BeneFusion VP3

(This manual is also applicable to BeneFusion VP3 Ex Infusion Pump)

Infusion Pump

Operator’s Manual

CE 0123

For this Operator’s Manual, the issue date is 2017-05.

Version: 3.0

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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.

Contents

1 Safety

1.1 Safety Information

The safety statements presented in this chapter refer to basic safety information that the operator must pay attention to and abide by when using the infusion pump. There are additional safety statements in other chapters or sections, which may be the same as or similar to the following, or specific to particular operations.

⚠Dangers

- **Indicates an imminent hazard that, if not avoided, could result in death, serious injury or damage to product/property.**

⚠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 Dangers

This Manual does not contain any information at the "Danger" level.

1.1.2 WARNING

⚠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.**
- **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 set 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 drug to be infused into the patient, so appropriate measures should be taken.**
- **The pump should not be placed more than 100 cm 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 is used with infusion sets recommended by manufacturers (please refer to** *6.10 Recommended Infusion Sets List* **for specific brands). When use of non-recommended infusion sets, please make sure to confirm relevant infusion performance (such as accuracy, bubble and pressure) on infusion pump, and contact the company for calibration service, the infusion sets can only be used after confirmation, otherwise SK Medical is not responsible for infusion performance (such as accuracy, 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.**
- **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.**

1.1.3 CAUTION

⚠CAUTION

- **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 installation of the infusion set and before infusion, check for leakages. If any are found, they should be rectified as soon as possible.**
- **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 36 hours to guarantee accuracy. For infusion sets of other brand, 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 4-8 hours after infusion begins to guarantee accuracy.**
- **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.**
- **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.**

1.1.4 NOTE

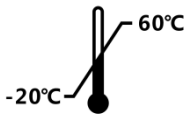
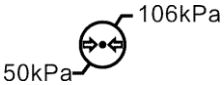
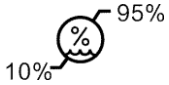
NOTE

- **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 of the equipment is developed according to the software development demands of IEC60601-1 standard, which can minimize the possibility of the risk caused by program error.**
- **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 DB9 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

The equipment you purchased may not provide you with all the following symbols.

	NOTE ! Refer to the accompanying document (This Manual)		ON/OFF
	Alternating current power supply (AC)		Battery
	Alarms		AUDIO PAUSED
	Clear/Back		Start
	Bolus	OK	Confirm
	Stop		Menu
	Move up/Increase		Move down/Decrease
	Move left		Move right
	Infusion set		Selected drug
	Caution		Lock
	Wireless modules work in order		Wireless transceiver
	DB9 interface		Night mode
	Drop sensor interface		Protected against defibrillation CF applied parts
	Date of manufacture		Manufacturer
	This side up		Keep away from rain
	Fragile, handle with care		Stacking limit by number

	Electronic equipment: dispose of separately to avoid polluting the environment		Serial number
	The European Union Representative Office		CE mark
IP34	Protected against solid foreign objects with a diameter no less than 2.5mm and protected against spraying liquid water		Environmentally-friendly use periods of electronic products (20 years)
	Recycle		Package shall be kept between -20 – 60°C during transport
	Package shall be kept between 50–106 kPa during transport		Package shall be kept between 10%–95% humidity during transport

2 Overview

2.1 Description

2.1.1 Indications for 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 Infusion Pump is suitable for adults, children and newborns in clinical departments.

This 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

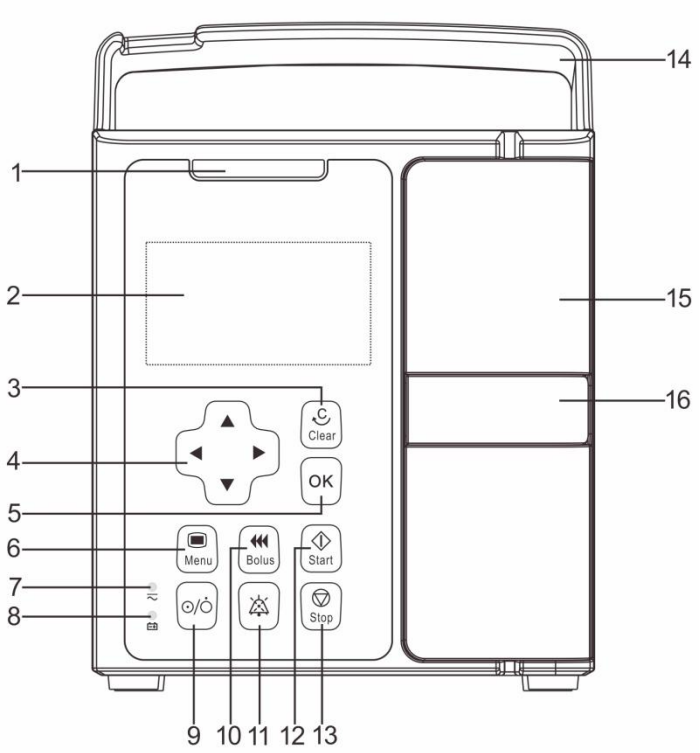
2.1.3 Appearance, Parts and Features

The Infusion Pump primarily consists of a housing and built-in battery. 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 drop sensor and wireless module are optional. Optional functions of the software comprise Rate Mode, Time Mode, Body Weight Mode, Sequential Mode, Drug Library, History Record, and Anti-bolus function.

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

The alarm light indicates different alarm levels in different colors and flash frequencies, please refer to ***Chapter 8 Alarms*** for details.

2. Display

Used for displaying infusion parameters and relevant content.

3. <**CLEAR/BACK**>

- Under non-setting status, indicate to return to the previous menu or operation.
- Under the setting status, indicate to clear the current set or cancel the edit.

4. <**DIRECTION**>

Used for adjusting value, change lines and pages.

5. <**OK**>

Used for confirming input operation and saving values.

6. <**MENU**>

- Under non-operation status, used for switching [**Main Menu**] interface and other interfaces.
- Under operation status, press and hold this key to lock; in locked state, press and hold to unlock.

7. AC/DC indicator light

- On: The pump is connected to an AC/DC power supply (including shutdown).
- Off: The pump is not connected to an AC/DC power supply.

8. Battery indicator

- Steady green indicates that the battery is charging.
- Flashing indicates that the battery is providing power.
- Light off indicates that there is no battery or the equipment is turned off and not connected to an AC power supply.

9. <**POWER**>

- Used for turning power on, entering in standby state and turning off operations.
- When power off, press and hold (>3 s) the key.

10. <**BOLUS**>

- During infusion, press this key to enter the Bolus settings screen.
- When the pump is stopped, press this key to enter the Purge prompt screen.

11. <**AUDIO PAUSED**>

Pauses alarm sound.

12. <**START**>

After installing the infusion set correctly and completing setting infusion parameters, press this key to start the infusion.

13. <**STOP**>

During infusion, press this key to stop infusion. Infusion stops caused by alarms, such as occlusion and so on, press this key to cancel the alarm.

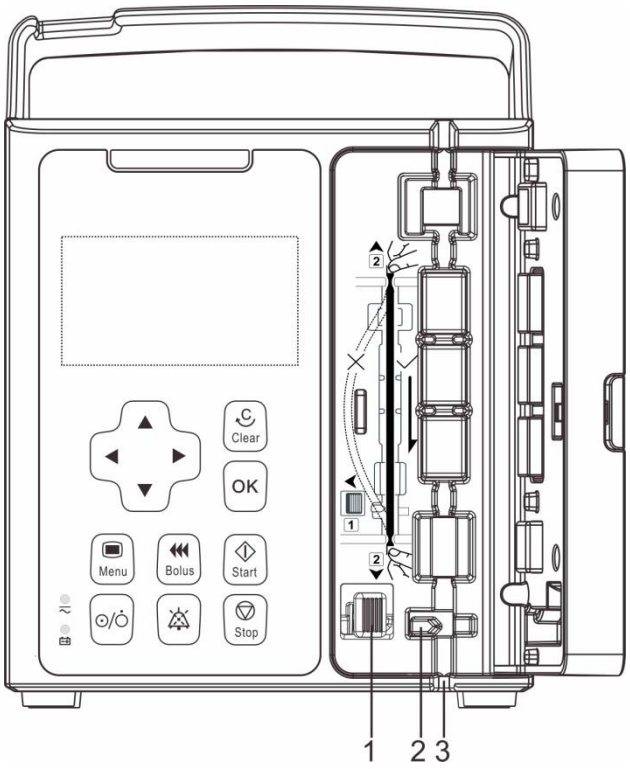
14. Handle

15. Door

16. Door holder

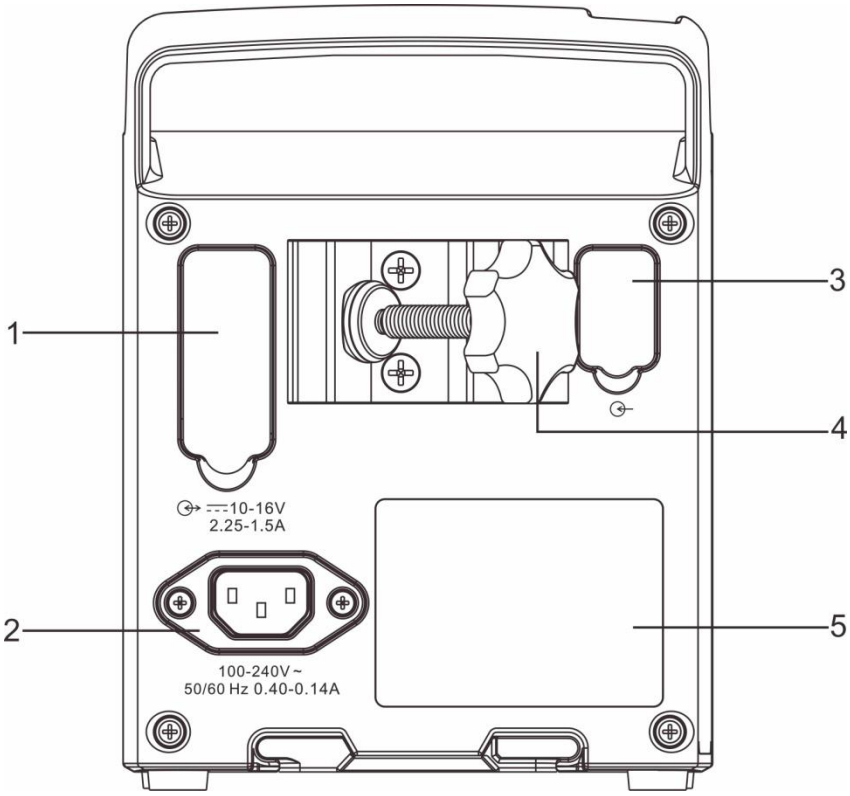
Pull it to open the door.

