

Space-Pack

USER MANUAL

P/N: IFU-6335203

Version: 01

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Size: 85mm×119mm

Content

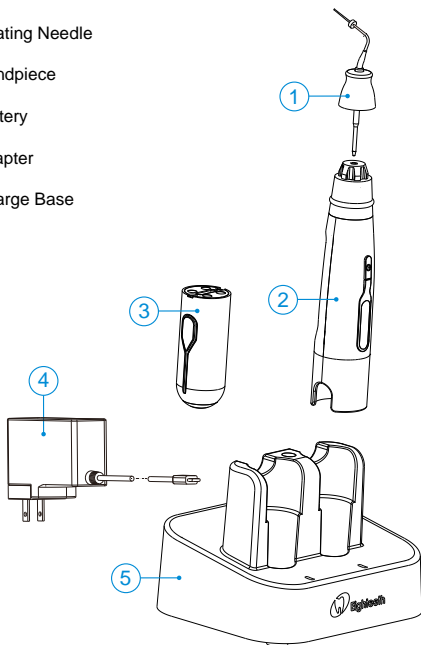
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1. Scope of Space-Pack




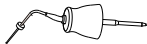


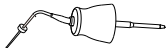

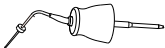
1.1 Parts Identification

- ① Heating Needle
- ② Handpiece
- ③ Battery
- ④ Adapter
- ⑤ Charge Base






1 Scope of Space-Pack

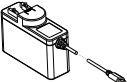
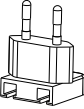

1.2 Components

<p>Handpiece (1 pc)</p> 	<p>Charge Base (1 pc)</p> 	<p>Battery (2 pcs)</p> 
<p>Heating Needle 40 (1 pc) Size: $\varnothing 0.4\text{mm}$</p> 	<p>Heating Needle 45 (1 pc) Size: $\varnothing 0.45\text{mm}$</p> 	<p>Heating Needle 50 (1 pc) Size: $\varnothing 0.5\text{mm}$</p> 
<p>Heating Needle 35 (1 pc) Size: $\varnothing 0.35\text{mm}$ (Optional accessories)</p> 	<p>Heating Needle 55 (1 pc) Size: $\varnothing 0.55\text{mm}$ (Optional accessories)</p> 	<p>Heating Needle 60 (1 pc) Size: $\varnothing 0.6\text{mm}$ (Optional accessories)</p> 

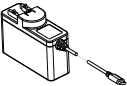


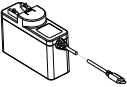

1 Scope of Space-Pack

<p>Heating Needle 90 (1 pc)</p> <p>Size: $\phi 0.9\text{mm}$</p> <p>(Optional accessories)</p> 	<p>Heating Needle 120 (1 pc)</p> <p>Size: $\phi 1.2\text{mm}$</p> <p>(Optional accessories)</p> 	<p>Heating Needle 150 (1 pc)</p> <p>Size: $\phi 1.5\text{mm}$</p> <p>(Optional accessories)</p> 
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For different regions, there are several different adapter options to be selected as follows.

Standard	Adapter	Power plug
<p>European standard</p> 	<p>Adapter (1 pc)</p>	<p>European standard power plug (1 pc)</p> 
<p>Multi-standard</p>	<p>Adapter (1 pc)</p>	<p>British standard power plug (1 pc)</p> 











1 Scope of Space-Pack

		Australian standard power plug (1 pc) 
		Argentina standard power plug (1 pc) 
American standard	Adapter (1 pc) 	American standard power plug (1 pc) 

2. Symbols used

	General warning sign
	Caution
	Serial number
	Catalogue number
	Batch code
	Medical device
	Manufacturer
	Country of manufacture
	Class II equipment
	Type B applied part
	Do not reuse
	Caution, hot surface
	Washer-disinfector for thermal disinfection

2 Symbols used

	Direct current
	Alternating current
	Keep dry
	Dispose of in accordance with the WEEE directive
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Consult instructions for use
	Manufacturer's Logo

3. Before Use

3.1 Scope of application

Space-Pack is intended for warming and softening gutta-percha master cones and searing off gutta-percha cones.

