SYS-70 Infusion Pump

Operation Manual

Before using the SYS-70 infusion pump, please read this Manual carefully and follow the safety precautions and operating instructions contained herein.

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

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- The product is used in accordance with this Manual.
- All installations, replacements, tests, modifications and repairs are conducted by professionals authorized by MEDCAPTAIN.
- All replacement components and accessories are provided by MEDCAPTAIN.
- All maintenance service records are kept.

Version Information

V1.0

- Operation manual version: First edition
- Software release version: V1
- Issued on: August 2018

V1.1

- Added warning and the enteral nutrition-related description.
- Issued on: March 2019

V1.2

- Added warning.
- Issued on: July 2019

Intellectual Property and Statement

V1.3

- Added the description that the sound of the **Battery Empty** alarm cannot be paused and the sound of a low-level alarm can be paused.
- Issued on: July 2020

V1.4

- Modify the production address
- Issued on: March 2021

V2.0

- Add the UDI symbol and description
- Issued on: October 2022

After-Sales Service

Thanks for purchasing our infusion pump.

- MEDCAPTAIN provides limited warranty for the product. That is, we provide free after-sales services for the product within the warranty period. The specific warranty period is stipulated on the sales contract. However, a product damage or fault is not covered by the warranty if it is caused by:
  - Man-made reasons.
  - Improper use.
  - Out-of-range grid voltage.
  - Force majeure such as natural disasters.
  - Replacement with or use of any component, accessory or consumable other than authorized by MEDCAPTAIN.
  - Other damages/faults not caused by the product itself.
- MEDCAPTAIN shall continue to provide paid maintenance service beyond the warranty period.
- Feel free to contact us or your local distributor if you have any problem in using the product.

Contact our Customer Service Department:

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

Postal code: 518055

Website: http://www.medcaptain.com

E-mail: mc.service@medcaptain.com

- We, as well as our distributors, have built a customer service network to solve your problems efficiently in a timely manner.

Contents

Contents

Contents

Contents

1 Overview

1.1 Intended Use

The SYS-70 infusion pump is intended to be used in combination with an infusion set for intravenous infusion of liquid drug or total parenteral nutrition or with an enteral giving set for enteral nutrition.

The SYS-70 infusion pump is applicable for the adult, pediatric, and neonatal patients in various clinical departments.

The SYS-70 infusion pump is intended to be used in such medical institutions as hospitals, clinics, and nursing homes as well as medical transport environment.

1.2 Contraindication

The SYS-70 infusion pump must not be used for blood transfusion.

1.3 Enteral Nutrition

The SYS-70 infusion pump may be used for enteral nutrition, too. Do not use enteral fluids for intravenous infusion as this may harm your patient. For this reason only use disposables dedicated and labeled for enteral nutrition.

⚠WARNING:

- The dedicated sets have different connection ports to avoid connections between enteral and IV infusions. Never inject IV infusions into enteral infusions or vice versa, never interconnect the two types of infusions.

⚠CAUTION:

- The air in line detector cannot be switched off on the infusion pumps for safety reasons. If the infusion pump is used for enteral application, it is recommended to increase the air limit to e.g. 300μl.
- Good practice is to keep the enteral infusions in separate stacks or docking stations to avoid any confusion with IV.

1.4 Product Features

The SYS-70 infusion pump of MEDCAPTAIN is a continuous high-precision infusion pump. This infusion pump is applicable for clinical continuous infusion of low-volume and high-concentration liquid or liquid drug. It can maintain a constant infusion rate and accurate dose during long-time infusion.

Overview

- The infusion tube used together with the infusion pump must conform to the requirements in the *ISO 8536-4: Infusion equipment for medical use-Part 4: Infusion sets for single use, gravity feed* or *ISO 8536-8: Infusion equipment for medical use-Part 8: Infusion sets for single use with pressure infusion apparatus* standard. However, before using a gravity infusion set, the user must evaluate the risk that might be introduced by the gravity infusion set.
- Users are allowed to customize all infusion sets conforming to the standard.
- 13 occlusion levels are available for selection, the minimum occlusion pressure is 75mmHg, and the dynamic pressure status of the tube can be displayed.
- The Pre OCCL alarm can be triggered before an infusion occlusion is caused.
- Large setting range of infusion rate: up to 1500 ml/h.
- Up to 8 infusion modes are supported.
- Wireless or wired networking for connecting to the infusion central monitoring system.
- 3.5-inch color touch screen, providing a convenient and efficient man-machine interaction interface.
- The display supports the night mode, reducing the optical interference with the patient and environment.
- Supporting connection to a nurse call button to implement the nurse call function.
- Supporting connection to a barcode scanner to implement the barcode scanning function.
- Providing three types of power supply: AC power supply, DC power supply, and built-in lithium battery.
- Supporting multiple types of battery configuration. Up to 20-hour operation duration if the pump works at middle infusion rate (25 ml/h at room temperature).
- Dual-CPU design and high-availability dual-channel audible alarm for real-time monitoring of the infusion status.
- Independent motor drive CPU and motor subdivision drive chip design.
- The ingress protection rating is IP34.
- A motor-driven pump door is equipped to make the operation more convenient.
- An automatic anti-free-flow clamp is equipped to prevent free flow of liquid.

2 Safety Warnings and Cautions

In this Manual, the precautions are classified by importance into warnings and cautions as defined below:

WARNING:

The precautions related to safety and effectiveness. Failure to follow them may cause personal injuries.

CAUTION:

The precautions related to guidance and suggestions. Failure to follow them may affect the normal use of the product.

Please read all warnings and cautions contained herein carefully.

WARNING:

- This product shall be used by or under the guidance of specialist clinicians. The operator shall be trained to use and operate this product.
- To avoid the risk of electric shock, connect the SYS-70 infusion pump to only the power supply system with protective earth.
- Do not touch the infusion pump and patient simultaneously when operating the pump.
- Before use, power on the device, ensure that the self-test is finished, and no error message is displayed. (For the error messages, see Chapter 8.)
- Check whether the infusion tube is kinked especially during infusion at a low rate. A lower infusion rate will result in a longer interval between the occlusion occurrence time and detection time, which will cause a long infusion pause, thereby causing insufficient dose.
- Do not use the infusion pump in a flammable environment.
- In the event of tube twisting, filter condensation, or intubation during the infusion, occlusion may be incurred, and the internal pressure of the infusion tube will increase when occlusion occurs. Once the causes for occlusion are removed, too much infusion liquid may be infused into the patient. Therefore, proper actions should be taken before removing the occlusion causes, for example, clamp the infusion tube.

- It is highly recommended that infusion sets of specified brands be used. If you use infusion sets not specified by the manufacturer, the infusion accuracy and alarm function cannot be guaranteed.
- If an infusion set of other brands is used or the infusion set parameters are not defined correctly, the infusion accuracy may be affected.
- The infusion pump is intended to work with the infusion set, infusion tube, infusion needle and other medical accessories compliant with the local laws and regulations. Contact your local distributor for more information.
- Operating the infusion pump against the requirements, procedures, warnings and cautions provided in this manual may cause an infusion failure, excessive or insufficient dose for treatment, and other potential risks.
- If you do not move or replace the infusion tube after it is squeezed for a long time, insufficient dose may be caused. Therefore, it is recommended that a drop sensor be installed and the drop detection function be enabled during the infusion.
- The use of the infusion pump should be monitored regularly by professional medical workers.
- High-frequency surgical equipment, mobile phones, wireless devices, and defibrillators may cause interference on the infusion pump. Therefore, keep the infusion pump away from these devices when using the pump.
- The infusion pump does not have a patient connection circuit. Prevent the patient from touching the infusion pump.
- This infusion pump must not be used as an ambulatory device. Otherwise, unknown risks may be caused.
- When operating the infusion pump or checking the pump's alarm system, stand in front of the pump at a position 1 m away from the pump and ensure that the pump is placed at a position 1 m above the ground.
- The altitude difference between the heart of patient (or infusion pump) and the infusion bottle above the pump should not be greater than 100 cm. Otherwise, the infusion accuracy and occlusion alarm accuracy may be affected.
- The infusion pump or its accessory should be disposed of according to local laws and regulations or the hospital’s regulations when it reaches the end of its service life. For details, contact the local distributor.
- Prevent other infusion systems or accessories from being connected to the patient's infusion tube. Otherwise, the infusion rate may change and air may be infused into the patient's body.

- The SYS-70 infusion pump meets the applicable requirements stipulated in the EN1789 standard. However, the infusion inaccuracy of the pump may exceed 5% when it operates at 0~5℃.

⚠ CAUTION:

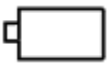
- The applied part of the infusion pump is the infusion tube.
- Before starting the infusion, ensure that the values set on the infusion pump are the same with the values on the prescription.
- Before separating the infusion set from the infusion pump, ensure that the roller clamp on the infusion set is closed to prevent infusion of excessive dose.
- When moving the section of the infusion tube in the infusion pump, ensure that this section is moved to a new position at least 10 cm away from the original position to ensure constant infusion accuracy.
- During infusion, the infusion pump precisely controls the infusion rate, infusion volume, and infusion time, and the high-availability dual-CPU and dual-channel alarm design helps monitor the speed and direction of the stepper motor in real time to effectively avoid excessive flow, insufficient flow, and backflow.
- When using an infusion stand for pump installation, ensure that the infusion pump is fixed tightly on the infusion stand and the infusion stand is stable.
- An occlusion alarm may be triggered during infusion of high-viscosity liquid at high infusion rate. In this case, set the occlusion level to a higher level or reduce the infusion rate.
- The drop sensor detects drops, but does not measure the infusion rate. If the liquid in the drip chamber drips constantly and a liquid flow is formed, no drop signal can be detected.
- Ensure that the infusion pump is placed beyond the reach of the patient and other unauthorized persons.
- Do not autoclave the infusion pump.
- Before using the built-in battery, check the battery to ensure that sufficient power is available. Recharge the battery if required.
- Ensure that the battery is installed before using the infusion pump. Otherwise, the infusion pump will be powered off without triggering an alarm in case of external power failure or short circuit, which will cause risks.

- If the infusion pump fails to act as specified herein for unknown reason, power it off and report the conditions (including the infusion set used, infusion rate, serial No. of the infusion pump, and liquid type) when the fault occurs to your local distributor or our after-sales service department.
- Do not touch the display screen by using sharp objects. Otherwise, the display screen may be damaged.
- Do not disassemble or reconstruct the infusion pump without permission.
- Short circuit may occur if infusion liquid flows into the AC power socket or any USB port. Before connecting the power cable, check if the connecting parts are dry. If any liquid splashes onto the infusion pump, use a dry cloth to scrub it and contact the maintenance personnel to test it before use.
- The delay of the infusion pump's alarm system is not longer than 1.5s.
- This product allows maintenance by authorized personnel. The authorized personnel can ask for such materials as the circuit diagram and list of components and parts from the manufacturer.
- The delay time from onset of alarm condition to the point where representation of alarm condition leaves the signal output part is no longer than 3s.

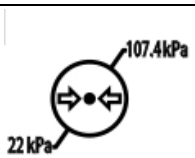
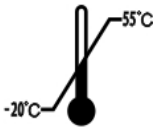
Safety Warnings and Cautions

Symbols

Table 2-1 Symbol description

Symbol	Description
	Model number
	Medical device
	Authorized representative in the European Community
	Serial number
	Unique device identifier
	Type CF applied part.
	CE Marking: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
IP34	Protected against solid foreign objects with a diameter no less than 2.5mm and splashing water.
	CAUTION
	General warning sign
	Date of manufacture
	Manufacturer
	Nurse call button
	Non-ionizing electromagnetic radiation
	Alternating Current
	Both direct and alternating current.
	Direct Current
	Battery

Safety Warnings and Cautions

	DISPOSAL: Do not dispose this product as unsorted municipal waste. Separate collection of such waste for special treatment is necessary.
	Refer to instruction manual/booklet.
	This way up
	Keep dry
	Atmospheric pressure limitation
	Humidity limitation
	Fragile, handle with care
	Keep away from sunlight
	Temperature limit
	Stacking limit by number
	HOME button. Used to return to the infusion preparation interface.
	ON/OFF button. Used to power on/off the pump.
	OPEN button. Used to open the infusion pump door.

3 Specifications

Name	Infusion pump
Model	SYS-70
Power Supply	AC power supply: 100-240 V AC, 50/60 Hz, 35 VA input power External DC power supply: 12V 2A Built-in battery: Configuration 1 (standard): one 11.1V 1500mAh lithium battery; model: 154457; Configuration 2 (optional): two 11.1V 1500mAh lithium batteries; model: 154457; Configuration 3 (optional): two 11.34V 2900mAh lithium batteries; model: 18650-3S; Continuous operation duration: Configuration 1: Not shorter than 5 hours (at 25 ml/h); not shorter than 2 hours (at 1500 ml/h). Configuration 2: Not shorter than 10 hours (at 25 ml/h); not shorter than 4 hours (at 1500 ml/h). Configuration 3: Not shorter than 20 hours (at 25 ml/h); not shorter than 8 hours (at 1500 ml/h). Test conditions: Fully-charged brand new battery is selected, screen brightness is adjusted to the lowest level, and WiFi is disabled at room temperature. Battery charging time: Configuration 1: Not longer than 4 hours in power-off state. Configuration 2: Not longer than 8 hours in power-off state. Configuration 3: Not longer than 15 hours in power-off state.
Compatible Infusion Set	All disposable infusion sets conforming to the *ISO 8536-4: Infusion equipment for medical use-Part 4: Infusion sets for single use, gravity feed AMENDMENT 1* or *ISO 8536-8: Infusion equipment for medical use-Part 8: Infusion sets for single use with pressure infusion apparatus* standard.
Infusion Mode	Rate Mode, Time Mode, Weight Mode, Trapezia Mode, LoadingDose Mode, Sequence Mode, Drip Mode, and Micro Mode

Specifications

Infusion Rate	0.10-1500ml/h The maximum infusion rate varies with the sizes of the infusion sets.
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 -1500ml/h (minimum increment: 1ml/h)
VTBI (Volume to be infused)	0.10 - 99.99ml (minimum increment: 0.01 ml) 100.0 - 999.9ml (minimum increment: 0.1 ml) 1000 - 9999ml (minimum increment: 1 ml)
Total Volume Display	0-99999.99ml
Infusion Accuracy	Infusion accuracy ≤ ±5%
Purge Rate	1500ml/h
Bolus Rate	Manual bolus rate: 1500ml/h Rapid quantitative bolus rate: 1500ml/h Automatic bolus rate: 0.1~1500ml/h
Bolus VTBI	0.10~50.00ml (minimum increment: 0.01ml)
KVO Rate	0.1-30.00ml/h The KVO rate is not higher than the current infusion rate.
Air Bubble Detection	Air bubble alarm accuracy: ±15ul or ±20% (whichever is greater). Single Bubble Size: 25, 50, 100, 200, 300, 500, and 800 (ul) Cumulated Bubble Size: 100ul/15min, 200ul/15min, 400ul/15min, 500ul/15min, 600ul/15min, 800ul/15min, and 1000ul/15min
Occlusion Level	75mmHg~975mmHg 13 levels are available for selection.

