Shenzhen Hawk Medical Instrument Co., Ltd.

HK-100II/HK-100 INFUSION PUMP

USER MANUAL

Please read the manual before using the product;

Please keep the manual for reference！

CE 0197

057-00171-01

Table of 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 HK-100, HK-100II infusion pump.

Version No.	Date of Preparation
V1.0.0	2021.01.07

User manual version upgrade instructions:

V X.Y.Z

V means version No. of user manual.

X means device has big upgraded: When software, hardware and construction of device have big modified, the user manual should be upgraded accordingly.

Y means the device has small improvement: In order to better using the device, the software, hardware and construction of device have been tiny improved (it is not necessary for re-registration after evaluation), the user manual should be upgraded accordingly.

Z means correcting information of user manual while the device has no changed. It only correct the wrong word/ diagram/explanation and so on.

1. Warnings & Cautions

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

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

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

c) The Infusion Pump has occlusion detection function. It gives occlusion alarm when the infusion needle fails to insert into intravenous vein properly or the needle deviates from its position inside the vein during infusion. As occlusion alarm is given only after the occlusion pressure reaching a certain value, the area around the needle may already become swollen or bleeding at this time.

   In addition, the occlusion alarm is not given maybe because the actual occlusion pressure not large enough to reach the occlusion alarm gate, therefore, it needs to check the insertion area regularly. If the insertion area seems abnormal, please take proper treatments such as re-inserting the needle.

d) The user must install the infusion set 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) Do not store or use the Infusion Pump in humid environment or environment with chemically active gases (including gas for sterilization). Such environments may have impact on internal electronic parts and thus bring degradation or damage to their functions.

o) It can be used for ambulance with DC: 12V by working with a voltage stabilizer.

P) Please use to meet the relevant laws and regulations, with a valid medical device registration certificate of the infusion tube, or cannot guarantee the accuracy of infusion and normal detection alarm.

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

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

b) When use the Infusion Pump the first time after purchasing or after long-time of storage, please connect it to AC power source and charge it for at least 10 hours with power on, or 3 hours with power-off. If not fully recharged, the internal battery can't support the Infusion Pump with enough power in case of AC power failure.

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

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

vacuum tube).

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

(3) The Infusion Pump shall not use the same electric cabinet as that of electric cautery apparatus, and having reliable ground connection.

d) Do not use mobile phone, wireless device or cardiac defibrillator within 1 meter near the Infusion Pump. Otherwise the high frequency noise/signal may cause wrong performance of the Infusion Pump. Make sure the Infusion Pump has ground connection and do not use the same power socket with that for the above-mentioned devices.

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

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

g) Keep the infusion bag, IV set and the Infusion Pump a certain distance from the AC power source and DC socket to prevent the medical liquid from splashing or 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) Recommend to change the segment of infusion set every 6 hours to guarantee the accuracy. The IV set may be out of shape due to long-hour squeeze by the peristaltic fingers and thus cause accuracy error. It is suggested to move to a new section (15 cm upward or downward) after every 6 hours of usage, and then start operation again. Or replace the IV set with a new one.

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

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

m) When using computer port, it may suffer interference from devices such as electric cautery apparatus, mobile phone, wireless device or cardiac defibrillator etc. Please try to keep away from the above-mentioned devices.

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

o) The Infusion Pump must be operated by well-trained professionals such as doctor, nurse and medical device expert.

p) Do not disassembly or modify the Infusion Pump or use it for other purposes other than normal infusion. Otherwise, the manufacturer takes no responsibility.

2. Introduction

2.1 Features

Compact and light weight

User-friendly interface, easy parameters setting

2.8 inch colorful LCD with detailed menu

Peristaltic system, better accuracy.

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

Apply to vertical pole or horizontal bar Removable pump body for easy cleaning.

Product models

Model/Description		HK-100	HK-100II
Infusion modes	Rate mode	√	√
	Drip mode	√	√
	Time mode	√	√
	Micro mode	√	√
	WT. Mode	X	√

	Dose mode	X	√
	Drug library	X	√
	Sequential	X	√
	Programmable	X	√
	TPN mode	X	√
	Intermittent	X	√
Remark: √ means with the function， X means without the function			

2.2 Application scope

It is used in hospitals where patient need intravenous infusion at preset infusion rate and volume limit.

2.3 Type and specifications

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

2.4 Operating conditions

a) Temperature: 5℃-40℃

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

2.5 Affection on environment and energy

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

2.6 Date of manufacture & life span

The life span of the infusion pump (battery is not included) and its cable is 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. Components

The Infusion Pump is mainly composed of 5 parts: microcomputer system, pump body, detection device, alarm system and Input & display part.

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 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) and audible alarm (loudspeaker and buzzer) etc.

Input & display part: Press keypad to set all parameters such as infusion volume and flow rate. LCD displays all parameters and present operation status.

4. Technical and specifications

Infusion accuracy	±5%
Applicable infusion set	Various brand of infusion set 15, 20, 60 drops/ml, Infusion set external diameter: 3.4~4.5mm. Infusion set used in this pump should meet the requirements of ISO 8536-4: 2019 Optional: Hawkmed brand dedicated infusion set
Infusion modes	1. Rate mode 2. Drip mode 3. Time mode

	4. WT. Mode (Body weight mode) 5.Dose mode 6. Drug library 7. Sequential 8. Programmable 9. TPN mode 10. Intermittent 11. Micro mode
Flow rate range	0.1-1200ml/h Increment options: 0.01ml/h, 0.1ml/h, 1ml/h, 10ml/h or 100ml/h
Volume to be infused (VTBI)	1-9999ml,or 0 (no limit on VTBI) Increment options: 0.01ml, 0.1ml, 1ml, 10ml, 100ml or 1000ml
Volume infused	0.0-36000ml
Alarm functions	Visual and audible alarms: Door open, Air-In-Line, Occlusion, Infusion completion, infusion near over, No operate, Low Battery, Battery exhausted, malfunction etc.
KVO rate	0-10ml/h, preset by the user; default: 1ml/h
Bolus	Manual bolus & auto bolus: Bolus rate:0.1-1200ml/h default: 1000ml/h Bolus VTBI: 0-9999.99ml For manual bolus, bolus VTBI is 0, bolus time is 0. Bolus for micro mode: Bolus rate: 0.1-100ml/h, default: 100ml/h Bolus VTBI: 0-1000ml
Purge	Purge rate: 0.1-1200ml/h default: 600ml/h Purge VTBI:0-9999.99ml
Air Bubble detection	Levels adjustable: L1, L2, L3, L4, L5, L6, Default: L2 (level 2, please refer to 8.3.4) Tube type: normal / thin Default: normal tube

Occlusion pressure	1~13 levels(10-130kpa, 1=lowest level, 13=highest level) Default: level 8 Unit options: kPa, bar, mmHg, psi Default unit: kPa
Anti-bolus function	Diminishes the volume of unwanted Bolus injected to the patient after removal of the occlusion cause.
RS-232 port (optional)	RS-232 port enables user to check infusion/alarm record in computer terminal.
Water Proof Level	IP24
AC power	100-240V 50/60Hz
Battery	Lithium Polymer 7.4V 1900mAh. Recharge time: 10h with power on, 3h with power off. Running time: more than 5h at rate of 25ml/h, environment temperature 25℃ after being fully charged.
Power consumption	35VA
DC	DC 12V ±1.2V NOTE: It cannot be used for ambulance.
Fuse	Slow fuse, 250V 2A
Operating conditions	Environment temperature: 5℃～40℃ Relative humidity: 10-95% (no frosting) Air pressure: 86kPa～106kPa
Dimensions	145(L)x 120(H)x 100(W, not including pole clamp)mm
Net weight	≤1.4kg

5. Installation

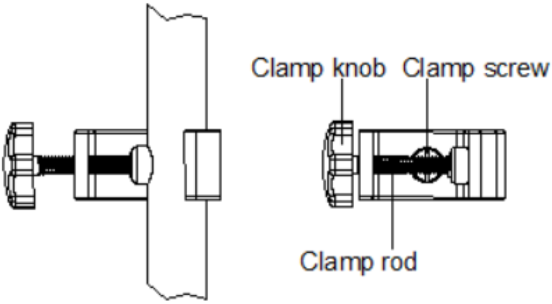
5.1 Installation conditions and technical requirements

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

5.2 Installation method and cautions

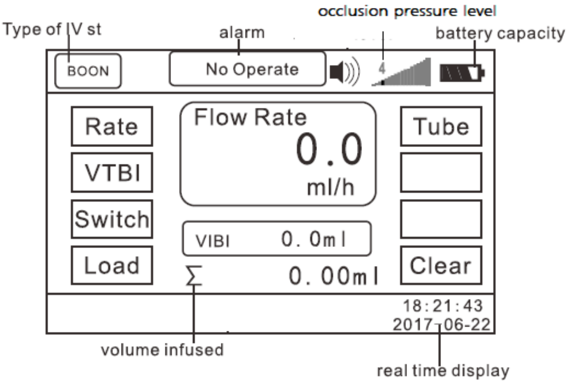
If the pole clamp is in the same direction with IV stand or bar, loose the clamp screw then rotate the pole clamp 90° to suit the direction of the IV stand or bar.

