



Applicable for ES90 & ES70
Version No.: A/1

INSTRUCTIONS FOR USE

Surgical Drive System

■ Equipment Classification:

Classification by type of anti-electric shock:

- Class I equipment

Classification by degree of anti-electric shock:

- Type BF applied part: 

Classification by degree of protection against inlet fluid

- General equipment: IPX0, foot pedal switch: IPX6

Classification by the sterilization or disinfection method recommended by the manufacturer:

- See Chapter 7 for sterilization

Classification by the degree of safety when used in flammable anaesthetic mixture with air or in flammable

anaesthetic mixture with oxygen or nitrous oxide:

- Equipment which cannot be used in flammable anaesthetic mixture with air or in flammable anaesthetic mixture with oxygen or nitrous oxide.

Classification by operation mode:

- Intermittent operation

This product is designed for intermittent operation mode S3, that is, it will pause for 10 minutes after 3 minutes of operation time. The user shall be responsible for the use and shutdown of the system timely.

1. Scope Of Application And Population

Scope Of Application/Intended Use : It is used in combination with a registered tool matching the declared product for cutting, grinding and drilling operations in open operation.

Users : It is used only by qualified and trained physicians in hospitals, clinics or laboratories.

Applicable For : Patients who have been confirmed as suitable ones by the attending physicians.

Operation Places : It is suitable for use in non-household and hospital special low-voltage power supply network which is not directly connected with the domestic residential low-voltage power network.

Contraindications In Patients : Metal allergy.

(1) Applicable For : Patients who have been confirmed as suitable ones by the attending physicians.

(2) Contact Form : Contact with human mouth via handpiece.

2. Specifications

*It Is A Conventional Device (Namely The Sealed Device Without Protection From Seepage Water).


Model	ES90, ES70
Host Size	Length 260mm × width 240mm × height 110mm
Input Voltage	220VAC
Allowable Voltage Fluctuation	±10%
Rated Current	0.1A-0.8A
Frequency	50Hz/60Hz
Power Fuse	2*250V-T1.6AH
Maximum Power Consumption	180VA



Motor Rated Working Voltage	DC32V
Motor Rotation Mode	Forward/reverse rotation
Motor Speed Range	0r/min~40000r/min
Motor Size	Diameter Φ21.7mm × height 70.5mm
Sterilization Method	High-temperature and high-pressure steam sterilization for 5min at 134°C
Maximum Allowable Hanging Load:	≤1.5KG
Operating Environment	Temperature 10°C~30°C; humidity: 15%RH~80%RH; and air pressure 860hPa~1060hPa
Transportation And Storage Environment	Temperature 0°C~60°C; humidity: 8%RH~93%RH; and air pressure 700hPa~1060hPa
Date Of Production	See equipment body, minimum unit box, and warranty card
Service Life	5 years from the date of manufacture

3. Safety Cautions And Precautions And Hazard Matters

■ Please read the following safety cautions and precautions carefully before use to master the correct use method.

■ Please pay attention to the representation of hazard matters so as to avoid damage to you and others caused by incorrect use. The following items are classified according to the degree of possible danger and/or damage, which are all cautions and precautions for safe use. Please read through and abide by them carefully.

Classification Of Cautions And Precautions	 Severity of the possible danger or damage
Warning	Caution and precaution indicating the possibility of causing injury to personnel or the damage to objects
Attention	Caution and precaution indicating the possibility of causing minor or severe injury and damage to objects
Notice	Caution and precaution that you are required to follow for your safety

 Warnings
<ul style="list-style-type: none"> · Do not touch the power wire with wet hands to prevent electric shock. · Do not attach the control components to water or other liquids, which may cause electric shock and other risks due to short circuit. · If there is smoke or peculiar smell like resin burning, please directly turn off the power and entrust repair immediately. · Do not use in a room with explosion risk or near flammable substances. · Pay full attention to vibration, heat and noise and other phenomena and stop immediately if you feel abnormal before or during the use.
 Attentions
<ul style="list-style-type: none"> · Take the safety of patient as the priority, and be sure to pay attention to the safety when using this product. · This product shall be used by the qualified and trained physicians only. · Please connect each part accurately, otherwise, it may cause LED light off, water leakage or air leakage. · Do not strongly impact this product, and especially do not make this product fall. Otherwise, it may cause a failure in function. · Do not twist the electrical conductors when installing the control host or motor. Do not apply abnormal force during installation.

- Only use a saw blade in good condition, and be discreet when the saw blade is moving.
- Use the saw blade approved by the Company only.
- Replace the saw blade after each treatment.
- Insert the saw blade only when the medical device is at rest.
- Contact of the saw blade with human tissue may result in tissue injury.

⚠️ **Attentions**

- Do not connect the micro brushless direct-current motor to other models or Surgical Drive Systems of other manufacturers to avoid abnormal operation.

Control host

- Do not replace the wire near the gas burner. Do not repair the burnt motor wire and replace it with a new one.
- Please pay full attention to looseness, vibration, abnormal sound, heating (temperature), etc. Before use, please make sure to make it rotate outside the patient's mouth for inspection. At this time, even if you feel a slight abnormality, please stop using it and contact the dealer.
- Do not splash water on this device, which may cause fire or electric shock due to short circuit.

Handpiece

- Do not use it under high load for a long time. Otherwise, it may cause heat.
- Please remove the handpiece after the motor stops rotating completely.
- Do not connect/disassemble the handpiece during the operation.
- Be sure to adjust the rotation speed within the allowable rotation speed range of the handpiece before use.
- Do not perform high-temperature and high-pressure steam sterilization (or any other high-temperature sterilization) on the control host, etc.
The operator shall be responsible for the correct operation control, maintenance and inspection of this device.

Notices

- If a computer or LAN cable is placed close to the working motor or motor wire, sometimes it will exert an influence. In addition, if there is a receiver such as a radio near the motor or the motor wire, noise may sometimes be generated.
- After use, please turn off the power.

⚠️ **Cautions And Precautions**

Please read through the following carefully before use.

1. This device shall only be used for the purposes involved herein. Please operate in strict accordance with the Instructions for Use. We will not assume any responsibility for any accident caused by the failure to operate according to the Instructions for Use.
2. Before use, make sure that the voltage is within the operating range. Improper input voltage will damage this device and cause harm to the operator and patient.
3. Please use the original accessories, such as: brushless direct-current motor. The Company will not be liable for any problems and hazards caused by the use of relevant accessories not provided by it.
4. This product is an electronic product. Do not insert anything into this device so as to avoid electric shock hazard.
5. When installing the control box, avoid twisting the connecting tube or power wire.
6. Avoid liquids such as cleaning agents from entering the host to avoid short circuit or other problems.
7. Cut off the power immediately if any abnormality in this device. It is not allowed to modify this device circuit or components without authorization. Any disassembly or modification may result in device abnormalities.

