BeneFusion SP3 Vet

Syringe Pump

Operator's Manual



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Preface

Manual Purpose

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

Illustrations

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

Conventions

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

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1 Safety

1.1 Safety Information

WARNING

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

ACAUTION

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

NOTE

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

1.1.1 Warnings

WARNING

- Device, cables and accessories must be inspected before use to guarantee their normal and safe operation.
- This equipment can only be connected to the socket with ground protection. Please adopt a rechargeable battery instead of the socket as the power supply if the socket is not provided with a ground lead.
- To prevent fire or explosion, do not operate the equipment in the presence of anesthetic, flammable or explosive materials.
- Do not open the equipment casing as there is the impending danger of electric shock. Equipment maintenance and upgrades must be carried out by maintenance technicians whom are trained and licensed by the manufacturer. Moreover, the process must be done only after the AC power supply is disconnected. Maintenance carried out by individuals non-affiliated to the manufacturer or by non-licensed personnel may affect the safety, performance and function of the product.
- When used with electrosurgery equipment, the safety of animals should be ensured.
- The animal's clinical condition and the working condition of the syringe 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 animal. If the alarm volume is less than the surroundings volume, which can further lead to operators identify alarm mistakenly.
- The interconnection of other infusion systems or ACCESSORIES to the PATIENT LINE may lead to performance degradation and failure to achieve the expected performance, the working condition of the pump and patient's clinical condition shall be monitored regularly.
- Please carefully install the power line and cables with various accessories to prevent the animal 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 cannula knots, filter coagulation and occlusions arising from needle insertion can cause the pressure inside the syringe to rise during infusion. When this occurs, removing the occlusion can cause excessive liquid to be infused into the animal, so appropriate measures should be taken.
- This equipment has to be used with professional medical consumables, and its accuracy cannot be guaranteed when it is used with a syringe

which is a non-standard consumable or a consumable without calibration, please contact the company for calibration service.

- Do not touch the animal when connecting the peripheral equipment via the input/output signal ports to prevent animal leakage current from exceeding the requirements specified by the standard.
- In the process of defibrillation, do not touch animal and other non-defibrillation equipments to prevent electric shock damage, and defibrillation will not affect the basic performance (such as infusion accuracy, alarm and signal transmission) of the pump.
- The equipment use a mains plug as isolation means to the mains power.
 Do not locate the equipment in a place difficult to operate the mains plug.

1.1.2 Cautions

ACAUTION

- Use the accessories specified in this Operator's Manual to guarantee the animal's safety.
- When this syringe 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.
- Electromagnetic fields may affect equipment performance. This makes it necessary for other equipment used in the vicinity of the pump to meet EMC standards. Mobile phones, X ray and MRI equipment are all potential interference sources because of their high-intensity electromagnetic radiation.
- Before the equipment is connected to the power supply, check that the voltage and frequency of the power supply match the specifications on the label or in this Operator's Manual.
- Please install and carry the equipment correctly to protect the equipment from damage from drops, impacts, violent shaking or other external mechanical forces. The equipment should be observed to verify normal operation after fall, otherwise it cannot be used.
- Disposable accessories must be disposed of after use in accordance with the relevant hospital regulations.
- Avoid direct sunshine, high temperatures and dampness.
- Check the built-in battery before use to make sure it has sufficient power. Recharge the battery if necessary.
- The syringe with the luer taper is recommended for use, which can
 effectively prevent animals from under current caused by the
 occurrence of the cannula to slip out when under tension.

1.1.3 **Notes**

NOTE

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

1.2 Equipment Symbols

Some symbols may not appear on your equipment.

(3)	Refer to instruction manual/booklet	0/0	ON/OFF
\triangle	Caution	SN	Serial number
~	Alternating current	- +	Battery
$\overline{\sim}$	Both direct and alternating current	===	Direct current
\triangle	Alarms		AUDIO PAUSED
Ç	Clear/Back		Start; start of action
***	Bolus	ок	Confirm

\bigcirc	Stop		Menu
A	Move up/Increase	V	Move down/Decrease
◀	Move left		Move right
<u>্</u>	Configured wireless module and connected successfully		Non-ionizing electromagnetic radiation
	Night mode	- W -	DEFIBRILLATION-PROOF TYPE CF APPLIED PART
M	Date of manufacture		Manufacturer
11	THIS WAY UP	*	Keep dry
Ţ	Fragile, handle with care	X □	STACKING LIMIT BY NUMBER
A	Comply with the requirements of Directive 2012/19/EU Waste Electrical & Electronic Equipment	IP34	Protected against solid foreign objects with a diameter no less than 2.5mm and protected against spraying liquid water
EC REP	Authorized representative in the European Community	(€	CE mark, comply with the requirements of the Council Directive 93/42/EEC (Medical Device Directive).
	Recovery/recyclable	\Rightarrow	Input/output
20	Environmentally-friendly use periods of electronic products (20 years)	1	Temperature limitations
Θ	Atmospheric pressure limitations	A	Humidity limitations

2 Overview

2.1 Description

2.1.1 Intended Use

The syringe pump is used in conjunction with the syringe to control the dose of liquid infused into the animal's body.

The syringe pump is expected to be used in institutes or units with healthcare capabilities. This includes but is not limited to hospitals.

⚠ WARNING

The syringe 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

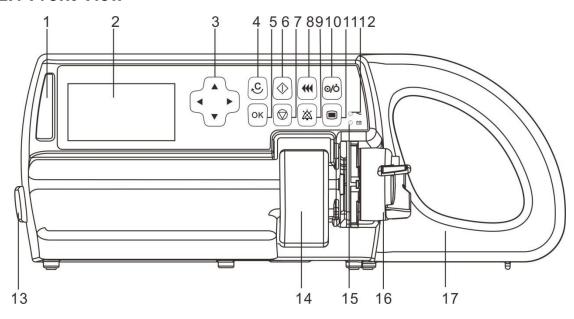
2.1.3 Appearance, Parts and Features

The syringe pump primarily consists of a housing, pole clamp and BeneFusion DS3 Infusion Supervision System. By precisely controlling the rotational speed of the stepping motor, the screw rod is driven to run at the set speed, the dose of liquid infused into the animal's body by syringe can be controlled, the syringe pump can be used for precise and continuous infusion of liquids, and all components are suitable for use in animal environment. Wireless modules are optional. Functions of the software comprise Rate Mode, Time Mode, Body Weight Mode, Intermittent Mode, Drug Library, History Record, and Anti-bolus function.

The syringe pump also includes syringes as applied parts. Since some parts and functions are optional, the syringe 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. <DIRECTION>

Used for adjusting value, change lines and pages.

