

Instruction of Use



CE
1639

Micromotor Control unit for Dental Handpiece
EL-M40S, EL-M40C

MICRO NX
GET THE ANSWER



Federal law restricts this device to sale by or on the order a dentist



Catalogue number



Serial number



Manufacturer



Authorized representative in the European Community



Date of manufactured



B type applied part



Alternating current



Keep dry



Caution



Consult Instruction for use



Do not dispose of with domestic waste

IPX1

Water proof grade

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1. Introduction

1.1 Operation of Principle

This product is an electric motor controller that provides rotational movement to a handpiece used during dental procedures to cut a tooth. This product consists of a control unit, micromotor, adapter and foot switch.

1.2 Intended Use (Purpose of Use)

This device is a motor and controller to deliver rotational motion required for dental treatment such as cutting a tooth.

1.3 Intended Operator

This product can be used by only a licensed dentist and completed dental curriculums.

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.
- 2) Ensure that the product is used only by experts.
- 3) Ensure that the product is used only as intended.

2. Safety

2.1 Danger

- 1) This product must be connected to the rated power. Power outside the range of the rated power cannot be used.

2.2 Warning

- 1) Check the sound, vibration and overheat of the product before inserting the device inside the patient's mouth. Contact the supplier without delay if any operational issue is discovered.
- 2) Do not disconnect or insert 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 there is an inflammable or explosive material.
- 5) The control unit does not have a part that can be repaired by the user. Do not disassemble it.
- 6) Place the device on a stable place. Do not drop the device or give an impact to it.
- 7) Do not use a mobile phone or wireless RF communication device near the electrical medical device to prevent adverse effect on the device.
- 8) To avoid the risk of electrical shock, this product must only be connected to a power source with protective earth.
- 9) No modification of this equipment is allowed.
- 10) Don't use the foot switch in the places where there is water, like the emergency room or the operating room.

2. Safety

2.3 Caution

- 1) The product cannot be connected to a handpiece that does not meet the standard requirements.
- 2) If the motor runs abnormally, stop using the device immediately and request the supplier to repair the product.
- 3) Check if it is set within the range of acceptable speed before using the speed control switch.
- 4) Use the adapter that is provided by the manufacturer.
- 5) Do not disassemble or modify the motor and the control unit. It can be damaged the product.
- 6) The use of a part or component may increase the electric discharge or reduce the durability of the product.

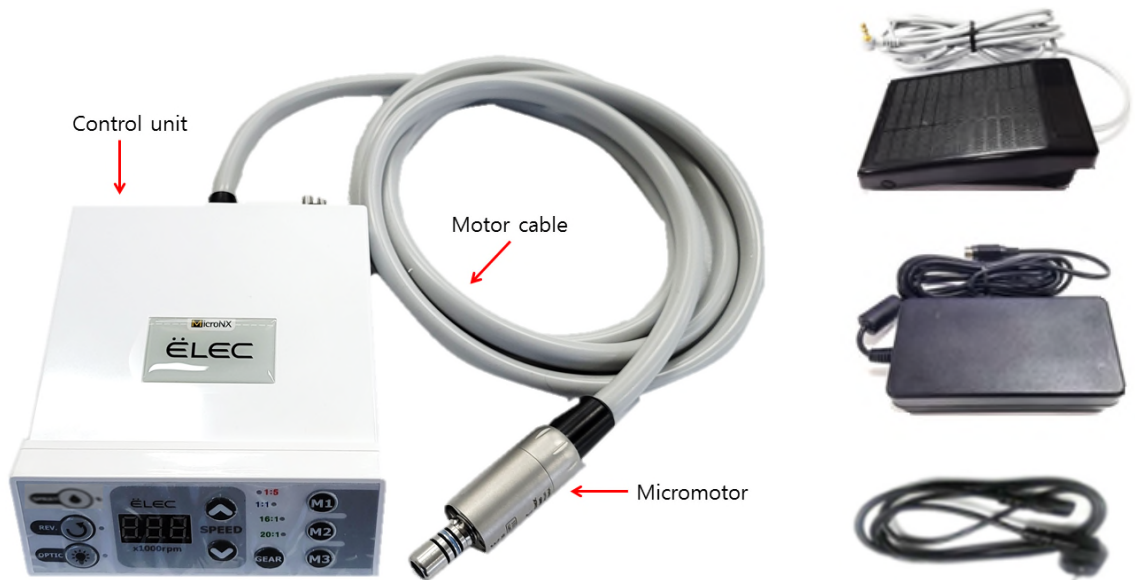
2.4 Notice

- 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.
- 5) During vibration, the motor and the motor cable may affect computer and LAN cable. Noise could be heard during operation near a radio receiver.

