mectron
medical technology

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COMPACT PIEZO LED

USE AND MAINTENANCE MANUAL

CE
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ES	Este documento y las respectivas traducciones están disponibles en el sitio web “manuals.mectron.com”. Utiliza el código QR para acceder al sitio web. En referencia a las instrucciones para uso (eIFU), es necesario disponer de un software de lectura de archivos PDF, por ej. Adobe Reader. Si desea las instrucciones para uso en formato impreso, rellene completamente el formulario de la última página y envíelo a la dirección indicada. El manual impreso de las instrucciones para uso se le enviará gratuitamente antes de siete días.
ET	See dokument ja selle tõlked on saadaval veebisaidil manuals.mectron.com. Saidile pääsemiseks kasutage QR-koodi. Elektroonilise kasutusjuhendi (eIFU) vaatamiseks on vajalik PDF tarkvara, nt Adobe Reader. Kui Te peaksite soovima trükitud kasutusjuhendit, siis täitke palun täielikult vastav formular viimasel lehel ja saatke see nimetatud adressile. Me saadame Teile siis tasuta trükitud kasutusjuhendi 7 päeva jooksul.
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LT	Šis dokumentas ir jo vertimai pateikiami svetainėje „manuals.mectron.com“. Norėdami atidaryti svetainę, naudokite QR kodą. Elektroninei naudojimo instrukcijai (eIFU) matyti reikalinga PDF programinė įranga, pavyzdžiui Adobe Reader. Jeigu pageidautumėte spausdintinės naudojimo instrukcijos versijos, užpildykite visą paskutiniame puslapyje esančią formą ir nusiųskite nurodytu adresu. Per 7 dienas mes Jums nemokamai atsiųsime spausdintinę naudojimo instrukcijos versiją.
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1 INTRODUCTION

This manual applies to the following medical devices:

- COMPACT PIEZO LED (referred to as "device" in the text)
- SLIM SCALER HANDPIECE (referred to as "accessory/ies" in the text)
- Inserts
- Torque wrench

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

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

Depending on the level of severity, the safety requirements are classified with the following indications:

⚠ **WARNING**: Always referred to damage to persons

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

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

- check for any available updates in the *MANUALS section of the MECTRON website*[1];
- ask clarifications to Your Dealer;
- contact MECTRON After Sales Service.

1 http://mectron.it/en/technical-support/users-manuals/

1.1 Intended Use

⚠ **WARNING**: **Intended use.** Use the device and its accessories only for the intended purpose for which they are designed. Failure to comply with this requirement may cause serious injury to the patient, the operator, and damage/malfunction to the device.

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» **PIEZOELECTRIC ULTRASONIC SCALER**

With the appropriate inserts it is possible to perform the following treatments:

- **Scaling**: all the procedures for the removal of deposits of bacterial plaque and supragingival, subgingivali and inter dental stones, and removal of stains;
- **Periodontics**: periodontal therapy for scaling and root-planing/debridement, including cleaning and irrigation of the periodontal pocket;
- **Cleaning treatment of the implant surface**;
- **Endodontics**: all treatments for canal preparation, irrigation, filling, gutta-percha condensation, endodontic reprocessing and retrograde cavity preparation;
- **Restorative and prosthesis**: preparation of the cavities and removal of caries, removal of the prosthesis and of restoration materials in excess, condensation of the amalgam, finishing of the prosthetic stump.

» **SLIM SCALER HANDPIECE**

The SLIM scaler handpiece is a medical accessory device for a piezoelectric ultrasound scaler. With the appropriate inserts, the following treatments can be performed:

- **Scaling**: all procedures for the removal of bacterial plaque deposits and supragingival, subgingival, and interdental stones, and removal of stains;
- **Periodontology**: periodontal root planing and debridement therapy, including cleaning and irrigation of the periodontal pocket;
- **Cleaning treatment of the implant surface**;
- **Endodontics**: all treatments for root canal preparation, irrigation, filling, gutta-percha condensation, endodontic reprocessing and retrograde cavity preparation;
- **Restorative and prosthetics**: cavity preparation and removal of carious tissue, removal of prosthetics and excess restoration materials, amalgam condensation, finishing of prosthetic stump.

1.2 Description of the Device

COMPACT PIEZO LED is a multi-purpose piezoelectric ultrasonic scaler.
It is designed to equip the operator with a product featuring an innovative design and unique technical characteristics, and to ensure utmost patient comfort during treatment thanks to a broad scale of available power levels.
The device is equipped with an automatic tuning circuit that optimises power and frequency for each insert available, in order to always operate in conditions of maximum efficiency.
The handpiece is equipped with a 360° adjustable LED light and is autoclavable at a maximum temperature of 135°C for up to 20 minutes.

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

⚠ **WARNING: Qualified and specialist personnel.** The device and its accessories must be used exclusively by specialised personnel with appropriate medical knowledge. No specific training is required for the use of the device. The device and its accessories produce no side effects when used correctly. Improper use is manifested by the transfer of heat to the tissues.

1.2.1 Eligible Patient Group

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

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

This medical device can be used on patients of any age, weight, height, gender, and nationality, where applicable.

1.2.2 Patient Selection Criteria

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

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

All piezoelectric ultrasonic scaler device models are intended for professional use only. The user is therefore the only person able to decide if and how to treat their patients.

1.2.3 Indications for Use

Use of the device is suitable for all eligible patients (see *Chapter 1.2.1 on page 3*) whose doctor has prescribed professional scaling, periodontology, endodontic cleaning, implant site surface cleaning, a restorative or prosthetic technique, as part of the intended use of the device (see *Chapter 1.1 on page 2*).

1.2.4 Users

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

1.2.5 Operating Environment

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

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1.3 Disclaimer

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

- Misuse or use during procedures other than those specified in the destination of use of the product;
- The environmental conditions for preservation and storage of the device are not complying with the requirements indicated in *Chapter 9 on page 35*;
- The device is not used in accordance with all the instructions and requirements described in this manual;
- The electrical system of the places where the equipment is used do not comply with the laws in force and the related regulations;
- Assembly operations, extensions, re-adjustments, upgrades and repairs of the device are carried out by personnel not authorised by MECTRON;
- Misuse, abuse, abnormal use, negligent use, intentional misconduct or use exceeding the limits of the device indicated and allowed and/or normal wear or deterioration, ill-treatment and/or incorrect interventions;
- Any attempt to tamper with or modification of the device under every circumstance;
- Use of non original MECTRON inserts resulting in permanent damage to the thread of the handpiece with impaired functioning and risk of injury to the patient;
- Use of non original MECTRON inserts used in accordance with the settings designed and tested on the original MECTRON inserts. Correct use of the settings is only guaranteed with original MECTRON inserts;
- Shortage of stock material (handpiece, inserts, wrenches) to be used in case of a standstill due to faults or problems;
- Incorrect/omitted maintenance compared to what is stated in *Chapter 7 on page 34* of this manual;
- Breach of the requirements and the information contained in *Chapter 4.5 on page 16* of this manual;
- Breach of the requirements and the information contained in *Chapter 6 on page 19* of this manual;
- Unauthorised repairs in accordance with the indications contained in *Chapter 10.2 on page 45* this manual.

1.4 Safety Requirements

⚠ **WARNING**: **Contraindications.**
Do not use the device on patients with Pacemakers or other implantable electronic devices. This regulation also stands for the operator.

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

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

⚠ **WARNING**: **Contraindications.**
Interference from other equipment.
An electrosurgical scalpel or other electrosurgical units positioned near the COMPACT PIEZO LED device may interfere with the correct operation of the device itself.

⚠ **WARNING**: **Contraindications.**
Interference with other equipment.
Even if compliant with standard IEC/EN 60601-1-2, COMPACT PIEZO LED and related accessories may interfere with other devices in the vicinity. COMPACT PIEZO LED must not be used near with other appliances. However, if deemed necessary, the proper functioning of the device in that configuration must be checked and monitored.

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

⚠ **CAUTION**: In case the final user, operating in their own medical room or surgery, in order to comply with mandatory requirements, must periodically inspect the equipment present in the surgery, the test procedures to apply to medical electrical equipment and medical electrical systems for the safety assessment must be carried out following the standard IEC/EN 62353 'Medical electrical equipment - Periodic inspections and tests to be carried out after repair of medical electrical equipment'. The frequency of periodic inspections in the intended conditions of use described in this "Use and Maintenance" manual is once per year or every 2000 hours of use, whichever condition is satisfied first.

