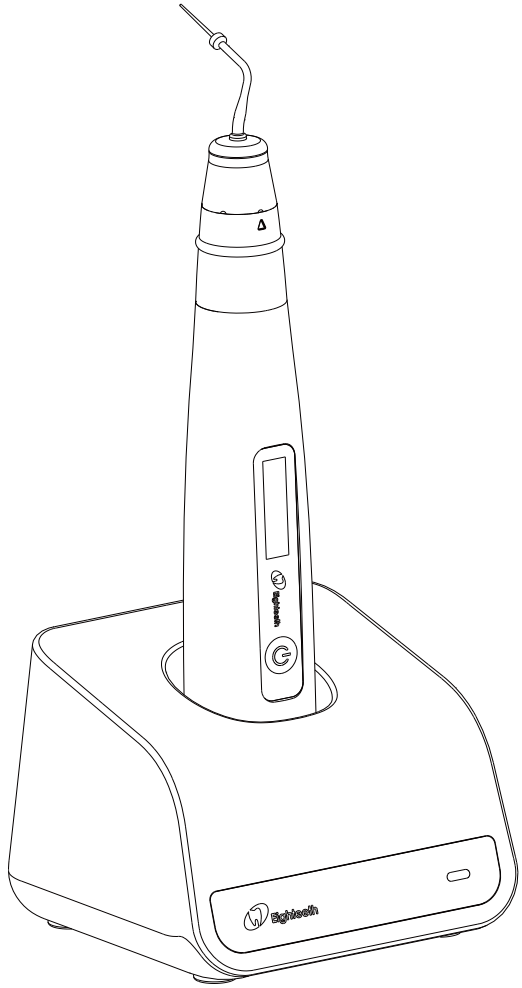
Eighteeth

CE 0197



Fast-Pack pro

USER MANUAL

Changzhou Sifary Medical Technology Co.,Ltd.

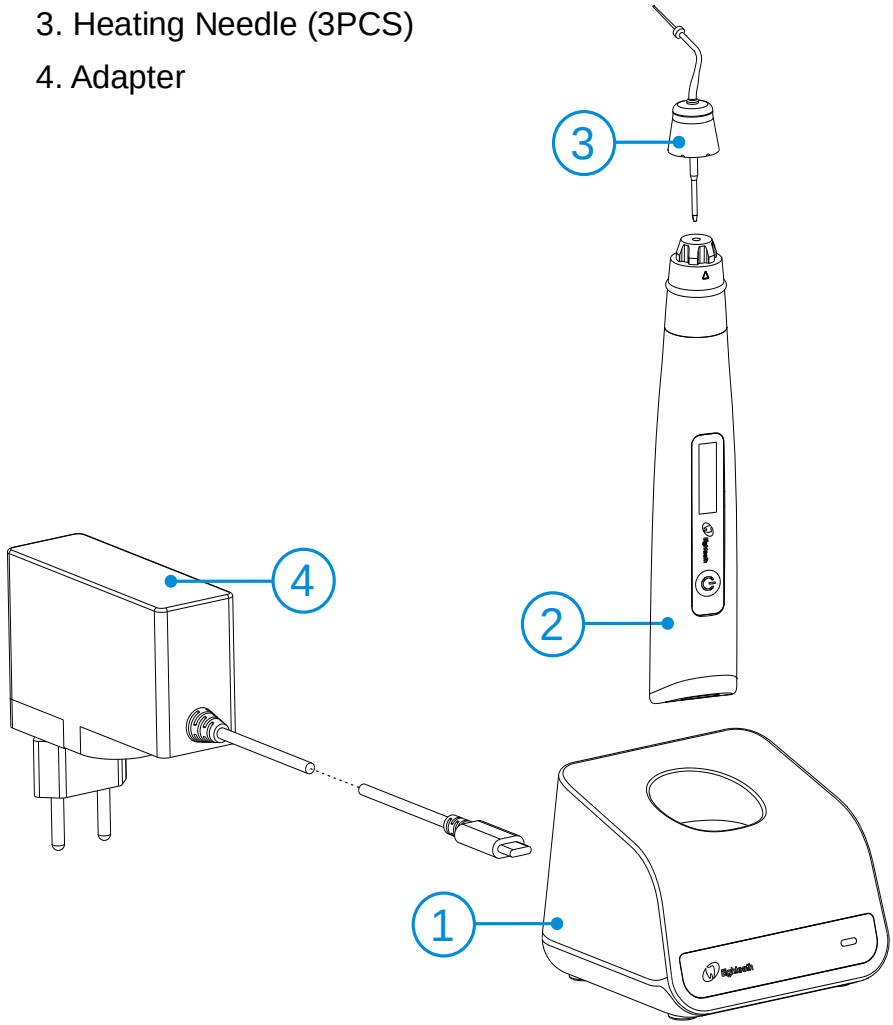
P/N: IFU-6335007
Version: 05
Issued: 2023.12.04
Size: 85mm×119mm

