

# Optima MCX

## ENG INSTRUCTIONS FOR USE

other languages available on [www.bienair.com/ifu](http://www.bienair.com/ifu)



0123 Rx Only  
REF 2100289-0003/2024.04

## Set Optima MCX REF 1700588-001



REF 1600959-001 (White)



REF 1600751-001



REF 1501938-001

## Set Optima MCX REF 1700589-001



REF 1600965-001 (Light Blue)



REF 1600751-001



REF 1501938-001

## Set Optima MCX REF 1700590-001



REF 1600966-001 (Pastel Orange)



REF 1600751-001



REF 1501938-001

## Set Optima MCX REF 1700591-001



REF 1600967-001 (Limetree Green)



REF 1600751-001



REF 1501938-001

## Set Optima MCX REF 1700592-001



REF 1600968-001 (Pink)



REF 1600751-001



REF 1501938-001

## Options



REF 1600036-006



REF 1501988-001

















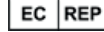


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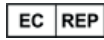


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# 1 Symbols

## 1.1 Description of symbols

Symbol	Description	Symbol	Description
	CE Marking with number of the notified body.		Non-ionizing electromagnetic radiation.
	Manufacturer.		Alternating current.
	Catalogue number.		OFF (power).
	Serial number.		ON (power).
	Medical Device.		Data Matrix code for product information including UDI (Unique Device Identification).
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Electrical safety. Type B applied part.
	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.		WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.
	Separate collection of electric and electronic equipment.		Authorized EC Representative in the European Community.
	Refer to instruction manual/booklet ( <a href="https://dental.bienair.com/fr_ch/support/download-center/">https://dental.bienair.com/fr_ch/support/download-center/</a> ).		General symbol for recovery/recyclable.

## 1.2 Description of symbols for Optima accessories

Symbol	Description	Symbol	Description
	CE Marking with number of the notified body.		Separate collection of electric and electronic equipment.
	Manufacturer.		Serial number.
	Catalogue number.		Electrical safety. Type B applied part.
	Medical Device.		Data Matrix code for product information including UDI (Unique Device Identification).
	Authorized EC Representative in the European Community.		Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.
	Sterilizable in autoclave up to the specified temperature.		

# 2 Identification, intended use and notation

## 2.1 Identification

Electronically controlled unit for dentistry allowing operation of an MCX micromotor with variable speed using the dental unit pedal.

## 2.2 Intended use

Product intended for professional use only.

The system fitted with a MCX micromotor is intended for use in general dentistry which includes restorative dentistry, dental prophylaxis and orthodontics.

The system is designed to control a dental MCX micromotor which can drive a dental handpiece (gear ratio 1:1 or 1:5) fitted with appropriate burs.

Any use other than that for which this product is intended is unauthorized and may be dangerous. The medical device meets all the current legal requirements.

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

*Note 1*

## 2.3 Intended patient population

The intended patient population of the Optima system includes any person visiting a dental practitioners' office to receive treatment in line with the intended medical condition. There is no restriction concerning subject age, race, or culture. The intended user is responsible to select the adequate device for the patient according to the specific clinical application.

## 2.4 Intended User

The Optima MCX is meant to be used only by dentists and dental professionals in dental offices.

## NOTES

**1** The technical specifications, illustrations and dimensions contained in these instructions are given only as a guide. They may not be the subject of any claim. The manufacturer reserves the right to make technical improvements to its equipment, without amending these instructions. For all additional information, please contact Bien-Air Dental SA at the address indicated on the back cover.

## 2.5 Intended medical conditions

General dentistry which includes restorative dentistry, dental prophylaxis and orthodontics.

## 2.6 Patient contra-indications and warnings


No specific patient contra-indication nor warning exist for the Optima MCX device when the device is used as intended.

## 2.7 In case of accidents

If an accident occurs, the Optima MCX must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer.

If any serious incident occurs in relation to the device, report it to a competent authority of your country, as well as the manufacturer through your regional distributor. Observe relevant national regulations for detailed procedures.

## 2.8 Notation

- **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.  
Tap ***Settings*** to open the ***Settings*** screen, change parameters and tap ***Done***.

# 3 Warnings & Precautions of Use

## **⚠ CAUTION**

According to IEC 60601-1:2005+A12012/AnnexG, electrified devices (motors, control units, couplers and attachments), can be safely used in a medical environment in which potentially explosive or flammable mixtures of anaesthetic substances are delivered to the patient only if:

1. The distance between the motor and the anaesthetic breathing circuit exceeds 25 cm.
2. The motor is not used simultaneously to the administration of the anaesthetic substances to the patient.

## **⚠ CAUTION**

To prevent any risk of electric shock, the Optima MCX unit must be connected only to a power supply network provided with a protective earth.

## **⚠ CAUTION**

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

## **⚠ CAUTION**

Ensure that the micromotor hose is not bent.

