Infusion Pump

User Manual

Product information

Product name: Infusion Pump

Product structure and composition: It is composed of control system and transmission system. The control system includes power board, main control board, key board, liquid crystal display, pressure detection system, door opening detection system, ultrasonic bubble detection system, heating control system, droplet detector, transmission system includes casing, machine fixing frame, Motor drive system, peristaltic extrusion system.

Application range: used for constant velocity intravenous infusion in the hospital.

Version information of user manual

Version No.: V2.5

Revision Date: Feb 2023

Statement

Our company does not make any form of guarantee, including (but not limited to) the implied warranty of

merchantability and fitness for a specific purpose.

Support and Maintenance

Warranty

Product warranty: one year for the main unit, three months for the parts.

Product damage caused by the following circumstances does not belong to the scope of the company's free warranty:

The product is damaged due to the following reasons:

- Improper operation
- Improperly connected to other devices
- Accident

Without the written authorization of the Company, the user changes the product without authorization

The product sequence number is torn off or unrecognizable

Notice

◎Do not use the pump in the presence of mixture of flammable anesthesia gas with air, oxygen or nitrous oxide.

◎Please read and understand the user manual before using the pump

◎Please check the parameter setting before starting work.

◎The product performance has nothing to do with gravity.

◎When there is air bubble in the tubing between the pump and patient, the air bubble must be cleared away manually.

◎When the room temperature is below 18℃ or the rate is more than 30ml/h, in order to avoid false occlusion alarms, it is not recommended to set the occlusion pressure to Low.

◎Occlusion alarm threshold is influenced by ambient temperature and material of IV set, occlusion alarm may not be accurate when the IV set is of poor quality.

◎Don not push hard on the contact terminal of the pressure sensor, the pressure sensor may be damaged.

◎When there are other infusion systems or accessories connected with the IV set of the pump, make sure no air bubble enter, and must be equipped with one-way valve.

◎The IV tubing will be clamped automatically by the anti-flow clamp to prevent free flow when the door of the infusion pump is open in single fault state.

◎In actual use, if the infusion set is not selected well or the parameters are not set correctly, the rate, infusion time and residual volume may be inaccurate

◎The target volume should be close to the actual volume in the container (Usually 15ml less than the actual volume). Otherwise, please use the drip detector to avoid the air bubble alarming when there's no fluid in the tubing.

◎The last setting of IV tubing type, KVO rate, Purge rate, pressure and IV set brand will be saved as default.

◎This product is prohibited for blood infusion.

◎In actual use, the IV tubing must be loaded in the pump according to correct order and direction, and straightened. Otherwise no medication or overdose flowing may occur, cause injury to patients.

◎When the door or other parts become deformed or damaged, they should be timely replaced with new parts, or, pump will not work properly, and cause injury to the patient.

◎Check the IV tubing type choice before pressing start key to work.

◎The battery discharge time are more than 4 hours, but the battery may not work for 4 hours as it will be influenced by run time, operation environment or undercharge.

◎If in doubt about network power grounding, please use internal battery

◎Environmental Protection: when the service life of the equipment and accessories (including battery) expire, please dispose them properly to prevent environmental pollution.

◎The pump should be fixed with the clamp supplied by the manufacturer or fixed by your own way. In order to avoid injury to the patient due to pump dropping, the pump can not be placed on the flat surface without fence.

◎The pump should be operated only by professional doctor or nurses, incorrect operations may cause injury to the patient.

◎The pump must be well grounded.

◎If the pump break down in actual use, immediately turn the pump off and stop working, timely , contact the manufacturer or dealer! In single fault state, the product may infuse no more than 1ml at maximum.

Product life

5 years

PRODUCTION DATE

See lable

The annotation of this manual

Warning: you should know how to avoid possible harm to patients and medical staff

Contraindication

Not used for analgesic drugs, chemotherapy drugs, insulin infusion.

Content

Chapter 1 Safety Guide

The electrical safety classification of this instrument is Class I, electric shock protection type is BF, it is a internal power supply, continuous operation device. BF type devices are devices with a specific degree of protection against electric shock.
BF type protection indicates that the patient connection should meet the requirements of permit of leakage current and dielectric strength as IEC60601-1 specified.

1.1 Safety Instructions

In order to avoid any possible injury, please abide by the following safety instructions when operating this instrument.

Warning: Avoid this pump working in the presence of flammable gases or anesthetic agent, may cause danger of explosion.

Warning: Do not throw the battery into fire, may cause danger of explosion.

Caution: This instrument must be serviced by authorized qualified engineer.

Caution: This instrument is designed for continuous operation, IP rating is IPX1, anti-drip device, avoid being splashed by water.

Caution: Keep instrument clean, avoid shaking.

Caution: Avoid high-temperature sterilization or electron beaming, γ radiation sterilization.

Caution: Avoid this pump working in the environment with high-frequency interference devices, make sure it is not interfered by the strong electromagnetic interference, such as radio transmitter, mobile phone.

Caution: Make sure this instrument is in good condition before use. Routine inspection should be performed every one month or shorter than that. If there's obvious damage on the instrument, please replace broken parts before use.

Caution: The following safety inspections must be performed by well-trained persons who have related knowledge and practical experience usually once every two years or

according to the regulations specified by public institutions.

◇Inspect if there's mechanical or functional damage on the instrument.

◇Inspect if the safety labels are legible.

◇Verify the instrument functions are still the same as the user manual describes.

Caution: Expired products should be disposed according to discarding standard of electronic products or returned to the manufacturer for the purpose of recycle.

Caution: Expired battery should be properly disposed according to related standard.

