

Instructions for use

**Electric Micromotor for
Dental Handpiece
EL-B40S, EL-B40L, EL-B40I, EL-B40M**

CE
0120

MicroNX

Symbols



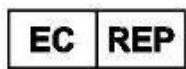
Catalog number



Serial number



Manufacturer



Authorized representative in European Community



Date of manufacture



B type applied part



Alternating current



Keep dry



Caution



Consult Instruction for use



Do not dispose of the device in domestic waste.

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1. Introduction

1.1 Operation of Principle

The subject device is contains an electric micromotor controller that provides rotational motions to a handpiece used during dental procedures to cut a tooth. This product consists of a controller a micromotor and control panel.

1.2 Intended Use (Purpose of Use)

This device is intended to be used as a controller of an electric micromotor for a dental handpiece used in the general dental applications.

1.3 Intended Operator

This device shall be used only a licensed dentist.

1.4 Indications

- 1) Dental caries treatment to restore the function of a tooth by removing the damaged part of the tooth.
- 2) Restoration of a fractured or broken tooth due to trauma
- 3) Correction of a deformed tooth.

1.5 Check before Use

- 1) Read the instruction manual before use. Failure to do so could result in serious danger.
- 2) Ensure that the product is used only by licensed dentist/authorized clinicians. Failure to do so could result in serious danger.
- 3) Ensure that the product is used only for its intended purpose. Failure to do so could result in serious danger.

2. Safety Information(Precautions and warning)

2.1 Danger

- 1) This product shall be used only under the rated power specified. Power outside the rated power range shall not be applied. Use of any other than the specified rating may cause electric shock or burns.

2.2 Warning

- 1) Check the sound, vibration and overheating of the product prior to putting the handpiece into the patient's mouth, Contact the supplier immediately if any operational issue is observed.
- 2) Do not handle the power cord with a wet hand to prevent an electric shock.
- 3) Do not expose the device to water to prevent an electric shock.
- 4) Do not use the device in a place where inflammable materials are around or risk of explosion exist.
- 5) The control unit does not have a part that can be repaired by the user. Do not disassemble it.
- 6) Place the device in the stable location. Do not drop the device to the ground or exert an external force that can damage the device.
- 7) Do not use a mobile phone or wireless RF communication device close by as such adjacent use may adversely influence this electrical device.
- 8) Make sure that the air and water supply connections between the chair and the product are smooth. If not supplied, there is a risk of burns.

2.3 Caution

- 1) Do not make a connection of the device with a handpiece that does not meet the standard requirements. Use the tips specified by the handpiece manufacturer. Invalid product use may result in tissue damage.
- 2) If the motor runs abnormally compared to a condition observed under a normal use, stop using the device immediately and make a repair request to the supplier. Using an improperly functioning product may result in electric shock, burns or tissue damage.
- 3) Check if the speed is set within the acceptable speed range prior to using the speed control button on the control panel. If it is set to an unintended setting, there is a risk of inadvertent burns or tissue damage.
- 4) Do not disassemble or tamper the micromotor or the control unit as. It may damage the device.

2. Safety Information(Precautions and warning)

- 5) Before use, check that the handpiece attached to the motor is operating smoothly. If something is wrong, please stop using. It may cause burns or tissue damage.
- 6) If the product is damaged, discontinue use and ask the manufacturer to repair it. There is a risk of electric shock, burns, or tissue damage.

