

Shenzhen Hawk Medical Instrument Co., Ltd.

Safety and Performance Information Relevant to

The User or Other

(INFUSION PUMP)

Model: hawk-i1

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



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Revision Notes:

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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-i1 infusion pump.

Version No.	Date of Preparation
V1.0.0	01-11-2025

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 Warnings & Cautions

Warning:

Personal casualties may be caused if precautions mentioned in this warning are violated.

A) The Infusion Pump uses peristaltic mechanism for medical fluid infusion, but cannot detect leakage caused by disconnection or crack of infusion set. It is required to inspect the infusion status regularly to prevent above problems.

B) During infusion process, please regularly check the status of dripping as well as the residual liquid inside the infusion bag/bottle to ensure correct performance of the infusion. The Infusion Pump does not directly measure quantity of fluid so it may not detect certain free flow in extremely special case. Even equipped with drop sensor, the Infusion Pump may not detect free flow that smaller than certain volume due to tolerance.

C) The Infusion Pump has occlusion detection function. It gives occlusion alarm when the infusion needle fails to insert into intravenous vein properly or the needle deviates from its position inside the vein during infusion. As occlusion alarm is given only after the occlusion pressure reaching a certain value, the area around the needle may already become swollen or bleeding at this time. In addition, the occlusion alarm is not given maybe because the actual occlusion pressure not large enough to reach the occlusion alarm gate, therefore, it needs to check the insertion area regularly. If the insertion area seems abnormal, please take proper treatments such as re-inserting the needle.

D) The user must install the infusion set straight and properly along the peristaltic fingers from left to right. Otherwise, infusion may not reach expected performance.

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 flow blockage that caused by infusion set knotting, filter or needle blocking, or needle occurring thrombosis etc. may lead to pressure increase inside the infusion set. Solving such blockage may be followed by temporary large-volume infusion. The correct method is to clamp the IV set near the insertion area tight before opening the pump door to release the pressure. Then release the clamping of IV set, get rid of the

occlusion problem and restart operation. If infusion restarting with blockage remaining, occlusion alarm shall sound again and the pressure inside the tube may keep increasing, which may result in disconnection or crack of the tube and further bring harm to the patient.

G) Recommended that keep the flow clip of IV set in downstream position of the Infusion Pump. In case of Air Bubble alarm, it is convenient for the user to clamp the flow clip and then squeeze the air bubble back into the drip chamber.

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 falling off or the stand collision with surrounding objects.

I)The Infusion Pump cannot parallel use with gravity infusion device, as the machine can't detect downstream occlusion or empty of gravity infusion set.

J) The Infusion Pump cannot use with possible large negative or positive pressure piping such as extracorporeal circuit. As in such case, the Infusion Pump cannot ensure infusion accuracy and correct alarm functions.

K)The Infusion Pump cannot use for blood transfusion.

L) Please install the IV set in correct direction (from left to right). If installing in a wrong direction, patient's blood may be sucked out.

M) Do not use the Infusion Pump near inflammable liquid or gas.

N) Never store or use this infusion pump in places with chemical and active gas (including gases for disinfection) or with much humidity, since it may affect the internal parts of infusion pump and finally lead to degradation or damage of their performance.

O) This infusion pump cannot be directly powered by vehicle power supply.

P) Medical staffs should have regular patrol inspection, instead of relying on alarm system only, so as to prevent accidents.

Q) Under single failure state, the maximum infusion quantity should be the remaining fluid in infusion bottle/bag. Keep monitoring the operation state of system during infusion and check infusion pipe, instead of relying on alarm function of this system.

R) Operator should not start infusion until the infusion parameters of infusion pump are conforming to the medical advices. Any nonconforming setting of parameters may lead to invalid operation.

S) Make sure there is no water on the external wall of infusion pipe, especially make sure do not let water flow to ultrasonic sensor; otherwise, it may fail to give alarm when

there is bubble.

T) 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.

U) When the pump is used with a non-standard infusion set or if the infusion set parameters are set inaccurately, there will be inaccuracy of the alarm and its normal detection function will not be maintained.

V) 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.

Cautions:

Personal injury or property loss may occur if violating these precautions.

A) Inspect the Infusion Pump before use, making sure it can work normally. If any malfunction is found, stop operation immediately and contact the distributor or the manufacturer. Besides, adhesion or leakage of medical liquid may lead to malfunction of the Infusion Pump. Therefore please clean the Infusion Pump and store it properly after each use.

B) When use the Infusion Pump the first time after purchasing or after long-time of storage, please connect it to AC power source and charge it for at least 10 hours with power on, (or 3.5 hours with power-off). If not fully recharged, the internal battery can't support the Infusion Pump with enough power in case of AC power failure.

C) If being used near electric cautery equipment, the pump may have misoperation due to the high-frequency noise wave. The following steps and measures should be adopted if it is used together with the medical electric burning device:

(1) Avoid using the Infusion Pump along with old-fashioned electric cautery apparatus (open vacuum tube).

