Copyright

Manual Version: V1

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Product Name: Infusion pump

Software Version: V1

Date of Manufacture: Refer to the Nameplate

Service life: 10 years

Company name: Shenzhen Comen Medical Instruments Co., Ltd.

Statement

Warranty

Comen is responsible for the safety, reliability and performance of the product only if all of the following conditions are met:

- The product is used in accordance with the User Manual.
- The product is installed, repaired or upgraded by personnel approved or authorized by Comen.
- The product's storage, operating and electrical environment meet product specifications.

- The product's serial number label or manufacturing mark is clearly legible. It has been certified by Comen, and it is confirmed that the product is manufactured by Comen.
- Damage caused by non-user factors (such as accidental fall, vandalism, etc.).

Comen provides free of charge services for all products based on Comen's Warranty Service Regulations. In addition, it also provides paid services for products beyond the scope of the warranty. The products need to be shipped to Comen for repair and the user shall bear freight expense (including customs fees).

Returns

If you need to return the product to Comen, please follow the below procedure:

Request for product return: Contact Comen's after-sales service department and inform them of the product number marked on the product's nameplate. If the equipment number is not legible, return will not be accepted. Please indicate the equipment number, production date, and a brief description of the reason for return.

After-Sales Service Department

Name: After-Sales Service Department of Shenzhen Comen Medical Instruments Co., Ltd.

Address: Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, 518106, Guangdong, P.R. China.

Tel.: +86-755-26431236

Fax: +86-755-26431232

Customer service hotline: +86-755-4007009488

Preface

This Manual describes the performance, operation methods and other safety information of the infusion pumps manufactured by Comen.

This Manual introduces the product according to the most complete configurations. The product you have purchased may not possess some configurations or functions.

Please read this Manual carefully before using the infusion pump. And keep it in a safe place for further reference by the operator.

Intended Users

This infusion pump is intended to be used by healthcare professionals.

Intended Patients

This infusion pump is applicable for adult, pediatric and neonatal patients of all clinical departments of the hospital.

Intended Institutions/Units

The infusion pump is expected to be used in professional healthcare facilities. It also supports the use in emergency environment, such as in ambulances.

Intended Body Parts, Tissues, or Areas of Interaction

This infusion pump can be used with an infusion set or blood transfusion set through which to be connected to human vein for drug infusion or blood transfusion. It can also be used with an enteral feeding tube which is to be connected to gastrointestinal route for nutrient solution feeding.

Emphasis

This product should be assembled, operated, maintained and repaired in accordance with the instructions in this User Manual. This product must be inspected regularly. If this product is faulty, unusable, worn, deformed, or contaminated, has damaged parts & missing parts and needs to be replaced or repaired, immediately contact your local customer service center or agent of Comen for assistance. Repair of this product and any parts thereof must be in accordance with the written instructions provided by our company and repaired by trained personnel. This product may not be altered without the written consent of Comen. If the product fails due to improper use, damage, or repaired by anyone other than Comen, the user who owns the product assumes full responsibility.

Illustrations

All illustrations provided in this Manual are for reference only. The menus, settings and parameters shown in the illustrations may be not exactly identical to those shown on the infusion pump.

Conventions

- —>: Represents operation steps.
- [Character]: Represents character strings in the software.

The password of user maintenance: please refer to the Service Manual for infusion pumps.

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Chapter 1 Safety Information

1.1 Overview of safety information

⚠ WARNING

- **It reminds you of serious consequences, adverse events, or security breaches. Failure to follow the warning will result in serious personal injury or death of the operator or the patient.**

⚠ CAUTION

- **It indicates potential danger or unsafe operation. If not avoided, it may lead to minor personal injury, product malfunction/damage, or property loss. It may also cause more serious damage in the future.**

⚠ NOTE

- **It emphasizes primary warnings or provides instructions or explanations so that this product can be used properly.**

⚠ WARNING

- **The pump should not be installed or stored in a location where liquid can easily spill, as liquid spills on the infusion pump's power cord can cause a short circuit.**
- **Don’t immerse or submerge the pump in liquid, and do not pour liquid on the device.**
- **Do not install or store the infusion pump in a chemical warehouse or where a gas discharges.**
- **Personnel using this product should be professionally trained. Anyone who is not**

authorized and trained must not perform any operations on the equipment.

- This pump is a portable device, but not for ambulatory use. It cannot be carried continuously by the patient during the infusion. When used on the road ambulance, the device is fixed installed.

⚠ CAUTION

- Do not install or store the infusion pump in locations where there is:
  - Direct sunlight or strong light.
  - Extreme air pressures.
  - Dust or corrosive gases in the air.
  - The presence of strong vibration.
  - An uneven or broken floor surface.
  - A heatheat source or heating equipment nearby.
  - A risk of water splashing onto the device.
- Do not use radio or TV near the infusion pump.

⚠ NOTE

- Install the pump in a place where it is easy to observe, operate and maintain.
- Place the User Manual near the pump so that it can be easily and quickly referred to when required.

⚠ WARNING

- Only use a specially designated power supply for the infusion pump, otherwise there is risk of fire or electric shock.
- Plug the device's power cord into a wall socket with grounding. Protect the power cord from wear and tear, as there is risk of fire or electric shock if the power cord is damaged.
- Do not unplug or plug in the power supply with wet hands, otherwise there is risk of electric shock.
- Maintenance of this product is required to be carried out by authorized personnel of Comen. Comen may conditionally provide authorized maintenance personnel with all necessary technical documents related to maintenance, such as circuit schematics

and key component lists.

- **Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.**
- **Disconnect the pump from the AC power supply before maintenance, cleaning or disinfection, or there may be some risk of electric shock.**
- **If the pump is disconnected from the AC power supply or the built-in battery is low or nearly depleted, corresponding alarms will be triggered. Under this condition, please connect the pump to the external power supply in time, as power outage during infusion will cause patient injury.**

⚠ CAUTION

- **Connect the power cord to an appropriate-sized socket.**
- **High-frequency instruments or equipment that consume lots of power, such as electrical surgical instruments, should be connected to separate AC socket.**
- **If you need to operate the infusion pump with a battery, check the charging status and battery status (whether the voltage is low, etc.) before operation. If it is used for the first time or after a long period, connect the battery to the AC power supply and fully charge it first.**

⚠ WARNING

- **Only professional clinicians, medical electrical engineers or qualified trained doctors and nurses are allowed to use this product.**
- **Before using this pump, you should read the entire manual carefully. Before you fully understand its operation, attempting to use this equipment will cause injury to the patient or user.**
- **Before using, you must check the device, cable and its accessories to ensure that they can work normally and safely.**
- **Do not place the power cord plug that disconnects the device from the AC power source in a location that is difficult for the operator to access.**
- **During use, the operator should always observe whether the device is properly connected to the power supply to avoid undesirable events such as shutdown caused by loose power connections.**
- **If the alarm volume is set too low or is completely turned off, the alarm will fail and**

the patient safety will be endangered. The most reliable patient monitoring method shall be to closely monitor the actual clinical situation of the patient.

- **This device can only be connected to a power socket with protective grounding. If the power socket isn't connected to a grounding conductor, please don't use this socket, but use the rechargeable batteries for power supply.**
- **Don't open the shell of this device to avoid possible electric shock hazard. The maintenance and upgrading of this device must be conducted by the service personnel trained and authorized by Comen.**
- **If the infusion pump fails or needs precision calibration, do not disassemble it by yourself. Please contact the manufacturer in time.**
- **The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. The packaging materials must be placed away from the children.**
- **Don't use this instrument near where there are flammable articles such as anesthetic to prevent explosion or fire from happening.**
- **Do not use in an environment with flammable anesthetic gas or other corrosive gas and dust.**
- **It is strictly forbidden to use a mobile phone or other wireless transmitting equipment at the same time within a 10-meter radius when the machine is working.**
- **It should not be used in an environment with direct sunlight.**
- **After turning on the power, the device conducts a self-test. If there is any error during the self-test, stop using the device immediately.**
- **The battery should not be replaced with a battery that is not dedicated to this device.**
- **The user shall protect the equipment from damage from impacts, drops, violent shaking or other external mechanical forces.**
- **Please carefully connect the power cord and the cables for various accessories to avoid the patient from being constricted, suffocated or the cables from getting entangled and keep them free from electrical interference.**
- **The equipment connected with the pump shall form an equipotential circuit (the protective grounding wire is effectively connected).**
- **When the pump is used with HF surgical equipment, the transducer and the cables must avoid conductive connection to the HF equipment to protect against burns to the patient.**
- **Electromagnetic fields will affect the performance of this device, so the use of other equipment near this instrument must meet corresponding EMC requirements. For example: mobile phone, X-ray or MRI equipment may be an interference source, because they will transmit high-strength electromagnetic radiation.**

- **This is not a therapeutic device.**
- **Setting a lower alarm volume can be dangerous for the patient.**
- **Please install and carry the equipment correctly to protect the equipment from damage from drops, impacts, violent shaking or other external mechanical forces.**
- **The operators shall not touch the patients and device at the same time.**
- **For relevant safety warning information and operation information of the control and management system used with this pump, please refer to the user manual of the relevant product.**
- **The alarm information displayed on the screen of this system is only for doctors' reference and cannot be used directly as a basis for clinical treatment.**
- **This device cannot be used in MRI and CT environment.**
- **If there is a problem with the installation of the external protective conductor or the integrity of its wiring, the device should be operated by an internal power source.**
- **During use, patients or their families cannot operate the equipment. Incorrect operation can cause danger to the patient.**
- **This pump cannot be used with high power, high temperature, high radiation, high noise, volatile corrosive gas equipment.**
- **This pump cannot be used in combination with high-frequency electrocautery and defibrillator.**
- **After each use of the pump, the power should be turned off to prolong its service life.**
- **The pump needs to be placed on a stable, vibration-free table or in a well-ventilated cabinet.**
- **This infusion pump should not be serviced or maintained while being used.**
- **Comen will conditionally provide users with technical materials such as circuit diagrams related to maintenance of the device as needed. This pump is only allowed to be repaired by after-sales maintenance engineers from Comen or authorized engineers.**
- **If the alarm volume is lower than the surrounding ambient noise level, it would lead to users having difficulties in identifying the status of the alarm and system operation, bringing potential danger to the patient.**
- **This pump cannot be used for infusion of analgesics, chemotherapy drugs and insulin.**
- **Before and after blood transfusion, wash the transfusion tube with intravenous saline.**

  When the blood of different donors is transfused continuously, after the previous bag of blood is exhausted, the blood transfusion set should be flushed with intravenous saline.
- **Please use the recommended disposable blood transfusion set and the operation**

process strictly follow the principle of aseptic operation. After use, the blood transfusion set should be strictly disinfected, destroyed and harmlessly treated.

- **It is recommended to change the transfusion set used for the transfusion of whole blood, blood components or biological agents every 4 hours. If the temperature increases, the change frequency should be increased.**
- **The nutrition tube should be washed with sterile saline before use. When it is used continuously, the tube should be washed every 4 to 8 hours.**
- **In order to ensure the infusion safety, please use the transfusion set for blood transfusion, the feeding tube for eteral nutrition and the infusion set for drug infusion.**
- **Always read manufacturer precautions and guidelines for medications, tubings and administration set used with this pump.**
- **Before starting any delivery, always confirm the set infusion parameters are always consistent with the doctor's order or prescription. Operating the infusion pump at an infusion rate other than that prescribed will cause inappropriate delivery, which can result in serious injury or death.**
- **Independ of the soft limits in the system, the selected values have to be the medically correct ones for the given patient.**
- **In case values relevant for the dose rate calculation (e.g. body weight) are changing, the flow rate and the dose rate will be updated.**
- **Before using low infusion rate for critical drugs, consider the start-up characteristics of this pump.**
- **In the event of tube twisting, filter condensation or intubation occlusion during infusion, the internal pressure of the tubing will increase. Once the causes for occlusion are removed, too much infusion liquid may be infused into the patient. Therefore, proper actions should be taken. For example, clamp the tube before removing the occlusion causes.**
- **The connection between the pump and the infusion system or the accessories connected to the patient line may cause the change of the infusion rate and increase the possibility of air input to the patient.**
- **Regularly check whether the infusion set and tubing for infusion and infusion flow are normal during operation.**
- **Defibrillation will not affect the basic performance (such as infusion accuracy, alarm and signal transmission) of the pump.**

⚠ CAUTION

- **To avoid damage to this instrument and to guarantee patient safety, please use the accessories designated in this User Manual.**
- **Before the device is switched on, please confirm whether the power supply used meets the requirements for power supply voltage and frequency designated in the nameplate label or in the User Manual.**
- **When this device and its accessories exceed their service life, they must be disposed of according to relevant local laws and regulations or the rules and regulations of the hospital.**
- **Disposable accessories must be recycled or properly disposed of.**
- **When using this device and its accessories, you should avoid using the pump and its accessories in direct sunlight, high temperature and humidity.**
- **The operating environment and power supply of this system must meet the requirements in the product specifications.**
- **In order to ensure infusion accuracy, the brand and sepcifications of the infusion set used must be the same as the selected infusion set in the system.**
- **Please use the infusion set recommended in this User Manual. If a non-specified infusion set is used, you need to calibrate the infusion pump; otherwise the infusion accuracy cannot be guaranteed.**
- **Before working with the built-in battery, check whether the battery has sufficient power and charge it if necessary.**
- **If there is any doubt about the installation or integrity of the wiring, the device should be operated by the built-in battery.**
- **After the infusion set is installed, and before starting the infusion, the user should check whether there are any leaks in the system. If there are any leaks present, they must be rectified prior to using this pump.**
- **After infusion is started, the user shall adjust the tube position or replace the transfusion components according to the infusion tube used. It is recommended to adjust the clamping position of the infusion tube every 6 to 8 hours and replace the infusion set every 8 hours to ensure accuracy.**
- **The infusion set and patient tube are treated as the applied part.**
- **The maximum infusion pressure at the end of the infusion set will be no higher than 1350mmHg under the condition of total occlusion at the end of the patient tube.**
- **The pump should not be placed more than 100cm above or below the level of the patient's heart. The smaller the height difference between the pump and the patient's heart, the more accurate the pressure test in the infusion cannula will be.**
- **The copyright of the device and its software is owned by our company.**

- **Do not modify this equipment without authorization of the manufacturer. Otherwise, hazards may result.**
- **Do no use an integral multiple socket-outlet or the AC power extension cord. Ensure that the sum of grounded leakage current does not exceed the allowable limit.**
- **When it is necessary to change the infusion set during infusion, please stop the infusion first and make sure that the selected brand of the infusion set in the system is the same as the infusion set actually used. If a non-recommended infusion set is going to be used, calibration is required. Otherwise the infusion accuracy will not be guaranteed.**

NOTE

- **This Manual introduces the product according to the most complete configurations. The product you purchased may not possess some configurations or functions.**
- **This pump cannot be used at home.**
- **When using the pump, the operator should be within 1 meter of the pump.**
- **The service life of the device is 10 years.**
- **Do not insert any devices not specified by Comen company into the USB interface, plug-in box interface, or expansion controller interface of the device.**
- **In a single fault condition, the maximum possible infusion volume will not exceed 0.5mL.**
- **If the pump is carrying out a bolus or a purging of the air system, no alarm is inhibited.**

1.2 Contraindications

None.

1.3 Side effect

None.

1.4 Symbols

- **Symbols on the device**

Symbols	Instructions	Symbols	Instructions
	Warning		Refer to the accompanying document
	Type CF, with the defibrillation-proof function		Serial number
	USB interface		Multifunction interface
	Pay attention to the correct direction of mounting the infusion tube		Main menu
IP33	Protected against solid foreign objects of Ø2.5 mm and greater; protected against spraying water.	CE 1639	Conformité Européene Complies with Medical Device Regulation (EU) 2017/745
	Manufacturer	100-240V~ 50/60Hz	Power specifications
	Bolus or purge		Alarm paused

	Start/Stop		Power on/off
	Symbol of infusion pump		Separate collection for electrical and electronic equipment
	Date of manufacture	/	/

- **Symbols on the packaging**

Symbols	Instructions	Symbols	Instructions
	This side up		Stacking Layer Limit (A is the actual number of devices that can be stacked is indicated on the packaging label)
	Fragile		Keep dry
	Temperature limit		Atmospheric pressure limit
	Humidity limit	/	/

- **Symbols on the interface**

Symbols	Instructions	Symbols	Instructions
	Maintenance		Patient information

	Parameter settings		System settings
	Main menu		Log
	Back		Scanner
	Reduce brightness		Increase brightness
	Increase pressure		Reduce pressure
	Increase volume		Reduce volume
	Volume off		Alarm settings
	Battery nearly full		Low battery
	The battery power is too low		Dead battery
	Battery being charged		No battery installed or damaged battery
	Battery being charged		Battery full
	Function on		Function off

	Stopped state or paused state		Infusion state
	Search		Audio off
	Previous page		Next page
	Night mode		USB connection successful
	CommunicateCommunication to other pumps or infusion workstation system		Drop clip is connected
	The wireless network is not connected		Very Weak signal
	Weak signal		Enter password
	Strong signal		No signal
	Lock screen icon		Screen unlock icon
	Alarm audio pause	/	/

Chapter 2 Principle

The infusion pump is a type of volumetric infusion pump. Through accurate control of the precision stepper motor by the microprocessor, the mechanical transmission structure is driven, causing regular movement of the peristaltic piece. Working with the sensors and the extruded plate, the rate of the disposable infusion set is accurately controlled, so that the infusion process will be controlled with high accuracy.

This infusion pump is applicable for clinical treatment requiring long-term, uniform and accurate control of the infusion rate and monitoring of the infusion process. It applies to infusion treatment in medical departments, surgical departments, pediatric departments, gynaecology and obstetrics departments, ICUs, CCUs and operating rooms in hospitals and other clinical applications.

Chapter 3 Product Overview

The design of this equipment complies with the domestic and international safety standards for medical electrical equipment.

⚠ WARNING

- **This product must only be used under appropriate conditions by professional clinicians, medical device technicians, or by suitably trained clinical medical personnel. 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.**

3.1 Structural composition

The infusion pump is mainly composed of a pump shell, motor driving system, input system, storage system, control system, display system, sensor monitoring system and alarm system.

3.2 Intended use

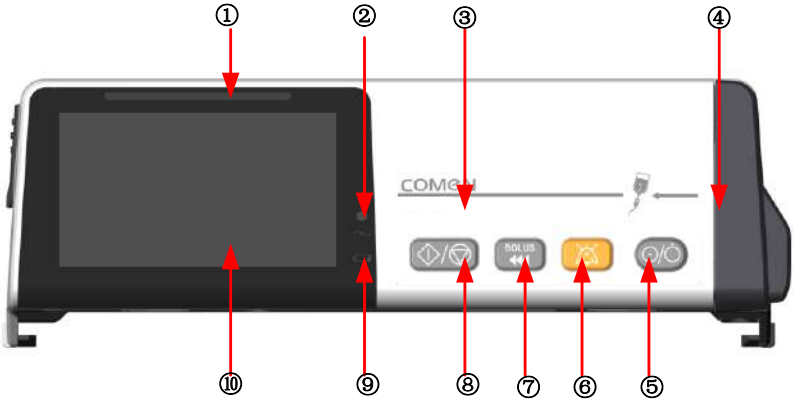
The infusion pump is suitable for adults, pediatrics, and neonates for the intermittent or continuous delivery of gastrointestinal nutrients, medications, blood, and blood products in introvenous or gastrointestinal route.

The infusion pump is expected to be used in professional healthcare facilities. It also supports the use in emergency environment, such as in ambulances.

The infusion pump is intended to be used by trained healthcare professionals.

3.3 Appearance

3.3.1 Front view

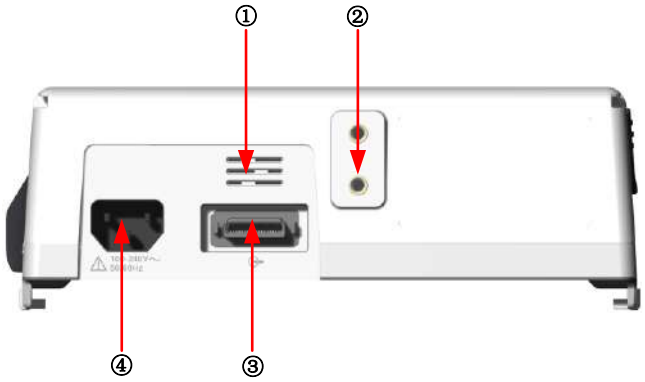


①	Alarm light	
②	AC indicator	On: The pump is connected to the AC power supply. Off: The pump is not connected to the AC power supply.
③	COMEN	Company logo
④	Door latch	To open or close the door of the pump
⑤	Power On/Off key	This button is used to power on/off and enter standby mode. Press this key to switch the pump on or off. In the off state, press and hold this key for more than 3 seconds and

		release, the pump will be turned on; when the power is turned on, and if in the non-infusion state, press the power key and select [**Turn Off**] in the dialog box, then the pump will shut down.
⑥	Alarm audio pause key	For high alarms and medium alarms where it is possible to pause the audio alarm, after pressing this key, the audio alarm will be paused for 2 minutes. In the audio paused state, the alarm indicators and alarm messages will continue to work. In the audio paused state, if a new alarm is triggered, the system will maintain the current audio paused state. Except for special alarms,, see ***Chapter 8 Alarm Messages*** for details.
⑦	Bolus/Purge key	Press this key during either paused or stopped states to enter the purge interface. Press this key during infusion to display the bolus interface. The purge volume will not be added to the total volume infused during purging, but the bolus volume will be added to the total volume infused during the bolus.
⑧	Start/Stop key	After installing the infusion set correctly and setting infusion parameters, press this key to start the infusion. During infusion and automatic bolus states, press this key to stop infusion. In the case that infusion is stopped

		by certain alarms, such as occlusion, press this key to cancel such alarms.
⑨	Battery indicator	On: Battery being charged Off: Battery not installed or battery full Flashing: Battery being used for power supply to the infusion pump
⑩	Display screen	

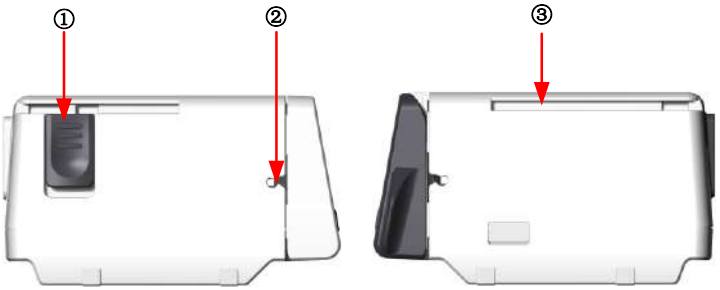
3.3.2 Rear view



①	Speaker holes
②	Pole clamp mounting holes (two)
③	Multifunction interface: DC power input interface; RS232 interface; Nurse call interface;

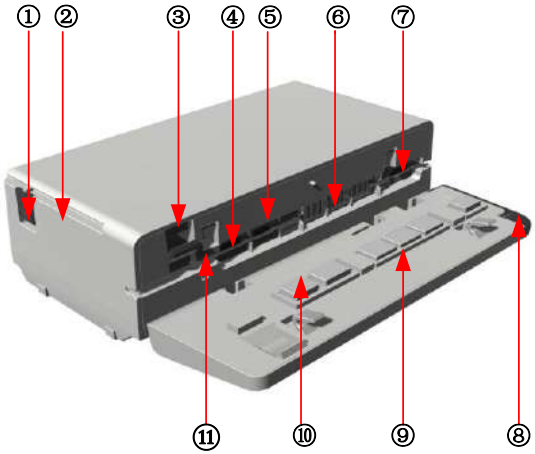
	KLink interface; USB interface (for connecting Scanner or for software upgrade)
④	Alternating current power supply (AC) port

3.3.3 Side view



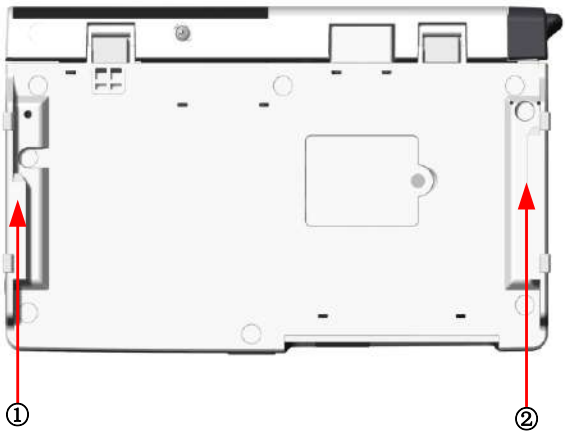
①	Multi-channel lock
②	Extension tube hook
③	Multi-channel connecting slide rail

3.3.4 Open door view



①	Multi-channel lock	⑦	Pressure sensor
②	Multi-channel connecting slot	⑧	Pump door switch
③	Anti-free-flow clamp button	⑨	Peristaltic extruded plate
④	Pressure sensor	⑩	Pressure sensor extruded plate
⑤	Bubble sensor	⑪	Flow regulator
⑥	Peristaltic system	/	/

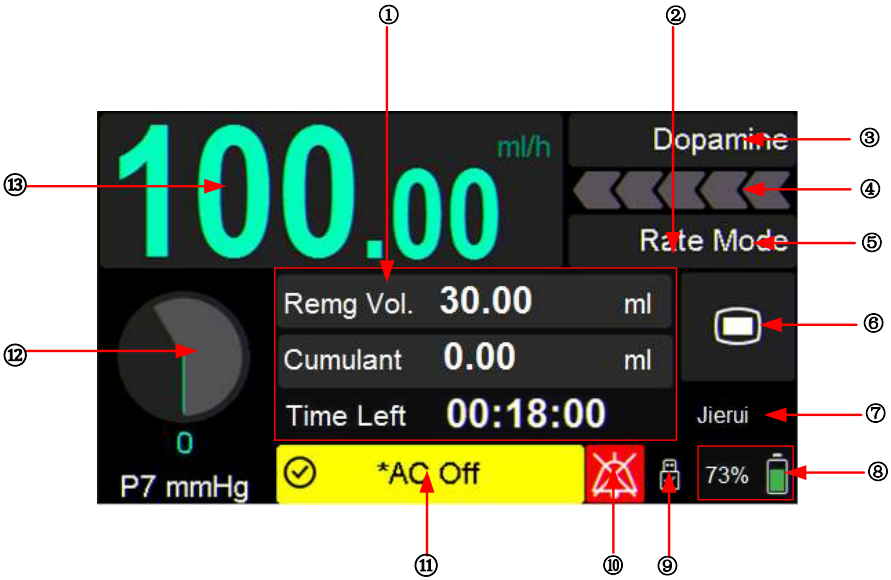
3.3.5 Bottom view



①	Multi-channel connecting slide rail
②	Multi-channel connecting slide rail

3.4 Screen display

The infusion pump is equipped with a touch screen. In addition, the brightness of screen can be adjusted. The main interface consists of alarm information, network connection status, battery status and other prompt information.



①	VTBI	⑧	Battery state of charge
	Total volume		Battery icon
	Time left	⑨	Wireless network icon 
②	Infusion mode		USB icon 
			WIFI icon 
			Night mode icon 
			Scanner 
			Relay infusion with other pumps or on the infusion workstation 
			Drip sensor icon 

			Screen locked icon 
③	Drug	⑩	Alarm audio pause icon
④	Status icon	⑪	Alarm information
⑤	Mode selection key	⑫	Pressure information
⑥	Main menu key	⑬	Rate and other parameters
⑦	Information of the infusion set	/	/
Note: Due to the different settings, the displayed information on the device screen may be different from the above figure.			

Chapter 4 Installation and Connection

⚠ WARNING

- **The software of this device is owned by our company. Without permission, any responsible organizations or individuals have no right to copy, modify and transfer by any means or forms.**
- **When this equipment is connected to other electrical equipment to form a combination of specific functions, if it is impossible to confirm whether the combination is dangerous from the specifications of each equipment (for example, the risk of electric shock due to the accumulation of leakage current), please contact us or qualified personnel of the hospital to ensure that the basic safety of all equipment in the combination is not compromised.**
- **When connecting this device with high frequency surgical equipment, the cable of this device shall not contact the high frequency surgical equipment to prevent patients from burn due to electricity leakage.**
- **All the simulation and digital equipment connected with this device must be products certified according to the designated IEC standards (e.g. IEC 60950-1 information technology equipment-safety and IEC 60601-1 medical electrical equipment – safety). Moreover, all the equipments connections shall conform to the latest edition of IEC 60601-1-1 System Standard. The staff in charge of connecting the additional equipment to the input/output signal port should configure the medical system and be respensible for the system's conformance to the IEC 60601-1-1 Standard. If you have any questions, please contact our company.**
- **In normal use, the operator should not touch the signal I/O ports and the patient simultaneously, otherwise it may cause patient injury.**
- **If more than one external equipment is connected to the pump at one time through the network connector or other signal interfaces, the total leakage current should comply with IEC60601-1.**

NOTE

- **This device should be placed in an approximately horizontal position.**
- **In order to ensure the normal operation of the device, please read this chapter and the safety information chapter before use, and install it as required.**
- **This product is not disinfected when it is delivered. Clean and disinfect the equipment before first use.**
- **Please fasten the pump by a clamp and connect the pump to the grounded AC power supply in case of using the pump in an ambulance. When connecting the pump to the DC power supply, please use the DC power supply cord designated by Comen.**
- **The equipment can be used on road ambulance of type A1, A2, B and C.**

4.1 Installation

4.1.1 Unpacking and examination

Please unpack the package in the correct way, carefully take out the device and accessories from the packaging box and keep the packaging materials for future transport or storage. Check the accessories one by one according to the packing list. Check if there is any mechanical damage and exposed wires. If you have any questions, please contact our sales department or agent immediately.

WARNING

- **If you find signs of damage to the pump, please contact with relevant personnel of your hospital or after-sales service of Comen.**
- **In order to prevent the infusion pump from being contaminated by microorganisms, do not remove the package of the pump prematurely. If the package of the pump is damaged, do not use it.**
- **Keep the packaging materials out of the reach of children. Disposal of the packaging materials is pursuant to applicable local laws and regulations or the waste disposal rules of the hospital.**

- **Please save the packaging materials for later transport or storage.**

4.1.2 Environmental requirements

The operating environment of the device should comply with the specified environment requirements in this Manual.

When the ambient temperature is 20℃, it takes 10 minutes for the pump to rise from the lowest storage temperature -20℃ to the temperature of expected use at intervals between 2 operations.