⚠ **CAUTION**: The electrical system of the premises in which the device is installed and used must comply with the rules in force and the relevant requirements of electrical safety.

⚠ **WARNING**: **Cleaning and sterilising new or repaired instruments.** All the new or repaired device components are not sterile. At first use and after each treatment they must be cleaned and sterilised by carefully following the instructions in *Chapter 6 on page 19*.

⚠ **WARNING**: **Infection control.**
For maximum patient and operator safety, before using all the parts and reusable components, make sure they have been previously cleaned and sterilised by following the instructions in *Chapter 6 on page 19*.

⚠ **CAUTION**: **Contraindications.** After having autoclaved the handpiece, inserts, torque wrench or any other sterilisable components/accessories, wait for them to completely cool down before reusing them.

⚠ **WARNING**: **Insert Breakage and Wear.**
High frequency oscillations and wear can, in rare cases, lead to the breakage of the insert. Deformed or damaged inserts are susceptible to breakage during use. Broken or worn inserts must not ever be used.
In the event of breakage check that no fragments remain in the treated part and at the same time use suction effectively to remove them.
It is necessary to instruct the patient to breathe through the nose during the treatment, or use a dental dam, so as to

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avoid to ingest fragments of broken inserts.
Check the state of wear of the insert and its integrity before and during each use.
If a drop in performance occurs, see to its replacement.
The state of wear of the most common inserts (S1, S1-S, S2, S5, P2, P4, P10) can be checked using the supplied INSERT-CARD.
To use the INSERT-CARD correctly:

- Position the insert on the INSERT-CARD so that the profile corresponds to the one printed on the card. The printed profile on the card has a red line indicating the limit of wear;
- If the insert is shorter than the limit of wear, its performance will be significantly inferior compared to that of a new insert, and should therefore be replaced.

If the layer of titanium nitride (gold-plated surface), where present, is visibly worn, the insert must be replaced. The use of a worn insert reduces its efficiency.
Diamond Inserts: diamond inserts must be replaced when the layer of titanium nitride is visibly worn and in any case after a maximum of 10 treatments.
When the nitriding is consumed, the cutting edge loses effectiveness; a possible regrinding harms the insert, therefore it is prohibited. Verify that the insert is not worn.
During the operation frequently check that the insert is intact, especially in the apical part.
During the operation avoid prolonged contact with the retractor or with metal instruments in use. Do not exert excessive pressure on the inserts during use.

⚠ **WARNING**: **Exclusively use original MECTRON inserts, components and spare parts.**

⚠ **CAUTION**: No modification is allowed to this device and related components/ accessories.

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

1.5 Symbols

Symbol	Description	Symbol	Description
CE 0051	Device compliant with Regulation (EU) 2017/745. Notified body: IMQ S.p.A.	c N US Electrical Safety ES 60601-1	Nemko brand Compliance with UL - CSA regulations
MD	Medical device		Caution
	Date of manufacture		Manufacturer
LOT	Batch number	SN	Serial number
UDI	Unique Device Identifier	REF	Product code
HIBC	Health Industry Bar Code	#	Model number
	Distributor		Consult instructions for use or consult electronic instruction for use
QTY.1	Quantity in package: 1		Temperature limits
NON STERILE	Non sterile	135°C	The sterilisable materials must be autoclaved and can resist up to a maximum temperature of 135°C
	"B" Part applied		Hazardous voltage
	Alternating current		Continuous current
	Generic warning signal [a]		Separate collection for waste of electrical end electronic equipment.
	Atmospheric pressure limits	%	Moisture limits

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Symbol	Description	Symbol	Description
	Keep dry		Fragile
Rx Only	For US market only **CAUTION:** Federal (US) law restricts the marketing of this device to prescription or licensed practitioner.		

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

2 IDENTIFICATION DATA

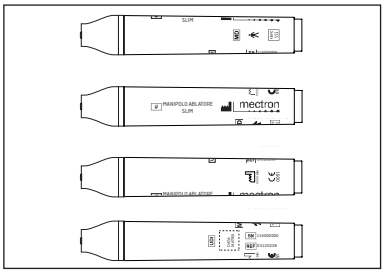
A correct description of the model and of the serial number of the device and its accessories will allow the After Sales Service to provide fast and effective answers.

Always provide this information every time that you contact MECTRON After Sales Service.

2.1 Scaler Handpiece Identification Data

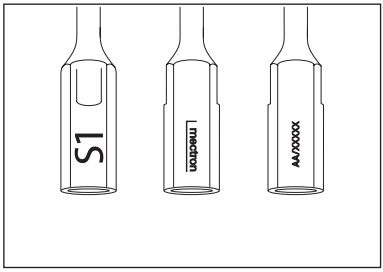
Each handpiece is laser-marked with the traceability data, UDI code included.

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



2.2 Inserts Identification Data

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



3 DELIVERY

3.1 List of Components

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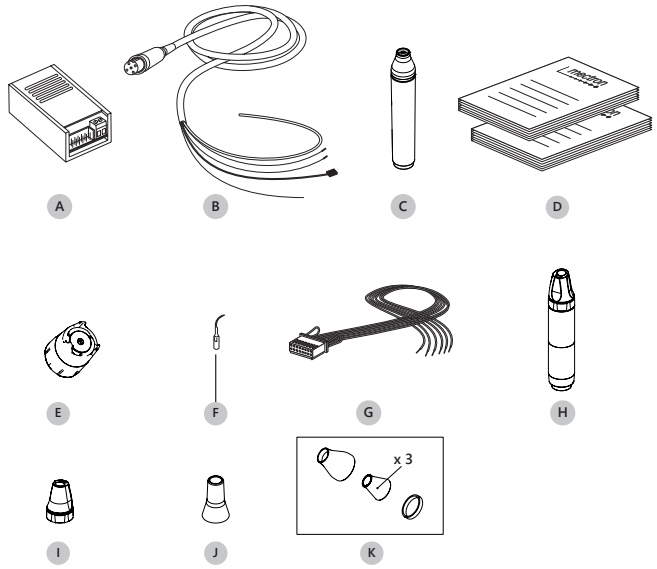
See figure below.
COMPACT PIEZO LED is supplied with the standard equipment, a set of variable components depending on the configuration and client requests, and components that can be ordered separately.

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

The packaging of the device cannot undergo strong impacts as contains electronic components, therefore the transport and the storage must be carried out with particular care..

All the material sent by MECTRON was controlled at the time of dispatch.
The device is shipped appropriately protected and packaged.
Upon receipt of the device, check for any possible damage caused during transport and in case any damage and/or defects is found, complain to the transporter.
Keep the packaging in case any items need to be sent to an Authorised MECTRON Service Centre and to store the device during long periods of non-use.

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



Basic Equipment		
Ref.	**Item**	**Note**
A	Device core unit	
B	Cord	
C	MANIPOLO ABLATORE SLIM	Slim Scaler Handpiece
D	Use and Maintenance Manual, Installation Manual, Online Documentation	

Components		
Ref.	**Item**	**Note**
E	K10 Torque wrench	
F	Inserts	
G	Wirings	
H	MANIPOLO ABLATORE LED	Led Scaler Handpiece
I	Front cone for LED handpiece	
J	Front cone no light for LED handpiece	
K	Light guide kit	Front cone, light guide and decorative ring for Slim scaler handpiece

4 USE

4.1 Controls

EN

COMPACT PIEZO LED offers a very broad power range: from a subgingival perio treatment in soft mode to more aggressive scaling. The description of the available commands to control COMPACT PIEZO LED is available in the manual supplied by the manufacturer of the dental unit on which it is installed.

4.2 Power On/Off

To switch COMPACT PIEZO LED and the relative LED light positioned on the top of the handpiece on and off, consult the manual supplied by the manufacturer of the dental unit on which it is installed.

4.3 Safety Requirements Before and During Use

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

⚠ **WARNING**: **Exclusively use original Mectron inserts, components and replacement parts.**

⚠ **WARNING**: **Use of non-original inserts not produced by MECTRON**: this entails permanent damage to the thread of the handpiece and compromises correct operation with the risk of causing harm to the patient.

