

Shenzhen Hawk Medical Instrument Co., Ltd.

Safety and Performance Information Relevant to

The User or Other

(Infusion Pump)

Model: InnoFusion IF-50, 907 V, 908 V

Please read the manual before using and installing the product;
Please keep the manual for reference!



Table of Contents

Revision Notes:.....	1
1 Warnings & Cautions	2
2 Introduction.....	6
2.1 Features.....	6
2.2 Intended use and contraindications.....	7
2.3 Type and specifications	8
2.4 Operating conditions.....	8
2.5 Impacts on environment and energy	8
2.6 Date of manufacture & life span.....	8
3 Components.....	9
4 Technical Parameters and Noun Interpretation	9
5 Installation and Adjustment.....	11
5.1 Installation conditions and technical requirements	11
5.2 Assembly/ Disassembly of Handle	11
5.3 Installation method and cautions	13
6 Appearance Introduction	14
6.1 Front View	14
6.2 Operation Panel.....	14
6.3 Screen Display.....	14
6.4 Rear view.....	14
6.5 Label	14
7 Precautions for Preparation and Operation.....	16
7.1 Preparation and inspection before use	16
7.2 Operation Precautions.....	17
8 Operation Method.....	18
8.1 Infusion Operation.....	18
8.2 Alarms and solutions.....	19
8.3 Infusion tube setting.....	19
8.4 User Info Settings.....	19
8.5 System Setting.....	19
9 Troubleshooting and Analysis.....	19

10 Safety Invention and Troubleshooting.....	20
10.1 Safety Invention and precautions	20
10.2 Troubleshooting.....	20
11 Maintenance, Inspection, Repair and Recovery.....	20
11.1 Routine maintenance.....	20
11.2 Maintenance during operation.....	22
11.3 Regular Inspection	22
11.4 Normal repair procedures	23
11.5 Maintenance for long-time storage.....	23
11.6 Recycling.....	23
12 Transport and storage	24
12.1 Precautions during transport.....	24
12.2 Storage Conditions	24
13 Package list.....	24
13.1 Standard configuration in a package:.....	24
13.2 Standard optional accessories.....	24
14 Open-package Inspection.....	25
15 After-sales service.....	25
Appendix I EMC Information.....	27
Appendix II.....	34
Table 1 Classification of alarms and color of alarm indicator light.....	34
Table 2 Characteristic parameters of alarm signals	34
Table 3 Occlusion response characteristic.....	35
Table 4 Starting Curve	36
Table 5 Trumpet Curves.....	37
Appendix III Cybersecurity	39
Table 1 Serial communication.....	39
Table 2 Wi-Fi communication.....	40
Table 3 Cascade	41
Table 4 Software upgrade.....	42

Revision Notes:

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On the premise of comply with relevant laws and regulations, we will revise the manual timely according to improvements of products or updates of laws and regulations.

This Manual applies to InnoFusion IF-50, 907 V, 908 V Infusion Pump.

Version No.	Date of Preparation
V1.0.1	12-11-2025

User manual version updating instructions:

V X.Y.Z

V: indicates version No. of the user manual.

X: indicates that the device had a major upgrade: When significant modifications are made to the software, hardware, and device construction, the user manual should be updated accordingly.

Y: indicates that the device had a minor upgrade: When slight modifications are made to the software, hardware, and device construction (re-registration after evaluation is not necessary) to enhance the function of the device, and the user manual should be updated accordingly

Z: indicates the corrective update to correct text errors or better describe the change or upgrade in the Manual without any changes to software and hardware. For example, text, illustrations correction, new illustrations, text descriptions.

1 Warnings & Cautions

Warning:

Failure to follow precautions below may result in the risk of death or injury to patients

- A)** The infusion pump uses a peristaltic mechanism for medical fluid infusion. Any leakage caused by a disconnection or crack of the infusion set will not be detected by the device. Hence, regular inspection of the device is required to prevent the problems mentioned above.
- B)** During infusion process, please regularly check the status of dripping as well as the residual liquid inside the infusion bag/bottle to ensure good performance of the infusion.
- C)** The infusion pump is equipped with an occlusion detection function that signals an occlusion alarm when the infusion needle is not properly inserted into the intravenous vein or when the needle deviates from its position inside the vein during infusion. However, as the occlusion alarm is sounded only after a certain occlusion pressure value is reached, the area around the needle may have already become swollen or is bleeding when the alarm sounds. In addition, if the actual occlusion pressure is not high enough to reach the occlusion alarm threshold, the alarm will not be triggered. Therefore, the insertion area needs to be checked on a regular basis. If the insertion area appears to be abnormal, please take proper measures such as by re-inserting the needle.
- D)** The user must install the infusion set in a straight and proper alignment along the peristaltic fingers from the right to left direction. If this is not done correctly, the infusion may not reach the expected performance level.
- E)** Make sure the IV set is properly installed to the location of air bubble sensor and the occlusion sensor (pressure detector). Air Bubble alarm or Occlusion alarm may not be given due to incorrect installation of IV set.
- F)** Infusion set knotting, filter or needle blocking, or needle occurring thrombosis etc. results in infusion flow blockage which may increase the pressure inside the infusion set. In solving such a blockage, there may be a temporary large-volume infusion that follows. The correct method is to clamp the IV set tightly as close as possible to the insertion area before opening the pump door to release the pressure. Once this is done, unclamp the IV set, get rid of the occlusion problem and restart the infusion. If the blockage still remains after the restart, this will trigger the occlusion alarm to sound again. Also, the pressure inside the infusion may constantly increase which may result in a disconnection or crack of the infusion set and bring further harm to the patient.
- G)** It is recommended to keep the flow clip of the IV set in a downstream position of the

infusion pump. This is to allow more convenience for the user, as the user can clamp the flow clip and then squeeze the air bubble back into the drip chamber in case the Air Bubble alarm goes off.

- H)** Fix the Infusion Pump well to infusion stand/bar and also ensure the stability of the stand/bar. Be cautious when moving the stand/bar and the infusion pump to prevent the Infusion Pump from falling off or colliding with surrounding objects.
- I)** As the infusion pump is unable to detect downstream occlusion or any emptying of the gravity infusion set, it cannot be used in parallel with the gravity infusion device.
- J)** The infusion pump cannot be used with potentially large negative or positive pressure infusion lines such as an extracorporeal circuit. Infusion accuracy and the correct alarm functions of the infusion pump may not be guaranteed if it is utilized with such components.
- K)** Please install the IV set with correct direction. If the IV set is installed in the wrong direction, the patient's blood may be sucked out as a result.
- L)** Do not use the Infusion Pump near inflammable liquid or gas.
- M)** Do not store or use the Infusion Pump in humid environment or an environment with chemically active gases (including gas for sterilization). Such environments may adversely affect the internal electronic parts by causing degradation or damage to their functions.
- N)** To prevent accidents from occurring, medical staff should conduct regular patrol inspections instead of solely relying on the alarm system.
- O)** During infusion, continuously monitor the running state of the system and check the infusion set regularly instead of relying only on the system's alarm function.
- P)** The infusion parameters of the infusion pump must comply with the medical advice before the operator can initiate the infusion process. Any inappropriate setting of parameters may lead to an invalid operation.
- Q)** Make sure that there is no water on the external wall of the infusion set and especially ensure that no water flows to the ultrasonic sensor; otherwise, the alarm may not go off when bubbles are present.
- R)** Please use IV sets that meet the requirements of this user manual, otherwise the alarm will be inaccurate and the normal detection function cannot be maintained.
- S)** Do not connect the unknown infusion system or accessory on patient's infusion tube or equipment, otherwise it may cause danger and will not guarantee the infusion accuracy and normal alarm function.