When the ambient temperature is 20℃, it takes 10 minutes for the pump to lower from the highest storage temperature 55℃ to the temperature of expected use at intervals between 2 operations.

If the device is working in an environment that fails to meet the requirements, the accuracy of the device may be affected and the components and circuits of the device may be damaged.

Use the device in an environment where vibration, dust, corrosive or combustible gases, extreme temperatures, and humidity are avoided.

⚠ WARNING

- **Please ensure that the infusion pump works under the specified environment, otherwise it will not meet the technical requirements specified in this manual, and may cause unforeseen consequences such as equipment damage.**

4.1.3 Fix the handle

Push down the multi-channel lock of the lower pump. Align the slide rails at both ends of the handle with the slide rail slots on the top of the pump, and slide from

the back to the front until the pump and handle are aligned. Then loosen the multi-channel lock. When you hear a click, the pump and handle are locked. When you need to remove the handle, firstly you need to push down the multi-channel lock of the lower pump, and slide the handle in the opposite direction to remove the handle.

A pole clamp can be installed at the rear of the pump, and the pole clamp can be adjusted by rotating the handle to fix the pump to the infusion pole.

4.1.4 Fix the pole clamp

Install the pole clamp by screws on the back of the pump and tighten the screws.

Rotate the handle of the pole clamp anticlockwise to allow the holder to be inserted into the pole clamp.

Rotate the handle of the pole clamp clockwise to fix the infusion pump on the infusion pole.

4.1.5 Fixing Multi-channel

Push down the multi-channel lock of the lower pump. Align the slide rail at the bottom of the upper pump with the slide rail slot of the lower pump, slide from back to front until the two pumps are aligned . Then loosen the multi-channel lock, when. When you hear a click, the pump and handle are locked.When separation is required, firstly you need to push down the multi-channel lock of the lower pump, slide the upper pump in the opposite direction to separate the two pumps.

Refer to the steps shown in ***4.1.4 Fix the holder***, the multi-channel combined pump can be fixed on the holder.

4.2 Preparation

4.2.1 Connect the AC power cord

Steps for connecting the AC power cord:

1. Before connecting the power cord, confirm that the AC power supply meets the specifications in this Manual.
2. Connect the power cable that came with the pump to a grounded socket.
3. Check whether the AC power indicator is on.

The AC power indicator is above the display. When the AC power is turned on, the white indicator lights up, indicating that the AC power connection is normal.

WARNING

- **Don't touch the power plug with wet or moist hands. If there is a liquid drug or residue on or around the power socket or plug, the user should completely clean and dry the area before plugging into the power supply, otherwise accidents or injuries may result.**

NOTE

- **Connect the power cable to a hospital-grade socket.**
- **When the device is equipped with a battery, recharge the battery after the device is transported or stored. If the device is started without an AC power supply, it may not work properly because of insufficient power in the battery. The battery is recharged when an AC power supply is connected, regardless of whether the infusion pump is started.**

Connect the equipotential grounding cable when necessary. Please refer to the content about equipotential grounding in this chapter.

4.2.2 Protective earthing

To protect both the patient and the operator, the metal housing of the device must be earthed. The device is supplied with a detachable power cable with integral 3-

pin plug, which shall be inserted into a grounded power outlet to connect the device to earth. If a grounded power outlet is not available, contact the electrician in your hospital.

⚠ WARNING

- **It is not allowed to connect the 3-pin power cable to a 2-pin power outlet.**

Connect the earth wire to the equipotential connector of the device. If it is unclear whether a particular combination of equipment is dangerous, such as risks caused by an accumulation of leakage current, the user should consult the relevant manufacturer or other experts in this field to ensure that the necessary safety of all the equipment will not be damaged by the proposed combination.

4.2.3 Condensation

Ensure that the pump is free from condensation during operation. When the pump is moved from one room to another, condensation may be formed due to exposure to damp air and temperature difference. In this case, do not use the pump until it has dried out.

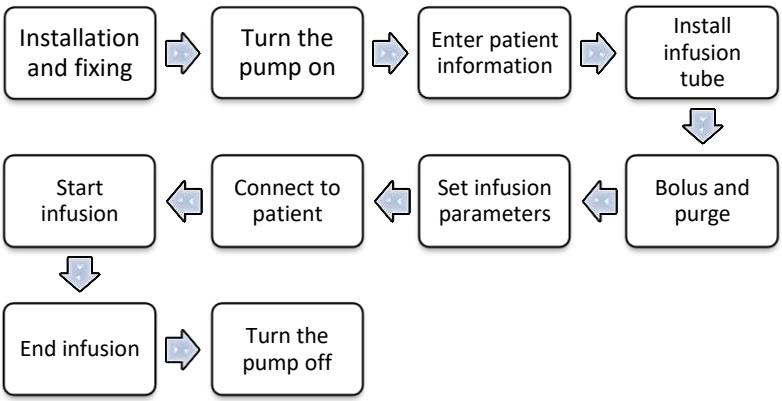
Note: Condensation forms when liquid or gas cools. For example, water vapor turns into water when it cools, and water turns into ice when it cools. The lower the temperature, the faster the condensation rate.

Chapter 5 Basic Operation

NOTE

- **When using the pump, the operator should be within 1 meter of the pump, which is helpful for the operator to observe the device.**

5.1 Steps



5.1.1 Turn the pump on

1. Prior to turning the pump on, confirm that the pump is free from mechanical damage and that cables and accessories are correctly connected.
2. Check if the device can be turned on normally:

After pressing the Power On/Off key, the device enters a self-test process. The alarm light is on for 1s; after that, the company logo is displayed; with a “beep” sound, and then the pump shows the main interface.

3. Check if the screen display and parameter display is normal.

NOTE

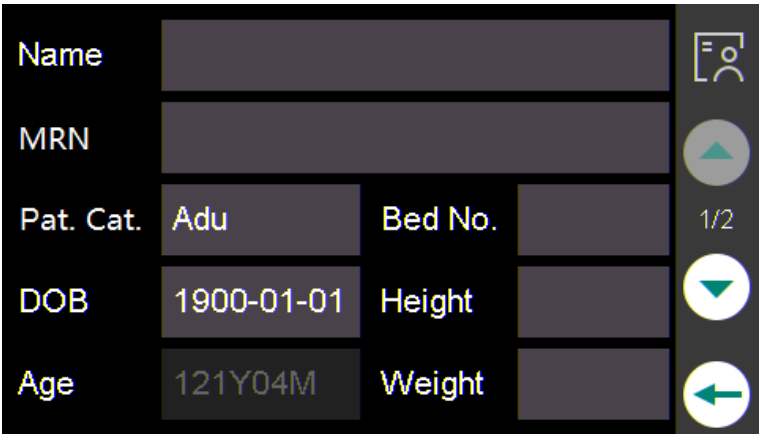
- **The system gives an alarm if a critical error is detected during self-test. If this happens please contact with the biomedical engineer in the hospital or the company’s maintenance engineer.**
- **Please pay close attention to the self-test process to ensure that the self-test finishes successfully. Otherwise, please do not use the infusion pump and contact us.**
- **If the infusion pump fails or is damaged, please contact us. At this time, do not use the pump for patient infusion.**
- **Check all functions to ensure that the pump can function normally.**
- **The built-in battery must be charged after each use to ensure sufficient battery power is available.**
- **After shut-down, in order to extend its service life, wait for at least 1 minute before you restart the pump.**

5.1.2 Enter patient information

NOTE

- **Patient information should be input properly before infusion.**

Press the menu key  to enter [**Main Menu**] → [**Patient Data**].



For this infusion pump, the barcode related to the patient can be scanned by the scanner to receive patient information.

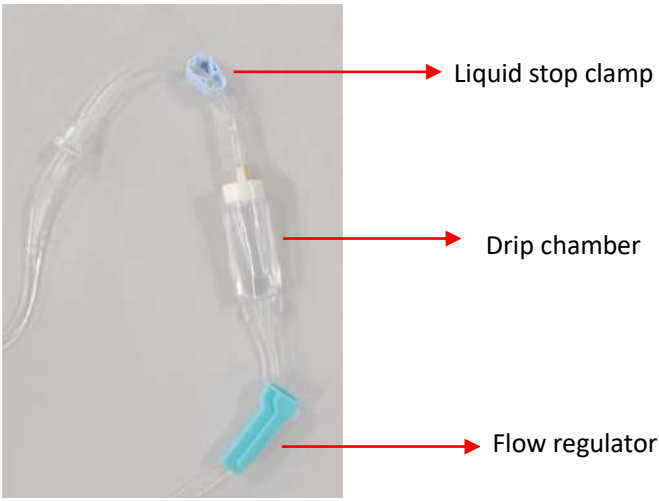
5.1.3 Install the infusion set

⚠ WARNING

- **The Infusion tube shall be firmly inserted in the tube track.**
- **Try to use the designated tube, otherwise, please calibrate as required.**
- **Follow the instruction on the device to install the infusion set.**
- **Before using the infusion pump, please confirm that the infusion set used is calibrated. Otherwise, the accuracy of the infusion cannot be guaranteed.**
- **Unpack the infusion set or tubing only when you use it, or it may be contaminated.**
- **Check the infusion set before use. Do not use the infusion set in case of any damage or contamination.**
- **Before infusion, please read carefully the manual of the infusion set manual carefully. Don't unpack the infusion set prematurely.**
- **Make sure that the infusion set has been granted with the relevant regulatory certification, CE marked, before application.**
- **When using non-recommended infusion sets, please make sure to confirm relevant infusion performance (such as accuracy, presence of air bubbles and pressure) on the infusion pump, and contact the company for a calibration service.**

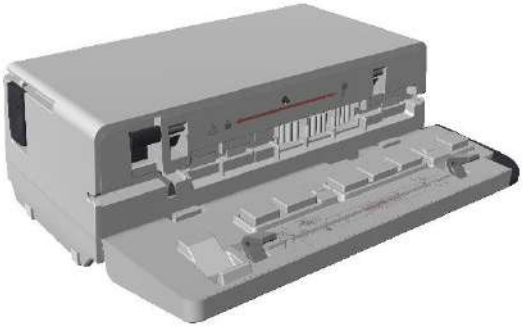
After the power switch is turned on, if it is detected that the infusion set is not installed, the interface for installing the infusion set will automaticallydisplay, and you can install the infusion set according to the installation guide.

1. Insert the needle into bottle vertically, allowing the liquid to enter into the drop chamber. Open the free-flow clamp or adjuster of the infusion set and wait until the liquid level is at 1/3 of the drop chamber, and then purge the air and close free-flow clamp or adjuster of infusion set.

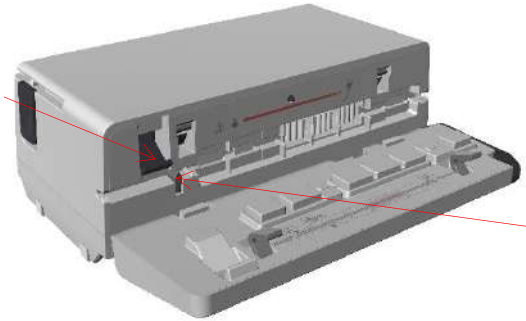


2. Lift up the door switch of the infusion pump with one hand, as shown in the figure:

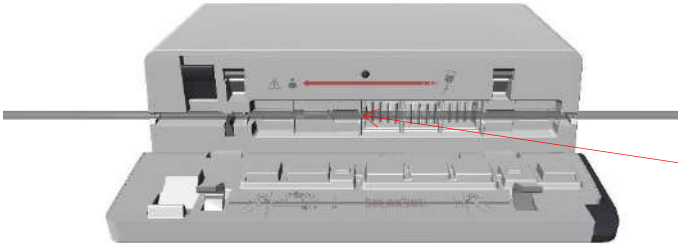
3. Open the door of the infusion pump, as shown in the figure:



4. Press down the switch of anti-free-flow clamp to open the anti-free-flow clamp, as shown in the figure:



5. Insert the infusion tube in the infusion tube slot, following the direction showed on the pump. As shown in the figure:



6. Arrange the infusion tube to make it cling to the infusion pump panel.
7. Close the door of the infusion pump.

5.1.4 Install the drip sensor

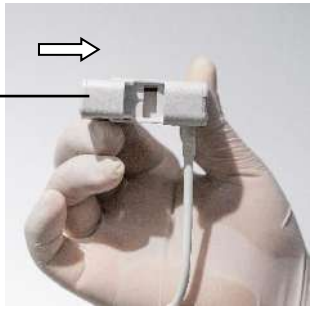
⚠ WARNING

- **The drip sensor shall not be used in an environment with direct sunlight.**
- **The fluid level in the drip chamber shall be at about 1/3 of the drip chamber, and the drip sensor shall be installed above the fluid level.**

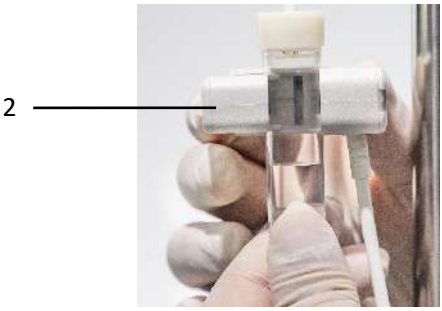
⚠ NOTE

- **When installing the infusion tube, please adjust the infusion tube to ensure that it is not bent or folded.**
- **When using the drip sensor, please ensure that the drip sensor is vertical to the drip chamber of the infusion set. If the drip sensor is tilted, the drip signal may not be detected or the detection may be abnormal, resulting in an audible and visual alarm.**

1. Hold the drip sensor with your fingers, and press it inwards to it:



2. Place the drip chamber of the infusion set in the drip sensor.



3. Loosen the drip sensor to make it tightly clamp the drip chamber of the infusion set, as shown in the figure:

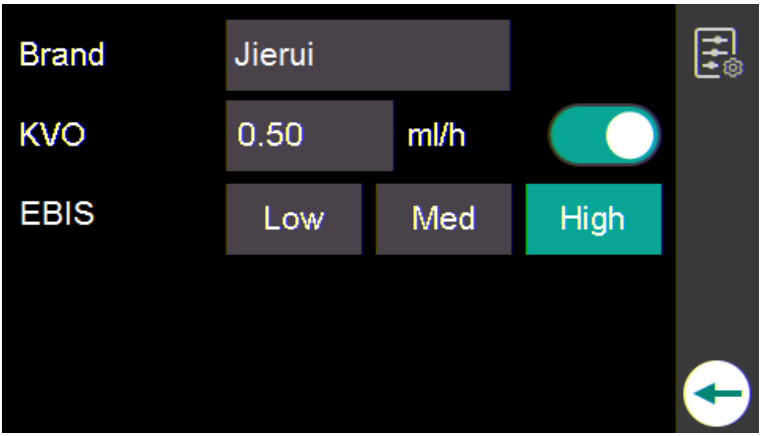
5.1.5 Selecting the infusion set brand

WARNING

- **This pump can only be used with highly flexible infusion sets. If the user needs to determine if the infusion set used is a highly flexible tube, you can contact Comen and we will provide a tube test.**
- **The Company shall not bear any responsibility for the consequence of non-calibrated infusion set if the non-recommended infusion set is used.**

NOTE

- **Infuson set parameters are determined by the infuson set used. Please select the parameters after check and confirmation, which cannot be changed arbitrarily.**
- **Before the infusion, make sure that the selected infusion set in the system are the same as the infusion set actually used. Otherwise the infusion accuracy is not guaranteed.**
- **When the infusion pump is in operation, the brand of the infusion set cannot be changed.**
- **When a new brand of infusion set is used for the first time, it must be calibrated.**



Press the menu key → select [**Param.**] → [**Brand**], to select the corresponding brand of the infusion set.

After selecting the corresponding brand, the selected brand will be displayed in the main interface. Please use the recommended infusion set. If other infusion sets are used, calibration is required to ensure infusion accuracy. Please contact us for calibration information. The recommended brands are shown as below:

Name	**Brand of infusion set**	**Manufacturer**	**Type**	**Certification**
Infusion set for single use (with needle)	BOON	Shenzhen Boon Medical Supply Co., Ltd	A2	CE_{0197}
Pressure-infusion set for single use	B.Braun	B. Braun Melsungen AG	4062981L	CE_{0123}
Transfusion sets for single use (with needle)	Jierui	Shandong Weigao Group Medical Polymer Co., Ltd..	/	CE_{0123}
Enteral nutrition feeding set for single use	Jev&Kev	Jiangsu JEVKEV MedTec Co.,Ltd.	JP2-1-105	CE_{0123}

Infusion set for single use	Custom1	/	/	/
Infusion set for single use	Custom2	/	/	/
Infusion set for single use	Custom3	/	/	/

5.1.6 Selecting the infusion mode

Press the mode select key (the name of the mode display in main screen) to enter [**Mode Select**] to select the infusion mode you want.

5.1.7 Purge

WARNING

- **When the device in the purge status, disconnect the infusion set from the patient. Otherwise, it will cause danger!**
- **The purge volume will not be added to the total volume of current infusion.**
- **For manual purge, the manual purge volume is set in [Maintenance]. For details, see *6.4.3 Manual bolus and manual purge*.**
- **When the automatic purge volume is set to 0, the infusion pump cannot start automatic purging.**

During the infusion, bubbles should be prevented from entering the blood with the liquid. Otherwise, it can cause a blood clot and pose a danger to the patient. Therefore, be sure to remove the bubbles from the infusion set and tubing completely before infusion.

The purge function can be performed when the device is in the paused or stopped states. The purge function settings are used as follows:

(1) When the device is in paused or stopped states, the purge interface will be displayed after pressing the BOLUS key.

(2) There are two keys on the purge interface, [**Start Purge**] and (back to the previous step), and two parameters: [**Purge Rate**] and [**Auto Purge Vol**].

(3) Click [**Purge Rate**] and [**Auto Purge Vol.**] on the interface to input the values with the keyboard.

(4) Click the [**Start Purge**] key, the device starts purging automatically, and the value of [**Purge Vol**] decreases as the device starts purging. Press to start or stop the purge.

(5) In addition, you can also press and hold BOLUS to start the purge manually, and the value of [**Purge Vol**] increases as the machine starts purging. Release the button BOLUS to stop manual purge.

5.1.8 Set infusion parameters

In each infusion mode, the operator can set infusion parameters with the soft keyboard.

5.1.9 Start infusion

When ready, connect the infusion set to the patient. Press the Start/Stop key to start the infusion, and the screen will display the running icon  . The arrows will move from right to left, indicating that the infusion is being performed.

NOTE

- **After infusion is started, the user shall adjust the tube position or replace the transfusion components according to the infusion tube used. It is recommended to adjust the the clamping position of the infusion tube every 6 to 8 hours and replace the infusion set every 8 hours to ensure accuracy.**

5.1.10 Bolus

NOTE

- **The bolus volume will be added to the total volume of the current infusion.**
- **Minimum rate and maximum rate for bolus are as follows: minimum rate: 0.1mL/h, maximum rate: 2000mL/h.**
- **For manual bolus, the manual bolus volume is set in [Maintenance]. For details, see *6.4.3 Manual bolus and manual purge*.**
- **When the automatic bolus VTBI is set to 0, the infusion pump cannot start automatic bolus after pressing the [Start Bolus] key.**

1. When the device is running in any mode, press the bolus button 

. The bolus interface will be displayed.

2. There are two keys- [**Start Bolus**] and  (back to the previous step) on the bolus interface, and parameters such as [**Bolus Rate**], [**Auto Bolus Vol.**] are also displayed.
3. Click [**Bolus Rate**] and [**Auto Bolus Vol**.] on the interface to input the corresponding values with the keyboard.
4. Click the [**Start Bolus**] key on the interface or press the start/stop key, the device starts bolus. In bolus state, press key 

to stop automatic bolus with the [**Bolus Vol.**] decreases. In addition, press and hold 

to can start manual bolus. The [**Bolus Vol.**] starts to increase.
5. Start bolus after the automatic bolus volume is set. When the automatic bolus volume is equal to VTBI, the bolus will be stopped automatically.

5.1.11 Infusion pause

During infusion, if it is needed to change the liquid container or replace the infusion set, etc., press  to enter Pause interface to stop the infusion. In the Pause state, press  to end the infusion, press  to continue, and press mode select key into [**Mode Select**] to modify the infusion parameters.

5.1.12 Change liquid drug bottle

Before replacing the liquid container, press the stop key to stop the infusion, and close the roller clamp to avoid the free flow causing injury to the patient.

⚠ WARNING

- **When replacing the liquid container or stopping the infusion, you must close the roller clamp, especially when the anti-free-flow clamp is opened, to avoid the free flow causing injury to the patient.**

5.1.13 Real-time monitoring

When the pump is connected to the Infusion Workstation System is connected, the operation of the pump and the infusion status can be monitored in real time. The log and the curve are available for observation on the system. For full details, please refer to the User Manual for Infusion Workstation System.

5.1.14 Infusion completed

If [**VTBI**] is not set during infusion, when the infusion is complete, if the drop sensor is installed, the [**Empty Bottle**] alarm will be triggered. If the drip sensor is not installed, the [**Bubble**] alarm will be triggered.

If [**VTBI**] is set during infusion, when the remaining infusion time reaches the [**Nearly Done**] (nearly done time) set by the user, the [**Nearly Done**] alarm will be triggered. If there is no interference, the infusion will keep going until the drug volume is completed, and the [**VTBI Done**] alarm will be triggered.

When the infusion is completed and there is liquid left, it will enter KVO mode. The KVO mode will run for up to 30 minutes. When KVO ends, the infusion will be stopped automatically, triggering the [**KVO Done**] alarm.

5.1.15 Standby

If the device is not to be used for infusion temporarily, and you do not want to shut it down, you can use standby mode. To enter the standby mode, press the On/Off key and select [**Standby**].

The device can only enter the standby mode when it is in a non-infusion state and there is no medium or high alarm. During standby, touch the standby time area to modify the standby time. The range of standby time is: 00:01:00~99:59:59 h:m:s. After ten minutes of standby, the screen brightness will automatically decrease. Touching any position of the screen or press any key will display a dialog box prompting [**Cancel standby?**]. Select [**Yes**] to exit the standby mode. When the pre-set standby time ends, the standby end alarm will be triggered.

NOTE

- **The infusion pump cannot enter the standby mode when there is a high alarm.**
- **During the infusion, it is not allowed to enter the standby mode.**

5.1.16 Remove infusion set

Please follow the reverse process of the operation steps stated in ***5.1.3 Install infusion set***.

WARNING

- **To prevent the pump from being damaged due to the drug liquid leakage, switch off the pump after disassembling the infusion set**
- **If there is a liquid drug or residue on or around the pump, the user should completely clean and dry the area before plugging into the power supply or turning on the pump, otherwise accidents or injuries may result!**

NOTE

- **Please dispose of or recycle used infusion sets in accordance with relevant regulations.**
- **Infusion sets are disposable, which shall not be used repeatedly.**

5.1.17 Clear cumulants

In non-infusion state, click [**Cumulant**] on the main interface into the page where user is allowed to clear the cumulant. Click [**Clear**] and it will display [**Clear cumulants?**], select [**Yes**] to clear the completed infusion volume.

5.1.18 Automatic cumulant calculation

The total cumulative infusion volume is displayed on the home screen. When the infusion is paused or stopped, the user can click [**Cumulant**] on the home screen to view the total cumulative infusion volume. The total cumulant updates in real time. Besides, there are other four kinds of cumulants that are automatically calculated in the system, including: 24h cumulant, Recent cumulant, Cumulant for custom time, and Timed cumulant (cumulant for custom time interval). The four kinds of cumulants update every 10 minutes (such as 9:10, 9:20 and 9:30).

- 24h cumulant: when the infusion is in paused or stopped state, click [**Cumulant**] on the main interface to display the cumulants for recent 24 hours.
- Recent cumulant: when the infusion is in paused or stopped state, click [**Cumulant**] on the main interface → [**Setup**], to select the recent time from 1 hour to 24 hours and then the corresponding recent cumulant will be displayed. For example, if you select 1 hour on the [**Setup**] interface, the cumulant in 1 hour before the current system time will be shown.
- Cumulant for custom time: when the infusion is in paused or stopped state, click [**Cumulant**] on the main interface → [**Cumulant Yesterday 00:00 to**

Today 00:00], to set the start time and the end time for automatic cumulant calculation. Pay attention to that the start time and end time cannot be set as the current system time, the minimum increment for time setting is 10 minutes and the custom time period cannot exceed 24 hours.

- Timed cumulant (cumulant for custom time interval): when the infusion is in paused or stopped state, click [**Cumulant**] on the main interface → [**Timed Cumul.**] (Timed cumulant), to select the time interval for automatic cumulant calculation. The available time intervals are 1 hour, 2 hour, 4 hour, 8 hour, 12 hour and 24 hour. After selecting the time interval, the corresponding cumulants of the past 24 hours will be displayed at the selected time interval. For example, if the user sets the [**Interval**] to 1h when the system time is 09:00, the device will display the cumulants at the 1h interval including [**08:00~09:00**], [**07:00~08:00**]…[**24:00~01:00**] (today) and [**23:00~24:00**]…[**09:00-10:00**] (yesterday).

5.1.19 Turn the pump off

If you are no longer using the pump, please follow these steps to turn it off:

(1) Confirm that the infusion pump can be stopped for use;

(2) Press the stop key to stop the infusion;

(3) Disconnect it from the patient;

(4) Save or clear patient data as required;

(5) Press the On/Off key, and then a dialog box containing [**Lock**], [**Turn Off**] and [**Standby**] will be displayed. select [**Turn Off**], and the device will be shut down.

(6) Disconnect the AC power cable.

There is an alternative method to switch off the infusion pump:

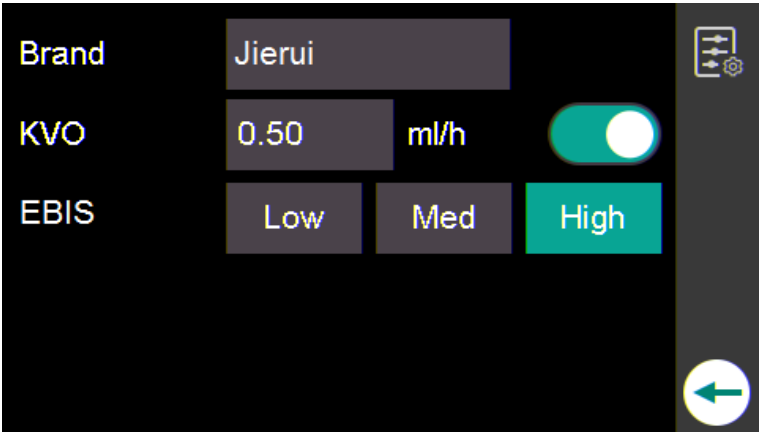
Press and hold the On/Off key and Start/Stop key simultaneously for at least 7s to turn off the pump.

NOTE

- **In the case of normal shutdown, the current data and stored data will be saved automatically.**
- **DO NOT shutdown during infusion.**
- **If the Poweroff Check switch has been set to OFF, the device cannot be shutdown during the infusion process, or shutdown if the infusion set has not been removed first.**

Chapter 6 Basic Settings

6.1 Parameter settings



6.1.1 KVO settings

Press the menu key  →[**Param.**] →[**KVO**] to turn on KVO mode. KVO is short for “Keep Vein Open”, that is, to keep the vein open. When the KVO function is turned on, if the total infusion volume reaches VTBI, there is liquid left in the infusion tube and there is no high alarm (such as bubbles), after the [**VTBI Done**] alarm, the infusion pump will automatically enter KVO mode to prevent blood backflow or vascular occlusion. The KVO mode runs for up to 30 minutes, after which the [**KVO Done**] alarm will be triggered.

KVO rate range: 0.10 ~5.00mL/h, and its factory default is 0.50mL/h. The minimum increment is 0.01mL/h. The KVO function can be turned off.

6.1.2 Empty-bottle Inspection Sensitivity(EBIS) settings

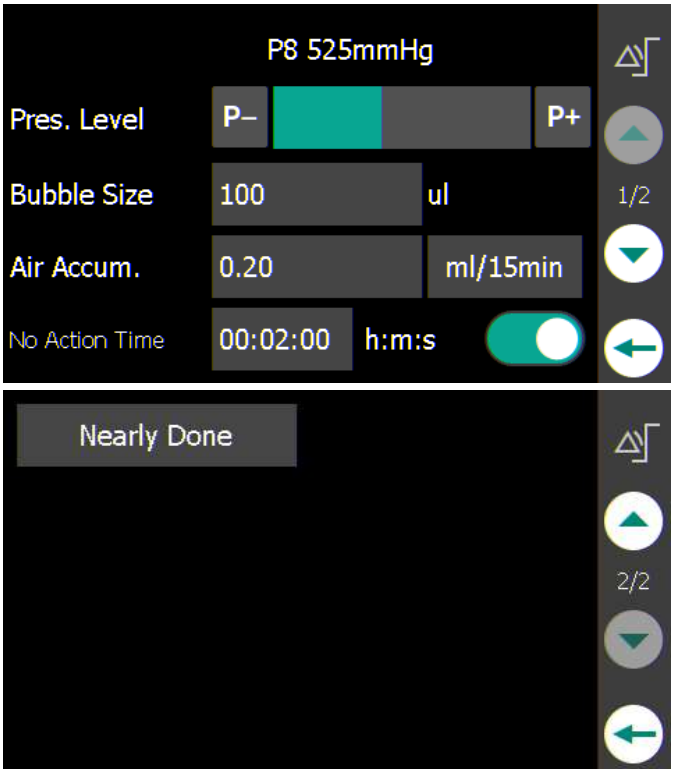
Press the menu key  →[**Param.**] → [**EBIS**], and the empty-bottle inspection sensitivity can be set to [**High**], [**Med**]or [**Low**]. When it is set to [**High**], the inspection sensivity is high and the system takes less time to trigger the [**Empty Bottle**] alarm; when it is set to [**Low**], the inspection sensitivity is low and the system takes longer to trigger the [**Empty Bottle**] alarm.

6.1.3 Automatic pressure release(Anti-bolus)

When the occlusion alarm is triggered, the motor is reversed, and the cannula pressure is then released, which prevents an additional aggressive dose to the patient after the occlusion is eliminated.

Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) → [**Param. Switch**] → [**Anti-bolus**]. The automatic pressure release function can be turned on or off.

6.2 Alarm settings



6.2.1 Occlusion pressure

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

6.2.1.1 Set occlusion pressure

Press the menu key → [**Alm Setup**] → [**Pres. Level**] (pressure level), and press P– or P+ to set occlusion pressure.

