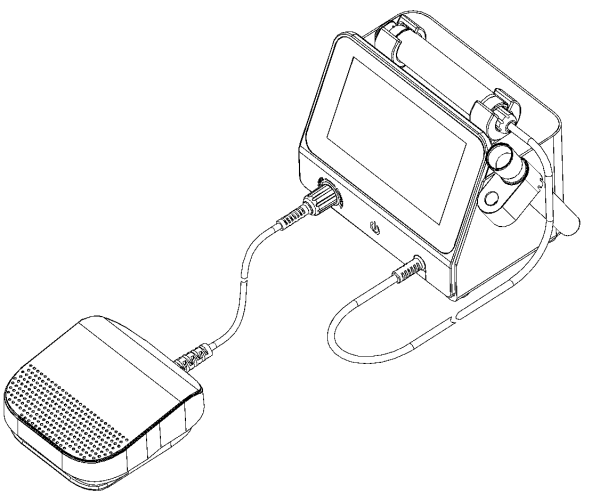
CE 0344

Eighteeth

E-FLOW



Dental Anesthetic Delivery System
USER MANUAL

Changzhou Sifary Medical Technology Co.,Ltd.

导出PDF时删除此页内容，此页不能有任何内容，但此页仍需保留

模板编号:SOP-001-R18　模板版本:01　模板变更编号:DCR-2021-007　模板生效日期:2021.04.30		
拟制: 日期:	审核1 日期:	审核2 日期:
审核3 日期:	/　/ /　/	批准: 日期:

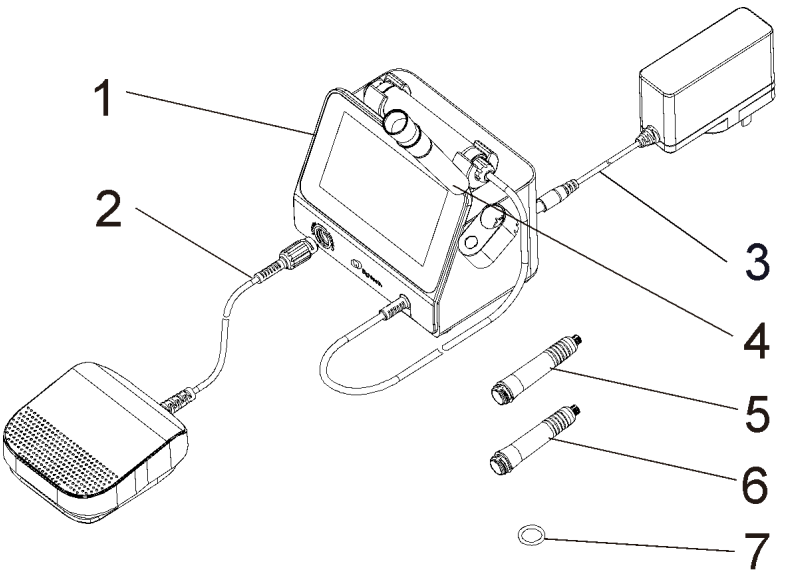
修订记录				
版本	变更编码	修订内容概述	修订人	生效日期
S01	CR-2023-72-02	新增	张凯	

Part NO: IFU-7235001
Version: S02
Issued: 2023.08.22
Size: 197mm×140mm

Content

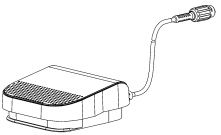
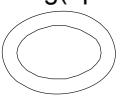
1 Scope of E-FLOW

1.1 Parts Identification

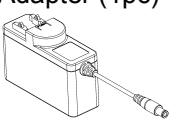
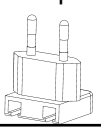
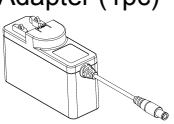
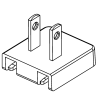
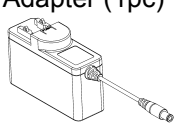
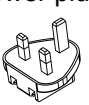


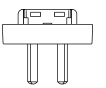
1. Main unit
2. Foot pedal
3. Adapter
4. Handpiece holder
5. Sleeve-M
6. Sleeve-UN
7. O-ring
8.

