mectron
medical technology

USE AND MAINTENANCE MANUAL

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MT-Bone

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IT	Questo documento e le relative traduzioni sono disponibili sul sito “manuals.mectron.com”. Usa il QR code per accedere al sito. Per poter visualizzare le istruzioni per d’uso in formato elettronico (eIFU) è necessario disporre di un software PDF, per esempio Adobe Reader. Nel caso Le servisse una copia stampata delle istruzioni per l’uso, Le chiediamo cortesemente di compilare in ogni sua parte il modulo nell’ultima pagina e di inviarlo all’indirizzo indicato. Provvederemo ad inviarLe gratuitamente, entro 7 giorni, una copia stampata delle istruzioni per l’uso.
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.
LV	Šis dokuments un tā tulkojumi ir pieejami vietnē “manuals.mectron.com”. Izmantojiet QR kodu, lai piekļūtu vietnei. Lai aplūkotu lietošanas instrukciju (eIFU), ir vajadzīga PDF programmatūra, piemēram, Adobe Reader. Ja vēlaties saņemt nodrukātu lietošanas instrukciju, aizpildiet visu veidlapu pēdējā lapā un nosūtiet to un nosūtiet uz norādīto adresi. 7 dienu laikā Jums tiks nosūtīta nodrukāta bezmaksas lietošanas instrukcija.
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PL	Niniejszy dokument i jego tłumaczenia są dostępne na stronie „manuals.mectron.com”. Użyj kodu QR, aby wejść na stronę. Do otwarcia elektronicznej instrukcji obsługi (eIFU) niezbędny jest program do plików PDF, np. Adobe Reader. Jeśli życzą sobie Państwo drukowaną wersję instrukcja użycia, prosimy o dokładne wypełnienie formularza na ostatniej stronie i odesłanie na podany adres. Prześlemy Państwu bezpłatnie drukowaną instrukcja użycia w ciągu 7 dni.
PT	Este documento e as respetivas instruções encontram-se disponíveis no site “manuals.mectron.com”. Utilize o QR Code para aceder ao site. Para visualizar as Instruções de utilização eletrônicas (eIFU) é necessário instalar um software para leitura de PDF, por exemplo, Adobe Reader. Jeśli życzą sobie Państwo drukowaną wersję instrukcji obsługi, prosimy o dokładne wypełnienie formularza na ostatniej stronie i odesłanie na podany adres. Prześlemy Państwu bezpłatnie drukowaną instrukcję obsługi w ciągu 7 dni.

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1 INTRODUCTION

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This manual refers to the following medical devices:

- MT-Bone (cited as "device" in the text)
- PIEZOSURGERY MT handpiece (cited as "accessories" in the text)
- PIEZODRILL MT handpiece (cited as "accessories" in the text)
- Reusable inserts for bone surgery
- Dynamometric wrench
- Irrigation kit
- Protective foils

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, safety information is classified with the following indications:

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

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

The aim of this manual is to make operators aware of the safety regulations, installation procedures, instructions for proper use and maintenance of the device and its accessories. Do not use this manual for purposes other than those strictly related to the installation, operation and maintenance of the device.
The information and illustrations in this manual were updated on the edition date shown on the last page.
Mectron continuously updates its products with possible changes to the device and its components.
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 at https://manuals.mectron.com/;
- ask Your Dealer for clarifications;
- contact Mectron After Sales Service.

⚠ **WARNING**: Carefully read and follow the recommendations in this manual to prevent patient and/or user safety from being compromised. Failure to comply may result in serious injury to the patient and/or operator.

2 INTENDED USE

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

MT-Bone, equipped with handpieces (PIEZOSURGERY MT and PIEZODRILL MT) and inserts, is a piezoelectric ultrasonic device intended for oral bone surgery in the following applications:

- osteotomy and osteoplasty techniques;
- implantology;
- periodontal surgery;
- orthodontic surgery;
- endodontic surgery;
- maxillofacial surgery.

MT-Bone, equipped with handpieces (PIEZOSURGERY MT and PIEZODRILL MT) and inserts, can operate as a piezoelectric scaler in the following dental applications:

- scaling: all procedures for the removal of bacterial plaque deposits and supragingival, subgingival and interdental calculus and the removal of stains;

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- periodontology: periodontal therapy for scaling and root-planing/debridement, including cleaning and irrigation of the periodontal pocket;
- endodontics: all treatments for canal preparation, irrigation, filling, gutta-percha condensation and retrograde cavity preparation;
- restorative and prosthetic dentistry: cavity preparation, removal of prostheses, amalgam condensation, finishing of cervical margins, preparation of inlays/onlays.

PIEZODRILL MT and PIEZOSURGERY MT handpieces are accessory medical devices for MT-Bone.
The PIEZODRILL MT and PIEZOSURGERY MT handpieces are intended for oral bone surgery and piezoelectric scaling when connected to MT-Bone and compatible inserts.
Always refer to the instructions and settings table supplied with the insert.

⚠ **WARNING**: The device and its accessories can be used in outpatient, private or hospital settings.

3 DESCRIPTION OF THE DEVICE

MT-Bone is equipped with two piezoelectric channels with different power and separate electronics, PIEZOSURGERY and PIEZODRILL.
PIEZOSURGERY and PIEZODRILL technologies associated to the two channels use piezoelectric ultrasonic technology to generate mechanical micro-vibrations, which allow safer and more efficient cutting or drilling of bone tissue, thus preserving the integrity of osteotomised surfaces.
PIEZOSURGERY technology has historically delivered intra-operative and post-operative clinical benefits that have been validated in the literature to date. The clinical benefits are listed below, divided into two categories: intra-operative clinical benefits and post-operative clinical benefits.
Intra-operative clinical benefits:

- Selective cutting: this feature ensures maximum safety for surgeons and patients and a reduced risk of damaging delicate tissues (nerves and blood vessels).
- Micrometric cutting: this feature ensures maximum surgical precision, intra-operative sensitivity and minimum bone sacrifice for the entire depth of the cut.
- Cavitation effect: this feature ensures maximum intra-operative visibility and a bloodless operating field.

Post-operative clinical benefits:

- Healing: guaranteed improved and faster healing.
- Oedema: guaranteed reduced post-operative bleeding and pain.

The "PS" channel allows use of the PIEZOSURGERY MT handpiece to which the Mectron multi-purpose compatible inserts can be connected (in accordance with the manual of each insert).
The "PD" channel allows use of the PIEZODRILL MT handpiece to which the Mectron multi-purpose compatible inserts can be connected (in accordance with the manual of each insert).

NOTE: The touch screen makes all the functions immediately available, which can be activated by simply tapping the pre-selected buttons on the screen. Using the graphic interface, the user can select the pre-selected insert (PIEZOSURGERY channel) or the operating step (PIEZODRILL channel) and set the irrigation values within a default range set by Mectron.

⚠ **WARNING**: **Explosion hazard.**
The device and its accessories cannot operate in environments where there are atmospheres saturated with flammable gases (anaesthetic mixtures, oxygen, etc.).

⚠ **WARNING**: **Qualified and specialist personnel.** The device and its accessories must be used strictly by specialised personnel such as a Surgeon with adequate medical knowledge; no training activities are required for the use of the deviceand its accessories. The device and its accessories produce no side effects when used correctly. Improper use is manifested by the transfer of heat to the tissues.

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3.1 Eligible Patient Group

MT-Bone, equipped with handpieces (PIEZOSURGERY MT and PIEZODRILL MT) and inserts, is designed to be used with the following patient groups:

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

MT-Bone, equipped with handpieces (PIEZOSURGERY MT and PIEZODRILL MT) and inserts, can be used on patients of any age, weight, height, gender and nationality.

3.1.1 Patient Selection Criteria / Contraindications

It is not recommended to use MT-Bone, equipped with handpieces (PIEZOSURGERY MT and PIEZODRILL MT) and inserts, 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. Pregnant or breastfeeding women, due to the restrictions associated with the possible use of medical solutions such as anaesthetics;
3. Patients with allergies;
4. Patients with diseases or clinical conditions for which surgery is not recommended or for which it may be contraindicated according to their doctor. Said conditions may include but are not limited to: heart disease, diabetes, cirrhosis, HIV infection, pregnancy or lactation, radiotherapy, chemotherapy, immunosuppressive therapy, allergies and psychiatric disorders;
5. Patients with unsuitable treatment sites.

All models of Mectron bone surgery devices and relative accessories are for professional use only. The user is therefore the only person able to decide if and how to treat their patients.

3.1.2 Indications for Use

MT-Bone, equipped with handpieces (PIEZOSURGERY MT and PIEZODRILL MT) and inserts, is indicated for all intended patients (see above) who have been prescribed a bone surgery procedure by their doctor, within the intended use of the device (see *Chapter 2 on page 1*).

3.2 Users

MT-Bone, equipped with handpieces (PIEZOSURGERY MT and PIEZODRILL MT) and inserts, must be used strictly by specialised and properly trained personnel, specifically the Surgeon/ Dentist who must be an adult, of any weight, age, height, gender, nationality and able-bodied.

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3.3 Operating environment

MT-Bone, with its accessories, 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.

⚠ **CAUTION**: remove the irrigation bag support rods and handpiece support before handling the device.

3.4 Disclaimer

The manufacturer Mectron disclaims all liability, express or implied, and cannot be held liable for direct or indirect personal injury and/or property damage, occurring as a result of incorrect procedures related to 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/or its components and which occurs in the following cases:

1. Misuse or use during procedures other than those specified in the destination of use of the product;
2. The environmental conditions for preservation and storage of the device are not complying with the requirements indicated in *Chapter 9 on page 52*;
3. MT-Bone, its handpieces (PIEZOSURGERY MT and PIEZODRILL MT) and inserts, are not used in accordance with all the instructions and requirements outlined in their respective manuals;
4. The electrical system of the facilities where the device is used does not comply with the electrical code compliance standards in force and the relative electrical safety precautions;
5. Assembly, extension, re-adjustment, upgrade and repair operations on the devices are carried out by personnel not authorised by Mectron;
6. Misuse, damage and/or incorrect operations;
7. Any attempt to tamper with or modify the devices under any circumstances;
8. Use of non-original Mectron inserts, which causes permanent damage to the thread of the handpiece with impaired functioning and risk of injury to the patient;
9. 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;
10. Shortage of stock material (handpiece, inserts, wrenches) to be used in case of faults or problems.

3.5 Safety Requirements

⚠ **WARNING**: **Explosion hazard.**
MT-Bone with accessories cannot operate in environments where the atmosphere is saturated with flammable gases (anaesthetic mixtures, oxygen, etc.).

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

⚠ **WARNING**: **Checking the condition of the device and its accessories before treatment.**
Always check that there is no water under the device MT-Bone. Before each treatment, always check the perfect working order of the device and its accessories and the efficiency of all its components. If operation anomalies are observed do not carry out the treatment. If the faults concern the device, contact an Authorised Mectron Service Centre.

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

⚠ **CAUTION**: To avoid any risk of electrical shocks this device must be grounded.

⚠ **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 the Cleaning and Sterilisation Manual.

⚠ **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 the Cleaning and Sterilisation Manual.

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

⚠ **WARNING**: Before each use, inspect each component for any damage. If damage is found, do not use it.

⚠ **WARNING**: **Insert Breakage and Wear.** High frequency oscillations and wear can, in rare cases, lead to the breakage of the insert. Deformed inserts or inserts that have been otherwise damaged are prone to breakage during use. Broken or worn inserts must never be used. In the event of breakage check that no fragments remain in the treated part and at the same time use suction effectively to remove them. The patient must be instructed to breathe through the nose during the treatment, or use a dental dam, so as to avoid ingesting fragments of broken inserts. 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. Using worn insert reduces the cutting performance and may cause necrosis of the treated bone surface. 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.

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

⚠ **WARNING**: **Contraindications.** Do not use MT-Bone and its accessories on patients with Pacemakers or other implantable electronic devices. This regulation also applies to the operator.