2.2.2 Front View with the Door Opened



1. Liquid check clip button
2. Liquid check clip
3. Infusion set slot

2.2.3 Rear View



1. DB9 interface, which combines the following interface functions:
- DC power input interface
- RS232 interface
- Nurse call interface

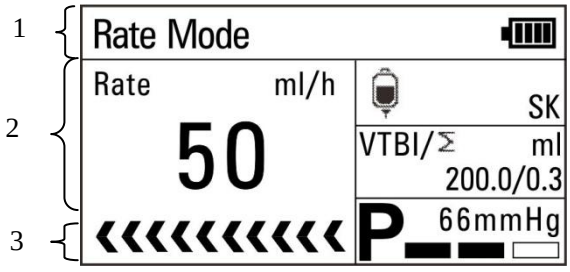
2. Alternating current power supply (AC) port

Connected by three-core-type power cord and AC power source.

3. Drop sensor interface
4. Pole clamp
5. Product label

2.3 Screen Display

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



1. Title bar

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

2. Parameter area

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

3. Prompt bar

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

-  The icon indicates normal running. Arrows move from right to left, and the running speed increases as the rate is increased.
-  Motor stops caused by alarms during infusion, no icon.

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 blue. Press ▼ or ▲ to move cursor up and down and confirm the location. Press OK to select the option or data value for further operation.

Note: Press ▼ or ▲ to "locate" cursor; press OK 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.**

NOTE

- **This equipment is in accordance with the EN 1789:2007+A1:2010 standard. It can be fixed on cross bar (square cross bar: 10 x 25 mm) or vertical bar (round vertical bar with diameter size of 15-38mm) of ambulance with advanced pole clamp. Please refer to** *3.1.3.2 Advanced Pole Clamp (Optional)* **for detailed operation of advanced pole clamp.**

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.

Please carefully remove the equipment and its accessories from the packaging in a correct manner, and inspect them against the packing list. Examine the equipment for any mechanical damage and ensure that the box includes all items on the packing list. Please contact the company if you have any queries.

NOTE

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

⚠WARNING

- **They must be kept out of the reach of children.The packaging materials 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.**

3.1.2 Operating Conditions

The operating environment of this infusion pump must meet the requirements in ***A.1.2 Operating Environment***, and in accordance with the emergency medical care requirements of medical equipment short-time operation of the valid version of the IEC60601-1-12 system.

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.

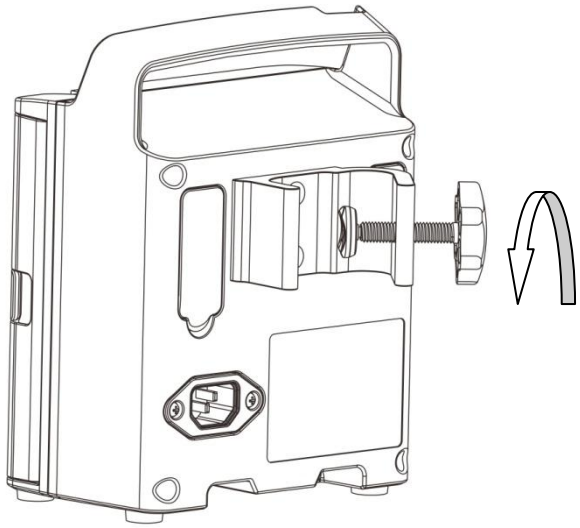
When the pump is transferred from one place to another, differences in temperature and humidity can cause condensation to form inside the pump. If this occurs, do not switch the pump to the "ON" state until the condensation has gone.

⚠WARNING

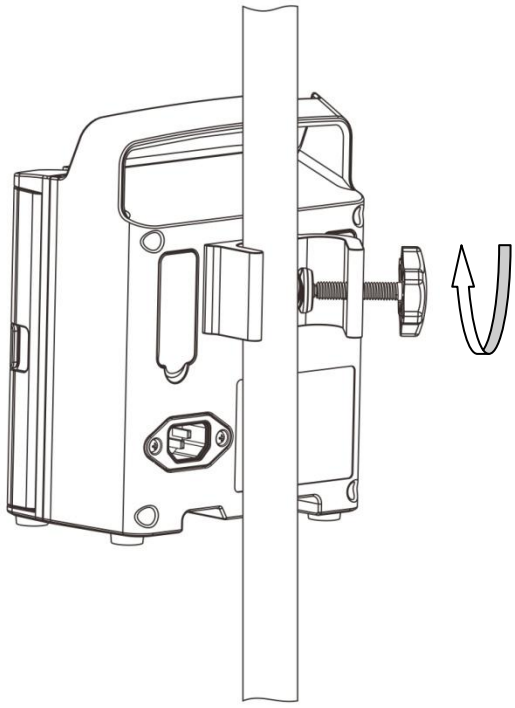
- **Please use only when the operating environment meets the requirements specified above. Otherwise, the pump's performance will not match the technical specifications in** *A Product Specifications***. Device failure and other unexpected consequences may also result.**

3.1.3 Mount the Clamp

3.1.3.1 Standard Pole Clamp



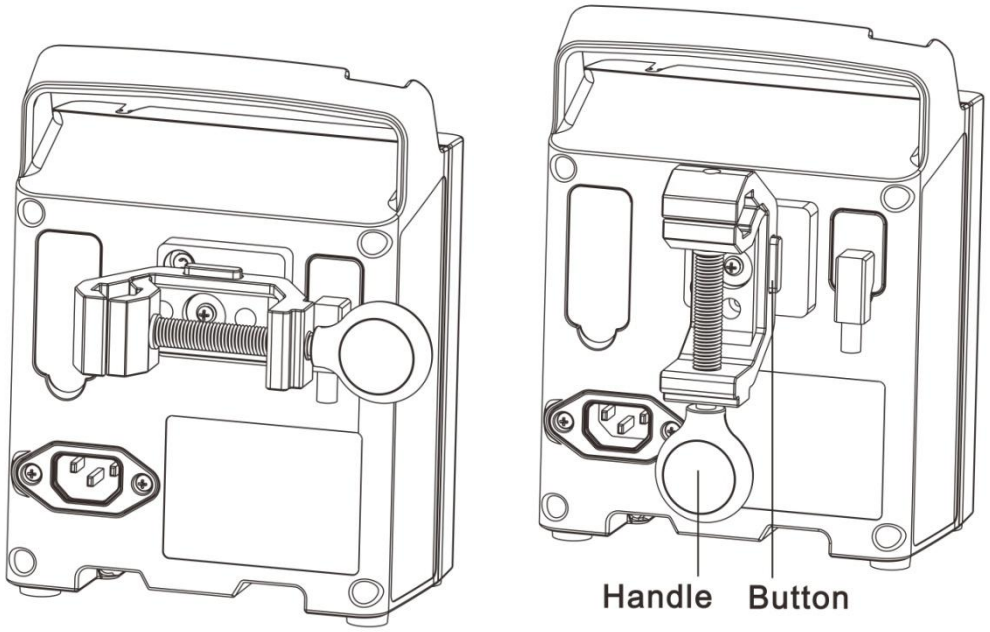
1. Turn counterclockwise to loosen the pole clamp until an IV stand can be inserted in.



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

3.1.3.2 Advanced Pole Clamp (Optional)

Press the button of pole clamp, horizontally or vertically adjust pole clamp, the button will pop-up after loosening the pole clamp. Turn the handle, pump can be fixed to cross bar (square cross bar: 10 x 25 mm) or vertical bar (round vertical bar with diameter size of 15-38mm).



3.1.4 Fix BeneFusion DS3 Infusion Supervision System (Optional)

NOTE

- **All components of the system are suitable for use in patient environment.**
- **Removing power cord is to disconnect equipment from power supply. Please ensure suitable clearance around the System to facilitate connect and remove power cord.**
- **System assembly and refit 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.**
- **Please ensure not simultaneously touch patient and device to prevent patient leakage current from exceeding the requirements specified by the standard.**
- **Only devices designated by the manufacturer can be connected to the system. Infusion pumps can only be installed to cross bar, syringe pumps can only be installed to vertical bar. Based on patient safety, do not insert devices that are not specified by the manufacturer into the system.**

3.1.4.1 Mount the Clamp and Fix Hanging Tower

BeneFusion DS3 Infusion Supervision System can be fixed to vertical bar of infusion support or hanging tower by standard or advanced pole clamp, please refer to ***3.1.3 Mount the Clamp*** for detailed operation. Please refer to ***3.1.4.3 Steps for Fixing Infusion Pump and Syringe Pump to BeneFusion DS3 Infusion Supervision System*** for detailed operation of inserting a pump.

NOTE

- **When BeneFusion DS3 Infusion Supervision System is fixed on infusion support / hanging tower, please ensure three pole clamps are fixed to the vertical bar of infusion support / hanging tower.**
- **Please take infusion bottle (bag) of pump / infusion support and pump out of BeneFusion DS3 Infusion Supervision System before carrying, which shall be carried separately, failure to adhere to these requirements will result in the system unbalance.**
- **Based on the requirements of IEC60601-1 standard, infusion support or hanging tower for fixing BeneFusion DS3 Infusion Supervision System shall bear 64kg at least, also nominal load bearing of 16kg, please ensure the bearing capacity of infusion support or hanging tower in accordance with the specified IEC60601-1 standard.**

3.1.4.2 Fix the Cart

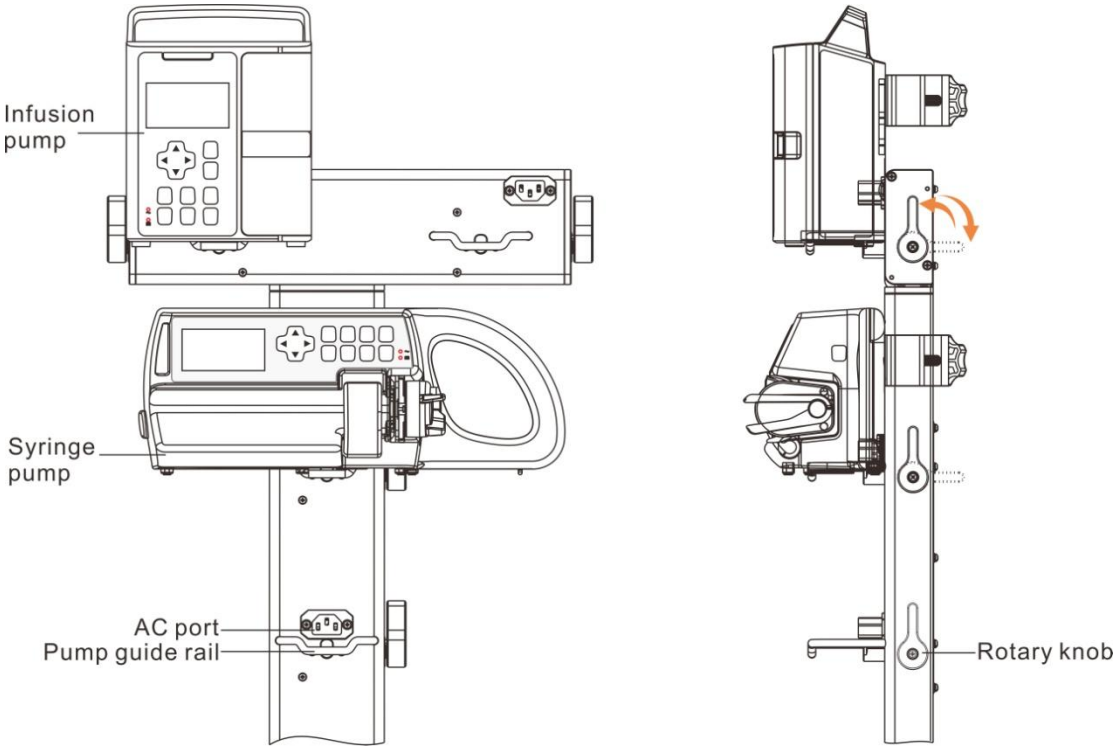
BeneFusion DS3 Infusion Supervision System (with cart) can be used directly after pumps are inserted. Please refer to ***3.1.4.3 Steps for Fixing Infusion Pump and Syringe Pump to BeneFusion DS3 Infusion Supervision System*** for detailed operation of inserting a pump.