1.2 Components

Main unit (1pc) 	Foot pedal (1pc) 	Handpiece holder (1pc) 
Sleeve -M (1pc) 	Sleeve -UN (1pc) 	O-ring(5pcs) 

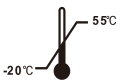
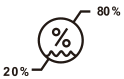
For different regions, there are several different adapter options to be selected as follows.

Standard	Adapter	Power plug
European standard	Adapter (1pc) 	European standard power plug (1pc) 
American standard	Adapter (1pc) 	American standard power plug (1pc) 
Multi-standard	Adapter (1pc) 	British standard power plug (1pc) 

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

2 Symbol Instruction

	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 Foreword

3.1 Scope of application

E-FLOW is intended for use only in subcutaneous or intramuscular injections of local anesthetic agents for dental applications. It should not be used for intravascular (IV) or other routes of administration.
This device must only be used in hospital environments, clinics or dental offices by trained and qualified dental personnel and not used in the oxygen-rich environment.

3.2 Contraindications

Intraligamentary injections are contraindicated in patients with active periodontal disease.

3.3 Intended user

This device should be used only by practitioners who are familiar with, and observe applicable labeling regarding the use of local anesthetic agents for dental applications.

Read the following warnings before use:

- The device should be used in combination with oral local anesthetic and sterile single use injection needle
- The cartridge of anesthetic shall be 1.7ml or 1.8ml bottle in accordance with ISO 11499, and the needle shall be sterile single use injection needle in accordance with ISO 7885.
- The device must not be placed in humid surroundings or anywhere 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 Dental Anesthetic Delivery System, including cables specified by the

manufacturer. Otherwise, degradation of the performance of this equipment could result.

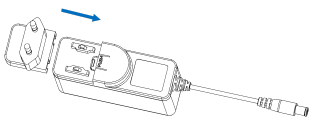
- Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.
- Gloves are compulsory during the operation.
- If irregularities occur in the device during treatment, switch it off. Contact the agency.
- Never open or repair the device yourself, otherwise, void the warranty.
- Do not use the device while charging.
- Do not place the device in a position where it might fall in case of injury to patients or damage to the device.
- When battery leakage occurs, handle the leakage according to local laws and regulations to avoid environmental pollution.
- The device should not be used in environments where flammable materials are present.
- Do not spray alcohol on the connection interface.
- Do not use conductive objects to detect the connection interface.
- It must be charged before first use.
- Batteries should be replaced only by trained service personnel, otherwise, the device may be damaged.
- If the package or equipment is damaged, contact the supplier or manufacturer.
- Use only original component

4 Basic operation

4.1 Charge

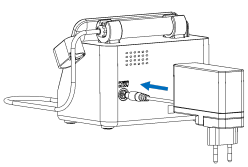
4.1.1 Installation of adapter

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



4.1.2 Connection of adapter

Plug one end of the adapter into the Main unit, plug the other end of the adapter into the power socket. The screen will appear the charging state.



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- Only the original adapter could be used.
- Do not position the device where it is difficult to disconnect the device quickly.
- Do not charge during working.
- If you do not use this product for a long time, please charge it at least once a month.

4.2 Preparation for injection

4.2.1 Installation of Foot pedal and Handpiece holder

Refer to the figure, turn the connector of foot pedal into the connector of the main unit clockwise and tighten properly; The connector of foot pedal can be rotated anticlockwise out of the connector of main unit.

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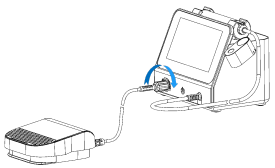
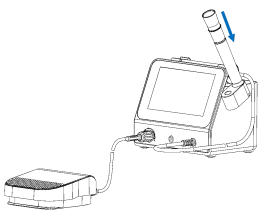
- Insert the Handpiece holder into the connector of main unit and gently pull the Handpiece holder from connector of main unit to ensure that the installation is firm.

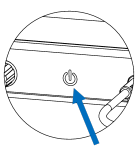


Refer to the figure, insert the Handpiece holder into the connector of main unit and press gently to the bottom.



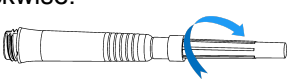
4.2.2 Startup

Press the power icon on the front of main unit to enable the E-FLOW system. At this time, the LOGO will appear on the screen accompanied by startup music.

