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# 1 Symbols

## 1.1 Description of symbols for BIOPOWER units

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="ce.png" alt="CE Marking" /> 0123</td>
<td>CE Marking with number of the notified body.</td>
<td><img src="recycling.png" alt="Recyclable materials" /></td>
<td>Recyclable materials.</td>
</tr>
<tr>
<td><img src="main_switch.png" alt="Main switch" /> - Power OFF.</td>
<td>Main switch - Power OFF.</td>
<td><img src="separate_collection.png" alt="Separate collection" /></td>
<td>Separate collection of electric and electronic equipment.</td>
</tr>
<tr>
<td><img src="main_switch.png" alt="Main switch" /> - Power ON.</td>
<td>Main switch - Power ON.</td>
<td><img src="manufacturer.png" alt="Manufacturer" /></td>
<td>Manufacturer.</td>
</tr>
<tr>
<td><img src="fuse.png" alt="Fuse Ø 5 x 20 mm." /></td>
<td>Fuse Ø 5 x 20 mm.</td>
<td><img src="light.png" alt="Light" /></td>
<td>Light.</td>
</tr>
<tr>
<td><img src="ac.png" alt="Alternating current." /></td>
<td>Alternating current.</td>
<td><img src="sound_alerts.png" alt="Sound alerts." /></td>
<td>Sound alerts.</td>
</tr>
<tr>
<td><img src="rf.png" alt="RF emitting device" /> (Interference may occur in the vicinity of equipment marked with this symbol).</td>
<td>RF emitting device (Interference may occur in the vicinity of equipment marked with this symbol).</td>
<td><img src="rx_only.png" alt="Rx Only" /></td>
<td>Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.</td>
</tr>
<tr>
<td><img src="caution.png" alt="CAUTION! Consult accompanying documents. Provides an instruction that should be observed for safety reasons." /></td>
<td>CAUTION! Consult accompanying documents. Provides an instruction that should be observed for safety reasons.</td>
<td><img src="reference_number.png" alt="Reference number." /></td>
<td>Reference number.</td>
</tr>
<tr>
<td><img src="refer.png" alt="Refer to the accompanying documents." /></td>
<td>Refer to the accompanying documents.</td>
<td><img src="serial_number.png" alt="Serial number." /></td>
<td>Serial number.</td>
</tr>
</tbody>
</table>

## 1.2 Description of symbols for BIOPOWER accessories

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="ce.png" alt="CE Marking" /> 0123</td>
<td>CE Marking with number of the notified body.</td>
<td><img src="thermo_washer_disinfectable.png" alt="Thermo washer disinfectable." /></td>
<td>Thermo washer disinfectable.</td>
</tr>
<tr>
<td><img src="expiration_date.png" alt="Expiration date." /></td>
<td>Expiration date.</td>
<td><img src="recycling.png" alt="Recyclable materials." /></td>
<td>Recyclable materials.</td>
</tr>
<tr>
<td><img src="do_not_reuse.png" alt="Do not reuse." /></td>
<td>Do not reuse.</td>
<td><img src="separate_collection.png" alt="Separate collection" /></td>
<td>Separate collection of electric and electronic equipment.</td>
</tr>
<tr>
<td><img src="sterilization.png" alt="Sterilized with Ethylene Oxyde." /></td>
<td>Sterilized with Ethylene Oxyde.</td>
<td><img src="sterilization_autoclave.png" alt="Sterilizable in autoclave up to the specified temperature." /></td>
<td>Sterilizable in autoclave up to the specified temperature.</td>
</tr>
<tr>
<td><img src="electrical_safety.png" alt="Electrical safety. Applied part type B." /></td>
<td>Electrical safety. Applied part type B.</td>
<td><img src="manufacturer.png" alt="Manufacturer." /></td>
<td>Manufacturer.</td>
</tr>
<tr>
<td><img src="reference_number.png" alt="Reference number." /></td>
<td>Reference number.</td>
<td><img src="serial_number.png" alt="Serial number." /></td>
<td>Serial number.</td>
</tr>
</tbody>
</table>
2 Identification, Intended Use and Notation

2.1 Identification

Electronically controlled tabletop device for dentistry allowing operation of a dental handpiece via an MX-i LED 3rd Gen micromotor with variable speed control by a pedal. A peristaltic pump conveys the physiological liquid via a disposable irrigation line without being contaminated. The device’s LCD display indicates and allows to control operation settings.

2.2 Intended use

The equipment is to be used by dentists and surgeons in dental offices and hospitals. The system is designed to control a dental MX-i LED 3rd Gen micromotor only which can drive a dental handpiece fitted with appropriate tools to cut hard and soft tissues in the oral cavity and to place dental implants. The system is intended for use in dentistry for implantology. Any use other than that for which this product is intended is unauthorized and may be dangerous. The system meets all the current legal requirements for medical devices.

The intended electromagnetic environment (per IEC 60601-1-2 ed. 4.0) is Professional healthcare facility environment.

2.3 Notation and chapter links

- A, B, C, etc.
  Text preceded by a letter indicates a procedure to be carried out step-by-step.
- 
  Indicates a procedure result.
- (1), (2), (3), etc.
  Text preceded by a number indicates text used in conjunction with an illustration.
- OK, Settings, etc.
  Text in bold italic font style indicates, on-screen elements such as buttons, menus, menu items, screen areas, values, fields when they are named and screen names.

