

Optima MCX

ENG Instructions for use

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CE
0120 Rx Only

REF 2100289-0000/2015.02

Set Optima MCX REF 1700588-001



REF 1600959-001 (White)



REF 1600751-001



REF 1501938-001

Options



REF 1600036-006

Set Optima MCX REF 1700589-001



REF 1600965-001 (Light Blue)



REF 1600751-001



REF 1501938-001



REF 1501988-001

Set Optima MCX REF 1700590-001



REF 1600966-001 (Pastel Orange)



REF 1600751-001



REF 1501938-001



REF 1502056-001

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

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1 Symbols

1.1 Description of symbols

Symbol	Description	Symbol	Description
	CE Marking with number of the notified body.		Alternate current.
	Manufacturer.		Electrical security. Applied part type B.
	Reference number.		Main switch - Power OFF.
	Serial number.		Main switch - Power ON.
Rx Only	CAUTION! In accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Move fully to the stop, in the direction indicated.
	Recyclable electrical and electronic materials.		4-hole connection and 4 electric (4VLM).
	Refer to the accompanying documents.		4-hole connection (4way).
	Recyclable materials.		Forward (ClockWise).
	CAUTION! Consult accompanying documents. Provides an instruction that should be observed for safety reasons.		Reverse (CounterClockWise).
	Interference may occur in the vicinity of equipment marked with this symbol.		

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 is intended for use in general dentistry and restorative dentistry by dentists and dental professionals in a dental office.

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.

Note 1

2.3 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.

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.

3 Warnings & Precautions of Use

CAUTION

This unit is not designed for use in an explosive atmosphere (anesthetic gas).

CAUTION

To prevent any risk of electric shock, this 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

Never connect a handpiece on a running micromotor.

CAUTION

Ensure that the MCX micromotor hose is not bent.

CAUTION

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

CAUTION

Modification of the device is forbidden.

4 Description

4.1 Optima MCX system overview

The Optima MCX connections (cables and hoses) consist of:

- Micromotor MCX hose (A);
- A pneumatic 4-way connection input (B);
- A power supply and plug cord (C).

