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Eighteeth

CE



Fast-Pack

USER MANUAL

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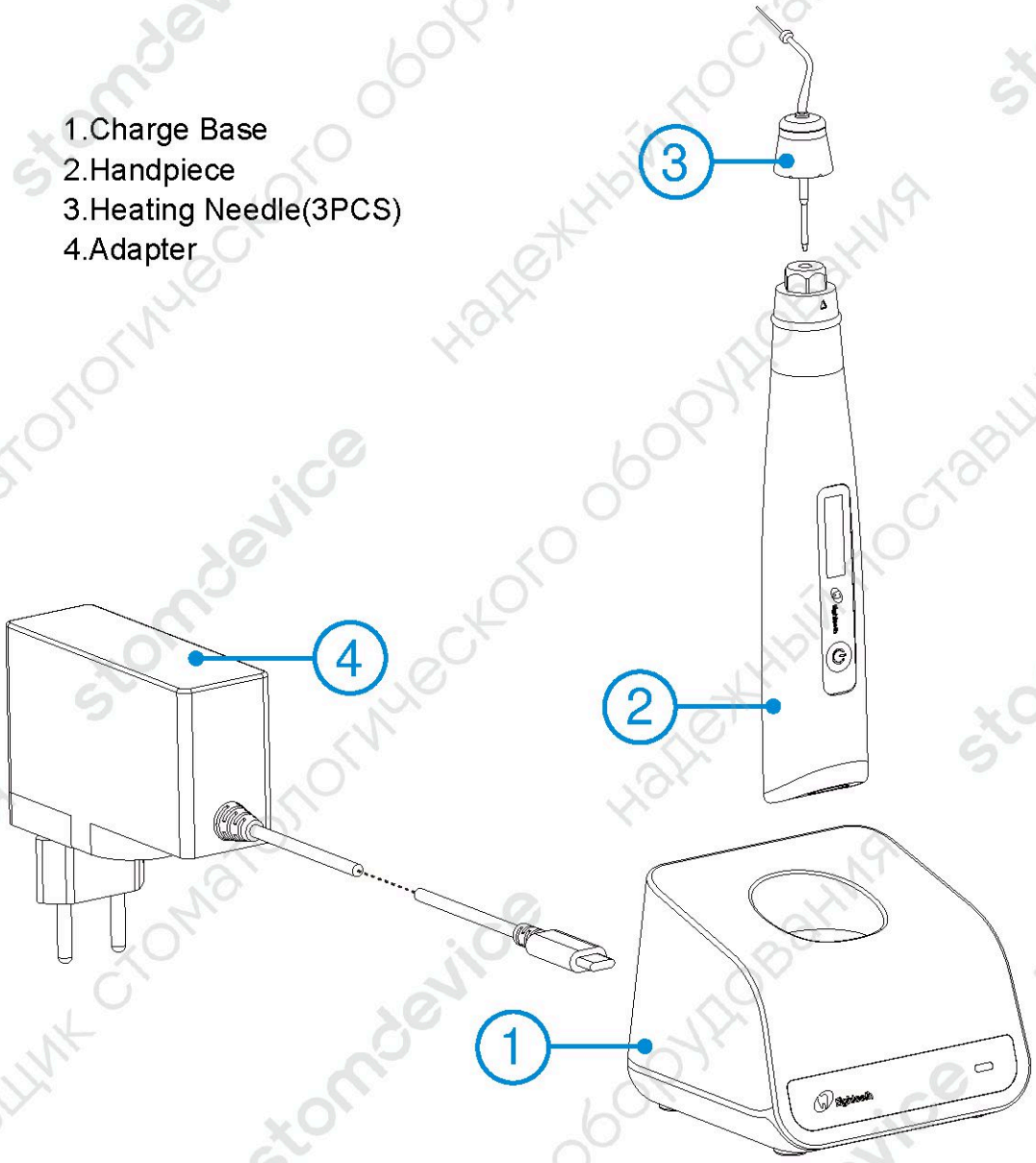
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1. Scope of Fast-Pack

