SYS-6010 Series Infusion Pump

Operation Manual

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

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

Intellectual Property and Statement

Statements

MEDCAPTAIN reserves the right for final interpretation of this manual.

MEDCAPTAIN reserves the right to modify the contents of this manual.

The modified contents should be reflected in the newly published manual version.

This manual is applicable to SYS-6010, SYS-6010T, and SYS-6010A infusion pumps.

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 conducted 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**
  - First edition
  - Issued on: 2016-03-05
- **V1.1**
  - Service interval modification and writing mistake correction
  - Issued on: 2016-07-30
- **V1.2**
  - Writing mistake correction
  - Issued on: 2016-10-30
- **V1.3**
  - Writing mistake correction
  - Issued on: 2017-07
- **V1.4**
  - Modify information of European Authorized Representative
  - Issued on: 2018-09

- **V1.5**
  - Added warning
  - Issued on: 2019-3
- **V1.6**
  - Optimize picture quality.
  - Issued on: 2019-4
- **V1.7**
  - Added warning.
  - Issued on: 2019-07
- **V1.8**
  - Changed the model and parameters of the built-in lithium battery. Added the continuous use time of the battery if the rate is 125ml/h.
  - Issued on: 2019-09
- **V1.9**
  - Added the description that the sound of the **Battery Out** alarm cannot be paused and the sound of a low-level alarm can be paused.
  - Issued on: 2020-02
- **V2.0**
  - Modify the production address
  - Issued on: 2021-03
- **V3.0**
  - Parameter modification
  - Issued on: 2021-05

After-Sale 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.
  - Natural disasters.
  - Replacement or usage of (non-original) parts, accessories and/or consumables without prior 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 your local distributor or directly to MEDCAPTAIN.

Contact our after-sales service department:

After-sales service provider: MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

After-sales address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Telephone: +86-755-26953369

Fax: +86-755-26001651

Postal code: 518055

Website: http: //www.medcaptain.com

E-mail: MC.service@medcaptain.com

- MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD. and all local distributors with established after-sales service agencies can effectively resolve your problems in time.

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.

Contents

Contents

1 Overview

1.1 Intended Use

This product is intended for hospitals to infuse liquid, liquid medicine, or blood into a patient at constant rate through the veins of the patient.

1.2 Contraindication

None.

1.3 Product Features

MEDCAPTAIN SYS-6010 Series is a micro-volume continuous-operation infusion pump. It ensures constant infusion rate 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.

- Support various brands of infusion sets compliant with the *ISO 8536-4: Infusion equipment for medical use-Part 4: Infusion sets for single use, gravity feed* and *ISO 8536-8: Infusion equipment for medical use-Part 8: Infusion sets for single use with pressure infusion apparatus*. However, before using a gravity infusion set, the user must evaluate the risk that might be introduced by the gravity infusion set.
- Provide eleven occlusion levels and display pressure status of the tube.
- Maximum infusion rate up to 1200ml/h.
- Provide calibration functions for infusion accuracy.
- Safety design by monitoring infusion states.
- Multiple modes of infusion.
- WI-FI module could be connected to the ICMS to monitor the infusion status.
- Nurse call function.
- Provide quick and convenient user-friendly touchscreen interface.
- Support night mode display to reduce light interference to patients and environment.
- Support barcode scanner connection.
- Support three types of power supply: AC power supply, DC power supply, and internal lithium battery. The lithium battery can power the infusion pump for not less than 5 hours (at 25ml/h rate).
- Double CPU and redundancy design for key units.
- 2-CPU design and dual-channel real-time monitoring of infusion status for preventing exceptions like insufficient or excessive dose and reporting an alarm in case of an exception in time.

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.
- Prior to use, carefully check the pump, power cord and accessories to ensure normal operation and safety.
- Pay extra attention to check whether the infusion line is twisted in the process of low-rate infusion. Low infusion rate requires a long time for the occlusion to be detected, which may cause the infusion to be suspended 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 be less than 100cm. A smaller height difference indicates a higher 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 increases. 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 infusion set to ensure the infusion accuracy and alarm function.
- Only the infusion 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 or cautions provided in this manual may cause infusion failure, inadequate or excessive dosing, and/or other potential risks.

- It is recommended to install the drop sensor and enable 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.
- The power cord and other affiliated lines should be kept properly to prevent patients from being tripped and avoid electromagnetic
- 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 earthing.
- The infusion pump and accessories near to end of the service life must be disposed of according to local regulations or hospital rules. If there is any problem, please contact the distributor or manufacturer.
- Do not replace any component of 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 Series and the patient simultaneously.
- This infusion pump supports blood transfusion. When this pump is used for blood transfusion, only a disposable consumable dedicated for blood transfusion can be used in combination with it.
- The methods of installing different types of infusion tubes on the pump are different. To obtain the information about how to prepare and use an infusion tube, refer to the instructions for use and package of this infusion tube.

⚠ **CAUTION:**

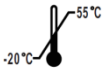
- The applied part of the infusion pump is the infusion tube and infusion needle.
- Infusion should be started only when the values on the prescription are the same as the values set on the infusion pump.
- In order to prevent extra infusion, close the rolling clamp of the infusion sets before separating the infusion sets from pump.
- Replace the infusion set or move the infusion set tube towards a certain direction for at least 10 cm every 8 hours during infusion to ensure continuous infusion accuracy.
- Please properly install or carry the infusion pump to avoid device damage caused by crash,

fall, violent mechanical vibration or other external force.

- Before pressing the [START] key, check if the infusion rate is correct, especially the position of the decimal point.
- An occlusion alarm may be generated when high-viscosity liquid is infused at high rate through a thin intravenous needle. In this case, increase the occlusion level or decrease the infusion rate.
- Infusion pump should be placed without the reach of patients and other irrelevant personnel.
- Avoid direct sunshine, high temperature and high humidity.
- Do not autoclave the infusion pump.
- Before using the internal battery, check the battery to ensure that sufficient power is available. Recharge the battery if required.
- Ensure that a battery is installed in the infusion pump before operation. Otherwise, the system may stop working without reporting 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 infusion 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-circuit. 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 cloth and use the pump after inspection by maintenance personnel.
- The maximum temperature at the applied part of the pump may reach 40.4℃ when the pump runs continuously under the highest environment temperature at the highest infusion rate.
- The infusion pump may not generate an infusion pressure that exceeds the maximum occlusion level 1175mmHg.
- The delay time between the onset of the alarm condition and the representation of the alarm is not longer than 150ms.
- After the pump is exposed to a defibrillation voltage, the recovery time of the pump is shorter than 1s (the pump functions properly during exposure to the defibrillation voltage).

Symbols:

EC REP	Authorized Representative in the European Community
CE 0123	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer
SN	Serial number
MD	Medical device.
	Defibrillation-proof type CF applied part
	Alternating current
	Direct current
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Separate collection of such waste for special treatment is necessary.
	CAUTION! Read the accompanying document.
	General warning sign
	Refer to the operation manual
IPX2	Level of protection against liquid intrusion
	Interference may occur near the devices with below sign.
	Nurse Call
	ON/OFF
	HOME

	OPEN
	Protective earth.
	This way up
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Atmospheric pressure limitation
	Temperature limit
	Humidity limitation
	Stacking limit by number (n is 5, 9…, for the specific value, see the product package box.)
	USB2.0 interface
	Direction of infusion
	When installing an infusion set, do not bend or twist the infusion set.

3 Product Specifications

Product name	Infusion pump
Model	SYS-6010 Series
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 7.2V 2600 mAh Battery model: 18650-2S1P-02 Continuous use time of battery: not less than 5 hours (for infusion at 25 ml/h rate with a new battery)
Compatible infusion sets	All disposable infusion sets conforming to the ISO 8536-4 and ISO 8536-8 standards
Infusion mode	SYS-6010A: Rate, Time, Weight, Loading Dose, Trapezia, Sequence, Micro and Drip Mode. SYS-6010 and SYS-6010T: Rate, Time, Weight, Sequence and Drip Mode.
Infusion setting range	0.10-1200ml/h
Minimum Increment of Infusion Rate	0.10-99.99ml/h (minimum increment: 0.01ml/h) 100.0-999.9ml/h (minimum increment: 0.1ml/h) 1000-1200ml/h (minimum increment: 1ml/h)
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	0.00-9999.99ml
Accuracy	±5%
Purge operation	1200ml/h
Bolus operation	0.1~1200ml/h Automatically calculate the bolus rate by bolus amount, cannot lower than the current rate.