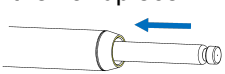


4.2.3 Installation of anesthetic, Sleeve and needle

Turn the needle with needle cover onto the Sleeve clockwise.



Insert the piston end of the oral local anesthetic into the handpiece.



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Please use sterile single use injection needle that fits the Sleeve.

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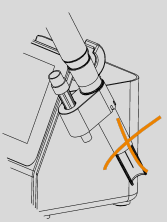
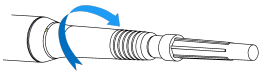
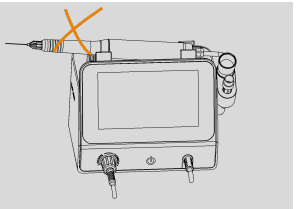
Insert the handpiece into the Handpiece holder when not in use. Do not insert a handpiece without needle cover into the Handpiece holder.



Do not place the handpiece with needle in the storage brackets.

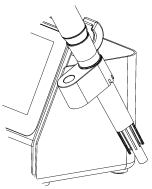
Turn the Sleeve with needle onto the handpiece clockwise.





4.2.4 Placement of handpiece

Insert the handpiece with the needle cover into the Handpiece holder.



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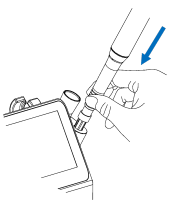
Make sure the pushrod has returned to the bottom before removing the needle

4.2.5 Remove the needle cap

Before injection, the needle cover should be removed as follows: Hold the Sleeve, insert the handpiece with the needle cover into the needle cover hole with appropriate force, and pull out the handpiece so that the needle cover remains in the needle cover hole .



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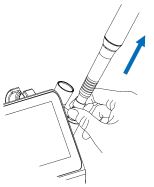
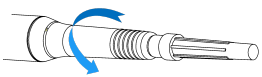
- Each anesthetic cartridge and needle can only be used for one patient.
- Dispose of used anesthetics and used needles according to relevant laws.
- Clean, disinfect and sterilize the Sleeve and Handpiece holder according to the user manual.

4.3 After injection

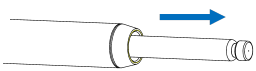
When you have completed the injection, follow these steps: Ensure that the pushrod is returned to the bottom (Refer to Section 6.3.11), insert the handpiece with the needle into the needle cover, hold the needle cover and pull the needle cover out of the needle cover hole.



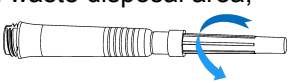
Then remove the Sleeve with needle anticlockwise;



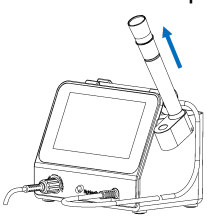
Then remove the anesthetic and discard it in the medical waste disposal area;



Then remove the needle with the needle cover anticlockwise and discard the used needle in the medical waste disposal area;

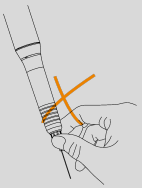


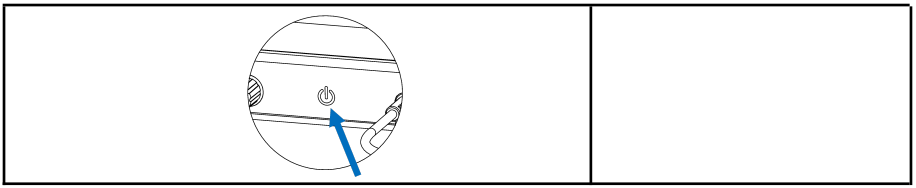
Then place the handpiece in the storage brackets and remove the Handpiece holder;



Finally, press the power icon on the front of the main unit to shut down the E-FLOW system.

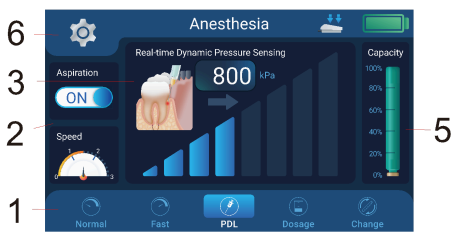
- Do not install or remove needles without needle cover protection , do not touch the top of the needle.