## **⚠ WARNING**

Never connect a handpiece on a running micromotor.

## **⚠ WARNING**

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

## **⚠ WARNING**

Modification of the device is forbidden.





## 4.2 Set supplied

### Optima MCX set REF 1700588-001

Designation	REF number
* CONSOLE OPTIMA MCX WHITE (1x)	1600959-001
** MOT MCX LED (1x)	1600751-001
** TRANSFORMER IOPTIMA (1x)	1501938-001
** CABLE MAINS 3 POLE EU (length 2.50 m) (1x)	1300066-001
** CABLE MAINS 3 POLE US (length 2.00 m) (1x)	1300067-001

\* The reference may vary depending on the colour set chosen.

\*\* Common to all the sets

### Optima MCX Color sets

Set	Unit REF
1700589-001 (Light Blue) - CONSOLE OPTIMA MCX BLUE	1600965-001
1700590-001 (Pastel Orange) - CONSOLE OPTIMA MCX ORANGE	1600966-001
1700591-001 (Limetree Green) - CONSOLE OPTIMA MCX GREEN	1600967-001
1700592-001 (Pink) - CONSOLE OPTIMA MCX PINK	1600968-001

## 4.3 Options

Designation	REF number
MAINT SPRAYNET (BOX 6 CANS)	1600036-006
BRACKET FOR iOPTIMA	1501988-001
SUPPORT OPTIMA MCX	1502056-001

## 4.4 Technical data

### Dimensions L x W x H

Optima MCX unit ..... 125 x 125 x 75 mm

Power Supply ..... 130 x 75 x 45 mm

### Weight

Optima MCX unit ..... 600 g

Power Supply ..... 650 g

### Electrical and pressure data

Voltage ..... 100-240 VAC

Frequency ..... 47-63 Hz

Nominal power ..... 90 W

Max input power ..... 160 W

Max. input pneumatic pressure ..... 5 bar / 72.5 psi

Min. input pneumatic pressure ..... 3 bar\* / 43.5 psi

Maximum air spray flow rate

according to ISO 14457: ..... 6 NI/min at 2.5 bar

Maximum water spray flow rate

according to ISO 14457: ..... 150 ml/min at 2.5 bar

\*Compatible with generic footpedals working within the pressure range of 3-5 bar and providing an output signal of 0-5V

### CAUTION

If the input pneumatic pressure is below the minimum threshold indicated above, the motor could not reach the setpoint speed.

**Environmental conditions**

Operating conditions	
Temperature limitation:	+10°C / +35°C
Relative humidity limitation:	30% - 80%
Air pressure limitation:	700 hPa - 1060 hPa

Storage	
Temperature limitation:	+0°C / +40°C
Relative humidity limitation:	10% - 80%
Air pressure limitation:	650 hPa - 1060 hPa

Transport	
Temperature limitation:	-20°C / + 50°C
Relative humidity limitation:	5% - 80%
Air pressure limitation:	650 hPa - 1060 hPa

**⚠ CAUTION**

Do not use Optima MCX outside the range of operating temperature.

**Classification**

Class IIa in accordance with European Regulation 2017/745 concerning medical devices.

**Electric insulation class**

Class I per IEC 60601-1 (apparatus protected against electric shocks).

**Degree of protection**

IP 40 (protection against insertion of objects larger than 1 mm).

**List of errors & Troubleshooting**

See chapter "7 List of errors & Troubleshooting" on page 17.

**Important:** Consult the Instructions for Use of the following devices:

Designation	IFU
Micromoteur MCX LED	2100231

**4.5 Performances**

Performances	
Speed accuracy	5% (in the range 1000-40000 RPM)
Light	Light ON when motor is running and for 10s after motor stops
Motor direction	CW and CCW

**4.6 Environmental protection and information for disposal**

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



This unit and its accessories must be recycled.

Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the unit 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).

## 4.7 Electromagnetic compatibility (technical description)

### **Precautions regarding Electromagnetic Compatibility (EMC)**

Electro-medical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

### 4.7.1 Electromagnetic compatibility warnings

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

#### **⚠ CAUTION**

Optima MCX 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, please 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 device, 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 as spare parts for internal components, may result in increased emissions or decreased immunity.

#### **⚠ CAUTION**

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

## 4.7.2 Electromagnetic compatibility – emissions & immunity

### Guidance and manufacturer's declaration - electromagnetic emissions

Optima MCX is intended for use in the electromagnetic environment specified below.

The customer or the user of Optima MCX should ensure that it is used in such an environment.


Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Optima MCX uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Optima MCX is suitable for use in all establishments including domestic establishments 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	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

### Guidance and manufacturer's declaration - electromagnetic immunity

Optima MCX is intended for use in the electromagnetic environment specified below.

