

INSTRUCTIONS FOR USE

Dental Engine for Implant Surgery / ISE-270C, ISE-270M

Symbols



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



Catalogue number



Serial number



Manufacturer



Authorized representative in the European Community



Date of manufactured



BF type applied part



Alternating current



Keep dry



Caution



Consult Instruction for use



Do not dispose of with domestic waste

IPX1

Water proof grade

Contents

Chapter 1. Overview	3
Chapter 2. Safety	4
Chapter 3. Product Description	6
Chapter 4. Installation	11
Chapter 5. Operation	14
Chapter 6. Maintenance	19
Chapter 7. Trouble Shootings	20
Chapter 8. Accessories and Service	21
Chapter 9. Electromagnetic Compatibility	22
Chapter 10. Disposal	24

Chapter 1. Overview

1.1 Operating Principle

This device is an unit that consists of a main body, BLDC (brushless DC) motor, and foot pedal switch for driving and operating a handpiece for dental implant procedures, to be used in dentistry in the field of implant surgery.

The main body of this device is powered by an external power supply that converts alternating current to direct current, which turns the BLDC motor; the rotation power of which combines with the handpiece to perform the dental implant procedure.

The main body of the implant unit can be adjusted in terms of its torque, rotation speed, water injection volume, and rotational direction.

The BLDC motor can be operated using the foot pedal switch.

1.2 Purpose of Use

This is an engine used to power handpieces used for implants when performing dental implant procedures.

1.3 Users

Only qualified dentists may use this device in a professional environment..

1.4 Indications of Use

- 1) Where there is an absence of gum or teeth caused by cavities, gum disease, accidents or tumors.
- 2) Where enamel ablation is not recommended so as to protect the adjacent natural teeth.
- 3) Where the patient does not want denture treatment.
- 4) Where the patient wants to replace partial or full dentures that were previously used with a fixed-type dental prosthesis.
- 5) Where the patient wants full dentures to be replaced with some partial dentures and some fixed-type.
- 6) Where the patient requires implant support in relation to the lower dentures to maintain the full denture and also improve its function.

1.5 Checklist Prior to Use

- 1) Be sure to read the user manual prior to use.
- 2) Only to be used by a professional in a professional environment..
- 3) Not to be used for anything other than its intended use.

Chapter 2. Safety (Warnings and Cautions)

2.1 Danger

- 1) When cause of abnormality is not detected or abnormality is not easily solved, contact the head office immediately.
- 2) When the display is wrongly shown, make inquiries to the head office. It is at risk for accident.
- 3) Do not bring any patient into contact with signal input section or signal output section and other connections.

2.2 Warning

- 1) Do not disassemble or make alterations to the product. Once the product is disassembled, you cannot get after-sale service from the company.
- 2) Do not inject oil into BLDC motor. It causes bearing breakdown and heat.
- 3) Do not clean the product using a solvent such as thinner, benzene, etc.
- 4) Use accessories and consumables provided with the product in accordance with specifications required by the company. When specifications other than required ones are used, it is at risk for accident.
- 5) When power cord, plug or socket is broken or damaged, do not use the product but make inquiries to the company. It is at risk for (electric) shock and fire.
- 6) Hold the plug to unplug the power cord and do not hold the plug with a wet hand. Also, do not use the product when the power plug is loose. It is at risk for electric shock and fire.
- 7) Do not locate near heating instruments or put a candle or a light around the product. It is at risk for fire.
- 8) Watch carefully whether the elderly and the infirm, the disabled or children are close to where the product is located and do not leave children alone.
- 9) Be careful not to drop foreign substances such as water and saline solution on implant engine controller and foot switch. When the product does not work normally or foreign substances are in the product, do not operate the product but make inquiries to the company.
- 10) Use the product only with intended use written in this manual and do not use in any way which is not recommended by the manufacturer.
The company is not liable for accident resulting from not observing the instruction manual.
- 11) Exterior equipment to connect to signal input section, signal output section and other connections should comply with relevant IEC standards.
- 12) To avoid the risk of electrical shock, this product must only be connected to a power source with protective earth.
- 13) Warning statement referring to the necessity for periodic checking or replacement of such an additional power source
- 14) Contain an instruction not to position the product so that it is difficult to operate the disconnection device.
- 15) Don't use the foot switch in the places that there is water, like the emergency room or the operating room.
- 16) Do not modify this equipment without authorization of the manufacturer.
- 17) Do not use a mobile phone or wireless RF communication device near the electric medical device to prevent adverse effect on the device.

