INFUSION PUMP OPERATION MANUAL C €0123



Intellectual property

This Operation Manual and its relative product intellectual property belongs to our company.

Any person or organization will not allow to copy, amend or translate any content of this operation manual without the permission of us.

Statement:

We reserves the right to interpret the operation manual.

We can revise the content of this operation manual without prior notice.

We will be not responsible for any software and equipment which is not provided by us.

We will only be responsible for the safety, reliability and performance in the following case:

- Installation, test, upgrade, maintenance are all done by our personnel or authorized person by our company..
- All the maintenance spare parts should be from us or accepted by us.
- Please follow the electrical appliance national standard and the instruction of the operation manual.
- Strictly follow the instruction of the operation manual.

Warranty and Maintenance Service

The warranty is 12 month for the device and main accessories warranty is 6 months, main accessories include Power Cord, Battery, Drip Sensor.

If the warranty period is not the same as above mentioned, please contact us. If it is not confirmed by us, please contact your supplier.

The warranty period starts from the date of the Invoice and it is the only proof to calculate the warranty period. For your benefit, please inform us the qualified installation within 30days, or the warranty date will starts from the date on the packaging till 30 days.

It will be free for after-sales service under warranty. It will be charged in the following case:

- Artificial damage
- Improperly operation
- Grid voltage is out of the ruled range.
- Force majeure
- Maintained by personnel not authorized by us.
- Use the spare parts which is not provided or confirmed by us.
- Fault which is not caused by the device itself.

When warranty period is expired, the service will be charged. If service charge is rejected to pay or not paid on time, then we will have the right to stop servicing until the charge is paid.

Table Content

SAFETY PRECAUTIONS	5
PRECAUTIONS	6
1.1 APPLICATION AND CONTRAINDICATIONS	
1.2 MAIN COMPONENT AND FUNCTION	
1.3 TECHNICAL PARAMETER	
1.3.1. Compliance	
1.3.2. Working and Transportation and storage conditions	
1.3.3. Power Supply	9
1.3.4. Battery	9
1.3.5. Physical Specification	9
1.3.6. Basic Parameter	9
1.4 FUNCTION DESCRIPTION	
1.5 COMPONENTS AND FUNCTION	
1.5.1. Components and Functions in the Front Housing	
1.5.2.Infusion Set Path Module	
1.5.3.LCD Display	
1.5.4.Function Button	
1.5.5.Function Module of Rear Housing	
1.5.6.Main unit structure	
CHAPTER 2. PACKING LIST AND OPERATION PROCESS	14
2.1 PACKING LIST	
2.2 OPERATION PROCESS	
CHAPTER 3. OPERATION GUIDELINE	
3.1 PREPARATION	16
3.1.1. Package Opened Inspection	
3.1.2. Environmental Standard	
3.1.3. AC Power Standard	
3.1.4.Install Power Cord	
3.2 INSTALLATION AND SETTING	
3.2.1.Install the device and Power On	
3.2.2.Install IV set and remove IV set	
3.2.3.Drip Sensor Installation(optional and need to confirm before order)	
3.2.4.Infusion parameter setting	
3.2.5.Clear Total Volume	
3.3 START INFUSION	
3.4 INFUSION FINISH	
3.5 System Paramter Setting	
3.5.1.Select IV set	
3.5.2.Select Infusion Mode	
3.5.3.Alarm Setting	

3.5.4.KVO setting	
3.5.5.BOLUS setting	
3.5.6.Drug Weight Mode	
3.5.7.Advanced Setting	
3.6 OTHER FUNCTION	
3.6.1.Purge	
3.6.2.Mute Function	
3.6.3.Infusing under battery	
3.6.4. Volume level setting	
3.7 ACOUSTIC AND VISUAL ALARM	
3.7.1.Alarm	
3.7.2.Alarm Level and Alarm way	
3.7.3.Action for alarm	
3.7.4.Alarm and solution	
3.8 OTHER ERROR	
3.9 OCCLUSION	
CHAPTER 4. PRODUCT DAILY CHECK, STORAGE AND TRANSPORTATION CONDITION	
4.1 DAILY CHECK	
4.1.1.Shell Clean	
4.1.2.Daily check for the pump door knob, door shaft and pump door	
4.1.3.Daily check for air sensor	
4.1.4.Daily check for the Peristaltic pump blade, pressure sensor.	
4.1.5.Daily check for infusion fluid path, cradle	
4.1.6.Daily check for the drip sensor	
4.2 BATTERY	
4.2.1. Charge Battery	
4.2.2.Battery performance inspection	
4.2.3.Replace battery	
4.3 REGULAR MAINTENANCE.	
4.3.1.Regular maintenance plan	
4.4 REPLACE THE COMPONENTS REGULARLY	
4.5 TRANSPORTATION AND STORAGE	
4.6 POLLUTION-FREE DISPOSAL AND RECYCLE	
4.7 COMPLIANCE	
CHAPTER 5. APPENDIX	
5.1 Appendix I Electromagnetic Compatibility	
5.2 APPENDIX IIIV TRUMPET CURVE	
5.3 APPENDIX 5 SYMBOL AND TERMS	

Safety Precautions

1.Warning and Note

In the instructions for the use of infusion pumps, according to the importance of the prompt information, they are divided into two categories: warning and note, meaning as follows:

Warning

Representation information involves security and validity. Failure to operate according to warning information may cause injury.

Note:

Representation of information involves guidance recommendations, failing to follow the attention information operation, may affect the normal use of products.

Be sure to read the warnings and attentions listed in this instructions carefully.

Warning

- (1) The device is not portable device and not used on the bed of the patient.
- (2) This device is used for Intravenous infusions, not used for eternal and intragastric infusion. It can only be used by well-trained clinical nurses or doctors.
- (3) Please use three-plug socket and make sure the connection well and don't touch the socket with wet hands.
- (4) It is not allowed to use voltage other than that specified on the product label, or else it might cause damage or even fire.
- (5) Please check the device and the accessories completely before use to make sure the normal safe working.
- (6) Please don't rely on the device alarm only and pay close attention to the remaining volume and air in the IV set any time during infusion.
- (7) Set the alarm value based on the patient's condition and keep a close eye on the patient rather than reply on the alarm only.
- (8) Stop using the device while alarming.
- (9) It is suggested to use good quality silicone tube with 0.9mm or more than 0.9mm infusion needle under high flow rate infusion(flow rate ≥800ml/h), or the accuracy will be effected.
- (10) Don't install other infusion control device in the same infusion line, or it may be dangerous.
- (11) Don't connect other brand infusion system or other brand accessories, or it may be dangerous.
- (12) Keep the IV line smooth, folded IV line will lead to occlusion and malfunction or other potential accident, such as under flow.
- (13) It is suggested to change the IV set pressing position every 5-6 hours.
- (14) Use the device within 120cm around the patient's heart.
- (15) Do not operate this device in environments where there are gas mixtures of flammable anesthetic, oxygen and oxidize ammonia, etc.
- (16) Do not operate this device in environments where there is strong sun light, cold and hot wind and dusty.
- (17) Microwave will influence the function of the device, the device near the infusion pump must meet the standard of EMC. Mobile phone, X-ray or MRI device will be the cause of malfunction due to its high frequency radiation.
- (18) It is not allowed to dismantle or modify the device. Opening the shell may be electrocuted. Maintenance or upgrade the device must be done by the well-trained or authorized staff from us.

- (19) To avoid patients being injured by over-flow or under-flow, please set infusion parameters correctly and calibrate before using a new IV set. The deviation may be $\pm 40\%$ for incorrect setting or uncalibrated IV Set
- (20) Check the device daily and check all the function in good condition if it is not used for long period.
- (21) Don't use the device for blood infusion.
- (22) Turn off the device and contact the supplier when there is malfunction.
- (23) Don't put the device to the place where it is hard to operate by the operator

Note:

- (1) Steady the infusion pump on the IV stand. Make sure the device installed steady before use.
- (2) It may lead to work improperly under hyperbaric environment like hyperbaric oxygen ation.
- (3) The device must be operated by medical professional staff, such as doctors, nurses, etc. Avoid operating by the patient himself.
- (4) Clean the surface of the device with the soft cloth with warm water.
- (5) Follow the local regulation or hospital rule when disposing the packing material and keep the packing material away from the children.

Precautions

Note:

This Operation Manual make a detailed introduction for the use, function and operation instructions. Please read the manual completely prior to using this device. Please carry out inspection and maintenance to the pump periodically according to the manual in order to avoid patient/user injury

The manual have the most complete function and features. Please pay attention to the relative model and the relative function and features. Any question, please contact us.

Please put the operation manual beside the device for easy reference.

Operator

The operation manual is only used by well-trained clinical nurse or doctors.

Others

The figures in the operation manual is only for reference. The settings or data in the figures may be not 100% same as the real ones.

