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Product Name: Syringe pump

Product Model: M800/M800A

Software Version: V1.0

Date of Manufacture: Refer to the Label

Service Life: 10 years (25℃/50% R. H.)

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

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- 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.

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After-Sales Service Department

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Preface

This user manual describes the performance, operation methods and other safety information of the M800 and M800A syringe pump manufactured by Comen.

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

Please read this manual carefully before using the syringe pump and keep it in a safe place for further reference by the operator.

Intended Readers

This user manual is suitable for professional clinical personnel or those who are expected to have knowledge and work experience in medical procedures, practices, and terminology necessary to monitor patients.

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 or 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 is 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 syringe pump.

Conventions

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

The password of user maintenance: 5188

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Chapter 1 Safety Information

1.1 Overview of safety information

WARNING

- **Alerts you to situations that may result in serious consequences or adverse events or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of the user or patient.**

CAUTION

- **Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in minor injury, product failure or damage, or property damage, or cause more serious injury in the future.**

NOTE

- **Emphasizes important precautions and provides instructions or explanations for better use of the product.**

WARNING

- **The pump should not be installed or stored in a location where liquid can easily spill, as liquid spills on the syringe pump's power plug may 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 syringe pump in a chemical warehouse or where a gas discharges.**

- **This pump is a portable device, which is allowed to be used in the ambulance (without type restriction).**

CAUTION

- **Do not install or store the syringe 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 heat source or heating equipment nearby.
  A risk of water splashing onto the device.
- **Do not use a radio or TV near the syringe 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 syringe pump, otherwise there is risk of fire or electric shock.**
- **Plug the device's power cord (only use the power cord supplied with the device) 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 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.**
- **If the syringe pump fails, do not disassemble it by yourself. Please contact the manufacturer in time.**
- **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.**
- **Independent of the soft dose limits in the system, the selected values have to be the medically correct ones for the given patient.**
- **If 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 a low infusion rate for critical drugs, consider the start-up characteristics of this pump.**
- **In the event of the tube becoming twisted, filter condensation or intubation occlusion during infusion, the internal pressure of the infusion tube will increase. Once the causes for occlusion are removed, too much infusion liquid may be infused into the patient. Therefore, appropriate actions should be taken. For example, clamp the tube before removing the causes of the occlusion.**
- **The connection between the pump and the infusion system or the accessories connected to the patient line may cause a change of the infusion rate and increase the possibility of air input to the patient.**
- **Regularly check whether the syringe, extension tube for infusion and infusion flow are normal during operation.**
- **Defibrillation will not affect the basic performance (such as infusion accuracy, alarms and signal transmission) of the pump.**

⚠ CAUTION

- **High-frequency instruments or equipment that consume lots of power, such as electrical surgical instruments, should be connected to a separate AC mains power**

socket.

- **If you need to operate the syringe 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

- **This product can only be used by professional clinicians, medical electrical engineers, or qualified doctors and nurses after training.**
- **The drug dose, drug volume and rate of infusion can only be set by professional clinicians, medical electrical engineers, or by qualified doctors and nurses after training.**
- **Before using, you should read the entire manual carefully. Before you fully understand its operation, attempting to use this device 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 posit the device to make it difficult to operate the power plug which uses to isolate the device circuits electrically form the supply mains.**
- **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.**
- **To avoid possible electric shock hazards, don't open the shell of this device. The maintenance and upgrading of this device must be conducted by the service personnel trained and authorized by Comen.**
- **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 out of children's reach.**
- **Do not use this device at a place where there is flammable anesthetic gas mixed with**

air or flammable anesthetic gas mixed with oxygen or nitrous oxide.

- **Do not use this device in an environment with flammable anesthetic gas or other corrosive gas and dust.**
- **Do not use this device in direct sunlight.**
- **Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.**
- **Do not replace the batteries with ones which are not approved by Comen.**
- **The equipment connected with the pump shall form an equipotential circuit (the protective grounding wire is effectively connected).**
- **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.**
- **When the pump is connected with HF surgical equipment, the sensor and the cables must avoid coming into contact with the HF equipment to protect against burns to the patient.**
- **An electromagnetic field will affect the performance of this device, so the use of other equipment near this device must meet corresponding EMC requirements. For example: Mobile phones and X-ray equipment may be interference sources, because they will transmit high-strength electromagnetic radiation.**
- **This is not a therapeutic device.**
- **Please install and carry the device properly to protect the device from damage caused by dropping, colliding, and strong vibration or other mechanical forces.**
- **The operators shall not touch the patients and the device at the same time.**
- **For the Infusion Workstation System and syringes used with this pump, refer to the instruction manual of the relevant product for the relevant safety warning information and operation information.**
- **The alarm information displayed on the screen of the pump is only for doctors' reference and cannot be used directly as a basis for clinical treatment.**
- **If there is a problem with the installation of the external power 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 device. Incorrect operation can cause danger to the patient.**
- **It is strictly forbidden to use a mobile phone or other radio transmitting equipment at the same time within a radius of 10 meters when the device is working.**
- **This pump cannot be used with high power, high temperature, high radiation, high**

noise, volatile corrosive gas equipment.

- **After each use of the pump, the power should be turned off to prolong service life.**
- **The pump needs to be placed on a stable, vibration-free table or in a well-ventilated cabinet.**
- **This syringe pump should not be serviced or maintained while being used.**
- **Comen will conditionally provide the user with technical documents related to maintenance such as circuit diagrams when necessary. The pump can only be maintained by an after-sales service engineer of Comen or an authorized engineer.**
- **When the alarm volume is set lower than the ambient noise level, it will lead to difficulty for users in identifying alarm conditions and operating status of the device, which will bring potential danger to the patient.**
- **A risk assessment should be conducted before selecting or changing alarm signals (such as alarm sound).**
- **When it is necessary to replace the syringe or extension tube during infusion, please stop the infusion first and make sure that the selected brand and specification of the syringe in the system are the same as the syringe actually being used. If a non-recommended syringe is going to be used, calibration is required. Otherwise the infusion accuracy will not be guaranteed.**

⚠ CAUTION

- **To avoid damage to this device 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 on 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 local relevant laws and regulations or the rules and regulations of the hospital.**
- **Disposable accessories must be recycled or properly disposed of.**
- **Avoid using this device and its accessories in direct sunlight, high temperature and humidity.**
- **The operating environment and power supply of this pump must meet the requirements in the product specifications.**
- **In order to ensure infusion accuracy, the brand and specification of the syringe used must be consistent with that selected on the device.**

- **Please use the syringe recommended in this user manual. If a non-specified syringe is used, the infusion accuracy will not be guaranteed.**
- **Before intending to operate the device by using the built-in battery, check whether the battery has sufficient power and charge it if necessary.**
- **The battery must be charged after each use to ensure enough battery power is available when next required.**
- **The syringe and the patient line (the part of the infusion line between the device and the patient) are treated as the applied part.**
- **When the end of the patient line is completely blocked, the maximum infusion pressure at the end of the infusion tube will not exceed 1350mmHg.**
- **Use the syringe pump within 100cm above and below the height of the patient's heart. The smaller the height difference between the syringe pump and the patient's heart, the more accurate the pressure detection in the tube.**
- **Always read manufacturer precautions and guidelines for medications, syringes and administration set used with this pump.**
- **Before starting any delivery, always confirm the set infusion parameters are consistent with the doctor's prescription. Operating the syringe pump at an infusion rate other than that prescribed will cause inappropriate delivery, which can result in serious injury or death.**
- **This pump cannot be used for blood transfusion.**
- **This pump cannot be used for the infusion of analgesics, chemotherapy drugs and insulin**
- **The copyright of the device and its software is owned by our company. Do not modify this equipment without authorization of the manufacturer.**
- **Do no use an integral multiple socket-outlet or an AC power extension cord. Ensure that the sum of grounded leakage current does not exceed the allowable limit.**

⚠ NOTE

- **This user manual introduces the product according to the most complete configuration. The product you purchased may not have 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 (25℃/50%R.H.).**

- **Do not insert any device not specified by Comen into the USB port, plug-in box interface and expansion controller interface.**
- **In a single fault condition, the maximum possible infusion volume will not exceed 0.2mL.**
- **If the pump is carrying out the bolus or purge function, the alarm system can operate normally.**

1.2 Contraindications

None.

1.3 Side effects

None.

1.4 Symbols

- **Symbols on the device**

Symbols	Instructions	Symbols	Instructions
	Warning		Refer to the accompanying document
	Defibrillation-proof type CF applied part		Serial number
	Multifunction interface		Main menu
IP33	Protected against solid foreign objects of⌀2,5	/	/

	mm and greater. Protected against spraying water.		
	Manufacturer	100-240V~ 50/60Hz	Power specifications
	Bolus/Purge		Alarm audio pause
	Start/Stop		Power On/Off
	Symbol of syringe pump		Separate collection for electrical and electronic equipment
	Date of manufacture	/	/

- **Symbols on the package**

Symbols	Instructions	Symbols	Instructions
	This Way Up		Stacking Limit by number (Maximum number of identical transport packages/items which may be stacked on the bottom package, where 16 is the limiting number.)

	Fragile, Handle With Care		Keep Away from Rain
	Temperature Limits		Atmospheric Pressure Limitation
	Humidity Limitation	/	/

- **Symbols on the interface**

Symbols	Instructions	Symbols	Instructions
	Alarm settings		Alarm audio pause
	Maintenance		Patient information
	Parameter settings		System settings
	Main menu		Log
	Alarm acknowledged		Volume muted
	Back		Scanner
	Reduce brightness		Increase brightness

	Increase pressure		Reduce pressure
	Increase volume		Reduce volume
	Battery being charged		Battery full.
	Battery nearly full		Low not sufficient
	Low battery		Dead battery
	Battery being charged		No battery installed or damaged battery.
	Function on		Function off
	Stopped/paused state		Infusion in progress
	Search		Audio off
	Previous page		Next page
	Night mode		USB connected successfully
	Precision Calibration		Relay infusion with other pumps

	Strong signal		No signal
	The wireless network is not connected		Very Weak signal
	Weak signal		Enter password
	Screen locked		Screen unlocked

Chapter 2 Overview

The design of this device 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 electrical engineers, or by suitably trained clinical medical and nursing staff. The operator must receive sufficient training before using this product. This product must not be operated by anyone who has not been authorized to do so or has not received suitable training.**

2.1 Structure and composition

The M800/M800A syringe pump is mainly composed of a pump shell, motor driving system, input system, storage system, control system, display system, sensor detection system and alarm system.

2.2 Principle

The infusion action of the syringe pump is controlled by a single-chip computer system that sends out control pulses to rotate the motor through the drive circuit. The rotating motor drives the screw and nut through the reduction mechanism to convert the rotational motion of the motor into the linear motion of the nut, which is connected to the push rod of the matching syringe to push the piston of the syringe for infusion. By setting the rotation speed of the motor, the speed of its propulsion to the matching syringe can be adjusted, so that the given drug dose and speed can be adjusted.

2.3 Intended use

2.3.1 Intended purpose

The M800/M800A syringe pump is intended for use on adult, pediatric and neonate patients for intermittent or continuous delivery of medications through clinical intravenous route of administration.

2.3.2 Indication for use

The syringe pump is for patients who need to receive various types of medications in controlled amounts through an intravenous route.

2.3.3 Intended users

The syringe pump is intended to be used by healthcare professionals.

2.3.4 Intended patient population

The syringe pump is applicable for adult, pediatric and neonatal patients. The PCA mode is only applicable to adult patients.

2.3.5 Intended body parts, tissues, or areas of interaction

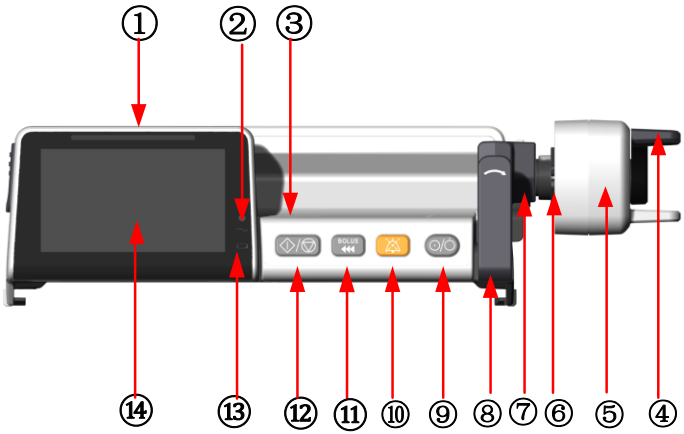
The syringe pump is used in conjunction with specific syringes and extension tubes, to control the dose of medications infused through the veins into the patients' body.

2.3.6 Intended use environment

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

2.4 Appearance

2.4.1 Front view

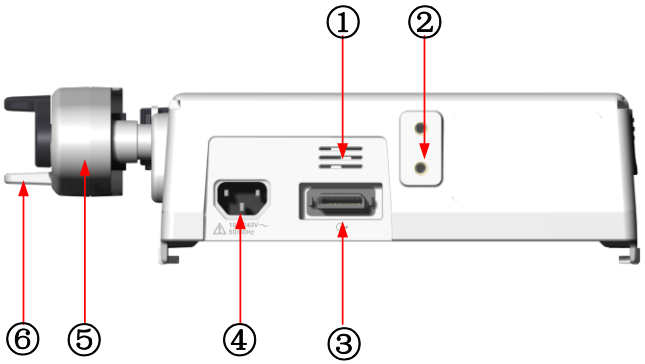


①	Alarm indicator	
②	AC indicator	On: The syringe pump is connected to the AC power supply. Off: The syringe pump is not connected to the AC power supply.
③	COMEN	Company logo
	M800/M800A	Product model

④	Finger grips	Used to control the opening and closing of the plunger flange gripper and control the activity of the push rod.
⑤	Push rod	For pushing the syringe plunger.
⑥	Plunger flange gripper	For clamping the syringe plunger flange.
⑦	Barrel flange clamp	For clamping the syringe barrel flange.
⑧	Syringe clamp	For clamping the syringe
⑨	Power On/Off key	This button is used to power the pump on/off and enter the standby state. Press and hold this key for more than 3s and then release, the pump will be turned on; when the pump is turned on and the pump is in the non-infusion state, namely in the paused or stopped status, press this key and select [**Turn Off**] in the dialog box to shut down the pump. The pump cannot be shut down during infusion.
⑩	Alarm audio pause key	For high and medium alarms where it is possible to pause the alarm audio, the alarm audio will be paused for 2 minutes after pressing this key. In the audio-paused state, the alarm indicator and alarm messages work normally. If a new alarm is triggered during the paused state, except special alarms, the device will maintain the current audio paused state. Please refer to ***Chapter 7 Alarms*** for details.

⑪	Bolus/Purge key	Press this key during paused or stopped states to enter the **Purge** interface. Press this key during infusion to enter the **Bolus** interface. The purge volume will not be added to the total volume of the current infusion, but the bolus volume will be added to the total volume of the current infusion.
⑫	Start/Stop key	After installing the syringe correctly and setting infusion parameters, press this key to start infusion. During infusion or in the automatic bolus state, press this key to stop infusion. On occasions where infusion is stopped by alarms, such as occlusion, press this key to acknowledge these alarms.
⑬	Battery indicator	On: Battery being charged Off: Battery not installed or battery full Flashing: Battery being used for power supply to the pump
⑭	Display screen	

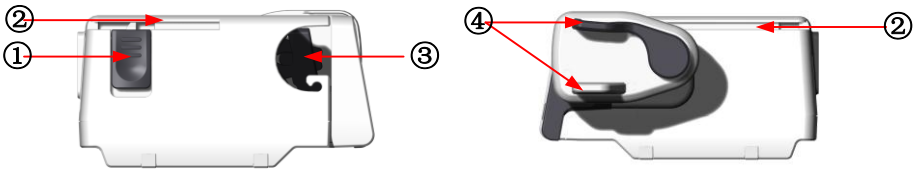
2.4.2 Rear view



①	Speaker holes
②	Pole clamp mounting holes (two)
③	Multifunction interface: a) DC power input interface; b) RS232 interface; c) Nurse call interface; d) USB interface (for connecting with the Scanner/for software update)； e) KLink interface (for connecting with the compatible patient monitors); f) PCA interface (for connecting with the PCA accessory); g) MX8900/MX8900A interface (for communicating with the MX8900/MX8900A Infusion Workstation System)
④	Alternating current power supply (AC) port

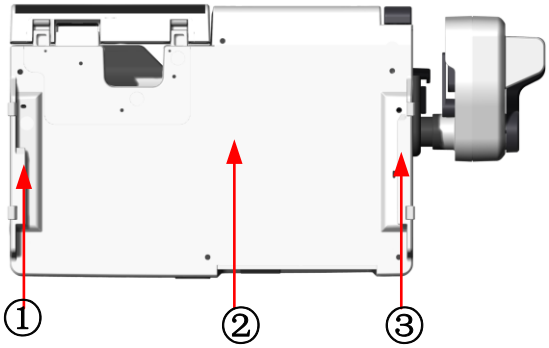
⑤	Push rod: for pushing the syringe plunger.
⑥	Finger grips: for controlling the opening and closing of the plunger flange gripper, or control the activity of the push rod.

2.4.3 Side view



①	Multi-channel lock.
②	Multi-channel connecting slide rail.
③	Syringe channel.
④	Pinch handle.

2.4.4 Bottom view

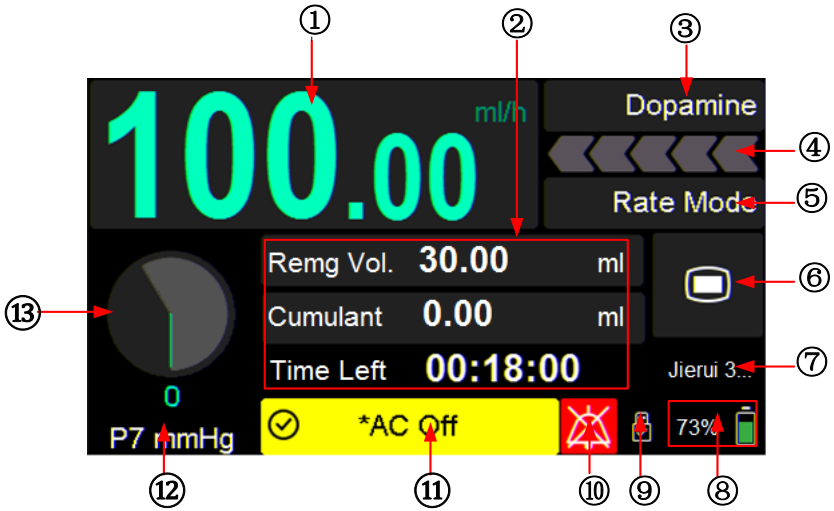


①	Multi-channel connecting slide rail.

②	Device label
③	Multi-channel connecting slide rail.

2.5 Screen display

The M800/M800A syringe pump is equipped with a touchscreen. In addition, the brightness of screen is adjustable. The screen displays the alarm information, battery status and other information.



