

MICROMOTORS MC2:

- · ISOLITE LK
- · ISOLITE LED
- · MC2 IR

riangle Only the removable sleeve can be sterilized / Do not Lubricate



ENG INSTRUCTIONS FOR USE.

Other languages available on https://dental.bienair.com/IFU



Packaging content (REF)



MOT ISOLITE LED REF 1600681-001



MOT ISOLITE LK REF 1600078-001



MOT MC2 IR REF 1600073-001

Optional accessories



BULB MOT

0-RING 8.1x0.73 REF 1500007-005 REF 1300967-010



BACK COVER WITH RING LK REF 211.60.18-001 Compatible with MOT ISOLITE LK



COVER MC2 LK LED REF 1501368-001 MOT ISOLITE LED



MAINT SPRAYNET® (BOX OF 6 CANS) REF 1600036-006



FLOWMETER REF 1600307-001



HOSE ISOLITE/MC2 COILED BLACK REF 1600315-001



HOSE ISOLITE/MC2 GREY REF 1600120-001



HOSE ISOLITE WATER ADJ GREY REF 1600134-001



HOSE ISOLITE SWIVEL GREY REF 1600132-001



HOSE ISOLITE/MC2 SWIVEL GREY REF 1600298-001

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ENG INSTRUCTIONS FOR USE

1 Symbols

1.1 Description of symbols used

Symbol			
•••	Manufacturer.	REF	Catalogue number.
CE 0123	CE Marking with number of the notified body.	SN	Serial number.
<u> </u>	WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.	MD	Medical device.
<u> </u>	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.	EC REP	Authorized EC Representative in the European Community.
•	Wear protective gloves.	Ö.	Lamp; lighting, illumination.
×	Temperature limit.	135°C ∭	Sterilizable in a steam sterilizer (autoclave) at the specified temperature.
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited prac- titioner.	(i)	Consult instructions for use or consult electronic instructions for use.
	Data Matrix code for product information including UDI (Unique Device Identification).	X	Recyclable electrical and electronic material.
"	Humidity limitation.		Atmospheric pressure limitation.
*	Keep away from rain.		General symbol for recovery/recyclable.

2 Identification & Intended Use

2.1 Identification

Medical devices manufactured by Bien-Air Dental SA.

Type:

Electric dental micromotor with internal spray and brushes. Non-sterilizable, protected from the oil of the handpieces. Removable, sterilizable sleeve.

MOT ISOLITE LK

Version with light bulb

MOT ISOLITE LED

Version with LED light

MOT MC2 IR

Version whitout light

Note: MC2 nomination includes MOT ISOLITE LK & MOT ISOLITE I FD

Description:

Bien-Air Dental micromotors are designed to transform electricity into mechanic rotation to drive dental straight handpieces and contra-angles.

2.2 Intended use

Product intended for use in general dentistry which includes restorative dentistry, dental prophylaxis and orthodontics treatments.

2.3 Intended patient population

The intended patient population for the device 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

Product intended for professional use only. Used by dentists and dental professionals.

2.5 Use Environment

Professional healthcare facility environment.

2.6 Intended medical conditions

General dentistry which includes restorative dentistry, dental prophylaxis, orthodontics and addresses the maintenance or reestablishment of dental health

2.7 Patient contra-indications and side effects

No specific patient contra indication, side effects nor warnings exist for the device when it is used as intended.

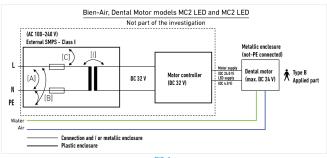
2.8 In case of accident

If an accident occurs, the device must not be used until repairs have been completed by a qualified, authorized and trained technician in a repair center.

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.

/ WARNING

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



Number of Mean of Protection required :

FIG. 1

[A] 1MOPP

[B] 1MOPP

[C] 2MOPP

[I] 2MOPP

Insulation diagram corresponding to the recommended installation of the motor in the dental unit.

3 User and Patient Safety: Warnings and Precautions for use

Este dispositivo médico deve ser utilizado por profissionais em conformidade com as disposições legais em vigor em matéria de segurança, saúde e prevenção de acidentes de trabalho, bem como com as presentes instrucões de utilização.