1.1 Parts Identification

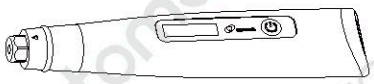
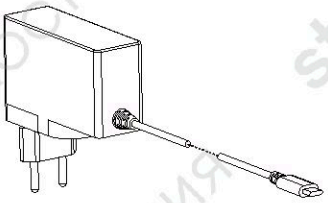
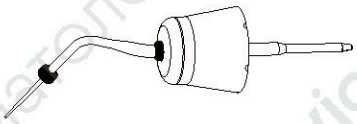
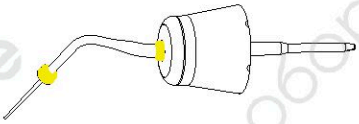
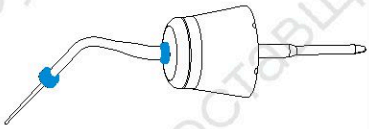
1.Charge Base
2.Handpiece
3.Heating Needle(3PCS)
4.Adapter



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1.2 Components and Accessories

Fast-Pack Handpiece (1pcs) Part No. 6351001 	Charge Base (1pcs) Part No. 6351003 	Adapter (1pcs) Part No. 6316001+ 6316005 
Heating needle S (1pcs) Size: 40/0.025 Color: Black Part No. 6351006 	Heating needle M (1pcs) Size: 50/0.05 Color: Yellow Part No. 6351007 	Heating needle L (1pcs) Size: 60/0.06 Color: Blue Part No. 6351008 

1.3 Options (sold separately)

Handpiece Base Part No. 6005002 

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2. Symbols used in the User Manual

WARNING	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
NOTE	Additional information, explanation of operation and performance.
SN	Serial number
REF	Catalogue number
	Manufacturer
	Date of manufacture
LOT	Lot of manufacture
	Class II equipment
	Type B applied part
CE	CE marking
	Direct current
	WEEE directive marking
	Keep dry
134℃	Can be autoclaved up to a maximum temperature of 134° Celsius
EC REP	Authorized Representative in the European Community
55℃ -20℃	Temperature limitation
80% 20%	Humidity limitation
106kPa 70kPa	Atmospheric pressure limitation
Eighteeth	Manufacturer's LOGO
	Consult instructions for use
	Washer-disinfector for thermal disinfection

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3. Before Use

3.1 Intended Use

Fast-Pack is intended for heating and cutting Gutta-percha outside the mouth during root canal treatment.

This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

3.2 Contraindications

This device must not be used in cases where a patient has been fitted with an implanted heart pacemaker (or other electrical equipment) and has been cautioned against the use of small electrical appliances (such as electric shavers, hair dryers, etc.)

Safety and effectiveness have not been established in pregnant women and children.

WARNING

Read the following warnings before use:

1. Do not use this device for any dental procedure other than root canal obturation.
2. Do not use the device in the presence of free oxygen, flammable anesthetic gas mixtures or flammable substances.
3. The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
4. Thermal hazard risk exists for patients.
5. Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
6. The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls, portable or mobile RF communication devices and do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.
7. Gloves and a rubber dam are compulsory during treatment.
8. If irregularities occur in the device during treatment, switch it off. Contact the agency.
9. Never open or repair the device yourself，otherwise, void the warranty.

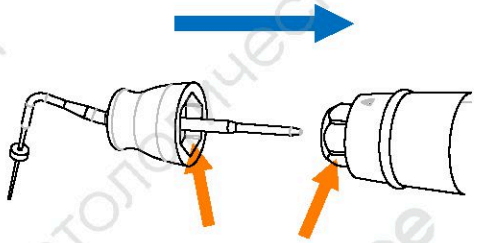
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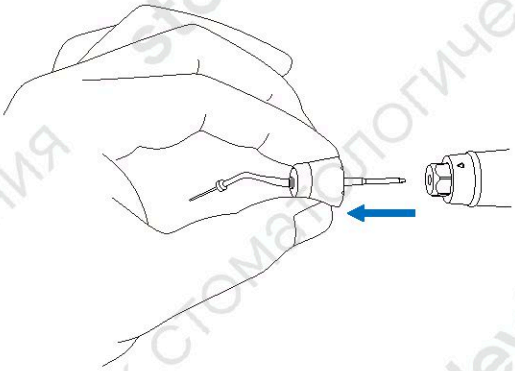
4. Installing the Fast-Pack