①	Rate	⑧	Battery state of charge
			Battery icon
②	VTBI	⑨	USB icon
	Cumulant		WIFI icon
	Time left		

			Night mode icon  Scanner  Relay infusion with other pumps  Screen locked icon 
③	Drug	⑩	Alarm audio pause icon
④	Status icon	⑪	Alarm information
⑤	Mode selection key	⑫	Pressure level
⑥	Main Menu key	⑬	Occlusion pressure display area
⑦	Syringe brand and type	/	/
Note: Due to the different settings, the displayed information on the device screen may be different from the above figure.			

Chapter 3 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 protect patients from burns due to electricity leakage.**
- **All the simulation and digital equipment connected with this device must be products certified according to the designated EN standards (e.g. EN 60950-1 information technology equipment-safety and EN 60601-1 medical electrical equipment-safety). Moreover, all equipment connection shall abide by the valid edition of EN 60601-1-1 System Standard. The staff in charge of connecting the additional equipment to medical system at the input/output signal port must confirm whether the system conforms to the EN 60601-1-1 Standard. If you have any question, please contact our company.**
- **In normal use, the operator shall not touch the signal I/O ports and the patient simultaneously, otherwise patient injury may result.**
- **If more than one external equipment is connected to the pump at the same time through the network interface or other signal interfaces, the total leakage current should be compliant with that specified in EN 60601-1.**

NOTE

- **This device should be placed in an approximately horizontal position.**
- **In order to ensure the normal operation of the device, read this chapter and the safety information chapter before use, and install it as instructed.**
- **This device is not disinfected when it is delivered. Clean and disinfect the device before first use.**

3.1 Installation

3.1.1 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 there is any question, please contact our sales department or agent immediately.

WARNING

- **If you find any damage to the pump, contact the relevant personnel of the hospital or after-sales service department of Comen.**
- **In order to prevent the syringe pump from being contaminated by microorganisms, do not unpack the pump prematurely. If the package is damaged, do not use it.**
- **Keep the packaging materials out of the reach of children. Please dispose of the packaging materials complying with the local laws and regulations or the waste disposal rules of the hospital.**
- **Please save the packaging materials for later transport or storage.**

3.1.2 Environment requirements

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

When the ambient temperature is 20°C, it takes 10 minutes for the pump to rise from the lowest storage temperature -20°C to the temperature of expected use.

When the ambient temperature is 20°C, it takes 10 minutes for the pump to lower from the highest storage temperature 55°C to the temperature of expected use.

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, erosive or combustible gases, extreme temperatures, and humidity are avoided.

⚠ WARNING

- **Please ensure that the syringe 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.**

3.1.3 Fit the handle

Push down on the multi-channel lock on the 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, release 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, and slide the handle in the opposite direction to remove it.

⚠NOTE

- **Please hold the handle for lifting or moving the device to avoid the device damage caused by dropping, colliding and strong vibration or other mechanical forces.**

3.1.4 Fit 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 counter-clockwise to allow the infusion pole to be inserted into the pole clamp.

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

⚠NOTE

- **When this pump is to be used in an ambulance, fasten the pump to the infusion pole in the ambulance by using a pole clamp.**

3.1.5 Multi-channel option

Push down on the multi-channel lock on the 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, release the multi-channel lock. When you hear a click, the pump and handle are locked. To separate the pumps, firstly you need to push down on the multi-channel lock of the lower pump, and slide the upper pump in the opposite direction to separate the two pumps.

Like the steps shown in ***3.1.4 Fit the pole clamp***, multi-channel combined pumps can be fixed on the infusion pole.

3.2 Preparation

3.2.1 Connect to the AC power supply

Steps for connecting the pump to the AC power supply:

1. Confirm that the AC power supply meets the specifications in this manual.
2. Connect one end of the power cord to the AC power port of the device and plug the other end to the grounded AC power source.
3. Check whether the AC power indicator light is on.

The AC power indicator is at the lower right corner of the display screen. When the pump is connected to the AC power source, the AC indicator light will remain on.

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, or accidents or injuries may result.**

NOTE

- **Connect the power cord to a hospital-grade socket.**
- **Recharge the battery after the device is transported or stored. If the device is started without connecting to an AC power supply, it may not work properly because of insufficient battery power. The battery is recharged when an AC power supply is connected, regardless of whether the device is switched on.**

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

3.2.2 Protective earthing

To protect 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 cord to a 2-pin power outlet.**

Connect the earth wire to the equipotential connector of the device. If you have any doubts about whether devices used together involve any electrical risks, such as risks caused by accumulation of leakage current, consult an expert in this field to ensure the safety of all devices.

3.2.3 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 differences. In this case, do not use the pump until it becomes fully dry.

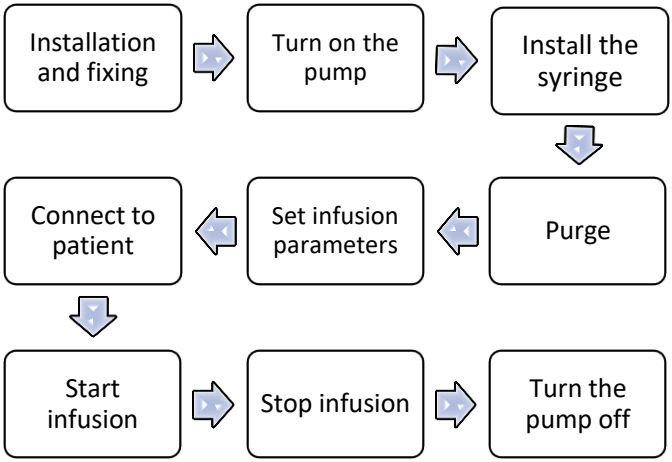
Note: Condensation forms when liquid or gas cools. For example, water vapor turns into water when it cools, and water turns into ice when it cools. The lower the temperature, the faster the condensation speed.

Chapter 4 Basic Operation

NOTE

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

4.1 Steps



4.2 Turn on the pump

1. Prior to turning on the pump, 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 pump enters the self-test process. The alarm light remains on for 1s with a “beep” sound; after that, the company logo is displayed and the pump shows the home screen.

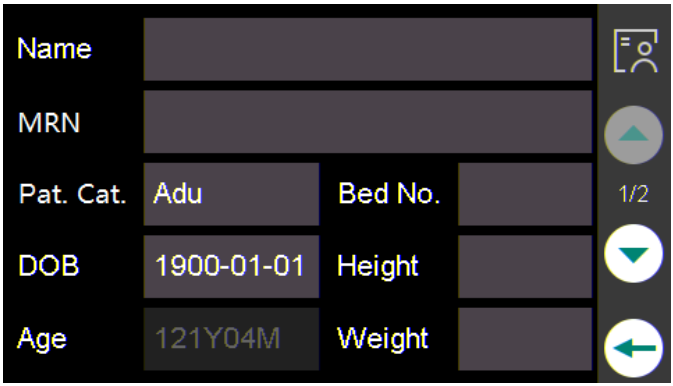
3. Check if the screen and parameter display is normal.

NOTE

- **The pump can be turned on and used normally after it is taken out from its lowest storage temperature to room temperature.**
- **The system gives an alarm when a critical error is detected during the 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 syringe pump and contact us.**
- **If the syringe 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 shutdown, in order to extend the service life of this pump, wait for at least 1 minute before you restart the pump.**

4.3 Input patient information

Press the menu key → Select [**Patient Data**].



The patient information can be received by scanning the patient's barcode.

NOTE

- **The infusion in Weight Mode can be started only when the patient information is filled.**

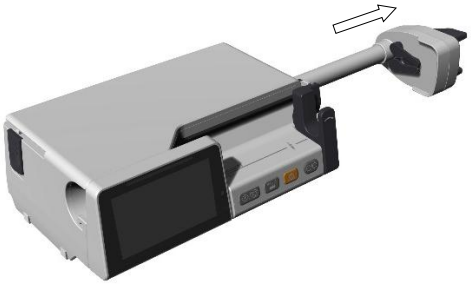
4.4 Install syringe

NOTE

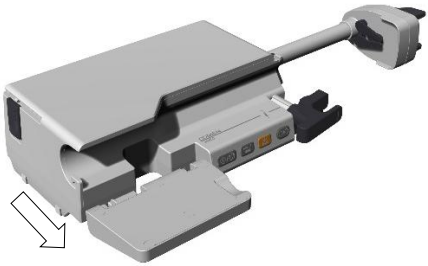
- **The barrel flange of the syringe must be properly engaged in the barrel flange clamp. Otherwise, the pump will display prompt messages.**
- **Before infusion, please read carefully the manual of the syringe. Unpack the syringe or tubing only when you use it, or it may be contaminated.**
- **Check the syringe before use. Do not use the syringe if there are any signs of damage or contamination. Don't unpack the syringe prematurely.**

After the pump is powered on, if it is detected that the syringe is not installed, the interface for installing the syringe will automatically display, and you can install the syringe according to the installation guide.

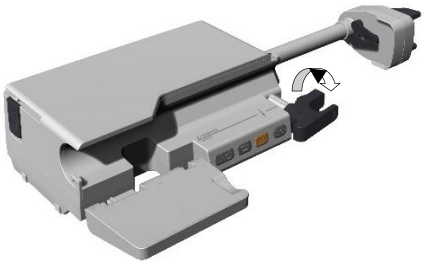
1. Open the plunger flange gripper by pinching the finger grips, and then pull the push rod to the right to the appropriate position.



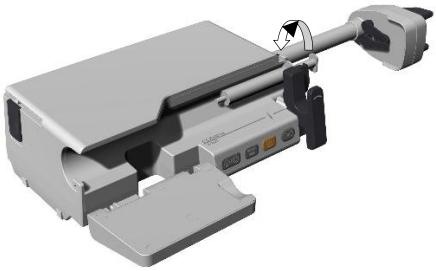
2. Open the door carefully.



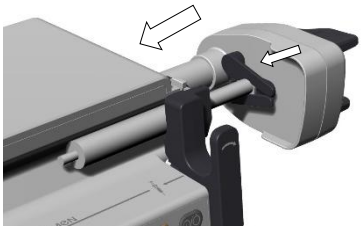
3. Pull the syringe clamp outwards and rotate it clockwise to open the barrel flange clamp.



4. Place the air-purged syringe filled with drug solution and connected with the extension tube and scalp vein needle in the syringe pump. The barrel flange of the syringe must be inserted into the barrel flange clamp of the pump. Rotate the syringe clamp counter-clockwise to the original position, and release it so that the clamp presses against the syringe.



5. Pinching the finger grips, push the push rod to the left to press against the syringe plunger flange. Release the finger grips, the plunger flange of the syringe will be clamped by the plunger flange gripper.



6. Close the door carefully.

4.5 Select syringe brand

WARNING

- **When using non-recommended syringes, please make sure to confirm relevant infusion performance (such as accuracy, presence of air bubbles and pressure) on the syringe pump.**
- **Make sure that the syringe has been granted with the relevant local certification, CE marked, before application.**

NOTE

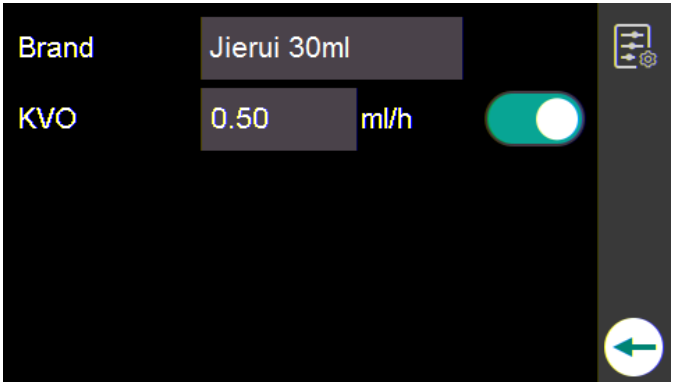
- **Before the infusion, confirm the selected brand and specification of the syringe in the**

system are consistent with the syringe actually being used. Otherwise the infusion accuracy is not guaranteed.

- **When the syringe pump is performing infusion, the brand of the syringe cannot be changed.**
- **When the syringe of a new brand is used for the first time, it must be calibrated. For the custom syringe, the syringe parameter can be customized and set in User Maintenance. Refer to 5.4.6 Precision Calibration for details.**
- **Before using the syringe pump, please confirm that the syringe used is calibrated. Otherwise, the accuracy of the infusion cannot be guaranteed.**

After installing the syringe, the device will automatically enter the interface for selecting the syringe brand and specification. You can set the syringe brand and specification based on the syringe actually being used, or set them according to the following steps:

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



After startup, if the pressure sensor cannot detect the syringe, the prompt message [**No Syringe is installed!**] will be shown in the alarm message area. See ***5. 4. 6 Precision Calibration*** for details. If you continue to use the same brand of syringes in the future, you don't have to set them again. If syringes of different brands are used, calibration is required to ensure infusion accuracy.

The available brands and specifications are listed in the table below:

Name	Brand	Specification	Manufacturer	Certification
Sterile syringe for single use	Jierui	2mL, 5 mL, 10 mL, 20 mL, 30 mL, 50/60 mL	Weigao Holding Co.,Ltd	CE0123
Sterile syringe for single use	Shuangge	2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL	Weigao Holding Co.,Ltd	CE0123
Sterile syringe for single use (with/without needle)	B-D	2mL, 5mL, 10mL, 20mL, 30mL, 50/60mL	Becton Dickinson S.A. Spain	CE0123

4.6 Purge

WARNING

- **When the device is in the purge status, the syringe pump shall be disconnected from the patient. Otherwise, it will cause danger!**
- **The purge volume is not added to the total cumulant volume of the current infusion.**
- **For manual purge, the manual purge volume is set in [Maintenance]. For details, see *5.4.3 Manual bolus and manual purge*.**
- **When the automatic purge volume is set to 0, the syringe pump cannot start automatic purge.**

During the infusion, bubbles should be prevented from entering the blood with the drug liquid. Otherwise, it can cause a blood clot and pose a danger to the

patient. Therefore, be sure to remove the bubbles from the syringe and extension tube completely before infusion.

The purge function can be performed only when the device is in the paused or stopped states.

(1) When the device is in the paused or stopped states, press the BOLUS key to enter the purge settings.

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

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

(4) Click the [**Start Purge**] key, the device starts purging automatically, and the value of [**Purge Vol**] decreases. 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. Release the BOLUS key to stop the manual purge.

4.7 Select infusion mode

Click the mode select key (the name of the mode displayed in main screen) to enter [**Mode Select**] to select the infusion mode.

4.8 Select drug

Press the mode selection key (the mode name displayed on the home screen) to enter [**Mode Select**]. There is a [**Drug**] selection box in the parameter settings of each mode. Click [**Search**] or turn the page to select the appropriate drug. After selection, the selected drug name will be displayed on the home screen.

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.**
- **The infusion parameters of certain drug shall be set by clinicians and doctors.**

4.9 Set infusion parameters

In each infusion mode, the operator can set infusion parameters according to the doctor's prescription.

4.10 Start infusion

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

NOTE

- **Users should regularly check the connection of the syringe, extension tube and pump to the patient and carry out infusion according to the instructions in this manual. The**

infusion performance can be ensured by using the extension tube specified by Comen (B.Braun IV-Standard-PE).

4.11 Bolus

NOTE

- **The bolus volume will be added to the total cumulant volume of the current infusion.**
- **Minimum rate and maximum rate for bolus: minimum rate: 0.1 mL/h, maximum rate: 2000 mL/h.**
- **For manual bolus, the manual bolus volume is set in [Maintenance]. For details, see *5.4.3 Manual bolus and manual purge*.**
- **When the automatic bolus VTBI is set to 0, the syringe pump cannot start automatic bolus.**

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

to enter the bolus settings.
2. There are two keys: [**Start Bolus**] and  (back to the previous page), and two parameters: [**Bolus Rate**] and [**Auto Bolus Vol.**] in the bolus settings.
3. Click [**Bolus Rate**] and [**Auto Bolus Vol**.] to input the parameter values with the keyboard.
4. Click the [**Start Bolus**] key or press the Start/Stop key  , the device starts automatic bolus with the [**Bolus Vol.**] decreasing. In the bolus state, press 

to stop automatic bolus. In addition, you can press and hold 

to start manual bolus with the [**Bolus Vol.**] increasing. Release 

to stop the manual bolus.
5. Start automatic bolus after setting the bolus VTBI and bolus rate. When the

automatic bolus volume is equal to the bolus VTBI, the bolus will be stopped automatically.

4.12 Infusion pause

If you need to replace the drug solution or the syringe during infusion, press  to pause the infusion. In the paused state, press  again to continue infusion, and press [**Mode Select**] key (the mode name displayed on the home screen) to modify the infusion parameters.

4.13 Real-time monitoring

When connecting this pump to the MX8900/MX8900A Infusion Workstation System, the operating status and the infusion status of the pump can be monitored in real time. The log and the curve are available for observation on the Infusion Workstation System. For full details, please refer to the user manual for MX8900/MX8900A Infusion Workstation System.

4.14 Infusion completed

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

If the [**VTBI**] is not set during infusion, when the remaining infusion time reaches the preset nearly done time, the [**Nearly Done**] alarm will be triggered. When the syringe is nearly emptied, the [**Near Empty**] alarm will be triggered.

When the infusion is completed and there is still drug solution in the syringe, the pump will enter the KVO mode if the KVO function is turned on. The KVO mode

will run for up to 30 minutes. When the KVO ends, the infusion will automatically stop, triggering the [**KVO Done**] alarm.

4.15 Standby

When the device is not used for infusion for the time being, you can set it to the standby mode if not shutting it down. To enter the standby mode, press the Power On/Off key  to display a dialog box and select [**Standby**].

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

NOTE

- **The syringe pump cannot enter the standby mode when there is a high priority alarm.**
- **The syringe pump is not allowed to enter the standby mode during infusion.**

4.16 Remove syringe

Follow the procedures shown in***4.1.3 Install the Syringe*** in reverse order to remove the syringe.

NOTE

- **The used syringes should be disposed of in accordance with applicable laws and regulations.**
- **Syringes are disposable, which must not be used more than once.**

WARNING

- **To prevent the pump from being damaged due to the drug liquid leakage, switch off the pump after disassembling the syringe.**
- **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.**

4.17 Clear cumulants

In the non-infusion state namely the paused or stopped states, click [**Cumulant**] on the home screen to view the [**Total Cumulant**]. Click [**Clear**] and it will display the prompt message [**Clear cumulants?**], and select [**Yes**] to clear the cumulative infusion volume if required.

4.18 Automatic calculation of cumulants

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. 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 total cumulant updates in real time and the other four kinds of cumulants update every 10 minutes (such as 9:10, 9:20 and 9:30).

- Total cumulant: when the infusion is in paused or stopped states, click [**Cumulant**] on the home screen to display the total cumulant.
- 24h cumulant: when the infusion is in paused or stopped state, click [**Cumulant**] on the home screen to display the cumulants for recent 24 hours.
- Recent cumulant: when the infusion is in paused or stopped state, click [**Cumulant**] on the home screen → [**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 home screen → [**Cumulant Yesterday 00:00 to Today 00:00**], to set the start time and the end time for automatic cumulant calculation.
- Timed cumulant (cumulant for custom time interval): when the infusion is in paused or stopped state, click [**Cumulant**] on the home screen → [**Timed Cumul.**] (Timed cumulant), to select the time interval for automatic cumulant calculation. The available time intervals are [**1hour**], [**2hour**], [**4hour**], [**8hour**], [**12hour**] and [**24hour**]. 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 [**1hour**] 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).

