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MICROMOTOR

OPERATOR'S MANUAL i-MMr • i-MMr L • i-MMr L FLUO i-MMs • i-MMs FLUO

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1. DESCRIPTION

1.1. DESCRIPTION OF THE DEVICE

REF	Name	Description	Light	Especially suitable for	Supplied as
95520662 95520671	i-MMs	MICROMOTOR	Yes	Implant & Endodontic	Non-Sterile and Re-usable
95520673 95520679 95520714	i-MMs FLUO	MICROMOTOR	Yes	Implant & Endodontic	Non-Sterile and Re-usable
95520660 95520669	i-MMr	MICROMOTOR	No	Prosthetic & Restorative	Non-Sterile and Re-usable
95520661 95520670	i-MMr L	MICROMOTOR	Yes	Prosthetic & Restorative	Non-Sterile and Re-usable
95520672 95520678 95520707	i-MMr L FLUO	MICROMOTOR	Yes	Prosthetic & Restorative	Non-Sterile and Re-usable

1.2. INDICATIONS FOR USE

The CEFLA Dental Micromotors are brushless electric micromotors controlled by a control unit inside CEFLA Dental Units.

They are intended to be connected with an ISO-type handpiece attachment: straight or contra-angle of equal, gear-reducing, or gear increasing speed.

They are intended for professional use in dental surgery such as: preventive dentistry, restorative applications, endodontic treatment, prosthetic applications and implantology practices.



Read carefully the user manual before using Micromotor.
The use of the device must respect the instructions provided.

1.3. IMPORTANT WARNINGS

For the correct interpretation of the instructions contained in this manual, the Italian version shall be valid as original text.

- The device is not suitable for use with blends of flammable anaesthetics and oxygen or nitrous oxide.
- The instrument is supplied non-sterile. Before use, proceed with the applicable reprocessing procedure as detailed in this manual.
- Use of electrically-powered devices may interfere with the operation of active implantable devices such as pacemakers or other active devices. In case of doubt regarding the treatment of patients with such devices, consult a cardiology expert or another competent medical institute.
- During use of the device dust and fragments from the patient's oral cavity or from the same device may be projected into the environment (organic and inorganic dust and metal dust, fragments of the device or its tips and potentially infected biological material).
- Protect the patient, when possible, using a dental dam.
- Instruct the patient to breathe through the nose in cases where the dental dam is not applicable.
- Medical personnel must wear suitable personal protective equipment.
- Suitably cool the surgical field during use.
- Use only handpieces and contra angles approved and legally marketed in your country.
- Use only drills (or other similar instruments) approved and legally marketed in your country and made with biocompatible materials complying with ISO 10993-1 and whose dimensions comply with EN ISO 1797-1.
- Use only lubricants approved and legally marketed in your country for dental handpieces.
- Before every use, check the correct locking of the handpiece on the micromotor and of the drill on the handpiece.
- Do not use damaged or worn handpieces.
- Make sure that during operation of the motor there is full flow of cooling air. If there is no cooling, stop using the device and contact the authorised technical service department.
- In case of visible damage, the emission of unusual noises and/or vibrations or if overheating is noticed, do not use the device and call authorised technical service assistance.
- LED radiation: do not stare into beam with the naked eye or look at it directly with optical instruments.
- For operators in Europe: any serious accident occurred in relation to the device must be reported to CEFLA s.c. and to the competent authority of the Member State where the user and/or patient lives.


















The Manufacturer will not be responsible for safety, reliability and performance of the device if:

- The essential requirements for the location, detailed in the Dental Unit User Manual are not respected.
- Assembly, addition, adjustment, calibration and repair processes are not carried out by authorised technical personnel.
- The device is modified, tampered with, not correctly serviced, incompatible spare parts and/or non-original components are used.
- The device is not used in compliance with the use instructions and its intended use.

CONTRAINDICATIONS

There are no contraindications related to the use of micromotors because they are not intended to get in contact with the patient.

1.4. SYMBOLS

	WARNING! Failure to observe may result in equipment damage or injury to the user and/or patient.
	Symbol to draw the attention on further information provided in the equipment user manual.
	NOTE: Identifies information that is especially important for the user and/or the assistant.
	Symbol corresponding to "APPLIED PART OF TYPE B" according to IEC 60601-1. It indicates the protection against direct and indirect contacts.
	Part that can be sterilized in autoclave.
	Mark of conformity with the requirements of (EU) Regulation 2017/745 on Medical Devices. Notified body: IMQ spa.
	Disposal symbol in accordance with Directive 2012/19/EU.
	Device identification code.
	Device serial number.
	Manufacturer.
	Equipment date of manufacture.
	Model number.
	For use only by trained medical personnel.
	Medical device.
	The operator's manual is provided in electronic format.
	Mark of conformity with technical regulations of Ukraine.
	China RoHS mark with Environmental Protection Use Period.