Caution: Keep away from the patient when replacing battery (around 1.5 meters away from the patient)

Chapter 2 Brief Introduction

2.1 Overview & Working Principles

This pump is a drip type infusion pump, a high-precision intelligent pump which is capable of accurately controlling the delivery rate of disposable IV set and monitoring the infusion course, by means of sensors and microprocessor accurately controlling precise stepper motor, driving transmission mechanism to drive peristaltic fingers regularly squeezing the IV tubing against the backplate.

Standard disposable sterile IV sets of qualified brand (hereinafter to be referred as IV set) is suitable for this pump, the calibration function makes IV sets of any brand is suitable for this pump. This pump has various sound and light alarm function, so that the user can make timely response to the pump to ensure the infusion is safe. It is specially suitable for clinical treatment which require continuously and precisely controlling infusion at a constant rate, meanwhile, monitoring the infusion course. It is widely used in internal medicine, surgical, paediatrician, obstetrics, ICU, CCU wards, operating rooms and other clinical infusion treatment (but does not apply to blood infusion).

2.2 Features

✧4.3” LED screen with 272×480 display, more clear.

✧Simple and convenient in operating, intuitive presence of working status.

✧A variety of visible and audible alarm,make infusion more safety.

✧Drug library with 210 kinds of medicine.

✧Storage1500 history events.

✧Multi-language support.

2.3 Specifications:

✧Adjustable Drop Rate Range: 1～400 drops/min (step: 1 drop/min).

✧Adjustable Volume Rate Range: 1～1200 ml/h (step: 0.1 ml/h)

✧ Flow Precision: within ±3% (using the IV set appointed by the manufacturer or calibrated high quality IV set) Mechanical precision: within ±2%

✧Purge Rate: 800 ml/h

✧KVO Rate: 1 ml/h (less than 100 ml/h);
2 ml/h (100～300 ml/h);
3 ml/h (greater than 300 ml/h);

✧Infusion Volume Range: 1 ml～ 9999.9 ml (step: 0.1 ml), accuracy:±3%

✧Maximum Accumulated Volume: 9999.9 ml

✧ Time Range: 1 min～ 9999 min (step: 1 min), accuracy:±3%

✧Occlusion Alarm Threshold:
High: 800 mmHg ± 200 mmHg (106kPa±26.7kPa)
Medium: 500 mmHg ± 100 mmHg (66.7kPa±13.3kPa)
Low: 300 mmHg ± 100 mmHg (40.7kPa±13.3kPa)

✧Alarm: Infusion Complete, Empty, Faulty Signal, Misoperation, Occlusion, Door Open, Air Bubble, Low Battery, Setting Error, AC power off, Idle.

✧Air Bubble Detector:
method: ultrasonic wave, sensitivity: ≥25μL.

✧Power Supply: AC100～240V, 50/60Hz;
Internal Battery: 11.1V rechargeable li-ion battery. Capacity: ≥2000mAh; the pump can work more than 4~5 hours at the flow rate of 25 ml/h after charging for 5 hours (Medium rate specified by GB 9706.27-2005).

✧Power: ≤40VA

✧Environment Requirements:

Conditions	Transport	Storage	Operation
Ambient Temperature	-30℃ ～+55℃	-30℃ ～+55℃	+5℃～+40℃
Relative Humidity	20%～95% (non-condensing)	20%～95%	20%～90%
Atmosphere Pressure	70kPa～106kPa	70kPa～106kPa	86kPa～106kPa

IV Set:

Disposable IV set of any brand is suitable for this pump, IV set of new brand should be calibrated to ensure the infusion accuracy.

⚠ Note:

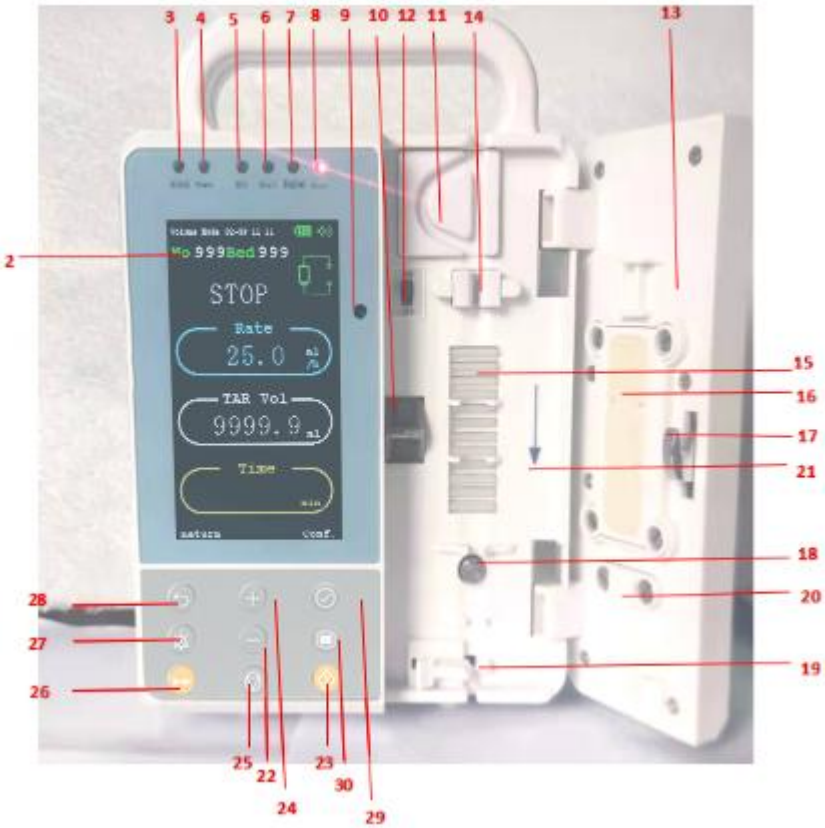
1)The IV set should be suitable for being sterilized by ethylene oxide, and conform to 《GB 8368-2005 disposable IV set, gravity type》; the IV tubing should be made of good elastic PVC materials, the wall thickness of the tubing should be 0.4～0.6mm; the IV tubing made of latex or silicone materials is not suitable for this pump, it may cause abnormal flow rate, incontrollable infusion, tubing breakage, and other possible dangers.