Em conformidade com estas disposições, o utilizador é responsável por garantir que só utiliza dispositivos que estejam em perfeito estado de funcionamento.

Electrical safety:

♠ WARNING

Electrical safety can only be claimed when the device is used according to the insulation diagram above. FIG. 1.

- Always refer to the dental unit instruction for use to confirm compatibility with the device and electrical safety compliance.
- When used according to the insulation diagram FIG. 1, the device is compliant to the following clauses of IEC 60601-1:
 - Leakage currents (clause 8.7)
 - Electrical insulation (dielectric strength) clause 8.8.3

For preserving partial compliance with IEC 60601-1, regular maintenance as well as a servicing every 12 months is recommended. Partial compliance with IEC 60601-1 is not guaranteed for a service period longer than 5 years.

Any motor not compliant with IEC 60601-1 must be installed according to IEC 60601-1 by posing adequate means of patient protection.

Electromagnetic compatibility:

/ WARNING

Electromagnetic compatibility of motors and compatible hoses has been verified for a test setup representing typical final application according to the insulation diagram FIG. 1. Electromagnetic compatibility must be validated for the final application after installation of the motor in the dental unit.

Magnetic disturbance can occur from other electromedical devices; refer to the EMC specifications below.

To prevent any risk of explosion, the warning below must be observed:

Æ

WARNING

According to IEC 60601-1:2005 +A1 2012 / 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:

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

To prevent any risk of infection, the warnings below must be observed:



WARNING

- The device is supplied not sterile. To avoid any infection, respect the cleaning, sterilization and maintenance procedure detailed in section 6. Only the removable sleeve can be sterilized.
- Medical personnel using or performing maintenance on medical devices that are contaminated or potentially contaminated must comply with universal precautions, in particular the wearing of personal protective equipment (gloves, goggles, etc.). Pointed and sharp instruments should be handled with great care.
- · Rest the device on a cleanable support.

To prevent any risk of motor overheating, the cautions below must be observed:

A CAUTION

- The motor needs to be connected to the dental unit air cooling system to avoid overheating and/or auto-limitation of the speed via the electronic board safety control.
- · Always ensure that the micromotor hose is not bent and that both the hose and the motor are in good condition.

To prevent any risk of injury and/or material damage the cautions below must be observed:

- · In the event of excessive vibrations, abnormal heating, unusual noise or other signs suggesting that the device is malfunctioning, work must be suspended immediately. In this case, contact a repair centre approved by Bien-Air Dental SA.
- · Never connect an instrument on a running micromotor.
- · Do not spray any lubricant or cleaning solution into the motor.
- · Never rinse the device to cool them.
- · It is essential to use dry, purified compressed air in the dental unit 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 and connectors.

3.1 Installation



♠ WARNING

Recommended installation corresponds to the insulation diagram FIG. 1.

4 Electromagnetic Compatibility (EMC)

4.1 EMC Caution

⚠ CAUTION

- Since compliance with the international standard IEC 60601-1-2 does not guarantee immunity against 56 worldwide (due to the different frequency bands used locally), avoid the presence of devices equipped with 56 broadband cellular networks in the clinical environment or ensure that the network functionality of these devices is disabled during the clinical procedure.
- Radio transmitting equipment, cellular phones, etc., should not be used in the immediate vicinity of the
 device, since this could affect its operation. Special precautions should be taken when using strong
 emission sources such as high-frequency surgical equipment and other similar devices, to ensure that
 HF cables are not routed above or near the device. If in doubt, please contact a qualified technician or
 Rien-Air
- 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.
- Since this device is intended to be used adjacent to or stacked with other equipment, the responsibility
 of verifying normal operation in the configuration in which it will be used falls onto the dental unit manufacturer
- 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.