In order to simplify the notation, in this manual:
- «Clockwise» is referred to as «CW»;
- «Counterclockwise» is referred to as «CCW»;
- Forward micromotor rotation mode is referred to as «FWD»;
- Reverse micromotor rotation mode is referred to as «REV»;
- Rotational speed unit «revolutions per minute» is referred to as «rpm»;
- Torque unit «newton centimetre» is referred to as «Ncm»;
- Micromotor control unit is referred to as «DMX».
3 Warnings & Precautions of Use

⚠️ CAUTION
The power plug is used for disconnection in case of problems, it must be easily accessible at all times.

⚠️ CAUTION
Never connect a handpiece on a running MX-i LED 3rd Gen micromotor.

⚠️ CAUTION
Any modification of the medical device is strictly forbidden.

⚠️ CAUTION
The device is not designed for use in an explosive atmosphere (anaesthetic gas).

⚠️ CAUTION
Do not attempt to open the device when it is connected to the electric mains. Risk of electrocution.

⚠️ CAUTION
The parameters contained in the dental procedures are indicative only. Bien-Air Dental SA cannot be held liable for them.

⚠️ CAUTION
The device must not be touched by the patient.

⚠️ CAUTION
Do not simultaneously touch the patient and the pump or contacts of connectors.

⚠️ CAUTION
Ensure that there is no water under the unit before switching it on.

⚠️ CAUTION
All connectors must be dry before use. Ensure the absence of residual moisture due to cleaning.

⚠️ WARNING
To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
4 Description

4.1 BIOPOWER system overview

FIG. 1

(1) Peristaltic pump lid
(2) Pedal connector
(3) LCD control screen
(4) Bracket support
(5) Main switch
(6) Fuse box
(7) Mains connector
(8) MX-i LED 3rd Gen micromotor
(9) Button to start/stop irrigation
(10) Foot control to reverse the rotation of the MX-i LED 3rd Gen micromotor
(11) “Program” button to go to next operation step
(12) Motor start
(13) MX-i LED 3rd Gen micromotor connector
(14) Control knob
4.2 Sets supplied

**BIOPOWER set REF 1700784-001**

<table>
<thead>
<tr>
<th>Designation</th>
<th>Bien-Air Dental REF number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIOPOWER unit (1x)</td>
<td>1601147-001</td>
</tr>
<tr>
<td>MX-i LED 3rd Gen micromotor (1x)</td>
<td>1601008-001</td>
</tr>
<tr>
<td>3-button pedal (1x)</td>
<td>1600631-001</td>
</tr>
<tr>
<td>Cable MX-i LED 3rd Gen (2m) (1x)</td>
<td>1601009-001</td>
</tr>
<tr>
<td>Sterile protective sheet</td>
<td>1502329-002</td>
</tr>
<tr>
<td>Pack of 5 disposable sterile irrigation lines</td>
<td>1500986-005</td>
</tr>
<tr>
<td>Pack of 10 attachment collars for fastening the</td>
<td>1307727-010</td>
</tr>
<tr>
<td>sterile irrigation line to a cable</td>
<td></td>
</tr>
<tr>
<td>Bracket for fluid bottle (1x)</td>
<td>1303393-001</td>
</tr>
<tr>
<td>Handpiece support (1x)</td>
<td>1301575-001</td>
</tr>
<tr>
<td>3P cable system, US/Asia, length 2m (1x)</td>
<td>1300067-001</td>
</tr>
<tr>
<td>3P cable system, Europe, length 2.5 m (1x)</td>
<td>1300066-001</td>
</tr>
<tr>
<td>3P cable system, Switzerland, length 2 m (1x)</td>
<td>1300065-001</td>
</tr>
<tr>
<td>Contra-angle handpiece CA 20:1 L Micro-Series (light) (1x)</td>
<td>1600692-001</td>
</tr>
</tbody>
</table>

4.3 Options

<table>
<thead>
<tr>
<th>Designation</th>
<th>Bien-Air Dental REF number</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-button pedal</td>
<td>1600631-001</td>
</tr>
<tr>
<td>MX-i LED 3rd Gen micromotor</td>
<td>1601008-001</td>
</tr>
<tr>
<td>Contra-angle handpiece CA 20:1 L KM Micro-Series (light)</td>
<td>1600786-001</td>
</tr>
<tr>
<td>Contra-angle handpiece CA 20:1 L KM (light)</td>
<td>1600785-001</td>
</tr>
<tr>
<td>Contra-angle handpiece CA 20:1 L Micro-Series (light)</td>
<td>1600692-001</td>
</tr>
<tr>
<td>Contra-angle handpiece CA 20:1 L (light)</td>
<td>1600598-001</td>
</tr>
<tr>
<td>Straight handpiece PM 1:1 Micro-Series</td>
<td>1600052-001</td>
</tr>
<tr>
<td>Sterile protective sheet</td>
<td>1502329-010</td>
</tr>
<tr>
<td>Pack of 10 disposable sterile lines 3.5 m</td>
<td>1501738-010</td>
</tr>
<tr>
<td>Kirschner/Meyer pack of 10 disposable sterile lines</td>
<td>1501635-010</td>
</tr>
<tr>
<td>Kirschner/Meyer type detachable irrigation set for CA 20:1 L KM and CA 20:1 L KM Micro-Series, comprising 10 rings and 10 tubes</td>
<td>1501621-010</td>
</tr>
<tr>
<td>Pack of 10 disposable sterile lines</td>
<td>1500984-010</td>
</tr>
<tr>
<td>Bracket for fluid bottle</td>
<td>1303393-001</td>
</tr>
<tr>
<td>Handpiece support</td>
<td>1301575-001</td>
</tr>
<tr>
<td>Cable MX-i LED 3rd Gen (2m)</td>
<td>1601009-001</td>
</tr>
<tr>
<td>3P cable system, US/Asia, length 2m</td>
<td>1300067-001</td>
</tr>
<tr>
<td>3P cable system, Europe, length 2.5 m</td>
<td>1300066-001</td>
</tr>
<tr>
<td>3P cable system, Switzerland, length 2 m</td>
<td>1300065-001</td>
</tr>
<tr>
<td>Pack of 10 attachments collars for fastening the sterile irrigation line to a cable</td>
<td>1307727-010</td>
</tr>
</tbody>
</table>