2.3 Caution

- 1) When any abnormality such as vibration, heat and strange sound is detected before or during use, stop using the product immediately and examine it.
- 2) Prepare extra consumables in using the product.
- 3) Ensure that speed which is recommended by the manufacturer is maintained on tools used for implant surgery. It is at risk for accident when it exceeds the permitted speed.

2.4 Notice

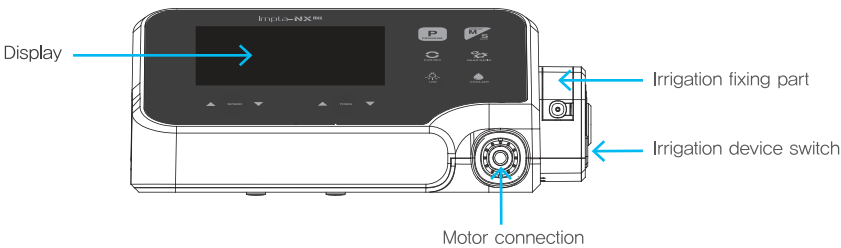
- 1) This product is manufactured to be used for implant surgery.
Ensure that the product is use in accordance with the intended use and correct procedure.
- 2) With priority to patient's safety, use the product with good care.
- 3) Read the instruction and thoroughly understand functions of each component before use.
- 4) Implant engine controller and foot switch are not subject to Autoclave.
When main body is contaminated by pollutant, turn the power off,
clean the product with clean and wet cloth and remove moisture with dry cloth.
- 5) Check whether input voltage corresponds with actual voltage after connecting the power supply.
- 6) Dispose irrigation tube as medical wastes after use.

Chapter 3. Product Description

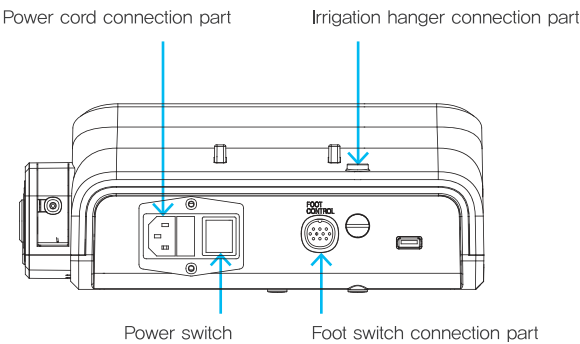
3.1 Description of System, Components and Functions