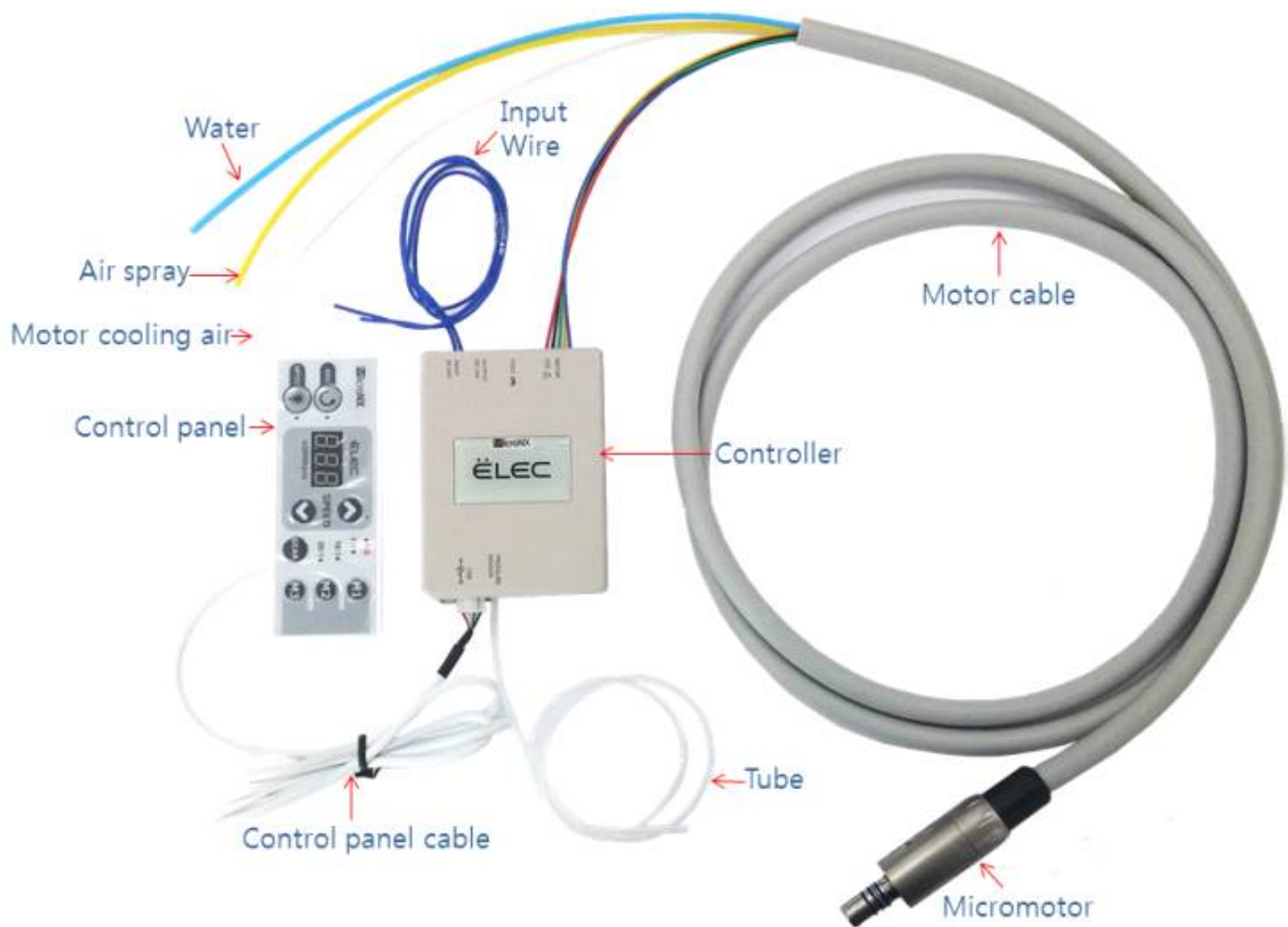
2.4 Notice

- 1) Read the User Manuals to understand the function of each part prior to use.
- 2) Use the device as instructed in the User Manuals.
- 3) Pay particular attention to the safety of the patient when using the device.
- 4) Scrap and recycle the device and its parts in accordance with relevant recycle regulations of the region.
- 6) Use handpieces that meet the coupling standard ISO3964.