4.19 Turn off the pump

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

1) Confirm that the syringe pump can be stopped for use;
2) Press the Start/Stop key  to stop the infusion;
3) Disconnect it from the patient;
4) Save or clear patient data as required;
5) Press the Power On/Off key  to select [**Turn Off**] in the dialog box displayed on the screen to shut down the device;

6) Disconnect the AC power cord.

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

Press and hold the Power 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 shut down.**

Chapter 5 Basic Settings

5.1 Parameter settings

5.1.1 KVO settings

Press the menu key  → [**Param.**] → [**KVO**], to turn on KVO mode. KVO is short for “Keep Vein Open”, i.e. to keep the vein open. During infusion, if the total infusion volume reaches VTBI, and there is liquid left after the infusion is completed and no high alarm (such Occlusion), and the KVO function is enabled, the syringe pump will automatically enter the KVO mode to prevent blood backflow or vascular occlusion.

The range of KVO rate is 0.10 ~ 5.00mL/h with the minimum increment of 0.01mL/h, and its factory default is 0.50mL/h. The KVO function can be turned on or off by the user.

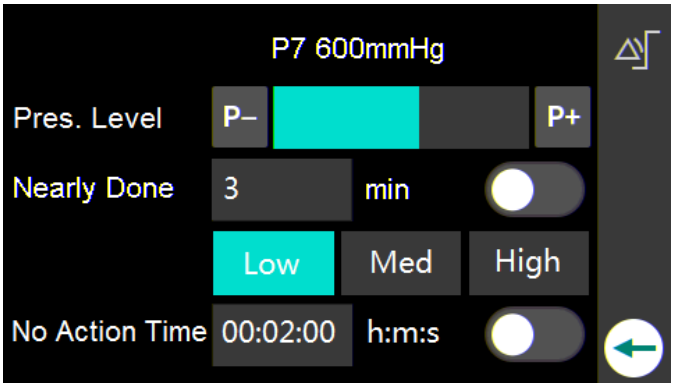
When this function is disabled, the pump will not enter KOV mode after the infusion of VTBI is done. When this function is enabled, it will enter the KVO mode after the [**VTBI Done**] alarm is triggered. The volume of KVO can be set. The KVO mode runs for up to 30 minutes, after which the [**KVO Done**] alarm will be triggered.

5.1.2 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 5188→ [**Param. Switch**] → [**Anti-bolus**]. The automatic pressure release function can be turned on or off.

5.2 Alarm settings



5.2.1 Occlusion pressure

Occlusion pressure is adjustable, which can meet the requirements for occlusion pressure of different patients during infusion. Pressure in the infusion tube or extension 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 the detected pressure exceeds the threshold.

5.2.1.1 Set occlusion pressure

Press the menu key → [**Alm Setup**] (Alarm Setup) → [**Pres. Level**] (Pressure Level). Press P− or P+ to set occlusion pressure. Occlusion pressure should be selected according to actual requirements.

WARNING

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

5.2.1.2 Set pressure unit

Press the menu key → [**Maintenance**] and enter the password 5188 → [**Pres. Unit**] (Pressure unit). There are 4 forms of pressure units: mmHg, kPa, bar and psi, and they can be selected according to actual requirements.

5.2.2 Nearly done (completed) setup

Press the menu key → [**Alm Setup**] → [**Nearly Done Setup**].

There are 3 modes in [**Nearly Done Setup**], including [**Distance Mode**], [**Time Mode**] and [**Volume Mode**]. The setting range of [**Distance Mode**] is 1-18mm, the setting range of [**Time Mode**] is 1-30 minutes, and the setting range of [**Volume Mode**] is 1-5mL.

After the parameters of the nearly done function is validly set, when the distance from the scale of drug solution to 0mL reaches the set distance, or the remaining infusion time reaches the set time, or the remaining drug volume reaches the set volume, the [**Nearly Done**] alarm will be triggered.

5.2.3 No-action time (No-operation time)

Press the menu key → [**Alm Setup**] → [**No-Action Time**] to turn on or turn off this function switch. When it is turned on, the no-action time can be set within 15s-5min. When the no-action time is set, the syringe pump is in the non-infusion state, and there is no operation during this time period, the pump alarm light is always on in yellow with the alarm message [**Operation Paused**] displayed on the display screen.

5.3 System settings

5.3.1 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, turn on the automatic screen lock function and input the automatic lock time. If there is no operation within the preset time, the screen will be automatically locked.

When screen is locked, the screen locked icon will be displayed on the screen and the user can press anywhere on the screen to select the lock screen icon and slide it to the unlocked icon to unlock the screen.

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

NOTE

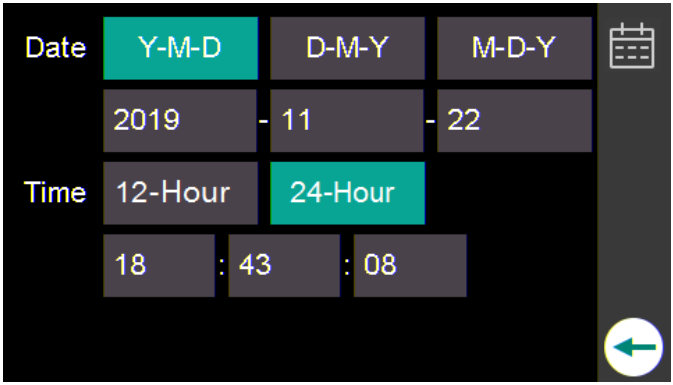
- **In the PCA mode, regardless of whether the infusion is in progress or whether the automatic screen lock is turned on, the screen will be locked automatically if there is no operation within 1 minute after entering the PCA mode. To unlock the PCA mode, you need to enter the password 5188.**

5.3.2 Manual screen lock

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

5.3.3 Date and time

Press the menu key → [**System**] → [**Date and Time**]. You can reset the system time according to the local time and select the date format and time format as required.



5.3.4 Screen brightness

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

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

5.3.5 Alarm volume

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

5.3.6 Minimum alarm volume (Min Alm Vol.)

Press the menu key  → [**System**] → [**Alm Tone**] (Alarm 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 1 to 10. Note: the minimum alarm volume is set to **1** by default.

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

5.3.7 System volume

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

5.3.8 Key light

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

5.3.9 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

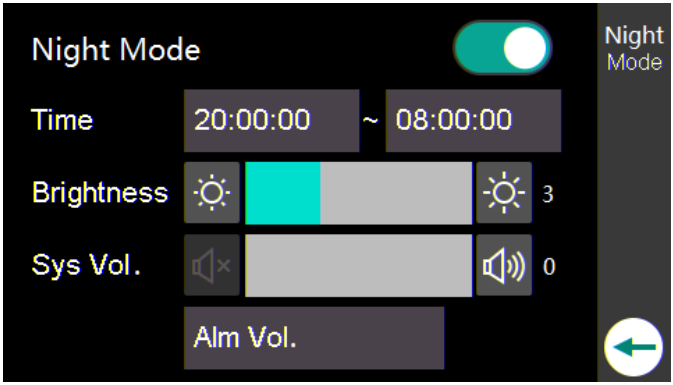
- **When the automatic brightness function is enabled, the screen brightness cannot be adjusted manually.**
- **The automatic brightness function is an optional feature. The product you purchased may not include this feature.**

5.3.10 Night mode

WARNING

- **Before entering the [Night Mode], please confirm the settings in [Brightness], [Sys Vol.] and [Alm Vol.]. If all those 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 device will all change to those of night mode. When the system time reaches the end time of the night mode setting, the system volume, alarm volume and screen brightness will automatically change to the previous 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 the 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 ***5.3.4 Screen brightness***, ***5.3.5 Alarm volume*** and ***5.3.7 System volume***.

5.3.11 Nurse call settings (For M800 only)

WARNING

- **Non-medical personnel are not allowed to modify the settings in the nurse call function.**
- **Only use the multi-functional cable delivered with the pump for the nurse call function.**
- **The Nurse Call System is required to meet the relevant IEC/ISO standard, with at least 2MOOP isolation from the supply mains power supply. Under normal conditions and single fault conditions, the maximum voltage accessible shall not exceed the rating. The max. voltage is 60Vd.c.**

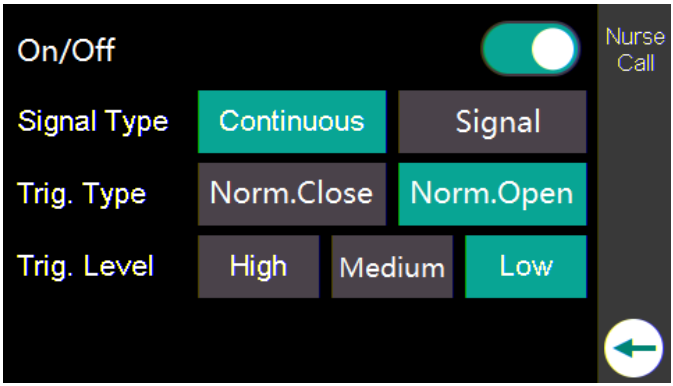
NOTE

- **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 auditory and visual alarms of the syringe 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.**
- **For the connection between the pump and the hospital nurse call system, please contact the after-sales department of Comen or the medical electrical engineer of your hospital.**

The nurse call is a function supporting the hospital nurse call system, which mainly has three parameters, i.e. signal type, 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 function is disabled, the related parameters cannot be set.

When the nurse call function is enabled, the user can [**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 is triggered whenever a medium or high alarm is triggered.
  c) Low: A nurse call is triggered whenever a low alarm, medium alarm or high alarm is triggered.

5.3.12 Treatment plan

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

5.3.12.1 Save as treatment plan

In the paused state, press the menu key  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.

5.3.12.2 Modify treatment plan

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

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

5.3.12.3 Apply treatment plan

Press the menu key  to select [**System**] → [**Treatment plan**]; select a treatment plan, and confirm the infusion parameters. Press the Start/Stop key  and the infusion parameters of the treatment plan will be applied for infusion.

5.3.13 Network connection

The M800/M800A syringe 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 key  →[**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 the WIFI setting menu.
4) Select your WIFI and input the password. The WIFI icon  will be shown at the lower right corner of the screen display, indicating the wireless network connection is successful.

NOTE

- **The device uses Transmission Control Protocol (TCP)/Internet Layer (IP).**
- **If you have any question about the internet connection, please contact us.**

5.4 User maintenance

5.4.1 Language settings

Press the menu key  → [**Maintenance**] and enter the password 5188 → [**Language**]. Select the language according to your requirements.

5.4.2 Unit settings

Press the menu key  → [**Maintenance**] and enter the password 5188 → [**Height Unit**] / [**Weight Unit**] / [**Pres. Unit**] (Pressure Unit). The units that can be set are: height unit (cm/inch), weight unit (kg/lb) and pressure unit (mmHg/psi/kPa/bar).

5.4.3 Manual bolus and manual purge

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

5.4.4 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.**] 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 [**Patient Data**] is set to [**Neo**] (Neonate), [**Ped**] (Pediatric) or [**Adu**] (Adult), the pressure range will be adjusted to the corresponding range according to the patient type, and the user can 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).

5.4.5 Parameter switch

5.4.5.1 Automatic pressure release (Anti-Bolus) switch

Please refer to ***5.1.2 Automatic pressure release (Anti-bolus)*** for details. This function is enabled by default. When the occlusion alarm is activated, the system automatically removes the pressure in the tubing. The purpose is to avoid unintended bolus and any harm to the patient. The function can be turned off by the user.

5.4.5.2 Auto restart switch

After turning on the [**Auto Restart**] switch and turning off the [**Anti-bolus**] switch, the infusion will paused when 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 are no other high priority alarms, 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.

5.4.5.3 Near empty timer switch

When [**VTBI**] is set to 0, the pump cannot calculate [**Time Left**] (the remaining infusion time) based on [**VTBI**] and [**Rate**]. When the [**Near Empty Timer**] switch is turned on, the pump will calculate the near-empty time according to the position of the photoelectric sensor and the value of [**Rate**]. When the [**Near Empty Timer**] switch is turned off and the VTBI is set to 0, the home screen will display the [**Total Time**] (The total infusion time).

⚠NOTE

- **Near Empty Timer is the time to finish the liquid in the syringe, the Time Left is the time to complete the preset volume.**

5.4.5.4 Poweroff check

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

5.4.5.5 Concen param (Concentration parameter) switch

For Weight Mode and Dose Time Mode, [**Conc.**] (Concentration) will be displayed when the switch of [**Concen. Param.**] is turned on. [**Drug Vol.**] and [**Drug Dose**] will be displayed when this switch is turned off. This function is disabled by default.

5.4.5.6 Drug param (Drug parameter)

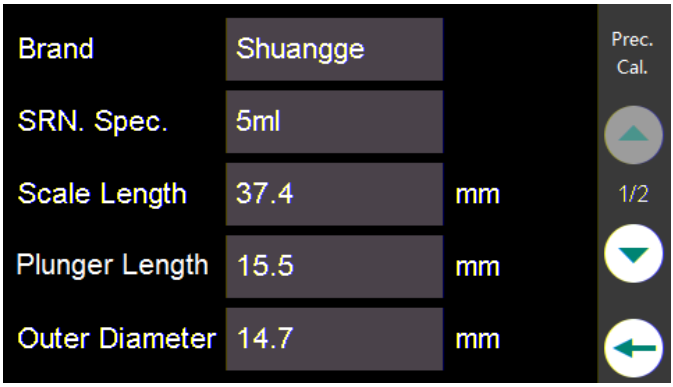
If this function is enabled, when the user adds a new drug into the drug library, the parameters of Soft/Hard Upper/Lower Limits have to be input in accordance with the actual drug. Thus, in the case of selecting this new drug, the infusion rate range of this drug can be generated and displayed when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

5.4.6 Precision calibration

NOTE

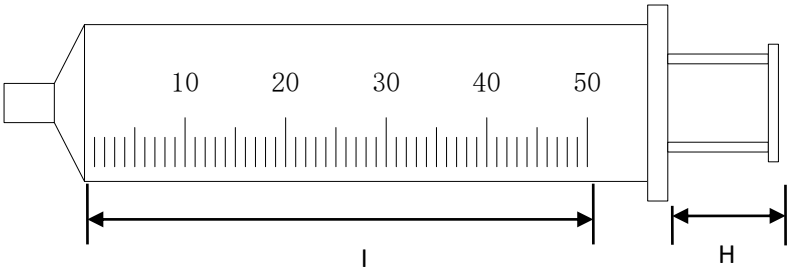
- **During infusion, if the syringe pump cannot correctly identify the syringe specification, the infusion must be stopped immediately.**
- **Enter the precision calibration interface, switch the syringe brand and syringe specifications, and observe whether there is any change in the scale length and plunger length. If there is a change, the data reading is successful.**
- **Modify the scale length and plunger length values according to the measured scale length data and plunger length data, and press the start key to save the modified data. Exit the custom syringe interface, enter the interface again, select the modified syringe brand and specifications, and determine whether the data is successfully modified.**
- **Click [Default SRN Setting] (Default syringe setting) to restore the value of all syringe brands to the system default value. You will hear a "beep" sound if the values are restored.**
- **Before precision calibration, please make sure that the syringe used has got the CE certification and refer to relevant instructions to confirm that the syringe can be used with this pump.**

Enter the user maintenance interface and select [**Prec. Cal.**] (Precision calibration). The parameters including syringe brand, syringe specifications, scale length (I) and plunger length (H) will be displayed.



The syringe specification can be customized and calibrated on the precision calibration interface. When using an undefined syringe in a system or the current infusion accuracy is inaccurate, calibration is required.

5.4.6.1 Manual calibration



1. As shown in the figure above, push the syringe to 0mL at the end, the length from the 0 mL scale to the nominal scale is I, and H is the length of the plunger.
2. After selecting the [**Prec. Cal.**] option, enter the syringe parameter setting interface. The setting parameters include the syringe brand, syringe specifications, scale length (I), and plunger length (H).

Parameters	Description
Brand	Shuangge, JieRui, B-D, User1, User2, User3
Specifications	2mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL.
Scale length (I)	After measuring the scale length with a caliper, enter the value in mm.
Plunger length (H)	After measuring the plunger length with a caliper, enter the value in mm.
Outer diameter	After measuring the outer diameter with a caliper, enter the value in mm.

3. Calibrate the 2/3mL, 5mL, 10mL, 20mL, 30mL, 50mL/60mL syringes according to Step 1 to 2.

5.4.6.2 Automatic calibration

1. Install the syringe to be calibrated at full scale and install it on the syringe pump. Note: The syringe does not need to be filled with liquid.
2. Click the menu key  → [**Maintenance**] and enter the password 5188 → [**Prec. Cal.**].
4. Select [**Prec. Cal.**] to enter the custom syringe interface, and select or enter the [**Brand**] and [**SRN Spec.**] (Syringe specification) of the syringe to be calibrated.
5. Select [**Start Cal.**] (Start calibration) to start the automatic calibration.
6. After the calibration is successful, it will automatically prompt [**Cal. Succeeded!**] (Calibration succeeded), and the scale length (I), plunger length (H) and outer diameter of the syringe being calibrated will be displayed on the screen. If [**Cal. Failed!**] (Calibration failed) is prompted, recalibration is required.

NOTE

- **For the syringes of special brands or specifications, please calibrate them manually if the automatic calibration fails.**

5.4.7 Syringe reset

On the user maintenance interface, click [**Prec. Cal.**] → [**Default SRN Setting**]. A dialog box will be displayed with the message [**Do you want to restore syringe default values?**]. Click [**Yes**] to restore the default values, or click [**No**] to return to the previous page.

5.4.8 Drug library

Selecting the options of [**Export**] and [**Import**] under the menu of drug library, the drug library of the Infusion Workstation System and this pump could be synchronized. This operation should be guided by Comen.

5.4.8.1 Add drug

Press the menu key  → [**Maintenance**] and enter the password 5188 → [**Drug Lib.**] (Drug library) → [**Add Drug**]. Input the name of drug and other parameters and click [**Save**].

5.4.8.2 Drug parameters

Press the menu key  → [**Maintenance**] and enter the password 5188 → [**Drug Lib.**] (Drug library) → [**Drug Param.**]. The device is endowed with 60 kinds of drug names in the drug library. The user can set the drug parameters such as

Soft/Hard Upper/Lower Limits of certain drug. When the [**Drug Param.**] in [**Param Switch**] is turned on, the infusion rate will be limited by the set range.

NOTE

- **Refer to the *Appendix VIII Drug Library* for the list of inserted drug names.**

5.4.8.3 Drug color

Press the menu key → [**Maintenance**] and enter the password 5188 → [**Drug Lib.**] → [**Drug Param.**]. Search or click the name of the drug that needs to be colored and select the color, and click [**Save**].

5.4.9 Brand library

Selecting the options of [**Export**] and [**Import**] under the menu of brand library, the brand library of the Infusion Workstation System and this pump could be synchronized. The synchronization of brand library should be guided by Comen.

5.4.9.1 Add brand

Press the menu key → [**Maintenance**] and enter the password 5188 → [**Brand Lib.**] (Brand library) → [**Add Brand**]. Input the brand name of the infusion set and click [**Save**].