4.4 Technical data

**Dimensions L x W x H**

- BIOPOWER unit ......................................... 240 x 240 x 102 mm
- BIOPOWER unit (with bracket) ...................... 240 x 240 x 482 mm
- Pedal ............................................................ 250 x 205 x 54 mm
- Pedal (with handle) .................................. 250 x 205 x 144 mm
- Motor cable (REF 1601009) ................... L 2.0 m
- Pedal cable ................................................. L 2.9 m

The pedal is waterproof (IP X8 in accordance with IEC 60529).

**Weight**

- BIOPOWER unit.......................................... 2.2 kg
- Pedal ............................................................ 830 g
- Bracket ........................................................115 g
- Cable ............................................................105 g

**Electrical data**

- Voltage.........................................................100 – 240 VAC
- Frequency .................................................. 50-60 Hz

**Environmental conditions**

- **CAUTION**
  - Do not use BIOPOWER outside the range of operating temperature.

**Classification**

Class Ia in accordance with European Directive 93/42/EEC concerning medical devices.

**Electric insulation class**

Class I per IEC 60601-1:

- MX-i LED 3rd Gen micromotor .............. REF 1601008-001
- Straight handpiece 1:1............................ REF 1600052-001
- CA 20:1 L..................................................... REF 1600598-001
- CA 20:1 L KM.............................................. REF 1600785-001
- CA 20:1 L KM Micro-Series.................... REF 1600786-001
- Irrigation lines........................................... REF 1500984-010
- KM Irrigation lines.................................... REF 1501635-010

**Degree of ingress protection**

IP 41 (protection against insertion of objects larger than 1 mm and dripping water (vertically falling drops)).

**Memory**

Memory storage of 5 steps settings including adjustment of speed, torque, rotation direction, irrigation, and contra-angle ratio for each step.

---

**Designation**

Bien-Air Dental

**REF number**

Pack of 10 fuses T4.0AH 250 VAC high breaking capacity 1307312-010

Knob 1307031-001
Languages
English.

Bracket for physiological liquid flask
Stainless steel.

Peristaltic pump
Pump delivery ...........................................From 30 to 150 ml/min. 
(5 levels)
Hose for pump ..........................................External Ø 5.60 mm 
.......................................................................Internal Ø 2.40 mm
Wall thickness ...........................................1.60 mm

Intended for use with: See Bien-Air Dental instructions for use
MX-i LED 3rd Gen micromotor ..............REF 2100245
Cable MX-i LED 3rd Gen .........................REF 2100163
Contra-angle CA 20:1 L, light ...............REF 2100209
Contra-angle CA 20:1 L KM ..........REF 2100209
Micro-Series, light.........................REF 2100209
Contra-angle CA 20:1 L KM .......................REF 2100209
Contra-angle CA 20:1 L KM .......................REF 2100209
Micro-Series, light.........................REF 2100209
Straight Handpiece 1:1 .........................REF 2100046

⚠️ CAUTION
The use of the system with other handpieces, motors or cables has not been validated/certified (speed and torque values are not guaranteed in this case).

List of errors & Troubleshooting
See chapter “10 List of errors & Troubleshooting” on page 20.

4.5 Environmental protection and information for disposal

The disposal and/or recycling of materials must be performed in accordance with the legislation in force.

Separate collection of electric and electronic equipment and accessories in view of recycling.
Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the device to its dealer or establish direct contact with an approved body for treatment and recovery of this type of equipment (European Directive 2002/96/EC).

4.6 Electromagnetic compatibility (technical description)

4.6.1 Precautions of use
This electronic control is in compliance with electrical safety standards in line with standard IEC 60601-1, and those governing electromagnetic compatibility in line with standard IEC 60601-1-2, fourth edition.

⚠️ CAUTION
The device must be used by a competent person, in particular in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and the current instruction for use. According to these measures, the user has the following obligations:
- to only use devices that are in perfect working order
- to make sure that the device is used solely for the purpose for which it is intended
- avoid contact with liquids.