Specifications

Occlusion Pressure Level Precision	When the occlusion level is 1, the occlusion alarm precision is 75^{+145}_{-70}mmHg. When the occlusion level falls within the range of 2~13, the occlusion alarm precision ≤ ±145mmHg.
Alarm Message	Near Finished, Finished, OCCL, Up OCCL, Low Battery, Battery Empty, No Battery, No Power Supply, Air Bubble, No Drop Sensor, No Drop, Drop Error, Reminder Alarm, Standby End, Pre OCCL, and Door Open.
Drug Library	The drug library function is available.
Wireless Networking	Enables the infusion pump to be connected to the infusion central monitoring system.
Operating Conditions	Temperature: 5 ℃~40 ℃ Humidity: 15%~95% RH, non-condensing Atmospheric pressure: 53.9~106.0kPa
Storage and Shipping Conditions	Temperature: -20 ℃~+55 ℃ Humidity: 10%~95% RH, non-condensing Atmospheric pressure: 22.0~107.4kPa
Classification	1. Class I / Internally powered equipment; 2. Type CF applied part; 3. IP34; 4. Not sterilized; 5. Not category AP / APG equipment; 6. Mode of operation: continuous
Dimensions	160(W) x 236(H) x 92(D)mm
Weight	About 1.42kg (including the battery of standard configuration)
Service Life	10 years
Date of Manufacture	See the product label.

Specifications

Main Safety Standards	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-2-24 Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers IEC 60601-1-8 Medical electrical equipment – Part 1-8:Generalrequirements for basic safety and essential performance-Collateral standard: General requirements ,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances –Requirements and tests

4 Product Composition

4.1 Structural Composition

The SYS-70 infusion pump mainly consists of the control system, motor drive unit, peristalsis module, detection system, alarm system, input and display system, pump shell, support structure, software assembly, and accessories. The accessories of the pump include the drop sensor (optional), nurse call button (optional), barcode scanner (optional), wired networking module (optional), and pole clamp.

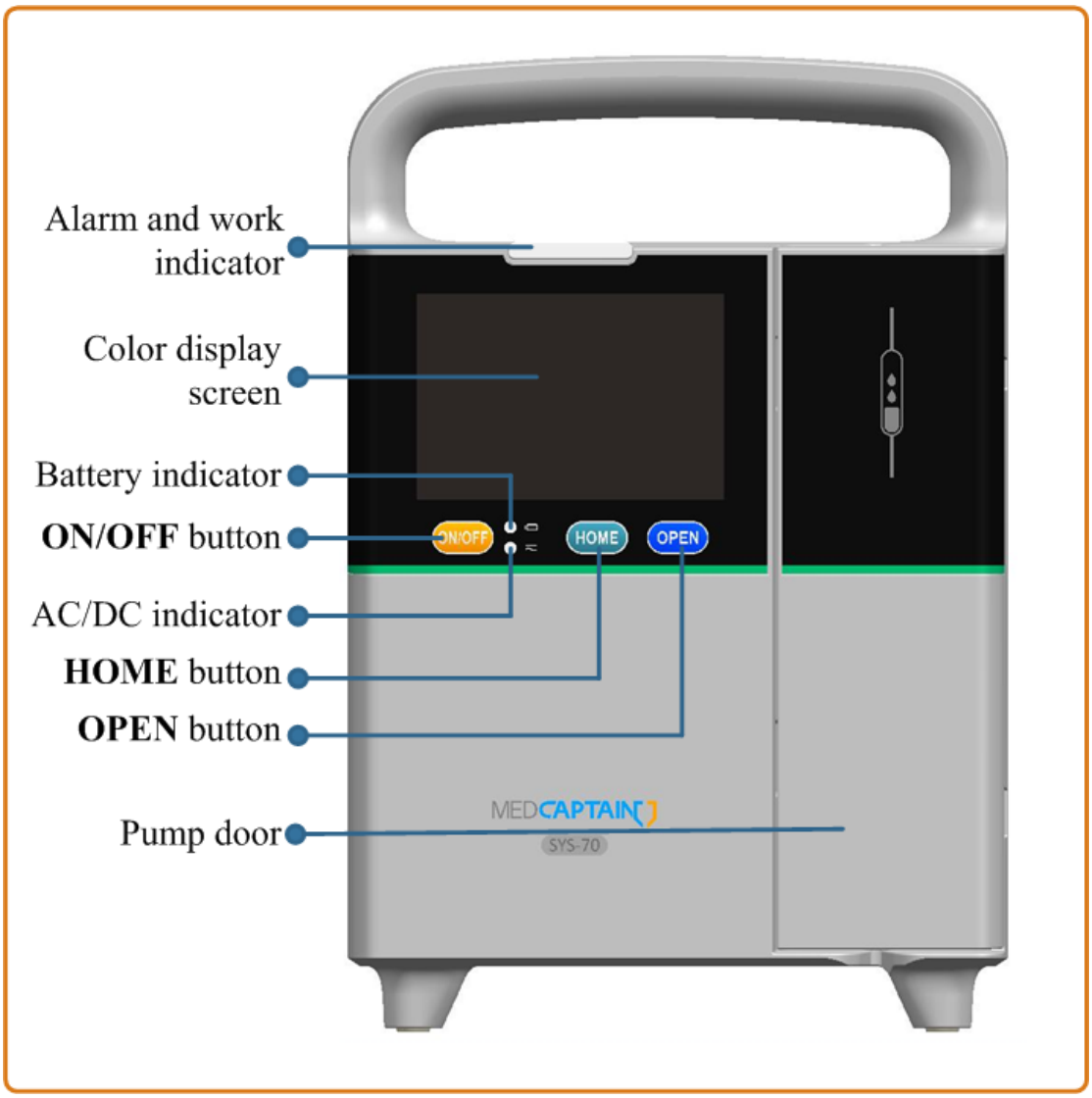
4.2 Working Principle

Defined as a volumetric infusion pump according to *IEC 60601-2-24*, the SYS-70 infusion pump is intended to generate a positive pressure for controlling the flow of liquid to be infused into a patient.

Through the man-machine interface of the infusion pump, an operator sets the drug, liquid flow rate, and liquid volume required for the patient based on the prescription and selects a matching infusion set based on the infusion set brand and specification indicated by the infusion pump. The control system of the infusion pump automatically converts the preset infusion set feature parameters and flow data into operating parameters of the drive motor. The drive motor drives the cam shaft of the peristalsis module to rotate through the speed reduction unit, the rotation of the cam shaft drives the pump finger to move in a straight reciprocating manner, and the pump finger together with the squeezing plate alternatively squeeze and release the outer surface of the infusion set in a reciprocating manner for driving the liquid in the infusion tube to flow to a certain direction continuously. In this way, the purpose of volumetric infusion at a constant rate is achieved.

During the running process of the infusion pump, the tube pressure sensor, air bubble sensor, drop sensor (optional), and motor speed sensor continuously monitor the running conditions of the infusion pump. In case of an exception, the infusion pump reports an alarm and stops running.

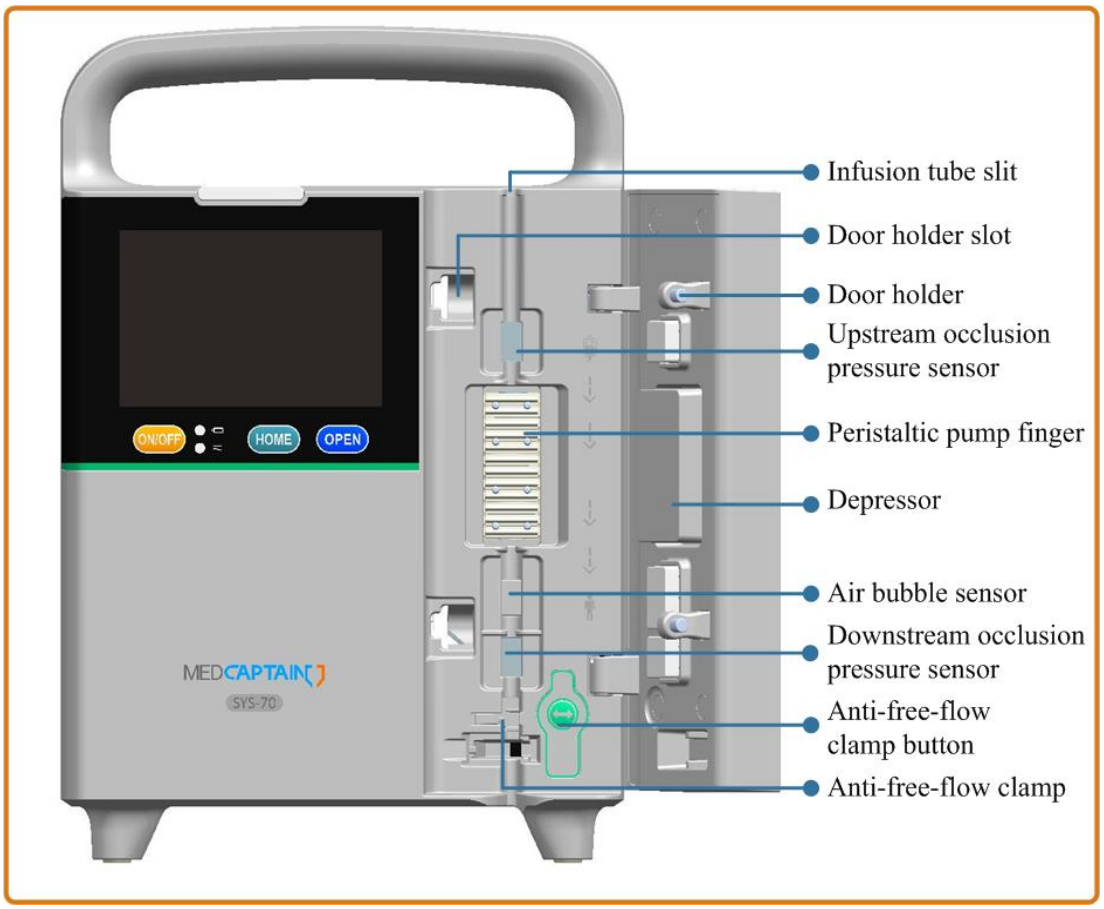
4.3 Main Components



- Alarm and work indicator: Used to indicate three levels of alarm during work. Three colors of indicators are built in the pump: red, yellow, and green.
- Color display screen: Used to display the contents of the main unit. This display screen is a color LCD with touch screen, and its resolution is 320 x 480 pixels.
- Battery indicator: Used to indicate the battery status. The battery indicator is steady green when the battery is being charged and blinking green when the battery is powering the device. When the battery is fully charged or no battery is installed, the battery indicator is extinguished.
- AC/DC indicator: Used to indicate the AC or DC power status. This indicator is steady green when the device is connected to an AC or DC power supply.

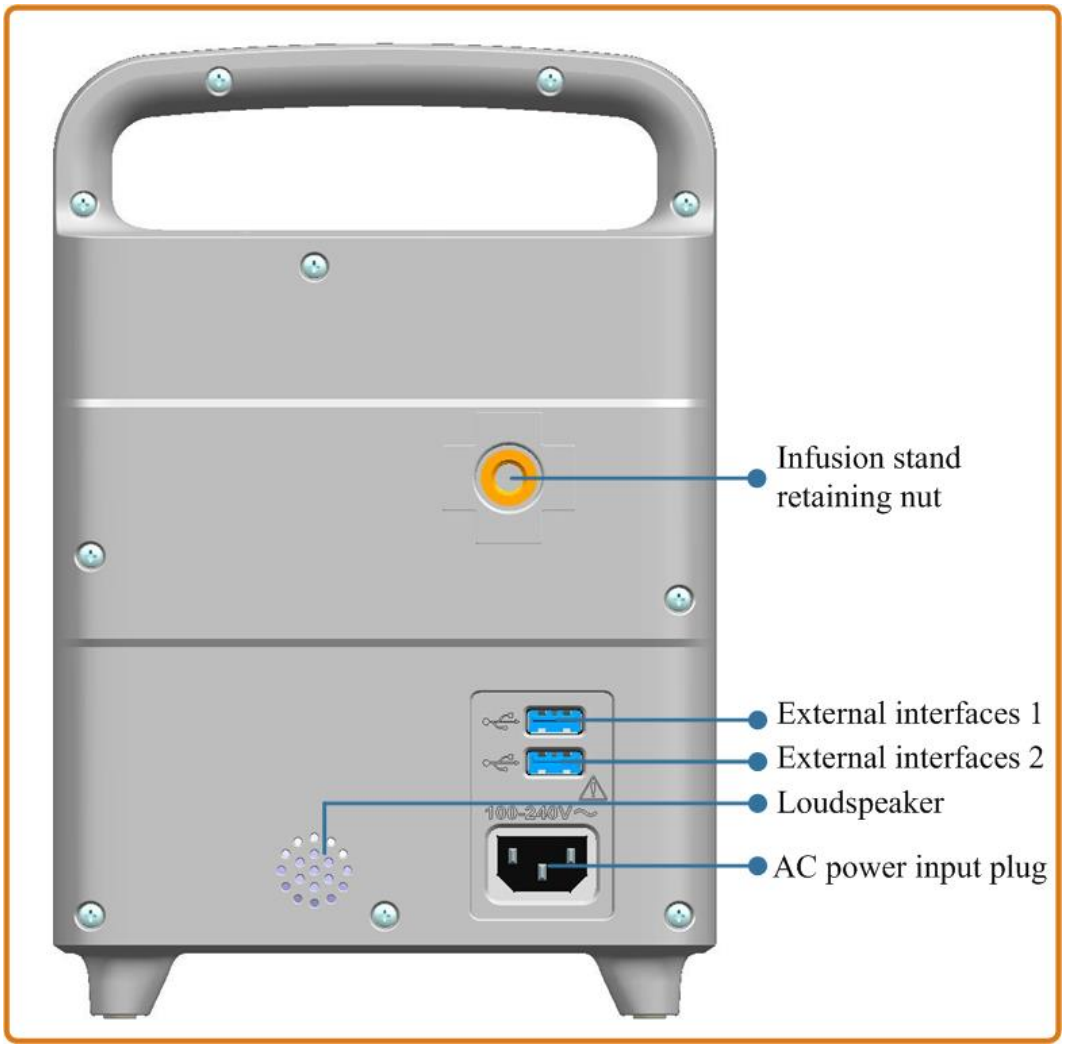
- **HOME** button: Main menu button.
  - Before infusion is started, you can press **HOME** to access the setting interface where **Infusion Set**, **System Set**, **History**, and **Patient File** are displayed. On any setting interface, you can press **HOME** once to return to the infusion preparation interface.
  - During infusion, you can press **HOME** to switch the format of the infusion interface and amplify the display of the infusion rate to three different levels.
- **ON/OFF** button: Used to power on/off the infusion pump. In power-off state, you can press **ON/OFF** to power on the pump. In power-on state, when you press **ON/OFF**, the screen displays three options (**Power Off**, **Standby**, and **Cancel**) for your selection. You can select **Power Off** to power off the infusion pump. You can also press and hold the **ON/OFF** button for 3s to forcibly shut down the pump.
- **OPEN** button: Used to open the pump door. No matter whether the pump is in power-on or power-off state, you can press the **OPEN** button to open the pump door. To close the pump door, you only need to gently push the pump door to be close to its original position, and the infusion pump will automatically close the pump door. During infusion, the pump does not respond when you press the **OPEN** button.