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

⚠ **WARNING**: **Interference from other equipment.** An electrosurgical scalpel or other electrosurgical units near the MT-Bone device and its accessories may interfere with its correct operation.

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

⚠ **CAUTION**: No changes to this device nor to its accessories are allowed.

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

⚠ **CAUTION**: Federal (US) law restricts the marketing of this device to prescription or licensed practitioner.

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

⚠ **WARNING:** In case of an adverse event and/or accident attributable to the MT-Bone device with accessories 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.

⚠ **WARNING**: MT-Bone, with its accessories and compatible inserts, is a device intended for bone surgery. However, prolonged contact and/or excessive force by the inserts on the soft tissue should be avoided as this may cause thermal damage and/or non-cutting injuries. Exercise extra caution when using sharp inserts. Prolonged mechanical operation of the cutting inserts may also cause cutting of soft tissue. In the vicinity of soft tissue/ nerves, it is recommended to complete cutting with a non-cutting diamond insert to minimise the potential risk of damaging the tissue.

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3.6 Symbols

Symbol	Description	Symbol	Description
CE 0051	Class IIa 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
	Importer	UK CA	UK Radio Equipment Regulation 2017
	Distributor	CH REP	Authorised representative in Switzerland
	Manufacturer	UK REP	Authorised representative in the United Kingdom
	Date of manufacture	MD	Medical device
UDI	Unique Device Identifier	HIBC	Health Industry Bar Code
LOT	Batch number	SN	Serial Number
#	Model number	REF	Catalogue number
	Caution		Consult instructions for use or consult electronic instruction for use
STERILE EO	Sterilised with Ethylene Oxide (EO)	NON STERILE	Non-sterile
	Sterilisable up to a max. temperature of 135°C		Do not re-sterilise
	Do not reuse		Use by date
	Connection of the foot switch		Type B applied part
	Alternating current	QTY.1	Quantity in package: 1
I	Power switch set to “on”	0	Power switch set to “off”

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Symbol	Description	Symbol	Description
	Equipotentiality		Earth
	Temperature limit		High voltage
	Humidity limitation		Atmospheric pressure limitation
"PS"	Graphic symbol identifying the PS Channel used to connect the PIEZOSURGERY MT handpiece.	"PD"	Graphic symbol identifying the PD Channel used to connect the PIEZODRILL MT handpiece.
IP20	Ingress Protection IP of the mechanical casing.	IP X8	Ingress Protection IP of the mechanical casing. Protected against the effects of continuous immersion
	Irrigation		Do not use irrigation
	Clock, time switch, timer.		Do not use if the packaging is damaged and consult instruction for use
	Fragile		Keep dry
	Keep away from sunlight		This way up
Rx only	For US market only **CAUTION**: Federal (US) law restricts the marketing of this device to prescription or licensed practitioner.		Separate collection for waste of electrical end electronic equipment

3.7 Identification Data

To facilitate quick and effective responses from our After-Sales Service, please provide:

- An exact description of the model and serial number of the device with accessories,
- An exact description of the model and lot number for the inserts

Always refer to these details every time that you contact a Mectron Authorised Customer Services Centre.

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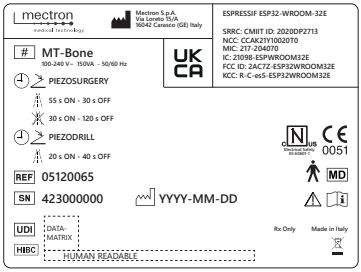
3.7.1 Device Nameplate

Each MT-Bone device is equipped with a nameplate indicating the main technical features and traceability data, including the UDI. This nameplate is located under the device. The complete technical specifications are provided in *Chapter 9 on page 52*.

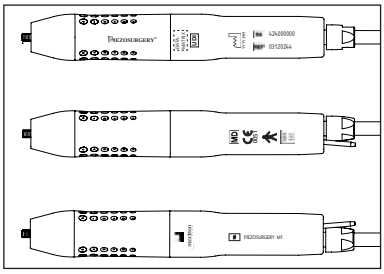
NOTE: The complete list of symbols and their description is provided in *Chapter 3.6 on page 7*.

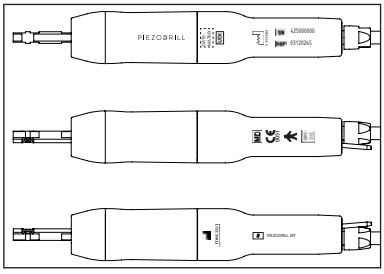


3.7.2 Accessories Identification Data

The traceability data, including the UDI code, is laser-engraved on each PIEZOSURGERY MT and PIEZODRILL MT handpiece.

NOTE: The complete list of symbols and their description is provided in *Chapter 3.6 on page 7*.

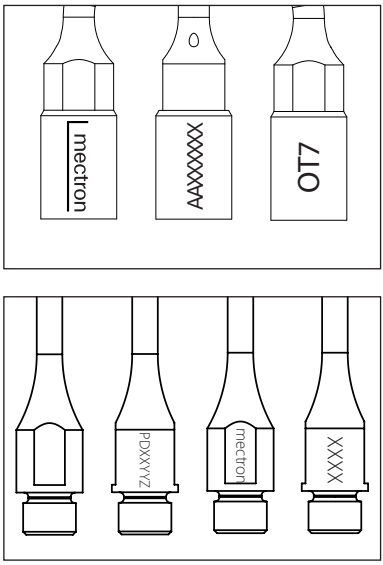




EN

3.7.3 Insert identification data

The traceability data is etched on each insert usable on the PIEZOSURGERY MT and PIEZODRILL MT handpieces. The traceability data, including the UDI code, is indicated on their packaging.



4 DELIVERY

4.1 List of MT-Bone components

MT-Bone comes with a standard supply and set of additional components that can be ordered separately, which vary depending on the configuration and client requests (See Tables on page 13).

⚠ **CAUTION**: Certain inserts require specific components and tools in order to be used correctly (for example, special-purpose kits and/or torque wrenches). Always read and follow the assembly and cleaning instructions supplied with the insert.

NOTE: Please refer to the Mectron website for a list of available and compatible components.

⚠ **CAUTION**: The handpiece and the cord cannot be separated.

The device packaging must be protected against impact as it contains electronic components. Therefore both the transport and storage must be carried out with particular caution.

Do not stack several boxes in order not to squash the packages below.

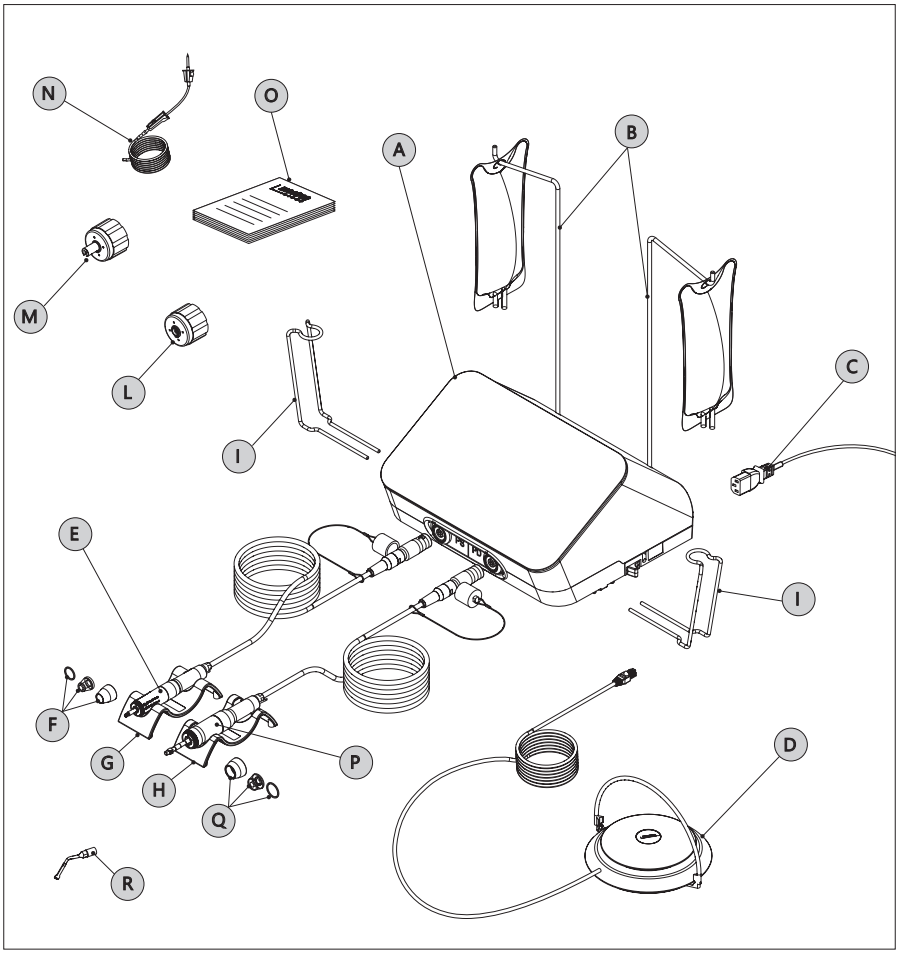
All the material sent by Mectron has been checked at the time of shipping.

The device and its components are delivered properly protected and packaged.

Upon receiving, check if there has been any damage during transport and, if so, submit a claim to the carrier. Keep the packaging for any returns to an Authorised Mectron Service Centre.

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

EN



Standard supply		
Ref.	**Item**	**Notes**
A	Console	
B	Irrigation bag support rods	
C	Power cord	Plug compatible with country of delivery
D	Foot pedal with bracket	
E	PIEZOSURGERY MT handpiece	
F	PIEZOSURGERY MT metal cone (no light), 3 light guides, 3 gaskets	
G	PIEZOSURGERY MT mobile handpiece support	
H	PIEZODRILL MT mobile handpiece support	
I	Fixed handpiece support	
L	K8 torque wrench	
M	K11 torque wrench	
N	Irrigation kit [a)]	
-	Touch screen protective foil [a)]	
O	Use and maintenance manual and Cleaning and sterilisation manual	

Components that can be bought separately		
Ref.	**Item**	**Notes**
P	PIEZODRILL MT handpiece	
Q	PIEZODRILL MT metal cone (no light), 3 light guides, 3 gaskets	
R	Inserts/inserts kit	
-	Compatible Mectron torque wrenches	
-	Inserts holder	
-	Surgical tray - small	
-	Adapter for thermal disinfection of inserts	
-	Adapter for thermal disinfection of handpiece	

a) Distributed by Mectron

EN

4.2 First Installation

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

⚠ **WARNING**: The place where the device is installed must meet the requirements set out in *Chapter 3.5 on page 5*.

MT-Bone can be purchased ready for use or may need to be enabled via the *MyMectron* app or by entering an activation key. If your device requires an activation key, the procedures may vary from country to country. Always refer to your dealer for details.

4.3 Safety Requirements During Installation

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

⚠ **WARNING**: **Interference from other equipment.** An electrosurgical scalpel or other electrosurgical units near the MT-Bone device and /or relative accessories may interfere with its correct operation.

⚠ **CAUTION**: The electrical system of the facilities where the device is used must comply with the electrical code compliance standards in force and the relative electrical safety precautions.

⚠ **CAUTION**: To avoid any risk of electrical shocks this device must be grounded.

⚠ **WARNING**: **Do not install the device in places where there is a risk of explosion.** Do not use this product where anaesthetic or inflammable gases are present.

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

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

⚠ **WARNING**: Do not install the device above or near heat sources. Ensure the installation allows adequate air circulation around the device. Leave suitable space, especially near the fan at the rear of the device.

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

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

⚠ **CAUTION**: Before connecting the handpiece cord to the device, check that the electrical contacts are perfectly dry. If necessary dry them with compressed air.