4.6.2 Electromagnetic compatibility warnings

⚠️ CAUTION
The BIOPOWER complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc., should not be used in the immediate vicinity of the device, since this could affect its operation. The device is not suitable for being used close to high-frequency surgical equipment, magnetic resonance imaging (MRI) and other similar devices where the intensity of electromagnetic disturbances is high. In any case, ensure that no high frequency cables are routed above or near the device. If in doubt, contact a qualified technician or Bien-Air Dental SA.
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BIOPOWER, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠️ CAUTION
The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Bien-Air Dental SA as spare parts for internal components, may result in increased emissions or decreased immunity.
4.6.3 Electromagnetic compatibility – emissions & immunity

Guidance and manufacturer’s declaration – Electromagnetic emissions
The BIOPOWER is intended for use in the electromagnetic environment specified below. The customer or the user of the BIOPOWER must ensure that it is actually used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The BIOPOWER uses RF energy for its internal operation only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td>The BIOPOWER is suitable for use in any building, including residential buildings and those directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes.</td>
</tr>
<tr>
<td>Emissions due to voltage fluctuations IEC 61000-3-3</td>
<td>Conforming</td>
<td></td>
</tr>
</tbody>
</table>

Guidance and manufacturer’s declaration – Electromagnetic immunity
The BIOPOWER is intended for use in the electromagnetic environment specified below. The customer or the user of the BIOPOWER must ensure that it is actually used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air</td>
<td>±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for other lines</td>
<td>±2 kV for power supply lines N.A.</td>
<td>Mains power quality should be that of a commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth</td>
<td>±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth</td>
<td>Mains power quality should be that of a commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>0% $U_T$ for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% $U_T$ for 1 cycle and 70% $U_T$ for 25/30 cycles at 0° 0% $U_T$ for 250 cycles at 0°</td>
<td>0% $U_T$ for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% $U_T$ for 1 cycle and 70% $U_T$ for 25/30 cycles at 0° 0% $U_T$ for 250 cycles at 0°</td>
<td>Mains power quality should be that of a commercial or hospital environment. If the user of the BIOPOWER requires continued operation during mains power interruptions, it is recommended that the BIOPOWER be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Magnetic field due to mains frequency (50/60 Hz) IEC 61000-4-8</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>Magnetic fields generated by the mains frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
Conducted disturbances induced by RF fields
IEC 61000-4-6

<table>
<thead>
<tr>
<th>Test freq. [MHz]</th>
<th>Max. power [W]</th>
<th>Immunity test level [V/m]</th>
<th>Distance: 0.3 m</th>
</tr>
</thead>
<tbody>
<tr>
<td>385</td>
<td>1.8</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>450</td>
<td>2</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>710, 745, 780</td>
<td>0.2</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>810, 870, 930</td>
<td>2</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>1720, 1845, 1970</td>
<td>2</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>2450</td>
<td>2</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>5240, 5500, 5785</td>
<td>0.2</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: U_T is the AC mains voltage prior to application of the test level.
Essential performance per IEC 60601-1: The essential performance is to maintain the visual luminous intensity of the LED and the motor speed. The maximum speed deviation is ±5%.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Radiated RF EM fields
IEC 61000-4-3

Proximity fields from RF wireless communications equipment
IEC 61000-4-3

IEC 610601 test level

3 \text{ V}_{\text{RMS}} \\
0.15 \text{ MHz} – 80 \text{ MHz} \\
6 \text{ V}_{\text{RMS}} \text{ in ISM bands} \\
0.15 \text{ MHz} – 80 \text{ MHz} \\
80\% \text{ AM at 1 kHz} \\

IEC 60601 test level

3 \text{ V}_{\text{RMS}} \\
0.15 \text{ MHz} – 80 \text{ MHz} \\
6 \text{ V}_{\text{RMS}} \text{ in ISM bands} \\
0.15 \text{ MHz} – 80 \text{ MHz} \\
80\% \text{ AM at 1 kHz} \\

Compliance level

3 \text{ V}_{\text{RMS}} \\
0.15 \text{ MHz} – 80 \text{ MHz} \\
6 \text{ V}_{\text{RMS}} \text{ in ISM bands} \\
0.15 \text{ MHz} – 80 \text{ MHz} \\
80\% \text{ AM at 1 kHz} \\

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile field radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BIOPower is used exceeds the RF compliance level mentioned above, the BIOPower should be observed to verify that it is operating normally. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the BIOPower.

NOTE: U_T is the AC mains voltage prior to application of the test level.
Essential performance per IEC 60601-1: The essential performance is to maintain the visual luminous intensity of the LED and the motor speed. The maximum speed deviation is ±5%.
5 Installation
5.1 Install the BIOPOWER system

**FIG. 1**
A. Place the BIOPOWER on a flat surface capable of bearing its weight.

⚠️ **CAUTION**
It may be positioned on a table, on a trolley or any other surface but in no circumstances on the floor.

**FIG. 2**
B. The fuse box may be opened with a screwdriver.
100 - 240 VAC = fuse T4.0AH 250 VAC REF 1307312-010.
*To replace a fuse, see chapter “11.4 Replacement of fuses” on page 23.*
C. Connect the power cable (1) to the connector (2).

**Note 1**

⚠️ **CAUTION**
The power plug is used for disconnection in case of problems, it must be easily accessible at all times.

**FIG. 3**
D. Connect the pedal cable to the input provided on the rear panel, guiding the connector and plug by means of the index pin on the connector.

⚠️ **CAUTION**
Do not lift the pedal holding the connection cable.
To disconnect the pedal cable pull the cable socket connector (1).
Do not pull the cable (2) without disconnecting the cable socket before.

**FIG. 4**
E. Connect the MX-i LED 3rd Gen micromotor cable to the motor output, guiding the connector and plug by means of the index pin on the connector.

**FIG. 5**
F. Align and attach the bracket to the housing provided on the rear of the console and suspend the flask or bottle.

**FIG. 6**
G. Check the packaging integrity, as well as the expiry date of the irrigation line on the label (1).

⚠️ **CAUTION**
The medical device must be used only with lines supplied by Bien-Air Dental to ensure trouble-free operation. These lines are sterile and for single use. Re-use may result in microbiological contamination of the patient.