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

⚠ **WARNING**: **Contraindications.** Do not use COMPACT PIEZO LED on patients with Pacemakers or other implantable electronic devices. This regulation also stands for the operator.

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

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

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

⚠ **WARNING**: **Infection control. First use:** All parts and reusable accessories (new or returned from an Authorised MECTRON Service Centre) are delivered in NON-STERILE conditions and must be treated before each use, according to the instructions provided in *Chapter 6 on page 19*. **Subsequent uses:** After each treatment, clean and sterilise all parts and reusable components according to the instructions in *Chapter 6 on page 19*.

⚠ **CAUTION**: For correct use of the device, the pedal must be pressed and the device started with the insert not in contact with the part to be treated, so that the electronic circuit is able to recognise the best point of resonance of the insert without interference, thus allowing optimum performance.

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

⚠ **WARNING**: Do not change the insert whilst the handpiece is in operation in order to avoid causing injury to the operator.

⚠ **WARNING**: **Insert Breakage and Wear.** High frequency oscillations and wear can, in rare cases, lead to the breakage of the insert. Deformed or damaged inserts are susceptible to breakage during use. Broken or worn inserts must not ever be used.
In the event of breakage check that no fragments remain in the treated part and at the same time use suction effectively to remove them.
It is necessary to instruct the patient to breathe through the nose during the treatment, or use a dental dam, so as to avoid to ingest fragments of broken inserts.
Check the state of wear of the insert and its integrity before and during each use.
If a drop in performance occurs, see to its replacement.
The state of wear of the most common inserts (S1, S1-S, S2, S5, P2, P4, P10) can be checked using the supplied INSERT-CARD.
To use the INSERT-CARD correctly:

- Position the insert on the INSERT-CARD so that the profile corresponds to the one printed on the card. The printed profile on the card has a red line indicating the limit of wear;
- If the insert is shorter than the limit of wear, its performance will be significantly inferior compared to that of a new insert, and should therefore be replaced.

If the layer of titanium nitride (gold-plated surface), where present, is visibly worn, the insert must be replaced. The use of a worn insert reduces its efficiency.
Diamond Inserts: diamond inserts must be replaced when the layer of titanium nitride is visibly worn and in any case after a maximum of 10 treatments.
When the nitriding is consumed, the cutting edge loses effectiveness; a possible regrinding harms the insert, therefore it is prohibited. Verify that the insert is not worn.
During the operation frequently check that the insert is intact, especially in the apical part.
During the operation avoid prolonged contact with the retractor or with metal instruments in use. Do not exert excessive pressure on the inserts during use.

⚠ **CAUTION**: **Contraindications.** After autoclaving the handpiece, the inserts, the torque wrench, or any other sterilisable component, wait until it has completely cooled before reuse.

⚠ **CAUTION**: **The electrical contacts inside the connectors on the handpiece and cord must be dry.** Before connecting the handpiece to its cord, make sure that the electrical contacts of the connector on both sides are perfectly dry, especially after the sterilisation cycle in an autoclave. If necessary dry the contacts by blowing them with compressed air.

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

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

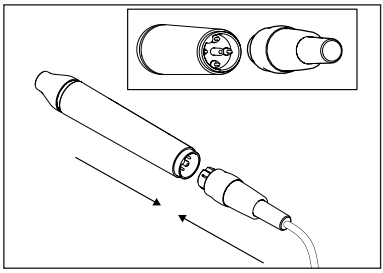
⚠ **WARNING**: **Infection control.** After prolonged non-use of the dental unit, run a water circuit cleaning cycle as indicated in the user manual supplied by the manufacturer of the dental unit.

EN

4.4 Instructions for Use

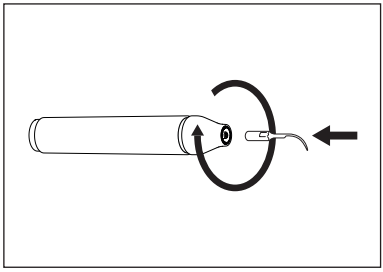
1

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



2

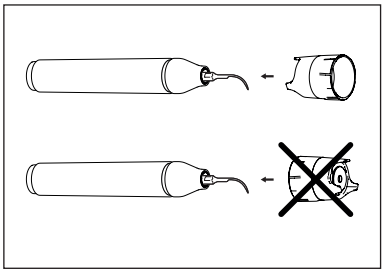
Screw in the preselected insert on the COMPACT PIEZO LED handpiece until it comes into contact



3

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

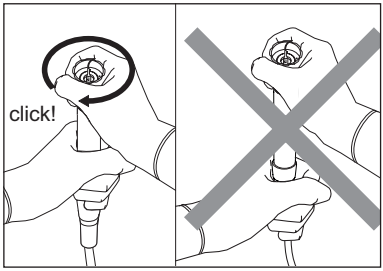
- Place the insert inside the MECTRON torque wrench as shown in the figure;



4

- Firmly grip the body of the handpiece;

⚠ **CAUTION**: Do not grab the handpiece by the nozzle and/or by the cord. Firmly hold the body of the handpiece and rotate only the torque wrench. Do not rotate the body during tightening.

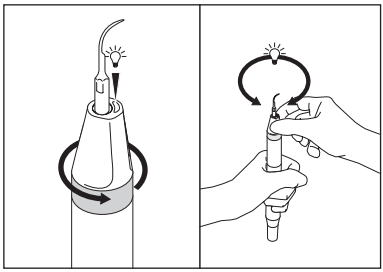


- Turn the torque wrench in a clockwise direction until the notch clicks (the external body of the torque wrench turns with respect to the body of the handpiece, emitting mechanical sounds);
- The insert is now optimally locked;

5

The position of the LED light on the nose cone of the MANIPOLO ABLATORE LED can be adjusted as follows:

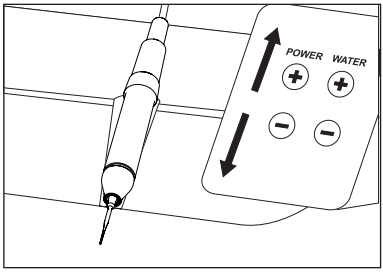
- Grip the handpiece body and slightly unscrew the metal ring at the base of the nose cone by turning it counter-clockwise;
- rotate the nose cone so that the LED light is in the desired and necessary position;
- to fix the position screw the metal ring in a clockwise direction.



5

Select the desired power and irrigation level based on the instructions provided by the manufacturer of the dental unit.

NOTE: Activate the WATER function to perform a treatment requiring irrigation, and deactivate it to perform a treatment that does not require irrigation.



7

Activate the COMPACT PIEZO LED.

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

4.5 Important Information on the Inserts

EN

⚠ **WARNING**:

- Before using the sterilised insert, check the integrity of the sterile packaging and inspect the product to ensure there is no damage. The insert will no longer be sterile if the packaging is broken or damaged. If the packaging is damaged, the insert MUST be sterilised again before use.
- Before starting to work, properly tighten the insert to the handpiece using the torque wrench.
- When the layer of titanium nitride is visibly consumed the insert must be replaced. The use of an insert too worn decreases its efficiency.
- Diamond Inserts: diamond inserts must be replaced when the layer of titanium nitride is visibly worn and in any case after a maximum of 10 treatments.
- Do not activate the handpiece while the insert is in contact with the part to be treated so that the electronic circuit can recognise the best point of resonance of the insert allowing optimum performance.
- Check the state of wear of the insert and its integrity before and during each use. If you experience a loss of performance provide for its replacement.
- Use only original Mectron inserts. The use of non-original inserts will void the warranty and damage the thread of the multipiezo handpiece, with the risk of no longer being able to correctly screw in the original inserts for subsequent use. In addition, the machine settings are tested and guaranteed for correct operation using only original Mectron inserts.
- Do not change in any way the shape of the insert, by bending it or filing it. This could cause it to break.
- Do not use an insert that has undergone deformation of any type.
- Do not attempt to sharpen an insert used.
- Always check that the threaded parts of the insert and the handpiece are perfectly clean - See *Chapter 6 on page 19* - Cleaning and sterilisation.
- Excessive pressure applied to the insert can cause it to break and potentially injure the patient.
- The Mectron inserts vibrate with longitudinal oscillation, with a back and forward movement. During the treatment, always keep the instrument in a tangential direction with respect to the surface of the tooth. Move the handpiece back and forward, applying slight side pressure.
- Do not point the instrument directly onto the surface of the enamel or implant. Position the tip/operating part only in a tangential direction with respect to the surface of the tooth or implant.
- The insert must be held in constant movement. If the insert is blocked it may cause overheating of the treated part. It is recommended to use continuous motions to minimise contact between the tip and the part. Do not block them against the tissues so as not to cause their overheating. It is advisable to increase the level of irrigation as the power level increases.

