MC3 LED, LK & IR



Only removable sleeve is sterilisable

Instruction

REF 2100195-0002/2014.05/ENG

English

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

Identification

MC3 LED, LK and IR dental electric micromotors with brushes. Sterilisable removable sleeve. Hardwearing. Protected from oil coming from handpieces; suitable for low speeds. Interchangeable

MC3 LED:

Version with light (LED), internal spray. MC3 LK:

Version with light (bulb), internal spray.

MC3 IR:

Version without light, internal spray.

Intended use

Product intended for professional use only. Use in dentistry for prophylaxis, general dentistry and endodontic work

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

Any use other than that for which this device is intended is prohibited and may prove dangerous.

Technical data and assembly

Classification

Class IIa in accordance with European Directive 93/42/EEC concerning medical devices. This medical device is in compliance with the legislation in

Coupling

The most commonly used coupling in the world as per ISO Standard 3964, with the handpiece retain-

MC3 LED & LK:

Version connector internal spray and light.

Version connector internal spray, without light.

Dimensions

Ø 21 x 94.3 mm

Weight

 $100 \mathrm{g}$

Speed

Maximum 40,000 rpm.

Recommanded rotation speed

60 rpm up to 40,000 rpm $\pm 10\%$; rotation in both directions.

Nominal voltage

In accordance with ISO 11498: 0 – 24 Vdc

Internal resistance

 $2.5 \pm 25\% \Omega$

Noise

In accordance with ISO 11498, less than 55 dBA at 45 cm (17.72 in).

Idle current

0.3 A - 24 Vdc

Current at max. power



Maximum 2.8 Ncm

Intermittent operation

2.8 A for 90 seconds; 3.7 A for 60 seconds; air cooling in 6 min.

Continuous operation

1.3 A approx. 0.7 Ncm.

3.5 V; 0.75 A

variable from 2.5 to 4.0 Vdc, 0.1 to 0.5 A, 15-38 klux.

The performance of the micromotor varies, depending on the type of electronic power supply used. We recommend that you use Bien-Air Dental electronic control units for optimum micromotor performance.

Electromagnetic compatibility

Corresponds to the electromagnetic compatibility in accordance with IEC 60601-1-2.

Declaration by the manufacturer regarding electromagnetic compatibility: refer to the tables on pages 2-3.

Electrical safety

According to IEC 60601-1 standard (General safety for Medical Electrical Equipement), the device shall be classified as a class II type B device.

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.

Assembly

Connecting the hose.

Connection recommended using 4VLM or 4VR400 Bien-Air Dental hoses.

Remove the turbine adaptor sleeve from the hose fig. 2a. Remove the sleeve from the motor fig. 2b. Check the rear of the motor and the joint on the hose are clean. Line up the connection components on the motor with those of the plug and insert until stop position fig. 2c. Fully tighten tube retainer fig 3a. Replace sleeve fig 3b.

Via compressed air from the unit. Place the flowmeter on the connector and set 10 normliter/min. fig. 1.

⚠ Important

Liquid or spray must not be allowed to penetrate inside the micromotor, due to risk of irreversible dam-

Never connect an instrument with a micromotor that is running.

Changing the bulb

MC3 LK: **fig 4**.

Box of 5 bulbs. Wear rubber gloves when carrying out this changing operation.



REF 1300097-001

REF 1500037-010

fig. 7

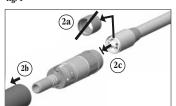
fig. 8

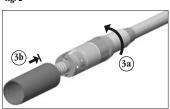
fig. 5

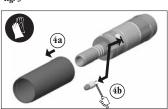
REF 1300105-001 REF 011.75.46-001

REF 1300132-010

fig. 1







Changing the LED

MC3 LED: The LED must only be changed by a Bien-Air Dental-approved repair centre.

Changing the carbon brushes

Attention: Precision work. Keep the carbon brushes dry and never let them come into contact with lubricant, as otherwise they may be irreversibly damaged. To remove the 2 carbon brushes, follow the procedure shown in figs 5-7. Blow dry, clean air across the apertures at the rear of the body of the motor. To reassemble, proceed in the reverse order.