WARNING

- **When setting the alarm threshold value of occlusion pressure , it shall be cautious, please pay particular attention to check if this alarm value is suitable for the current patient.**

6.2.1.2 Set pressure unit

Press the menu key → [**Maintenance**] and enter the password (please refer to the service manual) → [**Pres.Unit**]. There are four various forms of pressure units: mmHg, kPa, bar and psi, and they can be selected according to actual needs.

6.2.2 Bubble size

This is used to set the threshold of the bubble alarm. When the ultrasonic air-bubble sensor in the pump detects that the size of a single bubble is greater than the preset value during infusion, the bubble alarm will be triggered. Bubble sizes for drug infusion and blood transfusion are configurable in the range Level 1~8 (namely 15, 20, 25, 50, 100, 250, 500, 800ul); Bubble sizes for nutrient feeding are configurable in Level 1~11 (namely 15, 20, 25, 50, 100, 250, 500, 800, 1000, 5000, 10000ul). The single bubble sensitivity is 15ul.

6.2.3 Cumulative bubbles

This is used to set the threshold of the accumulated-air alarm. If the accumulated air volume within 15 minutes is greater than the preset value during infusion, the accumulated air alarm will be triggered.

Press the menu key  → [**Alm Setup**] → [**Air Accum.**] (air accumulant), and input the threshold of accumulated air (bubbles) alarm. Accumulated air range is: 0.10~1.0mL/15min or 0.10~4.00mL/h.

Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) → [**Param Switch**] → [**Air Accum.**]. The function can be turned on or off. When the function is enabled, and the accumulated volume within 15 minutes is greater than the preset value, the alarm will be triggered.

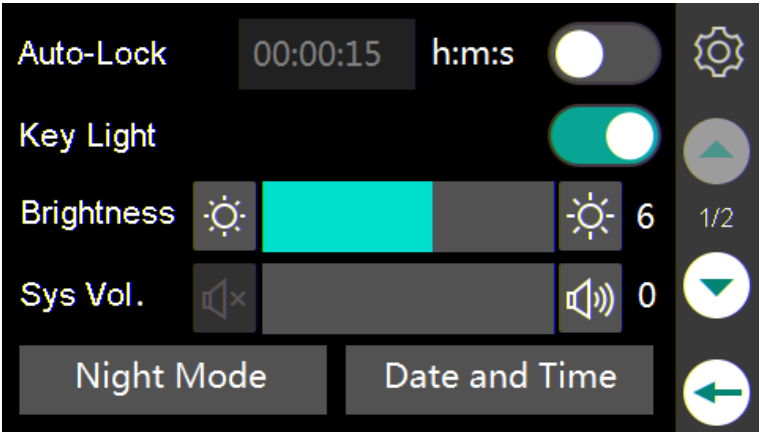
6.2.4 Nearly Done (completed) time

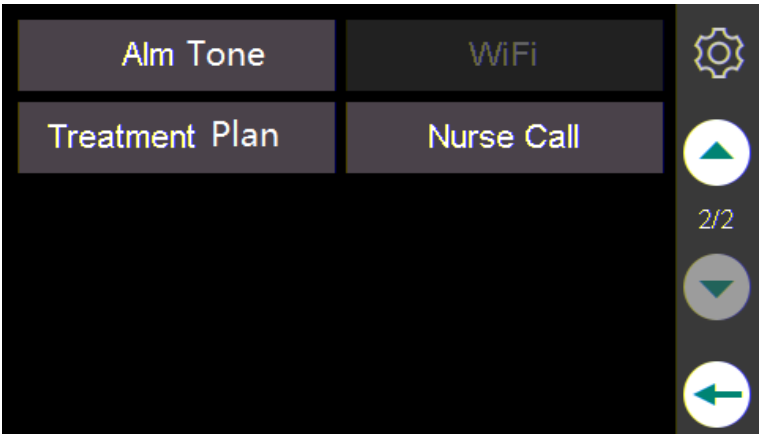
When the nearly done time is set and the remaining time of infusion decreases to the preset nearly-done time, the pump will trigger [**Nearly Done**] alarm, which can be set to the priority of [**Low**], [**Med**] (medium) and [**High**]. Press the menu key  → [**Alm Setup**] → [**Nearly Done**]. The nearly-done time range for setting is 1-30 minutes. This function is turned off when the setting is turned off.

6.2.5 No-Action time

Press the menu key → [**Alm Setup**] → [**No-Action Time**] to turn on or off this function. When it is turned on, the no-operation time range for setting is 15s-5min.. When the no-operation time is set validly, the pump is in the non-infusion state, and there is no operation during this time period, the [**Operation Paused**] alarm will be triggered with the alarm light always on in yellow. The alarm area displays [**Operation Paused**] on the home screen to alert the user to operate the pump timely. This function can be turned off.

6.3 System settings





6.3.1 Automatic screen lock

Press the menu key → [**System**] → [**Auto-Lock**]. The automatic screen lock function can be turned on or off. If you need to lock the screen automatically during the use of the device, you should turn on the automatic screen lock function and input the automatic screen lock time. If there is no operation within the preset time, the device will automatically enter the screen locked state. When the screen is locked, the screen-locked icon is displayed on the screen. Under this condition, press anywhere on the screen to select the screen locked icon and slide to the unlocked icon to exit the screen locked state.

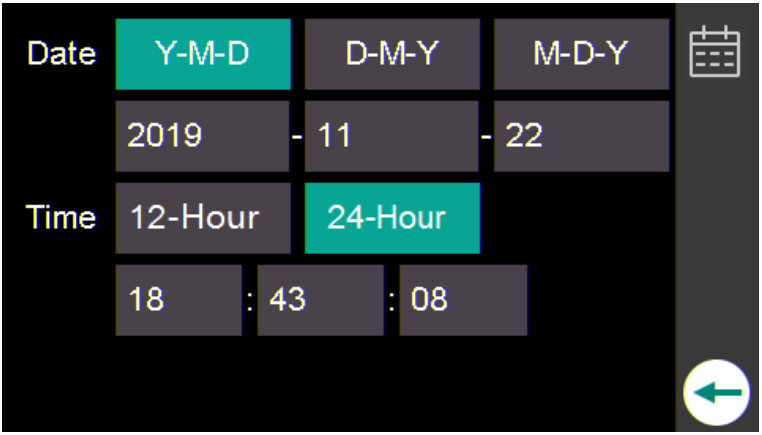
The screen lock function is to prevent misoperation during the infusion process and to prevent other personnel changing the infusion parameters. This function can only be enabled during the infusion.

6.3.2 Manual screen lock

Press the Power On/Off button to display a dialog box, and select [**Lock**] to enter the screen locked state. When the screen is locked, the lock screen icon  is displayed on the screen. Under this condition, press anywhere on the screen to select the screen locked icon and slide to the unlocked icon  to exit the screen locked state.

6.3.3 Time Settings

Press the menu key  → [**System**] → [**Date and Time**]. You can reset the system time according to the local time. The time to be set includes: year, month, day, hour, minute, and second. In addition, the user can select date format and time format.



6.3.4 Screen brightness

1) Press the menu key  → [**System**] → [**Brightness**].

2) Choose the appropriate brightness from Level 1 to Level 10. 10 is the brightest, 1 is the darkest.

6.3.5 Minimum Alarm volume (Min Alm Vol.)

Press the menu key  → [**System**] → [**Alm Tone**] → input the password (Please contact the aftersales personnel for the password) → **[Min Alm Vol.]** (Minimum alarm volume). The minimum alarm volume is adjustable from Level 1 to Level 10. Note: the minimum alarm volume is set to **1** by default.

Besides, the **[Alm Tone]** can be set on this interface and there are four alarm tones available, including **[Tone 1]**, **[Tone 2]**, **[Tone 3]** and **[Tone 4].**

6.3.6 Alarm volume

Press the menu key  → [**System**] → [**Alm Vol.**] (alarm volume). The alarm volume is adjustable from 1 to 10 levels. The maximum alarm volume that can be set is 10 while the minimum alarm volume depends on the set value in **[Min Alm Vol.]**.

6.3.7 System volume

Press the menu key  → [**System**] → [**Sys Vol**] (system sound volume). The system volume is adjustable from 0 to 10 levels.

6.3.8 Key light

Press the menu key  → [**System**]→ [**Key Light**]. The key light can be turned on or off.

6.3.9 Auto brightness

Press the menu key  → [**System**]→ [**Auto Brightness**]. This function can be turned on or off. When this function is turned on, the screen brightness is automatically adjusted according to the intensity of the ambient light.

NOTE

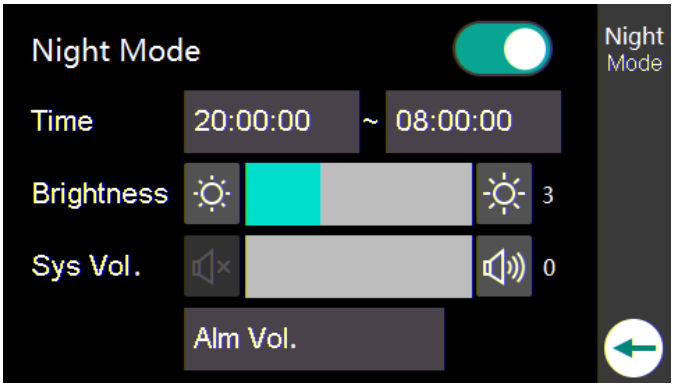
- **When the [Auto Brightness] function is turned on, the screen brightness setting will not work.**
- **The automatic brightness function is an optional feature. The product you purchased may not include this feature.**

6.3.10 Night mode

WARNING

- **Before entering the [Night Mode], please confirm the setting of [Brightness], [Sys Vol.] and [Alm Vol]. If all these settings are set to low levels, be alert to potential hazards.**

After entering the night mode, the system volume, alarm volume and screen brightness setting of the system will change into those of night mode. When the system time reaches the end time of the night mode setting, the volume and screen brightness are automatically changed to the previous volume and screen brightness settings.



1) Press the menu key and select [**System**] → [**Night Mode**].

2) Turn on the function switch. The default time is 20:00:00~08:00:00 in 24-hour format. The user can set the time period as required.

3) Set the [**Brightness**], [**Alm Vol.**]and [**Sys Vol.**] in the same way as **6.3.4** ***Screen brightness,*** **6.3.6** ***Alarm volume*** **and 6.3.7** ***System Volume.***

6.3.11 Nurse call settings

WARNING

- **Non-medical personnel are not allowed to modify the nurse call settings.**
- **The nurse call function must be used with a dedicated cable.**

NOTE

- **Medical staff should not use the nurse call function as a main means of alarm notification. The patient's condition should be judged by combining the audio and visual alarms from the infusion pump and the patient's clinical manifestations and symptoms.**
- **The nurse call function is an optional function, and the product you purchased may not have this function.**
- **The Nurse Call System is required to meet the relevant IEC/ISO standard, with at least**

2MOOP isolation from supply mains power supply. Under normal condition and single fault condition, the maximum voltage accessible shall not exceed the rating. The max. voltage is 60Vd.c.

The nurse call is a function supporting the hospital nurse call system, which mainly has three parameter settings, i.e. signal duration, triggering type and triggering level.

Press the menu key and select [**System**] → [**Nurse Call**] to turn on or off the nurse call function.

When the [**Nurse Call**] switch is turned off, the parameters related to the nurse call function cannot be set.

When the [**Nurse Call**] switch is turned on, there are three parameters, i.e. [**Signal Type**], [**Trig. Type**] (triggering type) and [**Trig. Level**] (triggering level).

- [**Signal Type**]
  a) [**Continuous**]: The system keeps calling during an alarm.
  b) [**Pulse**]: The system resumes back to normal after a 1s pulse is generated when a new alarm above the preset alarm level is triggered.
- [**Trig. Type**] (Triggering type)
  a) [**Norm. Close**]: The nurse call function is triggered by the normally closed signal.
  b) [**Norm. Open**]: The nurse call function is triggered by the normally

open signal.

- [**Trig. Level**] (Triggering level)
  a) High: A nurse call is triggered when a high alarm is triggered.
  b) Medium: A nurse call will be triggered whenever a medium or high alarm is triggered.
  c) Low: A nurse call will be triggered whenever a low alarm, medium alarm or high alarm is triggered.

6.3.12 Treatment plan

The function of the treatment plan is to save frequently used infusion parameters, which can be easily applied to infusion.

6.3.12.1 Save as treatment plan

In the paused state, press the menu hotkey  to select [**System**] → [**Treatment Plan**] → [**Add**], and input the name of treatment plan; select the infusion mode, and set the infusion parameters; click [**Save Plan**] → [**OK**] to exit the interface.

6.3.12.2 Modify the treatment plan

When the infusion parameters of a certain treatment plan are unreasonable, they can be modified according to the following steps:

Press the menu hotkey  to select [**System**] → [**Treatment Plan**]; select a certain treatment plan, and modify the infusion parameters.

6.3.12.3 Apply the treatment plan to infusion

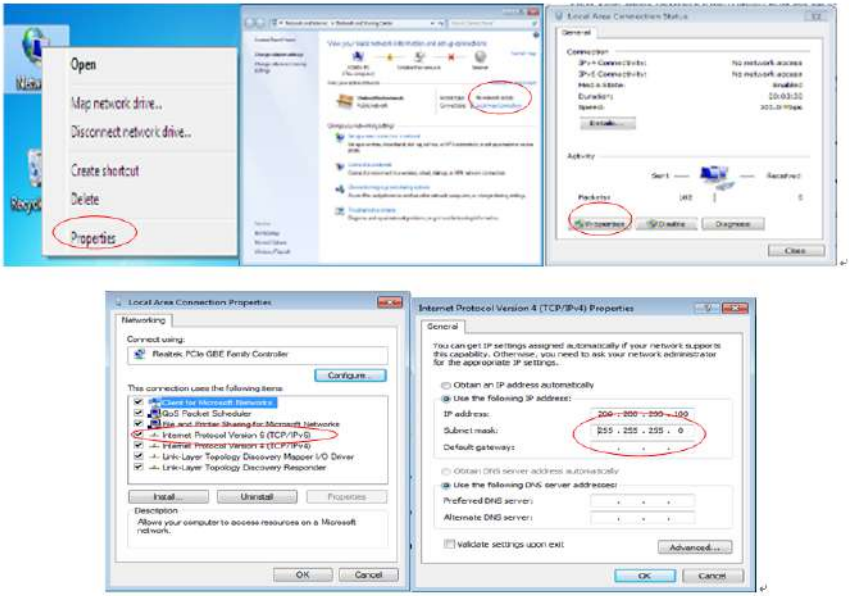
Press the menu hotkey  to select [**System**] → [**Treatment Plan**]; select a treatment plan, and confirm the infusion parameters. Press  to start the infusion.

6.3.13 Connect to Infusion Central Monitoring System (eCenter-IMS)

The infusion pump can communicate with the Infusion Central Monitoring System. Thus, the infusion parameters, infusion status and device status can be monitored on the Infusion Central Monitoring System.

6.3.13.1 How to get network information of Infusion Central Monitoring System?

On the desktop of the computer where the Infusion Central Monitoring System is installed. Right click “Network" on the desktop→ → click "Properties”→” → click “Local Area Connection" → Click "Properties" → double click “Internet Protocol Version(TCP/IPv4)". For an example of how to obtain Network Information (IP address 200.200.200.100 and subnet mask 255.255.255.0), see the screen photos shown below:



6.3.13.2 Connecting to network

The infusion pump can communicate with the Infusion Central Monitoring System through a wireless network.The supported frequencies are 2.4G & 5G and the steps for connection are as follows.

1) Press the menu hotkey  →[**System**] → [**WIFI**].

2) Set the [**IP Address**], [**Subnet Mask**], [**Gateway**] of the pump and input the server IP address and port number of the Infusion Central Monitoring System in [**Server IP**] and [**Port No.**]. When the [**DHCP**] is turned on, the pump's [**IP Address**], [**Subnet Mask**], [**Gateway**] will be automatically entered.

3) Turn on [**WIFI**] in WIFI setting menu.

4) Select your WIFI and input the password. After connecting to WIFI, the

infusion pump and the Infusion Central Monitoring System can successfully communicate with each other.

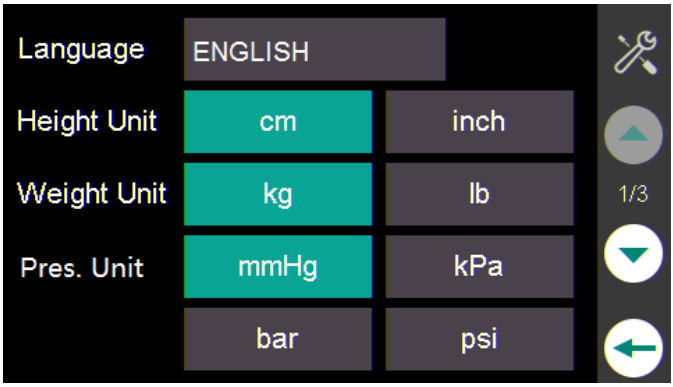
NOTE

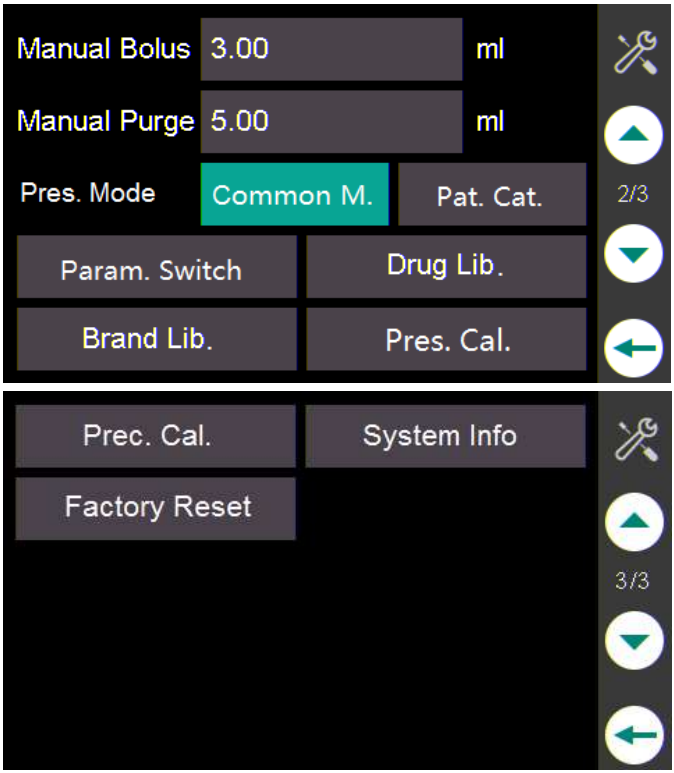
- **The device uses Transmission Control Protocol (TCP)/Internet Layer (IP).**
- **If you have any question about the internet connectionconnections, please contact us.**
- **For details, see the instrution manual of Comen's Infusion Central Monitoring System.**

6.3.13.3 Check connection

When the Infusion Central Monitoring System and the pump are successfully connected, the patient can be received at either the Infusion Central Monitoring System or the pump, and the patient information, rate, and VTBI can be viewed on the Infusion Central Monitoring System and the pump simultaneously. The infusion parameters and system settings must be set on the pump.

6.4 User maintenance





6.4.1 Language settings

Press the menu key → [**Maintenance**] and enter the password (please refer to the service manual) → [**Language**]. Select the language according to your requirements.

6.4.2 Unit settings

Press the menu key → [**Maintenance**] and enter the password (please refer to the service manual) → [**Height Unit**] / [**Weight Unit**] / [**Pres.**

Unit](Pressure Unit). The units that can be set are: height unit (cm/inch), weight unit (kg/Ib) and pressure unit (mmHg/psi/kPa/bar).

6.4.3 Manual bolus and Manual purge

The user can manually set the upper limit of manual bolus volume and manual purge volume. When the manual bolus/purge volume reaches the preset upper limit, manual bolus or manual purge will stop automatically. Manual bolus volume: 1-20mL, default: 3mL. Manual purge volume: 2-100mL, default: 5mL.

6.4.4 Pressure mode

Press the menu key  → [**Maintenance**] and enter the password 5188→ [**Pres. Mode**](pressure mode) to select [**Common M.**] (common mode) or [**Pat. Cat.**] (patient category).

The [**Common M.**] (common mode) is to adjust the appropriate pressure within the pressure range of Level 1~16, which are 50, 75, 150, 225, 300, 375, 450, 525, 600, 675, 750, 825, 900, 975, 1050, 1125mmHg).

When the pressure mode is selected to [**Pat. Cat.**] and the [**Pat. Cat.**] in the [**Patient Data**] is set to [**Neo**] (neonate), [**Ped**] (pediatric) or [**Adu**] (adult), the pressure range will be adjusted to the appropriate pressure range according to the patient type, and the user need to adjust the pressure according to the actual situation.

- The pressure range of neonate patients: Level 1~7 (50, 75, 150, 225, 300, 375, 450mmHg).
- The pressure range of pediatric patients: Level 6~11 (375, 450, 525, 600, 675, 750mmHg).
- The pressure range of adult patients: Level 7~16 (450, 525, 600, 675, 750, 825, 900, 975, 1050, 1125mmHg).

6.4.5 Parameter switch (Param. Switch)

6.4.5.1 Air Accum. switch (Air Accumulated switch)

See ***6.2.3. Cumulative bubbles***. This function is enabled by default and can be turned off by the user.

6.4.5.2 Automatic Pressure Release switch (Anti-Bolus switch)

When the occlusion alarm is activated, the system automatically withdraws the pressure in the tube. The purpose is to avoid unintended bolus and any harm to the patient.

Press menu key  → [**Maintenance**] and enter the password (please refer to the service manual) → [**Param Switch**] → [**Anti-bolus**]. This function is enabled by default.

6.4.5.3 Auto Restart Switch

Turning on [**Auto Restart**] switch and turning off [**Anti-bolus**] switch, the infusion will stop after the occlusion alarm is triggered. In the paused state, if the occlusion pressure decreases to less than half of the threshold value within one minute and there is no any high-level alarm, the pump will automatically restart the infusion. The pump will release the tube pressure by reducing the occlusion bolus when up to 5 consecutive auto-restart fails.

6.4.5.4 Upstream occlusion switch

Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) →[**Param Switch**] → [**Upstream Occlusion**] to turn on or off pressure detection function. When the function is turned on and the

upstream infusion tube is blocked, the upstream occlusion alarm will be activated to detect whether the flow regulator has been opened. This function is disabled by default.

6.4.5.5 Drip control switch

Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) →[**Param Switch**] → [**Drip Control**] to turn on or off the drip control function. This function can make the drip flow rate in drip mode closer to the flow rate set by the user. This function is disabled by default.

6.4.5.6 Drip sensor switch

Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) → [**Param Switch**] → [**Drip sensor**] to turn the drip sensor function on or off. When infusion is in drop mode, the drip sensor function will be turned on automatically. This function is disabled by default.

6.4.5.7 Poweroff check switch

When the [**Poweroff Check**] function is enabled, the infusion pump can be turned off when the infusion set is in position. But when the [**Poweroff Check**] function is disabled, the infusion set must be removed prior to shut down. This function is turned on by default.

6.4.5.8 Concen. Param. (Concentration parameter) switch

In weight mode and dose-time mode, [**Conc.**] (Concentration) will be displayed when this [**Concen. Param**] function is enabled. [**Drug Dose**] and [**Drug Vol**] will be displayed when this function is turned off. This function is disabled by default.

6.4.5.9 Drug param (Drug parameter) switch

If this function is enabled, when the user adds a new drug into the drug library, the parameters of Soft/Hard Upper/Lower Limits have to be input according to the actual drug, thus in the case of selecting this new drug, the infusion rate range of this drug can be generated and displayed when inputing the rate values. This function is disabled by default.

6.4.6 Infusion set calibration

Calibration is required when using a non-calibrated infusion set for the first time or if the user suspects that the accuracy of the infusion set is inaccurate. Please contact Comen after-sales maintenance engineers for calibration.

6.4.7 Pressure calibration

When you need to calibrate the system pressure, please contact a Comen after-sales maintenance engineer.

6.4.8 Drug

Press the mode selection key to enter [**Mode Select**]. A drug selection box in the parameter setting interface of each mode is designed for users to search for certain drugs. In addition, the user can turn the page to select the appropriate drug.

NOTE

- **There are 60 drug names in the drug library by default. If you need to add a new drug, please contact us to update the drug library.**

6.4.9 Drug Library and Brand Library

The Infusion Workstation System and this infusion pump can share the same drug library and brand library by using the [**Export**] and [**Import**] features in the menus of the drug library and the brand library. This procedure should be supervised by the Comen company.

6.4.9.1 Add drug

Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) → [**Drug Lib**] → [**Add Drug**]. Input the name of drug and click [**Save**].

6.4.9.2 Add brand

Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) → [**Brand Lib**] → [**Add Brand**]. Input the name and type of the brand and click [**Save**].

6.4.9.3 Set Drug Color

Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) → [**Drug Lib**] → [**Drug Param.**]. Search or click the name of the drug that needs to be colored and select the color, and click [**Save**].

6.4.10 Factory reset

In operation, you can change some settings under certain circumstances, but these changes are not necessarily appropriate or correct, especially when updating the

patient details or changing the brand of the infusion set. Therefore, in actual operation, you should restore the pump to the factory settings when required to ensure that the various configurations of the infusion pump are suitable for clinical infusion.

1. Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) → [**Factory Reset**].
2. Click [**Factory Reset**], a dialogue will displays [**Do you want to restore factory settings?**]. Click [**Yes**] to restore the factory default values, or click [**No**] to cancel this factory reset.

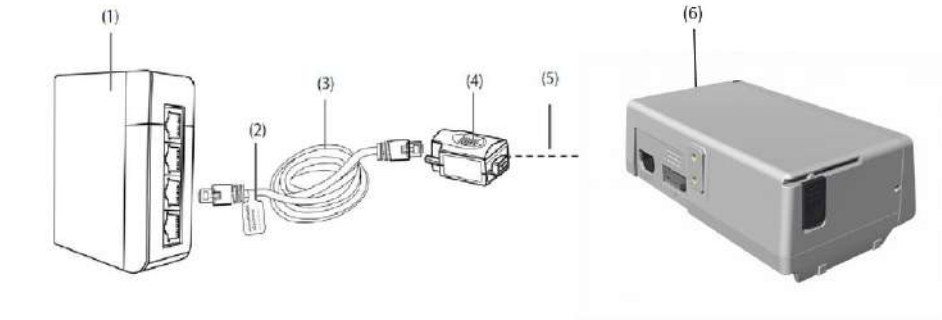
6.4.11 System information

1. Press the menu key  → [**Maintenance**] and enter the password (please refer to the service manual) → **[System Info]**.
2. Click **[System Info]** to display product information.

6.4.12 Connect to patient monitor (KLinK)

The infusion pump possesses the KLink function, which can be connected to the K12Pro/K12APro, K15Pro/K15APro, K18Pro/K18APro, K22Pro/K22APro Multi-parameter Patient Monitor for the user to view the infusion parameters, infusion status and alarm messages on the patient monitor.

The infusion pump is connected to a patient monitor through an ID box, shown as the diagram below.



(1) KLink module (2) Lable (3) Device connecting cable RJ45

(4) ID box (5) Conversion cable (6) Infusion pump

Please follow the steps below to connect the infusion pump and the patient monitor:

1. Insert the KLink module into the module slot of the patient monitor and then power on the patient monitor;
2. Turn on the infusion pump and press the menu key → [**Maintenance**] (please contact the aftersales personnel for the password) → [**Device Data Output**] to turn on the switch for the KLink function.
3. Use the device connecting cable RJ45 to connect the KLink module and the ID box;
4. Use the conversion cable to connect the ID box and the infusion pump. Ensure the conversion cable is firmly inserted into the multifunctional interface of the infusion pump;
5. Once connection, the indicator light of the ID box will turn on and the corresponding indicator light of the KLink module will turn on. Besides, the infusion pump will automatically register on the patient monitor and the infusion data of the pump will be displayed on the [**Integrated Devices**] area of the patient monitor and the alarm message of the pump will be displayed on the alarm message area of the patient monitor.

When the infusion starts, the infusion information displayed on the monitor will change accordingly. If an alarm occurs on the pump, the alarm message will be displayed in the alarm area of the patient monitor. The infusion parameters cannot be modified on the patient monitor. The alarm audio of the pump cannot be paused and alarms of the pump cannot be reset on the patient monitor.

Besides, the trend graph of infusion cumulant can be viewed on the **[InfusionView]** interface of the monitor.

For the details of connection between this pump and the monitor, please refer to the user manual for K12Pro/K12APro, K15Pro/K15APro, K18Pro/K18APro, K22Pro/K22APro Multi-parameter Patient Monitor.

⚠ WARNING

- **When connecting the infusion pump with the K12Pro/K12APro, K15Pro/K15APro, K18Pro/K18APro, K22Pro/K22APro Multi-parameter Patient Monitor, please use the KLink cable designated by Comen. Otherwise, the connection between the two devices will fail and the two devices may be damaged.**
- **The KLink module and the ID box above-mentioned are optional for the K12Pro/K12APro, K15Pro/K15APro, K18Pro/K18APro, K22Pro/K22APro Multi-parameter Patient Monitor. The KLink module and the ID box are produced by Comen and can be purchased separately.**

6.4.13 Connect to Infusion Workstation System

The infusion pump can be connected to the Infusion Workstation System. Once connected, the infusion workstation system can monitor the infusion status, collect infusion data from the single pump and supply power to the single pumps installed.

⚠ WARNING

- **This infusion pump can only be connected to the Infusion Workstation System manufactured by Comen. Connection to incompatible systems will make them malfunction.**
- **This infusion workstation system applies to real-time monitoring and centralized**

management of the operation status of infusion pump clinically, and can only be used by professional clinicians, medical electrical engineers, or qualified doctors and nurses after training.

- **The Infusion Workstation System is equipped with a built-in battery. After connecting the pump to the system, the Infusion Workstation System can supply power to the pump.**
- **When this infusion pump is used in conjunction with the system, please ensure that the system is connected to a suitable external power supply or that the internal battery is fully charged (the Infusion Workstation System is a continuous operation device with a power supply specification of 100-240V~, 50/60Hz, 6-3A). A power outage of the infusion workstation system during use may result in personal injury to the patient.**
- **For the function, precautions and warnings of the infusion workstation system, please refer to the user manual for the Infusion Workstation System.**

6.4.13.1 Installation of to the infusion workstation system

The method of installing the infusion pump to the Infusion Workstation System are as follows:

Before installation, make sure that the Unlock knob of the plug-in box unit is in  , remove the protective cover of the multifunction interface of the single pump and place the single pump horizontally on the supporting column. Ensure that the guide rails on both sides of the single pump are inserted into the guide rails of the plug-in box. When the pump is locked, the system will automatically recognize the single pump, and the Unlock knob will automatically be in  . If you need to take out the single pump, turn the Unlock knob to

 , and then take out the single pump.

