

Shenzhen Hawk Medical Instrument Co., Ltd.

**Safety and Performance Information Relevant to The
User or Other
(Infusion Pump)**

USER MANUAL

Model: HK-100、HK-100I、HK-100II

Please read the manual before using the product.

Please keep the manual for reference !



057-00686-00

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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 HK-100I, HK-100, HK-100II infusion pump.

Version No.	Date of Preparation
V1.0.0	2025-12-22

User manual version upgrade instructions:

V X.Y.Z

V indicates version No. of user manual.

X indicates that the device has a major upgrade: When software, hardware and construction of device have big modifications, the user manual should be updated accordingly.

Y means the device has small improvement: 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, the user manual should be updated accordingly.

Z means there is an amendment of user manual information while no changes were made to the device. This only corrects word/ diagram/explanation errors and so on.

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 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 straightly 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 pump 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 installed in a wrong direction, patient's blood may be sucked out.
- m) Do not use the Infusion Pump near inflammable liquid or gas.
- n) Do not store or use the Infusion Pump in humid environment or environment with chemically active gases (including gas for sterilization). Such environments may have impact on internal electronic parts and thus bring degradation or damage to their functions.
- o) It can be used for ambulance with DC: 12V by working with a voltage stabilizer.
- p) Please use the pump with a legally marketed infusion set and calibrate the pump before delivery to guarantee the accuracy of infusion and normal detection alarm.
- q) 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.
- r) The maximum deviation of accuracy when the supply container is lower than the pump body is $\pm 10\%$.
- s) 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.
- t) Do not use the same segment of the infusion set for more than 6 hours. The IV set may be out of shape due to long-hour squeeze by the peristaltic fingers and this can result in inaccuracies. It is suggested to progress to a new section (15 cm upward or downward) after every 6 hours of usage or replace the IV set with a new one, and then restart the operation.

- u) Do not position the equipment to make it difficult to operate the disconnection device.
- v) Unauthorized modifications to this equipment are not permitted, that may result in serious injury to patients.
- w) Loss of power may result in unacceptable risks. The equipment must be connected to a suitable power supply.
- x) The device must be connected to a certified DC power supply that conforming to IEC 60950-1/IEC 62368-1 or other relevant safety standards when powered by DC power source.
- y) To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- z) When the power loss duration does not exceed 30s, the alarm setting before the power loss can be automatically restored.
- AA) When this device is connected to the same infusion port as other infusion systems, backflow may occur due to mutual influence between the infusion tubes, or the response duration for blockage may be extended. Therefore, when connections to other infusion systems are required, a One-Way valve should be used at the end of the infusion line or done under the guidance of the local hospital.

Cautions: Failure to follow cautions below may cause injury of operator/patient or loss of property.

- 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 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 using near electric cautery equipment, the Infusion Pump may result in wrong operation due to the high frequency wave of electric cautery equipment. If the Infusion Pump has to be used with electric cautery equipment, please take proper measures as follows:

- (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) The Infusion Pump shall not use the same electric cabinet as that of electric cautery apparatus, and having reliable ground connection.
- 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 dripping 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) Recommend to change the segment of infusion set every 6 hours to guarantee the accuracy. The IV set may be out of shape due to long-hour squeeze by the peristaltic fingers and thus cause accuracy error. It is suggested to move to a new section (15 cm upward or downward) after every 6 hours of usage, and then start operation again. Or replace the IV set with a new one.
 - 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 disassembly or modify the Infusion Pump or use it for other purposes other than normal infusion. Otherwise, the manufacturer takes no responsibility.
- q) The alarm system's stored logs will not be affected during the period of complete power loss (both supply mains and internal power source), but the complete power loss event will not be recorded as an alarm in the logs.

2. Introduction

2.1 Features

Compact and light weight

User-friendly interface, easy parameters setting

2.8 inch colorful LCD with detailed menu

Peristaltic system, better accuracy.

Internal multiple reliable design and alarm functions, more stable and safer infusion.

Applicable to vertical pole or horizontal bar

Removable pump body for easy cleaning.

Product models

Model/Description		HK-100I	HK-100	HK-100II
Infusion modes	Rate mode	√	√	√
	Drip mode	√	√	√
	Time mode	√	√	√
	Micro mode	X	√	√
	WT. Mode	X	√	√
	Intermittent	X	√	√
	Dose mode	X	X	√
	Programmable	X	X	√
Remark: √ means with the function, X means without the function				

2.2 Intended Use

Clinical operators: This user group refers to the authorized and well-trained medical personnel allowed to operate this Infusion Pump in clinical situations.