(2) The distance between Infusion Pump and the body of electric cautery apparatus or its power source should be more than 25cm.

(3) Make sure power cables of electric burning device and infusion pump are induced from different power distribution cabinets and they are reliably earthed.

D) Do not use mobile phone, wireless device or cardiac defibrillator within 1 meter near the Infusion Pump. Otherwise the high frequency noise/signal may cause wrong

performance of the Infusion Pump. Make sure the Infusion Pump has ground connection and do not use the same power socket with that for the above-mentioned devices.

E) The Infusion Pump cannot use in area with radiotherapy equipment or magnetic resonance (MR) equipment or hyperbaric oxygen therapy.

F) Do not use pointed object like pen-tip or finger nail etc.) to press on keys of the Infusion Pump. Otherwise, the keys or the mask may suffer premature damage.

G) Keep the infusion bag, IV set and the Infusion Pump a certain distance from the AC power source and DC socket to prevent the medical liquid from splashing or dropping onto the socket to incur shortage of circuit. In addition, make sure the power plug and socket are dry before connecting to power source.

H) Try to use the medical liquid when it reaches or near room temperature. If infusion with low temperature fluid, the air dissolution inside the tube evaporate to many air bubbles, which cause frequent Air Bubble alarms.

I) In normal conditions, try to use AC or DC power source to extend battery service life. When use AC power source, making sure it is well connected to ground and please use the power cord that is standard configuration with the Infusion Pump. Just use battery when there is difficulty in ground connection or without AC power (such as AC power failure or mobile infusion).

J) Please do not use infusion pipe in the same pumping position for less than 6 hours (infusion pipe replacement cycle for infusion at flow velocity below 1ml/h should be less than 6h). The infusion pipe will deform and thus leading to flow error after long time use. It is suggested to move the infusion pipe upward for 15cm every time after 6h (infusion pipe replacement cycle for infusion at flow velocity below 1ml/h should be less than 6h) and then start infusion again, or replace with a new infusion pipe.

K) To prevent free flow after door open please make sure to close the flow clip of IV set before taking it out of the Infusion Pump.

L) Pay more attention to occlusion when infusion at low rate. The lower the rate, the more time needed for detecting occlusion, thus there may be a long interval of infusion interruption.

M) When using computer port, it may suffer interference from devices such as electric cautery apparatus, mobile phone, wireless device or cardiac defibrillator etc. Please try

to keep away from the above-mentioned devices.

N) If Infusion Pump falling off or suffering collision, stop using it immediately and contact the distributor or the manufacturer. Even there is no damage on appearance or no malfunction alarm, the internal parts may have damaged.

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 or modify the Infusion Pump or use it for other purposes other than normal infusion. Otherwise, the manufacturer takes no responsibility.

Q)The adapter intended to connect to USB type-A(DC12V) port needs to comply with I EC 62368-1 or IEC 60601-1 certification.

R)If the auditory alarm sound pressure level is set below the ambient noise level, it may prevent the operator from recognizing a high-priority alarm condition.

S)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.

T)The mains plug is the disconnecting device; do not place the equipment where this disconnecting device is difficult to operate.

U) When the power interruption time does not exceed 30s, the alarm events before the power off can be automatically restored.

V)During priming operation of the infusion pump, bubble alarms are suppressed; during bolus operation, all alarm signals function normally.

W)When the fluid container is positioned below the pump, but no lower than 0.5 m, the infusion accuracy shall be within $\pm 10\%$.

2 Introduction

2.1 Features

- ✧ User friendly interface, easy operation
- ✧ 8 occlusion levels adjustable
- ✧ Large memory function
- ✧ Multiple infusion modes to meet clinical requirements
- ✧ Double CPU for safe infusion
- ✧ Stackable feature to save space

2.2 Intended use and contraindications

It is used in conjunction with an infusion line to administer intravenous medication to patients. This infusion pump is suitable for adult, pediatric and neonatal patients in all clinical departments. The infusion pump is used in hospitals, clinics and other medical institutions.

Contraindications:The Infusion Pump is used in combination with an infusion set to administer intravenous drugs , but not for the 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, lipids, 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, disinfect and sterilize 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

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

2.3 Type and specifications

This product belongs to class I, type CF. It is volumetric Infusion Pump on continuous operation and with internal battery. It cannot be carried by patient for mobile use. It can't be used in mixed gases of flammable anesthetic gas with air, or of oxygen or nitrous oxide with flammable anesthetic, the applied part of the device is the infusion tubing, which is not included with the product.

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: 86.0kPa~106.0kPa

2.5 Impacts on environment and energy

This infusion pump may have certain electromagnetic radiation and interference on other devices. Such interference, if occurred, should be alleviated by adopting certain measures, such as rearranging position of infusion pump or inducing mains supply from different positions. For more information, please see Part 17 – Electromagnetic Compatibility (EMC) Information” of this Manual.

