hawkmed®

Shenzhen Hawk Medical Instrument Co., Ltd.

Hawk-fw1
Fluid Warmer

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Hawk-fw1 Fluid Warmer

Fluid warmer is a device heating fluid inside infusion set /blood transfusion set based on thermal transfer principle. It accepts various brand of infusion set/blood transfusion set.

Fluid Warmer Features

- Compact and light weight
- Colorful LCD screen with detailed info
- Double groove heating for two infusion sets
- Optional working with drop sensor
- Fast heating, 3~5 minutes to reach the set temperature
- With over-temperature & low temperature alarm
- Cut off the power supply automatically when overheat of fluid
- Two flexible installations: with hanger or pole clamp
- The pole clamp has hidden function, saving space

Specification	
Tube size	3~4.5 mm
Heating range	30 ℃ ~ 42 ℃, with increment of 1℃ or 0.1 ℃
Accuracy	≤ ± 1 ℃
Clasiffication	Class I / type B
Power	AC 100-240V, 50Hz/60Hz
Net weight	550g
Packing dimension:	22.0*19.0*12.1 cm

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ISO13485:2003/ISO9001:2008/CE certificate

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Shenzhen Hawk Medical Instrument Co., Ltd.

USER MANUAL

Fluid Warmer

Model: Hawk-fw1

CE 0197

057-00110-02

Contents

Revision Notes:

On the premise of comply with relevant laws and regulations, we'll revise the manual timely according to the improvement of products or update of laws and regulations.
This Manual applies to Hawk-fw1 Fluid Warmer.

Version No.	Date of Preparation
V1.0.0	2020.05.18
V1.1.0	2021.01.07
V1.1.1	2021.09.13

User manual version upgrade instructions:
V X.Y.Z
V means version No. of user manual.
X means device has big upgraded: When software, hardware and construction of device have big modified, the user manual should be upgraded accordingly.
Y means the device has small improvement: In order to better using the device, the software, hardware and construction of device have been tiny improved (it is not necessary for re-registration after evaluation), the user manual should be upgraded accordingly.
Z means correcting information of user manual while the device has no changed. It only correct the wrong word/ diagram/explanation and so on.

1. Product overview

1.1 Main Composition and Structure

The fluid warmer is mainly composed of the microcomputer system, warning device, temperature detector, alarm system and human-machine interface.

Microcomputer system: "brain" of the whole system used for intelligent control and management of the whole equipment and processing of detection signals.

Warming device: the heating wire in the silicone sheet is used for warming and the generated heat is transmitted to the liquid medicine in the infusion tube through the aluminum sheet.

Detector (self-check) : mainly composed of sensors, such as the Hall sensor (for door opening detection) and temperature sensor (for detection of the aluminum sheet temperature). The signals detected by the sensors are processed and then transmitted into the microcomputer system, followed by related operations.

Alarm system: after the signals detected by the sensors are processed by the microcomputer into alarm control signals, the alarm system will respond to attract the attention and take correct measures. The alarm system mainly consists of the light alarm (light-emitting diode), sound alarm (loudspeaker), screen display alarm, etc.

Human-machine interface: the infusion parameters are set via the buttons, such as the warming temperature. The parameters and current operating status are shown on the color LCD

1.2 Applicable Range

Fluid warmer is an equipment heating liquids inside blood transfusion tube/infusion tube based on thermal transfer principle, therefore, it is mainly used to heat liquid infused to human by transfusion tube/infusion tube.

Users of this device must be well trained professional persons.

1.3 Product Performance

Power supply: AC 100V—240V 50Hz/60Hz

Input power: ≤150VA

Temperature control accuracy: ≤±1℃

Temperature control range: 30℃～42℃ (The controlled temperature is 10℃ higher than surrounding temperature)

Degree of Protection Against the Ingress of Water: IPX4

Mode of operation: Continuous

Applied part: Heating Panel

Safety measures:

——1) When the temperature reaches 43℃, audible and visual alarms are issued and the heating circuit is cut off.

——2). Automatically power cut if the heater's temperature reaches 50℃±5℃.

Monitoring drip rate, bottle empty and giving alarm. (Optional)

Complete machine weight: ＜1kg

Dimension: 172*92*55mm

1.4 Medical Electronic Device Safety Classification

Class I,Type B applied part

1.5 Operational Environment

(1) Temperature: 5℃-30℃

(2) Relative humidity: 10%-93% （No frost）

(3) Atmosphere pressure: 86.0kPa～106.0kPa

1.6 Effects to Environment and Energy Resource

The fluid warmer may have a certain amount of electromagnetic radiation, which may interfere other devices. If this situation occurs, please take appropriate measures to reduce the interference, such as adjust the device's location, or connect power supply from other sources. For further information, please refer to EMC Information(Chapter Ⅺ of this user manual).

1.7 Contraindication

1) Not for use in warming platelets, cryo-precipitates, or granulocyte suspensions；

2) Not for use in warming heat-sensitive drugs.

3) Not used for preventing the development of hypothermia .

1.8 Attentions

(1) This device is used to heat drugs(or blood) inside infusion tube/blood transfusion tube. Don't use it for other purposes.

(2) Please follow doctor's instruction when using this device, ensure the drug can be heated, and check appropriate heating temperatures.

(3) Prevent impact or knocking on the device, please pick up and lay down gently.

(4) Please don’t heat broken blood transfusion tube or infusion tube.

(5) Read this user manual before installation and operation.

(6) Don't wash this device.

(7) Do not allow service or maintenance the equipment while used in patient.