2. Symbolic Description

List of Symbols Used in Instructions

Symbol	Indications
<u>_!</u>	Warning
	Defibrillation-proof type CF applied part. (Degree of protection against electrical shock)
\sim	AC POWER indicator : When illuminated the pump is connected to an AC power supply and the battery is being charged
÷	BATTERY indicator - When illuminated the pump is running on the internal battery. When flashing the battery power is low with less than 30 minutes of use remaining
IPX3	Protected against vertically falling drops of water
	Date of Manufacture
	Manufacturer
\$	MUTE button - Press to silence alarm for (approximately) 2 minutes. The alarm will resound after this time
۲	 BOLUS button - Press to access BOLUS soft key. Press and hold down soft key to operate. BOLUS - fluid or drug delivered at an accelerated rate. Pump is infusing Infusion set is connected to patient. Volume infused (VI) is added to the total volume infused displayed
<u></u>	ON/OFF button - Press once to switch the pump ON. Press and hold down for approximately 3 seconds to switch the pump OFF
(\bigcirc)	Non-ionizing radiation
X	Not for Municipal Waste
<u>††</u>	Upward
Ţ	Fragile goods, handled with care
Ť	Away from rain
	Away from direct sunshine
500x	Atmospheric pressure limit
and the second s	Humidity limit
780 - 270.	Temperature Limit
5	Stacking layer limit

Chapter 1. Introduction 1.1 Application and Contraindications

The infusion pump is intended to provide accurate and continuous intravenous infusion in medical centers for clinical treatment. The infusion pump can replace the traditional intravenous infusion to make the medicine infuse at a constant speed. By adjusting the input speed and time, the medicine can be injected uniformly and continuously, which can not only achieve the best effect of treatment, but also minimize the side effects of the treatment medicine. It is widely used in medicine, surgery, pediatrics, cardiovascular department, emergency department and operating room, especially in the infusion treatment of ICU and CCU ward.

- a) Scope of application: more than 40 kinds of drugs, such as dopamine, anesthetics, antihypertensive drugs, Pinpu sodium, mannitol, etc..
- b) Applicable departments: internal medicine, surgery, pediatrics, cardiovascular department, emergency department, gynecology, oncology department and operating room, especially for infusion treatment in ICU and CCU ward; not suitable for use in transportation.

Contraindications: It is forbidden to use blood transfusion, insulin, analgesia, chemotherapy and epidural anesthetics

1.2 Main component and function

The infusion pump is consisted by LCD display, front housing module, main control board, finger pump, driving module, door module, back housing module, battery, the system include circuit control system, alarm detection system, input out system and driving module system.

The infusion pump is consisted by the following parts:

- ■Circuit Control System: It is core of the whole system. It can intelligently control, manage and processing the signal of the system. The double CPU is monitoring and backing up each other. When one CPU has problem, the other will make alarm and stop the power supply and stop working to make sure the safety of the patient.
- Alarm system: Consisted by audio, visual alarm and message information to remind the user the abnormal information to avoid the harm to the patient, the detection system includes all kinds of sensor, such as air sensor(detect the bubble inside the IV tube), pressure sensor(detect the pressure inside the iv tube, etc.
- Input and display: Input the infusion parameter, eg. VTBI, flow rate, etc. Display the infusion parameter and alarm message.
- Mechanical driving setting: Finger Pump, the driving force of infusion with step motor moving and pressing the IV set.

1.3 Technical Parameter

1.3.1. Compliance

Protection against electric shocks : Class I, include the internal power supply

Protection against leakage current : Type CF, the part without defibrillation discharge effect

Protection against splashing fluid : IPX3

Working Mode : Constant infusion.

1.3.2. Working and Transportation and storage conditions

Temperature : $+5^{\circ}C \sim +40^{\circ}C$ Relative Humidity : $20 \sim 80\%$, not condensation Atmospheric Pressure : $70KPa \sim 106Kpa$ Transportation and Storage Temperature : $-20^{\circ}C \sim +50^{\circ}C$ Transportation and Storage Humidity : $10 \sim 95\%$, not condensation Transportation and Storage Atmospheric Pressure : $50KPa \sim 106Kpa$

Transportation and Storage Condition : No corroded air and good ventilated environment

1.3.3. Power Supply

Volt : 100~240V **Current :** 0.6~0.3A **Frequency :** 50Hz/60Hz

1.3.4. Battery

Quantity : 1 Type : Rechargeable Lithium battery Capacity : 3000mAh Rated Voltage : DC11.1V Max. Power : 25VA Operation time : ≤ 10 hr at 25ml/h after fully charged Recharging time : 14-16hrs

1.3.5. Physical Specification

Device Dimension : 145mm×150mm×200mm

Weight : $\approx 1.7 \text{ Kg}$

LCD Type : LCD with high brightness

LCD size : 3.2inch

1.3.6. Basic Parameter

Pump : Detachable peristaltic finger pump

Applicable IV set : Exclusive IV Set or standard single PVC IV Set(10, 15, 20 and 60 d/mL, with outer diameter $3.4 \sim 4.5 \text{mm}$)

Infusion Mode : Volume mode, bolus mode, drip mode, drug mode, volume/time mode

Flow Rate : 10d/m	l: $1.0 \text{ml/h} \sim 1200 \text{ml/h};$	$15d/ml: 1.0ml/h \sim 1200ml/h$
20d/m	nl: 1.0ml/h~1200ml/h;	60d/ml: 1.0ml/h~150ml/h
Drip Rate : 10d/m	l: 1.0d/min~200d/min;	15d/ml: 1.0d/min~300d/min
20d/m	nl: 1.0d/min~400d/min;	60d/ml: 1.0d/min~150d/min
Flow Rate Increme	nt : 10d/ml: 1.0~99.9ml/h in 0	0.1ml/h increment; $100 \sim 1200$ ml/h in 1ml/h increment
	15d/ml: 1.0~99.9ml/h in 0.	1 ml/h increment; $100 \sim 1200$ ml/h in 1 ml/h increment
	20d/ml: 1.0~99.9ml/h in 0.	1 ml/h increment; $100 \sim 1200$ ml/h in 1 ml/h increment
	60d/ml: 1.0~99.9ml/h in 0.	1ml/h increment; $100 \sim 150$ ml/h in 1ml/h increment
Drip Rate Increme	nt : in 1 d/min increment	
VTBI : 0.1-9999.9	ml; in 0.1ml increment	
Total Volume : 0-9	9999.9ml	
Time Setting : 1 m	nin~99h00min (or>99h)	
Flow Rate Deviatio	n : $\leq \pm 5\%$ (Standard PVC exc	lusive or single use IV set after calibration, and Except under
	single fault condition)	
KVO : 1.0~5.0m	l/h adjustable (keep vein open at	the lowest speed)
Purge Rate : 10	15, 20d/ml: 600ml/h, with purg	e rate display

60d/ml: 150ml/h, with purge rate display

Occlusion Pressure Sensor : Up pressure sensor (optional and need to confirm before order), down pressure sensor detection, Up occlusion sensor: -10KPa~-70KPa, down occlusion sensor: 40KPa~ 130KPa, down occlusion with 10 level adjustable with dynamic pressure value display (Up pressure sensor is optional and need to confirm the model before order)

Air Bubble Detector : Ultrasonic air detection, $>50\mu$ l air bubble, single bubble $50\sim300\mu$ l, 10 level adjustable

Alarm Volume : Alarm volume with 10 level adjustable

Button Function : Total Number keypad, user friendly

BOLUS : Bolus Function, flow rate adjustable

Night Mode : LCD become dim in 2min after night mode on.

Motor Anti- Reverse Function : Motor anti-verse function and monitor the motor constantly.

Self-Testing : Real time self-testing

Acoustic and Visual Alarm : Air bubble in line, upstream occlusion, downstream occlusion, door open, finish, standby time expired, battery low, no battery, battery disconnection, AC Power disconnection, motor error, pump error, pressure sensor disconnection, parameter error, drop sensor error, drop sensor disconnection, free flow, bottle empty, system abnormal, communication error, IV set not calibrated, air sensor error

IV set management and calibration : Open system, acceptable all kinds of IV set after calibration.

Note:

- The specification change can be changed without prior notice.
- The Drip sensor error, drip sensor disconnected, free flow, bottle empty is for optional model and need to confirm before order.
- Under single fault condition: the infusion deviation should also be limited. For example, when over flow and under flow are found, the infusion deviation should be ≤±12%. When the infusion deviation is more than 12%, the pump error alarm will occur, it suggests that the infusion pump is over infusion and under infusion.

1.4 Function Description

- 1.4.1. The infusion pump with full function of acoustic and visual alarm and exact infusion-controlled system with high safety and reliability. It can make all kinds of alarm, eg. Air in line, infusion finish, occlusion, battery low, door open and infusion abnormal.
- 1.4.2. Infusion pump is available for the intravenous infusion of normal brine and dextrose, is also for the infusion of high surface tension.
- 1.4.3. Exclusive IV Set and standard single used PVC IV set is applicable.
- 1.4.4. The battery supply system can guarantee the continuous infusion when the patient needs to be moved or the AC power is disconnected. (The life can be more than 10hrs at the speed of 25ml/h after it is fully charged.

1.5 Components and Function

Infusion pump is made of LCD display, front shell module, main control board, finger pump, driving module, back shell module, battery, the system includes circuit control system, alarm detection system, input & output system, and mechanical driving system.

Circuit system is consisted by mother board, display control board, power board and all kinds of transfer board;

Input & Output system is consisted by LCD, speaker, keypad and alarm light, etc.

Alarm detection system is consisted by pressure detection sensor, air sensor, drop sensor, etc.

Motor driving system is consisted by motor driving system, front and back shell and peristaltic finger pump, etc. **Note:**

- Air Sensor can detect the 50µl or more than 50µl bubble. It can make visual and acoustic alarm after air bubble detection and stop infusion to avoid the bubble into the body of the patient.
- Please pay close attention to the patient during infusion and don't reply on the alarm only for the air bubble.