- T)** When in doubt about the protective grounding, the internal power supply should be used.
- U)** Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- V)** Please do not place the power plug where it is difficult to operate the disconnecting device.

Cautions:

Violation of any of these precautions may lead to personal injury or loss of property.

- A)** Inspect the Infusion Pump before using, making sure it can work normally. If any malfunction is found, stop the operation immediately and contact the distributor or the manufacturer for further action. Any adhesion or leakage of medical liquid may lead to malfunction of the Infusion Pump. Therefore, please clean the Infusion Pump and store the infusion pump properly after every usage.
- B)** When using the Infusion Pump for the first time after purchasing or after long-time of storage, please connect the pump to AC power source and charge it for at least 20 hours with power on. If the device is not fully charged, the internal battery will not have sufficient power to support the infusion pump in any case of AC power failure.
- C)** If the infusion pump is used within the vicinity of electric cautery equipment, the Infusion Pump may exhibit faulty operation due to the disturbance of high-frequency sound waves. In the event where the pump must be used alongside this equipment, please adhere to the following measures:
 - (1) Avoid using the Infusion Pump along with old-fashioned electric cautery apparatus (open vacuum tube).
 - (2) Ensure that the distance between Infusion Pump and the body of electric cautery apparatus or its power source is more than 25cm.
 - (3) Make sure that the respective power cables of the electric burning device and infusion pump are induced from different power distribution cabinets and are reliably earthed.
- D)** Do not use any mobile phone, wireless device or cardiac defibrillator within one meter of the Infusion Pump as the high-frequency sound/signal emitted may cause malfunction of the Infusion Pump. Make sure the Infusion Pump has an established ground connection and do not use the same power socket as the ones connected to the devices mentioned above.

- E)** The use of the infusion pump is strictly prohibited in areas where radiotherapy equipment, magnetic resonance (MR) equipment or hyperbaric oxygen therapy are present.
- F)** Do not use any pointed objects such as pen-tips or fingernails to press the keys on the Infusion Pump so as to avoid premature damage to the keys or the device.
- G)** Keep the infusion bag, IV set and the Infusion Pump at a certain distance from the AC power source and DC socket to prevent any medical liquid from spilling or dripping onto the socket and incurring a short circuit. In addition, please make sure that the power plug and socket are dry before connecting to power source.
- H)** It is recommended to use the medical liquid that is approaching or approximately at room temperature. If temperature of the infusion fluid is too low, the air dissolution inside the infusion line will evaporate and form many air bubbles, which will cause air bubble alarms to go off frequently.
- I)** Under normal conditions, it is recommended to use AC power source to extend the battery service life. When using the AC power sources, make sure that it has a good ground connection and please use a power cord that is compatible with the Infusion Pump. Whenever there is difficulty in establishing a ground connection or in cases where the AC power is unavailable (such as during AC power failure), use the battery as the power source.
- J)** It is recommended to replace disposable infusion sets every 24 hours. If using non recommended infusion sets, it is recommended to replace the compression position every 6 hours. Additionally, it is recommended to replace the disposable enteral nutrition infusion tubing every 24 hours.
- K)** Please ensure that the flow clip of the IV set is closed before taking it out of the infusion pump in order to prevent free flow from occurring.
- L)** Pay more attention to occlusion when the infusion has a low flow rate. It normally takes a longer time to detect occlusion when the device is operating at a lower flow rate. This is to prevent a long infusion interruption duration from taking place.
- M)** Interference from devices such as electric cautery apparatus, mobile phones, wireless devices or cardiac defibrillators etc. can occur when using a computer port Please try to keep away from the above-mentioned devices.
- N)** In the event that the infusion pump falls off or suffers a collision, stop the operation immediately and contact the local representative in your country. This is necessary because even if there is no visible damage externally or no malfunction alarm goes off, there may have been damage to the internal parts.

- O)** The infusion pump must be operated by or under the guidance of clinically trained and qualified technicians who have received a training related to the use of this device.
- P)** Do not disassemble, modify or use the infusion pump for purposes other than for normal infusions. Under such circumstances, Hawkmed will assume no responsibility for any incidents that may occur, nor will the product performance be guaranteed or covered by the warranty.
- Q)** The infusion direction of this Infusion Pump is from right to left, please make sure that the infusion set is installed correctly.
- R)** During the period when alarm system completely loses power (both AC power and internal battery power), the history records stored in the system will not be affected, but this power off will not be recorded as alarm event.
- S)** If the same or similar equipment used in any independent area uses different alarm presets, there will be potential dangers, such as: intensive care units, cardiac operating rooms, etc.
- T)** If the alarm system cannot restore the alarm settings after the power supply is interrupted, stop using the equipment, and reset the alarm system and confirm.
- U)** When the power interruption time does not exceed 30s, the alarm events before the power off can be automatically restored.
- V)** The Infusion Pump should be used within 50cm range above or below the height of the patient's heart. When the height difference between the Infusion Pump and the patient's heart is smaller, the pressure detection is more accurate.
- W)** Check whether the current alarm preset is applicable to each patient before using the infusion pump.
- X)** Drop sensor may fail when using light proof IV set for infusion.
- Y)** When the enteral nutrient solution is injected, pay close attention to the patient's state, such as vomiting, abdominal distension, diarrhea, abdominal pain, choking, respiratory pattern change and other conditions should be dealt with in time.

2 Introduction

2.1 Features

User friendly interface, detailed menu display, 5-inch IPS full-view display, capacitive touch screen, mobile phone-like operating experience, easy operation and setting

- ◇ IrDA communication, realize wireless stackable function

- ✧ U dusk upgrade, easy to operate
- ✧ 13 levels occlusion pressure optional
- ✧ Applicable for various brands of infusion set, support self-define new brands
- ✧ Various infusion modes for user's option, convenient for clinical use
- ✧ Visual & audible alarms and double CPU system ensure stable and safer infusion
- ✧ Arc shape, ergonomic design, easy for clean

Remarks: The optional functions in the corresponding technical requirements can be selected by customers.

2.2 Intended use and contraindications

The infusion pump is intended for use for the delivery of medications, solutions, nutrition, lipids, blood and blood components indicated for infusion therapy through an intravenous (IV) route or enteral route.

Warning: The device is not used for infusion of analgesic drugs, chemotherapy drugs or insulin.

2.2.1 Indication

Infusion pumps are for patients who need receive various types of medications, solutions, nutrition, lipids, blood and blood components in controlled amounts through an intravenous (IV) route or enteral route.

2.2.2 Intended Users

- 1) Clinical operators: This user group refers to the authorized and well-trained medical personnel allowed to operate this Infusion Pump in clinical situations.
- 2) Reprocessing personnel: This user group refers to those who clean and disinfect the Infusion Pump and its accessories.
- 3) Service personnel: This user group refers to the authorized customer service engineers who are responsible for calibrating its components, and for service or modifications to the Infusion Pump as permitted.

2.2.3 Intended Patient Population

This infusion pump is suitable for adults, children, and newborns(<28days and premature babies>0.1 kg) in such locations as the delivery room, ICU, NICU, emergency room, general ward, high dependency wards, and departments.

2.2.4 Intended conditions of use

The infusion pump is intended to be used in medical institutions, such as hospitals, clinics.

2.2.5 Contra-indications

None.

2.2.6 Side-effects

None.

2.2.7 Clinical Benefit

The infusion pump allows administration of medications, solutions, nutrition, lipids, blood and blood components accurately and continuously through an intravenous (IV) route or enteral route.

2.3 Type and specifications

This product belongs to class I and defibrillation-proof type CF application. It is a continuous operation device equipped with internal batteries. Carrying of the device by patients or the use of the device in environments where gas mixtures of flammable gas and air or oxygen with nitrous oxide is not allowed.

