compact piezo P2K

Manual of use and maintenance
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00.0 Introduction

00.1 Introduction

Read this manual carefully before you begin any operation for installation, use, maintenance or any other handling of the device. Always keep this manual at hand.

Important: In order to avoid injury to persons or damage to property, read the paragraphs on “Safety measures” in this manual very carefully. Depending on the level of seriousness, the safety measures are classified as follows:

⚠️ DANGER (always referred to injuries to people)
⚠️ WARNING (referred to possible damage to property)

The purpose of this manual is to inform the operator of all safety measures, instructions for proper use and maintenance of the device.

Tampering with the device is not authorized for any reason.

If any anomaly is detected, contact Mectron Assistance Centre.

Any attempt to tamper with or modify the device by the operator or non authorized personnel will invalidate the guarantee and relieve the Manufacturer of any responsibility in case of injury to people or damage to property.

All the information and illustrations have been updated to the date of issue referred to on the last page.

MECTRON has undertaken to continuously upgrade its products with possible modifications and accessories. In the case of discrepancies between the descriptions contained in this manual and the components of the device, contact your Retailer or MECTRON’s Post-sale Service.

The use of this manual for purposes other than those strictly concerning installation, use and maintenance of the device is strictly forbidden.

00.2 Description of the device

The Compact Piezo P2K is the most modern piezoelectric ultrasound scaler which uses ultrasound technology in dentistry. An integrated feedback system controls the power charge and adapts it to the requirements of the operator in just a few hundredths of a second. In this way, in all fields of application such as endo, scaling and perio, the Compact Piezo offers the best performance for every situation.

The Compact Piezo P2K can be used together with the Starlight p (optional), a photopolymerizing light for dental composites. The light is connected to the scaler cord.

The device automatically recognizes its insertion.
00.3 Intended use

With the relative accessories the device can be applied for the following treatments:
- endodontia: for reaming ducts;
- tartar removal: for removing plaque and tartar from the dental surface;
- periodontal therapy for scaling and root-planning without damaging the periodontal tissues;
- retrograde micro-surgery for ultrasound treatment of the root apex;
- condensation of the amalgam and of the gutta-percha;
- removal of bridges and crowns;
- polishing of fillings.

00.4 Safety measures

Mectron declines all responsibility for direct or indirect injury to persons or damage to property in the following cases:
1. The device is not used for the purpose for which it was designed.
2. The device is used not in conformity with the instructions and prescriptions described in this manual.
3. The electric system to which the device is connected does not conform to the existing laws and relative prescriptions.
4. The assembly, extension, adjustment, modification and repair operations are carried out by personnel other than Mectron authorized personnel.
5. The environmental conditions in which the device is kept and stored do not conform to the prescriptions indicated in the technical data section.
6. **DANGER Using non original Mectron inserts:** this causes a permanent damage to the threading of the handpiece thereby prejudicing a correct performance and risking injury to the patient. **In this case the manufacturer’s guarantee and the type-approval of the device will no longer be valid!**

**DANGER: Qualified and specialized personnel only.**
This device must be operated exclusively by specialized or specifically trained personnel. Operating the device does not cause any collateral effects if used properly.

**DANGER: Use.**
Only use the device for the purpose for which it was designed (see paragraph “00.3”). Failure to comply to this prescription may cause serious injury to the patient, the operator and damage/faults to the device.

**DANGER: Contraindications.**
Do not use the ultrasound tartar scaler on patients with cardiac stimulator (Pace-maker) or other electronic implants. This prescription is intended also for the operator.

**DANGER: Cleaning, disinfecting, sterilizing new and repaired products.**
All new or repaired products are delivered un-sterilized. Before using, all new or repaired products must be cleaned, disinfected and sterilized scrupulously following the instructions in chapter “05.0”.

**DANGER: Infection control.**
For maximum security of patient and operator, only use clean, disinfected and sterilized accessories. Scrupulously follow the instructions in chapter “05.0”.
⚠️ **DANGER:** Only use original Mectron accessories and spares.