3.1.1 Main Controller

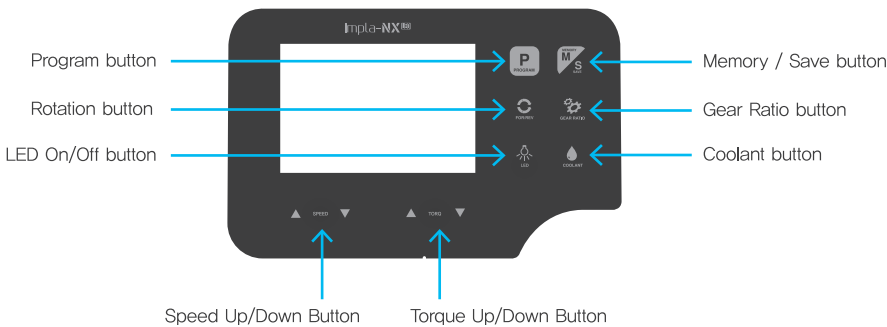
1) Front



2) Rear

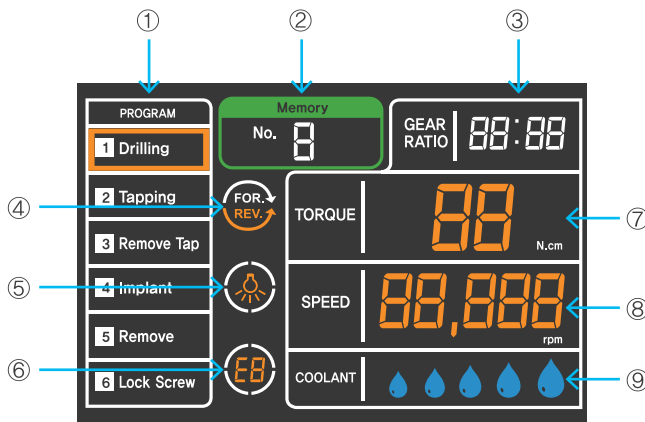


3) Pannel



Chapter 3. Product Description

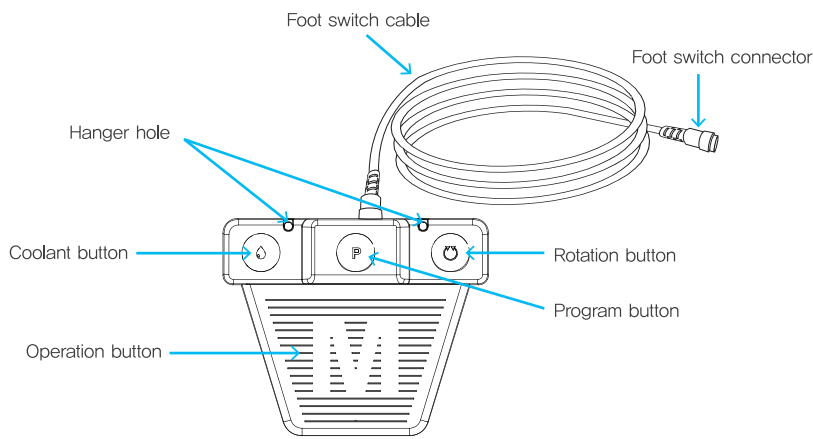
4) Display / ISE-270C, ISE-270M



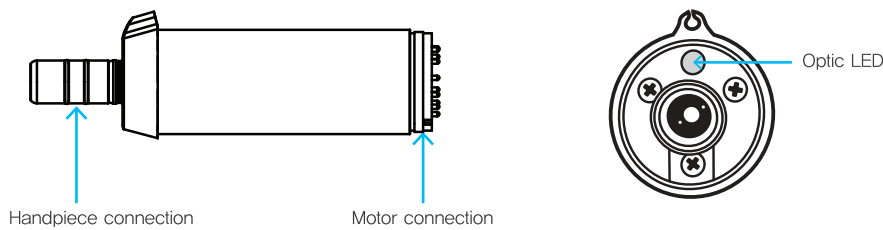
No.	Name	Function
1	Program display	Indicates function being used during surgery.
2	Memory	Memory indicates the number of saved set value in using it.
3	Gear ratio display	Indicates gear ratio currently selected for use.
4	Display for direction of rotation	Indicates direction of motor's rotation and flickers during operation of engine.
5	Optic LED Display	Indicates the status of the motor LED.
6	Error display	Error indicates the corresponding number of error upon its occurrence.
7	Torque display	Indicates the set torque value upon operation stand-by and the ratio of actual load torque compared to set torque value during operation.
8	Speed display	Indicates the set rotation speed upon operation stand-by and the actual rotation speed during operation.
9	Coolant display	Indicates injection a mount of water in 5 levels.

Chapter 3. Product Description

3.1.2 Foot switch (FS-V2)



3.1.3 Motor (ISM-B70L)



Chapter 3. Product Description

3.2 Product Performance

1) Main controller (ISE-270C / ISE-270M)

Power Supply Voltage	100–120/220–240 V
Frequency	50/60Hz
Power Consumption	150VA
Max. Coolant flow rate	110 ml/min
Fuse	2 × T2AL 250V
Dimension	285×250×120 mm [Width×Length×Height]

2) Motor (ISM-B70L)

Speed	200 ~ 40,000 rpm
Max. Torque	7 Ncm
Max. Current	6 A
Dimension	Ø24 × L100 mm
Optic	White LED
Weight	156g

3) Foot Switch (FS-V2)

Speed control	Variable
Control Functions	Program control / Coolant control / Forward/Reverse

Chapter 3. Product Description

3.3 Classification of Device

3.3.1 Type of protection against electric shock

Class I equipment

3.3.2 Degree of protection against electric shock

Type BF applied part :



