

Blood Infusion Warmer

Operation Manual



Statement:

We reserve the right to interpret the operation manual.

We can revise the content of this operation manual without prior notice. The revised version will be in the new version operation manual.

This Manual is the operation guide only for Blood Infusion Warmer (hereinafter refer as” Infusion Warmer. We will not be responsible for any loss or hurt if following this manual for other use.

We will be not responsible for any software and equipment which is not provided by us.

We confirm the information in this Operation Manual is correct and reliable but not guarantee the content of this Manual.

Please read this manual carefully before operating the blood infusion warmer.

We will only be responsible for the safety, reliability and performance in all the following case:

- Installation, test, upgrade, maintenance are all done by our personnel or authorized person by us.
- All the maintenance spare parts should be from WE or accepted by our.
- Follow the electrical appliance national standard and the instruction of the operation manual.
- Strictly follow the instruction of the operation manual.

Warranty and Maintenance Service

The warranty is 12month for the device and accessories warranty is 6months, accessories is Power Cord

If the warranty period is not the same as above mentioned, please contact us. If it is not confirmed with us, please contact to your supplier.

The warranty period starts from the date on the Maintenance Card. Maintenance Card and the Invoice is the only proof to calculate the warranty period. For your sake, please inform us the qualified installation within 30days, or the warranty date will starts from the date on the package over till 30 days.

It will be free for after-sales service under warranty. It will be charged in the following case:

- Artificial damage
- Improperly operation
- Grid voltage is out of the ruled range.
- Force majeure
- Maintained by personnel not authorized by us.
- Use the spare parts which is not provided or confirmed by us
- Fault which is not caused by the device itself.

After warranty, the service will be charged. If service charge is rejected to pay or not paid on time, then we will have the right to stop servicing until the charge is paid.

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Precaution

Note:

This Operation Manual makes a detailed introduction for the use, function and operation instructions. Please read the manual completely prior to using this device. Please carry out inspection and maintenance periodically according to the manual to avoid patient/user injury

The manual have the most complete function and features. Please pay attention to the relative model and the relative function and features. Any question, please contact us.

Please put the operation manual beside the device for easy reference.

Operator

This operation manual is only used by well-trained clinical nurse or doctors.

Others

The figures in the operation manual are only for reference. The settings or data in the figures may be not 100% same as the real ones.

Warnings

- (1) This device is used for heating the infusion, blood transfusion and can used only by the well trained doctors or nurse for clinical use.
- (2) Please steady the device on the IV stand before use to avoid falling down to the floor.
- (3) It is advisable not to share the same power cord with other device during the working of this device and use the match power cord of this device. Do make sure the well connection and don't touch the power socket by wet hands.
- (4) It is not allowed to use voltage other than that specified on the product label, or else it might cause damage or even fire.
- (5) Please check the device and the accessories completely before use to make sure the normal safe working.
- (6) Please don't rely on the device alarm only and pay attention to the temperature of the infusion fluid or blood.
- (7) Please stop to use the device during alarming.
- (8) Don't connect other brand heating device or other brand heating accessories with this device, or it may lead to wrong heating temperature or dangerous infusion.
- (9) Please keep the infusion line straight and unfolded to prevent the infusion drug chemical reaction due to long time occlusion and heating.
- (10) Do not operate this device in environments where there are gas mixtures of flammable anesthetic, oxygen and oxidize ammonia, etc.to prevent fire or explosion.
- (11) Don't use the device where there is strong sunlight, cold & hot wind or dusted environment.
- (12) Microwave will influence the function of the device. Other device near the device must meet the EMC standard. Mobile phone, X-ray or MRI device will be the cause of malfunction due to its high frequency radiation.
- (13) The device must be operated by medical professional staff, such as doctors, nurses, etc. Don't operate this device by others except the above person.
- (14) It is not allowed to dismantle or modify the device. Opening the shell may be electrocuted. Maintenance or upgrade the device must be done by the well-trained or authorized staff from us.
- (15) Check the device daily and check all the function in good condition if it is not used for long period.
- (16) Obey the local regulation or hospital rule when disposing the packing material and keep the packing material away from the children.
- (17) The life of this device is 5 years. It may be dangerous and not advisable to use the device again after the life time expired.
- (18) Turn off the device and contact the supplier when there is malfunction.