⚠️ **WARNING:** Contraindications.
Do not scale the tartar on metal or ceramic prosthetic dentures. The ultrasound vibrations could loosen the dentures.

⚠️ **DANGER:** Contraindications.
Do not scale without water irrigation to avoid over heating the insert which can damage the tooth. Scaling without irrigation can be done exclusively with the special “Dry Work” inserts.

⚠️ **DANGER:** Insert wear and breaking.
The high frequency vibrations and wear and tear can, in some rare cases, lead to the insert breaking.
Deformed or otherwise damaged inserts are susceptible to breaking during use. Broken or worn inserts must never be used.
When the nitriding wears off, the insert looses its effectiveness; always check that the insert is not worn.
While using, avoid prolonged contact with other metal instruments. Do not use excessive force on the inserts while using.
To avoid the patient swallowing a fragment of broken insert, always instruct the patient to breath through the nose during treatment.

⚠️ **DANGER:** Do not use the device in places where there is a risk of explosion.
The device must not be operated in the presence of inflammable gases (anaesthetic compounds, oxygen, etc.).
01.0 Identification data

01.1 Identification data

A precise description of the model and indication of the serial number of the device will enable prompt and effective answers from our Post-Sales Service. Always refer to this data when contacting Mectron’s Technical Assistance Service.

01.2 Scaler handpiece ID Tag

The serial number of the scaler handpiece is engraved on the grey connector of the same (Fig. 1 - Ref. A).

02.0 Type testing

02.1 Device type-testing

All MECTRON devices are rigorously checked and type-tested. During this test, the components are subjected to a series of work cycles. Eventual malfunction deriving from faulty components is detected and highlighted in this phase. This procedure guarantees the reliability and performance of all its components.

03.0 Delivery

03.1 Delivery of the device

The packed device must be protected from being knocked about due to its electronic components. Therefore, transport and storage requires particular attention. Do not put one carton on top of another to avoid crushing the ones underneath. All goods forwarded by MECTRON have been carefully checked before sending. The device is delivered opportune protected and packed. On receipt of the device, check for any eventual damage occurred during transport and if so, issue a complaint to the hauling firm.
03.2 Standard tool supply list

1. Scaler handpiece (Fig. 2 - Ref. A).
2. Torque wrench K6 (Fig. 2 - Ref. B).
3. Insert Kit, composed of 4 inserts (Fig. 2 - Ref. C).

This standard supply may vary according to the promotional campaigns.

Fig. 2
04.0 Use

04.1 Controls

The description of the controls available for operating the Compact Piezo, are contained in the manual provided by the manufacturer of the dentist's unit.

04.2 Switching on and off

To switch the Compact Piezo on and off, refer to the manual provided by the manufacturer of the dentist's unit.

04.3 Safety measures during use

⚠️ DANGER: Contraindications.
Do not use the ultrasound tartar scaler on patients with cardiac stimulator (Pace-maker) or other electronic implants. This prescription is intended also for the operator.

⚠️ DANGER: Contraindications.
Do not scale without the water irrigation to avoid over heating the insert which can damage the tooth. Scaling without irrigation can be done exclusively with the special “Dry Work” inserts. For further information consult the Mectron inserts catalogue.

⚠️ DANGER: Insert wear and breaking.
The high frequency vibrations and wear and tear can, in some rare cases, lead to the insert breaking. Deformed or otherwise damaged inserts are susceptible to breaking during use. Broken or worn inserts must never be used.
When the nitriding wears off, the insert looses its effectiveness; always check that the insert is not worn.
While using, avoid prolonged contact with other metal instruments. Do not use excessive force on the inserts while using.
To avoid the patient swallowing a fragment of broken insert, always instruct the patient to breath through the nose during treatment.

⚠️ DANGER: Infection control.
For maximum safety of the patient and operator, clean, disinfect and sterilize the piezoelectric handpiece, inserts and key after use. Follow the instructions in chapter 05.0 “CLEANING, DISINFECTING AND STERILIZING”.

⚠️ WARNING: Contraindication.
Do not scale the tartar on metal or ceramic prosthetic dentures. The ultrasound vibrations could loosen the dentures.