3.3.3 Mode of operation

Continuous operation

3.3.4 Applied parts

Handpiece: Used in connection with a micromotor

※ Handpieces are not included in the this package,

3.4 Environmental Conditions (Storage, Relocation, Operation)

1) Storage conditions

Temperature : $-10^{\circ}\text{C} \sim +50^{\circ}\text{C}$

Humidity : 10 ~ 85%

Air pressure : 500hPa ~ 1060hPa

2) Relocation conditions

Temperature : $-10^{\circ}\text{C} \sim +50^{\circ}\text{C}$

Humidity : 10 ~ 85%

Air pressure : 500hPa ~ 1060hPa

3) Operation conditions

Temperature : $+10^{\circ}\text{C} \sim +35^{\circ}\text{C}$

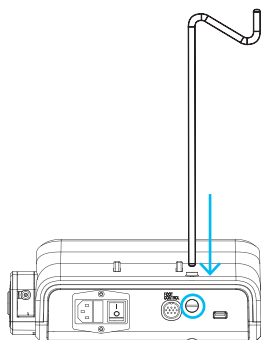
Humidity : 30 ~ 85%

Air pressure : 700~1060 hPa

Chapter 4. Installation

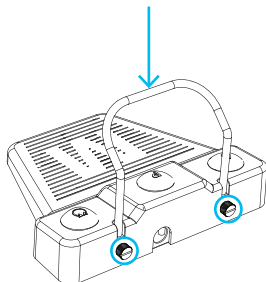
4.1 Installation of hanger and Foot switch hanger

4.1.1 Installation of hanger



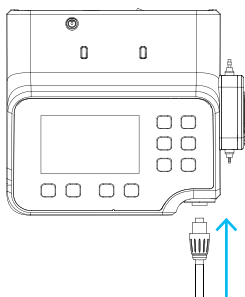
- ① Insert Irrigation Hanger into Hanger hole.
- ② Fix by connecting Hanger bolt.

4.1.2 Installation of Foot switch hanger



- ① Insert Foot switch hanger into Hanger hole.
- ② Fix by connecting Hanger bolt.

4.2 Connection of Motor



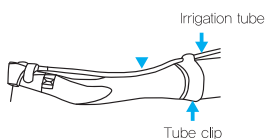
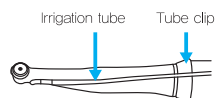
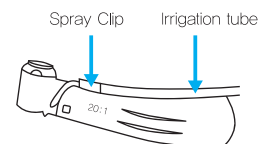
- ① Fit the motor connector into groove.
- ② Connect the motor connector CAP.



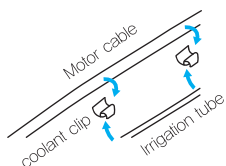
Be careful to fit into the connector upon connection.

Chapter 4. Installation

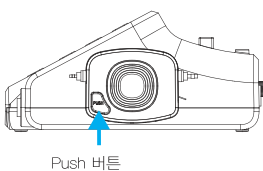
4.3 Installation of irrigation tube



- ① Attach the irrigation tube to the straight or contra-angle handpiece.

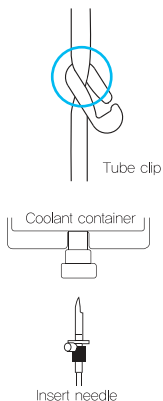


- ② Attach the motor cable and irrigation tube in regular intervals using the coolant clip.



- ③ Open Irrigation cover by pressing Push button.
- ④ Put Irrigation tube in the groove.
- ⑤ Close Irrigation cover.

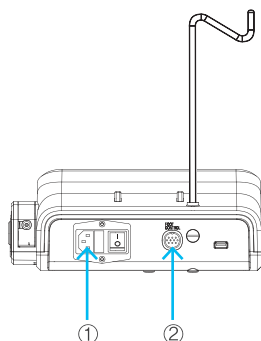
Chapter 4. Installation



- ③ Close the tube clip.
- ④ Open the tube clamp before start-up.

- ① Stick the insert needle into the coolant container.
- ② Hook-in the coolant container on the bottle holder.

4.4 Connection of power cord and foot switch



- ① Connect power cable to power cable terminal.
- ② Connect Foot switch connector to Foot switch terminal



Be careful to fit into the groove upon connection.

