# User Manual
# Vet1 Vetpump Pro VP-50


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# Preface

## 1 Application Scope

Applicable to infusion pumps of our company.

This User Manual describes the product's most complete configuration, the accessories and functions may not be existed in the product of the user, for more detailed information, please contact manufacturer.

## 2 Applicable Object

It is applicable to the professional trained nurse, anesthetist, and the repair and maintenance technicians of this equipment.

## 3 Use Instructions

This User Manual covers the basic information on the safety and effectiveness of the product for guiding the operator to correctly install, test, operate, use and maintain the product. Please read this manual thoroughly before use and use the product in a correct way. Please carefully keep the User Manual for future use.

Our company is responsible for the reliability and performance of the equipment only all following conditions are met:

- Use the equipment according to this User Manual.
- The equipment can only be disassembled, assembled, replaced, tested, improved and repaired by the professional technicians of our company.
- All components and accessories as well as consumables for repairing are provided by manufacturer.
- Relevant electric devices meet the international standard IEC/EN 60601-1 and this User Manual.

## 4 Paraphrase

【】 means mechanical button

『』 means touch button

( ) further Information

- means inapplicable

√ means accordant

→ means operation steps

**Bolus**: Infuse large volume liquid in a short time.

**KVO**: Keep the vein open, prevent blood back to the IV tube and needle to be blocked.

**Anti-bolus**: Motor automatically reverse while the IV tube needle with high pressure.

**IrDA**: infrared communication

**Warning /Attention**: it may possibly cause physical injury or death if the cautions covered in the Warning are not obeyed.

**Caution**: it may possibly cause physical injury or property loss if the cautions are not obeyed.

**Note**: in case fails to follow the supplementary or prompt information on the operation instructions may possibly cause physical injury the equipment fault or property loss if it is not obeyed.

**Accessories**: the optional components which are necessary and (or) suitable for using with the equipment in order to achieve the expected purpose, or provide convenience for achieving the expected purpose, or improve the expected purpose, or increase the additional functions of the equipment.

# 5 Description on Revision of User Manual

Without Declaration any institute or individual are prohibited to copy, modify or translate the contents speculated in this User Manual.

This User Manual will be revised subject to product improvement, laws updating or instructions improving basing on the preconditions of meeting related laws and regulations, and all revised records will be stated in the new version.

| Version | Revising Date | Revised Content |
|---|---|---|
| V1.0 | 2019.3.20 | First edition |
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# Chapter1 Safety Instructions

## 1.1 Warnings

⚠

- Before using, please check the equipment, connecting wire and accessories to ensure that it can work normally and safely. If there's anything abnormal, immediately stop working and contact our after sale service department. Additionally, the adhesion or intrusion of fluid/drug may possibly cause the equipment fault and malfunction. Therefore, please clean the equipment after use, and store it correctly.

- This equipment must be operated by trained professional medical care personnel.

- This equipment is not applicable to blood transfusion.

- It is not allowed to put and use the equipment in the environment with anesthetic and other inflammable or explosive articles to avoid fire or explosion.

- It is not allowed to store or use the equipment in the environment with active chemical gas (including gas for disinfecting) and moist environment since it may influence the inside components of the infusion pump and may possibly cause performance drop or damage of the inside components.

- The operator shall guarantee that the inputted infusion parameters of this equipment are the same as the medical advice before starting infusion.

- Please correctly install the infusion apparatus according to the infusion indication direction of this equipment, ensure that infusion tube smoothly and straightly cross the creep device. Otherwise, it may possibly suck blood from the patient or fails to reach the expected performance.

- Please do not only depend on alarm system during use, please periodically check it to avoid accident.

- Tightly fix this equipment on the infusion stand and ensure the stability of the infusion stand. Be careful when moving the infusion stand and this equipment to avoid the equipment dropping and infusion stand falling or knocking the surrounding objects.

- If the infusion tube is twisted, or the filter or needle is obstructed, or blood in the needle which may obstruct the infusion, the pressure in the infusion tube will rise. When removing such occlusion, it may possibly cause "bolus injection" (temporary excess infusion) to the patient. The correct method is to tightly hold or clamp the infusion tube near the puncturing position, then open the door to drop the pressure in the infusion tube. Then loosen the infusion tube, solve the reason of occlusion, and restart infusion. If infusion is restarted when the occlusion reason exists, then it may cause occlusion alarm persistently, and the pressure in the infusion tube may keep rising, and may break or cut off the infusion tube, or hurt the patient.

- This equipment injects fluid/drug through extruding the infusion tube, but it can't detect the leakage if the infusion line is cut off or broken. Therefore, please periodically check it to avoid above fault during the working period.

- During infusion, please periodically check the dripping state of the fluid and the fluid/drug in the intravenous infusion bag/container, so as to ensure the correct working during infusion. This equipment doesn't directly measure the quantity of infusion fluid, therefore, it is possible that this equipment can't detect the free infusion flow under the extremely special condition. Even the drop sensor is adopted, it is possible that this equipment can't detect the free infusion flow which is less than the specific value for the demands of tolerance.

- This equipment has the occlusion detection function for detecting and alarming when the infusion needle deviates the position in the vein or the needle is not correctly punctured in the vein. However, it only alarms when the occlusion pressure has reached certain numerical value, and the puncturing part may possibly have become reddish, swelling or bleeding, additionally, it is possible that the device doesn't alarm for a long period if the actual occlusion pressure is lower than the alarm threshold value, therefore, please periodically check the puncturing part. If there's any abnormal phenomenon for the puncturing part, please timely take suitable measures, such as puncturing again.

- Only those infusion apparatus, line, infusion needle and other medical components that meet the local laws and regulations and the requirements covered in and this User Manual can be adopted, it is suggested to adopt the infusion apparatus with same brand as defaulted in this equipment. It can't ensure the infusion accuracy if the unsuitable infusion line is adopted. The drop sensor is based on infrared sensor technology, if the drip sensor function is turned on, the light-proof pipeline is not applicable, otherwise the drip sensor mode may fail.

- It is not allowed to disassemble or refit this equipment or use it for other purposes except normal infusion.

- No one is allowed to repair this equipment except our company or the authorized repair technician of our company.

- To avoid risk of electric shock,this equipment must only be connected to a supply mains with protective earth.

# 1.2 Cautions

⚠

- Before its first use after purchase, or this equipment is not used for a long period, please charge the equipment with AC power supply. If it is not fully charged, under power failure, the equipment can't continue working with built-in battery power supply.

- This equipment can't be used in the places with radiological installation or magnetic resonance equipment as well as the places with high pressure oxygen therapy.

- Other devices near this equipment must meet corresponding EMC requirements, otherwise, it may influence the performance of this equipment.

- Under general conditions, please use AC power supply as much as possible since it can prolong the service life of the battery at a certain degree. When using AC power supply, ensure that the grounding wire is reliably connected with the ground, and only the AC power wire attached with this equipment shall be adopted, please pay attention to the plug position of the power cord to ensure that you can disconnected it at any time. The built-in battery can only be used as the assistant power supply when the AC power supply can't reliably connect with the ground and is not under normal conditions (power failure or in-transport infusion).

- Before connecting this equipment with power supply, please keep the power socket and plug dry, and the power voltage and frequency meet the requirements listed in the equipment label or this User Manual.

- The equipment is equipped with the audible and visual alarm system, and the red and yellow alarm indicators will light on by turn to check if the alarm system can work normally, and the speaker makes the "beep" sound.

- Please keep the equipment away from the AC power socket for a certain distance to avoid fluid/drug splashing or dropping in the socket, otherwise, it may possibly cause short circuit.

- Please use the fluid/drug after it has reached or nearly reached room temperature. When the fluid/drug is used at low temperature, the air which is dissolved in the fluid/drug may cause more air bubbles and result in frequent air bubble alarm.

- It is not allowed to press and operate the button with sharp object (such as pencil tip and nail), otherwise, it may possibly cause early damage to button or surface film.

- Please do not use the infusion tube over 8 hours at the same pumping position. Infusion tube may distort after using for a long time and cause flow rate error. It is suggested to replace the pumping position or directly replace the infusion tube once every 8 hours.

- Please tightly close the flow rate adjuster of the infusion apparatus before taking out the infusion apparatus to avoid infusion free flow.

- Under the condition of low flow rate infusion, please pay special attention on occlusion. The lower the infusion flow rate, the longer the time of detecting occlusion, and it in turn may possibly cause a long time infusion stop during this period.

- If the equipment suffered from dropping or impacting, please stop using it immediately, and contact our after sale service department, because the inside components of the equipment may be possibly damaged even the appearance is not damaged and abnormality is not occurred when working.

## 1.3 Dialogue window

Dialogue window mainly content include operation select, operation confirm etc. tips information. For instance:

## 1.4 Symbols

Not all of the below symbols are existed in the equipment you have purchased.

**Table 1.4-1**

| Marks | Description | Marks | Description |
|---|---|---|---|
| LOT | Lot Number | | Class I Equipment |
| SN | Serial Number | IP34 | Ingress Protection(Prevent solid objects larger than 2.5mm in diameter and water intrusion from splashing in all directions) |
| | Attention, consult accompanying documents | | Alternating Current |
| | Defibrillation proof type CF applied Part | | Handle with harmless method |
| | Date of Manufacture | | Manufacturer |
| 20 | environment-friendly use period (20 years) | | Non-ionizing radiation |
| EC REP | Authorized Representative in the European Community | | Please refer to User Manual /Handbook |
| | Unlock | | Lock |
| | Input and output | CE 0197 | Notified Body |

# Chapter2 Overview

## 2.1 Application Scope

### 2.1.1 Expected Purpose

This product is used for constant speed intravenous infusion in hospital.

### 2.1.2 Expected Working Environment

Including but not limiting to: hospital ICU (intensive care unit), operating room, neonate intensive care unit(NICU).

### 2.1.3 Suitable object

Adult, child or neonate.

## 2.2 Contraindications

No

## 2.3 Working Principle

This equipment is a kind of instrument which can drive the pump to extrude the infusion tube for accurately control of the infusion drops or infusion flow rate with the motor, and is capable of guaranteeing to convey drug fluid safely in the vein of patient with even rate and accurate dosage.

## 2.4 Structure and Performance

### 2.4.1 Structure and Performance

The infusion pump mainly composes of the main unit and built-in battery, and can be installed with the drop sensor. This equipment provides several infusion modes, such as rate mode, time mode, body weight mode, drip mode, drug library mode, ramp up/down mode, loading dose mode and sequence mode. Additionally, it also has functions such as history records, drug library, Anti-bolus, and alarm and so on.