Content

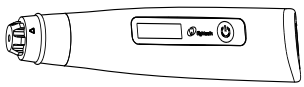
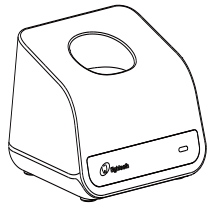
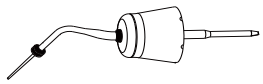
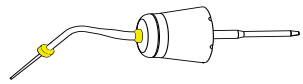
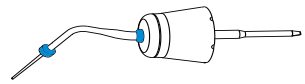
1. Scope of Fast-Pack pro

1.1Parts Identification

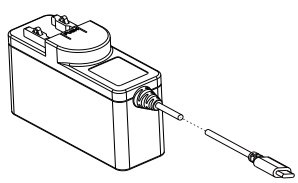
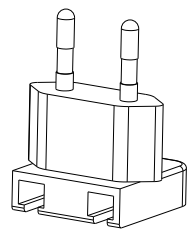
1. Charge Base
2. Handpiece
3. Heating Needle (3PCS)
4. Adapter

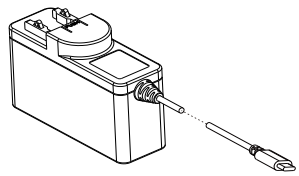
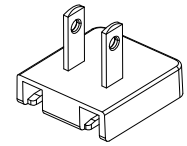
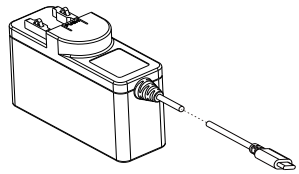
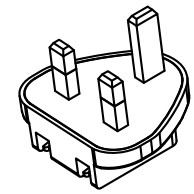
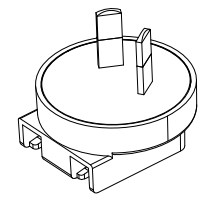
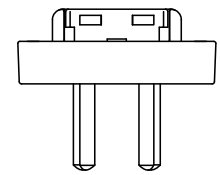


1.2Components

Fast-Pack pro Handpiece (1pc) Part No: 6351057 	**Charge Base (1pc)** Part No: 6351003 	
Heating Needle S (1pc) Size: 40/0.025 Color: Black Part No: 6351058 	**Heating Needle M (1pc)** Size: 50/0.05 Color: Yellow Part No: 6351059 	**Heating Needle L (1pc)** Size: 60/0.06 Color: Blue Part No: 6351060 

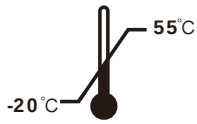
For different regions, there are several different adapter options to be selected as follows.

Standard	Adapter	Power plug
European standard	**Adapter (1pc)** Part No: 6316012 	**European standard power plug (1pc)** Part No: 6316005 

<table>
<tr><td rowspan="1">American standard</td><td>Adapter (1pc)
Part No: 6316012
  </td><td>American standard power plug (1pc)
Part No: 6316008
  </td></tr>
<tr><td rowspan="3">Multi-standard</td><td rowspan="3">Adapter (1pc)
Part No: 6316012
  </td><td>British standard power plug (1pc)
Part No: 6316006
  </td></tr>
<tr><td>Australian standard power plug (1pc)
Part No: 6316007
  </td></tr>
<tr><td>Argentina standard power plug (1pc)
Part No:6316011
  </td></tr>
</table>

2. Symbols used in the User Manual

	General warning sign
	Caution
	Serial number
	Catalogue number
	Batch code
	Medical device
	Authorized representative in the European Community
	Manufacturer
	Country of manufacture
	Washer-disinfector for thermal disinfection
	Class II equipment
	Type B applied part
	Keep dry
	CE marking
	Dispose of in accordance with the WEEE directive
	Direct current
	Consult instructions for use

Eighteeth	Manufacturer’s LOGO
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Temperature limit
	Humidity limit
	Atmospheric pressure limit

3. Before Use

3.1Scope of application

Fast-Pack pro 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.