4. <CLEAR/BACK>

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

5. **<OK>**

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

6. **<START>**

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

7. **<STOP>**

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

8. **<BOLUS>**

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

9. <AUDIO PAUSED>

Pauses alarm sound.

10. **<POWER>**

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

11. **<MENU>**

- Used for entering [Main Menu] interface.
- Under operation status, press and hold this key to lock; in locked state, press and hold this key to unlock.
- 12. 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.
- 13. Extension cannula clamp

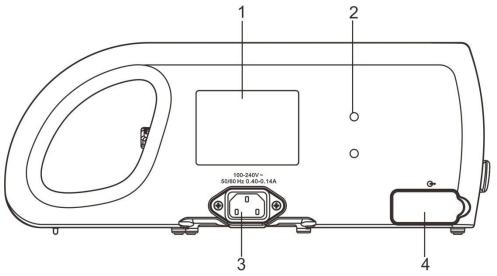
Fixes the extension cannula.

- 14. Syringe fixation clamp
- 15. Battery indicator light
- Steady green indicates that the battery is charging (including shutdown).
- Flashing green indicates that the battery is providing power.
- Light off indicates that the pump is turned off and not connected to an AC power supply.
- 16. Slider

Secures syringe and drives plunger assembly.

17. Handle

2.2.2 Rear View

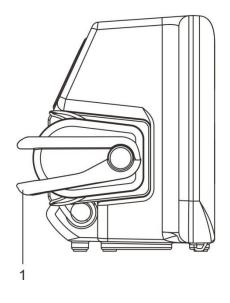


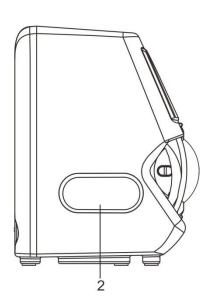
- 1. Product label
- 2. Pole clamp mounting holes (two)
- 3. AC power supply port

Connection for the AC power cord.

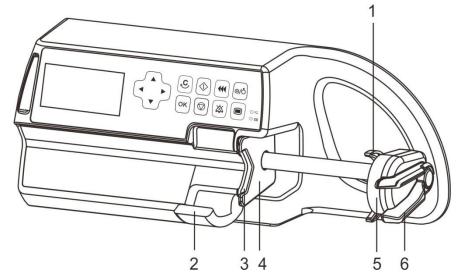
- 4. Multifunction interface with the following functions:
- DC power supply port
- RS232 interface
- Nurse call interface

2.2.3 Side View



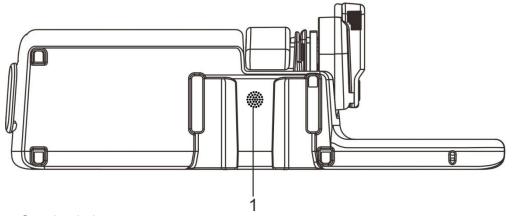


- 1. Handle
- 2. Extension cannula clamp



- 1. Clip
- 2. Syringe fixation clamp
- 3. Slot
- 4. Spindle clamp
- 5. Slider
- 6. Handle

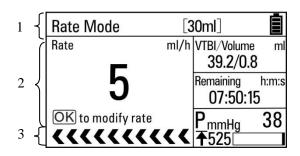
2.2.4 Bottom View



1. Speaker hole

2.3 Screen Display

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



1. Title bar

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

2. Parameter area

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

3. Prompt bar

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

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

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

3 Installation and Setting

3.1 Installation

WARNING

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

NOTE

 This equipment is in accordance with the EN 1789:2007+A2:2014 standard.

3.1.1 Out of Box Audit (OOBA)

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

WARNING

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

NOTE

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

3.1.2 Operating Conditions

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

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

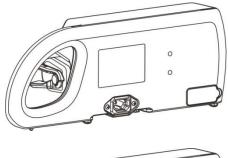
When the pump is transferred from one place to another, differences in temperature and humidity can cause condensation to form inside the pump. If this occurs, do not switch the pump to the "ON" state until the condensation has gone.

WARNING

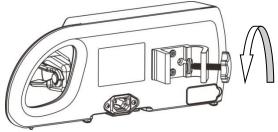
 Please use only when the operating environment meets the requirements specified above. Otherwise, the pump's performance will not match the technical specifications in A Product Specifications. Device failure and other unexpected consequences may also result.

3.1.3 Mount the Clamp

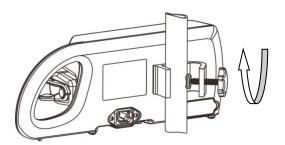
3.1.3.1 Standard Pole Clamp



1. Align the mounting holes on the pole clamp with the mounting holes on the back side of the machine, and tighten the screws.



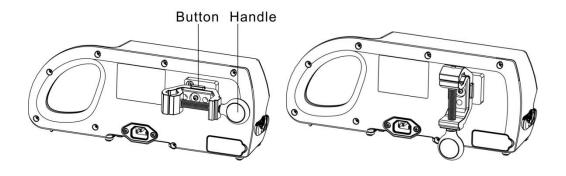
2. Turn counterclockwise to loosen the pole clamp until an IV stand can be inserted in.



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

3.1.3.2 Advanced Pole Clamp (Optional)

Align the mounting holes on the pole clamp with the mounting holes on the back side of the machine, and tighten the screws. 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 round cross bar or vertical bar (diameter size of 15-32mm).



3.1.4 Fix BeneFusion DS3 Infusion Supervision System

(Optional)

The device can be located in the BeneFusion DS3 Infusion Supervision System.

NOTE

- All components of the system are suitable for use in animal 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 animal and device to prevent animal leakage current from exceeding the requirements specified by the standard.
- Only devices designated by the manufacturer can be connected to the system. Based on animal safety, do not insert devices that are not specified by the manufacturer into the system.

3.1.5 Connect the AC Power Source

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

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

MARNING

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

NOTE

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

3.2 Conventional Settings

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

3.2.1 Adjust Alarm Sound Volume

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

3.2.2 Adjust Screen Brightness

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

3.2.3 Set Language

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

3.2.4 Set Date and Time

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

ACAUTION

- 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.