### 2.4.2 Accessories

Drop sensor (optional) , the drop sensor is suitable for any type of infusion equipment.

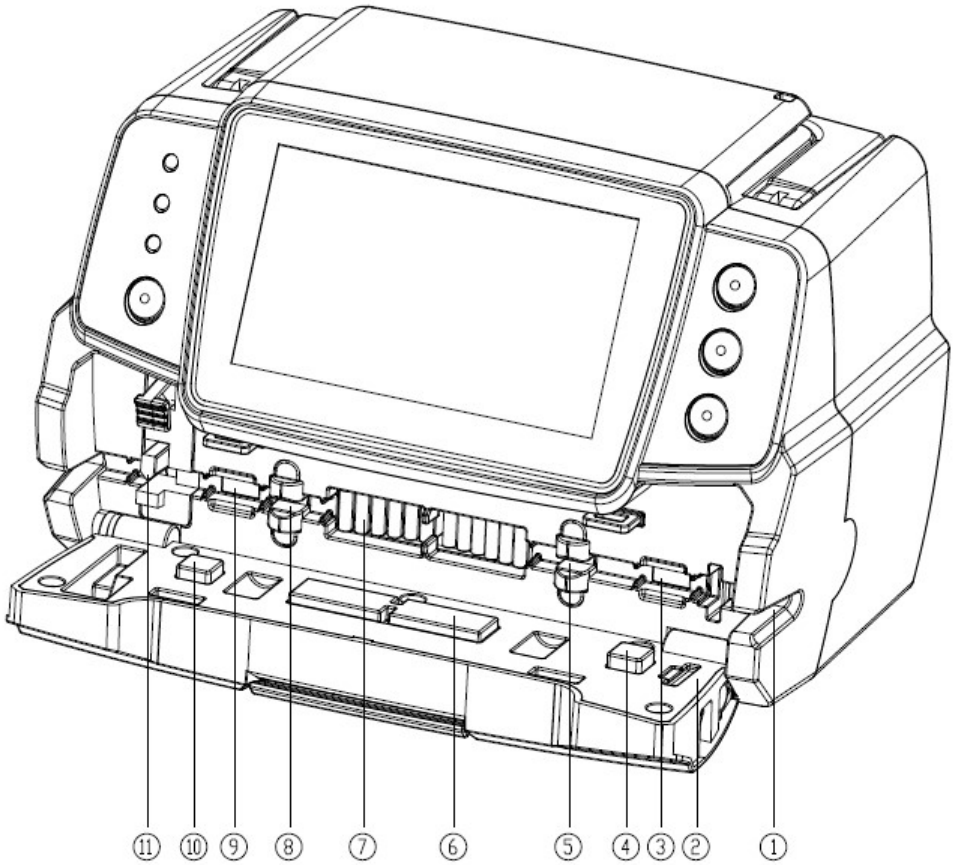
# 2.5 Product Specification

| Safety Classification | |
|---|---|
| Electric protection Type | Class I |
| Electric protection Level | Defibrillation proof type CF applied Part |
| Ingress Protection | IP34 (Prevent solid objects larger than 2.5mm in diameter and water intrusion from splashing in all directions) |
| Working mode | Continuous |
| Classification | Portable equipment, non-portable infusion pump |
| Specification Parameters | |
| Infusion apparatus specification | 20 drops |
| System Accuracy | ±5% |
| Drip Infusion Rate Accuracy | ±10% or ±1drops/min |
| Infusion Rate | 0.10-1500ml/h |
| Drip mode range | 1~500drops/min |
| Bolus Rate | 0.1-1500ml/h |
| Bolus preset | 0.1-50ml |
| KVO Rate | 0.1-5.00ml/h |
| Micro mode setting range | 100-1500ml/h |
| Minimum flow rate increment | 0.01ml/h |
| VTBI | 0-9999.99ml, minimum step is 0.01ml |
| Total Volume Infused | 0-9999.99ml, minimum step is 0.01ml |
| Time Range | 1min-99hrs59min |
| Fuse Type | slow fuse 2A 250V |
| Dimensions | 199(W)*111(D)*126.5(H) mm |
| Weight | 1.4kg |
| Power Supply | |
| AC power supply | 100-240V 50/60Hz |
| Input power | 50VA |

| | |
|---|---|
| DC power supply | DC 12V |
| Battery Specifications | Specification: 7.4V 2500mAh<br>Charging time: a single battery is 4.5h , two battery is 9h.(under OFF status)<br>Working time:a single battery is over 4h , two battery is over 8h.(after completely charging the new battery, when the environment temperature is 25℃ and flow rate is 25ml/h, the constantly working time) |
| Alarm | |
| Alarm signal sound pressure level | When the sound is set at lowest level, alarm signal sound pressure level ≥50dB(A)<br>When the sound is set at highest level, alarm signal sound pressure level ≤80dB(A) |
| Alarm information | VTBI near end,VTBI infused, Pressure high, Check upstream, Battery nearly em ply, Battery empty, No battery inserted, No power supply, Reminder alarm, Stand by time expired, KVO finished, Drop sensor connection, Drop error, Air bubble, Door Open |
| Environment | |
| Non AP/APG type equipment | Do not use it in the environment with inflammable anaesthetic gas mixed with air, and inflammable anaesthetic gas mixed with oxygen or nitrous oxide |
| Operating | (1) temperature: 5-40℃<br>(2) humidity: 20-90%, non-condensable<br>(3) atmospheric pressure: 86-106kPa |
| Transport & Storage | (1) temperature: -20-60℃<br>(2) humidity: 10-95%, non-condensable<br>(3) atmospheric pressure: 50-106kPa |
| Safety Standard | |
| Main Safety Standards | IEC 60601-1:2005+A1:2012<br>Medical Electrical Equipment, Part 1: General Requirements for basic safety and essential performance<br><br>IEC60601-2-24:2012<br>Medical electrical equipment – Part 2-24: Particular requirements for the safety o f infusion pumps and controllers<br><br>IEC60601-1-8：2006+A1：2012<br>Medical electrical equipment –Part 1-8: General requirements for basic safety an d essential performance –Collateral Standard: General requirements, tests and gui dance for alarm systems in medical electrical equipment and medical electrical sy stems<br><br>EN60601-1-2:2007+AC:2010<br>Medical Electrical Equipment - Part1-2: General requirements for basic safety an d essential performance-Collateral standard:Electromagnetic compatibility-Requi rements and tests |

# Chapter3 Appearance

## 3.1 Front View




① Tubing guide

② Pump door

④⑥⑩ Pressure Plate

③Pressure sensor-UPSTREAM

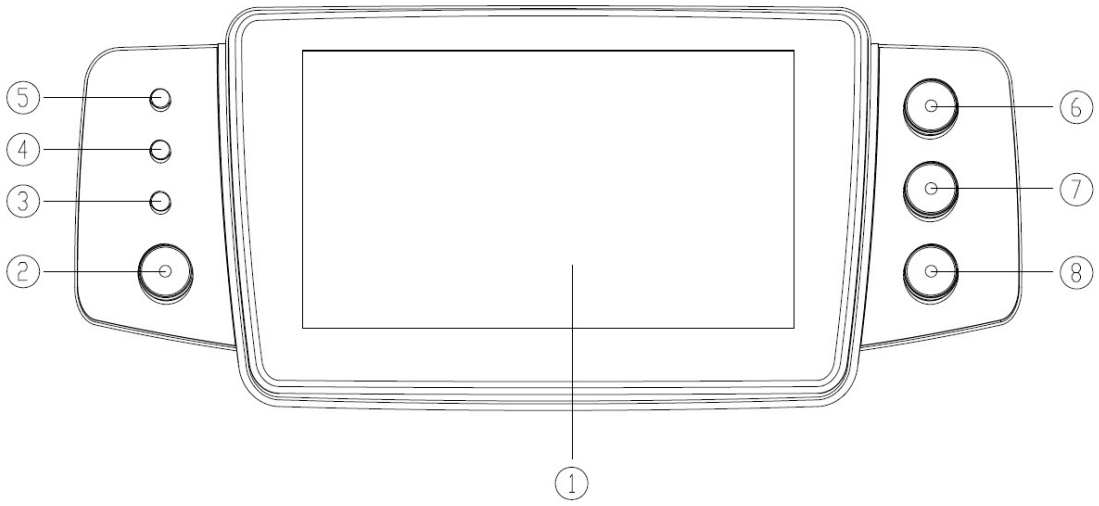
⑦ Pump tablets

⑨ Pressure sensor-DOWNSTREAM

⑤⑧Air–in-line sensor

⑪Anti-free flow clamp

# 3.2 Operation Panel




① Touch Screen

②【Power】

Pump power switch, press and hold for 3 seconds, pump power off. Standby selection button.

③ AC indicator light

When connecting with AC power supply, AC indicator lights on.

④ Alarm indicator

While pump alarms, indicator light glitter, different level different frequency and color, more information please **refer to Chapter 10.1**

⑤ Running lights

⑥【Start/stop】

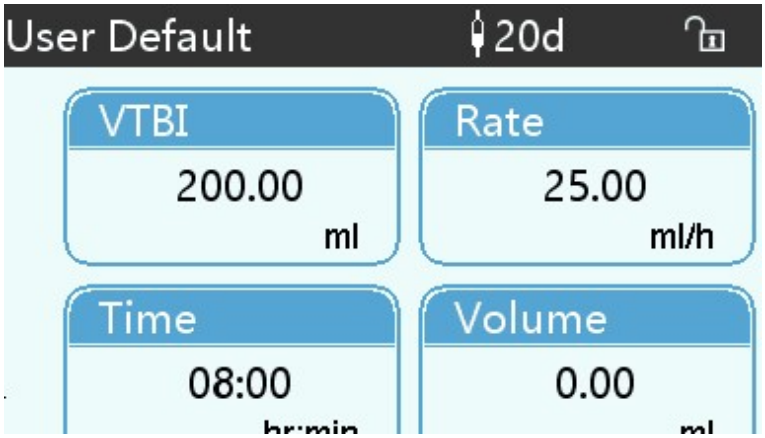
⑦【Bolus/Purge】

⑧【Home】

Enter system home page.

# 3.3 Display Screen

The display screen interface layout composes of title bar and typical interface.




## 3.3.1 Title Bar

Title bar displays real-time state information and is not touchable, the left upper corner displays the name of current editing parameter.

