USER MANUAL

SYRINGE PUMP

(EN-S9, EN-S9 Smart)

CE 0197

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Preface

1 Application Scope of the User Manual

Applicable to EN-S9/EN-S9 Smart syringe pumps of our company.

This User Manual describes the product's most complete configuration, accessories and functions which may not exist in the product of the user, for more detailed information, please contact manufacturer.

2 Applicable Object of the User Manual

It is applicable to the professional trained nurse, doctor, and maintenance technician of this device.

3 Use Instructions

This User Manual covers the basic information on the safety and effectiveness of the product for guiding the operator to correctly install, test, operate, use and maintain the product. Please read this manual thoroughly before use and use the product in a correct way. Please carefully keep the User Manual for future use.

Our company is responsible for the reliability and performance of the device only all following conditions are met:

- Use the device according to this User Manual.
- The device can only be disassembled, assembled, replaced, tested, improved and repaired by the professional technicians of our company.
- All components and accessories as well as consumables for repairing are provided by manufacturer.
- Relevant electric devices meet the international standard IEC/EN 60601-1 and this User Manual.

4 Paraphrase

【】 means mechanical button

〖〗 means touch button

( ) further Information

- means inapplicable

√ means accordant

→ means operation steps

Bolus: Infuse large volume of liquid in a short time.

KVO: Keep vein open, prevent blood back to the IV tube and needle blocked.

Anti-bolus: Motor automatically reverse while the IV tube with high pressure.

IrDA: Infrared ray communication

DERS: Dose Error Reduction Systems

DPS: Used to indicate real-time detection and dynamic display of blocking pressure.

Warning /Attention: it may possibly cause physical injury or death if the cautions covered in the Warning are not obeyed.

Caution: it may possibly cause physical injury or property loss if the cautions are not obeyed.

Note: in case fails to follow the supplementary or prompt information on the operation instructions may possibly cause physical injury the device fault or property loss if it is not obeyed.

Accessories: the optional components which are necessary and (or) suitable for using with the device in order to achieve the expected purpose, or provide convenience for achieving the expected purpose, or improve the expected purpose, or increase the additional functions of the equipment.

Content

Chapter1 Safety Instructions

1.1 Warnings

- Before using, please check the device, connecting wire and accessories to ensure that it can work normally and safely. If there's anything abnormal, immediately stop working and contact our after sale service department. Additionally, the adhesion or intrusion of fluid/drug may possibly cause the device fault and malfunction. Therefore, please clean the device after use, and store it correctly.
- This device must be operated by trained professional medical care personnel.
- Patients are not allowed to maintain, clean, or export historical records etc., of the device or its components when using the device.
- Users operating this equipment are not permitted to privately disassemble the equipment or equipment components for maintenance and servicing, cleaning, exporting of history, etc. (Unauthorized disassembly may result in electrical shock hazards (switching on the power supply), short-circuiting of components, damage to sensors, etc., which may affect the accuracy of the device, deviations in performance such as pressure, etc.).
- To avoid the risk of electric shock, the unit must be connected to a power supply network with protective earth.
- This device is not allowed to use in an environment containing combustible anesthetic gas mixed with air, oxygen or nitrous oxide (N_2O) to prevent fire or explosion.
- It is not allowed to store or use the device in the environment with active chemical gas (including gas for disinfecting) and moist environment since it may influence the inside components of the syringe pump and may possibly cause performance drop or damage of the inside components.
- The operator shall guarantee that the set injection parameters of this device are the same as the medical advice before starting injection.
- Please do not rely solely on the alarm system during use. Healthcare professionals should make regular rounds and pay attention to the patient's status, such as vomiting, bloating, diarrhea and abdominal pain, which should be dealt with promptly by healthcare professionals.
- Tightly fix this device on the injection stand and ensure the stability of the injection stand. Be careful when moving the injection stand and this device to avoid the device dropping and injection stand falling or knocking the surrounding objects.
- If the injection tube is twisted, or the filter or needle is obstructed, or blood in the needle which may obstruct the injection, the pressure in the injection tube will rise. When removing such occlusion, it may possibly cause "bolus injection" (temporary overdose injection) to the patient. The correct method is to tightly hold or clamp the injection tube near the puncturing position, drop the pressure in the injection tube. Then loosen the injection tube, solve the reason of occlusion, and restart injection. If injection is restarted when the occlusion reason exists, then it may cause occlusion alarm persistently, and the pressure in the injection tube may keep rising, and may break or cut off the injection tube, or hurt the patient.
- This device should be placed within 0.65 meters of the patient's heart height. The closer the distance to the heart, the higher the accuracy of the work data.
- This device has the occlusion detection function for detecting and alarming when the injection needle deviates the position in the vein or the needle is not correctly punctured in the vein. However, it only alarms when the occlusion pressure has reached certain numerical value, and the puncturing part may possibly have become reddish, swelling or bleeding, additionally, it is possible that the device doesn't alarm for a long period if the actual occlusion pressure is lower than the alarm threshold value, therefore,

please periodically check the puncturing part. If there's any abnormal phenomenon for the puncturing part, please timely take suitable measures, such as puncturing again.

- Please use disposable sterile syringes and other medical components which comply with local laws and regulations and provisions of this manual. It is recommended to use syringes of the built-in brand of the device. If a syringe with a non-built-in brand is used, please add and calibrate it according to the chapter 8.3, otherwise the working accuracy will not be guaranteed. Please use a syringe and extension tube with a screw, otherwise the patient may be injured due to the pulling of the tube.
- If the ambient temperature exceeds the predetermined range, the injection precision will decrease and even the operation will be abnormal.
- The viscosity and specific gravity of the injection liquid will affect the injection accuracy.
- To set or change the parameters of the device, it must be carried out by trained professionals.
- Avoid device running with faults, so as not to cause medical accidents and endanger the health and even life of patients.
- It is not allowed to disassemble or refit this device or use it for other purposes except normal injection.
- When the device is in use, it is connected to the power supply via a soft power cord with a power plug. If necessary, the plug can be unplugged to disconnect the device from the power supply. Please do not place the device in a location that is difficult to operate the disconnection mechanism.
- If any operator requests more information such as circuit diagrams, part lists and product descriptions so that repairs can be carried out by qualified technicians, please contact us.
- No one is allowed to repair, disassemble and modify this device without the manufacturer's authorization.

1.2 Cautions

- Before its first use after purchase, or this device is not used for a long period, please charge the device with AC power supply. If it is not fully charged, under power failure, the device can't continue working with built-in battery power supply.
- For new device, or device put into use after storage for a period of time, or ready to use after repair, please check and ensure:

The appearance of the device is in good condition, no cracks, no leakage, clean and tidy;

The moving parts are flexible and effective, such as the pump door opening and closing flexibly, and the button is pressed smoothly and effectively.

The brightness of the display screen is uniform, no bad point, and the touch screen operation is flexible and effective;

The power cable is installed firmly and is not easy to be pulled off.

Set and check system time to ensure that history records are recorded correctly.

- This device can't be used in the places with radiological equipment or magnetic resonance device as well as the places with high pressure oxygen therapy.
- Not to position device to make it difficult to operate the disconnection device.
- The DC power supply is only suitable for applications where a backup power supply is required. Only use the DC power supply line provided by the manufacturer.
- Other devices near this device must meet corresponding EMC requirements, otherwise, it may influence the performance of this device.
- Avoid direct sunlight, high temperature or high humidity.
- If only the internal battery is used for power supply, ensure that the battery is fully charged before use and still in effective working condition.
- Under general conditions, please use AC power supply as much as possible since it can prolong the

service life of the battery at a certain degree. When using AC power supply, ensure that the grounding wire is reliably connected with the ground, and only the AC power wire attached with this device shall be adopted. The built-in battery can only be used as the assistant power supply when the AC power supply can't reliably connected with ground and is not under normal conditions (power failure or moving injection).

- Before connecting this device with power supply, please keep the power socket and plug dry, and the power voltage and frequency meet the requirements listed in the device label or this user manual.
- The device is equipped with the audible and visual alarm system, and the red and yellow alarm indicators will light on by turn to check if the alarm system can work normally, and the speaker makes the "beep" sound.
- Please keep the device away from the AC power socket for a certain distance to avoid fluid/drug splashing or dropping in the socket, otherwise, it may possibly cause short circuit.
- It is not allowed to press and operate the button with sharp object (such as pencil tip and nail), otherwise, it may possibly cause early damage to button or surface film.
- Under the condition of low flow rate injection, please pay special attention on occlusion. The lower the injection flow rate, the longer the time of detecting occlusion, and it in turn may possibly cause a long time injection stop during this period.
- If the device suffered from dropping or impacting, please immediately stop using it, and contact our after sale service department, because the inside components of the device may be possibly damaged even the appearance is not damaged and abnormality is not occurred when working.
- Read carefully the warnings, precautions and procedures in this user manual.
- The heating part is above the motor housing, the maximum temperature is between 41 ° C and 43 ° C (Note: as the product temperature rises, if the patient feels uncomfortable or has discomfort, he should call the nurse immediately to confirm).
- The syringe installed in the pump passes through the heat transfer, and the temperature of the liquid medicine does not exceed 41℃.Usually the operator is in contact with the plastic casing for less than 1 minute.

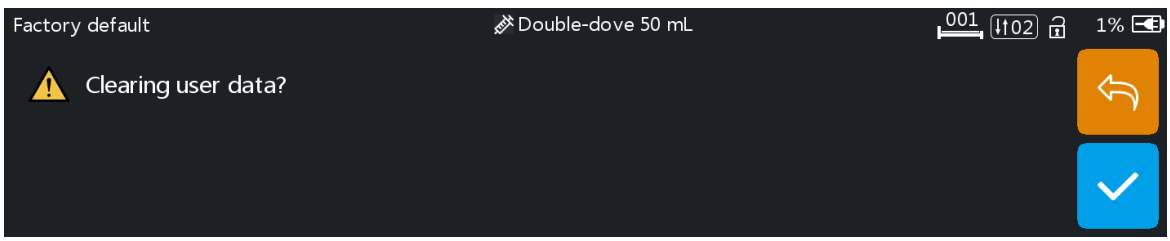
1.3 Dialogue Window

Displayed in the form of a message box on the device display. Mainly for operation confirmation, parameter setting errors, etc.

For instance:

Figure1.3-1 Operation confirm

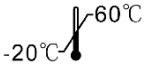
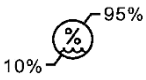
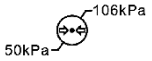
Figure 1.3-2 Parameter error



1.4 Symbols

Not all of the below symbols are existed in the device you have purchased.

Table 1.4-1

Marks	Description	Marks	Description
	Batch code		Protective earth (ground)
	Serial number	**IP44**	Protection Level. Prevent the pouring of solid objects larger than 1.0 mm in diameter and the intrusion of splashing water in all directions
	Caution		Both direct and alternating current
	Defibrillation-proof type CF applied Part		battery
	Date of Manufacture		Handle with harmless method
	environment-friendly use period (20 a)		Manufacturer
	Authorized Representative in the European Community		Non-ionizing electromagnetic radiation
	Input / output		Direct current
	Unlock		Lock
	This side up		Fragile items
	Keep dry		Stacking level limit
	CE-mark/Notified Body		Please refer to the instruction manual/manual
	Transportation package temperature limit range is-20～60℃		The limited humidity range of transportation package is 10%～95%
	The environmental pressure of transportation package is limited to 50～106kPa		

Chapter2 Overview

2.1 Application Scope

2.1.1 Expected Purpose

The syringe pump is used together with syringe to control the dose of liquid infused into patient's body, for example intravenous infusion.

2.1.2 Expected Working Environment

The syringe pump is expected to be used in institutes or units with healthcare capability. Including but not limited to: emergency department, ICU (intensive care unit), NICU (neonate intensive care unit), operating room.

2.1.3 Suitable Objects

Adult, Pediatric or Neonate

2.2 Contraindications

None.

2.3 Working Principle

The syringe pump is a kind of medical instrument that uses the motor driving force to drive the screw rod to turn the rotating motion into linear motion, push the piston of the syringe to inject, and input the liquid medicine in the syringe into the human body.

2.4 Structure and Performance

2.4.1 Structure and Performance

The syringe pump consists of pump housing, motor drive system, input system, storage system, control system, display system, sensor monitoring system and alarm system. The device has a variety of injection Modes, such as mL/h Mode, Body-weight Mode, Sequence Mode, Dose Mode, Body surface Mode, Intermittent Mode, Loading-dose Mode, Ramp up/down Mode, TIVA Mode. It also has DERS, history records, drug library, anti-bolus and alarm functions and so on.

2.4.2 Application parts

Syringe.

2.4.3 Functional Specifications

This device has two Models: EN-S9, EN-S9 Smart, the main function differences are shown in table below.

Function /Model	EN-S9	EN-S9 Smart
mL/h Mode	●	●
Body-Weight Mode	●	●
Dose Mode	●	●
Loading-Dose Mode	●	●
Sequence Mode	○	●
Body Surface Mode	○	●

Intermittent Mode	○	●
Ramp Up/Down Mode	○	●
TIVA Mode	○	●
Cascade Mode(Infrared)	●	●
Micro Mode	●	●
WIFI	○	●
Occlusion pressure	150～975mmHg 12 grades is adjustable	50～1125mmHg 15 grades is adjustable
Remarks :“●”Standard;“○” optional.		

Note: This User Manual describes the most complete configuration and functions, due to Model difference or optional components, not all functions are equipped in the product you purchased.