Chapter 1. Introduction

1.1 Application

It is intended to provide continuous heating during infusion and blood transfusion.

1.2 Working Principle

The blood infusion warmer is to heat the infusion fluid by continuous heating the fluid inside the IV tube and deliver the heat to fluid through the extended tube. The temperature can be set between 32°C ~42°C and the control heating board will work based on the set temperature to reach the fluid target temperature.

1.3 Components and Function

The blood infusion warmer is consisted by the following parts:

- Main Control System: It is the core of the whole system. It can intelligently control, manage and processing the signal of the system.
- Heating Device: Consisted by the heating sheet and the heating exchanger. Deliver the heat to the fluid through exchanger.
- Detection Sensor: Consisted by different kinds of sensor, e.g. Temperature detection sensor.
- Alarm system: Consisted by audio, visual alarm, remind the user the abnormal information to avoid the harm to the patient.
- Input and display: Input the heating parameter, e.g. Temperature, alarm message and other parameter.

1.4 Technical Specification

1.4.1 Safety Compliance

Protection against electric shocks: Class II, include the internal power supply

Protection against leakage current: Type BF, the part without defibrillation discharge effect

Protection against splashing fluid: IPX1

Working Mode: Constant working mode

Input Voltage: 100-240V

Frequency: 50Hz/60Hz

Power: 85VA

1.4.2 .Working and Transportation and storage conditions

Temperature: +5°C ~+30°C

Relative Humidity: 20~80%, not condensation

Atmospheric Pressure: 70KPa~106Kpa

Transportation and Storage Temperature: -20°C ~+55°C

Transportation and Storage Humidity : 10~95%, not condensation

Transportation and Storage Atmospheric Pressure: 50KPa~106Kpa

Transportation and Storage Condition: No corroded air and good ventilated environment

1.4.3 Physical Specification

Device Dimension: 180mm×70mm×35mm

Weight: ≈0.2KG (without knob); 0.4kg (with knob)

Display Type: LED

1.4.4 Basic Parameter

Applicable IV set: Exclusive IV Set or standard single PVC IV Set (20 and 60 d/mL, with outer diameter 3.4 ~ 4.5mm)

Temperature Range: 35°C ~42°C (95~107.6F)

Optional Unit: (°C) and (°F)

Temperature Accuracy: ±1°C or±1.8°F

Warning up time: ≤2min

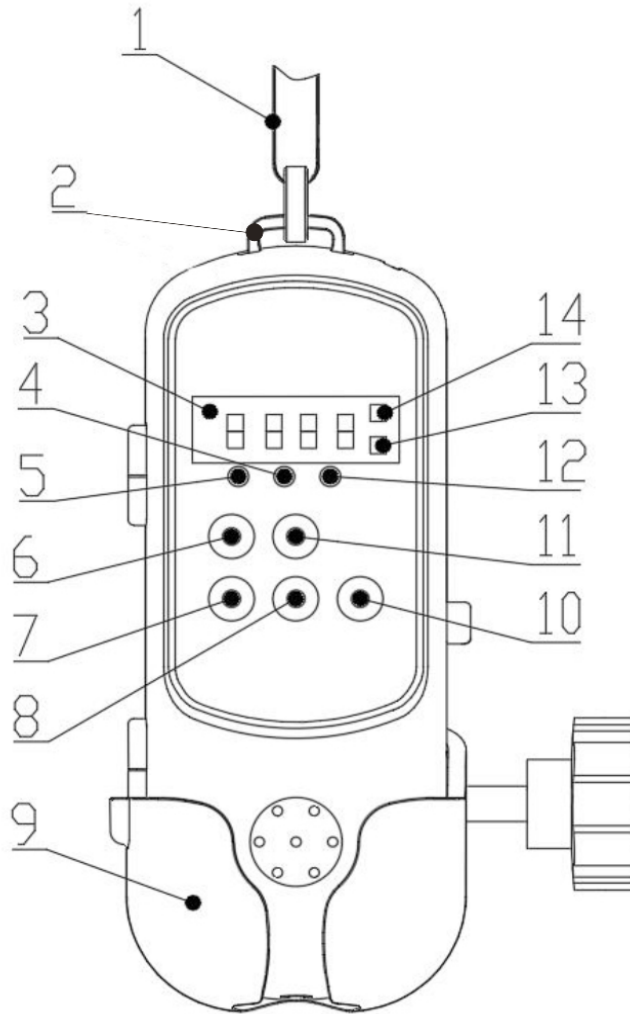
Overheat Protection: 48°C

Alarm: Overheat, low temperature, system error, door open, heating alarm

● Note:

The specification will not be subject to change without prior notice.