3.2Contraindications

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.

Read the following warnings before use:

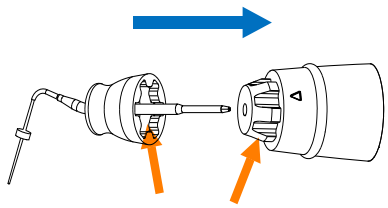
- The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
- Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
- The device requires special precautions with regard 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 and do not use this system near the active HF Surgical Equipment in the hospital. 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 Fast-Pack pro, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- If the package is damaged before opening, contact the agency.
- Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.
- Gloves and a rubber dam are compulsory during treatment.
- If irregularities occur in the device during treatment, turn it off. Contact the agency.

- Never open or repair the device yourself，otherwise, void the warranty.
- Use only original components.
- Do not use the device in the presence of free oxygen, flammable anesthetic gas mixtures or flammable substances.
- When battery leakage occurs, handle the leakage according to local laws and regulations to avoid environmental pollution.
- Do not use this device for any dental procedure other than root canal obturation.
- Thermal hazard risk exists for patients. Cautions should be exercised at temperature settings above 200℃.
- The heating needle must be cleaned, disinfected and sterilized prior to and following every treatment.
- Do not immerse the device in any liquid or spray any fluid directly onto the device.
- Do not use conductive objects to detect the charge interface.
- Please follow the Gutta-percha's instruction for use when Gutta-perchas are used during the operation.
- A fall may cause damage to the machine.
- Batteries should be replaced only by trained dealers and manufacturers.
- Battery replacement by untrained personnel may cause damage to the machine.
- If an adverse reaction like allergy or irritation occurs due to contact with the heating needle, please stop using inmmediately and seek treatment.

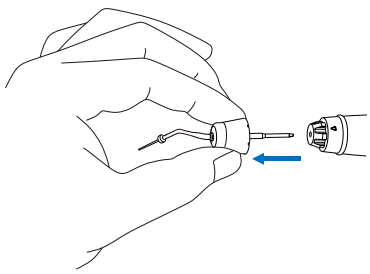
4.Installing the Fast-Pack pro

4.1Installation of heating needle

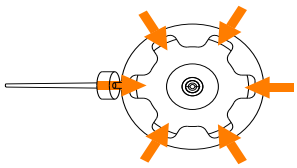
Make sure the hexagon plum blossom groove on heating needle is aligned with the hexagon plum blossom boss on handpiece, push till to position.



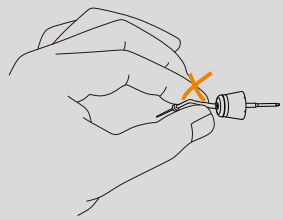
Holding the grey shell to pull the heating needle out from the handpiece.



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

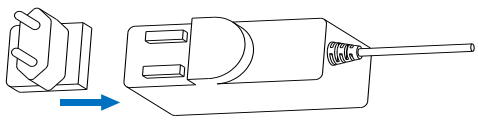


- Do not use corroded and fractured heating needle.
- Do not polish heating needle
- After the operation is completed, wait for the heating needle to cool down and remove it to prevent the heating needle from being damaged accidentally.
- The cooling process will take about 2-3 seconds and the real-time temperature will show on the screen.
- 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.



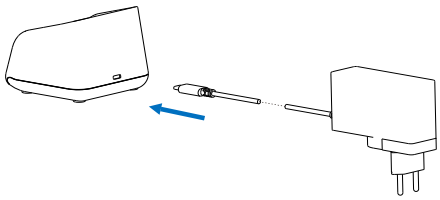
4.2Installation of adapter

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

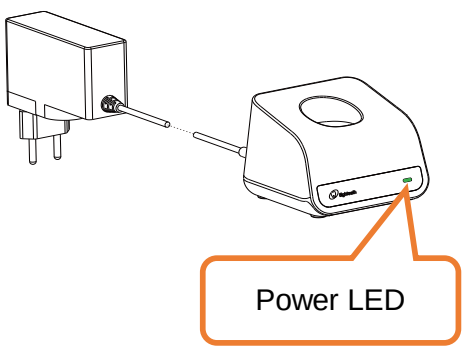


4.3Connecting charge base

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

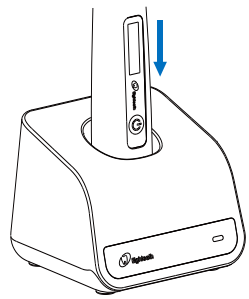


The Power LED on charge base will light up.