When fixing the pole clamp to IV stand or bar, use the other hand to hold the infusion pump until the clamp is well fixed.

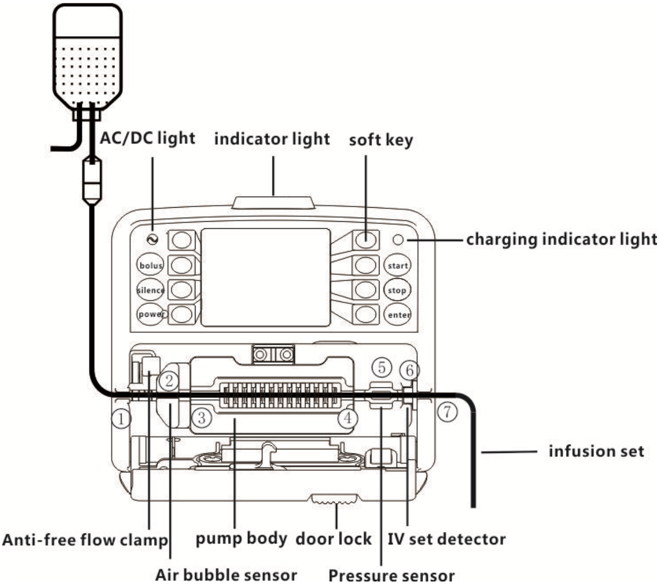


6. External Features

6.1 Front panel (Diagram 1)



(LCD display)



(diagram 1)

Description	Functions
BOLUS key	In 'stop' status, press & keep finger on 'bolus' key, the pump starts purging (default purge rate: 600ml/h). After releasing the finger, purging stops. During operation, press & keep finger on 'bolus' key, the pump starts bolus infusion (bolus rate preset by the user). Release the finger, bolus infusion stops and the pump continues infusion at original rate.
SILENCE key	Press this key to silence the alarm sound
POWER key	Switch on / off the Infusion Pump. In 'power off' status, press this key until LCD screen displays, which means the pump is switched on. In 'power on' & 'stop' status, or in 'alarm' case, press this key for about 2 seconds, the pump shall be switched off.

START key	In ‘stop’ status, press this key to start infusion.
STOP key	Press this key to stop infusion, or clear alarm indicator light and message
ENTER key	Press this key to confirm / save the parameter newly setting
Soft key	The soft keys have various functions. Pressing the key next to the text displayed in the LCD, the text will be highlighted for further parameters setting by pressing soft keys again.
AC / DC indicator light	If on, it indicates there’s AC/DC input; if off, it indicates there’s no AC/DC input.
Indicator light	Indicator light on top of the pump indicates operating status/alarms cases. If the IV set is correct installation 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 operation. The green indicator light flashes when the infusion is in normal progress. If high-priority alarm occurs during operation, the indicator light shall turn red and flash. If middle-priority alarm occurs during operation, the indicator light shall turn yellow and flash. If low-priority alarm occurs during operation, the indicator light shall turn yellow but not flash. ★ Please refer to Annex Table I for priority of alarm classification
Charging indicator light	This indicator light on means the battery is recharging.
Door lock	Pressing the door lock, the door shall pop open automatically. Press the door with a bit force to close the door. A ‘click’ sound indicates the door is well closed.
IV set detector	It can identify the dedicated IV set, or prevent the IV set from being installed in wrong direction. This function is optional.

6.2 Rear panel (Diagram 2)

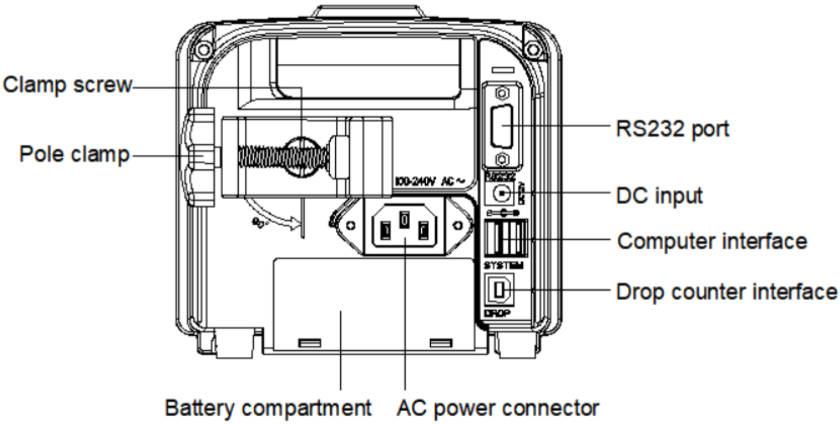


diagram 2 Rear Panel

Description	Functions
Pole clamp	It is used to fix the infusion pump on IV stand. Loose the clamp screw to change the direction of pole clamp. (Horizontal or vertical optional)
Battery compartment	Battery location. Open it from the bottom of machine.
AC power connector	The socket for connecting to AC power source.
RS-232 port	It is used to connect infusion pump to standard PC to transfer infusion history records. **Note: This process must be carried out when machine in non-infusion state.** And this port is interfacing with infusion management system via a WIFI signal projector (WIFI signal projector is optional).
DC input	It can be connected to exterior DC power supply (12V±1.2V). Must use the adapter that in accordance with IEC 60601-1.
computer interface	This socket is for upgrading program

Drop counter interface	This interface is for connecting to exterior drop sensor to detect the drop rate. The drop sensor cannot be exposd to sunshine, when using drop sensor, squeeze the drip chamber to fill it with 1/3 of the liquid. (This function is optional)

6.3 Label

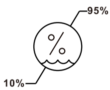
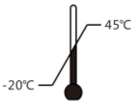
6.3.1 Product label (on the back shell)

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

6.3.2 Symbols and significance

(Table 1)

Symbols	Descriptions
LOT	Production batch No.
SN	Product serial No.
	Caution, consult accompanying documents
	Consult instruction for use
	Type CF
	Protective Earthing
IP24	Protection level
~	AC power

	DC power
	Dispose in environmental-friendly way
	Date of production
	manufacturer
	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
	Authorized Representative in the European Community

	Keypad lock icon
	WIFI signal
 36℃	Heating
	Night mode

7. Preparation and inspection

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

(1) The 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) The power cord can be plugged in tight, not easy to loose.

(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) In addition to the infusion pump built-in brand infusion, the user before using other infusion sets, must be calibrated before use.

8. Operation Method

In order to ensure the accuracy of infusion, it is recommended to use the pump built-in infusion tube brand (Boon A2 (1ml = 20 drops), the special infusion tube of Hawkmed (1ml = 20 drops).

8.1 Operation

The whole infusion operation contains the following processes:

1) Fix the Infusion Pump and connect it to AC power.

2) Switch on / off.

3) Fill the IV set with medical liquid and install it in the Infusion Pump.

4) Set infusion parameters.

5) Purge the air in line.

6) Clear Σ (volume infused) .

7) Start infusion .

8) Bolus infusion.

9) Stop infusion.

10) Infusion completion .

11) Replace IV set and infusion bag/bottle.

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

8.1.2 Switch on/ off.

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

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

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

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

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

(2) Install the IV set

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

8.1.4 Infusion mode selection

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

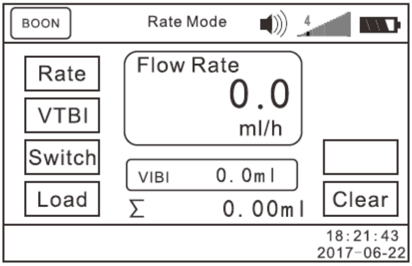
Attention:

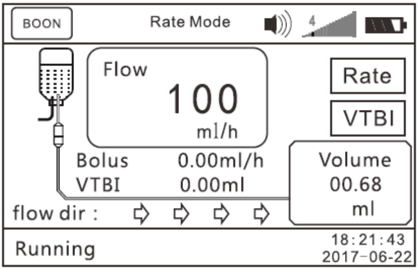
1. Different infusion modes need to set different parameters.
2. Under Time Mode, when flow rate (result from volume limit divided by infusion time) more than maximum flow rate of system 1200ml/h, the system will display the infusion time （result from volume limit divided by 1200ml/h）.