This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in the oxygen-rich environment.

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.



Before use, please read the following instructions carefully:

- You should carefully read and understand all the contents of the manual before operating.
- All warnings and instructions on the equipment should be followed during operation.
- The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
- Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
- Do not use this device in environments with free oxygen, anesthetic gases, or flammable materials. This device must be operated, used, and stored in a safe environment. Do not use this device in an oxygen rich environment.
- This device may cause radio interference or disrupt the operation of nearby devices. At this point, the orientation or placement should be readjusted and shielding should be set up in close proximity to the equipment to minimize its interference impact. The electromagnetic radiation emitted by this device complies with relevant regulatory requirements.
- This device requires special precautions regarding electromagnetic compatibility (EMC).

3 Before Use

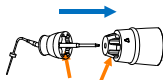
Do not use this device near strong fluorescent lamps, wireless transmitters, remote control devices, handheld and mobile high-frequency communication devices.

- Do not charge, use, or store this device at high temperatures. Please pay attention to the usage and storage conditions.
- Gloves and rubber barriers must be used during treatment procedures.
- Please do not disassemble or repair this device without authorization, otherwise it will automatically lose its warranty qualification.
- If any abnormal phenomena occur during the treatment process, please immediately shut down the device and contact the local dealer for handling.
- If the battery leaks, please stop using it immediately and contact your local dealer for assistance.
- Do not use accessories outside of our company, otherwise it may cause damage to the product. If any problems occur when using accessories outside of our company, our company will not be responsible.
- Prohibit the use of non-original accessories.
- Severe impacts, such as falling from a high position, may cause equipment damage. To prevent equipment damage, please avoid it from being hit or accidentally dropped.
- Do not use this device for treatments other than root canal filling.
- Do not spray alcohol or touch the connection interface with conductive objects.
- Ensure that the charging interface is dry and free of liquid inside during charging.
- Do not place this device in places where it is difficult to operate and disconnect the device.
- To ensure stable operation of the equipment, it is recommended to contact the dealer annually for equipment maintenance.
- Do not load and use the device for a long time. Otherwise, the temperature of the equipment will increase, which may cause minor burns to the operator or patient.

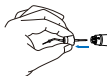
4. Installing the Space-Pack

4.1 Installing the Heating Needle

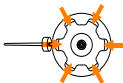
Make sure the hexagon plum blossom groove on heating needle is aligned with the hexagon plum blossom boss on handpiece, push till to position.



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.



- After the operation is completed,

wait for the heating needle to cool down and remove it in time. The cooling process takes about 2-3 seconds, and the real-time temperature will be displayed on the screen.

- Do not polish the heating needle.
- Do not use corroded or broken the heating needle.
- Before use, please confirm that the heating needle is installed in place to prevent it from falling off during use.
- Worn heating needle may cause uneven heating. The operator should replace the heating needle with a new one based on clinical conditions. The replaced heating needle should be placed in the appropriate disposal container.
- Even if the heating needle cools down already, we strongly recommend not to touch the tip part on heating needle, there is a risk of heat injury or damaging the heating needle. Hold the grey shell to remove.



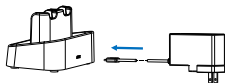
4.2 Installing the Adapter

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



4.3 Connecting the charge base

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



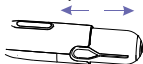
The Power LED on charge base will light up in blue.



- Only the original adapter can be used.
- Don't position the device where it is difficult to operate the disconnection device.

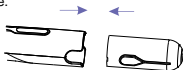
4.4 Replacing the battery

Pull out the battery outward.



Align the raised part of the fully charged battery with the groove of the handpiece and insert it until you hear

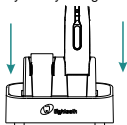
the click indicating that the battery is securely in place.