Bolus VTBI	0.10-50.00ml
Anti-Bolus	Anti-bolus function, unintended bolus ≤ 1.0 ml
KVO rate	0.1-5.0ml/h
Single Bubble	Air bubble alarm accuracy is ±15μl or ±20% (whichever is greater). Bubble Level: 25, 50, 100, 200, 300, 500, and 800 (μl)
Total Bubbles	Bubble Level: 100μl/15min, 200μl/15min, 400μl/15min, 500μl /15min, 600μl/15min, 800μl/15min, and 1000μl/15min
Occlusion level	SYS-6010A: 225mmHg~975mmHg, 11 levels are available SYS-6010 and SYS-6010T: 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 , Standby Time Expired, Pre OCCL
Special function	Repeat alarming: After the sound of an alarm is muted, this alarm is reported again two minutes later if it persists. Event recording: A maximum of 2000 events can be stored for playback. Sound volume: 10 levels are available Power supply switching: When AC/DC power supply is cut off, the infusion pump automatically switches to internal battery supply Barcode scanning: Input the patient information by barcode scanning
WI-FI function	Connect Infusion Central Monitoring System to monitor the infusion status.
Drug Library(only for SYS-6010A)	A maximum of 2,000 drug types can be stored.
Operating conditions	Temperature: 5℃ to 40℃ Humidity:15% to 95% RH, non-condensing Pressure altitude: 70.0 kPa-106.0 kPa

Product Specifications

Operating Altitude	≤ 3000m
Storage and shipping conditions	Temperature: -20 ℃ to +55 ℃ Humidity: 10% to 95% RH, non-condensing Pressure altitude: 22.0kPa-107.4kPa
Classification	1. Class I / Internally powered equipment; 2. Defibrillation-proof 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 1.4 kg (including battery)
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 EN1789:2007+A2:2014:Medical vehicles and their equipment-Road ambulances

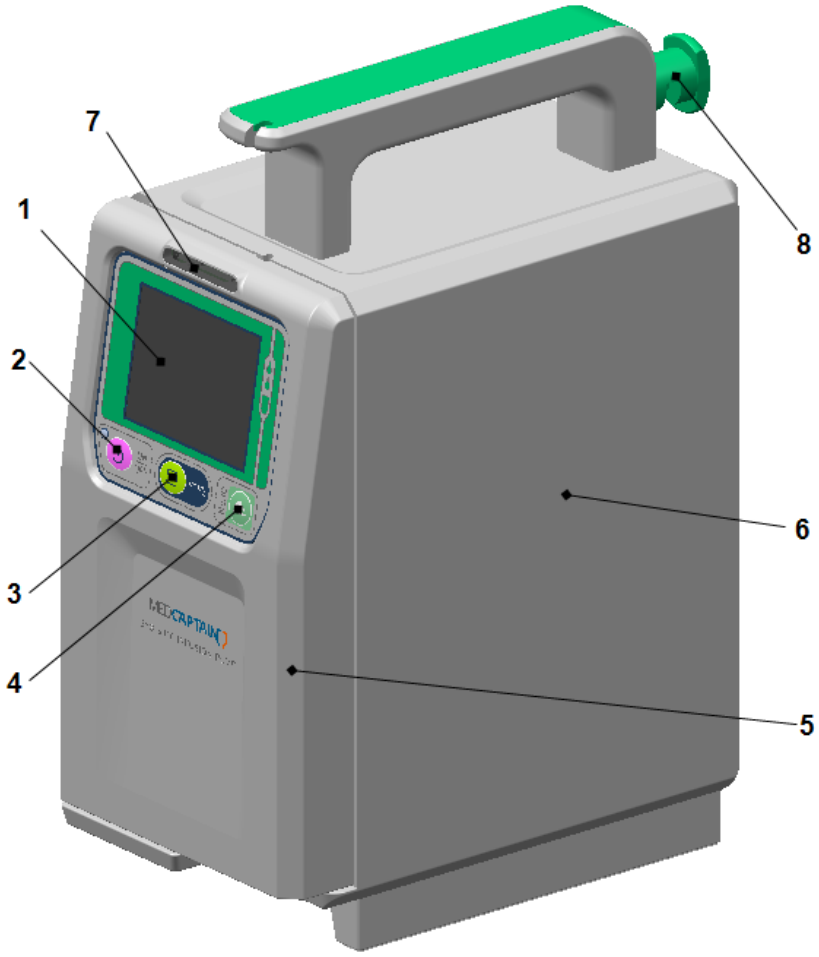
4 Product Description

4.1 Operating Principle

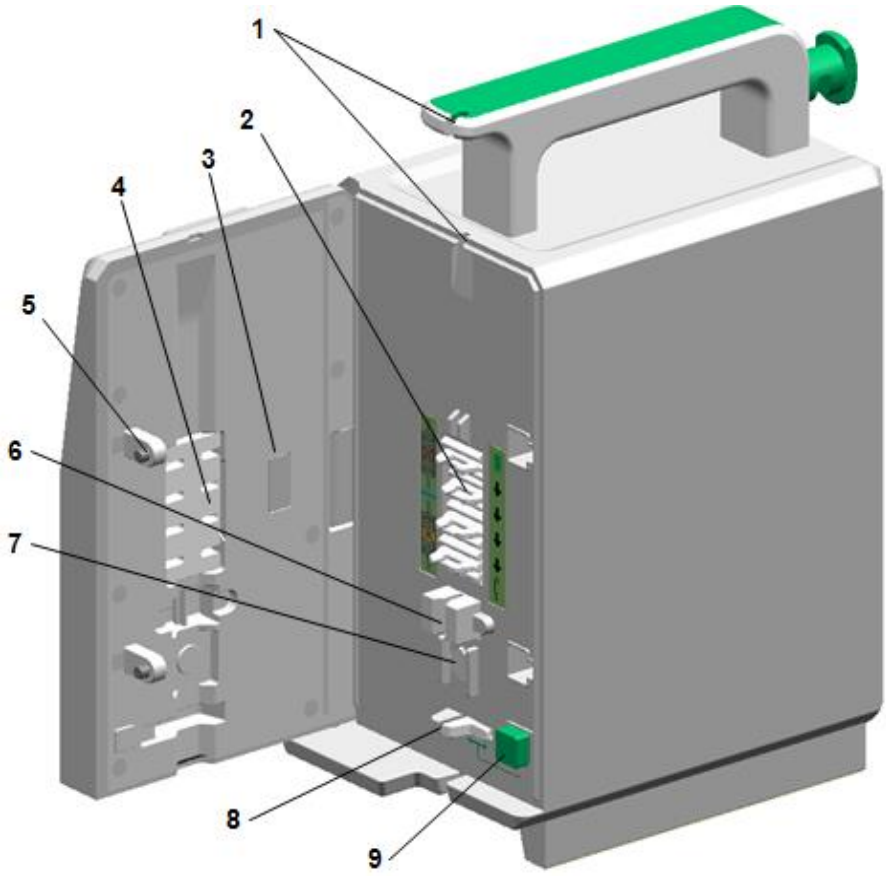
The SYS-6010 Series infusion pump mainly consists of pump shell, display screen and operating system, monitoring system, alarm system, motor drive system, tubing peristaltic module, power supply system, drop sensor, WI-FI communication module (optional), handle (optional) and pole clamp (optional).

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

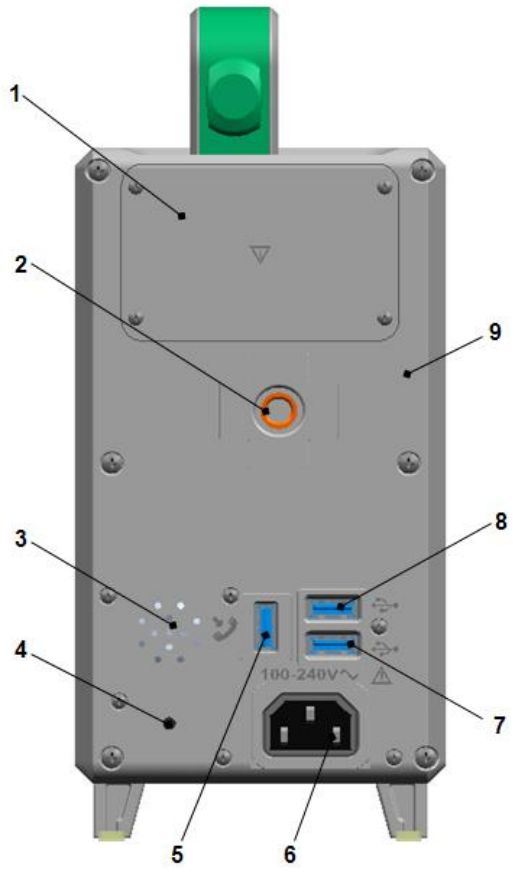


1 –Touchscreen	2 – [HOME]key	3 – [ON/OFF]key
4 –[OPEN]key	5 –pump door	6 –Shell
7 –Alarm indicator	8 –Drop sensor holder	



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

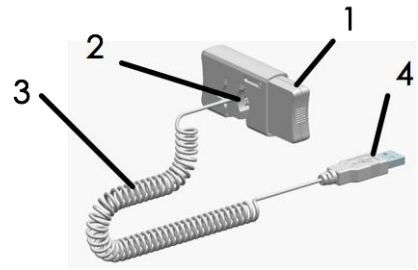
- Battery chamber. Replaceable battery inside the chamber.
- Threaded hole. To fix the pole clamp, then fix the pump to the IV pole via the pole clamp.
- Buzzer. To alarm in high, medium or low level during infusion and enable voice conversation.
- Auxiliary alarm. Audible alarm sounds when product functions abnormally.
- AC power inlet. To connect the external AC power source.
- External inlets1, 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, and external DC power cord. The external inlet 1 and 2 can be used as the interface for the local WLAN.

⚠ **CAUTION:**

- Only the accessories or devices specified by the manufacturer are allowed to be connected to the pump. Otherwise, an electric shock may occur. See Table4-1.

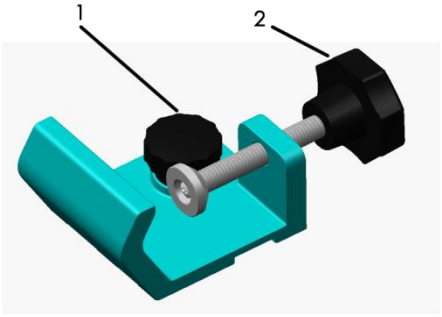
- Additional equipment connected to medical electrical equipment through the network/data coupling (USB or LAN port) must comply with the respective IEC or ISO standards (e.g. IEC 60950 and IEC 62368-1 for data processing equipment). All configurations shall comply with the requirements for medical electrical systems (see clause 16 of the 3Ed. of IEC 60601-1, respectively).
- Anybody connecting additional equipment to medical electrical equipment configurations a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.
- The plug is used to disconnect from the mains supply. Install the pump at a position where an operator can insert and remove the plug conveniently.

