hawk-i1 INFUSION PUMP

USER MANUAL

Shenzhen Hawk Medical Instrument Co., Ltd

Please read the manual before using the product.
Please keep the manual for reference !

057-00191-00

Contents

Revision Notes:

On the premise of comply with relevant laws and regulations, we'll revise the manual timely according to the improvement of products or update of laws and regulations.

This Manual applies to hawk-i1 infusion pump.

Version No.	Date of Preparation
V1.0.0	25-07-2022

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 and 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 tube, 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 outward apperance of infusion tube, especially make sure do not let water flow to ultrasonic sensor; otherwise, it may fail to give alarm when there is a bubble.

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 tube in the same pumping position for more than 6 hours (infusion tube replacement cycle for infusion at flow velocity below 1ml/h should be less than 24h). The infusion tube will deform and thus cause flow error after long time use. It is suggested to move the infusion tube upward for 15cm every time after 6h (infusion tube replacement cycle for infusion at flow velocity below 1ml/h should be less than 24h) and then start infusion again, or replace with a new infusion tube.

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 well-trained professionals such as doctor, nurse and medical device expert.

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.

2. Introduction

2.1 Features

- ✧ User friendly interface, easy operation
- ✧ 13 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 Major Uses and Scope of Application

It is applicable to constant-speed intravenous infusion to patients in hospital.

2.3 Type and Specification

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.

2.4Operating conditions

(1) Temperature: 5℃-40℃

(2) Relative humidity: 10%-95% (no frosting)

(3) Atmospheric pressure: 86.0kPa~106.0kPa

2.5Impacts 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 5 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.

3. Operating Principle and Constituent Parts

3.1 Operating Principle

This infusion pump is a kind of instrument that drives pump tablet to squeeze infusion tubes in sequence with its motor to control accurate drop number or infusion speed, ensure uniform liquid flow and enable

drugs to enter patient's veins correctly and safely so as to take effect.

3.2 Constituent Parts

The infusion pump is mainly composed of microcomputer system, pump, detection device, alarm system and HMI.

Microcomputer system: the brain of the whole system, giving an intelligent control and management to the whole system and processing signals detected, adopting double CPU;

Pump body: the heart of the whole system and the driving force of transfusing medical liquid, squeezing medical liquid forward along peristaltic fingers driven by step motor.

Detection device: mainly containing sensors, such as ultrasonic sensor (for detecting air bubble in line) and pressure sensor (for detecting occlusion) etc. They can detect corresponding signals, which after being amplified and transferred to microcomputer system for signal processing and thus incur control instruction for corresponding operation.

Alarm system: The signals detected by the sensor, after being processed by the microcomputer, shall incur alarm control signal and then at the response of alarm system, which alert the user for immediate correct operation. It contains mainly photoelectric alarm (light emitting diode), audible alarm (loudspeaker and buzzer) and screen display alarm.

HMI: to set parameters of infusion through keys, such as infusion volume and speed. It can display all parameters and current working state through color LCD.

4. Technical Characteristics and Parameters

Parameters	Description
Applicable infusion set	(1) ,20 drips/ml, 60 drips/ml infusion set (2) Dedicated infusion set (1ml = 20 drips, optional)
Infusion accuracy	±5% (dedicated set ±3%, 10-35℃, test volume 2ml)
Infusion modes	Multi Mode Rate Mode Time Mode

	Weight Mode Intermittent Program Mode TPN Mode Drop Mode Sequential Micro Mode Loading Dose Mode PiggyBack Drug library mode Link function for 2units syringe pump (available for stacked syringe pumps together with connected a USB cable)
Infusion rate	0.10-1200.00ml/h, increment 0.01ml/h
Dripping rate	1-400 drips/min
Preset value	0-9,999.99ml, increment 0.01ml
Volume infused (∑)	0-36,000ml
KVO rate	0.10-20.00ml/h, increment 0.01
Bolus	0.10-1200.00 ml/h, increment 0.01ml/h
Purge	0.10-1200.00ml/h, increment 0.01ml/h
Occlusion pressure	30kPa-138kPa, 13 level adjustable
Waterproof level	IPX3
AC power supply	100-240V~ 50/60Hz
Internal battery	Li_Polymer 7.4V 1900mAh; Recharge time: 10h with power on, 3.5h with power off. Running time: more than 5h at rate of 25ml/h, environment temperature 25℃ after being fully charged.

	Charging and discharging cycle: more than 300 cycles
DC	DC12 ± 1.2V, 1.5A, CE certified
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	1.4 kg

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

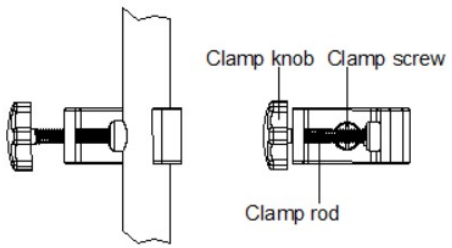
Method 1: Put the infusion pump on stable platform.

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.

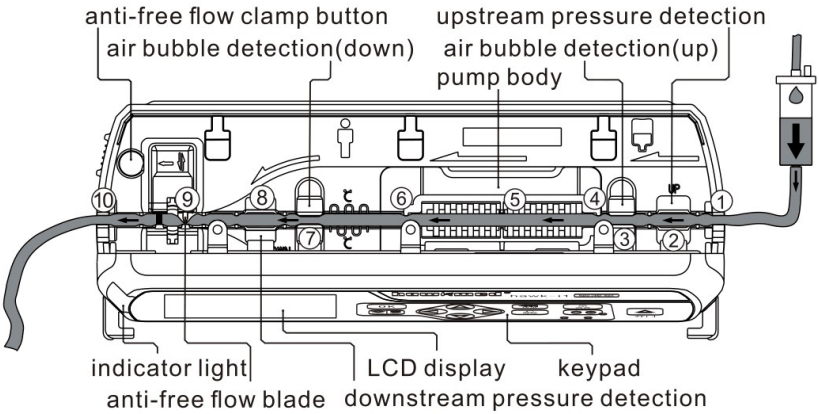
(2) Clamp to IV pole (the IV pole should meet the requirements of balance and mechanical strength), screw down the knob to fix the position of infusion pump. When fixing the pole clamp to IV stand or bar, use the other hand to hold the Infusion Pump until the clamp is well fixed, only release the hand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

Remark: Mechanical strength of IV pole: yield strength≥170MPa, tensile strength≥480MPa, load-bearing requirement≥13kg, verticality of IV pole≤5°.



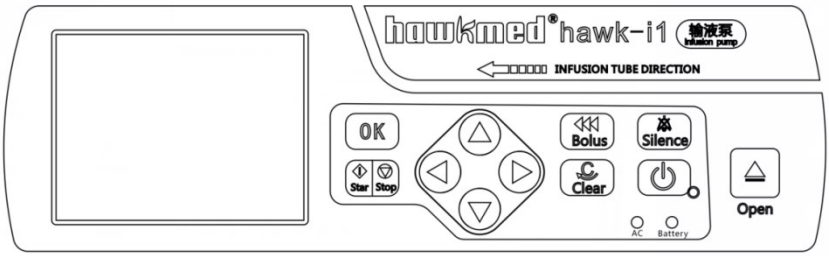
6. Appearance Introduction

6.1 Front View



(Fig.1 Front View)

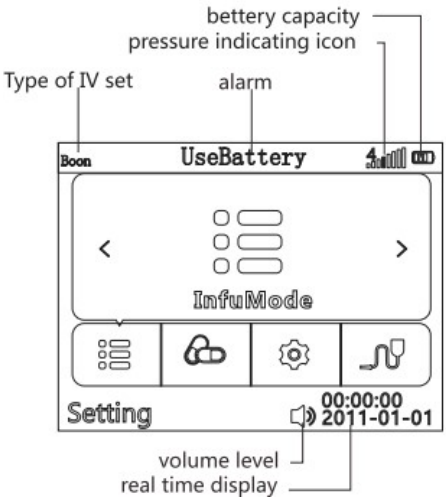
6.2 Operation Panel



Description	Function
Silence key	Press this key to silence the alarm sound. The visible alarm info can't be removed by SILENCE key
 Power key	Switch on / off the infusion pump. 1. Switch on: in 'power off' status, keep pressing this key until LCD screen displays, and the indicator light is on. 2. Switch off: in 'switch on' status, keep pressing this key until hear a sound "beep" and the indicator light is off.
BOLUS key	In 'stop' status, keep pressing 'BOLUS' key, the pump starts purging; release this key, purge stops. During operation, press Bolus key for bolus setting and bolus infusion. Bolus infusion (bolus rate preset by the user). Release the key, bolus infusion stops and the pump continues infusion at original rate.
Clear/back key	1. Clear the alarm for both sound and visible info 2. Back to the previous menu 3. This key will work as home key when keep pressing for about 3 seconds, the machine will go back to main menu.
OK key	1. To select the parameter and make it editable 2. Save the setting value
Start key	In 'stop' status, press this key to start infusion.
Stop key	Press this key to stop infusion.
Door open key	Under shutdown status, press this key to open the door and switch on the machine at the same time. This key is invalid during infusing.
AC/Battery Indicator light	If on, it indicates there's AC/DC input; if off, it indicates there's no AC/DC input.

Indicator light	1. Indicator light indicates operating status/alarms cases. 2. If the IV set is installed correctly and with no air in line, the indicator light shall be green after the door is closed, which also indicating the pump is ready for starting infusion. 3. The green indicator light flashes when the infusion is in normal progress. 4. If high-priority alarm occurs during operation, the indicator light shall turn red and flash. 5. If middle-priority alarm occurs during operation, the indicator light shall turn yellow and flash. 6. If low-priority alarm occurs during operation, the indicator light shall turn yellow but not flash. * Please refer to Annex I Table 1 for priority of alarm classification.
Charging indicator light	This indicator light on means the battery is recharging. This indicator light off means the battery is not charging.
(Up key) (Down key)	1. When selecting the parameters, press the keys to previous or next parameter. 2. When setting the value, press this keys to increase or decrease the value.
(Left key) (Right key)	1. When selecting the parameters, press the keys to left/right parameter, or previous/next page. 2. When setting the parameters, press the keys to move left/right.

6.3 Screen Display



(Fig.2 Screen Display)

Battery icon:

1) Green wave appearing indicates the battery is charging.

2) The battery icon indicates status of battery remaining capacity.

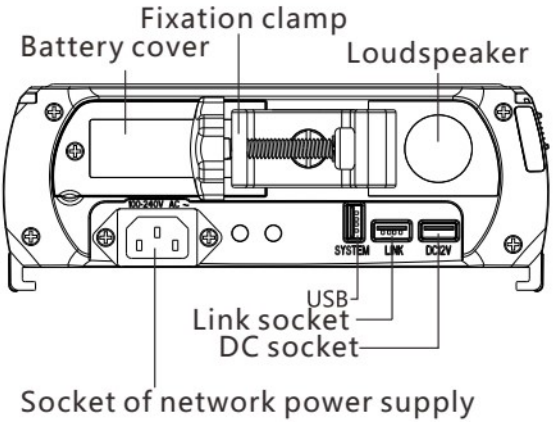
3) If the icon of battery is in red, then the battery is damaged or not connected with battery.