**Table3.3.1-1: Title Bar Icon**

| Icon | Paraphrase | Description |
|---|---|---|
|  | Infusion apparatus indication icon | Infusion apparatus indication icon |
|  | Lock screen indication icon | Unlock state icon is  |
|  | WIFI indication icon | Indicate WIFI connection state. |
|  | Battery charging indication icon | Display the current battery charging state |
|  | Battery status indication icon | The percentage numerical value at the left side of the icon displays the remained battery.<br>Since the remained battery may change, it may possibly show the following states:<br>  |

## 3.3.2 Typical Interface

During pre-infusion and infusion, the typical interface will display the following: main interface, working interface, alarm interface, prompt interface, control panel, parameters setting, input method, standby interface etc.

### 3.3.2.1 Typical Interface Icon Paraphrase

**Table3.3.2.1-1**

| Icon | Paraphrase | Description |
|---|---|---|
| | Start | Click this icon, start infusion |
| | Stop | Click this icon, infusion stop |
| | Bolus/Purge | 1. During infusion, it is『Bolus』function, click it to start fast infusion<br>2. Before infusion starting, it is『Purge』function, click it to exhaust air from the IV set |
| | Home | Click this icon, return to the main interface |

### 3.3.2.2 Input Method Interface

The input method interface composes of the title bar, input box, editing box.

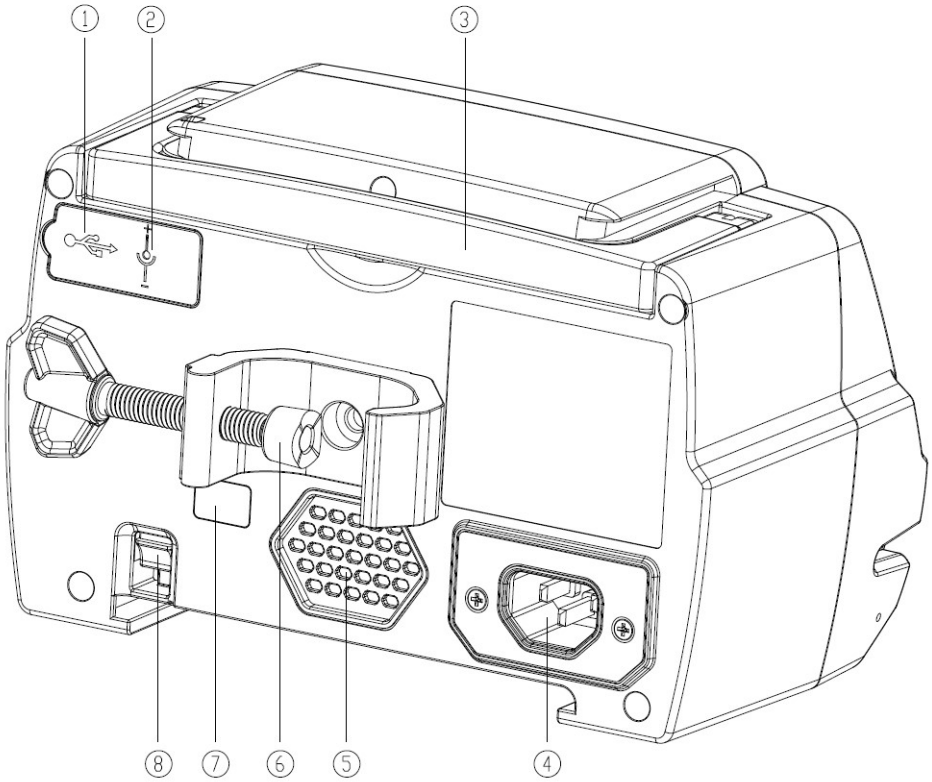

1) Title bar: display the name of current editing parameter.
2) Input box: real-time display the input content.
3) Editing box: It composes of the main button area and function button area.

The main button area composes of the numerical value, letters and icons, click it continuously to change the sequence.

The function button area composes of clear button, backspace button, 『 』, 『 』, 『 』and『Shift』.

| **Icon** | **Paraphrase** | **Description** |
|---|---|---|
| | Backspace button | Click it to backspace delete |
| Shift | Shift button | Click it to switch the capital and lowercase English letters |
| | Cancel button | Click it to cancel editing and exit |
| | OK button | Click it to save editing and exit |
| | Backspace button | Click it to backspace delete |

# 3.4 Rear View




① USB Port

Port for software upgrade and drop sensor

② DC Input Port

External 12V DC power supply

③ Handle

④ A/C Adapter Port

External 100-240V 50/60Hz AC power supply

⑤ Loudspeaker

⑥ Pole Clamp

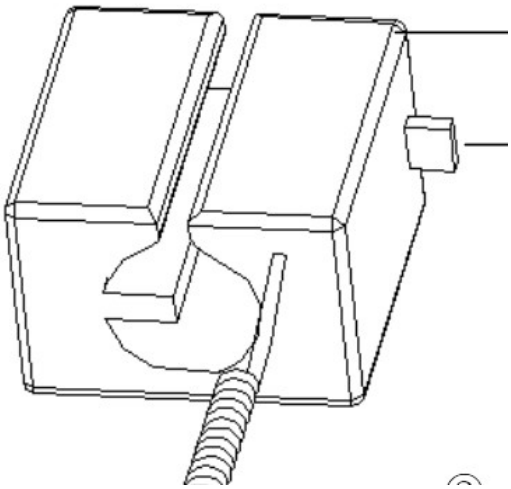
Using for fixing the equipment on the infusion stand

⑦ IrDA

Using for communicating with infusion docking station(Optional)

⑧ Latch for stackable function

# 3.5 Drop sensor (optional)



① Housing

② Slider

Push the slider to left direction to adjust the spacing, loosen the slider to automatically return

③ Cable

Connect this equipment drop sensor port

# Chapter4 Installation

## 4.1 Unpacking and Checking

1) Please check the appearance before unpacking, if broken, please contact the transportation company or our after-sale service department quickly.

2) Please carefully open the package to avoid damaging the equipment and relevant accessories.

3) After unpacking, please check the objects according to the packaging list, if there is insufficient or damaged accessories, please contact our company as soon as possible.

4) Please keep relevant accessories, warranty card and User Manual.

5) Please keep the packing case and packing materials for future transportation or storage.

⚠ Warning: Please put the packing materials out of reach of children. Please obey local laws and regulations or the hospital waste treatment system to handle the packing materials.

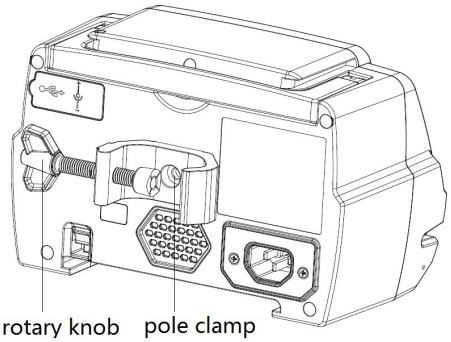
## 4.2 Installation

⚠ Warning:

- This equipment shall be installed by the designated technicians of our company.
- All devices that connect with this equipment must pass the designated IEC standards (for example: IEC60950 information technology equipment safety and IEC60601-1 medical electric device safety) certification, and all devices must be connected according to the valid version of IEC60601-1-1 system. The technician who takes charge of connecting to additional devices with the equipment interface is responsible for meeting the IEC60601-1-1 standard. Please contact our company if you have any enquiry.
- When connecting this equipment with other electric devices to form the combination with special function, if the combination can't be confirmed dangerous or not, please contact our company or the electric expert of hospital to ensure that the necessary safety of all devices in the combination won't be destroyed.
- This equipment must be used and stored in the environment regulated by our company.

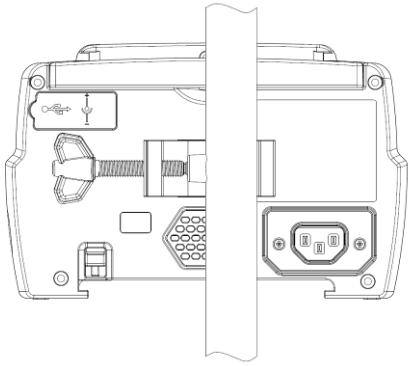
## 4.2.1 Install the Infusion Pump

(1) Rotate the pole clamp screw(knob) and unscrew to leave the space.




(2) Lock the Pole Clamp on the infusion stand, adjust the position of the infusion pump, tighten the pole clamp to fix the infusion pump on the infusion stand (shown in drawing below). Hold the infusion pump when tightening the fixing clamp; loose it after tightening to avoid falling.

(3) The pole clamp supports the vertical pole at default state. To adjust the pole clamp direction, please remove the bolt from the pole clamp screwdriver, take out the pole clamp and adjust the direction, then tighten the bolt.

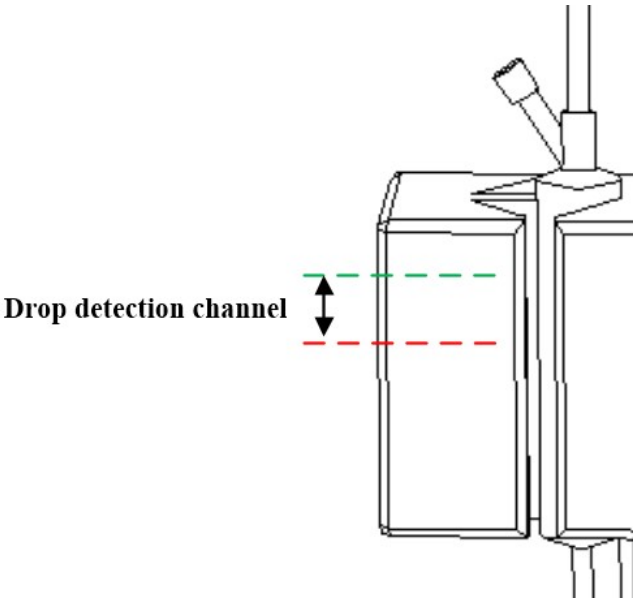


## 4.2.2 Install the Drop sensor

(1) Insert the drop sensor plug into the drop sensor port of this equipment and ensure tight connection.

(2) Drop start should be above the green line.

(3) Liquid level should be below the red line.




⚠ Warning:

● The fluid/drug volume in the murphy's dropper must be less than 1/3 of its volume.

● The drop sensor shall be vertical.

- Drop sensor infrared sensor technology, while drip mode is on, light-shielding pipeline is not suitable, otherwise the drip mode may fail.

# Chapter5 Use Preparation & Cautions

## 5.1 Use Preparation

The new equipment, or reusing after storing for a period, or reusing after repair, please check it to ensure before use:

- The equipment appearance is clean and under good condition without crack and leakage.
- The moving components are smooth and effective, for example: the pump door can be opened and closed smoothly, the button is effective.
- The touch screen can be operated smoothly and effectively.
- The power wire is installed tightly and won't be easily damaged when pulling.
- Set and check the system time to ensure that the history records will be correctly recorded.
- In case only built-in battery is adopted for supplying power, please charge it to full before using, and ensure that the battery keeps at the effective working conditions.
- Carefully read the Warnings, Cautions and Operation Steps listed in this User Manual.