4.3 Drop Sensor



1 –Button 2 –Drip hole 3 –Cable 4 –Socket

4.4 Pole Clamp



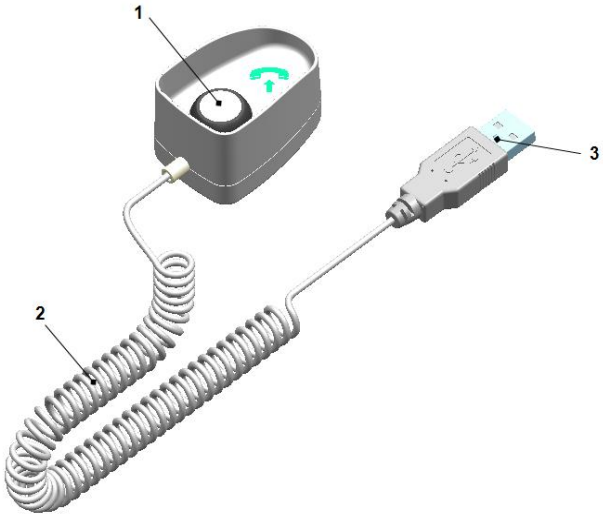
1 - Mounting screw 2 - Mounting knob of IV poled

⚠ **CAUTION:**

- The recommended diameter of the IV pole is 16~36mm. Any size beyond this range may cause insecure installation.
- Ensure that the floor is solid and level. Don’t fix other equipment on the IV pole to prevent the pole from falling over.

- During installation, ensure that the knob and mounting screw are tightened up.

4.5 Nurse Call



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
Power cable	Standard configuration by factory
Lithium battery pack	7.2V @ 2600mAh
Nurse Call	MP-2
Drop sensor	MP-3
Barcode scanner	MP-4
Pole clamp	——
DC power cable	—

5 Preparations for Use

- Before using the infusion pump, read carefully the operation procedures and precautions in this manual.
- Before using the infusion pump for the first time, set 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 hours connected to an external power supply.
- Place the infusion pump on a stable platform.
- Alternatively, 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.
  - This equipment is in accordance with the EN1789:2007+A2:2014 standard. It can be fixed on ambulance with 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.
- For the first time to use the infusion pump or after changing the infusion brand set, please contact the engineer authorized by Medcaptain to conduct an infusion accuracy calibration.

⚠ **CAUTION:**

- Do not install the infusion pump at a place not convenient for an operator to connect the AC power.

6 Operating Instructions

6.1 Display and Keys

- Display

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

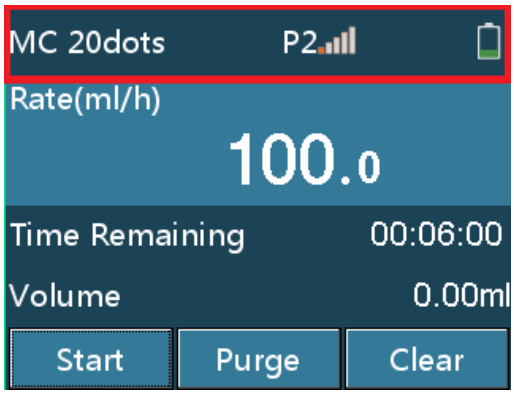
4 –ON/OFF key | 5-OPEN key

The alarm indicator indicates the alarm severity (high, medium, or low) with three colors: red, yellow and green. The alarm severity is determined based on the criticality of infusion information.

TFT Touchscreen, resolution: 320x240 pixels

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

Information area: Displays the infusion set brand and specification, occlusion level, real- time pressure, external power source, battery capacity and WI-FI signal. Touch the brand and specifications zone to enter the page for infusion set brand adjustment. Touch the occlusion pressure level to enter the page for occlusion level selection. See below for further description.



Occlusion pressure level: 2


Real-time occlusion pressure: Five bars in total. A larger number of illuminated bars indicates a higher pressure.

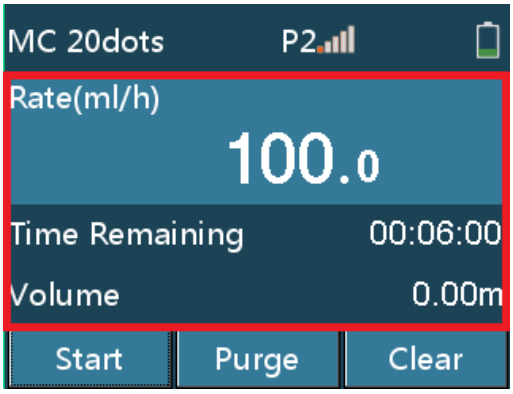

External power source symbol. This symbol is displayed when the pump is connected to an external AC/DC power source.


Screen lock symbol. Two states exist: lock and unlock.

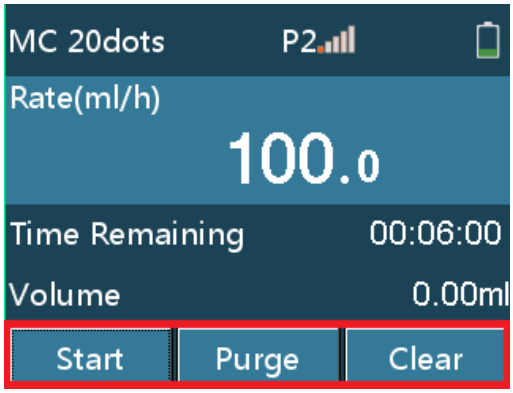

Battery volume and charging status. Three bars in total. A larger number of illuminated bars indicates a higher remaining battery capacity.


WI-FI signal

Work data area: Displays the current infusion rate and infusion volume or displays different infusion work data based on different infusion modes. The work data can be adjusted by touching the specific zone in different working modes.



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



- Keys

In addition to touchscreen keys, three keys are available on the key panel: [HOME], [ON/OFF] and [OPEN].

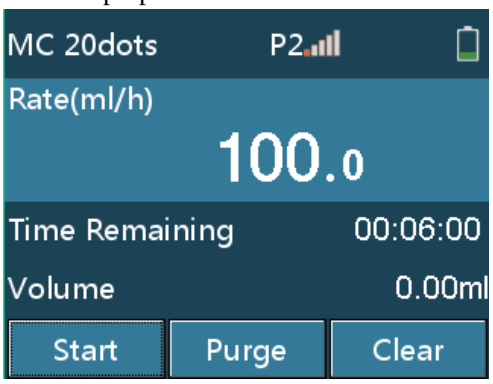
- [HOME]: Main menu key. Before infusion, press [HOME] once to enter a setting menu, such as Infusion set, Local set, History and Interconnect set. To return to the infusion preparation screen, press [HOME] once again on any setting interface. During infusion, press [HOME] to switch to infusion interface, enlarge and display the infusion rate.
- [ON/OFF]: Key for switching on/off the pump. When the pump is off, press [ON/OFF] to turn on the pump. When the pump is on, press [ON/OFF] and select [Power Off]] or press and hold [ON/OFF] for 3 seconds to shut down the pump.
- [OPEN]: Door open key. The pump door opens automatically when [OPEN] is pressed no matter whether the power is on or off. Push the door forward gently till you feel a resistance and hold for a while for the door to close automatically.

6.2 Starting the Pump

⚠ **CAUTION:**

- Start the pump and then install the infusion set.
  - Press [ON/OFF] to start the pump.
  - The self-test starts and startup interface appears.
  - After self-test finishes, the infusion preparation interface is displayed.
  - The screen displays patient information, infusion brand and occlusion level stored last time the device is powered off.
  - If the self-test is abnormal, corresponding information is displayed in the information area.

Infusion preparation interface:



WARNING:

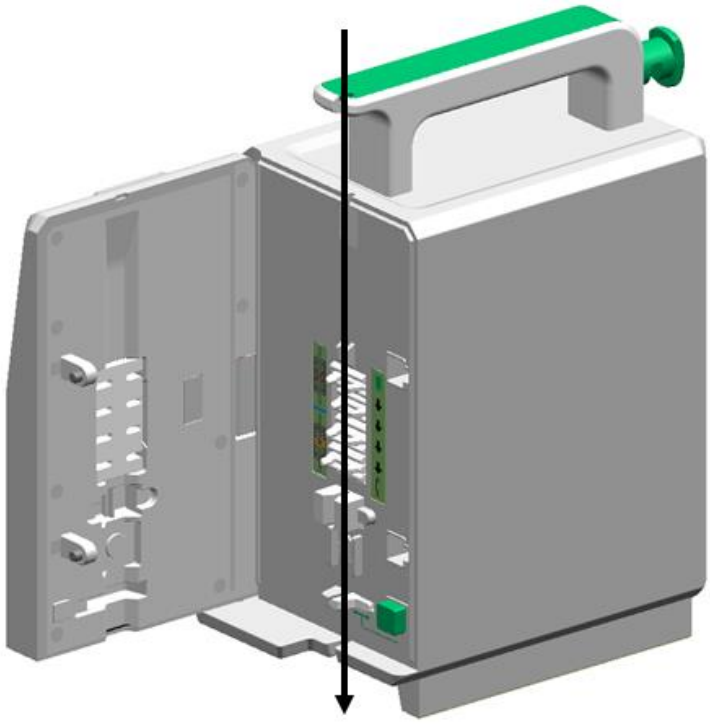
- After the pump is powered on, confirm that the loudspeaker and alarm indicator work properly. In addition, check if the self-test is finished and no error messages appear. (Refer to Chapter 8 Troubleshooting.)
- Ensure that the infusion set brand displayed is consistent with the brand of the infusion set actually used.
- If the infusion set brand set differs from the brand of the infusion set actually used, the infusion accuracy and alarm function cannot be guaranteed.