2.6 Date of manufacture & life span

The life span of the infusion pump (battery is not included) and its cable is 8 years. Please refer to label for date of manufacture.

2.7 Version of software

The version of the user manual for infusion pump's software is V01.

2.8 Statement

This device is compliant with the Medical Devices Regulation 2017/745. According

to this regulation, it is a class IIb device. This model carries the marking:



In accordance with the requirements of the Medical Device Regulation 2017/745, this device is compliant with the following standards:

No.	Standard No.	Standard Description
1	EN ISO 13485:2016+A1:2021	Medical devices – Quality management systems – Requirements for regulatory purposes
2	EN 60601-1:2006+A1:2013 +A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3	EN 60601-1-8:2007+A1:2013 +A2:2021	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
4	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
5	EN 60601-1-6:2010+A1:2015 +A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
6	EN 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
7	EN 60601-2-24:2015	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers
8	EN 62304:2006+A1:2015	Medical device software-Software life cycle processes

9	EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
10	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
11	EN ISO 20417:2021	Information supplied by the manufacturer with medical devices
12	EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
13	EN IEC 81001-5-1:2022	Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle
14	ISTA 2A:2011	Packaged-Products 150 lb (68 kg) or Less
15	EN IEC 62506:2023	Methods for Product Accelerated Testing

3 Components

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4 Technical Parameters and Noun Interpretation

Parameters	Description
Applicable infusion set	(1) 15 drops/ml, 20 drops/ml, 60 drops/ml infusion set (2) Dedicated infusion set (1ml = 20 drops, optional)
Infusion accuracy	$\leq \pm 5\%$
Bolus infusion accuracy	$\leq \pm 10\%$ or $\pm 0.05\text{ml}$, whichever is greater.
Infusion modes	Multi Mode Rate Mode

	Time Mode Weight Mode Intermittent Drip Mode Sequential Micro Mode Drug Lib
Infusion rate	0.1-1200ml/h, increment 0.1ml/h
Dripping rate	1-400 drops/min, increment 1d/min
Preset value	0.1-9,999.9ml, increment 0.1ml
Volume infused (Σ)	36,000ml
KVO rate	0.1-10 ml/h, increment 0.1
Bolus	0.1-1200 ml/h , increment 0.1
Bolus Preset value	1.0-100ml, increment 0.1
Maximum output pressure	160 kPa.
Purge	0.1-1200ml/h, increment 0.1
Occlusion pressure	10.0-160.0kpa (8-level adjustable; under normal operating conditions, the maximum infusion pressure shall not exceed 160 kPa.)
Low battery alarm limit	Voltage of internal batteries is lower than 7.1V
Battery exhausted alarm limit	Voltage of internal batteries is lower than 6.65V
SPL (sound pressure level) of alarm signal	SPL of alarm signal not lower than 45dB(A)
Waterproof level	IP34
AC power supply	100-240V 50/60HZ (AC power supply to the pump by AC power cord or Infusion Pump Management Unit with AC power cord)
DC	DC12 \pm 1.2V, 1.5A

Power consumption	35VA
Fuse	Slow fuse Specification: 250V 2A (Maximum fusing time is 10 seconds when current is 5.5A)
Dimensions	212*138*80 (L*W*H)mm (Pole clamp excluded)
Weight	1.4Kg
Single fault infusion volume	≤0.5ml
Air bubble detection	Air bubble size 4 levels adjustable Level 1: 50 μ l Level 2: 100 μ l Level 3: 200 μ l Level 4: 300 μ l (Deviation: ±20%, Test verification default: 25 mL/h)
Internal battery	Rechargeable lithium-polymer battery: 7.4 V, 1 900 mAh Charging time: ≥ 10 h when powered on; ≥ 3.5 h when powered off. Operating time: > 4.5 h (with a brand-new, fully-charged battery at 25 ° C and 25 mL/h). Maximum-flow operating time: > 2.5 h (with a brand-new, fully-charged battery at 25 ° C and 1200 mL/h). Charging and discharging cycle: more than 300 cycles

5 Installation and Adjustment

5.1 Installation conditions and technical requirements

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

5.2 Installation method and cautions

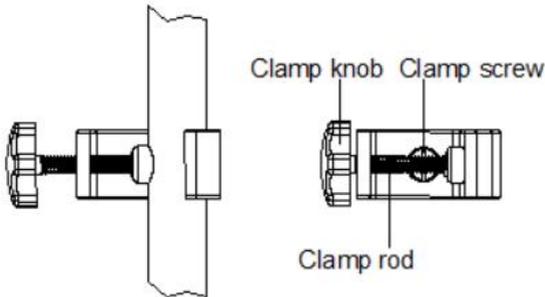
Method 1: Put the infusion pump on stable platform.

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, If the pole clamp is in the same direction with that of IV stand or bar, rotate 90° to suit the

direction of the IV stand or bar.

