

**BeneFusion VP5/
BeneFusion VP5 Ex/
BeneFusion VP5 Neo**

Infusion Pump

Operator's Manual



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Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your equipment.

Conventions

- ***Italic text*** is used in this manual to quote the referenced chapters or sections.
- [] is used to enclose screen texts.
- <> is used to enclose the keys.
- → is used to indicate operational procedures.

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1 Safety

1.1 Safety Information

WARNING

- Indicates a potential hazard or unsafe practice that, if not avoided, could result in death, serious injury or damage to product/property.
-

CAUTION

- Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury, product malfunction or damage to product/property.
-

NOTE

- Provides application tips or other useful information to ensure that you get the most out of the product.
-

1.1.1 Warnings

WARNING

- Device, cables and accessories must be inspected before use to guarantee their normal and safe operation.
 - This equipment can only be connected to the socket with ground protection. Please adopt a rechargeable battery instead of the socket as the power supply if the socket is not provided with a ground lead.
 - To prevent fire or explosion, do not operate the equipment in the presence of anesthetic, flammable or explosive materials.
 - Do not open the equipment casing as there is the impending danger of electric shock. Equipment maintenance and upgrades must be carried out by maintenance technicians whom are trained and licensed by the manufacturer. Moreover, the process must be done only after the AC power supply is disconnected. Maintenance carried out by individuals
-
-

non-affiliated to the manufacturer or by non-licensed personnel may affect the safety, performance and function of the product.

- When used with electrosurgery equipment, the safety of patients should be ensured.
- The patient's clinical condition and the working condition of the infusion pump must be monitored carefully, the alarm volume and alarm levels need to be set according to the actual needs. Operation and performance relying solely on the auditory alarm system alone is not sufficient, and setting the alarm at a low volume may endanger the patient. If the alarm volume is less than the surroundings volume, which can further lead to operators identify alarm mistakenly.
- The interconnection of other infusion systems or ACCESSORIES to the PATIENT LINE may lead to performance degradation and failure to achieve the expected performance, the working condition of the pump and patient's clinical condition shall be monitored regularly.
- Please carefully install the power line and cables with various accessories to prevent the patient from choking or suffocation caused by entanglement of the cables or by electrical disturbance.
- The packaging materials must be disposed of in compliance with local laws and regulations or the hospital policy on waste management. They must be kept out of the reach of children.
- Infusion tube knots, filter coagulation and occlusions arising from needle insertion can cause the pressure inside the infusion set to rise during infusion. When this occurs, removing the occlusion can cause excessive liquid to be infused into the patient, so appropriate measures should be taken.
- The pump should not be placed more than 100cm above or below the level of the patient's heart. The smaller the height difference between the pump, the more accurate the pressure test in the infusion cannula will be.
- It is recommended that infusion pump with conventional infusion sets is used with infusion sets recommended by manufacturers (please refer to *6.10.1 Infusion Pump with Conventional Infusion Sets* for specific brands). When use of non-recommended infusion sets, please make sure to confirm relevant infusion performance (such as accuracy, air bubble and pressure) on infusion pump, and contact the company for calibration service. Air bubble calibration, Accuracy Calibration and Pressure Calibration shall be performed sequentially, the infusion sets can only be used after confirmation, otherwise Mindray Scientific is not responsible for infusion performance (such as accuracy, air bubble and pressure) and relevant alarm function of the infusion pump. Its accuracy cannot be guaranteed when the pump is used with an infusion set without calibration.

-
-
- **Infusion pump with specified infusion sets has to be used with specified infusion sets.**
 - **When operating the pump and under non-running status, please carefully check whether there is leakage from the tube export of the infusion set, and drop needle of the drip chamber. If any leakage is found, please contact the manufacturer for maintenance and confirmation.**
 - **Do not touch the patient when connecting the peripheral equipment via the input/output signal ports to prevent patient leakage current from exceeding the requirements specified by the standard.**
 - **In the process of defibrillation, do not touch patient and other non-defibrillation equipments to prevent electric shock damage, and defibrillation will not affect the basic performance (such as infusion accuracy, alarm and signal transmission) of the pump.**
 - **The equipment use a mains plug as isolation means to the mains power. Do not locate the equipment in a place difficult to operate the mains plug.**
-
-

1.1.2 Cautions



-
- **Use the accessories specified in this Operator's Manual to guarantee the patient's safety.**
 - **When this infusion pump and its accessories exceed their service life, they must be disposed of in accordance with local statutes or hospital regulations. If you have any queries, please contact your distributor or the manufacturer.**
 - **After loading the infusion set and before infusion, check for leakages. If any are found, they should be rectified as soon as possible.**
 - **Infusion pump with conventional infusion sets: For SK series infusion sets, it is recommended to replace the infusion set or adjust the fixing site of the infusion set after the infusion has been running for 24 hours to guarantee accuracy. For infusion sets of other brands, it is recommended to test the service life of the infusion set to determine the time interval of changing the fixing site of the infusion set; if the service life of the infusion set is not tested, it is recommended to adjust the fixing site of the infusion set every 4 hours after infusion begins to guarantee accuracy, and reload the new tube without extrusion.**
 - **Infusion pump with specified infusion sets: It is recommended that the time interval of changing infusion sets should be less than 72 hours.**
 - **Electromagnetic fields may affect equipment performance. This makes it**
-

necessary for other equipment used in the vicinity of the pump to meet EMC standards. Mobile phones, X ray and MRI equipment are all potential interference sources because of their high-intensity electromagnetic radiation.

- Before the equipment is connected to the power supply, check that the voltage and frequency of the power supply match the specifications on the label or in this Operator's Manual.
- Please install and carry the equipment correctly to protect the equipment from damage from drops, impacts, violent shaking or other external mechanical forces. The equipment should be observed to verify normal operation after fall, otherwise it cannot be used.
- Disposable accessories must be disposed of after use in accordance with the relevant hospital regulations.
- Avoid direct sunshine, high temperatures and dampness.
- Check the built-in battery before use to make sure it has sufficient power. Recharge the battery if necessary.
- The infusion set with the luer taper is recommended for use, which can effectively prevent patients from under current caused by the occurrence of the cannula to slip out when under tension.







1.1.3 Notes





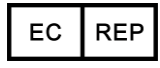













NOTE

-
- Install the equipment in a position where it can be easily accessed for inspection, operation and maintenance.
 - Keep this Operator's Manual near to the equipment for future ease of reference.
 - The software was developed in compliance with IEC62304. The possibility of hazards arising from software errors is minimized.
 - This Operator's Manual describes the most complete functional configuration of the equipment. The product you are using may not have some of the settings or functions described herein.
 - Do not insert devices that are not specified by the manufacturer into the multifunction interfaces.
 - During infusion, the infusion pump can accurately control the rate, infusion volume and infusion time, and monitor the operation in real-time, to effectively prevent over currents, under currents and instances of backflow.
 - The device is not in touch with the drugs or patients directly. Thus, there is no need to process Biocompatibility test on it.
-

1.2 Equipment Symbols

Some symbols may not appear on your equipment.

| | | | |
|---|---|---|---|
|  | Refer to instruction manual/booklet |  | ON/OFF |
|  | Alternating current |  | Battery |
|  | Direct current |  | Caution |
|  | Alarms |  | AUDIO PAUSED |
|  | Clear/Back |  | Start; start of action |
|  | Bolus |  | Confirm |
|  | Stop |  | Menu |
|  | Move up/Increase |  | Move down/Decrease |
|  | Move left |  | Move right |
|  | Night mode |  | Equipotentiality |
|  | Input |  | Input/output |
|  | Wireless networking, normal communication with BeneFusion CS5 Infusion Supervision System |  | Wireless networking, no communication with BeneFusion CS5 Infusion Supervision System |
|  | Wireless network is establishing a network connection |  | Non-ionizing electromagnetic radiation |
|  | Current pump communicated successfully with BeneFusion DS5 Infusion Supervision System |  | Current pump has forward relayed No.X pump |
|  | Executed prescription |  | Pause prescription |

| | | | |
|---|---|---|--|
|  | Executing prescription |  | Non-executed prescription |
|  | Date of manufacture |  | Manufacturer |
|  | Authorized representative in the European Community |  | Serial number |
|  | Recovery/recyclable |  | DEFIBRILLATION-PROOF TYPE CF APPLIED PART |
|  | THIS WAY UP |  | Keep dry |
|  | Fragile, handle with care |  | STACKING LIMIT BY NUMBER |
|  | Environmentally-friendly use periods of electronic products (20 years) |  | CE mark, comply with the requirements of the Council Directive 93/42/EEC (Medical Device Directive). |
| IP23 | Protected against solid foreign objects with a diameter no less than 12.5mm and protected against spraying liquid water |  | Comply with the requirements of Directive 2012/19/EU Waste Electrical & Electronic Equipment |
|  | Atmospheric pressure limitations |  | Humidity limitations |
|  | Temperature limitations | | |

2 Overview

2.1 Description

2.1.1 Intended Use

The infusion pump is used in conjunction with the infusion set to control the dose of liquid infused into the patient's body. The pump may also be used for blood transfusion. For this therapy only use disposables dedicated and labelled for transfusion.

The infusion pump is suitable for adults, children and newborns in clinical departments.

The infusion pump is expected to be used in institutes or units with healthcare capabilities. This includes but is not limited to: outpatient departments, emergency departments, wards, ICU, operating rooms, observation rooms, clinics, and nursing hospital.

WARNING

- **The infusion pump is for clinical use. It must only be used under appropriate conditions by professional clinicians, medical device technicians, or by suitably trained nurses. Personnel using this product must receive sufficient training. This product must not be operated by anyone who has not been authorized to do so or has not received suitable training.**
-

2.1.2 Contraindications

None

2.1.3 Appearance, Parts and Features

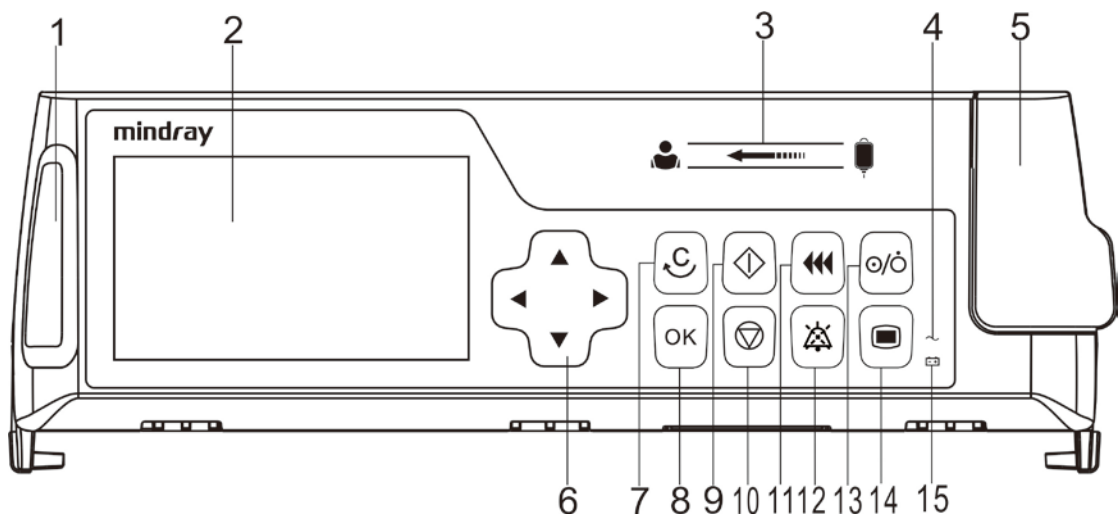
The infusion pump primarily consists of a housing, a motor drive system, an input system, a memory system, a control system, a display system, a sensor-based monitor system and an alarm system. Eccentric camshaft is driven by stepper motor during operation, making the fixed upper slider moves up and down sequentially and regularly, infusion set is extruded regularly, and liquids in infusion set can flow directionally at a certain rate, and all components are suitable for use in patient environment. The wireless module and drop sensor are optional. Optional functions

of the software comprise Rate Mode, Time Mode, Body Weight Mode, Ramp Up/Down Mode, Sequential Mode, Loading Dose Mode, Micro-infusion Mode, Drug Library, History Record and Anti-bolus Function.

The infusion pump also includes IV sets as applied parts. Since some parts and functions are optional, the infusion pump you purchased may not contain these additional parts and their relevant functions.

2.2 Host

2.2.1 Front View



1. Alarm light
Indicates different alarm levels using colors and frequencies, please refer to **Chapter 8 Alarms** for details.
2. Display
Shows the infusion parameters and details.
3. Direction of flow label
Informs the user on the proper direction of flow for infusion setup.
4. AC indicator light
 - On: The pump is connected to an AC power supply (including shutdown).
 - Off: The pump is not connected to an AC power supply.
5. Door latch
Opens the door for loading and unloading the set.

6. **<DIRECTION>**

Used for adjusting value, changing lines and pages.

7. **<CLEAR/BACK>**

- Under the setting status, press this key to set the value to "0".
- Edited value is "0", press this key to return the value to the previous value.
- Under non-setting status, press this key to return to the previous menu.

8. **<OK>**

Used for entering setting status, confirming input operation and saving value.

9. **<START>**

- After the infusion set is loaded correctly and the infusion parameters are set, press this key to start the infusion.
- In the [**Bolus**] settings screen, after bolus parameters are set, press this key to auto bolus.

10. **<STOP>**

During infusion, press this key to stop infusion. Infusion stops caused by alarms (such as Occlusion), press this key to cancel the alarm.

11. **<BOLUS >**

- During infusion, press this key to enter the [**Bolus**] settings screen.
- Under non-running status, press this key to enter the [**Purge Air**] prompt screen.

12. **<AUDIO PAUSED>**

Pauses alarm sound.

13. **<POWER>**

Used for turning power on, entering in standby state and turning off operations.

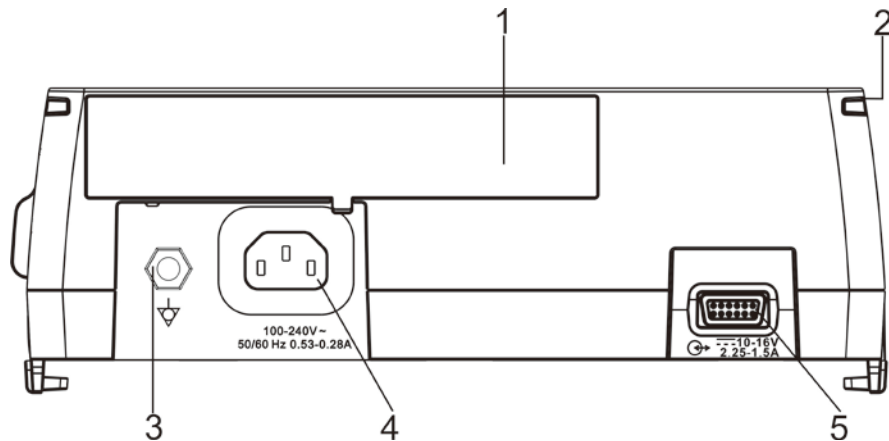
14. **<MENU>**

- Used for entering [**Main Menu**] interface.
- Under operation status, press and hold this key to lock; in locked state, press and hold this key to unlock.

15. Battery indicator light

- Steady green: The battery is charging (including shutdown).
- Flashing: The pump is running on battery power.
- Off: There is no battery or the battery is not working.

2.2.2 Rear View



1. Battery compartment

2. Connection rail

Track for stacking pumps.

3. Equipotentiality terminal

When other device and infusion pump are used together, please adopt wires to connect other devices and equipotential port of the pump, to eliminate ground potential difference between different devices and ensure safety.

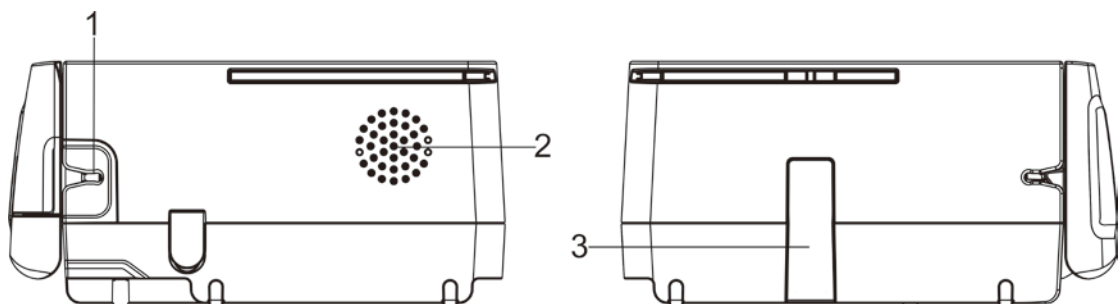
4. AC power supply port

Connection for the AC power cord.

5. Multifunction interface with the following functions:

- DC power supply port
- RS232 interface
- Nurse call interface

2.2.3 Side View



1. Tubing channel

Loading track for the IV administration set

2. Speaker

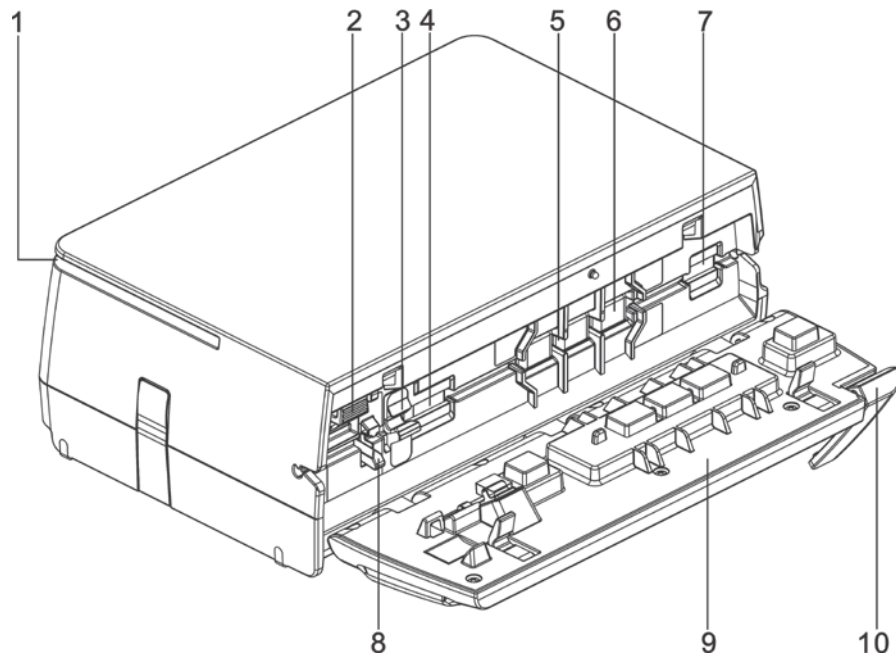
Provides sound for audible alarms.

3. Multi-channel pumps hasp

Used to secure the stacked pumps.