6.3 Infusion Set Installation

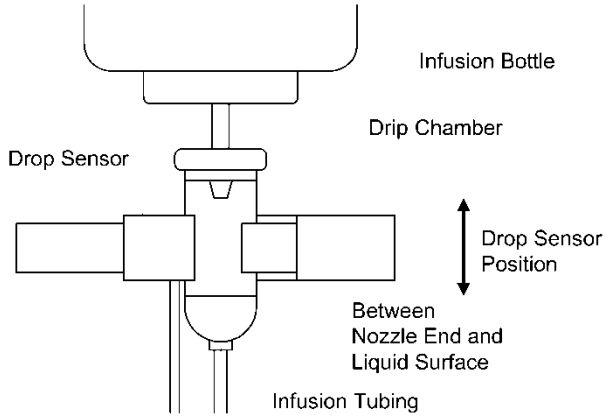
- Insert the needle into IV bottle vertically, and the liquid infuses into the drop chamber.
- When the liquid level is at 1/3 of the drop chamber, open the roller clamp.
- Infuse liquid into the tube to purge the air, and then close the roller clamp to avoid free flow.
- Press [OPEN] to open the pump 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, and then stretch the tube. Make sure that the tube is inside both ends of the tube slit, and then push the pump door to close it.

CAUTION:

- Ensure that the infusion bottle is higher than the patients and pump for 20-80cm.
- The roller clamp must be installed between the patient and pump and under the pump to avoid undetected upstream occlusions.
- Inaccurate infusion may be caused if the tube is too loose or too tight.
- The tube must be fixed into the air bubble sensor completely.
- Before replacing the IV bottle (IV bag), stop the infusion and close the roller clamp.
- Before closing the pump door, ensure that no foreign matters block the door.



- Install the drop sensor



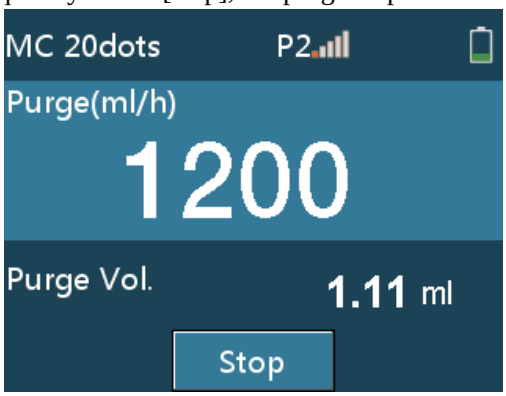
⚠ **CAUTION:**

- To ensure the accuracy of drop detection, the drop sensor should be installed as close as possible to the down liquid level. The liquid level is appropriate to be at the 1/3 of the drop chamber.
- The liquid in the drip chamber should lower than drop sensor.
- Prevent the drop sensor from being tilt and always stay out of the sun during infusion.
- Prevent the drip bottle from being clipped too tight by the drop sensor.
- The drop sensor detects drip but does not measure fluid flow. Drop signal is undetectable if continuous fluid 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.
- Purging can be done only in non-infusion process.
- Stop purging after ensuring that liquid is drained out from the needle.
- Air bubble detection alarm function is disabled during purge.
- Click [PURGE], and then click [yes] on the pop-up interface, the infusion pump starts purging quickly. Click [stop], the purge stops.



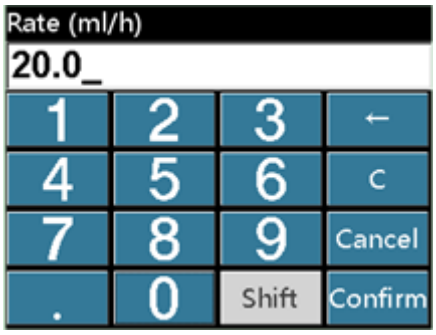
- The green indicator flashes during purging.

CAUTION:

- When high viscosity IV fluids are infused through thin vein needle by bolus operation, occlusion alarm may be generated. In this case, reduce the infusion rate 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.

WARNING:

- VTBI is not set or set improperly for the infusion. Consequently, the Near End and Infusion End alarms may fail.

⚠ **CAUTION:**

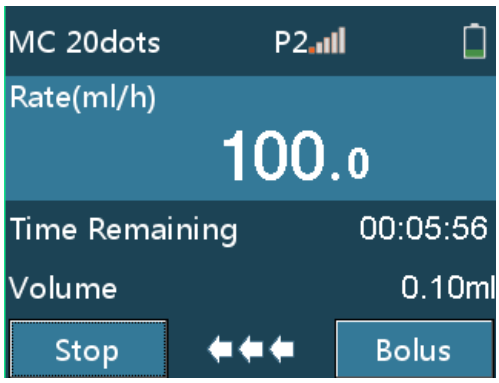
- After you change the infusion rate and confirm the change during infusion, subsequent infusion is performed at the rate after the change.

6.6 Puncture

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

6.7 Starting Infusion

Click [START] to start infusion at the setting rate. The green indicator flashes.

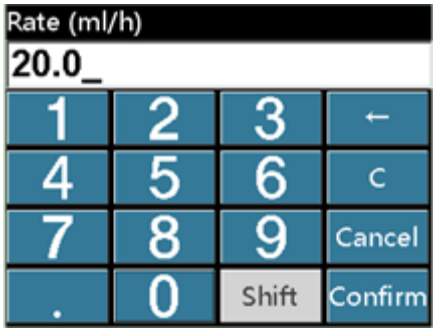


⚠ **CAUTION:**

- Infusion should be started only when the values on the prescription are the same as the values set on the infusion pump.
- If no operation is performed after infusion set installation for more than 2 minutes, the START-REMINDER alarm is reported.

6.8 Changing Rate During Infusion

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



- After entering the rate, if you click [Cancel], the system returns to the original infusion interface without change. If you click [Confirm], the system returns to original infusion interface and operates at the new rate.

⚠ **CAUTION:**

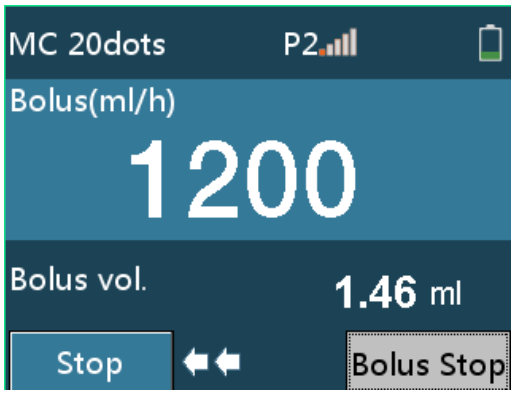
- If no operation is performed on the reference or rate setting interface for more than 10 seconds, the system returns to the infusion interface automatically.

6.9 Bolus

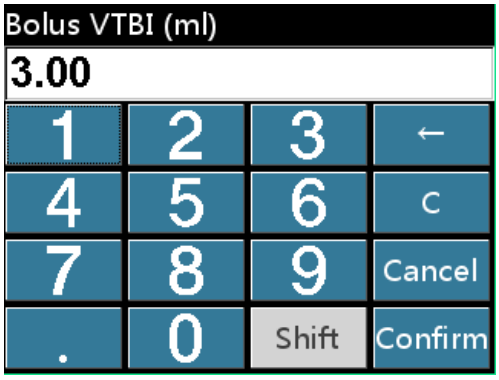
SYS-6010T and SYS-6010A: Support three bolus modes, that is, manual bolus, rapid quantitative bolus, and automatic bolus.

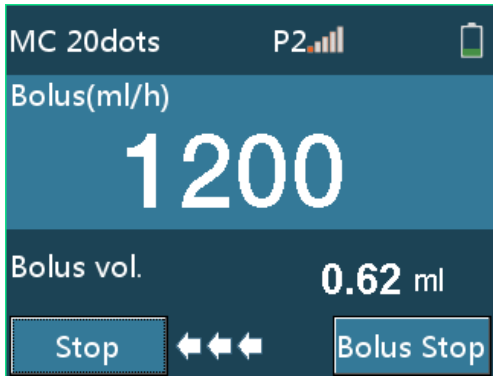
SYS-6010: Only supports automatic bolus.

- Choose “Manual bolus”, during the infusion, press and hold [Bolus] for 1s to enter the bolus interface. Bolus continues while the button is pressed and held and stops immediately when the button is released.