- Leave the ultrasonic vibrations to work, do not exert excessive pressure on the inserts during use. Apply slight force on the insert for optimum performance.
- When the insert is used in interproximal spaces, do not block the instrument or leverage on the operating part. The inserts must be left free to vibrate.
- In endodontic root canal therapy, never operate the files outside of the root canal to prevent them from breaking.

To prevent breakages, create a smooth path with a manual endo file and plan the most direct possible path of access to minimise any bending of the insert. Make delicate movements. Examine the file often for signs of wear. If the file breaks inside the canal, avoid contact between the instrument and the broken file to stop it from being pushed further it. Do not apply pressure on the insert in an axial direction.

EN

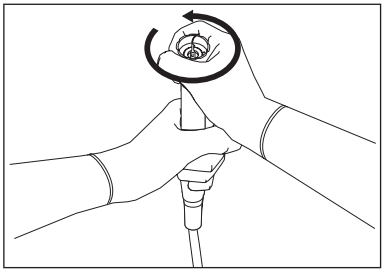
5 DISASSEMBLING PARTS FOR CLEANING AND STERILISATION

Before carrying out the cleaning procedures described in *Chapter 6 on page 19*, disconnect all accessories and components of the COMPACT PIEZO LED.

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

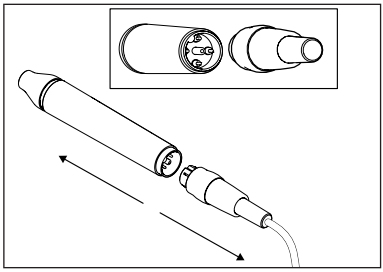
1

If present, remove the insert from the handpiece using the torque wrench;



2

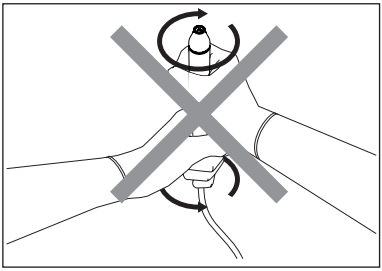
Disconnect the handpiece from the relative cord;



EN

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

3

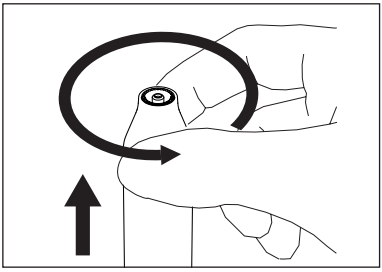


4

Unscrew the nose cone from the handpiece.

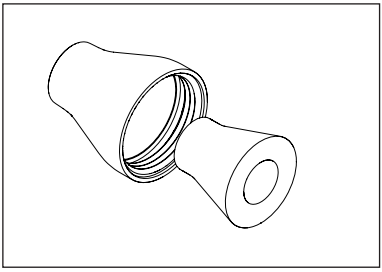
⚠ **CAUTION:** The nose cone has a light pipe. If the nose cone is unscrewed, the light pipe will no longer be held in place and may slide and be disconnected. Be careful not to lose the light pipe.

NOTE: On the Front cone for LED scaler handpiece, the metal ring cannot be separated from the plastic cone.



5

Remove the light pipe from the nose cone.



6 CLEANING AND STERILISATION

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

⚠ **CAUTION:** To disinfect the device components, it is recommended to use water-based disinfectant solutions, with neutral pH (pH 7).

DO NOT USE as disinfectant agents:

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

as they can discolour and/or damage the materials of the device and its components.

The manufacturer assumes no responsibility for damage caused by the substances indicated above. In case of damage caused by these substances, it will not be possible to make use of the Guarantee.

EN

6.1 Cleaning the Sterilisable Components

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

The sterilisable parts of the device are:

- Scaler handpiece;
- Scaler nose cone;
- Inserts;
- Inserts tightening wrench.

Before proceeding with operations to check cleanliness (*Chapter 6.2 on page 30*), drying and lubrication (*Chapter 6.3 on page 31*) and then sterilisation (*Chapter 6.4 on page 32*), one of the two possible cleaning methods explained in detail in the following chapters must be selected.

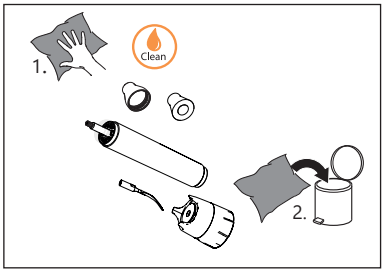
⚠ **CAUTION**: The instructions supplied below have been validated by the manufacturer of the medical device as ABLE to prepare a medical device for re-use. The process manager is responsible for ensuring that the processes repeated are effectively performed using the equipment, materials and staff in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

6.1.1 Pre-Cleaning

After having observed the indication provided in the *Chapter 5 on page 17*, proceed as follows:

1

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



EN

6.1.2 Manual Cleaning

Manual cleaning can be carried out as an alternative to the automatic cleaning described in *Chapter 6.1.3 on page 28*.

» **REQUIRED MATERIALS**

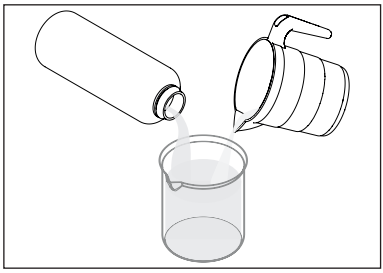
- Enzymatic detergent at pH 6-9;
- Water;
- Container for immersion in the enzymatic liquid;
- Ultrasonic tank;
- Clean, soft, low-lint cloths;
- Brush with soft nylon bristles;
- Syringe;
- Demineralised water

» **PROCEDURE**

1

Prepare a solution of enzymatic detergent [a] with pH 6-9, according to the instructions of the manufacturer (preferably use tap water).

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



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

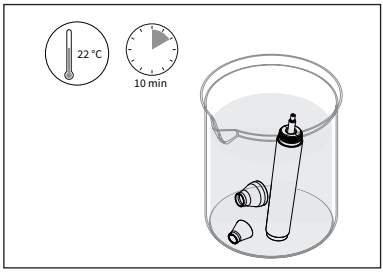
EN

6.1.2.1 Scaler Handpiece

2

Completely immerse the scaler handpiece, nose cone, and light pipe in the enzymatic solution [a],. Leave to soak for 10 minutes at 22 °C ±2 °C;

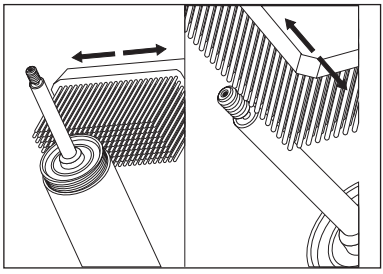
a) Process validated by independent bodies with ENZYMEC enzymatic detergent, 0.8% v/v.



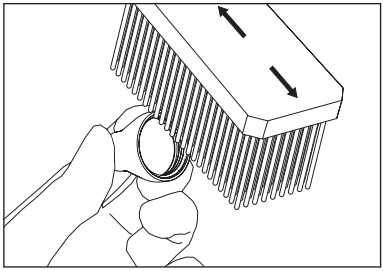
3

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

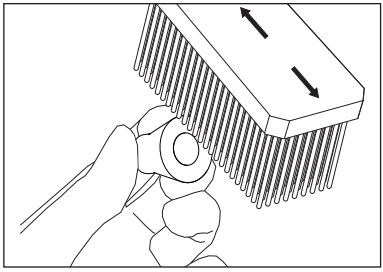
- thread of the scaler handpiece;
- titanium shaft;



- external and internal parts of nose cone;



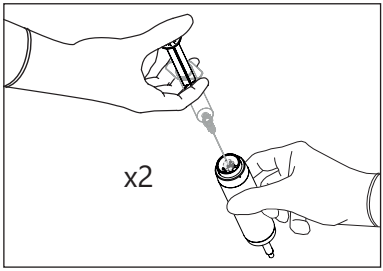
- external and internal parts of light pipe.