Reprocessing personnel: This user group refers to those who clean, disinfect and sterilize the Infusion Pump and its accessories.

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.

2.3 Type and specifications

This product belongs to class I, type CF. It is a volumetric Infusion Pump on continuous operation and with internal battery. It cannot be carried by patient for portable 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 CF applied part is disposable infusion tube that is not included in the system. The maximum temperature of applied part is 45°C according to IEC60601-1 standard, and the duration of PATIENT with skin is a time ≥ 1 min and < 10 min.

2.4 Operating conditions

- a) Temperature: 5°C-40°C
- b) Relative humidity: 10-95% (no frosting)
- c) Atmosphere pressure: 86kPa~106kPa

2.5 Affection on environment and energy

This product may have certain electromagnetic radiation which may influence other devices. In such case, please take proper measures to reduce the interference such as re-locating the Infusion Pump or using AC power from a different source.

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 V02.

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 - Part2-24: 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 and specifications

Infusion accuracy	<p>a) Flow rate ≥ 1.00 ml/h, Accuracy $\leq \pm 5\%$.</p> <p>b) Flow rate < 1.00 ml/h, Accuracy $\leq \pm 10\%$.</p> <p>c) KVO infusion accuracy $\leq \pm 10\%$.</p> <p>d) Bolus infusion accuracy $\leq \pm 5\%$ or ± 0.05 ml, whichever is greater.</p>
Applicable infusion set	<p>Various brand of infusion set 15, 20, 60 drips/ml, Infusion set external diameter: 3.4~4.5mm. Optional: Boon, JieRui or Hawkmed brand dedicated infusion set.</p>
Infusion modes	<ol style="list-style-type: none"> 1. Rate mode 2. Drip mode 3. Time mode 4. WT. Mode (Body weight mode) 5. Dose mode 6. Programmable 7. Intermittent 8. Micro mode

Flow rate range	0.1-1200.0ml/h Increment options: 0.1ml/h, 1ml/h, 10ml/h or 100ml/h
Volume to be infused (VTBI)	0.1-9999.9ml, or 0 (no limit on VTBI) Increment options: 0.1ml, 1ml, 10ml, 100ml or 1000ml
Drip rate	1-400 drips/min increment: 1drip/min, 10drips/min, 100drips/min Drip rate accuracy(Use with drip speed sensor): within $\pm 10\%$ Drip rate accuracy(Not used with drip sensor): within $\pm 20\%$
Volume infused	0-36000ml
Alarm functions	Visual and audible alarms: Door Open, Occlusion, Air Bubble, LowBattery, B. Exhaust, On Battery, Error 0xE0, Error 0xE1, Error 0xE2, Error 0xE3, PRESS ERR, Drip Abnor, Finished, Empty, Check tube, Battery fail, AC Fail, No Operate, AlmostDone, Shutdown timer, Standby end.
KVO rate	0.1-10.0ml/h, preset by the user; default: 1.0ml/h
Bolus	Manual bolus & Auto bolus: Bolus rate: 0.1-1200.0ml/h Default: 1000.0ml/h Bolus VTBI: 0.1- 100.0ml For manual bolus, Bolus VTBI is 0, Bolus time is 0. Bolus for micro mode: Bolus rate: 0.1-100.0ml/h, Default: 100.0ml/h Bolus VTBI: 0, 0.1 -1000.0ml
Purge	Purge rate: 0.1-1200.0ml/h Default: 600.0ml/h Purge VTBI: 0-9999.9ml
Air Bubble detection	5 adjustable alarm triggering levels: 1 level: 25ul, 2 level: 50ul, 3 level: 100ul, 4 level: 200ul, 5 level: 300ul. Accumulated bubbles: Each single bubble level corresponds to the cumulative bubble within 1 hour, the limit is 800ul. Default: 1 level (25ul)

Occlusion pressure	High, medium and low 3 gears are adjustable, the default is mid-range Low gear (L): 40-100kPa Mid-range (M): 70-130kPa High-grade (H): 100-160kPa Unit options: kPa, bar, mmHg, psi Default unit: kPa
Single failure infusion volume	≤0.5ml
Anti-bolus function	Diminishes the volume of unwanted Bolus injected to the patient after removal of the occlusion cause.
RS-232 port (optional)	It is used to connect syringe pump to standard PC to transfer infusion history records. Note: This process must be carried out when machine in non-infusion state. The RS232 communication line must use shielded wire. And this port is interfacing with infusion management system via a WIFI signal projector (WIFI signal projector is optional).
Water Proof Level	IP24
AC power	100V-240V ~ 50Hz/60Hz
Battery	Lithium Polymer 7.4V 1900mAh. Recharge time: 10h with power on, 3h with power off. Running time: more than 5h at rate of 25ml/h, environment temperature 25°C after being fully charged.
Power consumption	35VA
DC	DC 12V ±1.2V NOTE: It cannot be used for ambulance.
Fuse	Slow fuse, 250V 2A
Operating conditions	Environment temperature: 5°C~40°C Relative humidity: 10%-95%RH Air pressure: 86kPa~106kPa
Dimensions	145(L)×120(H)×100(W, not including pole clamp) mm
Net weight	≤1.4 kg