4.2 Electromagnetic compatibility - emissions & immunity

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

Guidance and manufacturer's declaration - Electromagnetic emissions:

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The device uses RF energy for its internal operation only. The- refore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The device is suitable for use in any building, including resident buildings and those directly connected to the public low-voltage
Harmonic emissions IEC 61000-3-2	N/A	power supply network that supplies buildings used for residential purposes.
Emissions due to voltage fluctuations (flicker) IEC 61000-3-3	N/A	

ENG

Guidance and manufacturer's declaration – Electromagnetic immunity:

Immunity test	IEC 60601 test le- vel		Electromagnetic environment - guidance
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic
IEC 61000-4-2	±2 kV air	±2 kV air	tile. If floors are covered with synthetic ma- terial, the relative humidity should be at least
	±4 kV air	±4 kV air	30%.
	±8 kV air	±8 kV air	
	±15 kV air	±15 kV air	
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines	N/A	N/A
ILC 01000-4-4	±1 kV for other lnes		
Surge IFC 61000-4-5	±0.5 kV line to line	N/A	N/A
IEC 61000-4-5	±1 kV line to line		
	±0.5 kV line to earth		
	±1 kV line to earth		
	±2 kV line to earth		
Voltage dips, short in- terruptions and voltage variations on	0 % U _T for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	N/A	N/A
power supply input lines IEC 61000-4-11	0% U _T for 1 cycle 70% U _T for 25/30 cycles at 0° 0% U _T for 250/300 cycles at 0°		
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.

Immunity test	IEC 60601 test level	Complianc	e level	Electromagnetic environment - gui- dance
Conducted dis- turbances induced by	3 VRMS 0,15 MHz – 80 MHz	3 VRMS 0,15 MHz – 80 MHz		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 fol-
RF fields IEC 61000-4-6	6 VRMS in ISM bands 0,15 MHz – 80 MHz	6 VRMS in ISM bands 0,15 MHz – 80 MHz		
	80 % AM at 1 kHz	80% AM at	1 kHz	lowing 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 com-	Test freq. [MHz]	Max. po- wer [W]	Immunity	Distance: 0.3 m
munications equipment IEC 61000-4-3	385	wei [W]	test level [V/m]	
	450	1.8	27	
	710, 745, 780	2	28	
	810, 870, 930	0.2	9	
	1720, 1845, 1970	2	28	
	2450	2	28	
	5240, 5500, 5785	2	28	
		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 $\pm 10\%$.

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

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

(1) 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 device is used exceeds the RF compliance level mentioned above, the device 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 device.





FIG. 2

5 Description5.1 Overview

FIG. 2

- (1) Motor nose
- (2) Motor body
- (3) Hose/motor connection

Note: The technical specifications, illustrations and dimensions contained in these instructions are given merely as an indication. They may not give rise to any claim.

The original language of those instructions for use is English.

For any further information, please contact Bien-Air Dental SA at the address given on the back cover.





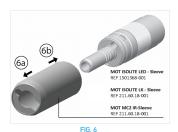
FIG. 4



FIG.

5.2 Assembly and preparation

- 1. Check that the rear of the motor and the hose connector are clean and dry.
- Position the motor and its proprietary hose (without the ring provided with hoses REF. 1600120-001 & REF. 1600315-001) as shown in (FIG. 3). Rotate it to find the exact position and push it into the motor.
- 3. Holding the motor fully screw the hose sleeve to the rear motor connection (FIG. 4).
- 4. Place the flowmeter on the nose attachment then activate the cooling air and measure the airflow. The value is measured in the middle of the flowmeter's ball according to standard JIS B7551 (FIG. 5).
- If the cooling airflow is not in the range of 8 normliter/min (+/-10%), tune the air pressure to meet this requirement.





Removing and replacing the sleeve:

- 1. Remove the motor from its hose.
- 2. In order to remove the sterilizable sleeve from the motor, push it forward as shown in FIG. 6a.
- 3. Replace the sterilizable sleeve by pushing it (FIG. 6b). Great care should be taken during this operation as to not damage the nose 0-ring when replacing the sleeve.

Changing the bulb:

FIG. 7

ISOLITE LK

Wear rubber gloves when carrying out this changing operation.

- 1. Remove the sterilizable sleeve.
- Remove the bulb using the small hole on the side by pushing it forward (avoid touching the glass part of the bulb) (FIG. 7).

