# Infusion Pump MP-60

# Operation Manual

Please read this “Operation Manual” carefully and follow “Precautions for Use” before using the MP-60 Infusion Pump.

MEDCAPTAIN MEDICAL TECHNOLOGYCO., 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 case that:

- Use in accordance with the Operation manual.
- All disassembly, replacement, test, modification and repair are executed by qualified persons 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
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- **V2.0**
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- **V2.1**
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# Intellectual Property and Statement

- **V2.2**
  - Service interval modification and writing mistake correction
  - Publish date：2016.7.30

# 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.
  - Replacing or using parts, accessories and consumables without approval of MEDCAPTAIN.
  - Other troubles not caused by product itself.

  If the warranty period is expired, we couldcontinue 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:

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- 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.

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# 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 MP-60 is a micro-continuous infusion pump. It ensures constant infusion speed and accurate dosing volume during longtime 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 eleven 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.
- Two-way alarm for monitoring the main control circuit and motor drive circuit

# Overview

- Independent motor driving CPU and motor subdivided drive chip design.
- Setting and giving automatic prompt of maintenance interval.
- Modular installation design enables multi-channel pumps among pumps.

Note:

Handle, pole clamp, barcode scanner, WIFI communication module, voice communication, nurse call and relay infusion function are optional, dependingon 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 for blood transfusion.
- Prior to use, please check the status of the pump, power cord and other related accessories to ensure the device could be used normally and safely
- 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.
- To avoid the risk of fire or explosion, do not use the infusion pump in a flammable or oxygenated environment.
- The altitude difference between the pump and heart position of the patient should not be larger than 100cm. Smaller difference of the altitude will increase the accuracy of the pressure sensor’s result.
- 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.
- To guarantee the infusion safety and alarming function, it is recommended that you use the IV sets specified by the manufacturer only..
- 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.
- 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 without moving or replacing the tube may cause an inadequate infusion.
- There should be a regular monitoring by clinical professionals to observe the clinical situation and infusion pump working conditionwhen using the device,
- The power cord or other affiliated lines should be kept properly to avoid any risk of twining on patient or electrical disturbance.
- 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 a supply mains with protective earth.
- If the pump and its related accessories are reaching over the life time, they must be crapped and disposed in accordance with the local laws or hospital ordinances. Please contact your local representative for further details.
- 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 MP-60 and the patient simultaneously.

**CAUTION:**

- The infusion set is treated as the applied part of the pump.
- Check the setting values on the prescription and infusion pump.The infusion can be started when both values are equal.
- 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 interface, replace the IV sets or move the IV sets tubing more than 10cm, to keep the infusion accuracy continuously.
- Ensure that the infusion pump has been fixed tightly on the stand and the stand is stable. Prevent the pump from collision, dropping mechanical vibration or other impact of external forces to avoid damage on the pump.

# Precautions For Use

- Before pressing the [START] key, check if the infusion speed is correct, especially the position of the decimal point.
- Do not operate on the display with sharp objects. Otherwise, the display may be damaged.
- 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.
- The drop sensor detects drops, but not the flow rate. If the liquid in the drop chamber keeps dripping into continuous liquid flow, the drop signal cannot be detected.
- Infusion pump should be placed without the reach of patients and other irrelevant personnel.
- Avoid direct sunlight, 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 screen 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.
- The maximum temperature at the applied part of the pump may reach 41.1℃, when running continuously under the highest environment temperate at the highest infusion rate.
- 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

occlusionwhen sensor failed.

- The delay time between the onset of the alarm condition and the representation of the alarm is no longer 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 pager |
|  | ON/OFF |
|  | HOME |

# 3 Product Specifications

| | |
|---|---|
| **Product name** | Infusion pump |
| **Model** | MP-60 |
| **Power supply** | AC power supply:<br>AC 100-240V,50/60 Hz, power consumption 45 VA<br>External DC power supply: DC 12 V 1A<br>Internal battery: lithium battery 11.1 V 1500 mAh<br>Battery model: 154457<br>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 disposable IV sets conform to the standard |
| **Infusion mode** | Rate, Time, Weight, Sequence, Relay, Drip Mode |
| **Infusion setting range** | 0.1-1200.0mL/h or（0.03-400d/min） <br>See the least increment in chart 6-3 |
| **VTBI setting range** | 0.1 - 99.99（Least increment 0.01） <br>100 - 999.9（Least increment 0.1） <br>1000 - 9999（Least increment 1） |
| **Total volume display** | 0-99999.99ml |
| **Accuracy** | ±5% |
| **Purge operation** | 1200.0ml/h |
| **Bolus operation** | 0.1~1200.0ml/h<br>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 ≥$0.025^{+0.025}_{-0}$mL |
| **Occlusion level** | 300mmHg~900mmHg，3 levels are available |
| **Alarm** | Near Finished, Finished, OCCL, Low Battery, Battery Empty, No Battery, No Power Supply, The Pump Door Open, Air Bubble , No Drip Sensor, No Drips, Drips Abnormal, Reminder Alarm , Relay Index Duplicate, Infusion Start Fail , Standby Time Expired |
| **Special function** | Repeat alarming:If there is still alarm after mute alarm sound, it will |

# Product Specifications

| | |
|---|---|
| | alarm again in 2 minutes<br>Event recording: Can store and playback 2000 events maximum<br>Sound volume: 11 levels are available<br>Power supply switching: When AC/DC power supply is cut off ,the infusion automatically switch to internal battery supply<br>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** | Temperature: 5℃ to 40℃ Humidity:15% to 95% RH<br>Pressure altitude: 70.0kPa-106.0kPa |
| **Storage conditions** | Temperature: -20℃ to +55℃ Humidity: 10% to 93% RH<br>Pressure altitude:22.0kPa-107.4kPa |
| **Operation Mode** | Continuous operation |
| **Classification** | 1. Class I / Internally powered equipment;<br>2. Type CF applied part;<br>3. IPX2;<br>4. No sterilization requirement for pump<br>5. Not category AP / APG equipment;<br>6. Mode of operation: continuous |
| **Dimensions** | 202(W) ×74(H) ×133(D)mm |
| **Weight** | About 1.6 kg (including battery) |
| **Service Life** | 10 years |
| **Main safety standards** | IEC60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance<br>IEC60601-2-24 Medical electrical equipment –Part 2-24: Particular requirements for the safety of infusion pumps and controllers<br>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<br>IEC60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility requirements and tests |

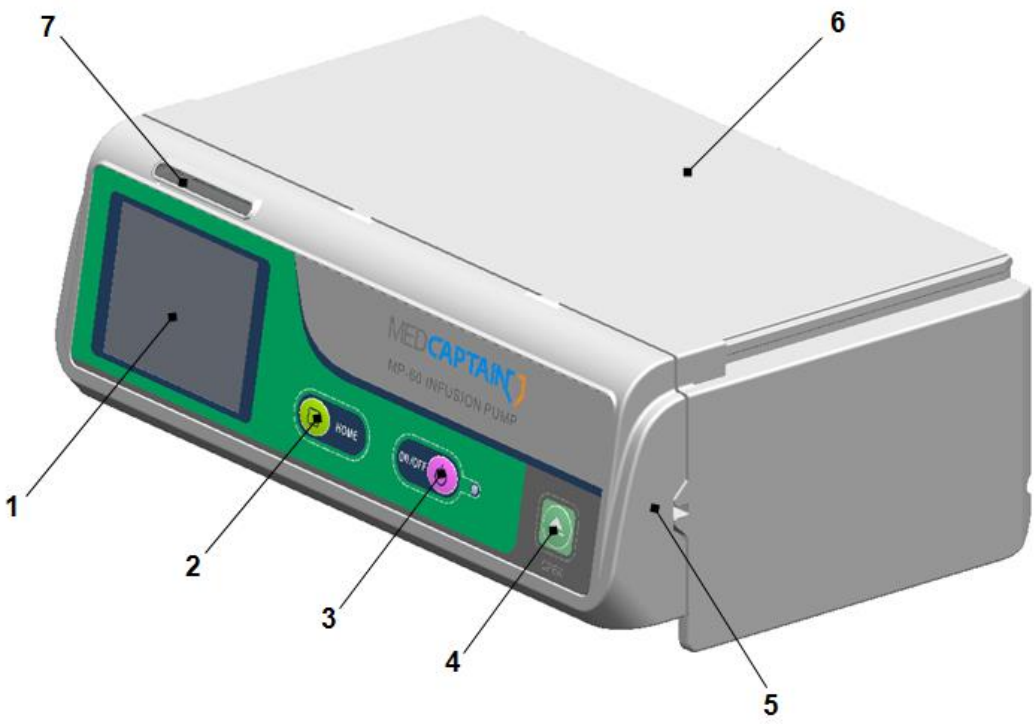
# 4 Product Description

## 4.1 Principle of Operation

The MP-60 infusion pump mainly consists of pump shell, display screenand 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