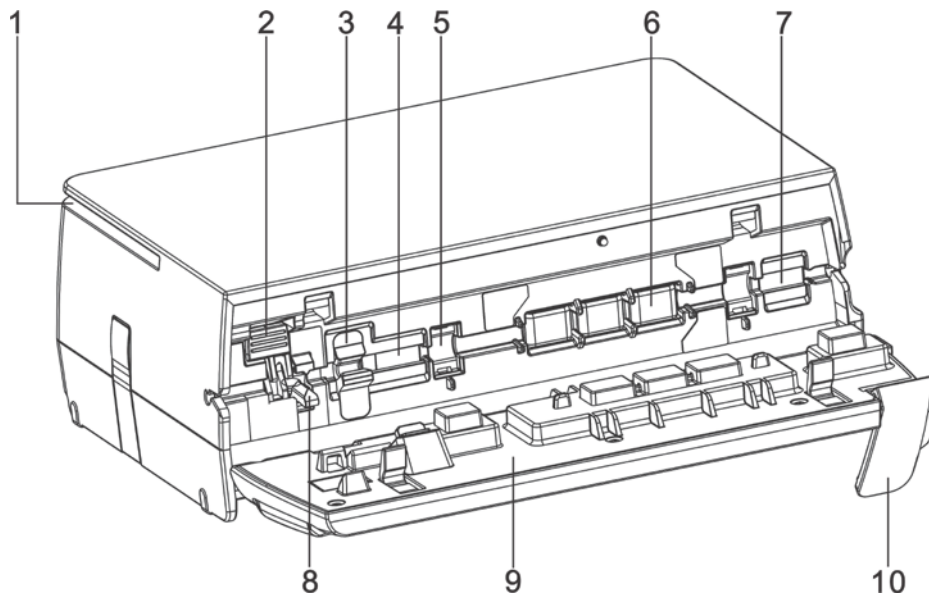
2.2.4 Side View with the Door Opened

2.2.4.1 Infusion Pump with Conventional Infusion Sets



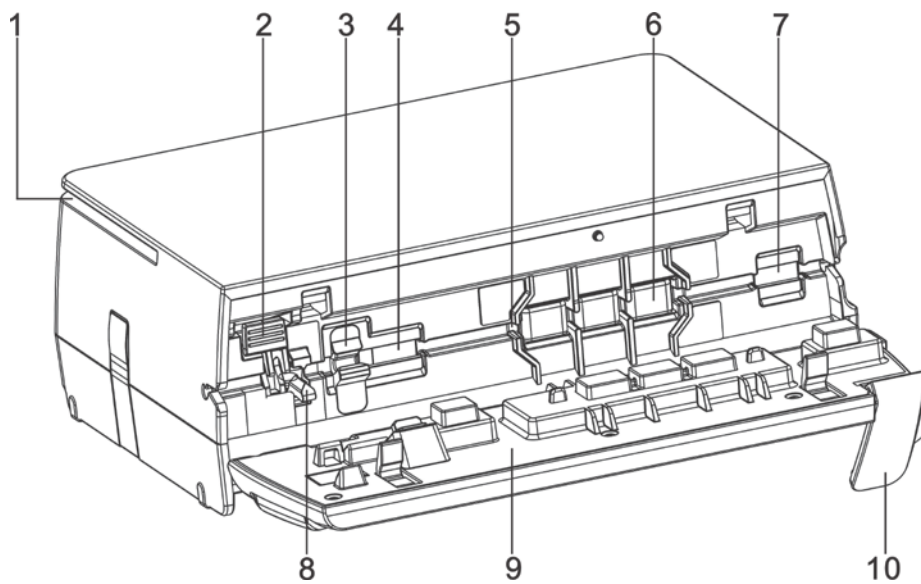
1. Connection rail
2. Liquid check clip button
3. Ultrasonic sensor
4. Downstream pressure checkout slot
5. Infusion set slot
6. Waterproof membrane
7. Upstream pressure checkout slot
8. Liquid check rod
9. Door
10. Door latch

2.2.4.2 Infusion Pump with Silicone Specified Infusion Sets



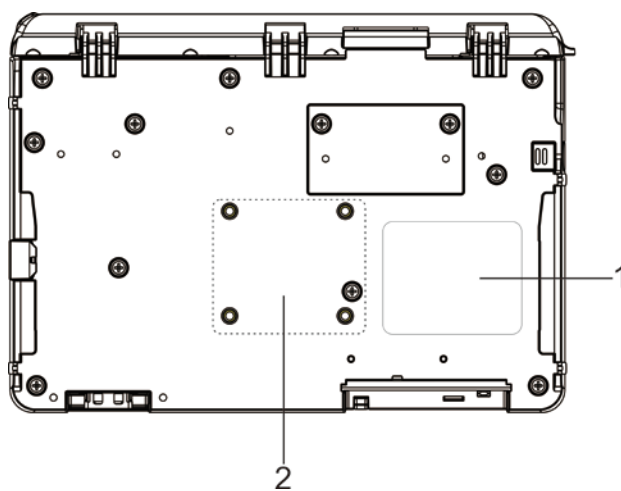
1. Connection rail
2. Liquid check clip operating lever
3. Ultrasonic sensor
4. Downstream pressure checkout slot
5. Locating slot
6. Waterproof membrane
7. Upstream pressure checkout slot
8. Liquid check rod
9. Door
10. Door latch

2.2.4.3 Infusion Pump with PVC Specified Infusion Sets



1. Connection rail
2. Liquid check clip operating lever
3. Ultrasonic sensor
4. Downstream pressure checkout slot
5. Infusion set slot
6. Waterproof membrane
7. Upstream pressure checkout slot
8. Liquid check rod
9. Door
10. Door latch

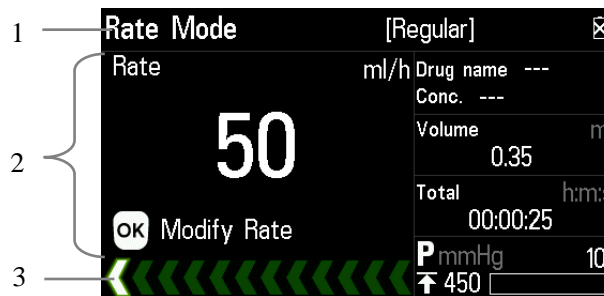
2.2.5 Bottom View



1. Product label
2. Placement area for pole clamp

2.3 Screen Display

This infusion pump has a built-in LCD screen. The display information comprises three main parts:



1. Title bar



Displays current infusion mode, drug information, alarm information, battery icon, and etc.

2. Parameter area

Displays every parameter and the parameter value of the current screen.

3. Prompt bar


Displays run icon and so on. The run icon on the screen displays the running operation:

-  Green icon indicates normal running. Arrows move from right to left, and the running speed increases as the rate is increased.
-  Blue icon lighting indicates bolus.

2.4 Cursor

In the main screen and parameter settings screen, when the cursor is located at an option or at a data value, the grounding of the option or the data value will turn to

white and the font will become black. Press  or  to move cursor up or down

and confirm the location. Press  to select the option or data value for further operation.

Note: Press  or  to "locate" cursor; Press  to "Select".

3 Installation and Setting

3.1 Installation

WARNING

- Equipment assembly and refit (including correct protective grounding connection) during life period must be carried out by maintenance technicians whom are trained and licensed by the manufacturer, and evaluated according to the specified IEC60601-1. Please contact the company if you have any queries.
 - The software copyright for this equipment belongs to the manufacturer. Unless explicitly authorized, any alteration, reproduction or sale by any means or in any form by any organization or individual is prohibited.
 - All the analog equipment and digital facilities should be certified according to the specified IEC standard (such as: IEC60950 Information Technology Equipment Safety and IEC60601-1 Medical Electrical Equipment Safety). Moreover, all equipment should be connected based on the requirements of the valid version of the IEC60601-1 system. The qualified individual responsible for connecting auxiliary equipment to the input and output signal ports is also accountable for making the system in accordance with the IEC60601-1 standard. Please contact the company if you have any queries.
 - When this equipment combining with other electrical equipments forms a combination with a special function, and the user cannot determine whether there is an impending danger from each equipment specification (such as a danger of electric shock due to aggregation of current leakage), please contact the company or a specialist in the field at the hospital, to guarantee that all equipment in the combination are safe enough and will not be damaged.
 - Please make sure this equipment is securely fixed and positioned. Positioning changes and severe shock can lead to minor changes in the delivery accuracy.
-

3.1.1 Out of Box Audit (OOBA)

Please check the packing case carefully before opening the box. If there is any damage, please contact the distributor or manufacturer immediately.

 **WARNING**

- The packaging materials must be kept out of the reach of children. They must be disposed of in compliance with local laws and regulations or the hospital policy on waste management.
 - The equipment may be contaminated by microbes during storage, transport and use. Please ensure that the package is undamaged before using, do not use if there is any damage.
-

NOTE

- Keep the packing case and packaging materials for future transportation or storage.
-

3.1.2 Operating Conditions

The operating environment of this infusion pump must meet the requirements in **A.1.2 Operating Environment**.

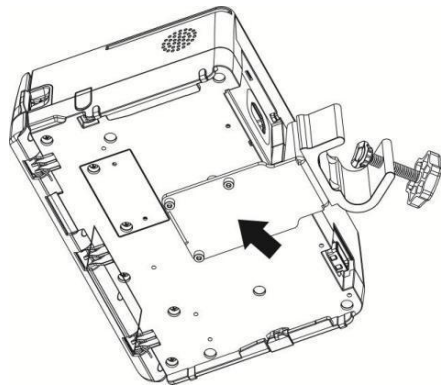
The operating environment should also be appropriately protected from noise, vibration, dust, and corrosive, inflammable or explosive substances. If installed inside the equipment case, a sufficient space before and after the equipment case should be ensured to facilitate operation, maintenance and repairing work. There should be a 2" (5 cm) gap around the infusion pump to ensure that air can circulate freely for a better cooling effect.

When the pump is transferred from one place to another, differences in temperature and humidity can cause condensation to form inside the pump. If this occurs, do not switch the pump to the "ON" state until the condensation has gone.

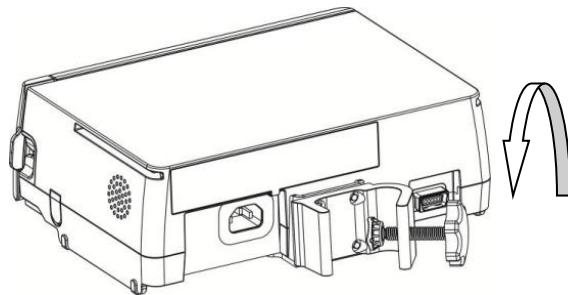
 **WARNING**

- Please use only when the operating environment meets the requirements specified above. Otherwise, the pump's performance will not match the technical specifications in *A Product Specifications*. Device failure and other unexpected consequences may also result.
-

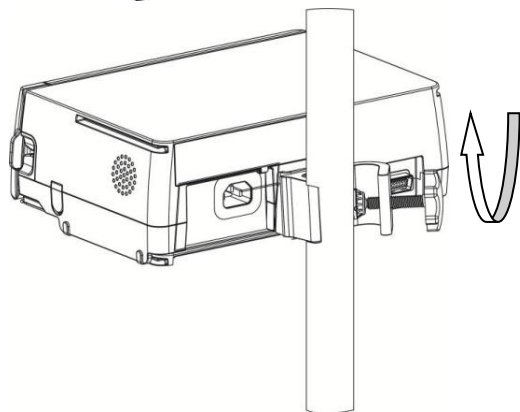
3.1.3 Mount the Clamp



1. Align the mounting holes on the installation dead plate with the installation screw holes on the bottom of the machine, and tighten the screws.



2. Turn counterclockwise to loosen the pole clamp until an IV stand can be inserted in.

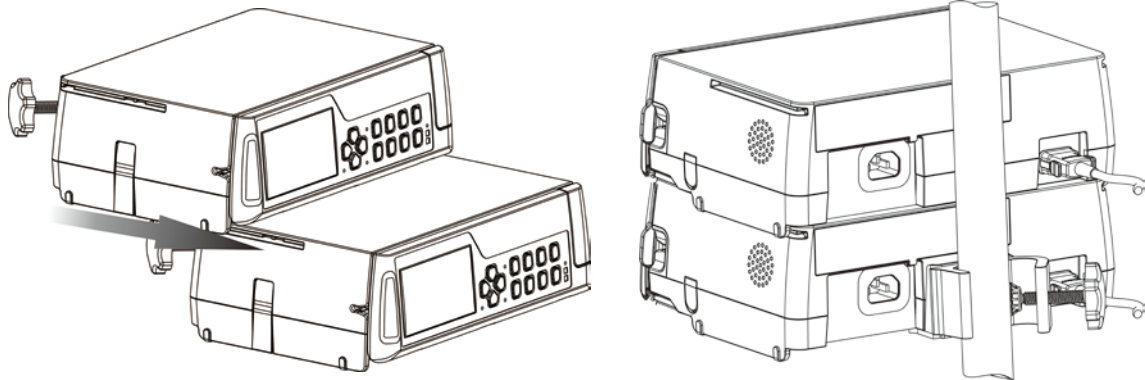


3. Tighten the pole clamp clockwise to firmly fix the device on the IV stand (round vertical bar with diameter size of 15-32mm).

3.1.4 Multi-channel Pumps Combination

A maximum of 2 pumps can be combined (infusion pump and syringe pump can be cross combined).

When multi-channel pumps are combined, align the rail on the bottom of the upper pump to the rail slot on the top of the lower pump, slide from backward to frontward until the alignment is matched, then strain the two pumps by the hasps. When disconnecting, hold the upper-part of the hasp of the upper pump and pull out the lower pump.



⚠ WARNING

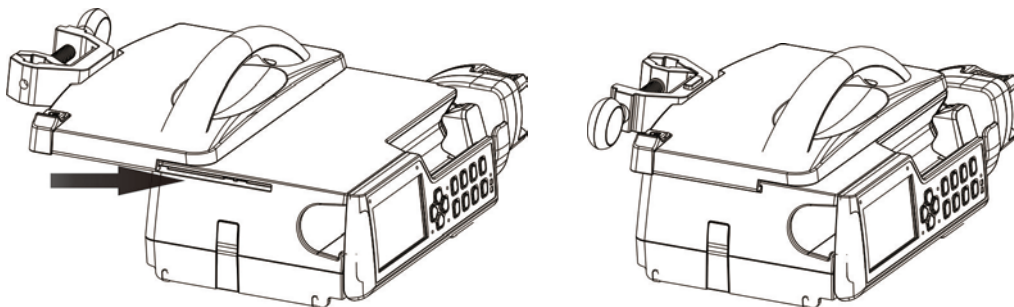
- The infusion pump must be installed horizontally.

NOTE

- Please ensure the stand is stable before installation.
- When the pumps are overlapped, all fixing clamps except the fixing clamps of the lowest pump should be removed, otherwise, the pumps can't be used overlapped.

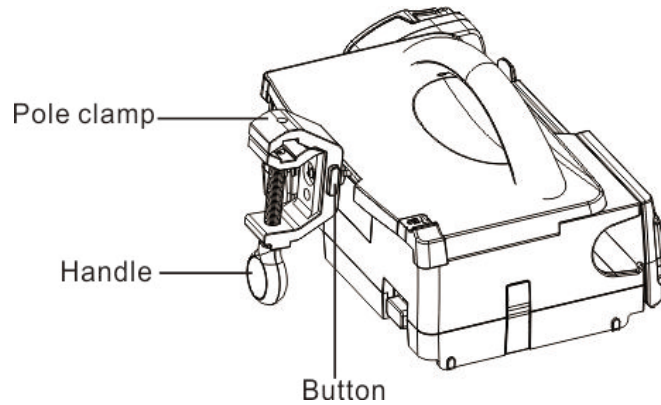
3.1.5 Mount the Handle Set

Align the rail on both sides of the handle set to the rail slot on the top of the lower pump; slide from backward to forward until the alignment is matched. When disconnecting, toggle the button of the handle set outward and pull out the handle set or pump.



Press the button of pole clamp, horizontally or vertically adjust pole clamp, turn the handle, pump can be fixed to cross bar or vertical bar.

- Square tube: Width 10mm, length 15-40mm
- Round tube: External diameter $\varnothing 15 \sim \varnothing 40$



NOTE

-
- **Only 2 pumps (syringe pump and infusion pump can be cross combined) can be carried by the handle set, or the handle of the handle set might be broken. Please refer to 3.1.4 Multi-channel Pumps Combination for the combination operation of multi-pump.**
-

3.1.6 Connect the AC Power Source

To connect the pump to the AC power source, follow this procedure:

1. Always use the accompanying power cord delivered with the pump, and check that both ends of the power cord and surroundings without liquid drug and other residues.
2. Connect one end of the power cord to the device's AC power supply port, and check that internal and surrounding AC power supply port without liquid drug and other residues.
3. Insert the other end of the power cord into the three-plug connector. Check that the AC indicator light is on.

WARNING

-
- **The earthing wire in the three-plug connector should be grounded, if there is a doubt whether the AC power system is grounded or not, please adopt the built-in battery and contact an electrical technician at the hospital or the company.**
 - **Do not touch the power plug with wet or moist hands! If there is a liquid drug or residue on or around the both ends of the power cord, power socket or plug, device's AC power supply port, the user should completely clean and dry the area before plugging into the power supply, or accidents or injuries may result!**
-

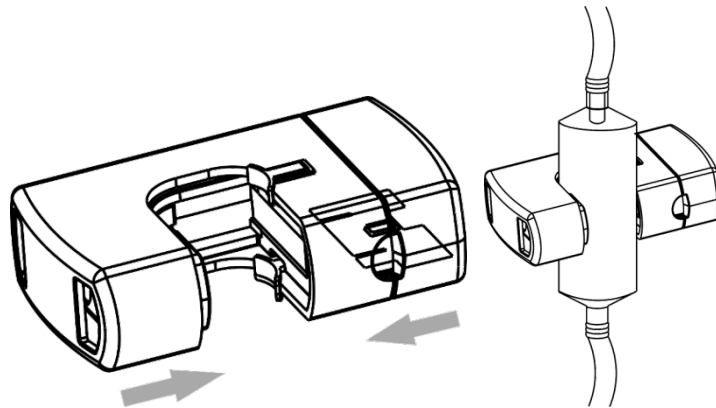
NOTE


- **Compatible power supply: 100–240V~, 50/60Hz.**
 - **The AC power cable should be correctly inserted and secured into the socket.**
 - **Removing power cord is to disconnect equipment from power supply. Please ensure suitable clearance around the device to facilitate connect and remove power cord.**
-

3.1.7 Install and Operate the Drop Sensor (Optional)

NOTE

- **This section should be used with the optional drop sensor. The user may skip the instructions in this section if a drop sensor is not included with the infusion pump.**
-



1. Firmly insert the signal line of drop sensor into the drop sensor interface of the pump.
2. Clip the drop sensor to the drip chamber, making sure that the drop sensor is above the surface of the liquid.
3. Press  to start the infusion. The light of drop sensor flashes green when liquid is detected in normal infusion status.

WARNING

- Drop sensor must be installed correctly when the infusion pump is equipped with a drop sensor, otherwise the pump can't be used normally.
 - For 60drop/ml infusion sets, it is recommended to set the rate <1000ml/h. Otherwise, the [Empty] alarm will be triggered mistakenly.
 - Small liquid drops in drip chamber might be left on its wall after long time infusion, the medical staffs need to confirm and eliminate the drops. Otherwise, the accuracy of drop rate check will be affected, and the [Empty] alarm will be triggered.
-
-

NOTE

- The surface of the liquid in the drip chamber must be lower than the drop sensor, which should be between 1/3 and 1/2 of the drip chamber.
 - The positioning block of the drip chamber must be inserted vertically through the positioning groove on the drop sensor.
 - Do not excessively tilt the drop sensor, or expose it to direct sunlight during infusion. Otherwise, accuracy of the drop sensor may be influenced.
 - Make sure that the drip chamber is not clamped too tightly by the drop sensor.
 - It is suggested that the signal line of drop sensor should be changed every six months.
-

3.2 Conventional Settings

This chapter only introduces the general settings for the infusion pump, please refer to other relative chapters for parameters and other feature settings.

3.2.1 Adjust Alarm Sound Volume

1. Select [Main Menu]→[System Options]→[Sound Volume].
2. Select [Sound Volume]: 1-8. 1 for the lowest volume; 8 for the highest volume.

3.2.2 Adjust Screen Brightness

1. Select [Main Menu]→[System Options]→[Brightness].
2. Select [Brightness]: 1-8. 8 for the brightest setting, and 1 for the darkest setting. When operating on battery power, you can set a low Brightness to save the power of the battery.