Pressure indicating icon:

(1) Except for the first vertical line, the lines from the left to the right are corresponding to 13 levels of occlusion. The red one means the preset occlusion level.

(2) Pressure indicating icon shows the pressure in tube. With the changing of pressure in infusion tube, pressure indicating icon will appear green surge wave. When the green wave reaches or passing the red vertical line, the infusion pump will give occlusion alarm. This icon just show the pressure changing in the infusion set, not the alarm signal.

6.4 Rear View



(Fig.3 Rear View)

Description	Function
Battery cover	The lithium battery is installed inside and it is opened from bottom case.
Pole clamp	To fix infusion pump on IV pole. Loosen the clamp screw to change the direction of pole clamp. (Horizontal or vertical optional)
Socket of network power supply	To connect with external 100V-240V 50/60Hz AC power supply.
USB Port	Used for upgrading software or transferring infusion history records. Connect with the PC according with the standard of IEC 60950-1-2005 Information technology equipment - Safety - Part 1: General requirements to output infusion records to PC. **Note: This process must be carried out when machine in non-infusion state.**
DC12V /Drop sensor port	This port for DC12V; Drop sensor port works with Hawkmed drop sensor only.

Link interface	Used to connect with Hawkmed workstation.

6.5 Label

6.5.1 Product label (on the back shell)

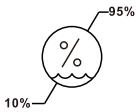
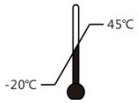
The label contains information such as manufacturer, date of production, product serial No., classification, waterproof level, etc.

6.5.2 Symbols and significance

(Table 1)

Symbols	Descriptions
LOT	Production batch No.
SN	Product serial No.
	Caution, consult accompanying documents
	Please refer to instruction manual
	Type CF
	Protective Earthed
IPX3	Waterproof level: dripping water by slope angel 60°
	AC power
	DC power

	Dispose in environmental-friendly way
	Date of manufacture
	Manufacturer
	Stop action
	Turn on/off
	Silence alarm sound
	Caution Against Wet
	Fragile. Handle with care!
	Keep upright during transport
	5 layers at most of the same package

	Transport package humidity 10 ~ 95%
	Transport package temperature -20°C ~ 45°C
	Power supply is connected.
	Use internal power

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 user should calibrate the IV set before using a new brand except the built-in brands in this 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:JieRui, BOON, LX, Hawkmed.

8.1 Infusion Operation

8.1.1 Fix the Infusion Pump and connect it to AC power

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.

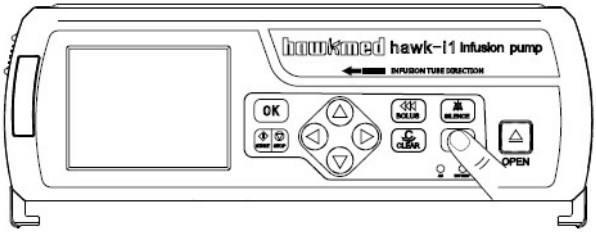
8.1.3 Fill the IV set and install the IV set properly.

1) Fill the IV set

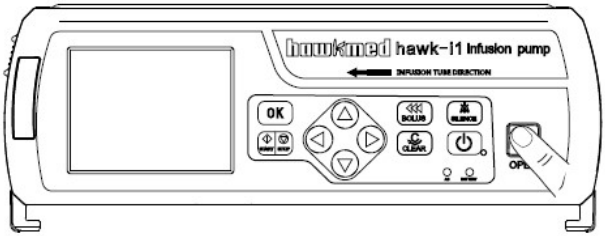
Connect IV set with infusion bag/bottle and then squeeze the drip chamber to fill with 1/2 of liquid. Open the flow clip and let the fluid flow to the tip of the needle, then close the flow clip.

2) Install the IV set

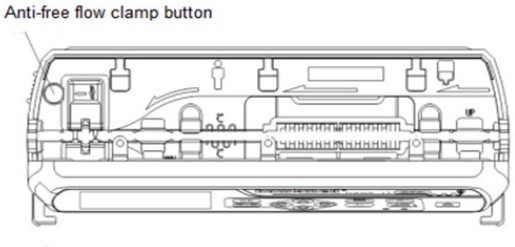
① Press Power key for about 2-3 seconds to switch on the pump



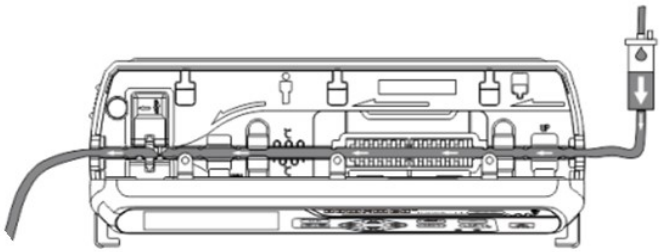
② Press OPEN key for about 2 seconds to open pump door



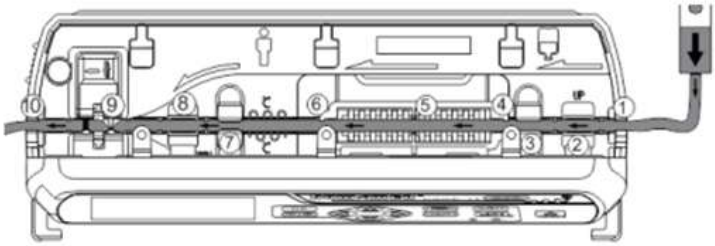
③ Press Anti-free flow clamp button to open the clamp



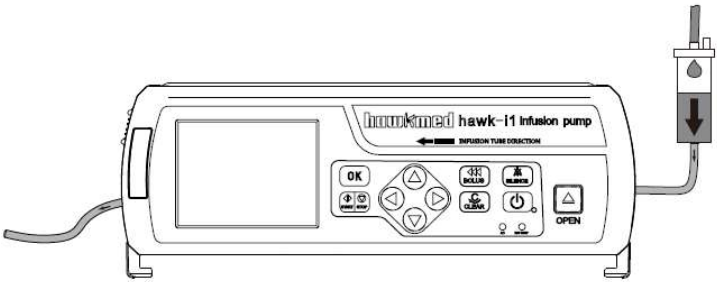
④ Pull the IV set straight



⑤ Install the IV set from right to left, make sure the IV set is properly inserted in all positions from ① to ⑩ as below show.

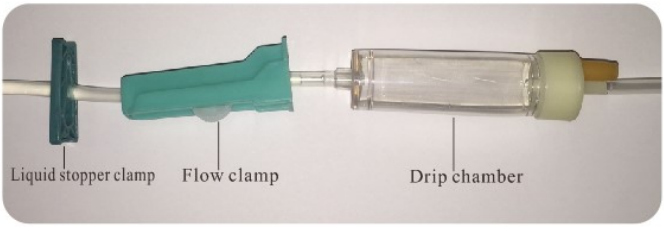


⑥ Close the pump door and set the infusion parameters. Press BOLUS key to exhaust air bubble, START key to start infusion. STOP Key to stop infusion.



When using Hawkmed dedicated infusion set (Fig.4), please make sure the correct installation of infusion set.

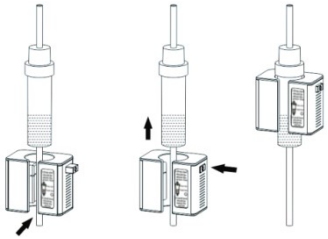
If the green indicator light is not on, follow “Step 8.1.5 Purge” to purge all the air inside the tube. Then the green indicator light shall be on.



(Fig. 4: Hawkmed dedicated infusion set)

Attention: Please make sure there is no liquid on the external wall of infusion set, and no liquid on ultrasound sensor; otherwise it may fail to give Air bubble alarm even there is air bubble in line.

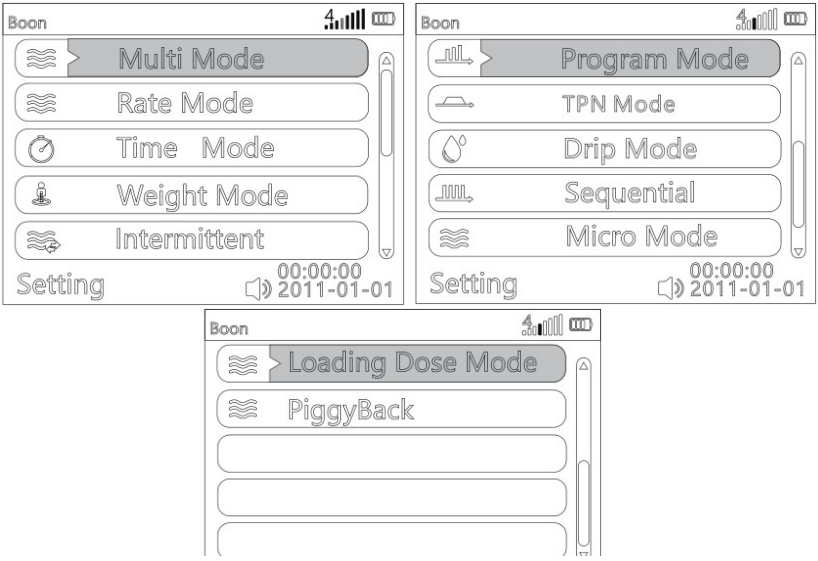
Drop sensor connection (Optional):



1. Install the drop sensor as per above figures (Note: The liquid level should be lower than the red line label).
2. Insert the drop sensor cable to DROP interface on back of pump.

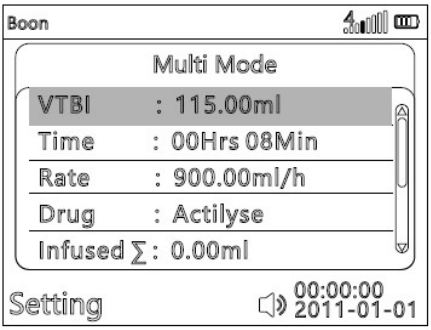
8.1.4 Infusion parameters setting

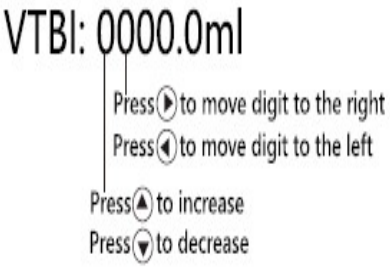
Press OK key to select “InfuMode” in the main menu, the pump will display below infusion modes.



Select infusion mode by pressing ▲▼◀▶ key, press OK key to enter the parameter setting interface of the infusion mode.

（1）Multi Mode





(Fig. 5)

Under Multi Mode, there are VTBI, Time & Rate. Set two of these parameters, the third one will be calculated automatically. For example, after input VTBI & Time, Rate will be calculated automatically.

When Multi Mode is with blue background, press OK key then VTBI is with blue background, press OK key to set VTBI. The current editable position will be with white rectangle background, input the value according to (Fig. 5), press OK key to confirm.

Press ▼ to move to Time, same way to input its value as VTBI. After setting VTBI and Time, Rate is calculated automatically.

If want to input Rate parameter, Press ▼ to Rate, same way to input its value as VTBI, press OK key to confirm, then Time is calculated automatically.

Press ▼ to move to Drug. Drug will be with blue rectangle background. Press OK key to enter Drug/ Medicine name selection interface. “Auto search” means user can search the drug name by alphabet. “Manual search” means user can search the drug name by drug categories manually. “NONE” means no drug name. It is recommended to use the Auto search function for more convenience.