## 5.2 Operation Cautions

⚠ Cautions:

- Avoid direct sunlight, high temperature or high humidity.
- The equipment shall be put at the position less than 1.2m (both up and down) to the heart of the patient.
- The parameters can only be set or changed by the trained and professional personnel.
- Avoid the equipment working with fault so as to avoid medical negligence, which may hurt the health and even life of the patient.
- It may possibly drop the infusion accuracy or abnormal work of the equipment if the working environment temperature exceeds the designated range.
- The viscosity and specific gravity of infusion fluid will influence the infusion accuracy.

# Chapter6 Basic Operation

## 6.1 Operation Flow

¤ Mount the infusion pump on the IV stand: **refer to Chapter 4.2**

¤ Power on: press  two seconds, Power on equipment, **refer to Chapter 6.2.2**

¤ Install IV Set: **refer to Chapter 6.2.3**

¤ Confirm IV set brand name: Select infusion tube brand or add new brand

¤ Remove air bubble from the line: **refer to Chapter 6.2.5**

¤ Select infusion mode: Select infusion modes according to requirement

¤ Set infusion parameters: set infusion parameters according to requirement

¤ Connect the infusion line with the patient

¤ Start infusion press  , start infusion

¤ Infusion finish **refer to Chapter 6.2.9**

¤ Remove the IV Set **refer to Chapter 6.2.11**

¤ Power off or Standby **refer to Chapter 6.2.12**

# 6.2 Infusion Operation

## 6.2.1 Equipment Installation

Mounting the device on the infusion stand according to **Chapter 4.2**, connect with AC power supply，check the AC indicator lights. Battery will start to charge once AC power connected.

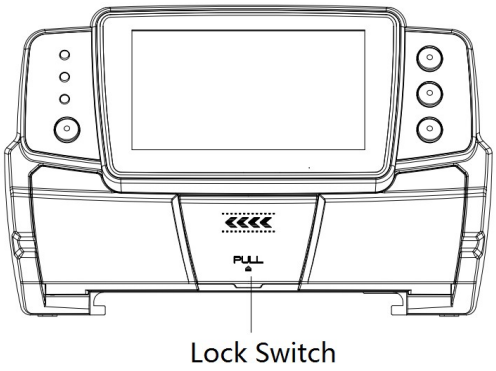
## 6.2.2 Starting and Self-test

1) Press  two seconds，power on the equipment.
2) After power on, the system will automatically check the motor, sensor, battery, memorizer, CPU communication, alarm indicator.
3) After passing self-test, pump enters into rate mode interface.

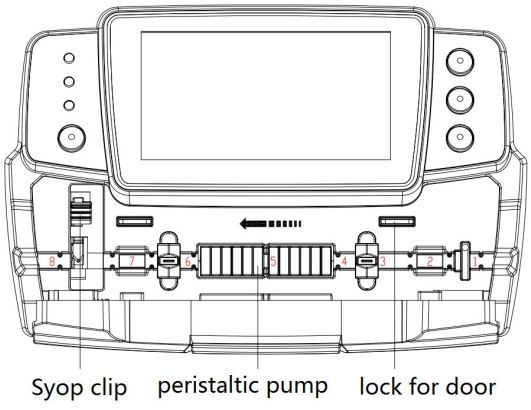
⚠Warning: ● If self-test failed, pump cannot operate properly or damaged, it cannot used for patient infusion, please contact the company.

## 6.2.3 Infusion Apparatus Installation

1) Connect the IV line with the infusion bottle.
2) Extrude the drip chamber, when the fluid has reached 1/2 position of the drip chamber, open the roller clamp.
3) Fill fluid/drug to the injection needle to remove air, then close the roller clamp.
4) Pull the lock switch in the middle of the pump door from the lower side, then open the door.
5) Push up anti-free flow clamp to open it.




6) Install the infusion tube in the infusion tube slot according to direction indicator and Drawing below, press the IV set in the pump inwards to make it attach the peristaltic pump. Ensure that items 1-8 shown in Drawing below are correctly installed.
7) Manually push the pump door with both thumbs on left and right side, it will make a “click” sound after it is correctly closed.
8) Click 『Settings』→ 『Commonly used tube brand』, select infusion apparatus brand.




⚠Warning: ● It is suggested to use the infusion apparatus brand defaulted in this system.
● Please confirm that the infusion apparatus brand

and specification displayed in the display screen is accordant with the actual one in use.
● Although this equipment supports user-defined infusion apparatus function, in order to ensure the infusion accuracy, the user is strongly suggested to contact our company, and ask the professional technician of our company to set and test the user-defined infusion apparatus.

9) Install Drop sensor

Please install it according to Chapter 4.2.2. After installing, click 『Settings』→ 『Drop sensor』 to activate the drop sensor function.

⚠ Caution ● The default state of drop sensor function is OFF, this function can be manually activated by the user when the drop sensor is adopted.

## 6.2.4 Set Infusion Parameters

**refer to Chapter 7.**

## 6.2.5 Purge Air

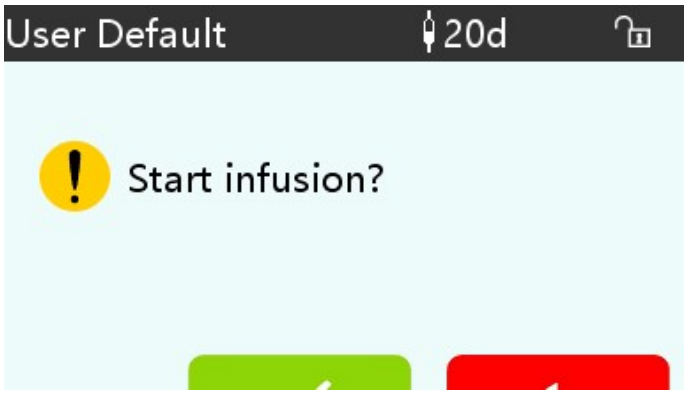
Under the parameters setting interface, Press 【Bolus】button on product panel and hold on, Or touch the screen purge icon ◀◀ to eliminate the air bubble in the line .
The purge total volume is not calculated in the Total Volume Infused.

⚠Cautions:

● Before purge air, double check to confirm the infusion line is **not connected** with the patient.
● Purge rate is the max rate, when purge volume ≥5ml, purge will automatically stop.

## 6.2.6 Start Infusion

Connect IV tube with patient, confirm infusion parameters, Press【Start】button ⓘ, click 『yes』 ✔ in the pop-up prompt interface, start infusion.




## 6.2.7 Changing the Rate During infusion

Under running interface, click rate number in touch screen or【Stop】 ⓘ, and enter parameters

setting interface, reset target infusion rate.
, and then enter parameters setting interface, reset target infusion rate.

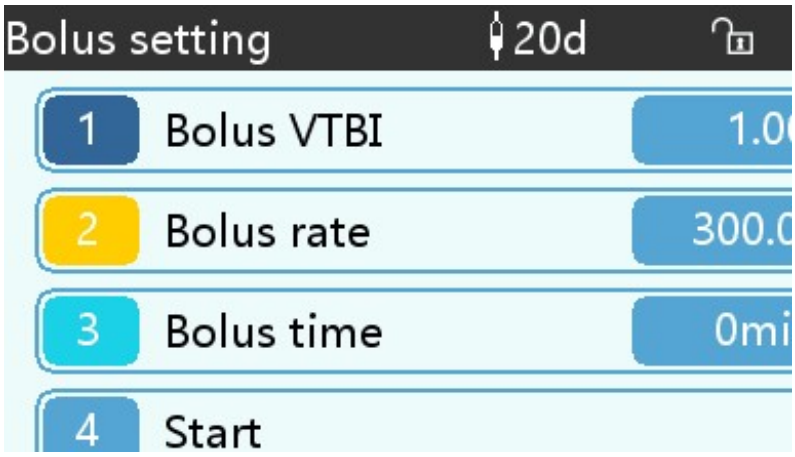
⚠ Note: ●Only the ***rate mode, drip mode*** and ***Body weight mode*** support online rate modification function during infusion without press【Stop】

## 6.2.8 Bolus Application

In operation, Bolus functions have two operation modes: Manual bolus and Automatic bolus.

(1) **Manual bolus**: press and hold the 【Bolus】button on product panel, pump will work at the max flow rate or set max bolus rate under setting interface, release the button, pump will back to the previous setting infusion rate.

(2) **Automatic bolus**: Under the running interface, click『Bolus』on touch screen, set two parameters among bolus infusion volume, rate and time, click『Start』. it will beep at every 1ml infused. After bolus infusion finished, the equipment back to the previous infusion rate.




## 6.2.9 Infusion Completion

When remaining infusion time is near preset volume to be infused completion time, pump will alarm. If ignore it, the system will keep alarming until complete VTBI infusion, For more information pls **refer to Chapter 8.1.10**

After VTBI completed, it activates VTBI infused alarm, if KVO function is ON, the equipment automatically starts KVO function, click 『OK』in the alarm interface to stop KVO and eliminate alarm.

The default working time of the KVO system is 30min, after reaching the time, it will activate KVO completion alarm and stop infusion.

Please **refer Chapter 8.1.1** to set KVO rate.

## 6.2.10 Stop Infusion

During infusion or after infusion, click , infusion stop. It will return to the parameter setting

interface display Total Volume Infused and adjustable parameters.

## 6.2.11 Remove the Infusion Apparatus

Disconnect the IV set's extension line from the patient, then remove the IV sets.
Replace IV set, please follow the steps of **Chapter 6.2.3**.

## 6.2.12 Power OFF or Standby

Method 1: hold the 【Power】Button till the screen is OFF, the equipment is OFF.
Method 2: press the 【Power】Button to enter into OFF interface.

(1) Turn off the equipment: click 『Power off』icon, the equipment is turned OFF.
(2) Standby: click『Standby』icon to enter into standby time setting interface, set the standby time. Under standby state, the screen brightness will be lowest, after standby, the screen brightness will be recovered.
(3) Cancel: click『Cancel』, return to the interface before OFF setting.

⚠Note:

● The equipment has standby function only under the non-working state.

## 6.2.13 Replace Infusion Line/Infusion Container

★ Please replace the infusion tube assembly according to the following steps:
- Close the flow rate adjuster of the infusion tube assembly, open the infusion pump door, and then remove the infusion tube assembly.
- According to the manual Chapter 6.2.3, prefill and install the new infusion tube assembly.
- Operate to restart infusion according to the above infusion steps if needed.