(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. Remark: Mechanical strength of IV pole: yield strength \geq 170MPa, tensile strength \geq 480MPa, load-bearing requirement \geq 13kg, verticality of IV pole \leq 5°.



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.

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)

The label contains information such as manufacturer, date of production, product serial No., classification, waterproof level, etc.

6.5.2 Symbols and significance

(table1)

Symbols	Descriptions
	Production batch No.
	Product serial No.
	Prohibition
	Please refer to manual
	Defibrillation-proof type CF applied part
	Protective Earthed
IP34	The enclosure is protected against solid objects larger than 2.5 mm in diameter. The enclosure is protected against splashing water from any direction.
	AC power
	DC power

	<p>Dispose in environmental-friendly way</p>
	<p>Date of manufacture and Country of manufacture, CN: China</p>
	<p>Manufacturer</p>
	<p>Stop action</p>
	<p>Turn on/off</p>
	<p>Audio paused (When an alarm is active, pressing this key will silence the alarm tone for no more than 2 minutes; after this interval the alarm tone will resume automatically.)</p>
	<p>Caution Against Wet</p>
	<p>Fragile. Handle with care!</p>
	<p>Keep upright during transport</p>
	<p>5 layers at most of the same package</p>
	<p>Humidity limitation</p>
	<p>Temperature limit</p>
	<p>Atmospheric pressure limitation</p>
	<p>Medical device</p>

	Model number
	EU Authorised representative
	This device is provided with a CE marking in accordance with the regulation 2017/745. 0197 is the Notified Body number.
	Unique device identifier
	EU Importer
	EU distributor
	Prohibition
	Atmospheric pressure limit
	External Power Supply Icon
	Internal Power Supply

7 Precautions for Preparation and Operation

7.1 Preparation and inspection before use

Whether the Infusion Pump is a new one, or it has been stored for a period of time, or it just has been repaired, please check the following terms before use:

- (1) The outlook remains good, clean, no crack and no leakage.
- (2) All keys are responsive. No invalid key or stuck key.
- (3) The door opens agilely and can be closed tight.
- (4) Device cannot be placed in place where it may be crushed. The power cord should be plugged in tight, not easy to pull off.
- (5) If Infusion Pump worked on internal battery only, charge it fully before use and also make sure the battery is still valid for use.

- (6) Set and check system time to make sure the history events are recorded correctly.
- (7) Please read the precautions and operation steps of this user manual carefully.

7.2 Operation Precautions

- (1) It should be free from direct sunlight, high temperature or high humidity.
- (2) Do not run the infusion pump with malfunction to avoid medical accident and endangering the patients.
- (3) The parameters of infusion pump should be set or changed by trained and professional staffs.
- (4) The Infusion pump should be placed within 1.2 meters above or below patient's heart.
- (5) If the panel is damaged, please replace it in time to protect the infusion pump from being damaged by the leaked liquids.
- (6) If the infusion pump is not used within specified range of ambient environment, will decrease the accuracy of infusion and even lead to abnormal operation.
- (7) The viscosity and proportion of infusion liquids may affect the accuracy of infusion pump.
- (8) The device must be calibrated before starting infusion with any new, built-in, or Self-define tube infusion set.
- (9) The liquid level of the liquid supply container should be higher than that of the infusion pump by $0.5m \pm 5cm$, and infusion outside this distance will affect the infusion accuracy of the infusion pump.

8 Operation Method

In order to ensure infusion accuracy and save the time for calibration, it is suggested to use IV sets of the following brands: Boon, LX, Suyun.

8.1 Infusion Operation

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

Adjust the pole clamp to fix the Infusion Pump properly to a stand and connect it to AC power. The AC indicator light  (on lower right corner) shall be on.

8.1.2 Switch on/off

Press Power key  few seconds, the pump will turn on, making self-testing and displaying self-testing result. It will test: communication Info, Press sensor, Air bubble

sensor, Dedicated IV set, AC Info and Battery Info. The test result (OK or FAIL) will be displayed on LCD.

Self-testing result:

(1) Communication information: √ indicates CPU normal; × indicates CPU abnormal;

(2) Battery information: √ indicates internal battery normal; × indicates internal battery abnormal;

(3) AC information: √ indicates AC connected well; × indicates AC fail;

(4) Pressure sensor: √ indicates normal pressure detection; × indicates: abnormal pressure detection;

(5) Air bubble sensor: √ indicates normal air bubble sensor; × indicates abnormal air bubble sensor or IV set was installed in the pump already;

(6) Dedicated IV set: √ indicates normal dedicated IV set sensor; × indicates: abnormal installation of dedicated IV set or IV set is installed in the pump already;

Attention: 1. If Air bubble sensor test FAIL, system will show “Is the infusion set installed?”, please choose the answer according to the facts, the system will predicate per your choice.