⚠ **WARNING**: Before using the irrigation kit, check the integrity of the sterile packaging and inspect the product to ensure there is no damage. Do not use the irrigation kit if the packaging is open or damaged. The irrigation kit will no longer be sterile if the packaging is broken or damaged. If the packaging is damaged, dispose of the kit. Do not re-sterilise and re-use the set.

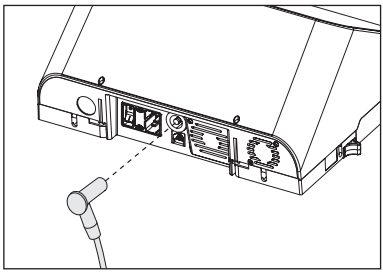
⚠ **CAUTION**: Do not allow the device console or foot pedal to get wet. If any liquid enters the device console or foot pedal, damage may occur.

⚠ **CAUTION**: It is prohibited to make any changes to these devices.

4.4 Connecting the Device

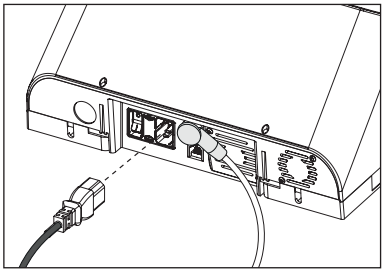
1

Equipotential plug: the device is equipped with an additional equipotential plug at the rear of the device. The plug complies with DIN 42801. Insert the connector of the equipotential cable (not connected) to the plug on the back of the device. The purpose of the additional equipotential connection is to reduce the potential differences that may occur during operation between the device console and the conductive parts of other objects within the medical environment;



2

Plug the power cord into its socket at the rear of the device. Connect it to the socket in the wall;

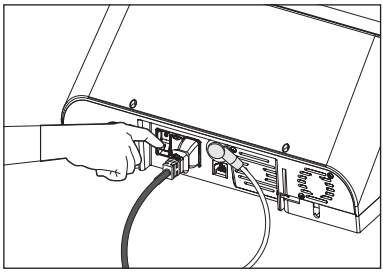


EN

4.5 Switching on the Device

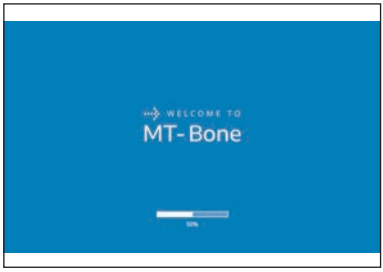
Switch on the device via the main switch at the rear of the device console, taking care not to press the foot pedal during this step.

3



When the user switches on the device, the following screen appears for about one minute. The bar shows the progress of the power-up.

4



4.6 Language Selection and Device Activation

The default language for the graphic interface is “English”.

5

During the first installation, the language must be selected from among those available by tapping on the relative button. Once the desired language has been selected, continue by pressing “Continue”.

6

7

The country must then be selected. A drop-down menu appears with a list of selectable countries and the order of the countries depends on the previously selected language.

8

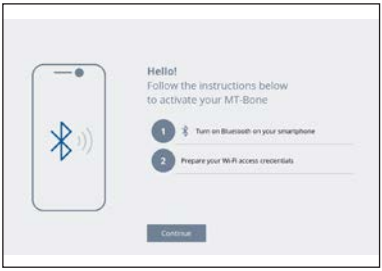
Once the country has been selected, it is possible to select “Continue” and proceed with activation of the device.

4.7 Activating the Device via APP

EN

A few seconds after selecting the country, the following screen appears, prompting the user to prepare for device activation.

9

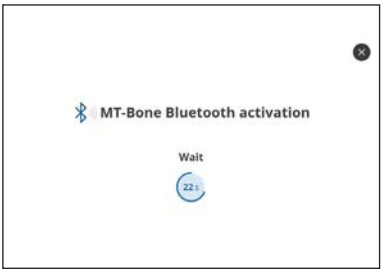


Continuing on, the next screen provides instructions for downloading the Mectron application (*MyMectron*), through which the user registers and creates his Clinic. Alternatively, the device allows activation by code (see *Chapter 4.8 on page 20*). Activation by code can be accessed by clicking on the "Activate via Code" button.

10

After pressing the "Continue" button, the following screen appears on the MT-Bone monitor. This is a waiting screen informing the user that the device's Bluetooth is being activated.

11



Once the Bluetooth is activated, a new screen is shown with instructions to pair the MT-Bone device with the app on the user's smartphone. This procedure must be completed within the time indicated on the screen. To make the pairing, the user must add a new device via the appropriate button (+) in the app, then select the MT-Bone device to be activated. The identifier of your MT-Bone is shown on the screen.

12

EN

If the procedure is not completed within the specified time, or is not successful, the "Time Expired. TRY AGAIN" button appears on the screen, allowing the timer to be restarted and the pairing procedure to be repeated.

13

The following screen confirms that the pairing has been successful. The app will now ask the user to complete the activation of the MT-Bone device: select the Wi-Fi network and enter the password. There is no time limit to complete this operation.

14

If the user has completed all the necessary procedures on the smartphone, MT-Bone shows the following screen confirming that the device is properly activated and a user profile can be created or the device can be used.

15

NOTE: The *MyMectron* application can only be downloaded from the Apple App Store and the Google Play Store.

NOTE: To configure Wi-Fi at a later date or update its credentials, please refer to the procedure described in *Chapter 6.6.1 on page 48*.

EN

4.8 Activating the Device by Code

The device can alternatively be activated by a seven-digit code, when provided. The instructions and/or activation code are inside the case with which the device was delivered
In this case, the code must be keyed into the touch surface.

16

If the entered code is correct, the system allows you to proceed.
Press the "Continue" button to proceed with the configuration.

If the code is incorrect, an error message will appear with a red icon. The system will inform the user that the device has not been activated and the user must re-insert the code to proceed.

EN

4.9 Creating a User Profile

The user can create a user profile and create the list of "My inserts" to optimise the use of the PIEZOSURGERY channel.
This step is not mandatory and can be done at a later stage by going to the SETTINGS section. It is also possible to create multiple user profiles.
See *Chapter 5.8 on page 35.*

NOTE: Creating a user profile is not mandatory, but it is the only way to manage multiple users and store their customised settings.

17

18

This configuration step is dedicated to selecting the PIEZOSURGERY inserts that the user can view in the "My inserts" list. The inserts catalogue is organised into categories and also includes a search field. The insert can be selected using the following methods:

- scroll the list of all available inserts;
- filter the list of available inserts by type;
- use the search function.

19

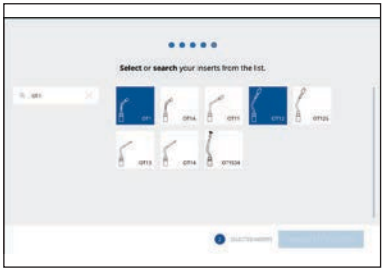
By selecting the "Search" field, it is possible to insert a string of characters to search for a specific insert. The search results appear on the right.

EN

20

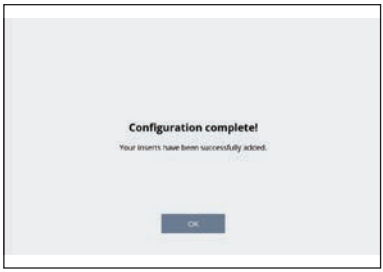
The desired inserts can now be selected. The number of selected inserts appears in the bar at the bottom of the screen. When all the inserts have been selected, it is possible to proceed by selecting the "Add inserts" button.

NOTE: the inserts are displayed in alphabetical order on the PIEZOSURGERY function screen.



21

Configuration is now complete and the user can use the device.



22

If a handpiece has been connected, the user is directed to the INFO screen and by selecting the FUNCTIONS button, they will be directed to the function screen for the connected handpiece.
If both handpieces are connected, the user is directed to the INFO screen and by selecting the FUNCTIONS button, they will be directed to the PIEZODRILL function screen by default. It will then be possible to select the desired channel by selecting the relative button.

NOTE: at least one insert must be added to the "My inserts" list to continue as a generic user. The user can then add other inserts using the "+" or "✎" button in the PIEZOSURGERY function screen.

NOTE: if a user profile is not created in the screen, only the word "Welcome" will appear at the top left of the screen.

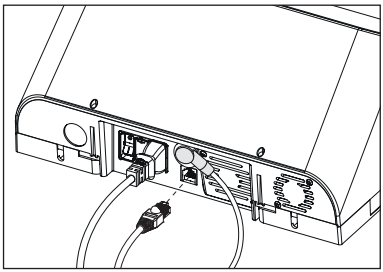
NOTE: if no handpieces have been connected, by selecting "OK" the user is directed to the INFO screen.

5 CONNECTING THE COMPONENTS AND CONFIGURATION

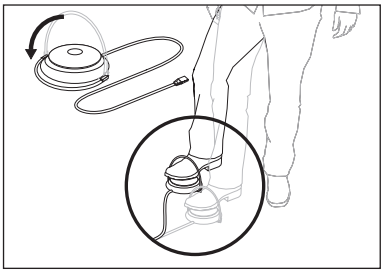
EN

5.1 Connecting the Foot Pedal

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



NOTE: the foot pedal comes with a bracket allowing it to be moved to the most suitable place for its operation, without the user needing to touch it with their hands.



The bracket can also be placed horizontally if it is not used.

⚠ **CAUTION**: Pay attention to the positioning of the foot pedal, which must be such that it is only activated intentionally by the operator.

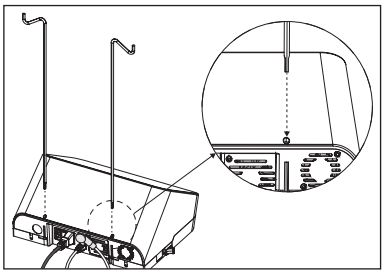
EN

5.2 Connecting the Irrigation Bag Support Rod and Handpiece Support

Insert the irrigation bag support rod (or both if both handpieces are used) in the dedicated hole at the back of the device, as far in as it will go.
The rod coupling is specially shaped to block its movement and prevent rotation.

⚠ **CAUTION**: Insert the bag support rods facing outwards with respect to the device as shown in the figure.

1

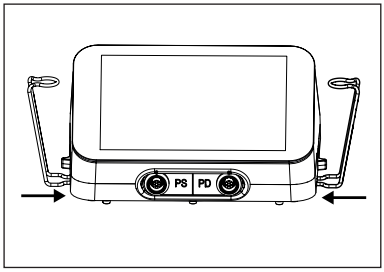


Insert the fixed handpiece support in the dedicated slots.

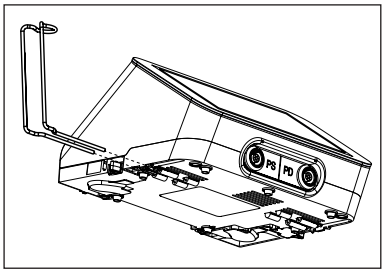
NOTE: The handpiece support can be placed in two different positions: right side, left side;

⚠ **WARNING**: The support must be used strictly to stow the PIEZOSURGERY MT or PIEZODRILL MT handpiece.

2



NOTE: to facilitate insertion, lift the device slightly to be able to see the slots.



5.3 Connecting the Handpieces to the Device

The PS channel allows use of the PIEZOSURGERY MT handpiece to which the multi-purpose PIEZOSURGERY inserts can be connected.
The PD channel allows use of the PIEZODRILL MT handpiece to which the multi-purpose inserts in the PD family can be connected.
Remove the cap from the cord connector, if present, and insert the cord connector in the dedicated socket on the front panel of the device console, matching the marked point on the connector with the marked point on the ring of the device console. Slightly push the handpiece-cord connector until it stops;

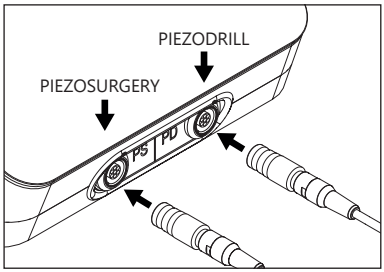
⚠ **CAUTION:** To avoid damaging the handpiece-cord, always hold it by the connector during connection and/or disconnection. Never pull the cord.