6.4.13.2 Alarm synchronization

When this infusion pump is connected to the infusion workstation system, once an alarm is generated on the pump, the alarm message will be displayed and the alarm indicator light will be turned on or flash both on the pump and the infusion workstation system. The alarm audio of the alarm generated on the infusion pump will be sent out through the infusion workstation system. Therefore, the alarm audio can be paused for 2 minutes on the system. Besides, there are some alarms of the pump that can be acknowledged or reset on the infusion workstation system, as shown below.

- [**AC Off**]: press the Alarm Audio Pause key of the infusion workstation system to acknowledge the [**AC Off**] alarm of the infusion pump. Thus, the alarm light both on the infusion pump and the system will be canceled and the alarm audio sent out by the system will be cleared.
- [**Low Battery**]: press the Alarm Audio Pause key of the infusion workstation system to acknowledge the [**Low Battery**] alarm of the infusion pump. Thus, the alarm light both on the infusion pump and the system will be canceled and the alarm audio sent out by the system will be cleared.
- [**Nearly Done**]: press the Alarm Audio Pause key of the infusion workstation system to acknowledge the [**Nearly Done**] alarm of the infusion pump. Thus, the alarm light both on the infusion pump and the system will be canceled and the alarm audio sent out by the system will be cleared.
- [**Relay Failure**]: Press the Alarm Audio Pause key of the infusion workstation system to reset the [**Relay Failure**] alarm of the infusion pump. Thus, the alarm message and alarm light both on the infusion pump and the system will be canceled and the alarm audio sent out by the system will be cleared.

- [**Communication Error**]: Press the Alarm Audio Pause key of the infusion workstation system to reset the [**Communication Error**] alarm of the infusion pump. Thus, the alarm message and alarm light both on the infusion pump and the system will be canceled and the alarm audio sent out by the system will be cleared.
- [**Standby Ended**]: Press the Alarm Audio Pause key of the infusion workstation system to reset the [**Standby Ended**] alarm of the infusion pump. Thus, the alarm message and alarm light both on the infusion pump and the system will be canceled and the alarm audio sent out by the system will be cleared.

⚠ WARNING

- **When an alarm is generated no matter on the infusion pump or the Infusion Workstation System, please check the patient's condition first.**

Chapter 7 Infusion Modes

WARNING

- **The infusion parameters of drug shall be consistent with the prescription determined by doctor. This pump do not provide any drug parameters, and the parameters initially displayed in the system are for functional illustration ONLY, not for reference.**
- **Comen is not responsible for the consequence caused by incorrect infusion parameters.**
- **To ensure the personal safety, please do not modify the infusion parameters and settings other than the rate during the infusion process. If it is necessary to modify the infusion parameters, stop current infusion first.**

NOTE

- **All of the modes in this chapter supports drug library function, which excludes the specific infusion parameters for each drug.**
- **The infusion pump does not support relay function when it is under Intermittent Mode, Sequence Mode and First Dose Mode. It will prompt "Relay disabled in current infusion mode!"if the user is trying to use relay function under any of these three modes.**

Press the mode area on the home screen to enter [**Mode Select**] and select the mode as needed.

7.1 Rate mode

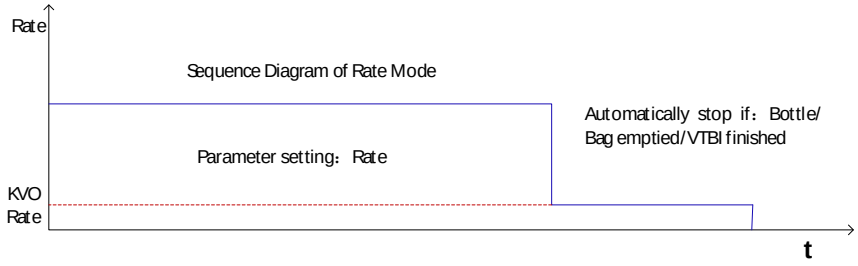
In Rate Mode, the user needs to set the rate and VTBI, and the system will automatically calculate the infusion time. Then the infusion is performed until the VTBI is finished or the infusion set is emptied. The user can modify the infusion

rate during infusion and the modification takes effect immediately.

The main parameters of Rate Mode are:

Parameter	Parameter range	Minimum increment	Unit
Rate	0.10~2000.00	0.01	mL/h
VTBI	0.10~9999.99	0.01	mL
Time	00:00:01~ 99:59:59	00:00:01	hh:mm:ss

The infusion sequence diagram of Rate mode is shown in the figure below:



NOTE

- **In this mode, only rate can be modified during running. It is valid immediately after modification, and the remaining time is calculated by: remaining VTBI/modified rate.**
- **The VTBI can be modified during pause.**

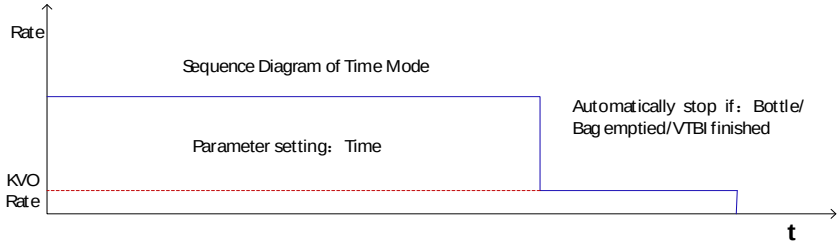
7.2 Time mode

The Time Mode is a mode in which infusion is performed at a rate that is calculated by the set time and VTBI until the VTBI is complete or the infusion set is emptied. The user can modify the infusion rate during infusion and the modification takes effect immediately. The remaining time is calculated by dividing remaining VTBI by the rate modified.

The main parameters of Time Mode are as follows:

Parameter	Parameter range	Minimum increment	Unit
Time	00:00:01~99:59:59	00:00:01	hh:mm:ss
VTBI	0.10~9999.99	0.01	mL
Rate	0.10~2000.00	0.01	mL/h

The infusion sequence diagram of Time Mode is shown in the figure below:



NOTE

- **The infusion rate can be modified during running. Modifying other infusion parameters, such as VTBI and time, please pause the infusion first.**

7.3 Drip mode

The Drip Mode is a mode in which the infusion is performed at a constant flow rate calculated from the set drip rate.

The main parameters of Drip Mode are as follows

Parameter	Parameter range	Minimum increment	Unit
Type	10~60	1	d/mL
Rate	The maximum drip rate can be calculated according to the maximum capacity rate of	1	d/min

	400.00mL/h and the drip coefficient of the infusion set; Drip rate (d/min) = 400(mlL/h) ×Drip coefficient (drop/mL)/ 60(min/h).		
VTBI	0.10~9999.99	0.01	mL
Time	00:00:01~99:59:59	00:00:01	hh:mm:ss

Note:

- The drip coefficient is the specification of the infusion set, that is, how many drops per ml.
- After modifying the drip rate, the infusion time will be automatically calculated according to the VTBI and infusion set specification.

NOTE

- **In drip mode, it is not required to set VTBI, of which the default is 0.**
- **Only the rate is allowed to be modified during operation in this mode and it is valid immediately after modification.**
- **The rate and VTBI can be modified during pause.**

7.4 Weight mode

In the Weight Mode, the user needs to input the drug concentration (or dose drug and drug volume), weight and dose rate, and then the infusion rate will be calculated automatically. In this mode, the infusion is performed at the rate calculated acocording to the set drug concentration (or dose drug and drug volume), weight and dose rate, until the VTBI is finished or the infusion set is emptied. During infusion, the user can modify the dose rate.

The main parameters of Weight Mode are as follows:

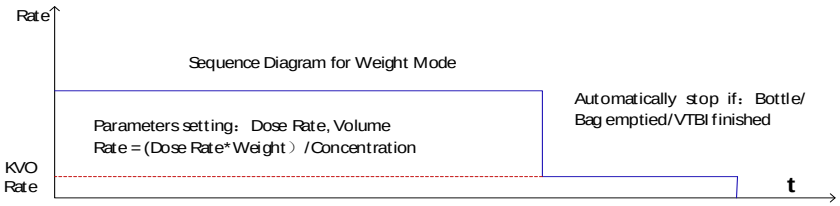
Parameter	Parameter range	Minimum increment	Unit
Drug dose	0.001~999.999	0.001	U, IU, KU, g, mg, ug, ng
Drug volume	0.10~9999.99	0.01	mL
Concentration	0.001~9999.999	0.001	U/mL, IU/mL, KU/mL, g/mL, mg/mL, ug/mL, ng/mL
Weight	0.1~500kg/0.2~1102.3lb	0.1	Kg, Ib
VTBI	0.10~9999.99	0.01	mL
Dose rate	0.001~999.999 (The dose rate range is calculated according to different weight, concentration, and maximum and minimum flow rate range, subject to the range specified here)	0.001	U/kg/h, IU/kg/h, KU/kg/h, g/kg/h, mg/kg/h, ug/kg/h, ng/kg/h, g/kg/min, mg/kg/min, ug/kg/min, ng/kg/min, U/kg/min, IU/kg/min, KU/kg/min
Rate	0.10~2000.00 (Non-editable)	0.01	mL/h

The calculation formula of the weight mode:

- Drug concentration = Drug dose/Drug volume;
  When the user sets any two parameter values among the drug concentration, drug dose and drug volume, the remaining one will be calculated automatically according to the formula.
- Rate = (Dose rate * Weight)/Drug concentration;

When the drug concentration > 0 and rate > 0, the infusion will start with the calculated rate after turning on the infusion pump and when the cumulative infusion volume reaches the VTBI, the infusion will stop.

The infusion sequence diagram of Weight Mode is as follows:



NOTE

- **Only dose rate can be modified during operation in this mode. Modifying other infusion parameters, please pause the infusion first.**
- **When the set dose rate exceeds the range in the table, the calculated rate will exceed the rate range in the above table: MIN = (Minimum dose rate * Drug concentration) / weight; MAX = (Maximum dose rate * Drug concentration) / weight.**

7.5 Dose Time mode

The Dose Time Mode is a mode in which the dose rate, infusion rate are calculated based on the input pre-dose (dose to be infused), time and drug concentration (or Drug dose and Drug volume). In this mode, the infusion is performed continuously until the VTBI is complete or the infusion set is emptied.

The main parameters of Dose Time Mode are as follows:

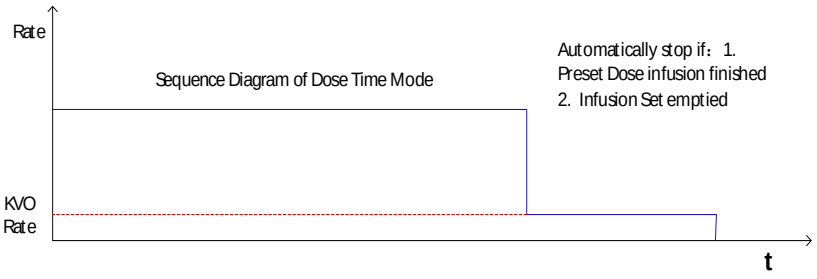
Parameter	Parameter range	Minimum increment	Unit
Drug dose	0.001~999.999	0.001	g, mg, ug, ng, U, IU, KU
Drug volume	0.10~9999.99	0.01	mL

Concentration	0.001~9999.999	0.001	g/mL, mg/mL, ug/mL, ng/mL, U/mL, IU/mL, KU/mL
Predose	0.001~999.999	0.001	U, IU, KU, g, mg, ug, ng
Time	00:00:01~99:59:59	00:00:01	hh:mm:ss
Dose Rate	0.01~999.999 (non-editable)	0.001	U/h, IU/h, KU/h, g/h, mg/h, ug/h, ng/h
Rate	0.10~2000.00 (non-editable)	0.01	mL/h
VTBI	0.10~9999.99(non-editable)	0.01	mL

The Calculation formula of Dose Time Mode:

- Drug concentration = Drug dose/Drug volume;
- Dose rate = Predose/time;
- Rate =(Predose/drug concentration)/time;
- VTBI=Predose/Concentration

The sequence diagram of Dose Time Mode is as follows:



NOTE

- **It is not allowed to modify any parameters during running in time mode. Infusion parameters except the dose rate, rate and time can be modified when the infusion is paused.**

7.6 Intermittent mode

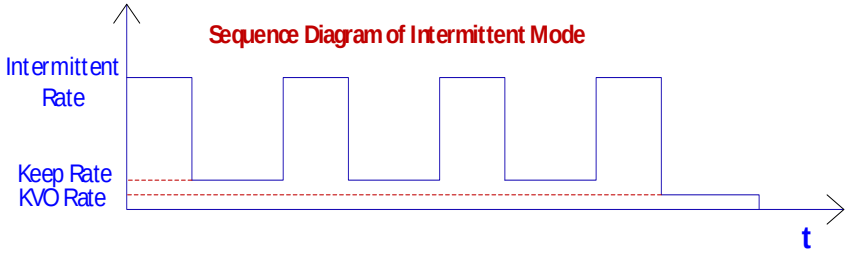
The Intermittent Mode is a mode of which the pump will firstly finish the infusion of set **[Intmt. Vol.]** (intermittent volume) at the **[Intmt. Rate]** (intermittent rate) set by the user, and then start to infuse at a rate of **[Keep Rate]** for a period of time set in **[Interval]**. When the interval ends, it will restart the above infusion tasks in a cycle again, until the total VTBI is infused or the infusion set is emptied. During infusion, the user can modify the intermittent rate. If the drug liquid is infused at the intermittent rate, the modification will take effect immediately; if the drug liquid is infused at the keep rate, the modification will take effect until the infusion continues at the intermittent rate.

The main parameters of Intermittent Mode are as follows:

Parameter	Parameter range	Minimum increment	Unit
Intermittent Volume	0.10~9999.99	0.01	mL
Intermittent Rate	0.10~2000.00	0.01	mL/h
Keep Rate	0.10~5.00	0.01	mL/h
Interval	00:00:01~99:59:59	00:00:01	hh:mm:ss

Total VTBI	0.10~9999.99	0.01	mL

The infusion sequence diagram of Intermittent Mode is as follows:



NOTE

- **During the infusion in this mode, the intermittent rate can be modified while the keep rate cannot be modified.**

7.7 Ramp mode

The ramp mode determines the steady flow rate by setting the ramp-up time, and ramp-down time, total time and VTBI. During the ramp-up time and ramp-down time, the minimum flow rate rises to steady flow rate through 9 phases, and the steady flow rate reduces through 9 phases.

The main parameters of Ramp Mode are as follows:

Parameter	Parameter range	Minimum increment	Unit
VTBI	0.10~9999.99	0.01	mL
Total time	00:00:01~99:59:59	00:00:01	hh:mm:ss
Up time	Up time=Total time-Down time	00:00:01	hh:mm:ss
Down time	Down time=Total time–Up time	00:00:01	hh:mm:ss
Steady rate	0.10~2000.00 (non-editable)	0.01	mL/h

Note:

1. When the ramp up time is null:

- Total time=Down time; Directly enter the ramp down phase until the infusion is completed.
- Total time > Down time: Steady time = Total time – Down time; Directly enter the steady phase, after the time of steady phrase, and then enter the down phase until the infusion is completed.

2. When the ramp down time is null:

- Total time = Up time: Directly enter the ramp up phrase until the infusion is completed.
- Total time > Up time: Steady time = Total time – Up time. Enter the ramp up phase firstly and then enter the steady phase until the infusion is completed.

3. When both the ramp up and ramp down time are null:

Directly enter the steady phase and keep infusion at the steady rate until the infusion is completed.

4. When both the ramp up time and ramp down time are not null:

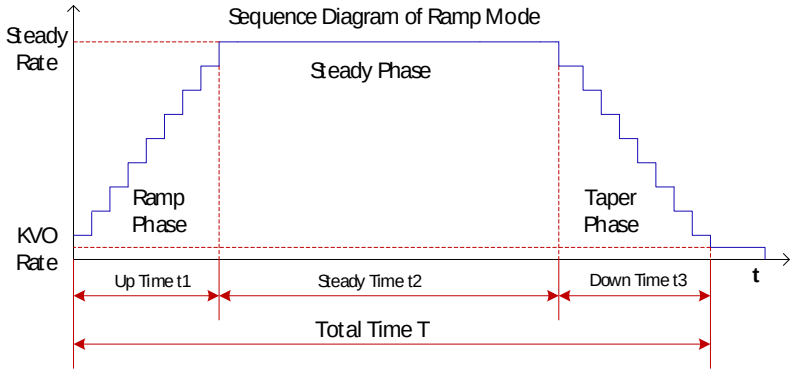
Enter the ramp up phase firstly and then move into the steady phase and finally enter the ramp down phase.

5. In this mode, Total time ≥ Up time + Down time

Clinical significance: Abrupt drug withdrawal of some vasodilators, such as nitroglycerin and triclopidine, can cause rebound vasoconstriction and thus result in angina attacks. This mode can be used to gradually reduce the dose to achieve

the goal of complete drug withdrawal.

The infusion sequence diagram of Ramp Mode is as follows:



NOTE

- **Do not modify any parameters during infusion. If any parameter is modified in the infusion-paused state, the infusion will be stopped.**
- **The steady rate can only be calculated by the system and cannot be entered by the user.**
- **When neither the Up time nor the Down time is set, the infusion is performed at the steady rate.**

7.8 Sequential mode

Multiple different sequences can be set in the Sequential Mode. The user need to define the infusion parameters (Rate, VTBI and Time) of each sequence in the infusion cycle. The device performs the infusion task one by one according to the set sequence.

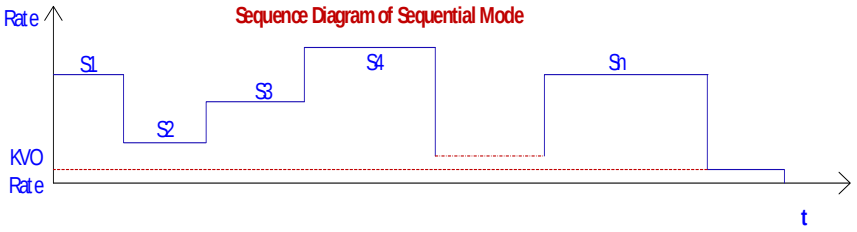
The main parameters of Sequential Mode are as follows:

Parameter	Parameter range	Minimum increment	Unit
VTBI 1	0.10~9999.99	0.01	mL
Rate 1	0.10~2000.00	0.01	mL/h
Time 1	00:00:01~99:59:59	00:00:01	hh:mm:ss
…	…	…	…
VTBI 10	0.10~9999.99	0.01	mL
Rate 10	0.10~2000.00	0.01	mL/h
Time 10	00:00:01~99:59:59	00:00:01	hh:mm:ss

Note:

1. There are up to 10 sequences in this mode.
2. When there is a sequence that only sets the flow rate or VTBI, the sequence is invalid and the infusion cannot be started.
3. The sum of VTBI of all sequences in this mode shall not be greater than 9999mL. Otherwise, the exceeding part cannot be infused due to the total volume limit.
4. Only the rate of the current sequence can be modified during infusion in this mode.
5. During pause state, the parameters of all the sequences can be modified. If the VTBI is modified, the infusion resumes with the new VTBI.

The infusion sequence diagram of Sequential Mode is as follows:



NOTE

- **There are up to 10 sequences in this mode.**
- **When there is a sequence that only sets the flow rate or VTBI, it cannot be started.**
- **The sum of VTBI of all sequences in this mode must not be greater than 9999.99ml.**
- **During the running of this mode, only rate can be modified.**
- **In the paused state, only the running sequence and the parameters of the non-running sequence can be modified.**

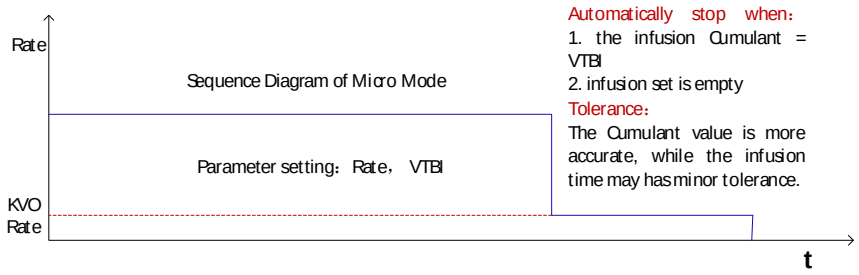
7.9 Micro mode (Micro-infusion mode)

Under Micro Mode, the infusion is performed at the preset rate constantly until the VTBI is finished or the infusion set is emptied. In this mode, the maximum rate that can be set is 100mL/h, maximum VTBI 100mL.

The main parameters of Micro Mode are as follows:

Parameter	Parameter range	Minimum increment	Unit
Rate	0.10~100.00	0.01	mL/h
VTBI	0.10~1000.00	0.01	mL
Time	00:00:01~99:59:59	00:00:01	hh:mm:ss

The infusion sequence diagram of Micro Mode is as follows:



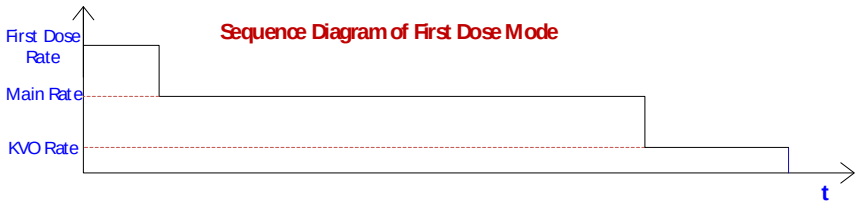
7.10 First dose mode

The First Dose Mode is a mode in which the pump firstly completes the infusion of **[First Dose Volume]** at the **[First Dose Rate]** and then performs the infusion at the **[Main Rate]** until the **[Total VTBI]** is finished.

The main parameters of First Dose Mode are as follows:

Parameter	Parameter range	Minimum increment	Unit
First dose rate	0.10~2000.00	0.01	mL/h
First dose volume	0.10~9999.99	0.01	mL
First dose time	00:00:01~99:59:59	00:00:01	hh:mm:ss
Main rate	0.10~2000.00	0.01	mL/h
Total VTBI	0.10~9999.99	0.01	mL
Main time	00:00:01~99:59:59	00:00:01	hh:mm:ss

The infusion sequence diagram of First Dose Mode is as follows:



Chapter 8 Alarm Messages and Troubleshooting

8.1 Overview

An alarm is a prompt generated by the infusion pump to medical workers by means of sound or light when abnormal situation occurs to a patient during the use of infusion pump, or when the infusion of the patient cannot continue due to the unexpected breakdown or pause of the infusion pump. In standby mode, the normal response of the alarm system function is not affected, but the alarm audio and light will be disabled. All alarms are technical alarms.

When there are multiple alarms and prompt messages, each message will be displayed in turn.

⚠ WARNING

- **It is potentially hazardous to use the same or similar equipment with different alarm presets within the same area (e.g., ICU).**
- **The alarm messages and other information displayed on this device are only for reference by clinicians and cannot be directly used as the basis for clinical treatment.**
- **Setting alarm limits to extreme values may render the alarm system useless.**
- **A hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit. The operator should check that the current alarm preset is appropriate prior to use on each patient.**

⚠ NOTE

- **When the alarm volume is low, it may be drowned by surrounding ambient noise, so the alarm volume should be greater than surrounding ambient noise.**

- **The sound intensity of the alarm signal of this device is 45-85dB.**
- **The maximum alarm delay is 3s.**

8.2 Terms and definitions

- **Alarm condition**: state of the alarm system when it has determined that a potential or actual hazardous situation exists for which operator awareness or response is required.
- **Alarm signal**: type of signal generated by the alarm system to indicate the presence (or occurrence) of an alarm condition.
- **Audio Paused**: state of limited duration (2 minutes) in which the alarm system or part of the alarm system does not generate an auditory alarm signal.
- **Alarm acknowledged**: state of an alarm system initiated by operator action, where the auditory alarm signal associated with a currently active alarm condition is inactivated until the alarm condition no longer exists or until a predetermined time interval has elapsed.
- **Alarm Clearance**: when the alarm signal is eliminated, this alarm is cleared accordingly.

8.2.1 Alarm level

According to the severity of the alarm, the alarms of this device can be divided into high, medium and low alarms. All alarm levels have been set at the factory, and they cannot be changed by the user.

	Technical alarm
High alarm	Serious device failures or mis-operations may result in failure to infuse the patient, which will threaten his/her life.
Medium alarm	Some device failures or mis-operation may not endanger the patient's safety, but will affect normal infusion.
Low alarm	Some device failures or mis-operation may result in certain malfunctions, but will not endanger the patient's safety.

8.3 Alarm Signal

When an alarm is triggered the device will alert the user through the following audio and visual modes:

- Alarm light
- Alarm audio
- Alarm message

The alarm light, alarm audio and alarm message respectively distinguish the level of the alarm in different ways.

8.3.1 Alarm light

When the alarm is triggered, the alarm indicator will indicate different levels of alarms generated in different light colors and flashing frequency.

- High alarm: Red, frequency 1.6Hz, flashes twice every second, duty cycle 50%.
- Medium alarm: Yellow, frequency 0.55Hz, flashes once every 2 seconds, duty cycle 50%.
- Low alarm: Yellow, light constant on

8.3.2 Alarm audio

Alarm audio/sound refers to different levels of alarms generated by the pump with different audible characteristics.

- High alarm: beep-beep-beep--beep-beep----beep-beep-beep--beep-beep (Repeats every 6s).
- Medium alarm: beep-beep-beep (Repeats every 15s).
- Low alarm: beep-beep-beep (Repeats every 20s)

NOTE

- **The alarm audio of some alarms of low priority is the same as that of medium-priority alarms, such as "Nearly Done", "Operation Paused", "Near Empty" and "Low Battery". When the four alarms are triggered, the device will give the "beep-beep-beep" sound every 15s.**

8.3.3 Alarm message

When the alarm is triggered, a corresponding alarm message will be shown in the alarm area on the screen.

Different number of the symbol “*” is added in front of alarm messages to indicate the alarm levels:

- High-level: ***
- Medium-level: **
- Low-level: *

Different background colors are used to indicate the alarm levels:

- High-level: red background and white font
- Medium-level: yellow background and black font
- Low-level: yellow background and black font

8.4 Alarm audio pause

- You can press the Alarm Audio Paused key to pause the alarm audio for 2 minutes. When the pause time expires, the alarm audio will automatically resume.
- When the alarm sound is paused, and all other alarm signals work normally, alarm audio paused icon  is displayed on screen.
- During the pause time, if a new alarm is triggered, the alarm sound is still paused until the 2 minutes countdown time finished.
- During the pause time, you can press the Alarm Audio Paused key to resume the audio alarm.

8.5 Multi-level alarm rules

- When multiple alarms of different levels occur at the same time, the alarm light and alarm sound are the same as the alarm of the highest level and the alarm messages are displayed in turn.

- If there are multiple alarms of the same level, each alarm of the same level is displayed in turn at a circulative manner.

⚠ WARNING

- **When multiple alarms of different priority are generated simultaneously, the device will activate the warning sound and light for the alarm of the highest priority.**

8.6 Alarm acknowledged

For some alarms, when an alarm is triggered, you can choose to continue to operate the infusion pump and acknowledge the alarm condition, and to deactivate the alarm audio and alarm light.

You can press the Alarm Audio Paused key to acknowledge the alarm conditions: **[*Low Battery**], **[*Nearly Done]** and **[*AC off**]. For other alarm conditions, see ***8.4 Alarm audio paused***.

When an alarm is acknowledged, the symbol "  " is shown following the alarm message on screen. Both the audio alarm signal and its alarm indicator light are cancelled. In addition, the alarm audio off icon  is displayed on screen.

But if there are any other alarms simultaneously, the alarm indicator light remains active and the illumination characteristic will be based on the priority of the alarm.

The acknowledged status of these alarms can be cancelled in the following ways:

- [***Low Battery**]：Restart the device, and then the alarm resumes.
- [***AC Off**]: Restart the device without AC power, and then the alarm resumes.
- [***Nearly Done**]: Stop the infusion by pressing the [**Stop**] key, and then the alarm resumes.

NOTE

- **For the alarms "Low Battery", "Nearly Done" and "AC Off", you can press the Alarm Audio Paused button to deactivate the alarm audio. And the symbol "**  **" is shown following the alarm message on screen.**
- **When the alarm that can be acknowledged and the alarm whose audio can be paused are triggered at the same time, if you press the Alarm Audio Paused button, the former one is acknowledged, and the alarm audio of the latter one is paused.**
- **When the alarm condition does not exist, the acknowledged status will automatically end.**

8.7 Alarm rules

- When multiple alarms of different priorities occur at the same time, the alarm indicator light and auditory alarm are the same as highest priority, and each alarm message is displayed in turn.
- If there are multiple alarms of the same priority, each alarm message of the same priority is displayed in turn.

WARNING

- **When multiple alarms of different priority are generated simultaneously, the device will activate the warning sound and light for the alarm of the highest priority.**

8.8 Alarm record settings

Press the menu key → [**Log**]. The log is used for recording certain history information during the operation of the device. The main log content of the pump is as follows:

1. On/Off

2. Standby

3. Rate changes

4. Parameter settings

5. Alarm

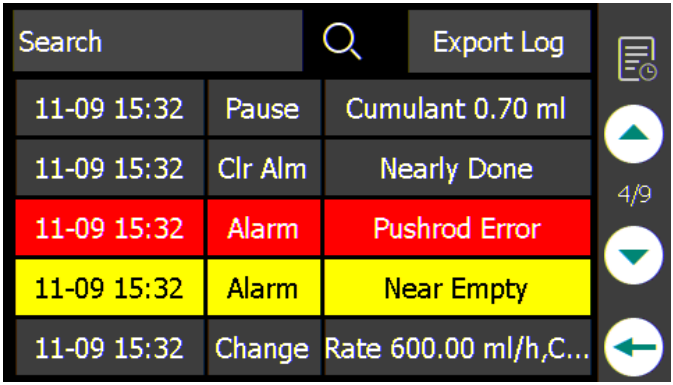
6. Cancel the alarm

7. Status alteration (KVO, Bolus, Infusion, Pause, Stop, Purge)

NOTE

- **The infusion pump can store at least 2000 logs.**
- **The doctor is not allowed to delete a single log, nor delete, modify or import a log file.**
- **If there is not enough storage space, when the log stores a new record, the oldest record will be deleted accordingly.**
- **After the infusion pump loses all the power or shuts down, the stored alarm log will not be deleted, the contents of the log will not change and the time of power outage will be recorded.**
- **The alarm settings of the device will be automatically restored when the power interrupted less than 30 seconds.**
- **When the pump loses both the AC and battery power supply, the log of the power failure, including the event itself and the time when the event occurs, will not be recorded. The log of normal shutdown of the device will be recorded.**

The alarm events are also stored in the log, including the date and time when the alarm is generated, the alarm priority and alarm messages, as shown below. The alarm priority is shown by the different background and font color of the log (the log of high-priority alarms: red background and white font; the log of low- and medium-priority alarms: yellow background and black font).