3. Description

3.1 Description of System, Components and Functions

EL-M40C



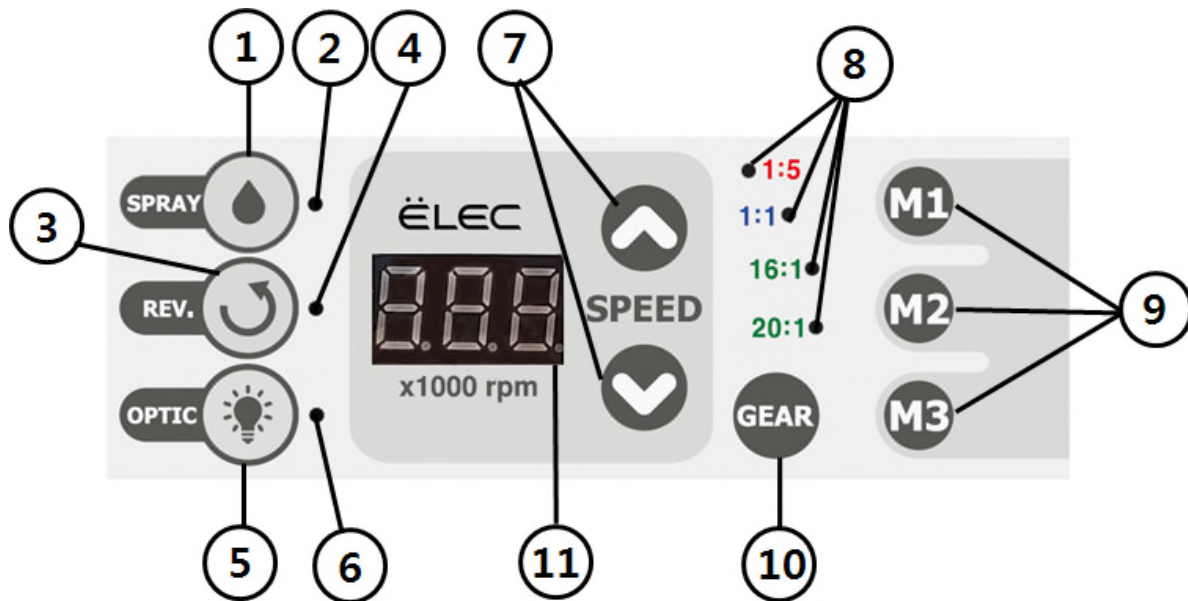
EL-M40S



3. Description

3.1.1 Control Unit

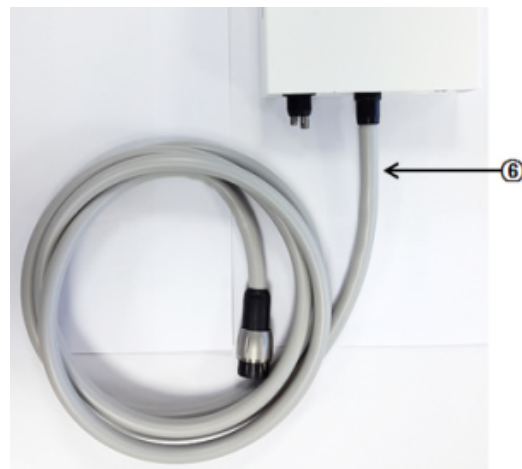
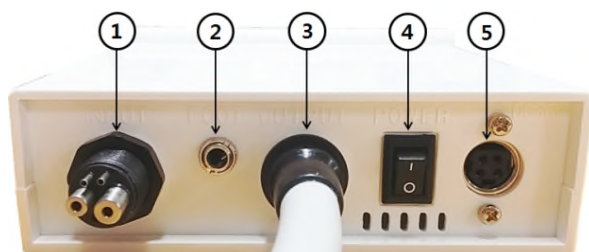
1) Front



No.	Name	Description
1	Spray ON/OFF button	Used to select the water spray. (Available only in EL-M40C)
2	Spray stated indicator	Displays the spray state (SPRAY ON means water is sprayed).
3	Rotation direction selection button	Used to select the rotational direction (CW/CCW) of the motor and change the mode.
4	Motor operation direction indicator	Displays the current operation direction of the motor (it is turned when the opposite direction is selected).
5	Motor LED ON/OFF button	Used to turn on and off the motor LED and release the mode.
6	Motor LED stated indicator	Displays the set state of the motor LED (LED On means the LED is turned on).
7	Speed controller	Used to set the rotational speed and the maximum speed of the motor.
8	Selected gear indicator	Displays the selected gear ratio of the handpiece.
9	Production selection button	Used to save the set values in the memory and select a saved program.
10	Gear selection button	Used to select the gear ratio of the handpiece connected to the motor.
11	Speed indicator	Displays the rotational speed of the handpiece.

