

Micromotors MX-i LED MX-i

Instruction

REF 2100245-0004/2014.05/ENG



CE
0120

English

Medical devices entirely made in Switzerland by Bien-Air Dental SA.

Type

Direct current electric brushless micromotor, self-ventilated, sterilisable.

Description MX-i LED with LED.

Description MX-i without light.

⚠ Important

This motor must only be used with Bien-Air Dental cable and electronic controls. Otherwise, performance or safety can not be guaranteed. Never mount an instrument on a rotating motor.

Intended use

Product intended for professional use only. Use in dentistry for implantology, dental surgery and endodontic work. The device is not designed for use in an explosive atmosphere (anaesthetic gas).

Technical data

Classification

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

Coupling

Nose in accordance with ISO 3964, without internal spray, with light.

Dimensions MX-i LED

Ø 23.2 x 90.9 mm, incl. the nose.
Ø 23.2 x 68.7 mm, without the nose.

Dimensions MX-i

Ø 23.2 x 100.4 mm, incl. the nose.
Ø 23.2 x 68.7 mm, without the nose.

Cooling

Self-ventilated.

Weight

119 g (without cable).

Rphase

300 mOhm (one phase), Y-connection.

Lphase

25 µH (one phase).

Torque constant

0.62 N.cm / A.ms.

⚠ Important

Actual performances and safety are dependent on the type of electronic supply used.

Assembly

⚠ Important

Never connect an instrument on a running micromotor.

Junction

Only with a REF 1600606-001 power cable. Check that the rear of the motor and the cable connector are clean. Position the motor as shown in **fig. 1**. Rotate it to find the exact position and push in connector **fig. 2A**. Tighten the nut to the limit stop **fig. 2B**.

Changing the seals, **fig. 3**

Performances with iChiropro

Electromagnetic compatibility and safety

Complies with the ISO 11498 (dental handpieces – Low voltage electric dental motors). The device must be classed as a class II and B type unit. The corresponding terminology is defined in sections 3.14 (3.13 if Class I) & 3.132 of the IEC 60601-1 (Medical electrical equipment – Part 1: General requirements for basic safety and key performances).

Rotation speed

From 100 to 40,000 rpm $\pm 5\%$, clockwise and anti-clockwise.

Mechanical power

Max 140 W $\pm 5\%$ at 25,000 rpm.

Torque

Max. 5.0 Ncm between 200 and 25,000 rpm (limited electronically). Max. 2.0 Ncm at 40,000 rpm.

Idle current

0.26 A.

Max. admissible current

8 A (at peak).

Noise level

Less than 60 dBA at 45 cm.

Luminous intensity MX-i LED

REF 1600755-001


Greater than 12 klux with CA 20:1 L.

Operating times

Max. continuous duration not exceeding 40°C/104°F on exterior of motor (ambient temperature 20°C/68°F):

- 5 min. low charge (40,000 rpm, 0.8 N.cm), followed by 40 min. cooling
- 40 s medium charge (20,000 A, 2 N.cm)
- 10 s high charge (1000 A, 4 N.cm).

Disposal

 This device must be recycled. 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).

Maintenance

⚠ Important

- The instrument is delivered "non sterile".
- Before using for the first time and within a maximum of 30 minutes after each treatment, clean, disinfect the attachment, then sterilise. Observing this procedure eliminates any blood, saliva or saline solution residues.
- Do not immerse in an ultrasonic bath.
- 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.

In the event of prolonged disuse, the instrument must be stored in a dry environment. Clean and sterilise the instrument before reuse.

Installation

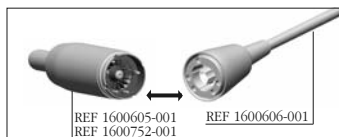


fig. 1

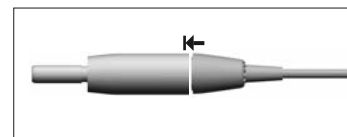


fig. 2A

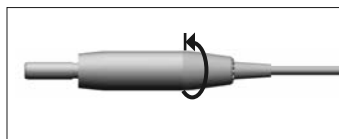


fig. 2B



fig. 3

Cleaning Instructions

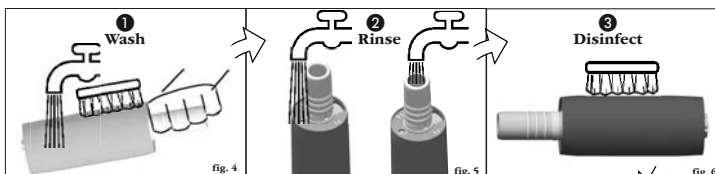


fig. 4

fig. 5

fig. 6



fig. 9

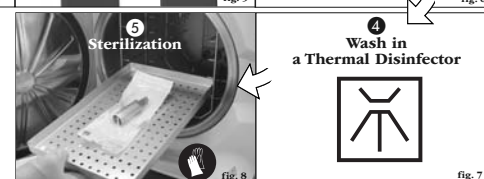


fig. 8

fig. 7

Precautions of use

The standard precautions in particular wearing individual protection equipment (gloves, glasses...), must be complied with by healthcare personnel working with contaminated or potentially contaminated medical instruments. Pointed and sharp instruments should be handled with great caution.

Check that the steriliser and the water that is used are clean. After each sterilisation cycle, remove the device from the sterilising apparatus immediately, in order to reduce the risk of corrosion. We recommend that the motor is cleaned and sterilised as described below before the initial first use and subsequently after each treatment.

1 Cleaning

The external surface of the motor must be cleaned to remove impurities as follows **fig. 4**.

- Hold the motor by the nose under running water ($< 38^{\circ}\text{C}$) as shown in the diagram below
- With the aid of a soft bristled brush, clean the external surface of the motor.