Product Composition



- Infusion tube slit: Located at both ends of the infusion pump and used to ensure that the infusion tube in the pump door is a straight line.
- Door holder and door holder slot: The two door holders are used to fasten the pump door when it is closed.
- Upstream occlusion pressure sensor and downstream occlusion pressure sensor: Used to monitor the occlusion pressure in the infusion tube.
- Air bubble sensor: Used to monitor the air bubble in the infusion tube.
- Depressor and peristaltic pump finger: Driven by the stepper motor, the depressor and peristaltic pump finger squeeze the infusion tube to implement liquid flow.
- Anti-free-flow clamp: Used to stop liquid flow when the pump door is open, thereby avoiding infusion backflow.
- Anti-free-flow clamp button: Used to open or close the anti-free-flow clamp.

Product Composition



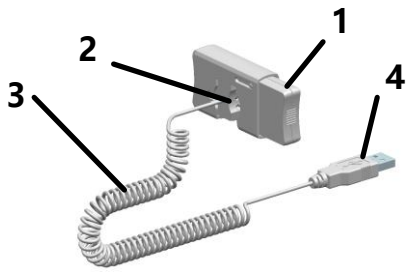
- Infusion stand retaining nut: Used to fasten the pole clamp. The infusion pump is fastened to the infusion stand using the pole clamp.
- Loudspeaker: Used to give the alarm sound during the infusion.
- AC power input plug: Used to connect to an external AC power supply.
- External interfaces 1 and 2: The two USB3.0 interfaces can be used to connect two external devices simultaneously. The external devices include the drop sensor (optional), barcode scanner (optional), wired connection module (optional), and external DC power supply.

⚠CAUTION:

- Do not insert the accessories which are not specified by the manufacturer into the external inlets.

- 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 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see clause 16 of the 3Ed. of IEC 60601-1).
- Anybody connecting additional equipment to medical electrical equipment configurations of a medical system is 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. In case of any doubt, consult your local distributor or the after-sales service department of the manufacturer.

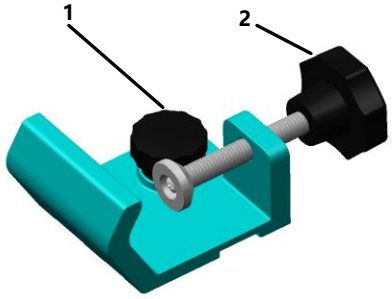
4.4 Drop Sensor (Optional)



1 – Button 2 – Drop hole 3 – Cable

4 –Plug

4.5 Pole Clamp

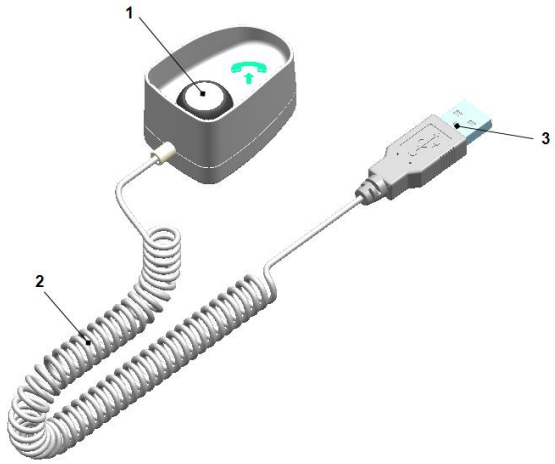


1 – Infusion pump retaining knob 2 - Infusion stand retaining knob

WARNING:

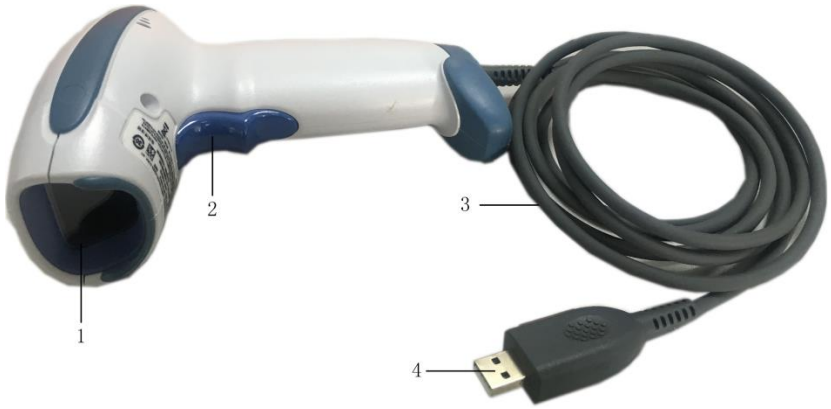
- Please evaluate and ensure the installation reliability, installation stability, and bearing capacity of the infusion stand. When the infusion pump and other devices are fastened to the infusion stand concurrently, please evaluate the center of gravity of the infusion stand and ensure that the infusion stand is smooth and steady.
- It is recommended that the diameter of the infusion stand range from 12 to 30 mm. An infusion stand with a diameter exceeding this range may cause unstable installation.

4.6 Nurse Call Button (Optional)



1 – Button 2 – Cable 3 – Plug

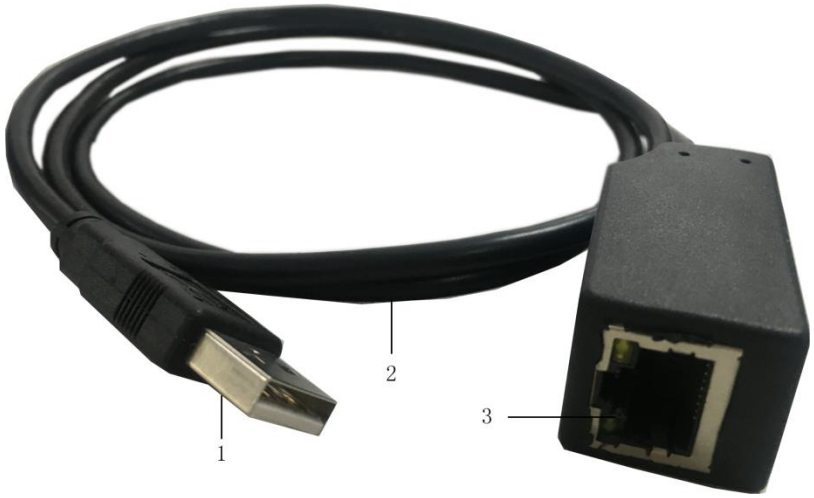
4.7 Barcode Scanner (Optional)



1 – Scan window 2 – Button 3 – Cable

4 – Plug

4.8 Wired Connection Module (Optional)



1 – Plug 2 – Cable 3 – Network port

4.9 Standard Accessories

1 – AC power cable × 1

2 – Pole clamp × 1

3 – Operation manual × 1

4 – Quick start guide × 1

5 – Packing list × 1

4.10 Optional Accessories

Table 4-1 List of optional accessories

Name	Description	PN
AC power cable	Europe Plug	1462-00004-01
	USA Plug	1462-00005-01
	UK Plug	1462-00006-01
	India Plug 250v 10a	1462-00010-01
	Brazil Plug	1462-00113-01
	South Africa Plug	1462-00114-01
	Israel Plug	1462-00188-01
	Swiss Plug	1462-00317-01
Lithium battery pack	11.1V@1500mAh	1457-00003-01
Lithium battery pack	11.34V@2900mAh	1457-00001-01
Nurse call button	MP-2	1202-00019-01
Drop sensor	MP-3	1202-00154-01
Barcode scanner	MP-4	1454-00022-66
Wired connection module	MP-6	1203-00004-01

5 Installation Instructions

5.1 Environment Requirements

To ensure normal operation of the device, please ensure that the installation environment meets the following requirements:

- The installation platform is smooth and stable.
- If the infusion pump needs to be installed on an infusion stand, the infusion stand must be stable.
- No large noise source or power supply interference exists.
- The environment shall be dust-free if possible.
- No corrosive or flammable gas exists.
- No flammable or explosive materials exist.

5.2 Open Package Inspection

Before opening the package, please inspect the packaging box carefully. In case of any damage, please contact your local distributor immediately.

Please open the package in a correct way, take out the device and other accessories carefully, and check them according to the packing list. Check whether there is any mechanical damage on the device and whether the actual items are consistent with the packing list. In case of any doubts, please contact your local distributor immediately.

WARNING:

- The device might be contaminated by microorganism during storage and transportation. Therefore, check whether the package is intact before use. In case of any damage, do not use the device.

CAUTION:

- Please retain the packing box and packing materials for future transportation and storage.

5.3 Connecting the Power Supply

1. Use the original AC power cable.
2. Insert one end of the AC power cable into the AC power input socket on the rear panel of the infusion pump.
3. Insert the other end into a matching socket that is already connected to AC power supply.

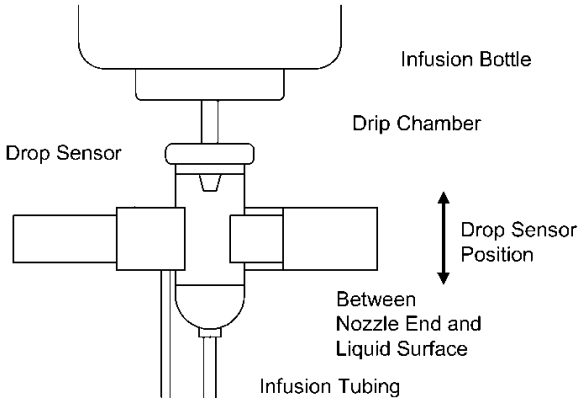
WARNING:

- Do not touch the power plug with a wet hand. If any liquid or liquid residue exists on or around the power plug or power socket, remove the liquid or liquid residue before plugging in the device. Otherwise, an accident may be incurred.
- Use the power cable delivered together with the device to ensure that the device is properly grounded. If the device is not properly grounded, the safety performance cannot be guaranteed and an electric shock may be incurred.
- Do not install the infusion pump at a place where the disconnection device is difficult to operate.

CAUTION:

- The AC power cable must be firmly and fully inserted into the power socket.

5.4 Installing the Drop Sensor



CAUTION:

- To ensure the accuracy of drop detection, install the drop sensor as close as possible to the liquid level. It is recommended that the height of the liquid level should be 1/3 of the height of the drop chamber.
- Prevent the drop sensor from being tilt and avoid direct sunlight and direct strong light during infusion.

6 Operating Instructions

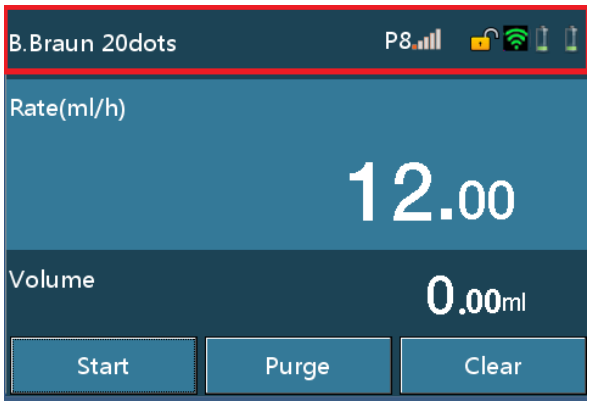
6.1 Preparations

- Before using the infusion pump, please read the operation procedures and precautions in this manual carefully.
- For correct historical records, please set the date and time before the first use of the infusion pump.
- Select an infusion set brand before the first use of the infusion pump.
- Charge the built-in battery by connecting the infusion pump in power-off state to the external power at least for 10 hours before the first use of the infusion pump.
- Place the infusion pump on a stable platform.
- Alternatively, fix the infusion pump onto the infusion stand using the pole clamp:
  - Align the pole clamp with the screw hole at the back of the infusion pump and tighten the infusion pump retaining knob.
  - Make the retaining clamp of the pole clamp to clamp the infusion stand, adjust the infusion pump to the appropriate position and tighten the infusion stand retaining knob.

6.2 Display

The main interface consists of three areas: information area, data area, and button area.

- Information area: Displays the infusion set brand and specification, occlusion pressure level, real-time pressure status, WiFi signal, screen lock state, external power supply, and battery level. Relevant icons are described as follows:



 indicates that the occlusion pressure level is set to level 8.

 indicates the real-time occlusion pressure. This icon consists of 5 bars in total. A greater number of illuminated bars indicate a higher occlusion pressure.

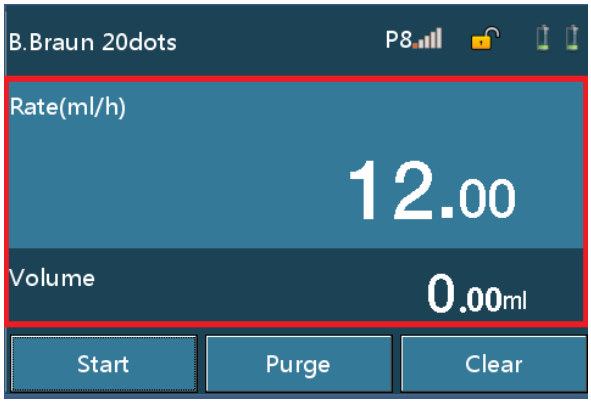
 External power input symbol. This symbol is displayed when the pump is connected to an external AC or DC power supply.

 Screen lock symbol, used to indicate that the screen is locked or unlocked.

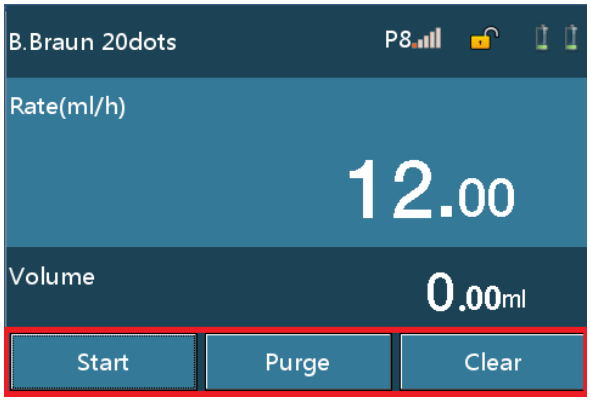
 indicates the battery level and charge state. This icon consists of 4 bars in total. A greater number of illuminated bars indicate a higher battery level.

 WiFi signal.

- Data area: Displays the current infusion rate and total volume or displays different infusion data based on different infusion modes.