3. Product Description

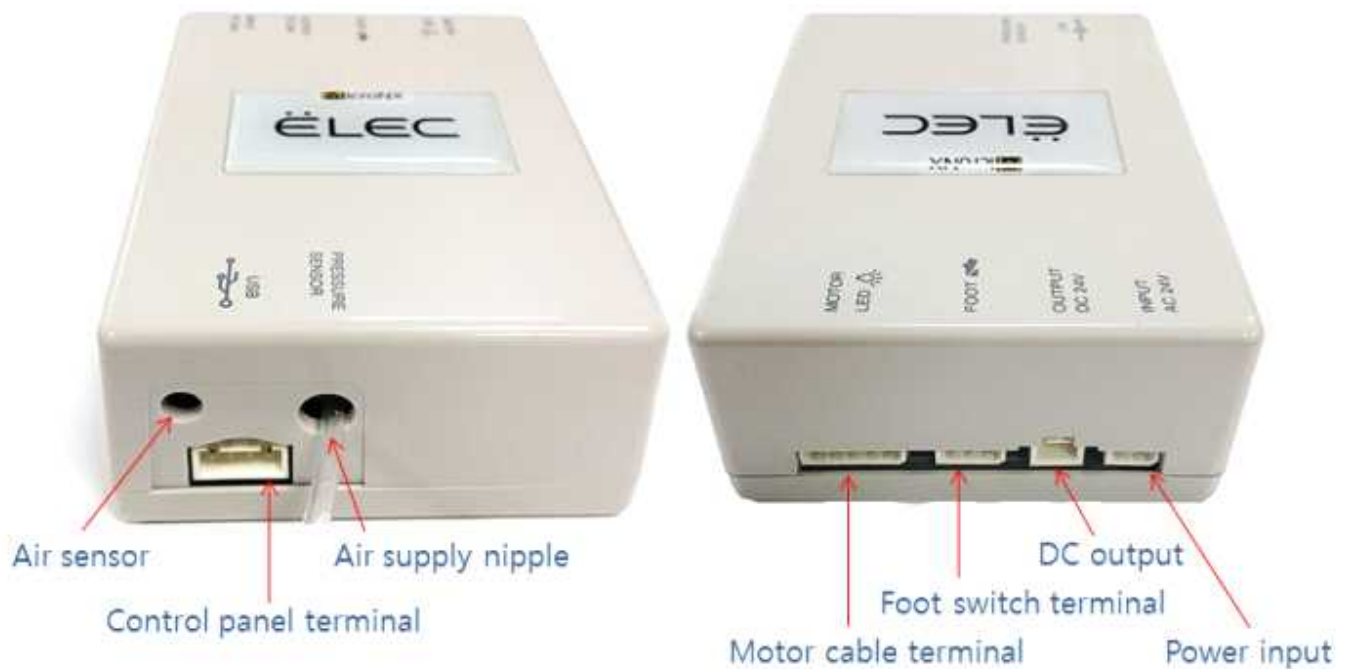
3.1 Description of System, Components and Functions

※ The foot switch is optional.