⚠️ WARNING: Contraindication.
After sterilizing the handpiece in the autoclave, wait until it has completely cooled before using.

⚠️ WARNING: The electrical contacts inside the handpiece connectors and the cord must be perfectly dry.
Before connecting the handpiece to the cord, make sure the electrical contacts of both connectors are perfectly dry, especially after the autoclave sterilization cycle.
If necessary, dry the contacts by blowing air with a syringe.
⚠️ **WARNING:** For a correct use of the device it is necessary to press the pedal and activate when the insert not touching the part to be treated so that the electronic circuit can recognize the best resonance point of the insert without interference and thus enable an optimal performance. On the contrary, contact, prior to activation with the part to be treated or other surfaces, may cause the activation of the protection devices.

**04.4 User instructions**

1. Connect the scaler handpiece correctly to the cord, making sure that the electric contacts are perfectly dry. If necessary dry these by blowing air with a syringe.
2. Screw the selected insert onto the scaler handpiece (Fig.3 - Ref.A).
3. Lock the insert with the torque wrench provided with the device.
   - For a correct use of the torque wrench (Fig.3 - Ref.B) operate as follows:
     - Hold the handpiece firmly;
     - **⚠️ WARNING:** Do not hold the handpiece by the end part and/or cord but only by the plastic body (Fig.3 - Ref.C) and do not rotate while locking.
     - Turn the key clockwise until it clicks (the outer body of the key rotates with respect to the handpiece body releasing mechanical "CLICK" signals).
     - The insert is now perfectly locked.
4. Select the power level required according to the indications provided by the manufacturer of the dentist's unit.
5. If treatment with irrigation is required, enable the Water function, as described in the indications provided by the manufacturer of the dentist’s unit.
   - If treatment without irrigation is required, disable the Water function.
6. Enable Compact Piezo function and adjust the water flow using the special regulator, following the instructions provided by the manufacturer of the dentist’s unit.
7. The device is provided with a sophisticated electronic circuit which enables the scaler to compensate the wear of the insert, thus always maintaining a high performance level of the ultrasound generator.
8. At the end of the treatment, place the scaler handpiece back on its lodging.

![Fig. 3](image-url)
04.5 Checking the wear and tear of the insert

1 Periodically check the state of wear and tear of the insert and replace it if a reduction in the level of performance is noticed.
2 Do not deform the insert by bending or filing.
3 Replace the insert which has been deformed, knocked, damaged or which is simply worn.
4 If the insert is excessively worn, the scaler will be switched off by the APC protection circuit.

05.0 Cleaning, disinfecting and sterilizing

05.1 Cleaning and disinfecting

⚠️ WARNING: Clean preferably using an enzyme detergent (pH 6-9), carefully following the manufacturer’s instructions.

⚠️ WARNING: If a disinfectant is used, make sure you are using a non aggressive neutral pH (pH7) disinfectant solution. Carefully follow the manufacturer’s instructions.

⚠️ WARNING: Do not use hydrogen peroxide for disinfecting but only neutral pH (pH7) disinfectants. If necessary, rinse with sterilized water.

⚠️ DANGER: After cleaning and before sterilizing, accurately check all parts under a strong light, with particular attention to those parts which can hide residual dirt (threading, cavities, grooves) and, if necessary, repeat the washing cycle. Check also the integrity of those parts and elements which could have deteriorated through use.

05.2 Sterilization

⚠️ WARNING: Sterilize exclusively in steam autoclave. Do not use any other sterilizing procedure (dry heat, irradiation, ethylene oxide, gas, low temperature plasma, etc).

⚠️ WARNING: Do not overload the steam sterilizer.

⚠️ DANGER: Infection control – Parts that can be sterilized - Scrupulously remove all residual dirt before sterilizing. In order to prevent bacterial or viral infections, always wash and sterilize the following components after every treatment:
1 Handpiece;
2 Inserts;
3 Torque wrench.