NOTE

- **The maximum load of infusion pole is 2 kg.**
- **This system must be placed on an even surface for use.**
- **Please take infusion bottle (bag) of pump / infusion support and pump out of the cart before carrying, which shall be carried separately, failure to adhere to these requirements will result in the system unbalance**
- **Please install and carry the system and its components in an appropriate fashion to avoid dropping of the pump collision or severe shock or damage caused by external mechanical forces.**

3.1.4.3 Steps for Fixing Infusion Pump and Syringe Pump to BeneFusion DS3 Infusion Supervision System

Before inserting a pump, please ensure that BeneFusion DS3 Infusion Supervision System is at horizontal position, and its rotary knob is at horizontal position. The multi-channel pumps connection slot must engage in the pump guide rail of BeneFusion DS3 Infusion Supervision System, and AC port of the pump must engage in the AC port of BeneFusion DS3 Infusion Supervision System, toggle the rotary knob in direction of arrow to vertical position, then the pump is locked. To release, toggle the rotary knob in direction of arrow to horizontal position and remove the pump.



3.1.5 Connect the AC Power Source

1. Please confirm to use the original three-core-type power cord.
2. Insert one end of the power line into the AC socket on the back panel of the infusion pump.
3. Insert the other end of the power line into the matched three-plug connector connecting to the AC power.

⚠WARNING

- **The earthing wire in the three-plug connector should be grounded. The connection of the protective earthing terminal of all fixed or permanently installed medical devices and external protective earthing system should be connected and verified based on the requirements of the valid version of the IEC60601-1-12 system. 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 power socket or plug, the user should completely clean and dry the area before plugging into the power supply, or accidents or injuries may result!**

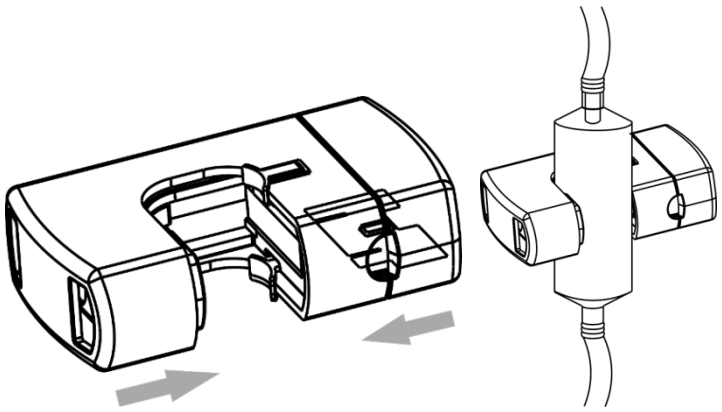
NOTE

- **Compatible power supply: 100–240 V～, 50/60 Hz.**
- **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.**

3.1.6 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 connecting port on the right side panel 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

- **For 60drop/ml infusion sets, it is recommended to set the rate <1000ml/h. Otherwise, the [Empty bottle] 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 bottle] 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 singal 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 Set Language

1. Select [**Main Menu**]→[**System Option**]→[**Language**].
2. Select [**Language**] from the [**Language**] according to actual needs.

3.2.2 Adjust Screen Contrast

1. Select [**Main Menu**]→[**System Option**]→[**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 Contrast to save the power of the battery.

3.2.3 Set Date and Time

1. Select [**Main Menu**]→[**System Option**]→[**System 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.**

3.2.4 Adjust Volume

1. Select [**Main Menu**]→[**System Option**]→[**Volume**].
2. Select [**Volume**]:1-8.1 for the lowest volume;8 for the highest volume.

3.3 Restore Factory Default

During operation, you may change some settings in some situations. However, the changes may not be appropriate or correct, especially when patient or infusion set brands are changed. Therefore, you should restore the system to the default factory settings during operation according to actual needs, to guarantee that each configuration of the infusion pump is applicable for clinical use. For some default factory settings of this equipment, please refer to ***C Default Factory Settings***.

Select [**Main Menu**]→[**System Maintenance**]→Input User Maintenance Password →[**Restore factory default**], and restore the factory default settings as prompted on screen, some parameters of General Option, System Option and System Maintenance will be restored to default values.

4 Basic Operation

4.1 Infusion Flow Chart

Turn pump on	Press  to activate and turn on the pump, the pump will run start-up checks and display the start-up screen;
Install infusion set	Please refer to ***4.2.2 Insert the Infusion Set***;
Select brand	Select according to the infusion set brand currently being used;
Select infusion mode	Select infusion mode;
Purge	Refer to ***4.2.8 Purge;***
Set infusion parameters	Refer to ***4.2.9 Set Infusion Parameters;***
Connect patient	Connect to the patient;
Start infusion	Press  ;
Finish	Press  ;
Remove infusion set	Shut down the Robert clip (or flow rate regulator), disconnect from the patient, and remove the infusion set in a correct manner;
Turn pump off	Hold down (>3 s)  , until the Power Off progress bar complete.

4.2 Operational Procedures

4.2.1 Turn on the Pump

Please turn on the device as in the following steps:

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:
   - The system will give out a sound "di" —— indicating the self-testing of the loudspeaker to be successful.
   - The color of the alarm indicator lamp will change from red to yellow, turn on and off orderly —— indicating the self-testing of the alarm lamp to be successful.
   - The system will give out a sound of "di" —— indicating the self-testing 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.**

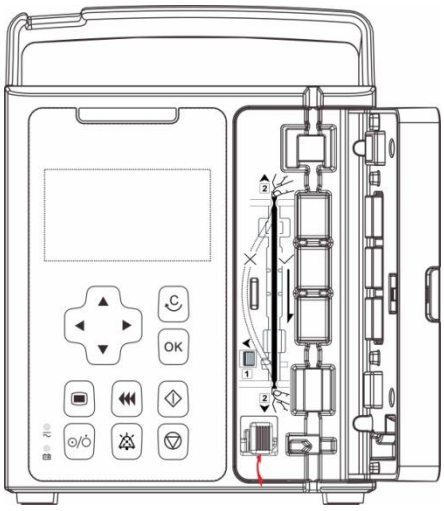
4.2.2 Insert the Infusion Set

System will inspect whether infusion set is installed after completing the self-test: If infusion set is installed, enter the [**Infusion set selection**] interface; If infusion set is not installed, enter the infusion set [**Installation Guide**] interface. If the infusion set is not required to install, please press 

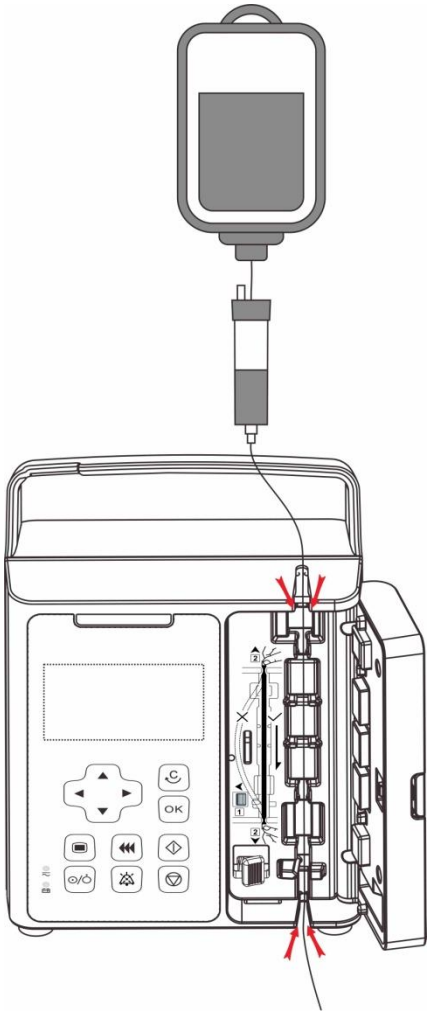
to skip the step.

Install infusion set according to the following method:

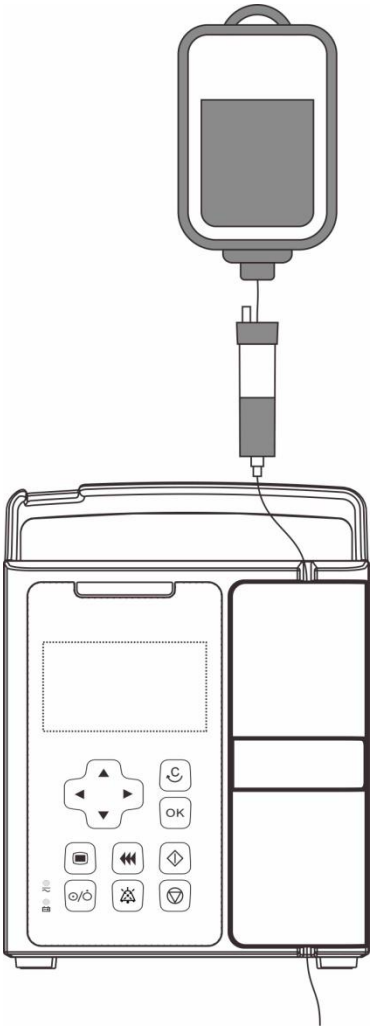
1. Pull the door holder and open the door.



2. Pull the liquid check clip button upward left, and open the liquid check clip.



3. Straighten the infusion set, align the central tube seat, put it in flatly, and install the infusion set as shown in the figure.



4. Close the door, the interface will enter [**Infusion set selection**] interface, indicating that the infusion set is installed correctly; otherwise, it needs to be reinstalled.

⚠WARNING

- **The infusion set should be firmly inserted 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 installed correctly.**

4.2.3 Change the Infusion Set

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 Stop to stop the pump.
2. Pull the door holder, open the door, pull the liquid check clip button upward left, and take out the installed infusion set.
3. Please refer to ***4.2.2 Insert the Infusion Set*** to reinstall 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 Stop to stop the pump.
2. Take out the installed infusion bottle (bag), and reinstall it.

4.2.5 Select Infusion Set Brand

On the [**Infusion set selection**] screen, press ▲ ▼ to select the infusion set brand, and press OK for confirmation. Specific brand, please refer to ***6.10 Common Infusion Set Brands***.