(8)Warning: Class I equipment, to avoid the risk of electric shock, the equipment must only be connected to a supply mains with protective earth.

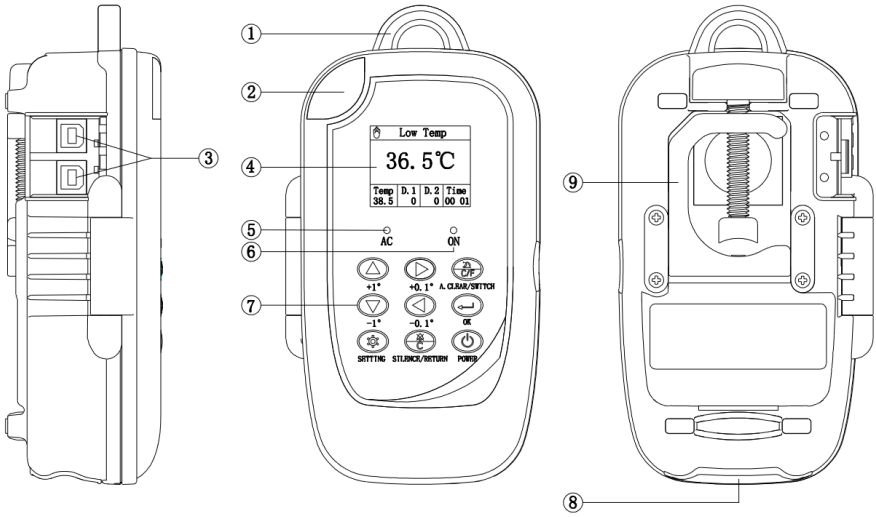
(9) Warning: No modification of this equipment is allowed

(10). If any operator requests more information such as circuit diagrams, parts list and product descriptions, for repairs carried out by qualified technical personnel, please contact us

(11) Warning: the use of disposable blood transfusion devices and infusion devices should comply with the corresponding hygienic and quality standards of the competent authorities and forbid cross use. After the use of disposable infusion device and blood transfusion, the operator will treat it as medical waste.

2. Exterior Diagram

2.1 Complete Machine Diagram



①hand ring ②light cover ③drop sensor port

④Display interface ⑤ AC indicator light ⑥switch on indicator light

⑦keypad ⑧Power cable interface ⑨Fixing clamp(Hidden status)

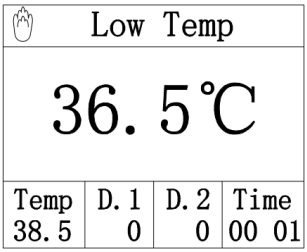
2.2 Accessory

Name	Mode	Material code
Suspension belt	——	056-00190-00
AC Power cord	H05VV-F 3X0.75mm^2	057-00025-00
Drop sensor (Shown as upper-side picture)	Hawk-DS	013-00063-00

Note: While using the drop sensor, the machine will give drip abnormal and empty bottle alarm.

3. Introduction of Operation Interface

3.1 Switch on, Operating and Standby Interfaces



3.2 Introduction of Operation Interface

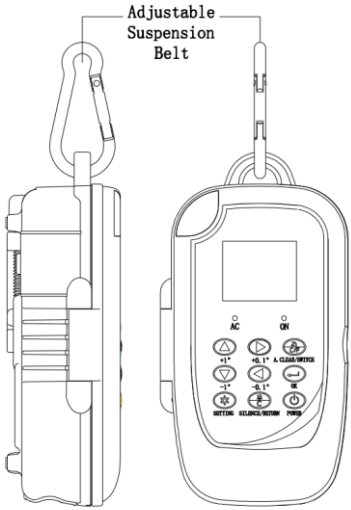
Please refer to section 4.2 of this user manual.

4. Installation & Operation Instructions

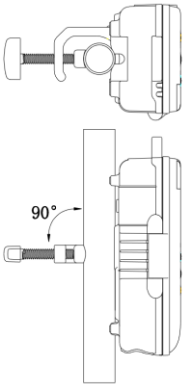
4.1 Installation

Two methods to install this device:

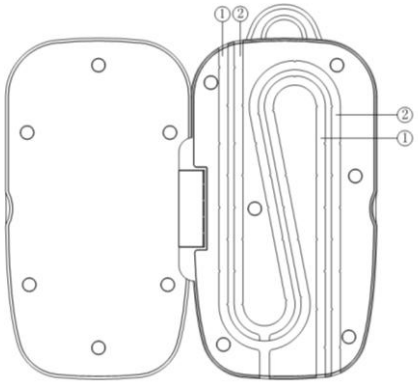
1. Use hanging ring to hang the device



2.Pole Clamp install illustration:(Open the hidden pole clamp and rotate 90 °, same as below second photo)



Note: This device has two Tube Channel Installation Slots for warming the fluid or blood, can be installed two Tube Channels or one Tube Channel. Illustration as below:



①：1st Tube Channel Installation Slot

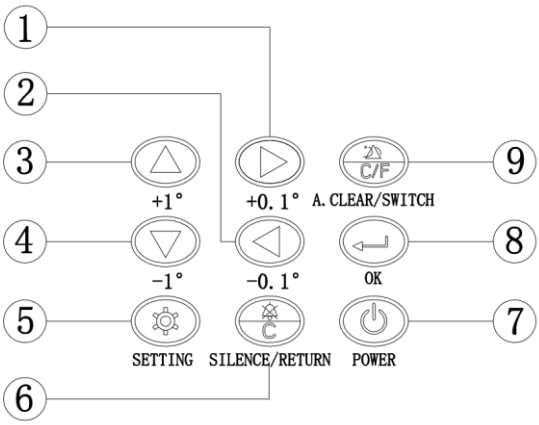
②：2nd Tube Channel Installation Slot

4.2 Instructions for use

The product is mainly used for heating the fluid or blood in transfusion tube.

