Infusion Pump SYS-6010

Operation Manual

Please read this “Operation Manual” carefully and follow “Precautions for Use” and “Preparations for Use” before using the SYS-6010 Infusion pump.

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

Intellectual Property and Statement

Statements

MEDCAPTAIN reserves the right for final interpretation of this Service Manual.

MEDCAPTAIN reserves the right to modify the contents of this service manual for a more accurate and effective service quality. The modified contents should be reflected in the newly published service manual version.

MEDCAPTAIN is responsible for safety, reliability and performance of this equipment only in the condition that:

- Use in accordance with the Operation manual.
- All disassembly, replacement, test, modification and repair are executed by qualified personnel approved by MEDCAPTAIN.
- All replacement parts, supporting accessories and consumables during the maintenance are provided by MEDCAPTAIN.
- Maintenance records for product are reserved.

Version Information

- **V1.0**
  - Firstly publish
  - Publish date：2013.12.30
- **V2.0**
  - Registration change and content modification
  - Publish date：2014.5.30
- V2.1
  - Interface Modification
  - Publish date：2016.3.5

After Service

Thank you for using the infusion pump of MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

- During the warranty period, we provide free after-sale services except the following causes:
  - Artificially damaged.
  - Inappropriate use.
  - The voltage of supply network exceeds the range.
  - Irresistible natural disasters.
  - Replace or use parts, accessories and consumables without approval of MEDCAPTAIN.
  - Other troubles not caused by product itself.

  After the warranty period, we continue to provide charged maintaining service. If you have any question when using the infusion pump, please contact local distributor or directly contact us at any time.

  The after-sales service contact details of Medcaptain Medical Technology Co., Ltd. are as follows:

  Address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan District, Shenzhen, P.R.China

  Telephone:+86-755-26953369

  Fax: +86-755-26001651

  Postal: 518055

  Website: http://www.medcaptain.com

  E-mail:info@medcaptain.com

- MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD. and all local dealers established after-sales service agencies, can effectively, timely solutions to your problems.

WARNING:

- The device should be operated by clinic medical staffs or under the instruction of special clinic medical staffs. The operator should have been trained on how to use this product.

Overview

1 Overview

1.1 Intended use

This product is intended for hospitals to infuse liquid at constant-speed or liquid medicine continuously through the veins of patients.

1.2 Contraindication

None.

1.3 Product Features

MEDCAPTAIN SYS-6010 is a micro-continuous infusion pump. It ensures constant infusion speed and accurate dosing volume during long time infusion.

This infusion pump is used for continuous and micro-volume infusion of liquid or liquid medicine of little volume and high concentration, including, but are not limited to the infusion of chemotherapeutic agents, cardiovascular drugs, antineoplastic, oxytocic, anticoagulant, anesthetic agents.

- All current disposable IV sets conform to the standard are supportable.
- New IV set conform to the standard can be customized.
- Providing three occlusion levels and displaying pressure status of the tube.
- Maximum infusion rate can be set to 1200mL/h.
- Calibration functions for infusion accuracy is available.
- Safety design by monitoring infusion states.
- Multiple modes of infusion.
- Configure with multi-channel infusion workstation, realizing relay infusion function.
- WIFI module could be connected to the ICMS to monitor the infusion status.
- Nurse call function.
- Voice Communication function.
- Touchscreen, providing quick and convenient man-machine interface.
- Display night mode, reducing light interference to patients and environment.
- Connection to barcode scanner function.
- Three types of power supply: AC power supply, DC power supply, and internal lithium battery are available. The lithium battery can power the infusion pump for no less than 5 hours (at 25ml/h rate).
- Double CPU and redundancy design for key units.

Overview

- Two-way alarm for monitoring the main control circuit and motor drive circuit
- Independent motor driving CPU and motor subdivided drive chip design.
- Setting and giving automatic prompt of maintenance interval.

Note:

Pole clamp, barcode scanner, WIFI communication module, voice communication, and nurse function are optional l, depending on the user's need.

2 Precautions for Use

In this manual, precautions are classified into warning and caution according to the importance. The meanings are as follows:

WARNING:

The information is about safety and efficiency. Operation against the warning may cause injuries.

CAUTION:

The information is about guiding suggestions. Operation against the caution may affect normal use of the product. Read carefully the warnings and cautions in this manual.

WARNING

- The infusion pump must be operated by clinical professionals.
- The infusion pump cannot be used to transfer blood.
- Prior to use, carefully check the pump, power cord and accessories, to ensure the normal operation and safety.
- Pay extra attention to kinks of the infusion line when it is used for low-infusion. The smaller the set infusion rate becomes, the longer it takes from the occurrence of occlusion to its detection, which may suspend the infusion for a long time.
- Do not use the infusion pump in the environment of flammable anesthetic gas or rich oxygen.
- The height difference between infusion pump and patient should less than 100cm. The lower of the height difference is, the pressure testing of the infusion tube is more accurate.
- In the event of tube twisting, filter condensation or intubation occlusion during infusion, the internal pressure of the infusion tube will increase. Once the causes for occlusion are removed, too much infusion liquid may be infused into the patient. Therefore, proper actions should be taken. For example, clamp the infusion tube before removing the occlusion causes.
- The infusion pump must be used with the recommended IV set to ensure the infusion accuracy and alarm function.
- Only the IV set, tube, infusion needle and other medical parts complying with the local regulations can be used on the infusion pump. Contact your local distributor for more information.

Precautions For Use

- Operations against the requirements, procedures, warnings and cautions provided in this manual may cause infusion failure, inadequate over dosing, or other potential risks.
- It is recommended to install the drop sensor and open the drop monitoring function. A long time extrusion may cause without moving or replacing the tube an inadequate infusion.
- There should be a regular monitoring to patient’s real clinical situation and performance of the pump, by clinical professionals.
- Place the power cord and cables of accessories carefully, avoiding cable tangle, patient winding or electrical interference.
- High-frequency surgical equipment, mobile phone, wireless device and defibrillator may have interference on the infusion pump. Keep away from such devices while operating.
- To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.
- The infusion pump and accessories near to service life time must be scrap according to local regulations or hospital rules. If there is any problem, please contact the distributor or manufacturer.
- Do not modify this equipment without authorization of the manufacturer.
- When operating the pump or checking the pump's alarm system, the operator shall be in front of the device, no farther than 1 meter.
- There is no patient circuit in this device. The output of the equipment is not allowed to be accessible to patient.
- The operator shall not touch SYS-6010 and the patient simultaneously.

CAUTION:

- The administration set is treated as the applied part.
- Check the setting values on the prescription and infusion pump. , the infusion can be started without moving or replacing the tube.
- In order to prevent extra infusion, close the rolling clamp of the IV sets before separating the IV sets from pump.
- Follow the tube replacement alarm on the display, replace the IV sets or move the IV sets tubing to more than 10cm, so as to keep the infusion accuracy continuously.
- Please properly install or carry the infusion pump, avoiding device damage through crash, fall, violent mechanical vibration or other external force.

Precautions For Use

- Before pressing the [START] key, check if the infusion speed is correct, especially the position of the decimal point.
- Occlusion alarm may occur when high-viscosity liquid is infused at high speed through a thin intravenous needle. Increase the occlusion level or decrease the infusion speed.
- Infusion pump should be placed without the reach of patients and other irrelevant personnel.
- Be away from direct sunshine, high temperature and high humidity.
- Do not disinfect the infusion pump by using high-pressure steam sterilization method.
- Before using the internal battery, check the battery to ensure that sufficient power is available. Recharge, if required.
- Ensure that the infusion pump always has a battery installed during operation. Otherwise, the system may stop without issuing an alarm when external power is interrupted due to power failure or a short circuit, causing an unsafe condition.
- If the infusion pump cannot work as described in this manual for unknown reasons, stop it and report the details (including IV set, infusion flow, serial number of infusion pump, and type of infusion liquid) to your local distributor or our customer service department.
- Do not operate on the display using sharp objects. It may damage the screen..
- Do not disassemble or reconstruct the infusion pump without authorization.
- Liquid intrusion into the AC power socket, USB or nurse call socket may cause short-circuiting. While connecting the power cable, check if the connecting parts are dry. If liquid spills on the infusion pump, clean the pump with a dry wiper. Use after the service engineer checking.
- Applied parts administration set, which is not intended to deliver heat, during normal use the maximum temperature at applied part maybe up to 40.4°C.
- Before use, carefully check if the occlusion pressure test function of the infusion pump is normal. The Maximum infusion pressure at the end of the infusion tube generated by the pump may be up to 3500mmHg under the condition of occlusion when sensor failed.
- When the infusion pump is working, the delay time from alarm triggered to give out alarm information is less than 150ms.

Precautions For Use

Symbols:

	Authorized Representative in the European Community
	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer
	Specifies serial number
	TYPE CF APPLIED PART
	Alternating current
	Direct current
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	CAUTION! Read the accompanying document.
	General warning sign
	Refer to instruction manual / booklet
IPX2	Level of protection from liquid intrusion
	Interference may occur near the devices with below sign.
	Nurse call
	ON/OFF
	HOME
	OPEN

3 Product Specifications

Product name	Infusion pump
Model	SYS-6010
Power supply	AC power supply: AC 100-240V,50/60 Hz, power consumption 45 VA External DC power supply: DC 12 V 1A Internal battery: lithium battery 11.1 V 1500 mAh Battery model: 154457 Time of battery continuous use: no less than 5 hours (for infusion at 25 mL/h rate with a new battery)
Fuse	T1.6AL 250VAC
Compatible IV sets	All 20d/ml disposable IV sets conform to the standard, 20d/mL
Infusion mode	Rate, Time, Body Weight, Sequence, Micro, Relay, Drip Mode
Infusion setting range	0.1-1200.0mL/h or (0.03-400d/min) (20d/Ml IV set) See the least increment in chart 6-3
VTBI setting range	0.1 - 99.99 (Least increment 0.01) 100 - 999.9 (Least increment 0.1) 1000 - 9999 (Least increment 1)
Total volume display	0-99999.99ml
Accuracy	±5%
Purge operation	1200.0ml/h(20d/ml IV set)
Bolus operation	0.1~1200.0ml/h(20d/ml IV set) Automatically calculate the bolus rate by bolus amount, cannot lower than the current rate.
KVO rate	0.1-5.0mL/h
Air-bubble sensor	Sensitivity: detect air-bubble $\geqslant 0.025^{+0.025}_{-0}\,\mathrm{mL}$
Occlusion level	300mmHg~900mmHg，3 levels are available
Alarm	Near End, Infusion End, Occlusion Alarm, Low Battery, Battery Empty, No Battery, No Power Supply, Door Open, No Drop Sensor, No drop, Drop Error, Air Bubble, Reminder Alarm and Standby Finish.
Special function	**Repeat alarming:** If there is still alarm after mute alarm sound, it will alarm again in 2 minutes