⚠CAUTION

- **Please confirm that the current selected brand is the same as the brand actually used.**

4.2.6 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**]→[**General Option**]→[**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**]. On this interface, users can press   and 

to select mode. Please refer to ***Chapter 5 Infusion Mode*** for detailed introduction of each infusion mode.

4.2.8 Purge

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 set should be eliminated before the infusion.

On infusion parameters setting interface, press 

to enter [**Purge**] prompt screen. Hold down 

to enter [**Purge**] running screen, release 

after the air bubbles are purged.

⚠WARNING

- **During the purge, please disconnect the pump from the patient. Otherwise, the patient will be in serious danger!**

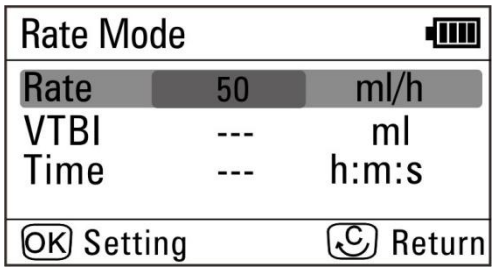
NOTE

- **Purge rate can not be changed.**
- **[Air in line] alarm will not be triggered during purge.**

4.2.9 Set Infusion Parameters

Under each infusion mode, the users should master the following basic function of the keys:

- ▲ ▼: Under the non-setting status, move the cursor up and down; Under the setting status, indicate to increase/decrease the data value.
- ◄ ►: Under the non-setting status, move the cursor to the right and left; Under the setting status, indicate to increase/decrease the editing space.
- OK: Indicate to confirm the current selection or settings.
- Clear: Under the non-setting status, indicate to return to the previous menu; Under the setting status, indicate to clear the current set or cancel the edit.



As shown above, the procedure for setting the parameter values is as follows:

Step 1: Press ▲ or ▼ to move the cursor up or down and select the parameter that requires setting;

Step 2: Press OK to enable the currently selected parameter by using the cursor for making adjustments;

Step 3: Depending on the preset parameter value, press ◄ or ► to select the editing space;

Step 4: After confirming the editing space, press ▼ or ▲ again to increase or decrease the relevant value;

Step 5: Repeat step 3 and step 4 until finishing all value settings, and press OK for confirmation after completing both steps. The settings are now complete.

The parameter value should not exceed the parameter range defined by this equipment, please refer to ***Chapter 5 Infusion Mode*** for each parameter range, otherwise, the parameter value will be modified automatically to the maximum value defined when the setting exceeds the maximum value set, press ▼ again at the

original space or top of the digit to restore the original value. For example, if the maximum parameter value is 2000, while the current value is 1500, once the user presses  at the thousands digit, the value will be changed automatically to 2000, press  again at the thousand digit to recover to 1500. When the parameter reaches the maximum value, press  at any digits, the value will not change, and the prompt bar displays [**Value Reached Limit**].

4.2.10 Infusion

When ready, connect the infusion set to the patient. Press 

to start the infusion, and the screen will display the running icon, the arrows will move from right to left, and the running speed will increase, which will indicate that the rate will also increase.

⚠WARNING

- **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 solution 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 Bolus to enter [**Bolus**] settings screen. There are two ways to start the bolus:

- Manual Bolus: Set bolus parameters, press and hold Bolus to manual bolus, and release to return to the original rate.
- Auto Bolus: Set bolus parameters, press ◄ to auto bolus.

NOTE

- **If the maximum rate ≤800ml/h, the previous bolus rate ≤current rate <maximum rate, bolus rate is the maximum rate.**
- **If the maximum rate >800ml/h, the previous bolus rate ≤current rate : current rate <800ml/h, bolus rate is 800ml/h ; current rate ≥800ml/h, bolus rate is the maximum rate.**
- **If no operation is performed within 2 minutes, the infusion pump will automatically exit the Bolus Settings screen and the procedure must be repeated.**
- **[VTBI Near Done] alarm will not be triggered during bolus.**
- **Occlusion pressure will automatically switch to "High" level when bolus, patient's clinical condition and working condition of the infusion pump must be monitored carefully.**

4.2.13 Change the Rate during Operation

In any run screen in the infusion mode, press OK, ▲, ▼, ◄ or ► to change the value of the [**Rate**] into the adjustable state, thus to set the expected rate, press OK or Start 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 rate check**] is on, the [**Empty bottle**] alarm will be triggered; if drop sensor is not installed, the [**Air in line**] 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 [**VTBI Near Done**] 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 Done**] 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-operation status, tap (<3 s)  to enter [**Standby**] interface, default display the previous standby time, press  to modify standby time (range is 00:01-99:59 hh:mm), press  for confirmation after modifying. 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  to confirm quit, and the screen will enter to the interface before standby appears. Press  to remain in standby status.

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 (>3 s)  , until the Power Off progress bar complete, and the power will turn off.

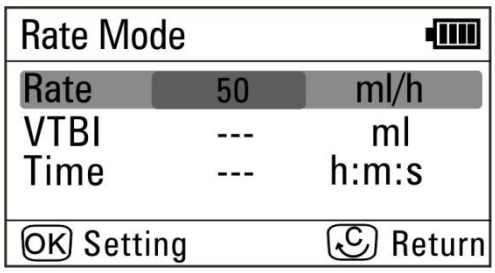
NOTE

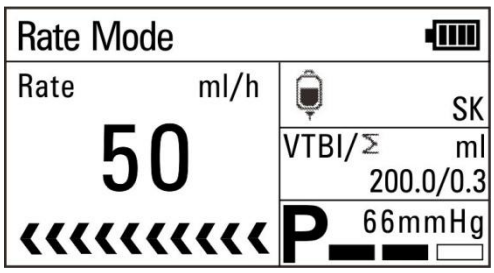
- **When powering off normally, the current operating data and saved data will be autosaved.**

5 Infusion Mode

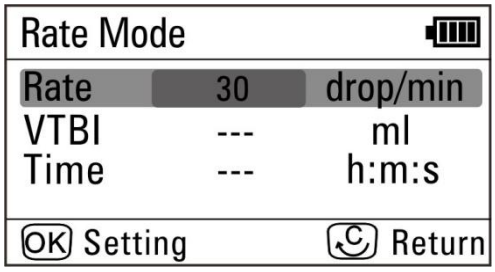
5.1 Rate Mode

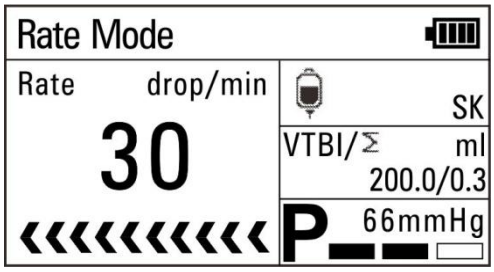
- Unit of Rate (ml/h)





- Unit of Rate (drop/min)

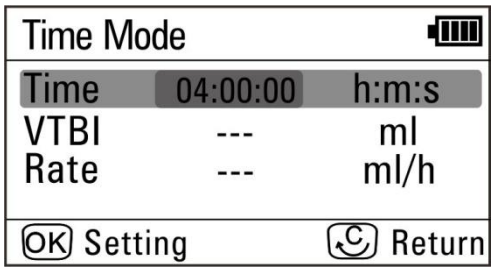


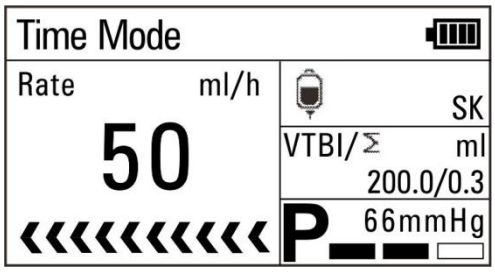


Mode	Parameters	Parameter Range
Rate Mode	Rate	Unit of Rate (ml/h): 0.1-1500ml/h
		Unit of Rate (drop/min): 1-(400 ml/h *drip/60)
	VTBI	0.1-9999ml
	Time	00:00:01-99:59:59 h:m:s Set [**Rate**] and [**VTBI**], then calculate [**Time**] automatically; Set [**Rate**] and [**VTBI**], modify [**Time**], and the [**VTBI**] will not change and will automatically calculate [**Rate**].
Unit of “drop/min” setting: Select [**Main Menu**]→[**General Option**]→[**Drip setting**], select [**drop/min**]→[**On**], and set the “drip”. If [**Off**] is selected, “ml/h” and “drop/min” can not be switched, the default unit of rate is ml/h.		

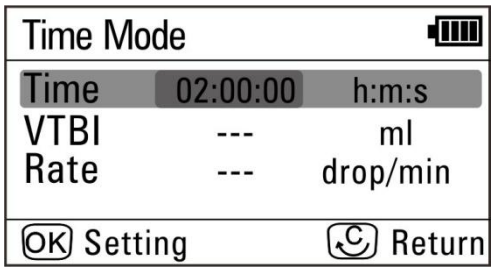
5.2 Time Mode

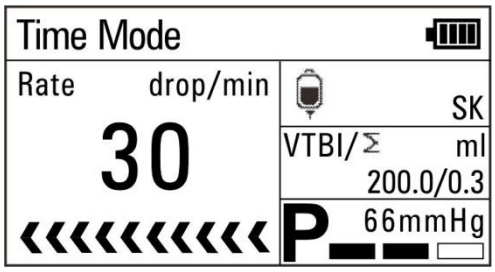
- Unit of Rate (ml/h)





- Unit of Rate (drop/min)



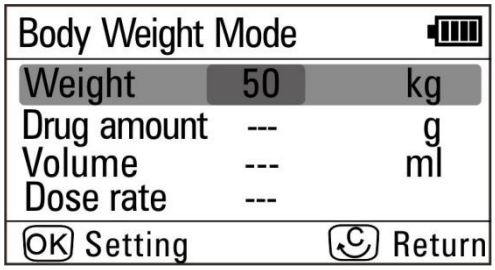


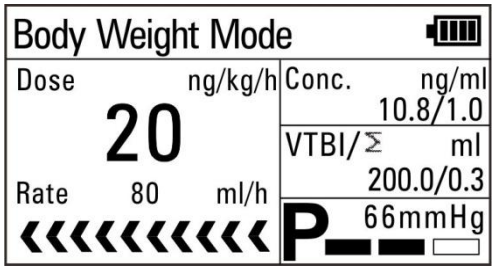
Mode	Parameters	Parameter Range
Time Mode	Time	00:00:01-99:59:59 h:m:s
	VTBI	0.1-9999ml
	Rate	Same as Rate Mode Set [**Time**] and [**VTBI**], then calculate [**Rate**] automatically; Set [**Time**] and [**VTBI**], modify [**Rate**], and the [**VTBI**] will not change and will automatically calculate [**Time**].

5.3 Body Weight (BW) Mode

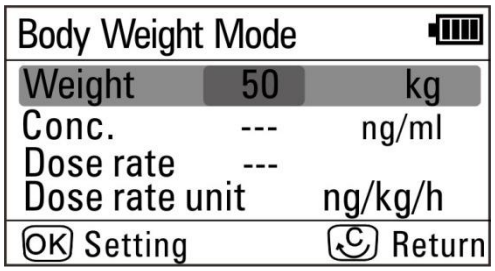
1. Select [**Main Menu**]→[**General Option**]→[**BW Mode**].
2. Select [**BW Mode**] configuration: Standard or Simple.
3. Press Menu to enter [**Main Menu**], then select [**Body Weight Mode**].