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

8.1.5 Set infusion parameters

1) Rate Mode





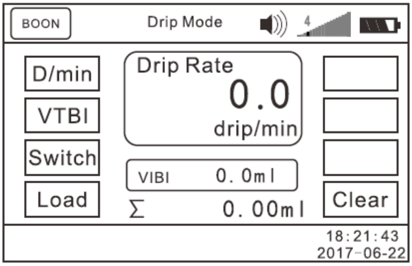
Rate: Press for ‘Rate’ and input rate value. Press ENTER key to save the value and exit.

VTBI: Press for ‘VTBI’ and input volume to be infused. If you are to infuse all the liquid inside the bottle, do not input VTBI value (just leave it as ‘0ml’). Press ENTER key to save the value and exit.

Press START key to start infusion.

It could change flow rate and VTBI without stopping infusion. Press rate soft key (the first soft key on top right) and VTBI soft key (the second soft key on top right), change and save the value, the device will work under new parameters.

2) Drip Mode



If well installation of drop sensor and open its function as per 8.3.19, set the infusion mode as drip mode, the infusion pump will ensure the actual drops equal to the setting by drop sensors.

If well installation of drop sensor and open its function, there is no need to adjust “drops/ml” in ‘parameter setting interface’.

When there is no drop sensor, please follow the following instructions:

(1) Press and hold on STOP key first, then press (1st soft key on top left), entering ‘parameter setting interface’. Press for 'D./ml' and input the number of drops equivalent to 1ml as specified on the package of IV set selected for use. Press ENTER key to save/exit. Press and hold on STOP key first, then press (1st soft key on top left) to return to previous menu.

★ Regarding drip mode, it must input the number of drops equivalent to 1ml as specified on the package of the IV set. (e.g. For "Boon" brand of IV set, it specifies 20 drops/1ml ±0.1ml. You then input the value '20' in 'D./ml'.)

(2) After setting the D./ml value, check and verify it.

Set drop rate as 50 drop/min and VTBI as 5ml. Start infusion and count with your eyes the actual number of drops within the 5ml. If the actual number of drops counted is too different from the pre-set D./ml value, you need to adjust the D./ml value according to the actual D./ml value measured by counting. (e.g. Set D./ml value of 'Boon' IV set as 20, drop rate as 50 drop/min and VTBI as 5ml. The actual number of drops counted should be supposedly 100 drops. If there are only 75 drops within 5ml, you then need to enter ‘parameter setting interface’ to adjust D./ml value as 15.)

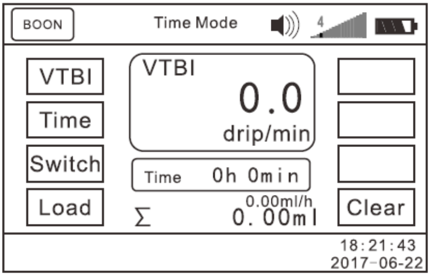
(3)Drop rate: Press for 'D/min', input drop rate needed, press ENTER key to save and quit to previous menu.

VTBI: Press for 'VTBI' and input VTBI value. If it needs the whole bottle of medical liquid, please leave it as 0. Press ENTER key to save and quit to previous menu.

Load: Press for 'Load'. It can directly load the rate and VTBI of last infusion.

★ After pressing 'Load', please check and verify if the rate and VTBI are the ones you need for this infusion, otherwise you need to reset the rate and VTBI.

3) Time Mode

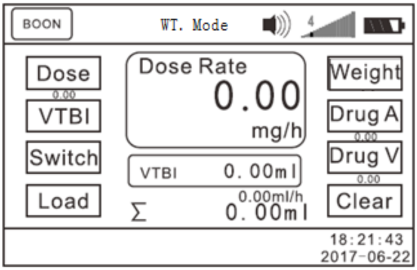


VTBI: Press for 'VTBI' and input volume to be infused. Press ENTER key to save the value and exit.

Time: Press for 'Time' and input time value. Press ENTER key to save the value and exit.

Press START key to start infusion.

4) Body Weight Mode (WT. Mode)



Press for 'Dose' and input Dose Rate (0.1-2000). Press ENTER key to save the value and exit to the previous menu.

Press for 'VTBI' and input volume to be infused. If infusing all the liquid inside the bottle, do not input VTBI value (just leave it as '0ml'). Press ENTER key to save the value and quit to the previous menu.

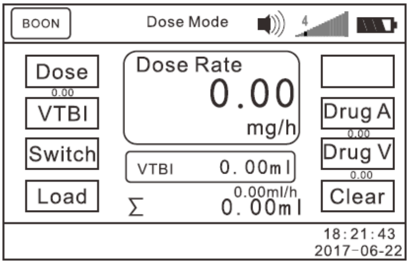
Press for 'Weight' and input value (0.1-300 kg). Press ENTER key to save the value and exit to the previous menu.

Press ◯ for setting of Drug A (Drug amount) and Drug V (drug volume).

The flow rate will be calculated automatically after input all above parameters.

It allows to change dose value without stopping infusion. Press dose soft key, change and save the value, the infusion pump will work under new dose rate.

5) Dose Mode

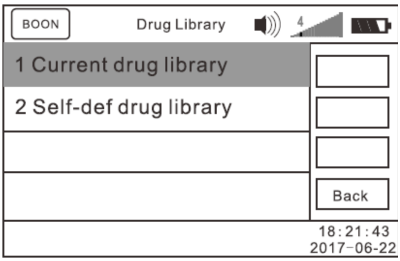


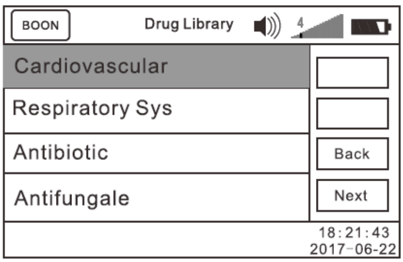
Input parameters of dose, VTBI, Drug A (Drug amount) and Drug V (drug volume), the flow rate will be calculated automatically.

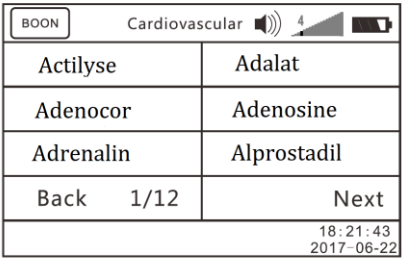
It allows to change dose value without stop of infusion. Press dose soft key, change and save the value, the infusion pump will work under new dose rate.

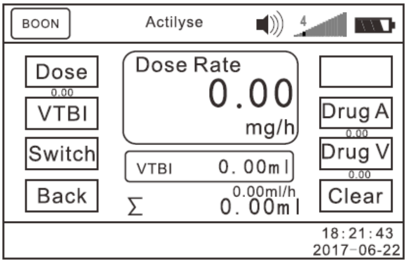
6) **Drug Library Mode**

Current drug library:





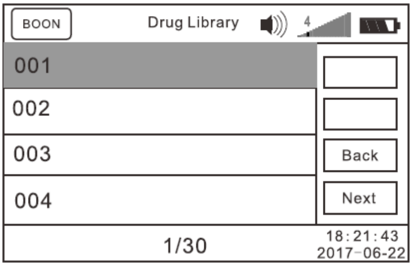


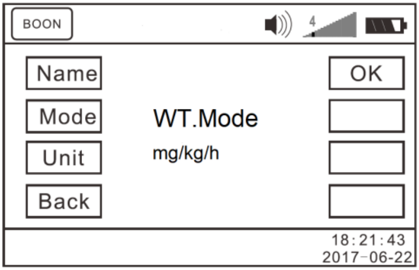


Press soft key of “1 Current drug library”, press “Next” soft key to review the rest drug categories. There are total 5 pages.

Press four soft keys on left to select specific drug category. Press soft key of specific drug name to select the drug. The machine will display drug library infusion mode. Drug name will be displayed at top of screen. Input infusion parameters and press START key to start infusion.

User self-define drug library:





Press soft key of “2 Self-define drug library”, press soft key (001, 002,003...), press “name” soft key, press “+” or “—” to select the 26 alphabet(A,B,C......Z) and digital number (0-9). Press SILENCE key to input space or remove alphabet & digital number.

After setting one letter, press “→ ”soft key to go to next letter. Press “←” soft key to change previous letter.

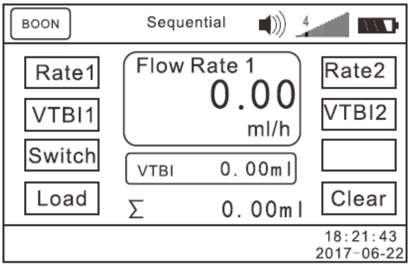
After setting the drug name, press ENTER key to save the setting.

Press “Mode” soft key, press “+” or “—” to select infusion mode (Dose mode, Rate mode, weight mode) .

Press “Unit” soft key to select dose unit. It is no need to set dose unit for rate mode.

Press “OK” soft key to enter selected infusion mode. Drug name will be displayed at top of screen. Input infusion parameters and press START key to start infusion.