EN

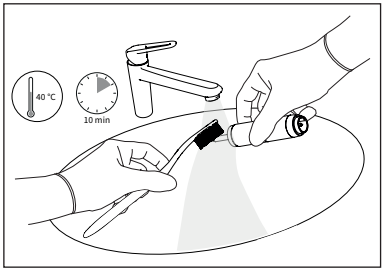
4

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



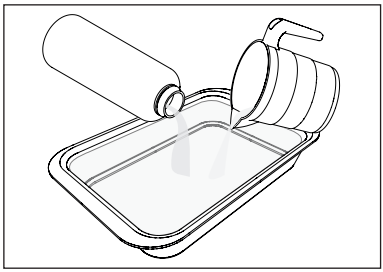
5

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



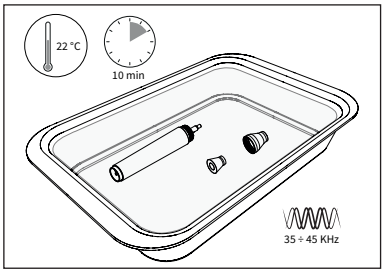
6

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



7

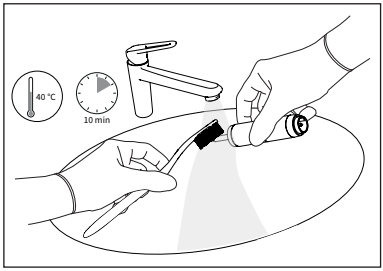
Place the scaler handpiece, nose cone, and light pipe in the ultrasonic tank immersed in the enzymatic detergent solution at 22 °C ±2 °C and run a cycle for at least 10 minutes;



EN

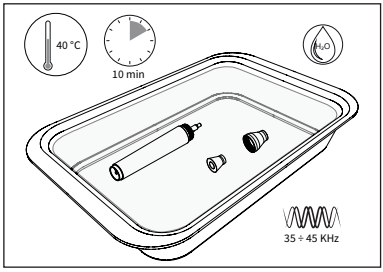
8

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



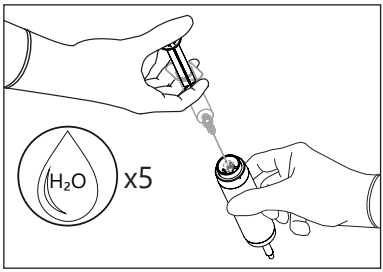
9

Place the scaler handpiece, nose cone, and light pipe in the ultrasonic tank immersed in demineralised water at 40 °C ±5 °C and run a cycle for at least 10 minutes;



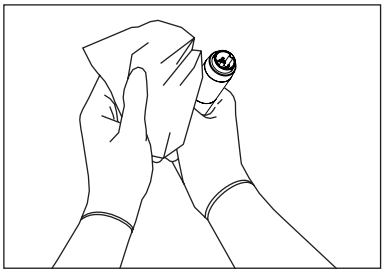
10

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



11

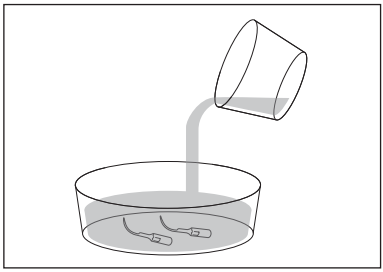
Dry the surface of the scaler handpiece, nose cone, and light pipe with a clean, non-abrasive, low-lint cloth.



6.1.2.2 Inserts

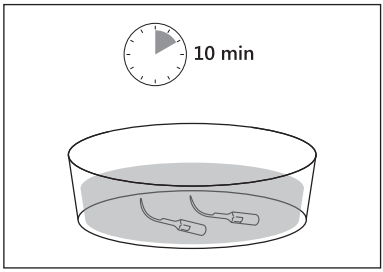
12

Place the insert in a clean container, add enough solution to the container to cover the insert.



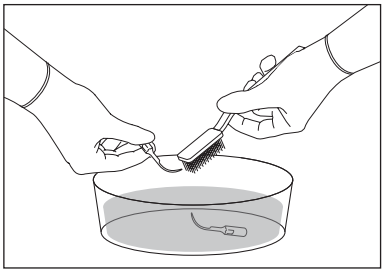
13

Leave to soak in the enzymatic cleaner solution for at least 10 minutes.
This process reduces the amount of blood, proteins and mucus present on the insert;



14

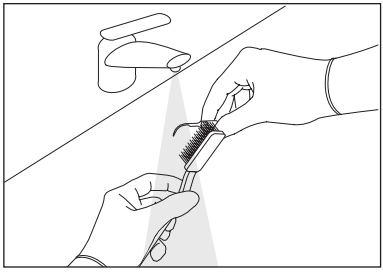
During immersion in the enzymatic solution, delicately brush the surface of the insert using a brush with soft nylon bristles to eliminate all traces of visible dirt.
Use a clean, soft nylon bristle brush for exterior surfaces, a clean, soft nylon bristle brush for interior cavities and crevices.
Thoroughly clean difficult areas such as the cutting edges and in particular the spaces between the cutting edges.



15

Remove the device to be cleaned from the enzymatic cleaning solution.

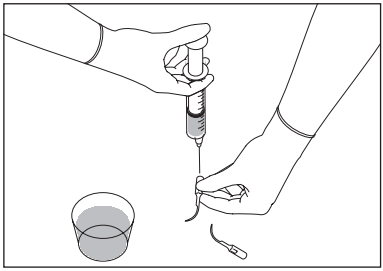
Rinse the insert under running water and brush the device with a clean soft nylon bristle toothbrush for at least 1 minute.
Repeat this procedure until all visible dirt is eliminated.



EN

16

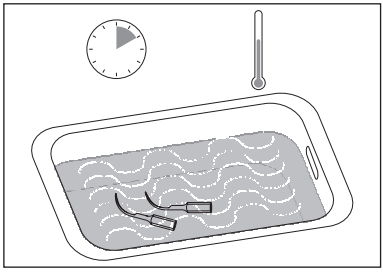
With a syringe (min. 20 ml) inject the enzymatic detergent solution three times into the cavity of the insert to effectively remove residues from the internal surface.



17

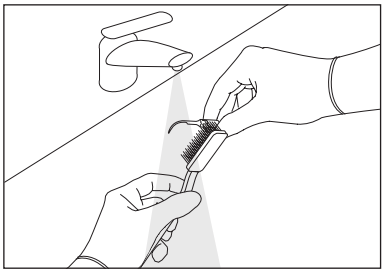
Place the insert in the basket in the ultrasonic tank at room temperature; Completely immerse the insert in fresh enzymatic detergent solution [a] (see step 1) and sonicate for at least 10 minutes.

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



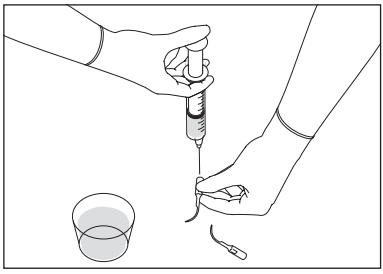
18

Delicately brush the surface of the insert again using the brush with soft nylon bristles.
Rinse the insert under running water and brush the device with a clean soft nylon bristle toothbrush for at least 1 minute.



19

Rinse the lumen by injecting demineralized water three times using a 20 ml syringe and then place the insert in a clean container covered with demineralized water for at least 1 minute.