8. Turn off the power after use every time. For long-term placement, drain off the water from this device and hoses first.
9. Avoid strong electromagnetic interference on this device. Do not place this device near strong electrical equipment or patients with a pacemaker.
10. Unstable voltage or magnetic field interference will affect the proper operation of this device.
11. This device is not sterilized at the time of delivery. Please sterilize the handpiece and motor for the first time.
12. External accessories available from other manufacturers.
 - Only the registered and valid pre-sterilized disposable water supply pipe is used, with a specification of 6mm*4mm for extrusion section. If the water supply pipe does not conform to the specification, the water supply flow of cooling system may be reduced.
 - Only the handpiece that complies with the Company's requirements is used. If the handpiece does not meet the requirements mentioned above, this device failure may occur.
 - This product cannot be repaired on site.
13. This product is not suitable for neurosurgery and endoscopic surgery, and it is only suitable for general surgery.

Responsibilities Of The Manufacturer

The manufacturer shall assume the responsibility for the safety, reliability and performance of the Surgical Drive System only when operating in accordance with the following instructions:

- The Surgical Drive System must be used in accordance with the Instructions for Use.
- Any component of the Surgical Drive System cannot be repaired and assembled by the user. If maintenance and assembly are required, it must be carried out by the authorized exquisite service partners.
- When conducting electrical installation in the place of use, relevant provisions of GB 9706.15-2008 Medical Electrical Equipment or applicable regulations of your country must be observed.
- If this device is disassembled without authorization, all warranty requirements and any other requirements within the warranty period will be invalid.
- Appearance requirements
This device surface processing, gloss and color shall be uniform, without scar, and the knurling shall be clear, without sharp edge, burr, scratch and other defects.

4. List Of Accessories

Host	x1
Instructions for Use	x1
Power wires	x1
Fitting seal	x1
Motor (including cables)	x1
Foot pedal (including hook)	x1
Ceramic tube 1.6A 250V fuse	x2
Certificate of Conformity	x1
Handpiece	Optional
Sheath	Optional

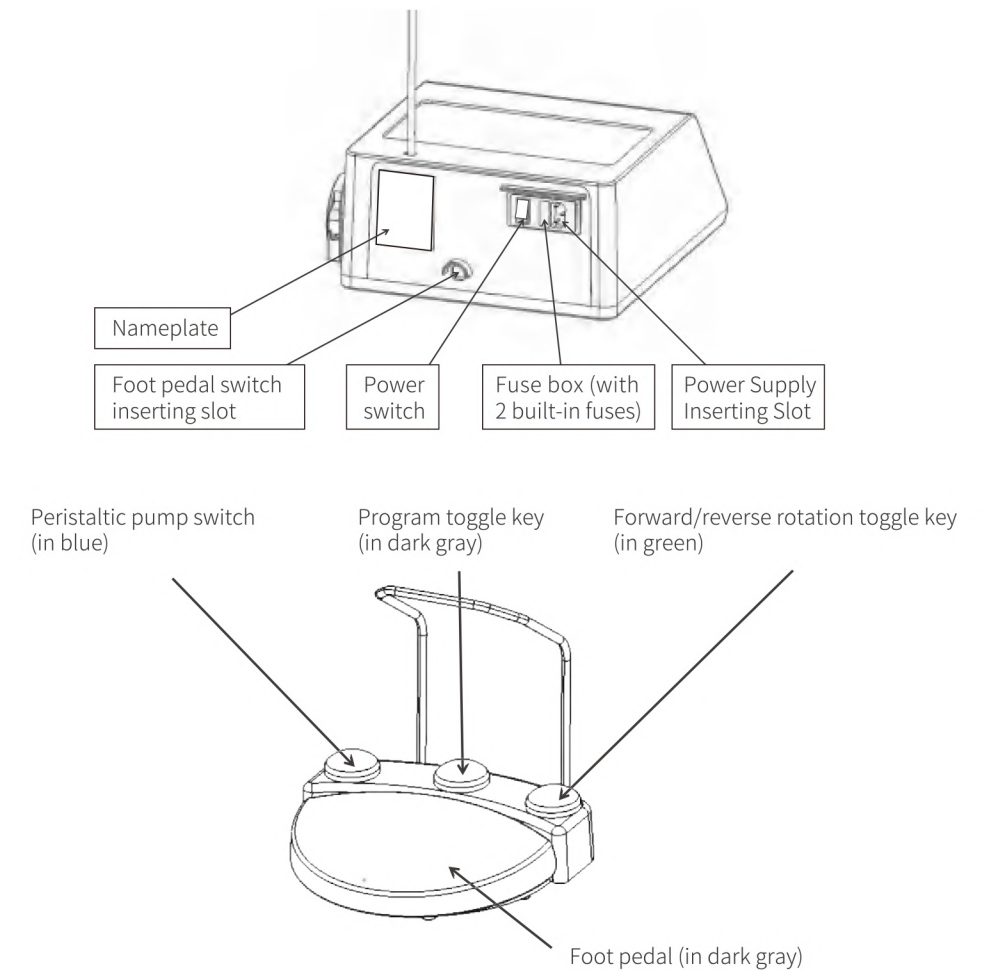
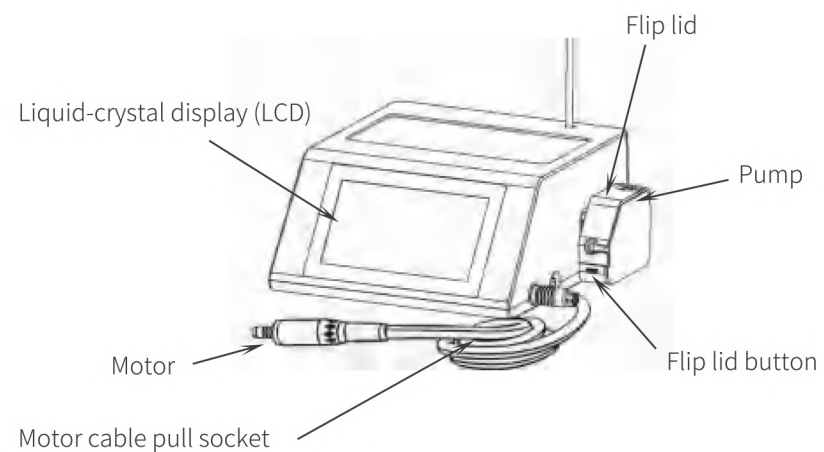
5. Construction And Assembly

The Surgical Drive System is composed of a host, a motor (including cables), a handpiece (optional), a grinding head and a foot pedal.