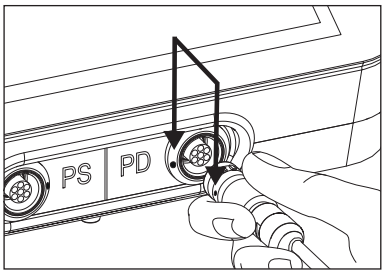
NOTE: the PIEZOSURGERY MT and PIEZODRILL MT handpiece connectors are designed to be connected strictly to their matching channel by means of their visible geometric distinction.

In addition, a red dot marked on both connectors and on the relative machine-side connectors indicates the correct positioning of the connector itself when connecting the device.
Moreover, the channels are identified by:

- the writing "PS" for the PIEZOSURGERY MT handpiece and grey colour code;
- the writing "PD" for the PIEZODRILL MT handpiece and black colour code.

1





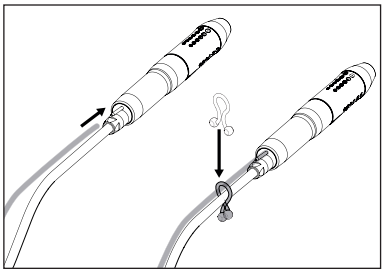
EN

EN

5.4 Assembling the Irrigation Kit

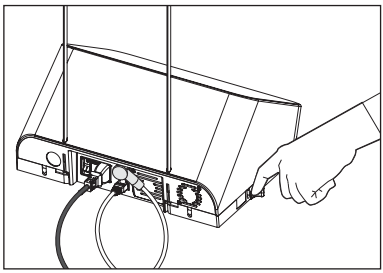
1

Open the packaging of the pre-sterilised handpiece and of the Irrigation Kit, removing the tube and the fixing clips.
Connect the end part of the irrigation tube to its coupling on the handpiece.
Fix the irrigation tube to the handpiece-cord using the supplied clips, making sure to fix at least one clip near the machine-side connector so that the irrigation kit tube slides parallel to the entire cord.



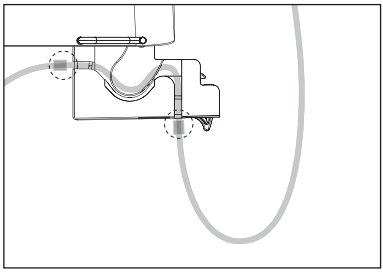
2

Open the peristaltic pump cassette as far as it will go using the side key towards the front of the device.



3

Insert the part of the irrigation tube with a larger diameter in the peristaltic pump for a length of 15 cm. The part of the tube to be inserted in the cassette is that between the two joints that also prevent the tube from sliding.



4

Fully close the peristaltic pump cassette;

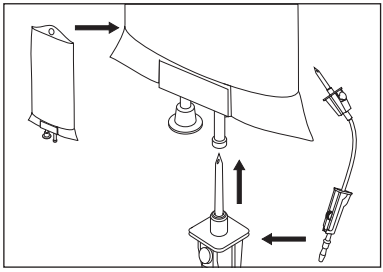
EN

5

Place the bag on the relative rod.
Remove the protective cap from the perforator
Insert the perforator in the irrigation bag (bag not supplied).

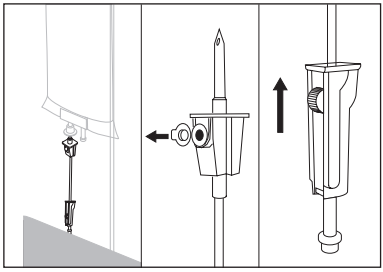
⚠ **WARNING**: The irrigation kits are supplied in sterile packaging. Check that the packaging is intact. If damaged, do not use it and send it for proper disposal.

⚠ **WARNING**: The support rod for the saline solution container must only be used for bags containing maximum 1000 ml (max 1.1 kg).



6

Open the air inlet on the tubing before operating. Open the irrigation tube clamp, if closed.



5.5 Disconnecting the Handpieces

To disconnect the handpiece-cord connectors, simply grab the connector firmly and pull it out.

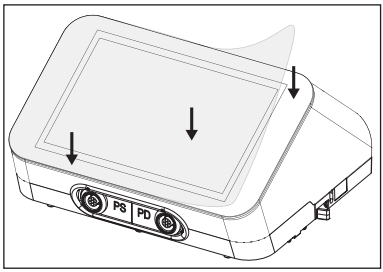
⚠ **CAUTION:** To avoid damaging the handpiece-cord, always hold it by the connector during connection and/or disconnection. Never pull the cord.

EN

5.6 Positioning the Protective Foil (optional)

Clean the touch screen with a soft, low-lint cloth and position the sterile protective foil on the surface of the clean touch screen.

⚠ **WARNING**: The protective foils are supplied in sterile packaging. Check that the packaging is intact. If damaged, do not use it and send it for proper disposal.



5.7 Description of the Controls

The MT-Bone screen has an integrated Touch Screen. The controls can be selected by simply tapping the pre-selected buttons on the screen.

NOTE:

DARK GREY: button enabled and if selected opens the corresponding page.

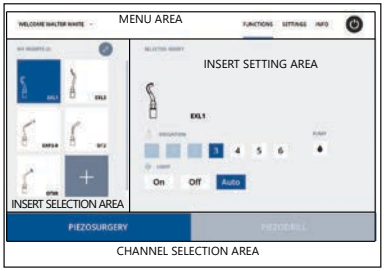
LIGHT GREY: button not selectable (double sound feedback).

WHITE: button selectable (sound feedback).

⚠ **CAUTION:** Do not use sharp or pointed objects on the LCD screen. This could damage the Touch Screen or the screen itself. The desired settings can be selected by simply tapping with a finger, even with a latex glove.

EN

After the first start-up (see *Chapter 5 on page 23)*, the home screen will appear when the device is switched on.
The home screen is divided into 4 main areas:
Menu area;
Insert selection (PIEZOSURGERY channel) and power selection (PIEZODRILL channel) area;
Insert setting (PIEZOSURGERY channel) and implant site preparation (PIEZODRILL channel) area;
Channel selection area**.**



The buttons and controls available in the **Menu area** are described below:

- **USER NAME BUTTON**

  Displays the name of the selected user. This is a drop-down menu from which to select the desired user, if previously created.

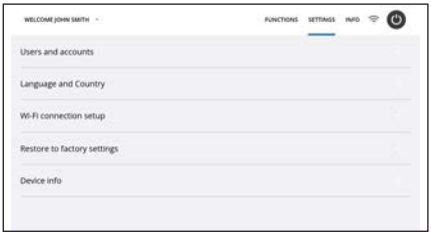
- **FUNCTIONS BUTTON**

  The user is directed to the function screen (PIEZOSURGERY or PIEZODRILL depending on the handpiece being used).

EN

- **SETTINGS BUTTON**

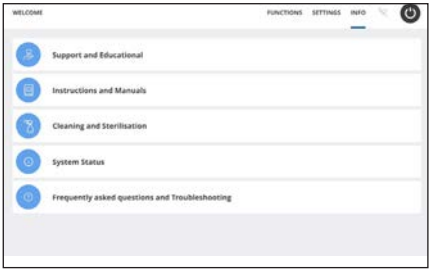
  Opens the screen with the device settings menu.



- **INFO BUTTON**

  Opens the screen containing supporting information relating to documentation, frequently asked questions, client help references, etc.

  An orange dot on the INFO icon indicates to the user that a new error is present. The error will be listed in the System Status section of the interface



- **WI-FI BUTTON**

  Enables/disables the Wi-Fi connection:

  The Wi-Fi can be in three different statuses:

  - Disabled
  - Enabled with no connection
  - Enabled and connected

- **SHUTDOWN BUTTON**

  Ends the work session.

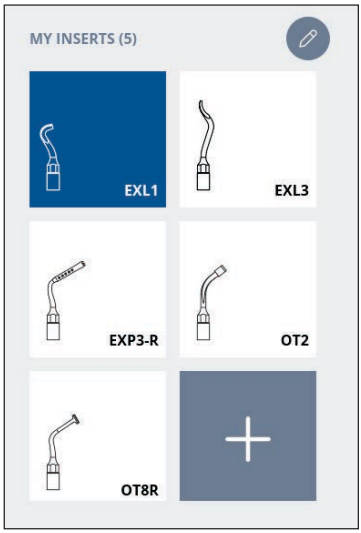
- **CANCEL BUTTON**

  Removes the message and cancels the command.

The buttons and controls available in the **insert selection/power selection area** are described below:

- **"MY InsertS" BUTTONS**

  Allows selection of the insert to be used in the procedure.



- **EDIT BUTTON**

  Allows the list of inserts to be edited.

- **PIEZODRILL CHANNEL POWER LEVEL BUTTON**

  Allows selection of the PIEZODRILL MT handpiece power level.

EN

The buttons and controls available in the **insert setting/implant site preparation area** are described below:

- **PUMP BUTTON**

  The device has a PUMP button. The PUMP function must be used at the start of the treatment to push the liquid towards the insert, so as to start the surgery with irrigation, otherwise an error message appears.

  This procedure must also be performed after each time the device is used and before cleaning, disinfecting and sterilising all its parts (See Cleaning and Sterilisation Manual).

- **FLOW RATE BUTTON**

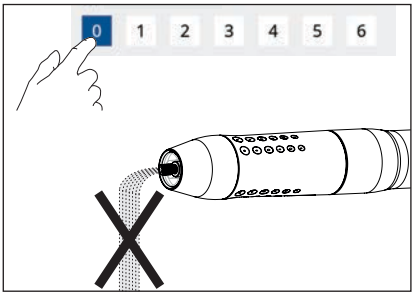
  Using the numeric buttons, it is possible to change the irrigation quantities within a default range set by the manufacturer.

  The set irrigation level is kept in memory

  There are 7 flow rate levels:

  - 0 = the pump function is off: no irrigation flows from the insert.
  - From 1 to 6 = the pump flow rate ranges from 4 or 8 ml/min to 75 ml/min., depending on the insert.

  The possibility to choose the irrigation flow rate depends on the selected insert.



NOTE: treatment without irrigation is only possible for inserts compatible with this setting. If an irrigation rate of less than 8 ml/min is required, for the OP1, OP2, OP3, OP3A and SLC inserts, select level 1 (approx. 4 ml/min).
For all other inserts irrigation level 1 corresponds to approx. 8 ml/min.

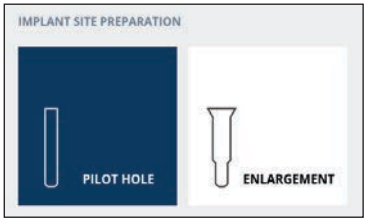
- **LIGHT BUTTON**

  Depending on the type of operation to be performed, there are 3 possible "LIGHT" options:

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

- **OPERATING STEP BUTTONS**

  These buttons must be selected based on the preparation of the pilot hole or enlargement.



EN

The buttons and controls available in the **channel selection area** are described below:

- **FUNCTION SCREEN BUTTONS**

  These buttons are used to select the PIEZOSURGERY or PIEZODRILL function screen (see sections 6.9 and 6.10).

  They are selectable if the handpiece is connected.

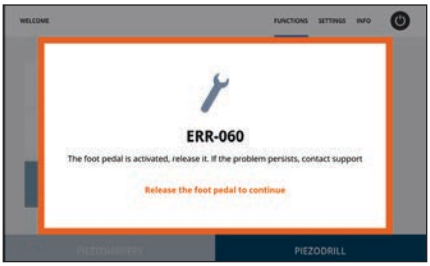
  NOTE: The selection buttons can be displayed in different colours to indicate the status of the associated function. The colours and relative status are described below:

  LIGHT BLUE: colour identifying the PIEZOSURGERY channel, when it is selected.