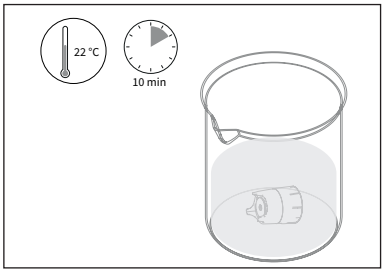


EN

6.1.2.3 Inserts Tightening Wrench

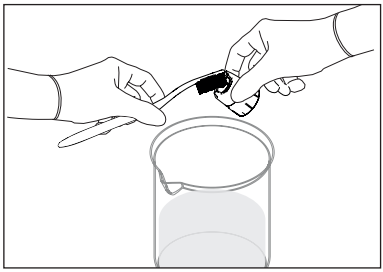
20

Place the torque wrench in a clean container, add enough solution to the container to cover the torque wrench.
Soak the torque wrench in the enzymatic cleaner solution for at least 10 minutes.



21

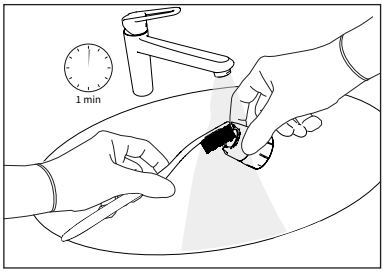
After immersion in the enzymatic solution, gently brush the surface of the torque wrench with a soft nylon bristle brush to eliminate all traces of visible dirt on both the external and internal parts (for at least 2 minutes, paying greater attention to the lumen).



22

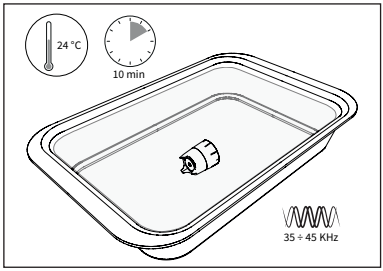
Remove the torque wrench from the enzymatic cleaning solution.

Rinse the torque wrench under running water and brush it with a clean, soft nylon bristle brush for at least 1 minute. Use a clean toothbrush to brush the internal cavities and crevices under running water.



23

Prepare an enzymatic detergent solution at pH 6-9, according to the manufacturer's instructions (preferably use tap water).
Place the torque wrench in a stainless steel instrument tray basket; place the basket in the ultrasonic tank; Completely immerse the wrench in fresh enzymatic cleaner solution[a)] (see step 1) and sonicate for at least 10 minutes.

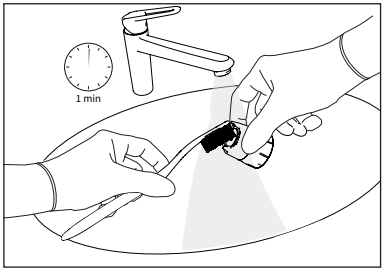


a) Process validated by independent bodies with ENZYMEC enzymatic detergent, 0.8% v/v.

EN

Rinse the torque wrench under running water and brush the device with a clean, soft nylon bristle brush for at least 1 minute. Use a clean brush to brush the internal cavities and crevices under running water. Rinse/soak the torque wrench with demineralized water for at least 1 minute.

24



6.1.3 Automatic Cleaning

Automatic cleaning can be carried out as an alternative to the manual cleaning described in *Chapter 6.1.2 on page 21*.

» **REQUIRED MATERIALS**

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

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

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

⚠ **WARNING**: On completion of the cleaning cycle in the thermal-disinfector, the scaler handpiece remains at the wash temperature for a long time. Use appropriate precautions when extracting the scaler handpiece from the thermal-disinfector to prevent injury to the operator.

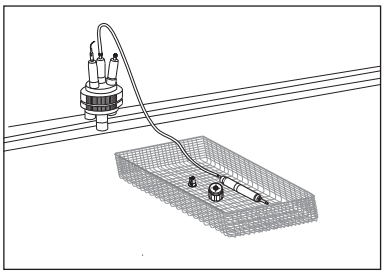
⚠ **CAUTION**: Owing to its conformation, the scaler handpiece can rotate. When not in use, the scaler handpiece must always be placed on its support.

NOTE: The insert and torque wrench must be processed separately. Do not leave the insert inserted in the torque wrench.

» **PROCEDURE**

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

1



2

Sequence and parameters applicable to the cycle:

- 3 min, Prewash with cold deionized water;
- 5 min, Wash with alkaline detergent and deionized water at 55°C ±2°C (131°F ±3.6°F);
- 2 min, Neutralization with suitable solution and deionized water at 40°C ±2°C (104°F ± 3.6°F);
- 2 min, Rinse with cold deionized water at 32°C ±2° (89.6°F ± 3.6°F);
- 5 min, Thermodisinfection at 93°C (199.4°F) with deionized 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 (194°F) for 5 min determines a value of A0 3000.

6.2 Cleaning Check

» **MATERIALS REQUIRED**

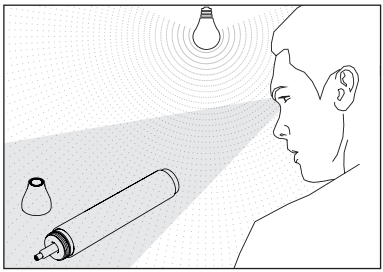
- Light source;
- 2.5X Magnifier.

EN

» **PROCEDURE**

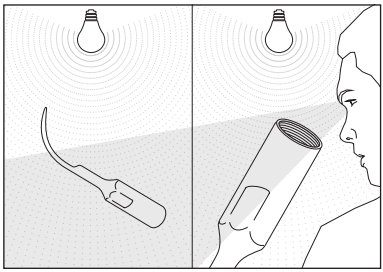
1

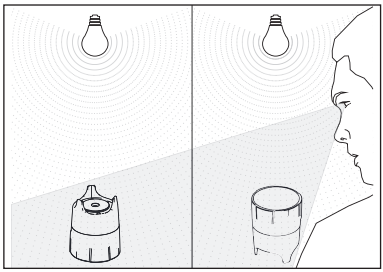
Once the cleaning operations have been completed, check the scaler handpiece and scaler nose cone under an adequate source of light, if necessary using a magnifying glass 2.5X, paying attention to any parts that may conceal soil residue (threading, cavities, grooves) and, if need be, repeat the cleaning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



2

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





6.3 Drying and Lubrication

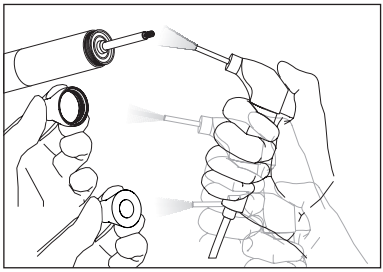
» **MATERIALS REQUIRED**

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

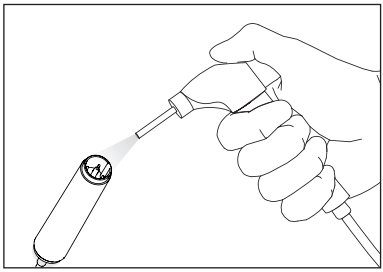
» **PROCEDURE**

1

Thoroughly dry all parts of the scaler handpiece, scaler nose cone, and light pipe by blowing them with compressed air;

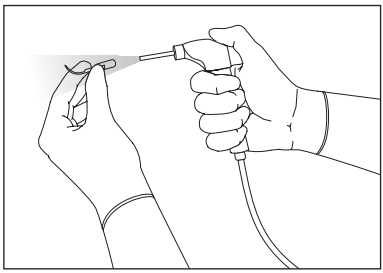


⚠ **CAUTION**: The scaler handpiece electrical contacts must be dry at the start and end of the sterilisation cycle, before the cord is connected to the device. Always make sure that the electrical contacts of the connector are perfectly dry, if necessary dry them blowing with compressed air.