The pump supports the functions of log search and log export:

Search	Information can be found by searching the medical record number, or action, or description. Firstly, enter the string to be searched in the input field with the full keyboard (the input field can show a field that can be obscured when no value is input), and then click the " √ " key to list the items of the string that can be matched. A list of matches will be shown.
Export	Press the menu key → [**Log**]. Insert a USB flash drive in advance and click the [**Export Log**] to display the prompt message "Exporting...". 1) File export format: "txt" 2) When the screen displays [**Export Succeeded!**], click

	[**OK**] to complete the export. Note: All the log will be exported by default when exporting.

⚠NOTE

- **Do not export logs during the infusion.**

8.9 Alarm system self-test

Upon startup of the pump, the alarm system will perform a self-test of the alarm light and audio.

- ✧ The red alarm light and the yellow light turn on for 1s in turn, and then the alarm lights turn off.
- ✧ During alarm light self-test, the alarm system makes a “beep” sound for a self-test of the alarm audio.

8.10 Alarm messages

The following is a list of some of the most important alarm messages; however, some alarm messages may not be listed. In addition, a corresponding relevant solution for each alarm message is shown. If the problem still exists after you implement the relevant solution provided below, please contact our maintenance personnel.

⚠ WARNING

- **When an alarm occurs, the patient's condition should be checked first and the cause of the alarm should be resolved before resuming infusion.**

Name	Alarm level	Cause	Solution
Upstream Occlusion	High	For the line between the liquid supply and the equipment, the causes are: a) the infusion tube is knotted or kinked, b) the strainer is blocked, or, c) the flow regulator or the hydraulic clamp of the infusion set is not fully opened.	Remove the cause for excessive pressure in the infusion tube. Reset the alarm by pressing the Start/Stop key, and then continue the infusion by pressing the Start/Stop key.
Downstream Occlusion	High	For the line between the patient and equipment, the infusion tube is knotted or kinked, a relatively small needle is used at a high flow rate, or the occlusion alarm level is excessively low.	Please remove the cause for excessive pressure in the infusion tube. Confirm whether the pressure level is reasonable. [**Pres. Level**] can be reset if needed. Reset the alarm by pressing the Start/Stop key.

			Remove the cause for excessive pressure, and then continue the injection by pressing the Start/Stop key.
Air in Line	High	During the infusion, the ultrasonic bubble sensor detects that the volume of a single bubble exceeds the set value.	Disconnect the patient, and press the Bolus/Purge key for purging. Check whether the bubble threshold is set reasonably. It can be reset if needed. Reset the alarm by pressing the Start/Stop key.
Air Accum. (Air Accumulated)	High	During the infusion, it is detected that the cumulative volume of bubbles within 15 minutes reaches the set value.	Disconnect the patient, and press the Bolus/Purge key for purging. Check whether the bubble threshold is set reasonably. It can be reset if needed. Reset the alarm by pressing the Start/Stop key.
Drip Error	High	During the infusion in the drip mode, the drip clamp signal is not detected.	Reset the alarm by pressing the Start/Stop key. Install or replace the drip clamp.
Door Open	High	The door is opened during the infusion, or the infusion is started	Reset the alarm by pressing the Start/Stop key. Close the pump door.

		before the pump door is fully closed.	
VTBI Done	High	The infusion volume reaches the preset volume. During the infusion in the time mode, the infusion time reaches the preset time. Upon completion of theVTBI, if the set KVO rate is not equal to 0, the system will automatically start the infusion at the KVO rate.	Confirm whether to change or refill the drug. Reset the alarm by pressing the Start/Stop key.
KVO (Keep Vein Open) Done	High	In the KVO state, the runtime reaches the preset time for KVO.	Confirm whether to change or refill the drug. Reset the alarm by pressing the Start/Stop key.
Bottle Empty	High	During the infusion in the drip mode, the drip sensor detects that the drug bag or bottle is empty. In this case, the infusion will be suspended and the device will be stopped.	Confirm whether to change or refill the drug. Reset the alarm by pressing the Start/Stop key.

Nearly Done	Low Med/ High	The remaining infusion time reaches the set near completion time. This function is available in the rate mode, weight mode, time mode, dose time mode, drip mode, micro mode, ramp mode and sequential mode only.	Confirm whether to change or refill the drug or stop the infusion. Stop the infusion, or this alarm will automatically stop upon the completion of the infusion. Acknowledge this alarm by pressing the Alarm Audio Pause key to remove the alarm audio and light. The symbol "✓" is followed by the alarm message.
Operation Paused	Low	After the infusion set is installed, there is no any operation during the set [**No Action Time**]. The alarm will be triggered to alert the user to operate timely.	The alarm can be removed by pressing any key or operating the touch screen.
Low Battery	Low	The battery is low only when the power is supplied by the internal battery.	Connect the AC power supply to remove the alarm. Acknowledge this alarm by pressing the Alarm Audio Pause key to remove the alarm audio and light. The symbol "✓" is followed by

			the alarm message after resetting.
Dead BAT (Dead battery)	High	When power is to be supplied by a battery, but the battery is dead. After a dead battery alarm is given, the machine automatically stops the infusion. Three minutes later, the machine automatically shuts down, and saves relevant parameters that need to be saved in case of a power failure.	Connect the external power supply. For this alarm, the alarm audio cannot be muted, and the alarm cannot be removed by pressing any key. Only when the AC power supply is connected, will the alarm be automatically cancelled. The machine will not automatically shut down.
System Error	High	The internal communication of the equipment is abnormal.	Stop using the pump immediately, and please contact the service personnel of the manufacturer. The alarm can be stopped by shutting down the machine.
Photoelectric Err (Photoelectrical error)	High	Photoelectric detection module failure.	When the alarm is triggered, the infusion will be stopped immediately. Please disconnect the patient from the device, shut

			down the device and contact the service personnel of the manufacturer.
Motor Speed Err (Motor speed error)	High	During the infusion, the CPU that controls the motor detects that the motor speed is inconsistent with the preset speed.	The alarm can be stopped by shutting down the machine. Check whether the motor is being slowed or trapped by any foreign body, and then perform a retest. If the alarm remains, please contact service personnel of the manufacturer.
Motor Dir Err (motor direction error)	High	During the infusion, the CPU that controls the motor detects that the motor direction is inconsistent with the preset direction.	Stop using the pump immediately, and please contact the service personnel of the manufacturer. The alarm can be stopped by shutting down the machine.
Abn. Drip Rate (abnormal drip rate)	High	In Drip Mode infusion, drip sensor detects that the drip rate is too fast or too slow.	Reset the alarm by pressing the Start/Stop key; check the connection of the drip sensor; replace the drip sensor; if the error remains, please contact the manufacturer's service personnel.

Slave Speed Err	High	During infusion, it is detected from the drive CPU that the motor running speed is inconsistent with the preset speed.	The alarm can be stopped by shutting down the machine. Check whether the motor is being slowed or trapped by any foreign body, and then perform a retest. If the alarm remains, please contact service personnel of the manufacturer.
Slave Dir Err (slave direction error)	High	During infusion, it is detected from the CPU that the motor running direction is inconsistent with the preset direction.	Stop using the pump immediately, and please contact the service personnel of the manufacturer.The alarm can be stopped by shutting down the machine.
Motor Power Err	High	The motor power supply parameter is abnormal.	Stop using the pump immediately, and please contact service personnel of the manufacturer. The alarm can be stopped by shutting down the machine.
Battery Disconnected	High	When it is detected that the battery is not connected or the battery is off during running, the Battery Disconnected alarm	Install the battery, or check whether the battery is installed correctly. If the alarm remains, please contact the service

		occurs. In that instance the infusion cannot be performed, and it will automatically stop if the infusion is in progress.	personnel of the manufacturer.
Up Pres. Sen. Err(Upstream Pressure Sensor Error)	High	This alarm is triggered by damage or malfunction of the pressure detection sensor between the liquid supply and the equipment.	For this hardware fault, please stop using the infusion pump immediately and contact the company.
Down Pre Sen. Err (Downstream pressure sensor failure)	High	This alarm is triggered by damage or malfunction of the pressure detection sensor between the patient and the equipment.	For this hardware fault, please stop using the infusion pump immediately and contact the company.
Standby Ended	Low	The standby time exceeds the set standby time.	Press the Alarm Audio Pause key to cancel the alarm.
IP Repeat	Medium	After the pump is connected to the network, it is detected	Reset the IP address or disconnect the network to stop the alarm.

		that the same IP address exists in the network.	
AC Off	Low	The AC power is not connected or the power cable falls off during use. The machine automatically switches to battery power.	Connect the AC power supply to clear the alarm. Acknowledge this alarm by pressing the Alarm Audio Pause key to remove the alarm audio and light. The symbol "  " is followed by the alarm message.
Communication Error	Low	After the pump is connected to the Infusion Central Monitoring System and the communication is successful, the alarm is triggered due to the disconnection from the network or for other causes.	Check whether the pump is correctly connected to the network. Remove the alarm by pressing the Alarm Audio Pause key.
Relay Failure	High	During the relay infusion (which is performed after the infusion pump is connected to the	Check the infusion pump that has not completed the infusion. Remove the alarm by pressing the Alarm Audio Pause key.

		Infusion Work Station), the infusion pump is uninstalled, or the realy infusion does not start successfully.	

8.11 Prompt messages

Prompt messages	Cause	Solution
Infusion Set Not Found	When it is detected that the infusion set is not installed, the prompt message will be displayed on the main interface.	Reinstall the infusion set.
Drip Sensor Not Installed	In Drip Mode, infusion starts when the drip sensor is not installed.	Install the drip sensor.
Invalid Parameters!	Some parameter errors exist when infusion starts	Check whether the infusion parameters are set correctly.

8.12 Troubleshooting

⚠ WARNING

- **This chapter is only for designated users to eliminate simple faults. If you encounter a fault that is not included in this chapter, or if you still have not solved the fault after trying the troubleshooting methods listed below, please contact the user service organization designated by Comen. Do not repair the device without authorization.**
- **Maintenance can only be done by authorized personnel of the Comen company. Repairing equipment by unauthorized personnel may cause personal injury or equipment damage.**
- **Maintenance must be strictly based on the technical information provided by the Comen company. For related technical materials, please contact the user service organization designated by the Comen company or the local agent.**

Fault	Cause Analysis	Solution
The power plug is connected and all lights are off.	The power switch is not turned on	Turn on the power switch
	Poor cable connection	Check whether the power cable has become disconnected, or that the fuse has blown in the plug, or that a wire has become disconnected from the plug terminals.

		Then take appropriate measures.
	The power supply is not connected	Connect the power cord
Inaccurate rate	The infusion set is improperly installed	Reinstall it as required
	The drip detector is not installed or is improperly installed	Reinstall the drip detector as required
	The infusion set is not calibrated	Calibrate the infusion set as required before using it again
There is dripping in the tube when the device is off	The infusion set is improperly installed or the infusion set used does not meet the requirement	Readjust the infusion set
	The component is damaged or deformed, or the screw is loose	Readjust or replace the component (adjustment shall be made by professionals)

Low battery alarm	The device is unused for a too long a period, or the battery level is low	Charge the batterybattery
	The built-in battery is damaged or has become faulty because of improper use	Replace the battery
No display upon startup	The battery voltage is too low	Charge the battery or replace it with a new one
	System error	Restart the device. If the problem still exists, contact the manufacturer for repair.
“Occlusion” alarm is frequently triggered during infusion	The infusion tube is knotted or kinked.	Recheck the infusion tube
	The set pressure level is too low	Raise the set pressure level
	Error of the pressure detection system	Contact the manufacturer for repair
“Bubble” alarm is frequently	After using the infusion tube for a period of time,	Change the position of the infusion tube so that the

triggered during infusion	the installation position is changed, and a deformed, damaged or dirty part of the infusion tube is installed at the position of the bubble sensor.	filled tube is inside the pump door, and the tube without deformation, damage or dirt is at the position of the bubble sensor.

8.13 Check the Alarm System

WARNING

- **Please perform the alarm system check before infusion and in the condition that the patient is disconnected with the infusion pump, or the patient's safety cannot be ensured.**

The infusion pump will perform a power-on self-test for the alarm system once powered on. You can judge whether the alarm system works properly as described below and in chapter ***5.1.1 Turn the pump on.*** If the alarm self-test fails, stop using the infusion pump and contact our company for repair as soon as possible.

- **Up Occlusion Alarm**

Check under the following conditions:

Infusion set	Rate	Maximum occlusion pressure threshold	Occlusion alarm response time
BOON 20d	1mL/h	50mmHg	Within 3 mins

During the infusion stage, purge the tube and maintain the rate of 1mL/h; open the three-way valve, set the occlusion alarm threshold as 50mmHg, and then block the tube; check whether the occlusion alarm response time is within the acceptable range shown in the table above.

- **AC off**

When the pump is turned on, and the device is not connected to AC mains or the power cable falls off, the AC off alarm will be triggered.

Chapter 9 Battery

9.1 Overview

The infusion pump is equipped with a built-in rechargeable battery. When the pump is connected to the AC power supply, the battery can be charged automatically to full regardless of whether the device is turned on or off. In the event of an unexpected power outage, the system will automatically use the battery for power supply, thus avoiding interruption of device operation. After the pump is disconnected from the AC power supply, the battery indicator flashes, indicating the battery is being used for power supply.

The battery icon displayed on the front panel indicates the current battery status:

	Battery full		No battery installed or damaged battery.
	Battery nearly full		Battery not sufficient
	Low battery		Dead battery
	Battery being charged		Battery being charged

NOTE

- **If the device is provided with a built-in battery, the battery must be charged after each use to ensure sufficient battery reserve.**

- **If there is any doubt about the installation or wiring integrity of the external conductor, the device should be powered by the built-in battery.**

⚠ WARNING

- **Improper replacement of the lithium battery will result in unacceptable risks.**
- **Replacement of the lithium battery by unprofessional personnel may result in risks.**
- **Battery electrolyte is hazardous. If battery electrolyte comes into contact with your skin or enters your eyes, please wash with clean water immediately and seek medical advice.**
- **Please keep the battery out of the reach of children.**
- **When the battery is being used to power the device, the device will be powered off automatically when the battery level is low.**
- **If the battery is damaged or there is any sign of battery leakage, it should be replaced immediately.**

9.2 Replacing or installing the battery

⚠ WARNING

- **Only use the battery designated by the manufacturer.**
- **Do not remove the battery when the device is in operation.**
- **Replacing or installing the battery requires disassembling the pump. Do not disassemble the pump to replace or install the battery by yourself. Please contact the manufacturer or an engineer authorized by Comen to perform battery replacement or installation, or the pump may be damaged.**

9.3 Optimizing and checking battery performance

1. Optimize battery performance

If it is the first time the battery is to be used, please ensure that the battery has undergone at least two complete optimization cycles. A complete optimization

cycle means uninterrupted charging until the battery is fully charged, and then discharging it until the pump shuts down automatically.When optimizing the battery, you should ensure that:

1) Completely disconnect the device from the patient and stop all monitoring and measurement.
2) Put the battery for optimization in the battery case of the device.
3) When charging the battery, please at least ensure that the battery is charged without interruption for at least 6h until it is fully charged.
4) Disconnect the AC power supply, and use the battery for power supply to the device until the device shuts down automatically.
5) Battery optimization is finished.

2. Check battery performance

The service life of the battery varies with storage, the environment where the battery is used, frequency of battery discharge and service time. The battery performance will degrade gradually even if the battery is not used.

Follow the steps below when checking the battery:

1) Determine whether the battery is damaged. When the battery icon shows  , it indicates the battery is damaged or there is no battery in the battery case.
2) Check whether the battery can be charged normally when connected to the AC power supply.
3) Completely disconnect the device from the patient and stop all monitoring and measurement.
4) When charging the battery, please ensure that the battery is charged without interruption for at least 6h until it is fully charged.

5) Disconnect the AC power supply, and use the battery to power the device until the device shuts down automatically. During this procedure record the start and end time of discharging.
6) The length of the discharging time reflects the performance of the battery.
7) When the discharging time reduces to less than 50% of the initial value, please replace the battery.

NOTE

- **In order to prolong the service life of the rechargeable battery, if the battery is stored for a long period of time, it is suggested that the battery should be charged every three months to prevent excessive discharging.**
- **The length of time the battery can provide power to the device depends on the configuration and operation of the device. For example, operating the device frequently on battery power only will reduce the power available from the battery.**

9.4 Recycling batteries

The internal battery can be charged and discharged for 300 times. If the battery is obviously damaged or cannot be charged, it should be replaced, and the waste batteries should be properly recycled in accordance with applicable laws and regulations or the rules of the hospital.

WARNING

- **Do not disassemble or short-circuit the battery or place it in fire; otherwise battery fire, explosion, leakage of hazardous gas or other hazards may be caused.**
- **If the battery is obviously damaged or runs out, it should be replaced. Waste batteries should be properly recycled in accordance with applicable laws and regulations or the rules of the hospital.**

Chapter 10 Cleaning and Disinfection

Only materials and methods listed in this chapter that are accepted by the Company can be used for cleaning or disinfection of the device. For any damage arising from use of unaccepted materials or methods, we will not provide any warranty.

We will not assume any liability for the effectiveness of listed chemicals or methods when they are used as infection control means. For infection control methods, please consult the Infection Prevention Department or an epidemiologist in your hospital, or refer to local policies that apply to your hospital and country.

10.1 Overview

Please keep the device and its accessories free from dust. After cleaning, please check the device carefully. If there is any evidence of ageing or damage, please stop using it immediately. If it is necessary to send the device back to Comen for repair, please clean it first. Please observe the following precautions:

- ✧ Please dilute detergent and disinfectant as specified by the manufacturer, or apply a concentration as low as possible.
- ✧ Never allow any liquid to flow into the housing.
- ✧ Never pour any liquid onto any part of the device or on to any accessory.
- ✧ Never soak the device in any liquid.
- ✧ Do not use any frictional material, bleaching powder or strong solvent (e.g., acetone or detergent containing acetone).

NOTE

- **During cleaning and disinfection, always keep the device upright to prevent liquid from entering the inside of the unit.**
- **Before cleaning the pump, please power it off and disconnect it from the AC power supply.**

WARNING

- **High pressure or high temperature sterilization of the infusion pump and its accessories is not allowed.**
- **Only use detergents and disinfectants recommended in this Manual. Use of other detergents and disinfectants will result in damage to the device or cause safety risks.**
- **Before cleaning the pump, please power it off and disconnect it from the AC power supply.**
- **Never use EtO (ethylene oxide) to disinfect the pump.**
- **Never leave any disinfectant on any surface or accessory of the device. Please use a wet cloth to wipe it clean immediately.**
- **It is not allowed to use detergent mixture; otherwise hazardous gases will be generated.**
- **Disposable accessories should not be reused after cleaning and disinfection to avoid cross infection.**
- **To protect the environment, disposable accessories must be recycled or dealt with properly.**
- **After cleaning, if the cable is damaged or shows any evidence of ageing, it should be replaced with a new cable.**
- **High-temperature sterilization of the pump and all accessories is not allowed.**
- **Never use any cleaning solution not recommended in this Manual; failure to do so may result in permanent damage to the device, sensor or cable.**
- **Never soak the connector and other accessories in any solution for cleaning or disinfection.**

Caution

- **If you accidentally pour liquid on the device or accessories, please contact the maintenance personnel or Comen immediately.**

10.2 Cleaning and disinfection

The pump should be kept clean. It is suggested that the external surface of the housing should be cleaned frequently. The cleaning frequency should be increased in order to avoid cross infection, and the accessories should be cleaned on a regular basis, especially in environments with extreme conditions or very windy and dusty places. Prior to cleaning, please first consult or be informed of the relevant rules of your hospital on device cleaning.

➢ Cleaning steps:

1) Power the device off, and unplug the power cable.
2) Use a soft cloth dipped with an appropriate amount of detergent to wipe the housing of the device.
3) Use a soft cloth dipped with an appropriate amount of detergent to wipe the display screen of the device.
4) When necessary, you can use a soft, dry cloth to remove residual detergent.
5) Put the device in a cool, well-ventilated environment to air-dry it.

The following detergents are suitable for use:

Name	Concentration
Clean water	/
Ethanol	75%

The disinfection operation may harm the device to a certain extent. It is suggested that the device can be disinfected only when it is considered necessary in the maintenance plan of your hospital. Before disinfection, clean the device first.

The following detergents are suitable for use:

Name	Concentration
Isopropanol	70%
Glutaraldehyde solution	2%
Sodium hypochlorite solution	0.5%
Hydrogen peroxide	3%

NOTE

- **The disposable infusion sets are not allowed to be repeatedly sterilized or reused.**
- **In order to protect the environment, disposable infusion sets should be recycled or properly disposed of.**

Chapter 11 Maintenance

11.1 Maintenance Checks

Before use of the pump, or every 6-12 months or after each maintenance or upgrade, a comprehensive check, including functional safety check, of the device should be carried out by qualified technical maintenance personnel having received training.

The inspection items should include:

1) Check if the operating environment and the power supply for the monitor conform to relevant requirements.
2) Check if the device and its accessories have any mechanical damage.
3) Check if the power cable is free from abrasion and has good insulation performance.
4) Check all functions of the device, and ensure that the device is in good working status.
5) Check if all accessories used are those designated by the manufacturer.
6) Check if the battery performance is OK.
7) Check if the wiring impedance and the leakage current conform to relevant requirements.
8) Confirm that the equipment has been cleaned and disinfected.

If there is any evidence of functional failure of the device, it is not allowed to use this pump for patient infusion. Please contact Comen or a biomedical engineer of your hospital.

All safety checks or maintenance work requiring disassembly of the device should be performed by professional maintenance personnel. Operation by unprofessional personnel may result in malfunction of the device or safety hazards, and may also endanger personal safety.

Upon request by the user, Comen will conditionally provide relevant circuit diagrams to help the user to repair user-serviceable components of the device by appropriate and qualified technicians.

⚠ WARNING

- **The hospital or organization using this pump should establish a sound maintenance plan; failure to do so may result in malfunction of the device and unpredictable consequences, and may also endanger personal safety.**
- **The device must be served and maintained by the service personnel trained and authorized by Comen who are familiar with the operation and structure of the device.**
- **All safety checks or maintenance work requiring disassembly of the device should be performed by professional maintenance personnel. Operation by unprofessional personnel may result in malfunction of the device or safety hazards, and may also endanger personal safety.**
- **No parts of the device can be serviced or maintained while the equipment is in use with the patient.**
- **If there is any evidence of functional failure of the device, please contact our company.**
- **The power cord/ fuse is not intended to be replaced by operator, otherwise may result in hurt.**
- **All parts involved in maintenance and replacement shall be those designated by Coman.**
- **At the end of the service life, the pump and its accessories must be disposed of in accordance with the local laws and regulations or the rules of the hospital.**

11.2 Maintenance plan

11.2.1 Maintenance testing

The following tasks can be fulfilled only by professional maintenance personnel recognized by the company. If the following maintenance is needed, please timely contact the maintenance personnel. Prior to test or maintenance, the device must be cleaned and disinfected.

Inspection and maintenance tasks	Frequency
Carry out safety checks according to IEC60601-1	At least once every two years. Or after accidental dropping of the device, replacement of the power supply or as needed.
Battery	Refer to the battery-related chapter in this Manual.

11.3 Pollution-free Treatment and Recycling

- Used batteries shall be disposed of according to applicable laws and regulations.
- At the end of the service life, the pump and its accessories must be disposed of in accordance with the local laws and regulations or the rules of the hospital.

Appendix I. Accessories

When using this device, the manufacturer recommends the following accessories.

⚠ WARNING

- **Please use the accessories specified by the manufacturer. Using other types of accessories may damage the device.**
- **Disposable accessories can only be used once. Repeated use may cause performance degradation or cross-infection.**
- **If you find any signs of damage to an accessory or its packaging, do not use this accessory.**
- **When connecting the pump to the DC power supply, please use the adaptor designated by Comen.**

⚠ NOTE

- **This Manual introduces this product according to the most complete configuration and functions. The product you purchased may not have certain configurations or accessories.**

Recommended infusion sets/transfusion tube/feeding tube：

Name	Brand of infusion set	Manufacturer	Type	Certification
Infusion set for single use (with needle)	BOON	Shenzhen Boon Medical Supply Co., Ltd	A2	CE$_{0197}$
Pressure-infusion set for single use	B.Braun	B. Braun Melsungen AG	4062981L	CE$_{0123}$
Transfusion sets for	Jierui	Shandong Weigao Group	/	CE$_{0123}$

single use (with needle)		Medical Polymer Co., Ltd..		
Enteral nutrition feeding set for single use	Jev&Kev	Jiangsu JEVKEV MedTec Co.,Ltd.	JP2-1-105	CE_{0123}

Accessories：

No.	Name
1	Power Cable (EU Standard)
2	Pole clamp (Standard)
3	Drip sensor (Optional)
4	Portable handle (Optional)

Appendix II. Product Specification

1) Product classification

Item	Type
Type of protection against electric shock	Class I with internal power supply
Level of protection against electric shock	Type CF defibrillation-proof applied part: the infusion set for patients' use.
Level of protection against dust and water ingress	IP33 (Protected against solid foreign objects of 2,5mm ∅ and greater, protected against spraying water)
Classified according to the safety level applied in the case of air mixed with flammable anesthetic gas, oxygen or nitrous oxide	Not applicable.
Non-permanently installed equipment or permanently installed equipment	Non-permanently installed equipment
Work mode	Continuous operation equipment
Mobility	Portable device (fixed installed when used on road ambulatance)
Conformity with standards	IEC60601-2-24, IEC60601-1-8, IEC60601-1, IEC60601-1-2, IEC60601-1-12 2020 and EN1789
Pollution degree	2

Explosion proof grade	Non-applicable

2) Physical specification

Item	Specifications
Dimension	≤216mm*135mm*77mm (Length*Width*Height)
Weight	≤1.5kg (with battery)
Display screen	Type: Color TFT LCD
	Size: 3.5-inch
	Resolution: 480×272
	Touch screen: 3.5-inch, capacitive touch screen

3) Power supply

Item		Specifications
Input voltage		AC input voltage: 100-240V~ External DC power supply: DC 12-16V
AC input frequency		50/60Hz
Fuse		PSL300 3A/16V/ Plug-in fuse
Power supply		External AC or use built-in battery for power supply
Input current		AC power supply: 0.5-0.3A External DC power supply: 2.0-1.0A
Built-in battery	Battery specifications	Standard：11.1V⎓2200mAh, rechargeable lithium-ion battery. Rated voltage: 11.1V； Optional：10.8V⎓3350mAh, rechargeable lithium-ion battery. Rated voltage: 10.8V;
	Charging time	Standard: In the shutdown state, the charging time is not more than 4 hours. Optional: In the shutdown state, the charging time is not more than 6 hours.

	Working time	Standard :When the screen brightness, the system volume, and alarm volume are the lowest level, and WIFI is turned off, after the battery is fully charged, the pump can be operated at the rate of 25mL/h for at least 9 hours. When the screen brightness, the system volume, and alarm volume are the lowest level, and WIFI is turned off, after the battery is fully charged, the pump can be operated at the rate of 2000mlL/h for at least 2.5 hours. Optional：When the screen brightness, the system volume, and alarm volume are the lowest level, and WIFI is turned off, after the battery is fully charged, the pump can be operated at the rate of 25mL/h for at least 13 hours. When the screen brightness, the system volume, and alarm volume are the lowest level, and WIFI is turned off, after the battery is fully charged, the pump can be operated at the rate of 2000mL/h for at least 3.5 hours.
	Shutdown delay	About 30 minutes (New battery, since the first low battery alarm)

4) Environmental specifications

Item	Specification	
Working conditions	Ambient temperature	5℃~40℃
	Relative humidity	15%~95%, non-condensing
	Barometric pressure	57.0kPa~106.0kPa

Transit operation condition	-20°C to +50°C; 15% to 90% relative humidity, non-condensing @20 min
Transport and Storage conditions	Please protect the pump against violent impact, vibration, rain and snow in transport. The packed device should be transported in a well-ventilated enviromentenvironment without corrosive gas (ambient temperature: -20 ℃ ~+55 ℃ ; relativge humidity: 10%~95%; barometric pressure: 50.0kPa~106.0kPa).

5) LED indicator

Item	Specifications
AC power indicator	1 (white)
Battery status indicator	1 (white)
On/Off indicator	1 (white, with light)
Alarm indicator	1 (red and yellow)

6) Interface

Interface	**Function**	Specifications
AC power interface	AC power supply port	1
Multi-function interface	DC power supply port; RS232 interface; USB interface (scanner interface / system upgrade); Nurse call interface; KLink interface; interface (for connecting Infusion Workstation System.)	1

	Notes: a) Serial transmission protocol: The software carries out serial communication through a multi-function interface, and our company's own encrypted RS232 protocol. b) WIFI transmission protocol: IEEE802.11a/b/g/n, encryption method:WPA2/AES c) USB transmission protocol: Standard protocol USB2.0	
Drip sensor interface (mini USB)	To connect drip sensor	1

7) Signal output

Auxiliary output interface	
Conformity with Standards	The short circuit protection and leakage current meets the requirements of IEC60601-1.
Output impedance	50Ω
Nurse call signal output	
Drive method	Driven by a relay
Electrical Specifications	Contact rating: 60V d.c (Vpeak a.c) @ 1 A
Relay functionality	Normally open or Normally closed (Optional)

8) Parameters

Parameter name	Description
Infusion set standard requirements	The infusion set used with the infusion pump should meet the requirements of standard ISO 8536-4 ISO 8536-8.
Infusion set brands	BOON, B.Braun, Jev&Kev (Nutrient), Jierui (Blood), User1, User2, User3
Range of rate & unit of rate	Range of rate: 0.10 ~2000.00mL/h; Minimum increment: 0.01mL/h; Drip rate range: 1~400d/min; Minimum increment: 1d/min. Units: mL/h, g/h, mg/h, ug/h, ng/h, g/kg/h, mg/kg/h, ug/kg/h, ng/kg/h, g/kg/min, mg/kg/min, ug/kg/min, ng/kg/min, U/kg/min, U/kg/h, KU/kg/min, KU/kg/h, IU/kg/min, IU/kg/h, U/h, KU/h, IU/h.
Drip	10~60 drop/mL; increment: 1 drop/mL; default value: 20 drop/mL.
Flow rate stability	At the rate of 1mL/h, the interval between two drops is no more than 3 minutes.
Long-term infusion accuracy	At the rate of 25mL/h, the infusion accuracy within 24 hours is not more than ±4.5%.
Bolus and purge rate range	The bolus rate is adjustable within the following rate range:0.10~2000.00mL/h; Default value: 800.00mL/h; Minimum increment: 0.01mL/h.