When “Auto search” is with green background, press OK key, press ▲ to select the initial letter of drug name. Then press ▶ to the second letter, ▲ to select the second letter of drug name. When desired drug name comes out, press OK key, and ▼ to choose the drug name, press OK to confirm. The pump will turn back to Multi Mode parameter setting interface.

For “Manual search” function, press ▼ to move to “Manual search”. When “Manual search” is with green background, press OK key, ▲▼◀▶ to select drug category as per request, then press OK key to enter. Press ▲▼◀▶ key to select desired drug name, press OK key to confirm. The pump will turn back to Multi Mode parameter setting interface.

If no drug name, press ▼ to move to “NONE”, OK key to confirm and turn back to Multi Mode parameter setting interface automatically. The pump will not display the drug name.

Press ▼ to move to Infused∑, Infused∑ will be with blue rectangle background. Press OK key to enter sub-menu. Press OK key to return, or press 

key to clear the volume infused.

Press Start key to start infusion.

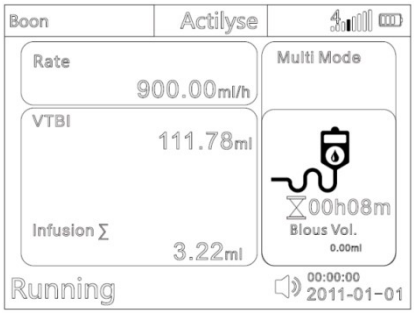
There are two switchable working interfaces:

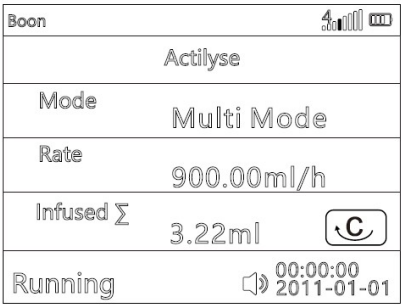
One is simple interface with large font, displaying only drug name, infusion mode, rate & volume infused.

The other one is multiple parameters interface with smaller font, displaying all related parameters.

User could press 

key to switch between these two interfaces.





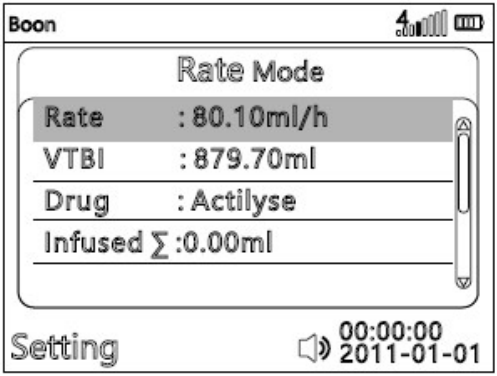
Multiple parameters interface Simple interface

Notice: All the infusion modes allow to start infusion without selecting the drug except Drug Library mode. Press Stop key to stop infusion.

To re-select the infusion mode, press return key 

to exit.

（2）Rate Mode



Press ▼ to move to Rate Mode, Rate Mode is with blue rectangle background, press OK key to enter parameter setting interface of rate mode. Press OK key to choose the Rate. The current editable position will be with white rectangle background, input the value according to (Fig. 5), press OK key to confirm.

Press ▼ to move to VTBI, same way to input its value as above Rate.

Press ▼ to move to Drug. Drug name selection method is the same as that of Multi Mode.

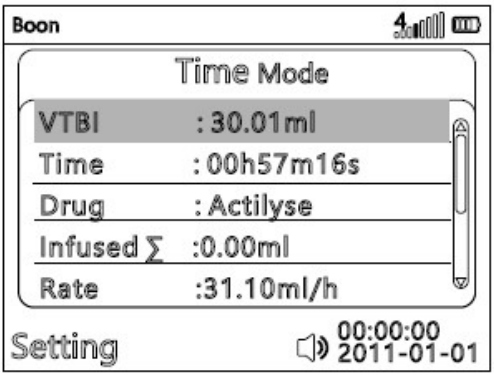
Press ▼ to move to Infused∑, Infused∑ will be with blue rectangle background. Press OK key to enter sub-menu. Press OK key to return, or press CLEAR key to clear volume infused.

After finishing above the parameters, press Start key to start infusion.

Press Stop key to stop infusion.

To re-select the infusion mode, press Return key CLEAR to exit.

（3）Time Mode



Press ▼ to move to Time Mode, Time Mode is with blue rectangle background, press OK key to enter parameter setting interface of Time Mode. Press OK key to choose the VTBI. The current editable position will be with white rectangle background, input the value according to (Fig. 5), press OK key to confirm.

Press ▼ to move to Time, same way to input its value as above VTBI. After setting VTBI and Time, Rate will be calculated automatically.

Press ▼ to move to Drug. Drug name selection method is the same as that of Multi Mode.

Press ▼ to move to Infused∑, Infused∑ will be with blue rectangle background. Press OK key to enter sub-menu. Press OK key to return, or press CLEAR key to clear volume infused.

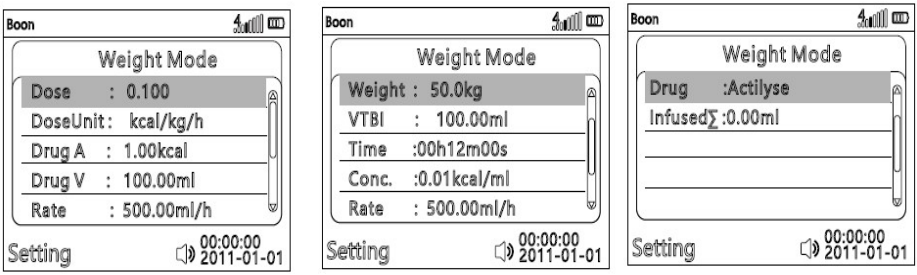
After finishing above the parameters, press Start key to start infusion.

Note: If Rate > 1200ml/h, press Start key, it will remind "Flow rate is out of range, please reset the

parameters". Press CLEAR to parameter setting interface to reset the parameters.
Press Stop key to stop infusion.

To re-select the infusion mode, press Return key CLEAR to exit.

（4）Weight Mode



Press ▼ to move to Weight Mode, Weight Mode is with blue rectangle background, press OK key to enter parameter setting interface of Weight Mode. Press OK key to choose Dose. The current editable position will be with white rectangle background, input the value according to (Fig. 5), press OK key to confirm.

Press ▼ to move to Dose Unit. Dose Unit will be with blue rectangle background. Press OK key to choose the Dose Unit.▲▼ to select the unit, press OK key to confirm. Available dose units: mg/kg/h, mg/kg/min, ug/kg/h, ug/kg/min, ng/kg/h, ng/kg/min, g/kg/h, g/kg/min, mmol/kg/h, mmol/kg/min, mEq/kg/h, mEq/kg/min, IU/kg/h, IU/kg/min, U/kg/h, U/kg/min, kU/kg/h, kU/kg/min, kcal/kg/h, kcal/kg/min, cal/kg/h, cal/kg/min, mol/kg/h, mol/kg/min.

Press ▼ to move to Drug A (Drug Amount), same way to input its value as above Dose. Then drug unit will be with white rectangle background, press OK key to confirm or press ▲▼to change drug unit. If drug unit is changed, dose unit will be changed accordingly.

Press ▼ to move to Drug V (Drug Volume), same way to input its value as above Dose.

Press ▼ to move to Weight, same way to input its value as above Dose. Weight is allowed to be 0. When weight is 0, dose unit will be without kg (for example, mg/h, mg/min). Then Rate is calculated automatically.

Press ▼ to move to VTBI, same way to input its value as above Dose. Then Time will be calculated accordingly. If input the value of Time, VTBI will be changed automatically.

“Conc.” means concentration. Concentration is calculated automatically (Conc.=Drug A/ Drug V).

Press ▼ to move to Drug. Drug name selection method is the same with that of Multi Mode.

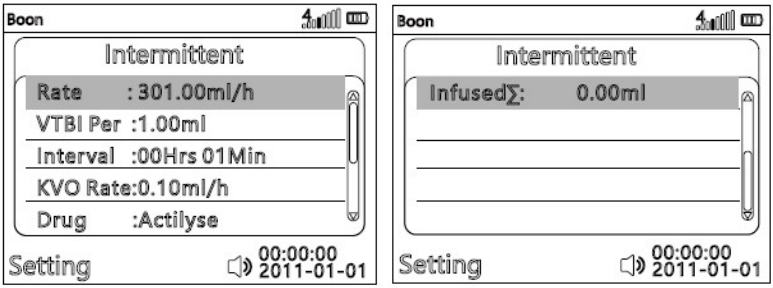
Press ▼ to move to Infused∑, Infused∑ will be with blue rectangle background. Press OK key to enter sub-menu. Press OK key to return, or press CLEAR key to clear volume infused.

After finishing above parameters, press Start key to start infusion.

Press Stop key to stop infusion.

To re-select the infusion mode, press Return key CLEAR to exit.

(5) Intermittent



Press ▼ to move to Intermittent mode. Intermittent mode is with blue rectangle background, press OK key to enter parameter setting interface of Intermittent mode. OK key to choose the Rate. The current editable position will be with white rectangle background, input the value according to (Fig. 5), OK key to confirm.

Press ▼ to move to VTBI Per. VTBI Per will be with blue rectangle background. VTBI Per means infusion volume of each time. Same way to input its value as above Rate.

Press ▼ to move to Interval, same way to input its value as above Rate.

KVO Rate: it is recommended not to change the KVO Rate.

Press ▼ to move to Drug. Drug name selection method is the same with that of Multi Mode.

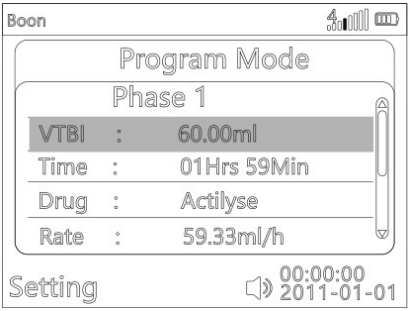
Press ▼ to move to Infused∑, Infused∑ will be with blue rectangle background. Press OK key to enter sub-menu. Press OK key to return, or press CLEAR key to clear volume infused.

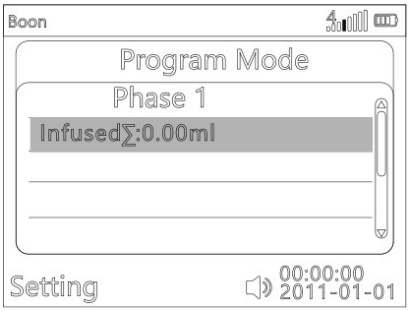
After finishing above parameters, press Start key to start infusion.

Press Stop key to stop infusion.

To re-select the infusion mode, press Return key  to exit.

（6）Program Mode





Press ▼ to move to Program Mode. Under program mode, the infusion is going under 12 sections/ phases. When the first phase finished, the second phase will start automatically. When second phase finished, the third phase will start automatically. It allows to infuse only one or only two phases.

Press OK key to enter Phase 1 setting, input VTBI & Time.

Press ▼ to move to Drug. Drug name selection method is the same with that of Multi Mode.