Seals replacement

- To change the o-rings REF 1300145-010/011.35.28-010, **fig. 8**.
- To change the flat seal REF 1300155-010/011.75.87-010, fig. 9. Remove seal, place it on the tubes and remount the attachment, fig. 2-3
- To change the o-rings REF 1300132-010/705.02.66-010, fig. 6.

Disposal

This device must to 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/

REF 1300145-010

REF 011.35.28-010

REF 1300155-010

REF 011.75.87-010

Maintenance

⚠ Important

Never lubricate the electric brush motor.

Only use maintenance products and components from Bien-Air Dental. The use of other products and components can void the guarantee.

Precautions for maintenance:

The universal precautions, in particular wearing of personal protective equipment (gloves, goggles, etc.), should be complied with by medical personnel using or performing maintenance on medical devices that are contaminated or potentially contam-

Pointed and sharp instruments should be handled with great caution.

Check that the steriliser and the water that is used are clean.

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After each sterilisation cycle, remove the device from the sterilising apparatus immediately, in order to reduce the risk of corrosion.

Suitable detergent

For manual cleaning-disinfection:

- 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 detergents that are corrosive or contain chlorine, acetone aldehydes or bleaches.
- 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

Manual cleaning/disinfection only

Attention :

Electric motors with brushes are not suitable for automatic cleaning/disinfection (in a washer/disin-

Clean and disinfect using a clean cloth soaked in a suitable product.

- · Never immerse in disinfectant solutions.
- Do not soak in physiological liquid (NaCl).
- Do not immerse in an ultrasonic bath.

Sleeve sterilisation

1 Only for motors with removable sleeve fig. 4.

Conditioning process

Wrap the removable sleeve in approved packaging for steam sterilisation

Important

The quality of the sterilisation depend very much on the cleanliness of the device. Only perfectly clean devices may be sterilised.

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.

Overhaul

Never disassemble the device. For any 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

Transport 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).

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 opera-

- · 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.

It is essential to use dry, purified compressed air in order to ensure the long working life of the device.

Maintain the quality of the air and the water by regular maintenance of the compressor and the filtration systems. The use of unfiltered hard water will lead to early blockage of the tubes, connectors and spray cones.

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 18 months from the date of invoicing.

Bien-Air Dental offers a 24-month guarantee for the glass-bar light conductors.

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

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.

EMC Precautions

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the user's manual. Essential performance was defined as the maintaining of the visual lightning intensity when powered at 3.5VDC.

Use of MC3

Attention:

The MC3 should not be used adjacent or stacked with other equipment. If adjacent or stacked use is necessary, the MC3 should be observed to verify normal operation in the configuration in which it will be used.

Attention:

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Bien-Air as replacements parts for internal components, may result in increased emissions or decreased immunity of the MC3.

3. Radio Transmitting Equipment Attention :

The MC3 motors comply with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc. shall not be used in the close proximity of the device since this could influence the performance of the device. Particular precaution must be considered during use of strong emission sources such as High Frequency surgical equipment and similar so that e.g. the HF cables are not routed on or near the device. If in doubt, please contact a qualified technician or Bien-Air Dental.

Guidance and manufacturer's declaration - electromagnetic emissions

The MC3 motors are intended for use in the electromagnetic environment specified below. The customer or the user of the MC3 motor should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions	•	The MC3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any
CISPR 11	Group 1	interference in nearby electronic equipment.
RF emissions		
CISPR 11	Class B	The MC3 is suitable for use in all establishments, including domestic establishments and those directly connected to the public
Harmonic emissions	Not applicable	low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2	Not applicable	
Voltage	Not applicable	
fluctuations/flicker emissions		
IEC 61000-3-3		

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Guidance and manufacturer's declaration - electromagnetic immunity