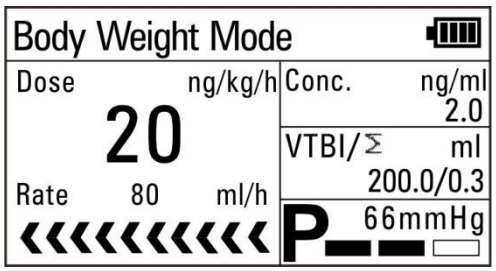
Standard Body Weight Mode:





Simple Body Weight Mode:





Mode	Parameters	Parameter Range
Body Weight (BW) Mode	Weight	0.1-300.0 kg/0.2-660.8 lb
	Drug amount	0.1-999.9
	Drug amount unit	g/mg/μg/ng/IU
	Volume	0.1-9999ml
	Conc.	0.1-100
	Conc. unit	g/ml, mg/ml, μg/ml, ng/ml, IU/ml
	Dose rate	0.1-999.9
	Dose rate unit	ng/kg/h, μg/kg/h, mg/kg/h, IU/kg/h, IU/kg/min, μg/kg/min , mg/kg/min, ng/kg/min
	Rate	0.1-1500ml/h
	VTBI	0.1-9999ml

NOTE:

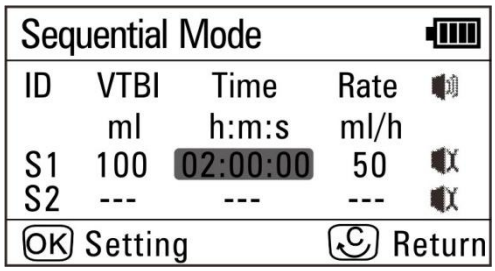
1. [**Conc.**] will be automatically calculated according to the formula *(Drug amount/Volume*).
2. [**Rate**] will be automatically calculated according to the formula *(Dose rate *Weight)/Conc*.

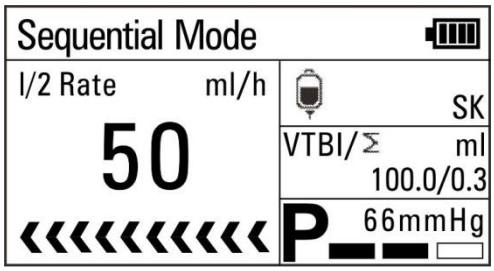
5.4 Sequential Mode

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.
- : A status sign denotes the need for a voice prompt after completing each sequence. Press OK to switch the activation state.





NOTE

- **If only set [Time] for a sequence, denoting that infusion of the sequence is stopped, and the next sequence will be started when arrived at the specific time.**
- **If only set [Time] or [VTBI] for a sequence, the infusion can not be started.**
- **If there is empty sequence between sequences, the infusion can not be started.**

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 Option**]→[**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 200 kinds of drugs available for users to select from.

1. Select [**Main Menu**]→[**General Option**]→[**Drug library**].
2. Select [**Drug library**]→[**On**]. If [**Off**] is selected, the following steps cannot be conducted.
3. In any one of the infusion mode setting interfaces, select [**Drug**]→[**Select Drug**].
4. In the [**Select Drug**] interface, press  to turn the pages to browse the whole drug list, and for further details, see ***C.5 Drug Library List***.
5. After the drug is selected, its name will appear on the Run screen.

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 Option**]→[**Occl. pressure**].
2. Occlusion pressure Degree 3, lowest at 150mmHg, and highest at 900mmHg. 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 resistence 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**]→[**General Option**]→[**Unit of pressure**].
2. Select [**Unit of pressure**]: 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 cannula 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:

- 1 solid area indicates low occlusion pressure
- 2 solid areas indicate medium occlusion pressure
- 3 solid areas indicate high occlusion pressure

6.3.4 Automatic Pressure Release Function (Anti-Bolus)

When occlusion occurs, infusion will stop and the [**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 the Air Bubble Size

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 Option**]→[**Bubble size**].
2. Select [**Bubble size**], five levels of air bubble can be selected, lowest at 50μl, and highest at 800μl. Air bubble 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 Accumulated Bubble

1. Select [**Main Menu**]→[**General Option**]→[**Accum. bubble**].
2. Select [**Accum. bubble**]: 0.1-4.0ml/h is adjustable.

6.6 Drip Setting

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

6.7 Key Lock Function

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

- Automatic Locking:

1. Select [**Main Menu**]→[**General Option**]→[**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 closing automatic locking function.

- Manual Locking: In the running interface, under the unlocking condition, press and hold 

(>3 seconds) to lock the key board.

If unlocking is needed, press and hold 

(>3 seconds) to unlock, it is automatically locked during the high-level alarm.

6.8 Reminder Function

1. Select [**Main Menu**]→[**General Option**]→[**Reminder time**].
2. Select [**Reminder time**]: Off, 1-5min. After a specific time is set, the infusion set is inserted. If no operations are performed to the pump within the set time (including operations on the keyboard, the slider and the pull handle), and the [**Reminder**] alarm will then alert the user to proceed to the next step. [**Off**] indicates closing the function.

6.9 Time Near End

1. Select [**Main Menu**]→[**General Option**]→[**Time near end**].
2. Select [**Time near end**]: Off, 1-30min (when <10min, the stair-step is 1min, and when ≥10min, the stair-step is 5min). After a specific time set, when the remaining infusion time is close to the [**Time near end**] set by the users, [**VTBI Near Done**] alarm will be triggered. [**Off**] indicates closing the function.

6.10 Common Infusion Set Brands

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

1. Select [**Main Menu**]→[**General Option**]→[**Commonly used tube**].
2. Select in [**Commonly used tube**] according to actual needs.

Note: Please ensure that at least one “Commonly used tube” to be selected.

Recommended Infusion Sets List

No.	Infusion Set Brand	Specifications and Model
1	B. Braun	Intrafix SafeSet
2	SK	ZPQ, JMB,150ml, SK-B

⚠WARNING

- **This equipment has to be used with high elastic tube. If you are not sure whether the tube is high elastic tube, please contact us for tube test.**

6.11 Bed No. Settings

1. Select [**Main Menu**]→[**System Maintenance**]→Input User Maintenance Password “4321” →[**Bed No.**].
2. Select [**Bed No.**]: 1-999. [**---**] indicates invalid values. Beds can be differentiated through setting Bed No.

6.12 View Department

The infusion pump are net-connected with BeneFusion CS5 Infusion Supervision System through the approach of wireless networking, and the system contains department information, the system will automatically distribute department information to all infusion pumps when pumps are on.

Select [**Main Menu**]→[**System Maintenance**]→Input User Maintenance Password “4321”→[**Department**] to view the department information.

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 1500 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**]→[**System Option**]→[**History Record**].
2. Select [**History Record**]: Each page can demonstrate up to 2 records, and press  to turn the pages.

7.2 Power-down Save

To prevent the loss of patient data when the infusion pump suddenly powers down, the infusion pump provides the function of the power-down data 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 [**Nurse call**] in [**System Option**], and set in the open menu:

- Switch

On: Indicates the opening of the nurse call function.

Off: Indicates the closing of the nurse call function.

- Signal type

1. 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.

2. 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

1. **Normally Close**: Select when the hospital call system is set as [**Nor. Close**].
2. **Normally Open**: Select when the hospital call system is set as [**Nor. 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 infusion pump can be configured with the wireless modules, and be net-connected with BeneFusion CS5 Infusion Supervision System through the approach of wireless networking.Through the network:

- The infusion pump sends real-time infusion parameters, drug information, alarm information, prompt information, Bed No. and other information to BeneFusion CS5 Infusion Supervision System.
- BeneFusion CS5 Infusion Supervision System and infusion pump can display synchronously. For detailed descriptions, please refer to the instructions of BeneFusion CS5 Infusion Supervision System (hereinafter called 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.

When using wireless modules to connect to the Internet while using the infusion pump, the wireless icon on the upper-right corner indicates the working condition of the wireless modules:

-  Wireless modules work in order
- No icons No wireless modules configured or connect BeneFusion CS5 Infusion Supervision System

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.**

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;
4. Export data.

7.6 WLAN Setting

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

1. Select [**Main Menu**]→ [**System Option**] → [**WLAN Setting**], then select [**On**] to enable Wi-Fi function.
2. Select [**Advanced Settings**], there are two ways to distribute IP address:

- DHCP: Check the checkbox to activate DHCP, IP address, subnet mask and gateway can not be modified, automatically obtain an IP address.
- Manually: Uncheck the DHCP checkbox, enter IP address, subnet mask and gateway.

3. Available networks shall be displayed:

- If password is required for to-be-connected network, please enter the password.
- If password is not required for to-be-connected network, you can connect the network directly.

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.**

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, mid-level alarms and low-level alarms.

8.2 Alarm Types

When an alarm is triggered, the infusion pump will use the following visual and audible methods to alert the user:

- Visible alarms
- Audible alarm
- Alarm Information

Among the visible alarms and audible alarms, the alarm information will distinguish alarm levels in different ways.

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%
Mid-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 ***D Alarm Information****:*

- Occlusion
- Air in line
- Door opened
- VTBI Done
- KVO Finish
- Battery Low
- Battery Empty
- No AC Power
- Reminder
- System Error
- VTBI Near Done
- Standby Time Expired
- System abnormal
- Tube not inserted
- Drop error
- Empty bottle
- No communication

NOTE

- **The [No Communication] 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 battery empty) and medium level alarms, press  to pause alarm sound for 2 minutes, no alarm sound is made in any case. When the alarm pause time expires, the alarm tone will sound. Press 

to cancel high level alarms (except battery empty and system error).

■ For low level alarms, press  , no alarm sound, alarm information and alarm light, until it is triggered next time.

NOTE

- **[Battery Empty] 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** *D 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. Inserting fuel cell or changing battery by personnel who has not received suitable training may cause such danger as overtemperature, fire or explode.**

The infusion pump is configured with rechargeable Lithium ion 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 left and right. 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.

The power supply by the battery can only be sustained for a limited period of time. The [**Battery Empty**] 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 three 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. 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. Switch the infusion pump over to AC power again and charge the battery incessantly for over 10 hours.
5. 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.

Note: 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, battery capactiy decreases with increase in charging and discharging times. If the maintenance and storage of the battery is appropriate, the lifespan of the Lithium ion battery is no less than 300 times of full charging and discharging. If the use of battery is improper, its lifespan shall be shortened or in failure status. We recommend replacing the lithium battery every 3 years.**
- **Please connect to the AC power source if [Battery Empty] alarm is triggered. To prevent battery not used for a long time or in battery empty status, if battery is not charging more than two months after battery is empty, battery will be in failure status. Do not charge the failure battery, and replace the failure battery.**
- **If battery will not be used for a long time, we recommend keeping the battery in a fully charged state and charging the battery every two months for lifespan guarantee. Please replace the battery if the length of its lifetime is obviously shortened during optimization.**
- **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 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%).

