mectron
medical technology

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COMPACT PIEZO P2K

INSTALLATION MANUAL

CE
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DA	Dette dokument og dets oversættelser er tilgængelige på webstedet “manuals.mectron.com”. Brug QR-koden til at få adgang til webstedet. En PDF-software, så som f.eks. Adobe Reader, er nødvendig til læsning af elektroniske betjeningsvejledning (eIFU). Hvis du ønsker en trykt brugsvejledning, bedes du udfylde alle punkter i formularen på sidste side og sende formularen til den nævnte adresse. Så sender vi dig gratis en trykt brugsvejledning inden for 7 dage.
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ES	Este documento y las respectivas traducciones están disponibles en el sitio web “manuals.mectron.com”. Utiliza el código QR para acceder al sitio web. En referencia a las instrucciones para uso (eIFU), es necesario disponer de un software de lectura de archivos PDF, por ej. Adobe Reader. Si desea las instrucciones para uso en formato impreso, rellene completamente el formulario de la última página y envíelo a la dirección indicada. El manual impreso de las instrucciones para uso se le enviará gratuitamente antes de siete días.
ET	See dokument ja selle tõlked on saadaval veebisaidil manuals.mectron.com. Saidile pääsemiseks kasutage QR-koodi. Elektroonilise kasutusjuhendi (eIFU) vaatamiseks on vajalik PDF tarkvara, nt Adobe Reader. Kui Te peaksite soovima trükitud kasutusjuhendit, siis täitke palun täielikult vastav formular viimasel lehel ja saatke see nimetatud adressile. Me saadame Teile siis tasuta trükitud kasutusjuhendi 7 päeva jooksul.
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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.
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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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SV	Detta dokument och dess relativa översättningar finns tillgängliga på webbplatsen ”manuals.mectron.com”. Använd QR-koden för att få tillgång till webbplatsen. För att se och läsa bruksanvisningen i elektroniskt format (eIFU) krävs en PDF-mjukvara, t.ex. Adobe Reader. Vill du ha en tryckt bruksanvisning fyll då i formuläret på sista sidan komplett och skicka det till den angivna adressen. Vi sänder då en tryckt bruksanvisning till dig utan kostnad, inom sju dagar.

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CONTENTS

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1 INTRODUCTION

This manual applies to the following medical devices:

- COMPACT PIEZO P2K (referred to as "device" in the text)
- SCALER HANDPIECE (referred to as "accessories" in the text)
- Inserts
- Torque wrench
- Front cone without light

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

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

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

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

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

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

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

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

1.1 Intended Use

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

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» **PIEZOELECTRIC ULTRASONIC SCALER**

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

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

» **SCALER HANDPIECE**

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

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

1.2 Description of the Device

COMPACT PIEZO P2K is a multi-purpose piezoelectric ultrasonic scaler.
It is designed to equip the operator with a product featuring an innovative design and unique technical characteristics, and to ensure utmost patient comfort during treatment thanks to a broad scale of available power levels.
The device is equipped with an automatic tuning circuit that optimises power and frequency for each insert available, in order to always operate in conditions of maximum efficiency.

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

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

1.2.1 Eligible Patient Group

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

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

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

1.2.2 Patient Selection Criteria

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

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

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

1.2.3 Indications for Use

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

1.2.4 Users

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

1.2.5 Operating Environment

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

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1.3 Disclaimer

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

- Misuse or use during procedures other than those specified in the destination of use of the product;
- The environmental conditions for preservation and storage of the device are not complying with the requirements indicated in *Chapter 9 on page 32*;
- The device is not used in accordance with all the instructions and requirements described in this manual;
- The electrical system of the places where the equipment is used do not comply with the laws in force and the related regulations;
- Assembly operations, extensions, re-adjustments, upgrades and repairs of the device are carried out by personnel not authorised by MECTRON;
- Misuse, abuse, abnormal use, negligent use, intentional misconduct or use exceeding the limits of the device indicated and allowed and/or normal wear or deterioration, ill-treatment and/or incorrect interventions;
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- Any attempt to tamper with or modification of the device under every circumstance;
- Use of non original MECTRON inserts resulting in permanent damage to the thread of the handpiece with impaired functioning and risk of injury to the patient;
- Use of non original MECTRON inserts used in accordance with the settings designed and tested on the original MECTRON inserts. Correct use of the settings is only guaranteed with original MECTRON inserts;
- Shortage of stock material (handpiece, inserts, wrenches) to be used in case of a standstill due to faults or problems;
- Incorrect/omitted maintenance compared to what is stated in *Chapter 7 on page 31* of this manual;
- Breach of the requirements and the information contained in *Chapter 4.5 on page 16* of this manual;
- Breach of the requirements and the information contained in *Chapter 6 on page 18* of this manual;
- Unauthorised repairs in accordance with the indications contained in *Chapter 10.2 on page 42* this manual.

1.4 Safety Requirements

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

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

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

⚠ **WARNING**: **Contraindications. Interference from other equipment.** An electrosurgical scalpel or other electrosurgical units positioned near the COMPACT PIEZO P2K device may interfere with the correct operation of the device itself.

⚠ **WARNING**: **Contraindications. Interference with other equipment.** Even if compliant with standard IEC/EN 60601-1-2, COMPACT PIEZO P2K and related accessories may interfere with other devices in the vicinity. COMPACT PIEZO P2K must not be used near with other appliances. However, if deemed necessary, the proper functioning of the device in that configuration must be checked and monitored.

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

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

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

⚠ **WARNING**: **Cleaning and sterilising new or repaired instruments.** All the new or repaired device components are not sterile. At first use and after each treatment they must be cleaned and sterilised by carefully following the instructions in *Chapter 6 on page 18*.

⚠ **WARNING**: **Infection control.** For maximum patient and operator safety, before using all the parts and reusable components, make sure they have been previously cleaned and sterilised by following the instructions in *Chapter 6 on page 18*.

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

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

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

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

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1.5 Symbols

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

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

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

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2 IDENTIFICATION DATA

A correct description of the model and of the serial number of the device and its accessories will allow the After Sales Service to provide fast and effective answers.
Always provide this information every time that you contact MECTRON After Sales Service.