3. Description

2) Rear



No.	Name	Description
1	Tubing Connector	Supplies air and water (ISO 9168)
2	Foot Switch Connector	Connects the control unit and the foot switch.
3	Motor Connector	Is connected to run the motor (it cannot be separated from the control unit.)
4	Power Switch	Power switch of the control unit.
5	Adapter Connector	Through which power is supplied from the adapter.
6	Motor Cable	Connects the control unit and the motor.

3.1.2 Micromotor (ELM-B40S)



No.	Name	Description
1	Handpiece connector	To which the handpiece is connected (ISO 3964).
2	Body	In which the electric energy is converted into the rotational power.
3	LED	LED installed in the motor.

3. Description

3.2 Product Performance

1) Control Unit

Model	EL-M40S
Input	100-240V~, 1.4-0.7A, 47-63Hz
Power Consumption	105 VA(Max.)
Dimension	133 × 113 × 45 mm [Width × Length × Height]
Speed range	1,000 ~ 40,000 rpm
Gear ratio	1:5, 1:1, 16:1, 20:1
Program memory	3
Class of protection	IPX0

2) Micromotor

Model	ELM-B40S
Max. Speed	40,000 rpm
Dimension	Ø20 × L63 mm
Weight	68g
Coupling	ISO 3964
Optic	White LED
Internal Irrigation	Yes

3) Foot Switch

Model	FS-30
Function	Motor On/Off
Class of protection	IPX1

4) AC/DC Adapter

Model	FSP105-KEAM1
Input	100-240 VAC , 1.4-0.7A
Frequency	47-63Hz
Output	36-38 VDC, 2.92 A
Power	105 W
Dimension	76 × 146 × 40 mm [Width × Length × Height]

3. Description

3.3 Classification of Devices

3.3.1 Type of protection against electric shock

Class I equipment

3.3.2 Degree of protection against electric shock

Type B applied part : 

3.3.3 Mode of operation

Continuous operation

3.3.4 Applied parts

Handpiece(sold separately)

※ Handpiece is not supplied by the manufacturer.

3.4 Environmental Conditions (Storage, Relocation, Operation)

1) Storage conditions

Temperature : 0°C ~ +50°C

Humidity : 10 ~ 80%

Air pressure : 500hPa ~ 1060hPa

2) Relocation conditions

Temperature : 0°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



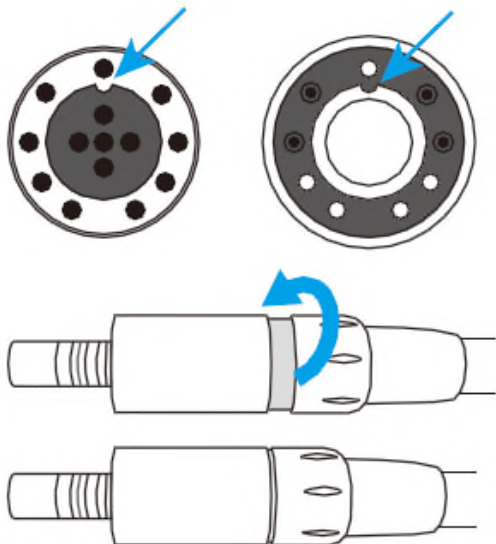
CAUTION

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


4. Installation

4.1 Connection between the motor and the cable (Tubing).

- ① Check any damage to the cable and the connection pins of the motor prior to making the connection.
- ② Connect the cable to the motor as presented below.



	① Check the holes of the cap and pins of the motor terminal.
	② Insert the pins of the connection terminal of the motor into the holes of the cap.
	③ Turn the cap anticlockwise and set after making the connection.

4.2 Handpiece Tubing Connector


	① Check the shape of the tubing of the unit chair and the back terminal of the control unit.
	② Connect the tubing to the control unit and close it to prevent the leakage of air and water.

4. Installation

4.3 Connection of foot switch

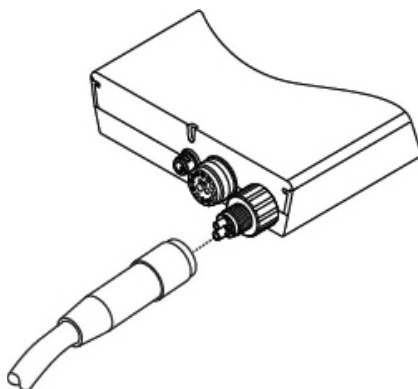
 	<p>① Check the physical condition of the foot switch terminal of at the rear side of the control unit and the connection jack of the foot switch.</p> <p>② Insert the connection jack of the foot switch into the foot switch terminal at the rear side of the control unit.</p>
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4.4 Connecting the AC/DC adapter

	<p>① Insert the AC/DC adapter plug into the adapter connector.</p> <p>⚠ Be careful to fit into the groove upon connection.</p> <p>⚠ Do not use an adapter other than the specified product.</p>
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4.5 Disconnection

The device can be disconnected in a reversed order of normal connection instructions provided herein.