Press ▼ to move to Infused∑, Infused∑ will be with blue rectangle background. Press OK key to enter sub-menu. Press OK key to return, or press  key to clear volume infused.

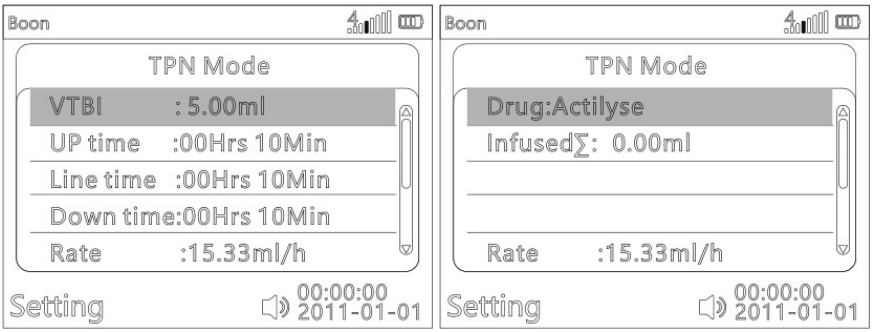
Press ▶ move to Phase 2 ~ 12, same way to set the parameters.

After input all necessary parameters, press START key to start infusion.

Press Stop key to stop infusion.

To re-select the infusion mode, press Return key  to exit.

（7）TPN Mode



Press ▼ to move to TPN Mode. Press OK key to enter parameters setting interface.

Input VTBI, UP time, Line time & Down time, the Rate will be calculated automatically for each phase (display in Running status).

During up time, flow rate keeps increasing.

During line time, flow rate is uniform/ constant, this Rate displays after setting VTBI, UP time, Line time & Down time.

During down time, flow rate keeps decreasing.

Press ▼ to move to Drug. Drug name selection method is the same with that of Multi Mode.

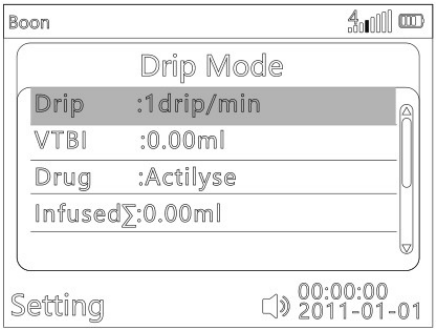
Press ▼ to move to Infused∑, Infused∑ will be with blue rectangle background. Press OK key to enter sub-menu. Press OK key to return, or press CLEAR key to clear volume infused.

After input all necessary parameters, press START key to start infusion.

Press Stop key to stop infusion.

To re-select the infusion mode, press Return key CLEAR to exit.

（8）Drip Mode



Press ▼ to move to Drip Mode. Press OK key to enter parameters setting interface.

Users could input Drip rate, VTBI and Drug name, press START key to start infusion.

If there is no drop sensor, the infusion pump cannot ensure the actual drips are equal to the setting drip rate, and no Empty alarm.

When equipping with drop sensor, the infusion pump will ensure actual drips are equal to the setting drip rate. And there is Empty alarm when no fluid passing through the drop sensor.

If the drop sensor is equipped on infusion pump, please make sure Drop Sensor is set ON in pump Admin Settings, please refer to 8.4.20 Admin Settings for details.

After set Drop Sensor ON, go back to Drip Mode.

Input Drip rate, VTBI and Drug name, press START key to start infusion.

Press Stop key to stop infusion.

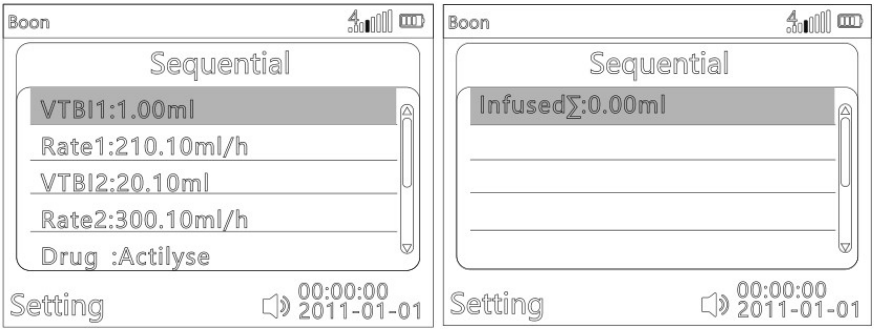
To re-select the infusion mode, press Return key CLEAR to exit.

Accuracy:

With Drop sensor, when drip rate is more than 10 drips/min,the accuracy is within ±5%. When drip rate is less than or equal to 10 drips/min, the accuracy is within ±10% or ±1 drip.Take the broad value.

Remark: If the drip rate is less than 100 drips/min, use the default infusion set brand JieRui (1ml=20 drips). If the drip rate is greater than 100 drips/min, use infusion set brand Suyun (1ml=60 drips).

（9）Sequential Mode



Press ▼ to move to Sequential mode. Press OK key to enter parameters setting interface.

Under Sequential mode, the infusion is going under 2 sections. When the first section finished, the second section will start automatically.

Input VTBI 1& Rate 1for first section.

Input VTBI 2 & Rate 2 for second section.

Press ▼ to move to Drug. Drug name selection method is the same with that of Multi Mode.

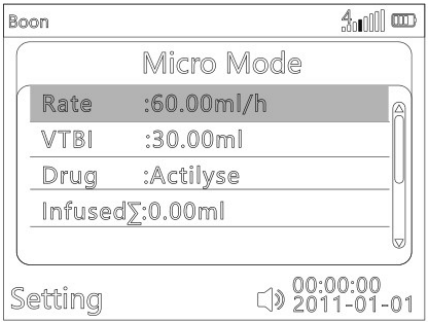
Press ▼ to move to Infused∑, Infused∑ will be with blue rectangle background. Press OK key to enter sub-menu. Press OK key to return, or press C CLEAR key to clear volume infused.

After finish above the parameters, press Start key to start infusion.

Press Stop key to stop infusion.

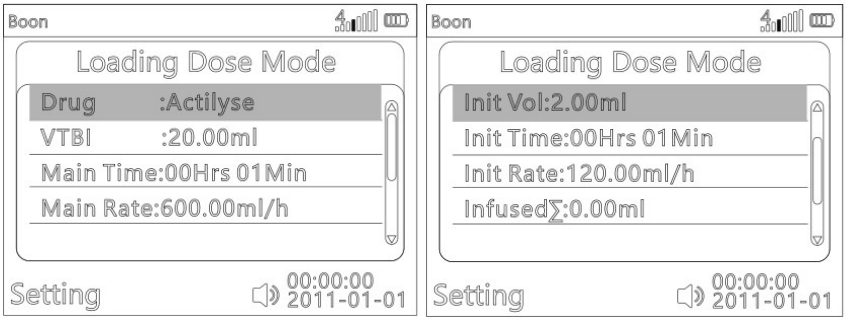
To re-select the infusion mode, press Return key C CLEAR to exit.

(10) Micro mode



Under micro mode, the maximum flow rate is 100ml/h, maximum volume limit is 1000ml. It is suitable for neonate, infant, toddler and child. The operation method is the same as rate mode.

(11) Loading Dose Mode



Press ⓥ to move to loading dose mode. Press OK key to enter parameters setting interface.

Under loading dose mode, the infusion is going under 2 sections: Initial section and main section (the remaining part).

VTBI here means total volume to be infused.

VTBI minus initial volume, the remaining volume will be for main rate & main time.

Input drug name as per that of Multi Mode.

Input VTBI (VTBI cannot be 0. If VTBI is 0, the machine will not work)

Input Init Vol (Initial volume) and Init Time (initial time), Initial rate will be calculated automatically.

Go back to input Main time, main rate will be calculated automatically.

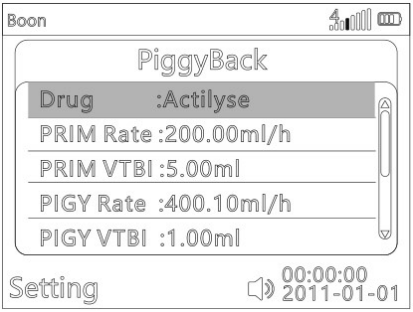
After finish entering the parameters, press Start key to start infusion.

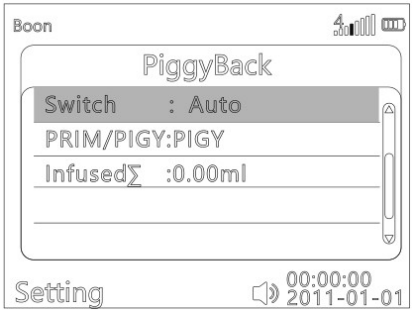
Press Stop key to stop infusion.

To re-select the infusion mode, press Return key 

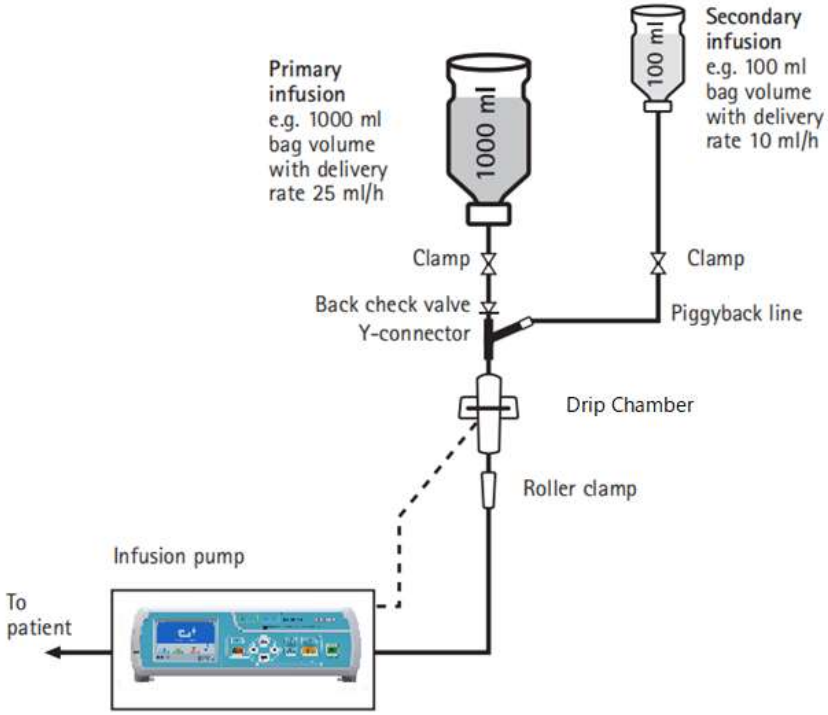
to exit.

(12) PiggyBack Mode





The piggyback-mode offers the possibility to interrupt the current (primary) infusion temporarily in order to administer a piggyback (secondary) infusion. Above the pump the piggyback-infusion line is connected with a Y-connector to the administration set. The secondary infusion bag is supposed to be located approx 20 cm higher than the primary infusion bag. All infusion lines need to be filled completely. A back check valve has to be placed according to the drawing below.



Press ⓥ to move to Piggyback mode. Press OK key to enter parameters setting interface.

Input drug name as per that of Multi Mode.