H. Remove the single-use sterile irrigation line (2) from its pouch.

**FIG. 7**
I. Connect the flexible hose of the irrigation line to the spray tube of the handpiece or contra-angle.

**FIG. 8**
J. Install the peristaltic cassette (1) in the peristaltic pump (2). Check that the cassette is clipped correctly.

**FIG. 9**
K. Close the pump lid (3). If there is resistance to closing, open the lid again and check the correct positioning of the cassette. When the lid is correctly closed, the user should hear a click sound.

⚠️ **CAUTION**
Do not run the pump while the lid is open.

⚠️ **CAUTION**
Do not run the pump without irrigation line.

⚠️ **CAUTION**
Risk of pinching!

**FIG. 10**
L. Perforate the cap of the physiological liquid flask with the pointed end of the irrigation line after removing the protective cap.

⚠️ **CAUTION**
There is no detection of empty physiological liquid flask! Always check the content of the flask before operating.

**FIG. 11**
M. Attach the irrigation line on the motor cable using the 3 attachment collars REF 1307727-010.

5.2 On/off procedure

The device can be switched on and off in complete safety using the main switch on the BIOPOWER.

⚠️ **CAUTION**
Do not switch off the device while the motor is running.

---

**NOTES**

1 The equipment is powered by the mains power supply (100 - 240 VAC / 150W / 50-60Hz).
6 Interface overview

6.1 BIOPOWER modes

The BIOPOWER allows to visualize and control operation parameters by the means of the LCD display. A unique screen allows to use the following modes:

**FIG. 1**
- Operation mode (to perform an operation in 3 steps)
  See chapter “7 Operation” on page 14 for details.

**FIG. 2**
- Settings mode (to set up operation parameters)
  See chapter “8 Settings” on page 16 for details.

**FIG. 3**
- Special modes (to test system and reset settings)
  See chapter “9 Special modes” on page 18 for details.

**FIG. 4**
A. Long press on the rotating knob (1) to switch between Operation and Settings modes.

**Note 1**
See chapter “6.2 Rotating knob functions overview” on page 12 for details.

See chapter “9 Special modes” on page 18 for entering special modes.

6.2 Rotating knob functions overview

**Note 2**

<table>
<thead>
<tr>
<th>Knob action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CW rotation</td>
<td>Increase current value, go to the element on the right</td>
</tr>
<tr>
<td>CCW rotation</td>
<td>Decrease current value, go to the element on the left</td>
</tr>
<tr>
<td>One short press (Operation mode)</td>
<td>Go to the next programmed step, acknowledge error messages</td>
</tr>
<tr>
<td>One short press (Settings mode)</td>
<td>Enter selected setting, validate and store the current setting value, exit the current setting, acknowledge error messages</td>
</tr>
<tr>
<td>One long press</td>
<td>Switch between Operation and Settings modes</td>
</tr>
<tr>
<td>Double short press</td>
<td>Enter special modes (only when gear ratio is selected in settings mode)</td>
</tr>
</tbody>
</table>
6.3 Sound alerts

<table>
<thead>
<tr>
<th>Sound alert</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>One short beep</td>
<td>Activating irrigation, going to next step, and switching rotation direction to FORWARD</td>
</tr>
<tr>
<td>Two short beeps</td>
<td>Deactivating irrigation, and switching rotation direction to REVERSE</td>
</tr>
<tr>
<td>Two long beeps</td>
<td>Switching from low speed to high speed programmed step</td>
</tr>
<tr>
<td>Alternate short beeps</td>
<td>Warning notifications</td>
</tr>
<tr>
<td>Alternate medium beeps</td>
<td>Micromotor REVERSE running indicator</td>
</tr>
<tr>
<td>Alternate long beeps</td>
<td>System failure notification</td>
</tr>
</tbody>
</table>

**NOTES**

1. The Operation mode is the default startup mode.
2. Any knob or pedal action will be ignored when the motor is running.
7 Operation

7.1 Operation screen description

The Operation screen differs whether the micromotor is stopped or running and depending on the active step. It allows to perform an operation in 3, 4 or 5 predefined steps P1, P2, P3, P4, P5 (which can respectively be used to program settings for the bone preparation, drilling, threading and implant insertion phases), and displays the following information:

1. Step P1 (inactive step, in black)
2. Step P2 (inactive step, in black)
3. Step P3 (active step, in green)
4. P4 and P5 steps are disabled by default, see “Number of steps” on page 18 for enabling them.
5. Speedometer
6. Torquemeter
7. Contra-angle ratio
8. Bar graph for torque
9. Operation settings symbols

See chapter “8 Settings” on page 16 for details on adjusting settings.

7.2 Perform an operation, steps P1 and P2

A. Operate by pressing the footpedal to adjust the MX-i LED 3rd Gen micromotor speed.
B. All inactive steps symbols turn off when the motor is running.
C. Speedometer (1) displays the set micromotor maximum reachable speed in cyan.

Note 1
Note 2
Note 3
Note 4
Note 5 - 6 - 7

7.3 Perform an operation, steps P3, P4 and P5

A. In steps P3 (1), P4 and P5, operate by pressing the footpedal to adjust the MX-i LED 3rd Gen micromotor speed.
B. All inactive steps symbols turn off when the motor is running.
C. Speedometer (2) displays real-time value.
D. Torquemeter (3) displays real-time value.
E. The torque bar (5) displays ratio between the real-time torque value (represented by cyan dots when the micromotor is running) and the maximum reached torque (represented by green dot).