2. If not connect with AC power, but use battery, it will show FAIL, in this situation the pump is working on battery.

3. Please keep an eye on the self-testing. If there is any abnormal, please contact distributor or manufacturer. Do not use it forcibly.

Press POWER key  for about 2 seconds to turn off the machine.

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
Frequent Air Bubble alarm	The IV set is too soft or too thin	Replace IV set
	Small air bubble in the IV set	Select a higher level air bubble filter. ★ Note: After changed pressure level, please observe patients' condition continually, if feel uncomfortable, shall stop infusion and return to previous pressure level immediately.
Accuracy discrepancy	The IV set is not calibrated	Calibrate the accuracy of IV set

	The IV set currently used does not match the default brand.	Select correct brand of IV set
	Due to variation in weather and temperature, the internal parameters of the pump incompatible with that of the IV set actually used.	Re-calibrate the accuracy of IV set.
	Certain parts of the machine may be defective.	Contact distributor or manufacturer for repair

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 overheating or burnt.

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.

If the Infusion Pump caught fire or displays any other malfunction, please disconnect the power immediately and contact the sales agent /manufacturer.

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	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	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	Method: Surface wiping Reagent: Water Operation: Dip a soft cloth in cleaning agent and wipe the shell, focusing on addressing the gaps between the buttons Rinse: Dry with a lint free cloth and wipe dry

Disinfection	Method: Wipe and disinfect Reagent: 75% ethanol Contact time: ≥ 1 minute Attention: Avoid liquid infiltration into the interface
Drying	Natural air drying or drying with a lint free cloth; Disable heating equipment for drying

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 anti-free flow clamp (once every 2 years)

Check if the anti-free flow clamp can stop the free flow effectively.

- (1) Install IV set in the Infusion Pump. Close the door and open the flow clip of IV set.
- (2) Keep pressing BOLUS key until liquid drops from the tip of needle.
- (3) Open the pump door.
- (4) Observe and confirm no liquid drips from the needle and no liquid drops into drip chamber.

11.3.2 Check the alarm function of occlusion sensor (once every 2 years)

Check if the Occlusion alarm is given within 2-10 seconds.

- (1) The testing conditions: The Infusion Pump should be 20cm away from the flow clip of IV set and 30cm away from the filter, flow rate at 150 ml/h, volume to be infused as 200ml, and occlusion level as middle.
- (2) Install IV set in the Infusion Pump. Close the door and open the flow clip of IV set.
- (3) Upon pressing START key, use a stopwatch to measure the time taken for occlusion alarm.

11.3.3 Inspect delivery accuracy (once every 2 years)

The Infusion Pump built in mechanism driving system which may suffer abrasion during usage. Frequently use of the machine and variation on temperature may cause

accuracy error. It requires check infusion accuracy periodically.

- (1) Install IV set in the Infusion Pump. Close the door and open the flow clip of IV set.
- (2) Calibrate the accuracy as per instructions of 8.3.7.
- (3) After calibration, setting flow rate at 150ml/h and volume to be infused as 10ml to test delivery accuracy. The delivery accuracy should be within +3%.

11.3.4 Inspect internal battery

The battery shall reduce the performance due to prolonged usage, please check the battery capacity every 2 years.

- (1) First recharge the battery fully 10 hours with power on, or 3 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 90 minutes, the battery is in good condition.

---If Infusion time more than 45 minutes but less than 90 minutes, the battery starts low quality but still can be used.

---If infusion time less than 45 minutes, the battery reaches the end of its life and needs to be replaced.

The battery must be replaced by a trained professional. It is recommended to contact the distributor or the manufacturer to replace the battery.

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.

11.3.5 Replace internal battery

It is better to replace the battery every 2 years. It is advised to contact the supplier once battery is expired because they are not easy to be replaced. Battery replacement steps are listed as follows:

- (1) Unscrew the screws at the back 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.
- (4) The used battery can be sent back to manufacturer or distributor, or can be scrapped according to legally proper way.

11.4 Normal repair procedures

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 service life of this product is 8 years. After the equipment reaches the service life, it should be disposed according to local laws and regulations.(For more information, please contact manufacturer or our distributors.)

WARNING: Disposal of parts, batteries, packaging materials and accessories must comply with local laws, regulations or the hospital's waste disposal system.

12 Transport and storage

12.1 Precautions during transport

1. Place the product as per No. of layers indicated on packing carton.
2. Temperature: $-20^{\circ}\text{C}\sim+55^{\circ}\text{C}$;
3. Relative humidity: 10~95% (no frosting)
4. Atmosphere pressure: 50.0kPa~106.0kPa

12.2 Storage Conditions

Storage temperature: -20°C~+55°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	Hawk-DS2
Handle	HK-HLi1
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>

16. EMC Information



Note:

- **hawk-i1** 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 electromagnet 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:

- **hawk-i1** 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			
<p>The infusion pump is intended for use in the electromagnetic environment specified below. The customer or 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	The 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 CISPR 11	Class A	The infusion pump 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.	
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>The 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