1.5.1. Components and Functions in the Front Housing



1.5.2.Infusion Set Path Module



1.5.3.LCD Display



1.5.4. Function Button



1.5.5.Function Module of Rear Housing



1.5.6.Main unit structure



Chapter 2. Packing List and Operation Process

2.1 Packing List

Please check the following parts once opening the package:

(1)	Infusion Pump1	pc
(2)	Power Cord1	pc
(3)	Drip Sensor1	pc
(4)	Operation Manual1	pc
(5)	Quick Operation Guide1	pc
(6)	Quality Inspection Certificate1	pc

2.2 Operation Process



Note:

- If the IV set and infusion unit is the same as last operation, then please input the flow rate, time, VTBI directly (The step to select unit, IV Set, alarm setting can be skipped)
- The previous parameter except the infused volume will be kept in memory after power off.

Chapter 3. Operation Guideline 3.1 Preparation

3.1.1. Package Opened Inspection

Before package open, please check the package carefully and confirm whether any parts is broken. If any, please contact the forwarder or supplier immediately.

If all is ok, then please open it properly and take out the device and other spare parts. Check the parts list and make sure all is well. If any question, please contact us.

Note:

- Please put packing material where the child can't reach. Follow the local regulation or hospital rule when dealing with the packing material.
- Keep the packing material in stock for future use.

3.1.2. Environmental Standard

Please keep the infusion pump away from the noisy, shaking, dusty, corrosive, flammable, explosive environment. Please keep at least 5cm distance around the device to make good loss of heat and good air recycle.

When the device is moved to other environment, it may have condensation due to the temperature difference, in which case, please don't start the device until the condensation finish.

Mobile phone, X-ray or MRI device will be the cause of malfunction due to its high frequency radiation. Please don't use the infusion pump near the radiation device to avoid unpredictable influence.

3.1.3. AC Power Standard

Please run the device under the AC Power range on the label only.

Note:

- Use the proper AC Power supply based on the power voltage setting. Or it will make damage to the device or cause fire.
- The fuse of the power supply is 5*20mm, Ceramic tube high breaking fuse, model: 5N-series; rated voltage: AC 250V, rated current : 2.5A; rated breaking capacity: 1500A.

3.1.4.Install Power Cord

Connect the Power Cord into the socket in the back shell of the infusion pump and connect to the AC Power. The \sim will be flashing on the keypad, the battery will start to recharge at the same time. Flashing indicate recharging.

Note:

- AC Power voltage range is 100~240V,50/60Hz.
- Please make sure the power cord connect it well.
- Put the power cord in order to avoid any hurt to the people around it.

3.2 Installation and Setting

3.2.1.Install the device and Power On

- 3.2.1.1. Install the device straightly and tightly. Connect to AC Power and ED will be flashing on the keypad.
- 3.2.1.2. Press Power Button around 2s and the device will start self-testing to check whether all function can be working normally. If any wrong, it will show the alarm on the screen (eg. AC Power Lost)
- 3.2.1.3. The device will manage the battery automatically.

Note:

• The device will be under battery supply automatically if AC Power disconnected or lost. 📼 will be on and alarming AC Power Lost with acoustic and visualize alarm to remind the operator. It can be removed by press CLR on the keypad.

3.2.2.Install IV set and remove IV set

Close the roller clamp of IV set and insert it into the solution container.

- 3.2.2.1. Press the drip chamber to fill it up to 2/3 full.(less than 1/3 in the drip mode)
- 3.2.2.2. Open the roller clamp and prime the air in the iv set and then close the roller clamp
- 3.2.2.3. Open the pump door and place the IV set in the Position A
- 3.2.2.4. Put the IV set in the fluid path B,C,D vertically.
- 3.2.2.5. Turn the clamp module E to the left to install the IV set straightly.
- 3.2.2.6. Close the pump door
- 3.2.2.7. Open the roller clamp
- 3.2.2.8. Please close the roller clamp after infusion finish, then turn the clamp module E to the left and take out the IV set.(please refer $3.2.2.1 \sim 3.2.2.8$ the iv set replacement method)

To avoid free flow When install the IV set:

Make sure the IV set in the fluid path full of fluid and close the roller clamp to avoid the free flow. Before closing the door, make the transfusion pipe pass vertically through the middle of the pressure plate and the peristaltic pump, ensure that the pressure plate and the peristaltic pump can clamp the transfusion device after closing the door and to avoid the free flow.

Changing the Fluid bottle: (please refer 3.2.2.9~3.2.2.13the iv set replacement method)

- 3.2.2.9. Ensure that infusion pump is in vertically hanged.
- 3.2.2.10. Remove bag spike on infusion set from empty / used container. Discard empty / used container according to hospital regulation.
- 3.2.2.11. Insert spike into new container.
- 3.2.2.12. Squeeze the drip chamber approximately half full or up to fill line (if the drip chamber is marked) with fluid.



А

В

С

D

Е



3.2.2.13. Restart infusion, see "Start Infusion".

Installation height requirements of Fluid Container:

The height of the infusion bag is the vertical distance from the hanging bag to the IV needle when patient lying on the patient bed and it should not be less than 60cm.

Warning

- Prime the air in the line before infusion.
- It is not allowed to put infusion bag or drip chamber reversely during infusion.
- Deal with the alarm after infusion finished.
- Make sure the whole IV set, infusion bag and IV path is closed totally.
- Pay attention to the patient, alarm and IV path smooth or not

Note:

- After the pump door is closed, there will be no drop falling down to the drip chamber(no free flow). If any drop falling, please install the IV set again.
- Make sure the IV set unblock, or the block fluid will lead to Occlusion Alarm.
- Please change the pressing postion of the IV set every 5-6hr or raplace one new IV set to avoid the big infusion deviation or IV set broken which is dangerous to the patient. Please replace the new IV set used more than 24hr.
- IV set installed too loose or tight will lead to infusion abnormal.
- The position D on the air sensor should be installed well to the bottom, or there will be Air bubble alarm.
- The paristaltic finger pump moduld in Position B,C must be from our company orginal. Please contact us for replacement need.

3.2.3. Drip Sensor Installation

- 3.2.3.1. Please connect the drip sensor on the back shell cord and the fluid can be more than 1/3 on the drip chamber (as the photo below on the left)
- 3.2.3.2. Position the drip sensor at the middle between the drip chamber and the fluid and make sure the drip chamber vertically (as the photo)
- 3.2.3.3. The light on the drip sensor will be flashing when the drop is falling down.





Note:

- Drip Sensor must be from our company original. Please contact our company for replacement.
- Under the drop mode, it can detect and control the drip rate but can't guarantee the infusion accurate volume.
- Please avoid the fluid splashing in the drip chamber or there will be misdetection of the drip sensor.
- Please replace the IV set used more than 24hr.
- Please avoid the direct sunshine and make sure drip sensor straightly during infusion.
- If the light on the drip sensor is not flashing or flashing too much, please replace the drip sensor.
- Please replace the drip sensor when there is Drop Sensor error alarm during infusion.
- It will stop infusion when there is no drop falling down to avoid air coming into the body.
- To clean or disinfect the drip sensor, please follow the step on Chapter 4,4.1.6 for the daily check.

3.2.4.Infusion parameter setting

- 3.2.4.1. Set the flow rate after device is powered on or input the flow rate by numeric keypad.
- 3.2.4.2. Press ∧ or ∨ to set other parameter or press Enter to the standby interface to set other parameter. The Volume, time, flow rate, drip rate, Infused volume can be set in the main interface.
- 3.2.4.3. Press \bigwedge or \bigvee to confirm the last setting and proceed the next setting.
- 3.2.4.4. Set the time from hour to mins, eg.12hr30min, please input 1230.
- 3.2.4.5.Flow rate range:

Iv set size	Flow rate(ml/h)	Drip rate (d/min)	VTBI
10d/ml	1.0~1200.0ml/ml	1~200d/min	0.1-9999.9ml
15d/ml	1.0~1200.0ml/ml	1~300d/min	0.1-9999.9ml
20d/ml	1.0~1200.0ml/ml	1~400d/min	0.1-9999.9ml
60d/ml	1.0~150.0ml/ml	1~150d/min	0.1-9999.9ml

Note:

- Infusion time will be calculated automatically after flow rate and VTBI is set. If the time is revised, the flow rate will be changed accordingly.
- Press CLR button to input again and Exit to cancel again.
- The unit is ml/h, d/min. Under the Volume Mode, if the unit is set to be d/min, the infusion will be defaulted with the unit ml/h. D/min will be as reference during the whole infusion and not guarantee the accurate infusion. Under Drip Mode, if the unit is ml/h, the infusion will be defaulted with the unit d/min. Ml/h will be as reference during the whole infusion and not guarantee the accurate infusion.

3.2.5.Clear Total Volume

- 3.2.5.1.In the standby mode, press Set/Enter to proceed the setting.
- 3.2.5.2. Press \bigwedge or \bigvee to the Total Volume and press Clear button and Enter to confirm.

Note:

• Total Volume will be the single infusion volume and will be cleared after device is restarted.

3.3 Start Infusion

- 3.3.1. Make sure the device and IV set is installed well.
- 3.3.2. Confirm the set infusion parameter is correct.
- 3.3.3. Confirm no air in line and start the venipuncture.
- 3.3.4. Press Start/Stop button in the standby mode to start the infusion and the LCD will be showing Infusing and the light will be flashing on the right of the LCD.
- 3.3.5. Double click Purge button to start the BOLUS mode.