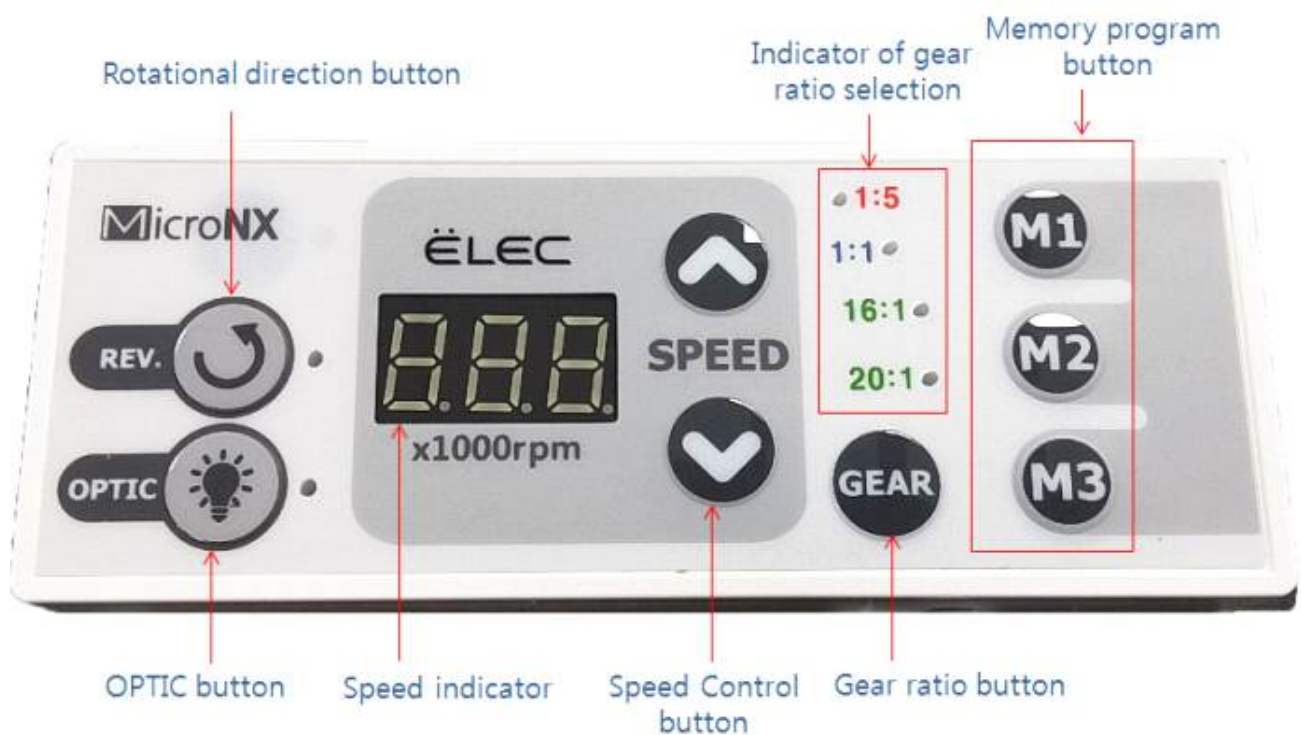


3. Product Description

3.1.1 Controller



3.1.2 Control panel (option)



3. Product Description

3.2 Product Performance

1) Controller (EMT-B40K)

Power Supply voltage	AC 24V
Frequency	50/60HZ
Consumption	100VA(Max.)
Dimension	96mm × 72mm × 34.5mm [Width×Length×Height]

2) Micromotor

Package Model Name	EL-B40S	EL-B40L	EL-B40I	EL-B40M
Micromotor Model Name	ELM-B40S	ELM-B40L	ELM-B40I	ELM-B40M
Max. Speed	40,000 rpm			
Dimension	∅ 20(D)X63(L)mm	∅ 20(D)X72(L)mm		
Weight	68g			
Coupling	ISO 3964			
Optic	○	○	×	×
Irrigation	○	○	○	×

3) Control panel (option)

Speed control	Button type
Gear ratio	1:5, 1:1, 16:1, 20:1 (selectable option)