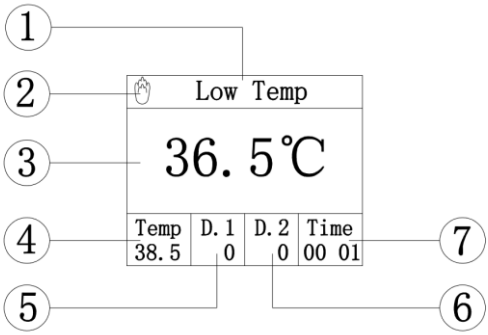
In addition, it can detect the infusion drop rate and alarm when bottle is empty.

1. Instructions of keypad：



Serial number	Description	Function
①		In main interface or standby interface means +0.1° temperature value. In setting menu interface, it indicates "To Right" navigation key
②		In main interface or standby interface means -0.1° temperature value. In setting menu interface, it indicates "To Left" navigation key
③		In main interface or standby interface means +1° temperature value. In setting menu interface, it indicates "To UP" navigation key
④		In main interface or standby interface means -1° temperature value. In setting menu interface, it indicates "To Down" navigation key
⑤		Enter the setting menu
⑥		Return to the upper level menu; clear the alarm sound if there's alarm
⑦		Power key – Keep pressing Power for seconds to switch on/ switch off the device
⑧		In setting menu interface Enter is confirm key, No effect in the main menu
⑨		In the main menu, Switch to the unit of temperature. It can clear the alarm sound if there's alarm

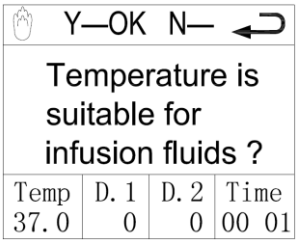
2. Main Interface:



Serial number	Description	Function
①	Alarm Display Area	When alarm occurs, display the relevant alarm symbol
②	Heating Symbol	When the symbol is displayed, it indicates that the heating plate is warming up
③	Real-time Temperature	Display Heating Plate Real Time Temperature
④	Set the temperature	Display the setting temperature
⑤	Drop 1	Drop rate of 1st Tube Channel
⑥	Drop 2	Drop rate of 2nd Tube Channel
⑦	Operating Time	Total operating time of the device

Attention:

When the setting temperature exceeds 37℃, the following confirmation interface will pop up. Users need to confirm whether the drug or other infusion fluids are safety at the setting temperature, and then adjust the temperature upward after confirmation.



3、Setting interface:

After press "Setting" Key, enter the following interface sequentially:

Interface	Description	Function
1st Interface	Temperature setting	Set the target temperature and press "OK" key to save the settings
	Drop1 Setting	1. Set empty bottles alarm and abnormal accuracy alarm; 2.Set Drop rate of 1st tube channel; 3. set Drop 1 ON or OFF; 4.set the accuracy (Default: 100 drops/min, accuracy ±10%; accuracy is adjustable during ±5% ~ 35%), press “OK” key to save the setting
	Drop2 Setting	1. Set empty bottles alarm and abnormal accuracy alarm; 2. Set Drop rate of 2nd tube channel; 3. set Drop 2 ON or OFF; 4.set the accuracy (Default: 100 drops/min, accuracy±10%; accuracy is adjustable during ±5% ~ 35%), press “OK” key to save the setting
	Backlight	Set the LCD screen backlight bright or dark, and press the "OK" key to save the settings

2nd Interface	Volume	Set the speaker volume, the speaker volume is 8 levels, and press the "OK" key to save the settings. High volume>65dB,Low volume≥45dB
	Volume of Key	Set the key sound to ON or OFF, and press the "OK" to save the settings
	Restore to factory settings	Restore all the specifications to factory settings
	Language Settings	Set up language, choose English or Chinese, Press "OK" key to save settings
3rd Interface	Device Information	Review the information of device, software version, etc.

4.3 Power on / off

1.Keep pressing "Power" key until the LCD display is ON

2.Keep Pressing "Power" key 2 seconds, the display will be off.

4.4 Operation Steps

1. Sterilize and clean the surface of the Fluid Warmer.
2. Fix the device per the install illustration, connect to power supply;
3. Install the fluid/blood transfusion tube to the corresponding heating plate slot, close the front cover, insert the drop sensor into the corresponding socket (if required), switch on the device.
4. According to the actual need to set the parameters, and press the "OK" key to save the settings, after back to the main interface, the Fluid Warmer will operate normally;
5. Switch off the device, and pull out the power plug from the AC socket after warming.
6. Sterilize and clean the surface of the Fluid Warmer.