5.4.9.2 Common brands

Press the menu key → [**Maintenance**] and enter the password 5188 → [**Brand Lib.**] (Brand library) → [**Select Brand**]. Select [**Select Brand**] on the brand library interface to view the list of commonly-used brands. The user can check or

uncheck the box at the right of the brand name. After installing the infusion set properly, the checked brands will be shown on the brand selection interface.

5.4.9.3 Delete brands

Press the menu key → [**Maintenance**] and enter the password 5188 → [**Brand Lib.**] (Brand library) → [**Select Brand**] to delete the brand of infusion sets from the brand library.

5.4.10 Factory reset

During use, you may change some settings under certain circumstances, but these changes are not necessarily appropriate or correct, especially when admitting or discharging patients or changing the syringe brand. Therefore, in the actual operation, you should restore the factory settings as required to ensure that the various configurations of the syringe pump are suitable for clinical infusion.

1. Press the menu key → [**Maintenance**] and enter the password 5188 → [**Factory Reset**].
2. Click [**Factory Reset**], and a dialog box will display [**Do you want to restore factory settings?**]. Click [**Yes**] to restore the factory default settings, or click [**No**] to return to the previous page.

5.4.11 System information

1. Press the menu key → [**Maintenance**] and enter the password 5188 → [**System Info**] (System information).
2. Click [**System Info**] to display the device information.

5.4.12 Pressure calibration

When the calibration of occlusion pressure is not accurate, please contact the after-sales maintenance engineer of Comen to carry out the pressure calibration.

NOTE

- **Pressure calibration should be performed by or under the guidance of maintenance engineers of Comen. For calibration steps, please refer to the service manual.**

Chapter 6 Device Interconnection

The M800/M800A syringe pump can be connected with external devices, such as the K12Pro/K12APro, K15Pro/K15APro, K18Pro/K18APro, K22Pro/K22APro Multi-parameter patient monitors and the MX8900/MX8900A Infusion workstation system of Comen, thus realizing the function of transmitting infusion parameters, infusion status and alarm messages. Furthermore, the syringe pump can communicate with the Infusion Central Monitoring System (eCenter-IMS) through wireless network, for central monitoring of the bedside pumps and the infusion status of patients.

NOTE

- **The communication interface protocol is Comen's own set of partially proprietary communication protocols.**
- **The external devices including the compatible infusion workstation system and the patient monitors are required to meet the relevant IEC/ISO standard, with at least 2MOOP isolation from the supply mains power supply, and at least 1MOPP isolation from SIP/SOP.**
- **The compatible external devices are intended for real-time monitoring and centralized management of the operation status of infusion pump clinically, and can only be used by professional clinicians and be maintained by qualified medical electrical engineers.**
- **For the function, precautions and warnings of the infusion workstation system and the patient monitors as well as the Infusion Central Monitoring System, please refer to the user manuals for them.**

WARNING

- **This syringe pump can be connected to the MX8900/MX8900A Infusion workstation system and K12Pro/K12APro, K15Pro/K15APro, K18Pro/K18APro, K22Pro/K22APro Multi-parameter patient monitors manufactured by Comen only. Connection to incompatible systems will cause malfunction or device damage.**
- **The infusion workstation system and the connected infusion pump shall be specified as an ME system. The copyright of the ME system and its software is owned by our company. Do not modify the ME system without authorization of the manufacturer.**
- **After successful connection to the infusion workstation system, the system can supply power to the infusion pump. Thus, please ensure the system is connected to a suitable external power supply (the MX8900/MX8900A Infusion Workstation System is a continuous operation device with a power supply specification of 100-240V~, 50/60Hz, 6-3A), or the battery of the system is sufficient. A power outage of the Infusion Workstation System during use may result in personal injury to the patient.**
- **When an alarm is generated no matter on the infusion pump or the compatible external devices or systems, please check the patient's condition first.**
- **When connecting the syringe pump with the compatible patient monitors, please use the KLink cable delivered with the patient monitor. Otherwise, the connection may fail and the devices may be damaged.**
- **The KLink module and the ID box are optional for the patient monitors. Using other modules, connectors or cables on the market will cause malfunctions.**
- **The compatible patient monitors should be placed outside the patient environment of the infusion pump.**
- **If the connection between the infusion pump and the external devices is lost, the data transmission between the pump and the external devices and the functional synchronization between the pump and the infusion workstation system will fail.**

6.1.1 Connect to MX8900/MX8900A Infusion Workstation System

The M800/M800A syringe pump can be connected to the MX8900/MX8900A 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.

6.1.1.1 Installation of the M800/M800A to the Infusion Workstation System

The method of installing the syringe pump to the MX8900/MX8900A 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.

6.1.1.2 Alarm synchronization

When this syringe 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 system. The alarm audio of the alarm generated on the syringe pump will be sent out through the Infusion Workstation System. Therefore, the alarm audio can only be paused for 2 minutes on the system.

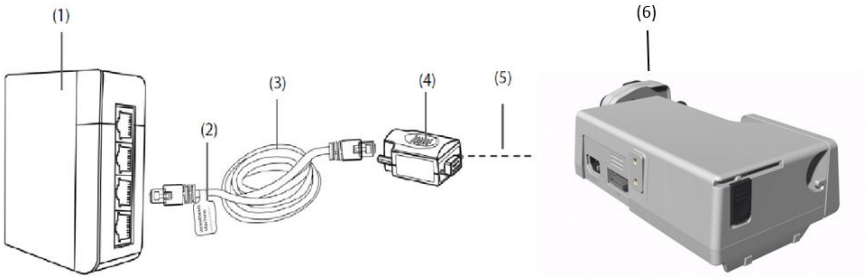
In addition, there are some alarms of the pump that can be acknowledged on the Infusion Workstation System, as shown below.

- [**AC Off**]: press the Alarm Audio Pause key on the Infusion Workstation System to acknowledge the [**AC Off**] alarm of the syringe pump. Thus, the alarm light both on the syringe 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 on the Infusion Workstation System to acknowledge the [**Low Battery**] alarm of the syringe pump. Thus, the alarm light both on the syringe pump and the system will be canceled and the alarm audio sent out by the system will be cleared.
- [**Near Empty**]: press the Alarm Audio Pause key on the Infusion Workstation System to acknowledge the [**Near Empty**] alarm of the syringe pump. Thus, the alarm light both on the syringe 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 on Infusion Workstation System to acknowledge the [**Nearly Done**] alarm of the syringe pump. Thus, the alarm light both on the syringe 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 on the Infusion Workstation System to acknowledge the [**Relay Failure**] alarm of the syringe pump. Thus, the alarm message and alarm light both on the syringe 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 on Infusion Workstation System to acknowledge the [**Communication Error**] alarm of the syringe pump. Thus, the alarm message and alarm light both on the syringe 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 on the Infusion Workstation System to acknowledge the [**Standby Ended**] alarm of the syringe pump. Thus, the alarm message and alarm light both on the syringe pump

and the system will be canceled and the alarm audio sent out by the system will be cleared.

6.1.2 Connect to the patient monitor (KLink)

The M800/M800A syringe pump supports 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 connected patient monitor. The syringe pump can be connected to a patient monitor through an ID box, shown as the diagram below.



(1) KLink module

(2) Label

(3) KLink-ID Ethernet Cable

(4) ID Box

(5) KLink-Serial Cable-Type E

(6) Syringe pump

Please follow the steps below to connect the syringe 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 syringe 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 KLink-ID Ethernet Cable to connect the KLink module and the ID Box;
4. Use the KLink-Serial Cable-Type E to connect the ID Box and the syringe pump. Ensure the KLink-Serial Cable-Type E is firmly inserted into the multifunctional interface of the syringe pump;
5. Once the connection is made, the indicator light of the ID Box will turn on and the corresponding indicator light of the KLink module will turn on. In addition, the syringe pump will automatically register on the patient monitor, after which the infusion data of the pump will be displayed on the [**Integrated Devices**] area and the alarm message of the pump will be transmitted and displayed in the alarm message bar on the display screen of the patient monitor.

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

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

For the details of the KLink module, please refer to the user manual for KLinK module.

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

The M800/M800A syringe pump can communicate with the Infusion Central Monitoring System (V1). Thus, the infusion parameters, infusion status and device status can be monitored on the Infusion Central Monitoring System.

Steps for communicating with the Infusion Central Monitoring System:

1. Install the Infusion Workstation Monitoring System on your computer and log in the system by entering the username and password.
2. Connect to a wireless network. For detailed steps of connecting to a wireless network, please refer to ***6.3.13 Network connection***.
3. Input the server IP address and port number of the Infusion Central Monitoring System in [**Server IP**] and [**Port No.**] in the interface of WIFI settings. Ensure that the pump is in the same network environment as the Infusion Central Monitoring System.
4. Press the menu key  → [**Maintenance**] and enter the password 5188. Select [**Device Manager**] and click [**Bed No.**] to select the bed number displayed below the search bar for binding the syringe pump with the bed no. on the Infusion Central Workstation System.

6.1.3.1 Check communication status

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 will be displayed on the Infusion Central Monitoring System and the pump simultaneously. However, the infusion parameters and system settings must be set on the pump.

Chapter 7 Infusion Modes

NOTE

- **The drug library function is available under all modes, which does not provide the specific infusion parameters for each drug.**
- **The M800/M800A syringe pump does not support the relay function when it is under PCA Mode, Intermittent Mode, Sequence Mode and First Dose Mode. It will prompt "Relay disabled in current infusion mode!" if the user is trying to use the relay function under any of these modes.**

WARNING

- **The infusion parameters of drug shall be consistent with the prescription determined by clinicians. This pump does 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 consequences caused by incorrect infusion parameters.**
- **To ensure 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 other infusion parameters, stop current infusion first.**

Press the mode area on the home screen to enter [**Mode Select**] and select the mode according to the doctor's prescription.

7.1 Rate mode

In Rate Mode, the user needs to set the rate and VTBI, and the device will automatically calculate the infusion time. Then the infusion is performed until the VTBI is finished or the syringe 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 (The maximum rate depends on the different syringe specifications. The maximum rates of 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL syringes are 90mL/h, 150.00mL/h, 300.00 mL/h, 600.00mL/h, 1200.00mL/h, 2000.00mL/h respectively).	0.01	mL/h
VTBI	0.10 ~ 9999.99	0.01	mL
Time	00:00:01 ~ 99:59:59	00:00:01	h:m:s

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 finished or the syringe is emptied. The user can modify the infusion rate during infusion and the modification takes effect immediately. The remaining time is calculated by dividing the remaining VTBI by the rate modified.

The main parameters of Time Mode are:

Parameters	Parameter range	Minimum increment	Unit
Time	00:00:01 ~ 99:59:59	00:00:01	h:m:s
VTBI	0.10 ~ 9999.99	0.01	mL

Rate	0.10 ~ 2000.00 (The maximum rate depends on the different syringe specifications. The maximum rates of 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL syringes are 90mL/h, 150.00mL/h, 300.00mL/h, 600.00mL/h, 1200.00mL/h, 2000.00mL/h respectively.)	0.01	mL /h

7.3 Weight mode

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

The main parameters of Weight Mode are:

Parameters	**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/m, mg/mL, ug/mL, ng/mL, U/mL, IU/mL, KU/mL
Weight	0.1~500kg/0.2~1102.3lb	0.1	Kg, Ib
Dose rate	0.001~999.999	0.001	g/kg/h,

	(The dose rate is calculated according to the weight and the concentration and must fall into the rate range of syringe actually used.)		g/kg/min, mg/kg/h, mg/kg/min, ug/kg/h, ug/kg/min, ng/kg/h, ng/kg/min, U/kg/h, U/kg/min, IU/kg/h, IU kg/min, KU/kg/h, KU/kg/min
Rate	0.10~2000.00 (The maximum rate depends on the different syringe specifications. The maximum rates of 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL syringes are 90mL/h, 150.00mL/h, 300.00mL/h, 600.00mL/h, 1200.00mL/h, 2000.00mL/h respectively.)	0.01	mL/h
VTBI	0.10~9999.99	0.01	mL

Note:

1. Only dose rate can be modified during infusion in this mode, and it is valid immediately after modification.

Calculation rules for parameter ranges:

Weight: MIN = 0.1kg MAX = 500.0kg

Concentration: MIN = 0.001 MAX = 9999.999

VTBI: MIN = 0.10 MAX = 9999.99

Dose rate: MIN = (0.1mL/h*Concentration) / Weight

MAX = (The maximum rate of current syringe*Concentration) / Weight

2. Calculation formula:

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)

7.4 Dose time mode

The Dose Time Mode is a mode in which the dose rate, infusion rate and VTBI 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 finished or the syringe is emptied.

The main parameters of Dose Time Mode are:

Parameters	Parameter range	Minimum increment	Unit
Drug dose	0.001 ~ 99999.999	0.001	g, mg, ug, ng, U, IU, KU
Drug volume	0.00 ~ 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
Pre-dose	0.001 ~ 999.999	0.001	U, IU, KU, g, mg, ug, ng
Time	00:00:01 ~ 99:59:59	00:00:01	h:m:s
Dose Rate	The dose rate is calculated automatically after setting the values of pre-dose, infusion time and concentration (or drug dose and drug volume).	0.001	U/h, IU/h, KU/h, g/h, mg/h, ug/h, ng/h
Rate	The rate (infusion rate) is calculated automatically after setting the values of pre-dose, infusion time and concentration.	0.01	mL/h
VTBI	The VTBI is calculated automatically after setting the values of pre-dose, infusion time and concentration.	0.01	mL

Note:

1. Detailed parameter ranges:
   - ✧ Concentration: MIN = 0.001 MAX = 9999.999,
2. It is not allowed to modify the rate during infusion in this mode.

   The main parameters of Dose Time Mode are time and pre-dose. If the time >0 and the pre-dose volume >0, the dose rate can be calculated according to the three formulas:
   - ✧ Dose rate = Pre-dose/Time;
   - ✧ Rate = VTBI/Time;
   - ✧ VTBI = Pre-dose/Concentration.

7.5 Intermittent mode

The Intermittent mode is a mode of which the pump will firstly finish the infusion of [**Intmt. Vol**.] (Intermittent volume) at the [**Intmt. Rate**] (Intermittent rate) set by the user, and then continue to infuse at a rate of [**Keep Rate**] for a period of time [**Interval**]. When the interval ends, it will restart the above infusion tasks in a cycle, until the total VTBI is finished or the syringe is emptied.

The main parameters of Intermittent Mode are:

Parameters	Parameter range	Minimum increment	Unit
Intermittent volume	0.10 ~ 9999.99	0.01	mL
Intermittent rate	0.10 ~ 2000.00 (The maximum rate depends on the different syringe specifications. The maximum rates of 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL syringes are 90mL/h,	0.01	mL/h

	150.00mL/h, 300.00mL/h, 600.00mL/h, 1200.00mL/h, 2000.00mL/h respectively.)		
Keep rate	0.10 ~ 5.00	0.01	mL/h
Interval	00:00:01 ~ 99:59:59	00:00:01	h:m:s
Total VTBI	0.10 ~ 9999.99	0.01	mL

NOTE

- **The intermittent rate can be modified while the keep rate cannot be modified during infusion under this mode.**

7.6 Ramp mode

The Ramp Mode determines the steady rate by setting the ramp-up time, ramp-down time, total time, and VTBI. Then, the infusion is performed at the steady rate. During the ramp-up time, the minimum flow rate rises to steady rate through 9 phases, and during the ramp-down time, the steady rate reduces through 9 phases. The main parameters of Ramp Mode are:

Parameters	Parameter range	Minimum increment	Unit
VTBI	0.10 ~ 9999.99	0.01	mL
Total time(t)	00:00:01 ~ 99:59:59	00:00:01	h:m:s
Up time(t1)	Up time = Total time - Down time	00:00:01	h:m:s
Down time(t2)	Down time = Total time - Up time	00:00:01	h:m:s

Steady rate	0.10 ~ 2000.00 (The steady rate is non editable. The maximum rate depends on the different syringe specifications. The maximum rates of 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL syringes are 90mL/h, 150.00mL/h, 300.00mL/h, 600.00mL/h, 1200.00mL/h, 2000.00mL/h respectively.)	0.01	mL/h

Note:

1. When the ramp up time is null:

✧ Total time = Down time;

The infusion directly enters the ramp down phase until the infusion is completed. The initial flow rate of ramp down phase=VTBI/(Total time/2); the flow rate of ramp down phase= the initial flow rate of ramp down phase/10

✧ Total time > Down time:

Steady time = Total time - Down time. The infusion directly enters the steady phase. After the time of steady phrase, it enters the ramp down phase until the infusion is completed.

Steady Rate = VTBI/(Down time/2 + Steady time); The Falling Flow Rate = Steady Rate/10.

2. When the ramp down time is null:

✧ Total time = Up time

The infusion directly enters the ramp up phrase until the infusion is completed. The flow rate of ramp up phase=VTBI/(Total time/2)/10.

✧ Total time > Up time

Steady time = Total time – Up time. The infusion enters the ramp up phase firstly and then enters the steady phase until the infusion is completed.

Steady rate = VTBI/(Up time/2 + Steady time); The flow rate of ramp up phase = Steady rate/10.

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

✧ Directly enter the steady phase and keep infusion with the steady rate until the infusion is completed; Steady rate = VTBI/Total time.

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. Steady rate = VTBI/((Up time + Down time)/2 + Steady time); The flow rate of ramp up phase = The flow rate of ramp down phase/10.

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

⚠ **NOTE**

- **Rate cannot be modified on the home screen during the infusion under this mode.**

7.7 Sequential mode

Multiple different sequences can be set in the Sequential Mode. The user needs to define the infusion parameters (Rate, VTBI and Time) of each sequence in an

infusion cycle. The device performs infusion according to the set sequence.

The main parameters of Sequential Mode are:

Parameter	Parameter range	Minimum increment	Unit
VTBI 1	0.10 ~ 9999.99	0.01	mL
Rate 1	0.10 ~ 2000.00 (The maximum rate depends on the different syringe specifications. The maximum rates of 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL syringes are 90mL/h, 150.00mL/h, 300.00mL/h, 600.00mL/h, 1200.00mL/h, 2000.00mL/h respectively.)	0.01	mL/h
Time 1	00:00:01 ~ 99:59:59	00:00:01	h:m:s
…	…	…	…
VTBI 10	0.10 ~ 9999.99	0.01	mL
Rate 10	0.10 ~ 2000.00 (The maximum rate depends on the different syringe specifications. The maximum rates of 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL syringes are 90mL/h, 150.00mL/h, 300.00mL/h, 600.00mL/h, 1200.00mL/h, 2000.00mL/h respectively.)	0.01	mL/h
Time 10	00:00:01 ~ 99:59:59	00:00:01	h:m:s

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 must not be greater than 9999.99mL.
4. During the infusion in this mode, only the rate of running sequence can be modified. During the paused state, the parameters of all the sequences can be modified. If the VTBI is modified, the infusion will resume with the new VTBI.

7.8 Micro mode (Micro-infusion mode)

Under Micro 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 syringe is emptied. In this mode, the maximum rate and maximum VTBI that can be set are 100mL/h and 100mL.