3.2.3 Set Language

1. Select **[Main Menu]**→**[User Maintenance]**→Input User Maintenance Password→**[Language]**.
2. Select from the **[Language]** according to actual needs.

3.2.4 Set Date and Time

1. Select **[Main Menu]**→**[User Maintenance]**→Input User Maintenance Password→**[Date and Time]**.
2. Set **[Time]** and **[Date]**.
3. Select **[Time format]: [24h]** or **[12h]**.
4. Select **[Date format]: [yyyy-mm-dd]**, **[mm-dd-yyyy]** or **[dd-mm-yyyy]**.

CAUTION

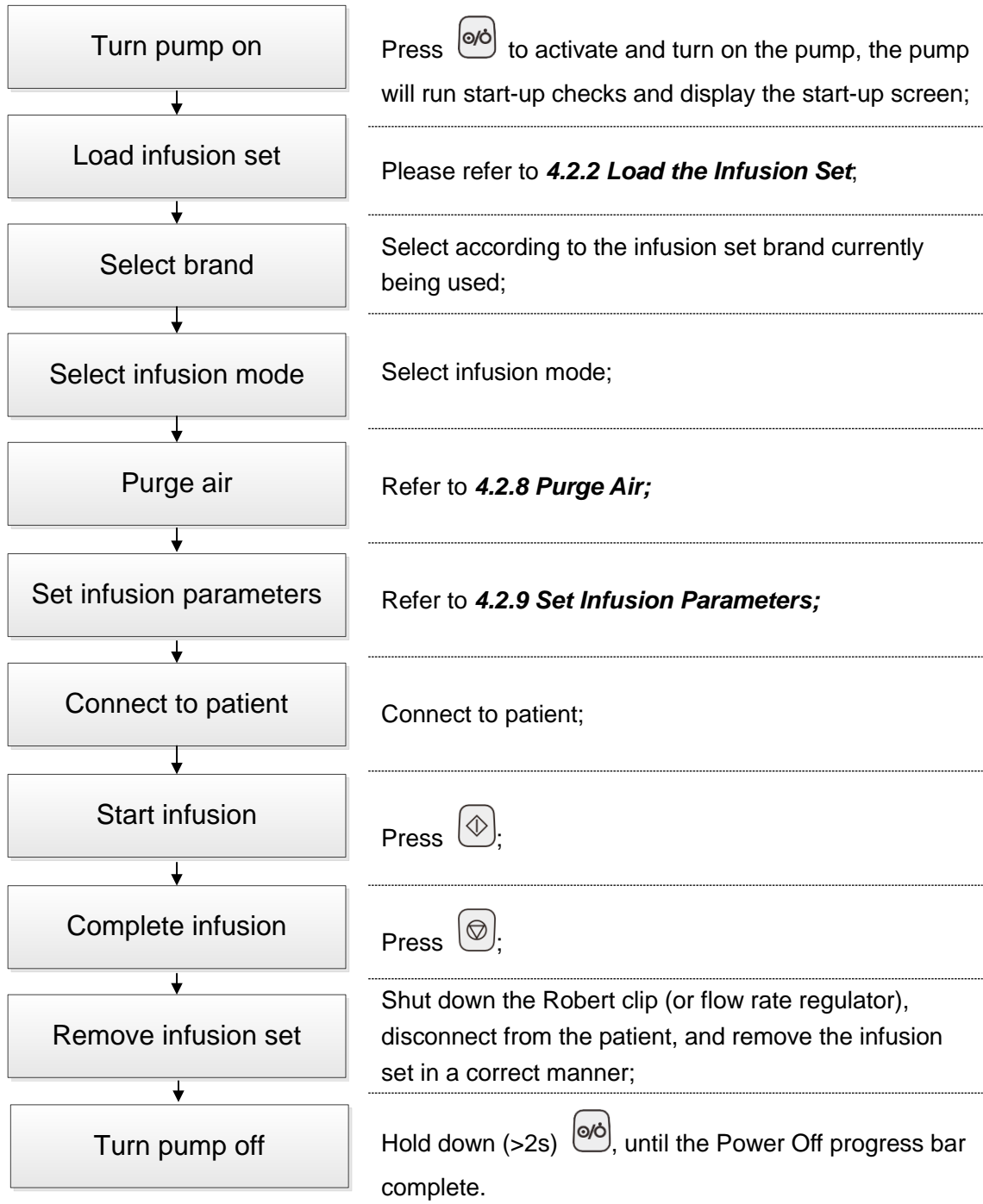
- Please check the system date and time to keep accurate records in the History function.
 - After changing the time format or date format, the record will update new format automatically.
 - For infusion pump inserted to BeneFusion DS5 Infusion Supervision System, time and date can't be changed.
-

3.3 Restore Factory Default

Select **[Main Menu]**→**[Manufacturer Maintenance]**→Input Manufacturer Maintenance Password→**[Factory Default]**, and restore the factory default settings as prompted on screen, some parameters will be restored to default values.

4 Basic Operation


4.1 Infusion Flow Chart



4.2 Operational Procedures

4.2.1 Turn on the Pump

To turn on the device, follow this procedure:

1. Perform a safety inspection referring to **11.1 Inspection** before turning on the pump.
2. Press , the system will initiate the self-test and the screen will display the **[System Self-test]** interface:
 - System will give out a sound "di"- indicating the self-test of the loudspeaker to be successful.
 - The color of the alarm indicator light will change from red to yellow, turn on and off orderly- indicating the self-test of the alarm light to be successful.
 - System will give out a sound "didi"- indicating the self-test of the buzzer to be successful.
3. Enter the operation interface after successfully completing the system self-test, and now you can operate the system through the key board.


WARNING

- **Please monitor the self-test process to make sure that the speaker, the alarm light, and the buzzer are all self-tested successfully. Otherwise, please contact the company and do not operate the pump until maintenance is performed.**
 - **Please contact the company if the infusion pump is damaged or cannot operate properly, and it cannot be used for patient infusion.**
-

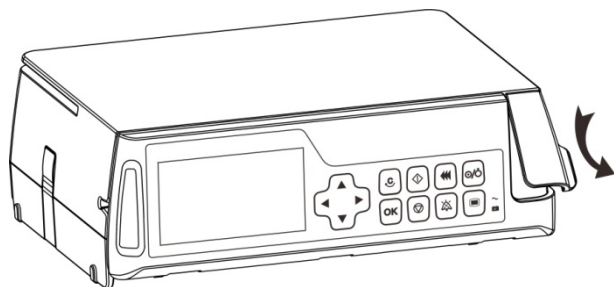
4.2.2 Load the Infusion Set

4.2.2.1 Infusion Pump with Conventional Infusion Sets

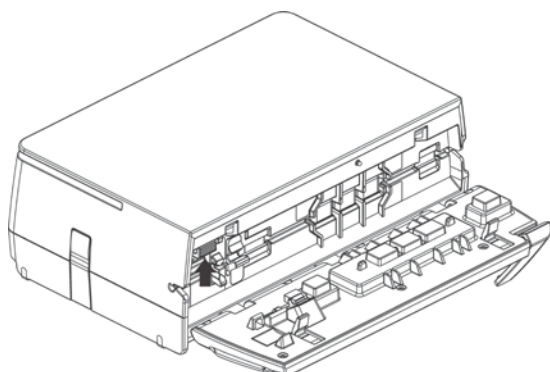
System will inspect whether the infusion set is loaded after completing the self-test:

- If infusion set is not loaded, enter the infusion set **[Loading Guide]** interface; If the infusion set is not required to load, press  to skip the step.
- If infusion set is loaded incorrectly and door is closed, enter the **[Loading Error]** interface.
- If infusion set is correctly loaded and door is closed, and **[User Maintenance]**→**[Brand Selection]**→**[On]**, enter the **[Set Selection]** interface; if the switch of **[Brand Selection]** is **[Off]**, then skip the **[Set Selection]** interface.

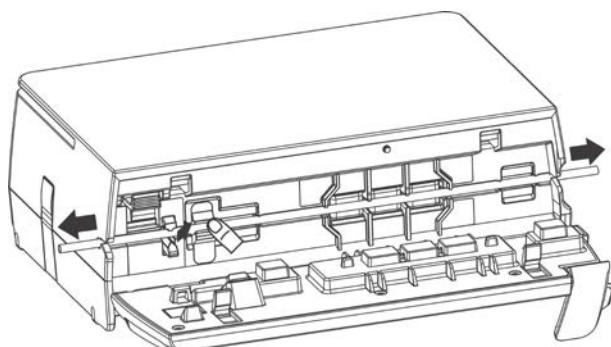
Load infusion set according to the following method:



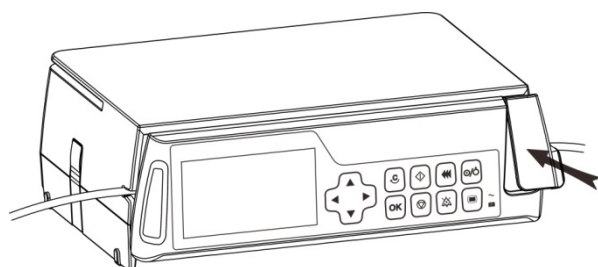
1. Pull the door latch up to open the door.



2. Push up the free flow clamp.



3. Load the set, confirm it is firmly loaded into the tube slot, and adjust or press the set at the gray zone, to confirm the set is loaded correctly.




4. Push the door latch and close the door gently, the system will enter the **[Set Selection]** interface, indicating that the infusion set is loaded correctly; otherwise, it needs to be reloaded.

⚠ WARNING

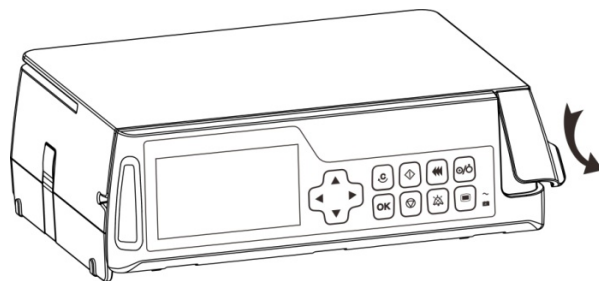
- The infusion set should be firmly loaded into the slot, and not jutting on the outside of the slot.
 - Before using this infusion pump, the infusion pump, infusion set and other accessories should be loaded correctly.
-

4.2.2.2 Infusion Pump with Silicone Specified Infusion Sets

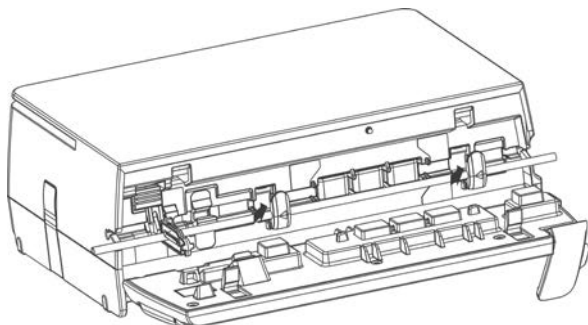
System will inspect whether the set is loaded after completing the self-test:

- If infusion set is not loaded, enter the infusion set **[Loading Guide]** interface; If the infusion set is not required to load, press  to skip the step.
- If conventional infusion set is loaded correctly or silicone specified infusion set is loaded incorrectly, and door is closed, enter the **[Loading Error]** or **[Loading Guide]** interface.
- If silicone specified infusion set is correctly loaded and door is closed, and **[User Maintenance]**→**[Brand Selection]**→**[On]**, enter the **[Set Selection]** interface; if the switch of **[Brand Selection]** is **[Off]**, then skip the **[Set Selection]** interface.

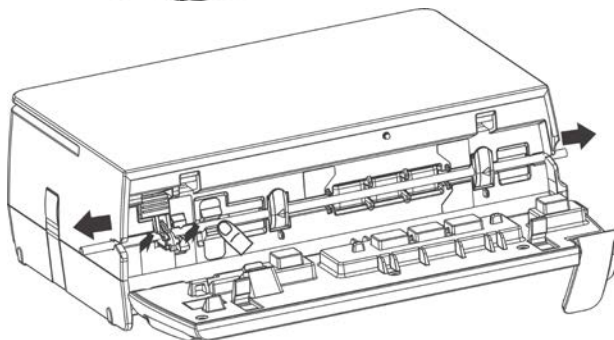
Load infusion set according to the following method:



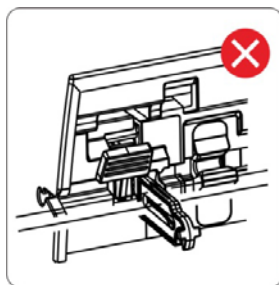
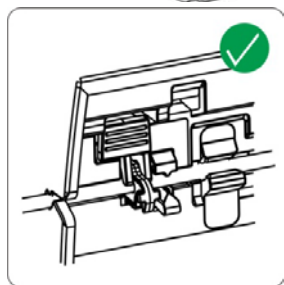
1. Pull the door latch up to open the door.

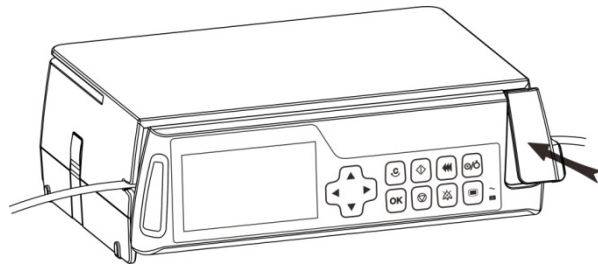


2. Load the set clips to the locating slot, in the direction indicated by the arrow.



3. Adjust the slide clamp, insert it into the operating lever; load the set, confirm it is firmly loaded into the tube slot, and adjust or press the set at the gray zone, to confirm the set is loaded correctly.






4. Push the door latch and close the door gently, the system will enter the **[Set Selection]** interface, indicating that the infusion set is loaded correctly; otherwise, it needs to be reloaded.

WARNING

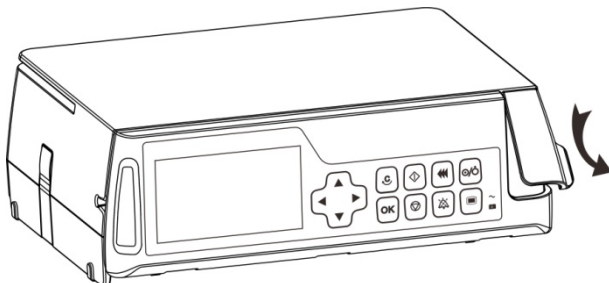
- The infusion set should be firmly loaded into the slot, and not jutting on the outside of the slot.
 - Before using this infusion pump, the infusion pump, infusion set and other accessories should be loaded correctly.
 - Infusion pump with silicone specified infusion sets has to be used with silicone specified infusion sets.
-

4.2.2.3 Infusion Pump with PVC Specified Infusion Sets

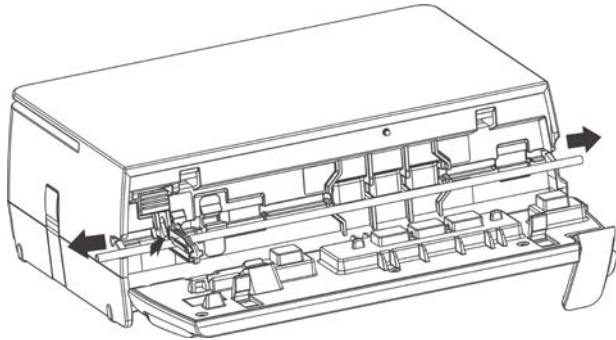
System will inspect whether the set is loaded after completing the self-test:

- If infusion set is not loaded, enter the infusion set **[Loading Guide]** interface; If the infusion set is not required to load, press  to skip the step.
- If conventional infusion set is loaded correctly or PVC specified infusion set is loaded incorrectly, and door is closed, enter the **[Loading Error]** or **[Loading Guide]** interface.
- If PVC specified infusion set is correctly loaded and door is closed, and **[User Maintenance]**→**[Brand Selection]**→**[On]**, enter the **[Set Selection]** interface; if the switch of **[Brand Selection]** is **[Off]**, then skip the **[Set Selection]** interface.

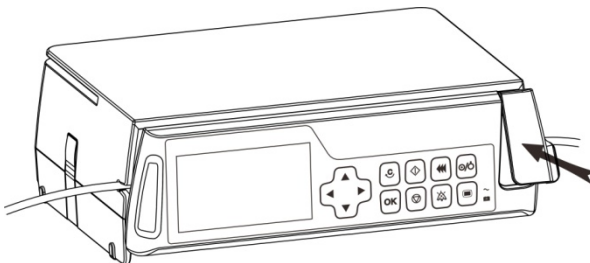
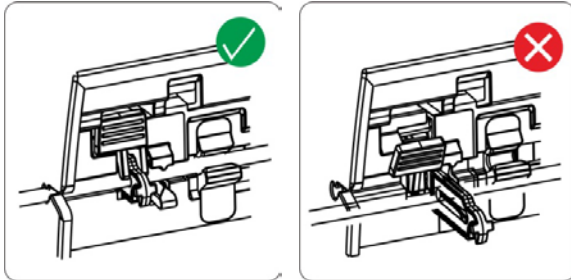
Load infusion set according to the following method:



1. Pull the door latch up to open the door.



2. Adjust the slide clamp, insert it into the operating lever; load the set, confirm it is firmly loaded into the tube slot, and adjust or press the set at the gray zone, to confirm the set is loaded correctly.



3. Push the door latch and close the door gently, the system will enter the **[Set Selection]** interface, indicating that the infusion set is loaded correctly; otherwise, it needs to be reloaded.


WARNING

- The infusion set should be firmly loaded into the slot, and not jutting on the outside of the slot.
- Before using this infusion pump, the infusion pump, infusion set and other accessories should be loaded correctly.
- Infusion pump with PVC specified infusion sets has to be used with PVC specified infusion sets.

4.2.3 Change the Infusion Set

4.2.3.1 Infusion Pump with Conventional Infusion Sets


Follow the steps below to change the infusion set:

1. To prevent patient injury due to free flow, before changing the infusion set or extruded tube, please shut down the Robert clip (or flow rate regulator). During infusion, press  to stop the pump.
2. Pull the door latch up to open the door, pull the liquid check holder button upward, and take out the loaded infusion set.

-
3. Please refer to **4.2.2.1 Infusion Pump with Conventional Infusion Sets** to reload the infusion set.


4.2.3.2 Infusion Pump with Silicone Specified Infusion Sets

Follow the steps below to change the silicone specified infusion set:

1. To prevent patient injury due to free flow, before changing the infusion set, please shut down the Robert clip (or flow rate regulator). During infusion, press  to stop the pump.
2. Pull the door latch up to open the door, and push the door downward till the liquid check clip of the infusion set completely falls off from door hook.
3. Press the liquid check clip operating lever of the infusion pump, take out the liquid check clip and clips of the infusion set, and take out the loaded infusion set.
4. Please refer to **4.2.2.2 Infusion Pump with Silicone Specified Infusion Sets** to reload the infusion set.


4.2.3.3 Infusion Pump with PVC Specified Infusion Sets

Follow the steps below to change the PVC specified infusion set:


1. To prevent patient injury due to free flow, before changing the infusion set, please shut down the Robert clip (or flow rate regulator). During infusion, press  to stop the pump.
2. Pull the door latch up to open the door, and push the door downward till the liquid check clip of the infusion set completely falls off from door hook.
3. Press the liquid check clip operating lever of the infusion pump, take out the liquid check clip of the infusion set, and take out the loaded infusion set.
4. Please refer to **4.2.2.3 Infusion Pump with PVC Specified Infusion Sets** to reload the infusion set.

4.2.4 Change the Infusion Bottle (Bag)

Follow the steps below to change the infusion bottle (bag):

1. To prevent patient injury due to free flow, before changing the infusion bottle (bag), please shut down the Robert clip (or flow rate regulator). During infusion, press  to stop the pump.
2. Take out the loaded infusion bottle (bag), and reload it.