As for ES90, it is composed of a host, a motor (including cables), a handpiece (swing saw handpiece: SH32W1, reciprocating saw handpiece: SH41W1, sagittal saw handpiece: SH41W2, 20° straight handpiece: SH11W3, 1:1 straight handpiece: SH11W2, 40:1 bending handpiece: W401LW, 1:4.2 bending handpiece: W142LW, 1:5 bending handpiece: W15LW, 1:1 bending handpiece: W11L) (optional) and a foot pedal switch.

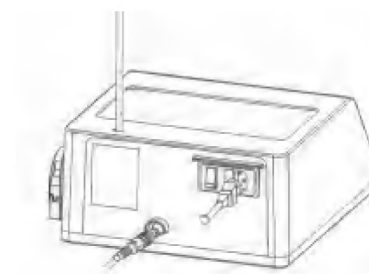
As for ES70: it is composed of a host, a motor (including cables), a handpiece (20° straight handpiece: SH11W3, 40:1 bending handpiece: W401LW, 1:4.2 bending handpiece: W142LW, 1:5 bending handpiece: W15LW, 1:1 bending handpiece: W11L) (optional), and a foot pedal switch.

5.1. Name Of Parts (Accessories)



5.2. Connection Of Components

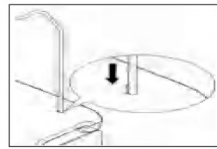
5.2.1 Host Wiring



① As shown in the figure, insert power wire.
 Insert the pedal interface into the corresponding inserting slot of the host.
⚠ Attention
 · When the foot pedal is connected to the host, please note that it shall not come loose with slight pull force after insertion.

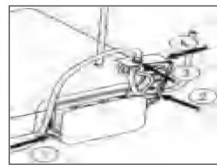
⚠ Attention

- Do not use power wires other than our accessories, and can only connect to grounded sockets.
- Do not use the water with impurities, which may block up the motor or handpiece.
- Do not use the force greater than the specified value to pull the motor wire, which may cause loosening or damage.
- Do not use it in the conditions rather than the recommended environment

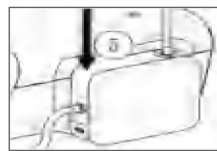


⚠️ ② Insert the support bar.
Please pay attention to bayonet position. (Maximum hanging weight is 1.5KG)

5.2.2 Installation Of Hose Clamping Into Peristaltic Pump



③ Open the peristaltic pump cover and install the disposable water supply pipe.
Note: Use the same procedure to remove the disposable water supply pipe for oral implants.



④ Close the water pump cover.
Note: Use the same procedure to remove the disposable water supply pipe for oral implants.

5.2.3 Assembly And Disassembly Of Motor/Motor Cable

As shown in the figure, carefully insert the motor wire interface into the inserting slot of the host with a slightly strong force until it stops, then the cable plug will be automatically locked to prevent come off.

When disassembling, hold the pattern part of the cable connector with two fingers, pull out the enclosure of the cable plug horizontally.

⚠️ **Note:** Do not pull the motor cable with a strong force directly, or it may cause damage to the motor cable plug.

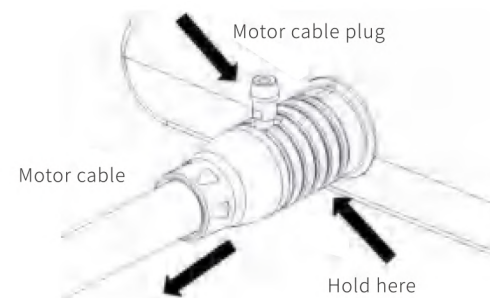
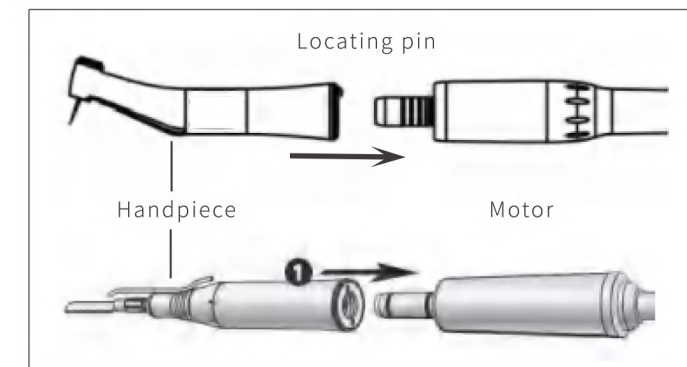


Diagram for assembly and disassembly of motor cable

5.2.4 Assembly And Disassembly Of Motor/Handpiece

Insert the handpiece into the inserting slot of the motor and rotate it until you hear a "click" that coincides with the anchor point. To remove when disassembling, hold the motor and handpiece tightly and pull out straightly. When inserting the handpiece, properly insert the locating pin to avoid abnormal rotation.

*The handpiece needs to be purchased separately.



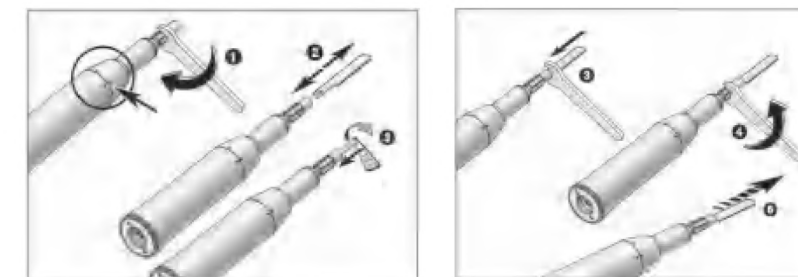
⚠️ **Attentions**

- Do not oil the motor (which has been lubricated for long-term use).
- Be careful to use the grease-filled handpiece accessories (E type interface). Put the handpiece vertically until the excess cleaning oil is exhausted. Wipe the handpiece clean and then connect to the motor.
- Do not install or remove the handpiece when the motor is operating.
- Be careful not to connect the oily handpiece to the motor to prevent oil from flowing into the motor and accordingly causing failure.
- Store the oily handpiece separately and install it when use.
- Do not bring water into the motor to avoid causing failure.
- The maximum temperature of the motor is 55°C.