- When the machine is not used for a long time, the battery should be removed.

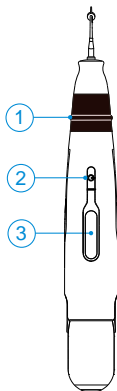
4.5 Charging handpiece and battery

Place the handpiece (with the battery installed) or the battery into the charge base. The charging indicator light on the base will turn green to indicate a proper connection. A flashing green light indicates that charging is in progress. A steady green light indicates that the battery is fully charged.



- If the green light does not turn on when the handpiece (with the battery installed) or the battery is placed on the base, it means the handpiece (with the battery installed) or the battery is not properly positioned. Remove the handpiece (with the battery installed) or the battery and reposition it until the green light turns on.

5. Use Interface



- ① ○ Main switch
- ② ⏻ Power switch
- ③ Display Screen

Turn Power On

Long press ⏻.

Change Memory Mode

Short press ⏻ to change temperature memory mode from T1 to T5.

Memory Parameter Setting

During standby state, holding down press ⏻ then press ○ to enter memory parameter setting. Parameter T1 to T5 can be set independently.

Heating

During standby state, long press ○.

Turn Power off








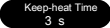





During standby state, long press ⏻ more than 2 seconds.

Advanced Setting
















During power off state, holding down press ⏻, then press ○ to enter advanced setting. Press ⏻ till target setting, press ○ to adjust, then press ⏻ to confirm.

6. Setting

6.1 Memory Parameter Setting



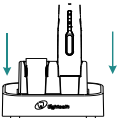
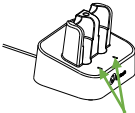

	<p>Space-Pack has 5 memory modes, from T1-T5. In standby mode, press  to switch, and the memory mode code will change accordingly.</p>
	<p>In T1-T5 memory mode, holding down press  in 2 seconds to enter the "Temperature" setting interface and change the temperature in this memory mode.</p> <p>Press  till target temperature, the temperature can be set 90°C, 120°C, 150°C, 180°C, 200°C, 230°C, 250°C.</p> <p>Press  to confirm and enter next interface.</p> <div data-bbox="329 639 935 789" style="background-color: #f0f0f0; padding: 10px;">  <ul style="list-style-type: none"> ● The temperature setting above 200°C should be carefully selected. </div>
	<p>Enter the "Keep-heat Time" interface to change the keep heating time in this memory mode.</p> <p>Press  till target time, the time can be set 3s, 5s, 8s and 10 s.</p> <p>Press  to confirm and enter next interface.</p>
	<p>Enter the "CoolingDisplay" interface to change the cooling display time in this memory mode.</p> <p>Press  till target time, the time can be set 0s, 3s, 5s and 10 s.</p> <p>Press  to confirm and enter next interface.</p>

6.2 Advanced Setting




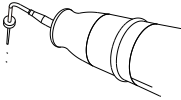
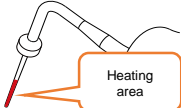
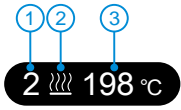
	<p>During power off state, holding down press , then press  to enter advanced setting, the "AutoPowerOff" will appear on the display screen. Press  to adjust, the auto power off time can be set to 5, 10 and 15 minutes.</p> <p>Press  to confirm and enter next interface.</p>
	<p>Enter the "Beep Volume" interface to change the volume of the prompt sound. Press  to adjust. The "Beep Volume" can be set to 0, 1 and 2.</p> <p>Press  to confirm and enter next interface.</p>
	<p>Enter the "RestoreSettings" interface to change the reset settings. Press  to adjust.</p> <p>Press  to confirm and enter next interface.</p> <div data-bbox="329 639 933 786">  <ul style="list-style-type: none"> ● If choose "YES", all the setting parameters will be covered by factory settings. </div>
	<p>Enter the " Save " interface to confirm whether to save the settings. Press  to adjust, press  to save and power off.</p>