<p>Electrostatic discharge IEC 61000-4-2</p>	<p>±8 kV contact discharge ±15 kV air discharge</p>	<p>±8 kV contact discharge ±15 kV air discharge</p>	<p>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%.</p>
<p>Electrical fast transient burst IEC 61000-4-4</p>	<p>±2kV to power line ±1kV to input/output line</p>	<p>±2kV to power line</p>	<p>Network power should have the quality that is typical for application in commercial environment or hospital.</p>
<p>Surge IEC 61000-4-5</p>	<p>±1 kV line to line ±2 kV line to ground</p>	<p>±1 kV line to line ±2 kV line to ground</p>	<p>Network power should have the quality that is typical for application in commercial environment or hospital.</p>
<p>Temporary voltage drop, short interruption and voltage variation on power input line 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)</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</p>	<p>Network power should have the quality that is typical for application in commercial environment or hospital. If users of the infusion pump need to operate it continuously during</p>

	<p>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>(On U_T, 30% temporary drop) <5 % U_T, continuous for 5s (On U_T, >95% temporary drop)</p>	<p>power interruption, it is suggested to adopt UPS or battery for power supply.</p>
<p>PFMF (50/60Hz) IEC 61000-4-8</p>	<p>400A/m</p>	<p>400A/m/50Hz/60Hz</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

The infusion pump 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	IEC 60601 Test Level	Compliance level	Electromagnetic Environment – Guidance
Conducted RF	3 Vrms	3V 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communication device should not be closer to any part of Hawk-s1 infusion pump 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
IEC 61000-4-6		385MHz-578 5MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	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 Compliance level in each frequency range. There may be interference around the devices with the following
Radiated RF IEC 61000-4-3	150 kHz to 80 MHz 6 V in ISM		

	<p>and amateur radio bands between 0,15 MHz and 80 MHz</p> <p>3 V/m</p> <p>80 MHz to 2.7 GHz</p> <p>385MHz-5785 MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</p>		<p>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 infusion pump is higher than the applicable RF Compliance level, the 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 infusion pump.</p> <p>b Field strengths should be lower than 3 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

The 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 infusion pump.

Rated maximum 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 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
Door open alarm	High as priority	Red light /2Hz
Air Bubble alarm	High as priority	Red light /2Hz

Air or Occl. alarm	High as priority	Red light /2Hz
Occlusion alarm	High as priority	Red light /2Hz
B. Exhaust alarm	High as priority	Red light /2Hz
B. Fault alarm	High as priority	Red light /2Hz
Tube error alarm	High as priority	Red light /2Hz
Empty alarm	High as priority	Red light /2Hz
Drip Abnor alarm	High as priority	Red light /2Hz
Finished alarm	High as priority	Red light /2Hz
Almost Done alarm (Three sound cycle)	Low as priority	Yellow light /0.5Hz
AC Fail alarm	Low as priority	Yellow light long bright
No operation alarm (Three sound cycle)	Low as priority	Yellow light long bright
Low battery alarm (Three sound cycle)	Low as priority	Yellow light long bright
TimeShutdown alarm	Low as priority	Yellow light long bright
Standby ends alarm	Low as priority	Yellow light long bright

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

Table 2 Alarm sound interval time

Alarm level	Intervals	Alarm information
High	8s±2s	Black on red
Low	25s±2s or no repeating	Black on yellow

Note: Only the three alarms "No operation", "Almost Done" and "Low Battery" sound three tones at intervals of 25s±2s, All other low-priority alarms sound once only and do not repeat.

Table 3 Occlusion response characteristic

BOON infusion set is used in this test. Test data is measured at flow rate of 1ml/h and 25ml/h respectively, when the flow clamp is 20cm from infusion pump and the filter is 30cm from the infusion pump.

Flow rate (ml/h)	Occlusion Alarm Level	Occlusion alarm time (h/min)
0.1	1 level(Lowest)	<4h
	8 level(Highest)	<20h
1	1 level(Lowest)	<53
	8 level(Highest)	<170
25	1 level(Lowest)	<3
	8 level(Highest)	<11