2.5 Product Specification

Safety Classification	
Electric protection Type	Class I
Electric protection Level	Defibrillation proof type CF applied Part(The applied part is the syringe and infusion line mounted on the pump)
Protection against fluid ingress	IP44
Working Mode	Continuous operation
Classification	Transportable device syringe pump
Specification Parameters	
Syringe specification	1mL, 2/3mL, 5/6mL, 10/12mL, 20/25mL, 30/35mL, 50/60mL
Injection Accuracy	According to IEC 60601-2-24:2012 standard test conditions: Injection accuracy error≤±1.8%(After Calibration) According to IEC 60601-2-24:2012 standard test conditions: Bolus injection accuracy error≤±2% or ≤ 0.05 mL which is larger Machine accuracy(system): ≤0.5% Repeatability error: ≤2% The test under normal conditions (20 °C ± 2 °C, 65 %± 5 % RH).
Injection Rate	1mL syringe:(0.01～50)mL/h 2/3mL syringe:(0.01～150)mL/h 5/6mL syringe:(0.01～300)mL/h 10/12mL syringe:(0.1～800)mL/h 20/25mL syringe:(0.1～1200)mL/h 30/35mL syringe:(0.1～1500)mL/h 50/60mL syringe:(0.1～2300)mL/h
Bolus Rate	1mL syringe:(0.01～50)mL/h 2/3mL syringe:(0.01～150)mL/h 5/6mL syringe:(0.01～300)mL/h 10/12mL syringe:(0.1～800)mL/h 20/25mL syringe:(0.1～1200)mL/h 30/35mL syringe:(0.1～1500)mL/h 50/60mL syringe:(0.1～2300)mL/h

	Note:When the bolus preset volume≤5mL, the bolus speed is automatically limited to≤25mL/h; conversely, when the bolus preset volume > 5mL, the bolus speed supports the maximum speed of the respective specifications.
Bolus VTBI	1mL syringe:0.1～1mL 2/3mL syringe:0.1～2/3mL 5/6mL syringe:0.1～5/6mL 10/12mL syringe:0.1～10/12mL 20/25mL syringe:0.1～20/25mL 30/35mL syringe:0.1～30/35mL 50/60mL syringe:0.1～50/60mL
Bolus VTBI unit	mL, ng, mcg, mg, g, U, KU, IU, EU, mmol, mol, kcal
Purge Rate	1mL syringe:50mL/h, non-adjustable 2/3mL syringe:150mL/h, non-adjustable 5/6mL syringe:300mL/h, non-adjustable 10/12mL syringe:800mL/h, non-adjustable 20/25mL syringe:1200mL/h, non-adjustable 30/35mL syringe:1200mL/h, non-adjustable 50/60mL syringe:1200mL/h, non-adjustable
Micro Mode Rate Range	1mL syringe:(0.1～50)mL/h 2/3mL syringe:(0.1～150)mL/h 5/6mL syringe:(0.1～200)mL/h 10/12mL syringe:(0.1～200)mL/h 20/25mL syringe:(0.1～200)mL/h 30/35mL syringe:(0.1～200)mL/h 50/60mL syringe:(0.1～200)mL/h
Rate setting increment	(0.01～99.99)mL/h, minimum increment is 0.01mL/h; (100～999.9)mL/h, minimum increment is 0.1mL/h; (1000～2300)mL/h, minimum increment is 1mL/h.
VTBI	0.01-9999.99mL, minimum increment is 0.01mL
Intermittent VTBI	0.01-9999.99mL, minimum increment is 0.01mL
Volume	0-99999.99mL, minimum increment is 0.01mL
Injection Time range	00:00:01～99:59:59(h:m:s), minimum increment is 1s
Intermittent Time range	00:00:01～99:59:59(h:m:s), minimum increment is 1s
Height setting range	(0.1~250)cm, (0.1~98.5)inch, minimum increment is 0.1
Height unit	cm,inch
Weight setting range	(0.1～500)kg, (0.3～1101.4)lb, minimum increment is 0.1
Weight unit	kg, lb
Drug Dose setting range	0.001～99999, minimum increment is 0.001
Drug Dose unit	ng,mcg,mg,g,U,kU,IU,EU,mmol,mol,kcal
Drug Volume setting range	(0.01～9999.99)mL;minimum increment is 0.01 mL
Dose Rate setting range	0.001～99999, minimum increment is 0.001
Dose Mode Dose Rate unit	ng/min, mcg/min, mg/min, g/min, U/min, KU/min, IU/min, EU/min, mmol/min, mol/min, kcal/min;

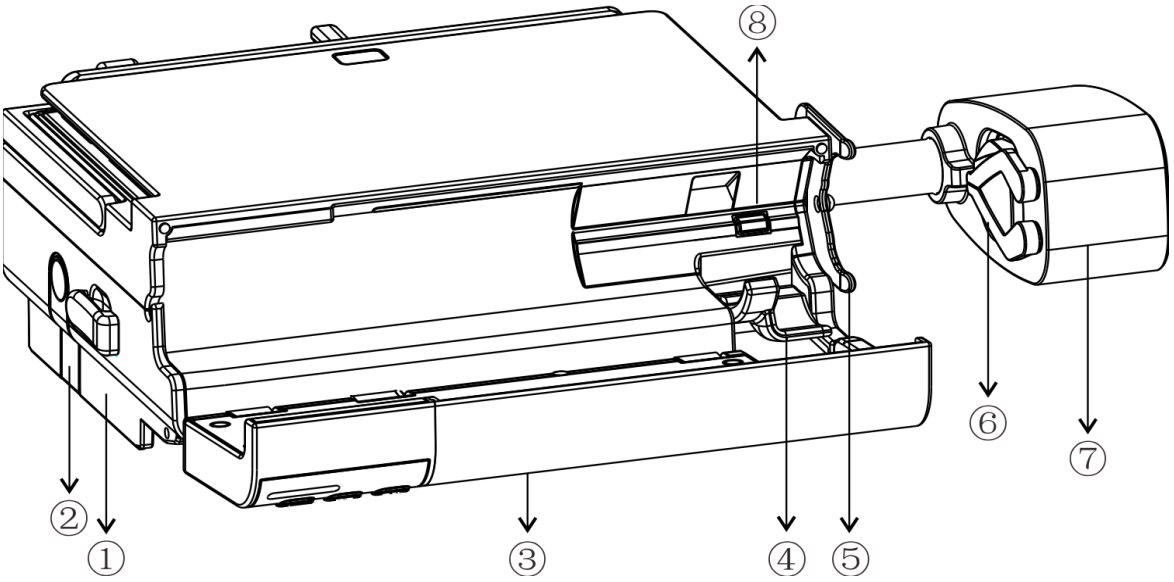
	ng/h, mcg/h, mg/h, g/h, U/h, KU/h,IU/h, EU/h,mmol/h, mol/h, kcal/h; ng/24h, mcg/24h, mg/24h, g/24h, U/24h, KU/24h, IU/24h, EU/24h, mmol/24h, mol/24h, kcal/24h
Body-Weight Mode Dose Rate unit and TIVA Mode Maintain Dose Rate unit	ng/kg/min, mcg/kg/min, mg/kg/min, g/kg/min, U/kg/min, KU/kg/min, IU/kg/min, EU/kg/min, mmol/kg/min, mol/kg/min, kcal/kg/min; ng/kg/h, mcg/kg/h, mg/kg/h, g/kg/h, U/kg/h, KU/kg/h, IU/kg/h, EU/kg/h, mmol/kg/h, mol/kg/h, kcal/kg/h; ng/kg/24h, mcg/kg/24h, mg/kg/24h, g/kg/24h, U/kg/24h, KU/kg/24h, IU/kg/24h, EU/kg/24h, mmol/kg/24h, mol/kg/24h, kcal/kg/24h.
Body surface Mode: Dose Rate unit	ng/㎡/min, mcg/㎡/min, mg/㎡/min, g/㎡/min, U/㎡/min, KU/㎡/min, IU/㎡/min, EU/㎡/min, mmol/㎡/min, mol/㎡/min, kcal/㎡/min; ng/㎡/h, mcg/㎡/h, mg/㎡/h, g/㎡/h, U/㎡/h, KU/㎡/h, IU/㎡/h, EU/㎡/h, mmol/㎡/h, mol/㎡/h, kcal/㎡/h; ng/㎡/24h, mcg/㎡/24h, mg/㎡/24h, g/㎡/24h,U/㎡/24h, KU/㎡/24h, IU/㎡/24h, EU/㎡/24h, mmol/㎡/24h, mol/㎡/24h, kcal/㎡/24h.
Conc. setting range	0.001～9999.99, minimum increment is 0.001
Conc. unit	ng/mL, mcg/mL, mg/mL, g/mL, U/mL, kU/mL, IU/mL, EU/mL, mmol/mL, mol/mL, kcal/mL
KVO Rate	(0.01～10)mL/h , minimum increment is 0.01mL/h, 0 means off
KVO Time	(1～120)min
KVO Rate Accuracy	≤±4.5%
Occlusion Pressure	EN-S9 Smart: 15 grades is adjustable: (50,150,225,300,375,450,525,600,675,750,825,900,975,1050,1125) mmHg; EN-S9: 12 grades is adjustable: (150,225,300,375,450,525,600,675,750,825,900,975)mmHg.
Dosage of pills to prevent accidents	≤0.2mL
Maximum Injection Pressure	≤1350mmHg
Bolus under single fault	a) When device in a single fault condition(Blocking level is 15), maximum bolus≤3mL; b)When device in a single fault condition(Blocking level is 8), maximum bolus≤2mL.
Dimensions	≤260(W) * 165(D) * 82(H)mm(No fastening clamp)
Weight	≤2.2kg(No fastening clamp)
Power Supply	
AC power supply	100V-240V AC, 50Hz/60Hz, 0.45A-0.2A
Input power	≤50VA
DC power supply	DC 12V-16V, 2.0A-1.0A
Battery	
Battery Model	303763
Battery type	lithium battery
Battery specification	11.1V 2600mAh
Charging time	Off status≤6h

Running time	Restore factory default status, use a new battery full of electricity to power. Running at 5 mL/h, the running time from start-up to exhaustion of alarm batteries is not less than 9 hours. Running at 2300 mL/h, the running time from start-up to exhaustion of alarm batteries is not less than 2 hours.
Network connectivity and network security	
WiFi module working frequency	2.4GHz(2.412GHz~2.484GHz) 5GHz(5.17GHz-5.25GHz)(5.725GHz-5.835GHz)
Interface type	WiFi communication
WIFI protocol	Supports IEEE 802.11a/b/g/n wireless standards and adopts UDP protocol format.
Serial Transmission Protocol	Serial communication through multi-function interface, using enterprise self-encryption protocol.
Encryption	WEP64/WEP128/TKIP/AES
User access	The WiFi password needs to be set, The communication protocol includes independent IP, server IP and port number, and the password is used for authentication.
USB Transmission Protocol	Support standard USB2.0 protocol
Infrared characteristics	Baud rate 9600, non-continuous, pulse form, $\lambda = 940$ nm The transmitter and receiver modules are powered up when the IR switch is activated.
Software Release Version	
EN-S9	1
EN-S9 Smart	1
Alarm	
Alarm signal sound pressure level	When the sound is set at lowest level, alarm signal sound pressure level ≥45dB(A) When the sound is set at highest level, alarm signal sound pressure level ≤80dB(A)
Alarm information	High: VTBI Done, Stream Occlusion, Syringe Empty, Syringe Movement, Check Syringe, Battery Empty, Backup Battery Exhaustion, System Error, KVO Finished, Over Dose Of Drug. Low: VTBI Near End, Syringe Near Empty, No Battery Inserted, Battery Nearly Empty, No Power Supply, Reminder Alarm, Cascading Interrupts, Standby Time End.
Environment	
Non AP/APG type equipment	Do not use it in the environment with inflammable anesthetic gas mixed with air, and inflammable anesthetic gas mixed with oxygen or nitrous oxide
Operating	(1) temperature: 5-40℃ (2) humidity: 15-95%, non-condensable (3) atmospheric pressure: 57-106kPa
Transport & Storage	(1) temperature: -20~60℃ (2) humidity: 10%~95%, non-condensable (3) atmospheric pressure: 50kPa~106kPa
Safety Standard	
Main Safety	IEC 60601-1:2005+A1:2012+A2:2020 Medical Electrical Equipment-Part 1: General Requirements for basic Safety and essential performance IEC 60601-1-2 :2014+A1:2020

	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests IEC 60601-1-8:2006+A1:2012+A2:2020 Medical electrical equipment –Part 1-8: General requirements for basic safety and essential performance–Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-2-24: 2012 Medical electrical equipment –Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers

Chapter3 Appearance

3.1 Front View



① Extension tube clip (For syringe extension tube attaching)

② Lock

③ Pump door

④ Rotary handle

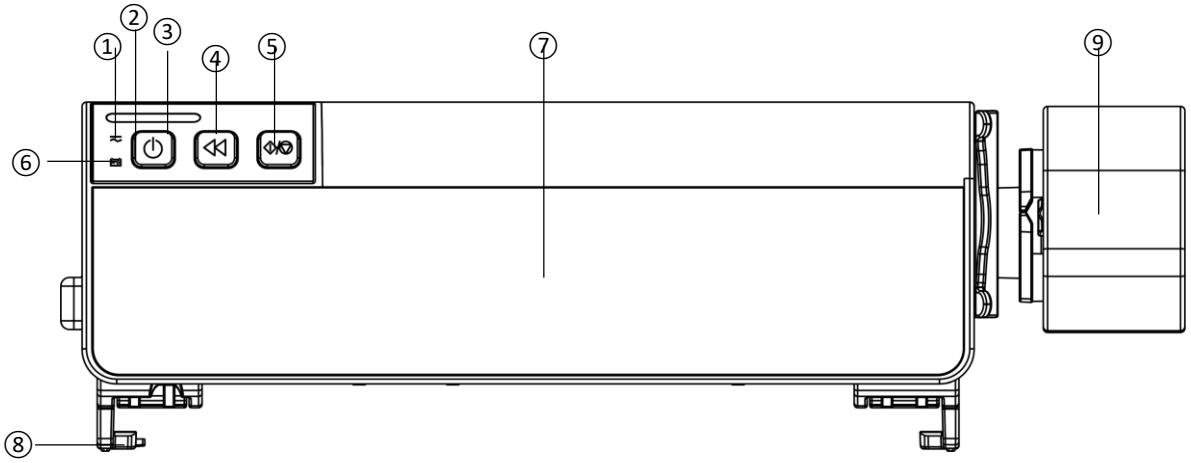
⑤ Flange plate(Pull the fixture lever, put the syringe flange into the slot.)

⑥ Syringe clip(Clamp the syringe plunger)

⑦ Slider box

⑧Syringe installation test (can be set to off)

3.2 Operation Panel



① AC/DC indicator(green)

Turn on: Connect AC/DC power supply

Turn off: dis-connect AC/DC power supply

②【Power】

Press the power button shortly to enter setting interface, the user can set the power off, standby (time) or cancel.

Press and hold the power button until the screen turns off and the pump turns off.

③ Alarm indicator (red/yellow)

While pump alarms, indicator light glitters, with different frequency and color, more information please refer to Chapter 7.1.

④【Bolus/Purge】

⑤【Start/Stop】

⑥ Battery indicator (green)

Indicator flashing: device on, battery charging/power supply

Indicator lights on: the battery is full of electricity.

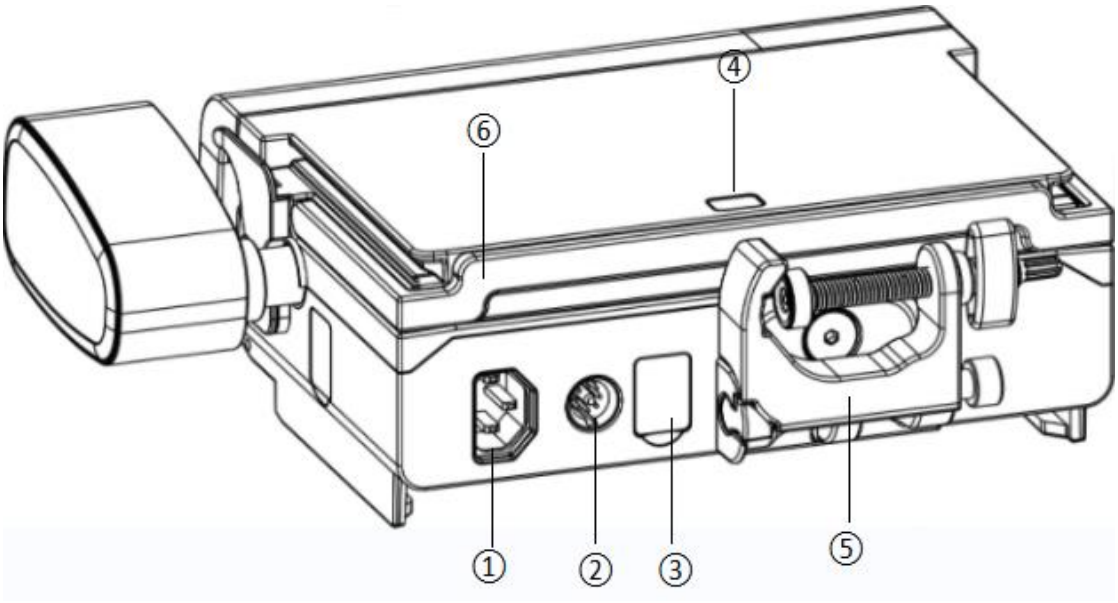
Indicator lights off: device shut down, no batteries

⑦ Touch screen

⑧ Guide rail(For pumps stacking and used in conjunction with Infusion Information Collect System)

⑨ Lead-screw

3.3 Back View



① AC Power interface (Support 100-240V 50/60Hz AC)