Input PRIM Rate (Primary rate)

Input PRIM VTBI (Primary volume)

Input PIGY Rate (Secondary rate)

Input PIGY VTBI (Secondary volume)

Switch: Auto or Manual. Auto means when secondary infusion is complete, the device will start primary infusion automatically. Manual means when secondary infusion is complete, the device will stop and display the tip “Press OK key for PRIM infusion or press STOP key to pause”. User could follow the tip to continue.

PRIM / PIGY: The default setting is PIGY (to start secondary infusion first)

If change PIGY to PRIM, please ensure to close PIGY infusion manually and press START key, the device will start primary infusion only.

Press ▼ to move to Infused∑, Infused∑ will be with blue rectangle background. Press OK key to enter sub-menu. Press OK key to return, or press CLEAR key to delete volume infused.

After finish entering the parameters, press Start key to start infusion.

Press Stop key to stop infusion.

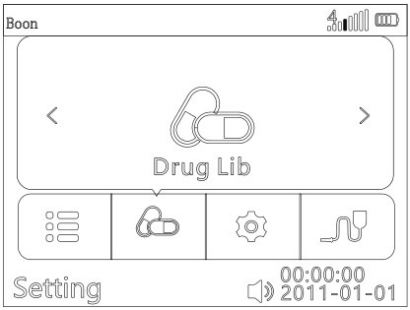
To re-select the infusion mode, press Return key CLEAR to exit.

Note:

The precondition to start the piggyback function is that the pump is stopped.

Please input the VTBI according to volume of fluid bottle.

2. Select Drug library mode in main menu



In the main menu, press ▶ key then press OK key to select “Drug lib”.

This interface has four items:

Auto search function:

It means user can search the drug name by alphabets. “Manual search” means user can search the drug name by drug categories manually. “Commonly used drugs” allows users to add the drugs being used frequently.

When “Auto search” is with green background, press OK key, press ▲ to display initial letter of drug name. Press ▶ to the second letter, press ▲ to display the second letter of drug name. When desired drug name displays, press OK key, press ▼ key to choose the drug name, press OK to confirm. The device will turn to parameter setting interface automatically. Drug name will be displayed on the top of screen.

Manual search function:

Press ▼ to move to “Manual search”. When “Manual search” is with green background, press OK key, press ▲▼◀▶ key to select drug category as per request, then press OK key to enter. Press ▲▼◀▶ key to select desired drug name, press OK key to confirm. The device will turn to parameter setting interface automatically. Drug name will be displayed on the top of screen.

Commonly used drugs function:

It allows users to add the drugs being used frequently. It has to add the frequently used drug names before using this function. Press ▼ key, “Commonly used drugs” is with green background, press OK key. Press ▼ key to select the number, press OK key, press ▼ key to select “Add/Modify”, press OK key, then select the required drug name and press OK key to confirm. It could totally add 30 frequently used drug names.

Self-define drug:

Press ▼ key, the “Self-define drug” is in green background, press OK key, press OK key to select drug 001, press ▼ key and OK key to select “Name”. User could change the name by ▲▼◀▶ key. Select Dose unit and input recommended dose volume.

After changing these parameters, press ▲ to choose “Enter”, press OK key, it will display drug library parameter setting interface with new drug name. After inputting parameters, press START key to start infusion.

(Note: in the drug library parameter setting interface, choose “Dose” by pressing OK key, you can set dose limit (Pass word: 111111). It contains hard limit, maximum soft limit and minimum soft limit.)

3) **Setting Range of parameters in each Infusion Modes (For Reference)**

Table 2 Parameters under each infusion mode

Parameters		Setting range
Multi Mode	Volume limit	0-9999.99ml
	Time	0-99h59min
	Rate	0.10-1200.00ml/h
Rate mode	Flow rate	0.10-1200.00ml/h
	Volume limit	0-9999.99ml
Time mode	Volume limit	0-9999.99ml
	Infusion Time	0-99h59min
Weight mode	Dose	0.001-2000.00
	Dose unit	mg/kg/h, mg/kg/min, ug/kg/h, ug/kg/min, ng/kg/h, ng/kg/min, g/kg/h, g/kg/min, mmol/kg/h, mmol/kg/min, mEq/kg/h, mEq/kg/min, IU/kg/h, IU/kg/min, U/kg/h, U/kg/min, kU/kg/h, kU/kg/min, kcal/kg/h, kcal/kg/min, cal/kg/h, cal/kg/min, mol/kg/h, mol/kg/min.
	Drug A (drug amount)	0-2000.00mg, minimum increment 0.01 Unit:: mg,ug,ng,g,mEq,mmol,IU,

		U,KU,kcal,cal,mol
	Drug V (drug volume)	0-9999.99 ml
	Weight	0-300.0 kg
	Dose limit	0-2000ml
	Time	0 ~ 99hrs59min59s
	Concentration	decided by drug amount & drug volume
Intermittent mode	Flow rate	0.1.0-1200.00ml/h
	Volume limit each time	0-9999.99ml
	Interval	0-99h59min
	KVO rate	0.10-20.00 ml/h
Program Mode	phase	1-12 phase
	VTBI	0-9999.99ml
	Time	0-99h59min
TPN Mode	VTBI	（0.00-9999.99） ml
	Up time	0hrs 0min-99hrs 59min
	Line time	0hrs 0Min-99hrs 59min
	Down time	0Hrs 0Min-99Hrs 59Min
Drip mode	Drip rate	0-400drip/min
	Volume limit	0-9999.99ml
Sequential	VTBI 1: 0 - 9999.99 ml Rate 1: 0.10 - 1200.00ml/h	
	VTBI 2: 0. - 9999.99 ml Rate 2: 0.10 - 1200.00 ml/h	
Micro Mode	Rate	0.01 - 100.00ml/h
	VTBI	0-1000.00ml
Loading dose mode	VTBI	0 - 9999.99 ml
	Main time	0hrs 0min-99hrs 59min

	Main rate	0.10-1200.00ml/h
	Initial volume	0 - 9999.99 ml
	Initial time	0hrs 0min-99hrs 59min
	Initial rate	0.10-1200.00ml/h
Piggyback	PRIM rate	0.10-1200.00ml/h
	PRIM VTBI	0 - 9999.99 ml
	PIGY rate	0.10-1200.00ml/h
	PIGY VTBI	0 - 9999.99 ml

8.1.5 Purge

Press Bolus key until the air bubble in infusion tube is totally exhausted, and then close the flow clamp tightly. The volume generated by "purge" is not calculated in accumulated volume.

Press BOLUS key one time to enter purge rate and VTBI setting interface.

When Purge VTBI is 0, keep pressing Bolus key for purge function.

When Purge VTBI is not 0, press ◀ key for auto purge function.

Note: "purge" only use when machine is in non-infusion status, and infusion tube is not connected to patients.

8.1.6 Start Infusion

Check if parameters are correct and then push "Start" key to start infusion. Only Bolus and Stop key are available during the infusion except alarm. Under infusion status, the word "Running" will be displayed on bottom of screen; the indicator light will flash in green.

8.1.7 Bolus (Fast infusion)

1) Manual bolus: During infusion process, press bolus key (one touch) to enter bolus setting interface. When bolus VTBI and time are 0ml, keep pressing Bolus key for fast infusion. The infusion pump will work at preset bolus rate. It will return to previous infusion rate after releasing your finger.

2) Auto bolus: During infusion process, press bolus key (one touch) to enter bolus setting Interface. After setting bolus rate/bolus VTBI/ bolus time, press ◀ key to start auto bolus function.

It will return to previous infusion rate after reaching the target bolus volume.

8.1.8 Stop infusion

Press Stop key to stop the infusion. The interface will show volume infused and adjustable parameters.

(1) User could reset the parameters in this interface and press START key to continue infusion.

(2) To re-select the infusion mode, press Return key 

to exit.

8.1.9 Infusion complete

After the preset volume was completed or the accumulated volume reached 36,000ml, the infusion pump will activate KVO function and give finish alarm. Press Stop key to stop the infusion.

8.1.10 Replacement of infusion set and liquid container

★ If you need to replace IV set, please follow steps below:

Close the flow clip of IV set. Open the pump door and take out the IV set.

As per instructions of 8.1.3, fill the new IV set with medical fluid and install it properly. Restart infusion as required.

★ The IV set may be out of shape due to long hours of squeezing by the peristaltic system and which can cause accuracy error. It is suggested to change the section of the infusion set that is against peristaltic chips or replace with a new infusion set after continuously working for 6 hours.

★ If need to replace an infusion bottle, please follow steps below:

Close the flow clip of IV set. Open the pump door and take out the IV set.

Disconnect IV set from infusion bottle.

Reconnect the IV set to a new infusion bottle.

Fill in and install the IV set as per instructions of 8.1.3.

Restart infusion as per infusion instructions of 8.1.

8.1.11 Battery indicator

1. When battery is supplying power, the screen will display “on battery” and the battery indicator light will be on.

2. When battery voltage is lower than 7.4V, the device will give an alarm and show low battery voltage.

3. In case of Li-polymer battery damaged or cannot be used, it should be replaced by a professional

personnel. Wasted and old Li-polymer batteries cannot be disposed at will; instead, they should be sorted and then disposed in order to prevent environmental from pollution.

8.2 Alarms and Solutions

The following alarms may occur in infusion preparation and infusion process. Please operate according to the instructions.

(Table 3)(See Table 1, 2 and 3 of Appendix 1 for alarm relevant parameters)

Alarm	Cause for alarms	Solutions
No operate	No operation is made after 10min when the pump is in non-operation and non-alarm status after turning it on.	Press any key to eliminate the alarm ★Remark: This alarm can be set off, refer to **8.4.9** of this Manual for details.
Door open	The door of infusion pump is opened during purging/infusion process	Press SILENCE key to eliminate alarm sound; close the door to eliminate alarm.
Almost Done	3min before the preset infusion volume is completed.	Press SILENCE key to eliminate the alarm ★Remark: This alarm can be set off, refer to **8.4.10**of this Manual for details.
finished	1. Preset infusion volume is completed 2. When the cumulative volumereaches36,000ml	Press SILENCE key to eliminate alarm sound, press Stop key to eliminate the alarm and press clear associated key to clear the cumulative volume.
Air bubble	1 There is air bubbles inside infusion set	Press SILENCE to eliminate alarm sound, open the door to exhaust the air bubble inside infusion set and then press Start key to restart infusion.
	2. Infusion tube is not installed properly	Reinstall the infusion tube correctly according to **8.1.3.**

	3. The sensor of infusion pump is faulted	Please contact the distributor or manufacturer to repair.
Occlusion	1. The infusion loop is blocked	Press SILENCE key or open the door to eliminate the alarm.
	2. The occlusion sensitivity is level too high.	Please refer to **8.4.3** of this Manual and adjust the occlusion pressure alarm parameter of infusion pump.
	3. The sensor of infusion pump is faulted	Please contact the distributor or manufacturer to repair.
AC fail	AC power cord falls off/is cut off after turning the device on. When AC fail and battery exhausted during infusion, the pump will alarm in buzzing and flash red light for 3 mins	Press SILENCE to eliminate alarm. Insert the AC/AC power cord again.
On Battery	1. AC/DC is not connected to the infusion pump before turning it on.	Press SILENCE key to eliminate alarm. Check if the power line is plugged or tightly plugged or not.
	2. Power circuit of the infusion pump is with problem.	Ask the manufacturer to inspect and repair.
Low battery (battery can be used only when power failure or in moving process)	1. At least 30min before the infusion stops because of the battery running out.	Press SILENCE key to eliminate alarm sound. If the alarm is given after 2min without AC connected, it will alarm again. Stop using it and charge the battery fully.
	2. The battery is aging or the charging circuit of infusion pump is faulted.	Please contact the distributor or manufacturer to repair.