4.5 Disconnection

Disconnection of the product takes place in reverse order of connection.

Chapter 5. Operation

5.1 General use

- ① Turn on the Power switch of implant engine controller.
- ② Programs are selected in turn by pressing Foot switch or Program button of implant engine controller.
- ③ Check the displayed Torque, Speed, Coolant, Gear and Direction of rotation.
- ④ It starts rotating upon pressing Foot switch. It rotates at low speed with light press on Foot switch and rotates at full speed with hard press. When water injection status is preset, Pump starts rotating as well.
- ⑤ When load reaches the maximum value of preset torque during use, motor stops rotating.
- ⑥ It stops rotating upon releasing Foot switch.

5.2 Program Mode

5.2.1 Selecting a program



Program Button

A user selects a program necessary for surgery with this button. Program alters in turn from number 1 to 6 upon pressing Program button each time. It alters in order of Drilling→Tapping→Remove Tap→Implant→Remove→Lock screw. Cursor locates on border of the selected program.

5.2.2 Deleting a program



Program Button

This function deletes an unnecessary and unused programs. Selects an unused program and Deletes pressing this button more than 3 seconds.

5.2.3 Restoring programs



Rotation Button

This function restores the deleted programs. Restores all deleted programs pressing this button more than 2 seconds.

Chapter 5. Operation

5.3 Memory function

5.3.1 Change Memory number



Memory/Save
Button

It loads memory address where detailed figures (Gear ratio, Torque, Speed, For/Rev, Coolant) of each function in program are saved. Memory address alters in turn from number 1 to 9 upon pressing Memory button each time.

LCD Display	Memory1	Memory2	Memory3
	① Drilling set value	① Drilling set value	① Drilling set value
	② Tapping set value	② Tapping set value	② Tapping set value
	③ Remove tap set value	③ Remove tap set value	③ Remove tap set value
	④ Implant set value	④ Implant set value	④ Implant set value
	⑤ Remove set value	⑤ Remove set value	⑤ Remove set value
	⑥ Lock screw set value	⑥ Lock screw set value	⑥ Lock screw set value

※ Initial setting (Factory settings) : Memory

Program	Gear ratio	Torque[Ncm]	Speed[rpm]	Motor direction	Coolant level
Drilling	20:1	55	1,500	Foward	4
Tapping	20:1	40	50	Foward	3
Remove tap	20:1	40	50	Reverse	3
Implant	20:1	40	50	Foward	3
Remove	20:1	55	50	Reverse	0
Lock screw	20:1	10	50	Foward	0

5.3.2 Saving data



Memory/Save
Button

It saves detailed figures in memory which are currently set (Gear ratio, Torque, Speed, For/Rev, Coolant) for each function in program. Press and hold the memory button for 2 seconds and the border with the memory number flashes along with a beep. Press the memory button to select a memory address to store the number, and press the system button for 2 seconds, the frame with the memory number will flash alternately, and the frame will be off with a beep sound, then the saving is complete.

Chapter 5. Operation

5.4 LED On/Off



LED On/Off
Button

Press Optic/Non optic button to operate LED within the motor
ISM-B70L which is designed for Optic,

5.5 Changing Gear ratio



Gear ratio
Button

It selects gear ratio in accordance with that on handpiece,
Gear ratio alters upon pressing Gear ratio button each time,



LCD Display

Gear Ratio :

① 1:1 ② 1:2 ③ 16:1 ④ 20:1 ⑤ 27:1 ⑥ 32:1

It alters in turn from number ① to ⑥ upon pressing
the button each time.

5.6 Setting direction of motor rotation



Rotation
Button

The initial setting is Forward direction and Reverse is selected upon
pressing the button,

The letter and arrow are turned on upon selecting Reverse with beep.



LCD Display

- ① The letter and arrow are turned on upon selecting Forward.
- ② The letter and arrow flickers during the motor operation.
- ③ The same goes for selecting Reverse with beep.

5.7 Controlling water injection rate



Coolant
Button

Water injection rate alters in turn by five levels upon pressing Coolant button.



LCD Display

- ① 30ml/min ② 50ml/min ③ 70ml/min
- ④ 90ml/min ⑤ 110ml/min

5.8 Change in torque value (Main function)



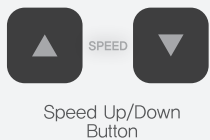
You can adjust the speed by pressing the torque UP/DOWN button.
The torque cannot be adjusted when the motor is running.