5. Installation

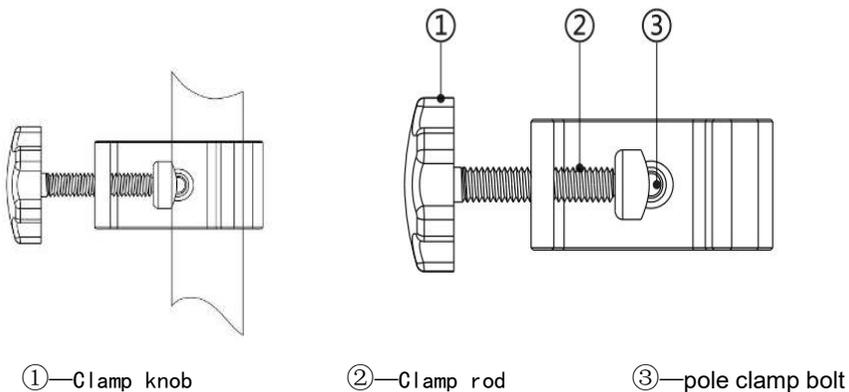
5.1 Installation conditions and technical requirements

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 Installation method and cautions

If the pole clamp is not in the same direction with that of IV stand or bar, adjust it to suit the direction of the IV stand or bar.

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.



6. External Features

6.1 Front panel (Diagram 1)

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6.2 Rear panel (Diagram 2)

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6.3 Label

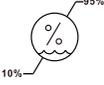
6.3.1 Product label (on the back panel)

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6.3.2 Symbols and significance

(Table 1)

Symbols	Descriptions
	Production batch No.
	Product serial No.
	Prohibition
	Please refer to manual
	Type CF
	Protective Earthing
IP24	The device against ingress of solid foreign objects $\geq 12.5\text{mm}$ diameter and splashing water
	Infusion liquid flow direction identification: the infusion liquid flows from left to right.
	Alternating current
	Direct current
	Battery and waste electrical and electronic device must be disposed of in accordance with the locally applicable regulations, not with domestic waste.
	Date of manufacture and Country of manufacture, CN: China
	manufacturer

	<p>Keep dry</p>
	<p>Fragile,handle with care!</p>
	<p>This way up</p>
	<p>Stacking limit by number 5</p>
	<p>humidity limitation</p>
	<p>temperature limitation</p>
	<p>Authorized Representative in the European Community</p>
	<p>This device is provided with a CE marking in accordance with the regulation 2017/745. 0197 is the Notified Body number.</p>
	<p>Keypad lock icon</p>
	<p>Night mode</p>
	<p>Importer</p>
	<p>Model number</p>
	<p>Unique device identifier</p>

	Medical device
	Audio Paused
	Atmospheric pressure limitation
	Unique device identifier
	EU Importer
	EU distributor
	WIFI signal

7. Preparation and inspection

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 appearance of the pump remains good, clean, with no cracks and leakages
- (2) All keys are responsive. No invalid key or stuck key.
- (3) The door can be opened in a smooth manner and can be closed securely.
- (4) The power cord should be attached securely to ensure that it does not easily become loose
- (5) If Infusion Pump worked on internal battery only, charge it fully before use and also make sure the battery is in good condition for use.
- (6) In addition to built-in brand infusion sets, the infusion pump should be calibrated before using a new brand of infusion set.
- (7) The Infusion Pump has occlusion detection function. It gives occlusion alarm when the infusion set is blocked that produce under-infusion.
- (8) The infusion Pump has malfunction detection function. It gives high priority alarm when the pump is fault that produce over-infusion.

8. Operation Method

In order to ensure the accuracy of infusion, it is recommended to use the pump built-in infusion set brand (Boon B2 (1ml = 20 drips), the dedicated infusion set of Hawkmed (1ml = 20 drips).