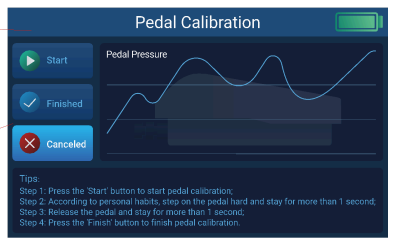


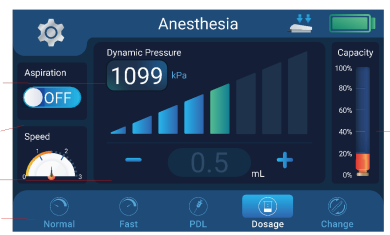


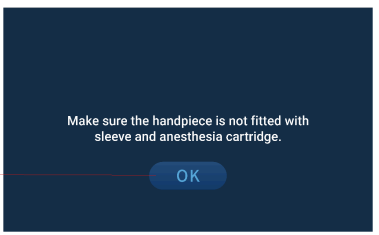
5 Function and use

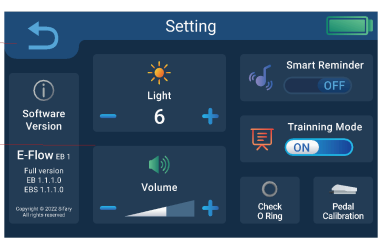
5.1 User interface

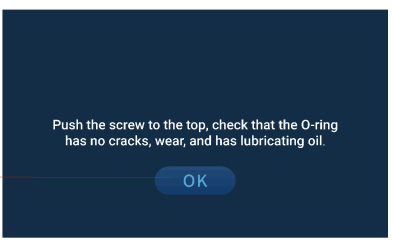


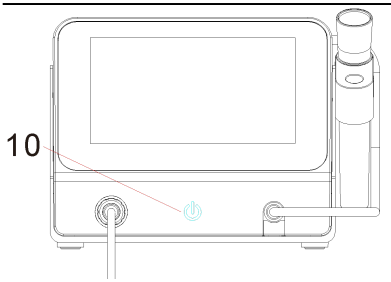




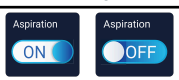


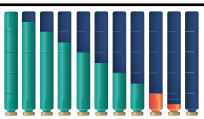
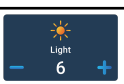
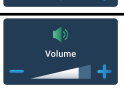


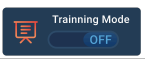
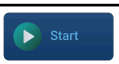
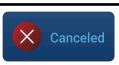




5.2 Icon

Area	Name	Icon	Paraphrase
1	Normal mode		Low and medium speed injection mode
	Fast mode		Medium and fast speed injection mode
	PDL mode		Only low speed injection mode
	Dosage mode		Dosage setting injection mode
	Change anesthetic		Control pushrod back to the bottom, change anesthetic
2	Aspiration		Aspiration on/off
	Injection speed		Low speed
			Medium speed
			High speed
3	Pressure value		Indicates the reference value of real-time injection pressure

	Pressure bar chart		The pressure bar chart consists of 8 cells, with the number of light cells increasing from left to right as the pressure value increases
4	Dosage setting		Set injection dosage
5	Anesthetic capacity		Indicate remaining Anesthetic dose
6	Setting		System parameter setting
	Foot pedal state		Unconnected
			Connected but not be pressed
			Connected and be pressed
	Battery capacity		Display the power state, when the red is displayed, it means that the power is very low and needs to be charged
	Charging indication		The machine is charging When this symbol appears
	Return		Return to the previous interface
7	Light setting		Screen light setting
	Volume setting		Volume setting
	Smart reminder		Volume setting on/off

			
	Trainning mode	 	Trainning mode on/off
	Check o-ring		O-ring maintenance follow the system prompts
	Foot pedal calibration		Calibrate the stroke of the foot pedal
8	Start calibration		Start calibration
	Finish calibration		Finish calibration
	Cancel calibration		Cancel calibration
9	Confirm		Confirm the information and go to the next step
10	Power on/power off		Press it to turn the power on/off

5.3 Product function

5.3.1 Injection speed

E-FLOW has three Injection speed,
Low speed（1）, 0.3ml/min
Medium speed（2）, 1.7ml/ min
High speed（3）, 3.5ml/ min

5.3.2 Injection mode switching

E-FLOW has 4 injection modes, the injection mode can be switched by clicking the icon with your finger
1) PDL mode, only low speed
2) Normal mode , low and medium speed
3) Fast mode, medium and fast speed
4) Dosage mode, low and medium speed
The injection mode can be switched during injection.