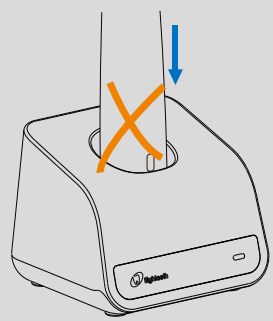


- Only the original adapter could be used.
- Do not position the device where it is difficult to operate the disconnection device.

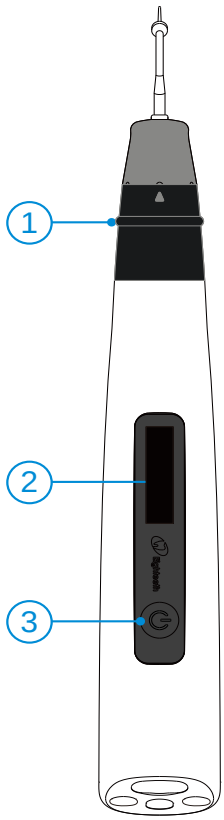
Put the handpiece into the charge base, the charge state will show on the screen.



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



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 to enter memory parameter setting. Parameter T1 to T5 can be set independently.

Heating

Long press

Turn Power Off

Long press for more than 2 seconds.

Advanced setting

During power off state, holding down press then press for 2 seconds to enter advanced setting. Press till target setting, press to adjust, then press to confirm.

6.Setting

6.1Memory Parameter Setting

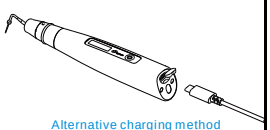
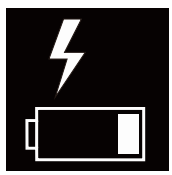
	Fast-Pack pro has 5 memory programs, press ⏻ to change during standby state, the memory number T1 will change accordingly.
	During any memory, holding down press ⏻ then press O , the “Temperature” of this memory can be changed. Press O till target temperature, the temperature can be set to 90℃, 120℃, 140℃, 150℃, 160℃, 180℃, 200℃, 220℃, 250℃ and 300℃. Press ⏻ to confirm.
	Press ⏻ again, the “Keep-heat Time” of this memory can be changed. Press O till target time, the time can be set to 3, 5, 8 and 10 seconds. Press ⏻ to confirm.
	Press ⏻ again, the “CoolingDisplay” of this memory can be changed. Press O till target time, the time can be set to 0, 3, 5 and 10 seconds. Press ⏻ to confirm.

6.2Advanced Setting

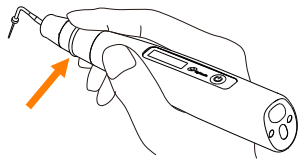
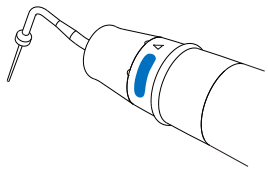
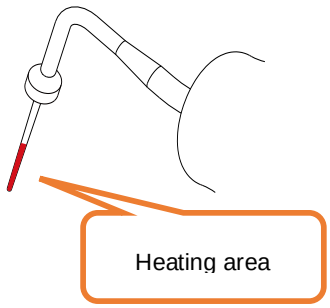
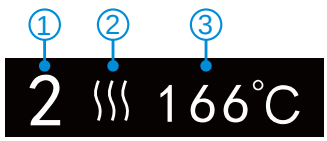
	During power off state, holding down press ⏻ then press O for 2 seconds to enter advanced setting, the “AutoPowerOff” will appear on the display screen. Press O to adjust, the auto power off time can be set to 5, 10 and 15 minutes. Press ⏻ to confirm.
	Press ⏻ again, the “Beep Volume” can be changed. Press O to adjust, the “Beep Volume” can be set to 0, 1 and 2. Press ⏻ to confirm.
	Press ⏻ again, the “RestoreSettings” can be changed. Press O to adjust and press ⏻ to confirm. ⚠ ● If choose “YES”, all the setting parameters will be covered by factory settings.
	Press ⏻ again, confirm the setting need to save or not. Press O to adjust and press ⏻ to save and power off.