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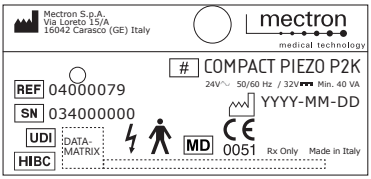
2.1 Device ID Plate

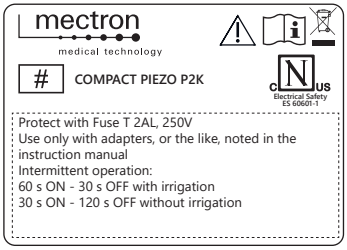
Each device is equipped with an identification plate indicating the main technical characteristics and serial number. The ID plate is located on the side of the COMPACT PIEZO P2K module. The complete technical specifications are provided in *Chapter 6 on page 26*.

NOTE: The complete list of symbols and their description is provided in *Chapter 1.5 on page 6*.



Additional symbols and characteristics of the device are provided on a separate plate. This ID plate is located on the side of the COMPACT PIEZO P2K module.

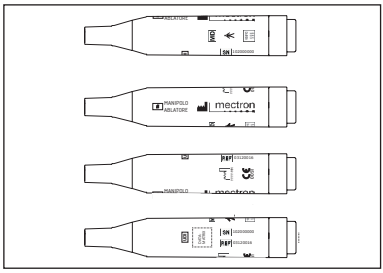
NOTE: The complete list of symbols and their description is provided in *Chapter 1.5 on page 6*.



2.2 Scaler Handpiece Identification Data

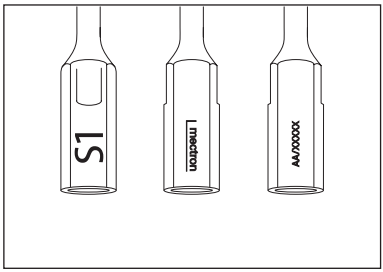
Each handpiece is laser-marked with the traceability data, UDI code included.

NOTE: The complete list of symbols and their description is provided in *Chapter 1.5 on page 6*.



2.3 Inserts Identification Data

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



3 DELIVERY

3.1 List of components

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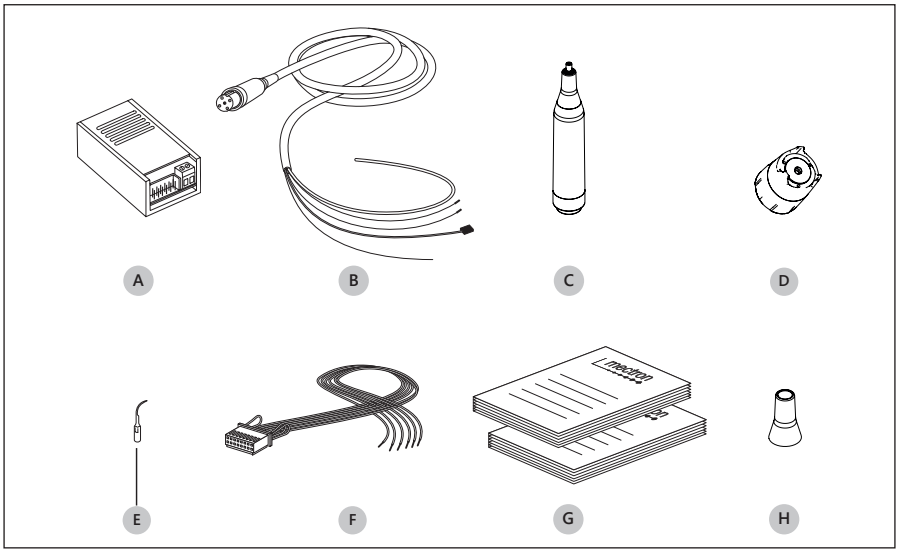
See figure below.
COMPACT PIEZO P2K is supplied with the standard equipment, a set of variable components depending on the configuration and client requests, and components that can be ordered separately.

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

The packaging of the device cannot undergo strong impacts as contains electronic components, therefore the transport and the storage must be carried out with particular care.
All the material sent by MECTRON was controlled at the time of dispatch.
The device is shipped appropriately protected and packaged.
Upon receipt of the device, check for any possible damage caused during transport and in case any damage and/or defects is found, complain to the transporter.
Keep the packaging in case any items need to be sent to an Authorised MECTRON Service Centre and to store the device during long periods of non-use.

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



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Standard supply		
Code	**Item**	**Description**
A	Device core unit	
B	Cord	
C	Scaler Handpiece	SCALER HAND-PIECE
G	Use and Maintenance Manual Installation Manual Online Documentation	

Components		
Code	**Item**	**Description**
D	Torque wrench K10	
E	Inserts	
F	Wiring	
H	Front cone without light	

4 INSTALLATION

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COMPACT PIEZO P2K, in order to operate must be connected to a dental unit.
The dental unit mechanically houses the pilot module, supplies power to the module, and supplies water to cool the handpieces and inserts.
The dental unit to which COMPACT PIEZO P2K is connected must be a medical device that complies with general and applicable product regulations for the specific category of dental unit, and in general, satisfy the following standards:

- ISO 7494 Dentistry – Stationary dental units and dental patient chairs;
- ISO 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

⚠ **CAUTION:** Check that the dental unit to which COMPACT PIEZO P2K is connected satisfies the specified requirements.

4.1 Safety Requirements During Installation

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

⚠ **WARNING**: Install the device in a safe place protected from impact or accidental water or liquid spray.

⚠ **WARNING**: Do not install the device above or near sources of heat. Arrange during installation for a suitable circulation of air around the device.

⚠ **CAUTION**: The water hose of the scaler handpiece cord must be directly connected to the dental unit cold water circuit.

⚠ **CAUTION**: The voltage of the power supply line to which the device is connected must be compatible with the technical specifications (see *Chapter 6 on page 26)* and envisaged connection layout.

⚠ **CAUTION**: For the correct power supply, use a power adapter compliant with IEC/EN 60601-1 having the following characteristics:

- 24 V~ 50/60 Hz or
- 32 V⎓ with minimum power 40VA.

⚠ **CAUTION**: Do not invert the position on the connector of the red wire and black wire of the scaler handpiece cord.

⚠ **CAUTION**: Do not wire the red and black wires of the scaler handpiece cord together with other cables.

⚠ **CAUTION**: If long connections are required for the power supply, use wires with a suitable wire gauge, for example 1.5 mm^2.

⚠ **CAUTION**: It is prohibited to make any changes to this device.

⚠ **WARNING**: The installer or manufacturer of the dental unit on which the COMPACT PIEZO P2K module has been installed is responsible for ensuring the product and entire system remain compliant with IEC/EN 60601-1 in force".

