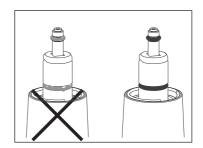
O-rings must always be in good conditions without the presence of residues of powder or cuts

#### **↑** WARNING: Controindications.

The front terminal can clog in case of broken, worn o-rings or powder residues.

# **⚠** WARNING: Exclusively use Mectron original accessories and spare parts.

In case of o-rings' usury or breakage, exclusively use the kit supplied by Mectron.



#### 07.2 CHECK TURBINE FAST GRAFT

Periodically check o-rings' conditions on the turbine fast graft.

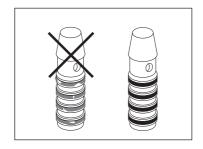
O-rings are useful to keep separate the outsourcings of powder and water separate.

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

#### **MARNING: Contraindications.**

Starjet 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:

- Polisher tips, 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 of in accordance to the local regulations in force concerning hospital wastes.

The Starjet must be disposed of 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.

# 09 TECNICHAL DATA

Apparatus in accordance with EEC Directive 93/42:	Class IIa
Apparatus for intermittent operation:	60 sec. ON - 10 sec. OFF
Standard water pressure provided by the dental unit for a turbine:	from 1 to 3 bar (from 1000 hPa to 3000 hPa) max 40°C.
Standard air pressure provided by the dental unit for a turbine:	2,0 - 3,0 bar (2000 hPa - 3000 hPa).
Operating conditions:	From +10°C to +35°C Relative humidity from 30% to 75% Air pressure P: 800hPa/1060hPa
Transport and storage conditions:	from -10°C to +35°C Relative humidity from 10% to 70% Air pressure P: 500hPa/1060hPa
Weights and sizes:	~ 155 g L - I - h ~ 200 x 90 x 50 mm Weight and sizes may vary depending on the various configurations

# 10.1 QUICK SOLUTION TO PROBLEMS

If the device doesn't appear to functioning properly, read the instructions once again and then 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 Starjet is connected to the turbine and the powder container is pressurised	Disconnect the Starjet from the turbine so as to depressurise the internal circuit
Leakage of	Cap not correctly screwed in place	Screw the cap on correctly
powder from the cap of the	The cap seal is not properly positioned in its place	Check the positioning of the cap seal
container	Residues of powder in the thread	Read point "06.1"
	Dental unit not connected to the air circuit	Check the connection between the dental unit and the air circuit
	The tank of the Starjet is empty	Read point "05.2"
No powder comes out of the front terminal of the	Front terminal polisher clogged due to excessive moisture in the powder or insufficient cleaning/maintenance	Read point "05.3" "06.1", "06.3", and "07.0". Remove the powder from the container and clean it with a dry cloth.
polisher during operation	The Starjet device duct is clogged due to an excessive amount of humidity in the powder or insufficient cleaning/maintenance	Read paragraph "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	Dental unit not connected to the water circuit	Check the connection between the dental unit and the water circuit
out of the front terminal of the	Water too hard	Read point "06.3 - 07.0"
polisher during operation	Water filter of dental unit clogged	Check the connection to the water circuit of the dental unit

Problem	Possible cause	Solution
	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")
Treatment ineffective	Front terminal of the polisher clogged by too much moister in the powder or insufficient cleaning/maintenance	Read point "05.3" "06.1", "06.3", and "07.0". Remove the powder from the container and clean it with a dry cloth.
	Water/powder flow is irregular and/or intermittent	Check the o-ring terminal cleaner insert (see paragraph 07.1)

# 10.2 SENDING THE DEVICE TO AN AUTHORISED MECTRON SERVICE CENTER

In the event that technical assistance is needed on the device, contact one of the Authorized Mectron Service Centers or your Retailer. 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 Authorized Mectron Service Center, following the instructions provided in the Chapter 06 - Cleaning, disinfection and sterilisation

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

The cleaning and sterilization requirements are in line with those in force concerning the safeguarding of health and safety in the workplace, as per Law Decree 626/94 and DLgs 81/08 and its subsequent amendments, both laws of the Italian State.

In the event that customer does not fulfill the requirements, Mectron reserves the right to charge him or her for the cleaning and sterilization 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

## ① CAUTION: Package

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

Once the material has been received by the Authorized Mectron Service Center, 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 Authorized Mectron Service Center or your retailer.

Unauthorized 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

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

Mectron provides a warranty on all new Starjet purchased from a retailer or a Mectron 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, Mectron commits itself to repair (or at its own free choice, replace) those product parts that were to proved defective according to its judgment, free of charge.

Entire replacement of the Mectron 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 of the instructions and precautions described and outlined in this manual.
- The electrical system in which the device is used is not compliant to electrical code compliance standards and to the relative precautions.

- The assembly operations, extensions, adjustments, updates, and repair works are performed by personnel not authorized by Mectron.
- 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-authentic Mectron inserts, accessories, and spare parts that can compromise correct device operation and cause harm to the patient.
- Accidental breakage due to transport
- Damages due to incorrect use or negligence, or to connection to a power voltage other than the one required
- Warranty expiration

**NOTE:** The warranty is valid only if the warranty sheet annexed to the product has been filled out in all its parts, and sent to our offices or possibly to the retailer or Mectron importer within 20 (twenty) days 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/Mectron 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 Authorized Mectron Service Center.

The indications that appear in this publication are not binding and 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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