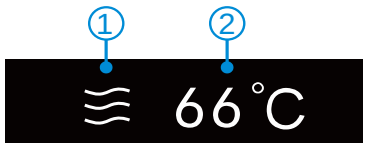
7.Operation

7.1Charge

<table>
<tr>
<td>  </td>
<td>Display the present remaining amount of the battery.
When the battery icon appears and flashes on the screen, it means the remaining battery power is less than 15%. Please charge the device in time.
 
● If the power is less than 15%, the device must be recharged within 30 days, otherwise the battery will be damaged.</td>
</tr>
<tr>
<td> 
Alternative charging method</td>
<td>Charge without charge base is also available, connect adapter to handpiece directly, the charge state will show on the screen.
Charge with charge base is recommended (See chapter 4.3).
 
● Only the original adapter could be used.
● Do not use the device while charging.
● The handpiece power connector can only be used to connect the original adapter cord for charging purpose.</td>
</tr>
<tr>
<td>  </td>
<td>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.
 
● 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.</td>
</tr>
</table>

7.2Heating

	Press ○ to heat the heating needle.
	The indicator LED lights up during heating. ⚠ ● Needle heating speed is fast, operation should be extra careful. ● Do not place the heated heating needle in the root canal for more than 4 seconds to prevent thermal injury to the patient. ● The continuous use time of the device should not exceed 10 minutes.
	Only the end of the heating needle (about 4-5mm) can be heated. Use this area to cut the gutta percha.
	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

	Release O, the heating needle will cool down. ① Cooling indication ② Real time cooling temperature When the set time of “CoolingDisplay” is reached, the screen will switch to the standby interface.

8.Cleaning, Disinfection and Sterilization

8.1Foreword

For hygiene and sanitary safety purpose, the component（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.

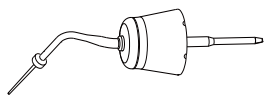
Reprocessing procedures have only limited implications to these dental instruments. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no 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.

8.2General 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 tips and wrench with an ultrasonic cleaning device.
- Do not use bleach or chloride disinfectant materials.

8.3Autoclavable Components

Autoclavable Components	
Heating needle	

- Only the components above can be autoclaved.
- Before first use and after each use, sterilize the above components.
- Sterilization no more than 250 times.

Reprocessing Instructions	
Preparation at the Point of Use:	Before cleaning, disconnect the heating needles from the handpiece. Refer to Chapter 4.1 of this manual for disassembly instructions. Remove gross contaminations from the components with code water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding. 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.
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state. Observe suitable personal protective measures.

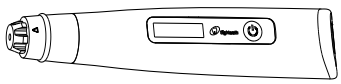
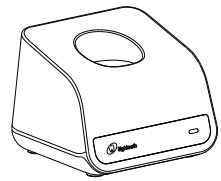
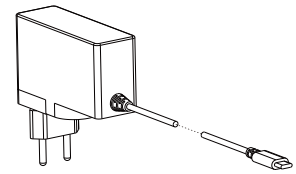
Pre-Cleaning:	Do a manual pre-cleaning, until the components are visually clean. Submerge the components in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristol brush.
Cleaning:	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Carefully put the components into the washer-disinfector on a tray and set the parameters as follows, then start the program: • 4 min pre-washing with cold water (<40°C); • emptying • 5 min washing with a mild alkaline cleaner at 55°C; • Emptying • 3 min neutralising with warm water (>40°C); • emptying • 5 min intermediate rinsing with warm water (>40°C); • Emptying The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert). Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.  ● 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).
Disinfection:	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN ISO 15883).

	A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000. After manual cleaning, the instruments should be automated disinfected immediately. A manual disinfection is not recommended.
Drying:	Automated Drying: Drying the outside of instruments through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until the instrument is visibly clean. Before packaging and autoclaving, make sure that the components have been maintained according to the manufacturer's instruction.
Packaging:	Pack the instruments in an appropriate packaging material for sterilization.  ● 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℃ and in accordance with EN ISO 11607.
Sterilization:	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. Minimum requirements: 3 min at 134 °C (in EU: 5 min at 134 °C). Maximum sterilization temperature: 137°C. Drying time: at least 8min. Flash sterilization is not allowed on lumen instruments!  ● 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 cycles parameters). ● The sterilization procedure must comply with EN ISO 17665. ● Waiting for cooling before touching.
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.  ● Sterility cannot be guaranteed if packaging is open, damaged or wet. ● Check the packaging before using it (packaging integrity, no humidity and validity period).
Reprocessing validation study information	The above-mentioned reprocessing process (cleaning, disinfection, sterilization) has been successfully validated. Refer to cleaning/disinfection validation report No. RDS2020D0074 001 and sterilization validation report No. RDS2020S0082 001.