★ Please replace the fluid/drug container according to the following steps:
- Close the flow rate adjuster of the infusion tube assembly.
- Remove the fluid/drug container from the infusion tube assembly.
- Connect the infusion tube with the new fluid/drug container.
- Restart infusion according to the above steps of replacing infusion tube assembly.

⚠Warning: ● The infusion tube will distort if it works for a long period and result in bad accuracy or flow rate error, it is suggested to replace the pumping position or infusion tube assembly after working for 8h.

# Chapter7 Set Infusion Parameters

## 7.1 Introduction to Infusion Parameters Setting

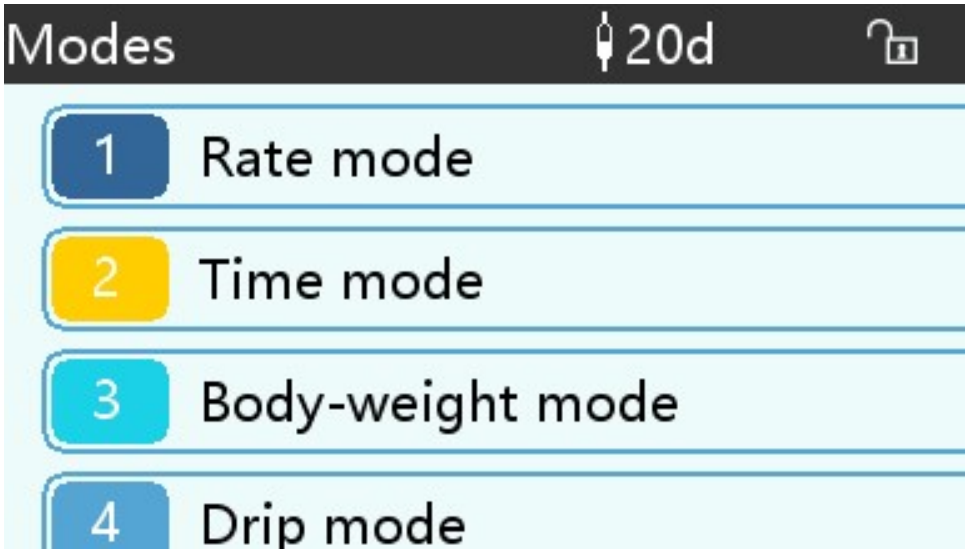
(1) The drug information can be displayed in the infusion running interface only when the drug library is under active state.
Click『Settings』 icon in the main interface to enter sub-menu, find 『Drug Library』 menu item, click to enter then set the ON/OFF state of drug library and select drug. Please refer to this User Manual Chapter 9.1 for details.
(2) For both the rate set in infusion parameter and the rate calculated by the system, the range is the system default flow rate of the current working infusion apparatus specification.
(3) If didn't set VTBI (Volume to be infused), which means to complete the fluid/drug in the infusion container.

## 7.2 Infusion Parameters Setting Range

| Infusion Parameter | Parameter Range |
|---|---|
| VTBI | 0-9999.99ml |
| Rate | 0.1-1500ml/h |
| Time | 1min-99hrs59min |
| Weight(Body weight) | 0.1-300kg |
| Conc.unit(Concentration unit) | ug/ml, mg/ml, g/ml, U/ml, kU/ml, IU/ml, EU/ml, mmol/ml, mol/ml, kcal/ml |
| Volume(Fluid amount) | 0.1-9999.99ml |
| Dose rate | 0.1-9999.99 |
| Dose unit | Unit(/kg)/min, Unit(/kg)/h,the Uint is Conc.uint |
| Drop rate | 1-500 drops/min |

## 7.3 Infusion Mode Setting

After starting the equipment and self-test, the equipment automatically enters into the rate mode parameters setting interface, to select other mode, click『Menu』icon to enter into the main interface, click『Modes』icon to enter into the mode selection menu interface, and select preset infusion mode.




### 7.3.1 Rate Mode

Under this mode, it allows to set three parameters: Rate, VTBI (Volume to be infused) and Time, set any two of the three parameters, and the system will automatically calculate the third parameter, if the VTBI is 0, then the equipment works at the set rate till stop with alarm.

### 7.3.2 Time Mode

Under this mode, it allows to set VTBI(Volume to be infused) and Time, the system will automatically calculate the speed, speed = Volume(ml) /time(min)

### 7.3.3 Body Weight Mode

Under this mode, set the Weight(body weight), Acti agentia(drug mass), Conc.unit(concentration unit), Volume(fluid volume), Dose rate, Dose unit, VTBI.
The system will automatically calculate the flow rate from the specified dose rate (ug/kg/min, mg/kg/min, ug/kg/h, mg/kg/h,…etc) according to related formula {dose rate × weight}/{Acti agentia(drug mass)/Volume(fluid volume)}, and automatically calculate the time according to (VTBI) /(flow rate).

### 7.3.4 Drip mode

Under this mode, set the VTBI and drop rate, and the system will automatically calculate the infusion flow rate and time.

⚠Note: ● The flow rate under drip mode is calculated according to the specification of the current infusion apparatus, before adopting the drip mode, please confirm that the specification of the current infusion apparatus is accordant with the specification displayed in the interface title bar display, if it is not accordant, please contact the equipment maintenance technician to modify, otherwise, it may cause serious deviation of flow rate.

### 7.3.5 Drug library mode

Under this mode, set the Weight(body weight), Conc.unit(concentration unit), Dose and VTBI, the speed will automatically calculated according to this parameters.

### 7.3.6 Ramp up/down mode

Ramp up/down mode means to automatically increase the flow rate till reaching stable flow rate within the set rise time of the equipment through setting the rise time and fall time, after holding for a period, it automatically drops the flow rate within the set fall time. The rising or dropping stage is implemented in multiple stages.
Under this mode, set VTBI, rate in the stable stage, rise time and fall time, the system will automatically calculate the rising and dropping rate.

### 7.3.7 Loading dose mode

The Loading dose mode means to infusion with the Loading flow rate according to the Loading time, after reaching the Loading time, it works at the Maintain rate till complete the VTBI(Volume to be infused).
Maintain time = (VTBI -Loading VTBI) /Maintain rate
Under this mode, set the VTBI, Maintain rate, Loading rate, Loading time, system automatically calculate Loading dose VTBI and Maintain time.

⚠Note: ● VTBI must be greater than the Loading dose VTBI otherwise, when setting exceeds the limit, the excess part can’t be set.

### 7.3.8 Sequence Mode

Sequence mode means to infuse according to the set sequence after setting the rate and time of different sequence groups. This pattern supports setting up multiple sequences.

# Chapter8 System Setting

## 8.1 Settings

Click『Settings』icon in the main interface to enter into parameters setting interface.

### 8.1.1 Drug Library

Click on the preset drug name, the selected drug will be reflected in infusion mode parameters.
This feature can be turn on and off.
（1）No less than 2000 drugs, can be imported through external tools, with upper and lower limit, concentration configuration, color configuration and other functions.
（2）Suport 30 drugs, without upper and lower limit.

### 8.1.2 KVO Rate

Click『KVO rate』, input the numerical value, after confirming, click『OK』.
Please refer to Chapter 2.5 for the adjustable KVO range.

### 8.1.3 Bolus Rate

Set the default Bolus rate. Please refer to **Chapter 2.5** for the range of bolus rate.

### 8.1.4 Commonly used tube brand

For the built-in infusion apparatus brand of the system, after installing the infusion apparatus, click『Commonly used tube brand』to enter into the infusion apparatus brand selecting interface, and click the preset brand option.
The system built-in infusion apparatus brand: Boon.

⚠ ● The infusion apparatus of different brand may possible cause flow rate deviation, when use, please confirm if the displayed information in the interface is accordant with the actual infusion apparatus in use.

### 8.1.5 DPS

DPS, Dynamic pressure detection can be carried out after opening, alarm can be triggered when the pressure continues to rise or suddenly falls, this function is optional

### 8.1.6 Occlusion Pressure

Click『Occlusion pressure』to enter into occlusion pressure level setting interface, move the long box to the preset level, after confirming, click『OK』.

The higher the level, the higher the occlusion level, it is suggested to select suitable occlusion pressure according to actual requirement.

⚠Warning:

● When adopting fluid/drug of high viscosity and the occlusion pressure is set at low level, it is possible that the system will report occlusion alarm even when the line is not obstructed, under this condition, please carefully observe the pressure indication icon in the display screen and infusion line, and rise the occlusion pressure if needed.

● When the occlusion pressure is set at high level, it may possibly cause the patient uncomfortable, after rising the occlusion pressure, please carefully observe the condition of the patient, and immediately take measure if there's any abnormality.

● Under the equipment fault state, the max pressure generated by the infusion line is 300kPa. Under single fault state, the max infusion volume is 2ml.

**(Table: Relation of Occlusion level and Pressure)**

| **Occlusion Pressure Level: 3 levels** | | | | | |
|---|---|---|---|---|---|
| Level | Pressure Intensity (mmHg) | Level | Pressure Intensity (mmHg) | Level | Pressure Intensity (mmHg) |
| 1 | 300 | 2 | 600 | 3 | 900 |

| **Occlusion Pressure Level: 12 levels** | | | | | |
|---|---|---|---|---|---|
| Level | Pressure Intensity (mmHg) | Level | Pressure Intensity (mmHg) | Level | Pressure Intensity (mmHg) |
| 1 | 75 | 2 | 150 | 3 | 225 |
| 4 | 300 | 5 | 375 | 6 | 450 |
| 7 | 525 | 8 | 600 | 9 | 675 |
| 10 | 750 | 11 | 825 | 12 | 900 |

## 8.1.7 Pressure Unit

Click 『Pressure unit』 to enter into pressure unit select setting interface, four units are available: mmHg, kPa, bar, PSI, click the preset unit option.

⚠ Note: ● Please carefully confirm when changing the current pressure unit.

| Unit Mark | Unit Conversion |
|---|---|
| kPa | 1 kPa=7.5mmHg=0.145psi=0.01bar |
| PSI | 1psi=51.713mmHg=6.895kpa=0.069bar |
| Bar | 1bar=787.5mmHg=15.225psi=105kPa |

### 8.1.8 Bubbles Size

Click『Bubbles size』to enter into air bubble size setting interface, move the long box to the preset level, confirm and then click『OK』.