3.3 Restore Factory Default

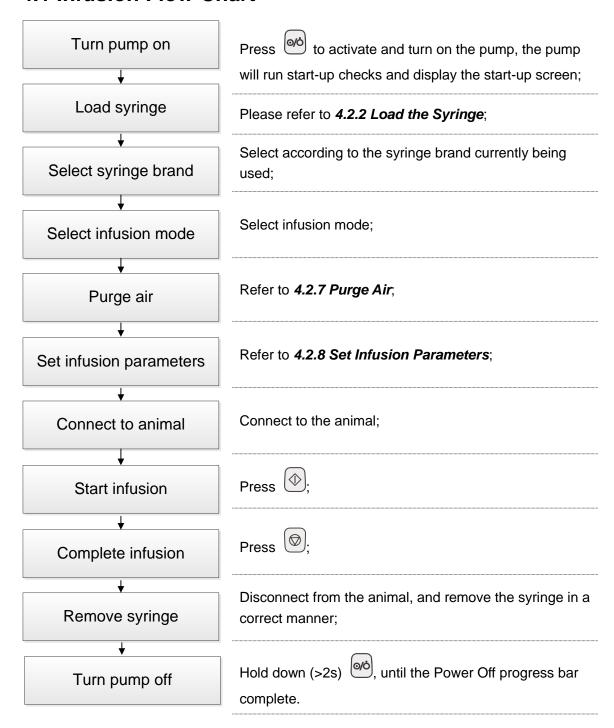
During operation, you may change some settings in some situations. However, the changes may not be appropriate or correct, especially when animal or syringe brands are changed. Therefore, you should restore to the default factory settings during operation according to actual needs, to guarantee that each configuration of the syringe pump is applicable for clinical use. For some default factory settings of this equipment, please refer to **A.4 Specifications.**

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

4

Basic Operation

4.1 Infusion Flow Chart



4.2 Operational Procedures

4.2.1 Turn on the Pump

To turn on the device, follow this procedure:

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

WARNING

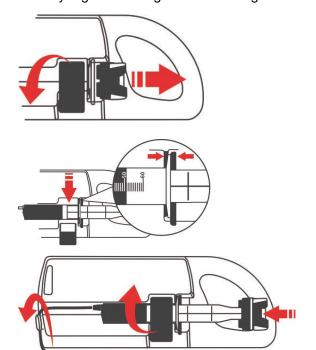
- Please monitor the self-test process to make sure that the speaker, the alarm light, and the buzzer are all self-tested successfully. Otherwise, please contact the company and do not operate the pump until maintenance is performed.
- Please contact the company if the syringe pump is damaged or cannot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

4.2.2 Load the Syringe

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

- If syringe is not loaded or incorrectly loaded, enter the syringe [Loading Guide] interface; If the syringe is not required to load, press to skip the step.
- If syringe is correctly loaded, and [User Maintenance]→[Brand Selection]→[On], enter the [Syringe Selection] interface; if the switch of [Brand Selection] is [Off], then skip the [Syringe Selection] interface.

Load syringe according to the following method:



- 1. Open the syringe fixation clamp, squeeze the handle to open the clip, and then move the slider to the appropriate position.
- 2. Align the syringe flange with the slot, then load it into the slot, and clamp the syringe.

(Tip: Flange location)

3. Align the slider to and snugly against the syringe plunger, making the clip clamps firm to the thumb rest. Close the syringe clamp gently.

MARNING

- The flange of the syringe should be firmly loaded into the slot, and not jutting on the outside of the flange plate.
- Before using this syringe pump, the syringe pump, syringe and other accessories should be installed correctly.
- Before using this syringe pump, the brand and specifications of the syringe used must be confirmed. The brand of syringe pump should be calibrated on the equipment. If there are no settings for the syringe used, the rate and the alarms may not be accurate.

4.2.3 Change the Syringe

Follow the steps below to change the syringe:

1. To prevent animal injury, before changing the syringe during infusion, press to stop the pump.



- 2. Open the syringe fixation clamp, squeeze the handle to open the clip, move the slider to the appropriate position, and take out the loaded syringe.
- 3. Please refer to **4.2.2 Load the Syringe** to reload the syringe.



On the [Syringe Selection] screen, press to select the syringe brand and size of the syringe currently being used, and press for confirmation.

MARNING

A new syringe brand should be calibrated when used for the first time.

ACAUTION

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

4.2.5 Parameter Memory Function

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

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

4.2.6 Select Infusion Mode

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

4.2.7 Purge Air

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

before the infusion. Under non-running status of any infusion mode, press to enter [Purge Air] prompt screen. Hold down to enter [Purge Air] running

screen, release after the air bubbles are purged.

MARNING

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

NOTE

• Purge rate can not be changed.

4.2.8 Set Infusion Parameters

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



4.2.9 Infusion

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

MARNING

- Users should inspect and confirm whether the parameter settings are correct before infusion.
- Users should regularly monitor the connection between the syringe, extension cannula, pump and animal, 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.

4.2.10 Infusion Pause

During infusion, if changing the drug liquid or syringe 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.

4.2.11 BOLUS

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

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

NOTE

- If no operation is performed within 2 minutes, the syringe pump will automatically exit the Bolus Settings screen and the procedure must be repeated.
- Animal's clinical condition and working condition of the syringe pump must be monitored carefully.

4.2.12 Change the Rate during Operation

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

4.2.13 Complete

If [VTBI] is not set during the infusion, when the time in which the remaining liquid needs to reach [Time Near End], the [Syringe Near Empty] alarm will be triggered, and this alarm can be cancelled automatically until the syringe is empty. Set [Time Near End], please refer to 6.6 Time Near End.

When the remaining infusion time is close to the [Time Near End] set by the users, the [Time Near End] alarm will be triggered. If no action has been taken, the alarm will not be cancelled automatically until the infusion is completed, and then switch to [VTBI Complete] alarm. After KVO mode runs for 30 minutes, the [KVO Finish] alarm will be triggered. Set KVO rate, please refer to 6.1 KVO.

4.2.14 Standby

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

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

4.2.15 Turn off the Pump

Follow the steps below to turn off the syringe pump:

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

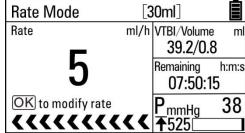
NOTE

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

5 Infusion Mode

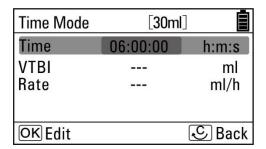
5.1 Rate Mode

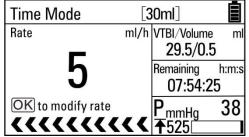




Mode	Parameters	Parameter Range
Rate Mode	Rate	5ml syringe: 0.1-150ml/h 10ml syringe: 0.1-300ml/h 20ml syringe: 0.1-600ml/h 30ml syringe: 0.1-900ml/h 50ml/60ml syringe: 0.1-2000ml/h
	VTBI	0.1-9999ml
	Time	00:00:01-99:59:59 h:m:s

5.2 Time Mode



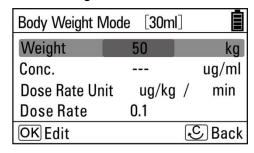


Mode	Parameters	Parameter Range
	Time	00:00:01-99:59:59 h:m:s
	VTBI	0.1-9999ml
Time Mode	Rate	5ml syringe: 0.1-150ml/h 10ml syringe: 0.1-300ml/h 20ml syringe: 0.1-600ml/h 30ml syringe: 0.1-900ml/h 50ml/60ml syringe: 0.1-2000ml/h

5.3 Body Weight Mode

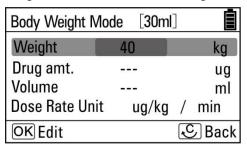
- Select [Main Menu]→[User Maintenance]→Input User Maintenance Password→[BW Mode Configuration].
- 2. Select [BW Mode Configuration]: Conc., Drug Amount and Volume.
- 3. Select [Main Menu]→[Select Mode]→[Body Weight Mode].