The customer or the user of Optima MCX must ensure that it is actually used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for other lines	±2 kV for power supply lines N.A.	Mains power quality should be that of a commercial or hospital environment.
Surge IEC 61000-4-5	±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	±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	Mains power quality should be that of a commercial or hospital environment.

Immunity test	IEC 60601 test level		Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	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 cycle, at 0°		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 cycle, at 0°	Mains power quality should be that of a commercial or hospital environment. If the user of the Optima MCX requires continued operation during mains power interruptions, it is recommended that the Optima MCX be powered from an uninterruptible power supply or a battery.
Magnetic field due to mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m		30 A/m	Magnetic fields generated by the mains frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 $V_{RMS}$ 0,15 MHz – 80 MHz  6 $V_{RMS}$ in ISM bands 0,15 MHz – 80 MHz  80% AM at 1 kHz		3 $V_{RMS}$ 0,15 MHz – 80 MHz  6 $V_{RMS}$ in ISM bands 0,15 MHz – 80 MHz  80% AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> 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	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz		3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Test freq. [MHz]	Max. power [W]	Immunity test level [V/m]	Distance: 0.3 m
	385	1.8	27	
	450	2	28	
	710, 745, 780	0.2	9	
	810, 870, 930	2	28	
	1720, 1845, 1970	2	28	
	2450	2	28	
5240, 5500, 5785	0.2	9		
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%.				

a. 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 Optima MCX is used exceeds the RF compliance level mentioned above, the Optima MCX 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 Optima MCX.

## NOTES

- 1 At 80 MHz and 800 MHz, the higher frequency range applies.
- 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



FIG. 1

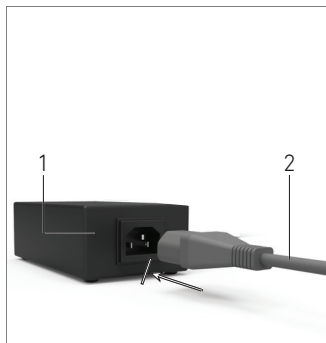


FIG. 2

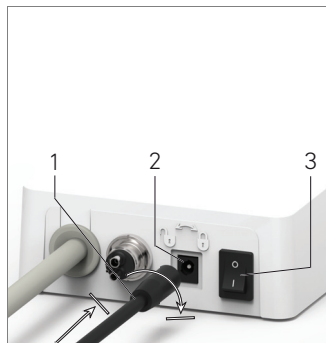


FIG. 3

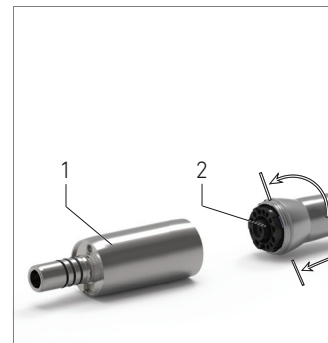


FIG. 4

## 5 Installation

### 5.1 Install the Optima MCX system

Pictogram used	
	Movement to the stop in the direction indicated.

#### ⚠ CAUTION

Before installing, please read carefully this product instruction.

#### Note 1

#### FIG. 1

**A.** Place the Optima MCX on a flat surface capable of bearing its weight.

#### ⚠ CAUTION

It may be positioned on a table, on a trolley or any another surface but in no circumstances on the floor. It is not designed to be placed on wet surfaces or to come in contact with liquids.

#### FIG. 2

**B.** Connect the power cord (2) to the power supply (1) and plug to the mains.

#### Note 2

#### FIG. 3

**C.** Connect the power supply cable (1) to the input connector (2) and turn right to lock.

#### ⚠ CAUTION

Ensure that the power switch (3) is off «0».

#### FIG. 4

**D.** Connect the MCX cable (2) to the MCX micromotor (1), by guiding the connector and plug with the index pin on the connector and tighten (CW).

#### ⚠ CAUTION

Always ensure the device is used with its proprietary accessories.



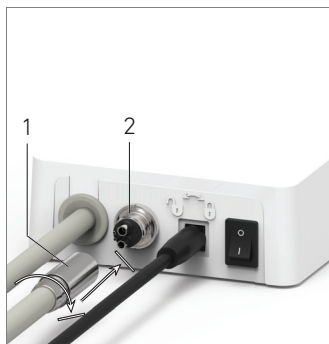


FIG. 5



FIG. 6

**FIG. 5**

**E.** Connect the 4-way hose (1) to the 4-way connector of the Optima MCX unit (2):

- First guide the sleeve and carefully and firmly insert the hose sleeve, by matching the connector and the coupling.
- Tighten (CW)

**FIG. 6**

**F.** Switch on the water and power supply of the dental unit (refer to your dental unit instructions).

**G.** Switch on the Optima MCX (1) («I» = ON).

↳ The led (2) turns green (power on).

↳ The Optima MCX is ready for use.