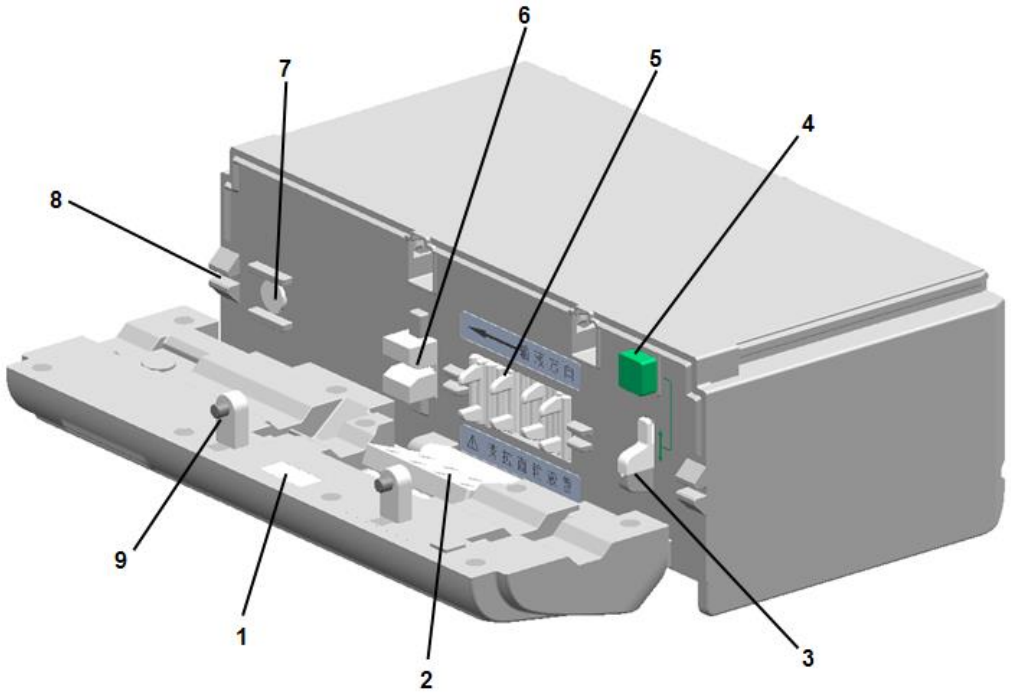



**1 –Touchscreen** **2 – [HOME]key** **3 – [ON/OFF]key**

**4 –[OPEN]key** **5 –pump door** **6 –Shell**

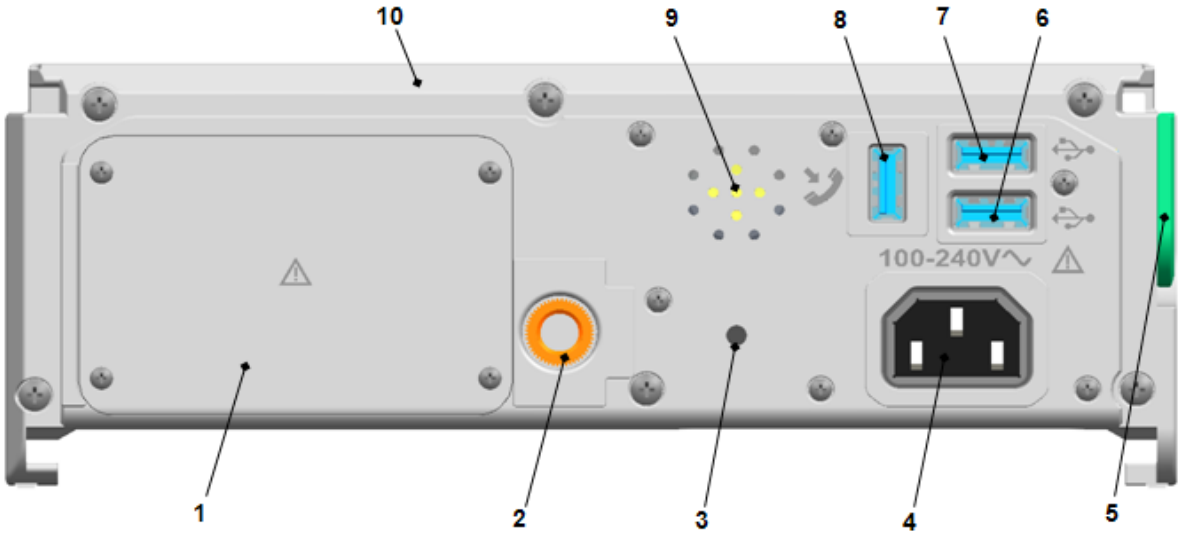
**7 –Alarm indicator**

# Product Description




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

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




**1 –Battery cover** **2 –Threaded hole** **3 –Auxiliary alarm**

**4 – AC power inlet** **5 –Combination clamp** **6 –External inlet 1**

**7 –External inlet 2** **8 –External inlet 3** **9 –Buzzer**

**10 – Shell**

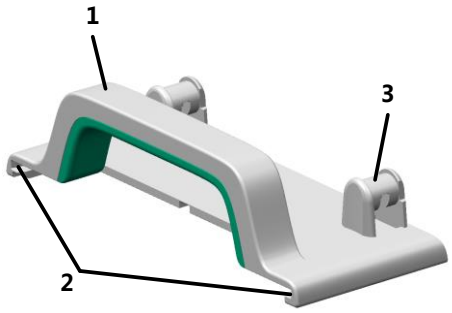
- Battery chamber. Replaceable battery inside the chamber.
- Threaded hole. To fix the pole clamp, then fix the pump to the IV pole via the pole clamp.
- Auxiliary alarm. Audible alarm sounds when product functions abnormally.
- Buzzer. To alarm in high, medium or low level during infusion and enable voice conversation.
- 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 3 external devices at the same time. The external devices include drop sensor, barcode scanner, external DC power cord. The external inlet 1 and 2 could be used as the interface for the local WLAN.

**CAUTION:**

- Only the accessories or devices specified by the manufacturer allowed to be connected to the Pump. Otherwise may cause electrical shock. See Table4-1.
- 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

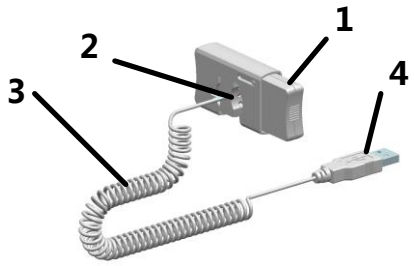
it is difficult to operate the disconnection device.