8.1 Operation

The whole infusion operation contains the following processes:

- 1) Fix the Infusion Pump and connect it to AC power.
- 2) Switch on / off.
- 3) Dedicated infusion set function(optional): If you use a dedicated infusion set for the first time, you need to enter "System Settings" --> "DedSet" --> "DedicatedSet" to "ON" state and then shut down and restart. If it is already set before, after switch on, please follow the indications displayed on device to install the dedicated infusion set.
- 4) Fill the IV set with medical liquid and install it in the Infusion Pump.
- 5) Set infusion parameters.
- 6) Purge the air from the infusion set.
- 7) Clear Σ (volume infused) .
- 8) Start infusion.
- 9) Bolus infusion.
- 10) Stop infusion.
- 11) Infusion completion.
- 12) Replace IV set and infusion bag/bottle.

8.1.1 Adjust the pole clamp to fix the Infusion Pump properly to a stand/bar/cage and connect it to AC power. The AC indicator light AC(on upper left corner) shall be on.

8.1.2 Switch on/ off.

Press Power key for about 2 seconds, the pump will be switched on and display self-testing interface. Self-testing includes pressure sensor, air bubble sensor, AC power, Battery and so on. The test result (OK or FAIL) will be displayed on LCD.

Attention: Please keep an eye on the self-testing result. If any item failed and cannot be solved, please contact manufacturer or distributor for service. Please DO NOT force to use it.

Press POWER key for about 3 seconds to turn off the pump.

8.1.3 Fill the IV set and install the IV set properly.

(1) Put the flow clip downstream of the Infusion Pump and close the flow clip tight.

Connect IV set to infusion bag/bottle and then squeeze the drip chamber to fill with 1/2 of liquid. Open the flow clip and let the fluid flow to the tip of the needle. Then close the flow clip again.

(2) Install the IV set

Press door lock and the door shall pop open. Upward the anti-free flow clamp and place it at top of right side plastic block. Then pull the IV set straight and install it in correct direction as shown in Diagram 1 (from left to right), making sure the IV set is properly inserted in all positions from ① to ⑦. Press the door to close it (A 'click' sound indicates the door is well closed). If the air detector detects no air inside the tube, the indicator light on top of the pump shall be on, which indicates the pump is ready for operation. If the green indicator light is not on, follow "Step 8.3.26 Purge" to purge all the air inside the tube. Then the green indicator light shall be on.

8.1.4 Infusion mode selection

The default infusion mode is Rate Mode, press "Switch" key to access to the other infusion modes. The pump will sequentially display Rate Mode, Drip Mode, Time Mode, Body Weight Mode, Dose mode, Sequential, Programmable, TPN mode, Intermittent & Micro mode. Press corresponding soft key to select the infusion mode.

Attention:

1. Different infusion modes need to set different parameters.
2. Under Time Mode, when flow rate (result from volume limit divided by infusion time) more than maximum flow rate of system 1200ml/h, the system will display the infusion time (result from volume limit divided by 1200ml/h) .
3. The length of the infusion tube from the air bubble sensor to the human body should be no less than 1 m.

Under Body Weight Mode, if flow rate (result from entering parameters) more than system default maximum rate, the system will alert flow rate out of range and users need to reset parameters.

8.1.5 Set infusion parameters

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8.1.6 Purge

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8.1.7 Clear the volume infused

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8.1.8 Start infusion

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8.1.9 Bolus infusion

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8.1.10 Stop infusion

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8.1.11 Infusion completion

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8.1.12 Replace IV set and infusion bottle

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8.2 Alarms and solutions

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8.3 Parameters Setting and Accuracy Calibration

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8.4 Select language and restore default

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8.5 Operation Precautions

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9. Malfunction Analysis and Solutions

Problems	Causes	Solutions
Frequent Air Bubble alarm	The IV set too soft or too thin.	replace IV set
	Small air bubble in the IV set.	Select a higher level air bubble filter.
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 the 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 pump may be defective.	Contact distributor or manufacturer for repair

Beside the problems mentioned in 8.2, please contact the distributor / 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 features which protect it against excessive pressure, overheating or short circuit, etc. to avoid overheating or burns from occurring .

10.2 Troubleshooting

(1) If the Infusion Pump gives system error alarm, stop the operation and contact the distributor for repair. It can be used again only after it has been 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 distributor/manufacturer.

11. Maintenance, Inspection, repair and recycling

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). Using a soft cloth, dip it in an appropriate amount of water or 75% ethanol and squeeze it dry
- 2). Wipe the display screen.
- 3). Wipe the surface of the pump or accessories, taking care to avoid interfaces and metal parts.
- 4). 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

11.2 Maintenance during operation

The maintenance mainly concerns the cleaning of the pump body and surrounding areas. Medical liquid may drip into the Infusion Pump during infusion process. Certain medical fluid may corrode the pump body and certain may stick on the peristaltic fingers, therefore clean the Infusion Pump every time after infusion completion. The device shall not be serviced and maintained during while in use with the patient.