② Work Station port（Connects to ENMIND workstations only）

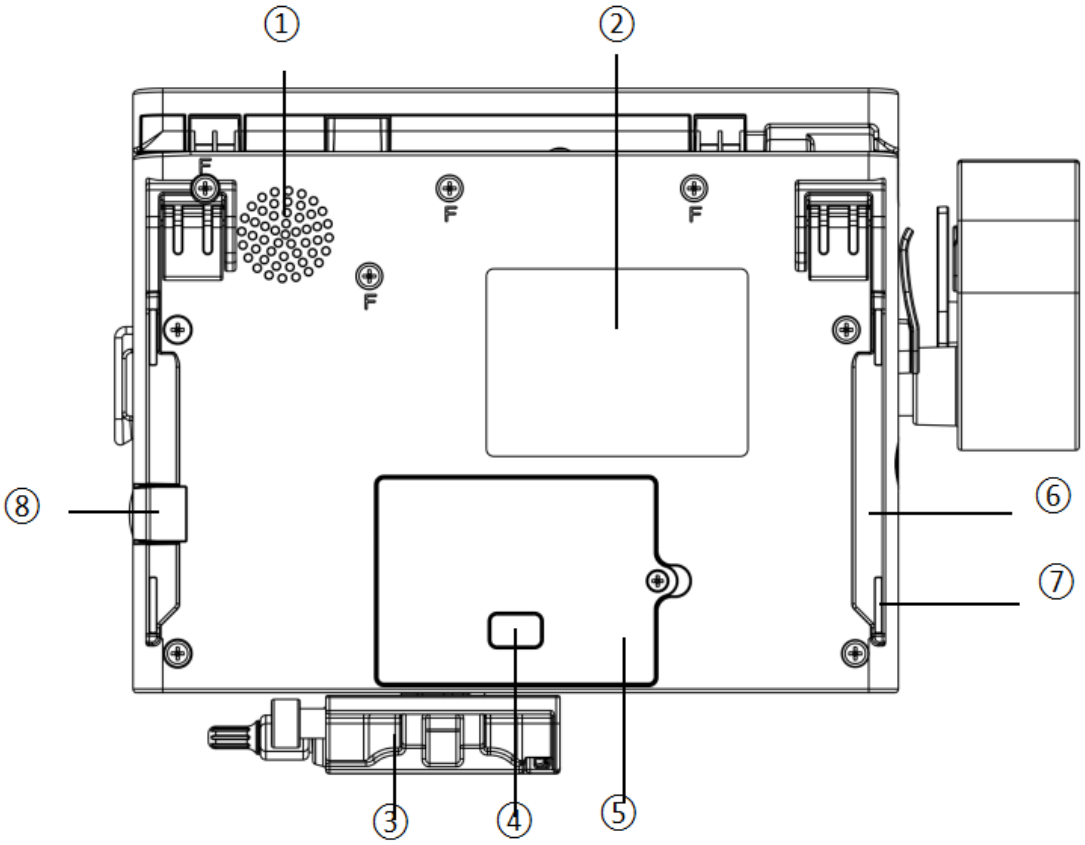
③ Multi-function interface 1(type-c, Support DC12-16V，input 2.0-1.0A): For connecting DC power, connecting the nurse call cable of the hospital's call system, import and export data（The equipment supplying power to the DC should comply with IEC 60601-1, and when this interface is connected to a PC to export data, the PC should comply with IEC 62368-1. Injections are not allowed to start during data import and export.）;

④ Infrared data port: Used for communication between two pumps when pumps stacking.

⑤ Clamp (Used to secure device to infusion stand)

⑥ Handle

3.4 Bottom view



① Loudspeaker

② Product label

③ Clamp

④ Infrared data port

Used for communication between two pumps when pumps stacking.

⑤ Battery cover

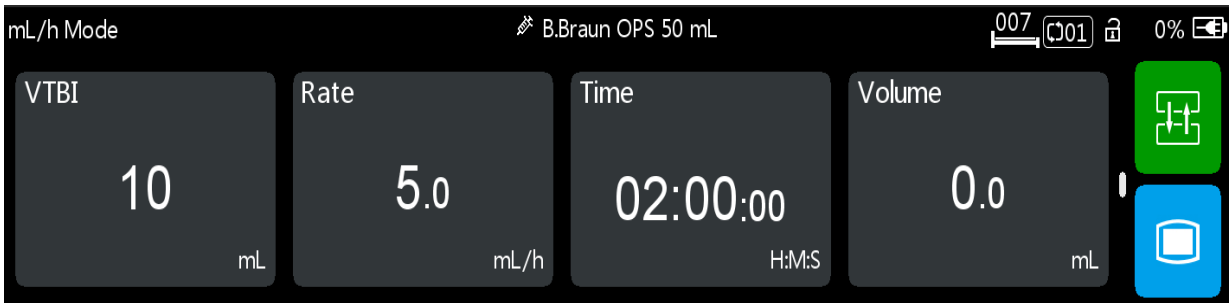
⑥ Guide rail

⑦ Rubber pad

⑧ Lock

3.5 Display screen

The display screen interface layout composes of title bar and typical interface.



3.5.1 Title bar

Title bar displays real-time state information and is not touchable, the left upper corner displays the name of current editing parameter.

Table 3.5.1-1

Icon	Paraphrase	Description
	Syringe indication icon	/
	Lock screen indication icon	Unlock state icon is
	WIFI indication icon	Indicate WIFI connection state.
03	Sequence Cascade	①When the syringe pump is connected to the Infusion Work Station, it indicates the current channel number; ②When pumps stacking, it means that the current pump is in the state of sequence cascade, and the number indicates its serial number in the line.
03	Loop Cascade	When the syringe pump is connected to the Infusion Work Station, it means that the current pump is in the state of loop cascade, and the number indicates the current channel number.
001	Bed No.	It means current Bed No.
	Battery charging indication icon	Display the current battery charging state
	Battery status indication icon	The percentage numerical or remaining time value at the left side of the icon displays the remained battery. Since the remained battery may change, it may possibly show the following states:

3.5.2 Typical Interface

The following interfaces are displayed during preparation and infusion: main interface, running interface, alarm interface, reminder interface, menu, parameter setting interface, input method interface, and standby interface.

3.5.2.1 Typical Interface Icons

Table 3.5.2.1-1

Icon	Paraphrase	Description
	Cascade	Enter【Cascade setting】menu.
	Menu	Click the icon to enter the menu interface.
	Home	Click the icon to enter the main interface.

	Page indication	The gray icon indicates the current page, and the total number of icons indicates the total number of pages.
	Power off	Click the icon to turn off the device.
	Cancel	Click the icon to cancel the current operation.
	Confirm	Click the icon to confirm the current operation.
	Return/Cancel	Click this icon, cancel the current operation and return to the back menu
	Mute	Click the icon to pause the alarm sound.
	Standby	Click the icon to enter the standby state.
	ON	Mean this function is ON
	OFF	Mean this function is OFF.

3.5.2.2 Input method interface

The input method interface contains the title bar, input box, and edit box.

(1) Title bar: display the parameter name currently edited.

(2) Input box: real-time display of input content.

(3) Edit box: Include main keypad and function key.

- The main keypad consists of numeric keys and symbol keys. You can click continuously to switch.
- Function key consists of 『Backspace』, 『Cancel』, 『Confirm』, and 『Case switch』.

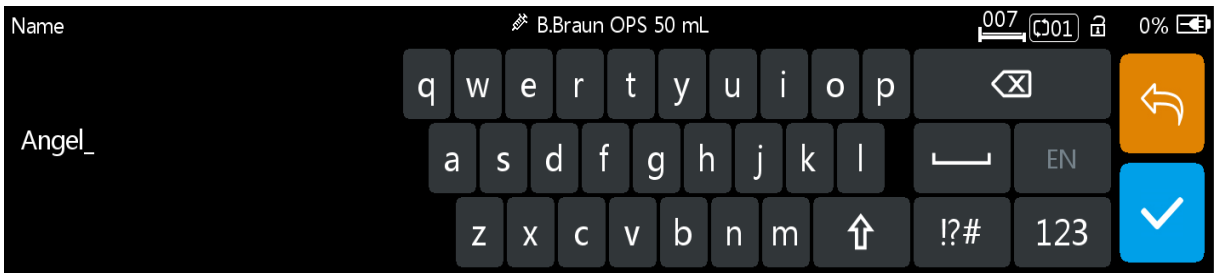


Table3.5.2.2-1

Icon	Paraphrase	Description
	Backspace	Delete
	Case switch	English case switch
	Cancel	Cancel editing and exit
	Confirm	Save input and exit
	Space	/
!?#	Symbol Keys	Symbol switch
123	Numeric Keys	Numeric switch

Chapter4 Installation

4.1 Unpacking and Checking

1) Please check the appearance before unpacking, if broken, please contact the transportation company or our after-sale service department quickly.
2) Please carefully open the package to avoid damaging the device and relevant accessories.
3) After unpacking, please check the objects according to the packing list, if there are insufficient or damaged accessories, please contact our company as soon as possible.
4) Please keep relevant accessories, User Manual.
5) Please keep the packing case and packing materials for future transportation or storage.

⚠ Warning: Please put the packing materials out of the reach of children. Please obey local laws and regulations or the hospital waste treatment system to handle the packing materials.

4.2 Installation

⚠ Warnings:

- This device shall be installed by the designated technicians of our company.
- All devices that connect with this equipment must pass the designated IEC standards (for example: IEC 60601-1 medical electric device safety) certification, and all devices must be connected according to the valid version of IEC 60601-1 system. The technician who takes charge of connecting to additional devices with the equipment interface is responsible for meeting the IEC 60601-1 standard. Please contact our company if you have any enquiry.
- When connecting this device with other electric devices to form the combination with special function, if not sure whether there is a danger, please contact our company or the electric expert of hospital to ensure the necessary safety of all devices in the combination.
- This device must be used and stored in the environment regulated by our company.

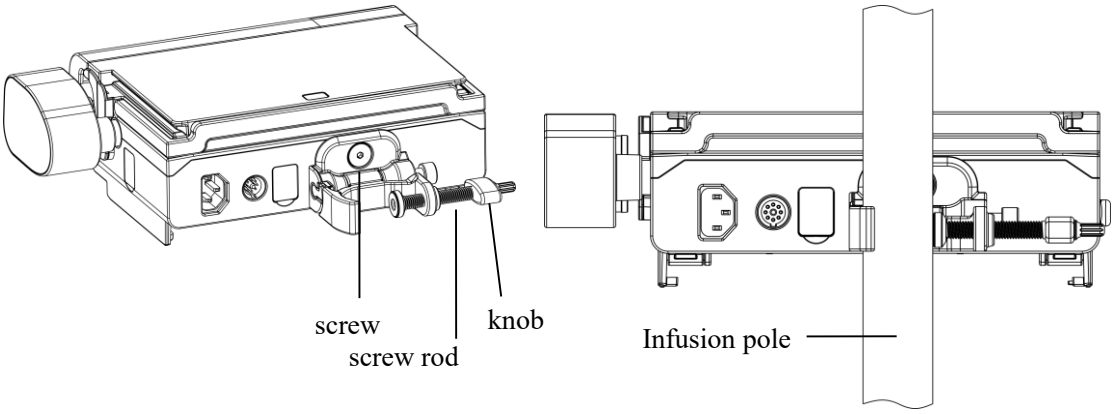
4.2.1 Install the syringe pump

(1) Turn the clamp down 90℃, rotate the pole clamp screw (knob) and unscrew to leave the space.

(2) Lock the pole clamp on the infusion stand (Tensile safety factor 8 times), adjust the position of the syringe pump, tighten the pole clamp to fix the syringe pump on the infusion stand (shown in drawing below). Hold the syringe pump when tightening the fixing clamp; loose it after tightening to avoid falling.

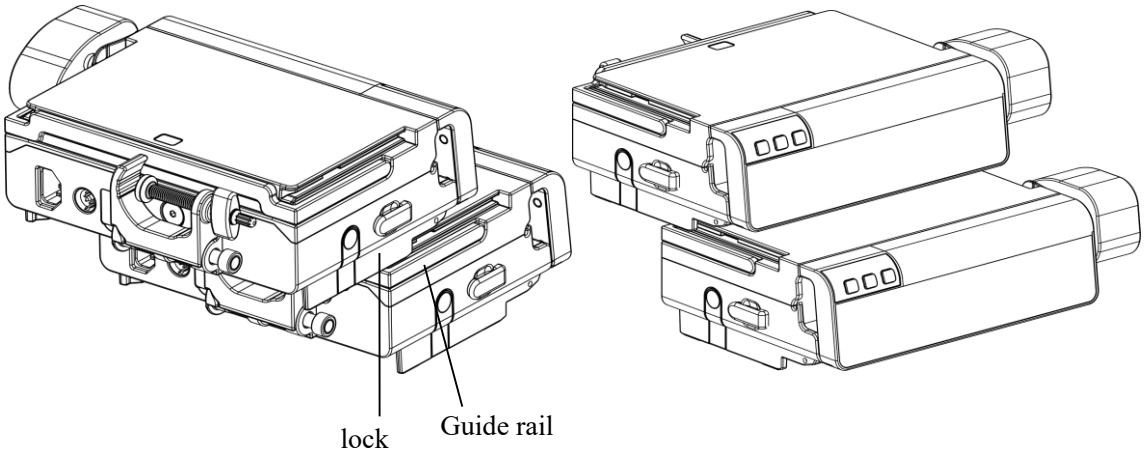
(3) The clamp supports the vertical pole at default state. To adjust the direction of the clamp, you need to hold the whole clamp and rotate it counterclockwise for 90°, and then turn the clamp down 90℃ to support the use of the crossbar.

Note: The device should be firmly fixed to the infusion pole (this device supports round rod infusion pole and square rod infusion pole, round rod infusion pole should meet the diameter of 15-32mm, the minimum bearing capacity should be≥20kg, square rod infusion pole should meet the size of 26 (length) *10 (width) mm, the minimum bearing capacity should be≥20kg). And ensure the stability of the infusion pole. Be careful when moving the infusion pole and the device to prevent the device from slipping, the pole from falling or colliding with nearby objects.



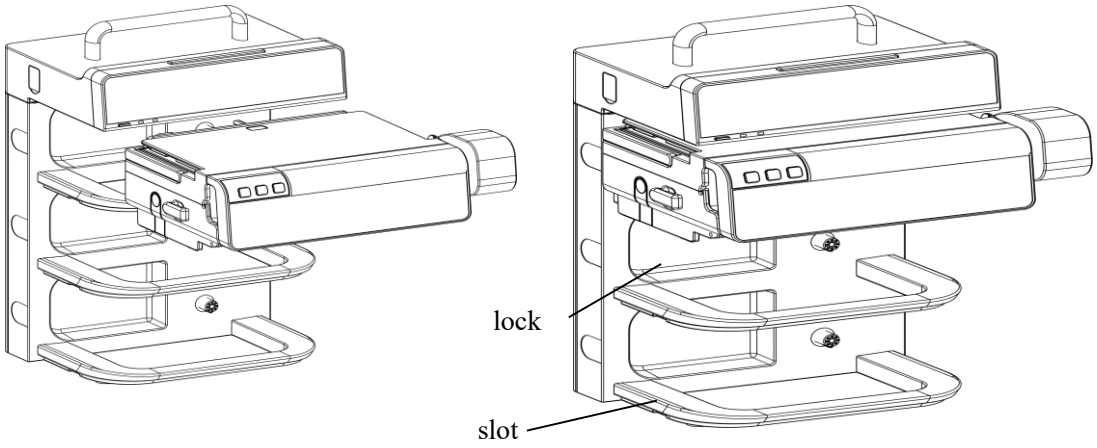
4.2.2 Stack the pumps

This device supports stacking. When two pumps are stacked, align the guide rail of the pump that needs to be stacked above horizontally from the rear to the slot of the pump that is stacked below, and then push the pump forward. When the equipment is locked, a "click" will be heard. If you want to separate the equipment, press the lock on the left side of the pump stacked above and push back to remove the pump.
Up to three pumps can be stacked together at a time to avoid external mechanical impact.