## 4.3 Handle




**1 –Handle** **2 –Slide rail** **3 –Tubing management bracket**

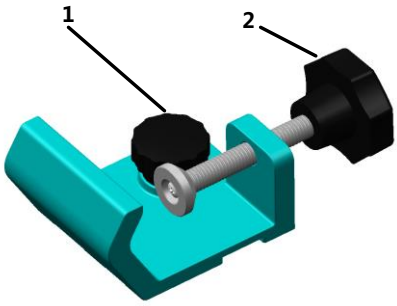
## 4.4 Drop sensor




**1 –Button** **2 –Drop hole** **3 –Cable**

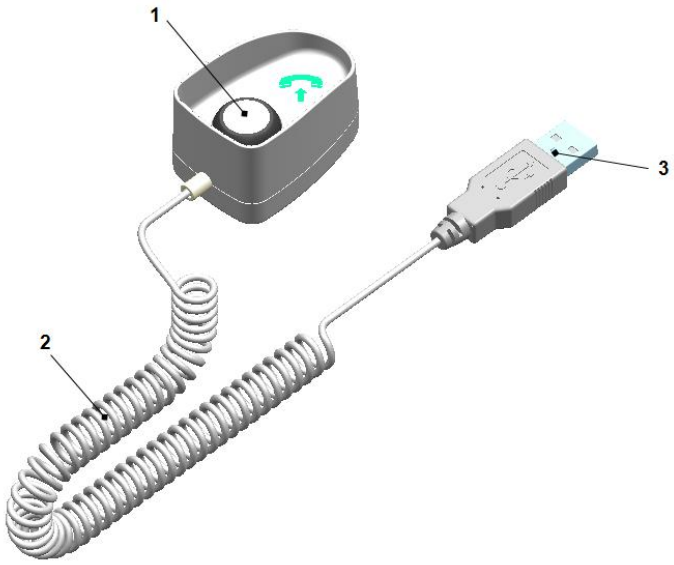
**4 –Socket**

## 4.5 Pole Clamp




**1 – Mounting screw** **2 – Mounting knob of infusion stand**

## 4.6 Nurse Pager




**1 –Button** **2 –Cable** **3 –Socket**

## 4.7 Accessories accompanied

**1 –AC power cord 1** **2 – Pole clamp 1**

**3 – Handle 1** **4 – Operation manual 1**

**5 –Packing list1** **6 -– Quick-operation instruction 1**

## 4.8 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 |
| Handle | MP-1 | 9113000002 |
| Nurse pager | MP-2 | 9113001002 |
| Drop sensor | MP-3 | 9114002521 |
| Barcode scanner | MP-4 | 9005000008 |
| Pole clamp | —— | 9114002501 |

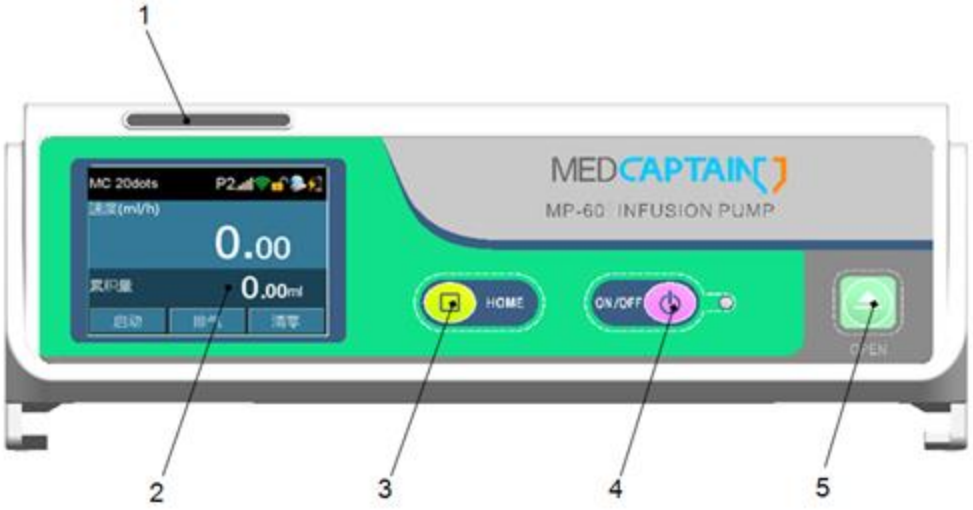
# 5 Preparations for Use

- 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 pump.
- 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 hours after 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 your local distributor for help.

# 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 IV set brand and specification, occlusion level, real- time pressure, external power source, battery capacity and WIFI signal. Touch the brand and specifications zone to enter a page of IV set brand adjustment. Touch the occlusion pressure level to enter a page of occlusion level selection. See below for further description.


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.

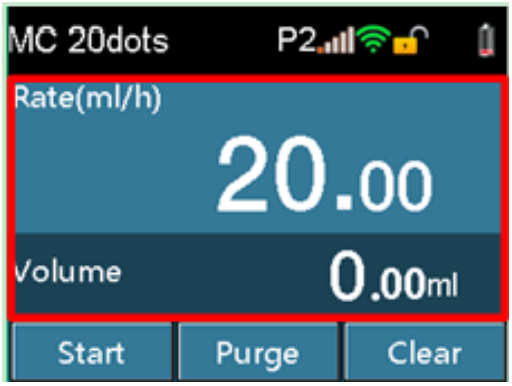

Screenlock symbol, consists of lock and unlock.


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

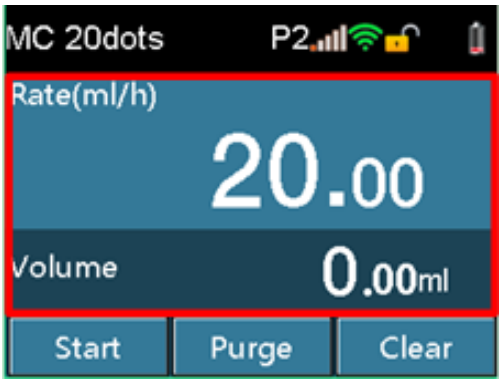

WIFI signal


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 [ON/OFF] to turn on the pump. When the pump is on, press [ON/OFF], and shutdown interface pops up, select [Power Off]]or long press [ON/OFF]for 3 seconds to 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:**

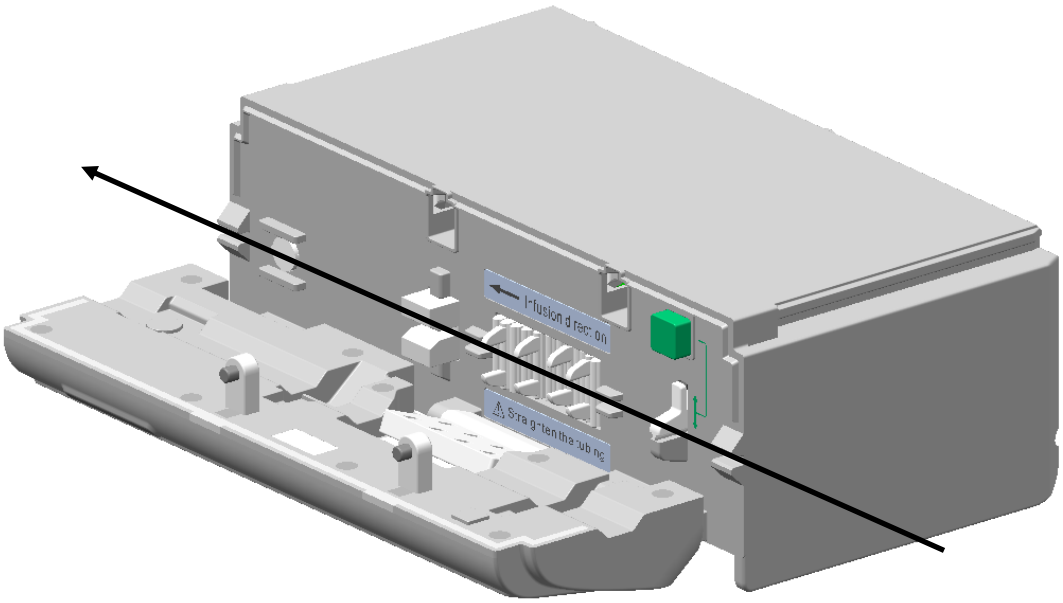
- After the power switch is turned on, confirm the loudspeaker, warning indicator is working all right, and check if the self-test is finished and no error messages appear. (Refer to Chapter 8 Troubleshooting.)
- Ensure the displayed IV set brand corresponds with the using IV set brand.
- If the IV set 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