Product Specifications

	Event recording: Can store and playback 2000 events maximum **Alarm volume setting:** 11 levels of alarm voice are available **Power supply switching:** When AC/DC power supply is cut off ,the infusion automatically switch to internal battery supply **Barcode scanning:** Input the patient information by barcode canning
WIFI function	Connect infusion workstation, nurse pager, voice communication and infusion pump information network
Operating conditions	Ambient temperature: 5℃-40℃ Relative humidity: 15%-95%, no condensation Atmospheric pressure: 70.0 kPa-106.0 kPa
Storage conditions	Ambient temperature: -20℃-55℃ Relative humidity: 10%-98%, no condensation Atmospheric pressure: 22.0 kPa-107.4 kPa
Classification	1. Class I / Internally powered equipment; 2. Type CF applied part; 3. IPX2; 4. No sterilization requirement for pump 5. Not category AP / APG equipment; 6. Mode of operation: continuous
Dimensions	100(W) ×230 (H) ×190(D)mm
Weight	About 1.2 kg (including battery)
Manufacture date	See label in the bottom of the device
Main safety standards	IEC60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC60601-2-24 Medical electrical equipment –Part 2-24: Particular requirements for the safety of infusion pumps and controllers IEC60601-1-8 Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility requirements and tests

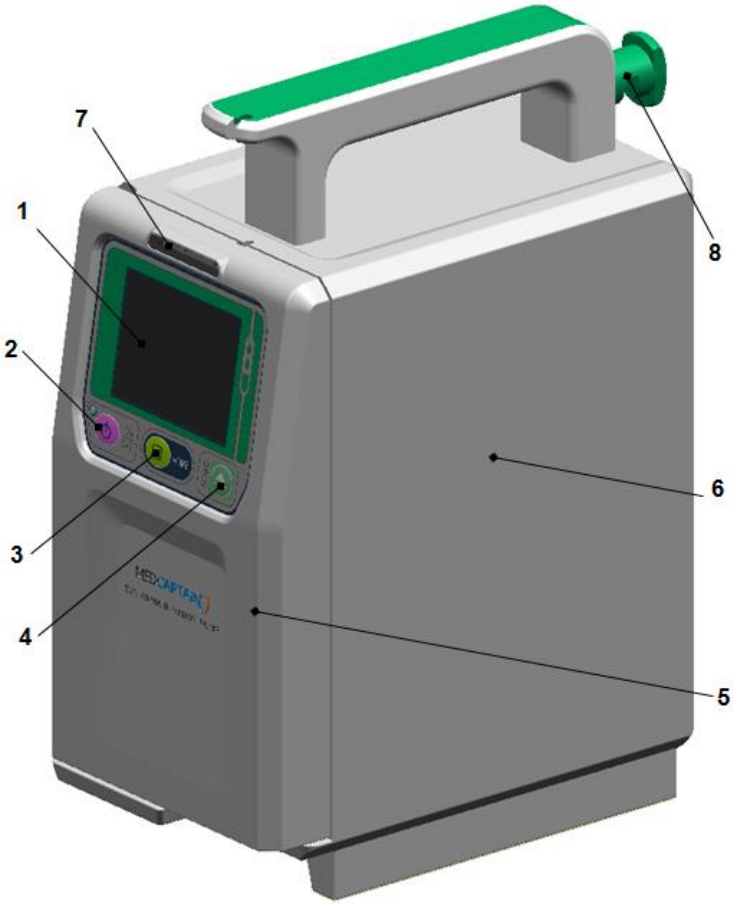
4 Product Description

4.1 Principle of Operation

The SYS-6010 infusion pump mainly consists of the pump shell, display and operating system, monitoring system, alarm system, motor drive system, tubing peristaltic module, power supply system, drop sensor, WIFI communication module (optional), handle (optional) and pole clamp (optional).

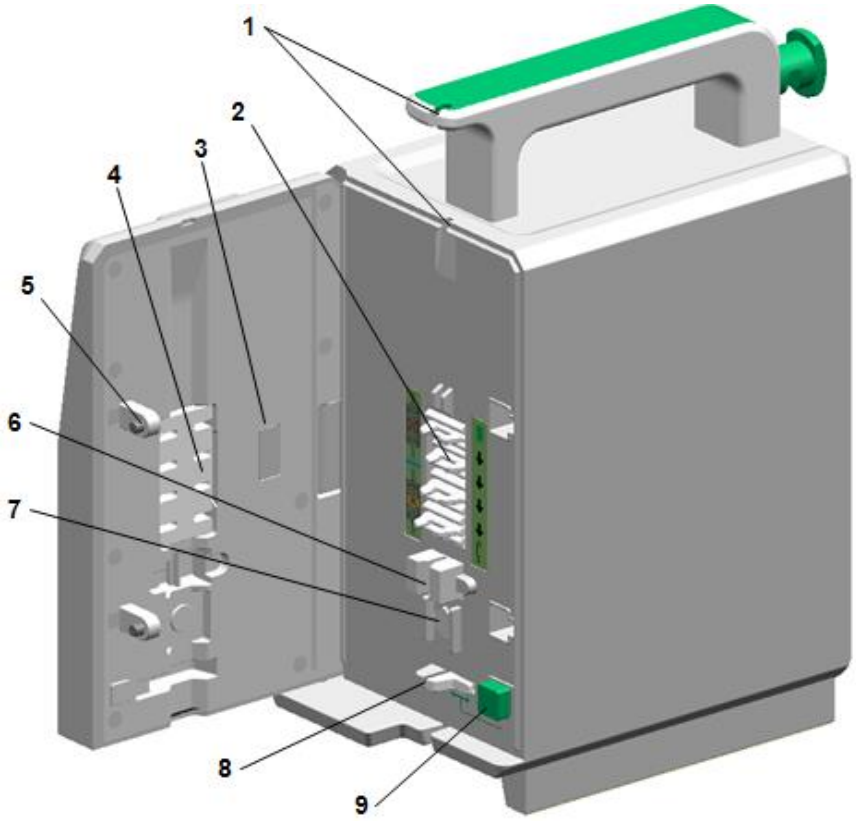
The infusion pump adopts the dual processor structure, controls the motor precisely, drives the peristaltic sheet to infuse through the mechanical drive device, monitors the sensors and infusion process, and provides sound and light alarms.

4.2 Composition of Infusion Pump



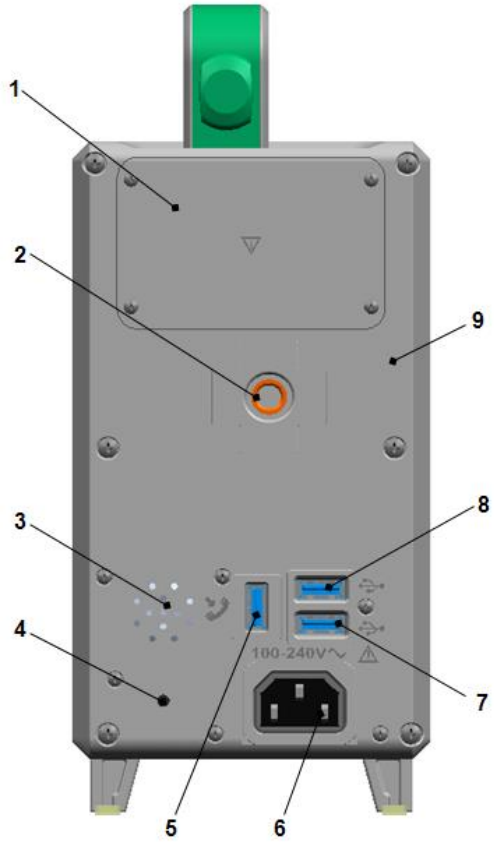
1 –Touchscreen	2 – [HOME]key	3 – [ON/OFF]key
4 –[OPEN]key	5 –pump door	6 –Shell
7 –Alarm indicator	8 –Drop sensor holder	

Product Description



1 –Infusion tube slit	2 –Peristaltic pump tablets	3 – Lighting lamp
4–Depressor	5 –Catch	6 – Air bubble sensor
7 –Pressure sensor	8 –Anti-free-flow clamp	9 –Anti-free-flow clamp button

- Infusion tube slit. At sides of pump to guide the infusion tube in a line behind the pump door.
- Depressor and peristaltic plate. Driven by the step motor, press and move the tube to realize liquid flow.
- Lighting lamp. To provide lighting in a dim environment, so as to install and check the infusion tube.
- Catch. The two catches are used to close the pump door.
- Pressure sensor and bubble sensor. Sensors monitor occlusion pressure and air bubble inside the infusion tube.
- Anti-free-flow clamp. Stop liquid flow and infusion backwards after the pump door opens.
- Anti-free-flow clamp button. Press the button and the clamp will automatically open or close.



1 –Battery cover	2 –Threaded hole	3 –Buzzer
4 –Auxiliary alarm	5 –External inlet 1	6 –AC power inlet
7 –External inlet 2	8 –External inlet 3	9 –Shell

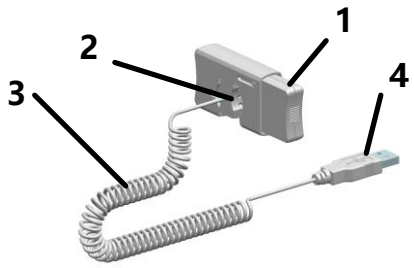
- Battery chamber. Replaceable battery inside the chamber.
- Threaded hole. To fix the pole clamp, then fix the pump to the IV pole via the pole clamp.
- Buzzer. To alarm in high, medium or low level during infusion and enable voice conversation.
- Auxiliary alarm. Audible alarm sounds when product functions abnormally.
- AC power inlet. To connect the external AC power source.
- External inlets 1, 2 and 3. The three inlets share the same signal and can be connected to 2 external devices at the same time. The external devices include drop sensor, barcode scanner, and external DC power

CAUTION:

- Only the accessories or devices specified by the manufacturer allowed to be connected to the Pump. Otherwise may cause electrical shock. See Table 4-1.

- The person who connects the devices and accessories to each other or who uses the devices and accessories is responsible and liable for installation and operation that complies with IEC/EN 60601-1-1 or clause 16 of IEC 60601-1.
- The plug is used as disconnect to the mains supply, do not position the pump so that it is difficult to operate the disconnection device..