1.5. Outer Structure



Button and Function:

- 1、 Lanyard----To Hang the blood infusion warmer
- 2、 Lanyard hole---To hang the lanyard
- 3、 Display---To display the temperature and the alarm message
- 4、 Running Light---Keep flashing during temperature rising and keep it on after reaching the set temperature
- 5、 Low Temperature Alarm light---Flashing during low temperature alarm.
- 6、 Temperature Unit convert--- (°C) and (°F) convert
- 7、 Mute Button---Silence for 2mins by pressing the Mute button after alarm.
- 8、 Minus Button---Lower the temperature, increment: 0.1°C
- 9、 Knob---To attach the blood infusion warmer in the IV Stand
- 10、 Stop/start Button---Start or stop the device
- 11、 Plus Button---Increase the temperature, increment: 0.1°C
- 12、 Overheat alarm light (High Temperature Alarm) ---Flashing when high temperature alarm
- 13、 °F temperature—Select °F temperature unit when the light on
- 14、 °C Temperature---Select °C as temperature unit when the light on

Chapter 2. Operation

2.1 Preparation

2.1.1 Open the box and inspection

Please check the carton before opening the box to make sure if any damage during transportation. If any, please contact the forwarder or our company immediately.

If the packing is ok, please dismantle the package and take out and check the warmer and other accessories carefully. Please check whether all parts is complete and any mechanical damage. If any doubt, please contact us immediately.

Note:

- Please put packing material where the child can't be reached. Follow the local regulation or hospital rule when dealing with the packing material.
- Keep the packing material in stock for future use.

2.1.2 Environment Standard

Please keep the warmer away from the noisy, shaking, dusty, corrosive, flammable, explosive environment. Please keep at least 5 cm distances around the device to make good loss of heat and good air recycle.

When the device is moved to other environment, it may have condensation due to the temperature difference, in which case, please don't start the device until the condensation finish.

2.1.3 AC Power

Please run the device under the AC Power range on the label only.

Note:

- Use the proper AC Power supply based on the power voltage setting. Or it will make damage to the device or fire disaster.

2.1.4 Power Cord Installation

Connect the power cord to the warmer and connect the AC power, the device will start automatically. Disconnect the AC Power; the device will switch off automatically.

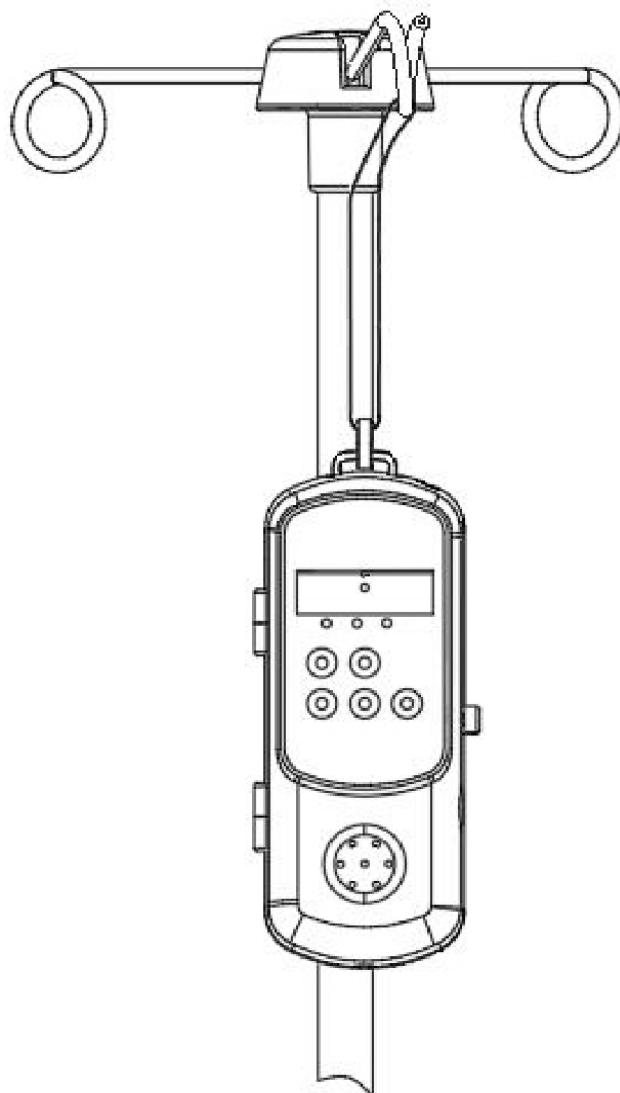
Note:

- Please make sure the Power Cord connect the warmer cord tightly.

2.2 Blood Infusion Warmer Installation

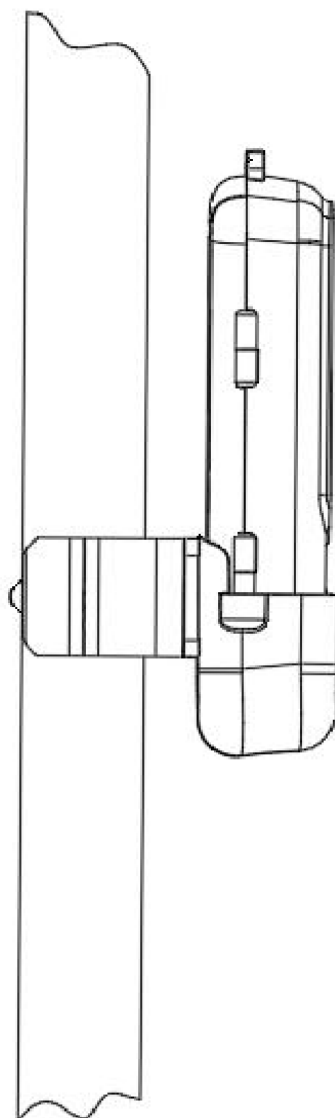
2.2.1 Hang the device on the stand

Hang the device on the stand:



2.2.2 Hang the warmer on the stand with the knob

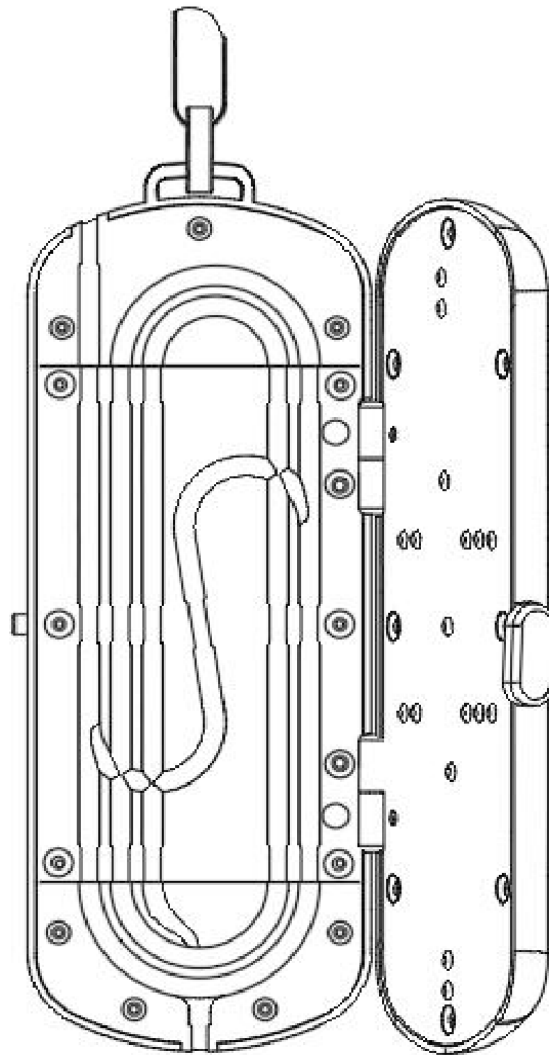
Use the knob to hang the warmer on the stand.