4.1 Installation of heating needle

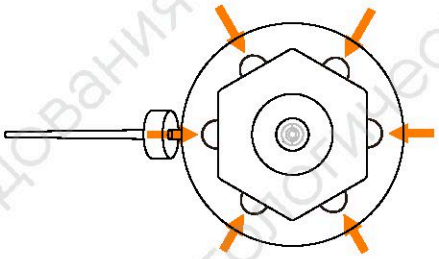
Make sure the inner hexagon notch on heating needle is aligned with the outer hexagon boss on handpiece, push till to position.



Holding the grey shell to pull the heating needle out from the handpiece.

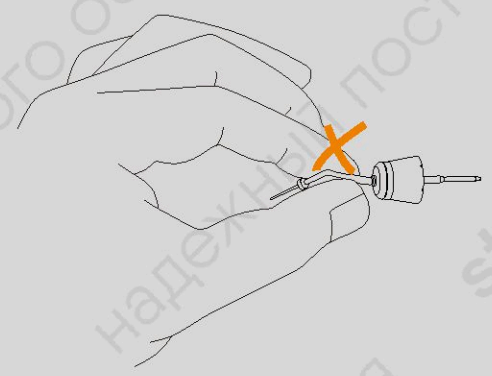


The heating needle can be installed in any one of 6 orientations. Pull it out from handpiece then can be installed in other orientations.



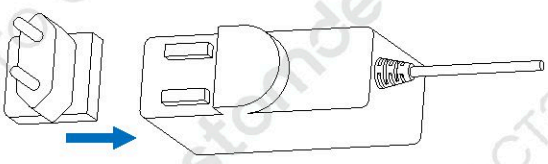
WARNING

- To remove the heating needle, wait for it to cool down, it takes about 2-3 seconds, and real-time temperature will show on the screen.
- Even the heating needle cool down already, we strongly recommend not touch the metal part on heating needle, there is a risk of heat injure or damage the heating needle, hold the grey shell to remove.



4.2 Installation of adapter

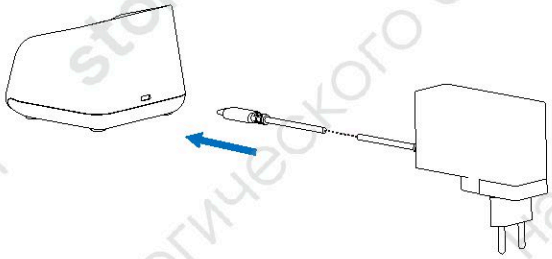
Plug the head into the base if they are separated in the package.



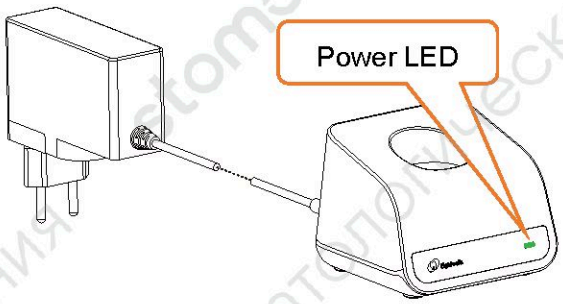
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4.3 Connecting charge base

Plug the USB of adapter into the charge base, and plug the other end into a power outlet.



The Power LED on charge base will light up.



NOTE

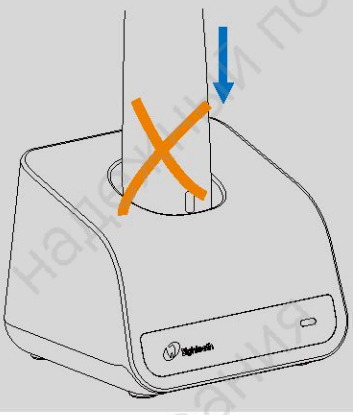
Only the original adapter could be used.