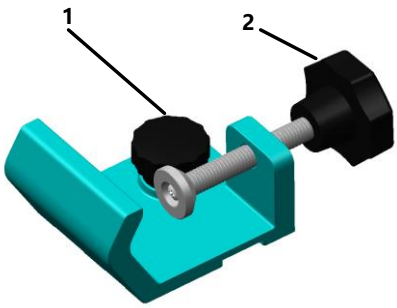
4.3 Drop sensor



1 –Button 2 –Drip hole 3 –Cable

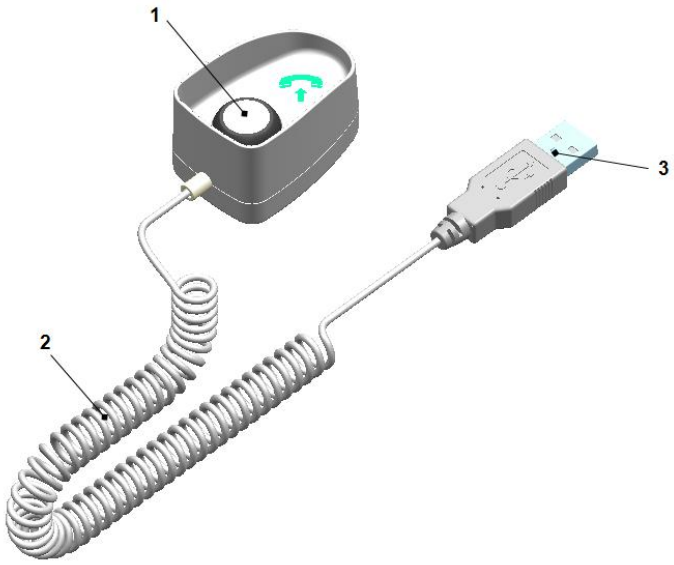
4 –Socket

4.4 Pole Clamp



1 - Mounting screw 2 - Mounting knob of infusion stand

4.5 Nurse Pager



1 –Button 2 –Cable 3 –Socket

4.6 Accessories accompanied

1 –AC power cord	1	2 - Pole clamp	1
3 –Operation manual	1	4 - Packing list	1
5 –Quick-operation instruction	1		

4.7 Optional Accessories

Table 4-1 List of Optional Accessories

Options	Description	Parts code
Power cable	Standard configuration by factory	7000000005
Lithium battery pack	11.1V@1500mAh	7404000006
Nurse pager	MP-2	9113001002
Drop sensor	MP-3	9114002521
Barcode scanner	MP-4	9005000008
Pole clamp	——	9114002501

5 Preparations for Use

- Before using the infusion pump, read carefully the Operation Manual and precautions in this manual.
- When using the infusion pump for the first time, set up the date and time to ensure that history can be recorded correctly.
- Before using the infusion pump for the first time, set the brand of infusion set.
- Before using the infusion pump for the first time, recharge the internal battery fully. If the infusion pump is off, the battery can be charged fully at least 10 hoursafter being connected to an external power supply.
- Place the infusion pump on a stable platform.
- Or use the provided pole clamp to mount the infusion pump on an infusion stand.
  - Put the infusion pump on the pole clamp while aligning the retaining knob with the threaded hole, and rotate the handle to fix the infusion pump on the pole clamp.
  - Clamp the pole clamp on the infusion stand, adjust the infusion pump to an appropriate position, and tighten the retaining knob for infusion stand on the pole clamp.
- Connect external power supply.
  - Insert the supplied AC power cord into the AC inlet on the right side of the infusion pump. Plug the cord into an AC power outlet with grounding terminal.
  - To power the infusion pump with external DC power supply, contact local distributor for help.

CAUTION:

- Do not install the infusion pump to a place that is difficult to connect the AC power.

6 Operating Instructions

6.1 Display and keys

- Display

1 –Alarm indicator 2 –TFT Touchscreen 3 –Home key

4 –ON/OFF key 5-OPEN key

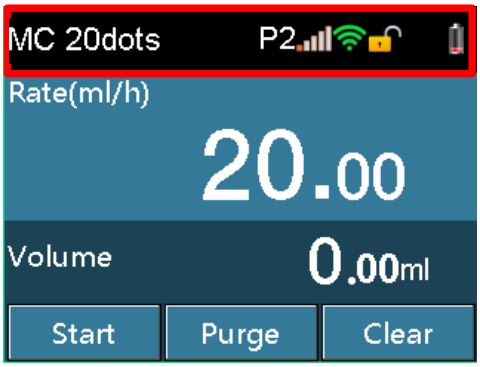
The alarm indicator indicates alarms with three colors: red, yellow and green represent three levels of high, medium and low, depending on the importance of infusion information.

TFT Touchscreen, resolution: 320X240

The display is divided into three areas: information area, work data area and function key area. See below for further description.

Information area: to display the patient name, record No., bed No., IV set brand and specifications, occlusion pressure level, real-time pressure, external power supply and battery volume.

Click the brand and specification area to modify the infusion brand. Click occlusion pressure level or real-time pressure state area to modify the occlusion pressure level.



P2 Occlusion pressure level: 2

Occlusion pressure real-time: a full set of 5 bars. The more bars displayed, the larger pressure it is.

External power source. Displays when external AC/DC power source is connected.

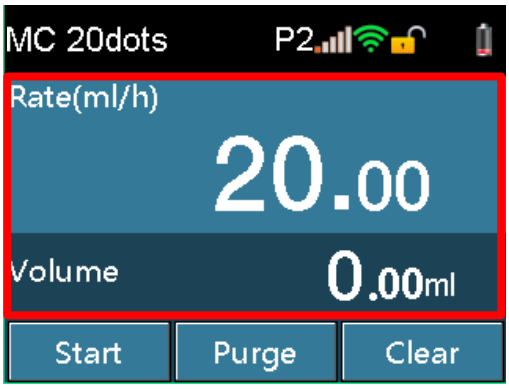
Screen lock symbol, consists of lock and unlock.

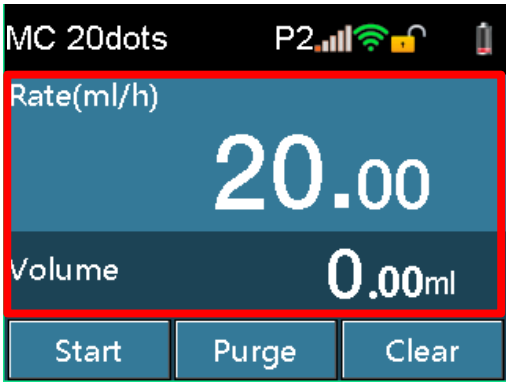
Battery volume and charging states: a full set of 4 bars, the more bars displayed, the larger battery volume.

WIFI signal

Display when connecting to workstation

Work data area: Displays infusion rate, infusion volume or different infusion work data according to different infusion mode. The work data could be adjusted by touching the specific zone in difference working mode.





Function key area: Touchscreen includes keys of [Start], [Purge], [Clear], [Stop]. Setting keys such as numbers and letters appear on corresponding interfaces.

- Keys

Except touchscreen keys, there are also 3 keys on the key panel: [HOME], [ON/OFF] and [OPEN]

- [HOME]: Main menu key. Before infusion, press [HOME] once to enter a setting menu, such as Infusion set, Local set, History and Interconnect set. To return to the infusion preparing interface, press [HOME] once again in any setting interface. During infusion, press [HOME] to switch to infusion interface, enlarge and display the infusion rate.
- [ON/OFF]: Switch on/off key. When the pump is off, press and hold [ON/OFF] for 1 second to switch it on. When the pump is on, press [ON/OFF] , and a prompt pops up: Are you sure to shut down? Press the key on the display to shut down or press and hold for 3 seconds to force shutdown.
- [OPEN]: Door open key. Press [OPEN] and the pump door open automatically, no matter the power is on or off. Push the door forward slightly till you feel the resistance, the door closes automatically.

6.2 Start up

CAUTION:

- Start up and then install the IV set.
  - Press [ON/OFF] to start up.
  - The self-test starts and start up interface appears.
  - After self-test finishes, it enters infusion preparing interface.
  - The screen displays patient information, infusion brand and occlusion level stored last time the device powered off.
  - If the self-test is abnormal, corresponding information will appear on information area.

Infusion preparation interface:

WARNING:

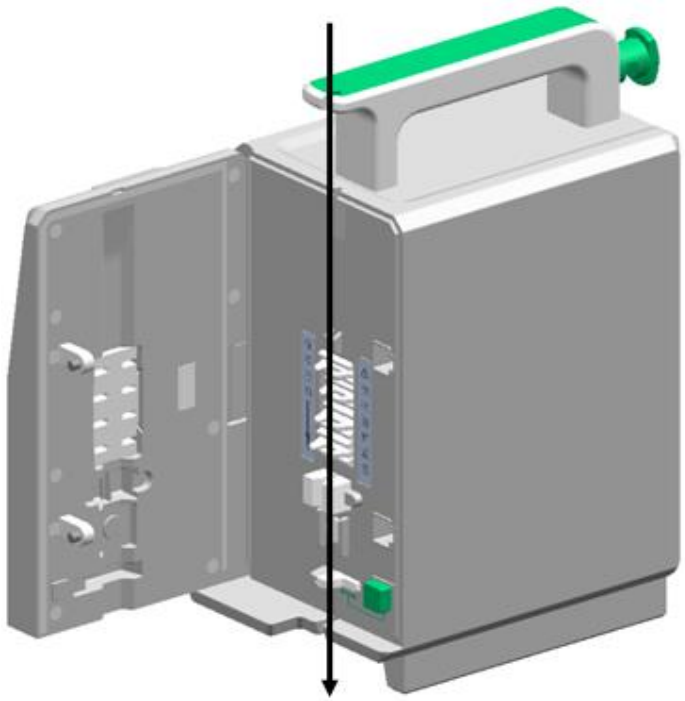
- After booting, check if the buzzer, alarm indicator are successfully self-checked and without error alarms (error alarms see chapter 8 Troubleshooting in this manual).
- Ensure the displayed IV set brand corresponds with the using IV set brand.
- If the IV set brand set is different from the using IV set brand, the infusion accuracy and alarm function cannot be guaranteed.
- Previous patient information will be cleared if [Yes] is selected on the New Patient screen.

6.3 IV set installation

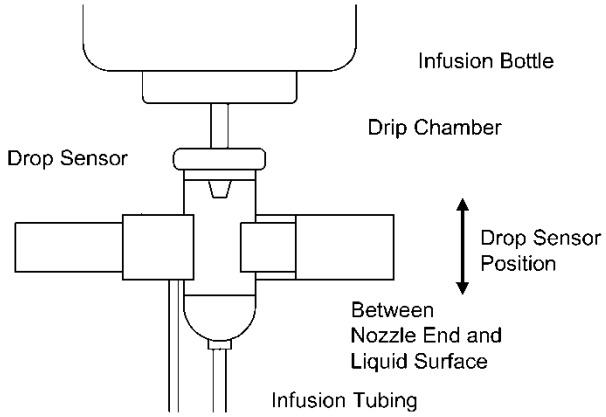
- Insert the needle into IV bottle vertically, and the liquid infuses into the drop chamber.
- When the liquid level is at 1/3 of the drop chamber, open the roller clamp.
- Infuse liquid into the tube to purge the air, and then close the roller clamp.
- Press [OPEN] to open the pump door.
- Press [Anti-Free-Flow Clamp] to open the anti-free-flow clamp, place the tube inside the clamp, and press the key again to clamp the tube.
- Place the tube inside the air bubble sensor and pressure sensor in sequence, then stretch the tube. Make sure the tube is inside both ends of the tube slit, and then push the pump door to close it.

CAUTION:

- The height range of the liquid container above the PATIENT and/or pump should be 20-80cm.
- Too loose or too tight tube may cause inaccurate infusion.
- The tube must be fixed into the air bubble sensor completely.