  DARK BLUE: colour identifying the PIEZODRILL channel, when it is selected.

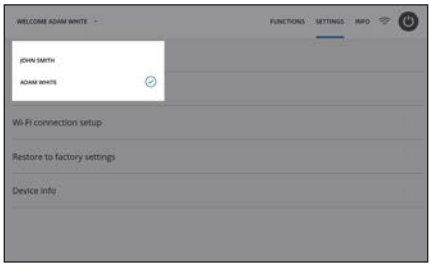
- **SYMBOLS**

  MT-Bone is provided with a diagnostic circuit that allows the detection of malfunctions and viewing of their type on the screen by means of a symbol and orange-framed pop-up. To help the user identifying the part that is non-functioning there are four symbols described in *Chapter 10.1 on page 61*.

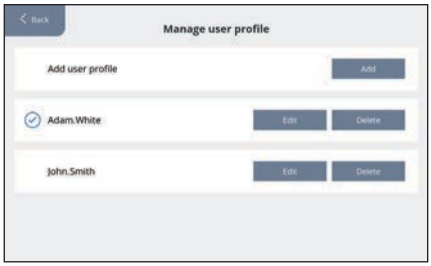


5.8 User Selection and Management (optional)

If the user has previously created an account, the Username is displayed at the top, to the left of the menu.
The user can easily switch from one account to the other by selecting the Username in the drop-down menu.



The user profile can likewise be managed from the relative section in the Settings area.
The active profile is indicated by a tick icon.
The user can edit their account information (Username), delete their account or Add another account and switch from one profile to another by selecting it.



5.9 PIEZOSURGERY Channel Function Screen

When the device is switched on and at least one handpiece is connected, the settings screen for that handpiece is displayed.
Alternatively, the PIEZOSURGERY screen can be selected by tapping the button at the bottom of the display.
The applications of the PIEZOSURGERY channel can then be used with the PIEZOSURGERY MT handpiece. On this screen, it is possible to select the insert from the "My inserts" list (left-hand side of the display), view it enlarged on the right-hand side, select the desired flow rate (within a default range), select the handpiece LED on/off options and activate the PUMP function.
The user can configure the device by simply tapping the touch screen, selecting the insert inserted on the PIEZOSURGERY MT handpiece according to the selected clinical application.
Depending on the set insert, the electronic feedback system will automatically adjust the correct working frequency and ideal power level.

EN

5.10 PIEZODRILL Channel Function Screen

When the device is switched on and at least one handpiece is connected, the settings screen for that handpiece is displayed.
Alternatively, the PIEZODRILL screen can be selected by tapping the button at the bottom of the display.
The applications of the PIEZODRILL channel can then be used with the PIEZODRILL MT handpiece. On this screen, it is possible to select the operating step (pilot hole or enlargement) to develop the hole, the power level (left-hand side of the display), the desired flow rate (within a default range), the handpiece LED on/off options and activate the PUMP function.
The user can configure the device by simply tapping the touch screen, selecting the operating step that requires use of the insert inserted on the PIEZODRILL MT handpiece.

NOTE: see the instructions for use of the PIEZODRILL inserts for the operating phases and steps.

Depending on the set phase, the electronic feedback system will automatically adjust the correct working frequency and the ideal range for the power to be fed to the insert.

5.11 SETTINGS Screen

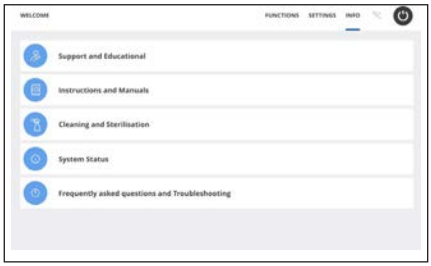
This screen includes the following items:

- **Users and Accounts**: in this section, it is possible to add, edit and delete users.
- **Language and Country**: in this section, it is possible to change the language and country initially selected when the device was first activated.
- **Wi-Fi connection setup**: this section allows you to change the Wi-Fi configuration of the device. If the device has never been connected to a Wi-Fi network, it allows the first connection to be made. Otherwise, it offers the possibility to replace the existing network or change its credentials.
- **Restore to factory settings**: in this section, it is possible to delete user data and settings.
- **Device Info**: this section displays information about the device.

5.12 INFO Screen

The MT-Bone Info screen includes the following items:

- **Support and Training Material**: features a QR code to open the relative page on the Mectron website.
- **Instructions and User Manual**: features a QR code to open the relative page on the Mectron website.
- **Cleaning and Sterilisation**: features a QR code to open the relative page on the Mectron website.
- **System Status:** lists the errors of the System.
- **FAQ and Troubleshooting**: features a QR code to open the relative page on the Mectron website.



EN

6 INSTRUCTIONS FOR USE

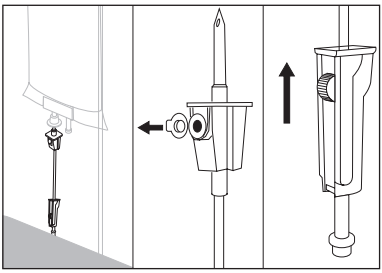
6.1 PIEZOSURGERY Channel Instructions for Use

EN

After having connected all the requested components as shown in *Chapter 5 on page 23* proceed as follow:

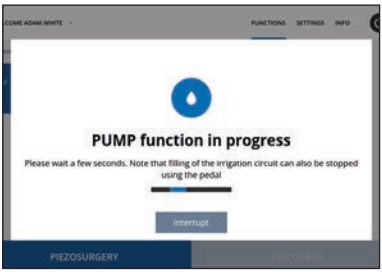
1

Open the air inlet on the tubing before operating. Open the irrigation tube clamp, if closed;



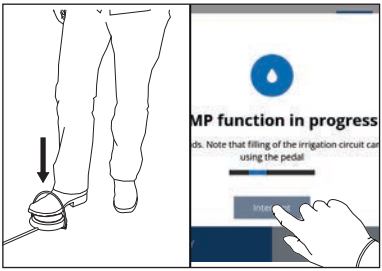
2

Tap the PUMP function on the touch screen to fill the irrigation circuit: all other functions will be disabled and a message will appear informing the user of its progress;



3

The cycle can be stopped as soon as liquid is seen flowing out from the PIEZOSURGERY MT handpiece by pressing “Stop” or alternatively by pressing on the foot pedal.
The PUMP function is disabled and the touch surface becomes active again in the last setting used;

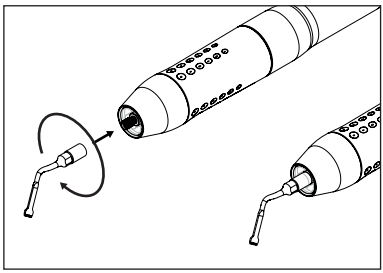


EN

4

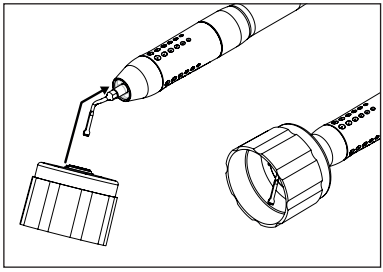
Screw the preselected insert onto the PIEZOSURGERY MT handpiece until it stops;

⚠ **WARNING**: PIEZOSURGERY inserts can only be mounted on the PIEZOSURGERY MT handpiece.



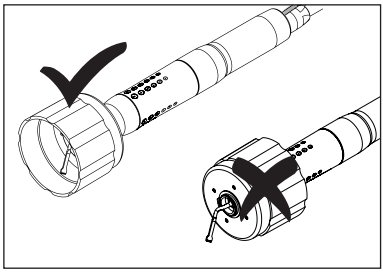
5

Tighten the insert using the K8 Mectron torque wrench;
For correct use of the Mectron torque wrench, proceed as follows:



6

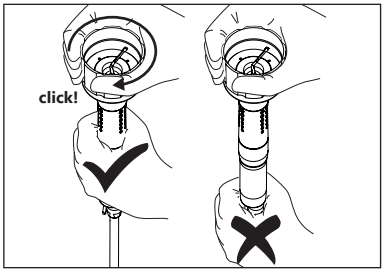
Place the insert inside the torque wrench, as shown;



7

Hold the handpiece body firmly;

⚠ **CAUTION:** Do not grab the handpiece by the end part and/or the cord. Grab it only by the central body. Do not turn the handpiece, instead it must be held steady and only turn the wrench.
Turn the torque wrench in a clockwise direction until the notch clicks (the external body of the torque wrench turns with respect to the body of the handpiece, emitting mechanical "CLICK" sounds).

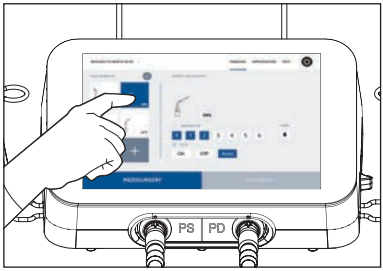


The insert is now optimally locked;

EN

8

On the touch screen, select the insert mounted on the handpiece. The default flow rate and the selectable levels are displayed. To select another insert, tap the corresponding button;



The selected insert will be displayed on the right-hand side of the display;
For each insert, the device sets the ideal operating settings. Using the numeric buttons, it is possible to change the irrigation quantities within a default range set by the manufacturer and to select the LED handpiece status;

9

Check the wear and integrity of the insert before and during each use;

10

Before using the insert, check that the operating site has been prepared, having previously displaced the soft tissue;

11

Start the handpiece before the insert comes into contact with the part to be treated;

12

The insert must be kept in constant movement and must not remain still inside the bone;

13

Apply slight and constant force on the insert for best performance.

6.2 PIEZODRILL Channel Instructions for Use

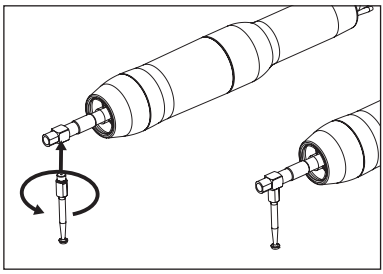
After connecting all the requested components as illustrated in *Chapter 5 on page 23* proceed as described in points 1, 2 and 3 of section 7.1, then proceed as follows:

⚠ **WARNING**: PD inserts can only be mounted on the PIEZODRILL MT handpiece.

EN

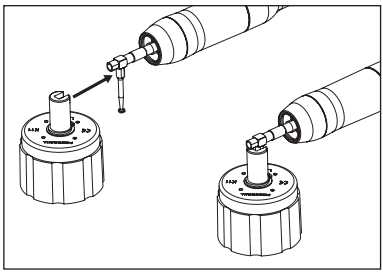
1

Screw the preselected insert onto the PIEZODRILL MT handpiece until it stops;



2

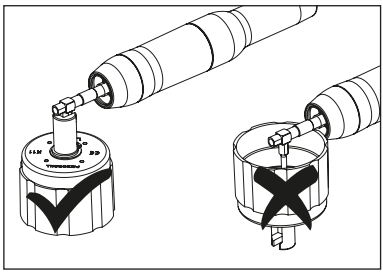
Tighten the insert using the K11 Mectron torque wrench specifically for the PIEZODRILL MT handpiece;
For correct use of the Mectron torque wrench, proceed as follows:



3

Place the insert inside the torque wrench, as shown;

⚠ **CAUTION:** when tightening, take care not to exert any shear forces perpendicular to the axis of the insert as this may damage the threaded coupling between the handpiece and the insert itself.