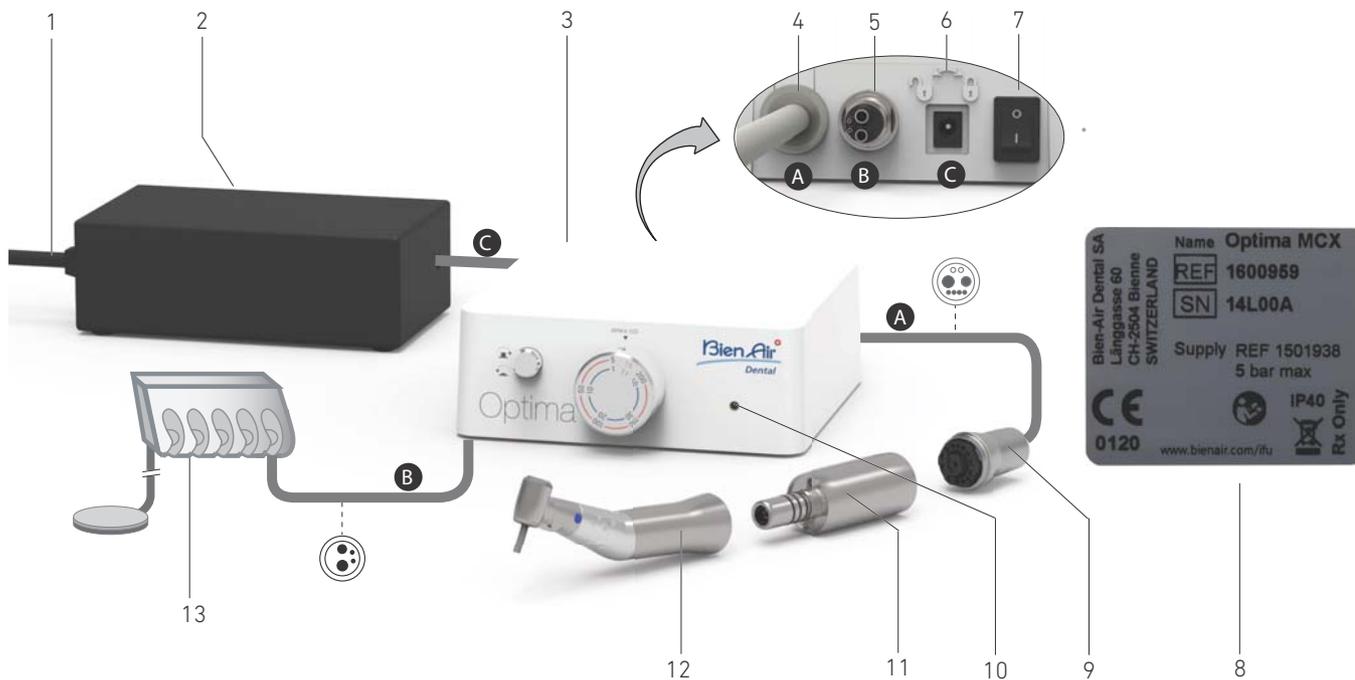


FIG. 1

- | | |
|---|---|
| <ul style="list-style-type: none"> (1) Power supply cord (2) Power Supply and plug cord (C) (3) Optima MCX unit (4) Micromotor MCX hose output (A) (5) 4-way connector input, air and water inlet from your pneumatic unit (B) (6) Power input connector (with lock) (C) (7) Main power switch | <ul style="list-style-type: none"> (8) Label (under the unit) (9) Micromotor MCX connector (A) (10) Optima MCX status light (green power on) (11) MCX micromotor* (12) Handpiece* [not provided in set] (13) Dental unit with pedal (B) [not provided in set] |
|---|---|

*Applied parts (per IEC 60601-1)

4.2 Set supplied

Optima MCX set REF 1700588-001

Designation	REF number
Optima MCX unit (1x)	1600959-001
*MCX Micromotor LED (1x)	1600751-001
*Power supply (1x)	1501938-001
*3P cable system, Europe, length 2.50 m (1x)	1300066-001
*3P cable system, US/Asia, length 2.00 m (1x)	1300067-001

* Common to all the sets

Optima MCX Color sets

Set	Unit REF
1700589-001 (Light Blue)	1600965-001
1700590-001 (Pastel Orange)	1600966-001
1700591-001 (Limetree Green)	1600967-001
1700592-001 (Pink)	1600968-001

4.3 Options

Designation	REF number
Spraynet, cleaning spray 500 ml, box of 6 cans	1600036-006
iOptima/Optima support bracket for for installation beside the dental unit	1501988-001
iOptima/Optima support bracket for installation under the dental unit	1502056-001

4.4 Technical data

Dimensions L x W x H

Optima MCX unit	125 x 145 x 75 mm
Micromotor MCX hose.....	L 1.66 m
MCX micromotor (including nose).....	∅ 21 x L 64 mm
Power Supply	130 x 75 x 45 mm

Weight

Optima MCX unit.....	600 g
Power Supply	650 g
MCX micromotor.....	76 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 / 43.5 psi
Min. input pneumatic pressure	3 bar / 40.6 psi

⚠ CAUTION

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

Environmental conditions

Environmental conditions	Operating	Transport and storage (max. 15 weeks)
Temperature	+10°C (50°F) to +25°C (77°F)	-25°C (-13°F) to +70°C (158°F)
Relative humidity	30% to 80%	10% to 100%
Atmospheric pressure	700 hPa to 1060 hPa	500 hPa to 1060 hPa
Altitude	0 to 3'048 m (0 to 10'000 ft)	-

⚠ CAUTION

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

Classification

Class IIa in accordance with European Directive 93/42/EEC 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 15.

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

Micromotor MCX LEDSee doc. REF 2100231

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.



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).

4.6 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.

⚠ CAUTION

Dental professionals need to be aware of potential electromagnetic interference between electronic dental devices and active implantable medical devices, and should always inquire about any devices implanted in the patient.

⚠ CAUTION

Optima MCX complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc. shall not be used in close proximity to the unit since they could influence the performance of the unit. Special precautions must be taken when using strong emission sources such as High Frequency surgical equipment and similar equipment so that the HF cables are not routed on or near the unit. If in doubt, please contact a qualified technician or Bien-Air Dental SA. Optima MCX should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, Optima MCX should be monitored to verify normal operation in the configuration in which it will be used.