2. TECHNICAL DATA

	i-MMs i-MMs FLUO	i-MMr i-MMr L i-MMr L FLUO
Type	Brushless	
Power supply	32Vdc \pm 12,5%	
Maximum absorption	6 A	4.5 A
Maximum electrical power absorbed	170 W	120 W
Maximum speed	40,000 \pm 10% rpm	40,000 \pm 10% rpm
Minimum speed	100 \pm 10% rpm	100 \pm 10% rpm
Maximum torque	5.3 Ncm	3.3 Ncm
Cooling type	Forced air	
Working times	Intermittent: 5 min. ON, 5 min. OFF	
Power supply	300 \pm 20 kPa (3 \pm 0.2 bar)	
Water supply	250 \pm 20 kPa (2.5 \pm 0.2 bar)	
Consumption	Cooling air	~ 25 NI/min
	Spray Air	~ 5 NI/min
	Spray Water	~ 150 cc/min
Spray	Integrated	
Classification	Class IIa (EU) Regulation 2017/745 on Medical Devices Class II type B (IEC 60601-1)	
Emissions classification	CISPR 11 Class A Group 1 (IEC 60601-1-2)	
Handpiece coupling	ISO 3964 TYPE 2 for version without LED. ISO 3964 TYPE 3 for version with LED compatible with INTRAmatic® Lux.	
LED lighting	5000 K - 20000 mlm (White LED), 0.34 W/m ² Near UV (Only for the FLUO version)	
Applicable regulations	IEC EN 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62304, ISO 15223-1, ISO 9687, IEC 62471, ISO 14457	
Dimensions	47.5 mm	35 mm
Weight	77 g (+/-1g)	64 g (+/-1g)
Noise	54 dB(A)	58.5 dB(A)
Cooling fluid regulation	On dental equipment	

For correct operation, the device must be connected to the specific power supply and electronic control circuits, designed by the manufacturer, by way of suitable connection supply tubing.

The manufacturer undertakes to provide, upon request, wiring diagrams, component parts lists, calibration instructions or any other information that may be needed by authorized technical service assistance personnel.

The manufacturer reserves the right to make changes at any time and without prior notice.

2.1. MODE OF USE

The method of application of the device is intermittent. The operational cycle indicated respects the following times:

Type of Instrument	Operation (minutes)	Pause (minutes)
i-MMs	5	5
i-MMs FLUO	5	5
i-MMr	5	5
i-MMr L	5	5
i-MMr L FLUO	5	5

2.2. ENVIRONMENTAL CONDITIONS FOR USE

- Ambient Temperature $10 \div 40$ °C
- Relative Humidity $30 \div 75$ %
- Atmospheric Pressure $700 \div 1060$ hPa ($700 \div 1060$ mBar)

2.3. ENVIRONMENTAL CONDITIONS PERMITTED FOR TRANSPORT AND WAREHOUSING

- Ambient Temperature between $-20 \div +70$ °C
- Relative Humidity $10 \div 100$ %
- Atmospheric Pressure $500 \div 1060$ hPa ($500 \div 1060$ mBar)

2.4. APPLIED PARTS

The parts that, during standard use, necessarily come into contact with the patient in order for the device to carry out its functions correctly, are the handle covers.

3. OPERATION OF THE DEVICE

3.1. CONNECTION TO THE POWER SUPPLY INSTRUMENT TUBING

Bring the motor next to the instrument tubing and rotate it, on the connector itself until the coupling point is found. Insert the motor completely and then fully tighten the ring nut.

3.2. CONNECTION AND DISCONNECTION OF THE HANDPIECE

Handpieces complying with ISO 3964 and with the INTRAmatic® Lux. type may be used. Insert the handpiece on the coupling until the connection “click” is heard.



**Never mount a handpiece onto a motor that is running.
To detach the handpiece from the motor pull lightly.**

3.3. OPERATING PARAMETERS

Operational modes, speed adjustment, inversion of the rotation direction, continuous or reciprocating movements, torque adjustment, spray and LED lighting activation (if available) are to be made through the Dental Unit command panel. Refer to the Dental Unit instruction manual for the setting of the operational parameters.

3.4. ILLUMINATION DEVICE

In the micro-motors set up with LEDs for lighting of the surgical field, these light up automatically when the micro-motor is running. Only with the FLUO version of the micromotor the user can switch by means of a control on the console between the two types of LEDs, white or near UV, that are provided with the handpiece.