The main parameters of Micro Mode are:

Parameters	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	h:m:s

7.9 First dose mode

The First Dose Mode is a mode in which the pump firstly completes the infusion of [**FDose Vol.**] (First dose volume) at the [**FDose Rate**] (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:

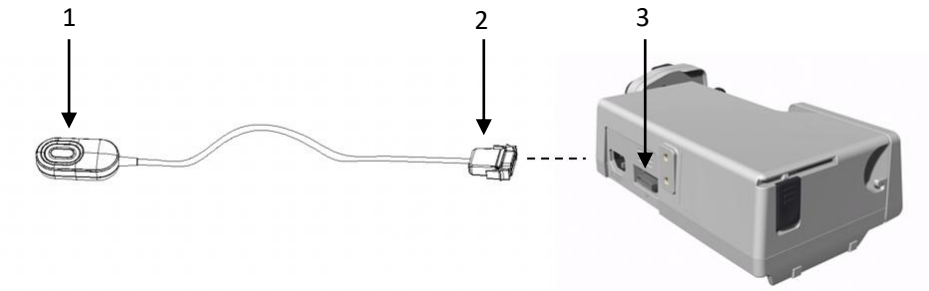
Parameters	**Parameter range**	**Minimum increment**	**Unit**
First dose rate	0.10 ~ 2000.00 (The maximum rate depends on the different syringe specifications. The maximum rates of 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL syringes are 90mL/h, 150.00mL/h, 300.00mL/h, 600.00mL/h, 1200.00mL/h, 2000.00mL/h respectively.)	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	h:m:s
Main rate	0.10 ~ 2000.00 (The maximum rate depends on the different syringe specifications. The maximum rates of 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL syringes are 90mL/h, 150.00mL/h, 300.00mL/h,	0.01	mL/h

	600.00mL/h, 1200.00mL/h, 2000.00mL/h respectively.)		
Total VTBI	0.10 ~ 9999.99	0.01	mL
Main time	00:00:01 ~ 99:59:59	00:00:01	h:m:s

7.10 PCA mode (for M800 only)

The PCA (Patient Controlled Analgesia) mode is the unique infusion mode of the M800/M800A syringe pump. PCA refers to patient controlled analgesia, which means that when a patient feels pain, a medicine dose set by the clinician will be infused into the patient through a computer-controlled micro-pump by pressing the button of the PCA accessory for analgesia by himself/herself.

To realize the patient controlled analgesia, the PCA accessory should be connected to the syringe pump, shown as below:



1. PCA button

2. PCA plug

3. Multifunctional interface of the pump

The PCA mode is clinically applied to: 1. Treatment of postoperative acute pain; 2. Labor analgesia; 3. Cancer pain treatment; 4. Burn pain treatment; 5. Medical pain treatment; 6. Traumatic pain treatment; 7. Pain treatment of childhood diseases; 8. Treatment of other acute pain diseases.

The main parameters of PCA Mode are:

Parameters	Parameter range	Minimum increment	Unit
Drug concentration	0.001 ~ 9999.99	0.001	U/mL, IU/ mL, g/ mL, mg/ mL, ug/ mL, ng/ mL
Loading dose	0.10 ~ 20.00	0.01	mL
Loading rate	0.10 ~ 100.00	0.01	mL/h
PCA dose	0.10 ~ 20.00	0.01	mL
PCA rate	0.10 ~ 100.00	0.01	mL/h
Keep rate	0.10 ~ 20.00	0.01	mL/h
Lockout time	1 ~ 60	1	min
1H-Limit	0.01 ~ 20.00	0.01	mL
4H-Limit	0.01 ~ 60.00	0.01	mL

PCA dosing stage:

1. PCA rate: The PCA rate is fully self-controlled by the patient. When the patient is in pain, he/she presses the PCA control device and gives a single dose at the PCA rate. The loading dose, loading rate and keep rate cannot be set.

2. Keep rate + PCA rate: The infusion is performed at the keep rate. If the infusion time is less than the lockout time, the infusion at the PCA rate cannot be started; if the infusion time is greater than the lockout time, press the PCA button to start infusion.

3. Loading rate + Keep rate + PCA rate: When the patient is in pain, the loading dose will be given at the loading rate to the patient to quickly eliminate the

pain. Then, the infusion enters the lockout phase, in which the infusion is performed at the keep rate. If the PCA button is pressed at this time, the prompt message “PCA cannot start during lock time” will be displayed. When the lockout time is over, after pressing the PCA button, the infusion will continue at the PCA rate until the PCA dose is finished. After that, the infusion will still continue at the keep rate and it will enter the PCA phase again if the PCA button is pressed. The infusion is performed in cycle until the syringe is emptied.

4. Continuous infusion: Drugs are infused at the keep rate.

5. Lockout time: The interval between two effective medications. The purpose of setting the lockout time is to prevent toxication caused by overdose or repeated medication before the medication previously infused is fully effective.

Note:

- ✧ In PCA mode, the rate cannot be modified on the home screen.
- ✧ The bolus function is disabled in PCA mode, the prompt message [**Bolus key disabled in PCA mode!**] will be displayed if the bolus key is pressed during infusion.
- ✧ In PCA mode, the drug, drug concentration, loading dose, loading rate, PCA dose, PCA rate, keep rate, lockout time, 1-hour limit and 4-hour limit should be set. The loading dose and the loading rate should be either null or valid at the same time.

Chapter 8 Alarms

The distributed alarm system allows the alarm information transmission from the infusion pump to the compatible patient monitor, the Infusion Workstation System or the Infusion Central Monitoring System after successful communication. Once the infusion pump is successfully connected with the external devices, when there are some abnormalities during the infusion process or the infusion pump fails, the alarms of the infusion pump will be sent to them. Thus, the connected devices or systems will send out the alarm sound and display alarm messages for alerting the medical staff.

8.1 Overview

An alarm is a prompt generated by the syringe pump to medical workers by means of sound or light when an abnormal situation occurs to a patient during the use of the syringe pump, or when the infusion of the patient cannot continue due to the unexpected breakdown or pause of the syringe pump. In standby mode, the normal response of the alarm system function is not affected, but the alarm sound 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

- **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.

- **Before infusion, please ensure that the alarm settings are suitable for the current patient.**

⚠ **NOTE**

- **When the alarm volume is low, it may be obscured by surrounding ambient noise, so the alarm volume should be greater than the surrounding ambient noise.**
- **The sound intensity of the alarm signal of this device is 45-85dB.**
- **The alarm condition delay of all alarms is within 2s.**
- **The delay time from the onset of the alarm condition to the point that the representation of the alarm condition leaves the signal input/output part is within 1s.**
- **The maximum alarm signal generation delay of the distributed alarm system is within 2s.**

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**: a 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.

8.3 Alarm priority

According to the severity of the alarm, the alarm of the syringe pump can be divided into high, medium and low priorities.

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

8.4 Alarm signals

When an alarm is generated, the pump will alert the user through the following audio and visual alarm signals:

- Alarm light
- Alarm audio
- Alarm message

The alarm light, alarm audio and alarm message distinguish the alarm priority in different ways.

8.4.1 Alarm light

When an alarm is triggered, the alarm indicator will indicate different alarm priorities in different light colors and flashing frequency.

- High priority alarm: Red, frequency 1.6Hz, flashes twice every second, duty cycle 50%.
- Medium priority alarm: Yellow, frequency 0.55Hz, flashes once every 2 seconds, duty cycle 50%.
- Low priority alarm: Yellow, light remaining on without flashing.

8.4.2 Alarm audio

When an alarm is generated, the device sends out the alarm audio with different patterns to indicate the alarm priority.

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

NOTE

- **The alarm audio of some low priority alarms 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.**

8.4.3 Alarm message

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

Different background colors are used to indicate the alarm priorities:

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

Different total of the symbol "*" is added in front of alarm messages to indicate the alarm priorities:

- High priority alarm: ***
- Medium priority alarm: **
- Low priority alarm: *

8.5 Alarm audio pause

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

8.6 Alarm rules

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

- If there are multiple alarms of the same priority, each alarm message of the same priority is displayed in turn.

8.7 Alarm acknowledged

When some alarms are triggered, such as [**Low Battery**], [**Nearly Done**], [**Near Empty**] and [**AC off**], you can acknowledge the alarm condition, deactivating the alarm audio and alarm light, and continue to operate the device. For other alarm conditions, see ***7.5 Alarm audio pause***.

When an alarm is acknowledged, the acknowledged icon  is shown before the alarm message and the alarm audio off icon  after the alarm message. Both the audio alarm and alarm light are cancelled.

For the following alarms, after pressing the Alarm Audio Pause key, all the alarm signals including the alarm light, alarm audio and alarm message, will be eliminated.

- [**Standby Ended**]:
- [**Communication Error**]
- [**Relay Failure**]
- [**1H-Limit Exceeded**]
- [**4H-Limit Exceeded**]

NOTE

- **The audio of alarms such as "System Error", "Motor Dir. Err", "Motor Speed Err", "Slave Dir. Err", "Motor Pos. Err", and "Pres. Sensor Err" cannot be paused by pressing the Alarm Audio Pause key.**
- **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 Pause button, the former**

one is acknowledged, and the alarm audio of the latter one is paused.

- **Under the condition that the current alarm is acknowledged, the alarm system can still work normally. When a new alarm is triggered, the alarm light and alarm audio will be activated with the alarm message displayed on the screen.**

8.8 Alarm record setting

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

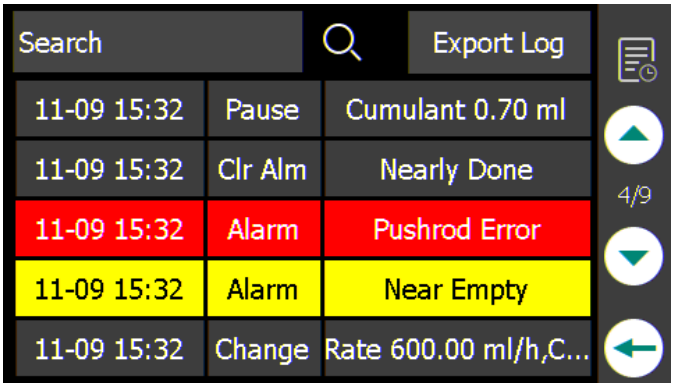
1. On/Off
2. Standby
3. Infusion rate changes
4. Parameter settings
5. Alarm
6. Alarm clearance
7. Status alteration (KVO, Bolus, Operation, Pause, Stop, Purge)

⚠ NOTE

- **The syringe pump can store at least 2000 logs.**
- **The user is not allowed to delete, modify, or import a log file.**
- **If there is not enough storage space, when a new log is stored, the oldest one will be deleted accordingly.**
- **After the syringe pump loses all the power or shuts down, the stored alarm log will not be deleted and the contents of the log will not change.**

- **After the power failure, the alarm settings of the device will be automatically restored when rebooting.**
- **In the case of the AC power supply disconnection, the alarm event and the time when the event occurs, will be recorded in the log.**

The alarm events are also recorded in [**Log**], including the date and time when the alarm is generated, the alarm priority and the alarm message. The alarm priority is indicated by the different background and font color of the log, as shown below (the log of high priority alarms: red background and white font; the log of medium and low priority alarms: yellow background and black font).



The pump supports the functions of log search and 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 keyboard (the input field can show a field that can be obscured when no value is input), and then click "√" to list the items of the string that can be matched.
Export	Press the menu key → [**Log**]. Insert a USB flash drive in advance and click the [**Export Log**] to display the message [**Exporting...**]. 1) File export format: txt

	2) When the screen displays [**Export Succeeded!**], click [**OK**] to finish the log export.

⚠NOTE

- **Do not export logs during the infusion.**
- **All logs will be exported by default when exporting the log.**

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 alarm indicator light turns red and then yellow for 1s respectively, and then turns off
- ✧ During the alarm light self-test, the alarm system makes a “beep” sound for a self-test of the alarm audio.

8.10 Alarm messages

⚠ WARNING

- **When an alarm occurs, the patient’s condition should be checked first, and the infusion should be continued after resolving the cause of the alarm.**

Name	Alarm priority	Cause	Solution
Occlusion	High	The infusion tube is knotted or kinked, the needle being used is blocked or the occlusion pressure reaches the preset threshold value.	Please remove the cause of excessive pressure in the infusion tube. Confirm whether the pressure level is reasonable. [**Pres. Level**] can be reset if required. Press the Start/Stop key to eliminate all the alarm signals.
Syringe Loose	High	During the infusion, it is detected that the syringe is not firmly fastened by the clamp.	Reinstall the syringe. Press the Start/Stop key to eliminate all the alarm signals.
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 the VTBI, if the set KVO rate is not equal to 0, the system will	Confirm whether to change or refill the syringe. Press the Start/Stop key to eliminate all the alarm signals.

		automatically start the infusion at the KVO rate.	
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 syringe. Press the Start/Stop key to eliminate all the alarm signals.
Syringe Empty	High	During the infusion, it is detected that the syringe has been emptied. If this alarm is triggered, the infusion will be automatically stopped.	Confirm whether to change or refill the syringe. Press the Start/Stop key to eliminate all the alarm signals.
Near Empty	Low/Med/High	During the infusion, it is detected that the near empty time reaches the preset nearly done time.	Confirm whether to change or refill the syringe. The alarm will automatically stop when the infusion is stopped or finished. Press the Alarm Audio Pause key to acknowledge the alarm, removing the alarm audio and light. The symbol  is followed by the alarm message.

Pres. Sensor Err (Pressure Sensor Error)	High	A pressure sensor error is detected.	Stop using the pump immediately, and please contact the service personnel of the manufacturer. The alarm can be stopped by shutting down the device.
Pushrod Error	High	A pushrod error is detected during infusion.	Check whether the pushrod can be pushed and pulled out normally. Press the Start/Stop key to eliminate all the alarm signals. Reinstall the syringe, and check whether the syringe specification can be identified correctly.
Nearly Done	Low/ Med/ High	After the parameters of nearly done function is validly set, when the distance from the scale of drug solution to 0mL reaches the set distance, or the remaining infusion time reaches the set time, or the	Confirm whether to change or refill the syringe or stop the infusion. This alarm will automatically stop upon the completion of the infusion. Press the Alarm Audio Pause key to acknowledge the alarm, removing the alarm audio and light. The symbol

		remaining drug volume reaches the set volume, the [**Nearly Done**] alarm will be triggered.	 is followed by the alarm message.
Operation Paused	Low	After the syringe is installed, there is no any operation during the set [**No Action Time**]. The alarm will be triggered to alert the user to use the pump timely.	The alarm can be removed by pressing any key or operating the touch screen.
Low Battery	Low	The battery charge is low and the pump is not connected to the mains AC power supply and the battery is not being charged.	Connect the AC power supply to remove the alarm. Press the Alarm Audio Pause key to acknowledge the alarm, removing the audible alarm and light. The symbol  is followed by the alarm message.
Dead BAT (Dead battery)	High	When power is to be supplied by a built-in battery, but the battery is dead. After a dead battery alarm is given, the machine	Connect the device to the external AC power supply and then the alarm will be removed.

		automatically stops the infusion. Three minutes later, the device automatically shuts down, and saves relevant parameters that need to be saved in case of a power failure.	
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 device.
Photoelectric Err (Photoelectric 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	High	During the infusion, the CPU that controls the motor detects that the motor speed	When the alarm is triggered, the infusion will be stopped immediately.

(Motor Speed Error)		is inconsistent with the preset speed.	Please disconnect the patient from the device, shut down the device and contact the 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.	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.
Slave Speed Err (Slave Speed Error)	High	During infusion, it is detected from the drive CPU that the motor running speed is inconsistent with the preset speed.	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.
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.	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 Power Err (Motor Power Error)	High	The motor power supply parameter is abnormal.	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 Pos. Err (Motor Positioning Error)	High	It is detected that the photoelectric syringe positioning sensor is abnormal.	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.
Battery Disconnected	High	When it is detected that the battery is not connected or the battery is off during running, the Battery Disconnected alarm occurs. In that instance the infusion cannot be performed, and it will	Please contact the service personnel of the manufacturer to check whether the battery is installed properly or to replace the battery. The operator is not allowed to install the battery by himself or herself.

		automatically stop if the infusion is in progress.	
Standby Ended	Low	The standby time exceeds the set standby time.	Press the Alarm Audio Pause key to acknowledge the alarm, removing the audible and visible alarm signals.
IP Repeat	Medium	After the pump is connected to the network, it is detected that the same IP address exists in the network.	Set the IP address again or disconnect the network to stop the alarm.
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 to the AC power supply to remove the alarm. Press the Alarm Audio Pause key to acknowledge the alarm, removing 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	Check whether the pump is correctly connected to the network. Press the Alarm Audio Pause key to acknowledge the alarm, eliminating the

		successful, the alarm is triggered due to the disconnection from the network or for other causes.	audible and visible alarm signals.
Relay Failure	High	During the relay infusion (which is performed after the syringe pump is connected to the Infusion Work Station), the syringe pump is uninstalled, or the relay infusion does not start successfully.	Check the syringe pump that has not completed the infusion in the sequence. Press the Alarm Audio Pause key to acknowledge the alarm, eliminating the audible and visible alarm signals.
1H-Limit Exceeded	High	The alarm can only be triggered in the PCA Mode. During infusion in the PCA mode, if the infusion volume in 1 hour exceeds the set value in [**1H-Limit**], the alarm will be triggered.	Press the Start/Stop key to eliminate all the alarm signals.

4H-Limit Exceeded	High	The alarm can only be triggered in the PCA Mode. During infusion in the PCA mode, if the infusion volume in 4 hours exceeds the set value in [**4H-Limit**], the alarm will be triggered.	Press the Start/Stop key to eliminate all the alarm signals.

8.11 Prompt messages

In order to reduce unnecessary alarms, the syringe pump is designed with prompt messages to attract the attention of the user when operating the device.

Prompt messages	**Cause**	**Solution**
No syringe is installed!	When it is detected that the syringes not installed, the prompt message will be displayed on the home screen.	Reinstall the syringe.
Syringe is not in place!	The system does not detect the barrel flange of the syringe when the pump starts up, the prompt message will be displayed on the home	Reinstall the syringe.

	screen.	
Plunger is not installed in place.	The system detects the syringe's plunger is not installed correctly when the pump starts up, the prompt message will be displayed on the home screen.	Reinstall the syringe.
Syringe Spec. Error!	The system detects that there are some specification errors in the plunger length and scale length when the pump starts up, the prompt message will be displayed on the home screen.	Reinstall the syringe and select the correct syringe brand and specification.
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 Comen. Repairing equipment by unauthorized personnel may cause personal injury or equipment damage.**
- **Maintenance must be strictly based on the technical information provided by Comen. For related technical materials, please contact the user service organization designated by Comen or the local agent.**

Fault	Cause analysis	Troubleshooting
Inaccurate rate	The barrel flange of the syringe is not inserted into the barrel flange clamp.	Reinstall the syringe.
	Syringe does not match.	Select the syringe recommended in the table in ***4.5 Select syringe brand***.
Battery under voltage alarm shortly after startup	The pump's battery has not been charged after the previous battery-powered operation, or the battery has not been used for a long period of time after previously being fully charged.	Shut down the pump and charge the battery.

	The built-in battery has been used improperly, and is damaged.	Replace the battery.
Blood return at the beginning of infusion	The needle is inserted into the vein without pressing the Bolus key to eliminate the mechanism gap.	Make sure that there is no air in the infusion tube, press the Bolus key to push the blood into the vein.
	The barrel flange of the syringe is not inserted into the barrel flange clamp of the syringe pump	Reinstall the syringe correctly.
Erratic movement of pushrod	The pump's push rod is stuck due to the drug solution.	Wipe off with alcohol.