Note: The recovery time of defibrillation prevention application part is 1 second.

2.4 Operating conditions

- (1) Ambient temperature: 5°C~40°C
- (2) Relative humidity: 10%~95% (non-condensing)
- (3) Atmosphere pressure: 57.0kPa~106.0kPa

2.5 Impacts on environment and energy

This infusion pump may emit electromagnetic radiation and this could result in interference on other devices. Certain measures should be adopted to alleviate the interference, such as by rearranging the position of the infusion pump or inducing the mains supply from different positions. For more information, please refer to Appendix 1 "Electromagnetic Compatibility (EMC) Information" of this manual.

2.6 Date of manufacture & life span

The life span of the Infusion Pump (exclude battery and AC power cable) is 10 years. Please refer to label for date of manufacture. In case of aging, damage or poor contact

of AC power cables, contact the manufacturer or dealer.

3 Components

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4 Technical Parameters and Noun Interpretation

Technical Parameters (InnoFusion IF-50, 907 V, 908 V)	
Infusion accuracy	Infusion rate Accuracy $\leq \pm 5\%$ Bolus volume Accuracy $\leq \pm 5\%$ or $\pm 0.02\text{ml}$ (Choose the higher value) Drip rate Accuracy $\leq \pm 10\%$
Infusion rate	(0.10~2300.00) ml/h, Increment 0.01ml/h
Infusion rate (Blood transfusion)	(0.10~2000.00) ml/h, Increment 0.01ml/h
Drip rate	(1~400) d/min
Volume to be infused (VTBI)	(0.10~9999.99) ml, Increment 0.01ml
Bolus rate	(0.10~2300.00) ml/h, Increment 0.01ml/h
Bolus VTBI	(0.10~100.00) ml, Increment 0.01ml
KVO rate	Set range: (0.10~5.00) ml/h, Increment 0.01ml/h. The KVO function can be turned on/off.
Purge	set range: (1000.00~2300.00)ml/h, Increment 0.01ml/h
Volume infused (Σ)	(0.00~99999.99) ml, Increment 0.01ml
Weight range	(0.1~499.00) kg
Maximum output pressure	180kPa
Occlusion pressure	(10.0~130.0)kPa (13 level adjustable, Pls refer to 8.5.5 in this manual)
Air bubble detection	Air bubble size 6 levels adjustable: Level 1:15 μl 、Level 2:50 μl 、Level 3:100 μl 、Level 4:250 μl 、 Level 5:500 μl 、Level 6:800 μl (Deviation: $\pm 20\%$) Air cumulative 10 levels adjustable:

	Level 1 ~Level 1 0: (0.1~1.0) ml/15min
Infusion mode	Rate Mode, Time Mode, Multi Mode, Drip Mode, Weight Mode, Dose mode, Intermittent mode, Sequential mode, Program Mode, Ramp Mode, Micro Mode, Piggyback, Loading Dose Mode
Single fault infusion volume	≤0.5ml
Waterproof level	IP44
Electrical classification	Class I and Defibrillation-proof Type CF
AC power supply	100-240V~ 50/60Hz
Internal battery	DC11.1V, rechargeable lithium polymer battery, 4400mAh Under standard testing conditions: Medium rate running time: greater than 10 hours Maximum rate running time: greater than 5 hours Charging time: 8 hours with power off
Input power	35VA
DC	DC 15V±10% 2.5A; DC power supply to the pump by Infusion Pump Management Unit
Fuse	Slow fuse:250V 2A
Dimensions	215 x 160 x 83(L*H*W ,Pole clamp excluded)mm
Weight	1.9kg (Net weight of machine Battery included, accessories excluded)
Main safety standard	EN 60601-1:2006+A1:2013+A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-8:2007+A1:2013+A11:2017+A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-2:2015+A1:2021 Medical electrical equipment - Part 1-2:

	General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests EN 60601-2-24:2015 Medical electrical equipment - Part2-24: Particular requirements for the safety of infusion pumps and controllers
Dedicated infusion set	InnoFusion IF-50, 907 V, 908 V use dedicated infusion set
Noun Interpretation	
Bolus	Fast infusion
Purge	Exhaust the air bubble from the infusion tube
Anti bolus function	Diminishes the volume of unwanted Bolus given to patient after removal of the occlusion cause.

5 Installation and Adjustment

5.1 Installation conditions and technical requirements

The Infusion Pump can be fixed to a vertical IV pole or horizontal bar with diameter of 12-35mm, or on platform with slope angle not exceeding 5°.

5.2 Assembly/ Disassembly of Handle

5.2.1 Installation of handle

Installation: Hold the infusion pump, meantime using another hand holding on the handle, push the slide rail of the handle directly into the slide groove of the infusion pump till the end by the side of screen.

Split: Push down the lock and hold it, push and pull the handle behind the infusion pump, and leave the machine. (1: handle 2: lock buckle)

Note: The recommended number of load-bearing pumps for the handle is two. If you want to lift multiple pumps, please hold the bottom of the pumps with your hands and lift them.

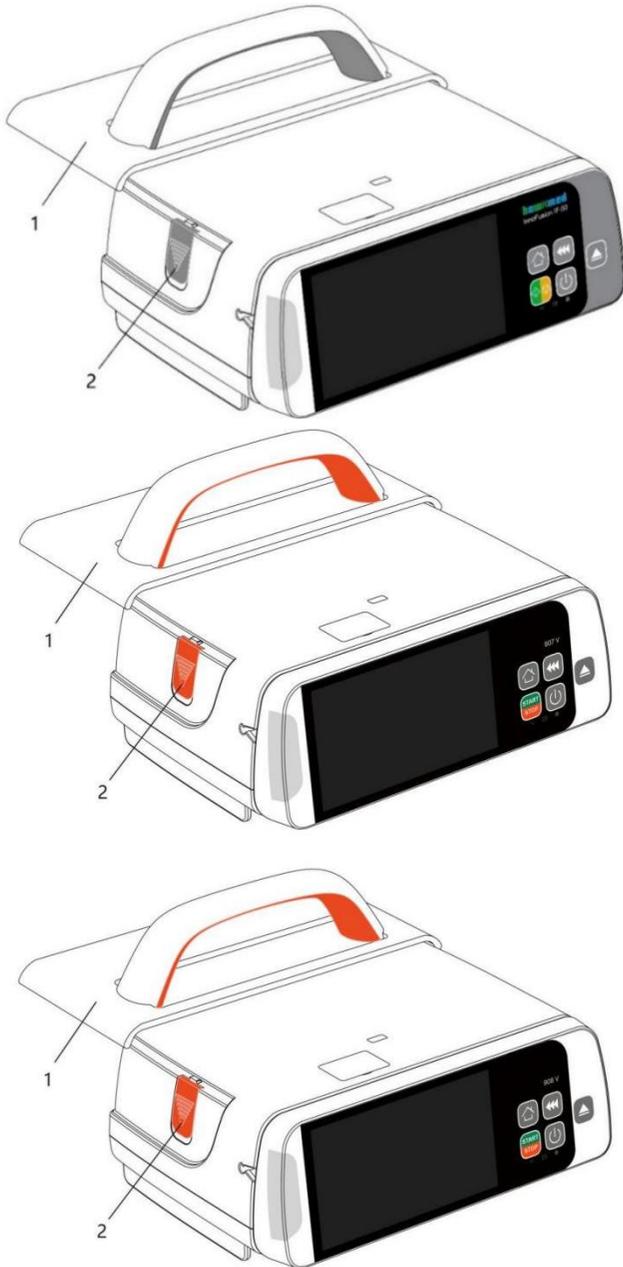


Figure 521-1. InnoFusion IF-50, 907 V, 908 V

5.2.2 Installation of pole clamp

Installation ways: vertical and horizontal.