After the motor stops, the LED remains lighted for a pre-set time. Lighting depends on settings made on the Dental Unit.

4. REPROCESSING

RACCOMANDATION: reprocess shall be performed within 30 minutes of the end of use.
The micromotors have been tested for 250 cycles (as required by EN ISO 14457).



Before sanitisation operations, the operator must detach the handpiece from the micromotor and the micromotor from the dental units tubing.

Before reprocessing, visually inspect the micromotor. Reprocess only micromotors free of any unacceptable deterioration such as corrosion and damages.

To maintain a level of hygienic security, at the end of each use and within a short time he must clean, disinfect and sterilize the micromotor.

4.1. CLEANING

For cleaning follow the instructions below:

- Create a cleaning solution following the instructions for light organic debris.



Use a cleaner that is legally marketed and approved in your country (see paragraph PRODUCTS TO BE USED).

- Soak a lint-free cloth in the prepared detergent solution and tightly wrap the micromotor for 2 minutes.



Pay particular attention to have the cloth contact the front and rear connections of the device.

- Unwrap the device and dispose of the wipe.
 - Soak a new lint-free cloth in the detergent solution and wipe the device by the following:
 - 1 Wipe the external surface. Repeat this step using a fresh portion of the wipe if any visible soil remains.
 - 2 Wipe the mating surface where the handpiece connects by wrapping the shaft housing with the wipe and rotating the device. Repeat this step with a fresh portion of the wipe if visible soil remains.
 - 3 Wipe the edge of the anterior mating surface. Press the wipe against the surface and rotate the device a few times both clockwise and counterclockwise. Repeat this step with a fresh portion of the wipe if visible soil is observed.
-
- Pay particular attention to the screw heads, recesses, and crevices of the device.*
- 4 Wipe the edge of the rear mating surface of the device. Press the wipe against the surface of the device and rotate the device.
 - 5 Repeat only step 4.1.
 - Soak a new lint-free cloth in water (do not use saline solution) and wipe the micromotor by the following:
 - 1 Wipe the external surface.
 - 2 Wipe the mating surface between the handpiece and micromotor by wiping the stud and rotating the device a few times clockwise and counterclockwise.
 - 3 Wipe the edge of the anterior mating surface. Press the wipe against the surface to achieve good contact and rotate the device a few times both clockwise and anti-clockwise.
 - 4 Wipe the edge of the rear mating surface of the device. Press the wipe against the surface to have good contact and rotate the device a few times.
 - Using compressed air, dry the article.
 - Using a new clean lint-free cloth, wipe the device to remove any excess of water or lubricant.

VISUAL INSPECTION.

At the end of the cleaning procedure, visually inspect the device under normal lighting conditions.
If any visible soil is present, repeat the cleaning procedure.

4.2. STERILISATION

Before each autoclave cycle lubricate the micromotor with a quick squirt of a lubricant for dental handpieces legally marketed and approved in your country (see paragraph PRODUCTS TO BE USED).

Spray the lubricant into the central hole in the back side of the micromotor only.



Reconnect the motor onto the instrument tubing and activate it so as to expel the excess lubricant.

Dry the outside of the micromotor with gauze or cotton wool before proceeding on with sterilisation.

Set following parameter according to Type of sterilizer:

Type of Sterilizer (EU market)	Exposure time at 121 °C	Exposure time at 134 °C	Drying time
Dynamic-air-removal (e.g., prevacuum)	20 min	4 min	40 min

Type of Sterilizer (USA market)	Exposure time at 250° F	Exposure time at 270° F	Drying time
Gravity displacement	30 min	/	40 min
Dynamic-air-removal (e.g., prevacuum)	/	4 min	40 min



- For sterilization use a wrap legally marketed and approved in your country (see paragraph PRODUCTS TO BE USED).
- Do not use ultrasound cleaners.
- Do not immerse the handpiece in disinfectant or sanitizing solution.
- Never sterilise the handpiece in a dry heat steriliser.
- Do not leave the handpiece in the autoclave, but remove it immediately after the cycle.
- Periodically check the autoclave according to the requirements of the manufacturer. Temperatures higher than the indicated limit may damage the micromotor.

4.3. PRODUCTS TO BE USED

The Manufacturer recommends to use the following products:



CEFLA s.c. does not guarantee proper device operation if products other than those indicated are used.

EU market

DETERGENT FLUIDS	• IC100 (ALPRO MEDICAL GMBH) or other CE marked detergent
LUBRICATING OILS	• Daily Oil PLUS – 500 ml (CEFLA s.c.)
STERILIZATION WRAPS	• Use only CE marked sterilization wraps

USA market

DETERGENT FLUIDS	• Sani ProZyme™ - 3,8l (Crosstex)
LUBRICATING OILS	• Statcare™ - 500ml (SciCan)
STERILIZATION WRAPS	• H200 - (Halyard Health)



All the products listed above must be stored and used according to the instructions of their Manufacturers.