Warning

- The selected IV set brand, size and the used IV set not matched will lead to incorrect infusion volume, such as over flow or under flow. So please make sure the selected IV set brand, size same as the infusing IV set.
- Delaying to change the IV set will lead to not correct flow rate and under flow infusion. So make sure to follow the operation manual strictly and replace the IV set in time.
- Clamp module used incorrectly will lead to over flow infusion. Make sure to install the IV set correctly and use the clamp module correctly
- Regular incorrect maintenance, incorrect and improper calibration will lead to abnormal working as over flow and under flow. Please make sure to strictly follow the regular maintenance step and calibration step
- Too much force on the finger pump will lead to IV set broken and under flow infusion. If the sound of the finger pump and the spring plate is too big, please contact the manufacturer or distributor for maintenance
- Occlusion during infusion will lead to under flow. Pay close attention to the patient status and the smooth IV path.

Note:

- Remaining volume will be decreasing during infusion.
- Remaining infusion time will be showed on the LCD VTBI is set correctly.
- It is suggested to replace the new IV set or change the pressing IV set position every 5-6h to avoid high deviation or alarm error.
- The IV set can't be used for more than 24h.

3.4 Infusion finish

- 3.4.1. After VTBI reaches 0, it will come to KVO Mode with audio and visual alarm on the LCD and keep KVO infusing.
- 3.4.2. Press Start/Stop to stop infusion.
- 3.4.3. Remove the infusion needle.
- 3.4.4. Press Power button around 2 second to switch off the device.
- 3.4.5. Close the roller clamp, open the pump door and take out the IV Set.
- 3.4.6. Disconnect the AC Power and take away the device.

Note:

- To start a new infusion, please set the parameter and press Start/Stop to proceed.
- •The last infusion parameter except Total Volume will be kept in memory after the device powered off.

3.5 System Paramter Setting

3.5.1.Select IV set

- 3.5.1.1. Press Menu to enter into main menu.
- 3.5.1.2. Press \wedge or \vee to "1. Select IV set "and press Set/Enter to proceed."
- 3.5.1.3. Press ∧ or ∨select the desired the IV set and press Set/Enter to proceed. The defaulted brand is Pingan, Longxin, Hongda, Hanahao, etc. Please follow Chapter 3.5.7.2 to add other 12 IV set brand.
- 3.5.1.4. Press Exit to proceed.

Note:

- Please calibrate the IV set brand before use.
- Uncalibrated IV set can't be used and select the IV brand wrongly will lead to incorrect infusion.
- The defaulted IV set may be different for differ delivery lot.
- The installed IV set and the selected IV set brand must be the same, or it will lead to inaccurate infusion.

3.5.2. Select Infusion Mode

- 3.5.2.1. Press Menu to enter into the main menu.
- 3.5.2.2. Press \bigwedge or \bigvee to "2. Infusion Mode "and press Set/Enter to proceed."

3.5.2.3. Press \bigwedge or \bigvee to select the desired infusion mode and press Set/Enter to proceed

3.5.2.4. Press Exit to proceed.

Note:

• Under Volume Mode, ml/h can guarantee the accurate infusion and d/min will be as reference only due to the IV set deviation or drug solution difference.

3.5.3.Alarm Setting

- 3.5.3.1. Press Menu to enter into the main menu.
- 3.5.3.2. Press \bigwedge or \bigvee to "3. Alarm Setting" and press Set/Enter to proceed.
- 3.5.3.3. Select the desired Alarm level. 0-9 is the alarm sensitivity with L0-L9. The lower Level it is , the higher sensitivity it will be. The occlusion level, air setting can be set in this item.
- 3.5.3.4. Press Exit to proceed.
- 3.5.3.5. The defaulted occlusion level, air bubble level is Level 5.

Note:

- The occlusion sensitivity range is 40-130Kpa and the sensitivity has 10 level to be selected
- The occlusion adjustable sensitivity can control the Bolus amount effectively after occlusion The higher sensitivity it is, the smaller Bolus amount there will be after occlusion.
- The bubble sensitivity range is >50 μ l, single bubble is 50 \sim 300 μ l with 10 level adjustable.

3.5.4.KVO setting

The infusion will keep infusing with KVO rate to keep vein open after infusion finish.

- 3.5.4.1. Press Menu to enter into the main menu in the standby mode.
- 3.5.4.2. Press \bigwedge or \bigvee to "4 KVO Rate" and press Enter to proceed.
- 3.5.4.3. Press ∧ or ∨ to select "Default Rate". The KVO rate will be the defaulted KVO when selecting Default KVO rate: flow rate >10ml/h, defaulted KVO is 3ml/h, flow rate ≤10ml/h, defaulted KVO is 1ml/h.
- 3.5.4.4. Press \bigwedge or \bigvee to select " Define KVO" and press Enter to proceed(range is 0.1-5ml/h)
- 3.5.4.5. KVO deviation $\leq \pm 10\%$, calibration method is following:
- Prepare one infusion pump, measure cup, stop watch, electric scale, IV set, paraffin oil, one bag of 0.9% saline.
- Put small amount of paraffin oil into the measure cup and weight it. The paraffin oil can protect the saline volatilized. Use the electric scale to weight the total weight.
- Set the KVO rate to be 1ml/h and measure the infused saline in the measure cup until it comes into KVO and the time on the stop watch will be 10h.
- After 10hr, use the total weight on the measure cup minus the original weight on the measure cup. If the amount is 9.0-11.0, then the KVO setting is qualified.

Note:

• Defaulted KVO or Define KVO is optional.

3.5.5.BOLUS setting

Bolus is mainly used for a fast rate with a fixed amount at the start of infusion and then enter into a normal constant rate. Once the bolus fixed volume is finished, it will come into a normal constant infusion mode automatically.

3.5.5.1. Press Menu/Exit to the main menu.

- 3.5.5.2. Press \bigwedge or \bigvee to "5 .Bolus Setting" and press Enter to proceed.
- 3.5.5.3. Press \land or \bigvee to select "1. Bolus rate" and press Enter to input the Bolus rate and then press Enter to confirm and exit.
- 3.5.5.4. Press ∧ or ∨to select "2. Bolus VTBI" and press Enter to input the Bolus Volume, then press Enter to confirm and exit.
- 3.5.5.5. Press ∧ or ∨ to select "3. Add to Total Volume?" and press Enter to proceed. Press"0" means No, Press"1 means Yes. Selecting Yes, the bolus VTBI will be calculated into the Total Volume, the VTBI in the

infusion interface will decrease accordingly. Selecting No, the bolus VTBI will be not calculated into the Total Volume and the VTBI in the infusion interface will keep the same as the previous setting. Press Set/Enter to confirm and exit.

- 3.5.5.6. Press Menu to come back to the Standby mode and double click Purge button to the Bolus Mode.
- 3.5.5.7. Press Start/Stop to start the Bolus Mode and press Set/Enter to proceed.
- 3.5.5.8.d It will come to the normal constant infusion mode after bolus finish.
- 3.5.5.9. Press Start/Stop will stop the infusion and come back to the standby mode during infusion. Press Start/Stop to the normal infusion and double click Purge to the Bolus Mode.
- 3.5.5.10.Bolus deviation is $\leq \pm 5\%$, testing method is following:
 - Prepare infusion pump, measure cup, stop-watch, IV set and one bag of 0.9% saline.
 - Weight the total weight of the measure cup with the electric scale.
 - Double Click Purge button to the Bolus Mode with flow rate 600ml/h, VTBI 5ml and start the infusion.
 - Drop the saline into the measure cup and weight the total weight of the measure cup after bolus finish. If the total weight minus the measure cup equals 4.5-5.5, then it deviation is qualified.

Note:

- Bolus VTBI is added into the total volume? 1 means Yes, 0 means No.
- BOLUS VTBI range: 0.1~5.0ml.
- BOLUS flow rate range: 20d/ml: 1~1200ml/h, default rate is 600ml/h.
 - 60d/ml: $1\sim150$ ml/h, default rate is 150ml/h.
- Once Bolus finish, there will be Bolus Finish alarm in the LCD for one second and then clear automatically.
- When there is Occlusion, air in line error, it will stop infusing with corresponding alarm.(Refer to 4.7.4 alarm information)

3.5.6.Drug Weight Mode

- 3.5.6.1. Press Menu/Exit to the main menu.
- 3.5.6.2. Press \bigwedge or \bigvee to "6 .Drug Weight Mode" and press Enter to proceed.
- 3.5.6.3. Press \bigwedge or \bigvee to select the mode"Drug 1-Drug 2" and press Enter to proceed.

3.5.6.4. Take Drug 1 for example, press Enter to the sub-menu:

- **Drug Name;** Press Set/Enter to set the name and press \Box to move the cursor and press \triangle or ∇ to select the letter or number to edit the drug name and press Set/Enter to exit.
- Unit: Press Set/Enter and press Λ or \forall to select the unit: ug/kg/h, ug/kg/min, mg/h, ug/h, mg/kg/h, mg/kg/min and Enter to exit.
- **Dose Rate:** Press Set/Enter to set and press . to select the number and set the dose rate.

Weight: Press Set/Enter to set and press to select the number and set the patient weight.

Solution: Press Set/Enter to set and press to select the number and set the solution.

- **Dose:** Press Set/Enter to set and press [] to select the number and set the dose. The Concentration and infusion rate will be calculated automatically.
- 3.5.6.5. Move the cursor to
 Selected and press Set/Enter to proceed.
- 3.5.6.6. Press Menu/Exit to the standby interface to start the infusion.

Note:

- To Exit the Drug Weight Mode, select □ Unselected and press Set/Enter to proceed. Or press ∧or∨ to change the infusion rate in the standby interface and press Set/Enter to exit the drug weight mode.
- To build new drug, move the cursor to New drug and press Set/Enter to build new drug.