See chapter "6 Operation" on page 16.

**NOTES**

**1** In order to conform to the IEC 60601-1-2 standards, take into account the different routes of the wires through the system (bend, fold, section etc) (see chapter "4.1 Optima MCX system overview" on page 7) and only use the power supply provided with the Optima MCX. In order to maintain warranty, this unit must be installed with the greatest care. Follow all the necessary instructions. Protect the unit from direct sunlight and dust. Keep the original packaging for storage and shipment.

**2** The equipment is powered by your mains power supply (100-240 VAC).



FIG. 1



FIG. 2

## 6 Operation

### 6.1 MCX micromotor speed

FIG. 1

Set the maximum speed by turning the speed knob (1) CW to increase the speed.

The maximum speed can be set any value between 1000 rpm and 40000 rpm (for the 1:1 gear ratio and between 5000 rpm and 200000rpm for the 1:5 gear ratio).

The speed knob display corresponds to rotation per minute (RPM) x 1'000.

### 6.2 MCX micromotor rotation direction



Pictogram used	
	Forward (ClockWise - CW).
	Reverse (CounterClockWise - CCW).

FIG. 2

Change rotation direction by pressing the button (1).

- Pressed = Reverse (CounterClockWise - CCW)
- Unpressed (or normal status) = Forward (ClockWise - CW)

#### ⚠ CAUTION

Always check the instrument rotation direction (CW or CCW) before using it.

### 6.3 Standard Use

- Connect a handpiece.
- Set the maximum speed.
- Select the rotation direction to Forward or Reverse
- Press the dental unit pedal to start the MCX micromotor (pedal mode is progressive).

#### ⚠ CAUTION

If the footpedal is pressed before switching on the unit, the MCX micromotor will not start to run until the footpedal is released and pressed again.

#### ⚠ CAUTION

Verify that the handpiece gear ratio corresponds to one of those displayed on the speed knob.

# 7 List of errors & Troubleshooting

## 7.1 Device operating error

Error	Cause of error	Action
The motor doesn't start	The pedal is already pressed when starting the device.	Release the footpedal and press again.
	The motor is not connected.	Check motor connection. Contact Bien-Air Dental SA.
	The motor cable may be defective.	Check motor cable. Contact Bien-Air Dental SA.
	System electrical fault.	Contact Bien-Air Dental SA.
The motor stops	The motor is blocked for more than 2 seconds.	Release the footpedal and press again.
	The motor control card limits the power supplied to the motor to prevent motor overheating.	Avoid extended use.
	Overheating of motor control card (electrical control of motor).	Wait until the system cools. Contact Bien-Air Dental SA.
	System electrical fault.	Contact Bien-Air Dental SA.

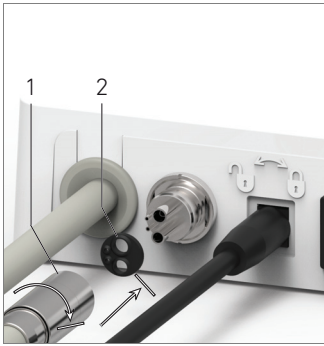


FIG. 1

## 8 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.

### 8.1 Servicing

Never disassemble the device. For any modification and repair, we recommend to contact your regular supplier or Bien-Air Dental SA directly at the address indicated on the back cover.

#### Service period

The device was tested by simulating more than 6,000 clinical procedures (corresponding to a service period of 4 to 6 years).

#### Note 1

### 8.2 Cleaning-disinfection

- Clean the surfaces of the Optima MCX unit by gently rubbing for about 15 seconds with a clean cloth soaked in a suitable product (i.e. Bien-Air Dental Spraynet or isopropyl alcohol).
- Do not immerse in disinfectant solution.
- Do not immerse in an ultrasonic bath.

### 8.3 Important

For maintenance of micromotors: see IFU

Designation	IFU
Micromoteur MCX LED	2100231

### 8.4 Replace 4VL seal

FIG. 1

### ⚠ CAUTION

Immediately replace any damaged or leaking O-rings and seals. Never use sharp tools.

- Switch off the water and the dental unit power supply.
- Switch OFF the Optima MCX unit «0».
- Unscrew and unplug the 4VL hose (1).
- Remove the damaged 4VL seal (2).
- Replace with a new 4VL seal (REF 1302403-010).

↩ Refit hose, switch ON units and water.

See chapter "5.1 Install the Optima MCX system" on page 14 for details.

## NOTES

- 1 Bien-Air Dental SA asks the user to check the relevant IFU for the dynamic devices inspection.

# 9 General information and guarantee

## 9.1 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, and must avoid contamination through the use of the product.

## 9.2 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 for:

- 12 months for the power supply
- 24 months for the Optima MCX unit
- 36 months for series MCX LED electric micromotors.

from the date of invoicing.

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 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.



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