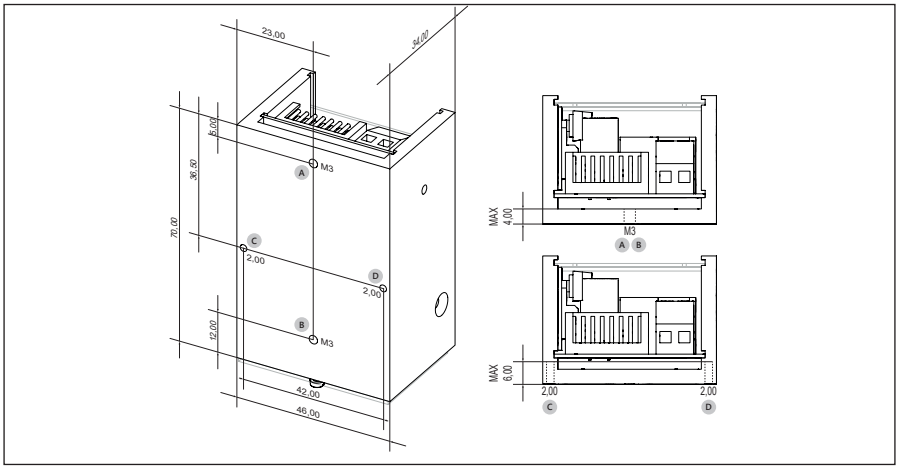
⚠ **CAUTION**: Before connecting the handpiece to its cord, check that the electrical contacts are perfectly dry, on both parts. If necessary dry them with compressed air.

4.2 Mechanical Installation

The following figure shows the dimensions of the module.
The module can be secured to the dental unit by means of two M3 threaded holes (Ref. A and B), or alternatively, by means of two holes with diameter 2 mm (Ref. C and D).

⚠ **WARNING**: The M3 screw used to secure the module must not penetrate the inside of said module for more than 4mm as it may damage the circuits.

The holes with diameter 2 mm have a maximum depth of 6 mm.
The module is also supplied with holes on the sides, but these must NOT be used to secure it. The holes on the sides are used to attach several internal components.



EN

4.3 Electrical Connections

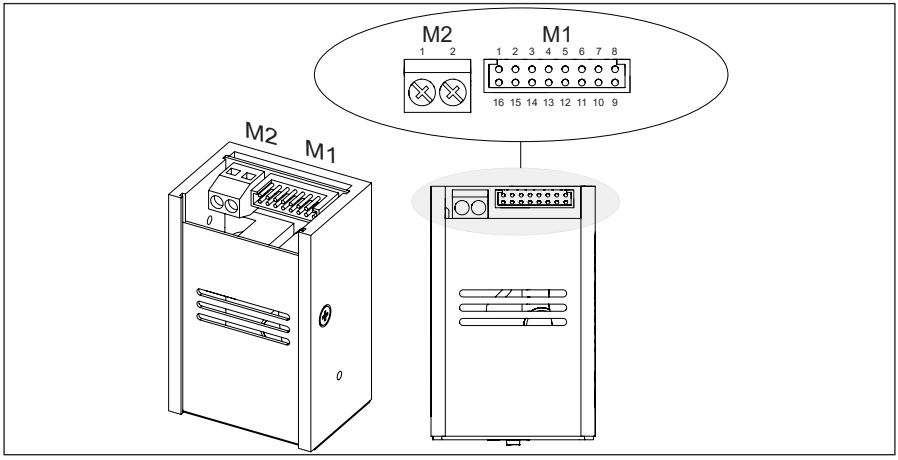
COMPACT PIEZO P2K allows various electrical configurations to satisfy the characteristics of the dental unit in which it is housed.
The dental units to which the COMPACT PIEZO P2K device can be connected must be able to provide one of the following power supplies:

- 24 V~ 50/60 Hz or
- 32 V⎓

with minimum power 40VA.
Moreover, it must have a 2A, 250V safety fuse.

For the electrical connections, the COMPACT PIEZO P2K device is equipped with 2 connectors (see following figure):

- **M1** : connector with 2x8 contacts for the module controls;
- **M2** : connector with 2 contacts for connection of the handpiece cable (piezoelectric elements control).



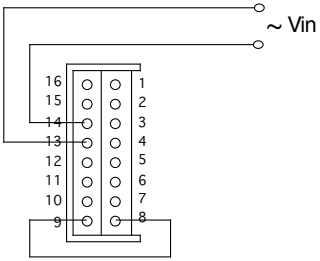
M1 Connector Pin-Out			
Pin	**Signal**	**Pin**	**Signal**
1	Reserved	9	Bypass capacity
2	RIS	10	GND
3	TX	11	Pedal +
4	RX	12	Power Selection
5	Valve	13	AC In
6	Power Control	14	AC/DC In
7	Pedal -	15	GND
8	+Vdc	16	Reserved

M2 Connector Pin-Out	
Pin	**Signal**
1	Vout handpiece

M2 Connector Pin-Out	
Pin	**Signal**
2	Neutral

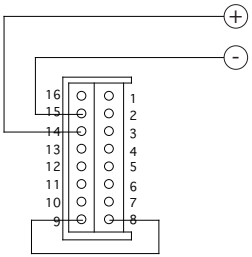
4.3.1 Alternate 24V Power Supply

To power the module at 24V~ 50/60 Hz connect pins 13 and 14 (see figure and table on previuous page).
Connect pins 8 and 9 to insert the bypass capacity present on the board to filter any disturbances on the power supply.
Observe the voltage and current values indicated on the plate.



4.3.2 Direct 32V Power Supply

To power the module at 32V⎓ connect the power supply positive on pin 14 and the negative on pin 15.
Connect pins 8 and 9 to insert the bypass capacity present on the board to filter any disturbances on the power supply.
Observe the voltage and current values indicated on the plate.



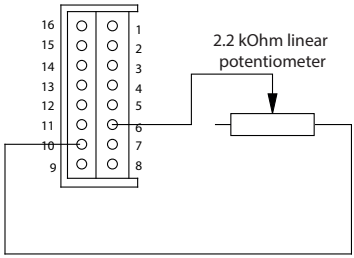
EN

4.3.3 Power Regulation

The COMPACT PIEZO P2K piezoelectric module allows regulation of the handpiece power by means of the controls on the dental unit, in different modes explained below, covering the needs of most dental units available on the market.