3.5.7.Advanced Setting

3.5.7.1. Calibrate IV Set

To make sure the exact deviation and safe infusion, please calibrate all the IV set before use due to the size difference between different IV set brands. Exclusive IV brand is the first choice and it is suggested to use singled used PVC IV set with diameter, following manufacturer is recommended:

Manufacturer	Iv set size
Hanahao	20d/ml, 60d/ml

Please use 0.9% normal saline or pure water as the calibration infusion fluid to make sure exact calibration. Please refer to the following calibration step:

- (1) Prepare one pc electronic scale or measure cup or 20ml size syringe.
- (2) Prepare one bottle or bag filled with 0.9% normal saline or pure water
- (3) Close the Roller Clamp of the IV set and connect it to the bottle or bag.
- (4) Press the Drip Chamber and make the fluid around 2/3 of the drip chamber. Turn on the Roller Clamp and prime the air in the IV set and then close the Roller Clamp
- (5) Open the pump door and install the IV set correctly.
- (6) Open the Roller Clamp and put the IV set needle into the vessel:

If use the electronic scale, please deduct the weight of the vessel.

- or Measure cup
- Or 20ml syringe(put the needle inside it)
- (7) Press Menu to enter into the main menu in the standby interface.
 Press ∧ or ∨ to select"7 Advanced Setting) and press Set/Enter to proceed.
- (8) Press A or V to select: 1. Calibrate IV set" and press Set/Enter to proceed.
- (9) Input VTBI and Flow Rate. Press Aor V to select "3. Uncalibrated IV Set" and press Set/Enter to proceed.
 Press Set/Enter to select the IV set and come back to the calibration interface(Defaulted IV set is the using brand)
- (10) Press Start/Stop to start the calibration(LCD will show Calibrating.
- (11) There will be acoustic and visual alarm after calibration finish and please Input the real Infused Volume.
- (12) Input the net weight/volume on the electric scale or the measure cup or the syringe.
- (13) Press Set/Enter to proceed. It will show" Confirm the input?" If it is correct value, then press Set/Enter to proceed. If it is not correct value, then press Menu/Ext to input the real value again.

(14) Calibration Finish.

- Note:
- The defaulted IV set calibration value is the empirical value which is tested for many times, which can be used directly. Please do the calibration for the new built IV set before use.
- If there is any alarm during calibration, eg. Door Open, it will show Calibration Failed, please calibrate again!" Press Set/Enter to remove the alarm error and do the calibration again.
- If the real infused volume and the set volume has big difference, it will show "Failed, calibration deviation too big, please press Set/Enter". Then please do the calibration again.
- When testing the accuracy in the factory, use the brand of hanahao infusion set to test and verify the accuracy. The other defaulted IV set calibration value is the empirical value which is tested for many times, which can be used directly. If the default brand infusion accuracy is found to be inaccurate, Please do the calibration for the IV set before use..
- The preferred brand of hanahao infusion device is recommended.

3.5.7.2.Edit IV set

It is used to add IV brand or edit the IV Brand and IV size (eg. 20ml to be 60ml IV set)and delete the IV brand.

- (1) Press Menu to the main menu.
- (2) Press for ∇ to select "7. Advanced Setting" and press Set/Enter to proceed.
- (3) Press for \bigvee to select" 2. Edit IV Set" and press Set/Enter t proceed.

1. Build new IV Set

- (1) Move the cursor to "1. Build IV Set" and press Set/Enter to proceed.
- (2) Select" 1. IV Set Name" and press Set/Enter to input the name.
- (3) Press for V to select the letter or number. Press f to move the cursor.
- (4) Press Set/Enter to confirm and Exit the setting.
- (5) Press for ∇ to select "2. IV Set Size" and press Set/Enter to proceed. Press for ∇ to select 20d/ml or 60d/ml and input the value on the IV set package(eg.20 drop water equals (1±0.1), then select 20d/ml)
- (6) Move the cursor to "3. Save and Exit" and press Set/Enter to save the setting. Exit will not save the setting.

2. Delete IV set

- (1) Move the cursor to "2. Delete IV Set" and press Set/Enter to proceed.
- (2) Press for V to select the IV Set to be deleted and press Set/Enter. It will show " Deleted ?" Press OK to proceed and Exit to cancel.

3. Edit IV set

- (1) In the Edit IV set menu, move the cursor to "3. Edit IV set" and press Set/Enter to proceed.
- (2) Press Λ or ∇ to select the IV Set to be edited and press Set/Enter to proceed.
- (3) Press Set/Enter to "1. IV Set Brand" and press ∧or ∨ to select the letter or number. Press [] to move the cursor.
- (4) Press Set/Enter to confirm and Exit the setting.
- (5) Press for ∇ to select "2. IV Set Size" and press Set/Enter to proceed.
- (6) Press Set/Enter to confirm and Exit.
- (7) Move the cursor to "3. Adjust the Value" and press Set/Enter to proceed. Press or V to change the value(range is -20%~+20%). This function is mainly used to adjust the calibration value though the calibration is done but with big deviation to make the deviation better. Eg. After calibration is done, the VTBI is 100ml, the real Infused value is 105ml, there is extra 5%, then the value can be adjusted -5% to make the accurate infusion.
- (8) Move the cursor to "4. Save& Exit" to confirm the setting and press Menu/Exit to exit.

Note:

- Don't use the uncalibrated IV set or it will have over flow or under flow danger to the patient.
- New built IV Set must be calibrated before use.
- It can store 12 IV brands including the defaulted IV set.
- The IV set being used can't be deleted. To get back the deleted IV set, please press Clear and Mute button and Clear and . to the factory setting.
- Don't revise the saved IV set brand, or the infusion will be not accurate.

3.5.7.3. No Operation setting

This function is used to set no operation alarm time to remind operation again.

- a. Press Menu/Exit to the main menu and press Λ or ∇ to ". Advanced Setting" and press Set/Enter to proceed and move the cursor to "3. No operation time setting" and press Set/Enter to proceed.
- b. Press \bigwedge or \bigvee to adjust the time (range from 0.5-5mins, 0.5 as a level step)
- c. Press Set/Enter to confirm and exit the setting.

3.5.7.4. Motor Setting

This function is used to set the motor voltage to make sure the motor working smoothly if there is stuck or skidded during infusion.

- a. Press Menu/Exit to the main menu and press 🛆 or 🔽 to "7. Advanced Setting" and press Set/Enter to proceed the Motor Setting.
- b. Press \bigwedge or \bigvee to edit the value (T1-T5, the bigger the value it is, the stronger force distance it will be.

c.Press Set/Enter to confirm and exit.

3.5.7.5. Other Setting

Press Menu/Exit to the main menu and press \land or \lor to "7. Advanced Setting" and press Set/Enter to proceed .This is used to start the Night Mode, press \land or \lor to make the setting and press Set/Enter to select.

- **a.** Pressure detection: Once the function is on, there will be acoustic and visual alarm when there is upstream occlusion.(Defaulted to be on).
- **b.** Volume-drip mode calibration value: Once the function is on, the calibration value will be the volume calibration value under drip mode and the calibration value under drip mode will be not be taken as standard.
- c. Night Mode: LCD will become dim in 2mins after starting the night mode
- d. Drip-Volume Mode: When this function is on, it will be running with the drip sensor in the volume mode.

Note:

• Drip-Volume Mode and Volume-Drip Mode is optional and need to confirm the model before order.

3.5.7.6. Software information

- a. Press Menu/Exit to the main menu and press \bigwedge or \bigvee to "7. Advanced Setting" and press Set/Enter to proceed .
- b. Press \bigwedge or \bigvee to 6.Software information.
- c.Press Set/Enter to confirm and exit.
 - It will show the software version and software released date.

3.6 Other function

3.6.1.Purge

This function is used to full the fluid faster into the iv set and to prime the bubble in the IV set. The method is following:

- 3.6.1.1. In the Stop Mode, long press Purge button around 1s to proceed.
- 3.6.1.2. Stop pressing the Purge button to stop priming.
- 3.6.1.3. Purge rate: 20d/ml: 600ml/h, 60d/ml: 150ml/h, purge infused volume will be showed and not calculated into the Total Volume.

Note:

- Purge function is used to prime the bubble and not for body infusion.
- Double click Purge button will come into Bolus Mode. Bolus Infused Volume can be calculated into the Total volume.
- Purge rate deviation <10%.
- Long press Bolus button to prime the bubble, air bubble, door open, and battery lost alarm will not stop the priming and alarm message will be displayed in the screen. Communication error, down occlusion, battery ran out alarm will make the priming stop.

3.6.2.Mute Function

- 3.6.2.1.Press Mute button again after 2mins. The alarm will keep going after the 2seconds mute status.
- 3.6.2.2.Press Mute after 2s, mute function will stop working automatically if there is any alarm during infusing for safety purpose, there will be audio and visual alarm.
- 3.6.2.3.Exit the mute status after pressing 📓 again.

3.6.3.Infusing under battery

- 1. The power source will be battery supply in the following situation:
 - Device keeps running without connecting to AC power.
 - AC power supply disconnect suddenly.
- 2. Under battery supply:
 - a. AC power is disconnected, the device work under battery supply automatically. AC power indicator is off, battery indicator is on, alarm light is on, low level alarm is on, the device keeps working under battery supply.
 - b. The device works under battery and battery capacity is decreasing from full to 1 grid.
 - c. When the battery capacity is low, it will have low battery alarm, the battery icon keeps flashing with acoustic and visual alarm, which means the device can work around 30mins and reminds to connect to AC power.
 - d. When the battery capacity ran out, it will stop to work and keeps alarming around 3mins and then will power off automatically.