⚠ Injection with high speed should be more careful.

⚠ Switching injection mode during injection may result in a change in injection speed.

5.3.3 Foot pedal control

E-FLOW controls the start stop and injection speed by the foot pedal, press the foot pedal to start the injection, and release the foot pedal to stop the injection. The "front section" and "back section" of the foot pedal stroke match the two speeds under the injection mode. The operator can switch the injection speed at the injection mode by pressing the foot pedal to the "front section" or "back section"

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In PDL mode, the "front section" and "back section" of foot pedal stroke are both low speed

5.3.4 Foot pedal calibration

1) Click the "Foot pedal correction" icon 

to enter the "Foot pedal correction" interface;

2) Click the icon 

, press the foot pedal and hold it for more than 1 second. If you want to shorten the pedal stroke, please press the pedal shorter, or press deeper;

3) Release the pedal and after more than 1 second, click the icon 

to complete the foot pedal correction;

4) If you want to abandon the foot correction, click the icon 

.

⚠

Recalibrate the foot pedal after replacement

5.3.5 Auto injection

This function enables the operator to maintain low speed injection without continuing to step on the foot pedal. This function is only applicable in "PDL mode". Auto injection is used:

1) Click the icon 

to start" PDL mode ", press the pedal;

2) After three "Beeps" sound, the device will sound "auto injection" prompt tone, and the foot

will leave the pedal within 3 seconds, and the device will start auto injection;

Note:

3) If you do not want to use the "auto injection" function, do not take your foot off the foot pedal within 3 seconds after the "auto injection" voice;

4) If you need to exit the "auto injection" function, press down the foot until the pedal status shows  and release it.

5.3.6 Dosage setting injection

The system is equipped with an injection mode in which the injection dosage can be set. This function is only applicable in "dosage mode". When using dosage setting injection:

1) Click the icon 

to start "dosage mode".

2) Click  or  to set the dosage, the step value is 0.1mL

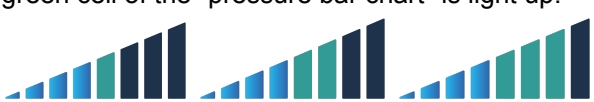
⚠

The maximum dosage can be set to 1.7mL

5.3.7 Pressure feedback

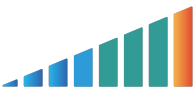
1) The system can feedback the injection pressure in real time and display it on the screen through the "pressure bar chart" and "pressure value". With the number of light cells of "pressure bar chart" increasing from left to right as the "pressure value" increasing.

2) In "PDL mode", when the displayed "pressure value" is bigger than the value set in the system, the prompt tone "beep" becomes higher, and the green cell of the "pressure bar chart" is light up.



3) When the system pressure is too high, the system will sound a sharp prompt tone, and the

last orange cell of "pressure bar chart" will light up, and the system will automatically stop injection. After the pressure is released, press the foot pedal again to continue the injection operation.



5.3.8 Smart reminder

When "smart reminder" is enabled (click the icon 

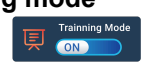
with your finger to turn this function on and off), the system will add the following prompt tone:

1) When the dosage of anesthetic is less than 20%, the system will prompt "remain low"; When the dosage is exhausted, the system will prompt "cartridge empty ".

2) In PDL mode, the first green cell of "pressure bar chart" lights up, and the system will prompt "PDL".

3) When the system pressure is too high, the system will sound "over pressure".

5.3.9 Trainning mode

Click the icon 

with your finger to turn this function on and off. "Training mode" includes all the prompt tone of "smart mode," as well as some additional prompt tone.

5.3.10 Aspiration

Click the icon 

with your finger to turn this function on and off. When the aspiration is enabled, in any injection mode, after releasing the foot pedal to stop the injection, the pushrod will drive the anesthetic piston to retract for a certain

⚠

It is recommended to enable "smart reminder ".

distance and then return to the previous position, which is called "aspiration" .