2) The maximum actual flow rate is influenced by IV set elasticity, quality, parameters and run time, so it may not reach 1200 ml/h, but at least 600 ml/h.

3) The flow rate accuracy varies with the manufacturer of IV set, operation ambient temperature, run time, concentration of medication and other factors, so the IV set should be calibrated before use.

Chapter 3 Structure and Components

3.1 Appearance



2—LCD display 3—Alarm indicator 4—AC indicator

5—bubble indicator light 6—block indicator light 7—signal indicator light 8—door open indicator light

9—Remote control receiving port 10—Door pin seat 11—Heater 12—Heating control switch

13—door 14—bubble detector 15—peristaltic sheet 16—extrusion plate

17—door hook 18—pressure sensor 19—liquid stopper 20—pressure plate

21—liquid flow direction 22—down button 23—start button 24—up button

25—Stop key 26—Fast forward key 27—Mute key 28—Back key

29—Enter key 30—Menu key

Note: The meanings of equipment labels and displayed icons or symbols are as follows:

~ Indicates AC	⎓ Indicates DC	Indicates BF type general equipment
means mute		⚠Notice! view random files
OFF Indicates disconnection (total power supply)	ON Indicates on (total power supply)	

3.2 display

The display interface is shown in Figure 3-1:

Figure 3-1

shows the functions of the main interface, including drop mode, volume mode, time mode, drug library, history record and setting functions. In addition: 15:45 is the system time. 02-09 is the system date. When turned off, the internal battery continues to supply power to ensure the clock is accurate.

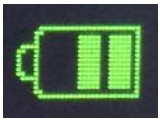


Figure 3-2

Figure 3-3

Figure 3-2 is the icon of battery power, which has four states: full, one space missing, two spaces missing, and all empty. Can work at medium speed for about 30 minutes, when all-empty symbols start to appear, the instrument stops working.

Figure 3-3 shows the volume of the speaker, which can be adjusted in three levels, press the up button or down button to increase or decrease the volume. When the volume is adjusted to the minimum, the sound pressure within 1 meter near the instrument is greater than 65 decibels.Adult means adult mode.

3.3 Keys Instruction

Back key ——When the cursor stops on the item that needs to return to the interface, press this key to adjust to the previous interface.

Up button——When the cursor stops at the parameter selection item that needs to be set, press this button to adjust the parameter, press and hold the number value to increase rapidly.

Down button——When the cursor stops at the parameter selection item that needs to be set, press this button to adjust the parameter, press and hold the number value to decrease rapidly.

Fast-forward key——In the non-working state, click this button, and the screen "fast-forward" will start to flash. If you click this button again within 3 seconds and hold it down, it will enter the fast-forward state, and it will stop after releasing it Fast forward, and return to the parameter setting state; if you do not click this button again within 3 seconds, it will exit the fast forward state, and the fast forward prompt will disappear automatically.

In the state of infusion, click this button, and the screen "fast forward" will start to flash. If you click this button again within 3 seconds and hold it down, it will enter the state of "fast forward infusion". After releasing it, it will return to the normal infusion state.

Confirmation key——In order to avoid misuse, when adjusting the tube type of "infusion set" and "accuracy" calibration, after selecting the parameter, you must press the "confirmation" key again to adjust the parameter value through the up and down keys.

Start key——After setting all the parameters, press this key to start the infusion, and the infusion pump enters the infusion state at the same time.

Stop key—— Press this key in the state of infusion, the infusion pump will stop working and return to the parameter setting state. If an alarm occurs during work, press this key to clear the alarm and return to the parameter setting interface.

Mute key——When an alarm occurs during work, press this key to eliminate the alarm sound, and deal with the alarm within 2 minutes or return to the setting interface, otherwise the alarm sound will sound.

Menu key - enter the menu interface

Chapter 4 Instrument Installation and Operating Instructions

4.1 Fixing and installation of the pump

Fix the pump at the appropriate height of the infusion stand with the fixing bracket behind the pump. The pump is a mobile device and needs to be used together with a medical infusion stand with good stability (the infusion stand used by our company can also be selected). It is fixed on the infusion stand and cannot be used as a portable device. It cannot be placed on the table or placed on the patient's bed. Before use, please confirm that the product is installed stably and firmly, and will not fall over.

Note: After the installation is complete, make sure that the infusion pump is installed stably and securely, that it does not slip off after being fixed on the infusion stand, and that it does not fall over after being tilted at 20 degrees.

4.2 Loading, priming, changing and repacking of infusion lines

4.2.1 Loading

1) Hang the infusion bottle (bag) filled with medicinal liquid on the medical infusion stand. The infusion bottle (bag) should be 20cm-80cm higher than the patient's heart, and connect the infusion set to the infusion bottle (bag).

2) Close the flow regulator, squeeze the dripping pot by hand to make about 1/2 of the liquid in the dripping pot.

3) Open the flow regulator, remove the air from the infusion line, and close the flow regulator.