4.5 Alarms and solution

Description	Alarm	Reasons and Solutions
Door open	The front cover is open or not cover well	Detect the front cover is opened or not cover well, show alarms in visual and audible, press "SILENCE/RETURN" key to clear the audible alarm
Temperature abnormity： High temperature Low temperature	The temperature is 1℃ higher or lower than the setting temperature	Heating function is abnormal. Show visual and audible alarm, when the temperature goes back to the control range, the alarm will disappear automatically. Press SILENCE/RETURN" key to clear the audible alarm. Try again, if the alarm still exists, please return to factory for repair.
Drop1 E	Drop 1 Empty	Detect the infusion bottle of 1st tube channel is empty. Show visual and audible alarm, press "A.CLEAR/SWITCH" key to clear the visual alarm, press "SILENCE/RETURN" key to clear the audible alarm.
Drop2 E	Drop 2 Empty	Detect the infusion bottle of 2st tube channel is empty. Show visual and audible alarm, press "A.CLEAR/SWITCH" key to clear the visual alarm, press "SILENCE/RETURN" key to clear the audible alarm.
Drop1 A	Drop 1 abnormal	Detect drop rate of 1st tube channel is abnormal. Show visual and audible alarm, when Drop rate goes back to the correct rate, then the alarm will disappear automatically, press "SILENCE/RETURN" key to clear the audible alarm.

Drop2 A	Drop 2 abnormal	Detect drop rate of 2nd tube channel is abnormal. Show visual and audible alarm, when Drop rate goes back to the correct rate, then the alarm will disappear automatically, press ”SILENCE/RETURN” key to clear the audible alarm.
0xE0 alarm	Communication failure	Notify the manufacturer for maintenance.
0xE1 alarm (Over temperature alarm)	Temperature sensor failure causes heating plate temperature to reach or exceed 43℃.	
0xE3 alarm	Data failure	

4.6 Operation precautions

1. Before operating the device, please check with the pharmacist, make sure the medicine can be heated or not.

2. Before operating the device, please check the device is damaged or not, any liquid or wet there.

3. Please refer to the illustration of user manual to install the device correctly.

4. Please operate the device per above operation steps. If there is alarm, must solve it before using the device.

5. If using the drop sensor, make sure the drop sensor socket is corresponding to the right infusion tube slot.

6. The device must be operated by well-trained professionals only.

7. Before being used formally, it is necessary to confirm the effectiveness of the alarm system.

Operating steps: turn on, then open the door. If the equipment triggers an "open door" alarm, the alarm system is normal. Otherwise, it's abnormal.

4.7 Special instructions for the personal use

Do not recommend for personal use. If consumers have to use it individually, must check with pharmacist the medicine can be heated or not, and confirm the appropriate heating temperature too.

5. Product accessories, consumables

5.1 Product accessories、 consumables

- Suspension belt
- Drop sensor
- AC Power cord

5.2 Instructions of product accessories, consumables

Please refer to 2.2 accessories illustration.

5.3 Product accessories replacement cycle and replacement methods

Replace if damaged. Please refer to 4.1 illustration for replacement methods

5.4 Product accessories, consumables precautions

Not yet found.

5.5 Infusion and Transfusion sets

1） ISO 8536 series standard should be met for infusion sets.

2） ISO 1135 series standard should be met for Transfusion sets.

3） Pipe diameter of Infusion and Transfusion sets should be within the scope of 3.2mm-4.5mm.

6. Product maintenance and maintenance methods

Shutdown and disconnect the AC power cord before cleaning

6.1 Routine maintenance

1.Should inspect the function of temperature controlling regularly (once every 2 months) as below steps: Switch on the device in room temperature (20±2)℃, set the device temperature to 36°C, when the device heating is stable (The heating symbol disappear), check the display temperature on interface, and use the temperature measure equipment to test the temperature of the heating grooved plate, both should in the range of 36±1℃.(Note: The accuracy of temperature measure equipment is ±0.5℃）

2.Keep surface of the device clean. Clean it with wet soft cloth, and dry it naturally. Do not use solvents like xylene, acetone or similar solvents which leads to corrode the Fluid Warmer.

3.The heating surface should be sterilized and cleaned thoroughly before and after use to avoid cross infection.

4. Keep the surface of the warmer away from sharp objects, otherwise the damages of the Fluid Warmer may lead to the tube channel broken, thus may cause patients' infection.

5. Keep the surface of the tube channel dry. Forbid any liquid immersing into the Fluid Warmer.

6. Inspect the pole clamp of Fluid Warmer before operation, prevent it falls during using and hurt people & damage device.

7. Daily maintenance includes the cleaning of outer shell. Clean it with wet soft cloth and natural drying. Do not use solvents like xylene or acetone or other similar solvents which may corrode the fluid warmer.

6.2 Troubleshooting and solution

When the following situations appear, means the device is broken down, please solve it per the following methods.

No.	Failure	Cause analysis	Solution
1	AC lights is not on	1. No AC power supply 2. Control circuit failure	1. Check the AC power supply 2. Contact the manufacturer/distributor
2	Not heated	1. Control circuit failure 2. Heating device failure 3. The heater failure	1. Contact the manufacturer/distributor 2. Contact the manufacturer/distributor 3. Contact the manufacturer/distributor
3	Alarm Note Error E0	It means CPU failed.	Contact the manufacturer/distributor
4	Alarm Note Error E1	Temperature sensor failure causes heating plate temperature to reach or exceed 43℃	The temperature detector is loose or damaged. Press the "SILENCE/RETURN" button to clear the sound prompt. Contact the manufacturer/distributor to deal with.
5	Alarm Note Error E3	It means incorrect	Parameter storage error, need to

		parameter and need restore factory settings.	restore the factory settings. Press the "SILENCE/RETURN" button to clear the sound. Enter the settings interface, select "restore factory settings" to return to normal.
When appearing 4-5 alarm, the alarm can't be eliminated even when the problem was solved.			1. Contact the manufacturer/ distributor

7. Transport and Storage

Storage conditions: Temperature: -20℃～+60℃;
Relative humidity: 10～93%(no frosting);
Atmosphere pressure: 50.0kPa～106.0kPa;

Transport:

Place the product as per No. of layers indicated on packing carton.
Temperature: -20℃～+60℃;
Relative humidity: 10～93%(no frosting);
Atmosphere pressure: 50.0kPa～106.0kPa;

8. Product life

8.1 Production date: See product label

8.2 Product life:

The product life is 5 years.