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: 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

- **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.**

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 operating and functioning 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**]→[**System Option**]→[**History Record**]. In the [**History Record**] interface, you can view the infusion parameters, alarm information and operation information, etc.

Select [**Main Menu**]→[**System Option**]→[**Version Information**]. In the [**Version Information**] interface, you can view the information of the version of the infusion pump system software 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
Power cord (Select PN according to sales area)	0020-20-12522 009-002755-00 009-002756-00 009-002757-00 009-002758-00 009-003358-00 009-003651-00 009-002758-00
Standard pole clamp	115-031551-00
Advanced pole clamp	115-031552-00
Nurse call cable	115-034140-00
RS-232 communication cable	115-034142-00
DC input cable	115-034144-00
Drop Sensor	115-013821-01
Floor model infusion stand	034-000321-00
Multi-channel pump stand	045-001434-00

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
IEC protection class	I
Protection against electric shock	CF Protected against defibrillation
Impurities and liquid ingress protection	IP34
Explosion protection level	Unsuitable
Operating mode	Continuous
Mobile level	Portable

NOTE:

- I: Type I devices
- CF: Class CF applied parts, can be directly used in the heart.
- IP34: Protected against solid foreign objects with a diameter no less than 2.5mm and protected against spraying water.
- Unsuitable: The device is unsuitable to be used in environments containing air mixed with flammable anesthetic gas, oxygen or nitrous oxide.
- 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.
- Portable infusion pump: Used to control the infusion of patients and are devices which can be carried by the patients continuously.

A.1.2 Operating Environment

Work environment	
Temperature	5 - 40ºC
Relative Humidity	15 - 95%, non-condensing
Atmospheric pressure	57 - 106 kPa
Storage environment	
Temperature	-20 - 60 ºC
Relative Humidity	10 – 95%, non-condensing
Atmospheric pressure	50 –106 kPa
Storage conditions	Corrosive-free and ventilated indoors
AC Power Supply	
Voltage	100 - 240 V～
Frequency	50/60 Hz
Current	0.40-0.14A
Fuse	Low interrupting rating, T1A 250 V～
External DC power supply	
Voltage	DC 10V-16V
Current	2.25-1.5A

A.2 Physical Specifications

Components	**Weight**	**Size**	**Remark**
Host	Less than 1.8 kg (Without pole clamp)	Less than 150 x 90 x 200 (mm) (length × width × height) (Without pole clamp)	Battery included.

A.3 Hardware Specifications

A.3.1 Display

Display	
Type	Monochrome LCD
Size (diagonal)	3 inches
Differentiation	240 x 128 pixels

A.3.2 Battery

Internal battery	
No. of batteries	1 (standard) or 2 (optional)
Battery type	Li-Ion ion battery
Shutdown delay	At least 30 mins (new battery, after the first low battery alarm)
Rated battery voltage	7.4 VDC
Battery capacity	2600 mAh (1 battery) or 5200 mAh (2 batteries)
Power supply time	Continuously operate at a rate of 25 ml/h, discharge for at least 4h (1 battery) or 8h (2 batteries) using a fully charged new battery. Continuously operate at the maximum selectable rate, discharge for at least 2h (1 battery) or 4h (2 batteries) using a fully charged new battery.
Charging time	When the pump is off, the charging time is not longer than 6h (1 battery) or 12h (2 batteries).

A.3.3 Host LED

Host LED	
Alarm light	1 (two colors: red and yellow)
AC/DC indicator light	1 (green)
Battery indicator light	1 (green)

A.3.4 Auditory Indicator

Speaker	Produce an alarm, the sound pressure is 55 - 80 dB(A) and key beep; Support multi-level volume functions; The alarm sound meets the requirements of the IEC60601-1-8 standard.

A.3.5 External Ports

Ports	
AC power supply port	1 AC power supply port
DB9 interface	1 DB9 interface, which combines the following interface functions: ■ DC power input interface ■ RS232 interface ■ Nurse call interface
Drop sensor interface	1 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	>1500 VAC
Action mode	Normally open or normally closed (optional)

A.4 BeneFusion DS3 Infusion Supervision System Specifications (Optional)

A.4.1 Safety Specifications

Safety	
IEC protection class	I
Liquid ingress protection	IP21
Protection against electric shock	CF Protected against defibrillation

NOTE:

- I: Type I devices
- CF: Class CF applied parts, can be directly used in the heart.
- IP21: Protected against solid foreign objects with a diameter no less than 12.5mm and protected against dripping water falling vertically

A.4.2 Operating Environment

Work environment	
Temperature	0 - 40ºC
Relative Humidity	15 - 95%, non-condensing
Atmospheric pressure	57 - 106 kPa
Storage environment	
Temperature	-40 - 70 ºC
Relative Humidity	10–95%, non-condensing
Atmospheric pressure	50–106 kPa
AC Power Supply	
Voltage	100 - 240 V～
Frequency	50/60 Hz
Current	2.40 - 0.84A
Fuse	F5AL250V

A.4.3 Hardware Specifications

BeneFusion DS3 Infusion Supervision System (2-Channel syringe pumps+ 4-Channel infusion pumps)	
Size	Less than 400mm x 180mm x 730mm (length × width × height)
Weight	Less than 5.5kg (without pole clamp)
BeneFusion DS3 Infusion Supervision System (4-Channel syringe pumps+ 2-Channel infusion pumps)	
Size	Less than 400mm x 180mm x 770mm (length × width × height)
Weight	Less than 4.5kg (without pole clamp)
BeneFusion DS3 Infusion Supervision System (2-Channel syringe pumps+ 4-Channel infusion pumps, with cart)	
Size	Less than 650mm x 650mm x 1300mm (length × width × height) (cart base included) Less than 650mm x 650mm x 1900mm (length × width × height) (cart base and infusion pole included)
Weight	Less than 31.0kg (with cart base 24.0kg); Less than 31.5kg (with cart base 24.0kg and infusion pole 0.4kg)
BeneFusion DS3 Infusion Supervision System (4-Channel syringe pumps+ 2-Channel infusion pumps, with cart)	
Size	Less than 650mm x 650mm x 1300mm (length × width × height) (cart base included) Less than 650mm x 650mm x 1900mm (length × width × height) (cart base and infusion pole included)
Weight	Less than 30.0kg (with cart base 24.0kg); Less than 30.5kg (with cart base 24.0kg and infusion pole 0.4kg)

A.5 Specifications

Parameters	Specifications
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 infusion set sizes (ml)	Infusion set diameter: 3.5-4.5mm Infusionset thickness: 0.8-1.2mm
Rate range	Unit of Rate (ml/h): 0.1-1500, the increment is 0.1 ml/h Unit of Rate (drop/min): 1-(400 ml/h *drip/60), the increment is 1 drop/min
Drip range	10-60 drop/ml, the increment is 1 drop/ml
Bolus rate range	0.2-1500ml/h Note: Bolus accuracy is not declared.
Purge rate range	800ml/h, nonadjustable
VTBI range	0.1-9999 ml, the increment is 0.1 ml
Volume range	0.1-9999 ml, the increment is 0.1 ml
Time display range	00:00:01-99:59:59 h:m:s
Standby time range	00:01-99:59 hh:mm
Infusion mode	Rate Mode, Time Mode, Body Weight Mode and Sequential Mode
KVO rate	0.1 - 5.0 ml/h, the increment is 0.1ml/h
Drug library	On, Off
Anti-bolus switch	On, Off
Occl. pressure	1 - 3, respectively are 150±113 mmHg(20±15.1kPa), 525±113 mmHg(70±15.1kPa), 900±180 mmHg(120±24 kPa) Maximum occlusion pressure is about 1300mmHg.
Unit of pressure	mmHg, kPa, bar and psi
Bubble size	1 - 5, respectively are (50, 100, 250, 500, 800) μl Sensitivity of single bubble is 50μl.
Accum. bubble	0.1-4.0ml/h
Auto-lock time	Off, 1 - 5 min, step for 1min
Reminder time	Off, 1 - 5 min, step for 1min

Time near end	Off, 1- 30 min when the time is <10min, step for 1min, and step for 5 min when the time is ≥ 10 min
Bed No.	1-999
Volume	1 - 8
Brightness	1 - 8
System Date and Time	Time:_ _:_ _
	Date:_ _ _ _-_ _-_ _
	Time format: 12h, 24h
	Date format: yyyy - mm - dd, mm - dd - yyyy or dd - mm - yyyy
System language	You can select language according to actual needs.
History Record	Can store up to 1500 records.
Nurse call	On, Off
Accuracy	Accuracy error ≤±5%
Alarm Information	Occlusion, VTBI Done, Battery Empty, VTBI Near Done, Reminder, Battery Low, No AC Power, System Error, System abnormal, KVO Finish, Standby Time Expired, Tube not inserted, Air in line, Door opened, Empty bottle, Drop error and No communication
Status indicators	Stop, infusion, bolus, KVO, pause, standby, alarm and purge
Dose of single fault	About 1.2ml
Night mode	Switch: On, Off
	Start time: 00:00-23:59 hh:mm
	End time: 00:00-23:59 hh:mm
	Volume: 1-8
	Brightness: 1-8

A.6 A Reference Table Showing Occlusion Alarm Delay and Possible Dose

Occlusion pressure (Level)	Rate (ml/h)	Time of occlusion alarm (hh:mm:ss)	Bolus (ml)
Low	0.1	01:16:46	0.040
	1	00:07:25	0.033
	25	00:00:08	0.021
Medium	1	00:25:57	0.050
	25	00:00:48	0.028
High	0.1	08:36:34	0.069
	1	00:44:08	0.055
	25	00:01:45	0.037

NOTE

- **Test conditions:**

  FLUKE IDA4 PLUS tester
  Infusion set brand: SK
  Test temperature: 20±2℃
  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.7 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.