4) Pull up the door handle, open the pump door, pass the infusion tube from top to bottom according to the infusion direction, pass the bubble detector and peristaltic sheet in turn, turn the head of the liquid stopper to the left to open the liquid stopper, and clamp the infusion tube in the The liquid stopper is stuck in the groove, and then drawn out from the groove of the pump casing.

5) Pull up the door hook handle, make the door hook buckle the door pin seat inward, press down the door hook handle, close the pump door, check that the pump door should be flush with the pump casing, and then open the flow regulator on the infusion set .

4.2.2 Priming (cleaning)

Double-click the fast-forward button continuously, press and hold it for the second time, enter the fast-forward state, release the air in the air until the needle tip leaves the liquid medicine, and then insert the needle into the patient's vein (artery) after the perfusion (cleaning) is completed, that is, Infusions can be started as required.

4.2.3 Replacement or reinstallation of the infusion line

Please close the flow regulator of the infusion set after the infusion is completed or press the stop button to prevent self-flow. Take out the infusion set, and replace or reinstall the infusion set according to the above 4.2.1 method.

Notice:

1) The continuous use time of the infusion line: according to the regulations of the corresponding manufacturer, after working continuously for 4 to 5 hours, please stop the machine and replace it with another infusion line that has not been squeezed or replace it with a new infusion set work again. If the infusion set tube is squeezed for a long time, the infusion speed may be inaccurate, or if the infusion tube is squeezed and damaged, it may cause leakage of the drug solution, air bubbles entering and other serious consequences (such as drug solution contamination). Therefore, after the infusion set has been working continuously for about 12 hours, please replace it with a new disposable infusion set.

2) Prevention of overcurrent: When the stopper of the disposable infusion set needs to be pierced into or taken out of the infusion bottle with a piercer, the mouth of the infusion bottle must be vertically upward to prevent overcurrent caused by the overflow state.

3) Prevention of self-flow: After filling (cleaning) the infusion line and before closing the pump door, the flow regulator of the disposable infusion set must be closed to prevent the liquid from flowing. After closing the pump door and opening the flow regulator of the infusion set, make sure that no liquid drips from the needle or drip pot of the infusion set. If the infusion pump leaks, check the installation of the infusion tube, otherwise, it cannot continue to work!

1) When the infusion line is blocked, the infusion line cannot be perfused (cleaned) through the infusion pump, and can only be perfused (cleaned) manually.

2) When installing the infusion tube, it must be ensured that the drip pot is located in the pipeline between the infusion bottle (bag) and the pump, and the flow regulator is located in the pipeline between the pump and the patient. It should be in the open state before starting the pump.

3) When reinstalling the infusion line, do not install the extruded infusion line on the bubble detector, otherwise, false alarms will occur due to air bubbles in the line.

4) The infusion pipeline should be straightened in the direction of the arrow in the pump, and the drip pot should be placed vertically to prevent air from flowing into the pipeline.

Chapter 5 Function introduction

5.1 Infusion function

5.1.1 Introduction of Infusion Mode

The infusion pump has 3 infusion modes: drop count mode, volume mode, and time mode, and the infusion mode can be selected on the main interface.

1. Drop count mode

The unit of the rate in drop mode is "drop/min". After setting the rate and installing the drop detector correctly, press the start button to start the infusion. When the infusion volume is set to "----", it means The volume of infusion is not limited.

In drop count mode, the device controls the drip speed instead of the infusion volume, and the drop count detector must be installed correctly. When the drop count detector does not detect the drop count within a certain period of time, the device will send out an empty bottle alarm. and stop working.

2. Capacity mode

In volume mode, the device completes the infusion by controlling the infusion volume. After setting the infusion volume and rate, press the start button to start working. When the accumulated volume is equal to the set infusion volume, the device automatically enters the KVO state and sends out an alarm.

3. Time mode

In the time mode, the user can set the infusion time and volume by himself, and the system can calculate the infusion rate by itself, and the rate range is 1-1200ml/h. The guaranteed rate is within this range. After setting the parameters, press the start key to start the infusion.

Note: When changing the time, if the time cannot be increased or decreased, this is normal and not a device

There is a problem, but to ensure that the speed set by the user is within the valid range.

5.1.2 Infusion parameter setting

In the infusion interface, press the increase or decrease key to move the cursor to the option to be set (the background color of the selected option is pink, and the unselected option is blue), and press the enter key to change the option from the selected state to It can be set, you can press the increase or decrease key to change the parameter value.

5.2 Drug Library

The device has built-in more than 210 drugs in 13 categories including cardiovascular, respiratory system, antibiotics, antiviral, digestive system, nervous system, painkillers, urinary system, blood system, endocrine system, anesthetics, muscle relaxants, and antitumor drugs. The medicine can be selected by the user, if the user fails to find the medicine used in the 210 kinds of medicines in the device, the user can choose to customize.

5.2.1 Choice of drug

Turn on the machine, press the increase or decrease key to move the cursor to the "drug library" option, press the enter key to enter the drug type selection interface, select the drug type according to clinical needs, press the enter key to enter the drug selection interface, select the drug, and then press the enter key to enter the drug selection interface. Parameter setting interface.

5.2.2 Drug parameter setting

The parameter setting interface is shown in Figure 5-1.

Dosage indicates the dose of medicine used, body weight indicates the weight value of the patient, medicine amount indicates the amount of medicine used, and medicine liquid volume indicates the volume of medicine in the infusion bag or infusion bottle during infusion. The values of these parameters must be input according to the actual situation, and Select the correct dose and drug volume unit, and then the system will automatically convert to the infusion rate.