4.2.3 Connect to the Infusion Work Station

When connecting the pump and Infusion Work Station, keep the pump horizontally aligned with the plug-in box slot and push the pump into the plug-in box slot. When the pump is locked, a "click" will be heard.
If you need to pull out the pump from the slot of the plug-in box, press the lock on the left side of the pump and take out the pump at the same time.
Note: After the pump is connected to the Infusion Work Station, the alarm sound of the pump will be muted, and the alarm sounds through the Infusion Work Station.


lock
slot

Chapter5 Basic Operation

5.1 Operation Flow

¤ Power on

¤ Install Syringe

¤ Purge

¤ Set Injection Parameters

¤ Connect the patient

¤ Start Injection

¤ Injection done and then remove the syringe

¤ Power off or Standby

5.2 Injection Operation

5.2.1 Power ON and Self-Test

(1)Press  , power on the device.

(2) After power on, the system will automatically check the sensor, memorizer, CPU communication, loudspeaker, LED indicator and so on. When self-testing, the device gives an alarm sound, and the alarm light is lit in yellow and red respectively.

(3)After the self-test is successful, the interface shows: 『New Treatment』 and 『Last Treatment』.

Select 『New Treatment』 to enter directly the mL/h Mode setting interface.

Select 『Last Treatment』 to enter the last setting interface that last used Mode.

Warnings:

- when starting up, please pay attention to whether the alarm system of the device performs self-test as described above, and whether there is an alarm related to self-test. If the self-test item does not pass, please contact the company and you are not allowed to continue using the device.
- To ensure that you can clearly see the main interface of the device, you are advised to operate and use the device within 1 meter of the device.

5.2.2 Install Syringe

(1) Open the pump door, press the rotary handle and the syringe clip will automatically open, and the slider box will automatically push to the right to the maximum position.

(2) Push the syringe into the slot and ensure the curled edge of the syringe into the slot as shown in the figure.

(3) Push the rotary handle to rebound and compress the syringe.

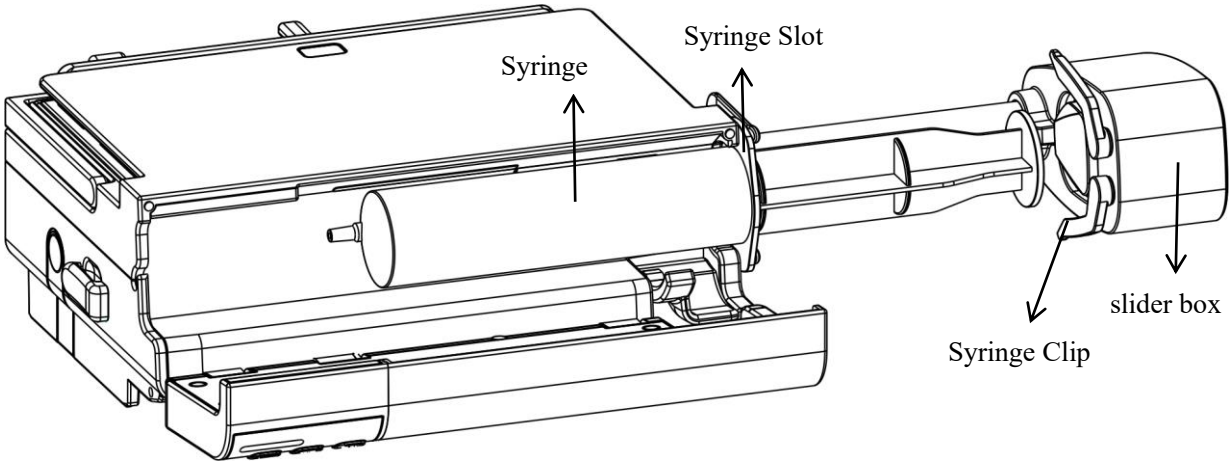
(4) When the syringe is in place, the slider box of the device will automatically push to the left, and when the slider box touches the end of the syringe plunger, the syringe clip will automatically grab the syringe plunger flange.

(5) Hang the extension tube of the syringe on the extension hook and put the syringe inside the extension tube clip.

(6) Close the door.

After installing the syringe, make sure it is in place. After the installation is successful, the device can automatically identify the specifications of the syringe and display the identified specifications in the brand

selection area.



⚠Warnings:

- It is recommended that users use the syringe brand built into the system.
- Please confirm the syringe brand specifications displayed on the operation interface, which is consistent with the actual use.
- Although the device supports the function of a custom syringe, in order to ensure the accuracy of the injection, it is strongly recommended that the user contact the company and be set and tested by the company's professionals.

Notes:

- Check to make sure there are no bubbles in the syringe.
- For ME equipment components and application parts that may be touched, according to the requirements of IEC 60601-1clause 11.1.3 table 23, the probability of contact and the duration of contact shall be considered [10s, 60s].
- Make sure that the syringe is installed correctly. Otherwise, the accuracy cannot be guaranteed. It may even cause damage to the patient due to the lack of drug output or large dose output due to siphoning.

5.2.3 Selection of syringes

On the syringe brand selection screen, simply click on the brand of infusion set currently in use. See section 6.1.8 for specific brands.

⚠Warning: Double dove and B.Braun OPS are the brands of syringes built into the device, if you use non-built-in brands of syringes, please calibrate the relevant performance (accuracy, pressure) on the syringe pump first, and make sure that it passes before you use it, or you will not be able to ensure the performance of the infusion and the accuracy of the work.

5.2.4 Select Injection Mode

Click『Menu』to enter main interface, and then click『Modes』to enter Mode menu interface to select the injection Mode.

5.2.4.1 mL/h Mode

In this Mode, it allows to set three parameters: Rate, VTBI (Volume to be infused) and Time. Set any two parameters, and the system will automatically calculate the third parameter, if the VTBI is 0, then the device works at the set rate till stop with alarm.

5.2.4.2 Body-Weight Mode

In this Mode, it allows to set parameters such as Weight, Drug Dose, Drug Volume, Conc.unit (concentration unit), Conc.(concentration), Dose Rate, Dose Unit, VTBI and Rate. Entering one of the parameters of Dose Rate or Rate, the system will automatically calculate another parameters and injection time. The conversion formula is as follows:

Rate (mL/h) = Dose Rate * Weight / Conc.

Dosing Rate = Rate * Conc. / Weight

Time = VTBI/Rate

5.2.4.3 Loading-Dose Mode

The Loading-Dose Mode is to infuse at the Loading Rate according to the Loading time, and after the Loading time ends, it runs at the Maintain Rate until the VTBI is infused.

In this Mode, it allows to set parameters such as VTBI, Loading Rate, Loading Time and Maintain Rate. Only enter the VTBI and Maintain Rate, the system will automatically calculate the total injection time.

Loading-dose = Loading Rate × Loading Time

Maintain Time = (VTBI - Loading-dose) / Maintain Rate

Notes:

- The VTBI must be greater than the Loading-dose, otherwise the injection cannot be started.
- If the first dose parameter is not set, it will directly enter the maintenance phase.

5.2.4.4 Ramp Up/Down Mode

Ramp up/down Mode means the device automatically increase the rate within the set rise time until it reaches stable rate, and after maintaining for a period of time, it automatically reduces the rate within the set fall time. The ascending or descending phase is divided into 9 stages on average.

In this Mode, you can set VTBI, Rate (stable stage), Rise Time and Fall Time, the system will automatically calculate the rising and falling rate.

5.2.4.5 Sequence Mode

In this Mode, the rate and Time can be set for each sequence, and the device starts injection in sequence according to the pre-set sequence.

If there is a sequence that only sets the rate but not the time, it cannot be started. When more than two sequences are set, you only need to input the effective rate of one sequence and the time of the rest of sequences to started.

This Mode supports up to 12 sequence.

5.2.4.6 Body Surface Mode

In this Mode, it allows to set parameter such as Weight, Height, Drug Dose, Drug Volume, Conc.unit (concentration unit), Conc.(concentration), Dose Rate, Dose Unit and VTBI, After inputting Weight, Height, VTBI and Conc., the system will automatically calculate the injection rate. The conversion formula is as follows:

Rate (mL/h) = Dose Rate * body surface area / Conc.

Time = VTBI / Rate

5.2.4.7 Dose Mode

In this Mode, it allows to set parameter such as Drug Dose, Drug Volume, Conc.unit (concentration unit), Conc.(concentration), Dose Rate, Dose Unit, VTBI and Rate, After inputting VTBI and Conc., and then arbitrarily inputting one of the parameters of Dose Rate or Rate, the system will automatically calculate the other parameter and time. The conversion formula is as follows:

Rate (mL/h) = Dose Rate / Conc.

Dose Rate = Rate * Conc.

Time = VTBI / Rate

5.2.4.8 Intermittent Mode

The Intermittent Mode is divided into injection phase and maintenance phase. After the injection phase ends, it automatically switches to the maintenance phase. Intermittent Mode supports automatic cycle injection.

In this Mode, it allows to set parameters such as VTBI, Intermittent Reserve, Rate, Maintain Rate and Intervals, and only input the Intermittent Reserve, Rate and Intervals, the injection time could be automatically calculated.

Note: The maintain rate is an optional parameter. If the maintain rate is not set, the injection will not be started during the maintenance stage.

5.2.4.9 TIVA Mode

In this Mode, it allows to set Weight, Conc.unit (concentration unit),Drug Dose, Drug Volume, Conc. (concentration) basic parameters, then setting Loading Dose, Induction Time for Induction Stage, setting Maintain Dose Rate ,Maintain Dose Rate unit for Maintenance Stage, the system will automatically calculate the injection flow rate.

After starting the run, the injection is first carried out at the Induction Rate and then at the flow rate calculated by maintaining the dose rate at the end of the induction time until it is stopped manually or after triggering an alarm.

5.2.5 Set Injection parameters

Please refer to Chapter 2.5 and 5.2.4 of this User Manual for operation.

5.2.5.1 Cascade

This device supports the cascade function, which can be cascaded through the Infusion Work Station or the infrared module of the pump to realize the three cascade modes: sequence cascade, Loop cascade and customization cascade. After the cascade is turned on, the pump will infuse in accordance with the set sequence.

Sequence cascade: After starting the infusion, the stacked pumps will infuse in a top-to-bottom order. The whole infusions end when the last pump infusion is completed.

Loop cascade: After starting the infusion, the pumps will infuse in the order of the cycle number. After the last pump completes the infusion, start the infusion of the first pump again, and automatically enter the next cycle.

Customization cascade: After starting the infusion, the pumps will infuse in the order of the cascade number. After the pump with front serial number completes the infusion, the pump with latter serial number will automatically starts the infusion until the last pump completes the infusion.

Note: Modes that support cascade: mL/h Mode, Body-weight Mode, Body surface Mode, Dose Mode

5.2.5.2 Stack Cascade

When multiple pumps are stacked together, and sequence cascade and customization cascade can be achieved through infrared. For the stacking steps, please refer to chapter 4.2.2 of this manual.

Cascade infusion steps:

(1) Stack the pumps, then enter the Network interface to turn on the cascade switch, and then start the infusion of the first pump in the cascade chain;

(2) Set the infusion parameters of each pump in the chain;

(3) Click the  icon on the pump that needs to be cascaded to enter the cascade setting interface, and select 『Cascade To Pump Above』 or 『Cascade To Pump Below 』;

(4) If necessary, turn on the loop cascade switch on the last pump in the cascade chain.

Notes:

- Up to 3 pumps are supported for stacking cascade.
- You can only set top-to-bottom or bottom-to-top cascade according to the stacking order.

5.2.5.3 Online Cascade

By connecting to the Infusion Work Station, the device can realize sequence, Loop and customization cascade.
Cascade infusion steps:
(1) Connect the pump to the Infusion Work Station, and then start the infusion of the first pump in the Cascade chain;
(2) Set the infusion parameters of each pump in the chain;
(3) Click the  icon on the pump that needs to be cascaded to enter the Cascade setting interface, and select 『Cascade To Channel X』("X" means channel number);
(4) If necessary, turn on the Loop Cascade switch on the last pump in the cascade chain.

5.2.5.4 Cancel Cascade

If you need to cancel the cascade, click 『Cancel Cascade』 on the current pump to cancel the cascade of this pump and subsequent pumps.
Note: For loop cascade, click 『Cancel Cascade』 on the current pump, the whole cascade chain will be disconnected.

5.2.6 Purge bubble

To prevent air from entering the body, the air bubbles in the tube must be removed before infusion. The purge volume is not calculated in the total Volume. There are two ways of manual purge and automatic purge.

Manual purge: In parameter preparation interface of any injection Mode, short press the 【Bolus/Purge】 button to enter the purge setting interface, and then long press the 【Bolus/Purge】 button, the device will start the purge according to the default maximum flow rate of the system (see 2.5 of this manual). Release the button to stop the purge.

Automatic purge: In parameter preparation interface of any injection Mode, short press the 【Bolus/Purge】 button to enter the purge setting interface to set the Purge VTBI, and then click 『Start Automatic Purge』, and return to the preparation interface after purging. Press the 【Start/Pause】key to end the purge in advance.

Notes:

- Purge bubble can only be performed when non-injection state and the injection tube is not connected to the patient.
- For manual purge, the purge will automatically stop when the single purge volume is greater than or equal to 5mL (For 1mL size syringe, stop when it is greater than or equal to 1mL. For 2/3mL size syringe, stop when it is greater than or equal to 2mL syringes).
- After purge is started, the blocking pressure level is automatically adjusted to the maximum gear.

5.2.7 Start injection

Connect the injection tube group to the patient, after confirming the parameters are correct, press the 【Start/Pause】 button to start the injection.

5.2.8 Change parameters during Injection

During injection, the rate and dose rate can be changed without stopping the injection.
Select the parameter area that needs to be changed in the injection operation interface, reset the injection

parameters in the pop-up parameter setting interface, click  after confirming that it is correct, the syringe pump will infuse with the new injection parameters.

Note: All injection modes except "Sequence Mode, Ramp up/down Mode, Loading-Dose Mode and TIVA Mode" support the online titration function.

5.2.9 Quick setting

Swipe up on the right side of the running interface to bring up the quick menu. This menu supports change brightness, and occlusion pressure.

5.2.10 Bolus

This device supports bolus injection, there are two ways of manual bolus and automatic bolus. The bolus volume is calculated in the total Volume.

Manual bolus: Short press the 【Bolus/Purge】button on the running interface to enter the bolus setting interface, and then long press the 【Bolus/Purge】 button, the device will infuse according to the bolus rate. Release the button and the device will restore its original rate for injection.

Automatic bolus: Short press the 【Bolus/Purge】button on the running interface to enter the bolus setting interface, set any two parameters of the bolus VTBI, bolus rate and bolus time, and then click 『Start Automatic Bolus』.After the bolus VTBI is completed, the device will restore its original rate for injection. Press【Start/Pause】key to end bolus injection in advance.

You can change the bolus unit in parameters setting.

Note:

- During bolus injection, the pump will give a beep when every 1mL volume is completed.
- For manual bolus, the bolus will automatically stop when the bolus volume accumulates 5mL.
- After bolus is started, the blocking pressure level is automatically adjusted to the maximum gear.

5.2.11 Pause Injection

During injection, press 【Start/Pause】 to suspend injection and return to the parameter setting interface.

5.2.12 Injection Completion

After the VTBI is completed, the “VTBI near end” is triggered. If the KVO function is enabled, the device will automatically start KVO. Click  in the alarm interface to stop KVO and eliminate the alarm. If the alarm is not confirmed, the “KVO finished” alarm will be triggered when the preset KVO time is reached.