7. Operation

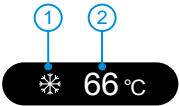

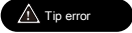

7.1 Charge

	<p>Display the present remaining amount of the battery.</p> <p>This icon indicates that the remaining battery is less than 15%, please charge in time.</p> <div data-bbox="381 368 921 551">  <ul style="list-style-type: none"> ● If the battery power is less than 15%, the device must be recharged within 30 days, otherwise the battery will be damaged. </div>
	<p>Place the handpiece (with the battery installed) or the battery into the charge base. Both slots on the base have the same function and can charge the device.</p>
 <p>Power and charging status indicator lights</p>	<p>During charging, the green charging indicator light on the base will flash. When the battery is fully charged or nearly fully charged, the green indicator light will stay on. It takes about 1 hour to fully charge the battery. If the remaining battery level or the condition of the battery (such as aging) varies, the charging time may differ.</p> <p>According to the usage of the device, the battery can be recharged 300 times, and then the battery level will significantly decrease.</p> <div data-bbox="381 1139 921 1286">  <ul style="list-style-type: none"> ● Do not use non original batteries. If the wrong battery is used, electronic components will be damaged. </div>

7.2 Heating

	<p>Press  to heat the heating needle.</p> <div style="background-color: #f0f0f0; padding: 10px; border: 1px solid #ccc;">  <ul style="list-style-type: none"> ● The continuous heating time of the heating needle on the Gutta-percha should not exceed 4 seconds to prevent thermal burns. ● The heating speed of the heating needle is fast, so be extra careful of burns during operation. </div>
	<p>During heating, the buzzer continuously sounds, and the screen displays the current temperature.</p>
	<p>Only the end of the heating needle (about 4-5mm) can be heated. Use this area to cut the Gutta-percha.</p>
	<ul style="list-style-type: none"> ① The "Keep-heat Time" will display on the screen. When the set time is reached, the heating process will stop. ② Heating indication ③ Real time heating temperature

7 Operation

	<p>Release  or reach the set heating time, the heating needle will cool down.</p> <p>① Cooling indication</p> <p>② Real time cooling temperature</p> <p>When the set time of "CoolingDisplay" is reached, the screen will switch to the standby interface.</p>
 <p>Tip error</p>	<p>If the heating needle is not installed correctly, or the heating needle is broken, the "Tip error" will appear.</p>
 <ul style="list-style-type: none">● After use, please promptly place the handpiece back on the charge base.	

8. Cleaning, Disinfection and Sterilization

8.1 Foreword

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.

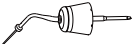
Reprocessing procedures have only limited implications to this dental device. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. The heating needle are verified to be able to withstand 250 times reprocessing cycles. The device should no longer be reused in case of signs of material degradation.

In case of damage, the device should be reprocessed before sending back to the manufacturer for repair.

8.2 General recommendations

- The user is responsible for the sterility of the product before the first use and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
- Clean the products within two hours after each use.
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- The water quality must meet the requirements of EN 13060.
- Thoroughly clean and wash the components before autoclaving.
- Do not use bleach or chloride disinfectant materials.

8.3 Autoclavable accessories

Autoclavable accessories	
Heating Needle	

8 Cleaning, Disinfection and Sterilization




- Only the above components can undergo high-temperature steam sterilization and can withstand up to 250 cycles of high-temperature steam sterilization.
- Before first use and after each use, the heating needle components must be sterilized with high-temperature steam.