9. Product labels explanation

9.1 Product labels (on the back shell of Fluid warmer)

This label according to the relevant standards, displaying manufacturer, production date, batch No., equipment classification and other information.

9.2 Symbols and Significance

Symbols	Descriptions	Symbols	Descriptions
LOT	Production batch No.		Protective Earthing
SN	Product serial No.	**IPX4**	Degrees of protection against water : water splashed against the enclosure from any direction shall have no harmful effects
	Caution, consult accompanying documents		AC power
	Type B		DC power
	Date of production		Caution, consult instruction for use
	Manufacturer		Dispose in environmental-friendly way

10. After sales service

The free warranty for the fluid warmer is one year.

Note: The following situation is not within the range of free maintenance and repair.

(1) Malfunctions resulting from improper operation, or modification / repair of the fluid warmer without supplier's knowledge and permission.

(2) Bruise or damage caused by improper handling during transport.

(3) Malfunction or damage caused by fire, salt, poisonous gas, earthquake, hurricane, flood, abnormal electric voltage or any other natural disaster.

For all the malfunctions and damage due to above reasons, the manufacturer can offer repair but charge for the cost.

Recycling

The normal working life of the Fluid warmer and power cable is five (5) years. The usage frequency and maintenance property level shall affect working life of machine. When exceeding the normal working life, the fluid warmer needs to be well scrapping. Please contact the manufacturer or distributor for more info。

The scrapped Infusion Pump and power cable can be sent back to manufacturer or distributor， or can be scrapped according to legally proper way.。

11. Electromagnetic Compatibility (EMC) Information

 **Attention:**

- Hawk-fw1 fluid warmer meet EN 60601-1-8 standard electromagnetic compatibility requirements;
- The user should install and use the electromagnetic compatibility information provided by the random document;
- Portable and mobile RF communication devices may affect the performance of Hawk-fw1 fluid warmer, use to avoid strong electromagnetic interference, such as near mobile phones, microwave ovens, etc.
- The guide and the manufacturer's statement are described in the annex.

 **Warning:**

- Hawk-fw1 fluid warmer should not be close to or stacked with other equipment, if you have to close or stacked use, you should observe the verification in the use of its configuration can be

normal operation;

- Class A equipment is intended for use in industrial environments, and it may be difficult to ensure that electromagnetic compatibility is potentially difficult in other environments due to Hawk-fw1 fluid warmer conduct harassment and radiation harassment;
- Besides internal components provided by manufacturer of the Hawk-fw1, using the other brand accessories and cables may result in Hawk-fw1 increasing emitting or decreasing immunity.

Enclosure：

Guidance and manufacturer's statement - Electromagnetic emission		
Hawk-fw1 fluid warmer is expected to be used in the following specified electromagnetic environment, the purchaser or the user should ensure that it is used in this electromagnetic environment:		
Emission Test	**Compliance**	**Electromagnetic Environment–Guidance**
Radio-frequency emission IEC/CISIPR 11	Group 1	Hawk-fw1 only uses its radio frequency for its internal functions. As a result, its RF emissions are low and there is little chance of interfering with nearby electronics.
Radio-frequency emission IEC/CISIPR 11	Class A	Hawk-fw1 is applicable for use in all facilities that are non-domestic and not directly connected to a residential low-voltage residential network for home use.
Harmonic emission IEC 61000-3-2	Not applicable	
Voltage fluctuation / scintillation emission IEC 61000-3-2	Not applicable	

Guidance and Manufacturer's Declaration-Electromagnetic Immunity			
Hawk-fw1 Fluid warmer machine is expected to be used in the following electromagnetic environment. Purchasers and users should ensure that they will use the product in the following electromagnetic environment：			
Immunity test	**EN 60601 test level**	**Conformance level**	**Electromagnetic environment – Guidance**
Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The floor should be covered with wood, concrete or tiles; if it is covered by composite materials, then the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	±2kV to power line ±1kV to input/output lin	±2kV to power line	Network power should have the quality that is typical for application in commercial environment or hospital.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Network power should have the quality that is typical for application in commercial environment or hospital.

Temporary voltage drop, short interruption and voltage variation on power input line IEC 61000-4-11	<5 % U_T, continuing for 2.5 cycle (On U_T, >95% temporary drop) 40 % U_T, continuous for 5 cycles (On U_T, 60% temporary drop) 70 % U_T, continuous for 25 cycles (On U_T, 30% temporary drop) <5 % U_T, continuous for 5s (On U_T, >95% temporary drop)	<5 % U_T, continuing for 2.5 cycle (On U_T, >95% temporary drop) 40 % U_T, continuous for 5 cycles (On U_T, 60% temporary drop) 70 % U_T, continuous for 25 cycles (On U_T, 30% temporary drop) <5 % U_T, continuous for 5s (On U_T, >95% temporary drop)	Network power should have the quality that is typical for application in commercial environment or hospital. If users of Hawk-fw1 blood infusion warmer need to operate it continuously during power interruption, it is suggested to adopt UPS or battery for power supply.
PFMF （50/60Hz） IEC 61000-4-8	400A/m	400A/m/50Hz/60Hz	PFMF should have the PFMF characteristics of typical places in commercial environment or hospital.
Note: U_T refers to the AC voltage before applying test voltage.			