5. MAINTENANCE

At least once a week lubricate the O-Ring seals found in the handpiece coupling with silicone lubricating grease. Wearing disposable gloves, apply a film of grease on the fingertips and lubricate with the fingers.

If liquids that potentially leave incrustations are used to supply the spray, it is recommended that the circuit be flushed well with water at the end of each use.

The manufacturer requires an annual check or overhaul of the device by authorised service assistance personnel.

5.1. REPAIRS AND OVERHAULS

Installation, overhaul, calibration and repair of the device must be performed exclusively by technical service assistance personnel authorised by the manufacturer.

5.2. TROUBLESHOOTING

FAULTS	PROBABLE CAUSES	INTERVENTION SUGGESTED
The motor does not turn.	Motor blocked.	Request technical service assistance.
	Blocked handpiece.	Lubricate the handpiece.
		Send the handpiece to technical service assistance.
	Electronic control board broken.	Request technical service assistance.
	Instrument tubing broken.	Request technical service assistance.
The motor runs but its speed is not adjustable.	Adjustment command broken.	Request technical service assistance.
	Electronic control board malfunction.	Request technical service assistance.
The motor functions sporadically.	Instrument tubing defective.	Substitute the instrument tubing.
	Bearings damaged.	Request technical service assistance.
The motor does not provide sufficient torque.	Torque set to its minimum.	Recover the proper adjustment.
	Endodontics mode selected.	Recover the proper adjustment.
	Power supply / motor malfunction.	Request technical service assistance.
The motor overheats.	Insufficient cooling air.	Request technical service assistance.
	Handpiece with strong friction.	Lubricate the handpiece.
		Send the handpiece to technical service assistance.
The motor turns regularly. The burr does not turn.	Handpiece not connected properly.	Slide the handpiece out and reinsert it properly.
	Handpiece broken.	Send the handpiece to technical service assistance.
	Defective transmission coupling.	Request technical service assistance.
The handpiece rotates on its coupling.	Blocked handpiece.	Send the handpiece to technical service assistance.
The handpiece does not remain inserted on the micro-motor.	Handpiece damaged.	Substitute the handpiece.
	Motor hook ring damaged.	Request technical service assistance.
Water leakage at the handpiece.	O-ring seals worn or damaged.	Substitute the O-rings.
Water leakage at the instrument tubing coupling.	O-ring seals worn or damaged.	Substitute the O-rings.

6. SCRAPPING

Scrapping the device must be carried out with respect for the laws in force for electrical and electronic equipment, according to the individual national laws.

The materials used for the manufacture are not harmful for human beings or animals that come into contact with or are exposed to them.

7. GUARANTEE CONDITIONS

The manufacturer provides the end user with a 12-month warranty, starting from the date of installation, covering all operational faults, defects of materials or manufacture.

In case of justified complaints the manufacturer or the Authorised Repair Centre will proceed with the repair or substitution of the product free of charge.

To be able to make use of the free repair or substitution, it is an indispensable condition that, shipped together with the device, there is a proof of user's purchase document for the same device, which must include clearly legible references to the product, its serial number and date of purchase.

The guarantee expires when any damages and/or their consequences may be attributed to unsuitable procedures or modifications of the product performed by third parties not authorised by the manufacturer: that is, if non-original spare parts or components are used.


The recognition of any other claims from any origin whatsoever, in particular any requests for indemnification for damages or interest are excluded.

The manufacturer may not be held responsible for damages, or injuries and their respective consequences derived:

- From excessive wear.
- From connection of the instrument not compliant with the CE regulations.
- From improper tampering or maintenance performed by unauthorised personnel.
- From use of non-original accessories or spare parts.
- From the lack of observance of the instructions for use, for assembly or maintenance, or from improper use of the product.
- From unusual chemical, electrical or electronic influxes.
- From faulty connections (air water, electricity).

The guarantee does not cover the conductors such as the flexible "fibre optics", nor any other elements made of synthetic materials.

8. DISPOSAL

 Dispose of the device and accessories in compliance with local regulations.
Abide by national recycling laws and the hospital's current recycling procedures in order to ensure proper disposal of the Micromotor device.
For more information on recycling, contact the Minister of the Environment or local authorities.

 **Do not dispose of this product as household waste. The directive does not apply to contaminated products.**

9. MANUFACTURER

Manufactured by

CEFLA s.c.

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