- Install the drop sensor



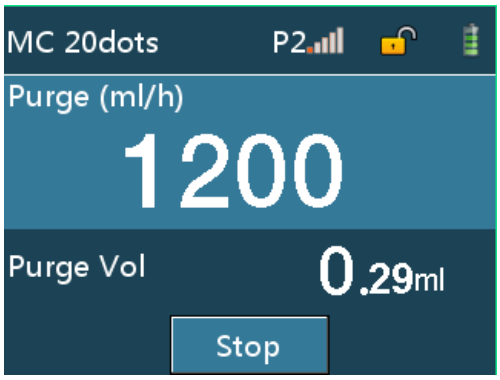
CAUTION:

- To ensure the accuracy of drop detection, the drop sensor should be installed as far as possible close to the down liquid level. The liquid level is approprite to be in the 1/3 of the drop champer.
- The liquid in the drip chamber should lower than drop sensor.
- Avoid inclining the drop sensor and exposing to direct sunlight during infusion.
- Do not clamp the drop sensor too tight.
- The drop sensor detects drip but not infusion volume. If liquid continuous drip in the chamber, being non-stop liquid flowing, the drop sensor cannot detect it.

6.4 Purge

WARNING:

- Before purging the IV line, ensure that the IV line is not connected to patients.
- Priming can be done only in non-infusion process.
- Ensure liquid has run out from the needle before stopping purging.
- Air bubble detection alarm function is closed during purge.
- Click [PURGE], then click [yes] on the pop-up interface, the infusion pump would purge quickly. Click [stop], the purge stops.



- The green indicator flashes when purging.
- Relationship between IV set specifications and purge rate, refer to the Table 6-1.

Table 6-1 Relationship between IV set specifications and purge rate

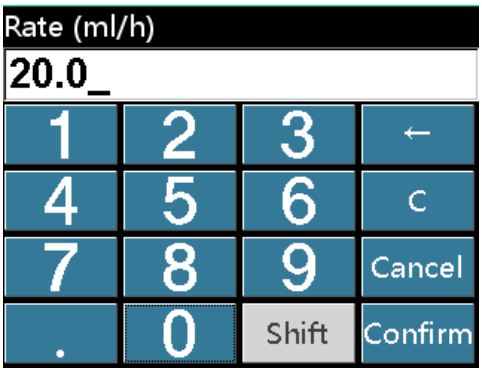
IV set specification (d/mL)	Purge rate (mL/h)
20	1200.0

CAUTION:

- When high viscosity IV fluids are infused through thin vein needle by bolus operation, occlusion alarm may occur. In such conditions, reduce the infusion speed to purge.
- Total volume cannot be cleared after infusion starts.
- The purging volume would not be account to total infusion volume.

6.5 Setting the infusion rate

- Click the rate area on the Touchscreen to enter the setting interface.



- Click [CLEAR] to clear the total volume.
- Relationship between IV set specifications and range, see Table 6-2. The minimum increment see Table 6-3.

Table 6-2 Relationship between IV set specifications and range

IV set specification (d/mL)	Setting range (mL/h)
20	0.1-1200.0

Table 6-3 Relationship between rate range and the minimum increment

Rate range (ml/h)	Minimum increment (ml/h)
0.10 - 99.99	0.01
100 - 999.9	0.1
1000 - 1200	1

CAUTION:

- If the flow rate is changed in the infusion process, the infusion will be done at the new flow rate.

6.6 Puncture

Insert the vein infusion needle into the patient's vein.

6.7 Starting Infusion

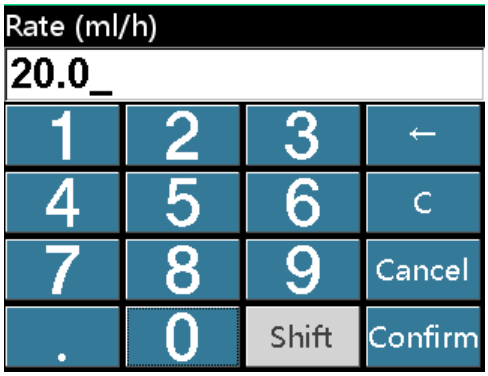
Click [START], start infusion at the setting rate and green indicator flashes.

CAUTION:

- Infusion can only start when the recipe value equals to the set value.
- If no operation is performed after IV set installation for more than 2 minutes, START-REMINDER alarm sounds.

6.8 Change rate during infusion

- Click the rate display area on the screen, enter and change the rate on the pop-up interface.



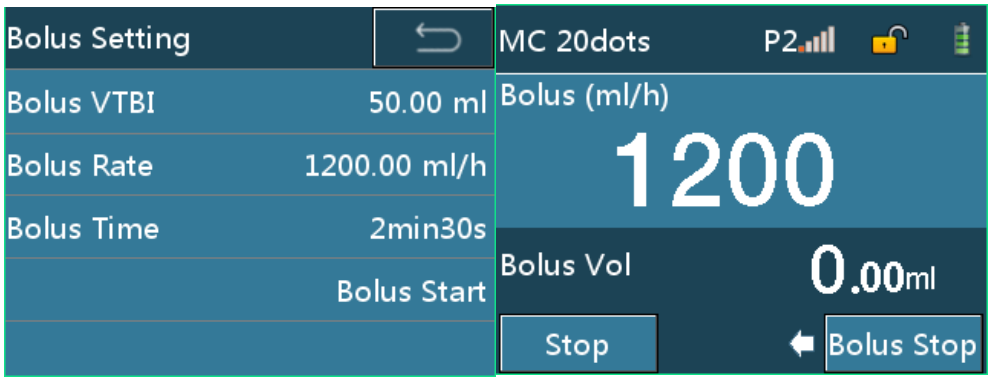
- After entering the rate, if click [Cancel], it will return to original infusion interface without change; Click [Confirm], it will return to original infusion interface and operates at the new rate.

CAUTION:

- If no operation is performed in reference and setting rate interfaces for more than 10 seconds, it will return to infusion interface automatically.

6.9 Bolus

- During infusion, press [Bolus] to enter the bolus setting interface. Set any two parameters among the Bolus VTBI, Bolus Rate and Bolus Time. Click [BolusStart] to enter bolus interface or click [BolusStop] to stop bolus as below pictures.



Bolus rates are different depending on the IV set specification as follows.

Table 6-4 Relationship between IV set specification and flow rate

IV set specification (d/ml)	**Bolus rate(ml/h)**	**The minimum bolus volume(ml)**	**The maximum bolus volume(ml)**
20	0.1-1200.0	0.1	50.0

CAUTION:

- Current bolus volume is displayed when bolus is running.
- Bolus volume will be accumulated into the total volume.

6.10 Stopping Infusion

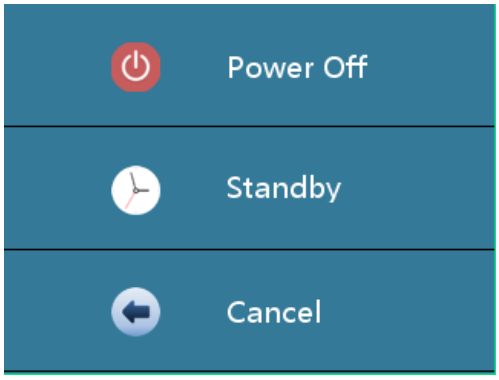
In the infusion process or after infusion, press the [STOP] key to stop the operation and green indicator will be off.

6.11 Replacing or adjusting IV set

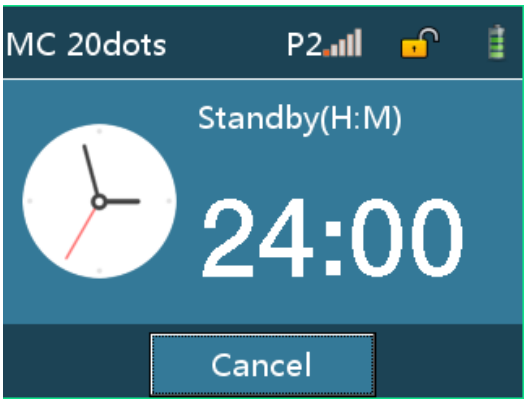
An extrusion damage of tube in continuous infusion of the IV set would affect the infusion precision. After about 8-hour or regulated hour continuous infusion of the IV set, the infusion should be stopped, open the pump door, and move the IV tube about 10 cm from the original position, so that the IV tube functions better. Changing the whole IV set is better solution.

6.12 Turning the Power Off

- Press the [ON/OFF] key, choose Power Off, Standby or Cancel.



- Click [Power Off] to shutdown.
- Click [Standby] to enter standby interface, the standby time can be modify.



- Click [Cancel] to return to previous interface.

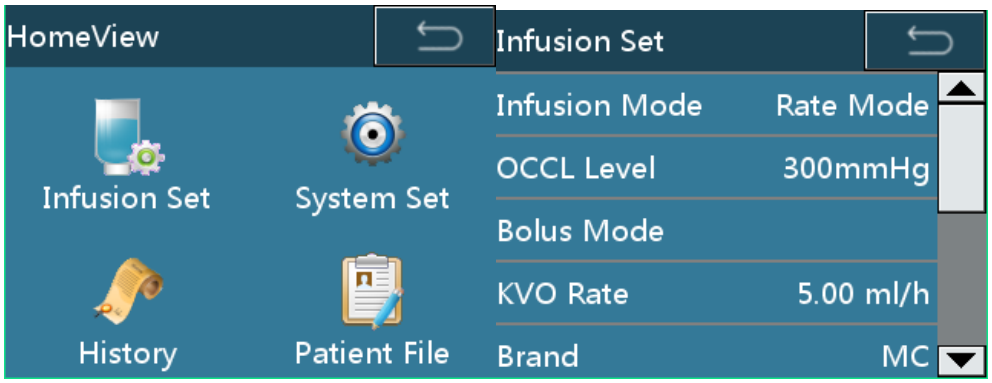
7 Setting the Infusion Pump

CAUTION:

- After shutting down the pump, all parameter settings will be automatically saved.
- Parts of parameters will not be saved in force shutdown.

7.1 Infusion setting

Press [HOME] key to enter the setting interface, click [Infusion Set] to enter the detailed infusion setting interface.



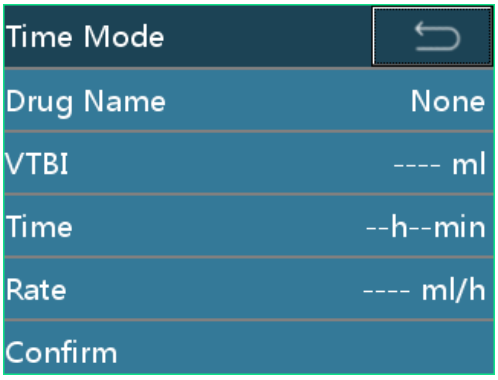
7.1.1 Infusion mode

- **5** infusion modes: Rate, Time, Body Weight, Sequence, Drip mode are available.
  - Rate mode

Under the Rate Mode, set the drug name, rate and VTBI, click [Confirm] to operate.

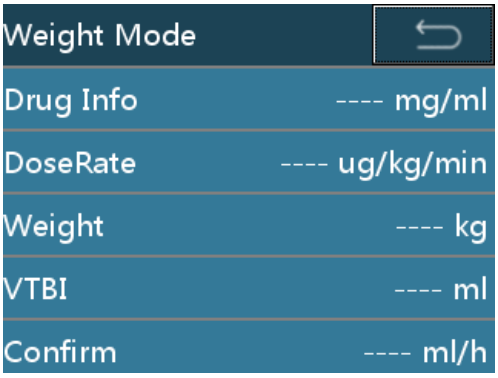
  - Time mode

Under the Time Mode, set the drug name, VTBI and Time, click [Confirm] to operate.