5.2.13 Remove the syringe

Disconnect the syringe extension tube with the patient, then remove the syringe.

Replace syringe, please follow the steps of Chapter 5.2.2.

5.2.14 Check Volume

Click 『Volume』on prepare interface to enter to view the injection record.

Cumulative volume displays the cumulative volume of injection in the set time period. Set the time period and interval, and you can view the injection volume during this period.

『Last 24 Hours』 shows the cumulative volume of injection in the most recent period. Set the required time, and you can check the injection volume during this period. The time setting range is 1~24 hours.

『Current Volume』displays the current cumulative volume of injection, click 『Current Volume』 to choose to clear the cumulative volume.

Click  to choose to clear all injection records.

5.2.15 Power off or Standby

5.2.15.1 Power off

Method 1: Press and hold the 【Power】button until the screen turns off and the device shuts down.

Method 2: Short press the 【Power】 button to enter the shutdown interface, and click 『Power Off』 to shut down the device.

Click 『Back』 to return to the interface before the shutdown setting.

⚠ Warning: The push-pull box is automatically reset when the unit is switched off, do not block the middle of the reset stroke with your hands or objects to prevent the moving parts from being pinched.

5.2.15.2 Standby

Method 1: Short press the 【Power】 button to enter the shutdown interface, click 『Standby』 to enter the standby state, and set the standby time, the standby time range: 1min ~ 99hr59min.

Method 2: Short press the 【Power】 button to enter the shutdown interface. After waiting for 3 seconds without any operation, the device will automatically enter the standby state.

During standby, the screen brightness will be adjusted to the lowest level. After the standby is over, the "Standby time expired" alarm will be triggered and the screen brightness will be restored.

Notes:

- The shutdown and standby operations can only be performed when the device is not running.
- Please remove the syringe before power off.
- Please confirm that the slider box has been pushed back in place before shutting down, otherwise the slider box cannot be pushed back after shutting down.

Chapter6 System Setting

6.1 Settings

Click『Settings』icon in the main interface to enter into parameters setting interface.

6.1.1 Drug library

Click 『Settings』 icon in the main interface to enter sub menu, find 『Drug Library』 menu item, click to enter then set the ON/OFF state of drug library and select drug.

6.1.1.1 Drug library management

This device supports the function of drug library, users can use and manage drugs. Drugs can be imported through external tools, and can store up to less than 5,000 drugs and less than 30 drug categories.

Click 『Drug Information』, the user can choose the drug, the drug is color-coded and supports the search function;

Click 『Drug Manage』, the device support users to manage the drug library, such as adding new drugs, adding new drug categories, and deleting and editing.

(1)『Drug List Add』Function: Enter 『Drug Manage』and select『Drug List Add』, select the label color (you can choose any one of the 14 colors), enter the category name, select √ and confirm that the new category is successful.

(2)『Drug List Delete』Function: Enter 『Drug Manage』and select『Drug List Delete』,Select the name of the category to be deleted, a pop-up prompt will appear as shown below, selecting √ will delete the category and all drug information under the category.

(3)『Drug List Edit』Function: Enter 『Drug Manage』and select『Drug List Edit』,Select the category name to be edited to make changes to the drug category name and After the category color has been successfully modified, the color of all drugs under that category will be modified.

(4)『Drug Add』Function: Enter 『Drug Manage』and select『Drug Add』,Select the drug class of the new drug, enter the complete drug parameter information (dose rate units can be selected with or without kg), select √ and confirm the success of the new drug (note: only drugs with parameters can be created with the DERS switch turned on, otherwise only the drug name can be created).

(5)『Drug Delete』Function: Enter 『Drug Manage』and select『Drug Delete』,Select the name of the drug to be deleted (you can use the drug search function to locate it quickly), a pop-up message will appear, and selecting √ will delete the information for that drug.

(6)『Drug Edit』Function: Enter 『Drug Manage』and select『Drug Edit』,Select the name of the drug to be edited (you can quickly locate it using the search for the drug's initials) and modify the drug name as well as the drug parameter information (note: you can only modify the drug parameter information if the DERS switch is turned on, otherwise you can only modify the drug name).

6.1.1.2 DERS

The DERS function is only available for drug libraries. After turning on the DERS switch, the user can edit the drug parameters such as Conc.(concentration), and dose rate hard range, dose rate soft range and recommended rate. When using this drug injection, the Drug Dose Limits Exceeded alarm is triggered when bolus for a period of time.

(1) Hard limit

If the "soft range of Dose Rate" set by the user exceeds the "hard range of Dose Rate" when editing drug parameters, the device will reject this setting, and then the user can reset the parameters within the limits.

(2) Soft limit

When the drug is called up for injection, the user-set "Dose Rate" must be within the soft range of the Dose

Rate.

6.1.2 KVO

KVO means to keep vein open. The syringe pump starts KVO after completing the injection, and keeps the opening rate and continues the injection to prevent blood return or vascular obstruction.

Click 『KVO Rate』 to set the KVO speed. Please refer to chapter 2.5 of this manual for the KVO rate range.

Click 『KVO Time』 to set the KVO time. Please refer to chapter 2.5 of this manual for the KVO time range.

6.1.3 Bolus Rate

Click the 『Bolus Rate』 box, input the value, and click  after confirming the parameter is correct.

For the adjustable range of bolus rate, please refer to chapter 2.5 of this manual.

6.1.4 Occlusion Pressure

Click 『Occlusion Pressure』 to enter the occlusion level setting interface, drag the bar to move to the preset level, and click  after confirming that it is correct.

The higher the level, the higher the occlusion level. It is recommended to select an appropriate occlusion pressure according to actual needs.

The EN-S9 occlusion level is 12 levels adjustable.

level	pressure(mmHg)	error(mmHg)
1	150	±100
2	225	±100
3	300	±100
4	375	±100
5	450	±100
6	525	±100
7	600	±100
8	675	±100
9	750	±120
10	825	±150
11	900	±150
12	975	±200

The EN-S9 Smart occlusion level is 15 levels adjustable.

level	pressure(mmHg)	error(mmHg)
1	50	±40
2	150	±100
3	225	±100
4	300	±100
5	375	±100
6	450	±100
7	525	±100
8	600	±100
9	675	±100
10	750	±120

11	825	±150
12	900	±150
13	975	±200
14	1050	±200
15	1125	±200

Special instructions:

(1) When selecting the lowest level 50mmHg, the flow rate is limited to ≤100mL/h, and the other levels 2 to 15 have no flow rate limit. If the user sets the flow rate to be greater than 100mL/h, the software alarm limit will be automatically adjusted to the level of 150mmHg.

(2) When selecting a 2/3mL size syringe, the maximum selectable occlusion pressure is limited to 600 mmHg. When the 1mL size syringe is selected, the occlusion pressure is only declared at 450 mmHg Other specification syringes have no such limit.

When the end of the pipeline is completely blocked, the maximum injection pressure generated by the device is less than or equal to 1350mmHg.

⚠Warnings:

- When adopting fluid/drug of high viscosity and the occlusion pressure is set at low level, it is possible that the system will report occlusion alarm even when the line is not obstructed, under this condition, please carefully observe the pressure indication icon in the display screen, and rise the occlusion pressure if needed.
- When the occlusion pressure is set to high grade, the larger pressure inside the pipeline is likely to be washed away from the extension tube connected to the syringe. Please confirm that the extension tube is securely attached to the syringe.
- When the occlusion pressure is set at high level, it may possibly cause the patient uncomfortable, after rising the occlusion pressure, please carefully observe the condition of the patient, and immediately take measure if there's any abnormality.

6.1.4.1 DPS (Dynamic Pressure System)

The syringe pump can display the currently set occlusion level, can detect and display the pressure of the current pipeline in real time, and display the status of the pressure through different icons and colors. The displayed pressure threshold status includes: normal pressure threshold, near occlusion alarm threshold, occlusion alarm threshold.

6.1.4.2 Pressure prediction function

The device has the pressure prediction function. When the pressure is detected to rise or fall, it can automatically predict and trigger the system response.

6.1.5 Finish Pre-Alarm

The finish pre-alarm refers to the alarm triggered when the remaining injection time reaches the preset near-completion alarm time.

Click 『Finish Pre-alarm』 to enter the pre-alarm time setting interface, and select the preset time option. Pre-alarm time adjustable range: off, 1min, 2min, 5min, 10min, 15min, 20min, 30min. Set to off and password protected (en@2341).

6.1.6 Reminder alarm

Reminder alarm means that the system will activate "Reminder alarm" if no button is operated within the preset time for "Reminder alarm" when the device is under no injection no alarm state.

Click 『Reminder Alarm』to enter the time for reminder alarm setting interface, select the preset time option .

The adjustable range of time for reminder alarm is: off,30s, 1min, 2min, 5min, 10min, 15min, 20min, 30min. Set to off and password protected (en@2341).

6.1.7 Units setting

6.1.7.1 Pressure unit

Click 『Pressure Unit』 to enter the interface of pressure unit. Four units are available: mmHg, kPa, bar and psi. The conversion between units is as follows:

Unit symbol	Conversion
mmHg	1mmHg=0.133kPa=0.019psi=0.001bar
kPa	1 kPa=7.5mmHg=0.145psi=0.01bar
psi	1psi=51.724mmHg=6.897kPa=0.069bar
bar	1bar=750mmHg=14.5psi=100kPa

Note: Carefully confirm while changing the current pressure unit.

6.1.7.2 Weight unit

Click 『Weight Unit』 to enter the weight unit setting interface. There are kg and lb options, of which 1kg=2.205lb.

6.1.7.3 Height unit

Click 『Height Unit』 to enter the height unit setting interface. There are cm and inch options, of which 1cm=0.394inch.

6.1.7.4 Bolus volume unit

Click 『Bolus Volume Unit』 to enter the bolus volume unit setting interface. There are mL and Dose option.

6.1.8 Syringe brand

The device supports up to 200 syringe brands, including built-in brands and new custom brands.

In the parameter menu, click 『Commonly Used Tube Brand』 to enter the syringe brand selection interface, select the commonly used syringe brand, and the preset brand will pop up for selection after the syringe is installed;

Click 『Search』to search the syringe brand.

Recommended syringe brands:

Syringe brand	Specification
Double-dove	1mL, 2/3mL, 5/6mL, 10/12mL, 20/25mL, 30/35mL, 50/60mL
B.Braun Original Perfusor Syringe	20, 50mL

⚠Warning: The syringe of different brand may possible cause flow rate deviation, when use, please confirm if the displayed information in the interface is accordant with the actual working syringe brand.

6.2 General

In the main interface, click『General』to enter into the equipment setting interface.

6.2.1 Network

This device supports wireless interconnection and wired interconnection. The interconnection can realize information upload: upload the patient information, injection status, and alarm information of the pump to the Central Infusion Management System.

Notes:

- This function needs to be set by professional device maintenance personnel.
- After the interconnection function is turned on, the device can periodically transmit device data to the outside world. The data can only be used for display and does not provide any treatment suggestions.
- When WiFi communication is interrupted, it does not change the status of the pump end or have an effect on operation. The alarm for communication interruption will only be displayed on the EN-C7.

6.2.1.1 Wireless interconnection

Wireless interconnection operation steps:

(1) Click 『Wi-Fi Settings』 enter setting interface to turn on the 『WIFI』 switch;

(2) Go to 『Recently Connected』 Click 『Refresh List』 to select a WiFi for connection, or enter 『Add Network』 to add a new WiFi;

(3) Configure the local IP, subnet mask and default gateway parameters;

(4) Enter 『Server Settings』 to configure the server IP and server port.

This device supports the DHCP function, and when the DHCP switch is turned on, the IP address and other information can be obtained automatically.

Notes:

- The wireless access must be set by the professional technician recognized by our company.
- The transmitted data of this device doesn't provide any suggestion on therapy, and this data shall not be used for calculating the therapeutic schedule.
- When the data is adopted by the third party's equipment or software, it is only for displaying, and shall not be used for alarming or calculating.

6.2.1.2 Wired interconnection

The device can realize wired interconnection through Infusion Work Station.

6.2.2 Sound

Click 『Sound』 and enter the system password en@2341 to enter the sound setting interface. Slide to set the level, confirm and click  , the higher the level, the louder it is. You are advised to select an appropriate sound level as required.

Sound level: 1 to 10 levels are optional, respectively 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%. The default is 10%.

 Warning: Volume levels need to be set according to actual usage. The sound level at the pump end must not be lower than the ambient volume level, and adjusting the volume is password protected.

6.2.3 Date & Time

Click 『Date &Time』 to enter the date and time setting interface. On this interface, you can set the system date, time, and format.

『Use 24-hour Format』 is a time format setting. If you turn it on, it is in 24-hour format. If you turn it off, it is in 12-hour format.

Click『Select Date Format』, the date format can be British, American and Chinese.

Set the time and date format. Click 『Date』 and 『Time』 to set the date and time.

6.2.4 Screen lock

In the running state, the device has an automatic screen lock function. Click 『Screen Lock』 to enter the automatic screen lock setting interface. This function can be turned on or off.

The automatic screen lock time can be set to off, 15s, 30s, 1min, 2min, 5min, 10min and 30min. It means

that the device automatically locks the screen when there is no user touch the screen or press the key within the set time after the device starts running.

Unlock: Press any key or touch the screen on the lock screen, an operation selection interface will pop up, click 『Yes』 to unlock the screen.

Note: When an advanced alarm occurs, the device will be automatically unlocked.

6.2.5 Brightness

Click 『Brightness』 to enter the brightness setting interface. Slide to set the level, confirm and click  , the higher the level, the brighter it is. You are advised to select an appropriate bright level as required.

Brightness level: 1 to 10 levels are optional, respectively 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%.

6.2.6 Night Mode

Click 『Night Mode』 to enter into night Mode switch setting interface to set the start and end time of the night Mode and the night brightness, at night, the system automatically adjusts the brightness to the User defined value.

6.2.7 Nurse call

The nurse call function means that the device can output signals to the nurse call system to call the nurse when an alarm occurs.

Click 『Nurse Call』 to enter the interface for setting parameter. Enter『Nurse Call Alarm Level』 to set the alarm level triggering the nurse call, which is adjustable in two levels. Enter『Mode Setting』to Set the output signal type, high output or low output can be selected.

Notes:

- The nurse call function must be used with special cable.
- The user shall not only depend to cascade on the nurse call function as the main alarm notice Mode, and shall identify according to the equipment alarm and the patient state.

6.3 Patient

On the main interface, click 『Patient』 to enter the setting interface.

6.3.1 Patient Information

Click 『Patient Information』 to enter the patient information setting interface. The bed number, MRN (medical record number), name, patient type, gender, age, weight and height can be set.

Click 『Delete Patient』 to delete all information of the current patient.

6.3.2 Prescription

Click 『Prescription』 and input the system password en@2341 to enter the prescription interface, and view the prescription information.

When the device is connected and idle, it can receive prescription and update the list of prescription, including the prescription of the day, unfinished prescription and finished prescription.

Click 『Prescription Of The Day』option, the interface will display the unfinished prescription of the day and their execution time.

Click 『Unfinished Prescription』, and the interface displays the prescription which status as Checked Not Executed, Executing prescription, Completed, Execution Interrupt. Click 『Finished Prescription』option, the interface shows that the finished prescription.

The steps to carry out the prescription are as follows:

(1) Click to enter the 『Prescription Of The Day』 or 『Unfinished Prescription』 interface;

(2) Select the prescription to be executed and click  ;

(3) Enter the mL/h Mode parameter preparation interface, after confirming that the parameters are correct, press the start button to start the injection.

6.4 Records

Click『Records』in the main interface to enter setting interface. The device can store up to 5000 historical records. When the storage is full, the new records overwrites the old ones.