- Button area: All buttons in this area are touch buttons, including **Start**, **Purge**, **Clear**, **Stop**, and **Bolus**. In addition, touch buttons for settings are also available, for example, digit and letter input buttons, which are displayed on different user interfaces (UIs).



6.3 Power On the Pump

1. Press **ON/OFF** to start the pump.
2. The infusion pump conducts a self-test and displays the startup interface.
3. The system enters the infusion preparation interface after the self-test finishes, and the infusion preparation interface displays the parameters saved before last shutdown, such as the infusion set brand and occlusion pressure level. If an exception is found during the self-test, corresponding information is displayed in the information area.

WARNING:

- During the startup, please confirm that the loudspeaker and alarm indicator work properly, the infusion pump passes the self-test, and no error alarm information is displayed.
- Before installing the infusion set, please start the infusion pump.

6.4 Install the Infusion Set

1. Vertically insert the needle of the infusion set into the infusion bottle to let liquid flow into the drop chamber.
2. When the liquid level is at 1/3 of the drop chamber, open the roller clamp of the infusion set.
3. Infuse liquid into the tube to purge the air, and then close the roller clamp to avoid free flow.
4. Press **OPEN** to open the pump door.
5. Press **Anti Free Flow** to open the anti-free-flow clamp, place the tube in the anti-free-flow clamp, and press **Anti Free Flow** again for the anti-free-flow clamp to automatically clamp the tube.
6. Press the tube into the air bubble sensor and pressure sensor in sequence, stretch the tube, ensure that the tube is inside both ends of the tube slit, and push the pump door back to close it.

WARNING:

- Before closing the pump door, ensure that no foreign matters block the door.
- Ensure that the displayed infusion set brand and specification are consistent with those of the installed infusion set. Otherwise, infusion accuracy is not

guaranteed and the alarm function may fail.

- If the infusion set brand selected on the infusion pump differs from the actual infusion set brand, the infusion accuracy and alarm function cannot be guaranteed.

⚠ **CAUTION:**

- If the installation of the infusion tube is too loose or tight, the infusion flow may be inaccurate.
- To change the drug liquid or infusion tube when the infusion is in progress, you need to stop the infusion and close the roller clamp before the change.
- Ensure that the infusion tube is installed at the detection position of the air bubble sensor to prevent air from being infused into patient's body.
- The height range of the liquid container above the patient and/or pump should be 20-80cm.
- The correct direction of flow is from the top to bottom, before start infusion ensure the IV tube is correctly loaded.

6.5 Purge

1. Tap **Purge** on the infusion preparation interface and tap **Yes** in the displayed dialog box to purge the air quickly.
2. When liquid is discharged from the infusion needle, tap **Stop** to stop

purging.

WARNING:

- Before performing the purge operation, ensure that the infusion tube is not connected to a patient.
- The purge operation can be performed only when the infusion is not started.
- Stop the purge operation only after ensuring that liquid is discharged from the infusion needle.

CAUTION:

- If a small infusion needle is selected for infusion of high-viscosity solution, an occlusion alarm may be reported during the purge. In this case, reduce the infusion rate for infusion rather than perform the purge operation.
- The Air Bubble alarm will not be triggered during the purge operation.
- After infusion starts, the total volume cannot be cleared.

6.6 Set the Infusion Rate

1. Tap the rate display area on the touch screen to access the setting interface.
2. Enter the rate value to be set, and tap **Confirm** to finish the setting.
3. On the main interface, you can tap **Clear** to clear the total volume data.

WARNING:

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

6.7 Puncture

Stick the intravenous needle into the vein of the patient.

6.8 Start Infusion

After you tap the **Start** button, the infusion pump starts to infuse liquid at the preset infusion rate and the work indicator is steady green.

CAUTION:

- Before starting the infusion, ensure that the values set on the infusion pump are the same with the values on the prescription.
- Before pressing the **Start** button, check whether the infusion rate is set

properly (pay special attention to the position of the decimal point).

- If no operation is performed for 2 minutes, the Reminder Alarm is reported.

6.9 Change the Infusion Rate During Infusion

1. Tap the rate display area and set the infusion rate on the displayed interface. You can input the desired infusion rate for a change.
2. After changing the infusion rate, you can tap Cancel to return to the original infusion interface with the infusion at the original infusion rate or tap Confirm to return to the original infusion interface with the infusion at the new infusion rate.

⚠ CAUTION:

- If no operation is performed on the prompt interface or rate setting interface for about 10s, the system automatically returns to the infusion interface.
- After you change the infusion rate and confirm the change during the infusion, the pump infuses liquid at the new infusion rate.

6.10 Bolus

The infusion pump supports three bolus modes: manual bolus, rapid quantitative bolus, and automatic bolus.

- Manual bolus: Press **HOME** to access the setting interface, choose **System Set** > **Bolus Mode**, and select **Manual Bolus**. During the infusion, you can tap and hold the **Bolus** button for 1s to start bolus and access the bolus interface. After you release the button, the bolus stops.
- Rapid quantitative bolus: Press **HOME** to access the setting interface, choose **System Set** > **Bolus Mode**, and select **Rapid quantitative Bolus**. During the infusion, you can tap **Bolus** to access the **Bolus VTBI** interface, set the bolus volume, and tap **Confirm** to start bolus. When you tap **Bolus Stop**, the system stops bolus and returns to the infusion interface.
- Automatic bolus: Press **HOME** to access the setting interface, choose **System Set** > **Bolus Mode**, and select **Automatic Bolus**. During the infusion, you can tap **Bolus** to access the **Bolus Setting** interface, set either two of **Bolus VTBI**, **Bolus**

Rate, and **Bolus Time**, and tap **Bolus Start** to start bolus and access the bolus interface. After you tap **Bolus Stop**, the bolus stops.

⚠ **CAUTION:**

- The volume displayed on the bolus interface is the current accumulated bolus volume. The bolus volume is included in the total volume.

6.11 Stop Infusion

During or after the infusion, you can tap **Stop** to stop the infusion. The green work indicator extinguishes when the infusion stops.

6.12 Replace or Adjust the Infusion Set

After the infusion set works continuously for a period of time, the infusion tube will be impaired due to extrusion, which will affect the infusion accuracy. After the infusion set has been working for about 8 hours (or a duration stipulated by the local regulation), the following operations are recommended to ensure the infusion accuracy: stop infusion, open the pump door and anti-free-flow clamp, and move the part of the infusion tube at the position of the pump finger to a new position about 10cm away from the original position, reinstall the infusion set, and continue the infusion. To replace the infusion set, see section 6.4.

6.13 Power Off the Pump

You can press the **ON/OFF** button and then tap a corresponding button to power off the pump, make the pump enter standby state, or cancel the operation.

- Tap the **Power Off** button to power off the pump.
- Tap the **Standby** button to make the pump enter standby state. In addition, you can modify the standby time. After the standby time expires, the screen automatically displays the infusion preparation interface.
- Tap the **Cancel** button to return to the infusion preparation interface.

7 Settings

7.1 Infusion Settings

Press **HOME** to access the setting interface. Tap the **Infusion Set** button to access the **Infusion Set** interface.

7.1.1 Infusion Mode

The infusion pump supports 7 infusion modes: Rate Mode, Time Mode, Weight Mode, Sequence Mode, LoadingDose Mode, Trapezia Mode, and Drip Mode.

- Rate Mode

In Rate Mode, the infusion pump infuses liquid at constant infusion rate set by the user and finishes the infusion when reaching the preset VTBI. Set **Drug Name**, **Rate**, and **VTBI** for this mode and tap **Confirm** to start infusion.

Infusion Mode	Parameter	Range
Rate Mode	Drug Name	All the drugs in the drug library
	Rate	0.10-1500 ml/h
	VTBI	0.10–9999 ml
Note: **Rate** is a mandatory parameter. **VTBI** is an optional parameter. If **VTBI** is not set, all the liquid in the IV bottle will be infused into the patient by default. During the setting, Infusion time=VTBI/Infusion rate.		

- Time Mode

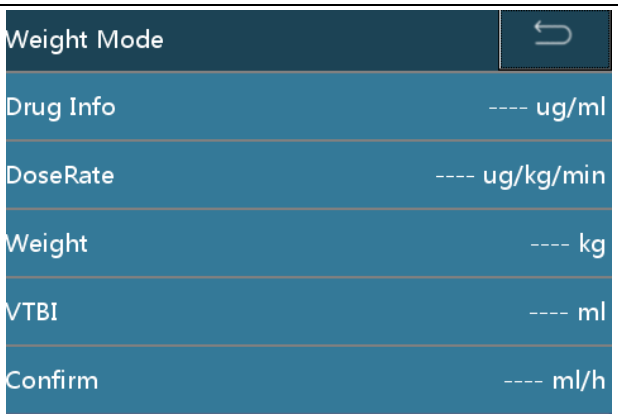
In Time Mode, the infusion pump infuses liquid at constant infusion rate set by the user and finishes the infusion when reaching the preset VTBI or time. Set **Drug Name**, **VTBI**, **Time**, and **Rate** for this mode and tap **Confirm** to start infusion.

Infusion Mode	**Parameter**	**Range**
Time Mode	Drug Name	All the drugs in the drug library
	VTBI	0.10–9999 ml
	Time	00:01-99:59 h:m
	Rate	0.10-1500 ml/h
Note: **VTBI=Rate x Time**. After any two of the three parameters are specified, the value of the third parameter is calculated automatically according to this formula.		

- Weight Mode

In Weight Mode, after a user sets **Weight** and **VTBI**, the infusion pump automatically calculates the infusion rate, infuses liquid at this infusion rate invariably, and finishes the infusion when reaching the preset VTBI or time. Set **Drug Info**, **DoseRate**, **Weight**, and **VTBI** for automatic calculation of the infusion rate, and then tap **Confirm** to start infusion.

Settings



Infusion Mode	Parameter	Range
Weight Mode	Drug Name	All the drugs in the drug library
	Conc Unit	ug/ml, mg/ml, g/ml, ng/ml, mIU/ml, IU/ml, kIU/ml, EU/ml, mol/ml, mmol/ml, kcal/ml, mEq/ml, U/ml, KU/ml
	Acti Agent	0.01~99999
	Acti Agent Unit	ug, mg, g, ng, mIU, IU, kIU, EU, mol, mmol, kcal, mEq, U, KU
	Volume	0.10~9999
	Conc	0.01~99999
	DoseUnit	µg/kg/min, mg/kg/min, g/kg/min, ng/kg/min, mIU/kg/min, IU/kg/min, µg/kg/h, mg/kg/h, g/kg/h, ng/kg/h, mIU/kg/h, IU/kg/h, µg/min, mg/min, g/min, ng/min, mIU/min, IU/min, µg/h, mg/h, g/h, ng/h, mIU/h, IU/h, mol/kg/min, mmol/kg/min, kcal/kg/min, mEq/kg/min, kIU/kg/min, EU/kg/min, mol/kg/h, mmol/kg/h, kcal/kg/h, mEq/kg/h, kIU/kg/h, EU/kg/h, mol/min, mmol/min, kcal/min, mEq/min, KIU/min, EU/min, mol/h, mmol/h, kcal/h, mEq/h, kIU/h, EU/h, KU/kg/min, KU/kg/h, KU/min, KU/h, U/kg/min, U/kg/h, U/min, U/h
	DoseRate	0.01~99999
	Weight	0.10~300.0 kg

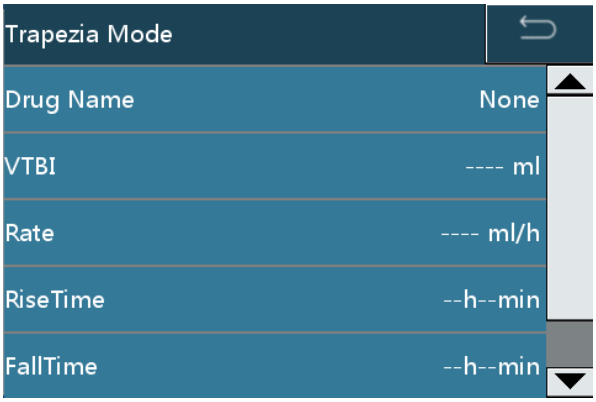
	VTBI	0.10–9999 ml

Notes:

- **Conc.**: This parameter can be directly input or obtained by calculation according to the following formula: **Conc.**=**Acti Agent**/**Volume**.)
- **Rate**=[**DoseRate** (if the unit includes kg)/**Conc**] x **Weight**.
- **Rate**=**DoseRate** (if the unit does not include kg)/**Conc**.
- **Time Remaining**=**VTBI**/**Rate**.

■ Trapezia Mode

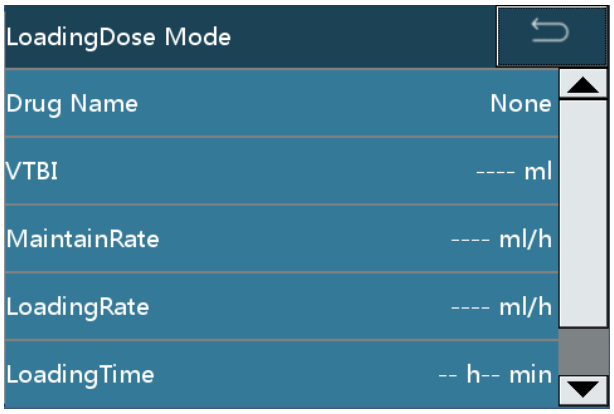
In Trapezia Mode, the infusion rate gradually increases by 10% of the target maintain rate each time and reaches the target maintain rate after increase for 10 times within the preset rise time. Finally, the infusion rate gradually decreases for 10 times until the infusion rate is 0 and the infusion is finished within the preset fall time. Set **Drug Name**, **VTBI**, **Rate**, **RiseTime**, and **FallTime** for automatic calculation of the infusion rate, and then tap **Confirm** to start infusion.



Infusion Mode	Parameter	Range
Trapezia Mode	Drug Name	All the drugs in the drug library
	VTBI	0.10–9999 ml
	Rate	0.10-1500 ml/h
	RiseTime	00:01-99:59 h:m
	FallTime	00:01-99:59 h:m

- LoadingDose Mode

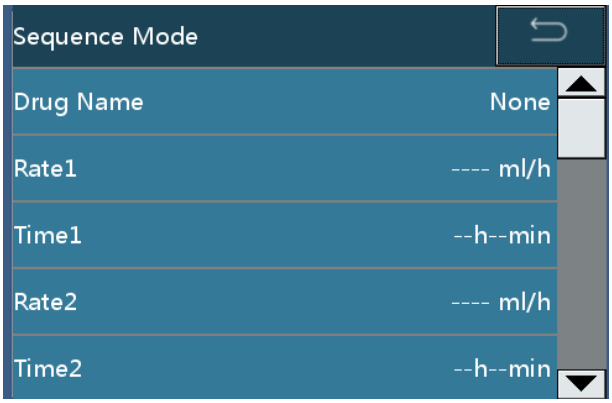
The LoadingDose Mode includes two phases: loading phase and maintain phase. In loading phase, the infusion pump infuses liquid at the preset loading rate invariably. After the preset loading time expires, the infusion pump enters the maintain phase. In maintain phase, the infusion pump infuses liquid at the preset maintain rate invariably and finishes the infusion when reaching the preset VTBI. Set **Drug Name**, **VTBI**, **MaintainRate**, **LoadingRate**, and **LoadingTime** for automatic calculation of the infusion rate, and then tap **Confirm** to start infusion.