Reprocessing instructions

Preparation at the point of use	<p>Remove gross contaminations from the components with a cloth, which dipped in cold water (0-40°C) immediately after use. Don't use a fixating detergent or hot water (40-100°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.</p> <div data-bbox="336 582 409 646"> </div> <ul style="list-style-type: none"> ● Do not wipe the motor 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.
Transportation	<p>Safe storage and transportation to the reprocessing area to avoid any damage and contaminate on to the environment.</p>
Preparation for Decontamination	<p>The devices must be reprocessed in a disassembled state.</p> <div data-bbox="336 1018 409 1082"> </div> <ul style="list-style-type: none"> ● Observe suitable personal protective measures.
Pre-Cleaning	<p>Manually pre clean until the appearance of the components is clean. Immerse the above components in a cleaning solution and rinse with a cold water spray gun for at least 10 seconds. Clean the surface with a soft bristled brush.</p>



8 Cleaning, Disinfection and Sterilization

Cleaning	<p>Automated cleaning:</p> <p>Carefully put the components into the washer-disinfector on a tray and set the parameters as follows, then start the program:</p> <p>4 min pre-washing with cold water (0-40°C);</p> <p>Emptying</p> <p>5 min washing with a mild alkaline cleaner (pH value between 7.5 and 8.5) at 55±2°C;</p> <p>Emptying</p> <p>3 min neutralising with warm water (40-60°C);</p> <p>Emptying</p> <p>5 min intermediate rinsing with warm water (40-60°C);</p> <p>Emptying</p> <p>Note: The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert) and Rapid-A520 Washer-disinfector from Shandong Xinhua Medical Device Co., Ltd.</p> <div data-bbox="339 758 964 979"><ul style="list-style-type: none">● Use only approved wash-disinfectors according to EN ISO 15883, maintain and calibrate it regularly.● Please strictly follow the concentration of cleaning agent provided by the manufacturer for cleaning.</div>
Disinfection	<p>Automated Thermal Disinfection in washer/disinfector under consideration of national requirements with regard to A0 value (refer to EN ISO 15883).</p> <p>A disinfection cycle of 5 min disinfection at 93±2°C has been validated for the device to achieve an A0 value of 3000.</p> <p>After cleaning, the parts should be automated disinfected or sterilized immediately. A manual disinfection is not recommended.</p>

8 Cleaning, Disinfection and Sterilization

Drying	<p>Automated Drying:</p> <p>Drying the devices according to drying program of washer/disinfector by setting parameter 120 °C, 15 min.</p> <p>If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of devices by using sterile compressed air.</p>
Functional Testing, Maintenance	<p>Visual inspect the cleanliness of the components and reassemble them. Conduct functional testing according to instructions of use. If necessary, perform reprocessing process again until the components are visibly clean.</p> <p>Before packaging and autoclaving, make sure that the components have been maintained according to the manufacturer's instruction.</p>
Packaging	<p>The devices that require sterilization can be packaged together in one pouch, but it is necessary to ensure that the packaging pouch is large enough and will not be damaged due to excessive volume.</p> <div data-bbox="336 768 964 986">  <ul style="list-style-type: none"> ● 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 °C and in accordance with EN ISO 11607. </div>
Sterilization	<p>Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.</p> <p>Minimum requirements: 5 min at 134±2°C</p> <p>Drying time: at least 8min</p> <div data-bbox="336 1239 964 1312">  </div>

8 Cleaning, Disinfection and Sterilization



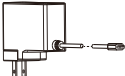

	<ul style="list-style-type: none">● Use only approved autoclave devices according to EN 13060 or EN 285.● Use a validated sterilization procedure according to EN ISO 17665.● Respect the maintenance procedure of the autoclave device given by the manufacturer.● Use only this recommended sterilization procedure.● Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycle parameters).● Wait for cooling before touching.
Storage	<p>Store the sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and User Manual.</p> <div><ul style="list-style-type: none">● Sterility cannot be guaranteed if packaging is open, damaged or wet.</div>
<div><p>● 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.</p><ul style="list-style-type: none">● Please comply with relevant regulations for cleaning, disinfection, and sterilization.● Please be careful during maintenance to avoid cross infection.● The next patient should replace the cleaned, disinfected, and sterilized the heating needle.</div>	

8 Cleaning, Disinfection and Sterilization




- The heating needle are easily damaged by external forces, so be careful when maintaining them.
- Be careful when cleaning, disinfecting, and sterilizing, and wear disposable sterile gloves to avoid cross infection.