7) Sequential



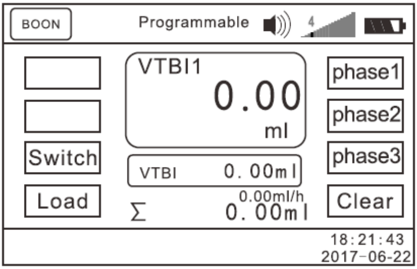
Under sequential mode, the infusion is going under 2 sections. When the first section finished, the second section will start automatically.

Input rate 1 & VTBI 1 for first section.

Input rate 2 & VTBI 2 for second section.

Press START key to start infusion.

8) Programmable



Under programmable mode, the infusion is going under 3 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 use only one or only two phases.

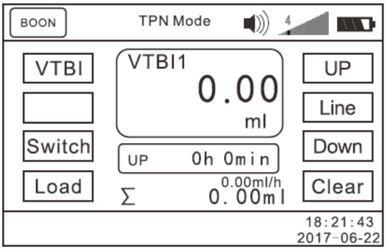
Input VTBI 1 & Time 1 for first phase1.

Input VTBI 2 & Time 2 for phase 2.

Input VTBI 3 & Time 3 for phase 3.

Press START key to start infusion.

9) TPN mode



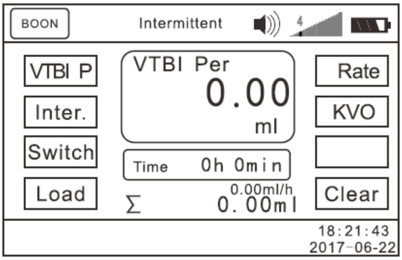
Input VTBI, up time, line time & down time, the flow rate will be calculated automatically for each phase. Press START key to start infusion.

During up time, flow rate keeps increasing.

During line time, flow rate is uniform/constant.

During down time, flow rate keeps decreasing.

10) Intermittent Mode

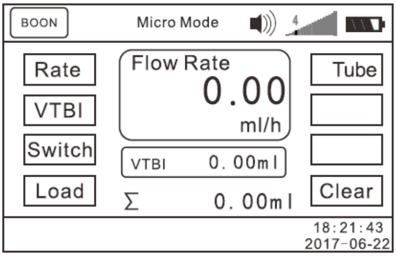


Under intermittent mode, the infusion will be paused by interval time.

Input parameters of VTBI P (VTBI Per time), inter.(interval time), Rate, press START key for infusion.

For example, VTBI P=30ml, Interval time = 10mins, rate=100ml/h, when infusion pump finished infusion of 30ml medication, it will pause for 10mins and then start another 30ml.

11) Micro mode



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

12) Load

Press “Load” soft key to upload the parameters of last infusion. Please check if the loaded parameters are the needed one, if not, please input the required parameters.

8.1.6 Purge

In ‘stop’ status, press & hold on BOLUS key until all air inside the tube is purged.

8.1.7 Clear the volume infused

Press ◯ for ‘clear’ to clear Σ (volume infused) as ‘0.0ml’.

★ If Σ (volume infused) is not cleared after VTBI completion, when the next VTBI less than the previous Σ (volume infused), the pump shall give FINISH alarm and this FINISH alarm can only be eliminated by clearing the previous Σ (volume infused).

8.1.8 Start infusion

Confirm the top indicator light turning green and the IV set clipper is open, press START key to start infusion. Flow rate and VTBI shall display in the middle and Σ (volume infused) shall display in the lower right corner.

During infusion, only BOLUS key and STOP key shall function.

8.1.9 Bolus infusion

There are manual bolus and auto bolus.

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 “Auto B” soft key, the pump will start auto bolus function.

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

8.1.10 Stop infusion

During infusion, press STOP key to stop infusion. Press START key to re-start infusion.

8.1.11 Infusion completion

After VTBI completion or Σ (volume infused) reaching 36000ml, the pump shall start KVO function automatically. Press STOP key to stop infusion.

★ KVO function means keep patient’s vein open by infusing at a pre-set low rate.

8.1.12 Replace IV set and infusion bottle

★ 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 squeeze by the peristaltic system and which can cause accuracy error. It is suggested that change the section of the infusion set that is against peristaltic chips or replace a new infusion set after continuously working for 6 hours.

★ If need to replace 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 8.1.4

8.2 Alarms and solutions

During infusion preparation and infusion process, alarms may occur as follows. Please treat them as per instructions below. Table 2（Refer to Annex Table 1, 2 & 3 for corresponding alarm parameters）

Name of alarms	Cause for alarms	Solutions
No Operate alarm	If there is no operation on machine for 2 minutes after switch on , it shall give 'no operate' alarm.	Press SILENCE key to clear the alarm sound. Press any key to clear the alarm. ★ This alarm function can be closed (See 8.3.14)
Door Open alarm	The pump door is opened during infusion.	Press SILENCE key to clear the alarm sound. Close the pump door to eliminate the alarm.
AlmostDone alarm (infusion near over)	Three (3) minutes before VTBI completion	Press SILENCE key to clear the alarm sound, open the door or press STOP key to clear the alarm indicator light and message. ★ This alarm function can be set as 'OFF' if there is no need. (See 8.3.15)
Finished alarm	1. The VTBI is completed. 2. Volume infused reaches 36000ml.	Press SILENCE key to silence the alarm sound. Press STOP key to clear the alarm indicator light and message. Press for 'clear' to clear Σ (volume infused) as '0'.
Air Bubble alarm	1. Air bubble inside the tube.	Press SILENCE key to clear the alarm sound. Open the door to get rid of air bubble in the tube and then press START key to start infusion again.

	2. The IV set is improperly installed.	Install the IV set in correct way as instruction in 8.1.3.
	3. The air sensor is defective.	Contact distributor / manufacturer for repair.
AC Fail alarm	Power failure or AC power plug off after switch on.	Press SILENCE key to clear the alarm sound, STOP to clear the alarm indicator light and message, and re-plug in the power cord properly.
Occlusion alarm	1. The infusion set is blocked.	Press SILENCE key to clear the alarm sound, STOP to clear the alarm indicator light and message. Open the door to eliminate the occlusion properly and press START key to start infusion again.
	2. The occlusion sensitivity is too high.	Adjust occlusion level of the Infusion Pump as per instructions of 8.3.3.
	3. The pressure sensor is defective.	Contact distributor / manufacturer for repair.
Use Battery alarm	1. AC power is not plugged in.	Press SILENCE key to silence alarm sound, STOP to clear the alarm indicator light and message. Check whether the AC power cord is plugged in or not well inserted.
	2. The Infusion Pump's electric circuit has problem.	Contact distributor / manufacturer for repair.

Low Battery alarm (when battery has to be used during power failure or mobile infusion)	1. Thirty (30) minutes before the battery capacity is exhausted.	Press SILENCE key to silence the alarm sound. If AC power cord is not plugged in, the alarm shall sound again 2 minutes later. Stop infusion and connect to AC power to charge the battery fully.
	2. The battery is aging or the Infusion Pump's charging circuit is defective.	Contact distributor / manufacturer for repair.
B. Exhaust alarm (battery depleted alarm. when battery has to be used during power failure or mobile infusion)	1. Three (3) minutes before the battery capacity is exhausted.	Press SILENCE key to silence the alarm sound. Stop infusion and connect to AC power to charge the battery fully.
	2. The battery is aging or the charging circuit of the Infusion Pump is defective.	Contact distributor / manufacturer for repair.
Check tube	IV set is not the Hawkmed brand dedicated infusion set	Press SILENCE key to clear the alarm sound. Install the IV set in correct way after switching on the pump. ★ NOTE: It is applicable to the infusion pump that has special infusion set recognition function.
0xE0,0xE1 **0xE2,0xE3**	1. 0xE0: data communication error.	Reboot the machine and load the parameters of last infusion to try operation again. If problem still occurs, contact distributor / manufacturer for repair.

	2． 0xE1: The Infusion Pump's driving system has problem.	Reboot the machine and load the parameters of last infusion to try operation again. If problem still occurs, contact distributor / manufacturer for repair.
	3. 0xE2: The Infusion Pump's motor has problem.	Reboot the pump and load the parameters of last infusion to try operation again. If problem still occurs, contact distributor / manufacturer for repair.
	4. 0xE3: The Infusion Pump's data storage system has problem.	Reboot the pump to try operation again. If problem occurs again, try to restore default setting to try again. If problem still occurs, contact distributor / manufacturer for repair. ★ After restoring factory default setting, you need to calibrate the IV set parameters again.

8.3 Parameters Setting and Accuracy Calibration

This chapter illustrates how to set infusion parameters.

After switch on the pump, press and hold on STOP key first, then press ◯ (1st soft key on top left) to enter 'parameter setting interface'. If the first page has no parameters for setting, press ◯ (4th soft key on the right) to skip to 'next' page for setting. For any parameter setting, press ENTER key to save the value. After all parameters are well setting, press and hold on STOP key first, then press ◯ (1st soft key on top left) to quit to main menu.