11.3 Periodic Inspection

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 on the Infusion Pump. Close the door and open the flow clip of IV set.
- (2) Keep pressing BOLUS key until liquid drips from the tip of needle.
- (3) Open the pump door.
- (4) Observe and confirm no liquid drips from the needle and no liquid drips 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 Level 8.

(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 Check the alarm function of air bubble sensor (once every 2 years)

Testing method:

(1) Install IV set in the Infusion Pump and set flow rate at 150ml/h, volume to be infused as 200ml, air bubble detection level as Level 1 (25ul) and then start infusion.

(2) Reverse the drip chamber to let in some air flow into the tube. Use finger to flip the tube to create an air bubble.

(4) When the Infusion Pump gives Air Bubble alarm, open the door and check if there is any air bubble in the tube near the air bubble sensor.

★ When air bubble detection level setting as Level 1 (25ul), Air Bubble alarm shall be given upon detection the size of air bubble about ≤ 4 mm.

11.3.4 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 pump 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 $\pm 3\%$.

11.3.5 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.

Replace internal battery

(1) Unscrew the screws at the bottom of pump; 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.

11.4 Normal repair procedures

The repair job should be performed by supplier or distributor. It needs to make a complete inspection on pump after maintenance. If necessary, our company can offer circuit diagram and components list to authorized maintenance personnel. If needed, contact the manufacturer for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.

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 13.2 for detailed storage conditions.

To ensure that this pump remains in good operating condition after a long-time storage period, please carry out the following maintenance procedures:

(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.

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. Electro Magnetic Compatibility declaration

Warning:

- Enteral feeding pump should not be used in proximity or in stack with other devices, and if it must be used in proximity or in stack, it should be observed and verified to operate normally in the configuration used;
- Except for cables sold by the manufacturer of enteral feeding pump as spare parts for internal components, the use of accessories and cables other than specified may result in increased emission or reduced disturbance immunity of enteral feeding pump.

Caution:

- Enteral feeding pump meets the electromagnetic compatibility requirements of IEC60601-1-2 Clause 201.17.202. The Essential Performance of devices are defined as:

1) Flow rate ≥ 1.00 ml/h, Accuracy $\leq \pm 5\%$, flow rate < 1.00 ml/h, Accuracy $\leq \pm 10\%$,

Bolus infusion accuracy $\leq \pm 5\%$ or ± 0.05 ml, whichever is greater

2) Protection against unintended bolus volumes and occlusion

3) Correct alarm signal of high-priority

- User should install and use according to the Electromagnetic Compatibility information provided by random file.
- Portable and mobile RF communication equipment may affect the performance of enteral feeding pump, please avoid strong electromagnetic interference during usage, such as near mobile phone, microwave oven, etc.

Please see enclosed Guideline and manufacturer' s statement:

Guidance and manufacture's declaration – electromagnetic emission

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.

Emission test	Compliance	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 emission CISPR 11	Class B	The Infusion pump is 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 manufacture's declaration – electromagnetic immunity

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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Infusion pump requires continued operation during power mains interruptions, it is recommended that the Infusion pump be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	400A/m	400A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity

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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms</p> <p>150 kHz to 80 MHz</p> <p>10 V/m</p> <p>80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>10 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Infusion pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.167 \sqrt{P}$ $d = 1.167 \sqrt{P}$ <p>80 MHz to 800 MHz</p> $d=2.333 \sqrt{P}$ <p>800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF</p>

			<p>transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Infusion pump is used exceeds the applicable RE compliance level above the Infusion pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Infusion pump.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Infusion pump.

The Infusion pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Infusion pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Infusion pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 KHz to 80 MHz $d = 1.167 \sqrt{P}$	80 MHz to 800 MHz $d = 1.167 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333 \sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

13. Transport and storage

13.1 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

13.2 Storage conditions

Storage temperature: $-20^{\circ}\text{C} \sim +45^{\circ}\text{C}$ (With battery)
 $-20^{\circ}\text{C} \sim +60^{\circ}\text{C}$ (Without battery)

Relative humidity: 10~95% (no frosting)

Atmosphere pressure: 50.0kPa~106.0kPa

14. Package list

14.1 Standard configuration in a package

- ① Infusion Pump 1 unit
- ② AC power cord 1 set
- ③ User Manual 1 pcs
- ④ Warranty card 1 pcs
- ⑤ Product qualification certificate 1 pcs

14.2 Optional and replaceable parts

Name	Model	Specification
Power cord	KC-015	AC250V, 16A
Lithium battery	AEC903466	7.4V,1900mAh
Drop sensor	Hawk-DS	5Vd.c.