Vertical: slide the pole clamp along the slot from left to right.

Horizontal: slide the pole clamp along the slot from bottom to top.

Disassembly: Turn the knob to exit the screw rod of the pole clamp, press the bump in the center of the pole clamp and slide it out in the opposite direction to the installation method to complete the disassembly of the pole clamp.

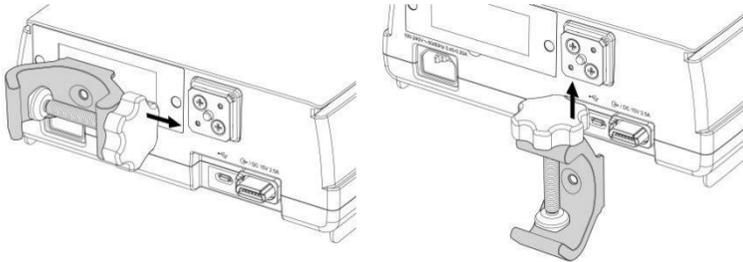


Figure 522-1.

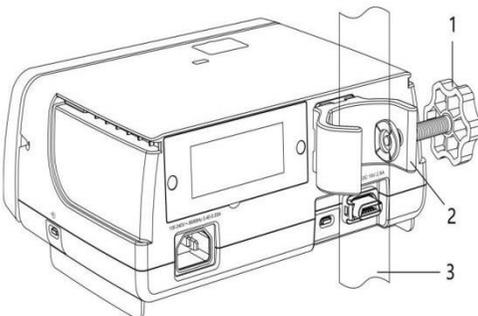
5.3 Installation method and cautions

Method 1: Put the infusion pump on stable platform.

Method 2: Fix the infusion pump to IV Pole as per below steps:

(1) Rotate the clamp knob of fixation screw out the rod, leave space for IV pole.

(2) Clamp to IV pole (the IV pole should meet the requirements of balance and mechanical strength), screw down the knob to fix the position of infusion pump. When fixing the pole clamp to IV stand or bar, use the other hand to hold the Infusion Pump until the clamp is well fixed, only release the hand after screwed tightly to avoid falling.



- 1 clamp knob of fixation screw
- 2 pole clamp
- 3 IV pole

Figure 53-1.

6 Appearance Introduction

6.1 Front View

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6.2 Operation Panel

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6.3 Screen Display

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6.4 Rear view

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6.5 Label

6.5.1 Product label (on the rear shell)

According to the relevant standard, this label contains information regarding manufacturer, date of manufacture, product Lot number, classification, Ingress Protection etc.

6.5.2 Symbols and significance

(table1)

Symbols	Descriptions	Symbols	Descriptions
 InnoFusion IF-50  908 V, 908 V	Start/Stop		Bolus
	Switch on/off		Home key
	Start		Stop
	Open the door		Back

	Return		Attention
	In connection		Connection failure
	Confirmed		Indicate that the alarm status is confirmed
	Bell, cancel temporary		Battery
	WIFI		DC power
	AC power		AC/DC
	USB interface		Protective earthing
	Multifunctional interface		Drop sensor interface
	Model number		Production batch number
	Product serial number		Defibrillation-Proof Type CF
IP44	Ingress Protection Rating: Protected against splashing water		Non-ionizing radiation
	Please refer to the instruction manual		Prohibition
	Waste Electrical and Electronic Equipment (WEEE)		Date of manufacture and Country of manufacture, CN: China
	Medical device		Manufacturer

	Unique device identifier		Importer
	EU Authorised representative		This device is provided with a CE marking in accordance with the Medical Device Regulation 2017/745. 0197 is the Notified Body number.
	Fragile. Handle with care!		Keep product dry
	This way up		Stacking limit (5)
	Temperature limit		Humidity limitation
	Atmospheric pressure limitation		

7 Precautions for Preparation and Operation

7.1 Preparation and inspection before use

Whether the infusion pump is new, has been stored for a period of time, or has been recently repaired, please check the following before use:

- (1) The appearance of the pump is still good, clean, with no visible cracks and leakages.
- (2) All the keys are responsive, and none of the keys are invalid or stuck.
- (3) When the door of the infusion pump opens and closes normally, the liquid-stop clamp can be raised and dropped to prevent free flow; after the infusion set is installed and the door is closed, the clamp can prevent free flow; and when the door is opened, the clamp can be dropped to prevent free flow.
- (4) The power cord should be attached securely and not loose easily.

- (5) If the infusion pump is operating on the internal battery alone, charge it fully before use and make sure that the battery is in good condition for use.
- (6) Set and check the system time to make sure that the event histories are recorded correctly.
- (7) Please read the warnings, precautions and operation steps of this user manual carefully.

7.2 Operation Precautions

- (1) Avoid exposing the infusion pump to direct sunlight, high temperature or high humidity.
- (2) If the infusion pump is unable to carry out its functions as described in this manual for unknown reasons, stop the operation and report the details (including SN, infusion mode, flow rate, photo or video about the malfunctions etc) to your local representative.
- (3) The infusion pump must be operated by trained healthcare professionals.
- (4) The infusion pump should be placed within 0.5 meters above or below the patient's heart level.
- (5) If the touchscreen display is damaged, please ensure timely replacement to protect the infusion pump from damage by leaked liquids.
- (6) If the operating environment temperature is not within the specified range, will affect the accuracy of infusion and normal operation.
- (7) The viscosity and proportion of infusion liquids may affect the accuracy of the infusion pump.
- (8) The device should be calibrated before a new brand of infusion set is used.
- (9) Pay attention to the choice of infusion line and function. Choose blood infusion set for blood transfusion; choose enteral feeding set for enteral feeding function. Avoid the wrong use of consumables and functions, which may lead to inaccurate precision, dose, pressure or air bubble alarm etc.
- (10) Disposable accessories can only be used once. Repeated use may lead to performance degradation or cross infection.
- (11) The liquid level of the liquid supply container should be higher than that of the infusion pump by $0.5\text{m}\pm 5\text{cm}$, and infusion outside this distance will affect the infusion accuracy of the infusion pump.

8 Operation Method

8.1 Infusion Operation

8.1.1 Fix the infusion pump and connect it to AC power source

Fix the infusion pump properly onto an IV stand and connect it to an AC power source. The AC indicator light  (bottom right corner) will light up. The battery will start charging as soon as it is connected to an external power source.

8.1.2 Switch on/off

Press the POWER key  until the LCD starts displaying 'Self-Check' interface to turn on the device.

The self-test information includes Communication, Pressure sensor, Dedicated IV set, AC power and Battery, etc.

Press POWER key  and release, select Power off to switch off the pump.

Note: Turning off the power switch will not cut off the AC power supply of this device. To completely disconnect the power supply, please unplug the power plug.

8.1.3 Install the Infusion Set Properly

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8.1.4 Infusion Parameters Setting

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8.1.5 Purge

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8.1.6 Start Infusion

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8.1.7 Bolus

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8.1.8 Stop infusion

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8.1.9 Infusion completed

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8.1.10 Replace an IV set

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8.2 Alarms and solutions

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8.3 Infusion tube setting

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8.4 User Info Settings

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8.5 System Setting

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9 Troubleshooting and Analysis

Failure	Cause Analysis	Solutions
Accuracy discrepancy	The infusion set is not properly installed in the infusion pump slot.	Please install infusion set correctly.
	The IV set currently used does not match correctly.	Please replace the infusion set brand or self-define infusion set brand.
	Internal parts of the infusion pump are damaged	Please send back to the distributor or manufacturer for inspection and repair.
Can't close the pump door.	Infusion set install incorrect or there is something in infusion set slot.	Please check infusion set installation

Beside the problems mentioned in 8.2, please contact the sales agent / manufacturer for repair.