5.2.5 Assembly And Disassembly Of Saw Blade/grinding Head/bur

It shall be used in conjunction with the tools that have been registered as medical devices.

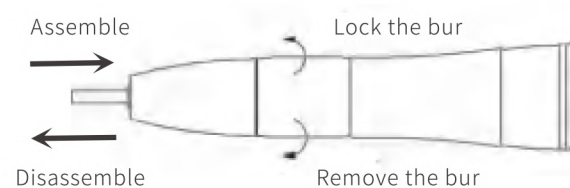
5.2.5.1 Replacement of saw blade.



- ① Loosen the fixing screws with a wrench or hand to ensure that the sleeve is always closed.
- ② Insert the saw blade to the block position, or remove it.
- ③ Press the saw blade and rotate it until the sound of engagement is heard.
- ④ Use a wrench to tighten the fixing screws.
- ⑤ Confirm the full-tooth engagement.

5.2.5.2 Replacement of grinding head/bur

Assembly and disassembly of straight handpiece bur/grinding head



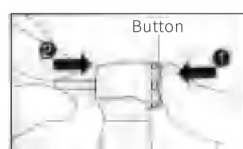
As shown in the figure:

- 1) Insert the bur/grinding head into the handpiece, rotate the rotary sleeve clockwise until you hear a click, push and pull the bur to confirm if it has been firmly installed.
- 2) Rotate the sleeve counterclockwise until you hear a click, open the chuck, and pull out the bur to take off the bur.

Assembly of bending handpiece bur:

As shown in the figure:

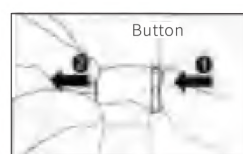
- 1) Press the button to open the chuck (1).
- 2) Insert the bur until it sits on the inside of the chuck and release the button (2).
- 3) Push and pull the bur to make sure it is firmly installed.



Disassembly of bending handpiece bur:

Press the button to open the chuck (1) and remove the bur (2)

As shown in the figure.



6. How To Use

- 1) The power switch "I/O" (on the back of this device) is used to turn the host on and off. This device can be shut down immediately regardless of any operation at any time.
- 2) After the power wire is plugged in, and the power supply is turned on, the display screen of the host will be on.
 - * **Motor stalling torque is 2.5N•cm. When the motor load is greater than it, the motor will automatically stop working.**
 - * **When 40:1 handpiece (W401LW) and tapping program are selected, the maximum output torque is 70N•cm (±10%).**

Item	Sub-item	Corresponding handpiece model	Handpiece speed (±10%)
Minimally invasive tooth extraction 1:4.2	Sterile tooth extraction	W142LW	0~168000 r/min
High-speed operation 1:5	Crown cracking	W15LW	0~200000 r/min
	Tooth preparation		
	Pulp exposing		
	Pulp trimming		
	Denture restoration		

Low-speed operation 1:1	Polishing	W11L	0~40000 r/min
	Caries removal		
	Renovation		
	Dental cavity preparation		
Implanting 40:1	Locating	W401LW	0~1000 r/min
	Guiding		
	Hole reaming		
	Tapping		15 r/min
	Implanting		
Electric osteotome (for ES90 only)	Drilling/grinding handpiece 1:1	SH11W2, SH11W3	0~35000 r/min

Item	Sub-Item	Corresponding handpiece model	Motor speed (±10%)	Handpiece corresponding frequency (±10%)
Electric osteotome (for ES90 only)	Reciprocating saw handpiece 3.2:1	SH41W1	15000 r/min	0~4687 c/min
	Swing saw handpiece 3.4:1	SH32W1	15000 r/min	0~4411 c/min
	Sagittal saw handpiece 3.2:1	SH41W2	15000 r/min	0~4687 c/min

3) Speed setting: Drag the speed regulating progress bar left and right on the display screen, to show the rotation speed of the handpiece in numbers on the screen. Drag to the left to reduce the speed and drag to the right to increase the speed. Press "-" to reduce the rotation speed and "+" to increase the rotation speed.

When the speed setting value is the upper limit value or the lower limit value of the speed in the current transmission ratio mode, the buzzer will give "Bi-Bi" sound, indicating that the speed has reached the limit value.

4) Flow setting: Drag the flow regulating progress bar left and right on the display screen, to display the flow on the screen in a digital percentage. Drag the left to reduce the flow, and drag the right to increase the flow. The flow regulating range is 0-100%, and the step amount is 10%, which is divided into 11 levels. Press "-" to reduce the flow and "+" to increase the flow.

5) Torsion setting: Drag the torsion regulating progress bar left and right on the display screen, to show the maximum allowable in numbers on the screen. Drag to the left to reduce the torsion and drag to the right to increase the torsion. The torsion regulating range varies according to different handpieces. See the torsion range in the table above. Press "-" to reduce the torsion and "+" to increase the torsion.

6) Motor light regulating

On/off: Click the LED icon to control the brushless direct-current motor to be on/off.

7) Forward and reverse rotation

Clicking the forward/reverse rotation icon will change the direction of operation of the motor.

8) Atomizing water switch (cooperating with the registered and valid pre-sterilized disposable water supply pipe, with a specification of 6mm*4mm for extrusion section)

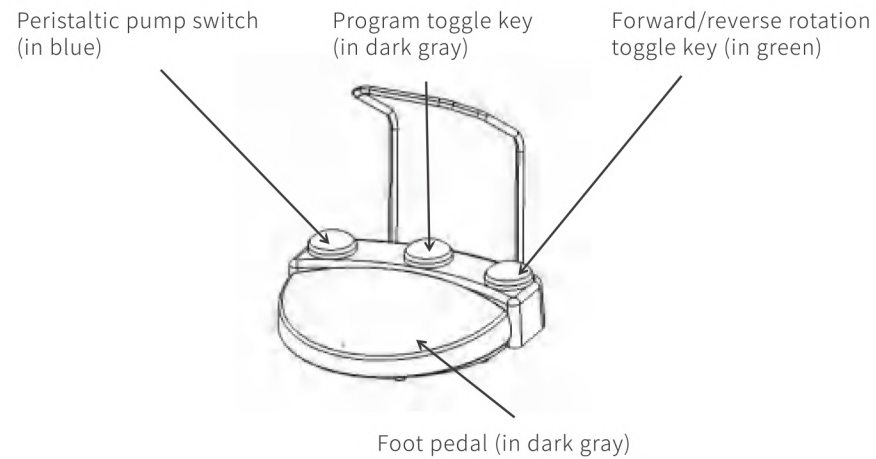
On/Off: Click the atomization icon to control atomized water to be on/off.