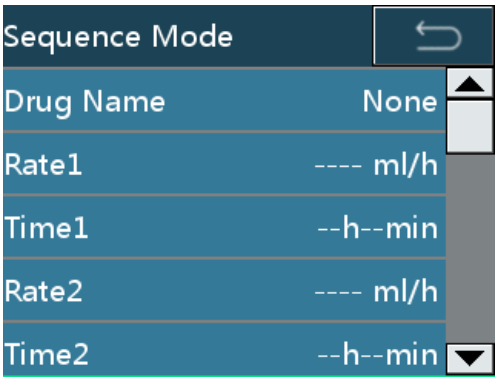
- BodyWeight mode

Under the Body Weight mode, set the **concentration**, VTBI, doserate and body weight, automatically calculate the rate, and then click [Confirm] to operate..



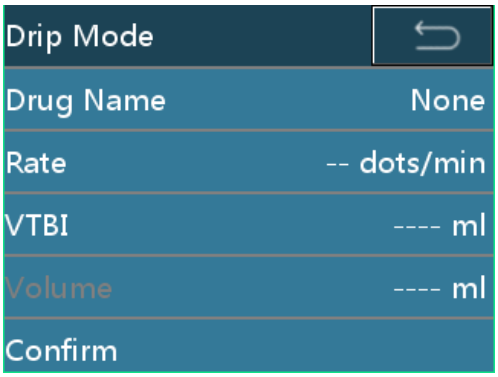
- Sequence Mode

Under the Sequence Mode, set the drug name, 10 sequence rate and time, click [Confirm] to operate in sequence.



- Drip Mode

Under the Drip Mode, set the rate and VTBI, click [Confirm] to operate in sequence.



CAUTION:

- According to the setting drop rate (dots/min) and current selected IV set (20d/ml), the infusion pump transfers drop rate (dots/min) to corresponding rate(ml/h) and controls the flow rate.
- Under the drip mode, the infusion pump controls flow rate (ml/h), not drip (dots/ml).

7.1.2Occlusion Level

3levels of occlusion are available (Factory setting is level 2).

Table 7-1 Relations between occlusion level and pressure

Occlusion level	Display	Pressure (mmHg)	Pressure (Kpa)	Pressure (bar)	Pressure (psi)
1	P 1	300	40	0.4	5.8
2	P 2	550	73	0.7	10.6
3	P 3	900	120	1.2	17.4

CAUTION:

- To prevent inputting extra amount of pills to patient after removing the occlusion alarm, the motor would automatically reverse and release the tubing pressure (Anti-Bolus) during the occlusion alarm.
- When you infuse viscous solution with the Occlusion Level setting of 1 and the tubing is clear, occlusion alarm tends to be issued. Carefully watch the  on the upper information area, and change the occlusion level if above 2 bars appear.
- When you operate the pump with the Occlusion Level setting of 3, the in-line pressure builds up substantially until Occlusion alarm is issued. Always make sure that the IV line is securely connected to the infusion.
- When a quick operation of infusing high viscosity fluid through fine vein needle occurs, occlusion alarm tends to be issued. When this happens, increase the occlusion level

or slowdown the infusion rate.

7.1.3KVO Rate

- The adjustable range of KVO is 0.1 - 5ml/h（stepping 0.01ml/h）,default 1ml/h;

7.1.4Brand

- You can choose the consumable brand by: [Home] -> [Infusion Set] -> [Brand]
- Several brands of 20d/mL IV set have been preset and customized. Users can select corresponding IV set brand according to clinical use.

⚠WARNING:

- The infusion pump must be used with the IV sets recommended by manufacturer.
- To add other brands of IV set, contact distributor or manufacturer. Setting and testing the new IV set by professionals to ensure the infusion accuracy and alarm function.

7.1.5Drip Detection

- Turn on the drip detection button, check the drop sensor and detect the drip during infusion,

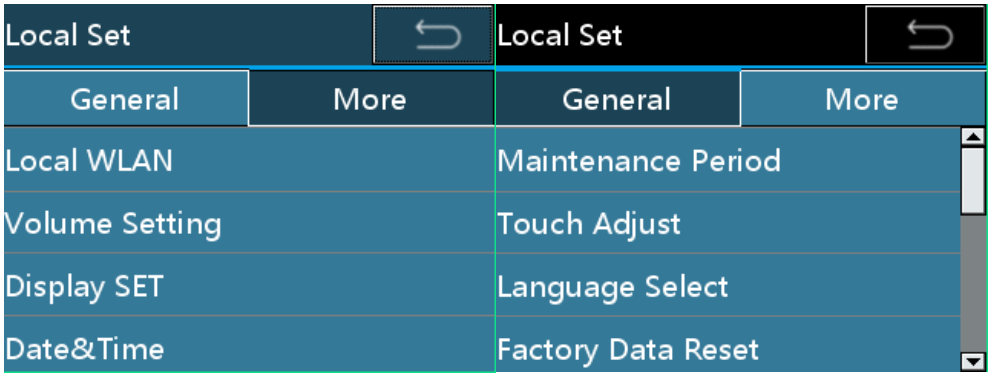
CAUTION:

- Turn on the drip detection button without connecting drop sensor will cause NO Drop Sensor alarm.

7.1.6NearEnd

- Near End alarm: by default 3 minutes before infusion finishing. The adjustable range is 1 - 30min（stepping1min）.

7.2 System Set



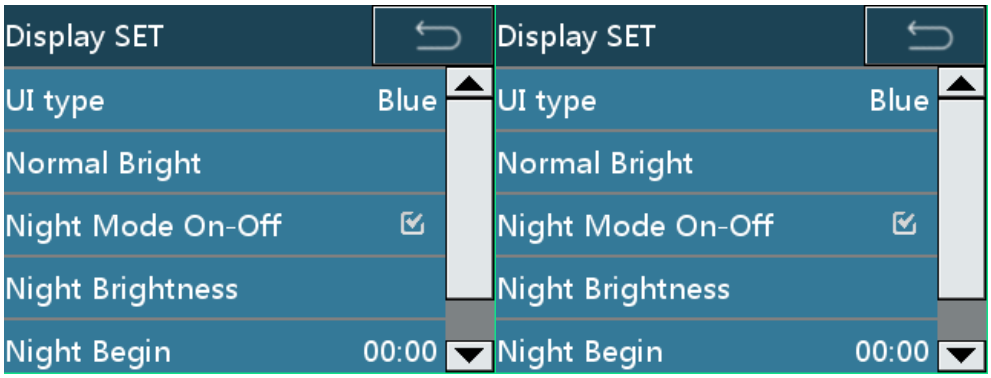
7.2.1Volume Setting

- **11** volume levels are available (The factory setting is level 5).

CAUTION:

- Do not set an alarm volume that is lower than the environment noise, or it may cause the alarm system to be out of work or the alarm cannot be correctly recognized timely.
- If setting alarm to extreme values that can render the alarm system useless. Check the alarm limited according to clinical condition.

7.2.2Display SET



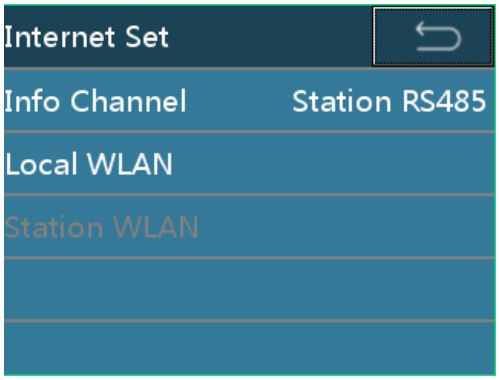
- Brightness and parameters of night mode can be set.
- 7 colors of the interface are available. Set [Night Brightness] and other parameters of night mode.

CAUTION:

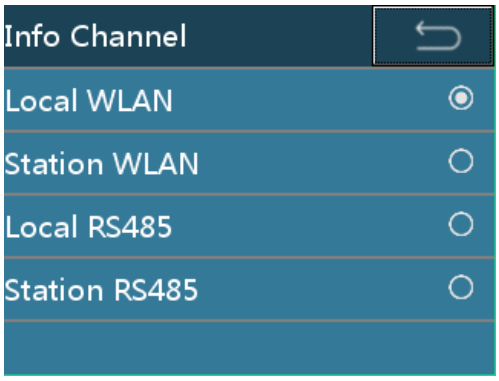
- Under the night mode, setting range of start time is 17：00-19:00，the range of finish time is the same as that of start time. By default, the start time is 0:00, finish time is 0:00.

7.2.3Internet Set

- [Info Channel], [Local WLAN], and [Workstation WLAN] (not available if the pump is not connected to a workstation) could be chose and set.



- Click [Info Channel] to choose the channel type.
  - Choose [Local WLAN] to use local WLAN channel to connect to the network, and the local WLAN parameters could be set.
  - Choose [Station WLAN] to use station WLAN channel to connect to the network, and the station WLAN parameters could be set.
  - Choose [Local RS485] to use local RS485 cable to connect to the network.
  - Choose [Station RS485] to use station RS485 cable to connect to the network.

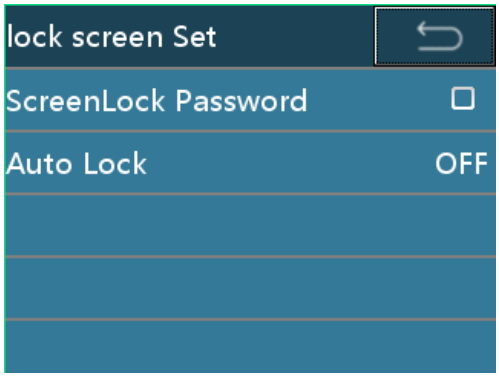


CAUTION:

- The setting of local port should be operated by professionals specified by manufacturer. Contact distributor or manufacturer.
- Only the accessory or devices supplied or specified by manufacturer allowed to be connected with the pump. Otherwise it may cause the pump not work normally or other unpredictable hazards.
- Click [Local WLAN]/[Station WLAN] to set up WLAN parameters.
- Configurate the WLAN and open it, input parameters like AP name, password and local IP. Exit and tip of “Config taking effect” appears in the interface and disappear after configurate successfully.

7.2.4Lock screen Set

- Click [ScreenLock Password] to enable/disable the screen lock password function. When the function is enable, a password is required to unlock the screen. When the function is disable, there will be no require on password to unlock the screen.
- Click [Auto Lock] to lock the screen. The Lock time can be OFF, 15s, 30s, 1min, 2min, 5min, 10min, 30min. OFF means to turn off the function by default.



7.2.5Collection Set

- [Mode Collection]: configurate with frequency-used infusion modes. After configuration, only the selected frequency-used infusion modes will be displayed in the 7.1.1 [Infusion Mode] page
- [Brand Collection]: configurate with frequency-used brands. After configuration, configuration, only the selected frequency-used brands will be displayed in the 7.1.4 [Brand] page.