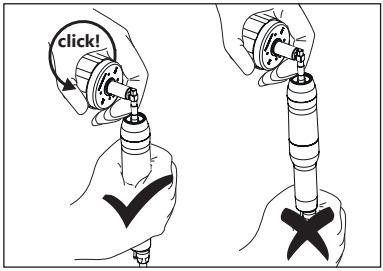


EN

4

Hold the handpiece body firmly;

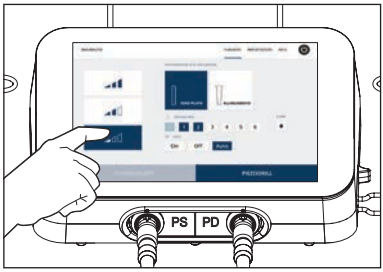
⚠ **CAUTION:** Do not grab the handpiece on the end and/or on the cord, but only on the body. Do not turn the handpiece, instead it must be held steady and only turn the wrench.
Turn the torque wrench in a clockwise direction until the notch clicks (the external body of the torque wrench turns perpendicular to the body of the handpiece, emitting mechanical "CLICK" sounds).



The insert is now optimally locked;

5

Select the operating step (PILOT HOLE or ENLARGEMENT) depending on the insert mounted on the handpiece.
To change the power level, select one of the three levels shown on the left-hand side of the screen.



Using the numeric buttons, it is possible to change the irrigation quantities within the selectable levels and to select the LED handpiece status.

6

Check the wear and integrity of the insert before and during each use;

7

Before using the insert, check that the operating site has been prepared, having previously displaced the soft tissue;

8

Start the handpiece before the insert comes into contact with the part to be treated;

9

The insert must be kept in constant movement and must not remain still inside the bone;

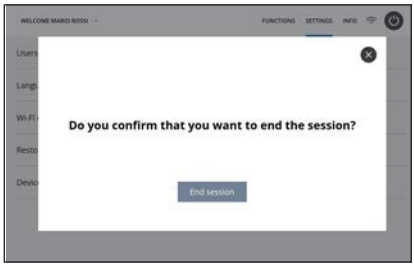
10

Apply slight and constant force on the insert for best performance.

6.3 Device Switching Off

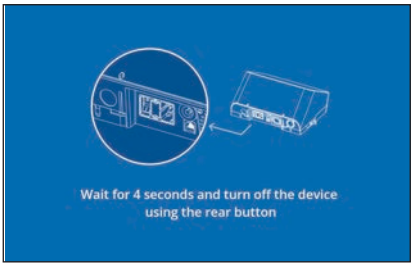
Tap the "OFF" button to end the work session.

Confirmation is requested. Select the “End Session” button to proceed with shutdown, select to return to the work screen.



Device switching off

When this screen appears, wait 4 seconds and switch the device off via the switch on the back.



EN

6.4 Safety Requirements Before and During Use

⚠ **WARNING**: Before starting work always ensure that you have all replacement parts (handpiece, inserts, wrenches) 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.

⚠ **WARNING: Checking the condition of the device and its relative accessories before treatment.** Always check that there is no water under the device. Before each treatment, always check the perfect working order of the device and the efficiency of its components. If operation anomalies are observed do not carry out the treatment. If the faults concern the device and/or its accessories, contact an Authorised Mectron Service Centre.

⚠ **CAUTION**: To avoid damaging the foot pedal cable, always hold it by the connector during connection and/or disconnection. Never pull the cable.

⚠ **CAUTION**: Do not twist or turn the foot pedal cable when inserting or removing it. Twisting may damage the connector.

⚠ **CAUTION**: Never force the handpiece cord connector into the device console connector as this may damage the handpiece-cord connector and/or the device. If the two connectors do not connect with reasonable ease, they probably don't match. Check that the marking of the handpiece-cord connector is facing upwards and that the handpiece connector matches the desired channel (grey for PIEZOSURGERY MT and black for PIEZODRILL MT).

⚠ **CAUTION**: Check that the handpiece is properly connected and in the right channel before using the system.

⚠ **WARNING**: **Infection control. First use**: All parts and reusable components (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 in the Cleaning and Sterilisation Manual. **Subsequent uses:** After each treatment, clean and sterilise all parts and reusable components according to the instructions in the Cleaning and Sterilisation Manual.

⚠ **WARNING: Sterile disposable.** Before using a sterile disposable object, check the integrity of the packaging to ensure that it is sterile. The object will no longer be sterile if the packaging is broken or damaged. Sterile disposable objects must be used only for one dedicated surgical procedure on one patient only. Disposable objects must not be reused and reprocessed. Segregate and dispose of each disposable object in accordance with current healthcare waste management regulations.

⚠ **WARNING**: The Irrigation kit is guaranteed for one use only. Segregate and dispose of this kit in accordance with current healthcare waste management regulations.

⚠ **WARNING**: Before using the device, check that the irrigation hose clamp is open. At the and of the surgical procedure, close the clamp before disconnecting the irrigation kit from the bag of saline solution.

⚠ **WARNING**: Check the saline solution level in the saline solution bag. Replace the saline solution bag with a new one before it finishes.

⚠ **CAUTION**: 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 cord connector must be dry.** Before connecting the handpiece to the device, check that the electrical contacts of the connector are perfectly dry, especially after the autoclave sterilisation cycle. If necessary dry the contacts by blowing them with compressed air.

⚠ **CAUTION: PUMP function.** The PUMP function must be used after each treatment before starting the cleaning and sterilisation procedures.

⚠ **WARNING**: To ensure the proper operation of the handpiece, always start it with the irrigation circuit properly installed and filled. To fill the irrigation circuit always use the PUMP function.

⚠ **WARNING**: Treatments that require irrigation. Always check the operation of the irrigation before and during use. Make sure that the liquid flows out from the insert. Do not use the device if irrigation is not working or the pump is faulty.

⚠ **CAUTION**: For correct use of the device, the foot 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 suitable for the treatment is the one inserted on the handpiece. Use only the Mectron torque wrench to secure the insert to the handpiece. Do not use other instruments such as pliers, forceps, etc...

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

.⚠ **CAUTION: Intermittent operation.** Prolonged use may cause the handpiece to overheat. See *Chapter 9 on page 52* for the average usage times (intermittent operation).

⚠ **WARNING**: MT-Bone, with compatible accessories and inserts, is rated for use in intermittent mode (as outlined in *Chapter 9 on page 52*). Continuous use of MT-Bone, with compatible accessories and inserts, for a prolonged period and in any case exceeding the stated limits may cause overheating, in particular of the handpiece. In case of overheating, avoid contact of the handpiece with the operator and patient.

⚠ **WARNING**: Pay particular attention to the sharp blades of cutting inserts. When tightening and removing these inserts, the blades may cause injury.

⚠ **WARNING**: Do not change the insert while the handpiece is in operation 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. Do not bend, change shape or sharpen an insert in any way. Folding an insert or levering on it can cause it to break. Deformed or otherwise damaged inserts, are susceptible to breakage during use. These inserts should never be used. Excessive pressure on the inserts during use can lead to breakage. In the event of breakage check that no fragments remain in the treated part and at the same time use suction effectively to remove them. The patient must be instructed to breathe through the nose during the treatment, or use a dental dam, so as to avoid ingesting fragments of broken inserts. 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. Using a worn insert reduces cutting performance and may cause necrosis of the treated bone surface. 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.

EN

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

⚠ **WARNING: Contraindications.** Do not use MT-Bone with relative accessories on patients with Pacemakers or other implantable electronic devices. This regulation also applies to the operator.

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

6.5 Important information on the Inserts

⚠ **WARNING**:

- The insert must be held in constant movement. Blocking or holding the insert in contact for a prolonged period may cause thermal damage to the treated part (for example, in the periodontal pockets, interdental septa or alveolar process during extraction procedures). Continuous motions should be used to minimise contact between the tip and the tissue. It is advisable to increase the flow rate as the power level increases.
- Apply slight and constant force on the insert for best performance. Do not apply excessive pressure, allow the ultrasonic vibrations to work.
- When the layer of titanium nitride is visibly consumed the insert must be replaced. Using an overly worn insert reduces its cutting 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 Mectron handpiece, with the risk of no longer being able to correctly screw in the original inserts upon subsequent use. In addition, the device 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 a used insert.
- Always check that the threaded parts of the insert and the handpiece are perfectly clean – See the Cleaning and Sterilisation Manual.
- Excessive pressure applied to the insert can cause it to break and potentially injure the patient.
- For proper use of the inserts, see the “Appropriate settings for inserts” sheet or the leaflet of the purchased Mectron insert.
- Before using MT-Bone, check that the operating site has been prepared, having previously displaced the soft tissue to avoid damaging it. It is possible that when cutting the bone, accidental contact of certain parts of the insert with the soft tissue may cause minor trauma. Use suitable protective tools to minimise this risk.

6.6 Wi-Fi – IoT Technology

NOTE: MT-Bone fulfills its intended purpose **without** the IoT (Internet of Things) platform and the Wi-Fi/BLE connection.

If the device cannot reach the Mectron server, the IoT functionality will automatically deactivate, but the device's ability to fulfill its indication for use remains unaffected and NO RISK to the patient and the user is raised.

The MT-Bone device is designed to take advantage of IoT (Internet of Things) technology through the Mectron IoT platform, available in countries where the service is enabled. The Mectron IoT platform allows the creation of a network of Mectron devices connected to the Internet, equipped with software that enables the exchange of data with Mectron's remote servers. This system offers several benefits, including improved device usability, optimised maintenance and extended device life.

Through the use of the Mectron IoT platform, MT-Bone can access the following services:

- Send the device diagnostic data to the Mectron cloud;
- First device activation (See *Chapter 4.7 on page 18*) or updating Wi-Fi credentials (see *Chapter 6.6.1 on page 48*);
- Updates of the User Interface (see Chapter 6.6.2 on page 48);
- Update of inserts database (see Chapter 6.6.2 on page 48);
- Updates of device features (see Chapter 6.6.2 on page 48);

The implementation of IoT technology on MT-Bone includes the following features:

1. Bluetooth communication: when the device is switched on, Wi-Fi credentials are transmitted from the smartphone application to MT-Bone's IoT board via a Bluetooth connection;
2. Wi-Fi connection: with an Internet access point to communicate with the Mectron server;
3. *MyMectron* app: to manage connectivity and authorisation for data exchange (protected and private) with the Mectron cloud.

All data that are sent to the Mectron private server are made available to users via the *MyMectron* App. All data access is protected by authentication and authorisation mechanisms to guarantee the security and confidentiality of the information.

The data collected through the IoT Technology will be managed, stored and used by Mectron with the utmost transparency, for purposes related to the improvement of MT-Bone's performance and for any purpose related to the analysis of usage patterns.

Mectron reserves the right not to activate or to suspend at any time, the implementation of the IoT Technology for MT-Bone, even if it is already active.

NOTE: Enabling of the IoT function depends on the availability of the *MyMectron* mobile application (app) for smartphone in the country where the device is sold and the reachability of the Mectron server.

The App can be downloaded from the Apple AppStore and the Google Play Store following this link: https://app.mectron.com or by framing the QR-Code:

Without communication with the Mectron Server, the IoT-managed functions will not be accessible.

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6.6.1 Wi-Fi connection configuration

The user has the option of updating the device's Wi-Fi configuration by selecting "Wi-Fi Connection Configuration" from the Settings section

The screen shows two separate procedures:

- one to make the first association in case the device has never been connected to a Wi-Fi network before;
- the other to replace the existing network or change its credentials.

Clicking "Continue" redirects the user to the screen described in point 11 of *Chapter 4.7 on page 18* Follow the steps outlined in that chapter to complete the Wi-Fi configuration update

6.6.2 Updates and related troubleshooting

NOTE: potential updates impacting safety and operating system updates are not released through the Mectron IoT platform. Such updates can't be installed without the Mectron personnel supervision. In the event of a safety update, Mectron will contact the customer to handle the update, ensuring its safe implementation.

The devices can be updated through the Mectron IoT platform to benefit from new inserts, graphic interface or device features modifications, enhancing the user experience.

NOTE: if the app or the Wi-Fi connection are not available, the user can update the device by contacting a Mectron authorised Service Centre and sending the device to the customer support.