The replacement should comply with the product standards, and contact the manufacturer for replacement.

For all the components replaced by dismantling the shell with a tool, should be operated by authorized maintenance personnel.

15. Open-package Inspection

Cautions for Open-package inspection:

- (1) Opening the packing carton carefully to avoid damaging the pump 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 defective pumps.
- (5) If there is any accessory lacking or damaged, please contact the supplier at the earliest.

16. 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

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Email: szhk@hawkmedical.cn

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

Annex I

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 priority	Red/ 2Hz
Air Bubble alarm	High priority	Red/ 2Hz
Occlusion alarm	High priority	Red/ 2Hz
B. Exhaust alarm	High priority	Red/ 2Hz
Finished alarm	High priority	Red/ 2Hz
Drip Abnor	High priority	Red/ 2Hz
PRESS ERR	High priority	Red/ 2Hz
Low Battery alarm	Low priority	Yellow, consistent
Almost Done alarm	Low priority	Yellow, consistent
AC Fail alarm	Low priority	Yellow, consistent
On Battery alarm	Low priority	Yellow, consistent
No Operate alarm	Low priority	Yellow, consistent
Shutdown timer	Low priority	Yellow, consistent
Standby end	Low priority	Yellow, consistent

Table 2 Alarm conditions and alarm signal delay

Names of alarms	Alarm condition delay	Alarm signal delay
Door Open alarm	10ms	100ms
Air Bubble alarm	110ms	100ms
Occlusion alarm	840s@1ml/h, 27s@25ml/h	100ms
LowBattery alarm	10ms	100ms
B. Exhaust alarm	500ms	100ms
Finished alarm	10ms	100ms
Drip Abnor	500ms	100ms
PRESS ERR	500ms	100ms
AlmostDone alarm	10ms	200ms
AC Fail alarm	10ms	200ms
On Battery alarm	10ms	200ms
No Operate alarm	120 ms	200ms
Shutdown timer	10ms	100ms
Standby end	10ms	100ms

Table 3 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: 1.Only the three alarms "No Operate", "Almost Done" and "Low Battery" sound three tones at intervals of 25s±2s, all other Low Priority alarms sound one tone and are not repeated.

2.The alarm volume is between 45dB and 85dB,Alarm volume measurement radius is 1 meter.

Table 4 Occlusion response characteristic

Flow Rate (ml/h)	OCCL alarm level	Occlusion pressure(KPa)	OCCLUSION alarm time	Unintended Bolus Volume(ml)
0.1	Low(L)	40-100kPa	<=20h	/
	High(H)	100-160kPa	<=24h	/
1	Low(L)	40-100kPa	<=1.5h	≤ 1.2
	High(H)	100-160kPa	<=2.5h	≤ 1.8
25	Low(L)	40-100kPa	<=3min	≤ 1.2
	High(H)	100-160kPa	<=6min	≤ 1.8

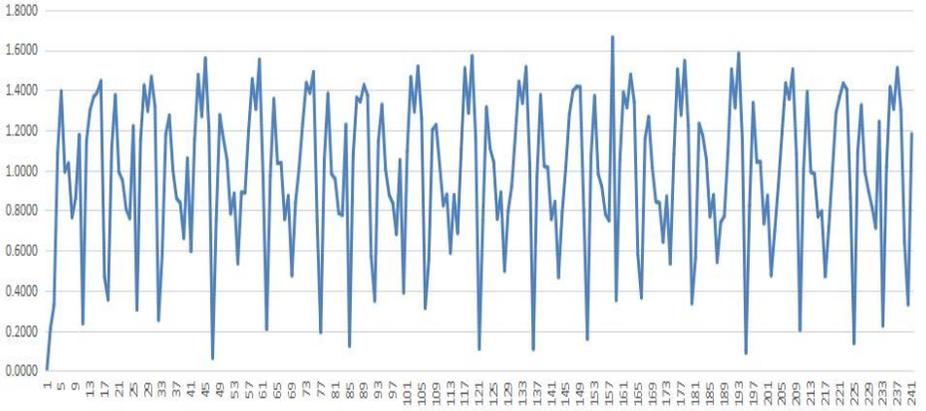
★ The above test uses 'Boon' brand IV set. All the data are obtained by following conditions:

The three-way tap is 1m away from the Infusion Pump; two operations at rate of 1ml/h and 25ml/h respectively.