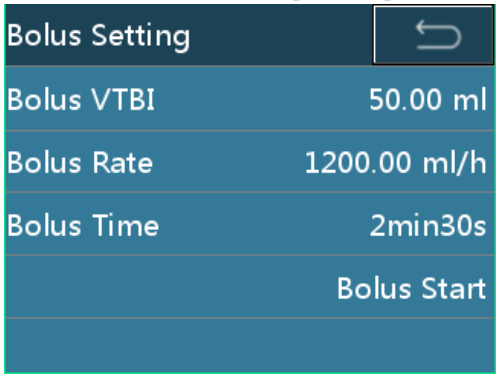


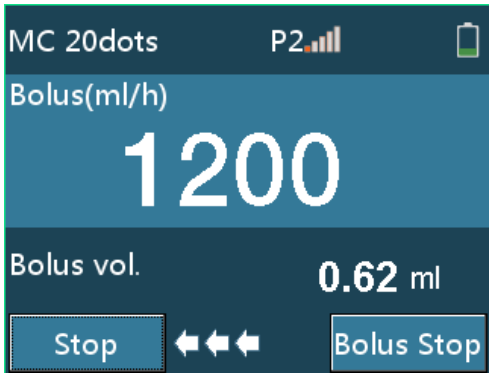
- Choose “Rapid quantitative Bolus”, during the infusion, click [Bolus] to enter the bolus VTBI interface, set the bolus volume, click [Confirm] to start and click [Bolus Stop] to stop the bolus and return to infusion interface.





- Choose “Automatic 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 infusion set specification as follows.

⚠ **CAUTION:**

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

6.10 Stopping Infusion

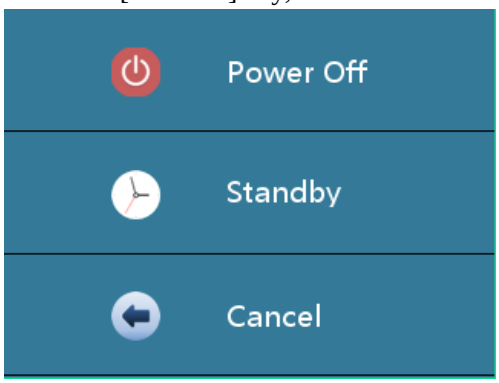
In the infusion process or after infusion, press the [STOP] key to stop the operation and green indicator will be off.

6.11 Replacing or Adjusting Infusion Set

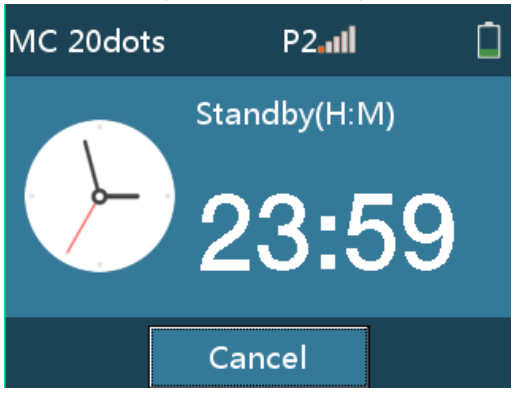
Due to extrusion, the tube of an infusion set is damaged after continuous infusion, which affects the infusion precision. After continuous infusion with an infusion set for about eight hours or for a locally stipulated number of hours, you are suggested to stop infusion, open the pump door, and move the IV tube to a position about 10 cm away from the original position to ensure continuous infusion precision. Alternatively, you can directly replace the whole infusion set.

6.12 Powering Off the Pump

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



- Click [Power Off] to shut down.
- Click [Standby] to enter standby interface, the standby time can be modified.



- Click [Cancel] to return to the previous interface.

7 Setting the Infusion Pump

⚠ **CAUTION:**

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

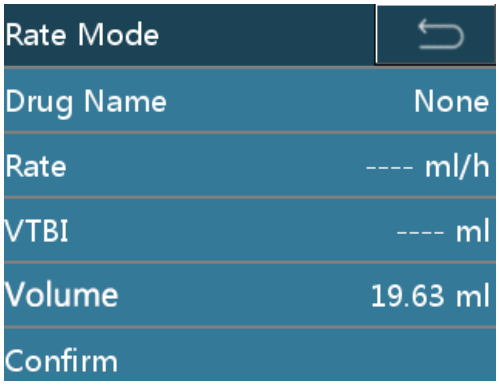
7.1 Infusion Set

Press the [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, micro mode, bubble level, near finished and recent therapy can be set and adjusted here.

7.1.1 Infusion Mode

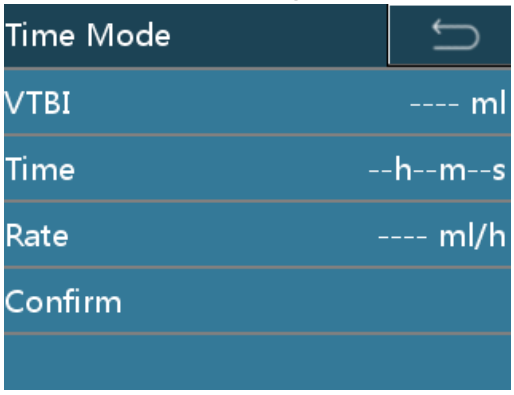
■ Rate mode

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



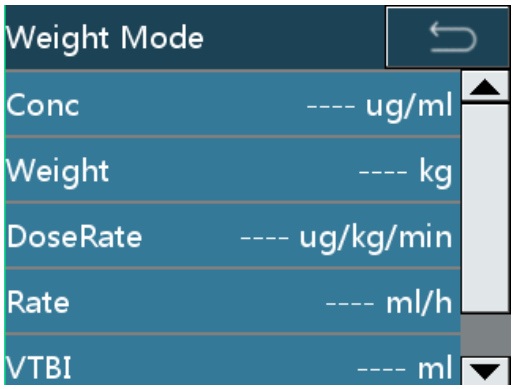
■ Time mode

In Time mode, set the drug name, VTBI and Time, and click [Confirm] to operate.



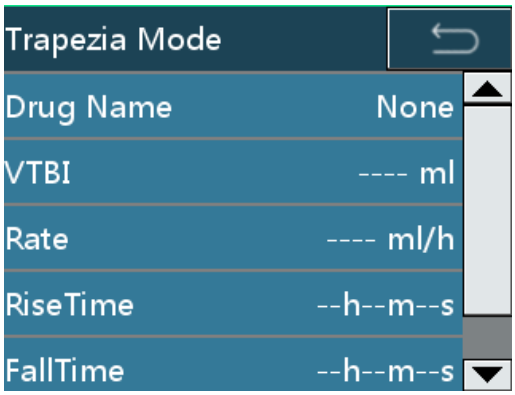
■ Weight mode

In Weight mode, set the drug Info, Dose Rate, Weight and VTBI, wait for the device to calculate the rate automatically, and then click [Confirm] to operate.



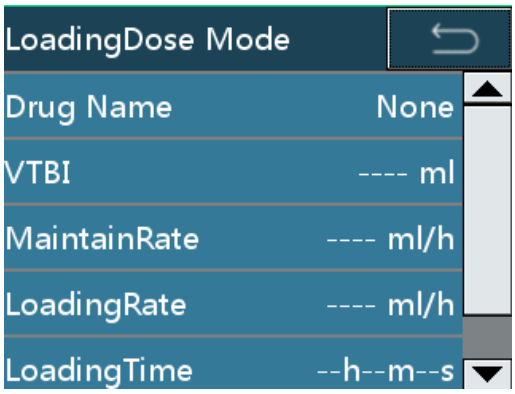
■ Trapezia mode

In Trapezia mode, set the drug name, VTBI, rate, rise time and fall time, wait for automatic calculation of the rate, and then click [Confirm] to operate.



■ Loading Dose mode

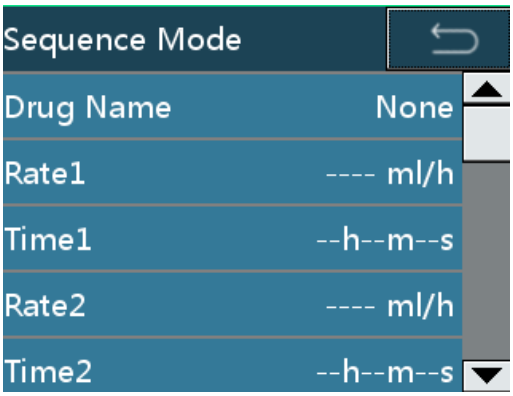
In Loading Dose mode, set the drug name, VTBI, maintain rate, loading rate and loading time, wait for automatic calculation of the rate, and then click [Confirm] to operate.



■ Sequence mode

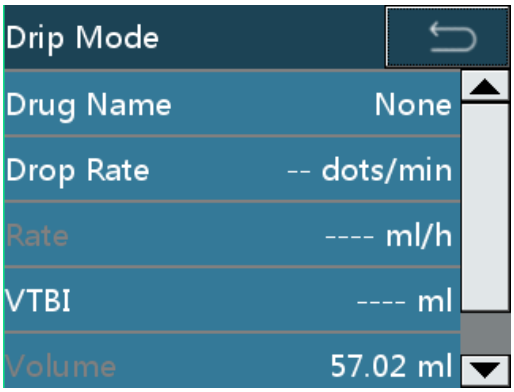
In Sequence mode, set the drug name, groups of sequence rate, and time, and click [Confirm] to operate in sequence.

SYS-6010: Supports 5 groups of sequence.
SYS-6010T and SYS-6010A: Support 10 groups of sequence.



■ Drip mode

In Drip mode, set the drug info, loading dose, loading time dose rate and weight, wait for automatic calculation of the rate, and then click [Confirm] to operate.



⚠ **CAUTION:**

- The pump will calculate the corresponding rate according to the current drip rate (dots/min) and current infusion set's specification.
- The pump controls the flow by using corresponding flow rate (ml/h) but not by detecting the drip rate (dots/ml).
- The drug library function (only for SYS-6010A) can be applied to all working modes. The therapy data of the drug library is not edited by the manufacturer.