8.4 Disinfection components

Disinfection components	
Handpiece	Charge Base
	
Adapter	
	
Battery	
	
Cleaning	Wipe the outer surface of the machine with a soft cloth soaked in Ethanol (70-80 vol% Ethanol) more than 5 times for 2 min each time, until there are no visible stains.
Disinfection	Wipe the outer surface of the machine with a soft cloth soaked in Ethanol (70-80 vol% Ethanol) more than 5 times for 2 min each time.
Drying	Use a dry lint free sterile cloth to wipe off the residual water on the devices until no water stains remain.

8 Cleaning, Disinfection and Sterilization

Inspection and maintenance	Visual inspect the cleanliness of the components and reassemble them. Conduct functional testing according to instructions of use. If necessary, perform reprocessing process again until the components are visibly clean.
Storage	Store the sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and User Manual.
<div><ul style="list-style-type: none">● Do not use disinfectants other than ethanol for disinfection (Ethanol 70 to 80 vol%).● Do not use excessive ethanol to prevent ethanol from seeping into the parts and damaging the internal parts.● The above components must be disinfected before first use and after each use.● When used by patients, the equipment should not be maintained or serviced.</div>	

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 level is too low.	Charging the handpiece (with battery installed) or 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.	/
The charging indicator light on the charge base does not turn green.	The handpiece (with battery installed) or the battery is not properly seated.	Please remove the main unit (with the battery installed) or the battery and then reposition it.	4.5
	Charge pin of charge base is unable to	Remove debris which between	/

9 Troubleshooting

	rebound.	move part and base of the charge pin.	
	Contactors are dirty.	Cleaning the surface of contactors.	/
	The charge base is broken.	Contact the dealer to repair the charge base	/
Handpiece screen does not appear.	The handpiece is broken.	Check if there is a sound of beep, and contact your distributor.	/
No sound.	Beep volume is set to 0.	Set beep volume to 1 or 2.	6.2


10. Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co.,Ltd.
Model	Space-Pack
Battery	Lithium ion battery: 3.7V, 1100mAh
Adapter input	100-240V~
Adapter output	6V $\overline{\square}$ 3A
Frequency	50/60Hz
Input	0.5A
Temperature	90°C~250°C, $\pm 20\%$
Type of protection against electrical shock	Class II, internal power supply equipment
Application part	B (Heating Needle)
Operation mode	Continuous operation
Waterproof protection strength	IPX0
AP/APG type equipment	Non AP/APG equipment
Anti defibrillation application part	None
Operating conditions	Ambient temperature: 5°C~40°C Relative humidity: $\leq 80\%$ Working altitude: <3000m above sea level
Transport and storage	Ambient temperature: -20°C~ +55°C

10 Technical Data

conditions	Relative humidity:20% ~ 80% Atmospheric pressure:70kPa~ 106 kPa
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11. EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The Space-Pack is intended for use in the electromagnetic environment specified below. The customer or the user of the Space-Pack should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Professional healthcare facility environment and Home healthcare environment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC61000-3-2	Class A	Professional healthcare facility environment.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliances	
<div><p>The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.</p></div>		

Guidance and manufacturer's declaration – electromagnetic immunity

11 EMC Tables

The **Space-Pack** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Space-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	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 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 %.
Electrical fast transients/bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Surges Line to line: ±0.5kV, ±1kV Surges Line to earth: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°	Mains power quality should be that of a typical commercial or hospital environment.