8.3.1 Set KVO rate

After entering 'parameter setting interface', press ◯ for 'KVO' and set required KVO rate. Then press ENTER key to save the value and exit.

8.3.2 Set Bolus

After entering 'parameter setting interface', press for 'Bolus', select 1 for Bolus of all infusion modes except Micro mode. Select 2 "Bolus-Micro" for micro mode.

There are two methods for Bolus: manual Bolus and auto Bolus.

Manual Bolus: set Bolus rate, keep VTBI as 0ml and time as 0, press ENTER to save the value.

Auto Bolus: set Bolus rate and VTBI >0ml, or bolus time > 1 min, press ENTER to save the value.

Bolus setting	Default value	Adjustable range
Bolus	Rate: 1000ml/h	0.1-1200ml/h
	VTBI: 0ml	0-9999.99ml (0 means manual bolus)
	Time: 0h0min	0h0min-99h59min (0 means manual bolus)
Bolus-Micro (for micro infusion mode only)	Rate:100ml/h	0.1-100ml/h
	VTBI: 0ml	0-1000ml (0 means manual bolus)
	Time: 0h0min	0h0min-99h59min (0 means manual bolus)

8.3.3 Set occlusion pressure level

The occlusion pressure has 13 levels (10kPa-130kPa). Four pressure units options: kPa, bar, mmHg, psi.

After entering 'parameter setting interface', press for 'Occl.' and select the level accordingly. Press ENTER key to save the value and exit.

The higher the occlusion pressure level, the higher the pressure value.

Occlusion pressure level	occlusion pressure value	Occlusion pressure level	occlusion pressure value
Level 1	10kPa	Level 8	80kPa

Level 2	20kPa	Level 9	90kPa
Level 3	30kPa	Level 10	100kPa
Level 4	40kPa	Level 11	110kPa
Level 5	50kPa	Level 12	120kPa
Level 6	60kPa	Level 13	130kPa
Level 7	70kPa		

Deviation: ± 7kPa in Level 1, ± 20% or ± 15kPa for the other levels, take the higher value.

Unit conversion table:

Unit	Unit conversion
kPa	1kPa=7.5mmHg=0.01bar=0.145psi
psi	1psi=51.724mmHg=6.897kPa=0.069bar
bar	1bar=750mmHg=100kPa=14.5psi

Attention: 1. When using a high viscosity liquid and the occlusion pressure level is setting to a low level, there is possible occlusion alarm even there is no block in infusion tube. Please carefully check the infusion tube and the pressure level indicated on top of LCD screen. If necessary, please increase the occlusion pressure level.

2. When the occlusion pressure is setting to a high level, the pressure accumulated in the infusion tube is large. Please confirm the infusion tube connected firmly.

8.3.4 Set air bubble level for detection

After entering 'parameter setting interface', press for 'Air L', press "Filter" soft key, select required air bubble level for detection. Then press ENTER key to save the value and exit.

Air bubble level	Size of air bubble
Level 1	About 25ul
Level 2	About 50ul
Level 3	About 100ul
Level 4	About 250ul
Level 5	About 350ul
Level 6	About 500ul

Default air bubble level: Level 2.

8.3.5. Select IV set brand

After calibration of infusion sets, entering 'parameter setting interface', press for 'Tube' and select a brand/ type of IV set (Boon, A, B, C ~ T). Then press ENTER key to save the value and exit.

List of recommended sets

No.	Brand of set	Model/ Specification
1	Boon	A2
2	Hawkmed	A-1

For new brand infusion set, self-define infusion set brand as follows:

1) Press STOP key and first soft key on top right at the same time.

The Tube brand become editable. Press "＋" or "－" to select the 26 alphabet(A,B,C......Z) and digital number (0-9). Press SILENCE key to input space.

2) After finish setting one letter, press "→ "soft key to go to next letter.

Press "←" soft key to change previous letter.

3) After finish setting the infusion set brand, press ENTER key to save the setting.

Infusion set brand name will be displayed on top left of LCD.

The infusion pump could store 20 brands infusion set's accuracy.

Press “＋” or “－” soft key to change to next infusion set brand. The LCD will display TUBE B, TUBE C....... User could self-define infusion set brand as per methods above.

★ After selecting a brand of IV set, its corresponding accuracy which has been calibrated shall be automatically effective.

★ The Infusion Pump uses IV set under brand of Boon for factory setting (default setting). Using the other brand of IV set needs calibrating the accuracy of that IV set, otherwise accuracy can’t be ensured.

8.3.6 Set drop/ml

After entering ‘parameter setting interface’, press ◯ for ‘D./ml’ and input the actual value of drops/ml as shown on the package of IV set. Then press ENTER key to save the value and exit.

8.3.7 Accuracy calibration of IV set

1. Calibration

Install the IV set as per instructions in 8.1.3, and prepare a measuring cup for flown-out liquid. After entering ‘parameter setting interface’, press ◯ for ‘Accu.’ to enter IV set calibration mode.

Press START key, the Infusion Pump shall start operation at 150ml/h. After it finishes VTBI (10ml), measuring the flown-out liquid in measuring cup, input this actual flown-out volume on “real” text of calibration interface. Then press ENTER key to save the value and exit. The calibration of this brand/type of IV set is completed.

The accuracy calibration is directly related to the measurement of the actual flown-out fluid/quality. Please use high-precision electronic scale or other measuring instrument (10ml syringe).

Test method in detail refer to Annex Ⅱ.

2. Compensate

It is only needed when accuracy out of ±5% after calibration. Press “2” for accuracy compensate.

1) 25 ml/h adjustment

2) 150 ml/h adjustment

3) 600 ml/h adjustment

4) 1200 ml/h adjustment

Use following formula to calculate the compensate value:

(VTBI-Volume infused)÷ VTBI×100% =compensate value

Enter compensate value by white text. Press “ENTER” key to save the value.

Attention: Please use positive number or negative number according to calculation result.

2.1 When current flow rate is within 0.1-25ml/h, press “1” to select “25ml/h adjustment”.

2.2 When current flow rate is within 25.01-150ml/h, press “2” to select “150ml/h adjustment”.

2.3 When current flow rate is within 150.01-600ml/h, press “3” to select “600ml/h adjustment”.

2.4 When current flow rate is within 600.01-1200ml/h, press “4” to select “1200ml/h adjustment”.

It is same method to input compensate value for different flow rate range.

8.3.8 Set alarm sound level

After entering ‘parameter setting interface’, press for ‘Next’ to turn to next page. Press for ‘Sound’ and select desired sound level (low, high). Then press ENTER key to save the value and exit.

8.3.9 Set LCD backlight level

After entering ‘parameter setting interface’, press for ‘Back L’ and press “+1” to select 1min, 2min, 3min, 4min, 5min (i.e. dark after 1min etc), DARK or press “-1” to select BRIGHTNESS. Then press ENTER key to save the value and exit.

★ Selecting ‘1min’ means the LCD shall automatically darken in 1 minute if no operation on keys.

8.3.10 Set key sound

After entering ‘parameter setting interface’, press for ‘Key S’ and select ON or OFF. Then press ENTER key to save the value and exit.

8.3.11 Set real date and time

After entering ‘parameter setting interface’, press for ‘Time’ and input value for year/month/day/hour/minute/second. Press ENTER key to save the value and exit.

8.3.12 Set pressure base value

After entering ‘parameter setting interface’, press for ‘Press’, it display “press 1 and its value, press 2 and its value, press 3 and its value”.

The smaller the pressure base value, the higher sensitivity of the occlusion alarm. It should be calibrated by a pressure gauge. Select occlusion pressure level (8.3.3), test actual pressure value by pressure gauge, then adjust pressure base value.

when actual pressure value is lower than pressure value displayed on the pump (for example, L4: 40 kPa), increase pressure base value; when actual pressure value is higher than pressure value displayed on the pump (for example, L4: 40 kPa), decrease the pressure base value.

“Press 1” is related to occlusion pressure level 1-4. Which means when use occlusion pressure level 1-4 for testing, the actual pressure value is out of pressure value displayed on the pump, it needs to adjust pressure base value in “Press 1”.

“Press 2” is related to occlusion pressure level 5-9. Which means when use occlusion pressure level 5-9 for testing, the actual pressure value is out of pressure value displayed on the pump, it needs to adjust pressure base value in “Press 2”.

“Press 3” is related to occlusion pressure level 10-13. Which means when use occlusion pressure level 10-13 for testing, the actual pressure value is out of pressure value displayed on the pump, it needs to adjust pressure base value in “Press 3”.