These components are made of materials that can resist at a maximum temperature of 135°C for a maximum period of 20 minutes.
The sterilization process (SAL 10^-6) in steam autoclave must be carried out following the parameters indicated below:
- Sterilization temperature 134°C (0°C ÷ +3°C interval) - Sterilization time: 4 minutes.
- Sterilization temperature 121°C (0°C ÷ +3°C interval) - Sterilization time: 16 minutes.

**05.3 Cleaning and sterilizing the handpiece in the autoclave**

⚠️ **WARNING:** Do not dip the handpiece into disinfectant solutions or other liquids as this could cause damage.

⚠️ **WARNING:** Do not dip the handpiece in an ultrasound tank.

⚠️ **WARNING:** Do not sterilize the handpiece with the insert switched on.

⚠️ **WARNING:** Do not use hydrogen peroxide as a disinfectant but only neutral pH disinfectants (pH7); If necessary, rinse with sterilized water.

Accurately clean the handpiece with particular attention to the threaded pin onto which the inserts are screwed (Fig.4 - Ref.B) and to the adjacent ring cavity.

1. Unscrew the insert;
2. Unscrew the rear metal cone (Fig.4 - Ref.A);
3. Clean and disinfect the handpiece using a low fiber release cloth dipped in an enzyme detergent solution (pH 6-9) and eventually with a neutral pH (pH7), non aggressive disinfectant solution;
4. Delicately brush the handpiece’s surface with a soft nylon brush with particular attention to the following parts:
   - Handpiece threading (Fig.4 - Ref.B);
   - Titanium stem (Fig.4 - Ref.C);
   - Rear cone (Fig.4 - Ref.A) on the outside and the inside.
5. Accurately rinse with running water to eliminate any residual detergent
6. Dry and reassemble the rear cone on the handpiece (Fig.4 - Ref.A);
7. Dry the electric contacts by blowing compressed air with the syringe;
8. Seal the handpiece (without inserts) singularly in a disposable bag;
9. Sterilize the handpiece in the steam autoclave following the instructions in chapter 05.2.

⚠️ **WARNING:** At the end of the sterilizing cycle, leave the handpiece to cool before using.

⚠️ **WARNING:** The electric contacts of the cord connector must be perfectly dry.

At the end of the sterilizing cycle, before connecting the cord to the device, make sure the electric contacts are perfectly dry, eventually dry the contacts by blowing compressed air with a syringe.
05.4 Cleaning and sterilizing the inserts in the autoclave

⚠️ **WARNING:** Clean preferably using an enzyme detergent (pH 6-9), carefully following the manufacturer’s instructions.

⚠️ **WARNING:** Do not use hydrogen peroxide for disinfecting but only neutral pH (pH7) disinfectants. If necessary, rinse with sterilized water.

1. Clean the insert (preferably in an ultrasound tank) and rinse with distilled water.
2. Dry the insert.
3. Disinfect the insert with a non aggressive, neutral pH (pH7) disinfectant solution and dry by blowing air with the syringe. This will prevent the formation of marks or rings on the insert’s surface.
   ⚠️ **WARNING:** Before starting the sterilization cycle, make sure the insert is properly dried also internally. For this purpose, blow air with the syringe through the cord hole.
4. Seal the inserts singularly into a disposable bag.
5. Sterilize the inserts in the autoclave following the instructions in paragraph 05.2.

05.5 Cleaning and sterilizing the torque wrench in the autoclave

⚠️ **WARNING:** Wash preferably using an enzyme detergent (pH 6-9), carefully following the manufacturer’s instructions.

1. Clean the key.
2. Disinfect the key with a non aggressive, neutral pH (pH7) disinfectant solution and dry.
3. Seal the key singularly in a disposable bag.
4. Sterilize the key in the autoclave following the instructions in paragraph 05.2.

06.0 Periodic maintenance

1. Before starting any maintenance operation, always switch off the device.
2. Periodically check the scaler handpiece cord. If it is damaged or deteriorated, contact the manufacturer of the dentist’s unit for replacement.

07.0 Disposal procedures and precautions

- The device must be disposed of and processed separately;
- The purchaser has the faculty to return the device at the end of its life to the retailer who will provide a new device; instructions for disposal are available at Mectron SpA;
- Failure to observe the previous points could be sanctioned in conformity with directive 2002/96/CE.