Note:

- The device can work more than 10hours under battery supply with the flow rate 25ml/h after fully charged.
- The device can work more than 4hours under battery supply with the flow rate 1200ml/h after fully charged.

3.6.4. Volume level setting

Volume adjustment is placed in the engineering mode. Entering the engineering mode requires a password, while pressing the "." and "CLR" to enter the engineering mode.

- a. Press \bigwedge or \bigvee to "7. volume level" and press Set/Enter to proceed .
- b. Press \bigwedge or \bigvee to edit the value (L0-L9, The higher Level it is , the higher volume it will be.)
- c. Press Set/Enter to confirm and exit.

3.7 Acoustic and Visual Alarm

3.7.1.Alarm

To remind the operator, there will be acoustic and visual alarm when there is any abnormal infusion or error, malfunction, which can't keep smooth infusion to the patient, standard is following:

- 1. The lowest level of alarm volume should be more than 45db and can be heard in 1m distance.
- 2. The defaulted time is 2mins for the mute alarm period.
- 3. The device keeps working during the alarm period.
- 4. It should stop to work when there is error alarm.
- 5.All alarms belong to technical alarms.
- 6.Inherent delay triggered by alarm condition: 2s
- 7. The alarm system will be self-checked during the start-up self-check, and the alarm function can be judged by checking the prompts of the machine self-check interface.

Warning

• Be cautious not to set the alarm limits to extreme values which may lead to the alarm system useless.

3.7.2. Alarm Level and Alarm way

3.7.2.1 Alarm Level

1.ALarm has two level: high and low level, details is following:

		Air bubble, up occlusion, down occlusion, door open, infusion finish,
Alarm	High level	battery ran out, battery disconnected, motor err, pump err, infusion
level		parameter err, drip sensor err, drip sensor disconnected, free flow,
		bottle empty, system err, comm err, iv set not calibrated, air sensor err
	Low level	no operation, low battery, AC power disconnected

- 2. When the alarm condition is relieved, the alarm signal stops automatically: Air bubble, occlusion, infusion finish, battery disconnected, motor err, pump err, infusion parameter err, drip sensor err, drip sensor disconnected, free flow, bottle empty, iv set not calibrated
- 3. If the alarm condition is cleared, the alarm signal can not stop automatically such as door open, battery ran out, system err, comm err, air sensor err if it is not removed totally.

3.7.2.2 Alarm way

The device will have light alarm, voice alarm, message alarm when there is alarm with acoustic and visual alarm to remind the operator. Distinguish the alarm in different way as following standard: Distinguish the alarm in different way as following standard:

Chart 1:

Alarm level	Alarm light color	Alarm light flashing frequency	percentage	Period	Alarm dB
High	Red	2.0±0.6Hz	20%-60% on	2-15seconds	Not less than 45dB in 1meter distance
Low	Yellow	on all the time	100% on	>15seconds	Not less than 45dB in 1meter distance

Chart 2:

Alarm	Alarm	Alarm light color				
level	sound	Red	Yellow	message	Nurse call	Operator to confirm
High	Yes	Flashing	Off	Air bubble, etc	no	CLR and silence 2min
						OK to confirm
Low	Yes	Off	Flashing	No operation,	no	CLR and silence 2min
				etc		OK to confirm

When there is more than 2 alarm trigger:

- 1. When the higher level alarm is triggered first, it will alarm "stop infusion "and alarm message displayed in the LCD and the other alarm message will be displayed accordingly from high level to low level alarm.
- 2.When the lower level alarm is trigger first, the infusion will keep going with alarm message displayed in the LCD. If other alarm belonging to higher level, then infusion will stop. High level alarm will display in advance of low level alarm, alarm sound will be the higher level sound.

3.7.3. Action for alarm

When there is alarm, please check the patient in priority.

When there is alarm, please take the following action:

- 1. Check the patient
- 2. Confirm the alarm type
- 3. Find the alarm reason
- 4. Find the way to remove the alarm
- 5. Confirm the alarm is removed.

3.7.4. Alarm and solution

Alarm	Possible cause	Solution	
Air in line	Air in the iv set	Press Mute and remove the air bubble then start again	
	IV set installed incorrectly	Refer to 3.2.2 iv set installation, install the iv set again	
	Bottle empty	Change new bottle fluid or stop infusion	
	Air sensor error	Contact supplier	
Door open	The pump door is open	Close the pump door	
	IV Clamp is not open	Open the IV clamp	
Upstream occlusion	Bottle fluid entrance is not open	Open the entrance or connect the intake tube.	
	IV clamp is not open	Open the IV clamp	
	IV set bent or folded	Straight and unfold the IV Set	
Downstream	Needle blocked	Check if the needle is blocked. Inject again if yes.	
occlusion	IV set is too hard or its diameter exceeds the acceptable limit.	Change IV Set or adjust the higher level of the downstream occl.	
No operation	No operation for more than	■Press Clear to remove the alarm	
	2min.	■ Press Starr/Stop to continue infusion.	
Infusion finish	Infusion is finished	 Change new infusion bottle to continue infusion finish and take out the IV set 	
Parameter error	VTBI or flow rate is 0, etc	Reset the parameter	
Motor error	Motor not working or working abnormal	Clear and press Start/Stop. Please stop and contact manufacturer if it is still abnormal.	
Battery Low	Battery capacity is low	Connect to AC Power to recharge and continue infusion.	
Battery Empty	Battery capacity is going to be empty	Connect to AC Power to recharge or power off	
AC Power disengaged	AC power disconnect	Connect to AC PowerPress Clear and continue under battery supply	
Pump Err	Pump abnormal	Connect manufacturer if it still work abnormally after press Clear and Start/Stop button	
Drin Sensor Frr	Drip Sensor broken	Contact manufacturer	
Drip Sensor En	Detection Err	Replace Drip Sensor or connect the Drip Sensor again.	
Drip Sensor Disconnected	Drip Sensor Disconnected	Connect Drip Sensor again	

Free Flow	Drop falling to the drip chamber in stop mode	 Check the IV set installed well or not Check whether the drip sensor is disturbed or strongly vibrated
Bottle Empty	No drop falling in to the drip chamber	 Fluid Finish Drip sensor installed not properly or correctly and can't detect the drop falling down Drip sensor must be installed between the fluid level and fluid entrance with sliding angel less than 20 degree.
Communication Err	Data communication error	Press Clear button to remove the alarm or restart the device. Contact the after-sales if it is not solved.
System Err	System error	Restart the device and contact after-sales service if it is not solved.
Failed! Calibrate again and press Set/Enter	Calibration failed	 Alarm or err during calibration, eg. Door open, air in line Big difference between real infused volume and calibration VTBI
IV set not calibrated	new IV set not calibrated	Calibrate following 2.5.7.1 IV set Calibration
Air Sensor Err	Air Detector damaged	Contact after sales service

Note:

- The possible infused volume in a single error is less than 0.7 mL.
- The possible infused pressure value in a single error is not more than 155KPa.
- The acoustic and visual alarm except the battery low and AC Power Disengaged alarm. will make the device stop infusing to remind the operator to avoid free flow caused by the error
- Please deal with the alarm in first priority after alarm to avoid the under flow hurt to the patient due to infusion paused.

3.8 Other error

Check the device as following before contact the supplier.

Phenomena Possible Cause		Actions	
con't he quitched on often	Battery installed correctly?	Install the battery correctly.	
press Power Button	AC Power Connected correctly?	Connect AC Power correctly	
Abnormal noise and infusion failed	Whether finger pump cassette is stuck.	Wash and clean the finger pump cassette	
Air in line alarm but no air in IV set after install the IV Set.	Install the IV set correctly? IV Set is out of shape?	 Press Clear to remove the alarm Install the IV Set correctly. Make sure the IV set on the air sensor is not seriously out of shape 	

3.9 Occlusion

All test methods are at ambient temperature about 20 C; humidity: 20-80%; atmospheric pressure: standard atmospheric pressure; in addition to battery testing, other tests use AC power supply, the length of the infusion tube from the bottom of the machine to the pressure testing instrument is 30-50 cm.

Level	Threshold	Real detection pressure value (kPa)		Trigger alarm time (s)	
Lever	level	20d/ml	60d/ml	20d/ml	60d/ml
L0	40kPa	39.33kPa	37.73kPa	40s	32s
L1	50kPa	49.60kPa	46.67kPa	45s	34s
L2	60kPa	58.67kPa	55.87kPa	50s	41s
L3	70kPa	66.93kPa	64.40kPa	61s	51s
L4	80kPa	79.07kPa	75.60kPa	71s	60s
L5	90kPa	88.93kPa	84.13kPa	83s	65s
L6	100kPa	98.40kPa	87.73kPa	91s	71s
L7	110kPa	109.80kPa	104.50kPa	106s	82s
L8	120kPa	119.30kPa	117.20kPa	111s	98s
L9	130kPa	128.10kPa	128.20kPa	116s	112s

1. Alarm threshold level, longest delayed alarm time and possible infused dose volume reference datasheet.

2. The longest time between the alarm pressure value from occlusion threshold at the minimum and medium rate and trigger alarm time during the working of the device (The alarm threshold is set to minimum and maximum respectively):