Optional dose unit: ug/kg/min, ug/kg/h, mg/min, mg/h, mg/kg/min, mg/kg/h, g/h, g/kg/min, g/kg /h, IU/h, U/min, U/h, ml/h, ng/kg/min, ug/h.

Optional units for drug dosage: g, mg, ug, ng, ml, U, IU.

Figure 5-1

The drug dosage unit and dosage unit must be the same type of unit, otherwise the rate cannot be calculated, and the rate position will display "unit error". If the calculated rate exceeds the rate range (1-1200ml/h), the rate position will display "out of range ". At this time, the cursor cannot move to the confirmation option, and the confirmation option can only be selected when the calculated rate does not exceed the rate range, and then press the confirmation key, the system interface jumps to the volume mode infusion interface, and the infusion rate is equal to the rate calculated when setting parameters , the drug name is displayed on the upper left corner of the screen, press the start button to start the infusion.

After the drug library parameter is set, it can only be kept temporarily, and it will automatically return to the default value after restarting the machine.

5.3 History

The infusion pump can store 1500 historical records, and the contents of the records are arranged in chronological order, which is convenient for users to view. The record content is shown in Figure 5-2.

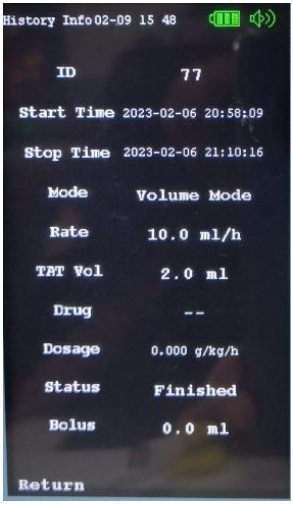


Figure 5-2.

Note: ①The drug name and dosage can only be recorded after the drug is selected and worked, otherwise it is shown in Figure 5-2.

②Status records the specific status when the infusion is stopped, including: manual stop, alarm, infusion completion and other states.

5.4 Setting options

The setting options include language, date and time setting, basic parameters, and calibration.

5.4.1 Language Settings

In the setting interface, move the cursor to the language option, press the enter button to enter the language setting interface, then select the language option to be used and press the enter button, the system will automatically restart and switch the language version.

5.4.2 Date and time setting

Date and time setting: move the cursor to the date and time option, press the enter key to enter the date and time setting interface, in this interface the user can set the specific time and time display format (including: year-month-day, month-day-year, day -month-year). After the setting is completed, move the cursor to the confirmation option, press the confirmation key to save the modification and return to the previous interface; if you directly press the return key, return to the previous interface but the set parameters will not be saved, and the time and date will be saved as they are.

5.4.3 Basic parameter setting

In the basic parameter setting interface, the user can set the alarm and prompt volume, department, bed number, heating temperature, infusion set specifications, blockage alarm level and infusion accuracy.

The heating temperature can be set in the range of 25-50°C, the blocking alarm level has three levels of high, medium and low to choose from, and the precision adjustment range is ±35%. Infusion set Select the corresponding infusion set specifications according to the actual situation.

5.4.4 Calibration

When it is found that the infusion accuracy error is large, the infusion pump should be calibrated. The infusion pump calibration method:

1) Enter the "Settings" page, select "Calibration" to enter the calibration interface to set parameters;

2) Set the infusion speed to xxml/h and the infusion volume to xxml (for example, set the infusion speed to 25ml/h and the infusion volume to 25ml), start the infusion, and collect the output liquid with a graduated cylinder until the infusion is complete.

3) After the infusion is completed, enter the value displayed on the balance into the "calibration value", and press the "OK" button to complete the calibration.

5.5 Other auxiliary functions

5.5.1 Fast Forward

The fast-forward method is: press the fast-forward key twice continuously, press and hold it for the second time to enter the fast-forward state, and release it to automatically exit the fast-forward state.

Fast forward is divided into fast forward in working state and fast forward in non-working state:

Working status - mainly used to temporarily increase the infusion volume during the infusion process. At the end of the fast forward, the fast forward volume will be automatically added to the accumulated volume.

Non-working state - mainly used to eliminate air bubbles in the infusion set pipeline and lavage, the fast-forward amount at this time is not calculated into the cumulative amount.

5.5.2 KVO (keep vein open)

When the infusion completes the alarm, the pump will continue to run at a very low rate to keep the vein open and prevent blood from returning and blocking the line. Please refer to 2.3 for the KVO rate.

Chapter 6 Alarm reminder and alarm elimination

This device is of the type of infusion alarm.

Infusion alarms include infusion completion alarm, air bubble alarm, blockage alarm, door open alarm, empty bottle alarm, signal error alarm, battery undervoltage prompt, and AC disconnection prompt.

6.1 Infusion complete alarm

When the infusion of the set infusion volume is completed, the "alarm" light will light up and an alarm sound will be issued, and the system will automatically enter the KVO mode, and the interface will have a text prompt of "KVO".

6.2 Bubble alarm

When there are air bubbles in the infusion set pipeline and the air bubbles pass through the air bubble detector, the device will automatically stop the infusion, the “bubble” alarm light and the “alarm” light will light up, and an alarm sound will sound, and the screen will display an “error” prompt. Air bubbles in the tubing must be removed before the infusion can be restarted.

Note: The infusion pump will not detect air bubbles when the infusion pump is stopped, and the air bubbles in the pipeline can be removed by fast access, but it must be ensured that the infusion set is not connected to the human body at this time.