	Bolus VTBI: 0.10~99.99mL Purge VTBI: 0.01~9999.99mL
VTBI range	0.10~9999.99mL, minimum increment: 0.01mL.
Cumulant range	0.00~9999.99mL, minimum increment: 0.01mL. The system can calculated the total cumulant and other 4 kinds of cumulants: 24h cumulant, Recent cumulant, Cumulant for custom time, and Timed cumulant (cumulant for custom time interval).
Preset time range	00:00:01~99:59:59 h:m:s, minimum increment: 1s.
Standby time range	00:01:00~99:59:59 h:m:s, minimum increment: 1s.
Weight range	0.1~500kg/0.2~1102.3lb, minimum increment: 0.1
Drug dose range	0.001~99999.999 g/mg/ug/ng/IU; Minimum increment: 0.001
Drug volume range	0.10~9999.99mL; minimum increment: 0.01mL
Dose rate	0.001~999.999ug/kg/min; Unit: ng/kg/h, ug/kg/h, mg/kg/h, IU/kg/h, IU/kg/min, ug/kg/min, mg/kg/min, ng/kg/min, g/kg/h, g/kg/min, KU/kg/min, KU/kg/h, U/kg/min, U/kg/h. Minimum increment: 0.001.
Drug concentration	0.001~9999.999; Minimum increment: 0.001; Units: U/mL,IU/mL,KU/mL,g/mL,mg/mL,ug/mL, ng/mL. This function can be turned off.
Infusion mode	Rate mode, Time Mode, Drip Mode, Weight Mode, Dose-

	Time Mode, Intermittent Mode, Sequential Mode, First Dose Mode, Ramp Mode, Micro Mode.
KVO rate (Keep veins open)	KVO rate is adjustable. Range: 0.10~5.00mL/h. KVO default value: 0.50mL/h. Increment: 0.01mL/h. KVO function can be truned off. When KVO is turned off and the infusion of VTBI is completed it will not enter the KVO mode. When the infusion is completed, it will enter the KVO mode. The infusion volume in KVO mode can be set. The KVO mode will run for a maximum of 30 minutes. When the KVO ends, the infusion will be automatically stopped, triggering the [**KVO Done**] alarm. The accuracy of the KVO rate is same as the accuracy of infusion.
Drug library	The system can store 5000 drug names. There are 60 default drug names in drug library.
Occlusion pressure	Down Occlusion: There are 16 levels of pressure threshold that can be adjusted:50, 75, 150, 225, 300, 375, 450, 525, 600, 675, 750, 825, 900, 975, 1050, 1125mmHg; Default setting: the 8th level (525mmHg). Up Occlusion: Up-occlusion alarm is supported. Error: for the pressure of 50mmHg, the error is -45~+75mmHg; for the pressure of 75mmHg, the error is ±50mmHg; for other pressure levels, the error is ±15% or ±75mmHg, whichever is larger. Unit: mmHg, kPa, bar, psi.

The occlusion alarm response time and unintended bolus	a) When the infusion rate is 1mL/h and the pressure level is P1, the maximum occlusion alarm response time ≤5min; b) When the infusion rate is 1mL/h and the pressure level is P16, the maximum occlusion alarm response time ≤75min; c) When the infusion rate is 25mL/h and the pressure level is P1, the maximum occlusion alarm response time ≤30s and the unintended bolus is not more than 0.1mL. d) When the infusion rate is 25mL/h and the pressure level is P16, the maximum occlusion alarm response time≤5min and the unintended is not more than 0.3mL.
Anti-Bolus	When there is an occlusion alarm, the tube pressure is automatically withdrawn to avoid damage to the patient by an unintended bolus. The function canbe tured oncan be turned on or off.
Dynamic pressure detection (DPS)	During infusion, pressure changes at the patient will be displayed in real time.
Bubble	Bubble size for drug infusion and blood transfusion: Level 1~8, which are 15ul, 20ul, 25ul, 50ul, 100ul, 250ul, 500ul, 800ul. The sensitivity of a single bubble is 15ul; Bubble size for nutrient infusion: Level 1~11, which are

	15ul, 20ul, 25ul, 50ul, 100ul, 250ul, 500ul, 800ul, 1000, 5000, 10000ul. Air accumulated: 0.10~4.00mL/h or 0.1~1.00mL/15min. (This function can be turned off).
No action time	Range: 15s-5min; increment: 1s. (The function could be off.)
Screen lock	With automatic locking and manual locking
Nearly done/empty time	Time range: 1-30min; increment is 1min. This function can be turned off.
Empty bottle sensitivity	High, Medium, Low
Alarm volume	Level 1~10
System volume	Level 0~10, 0 is to turn off the system volume.
Screen brightness	Level 1~10 (adjustable)
Automatic brightness	The screen brightness is automatically adjusted according to the intensity of the ambient light. This function is optional.
System date and time	Built-in real time clock, powered by coin cell battery. System time: __:__:__ System date: ____-__-__ Time format: 12-Hour, 24-Hour Date format: [**M-D-Y**](month-day-year), [**Y-M-D**](year-month-day) or [**D-M-Y**](day-month-year).
Logging	At least 2000 logs.
Nurse call	With the nurse call function. It can be turned on or off.

Accuracy of infusion	The specific accuracy range of the standard brand infusion set is as follows (IEC/EN 60601-2-24): Infusion rate :0.10~2000.00mL/h, accuracy of infusion:≤±4.5%[1] (As for specified and calibrated infusion set, accuracy of infusion:≤±3%) Accuracy of bolus: ≤±5% or ±0.02mL, whichever is larger. Accuracy of drip rate: ≤±10%.
Alarm information	Alarm requirements comply with IEC60601-1-8 standard. The infusion pump has the following alarm functions: High level alarm: Upstream Occlusion, Downstream Occlusion, Air in Line, Air Accum. (Air accumulated), Drip Error, Door Open, VTBI Done, KVO Done, Bottle Empty, System Error, Motor Speed Err, Motor Dir Err (motor direction error), Abn. Drip Rate (abnormal drip rate), Slave Speed Err, Slave Dir Err (slave direction error), Motor Power Err, Battery Disconnected, Up Pres. Sen. Err(Upstream Pressure Sensor Error), Down P-sensor Err (Downstream pressure sensor failure), Dead BAT (Dead battery), Relay Failure, Photoelectric Err (Photoelectrical error).

[1] Note: the accuracy with back pressure (+100mmHg and -100mmHg) and the supply container below the pump at a distance of 0.5m also falls into the range of ≤±4.5%.

	Medium level alarm: IP Repeat Low level alarm: Operation Paused, Low Battery, Standby Ended, AC Off, Communication Error,. The [**Nearly Done**] alarm can be set to high/medium/low priority by users.
Prompt message	Infusion Set Not Found, Drip Sensor Not Installed, Invalid Parameters!
Night mode	After entering night mode, the system volume, alarm volume andscreen brightness are automatically changed to the volume and brightness set by the night mode. When time set for night mode ends, it is automatically changed to the previous settings.
Key light	With Key light function (It can be turned on and off)
System information	With the function of viewing the version of system software and module software.
Information system application	The pump communicates with infusion workstation through a wireless network.
Self-check function	With automatic power-on check function
Patient information	With patient information input and viewing functions
Power-down save	With power-down save function
Data export	With data export function
Status indication	Stop, infusion, bolus, KVO, pause, standby, alarm, purge
KLink function	With the KLink connection function
Drug color	With the function of setting background color for drug

	names.

9) WLAN

WLAN	Function		ACM	TM
	Frequency	2.4GHz	Y	Y
		5GHz	Y	Y
	Working Modes	STA	Y	Y
		SoftAP	Y	/

10) WLAN specifications

Item	Type	
WI-FI technology	IEEE802.11 a/b/g/n	
Frequency	2.4GHz	
Modulation type	STA	
Interface-UART	Baud rate supporting: 9600~921600	
Power supply (VBAT)	3.0-3.6V	
Temperature range for storage	- 40°C to 125°C	
Temperature range for operating	- 30°C to 85°C	
ESD protection	2000V	
ESD protection	400V	
Maximum current consumption in Transmit Mode	377mA	
Performance Parameters of 2.4G Transmitting		
RF range	2400~2500MHz	
Pmax	1Mbps Dsss	17.63dBm
	6Mbps	17.98dBm
	54 Mbps	16.06dBm
	MCS7 (20MHz)	13.51 dBm
	MCS7 (40MHz)	13.51 dBm

	MCS7 (20MHz, SGI)	13.51 dBm
	MCS7 (40MHz, SGI)	13.51 dBm
Performance Parameters of 2.4G Receiving		
RF range	2400~2500MHz	
RX sensitivity	1Mbps Dsss	-88dBm
	11Mbps CCK	-88dBm
	54 Mbps OFDM	-75dBm
	MCS0 (20MHz)	-86dBm
	MCS7 (20MHz)	-73dBm
	MCS0 (20MHz)	-83dBm
	MCS7 (40MHz)	-70dBm

11) Alarm System

Item	Specifications
The alarm system complies with IEC 60601-1-8.	

Appendix III. Infusion Performance

1. Flow rate accuracy characteristics

NOTE

- **The accuracy of the flow rate may be slightly reduced if the ambient temperature is too high or too low.**
- **Infusion accuracy does not reflect clinical criteria, such as the patient's age, weight and medication used.**
- **Infusion accuracy may be affected by the use environment of the infusion pump (Such as pressure, temperature, humidity, and infusion components).**

1) BOON 20 drops/mL infusion set； Testing mode: Rate Mode

Infusion set used in the test: BOON 20 drops/mL infusion set

Test method: According to the method as specified in IEC 60601-2-24

Ambient temperature: 25℃±5℃

The test results are shown as follows:

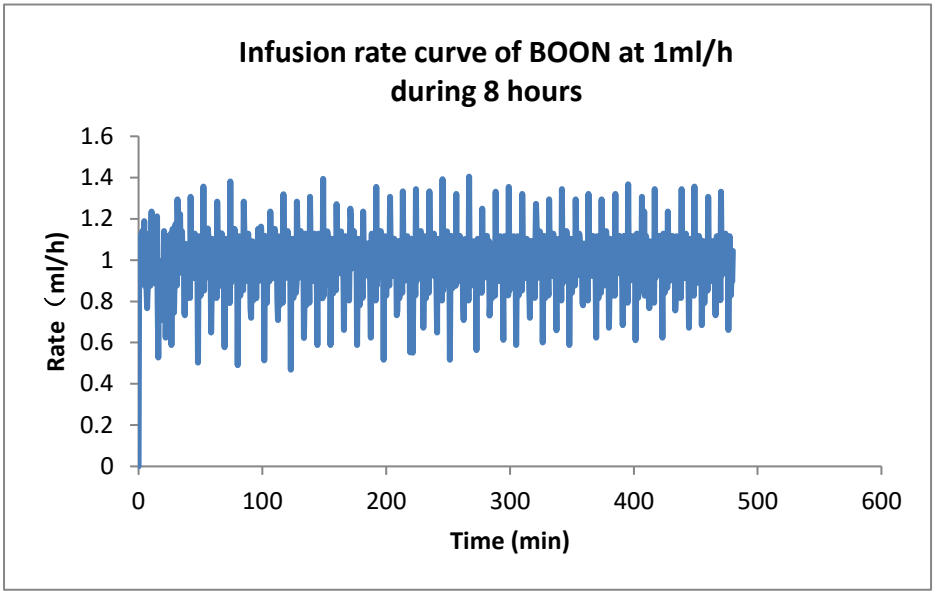
Sample quantity of infusion pump: 3

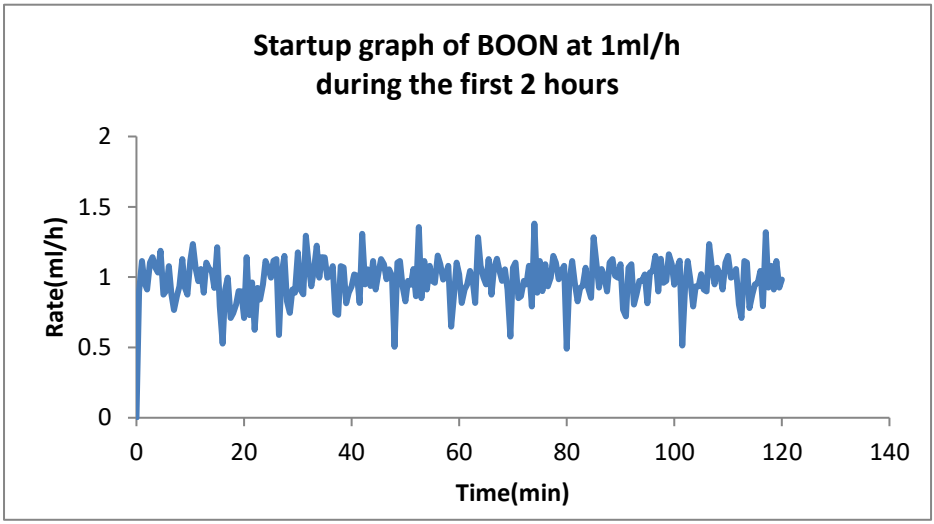
Sample quantity of infusion set: 3

Sampling rate: 1mL/h

Sampling interval : 0.5min

Test period : T=480min





Sample quantity of infusion pump: 3

Sample quantity of infusion set: 3

Sampling rate: 1mL/h

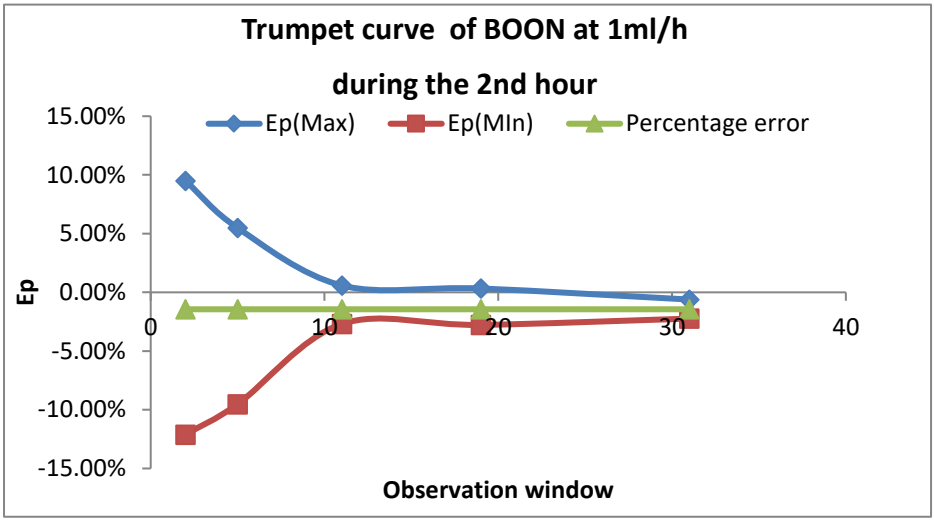
Sampling interval : 0.5min

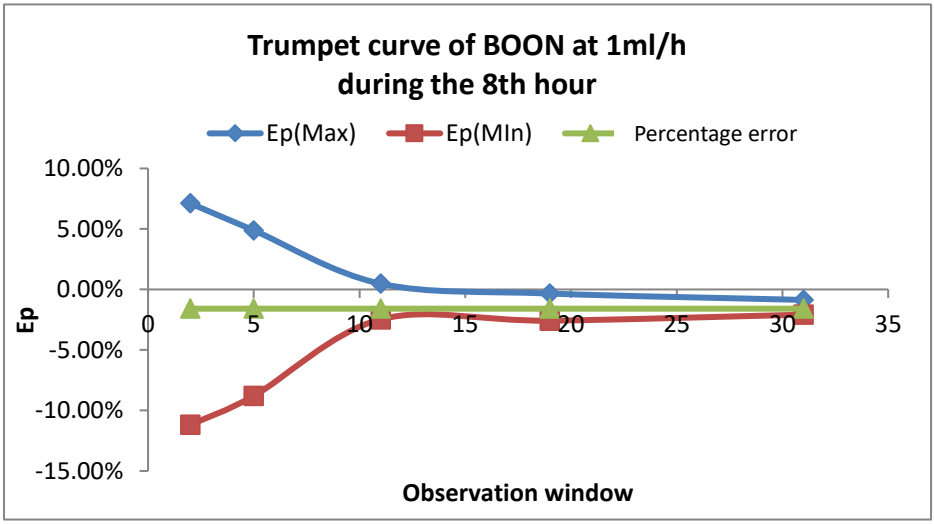
Observation window duration Pi=2, 5, 11, 19, 31 min

Ep (Max): Pi maximum error in observation window

Ep (Min): Pi minimum error in observation window

A: Average percentage of the overall errors of the rate measured





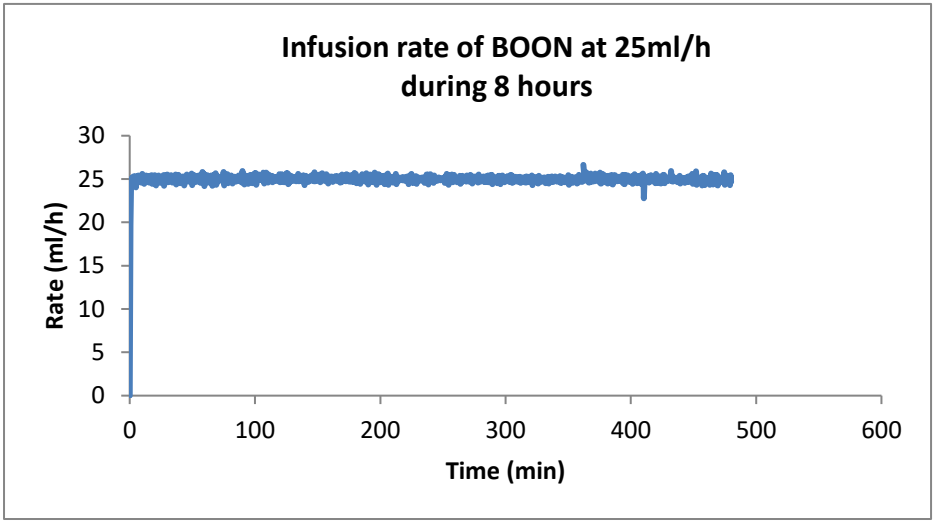
Sample quantity of infusion pump: 3

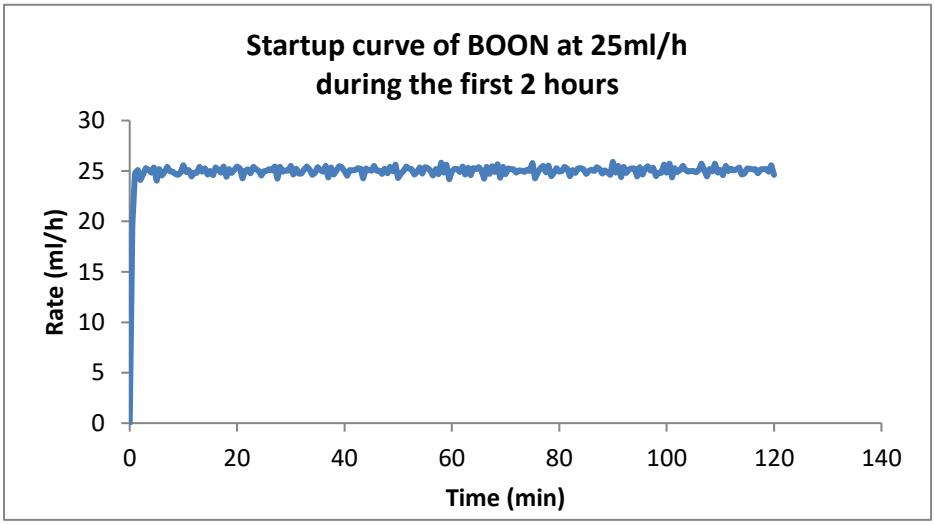
Sample quantity of infusion set: 3

Sampling rate: 25mL/h

Sampling interval: 0.5min

Test period: T=480min





Sample quantity of infuion pump: 3

Sample quantity of infusion set: 3

Sampling rate: 25mL/h

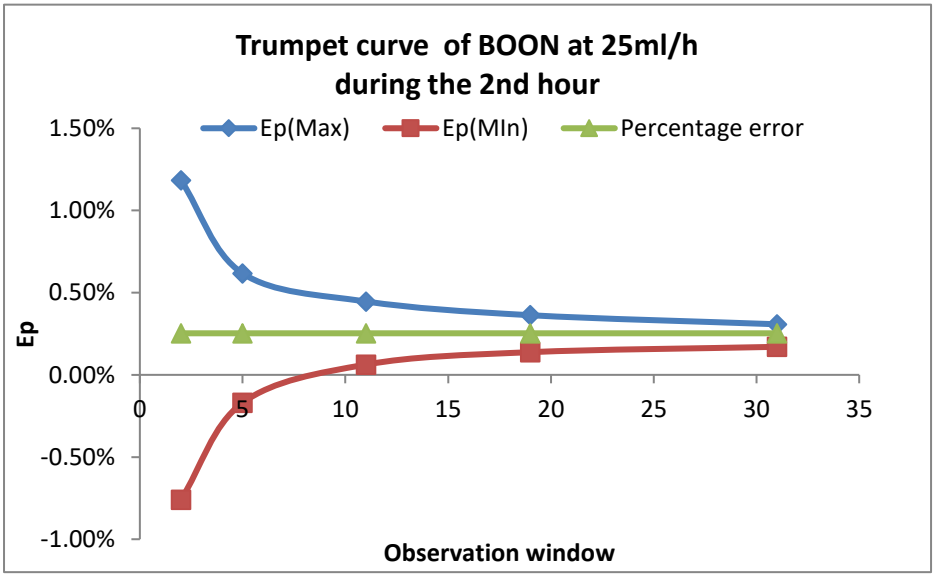
Sampling interval: 0.5min

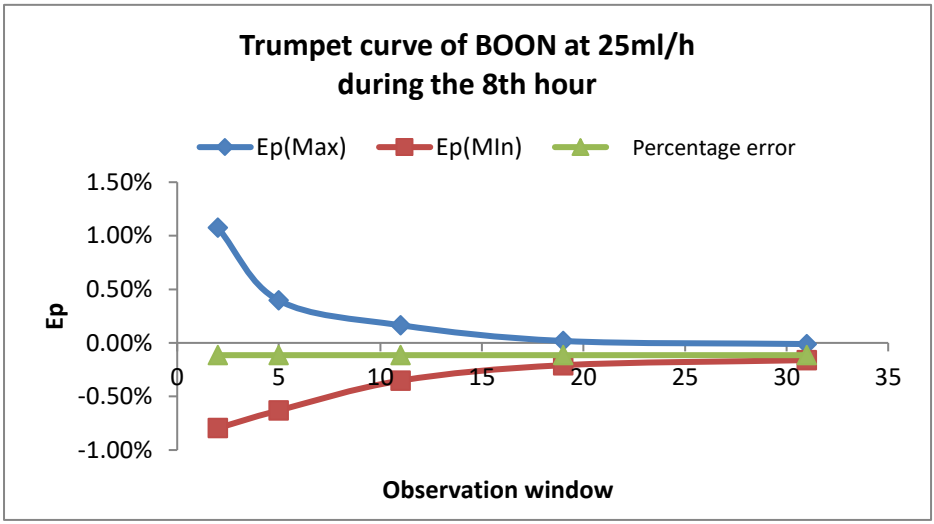
Observation window duration Pi=2, 5, 11, 19, 31min

Ep (Max): Pi maximum error in observation window

Ep (Min): Pi minimum error in observation window

A: Average percentage of the overall errors of the rate measured





2) B.Braun 20 drops/mL pressure infusion set； Testing mode: Rate Mode

Infusion set used in the test: B.Braun 20 drops/mL pressure infusion set

Test method: According to the method as specified in IEC 60601-2-24

Ambient temperature: 25℃±5℃

The test results are shown as follows:

The startup curve of B.Braun at 1mL/h

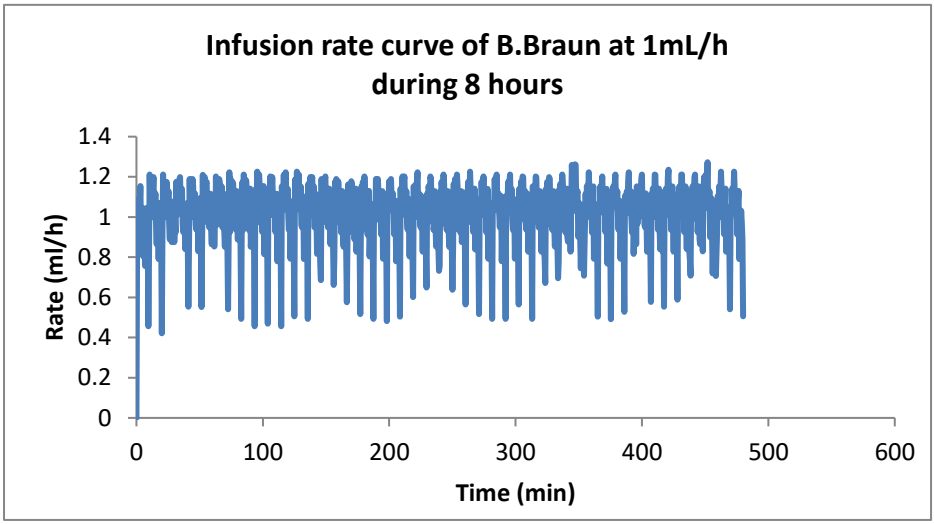
Sample quantity of infusion pump: 3

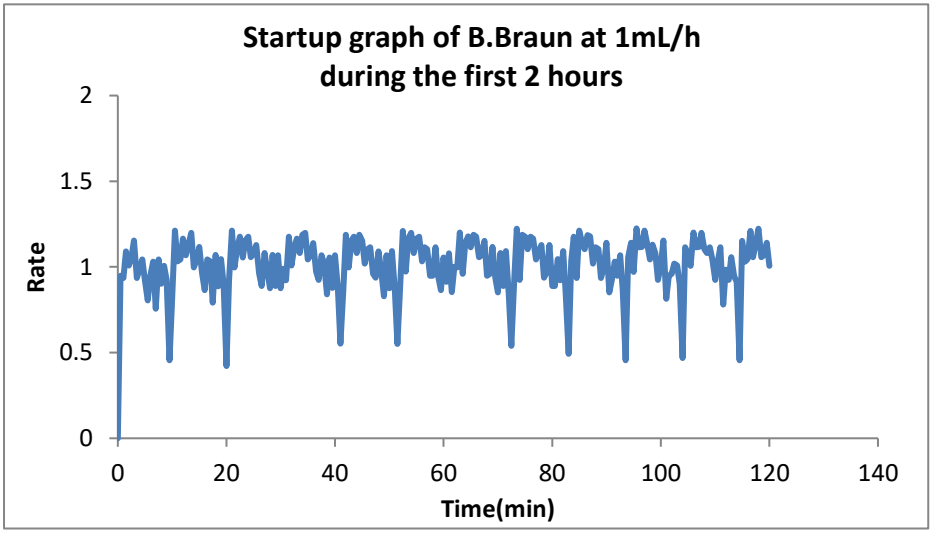
Sample quantity of infusion set: 3

Sampling rate: 1mL/h

Sampling interval : 0.5min

Test period : T=480min





Sample quantity of infusion pump: 3

Sample quantity of infusion set: 3

Sampling rate: 1mL/h

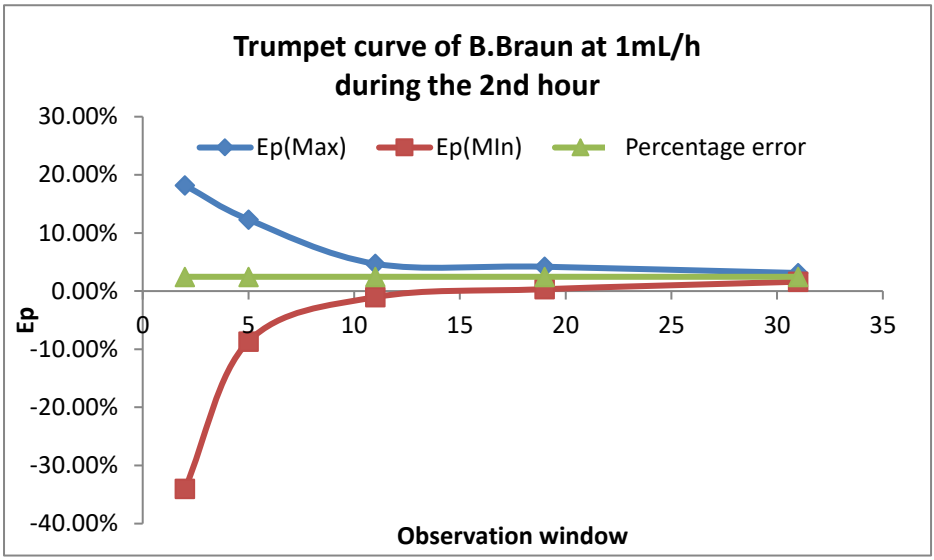
Sampling interval : 0.5min

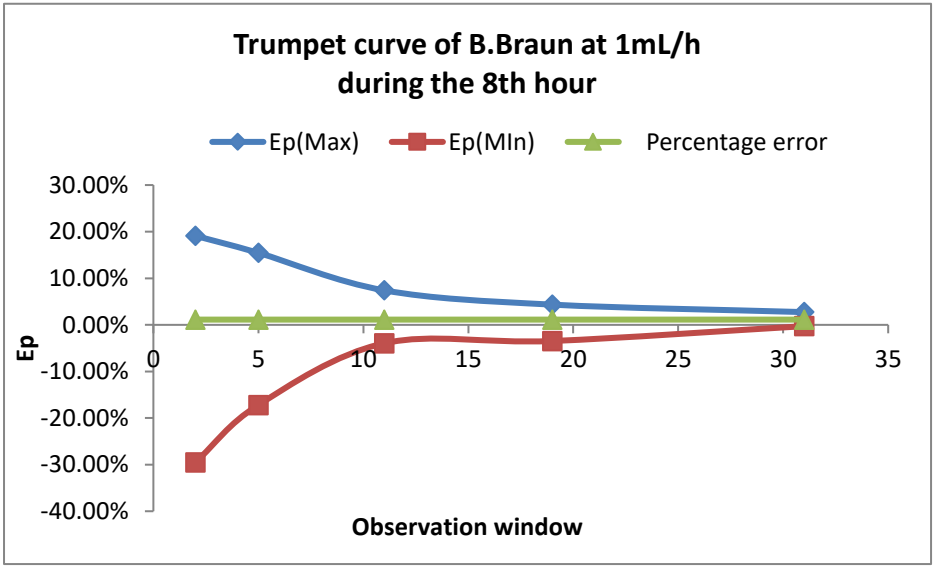
Observation window duration Pi=2, 5, 11, 19, 31 min