10 Safety Invention and Troubleshooting

10.1 Safety Invention and precautions

1. AC power: built-in double fuses. When short circuit or any other malfunction occurs, the fuse shall cut off circuit in advance.

2. DC input: built-in fuse. When short circuit or any other malfunction occurs, the fuse shall cut off circuit in advance.

3. Battery protection: The battery contains protective devices against excessive pressure, over heat or short circuit, etc. to avoid.

10.2 Troubleshooting

- (1) If the Infusion Pump gives system error alarm, stop the operation and contact the sales agent for repair. It can be used again only after it is well repaired and tested. Infusion Pump working with malfunctions may incur unpredictable damage.
- (2) If the Infusion Pump caught fire or displays any other malfunction, please disconnect the power immediately and contact the sales agent /manufacturer.
- (3) In case of the failure that the pump door cannot be opened, if it is necessary to open the door urgently, open the white silicone cover on the top of the machine, pry the metal parts with tweezers, and then push the door assembly to the right until the door is opened. When the door opens, contact the manufacturer or distributor for repair.

11 Maintenance, Inspection, Repair and Recovery

In order to maintain the pump's performance, a preventive maintenance inspection must be carried out at least once every 3 years. Shutdown and disconnect the DC / AC power cord before cleaning.

11.1 Routine maintenance

Daily maintenance includes the cleaning of outer shell and pump body. 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 infusion pump.

Disinfect the infusion pump according to your hospital's disinfection protocols. Should cleaning pump before disinfection. Follow the manufacturer's instructions for diluting and using the disinfectant. The recommended disinfectant is: Ethanol 75%.

Disinfection steps:

1. Remove the infusion tube and fixing clip of the pump, soak the water with a dust-free cloth and squeeze it dry, wipe the pump shell until the surface is free of dust, stains and fiber residues.
2. Using a soft cloth, dip it in an appropriate amount of water or 75% ethanol and squeeze it dry.
3. Wipe the display screen.
4. Wipe the surface of the pump or accessories, taking care to avoid interfaces and metal parts.
5. Using dry cloth to wipe off the cleaning agent on the pump or accessory surface, and air it dry in a cool, ventilated environment.

Note: To avoid damage to the pump or accessories by improper disinfection, please disinfect them only when necessary according to your hospital's system.

Instructions	
Warnings	<ol style="list-style-type: none"> 1. Before cleaning or disinfecting equipment or accessories, you must shut down the machine and unplug the power cord 2. Do not immerse equipment or accessories in liquids 3. Do not pour liquids onto equipment or accessories or into the enclosure
Preparation before cleaning	<ol style="list-style-type: none"> 1. Turn off the power and disconnect the power cord 2. Remove the infusion tube 3. Wipe off any residual liquid on the surface with a lint free cloth
Cleaning	<p>Method: Surface wiping Reagent: Water</p> <p>Operation: Dip a soft cloth in cleaning agent and wipe the shell, focusing on addressing the gaps between the buttons</p> <p>Rinse: Dry with a lint free cloth and wipe dry</p>
Disinfection	<p>Method: Wipe and disinfect Reagent: 75% ethanol Contact time: \geq 1 minute Attention: Avoid liquid infiltration into the interface</p>
Drying	<p>Natural air drying or drying with a lint free cloth; Disable heating equipment for drying</p>

11.2 Maintenance during operation

The maintenance during operation mainly concerns the cleaning of push handle and surrounding areas. Medical liquid may drip into the infusion pump during infusion process. Certain medical fluid may corrode the pump body; therefore clean the infusion pump timely after infusion completion.

11.3 Regular Inspection

It is recommended that a technical safety check of the equipment be carried out every two years, including verification that the alarm system is functioning.

11.3.1 Inspect the appearance

- (1) Infusion pump appearance intact, clean and tidy, no cracks, no leaks
- (2) Each key is flexible and effective, no invalid or sticky phenomenon
- (3) When Press the door open button, pump door will open automatically.
- (4) Power cord appearance without damage, tight installation, can't be pulled off easily.

11.3.2 Inspect delivery accuracy

When the infusion accuracy is incorrect, refer to section **8.5.9** for calibration, it is recommended to contact the distributor for maintenance

11.3.3 Inspect internal battery

The battery shall reduce the performance due to prolonged usage, please check the battery every 3 months or when the runtime of the battery is significantly reduced.

- (1) First recharge the battery fully (8 hours with power off)
- (2) Let Infusion Pump work on battery only and set flow rate at 25ml/h. Record the whole working time when the battery is exhausted.
 - If infusion time more than 10 hours, the battery is in good condition.
 - If Infusion time more than 8 hours but less than 10 hours, the battery starts low quality but still can be used.
 - If infusion time less than 5 hours, the battery reaches the end of its life and needs to be replaced.

Replace internal battery

The battery is better to be replaced once three years, the battery must be replaced by trained professionals, it is recommended to contact the distributor or manufacturer to replace the battery once battery is expired.

Battery replacement steps are listed as follows:

- (1) Unscrew the screws at the side of machine; remove the battery cover
- (2) Unplug the battery cable and take out the battery.
- (3) Install the new battery. Please make sure the battery cable won't be squeezed by the battery Cover. Then install battery cover. After replacing new battery, please check its working condition.

Note: if the replacement is not carried out according to the manufacturer's instructions, it may cause equipment failure, electric shock, fire or explosion risk.

11.4 Normal repair procedures

If pump is to be found abnormal, please do not disassemble and repair the machine by yourself, the repair job should be performed by supplier or distributor. It needs to make a complete inspection on machine after maintenance. If necessary, our company can offer circuit diagram and components list to authorized maintenance personnel.

11.5 Maintenance for long-time storage

If the Infusion Pump will not be used for long time, it should be placed in packing carton and avoid direct sunlight and keep it in cool and dry place. Refer to 12.2 for detailed storage conditions.

When using an Infusion Pump of long time storage, please refer to following steps before use:

- (1) Calibrate the Infusion Pump to ensure infusion accuracy and avoid possible medical accident.
- (2) Test Air Bubble and Occlusion alarm.
- (3) Test the working time and recharging time of battery to ensure the battery can still be used.
- (4) Discharge and charge the battery every 3 months to ensure its service life.

11.6 Recycling

The machines and its cable which have been used over its life span should be scrapped. For more information, please contact manufacturer or our distributors. (Whether it is used frequently or not and whether it is repaired properly or not will impact infusion pump's life span.)

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

12 Transport and storage

12.1 Precautions during transport

1. Place the product as per No. of layers indicated on packing carton.
2. Temperature: $-30^{\circ}\text{C}\sim+70^{\circ}\text{C}$;
3. Relative humidity: 10~95% (no frosting)
4. Atmosphere pressure: 50.0kPa~106.0kPa

12.2 Storage Conditions

Storage temperature: $-30^{\circ}\text{C}\sim+70^{\circ}\text{C}$

Relative humidity: 10~95% (no frosting)

Atmosphere pressure: 50.0kPa~106.0kPa

13 Package list

13.1 Standard configuration in a package:

Name	Number
Infusion Pump	1 unit
AC power cord	1 set
User Manual	1 pc
Product qualification certificate	1 pc
Warranty card	1 pc
Pole clamp	1 pc

13.2 Standard optional accessories

Accessory name	Model/Specification
Drop sensor	HK-DS2
Handle	HK-HL50

Multi-functional interface cable	/
----------------------------------	---

The use of the above accessories must comply with the relevant standards of our company, to replace the above equipment, please contact Shenzhen Hawk Medical Instruments Co.,Ltd., if use the accessories not in the list will lead abnormal situation, like can't recognize, wrong accuracy, occur alarms and so on.