Infusion Mode	**Parameter**	**Range**
LoadingDose Mode	Drug Name	All the drugs in the drug library
	VTBI	0.10–9999 ml
	MaintainRate	0.10-1500 ml/h
	LoadingRate	0.10-1500 ml/h
	LoadingTime	00:01-99:59 h:m
Notes: Loading Volume=**LoadingTime** x **LoadingRate** Maintain Time=(**VTBI** - Loading Volume)/**MaintainRate**		

■ Sequence Mode

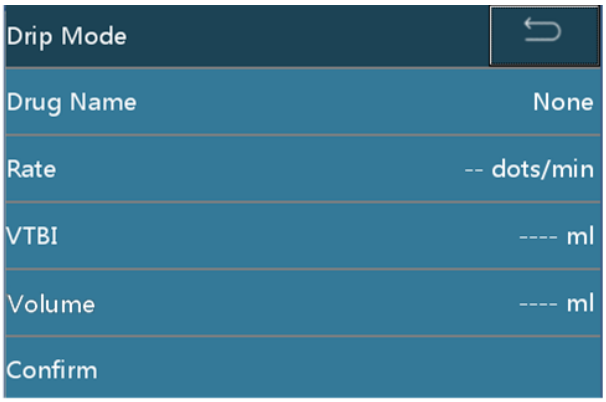
In Sequence Mode, the infusion pump successively infuses liquid based on various infusion sequences set for the pump. Different infusion rates and infusion time can be set for these infusion sequences. In sequence mode, when the infusion time set for an infusion sequence expires, the infusion pump starts infusion based on the next sequence. When all sequences are finished, the entire infusion is finished. Set **Drug Name** as well as **Rate** and **Time** for all the sequences, and then tap **Confirm** to start infusion.



Infusion Mode	**Parameter**	**Range**
Sequence Mode	Drug Name	All the drugs in the drug library
	Time *n*	00:01-99:59 h:m
	Rate *n*	0.10-1500 ml/h
Note: **VTBI**=**Rate** x **Time**. The total infusion volume is the sum total of the **VTBI** values respectively set for all the sequences.		

■ Drip Mode

In Drip Mode, the infusion pump automatically calculates the remaining time based on the size of the infusion set selected, infuses liquid based on the remaining time, and finishes the infusion when reaching the preset VTBI. Set **Drug Name**, **Rate**, and **VTBI** for this mode and tap **Confirm** to start infusion.



Infusion Mode	Parameter	Range
Drip Mode	Drug Name	All the drugs in the drug library
	Rate	0.1-500.0 dots/min
	VTBI	0.10–9999 ml
Note: **Time=VTBI/Rate**.		

⚠ CAUTION:

- Based on the setting of the drop rate (dots/min) and the specification of the currently selected infusion set, the infusion pump converts the drop rate (dots/min) into a corresponding rate (ml/h) and controls the flow rate.
- In Drip Mode, the control target of the infusion pump is still the flow rate (ml/h) rather than the drop rate (dots/ml).
- All the infusion modes support the drug library. The manufacturer does not provide the drug parameters in the drug library.

7.1.2OCCL Level

Thirteen occlusion levels are available for selection (the default occlusion level is level 8).

Table 7-1 Relationship between the occlusion level and pressure

Occlusion Level	Display	Intensity of Pressure			
		(mmHg)	(kPa)	(bar)	(psi)
1	P 1	75	10	0.1	1.45
2	P 2	150	20	0.2	2.9

3	P 3	225	30	0.3	4.35
4	P 4	300	40	0.4	5.8
5	P 5	375	50	0.5	7.25
6	P 6	450	60	0.6	8.7
7	P 7	525	70	0.7	10.15
8	P 8	600	80	0.8	11.6
9	P 9	675	90	0.9	13.05
10	P 10	750	100	1	14.5
11	P 11	825	110	1.1	15.95
12	P 12	900	120	1.2	17.4
13	P 13	975	130	1.3	18.85

⚠ CAUTION:

- In order not to infuse extra volume into the patient's body after the occlusion alarm is eliminated, the motor automatically and reversely rotates to release the tube pressure in case of an occlusion alarm (anti-bolus function).
- If the occlusion level is set to level 4 or lower and high-viscosity solution is selected for infusion, an occlusion alarm may be reported even if there is no occlusion in the tube. Carefully observe the occlusion status icon  in the information area on the screen. When over 2 bars of this icon are illuminated, you need to adjust the occlusion level to a higher level.
- If the occlusion level is set to level 8 or higher, the occlusion alarm is triggered only when a relatively high pressure is accumulated in the tube. Please ensure that the infusion tube is firmly connected to the infusion set.
- An occlusion alarm may be triggered when a small intravenous needle is used for infusion of high-viscosity liquid at high infusion rate. In this case, set the occlusion level to a higher level or reduce the infusion rate.
- In case of a single fault, the maximum occlusion pressure that might be generated is 3000 mmHg.

7.1.3Bolus Mode

Three bolus modes are available for selection: manual bolus, rapid quantitative bolus, and automatic bolus, see section 6.10.

7.1.4KVO Rate

KVO Rate allows setting. The setting range is 0.1 -30ml/h (minimum increment: 0.01ml/h), and the default value is 1 ml/h.

If the KVO function is enabled, the system automatically starts KVO when the infusion of VTBI finishes.

7.1.5Brand

The infusion pump allows you to select the brand of the infusion set. The preset Medcaptain 20d/ml infusion set and B.Braun 20d/ml infusion set are recommended.

List of Built-in Consumables

Brand	Specification
Medcaptain	20d/ml
B.Braun	20d/ml

⚠ CAUTION:

- To add an infusion set of other brand, you are strongly recommended to contact the supplier of the infusion pump. Professional staff of the supplier will conduct setting and test to ensure the infusion accuracy.
- If you want to set the infusion set on your own, please contact your local distributor.
- 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* or *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 Micro Mode

Users are allowed to enable or disable the micro mode and set the maximum rate in all infusion modes. The setting range is 0.10~1500ml/h.

7.1.7 Set Bubble Size

- Single Bubble Size

The **Single Bubble Size** parameter is configured on the infusion pump. This parameter can be set to any of the following seven levels: 25, 50, 100, 200, 300, 500, and 800 (ul). The default value of this parameter is 100ul. An alarm is reported if a single bubble exceeds the limit.

- Cumulated Bubble Size

The **Cumulated Bubble Size** parameter is configured on the infusion pump. This parameter can be set to any of the following seven levels: 100ul/15min, 200ul/15min, 400ul/15min, 500ul/15min, 600ul/15min, 800ul/15min, and 1000ul/15min. The default value of this parameter is 800ul/15min. An alarm is reported if the bubbles accumulated in 15min exceed the limit.

7.1.8 Near Finished

Users are allowed to set the time of reporting an alarm before the infusion is near finished. The default time is 3min before the infusion is finished, and the adjustable range is 1 – 30min (minimum increment: 1min).

7.1.9 Recent Therapy

The recent 20 therapies are recorded. After selecting a therapy and confirming the parameters, the user can directly start the infusion.

⚠ CAUTION:

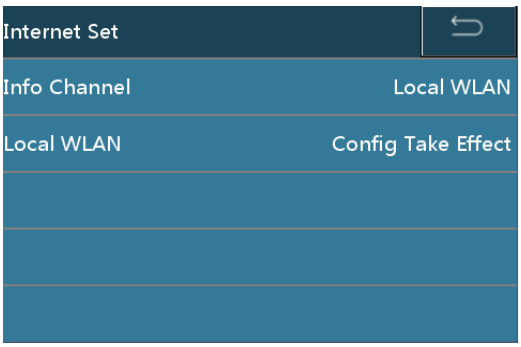
- The drop detection function can be enabled in all infusion modes.
- After the drop detection function is enabled, the infusion pump detects whether a drop sensor is connected in real time. The drop sensor is used to monitor the infusion rate in each infusion mode.

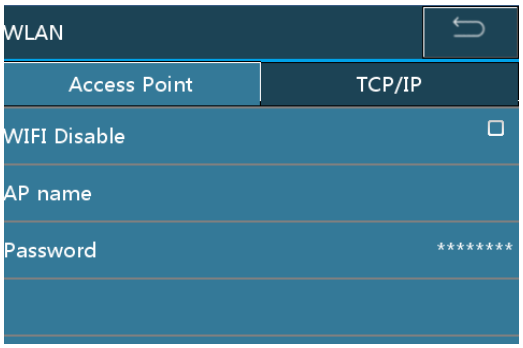
7.2 System Set

Press **HOME** to access the setting interface. Tap the **System Set** button to access the System Set interface.

7.2.1Internet Set

- Info Channel
  1. Press **HOME** to access the setting interface.
  2. Choose **System Set** > **Internet Set** > **Info Channel**.
  3. Select Local WLAN or Local RS485. Select Local WLAN if you want wireless networking and Local RS485 if you want wired networking.
- Local WLAN (The following settings are not required if **Local RS485** is selected.)
  1. Press **HOME** to access the setting interface.
  2. Choose **System Set** > **Internet Set** > **Local WLAN**.
  3. On the WLAN interface, deselect WIFI Disable, input the access point name, password, and local IP address, and then exit the current interface. The prompt "Config Take Effect" is displayed and disappears after the configuration is successful.





7.2.2Volume Setting

Ten volume levels are available for selection. The default volume level 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 properly identified.
- The alarm system may fail if the alarm volume is set to a value exceeding the upper volume limit. Please check the alarm limit based on the clinical environment.

7.2.3Display SET

The UI type, brightness, and night mode can be selected on the **Display SET** interface.

⚠ CAUTION:

- The setting range of the night mode start time/finish time is 17:00 – 09:00. By default, both the start time and finish time is 00:00.

7.2.4 Lock screen Set

On the **Lock screen Set** interface, you can select/deselect **Screen Lock Password** to determine whether a password is required for screen unlock. In addition, you can disable the auto lock function by selecting **OFF** on the **Auto Lock** interface or enable the auto lock function by selecting an exact auto lock time. Seven auto lock time options are available for selection: 15s, 30s, 1min, 2min, 5min, 10min, and 30min.

7.2.5 Collection Set

- **Mode Collection**: Allows you to configure the common infusion mode. After configuration, only the selected common infusion modes are displayed on the **Infusion Mode** interface described in section 7.1.1.
- **Brand Collection**: Allows you to configure the common infusion set brand. After configuration, only the selected common infusion set brands are displayed on the **Brand** interface described in section 7.1.5.
- **Drug Collection**: Allows you to configure the common drug. After configuration, the selected common drugs are placed at the top for drug selection in various modes. By default, no common drug is selected. The manufacturer does not provide the drug parameters in the drug library.

7.2.6 Linkage mode

You can select/deselect **Linkage mode** to determine whether to use the anti-free-flow clamp linkage mode. After selecting **Linkage mode**, you need to press and hold the anti-free-flow clamp button to open the clamp. After you release the button, the anti-free-flow clamp closes automatically.

7.2.7 Save Current Parameter

You can select/deselect **Save Current Parameter** to determine whether to save the current parameter.

7.2.8Pressure Unit

On the **Pressure Unit** interface, four pressure units are available for selection: **mmHg**, **kPa**, **bar**, and **psi**.

7.2.9Date& Time

On the **Date& Time** interface, you can set the date, time, and date format for the infusion pump. In addition, you can decide whether to use 24-hour format.

7.2.10 Alarm Set

On the **Alarm Set** interface, you can set the levels of the Reminder Alarm and Near Finished alarm. In addition, you can select/deselect **No Power Supply** to make the alarm system report or not report an alarm when no AC power supply is available and select/deselect **Up OCCL** to make the alarm system report or not report an alarm in case of upper occlusion.

⚠ **CAUTION:**

- You are advised to contact your local distributor for change of the alarm settings.

7.3 History

Table 7-2 lists the historical events.

Table 7-2 List of historical events

Event	Recorded Information
On	Occurrence time.
Off	Occurrence time.
Standby	Occurrence time and standby time.
Start	Occurrence time, flow rate, and Volume.
Bolus Start	Occurrence time, bolus rate, and bolus mode.
Bolus Stop	Occurrence time, bolus rate, and bolus volume.
Stop	Occurrence time, rate, and volume.
KVO	Occurrence time and KVO rate.
KVO stop	Occurrence time, KVO rate, and KVO volume.
Rate change	Occurrence time, flow rate before change, and flow rate after change.
Alarm	Occurrence time, alarm content, and fault code for a system fault.
Purge	Occurrence time, purge rate, and volume.
Stop purge	Occurrence time, purge rate, and purge volume.

⚠ CAUTION:

- If both the external power supply and internal power supply of the infusion pump are faulty, the alarm logs are automatically stored in the internal storage. The alarm logs will not be affected by the power failure time. When the power supply recovers from the fault, the system automatically loads the alarm logs.
- After the infusion pump is powered off, the historical records can be stored for up to 10 years.
- A maximum of 2,000 historical events can be stored by the infusion pump for playback. When the number of events stored on the infusion pump exceeds 2000, the earliest event is automatically replaced.
- The alarm system cannot be powered off separately. It can only be powered off by powering off the infusion pump. In addition, the power-off time is presented in the historical records.

7.4 Patient File

1. Press **HOME** to access the setting interface. Tap the **Patient File** button to access the **Patient File** interface.
2. Set **Department**, **Room No.**, and **BedNo.**, and then tap the **Patient Data** button.
3. On the displayed **Patient Data** interface, you can tap **New** or **Modify** to add or modify patient data. If you tap **New**, the previous patient data is cleared automatically.

7.5 Power by Built-in Battery

- If the infusion pump is not connected to an AC/DC power supply, the infusion pump will be powered by the built-in battery.
- In case of external power failure, the built-in battery starts operation and the yellow indicator illuminates with a short alarm sound.
- If you have any doubts about the integrity or wire of the protective earth, unplug the device for the battery to power the device.
- 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 appropriate remaining capacity of the built-in battery is indicated by the battery icon. When the battery operates, the remaining battery capacity is

indicated by the number of illuminated bars in the battery icon. For details, see Table 7-3.

Table 7-3 Status of the battery level icon during battery discharge

Status of the Battery Capacity Icon	Remaining Battery Capacity		
	Battery Configuration 1	Battery Configuration 2	Battery Configuration 3
Four bars illuminated	The infusion can last for about 300 minutes.	The infusion can last for about 600 minutes.	The infusion can last for about 1200 minutes.
Three bars illuminated	The infusion can last for about 180 minutes.	The infusion can last for about 360 minutes.	The infusion can last for about 720 minutes.
Two bars illuminated	The infusion can last for about 120 minutes.	The infusion can last for about 240 minutes.	The infusion can last for about 480 minutes.
One bar illuminated (green)	The infusion can last for about 60 minutes.	The infusion can last for about 120 minutes.	The infusion can last for about 240 minutes.
One bar illuminated (red)	The infusion can last for about 30 minutes.	The infusion can last for about 50 minutes.	The infusion can last for about 100 minutes.