3. Product Description

3.4 Environmental Conditions (Storage, Relocation, Operation)

1) Storage conditions

Temperature : -10°C ~ +50°C

Humidity : 10 ~ 80%

Air pressure : 500hPa ~ 1060hPa

2) Relocation conditions

Temperature : -10°C ~ +50°C

Humidity : 10 ~ 80%

Air pressure : 500hPa ~ 1060hPa

3) Operation conditions

Temperature : +10°C ~ +35°C

Humidity : 30 ~ 80%

Air pressure : 700~1060 hPa

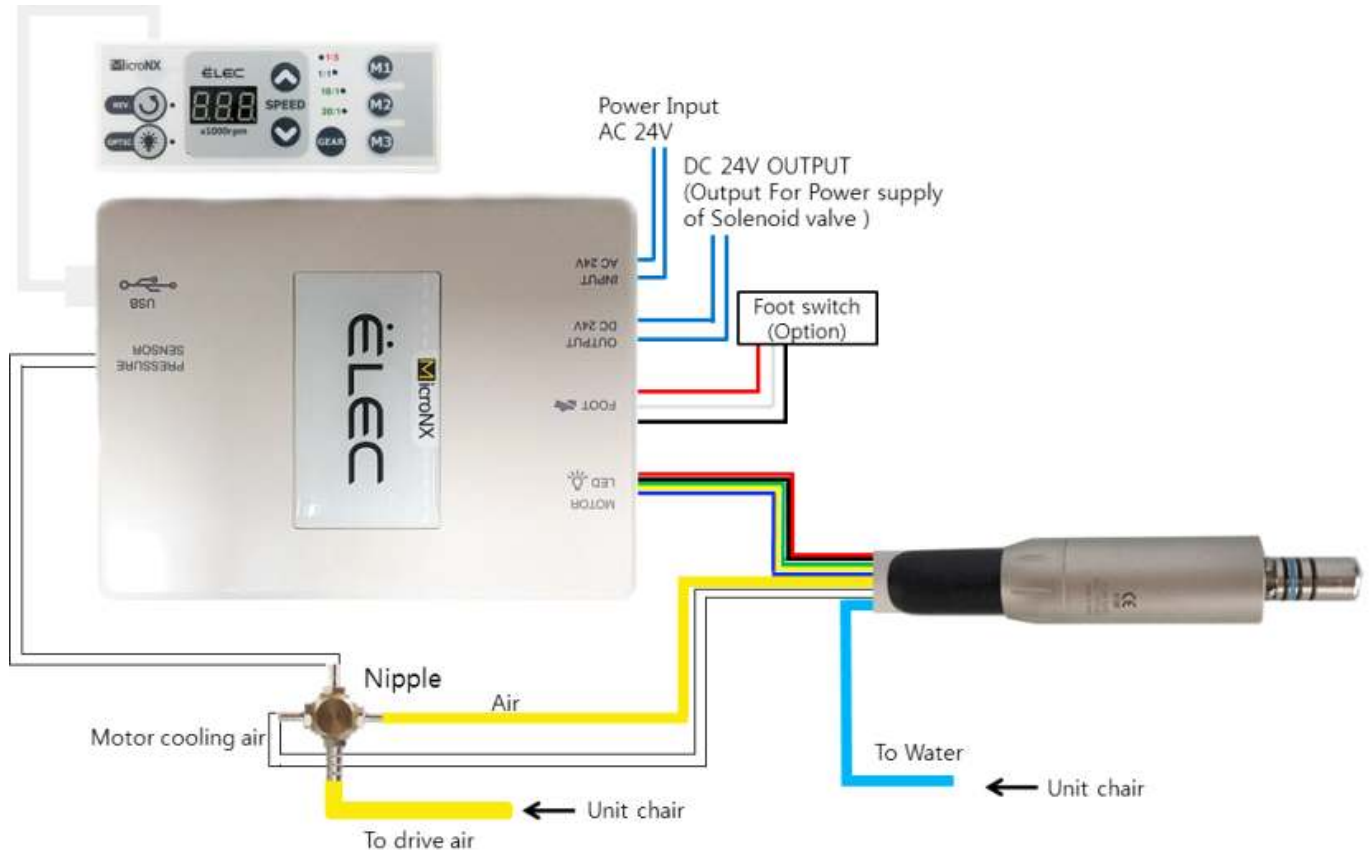


CAUTION

☞ Operation of the device in an environment other than the one specified by manufacturer may cause its malfunction.

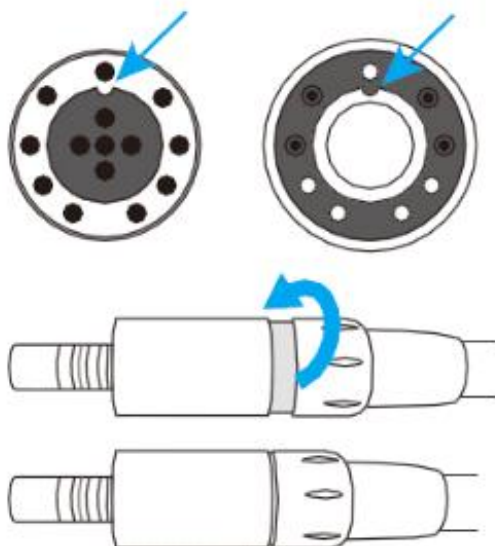
4. Installation

4.1 Connecting the Micromotor with a Control unit



4.2 To connect the Foot Switch and Control unit

4.2.1 Micomotor



- ① Identify the holes of the connector cable cap and pins of the micromotor terminal for connection.
- ② Insert the pins of the connection terminal of the micromotor into the holes of the connector cable cap.
- ③ Turn the cap anticlockwise to secure the connection



4. Installation

4.2.2 Controller



- ① Connect the 5-pin connector of the Motor Cable to the controller.
- ② Insert the Control Panel Cable into the controller as shown above.
- ③ Connect the Power Connector(Input Wire) to the connector of the controller as shown above.
- ④ Check the Tube that inserted into controller.

WARNING

-  Do not plug the power cable into the mains with a wet hand to prevent the occurrence of electric shock.
-  Do not apply voltage beyond the rated power to prevent damage to the device and fire.

5. Operation

5.1 How to Operate the Product

5.1.1 Operation of the motor

- 1) Check the connection of the cable to the foot switch.
- 2) Set the drive mode of the motor to an intended mode.
- 3) Run the motor in accordance with the operating procedure of the selected drive mode.
- 4) In the Press Pedal (PP) mode, set the speed control knob on the display panel to an intended speed and run the motor by pressing the air pedal.
- 5) In the Electric Pedal (EP) mode, set the speed control knob on the display panel to an intended speed and run the motor by pressing the foot switch.
- 6) In the Hand Control (HD) mode, run the motor by setting the speed control knob on the display panel to an intended speed.