LCD Display / Change the torque value of motor, 5 Ncm increase.

Gear ratio	Torque(Ncm)	Gear ratio	Torque(Ncm)
1:1	—	1:2	—
16:1	5~60	20:1	5~70
27:1	5~80	32:1	5~80

5.9 Change in speed (Main function)



You can adjust the speed by pressing the speed UP/DOWN button.
The speed cannot be adjusted when the motor is running.



LCD Display

Gear ratio	Speed(rpm)	Gear ratio	Speed(rpm)
1:1	200~40,000	1:2	400~80,000
16:1	12~2,500	20:1	10~2,000
27:1	7~1,481	32:1	6~1,250

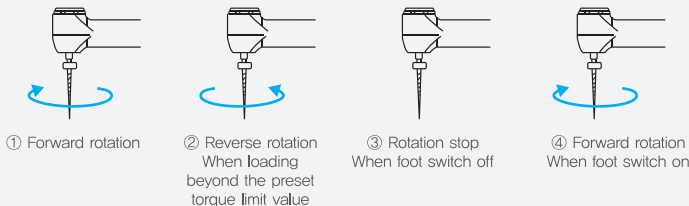
Chapter 5. Operation

5.10 Thread cutting function

2 Tapping

Activating the thread cutting function is only possible with the Tapping program.

LCD Display



5.11 Auto Calibration



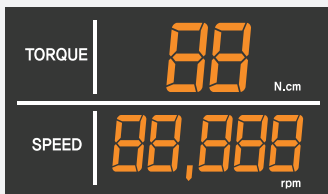
It is performed when the error of motor's rotation speed is higher than the set speed during operation of implant engine.

When 'Set value adjustment button' are pressed at the same time, the motor starts with a beep sound, the speed increases from 0 to 40,000rpm on the display, then the motor stops, and calibration is complete. Check the set speed and actual speed by restarting the implant engine.



Auto Calibration is performed upon simultaneously pressing both buttons longer than 2 seconds.

5.12 Operation of implant engine (Main function)



LCD Display

Implant engine operates upon completion of all settings. When motor operates by pressing Foot switch, the letter 'R' on display and the surrounding border flickers in turn. The torque and speed indicate the current figures and a beep sounds when altered torque value reaches 90% of set value. Motor stops when it reaches 100% of set value.

Chapter 6. Maintenance

6.1 Manual cleaning

- 1) Separate the motor and Foot Switch connected in the Control Unit,
- 2) Prepare a cloth (preferably cotton) or soft brush moistened with isopropyl alcohol,
- 3) Clean foreign substance on the entire surface and in the gaps with cloth or brush soaked in isopropyl alcohol for at least 2 minutes,
- 4) Repeat the cleaning process if foreign substance is found.



Clean the product before and after use.

6.2 Inspection

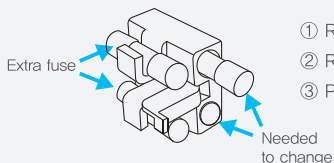
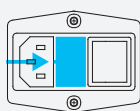
- 1) Inspect whether there is any foreign substance visible to the naked eye,
- 2) Check the operating condition,
- 3) Repeat the cleaning process if foreign substance is found.
- 4) Repeat the above procedure for every single use,

6.3 Sterilization

Sterilization of motor and irrigation tube by moist heat in accordance with ISO 17665-1, 2 in a steam sterilizer (Autoclave).

- 1) Gravity displacement type sterilizer
 - At least 30 minutes at 121°C
 - Drying time: 30 minutes,
- 2) Air-removal steam sterilization(pre-vacuum)
 - At least 4 minutes at 132°C
 - Drying time: 30 minutes,

6.4 Change fuse



- ① Remove the fuse box with a flat screwdriver,
- ② Replace the fuses by the new ones,
- ③ Put the fuse box,