7.1.2 Occlusion Level

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

Table 7-1 Relationship between occlusion level and pressure

Occlusion level	Display	Pressure(mm Hg)	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:**

- When an occlusion alarm is reported, the motor automatically rotates reversely to release the tube pressure (Anti-Bolus) for preventing infusion of extra amount of pills into a patient after the occlusion alarm is cleared. When the tube pressure drops to 30% of the occlusion pressure, Anti-Bolus automatically stops.
- When you infuse viscous solution with the Occlusion Level setting under 1 and the tubing is clear, occlusion alarm tends to be generated. Carefully watch the  symbol in the upper information area, and change the occlusion level if more than 2 bars are illuminated.
- When you operate the pump with the Occlusion Level setting on level 3, the in-line pressure builds up substantially until Occlusion alarm is generated. Always make sure that the IV line is securely connected to the pump.
- An occlusion alarm may be generated when high-viscosity liquid is infused at high rate through a thin intravenous needle. In this case, increase the occlusion level or decrease the infusion rate.

7.1.3 Bolus Mode

- Three bolus modes are available: Manual Bolus, Rapid quantitative Bolus and Automatic Bolus. Please refer to chapter 6.9 for further instructions.

7.1.4 KVO Rate

- KVO-rate can be adjusted from 0.1ml/h to 5ml/h (Step by 0.01ml/h). The default rate is 1ml/h.

7.1.5 Brand

- You can choose the consumable brand in the following sequence: [Home] > [Infusion Set] > [Brand].
- Several brands of 20d/mL infusion set have been preset and customized. Select the infusion

accordingly for clinical use.

⚠ **CAUTION:**

- Users must use the consumable brand which is specified by the manufacturer.
- To add infusion set of other brand, users are strongly recommended to contact the supplier of the infusion pump to set and test, so as to ensure the infusion accuracy.
- Only the infusion set complying with the requirements in *ISO 8536-4: Infusion equipment for medical use-Part 4: Infusion sets for single use, gravity feed* and *ISO 8536-8: Infusion equipment for medical use-Part 8: Infusion sets for single use with pressure infusion apparatus* can be used on this infusion pump. However, before using a gravity infusion set, the user must evaluate the risk that might be introduced by the gravity infusion set. If you are not sure whether the infusion set meets the requirements, please contact your local distributor.

7.1.6 Drip Mode Set

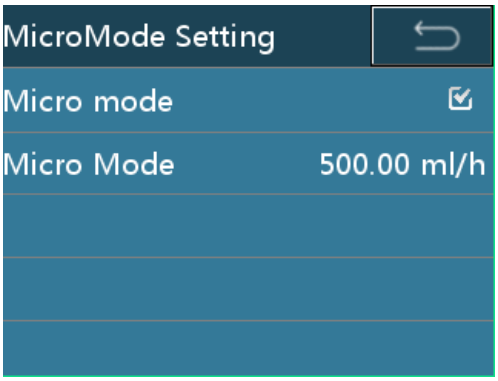
- Open the drip mode, detect the drop sensor and count the drops during infusion.

⚠ **CAUTION:**

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

7.1.7 Micro Mode Set

- After Micro mode is selected, the maximum rate can be set in the mode.



7.1.8 Bubble Level

- The infusion pump allows you to set the bubble level for the single bubble and total bubbles.
- Bubble level for single bubble: 25, 50, 100, 200, 300, 500, and 800 (μl).
- Bubble level for total bubbles: 100μl/15min, 200μl/15min, 400μl/15min, 500μl/15min, 600μl/15min, 800μl/15min, and 1000μl/15min.

  Note: When the bubble level for total bubbles is set to 100μl/15min, the infusion pump reports an alarm if the total bubbles reach 100μl within 15min.

⚠ **CAUTION:**

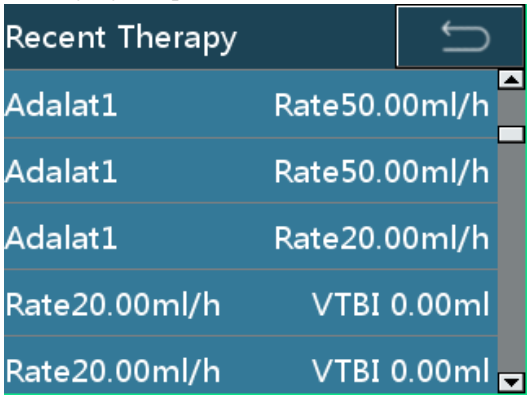
- Choose L gear level to detect bubbles may cause discomfort or danger to the patient, according to the actual clinical choose the right gear, and closely observe if there is any abnormal immediate measures should be taken

7.1.9 Near Finished

- The Near Finished alarm is generated when infusion is almost completed. The duration from generation of this alarm to infusion completion can be adjusted from 1 min to 30 min (adjustment step: 1 min). By default, this alarm is generated 3 minutes before infusion completion.

7.1.10 Recent Therapy

- The therapies of the recent 20 times are recorded. The recorded therapy can be started directly by simple selection.



7.2 Local Set

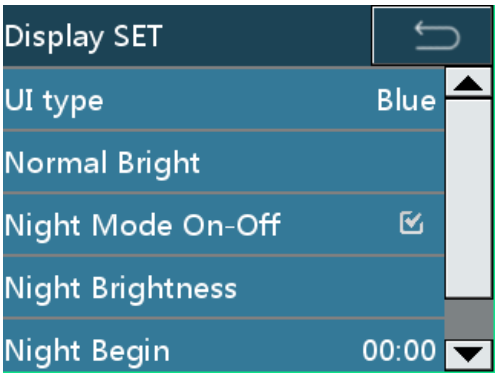
7.2.1 Volume Setting

- Ten volume levels are available (the factory setting is level 5).

⚠ **CAUTION:**

- Do not set the alarm volume to a level lower than the ambient noise to ensure that the alarm can be recognized correctly.

7.2.2 Display SET



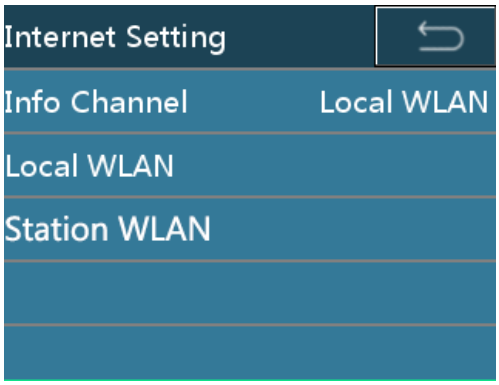
- Seven different color options are available for UI type.
- The brightness can be adjusted in [Normal Bright].
- All the parameters of the night mode can be adjusted here.

⚠ **CAUTION:**

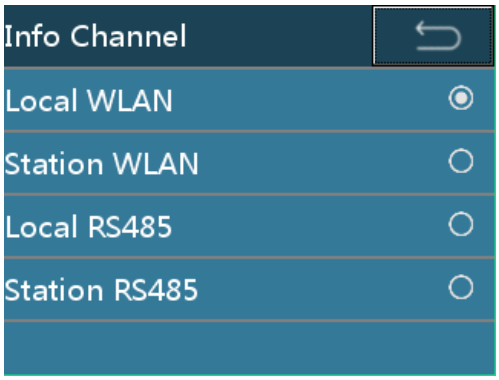
- In night mode, the setting range of start time is 17:00-09:00, and the setting range of finish time is the same as that of start time. By default, the start time is 00:00 and finish time is 00:00.

7.2.3 Internet Set

- [Info Channel], [Local WLAN].

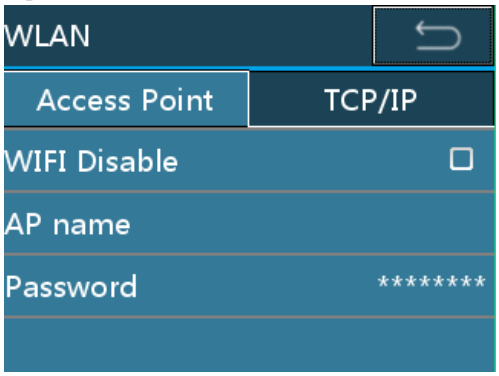


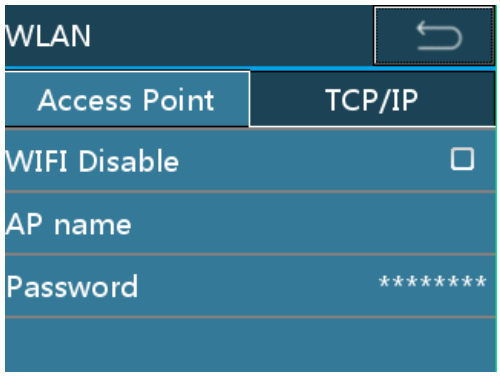
- Click [Info Channel] to choose the channel type.
  - Choose [Local WLAN] to use local WLAN channel to connect to the network, and the local WLAN parameters can be set.
  - Choose [Station WLAN] to use station WLAN channel to connect to the network, and the station WLAN parameters can be set.
  - Choose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

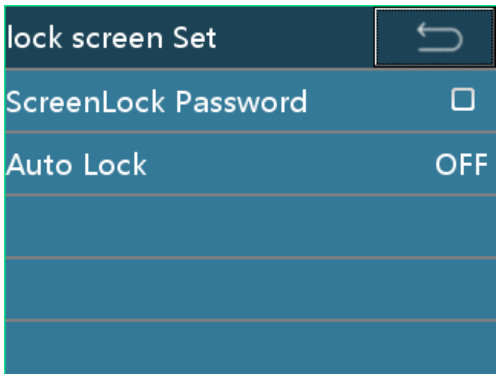
- The setting of local port should be operated by professionals specified by the manufacturer. Contact the distributor or manufacturer.
- Only the accessory and devices supplied or specified by the manufacturer are allowed to be connected to the pump. Otherwise, pump exception and other unpredictable hazards may be incurred.
- Click [Local WLAN]/[Station WLAN] to set up WLAN parameters.
- [WI-FI Disable] must be deselected, the AP name and Password of the network must be input, and the TCP/IP's information must be set.