8.13 Check the alarm system

WARNING

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

The syringe 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 ***4.2 Turn on the pump***. If the alarm self-test fails, stop using the syringe pump and contact our company for repair as soon as possible.

- **Occlusion Alarm**

Check under the following conditions:

Syringe	Infusion Rate	Maximum occlusion pressure threshold	Occlusion alarm response time

Jierui 50mL	50mL/h	300mmHg	Within 5min

During the infusion, initially purge the tube and maintain the rate of 50mL/h; set the occlusion alarm threshold as 300mmHg, open the three-way valve and then block the tube; check whether the occlusion alarm response time is within the acceptable range shown in the table above.

- **Pushrod Error**

During infusion, press and pull the pushrod, and check the alarm message displayed on the screen and the alarm audio.

- **Syringe Loose**

During infusion, pull the clamp and allow the syringe to become loose, and then check the alarm message displayed on the screen and the alarm indicator and the alarm audio.

Chapter 9 Battery

9.1 Overview

The M800/M800A syringe pump is equipped with a built-in rechargeable battery. When the device 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 unexpected power outage, the system will automatically use the battery for power supply, thus to avoid the interruption of device operation. After the device is disconnected from the AC power supply, the battery indicator flashes, showing that it is using the battery for power supply.

The battery icon displayed on the home screen 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 power cord, 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 for power supply, the device will be powered off automatically when the battery power is exhausted.**
- **If the battery is damaged or there is any sign of battery leakage, it should be replaced immediately.**

9.2 Replace or install the battery

The device is equipped with a built-in battery. When using the built-in battery for power supply, please ensure that the battery reserve is sufficient. If the working time of the battery is obviously reduced and lower than the time specified in this User Manual, please contact the after-sales personnel for optimizing the battery performance or replacing 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.**

- **For the procedures of battery replacement, please refer to the service manual for the M800/M800A syringe pump.**

9.3 Optimize and check 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 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, environment of use, 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 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.**
- **Please check and optimize the battery performance regularly.**

9.4 Recycle batteries

The built-in battery of M800/M800A syringe pump can be charged and discharged for up to 300 times.

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 cannot be charged, 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 the 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 unauthorized 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 a means of infection control. For infection control methods, please consult the Infection Prevention Department or an epidemiologist in your hospital, or refer to the 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 syringe 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 and 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 aging, it should be replaced with a new cable.**
- **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 any connectors or accessories in any solution for cleaning or disinfection.**
- **Do not expose the pump to high-temperature disinfection or electron beam or γ radiation sterilization.**
- **Avoid cleaning the pump with xylene, acetone, or similar solvents to avoid damage to the housing.**
- **After each cleaning and disinfection, check the device and its accessories carefully. If there is any signs of damage or aging of the device, stop using it immediately.**

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. Especially in environments with tough conditions or very windy and dusty places, the cleaning frequency should be increased in order to avoid cross infection, and the accessories should be cleaned on a regular basis. 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 cord.
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 and accessories, such as the pole clamp, the portable handle and the PCA accessory and so on.
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 syringes or tubes used are not allowed to be repeatedly sterilized or reused.**
- **In order to protect the environment, disposable syringes or tubes should be recycled or properly disposed of.**

Chapter 11 Maintenance

WARNING

- **During use, please do not repair or maintain the device yourself so as to avoid danger.**
- **Please contact service personnel of the manufacturer for maintenance of the device. Anyone who is inexperienced in the maintenance of such device is not allowed to engage in such maintenance.**

NOTE

- **Damaged parts shall be replaced by those produced or sold by our company. Tests shall be conducted after replacement to ensure the device conforms to the specification requirements of the manufacture.**
- **Please contact the after-sales service department of Comen if you need service support.**
- **If you want to know more about product information and related technical materials, please contact our after-sales service department, and we will provide documents of some parts according to specific conditions.**

11.1 Maintenance checks

Before use of the pump, or every 6-12 months or after each maintenance or upgrade, a preventive check and maintenance should be conducted for the device and its part, in order to guarantee the normal and safe operation of the device.

The inspection items should include:

1) Check if the operating environment and the power supply for the device conform to relevant requirements.
2) Check if the device and its accessories have any mechanical damage.

3) Check if the power cord 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 maintenance plan; failure to do so may result in malfunction of the device and unpredictable consequences, and may also endanger personal safety.**
- **The disassembly and/or maintenance of this syringe pump should be performed by the qualified after-sales engineer trained or authorized by Comen, who should be familiar with the structure and operation of this 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.

- **All parts involved in maintenance and replacement shall be those designated by Comen.**
- **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 the operator, otherwise it may result in harm to the operator.**
- **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 contact the maintenance personnel. Prior to test or maintenance, the device must be cleaned and disinfected.

Inspection and maintenance tasks	Frequency
Carry out safety check according to EN 60601-1	At least once every two years. After a dropping of the device, replacement of power supply or as required.
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 the 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.**
- **For the recommended syringes and extension tube (B.Braun IV-Standard-PE), the material, transparency, inner diameter and length may vary due to the different product lot. Thus, calibration is necessary before using them for infusion.**

✧ **Recommended syringes:**

Syringe name	Brand	Type of syringe	Manufacturer	Certification
Sterile syringe for single use	Jierui	2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL	Weigao Holding Co.,Ltd	CE0123

Sterile syringe for single use	Shuangge	2mL, 5mL, 10mL, 20mL, 30mL, 50/60mL	Weigao Holding Co. Ltd	CE0123
Sterile syringe for single use (with/without needle)	B-D	2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL	Becton Dickinson S.A. Spain	CE0123

✧ **Accessories**

No.	Name
1	Power Cable (EU Standard)
2	Pole clamp (Standard)
3	Portable handle (optional)
4	PCA accessory (Optional)

Appendix II Product Specifications

1) Product classification

Item	Type
Type of protection against electric shock	Class I, with internal power supply, DC power supply.
Level of protection against electric shock	Defibrillation-proof type CF applied part: Extension tube 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. The device is not suitable to be used in environments containing air mixed with flammable anesthetic gas, oxygen or nitrous oxide.
Whether there is signal output or input part	Yes
Non-permanently installed equipment or permanently installed equipment	Non-permanently installed equipment
Work mode	Continuous operation equipment
Mobility	Portable device but not for ambulatory use
Applied part	Syringe and patient tube
Conformity with Standards	EN 60601-2-24: 2015; EN 60601-1-8: 2007+A1: 2013+A2: 2020; EN 60601-1-6: 2010+A1: 2015+A2: 2020; EN 60601-1:

	2006+A1: 2013+A2:2021; EN 60601-1-2: 2015+A1:2021; EN 60601-1-12: 2015+A1: 2020; EN 1789: 2020
Pollution degree	2

2) Physical specification

Item	Specifications
Dimension	≤290mm*146.5mm*77.5mm (Length*Width*Height)
Weight	≤1.55kg (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
Input current		AC power supply: 0.5-0.3A External DC power supply: 2.0-1.0A
AC input frequency		50/60Hz
Power supply		External AC or use built-in battery for power supply
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, system volume and alarm volume are at the lowest levels, and WIFI is turned off, after the battery is fully charged, the pump can be operated at the rate of 5mL/h (the intermediate rate) for at least 10 hours. Optional: When the screen brightness, system volume and alarm volume are at the lowest levels, and WIFI is turned off, after the battery is fully charged, the pump can be operated at the rate of 5mL/h (the intermediate rate) for at least 15 hours.
	Internal battery depletion alarm condition	With a new and fully charged battery, this pump will give a low priority alarm for at least 30 minutes before delivery ceases due to battery exhaustion.

4) Environmental specifications

Item	Specification	
Working conditions	Ambient temperature	5°C ~40°C
	RH	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 room without corrosive gas (Ambient temperature:	

	-20°C~+55°C; Relative 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 key light)
Alarm indicator	1 (red for high priority alarms; yellow for medium and low priority alarms)

6) Interface

Interface	Function	Quantity
AC power interface	AC power	1
Multi-function interface	DC power supply interface; RS232 interface; Nurse call interface; USB interface (for connecting the scanner or for system upgrade); KLink interface MX8900/MX8900A interface (for connecting the MX8900/MX8900A Infusion Workstation System) PCA interface. a) Nurse call interface: Serial transmission protocol: The software carries out serial	1

	communication through the multi-function interface, and our company's own encrypted protocol. b) WIFI transmission protocol: IEEE802.11a/b/g/n, encryption method: WPA2/AES c) USB transmission protocol: Standard protocol USB2.0	

7) Signal output

Auxiliary output interface	
Conformity with Standards	The short circuit protection and leakage current meet the requirements of EN 60601-1.
Output impedance	50Ω
Nurse call signal output	
Drive method	Driven by the relay
Electrical Specifications	Contact rating: 30V d.c (Vpeak a.c) @ 1 A
The way of action	Normal open or Normal close (Optional)

8) Specifications & Parameters

Parameter name	Description
Syringe requirements	The syringe for use with syringe pump should meet the requirements of standard ISO 7886-2: Sterile hypodermic syringes for single use —Part 2: Syringes for use with power-driven syringe pumps.

	Commonly used syringe brands: Jierui, Shuangge, and B-D Applicable syringe specifications: 2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL. Recommended extension tube: B.Braun (IV-Standard-PE)
Range of rate & unit of rate	Range of rate: 0.10~2000.00mL/h; Minimum increment: 0.01mL/h; The rate range for syringes of different specifications: 50/60mL: 0.10~2000.00mL/h. 30mL: 0.10~1200.00mL/h. 20mL: 0.10~600.00mL/h. 10mL: 0.10~300.00mL/h. 5mL: 0.10~150.00 mL/h. 2/3mL: 0.10~90.00 mL/h. Unit of rate: 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.
Bolus and purge rate range	The bolus/purge rate is adjustable within the following rate range: 50/60mL syringe: 0.10~2000.00mL/h (adjustable); The default rate: 1500.00mL/h. 30mL syringe: 0.10~1200.00mL/h (adjustable); The default rate: 600.00mL/h. 20mL syringe: 0.10~600.00mL/h (adjustable); The default rate: 400.00mL/h. 10mL syringe: 0.10~300.00mL/h (adjustable); The default rate: 300.00mL/h.

	5mL syringe: 0.10~150.00mL/h (adjustable); The default rate: 150.00mL/h. 2/3mL syringe: 0.10~90.00mL/h (adjustable); The default rate: 90.00 mL/h. Bolus/purge VTBI range: 50/60mL syringe: 0.10~50.00mL (adjustable). 30mL syringe: 0.10~30.00mL (adjustable). 20mL syringe: 0.10~20.00mL (adjustable). 10mL syringe: 0.10~10.00mL (adjustable). 5mL syringe: 0.10~5.00mL (adjustable). 2/3mL syringe: 0.10~2.00mL (adjustable). Minimum increment: 0.01mL.
VTBI range	Range: 0.10~9999.99mL, minimum increment: 0.01mL. (Note: the VTBI range of the Micro Mode: 0.10~1000.00mL, minimum increment of the Micro Mode: 0.01mL).
Cumulant range	Range: 0.00~9999.99mL. Minimum increment: 0.01mL.
Drug dose	Range: 0.001~999.999; Unit: g/mg/ug/ng/IU/U/KU; Minimum increment: 0.001(g/mg/ug/ng/IU/U/KU)
Drug volume	Range：0.10~9999.99mL; Minimum increment: 0.01mL.
Dose rate	Range: .001~999.999; 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	Range: 0.001~9999.999; Minimum increment: 0.001; Unit: U/mL, IU/mL, KU/mL, g/mL, mg/mL, ug/mL, ng/mL. This function can be turned off.
Time range	00:00:01~99:59:59 h:m:s.
Standby time range	00:01:00~99:59:59 h:m:s.
Weight set range	Range: (0.1~500)kg/(0.2~1102.3)Ib. Minimum increment: 0.1 (kg/Ib).
Infusion mode	Rate Mode, Time Mode, Weight Mode, Sequential Mode, First Dose Mode, Micro Mode, Ramp Mode, Dose Time Mode, Intermittent Mode, PCA Mode.
Parameters of PCA mode	The parameters of PCA mode include: Drug concentration, Loading dose, Loading rate, PCA dose, PCA rate, Keep rate, Lockout time, 1H-Limit and 4H-Limit. a) Drug concentration: 0.001~9999.999; minimum increment: 0.001; b) Loading dose: 0.01~20.00mL; minimum increment: 0.01mL; c) Loading rate: 0.10~100.00mL/h; minimum increment: 0.01mL/h; d) PCA dose: 0.01~20.00mL; minimum increment: 0.01mL; e) PCA rate: 0.10~100.00mL/h; minimum increment: 0.01mL/h; f) Lockout time: 1~60min; minimum increment: 1min. g) 1H-Limit: 0.01~20.00mL; minimum increment: 0.01mL;

	h) 4H-Limit: 0.01~60mL; minimum increment: 0.01mL.
KVO rate (Keep veins open)	KVO rate is adjustable. Range: 0.10~5.00mL/h. KVO default value: 0.50mL/h. Minimum increment: 0.01mL/h. When the infusion is completed, the device 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. KVO function can be turned off. When KVO is turned off, the device will not enter the KVO mode after the infusion of VTBI is completed.
Drug library	The system stores 5000 drug names. There are 60 drug names by default.
Occlusion pressure	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). Error: For 50mmHg, the error is -45~+75mmHg; for 75mmHg, the error is ±50mmHg; for other levels, the error is ±15% or ±75mmHg, whichever is greater. 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 ≤20min;

	b) When the infusion rate is 1mL/h and the pressure level is P16, the maximum occlusion alarm response time ≤240min; c) When the infusion rate is 5mL/h and the pressure level is P1, the maximum occlusion alarm response time ≤5min and the unintended bolus is not more than 0.2mL. d) When the infusion rate is 5mL/h and the pressure level is P16, the maximum occlusion alarm response time⩽40min and the unintended is not more than 0.2mL.
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 can be turned on or off.
Time left	The accuracy of infusion time left is ±2.5%.
Dynamic pressure display (DPS)	During infusion, pressure changes at the patient will be displayed in real time.
No action time	15s~5min. The function can only be enabled under the condition of infusion paused or stopped, and can be turned off.
Screen lock	With automatic locking and manual locking function.
Nearly done /empty time	1-30min; increment: 1min. When the set time period ≤10min, the increment is 1min; when the set time period >10min, the increment is 5min. This function can be turned off.
Alarm volume	1-10 (Adjustable)

Screen brightness	1-10 (Adjustable)
Automatic brightness	With the automatic brightness adjustment function. 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 a 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 nurse call function. The nurse call function can be turned on or off.
Accuracy of syringe pump	The infusion accuracy range of using the recommended syringes and the extension tube is as follows: Infusion rate: <1.00mL/h, accuracy: ≤±5%; Infusion rate: ≥1.00mL/h, accuracy: ≤±1.8%.[1] Mechanical error ≤±1%; Under the condition of standard test, the accuracy of bolus VTBI is ≤±2% or±0.05mL, whichever is greater.
Alarm information	The alarm system complies with the standards of EN 60601-1-8 and EN 60601-1-24. The syringe pump has the following alarm functions: High priority alarms:

[1] The accuracy of syringe pump with back pressure (+100mmHg and -100mmHg) also falls into the following range: Infusion rate : <1.00mL/h, accuracy: ≤±5%; Infusion rate: ≥1.00mL/h, accuracy: ≤±1.8%.

	Occlusion, VTBI Done, KVO Done, Syringe Empty, Syringe Loose, System Error, Dead Battery, Battery Disconnected, Pushrod Error, Motor Speed Err (Motor speed error), Motor Dir. Err (Motor direction error), Slave Dir. Err (Slave direction error), Slave Speed Err (Slave speed error), Motor Power Err (Motor power error), Pres. Sensor Err (Pressure sensor error), and Motor Pos. Err (Motor positioning error), 1H-Limit Exceeded, 4H-Limit Exceeded, Relay Failure, Photoelectric Err (Photoelectric error). Medium priority alarms: IP Repeat Low priority alarms: Operation Paused, Low Battery, Standby Ended, Near Empty, Communication Error, AC Off. The [**Nearly Done**] alarm can be set to high/medium/low priority by users.
Prompt message	No syringe is installed! Syringe is not in place! Plunger is not installed in place. Syringe Spec. Error! (Syringe specification error.) Invalid Parameters!
Night mode	After entering night mode, the system volume, alarm volume and screen brightness are automatically changed to the volume and brightness settings of the night mode. When the time set for night mode ends, the system volume, alarm volume and screen brightness will automatically change 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.
Connection with other devices	The pump can be connected to the MX8900-L/MX8900A-L Infusion Workstation System and can communicate with the Infusion Central Monitoring System (eCenter-IMS) through a wireless network.
Self-test function	With automatic power-on self-test 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
Stacking	With stacking function
KLink	With the KLink connection function
Drug color	With the function of setting the background color of drug name.