By using the *MyMectron* app the user can check for, and eventually update, the software installed in the device.

NOTE: guided procedures and user information can be found on the *MyMectron* app. Refer to the *MyMectron* app for details regarding the supported functions.

If an updated software version is available, the user will receive notification via the *MyMectron* app.

If desired, the user can accept the software update. It is not mandatory to proceed with the update.Only registered users can confirm an update.

The device will be rebooted as soon as the update is accepted by the user or on *MyMectron* app. When the installation procedure is complete, the device is ready to be used and a courtesy push notification is sent to the mobile application.

NOTE: It is important not to switch off the device during this process to avoid triggering reset procedures.

NOTE: In case the software update is not accepted by the user or on *MyMectron* app, the device will not restart and it will remain unchanged and unaffected during use.

SAFETY:

The latest installed software version is always available for the auto-repair process. Therefore, if the diagnostic process detects an error on the disk when the device is rebooted, the device can still be made operational.

The device has a software protection

mechanisms allowing the update to be completed if the process is accidentally interrupted. It includes an auto-repair mechanism allowing the reactivation of the latest installed version in case the device's flash memory is corrupted.

TROUBLESHOOTING:

Refer to Chapter 10.3 on page 67.

6.6.3 Cyber-attack identification and troubleshooting

NOTE: Failure of the IoT technology (Wi-Fi and/or BLE) does not affect the intended functionality of the device in any way whatsoever. The essential functions of the device described in this manual do not depend on IoT technology.

Considering the security measures implemented in the design and the nature of the device, a cybersecurity attack is highly improbable. Nevertheless, certain occurrences that can signal a cybersecurity attack are listed in the Troubleshooting table. In that table, the steps to be followed in the occurrence of an unexpected or suspected cybersecurity incident are reported. This is important to minimize its impact and prevent further damage.

TROUBLESHOOTING:

Refer to Chapter 10.4 on page 67.

6.6.4 Support

In any case support is needed, please contact a Mectron authorised Service Centre.
Servicing is performed only by qualified personnel. The user is not allowed to perform any servicing procedure.
Mectron has established internal procedures to handle security complaints, solve issues identified through biannual post market analysis and address any necessary changes in the event of failure of the device and its accessories.
Mectron, following its internal procedures, ensures support as long as the device and its accessories remain in the field and are not withdrawn.

6.6.5 Infrastructure Requirements

In order to correctly configure IoT technology for the MT-Bone device, the Wi-Fi network (points 1, 2 and 3 below) and Bluetooth (point 4 below) must meet the following requirements:

1. WPA safety protocol enabled - required to secure the network;
2. DHCP enabled - required for automatic assignment of a local address in the network;
3. If there is a firewall, ensure it allows outbound connections from the configured local network at least on ports 123, 443 and 8883;
4. Bluetooth (BLE) version - the smartphone used must be equipped with Bluetooth version 4.2 or higher.

CONSEQUENCES IN CASE OF NON-COMPLIANCE

If requirements 2 and 3 are not met, IoT functionality will be disabled due to the inability to establish communication with the Mectron server. If the Wi-Fi network does not meet requirement 1, the network will not be accepted or displayed among the usable networks when configuring the connection in the smartphone app. If requirement 4 is not met, the *MyMectron* app will not be able to detect the MT-Bone device.

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6.6.6 Technical information on connection port/interface

Port/ Interface	Protocol	Port Number	Functionality	Direction	Approved Destination End-Points
Bluetooth	BLE	N.A.	Sending Wi-Fi credentials	Incoming	Eeprom device WSP32
Port 443	HTTPS	443	Secure web traffic	Both	Proprietary Protocol
Port 123	UDP	123	Network Time protocol	Incoming	Used for time synchronization
Port 8883	TCP	8883	Cloud Access Service	Incoming	Access HUB

6.6.7 Device Protection Features for Cybersecurity

The device is designed to ensure that its safety is not compromised by a cyber-attack or software error in relation to its indication for use.
The device does not handle, record or transmit any patient-related data, whether sensitive or non-sensitive (there is no need of sanitizing the product to ensure a securely decommissioning).
To enhance security and reduce the risk of cyber-attacks, the following measures have been implemented:

- User access to the device's operating system is completely restricted;
- A proprietary firewall is active between the medical domain of MT-Bone and its IoT,
- Updates and installations can only be performed using signed and encrypted software supplied by Mectron;
- The user cannot create custom configurations and only has the rights of using the device (no levels of access are foreseen).

In addition, Mectron has established dedicated verification controls and technical solutions (e.g. ship the device in a lock state) to ensure device integrity (e.g. remain free of malware) before shipping.

6.6.8 Software Bill of Materials (SBOM)

The user can check the device SBOM navigating the User Interface. Select SETTINGS and then DEVICE INFO.

7 MAINTENANCE

If the devices are not used for a long period, observe the following recommendations:

1. Disconnect the device from the mains;
2. In case of long periods of non-use, stow the device in a safe place in its original packaging;
3. Before using the device again, clean and sterilise the handpiece and the wrench following the instructions in the Cleaning and Sterilisation Manual;
4. Check that the inserts are not worn, deformed or broken, paying particular attention to the integrity of the tip.

⚠ **WARNING**: Periodically check the integrity of the power supply cable; when it appears to be damaged replace it with

original Mectron spare part.

8 METHODS AND PRECAUTIONS FOR DISPOSAL

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

- Inserts, when worn or broken;
- Sterile irrigation kit after each use;
- Insert torque wrench, dispose of when used or broken.

Disposable materials and materials representing a biological risk must be disposed of in accordance with the local regulations in force concerning healthcare waste management.

MT-Bone, with relative accessories, must be disposed of and treated as waste subject to separate collection.
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.
Failure to comply with the previous points may lead to penalties imposed under the Waste of Electrical and Electronic Equipment (WEEE) Directive.

9 TECHNICAL DATA

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Device compliant with Regulation (EU) 2017/745	Class IIa
Classification under the IEC/EN 60601-1	I Parts applied: type B (insert) IP 20 (device) IP X8 (foot pedal model FS-06)
Essential performance	According to the standard IEC 80601-2-60 the device has no essential performance
Device for intermittent operation	PIEZOSURGERY: 55sec. ON - 30sec. OFF with irrigation 30sec. ON - 120sec. OFF without irrigation PIEZODRILL: 20sec. ON - 40 sec. OFF with irrigation
Power Supply	100-240 V~ 50/60 HZ
Max. Power Consumption	150 VA
Fuses	Type 5 x 20 mm, T 1.6AL, 250V
Battery	The device is equipped with a backup battery, which can only be replaced by an Authorised Mectron Service Centre. Model: BR/CR 1220
Working Frequency	Automatic Scan From 24 KHz to 36 KHz
Peristaltic pump flow rate	Adjustable using the touch screen: 7 flow rate levels: from 0 to 6 (from 0 to about 75ml/min) **NOTE**: The minimum and maximum flow rate settings are set by Mectron according to the type of insert.
Handpiece LED system:	Light function set to AUTO: The handpiece LED lights up as soon as the device starts working, and turns off 3 seconds after the foot pedal is released. Light function set to ON: The handpiece LED is always lit; after 100 seconds of non-use of the foot pedal, it turns off by itself and the light function switches to AUTO. Light function set to OFF: The handpiece LED is always off. White LED light power risk-free according to standard IEC/EN 62471

Protections of the APC Circuit	Missing handpiece; Broken cord wire; Insert not correctly tightened or broken; Control with incorrect frequencies; Abnormal current draw by handpiece; Overtemperatures; Range of validity for the main analogue signals; External hardware watchdog.
Wi-Fi / BLE operating frequency range	2400 ÷ 2483.5 MHz, maximum power limit 20 dBm
Operating Conditions	from 10°C to 35°C Relative humidity from 30% to 75% Air pressure P: 700hPa/1060hPa
Transport and Storage Conditions	from -10°C to 60°C Relative humidity from 10% to 90% Air pressure P: 500hPa/1060hPa
Altitude	lower than or equal to 3000 metres
Weights and dimensions	4.7 kg 330 x 260 x 162 mm (L x W x H)[a)] 412 x 260 x 426 (with irrigation bag support rods and handpiece support)

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

9.1 Electromagnetic Compatibility IEC/EN 60601-1-2

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

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

⚠ **WARNING: Interference by other equipment.** An electrosurgical scalpel or other electrosurgical units near the MT-Bone device and its accessories may interfere with the correct operation.

⚠ **WARNING:** MT-Bone, with relative accessories, requires special EMC precautions and must be installed and commissioned in compliance with the EMC information in this chapter.

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

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9.2 Guide and Manufacturer's Declaration - Electromagnetic Emissions

MT-Bone, with relative accessories, is designed to operate in the electromagnetic environment specified below. The purchaser or user of MT-Bone should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	MT-Bone 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	MT-Bone 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

MT-Bone, with relative accessories, is designed to operate in the electromagnetic environment specified below. The purchaser or user of MT-Bone should ensure that it is used in such an environment.

Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV 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%.
Radiated EM RF fields [a)]	IEC 61000-4-3	3 V/m [f)] 80 MHz - 2,7 GHz [b)] 80% AM at 1 kHz [c)]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended and calculated distances from the equation applicable at the frequency of the transmitter.
RF proximity fields from wireless communication equipment	IEC 61000-4-3	See *Chapter 9.5 on page 59*	

Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
Magnetic field at network frequency [d]	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Power supply frequency magnetic fields should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See *Chapter 9.6 on page 60*	Portable and mobile RF communication equipment must be used at a separation distance of at least 0.15 m from the field sources.

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

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

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

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

e) Empty.

f) Before applying the modulation.

9.4 Guide and the Manufacturer's Declaration - Electromagnetic Immunity

9.4.1 Power Connection BC Input

MT-Bone, with relative accessories, is designed to operate in the electromagnetic environment specified below.
The purchaser or user of MT-Bone 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.
Differential mode pulses [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.

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Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
Common mode pulses [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)] A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)]	The quality of the network voltage should be that of a typical commercial or hospital environment.
		0 % UT; 1 cycle and 70 % UT; 25/30 cycle [h)] Single phase: at 0°	
Voltage interruptions [f) i) o)]	IEC 61000-4-11	0 % UT; 250/300 cycle [h)]	The quality of the network voltage should be that of a typical commercial or hospital environment.

a) Empty.

b) During the test, all MT-Bone cables must be connected.

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

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

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

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

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

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

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

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

k) Not applicable to CLASS II devices and systems.

l) Direct coupling must be used.

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

n) The ISM bands (industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur 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 devices and systems with NOMINAL input current less than or equal to 16 A / phase and devices and systems with NOMINAL input current greater than 16 A / phase.

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

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

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

9.4.2 Points of Contact with the Patient

MT-Bone, with relative accessories, is designed to operate in the electromagnetic environment specified below.
The purchaser or user of MT-Bone should ensure that it is used in such an environment.

Phenomenon	Essential EMC standard or test method	Immunity test values	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) [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.

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- 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

MT-Bone, with relative accessories, is designed to operate in the electromagnetic environment specified below.
The client or user of MT-Bone must 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.
Common mode pulses [a)]	IEC 61000-4-5	± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conductive disturbances induced by RF fields [d) g) j) k)]	IEC 61000-4-6	3 V [h)] 0.15 MHz - 80 MHz 6 V [h)] in 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 only applies to output lines connected directly to 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 the modified start frequency with respect to cable length and device size.

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

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

MT-Bone, with relative accessories, is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The purchaser or operator of MT-Bone can help prevent electromagnetic interferences by guaranteeing a minimum distance between the mobile and portable RF communication devices (transmitters) and MT-Bone, 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 value (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 Band LTE 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						

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Test Freq. (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Max power (W)	Distance (m)	Immunity test value (V/m)
1720 1845 1970	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
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 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9

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

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

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

NOTE: If necessary to reach the immunity test level, the distance between the transmitter antenna and MT-Bone can be reduced to 1 m. The test distance of 1 m is allowed by IEC 61000-4-3.