2 Rinsing

Rinse the exterior and interior of the motor nose under running water for 10 seconds. ($< 38^{\circ}\text{C}$) **fig. 5**.

3 Disinfection

- Carefully rub the external surfaces of the motor, for approximately one minute, with a soft bristle brush impregnated with a detergent or disinfectant solution **fig. 6**.
- Rinse the exterior of the motor under running water ($< 38^{\circ}\text{C}$).

Suitable detergents

- Detergent or detergent-disinfectant (pH 6-9.5) recommended for cleaning-disinfection of dental or surgical instruments.
- Quaternary ammonium- and/or enzyme-based surfactants.
- Do not use solutions that are corrosive or contain chlorine, acetone aldehydes or bleaches.
- Do not soak in physiological liquid (NaCl).

4 Automatic cleaning-disinfection

⚠ Note:
only for instruments engraved with  **fig. 7**.

Cleaner - disinfectant

Use a validated cleaner-disinfectant with the adequate detergent.

Washing cycle

Select the specified washing cycle for these instruments which should be compatible with the detergent manufacturer's instructions.

Recommended temperatures for the attachments:

Pre-wash

Water: cold to maximum 35°C (95°F) – Duration 2 mins.

Wash

Water: 50 to 65°C (122 to 149°F) – Duration 5 mins.

Rinsing

Water: cold to maximum 35°C (95°F) – Duration 2 mins.

Thermal disinfection

Water: 80 to 97°C (176 to 206.6°F) – Duration 5 mins.

Drying

Air: 65 to 75°C (149 to 167°F) – Duration 25 mins.

⚠ Note: Never rinse the devices to cool them.

5 Sterilisation

Do not use a sterilisation procedure other than the one described below.

Procedure:

Fractionated pre-vacuum steam sterilisation, Class B cycle acc. to EN13060. The procedure has been validated according to ISO 17664. All Bien-Air Dental straight handpieces are sterilisable in an autoclave up to 135°C (273.2°F). Duration: 3 or 18 min., depending to the national requirements in force.

Important

The quality of the sterilisation depends very much on the cleanliness of the device. Only perfectly clean devices may be sterilised **fig. 8**.

The instrument will function in excess of 500 sterilisations.

6 Lubrication

⚠ Important

The Bien-Air Dental motor MX-i LED/MX-i is maintenance free. Do not spray any lubricant or cleaning solution into the motor fig. 9!

Servicing

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

Bien-Air Dental asks the user to have its dynamic instruments checked or inspected at least once a year.

Transportation and storage conditions

Temperature between -40°C (-40°F) and 70°C (158°F), relative humidity between 10% and 100%, atmospheric pressure 50 kPa to 106 kPa (7.3 to 15.3 psi).

Information

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.

Other precautions for use

The device must be used by a qualified professional in compliance with the current legal provisions concerning workplace safety, health and accident prevention measures, and these working instructions. In accordance with these requirements, the operators:

- must only use operating devices that are in perfect working order; in the event of irregular functioning, excessive vibration, abnormal heating or other signs indicating malfunction of the device, the work must be stopped immediately; in this case, contact a repair centre that is approved by Bien-Air Dental;
- 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.

Rest the device on a suitable support to avoid risks of infection for yourself, the patient or third parties.

- To ensure the lifetime of the instrument, it is essential to maintain the quality of the cooling air and water utilised.

The compressed air should be dry and purified and the compressor should be regularly maintained.

To avoid the tubing and connectors from blocking, the water should be filtered and purified to avoid impurities and build-up of high levels of calcium deposits.

Guarantee

Terms of guarantee

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

The device is covered by this guarantee for 36 months from the date of invoicing.

In the event of justified claim, Bien-Air Dental or its authorised representative will fulfil 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 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 "fibre optic" type 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 authorised by Bien-Air Dental.

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.

List of Bien-Air Dental SA registered trade mark products ©:

Aquilon®	Eolia®	Lubrifiuid®	Prestilina®
Bora®	Gyro®	Lubrimed®	Spraynet®
Boralina®	Gyrolina®	MX®	
ChiroPro®	Isolite®	PowerCare®	

In these instructions, "Device" corresponds to the product described in the heading "Identification". For example, turbine, contra-angle, handpiece, micromotor, tube, electronics, connectors, station etc.

REF	Legend
1600755-001	MX-i LED micromotor with LED, sterilisable
1600825-001	MX-i micromotor without light, sterilisable
1600606-001	Cable for MX-i LED and MX-i micromotors, sterilisable
1300967-010	O-Ring for MX-i LED and MX-i micromotors

Symbols

	Manufacturer.
	CE Marking with number of the notified body.
	Electrical security. Applied part type B.
	Attention.
	Light.
	Wear rubber gloves.
	Sterilisable at the specified temperature.
	Machine washable.
	Recyclable electrical and electronic materials.
	Move in the direction indicated.
	Move fully to the stop, in the direction indicated.

This product may be covered by one or more of the following patents:

EP Europe: 745358 / 688539 / 948294 / 1145688 / 1563800 / 1563801 / 1675523 / 1753360 **DE Germany:** 29616023.7

DK Denmark: 9600315 **FR France:** 2722972 **CH Switzerland:** 693922 **CN China:** 100528099 / 100522100 / 100522099 /

100553584 **JP Japan:** 3892485 / 4298933 / 7000419 **US United-States:** 5453008 / 6033220 / 6319003 / 7214060 / 7448870

RU Russia: 2361540 / 2361541 / 2372046

REF 1600755-001 MOT MX-i LED / REF 1600825-001 MOT MX-i

Set supplied

MX-i LED



REF 1600755-001

MX-i



REF 1600825-001

Optional accessories



REF 1600606-001



REF 1300967-010



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