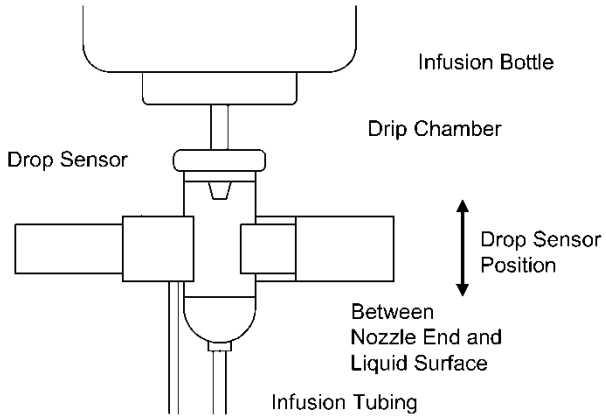
- Insert the needle into IV bottle vertically, and the liquid infuses into the drop chamber.
- When the liquid level is at 1/3 of the drop chamber, open the roller clamp.
- Infuse liquid into the tube to purge the air, and then close the roller clamp.
- Press [OPEN] to open the pump door.
- Press [Anti-Free-Flow 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 liquidcontainer above the PATIENT and/or pumpshould 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



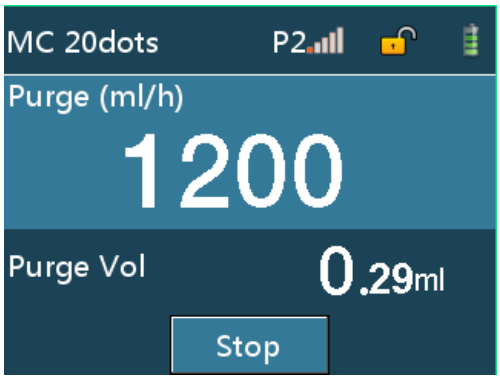

**CAUTION:**

- 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 level must be lower than the drop sensor.
- Prevent the drop sensor from being tilt and always stay out of the sun during infusion.
- Avoid the drip bottle is clipped too tight by drop sensor.
- Drop sensor detects the drop but not Measures fluids flow. Drop signal are undetectable if the continuous fluids flow is formed in the drip bottle.

## 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 and alarm function wiil be 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

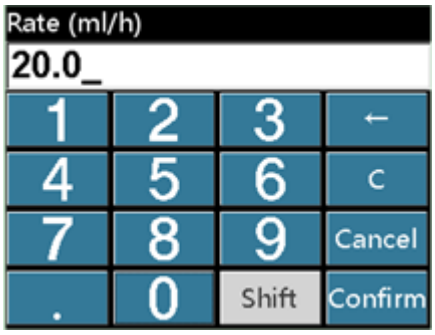
| IV set specification ( d/mL ) | Purge rate ( mL/h ) |
|---|---|
| 20 | 1200.0 |

**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 volume under the purge function will not be calculated into the total 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:**

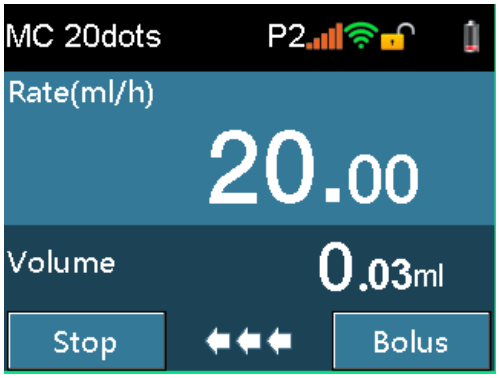
- If the flow rate is changed in the infusion process, the infusion will be done at the new flow rate.

## 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.

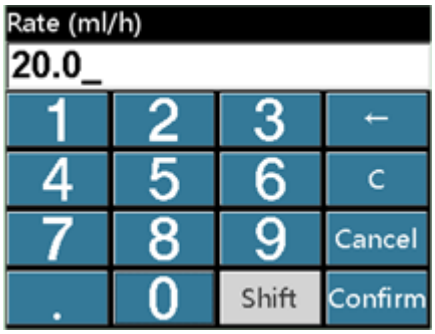



**CAUTION:**

- 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.



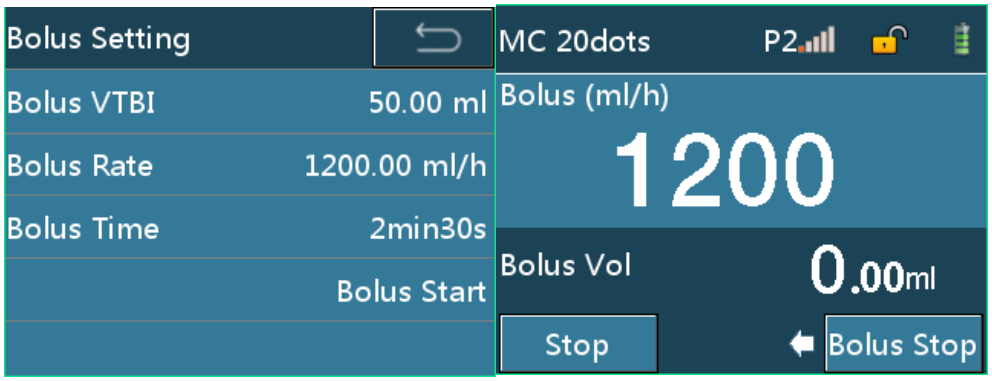

- After entering the rate, if click [Cancel], it will return to original infusion interface without change; Click [Confirm], it will return to original infusion interface and operates at the new rate.

**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; click [Bolus] to enter the bolus setting interface. Set any two of Bolus VTBI, Bolus rate and Bolus Time, click [Bolus Start] to enter the bolus interface, click [Bolus Stop] to stop the bolus.




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

Table 6-4Relationship 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

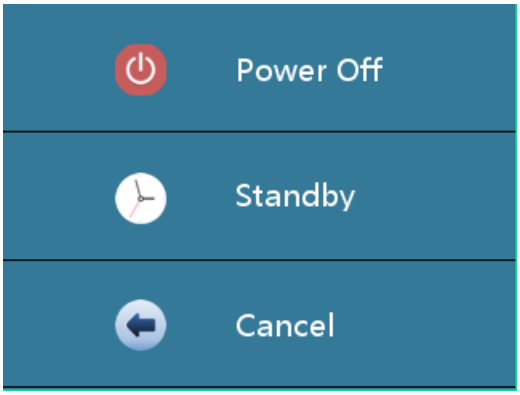
In the infusion process or after infusion, press the [STOP] key to stop the operation and green indicator will be off.

## 6.11 Replacing or adjusting IV set

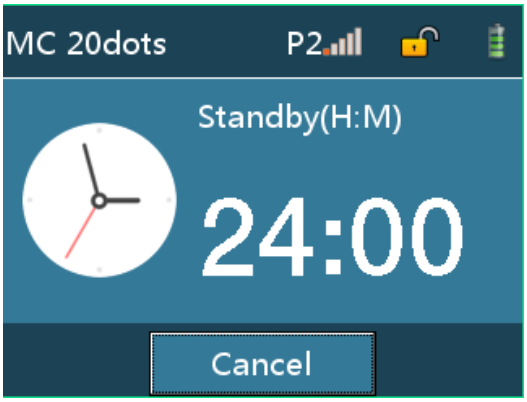
An extrusion damage of tube in continuous infusion of the IV set would affect the infusion precision. After about 8-hour or regulated hour continuous infusion of the IV set, the infusion should be stopped, open the pump door, and move the IV tube about 10 cm from the original position, so that the IV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

.