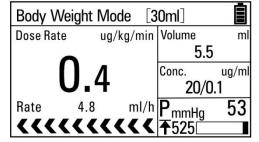
Conc. Configuration:





Drug Amount and Volume Configuration:





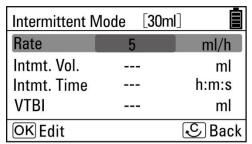
Mode	Parameters	Parameter Range
	Weight	0.1-300.0 kg/0.2-660.8 lb
	Drug amt.	0.1-99999
	Drug amt. unit	ng, μg, mg, g, mU, U, kU, EU, mmol, mol, kcal, mEq
	Volume	0.1-9999ml
	Conc.	0.1-9999
	Conc. unit	ng/ml, µg/ml, mg/ml, g/ml, mU/ml, U/ml, kU/ml, EU/ml, mmol/ml, mol/ml, kcal/ml, mEq/ml
Body	Dose Rate	0.1-9999
Weight Mode	Dose Rate Unit	ng/kg/min, ng/kg/h,ug/kg/min, ug/kg/h,ug/kg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, g/kg/min, g/kg/h, mU/kg/min, mU/kg/h, U/kg/min, U/kg/h, U/kg/24h, kU/kg/h, EU/kg/h, mmol/kg/h, mol/kg/h, kcal/kg/h, kcal/kg/24h, mEq/kg/min, mEq/kg/h
	VTBI	0.1-9999ml
	Rate	5ml syringe: 0.1-150ml/h 10ml syringe: 0.1-300ml/h 20ml syringe: 0.1-600ml/h 30ml syringe: 0.1-900ml/h 50ml/60ml syringe: 0.1-2000ml/h
NOTE:		, 5

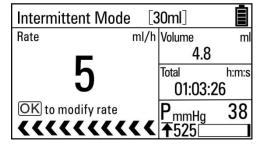
NOTE:

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

5.4 Intermittent Mode

In Intermittent Mode, by setting the rate, Intmt. vol., Intmt. time and VTBI to control the infusion. It is suitable for the infusion of long-term analgesia drugs.





Mode	Parameters	Parameter Range
Intermittent	Rate	5ml syringe: 0.1-150ml/h 10ml syringe: 0.1-300ml/h 20ml syringe: 0.1-600ml/h 30ml syringe: 0.1-900ml/h 50ml/60ml syringe: 0.1-2000ml/h
Mode	Intmt. Vol.	0.1-9999ml
	Intmt. Time	00:00:01-99:59:59 h:m:s
	VTBI	0.1-9999ml

Note: After a certain intermittent infusion period is finished, system will display the remaining time for the next startup, press to continue the infusion.

6 Setting Parameters

6.1 KVO

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

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

6.2 Drug Library

The product is configured with a drug library with drugs available for users to select from.

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

List of Drugs

Metoprolol	Dobutamine	Insulin	Flumazenil
Amiodarone	Dopamine	Sodium Nitroprusside	Fentanyl
Esmolol	Epinephrine	Diazoxide	Remifentanil
Lidocaine	Isoprenaline	Nimodipine	Morphine
Propafenone	Norepinephrine	Mannitol	Diazepam
Nitroglycerin	Atropin	Furosemide	Midazolam
Nicardipine	Succinylcholine	Phentolamine	Magnesium
			sulfate
Isosorbide dinitrate	Pancuronium	Urapidil	Dexmedetomidine
			Hydrochloride
Diltiazem	Aminophylin	Metaraminol Bitartrate	potassium
			chloride
Digoxin	Heparin	Propofol	vasopressin

6.3 Occlusion Pressure

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

6.3.1 Set Occlusion Pressure

- 1. Select [Main Menu]→[General Options]→[Pressure].
- Select [Pressure]: Occlusion pressure Degree 5, lowest at 75mmHg, and highest at 900mmHg. Occlusion pressure should be selected according to actual needs.

ACAUTION

 If the animal experiences discomfort at a higher occlusion pressure, monitor the animal's physical conditions under the higher occlusion pressure closely, and take measures instantly if any abnormal condition occurs.

6.3.2 Set Pressure Unit

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

ACAUTION

• 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 animal, in order to find the cannula occlusion at an earlier time and to prevent the occurrence of further complications.

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 animal after the occlusion is eliminated.

6.4 Key Lock Function

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

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

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

6.5 Reminder Function

- 1. Select [Main Menu]→[General Options]→[Reminder Time].
- 2. Select [Reminder Time]: Off, 1-5min. After a specific time is set, the syringe is loaded. 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 switching off the function.

6.6 Time Near End

- 1. Select [Main Menu]→[General Options]→[Time Near End].
- 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, [Time Near End] alarm will be triggered. [Off] indicates switching off the function.

6.7 Commonly Used Syringes

There are multiple built-in commonly used syringe brands in the syringe pump, making it convenient for the user to select from. Only 5ml, 10ml, 20ml, 30ml and 50ml/60ml syringes that comply with national standards should be used with this syringe pump. For specific syringe brands, please refer to actual syringes as the standard.

- Select [Main Menu]→[User Maintenance]→Input User Maintenance Password→[Syringes].
- 2. Select in [Syringes] according to actual needs.

Note: Please ensure that at least one "Syringes" to be selected.

Brand and model of compatible syringes:

No.	Brand and Model	5ml	10ml	20ml	30ml	50ml
1	Dove Sterile Hypodermic Syringes for Single Use	V	V	V	V	√
2	B.Braun Original Perfusor Syringe			\checkmark		√

7 Other Functions

7.1 History Record

The syringe 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 syringe pump powers down.

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

7.3 Nurse Call

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

Switch

On: Indicates switching on the nurse call function.

Off: Indicates switching off the nurse call function.