4.2.5 Select Infusion Set Brand

On the [Set selection] screen, press   to select the infusion set brand, and press  for confirmation.

CAUTION





- Please confirm that the current selected brand is the same as the brand actually used, or its accuracy cannot be guaranteed.
-

4.2.6 Parameter Memory Function

In clinical treatments, the medical staffs need to initiate the infusion as soon as possible during emergency situations, infuse the liquid drug into the patient's body in the shortest time possible, and set the detailed parameters later during infusion.




1. Select [Main Menu]→[User Maintenance]→Input User Maintenance Password→[Para. Memory].
2. Select [Para. Memory]→[On]. If [Off] is selected, the following steps cannot be conducted.
3. After selecting the infusion set brand, the previous infusion screen will appear, the previous therapy parameters will be loaded, the users can use the previous treatment parameters.

4.2.7 Select Infusion Mode

Press  to enter [Main Menu]→[Select Mode]. On this interface, users can press   and  to select infusion mode. Please refer to **Chapter 5 Infusion Mode** for detailed introduction of each infusion mode.

4.2.8 Purge Air

During infusion, the user should prevent air bubbles from entering the blood with the liquid drug, which may form an aeroembolism and put patients in serious danger. Therefore, air bubbles in the infusion tube should be eliminated before the infusion.

Under non-running status of any infusion mode, press  to enter [Purge Air] setting screen, set [Purge Rate], then hold down  to purge at the set rate, release  after the air bubbles are purged.







WARNING

- Please disconnect the pump from patient before purge. Otherwise, the patient will be in serious danger!
-
-


NOTE

- [Air in line] and [Accumulate air] alarms will not be triggered during purge.
-

4.2.9 Set Infusion Parameters

Under each infusion mode, users can set infusion parameters by pressing  ,  ,  ,  ,  and .

4.2.10 Infusion

When ready, connect the infusion set to the patient. Press  to start the infusion, and the screen will display the green running icon. An arrow moves from right to left. The speed of the arrow increases as the rate is increased.



WARNING

- Users should inspect and confirm whether the parameter settings are correct before infusion.
 - If there is a liquid drug or residue on the ultrasonic sensor or the nearby tube surface, the user should completely clean the area before infusion.
 - Users should regularly monitor the connection between the infusion set, pump and patient, and infuse according to the method mentioned in the manual.
-

NOTE


- When in running status, if there is no operation in other interface over 2 minutes, it will return to the running screen automatically.
-



4.2.11 Infusion Pause

During infusion, if changing the drug liquid or infusion set is needed, press  to enter the [Pause] interface to stop the infusion. On the [Pause] screen, press  to return to the parameters setting interface, and you can modify infusion parameters;

Press  to continue the infusion.

4.2.12 BOLUS




In any run screen in the infusion mode, press  to enter the **[Bolus]** settings screen. There are two ways to start the bolus:

- Manual Bolus: Set **[Bolus Rate]**, press and hold  to manual bolus, and release to return to the original rate.
- Auto Bolus: Set **[Bolus Rate]**, **[Bolus VTBI]** and **[Bolus Time]**, press  to auto bolus.

NOTE

-
- **Patient's clinical condition and working condition of the infusion pump must be monitored carefully.**
-

4.2.13 Change the Rate during Operation



Rate may be modified without stopping the infusion. In any running screen of the infusion mode, press  to change the value of the **[Rate]** into the adjustable state, thus to set the expected rate, press  or  again for confirmation, then start to infuse under the new set rate.



4.2.14 Complete

When **[VTBI]** is not set during the infusion and infusion is completed, if drop sensor is installed and the switch of **[Drop sensor]** is on, the **[Empty]** alarm will be triggered.

When **[VTBI]** is set during the infusion and the remaining infusion time is close to the **[Time Near End]** set by the users, the **[Time Near End]** alarm will be triggered. If no action has been taken, the alarm will not be cancelled automatically until the infusion is completed, and then switch to **[VTBI Complete]** or **[Empty]** alarm. Set **[Time Near End]**, please refer to **6.9 Time Near End**. When infusion is completed, enter to **[KVO]** mode, and KVO mode will run for 30 mins at most. Infusion will stop automatically after the KVO is finished, and the **[KVO Finish]** alarm will be triggered. Set KVO rate, please refer to **6.1 KVO**.


4.2.15 Standby

Under non-running status, press  to enter the standby countdown shutdown interface. Press  to modify standby time (range is 00:01-99:59 h:min). The pump cannot be put in standby mode if there is a high level alarm.

When the standby state is ended, the title bar will display [**Standby Time Expired**], press  or  to cancel alarm.

4.2.16 Turn off the Pump

Follow the steps below to turn off the infusion pump:

1. Disconnect from the patient;
2. Hold down , until the Turn Off progress bar complete, and the power will turn off.

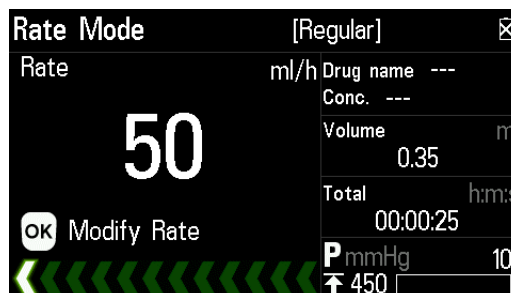
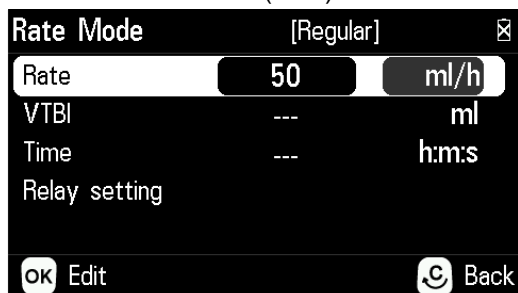
NOTE

-
- **When powering off normally, the current operating data and saved data will be autosaved.**
-

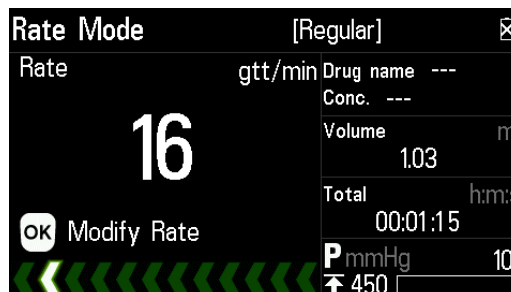
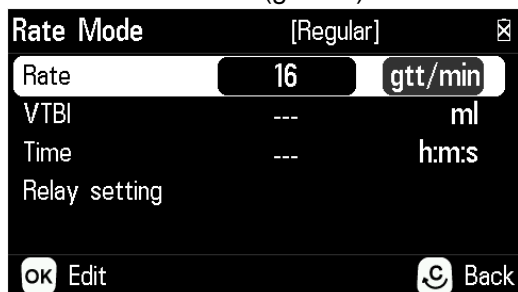
5 Infusion Mode

5.1 Rate Mode

■ Unit of Rate (ml/h)



■ Unit of Rate (gtt/min)



| Mode | Parameters | Parameter Range |
|--|------------|---|
| Rate Mode | Rate | Unit of Rate (ml/h): 0.1-2000ml/h |
| | | Unit of Rate (gtt/min): 1-(400*Drip/60) gtt/min |
| | VTBI | 0.1-9999.99ml |
| | Time | 00:00:01-99:59:59 h:m:s |
| Please refer to 6.6 Drip Setting for the settings of the unit of "gtt/min". | | |

5.2 Time Mode

■ Unit of Rate (ml/h)

Time Mode [Regular] [X]

Time 04:00:00 h:m:s

VTBI --- ml

Rate --- ml/h

Relay setting

OK Edit Back

Time Mode [Regular] [X]

Rate 50 ml/h

Drug name ---

Conc. ---

VTBI/Volume 199.96/2.05 ml

Remaining 03:59:57 h:m:s

OK Modify Rate

P mmHg 10

450

■ Unit of Rate (gtt/min)

Time Mode [Regular] [X]

Time 04:00:00 h:m:s

VTBI --- ml

Rate --- gtt/min

Relay setting

OK Edit

Time Mode [Regular] [X]

Rate 16 gtt/min

Drug name ---

Conc. ---

VTBI/Volume 191.97/2.37 ml

Remaining 03:59:58 h:m:s

OK Modify Rate

P mmHg 10

450

| Mode | Parameters | Parameter Range |
|-----------|------------|-------------------------|
| Time Mode | Time | 00:00:01-99:59:59 h:m:s |
| | VTBI | 0.1-9999.99ml |
| | Rate | Same as Rate Mode |

5.3 Body Weight Mode

1. Select [Main Menu]→[User Maintenance]→Input User Maintenance Password→[BW Mode Configuration].
2. Select [BW Mode Configuration]: Conc., Drug Amount and Volume.
3. Select [Main Menu]→[Select Mode]→[Body Weight Mode].

Conc. Configuration:

Body Weight Mode [Regular] [X]

Weight kg

Conc. --- ug/ml

Dose Rate Unit ug/kg / min

Dose Rate ---

VTBI --- ml

OK Edit Back

Body Weight Mode [Regular] [X]

Dose Rate ug/kg/min

Drug name --- 200 ug/ml

Volume 2.72 ml

Total 00:03:27 h:m:s

Rate 30 ml/h

P mmHg 10

450

Drug Amount and Volume Configuration:

Body Weight Mode [Regular] [X]

Weight kg

Drug amt. --- ug

Volume --- ml

Dose Rate Unit ug/kg / min

Dose Rate ---

OK Edit Back

Body Weight Mode [Regular] [X]

Dose Rate ug/kg/min

Drug name --- 200 ug/ml

Volume 2.57 ml

Total 00:03:09 h:m:s

Rate 30 ml/h

P mmHg 10

450

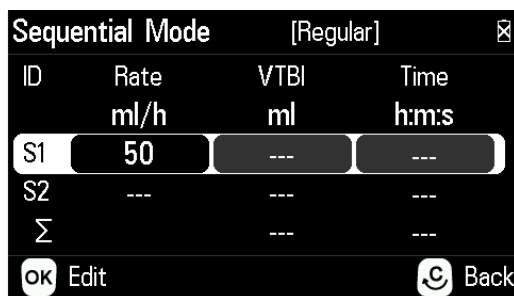
| Mode | Parameters | Parameter Range |
|--|----------------|---|
| Body Weight Mode | Weight | 0.1-300.0 kg/0.2-660.8 lb |
| | Drug amt. | 0.1-999.9 |
| | Drug amt. unit | ng, µg, mg, g, mU, U, kU, EU, mmol, mol, kcal, mEq |
| | Volume | 0.1-9999.99ml |
| | Conc. | 0.1-9999 |
| | Conc. unit | ng/ml, µg/ml, mg/ml, g/ml, mU/ml, U/ml, kU/ml, EU/ml, mmol/ml, mol/ml, kcal/ml, mEq/ml |
| | Dose Rate | 0.01-999.99 |
| | Dose Rate Unit | ng/kg/min, µg/kg/h,ug/kg/min, ug/kg/h,ug/kg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, g/kg/min, g/kg/h, mU/kg/min, mU/kg/h, U/kg/min, U/kg/h, U/kg/24h, kU/kg/h, EU/kg/h, mmol/kg/h, mol/kg/h, kcal/kg/h, kcal/kg/24h, mEq/kg/min, mEq/kg/h |
| | VTBI | 0.1-9999.99ml |
| Rate | 0.1-2000ml/h | |
| NOTE: | | |
| 1. [Conc.] will be automatically calculated according to the formula (<i>Drug amt. / Volume</i>). | | |
| 2. [Rate] will be automatically calculated according to the formula (<i>Dose Rate *Weight)/ Conc.</i> | | |

5.4 Sequential Mode

Several different sequences (parameter group) can be set in Sequential Mode, and the infusion pump infuses according to the set infusion sequence.

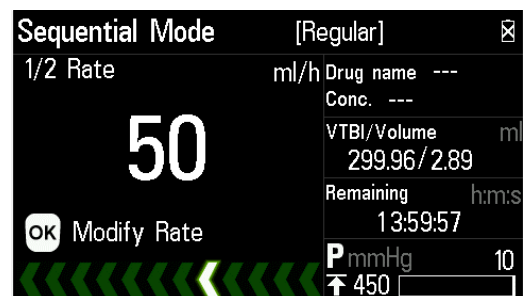
5 sequences can be set in this mode. The rate of the current sequence can be changed during the operation process. In Sequential Mode, the VTBI, Rate, and Time are settable and the ranges of the set values are taken to be the same with Rate Mode.

➤ Σ : A sign denotes the total VTBI and the total time of all sequences.



| ID | Rate ml/h | VTBI ml | Time h:m:s |
|----------|--------------|------------|---------------|
| S1 | 50 | --- | --- |
| S2 | --- | --- | --- |
| Σ | | --- | --- |

OK Edit Back



| 1/2 Rate | ml/h | Drug name | --- |
|----------|------|-------------|-------------------|
| 50 | | Conc. | --- |
| | | VTBI/Volume | ml 299.96/2.89 |
| | | Remaining | h:m:s 13:59:57 |
| | | P mmHg | 10 |
| | | ↑ | 450 |

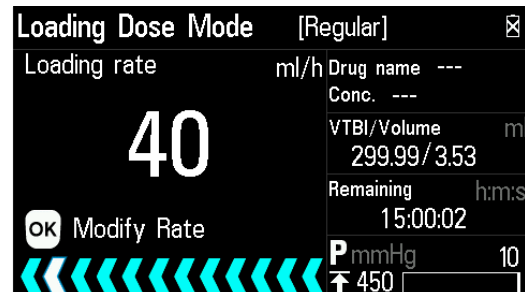
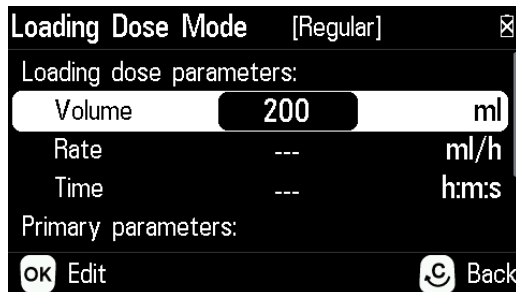
OK Modify Rate

NOTE

- If only set [Rate] or [VTBI] for a sequence, the sequence is invalid.
 - If there is invalid sequence between sequences, the infusion can not be started.
-

5.5 Loading Dose Mode

Loading Dose Mode infuses [VTBI] of loading dose at the rate of [Loading Rate], then operates at [Main rate] until [VTBI] of the primary parameters is completed. Primary parameters [VTBI] are [Total VTBI].



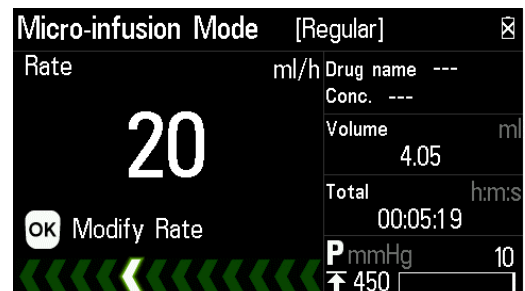
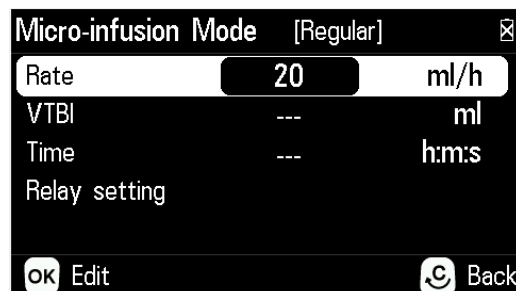
| Mode | Parameters | | Parameter Range |
|-------------------|-------------------------|-----------------------|-------------------------|
| Loading Dose Mode | Loading dose parameters | Volume, Rate and Time | The same with Rate Mode |
| | Primary parameters | VTBI, Rate and Time | The same with Rate Mode |

NOTE:

- Total VTBI should be greater than loading VTBI, and if set over the specified limit, the parameters that exceed the system limit can not be set.
- When any two parameters of the loading dose are null, the pump will run at the [Rate] of primary parameters until the infusion set is empty or infusion is completed.

5.6 Micro-infusion Mode

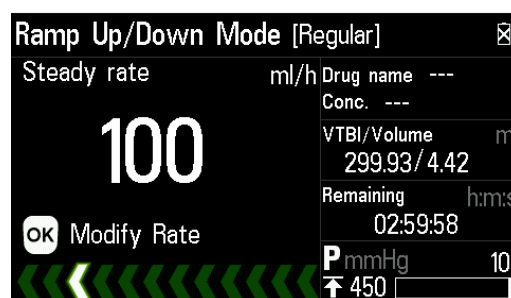
Clinically, the Micro-infusion Mode is mainly used for the infusion of children and newborns at low rate.



| Mode | Parameters | Parameter Range |
|---------------------|------------|-------------------------|
| Micro-infusion Mode | Rate | 0.1-100ml/h |
| | VTBI | 0.1-1000ml |
| | Time | 00:00:01-99:59:59 h:m:s |

5.7 Ramp Up/Down Mode

In Ramp Up/Down Mode, by setting the [Ramp up time] and [Ramp down time], the infusion pump will increase the rate (divided as 9 stages) automatically during the [Ramp up time] until the rate is steady, sustaining for a period of time, and then decrease the rate during the [Ramp down time].



| Mode | Parameters | Parameter Range |
|-------------------|----------------|-------------------------|
| Ramp Up/Down Mode | VTBI | 0.1-9999.99ml |
| | Total time | 00:00:01-99:59:59 h:m:s |
| | Ramp up time | 00:00:01-99:59:59 h:m:s |
| | Ramp down time | 00:00:01-99:59:59 h:m:s |

NOTE:

1. [Steady rate], [Up rate], and [Down rate] are calculated automatically, and the range is the same as the rate of Rate Mode.
2. When both ramp up time and ramp down time are null, the pump will run at the Steady rate until the infusion is complete. Steady rate=VTBI/Total time.

6 Setting Parameters

6.1 KVO

KVO (Keep Vein Open) means to keep the vein open, during which the infusion pump continues infusion at a very low rate after finishing the infusion in order to prevent blood backflow or vascular occlusion.

1. Select [**Main Menu**]→[**General Options**]→[**KVO Rate**].
2. Select [**KVO Rate**]: 0.1-5.0ml/h is adjustable.

6.2 Drug Library

The product is configured with a drug library with a collection of 2,000 kinds of drugs available for users to select from.

1. Select [**Main Menu**]→[**User Maintenance**]→Input User Maintenance Password→[**Drug Library**].
2. Select [**Drug library**]→[**On**], [**Off**] indicates switching off the function.
3. Select [**Drug**] on the parameters setting interface. After the drug is selected, its name will appear on the Run screen.

List of Built-in Drugs

| | | | |
|---------------------|------------------------|----------------------|-----------------|
| Epinephrine | Noradrenaline | Isoprenaline | Phenylephrine |
| Dopamine | Dobutamine | Aramine | Ephedrine |
| Phentolamine | Metoprolol Tartrate | Uradil hydrochloride | Atropine |
| Anisodamine | Scopolamine | Belladonna | Probanthine |
| ProPafenone | Amiodarone | Esmolol | Lidocaine |
| Nicardipine | Nitroglycerin | Isosorbide Dinitrate | Diltiazem |
| Deslanoside | Digoxin | Nitroprusside | Heparin Sodium |
| Furosemide | Mannitol | Aminophylline | Ringer Lactate |
| hydroxyethyl starch | propofol | Etomidate | Ketamine |
| Flumazenil | Midazolam | Dexmedetomidine | Diazepam |
| Morphine | Fentanyl | Remifentanil | Succinylcholine |
| Pancuronium | Magnesium Sulphate | Hexadecadrol | Insulin |
| 10%NaCl | 25%MgSO | 10%KCl | 50%Glucose |
| Calcium Gluconate | | | |

6.3 Occlusion Pressure

Occlusion pressure is adjustable, which can meet the requirements for occlusion pressure of different patients during infusion. Pressure in the infusion tube can be measured by the built-in pressure sensor, pressure can be calculated by the internal CPU, which is compared with the preset occlusion alarm threshold. **[Occlusion]** alarm will be triggered if pressure exceeds the threshold.