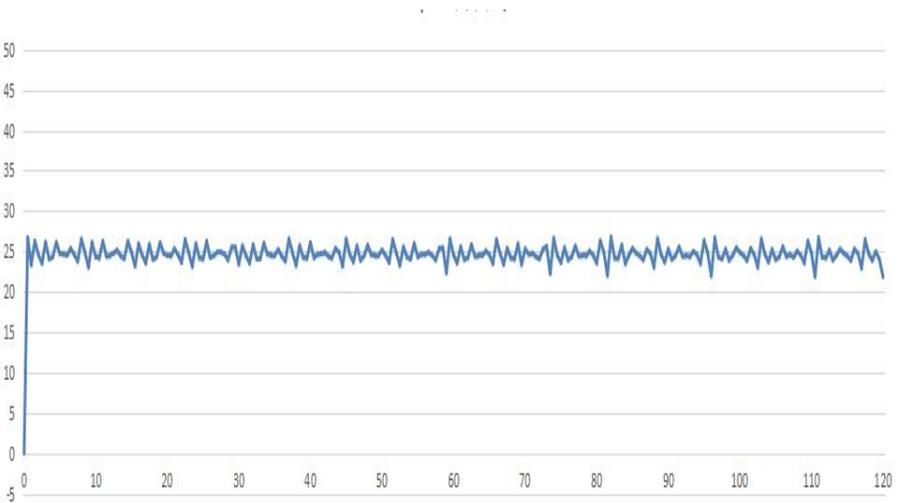
★ The Infusion Pump has anti-bolus function: pressure inside the tube shall release automatically after giving occlusion alarm.

★ Temperature and length do not affect the blocking alarm activation time.