5.3.11 Change anesthetic

When the injection operation is complete or anesthetic is exhausted, it is necessary to return the pushrod and remove the used anesthetic. The anesthetic can be removed according to the actual situation in the following way:

1) When the anesthetic is exhausted

After the "auto injection" function is enabled and the anesthetic is exhausted, the pushrod will stop extending automatically, press on the foot pedal until the foot pedal state shows  and release, the pushrod will automatically return to the bottom, and then the anesthetic can be removed according to the steps in Chapter 5.3;

When the "auto injection" function is not enabled and the anesthetic is exhausted, the pushrod will stop extending automatically, release the foot pedal, and the pushrod will automatically retract to the bottom. Then the cartridge can be removed according to the steps in Chapter 5.3.

2) When the anesthetic has not been exhausted

When the anesthetic has not been exhausted and the injection operation has been completed, click the icon  on the screen and the pushrod will automatically retracted to the bottom. Then the anesthetic can be removed according to the steps in Section 5.3.

5.3.12 Charging

When the battery capacity  appears, it means the remaining battery power is less than 15%. Please charge the device in time.

⚠

Make sure the pushrod has returned to the bottom before replacing the anesthetic cartridge.

⚠

- If the power is less than 15%, the device must be recharged within 30 days, otherwise the battery will be

Charging indication  appears on the screen, 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.	damaged. ● Only trained technician or distributor can replace the battery. The electronic parts will be damaged if use a wrong battery or install in a wrong way.

6 Cleaning disinfection sterilization and maintenance

6.1 Foreword

For hygiene and sanitary safety purpose, the components (Sleeve, Handpiece holder) 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. 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.

6.2 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.).

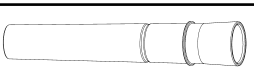
● Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the IFU of the disinfecting solution manufacturer.

● 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 use bleach or chloride disinfectant materials.

6.3 Cleaning disinfection sterilization

Autoclavable Components			
Sleeve		Handpiece holder	
⚠			

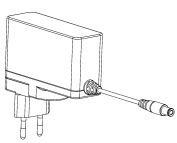
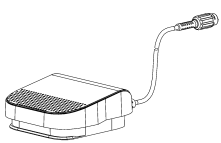
● Only the components above can be autoclaved. ● Before first use and after each use, clean disinfect and sterilize the above components.	
Reprocessing Instructions	
Preparation at the Point of Use:	Before cleaning, disconnect the components from the Main unit. Refer to Chapter 4.3 of this manual for disassembly instructions. Remove gross contaminations from the components with cold 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 components 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).  ● 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 automated cleaning, the components should be automatedly disinfected immediately. A manual disinfection is not recommended.
Drying:	Automated Drying: Dry the outside of the components through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of the components by using sterile compressed air.
Functional Testing, 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. Before packaging and autoclaving, make sure that the components have been maintained according to the manufacturer's instruction.
Packaging:	Pack the components 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:	Sterilize the components 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:	Store the sterilized components in a dry, clean and dust free environment at modest temperatures, refer to labels 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).

- 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.

Disinfection components		
Main unit	Adapter	Foot pedal
		
Preparation before processing:	Before cleaning and disinfecting, make sure the power is off.	
Cleaning:	Wipe all the exterior surfaces of the components thoroughly with a cloth lightly moistened with Ethanol (70- 80 vol% Ethanol) at least 3 min, repeat for 5 times. ⚠ Click the icon Check O Ring, extend the pushrod, clean the surface of the pushrod.	
Disinfection:	Wipe all the exterior surfaces of the components thoroughly with a cloth lightly moistened with Ethanol (70- 80 vol% Ethanol)at least 3 min, repeat for 5 times. ⚠ Click the icon Check O Ring, extend the pushrod, disinfect the surface of the pushrod.	
Drying:	Use a lint free cloth to wipe the surfaces.	
Inspection and maintenance:	Visual inspection for cleanliness of the components. Functional testing according to the user manual. If	

	necessary, perform reprocessing process again until the components are visibly clean. Before packaging, make sure that the components have been maintained according to the manufacturer's instruction.
Storage:	Storage of the processed device in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

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- Before first use and after each use, clean and disinfect the above components.
- Do not use anything except Ethanol (70- 80 vol% Ethanol).
- Do not use too much ethanol as it's going into machine and damage the components inside.
- Do not allow any moisture to get into the device.