Put the handpiece all the way into the charge base, the charge state will show on the screen.

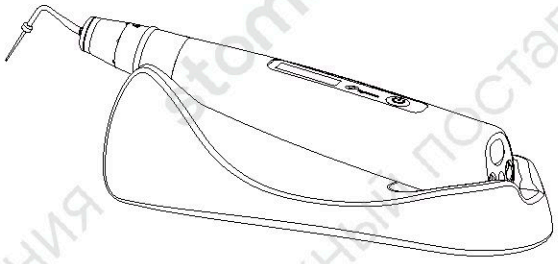


NOTE

Put the handpiece into the charge base in the right direction, otherwise the handpiece will not be charged.



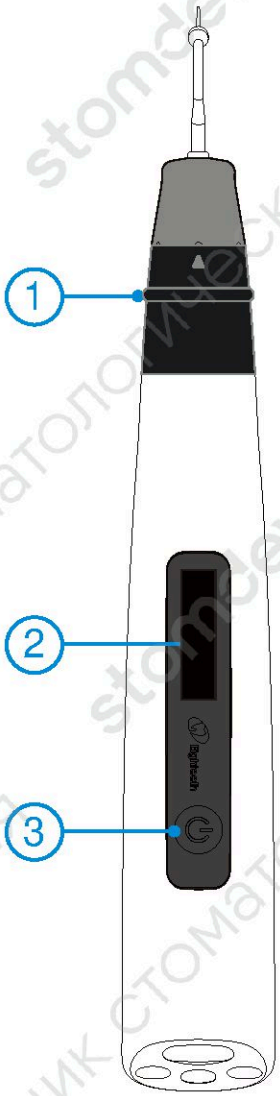
If only need a base to put the device on dentist element of dental chair (without charge function), handpiece base is recommended to use instead of charge base.



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5.Use Interface



① Main switch

② Display Screen

③ Power switch

Turn Power On

Long press

Change Memory

Shot press to change temperature memory from T1 to T5

Memory Parameter Setting

During standby state, holding down press then press in 2 seconds to entry memory parameter setting, parameter of T1 to T5 can be set independently

Heating

Long press

Turn Power Off

Long press more than 2 seconds

Advanced setting

During power off state, holding down press then press to entry advanced setting, Press till target setting, press to adjust, then press to confirm

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6.Setting

6.1 Memory Parameter Setting

	Fast-Pack has 5 memory programs, press ⏻ to change during standby state, the memory number T1 will change according.
	During any Memory, holding down press ⏻ then press O in 2 seconds, the “Temperature” of this memory can be change. Press O till target temperature, the temperature can be set from 90℃ to 250℃. press ⏻ to confirm.
	Press ⏻ again, the “Keep-heat Time” of this memory can be change. Press O till target time, the time can be set 3, 5, 8 and 10 seconds. press ⏻ to confirm.
	Press ⏻ again, the “CoolingDisplay” of this memory can be change. Press O till target time, the time can be set 0, 3, 5 and 10 seconds. press ⏻ to confirm.

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6.2 Advanced Setting

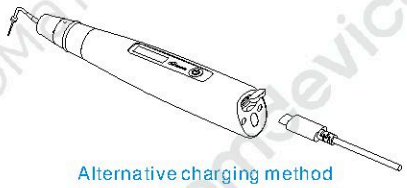
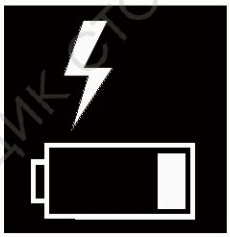
AutoPowerOff 5 Min	During power off state, holding down press  then press  to entry advanced setting, the "AutoPowerOff" will appear on the display screen. Press  to adjust, the auto power off time can be set 5, 10 and 15 minutes press  to confirm.
Beep Volume Vol 1	Press  again, the "Beep Volume" can be change, press  to adjust, the "Beep Volume" can be set 0, 1 and 2. press  to confirm.
RestoreSettings NO YES	Press  again, the "RestoreSettings" can be change, press to adjust, press  to confirm. **NOTE** If choice "YES", all the setting parameters will be covered by factory settings.
Save NO YES	Press  again, confirm the setting need to save or not, press to adjust, press  to save and power off.