14 Open-package Inspection

Cautions for Open-package inspection:

1. Opening the packing carton carefully to avoid damaging the machine or its accessories.
2. Handle with care all items inside the package.
3. Keep all accessories, warranty card and User Manual well for future use and reference.
4. Keep some packing cartons in case of using them to deliver pump.
5. If there is any accessory lacking or damaged, please contact the supplier at the earliest.

15 After-sales service

The warranty for the Infusion Pump is one (1) 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 Infusion pump 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.

After-sales service provider:

Shenzhen Hawk Medical Instrument Co. ,Ltd.

1st-5th Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road,
Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109
Guangdong P.R. China

Tel.: 0086 755-83151901

Fax: 0086 755-83151906

Email: szhk@hawkmedical.cn

Website: <http://www.hawkmed.com.cn>

Appendix I EMC Information



Note:

- **InnoFusion IF-50, 907 V, 908 V** infusion pump conforms to EMC relevant requirements of IEC 60601-1-2 standard;
- Users should install and use the product according to the EMC information provided by random documents;
- Since portable and mobile RF communication device may affect the performance of infusion pump, strong electromagnetic interference should be avoided, for example, do not use it close to mobile phone or microwave;
- See attachments for the guidance and manufacturer's declaration.



Warning:

- **InnoFusion IF-50, 907 V, 908 V** infusion pump should not be put close to or stacked on other devices. If it has to be put close to or stacked on other device, it should be observed and verified that if it can operate normally under its application configuration;
- Class A device is planned to be used in industrial environment. Due to the conducted disturbance and radiated disturbance of infusion pump, it may be difficult to ensure EMC in other environment;
- To use accessories and cables not provided by infusion pump manufacturer, which may increase emission or reduce interference immunity of the pump.

Attachments:

Guidance and Manufacturer’s Declaration– Electromagnetic emission		
<p>InnoFusion IF-50, 907 V, 908 V infusion pump is intended for use in the electromagnetic environment specified below. The customer of the user of the Infusion pump should assure that it is used in such an environment. :</p>		
Emission Test	Conformance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	InnoFusion IF-50, 907 V, 908 V infusion pump use 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 CISPR11	Class B	<p>InnoFusion IF-50, 907 V, 908 V infusion pumps suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</p>
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration-Electromagnetic Immunity			
<p>InnoFusion IF-50, 907 V, 908 V infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of Infusion pump should assure that it is used in such an environment:</p>			
Immunity Test	IEC 60601 Test Level	Conformance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) 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 line	±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.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.</p>	<p><5 % U_T, continuing for 0.5 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)</p>	<p><5 % U_T, continuing for 0.5 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)</p>	<p>Network power should have the quality that is typical for application in commercial environment or hospital. If InnoFusion IF-50, 907 V, 908 V infusion pump user need to operate it continuously during power interruption, it is suggested to adopt UPS or battery for power supply.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>400A/m</p>	<p>400A/m/50Hz/60 Hz</p>	<p>PFMF should have the PFMF characteristics of typical places in commercial environment or hospital.</p>
<p>Note: U_T refers to the AC network voltage before applying test voltage.</p>			

Guidance and Manufacturer’s Declaration-Electromagnetic Immunity

InnoFusion IF-50, 907 V, 908 V infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of Infusion pump should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Conformance Level	Electromagnetic Environment – Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>10 V (RMS) 150 kHz ~ 80 MHz</p> <p>10 V/m 80 MHz ~ 2.5 GHz</p>	<p>10 V (RMS)</p> <p>10 V/m</p>	<p>Portable and mobile RF communication device should not be closer to any part of InnoFusion IF-50, 907 V, 908 V infusion pump than the recommended isolation distance while using, including cables. This isolation distance should be calculated with the formula corresponding to transmitter frequency.</p> <p>Recommended isolation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ <p><i>P</i> —the maximum rate output power of transmitter provided by transmitter manufacturer, in W;</p> <p><i>d</i>—recommended isolation distance, in m.</p> <p>The field strength of fixed RF transmitter is determined by the survey of electromagnetic field. Should be lower than Compliance level in each</p>

			<p>frequency range. There may be interference around the devices with the following symbol.</p> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: This guidance may not apply to all situations, electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.</p>			
<p>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 the InnoFusion IF-50, 907 V, 908 V infusion pump is higher than the above applicable RF Compliance level, the InnoFusion IF-50, 907 V, 908 V infusion pump should be observed to verify if it can operate normally. If abnormal performance is observed, then supplementary measures might be necessary, for example, readjustment of the direction or location of the InnoFusion IF-50, 907 V, 908 V infusion pump.</p> <p>b) Field strengths should be lower than 10 V/m within the whole frequency range of 150KHz~80MHz.</p>			

Recommended Isolation Distance between Portable and Mobile RF Communication Device and the infusion pump

InnoFusion IF-50, 907 V, 908 V infusion pump 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 the **InnoFusion IF-50, 907 V, 908 V** infusion pump.

Rated maximum output power of transmitter W	Isolation Distance Corresponding to Different Frequencies of Transmitter/m		
	150kHz ~ 80MHz $d = 1.2\sqrt{P}$	80MHz ~ 800MHz $d = 1.2\sqrt{P}$	800MHz ~ 2.5GHz $d = 2.3\sqrt{P}$
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 Rated maximum output power of transmitter not listed in the table above, isolation distance d, 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: At 80 MHz and 800 MHz, the formula of higher frequency range applies.

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

Appendix II

Table 1 Classification of alarms and color of alarm indicator light

Classification of alarms	Alarm priority	Color and frequency of alarm indicator light
Upper Occlusion	High priority	Red light /2Hz
Occlusion	High priority	Red light /2Hz
Battery exhausted	High priority	Red light /2Hz
Finished	High priority	Red light /2Hz
Door open	High priority	Red light /2Hz
No Tube	High priority	Red light /2Hz
Air bubble	High priority	Red light /2Hz
Empty	High priority	Red light /2Hz
Abnormal drip rate	High priority	Red light /2Hz
Dedicated infusion tube error	High priority	Red light /2Hz
Connection failure	High priority	Red light /2Hz
System error	High priority	Red light /2Hz
No external power	Low priority	Yellow light long bright
Low battery	Low priority	Yellow light long bright
Pre-occlusion	Low priority	Yellow light long bright
Almost done	Low priority	Yellow light long bright
Abnormal battery power supply	Low priority	Yellow light long bright
No operation	Low priority	Yellow light long bright

Note: The inherent delay of the alarm is less than 100ms.

Table 2 Characteristic parameters of alarm signals

Alarm Priority Level	Interval Time	Alarm Information
High priority	8s±2s	Red background with white letters
Low priority	25s±2s or not repetition	Blue background with white letters

Note: Only the four alarms "No operation", "Almost Done", "Abnormal battery supply" and "Low Battery" sound threetones at intervals of 25s±2s, all other Low Priority alarms sound one tone and are not repeated.