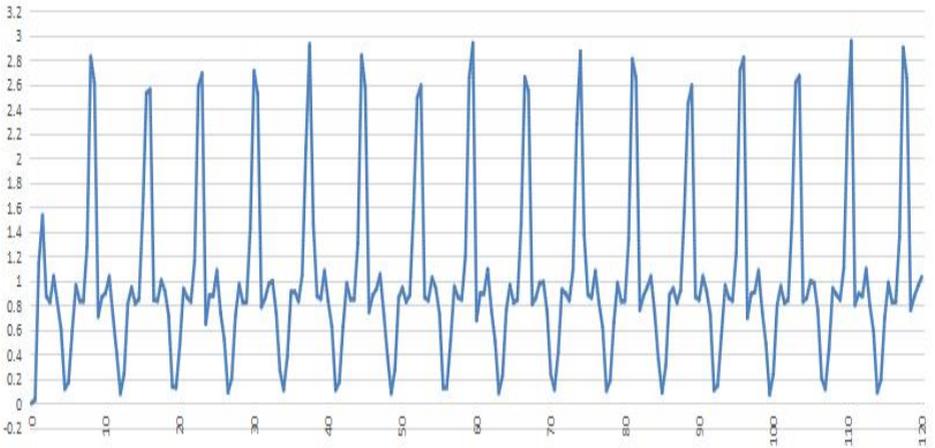
Unintended Bolus Volume

Flow Rate(ml/h)	Occlusion alarm level	Unintended Bolus Volume(ml)
25.00	Lowest (1 level)	<0.26
	Highest (8 level)	<1.00

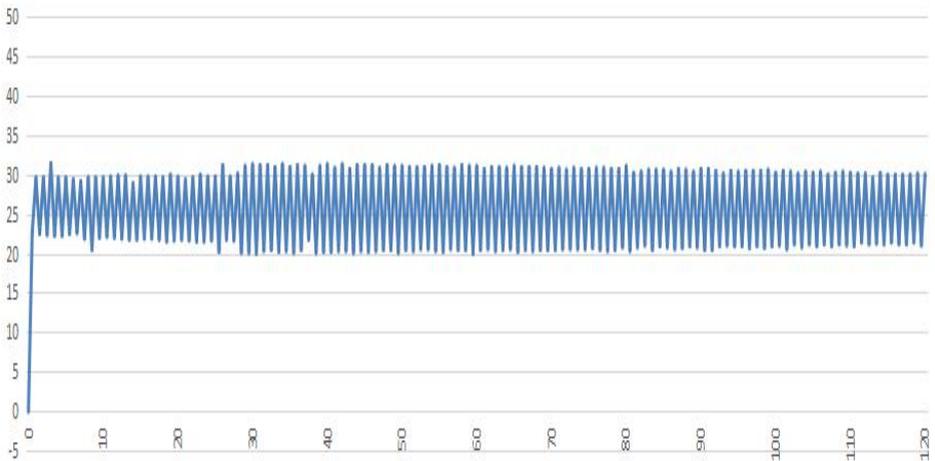
The below data only represent the conclusions obtained with the Boon infusion set used in the experiment. The test temperature is $20^{\circ}\text{C}\pm 2^{\circ}\text{C}$, and the pipeline length is 1m. Because this product has a pressure release function, the pressure system is automatically released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

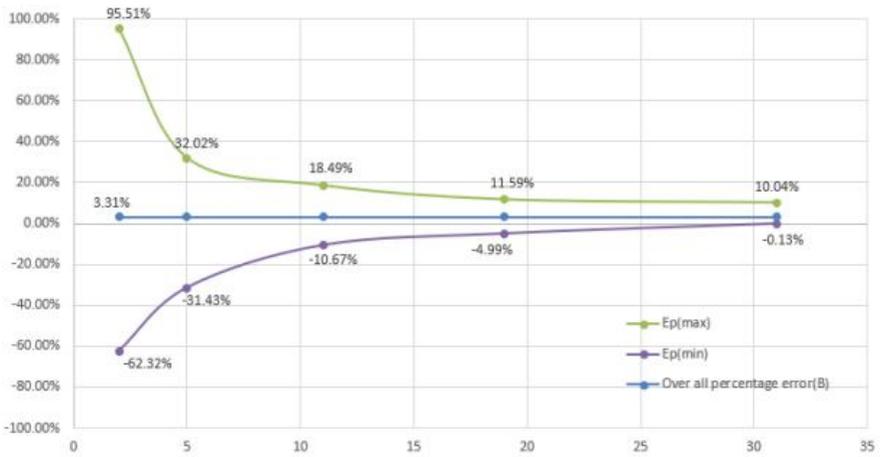
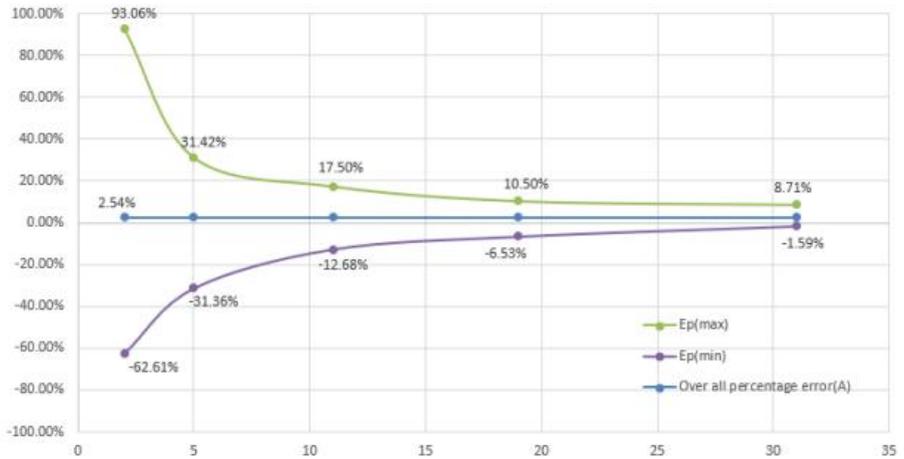