- Before sterilization, please remove the heating needle.
- 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.

8.4Disinfection components

Disinfection components		
Fast-Pack pro Handpiece	**Charge Base**	**Adapter**
		
Wipe all the surfaces with a cloth lightly moistened with Ethanol for Disinfection (Ethanol 70 to 80 vol%) at least 2min, repeat for 5 times.		
⚠ ● 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 immerse the device in any liquid or spray any fluid directly onto the device. ● Do not allow any moisture to get into the device.		

9.Error Indication

	When the battery is nearly empty, press the Main switch, this warning will appear on the screen, the device cannot work. Please charge the device in time.
	If the heating needle is not installed correctly, or the heating needle is broken, the “Tip error” will appear.

10.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 is unable to rebound.	Remove debris which is between moving part and base of the charge pin.	/
	Contactors are dirty.	Cleaning the surface of contactors.	/
	The charge base is broken.	Connect adapter to handpiece directly, and contact your distributor.	/
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 set to 0.	Set beep volume to 1 or 2.	6.2

11.Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co.,Ltd.
Model	Fast-Pack pro
Dimensions	20cm x 10cm x 11cm±1cm (package)
Gross Weight	1kg±10%
Power supply	Lithium ion battery: 3.7V, 2600mAh, ±10%
Charger power supply	AC 100-240 V, ±10%
Charger power output	6V ⎓ 3A
Frequency	50/60Hz, ±1 Hz
Charge power input	500mA
Temperature	90℃~300℃，±20%
Electrical safety class	Class II
Applied part	B(Heating needle)
IPX specification	IPX0; do not operate under wet conditions
Operation mode	Continuous operation
Operating conditions	Use: in enclosed spaces Ambient temperature:10°C ~ 40 °C Relative humidity: 30% ~ 75% Atmospheric pressure: 70kPa~106kPa
Transport and storage conditions	Ambient temperature: -20 °C~55 °C Relative humidity: 20% ~ 80 % Atmospheric pressure: 70kPa~106kPa

12.EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The **Fast-Pack pro** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Fast-Pack pro** 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	

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.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Fast-Pack pro is intended for use in the electromagnetic environment specified below. The customer or the user of the Fast-Pack pro 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°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT;	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices

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

Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 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	3 V	Portable and mobile RF communications equipment should be usedno closer to any part of the **Fast-Pack pro**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended minimum separation distances** See the RF wireless communication equipment table in "Recommended minimum separation distances"
Radiated RF EM fields IEC 61000-4-3 .	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz	3V/m	
Proximity fields from RF wireless communication equipment IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"	Complies	

Recommended minimum separation distances

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 **Fast-Pack pro** 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 **Fast-Pack pro** as recommended below.

Test frequency (MHz)	Band (MHz	Service	Modulation	Maxi-mum powe (W)	Dis-tance (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± 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, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation 217Hz	2	0.3	28
1845						
1970						

		LTE Band 1, 3, 4, 25; UMTS				
2450	**2400-2570**	**Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7**	**Pulse modulation 217Hz**	**2**	**0.3**	**28**
5240	**5100-5800**	**WLAN 802.11 a/n**	**Pulse modulation 217Hz**	**0.2**	**0.3**	**9**
5500						
5785						

Guidance and manufacturer's declaration – electromagnetic immunity			
The Fast-Pack pro is intended for use in the electromagnetic environment specified below. The customer or the user of the Fast-Pack pro should assure that it is used in such an environment.			
Proximity magnetic fields	**IEC 61000-4-39 test level**	**Compliance level**	**Electromagnetic environment – guidance**
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	

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Adapter Cable	2	No	/

Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2020 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

1. Use of accessories and cables other than those specified or provided by the manufacturer of **Fast-Pack pro** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **Fast-Pack pro** and result in improper operation.
2. Use of **Fast-Pack pro** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **Fast-Pack pro** 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 Ultra X, 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.

13.Statement

Service Life

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

It is recommended that the equipment be checked and repaired at the dealer once a year

Warranty Period

Fast-Pack pro has a 12-month warranty period starting from the date of delivery to the customer. If the damage is proved to be caused by the user's use error, warranty is voided.

Maintenance

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

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

- Handpiece
- Heating needle

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

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