Note 8
Note 9
Note 5 - 6 - 7

8 Settings

A. If necessary, release the footpedal to perform the following actions:
B. Torquemeter (3) displays maximum reached value together with the Max symbol (4).
C. Torque bar (5) dots that were displayed in cyan turn black, except for the maximum value dot which turns green.
• Turn the knob CW or CCW to respectively increase or decrease the micromotor maximum reachable torque (quick setting mode).

The torquemeter (3) turns cyan and displays the set micromotor maximum reachable torque.

Note 11
• Long press on the knob to change operation settings. See chapter “8 Settings” on page 16 for details.

Note 9
C. Short press on the footpedal’s orange button or on the knob to go to the next step.

The next step symbol turns green and the step’s last used settings are restored.

Note 7 - 10

1 Real-time speed value is displayed in black when the MX-i LED 3rd Gen micromotor is running. Maximum reachable speed value stored is displayed in cyan when the MX-i LED 3rd Gen micromotor is not running, in steps P1 and P2.

2 Torquemeter is only displayed when micromotor speed is below 100 RPM in steps P1 and P2.

3 The contra-angle ratio is cyan-colored for direct-drive and green-colored for reduction gears.

4 Torque bar graph is only displayed when micromotor speed is below 100 RPM.

5 Each step settings are restored from the corresponding step last used settings, excluding quick settings made directly in the Operation mode.

6 In REVERSE mode, the rotation direction symbol (rieben) blinks and there is a sound alert (alternate medium beeps). The Torque value is automatically increased in REVERSE mode when torquemeter is displayed. The torque value can be increased from 0 to 10 Ncm, see chapter see “Reverse torque boost value” on page 18 to adjust it.

7 Actions on footpedal’s buttons have no effect when the micromotor is running.

8 Changing the torque in steps P1 or P2 can only be performed through the Settings mode.

9 The torque boost can only be activated when the torquemeter is displayed in Operation mode, in low speed steps (<100 RPM).

10 For safety reasons, the speed setting icon turns red and blinks together with the speedometer for 2 seconds when switching from low speed to high speed (≥100 RPM) step.

11 Changing the speed in steps P3, P4 and P5 can only be performed through the settings mode.
8 Settings

The Settings mode allows changing all parameters of each step. It is accessed by long pressing the knob from the Operation mode and leaved by also long pressing the knob or by running the motor. All changes made in this mode are automatically saved for the corresponding step.

**Note 1**

A. From the Settings mode menu, navigate through the operation parameters by turning the knob CW or CCW.

- The selected parameter symbol (1) is encased in a cyan square and an arrow points on it.

B. If necessary, short press on the footpedal’s orange button to go to the next step without going back to the Operation mode.

- The Settings mode is still displayed, the next step symbol turns green and the step’s last used settings are restored.

C. Short press on the knob to change the selected parameter setting (setting sub-mode).

- The selected setting sub-mode is displayed.

**8.1 MX-i LED 3rd Gen micromotor speed**

A. From the Settings mode menu, select the symbol and short press on the knob to change maximum reachable speed.

**FIG. 2**

B. Turn the knob CW or CCW to respectively increase or decrease micromotor maximum reachable speed.

- The speedometer (1) displays the set maximum reachable speed.

C. Short press on the knob to exit speed setting.

- New maximum reachable speed is saved and the Settings mode menu is displayed again, FIG. 1.

**8.2 MX-i LED 3rd Gen micromotor torque**

A. From the Settings mode menu, select the symbol and short press on the knob to change maximum reachable torque.

**FIG. 3**

B. Turn the knob CW or CCW to respectively increase or decrease micromotor maximum reachable torque.

- The torquemeter (1) displays the set maximum reachable torque.

C. Short press on the knob to exit torque setting.

- New maximum reachable torque is saved and the Settings mode menu is displayed again, FIG. 1.

**8.3 MX-i LED 3rd Gen micromotor rotation direction**

A. From the Settings mode menu, select the symbol and short press on the knob to change rotation direction.

**Note 1**

B. Turn the knob CW or CCW to alternatively toggle between FORWARD (↑) and REVERSE (↓) micromotor rotation.

C. Short press on the knob to exit rotation direction setting.

- Rotation direction is saved and the Settings mode menu is displayed again.

**Note 2**
8.4 Irrigation level

A. From the Settings mode menu, select the symbol and short press on the knob to change irrigation level.

Note 1
FIG. 4
B. Turn the knob CW or CCW to set up the irrigation level (1).
6 levels of adjustment are possible:
irrigation OFF, 30ml/min, 60ml/min, 90ml/min, 120ml/min, 150ml/min.

Note 3
C. Short press on the knob to exit irrigation level setting.

Irrigation level is saved and the Settings mode menu is displayed again.

8.5 Contra-angle ratio

A. From the Settings mode menu, select the symbol and short press on the knob to change the contra-angle ratio.

B. Turn the knob CW or CCW to change the contra-angle ratio.

C. Short press on the knob to exit the contra-angle ratio setting.

The contra-angle ratio is cyan-colored for direct-drive and green-colored for reduction gears.

NOTES

1. The rotation direction and the irrigation level symbols differ depending on the actual settings.

2. The torque value is automatically increased in REVERSE mode when torquemeter is displayed. The torque value can be increased from 0 to 10 Ncm, see chapter “Reverse torque boost value” on page 18 to adjust it.