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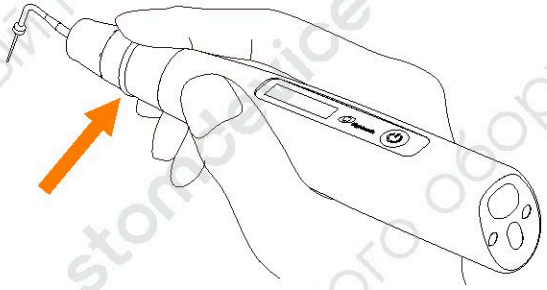
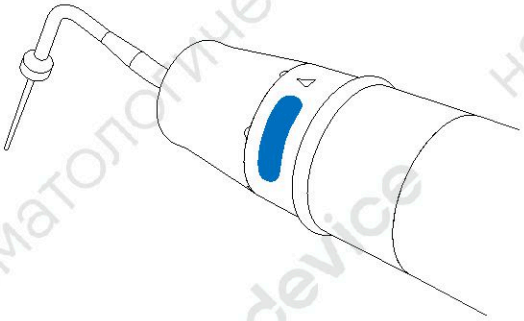
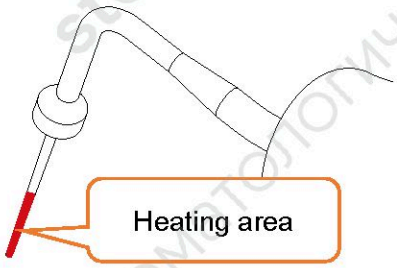
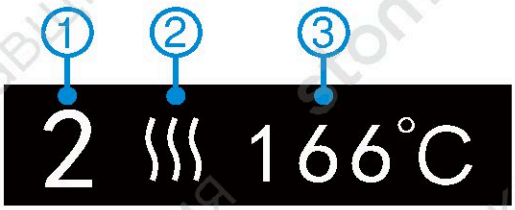
7.Operation

7.1 Charge

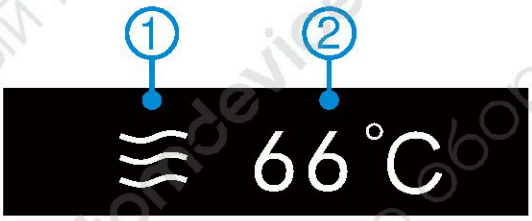
	Displays the present remaining amount of the battery. Less than 15% remains, please charge.
	NOTE If the power if less than 15%, must be recharged within 30 days, otherwise the battery will be damaged.
 Alternative charging method	Charge without charge base also available, using adapter connect to handpiece directly, the charge state will show on the screen. Charge with charge base is recommended **(See chapter 4.3 Connecting charge base)**. **NOTE** Only the original adapter could be used.
	Charging indication appears on the screen, and flashes slowly, when battery is fully charged or in a state near full charge, the flash will stop. Fully charged will take about 4 hours, depending on residual battery power and battery state. It can be recharged 300-500 times, depending on the operating conditions of the device. **WARNING** Do not change the battery, only trained technician or distributor can change the battery, the electronic parts will be damaged if use a wrong battery or install with a wrong way.

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7.2 Heating

	Press and hold the raised ridge on the ring switch to heat the heating needle.
	The indicator LED lights up during heating.
	Only the end of heating needle (about 4-5mm) will be heated, use this area to cut the gutta percha.
	① The “Keep-heat Time” will display on screen, When the set time is reached, heating process will switch off. ② Heating indication ③ Real time heating temperature

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	Release your finger from the ring switch, the heating needle will be cooling. ① the cooling indication will appear. ② Real time temperature of cooling heating needle will appear. When the set time of “CoolingDisplay” is reached, will change to standby interface.
	If the heating needle isn’t installed properly, or the heating needle broken, the “Tip error” will appear.