Ep (Max): Pi maximum error in observation window

Ep (Min): Pi minimum error in observation window

A: Average percentage of the overall errors of the rate measured





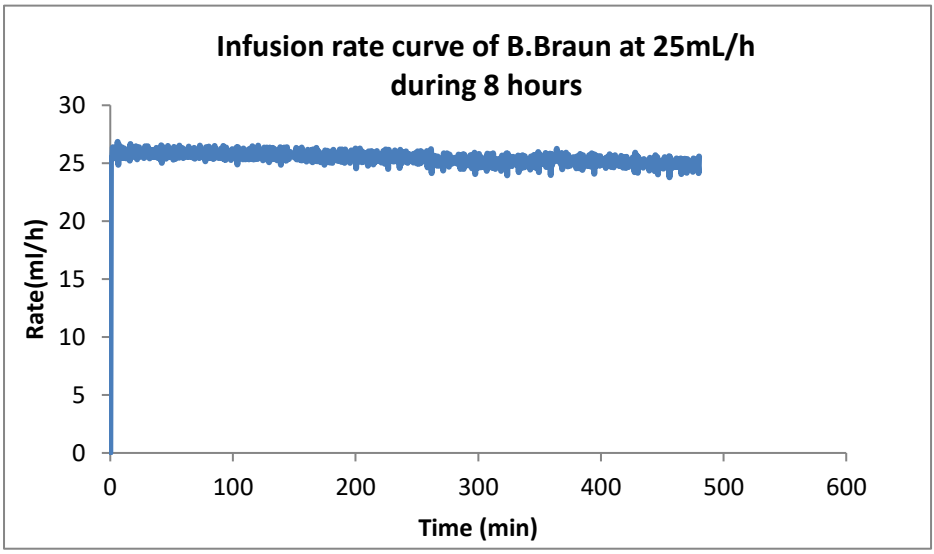
Sample quantity of infusion pump: 3

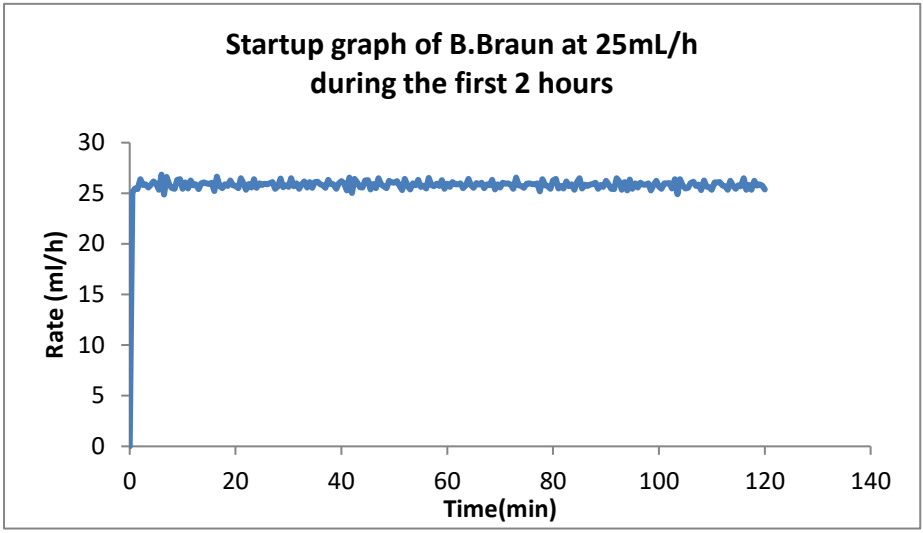
Sample quantity of infusion set: 3

Sampling rate: 25mL/h

Sampling interval: 0.5min

Test period: T=480min





Sample quantity of infuion pump: 3

Sample quantity of infusion set: 3

Sampling rate: 25mL/h

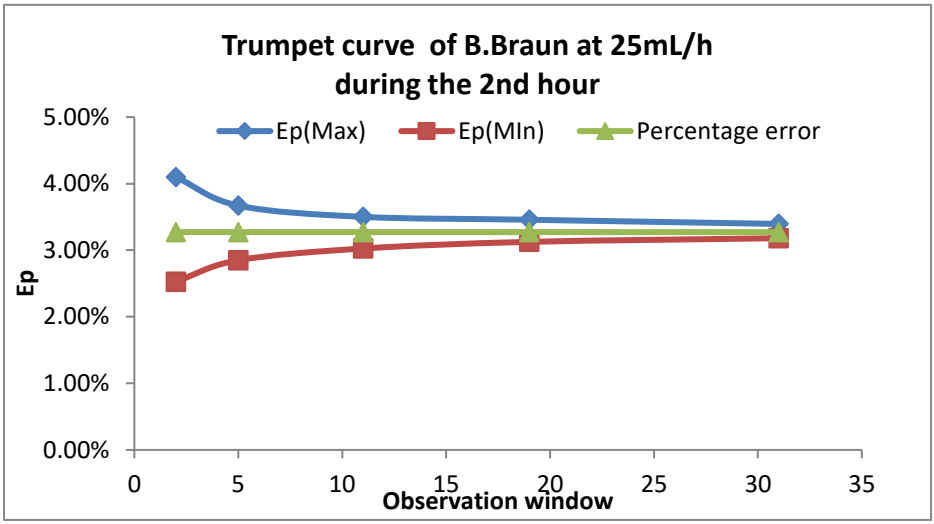
Sampling interval: 0.5min

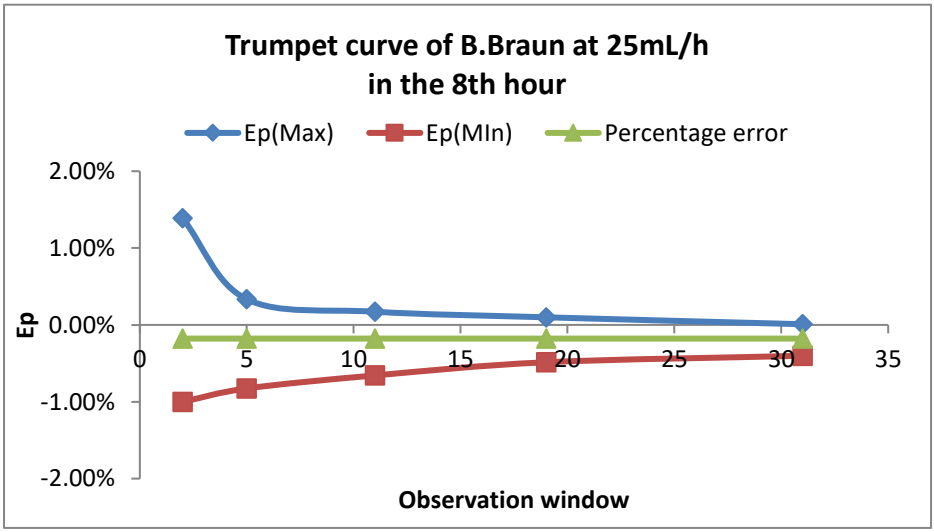
Observation window duration Pi=2, 5, 11, 19, 31min

Ep (Max): Pi maximum error in observation window

Ep (Min): Pi minimum error in observation window

A: Average percentage of the overall errors of the rate measured





3) Jierui 20 drops/mL transfusion set； Testing mode: Rate Mode

Infusion set used in the test: Jierui 20 drops/mL transfusion set

Test method: According to the method as specified in IEC 60601-2-24

Ambient temperature: 25℃±5℃

The test results are shown as follows:

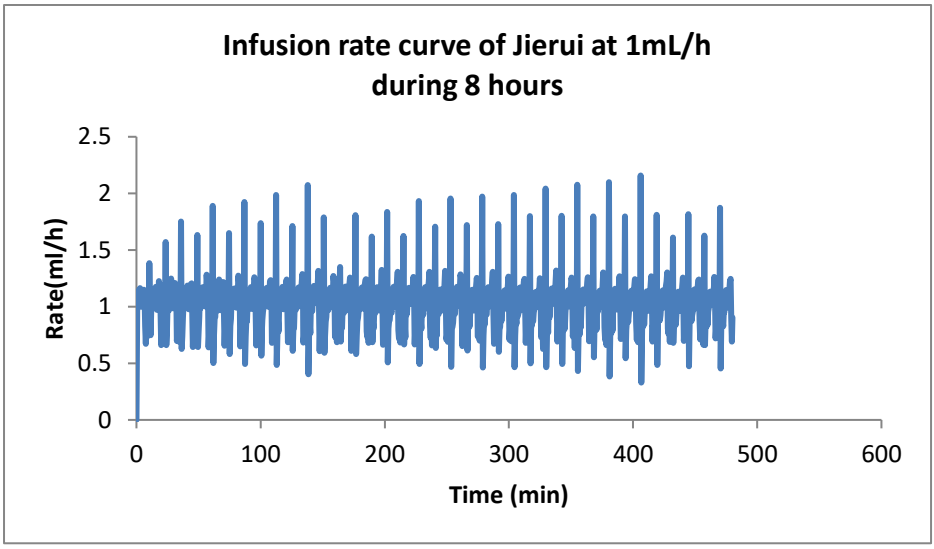
Sample quantity of infusion pump: 3

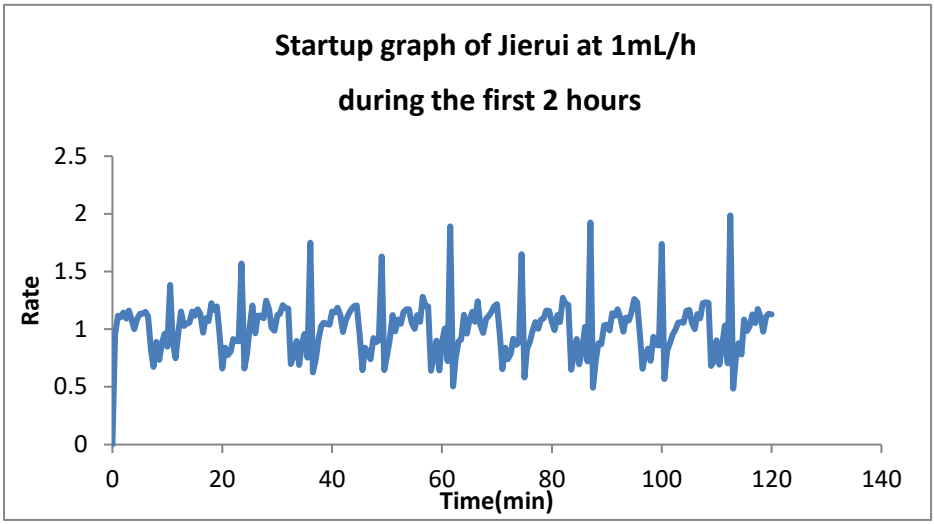
Sample quantity of infusion set: 3

Sampling rate: 1mL/h

Sampling interval : 0.5min

Test period : T=480min





Sample quantity of infusion pump: 3

Sample quantity of infusion set: 3

Sampling rate: 1mL/h

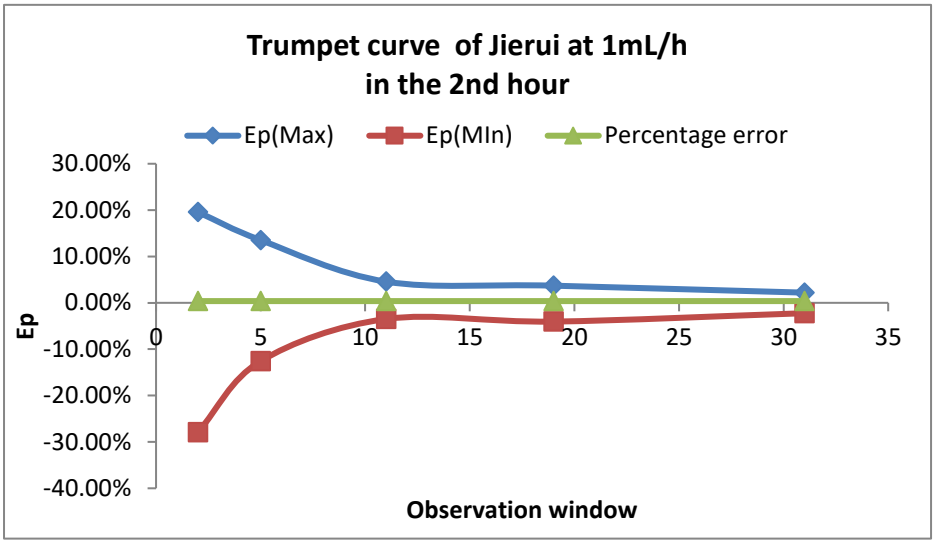
Sampling interval : 0.5min

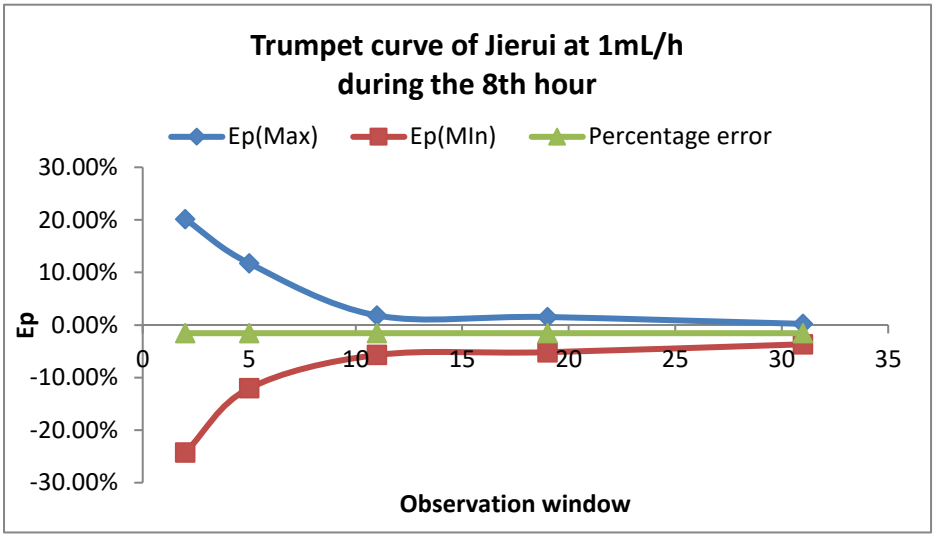
Observation window duration Pi=2, 5, 11, 19, 31 min

Ep (Max): Pi maximum error in observation window

Ep (Min): Pi minimum error in observation window

A: Average percentage of the overall errors of the rate measured





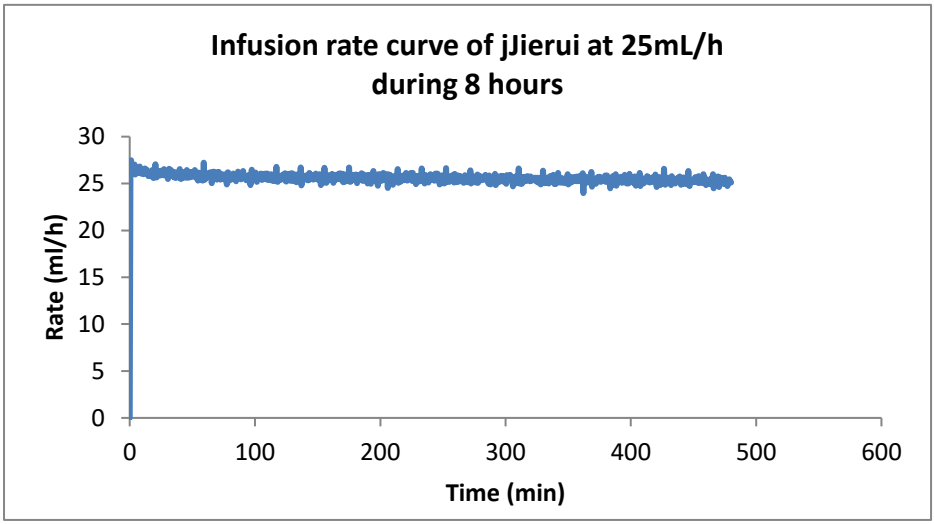
Sample quantity of infusion pump: 3

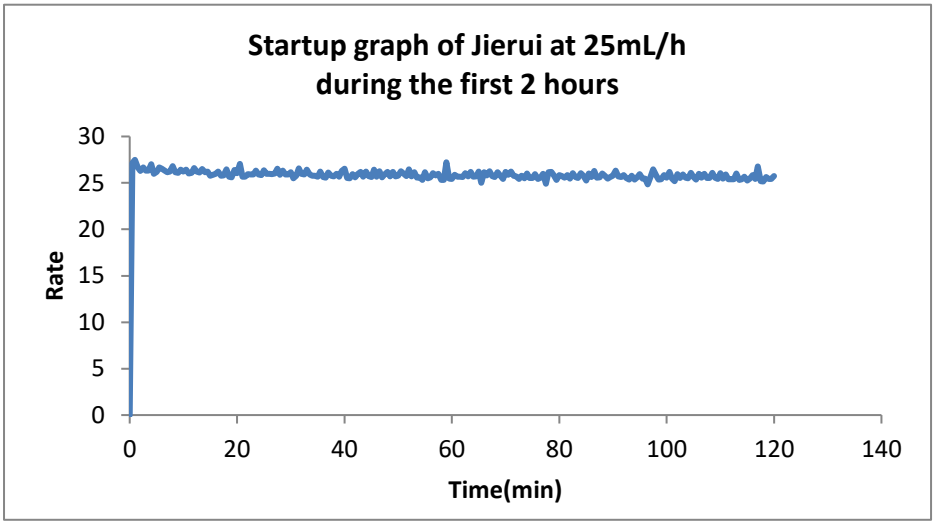
Sample quantity of infusion set: 3

Sampling rate: 25mL/h

Sampling interval: 0.5min

Test period: T=480min





Sample quantity of infuion pump: 3

Sample quantity of infusion set: 3

Sampling rate: 25mL/h

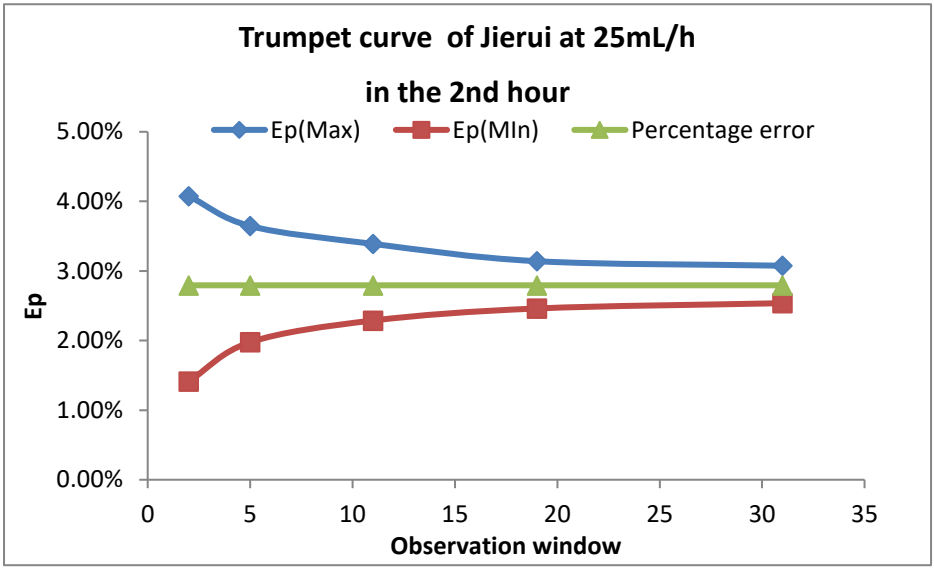
Sampling interval: 0.5min

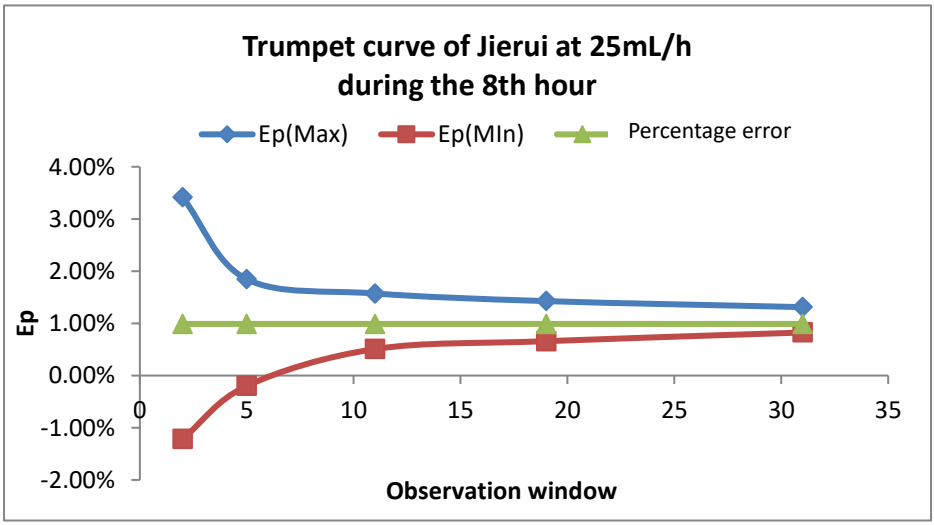
Observatoin window duration Pi=2, 5, 11, 19, 31min

Ep (Max): Pi maximum error in observation window

Ep (Min): Pi minimum error in observation window

A: Average percentage of the overall errors of the rate measured





4) Jev&Kev 20 drops/mL enteral nutrition feeding set；Testing mode: Rate Mode

Infusion set used in the test: Jev&Kev 20 drops/mL enteral nutrition feeding set

Test method: According to the method as specified in IEC 60601-2-24

Ambient temperature: 25℃±5℃

The test results are shown as follows:

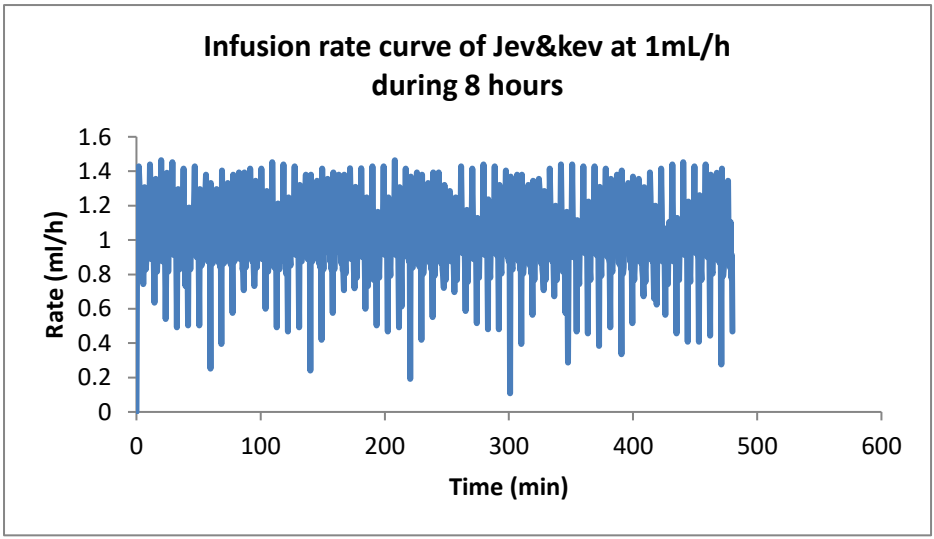
Sample quantity of infusion pump: 3

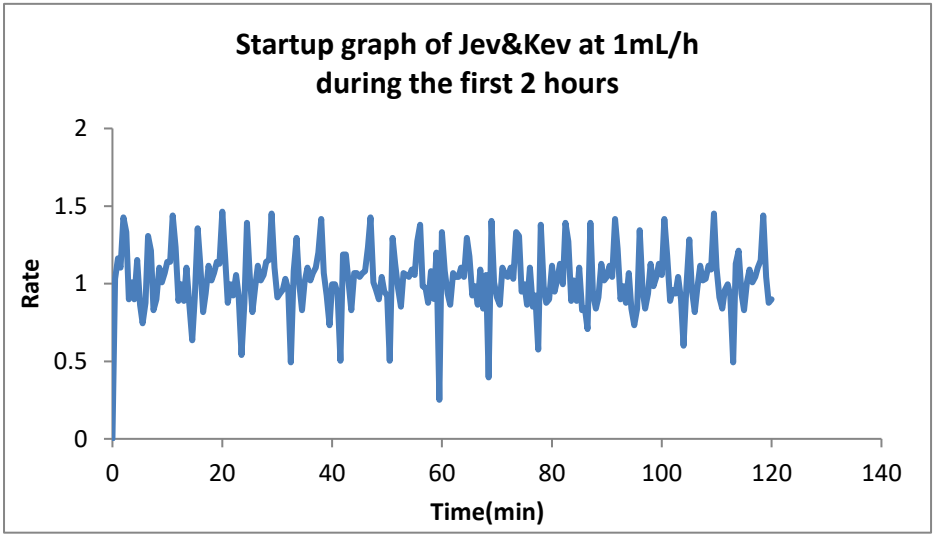
Sample quantity of infusion set: 3

Sampling rate: 1mL/h

Sampling interval : 0.5min

Test period : T=480min





Sample quantity of infusion pump: 3

Sample quantity of infusion set: 3

Sampling rate: 1mL/h

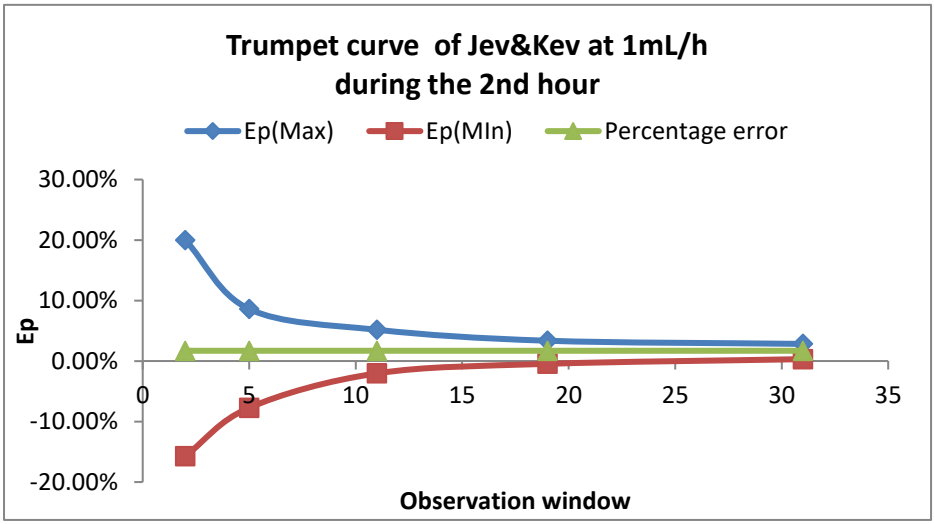
Sampling interval : 0.5min

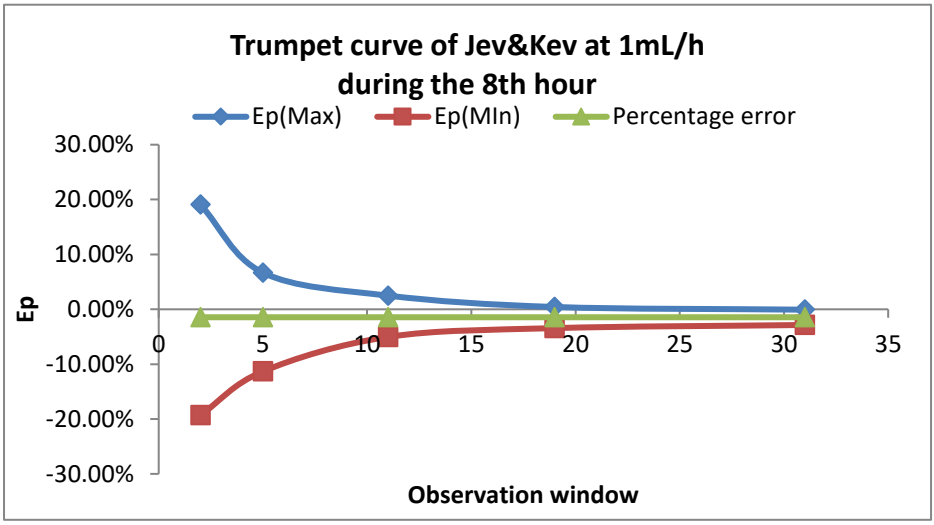
Observation window duration Pi=2, 5, 11, 19, 31 min