6.3.1 Set Occlusion Pressure

1. Select **[Main Menu]**→**[General Options]**→**[Pressure]**.
2. Select **[Pressure]**: Occlusion pressure Degree 12, lowest at 75mmHg, and highest at 975mmHg. Occlusion pressure should be selected according to actual needs.

CAUTION

- **If the patient experiences discomfort at a higher occlusion pressure, monitor the patient's physical conditions under the higher occlusion pressure closely, and take measures instantly if any abnormal condition occurs.**
- **When the infusion set with ultrafilter at a lower occlusion pressure, the **[Occlusion]** alarm might be triggered at high rate due to resistance generated from liquid flow of ultrafilter. Select a higher occlusion pressure or lower rate to cancel alarm.**

6.3.2 Set Pressure Unit

1. Select **[Main Menu]**→**[User Maintenance]**→Input User Maintenance Password→**[Pressure Unit]**.
2. Select **[Pressure Unit]**: The 4 various forms of pressure units, mmHg, kPa, bar and psi are converted automatically, and can be selected according to actual needs.




CAUTION

- **Carefully confirm the edit when changing the current pressure unit.**

6.3.3 Dynamic Pressure Scanning (DPS)

During the infusion, the bottom-right corner of the Run screen demonstrates real-time pressure changes of the patient, in order to find the tube occlusion at an earlier time and to prevent the occurrence of further complications.

The pressure icon on the screen indicates the condition of the current pressure:

- ◆  When the progress bar is white, this indicates that the current pressure value is below 80% of the occlusion pressure.
- ◆  When the progress bar is yellow, this indicates that the current pressure value is above 80% and below 95% of the occlusion pressure.
- ◆  When the progress bar is red, this indicates that the current pressure value is above 95% and below 100% of the occlusion pressure.

NOTE

-
- **When occlusion occurs in the infusion set before entering the device, or occlusion pressure reaches the threshold value. The occlusion alarm will sound, and the screen will display “Upstream occlusion”.**
 - **When occlusion occurs in the infusion set between the device and the patient, or occlusion pressure reaches the threshold value. The occlusion alarm will sound, and the screen will display “Downstream occlusion”.**
-

6.3.4 Automatic Pressure Release Function (Anti-Bolus)

When occlusion occurs, infusion will stop and the [Downstream occlusion] alarm will be triggered. After the alarm is triggered, the motor is reversed, and the cannula pressure is then released. This prevents an additional aggressive dose to the patient after the occlusion is eliminated.

6.4 Set Air Detection

Air bubble size indicates the size of air bubble that can be monitored in the tube. The lower of the bubble size, the smaller air bubble can be identified. Bubble in the infusion tube can be measured by the built-in ultrasonic sensor, bubble size can be calculated by the internal CPU, which is compared with the preset threshold. [Air in line] alarm will be triggered if bubble size exceeds the threshold.

1. Select [Main Menu]→[General Options]→[Air detection].
2. Select [Air detection], 6 levels of air detection can be selected, lowest at 20µl, and highest at 800µl. Air detection level should be selected according to actual needs.

CAUTION

- If the patient experiences discomfort or danger at a higher air bubble filter level, monitor the patient's physical conditions and select the actual needed level. Measures should be taken instantly if any abnormal condition occurs.
-


6.5 Accumulate Air


1. Select **[Main Menu]**→**[General Options]**→**[Accumulate air]**.
2. Select **[Accumulate air]**: 0.1-4ml is adjustable.


6.6 Drip Setting

1. Select **[Main Menu]**→**[General Options]**→**[Drip setting]**.
2. Select **[gtt/min]**→**[On]**, and set the “Drip”. On infusion parameters setting interface of Rate Mode and Time Mode, “ml/h” and “gtt/min” can be switched. If **[Off]** is selected, “ml/h” and “gtt/min” can not be switched.

6.7 Key Lock Function

When locked, an  icon in the upper-right corner of the screen emerges. The following are two ways for automatic lock and manual lock:

- Automatic Lock:
 1. Select **[Main Menu]**→**[General Options]**→**[Auto-lock Time]**.
 2. Select **[Auto-lock Time]**: Off, 1-5min. After a specific time is set during the running state, and if there is no operation or high level alarm within the set Auto-lock time, the key board will be auto-locked. **[Off]** indicates switching off the function.
- Manual Lock: In the running interface, under the unlocking condition, press and hold (>3 seconds)  to lock the key board.

Note: If unlocking is needed, press and hold (>3 seconds)  to unlock, it is automatically unlocked during the high level alarm.

6.8 Reminder Function

1. Select **[Main Menu]**→**[General Options]**→**[Reminder Time]**.
2. Select **[Reminder Time]**: Off, 1-5min. **[Off]** indicates switching off the function.

6.9 Time Near End

1. Select [Main Menu]→[General Options]→[Time Near End].
2. Select [Time Near End]: Off, 1-30mins. [Off] indicates switching off the function.

6.10 Commonly Used Infusion Sets

There are multiple built-in commonly used infusion set brands in the infusion pump, making it convenient for the user to select from. For specific infusion set brands, please refer to actual infusion device.

6.10.1 Infusion Pump with Conventional Infusion Sets

1. Select [Main Menu]→[User Maintenance]→Input User Maintenance Password→[Infusion Set].
2. Select in [Infusion Set] according to actual needs.

Note: Please ensure that at least one “Infusion Set” to be selected.

Brand and model of compatible infusion sets:

| No. | Type | Brand and Model | specification |
|-----|---------|--------------------------|---------------|
| 1 | Regular | BOON A2 | 20drops |
| 2 | Regular | B.Braun Intrafix Safeset | 20drops |

WARNING

- It is recommended that infusion pump is used with high elastic tube. If you are not sure whether the tube is high elastic tube, please contact us for tube test.
-

6.10.2 Infusion Pump with Silicone Specified Infusion Sets

1. Select [Main Menu]→[User Maintenance]→Input User Maintenance Password→[Infusion Set].
2. Select in [Infusion Set] according to actual needs.

Note: Please ensure that at least one “Infusion Set” to be selected.

Brand and model of silicone specified infusion sets:

| No. | Type | Brand | Model |
|-----|-----------------|---------|----------|
| 1 | Regular | Mindray | M-IS-0** |
| 2 | Regular | Mindray | M-IS-1** |
| 3 | Light-sensitive | Mindray | M-LS-0** |
| 4 | Regular | Mindray | M-NS-0** |
| 5 | Regular | Mindray | M-BS-0** |
| 6 | Regular | / | IM-Set |

6.10.3 Infusion Pump with PVC Specified Infusion Sets

1. Select **[Main Menu]**→**[User Maintenance]**→Input User Maintenance Password→**[Infusion Set]**.
2. Select in **[Infusion Set]** according to actual needs.

Note: Please ensure that at least one “Infusion Set” to be selected.

Brand and model of PVC specified infusion sets:

| No. | Type | Brand | Model |
|-----|-----------------|-------|----------|
| 1 | Regular | SK | SK ZPQ |
| 2 | Regular | SK | SK 150mL |
| 3 | Light-sensitive | SK | SK JMB |

6.11 Set the Sensitivity of Empty Bottle Alarm

1. Select **[Main Menu]**→**[General Options]**→**[Empty Sensitivity]**.
2. Select **[Empty Sensitivity]: High** and **Low**. **[High]** indicates high sensitivity of **[Empty]** alarm detection, **[Empty]** alarm will be triggered in shorter time; **[Low]** indicates low sensitivity of **[Empty]** alarm detection, **[Empty]** alarm will be triggered in longer time. It can be selected according to actual needs.

Note: **[Empty Sensitivity]** option is not visible when the switch of **[Drop sensor]** is off.



7 Other Functions

7.1 History Record

The infusion pump when in use will produce some key data stored in **[History Record]**, providing foundation for the treatment review and maintenance review at a later period. The attribute of recording events includes action, time and description.

A record is created once an event occurs. The memory can store up to 2000 records. Once the memory is full, the oldest records will be removed first. History record will not loss when the infusion pump powers down.

1. Select **[Main Menu]**→**[History Record]**.
2. Select **[History Record]**: Each page can demonstrate up to 3 records, and press

  to turn the pages.

7.2 Power-down Save

To prevent the loss of patient data and alarm settings when the infusion pump suddenly powers down, the infusion pump provides the function of the power-down data and alarm settings storage. If the infusion pump powers down suddenly after it is restarted, the last infusion parameters will display the alarm information and will remain in consistency with those before the power-down, and will be reloaded. You can refer to **[History Record]** to view such information as infusion parameters and alarm.

7.3 Nurse Call

Select **[Main Menu]**→**[System Options]**→**[Nurse call]** , and set in the open menu:

■ Switch

On: Indicates switching on the nurse call function.

Off: Indicates switching off the nurse call function.

■ Signal type

Continuous: Indicates that the output nurse call signal type is the same as that of the alarm existence time, i.e., from the occurrence of the alarm to the end of it.

Pulse: Indicates the output nurse call signal is a pulse signal with the type of 1 second.

When several alarms exist at the same time, only one pulse signal can be outputted.

If the current alarm is not removed and another alarm occurs, then one additional pulse signal is outputted.

■ Trigger type

Normally Close: Select when the hospital call system is set as **[NORM. Close]**.

Normally Open: Select when the hospital call system is set as **[NORM. Open]**.

- Alarm level: Three options: **[High]**, **[Medium]** and **[Low]**. The system sends nurse call signals according to the alarm at the selected alarm level or above.

WARNING


- **Non-medical personnel are forbidden to modify the nurse call setting.**
- **The nurse call function must be used in conjunction with a special cable.**

NOTE

- **Medical personnel should not consider the nurse call function as the main alarm notice approach, and rather combine the sound and visual alarms of the infusion pump and the clinical performances and symptoms of the patient in order to judge the patient's conditions and take further attention as needed.**

7.4 Wireless Networking (Optional)

The pump can be net-connected through built-in Wi-Fi module.

1. Select **[Main Menu]**→**[User Maintenance]**→Input User Maintenance Password→**[WLAN Setting]**, then select **[On]** to enable Wi-Fi function.
2. Select **[Ap Settings]**:
 - Select **[SSID]**: Input the name of the to-be-connected network.
 - Select **[Password]**: If password is not required for to-be-connected network, you can connect the network directly; If password is required for to-be-connected network, please enter the password.
 - Select **[Encryption mode]**: Set the encryption mode of the to-be-connected network, which shall be the same encryption mode as the Ap.
 - After the above settings are completed, select **[Confirm]** and press .
3. Select **[Advanced Setting]**, there are two ways to distribute IP address:
 - DHCP: IP address, Mask and Gateway can't be modified, automatically obtain an IP address.
 - Manually: Enter IP address, Mask and Gateway.

Note: The wireless icon on the upper-right corner indicates the pump is configured with wireless module and connected successfully. No icon indicates no wireless module is configured or no connection.

After the pump and BeneFusion CS5 Infusion Supervision System (hereinafter called CIMS) are communicated successfully over wireless network, the pump sends real-time Bed No., version information, infusion parameters and other information to CIMS, CIMS and the pump can display synchronously. For detailed descriptions,

please refer to the instructions of CIMS. Normal communication of the pump and CIMS depends on whether the network connection is successful, operators are unable to observe the operation status of the pump in real time when the communication is interrupted. After the network connection settings of the pump and CIMS are modified, operators shall reset the network connection as required in the manual to ensure the communication of the pump and CIMS are restored.

NOTE

-
- **Wireless security transmission distance is no more than 50 meters.**
 - **2.4 GHz Wi-Fi frequency range, WEP and WPA/WPA2 security modes and 802.11b/g/n wireless standard are supported.**
 - **The settings of the wireless network must be conducted by technicians approved by the company or maintenance staff designated by the company.**
 - **It is recommended that not access the pump to public network. If the pump is required to access to public network, firewall shall be added to prevent cyber attacks.**
-



7.5 Data Export

To export the data in the infusion pump, please refer to the following steps:

1. Log on PC tools, and connect the PC to the infusion pump;
2. When the infusion pump is in working communication with the PC, the PC automatically reads all the data in the pump;
3. Select **[History Record]** in PC tools, and export data.


7.6 Relay Setting

Multi-syringe pumps/infusion pumps have been inserted to BeneFusion DS5 Infusion Supervision System and the pumps are on, follow the steps below to start relay mode:

1. Select **[Main Menu]**→**[Select Mode]**, then select **[Relay setting]** in each mode.
2. Set the slot No. of the “Forward channel”, press  to save. If the slot of “Forward channel” pump is infusion pump, please input VTBI parameter value of the pump.
3. When the upstream channel finishes infusion, the downstream channel with  will start running automatically. When the last relayed pump finishes infusion, **[VTBI Complete]** alarm will be triggered.

7.7 Patient Information


Infusion pump has been inserted to BeneFusion DS5 Infusion Supervision System and the system contains patient information, the system will automatically distribute patient information to all infusion pumps when pumps are on.

Select **[Main Menu]**→**[Patient Information]** to view the patient information (Department, Bed No. and other information), beds can be differentiated through setting bed number; press  to discharge patient.




NOTE

-
- **For infusion pump inserted to BeneFusion DS5 Infusion Supervision System, patient information can't be discharged and Bed No. can't be changed in pump.**
-

7.8 Day's Prescription

Infusion pump has been inserted to BeneFusion DS5 Infusion Supervision System and the system contains prescription information, the system will automatically assign all non-executed prescription to all idle infusion pumps when pumps are on. You will enter the **[Prescription detail]** interface, press  to execute prescription.

To execute prescription:

1. Select **[Main Menu]**→**[Day's Prescription]**, press  to enter the **[Prescription detail]** interface.
2. In the **[Prescription detail]** interface, press  to execute prescription and enter the infusion parameter setting interface.
 - If infusion mode is specified in prescription, the pump will start infusion as the specified mode.
 - If infusion mode is not specified in prescription, then Rate Mode for pedia or adult; Micro-infusion Mode for neonate.
3. When ready, press  to start infusion.

8 Alarms

The alarm is used in order to alert the medical staff by means of sound and light when abnormal situations occur during the infusion procedure which can lead to infusion changes or when the infusion of the patient cannot continue due to the unexpected breakdown or pause/delay of the infusion pump.

WARNING

- It is potentially hazardous to use the same or similar equipment with different alarm presets within the same area.
 - Responsible organization shall evaluate the risks before selecting other alarm sound, for the user may get used to the previous alarm sound, operators may not perceive the alarm in a timely manner due to new alarm sound.
-

8.1 Alarm Level

According to the severity scale of the alarm, the alarms of the infusion pump can be classified to high level alarms, medium level alarms and low level alarms.

8.2 Alarm Types

When an alarm occurs, the pump indicates it to you through visual or audible alarm indications. For more information, see the following table.

| Alarm level | Color of alarm light | Audible alarm frequency | Flashing light frequency | Light/no-light ratio |
|---------------------|----------------------|-------------------------|--------------------------|----------------------|
| High level alarms | Red | 10 seconds | 2.0±0.6Hz | 20%-60% |
| Medium level alarms | Yellow | 15 seconds | 0.6±0.2Hz | 20%-60% |
| Low level alarms | Yellow | 20 seconds | Steady | 100% |

8.2.1 Multi-level Alarm Rules

When several alarms occur simultaneously, the alarms proceed according to the following rules:

- When several alarms at different levels occur, the visible alarms and audible alarms are consistent with the highest level alarms.
- When several alarms at different levels occur, only the highest level alarm is displayed, and after it is cancelled, the lower level alarm will then be displayed.
- When several alarms at the same level occur, the alarm information will be demonstrated in an alternate manner.





The title bar of the infusion pump screen will display the corresponding alarm information during the alarm blast, to see more details in ***C Alarm Information***.

NOTE

-
- **The [Communication interrupted] alarm of the pump and BeneFusion CS5 Infusion Supervision System are delayed for 3 minutes, while other alarms are delayed for less than 5 seconds.**
-

8.3 Alarm Handling Rules

Under normal working conditions, when an alarm occurs, all the alarm types of the infusion pump will alert according to their respective alarm levels. In addition, the user can pause the alarm sound according to demands.

- For high level (except No Battery) and medium level alarms, press  to pause alarm sound for 2 minutes. When the alarm pause time expires, the alarm tone will sound. Press  to cancel high level alarms (except No Battery and System Error).
- For low level alarms (Reminder, Time Near End, and Low Battery), press  to acknowledge the alarm condition, system will give out a sound "du" every 5min, and a "√" appears before the alarm message, indicating that the alarm is acknowledged.
- For low level alarms (No AC Power, Communication interrupted, Infusion interrupted, Please reset time, Para.Unconfirmed), press  to cancel alarm.

NOTE

-
- **[No Battery] alarm sound is unable to be paused.**
-

8.4 Alarm Countermeasures

WARNING

- **When an alarm is triggered, the patient's condition should be checked firstly and operation should only be allowed to proceed after the reason for the triggering of the alarm is ruled out.**
-

When an alarm is triggered, please follow these steps and take appropriate action:

1. Check the patient;
2. Check the alarm type and the parameter which triggered the alarm;
3. Determine the reason for the alarm;
4. Eliminate the reason for the alarm;
5. Check whether the alarm has cleared.

NOTE

- **Please refer to *C Alarm Information* for specific handling procedures for each alarm.**
 - **The operator position shall be the normal operating position of the infusion pump (0.5m). Otherwise, operators might identify alarm mistakenly.**
-

9 Battery

WARNING

- **The battery can not be disassembled. The battery should be changed by maintenance staff designated by the company only. Changing the battery incorrectly or changing battery by personnel who has not received suitable training may cause such danger as overtemperature, fire or explode.**
 - **Use only manufacturer-specified battery for this device. Use of a different battery may cause such danger as overtemperature, fire or explode.**
 - **Do not touch the battery charging terminal and patient at same time to prevent patient leakage current from exceeding the requirements specified by the standard.**
-
-

NOTE

- **Please remove the batteries before conveying or when out of use for a long time.**
 - **When the built-in battery and external power encounter failure, the display will off, a high level alarm will be triggered, the buzzer will sound out and the red alarm light will continuously flash.**
-

The infusion pump is configured with rechargeable Lithium batteries to ensure that the infusion pump can be used normally under the condition of the patient's migration within the hospital or during the circumstance of a power failure. When the infusion pump switches to the AC power, the battery can be charged regardless of whether the infusion pump is on or off. The battery is chargeable only within the infusion pump. During charge, the battery icon in the upper-right corner of the screen floats up and down. If the battery icon stops floating and is completely filled, it indicates that the battery is fully charged. Under the condition of a sudden power failure, the pump will automatically use the battery to provide power as a backup.

The battery icon on the screen indicates the condition of the battery:



The battery jar of the infusion pump is installed with batteries, and the white fill area indicates the quantity of electricity.



Low battery electric quantity indicates that charging is needed.



When the battery is empty, charging is needed immediately.



No battery is installed in the infusion pump.

The power supply by the battery can only be sustained for a limited period of time. The **[No Battery]** alarm will be triggered when the battery voltage is too low, and red alarm light will flash. The alarm will continue within the remaining time of the battery's electric quantity and cannot be paused. Now, the infusion pump should be switched on to AC power for charging.

9.1 Battery Performance Optimization

When the battery is used for the first time, at least two complete optimizing cycles should be ensured. A complete optimizing cycle contains the following: Charging incessantly, and then discharging until the power of the infusion pump runs out. During usage, regularly optimizing the battery performance will extend its lifespan. It is suggested that the battery should be optimized when in use or in storage for two months, or when the running time of the battery is significantly shortened.