9) Program reading and writing

Reading: Click the read-write setting icon once to enter the recently stored setting program; click again to enter the next setting program to save the current interface setting program.

Writing: Press and hold the read-write setting icon for three seconds. When you hear a beep, write the parameters set on the current screen. (The upper left corner shows the program memory bit number)

6.1. How To Use Foot Pedal Switch



6.1.1 Blue key (peristaltic pump on/off) – left convex key

Press the blue key of the foot pedal switch to turn on or off the peristaltic pump.

6.1.2 Dark gray toggle key (program switching) – middle convex key

Step on the program toggle key to achieve the switching among different programs in turn.

6.1.3 Green forward/reverse toggle key (forward/reverse rotation) – right convex key

Press the forward/reverse toggle key to switch between the forward and reverse rotation modes of the motor.

When forward or reverse operation is selected, it can be seen a corresponding change in the direction of rotation displayed by the forward and reverse rotation icons.

This forward/reverse rotation switch can also be switched on the display screen by clicking the forward/reverse rotation icons.

6.1.4 Foot pedal “stepless speed change” function setting – middle big pedal

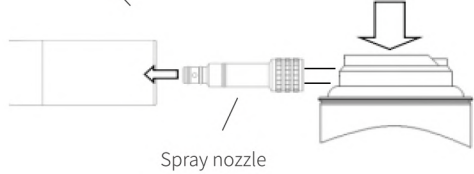
The speed of the motor increases or decreases as the foot pedal is depressed. The pedal motor can only work if the foot switch is pressed.

7. Cleaning, Disinfection And Sterilization (Involving Motor And Handpiece)

7.1 Cleaning, disinfection and sterilization before initial use and after each use:

Process	Process Stage	Relevant Aspect	Requirements	Cautions And Precautions
Whole Process	Whole Process	Whole Process	1. To prevent infection, please wear protective equipment such as goggles, masks, gloves, and protective clothing.	

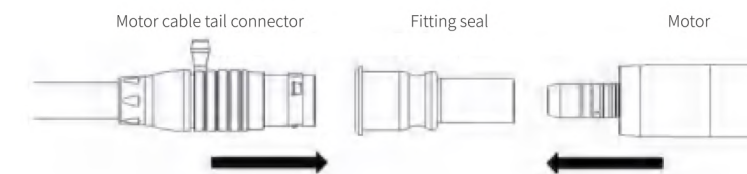
On-site preparation after use	Removal of contamination	Motor (including cables) disinfection	1. Please turn off the power supply. 2. Remove the motor (including cables) from the host. (Refer to 5.2.3 Assembly and disassembly of motor/motor cable) 3. After each use, use wet tissues for preliminary cleaning in time to remove obvious dirt. Screw one end of fitting seal into the motor wire connection, and install the other end of fitting seal to the insertion part of the motor guide sleeve (Refer to 7.2). 4. After removing obvious dirt, put it into special tray and send it to cleaning room in time.	Only wet tissues with no protein stabilization can be used.
		Handpiece disinfection	1. Confirm that the motor and handpiece have stopped running. 2. Remove the handpiece from the motor (Refer to 5.2.4 Assembly and disassembly of motor/handpiece). 3. After each use, use wet tissues for preliminary cleaning in time to remove obvious dirt. After removing obvious dirt, put it into special tray and send it to cleaning room in time	
	Preparation for transportation	Safe transportation of containers	The motor (including cables) (with fitting seal) and handpiece shall be transported in a tray to prevent falling and protect health care personnel.	The trays must be sterilized after use to prevent secondary contamination.
Preparation for cleaning	Preparation	Tool preparation	Prepare brushes, cotton swabs, absorbent cloths and rigid sterilization containers with vent holes.	/
Cleaning	Manual cleaning	Stains removal	1. Rinse with softened water (<38°C) and brush first, and clean this product to be sterilized with an absorbent cloth. a. Surface cleaning: Rotate the motor (including cables) and handpiece to clean the surface and remove any liquid residues with an absorbent cloth or brush until they are visually clean. b. Clearance and contact parts cleaning: Brush the gap between the motor (including cables) tail and handpiece tail back and forth repeatedly with a brush until there is no stain residue upon visual inspection, and then wipe it with an absorbent cloth. c. As for the handpiece bracket, directly rinse off the visible stains and wipe it with an absorbent cloth. d. Put the used wipes and gloves in the medical waste box and replace them with new ones. 2. Use enzyme cleaning agent and absorbent cloth to wipe and clean the motor (including cables) (with fitting seal), handpiece and handpiece bracket which have been cleaned in the first step to ensure that all gaps and accessible surfaces are cleaned by wiping. 3. Pay attention to the gap and groove, and press with a cotton swab stained with enzyme cleaning agent, and rotate to clean these areas until no stain residue can be seen on the swab. 4. Rinse again with softened water (<38°C) and brush. 5. Use sterile absorbent cloth to blot up and set it aside for a period of time to dry naturally. 6. If necessary, repeat the above steps until the product to be sterilized is thoroughly cleaned and has no visible stains.	During flushing, the motor connection port of motor and handpiece shall face down to avoid water from flowing into the motor. If there is water inside the handpiece, use a spray gun to spray air inward from the end of the handpiece to remove water. Do not place the motor and handpiece immersed in a liquid or in an ultrasonic cleaner. If the operator's vision is defective, it is recommended to wear suitable glasses when observing residual stains. Please observe the residue of stains in a bright environment.
Disinfection			Wear medical gloves and pour 75% medical alcohol over an absorbent cloth, wipe the surface of motor (including cables) (with fitting seal) for 3 times, last for 20 seconds each time at a room temperature of 20~30°C, set it aside for one minute after wiping to wait for alcohol to volatilize, and perform a visual inspection to confirm if there is no liquid.	