5. Operation

5.1 How to Operate the Product

5.1.1 Speed adjustment (Main function)



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.

5.1.2 Setting a rotational direction



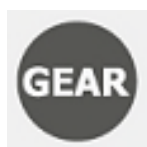
- 1) The rotational direction of the micromotor can be selected by pressing the Rotation button on the control panel when the micromotor is not running.
- 2) When the light indicating a rotational direction gets turned off, the rotational direction is set back to the normal forwarding direction (clockwise);

5.1.3 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.

5.1.4 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.

5.1.5 Setting water spray (Available only in EL-M40C)



The water spray function can be turned on or off by pressing the SPRAY button on the display.

* EL-M40S is basically capable of SPRAY.

5. Operation

5.1.6 Selection of the program 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.



3) 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.

5.2 Caution for Operation

- During surgery, keep checking the status of device and patient.
- When abnormality is detected from the device or patient, take a proper measure such as stopping the operation of device with patient's safety secured.
- Do not allow a patient to approach the device.

6. Maintenance

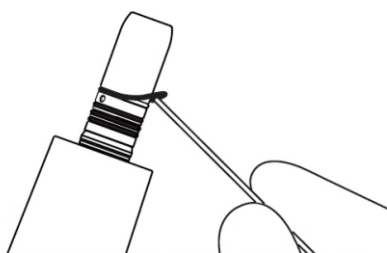
6.1 Manual cleaning

- 1) Disconnect the motor connected to the motor cable (tubing) of the control unit.
- 2) Prepare a piece of cloth (cotton) or soft brush and isopropyl alcohol.
- 3) Clean the surface of the motor with the cloth or soft brush soaked in isopropyl alcohol for at least 3 minutes.
- 4) Repeat the aforesaid procedure when foreign matters are found.

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.

6.3 Changing the O-ring



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



NOTICE

Replace the O-ring if

- ☞ Leak Water or air leaks,
 - ☞ 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.



NOTICE

- ☞ If you want to purchase additional O-rings, ask to the manufacturer.

7. Troubleshooting

7.1 Description of Error Message

1) Types of Errors

Error code	Status	Cause of error	Remedy
E1	Motor connection error.	Poor motor connection	Check the connection.
E2	Motor defect	Poor motor Connection or motor damage	Replace the motor if the connection has no damage.
E3	Motor overload	Micromotor is being overloaded.	Stop running the motor and reuse it after cooling it down for 3 minutes or longer.

7.2 Breakdown Description

Status	Possible causes	Remedies
When the motor is not running.	Improper power cable connection.	Check the power connection.
	Improper connection of the connection cable.	Check the condition of the connection cable.
	Display panel breakdown	Contact for repair.
	Controller breakdown	Contact for repair.
	Motor breakdown	Contact for repair.
When the speed cannot be controlled.	Improper connection of the connection code.	Check the connection condition.
	Display panel breakdown	Contact for repair.
When the rotational direction cannot be changed.	Improper connection of the connection code.	Check the connection condition.
	Display panel breakdown	Contact for repair.
When the optic LED is not turned on.	Breakdown of LED inside the motor.	Contact for repair.

8. A / S

8.1 Accessories



Micromotor [ELM-B40S]



AC/DC Adapter
[FSP105-KEAM1]



AC Cord



Foot Switch [FS-30]



O-ring
(a set of 4)



※Select option

External panel cable



※Select option

External Control Panel
(ELCP-VL)



Instructions for use

8.2 Information on After-Sale Service

- ▶ Manufacturer : MICRO-NX Co., Ltd.
- ▶ Made in : Republic of Korea
- ▶ Address : 22, Maeyeo-ro 1-gil, Dong-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
- ▶ Life of components and replacement cycle
 - Micromotor and cable, Foot Switch : 1 year
 - Battery : 6 months
 - Damage due to customer's mistake, misuse of the product and normal abrasion of motor 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 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.

10.1.2 Disposal of the packaging material

- All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. This way, you will contribute to the recycling of raw materials and the avoidance of waste.



1639 The EU directive 93/42/EEC was applied in the design and production of this medical device.



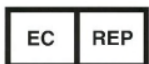
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