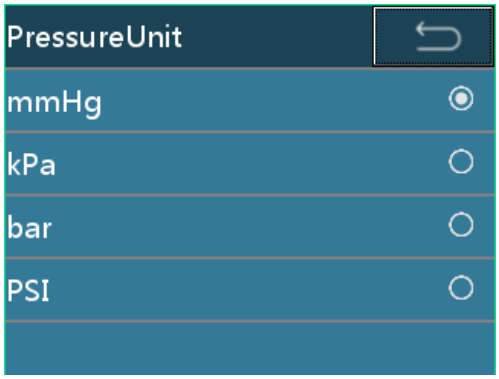
7.2.6Linkage mode

- If the linkage mode is turned on, press the anti-free flow clamp button to open the clamp, and release the button to clamp the tube.

7.2.7PressureUnit

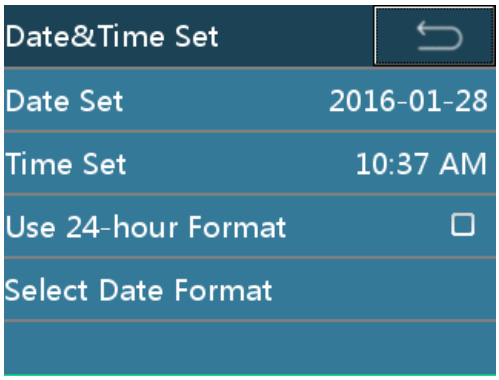
- Choose the measurement unit for the pressure. The optional units are: mmHg, kPa,

bar and PSI. The default setting is mmHg.



7.2.8Date&Time set

- Set the date, time, and their format.



7.2.9Maintenance

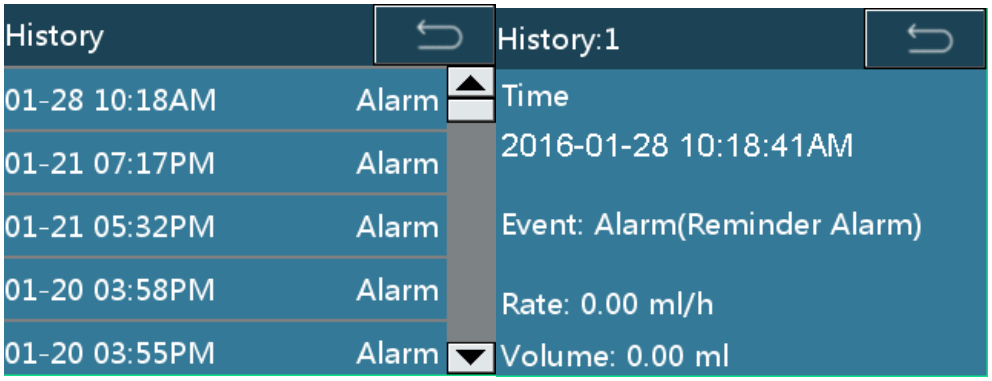
- In the [Maintenance], users can operate items like Language Select, Touch Adjust, Factory Data Reset and check the Version Info.
  - [Homepage] ->【Local Set】->【Maintenance】->【Version Info】. Review versions of system in [Version Info] interface.

7.3 History

The history records are as Table 7-2.

Table 7-2 History records

Event	Record Parameters
Start up	Occurred time
Shutdown	Occurred time
Standby	Occurred time, standby set time
Start	Occurred time, rate, VTBI
Bolus	Occurred time, Bolus rate, Bolus way
Bolus stop	Occurred time, Bolus rate, Bolus accumulated volume
Stop	Occurred time, rate, accumulated volume
KVO	Occurred time, accumulated volume, KVO rate
KVO stop	Occurred time, KVO rate, KVO accumulated volume
Flow rate change	Occurred time, Flow rate before and after change
Alarm	Occurred time, alarm event, system trouble with trouble code
Purge	Occurred time, purge rate, accumulated volume
Purge stop	Occurred time, purge rate, purge accumulated volume

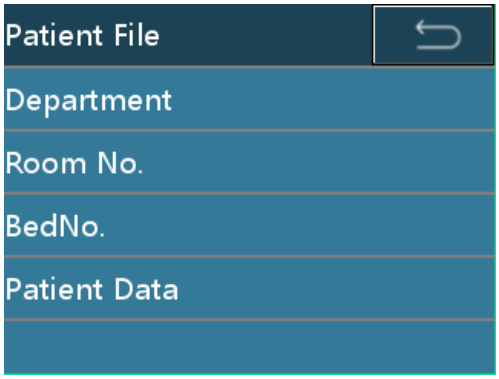


CAUTION:

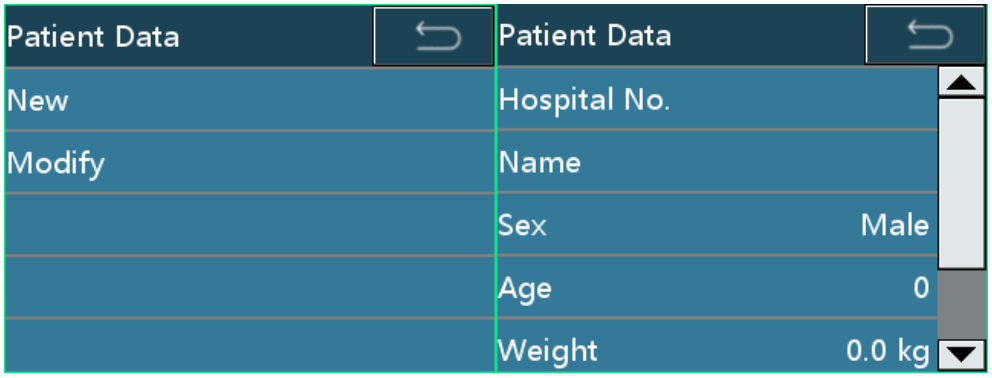
- The history records could be saved when power is cut.
- 2000 history records are available to be stored at maximum. If the amount reaches storage limit, the earliest record would be removed.
- Alarm system can't be powered off separately by operator unless the pump is powered off. The time of powering off is captured in the history records.

7.4 Patient File

- Click [Patient File] to enter the patient file page. The [Department], [Room No.], [Bed No.] and [Patient Data] could be set up.



- Click [Patient Data] option to enter patient data setting page. Choose [New] to build a new patient data and the previous patient data will be cleared automatically. Choose [Modify] to modify the current patient data.



CAUTION:

- If the pump is inserted to a working station, once the patient file on the pump is changed, the data on the station will be synchronized at the same time.

7.5 Use Internal battery

- If there is not any AC/DC power supply, the internal battery operates.
- When external battery stops working, the internal battery starts and the yellow indicator lights with a short alarm sound.
- Before first use or reuse before a long time, please charge at least 10 hours.
- The approx. remaining power in the built-in battery is displayed by [battery] indicators. During battery operation, battery discharged is shown by a decreasing number of active indicators. For details, see Table 7-3.

Table 7-3when battery works, the [Battery capacity] diagram state

[Battery capacity]state	The remaining capacity*1)
Four bars light	Operation will be possible for 300 minutes.
Three bars light	Operation will be possible for 210 minutes.
Two bars light	Operation will be possible for 140 minutes.
One bars light(green)	Operation will be possible for 70 minutes.
One bars light(red)	Operation will be possible for 30 minutes.

***1)** Working conditions:

- New battery (within one year of manufacture).
- Operating at 25mL/h using a 20d/ mL infusion. Close WIFI function.
- Room temperature of 25°C.

- When the infusion pump is connected to any external AC or DC power supply, the charge of the built-in battery starts. When battery is charging, a lightning symbol will be displayed at the left side of the battery symbol on the screen.

CAUTION:

- Once be connected to external supply power, the battery would be charged.
- Use AC power to charge the battery. if recharged by an external 12 V DC power supply, the battery cannot be fully charged (50% at most).
- During infusion and the pump powered by battery, if a low-battery alarm occurs, press [SILENCE] to silence the alarm, the alarm will repeat in two minutes, connect the pump to AC/DC power supply immediately. If battery empty alarm occurs, the silence does not function and infusion will stop.
- The infusion pump would shutdown automatically 3 minutes before battery drains.
- To infuse at the rate of 1200ml/h with a new battery fully charged, the battery can be continually used for2h42min.
- The actual battery duration may be different and affected by the ambient temperature，flow rate, external communication, etc.
- If the battery is aging, the actual battery duration may be shorter. Periodically check the battery.

7.6 Connecting to the <Infusion Central Monitoring System>(optional)

Infusion pumps can be connected to the < Infusion Central Monitoring System >, which can obtain working states of pumps remotely.

Caution：

- Infusion pump cannot be operated through the < Infusion Central Monitoring System >.

7.7 Nurse pager (optional)

After infusion pump is connected to the central station, patient can press nurse pager in bed, and then the central station in nurse station would gives out sound tip and display patient's information in screen, so that the nurse can take care of the patient in time.

7.8 Voice communication(optional)

After infusion pump is connected to the central station, patient can press nurse pager in bed, and then the central station in nurse station would gives out sound tip. Nurse can press the talk-listen button and communicate with patient in real time to know the information.

7.9 Connecting a barcode scanner (optional)

After a barcode scanner is connected to the pump, the patient information, such as record No. and hospital No., can be scanned, and the patient information in the pump will update automatically by pump prompts. The barcode scanner can scan maximum 18 figures.

7.10 User-specific Requirements (optional)

7.10.1 Maximum Flow rate

Parameters the maximum flow rate is already set with the infusion pump. For any modification, contact your local distributor.

8 Troubleshooting

8.1 Alarm

The infusion pump provides users with a variety of status information about itself and its injection process. If any abnormality is detected, the infusion pump sounds an alarm and notes users in the form of sound, light, and character.

All the alarms on this pump are the technical type alarm.

Considering the importance of abnormal information, alarm information is classified into three levels from the viewpoint of security: low-level, mid-level, and high-level alarms. For audio and visual expressions of alarms at three levels, see Table 8-1. The alarm volume ranges from 45 dB to 85 dB.

Table 8-1 Alarm severity and the audio and visual expressions of each level

Alarm	Sound	Light
Low-level alarm	Give out three beeps at intervals of 25 seconds.	The yellow indicator keeps on.
Mid-level alarm	Give out three beeps at intervals of 15 seconds.	The yellow indicator flashing.
High-level alarm	Give out a series of beeps at intervals of 15 seconds.	The red indicator flashing.

When an alarm occurs, press [SILENCE] to silence the alarm. But the buzzer beeps again if you do not eliminate the mid/high-level alarm within 2 minutes.

CAUTION:

- The setting of the alarm will be saved when the power is cut. When the pump restarts from a power failure situation, the alarm setting will be reloaded to the system and remains the same as it was before the power failure.

WARNING:

- Potential hazard can exist if different ALARM PRE-SETS are used for the same or similar equipment in any single area.