Operating conditions:

- A fully-charge brand new battery is used.
- A 20d/ml infusion set is used, the infusion rate is 25 ml/h, and the wireless networking function is disabled.
- The ambient temperature is about 25 ℃.
- When the infusion pump is connected to an external AC/DC power supply, the built-in battery starts to be charged. During battery charge, a lightning symbol is displayed on the left of the battery icon.

⚠ **CAUTION:**

- The battery starts to be charged when the pump is connected to an external power supply.

- Use the AC power to charge the battery only. If you use 12 V DC power to charge the battery, the battery cannot be fully charged (the battery can be charged to 50% of its full capacity at most).
- The Low Battery alarm will be triggered in case of low battery. You can tap **Silent** to silence the alarm. However, the alarm sound will be given again 2 minutes later. When a low battery alarm is reported, please connect the pump to an external power supply. The infusion cannot be started if the pump has little remaining capacity.
- The infusion pump is powered off 3 minutes before the battery power is exhausted.
- The actual operation duration of the battery is relevant to the room temperature, infusion rate, and external communication and thereby may be different from that listed in the preceding table.
- Aging may shorten the battery operation duration. Please perform regular battery maintenance as stipulated.
- Please replace the battery every 2 years to ensure the battery operation duration.
- If the pump uses brand-new lithium battery of configuration 1, configuration 2, or configuration 3 to infuse liquid at the maximum rate (1500ml/h), the maximum continuous operation duration is not shorter than 2h, 4h, or 8h respectively.

7.6 Drug Library

The SYS-70 infusion pump supports drug library, and a maximum of 2,000 drug types can be stored in the drug library to facilitate drug selection for users.

1. A drug parameter cannot be set to a value exceeding the hard limits. If a drug parameter is set to a value exceeding the soft limits but this value does not exceed the hard limits, the infusion pump gives a prompt and it can still be started. To configure the drug parameters (for example, the default drug concentration, the dose rate, hard limits, soft limits, and etc.), contact the local distributor.
2. You can collect frequently used drugs by referring to section 7.2.5.
3. You can select the drug when setting the infusion mode according to section 7.1.1.

7.7 Nurse Call Button (Optional)

After the infusion pump is connected to the infusion central monitoring system, when a patient presses the nurse call button, a sound is given by the infusion central monitoring system at the nurse station to draw the nurse's attention and the information of this patient is displayed on the screen. Then, the nurse can go and nurse the patient in time.

7.8 Barcode Scanner (Optional)

You can scan the patient data (such as medical record No. and hospital No.) and follow the system instructions to update the patient data on the infusion pump once the infusion pump is connected to the barcode scanner.

The barcode scanner supports scanning of a barcode generated by using a character string consisting of up to 18 characters.

7.9 Wireless/Wired Networking Module (Optional)

The infusion pump can be connected to the infusion central monitoring system through the wireless/wired networking module. After the connection, the work state of the infusion pump can be remotely obtained through the infusion central monitoring system.

⚠ CAUTION:

The infusion pump cannot be operated through the infusion central monitoring system.

8 Alarm Indication and Troubleshooting

8.1 Alarm Levels

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

Based on the criticality of the exception information, alarms are classified into three levels: low, middle, and high. Table 8-1 describes the sound-light presentation mode of these three levels of alarm. The alarm volume ranges from 45 dB to 85 dB. All the alarms on this pump are technical alarms.

Table 8-1 Alarm levels and corresponding alarm sound and light

Alarm Level	Alarm Sound	Alarm Indicator Status
Low	“Di-di-di” is given every 24s.	The yellow indicator is steady on.
Middle	“Di-di-di” is given every 24s.	The yellow indicator flashes.
High	“Di-di-di—di-di-—Di-di-di—di-di ” is given every 15s.	The red indicator flashes.
Prompt	“Di-di” is given transiently.	The corresponding indicator flashes.

After an alarm (except **Battery Empty**) is triggered, you can tap **Silent** to silence the alarm. Two minutes later, the alarm sound is given again if the alarm level still exists.

8.2 Alarms and Elimination Methods

Table 8-2 Alarm message, alarm level, alarm cause, and troubleshooting

Alarm Content	Alarm Level	Alarm Cause	Troubleshooting
No Power Supply	Low	No external AC or DC power.	Connect to the external AC or DC power immediately.
No Battery	Middle	No built-in battery or built-in battery failure.	Install the battery.

Alarm Indication and Troubleshooting

Alarm Content	Alarm Level	Alarm Cause	Troubleshooting
Low Battery	Low	Low battery power.	Connect to the external AC or DC power immediately.
Battery Empty	High	The battery power is exhausted.	Connect to the external AC or DC power immediately.
Near Finished	Low	The infusion will be completed.	Wait until the infusion is completed.
OCCL	High	1. The infusion tube is occluded. 2. A low occlusion level is set for infusion of high-viscosity liquid. 3. The system will automatically reduce the volume when an occlusion occurs.	Tap **Stop** to eliminate the alarm. Identify and remove the occlusion cause and resume the infusion.
Up OCCL	High	The infusion tube is occluded at the part between the pump finger and drop chamber.	Tap **Stop** to eliminate the alarm. Identify and remove the occlusion cause and resume the infusion.
Air Bubble	High	1. There is air bubble inside the infusion tube. 2. A deformed infusion set is installed on the air bubble sensor.	Tap **Stop** to eliminate the alarm. Check that the part of the infusion set installed on the air bubble sensor does not deform, and remove the air bubble.

Alarm Indication and Troubleshooting

Alarm Content	Alarm Level	Alarm Cause	Troubleshooting
Finished	High	The infusion is finished.	Tap **Stop** to eliminate the alarm.
Reminder Alarm	Low	No button operation is performed in 2 minutes after the infusion set is installed.	Tap any button to eliminate the alarm.
Drop Error	High	Drop detection is abnormal during the infusion.	Tap **Stop** to eliminate the alarm. Check the installation of the drop sensor.
No Drop Sensor	Middle	The drop detection function is enabled but the drop sensor is not installed during the infusion.	Install the drop sensor, or stop infusion and disable the drop detection function.
No Drop	High	No drop is detected during the infusion.	Tap **Stop** to eliminate the alarm. Check the installation of the drop sensor and the status of the infusion tube.
Standby End	Middle	The standby time is out.	Tap **Cancel** to exit the standby state.
Pre OCCL	Middle	The occlusion pressure reaches 70% of the occlusion level setting value.	Release the pressure to eliminate the alarm.

Alarm Content	Alarm Level	Alarm Cause	Troubleshooting
Door Open	Low	The door is opened when the device is in standby state.	Close the pump door to eliminate the alarm.

8.3 Faults and Troubleshooting

In case of a fault, a prompt is displayed on the screen and a high-level alarm is reported.

Table 8-3 Fault symptoms and troubleshooting

Fault Content	Troubleshooting
Sensor Error	Record the fault content, power off the device, and contact your local distributor.
Motor Error	
Circuitry Error	
Driver COM ERROR	
Pump Finger Error	
Door Error	
Bubble Sensor Error	
System Error	

9 Cleaning and Disinfection

It is highly recommended that the materials and methods listed in this chapter be used for cleaning and disinfection of the device. If other materials or methods are used, the device may be damaged or its service life may be shortened.

⚠CAUTION:

- In case of any doubts about the use of the detergent or disinfectant, please consult the local distributor.
- Please dispose of the wastes generated after the cleaning and disinfection according to the relevant regulations of the local hospital.

9.1 Preparations

1. Before the cleaning and disinfection, disconnect the device from the patient.
2. Power off the device and disconnect the device from the AC or DC power supply.
3. Remove the infusion consumable and accessories (for example, drop sensor and barcode scanner) connected to the pump.
4. Wear a pair of rubber gloves and a gauze mask to prevent contaminants from splashing onto your skin during the cleaning and disinfection.
5. You are not allowed to disassemble this device for cleaning and disinfection. To disassemble this device for further cleaning and disinfection, please contact the local distributor.
6. Prepare several pieces of soft medical gauze, a detergent container, and a disinfectant container.

9.2 Cleaning

⚠WARNING:

- Do not immerse the device in the detergent solution.
- Prevent the solution from seeping into the device.
- Do not use organic solvent, halogenated solvent, petroleum-based solvent, glass detergent, acetone, or other irritant detergents.
- Only manual cleaning is allowed to be adopted for this device. Do not adopt the automatic cleaning mode for this device.

Cleaning procedure:

1. Completely immerse a piece of soft medical gauze in neutral or slightly alkaline detergent solution, wring out the gauze, and then use the gauze to wipe the device surface.
2. Wipe all the surfaces of the device in sequence until all the contaminants are removed from the device surface.
3. Ensure that all the edges and corners of the device are completely cleaned.
4. After the cleaning, use a piece of dry medical gauze to remove the residual detergent solution.

The following table lists the detergents recommended for the device.

Table 9-1 Recommended detergents

Detergent Name	Cleaning Method
Clean water	Wipe
Soapy water (pH value: 7.0~10.5)	Wipe

9.3 Disinfection

WARNING:

- Do not immerse the device in the disinfectant solution.
- Prevent the solution from seeping into the device.
- Use the disinfectant according to its operation manual.
- Do not autoclave the device.
- Only manual disinfection is allowed to be adopted for this device. Do not adopt the automatic disinfection mode for this device.

Disinfection procedure:

1. Before the disinfection, clean the device according to the method provided in section 9.2.
2. Completely immerse a piece of soft medical gauze in the intermediate-efficiency or high-efficiency disinfectant solution, wring out the gauze, and then use the gauze to wipe the device surface.

3. Wipe all the surfaces of the device in sequence. For the contact time of the disinfectant, see the operation manual of the disinfectant.
4. Ensure that all the edges and corners of the device are completely disinfected.
5. After the disinfection, immerse another piece of soft medical gauze in clean water, wring out the gauze, and then use the gauze to wipe the device surface for removing the residual disinfectant solution.

The following table lists the disinfectants recommended for the device and the required contact time for the disinfection.

Table 9-2 Recommended disinfectant solutions

Disinfectant Solution Name	Contact Time	Disinfection Method
75% alcohol	3min	Wipe
70% isopropanol	3min	Wipe
0.2% quaternary ammonium salt	20min	Wipe
3% hydrogen peroxide	30min	Wipe

9.4 Air Drying and Transportation

WARNING:

- Do not dry the device by using a drying machine or similar products.
- Connect the device to the power supply again after the device is completely dry.

1. After cleaning and disinfection, place the device in a shady, cool, and ventilated environment for air drying.
2. If you are not going to use the device soon after air drying, place the device in its original package for storage and transportation.

10 Maintenance

10.1 Regular Maintenance

Perform a maintenance inspection every 24 months to ensure safe operation and the longest possible life of the infusion pump. You can maintain some items by yourself and contact your local distributor to maintain some other items.

10.1.1 Checking the Appearance

- Appearance check: Check that no crack or damage exists.
- Button operation: Check that the buttons can be smoothly pressed and function properly.
- Check that all the sealing parts and the installation of the infusion pump are normal and no crack exists on any materials.

10.1.2 Checking the Power Cable

- Check the appearance of the power cable. If a surface damage or poor contact between plug and socket is found, contact the distributor for replacement in time.
- If the AC/DC power indicator is not illuminated after the infusion pump is connected to an AC/DC power supply or the infusion pump cannot be started, contact the distributor for maintenance in time.

10.1.3 Checking the Infusion Rate

Check the infusion rate once using a measuring cylinder and stopwatch.

The check conditions are as follows:

Infusion Set	Infusion Rate	Infusion Duration	Liquid Volume in Measuring Cylinder
B.Braun 20d/mL	120ml/h	6 min	11.4-12.6ml

If the flow volume actually infused does not fall within the range in the **Liquid Volume in Measuring Cylinder** column, contact the distributor for infusion pump accuracy calibration.

10.1.4 Checking the Alarm System

- Occlusion alarm

The check conditions are as follows:

Infusion Set	Infusion Rate	Occlusion Level	Alarm Time
B.Braun 20d/mL	120ml/h	P8	Within 1 minute

- Air bubble alarm

Add air into the infusion tube to form a bubble with a diameter ranging from 3 to 5 mm, start infusion, and check the alarm content displayed on the screen and the alarm sound when the bubble reaches the position of the air bubble sensor.

10.1.5 Electrical Safety Test

To ensure safety, please conduct a dielectric strength test, leakage current test, and ground impedance test according to the method stipulated in IEC 60601-1.

10.1.6 Checking the Built-in Battery

To ensure the battery performance, you must perform regular maintenance for the battery. The method is as follows:

- Connect the infusion pump to the AC power supply and recharge the battery for over 10 hours.
- Power on the infusion pump and install the infusion set.
- Set the infusion rate to 25 ml/h, and start the infusion. Record the start time.
- Make the infusion pump operates continuously until it stops due to low battery. Record the end time.
  - If the infusion lasts for 4 hours or longer, the battery is in good condition.
  - If the infusion lasts for 1 to 1.5 hours, the battery is close to the end of its service life.
  - If the infusion lasts for less than 1 hour, the battery has reached the end of its service life. In this case, the battery must be replaced. **You are advised to contact the distributor for battery replacement.**
- After battery status check is completed, recharge the battery for next use.

WARNING:

- Battery ageing is an inherent characteristic of the battery. To ensure the operation safety of the infusion pump, please contact the distributor for battery replacement after the built-in battery has been used for 2 years.
- Please ensure that the infusion pump is not in use during battery replacement.

10.2 Maintenance

- In case of any fault, contact your local distributor for repair.
- To prevent serious risks, do not disassemble or repair the infusion pump by yourself. We and our distributors shall not be held liable for any consequence caused by unauthorized disassembly and modification or use for improper purposes.
- If the infusion pump falls to the ground or it is affected by an external force, stop using the pump even if it seems normal. In addition, contact your local distributor to perform an inspection and judge whether the infusion pump has an internal problem.

WARNING:

- Infusion pump shall not be serviced or maintained while in use with the patient.
- Accessory replacement must be finished by trained professionals. Otherwise, a danger may be incurred.
- Do not service or maintain the infusion pump or its accessory when it is being used for a patient.
- Do not try to upgrade the infusion pump software by yourself. To upgrade the software, please contact your local distributor for help. The software upgrade must be finished by trained professionals. Otherwise, an exception of the infusion pump may be incurred.
- After software upgrade, the infusion pump must be calibrated by trained professionals before use.
- 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.
- Do not disassemble, short circuit, or throw the battery into fire to avoid the danger caused by linkage or explosion.

10.3 Storage

- Avoid water spills.
- Do not store the infusion pump in a hot and humid place.
- Store the infusion pump far away from excessive vibration, dust, and corrosive gas.
- Store the infusion pump out of direct sunlight and ultraviolet ray to avoid color fading.