⚠️ **DANGER:** Hospital waste.
The following objects should be treated as hospital waste:
- Worn or broken inserts;
- Worn or broken torque wrench.
08.0 Mectron scaler inserts and their use

S1 - S2 - S3 - S4 - S5: For general use in tartar removal;
S6 - S7 - S8: High performance, for general use in removal of large tartar deposits;
P1 - P2 - P3 - P4: For general use in removing concretion on root surfaces;
P10 - P11 - P12 - P13 - P14: For general use in removing concretion in deep root surfaces;
R1 - R2 - R3 - R4 - R5: For general use in the retrograde treatment of root ducts;
D1 - D2 - D3 - D4: For general use in amalgam condensation - polishing of fillings – lateral
condensation of the gutta-percha – removal of crowns, bridges and pins;
CM1 - CM2 - CM3 - CM4: For use in marginal finishing;
ER1 - ER2 - ER3 - ER4 - ER5: For general use in orthograde endodontia;
E1 - E2: File holder a 120° or 90° for endo files.

09.0 Symbols

WARNING: Please read carefully
the instructions for use.

Type “BF” applied part.

This device and its accessories shouldn’t be
disposed or treated as solid urban waste.

Serial number
Manufacturer

The sterilisable materials must be autoclave sterilised
and can withstand a maximum temperature of 135° C.

Device in accordance with EC Directive 93/42 EEC
Including EN 60601-1 and EN 60601-1-2
Notified body: CERMET
10.0 Problem solving

10.1 Procedure for sending the device, inserts and accessories for servicing

When sending the device, inserts and accessories for servicing at Mectron authorized centers, customers are kindly invited to respect the following norms:

1. Clean the device, inserts and accessories following the instructions in chapter “05.0 Cleaning, disinfecting and sterilizing”;
2. Sterilize the parts which can be sterilized following the instructions in chapter “05.0 Cleaning, disinfecting and sterilizing”:
   - Handpiece;
   - Insert/s;
   - Torque wrench.
3. Leave the sterilized components in the disposable bag which states the contents is sterilized;
4. If the device is still under guarantee, attach a photocopy of the purchase document;
5. When sending, if possible use the original packing or pack adequately to avoid damage during transport.

The above mentioned requests (points 1 and 2) conform to the compulsory requisites for health and safety on the work place as provided for in Leg. Decr. 626/9 and 81/08 and subsequent amendments, of the Italian C.C.

If the customer does not comply with the requirements as in Points 1 and 2, Mectron reserves the right to charge cleaning and sterilizing costs or refuse the goods received for servicing in non conforming conditions.

10.2 Rapid problem solving

If the device doesn’t seem to be working properly, read the instructions again and then check the following table:

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>POSSIBLE CAUSE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water does not come out of</td>
<td>The insert is intended for dry</td>
<td>Use an insert with water function</td>
</tr>
<tr>
<td>the insert</td>
<td>work</td>
<td></td>
</tr>
<tr>
<td>The water function is not</td>
<td>The water function is not</td>
<td>Activate water function</td>
</tr>
<tr>
<td>active</td>
<td>active</td>
<td></td>
</tr>
<tr>
<td>The insert is obstructed</td>
<td>The insert is obstructed</td>
<td>Remove obstruction from water passage</td>
</tr>
<tr>
<td>The handpiece is obstructed</td>
<td>The handpiece is obstructed</td>
<td>Contact MECTRON authorized technical assistance</td>
</tr>
<tr>
<td>PROBLEM</td>
<td>POSSIBLE CAUSE</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>----------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>The device is switched on but doesn’t work (APC automatic protection</td>
<td>The insert is not properly connected to the</td>
<td>Svitare e riavvitare correttamente l’inserto.</td>
</tr>
<tr>
<td>circuit activated)</td>
<td>handpiece.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The insert is worn, broken or deformed.</td>
<td>Sostituire l’inserto.</td>
</tr>
<tr>
<td></td>
<td>The handpiece’s connector or the cord are</td>
<td>Asciugare i connettori.</td>
</tr>
<tr>
<td></td>
<td>wet.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The handpiece is not connected to the cord</td>
<td>Connettere il manipolo al cordone.</td>
</tr>
<tr>
<td></td>
<td>A wire in the cord is disconnected</td>
<td>Rivolgersi al centro di assistenza tecnica autorizzata MECTRON più vicino.</td>
</tr>
<tr>
<td></td>
<td>The handpiece is broken</td>
<td>Rivolgersi al centro di assistenza tecnica autorizzata MECTRON più vicino.</td>
</tr>
<tr>
<td></td>
<td>The syntonic circuit is not functioning</td>
<td>Rivolgersi al centro di assistenza tecnica autorizzata MECTRON più vicino.</td>
</tr>
<tr>
<td>When working a hiss is heard coming from the scaler handpiece</td>
<td>The insert is not correctly locked to the</td>
<td>Unscrew the insert and screw back on properly</td>
</tr>
<tr>
<td></td>
<td>scaler handpiece.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The insert has not been fitted correctly on</td>
<td>Unscrew and screw back on</td>
</tr>
<tr>
<td></td>
<td>the handpiece.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The insert is worn, broken or deformed.</td>
<td>Replace insert</td>
</tr>
<tr>
<td></td>
<td>Insufficient insert maintenance</td>
<td>See paragraphs on “Safety measures”.</td>
</tr>
<tr>
<td>Insufficient power</td>
<td>The insert has not been fitted correctly on</td>
<td></td>
</tr>
<tr>
<td></td>
<td>the handpiece.</td>
<td></td>
</tr>
</tbody>
</table>


### 11.0 Technical data

| Device conforming to Dir. 93/42/CEE: | Class IIa |
| Classification as provided for in EN 60601-1: | II  
Type BF  
IP according to the indications provided by the manufacturer of the dentist’s unit |
| Intermittent function device: | 60” ON  30” OFF with irrigation  
30” ON 120” OFF without irrigation |
| Power supply tension: | Double isolation power supplier:  
- 24 Vac ± 10 % 50/60 Hz or  
- 32 Vdc ± 10 % |
| Max. power absorbed: | 40 VA |
| Working frequency: | Automatic scanning  
From 24 KHz to 36 KHz |
| Power: | Adjustable according to the indications provided by the manufacturer of the dentist’s unit |
| Water supply: | Adjustable according to the indications provided by the manufacturer of the dentist’s unit  
Working pressure: from 1 to 6 bar |
| APC circuit protections: |  
- No handpiece connected  
- Cord wire disconnected  
- Insert not properly locked or broken  
- Grounding protection activated |
| Working conditions: | from +10°C to +40°C  
Relative humidity from 30% to 75% |
| Transport and storing conditions: | from -10°C to +70°C  
Relative humidity from 10% to 90%  
Air pressure P: 500hPa/1060hPa |
11.1 Electromagnetic compatibility EN 60601-1-2

⚠️ **DANGER: Contraindications. Interference from other device**
An electro-surgical knife or other electro-surgical devices placed in proximity to the device may interfere with the correct performance of the same device.

⚠️ **DANGER: Contraindications. Interference with other device**
Even if conforming to IEC 60601-1-2 standards, the scaler may interfere with other devices placed in its proximity.

⚠️ **DANGER:** The device needs particular EMC precautions and must be installed and operated in conformity with the EMC information contained in this paragraph.

⚠️ **DANGER:** Portable and mobile radio-communication device may effect the correct performance of the device.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Conformity</th>
<th>Electromagnetic environment - Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions</td>
<td>Group 1</td>
<td>The Compact Piezo P2K uses RF energy only for its internal function. Therefore its RF emissions are very low and are unlikely to cause any interference with electromagnetic devices placed in its proximity.</td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td>The Compact Piezo P2K is suitable for use in any building, including domestic buildings, and those directly connected to the low tension public energy grid which supplies buildings for domestic use.</td>
</tr>
<tr>
<td>IEC 61000-3-2 harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3 Flicker/voltage</td>
<td>Conforming</td>
<td></td>
</tr>
<tr>
<td>fluctuation emissions</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Guide and manufacturer’s statement - Electromagnetic immunity