Table 3 Occlusion response characteristic

Occlusion alarm trigger time

Flow Rate (ml/h)	Occlusion alarm level	Occlusion alarm time(min)
1.00	1 level (Lowest)	<60
	13 level (Highest)	<300
25.00	1 level (Lowest)	<10
	13 level (Highest)	<60
0.10	1 level (Lowest)	<180
	13 level (Highest)	<3600

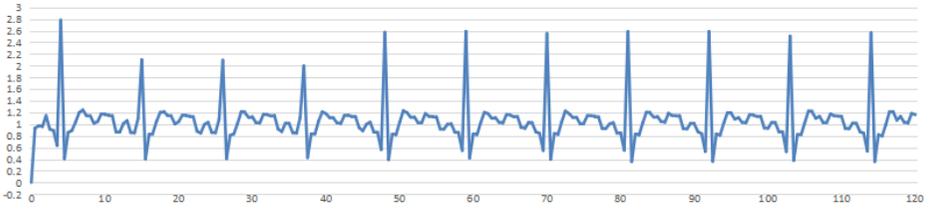
Unintended Bolus Volume

Flow Rate(ml/h)	Occlusion alarm level	Unintended Bolus Volume(ml)
25.00	Lowest (1 level)	<0.9
	Highest (13 level)	<2.0

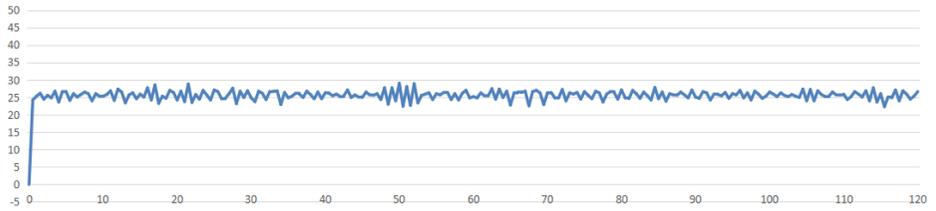
The below data only represent the conclusions obtained with the LX infusion set used in the experiment. The test temperature is $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$, and the pipeline length is 1m. Because this product has a pressure release function, the pressure system is automatically released after the occlusion alarm, so the bolus after occlusion released can be ignored.

Note: The occlusion alarm pressure, trigger time, and unintended bolus volume are all affected by experimental conditions, temperature, and pipeline length.

Table 4 Starting Curve

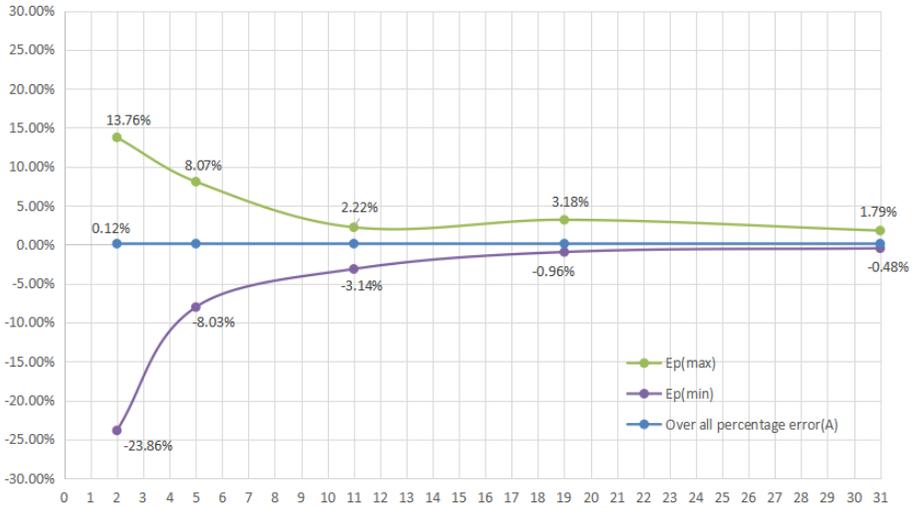


1ml/h Starting Curve(Ordinate: ml/h;Abscissa: min)

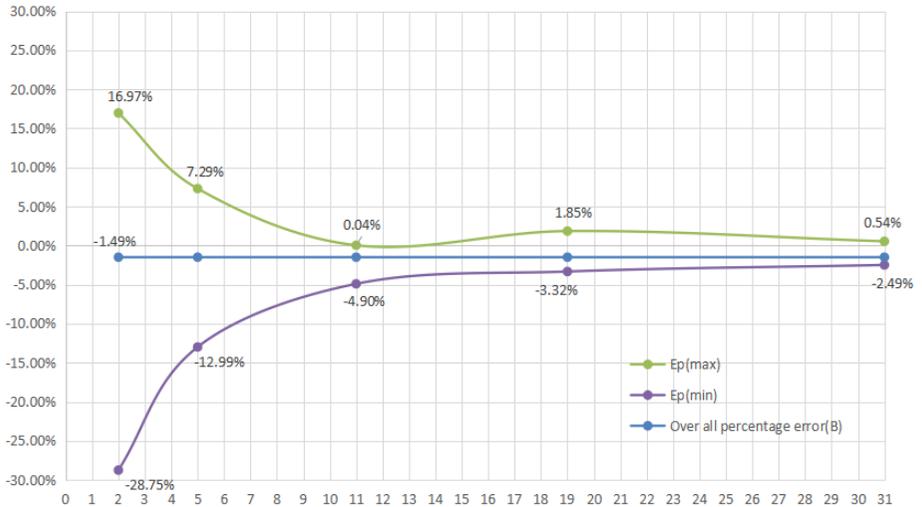


25ml/h Starting Curve(Ordinate: ml/h;Abscissa: min)

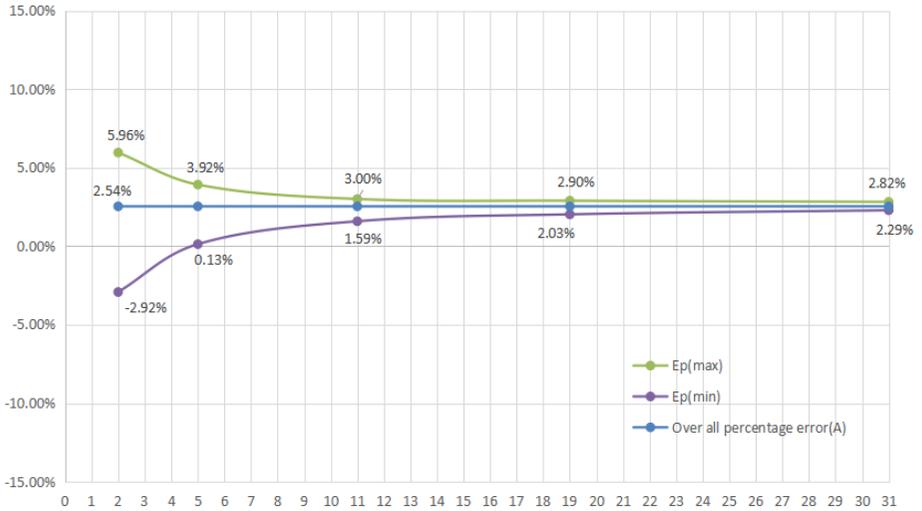
Table 5 Trumpet Curves



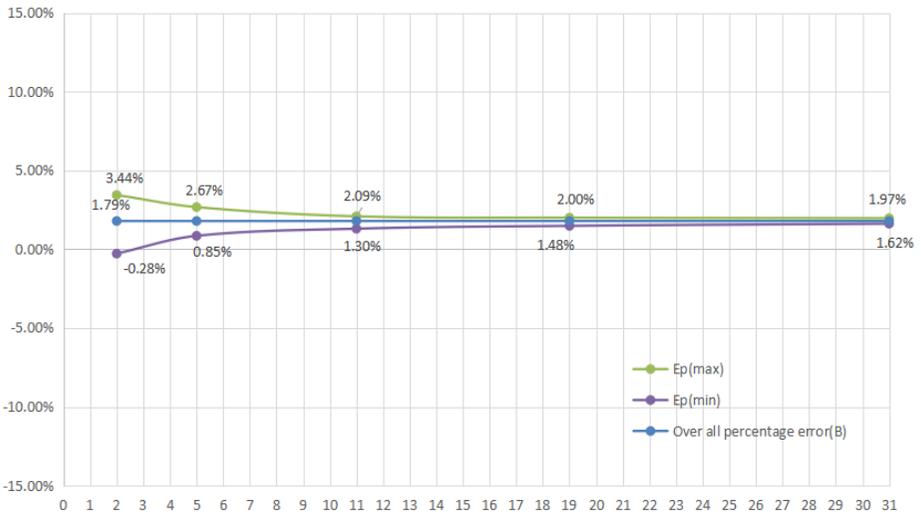
1ml/h 2ndh Trumpet Curves



1ml/h last 1h Trumpet Curves



25ml/h 2ndh Trumpet Curves



25ml/h last 1h Trumpet Curves

The above results are the data obtained by testing according to IEC 60601-2-24:2012 and the methods specified in the company's product standards, and represent the test results of 1 infusion pump unit sample and infusion set (LX brand) used in the test. For more information, please contact our after-sales service department.