2.3 IV Set Installation

2.3.1 IV set installation preparation.

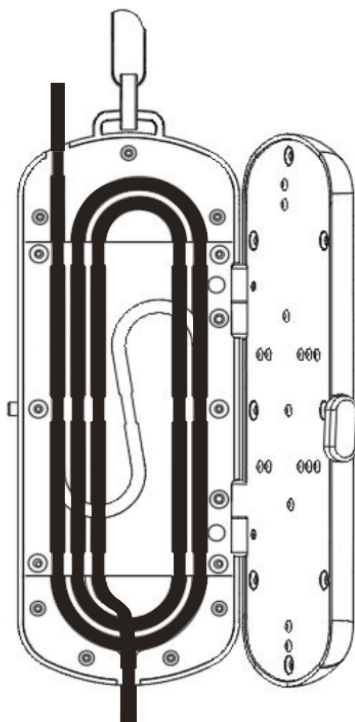
Prepare the IV set with fluid and prime the bubble inside the tube. Open the door as following picture:



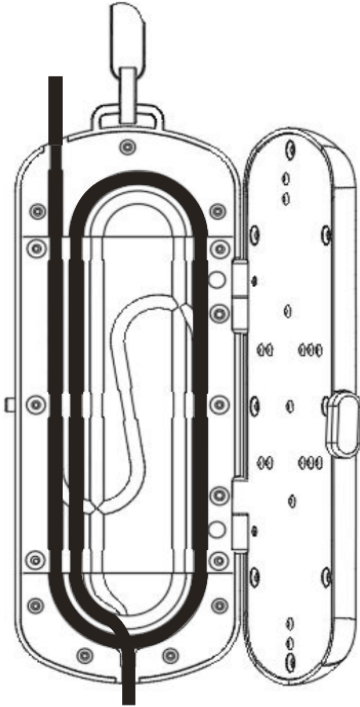
2.3.2 Heating Path Selection

Install the IV set end from up to down inside the heating path and select the path based on the IV set length and heating requirement:

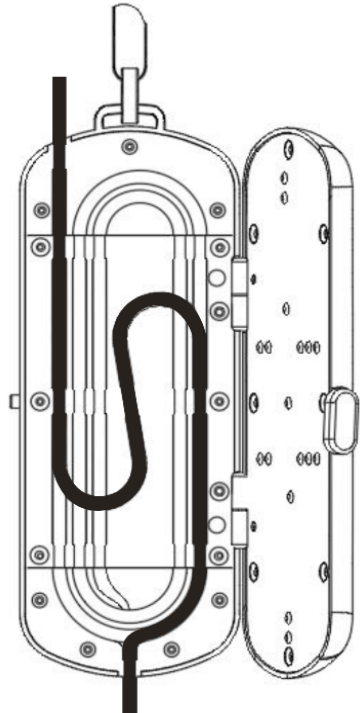
Long heating path installation reference :(heating length around 52cm)



Middle heating path installation reference: (Heating length around 31cm)



Short heating path installation reference: (heating length around 25cm)



2.4 Output Temperature Reference

Flow rate	Set Temp.: 35°C			Set Temp.: 37°C			Set Temp.: 42°C		
	Short Path	Middle Path	Long Path	Short Path	Middle Path	Long Path	Short Path	Middle Path	Long Path
25ml/h	22.0°C	22.5°C	25.1°C	22.3°C	22.6°C	25.2°C	22.6°C	24.1°C	25.3°C
100ml/h	23.7°C	25.4°C	29.2°C	24.3°C	26.7°C	30.8°C	25.8°C	28.8°C	32.6°C
200ml/h	26.1°C	28.5°C	32.7°C	26.8°C	28.6°C	33.6°C	28.9°C	30.4°C	36.8°C
400ml/h	25.3°C	26.7°C	31.6°C	25.4°C	27.8°C	33.1°C	27.8°C	31.1°C	35.7°C
600ml/h	24.7°C	26.1°C	30.8°C	25.2°C	27.2°C	32.2°C	27.3°C	29.3°C	33.9°C
1000ml/h	23.9°C	25.7°C	29.8°C	24.5°C	26.4°C	31.0°C	25.6°C	29.2°C	31.9°C

Note: Room Temperature 20°C, input fluid temperature 20°C, the distance between the IV set fluid exit and the warmer is around 10cm.