6.3 Blocking alarm

During the working process, when the needle or the infusion line is blocked, the "obstruction" indicator light and the "alarm" light are on, and the pump stops working, accompanied by sound and light alarms. Press the mute key or the stop key to eliminate the alarm sound, and the infusion set pipeline will It should comply with the standard GB 8368-2005 "Gravity Infusion Type of Disposable Infusion Sets" and the accumulative use time should not exceed 180 minutes, and there should be no rupture or leakage. The alarm threshold and trigger time are

related to the selection of alarm pressure, infusion rate, softness and hardness of the infusion set pipeline and the blocked position of the pipeline, etc. For the pressure threshold of the alarm, see 2.2 Technical parameters. When the infusion pump is running at a medium speed (25ml/h), the blockage alarm threshold:

Height: 800mmHg±200mmHg (106.7kPa±26.7kPa)

Medium: 500mmHg±150mmHg (66.7kPa±20kPa)

Low: 300mmHg±100mmHg (40.7kPa±13.3kPa)

After eliminating the blocking fault, press the start button to continue to work, or stop working according to the usage situation, and choose to adjust other alarm pressure thresholds. The maximum infusion pressure when the device is running is 150kPa.

6.4 Door open alarm

When the infusion pump is running, when the door of the infusion pump is opened, the infusion will stop automatically, the "alarm" light and the "door open" light will be on and an alarm will sound, and only the "door open" light will be on when the door is in the stop state without an alarm sound. When the door is open, the infusion pump cannot start the infusion, and there will be an "error" prompt when the start button is pressed.

6.5 Empty bottle alarm

When the drop speed mode is working, the device will automatically stop working, and an audible and visual alarm will be issued, and the screen will display "empty bottle" when the liquid in the infusion bottle is completely infused or the infusion tube is completely blocked, so that the drop number detection clip cannot detect the drop signal. Word. Continue to work after changing the liquid medicine or troubleshooting.

Note: There is an empty bottle alarm only in the drop counting mode

6.6 Signal error alarm

When the drop speed mode is working, the signal detection port of the drop count detector is completely blocked or the drop count detector breaks down, it will automatically stop working, and an audible and visual alarm will be issued, and the "alarm" indicator and "signal" alarm light will be on. Eliminate the cause of the alarm and restart to continue working.

6.7 Battery undervoltage prompt

When the battery is low, the battery icon on the screen flashes intermittently and turns red, and the pump will emit intermittent prompts. Press the mute button to eliminate the alarm sound. Under normal circumstances, the pump can work at a speed of 25ml/h At least 30min. At least 3 minutes before the battery power is exhausted, it will automatically stop working. At this time, the external AC power supply should be connected immediately to continue working.

Note: After the external AC power is connected, the power indicator light is on, and the pump is in the state of automatic charging. In the power-on state, the battery symbol changes to the charging state.

6.8 AC disconnection prompt

When the AC power is disconnected, the device will emit a beep, and the power light will go out, and the battery icon will display the current power level.

Chapter 7 maintenance and maintenance

◎Professional maintenance personnel must be trained to repair the product.

◎Do not use benzene, ethyl ketone and other organic solvents to clean the pump; regularly wipe the outer surface with a clean damp cloth and an appropriate amount of detergent, then wipe the surface with a clean damp cloth, and finally dry it with a clean cloth and place it on a dry shelf.

◎If the power indicator light is off after connecting to an external power supply, please contact our company for professional repairs, unauthorized repairs may cause greater damage or danger.

◎Considering the life of components and the safety of medical devices, it is recommended that the service life of medical devices should not exceed 5 years. If continued to be used, it may be dangerous due to unreliable operation of the equipment.

◎If replacing the fuse link, unplug the power cord first, the fuse link is a fast type tubular fuse link, the specification is F1AL (F means fast, L means low breaking capacity).

◎Maintenance of rechargeable batteries:

When not in use, please turn off the power switch to prolong the service life of the pump and protect the built-in battery to avoid damage to the battery due to excessive discharge.

The battery should be checked for charging and discharging once a month, so as not to affect the use due to insufficient battery power when working with the battery.

When the pump is not used for a long time, it should be charged once every 3 months to prevent the built-in battery from being automatically discharged and scrapped.

◎If the pump is not used for a long time, when it is used again, the system time needs to be reset, and the battery should be charged and discharged to check, so as not to work normally when there is no external power supply. The built-in battery has been charged and discharged about 300 times. If it cannot be charged and discharged normally, you should contact the manufacturer in time for replacement, and you cannot replace it without authorization.

◎Used disposable infusion sets should be disposed of in accordance with the treatment regulations for medical waste.

◎If the customer needs it, our company can provide circuit diagrams, component lists and other materials that meet the requirements of the standard (6.8.3C in GB9706.1-2007).

◎Inspect and maintain at least once a year. You can send the infusion pump back to the manufacturer or contact the manufacturer for inspection and maintenance.

◎Our company's product infusion pump, if there is any failure from the date of purchase, it will be replaced for free within one month and guaranteed for one year. Within one year of the warranty period, it should be sent back to the company for maintenance, and the company is responsible for all maintenance costs and shipping costs (except for built-in batteries and man-made damage).

◎Do not let water or cleaning fluid flow into the connector socket at the rear end of the infusion pump to prevent damage to the instrument

◎When cleaning the instrument, only wipe the outer periphery of the connector socket, not the inside of it

◎If the cable shows signs of damage or deterioration, it is forbidden to use it again.

◎The following conditions do not belong to the scope of free maintenance:

1. Damage caused by improper installation, use, maintenance and storage by customers;

2. Products that have exceeded the replacement and warranty period;

3. Valid certificates and warranty certificates are inconsistent or altered;

4. Disassemble the machine without the permission of the company;

5. The product is damaged due to human factors;

6. Damage caused by transportation, loading and unloading during customer repair;

7. Damage caused by force majeure such as earthquake, flood, fire, lightning strike and other natural disasters;

8. Other non-product reasons cause product failure or damage.

Notice:

1. If the product has performance problems within one month from the purchase, and the appearance is not damaged, it can be replaced with a new product of the same model and quantity after being tested and confirmed by the company's technical personnel.