3. When setting the irrigation level to OFF, all dots (1) are displayed in black. Irrigation level is off when the irrigation is completely turned off by means of the footpedal’s blue button, regardless of the active step. In this case, the OFF symbol is displayed in Operation mode. The irrigation is considered as a quick setting and therefore is turned ON when starting again from step P1.

4. The contra-angle ratio is cyan-colored for direct-drive and green-colored for reduction gears.
9 Special modes

The special modes allow to, in the following order:
- Display software version;
- Test LCD display;
- Define number of steps (3, 4 or 5);
- Define reverse torque boost value;
- Restore factory settings.

**Note 1**
A. From the Operation mode, long press on the rotating knob to enter Settings modes.

- The Settings mode is displayed.

**FIG. 1**
B. Turn the knob CW or CCW to select the contra-angle ratio symbol (1).

- The contra-angle ratio symbol is encased in a cyan square and an arrow points on it.

**Software version**
**FIG. 2**
C. Double short press on the knob to enter special modes.

- The contra-angle ratio symbol (3) turns blue to differentiate it from the ratio change cyan symbol.
- The software version is displayed as following:
  1. Major version
  2. Minor version

**LCD display test**
**FIG. 3**
D. Short press on the knob to test LCD display.

- All dots are displayed in black, except for the contra-angle ratio symbol (1).

**Number of steps**
E. Short press on the knob to define the number of steps.

- The step number screen is displayed.

**FIG. 4**
F. Turn the knob CW or CCW to alternatively display the 3, 4 or 5 text.

- Short press on the knob to define the number of steps.

**Reverse torque boost value**
Reverse torque boost allows an automatic increase of torque value when in REVERSE mode, in order to ease bur rotation when stuck.

- Short press on the knob to define reverse torque boost value.

- The reverse torque boost screen is displayed.

**FIG. 5**
J. Turn the knob CW or CCW to respectively define 5 Ncm or 10 Ncm boost value when 5 or 10 is displayed.

**Settings reset**
**FIG. 4**
K. Short press on the knob to display factory settings reset screen.

- The factory settings reset screen is displayed.

**FIG. 6**
L. Turn the knob CW or CCW to alternatively display the reset yes or reset no text (1).

**Note 3**
M. Short press on the knob to restore factory settings when the reset yes text is displayed, or short press to go back to the Settings mode when the reset no text is displayed.

- Reset can take up to 2 seconds. Meanwhile, the symbol is displayed, and the yes text is turned off. When reset is done, the Settings mode is displayed again.
NOTES

1. Pressing the footpedal has no effect in the Special modes.

2. Go through all the special modes to display the Settings mode again.

3. The reset no text is displayed by default.
# 10 List of errors & Troubleshooting

## 10.1 Safety warning (operating)

<table>
<thead>
<tr>
<th>Warning description</th>
<th>Message</th>
<th>Cause of warning</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Release pedal</td>
<td>🚨 Release pedal</td>
<td>• Pedal is pressed when accessing settings sub-modes.</td>
<td>• Confirm setting by pressing the knob.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pedal is pressed during device startup.</td>
<td>• Release footpedal and press it again.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pedal is pressed after recovering from an error.</td>
<td>• Release footpedal and press it again.</td>
</tr>
<tr>
<td>Low to high speed step transition</td>
<td>🚨 Low to high speed step transition</td>
<td>Speedometer blinking. User switches from low speed to high speed (≥ 100 RPM) step.</td>
<td>No action needed, the warning disappears after 2 seconds.</td>
</tr>
<tr>
<td>Motor jammed</td>
<td>🚨 Motor jammed</td>
<td>Motor is jammed for more than 2 seconds. Motor power supply is cut to avoid overheating.</td>
<td>Release footpedal, release the bur and press footpedal again.</td>
</tr>
<tr>
<td>Footpedal not connected</td>
<td>🚨 Footpedal not connected</td>
<td>Pedal is not connected to device.</td>
<td>Connect pedal to the device.</td>
</tr>
<tr>
<td>Motor not connected</td>
<td>🚨 Motor not connected</td>
<td>Motor is not properly connected to device. Motor hardware is damaged.</td>
<td>1. Acknowledge error.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Reconnect the motor cable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. If problem persists, contact Bien-Air Dental SA.</td>
</tr>
</tbody>
</table>
### 10.2 Device operating error