The MC3 motors are intended for use in the electromagnetic environment specified below. The customer or the user of the MC3 motor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2 Electrical fast transient/burst IEC 61000-4-4	±2 kV contact ±4 kV contact ±6 kV contact ±2 kV air ±4 kV air ±8 kV air ±2 kV for power supply lines ±1 kV for input/output lines	±2 kV contact ±4 kV contact ±6 kV contact ±2 kV air ±4 kV air ±8 kV air Not applicable	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Not applicable
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	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>U</i> T (>95 % dip in <i>U</i> T) for 0,5 cycle 40 % <i>U</i> T (60 % dip in <i>U</i> T) for 5 cycles 70 % <i>U</i> T (30 % dip in <i>U</i> T) for 25 cycles <5 % <i>U</i> T (>95 % dip in <i>U</i> T) for 5 sec	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A√m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical industrial location or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The MC3 motors are intended for use in the electromagnetic environment specified below. The customer or the user of the MC3 motors should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
		•	Portable and mobile RF communications equipment should be used no closer to any part of the MC3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommende separation distance	
Conducted RF IEC 61000-4-6	3 Vrms	10 V	$d = \left[\frac{3.5}{F_1}\right]\sqrt{P}$ 80 MHz to 800 MHz	
	150 kHz to 80 MHz	10 V	$d = \left[\frac{3.5}{E_1}\right]^{TP}$ $d = \left[\frac{7}{E_1}\right]^{TP}$ 800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]^{TP}$	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the tramitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, * sho be less than the compliance level in each frequency range. $^{\rm b}$	
			Interference may occur in the vicinity of equipment marked with the following symbol: ((***))	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and the MC3

The MC3 motors are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MC3 motors can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MC3 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter	Separation distance according to frequency of transmitter m			
W	$150 \text{ kHz to } 80 \text{ MHz}$ $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$	
0.01	0.035	0.035	0.07	
0.1	0.11	0.11	0.22	
1	0.35	0.35	0.7	
10	1.1	1.1	2.2	
100	3.5	3.5	7	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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^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 MC3 is used exceeds the applicable RF compliance level above, the motor MC3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MC3 motor.

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

Symbols



Manufacturer.



CE Marking with number of the notified body.



Attention.



Recyclable electrical and electronic material.



Wear rubber gloves





Sterilisable at the specified temperature.



Light.

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:

 $\textbf{EP Europe}: 745358 \,/\, 688539 \,/\, 948294 \,/\, 1145688 \,/\, 1563800 \,/\, 1563801 \,/\, 1675523 \,/\, 1753360$

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 1600680-001 MOT MC3 LED / REF 1600077-001 MOT MC3 LK / REF 1600071-001 MOT MC3 IR

REF Legend MC3 LED micromotor with internal spray and light 1600680-001 with LED 1600077-001 MC3 LK micromotor with internal spray and light with bulb MC3 IR micromotor with internal spray, without light 1600071-001 1500037-010/211.75.08-010 Carbon brushes 1300132-010/705.02.66-010 0-Ring 1300145-010/011.35.28-010 0-Ring 1300155-010/011.75.87-010 Flat seal 1300148-001/011.75.43-001 Sleeve MC3 LK, IR 1300105-001/011.75.46-001 Protective sleeve 1300097-001/011.75.37-001 Rear sleeve 1500007-005 Pack of 5 bulbs, for micromotors 1600307-001 Flow-meter for micromotors MC3 1600097-001 Hose 4VLM Grey, fixed connector, with air flow return 1600102-001 Hose 4VLM Grey, fixed connector without air flow return 1600098-001 Hose 4VLM Black, fixed connector with air flow return 1600103-001 Hose 4VLM Black, fixed connector without air flow return Hose 4VR Grey, Rotating connector, with air flow return 1600397-001 1600398-001 Hose 4VR Grey, Rotating connector, quick connector unit side, with air flow return

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

Aquilon®	Gyrolina®
Bora [®]	Isolite®
Boralina®	Lubrifluid®
ChiroPro®	Lubrimed®
Eolia [®]	MX®
Gyro®	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.

Set supplied







REF 1600077-001



REF 1600071-001

Optional accessories



REF 1300097-001 REF 011.75.37-001



REF 1300145-010 REF 011.35.28-010



REF 1300105-001



REF 1300155-010





REF 1300132-010 REF 705.02.66-010



REF 211.75.08-010

REF 1500037-010



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