Chapter 7. Troubleshooting

7.1 Description of Error Message

7.1.1 Error list

Code	Status	Cause of error	Remedy
E1	Error on motor sensor	Defective motor hall sensor, poor connection	Asking for repair
E2	Motor error	Defective motor and poor connection	Reconnecting and checking the motor Asking for repair
E3	Overload error	Overload on motor	Restart after turning off the power and then staying on stand-by
E4	Error on cooler temperature (Heat sink temperature error)	Cooler being overheated, breakdown of temperature sensor	Restart after turning off the power and then staying on stand-by
E5	Transformer error	Defective transformer, overheating	Asking for repair
E6	Error on circuit and voltage	Defective circuit	Asking for repair
E7	Error on pedal connection	Poor pedal connection	Reconnecting and checking the motor Asking for repair

7.1.2 Error display screen



LCD Display

Upon occurrence of error, a warning call is made and then the number subject to the error flickers on error display part of the screen.



Error number flickers and the surrounding border also flickers in turn, excluding the letters of 'Error.'

7.2 Breakdown Description

Error	Cause of error	Remedy
Display screen does not appear upon turning on the power on,	Inaccurate connection of power cord	Checking plug connection
	Breakdown of power cord	Asking for repair
	Breakdown of fuse	Replacing fuse
Motor does not operate upon stepping on the foot switch.	Inaccurate connection of power cord	Checking the connection
	Breakdown of foot switch	Asking for repair

Chapter 8. A / S

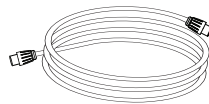
8.1 Accessories



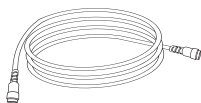
Motor for Engine (ISM-B70L)



Foot Switch (FS-V2)



Motor Connection Cable



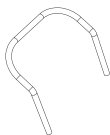
Foot Switch Cable



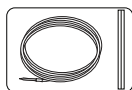
Power Cable



Irrigation Hanger



Foot Switch Hanger



Irrigation tube



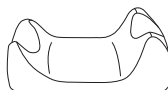
Tube Holder



Hanger Bolt



Motor cap for autoclave



Stand



Instruction for use

8.2 Information on After-Sale Service

- ▶ Manufacturer : MICRO-NX Co., Ltd.
- ▶ Made in : Republic of Korea
- ▶ Factory : 22, Maeyeo-ro 1-gil, Dong-gu, Daegu, 41059 Republic of Korea
+82-53-650-1000

8.3 Warranty

- ▶ Warranty period of the product
- ▶ Life of components and replacement cycle
 - Implant engine controller, motor : 1 year
 - Damage due to customer's mistake, misuse of the product and normal abrasion of motor bearing are not included.

Chapter 9. Electromagnetic Compatibility

9.1 Electromagnetic Emission

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.

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 B	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.

In a particular electromagnetic environment, the Dental Engine for Implant Surgery should meet the following essential performance. The criteria for compliance specified by the Micro-NX Co., Ltd. is as follow. It is to maintain water supply and the motor speed. The speed should have an error of less than 10%.

Immunity Test	IEC 60601- Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge(ESD) IEC61000-4-2	± 8kV contact ± 15kV air	± 8kV contact ± 15kV 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 N/A	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC61000-4-5	± 1kV line to line ± 2kV line to earth	± 1kV line to line ± 2kV line to earth	Mains power quality should be that of a typical commercial or hospital environment

Chapter 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	0% Ur for 0,5 cycle, at 0° ,45° ,90° ,135° , 180° ,225° ,270° and 315° 0% Ur for 1 cycles and 70% Ur for 25/30 cycles at 0° 0% Ur for 250 cycles at 0°	0% Ur for 0,5 cycle, at 0° ,45° ,90° ,135° , 180° ,225° ,270° and 315° 0% Ur for 1 cycles and 70% Ur for 25/30 cycles at 0° 0% Ur for 250 cycles at 0°	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.
Magnetic field due to mains frequency (50/60Hz) 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.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range.
Magnetic field due to mains frequency (50/60Hz) IEC 61000-4-8	3V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Interference may occur in the vicinity of equipment marked with the following. 

NOTE: Ur is the AC mains voltage prior to application of the test level.

^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.

Chapter 10. Disposal

10.1 Disposal guideline

10.1.1 Disposal of Main controller and foot switch and motor



- ▶ Follow your country specific laws, directives, standards and guidelines for the disposal of used electrical devices.
- ▶ 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.

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GET THE ANSWER



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



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