1ml/h Starting Curve(Ordinate:ml/h;Abcissa:min)

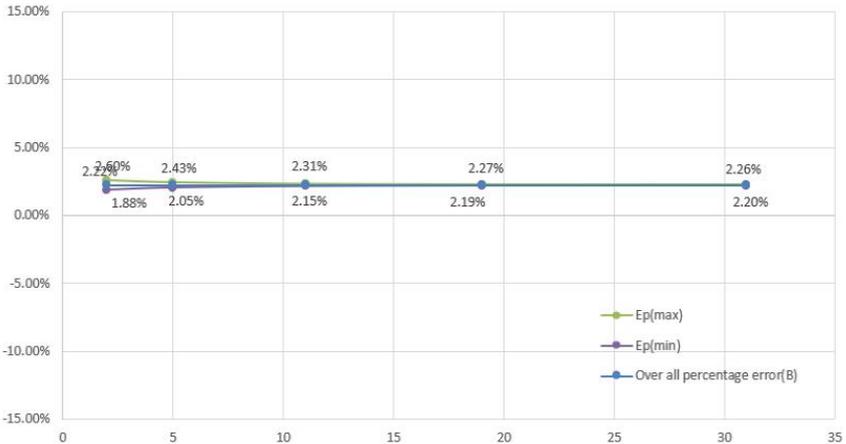
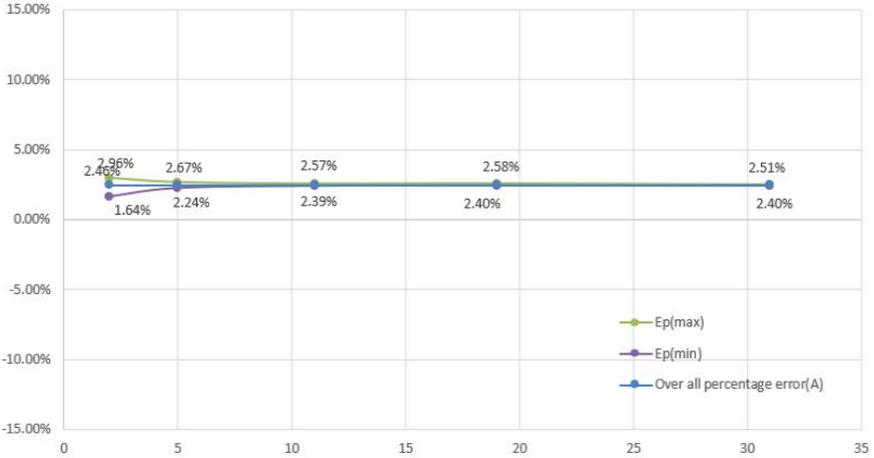


25ml/h Starting Curve(Ordinate:ml/h;Abcissa:min)

Table 6 Trumpet Curves



1ml/h Trumpet Curves



25ml/h 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 (Boon brand) used in the test. For more information, please contact our after-sales service department.

Appendix III Cybersecurity

Table 1 USB-A-SYSTEM upload history

Data type	Device Data
User access control mechanism	User identification via password
Electronic interface	Serial port
Technical features	Baud Rate: 115200
Network security feature configuration	Data transmission is unidirectional; device-side records cannot be deleted
Data backup and disaster recovery	Device-side records cannot be deleted
Operating environment	HyperTerminal for Windows 7 or compatible (or equivalent serial-communication software)
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	Generic Serial Protocol

Table 2 USB-A-SYSTEM firmware upgrade software

Data type	Device Data
User access control mechanism	Accessed via serial cable
Electronic Interface	Serial Port
Technical features	Baud Rate: 115200
Network security feature configuration	Communication method: bidirectional encrypted data transmission
Data backup and disaster recovery	Device-side records cannot be deleted
Operating environment	Client-side FlyMcu serial upgrade software

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	Generic Serial Protocol

Table 3 USB-A LINK interface

Data type	Device data
User access control mechanism	Accessed via Shenzhen Hawk Medical Instrument Co., Ltd infusion information collection system
Electronic Interface	USB interface
Technical features	Full-speed: 12 Mbps
Network security feature configuration	Communication method: bidirectional encrypted data transmission
Data backup and disaster recovery	Device-side 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	Generic CAN bus protocol
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Table 4 USB-A DROP interface

Data type	Device data
User access control mechanism	Accessed via drip-rate sensor connection
Electronic Interface	Serial Port
Technical features	Baud Rate: 115200
Network security feature configuration	Communication method: bidirectional encrypted data transmission
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	Generic Serial 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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