5.1.2 Speed adjustment



The speed can be set up to a maximum of 40,000 rpm (1:5 : 200,000 rpm, 1:1 : 40,000rpm, 16:1 : 2,500 rpm, 20:1 : 2,000 rpm) by pressing the speed control button on the control panel

5.1.3 Setting a rotational direction.



- 1) The rotational direction of the micromotor can be set by pressing the rotational direction button on the control panel when the motor is not running.
- 2) When the light indicating a rotational direction gets turned off, the rotational direction is set back to the normal forwarding direction (clockwise);

5.1.4 Setting optic LED On/Off



the LED installed in the micromotor can be turned on or off by pressing the OPTIC button on the control panel. This function is available only for ELEC-LED model.

5. Operation

5.1.5 Selection of handpiece gear ratio



- 1) The gear ratio can be displayed as 1:5, 1:1, 16:1 or 20:1 depending on the gear ratio of the handpiece selected with the use of the control panel.
- 2) The gear ratio can be adjusted to 1:5, 1:1, 16:1 and 20:1 in a sequential order each time the operator presses Gear ratio button. The selected gear ratio is highlighted.

5.1.6 Selection of the program operational mode



- 1) Press and hold the button for micromotor's operational Rotation and Optic button simultaneously for 3 seconds or longer.



- 2) Select the intended program mode by pressing the button for micromotor's operational direction.
 - EP(Electric pedal) : set the speed button on the display panel to an intended speed and run the motor by pressing the foot switch.
 - HD(Hand control) : run the motor by setting the speed button on the control panel to an intended speed.
 - PP(Press pedal) : set the speed button on the Control panel to an intended speed and run the motor by pressing the air pedal.



Electric Pedal
Mode



Hand Control
Mode



Press Pedal
Mode



- 5) Press and hold the Optic button for 3 seconds or longer to release configuration setting.

5.1.7 Memory program



- 1) How to save the program values : First customize settings of Rotation, Optic and so on; Press and then hold one of the three Memory buttons M1, M2, or M3 for 3 seconds or longer.
- 2) How to retrieve pre-saved program : Select the saved program by pressing M1, M2 or M3 button.

5. Operation

5.2 Cautions to be taken during use

- 1) During dental procedures/surgeries, continue close monitoring of the patient condition.
- 2) When an abnormal condition is observed for the patient or the device being used, take an appropriate measure including suspension of the use of the device to ensure the patient safety.
- 3) Do not allow the a patient to access the device.

6. Maintenance

6.1 Manual cleaning

- 1) Disconnect the motor from the motor cable (tubing), which connects it to the control unit.
- 2) Prepare a piece of cloth (cotton) or a soft brush soaked with isopropyl alcohol.
- 3) Clean the surface of the motor with the cloth or soft brush covered with isopropyl alcohol for at least 3 minutes.
- 4) Repeat the aforementioned cleaning steps procedure when foreign matters are found on the surface of the device.



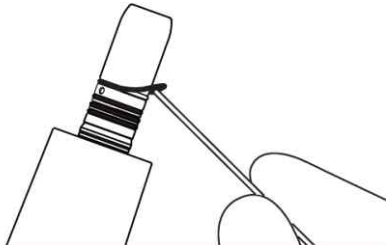
- Clean the product before and after use.

6.2 Sterilization

- 1) Disconnect the motor connected to the motor cable (tubing) of the control unit.
 - 2) Clean the motor in accordance with the procedure specified in 6.1.
 - 3) The steam sterilization must be conducted in accordance with ISO 17665-1, 2.
 - 4) Sterilize the motor with an autoclave at 132°C for 4 minutes. The maximum temperature of the autoclave is 135°C.
 - 5) The item must be dried for 30 minutes or longer after sterilization.
- ※ For the sterilization of handpiece, etc., check accompanied Operation Manuals.

6. Maintenance

6.3 Replacing O-Ring



- 1) Replace the O-ring if water or air leaks occur at a connection between the micromotor and handpiece or when it is difficult to install the handpiece.
- 2) Remove the O-ring on the micromotor and put on a new O-ring with a designated tool.