8.3.13 View the event logs/alarm records

After entering ‘parameter setting interface’, press for ‘Log’. Select ‘1 Upload log’, all infusion records can be viewed on computer (only available when connect the pump to computer by RS232 interface). Select ‘2 View log’, the pump can directly display the latest 1500 infusion / alarm information. Select ‘3 Back’’, the pump shall return to ‘parameter setting interface’.

(1) Upload log: upload infusion records to computer. Please refer to steps as follows:

a. Connect the Infusion Pump to a computer with RS-232 cable.

Computer (in power-on status)—click “start” (left bottom corner)—click “programs”—click “accessories’—click “communication”—click “hyper terminal”—click disconnect icon .

Then in “file” menu, select “properties” and set COM interface (according to actual 232 port).

b. In “115200 properties” interface, click “configure” and set “baud rate” as 115200 and data flow control as Xon/ Xoff.

c. After setting is complete, click call icon  to connect to terminal.

d. In Hyper Terminal interface to select "Transfer - Capture Text", recommending set up a txt named after an infusion pump serial number on the computer, and then click "Start."

e. Press 1 soft key, upload infusion records to computer terminal. Press “transfer-capture text” after finishing uploading. And all infusion/alarms records can be reviewed on the txt that setting previously. After finishing uploading, the infusion pump returns to superior menu interface automatically.

(2) 2 View Log: Select “2 View log” to view latest 1300 pieces of infusion / alarm information. Press ‘Prev.’ to check the previous records or ‘Next’ for next records. Press ‘Back’ to return to ‘Log’ interface. Select “3.Back” to return to parameter setting interface.

8.3.14 “No Operate” alarm on and off setting

After entering ‘parameter setting interface’, press for ‘Next’ to turn to next page. Press for ‘No Op’ and select ON or OFF. Then press ENTER key to save the value and exit.

“No Operate” alarm setting as on: in ‘stop’ status, “No Operate” alarm shall sound when no operation on keys in 2 minutes.

8.3.15 “Almost Done” alarm on and off setting

After entering ‘parameter setting interface’, press for “Almost Done” and select ON or OFF. Then press ENTER key to save the value and exit.

If setting as ON, “Almost Done” alarm shall sound 3 minutes before VTBI is complete.

8.3.16 Night mode on and off setting

After entering ‘parameter setting interface’, press for ‘NIGHT’ and select ON or OFF. Then press ENTER key to save the value and exit.

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

It is option to set Night mode start and stop automatically. After setting the start time and end time, the infusion pump will start and finish night mode automatically.

8.3.17 WIFI

The infusion pump supports connection to HK-M1000 infusion monitoring system wirelessly, it works through WIFI module (optional) and router (optional).

Start WIFI function: After entering ‘parameter setting interface’, select WIFI, set it ON to active the WIFI function. It will connect to the WIFI network which connected successfully last time.

WIFI functions: send the infusion status and alarms to HK-M1000 infusion monitoring system. For more information please refer to User manual of HK-M1000 Infusion monitoring system.

Attention: The configuration should be setting by the authorized engineer.

8.3.18 Dedicated set

After entering ‘parameter setting interface’, press for ‘DedSet’. The device display the password “00000”, press ENTER key, set the function on or off. When the setting is on, the infusion pump will only work when it detects the dedicated key. When the setting is off, the infusion pump will work without detection of dedicated key.

Change password of this function (Default password: 00000): Press “Code” soft key, input new password, press ENTER key to save it.

8.3.19 Drop sensor

After entering ‘parameter setting interface’, press for ‘sensor’, set the function on or off. When infusion pump is equipped with drop sensor, set the function as on. When the infusion pump is not equipped with drop sensor, set the function as off.

8.3.20 Inspection remind time

After entering ‘parameter setting interface’, press for ‘Maint’, set the function off as 0 or 1-48 months. This function will remind user make inspection of device as per setting time.

8.3.21 Keypad lock

After entering ‘parameter setting interface’, press for ‘KLock’ and press “+1” key for 1min, 2min, 3min, 4min or 5min, or press “-1” key to select OFF. Then press ENTER key to save the value and exit.

Setting as 1min means all keys shall be locked (except POWER key) after 1minute if no operation on keys. This icon  shall display on LCD.

To unlock the panel, press ENTER key + (2nd soft key on top left) together.

8.3.22 POST (Power on self-testing)

After entering 'parameter setting interface', press for 'POST', set the function on or off. When the setting is on, the infusion pump will make self-testing when turn on the device.

When the setting is off, the infusion pump will not make self-testing when turn on the device.

8.3.23 Machine info

It displays the machine software version and release version.

8.3.24 Standby Mode

It has to active Standby mode before using it. Please enter 'parameter setting interface', press for "StandB", make the setting as on, press ENTER key to save and exit.

In main menu interface, long pressing STOP key to enter standby mode setting interface. Input standby time, press ENTER key to save it. The infusion pump will start standby function as per setting time.

During the standby, all functions are disabled. Press any key to wake up.

8.3.25 Auto shutoff

After entering 'parameter setting interface', press for 'P_off'(Power off), set the function on or off.

When set the time as 0, which will close this function.

When set the time 1-120min, which means if no operation on the pump for 1-120 min, the infusion pump will turn off automatically.

8.3.26 Purge

After entering 'parameter setting interface', press for 'Purge', setting the purge rate and volume, press ENTER key to save and exit.

Purge	Default value	Adjustable range
	Rate: 600ml/h	0.1-1200ml/h
	Volume: 0ml	0-9999.99ml, 0 means manual purge. When volume large than 0, which means auto purge function.

Attention: Please use purge function before infusion, and please make sure the infusion line is not connected to the patient.

8.3.27 Bed No. Setting

Press and hold on STOP key first, then press ◯(4th soft key on left) to enter bed No. setting interface. After setting bed No., press ENTER key to save the value. Press and hold on STOP key first, then press ◯ (4th soft key on left) to exit.

★ If not setting the Bed No., the pump cannot be connected to HK-M1000 infusion monitoring system by WIFI. One bed can be connected with maximum 12 unit pumps.

8.4 Select language and restore default

Press and hold on STOP key first, then press ◯ (2nd soft key on left) to enter language setting interface. Press soft keys to select "1.Chinese", "2. English", etc.

Press the 4th soft key on left for "Restore Default", all factory settings shall be restored.

★ After selecting 'Restore Default', the accuracy need re-calibration.

Press and hold on STOP key first, then press ◯ (2nd soft key on left) to exit.

The default parameters at the factory are shown in this table:

Parameters	Factory default setting	Parameters	Factory default setting
Self-testing	On	Sound	High
KVO	1ml/h	Backlight	Bright
Bolus	1000ml/h	Key sound	On
Occlusion alarm	Level 8 (80kPa)	Time	
Air bubble alarm	Level 2 (50ul)	Pressure value	80
Infusion tube:	BOON	Log	
drop/ml	1ml=20drops	No operation	Off
Calibration		Almost done	Off
Night mode	Off	Dedicated set	Off (password:00000)
WIFI	Off	Drop sensor	Off
Inspection time	3 months	Device info	V01
Keypad lock	Off	Standby mode	On
Purge rate	600ml/h	Auto shutoff	0min (off)

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 valid Medical Device Registration Certificate.
- The Infusion Pump uses 'Boon' brand A2 IV 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. Malfunction Analysis and Solutions

Problems	Causes	Solutions
Frequent Air Bubble alarm	The IV set too soft or too thin.	replace IV set

	Small air bubble in the IV set.	Select a higher level air bubble filter.
Accuracy discrepancy	The IV set is not calibrated.	Calibrate the accuracy of IV set
	The IV set currently used does not match the default brand.	Select the correct brand of IV set.
	Due to variation in weather and temperature, the internal parameters of the pump incompatible with that of the IV set actually used.	Re-calibrate the accuracy of IV set.
	certain parts of the 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 recycling

11.1 Routine maintenance

Routine maintenance includes the cleaning of outer shell and pump body. Clean it with wet soft cloth. 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 the pump body and surrounding areas. Medical liquid may drip into the Infusion Pump during infusion process. Certain medical fluid may corrode the pump body and certain may stick on the peristaltic chips, therefore clean the Infusion Pump every time after infusion completion.

11.3 Periodic 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 on 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 Level 8.

(2) Install IV set in the Infusion Pump. Close the door and open the flow clip of IV set.

(3) Upon pressing START key, use a stopwatch to measure the time taken for occlusion alarm.

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

Testing method:

(1) Install IV set in the Infusion Pump and set flow rate at 150ml/h, volume to be infused as

200ml, air bubble detection level as Level 2 (50ul) and then start infusion.

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

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

★ When air bubble detection level setting as Level 2 (50ul), Air Bubble alarm shall be given upon detection the size of air bubble about 4mm.

11.3.4 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 ±3%.

11.3.5 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.

Replace internal battery

(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.

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 13.2 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.