8.2 Faults and Troubleshooting

Table 8-2 Alarm symptom, alarm level, fault cause, and troubleshooting

Alarm Symptoms	Alarm level	Causes	Troubleshooting
No Power Supply	Low-level	No external AC/DC power supply is connected.	Immediately connect the AC power supply or the external DC power supply.
No Battery	Mid-level	The infusion pump has no internal battery or the internal battery operates abnormally.	Replace the internal battery.
Low Battery	Mid-level	The internal battery is running critically low.	Immediately connect an AC power supply or an external DC power supply.
Battery out	High-level	The battery is out.	Immediately connect an AC power supply or an external DC power supply.
Near End	Low-level	It takes less than three minutes to complete the infusion.	Press [SILENCE] to stop the buzzing and wait until the infusion finishes.
Occlusion Alarm	High-level	The infusion tubeis fallen off.	Press [STOP] to stop the infusion to stop alarm. Check the infusion tube.
Air-bubble	High-level	1. Air bubble in the infusion line. 2. The flatten tube is fixed inside the air bubble detector.	Press [PURGE] to release air bubble quickly.
Infusion End	High-level	The limit amount or the infusion time is complete	Press [STOP] to stop infusion.
Reminder Alarm	Low-level	Forget to operate the alarm (no key operation is made two minutes after the IV set is installed).	Press any key to clear the alarm.
Drop Error	High-level	During infusion, the dripsare detected	Press [Stop] to remove the alarm. Check the drop

Alarm Symptoms	Alarm level	Causes	Troubleshooting
		abnormal.	sensor installation.
No Drop Sensor	Mid-level	During infusion, the drip detection function is turned on without drop sensor.	Install the drop sensor or stop infusion and turn off the drip detection function.
No Drop	High-level	During infusion, the drop sensor cannot check the drips.	Press [Stop] to remove the alarm. Check the drop sensor installation and infusion tubing.
Standby End	Mid-level	The standby time is up.	Press [Cancel] to exit.

8.3 Troubles and trouble shooting

When the device goes wrong, a corresponding trouble code appears in the interface and gives out high-level alarm.

Table 8-3 troubles and troubleshooting

Trouble code	Alarm level	Troubleshooting
Sensor Error	High-level	Record the trouble code and turn off, contact manufacturer or manufacturer's representatives
Motor Error	High-level	
Circuitry Error	High-level	
Diver COM Error	High-level	
Pump finger error	High-level	
Pump door error	High-level	
Bubble sensor error	High-level	
System Error	High-level	

9 Maintenance

9.1 Cleaning, Sterilizing

- Before cleaning the pump，be sure to turn off the power and disconnect the AC or DC power cables.
- If there is dirt on the pump，wipe it with wet soft cloth dampened with cold or lukewarm water.
- Use a piece of dry soft cloth to clean the AC power supply socket, USB socket or the nurse call socket，ensure that the socket is dry before using it.
- Do not use organic solvent such as alcohol or thinner.
- If disinfection is necessary，using the common disinfectors such as Chlorhexidine gluconate and Benzalkonium chloride. After using the agent with a soft cloth，wipe off it with a soft cloth dampened with water or warm water. When using the disinfecting agent，follow the caution of each agent.
- The infusion pump cannot be autoclaved.
- Never use a dryer or similar device to dry the infusion pump.
- If liquid spills onto the pump, check whether the pump still functions normally. Test the insulation and leakage current when necessary.
- Do not soak the infusion pump into water.

⚠WARNING:

- Do not clean or sterilize the pump when it is running.

9.2 Periodic Maintenance

Perform a periodic maintenance inspection to ensure safe operation and the longest possible life of the infusion pump，and check the infusion pump once every six months. Contact manufacturer or manufacturer’s representatives for any doubt.

9.2.1Checking the Appearance

- Appearance checking: There are no cracks and damages.
- Key operations: If the keys are pressed smoothly, they are available.

9.2.2Checking the Power Cable

- Check the appearance of the power cable. If the appearance is damaged and the plug and the socket are in poor contact, contact manufacturer or manufacturer’s

representatives for replacement in time.

- If you connect the infusion pump to the AC/DC power and there is no indication of powering on, contact manufacturer or manufacturer's representative for maintenance in time.

9.2.3Checking the infusion rate

- Check the infusion flow once every 6 months by the graduate and timer.

Checking condition:

IV set	Infusion rate	Infusion time	Volume in graduate
MC/B.Braun20d/mL	120mL/h	6min	11.5-12.5mL

9.2.4Alarm

- Occlusion alarm

Checking condition:

IV set	Infusion rate	Occlusion level	Alarm time
MC/B.Braun20d/mL	120mL/h	P5	Within 1 minute

- Air bubble alarm

Add in 3-5mm air in the upper infusion tube then start the infusion. When the air bubble reaches to air bubble sensor, check the displayed alarm information and sound.

9.2.5Electric and mechanical safety

To ensure safety, test the insulation voltage, leakage current, and earthling resistance according to the IEC 60601-1.

9.2.6Checking the Internal Battery

Perform the following inspections on the battery every 6 months:

- Connect to the AC power supply to recharge the battery for over 10 hours.
- Turn on the power.
- Set the infusion rate to 25 mL/h and start the infusion. Record the start time.
- Operate the system until it stops infusing due to low battery alarm. Record the finish time.
  - If the time from the start of the infusing to end of operation is 4 hours or more, the battery condition is good.
  - If the time from the start of the infusing to end of operation is 1 to 1.5 hours, the battery condition is reaching its service life.

- If the time from the start of the infusing to end of operation is less than 1 hour, the battery has reached its service life. Replace the battery. You are advised tocontact manufacturer or manufacturer's representative to replace the battery.

- When the battery lever check is complete, recharge the battery for next use.

9.2.7Replacing the Battery

- **Remove the internal battery.**
  - Turn the power off and disconnect the power cord.
  - Use a screwdriver to loosen the battery cover fixing screws at the bottom of the pump.
  - Remove the battery cover.
  - Disconnect the battery cable connector.
  - Remove the battery.
- **Install the internal battery.**
  - Insert the connector of the battery cable into the battery.
  - Insert the new battery into the battery compartment.
  - Attach the battery cover.
  - Use a screwdriver to tighten the screws securing the battery cover.

CAUTION:

- Remove the battery if the infusion pump is not likely to be used for some time.

WARNING:

- The battery must be replaced by trained professional, or it may cause risk.
- Please strictly install the matched battery provided by manufacturer following the replacing method of internal battery, or it may cause risk.
- Do not disassembly the battery, make it short out or throw to the fire, or it may cause injury by leakage or explosion.
- Dispose the waste battery comply with relevant laws and regulations.

9.3 Maintenance

- If any trouble，explain the situation to your local the manufacturer or manufacturer's representative and request for a repair.
- Never disassemble or try to repair the infusion pump or it may cause a serious failure. The manufacturer and the distributor shall not be responsible for any infusion pump that has been disassembled，modified or used for any purpose other than that for

which it is intended.

- If the infusion pump is dropped or subjected to impact，remove it from service even if it doesn't appear damaged externally. Request the manufacturer or manufacturer's representative to inspect it for a possible internal problem.

CAUTION:

- Serviceman could request for the related service manual from the manufacturer if needed.

Warning：

- The accessories replacement should be operated by professionals, or it will cause damage.
- Parts of the Pump are not serviced or maintained while in use with the patient.

9.4 Storage

- Avoid water spills.
- Never store in a hot and humid place.
- Store the pump out of excessive vibration，dust，and corrosive gas.
- Store the pump out of direct sunlight and ultraviolet ray as discoloration may result.

9.5 Transportation

You can deliver the infusion pump by using a common vehicle, but you must protect the infusion pump from being clashed, shook, or wetted by the rain and snow during the transportation. You must deliver the infusion pump in accordance with the method specified in the order contract.

9.6 Environmental Protection and Recovery

At the end of life，please contact the manufacturer or manufacturer's representative for dispose advise, or dispose by a suitable method according to the applicable environmental laws and regulations.

10 Infusion Accuracy Characteristics

The following test is performed in accordance with the IEC60601-2-24:2012 standard. It is used to observe the infusion accuracy and the occlusion response. (For detailed test conditions, see the IEC60601-2-24:2012 standard.)

CAUTION:

- The infusion accuracy and the occlusion response may be affected by the use conditions including the pressure, temperature, humidity, IV set, and infusion tube.
- The infusion accuracy does not reflect the clinical standards, for example, patients' age and weight and medicine taken.
- The data below only represents measured data in laboratory.
- The data below is the continuous 8-hour experiment data in laboratory. To ensure the infusion precision, it is recommended that the infusion tube be changed or moved every 8 hours.
- Under the single fault condition, the maximum infusion precision error maybe up to ±40%.

10.1 Flow Rate Characteristics

Start-up and Trumpet curves show the characteristics of the infusion pump after the injection begins and the injection changing status after the infusion pump reaches a normal flow rate.

The following test method is accordance with the method mentioned in chapter 201.12.1.102 of the standard IEC 60601-2-24:2012 (Please check above chapter for further details.).

- Accuracy test conditions:

  Temperature: 21℃;

  Relative humidity: 65%;

  Infusion type:MC（20d/mL）、（B.Braun 20d/mL）: for each.