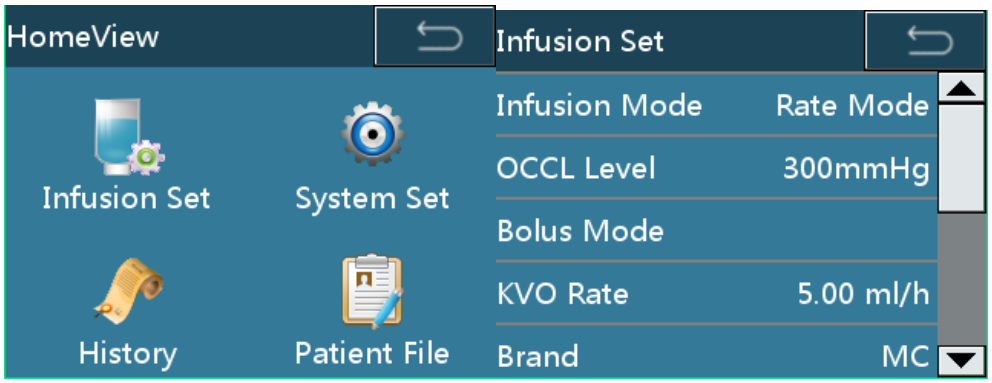
# 7 Setting the InfusionPump

**CAUTION:**

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

## 7.1 Infusion set

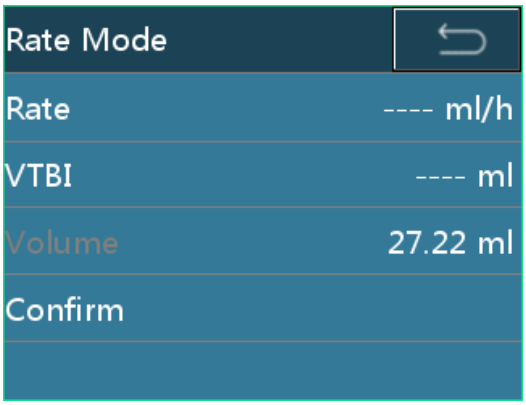
Press [HOME] key to enter the setting interface, click [Infusion Set] to enter the detailed infusion setting interface. Infusion set, occlusion level, bolus mode, KVO rate, brand, relay set,near finished could be set and adjusted here.




### 7.1.1Infusionmode

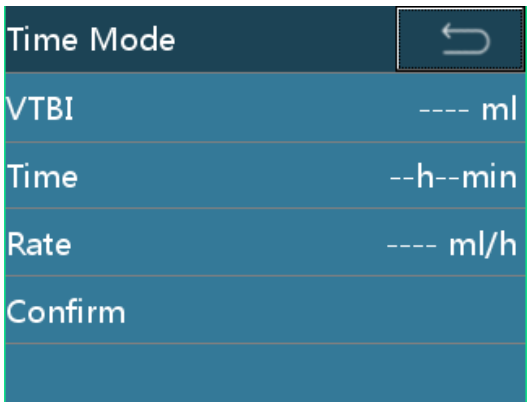
- 5infusion modes: Rate, Time, Weight, Sequence, Dripare aer available
  - Rate mode

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



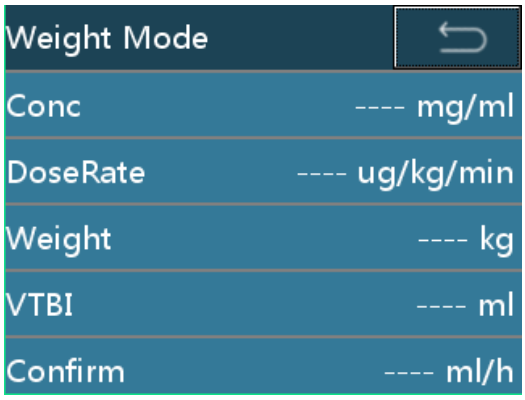

  - Time mode

Under theTimeMode, set the VTBI and Time, the rate will be calculated automatically, click [Confirm] to operate.



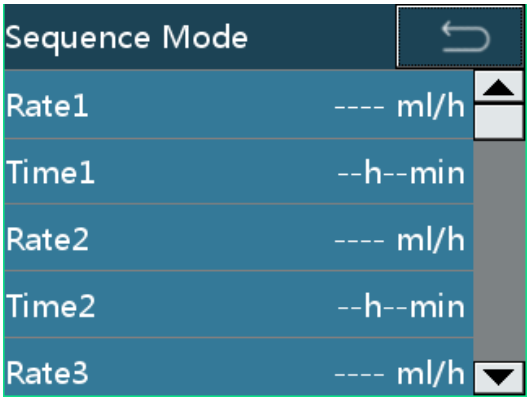

■ Weight mode

Under the WeightMode, set the Conc, DoseRate, Weight and VTBI, the device will calculate the rate automatically. Click [Confirm] to operate.



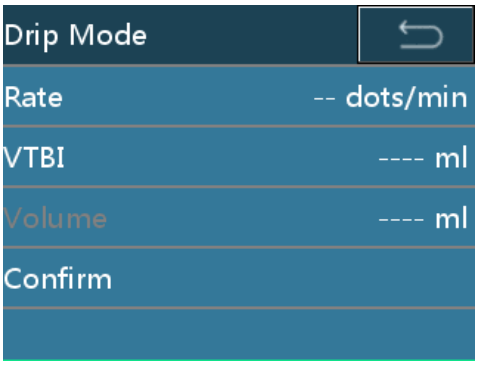

■ Sequence Mode

Under the Sequence Mode, set the 5 sequence rate and time, click [Confirm] to operate in sequence.




■ Drip Mode

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




**CAUTION:**

- The pump will calculate the corresponding rate according to the current drip rate (dots/min) and current IV set's spec.
- The pump control the flow by using corresponding flow rate (ml/h) but not by detecting the drip rate (dots/ml).

## 7.1.2Occlusion Level

- 3 levels 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 preventthe unblocked alarm to cause patients with extra amount of pills after input, Anti - Bolus alarm, electric opportunity back automatically release line pressure.
- When you infuse viscous solution with the Occlusion Level setting on level1 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 on level 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 pump.
- 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.

## 7.1.3Bolus Mode

- There are three modes: Manual Bolus, Rapid quantitative Bolus and Automatic Bolus. Please refer to the chapter 6.9 for further instructions.

## 7.1.4KVO Rate

- KVO-rate could be adjusted from 0.1ml/h to 5ml/h (Step by 0.01ml/h), Default rate: 1ml/h.

## 7.1.5Brand

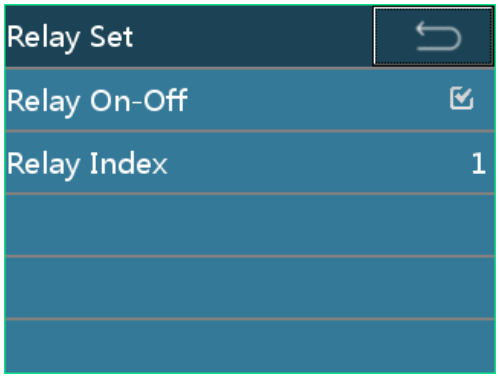
- You can choose the consumable brand by: [Home] -> [Infusion Set] -> [Brand].
- Several brands of 20d/mL IV set have been preset and customized. Select the infusion accordingly for clinical uses.

**CAUTION:**

- Users must use the consumable brand which is specified by the manufacturer.
- To add in infusion of other brand, users are strongly recommended to contact the manufacturer or manufacturer's representative to set and test, so as to ensure the infusion accuracy.

## 7.1.6Relay set

- Open relay mode, set the relay number under the mode.




**CAUTION:**

- The relay number must be set in sequence from number 1 when there are several infusion pumps or infusion pumps.

## 7.1.7Drip Mode Set

- Open the drip mode, detect the drop sensor and count the drops during infusion.