11.6 Recycling

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

(1) The scrapped Infusion Pump 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. Electro Magnetic Compatibility declaration

(1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

(2) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

(3) Caution: this machine should not be used adjacent to or stacked with other equipment and

that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

(4) Warning: The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the Infusion pump as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Infusion pump.

<table>
<tr><td colspan="3">Guidance and manufacture's declaration – electromagnetic emission</td></tr>
<tr><td colspan="3">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..</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment–guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Infusion pump use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class B</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

<table>
<tr><td colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
</table>

Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.

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

The Infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of Infusion pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.5 GHz	3 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Infusion pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.167 $\sqrt{P}$ d = 1.167 $\sqrt{P}$ 80 MHz to 800 MHz d=2.333 $\sqrt{P}$ 800 MHz to 2.5 GHz

			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless)			

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

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

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

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

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

For transmitters rated at a maximum output power not listed above, the recommended separation

distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

13. Transport and storage

13.1 Precautions during transport

(1) Place the product as per No. of layers indicated on packing carton.

(2) Temperature: --20℃～45℃;

(3) Relative humidity: 10～85% (no frosting)

(4) Atmosphere pressure: 50.0kPa～106.0kPa

13.2 Storage conditions

Storage temperature: -20℃～+45℃(With battery)

-20℃～+60℃(Without battery)

Relative humidity: 10～85% (no frosting)

Atmosphere pressure: 50.0kPa～106.0kPa

14. Package list

14.1 Standard configuration in a package

①Infusion Pump 1unit

② AC power cord 1set

③User Manual 1 pc

④Warranty card 1pc

⑤Product qualification certificate 1 pc

14.2 Optional parts

WIFI module

Drop sensor

15. 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.

16. After sales service

The warranty for the Infusion Pump is one (1) year. Within warranty, manufacturer can offer spare parts for free.

Note: The following situation is not within the range of warranty.

(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 spare parts but charge the cost. Local repair is responsible by distributors.

Annex Ⅰ

Table 1 Classification of alarms and color of alarm indicator light

Classification of alarms	Alarm priority	Color and frequency of alarm indicator light
Door Open alarm	High priority	Red/ 2Hz
Air Bubble alarm	High priority	Red/ 2Hz
Occlusion alarm	High priority	Red/ 2Hz
LowBattery alarm	High priority	Red/ 2Hz

B. Exhaust alarm	High priority	Red/ 2Hz
Finished alarm	High priority	Red/ 2Hz
Check tube alarm	High priority	Red/ 2Hz
AlmostDone alarm	Low priority	Yellow,steady
AC Fail alarm	Low priority	Yellow,steady
UseBattery alarm	Low priority	Yellow,steady
No Operate alarm	Low priority	Yellow,steady

Table 2 Alarm conditions and alarm signal delay

Names of alarms	Alarm condition delay	Alarm signal delay
Door Open alarm	10ms	100ms
Air Bubble alarm	110ms	100ms
Occlusion alarm	840s@1ml/h, 27s@25ml/h	100ms
LowBattery alarm	10ms	100ms
B. Exhaust alarm	500ms	100ms
Check tube	10ms	100ms
Finished alarm	10ms	100ms
AlmostDone alarm	10ms	200ms
AC Fail alarm	10ms	200ms
UseBattery alarm	10ms	200ms
No Operate alarm	120 ms	200ms

Table 3 Characteristic parameters of alarm signals

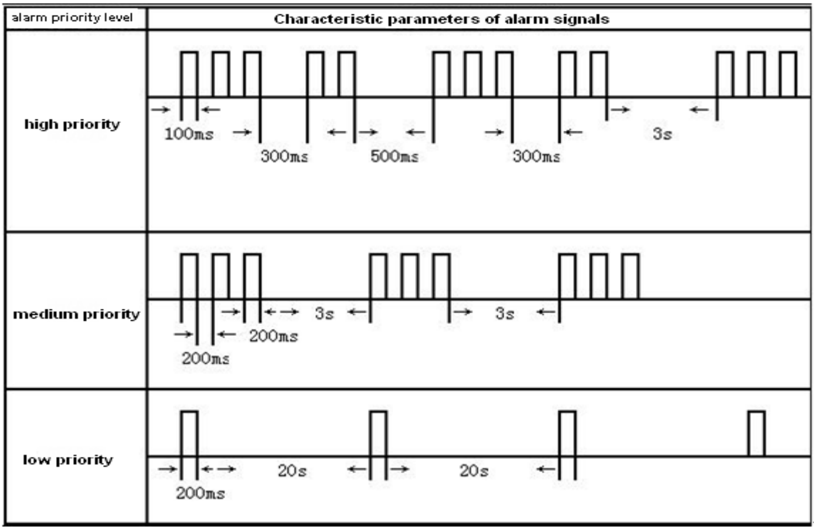


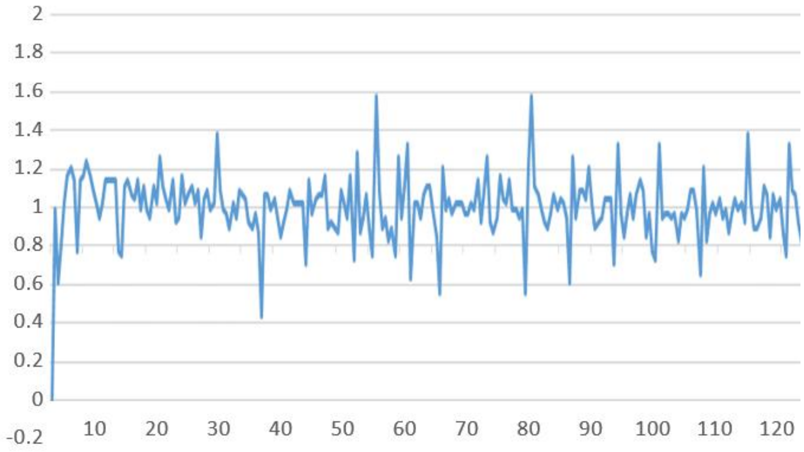
Table 4 Occlusion response characteristic

Flow Rate (ml/h)	OCCL alarm level	Occlusion pressure(KPa)	OCCLUSION alarm time	Dosage (ml)
1	1	14	0h8min17sec	0.17
	8	86	0h58min42sec	0.99
	13	138	1h48min26sec	1.69
25	1	13	0h0min23sec	0.16
	8	85	0h2min19sec	0.97
	13	134	0h3min31sec	1.48

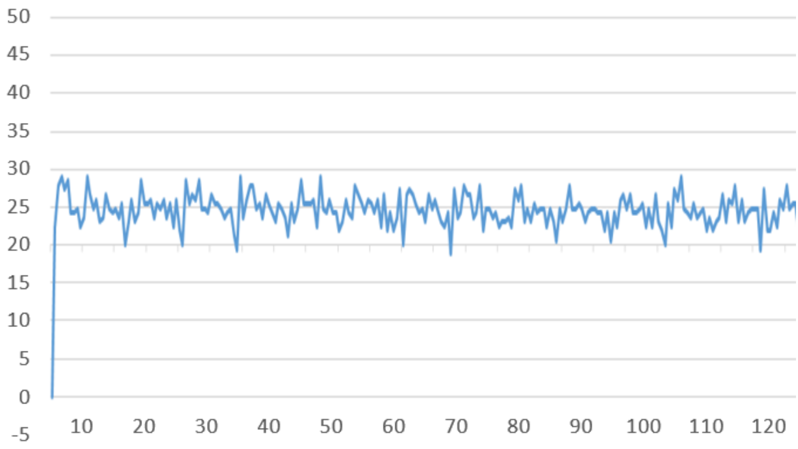
★ The above test uses ‘Boon’ brand IV set. All the data are obtained by following conditions: The three-way tap is 1m away from the Infusion Pump; two operations at rate of 1ml/h and 25ml/h respectively.