9) WLAN

	Function		ACM	TM
WLAN	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 (Human Body Model)	2000V	
ESD protection (Charged Device Model)	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)	-86 dBm
	MCS7 (20MHz)	-73 dBm
	MCS0 (20MHz)	-83 dBm
	MCS7 (40MHz)	-70dBm

Appendix III Infusion Performance

1. Flow rate accuracy characteristics

NOTE

- **Infusion accuracy does not reflect clinical criteria, such as the patient's age, weight and medication used.**
- **Infusion accuracy may be affected by the environment where the syringe pump is used (Such as pressure, temperature, humidity, and infusion components).**

1) BD 50mL syringe； Testing mode: Rate Mode

Syringe used in the test: BD 50mL syringe for single use

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

The test results are shown as follows:

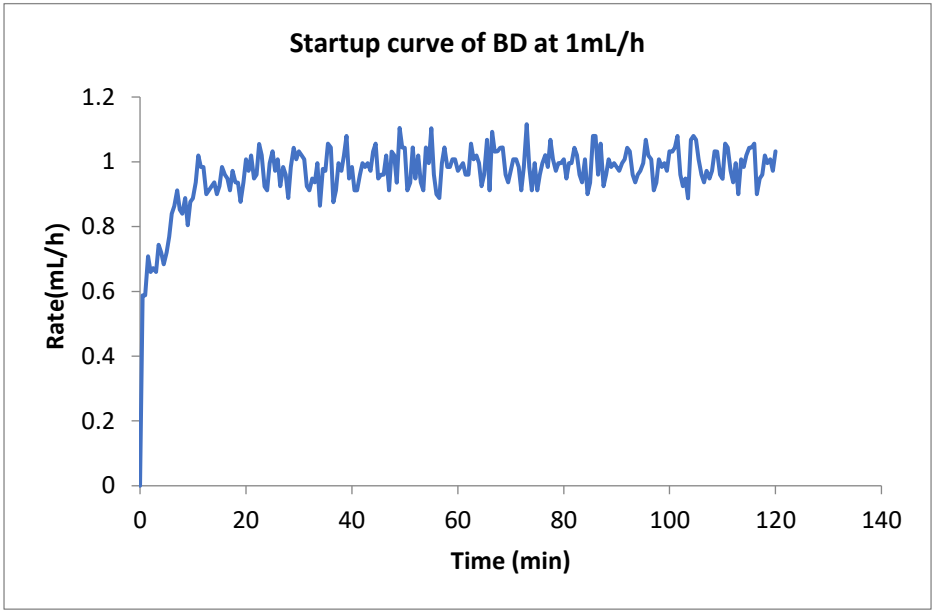
Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 1mL/h

Sampling interval: 0.5min

Test period: T=120min



Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 1mL/h

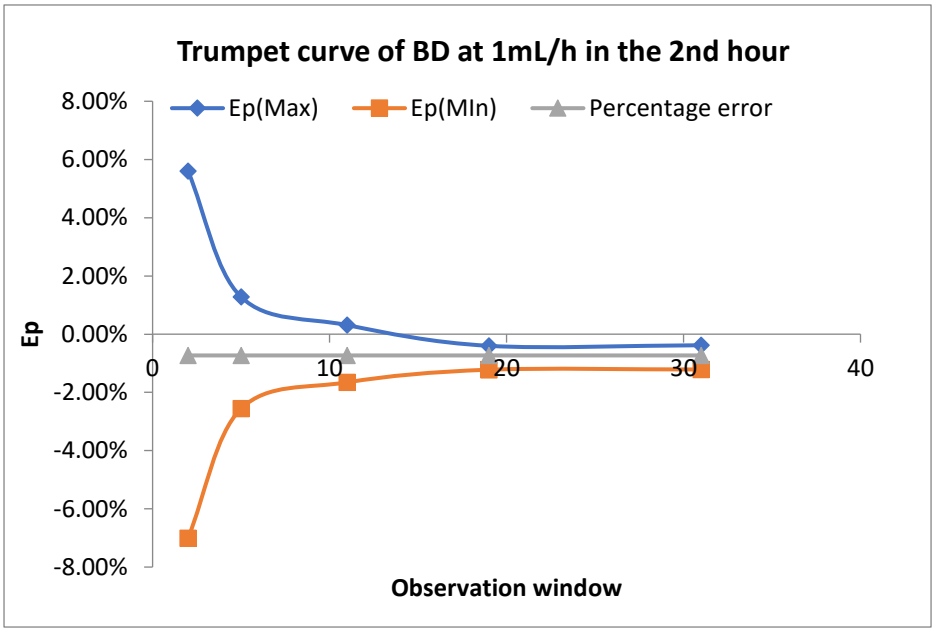
Sampling interval: 0.5min

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

Ep (Max): Pi maximum error in inspection window

Ep (Min): Pi minimum error in inspection window

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



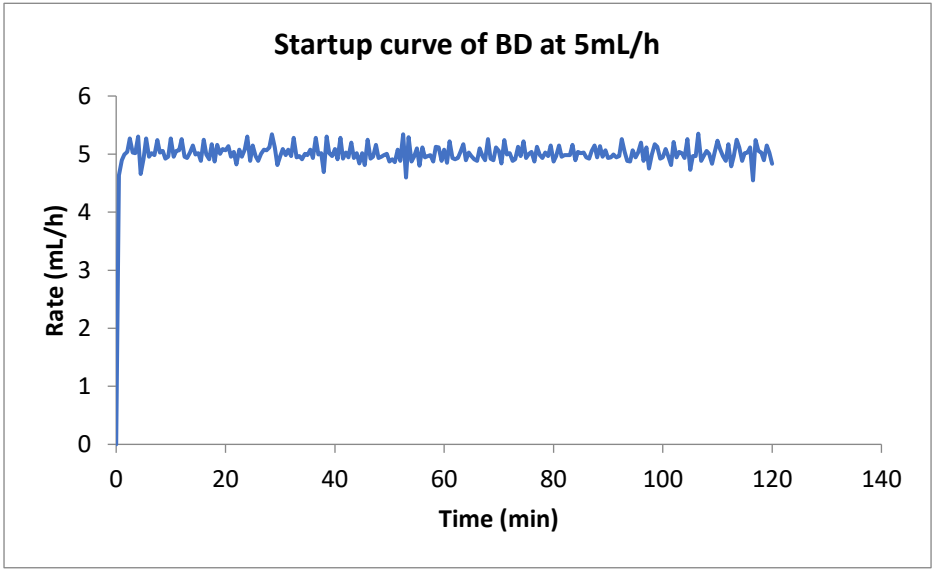
Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 5mL/h

Sampling interval: 0.5min

Test period: T=120min



Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 5mL/h

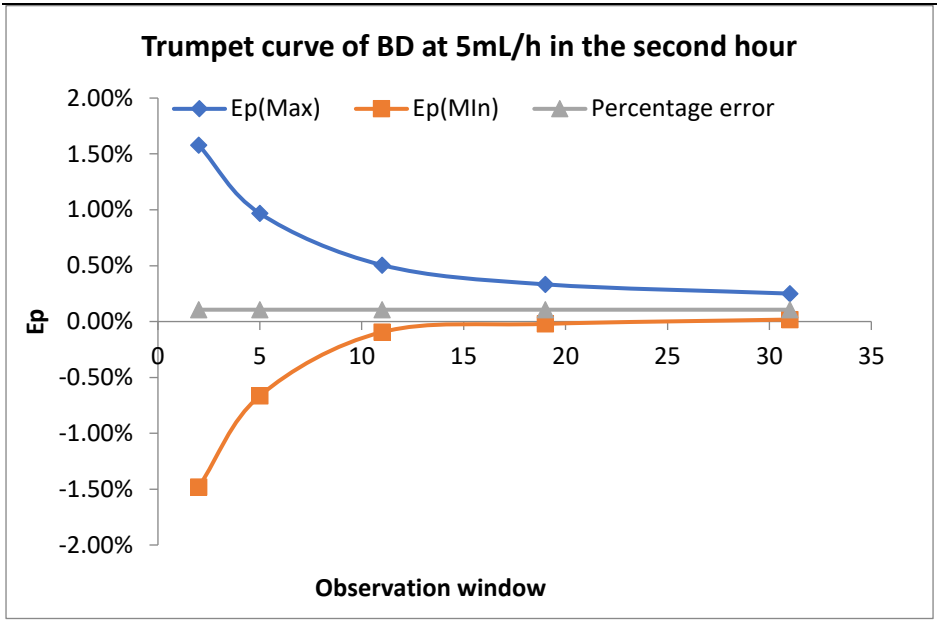
Sampling interval: 0.5min

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

Ep (Max): Pi maximum error in inspection window

Ep (Min): Pi minimum error in inspection window

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



2) Jierui 50mL syringe；Testing mode: Rate Mode

Syringe used in the test: Jierui 50mL syringe for single use

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

The test results are shown as follows:

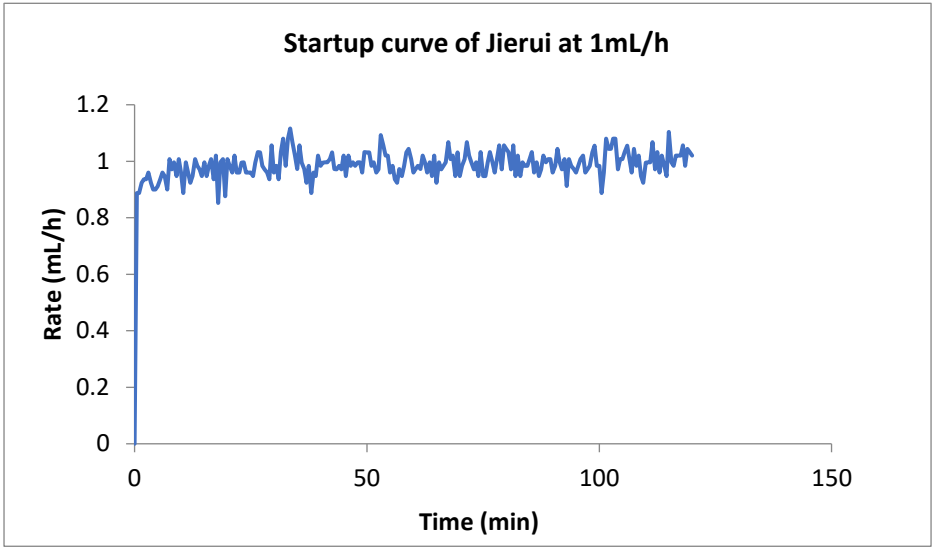
Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 1mL/h

Sampling interval: 0.5min

Test period: T=120min



Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 1mL/h

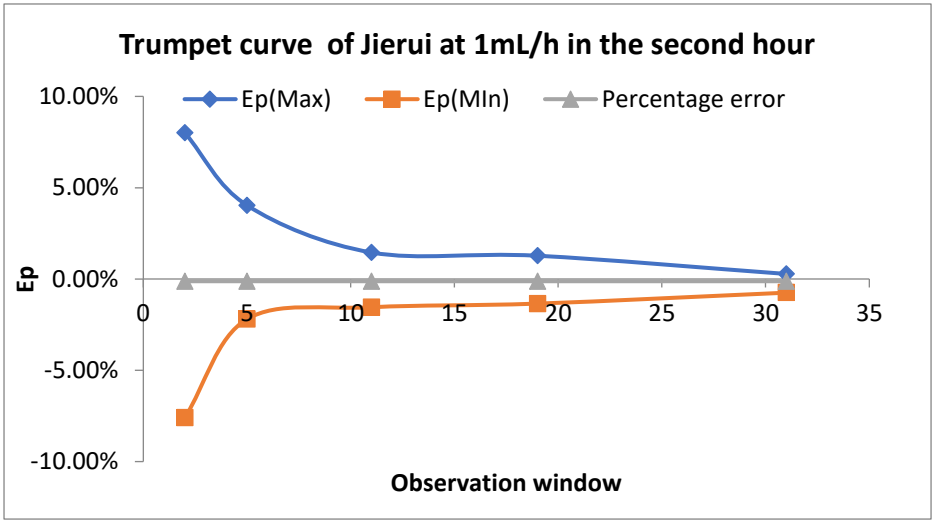
Sampling interval: 0.5min

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

Ep (Max): Pi maximum error in inspection window

Ep (Min): Pi minimum error in inspection window

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



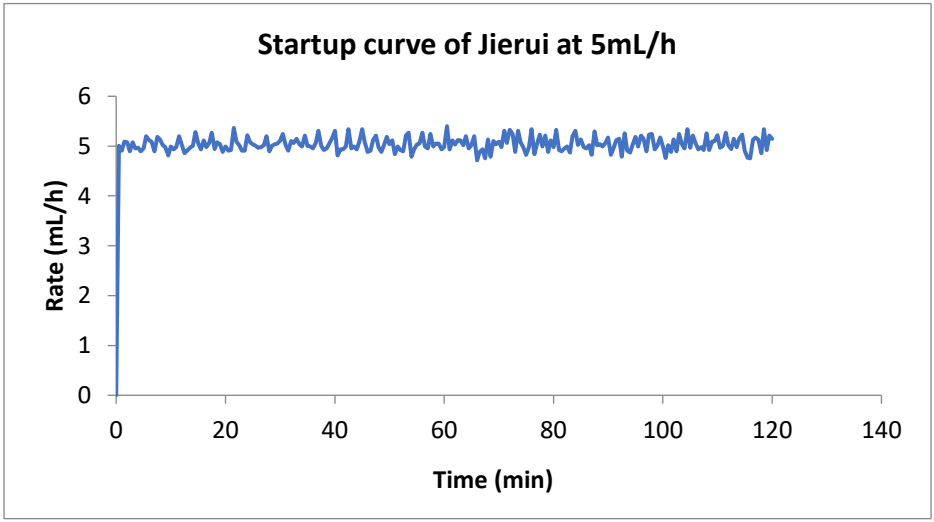
Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 5mL/h

Sampling interval: 0.5min

Test period: T=120min



Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 5mL/h

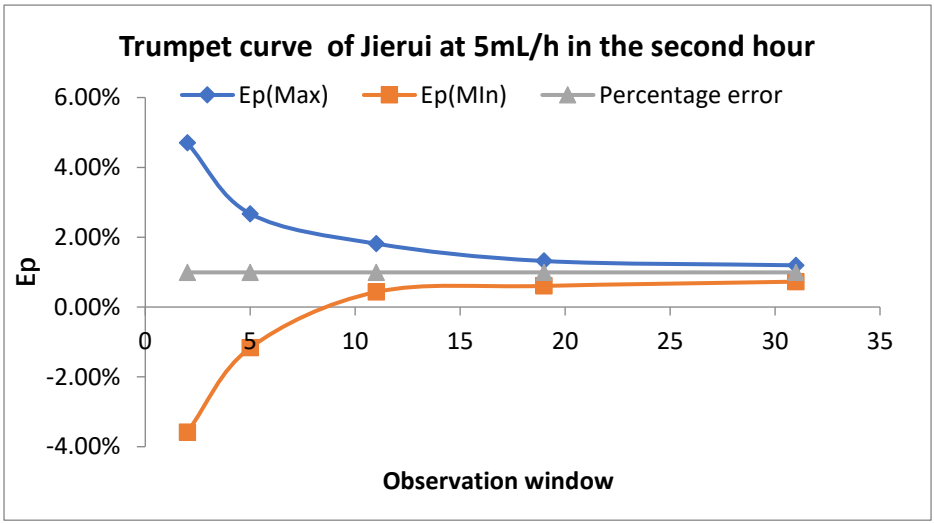
Sampling interval: 0.5min

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

Ep (Max): Pi maximum error in inspection window

Ep (Min): Pi minimum error in inspection window

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



3) Shuangge 50mL syringe； Testing mode: Rate Mode

Syringe used in the test: Shuangge 50mL syringe for single use

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

The test results are shown as follows:

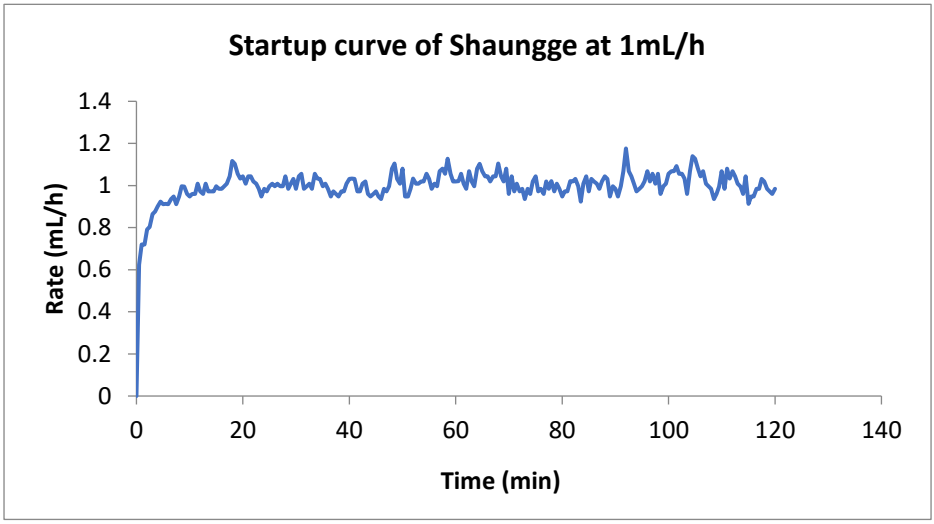
Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 1mL/h

Sampling interval: 0.5min

Test period: T=120min



Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 1mL/h

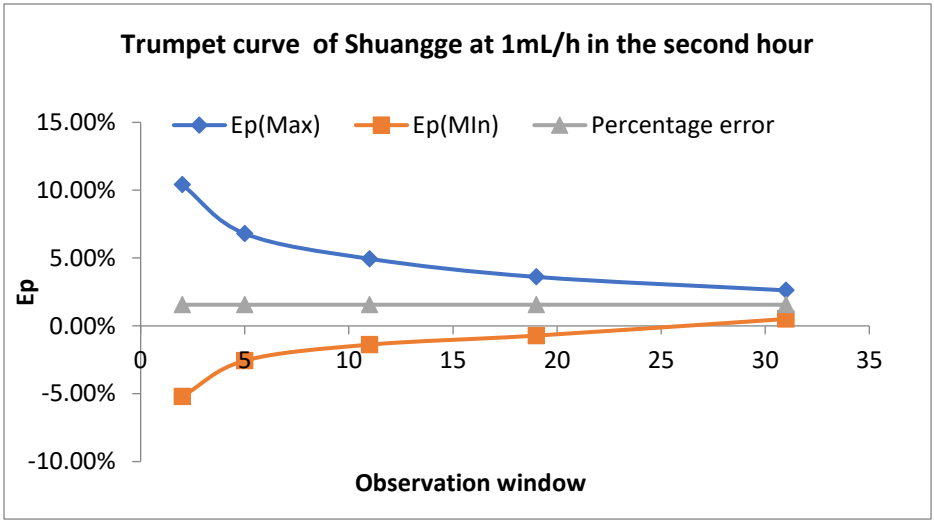
Sampling interval: 0.5min

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

Ep (Max): Pi maximum error in inspection window

Ep (Min): Pi minimum error in inspection window

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



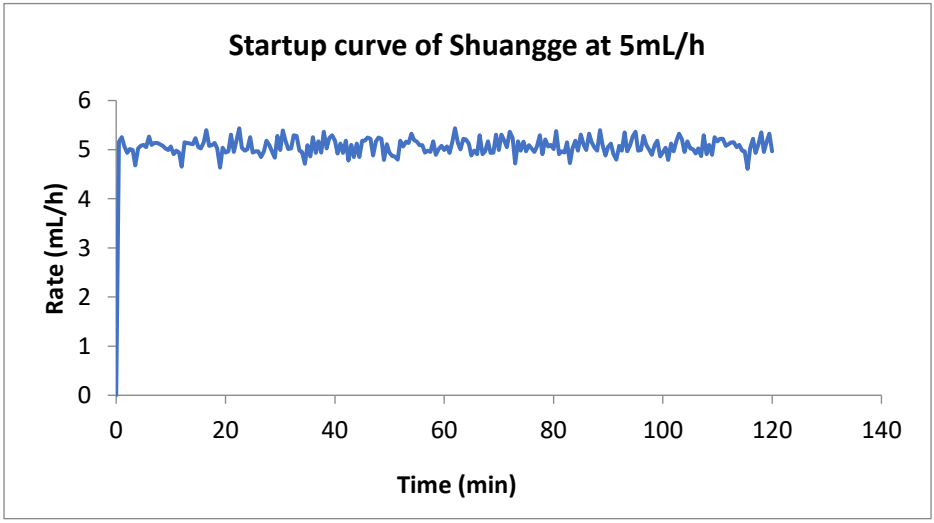
Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 5mL/h