7.2.4 Lock Screen Set

- Click [Screen Lock Password] to enable/disable the screen lock password function. When the function is enabled, a password is required to unlock the screen. When the function is disabled, no password is required to unlock the screen.
- Click [Auto Lock] to set the screen auto lock function. This function can be set to: OFF, 15s, 30s, 1min, 2min, 5min, 10min, or 30min. The default value is OFF, indicating that the screen auto lock function is disabled.



7.2.5 Collection Set

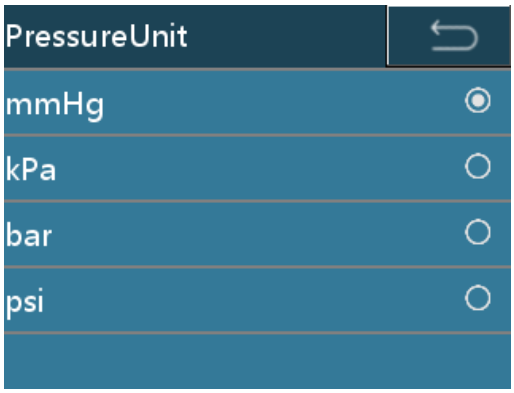
- [Mode Collection]: Choose the frequently used infusion mode from the [Infusion mode] option. Once the frequently used infusion modes are chosen, the unnecessary modes will not appear in the list of 7.1.1 [Infusion mode] option. The default setting is “all the four infusion modes are chosen”.
- [Brand 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”.
- [Drug Collection] (only for SYS-6010A): Choose the frequently used drug from the drug library. Once the frequently used drugs are chosen, the chosen drugs will be shown on the top of the drug library list. The default setting is “none of the drug is chosen”. The data of the drug library is not edited by the manufacturer.

7.2.6 Linkage 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.

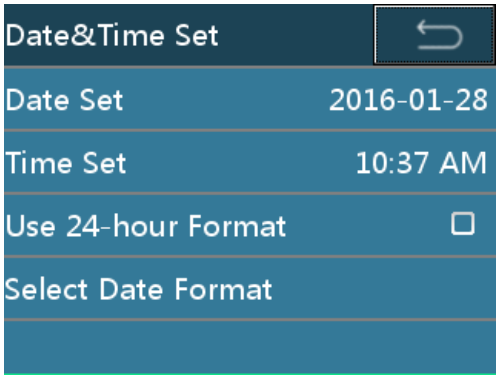
7.2.7 Pressure Unit

- Choose the measurement unit for the pressure. The optional units are: mmHg, kPa, bar andpsi. The default setting is mmHg.



7.2.8 Date & Time Set

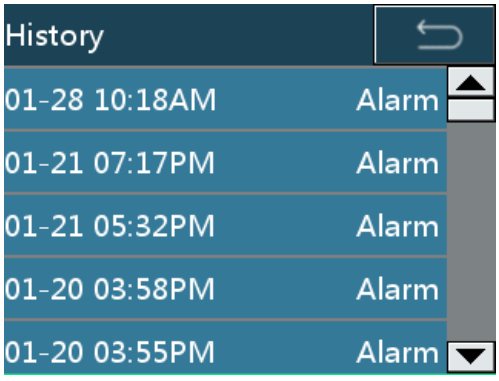
- Set the date, time, and their format.

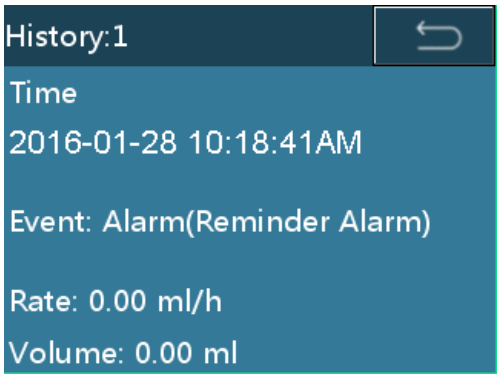


7.2.9 Maintenance

- 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 listed in Table 7-2.

Table 7-2 History records

Event	**Record Parameters**
Start up	Occurrence time

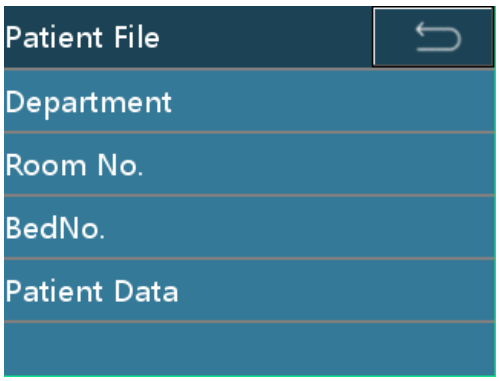
Shutdown	Occurrence time
Standby	Occurrence time, standby set time
Start	Occurrence time, rate, VTBI
Bolus	Occurrence time, Bolus rate, Bolus way
Bolus stop	Occurrence time, Bolus rate, Bolus accumulated volume
Stop	Occurrence time, rate, accumulated volume
KVO	Occurrence time, accumulated volume, KVO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

⚠ **CAUTION:**

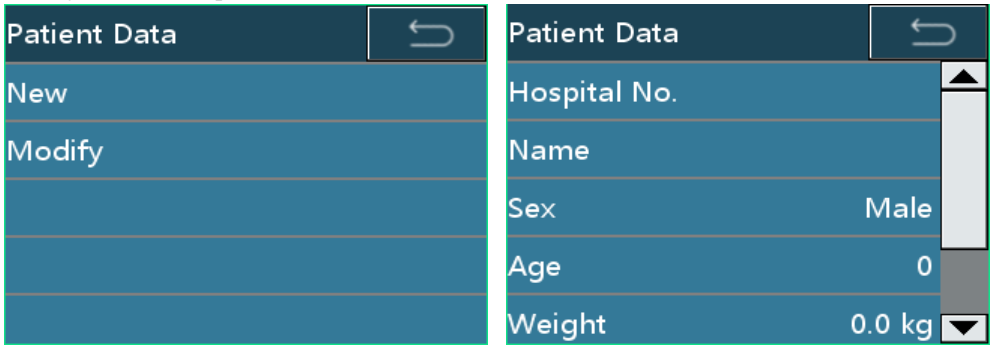
- The history records could be saved when power is cut.
- A maximum of 2000 history records can be saved. When the record number reaches the storage limit, the earliest record will be replaced by the new one.
- Alarm system can't be powered off separately by an operator unless the pump is powered off. 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] can be set.



- 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 no AC/DC power supply is available, the internal battery operates.
- When external battery stops working, the internal battery starts and the yellow indicator lights with a short alarm sound.
- Before using the pump for the first time or using the pump after the pump is not used for a long time, please charge the battery for at least 10 hours.
- The approximate 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.
- 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 [SILENT] 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.

- A fully charged new battery can be continuously used for not less than 2h at the rate of 1200 ml/h.
- A fully charged new battery can be continuously used for not less than 5h at the rate of 125 ml/h.
- 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 must not be operated through the < Infusion Central Monitoring System >.

7.7 Nurse Call (Optional)

After infusion pump is connected to the central station, patient can press Nurse Call in bed, and then the central station in nurse station would give out sound tip and display the symbol of Nurse Call in screen, so that the nurse can take care of the patient in time.

listen button and communicate with patient in real time to know the information.

7.8 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.

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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 generates an alarm and informs users in the form of sound, light, and character.

All the alarms on this pump are of technical type.

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 is steady on.
Mid-level alarm	Give out three beeps at intervals of 25 seconds.	The yellow indicator is flashing.
High-level alarm	Give out a series of beeps at intervals of 15 seconds.	The red indicator is flashing.

When an alarm (except **Battery out**) occurs, press [SILENT] to pause the alarm sound. But the buzzer beeps again if you do not eliminate the 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:**

- There will be a potential risk if the same or similar devices are using different alarm setting in any specialized region.

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 [SILENT] to stop the buzzing and wait until the infusion finishes.
Occlusion Alarm	High-level	The infusion tubes 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.

Alarm Symptoms	Alarm level	Causes	Troubleshooting
Reminder Alarm	Low-level	Forget to operate the alarm (no key operation is made two minutes after the infusion set is installed).	Press any key to clear the alarm.
Drop Error	High-level	During infusion, the drips are detected abnormal.	Press [Stop] to remove the alarm. Check the drop 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.
Pre OCCL	Middle-level	The occlusion pressure reaches 70% of the occlusion level setting value.	Release the pressure to eliminate the alarm.

8.3 Troubles and Troubleshooting

When the device is faulty, a corresponding trouble code appears on the interface and a high-level alarm is generated.

Table 8-3 Troubles and troubleshooting

Trouble code	Alarm level	Troubleshooting
Sensor Error	High-level	Record the trouble code, power off the pump, and 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 and Disinfection

- Before cleaning the pump, be sure to turn off the power and disconnect the AC or DC power cables, disconnect the device from the patient.
- 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 must not 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 disinfect 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.

9.2.1 Checking the Appearance

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

9.2.2 Checking 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.

9.2.3 Checking the Infusion Rate

- Check the infusion flow once every 2 years by using the graduate and stopwatch.