The Compact Piezo P2K is designed to work in the electromagnetic environment specified below. The client or user of the Compact Piezo P2K should always make sure that it is used only in such environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Level of conformity</th>
<th>Electromagnetic environment - Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-2 Electrostatic discharge (ESD)</td>
<td>±6 kV on contact ±8 kV in the air</td>
<td>±6 kV on contact ±8 kV in the air</td>
<td>Floors must be wood, concrete or ceramic. If the floor is lined with synthetic materials, the relative humidity should be at least 30 %</td>
</tr>
<tr>
<td>IEC 61000-4-4 Transients/fast electric trains</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV kV for power supply lines ±1 kV for input/output lines</td>
<td>The quality of the power supply should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td>IEC 61000-4-5 impulses</td>
<td>±1 kV in differential mode ±2 kV in common mode</td>
<td>±1 kV in differential mode ±2 kV in common mode</td>
<td>The quality of the power supply should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td>IEC 61000-4-11 Voltage blackouts, brief voltage interruptions and variations on the input power supply lines</td>
<td>&lt;5 % U_T (&gt;95 % U_T blackout) for 0,5 cycles 40 % U_T (60 % U_T blackout) for 5 cycles 70 % U_T (30 % U_T blackout) for 25 cycles &lt;5 % U_T (&gt;95 % U_T blackout) for 5 s</td>
<td>&lt;5 % U_T (&gt;95 % U_T blackout) for 0,5 cycles 40 % U_T (60 % U_T blackout) for 5 cycles 70 % U_T (30 % U_T blackout) for 25 cycles &lt;5 % U_T (&gt;95 % U_T blackout) for 5 s</td>
<td>The quality of the power supply should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td>IEC 61000-4-8 Grid frequency magnetic field (50/60 Hz)</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Grid frequency magnetic fields should have levels characteristic of a typical commercial or hospital environment</td>
</tr>
</tbody>
</table>

**NOTE:** $U_T$ is the grid voltage in a.c. before the application of the test level.
The Compact Piezo P2K is designed to work in the electromagnetic environment specified below. The client or user of the Compact Piezo P2K should always make sure that it is used only in such environment.

### Guide and manufacturer’s statement – Electromagnetic immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Level of conformity</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-6 RF conducted</td>
<td>3 Veff from 150 kHz to 80 MHz</td>
<td>3 Veff</td>
</tr>
<tr>
<td>IEC 61000-4-3 RF irradiated</td>
<td>3 V/m from 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
</tr>
</tbody>
</table>

**Electromagnetic environment Guide**

Portable or mobile RF communication device must not be used in close proximity of the product, including its cables, except when these respect the distances of separation recommended and calculated from the equation applicable to the frequency of the transmitter.

#### Recommended distances of separation

\[
d = 1,2 \sqrt{P}
\]

\[
d = 1,2 \sqrt{P} \text{ from 80 MHz to 800 MHz}
\]

\[
d = 2,3 \sqrt{P} \text{ from 800 MHz to 2.5 GHz}
\]

whereas \(P\) is the maximum nominal output power of the transmitter in Watts (W) according to the transmitter manufacturer and \(d\) is the separation distance recommended in meters (m).

The field intensity of the fixed RF, as determined by an electromagnetic investigation of the site, could be lower than the level of conformity in each frequency interval.

Interference may occur when in proximity to device marked with the following symbol:

---

**Note:**

1. at 80 MHz and 800 MHz the highest frequency interval is applied.
2. These guidelines might not apply to all situations. Electromagnetic propagation is influenced by the absorption and by the reflection of the structure, objects and people.

   a. The field intensity for fixed transmitters such as radio-telephone stations (mobiles and cordless) and land radio cars, amateur radio equipment, AM and FM radio transmitters, and TV transmitters, cannot be identified theoretically and precisely. To establish an electromagnetic environment caused by fixed RF transmitters, one should consider an electromagnetic investigation of the site. If the field intensity measured in the environment where the Compact Piezo P2K is being used, exceeds the above applicable level of conformity, one should examine the normal function of the Compact Piezo P2K. If abnormal performance is observed, it may be necessary to apply additional measures such as a different orientation or positioning of the Compact Piezo P2K.