⚠ 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 replacements parts for internal components, may result in increased emissions or decreased immunity of Optima MCX.

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. CISPR 11 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	Compliant	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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 lines no input/output	±2 kV for power supply lines ±1 kV for lines no input/output	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and outages IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of Optima MCX requires continued operation during power mains interruptions, it is recommended that Optima MCX be powered from an uninterruptible power supply or a battery.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<p>Note : U_T is the a.c. mains voltage prior to application of the test level.</p> <p>Essential performance: The essential performance is the maintaining of the visual lighting intensity of the LED and the maintaining of motor speed. Maximum allowed speed deviation is $\pm 5\%$.</p>			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of Optima MCX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> $d = 1.2\sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = 1.2\sqrt{P}$ $d = 2.3\sqrt{P}$ <p>800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol: </p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast 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 applicable RF compliance level above, the Optima MCX should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Optima MCX.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note 1 - 2

Recommended separation distances between portable and mobile RF communications equipment and the Optima MCX

The Optima MCX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Optima MCX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Optima MCX as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 - 2

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

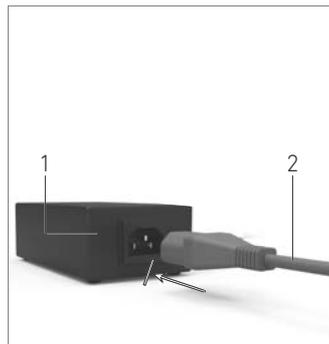


FIG. 2

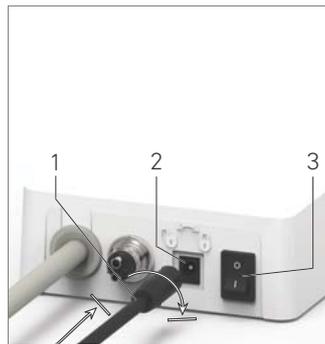


FIG. 3

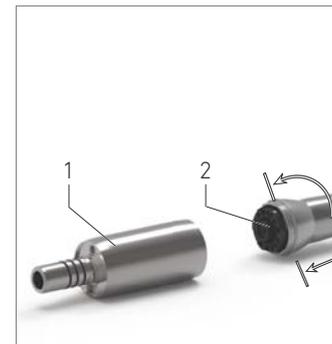


FIG. 4

5 Installation

5.1 Install the Optima MCX system

⚠ 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

⚠ CAUTION

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

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

Never connect a handpiece on a running micromotor.

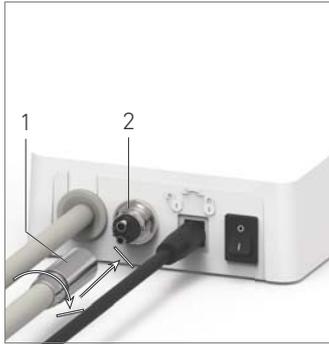


FIG. 5



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 14.

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 5) 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

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 representatives.
	The motor cable may be defective.	Check motor cable. Contact Bien-Air Dental representatives.
	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.

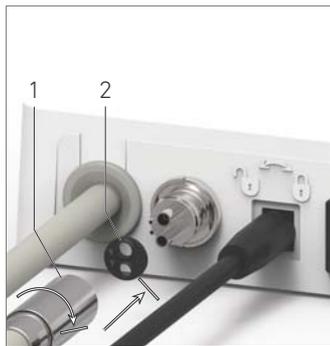


FIG. 1

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.

Note 1

8.2 Cleaning-disinfection

- Disinfect the surfaces of the Optima MCX unit and Micromotor MCX hose 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.) or with a disinfecting disposable wipe recommended for dental or surgical instruments.
- Products containing acetone, chlorine and bleaches are not recommended as disinfectants. To keep the surface of the hose in good condition, it is advisable to periodically wipe the complete length of it with a cloth dusted with talcum powder.
- Do not immerse in disinfectant solution.
- Do not immerse in an ultrasonic bath.

8.3 Important

For maintenance see instructions:

- Micromotor MCX LED (REF 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 «O».
- 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 12 for details.

NOTES

- 1** Bien-Air Dental SA recommends the user to have its dynamic instruments regularly checked or inspected.

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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