Maintenance/inside cleaning	Oil filling	For handpiece only	<p>Oil with cleaning lubricant. After the treatment of each patient or before high-pressure sterilization, please oil the handpiece with the following steps:</p> <ol style="list-style-type: none"> 1. Insert the spray nozzle into the cleaning lubricant nozzle. 2. Insert the spray nozzle into the end of the handpiece, hold the handpiece firmly, and spray oil for 2-3 seconds until the front end of the handpiece overflows. Fill oil repeatedly until no dirty oil is discharged from the front end. 3. When filling oil into the head of the handpiece (only applicable to the bending handpiece), please inject oil from the front end. <p>Example of oil filling: Straight/bending handpiece</p>  <p>Spray nozzle</p> <ul style="list-style-type: none"> · Do not reversely use cleaning lubricant. · Please hold the handpiece firmly. Otherwise, the handpiece may fly out or slip due to the pressure of oil filling. · Spray for cleaning until the oil mist is ejected from the front end of the handpiece head (about 2-3 seconds). · In order to discharge the excess oil inside the handpiece, please remove and set aside for about 15 seconds before idling. · Do not reverse the spray can. · Start this product for about 10 seconds after oil filling. · If you feel abnormal, don't repair it on site, please contact the dealer or manufacturer.
Drying	Blow drying		<p>Handpiece: Use a spray gun to inject air inward from the end of the handpiece for 30 seconds or a sterilized low-fiber floc cloth to dry until no visible liquid remain.</p> <p>Motor (including cables) and handpiece bracket: Use a pressure air gun to dry the surface or a sterilized low-fiber floc cloth to dry until no visible liquid remain.</p> <p>/</p>
Packaging	Packaging		<p>Put the motor (including cables) (with fitting seal), handpiece and handpiece bracket into sterilization pouch respectively and seal them. Only one set of motor (including cables) (with fitting seal) or handpiece and handpiece bracket is placed in one sterilization pouch.</p> <p>Sterilization pouches shall comply with ISO 11607-1:2006.</p>
Sterilization	Damp heat	Sterilization stage	<ol style="list-style-type: none"> 1. Perform high-temperature and high-pressure steam sterilization by pre-vacuum procedure according to the following method: (the durability specified in standard YY 0836-2011 shall be subject to sterilization at least 250 times. When using delicate motors (including cables) and handpiece, it is recommended to perform a maintenance after 250 times of sterilization or regularly once a year. 2. Timely clean and sterilize within the same day after use. 3. Perform high-temperature and high-pressure steam sterilization at 134°C and 220KPa for 5 minutes. 4. It is recommended that the sterilization load shall not exceed ten sets at a time, and it shall be tiled rather than stacking in the sterilizer. <p>The user shall establish the records and identifications of sterilization times and date in accordance with the instructions, standards and principles of the country (region).</p>

Storage	Storage	<ol style="list-style-type: none"> 1. It is suggested that the sterilized articles shall be stored in the storage rack or storage cabinet which shall be easy to be cleaned and not prone to rust in the storage room of sterile items; the storage environment shall be clean, bright, ventilated or with air purification device, with sufficient lighting; the temperature shall be 0°C~+60°C, the humidity shall be 8%RH~93%RH, and the air pressure shall be 700hPa~1060hPa. 2. Sterilized items shall be stored by classification in a relatively fixed storage position with clear identification. 3. After sterilization, the storage, marking and expiration date shall comply with the instructions, standards and principles of the country (region), and please follow the regulations of the hospital and clinic. 	<p>Please operate in accordance with the instructions, standards and principles of the country (region).</p>
---------	---------	---	--

7.2. Sterilization instructions

Only the motor (including cables) can be sterilized. The Company recommends to use autoclaves for sterilization. At initial use, or after the end of treatment for each patient, please follow 7.1 Cleaning, disinfection and sterilization before initial use and after each use to perform high-pressure sterilization. Parts that can be sterilized by high-temperature and high-pressure steam: motor (including cables), and fitting seal. Always put them in a high-pressure sterilization pouch before use, and keep in a place in a clean condition.



* EN13060 or ENISO17665-1 recommends to be sterilized at 134°C for not less than 5 minutes.

⚠ Attention

- Do not conduct high-temperature and high-pressure steam sterilization (or all high-temperature sterilization) on the host.
- Do not inject oil into the motor.
- Do not use oxidizing potential water (strong acid water, super acid water) or sterilized solution for cleaning, dipping and wiping this device, otherwise it may cause discoloration of plastic parts or corrosion of metal parts.
- If the surface is sterilized with fouling, rust may occur.
- When the O-ring of the motor head falls off, please replace it with a new O-ring (for protecting the motor) to avoid water from entering the motor and accordingly causing failure.
- * O-ring (for protecting the motor).

Handpiece bracket:

Use ordinary household detergent to clean the stains on the handpiece bracket, and sterilize it together with the motor.

Handpiece: Sterilize it before use, and follow 7.1 Cleaning, disinfection and sterilization before initial use and after each use to perform high-pressure sterilization.

8. Maintenance

The deterioration of the O-ring will make it difficult to install the handpiece accurately or cause water and air leakage, then replace the O-ring.

8.1. Replace the O-ring

Remove the deteriorated O-ring at the insertion part of the motor with a bur and other tools, and insert the new O-ring into the O-ring clamping groove.

O-ring (black): Product No. 315020

O-ring is a quick-wearing part, so it is recommended to replace it every six months.

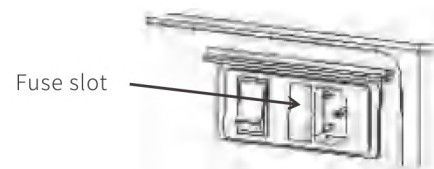


⚠️ Attentions

- There are three O-rings in total.
- If the O-ring deteriorates, the following phenomena may occur:
Water leakage, no effluent water, air leakage, no ventilation, shock, or difficulty of installing handpiece accurately.

8.2 Replacement of host fuse

The user can replace the fuse by himself or herself. The fuse slot is located near the power switch at the rear of this device.

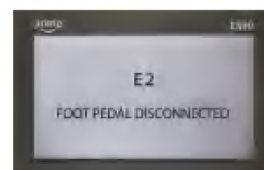


Remove the power plug, open the fuse slot with a screwdriver, and replace the fuse 1.6A 250V. Reinsert the fuse box into the fuse slot and reinsert the power plug.

9. Fault Description

Device protection:

This device has the function of fault self-diagnosis. When the system fails, the corresponding fault type will be displayed. When overload occurs, the motor unexpectedly blocks and the torque is greater than the nominal torque, or the buzzer emits a fault warning sound when fault occurs, and the fault code type will be displayed in the middle of the LCD screen as shown in the figure. The user can check and eliminate faults according to the fault information displayed on the fault status page. If the user can not eliminate the fault, the user shall promptly inform the manufacturer or designated sellers for maintenance.



Example of fault

Fault code	Fault description	Handling methods
E1	Over-voltage/under-voltage	<ol style="list-style-type: none"> 1. Disconnect the power switch. 2. Check whether the power supply voltage is within the range of 198V-242VAC. 3. Turn on the power switch again after confirmation.