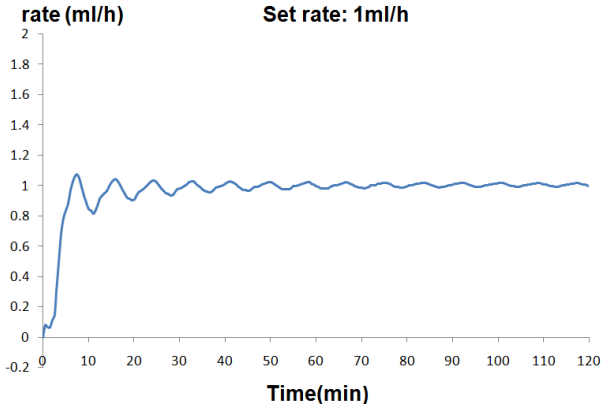
Plotted on the basis of data collected over a two-hour measurement period.
Infusion set brand: SK
Sampling quantity of pump: 3
Sampling quantity of infusion set: 3
Sampling interval: △ t =0.5 min
Test period: t =240 mins
Infusion rate: Q (m/h)

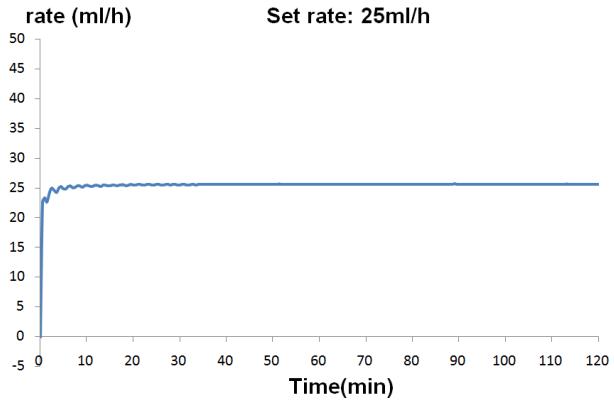
Flow rate deviation over time (p△ t)
Sampling interval: △ t =0.5 min
Observation windows: p△ t = 1, 2, 5, 11, 19, 31 mins
Maximum deviation over the course of a full observation window: Ep(Max) (%)
Minimum deviation over the course of a full observation window: Ep(Min) (%)
Average deviation: A (%) and B (%)

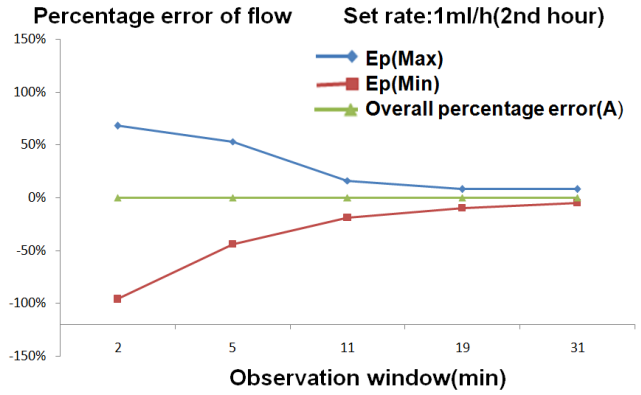
NOTE

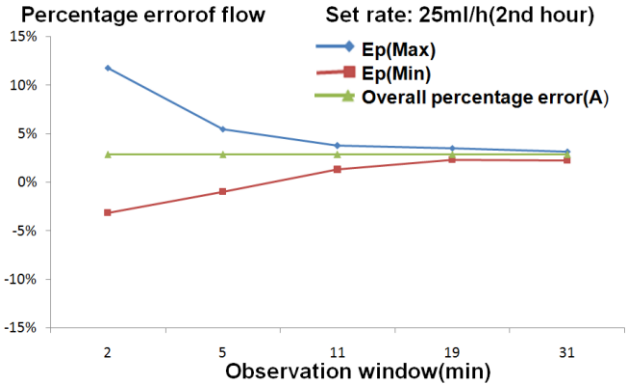
- **Infusion accuracy may be influenced by the pump's environment (such as pressure, temperature, humidity and any infusion consumables used).**

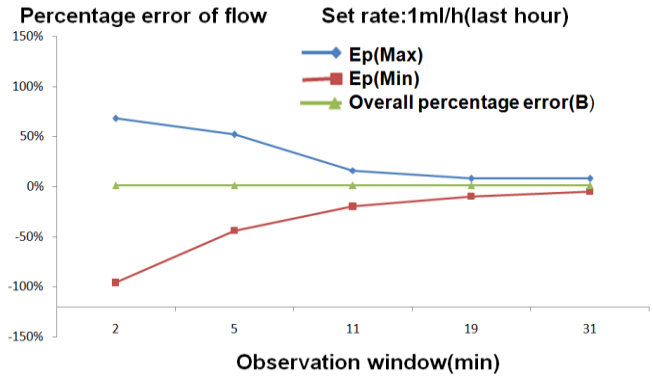
■ Unit of Rate (ml/h)

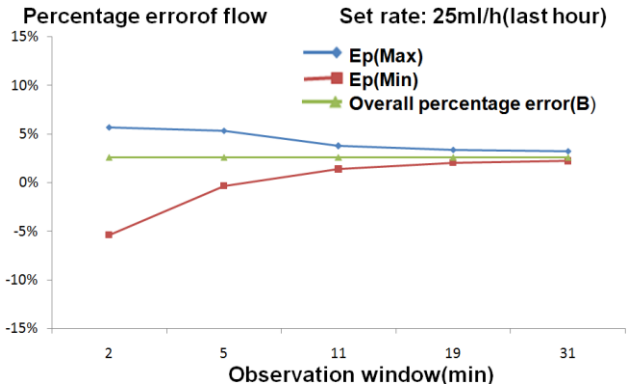






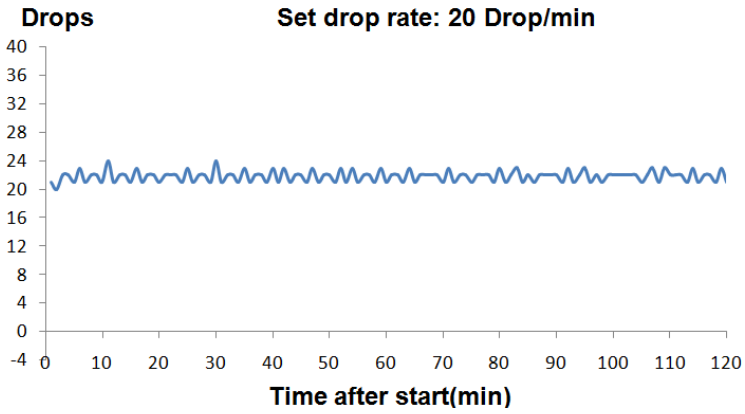




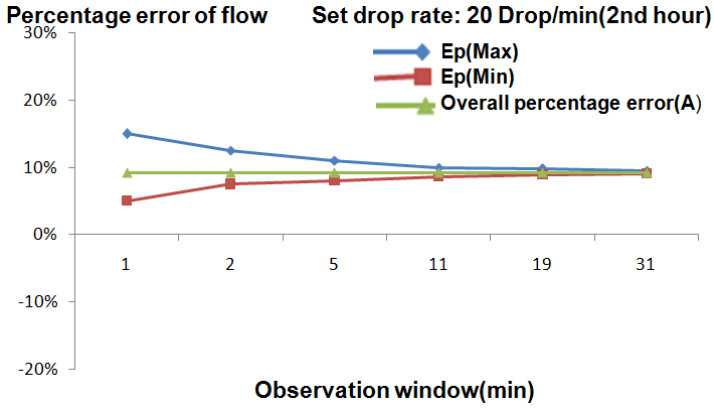


■ Unit of Rate (drop/min)

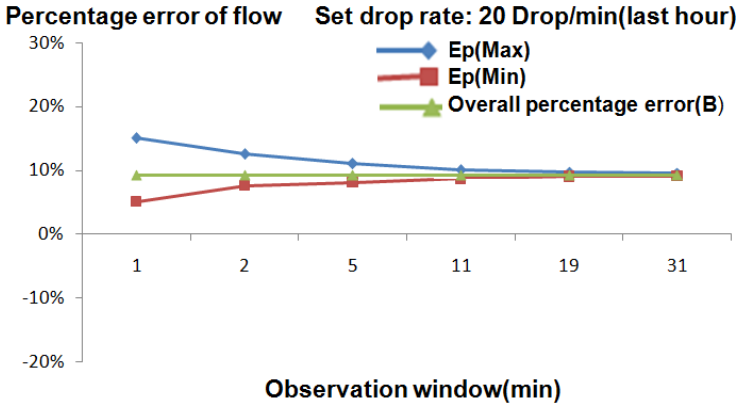
Sampling rate: 20 Drop/ min
Sampling interval: ∆ t =1 min
Test period: t =120 mins
Infusion rate: Q (Drop/ min)



Sampling rate: 20 Drop/ min
Sampling interval: ∆ t =1 min
Observation windows: p∆ t = 1, 2, 5, 11, 19, 31 mins
Maximum deviation over the course of a full observation window: Ep(Max) (%)
Minimum deviation over the course of a full observation window: Ep(Min) (%)
Average deviation: A (%)



Sampling rate: 20 Drop/ min
Sampling interval: ∆ t =1 min
Observation windows: p∆ t = 1, 2, 5, 11, 19, 31 mins
Maximum deviation over the course of a full observation window: Ep(Max) (%)
Minimum deviation over the course of a full observation window: Ep(Min) (%)
Average deviation: B(%)



B EMC and Radio Regulatory Compliance

B.1 EMC

This pump complies with EMC standard IEC60601-1-2 and IEC60601-2-24.

NOTE

- **Use of accessories, sensors or cables outside of the specified scope of this pump may increase electromagnetic emissions and/or lower the electromagnetic immunity of the pump.**
- **This pump may not be used in close proximity to or stacked with other equipment. If necessary, closely observe the pump to ensure that it is able to operate normally in its environment.**
- **Special care must be taken to protect the pump from electromagnetic interference. The following requirements describe the conditions in which the pump must be installed and maintained.**
- **The pump should not be used at the same time as any MRI (Magnetic Resonance Imaging) or other similar equipment in order to avoid the possibility of the pump malfunctioning or crashing due to electromagnetic interference.**
- **Even if other equipment is compliant with CISPR emission requirements, it may still interfere with pump operation.**
- **Where electromagnetic signals are weaker than the measuring device's sensitivity range, measurements may be inaccurate.**
- **This pump is intended to be used only by qualified medical professionals. Operation of the device may cause radio interference or disturbance of other equipment within the pump's vicinity. Mitigation measures may be necessary, such as the reorientation and the re-placement of the surrounding equipment or by shielding the appropriate venue.**
- **Portable and mobile RF communications equipment can affect the performance of measuring devices.**
- **Devices of A Type are intended to be used in hospital. This pump conducts emission and radiation disturbance, so there may be potential difficulty in guaranteeing EMC under other circumstances.**
- **User shall install and use the device according to the EMC information of random file.**

Guidance and statements regarding electromagnetic emissions		
This pump should be used in the electromagnetic environment for which it was designed. The customer or user should ensure that the pump is used in an electromagnetic environment that complies with the following conditions.		
Emission test	**Standard**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The pump only generates radio frequency energy incidentally from its internal functions. The pump's radio emissions are therefore very low and will not cause any electromagnetic interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The pump 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 emissions IEC61000-3-2	N/A	
Voltage fluctuations and scintillation IEC 61000-3-3	N/A	

Guidance and statements regarding electromagnetic immunity			
This pump should be used in the electromagnetic environment for which it was designed. The customer or user should ensure that the pump is used in an electromagnetic environment that complies with the following conditions.			
Immunity test	**IEC60601 test level**	**Standard**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Flooring must be wood, concrete or ceramic tile. If the floor is lined with synthetic materials there must be a relative humidity of at least 30%.
Electrical fast transient (EFT) IEC 61000-4-4	±2 kV power cord ±1 kV I/O cable	±2 kV power cord	The network power source must be of typical commercial or hospital quality.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	
Voltage drops, short interruptions and changes IEC 61000-4-11	<5% U_T (drop>95% U_T) 0.5 cycle 40% UT (drop 60% U_T) 5 cycles 70% UT (drop 30% U_T) 25 cycles <5% UT (drop>95% U_T) 5 seconds	<5% UT (drop>95% U_T) 0.5 cycle 40% UT (drop 60% U_T) 5 cycles 70% UT (drop 30% U_T) 25 cycles <5% UT (drop>95% U_T) 5 seconds	The network power source must be of typical commercial or hospital quality. If the pump needs to run continuously, we recommend using an uninterruptible power supply (UPS) in case of interruptions to the main power supply.
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	400 A/m	400 A/m	The power frequency magnetic field must be at a typical level for typical commercial or hospital environments.
NOTE:U_T refers to the voltage of the AC power network before voltage testing.			