Please follow the steps below during optimization:

1. Disconnect the pump from the patient and stop the infusion.
2. Insert the battery needing optimization into the battery jar of the infusion pump.
3. Switch the infusion pump on the AC power and charge the battery incessantly for over 10 hours.
4. Disconnect the AC power and use the battery to charge the infusion pump until the infusion pump is closed.
5. Switch the infusion pump over to AC power again and charge the battery incessantly for over 10 hours.

The battery optimization is now complete.

9.2 Check the Battery

The performance of the battery may decrease over time. Please follow the steps below when checking the battery:

1. Disconnect the pump from the patient and stop the infusion.
2. Switch the infusion pump on the AC power and charge the battery incessantly for over 10 hours.
3. Disconnect the AC power and use the battery to charge the infusion pump until the infusion pump is closed.
4. The length of the battery's lifetime reflects the performance of the battery.
5. If the length of the battery's lifetime is obviously shorter than that claimed in the specifications, please consider changing the battery or contact us.

NOTE

- **The lifespan of the battery depends on how frequently it is used and on how long it has been used. If the maintenance and storage of the battery is appropriate, the lifespan of the Lithium battery is about 5 years. Inappropriate use of the battery will shorten its lifespan. We recommend replacing the Lithium battery every 3 years.**
 - **The length of the battery's lifetime depends on the device configuration and operation, for example: Under the condition of the power supply by the battery, frequent infusion at a high rate will also shorten the length of the battery's lifetime.**
-

9.3 Insert Batteries

Batteries need to be replaced:

1. It is suggested to turn off the infusion pump power source, and disconnect the power source line.
2. Tilt or lay the infusion pump down.
3. Open the battery door, and unlock the battery lock.
4. Remove the old battery, install the new one into the battery box and insert the battery lock.
5. Close the battery door and return the infusion pump to its upright position.

9.4 Battery Recycling

If there is any obvious damage to the battery or to the battery capacity exhausts, it should be replaced and recycled appropriately. Please follow the applicable laws on recycling.

WARNING

- **The battery must not be disassembled, burned or short-circuited. Burning, exploding or leaking batteries can cause personal injury.**
-

10 Preservation and Sanitation

The pump must be cleaned or disinfected using the materials and methods listed in this section. The manufacturer will not be responsible for any damage or accident caused by cleaning and disinfection using other materials and methods.

The manufacturer shall not be held responsible for the efficacy of the following chemicals or methods for infection control. Please contact your hospital's infection prevention department or epidemiology specialists for advice on infection control practices.

10.1 Description

Please make sure that your device and other fittings are clean without dust. In order to prevent any damage to the device, please abide by the following rules:

- Dilute all cleaning agents and disinfectants in accordance with the manufacturer's instructions, or use as low a concentration as possible.
- Do not immerse or submerge the device in liquid.
- Do not pour liquid on the device or accessories.
- Avoid liquid from entering the pump body.
- Do not use abrasive materials (such as steel wool or silver polishes), or any strong solvent (such as acetone or any detergent containing acetone).

WARNING

- **Turn off the pump and disconnect the AC power source line from the socket before cleaning. Do not clean and disinfect the device, export history record and perform other operations when patients are using the pump.**
-
-

10.2 Cleaning

The pump should be cleaned regularly. If operating in dirty or sandy areas, cleaning should be more frequent. Before cleaning, please consult or refer to the hospital's specific regulations concerning medical device cleaning.

The recommended detergents include: Hydrogen peroxide (3%), Ethanol (70%), Isopropanol (70%).

To clean your equipment, follow these rules:

1. Turn off the pump and disconnect the AC power source line.
2. Wipe the display screen after soft cotton balls absorb an appropriate amount of detergent.
3. Use a piece of soft cloth which absorbs a modest amount of cleaning agent to wipe the surface of the device.
4. When necessary, use a piece of cloth to wipe off any excess cleaning agents.
5. Place the pump in a cool and ventilated environment to dry.

10.3 Disinfection

The operation of disinfection may cause certain damage to the infusion pump. You are recommended to disinfect only when it is necessary in your desired maintenance plan. Clean the equipment before disinfection.

The recommended disinfectants include: Ethanol (70%), Isopropanol (70%), glutaraldehyde-type 2% liquid disinfectant.

CAUTION

- **Never use EtO or formaldehyde for disinfection.**
 - **Do not conduct high pressure or high temperature disinfection for the infusion pump and its accessories.**
-

11 Maintenance

WARNING

- To avoid electric shock, stop using the device if you find its housing has signs of broken. Contact the service personnel for help in that case.
 - The hospital or medical facility using this infusion pump must set up a comprehensive maintenance plan. Failure to do so may result in equipment failure or other unexpected consequences, and may even jeopardize personal safety.
 - All safety inspections or maintenance work involving the disassembly of the device must be conducted by professional maintenance personnel. Actions by unqualified persons may result in device failure and may even jeopardize personal safety.
 - Please contact the company immediately if you encounter problems with the device (such as the warning label off).
 - The device and accessories shall not be served or maintained while in use with a patient.
-

11.1 Inspection

The infusion pump must be given a thorough inspection before use, after 6-12 months of continuous use, and after maintenance or upgrades, to ensure that it is operated and functioned normally.

The inspection criteria are:

- The environment and power supply meet requirements.
- The equipment and accessories have no mechanical damage.
- The power cord is not damaged and has sufficient electrical insulation.
- Accessories used with the pump are correct.
- The alarm system functions correctly.
- Battery performance.
- Self-checking and pump functions are normal.

If there are any forms of damage or abnormal circumstances, do not use the infusion pump and contact the company immediately.

11.2 Maintenance Plan

The following tasks must be conducted by professional maintenance personnel approved by the company. Please contact the company if the following maintenances are needed. Must clean and disinfect the device before the test or maintenance.

| Inspection/Maintenance Items | Frequency |
|--|--|
| Perform a safety inspection according to the IEC60601-1 standard. | Once every two years. Perform after the board is changed or the infusion pump is accidentally dropped. |
| Preventive maintenance (refers to the Maintenance Manual for pressure calibration, sensor calibration, and pump inspection). | Once every two years, or when you suspect the occlusion alarm is abnormal, the flow volume is inaccurate, or the infusion set is incorrectly identified. |

11.3 View Information

Select **[Main Menu]**→**[History Record]**. In the **[History Record]** interface, you can view the infusion parameters, alarm information, operation information and other information.

Select **[Main Menu]**→**[System Options]**→**[Version Information]**. In the **[Version Information]** interface, you can view the Software Version, Brand Library Version and other versions.

11.4 Safe Disposal and Recycling

Please contact the company for related information about safe disposal and recycling.

12 Accessories

WARNING

- Use the accessories specified in this chapter only. Other accessories may cause damage to this infusion pump, or cannot reach the specification in this manual.
- Please do not replace an accessory if its package or itself is damaged.

| Materials | PN |
|---|---------------|
| Lithium battery | 022-000161-00 |
| Power cord (Select PN according to sales area) | 009-004829-00 |
| | 009-004830-00 |
| | 009-004831-00 |
| | 009-004825-00 |
| | 009-004822-00 |
| 009-004823-00 | |
| Pole clamp | 115-022050-00 |
| Nurse call cable | 009-004287-00 |
| DC input cable | 009-004285-00 |
| Serial communication cable | 009-004286-00 |
| Handle set | 115-028601-00 |
| Drop sensor | 115-032580-01 |

Cable specifications:

| Item | Length (m) | Whether shielded | Comments |
|---------------------------------|------------|------------------|--------------------|
| Power cord | 2.5 | No | / |
| DC cable | 2.8 | No | With magnetic ring |
| Nurse call cable | 2.8 | No | With magnetic ring |
| Serial port communication cable | 2.8 | Yes | / |

NOTE

- **This Operator's Manual describes the most complete functional configuration of the system. The device you are using may not have some of the settings or functions described herein.**
-

A Product Specifications

A.1 Safety Specifications

A.1.1 Product Classification

Classified according to the China SFDA, this infusion pump is a Type II device. Classifications of this infusion pump according to the IEC60601-1 standard are as follows:

| Safety | |
|--|--|
| Components | Host |
| Type of protection against electrical shock | Class I |
| Degree of protection against electrical shock | Type CF defibrillation proof |
| Ingress Protection | IP23 |
| Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide | The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide |
| Mode of operation | Continuous |
| Mobile level | Portable |

NOTE:

- CF: Type CF applied parts, can be directly used in the heart.
- IP23: Protected against solid foreign objects with a diameter no less than 12.5mm and protected against spraying water.
- Portable devices: Can be moved from one place to another by one or more persons or by other means when the devices are in use or being used.

A.1.2 Operating Environment

| Work environment | |
|--------------------------|---------------------------------------|
| Temperature | 5-40°C |
| Humidity | 15-95%, non-condensing |
| Atmospheric pressure | 57-106kPa |
| Storage environment | |
| Temperature | -20-60°C |
| Humidity | 10-95%, non-condensing |
| Atmospheric pressure | 50-106kPa |
| Storage conditions | Corrosive-free and ventilated indoors |
| AC Power Supply | |
| Voltage | 100-240V~ |
| Frequency | 50/60Hz |
| Current | 0.53-0.28A |
| Fuse | Low interrupting rating, T 1A 250V~ |
| External DC power supply | |
| Voltage | DC 10V-16V |
| Current | 2.25-1.5A |

A.2 Physical Specifications

| Components | Weight | Size |
|------------|-----------------|---|
| Host | Less than 2.5kg | Less than 245 x 174 x 87(mm) (lengthxwidthxheight) |

A.3 Hardware Specifications

A.3.1 Display

| Display | |
|-----------------|-------------------------|
| Type | Color LCD |
| Size (diagonal) | 3.5 inches, ration 16:9 |
| Differentiation | 480 x 272 pixels |

A.3.2 Battery

| Internal battery | |
|-------------------|---|
| No. of batteries | One |
| Battery type | Lithium battery |
| Shutdown delay | About 30mins (new battery, after the first low battery alarm) |
| Battery voltage | 7.4VDC |
| Battery capacity | 4800mAh |
| Power supply time | By factory default, continuously operate at a rate of 25ml/h, discharge for at least 9h using a fully charged new battery; Note: Power supply time is relevant to rate. By factory default, continuously operate at the maximum selectable rate, typically discharge for about 5h using a fully charged new battery. |
| Charging time | When the pump is off, the charging time is not longer than 6h. |

A.3.3 Host LED

| Host LED | |
|-------------------------|-------------------------|
| Alarm light | 1 (red/yellow bi-color) |
| AC indicator light | 1 (green) |
| Battery indicator light | 1 (green) |

A.3.4 Auditory Indicator

| | |
|---------|---|
| Speaker | Produce an alarm, the sound pressure is 54-73 dB(A) and key beep; Support multi-level volume functions; The alarm sound meets the requirements of the IEC60601-1-8. |
|---------|---|

A.3.5 External Ports

| Ports | |
|----------------------------------|---|
| AC power supply port | One AC power supply port |
| Multifunction interface | One multifunction interface with the following functions: <ul style="list-style-type: none"> ■ DC power supply port ■ RS232 interface ■ Nurse call interface |
| Drop sensor interface (Optional) | One Drop sensor interface |

A.3.6 Signal Output Interface

| Nurse call signal output | |
|--------------------------|---|
| Driving mode | Relay drive |
| Electric specification | ≤60W, ≤2A, ≤36VDC, ≤25VAC |
| Isolation voltage | >1500VAC |
| Action mode | Normally open or normally closed (optional) |

A.4 Specifications

| Parameters | Specifications | Factory Default |
|--|---|-----------------|
| Infusion set standard | Infusion set used in conjunction with infusion pump should meet the requirements of ISO 8536-4:2004 Infusion equipment for medical use— Part 4: Infusion sets for single use, gravity feed, MOD | / |
| Compatible conventional set sizes (ml) | Infusion set diameter: 3.0-4.5mm Infusion set thickness: 0.8-1.2mm | / |
| Rate | Unit of Rate (ml/h): 0.1-2000ml/h, the minimum increment is 0.01ml/h Unit of Rate (gtt/min): 1-(400*Drip /60) gtt/min, the minimum increment is 1gtt/min Note 1: The maximum rate of the infusion system (infusion pump and infusion set) is affected by inner and outer diameter, material, elasticity of the infusion set and | --- |

| | | |
|---------------------------|--|-------------------|
| | <p>other factors. Therefore, infusion sets of different brand and model may differ in maximum rates.</p> <p>Note 2: The above declared rates are based on BOON A2 and B.Braun Intrafix Safeset infusion sets, and specified infusion sets, temperature of $20\pm 2^{\circ}\text{C}$.</p> | |
| Bolus Rate/ Purge Rate | 0.1-2000ml/h | / |
| VTBI | 0.1-9999.99ml | --- |
| Time | 00:00:01-99:59:59 h:m:s | --- |
| Volume | 0.01-9999.99ml | 0ml |
| Select Mode | Rate Mode, Body Weight Mode, Time Mode, Sequential Mode, Loading Dose Mode, Micro-infusion Mode and Ramp Up/Down Mode | Rate Mode |
| Pressure | <p>12 Levels are adjustable, respectively are (75, 150, 225, 300, 375, 450, 525, 600, 750, 825, 900 and 975)mmHg</p> <p>For 75mmHg, the error is $\pm 50\text{mmHg}$(6.7kPa); for other pressures, the error is $\pm 20\%$ or $\pm 113\text{mmHg}$ (15.1kPa), whichever is larger.</p> <p>Maximum occlusion pressure is about 1170mmHg.</p> <p>Note 1: The detected pressure of the infusion system (infusion pump and infusion set) is affected by inner and outer diameter, material, elasticity of the infusion set and other factors. Therefore, infusion sets of different brand and model may differ in the detected pressure range.</p> <p>Note 2: The above declared pressure is based on BOON A2 and B.Braun Intrafix Safeset infusion sets, and specified infusion sets, temperature of $20\pm 2^{\circ}\text{C}$.</p> | 450mmHg |
| Air detection | <p>6 Levels are adjustable, respectively are (20, 50, 100, 250, 500, 800) μl</p> <p>Sensitivity of single air bubble is 20μl.</p> <p>Note 1: The detected air detection of the infusion system (infusion pump and infusion set) is affected by inner and outer diameter, material, elasticity of the infusion</p> | 100 μl |

| | | |
|-----------------------|---|------------|
| | set and other factors. Therefore, infusion sets of different brand and model may differ in the detected air detection. Note 2: The above declared air detection is based on BOON A2 and B.Braun Intrafix Safeset infusion sets, temperature of 20±2°C. | |
| Accumulate air | 0.1-4ml | 1.5ml |
| KVO Rate | 0.1-5.0ml/h | 0.5ml/h |
| Time Near End | Off, 1-30 min when the time is <10min, step for 1min, and step for 5min when the time is ≥10min. | 3min |
| Max. Rate Limit | 0.1-2000ml/h | 2000ml/h |
| Drip Setting | Drip:10-60drop/ml | 20drop/ml |
| | gtt/min: On, Off | Off |
| Drip Abnormal | On, Off | Off |
| Empty Sensitivity | High, Low | Low |
| Auto-lock Time | Off, 1-5min, step for 1min | Off |
| Reminder Time | Off, 1-5min, step for 1min | 2min |
| Weight Unit | kg, lb | kg |
| Sound Volume | 1-8 | 4 |
| Brightness | 1-8 | 4 |
| Night Mode | On, Off | Off |
| Nurse call | On, Off | Off |
| History Record | Can store up to 2000 records. | / |
| Brand Selection | On, Off | On |
| BW Mode Configuration | Conc., Drug Amount and Volume | Conc. |
| Drug Library | On, Off | Off |
| Para. Memory | On, Off | Off |
| Date and Time | Time:__:__:__ | 00:00 |
| | Date:____-____-____ | 01-01-2018 |
| | Time format: 12h, 24h | 24h |

| | | |
|----------------------|---|--|
| | Date format: yyyy-mm-dd, mm-dd-yyyy or dd-mm-yyyy | Domestic: yyyy-mm-dd International: dd-mm-yyyy |
| Language | You can select language according to actual needs | / |
| Pressure Unit | mmHg, kPa, bar and psi | mmHg |
| Alarm Sound | Sound1, Sound2, Sound3 | Sound2 |
| Anti-bolus switch | On, Off | On |
| Drop sensor | On, Off | Off |
| Infusion accuracy | <p>Infusion pump with conventional infusion sets: Infusion accuracy of the whole rate $\leq \pm 5\%$</p> <p>Note 1: The infusion accuracy of the infusion system (infusion pump and infusion set) is affected by inner and outer diameter, material, elasticity of the infusion set and other factors. Therefore, infusion sets of different brand and model may differ in the infusion accuracy.</p> <p>Note 2: The above declared infusion accuracy is based on BOON A2 and B.Braun Intrafix Safeset infusion sets, temperature of $20 \pm 2^\circ\text{C}$.</p> <p>Infusion pump with silicone specified infusion sets: Infusion accuracy of the whole rate $\leq \pm 5\%$, temperature of $20 \pm 2^\circ\text{C}$.</p> <p>Infusion pump with PVC specified infusion sets: Infusion has run for 24h or has pumped 3L of fluid, infusion accuracy $\leq \pm 10\%$, temperature of $20 \pm 2^\circ\text{C}$</p> | / |
| Dose of single fault | 0.25ml Note: The above declared single fault is based on BOON A2 infusion set at a rate of 25ml/h | / |
| Status indicators | Stop, running, bolus, KVO, pause, standby, alarm and purge | / |
| Alarm Information | See complete information in C Alarm Information | / |

A.5 A Reference Table Showing Occlusion Alarm Delay and Possible Dose

A.5.1 Infusion Pump with Conventional Infusion Sets

| Occlusion Pressure (mmHg) | Rate (ml/h) | Time of Occlusion Alarm (hh:mm:ss) |
|---------------------------|-------------|------------------------------------|
| 75 | 0.1 | 02:54:30 |
| | 1 | 00:06:07 |
| | 25 | 00:00:30 |
| 975 | 0.1 | 19:01:01 |
| | 1 | 01:37:08 |
| | 25 | 00:02:00 |

| Pressure Setting | Rate (ml/h) | Bolus Volume (ml) |
|------------------|-------------|-------------------|
| 75 | 25 | <0.1 |
| 975 | 25 | <0.15 |

NOTE

-
- **Test conditions:**
 - FLUKE IDA4 PLUS tester
 - Infusion set brand and model: B.Braun Intrafix Safeset
 - Test temperature: 20±2°C
 - Extension tube length: 1 meter
 - Occlusion alarm pressure, alarm delays and bolus volume may vary depending on test conditions, temperature and tube length.
 - The above data are only typical values under normal test conditions. The actual data may vary as test conditions change. Please refer to the test data for the product you have purchased. Under the same standard occlusion value and rate, the higher the value of the tested pressure is, the longer the alarm time will be delayed.
-

A.5.2 Infusion Pump with Silicone Specified Infusion Sets

| Occlusion Pressure (mmHg) | Rate (ml/h) | Time of Occlusion Alarm (hh:mm:ss) |
|---------------------------|-------------|------------------------------------|
| 75 | 0.1 | 01:07:08 |
| | 1 | 00:05:02 |
| | 25 | 00:00:30 |
| 975 | 0.1 | 18:45:50 |
| | 1 | 01:19:12 |
| | 25 | 00:02:50 |

| Pressure Setting | Rate (ml/h) | Bolus Volume (ml) |
|------------------|-------------|-------------------|
| 75 | 25 | <0.1ml |
| 975 | 25 | <0.15ml |

NOTE

-
- **Test conditions:**
 - **FLUKE IDA4 PLUS tester**
 - **Infusion set brand and model: M-IS-000**
 - **Test temperature: 20±2°C**
 - **Extension tube length: 1 meter**
 - **Occlusion alarm pressure, alarm delays and bolus volume may vary depending on test conditions, temperature and tube length.**
 - **The above data are only typical values under normal test conditions. The actual data may vary as test conditions change. Please refer to the test data for the product you have purchased. Under the same standard occlusion value and rate, the higher the value of the tested pressure is, the longer the alarm time will be delayed.**
-

A.5.3 Infusion Pump with PVC Specified Infusion Sets

| Occlusion Pressure (mmHg) | Rate (ml/h) | Time of Occlusion Alarm (hh:mm:ss) |
|---------------------------|-------------|------------------------------------|
| 75 | 0.1 | 02:31:18 |
| | 1 | 00:05:16 |
| | 25 | 00:00:15 |
| 975 | 0.1 | 23.24.54 |
| | 1 | 01:37:18 |
| | 25 | 00:02:50 |

| Pressure Setting | Rate (ml/h) | Bolus Volume (ml) |
|------------------|-------------|-------------------|
| 75 | 25 | <0.1 |
| 975 | 25 | <0.15 |

NOTE

-
- **Test conditions:**
 - **FLUKE IDA4 PLUS tester**
 - **Infusion set brand and model: SK ZPQ**
 - **Test temperature: 20±2°C**
 - **Extension tube length: 1 meter**
 - **Occlusion alarm pressure, alarm delays and bolus volume may vary depending on test conditions, temperature and tube length.**
 - **The above data are only typical values under normal test conditions. The actual data may vary as test conditions change. Please refer to the test data for the product you have purchased. Under the same standard occlusion value and rate, the higher the value of the tested pressure is, the longer the alarm time will be delayed.**
-

A.6 Infusion Accuracy Curve and Trumpet Curve

The following typical infusion accuracy table expresses performance after infusion has started and infusion fluctuations occurring within a certain period of time after normal infusion flow volumes have been reached. The infusion accuracy table is for reference only, detailed infusion accuracy curve is in accordance with the final device.