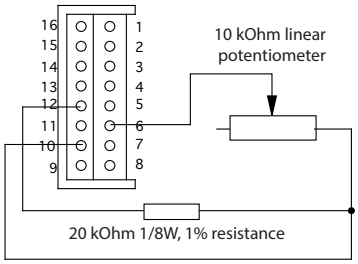
4.3.3.1 Power Regulation with 2.2 kOhm Potentiometer

Connect the 2.2 kOhm potentiometer between pins 6 and 10. The maximum power corresponds to resistance 0, and minimum to resistance 2.2 kOhm.



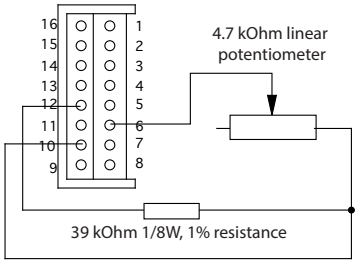
4.3.3.2 Power Regulation with 10 kOhm Potentiometer

Connect the 10 kOhm potentiometer between pins 6 and 10 and a 20 kOhm, 1/8W, 1% resistance between pins 12 and 10.
The maximum power corresponds to resistance 0.



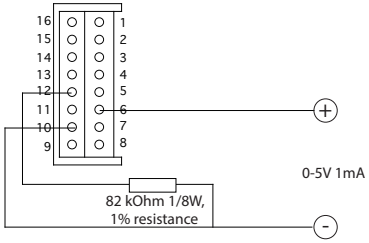
4.3.3.3 Power Regulation with 4.7 kOhm Potentiometer

Connect the 4.7 kOhm potentiometer between pins 6 and 10 and a 39 kOhm, 1/8W, 1% resistance between pins 12 and 10.
The maximum power corresponds to resistance 0.



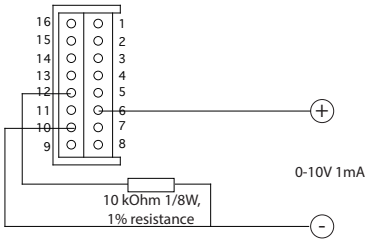
4.3.3.4 0-5 V Power Regulation

The power can be modulated with a variable voltage between 0 and 5 Volts applied between pins 6 and 10 (ground). Connect a 82 kOhm, 1/8W, 1% resistance between pins 12 and 10.



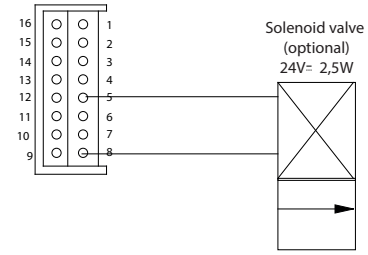
0-10 V Power Regulation

The power can be modulated with a variable voltage between 0 and 10 Volts applied between pins 6 and 10 (ground). Connect a 10 kOhm, 1/8W, 1% resistance between pins 12 and 10.



4.3.4 Solenoid Valve Control

The COMPACT PIEZO P2K provides an enabling in output for a solenoid valve on the handpiece irrigation circuit. The output distributes 24V with maximum power 2.5W.



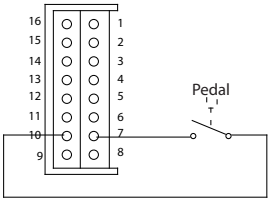
EN

4.3.5 Enabling

These connections allow the activation of the operating cycle. For these connections too, there are different configurations to suit the different types of dental units.

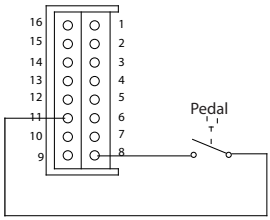
4.3.5.1 Enabling of Pedal with Negative Signal

The pedal must be connected to pins 10 and 7.



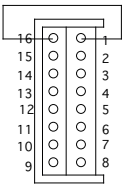
4.3.5.2 Enabling of Pedal with Positive Signal

The pedal must be connected to pins 8 and 11.



4.3.6 Other Connections

Pins 1 and 16 must always be connected to each other.



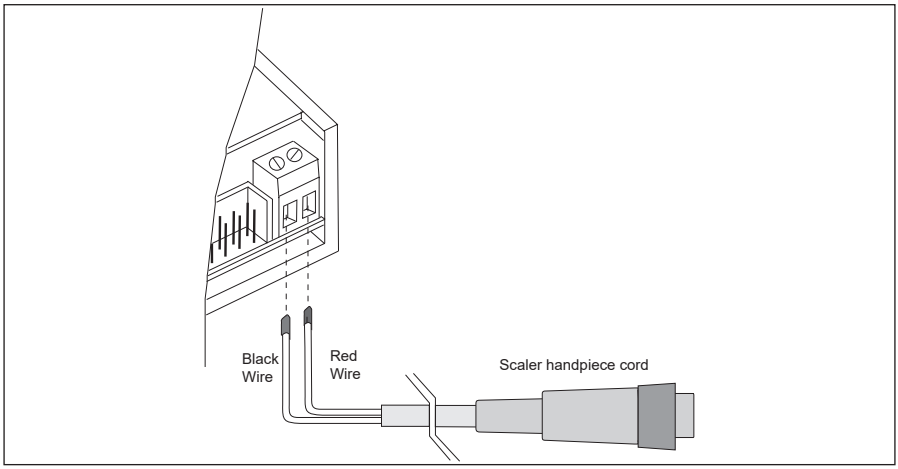
EN

4.3.7 Connecting the Cord of the Scaler Handpiece

Connect the piezoelectric pilot wires of the cord to the M2 terminal in accordance with the indicated polarity.

⚠ **CAUTION**: Do not invert the position on the connector of the red wire and black wire of the scaler handpiece cord.

⚠ **CAUTION**: Do not wire the red and black wires of the scaler handpiece cord together with other cables.



4.3.8 Standard Connections

To facilitate the installation of COMPACT PIEZO P2K in the different types of dental units, there are 7 available "standard" connection layouts, each equipped with a connecting cable to the different dental unit.

⚠ **CAUTION**: If long connections are required for the power supply, use wires with a suitable wire gauge, for example 1.5 mm^2.