NOTICE

Replace the O-ring if

- ☞ Water or air leaks occur,
- ☞ The handpiece vibrates abnormally,
- ☞ The supply of water or air cannot be stopped, or
- ☞ It is difficult to install or remove the handpiece.
- ※ There is no specific replacement period.
- ☞ If you want to purchase additional O-rings, contact the manufacturer.

7. Trouble shooting

7.1 Instructions to Handle Error Messages

7.1.1 Types of Errors

Error code	Error condition	Cause of error	Remedy
E1	Motor connection error.	Poor motor connection	Visually check the micromotor connection.
E2	Motor overload	Micromotor is being overloaded.	Stop running the motor and restart after cooling it down for 3 minutes or longer.

7.2 Descriptions of Malfunctions

Malfunction types	Cause of error	Remedy
When the motor is not running.	Poor connection with a power cable	Check the power connection.
	Poor connection with the connection cable	Check the connection condition with the cable.
	Display panel breakdown	Contact the manufacturer for a repair request.
	Controller breakdown	Contact the manufacturer for a repair request.
	Motor breakdown	Contact the manufacturer for a repair request.
When the micromotor speed can't get controlled.	Poor connection of the connection code	Check the connection condition.
	Display panel breakdown	Contact the manufacturer for a repair request.
When the micromotors' rotational direction cannot be changed.	Poor connection of the connection code	Check the connection condition.
	Display panel breakdown	Contact the manufacturer for a repair request.
When the optic LED is not working.	Breakdown of LED inside the motor	Contact the manufacturer for a repair request.

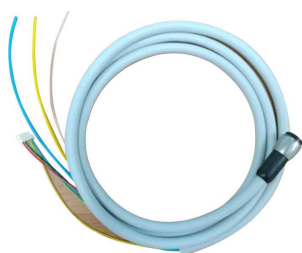
8. Accessories and Service

8.1 Accessories

8.1.1 Micromotor



8.2.2 Accessories for all models



Motor cable



Control panel



Control panel cable



O-ring



Tube

8.2 Information on After-Sale Service

- ▶ Manufacturer : MICRO-NX Co., Ltd.
- ▶ Country of Manufacture : Republic of Korea
- ▶ Address : 22, Maeyeo-ro 1-gil, Don-gu, Daegu, 41059 Republic of Korea
- ▶ Contact : +82-53-650-1000

micronx@micronx.co.kr

8.3 Warranty

- ▶ Warranty period of the product : 1 year
- ▶ Shelf life of components and replacement cycle
 - Micromotor and cable, Foot Switch : 1 year
 - Warranty does not cover damages incurred due to customer's own, misuse of the product and the normal wear and tear of micromotor bearing are not included.

9. Electromagnetic Compatibility

9.1 Electromagnetic Emission

The product is suitable for use in an specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF-emission CISPR 11	Group 1	The product use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF-emission CISPR 11	Class A	The product 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 purpose.
Harmonic emissions IEC 6100-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	complies	

9.2 Electromagnetic Immunity

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge(ESD) IEC61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floor 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/bursts IEC61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment

9. Electromagnetic Compatibility

Immunity Test	IEC 60601- Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<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 and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the re-commended 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 ^b in each frequency range Interference may occur in the vicinity of equipment marked with the symbol described lateral.



9. Electromagnetic Compatibility

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, people and animals.

^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 product is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the product.

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

9.3 Recommended Separation Distances between portable and mobile HF-communications equipment and the product

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product – according on output power and frequency of the communications equipment – as recommended in the following table.

Rated maximum output power of transmitter in watts (W)	Separation distance according to the frequency of transmitter in meter (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: At 80 MHz and 800MHz, 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, people and animals.

10. Disposal

10.1 Disposal guideline

10.1.1 Disposal of Implant Control Unit and Foot Switch and motor



- 1) Follow your country specific laws, directives, standards and guidelines for the disposal of used electrical devices.
- 2) Ensure that the parts are not contaminated on disposal.
- 3) [Micro motors can be reused in 250 cycles including sterilization and cleaning. We recommend disposal after this.](#)

10.1.2 Disposal of the packaging material

- All packaging materials have been selected considering environmentally protection and product disposal and can be recycled. Please send old/used packaging materials to the collection and reprocessing centers appropriate per local laws and regulations to minimize waste.



The EU directive 93/42/EEC was applied in the design and production of this medical device.

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