Signal type

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

Pulse: Indicates the output nurse call signal is a pulse signal with the type of 1 second. When several alarms exist at the same time, only one pulse signal can be outputted. If the current alarm is not removed and another alarm occurs, then one additional pulse signal is outputted.

Trigger type

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

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

WARNING

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

NOTE

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

7.4 Wireless Networking (Optional)

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

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

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

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

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

NOTE

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

7.5 Data Export

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

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

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 animal cannot continue due to the unexpected breakdown or pause/delay of the syringe pump.

WARNING

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

8.1 Alarm Level

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

8.2 Alarm Types

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

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

8.2.1 Multi-level Alarm Rules

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

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

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

NOTE

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

8.3 Alarm Handling Rules

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

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

NOTE

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

8.4 Alarm Countermeasures

MARNING

 When an alarm is triggered, the animal'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 animal;
- 2. Check the alarm type and the parameter which triggered the alarm;
- 3. Determine the reason for the alarm;
- 4. Eliminate the reason for the alarm;
- 5. Check whether the alarm has cleared.

NOTE

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

Battery

⚠ WARNING

- The battery can not be disassembled. The battery should be changed by maintenance staff designated by the company only. Changing the battery incorrectly or changing battery by personnel who has not received suitable training may cause such danger as overtemperature, fire or explode.
- Use only manufacturer-specified battery for this device. Use of a different battery may cause such danger as overtemperature, fire or explode.

NOTE

When the built-in battery and external power encounter failure, the display will off, a high level alarm will be triggered, the buzzer will sound out and the red alarm light will continuously flash.

The syringe pump is configured with rechargeable Lithium batteries to ensure that the syringe pump can be used normally under the condition of the animal's migration within the hospital or during the circumstance of a power failure. When the syringe pump switches to the AC power, the battery can be charged regardless of whether the syringe pump is on or off. The battery is chargeable only within the syringe pump. During charge, the battery icon in the upper-right corner of the screen floats up and down. If the battery icon stops floating and is completely filled, it indicates that the battery is fully charged. Under the condition of a sudden power failure, the system 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 syringe 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 [**No Battery**] alarm will be triggered when the battery voltage is too low, and red alarm light will flash. The alarm will continue within the remaining time of the battery's electric quantity and cannot be paused. Now, the syringe 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 syringe 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 animal and stop the infusion.
- 2. Switch the syringe 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 syringe pump until the syringe pump is closed.
- 4. Switch the syringe 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 animal and stop the infusion.
- 2. Switch the syringe 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 syringe pump until the syringe 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 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 [No Battery] alarm is triggered.
 To prevent battery not used for a long time or in No Battery 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 animals are using the pump.

10.2 Cleaning

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

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

To clean your equipment, follow these rules:

- 1. Turn off the pump and disconnect the AC power source line.
- 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 syringe pump. You are recommended to disinfect only when it is necessary in your desired maintenance plan. Clean the equipment before disinfection.

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

ACAUTION

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

11 Maintenance

AWARNING

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

11.1 Inspection

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

The inspection criteria are:

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

If there are any forms of damage or abnormal circumstances, do not use the syringe 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	Once every two years. Perform after the
to the IEC60601-1 standard.	board is changed or the syringe pump is
to the IEC60601-1 Standard.	accidentally dropped.
Preventive maintenance (refers to the	Once every two years, or when you
Maintenance Manual for pressure	suspect the occlusion alarm is abnormal,
calibration, sensor calibration, and	the flow volume is inaccurate, or the
pump inspection).	syringe is incorrectly identified.

11.3 View Information

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

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

11.4 Accuracy Calibration

The syringe in the syringe pump needs no daily calibration. But calibration is required when the syringe pump is used for the first time, is replaced with a new syringe brand or when you suspect the deviation of the flow volume is much larger.

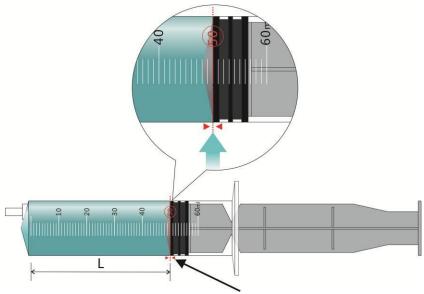
Prepare the following materials before the calibration:

Syringe: Standard 5ml, 10ml, 20ml, 30ml, and 50ml/60ml syringes, without liquid.

The steps for calibration are as follows:

- Load the syringe correctly and pull the syringe to the full scale position. "L" in the fig. below refers to the full scale position of the 50ml syringe.
- 2. Select [Main Menu]→[User Maintenance]→Input User Maintenance Password→[System Calibration]→[Accuracy Calib.].
- 3. Select Brand and Size of the current syringe in the [Syringe Selection] interface.

- 4. Press and the syringe pump starts automatic calibration.
- 5. The screen prompts [Calibration successful] after the calibration is successful.
- 6. Press c to exit the current interface.



Please align the front end of the plunger rod's sealing plug with the full scale position mark

NOTE

 The 60ml syringes used in this pump can only support 50ml for infusion at maximum, full range infusion is not supported.

11.5 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 syringe pump, or cannot reach the specification in this manual.
- Please do not replace an accessory if its package or itself is damaged.

Materials	PN
	009-002755-00
	009-002756-00
Power cord	009-003358-00
(Select PN according to sales area)	009-002757-00
	009-003651-00
	009-002758-00
Standard pole clamp	115-031551-00
Advanced pole clamp	115-031552-00
Nurse call cable	115-034140-00
RS232 communication cable	115-034142-00
DC input cable	115-034144-00
Pet bracket	115-033273-00

Cable specifications:

Item	Length (m)	Whether shielded	Comments
Power cord	2.5	No	/
DC cable	2.8	No	With magnetic ring
Nurse call cable	2.8	No	With magnetic ring
Serial port communication cable	2.8	Yes	1

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.1 Safety Specifications

A.1.1 Product Classification

Classifications of this syringe pump according to the IEC60601-1 standard are as follows:

Safety		
Components	Host	
Type of protection against electrical shock	Class I	
Degree of protection against electrical shock	Type CF defibrillation proof	
Ingress Protection	IP34	
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	
Mode of operation	Continuous	
Mobile level	Portable	

NOTE:

- CF: Type CF applied parts can be directly used in the heart.
- IP34: Protected against solid foreign objects with a diameter no less than 2.5mm and protected against spraying water.
- Portable devices: Can be moved from one place to another by one or more persons or by other means when the devices are in use or being used.