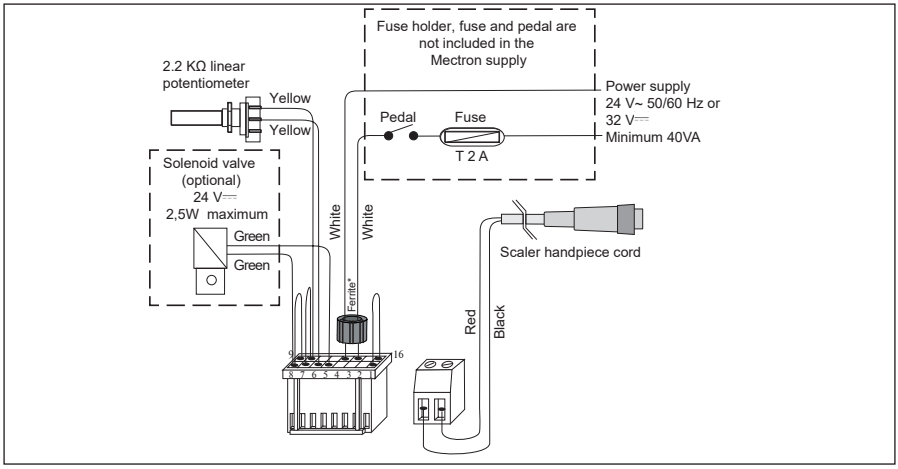
NOTE*: Near the connection on the module it is advisable to wind the power line 3 times on a ferrite (see following chapters). The ferrite is not supplied standard. Following is a brief list of the usable models:

- Philips CST17/9.5/13-3S4;
- Ferroxcube CST17/9.5/13-3S4;
- Wurth 74270091.

EN

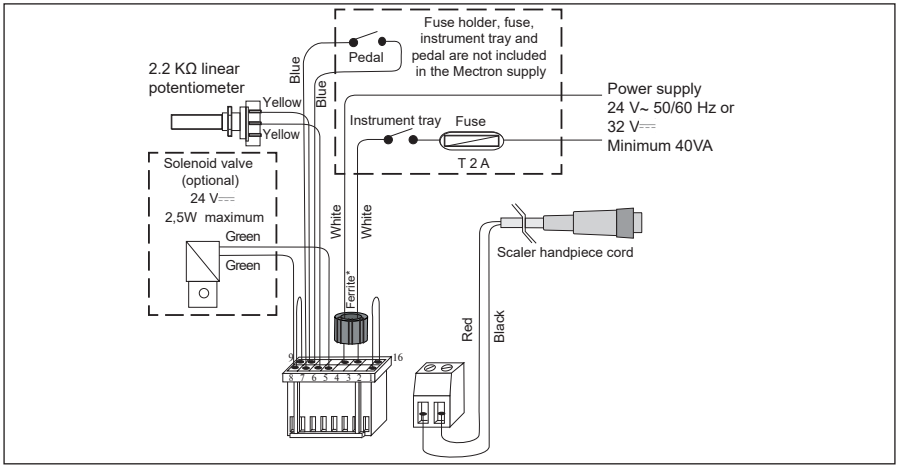
4.3.8.1 Layout A

The power supply (24 V~ 50/60 Hz ±10% or 32 V⎓ ±10%) and consent are provided by the pedal. The power is regulated by a 2.2KΩ linear potentiometer (see following figure).



4.3.8.2 Layout B

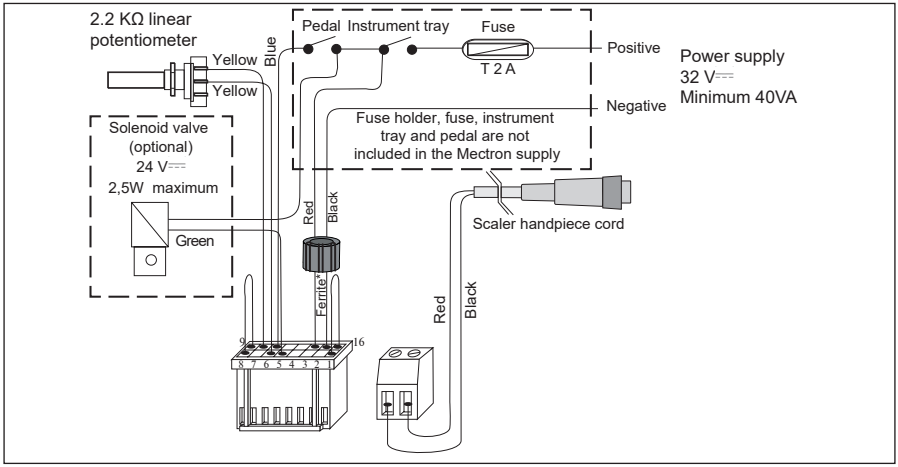
The power supply (24 V~ 50/60 Hz ±10% or 32 V⎓ ±10%) is provided by contact with the instrument tray and consent is provided by the pedal. The power is regulated by a 2.2KΩ linear potentiometer (see following figure).



EN

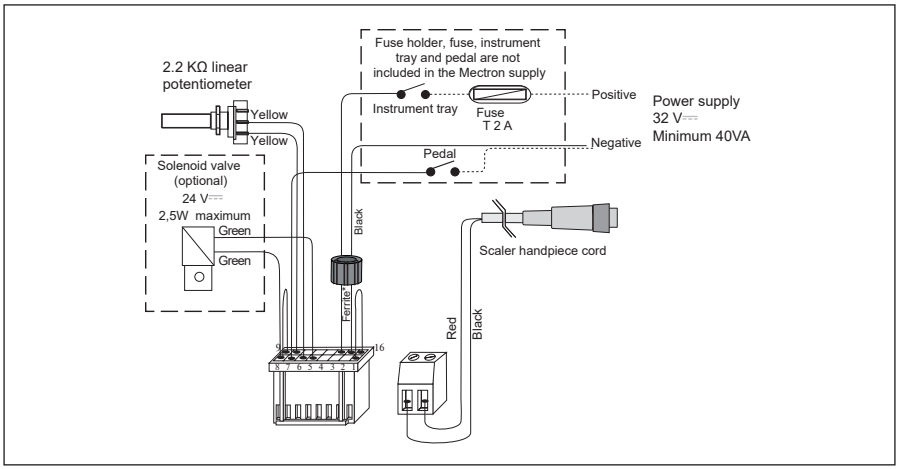
4.3.8.3 Layout C

The power supply (32 V⎓ ±10%) is provided by contact with the instrument tray and positive consent is provided by the pedal. The power is regulated by a 2.2KΩ linear potentiometer (see following figure). This type of connection allows very rapid ON/OFF cycles and does not occupy the external power circuit with high loads.