2.5 Parameter Setting

2.5.1 Connect to the AC Power

Connect to the AC Power and the device will be on automatically and LED shows the set temperature.


2.5.2 IV Set installation

- Prepare the IV Set or blood transfusion tube. Fill the fluid inside the tube and prime the bubble. Install the IV tube inside the heating path (long, middle, short path) based on the real needs.
- Install the IV tube end from up to down inside the heating path.
- Close the door and set the parameter

2.5.3 Temperature Setting



In the standby mode, press  ,  to set the temperature, increment: 0.1°C.

2.5.4 Temperature Unit Setting


In the standby mode, please press  to set C or F unit. It will show the unit once it is done

2.5.5 Start the warmer

a. Confirm all the setting

b. Press Start/Stop  to start the warmer. It will start to work based on the set temperature. The temperature on the LED shows the heating board temperature. If the temperature needs to be changed during heating, press  Start/Stop again to the standby mode and reset the temperature.

2.5.6 Finish Heating

Press  Start/Stop to the standby mode and take out the IV tube from the warmer. Disconnect the AC Power with the warmer.

Chapter 3 Alarm

3.1 Over Heat Alarm

When the heating board detects the temperature is 2°C higher than the set temperature, it will alarm intermittently and over heat alarm light keep flashing. At this time, please stop to use the device and restart it. Please send back to the factory for maintenance if the alarm is still on after restarting.

3.2 Low Temperature Alarm

When the heating board detects the temperature is 2°C lower than the set temperature, it will alarm intermittently and over heat alarm light keep flashing. At this time, please stop to use the device and restart it. Please send back to the factory for maintenance if the alarm is still on after restarting.

3.3 System Error Alarm

When it shows E001 on the LED if it is operated by mistake or fault with the device, please restart the device. Please send back to the factory for maintenance if the alarm is still on after restarting.

3.4 Warming up Alarm

The running light keeps flashing if the set temperature is not reached after starting. Once the warming up is ready, the light keeps on and stop flashing.

3.5 Door Open


It will show E002 on the LED if the door is open during working. Once the door is closed, the alarm will be clear and show the original temperature.

3.6 Alarm Introduction

3.6.1 Alarm Level

System Error, overheat and low temperature is the high level alarm. Other alarm is low level alarm. It will show the latest alarm when the same level alarm appears.

3.6.2 Alarm System Setting

Press  Mute Button can silence the alarm for 2mins but the alarm system is not closed.

3.6.3 Alarm Signal

When there is alarm,

The operator can see clearly the red alarming light flashing from 4m distance with the warmer.

The operator can hear the alarm intensity more than 45 decibels from 1m distance with the warmer.



3.6.4 Action for the Alarm

When there is alarm, please check the patient in priority.

When there is alarm, please take the following action:

1. Check the patient
2. Confirm the alarm type
3. Find the alarm reason
4. Find the way to remove the alarm
5. Confirm to remove the alarm.

3.6.5 Alarm and Error

Alarm	Possible Cause	Solution
Show the room temperature after switching on the warmer	Door not closed	Close the door
	Not Press  Start/Stop Button	Press  Start/Stop to start
	Detection sensor or heating system error	Contact supplier if problem is still after restarting.
Overheat Alarm	Direct sunlight or infrared light leads to the overheat temperature	Avoid the sunlight or infrared environment
	Electromagnetic interference	Avoid electromagnetic interference environment
	Detection sensor or heating system error	Contact supplier if problem is still after restarting.
System Error Alarm	Hardware System Error	Contact supplier if problem is still after restarting.

Chapter 4. Daily Check and Maintenance

4.1 Daily check

Please test the device completely before the first time use, 6-12 months continuous operation, maintenance or upgrading to make sure the device working normally.

Check the following item:

- Environment and power standard
- AC Power cord is isolated or not
- Device and accessory is not damaged mechanically.

- Alarm system function well
- Accuracy is in the standard range

Please contact distributor or manufacturer if any abnormal.

4.2 Clean and sterilize

Please use the mention below material and method to clean or sterilize the device. We will be not responsible for the damage or accident caused by other material and method clean or sterilization.

The listed chemical and method is only for control the infection. We will not bear any responsibility for its validity.