Checking condition:

Infusion set	Infusion rate	Infusion time	Volume in graduate
MC/B.Braun20d/ml	120ml/h	6min	11. 4-12.6ml

9.2.4 Alarm

- Occlusion alarm

Checking condition:

Infusion set	Infusion rate	Occlusion level	Alarm time
MC/B.Braun 20d/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.

9.2.5 Electric and Mechanical Safety

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

9.2.6 Checking 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 infusion time reaches 80% or more of the asserted battery operation time, the battery is in good condition.
  - If the infusion time is shorter than half of the asserted battery operation time, the battery reaches its service life and requires replacement. Contact the local distributor for battery replacement.
  - Record the infusion time when a battery alarm is triggered. If the infusion time is less than 30min after a Low Battery alarm occurs or the infusion time is less than 3min after a Battery Empty alarm occurs, contact the local distributor for battery replacement.
- After the battery level check is completed, recharge the battery for next use.

9.2.7 Replacing 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 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 can 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 Recycling

At the end of the product's service life, please contact the manufacturer or manufacturer's representative for disposal advice. Alternatively, dispose of the product and its battery according to the local 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 IEC 60601-2-24:2012 standard.)

⚠ **CAUTION:**

- The infusion accuracy and the occlusion response may be affected by the use conditions including the pressure, temperature, humidity, infusion 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.
- In single fault condition, the maximum infusion volume is 5ml.

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 performed in 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): 5 sets each.

Infusion pump: 1 set

Sampling interval: 0.5 min

Test Period: 120 min

Test Liquid: ISO 3696:1987 Class III water

Infusion Accuracy Characteristics

Table 10-1 Accuracy test result

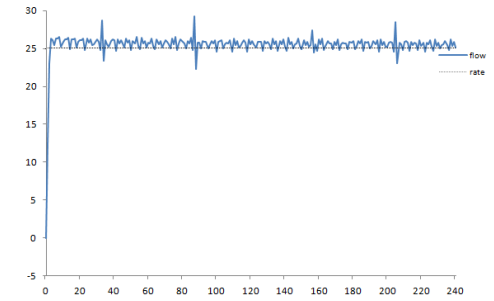
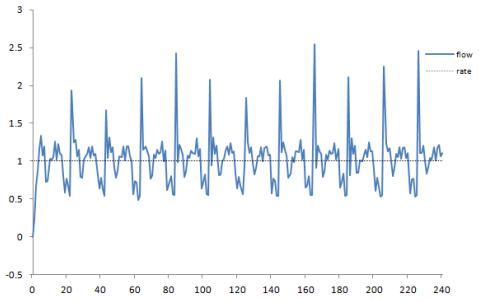
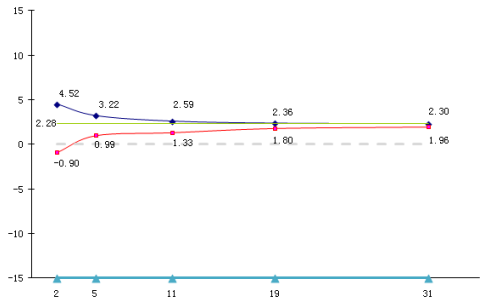
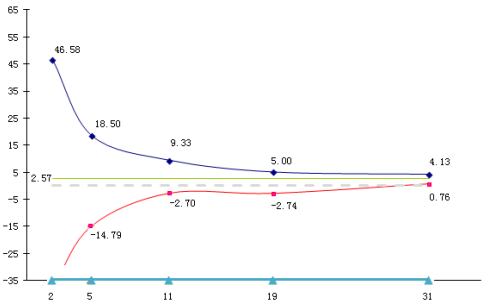
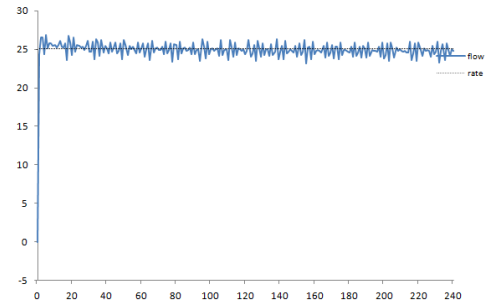
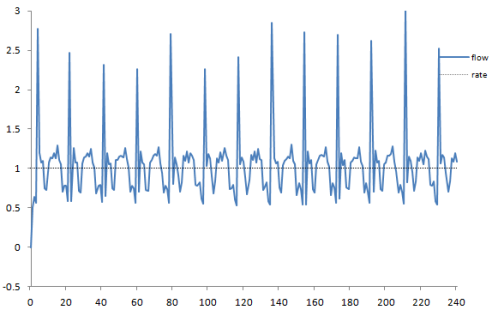
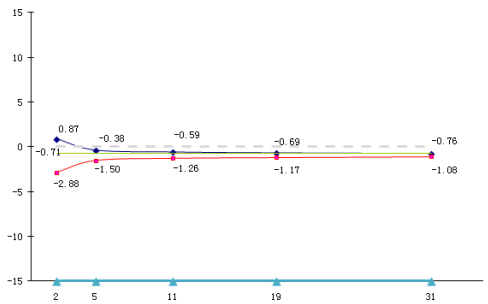
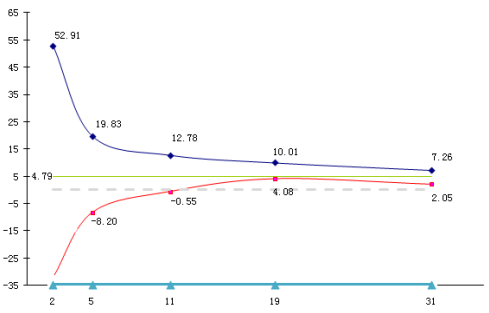
Administration set (infusion set) Brand	Accuracy (%)	Remarks
B.Braun 20d/ml	4.57	Minimum rate 1ml/h, normal condition
	0.49	Intermediate rate 25ml/h, normal condition
	0.56	Intermediate rate 25ml/h, with +13.3kpa backpressure
	1.44	Intermediate rate 25ml/h, with -13.3kpa backpressure
	-4.88	Intermediate 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 backpressure
	-0.57	Intermediate rate 25ml/h, with -13.3kpa backpressure
	-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 of MC 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 of B.Braun 1ml/h**
	
Trumpet curve ofB.Braun 25ml/h	**Trumpet curve ofB.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%;

Infusion type: (B.Braun 20d/ml): 3 sets.

Infusion pump: 1 set

Length of the infusion tube: 1m

Table 10-3 Occlusion level, alarm delay time and pill amount under the rate of 25ml/h (SYS-6010A)

Infusion rate	**Occlusion pressure level**	**Occlusion pressure (mmHg)**	**Occlusion alarm time (hh:mm:ss)**	**Bolus (ml)**
25ml/h	P1	300±100	00:01:17	0.12
	P11	900±200	00:04:06	0.39

Table 10-4 Occlusion level and alarm delay time under the rate of 1ml/h (SYS-6010A)

Infusion rate	**Occlusion pressure level**	**Occlusion pressure (mmHg)**	**Occlusion alarm time (hh:mm:ss)**
1ml/h	P1	300±100	00:16:00
	P11	975±200	00:38:15

Table 10-5 Occlusion level and alarm delay time under the rate of 0.1ml/h (SYS-6010A)

Infusion rate	**Occlusion pressure level**	**Occlusion pressure (mmHg)**	**Occlusion alarm time (hh:mm:ss)**
0.1ml/h	P1	300±100	01:07:00
	P11	975±200	07:31:34

⚠ **CAUTION:**

Unit conversion list

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

Appendix A Electromagnetic Compatibility (EMC)

The SYS-6010 Series Infusion Pump conforms to EMC standard IEC 60601-1-2.

Guidance and manufacturer's declaration – electromagnetic emissions		
The SYS-6010 series Infusion Pump should be used under the regulation electromagnet environment. The user should operate the SYS-6010 series Infusion Pump under following electromagnet environment.		
Emission measurement	conformance	Electromagnet environment-instructions
Radio-frequency emission CISPR 11	Group 1	SYS-6010 Series 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 series 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 series] is intended for use in the electromagnetic environment specified below. The customer or the user of the [SYS-6010 series] 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 series] requires continued operation during power mains interruptions, it is recommended that the [SYS-6010 series] be powered from an uninterruptible power supply or a battery.
Power frequency magnetic fields (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic 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 series] is intended for use in the electromagnetic environment specified below. The customer or the user of the [SYS-6010 series] 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 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 series], 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 d in meters (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 series] is used exceeds the applicable RF compliance level above, the [SYS-6010 series] 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 series].

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

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

The [SYS-6010 series] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [SYS-6010 series] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [SYS-6010 series] 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 distanced d in meters (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 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	SYS-6010A: 600mmHg SYS-6010 and SYS-6010T: 550mmHg
Near end	3min
Built-in consumable brand	MC (20d/ml), B.Braun (20d/ml)

System time

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

Appendix C Parameter Units

Parameter Name	Unit
Acti Agent	ng, ug, mg, g, U, kU, IU, EU, mmol, mol, kcal, mIU, kIU, mEq
Conc.	ng/ml, ug/ml, mg/ml, g/ml, U/ml, kU/ml, IU/ml, EU/ml, mmol/ml, mol/ml, kcal/ml, mIU/ml, kIU/ml, mEq/ml
DoseRate	x/min, x/kg/min, x/h, x/kg/h. (x is n ng, ug, mg, g, U, kU, IU, EU, mmol, mol, kcal, mIU, kIU, mEq)

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