2

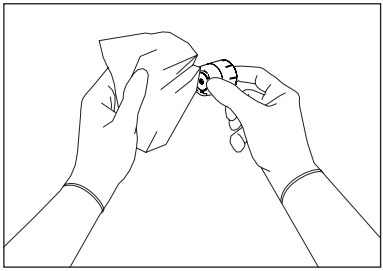
⚠ **CAUTION**: Before starting the sterilisation cycle, make sure that the insert is thoroughly dry both internally and externally. To do this, blow compressed air both externally and through the internal passage hole. This will prevent the appearance of stains, streaks on the surface or oxidation inside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



EN

3

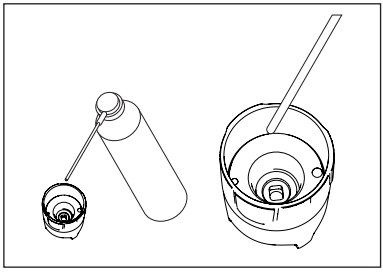
Dry the inserts tightening wrench using a soft, low-lint cloth;



4

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

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

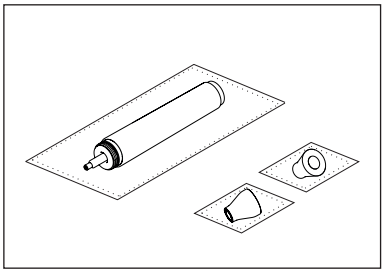


6.4 Sterilisation

» **PREPARATION**

1

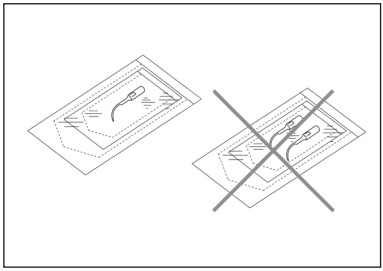
Seal the scaler handpiece (without inserts), scaler nose cone, and light pipe individually and separately in disposable sterilisation bags.



EN

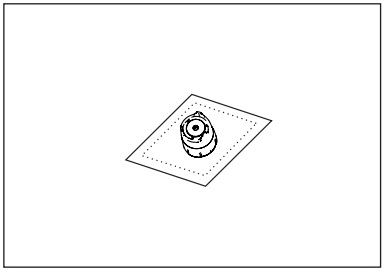
Seal the inserts individually inside a disposable bag for sterilisation.

2



Seal the wrench individually inside a disposable bag for sterilisation.

3



6.4.1 Sterilisation Method

TThe scaler handpiece and other sterilisable components are manufactured with materials that resist a maximum temperature of 135°C (275°F) for a maximum time of 20 minutes.
Once the scaler handpiece and the other sterilisable components have been put into bags individually, perform the steam sterilisation process in the autoclave.

⚠ **CAUTION:** Use sterilisation bags compliant with standard UNI EN ISO 11607-1.

The sterilisation process validated by Mectron S.p.A., in an autoclave with steam, guarantees a SAL 10^{-6} by setting the parameters indicated below:

- **Type of cycle**: 3 times Pre-vacuum
- **Minimum sterilisation temperature:** 132°C (270°F) (range 0°C÷ +3°C). (270°F ÷ 275°F)
- **Minimum sterilisation time:** 4 minutes.
- **Minimum drying time:** 20 minutes.

All stages of sterilisation must be carried out by the operator in compliance with the most current version of standards: UNI EN ISO 17665-1, UNI EN ISO 556-1 and ANSI/AAMI ST:46.

⚠ **CAUTION**: Do not sterilise the scaler handpiece with the insert screwed in.

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

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

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

⚠ **WARNING**: On completion of the sterilisation cycle in autoclave, the scaler handpiece remains at the sterilisation temperature for a long time. Use appropriate precautions when extracting the scaler handpiece from the autoclave to

prevent injury to the operator.

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

» **SPECIAL INFORMATION**

EN

Sterilisation parameters, in steam autoclave, used in Great Britain:

- Temperature: 134° C (273°F);
- Time: 3 minutes.

7 ROUTINE MAINTENANCE

1. Always turn the device off before performing maintenance works;
2. Periodically check the cord of the scaler handpiece. If the material is damaged or deteriorated, contact the manufacturer of the dental unit to have it replaced

8 METHODS AND PRECAUTIONS FOR DISPOSAL

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

- Inserts, when worn or broken;
- Inserts tightening wrench, when worn or broken.

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

⚠ **WARNING:** When handling the inserts, pay particular attention to the sharp, pointed, irregular parts to avoid any wounds or injuries.

COMPACT PIEZO LED and its accessories must be disposed of and treated as waste subject to separate collection.
Failure to comply with the previous points can result in a penalty pursuant to the directive on waste electrical and electronic equipment (WEEE).
The purchaser is entitled to deliver the device to be disposed of to the dealer who supplies them with new equipment; at Mectron, instructions for proper disposal are available.

9 TECHNICAL DATA

Device compliant with Regulation (EU) 2017/745	Class IIa
Classification under the IEC/EN 60601-1	The class definition is determined by the manufacturer of the dental unit which incorporates COMPACT PIEZO LED. Parts applied: type B (insert) IP 20 (device) IP according to indications provided by the manufacturer of the dental unit
Essential performance	According to the standard IEC 80601-2-60 the device has no essential performance
Device for intermittent operation	60 sec. ON - 30 sec. OFF with irrigation 30 sec. ON - 120 sec. OFF without irrigation
Power Supply	Power adapter compliant with IEC/EN 60601-1: • 24 V~ 50/60 Hz or • 32 V⎓
Max. Power Consumption	40 VA
Working Frequency	Automatic Scan From 24 KHz to 36 KHz
Power	Adjustable in accordance with the indications provided by the manufacturer of the dental unit.
Water supply	Adjustable in accordance with the indications provided by the manufacturer of the dental unit. Working pressure from 1 to 6 bar.
Handpiece LED system	Adjustable in accordance with the indications provided by the manufacturer of the dental unit White LED light power risk free according to standard IEC/EN 62471.
Protections of the APC Circuit	Missing handpiece; Breaking wire cord; Insert not correctly tightened or broken.
Operating Conditions	from 10°C to 40 °C (50°F-104°F) Relative humidity from 30% to 75% Air pressure P: 800hPa/1060hPa
Transport and Storage Conditions	from -10 °C to 60 °C (14°F-140°F) Relative humidity from 10% to 90% Air pressure P: 500hPa/1060hPa
Altitude	lower than or equal to 2000 metres

EN

9.1 Electromagnetic Compatibility IEC/EN 60601-1-2

⚠ **WARNING: Contraindications. Interference with other equipment**
Even if compliant with standard IEC/EN 60601-1-2, COMPACT PIEZO LED may interfere with other devices in the vicinity.

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

⚠ **WARNING: Contraindications. Interference from other equipment**
An electrosurgical scalpel or other electrosurgical units positioned near the COMPACT PIEZO LED device may interfere with the correct operation of the device itself.

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

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

9.2 Guide and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	COMPACT PIEZO LED uses RF energy only for its internal operation. Therefore, its RF emissions are very low and probably do not cause any interference with nearby electronic devices.
RF Emissions CISPR 11	Class B	COMPACT PIEZO LED is suitable for use in all buildings, including domestic buildings, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions of fluctuations voltage/flicker IEC 61000-3-3	Compliant	

9.3 Accessible Parts of the Casing

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

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30%.
Radiated RF EM fields [a]	IEC 61000-4-3	3 V/m [f] 80 MHz - 2,7 GHz [b] 80% AM a 1 kHz [c]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See *Chapter 9.5 on page 42*	
RATED power frequency magnetic fields [d]	IEC 61000-4-8	30 A/m 50 Hz o 60 Hz	The magnetic fields at the mains frequency should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See *Chapter 9.6 on page 43*	Portable and mobile RF communication devices shall be used with a separation distance of at least 0,15 m from the field sources.

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

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

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

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

e) Void.

f) Before modulation is applied.

9.4 Guide and the Manufacturer's Declaration - Electromagnetic Immunity

9.4.1 Power Connection BC Input

EN

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

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

a) Void.

b) All COMPACT PIEZO LED cables are attached during the test.

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

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

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

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

g) Applicable only to COMPACT PIEZO LED connected to single-phase a.c. mains.

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

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). COMPACT PIEZO LED with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j) ME EQUIPMENT and ME SYSTEMS that does not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).

k) Not applicable to CLASS II COMPACT PIEZO LED.

l) Direct coupling shall be used.

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

n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

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

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

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

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

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9.4.2 Points of Contact with the Patient

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

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

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

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

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

9.4.3 Parts Accessible to the Input / Output Signals

COMPACT PIEZO LED and related accessories is designed to operate in the electromagnetic environment specified below.

The purchaser or user of COMPACT PIEZO LED should ensure that it is used in such an environment.