The air bubble detector has 7 levels, when the volume of single air bubble or the total air bubbles within 15min in the line reach the preset air bubble alarm threshold value, it will activate air bubble alarm. The air bubble testing sensitivity is 20ul. It is suggested to select suitable level according to the actual requirement.

| Air Bubble detector level | Alarm Threshold Value |
|---|---|
| Level 1 | 50ul |
| Level 2 | 100ul |
| Level 3 | 200ul |
| Level 4 | 300ul |
| Level 5 | 450ul |
| Level 6 | 600ul |
| Level 7 | 800ul |
| | |

### 8.1.9 Reminder Alarm

Click『Reminder alarm』to enter into the time for reminder alarm setting interface, click the preset time option to set the reminder alarm time.

### 8.1.10 Finish Pre-Alarm

Time for pre-alarm refers to the time of activating near completion alarm when the fluid/drug infused volume is nearly reaching the preset value.

Click『Finish pre-alarm』to enter into the time for pre-alarm setting interface, click the preset time option,to set the finish pre-alarm time.

### 8.1.11 Drop Sensor

Click『Drop sensor』to set ON or OFF.

The “Drop error “ alarm function is only available only when the drop sensor is installed.

⚠Note: ● The default state for drop sensor function system is OFF, it can be manually turned on by the user when the drop sensor should be adopted. If the function is ON when the drop sensor is not installed, then the system will report “drop sensor connection” alarm.

### 8.1.12 Drop sensor level

The sensitivity of the drop sensor can be adjusted in three levels. The higher the level is, the more sensitive the detection will be, only no drop in the lower level, the alarm will be given.

### 8.1.13 Micro Mode

Click『Micro mode』to enter into micro mode setting interface. ON/OFF is optional in this function Optional. Under the ON mode, set the rate limit, then the infusion rate under any infusion mode is not allowed to exceed this limit.

### 8.1.14 Reset Total Volume

Click 『Reset total volume』, the interface displays the operation confirming prompt box, click 『Yes』to confirm reset, otherwise, please click『No』

## 8.2 General

In the main interface, click『General』to enter into the General equipment setting interface.

### 8.2.1 Date & Time

Click『Date &Time』to enter into the date and time setting interface. It allows to set the date, time and format in this interface.

When setting date and time, directly input the numerical value in the input method interface. For example, to preset one date “2018-08-31”, input “20180831”; to preset the time “13: 34”, input “1334”.

The time is displayed in 24h format or 12h format, the date is displayed in British type, American type or Chinese type, please set according to the requirement.

### 8.2.2 Brightness

Click『Brightness』to enter into display brightness setting interface. The brightness has 10 levels.

The equipment has the function of automatic brightness adjustment if external power supply is unavailable. When there is no external power supply, and the power is supplied by battery, if it is not operated within 3min, the system will automatically adjust the brightness to the lowest level, when it is touched or button is clicked by user or when there’s alarm, it will automatically recover the brightness.

### 8.2.3 Sound

Click『Sound』 to enter into the sound parameters setting interface, the volume has 10 levels. The

lowest volume is ≥50dB, and the highest volume is ≤80 dB. Move the long box to the preset value, after confirming, click『OK』

### 8.2.4 Screen Lock

Click『Screen lock』to enter into automatic lock screen setting interface, select ON or OFF.
Automatic lock screen time can be set at 15s, 30s, 1min, 2min, 5min, 10minor 30min and so on, which means that the equipment will automatically lock the screen if it is not touched or the button is pressed within corresponding time after starting.
Unlock: directly click『Cancel』in the lock screen interface.

⚠Note: ● The equipment will automatically unlock if there's high Level alarm.

### 8.2.5 Night Mode

Click『Night mode』to enter into night mode switch setting interface to set the start and end time of the night mode and the night brightness, at night, the system automatically adjusts the brightness to the User defined value.

### 8.2.6 Battery capacity display

Turn it on to show the battery life in the upper right corner of the screen, and turn it off to show the percentage of remaining battery life.

### 8.2.7 Nurse Call

Click『Nurse call』to select function ON and OFF.

⚠Note: ● The nurse call function must be used with special cable.

● The user shall not only depend on the nurse call function as the main alarm notice mode, and shall identify according to the equipment alarm and the patient state.

### 8.2.8 Nurse call alarm level

By selecting the nurse call alarm level, when the alarm level reaches the selected level, the nurse call alarm is conducted.

### 8.2.9 NetWork

This equipment supports wireless or wire interconnection, when it is equipped with wireless module and connects with the internet through WIFI, the equipment screen displays  icon.

Click『NetWork』in main interface to set the response.

⚠Note: ● This function shall be set by the professional equipment maintenance technician.

● After activating the interconnection function, the equipment can periodically transmit the equipment data to outside, and the data is only for displaying and doesn't provide any suggestion on therapy.

The interconnection channel supports WLAN and serial port modes, please select according to the actual requirement.

When WIFI function is in use, turn on the WLAN switch of the equipment, set the name and password of access point, and configure the TCP/IP parameters.

⚠Note: ● The wireless access must be set by the professional technician recognized by our company.

● The transmitted data of this equipment doesn't provide any suggestion on therapy, and this data shall not be used for calculating the therapeutic schedule.

● When the data is adopted by the third party's equipment or software, it is only for displaying, and shall not be used for alarming or calculating.

# 8.3 System

Click『System』under the menu interface, enter the system information setting interface

## 8.3.1 Language

This equipment supports simplified Chinese and English.

## 8.3.2 Factory Default

Click『Factory data reset』to clear the User defined option, and this function is open to the user.

## 8.3.3 SN(Serial Number)

Check the serial number of the equipment, and user can't modify the serial number.

## 8.3.4 Version

Check the software version in this interface.

## 8.3.5 Maintenance

More detail pls. refers to **Chapter 11**

# Chapter9 Other Functions

## 9.1 Patient Information System

Click『Patient』in the main interface to enter into setting interface.

### 9.1.1 Patient Information

Click『Patient』to enter into the patient information setting interface and set bed number, MRN, name, gender, age, body weight, height.

### 9.1.2 Prescription

Click『Patient』to enter into the patient information setting interface and enter the end of the sub menu, find menu item 『Prescription』and enter to set the medical advice ID, medical advice information, start time and state.

## 9.2 History entries

Click 『Records』in the main interface to enter submenu, click the “History entries” menu item into history records query interface. The equipment supports to save over 5000 history records, and can display the event name, event date and time (permanent preservation). When it is full, the new records will cover the old records with first in first out principle..

# Chapter10 Alarm Prompt and Troubleshooting

## 10.1 Introduction to Alarm Level

During infusion preparation and infusion, this equipment will alarm when reaching or exceeding the set alarm threshold value and prompt with sound, light and text. According to the importance of alarm information as well as the emergency and safety, the alarm is divided into three levels: high, middle and low. Please refer to table below for details:

| Alarm Level | Sound Signal Interval | Light color /flash frequency |
|---|---|---|
| High alarm | 10s | Red indicator flashes /2.0±0.6Hz |
| Middle alarm | 15s | Yellow indicator flashes / 0.6±0.2Hz |
| Low alarm | Once, not repeated | Yellow indicator lights on |

If there's alarm, the system will display the alarm interface, if the alarm level is high, click 『OK』, stop the alarm, and exit the alarm interface, if the alarm level is middle or low, click 『OK』, the sound signal will stop, and exit the alarm interface.
Click『Mute』to mute, if alarm is not eliminated, the alarm sound will be sent out 2min later.

⚠ Warning ● Some alarm threshold values of this equipment can be set by the user, for example: occlusion pressure, air bubble alarm, reminder alarm, VTBI infused pre-alarm, alarm sound volume and so on, the user shall confirm the parameters when set the alarm threshold value, otherwise, it may possibly influence the alarm function or infusion safety.

## 10.2 Multilevel Alarm Rules

When there're several alarms, the system will alarm according to the following rules:

**Table10.2-1**

| Multilevel Alarm | Rules |
|---|---|
| Several alarms of different levels generate simultaneously | Display the alarms of highest level with sound, light and text, report middle alarm after eliminating all alarms of highest level |
| Several alarms of same level generate simultaneously | Alarm circularly by turns, the time interval is 1s |

when alarming, the corresponding alarm information will display on the title of the screen. Refer to Appendix C for more information.

## 10.3 Alarm Treatment

⚠ Warning ● When there's alarm, please check the conditions of the patient, remove the reason of alarm and then continue working.

Please refer to Appendix C for the alarm solution.

## 10.4 Fault Analysis and Solution

When there's fault, the infusion pump screen will display the fault alarm information, this item is the alarm of high level. Please eliminate the fault alarm according to the prompt. If it can't be eliminated, please stop the equipment, contact our company to repair and test the equipment, do not put it into operation before the equipment has passed the inspection, otherwise, it may possibly cause unpredictable harm if it works with fault.

If the equipment is on fire/burns for unknown reason, or has other abnormal conditions, the user shall immediately cut off power supply and contact our customer service department.

- Under single fault state, the max infusion volume is 2ml.

# Chapter11 Maintenance

## 11.1 Cleaning, disinfecting and sterilizing

⚠ Warning

● Please cut off power supply and unplug the DC /AC power wire before cleaning the equipment.
● During cleaning and disinfecting, please keep the equipment horizontal and upwards to protect the equipment and accessories from fluid.

### 11.1.1 Cleaning

(1) The daily maintenance is mainly to clean the shell and pump body. It is inevitable that fluid/drug may flow in the equipment during infusion. Some fluid drug may corrode the pump and cause working fault. After infusion, please timely clean the equipment, wipe it with moist and clean soft fabric, and then naturally dry it.

(2) When cleaning the equipment interface, please wipe it with dry and soft fabric, confirm the interface is dry before using.

(3) Please do not soak the equipment in water. Although this equipment has certain waterproof function, when fluid splashes on the equipment, please check if it works normally, perform insulation and electric leakage test if needed.

### 11.1.2 Disinfecting

(1) Disinfecting may possibly cause harm of certain degree to the equipment, it is suggested to disinfect the equipment if it is needed.

Please disinfect the equipment with common disinfecting agent such as 50% sodium hypochlorite, cidex 2% glutaraldehyde + activating agent, 70% ethanol, 70% isopropyl alcohol and so on. Please follow the instructions of the disinfecting agent.

(2) After disinfecting, wet the soft fabric with warm water, dry the fabric and then wipe the equipment with it.

(3) Do not sterilize the equipment with high pressure steam sterilizer, do not dry the equipment with dryer or similar product.

⚠ Warning: ● Please do not adopt Cidex OPA orthophthalaldehyde, methyl ethyl ketone or similar solvent, otherwise, it may corrode the equipment.

## 11.2 Periodical maintenance

⚠ Notes: ● The medical mechanism shall set up complete maintenance plan, otherwise, it may possibly cause the equipment malfunction or fault, and may possibly hurt the physical safety.