Note: Log information recording is not affected by power supply and power failure status, and the log record storage time matches the electronic memory function.

6.4.1 History Events

Click 『History Events』to enter the history events interface. history events include Power On, Manual Shutdown, Automatic Shutdown, Standby, Standby End, Purge, Stop Purge, Purge End, Start, Stop, Bolus, Stop Bolus, Bolus End, Change, KVO, KVO End, Reset Total Volume, Brand Calibration. Each history event displays the event name, date, and time the event occurred.

6.4.2 Alarm Events

Click『Alarm Events』to enter the alarm event interface. Contains all alarm events, each alarm event displays the name of the alarm event, the date and time of occurrence, and the alarm priority.

6.4.3 Last Therapies

Click『Records』in the main interface to enter sub menu, click the “Last Therapies” menu item into medical records interface.

(1) This interface displays the latest 20 medical records, user may directly select it as the current injection plan, after confirming the parameters, then start injection.

(2) The system can save 20 medical records at most, when it is full, the new records will cover the old records by turn.

6.4.4 Export History Records

This device supports exporting history records through the maintenance tool.

Click 『Export History Records』 to enter the export state, then open the history record export tool on the PC, connect the Type C data cable, after the communication is realized, the history record can be read and exported to the PC, both text and Excel files format are supported.

6.5 System

Click『System』under the menu interface, enter the system information setting interface.

6.5.1 Language

This device supports simplified Chinese, English, etc. Click『Language』to change device language.

6.5.2 SN (Serial Number)

Check the serial number of the device, and user can’t modify the serial number by themselves.

6.5.3 Version

Check the software version in this interface.

6.5.4 System Maintenance

Press Menu to enter the main interface, click 『System』menu, choose 『Maintenance』, enter the

password(en@2341), enter the system maintenance setting interface.

6.5.4.1 Micro Mode

Click『Micro Mode』 to select the micro Mode to be turned on and off. Under the ON Mode, the injection rate under any injection Mode is not allowed to exceed this limit.

Micro Mode speed limit setting: Click『System』→『Maintenance』→enter password en@2341→『Micro Mode』to enter the micro Mode speed limit setting interface.

⚠ Warning: Speed setting requires department head nurse authority.

6.5.4.2 Department parameters

Enter the Department Parameter setting interface, the department parameters are protected by password(en@2341), and parameters such as Max Rate, Bolus Rate, Bolus VTBI, and Occlusion Pressure can be set. After this setting switch is turned on, the device will apply the above parameter settings.

6.5.4.3 Special parameters

This interface can open the special parameter switch of 50mmHg, 0.01mL/h, 1/1.2mL syringe specifications. If the switch is turned on, the occlusion pressure can be set to 50mmHg, the minimum injection rate can be set to 0.01mL/h, and the 1/1.2mL syringe can be recognized.

6.6 Anti-Bolus

When the line occlusion activates occlusion alarm, the system will automatically drop the line pressure to avoid additional impact bolus to the patient after contacting the occlusion.

⚠ Warning: The Anti-Bolus function is not active when the operator selects the 50mmhg or 150mmHg blocking gear.

6.7 Electronic memory function

After switching off the power, the electronic memory function will be kept for not less than 10 years.

When the power loss time is not more than 30s, all the parameter settings before the power loss will be automatically restored to the user setting values after the power is switched on.

6.8 Misplacement detection function

The interface gives a message when the operator incorrectly installs a syringe, which is turned on by default and can be set off.

Chapter7 Alarm Prompt and Troubleshooting

7.1 Introduction to Alarm Level

During injection preparation and injection, this device will alarm when reaching or exceeding the set alarm threshold value and prompt with sound, light and text. According to the importance of alarm information as well as the emergency and safety, the alarm is divided into three levels: high and low(The principle of alarm priority classification: when the device is running and the treatment is not affected, a low-level alarm is reported to remind the user). All alarms are technical alarms, no physiological alarms. Please refer to table below for details:

Table7.1-1

Alarm Level	Sound Signal Interval	Sound Signal	Duty cycle	Light color /flash frequency	Sound pressure range
High alarm	8s	Di di di-di di Di di di-di di	20%～60%	Red indicator flashes /2.0±0.6Hz	≥65dB(at maximum volume)
Low alarm	25s	Di di di	100%	Yellow indicator lights on	≥45dB(at lowest volume)

If there's alarm, the system will display the alarm interface. Click ✓ to exit the alarm interface.

Click to mute, if alarm is not eliminated, the alarm sound will be sent out again in 2min later.

When the shutdown time is less than 30 seconds, the alarm settings before the power loss will be automatically restored.

ALARM SIGNAL sound pressure level range:

45dB(A)≤the LOW PRIORITY auditory ALARM SIGNALS ≤the HIGH PRIORITY auditory ALARM SIGNALS≤80dB(A)

Alarm volume measurements are made according to the requirements of the ISO 3744 standard, receiving an audible alarm signal measured within an accurate range of 1m radius of the syringe pump.

This alarm system is provided with an OPERATOR ALARM SYSTEM log. When the equipment is powered off, the alarm system records "shutdown" in the log, and records the power off time in the log.

After the alarm system is completely powered off within a certain period of time (power supply and/or internal power supply), press the shutdown button and the alarm system will record "manual shutdown" in the log. After the battery is consumed to the limit, the alarm system will record "automatic power off" in the log and record the power off time in the log.

⚠ Warnings:

- Some alarm thresholds of this device can be set by the user without password protection restrictions: occlusion pressure, reminder alarm, VTBI Done, Pre-Finished Alarm. The user shall confirm the parameters when set the alarm threshold value, otherwise, it may possibly influence the alarm function or injection safety.
- An alarm audible signal with a sound pressure level lower than the ambient sound pressure level may prevent the operator from recognizing the alarm condition, which requires turning up the alarm audible gear.

7.2 Multi-level Alarm Rules

When multiple alarms occur, the alarms are carried out according to the following rules:

Table7.2-1

Multi-level Alarm	Rules
Several alarms of different levels generate simultaneously	Display the alarms of highest level with sound, light and text, until the highest alarm is all lifted, and then report the secondary alarm
Several alarms of same level generate simultaneously	Alarms occur circularly by turns, the time interval is 1.5s

7.3 Alarm Presets and Handling

1.Alarm presets shall be automatically effective and functional.

2.When the power loss time is not more than 30s, the alarm setting before the power loss shall be restored automatically. (Simulation test method: take out the battery and use only AC power supply, set the alarm settings, then cut off the power, within 30s, re-connect the AC power, start the equipment, and verify that the alarm settings are the same as those set before the power failure.)

⚠ Warning: When there's alarm, please check the conditions of the patient, remove the reason of alarm and then continue working.

Please refer to Appendix C for the alarm solution.

7.4 Fault Analysis and Solution

When there's fault, the Syringe pump screen will display the fault alarm information, this item is the alarm of high level. Please eliminate the fault alarm according to the prompt. If it can't be eliminated, please stop using, contact our company to repair and test the device, do not put it into operation before the device has passed the inspection, otherwise, it may possibly cause unpredictable harm if it works with fault.

If the device is on fire/burns for unknown reason, or has other abnormal conditions, the user shall immediately cut off power supply and contact our customer service department.

Under single fault state, the max injection volume is 2mL.

Notes:

- The distance between the operator and the pump should not exceed 0.5m, so as not to affect the operator to correctly identify the alarm.
- The visible distance of the alarm signal is 4 meters, within 4 meters you can see the alarm indicator or the simulated alarm indication area; the visible distance of the alarm information is 1 meter, within 1 meter you can see the alarm text and alarm icon.
- The single condition or path failure can be simulated to verify the normal detection function of the alarm system and sensor. For example: power-on self-test, real-time self-test during operation.

Chapter8 Maintenance

8.1 Cleaning, disinfecting

⚠ Warnings:

- Please cut off power supply and unplug the AC/DC power wire before cleaning the device.
- During cleaning and disinfecting, please keep the device horizontal and upwards to protect the device and accessories from fluid.

8.1.1 Cleaning

(1) The daily maintenance is mainly to clean the housing and pump body. It is inevitable that fluid/drug may flow in the equipment during injection. Some fluid drug may corrode the pump and cause working fault. After injection, please timely clean the device, wipe it with moist and clean soft fabric, and then naturally dry it.

(2) When cleaning the device interface, please wipe it with dry and soft fabric, confirm the interface is dry before using.

(3) Please do not soak the device in water. Although this device has certain waterproof function, when fluid splashes on the device, please check if it works normally, perform insulation and electric leakage test if needed.

8.1.2 Disinfecting

(1) Disinfecting may possibly cause harm of certain degree to the equipment, it is suggested to disinfect the equipment if it is needed.

Please disinfect the equipment with common disinfecting agent such as 70% ethanol, 10%saline, 1%Sodium hypochlorite, 2% Glutaraldehyde, 3%hydrogen peroxide, Jianzhisu quaternary ammonium salt air disinfectant spray and so on. Please follow the instructions of the disinfecting agent.

(2) After disinfecting, wet the soft fabric with warm water, dry the fabric and then wipe the equipment with it.

(3) Do not sterilize the equipment with high pressure steam sterilizer, do not dry the equipment with dryer or similar product.

⚠ Warnings:

- Do not sterilize the syringe pump with Cidex OPA o-phthalaldehyde, methyl ethyl ketone or similar solvents.
- Do not use any disinfection methods or products to sterilize this product, as you will be responsible for any damage.

8.2 Periodical maintenance

Notes:

- The medical mechanism shall set up complete maintenance plan, otherwise, it may possibly cause the equipment malfunction or fault, and may possibly hurt the physical safety.
- In order to ensure the safe use and prolong the service life of the equipment, it is suggested to periodically maintain and check it once every 6 months. Some items shall be maintained by the user, and some items shall be maintained by the dealer of the equipment.
- Please timely contact our company if the equipment is found defective.

8.2.1 Check the Appearance

(1) The appearance of the equipment shall be clean and under good condition without crack and water leakage.

(2) The buttons are flexible and effective without invalid phenomenon; the sensitivity of the touch screen is normal.

(3) The Syringe pump door can be smoothly opened and closed, the safety clamp switch is under good condition.

(4) The power wire is under good condition and installed tightly.

(5) After connecting with external power supply, check whether the AC and DC indicators of the device and the battery indicator are lit normally.

(6) Adopt the accessories designated by our company.

(7) The environment meets the requirements.

8.2.2 Performance Check

(1) Check whether the basic operation and injection function are normal according to 5.1 Operation Procedure.

(2) According to Appendix C and Chapter 7 Alarms, check whether the sound and light and reality alarm functions are normal.

(3) According to Chapter 9, Battery, check whether the battery meets the use standard.

Note: The inspection process needs to be disconnected from the patient, and healthcare personnel are not allowed to disassemble the equipment privately.

8.2.3 Maintenance Plan

The following check/maintenance items must be performed by the professional technician recognized by our company. If the following maintenances are necessary, please contact our company. Please clean and disinfect the equipment before testing or maintaining.

Maintenance Items	Cycle
Safety check according to IEC 60601-1	Once every 2 years, please check after replacing the printed circuit board assembly or the equipment is dropped or knocked.
Preventive system maintenance items (pressure calibrate, sensor calibrate, pump)	Every two years, when the equipment is used with blocking false alarms or poor injection accuracy.
Customize syringe brand, injection accuracy calibration	Maintenance is required when equipment is used for the first time, when syringes are used for the first time, or when a new custom brand is added. It is recommended that the accuracy performance of the brand of syringes used be checked every other year.

8.3 Add new brand and Calibration

In the 『System』 submenu, click 『Maintenance』 to enter into brand setting interface, enter password en@2341,create the consumables brand, delete and calibrate the brand.

⚠ Warning: It is suggested to contact our company or local dealer, and customize and calibrate it by professional technician, otherwise, the injection accuracy cannot be guaranteed.

⚠ Note: The built-in brand of the system shall not be deleted.

(1) Add new brand

⚠ Note: If the actual using syringe brand is not listed in the system, please create brand in this interface.

Click『Add New Brand』to enter the new brand interface, edit syringe brand name, specifications and other information.

(2) Delete

Enter into『Delete』interface, click it to delete user-defined syringe brand.

(3) Precision Calibration

⚠Notes:

- When first time use Non-built-in brand pump need calibration.
- When added new brand need calibration.
- When accuracy is not good need calibration.

Please calibrate the syringe when using the built-in brand for the first time, or the first add syringe brand, or after periodical maintenance.

Please prepare the following materials before calibrating:

The new syringes: 1mL, 2/3mL, 5/6mL, 10/12mL, 20/25mL, 30/35mL and 50/60mL each, 200mL measuring cup and electronic balance .

(4) Accuracy Calibrating Steps:

1) Select the syringe brand

2) Select syringe specification

3) Install syringe, pull the syringe piston beyond size scale line a little, press and hold on【bolus】, push the piston to the corresponding size line

4) Click『Calibrate』to start Calibrate, wait the calibration done.

5) Repeat above step 2~step 4 using different size syringes

6) After exiting the calibration interface, the calibration brand was selected as the current brand, and verify the injection accuracy by setting the parameters in the table below.

Syringe Specification	Injection Rate	VTBI	Standard O*utput* Volume(g)	±1.8%Accuracy corresponds to the amount of Output Volume(g)
1mL	50mL/h	1mL	0.99	0.97~1.01
2mL	150mL/h	2mL	1.99	1.95~2.02
5mL	300mL/h	3mL	2.99	2.94~3.04
10mL	800mL/h	5mL	4.99	4.90~5.08
20mL	1200mL/h	10mL	9.98	9.80~10.16
30mL	1500mL/h	15mL	14.97	14.70~15.23
50mL	2300mL/h	25mL	24.95	24.50~25.40
50mL	100mL/h	10mL	9.98	9.80~10.16

(5) Syringe Pressure Calibration

When a false positive of the blocking pressure is found or the error of the blocking pressure is too large, it is necessary to calibrate the blocking pressure of the syringe.

Please prepare the following materials before calibrating:

The new syringes: 1mL, 2/3mL, 5/6mL, 10/12mL, 20/25mL, 30/35mL and 50/60mL each 200mL measuring cup and Blocking pressure calibration test bench.

1) Select the syringe brand

2) Select syringe specification

3) Click on 『Syringe Pressure Calibration』, select the specification of the syringe to be calibrated, click on 『Calibrate』and click on 『Calibration point 1 Calibrate』;

4) Click on the【start】button to begin calibration, When the pressure indicator reaches near the prompt pressure, click the 【stop】button to stop the operation and input the pressure gauge reading to the calibration point 1 pressure;

5) Then Click the green arrow to enter the calibration point 2 calibration interface, Click on the【start】button to begin calibration, When the pressure indicator reaches near the prompt pressure, click the 【stop】button to stop the operation and input the pressure gauge reading to the calibration point 2 pressure;

6) After exiting the calibration interface, select the current brand as the brand just calibrated, then select the syringe specification corresponding to the blocking gear and test at a flow rate of 100 mL/h to see if the pressure indication is within the range.

Note: Accuracy Error % = (Dispensing Volume - Preset Volume)/Preset Volume*100%.

8.4 Repair

⚠ Warning: The maintenance of the equipment and the replacement of the components shall be carried out by professionals recognized by the company. Special attention shall be paid to the detection of the power supply when the power module is replaced. Observe whether there is a false alarm, connect the AC power supply, and the battery is charged normally.

8.4.1 Normal Repair Process

Please contact our company or authorized service personnel to repair if there's any fault, do not disassemble and repair the equipment. After repair, please perform overall test for the equipment. Our company may provide the circuit diagram and components list to the authorized repair technician if needed.