ISOLITE LED

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



FIG. 8

Changing the seals manually (no tool required)

FIG. 8

- Do not lubricate the O-ring
- Use proprietary 0-ring only
- Check that the 0-rings are neither broken nor scratched after mounting them

5.3 Technical data

Technical data	
Recommended air flow (measured at the motor nose)	8 NI/min (+/-10%)
Air pressure range	2.5 — 5 bar
Coupling	Nose in accordance with ISO 3964
Operating times	No limitations for the user. Operating times are electronically imposed by Bien-Air control boards, as a function of the applied torque.
Rotation speed range	60 — 40'000 rpm
Direction of rotation	Clockwise and anticlockwise
Luminous intensity	LED or bulb, 10 klux

5.4 Classification

Class IIa in accordance with European Medical Regulation (EU) 2017/745. Class II type B device in accordance with IEC 60601-1 standard.

5.5 Performances

Performances	MC2
Give speed and torque as preset	No maximum speed is defined by the user by imposing the voltage. Torque can be monitored via the current supply.
Speed value accuracy	+- 10%

5.6 Operating conditions

Operatin	Operating conditions			
**	Temperature range:	+10°C - +35°C (+50°F - +95°F)		
, (%)	Relative humidity range:	30% — 80%		
	Air pressure range:	700 hPa — 1060 hPa		



FIG. 9

6 Maintenance and servicing

6.1 Maintenance - General information

Clean the device and sterilize the removable sleeve prior to first use.

Within a maximum of 30 minutes after each treatment, clean the motor. Observing this procedure eliminates any blood or saliva residues.



- Follow your national directives, standards and guidelines for cleaning and sterilization recommendations.
- Electric motor with brushes are not suitable for automatic cleaning/disinfection in a washer-disinfector machine.

⚠ CAUTION

Do not spray any lubricant or cleaning solution into the motor. FIG. 9.

A CAUTION

Only the removable sleeve can be sterilized.

6.1.1 Suitable maintenance products

Only use original Bien-Air Dental SA maintenance products and parts or those recommended by Bien-Air Dental SA. Using other products or parts may cause faults during operation and/or void the warranty.

- Spraynet®
- Alkaline detergent or detergent disinfectant (pH 8-11) recommended for cleaning-disinfection of dental or surgical instruments. Disinfectant products composed either of didecyldimethylammonium chloride, quaternary ammonium carbonate or neutral enzymatic product. (e.g. neodisher® Mediclean) are also allowable.

6.2 Cleaning

∴ CAUTION

- Do not submerge in physiological liquid (NaCl) nor use saline solution to keep the device moist until it can be cleaned.
- Do not submerge in a cleaning bath.
- Do not clean in a washer-disinfectant unit, nor ultrasonic cleaner.
- Do not spray any cleaning solution into the mater.
- Always ensure that the motor contacts are kept clean.

The external surface of the motor must be cleaned to remove impurities as follows:

- Clean the external surface of the motor using low- linting textile moistened with recommended cleaning products.
- Do not allow water to seep in the motor either by the nose or by the hose connector.
- Dry the external surface of the motor with low linting textile moistened with Spraynet®.

6.3 Sterilization of the external sleeve

∴ CAUTION

- Only applicable for motors with removable sleeve.
- The quality of the sterilization is highly dependent on how clean the device is. Only perfectly clean devices may be sterilized.
- To improve the effectiveness of the sterilization, make sure the motor is completely dry.
- Do not use a sterilization procedure other than the one described below.
- Only use dynamic air removal cycles: pre-vacuum or steam flush pressure pulse (SFPP) cycles.
- If the sterilization is required by national directives, use only dynamic sterilizers: do not use a steam sterilizer with a gravity displacement system. As with all instruments, following each sterilization cycle, including drying, remove the device to avoid an excessive exposure to heat which can result in corrosion.

6.3.1 Procedure

- 1. Disassemble the external sleeve from the motor.
- Pack the removable sleeve in a packaging approved for steam sterilization.
- 3. Sterilize using steam, following dynamic air removal cycle (ANSI/AAMI ST79, Section 2.19), i.e. air removal via forced evacuation (ISO 17665-1, ISO/TS 17665-2) at 135°C (275°F), for 3 minutes or at 132°C (269,6°F) for 4 minutes. In jurisdictions where sterilization for prions is required, sterilize at 135°C (275°F) for 18 minutes.