● In order to ensure the safe use and prolong the service life of the equipment, it is suggested to periodically maintain and check it once every 6 months. Some items shall be maintained by the user, and some items shall be maintained by the dealer of the equipment.

● Please contact our company if the equipment is found defective.

### 11.2.1 Check the Appearance

(1) The appearance of the equipment shall be clean and under good condition without crack and water leakage.
(2) The buttons are flexible and effective without invalid phenomenon; the sensitivity of the touch screen is normal,
(3) The infusion pump door can be smoothly opened and closed, the anti-free flow clamp mechanism is under good condition.
(4) The power wire is under good condition and installed tightly.
(5) After connecting with external power supply, check whether AC indicator light is on.
(6) Adopt the accessories designated by our company.
(7) The environment meets the requirements.

### 11.2.2 Performance Check

- Self-test and infusion function works.
- Alarm function works well
- Battery performance.

### 11.2.3 Maintenance Plan

The following check/maintenance items must be performed by the professional technician recognized by our company. If the following maintenances are necessary, please contact our company. Please clean and disinfect the equipment before testing or maintaining.

| Maintenance Items | Cycle |
|---|---|
| Safety check according to IEC60601-1 | Once every 2 years, please check after replacing the printed circuit board assembly or the equipment is dropped or knocked. |
| Preventive system maintenance items (pressure | Once every 2 years, when the occlusion alarm, |

| | |
|---|---|
| calibrate, sensor calibrate, pump) | air bubble alarm, or infusion accuracy is doubt to be abnormal |
| Brand of user-defined infusion apparatus, infusion accuracy calibration | Using the equipment for the first time, infusion apparatus brand using for the first time, reusing the equipment after stopping for a very long period. |

# 11.3 Add new brand and Calibration

In the 『System』 sub-menu, click 『Brand maintenance』 to enter into brand setting interface, user can add new brand, delete and calibrate the brand.

⚠Warning: ● It is suggested to contact our company or local dealer, to customize or calibrate it by professional technician, otherwise, it may can't guarantee the infusion accuracy.

⚠Note: ● The built-in brand of the system shall not be deleted.

**(1) Add new brand**

⚠Note: ● If the actual using infusion apparatus brand is not listed in the system built-in brand, please add a infusion apparatus brand in this interface.
Set Infusion brand name and brand information.

**(2) Delete**
Enter into『Delete』interface, click it to delete user-defined infusion apparatus brand.

**(3) Calibrate**

⚠Note

- When first time use pump need calibration
- When added new brand need calibration
- When accuracy is not good need calibration.

The following materials shall be prepared before calibration:
Material preparation: Infusion pump, IV set, measure cylinder, electronic balance

Please calibrate the infusion apparatus when using the built-in brand infusion apparatus for the first time, or the first user-defined infusion apparatus brand, or after periodical maintenance.

Please prepare the following materials before calibrating:
One new and unused infusion apparatus, 20ml measuring cup or 20ml syringe.

**Calibrating Steps:**

1) Install infusion device as required and remove bubbles.
2) Put the needle into the measuring cup to collect the liquid.
3) Start the calibration according to the interface prompts, and start the infusion.
4) The device will automatically stop after 10 minutes of operation, read the liquid quantity in the measuring cup or calculate the liquid volume by weighing.
5) Input the data to the device, and complete calibration.
6) Exit calibration, the calibrated brand was selected as the current brand, and the infusion accuracy was verified at 25ml/h and 150ml/h flow rates, respectively.

# 11.4 Repair

## 11.4.1 Normal Repair Process

Please contact our company to repair if there's any fault, do not disassemble and repair the equipment. After repair, please perform overall test for the equipment. Our company may provide the circuit diagram and components list to the authorized repair technician if needed.

## 11.4.2 Maintenance for Long Term Store

If the equipment won't be used for a long period, please take out the battery, and pack it with the equipment in the package, and store it in the shade, cool and dry place without direct sunlight.
The following operations are necessary for using it again:

1. Verify the flow rate accuracy to avoid unconformity between the infusion apparatus parameters in the equipment and the actual parameters after it hasn't be used for a long period or caused by other reasons, otherwise, it may cause infusion error, influence the therapeutic effects and even cause medical negligence.

2. Perform air bubble and occlusion alarm test.

3. Test the battery discharging and charging duration to confirm that the battery is also usable.

# 11.5 Equipment Components/Accessories

⚠ Warning: ● Only the components and accessories designated by our company shall be adopted, otherwise, it may possibly damage the equipment or drop the equipment performance.

During the normal service life of the equipment, the battery is consumable, it is suggested to replace them once every 2 years, please contact the dealer or our company to replace them.

| Variety | Name | Code |
|---|---|---|
| Accessories | Drop sensor | |
| Equipment Components | Battery | |
| | Pole clamp | |
| | Power wire | |

## 11.6 Production Date

Please refer to the label of the product.

## 11.7 Recycling

The normal service life of this equipment is 10 years, and depends on the use frequency and maintenance. The equipment must be rejected after reaching the service life, please contact the manufacturer or the dealer to get more detailed information.

1. The obsolete equipment may be returned to the original dealer or manufacturer.
2. The used lithium-ion polymer battery has the same treatment method, or according to the applicable laws and regulations.
3. Please handle according to the equipment rejecting flow of your medical mechanism.

# Chapter12 Battery

This equipment is equipped with charging lithium-ion polymer battery to ensure the normal infusion when the equipment is moved or the external power supply is cut off.

When connecting external power supply, no matter the equipment is started or not, it can charge the battery. When charging, the equipment screen displays the battery charging indication icon  . In case only built-in battery is adopted for supplying power, and when the remained battery is less than 20%, please connect the equipment with external power supply to charge the battery.

⚠ Warning: ● Only the battery designated by our company shall be adopted.

## 12.1 Check the Battery Performance

The performance of the built-in battery may drop according to the using duration, it is suggested to check the battery once a month.

(1) Disconnect the equipment from the patient, and stop all infusions.

(2) Supply AC power to the equipment to charge the battery for 5h at least.

(3) Supply power for the infusion pump only with battery, infusion at the rate of 25ml/h, test the time till the battery runs down and the equipment is turned off.

- If the infusion time exceeds 7h, the battery keeps at good state.
- If the infusion time exceeds 5h but less than 7h, the battery starts deterioration, but it can be used temporarily.
- If the infusion time is less than 5h, the battery is reaching the service life, please replace the battery.

## 12.2 Replaced the Battery

It is better to replace the battery once every 2 years, it is suggested to replace the battery by the dealer or manufacturer.

The steps of replacing battery are shown as below:

(1) Cut off the power supply of the equipment, disconnect the power wire. Open the shells and take out the battery.

(2) Push the new battery into the battery chamber, and insert in the battery fastener.

(3) After replacing the battery, close the shells, and check the battery.

⚠ Warning: ● When replace the battery, please do not touch the 12V DC plug inside of the batter Chamber.

# Chapter13 After Sale Service

This product enjoys 1 year free warranty after purchase. The warranty period is from the installation date listed on the “Warranty Card”. The “Warranty Card” is the only voucher for calculating the warranty period, in order to maintain your benefit, please carefully fill into and keep the “Warranty Card”, and hand over the copy for the company to the installation technician.

The damages of the equipment caused by the following shall not enjoy free warranty service.

1. Fault caused by incorrect operation, unauthorized refitting or repair.

2. The damages caused by incorrect operation during the transportation process after purchase.

3. The fault and damages caused by fire, salt injury, toxic gas, earthquake, windstorm, flood, abnormal voltage and other natural disasters.

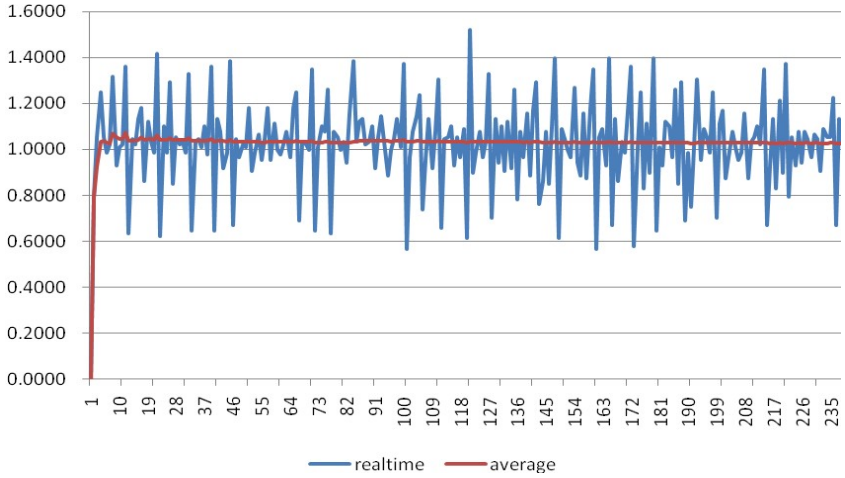
For the damages or faults mentioned above, our company provides repair services but chargeable according to the repair cost.