10.4 Transportation

The infusion pump is allowed to be transported using a common vehicle, but it must be protected from the drastic impact, vibration, and rain and snow splash during the transportation. In addition, the infusion pump must be transported in accordance with the requirements specified in the order contract.

10.5 Environmental Protection and Recycling

Contact your local distributor to recycle the retired infusion pump, or otherwise dispose of it and its battery in accordance with the local laws and regulations.

11 Infusion Characteristics

The following test is performed in accordance with the IEC 60601-2-24:2012 standard 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, such as the pressure, temperature, humidity, infusion set, and infusion tube.
- The infusion accuracy does not reflect the clinical standards, for example, patient's age and weight and medicine taken.
- In case of a single fault, the maximum volume that might be infused is 1.5 ml and the maximum infusion volume inaccuracy is up to ±24%.
- The experiment data only represents the measurement data in the lab.
- To ensure the infusion accuracy, it is recommended that the infusion tube be changed or moved every 8 hours.

11.1 Infusion Accuracy Characteristics

The start-up graph and trumpet curves show the characteristics of the infusion pump after the infusion starts and the changes of the infusion status within a period of time 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 brand: Medcaptain(20d/ml), (B.Braun 20d/ml): 5sets each.
  - Infusion pump: 1 set
  - Sampling interval: 0.5min
  - Test Period: 120min
  - Test Liquid: ISO 3696:1987 Class III water

Infusion Characteristics

Table 11-1 Accuracy test result

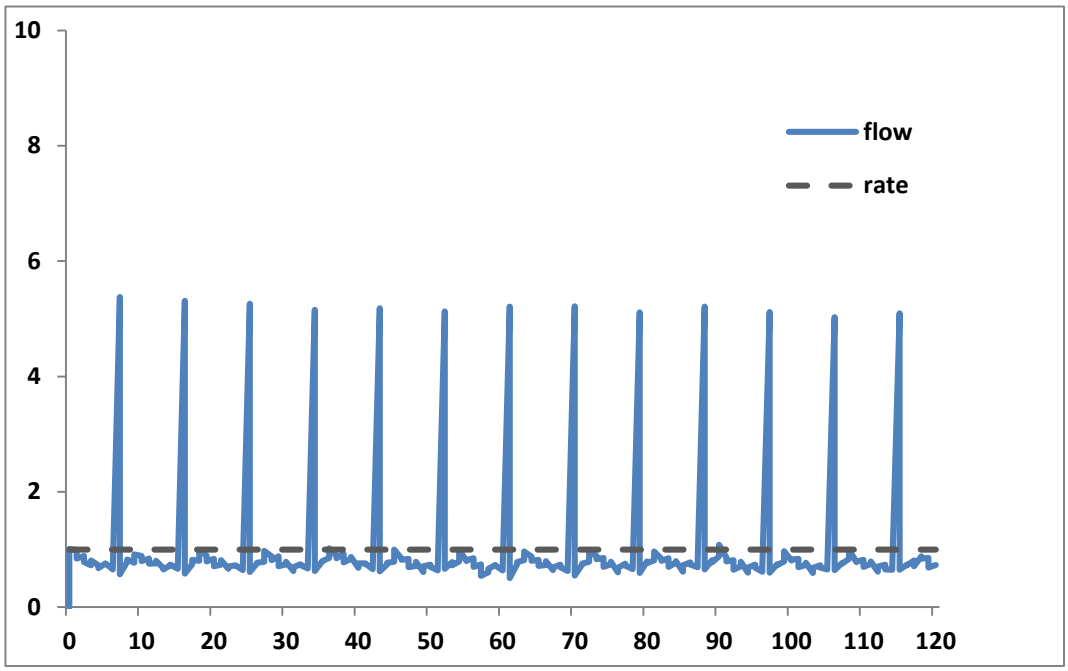
Administration set (IV set) Brand	Accuracy (%)	Remarks
B.Braun 20d/ml	+0.48	Minimum rate 1ml/h, normal condition
	+0.11	Intermediate rate 25ml/h, normal condition
	-3.59	Intermediate rate 25ml/h, with +13.3 kPa backpressure
	+0.52	Intermediate rate 25ml/h, with -13.3 kPa backpressure
	-4.04	Intermediate rate 25ml/h, when the supply container below the pump mechanism at a distance of 0.5m
Medcaptain(MC) 20d/ml	-0.07	Minimum rate 1ml/h, normal condition
	+1.37	Intermediate rate 25ml/h, normal condition
	+3.07	Intermediate rate 25ml/h, with +13.3 kPa backpressure
	+0.32	Intermediate rate 25ml/h, with -13.3 kPa backpressure
	-1.81	Intermediate rate 25ml/h, when the supply container below the pump mechanism at a distance of 0.5m

⚠ **CAUTION:**

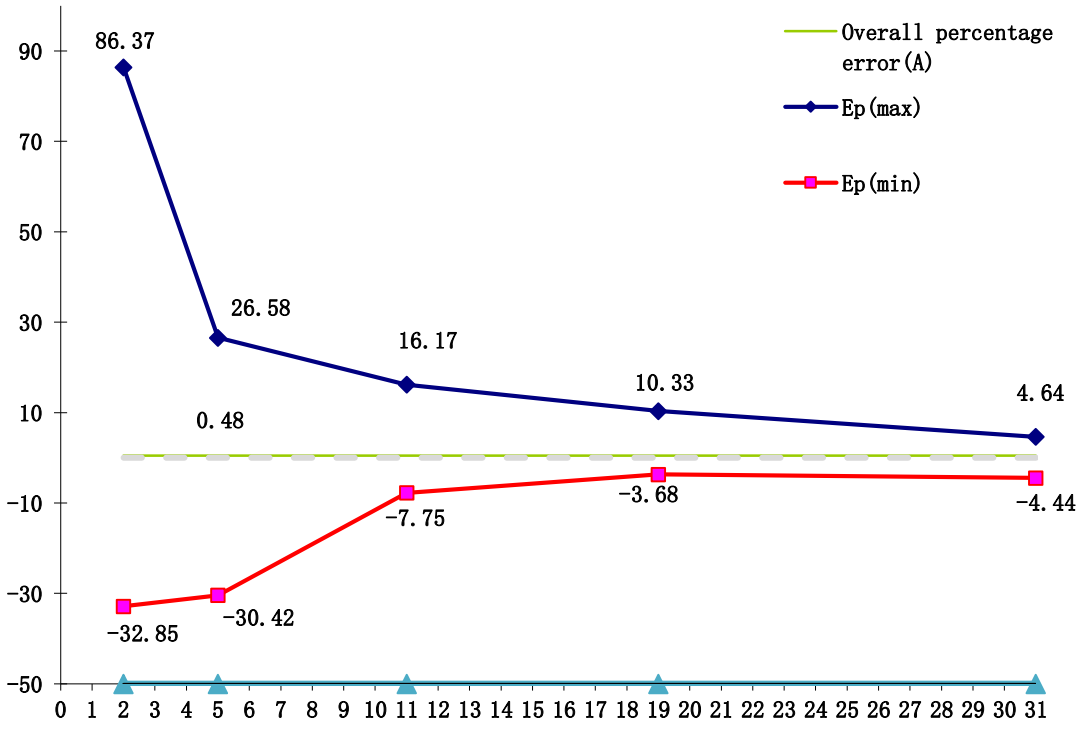
- To ensure the infusion accuracy, strongly recommend that the supply container is higher than the pump mechanism.