  Infusion pump: 1 set

  Sampling interval: 0.5min

  Test Period: 120min

  Test Liquid: ISO 3696:1987 Class III water

Infusion Accuracy Characteristics

■ Table 10-1 Accuracy test result

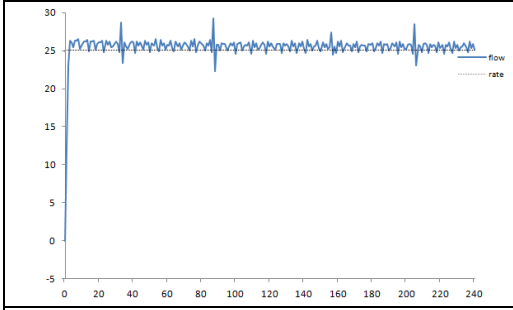
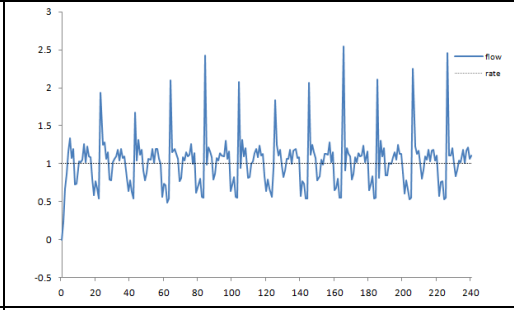
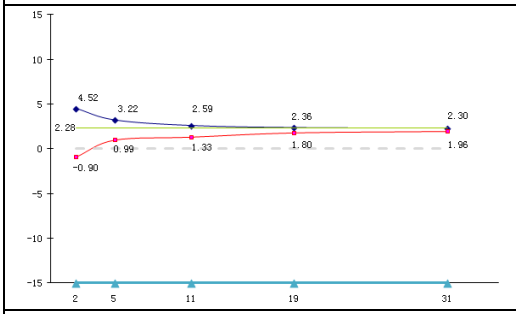
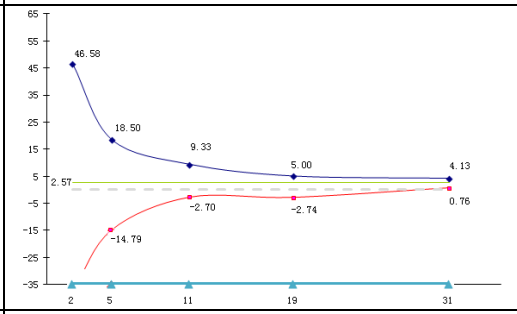
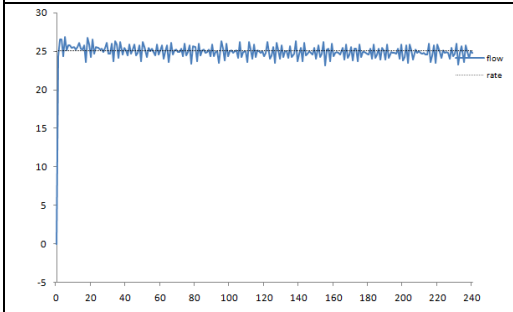
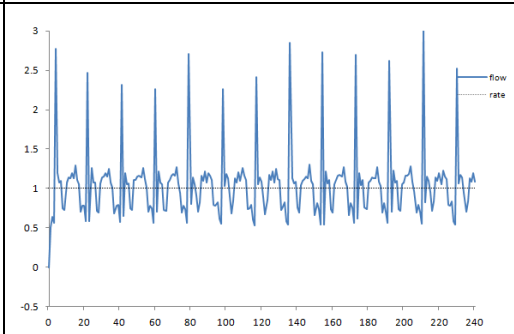
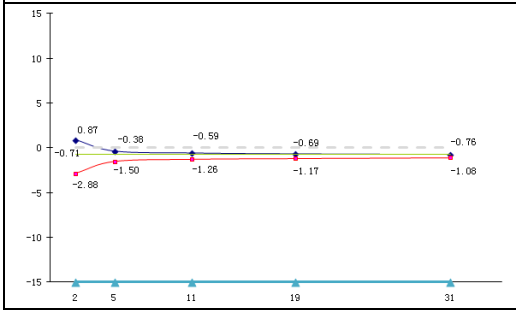
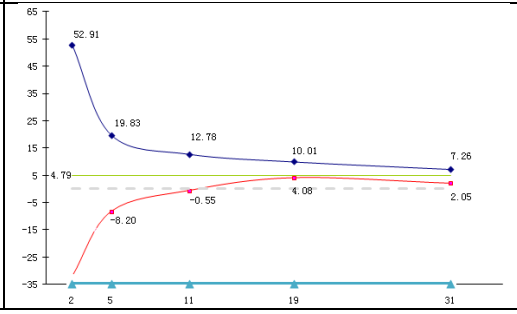
B.Braun 20d/mL	4.57	Minimum rate 1ml/h，normal condition
	0.49	Intermediate rate 25ml/h，normal condition
	0.56	Intermediate rate 25ml/h，with +13.3kpabackpressure
	1.44	Intermediate rate 25ml/h，with -13.3kpabackpressure
	-4.88	Intermediate rate 25ml/h，when the supply container below the pump mechanism at a distance of 0.5m
Medcaptain 20d/mL	-0.94	Minimum rate 1ml/h，normal condition
	1.26	Intermediate rate 25ml/h，normal condition
	-0.18	Intermediate rate 25ml/h，with +13.3kpa back pressure
	-0.57	Intermediate rate 25ml/h，with -13.3kpabackpressure
	-10.07	Intermediate rate 25ml/h，when the supply container below the pump mechanism at a distance of 0.5m

CAUTION:

- The accuracy maybe up to -10.07% when the supply container below the pump mechanism at a distance of0.5m.
- To ensure the infusion accuracy, strongly recommend that the supply container is higher than the pump mechanism.

Infusion Accuracy Characteristics

■ Table 10-2 Accuracy test result

Start-up curves of MC 25mL/h	Start-up curves ofMC 1mL/h
	
Trumpet curve of MC 25mL/h	**Trumpet curve of MC 1mL/h**
	
Start-up curves of B.Braun 25mL/h	**Start-up curves ofB.Braun 1mL/h**
	
Trumpet curve of B.Braun 25mL/h	**Trumpet curve of B.Braun 1mL/h**
	

10.2 Occlusion Characteristics

The occlusion characteristics are reflected by the longest delay time to start an alarm.

The following test method is accordance with the method mentioned in chapter 201.12.4.4.104 of the standard IEC 60601-2-24:2012 (Please check above chapter for further details.).

Occlusion test conditions:

Temperature: 21℃;

Relative humidity: 65%;

IV set：1 set of B.Braun （20d/mL）

Length of the infusion tube: 1m

Table 10-3 The occlusion level, alarm delay time and pill amount under the rate of 25mL/h

Infusion rate	**Occlusion pressure level**	**Occlusion pressure （mmHg）**	**Occlusion alarm time （hh:mm:ss）**	**Bolus (ml)**
25mL/h	I	300±100	00:01:20	0.19
	III	900±200	00:04:05	0.49

Table 10-4 The occlusion level and alarm delay time under the rate of 0.1mL/h

Infusion rate	**Occlusion pressure level**	**Occlusion pressure （mmHg）**	**Occlusion alarm time （hh:mm:ss）**
1mL/h	I	300±100	00:16:00
	III	900±200	00:42:00

Table 10-5 The occlusion level and alarm delay time under the rate of 0.1mL/h

Infusion rate	**Occlusion pressure level**	**Occlusion pressure （mmHg）**	**Occlusion alarm time （hh:mm:ss）**
0.1mL/h	I	300±100	01:07:00
	III	900±200	10:26:00

CAUTION:

Unit conversion list

Description	Unit	Unit conversion
Pressure	kPa	1kPa=7.5mmHg
	psi	1psi=51.724mmHg
	bar	1bar=750mmHg

Appendix A

Appendix A Electron Magnetic Compatibility (EMC)

The SYS-6010 infusion pump conforms to EMC standard EN 60601-1-2.

Guidance and manufacturer's declaration – electromagnetic emissions		
The SYS-6010 infusion pump should be used under the regulation electromagnet environment. The user should operate the SYS-6010 infusion pump under following electromagnet environment.		
Emission measurement	conformance	Electromagnet environment-instructions
Radio-frequency emission CISPR 11	Group 1	SYS-6010 infusion pump only use radio-frequency while operating its internal functions, therefore, the radio-frequency is much low and has little interference to the electronic devices nearby.
Radio-frequency emission CISPR 11	Class A	The SYS-6010 infusion pump can be used in any building including civil residence.
Harmonic emission IEC61000-3-2	Class A	
Voltage fluctuation and flashing IEC 61000-3-3	conform	

Appendix A

Guidance and manufacturer's declaration – electromagnetic immunity			
The [SYS-6010] is intended for use in the electromagnetic environment specified below. The customer or the user of the [SYS-6010] should assure that it is used in such an environment.			
IMMUNITY test	IEC60601test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient (EFT) IEC61000-4-4	±2 kV power cable ±1 kV I/O cable	±2 kV power cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV difference mode ±2 kV common mode	±1 kV difference mode ±2 kV common mode	
The voltage dropping, short interruption and voltage change IEC 61000-4-11	< 5% U_T (dropping > 95% U_T) 0.5 period 40% U_T (dropping 60% U_T) 5 period 70% U_T (dropping 30% U_T) 25 period < 5% U_T (dropping > 95% U_T) 5seconds	< 5% U_T(dropping > 95% U_T) 0.5 period 40% U_T(dropping 60% U_T) 5 period 70% U_T (dropping 30% U_T) 25 period < 5% U_T(dropping > 95% U_T) 5seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [SYS-6010] requires continued operation during power mains interruptions, it is recommended that the [SYS-6010] be powered from an uninterruptible power supply or a battery..
Power	3 A/m	3 A/m	Power frequency magnetic

frequency magnetic fields (50/60Hz) IEC 61000-4-8			fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE U_T is the AC. mains voltage prior to application of the test level.			

Appendix A

<table>
<tr><td colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The [SYS-6010] is intended for use in the electromagnetic environment specified below. The customer or the user of the [SYS-6010] should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity measurement</td><td>IEC 60601 measurement level</td><td>Conform level</td><td>Electromagnet environment-instruction</td></tr>
<tr><td>Conducted immunity IEC61000-4-6</td><td>3 Vrms 150k ~ 80MHz</td><td>3 Vrms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the [SYS-6010], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance:
$d = 1.2\sqrt{P}$
$d = 1.2\sqrt{P}$ 80M ~ 800MHz
$d = 2.3\sqrt{P}$ 800M ~ 2.5GHz
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).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range[b].
Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td>Radiation immunity IEC61000-4-3</td><td>3V/m 80M ~ 2.5GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

Appendix A

[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 [SYS-6010] is used exceeds the applicable RF compliance level above, the [SYS-6010] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [SYS-6010].

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Appendix A

Recommended separation distances between portable and mobile RF communications equipment and the [SYS-6010]

The [SYS-6010] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [SYS-6010] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [SYS-6010] 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).		
	150k ~ 80MHz $d = 1.2\sqrt{P}$	80M ~ 800MHz $d = 1.2\sqrt{P}$	800M ~ 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For 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 B The Default Factory Settings

This chapter lists some default factory settings of infusion pump. Users can not modify the default factory settings, but if necessary, they can recover the infusion pump to the default factory settings state.

Parameters

Parameters setting	The default factory setting
KVO flow rate	1ml/h
Pressure unit	mmHg
Occlusion pressure	P2（middle level）
Near end	3min
Built-in consumable brand	MC(5,10, 20, 30, 50ml), B.Braun(20,50ml)

System time

System time and date	The default factory setting
Time	00：00
Date	2014-1-1
Time form	24 hours
Date form	Year-month-day

Appendix C

Appendix CToxic and Hazardous Substances or Elements

Description	Plumbum Pb	Mercury Hg	Cadmium Cd	Chromium VI Cr(VI)	Polybrominated biphenyls PBB	polybrominated diphenyl ethers PBDE
pump shell	○	○	○	○	○	○
key and cover	○	○	○	○	○	○
label	○	○	○	○	○	○
display	×	×	×	×	×	×
hardware	○	○	○	×	○	○
connection wire	○	○	○	○	○	○
PCBA	×	○	○	○	○	○
packing material	○	○	○	○	×	×
battery	×	×	×	×	×	×
accessory	×	○	○	○	○	○

remark:

“○” shows that the content of this toxic and harmful substance in all homogeneous materials are under the regulated limitation requirement of SJ/T11363-2006.

“×”shows that he content of this toxic and harmful substance in one homogeneous materials is over the regulated limitation requirement of SJ/T11363-2006.

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

Registration address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan District, Shenzhen, P.R.China

Production address: 1-4 Floor,11th Building,Nangang Industrial Park, Songbai Road, Xili, Nanshan District, Shenzhen, P.R.China

After-sales service address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan District, Shenzhen, P.R.China

EU- Representative name: WellKang Ltd

EU- Representative address: Suite B, 29 Harley Street LONDONW1G 9QR, England, United Kingdom

Telephone: +86-755-26953369

CE 0123

Fax: +86-755-26001651

Postal code: 518000

Website: http://www.medcaptain.com

E-mail: info@medcaptain.com