Table 5 Starting Curves

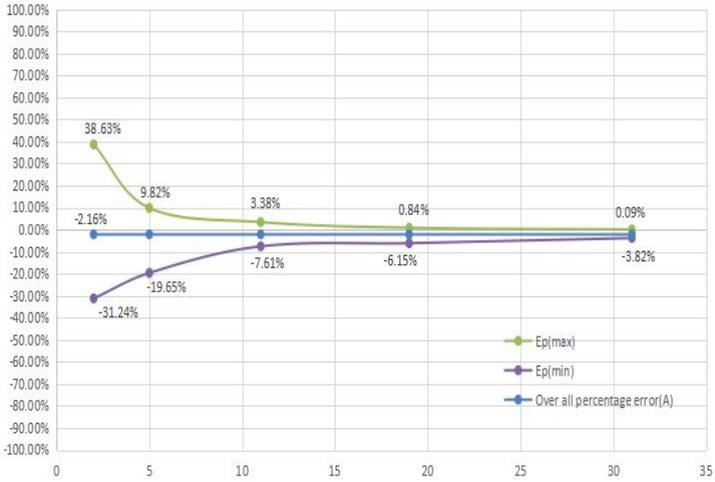


1ml/h Start-up Curve

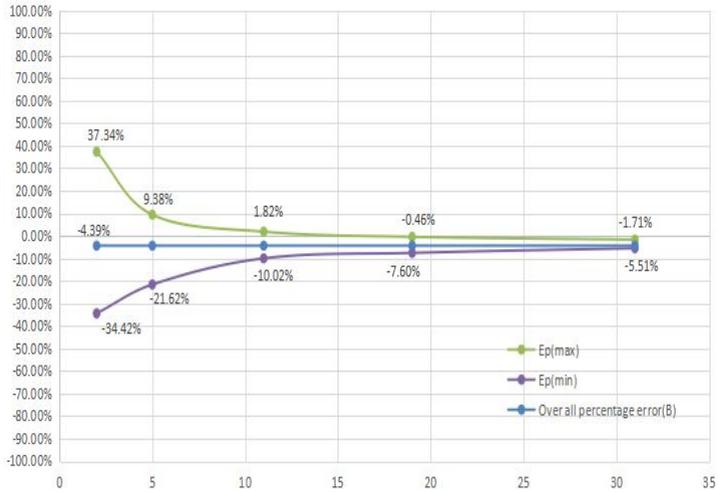


25ml/h Starting Curves

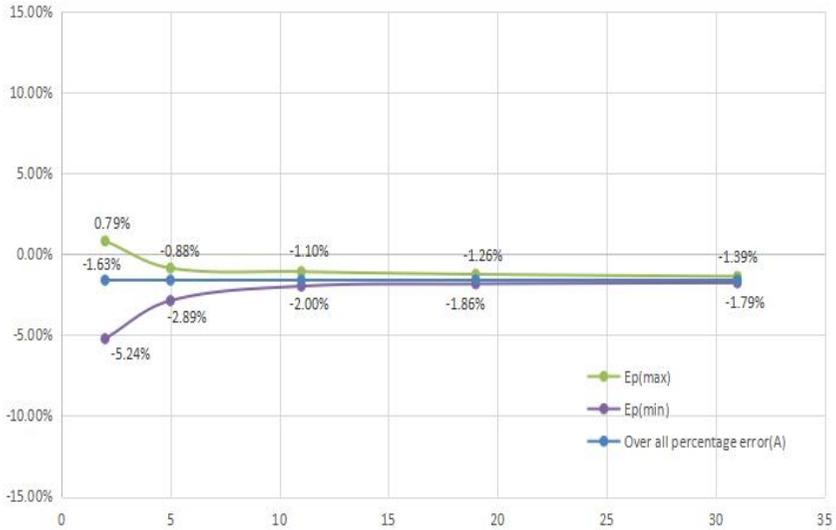
Table6 Trumpet Curves



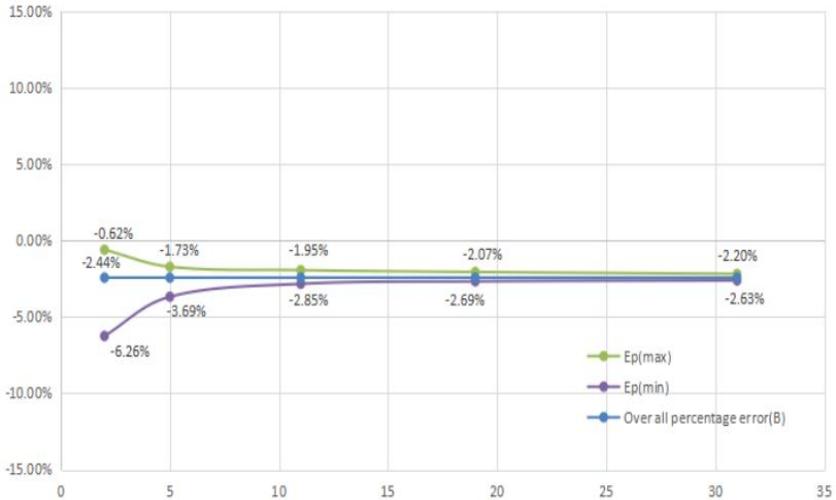
The 2nd hour Trumpet Curve at 1ml/h



The last hour Trumpet Curve at 1ml/h



The 2nd hour Trumpet Curve at 25ml/h



The last hour Trumpet Curve at 25ml/h

★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 II Cybersecurity

Table 1 Serial communication

Data type	Equipment operation information
User access control mechanism	Press the key combination to enter system settings.
Electronic interface	serial port
Technical features	A personal area network is formed by connecting with a wired 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
User access control mechanism	Press the key combination to enter system settings.
Electronic interface	Wi-Fi (IEEE 802.11)
Technical features	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.
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	Software environment: WIN7 and compatible versions; Hawkmed infusion monitoring software (HK-M1000), software version: V01 and compatible versions; Hardware environment: CPU: Intel i3, memory: \geq 4GB, hard disk: \geq 200GB free space, screen resolution \geq : 1920*1080 Network environment: 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 Drip counter interface

Data type	Device data
User access control mechanism	Default closed, automatically turned on when drip rate sensor is detected.
Electronic Interface	USB B
Technical features	Number of collected drops
Network security feature configuration	No 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	None

Table 4 Software upgrade

Data type	Device data
User access control mechanism	After shutdown, enter upgrade mode via the adapter board.
Electronic Interface	Universal Serial Interface
Technical features	Software upgrade
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	Serial Port 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.
Addition of new IT network connections	Connecting the PC to external networks may expose infusion pump data or control commands to broader network environments.	Ensure the PC is not connected to external networks. Use dedicated or validated PCs for data transmission.
Disconnection of IT network items	Incomplete cables, loose interfaces, failed software upgrades, or incomplete data exports; unstable Wi-Fi due to distance from the router or router malfunctions.	Inspect cable integrity and interface connections. Verify connectivity between the pump and the Central Infusion Management System or router functionality.
Updates to IT network-connected devices	Software upgrade tools or data export tools may fail to operate on updated devices.	Ensure compatibility of upgrade and data export tools with updated devices.
Upgrades to IT network-connected devices	Incorrect PC OS installation or missing security software may lead to tool malfunctions or data tampering.	Install a validated Windows OS and the latest security software on the PC.



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