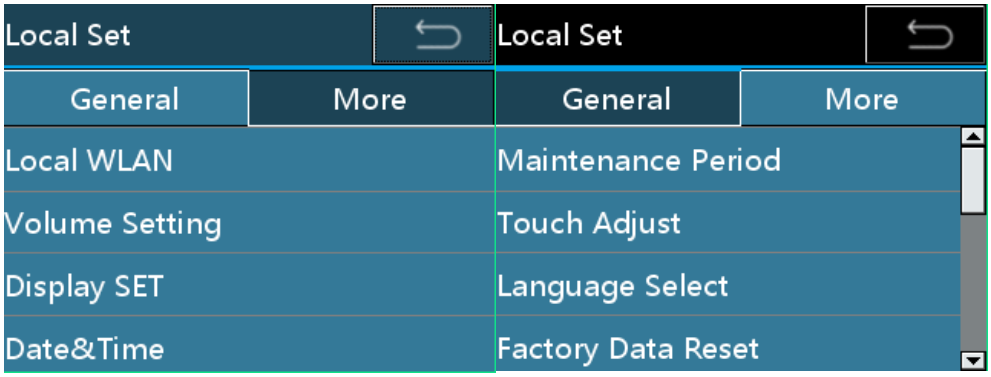
**CAUTION:**

- If disconnected the drop sensor but the drip mode is open, the pump produces no drop sensor alarm.

### 7.1.8NearFinished

- Near Finished Alarm: Alarm-time could be adjusted from 1min to 30min before Finished (Step by1min), Default time: 3min before Finished.

## 7.2 System Set



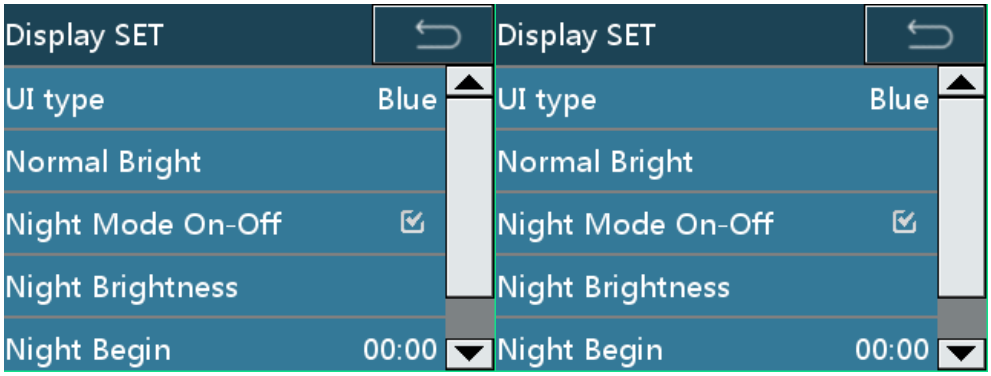

### 7.2.1Volume Setting

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

### 7.2.2Display SET



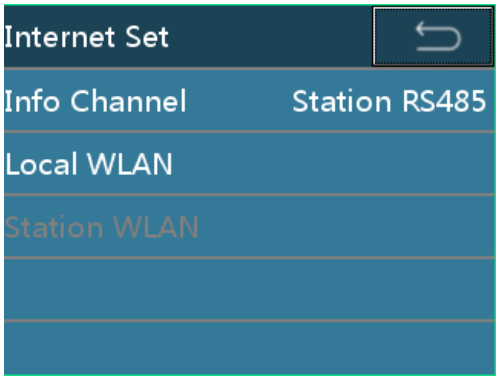
- There are seven different color options for UI type.
- The brightness could be adjusted in [Normal Bright].
- All the parameters of the night mode could be adjusted here.

**CAUTION:**

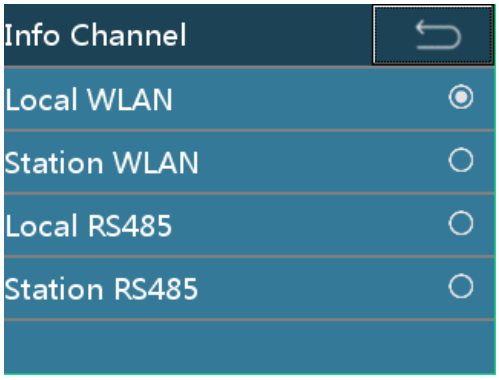
- Under the night mode, setting range of start time is 17:00-09:00, finish time range is the same as start time range. By default, the start is 00:00; finish time is 00:00.
- If the pump is inserted to a working station, once the display setting on the pump is changed, the setting on the station will be synchronized at the same time.

## 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.

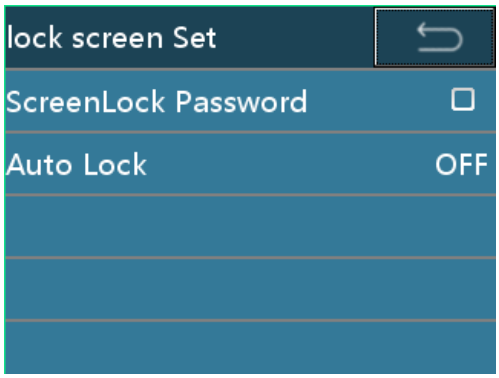


**CAUTION:**

- The pump could communicate with working station, and the working station could manage the alarm and implement relay function between pumps.
- The setting of [Local RS485] and [Station RS485] must be done by the manufacturer's representatives. Please contact manufacturer or local dealer for further information.
- 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.
- [WIFI Disable] option should be cancelled, the AP name, Password of the network should be inputted, and the TCP/IP's information should be set.


## 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 set up the screen auto lock function. This function could be set as: OFF, 15s, 30s, 1min, 2min, 5min, 10min, 30min. The default value is OFF, which means the screen auto lock function is disable.




## 7.2.5Collection Set

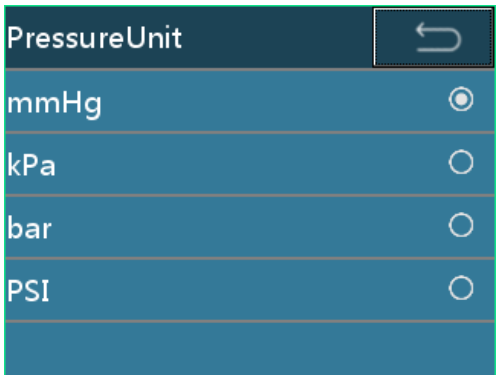

- [Mode Collection]: Choose the frequently used infusion mode from the [Infusion mode] option. Once the frequently used infusion modes are chosen, the unnecessary modes will not appear in the list of 7.1.1 [Infusion mode] option. The default setting is “all the four infusion modes are chosen”.
- [Brand Collection]: Choose the frequently used infusion set’s brand from the [Brand] option. Once the frequently used brands are chosen, the unnecessary brands will not appear in the list of 7.1.5 [Brand] option. The default setting is “all the preloaded brands are chosen”.

## 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.

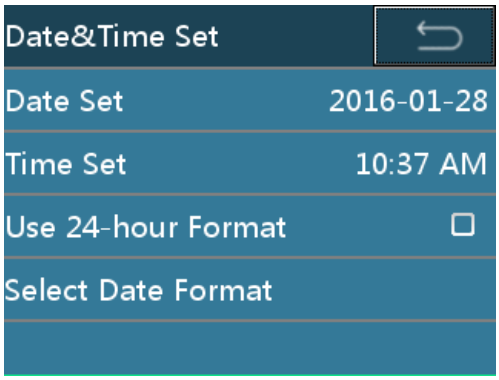
## 7.2.7PressureUnit

- 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

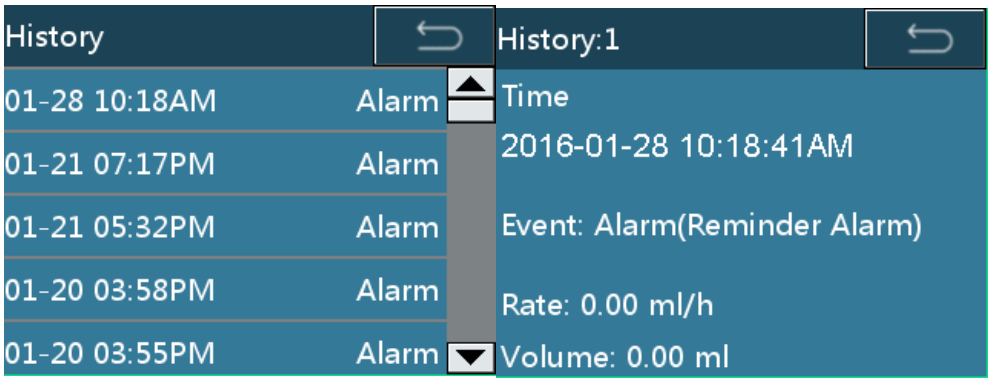
- Set the date, time, and their format.