Note :The sleeve sustains more than 1000 sterilizations

The recommended parameters for the sterilization cycle are:

- The maximum temperature in the autoclave chamber does not exceed 137°C (278.6°F), i.e. the nominal temperature of the autoclave is set at 134°C (273.2°F), 135°C (275°F) or 135.5°C (275°F) taking into account the uncertainty of the sterilizer with regard to temperature.
- The maximum duration of the interval at the maximum temperature of 137°C (278.6 °F) is in accordance with national requirements for moist heat sterilization and does not exceed 30 minutes.
- The absolute pressure in the chamber of the sterilizer is comprised in the interval 0.07 bar to 3.17 bar (1 psia to 46 psia).
- The rate of change of temperature does not exceed 15°C/min (59°F/min) for increasing temperature and -35°C/min (-31°F/min) for decreasing temperature.
- The rate of change of pressure does not exceed 0.45 bar/min (6.6 psia/min) for increasing pressure and -1.7 bar/min (-25 psia/min) for decreasing pressure.
- No chemical or physical reagents are added to the water steam.

6.4 Packing and storage

Storage condit	ions	
K.J. F	Temperature range:	0°C - +40°C (+32°F - +104°F)
, (X)	Relative humidity range:	10% — 80%
	Air pressure range:	650 hPa - 1060 hPa
*	Keep away from rain	

The device must be stored inside the sterilization pouch in a dry and dust free environment. The temperature must not exceed 55°C (131°F). If the device will not be used for 7 days or more after the sterilization, extract the device from the sterilization pouch and store it in the original package. If the device is not stored in a sterilization pouch or if the pouch is no longer sterile, clean, dry and sterilize the device before using it.



If the medical device has been stored refrigerated, allow it to warm up to room temperature prior to its use.

∴ CAUTION

Comply with the expiration date of the sterilization pouch which depends on the storage conditions and type of packaging.

6.5 Servicing

Bien-Air Dental SA recommends that the user has his or her dynamic devices checked or serviced every 12 months for preserving partial compliance with IEC 60601-1. The service period is 5 years.

∴ CAUTION

Except for the sterilizable sleeve, never disassemble the device. For all modification and repair, contact your regular supplier or Bien-Air Dental service centre.

7 Transport & disposal

7.1 Transport

Transpo	Transport conditions				
**	Temperature range:	-20°C - +50°C (-4°F - +122°F)			
	Relative humidity range:	5% — 80%			
	Air pressure range:	650 hPa — 1060 hPa			
*	Keep away from rain				

7.2 Disposal



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



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 2012/19/EU).

8 General information

8.1 Terms of guarantee

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

The warranty period is:

18 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 any kind whatsoever, particularly claims for damage or injury and the consequences thereof resulting from:

- · Excessive wear and tear
- · Infrequent or improper use
- · Failure to observe the servicing, assembly or maintenance instructions
- · Damage caused by unusual chemical, electrical or electrolytic influences
- · Faulty air, water or electrical connections

Are excluded.



The warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorized by Bien-Air Dental SA. Warranty requests will only be taken into consideration if the product is accompanied by a copy of the invoice or delivery note. The following information must be clearly indicated: purchase date, product reference and serial number.

8.2 References

REF	Legend
1600681-001	MOT ISOLITE (LED)
1600078-001	MOT ISOLITE LK
1600073-001	MOT MC2 IR
1600120-001	HOSE ISOLITE/MC2 GREY
1600132-001	HOSE ISOLITE SWIVEL GREY
1600134-001	HOSE ISOLITE WATER ADJ GREY
1600298-001	HOSE ISOLITE/MC2 SWIVEL GREY
1600315-001	HOSE ISOLITE/MC2 COILED BLACK
211.60.18-001	MOT ISOLITE LK SLEEVE
1501368-001	MOT ISOLITE LED SLEEVE
1300967-010	O-RING 8.1x0.73
1500007-005	BULB MOT (pack of 5)
1600307-001	Flowmeter, for micromotors
1600036-006	Spraynet® (box of 6 cans)



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