E2	Foot pedal control error	Turn off the power supply of this device, check the plug connection of the foot pedal part, and restart it.
E3	Motor phase missing/short circuit	Check whether motor connection is in good condition, and power on again after connection.
E4	Motor stalling/over-loading	Power on again after eliminating the cause of motor stalling.

If there is any problem, please check it again before sending it for repair. If it does not comply with any of the above conditions or there is no improvement after inspection, please contact the seller. If external conditions cause an overall fault of this device, it must be switched off and then restarted.

10. After-sales Service

This product is delivered after strict quality management and inspection. If the fault occurs in normal use during the warranty period, it can be repaired free of charge in accordance with the warranty provisions of the Company. Fault or damage caused by errors in use or unauthorized modification shall be repaired with fee during the warranty period. The service life of this product stipulated by the Company is 5 years.

Such period shall be the period for product repairing. With the consideration of the precision of the Surgical Drive System, professional testing equipment is required, so the personnel rather than the manufacturer professionals or the professionals trained by the manufacturer shall not repair this product on site.

If you have any questions, please contact the after-sales service provider or the dealer.

11. Disposal Of Waste Products

The Company attaches special importance to the responsibility of environmental protection, and the design of the Surgical Drive System and its packaging shall be as environmentally friendly as possible.

Disposal of the Surgical Drive System control board, drive board and brushless direct-current motors.

Dispose of the old electrical equipment in accordance with the principles, standards and requirements of your country (region).

Ensure that the spare parts will not cause pollution during disposal.

Waste disposal of packaging materials.

All packaging materials are selected according to environmental protection standards, which can be recycled. Please send the old packaging materials to the relevant collection and reprocessing system. In this way, you contribute to the recycling of raw materials, thus avoiding waste.

12. Guarantee

From the date of purchase, the manufacturer will guarantee the quality of this product for a period of one year provided that it is used according to the methods and procedures described herein. Some consumables are not covered under warranty. However, in case of your improper operation or self-repairing or failure to follow the Instructions for Use, we will release any warranty liability or other statements.

13. Symbols

Description of symbols:

	Disposal of waste products and accessories in accordance with the "Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU)"		Manufacturer
	Please consult and follow the Instructions for Use		Type BF applied part
	Compliance with MDD 93/42/EEC		Classification by degree of protection against inlet fluid
	The maximum high-pressure sterilization temperature of 134°C		
	External identification of device or device parts, indicating the presence of RF transmitters or the use of RF electromagnetic energy for diagnosis or treatment		
	Representation of safety cautions and precautions and hazard matters		Warnings and attentions
	Protectively earthed		Off
			On
	Foot pedal		Procedure
	Atomization		Reverse rotation
			Forward rotation
	Lighting		Reading and writing
			Class I: type of anti-electric shock: Class I equipment
	Fragile, handle with care		Upward
			No rain
	Packaging material recycling mark		Humidity limit
			Atmospheric pressure limit
	Temperature limit		Date of use
			Date of manufacture
	Please refer to the Instructions for Use		Serial No.
			EU authorized representative

T1.6AH/250V Fuse Hanging weight limited to 1.5kg: Maximum hanging weight of foot pedal hook and support bar

14. Emc Information (Electromagnetic Compatibility Information)

⚠ Caution:

· (Surgical Drive System) should comply with the relevant requirements of electromagnetic compatibility in Standard YY0505-2012.

- The user should install and use the EMC information provided in the random file.
- Portable and mobile RF communication equipment may affect the performance of (Surgical Drive Systems) and avoid strong electromagnetic interference when used, such as proximity to handpiece, microwave ovens, etc.;
- The guidelines and manufacturer statements are detailed in the attachment.

⚠ Caution:

- (Surgical Drive System) should not be used close to or stacked with other equipment. If it must be close or stacked, it should be observed and verified that it can operate normally in the configuration in which it is used.
- Except the transducers and cables sold by the manufacturer of (Surgical Drive System) as spare parts of internal components, the use of accessories, transducers and cables other than those specified may lead to the increase of emission or the decrease of noise immunity.

Serial number	Name	Cable length (m)	Shielded or not
1	power wire	1.5	No
2	Foot pedal connecting wire	2.8	Yes
3	Pipe body components	2.0	No

Annex:

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The purchaser or user of (Surgical Drive System) should ensure that it is used in the electromagnetic environment specified below:		
Emission test	Compliance	Electromagnetic Environment – guidance
GB4824 RF emission	Group 1	(Surgical Drive System) uses RF energy only for its internal function. As a result, its RF emissions are very low and may not cause any interference to nearby electronic devices.
GB4824 RF emission	Category B	(Surgical Drive System) is suitable for use in all facilities, including domestic and directly connected to the home for the residential public low-voltage power supply grid.
Gb17625.1 Harmonic emission	Category A	
GB17625.2 Voltage fluctuation/flicker emission	Compliance	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The purchaser or user of (Surgical Drive System) is intended for use in the electromagnetic environment specified below, and the purchaser or user of (Surgical Drive System) should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) GB/T 17626.2	± 6kV contact discharge ± 8kV air discharge	± 6kV contact discharge ± 8kV air discharge	The ground should be wood, concrete or ceramic tiles, and if covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient pulse group GB/T 17626.4	± 2kV to power wire	± 2kV to power wire	Grid power should be of quality typical in commercial or hospital settings.
Surge GB/T 17626.5	± 1kV wire-to-wire ± 2kV wire to ground	± 1kV wire-to-wire ± 2kV wire to ground	Grid power should be of quality typical in commercial or hospital settings.
Voltage sag, short-term interruption and voltage change on the input line GB/T 17626.11	<5% U _T lasting for 0.5 week (>95% dipping on U _T) 40% U _T lasting for 5 weeks (60% dipping on U _T) 70% U _T lasting for 25 weeks (30% dipping on U _T) <5% UT lasting for 5s (> 95% dipping on U _T)	<5% U _T lasting for 0.5 weeks (>95% dipping on U _T) 40% U _T lasting for 5 weeks (60% dipping on U _T) 70% U _T lasting for 25 weeks (30% dipping on U _T) <5% U _T lasting for 5s (>95% dipping on U _T)	Grid power should be of quality typical in commercial or hospital settings. If the user of the (Surgical Drive System) requires continuous operation during a power outage, and it is recommended that the (Surgical Drive System) should be powered from an uninterruptible power supply or battery.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m	The power frequency magnetic field should have the horizontal characteristics of power frequency magnetic field in typical places in typical commercial or hospital environment.


Note: U_T refers to alternating-current network voltage before test voltage is applied.