	IV set	Alarm threshold	Alarm pressure value (kpa)	Trigger alarm time (min)
20d/ml	20d/ml	L0 (40kpa)	38.33 kpa	18min33s
	200/111	L9 (130kpa)	133.56 kpa	48min22s
60d/ml	L0 (40kpa)	36.54 kpa	20min33s	
	L9 (130kpa)	128.60 kpa	46min42s	

a) When the equipment is running at the minimum rate

b)When the equipment is running at medium rate

IV set	Alarm threshold	Alarm pressure value (kpa)	Trigger alarm time (min)
20d/ml	L0 (40kpa)	39.34kpa	46s
	L9 (130kpa)	134.66 kpa	102s
60d/ml	L0 (40kpa)	37.59 kpa	50s
	L9 (130kpa)	130.60 kpa	109s

3. The bolus volume from the alarm threshold at the middle rate and minimum and maximum occlusion alarm threshold during device working reference chart:

Iv set	Alarm threshold (kpa)	bolus (g)
20.1/1	L0 (40kpa)	0.02g
20d/ml	L9 (130kpa)	0.15g
60d/ml	L0 (40kpa)	0.03g
	L9 (130kpa)	0.20g

When the occlusion occurs, the operator should immediately check the cause of the occlusion. If the folded infusion tube or the roller clamp of the infusion set is not opened, please open the infusion set roller clamp first and then set the infusion parameter, and then start the infusion . If the puncture site is swollen, please close the infusion set roller clampfirst and then remove the needle of the infusion set and open the door to release pressure, and then do the venipuncture again. Open the roller clamp of the infusion set, check the infusion setting parameters, and then start the infusion set, check the infusion setting parameters, and then start the infusion set, check the infusion setting parameters, and then

Note:

- The above test data is from the brand "Hanahao".
- The occlusion pressure, longest delayed alarm time and dose volume will be influenced by the test condition.
- The deviation of the occlusion alarm pressure value is±25kpa
- Test flow rate is 25ml/h (middle rate), minimum flow rate is 1ml/h.

Chapter 4. Product daily check, storage and transportation condition

For product maintenance requirement, we can provide the board circuit, components, reference chart, calibration instructions or other technical instructions. Please use the mention below material and method to clean or sterilize the device. We will be not responsible for the damage or accident caused by other material and method clean or sterilization. The listed chemical and method is only for control the infection. We will not bear any responsibility for its validity.

Please enquiry the hospital Infection Prevention Department or local epidemiological expert for the infection control method.

4.1 Daily Check

Ethylene oxide sterilization or ultrasonic sterilization can be used. Clean the device with

Note:

• Don't clean the device with diluent, alcohol, etc

4.1.1.Shell Clean

Clean the shell with soft cloth wet by warm water or diluted neutral detergent and wipe the shell and make the device dry after clean.

4.1.2. Daily check for the pump door knob, door shaft and pump door

Clean the pump door knob, door shaft and pump door with soft wet cloth and make it dry.

4.1.3. Daily check for air sensor

Clean the sensor cover with soft wet cloth and make it dry.

Note: Please don't make any damage to the sensor cover

4.1.4. Daily check for the Peristaltic pump blade, pressure sensor.

Don't wash the peristaltic pump blade, pressure sensor with water. Use soft cloth soaked in diluted neutral detergent to clean and make dry to make sue the blade working smoothly and flexibly and avoid being stuck by potion.

4.1.5. Daily check for infusion fluid path, cradle

Clean the infusion fluid path, cradle with soft cloth and make it dry.

4.1.6.Daily check for the drip sensor

Clean the drip sensor cover with soft cloth and make it dry.

Warning

- Power off and disconnect the AC socket and power cord before cleaning.
- Use the recommended dilute detergent and disinfectant or use the low concentration as possible.
- Don't soak the device into fluid and don't pour fluid on the device or components and don't make the fluid into the device.
- Do not use abrasive materials (such as steel balls or silver polish) and solvents similar to xylene or acetone to avoid damage to the shell.
- Optional detergents and disinfectants: warm water, diluted soapy water, diluted ammonia, sodium hypochlorite (bleaching powder for washing), hydrogen peroxide (3%), ethanol (70%), isopropanol (70%), etc.
- No gas (Eto) or formaldehyde should be used for disinfection.
- Stop to use the device and contact the manufacturer or distributor if pouring the water into the device or its components by accident, which lead to device abnormal working.

4.2 Battery

The internal rechargeable battery (hereinafter referred to battery) make sure the device continue the normal working during transport or no power supply. It will charge automatically when connecting to the AC Power. It will work under battery supply when there is no AC Power. Please take out the battery if it is not used for more than 3 months; the battery can discharge automatically, the life of the battery will decrease if not charge it every three month especially in high temperature.

4.2.1. Charge Battery

- 1. Connect to AC Power to charge when there is battery low alarm.
- 2. Please charge the battery if it is the first time use or it is put in stock for long period.
 - a. Before power on the device, the indicator \sim will be on and LCD will show the charging icon and the indicator on the keypad will be flashing after connecting to AC power.
 - b. Press $\stackrel{60}{=}$ around 5s to start the device, the indicator \sim on the keypad will be on, the $\stackrel{61}{=}$ and $\stackrel{61}{=}$ flashing means the battery is charging.
 - c、 Press 🧐 around 5s to turn the device, charging is going. After 16hrs, ⊡ off means charging finish.

Note:

- Please charge the battery every 3months to avoid battery damage if the device is kept in stock for long period.
- It takes 16hours for fully charged the battery after it is ran out.
- Battery is only for backup use and please connect to AC power during injection.

4.2.2.Battery performance inspection

Disconnect AC power, the battery can be back up around 10hours at the speed 25ml/h. The performance of the battery will degrade over time and please check the performance regularly. Check the battery as following step:

- a. Connect the device with AC power and charge it for 16hours.
- b. Disconnect the AC Power, let the device work at the speed of 25ml/h until the battery ran out and device power off automatically.

If it can work more than 120mins, it means battery is in good condition.

If it can work 60-120mins, it means battery is near the end life period.

If it work less than 60mins, it means battery is the end life.

c. Please recharge the battery after checking the battery for next time use.

• If the battery has obvious damage (bulk bag, deformation, leakage) or the battery cannot store power, it should be replaced in time and properly recycled.

4.2.3.Replace battery

The life of the battery depends on the use frequency and operation environment. The life is around 2years if it is used properly or the life may be shortened. It is advisable to replace the battery around 2years. If the battery has obvious damage (bulk bag, deformation, leakage) or the battery cannot store power, it should be replaced in time and properly recycled. Please follow the local regulation when dealing with the battery.

Step to replace the battery:

- a. Loosen the battery cover screw at the back shell of the device and take out the port to get the battery.
- b. Put new battery inside and connect to the power and put the battery cover well. Fix the screw well.

Warning

- Please don't disassemble or throw into fire or short-circuit the battery. Battery burning, explosion, or leakage will be harmful to human.
- The battery should not be disposed of as domestic waste.
- Battery is consumable and please replace it when the life is exhausted.
- Please get the original battery from manufacturer or distributor when replacing it.
- The device can only accept the specified battery from the manufacturer and the device may be damaged or cause fire from not specified battery.
- Please replace the battery when the battery is damaged or leakage.
- Don't use the faulted battery in the device.

4.3 Regular Maintenance

4.3.1.Regular maintenance plan

To make sure safety operation, please do the regular checking as the following plan:

Regular maintenance plan

Checking Item	Period	Maintenance Step
Check the appearance	Before use every time	Refer to 4.3.1.1
Check the power cord and the battery	Before use every time	Refer to 4.3.1.2
Check the accuracy	Every 6 month	Refer to 4.3.1.3
Check the alarm function	Every 6 month	Refer to 4.3.1.4

4.3.1.1 Check appearance

- Appearance: no damage or broken appearance.
- Keypad: all button can work
- The parts: finger pump, drip sensor, air sensor, pressure sensor, front door, IV set installation, no damage phenomenon.
- Clean the surface completely after or before long time storage.

4.3.1.2 Power cord, battery

- Check the appearance of the power cord and see if there is any damage or disconnecting problem with power socket, contact the manufacturer or distributor if there is any.
- If the AC power indicator is not on after connecting to power source and device can't be powered on, contact the manufacturer or distributor for maintenance.
- If the battery indicator is not flashing after connecting to AC Power and alarming battery lost, contact the manufacturer or distributor for maintenance. Refer to Chapter 4.2 for the battery maintenance and regular checking

4.3.1.3 Check the infusion accuracy

• Do the calibration every 6 months for the IV set and calibrate the new IV set, please refer to 3.5.7.1 for the calibration method.

4.3.1.4 Check the alarm function

1. Self-testing alarm system

It has self-testing function when starting the device to make sure the air sensor and other parts working normally. Self-testing system is used to check if the device can work normally or not. If there is any parts abnormal, please stop to use and contact the manufacturer or distributor.

2.Alarm sound, Alarm light color and Buzzer Check

- a) Alarm light color:Red light is always on for 2 seconds when starting up, and yellow light is always on if low-level alarm occurs after starting up, and red light flashes if alarm occurs.
- b) **Buzzer**: 2 seconds long buzz when power on $_{\circ}$
- c) Alarm sound: Low-level alarm ("Du-Du-Du") ,high-level alarm ("Du-Du-Du-Du-Du-Du-Du-Du-Du-Du-Du-Du")

3.Alarm function Check

Several main alarm detection methods are introduced here, Other alarms can refer to 3.7.5.