A.1.2 Operating Environment

Work environment			
Temperature	5-40°C		
Humidity	15-95%, non-condensing		
Atmospheric pressure	57-106 kPa		
Storage environment			
Temperature	-20-60 °C		
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, T5AL/250V		
External DC power supply			
Voltage	DC 10V-16V		
Current	2.00-1.25A		

A.2 Physical Specifications

Components	Weight	Size
Host	Less than 1.8kg (One battery included, without pole clamp)	Less than 340mm (length)x125mm (width) x135mm (height) (Without pole clamp)

A.3 Hardware Specifications

A.3.1 Display

Display	
Туре	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	Lithium battery	
Shutdown delay	At least 30 mins (new battery, after the first low battery alarm)	
Battery voltage	7.2V	
Battery capacity	2600 mAh (1 battery) or 5200 mAh (2 batteries)	
Power supply time	By factory default, continuously operate at a rate of 5 ml/h, discharge for at least 6h (1 battery) or 12h (2 batteries) using a fully charged new battery.	
Charging time	When the pump is off, the charging time is not longer than 5h (1 battery) or 10h (2 batteries).	

A.3.3 Host LED

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

A.3.4 Auditory Indicator

	Produce an alarm, the sound pressure is 56-80 dB(A) and key
Speaker	beep; Support multi-level volume functions; The alarm sound
	meets the requirements of the IEC60601-1-8.

A.3.5 External Ports

Ports		
AC power supply port	One AC power supply port	
Multifunction	One multifunction interface with the following functions:	
interface	■ DC power supply port	
	■ RS232 interface	
	■ Nurse call 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 Specifications

Parameters	Specifications	Factory Default
Syringe standard	Syringe used in conjunction with syringe pump should meet the requirements of ISO 7886-1: Sterile hypodermic syringes for single use.	/
Compatible syringe sizes	5ml, 10ml, 20ml, 30ml, 50ml/60ml	/
Rate	 5ml syringe: 0.1-150ml/h 10ml syringe: 0.1-300ml/h 20ml syringe: 0.1-600ml/h 30ml syringe: 0.1-900ml/h 50ml/60ml syringe: 0.1-2000ml/h The minimum increment is 0.1ml/h Note: The 60ml syringes used in this pump can only support 50ml for infusion at maximum, full dimension infusion is not supported. 	
Bolus Rate	 5ml syringe: 0.1-150ml/h 10ml syringe: 0.1-300ml/h 20ml syringe: 0.1-600ml/h 30ml syringe: 0.1-900ml/h 50ml/60ml syringe: 0.1-2000ml/h 	1. If the maximum rate of the spec. of syringe <800ml/h, the default bolus rate is the maximum rate of the spec. of syringe; 2. If the maximum rate of the spec. of syringe ≥800ml/h: current rate <800ml/h, and the default bolus rate is 800ml/h; if current rate ≥800ml/h, the default bolus rate is the maximum rate of the spec. of syringe.
Purge Rate	 5ml syringe: 150ml/h 10ml syringe: 300ml/h 20ml syringe: 600ml/h 30ml, 50ml/60ml syringe: 800ml/h 	 5ml syringe: 150ml/h 10ml syringe: 300ml/h 20ml syringe: 600ml/h 30ml, 50ml/60ml syringe: 800ml/h
VTBI	0.1-9999ml	
Time	00:00:01-99:59:59 h:m:s	
Volume	0.1-9999ml	0 ml
Select Mode	Rate Mode, Body Weight Mode, Time Mode, Intermittent Mode	Rate Mode

	5 Levels are adjustable, respectively are: 75±50mmHg (10.0±6.7kPa), 150±125mmHg (20.0±16.7kPa), 300±125mmHg (40.0±16.7kPa),		
Pressure	525±125mmHg (70.0±16.7kPa), 900±180mmHg (120.0±24.0kPa). Maximum occlusion pressure is about 1080mmHg. Note 1: The detected pressure of the infusion system (syringe pump and syringe) is affected by inner diameter, piston, material of the syringe and other factors. Therefore, syringes of different brand and model may differ in the detected pressure range. Note 2: The above declared pressure is based on Dove and B.Braun Original Perfusor Syringe (75mmHg is only available for B.Braun Original Perfusor Syringe at a rate of ≤100ml/h), temperature of 20±2°C.	525mmHg	
KVO Rate	0.1-5.0ml/h	0.5ml/h	
Time Near End	Off, 1-30min when the time is <10min, step for 1min, and step for 5 min when the time is ≥10min.	3min	
Max. Rate Limit	 5ml syringe: 0.1-150ml/h 10ml syringe: 0.1-300ml/h 20ml syringe: 0.1-600ml/h 30ml syringe: 0.1-900ml/h 50ml/60ml syringe: 0.1-2000ml/h 	 5ml syringe: 150ml/h 10ml syringe: 300ml/h 20ml syringe: 600ml/h 30ml syringe: 900ml/h 50ml/60ml syringe: 2000ml/h 	
Auto-lock Time	Off, 1-5 min, step for 1min	Off	
Reminder Time	Off, 1-5 min, step for 1min	2min	
Weight Unit	kg, lb	kg	
Sound Volume	1-8	4	
Brightness	1-8	4	
Contrast	150-220	170	
Night Mode	On, Off	Off	
Nurse call	On, Off	Off	
History Record	Can store up to 1500 history records	1	
Brand Selection	and Selection On, Off		

BW Mode Configuration	Conc., Drug Amount and Volume	Conc.
Drug Library	On, Off	Off
Para. Memory	On, Off	Off
	Time::	00:00
	Date:	01-01-2018
Date and Time	Time format: 12h, 24h	24h
	Date format: yyyy-mm-dd, mm-dd-yyyy or dd-mm-yyyy	Domestic: yyyy-mm-dd International: dd-mm-yyyy
Language	You can select language according to actual needs	1
Pressure Unit	mmHg, kPa, bar and psi	mmHg
Alarm Sound	Sound1, Sound2, Sound3	Sound2
Anti-bolus switch	On, Off	On
Infusion accuracy	Infusion accuracy ≤±2% or ±0.005ml/h, whichever is larger Note 1: The infusion accuracy of the infusion system (syringe pump and syringe) is affected by inner diameter, piston, material of the syringe and other factors. Therefore, syringes of different brand and model may differ in the infusion accuracy. Note 2: The above declared infusion accuracy is based on Dove and B.Braun Original Perfusor Syringe, temperature of 20±2°C.	
Mechanical accuracy	Mechanical accuracy error ≤±1%	/
Dose of single fault	About 1.2ml	/
Status indicators	atus indicators Stop, running, bolus, KVO, pause, standby, alarm and purge	
Alarm Information See complete information in <i>C Alarm Information</i>		/

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

Occlusion Pressure (mmHg)	Rate (ml/h)	Time of Occlusion Alarm (hh:mm:ss)
	0.1	01:16:01
75	1	00:08:35
	5	00:06:00
	0.1	09:11:42
900	1	00:53:13
	5	00:15:00

Pressure Setting	Rate (ml/h)	Bolus Volume (ml)
75	5	<0.2
900	5	<0.332

NOTE

• Test conditions:

✓ FLUKE IDA4 PLUS tester

✓ Syringe brand: B.Braun Original Perfusor Syringe

✓ Syringe specification: 20ml✓ Test temperature: 20±2°C

✓ Extension tube length: 1.5 meter

- Occlusion alarm pressure, alarm delays and bolus volume may vary depending on test conditions, temperature and tube length. Using large size syringes to infuse at low rate may cause longer occlusion alarm delay.
- The above data are only typical values under normal test conditions. The actual data may vary as test conditions change. Please refer to the test data for the product you have purchased. Under the same standard occlusion value and rate, the higher the value of the tested pressure is, the longer the alarm time will be delayed.