11 EMC Tables

<p>Voltage interruptions IEC 61000-4-11</p>	<p>180°, 225°, 270°, and 315°</p> <p>0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°</p> <p>0% UT; 250/300 cycle</p>	<p>225°, 270°, and 315°</p> <p>0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°</p> <p>0% UT; 250/300 cycle</p>	<p>If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered from an uninterruptible power supply or a battery</p>
<p>Rated Power frequency magnetic field IEC 61000-4-8</p>	<p>30 A/m 50Hz or 60Hz</p>	<p>30 A/m 50Hz or 60Hz</p>	<p>Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz</p>			
<p>Guidance and manufacturer's declaration – electromagnetic immunity</p>			
<p>The Space-Pack is intended for use in the electromagnetic environment specified below. The customer or the user of the Space-Pack should assure that it is used in such an environment.</p>			
<p>Immunity test</p>	<p>IEC 60601 test level</p>	<p>Compliance level</p>	<p>Electromagnetic environment - guidance</p>

11 EMC Tables

<p>Conducted disturbances induced by RF fields IEC 61000-4-6</p>	<p>3 V</p> <p>0.15 MHz – 80 MHz, 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz</p>	<p>3 V</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Space-Pack, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p>
<p>Radiated RF EM fields IEC 61000-4-3</p>	<p>3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz</p>	<p>3V/m</p>	<p>Recommended minimum separation distances</p>
<p>Proximity fields from RF wireless communication equipment IEC 61000-4-3</p>	<p>See the RF wireless communication equipment table in "Recommended minimum separation distances"</p>	<p>Complies</p>	<p>See the RF wireless communication equipment table in "Recommended minimum separation distances"</p>

Recommended minimum separation distances

11 EMC Tables

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **Space-Pack** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2020. The customer and/or user should help keep a minimum distance between RF wireless communications equipments and the **Space-Pack** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM \pm 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820,	Pulse modulation 18Hz	2	0.3	28
870						
930						

11 EMC Tables

		CDMA 850, LTE Band 5				
1720	170	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	240 257	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	510	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

Guidance and manufacturer's declaration – electromagnetic immunity

The Space-Pack is intended for use in the electromagnetic environment specified below. The customer or the user of the Space-Pack should assure that it is used in such an environment.

Proximity magnetic fields	IEC 61000-4-39 test level	Compliance level	Electromagnetic environment – guidance
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11 EMC Tables

Proximity magnetic fields	134.2kHz Pulse modulation 2.1 kHz	65A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	13.56MHz Pulse modulation 50 kHz	7.5A/m	



1. Use of accessories and cables other than those specified or provided by the manufacturer of Space-Pack could result in increased electromagnetic emissions or decreased electromagnetic immunity of Space-Pack and result in improper operation.

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Adapter Cable	2.0	No	/

2. Use of Space-Pack adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, Space-Pack and the other equipment should be observed to verify that they are operating normally.

3. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Space-Pack, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4. If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

12. Warranty

1. Space-Pack is warranted against manufacturing errors and defects in materials, and the warranty period is 12 months starting from the day of delivery to the customer.
2. Space-Pack should be repaired by the equipment technology department of Changzhou Sifary Medical Technology Co., Ltd. or maintenance service partners authorized by Changzhou Sifary Medical Technology Co., Ltd. Do not provide circuit diagram, bill of material, legends, calibration rules, and other maintenance materials to other organizations.
3. Should the quality assurance complaint be reasonable, Changzhou Sifary Medical Technology Co., Ltd. or maintenance service partner authorized by Changzhou Sifary Medical Technology Co., Ltd shall provide repairing service as soon as possible.
4. Should the damage be proved to be caused by the user's negligence in daily maintenance, warranty is then voided.
5. Changzhou Sifary Medical Technology Co., Ltd reserves the right to analyze and determine the cause of any problems.

13. Statement

Service Life

The service life of Space-Pack series products is 10 years.

Maintenance

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



Those parts of the equipment that shall not be serviced or maintained while in use with a PATIENT:

- Handpiece
- Heating Needle

Disposal

Comply with your national regulations, guidelines and requirements for the disposal of waste electrical equipment and medical devices.

Make sure the device is not mixed with other types of waste when it is being disposed of.

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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