<table>
<tr><th colspan="4">Guidance and statements regarding electromagnetic immunity</th></tr>
<tr><td colspan="4">This pump should be used in the electromagnetic environment for which it was designed. The customer or user should ensure that the pump is used in an electromagnetic environment that complies with the following conditions.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 Test level</th><th>Standard</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted immunity IEC61000-4-6</td><td>10 Vrms
150 k–80 MHz</td><td>10 Vrms</td><td rowspan="2">Portable and mobile radio frequency communications devices must be used at the stipulated distance away from the pump or any system components (including the cables). This isolation distance is calculated using appropriate formulas selected on the basis of the frequency of the radiation. Recommended calculation formulas for isolation distance are:
$d = 0.4\sqrt{P}$
$d = 0.2\sqrt{P}$ 80 M–800 MHz
$d = 0.4\sqrt{P}$ 800 M–2.7 GHz
Where P is the rated maximum output power of the transmitter, in W.d is the recommended distance, in m.
The field strength of the radio frequency transmitter obtained by measuring the electromagnetic field[a] must be within compliant levels for every frequency range[b].
May cause interference if used in close proximity to equipment with the following symbols:  </td></tr>
<tr><td>Radiated immunity IEC61000-4-3</td><td>10 V/m
80 M–2.7 GHz</td><td>10 V/m</td></tr>
<tr><td colspan="4">Note 1: Between 80 MHz–800 MHz, use a formula for higher frequency bands.
Note 2: The above guidance is not suitable for use in all conditions. Material structures, objects and people can absorb and reflect electromagnetic waves, affecting electromagnetic propagation.</td></tr>
<tr><td colspan="4">[a] Field strengths for radio (honeycomb and wireless) handset base stations and terrestrial mobile radio receiving apparatus, antenna reception apparatus, and FM and AM radio/television broadcasts cannot be accurately estimated using a purely theoretical approach.
The use of electromagnetic field measuring methods should be considered when estimating the electromagnetic environment produced by a fixed radio frequency transmitter. If the measured field strengths in the environment in which this pump is used exceed stipulated RF levels, the pump must be observed to check whether normal operation is possible. If any abnormal performance is observed, action must be taken immediately: for example, by changing the position of the pump or moving it to another environment.
[b] In a frequency range of 150 kHz–80 MHz, the field strength should be less than 3 V/m.</td></tr>
</table>

It is recommended that the pump be kept away from portable/mobile RF communications equipment			
The pump can be used in electromagnetic environments in which RF interference is controlled. In order to avoid electromagnetic interference, the customer or user should maintain the minimum recommended distance between the pump and portable/mobile RF communication equipment. The following recommended isolation distances are calculated on the basis of the maximum output power of the communications equipment.			
Transmitter ratings Maximum output power (W)	**Calculate isolation distances on the basis of transmitter frequencies (m)**		
	150 k–80 MHz $d = 0.4\sqrt{P}$	80 M–800 MHz $d = 0.2\sqrt{P}$	800 M–2.7 GHz $d = 0.4\sqrt{P}$
0.01	0.04	0.02	0.04
0.1	0.13	0.06	0.13
1	0.4	0.2	0.4
10	1.26	0.63	1.26
100	4	2	4
If the rated maximum output power of the transmitter is not included above, the isolation distance may be estimated by using the formula in the corresponding column. In the formula, P is the rated maximum output power of the transmitter as provided by the manufacturer, in W. Note 1: Between 80M-800MHz, use a formula for higher frequency bands. Note 2: The above guidance is not suitable for use in all conditions. Material structures, objects and people can absorb and reflect electromagnetic waves, affecting electromagnetic propagation.			

B.2 Radio Regulatory Compliance

RF Parameter

Radio devices	**2.4GHz Wi-Fi devices**
Operating frequency	2412MHz to 2472MHz
Modulation mode	DSSS and 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 Default Factory Settings

This chapter presents some default factory settings.User cannot change the factory default, but may restore to the default factory settings when it is necessary.

C.1 Alarms

Alarm Setting	Factory Default
Volume	4
Alarm sound	Sound2

C.2 Interface

UI	Factory Default
Brightness	4

C.3 Parameters

Setting Parameters	Factory Default
KVO rate	0.5ml/h
Drug library	Off
Unit of pressure	mmHg
Occl. pressure	525mmHg
Bubble size	100μl
Accum. bubble	1.5ml/h
Auto-lock time	Off
Reminder time	2min
Time near end	3min
Commonly used tube (Recommended brand)	B. Braun, SK
Bed No.	---
Standby time range	24:00

C.4 System Time

System Date and Time	Factory Default
Time	00:00
Date	01/01/2015
Time format	24h
Date format	Domestic: yyyy-mm-dd International: dd-mm-yyyy

C.5 Drug Library List

No.	Drug	No.	Drug
1	Aminophylline	21	Magnesium sulfate
2	Amiodarone	22	Mannitol
3	Atropine	23	MetaraminolBitartrate
4	Dexmedetomidine Hydrochloride Injection	24	Metoprolol Tartrate Tablets
5	Diazepam	25	Midazolam
6	Diazoxide	26	Morphine
7	Digoxin	27	Nicardipine
8	Diltiazem	28	Nimodipine
9	Dobutamine Hydrochloride	29	Nitroglycerin
10	Dopamine Hydrochloride	30	Noradrenaline Bitartrate
11	Epinephrine	31	Pancuronium
12	Esmolol	32	Phentolamine
13	Fentanyl	33	potassium chloride
14	Flumazenil	34	Propafenone Hydrochloride
15	Furosemide	35	Propofol
16	Heparin Sodium	36	Remifentani
17	Insulin	37	Sodium Nitroprusside
18	Isoprenaline Hydrochloride	38	Suxamethonium
19	Isosorbidedinitrate	39	Urapidil
20	Lidocaine Hydrochloride	40	vasopressin

D 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
[Occlusion]	High	When occlusion occurs in the infusion tube between the device and the patient, and occlusion pressure reaches the threshold value.	Press Stop to cancel alarm, eliminate the causes of the pressure of infusion tube, and then press Start to continue the infusion.
[Air in line]	High	Size of single bubble or bubbles accumulated in 1 hour reaches to the preset value.	Press Stop to cancel alarm.
[Door opened]	High	The infusion pump door is opened during infusion.	Press Stop to cancel alarm and close the door correctly.
[VTBI Done]	High	VTBI volume is completed.	Press Stop to cancel alarm.
[KVO Finish]	High	Alarm is triggered when KVO model runs 30 minutes.	Press Stop to cancel alarm.
[Battery Low]	Low	Only powered with built-in battery, battery charge is insufficient.	Connect to the power source to cancel alarm automatically.
[Battery Empty]	High	Only powered with built-in battery, battery is empty.	Connect to the AC power source, press Stop or to cancel alarm.

Alarm Information	Alarm level	Reason	Countermeasure
[No AC Power]	Low	Power cord disconnected when the network power source supply is powered.	Connect to the power source to cancel alarm automatically.
[Reminder]	Low	The infusion pump performs no operation during the set reminder time after the infusion set is installed to it.	Operate the pump or open the door to cancel alarm.
[System Error]	High	Motor operation error, data communication error, sensor failure and etc.	Alarm cannot be cancelled. Please stop operation and contact the company.
[VTBI Near Done]	Low	Required time for the remaining VTBI volume almost reaches the set [Time near end].	1. The alarm will not be cancelled automatically until the infusion is completed, and then switch to [VTBI Done] alarm. 2. Or press Stop to cancel alarm.
[Standby Time Expired]	Mid-level	Standby is completed.	Press Clear to cancel alarm, and then exit standby or continue standby by pressing .
[System abnormal]	Mid-level	Charging circuit error, supplying circuit error and etc.	Alarm cannot be cancelled. Please stop operation and contact the company.
[Tube not inserted]	Low	Door is opened during infusion, or infusion set is not inserted, and start infusion when the door is closed.	Correctly insert infusion set and close the door.
[Drop error]	High	If drop sensor is installed correctly and the switch of [Drop rate check] is on, current rate is ≤400ml/h, drop sensor detects that the drop rate deviates the preset value.	Press Stop to cancel alarm.

Alarm Information	Alarm level	Reason	Countermeasure
[Empty bottle]	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, [Empty bottle] alarm might be triggered.	Press  to cancel alarm.
[No communication]	Low	Infusion pump and BeneFusion CS5 Infusion Supervision System 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 restore the communication between infusion pump(s) and BeneFusion CS5 Infusion Supervision System.

NOTE

- **All alarm sounds can be paused by pressing  , except for the circumstance of [Battery Empty].**

E Symbols and Terms

E.1 List of Units

Abbreviation	Meaning
A	ampere
℃	centigrade
cm	centimeter
dB	decibel
g	gram
hr	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

E.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

E.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
DPS	Dynamic Pressure System
ECU(EICU)	Emergency Intensive Care Unit

Abbreviation	Meaning
EEC	European Economic Community
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
EtO	C2H4O
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

E.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
drop/min	drop/min=(ml/h×drip)/60

F 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	○: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006. ╳: 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 SJ/T11363-2006.						

G Declaration of Conformity

Declaration of Conformity V1.0

Declaration of Conformity

CE

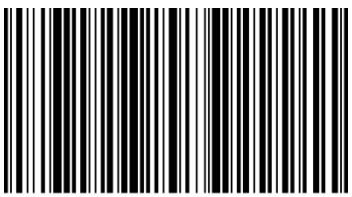
Manufacturer:	Shenzhen Shenke Medical Instrument Technical Development Co., Ltd. Bldg 2,5, Mindray Guangming Facility, 1203 Nanhuan Avenue, Yutang Block, Guangming District, 518016, Shenzhen, P.R.China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Infusion Pump
Model:	BeneFusion VP3, BeneFusion VP3 Ex

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.

Standards Applied:

☒ EN 60601-1:2006/A1:2013	☒ EN 60601-1-2:2007/AC:2010
☒ EN 62311 :2008	☒ ETSI EN 301 489-1 V2.1.1:2017-02
☒ ETSI EN 301 489-17 V3.1.1:2017-02	☒ EN 300 328 V2.1.1:2016-11
☒ EN60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013	

Start of CE-Marking:	2017-5-18
Place, Date of Issue:	Shenzhen
Signature:	.....
Name of Authorized Signatory:	Lei Ming
Position Held in Company:	Management Representative



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