A.6 Infusion Accuracy Curve

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.

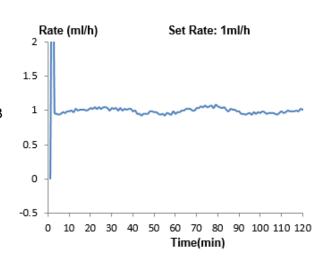
Plotted on the basis of data collected over a two-hour measurement period.

Syringe brand: B.Braun Original Perfusor Syringe Syringe specification: 20ml Sampling quantity of pump: 3 Sampling quantity of syringe: 3

Sampling rate: 1ml/h

Sampling interval: ∆t =0.5 min Test period: t =120 mins

Infusion rate: Q (m/h)

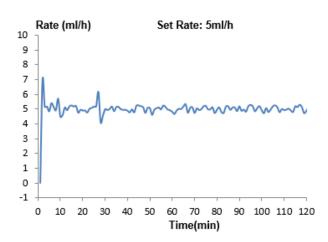


Syringe brand: B.Braun Original Perfusor Syringe Syringe specification: 20ml Sampling quantity of pump: 3 Sampling quantity of syringe: 3

Sampling rate: 5ml/h

Sampling interval: ∆t =0.5 min

Test period: t =120 mins Infusion rate: Q (m/h)



NOTE

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

A.7 Trumpet Curve

Flow rate deviation over time (p∆t)

Syringe brand: B.Braun Original Perfusor Syringe

Syringe specification: 20ml Sampling quantity of pump: 3 Sampling quantity of syringe: 3

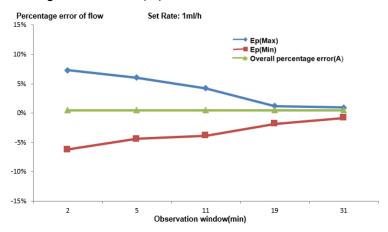
Sampling rate: 1ml/h

Sampling interval: ∆t =0.5 min

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

Maximum deviation over the course of a full observation window: EPmax (%) Minimum deviation over the course of a full observation window: EPmin (%)

Average deviation: A (%)



Syringe brand: B.Braun Original Perfusor Syringe

Syringe specification: 20ml Sampling quantity of pump: 3 Sampling quantity of syringe: 3

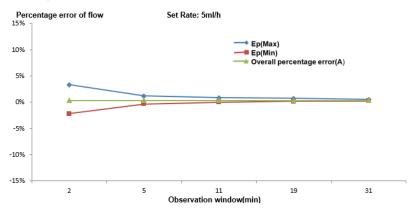
Sampling rate: 5ml/h

Sampling interval: ∆t =0.5 min

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

Maximum deviation over the course of a full observation window: EPmax (%) Minimum deviation over the course of a full observation window: EPmin (%)

Average deviation: A (%)



B EMC and Radio Regulatory Compliance

B.1 EMC

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

NOTE

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.
- The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.
- This device is intended for use in professional healthcare facility environment only. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.

Guidance and Declaration - Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance	
Conducted and radiated	Group 1	The device uses RF energy only for its	
RF EMISSIONS CISPR 11		internal function. Therefore, its RF	
		emissions are very low and are not likely to	
		cause any interference in nearby electronic	
		device.	
Conducted and radiated	Class A	The device is suitable for use in all	
RF EMISSIONS CISPR 11		establishments other than domestic and	
		those directly connected to the public	
		low-voltage power supply network that	
		supplies buildings used for domestic	
		purposes.	
Harmonic distortion	Class A	The device is suitable for use in all	
IEC 61000-3-2		establishments, including domestic	
Voltage fluctuations and	Complies	establishments and those directly	
flicker IEC 61000-3-3		connected to the public low-voltage power	
		supply network that supplies buildings used	
		for domestic purposes.	

NOTE

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

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

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

Guidance and Declaration - Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test	Compliance level	Electromagnetic
	level		environment -
			guidance
Electrostatic	±8 kV contact	±8 kV contact	Floors should be wood,
discharge	±15kV air	±15kV air	concrete or ceramic tile.
(ESD)			If floors are covered with
IEC 61000-4-2			synthetic material, the
			relative humidity should
			be at least 30%.
Electrical fast	±2 kV for power	±2 kV for power	Mains power quality
transient/burst	supply lines	supply lines	should be that of a
IEC 61000-4-4	±1 kV for	±1 kV for	typical commercial or
	input/output lines	input/output lines	hospital environment.
	(length greater	(length greater	
	than 3 m)	than 3 m)	
Surge IEC	±1 kV line(s) to	±1 kV line(s) to	
61000-4-5	line(s)	line(s)	
	±2 kV line(s) to	±2 kV line(s) to	
	earth	earth	
Voltage dips	0 % U _⊤ for 0,5	0 % U _T for 0,5	Mains power quality
and Voltage	cycle	cycle	should be that of a
interruptions			typical commercial or
IEC 61000-4-11	0 % U _⊤ for 1 cycle	0 % U _T for 1 cycle	hospital environment. If
	and 70 % U _T for	and 70 % U _T for	the user of our product
	25/30 cycles	25/30 cycles	requires continued
			operation during power
	0 % U _T for 250/300	0 % U _T for 250/300	mains interruptions, it is
	cycle	cycle	recommended that our
			product be powered
			from an uninterruptible

			power supply or a
			battery.
RATED power	30 A/m	30 A/m	Power frequency
frequency	50 Hz / 60 Hz	50 Hz / 60 Hz	magnetic fields should
magnetic fields			be at levels
IEC 61000-4-8			characteristic of a
			typical location in a
			typical commercial or
			hospital environment.