8.4.2 Maintenance for Long Term Store

If the equipment won't be used for a long period, please pack the equipment in the package, and store it in the shade, cool and dry place without direct sunlight.

The following operations are necessary for using it again:

1.Verify the flow rate accuracy to avoid unconformity between the syringe parameters in the equipment and the actual parameters after it hasn't be used for a long period or caused by other reasons, otherwise, it may cause injection error, influence the therapeutic effects and even cause medical negligence.

2. Perform air bubble and occlusion alarm test.

3. Test the battery discharging and charging duration to confirm that the battery is also usable.

8.5 Equipment Accessories /Components

⚠ Warnings:

- Only the components and accessories designated by our company shall be adopted, otherwise, it may possibly damage the equipment or drop the equipment performance.
- During the normal service life of the equipment, the battery and waterproof membranes are consumables, it is suggested to replace them once every 2 years, please contact the dealer or our company to replace them.

Accessories	Nurse call cable
	DC Power cable
	Power cable
components	Wifi module
	Locking mechanism
	One battery

8.6 Production Date

Please refer to the label of the product.

8.7 Recycling

The normal service life of this equipment is 10 years, and depends on the use frequency and maintenance. The equipment must be rejected after reaching the service life, please contact the manufacturer or the dealer to get more detailed information.

1. The obsolete equipment may be returned to the original dealer or manufacturer.
2. The used lithium-ion polymer battery has the same treatment method, or according to the applicable laws and regulations.
3. Please handle according to the equipment rejecting flow of your medical institutions.

Chapter9 Battery

This equipment is equipped with rechargeable lithium-ion polymer battery to ensure the normal injection when the equipment is moved or the external power supply is cut off.

When connecting external power supply, no matter the equipment is power on or not, the battery is charged. When charging, the equipment screen displays the battery charging indication icon  . In case only built-in battery is adopted for supplying power, and when the remained battery is less than 20%, please connect the equipment with external power supply to charge the battery.

Warning: Only the battery designated by our company shall be adopted.

9.1 Check the Battery Performance

The performance of the built-in battery may drop according to the using duration, it is suggested to check the battery once a month.

(1) Disconnect the equipment from the patient, and stop all injections.

(2) Supply public power to the equipment to charge the battery for 6h at least.

(3) Supply power to the Syringe pump only with battery, Injection at the rate of 5mL/h, test the time till the battery runs down and the equipment is turned off.

(4) If the battery power supply time is significantly lower than the time stated in the specification, consider replacing the battery or contacting us.

Notes:

- The warranty period of the equipment is 1 year. It is not recommended to purchase battery spare parts in large quantities.
- Recommendations for long-term use or storage of the device are: charge it to 50-80%, and then store it.
- Do a complete charge and discharge every 3 months, and then continue to charge to 50-80%, and then continue to store, so as to cycle storage.

9.2 Replace the Battery

It is recommended to replace the battery every 2 years, it is suggested to replace the battery by the dealer or manufacturer.

Warning: Untrained personnel are forbidden to replace the battery, otherwise it may cause the battery to burn, explode, leak and cause personal injury.

Chapter10 After Sale Service

The whole machine is guaranteed for 18 months, and the battery is guaranteed for 6 months. The warranty period is from the installation date listed on the “Warranty Card”. The “Warranty Card” is the only voucher for calculating the warranty period, in order to maintain your benefit, please carefully fill into and keep the “Warranty Card”, and hand over the copy for the company to the installation technician.

1.The damages of the equipment caused by the following shall not enjoy free warranty service.

2.Fault caused by incorrect operation, unauthorized refitting or repair.

The damages caused by incorrect operation during the transportation process after purchase.

3.The fault and damages caused by fire, salt injury, toxic gas, earthquake, windstorm, flood, abnormal voltage and other natural disasters.

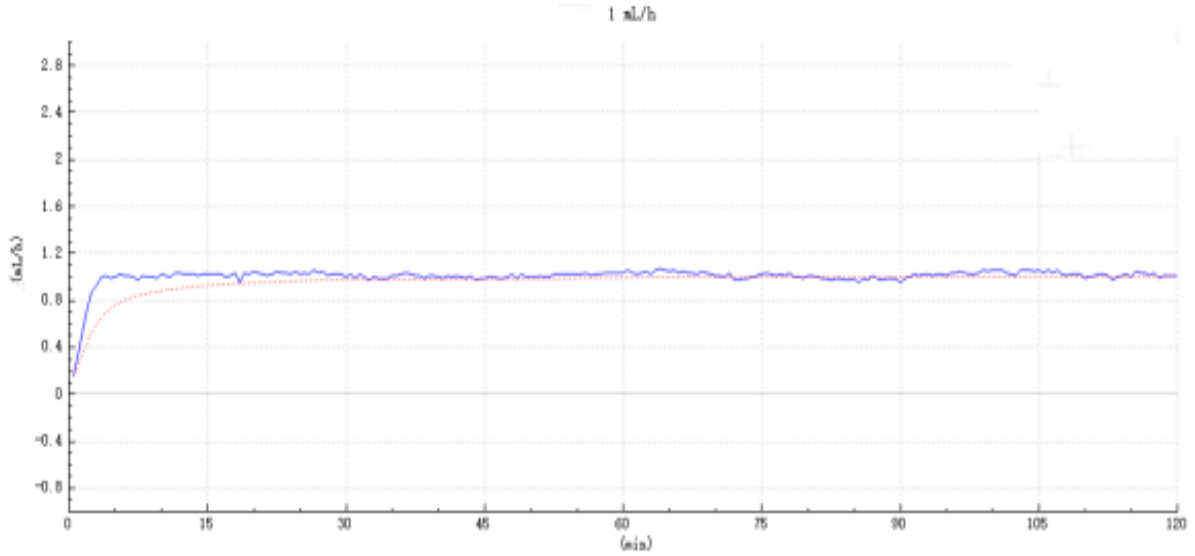
For the damages or faults mentioned above, our company provides repair services but charge at repair cost.

Chapter11 Appendix

Appendix A Injection Accuracy Characteristic

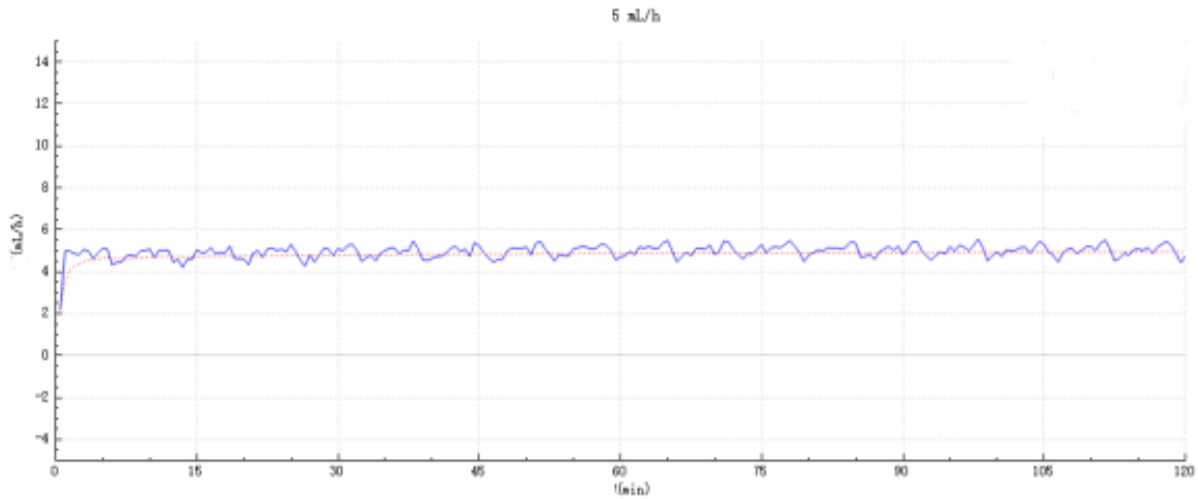
Appendix A.1 Start-up Graphs

Brand: Double-Dove Size:50/60mL
Sample QTY: 3 Units
Syringe sample QTY: 3 Sets
Flow Rate: 1.0mL/h
Measurement Interval: Δ t = 0.5min
Measurement duration: T = 8h



Graph 1 Start-up graph: Flow Rate 1.0 (mL/h) against time (min) plotted from data gathered during the first 2 h of the test period.

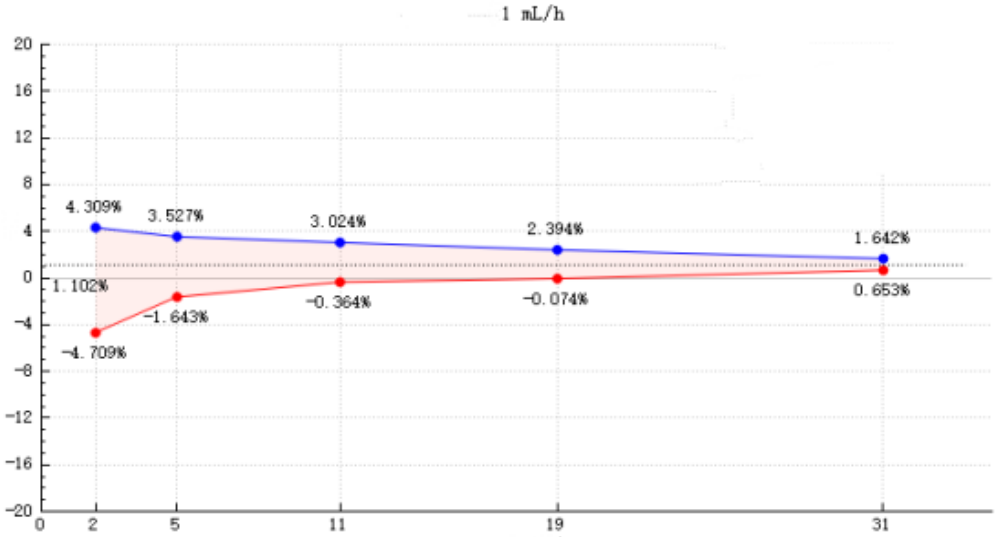
Brand: Double-Dove Size:50/60mL
Sample QTY: 3 Units
Syringe sample QTY: 3 Sets
Flow Rate: 5.0mL/h
Measurement Interval: Δ t = 0.5min
Measurement duration: T = 8h



Graph 2 Start-up graph: Flow Rate 5 (mL/h) against time (min) plotted from data gathered during the first 2 h of the test period.

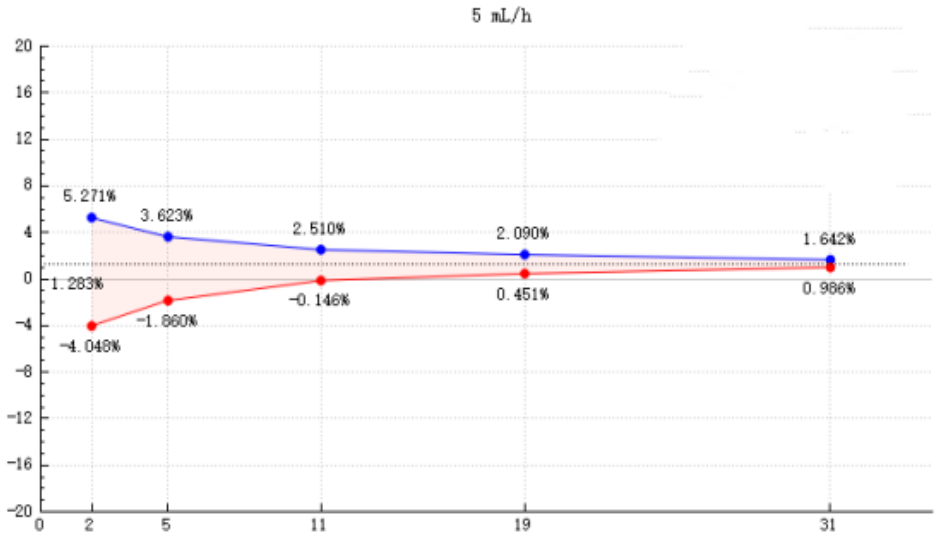
Appendix A.2 Trumpet Curves

Brand: Double-Dove Size:50/60mL	Sample QTY: 3 Units
Syringe sample QTY: 3 Sets	Flow Rate: 1.0mL/h
Measurement Interval: Δ t = 0.5min	Measurement duration: T = 8h



Graph 3 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period.

Brand: Double-Dove Size:50/60mL	Sample QTY: 3 Units
Syringe sample QTY: 3 Sets	Flow Rate: 5mL/h
Measurement Interval: Δ t = 0.5min	Measurement duration: T = 8h

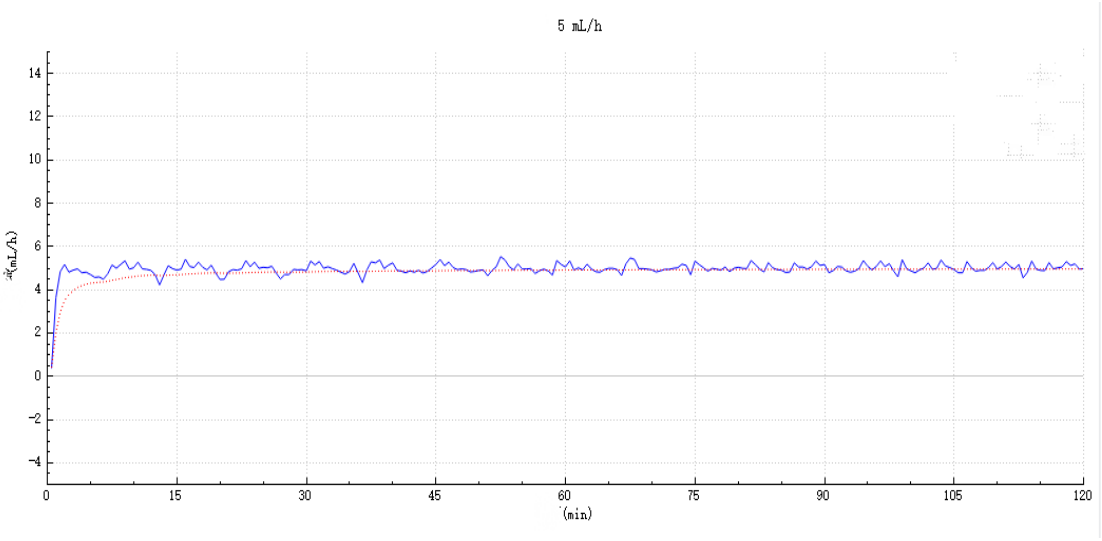


Graph 4 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period.

Note: Injection accuracy may be affected by the Syringe environment, such as pressure, temperature, humidity, syringe consumables and so on.