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

Table 5 Starting Curves

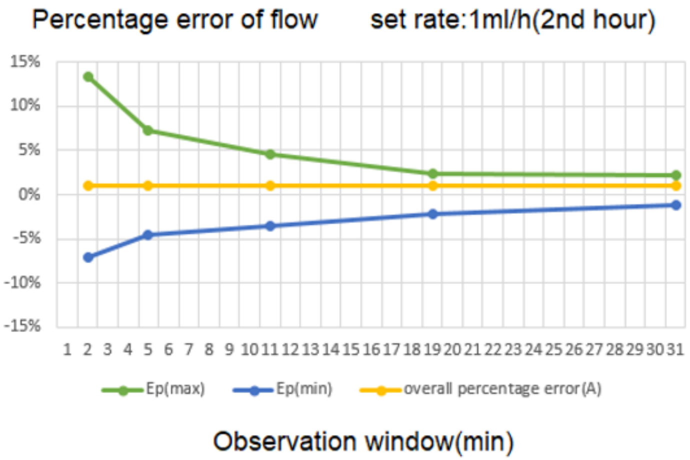


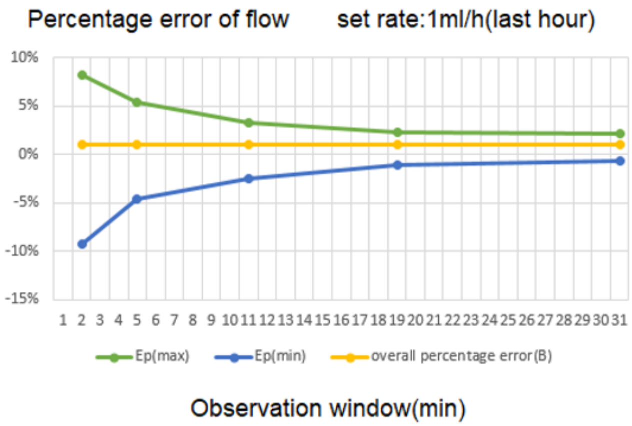
1ml Starting Curves



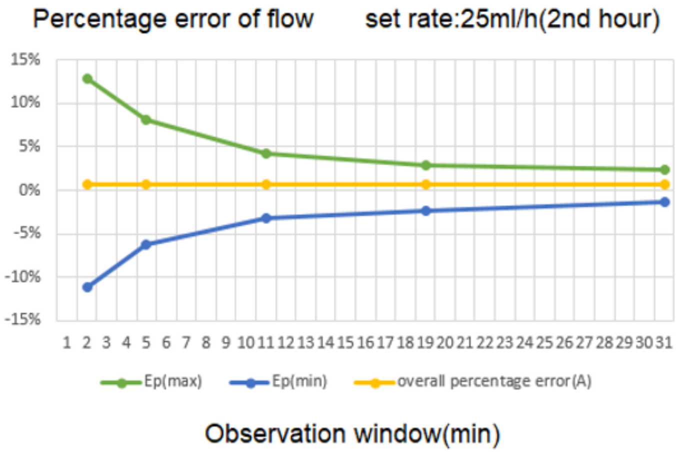
25ml Starting Curves

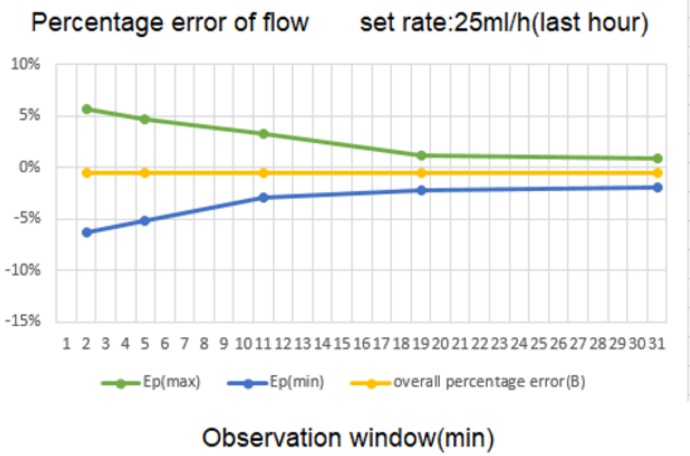
Table 6 Trumpet Curves





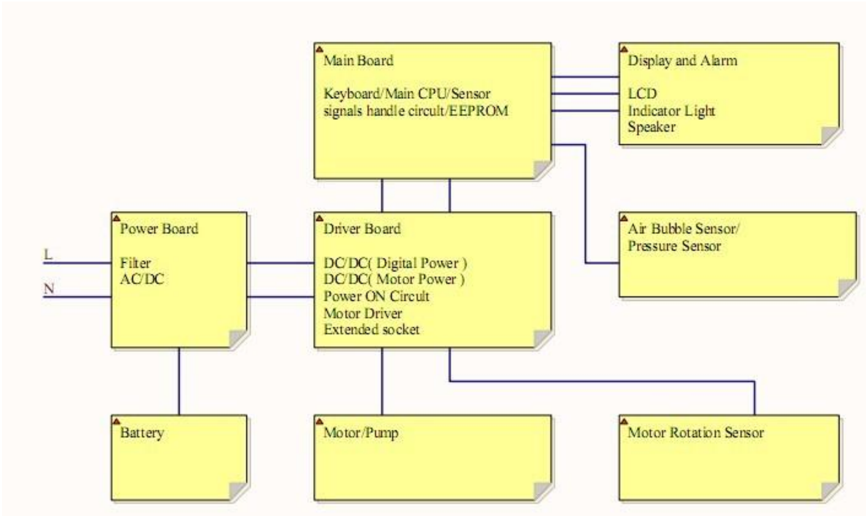
1ml Trumpet Curves





25ml Trumpet Curves

Table 7 circuit diagram

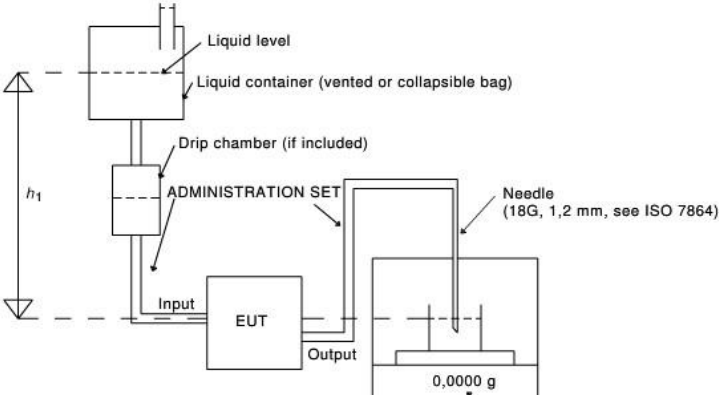


Appendix II Infusion pump flow volume accuracy test methods

1. Test method: gravimetric method.

2. Principle

Gravimetric method uses electronic balance as the calibration test equipment. 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. This method uses electronic balance to collect the total output volume of the infusion pump during test period. The error calculated by differences between preset volume and actual weighing weight.



(diagram 2-1)

3. Test Environment

3.1 Temperature: 20±2°C

3.2 Relative humidity: 60±15%

3.3 Atmospheric pressure: 86kPa～106kPa（645mmHg～795mmHg）(note: A 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,1.2mm, refer to GB15811)

4.3 Infusion set(infusion set for pump use or infusion set under Boon brand）

4.4 Connecting components (connecting pipe and injection needle)

4.5 Collector (beaker + anti-volatile paraffin oil)

5 Test procedures

5.1 Connect infusion pump, infusion set, electronic balance and container as diagram 2-1 (among it h is 50cm±20cm)

5.2 The balance is placed in suitable fixed position; the collector is placed in the balance. Put certain amount of water to beaker and certain drops of Anti-volatile oil. (Record the readings of electronic balance. Confirm weight change of collector per hour less than 0.001g / h before testing)

5.3 Connect a brand new infusion set as per instruction, immerse injection needle below the surface of fluid in collector and keep hanging. Ensure injection needle holder is relatively higher enough than fluid surface. (Prevent fluid level rises so immerse the injection needle holder).

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

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

5.6 Press and hold on STOP key first, then press (1st soft key on top left) to enter 'parameter setting interface', press for 'Accu.' to enter IV set calibration mode.

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 "real" text of calibration interface. Then press ENTER 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 +3%.

6. Supplements

6.1 The consistency of infusion set

The infusion set used in test procedure, the pipeline cross-sectional area of the size, the diameter consistency, resilience have a greater effect on accuracy of infusion pump. Usually require calibration prior to use.

6.2 Stability of connecting components

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

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 Effect by other factors

As per the effect by environmental of solution, it needs to check infusion liquid filter blockage after testing. When a blockage occurs, the test should be repeated.

6.5 High-quality dedicated infusion set:

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

b）Silicone tube working length: 320mm5mm

c）Tensile strength: 9.01.4N/mm²

d）Hardness: 562 Shore hardness A

e）Silicone tube wall manufacturing error: 0.0254mm

Note: Accuracy testing can also use infusion set that has similar performance as an alternative for peristaltic pump, such as Boon brand infusion set.

Manufacturer : Shenzhen Hawk Medical Instrument Co., Ltd.
Address: 1st Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community Longhua Street, Longhua District, Shenzhen, 518109, Guangdong, P.R.China
Tel: 0086-755-8315 1901
Fax: 0086-755-8315 1906
Email: szhk@hawkmedical.cn
Web: www.hawkmedical.cn

Name: WellKang Ltd
Address:The Black Church, St. Mary's Place,Dublin 7, D07 P4AX, Ireland
Tel 1: +353(1)2542900
Tel 2: +353 (1)4433560
Fax: +353(1)6864856
Web: www.CE-marking.eu & www.well-kang.com
Email: AuthRep@CE-marking.eu, AR@Well-Kang.com