NOTE

-
- **Infusion accuracy may be influenced by the pump's environment (such as pressure, temperature, humidity and any infusion consumables used).**
-

A.6.1 Infusion Pump with Conventional Infusion Sets

Plotted on the basis of data collected over a two-hour measurement period.

Infusion set brand and model: B.Braun Intrafix Safeset

Sampling quantity of pump: 3

Sampling quantity of infusion set: 3

Sampling interval: $\Delta t = 0.5\text{min}$

Test period: $t = 240\text{mins}$

Infusion rate: Q (m/h)

Flow rate deviation over time ($p\Delta t$)

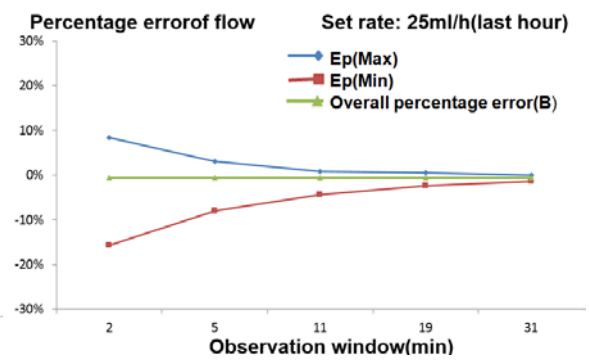
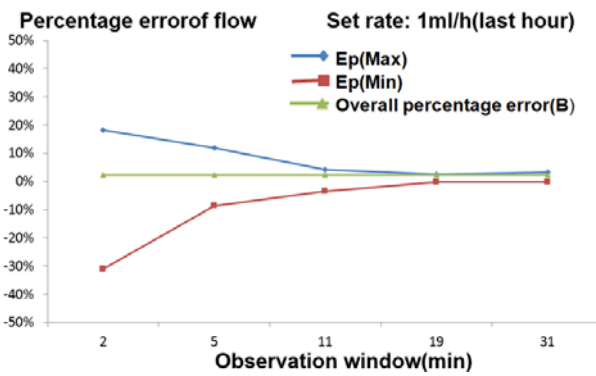
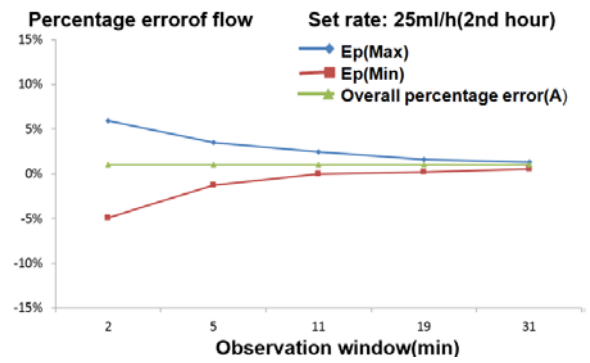
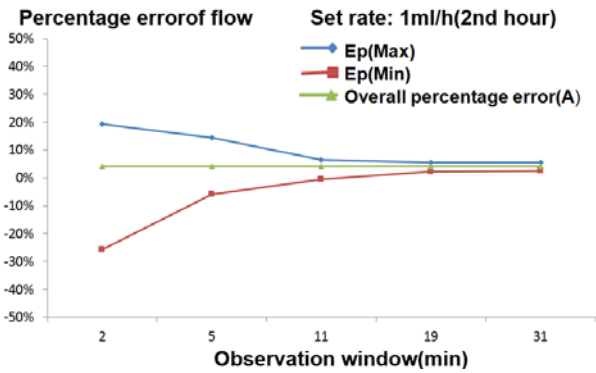
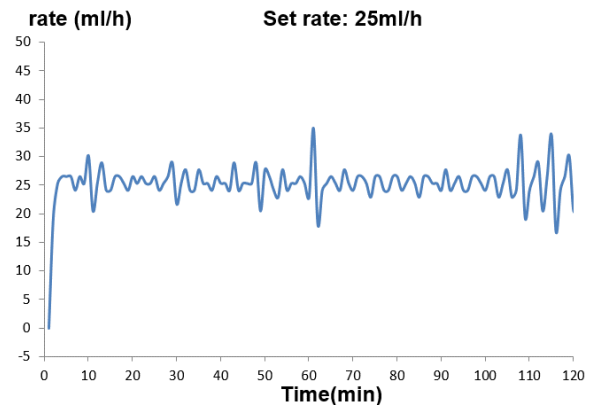
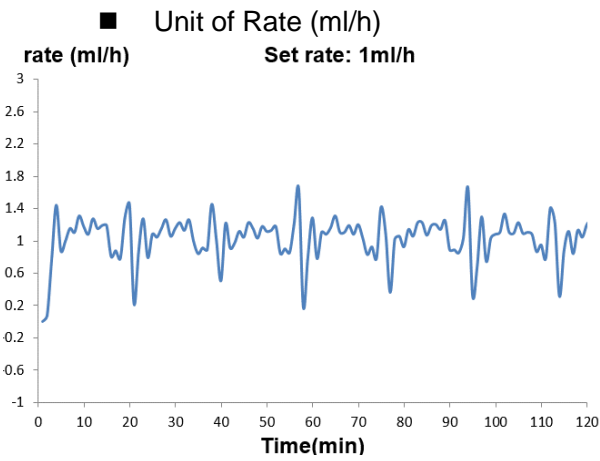
Sampling interval: $\Delta t = 0.5\text{min}$

Observation windows: $p\Delta t = 2, 5, 11, 19, 31\text{mins}$

Maximum deviation over the course of a full observation window: $Ep(\text{Max})$ (%)

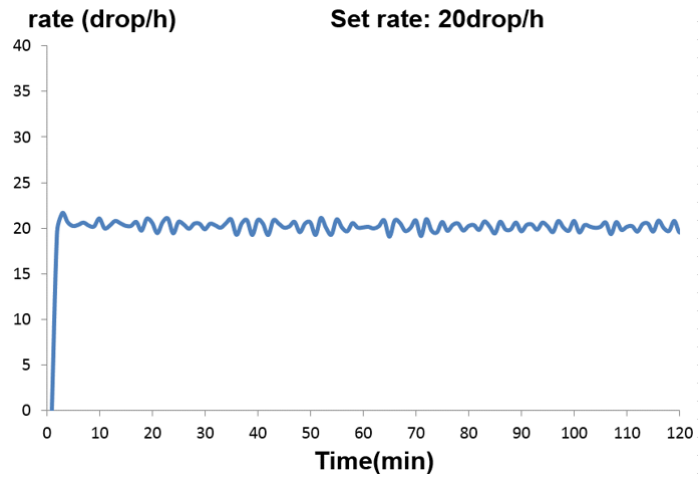
Minimum deviation over the course of a full observation window: $Ep(\text{Min})$ (%)

Average deviation: A (%) and B (%)

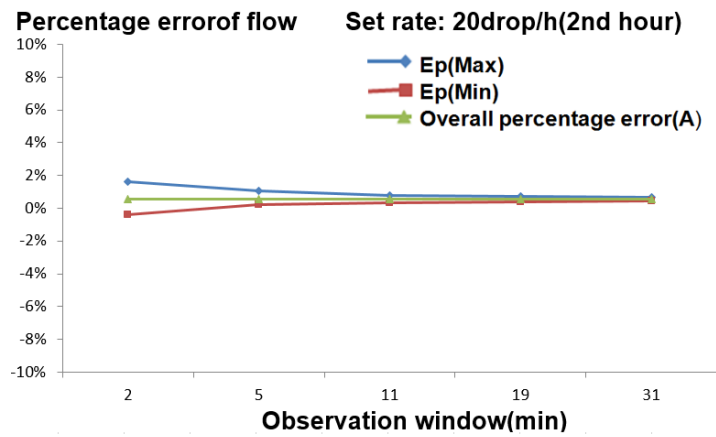


■ Unit of Rate (gtt/min)

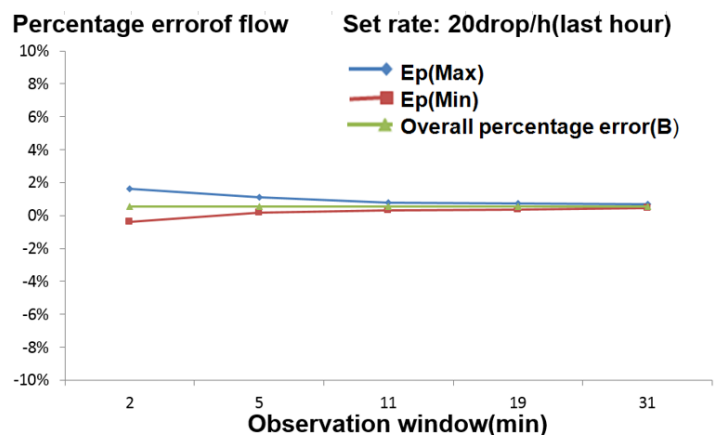
Sampling rate: 20gtt/min
 Sampling interval: $\Delta t = 0.5\text{min}$
 Test period: $t = 120\text{mins}$
 Infusion rate: Q (gtt/min)



Sampling rate: 20gtt/min
 Sampling interval: $\Delta t = 0.5\text{min}$
 Observation windows: $p\Delta t = 2, 5, 11, 19, 31\text{ mins}$
 Maximum deviation over the course of a full observation window: $E_p(\text{Max})$ (%)
 Minimum deviation over the course of a full observation window: $E_p(\text{Min})$ (%)
 Average deviation: A (%)



Sampling rate: 20gtt/min
 Sampling interval: $\Delta t = 0.5\text{min}$
 Observation windows: $p\Delta t = 2, 5, 11, 19, 31\text{ mins}$
 Maximum deviation over the course of a full observation window: $E_p(\text{Max})$ (%)
 Minimum deviation over the course of a full observation window: $E_p(\text{Min})$ (%)
 Average deviation: B (%)



A.6.2 Infusion Pump with Silicone Specified Infusion Sets

Plotted on the basis of data collected over a two-hour measurement period.

Infusion set brand and model: M-IS-000

Sampling quantity of pump: 3

Sampling quantity of infusion set: 3

Sampling interval: $\Delta t = 0.5 \text{ min}$

Test period: $t = 8 \text{ h}$ (1ml/h), 72h (25ml/h)

Infusion rate: Q (m/h)

Flow rate deviation over time ($p\Delta t$)

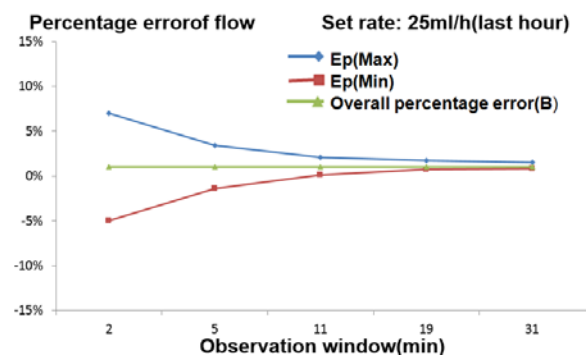
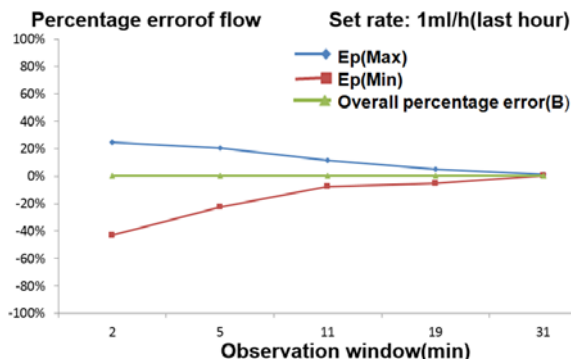
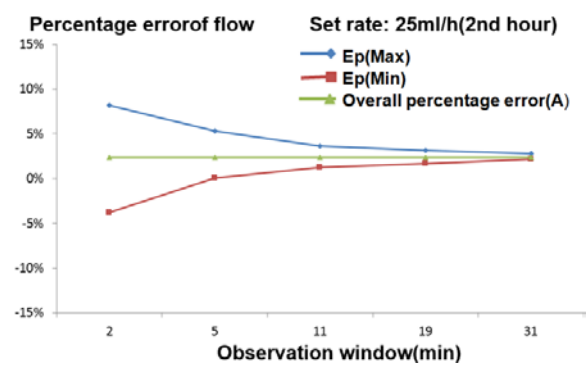
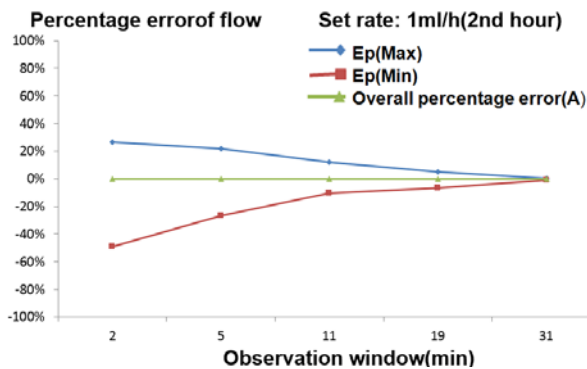
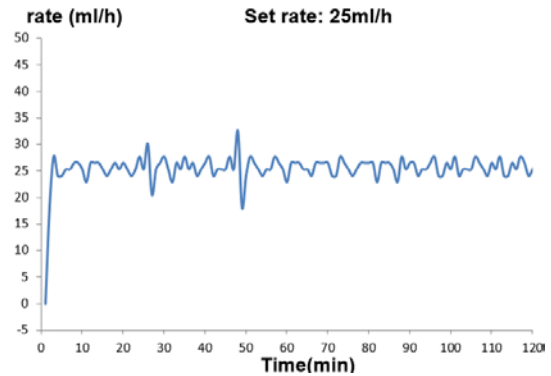
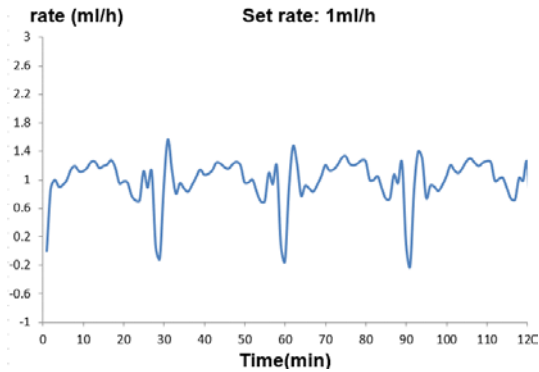
Sampling interval: $\Delta t = 0.5 \text{ min}$

Observation windows: $p\Delta t = 2, 5, 11, 19, 31 \text{ mins}$

Maximum deviation over the course of a full observation window: $Ep(\text{Max})$ (%)

Minimum deviation over the course of a full observation window: $Ep(\text{Min})$ (%)

Average deviation: A (%) and B (%)



A.6.3 Infusion Pump with PVC Specified Infusion Sets

Plotted on the basis of data collected over a two-hour measurement period.

Infusion set brand and model: SK ZPQ

Sampling quantity of pump: 3

Sampling quantity of infusion set: 3

Sampling interval: $\Delta t = 0.5 \text{ min}$

Test period: $t = 8 \text{ h}$ (1ml/h), 24h (25ml/h)

Infusion rate: Q (ml/h)

Flow rate deviation over time ($p\Delta t$)

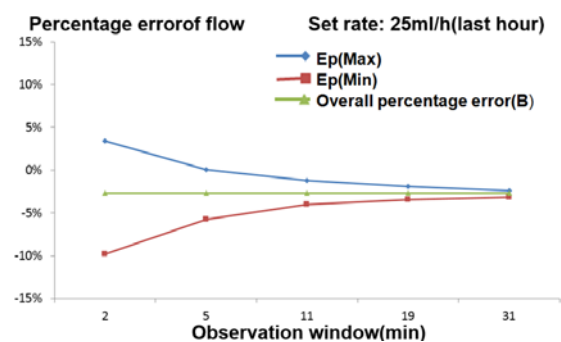
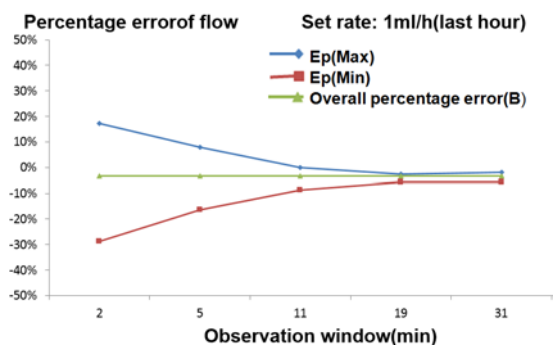
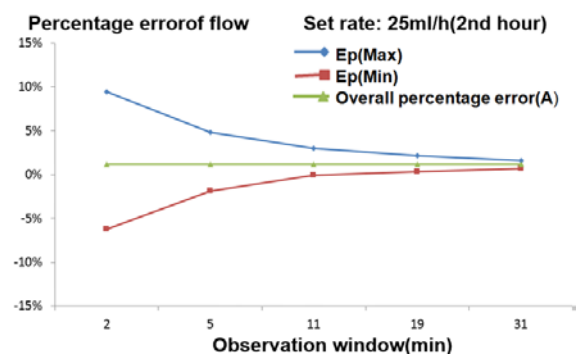
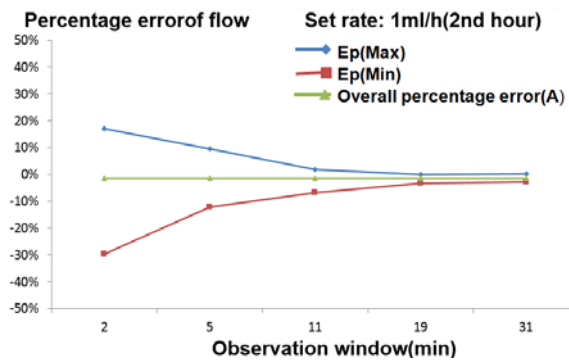
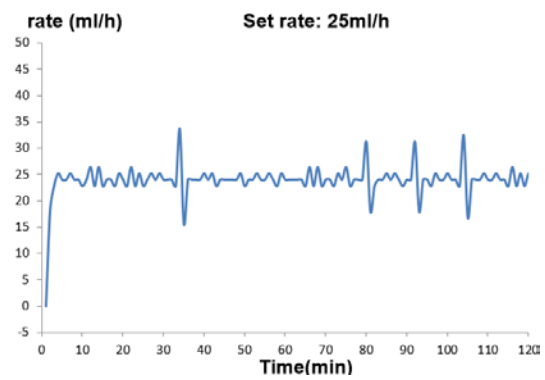
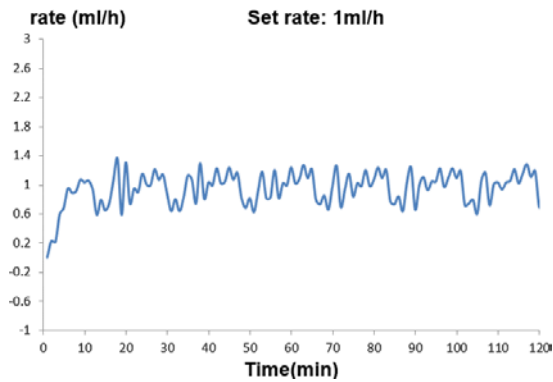
Sampling interval: $\Delta t = 0.5 \text{ min}$

Observation windows: $p\Delta t = 2, 5, 11, 19, 31 \text{ mins}$

Maximum deviation over the course of a full observation window: $Ep(\text{Max})$ (%)

Minimum deviation over the course of a full observation window: $Ep(\text{Min})$ (%)

Average deviation: A (%) and B (%)



B EMC and Radio Regulatory Compliance

B.1 EMC

The device meets the requirements of IEC 60601-1-2:2014.