4.3.8.4 Layout D

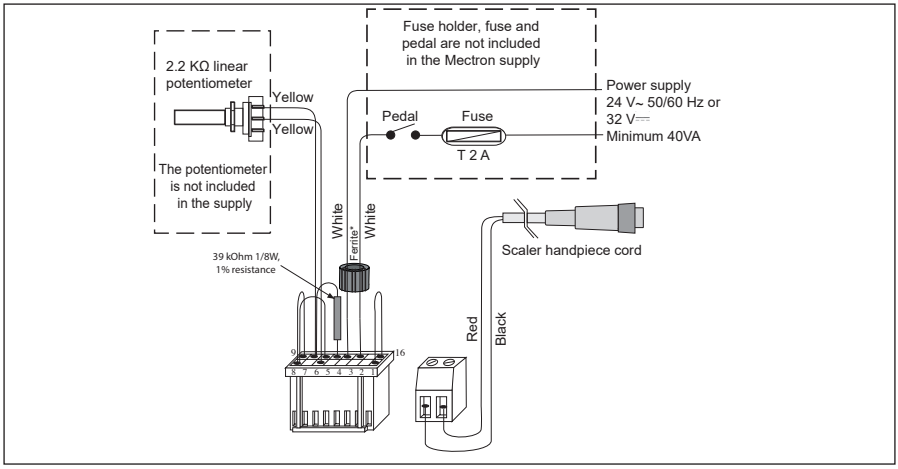
The power supply (32 V⎓ ±10%) is provided by contact with the instrument tray and negative consent is provided by the pedal. The power is regulated by a 2.2KΩ linear potentiometer (see following figure). This type of connection allows very rapid ON/OFF cycles and does not occupy the external power circuit with high loads.



EN

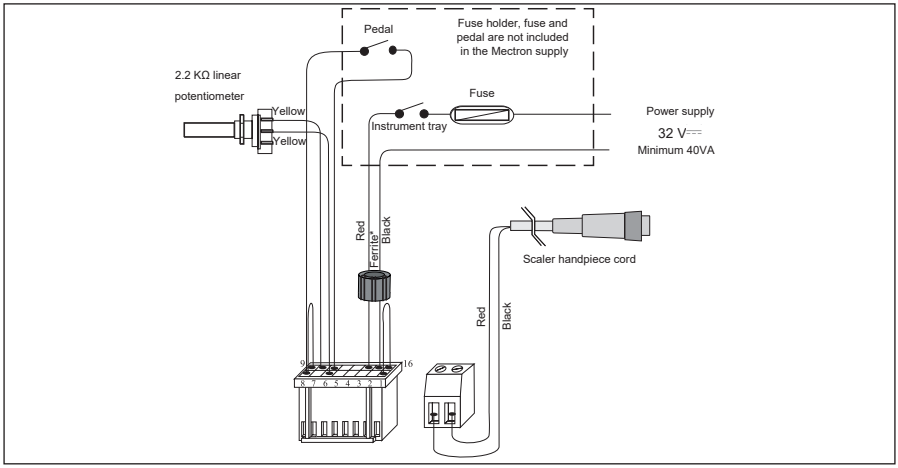
4.3.8.5 Layout E

The power supply (24 V~ 50/60 Hz ±10% or 32 V⎓ ±10%) and consent are provided by the pedal. The power is regulated by a 4.7KΩ linear potentiometer (see following figure).



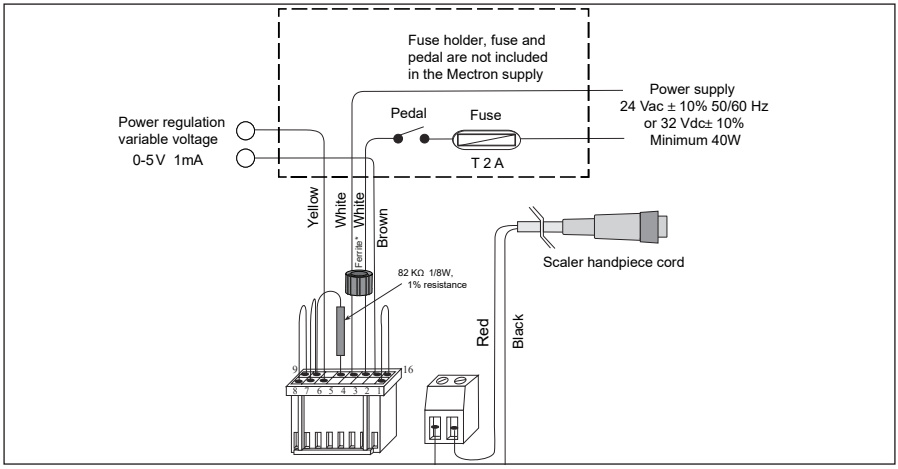
4.3.8.6 Layout F

The power supply (32 V⎓ ±10%) is provided by contact with the instrument tray and positive consent is provided by the pedal. The power is regulated by a 2.2KΩ linear potentiometer (see following figure).



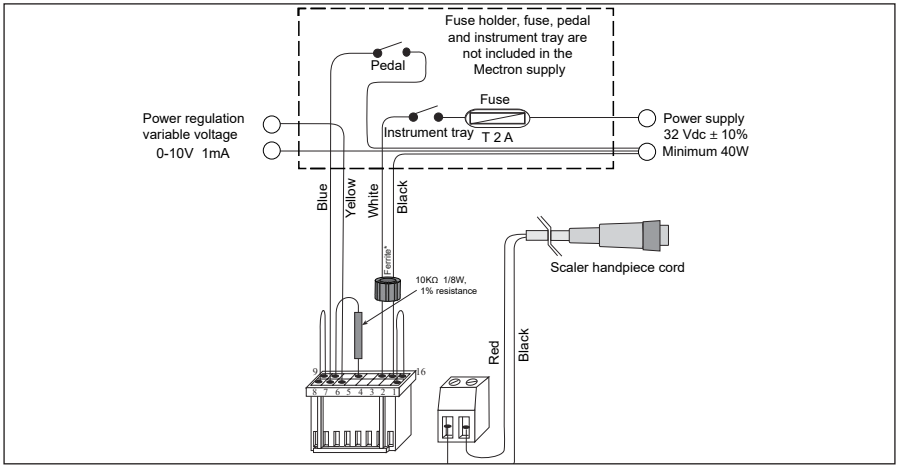
4.3.8.7 Layout G

The power supply (24 V~ 50/60 Hz ±10% or 32 V⎓ ±10%) and consent are provided by the pedal. The power is regulated by a variable voltage between 0 and 5 V (see following figure).



4.3.8.8 Layout H

The power supply (32 V⎓ ±10%) is provided by contact with the instrument tray and negative consent is provided by the pedal. The power is regulated by a variable voltage between 0 and 10 V(see following figure).