6.4 Maintenance

Lubricate components	
O-ring	

Check the O-ring for cracking, wear or lack of grease every time you turn the device on.
If cracked or worn, replace it.
If dry or unlubricated, lubricate with silicone gel.
Gently apply silicone gel to the surface of the O-ring as the pushrod is extended.

To extend the pushrod, perform the following operations: Click the icon 

and follow the prompts.

Cartridge of anesthetic damage
The cartridge may be damaged during insertion or during injection. If the cartridge is damaged, thoroughly remove all glass debris and liquids around the pushrod. The remaining glass debris will cause a failure.

You can clear it following the steps,
1) Take out the cartridge and large pieces of broken glass.

2) Turn the handpiece upside down and use the 

function to extend the pushrod and remove all glass debris or liquid.
3) Using compressed air, clean the handpiece and pushrod to remove liquid and glass debris.
4) Check the remaining glass debris and remove them thoroughly.
5) Disinfect the pushrod, replace the O-ring and lubricate it.

7 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.	4.1
The charging indication does not appear	Using a wrong adapter.	Use the original adapter.	4.1
	The adapter is not connected.	Check the connection.	/
Leakage	Battery leakage or handpiece leakage	Contact your distributor.	/
Unable to shut down	Press the power switch too short time.	Long press the power icon more than 3 second	4.3
Anaesthetic artridge broken	/	Cleaning glass debris	6.2
Injection pressure cannot be completely released during aspiration	The O-ring is abnormal	Lubricate or replace the O-ring	6.2

8 Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	E-FLOW
Dimensions	26.5cm x 19.5cm x 14.5cm±1cm（package）
Gross weight	1.8Kg±10%
Power supply	Lithium ion battery:DC11.1V, 2600mAh, ±10%
Charger power supply	AC100-240 V, ±10%
Input power	500mA
Charger power output	20V⎓0.9A
Frequency	50/60Hz,±1Hz
Injection speed	Low speed：0.3mL/min, ±10% Medium speed：1.7mL/min, ±10% High speed：3.5mL/min, ±10%
Injection dosage	0mL～1.8mL, ±10%
Electrical safety class	Class II
Applied part	B
Ingress protecting rating	Ordinary equipment (IPX0); Foot pedal (IPX1)
Operation mode	Continuous operation
Ambient conditions	Use: in enclosed spaces Ambient temperature: 10°C ~ 40°C Relative humidity: 30%-75% Atmospheric pressure: 70 kPa - 106 kPa
Transport and storage conditions	Ambient temperature: -20 °C ~ +55 °C Relative humidity: 20% - 80 % Atmospheric pressure: 70 kPa - 106 kPa

9 EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The E-FLOW is intended for use in the electromagnetic environment specified below. The customer or the user of the E-FLOW should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The E-FLOW 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 E-FLOW is suitable for use in all establishments other than domestic establishments, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Provided the following warning is heeded: Warning: This E-FLOW is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the E-FLOW or shielding the location.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The E-FLOW is intended for use in the electromagnetic environment specified below. The customer or user of the E-FLOW should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)=3Vrms	Portable and mobile communications equipment should be separated from the E-FLOW by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150kHz to 80MHz
	6Vrms in ISM bands between 0,15 MHz and 80 MHz	(E1)= 6Vrms in ISM bands	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	(E1)=3V/m	D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter. 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).

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The E-FLOW is intended for use in the electromagnetic environment specified below. The customer or user of the E-FLOW should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. 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 by absorption and reflection from structures, objects and people.			

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 005 is used exceeds the applicable RF compliance level above, the Model 005 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 005.
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.
3. The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

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 E-FLOW 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 E-FLOW 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 ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 **5500** **5785**	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

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

   Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Adapter	1.8	NO	/

2. Use of E-FLOW adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, E-FLOW and the other equipment should be observed to verify that they are operating normally
3. 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.

10 Statement

Service Life

The service life of E-FLOW series products is 5 years.

Warranty Period

E-FLOW 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.

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. Please deal with them according to the local environmental protection laws and regulation.

Rights

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NOTICE

Any serious incident should be reported to manufacturer and competent authority.