NOTE

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.**
 - **Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.**
 - **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 this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.**
 - **The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.**
 - **This device is intended for use in professional healthcare facility environment only. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**
-

| Guidance and Declaration - Electromagnetic Emissions | | |
|---|-------------------|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | |
| Emission test | Compliance | Electromagnetic environment - guidance |
| Conducted and radiated RF EMISSIONS CISPR 11 | Group 1 | The device 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 device. |
| Conducted and radiated RF EMISSIONS CISPR 11 | Class A | The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic distortion IEC 61000-3-2 | Class A | The device 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. |
| Voltage fluctuations and flicker IEC 61000-3-3 | Complies | |

NOTE

- **The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may affect this device even though they meet the requirements of CISPR.**
- **The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.**
- **If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location or stopping using the infusion pump system and contact the service personnel.**


If the device is operated within the electromagnetic environment listed in Table **Guidance and Declaration —Electromagnetic Immunity**, the system will remain safe and provide the following essential performance:

- **Operating mode**
- **Accuracy**
- **Function**
- **Protection against UNINTENDED BOLUS volumes**
- **Occlusion**
- **ALARM CONDITIONS regarded**
- **Data stored**

| Guidance and Declaration - Electromagnetic Immunity | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 ±15kV air | ±8 kV contact ±15kV 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 for power supply lines ±1 kV for input/output lines (length greater than 3 m) | ±2 kV for power supply lines ±1 kV for input/output lines (length greater than 3 m) | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line(s) to line(s) ±2 kV line(s) to earth | ±1 kV line(s) to line(s) ±2 kV line(s) to earth | |
| Voltage dips and Voltage interruptions IEC 61000-4-11 | 0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycle | 0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible |

| | | | |
|---|-------------------------|-------------------------|---|
| | | | power supply or a battery. |
| RATED power frequency magnetic fields IEC 61000-4-8 | 30 A/m 50 Hz / 60 Hz | 30 A/m 50 Hz / 60 Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Note: U_T is the A.C. mains voltage prior to application of the test level. | | | |

| Guidance and Declaration - Electromagnetic Immunity | | | |
|--|---|------------------|--|
| The device is intended for use in the specified electromagnetic environment. The customer or the user of the device should assure that it is used in such an environment as described below. | | | |
| Immunity test | IEC 60601 Test level | Compliance level | Electromagnetic environment - guidance |
| Conducted disturbances induced by RF fields IEC61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 10 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V} \right] \sqrt{P} \quad 150\text{k to } 80 \text{ MHz}$ |
| | 6 Vrms in ISM bands and amateur radio bands ^a between 0,15 MHz and 80 MHz | 6 Vrms | |
| Radiated RF EM fields IEC61000-4-3 | 10V/m 80 MHz to 2.7 GHz | 10V/m | $d = \left[\frac{3.5}{E} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ |
| Proximity fields from RF wireless communication s equipment IEC61000-4-3 | 27 V/m 380–390 MHz | 27 V/m | $d = \left[\frac{7}{E} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ 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). Field strengths from fixed RF transmitters, as determined by an |
| | 28 V/m 430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz | 28 V/m | |

| | | | |
|--|---|-------|---|
| | 9 V/m 704–787 MHz, 5100–5800 MHz | 9 V/m | electromagnetic site survey ^b , should be less than the compliance level in each frequency range ^c . Interference may occur in the vicinity of equipment marked with the following symbol:  . |
| <p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |
| <p>^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 0,15 MHz 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 10,15 MHz, 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.</p> <p>^b 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</p> <p>^c Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p> | | | |

Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and This Equipment

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

| Rated Maximum Output power of Transmitter Watts (W) | Separation Distance According to Frequency of Transmitter (m) | | |
|---|--|--|---|
| | 150 kHz to 80 MHz $d = \left[\frac{3.5}{V} \right] \sqrt{P}$ | 80 MHz to 800 MHz $d = \left[\frac{3.5}{E} \right] \sqrt{P}$ | 800 MHz to 2.7 GHz $d = \left[\frac{7}{E} \right] \sqrt{P}$ |
| 0.01 | 0.04 | 0.04 | 0.07 |
| 0.1 | 0.11 | 0.11 | 0.22 |
| 1 | 0.4 | 0.4 | 0.7 |
| 10 | 1.1 | 1.1 | 2.2 |
| 100 | 4 | 4 | 7 |

For transmitters at a maximum output power not listed above, the recommended separation distanced in 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 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.

B.2 Radio Regulatory Compliance

RF Parameter

| Radio devices | IEEE 802.11b/g/n (2.4GHz Wi-Fi) |
|---------------------|---------------------------------|
| Operating frequency | 2412MHz to 2472MHz |
| Modulation mode | DSSS, OFDM |
| Output power | ≤20dBm |














The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.







C Alarm Information





This chapter presents the alarm information of the infusion pump. Prompt information for operation guidance will not be presented in this chapter.





The table shows the appropriate countermeasures for each piece of information related to alarm triggering. If the problem still exists after operating according to the countermeasures, please contact the company.

| Alarm Information | Alarm Level | Reason | Countermeasure |
|------------------------|-------------|--|--|
| [Upstream Occlusion] | High | When the pump is infusing, the alarm is triggered due to an occlusion in the infusion tube between liquid source and equipment. Infusion is stopped after the alarm is triggered. | Press  to cancel alarm, check and eliminate the source of the alarm. |
| [Downstream Occlusion] | High | When the pump is infusing, the alarm is triggered due to an occlusion in the infusion tube between the equipment and the patient. Infusion is stopped after the alarm is triggered. | Press  to cancel alarm, check and eliminate the source of the alarm. |
| [Air in line] | High | Size of single air detection reaches to the preset value. Infusion is stopped after the alarm is triggered. | Press  to cancel alarm, check and eliminate the air in line. |
| [Accumulate air] | High | Size of accumulate air bubble accumulated in 1 hour reaches to the preset value. Infusion is stopped after the alarm is triggered. | Press  to cancel alarm, check and eliminate the air in line. |
| [Drop error] | High | If drop sensor is installed correctly and the switch of [Drop sensor] is on, drop sensor detects that the drop rate deviates the preset value. Infusion is stopped after the alarm is triggered. | Press  to cancel alarm, refill the drop chamber correctly or place the drop chamber vertically or avoid the strong light. |


| Alarm Information | Alarm Level | Reason | Countermeasure |
|--------------------|-------------|--|---|
| [No Battery] | High | 1. Only powered with built-in battery, battery is empty. 2. Built-in battery and external DC power encounter failure. | Connect to the AC power source to cancel alarm. |
| [VTBI Complete] | High | Infusion volume reaches the preset VTBI. | 1. Press  to cancel alarm. 2. Or alarm is cancelled when reach the KVO infusion time. 3. Or press  to confirm KVO infusion to cancel alarm. |
| [KVO Finish] | High | KVO infusion has run for 30 minutes. Infusion is stopped after the alarm is triggered. | Press  to cancel alarm. |
| [Door opened] | High | The infusion pump door is opened during infusion. Infusion is stopped after the alarm is triggered. | Press  to cancel alarm and close the door correctly. |
| [System Error] | High | Power supply voltage abnormal (overhigh), AD value of sensor abnormal, communication abnormal and other errors. | Alarm cannot be cancelled. Please stop operation and contact the company. |
| [Empty] | High | If drop sensor is installed correctly and the switch of [Drop sensor] is on, no liquid drop. Note: If drop sensor is not correctly inserted or the surface of the liquid in the drip chamber is abnormal, the alarm might be triggered. Infusion is stopped after the alarm is triggered. | Press  to cancel alarm, check and eliminate the source of the alarm. |
| [No Infusion Tube] | High | Infusion set is not loaded and start infusion when the door is closed. | Press  to cancel alarm, correctly load infusion set and close the door. |

| Alarm Information | Alarm Level | Reason | Countermeasure |
|------------------------|-------------|--|---|
| [Relay Invalid] | High | 1. Upstream channel has not start infusion or the infusion is unfinished, the communication with BeneFusion DS5 Infusion Supervision System is interrupted; 2. Or the upstream channel has not start infusion or the infusion is unfinished, the communication between the downstream channel and BeneFusion DS5 Infusion Supervision System is interrupted; 3. Or the upstream channel finishes infusion, the downstream channel is not in parameter setting interface, or not set valid parameters for starting infusion in parameter setting interface. | Press  or insert infusion pump to BeneFusion DS5 Infusion Supervision System. |
| [System Abnormal] | Medium | Power supply voltage abnormal (low) and other abnormal. | Alarm cannot be cancelled. Please stop operation and contact the company. |
| [Standby Time Expired] | Medium | Pump is in standby mode and standby time is completed. | Press  or  to cancel alarm. |
| [Reminder] | Low | The infusion pump performs no operation during the set reminder time after the infusion set is loaded. | 1. Operate the pump (except press ) to cancel alarm. 2. Or press  to acknowledge the alarm condition. |
| [Low Battery] | Low | Only powered with built-in battery, battery charge is insufficient. | 1. Connect to the AC power source to cancel alarm. 2. Or press  to |

| Alarm Information | Alarm Level | Reason | Countermeasure |
|-----------------------------|-------------|--|--|
| | | | acknowledge the alarm condition. |
| [Time Near End] | Low | Infusion remaining time reaches the setting value of [Time Near End]. | <p>1. The alarm will not be cancelled automatically until the infusion is completed, and then switch to [VTBI Complete] or [Empty] alarm.</p> <p>2. Or press  to cancel alarm.</p> <p>3. Or press  to acknowledge the alarm condition.</p> |
| [No AC Power] | Low | Power cord disconnects when the pump has connected to an AC/DC power supply. | <p>1. Connect to an AC/DC power supply to cancel the alarm.</p> <p>2. Or press  to cancel alarm.</p> |
| [Communication interrupted] | Low | Communication is abnormally interrupted for 3 minutes (due to pump been pulled out or internal abnormality) after pump inserted to BeneFusion DS5 Infusion Supervision System and communicated successfully with the system (no pump serial number conflict or version number compatible), or the pump and CIMS are communicated successfully over Wi-Fi, the network communication is abnormally interrupted for 3 minutes. After the alarm is triggered, infusion of the pump will not be influenced, and the pump continues infusion. | Press  or insert the pump to BeneFusion DS5 Infusion Supervision System, or restore the communication between the pump and CIMS. |

| Alarm Information | Alarm Level | Reason | Countermeasure |
|-------------------------------|-------------|--|--|
| [KVO Running] | Low | The alarm is triggered after [VTBI Complete] alarm is triggered and in KVO mode. | 1. Press  to stop infusion and cancel alarm. 2. Or the [KVO Finish] alarm is triggered when reach the KVO infusion time. |
| [Infusion interrupted] | Low | The alarm is triggered after any of the [Occlusion], [Air in line], [Accumulate air], [Door opened], [No Battery] or [Drop error] alarm is cancelled. | Press  or  to cancel alarm. |
| [Please reset time] | Low | RTC time is reset when the pump is on. | Reset the time or press  to cancel alarm. |
| [Para.Unconfirmed] | Low | The alarm is triggered if no operation is performed within 10s under the parameters setting status. | Press any key to cancel alarm. |
| [No Battery Inserted] | Low | No battery inserted or battery disengaged. | Correctly insert the battery. |
| [Pump serial number conflict] | Low | After inserted to BeneFusion DS5 Infusion Supervision System, the pump has the same serial number with other pump. The alarm is triggered by pumps with the conflicting serial number. | 1. Modify pump serial number and ensure different serial numbers in BeneFusion DS5 Infusion Supervision System. 2. Pull out the pumps with the conflicting serial number. |

NOTE

- All alarm sounds can be paused by pressing , except for the circumstance of [No Battery].

D Symbols and Terms

D.1 List of Units

| Abbreviation | Meaning |
|--------------|------------------------|
| A | ampere |
| °C | centigrade |
| cm | centimeter |
| dB | decibel |
| g | gram |
| h | hour |
| Hz | hertz |
| inch | inch |
| k | kilo |
| kg | kilogram |
| kPa | kilopascal |
| l | litre |
| lb | pound |
| m | meter |
| mg | milligrams |
| min | minute |
| ml | milliliter |
| mm | millimeters |
| mmHg | millimeters of mercury |
| s | second |
| µg | Microgram |
| V | volt |
| VA | volt ampere |
| W | watt |

D.2 List of Symbols

| Symbols | Meaning |
|---------|--------------------------|
| - | minus |
| % | percent |
| / | Per; divide; or |
| ~ | to |
| ^ | power |
| + | plus |
| = | equal to |
| < | less than |
| > | greater than |
| ≤ | less than or equal to |
| ≥ | greater than or equal to |
| ± | plus or minus |
| × | multiply |
| © | copyright |

D.3 List of Terms

| Abbreviation | Meaning |
|--------------|---|
| AC | Alternating current |
| Anti-Bolus | Anti-Bolus |
| BOLUS | Bolus |
| CCU(CICU) | Cardiac Intensive Care Unit |
| CE | Conformité Européenne |
| CISPR | International Special Committee on Radio Interference |
| CPU | Central processing unit |
| DC | Direct current |
| DHCP | Dynamic Host Configuration Protocol |
| DPS | Dynamic Pressure System |
| ECU(EICU) | Emergency Intensive Care Unit |

| Abbreviation | Meaning |
|--------------|--|
| EEC | European Economic Community |
| EMC | Electromagnetic compatibility |
| EMI | Electromagnetic interference |
| EtO | C ₂ H ₄ O |
| ICU | Intensive Care Unit |
| ID | Identification |
| IEC | International Electrotechnical Commission |
| IEEE | Institute of Electrical and Electronic Engineers |
| ISO | International organization for Standardization |
| KVO | Keep vein open |
| LED | Light emitting diode |
| Max | Maximum |
| MDD | Medical Device Directive |
| Min | Minimum |
| MRI | Magnetic resonance imaging |
| N/A | Not applied |
| NICU | Newborn Intensive Care Unit |
| OR | Operating room |
| SN | Series Number |
| TIVA | Total Intra Venous Anesthesia |
| VTBI | Volume To Be Infused |

D.4 List of Unit Conversion

| Unit Symbols | Unit Conversion |
|--------------|-----------------------------------|
| kPa | 1kPa=7.5mmHg=0.145psi=0.01bar |
| psi | 1psi=51.724mmHg=6.897kPa=0.069bar |
| bar | 1bar=750mmHg=14.5psi=100kPa |
| lb | 1 lb=0.454kg |
| gtt/min | gtt/min= (ml/hxdrip)/60 |

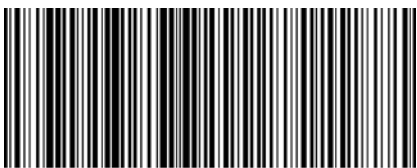
E Toxic and Hazardous Substances or Elements

| Name of the Parts | | Pb Pb | Hg Hg | Cd Cd | Cr(VI) Cr(VI) | PBB PBB | PBDE PBDE |
|-------------------|---|----------|----------|----------|------------------|------------|--------------|
| Device housing | Front housing | ○ | ○ | ○ | ○ | ○ | ○ |
| | Back housing | ○ | ○ | ○ | ○ | ○ | ○ |
| | Keys | ○ | ○ | ○ | ○ | ○ | ○ |
| | Facing | ○ | ○ | ○ | ○ | ○ | ○ |
| | Labels | ○ | ○ | ○ | ○ | ○ | ○ |
| Display | Display | ○ | ○ | ○ | ○ | ○ | ○ |
| Host | Host hardware | ○ | ○ | ○ | ○ | ○ | ○ |
| | Internal cables | ○ | ○ | ○ | ○ | ○ | ○ |
| | PCBA | ○ | ○ | ○ | ○ | ○ | ○ |
| Packaging | Cartons (K=K crimp paper) | ○ | ○ | ○ | ○ | ○ | ○ |
| | Foam packages (EPE) | ○ | ○ | ○ | ○ | ○ | ○ |
| | Plastic bag (PE) | ○ | ○ | ○ | ○ | ○ | ○ |
| General | Connecting pieces | ○ | ○ | ○ | ○ | ○ | ○ |
| | Power cord | ○ | ○ | ○ | ○ | ○ | ○ |
| Battery | Battery | ○ | ○ | ○ | ○ | ○ | ○ |
| Accessories | Accessories | ○ | ○ | ○ | ○ | ○ | ○ |
| Remark | <p>○: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in Directive 2011/65/EU.</p> <p>×: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in Directive 2011/65/EU.</p> | | | | | | |

F Declaration of Conformity

| | | |
|---|---|-----------|
| Declaration of Conformity V3.0 | | CE |
| Declaration of Conformity | | |
| Manufacturer: | Shenzhen Mindray Scientific Co., Ltd. 6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District, Shenzhen, P. R. China | |
| EC-Representative: | Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany | |
| Product: | Infusion Pump | |
| Model: | BeneFusion VP5, BeneFusion VP5 Ex, BeneFusion VP5 Neo | |
| <p>We herewith declare that the above mentioned products meet the provisions of the Council Directive 2014/53/EU concerning radio equipment. All supporting documentations are retained under the premises of the manufacturer.</p> | | |
| Standards Applied: | | |
| <input checked="" type="checkbox"/> EN 60601-1:2006/A1:2013 | <input checked="" type="checkbox"/> EN 60601-1-2:2007/AC:2010 | |
| <input checked="" type="checkbox"/> EN 62311 :2008 | <input checked="" type="checkbox"/> ETSI EN 301 489-1 V2.1.1:2017-02 | |
| <input checked="" type="checkbox"/> ETSI EN 301 489-17 V3.1.1:2017-02 | <input checked="" type="checkbox"/> EN 300 328 V2.1.1:2016-11 | |
| <input checked="" type="checkbox"/> EN60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013 | | |
| Start of CE-Marking: | 2017-5-18 | |
| Place, Date of Issue: | Shenzhen 2018.1.25 | |
| Signature: | <i>Bai Yanhong</i> | |
| Name of Authorized Signatory: | Bai Yanhong | |
| Position Held in Company: | Manager, Technical Regulation | |

P/N: 046-013877-00 (1.0)



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