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8.Maintenance

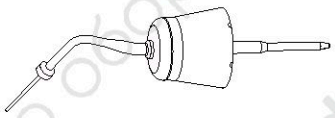
8.1 Foreword

The parts for clinical application contamination are the outer surfaces of the heating needle. For hygiene and sanitary safety purpose, the components (heating needle) must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent uses.
Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

8.2 General recommendations

- The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.
- The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
- Thoroughly clean and wash the components before autoclaving.
- Do not clean the cartridge with an ultrasonic cleaning device.
- Do not use bleach or chloride disinfectant materials.

8.3 Autoclavable Components

Autoclavable Components		
Heating needle		
WARNING ● Only the components above can be autoclaved. ● Before first use and after each use, sterilize the above components. ● Must be autoclaved after use for each.		
STEP NO.	**INSTRUCTIONS**	
1	Initial	Immediately after using, wipe gross contaminations

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	treatment at point of use	from the components, and put them in container for transportation. Prepare the components directly after treatment. **WARNING** Do not submerge the components or wipe them with any of the following functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agents to the components.
The following Step 2 to Step 4 are operated in a washer-disinfector: **WARNING** ● Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly. ● Follow instructions and observe concentrations given by the manufacturer (see general recommendations). ● Sufficient rinsing step should be available in purified water (max 10 germs/ml and max 0.25 endotoxin units/ml) ● Avoid any contact between the cartridge and any instrument, kit, support or container. ● Make sure the components are dry before moving to the #5 step.		
2	Cleaning: Automated	Carefully put the components (Heating needle) into the washer-disinfector and set the parameters as follows: - Pre-cleaning: water temperature <30℃, 2 min; - Cleaning: water temperature 45℃, 5 min; use an enzyme detergent solution (mild and aldehyde free solution) which is suitable to be used with washer-disinfector, and use in accordance with the IFU of the detergent solution manufacturer; - Rinsing: water temperature 45℃, 1 min (rinsing twice).
3	Disinfection: Thermal	Thermal disinfection at least 5 min at 90℃/194° F, make sure A0 value≥3000. Rinse with purified water at 70°C for 1 minute.
4	Drying	Heat: 20min, 90℃/194° F

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5	Maintenance and Inspection	Inspect components and sort out those with defects. Dirty components must be cleaned and disinfected again.
6	Packaging	Pack each component in a separate steam-sterilization pouch. **WARNING** ● Check the validity period of pouch given by the manufacturer to determine the shelf life. ● Use pouches which resist to a temperature up to 141℃(286°F) and in accordance with EN ISO 11607.
7	Sterilization	Steam sterilization at 134℃ at least 6 minutes. Minimum drying time after sterilization: 10 minutes. **WARNING** ● Use only approved autoclave devices according to EN 13060 or EN 285. ● Use a validated sterilization procedure according to ISO 17665. ● Respect the maintenance procedure of the autoclave device given by the manufacturer. ● Use only this recommended sterilization procedure. ● Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycles parameters). ● The sterilization procedure must comply with ISO 17665. ● Waiting for cooling before touching.
8	Storage	Keep the components in sterilization packaging in a dry and clean environment. **WARNING** ● Sterility cannot be guaranteed if packaging is open, damaged or wet. ● Check the packaging before using it (packaging integrity, no humidity and validity period).

NOTE

Heating needle head is easy to damage by external force, take care during maintenance.