2. Due to improper use or product maintenance beyond the warranty period, the company will charge the cost of the corresponding accessories;

3. The maintenance period of the built-in battery is six months according to the relevant national standards, and the cost of replacement beyond the warranty period shall be borne by the customer;

4. The power cord, packaging and accessories (manual, warranty card, certificate of conformity) do not belong to the scope of replacement warranty

5. Customers should pay attention to the packaging of the product during transportation to avoid damage to the product;

6. This warranty policy is only applicable to products used in China (excluding Hong Kong, Macau, and Taiwan).

Chapter 8 Common faults and troubleshooting

fault phenomenon	Possible cause of failure	resolvent
Rate inaccuracy	1. The infusion set is not installed correctly	Reinstall the infusion set
	2.The infusion set is not calibrated	Calibrate the infusion device
Pipeline fluid leakage under shutdown condition	1. The infusion set is not installed correctly or the infusion set that does not meet the requirements is used	Reinstall or replace the required infusion set
	2. Parts are damaged, deformed, or the screws are loose	Parts are replaced by professional maintenance personnel
The battery cannot be charged	1. Battery damage	Replace the battery
	2. No built-in battery is installed	Install built-in battery
Boot up without display	1. the battery is low and cannot be started	Connect AC
	2. System error	1. Restart
		2. Contact the manufacturer for maintenance

Chapter 9 Packaging and accessories

Attached accessories (configuration list)

serial number	name	Specifications / models	source	quantity
1	Infusion pump host	/	Self-produced	1 set
2	Remote control	/	Outsourcing	1 pcs
3	Power cord	1.8m	Outsourcing	1 pcs
4	User manual	/	Self-produced	1 copy
5	Product certification	/	Self-produced	1 copy

For replacement of accessories, please contact the manufacturer's after-sales department.

.Interpretation of the graphics, symbols, abbreviations and other contents used for the labeling of medical devices

	Note, refer to the attached documents		Fragile, put carefully
	Avoid rain		upward
	temperature extremes		Manufacturing date
	Humidity limit	SN	Serial number
	Atmospheric pressure limit		life span
	Limit of stacking layers		Fluid flow direction

IPX1	Protection of harmful liquid protection		Waste equipment should be treated according to the environmental protection regulations

NOTE

1 When unpacking, pay attention to the prompt on the packing box;

2 After unpacking, check the accessories and accompanying documents according to the packing list, and then start to check the device;

3 If you find that the goods of the package do not meet the requirements or the device cannot work properly during the startup inspection, please contact the sales department or after-sales service department of the company immediately;

4 Please use the supporting accessories provided by our company, otherwise it may affect the performance and safety of the machine. If you use the accessories provided by other companies, you should consult our after-sales service department in advance;

5 The packing box shall be properly stored for use in the periodic calibration or maintenance of the equipment .

Appendix A. Toxic and harmful substances or elements

Part name	Toxic and harmful substances or elements					
	lead（Pb）	mercury（Hg）	cadmium（Cd）	Hexavalent chromium（Cr（VI））	Polybrominated biphenyls（PBB）	Polybrominated diphenyl ether（PBDE）
shell	○	○	○	○	○	○
operation panel	○	○	○	○	○	○
PCBA	○	○	○	○	○	○
labeling	○	○	○	○	○	○
display screen	○	○	○	○	○	○
packing material	○	○	○	○	○	○
fitting	○	○	○	○	○	○
power cord	○	○	○	○	○	○
battery	○	○	○	○	○	○

remarks:

○： It means that the content of the toxic and harmful substance in all homogeneous materials of the component is below the limit requirements of SJ / T 11363-2006 standard.

×： It means that the content of the toxic and harmful substance in at least one homogeneous material of the component exceeds the limit requirement of the SJ / T 11363-2006 standard.

When the products and batteries are discarded after normal use, please comply with the laws and regulations of the local government.

Appendix B. Electromagnetic compatibility (EMC)

This device can generate, use and radiate radio frequency energy.This equipment can cause electromagnetic interference between other medical equipment or non-medical equipment and radio communication.According to the statement in YY0505-2012,This product belongs to the first group of Class A medical equipment with emission limit to provide corresponding protection measures to avoid interference. However, it is not fully guaranteed that electromagnetic interference will not occur under specific installation conditions.

When the equipment is found to cause interference (requiring confirmation from the switchgear), the operator (or authorized maintenance personnel) can eliminate the interference according to the following measures:

- Adjust or reposition the affected equipment;
- Increase the distance between this device and the affected device;
- Use another power supply to supply power to this device;
- Consult the maintenance engineer for more advice.

⚠ Note:Before using this equipment, please ensure that all EMC requirements contained in this manual are met.

⚠Note:This chapter will list the contents described in the YY0505-2012 table. The user shall be responsible for ensuring that the equipment and its nearby equipment meet the radio frequency interference parameters indicated in the general safety requirements.

⚠Note:Do not use equipment (mobile phones, radio transceivers or radio control

products) intended to transmit RF signals near this equipment, which may cause the operation to exceed the specified value. Please turn off this type of device when it is near this device. The operator shall be responsible for reminding the patient or other personnel near the equipment to fully comply with the above requirements.

⚠Note:The manufacturer will not be responsible for any interference caused by the use of non-recommended internal connecting cables or unauthorized modification or modification of this equipment.