Guidance and Manufacturer's Declaration- Electromagnetic Immunity

Hawk-fw1 Fluid warmer machine is expected to be used in the following electromagnetic environment. Purchasers and users should ensure that they will use the product in the following electromagnetic environment:

Immunity test	EN 60601 test level	Conformance level	Electromagnetic environment – Guidance
RF Conduct IEC 61000-4-6 RF radiation IEC 61000-4-3	3 V (effective value) 150 kHz～80 MHz 3 V/m 80 MHz～2.5 GHz	3 V (effective value) 3 V/m	Portable and mobile RF communication device should not be closer to any part of Hawk-fw1 blood infusion warmer than the recommended isolation distance while using, including cables. This isolation distance should be calculated with the formula corresponding to transmitter frequency. **Recommended isolation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz Where: P —the maximum rate output power of transmitter provided by transmitter manufacturer, in W; d— recommended isolation distance, in m [b]. The field strength of fixed RF transmitter is determined by the survey [c] of

			electromagnetic field. [d] should be lower than conformance level in each frequency range. Confirm that [d] is lower than conformance level in each frequency range. There may be interference around the devices with the following symbol. 

Note 1: Formula for high frequency ranges should be used between 80MHz and 800MHz.
Note 2: This guidance may not apply to all situations, since electromagnetic propagation may be affected by the absorption and reflection of buildings, objects and human bodies.

a Fixed transmitter, such as the base stations of wireless (cell/cordless) phones and ground mobile radio, amateur radio, amplitude modulation, FM radio broadcast and TV broadcast, etc., its field strength cannot be forecasted accurately in theory. Survey of electromagnetic fields should be taken into consideration in order to evaluate the electromagnetic environment of fixed RF transmitter. If it is measured that the field strength of the location of Hawk-fw1 blood infusion warmer is higher than the applicable RF conformance level, YXT-S3 syringe pump should be observed to verify if it can operate normally. If abnormal performance is observed, then supplementary measures, for example, readjustment of the direction or location of Hawk-fw1 blood infusion warmer, might be necessary.

b Strength filed should be lower than 3 V/m within the whole frequency range of 150KHz~80MHz.

Recommended Isolation Distance between Portable and Mobile RF Communication Device and Hawk-fw1 blood infusion warmer

Hawk-fw1 Fluid warmer machine is expected to use in the electromagnetic environment where RF radiated disturbance is under control. According to the maximum rated output power of communication device, purchasers or users can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication device (transmitter) and **Hawk-fw1** blood infusion warmer

Maximum rated output power of transmitter W	**Isolation Distance Corresponding to Different Frequencies of Transmitter/m**		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	**80 MHz ～ 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz～ 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output frequency of transmitter not listed in the table above, isolation distance, in m, is recommended. It can be determined with the formula in the frequency column of corresponding transmitter. *P* here is the maximum rated output power of transmitter, in W, provided by transmitter manufacturer.

Note 1: Formula for high frequency ranges should be used between 80MHz and 800MHz.

Note 2: This guidance may not apply to all situations, since electromagnetic propagation may be affected by the absorption and reflection of buildings, objects and human bodies.

Appendix 1

Table 1 Classification of alarms and color of alarm indicator light

Classification of alarms	Alarm priority	Color and frequency of alarm indicator light
Door open alarm	High as priority	Red light /2Hz
High temperature alarm	High as priority	Red light /2Hz
Low temperature alarm	High as priority	Red light /2Hz
Drop1 Empty alarm	High as priority	Red light /2Hz
Drop2 Empty alarm	High as priority	Red light /2Hz
Drop1 A alarm	High as priority	Red light /2Hz
Drop2 A alarm	High as priority	Red light /2Hz
0xE3 alarm	High as priority	Red light /2Hz
0xE1 alarm	High as priority	Red light /2Hz
0xE0 alarm	High as priority	Red light /2Hz

Table 2 Alarm Conditions and Alarm Signal delay

Name of alarm	**Alarm Condition Delay**	Alarm signal delay
Door open alarm	10ms	100ms
High temperature alarm	200ms	100ms
Low temperature alarm	200ms	100ms
Drop1 Empty alarm	840s@1ml/h 27s@25ml/h	100ms
Drop2 Empty alarm	840s@1ml/h 27s@25ml/h	200ms
0xE3 alarm	100ms	100ms
0xE1 alarm	100ms	100ms
0xE0 alarm	100ms	100ms

Table 3 Characteristic Parameter of Alarm Sound

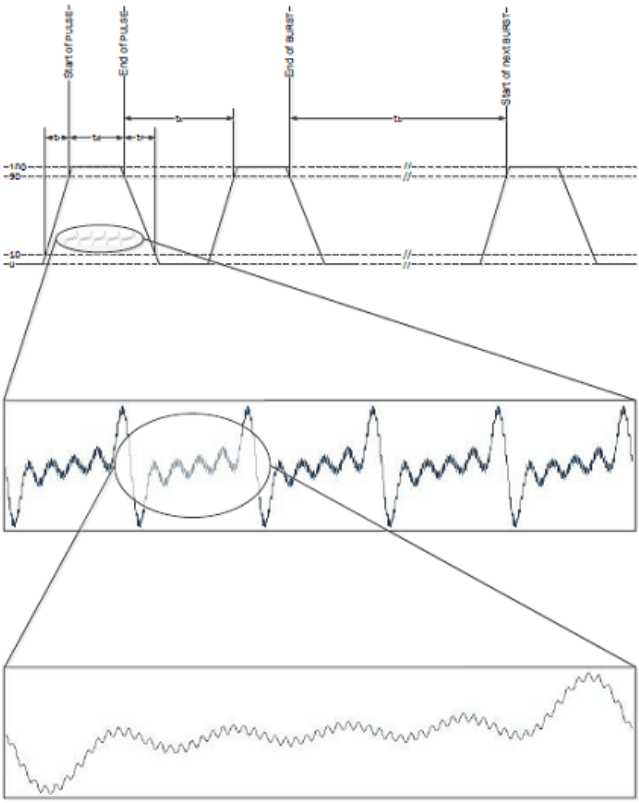
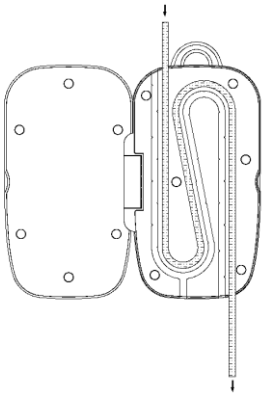