   b. The field intensity on a frequency interval of from 150 kHz to 80 MHz should be less than 3 V/m.
The Compact Piezo P2K is designed to work in an electromagnetic environment in which RF radiated disturbances are kept under control. The purchaser or user of the Compact Piezo P2K can contribute to prevent electromagnetic interference by ensuring a minimum distance between the RF mobile and cordless communication device (transmitters) and the Compact Piezo P2K, as recommended below, in relation to the maximum output power of the radio-communication devices.

<table>
<thead>
<tr>
<th>Maximum nominal output power of transmitter “W”</th>
<th>Separation distance from the frequency of transmitter “m”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>From 150 kHz to 80 MHz (d = 1,2 \sqrt{P})</td>
</tr>
<tr>
<td>0,01</td>
<td>0,12</td>
</tr>
<tr>
<td>0,1</td>
<td>0,38</td>
</tr>
<tr>
<td>1</td>
<td>1,2</td>
</tr>
<tr>
<td>10</td>
<td>3,8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters with a maximum nominal output power not indicated in the above table, the recommended separation distance \(d\) in meters (m) can be calculated using the equation applicable to the frequency of the transmitter, whereas \(P\) is the maximum nominal output power of the transmitter in Watts (W) according to the manufacturer of the transmitter.

Note:
(1) At 80 MHz and 800 MHz the highest frequency interval is applied.
(2) These guidelines might not apply to all situations. Electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.
12.0 Guarantee

All MECTRON devices undergo thorough final check to verify full working conditions before being marketed. MECTRON guarantees its products, if purchased new from a MECTRON retailer or importer, against material and manufacturing flaws for:
- 2 YEARS (TWO) from the date of purchase with regard to the device;
- 1 YEAR (ONE) from the date of purchase with regard to the handpiece.

During the period of validity of the guarantee, MECTRON undertakes to repair (or, to its discretion, replace), free of charge, the parts which it acknowledges as being faulty. Replacement of complete MECTRON products is excluded.

Mectron declines any responsibility for direct or in direct injury to people and damage to property in the following cases:
- The device is not used for the purpose for which it was designed.
- The device is used not in conformity with the instructions and prescriptions described in this manual.
- The electric system to which the device is connected does not conform to the existing laws and relative prescriptions.
- The assembly, extension, adjustment, modification and repair operations are carried out by personnel other than Mectron authorized personnel.
- The environmental conditions in which the device is kept and stored do not conform to the prescriptions indicated in the technical data section.
- The inserts, accessories and spare parts used are not original Mectron products and which can compromise the correct performance of the device and cause harm to the patient.

In this case the manufacturer’s guarantee and the type approval are no longer valid!

Not covered by the guarantee are: accidental damage due to transport, incorrect use or negligence; due it having been connected to a power supply other than that prescribed in the instructions. Indicator lights, handpieces and all the accessories are also not included in the guarantee. The guarantee is forfeited if the device has been tampered with or repaired by unauthorized personnel.

**WARNING**

The guarantee is only valid if the guarantee coupon attached to the product has been filled in every part and returned to the manufacturer, or eventually the retailer or importer within 20 (TWENTY) DAYS from the purchase date which is that indicated on the receipt/invoice issued by the retailer/importer.

In order to benefit from the guarantee, the client must send, at the latter’s expense, the device to be repaired to the MECTRON retailer/importer from whom the purchase was made. The device must be returned appropriately packed (possibly using the original packing), together with all its accessories and the form indicating:

a) Owner’s data and telephone number;
b) Retailer/importer data;
c) Photocopy of purchase document, invoice/receipt containing, date, name of device and serial number;
d) Description of malfunction.

Transport and damage caused during transport are not covered by the guarantee.

In case of faults due to accident or improper use or if the guarantee is expired, the repair of MECTRON products will be charged on the basis of the effective cost of the materials and labor required.