Recommended separation distances between portable and mobile RF communication equipment and (Surgical Drive Systems)

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The purchaser or user of (Surgical Drive System) is intended for use in the electromagnetic environment specified below, and the purchaser or user of (Surgical Drive System) should ensure that it is used in this electromagnetic environment:

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic Environment - Guidance
RF conduction GB/T 17626.6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should not be used closer to any part (Surgical Drive System) than the recommended isolation distance, including cables. This distance should be calculated by the formula corresponding to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz
RF radiation GB/T 17626.3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Where <i>P</i> is the maximum output rated power of the transmitter in watts (W) and <i>d</i> is the recommended separation distance in meters (m) based on the maximum output rated power of the transmitter provided by the transmitter manufacturer. ^b

			The field strength of the fixed RF transmitter is determined by ^a survey of the electromagnetic field and should be lower than the compliance level at each frequency range ^b . Interference may occur near equipment marked with the following logo. 
--	--	--	---

Note 1: At the frequency of 80MHz and 800MHz, the higher frequency band formula is used.

Note 2: These guidance may not be applicable in all cases where electromagnetic propagation is affected by absorption and reflection by buildings, objects and human bodies.

- a. Fixed transmitter field strengths are strong, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts and television broadcasts, whose field strengths cannot be theoretically accurately predicted. To assess the electromagnetic environment of a fixed RF transmitter, a survey of electromagnetic fields should be considered. If the measured field strength in the location (Surgical Drive System) is higher than the RF compliance level for the above application, observe (Surgical Drive System) to verify proper operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning (Surgical Drive Systems).
- b. In the whole frequency range of 150KHz~80MHz, the field strength should be lower than 3V/m.

(Surgical Drive Systems) are intended for use in an electromagnetic environment where radiated RF disturbances are controlled. Depending on the maximum output power of the communications equipment, the purchaser or user of (Surgical Drive Systems) can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and (Surgical Drive Systems) as recommended below.

Rated maximum output power of transmitter/W	Isolation distance of different frequency of transmitter/m		
	150kHz~80MHz $d = 1.2 \sqrt{P}$	80MHz~800MHz $d = 1.2 \sqrt{P}$	800MHz~2,5GHz $d = 2.3 \sqrt{P}$
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 rated maximum output power of transmitters not listed in the table above, the recommended separation distance *d*, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where *P* is the maximum output rated power of the transmitter provided by the transmitter manufacturer in watts (W).

Note 1: At the frequency of 80MHz and 800MHz, the formula for the higher frequency range is used.

Note 2: These guidance may not be applicable in all cases where electromagnetic propagation is affected by absorption and reflection by buildings, objects and human bodies.

15. Storage And Transportation

1. This device shall be handled with care to avoid vibration. The installation and storage environment shall be dry and cool. The storage and transportation temperature shall be 0°C~+60°C; the humidity during storage shall be

- 8%RH~93%RH, and the air pressure shall be 700hPa~1060hPa.
- 2. The working temperature shall be 10°C~30°C; the working humidity shall be 15%RH~80%RH, and the air pressure shall be 860hPa~1060hPa.
- 3. Don't place it together with toxic, corrosive, volatile, inflammable and explosive objects.
- 4. Avoid vibration and impact during transportation and place it carefully.

16. Inspection And Replacement Cycle Of Consumables

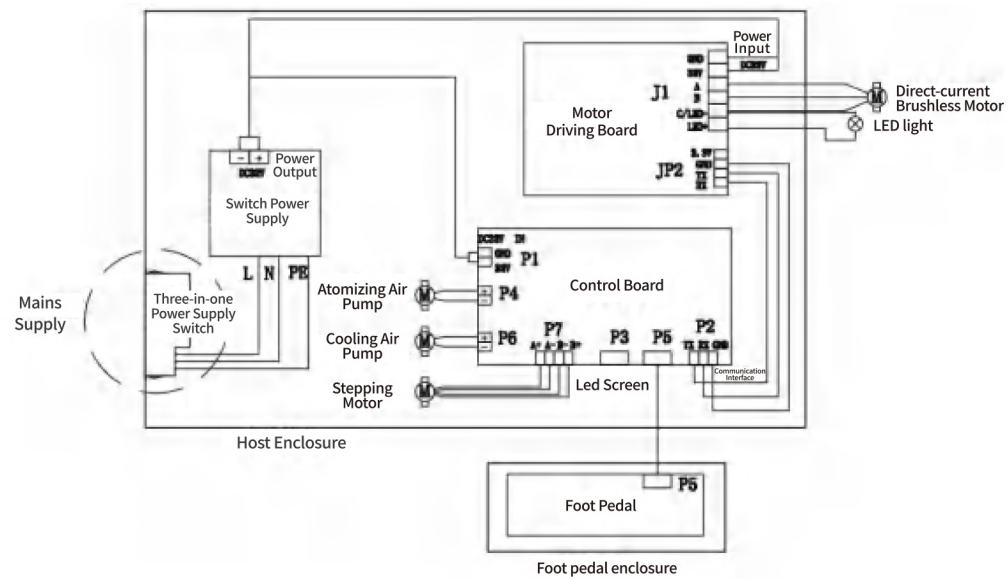
The function and safety inspection must be carried out on a regular basis and at least every one year (unless a shorter inspection period is prescribed by law). This inspection must be performed by a qualified professional organization and must include the following procedures:

- Visually check whether the external surface of this device is damaged.
- Measure whether this device has leakage current.
- Visually check whether there is safety problem on internal parts. For example, mechanical damage to the enclosure or indication of overheating.
- Carry out a functional test to check whether the maximum speed can be reached.
- It is suggested that only authorized exquisite service partners can carry out service and overhaul. This product cannot be repaired on site.

The replacement cycle of consumables is as follows:

Name	Replacement cycle	Replacement method
O-ring	Half a year	Send it to the after-sales service provider or be replaced by the cooperative agent appointed by Guangdong JINME Medical Technology Co., Ltd.

17. Circuit Connection Diagram



Product Name: Surgical Drive System
 Model/Specification: ES90、ES70
 Medical Device Registration Certificate No. /Technical Requirements No.: YXZZ 20232010876
 Production License No.: YSYJXSCX 20101883
 After-sales service provider: Guangdong JINME Medical Technology Co., Ltd.
 Date of production: as shown in the Certificate of Conformity
 Service life: 5 years or 600 times of sterilization for motor (including cables), handpiece, whichever comes first
 Date of preparing the Instructions for Use: December 22, 2020
 Date of revising the Instructions for Use: April 24, 2023