Appendix A.3 Start-up Graphs (+100mmHg Back Pressure)

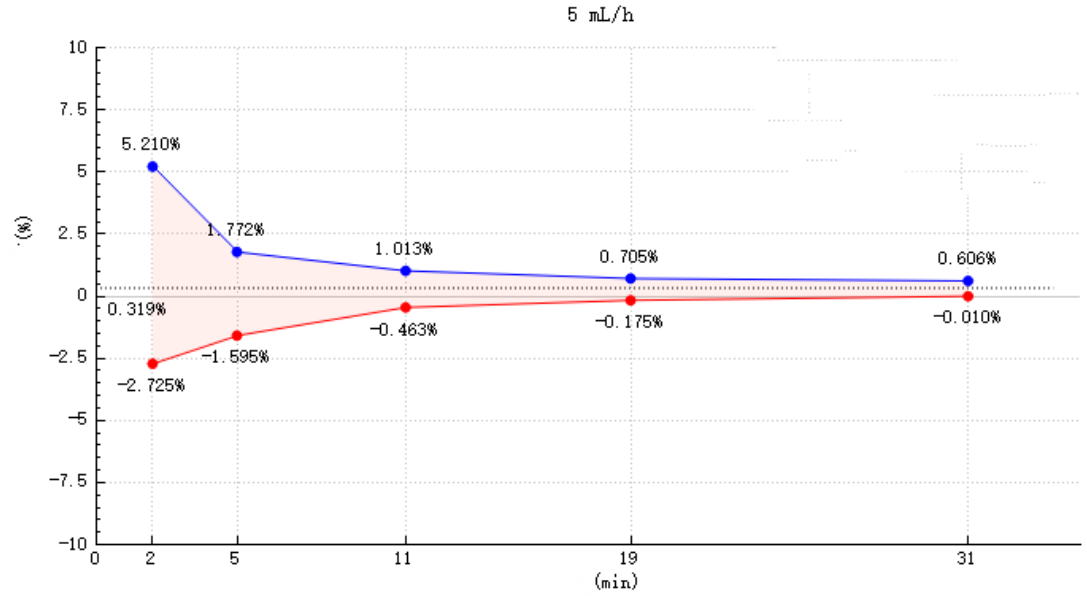
Brand: Double-Dove Size:50/60mL	Sample QTY: 3 Units
Syringe sample QTY: 3 Sets	Flow Rate: 5mL/h
Measurement Interval: Δ t = 0.5min	Measurement duration: T = 2h



Graph 5 Start-up graph: Flow Rate 5 (mL/h) against time (min) plotted from data gathered during the first 2 h of the test period.

Appendix A.4 Trumpet Curves(+100mmHg Back Pressure)

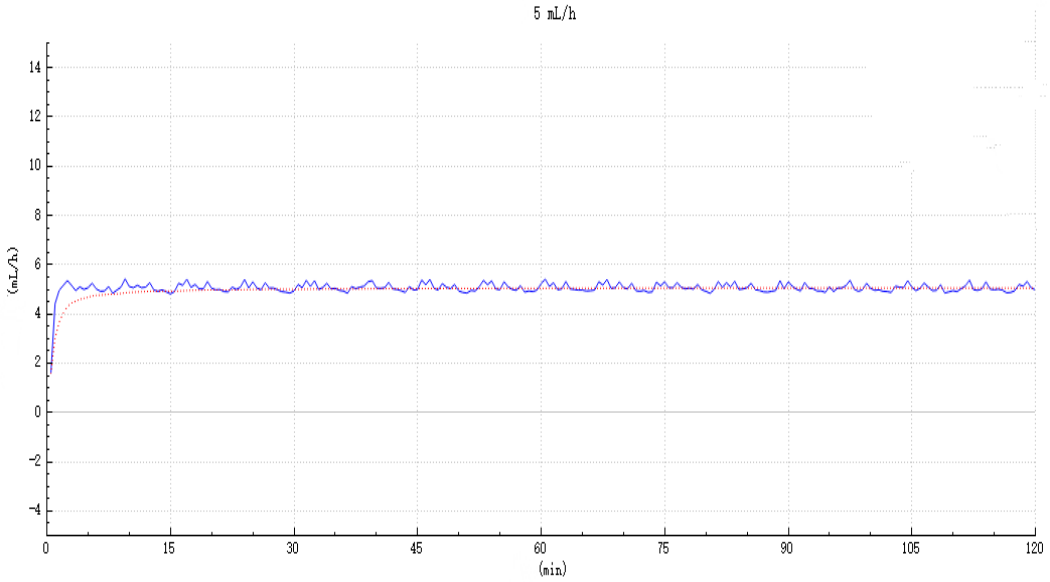
Brand: Double-Dove Size:50/60mL	Sample QTY: 3 Units
Syringe sample QTY: 3 Sets	Flow Rate: 5mL/h
Measurement Interval: Δ t = 0.5min	Measurement duration: T =2h



Graph 6 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period.

Appendix A.5 Start-up Graphs (-100mmHg Back Pressure)

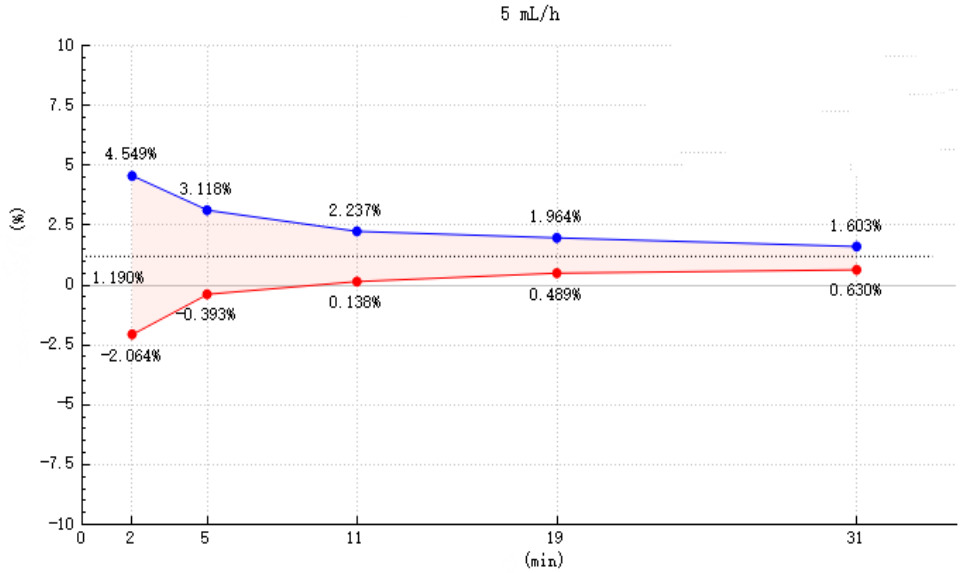
Brand: Double-Dove Size:50/60mL	Sample QTY: 3 Units
Syringe sample QTY: 3 Sets	Flow Rate: 5mL/h
Measurement Interval: Δ t = 0.5min	Measurement duration: T = 2h



Graph 7 Start-up graph: Flow Rate 25 (mL/h) against time (min) plotted from data gathered during the first 2 h of the test period.

Appendix A.6 Trumpet Curves(-100mmHg Back Pressure)

Brand: Double-Dove Size:50/60mL	Sample QTY: 3 Units
Syringe sample QTY: 3 Sets	Flow Rate: 5mL/h
Measurement Interval: Δ t = 0.5min	Measurement duration: T = 2h



Graph 8 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period.

Appendix B Occlusion Response Features

EN-S9 Smart Relationship between occlusion time and bolus:

Syringe specification	Occlusion alarm level	Occlusion Pressure (mmHg)	Flow rate (mL/h)	Time to occlusion Alarm (hh:mm:ss)	Pass criterion	Max bolus (mL)	Pass criterion (mL)
50/60mL	lowest	50	1	00:17:09	≤20min	0.0522	≤0.2
			5	00:03:07	≤5min	0.0652	≤0.2
	highest	1125	1	05:02:00	≤6hr	0.2144	≤0.3
			5	00:55:20	≤1hr	0.2356	≤0.3
20/25mL	lowest	50	1	00:07:59	≤10min	0.0589	≤0.2
			5	00:01:40	≤3min	0.0632	≤0.2
	highest	1125	1	01:03:00	≤1hr30min	0.1145	≤0.2
			5	00:13:24	≤15min	0.1323	≤0.2

EN-S9 Relationship between occlusion time and bolus:

Syringe specification	Occlusion alarm level	Occlusion Pressure (mmHg)	Flow rate (mL/h)	Time to Occlusion Alarm (hh:mm:ss)	Pass criterion	Max bolus (mL)	Pass criterion (mL)
50/60mL	lowest	150	1	00:29:53	≤40min	0.1002	≤0.2
			5	00:05:46	≤10min	0.1043	≤0.2
	highest	975	1	03:30:00	≤4hr	0.1525	≤0.2
			5	00:41:37	≤1hr	0.1428	≤0.2
20/25mL	lowest	150	1	00:08:40	≤10min	0.0721	≤0.2
			5	00:01:52	≤3min	0.0544	≤0.2
	highest	975	1	00:58:02	≤1hr10min	0.1627	≤0.2
			5	00:11:51	≤15min	0.1421	≤0.2

Notes:

- Conditions for testing above data: Syringe Brand: Double-Dove Size:50mL
- The occlusion alarm pressure, alarm delay time and bolus are influenced by the test conditions, temperature and line length. (The increase in line length will lead to the increase of alarm delay. Lower temperature will lead to poor elasticity of pipeline, exceeding the declared error range of occlusion pressure, resulting in inaccurate alarm pressure. The shortening in line length and higher temperature have no effect.)
- The above data is the typical value under the test conditions, please see the test data of the product for the actual data, the data may be different if the test conditions are different.

Appendix C Alarm and Solution

Alarm Type	Alarm Level	Alarm delay	Reason	Solution
VTBI Done	High	＜1s	The preset value injection Completion	Press【Alarm Reset】button to stop alarm
KVO Finished	High	＜1s	When the KVO running time reaches the preset KVO time, the injection pump stops running	Press 【Alarm Reset】button to stop alarm
Check Syringe	High	＜1s	Syringe drop off during injection	Re-install the syringe
Syringe Empty	High	＜1s	The liquid medicine in the syringe is empty.	Press【Alarm Reset】button to stop the alarm.
Stream Occlusion	High	The device runs at 1.0mL/h, and the occlusion pressure is set to the highest level. The delay for triggering the occlusion alarm should be ≤5h	1. Line occlusion during injection	Click 『Mute』 to silence, Manually solve the problem of occlusion, Press 【Start】 button to restart injection.
			2. Fluid/drug in the injection line of high viscosity, while the system occlusion level is set too low.	Rise the alarm Level, Press 【Start】 button to restart injection.
			3. The pressure sensor is damaged.	Please contact the dealer or manufacturer for repair.
Battery Empty	High	＜1s	When power is supplied by the built-in battery only, under low battery, the alarm duration is >30min	Immediately connect with external power supply.
			2. Battery ageing or the equipment charging circuit is fault.	Please contact the dealer or manufacturer for repair.
Backup Battery Exhaustion	High	＜1s	1.Backup battery is nearly exhausted	Immediately connect with external power supply.
			2. Backup battery is detached or aged	Please contact the dealer or manufacturer for repair.
Over Dose Of Drug	High	＜1s	While using drugs in drug library to infuse, alarm will be triggered if max dose limit in certain time is exceeded the preset limits.	Press 【Alarm Reset】button to stop alarm.
Syringe Movement	High	＜1s	The pump is moved or the extension tube is dislodged during the injection process.	Make sure the pump is secured or the extension tube is firmly connected.
System Error	High	＜3s (Set 100mL/h operation, analog sensor open circuit)	If system self-check fail or internal fault, system error alarm will give with code number.	Restart device to check whether alarm eliminated, if still exist, contact maintenance personnel.
Syringe Near Empty	Low	＜1s	The syringe is near empty status which is calculated by checking the liquid medicine remaining in the syringe by current flow rate.	This alarm can't be eliminated, waiting to syringe empty.
Standby Time End	Low	＜1s	During standby, after reaching the standby time.	Press 【Alarm Reset】button to stop alarm.

VTBI Near End	Low	＜1s	During injection, the remaining time of preset value reaches or is less than the set nearing completion time.	This alarm can't be eliminated, and waits till injection completes.
No Battery Inserted	Low	＜1s	No battery is installed or the internal battery is disconnected	Install battery after power off
Battery Nearly Empty	Low	＜1s	1. When power is supplied only with the built-in battery, under low battery, the alarm duration is >30min	The alarm automatically eliminates after connecting the external power supply.
			2. Battery ageing or the equipment charging circuit is fault.	Please contact the dealer or manufacturer for repair.
No Power Supply	Low	＜1s	Under ON state, AC power supply is adopted, but the AC power wire is dropped during the process	The alarm automatically eliminates after connecting the external power supply.
Reminder Alarm	Low	＜1s	After installing syringe tube, under non-working or alarm state, it is not operated within the set time of the system.	Click any button to stop.
Cascading Interrupts	Low	＜1s	Infrared is interrupted during the cascading process	Detect if the pump is displaced

Description: The maximum alarm delay time from the device generates an alarm to the Central Infusion Management System displays the alarm is less than 10s.

Note: When alarm rings, click the『Mute』icon on the screen to temporarily stop sound alarm for 2min. All of the above alarms are technical condition alarms. For troubleshooting and replacement please contact the manufacturer to provide access to the service manual.

System Error Reference Code:

System Error Name		System Error Definition
System Error 1	Ma-Mo	Main control board to driver board communication failure
	Ma-Dr	Main control board to monitoring board communication failure
	Dr-Mo	Monitoring board to driver board communication failure
System Error 2		Motor stall or over speed
System Error 3		Motor reverse rotation
System Error 4		Pressure sensor failure
System Error 6		EEPROM failure
System Error 7		Flash failure
System Error 8		No response failure (The master control chip sends a command to the driver chip or monitor chip and does not receive a response)
System Error 9		Operating system failure
System Error 10		Motor failure
System Error 11		Version failure
System Error 14		Main control board/driver board reset in injection operation state
System Error 15		Grip failure
System Error 16		FPC line communication failure

Appendix D EMC Electro Magnetic Compatibility declaration

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

⚠ Cautions:

This unit has been thoroughly tested and inspected to assure proper performance and operation!

This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

⚠ Warnings:

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the Syringe pump as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Syringe pump.

Even if other equipment meets the emission requirements of the corresponding national standards, the equipment or system may still be interfered with by other equipment

Type	**Emission frequency**	**modulation type**	**Frequency characteristics**	**Radiated power**	**Note**
WIFI	2.412GHz-2.482GHz	OFDM，CCK，DSSS	WIFI	Less than 20dBm	/
	5.17GHz-5.25GHz				
	5.725GHz-5.835GHz				

Guidance and manufacture's declaration – electromagnetic emission		
The Syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of the syringe pump should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The syringe pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The syringe pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity			
The syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of the syringe pump should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines +1 KV for input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) +2 KV line(s)to earth	± 1 kV line(s) to line(s) +2 KV line(s)to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT)for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the syringe pump requires continued operation during power mains interruptions, it is recommended that the syringe pump be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	400A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacture’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of syringe pump should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>10 Vrms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the syringe pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.167\sqrt{P}$
$d = 1.167\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>10 V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the syringe pump is used exceeds the applicable RE compliance level above the syringe pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the syringe pump.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.</td></tr>
</table>

Recommended separation distances between
portable and mobile RF communications equipment and the syringe pump .

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Appendix E Factory Default Data Set

Parameters	Default Setting	Parameters	Default Setting
Drug Library	OFF	KVO Rate	1.0mL/h
DERS	OFF	Screen Lock	1min
WIFI	OFF	Bolus Rate	Maximum speed according to syringe specifications
Night Mode	OFF	Reminder Alarm	2min
Micro Mode	OFF	Sound	10%
Nurse Call	OFF	Brightness	50%
Anti-Bolus	ON	Pre-Finish Alarm	2min
Anti-error pipe loading	ON	Occlusion Pressure	600mmHg
Special Parameters	1ml: OFF 50mmHg:OFF	Pressure unit selection	mmHg

Appendix F Unit conversion

Unit	Unit symbol	Unit conversion
Pressure unit	mmHg	1mmHg=0.133kPa=0.019psi=0.001bar
	kPa	1 kPa=7.5mmHg=0.145psi=0.01bar
	psi	1psi=51.724mmHg=6.897kPa=0.069bar
	bar	1bar=750mmHg=14.5psi=100kPa
Weight unit	kg	1kg=2.205lb
	lb	1lb=0.454kg
Height unit	cm	1cm=0.394inch
	inch	1inch=2.540cm

Version: V3.0
Revising Data: 10.09.2024