Note: U_T is the A.C. mains voltage prior to application of the test level.

Guidance and Declaration - Electromagnetic Immunity

The device is intended for use in the specified electromagnetic environment. The customer or the user of the device should assure that it is used in such an environment as described below.

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

9 V/m	9 V/m	electromagnetic site survey ^b , should
704–787 MHz,		be less than the compliance level in
5100-5800		each frequency range ^c .
MHz		Interference may occur in the vicinity
		of equipment marked with the
		(((•)))
		following symbol: `` A ''.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- ^a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
- ^b Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
- ^c Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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

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

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

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

B.2 Radio Regulatory Compliance

RF Parameter

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



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

C Alarm Information

This chapter presents the alarm information of the syringe 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	Alarm	_	_
Information	Level	Reason	Countermeasure
[Occlusion]	High	Infusion cannula blocked during infusion, and occlusion pressure reaches the threshold of preset occlusion pressure threshold. Infusion is stopped after the alarm is triggered.	Press to cancel alarm, check and eliminate the source of the alarm.
[No Battery]	High	 Only powered with built-in battery, battery is empty. Built-in battery and external DC power encounter failure. 	Connect to the AC power source to cancel alarm.
[VTBI Complete]	High	Infusion volume reaches the preset VTBI.	1. Press to stop infusion and cancel alarm. 2. Or alarm is cancelled when reach the KVO infusion time. 3. Or press ok to confirm KVO infusion to cancel alarm.
[KVO Finish]	High	KVO infusion has run for 30 minutes. Infusion is stopped after the alarm is triggered.	Press to cancel alarm.

[Syringe Disengaged]	High	Syringe is disengaged during infusion. Infusion is stopped after the alarm is triggered.	Check and eliminate the source of the alarm, press to cancel alarm.
[System Error]	High	Power supply voltage abnormal (overhigh), AD value of sensor abnormal, communication abnormal and other errors.	Alarm cannot be cancelled. Please stop operation and contact the company.
[Syringe Empty]	High	The syringe is empty during the infusion. Infusion is stopped after the alarm is triggered.	Check and eliminate the source of the alarm, press to cancel alarm.
[No Syringe]	High	Start infusion without loading syringe or loading syringe syringe incorrectly.	Correctly load the syringe or press to cancel alarm.
[System Abnormal]	Medium	Power supply voltage abnormal (low) and other abnormal.	Alarm cannot be cancelled. Please stop operation and contact the company.
[Standby Time Expired]	Medium	Pump is in standby mode and standby time is completed.	Press or to cancel alarm.
[Reminder]	Low	The syringe pump performs no operation during the set reminder time after the syringe is loaded.	1. Operate the pump (except press) to cancel alarm. 2. Or press to acknowledge the alarm condition.
[Low Battery]	Low	Only powered with built-in battery, battery charge is insufficient.	1. Connect to the AC power source to cancel alarm. 2. Or press to acknowledge the alarm condition.

[Time Near End]	Low	Infusion remaining time reaches the setting value of [Time Near End].	1. The alarm will not be cancelled automatically until the infusion is completed, and then switch to [VTBI Complete] or [Syringe Empty] alarm. 2. Or press to cancel alarm. 3. Or press to acknowledge the alarm condition.
[Syringe Near Empty]	Low	Required time for the remaining liquid within the syringe reaches the setting value of [Time Near End].	1. The alarm will not be cancelled automatically until the infusion is completed, and then switch to [VTBI Complete] or [Syringe Empty] alarm. 2. Or press to cancel alarm. 3. Or press to acknowledge the alarm condition.
[No AC Power]	Low	Power cord disconnects when the pump has connected to an AC/DC power supply.	1. Connect to an AC/DC power supply to cancel the alarm. 2. Or press to cancel alarm.

[Communication interrupted]	Low	Syringe 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 syringe pump(s) and BeneFusion CS5 Infusion Supervision System.
[KVO Running]	Low	The alarm is triggered after [VTBI Complete] alarm is triggered and in KVO mode.	1. Press to stop infusion and cancel alarm. 2. Or the [KVO Finish] alarm is triggered when reach the KVO infusion time.
[Infusion interrupted]	Low	The alarm is triggered after any of the [Occlusion], [Syringe Disengaged] or [No Battery] alarm is cancelled.	Press or to cancel alarm.
[Please reset time]	Low	RTC time is reset when the pump is on.	Reset the time or press to cancel alarm.
[Para. Unconfirmed]	Low	The alarm is triggered if no operation is performed within 10s under the parameters setting status.	Press any key to cancel alarm.

NOTE

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

D Symbols and Terms

D.1 List of Units

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

D.2 List of Symbols

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

D.3 List of Terms

Abbreviation	Meaning
AC	Alternating current
Anti-Bolus	Anti-Bolus
BOLUS	Bolus
CCU(CICU)	Cardiac Intensive Care Unit
CE	Conformité Européenne
CISPR	International Special Committee on Radio Interference
CPU	Central processing unit
DC	Direct current
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

D.4 List of Unit Conversion

Unit Symbols	Unit Conversion
kPa	1kPa=7.5mmHg=0.145psi=0.01bar
psi	1psi=51.724mmHg=6.897kPa=0.069bar
bar	1bar=750mmHg=14.5psi=100kPa
lb	1 lb=0.454kg

E Toxic and Hazardous Substances or

Elements

Pb Hg Cd Cr(VI) PBB PBDE Name of the Parts Cr(VI) **PBB** Pb Hg Cd **PBDE** 0 Front housing Back housing Device 0 Keys housing 0 0 0 0 0 0 Facing 0 0 0 0 0 0 Labels Display Display 0 0 Host hardware 0 0 0 0 0 0 Host Internal cables 0 0 0 0 0 0 **PCBA** Cartons (K=K crimp paper) Foam packages 0 0 0 0 0 Packaging (EPE) 0 0 0 0 0 0 Plastic bag (PE) 0 0 0 0 Connecting pieces General 0 Power cord 0 0 0 0 0 0 **Battery Battery** Accessories Accessories o: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in Directive 2011/65/EU. Remark X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in Directive 2011/65/EU.

Declaration of Conformity

Declaration of Conformity V2.0

CE

Declaration of Conformity

Manufacturer: Shenzhen Mindray Scientific Co., Ltd.

6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District,

518106 Shenzhen, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, Germany

Product: Syringe Pump

Model: BeneFusion SP3 Vet

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 60601-1-2:2015	
⊠ 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	

Start of CE-Marking: 2017-5-18

Place, Date of Issue: Shenzhen

Signature: Bai/anhoy >

Name of Authorized Signatory: Bai Yanhong

Position Held in Company: Manager, Technical Regulation