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

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

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

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

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

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

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

10 TROUBLESHOOTING

10.1 Diagnostic System and Symbols on the Screen

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MT-Bone is provided with a diagnostic circuit that allows the detection of malfunctions and viewing of their type on the screen by means of a pop-up window associated with a symbol and error number.
The error is not resettable if the pedal is not released.
The possible errors are summarised in the table below.

Symbol on touch screen	Error Number	Error Message
No symbol on the screen. Errors during start-up	ERR-016	Switch the device off and on again, if the problem persists, contact support
	ERR-021	Wait for the firmware on the piezoelectric control module to reset, after which the device will be ready for use
	ERR-022	Wait for the firmware on the device control module to reset, after which the device will be ready for use.
	ERR-032	Switch the device off and on again, if the problem persists, contact support
	ERR-090	The firmware on the device management module could not be restored. Turn the device off and on again, if the problem persists contact support.
	ERR-091	The firmware on the piezo management module could not be restored. Turn the device off and on again, if the problem persists contact support.
	ERR-001	Replace the handpiece.
	ERR-002	Replace the handpiece.
	ERR-004	Replace the handpiece.
	ERR-005	Unscrew the insert and screw it back correctly using the torque wrench, or replace it.

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Symbol on touch screen	Error Number	Error Message
	ERR-072	Internal error, contact support.
	ERR-073	Internal error, contact support.
	ERR-074	Hardware fault, contact support.
	ERR-075	Hardware fault, contact support.
	ERR-008	Switch the device off and on again, if the problem persists, contact support.
	ERR-009	Excessive pressure on the insert. Use lighter pressure. If the problem persists, contact support.
	ERR-010	Switch the device off and on again, if the problem persists, contact support.
	ERR-011	Switch the device off and on again, if the problem persists, contact support.
	ERR-012	Switch the device off and on again, if the problem persists, contact support.
	ERR-013	The foot pedal is activated, release it. If the problem persists, contact support.
	ERR-014	Internal problem, switch the device off and on again. If the problem persists, contact support.
	ERR-016	Switch the device off and on again, if the problem persists, contact support
	ERR-017	Check that the insert is not obstructed and position the tube properly. (See *Chapter 5.4 on page 26*). If the problem persists, contact support.
	ERR-018	Reset the error and run a PUMP cycle, if the problem persists, contact support.
	ERR-032	Switch the device off and on again, if the problem persists, contact support.
	ERR-033	Switch the device off and on again, if the problem persists, contact support.
	ERR-043	Select the desired language on the Users Profile. If the problem persists, contact support.
	ERR-044	Install the software update. Switch the device off and on again, if the problem persists, contact support.

Symbol on touch screen	Error Number	Error Message
	ERR-060	The foot pedal is activated, release it. If the problem persists, contact support.
	ERR-061	Device in overtemperature, wait in standby for the device to reach the correct temperature.
	ERR-062	Device in overtemperature, wait in standby for the device to reach the correct temperature.
	ERR-063	Note that the irrigation circuit must be filled via the PUMP button before starting the treatment.
	ERR-067	Re-set the User Profile. If the problem persists, contact support.
	ERR-076	Reset the error and run a PUMP cycle, if the problem persists, contact support.
	ERR-077	Wait for the device to return to the normal operating temperature, if the problem persists, contact support.
	ERR-078	Position the tube correctly (See *Chapter 5.4 on page 26*) and close the cassette of the relative channel.
	ERR-089	Reset the error and and run a PUMP cycle, if the problem persists contact support.
	ERR-092	Error in data processing. Switch the device off and on again to continue using it, if the problem persists, contact support.

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Symbol on touch screen	Error Number	Error Message
System Status	ERR-079	Internal fan not working correctly. Switch the device off and on again, if the problem persists, contact support.
	ERR-080	
	ERR-081	
	ERR-082	
	ERR-083	[PS CHANNEL] - The peristaltic pump sensor is not working correctly. Switch the device off and on again, if the problem persists, contact support. [PD CHANNEL] - The peristaltic pump sensor is not working correctly. Switch the device off and on again, if the problem persists, contact support.
	ERR-084	
	ERR-085	[PS CHANNEL] - The front light of the 'PIEZOSURGERY' handpiece is not working correctly. Switch the device off and on again, if the problem persists, contact support. [PD CHANNEL] - The front light of the 'PIEZODRILL' handpiece is not working correctly. Switch the device off and on again, if the problem persists, contact support.
	ERR-086	
	ERR-087	
	ERR-093	Defective SD card. Switch the device off and on again, if the problem persists, contact support

10.2 Quick Troubleshooting

Problem	Possible Cause	Solution
The device does not start after the switch is set to "I".	The terminal of the power supply cable is incorrectly inserted in the rear socket of the device.	Check that the power supply cable is securely connected.
	The power cable is faulty.	Check that the supply socket is working. Replace the power supply cable.
	The fuses are out of order.	Replace the fuses (See *Chapter 10.5 on page 68*).
The device is on but not working. No errors are shown on the screen.	The foot pedal plug is not properly inserted in the device socket.	Properly insert the foot pedal plug in the socket at the back of the device.
	The foot pedal does not work properly.	Contact an Authorised Mectron Service Centre.
The device is on but not working. One of the following symbols could appear on the screen: 	See *Chapter 10.1 on page 61* for the possible cause depending on the symbol.	See *Chapter 10.1 on page 61* for the action to be taken depending on the symbol.
During operation a faint whistling noise can be heard coming from the handpiece.	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 6.1 on page 38*).
	The irrigation circuit has not been completely filled.	Fill the irrigation circuit using the PUMP function (See *Chapter 6.1 on page 38*).

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Problem	Possible Cause	Solution
No liquid flows out from the insert during operation.	The type of insert does not provide for the flow of liquids.	Use an insert that provides for the flow of liquids.
	The insert is blocked.	Unscrew the insert from the handpiece and free 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 blocked.	Contact an Authorised Mectron Service Centre.
	The flow rate on the screen is set to "0".	Adjust the flow rate.
	The bag of fluid is empty.	Replace the bag with a full one.
	The irrigation kit air intake has not been opened.	Open the irrigation kit air intake.
	The irrigation kit tubes are not properly installed.	Check the connections of the tubes.
The device works properly but the pump is strained.	The impeller is exerting too much pressure on the tube in the peristaltic pump.	Check that the tube in the peristaltic pump is inserted properly (See Chapter *Chapter 5.4 on page 26*).
The pump rotates properly but liquid leaks from the handpiece when it is stopped.	The peristaltic pump cassette is not closed properly.	Check that the peristaltic pump cassette is perfectly closed (See *Chapter 5.4 on page 26*).
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 6.1 on page 38*).
	Insert broken, worn or deformed.	Replace the insert with a new one.

10.3 Software Updates Troubleshooting

Problem	Incident reponse plan
The User Interface reports a failure in the update procedure	The device can still be used since it automatically re-installs the previous SW version. Please, report the event to the Piezosurgery Inc Customer service.
During the update procedure the device is disconnected from the power source	Connect the device to the power source; it will automatically install the latest downloaded SW version.
During the update installation the Wi-Fi communication is interrupted or fails	The installation is in any case successfully completed since it does not require the Wi-Fi connection. The user can check the SBOM on the device to check for the last version installed.

10.4 Cyber-attack Troubleshooting

Problem	Incident reponse plan
Anomalous notification	1. Disconnect the device from the network (e.g., switch-off the router) to prevent potential damage from spreading to other devices. 2. If you possess other MT-Bone devices, ascertain their status as well. 3. Contact Piezosurgery Inc. Customer Service.
Repetitive Update requests	
Wi-Fi connection unavailable or malfunctioning	
Bluetooth pairing not available	

10.5 Replacing the Fuses

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

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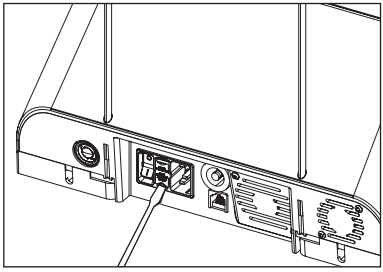
1

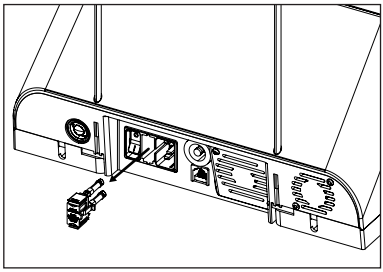
Use a blunt tool, if necessary, to open the fuse box located next to the power socket;



2

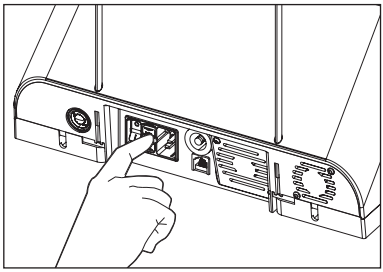
Extract the fuse holder compartment;

⚠ **WARNING:** Replace the fuses in respect of the characteristics indicated in *Chapter 9 on page 52*.



3

Reinsert the compartment in its place pressing firmly into the middle part of the fuse box.



10.6 Shipping to an Authorised Mectron Service Centre

If technical assistance is required on the devices, contact an Authorised Mectron Service Centre or your Dealer. Do not try to repair or modify the device and its components.
Clean and sterilise all parts that need to be sent to an Authorised Mectron Service Centre, following the instructions in the Cleaning and Sterilisation Manual supplied with the device.
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.
Should the client not adhere to the specified requirements, Mectron reserves the right to either charge for the cost of cleaning and sterilisation or to refuse goods that arrive in unsuitable conditions, returning them at the client's expense for proper cleaning and sterilisation. The device and its relative accessories must be returned suitably packaged and complete with all components and following information:

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

⚠ **CAUTION: Packaging.**
Pack the device and/or its rleative accessories in the original packaging to avoid damage during transport. If you are no longer in possession of the original packaging, please contact Mectron or your dealer If the device is returned in non-original or otherwise inadequate packaging with consequent damage caused by transport, Mectron reserves the right to refuse assistance and to return the device at the expense of the end client.

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.

11 WARRANTY

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All Mectron devices, before being marketed, are subjected to a careful final inspection that verifies their full functionality.
For MT-Bone devices and relative accessories, purchased new from a Mectron dealer or importer, Mectron provides a warranty for defects in material and workmanship valid for a period of:

- 2 (TWO) YEARS for the device from the date of purchase;
- 1 (ONE) YEAR for the handpieces complete with cord from the date of purchase.

The other components 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 device approval are not valid in the following cases:

- MT-Bone, with compatible accessories and inserts, are not used in accordance with the intended use.
- MT-Bone, with compatible accessories and inserts, are not used in accordance with all the instructions and requirements outlined in this manual.
- The electrical system of the places where the device is used does not comply with the electrical code compliance standards in force and the relative electrical safety precautions.
- Assembly operations, extensions, adjustments, updates and repairs are carried out by personnel not authorised by Mectron.
- The environmental conditions for preservation and storage of the device and of its accessories do not comply with the requirements indicated in *Chapter 9 on page 52*.
- Use of non-original Mectron inserts, components 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. Warranty expired 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.

E-Mail: mectron@mectron.com
FAX: +39 0185 351374

MECTRON S.p.A.
Via Loreto 15/A
16042 Carasco (Ge),
Italy

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) _____

MECTRON S.p.A.
Via Loreto 15/A
16042 Carasco (Ge), Italy

mectron
medical technology

mectron
medical technology

Mectron S.p.A.
Via Loreto 15/A
16042 Carasco (Ge) Italy
Tel. +39 0185 35361
Fax +39 0185 351374
www.mectron.com
mectron@mectron.com

Reseller - Rivenditore - Wiederverkäufer - Revendeur - Revendedor

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