## 7.2.9Maintenance

- Click [Maintenance] option to do the [Language Select], [Touch Adjust], [Factory Data Reset], and check the version information.
- To check the version information, follow the route of: [Home] -> [System Set] -> [Maintenance] -> [Version Info].

## 7.3 History




The history records are as Table 7-2.

Table 7-2 History records

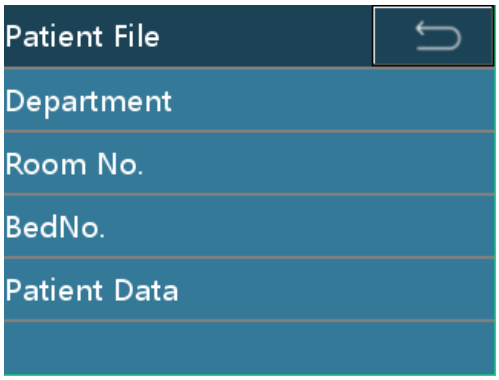
| Event | Record Parameters |
|---|---|
| Start up | Occurred time |
| Shutdown | Occurred time |
| Standby | Occurred time, standby set time |
| Start | Occurred time, rate, VTBI |
| Bolus | Occurred time, Bolus rate, Bolus way |
| Bolus stop | Occurred time, Bolus rate, Bolus accumulated volume |
|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

**CAUTION:**

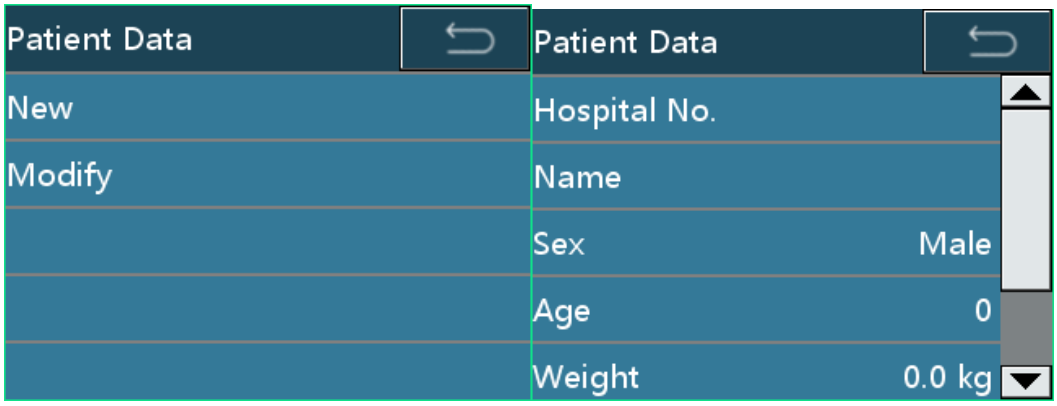
- 2000 history records are available to be stored at maximum. If the amount reaches storage limit, the earliest record would be removed.
- Alarm system can’t be poweredoff separately by operator unless the pump is powered off.The time of powering off is captured in the history records.

## 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:**

- If AC or DC power is connected, the battery will be recharged.
- Use AC power to charge the battery. If recharged by an external 12 VDC 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 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 pump will stop.
- 3 minutes before the battery empty, the pump will auto power off.
- New battery fully charged at 1200 ml/h rate of infusion, the battery of continuous use time is 2h42min.
- The actual battery duration may be different and affected bythe 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 permanentlywhen 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 differentALARM PRE-SETS are used for the same or similarequipment 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 | Low-level | The internal battery is running critically low. | Immediately connect an AC power supply or an external DC power supply. |
| Battery Empty | High-level | The battery is out. | Immediately connect an AC power supply or an external DC power supply. |
| Near End | Low-level | The infusion is end within the Near Finished Alarm setting period. | Wait until the infusion finishes. |
| Occlusion Alarm | High-level | 1.The infusion IV line is occluded；<br>2. The OCCL level is too low for high viscosity drug's infusion. | Press [STOP] to stop the injection. Check and remove the cause, continuous to inject. |
| Air-bubble | High-level | 1. Air bubble in the infusion line.<br>2. The flatten tube is fixed inside the air bubble detector. | Click [Stop] to remove the alarm, check if the tube installed in air-bubble probe is roll flattening. Press [PURGE] to release air bubble quickly. |
| Finished | High-level | The limit amount or the infusion time is complete | Press [STOP] to remove the alarm. |
| Reminder Alarm | Low-level | Forget to operate the alarm (no key operation is made two minutes after the IV sets is installed). | Press any key to clear the alarm. |

| Alarm Symptoms | Alarm level | Causes | Troubleshooting |
|---|---|---|---|
| Drop Error | Low-level | The drip rate is detected to be incorrect at the drip kettle during the infusion. | Press [Cancel] to remove alarm. And check the installation of the drop sensor. |
| No drop sensor | Mid-level | The drop sensor detection function is turned on, but drop sensor is not installed. | Install the drop sensor, or turn the drop sensor detection function. |
| No drop | High-level | No drop is detected by the drop sensor. | Press [Stop] to remove alarm, check the installation of the drop sensor and the IV set. |
| Standby Time Expired | Mid-level | Standby mode is end | Press cancel to exit Standby mode. |
| Relay Index Duplicate | High-level | Relay Index Duplicate | Reset Relay Index |
| Infusion Start Fail | High-level | Infusion pump cannot be started under the relay mode. | Check the infusion pump, remove the problem that causes the failure of start. |

## 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 troublecode 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, Disinfecting

- 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 2 years. 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 2 years by the graduate and timer.

Checking condition:

| IV set | Infusion rate | Infusion time | Volume in graduate |
|---|---|---|---|
| MC/B.Braun20d/mL | 120mL/h | 6min | 11.4-12.6mL |

## 9.2.4Alarm

- Occlusion alarm

Checking condition:

| IV set | Infusion rate | Occlusion level | Alarm time |
|---|---|---|---|
| MC/B.Braun 20d/mL | 120mL/h | P2 | 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 2 years:

- 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's replacement must be done by specialist who has been trained to finish such operation. Otherwise there will be a risk of danger.
- Please strictly follow the instruction to replace the battery, and the battery should be provided by the manufacturer. Otherwise there will be a risk of danger.
- Do not disassemble or short circuit the battery, do not through the battery into the fire. Otherwise there will be a risk of danger caused by the battery linkage or explosion.
- Please follow the local low to dispose the old battery.

## 9.3 Maintenance

- If any trouble，explain the situation to your localthe 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.
- Parts of the Pump are not serviced or maintained while in use with the patient.

**WARNING：**

- The accessories' replacement must be done by specialist who has been trained to finish such operation. Otherwise there will be a risk of danger.