B. Exhaust (In cases when only battery can be used at power failure or in moving process)	1. At least 3min before the pump turns itself off automatically for the battery running out.	Stop using and charge the battery fully.
	2. The battery is aging or the charging circuit of infusion pump is faulted.	Please contact the distributor or manufacturer to repair.
Check tube	1. Start the device after installation of hawkmed dedicated infusion set	Take off the infusion set, then turn off and turn on the machine to eliminate the alarm. ★**Note: The infusion pump has this function only when it works with hawkmed dedicated infusion set.**
0xE0, 0xE1 0xE2, 0xE3	1.0xE0: data communication error	Restart the infusion pump, load the last infusion setting and start infusion again. If the alarm is given again, contact with the manufacturer to inspect and repair.
	2.0xE1: transmission part failure	Restart the infusion pump, load the last infusion setting and start infusion again. If the alarm is given again, contact with the manufacturer to inspect and repair.
	3. 0xE2: motor operations failure	Restart the infusion pump, load the last infusion setting and start infusion again. If the alarm is given again, contact with the manufacturer to inspect and repair.

	4. 0xE3: memory fails	Restart the infusion pump. If the alarm is given again, restore factory defaults and restart the infusion pump; if the alarm is still not eliminated, contact with the manufacturer to inspect and repair. **★Note: Infusion tube parameters should be calibrated again after restoring factory defaults.**
Drip Abnor	1.Liquid Volume Empty alarm	Press SILENCE key to eliminate alarm sound; detect if the infusion bottle is empty and detect if the drop sensor is correctly installed. Press Clear key and then Start key to start infusion again. Please ask the manufacturer to inspect and repair if the alarm still cannot be eliminated.
	2. Abnormal drip rate	Press SILENCE key to eliminate alarm sound and test if the infusion tube is blocked. Press Clear key and then Start key to start infusion again. Please ask the manufacturer to inspect and repair if the alarm still cannot be eliminated.

Note: The set parameters (including alarm setting) are stored in memory chips. The saved data will not be lost after power failure and can be saved for more than 10 years. Alarm setting will be called out when the machine is turned on again.

Method to verify the normal operation of alarm system:

Note: The verification below cannot be carried out when the infusion tube is connected to patients; otherwise, patients will be risky.

1). AC power failure alarm

Unplug AC power cord after turning the pump on, the device will display AC fails and give alarm sound.

2). No operation alarm

The device will display “No Operation” and give alarm sound if no operation is made after 2min when the infusion pump is in non-operation and non-alarm status.

3). Low battery alarm

The device will display low battery and give alarm sound when battery voltage is lower than 7.1V.

4). Battery exhausted alarm

The device will display battery exhausted, stop operation and give alarm sound when battery voltage is lower than 6.65V.

5). Occlusion alarm

When infusion set is blocked artificially in operation process, the pressure indicator will increase to the right and the device will display occlusion and give alarm sound after a period of time (depends on flow rate).

8.3 Infusion Tube/set setting

8.3.1 Select brands of infusion set built in the device.

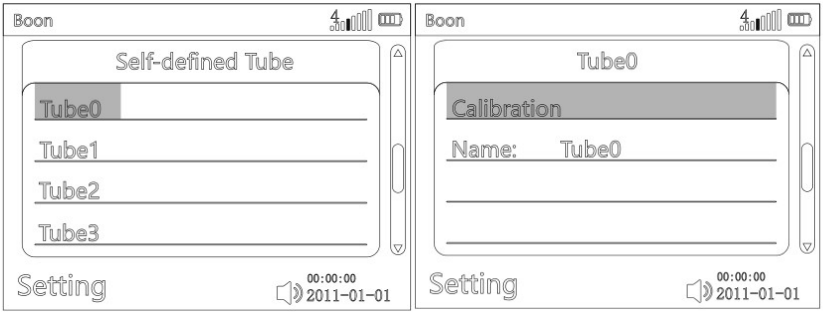
(1)Select “Infusion Tube/set” on main menu, press OK key to enter Infusion Tube interface. Press OK key to choose “Select Tube”, select the infusion set brand and press OK key to confirm.

★Note: The default infusion set on machine is JieRui brand, and it has been calibrated before delivery.

(3) To use the other brand of infusion set, user could self-define the infusion set brand name then do calibration as per 8.3.2.

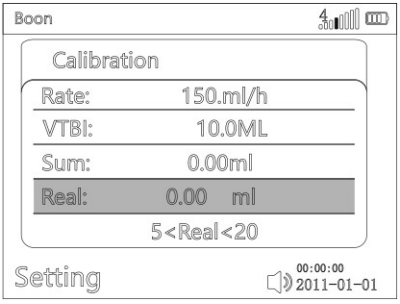
8.3.2 Self-defined tube and calibration

Select “self-defined tube”, press OK key, Infusion Set self-defined interface as follows:



Select a Tube number (for example Tube1) and press OK key. Press ▼ to "Name: Tube1" and press OK key. Use ▲▼◀▶ key to edit brand name and press OK key to confirm.

Press ▲ and OK key to enter calibration interface. Install the infusion set as per instructions in 8.1.3 and prepare liquid measuring device. Press START key, the Infusion Pump shall start infusion at 150ml/h and "Calibrating" will show on the interface. After finishing VTBI (10ml), measuring the flow-out liquid volume in measuring device, input this actual value in calibration interface ("Real" item). Then press OK to save the parameter and exit. The calibration of this brand/type of IV set is completed.

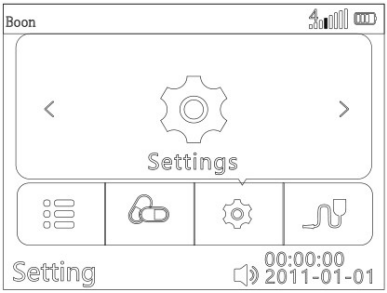


(Infusion set Calibration Interface)

The accuracy calibration is directly related to the measurement of the actual flown-out fluid. The measuring device could be measuring cup or 20 ml syringe. If high accuracy is required, please use high-precision electronic scale or other measuring instrument.

Test method in detail refer to Annex Ⅱ.

8.4 System Setting



Select “Settings” in the main menu, press OK key to enter.

Press ▲▼◀▶ key to select requested parameter, press OK key to make it editable, input required value, then press OK key to save the setting. All the setting parameters can be saved automatically after turn off the device, and storage time is 5 years.

8.4.1 Set alarm sound volume

Select “Settings” in the main menu, press OK key to enter. Press OK key to select ‘Sound’, press ▲ or ▼ key to select required sound volume (low, medium, high). Then press OK key to save the setting and exit.

Alarm sound volume is not lower than 45dB when setting as low level and not higher than 65dB when setting as high level.

8.4.2 KVO rate setting

Under “settings” interface, Press ▼key to select ‘KVO rate’, press OK and input required KVO rate: “OFF”, “0.1~20 ml/h” adjustable. Then press OK key to save the value and exit.

Special KVO: (on & off function)

Flow rate ≥10ml/h, KVO rate = 3ml/h

Flow rate <10ml/h, KVO rate = 1ml/h

Flow rate <1ml/h, KVO rate = set rate

★ KVO function means keep patient’s vein open by infusing at preset low rate.

8.4.3 Occlusion level setting

13 levels occlusion settings adjustable, pressure range: 10kPa~160kPa

The occlusion level and corresponding pressure value are shown as follows:

(Table 843-1)

Occlusion level	Pressure range	**Occlusion level**	Pressure range
Level 1	10-50 kPa	Level 7	64-104 kPa
Level 2	19-59 kPa	Level 8	73-113 kPa
Level 3	28-68 kPa	Level9	82-122 kPa
Level 4	37-77 kPa	Level10	91-131 kPa
Level 5	46-86 kPa	Level11	100-140 kPa
Level 6	55-95 kPa	Level12	109-149 kPa
		Level13	118-160 kPa

Note:

1. If use medical liquid of high viscosity and set low occlusion level, the machine may give occlusion alarm when there is no occlusion in the tube, In this case, please observe the pressure indicator on the screen and condition of extension tube, and set higher occlusion level if necessary.
2. When high occlusion level is set, the high pressure inside the infusion set may result in disconnection of extension tube, please confirm extension tube is firmly connected to the infusion set.

8.4.4 Key Sound setting

After entering “Key sound” setting interface, select “ON” or OFF”, then press OK key to save and exit.

8.4.5 Key lock setting

The optional setting including “Never”, “5min”, “4min”, “3min”, “2min” and “1min”.

★Remark: Setting as “5min”/ “4min”/ “3min”/ “2min” or “1min” means all keys shall be locked (except POWER key) after“5min”/ “4min”/ “3min”/ “2min” or “1min” if no operation on keys.

To unlock the keypad: press OK + clear key  together.

Press  to turn to next page.

8.4.6 Bolus setting

Press OK to enter “Bolus” setting interface, input Bolus rate, Bolus VTBI or Bolus Time, press OK to save the value.

8.4.7 Back light Setting

Select “Back Light” and press OK key, press OK key again to select “Setting”, press  or  key to adjust the brightness of screen. There are 10 levels brightness selection.

8.4.8 Night mode setting

Select “Night Mode” and press OK key, press OK key to choose “Mode”, press  or  key to select “ON”/ “OFF”/“AUTO”.

“ON”: turn on night mode immediately. “OFF”: turn off night mode. “AUTO” means after input start time and end time, the machine will start and finish night mode automatically.

If setting as ON,  shall display on LCD. Key sound shall be off; the screen shall turn dark; the indicator light shall be off during infusion. (If there is any alarm, the indicator light shall be on.)

8.4.9 No Operate Alarm Setting

After entering ‘parameter setting interface', press number key “1” to select “1-60min”, press ENTER key to save the setting.

“No Operation” alarm setting as “1-60mins”: in ‘stop' status, “No Operation” alarm shall sound when no operation on keypad in 1-60 minutes.

8.4.10 “Almost Done” alarm setting

Press OK to enter “Almost Done” setting interface, press ▲ or ▼ key to select “ON” or “OFF”. If the setting is “ON” and with preset VTBI, “Almost Done” alarm should sound 3 minutes before VTBI is complete.

Press ▶ to turn to next page. Press ◀ to turn to last page.

8.4.11 Infusion Log Setting

After entering “Infusion Log” setting interface, press OK to enter View Log. Infusion pump could store about 30000 pieces history records, including infusion time, infusion mode, VTBI/Rate, volume infused and alarms. When AC power failure or power off, the records could still be saved. When records are full, the new record will overwrite the old one. The records won’t be lost even the device without power. The content of the records cannot be modified. After shut down, the electronic memory is 5years.

Press ▼ to move to “View alarm log” and press OK key. It will display infusion time, infusion mode and all alarms info.