Please enquiry the hospital Infection Prevention Department or local epidemiological expert for the infection control method.

Please operate the device and the accessory in the dust free environment. To avoid damage, please follow the following regulation:

- Dilute the detergent and disinfectant with the instruction from the manufacturer or use the best possible lower concentration.
- Don't put the device into the fluid.
- Don't pour fluid into the device and its accessory.
- Don't put fluid into the device.
- Don't clean with the device with abrasive material (steel ball or polishing agent) or dimethyl benzene, acetone detergent to avoid shell damage.

Note:

- Disconnect with the AC Power and disconnect the AC Power with the socket before cleaning the device.
- Stop use the device and contact the manufacture or distributor if pour water into the device or accessory accidentally.

Please clean the device regularly and clean it more often in the serious environment polluted or sandstorm area. Contact the local medical equipment cleaning regulation before cleaning the device.

Following is the optional detergent and disinfectant:

- Warm water
- Diluted soap-sups
- Diluted ammonia water
- Sodium hypochlorite(Clean bleaching powder)
- H2O2 (3%)

- Ethanol (70%)
- Isopropyl alcohol (70%)

Recommended clean and sterilized step:

1. Switch off and disconnect the AC Power and the power socket
2. Wipe the shell with soft cloth wet by warm water
3. Wipe the shell and sterilize by cotton ball with 70% ethanol.
4. Keep the device in dry, ventilated area after cleaning and sterilization.

This above step is for reference only. Please try different proper way test the sterilization

Note:

- Don't sterilize with Eto or formaldehyde

4.3 Maintenance regularly

Routine maintenance

Interval period	Step
As hospital cleaning rules	Clean the surface completely before or after long time storage
Check at least one time per year	<ol style="list-style-type: none"> 1. Test the AC power socket and cable 2. Test the temperature accuracy before use

4.4 Pollution-free disposal and recycle

The life of the device is 5years. Please scrap disposal for the device used more than 5year and contact the manufacturer and distributor for more details

Dispose the device as following:

1. Deliver the disposed device back to the manufacturer or distributor for recycle.
2. Deliver the waste component to the manufacturer or distributor or dispose it following the local recycle regulation

4.5 Transportation and storage


Store the device in the following condition after cleaning:


Temperature: -20°C -55°C ; Relative Humidity: 10%~93%; Atmospheric Pressure: 70KPa~106KPa。


Please don't store the device in the following condition:

- a、 Environment with direct sunlight or strong light.
- b、 Environment with hot or wet air coming from heating installation, furnace and humidifier.
- c、 Environment with chemical materials, dust, and humidity.
- d、 Environment with water, dust, and humidity or shaking or unflat floor
- f、 Don't overlap the device more than 5laps.

4.6 Compliance

: Please read the operator manual prior to using this device!

: Protection against electric shocks: Class I with ground connection equipment.

: Protection against leakage current: Type CF equipment.

IPX1: Protection against splashing fluid.

Appendix

Note:

- It may increase the electromagnetic emission and lower the anti-electromagnetic interference if adding other accessories, sensor or cable.
- Don't put the device next to or overlap with other equipment. If necessity, please watch closely to make sure working normally.
- Maintenance and install the device in the environment complied with the EMS standard.
- Avoid operating the device with MRI or similar device at the same time, or it will lead to device problem or breakdown from the electromagnetic interference.
- Other equipment complied with CISPR emission standard also may interface the device.
- When the input signal range is lower than the specified lowest range, it will lead to temperature inaccurate.
- Potable and mobile RF communication equipment may influence the performance of the monitor.

Guidance and manufacturer's statement on anti-electromagnetic interference I


Applicable to all the devices and systems

1	Guidance and manufacturer's statement on anti-electromagnetic interference		
2	This device is predicted to be used in following electromagnetic environment. The buyer or user of the device should make sure to use it in this electromagnetic environment.		
3	Emissions test	Compliance	Guidelines on the electromagnetic environment
4	RF emissions CLSPR 11	Group 1	RF energy of this device is only applicable to the inner part. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	
6	Harmonic current IEC 61000-3-2	Class A	
7	Voltage fluctuation and flicker IEC 61000-3-3	Complies	