EN

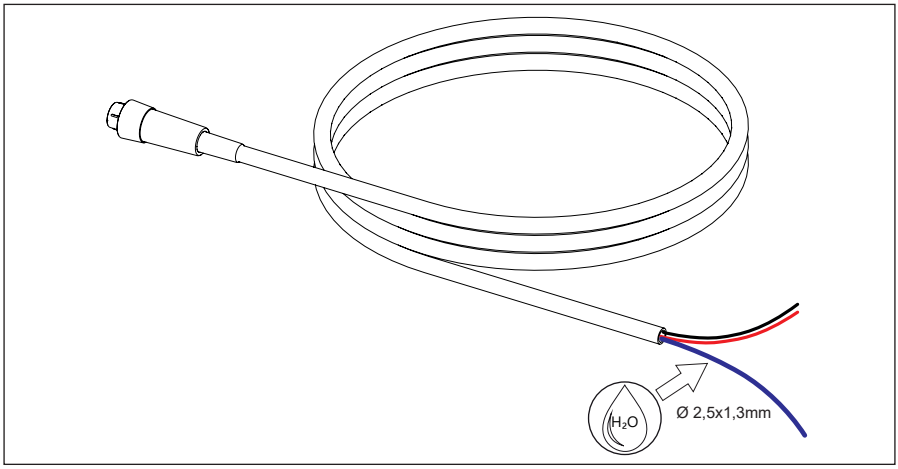
4.4 Water Connection

The COMPACT PIEZO P2K requires a water supply line to cool the handpiece and inserts during the operating cycle.
The device is sold with a connecting cable between the electronic module and handpiece equipped with a polyurethane tube with 1.3 mm internal diameter (see following figure).
The water line of the dental unit must satisfy the following requirements:

- Guarantee a supply pressure between: 1.00 ÷ 6.00 bar;
- Be fitted with a solenoid valve, 24 V 2.5W maximum, to control the opening of the irrigation circuit;
- Downstream of the pressure regulator and solenoid valve, be fitted with a valve dedicated to supplying the COMPACT PIEZO P2K handpiece and able to regulate and guarantee a water flow rate of 20 ÷ 30 ml/min.

For details of the procedure to regulate the pressure and flow rate, see the use and installation manual of the dental unit.
Connect the water circuit in a stable manner in compliance with standard ISO 60601, seeking to isolate the water circuit as much as possible from the live electrical parts.

⚠ **CAUTION**: The water hose of the scaler handpiece cord must be directly connected to the dental unit cold water circuit.



5 METHODS AND PRECAUTIONS FOR DISPOSAL

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

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

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

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

COMPACT PIEZO P2K and its accessories must be disposed of and treated as waste subject to separate collection.
Failure to comply with the previous points can result in a penalty pursuant to the directive on waste electrical and electronic equipment (WEEE).
The purchaser is entitled to deliver the device to be disposed of to the dealer who supplies them with new equipment; at Mectron, instructions for proper disposal are available.

6 TECHNICAL DATA

EN

Device compliant with Regulation (EU) 2017/745	Class IIa
Classification under the IEC/EN 60601-1	The class definition is determined by the manufacturer of the dental unit which incorporates COMPACT PIEZO P2K. Parts applied: type B (insert) IP 20 (device) IP according to indications provided by the manufacturer of the dental unit
Essential performance	According to the standard IEC 80601-2-60 the device has no essential performance
Device for intermittent operation	60 sec. ON - 30 sec. OFF with irrigation 30 sec. ON - 120 sec. OFF without irrigation
Power Supply	Power adapter compliant with IEC/EN 60601-1: • 24 V~ 50/60 Hz or • 32 V⎓
Max. Power Consumption	40 VA
Fuse	T 2AL, 250V (not included in Mectron supply)
Working Frequency	Automatic Scan From 24 KHz to 36 KHz
Power	Adjustable depending on the type of installation.
Solenoid valve control output	24V⎓, 2.5W
Water supply	Adjustable depending on the type of installation. Working pressure from 1 to 6 bar.
Protections of the APC Circuit	Missing handpiece; Breaking wire cord; Insert not correctly tightened or broken.
Diagnostics	Two-coloured green and red LED warning light (see *Chapter 7.1 on page 35*)
Operating Conditions	from 10°C to 40 °C Relative humidity from 30% to 75% Air pressure P: 800hPa/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 2000 metres
Dimensions and Weight	71x46x34 mm 120 g

Table 1 – Technical Data

6.1 Electromagnetic Compatibility IEC/EN 60601-1-2

⚠ **WARNING: Contraindications. Interference with other equipment**
Even if compliant with standard IEC/EN 60601-1-2, COMPACT PIEZO P2K may interfere with other devices in the vicinity.

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

⚠ **WARNING: Contraindications. Interference from other equipment**
An electrosurgical scalpel or other electrosurgical units positioned near the COMPACT PIEZO P2K device may interfere with the correct operation of the device itself.

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

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

6.2 Guide and Manufacturer's Declaration - Electromagnetic Emissions

COMPACT PIEZO P2K and related accessories is designed to operate in the electromagnetic environment specified below. The purchaser or user of COMPACT PIEZO P2K should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	COMPACT PIEZO P2K uses RF energy only for its internal operation. Therefore, its RF emissions are very low and probably do not cause any interference with nearby electronic devices.
RF Emissions CISPR 11	Class B	COMPACT PIEZO P2K 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	

6.3 Accessible Parts of the Casing

COMPACT PIEZO P2K and related accessories is designed to operate in the electromagnetic environment specified below.
The purchaser or user of COMPACT PIEZO P2K should ensure that it is used in such an environment.

EN

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30%.
Radiated RF EM fields [a]	IEC 61000-4-3	3 V/m [f] 80 MHz - 2,7 GHz [b] 80% AM a 1 kHz [c]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See *Chapter 6.5 on page 33*	
RATED power frequency magnetic fields [d]	IEC 61000-4-8	30 A/m 50 Hz o 60 Hz	The magnetic fields at the mains frequency should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See *Chapter 6.6 on page 34*	Portable and mobile RF communication devices shall be used with a separation distance of at least 0,15 m from the field sources.

a) The interface between the PATIENT physiological signal simulation, if used, and the COMPACT PIEZO P2K shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the COMPACT PIEZO P2K.

b) COMPACT PIEZO P2K that intentionally receives RF electromagnetic energy for the purpose of its operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

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

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

e) Void.

f) Before modulation is applied.