All infusion records can be transferred to computer (only available when connect the pump to computer by USB interface):

Upload infusion records to computer with USB cable. Please refer to steps as follows:

a. Open the super terminal (if there is no, please open the computer Main menu - Program - Annex - Communication - Super terminal, establish the super terminal named 115200 on the desktop. Click  disconnect icon to disconnect terminal connection. In the file menu, select "properties", set the COM port (according to actual USB port)

b. In 115200 property box, click on the “configuration”. Set the baud rate as 115200, date flow controls as Xon/Xoff.

c. After the setting, click call icon  , connect the terminal.

d. In the super terminal interface, select the “transfer - capture text”. Establish a txt file named after a infusion pump serial number and then click “start”.

e. Press OK to upload records to computer terminal; press “ transfer- capture text - Stop” after finishing uploading, And all infusion/alarms records can be reviewed on the txt that established previously. After finishing uploading, the infusion pump will return to the previous menu automatically.

8.4.12 Date and Time setting

Press OK to enter 'Date and Time' setting interface. Press OK key to select date and time data, the editable value is in white background. Press ▲▼◀▶ to change year/month/day/time and press OK key to save.

Select "Format" and press OK key, there are 3 formats of displaying: year-month-day, month-day-year, day-month-year.

8.4.13 Auto shutdown setting

Press OK to enter "Auto shutdown", press OK to choose "Setting". Options setting are "Never", 1-99mins. If setting as 30mins, the infusion pump will switch off automatically in 30mins if no operation on machine.

8.4.14 Language setting

Press OK to enter "Language" setting interface, press ▲ or ▼ to select required language, then press OK to save setting.

8.4.15 Patient Info setting

Press OK to enter "Patient info" setting interface, select patient 1 and press OK key, it could edit name, bed No., ID, age and gender of patient. It could edit 5 patients info.

Press ▶ to turn to next page. Press ◀ to turn to last page.

8.4.16 Pre-occlusion setting

Press OK to enter "Pre-occlusion" setting interface, press ▲ or ▼ to select "ON" or "OFF", press OK to save setting.

8.4.17 Pause setting

Press OK to enter "Pause" setting interface, press ▲ or ▼ to select "ON" or "OFF", press OK to save setting.

When the setting is ON, press STOP key after infusion, Pause Setting interface will be display.

It could input pause time and press OK key. The device will start counting down. When time became 0, the device will start infusion automatically. During this period, it could press START key to start infusion,

or press Clear key  to infusion mode parameter setting interface.

Make the setting is OFF to close pause function.

8.4.18 Purge setting

Press OK to enter “Purge” setting interface, it could adjust purge rate and purge VTBI.

Note: “purge” only use when machine is in non-infusion status, and infusion tube is not connected to patients.

8.4.19 Standby setting

Press OK to enter “Standby Setting”, press OK again, setting the time (not 0). Press power key, the infusion pump will start standby function immediately. During the standby, press any key to wake up. When the time is 0, the setting will display Never.

8.4.20 Admin Settings

Admin setting is for qualified technical engineers only. Please contact distributor or manufacturer for password to enter this interface. In this setting, it could set the WIFI, up pressure level, tending time, restore default, drop sensor, air level and review device info.

8.5 Operation Precautions

- After the IV set is continuously used for 6 hours, please change the section of IV set that is against the peristaltic chips, or replace a new one. Meanwhile pay attention to the length of the IV set. Use extension lines if necessary in case the IV set is stretched out of position when patient turns his body.
- Avoid direct sunlight, high temperature and high humidity.
- If the pump work on battery only, please check battery capacity before operation and make sure it has enough power. Otherwise, recharge the battery fully.
- Avoid using the Infusion Pump with problems, which may cause medical accidents and bring harm to patient’s health and even life.
- Only well-trained professionals are permitted to set or adjust infusion parameters.
- When infusion at high rate (≥800ml/h), large-sized needle (size 7 or above) should be used,

otherwise it shall influence infusion accuracy.

- The Infusion Pump should be placed within 1.2 meters above or below patient's heart.
- The damaged front panel (mask) needs to be replaced in time to prevent leakage.
- Infusion Pump works under conditions that exceed the prescribed range may influence infusion accuracy or even cause malfunction.
- The degree of viscosity and ratio of medical liquid may influence infusion accuracy.
- The IV set used on this Infusion Pump should get legally marketed Certificate.
- The Infusion Pump uses 'JieRui' brand set for factory settings. If users use the other brands of IV set, please calibrate its accuracy on machine before use.

8.6 Contraindications

No findings so far.

9. Troubleshooting

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.

(2) 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

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.

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

11.3.1 Inspect anti-free flow clamp (once every 2 months)

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 months)

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 months)

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 ±5%.

11.3.4 Inspect internal battery

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

(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.

11.3.5 Replace internal battery

It is better to replace the battery every year. 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 bottom 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.

11.6Recycling

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

1. The scrapped Infusion Pump and power cable can be sent back to manufacturer or distributor.

2. The used battery can be sent back to manufacturer or distributor, or can be scrapped according to legally proper way.

12. Transport and storage

12.1 Precautions during transport

1. Place the product as per No. of layers indicated on packing carton.
2. Temperature: -20℃~60℃;
3. Relative humidity: 10～95% (no frosting)
4. Atmosphere pressure: 50.0kPa～106.0kPa

12.2 Storage Conditions

Storage temperature: -20℃～+45℃(With battery); -20℃～+60℃(Without battery)

Relative humidity: 10～95% (no frosting)

Atmosphere pressure: 50.0kPa～106.0kPa

13. Package list

13.1 Standard configuration in a package:

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

13.2 Optional accessory

Portable handle

WIFI module

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 defective machines.
5. If there is any accessory lacking or damaged, please contact the supplier at the earliest. 15. After sales service.

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.

16. EMC Information

Note:

- The 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:

- The 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.

17 Guidance on Electromagnetic Biocompatibility

Guidance and Manufacturer's Declaration		
The infusion pump is intended for use in the electromagnetic environment specified below. The customer of the user of the Infusion pump should assure that it is used in such an environment.		
Emission Test	**Conformance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The infusion pump uses 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 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	Class A	

IEC 61000-3-2		
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer'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**	**Conformance Level**	**Electromagnetic Environment – Guidance**

Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The floor should be covered with wood, concrete or tiles; if it is covered by composite materials, then the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	±2kV to power line ±1kV to input/output line	±2kV to power line	Network power should have the quality that is typical for application in commercial environment or hospital.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Network power should have the quality that is typical for application in commercial environment or hospital.
Temporary voltage drop, short interruption and voltage variation on power input line IEC 61000-4-11	<5 % U_T, continuing for 0.5 cycle (On U_T, >95% temporary drop) 40 % U_T, continuous for 5 cycles (On U_T, 60% temporary drop) 70 % U_T, continuous for 25 cycles (On U_T, 30% temporary drop) <5 % U_T, continuous	<5 % U_T, continuing for 0.5 cycle (On U_T, >95% temporary drop) 40 % U_T, continuous for 5 cycles (On U_T, 60% temporary drop) 70 % U_T, continuous for 25 cycles (On U_T, 30% temporary drop) <5 % U_T, continuous for	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 power interruption, it is suggested to adopt UPS or battery for power supply.

	for 5s (On U_T, >95% temporary drop)	5s (On U_T, >95% temporary drop)	
PFMF (50/60Hz) IEC 61000-4-8	400A/m	400A/m/50Hz/60Hz	PFMF should have the PFMF characteristics of typical places in commercial environment or hospital.
Note: U_T refers to the AC network voltage before applying test voltage.			

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 IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and	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	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

Radiated RF IEC 61000-4-3	amateur radio bands between 0,15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	GHz 385MHz-5785MHz 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 symbol. 
Note 1: At 80 MHz and 800 MHz, the 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.			
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. b Field strengths should be lower than 3 V/m within the whole frequency range of 150KHz~80MHz.			
Recommended Isolation Distance between Portable and Mobile RF Communication Device and 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.

18. List of Factory Default Parameters

Parameters	**Factory defaults**	**Parameters**	**Factory defaults**
KVO	0.10 ml/h	Volume	High
Purge	1200 ml/h	Backlight	On
Bolus	1000.00 ml/h	Key tone	On
occlusion	Level 8	Pressure	100

Bubble	Off	No Operation	On
Infusion tube	tube A	almost done alarm	On
Drop /ml	1ml = 20 drips	Night mode	Off
Calibration	Flow rate 150 ml/h, volume to be infused: 10 ml	Key lock	Off

Appendix 1

Table 1 Classification of alarms and color of alarm indicator light

Classification of alarms	Alarm priority	Color and frequency of alarm indicator light
Door open alarm	High	Red light /2Hz
Air Bubble alarm	High	Red light /2Hz
Occlusion alarm	High	Red light /2Hz
B. exhausted alarm	High	Red light /2Hz
Check tube alarm	High	Red light /2Hz
Empty alarm	High	Red light /2Hz
Drip Abnormal alarm	High	Red light /2Hz
finished alarm	High	Red light /2Hz
Almost done alarm	Low	Yellow light /0.5Hz
AC fail alarm	Low	Yellow light,steady
No operate alarm	Low	Yellow light,steady
Low Battery alarm	Low	Yellow light ,steady

Table 2 Alarm Conditions and Alarm Signal delay

Name of alarm	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
Low battery alarm	10ms	100ms
battery exhausted alarm	500ms	100ms
Check tubealarm	10ms	100ms
Almost Done alarm	10ms	200ms
finished alarm	10ms	200ms
Empty alarm	10s@180ml/h	100ms
AC Fail alarm	10ms	200ms
Drip Abnormal alarm	10s@180ml/h	200ms
No operation alarm	120 ms	200ms

Table 3 Characteristic Parameter of Alarm Sound

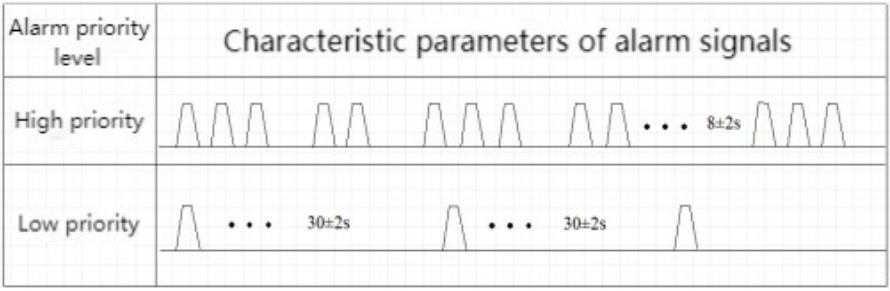


Table 4 Occlusion response characteristics

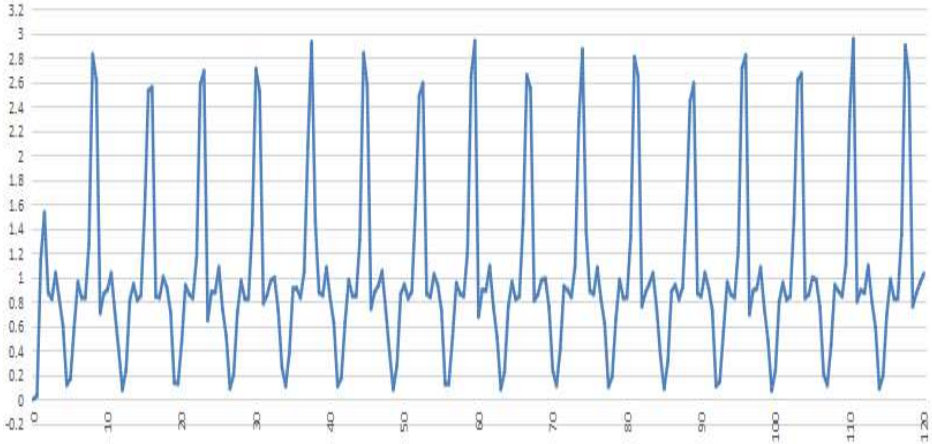
JieRui infusion set is used in this test. Test data is measured at flow rate of 1ml/h and 25ml/h respectively, when the flow clamp is 20cm from infusion pump and the filter is 30cm from the infusion pump,

* This infusion pump uses anti-bolus function that will be triggered after occlusion alarm, then automatically release pressure in the tube.