Figure 1

Characteristics	High piority
Number of Pluses in burst	10
Pulse spacing(ts)(See figure 1)	X
Between 1st and 2nd pulse	118
Between 2nd and 3rd pulse	118
Between 3rd and 4th pulse	359
Between 4th and 5th pulse	118
Between 5th and 6th pulse	0.73s
Between 6th and 7th pulse	118
Between 7th and 8th pulse	118
Between 8th and 9th pulse	359
Between 9th and 10th pulse	118
Interbutsr interval(tb)	3.62s
Difference in amplitude between anv two	

Table 4: Output temperature reference data

Single channel heating mode： It can be used in the case of high ambient temperature, high temperature of input liquid and low temperature of output liquid.

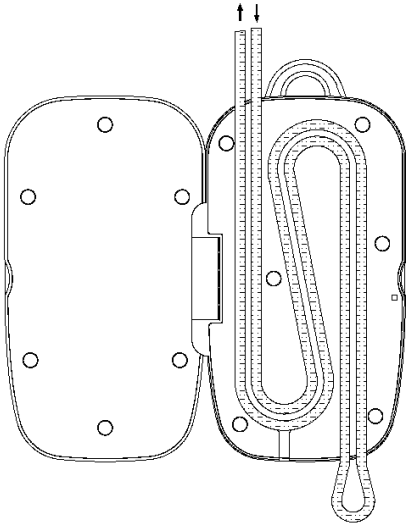


ambient temperature：21℃,Set temperature:37℃				
Distance(cm) / Flow(ml/h)	30	50	80	100
1200	25.5	25.5	25.1	25.
500	28.3	28.1	26.7	26.3
300	29.9	29.2	27.5	27.2
200	30.5	29.2	26.1	25.2
100	28.9	26.7	22.6	21
50	25.6	23.2	21	21.0
ambient temperature：21℃,Set temperature:42℃				
Distance(cm) / Flow(ml/h)	30	50	80	100
1200	26.8	26.8	26.1	26
500	30.1	29.7	28.0	27.7
300	32.3	31.2	28.0	27.4
200	33.0	31.0	27.2	26.5

100	31.6	27.8	21.6	21.0
50	26.3	22.9	21.	21.0

ambient temperature： 26℃,Set temperature:37℃				
Distance(cm) / Flow(ml/h)	30	50	80	100
1200	28.4	28.4	28.4	28.4
500	30.7	30.6	29.8	29.8
300	32.2	31.6	30.5	30.2
200	32.7	32.0	30.3	29.7
100	32.1	30.5	28.4	27.8
50	29.6	27.9	26.6	26.4
ambient temperature： 26℃,Set temperature:42℃				
Distance(cm) / Flow(ml/h)	30	50	80	100
1200	30.1	30.1	29.7	29.7
500	33.0	32.7	31.5	31.4
300	34.9	34.1	32.4	32.0
200	35.6	34.3	31.8	31.2
100	34.5	32.2	29.1	28.4
50	31.1	28.4	26.3	26.3

Double Channel heating mode： It can be used in the case of lower ambient temperature, lower input liquid temperature and higher output liquid temperature.



ambient temperature： 21℃,Set temperature:37℃				
Distance(cm) / Flow(ml/h	30	50	80	100
1200	26.8	26.6	26.1	26.1
500	31.7	31.4	29.8	28.2
300	32.1	30.7	29.1	27.6
200	32.8	31.2	28.4	26.2
100	32.1	29.7	24.3	21.0
50	32.2	27.5	23.9	21.0
ambient temperature： 21℃,Set temperature:42℃				
Distance(cm) / Flow(ml/h)	30	50	80	100
1200	29.1	29.0	28.5	28.0

500	35.9	35.3	33.1	32.7
300	36.4	35.1	33.0	31.3
200	36.7	34.8	31.8	30.2
100	36.2	33.1	30.1	26.3
50	35.7	31.7	24.8	21.3
ambient temperature： 26℃,Set temperature:37℃				
Distance(cm) / Flow(ml/h)	30	50	80	100
1200	30.3	30.1	29.7	29.3
500	32.8	32.4	31.6	31.8
300	34.4	33.3	31.9	30.5
200	34.1	32.4	30.6	28.9
100	32.8	30.5	27.8	26.3
50	29.1	27.7	26.7	26.1
ambient temperature： 26℃,Set temperature:42℃				
Distance(cm) / Flow(ml/h)	30	50	80	100
1200	32.4	32.3	32.2	31.5
500	36.3	35.7	34.6	32.3
300	37.7	36.5	34.5	31.7
200	37.8	35.6	33.3	30.6
100	35.4	32.0	27.8	26.0
50	31.6	27.4	26.3	26.0

Testing conditions:

See figure 2.