Ep (Max): Pi maximum error in observation window

Ep (Min): Pi minimum error in observation window

A: Average percentage of the overall errors of the rate measured





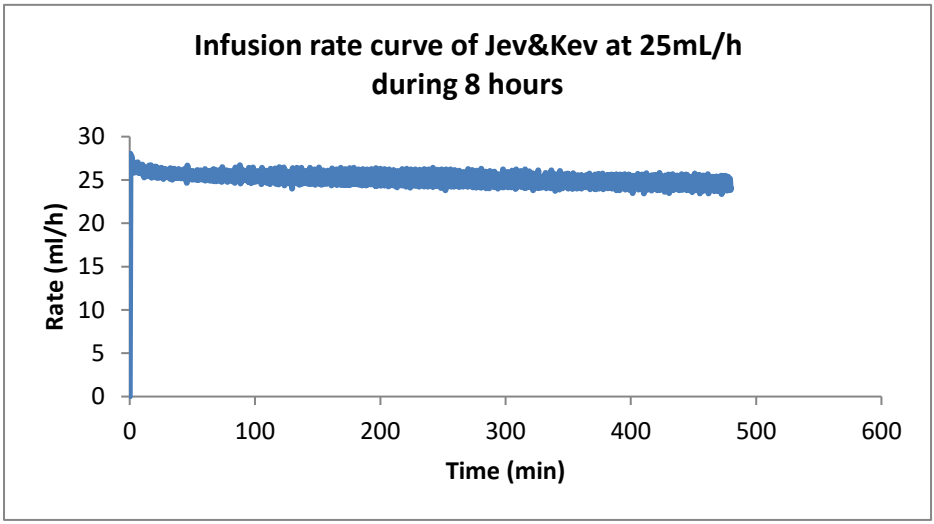
Sample quantity of infusion pump: 3

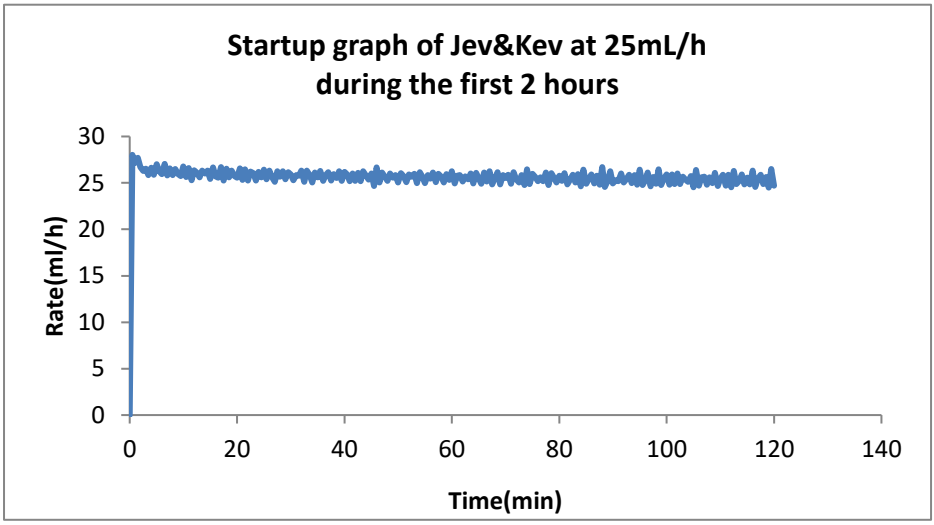
Sample quantity of infusion set: 3

Sampling rate: 25mL/h

Sampling interval: 0.5min

Test period: T=480min





Sample quantity of infusion pump: 3

Sample quantity of infusion set: 3

Sampling rate: 1mL/h

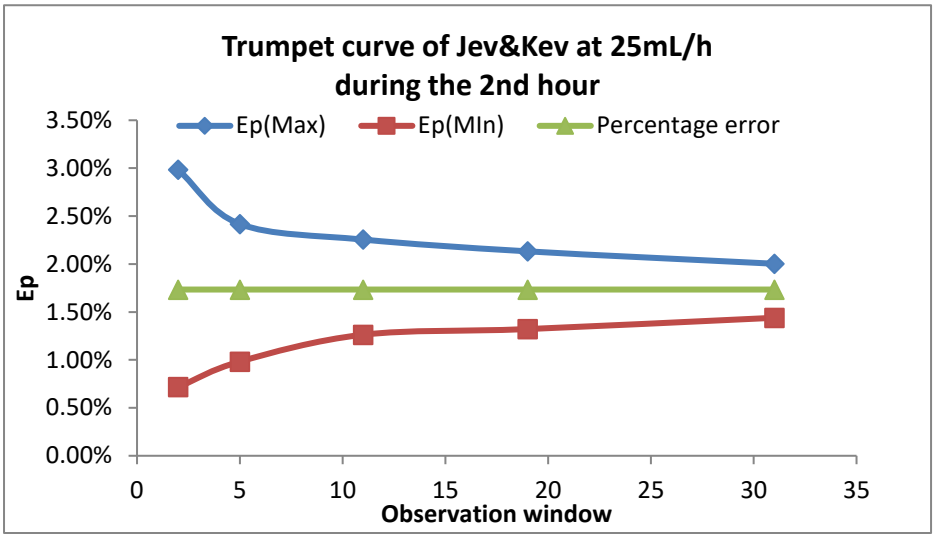
Sampling interval : 0.5min

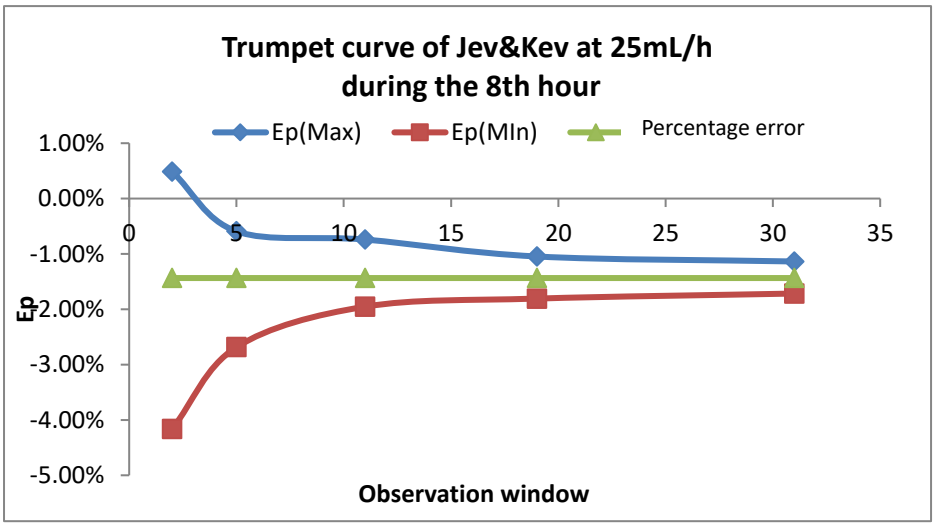
Observation window duration Pi=2, 5, 11, 19, 31 min

Ep (Max): Pi maximum error in observation window

Ep (Min): Pi minimum error in observation window

A: Average percentage of the overall errors of the rate measured





2. Results of bolus test

The bolus test results of the four recommended infusion/transfusion/feeding sets are as follows:

1) The testing result of using BOON 20 drops/mL infusion set:

Bolus setting	Calculated mean deviation from the set value	Calculated percentage deviation from the set value	Remarks
Minimum:0.1 mL	0.0024	Maximum positive percentage deviation：8.200% Maximum negative percentage deviation：-9.300%	Set flow rate: 25mL/h
Maximum:99.99 mL	0.5249	Maximum positive percentage deviation：4.66% Maximum negative percentage deviation：-2.96%	Set flow rate: 25mL/h
Maximum:99.99 mL	1.0444	Maximum positive percentage deviation：3.956% Maximum negative percentage deviation：-2.107%	Set flow rate: 2000mL/h

2) The testing result of using B.Braun 20 drops/mL pressure infusion set

Bolus setting	Calculated mean deviation from the set value	Calculated percentage deviation from the set value	Remarks
Minimum:0.1 mL	0.0014	Maximum positive percentage deviation：9.700% Maximum negative percentage deviation：-6.900%	Set flow rate: 25mL/h
Maximum:99.99 mL	1.3795	Maximum positive percentage deviation：4.167% Maximum negative percentage deviation：4.714%	Set flow rate: 25mL/h
Maximum:99.99 mL	1.4858	Maximum positive percentage deviation：0.710% Maximum negative percentage deviation：-3.307	Set flow rate: 2000mL/h

3) The testing result of usingJierui 20 drops/ml blood transfusion set:

Bolus setting	Calculated mean deviation from the set value	Calculated percentage deviation from the set value	Remarks
Minimum:0.1 mL	0.0017	Maximum positive percentage deviation：5.50%	Set flow rate: 25mL/h

		Maximum negative percentage deviation：-3.90%	
Maximum:99.99 mL	0.0620	Maximum positive percentage deviation：3.59% Maximum negative percentage deviation：-2.23%	Set flow rate: 25mL/h
Maximum:99.99 mL	0.2497	Maximum positive percentage deviation：2.09% Maximum negative percentage deviation：-3.85%	Set flow rate: 2000mL/h

4) The testing result of using Jev&Kev 20 drops/mL enteral nutrition feeding set:

Bolus setting	**Calculated mean deviation from the set value**	**Calculated percentage deviation from the set value**	**Remarks**
Minimum:0.1 mL	0.0002	Maximum positive percentage deviation：5.50% Maximum negative percentage deviation：-3.10%	Set flow rate: 25 mL/h

Maximum:99.99 mL	0.6310	Maximum positive percentage deviation：4.57% Maximum negative percentage deviation：-3.16%	Set flow rate: 25 mL/h
Maximum:99.99 mL	1.4171	Maximum positive percentage deviation：3.25% Maximum negative percentage deviation：-1.63%	Set flow rate: 2000 mL/h

3. Occlusion alarm response characteristic

The occlusion alarm time is the main indicator of the occlusion response characteristic; the following data only represent the conclusions obtained from the infusion set used in the test. Note: The occlusion alarm response time is affected by many factors such as infusion rate, the actual brand of the infusion set, infusion set specifications, volume of solution, and the length and pressure of patient tube.

1) The testing result of using BOON 20 drops/mL infusion set:

Rate (mL/h)	Occlusion Alarm Level	Occlusion pressure (mmHg)	Alarm Response Time (hh:mm:ss)	Bolus (mL/mg)
1	P1	32	00:02:38	/
1	P16	1033	00:59:10	/
25	P1	48	00:00:44	40mg
25	P16	1130	00:02:33	150mg

2) The testing result of using B.Braun 20 drops/mL pressure infusion set:

Rate (mL/h)	Occlusion Alarm Level	Occlusion pressure (mmHg)	Alarm Response Time (hh:mm:ss)	Bolus (mL/mg)
1	P1	20	00:02:26	/
1	P16	1085	00:55:14	/
25	P1	46	00:01:03	20mg
25	P16	1095	00:02:14	120mg

3) The testing result of usingJierui 20 drops/ml blood transfusion set:

Rate (mL/h)	Occlusion Alarm Level	Occlusion pressure (mmHg)	Alarm Response Time (hh:mm:ss)	Bolus (mL/mg)
1	P1	26	00:01:26	/
1	P16	1102	01:04:48	/
25	P1	96	00:00:05	1mg
25	P16	1130	00:01:35	12mg

4) The testing result of using Jev&Kev 20 drops/mL enteral nutrition feeding set:

Rate (mL/h)	Occlusion Alarm Level	Occlusion pressure (mmHg)	Alarm Response Time (hh:mm:ss)	Bolus (mL/mg)
1	P1	50	00:00:52	/
1	P16	1062	00:58:24	/
25	P1	72	00:00:04	11mg
25	P16	1156	00:01:48	35mg

NOTE

- **Occlusion alarm pressure, delay time, and large dose volume are all affected by test conditions, temperature, and length of tubing.**
- **The above data are only standard values under test conditions. Actual data may vary depending on different test conditions. Refer to the data tested for the product you purchased. For the same reference occlusion value and flow rate, the larger the measured pressure value, the longer the alarm delays.**

Appendix IV. EMC

NOTE

- **The infusion pump complies with the applicable EMC requirements in IEC60601-1-2 and IEC 60601-2-24.**
- **Please follow the EMC instructions in the User's Manual to install and use the device.**
- **Portable and mobile RF communication equipment may affect the performance of the infusion pump. To protect the pump against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.**
- **Refer to the attached guide and manufacturer's statement.**

WARNING

- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **Use of accessories and cables other than those specified or provided by the manufacturer of this the infusion pump could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
- **Please pay extra attention to the device's EMC performance and install and repair the infusion pump in an environment compliant with the following EMC requirements. Other equipment compliant with the transmission requirements of CISPR may also cause interference to the infusion pump.**

Accessories:

No.	Name	Length(m)	Shielded or not	Remarks
1	Power cord	3.0	No	/
2	Drip sensor cable	1.6	Yes	/

If this device is intended for use in an electromagnetic environment as defined in the electromagnetic immunity guide and statement, it shall remain safe and provide the following essential performance:

- Infusion Performance
- Occlusion Pressure
- Alarm

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Clause 5

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD)	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air

IEC 61000-4-2		
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m

IEC 61000-4-8		
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	

Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m

	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

Radio management compliance

The radio equipment used in this product shall comply with the main requirements and other relevant provisions of Radio Equipment Directive (RED) 2014/53/EU.

Appendix V. Default Settings

The following lists the important factory default settings in device configuration management. The user does not have the authority to change the content in the factory default configuration, but may change the setting content according to requirements and save it as a custom user configuration.

Bolus	Bolus rate	800.00mL/h
	Bolus volume	0.00mL
Purge	Purge rate	800.00mL/h
	Purge volume	0.00mL
Alarm settings		
Occlusion pressure	525mmHg (the 8th level)	
Nearly done	On	3min
No action time	On	2min
Bubble size	100ul	
Air Accumulated	0.20mL/15min	
Patient information		
Name	/	
MRN (medical record Number)	/	
Pat Type	Adu	
Bed No.	/	
DOB(date of birthday)	1900-01-01	
Height	/	
Age	/	

Weight	/	
Sex	M (Male)	
Blood	Other	
BSA	0.00m^2	
BMI	0.00	
Doctor	/	
Order	/	
Parameter settings		
KVO	On	0.5mL/h
Check empty	Low	
System settings		
Auto-Lock	15s	Off
Key light	On	
Auto Brightness	Off	
Brightness	Level 6	
System volume	Level 0	
Alarm volume	Level 8	
Night mode	Off	
	Time	20:00:00~08:00:00
	Brightness	Level 3
	Alarm volume	Level 3
	System volume	Level 0
Nurse Call	Off	
	Signal type	Continuous
	Triggering mode	Normally Open
	Triggering level	Low
Date/Time	Date format	Y-M-D

	Date	2000-1-1
	Time format	24-Hour
	Time	00:00:01
WIFI	Off	
	DHCP	On
	IP address	200.200.200.1
	Subnet Mask	255.255.255.0
	Gateway	200.200.200.1
	Server IP	200.200.200.100
	Port No.	5000
Maintenance		
Language	English	
Unit of Height	cm	
Unit of Weight	kg	
Pressure unit	mmHg	
Manual bolus	3.00mL	
Manual purge	5.00mL	
Pressure mode	Regular	
Parameter switch	Anti-bolus	On
	Auto Restart	Off
	Concentration Parameters	Off
	Drug Parameters	Off
	Poweroff Check	On
	Low Occlusion Level	Off
	Air Accumulated	On
	Upstream Occlusion	Off
	Drip Control	Off

	Drip Sensor	Off

Appendix VI. Terms

1. Abbreviations list

KVO=Keep Vein Open

SN=Series Number

LED=Light-Emitting Diode (indicator lamps)

TPN=Total Parenteral Nutrition

VTBI=Volume To Be Infused

MRI=Magnetic Resonance Imaging

BSA=Body Surface Area

EMC=Electromagnetic compatibility

IEC=International Electrotechnical Commission

ISO=International organization for Standardization

2. Glossary

KVO means keeping the vein open, and the infusion pump automatically injects at a very low rate after completing the infusion task to prevent blood from blocking the needle. The KVO rate is the minimum rate to keep the vein open.

Appendix VII. Network Security Information

NOTE

- **Installation, layout, debugging and maintenance of the wireless network must be completed by after-sale service engineers of Comen Company or the service personnel authorized by the Company.**
- **Wireless network layout must comply with local laws.**
- **Non-medical devices cannot be connected to the network.**
- **Radio-frequency interference can cause wireless network disconnection.**
- **In order to ensure network security and network stability, data communication of all network-related functions must use a closed network dedicated to the hospital. The hospital shall ensure the security of the private network.**
- **Secure network encrypted information, such as passwords, and prevent unauthorized personnel from accessing the encrypted information.**
- **Network disconnection may cause data loss and functional failure. Once the network is disconnected, please check patient infusion state and troubleshoot the disconnection.**
- **If communication between the infusion pump and the Infusion Workstation System is disconnected, it will be failed to collect real-time information of the infusion pump. Please do not rely on the Infusion Workstation System to obtain the running state of the infusion pump.**
- **If communication between the infusion pump and the Infusion Central Monitoring System is disconnected, please do not rely on the Infusion Central Monitoring System to obtain the running state of the infusion pump.**
- **When the wireless signal is weak, the data between the infusion pump and the Infusion Workstation System may be lost.**
- **When the communication is abnormal or the communication signal is weak, the data transmitted between the infusion pump and Infusion Workstation System may be lost.**
- **When the infusion pump communicates with the Infusion Workstation System, ensure that the IP address of the infusion pump and the server IP address of the Infusion Central Monitoring System are in the same network segment.**
- **Ensure that the IP address of the infusion pump is set correctly. For any issues with IP setup, please contact the service personnel. Incorrect network setting may result in**

data loss.

- The infusion pump is intended to be used in professional healthcare facilities by professional healthcare personnel.
- It is important to note that any facility using the Comen infusion pump and other equipment must take measures to protect the privacy of a patient's personal information in accordance with country-specific regulations, and consistent with the facility's policies for managing this information.
- No software installation required for the embedded device.
- Comen will make available on request of soft bill of material.

⚠ WARNING

- Improper use of the infusion pump could cause hazard to patients and device performance level.
- Do not connect to an unrecognized or unsecured network.
- Do not confirm remote connection requests or any other remote action unless it is initiated by the responsible organization as intended.
- For embedded device, the security update is integrated with the software application program update. The update is only allowed locally by authorized user.
- The device supports change of user passwords with strong password policy enforcement. It also supports a reminder to change the default passwords during first access.
- When the infusion pump reach end of life, do erase patient data and configuration data before enforce disposal policy.
- Before connect the infusion pump to other equipment, ensure that any connected device is free of malware.
- Only connect the device to the manufacturer indicate compatible and ensure that any connected device is free of malware.

⚠ CAUTION

- Use a virus scan on any USB stick before inserting it to prevent a virus or malware infection.
- The use of infusion pump outside of its intended purpose could pose cyber security

risks.

- **Do not use a device in the patient environment if it does not comply with IEC 60601-The whole installation, including devices outside of the patient environment, must comply with IEC/EN 60601-1.**

1. Working environment

Swap mode		
Hardware configuration	Processor	STM32F446VET6
	Storage	128 KB SDRAM
	Peripheral device	Qspi FLASH(16M)
	I/O	USB interface: USB standard interface
Software environment	System environment	Windows
	Security software	None
Network condition	Network interface	None
	Network type	None
	Network architecture	None
	Bandwidth	None
	Wire, wireless	Wireless
	Transport protocol	Custom network transport protocol
	Storage medium	None

	Storage format	None
User access mechanism	The local user identity authentication method is "user name + password authentication", the user type and authority are common users, and login password is not set. Settings such as alarm volume adjustment and factory reset and other settings require password.	
Software Update	Software update**s** must be carried out by the manufacturers' engineers. The common user cannot perform the software update.	

2. Interface control

1) Hardware interface

This device has a multi-function interface:

- Intended function: When using it for nurse call function, the nurse call cable should be connected to support the hospital nurse call system; when using it for USB function, connect the USB flash disk with the pump by an adapter for exporting logs and upgrading software.
- Intended operator: Authorized Comen technical maintenance personnel who have received relevant training on this product.
- Communication protocols: serial communication protocol (Comen's own encrypted RS232 protocol), USB protocol (Standard protocol USB2.0).
- Expected data direction: data is transmitted from the external tool to the device machine for software upgrade and from the device to the external tool for log export.

2) Software Interfaces

- **WIFI interface**
  - Intended function: Connection to a wireless router
  - Intended operator: clinicians and healthcare professionals who have received training related to this product, and technical

maintenance personnel authorized by Comen.
- Communication protocol: WIFI protocol (IEEE802.11a/b/g/n)
- Expected data direction: /

- **Network interface**
  - Intended function: connection to the Infusion Central Monitoring server
  - Intended operator: clinicians and healthcare professionals who have received training related to this product, and technical maintenance personnel authorized by Comen.
  - Communication protocol: TCP/IP protocol
  - Expected data direction: data transmission between the infusion pump and the server of the Infusion Central Monitoring System.

3. Recommendations to guarantee network security

Steps that can be taken to safeguard this information and the general security of the infusion pump:

- Physical Access: Limit use of the infusion pump to authorized users. Keep the device under physical control
- Active Use: Users of the infusion pump should take measures to limit patient data storage. Patient data should be removed from the infusion pump after the infusion procedure has ended.
- Network Security: The facility must take measures to ensure the security of any shared network to which the infusion pump may be connected to.
- Device Security: Only connect the device to the manufacturer indicate compatible and ensure that any connected device is free of malware.
- Keep the device updated.
- Use good password.
- Act on or follow-up on alerts, inconsistencies, strange behavior of a device and let the responsible organization (Health Delivery Organizations, HDOs) knows.

Appendix VIII. List of Key Components

No.	Name
1	Switching power supply
2	Lithium battery
3	Power outlet
4	Motor
5	LCD screen
6	Power cable

Appendix IX. Drug Library

WARNING

- **The factory default parameters of the pump cannot be directly used in clinical treatment. Before infusion, please ensure that the infusion parameters are consistent with the values prescribed by the physician. We do not provide any infusion parameter of any drug.**
- **We are not responsible for the consequences caused by incorrect type of drug and infusion parameters. Users should carefully read all the information provided by the drug manufacturer.**
- **Do not use this infusion pump to inject drugs with high viscosity, nutrient solution or lipids etc.**
- **Users can add drugs to the drug library. Please confirm that the drug has got CE certification before infusion and refer to relevant instructions to make sure that the drug can be infused using the infusion pump.**
- **To make sure that the drug can be injected with the selected infusion set, please confirm that the selected infusion set has got CE certification and please refer to the relevant instruction of the drug and infusion set before use.**

For example:

No.	Name
1	No drug
2	Adrenaline
3	Dopamine
4	Isoprenaline
5	Noradrenalin
6	Amiodarone
7	Ditiazem
8	Lidocaine
9	Esmolol

10	Nicardipine
11	Dobutamine
12	Dopexamine
13	Verapamil
14	Clonidine
15	Labetalol
16	Urapidil
17	Phentolamine
18	Nitroglycerine
19	Dobutamine Hydrochloride
20	Milrinone
21	Amrinone
22	Sodium Nitroprusside
23	Alprostadil
24	Phosphocreatine
25	Atorvastatin
26	Coenzyme Complex
27	Notoginsenoside
28	Amlodipine
29	Cinepazide
30	Valsartan
31	Xingnaojing
32	Nifedipine
33	Salvia
34	Ligustrazine
35	Ulinastatin
36	Irbesartan
37	Isosorbide Dinitrate
38	Isosorbide Mononitrate
39	Felodipine
40	Trimetazidine

41	Losartan
42	Calendulae Flower
43	Simvastatin
44	Methoxyphenamine
45	Acetylcysteine
46	Asarone
47	Aminophylline
48	Nikethamide
49	Trinitrine
50	Gangliosides
51	Oxiracetam
52	Edaravone
53	Vinpocetine
54	Sodium valproate
55	Nalmefene
56	Naloxone
57	Aescine
58	Meclofenoxate
59	Meropenem
60	Cefamandole
61	Levofloxacin

Appendix X. Consideration for Environmentally Conscious Design

1. Instructions for Minimizing Environmental Impact during Normal Use

This part is compiled based on the requirements of Clause 4 Protection of Environment, 4.5.2 Instructions for minimizing environmental impact during normal use of IEC 60601-1-9.

According to the requirements of this clause, manufacturer shall provide instructions for minimizing the environmental impact of the ME equipment during normal use in the accompanying documents.

The instructions cover the following items (Table 1).

Table 1 The requirements of Clause 4.5.2 and Instructions provided by manufacturer

The requirements of Clause 4.5.2	Instructions provided by manufacturer
1) Instructions on how to install the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Try to keep the integrity of the non-disposable packing material and put away the packing materials for future use or put into the specified location where complying with the rules and regulations of the Local government and the Hospital. Avoid overusing the cleaning reagents and other substances. For the reusable

	accessories, clean it with specified reagent and put away, and for the disposable one, deal with it in a collective way and put into the specified location where complying with the rules and regulations of the Local government and the Hospital. If not specified, please follow the rules and regulations of the Local government and the Hospital.
2) Instructions on how to use and maintain the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Use the specified accessories and cleaning and disinfection reagent to avoid harm to the machine and accessories and reduction of the service life. Use the medical device strictly following the instruction manual. And for maintaining the medical device, always dilute according to the manufacturer’s instructions or use lowest possible concentration. Never use bleach. Do not mix disinfecting solutions (such as bleach and ammonia) as this may result in hazardous or poisonous gases or liquids. When there is a need to maintain, please follow the

	Instruction for Use or follow the rules and regulations of the Hospital.
3) Consumption during NORMAL USE (e.g. energy, consumable materials/parts, disposables, water, gasses, chemicals/reagents etc.);	During normal use of this device, it will consume electricity (alternate current and direct current-battery). The disposable consumables shall be disposed of following the rules. For cleaning or disinfection for the cables and machine, the water and ethanol or isopropanol will be used and the waste liquid shall be thrown following the rules.
4) Emissions during NORMAL USE (e.g. WASTE water, WASTE consumable materials, acoustic energy, heat, gasses, vapours, particulates, HAZARDOUS SUBSTANCES and other WASTE);	During normal use, it is expected there will be some consumption of the medical device. To avoid unnecessary consumption such as acoustic energy, heat, gases, hazardous substances, etc, it's recommended that on the premise of normal operation, turn down the volume of alarm so that much interference will not be exerted to the environment. Also turn off the unused module in time to reduce the unnecessary heat emission and electricity consumption.

5) Information on the location within the ME EQUIPMENT of HAZARDOUS SUBSTANCES, radioactive sources and induced radioactive materials.	The battery is located on the back of the machine. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

2. Information for End of Life Management

This part is compiled based on Clause 4 Protection of Environment, 4.5.3 Information for end of life management of IEC 60601-1-9.

According to the requirements of this clause, the manufacturer shall provide the responsible organization with information for the proper disposal of the ME equipment at End of Life (EOL). And the manufacturer shall make available information to waste treatment facilities necessary for the environmentally responsible management of end of life ME equipment.

The information shall contain the following items (Table 2).

Table 2 The requirements of Clause 4.5.3 and Instructions provided by manufacturer

The requirements of Clause 4.5.3	Instructions provided by manufacturer
1) The location of components and parts within the ME equipment that contain stored energy or pose other hazards that can result in an unacceptable risk to disassemblers or others and methods for controlling such risks.	The battery is located on the bottem of the device. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

2) The identity and location of hazardous substances requiring special handling and treatment	The battery is located on the bottom of the device. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.
3) Disassembly instructions sufficient for the safe removal of these hazardous substances including radioactive sources and induced radioactive materials within the ME equipment.	For other hazards that may result in unacceptable risk, the main concern is the handling with battery: Risk of fire, explosion, or burns. Do not crush, puncture, disassemble or short circuit the battery. Do not dispose of the battery in fire or water. Do not place the battery in an environment whose temperature is above 60℃ (140℉). Store the battery in the -20℃ (-4℉) to 60℃ (140℉) environment. Use the specified charger only. Read instructions for use. Maximum Recommended Ambient is 45℃ (125℉). Dispose of used batteries promptly and in an environmentally-responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements.

	As for disposing of the medical device, to avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the medical device appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of parts and accessories such as thermometers, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

Appendix XI. Abbreviation List

Abbreviation	Full name
CPU	Central Processing Unit
LED	Light Emitting Diode
ICU	Intensive Care Unit
NICU	Newborn Intensive Care Unit
Auto	Automatic
KVO	Keep Vein Open
VTBI	Volume To Be Infused
AC	Altenating Current
DC	Direct Current
LCD	Liquid Crystal Display
MIN	Minimum
MAX	Maximum
ID	Identification
USB	Universal Serial Bus
IEC	International Electrotechnical Commission
CCC	China Compulsory Certification
CE	Conformite Europeenne
EMC	Electromagnetic ompatibility
IP	Internet Protocol
EN	English
Alm Setup	Alarm settings
Pres. Level	Pressure level
Air Accum.	Air or bubble accumulated
Med	Alarm priority: Medium
MRN	Medical Record Number
Pat. Cat.	Patient type or category
Bed No.	Bed number of patient
DOB	Date of birth

Blood	Blood Group; ABO blood group; Blood Type
BSA	Body Surface Area
BMI	Body Mass Index
Order	Doctor's order or prescription
Dose Time M.	Dose Time mode
Intmt. Mode	Intermittent mode
Seq. Mode	Sequential Mode
First Dose M.	First Dose Mode
Timed Cumul.	Timed cumulant
EBIS	Empty Bottle Inspetion Sensitivity
Auto-Lock	Automatic screen lock
Auto Brightness	Automatic brightness
Sys Vol.	System volume
Alm Vol.	Alarm volume
Min Alm Vol.	Minimum alarm volume
Alm Tone	Alarm tone
Y-M-D	Year-Month-Day
D-M-Y	Day-Month-Year
M-D-Y	Month-Day-Year
Trig. Type	Triggering type
Trig. Level	Triggering level
Norm. Close	Normally close
Norm. Open	Normally open
Pres. Unit	Pressure unit
Pres. Mode	Pressure mode
Common M.	Common mode
Param. Switch	Parameter switch
Drug Lib.	Drug library
Brand Lib.	Brand library
Pres. Cal.	Pressure calibration
Prec. Cal.	Precision calibration
System Info	System information
Anti-bolus	the pressure is automatically release
Auto-Restart	Automatic device restart after occlusion

Concen. Param.	Concentration parameter
Drug Param.	Drug parameter
Air Accum.	Air or bubble accumulated
INF. Pump	Infusion pump
INF. Driver	Infusion driver
Product S/N	Product serial number
Dead BAT	Dead battery
VTBI Done	the Volume To Be Infused is emptied or finished
Syringe Spec. Error!	Syringe Specification Error
KVO Done	The infusion is finished at preset Keep Vein Open rate
AC Off	AC power disconnected
IP Repeat	The IP already exists.
Motor Pos. Err	Motor positioning failure
Motor Dir. Err	the motor direction is abnormal
Motor Speed Err	the motor speed is abnormal
Slave Dir. Err	the slave/secondary direction is abnormal
Slave Speed Err	the slave/secondary speed is abnormal
Motor Power Err	the motor power supply is abnormal
Up Pres. Sen. Err	Upstream Pressure Sensor Error
Down P-sensor Err	Downstream pressure sensor failure
Abn. Drip Rate	Anormal drip rate
Bed No. Repeat	Bed number repeat
Drug Vol.	Drug volume
Intmt. Vol.	Intermittent volume
Intmt. Rate	Intermittent rate
FDose Rate	First dose rate
FDose Vol.	First dose volume
FDose Time	First dose time