Appendix III Cybersecurity

Table 1 Serial communication

Data type	Equipment operation information (alarm signal, Volume infused)
User access control mechanism	User identification by password, after-sales or designated dealers
Electronic interface	multi-function interface to serial port
Technical features	A personal area network is formed by connecting with a wired multi-function serial port line, and the RS232 standard protocol is used for one-way data communication through the electrical port. Communication interface configuration: 115200, the sending character is ASCII code.
Network security feature configuration	Data transmission type is one-way transmission; Device-side related records cannot be deleted.
Data backup and disaster recovery	The related records of the device cannot be deleted.
Operating environment	WIN7 and compatible versions; MobaXterm, software version: V21.2 and compatible versions; USB to serial driver CH340, software version: 3.5.2019.1 and compatible versions; Computers must comply with IEC 62368-1.
Security software	None
External software environment	Not applicable
Security software update	Not applicable
Off-the-shelf software	None
Off-the-shelf software list	Not applicable
Communication protocol	Universal serial port protocol

Table 2 Wi-Fi communication

Data type	Equipment operation information (alarm signal, infusion mode, flow rate, time, VTBI, Volume infused)
User access control mechanism	Use passwords for user identity authentication
Electronic interface	Wi-Fi (IEEE 802.11)
Technical features	<p>A local area network (LAN) is formed through wireless Wi-Fi, and Wi-Fi (IEEE 802.11b/g/n) standard protocol is used for one-way data communication. The modulation modes are BPSK, QPSK, QAM. The operating frequency range is 2.412GHz to 2.484GHz. The wireless rate is IEEE 802.11b: 1 to 11 Mbps, IEEE 802.11g: 6 to 54 Mbps, IEEE 802.11n: 6.5 to 65 Mbps. The transmit power is < 20 dBm (CE requirement: detection mode – RMS). Hawk Medical's private encryption method, the communication with the computer is a one-way data transmission, the infusion pump sends data to the computer, it will not accept any infusion control instructions sent by the computer, and will not send any operation instructions to the computer.</p>
Network security feature configuration	The data transmission type is one-way transmission; related records on the device side cannot be deleted.
Data backup and disaster recovery	The relevant records on the device side cannot be deleted
Operating environment	<p>Software environment: WIN7 and compatible versions; Hawkmed infusion monitoring software (HK-M1000), software version: V01 and compatible versions;</p> <p>Hardware environment: CPU: Intel i3, memory: \geq4GB, hard disk: \geq200GB free space, screen resolution \geq : 1920*1080</p> <p>Network environment:</p>

	Network architecture: C/S; Network type: LAN; Network bandwidth: not less than 100Mbps
Security software	None
External software environment	Not applicable
Security software update	Not applicable
Off-the-shelf software	None
Off-the-shelf software list	Not applicable
Communication protocol	WIFI 802.11b/g/n

Table 3 Cascade

Data type	Equipment operation information (Infusion finished situation, equipment number)
User access control mechanism	Use passwords for user identity authentication
Electronic Interface	Infrared
Technical features	Personal area network is formed through infrared wireless connection, and data communication is carried out through IrDA standard protocol through electrical port. SIR: 2.4 kbit/s to 115.2 kbit/s. MIR: 576 kbit/s to 1152 kbit/s. FIR: 4 Mbit/s. VFIR: 16 Mbit/s. Communication interface configuration: 115200, the sending character is ASCII code.
Network security feature configuration	The data transmission type is two-way encrypted transmission
Data backup and disaster recovery	Related records on the device side cannot be deleted
Operating environment	None
Security software	None
External software environment	Not applicable
Security software update	Not applicable

Off-the-shelf software	None
Off-the-shelf software list	Not applicable
Communication protocol	Universal serial port protocol

Table 4 Software upgrade

Data type	Device data
User access control mechanism	Under certain conditions, use a non-public key combination to enter the upgrade interface, click upgrade to upgrade the software
Electronic Interface	USB interface
Technical features	USB 2.0 standard interface
Network security feature configuration	The data transmission type is one-way transmission; related records on the device side cannot be deleted.
Data backup and disaster recovery	Device-side related records cannot be deleted
Operating environment	None
Security software	None
External software environment	Not applicable
Security software update	Not applicable
Off-the-shelf software	None
Off-the-shelf software list	Not applicable
Communication protocol	USB2.0 standard protocol

IT Network Instructions

1. IT Network-Related Risks

During data transmission between the infusion pump and a computer, the following risks may arise:

- (1) Malfunction of PC-side software: The downloaded software on the PC may fail to operate correctly.
- (2) Unauthorized physical access to embedded software: Risk of data leakage due to illegal tampering with embedded software.
- (3) Data interception or tampering during transmission: Third parties may intercept or alter transmitted data.

Corresponding control measures for the above risks are as follows:

- (1) Install firewalls and antivirus software on the PC.
- (2) Restrict data access: Data retrieval must be performed exclusively by internal professional technicians. Software maintenance must be conducted only by authorized personnel to prevent unauthorized access or data loss.
- (3) Implement data validation: Add checksum fields to verify data integrity. If checksum validation fails, discard corrupted data and request retransmission.

When performing data export or software updates, the above risks must be identified, analyzed, evaluated, and mitigated with appropriate control measures.

2. IT Network Update Instructions

The infusion pump software does not support remote network updates. If software-related security risks emerge during use, system security measures may be upgraded upon request by users or maintenance personnel.

The following table describes potential IT network changes, root causes, and mitigation measures:

Change Item	Root Cause Analysis	Mitigation Measures
IT network configuration changes	Security software is uninstalled or real-time protection is disabled; data transmitted to the pump may be tampered with; incompatibility between new drivers/firmware and existing hardware/software in test environments.	Verify security software configuration and activation before connecting the pump to the PC. Validate compatibility between devices and the Central Infusion Management System.

<p>Addition of new IT network connections</p>	<p>Connecting the PC to external networks may expose infusion pump data or control commands to broader network environments.</p>	<p>Ensure the PC is not connected to external networks. Use dedicated or validated PCs for data transmission.</p>
<p>Disconnection of IT network items</p>	<p>Incomplete cables, loose interfaces, failed software upgrades, or incomplete data exports; unstable Wi-Fi due to distance from the router or router malfunctions.</p>	<p>Inspect cable integrity and interface connections. Verify connectivity between the pump and the Central Infusion Management System or router functionality.</p>
<p>Updates to IT network-connected devices</p>	<p>Software upgrade tools or data export tools may fail to operate on updated devices.</p>	<p>Ensure compatibility of upgrade and data export tools with updated devices.</p>
<p>Upgrades to IT network-connected devices</p>	<p>Incorrect PC OS installation or missing security software may lead to tool malfunctions or data tampering.</p>	<p>Install a validated Windows OS and the latest security software on the PC.</p>



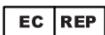
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