Infusion Characteristics

Start-up graph of B.Braun @ 1ml/h

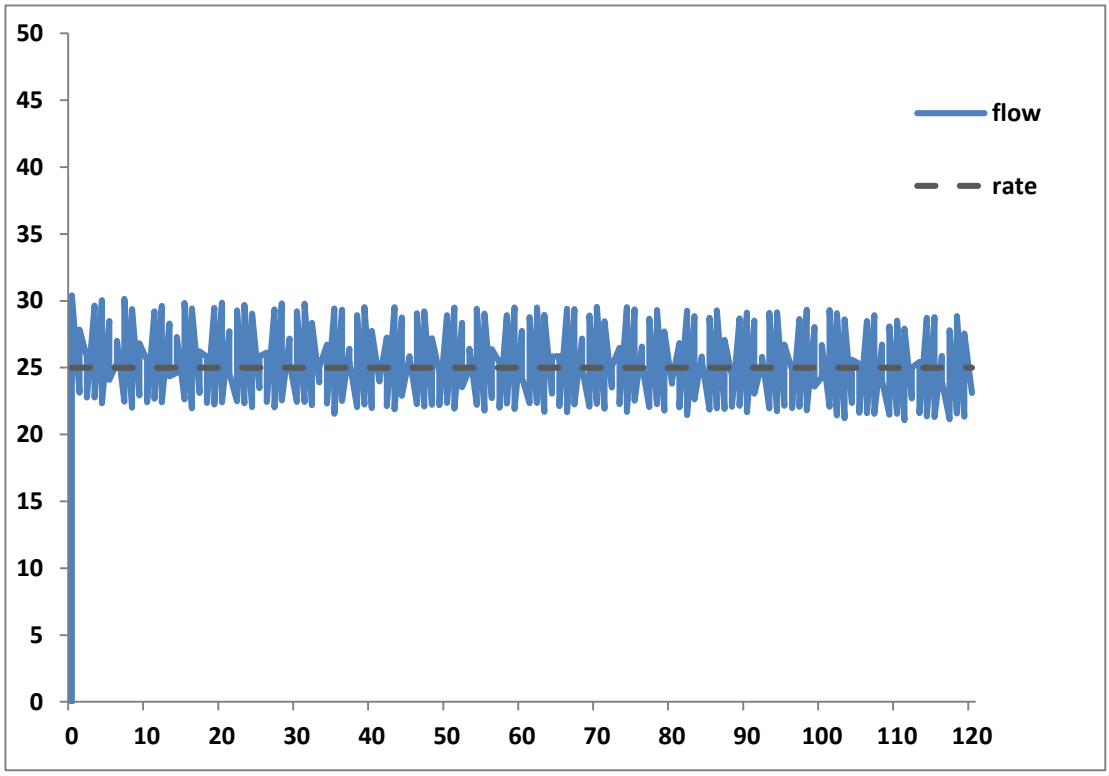


Trumpet curve of B.Braun @ 1ml/h

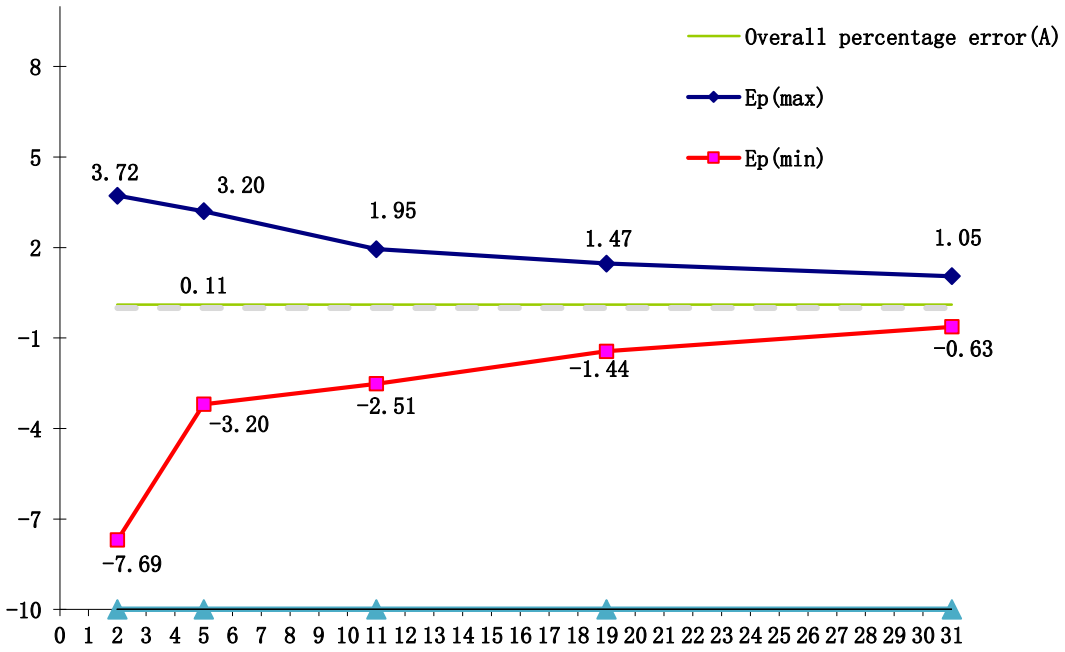


Infusion Characteristics

Start-up graph of B.Braun @ 25ml/h

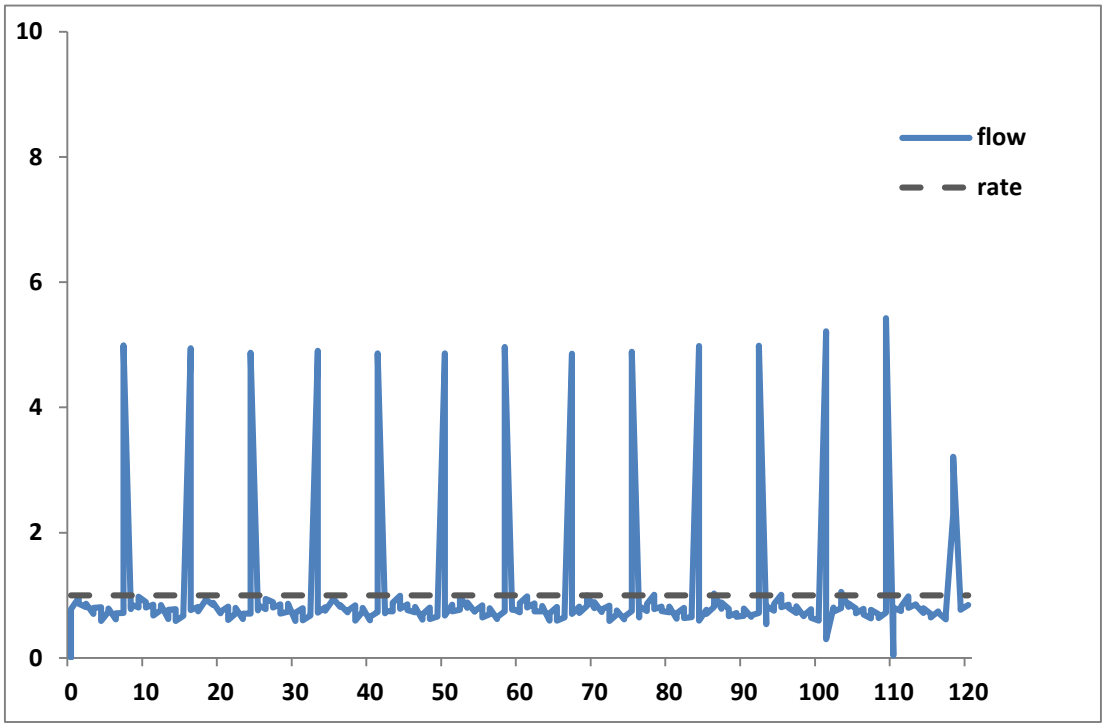


Trumpet curve of B.Braun @ 25ml/h

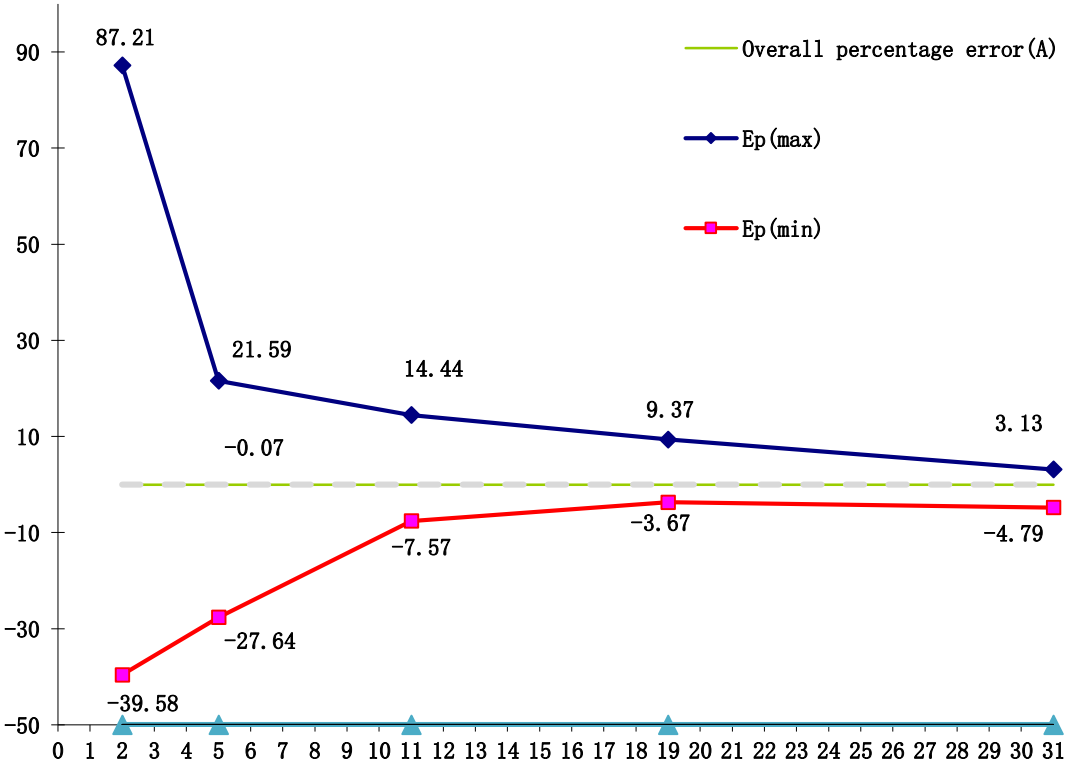


Infusion Characteristics

Start-up graph of Medcaptain @ 1ml/h

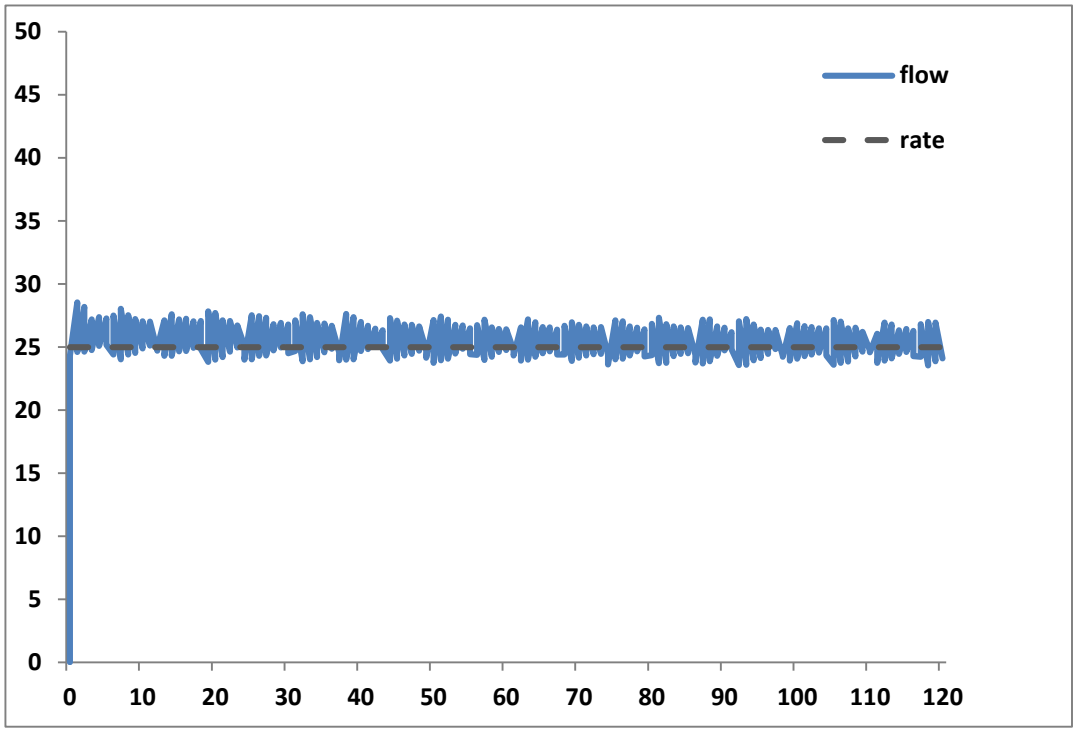


Trumpet curve of Medcaptain @ 1ml/h

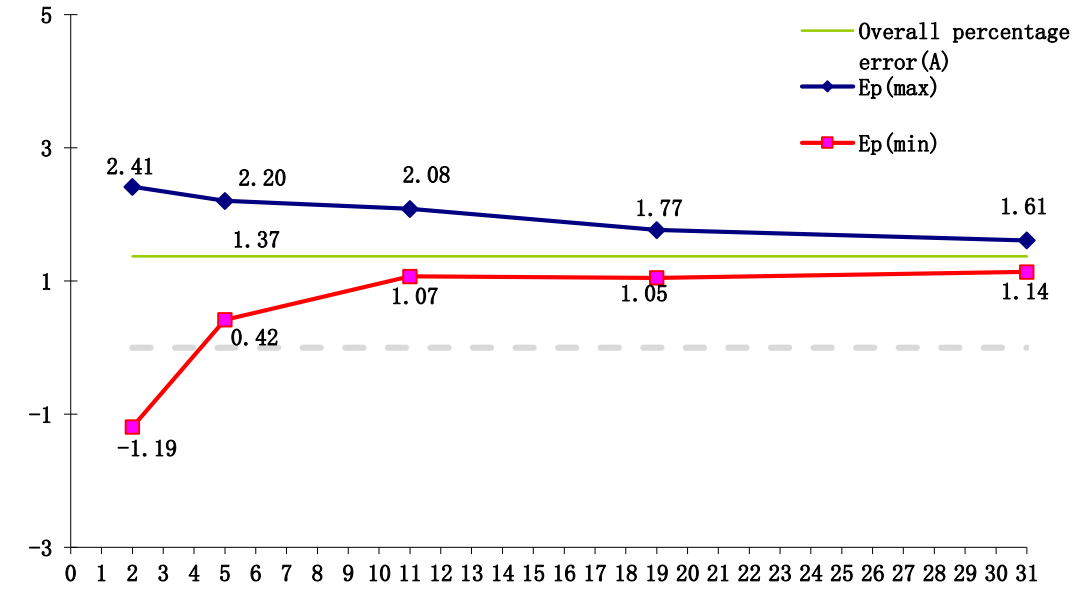


Infusion Characteristics

Start-up graph of Medcaptain @ 25ml/h



Trumpet curve of Medcaptain @ 25ml/h



11.2 Occlusion Response Characteristics

The occlusion characteristics are reflected by the longest delay time to start an alarm and performance of unintended bolus.

Infusion Characteristics

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

- Occlusion test conditions:
  - Temperature: 21 ℃;
  - Relative humidity: 65%;
  - IV Set: Medcaptain (20d/ml); 1 set
  - Length of the infusion tube: 1m

Table 11-2 Occlusion level and alarm delay time at the lowest rate

Infusion Rate	**Alarm Level**	**Occlusion Pressure (mmHg)**	**Occlusion Alarm Delay Time (hh:mm:ss)**
0.1mL/h	P1	75^{+145}_{-70}	01:20:33
	P13	975±145	09:52:11

Table 11-3 Occlusion level and alarm delay time at the lowest rate

Infusion Rate	**Alarm Level**	**Occlusion Pressure (mmHg)**	**Occlusion Alarm Delay Time (hh:mm:ss)**
1mL/h	P1	75^{+145}_{-70}	00:05:56
	P13	975±145	00:43:51

Table 11-4 Occlusion level, alarm delay time, and unintended bolus at middle rate

Infusion Rate	**Alarm Level**	**Occlusion Pressure (mmHg)**	**Occlusion Alarm Delay Time (hh:mm:ss)**	**Unintended Bolus (ml)**
25mL/h	P1	75^{+145}_{-70}	00:00:13	0.017
	P13	975±145	00:02:30	0.281

⚠CAUTION:

Unit conversion table:

Physical Variable	Unit	Unit Conversion
Intensity of pressure	kPa	1kPa=7.5mmHg
	psi	1psi=51.715mmHg
	bar	1bar=750mmHg

Appendix A Electromagnetic Compatibility (EMC)

⚠CAUTION:

- The SYS-70 Infusion Pump complies with EMC standard IEC 60601-1-2:2014.
- Users must install and use the SYS-70 Infusion Pump based on the EMC information provided in the accompanying document.
- Portable and mobile RF (Radio-Frequency) communication devices may affect the performance of the SYS-70 Infusion Pump. Avoid strong electromagnetic interference during the use, for example, stay away from mobile phone and microwave oven.
- For the declaration of emissions CLASS and group and immunity level, please see the Appendix.
- The SYS-70 Infusion Pump is suitable for home healthcare environments.
- The essential performance of the SYS-70 Infusion Pump is the infusion accuracy and high-level alarm function. If the essential performance is lost or degraded due to electromagnetic disturbances, the infusion may be inaccurate and the high-level alarm function may be abnormal.
- To assure that the SYS-70 Infusion Pump remains safe with regard to electromagnetic disturbances throughout the expected service life:
  - Conduct periodic maintenance based on the recommended maintenance/service interval and method provided in the operation manual.
  - After each maintenance, ensure that the internal structure, shielding system, and grounding system of the device remain complete and effective.

⚠WARNING:

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Only the following cables provided by the manufacturer are allowed to be used to meet the electromagnetic emission and anti-interference requirements.

No.	Cable Name	Length	Shielded
1	Power cable	2.5	No

2	Barcode scanner cable	2.2	No
3	Nurse call button cable	2.8	No
4	Drop sensor cable	2.8	No
5	Wired connection module cable	1.0	No
6	DC power cable	2.0	No

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SYS-70 Infusion Pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration – electromagnetic emissions		
The SYS-70 Infusion Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the SYS-70 Infusion Pump should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The SYS-70 Infusion Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SYS-70 Infusion Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC61000-3-2	Class A	
Voltage fluctuation flicker emissions IEC 61000-3-3	Complies	

Appendix A

Guidance and manufacturer's declaration – electromagnetic immunity			
The SYS-70 Infusion Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the SYS-70 Infusion Pump should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	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/burst IEC 61000-4-4	±2 kV 100KHz AC power cable ±2 kV 100KHz DC power cable(>3m) ±1 kV 100KHz SIP/SOP cable(>3m)	±2 kV 100KHz AC power cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line ±0.5 kV, ±1 kV, ±2 kV Line-to-ground AC power cable DC power cable(>3m) ±2 kV Line-to-ground SIP/SOP outdoor cable	±0.5 kV, ±1 kV Line-to-line ±0.5 kV, ±1 kV, ±2 kV Line-to-ground AC power cable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short	0% 0.5 cycle At 0°, 45°, 90°, 135	0% 0.5 cycle At 0°, 45°, 90°,	Mains power quality should be that of a typical

interruptions and voltage variations on power supply input lines IEC 61000-4-11	º; 180 º; 225 º; 270 ºand 315 º; 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 º 0% 300 cycle	135 º; 180 º; 225 º; 270 ºand 315 º; 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 º 0% 300 cycle	commercial or hospital environment. If the user of the SYS-70 Infusion Pump requires continued operation during power mains interruptions, it is recommended that the SYS-70 Infusion Pump be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The SYS-70 Infusion Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the SYS-70 Infusion Pump should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**

Appendix A

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz; 6 Vrms in ISM and amateur bands[a] between 0.15MHz and 80 MHz; 80% AM at 1 kHz	3 Vrms 150 kHz to 80MHz; 6 Vrms in ISM and amateur bands Between 0.15MHz and 80 MHz; 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the SYS-70 Infusion Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz; 80% AM at 1 kHz 27V/m:380-390 MHz; 28V/m:430-470 MHz; 9V/m:704-787MHz; 28V/m:800-960 MHz; 28V/m:1700-1990MHz; 28V/m:2400-2570MHz; 9V/m:5100-5800MHz;	10 V/m 80 MHz – 2.7 GHz; 80% AM at 1 kHz 27V/m:380-390MHz; 28V/m:430-470MHz; 9V/m:704-787MHz; 28V/m:800-960MHz; 28V/m:1700-1990MHz; 28V/m:2400-2570MHz; 9V/m:5100-5800MHz;	$d = 1.2\sqrt{P}$ 80M~800MHz $d = 2.3\sqrt{P}$ 800M~2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], a should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

Appendix A

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.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

The amateur radio bands between 0,15MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] 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-70 Infusion Pump is used exceeds the applicable RF compliance level above, the SYS-70 Infusion Pump 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-70 Infusion Pump.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [10] V/m

Appendix A

Recommended separation distances between portable and mobile RF communications equipment and the SYS-70 Infusion Pump

The SYS-70 Infusion Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SYS-70 Infusion Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SYS-70 Infusion Pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM and amateur bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur bands $d = 1.2\sqrt{P}$	80M~800MHz $d = 1.2\sqrt{P}$	800M~2.7GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance din meters (m) can be determined 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 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1

Appendix A

MHz to 10,15MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

RF Parameters

Item	Description
Working band	2.412GHz-2.484GHz
Transmitting power	<20dBm
Protocol	IEEE 802.11 b/g/n

Appendix B Factory Defaults

Here we list some factory defaults. You can change some parameters and, if necessary, restore their default settings.

Parameters:

Parameter	Factory Defaults
KVO Rate	1ml/h
Pressure Unit	mmHg
Occl level	P8 (middle)
Near Finished	3min

System Time

System Time and Date	Factory Defaults
Time	00:00
Date	2014-1-1
Time format	24h
Date format	Year-month-day

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