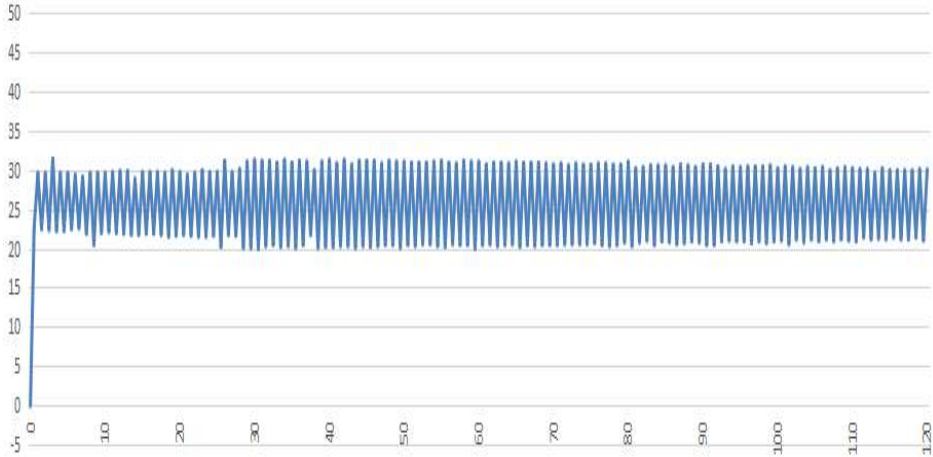
Flow rate (ml/h)	Occlusion Alarm Level	Blockage Pressure (kPa)	Occlusion alarm time	Dosage (ml)
1	Low	70	0h52min11sec	0.26
	Medium	93	1h9min16sec	0.39
	High	137	1h32min1sec	0.45
25	Low	61	0h1min45sec	0.26
	Medium	97	0h2min29sec	0.42
	High	147	0h3min34sec	0.50

Table 5 Start-up Curve

JieRui infusion set is used as test tube. The whole test is under room temperature.

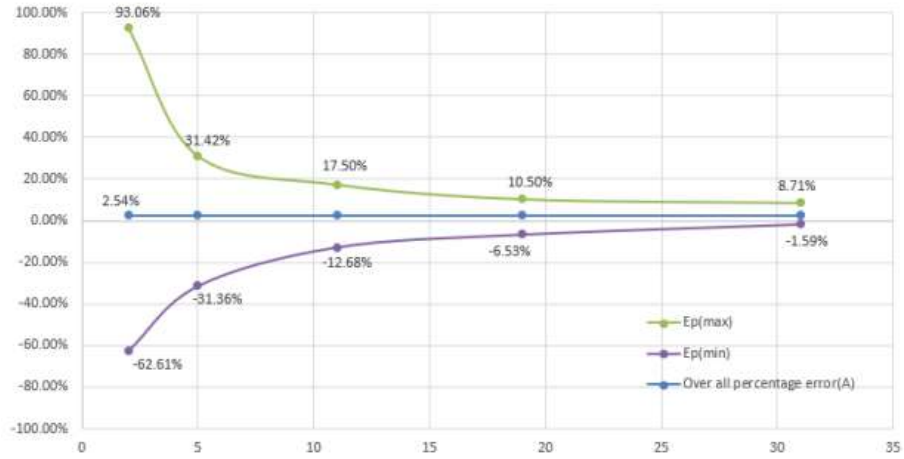


1ml Start-up Curve

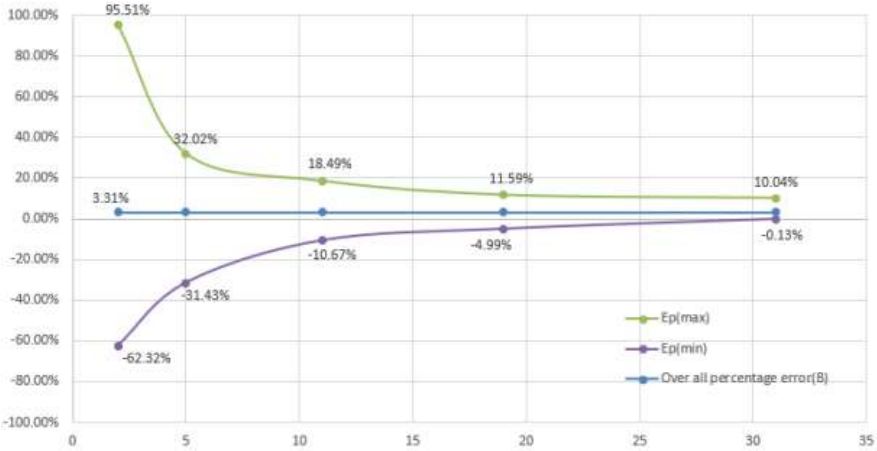


25ml Start-up Curve

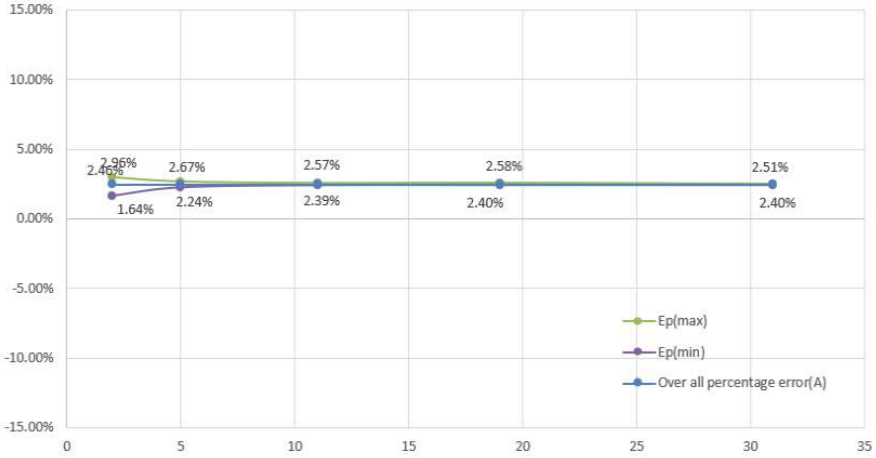
Table 6 Trumpet Curves



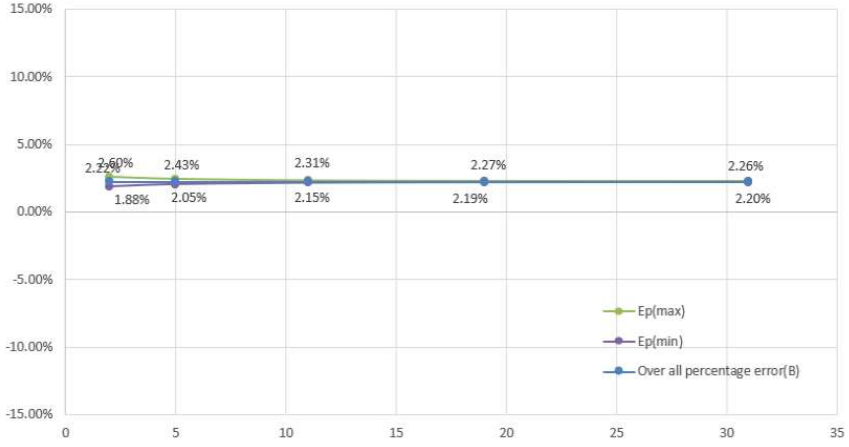
The 2nd hour Trumpet Curve at 1ml/h



The last hour Trumpet Curve at 1ml/h



The 2nd hour Trumpet Curve at 25ml/h



The last hour Trumpet Curve at 25ml/h

Appendix 2 Flow Accuracy Test Method for Infusion Pump

1. Test method: gravimetric method

2. Principle

Gravimetric method uses electronic balance. Connect calibration system as per diagram 2-1. Put certain volume of fluid into container (Container should add lid. If without lid it should add certain amount of paraffin oil to prevent evaporation). Injection needle should be under surface of fluid. Use container to collect the total output volume from infusion pump during test period. Then calculate the differences between preset volume and actual volume flowing out (weight on electronic balance)

3. Test Environment

3.1 Temperature: 20±2°C

3.2 Relative humidity: 60±15%

3.3 Atmospheric pressure: 860hpa~1060hpa (645mmHg~795mmHg) (note: 1 standard atmospheric pressure: 760mmHg)

4. Test instruments and reagents:

4.1. Calibrated electronic balance (Requires precision to more than three decimal places)

4.2 Injection needle (18G, 1.2 mm)

4.3 Infusion set

4.4 Connecting components (connecting infusion tube and needle)

4.5 container (beaker + anti-volatile paraffin oil)

5 Test procedures

5.1 Connect infusion pump, infusion set, electronic balance and container.

5.2 The balance is placed in suitable fixed position; the container on the balance. Put certain amount of water and certain drops of Anti-volatile oil to container (Record the reading of electronic balance)

5.3 Connect a brand new infusion set as per instruction, immerse injection needle below the surface of fluid in container and keep hanging.

5.4 The infusion pump is placed in proper position. Ensure infusion pump input terminal and the container fluid surface at the same level height. Turn on the machine.

5.5 Fix the tube and ensure no deformation of tubing due to movement or other reasons during testing.

5.6 Enter calibration interface (under system settings)

Press START key, the Infusion Pump shall start operation at 150ml/h. After it finishes VTBI (10ml), measuring the flown-out liquid (the balance reading after infusion finish – balance reading before infusion), input this volume on “actual” text of calibration interface. Then press OK key to save the value and exit. The calibration of infusion set is complete.

5.7 After calibration, set flow rate at 150ml/h, volume limit as 10ml. The flow rate accuracy should be within ±5%.

6. Supplements

6.1 The consistency of infusion set

The infusion set used in test procedure, the size of cross-sectional area of tube, the diameter consistency, resilience have effects on accuracy of infusion pump.

6.2 Stability of connecting components

Output terminal of infusion set and container used in test procedure, shaking and deformation of infusion set will affect the total output liquid.

6.3 The change of testing environment

The piping material is high polymer; the changes in the environment, especially temperature will change piping volume, thus affecting the amount of the output fluid.

6.4 High-quality infusion set (option):

a) Material: (only used within the length of the peristaltic system) platinum cured processing medical grade silicone tube.

b） Silicone tube working length: 320mm

c） Tensile strength: 9.01.4N/mm²

d） Hardness: 562, Shore hardness A

e） Silicone tube manufacturing wall thickness deviation: 0.0254mm

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