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

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

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

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

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

e) The connectors have to be tested in accordance with paragraph 8.3.2 and Table 4 of the standard IEC 61000-4-2:2008. For insulated connector housings, perform the air discharge test on the connector housing and pins using the probe with the rounded tip of the ESD generator, with the exception that only the connector pins that are tested are those that can be reached or touched, under the conditions of INTENDED USE, by the standard probe shown in Figure 6 of the general standard, applied in a bent or straight position.

f) It is necessary to use the capacitive coupling.

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

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

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

j) See IEC 61000-4-6:2013, Annex B, for modified start frequency versus cable length and equipment size.

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

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

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

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

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

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

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

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the COMPACT PIEZO LED may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

⚠ **WARNING:** Portable RF communication equipment (including peripheral devices as antenna cables and external antennas) must not be used closer than 30 cm (12 inches) to any part of the device COMPACT PIEZO LED, including the cables specified by the manufacturer. Otherwise, there may be a performance degradation of these devices.

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

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

Test Frequency	Modulation	Immunity test level (A/m)
30 kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

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

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

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

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10 TROUBLESHOOTING

10.1 Quick Troubleshooting

Problem	Possible Cause	Solution
The device is on but is not working (APC automatic protection circuit tripped).	The insert is not present or not correctly tightened on the handpiece.	Unscrew and correctly re-screw the insert
	The insert is worn, damaged, or deformed.	Replace the insert
	The connector of the handpiece or cord is wet.	Dry the connectors
	Handpiece not connected to the cord	Connect the handpiece to the cord
	Broken wire in the cord	Contact your nearest Authorised MECTRON Service Centre
	Faulty handpiece	Contact your nearest Authorised MECTRON Service Centre
	Tuning circuit malfunction	Contact your nearest Authorised MECTRON Service Centre
During operation a faint whistling noise can be heard coming from the scaler handpiece.	The irrigation circuit has not been completely filled	Fill the irrigation circuit
	The insert is not correctly tightened on the handpiece	Unscrew the insert and screw it back in correctly using the Mectron torque wrench (See *Chapter 4.4 on page 14*)
No liquid flows out from the insert during operation	The insert is the type without a liquid passage	Use an insert type with a liquid passage
	The Water function is not active	Activate the Water function
	The insert is clogged	Unscrew the insert from the handpiece and release the water passage of the insert by blowing compressed air through it. If the problem persists, replace the insert with a new one
	The handpiece is clogged	Contact an Authorised Mectron Service Centre

Problem	Possible Cause	Solution
Poor performance	The insert is not correctly tightened on the handpiece	Unscrew the insert and screw it back in correctly using the Mectron torque wrench (See *Chapter 4.4 on page 14*)
	Insert broken, worn or deformed	Replace the insert with a new one
	Poor maintenance of the insert	Clean the insert properly (see *Chapter 6 on page 19*)

10.2 Shipping to an Authorised Mectron Service Centre

If technical assistance is required on the machine, contact an Authorised Mectron Service Centre or your Dealer. Do not try to repair or modify the device and its accessories.
Clean and sterilise all parts that need to be sent to an Authorised Mectron Service Centre, following the instructions in *Chapter 6 on page 19*.
Leave the sterilised parts in the bag which certifies the sterilisation process.
The cleaning and sterilisation demands comply with the mandatory requirements for workplace health and safety protection pursuant to Legislative Decree 81/08 and Italian laws.
If the client fails to comply with the requirements, Mectron reserves the right to charge them the cost of cleaning and sterilisation or to refuse goods that arrive in unsuitable conditions, returning them at the client's own expense for proper cleaning and sterilisation.

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

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

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

Once the material is received at the Authorised Mectron Service Centre, the qualified technical personnel will evaluate the problem. The repair will be made only upon acceptance by the end client. For further details contact your nearest Authorised Mectron Service Centre or your dealer.
Unauthorised repairs can damage the system and void the guarantee and furthermore will disclaim Mectron from any liability for direct or indirect damage to persons or property.

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11 WARRANTY

All Mectron devices, before being marketed, are subjected to a careful final inspection that verifies their full functionality.
Mectron provides a warranty for COMPACT PIEZO LED, purchased new from a Mectron dealer or importer, which covers defects in material and workmanship for a period of:

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

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

- The device is not used in accordance with the intended use.
- The device is not used in accordance with all the instructions and requirements described in this manual.
- The electrical system of the places where the device is used does not comply with the laws in force and relative requirements.
- Assembly operations, extensions, adjustments, updates and repairs are carried out by personnel not authorised by Mectron.
- The environmental conditions for preservation and storage of the device do not comply with the requirements indicated in *Chapter 9 on page 35*.
- Use of non-original Mectron inserts, accessories, and spare parts that may compromise the correct operation of the device and cause injury to the patient.
- Accidental breakage during transport.
- Damage due to incorrect use or carelessness, or due to connection to a voltage other than that envisaged.
- Expired warranty.

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

CAUTION

The warranty starts from the date of purchase of the device, which evidence is given by the delivery note/purchase invoice issued by the Dealer / Importer or, in case of device with activation code, from the date of activation of the same.

In order to avail of the warranty service, the client must return the device, at their own expense, to the MECTRON dealer/importer from which they purchased the product.

The device must be returned together with the original packaging, accompanied by all the accessories and by a form containing:

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

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

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Your address / Ihre Adresse / Votre adresse / Вашият адрес / Vaše adresa / Din adresse / Η διεύθυνσή σας / Su dirección / Teie aadress / Vaša adresav Cím / Vostro indirizzo / Jūsų adresas / Jūsu adrese / Uw adres / Państwa adres / Seu endereço / Adresa dumneavoastră / Din adress

EN	Please send me, free of charge, a copy of the Instructions for Use of the following product (please complete below):
DE	Bitte senden Sie mir eine kostenfreie Gebrauchsanweisung des folgenden Produktes zu (bitte unten ausfüllen):
FR	Veuillez me faire parvenir gratuitement une notice d'utilisation pour le produit suivant (veuillez remplir ci-dessous) :
BG	Моля, изпратете ми безплатно ръководство за употреба за следния продукт на (моля, попълнете по-долу):
CS	Zašlete mi prosím zdarma návod k použití následujícího výrobku (vyplňte laskavě dole):
DA	Send mig venligst en gratis brugsvejledning til efterfølgende produkt (udfyld nedenfor):
EL	Παρακαλώ να μου στείλετε δωρεάν οδηγίες χρήσης και συναρμολόγησης του ακόλουθου προϊόντος (συμπληρώστε κάτω):
ES	Rogamos nos envíen gratuitamente una copia impresa del manual de instrucciones para uso del siguiente producto (por favor, rellenar abajo):
ET	Palun saatke mulle tasuta kasutusjuhend järgmise toote kohta (palun täitke altpoolt):
HR	Molim, pošaljite mi besplatne upute za uporabu sljedećeg proizvoda (ispuniti u nastavku):
HU	Kérem, küldjenek ingyenes használati utasítást a következő termékről (kérjük, töltse ki):
IT	Vogliate inviarmi gratuitamente le istruzioni per l'uso del seguente prodotto (compilare la parte sottostante):
LT	Atsiųskite man nemokamą šio gaminio naudojimo instrukciją (užpildykite apačioje):
LV	Lūdzu atsūtīt man produkta bezmaksas lietošanas instrukciju (aizpildīt zemāk):
NL	Stuur mij a.u.b. een gratis gebruikshandleiding van het volgende product (a.u.b. hieronder invullen):
PL	Proszę o przysłanie mi bezpłatnej instrukcji obsługi następującego produktu (proszę uzupełnić na dole):
PT	Enviem-me gratuitamente um exemplar das Instruções de utilização do seguinte produto (preencher em baixo):
RO	Vă rog să îmi trimiteți un exemplar gratuit din instrucțiunile de utilizare pentru următorul produs (vă rugăm să completați datele de mai jos):
SV	Skicka en kostnadsfri bruksanvisning för följande produkt (fyll i nedan):

Informazioni importanti per l'ordinazione del prodotto / Important information for product ordering:
Descrizione del prodotto / Product description (e.g. combi touch) _____

REF (e.g. 05120065) _____

SN (e.g. 423001234) _____

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