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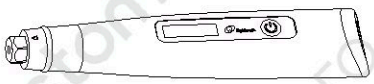
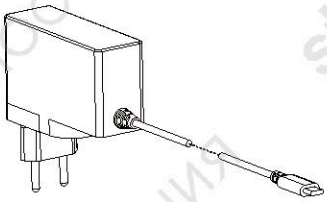
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The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

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8.4 Disinfection components

Disinfection components		
Fast-Pack Handpiece 	Charge Base 	Adapter 
Handpiece Base 		
Wipe the components with a piece of gauze that has been dampened with Ethanol for Disinfection (Ethanol 70 to 80 vol%) and wrung out thoroughly.		
NOTE ● Do not use anything except Ethanol for Disinfection (Ethanol 70 to 80 vol%). ● Do not use too much ethanol as it's going into machine and damage the components inside. Do not spray any liquid directly on the handpiece. Do not allow any moisture to get into the handpiece.		

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9.Troubleshooting

When trouble is found, check the following points before contacting your distributor. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your distributor.

Problem	Cause	Solution	Ref. chap
The power is not turned on.	The battery is flat.	Charge the battery.	7.1
	Press the power switch too short time.	Long press the power switch.	5
The power LED on charge base does not light.	Using a wrong adapter.	Use the original adapter.	4.3
	The adapter is not connected.	Check the connection.	4.3
	The plug of the adapter is not inserted into the outlet.	Check the connection.	/
	There is no electricity in the outlet.	Check the connection.	/
No charge indicator flash on handpiece screen	Put the handpiece into the charge base in the wrong direction.	Check the direction.	4.3
	Charge pin of charge base unable to rebound.	Remove debris which between move part and base of the charge pin.	/
	Contactors are dirty.	Cleaning the surface of contactors.	/
	The charge base broken.	Using adapter connect to handpiece directly, and Contact your distributor.	/
Handpiece screen does not appear	The handpiece broken.	Check if there is a sound of beep or motor, and Contact your distributor.	/
No sound.	Beep volume set to 0.	Set beep volume to 1, 2 or 3.	6.2

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10.Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co.,Ltd
Model	Fast-Pack
Dimensions	23cm x 17cm x 8cm±1cm (Outer box)
Weight	1kg±10%
Power supply	Lithium ion battery: 3.63V, 2600mAh, ±10%
Charger power supply	AC 100-240 V, ±10%
Charger power output	6V⎓3A
Frequency	50/60Hz, ±10%
Temperature	90℃~250℃
Electrical safety class	Class II
Applied part	B
Operating conditions	Use: in enclosed spaces Ambient temperature: 5°C / 40 °C Relative humidity: <80% Operating altitude < 2000m above sea level
Transport and storage conditions	Ambient temperature: -20 °C / +55 °C Relative humidity: 20% - 80 % Atmospheric pressure: 70kPa-106kPa

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11.EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The **Fast-Pack** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Fast-Pack** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **Fast-Pack** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **Fast-Pack** 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 purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The **Fast-Pack** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Fast-Pack** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±2, 4, 6 kV contact ±2, 4, 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

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Electrical fast transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable Not applicable	The test is applicable since the EUT does not have AC/DC power ports and signal/ interconnecting cable longer than 3m.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable Not applicable	The test is not applicable since the EUT does not have AC power port.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<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	Not applicable Not applicable Not applicable Not applicable	The test is not applicable since the EUT does not have AC power port.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity
The **Fast-Pack** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Fast-Pack** should assure that it is used in such an environment.

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Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V V/m 3.5 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **Fast-Pack**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended 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 in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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 be absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for ratio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated 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 **Fast-Pack** is used exceeds the applicable RF compliance level above, the **Fast-Pack** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating the **Fast-Pack**. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.			

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Recommended separation distances between portable and mobile RF communications equipment and the Fast-Pack.

The **Fast-Pack** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Fast-Pack** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Fast-Pack** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** 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 800 MHz, the separation distance for 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 and people.

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12.Statement

Service Life

The service life of Fast-Pack series products is 3 years.

Maintenance

MANUFACTURE will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Disposal

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. The lithium batteries are disposed as special refuse. Please deal with them according to the local environmental protection laws and regulation.

Rights

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to CHANGZHOU SIFARY MEDICAL TECHNOLOGY CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by SIFARY, any copy or fake product must take legal responsibilities.

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