## 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 experiment data only represents the measurement data in the lab.
- To ensure the infusion precision, it is recommended that the infusion tube be changed or moved every 8hours.
- Under the single fault condition, the maximum infusion precision error maybeup 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）: 5sets each.
  - Infusion pump: 1 set
  - Sampling interval: 0.5min
  - Test Period: 120min

# Infusion Accuracy Characteristics

- Test Liquid: ISO 3696:1987 Class III water

Table 10-1 Accuracy test result

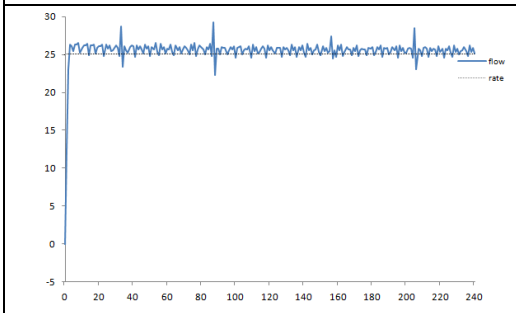
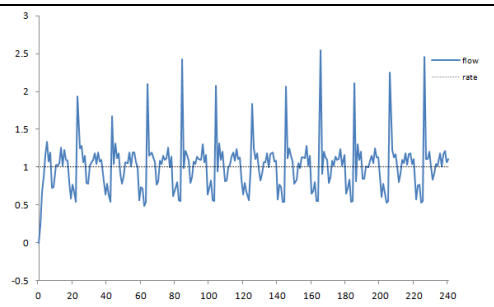
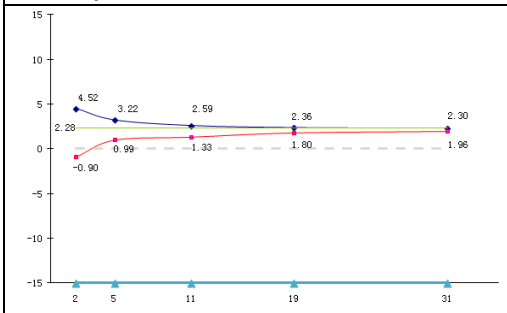
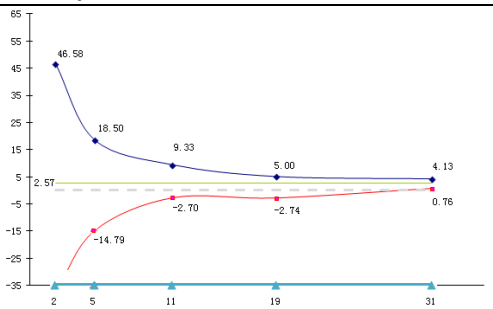
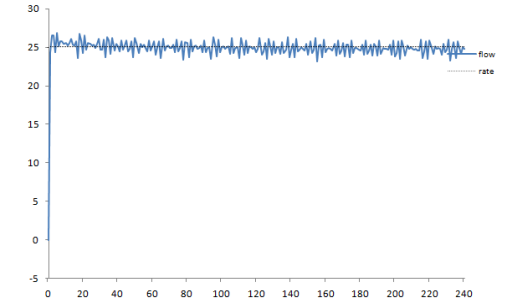
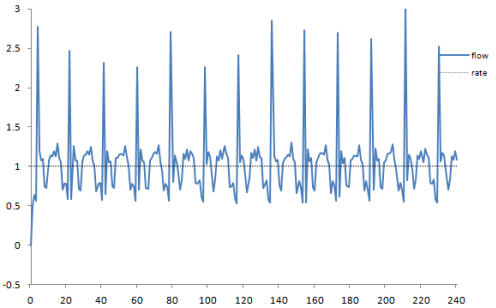
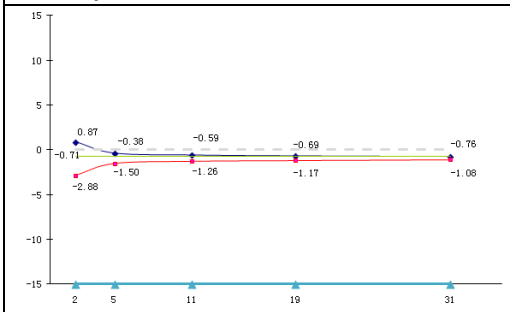
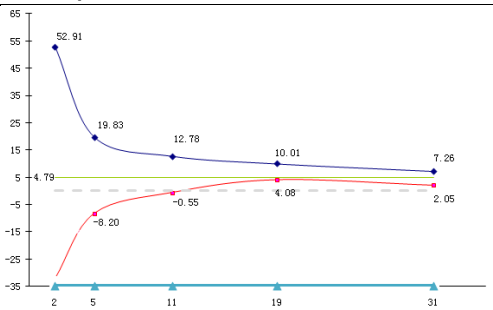
| Administration set (IV set) Brand | Accuracy(%) | Remaks |
|---|---|---|
| B.Braun 20d/mL | +4.79 | Minimum rate 1ml/h,normal condition |
| | -0.71 | Intermediate rate 25ml/h,normal condition |
| | +0.91 | Intermediate rate 25ml/h,with +13.3kpabackpressure |
| | +0.79 | Intermediate rate 25ml/h, with -13.3kpabackpressure |
| | -6.61 | Intermediate rate 25ml/h, when the supplycontainer below the pump mechanismat a distance of 0.5m |
| Medcaptain(MC) 20d/mL | +2.57 | Minimum rate 1ml/h, normal condition |
| | +2.28 | Intermediate rate 25ml/h,normal condition |
| | -1.10 | Intermediate rate 25ml/h,with +13.3kpabackpressure |
| | +1.00 | Intermediate rate 25ml/h, with -13.3kpabackpressure |
| | -11.62 | Intermediate rate 25ml/h,when the supplycontainer below the pump mechanismat a distance of 0.5m |

**CAUTION:**

- The accuracy maybe up to -11.62% when the supplycontainer below the pump mechanismat a distance of0.5m.
- To ensure the infusion accuracy, strongly recommend that the supplycontainer is higher than thepump 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%;

Length of the infusion tube: 1m

Table 10-3The 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 | 00:01:17 | 0.12 |
| | III | 900±200 | 00:04:06 | 0.39 |

Table 10-4The occlusion level and alarm delay time under the rate of 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 10-5The 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 Electron Magnetic Compatibility (EMC)

The MP-60 Infusion Pump conforms to EMC standard EN 60601-1-2.

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The [MP-60] is intended for use in the electromagnetic environment specified below. The customer or the user of the [MP-60] should assure that it is used in such an environment. | | |
| Emission test | Emission test | Emission test |
| RF emission<br>CISPR 11 | Group 1 | MP-60 infusion pump only use radio-frequency power while operating its internal functions, therefore, the radio-frequency emission is much low and has little interference to the electronic devices nearby. |
| Radio-frequency emission<br>CISPR 11 | Class A | The MP-60 infusion pump can be used in any building including civil residence. |
| Harmonic emission<br>IEC61000-3-2 | Class A | |
| Voltage fluctuation and flashing<br>IEC 61000-3-3 | Complies | |

# Appendix A

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The [MP-60] is intended for use in the electromagnetic environment specified below. The customer or the user of the [MP-60] should assure that it is used in such an environment. | | | |
| IMMUNITYtest | IEC60601test level | Compliance level | Electromagnetic environment –guidance |
| Electrostatic discharge ( ESD ) IEC 61000-4-2 | ±8 kV contact discharge<br>±15 kV air discharge | ±8 kV contact discharge<br>±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<br>±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<br>±2 kV common mode | ±1 kV difference mode<br>±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<br>40% $U_T$ ( dropping 60% $U_T$ ) 5 period<br>70% $U_T$ ( dropping 30% $U_T$ ) 25 period<br>< 5% $U_T$ ( dropping > 95% $U_T$ ) 5seconds | < 5% $U_T$( dropping > 95% $U_T$ ) 0.5 period<br>40% $U_T$( dropping 60% $U_T$ ) 5 period<br>70% $U_T$ ( dropping 30% $U_T$ ) 25 period<br>< 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 [MP-60] requires continued operation during power mains interruptions, it is recommended that the [MP-60] 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 a.c 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 [MP-60] is intended for use in the electromagnetic environment specified below. The customer or the user of the [MP-60] should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment –guidance</td></tr>
<tr><td>Conducted RF 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 [MP-60], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance:<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$ 80M ~ 800MHz<br>$d = 2.3\sqrt{P}$ 800M ~ 2.5GHz<br>where Pis the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and dis the recommended separation distance in metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td>Radiated RF 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.<br>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 dueto fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [MP-60] is used exceeds the applicable RF compliance level above, the [MP-60] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [MP-60].

[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 [MP-60]

The [MP-60] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [MP-60] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [MP-60] 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 din metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where Pis 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 inall situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# Appendix B

## 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(20d/ml)、B.Braun(20d/ml) |

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.

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