SN	Alarm	Detection methods Normal		abnormal
1	Air bubble in line	In the process of infusion, a bubbles larger than the bubble gear value are made to make the bubbles reach the position of the bubble sensor along the infusion tube	Alarm: Air in line	No alarm
2	Door open	Open the door of infusion pump in normal operation	Alarm: Door open	No alarm
3	Upstream occlusion	When the infusion pump is in normal operation, the clamp is used to clamp the infusion tube near the upper pressure sensor	Alarm: Upstream occlusion	No alarm
4	Downstream occlusion	Close the roller clamp of the infusion device when the infusion pump is working normally	Alarm: Downstream occlusion	No alarm
5	Pump Err	When the infusion pump is working normally, the infusion pump is not equipped with the pump body	Alarm: Pump Err	No alarm
6	Drip Sensor Disconnected	Pull out the drop sensor when the infusion pump is working normally	Alarm: Drip Sensor Disconnected	No alarm
7	Free Flow	Under the condition of Non-infusion and Under the drop mode, Make the light on the drip sensor flicker 10 times.	Alarm: Free Flow	No alarm
8	AC Power disengaged	When AC power is supplied, remove AC	Alarm: AC Power disengaged	No alarm
9	Battery Empty	Infusion pump batteries are about to run out	Alarm: Battery Empty	No alarm

4.4 Replace the components regularly

The device has exclusive components: battery, drip sensor and peristaltic finger pump can be replaced regularly depends on the real use condition. Battery is consumable and it is advisable to replace every two years.

Parts: Advised replace periodBattery: two yearPeristaltic finger pump: two yearDrip sensor: two year

4.5 Transportation and storage

Store the device in the following condition after cleaning:

Temperature: -20°C-50°C; Relative Humidity:: 10%~95%; Atmospheric Pressure: 50KPa~106KPa

Please don't store the device in the following condition:

- a. Environment with direct sunlight or strong light.
- b. Environment with hot or wet air coming from heating installation, furnace and humidifier.
- c. Environment with chemical materials, dust, and humidity.
- d. Environment with water, dust, and humidity or shaking or unflat floor
- f. Don't overlap the device more than 5laps.

4.6 Pollution-free disposal and recycle

The life of the device is 5 years. Please scrap disposal for the device used more than 5 year and contact the manufacturer and distributor for more details

Dispose the device as following:

- 1. Deliver the disposed device back to the manufacturer or distributor for recycle.
- 2. Deliver the waste battery to the manufacturer or distributor or dispose it following the local recycle regulation

4.7 Compliance



A: Please read the operator manual prior to using this device!

Protection against leakage current: Type CF equipment.

IPX3: Protection against splashing fluid.

Chapter 5. Appendix

5.1 Appendix I Electromagnetic Compatibility

Warning

- Keep away from active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used not closer than 30 cm (12 inches) to any part of the infusion pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note :

- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Please install and operate the device based on the Electromagnetic Compatibility information with the device packing.
- Portable and mobile RF communication equipment may affect the performance of the infusion pump, avoiding to use the device near strong electromagnetic interference, such as mobile phones, microwave ovens, etc.
- The device or system should not be used close to or stacked with other devices. If it must be used close to or stacked, please pay attention to the normal working under the configuration during use.
- Class A equipment is intended for use in industrial environments. Due to conducted disturbances and radiated disturbances by the infusion pump, it may be potentially difficult to ensure electromagnetic compatibility in other environments.
- In addition to the transducers and cables sold by the manufacturer of the device or system as spare parts for internal components, the use of additional accessories, transducers, and cables may result in increased emissions or immunity to the device or system.
- Use of accessories, transducers, or cables outside of the regulations with equipment and systems may result in increased emissions or immunity to emissions from equipment or systems.
- Use of accessories, transducers, or cables outside of the regulations with equipment and systems may result in increased emissions or immunity to emissions from equipment or systems.
- The device or system should not be used close to or stacked with other devices. If it must be used close to or stacked, please pay attention to the normal working under the configuration during use.

- Special EMC protection for infusion pumps is required and installation and maintenance are required in an environment that meets the following EMC information.
- The infusion pump should be avoided to use with MRI or similar equipment. Otherwise, the device may get malfunction or collapse due to electromagnetic interference.
- Even if other equipment meets the CISPR emission requirements, it may also interference to use of the infusion pump.
- Portable and mobile RF communication equipment may affect the performance of the infusion pump.

SN	ITEM	Length (m)	Hide or not	Note
1	POWER CORD	3.0	NO	/
	DRIP SENSOR CONNECTION LINE			
2	(optional and need to confirm the	1.6	YES	/
	model before order)			

Table 1 Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions			
Emissions test	Compliance		
RF emissions	Crown 1		
CISPR 11	Group 1		
RF emissions			
CISPR 11	Class [A]		
Harmonic emissions	Class A		
IEC 61000-3-2	Class A		
Voltage fluctuations/ flicker emissions	Comply		
IEC 61000-3-3	Comply		

Table 2 Guidance and manufacturer's declaration - electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic Immunity				
IEC 60601-1-2		Compliance level		
Immunity Test	Test level			
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact		
IEC 61000-4-2	±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±8 kV, ±15 kV air		
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines		
IEC 61000-4-4	±1 kV signal input/output	Not Applicable		

	100 kHz repetition frequency	100 kHz repetition frequency		
Surge	±0.5 kV, ±1 kV differential mode	±0.5 kV, ±1 kV differential mode		
IEC 61000-4-5	$\pm 0.5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$ common mode	± 0.5 kV, ± 1 kV, ± 2 kV common mode		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 Power frequency magnetic field	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle 30 A/m	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle 30 A/m 50Hz/60Hz		
IEC 61000-4-8	50Hz/60Hz			
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz		
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz		
NOTE U	NOTE U_T is the a.c. mians voltage prior to application of the test level.			

Table 3	Guidance a	and manu	facturer's	declaration	- electromagnetic	Immunity
Table 5	Guiuance a	апи шапи	lacturer s	ucciar ation	- electromagnetic	Immunity

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
IMMUNITY to RF wireless communications	385	380 -390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27

equipment)				FM			
		430 470	GMRS 460, FRS 460	$\pm 5 \text{ kHz}$			
	450			deviation	2	0.3	28
				1 kHz sine			
	710	704	LTE Band 13, 17	Pulse			
	745	/04 -		modulation	0,2	0.3	9
	780	787		217 Hz			
	810	800 – 960	GSM 800/900,				
	870		TETRA 800,	Pulse			
	930		iDEN 820,	modulation	2	0.3	28
			CDMA 850,	18 Hz			
			LTE Band 5				
	1720	1 700 – 1 990	GSM 1800;	Pulse modulation 217 Hz	2	0.3	28
	1845		CDMA 1900;				
	1970		GSM 1900;				
			DECT;				
			LTE Band 1, 3,				
			4, 25; UMTS				
		2 400	Bluetooth,				
			WLAN,	Pulse			
	2450	2 400 -	802.11 b/g/n,	modulation	2	0.3	28
		2 570	RFID 2450,	217 Hz			
			LTE Band 7				
5240			Pulse				
	5500	5500 5 100 - 5785 5 800	WLAN 802.11 a/n	modulation	0,2	0.3	9
578	5785			217 Hz			

5.2 Appendix IIIV Trumpet Curve

Trumpet curve indicates the trend of the max and min deviations of the infusion and pump. The detection proposals introduced for obtaining results in this aspect are based on EN60601-2-24. For more detailed information, please refer to this publication.

The following curve represents the results after using Hanahao infusion tube in the test; and it is considered as only one basis of the overall performance of the infusion pump. For more related information, contact the supplier.



Graph No.1 Start-up graph: Flow QI (1ml/h) against time (min) plotted from data gathered during the first 2 h of the test period (Minimum)- Administration set brand: Hanahao



Graph No.2 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period (Minimum) - Administration set brand: Hanahao.



Graph No.3 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error B plotted from data gathered during the last hour of the test period Administration set brand: Hanahao



Graph No.4 Start-up graph: Flow QI (25ml/h) against time (min) plotted from data gathered during the first 2 h of the test period (Minimum)-Administration set brand: Hanahao



Graph No.5 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period (Minimum) - Administration set brand: Hanahao



Graph No.6 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error B plotted from data gathered during the last hour of the test period Administration set brand: Hanahao



Graph No.7 Start-up graph: Flow QI(25ml/h) against time (min) plotted from data gathered during the first 2 h of the test period at back pressure of +13,33kPa- Administration set brand: Hanahao



Graph No.8 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period at back pressure of +13,33kPa- Administration set brand: Hanahao



Graph No.9 Start-up graph: Flow QI(25ml/h) against time (min) plotted from data gathered during the first 2 h of the test period at back pressure of -13,33kPa- Administration set brand: Hanahao



Graph No.10 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period at back pressure of +13,33kPa- Administration set brand: Hanahao



Graph No.11 Start-up graph: Flow QI(25ml/h) against time (min) plotted from data gathered during the first 2 h of the test period(Minimum) at condition of -0.5m - Administration set brand: Hanahao



Graph No.12 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period(Minimum) at condition of -0.5m - Administration set brand: Hanahao

5.3 Appendix 5 Symbol and terms

Unit reference sheet

Abbreviation	English
Min	Minute
Н	Hour
Hz	Hertz
Mg	Milligrams
G	Gram
Kg	Kilogram
kPa	Kilopascal
Ml	Milliliter

Unit reference sheet

Abbreviation	English	
MRI	Magnatic resonance imaging	
AC	Altenating current	
DC	Dirct current	
EMC	Electromagnetic compatibility	
KVO	Keep vein open	
IEC	International Electrotechnical Commission	
ISO	International organization for Standardization	
LED	Light emitting diode	
СРИ	Central processing unit	
RAM	Random access memory	
ROM	Read-only memory	
Eto	C2H4O	
BOLUS	Bolus	