Infusion set： BOON— A2, Diameter： 3.5mm.

Attention:

1） **The temperature of the patient's contact point is greatly influenced by the setting temperature, the ambient temperature and the infusion volume, so the setting temperature of the heater should be determined by combining the ambient temperature, the temperature of the input liquid and the layout of the pipeline;**

2） **It is recommended to use this product in the range of 100-500 ml/h infusion rate;**

3） **If the distance between the heater and the patient's end is too long, it will lead to greater heat loss. It is suggested that the user take additional insulation measures or shorten the length of the pipeline between the heater and the patient, or set higher temperature**

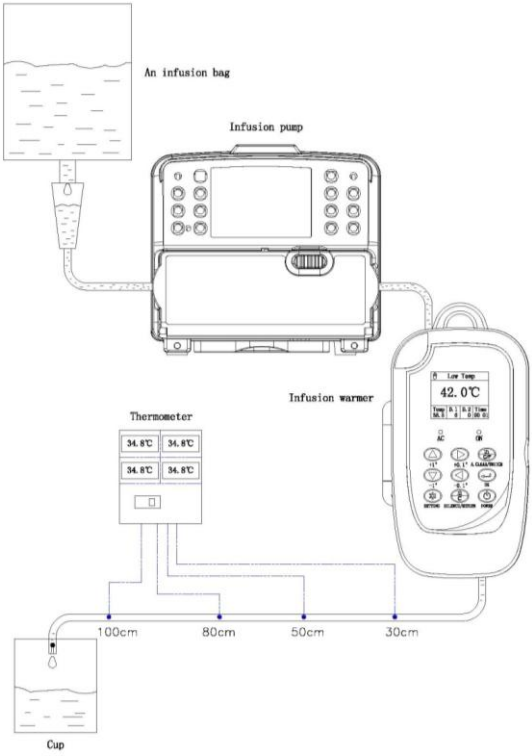


Figure2: Schematic diagram of test

Shenzhen Hawk Medical Instrument Co. Ltd.

Address:1st Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community Longhua Street, Longhua District, Shenzhen, 518109, Guangdong, P.R.China

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EC DECLARATION OF CONFORMITY

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:	**Shenzhen Hawk Medical Instrument Co. Ltd.** **1st Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109, Guangdong, P.R.China**
Name and address of the European Representative:	**WellKang Ltd** **The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland**

We declare under our sole responsibility that

the medical device:	**Fluid Warmer** **Model: Hawk-fw1** **GMDN Code: 47616**
of class:	**Rule 9(3.1/1), IIb** according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

Conformity assessment procedure:	**Directive 93/42/EEC Annex II, excluding Section 4**
Registration No.:	**HD 2183512-1**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

The expiry date of the above mentioned declaration of conformity is May 26, 2024.

Shenzhen, 2021-01-19
Place, date

General Manager
Name and function

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2183512-1

Manufacturer: Shenzhen Hawk Medical Instrument Co., Ltd.
1st Floor, Building C, Jianyetai Industrial Zone, No. 11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109 Guangdong P.R. China

Products:
- Infusion Pumps
- Syringe Pumps
- Enteral Feeding Pumps
- Fluid Warmers
- Infusion Pump Management Units

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 10918567-100

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Shengkui Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2183512-1

Manufacturer: Shenzhen Hawk Medical Instrument Co., Ltd.
1st Floor, Building C, Jianyetai Industrial Zone, No. 11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109 Guangdong P.R. China

The scope of certification includes the following manufacturing site:

No.	Location	Product groups manufactured
/01	Shenzhen Hawk Medical Instrument Co., Ltd. 2nd-4th Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109 Guangdong P.R. China	Infusion Pumps, Syringe Pumps, Enteral Feeding Pumps, Fluid Warmers and Infusion Pump Management Units

Report No.: 10918567-100

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2183512-1

Organization: Shenzhen Hawk Medical Instrument Co., Ltd.
1st Floor, Building C, Jianyetai Industrial Zone, No. 11 Minhuan Road,
Fukang Community, Longhua Street,
Longhua District, Shenzhen,
518109 Guangdong
P.R. China

Scope: Design and Development, Manufacture and Distribution of Infusion Pumps, Syringe Pumps, Enteral Feeding Pumps, Fluid Warmers and Infusion Pump Management Units

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10918567-100
Effective date: 2021-05-25
Expiry date: 2022-07-12
Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH TUVRheinland® Zertifizierungsstelle

Shengkui Zhong
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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2183512-1

Organization: Shenzhen Hawk Medical Instrument Co., Ltd.
1st Floor, Building C, Jianyetai Industrial Zone, No. 11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109 Guangdong P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	Shenzhen Hawk Medical Instrument Co., Ltd. 1st Floor, Building C, Jianyetai Industrial Zone, No. 11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109 Guangdong P.R. China	Design and Development, Distribution of Infusion Pumps, Syringe Pumps, Enteral Feeding Pumps, Fluid Warmers and Infusion Pump Management Units
/02	Shenzhen Hawk Medical Instrument Co., Ltd. 2nd-4th Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109 Guangdong P.R. China	Manufacture of Infusion Pumps, Syringe Pumps, Enteral Feeding Pumps, Fluid Warmers and Infusion Pump Management Units

Report No.: 10918567-100
Effective date: 2021-05-25
Expiry date: 2022-07-12
Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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