Guidance and manufacturer's statement on anti-electromagnetic interference			
This device is predicted to be used in following electromagnetic environment. The buyer or user of the device should make sure to use it in this electromagnetic environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Guidelines on the electromagnetic environment

Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	The ground should be made of wood, concrete, or ceramic. If the ground is covered by composite materials, the RH of the air should be not lower than 30%.
Electrical fast Transient burst IEC61000-4-4	±2kV Power cord ±1kV Input/output	±2kV Power cord ±1kV Input/output	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential mode ±2kV Common mode	±1kV Differential mode ±2kV Common mode	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, Short interruptions and voltage variations IEC 61000-4-11	<5%Ut (>95% dips in Ut) 0.5 cycle 40% Ut (60% dips in Ut) 5 cycle 70% Ut (30% dips in Ut) 25 cycle <5% Ut (>95% dips in Ut) 5 seconds	<5%Ut (>95% dips in Ut) 0.5 cycle 40% Ut (60% dips in Ut) 5 cycle 70% Ut (30% dips in Ut) 25 cycle <5% Ut (>95% dips in Ut) 5 seconds	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the users need to continue the operation during power failure; therefore, the uninterruptible power supply or battery power supply are recommended.
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3 A/m	3A/m	Electric power frequency magnetic fields should comply with the standards of the commercial or hospital usage.
Note	Ut is the AC mains voltage prior to application of test level.		

Guidance and manufacturer's statement on anti-electromagnetic interference II

Guidance and manufacturer's statement on anti-electromagnetic interference: applicable to all the non-living device and systems			
This device is predicted to be used in following electromagnetic environment. The buyer or user of the device should make sure to use it in this electromagnetic environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidelines
Conducted RF IEC 61000-4-6	3Vrms 150KHz to 80 MHz	3V	Portable and mobile RF communications device should not be placed closer to any parts of the device than the recommended separation distance. The separation distance should be calculated by the formula corresponding to the transmitter frequency. Recommended Separation Distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$
Radiation, RF, electromagnetic field IEC 61000-4-3	3V/m 80MHz to 2.5 GHz	3V/m	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 80MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800MHz to 2.5 GHz If p is the maximum rated output power (w) provided by the RF device manufacturers, d will be the recommended separation distance (m). (b) The field strength of fixed RF transmitters is determined by the investigation of the electromagnetic fields. Each band should be lower than compliance level. (a) (b) Device marked with the following tag would interfere with the nearby substances: 
Note 1. If the frequency of the communications device is 800MHz or higher, formula for the high band should be used.			
Note 2. The proposed guidelines may not be applicable to all conditions. Electromagnetic spread can be affected by absorption and reflection of buildings, substances, and human bodies.			
a) Field strength of the fixed transmitters (such as Wireless (cordless / cellular) telephones and ground mobile radio station, amateur radio, AM FM radio and television broadcasting) can not be predicted theoretically. In order to evaluate the electromagnetic environment of the fixed RF transmitters, the investigation of electromagnetic field should be taken into consideration. If the field strength of the place near to the device is higher than the RF compliance level, the device should be observed and checked to assure whether it can work normally. If abnormal performance is observed, the compensation measures may be necessary, for example, re-orientate and re-position the device.			
b) When the frequency range is between 150kHz and 80MHz, the field strength should be less than 3V/m.			

Maximum rated output power of the communications device (W)	Separation distance determined by the frequency of the communications device (m)		
	150KHz to 80MHz $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	80MHz to 800MHz $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended separation distance d (unit: m) can be determined by the formula in the corresponding column of the transmitter frequency. Here, p is the maximum rated output power rating provided by the manufacturer (unit: w).

Note 1. If the frequency of the communications device is above 80MHz-800MHz, the formula for high brand should be applied.

Note 2. The proposed guidelines may not be applicable to all conditions. Electromagnetic spread can be affected by absorption and reflection of buildings, substances, and human bodies.

Recommended separation distance between portable / mobile RF communications device and blood infusion warmer

This device is expected to be used in the electromagnetic environment where the radiation RF disturbance is controlled. Based on the maximum output power of the communication device, the buyers or users can prevent electromagnetic interference through maintaining the minimum distance between the portable/mobile RF communications device (transmitters) and the blood infusion warmer