Sampling interval: 0.5min

Test period: T=120min



Sample quantity of syringe pump: 3

Sample quantity of syringe: 3

Sampling rate: 5mL/h

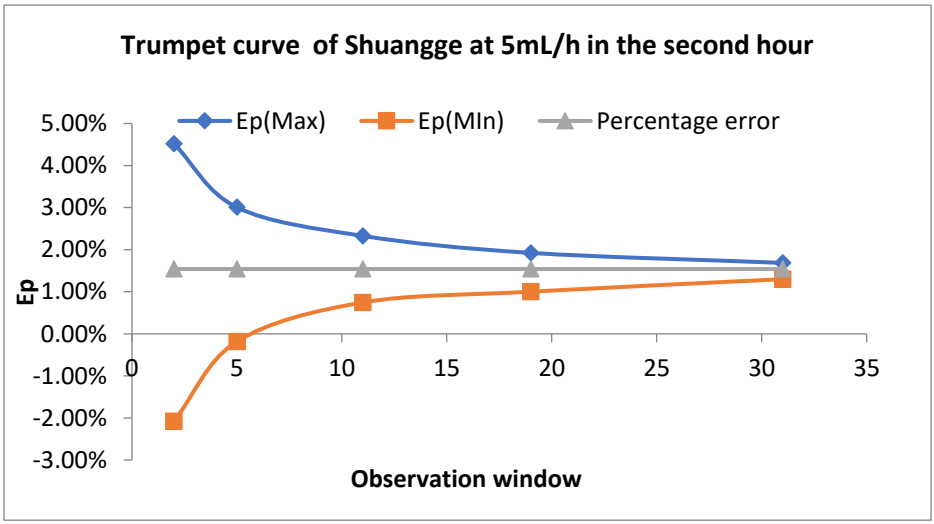
Sampling interval: 0.5min

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

Ep (Max): Pi maximum error in inspection window

Ep (Min): Pi minimum error in inspection window

B: 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 BD 50mL syringe:

Bolus setting	**Weight of 25 successive bolus deliveries (g)**	**Calculated mean deviation from the set value**	**Calculated percentage deviation from the set value**	**Remarks**
Minimum:0.1 mL	0.098/0.0978/0.0953/0.0989/0.0984/0.0984/0.0974/0.0972/0.0982/0.0987/0.1002/0.099/0.0967/0.0978/0.0968/0.0975/0.0986/0.0957/0.0993/0.098/0.0991/0.0986/0.0975/0.0993/0.0999	0.0019	Maximum positive percentage deviation：0.2% Maximum negative percentage deviation：-4.70%	Set flow rate: 5mL/h
Maximum: 50 mL	49.817/49.93/49.061/49.3688/49.2788/49.9815/49.815/49.7678/49.8257/49.8965/49.8974/49.8442/49.8453/49.8314/49.7023/49.8358/49.8803/49.8092/49.7182/49.693/49.7649/49.6	0.2406	Maximum positive percentage deviation：-0.037% Maximum negative percentage deviation：-1.878%	Set flow rate: 5mL/h

	468/49.9504/49.8648/ 49.9594			
Maximum: 50 mL	49.6482/50.137/49.1258/49.5492/49.9084/49.2303/49.2615/49.1673/49.4936/49.1881/49.5263/49.0655/49.2689/49.5775/49.0259/49.4258/49.5446/49.567/49.5781/49.2197/49.5456/49.5855/49.2354/50.998/49.3842	0.5097	Maximum positive percentage deviation：2.00% Maximum negative percentage deviation：-1.95%	Set flow rate: 2000mL/h

2) The testing result of using Jierui 50mL syringe:

Bolus setting	**Weight of 25 successive bolus deliveries (g)**	**Calculated mean deviation from the set value**	**Calculated percentage deviation from the set value**	**Remarks**
Minimum: 0.1 mL	0.1037/0.0972/0.0975/0.0942/0.0963/0.0995/0.0916/0.0981/0.0983/0.1004/0.0985/0.1018/0.0978/0.958/0.0948/0.095/0.0988/0.1/0.0989/0.983/0.0977/0.0965/0.0992/0.0965/0.1004	0.0021	Maximum positive percentage deviation：3.70% Maximum negative percentage deviation：--8.40%	Set flow rate: 5mL/h

Maximum: 50 mL	50.3791/50.3697/50.2275/50.2336/50.3423/50.3554/50.4227/50.5147/50.3481/50.4678/50.3555/50.1528/50.3938/50.0655/50.2897/50.1284/50.4748/49.3837/50.3224/50.3221/50.2411/49.9885/50.2843/50.5805/49.9898	0.2654	Maximum positive percentage deviation：1.161% Maximum negative percentage deviation：-1.233%	Set flow rate: 5mL/h
Maximum: 50 mL	49.8224/50.1028/49.9476/49.6579/49.7912/49.6396/50.412/50.4026/50.538/50.4166/50.5193/50.3912/50.3875/50.3942/50.4212/50.3734/50.3737/50.5078/50.5011/50.3602/50.5049/50.5069/50.4582/50.4943/50.5565	0.2992	Maximum positive percentage deviation：1.113% Maximum negative percentage deviation：-0.721%	Set flow rate: 2000mL/h

3) The testing result of using Shuangge 50mL syringe:

Bolus setting	**Weight of 25 successive bolus deliveries (g)**	**Calculated mean deviation from the set value**	**Calculated percentage deviation from the set value**	**Remarks**

Minimum: 0.1 mL	0.0999/0.0968/0.0972/0.0986/0.0946/0.0966/0.0967/0.0977/0.0944/0.0972/0.0959/0.0946/0.0976/0.0973/0.0968/0.1016/0.0991/0.0978/0.0971/0.0959/0.101/0.0969/0.1026/0.0987/0.0973	0.0024	Maximum positive percentage deviation：2.600% Maximum negative percentage deviation：-5.600%	Set flow rate: 5mL/h
Maximum: 50 mL	50.1609/50.499/50.1136/50.5699/50.6977/50.5194/50.5024/50.1186/50.5172/50.3619/50.3316/50.5005/50.3308/49.7928/50.1135/50.0827/50.6196/50.6485/50.1957/51.2111/50.3241/50.123/50.185/49.9891/50.1669	0.3470	Maximum positive percentage deviation：2.42% Maximum negative percentage deviation：-0.41%	Set flow rate: 5mL/h
Maximum: 50 mL	49.5838/50.2541/50.4453/50.0828/50.4535/50.2737/50.1294/50.4512/50.137/50.4093/50.3373/50.3003/50.5594/50.029/50.4277/50.6191/50.1192/49.8559/49.5986/49.6306/49.8808	0.1310	Maximum positive percentage deviation：1.2382% Maximum negative percentage deviation：-0.8324%	Set flow rate: 2000mL/h

	/50.004/49.8629/49.69 25/50.1373			

3. Occlusion alarm response characteristic and unintended bolus

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

1) The testing results of BD 20mL syringe：

Rate (mL/h)	Occlusion Alarm Level	Occlusion pressure measured (mmHg)	Alarm Response Time (h:m:s)	Bolus (mL/mg)
1	P1	50	00: 01:49	0.5mg
1	P16	1242	00:37:42	125.7mg
5	P1	46	00:00:22	1.1mg
5	P16	1230	00:07:10	106mg

2) The testing results of Jierui 20mL syringe：

Rate (mL/h)	Occlusion Alarm Level	Occlusion pressure measured (mmHg)	Alarm Response Time (h:m:s)	Bolus (mL/mg)
1	P1	72	00:01:22	28.9mg
1	P16	1172	00:35:34	124.3mg
5	P1	74	00:00:21	21.5mg
5	P16	1178	00:07:07	108.8mg

2) The testing results of Shuangge 20mL syringe：

Rate (mL/h)	Occlusion Alarm Level	Occlusion pressure measured (mmHg)	Alarm Response Time (h:m:s)	Bolus (mL/mg)
1	P1	54	00:02:01	1.8 mg
1	P16	1184	00:40:46	105.5 mg
5	P1	56	00:00:21	10.7 mg
5	P16	1186	00:08:27	78.5 mg

⚠ 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 M800/M800A syringe pump complies with the applicable EMC requirements in EN 60601-1-2.**
- **When the M800/M800A syringe pump is used with the MX8900/MX8900A Infusion Workstation System, the two devices form as a ME system, which complies with the applicable EMC requirements in EN 60601-1-2 and EN 60601-2-24.**
- **Please follow the EMC instructions in the User Manual to install and use the device.**
- **Portable and mobile RF communication equipment may affect the performance of the syringe pump M800/M800A. To protect the Monitor against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.**
- **Refer to the attached guide and manufacturer's statement.**

WARNING

- **Do not stack this product on/under or get it close to any other equipment. If you have to use it this way, firstly observe and verify whether it works properly in such conditions.**
- **Please pay extra attention to the device's EMC performance and install and repair the syringe 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.**
- **Using any accessory or cable other than those sold by the manufacturer as spare parts may cause higher electromagnetic emissions or lower electromagnetic immunity.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the M800/M800A syringe pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

Name	Cable length (m)	Shielded or not	Remarks
Power cord	3.0	Not shielded	/

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 accuracy: ≤ ±5%;
- The infusion pump shall have no high priority alarms during the test and the alarm system works normally;
- Protection against the unintended bolus and occlusion condition.

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

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

EN 61000-4-2	±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Electrical fast transient/burst EN 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 EN 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 EN 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 EN 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

declaration - electromagnetic immunity		
Immunity test	EN 60601 test level	Compliance level
Conducted RF EN 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 EN 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	EN 60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF EN 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 table below lists the configurations for different departments in configuration management and some of the most important default settings. Users will not be authorized to change the default settings.

Purge parameter		
Purge rate	50/60mL: 1500mL/h 30mL: 600mL/h 20mL: 400mL/h 10mL: 300mL/h 5mL: 150mL/h 2/3mL: 90mL/h	
Purge VTBI	0.00mL	
Bolus parameter		
Bolus rate	50/60mL: 1500mL/h 30mL: 600mL/h 20mL: 400mL/h 10mL: 300mL/h 5mL: 150mL/h 2/3mL: 90mL/h	
Bolus VTBI	0.00mL	
Alarm parameters		
Occlusion Pressure	525mmHg	
Nearly completed	On	3min
No-action Time	On	2min

Patient information		
Name	None	
Patient Type	Adult	
MRN	None	
Bed number	None	
Height	None	
Gender	Male	
Blood	Other	
Birth Date	1900-01-01	
Weight	None	
Doctor	None	
Order	None	
Parameter settings		
KVO	On	0.50mL/h
Automatic lock time	Off	15s
Brightness	6	
Alarm volume	8	
Audio System volume	0	
Key Light	On	
Auto-brightness	Off	
Night mode	Off	
	Time	20:00:00~08:00:00
	Brightness	3
	Alarm volume	3
	System volume	0
Nurse Call	Off	
	Signal duration	Continuous

	Trig. Mode (Triggering mode)	Normally Open
	Trig. Level (Triggering level)	Low
Date/Time	Date	Y-M-D
	Time	24-Hour
Language	English	
Unit of Height	cm	
Weight	kg	
Pressure Unit	mmHg	
Pressure mode	Regular	
Auto Pressure release (Anti-bolus)	On	

Appendix VI Terms

1. Abbreviations list

KVO=Keep Vein Open

LED=Light-Emitting Diode (indicator lamps)

TPN=Total Parenteral Nutrition

VTBI=Volume To Be Infused

MRI=Magnetic Resonance Imaging

BSA=Body Surface Area

2. Interpretation

PCA is a method that allows patients to decide when they need more pain relief and then to give it to themselves. Instead of ringing for a nurse, they can press the button attached to the pump, which delivers the pain relief straight into their body.

KVO means keeping the vein open, and the syringe 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 syringe pump and the Infusion Workstation System is disconnected, it will fail to collect real-time information of the syringe pump. Please do not rely on the Infusion Workstation System to obtain the running state of the syringe pump.**
- **If communication between the syringe 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 syringe pump.**
- **When the wireless signal is weak, the data between the syringe 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 syringe pump and Infusion Workstation System may be lost.**
- **When the syringe pump communicates with the Infusion Workstation System, ensure that the IP address of the syringe 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 syringe pump is set correctly. For any issues with IP setup, please contact the service personnel. Incorrect network setting may result in data loss.**
- **The syringe 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 syringe pump and other equipment must take measures to protect the privacy of the patient's personal information in accordance with the local regulations and the facility's policies for managing this information.**
- **No software installation is required for the embedded device.**
- **Comen will provide the software bill of material on the request of the user.**

WARNING

- **Improper use of the syringe pump could cause a hazard to patients and device performance level.**
- **Do not connect to an unrecognized or unsecured network.**
- **No other remote control is allowed.**
- **For the embedded device, the security update is integrated with the software update. The update is only allowed by an authorized personnel.**
- **The device supports change of user passwords with strong password policy enforcement. There is also a prompt to remind the user to change the default passwords during first access.**
- **When the syringe pump reaches the end of service life, erase patient data and configuration data before disposal.**
- **Only connect the device to other devices indicated as compatible by the manufacturer and ensure that any connected device is free of malware.**

CAUTION

- **Make sure the USB devices are free of malware before inserting to the device.**
- **The use of the syringe pump beyond its intended use could cause cyber security risks.**
- **Do not use a device in the patient environment if it does not comply with EN 60601-1. The device installation must comply with EN 60601-1-1.**

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	The local user identity authentication method is "user name +	

mechanism	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 device.
- 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 device, and technical maintenance personnel authorized by Comen.
  - Communication protocol: WIFI protocol (IEEE802.11a/b/g/n)

- Network interface
  - Intended function: Connection to the Infusion Central Monitoring System 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 syringe 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 syringe pump:

- Physical Access: Limit use of the syringe pump to authorized users. Keep the device under physical control
- Active Use: Users of the syringe pump should take measures to limit patient data storage. Patient data should be removed from the syringe 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 syringe pump may be connected.
- Device Security: Only connect the device to the compatible device indicated by the manufacturer and ensure that any connected device is free of malware.
- Keep the device updated.
- Use a strong password.
- Act on or follow-up on alerts, inconsistencies, strange behavior of a device and make the responsible organization aware (Health Delivery Organizations, HDOs).

Appendix VIII Drug Library

NOTE

- **The system's default 60 kinds of drugs are listed in the table below. The drug library can add drugs as required. If you need to add drugs, please contact us.**

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 syringe 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 relevant local certification before infusion and refer to relevant instructions to make sure that the drug can be infused using the syringe pump.**
- **To make sure that the drug can be injected with the selected syringe, please confirm that the selected syringe has got relevant local certification and please refer to the relevant instruction of the drug and syringe before use.**

No.	Name	No.	Name
1	No drug	32	Nifedipine
2	Adrenaline	33	Salvia
3	Dopamine	34	Ligustrazine
4	Isoprenaline	35	Ulinastatin

5	Noradrenalin	36	Irbesartan
6	Amiodarone	37	Isosorbide Dinitrate
7	Ditiazem	38	Isosorbide Mononitrate
8	Lidocaine	39	Felodipine
9	Esmolol	40	Trimetazidine
10	Nicardipine	41	Losartan
11	Dobutamine	42	Calendulae Flower
12	Dopexamine	43	Simvastatin
13	Verapamil	44	Methoxyphenamine
14	Clonidine	45	Acetylcysteine
15	Labetalol	46	Asarone
16	Urapidil	47	Aminophylline
17	Phentolamine	48	Nikethamide
18	Nitroglycerine	49	Trinitrine
19	Dobutamine Hydrochloride	50	Gangliosides
20	Milrinone	51	Oxiracetam
21	Amrinone	52	Edaravone
22	Sodium Nitroprusside	53	Vinpocetine
23	Alprostadil	54	Sodium valproate
24	Phosphocreatine	55	Nalmefene
25	Atorvastatin	56	Naloxone
26	Coenzyme Complex	57	Aescine
27	Notoginsenoside	58	Meclofenoxate
28	Amlodipine	59	Meropenem
29	Cinepazide	60	Cefamandole
30	Valsartan	61	Levofloxacin
31	Xingnaojing	/	/

Appendix IX Abbreviation List

Abbreviation	Meaning
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	Alternating Current
DC	Direct Current
LCD	Liquid Crystal Display
MIN	Minimum
MAX	Maximum
ID	Identification
USB	Universal Serial Bus
PM	Post Meridiem
AM	Ante Meridiem
IEC	International Electrotechnical Commission
CCC	China Compulsory Certification
CE	Conformité Européene
EMC	Electromagnetic Compatibility
IP	Internet Protocol
EN	English
Order	Doctor's order or prescription
Alm Setup	the settings of alarm
MRN	Medical Record Number
Pat. Cat.	patient type or category
Bed No.	Bed number of patient
DOB	Date of birth

M	Male (Gender)
F	Female (Gender)
Blood	Blood Group；ABO blood group；Blood Type
Auto-Lock	Automatic screen lock
D/C	Discharge(the patient from this device)
Sys Vol.	System sound volume
Alm Vol.	alarm sound volume
Med	Medium
BSA	Body Surface Area
Y-M-D	Year-Month-Day
D-M-Y	Day-Month-Year
M-D-Y	Month-Day-Year
Alm Tone	Alarm tone
Pres. Unit	Pressure unit
BMI	Body Mass Index
Predose	Preset drug dose volume
Dose Time M.	Dose Time mode
Intmt. Mode	Intermittent mode
Seq. Mode	Sequential Mode
First Dose M.	First Dose Mode
PCA Mode	PCA=Patient Controlled Analgesia
S	Sequence (S1=Sequence 1; S2=Sequence 2…)
Clr Alm	Clear alarm
Conc.	concentration
Single Vol.	Vol=volume
Remg Vol.	Remaining volume
Bolus Vol.	Bolus volume
Auto Bolus Vol.	Automatic bolus volume
SRN. Spec.	Syringe Specification
Drug Vol.	Drug (liquid drug) volume
Param.	Parameter Settings, this string "Param."is shown on the interface to set paramaters, readable and make sense when it is displayed on the screen
System Info	System Information

Dead BAT	Dead battery
VTBI Done	the Volume To Be Infused is emptied or finished
Syringe Spec. Error!	Syringe Specification Error
Bed No. Repeat	The bed number is already used. Use other numbers.
AC Off	AC power disconnected
FDose Rate	Rate of first dose
FDose Vol.	Volume of first dose
FDose Time	Time of first dose
Main Vol.	Main Volume
Total VTBI	Total Volume To Be Infused
Default SRN Setting	SRN = Syringe;Restore default value of syringe setting
Pres. Cal.	Pressure Calibration
Auto Purge Vol.	Volume of automatic purge
Trig. Type	the type of trigger
Trig. Level	the level of trigger
Norm. Open	open normally/ normal open
Norm. Close	close normally/ normal close
Clamp Err	Clamp is abnormal or failure
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
Slave Com. Err	the slave/secondary communication is error
EBIS	Empty Bottle Inspection Sensitivity
Pres. Mode	Pressure mode
Common M.	Common mode
Air Accum.	Air Accumulated
Anti-bolus	the pressure is automatically release
Drug Lib.	Drug library version
Brand Lib.	Brand library version
Product S/N	Product serial number
Intmt. Vol.	Intermittent volume

Intmt. Rate	Intermittent Rate
Load. Rate	loading rate
SYNC.	Synchronize
Cal. Succeeded	Calibration succeeded
Cal. Failed	Calibration succeeded
Prec. Cal.	Precision calibration
Start Cal.	Start calibration
SRN. Pump	Syringe pump
SRN Driver	Syringe pump driver
Pres. Level	Pressure level
Purge Vol.	purge volume
Concen. Param.	concentration parameter
Param. Switch	Parameter switch
Auto Restart	Automatic restart after occlusion alarm
Drug Param.	Drug parameter
Min. limit beyond max. limit!	the minimum limit shall be smaller than maximum limit
Vol.	volume
Plan	the heading of this interface is Treatment Plan, and below it displays Plan 1, 2, 3, 4…