Table I

Guide and manufacturer's statement- -electromagnetic emission		
[infusion pump] is expected to be used in the following electromagnetic environment, and the purchaser or user shall ensure that it is used in this electromagnetic environment		
Launch test	compliance	Electromagnetic Environment - Guidelines
radio-frequency emission GB 4824	Group 1	[infusion pump] uses RF energy only for its internal function. Therefore, its RF emission is very low, and the possibility of interference to nearby electronic equipment is very small.
radio-frequency emissionGB 4824	Class A	[infusion pump] is applicable to non-domestic and all facilities not directly connected to the public low-voltage power supply network of domestic residence.
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuation/flicker emission GB 17625.2	Not applicable	

Table 2

Guidelines and manufacturer's statement - Electromagnetic immunity			
[infusion pump] is expected to be used in the following electromagnetic environment, and the purchaser or user shall ensure that it is used in this electromagnetic environment.			
Anti-interference measurement	IEC60601 Test level	Coincidence level	Electromagnetic Environment - Guidelines
electrostatic discharge GB/T 17626.2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	The floor shall be wood, concrete or ceramic tile. If the floor is paved with synthetic materials, the relative humidity shall be at least 30%.
Electric fast pulse group GB/T 17626.4	±2 kV To power cord ±1 kV For input/output lines	±2 kV power cord	The network power supply should have the quality used in a typical commercial or hospital environment.
surge GB/T 17626.5	±1 kV Line to line ±2 kV Line to ground	±1 kV Line to line ±2 kV Line to ground	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage sag, short interruption and voltage change on power input line GB/T 17626.11	＜5% U_T，Continuous for 0.5 cycle (On U_T,> 95% down) 40% U_T, which was continued for 5 cycles (On U_T, 60% down) 70% U_T, which was continued for 25	＜5% UT（drop ＞ 95% UT）0.5 cycle 40% UT（drop 60% UT）5 cycle 70% UT（drop 30% UT）25 cycle ＜ 5% UT	The network power supply should have the quality used in a typical commercial or hospital environment.If the user of [infusion pump] needs to

	cycles (On U_T, 30% down) <5% U_T and continued for 5s (On U_T,> 95% down)	（ drop ＞ 95% UT）5 seconds	operate continuously during power interruption, it is recommended that [infusion pump] use uninterruptible power supply or battery power supply.
Power frequency magnetic field （50/60Hz） IEC 61000-4-8	3 A/m	3 A/m	The power-frequency magnetic field should have the horizontal characteristics of the power-frequency magnetic field in a typical place in a typical commercial or hospital environment.
Note: U_T is the AC net voltage before the test voltage is applied			

Table 3

Guidelines and manufacturer's statement - Electromagnetic immunity			
[infusion pump] is expected to be used in the following electromagnetic environment, and the purchaser or user shall ensure that it is used in this electromagnetic environment			
Anti-interference measurement	IEC60601 Test level	Coincidence level	Electromagnetic Environment - Guidelines

Radiofrequenc y conduction GB/T 17626.6	3 Vrms 150k～80MHz	3 Vrms	Portable and mobile radio frequency communication equipment should not be closer to any part of the mobile equipment, including cables, than the recommended distance. The distance shall be calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz~ 800MHz $d=2.3\sqrt{P}$ 800MHz~2.5GHz In formula: P---According to the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts（W）; d---Recommended interval distance, measured in meters (m).\ The field strength of the fixed RF transmitter is determined by the electromagnetic field survey [a]. In each frequency range, [b] should be lower than the compliance level. Interference may occur near the equipment marked with the following
radio-frequenc y radiation GB/T 17626.3	3 V/m 80M～2.5GHz	3 V/m	

			symbols. 

Note 1: At the frequency point from 80MHz to 800MHz, the formula of higher frequency is adopted.

Note 2: These guidelines may not be applicable to all situations. Electromagnetic transmission is affected by the absorption and reflection of buildings, objects and people.

[A] Fixed transmitter ,For example, the field strength of base stations of wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radio, AM and FM radio broadcasts, and television broadcasts cannot be accurately predicted in theory.In order to evaluate the electromagnetic environment of fixed RF transmitters, the investigation of electromagnetic sites should be considered.If the measured field strength of the mobile device is higher than the applicable RF compliance level, the mobile device should be observed to verify its normal operation.If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the direction or position of the mobile device.

[b] In the whole frequency range of 150kHz~80MHz,the field strength should be lower than 3V/m.

Table 4

Recommended isolation distance between portable and mobile radio frequency communication equipment and [infusion pump]			
[infusion pump] intended for use in controlled electromagnetic environments with RF radiation harassment.According to the maximum rated output power of communication equipment,[infusion pump] Buyers or users can prevent electromagnetic interference through the minimum distance between portable and mobile RF communication equipment (transmitter) and [infusion pump] recommended below			
Maximum rated output power of transmitter W	Calculate the isolation distance according to the frequency of the transmitter (m)		
	From 150kHz to 80MHz	From 80MHz to 800MHz	From 800MHz to 2.5GHz

	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.37
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the rated maximum output power of the transmitter not listed in the above table,Recommended isolation distance*d* ， In meters (m)， Can be determined by using the formula in the corresponding transmitter frequency bar,here *P is* the maximum output rated power of the transmitter provided by the transmitter manufacturer, measured in watts (W). Note 1: At 80 MHz and 800 MHz, the formula of higher frequency range is adopted. Note 2: These guidelines may not be applicable to all situations. Electromagnetic transmission is affected by the absorption and reflection of buildings, objects and human bodies.			