# Chapter14 Appendix

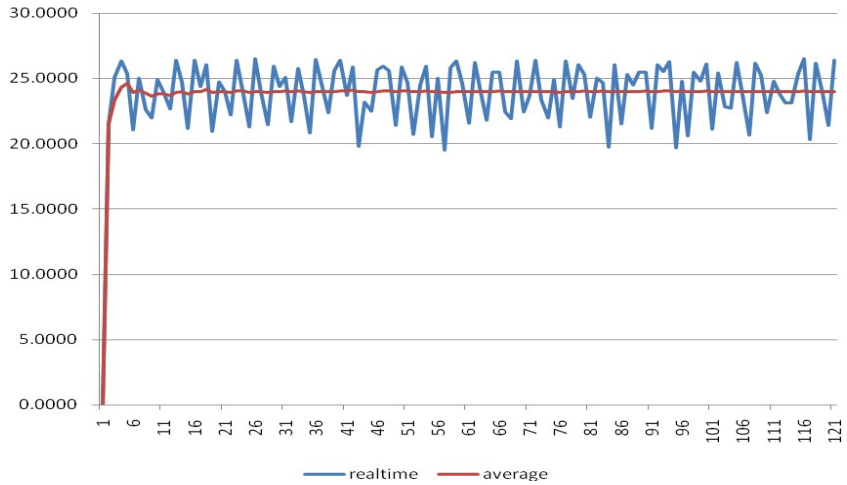
# Appendix A Start Up Graphs and Trumpet Curves

## Appendix A.1 Start-up Graphs

Brand and specification of infusion apparatus: Jierui(20 drops)
Flow Rate: 1ml/h
Measurement Interval: $\Delta t = 0.5min$
Measurement duration: T = 2h



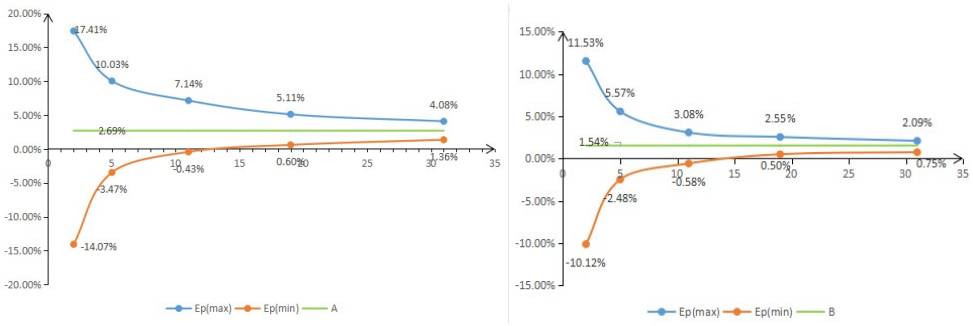

Brand and specification of infusion apparatus: Jierui (20 drops)
Flow Rate: 25ml/h
Measurement Interval: $\Delta t = 0.5min$
Measurement duration: T = 2h



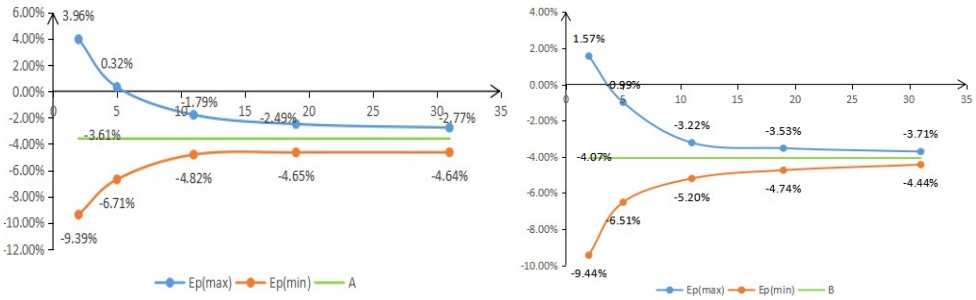

## Appendix A.2 Trumpet Curves

Brand and specification of infusion apparatus: Jierui (20 drops)

Flow Rate: 1ml/h
Measurement Interval: Δ t = 0.5min
Measurement duration: T = 8h




Brand and specification of infusion apparatus: Jierui (20 drops)
Flow Rate: 25ml/h
Measurement Interval: Δ t = 0.5min
Measurement duration: T = 2h




# Appendix B Occlusion Response Property

**When a occlusion alarm is triggered, the system will automatically processed Anti-bolus, Withdraw according to the current pressure level to reduce the amount of blocking pills.**

**Proocclusion time and bolus relation**:

| Flow Rate (ml/h) | Occlusion Pressure (mmHg) | | Time to occlusion alarm(min) | Max bolus (ml) |
|---|---|---|---|---|
| 1 | Low | 75 | 0h3min23sec | 0.007 |
| | High | 900 | 0h39min13sec | 0.137 |
| 25 | Low | 75 | 0h0min18sec | 0.005 |
| | High | 900 | 0h0min51sec | 0.128 |

**Occlusion time and bolus relation**:

| Flow Rate (ml/h) | Occlusion Pressure (mmHg) | | Time to occlusion Alarm(min) | Max bolus (ml) |
|---|---|---|---|---|
| 1 | Low | 300 | 0h3min48sec | 0.015 |
| | High | 900 | 0h45min53sec | 0.128 |
| 25 | Low | 300 | 0h0min17sec | 0.005 |
| | High | 900 | 0h1min21sec | 0.123 |

The alarm pressure intensity error for UNIFUSION Pump is ±20% or ±150mmHg, the higher value shall be taken.

⚠Notes: ● Conditions for testing above data: infusion apparatus brand Jierui.

- The occlusion alarm pressure, alarm delay time and bolus are influenced by the test conditions.
- The above data is the typical value under the test conditions, please see the test data of the product for the actual data, the data may be different if the test conditions are different

# Appendix C Alarm and Solution

| Alarm Type | Alarm Level | Reason | Solution |
|---|---|---|---|
| VTBI near end | Low | During infusion, the remaining time of reaches or is less than the set nearing completion time | This alarm can't be eliminated, and waits till infusion completes |
| VTBI infused | High | The preset value infusion Completion | Press 【Stop】button to stop alarm |
| Pressure high | High | 1. Line occlusion during infusion | Manually remove the reason of occlusion, Press【Start】button to continue infusion |
| | | 2. Fluid/drug in the actual infusion line has high viscosity, but the system occlusion level is set too low | Rise the alarm Level, Press【Start】button to continue infusion |
| | | 3. The pressure sensor is damaged | Please contact the dealer or manufacturer for repair |
| Pressure near threshold | Middle | Pipeline pressure increases close to the preset blocking level. | Check the connection of the pipeline, press 『OK』button to continue infusion |
| Pressure drop | Middle | When the pipeline pressure is high,the pressure suddenly decreases. | Check the connection of the infusion pipeline, press 『OK』button to continue infusion |
| Check upstream | High | The upper part of the line is obstructed during infusion, and in turn drops the line pressure intensity | Check if the rate regulating adjuster or fluid stopping device is opened at the upper part of the line, Press【Stop】button to stop alarm |
| Battery nearly empty | Low | 1. When power is supplied only with the built-in battery, under low battery, the alarm duration is >30min | The alarm automatically eliminates after connecting the external power supply. |
| | | 2. Battery ageing or the equipment charging circuit is fault. | Please contact the dealer or manufacturer for repair. |
| Battery empty | High | When power is supplied by the built-in battery only, under low battery, the alarm duration is >30min | Immediately connect with external power supply. |
| | | 2. Battery ageing or the equipment charging circuit is fault. | Please contact the dealer or manufacturer for repair. |
| **Alarm** | **Alarm Level** | **Reason** | **Solution** |

| | | | |
|---|---|---|---|
| No battery inserted | Low | Battery is removed | Keep connecting with external power supply, reinstall the battery |
| No power supply | Low | Under ON state, AC power supply is adopted, but the AC power wire is dropped during the process | The alarm automatically eliminates after connecting the external power supply. |
| No batterry and No power supply | High | Battery is removed and the AC power wire is dropped | reinstall the battery or connect the power supply |
| Reminder alarm | Low | After installing infusion tube , under non-working or alarm state, it is not operated within the set time of the system | Click any button to stop |
| Standby time expired | Middle | During standby, after reaching the standby time | Press【Stop】button to stop alarm |
| KVO finished | High | KVO working time reaches 30min, infusion pump stops working | Press【Stop】button to stop alarm |
| Drop sensor connection | Low | When turning on the drop sensor, the equipment is not connected with the drop sensor | Connect the drop sensor, or turn off the drop sensor in the menu |
| Drop error | High | The angle of inclination of the drip cup is too big or drop sensor is installed lower than the drip cup fluid level | Check the installation of drop sensor or drip cup fluid level, Press【Stop】button to stop alarm |
| | | The specification of infusion apparatus is not accordant with the specification displayed in the interface, which causes drop rate error. | Check if the infusion apparatus specification is accordant with displayed parameters, if it is not accordant, , it shall be modified by professional maintenance technician |
| Air bubble | High | Air bubble in the infusion line | Press【Stop】button to stop alarm, disconnect the line from the patient, exhaust air with air exhaust function, or open the infusion pump door to manually remove the air bubbles |
| Door Open | High | During infusion, the infusion pump door is opened | Close the infusion pump door to stop this alarm. |
| System Error | High | Internal failure or software exception | Turn off and Restart,if the alarm still exist, please contact the dealer or manufacturer for repair |

Note: When alarm rings, click the 『Mute』icon on the screen to temporarily stop sound alarm for 2min.

# Appendix D EMC Electro Magnetic Compatibility declaration

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.

⚠ Cautions:

- This unit has been thoroughly tested and inspected to assure proper performance and operation!

- 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.

⚠ Warnings:

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.

| **Guidance and manufacture's declaration – electromagnetic emission** | | |
|---|---|---|
| The Infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Infusion pump should assure that it is used in such an environment. | | |
| **Emission s test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF emissions<br>CISPR 11 | Group 1 | The Infusion pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class A | The Infusion pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable | |

| | | |
|---|---|---|
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Not applicable | that supplies buildings used for domestic purposes. |

**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 the Infusion pump should assure that it is used in such an environment.

| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
|---|---|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±6 kV contact<br>±8 kV air | ±8 kV contact<br>±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<br>IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 KV for input/output lines | ±2kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>±2 KV line(s)to earth | ± 1 kV line(s) to line(s)<br>±2 KV line(s)to earth | 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<br>IEC 61000-4-11 | <5% UT<br>(>95% dip in UT)<br>for 0.5 cycle<br><br>40% UT<br>(60% dip in UT)<br>for 5 cycles<br><br>70% UT<br>› in UT)<br>for 25 cycles<br><br><5% UT<br>(>95% dip in UT)<br>for 5 sec | <5% UT<br>(>95% dip in UT)<br>for 0.5 cycle<br><br>40% UT<br>(60% dip in UT)<br>for 5 cycles<br><br>70% UT<br>(30% dip in UT)<br>for 25 cycles<br><br><5% UT<br>(>95% dip in UT)<br>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<br>IEC 61000-4-8 | 3 A/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<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 10 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the Infusion pump, including cables, than the recommended separation |

| | | | |
|---|---|---|---|
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 10 V/m | distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = 1.167\sqrt{P}$<br>$d = 1.167\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz<br>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 metres (m).<br>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<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>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 3 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<br>$d = 1.167\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.167\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.333\sqrt{P}$ |
| 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 metres (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.

# Appendix E Factory Default Data Set

| Parameters | Default Setting | Parameters | Default Setting |
|---|---|---|---|
| KVO rate | 1ml/h | Commonly used tube brand | Boon |
| Occlusion pressure | 450mmHg | Sound | 40% |
| Bubble size | 1 levels (50ul) | Screen lock | ON |
| Finish pre-alarm | 2min | Brightness | 90% |
| Reminder alarm | 2min | Night mode | OFF |
| Pressure unit | mmHg | Nurse call | OFF |
| Micro mode | OFF | Drug library | OFF |
| Drop sensor | OFF | Relay mode | OFF |