<table>
<thead>
<tr>
<th>Error description</th>
<th>Cause of error</th>
<th>When</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ERROR 1</strong></td>
<td><strong>Motor short-circuit</strong></td>
<td></td>
<td>Replace motor and/or cable.</td>
</tr>
<tr>
<td></td>
<td>Electrical failure: short-circuit between motor phases.</td>
<td>In running mode.</td>
<td></td>
</tr>
</tbody>
</table>
| **ERROR 2**                       | **Main controller error**                                                     |                           | 1. Switch off system.  
2. Contact Bien-Air Dental SA.                                                         |
|                                   | Other fault condition detected by software.                                   | Any time.                 |                                                                                          |
| **ERROR 3**                       | **Motor driver communication timeout error**                                  | Failure of DMX controller. | 1. Switch off system.  
2. Contact Bien-Air Dental SA.                                                         |
|                                   | Failure of main controller RS-232.                                            | In running mode.          |                                                                                          |
| **ERROR 4**                       | **Invalid EEPROM memory**                                                    | Failure of EEPROM memory. | 1. Contact Bien-Air Dental SA.  
Acknowledging this error allows the operator to work normally but it will not allow settings to be saved or restored. This error will appear at each save or restoration attempt. |
|                                   | Any time.                                                                     |                           |                                                                                          |
| **ERROR 5**                       | **Motor drive over temperature**                                             |                           | 1. Wait for system cooling.  
2. If problem persists, contact Bien-Air Dental SA.                                      |
|                                   | Motor overload in a high temperature environment.                             | Any time.                 |                                                                                          |
|                                   | Failure of DMX controller.                                                    |                           |                                                                                          |
| **ERROR 6**                       | **Motor drive under voltage error**                                          |                           | 1. Acknowledge error.  
2. If problem persists, contact Bien-Air Dental SA.                                      |
|                                   | Motor overload in a high temperature environment.                             | Any time.                 |                                                                                          |
|                                   | Failure of power supply.                                                     |                           |                                                                                          |
| **ERROR 7**                       | **Motor driver over voltage error**                                          |                           | 1. Acknowledge error.  
2. If problem persists, contact Bien-Air Dental SA.                                      |
|                                   | Failure of power supply.                                                      | Any time.                 |                                                                                          |
|                                   | Tool used has a too high inertia.                                             |                           |                                                                                          |
| **ERROR 8**                       | **Irrigation pump general failure**                                          | Electrical failure: short-circuit to ground or to supply. Electrical failure: short-circuit between motor phases. | 1. Switch off system.  
2. Contact Bien-Air Dental SA.                                                         |
| **ERROR 9**                       | **Knob failure**                                                             |                           | 1. Switch off system.  
2. Contact Bien-Air Dental SA.                                                         |
11 Maintenance

⚠️ CAUTION
Only use original Bien-Air Dental maintenance products and parts or those recommended by Bien-Air Dental. Using other products or parts may cause operational failure and/or void the guarantee.

11.1 Servicing

Never disassemble the device. For any modification and repair, we recommend that you contact your regular supplier or Bien-Air Dental SA directly.

Note 1

11.2 Cleaning & disinfection

FIG. 1
- Disinfect the surfaces of the BIOPOWER unit and footpedal by gently rubbing with a clean cloth soaked in a suitable product (i.e. Bien-Air Dental Spraynet or isopropyl alcohol for about 15 sec.).
- Remove the knob (1) and sterilize it a class B autoclave at 135°C.

Note 2
- Do not immerse in disinfectant solution.
- Not designed for an ultrasonic bath.
- Use a new sterile irrigation line for each patient.
- Use a new sterile protective sheet for each patient.

11.3 Important

For maintenance: See Bien-Air Dental instructions for use
- MX-i LED 3rd Gen micromotor ..............REF 2100245
- Cable for micromotor.........................REF 2100163
- Contra-angle CA 20:1 L, light..............REF 2100209
- Contra-angle CA 20:1 L KM
- Micro-Series, light...............................REF 2100209
- Contra-angle CA 20:1 L KM
- Micro-Series, light...............................REF 2100209
- Contra-angle CA 20:1 L KM
- Micro-Series, light...............................REF 2100209
- Straight Handpiece 1:1 ......................REF 2100046
11.4 Replacement of fuses

A. Switch off the BIOPOWER unit.
B. Disconnect the mains cable.

⚠️ CAUTION
The power cable must be disconnected at least 10 seconds before opening the fusebox.

FIG. 2
C. Remove the fuse box (1) with a flat screwdriver.

FIG. 3
D. Replace the fuses (2) by the new ones and put the fuse box back (1) in place.

⚠️ CAUTION
Only use fuses T4.0AH 250 VAC REF 1307312-010.

NOTES

1. Bien-Air Dental SA recommends the user to have its dynamic instruments checked or inspected at least once a year.
2. The knob is hold magnetically. There is no need to preserve its angular position when removing it or putting it back in place.
12 General information and guarantee

12.1 General information

The device must be used by qualified professionals in compliance with the current legal provisions concerning occupational safety, health and accident prevention measures, and these instructions for use. In accordance with such requirements, the operators:

- must only use devices that are in perfect working order; in the event of irregular functioning, excessive vibration, abnormal heating or other signs that may indicate malfunction of the device, the work must be stopped immediately; in this case, contact a repair center that is approved by Bien-Air Dental SA;
- must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger.

12.2 Terms of guarantee

Bien-Air Dental SA grants the user a guarantee covering all functional defects, material or production faults.

The device is covered by this guarantee from the date of invoicing for:

- 12 months for the hose;
- 24 months for the BIOPOWER unit and CA 20:1 L Micro-Series;
- 36 months for the MX-i LED 3rd Gen micromotor.

In case of justified claim, Bien-Air Dental SA or its authorized representative will fulfill the company's obligations under this guarantee by repairing or replacing the product free of charge. Any other claims, of whatever nature, in particular in the form of a claim for damages and interest, are excluded.

Bien-Air Dental SA shall not be held responsible for damage or injury and the consequences thereof, resulting from:

- excessive wear and tear
- improper use
- non-observance of the instructions for installation, operation and maintenance
- unusual chemical, electrical or electrolytic influences
- poor connections, whether of the air, water or electricity supply.

The guarantee does not cover flexible “fiber optic” type light conductors, or any parts made of synthetic materials. The guarantee shall become null and void if the damage and its consequences are due to improper manipulation of the product, or modifications to the product carried out by persons not authorized by Bien-Air Dental SA.

Claims under the terms of the guarantee will be considered only on presentation, together with the product, of the invoice or the consignment note, on which the date of purchase, the product reference and the serial no. should be clearly indicated.