6.4 Guide and the Manufacturer's Declaration - Electromagnetic Immunity

6.4.1 Power Connection BC Input

EN

COMPACT PIEZO P2K and related accessories is designed to operate in the electromagnetic environment specified below.
The purchaser or user of COMPACT PIEZO P2K should ensure that it is used in such an environment.

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

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a) Void.

b) All COMPACT PIEZO P2K cables are attached during the test.

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

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

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

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

g) Applicable only to COMPACT PIEZO P2K connected to single-phase a.c. mains.

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

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). COMPACT PIEZO P2K with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

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

k) Not applicable to CLASS II COMPACT PIEZO P2K.

l) Direct coupling shall be used.

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

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

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

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

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

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

6.4.2 Points of Contact with the Patient

COMPACT PIEZO P2K and related accessories is designed to operate in the electromagnetic environment specified below.
The purchaser or user of COMPACT PIEZO P2K should ensure that it is used in such an environment.

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

a) The following applies:

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

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

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

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6.4.3 Parts Accessible to the Input / Output Signals

COMPACT PIEZO P2K and related accessories is designed to operate in the electromagnetic environment specified below. The purchaser or user of COMPACT PIEZO P2K should ensure that it is used in such an environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	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 the floor is covered with synthetic material, the relative humidity should be at least equal to 30%.
Electrical fast transients / bursts [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.
Surges Line-to-ground [a]	IEC 61000-4-5	± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conducted 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 a 1 KHz [c]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.

a) This test applies only to output lines intended to connect directly to outdoor cables.

b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

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

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

e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

f) Capacitive coupling shall be used.

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

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

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

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

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

6.5 Specifications of the tests for the Immunity of the Accessible Parts of the Casing to the Wireless RF Communications Device

COMPACT PIEZO P2K and related accessories is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The purchaser or operator of COMPACT PIEZO P2K can help prevent electromagnetic interferences by guaranteeing a minimum distance between the mobile and portable RF communication devices (transmitters) and COMPACT PIEZO P2K, as recommended below, in relation to the maximum output power of the radio communication devices.

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

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

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

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

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the COMPACT PIEZO P2K may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

⚠ **WARNING:** Portable RF communication equipment (including peripheral devices as antenna cables and external antennas) must not be used closer than 30 cm (12 inches) to any part of the device COMPACT PIEZO P2K, including the cables specified by the manufacturer. Otherwise, there may be a performance degradation of these devices.

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

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

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

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

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

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

7 TROUBLESHOOTING

7.1 Diagnostics

The device is equipped with an APC automatic protection circuit which is activated when operating faults occur on the components, and a two-coloured diagnostic LED (green and red), positioned on the board, which indicates when the module is powered.

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Device Powered Without Pedal Consent	
LED	**Description**
green lit	Correct operation.
green and red flashing alternately	Incorrect installation: • potentiometer not connected.
green and red lit	Indicates that the general protection was activated during the last cycle.
green lit and red flashing	Indicates that the failed tuning scan protection was activated during the last cycle.

Device Powered With Pedal Consent	
LED	**Description**
green lit	Correct operation.
green and red lit	Current limiter in operation.
green and red flashing alternately	Incorrect installation: • Power supply too low; • Power supply too high; • Potentiometer not connected.
red steadily lit	General protection tripped: • Handpiece not connected to the cord; • Tuning circuit malfunction; • Broken wire in the cord; • Faulty Handpiece.
red flashing	Failed tuning scan protection tripped: • Insert not present or not properly tightened on the handpiece; • The insert is worn, damaged, or deformed; • Handpiece/cord electrical contacts wet.

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7.2 Quick Troubleshooting

Problem	Possible Cause	Solution
The device is on but is not working. The red LED is steadily lit (APC automatic protection circuit tripped).	Handpiece not connected to the cord	Connect the handpiece to the cord
	Broken wire in the cord	Contact your nearest Authorised MECTRON Service Centre
	Faulty handpiece	Contact your nearest Authorised MECTRON Service Centre
	Tuning circuit malfunction	Contact your nearest Authorised MECTRON Service Centre
The device is on but is not working. The red LED flashes (APC automatic protection circuit tripped).	The insert is not present or not correctly tightened on the handpiece.	Unscrew and correctly re-screw the insert
	The insert is worn, damaged, or deformed.	Replace the insert
	The connector of the handpiece or cord is wet.	Dry the connectors
The device is on but is not working. The red and green LED flash alternately.	Power supply too low.	Supply the correct power.
	Power supply too high.	Supply the correct power.
	Potentiometer not connected.	Correctly connect the potentiometer.
During operation a faint whistling noise can be heard coming from the scaler 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 the Use and Maintenance Manual)
No liquid flows out from the insert during operation	The insert is the type without a liquid passage	Use an insert type with a liquid passage
	The Water function is not active	Activate the Water function
	The insert is clogged	Unscrew the insert from the handpiece and release the water passage of the insert by blowing compressed air through it. If the problem persists, replace the insert with a new one
	The handpiece is clogged	Contact an Authorised Mectron Service Centre

Problem	Possible Cause	Solution
Poor performance	The insert is not correctly tightened on the handpiece	Unscrew the insert and screw it back in correctly using the Mectron torque wrench (See the Use and Maintenance Manual)
	Insert broken, worn or deformed	Replace the insert with a new one

7.3 Shipping to an Authorised Mectron Service Centre

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

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

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

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

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

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8 WARRANTY

All Mectron devices, before being marketed, are subjected to a careful final inspection that verifies their full functionality.
Mectron provides a warranty for COMPACT PIEZO P2K, purchased new from a Mectron dealer or importer, which covers defects in material and workmanship for a period of:

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

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

- The device is not used in accordance with the intended use.
- The device is not used in accordance with all the instructions and requirements described in this manual.
- The electrical system of the places where the device is used does not comply with the laws in force and relative requirements.
- Assembly operations, extensions, adjustments, updates and repairs are carried out by personnel not authorised by Mectron.
- The environmental conditions for preservation and storage of the device do not comply with the requirements indicated in the Use and Maintenance Manual.
- 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.
- Expired warranty.

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

CAUTION

The warranty starts from the date of purchase of the device, which evidence is given by the delivery note/purchase invoice issued by the Dealer / Importer or, in case of device with activation code, from the date of activation of the same.
In order to avail of the warranty service, the client must return the device, at their own expense, to the MECTRON dealer/importer from which they purchased the product.
The devices must be returned together with the original packaging, accompanied by all the components and by a form containing:

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

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

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

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

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

REF (e.g. 05120065) _____

SN (e.g. 423001234) _____

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