GRASEBY

CE
2862

Graseby S20 Plus Syringe Pump User Manual

Version: 1.1

MDKMed Medical Technology Co., Ltd.
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Content

1 Symbols, Graphics and Warnings

1.1 Descriptions of Graphics and Symbols

	Caution		Read the User Manual
	Defibrillation prevention Type CF device	RoHS	Compliant to RoHS standards
	Date of manufacturing		Class II device
SN	Serial Number		Classified collection, uncontrolled discard not allowed
IP44	Ingress Protection Grade	~	AC (Alternating Current)
⎓ 15V	DC (Direct current)		Mute
	Lithium battery		Non-ionizing electromagnetic radiation
	Manufacturer	EU REP	European Representative

CE 2862	CE mark demonstrating compliance with RoHS and other EU directives	MD	Medical device marking

1.2 Warning

Please read the following information carefully, operation that does not strictly follow the guidance will possibly damage the device or do harm to patients' health.

1) The Syringe Pump is intended for clinical intravenous infusion. It must either be used with a syringe that is from the list of the recommended brands or with one from other brands after calibration is performed on the device.
2) Untrained personnel are not allowed to operate the device. The operator must carefully read this User's Manual, so as to prevent medical accidents caused by improper operation.
3) To prevent fire or explosion, it is forbidden to use this device in an environment where flammable or explosive matters are present.
4) Do not stack and use other devices that may generate external radio frequency interference or electromagnetic radiation that may affect the safe operation of this device.
5) The operator must use the recommended syringe calibrated in accordance with the requirements described in Section 10 Accuracy Calibration for Syringe in this manual, and make sure that the correct syringe brand and type are selected.
6) Unauthorized syringes are not recommended to use for infusion,

otherwise it may lead to infusion inaccuracy and even become unusable.

7) The installation height of this device should not be more than 1 meter above or below the patient's heart. It is recommended that the syringe pump be placed at the same height as the patient's heart when used.
8) It is forbidden to reuse the same syringe on another infusion device.
9) This device cannot be used as a portable device.
10) It is forbidden to use sharp objects to press on the buttons or the touch screen.
11) The Syringe Pump must be serviced and calibrated by trained professional technicians. Before maintenance, make sure to unplug the power cable that supplies power to the device. Untrained personnel are strictly prohibited from opening the device casing, otherwise the eligibility for warranty of the device will be lost.
12) Please make sure to use only the parts and accessories provided by manufacturers.
13) When hit hard or dropped, the pump should not be used until it has been checked by trained technical staff.
14) Except for wiping the outer surface of the device according to Section 15 Service and Maintenance in this manual, no other part of the device shall be serviced or maintained by users. If there is any abnormality in the device, please contact the customer service of manufacturers.
15) During the use of the device, the device should be placed smoothly and fixed firmly.

16) After loading the syringe, the operator is required to check whether the liquid medicine in the syringe leaks. If there is leakage, stop using the syringe and notify the customer service of manufacturers.
17) Operator should set the infusion parameters strictly based on the doctor's prescriptions. Mistakes in infusion parameter settings may cause harm to patients.
18) When an ordinary syringe is used continuously, the syringe needs to be replaced after the infusion task is completed or the syringe is emptied to maintain a higher injection accuracy.
19) The pump will stop operation automatically when there is an alarm. Press the Start/Stop key to resume operation after the alarm causing condition is removed.
20) To avoid failure or false alarm caused by a dirty occlusion sensor, operator should wipe clean the pump on a regular basis to keep it clean. Disconnect equipment from MAIN supply before cleaning.
21) If the sound pressure level of the audible alarm is less than the environmental noise, the operator should turn the alarm volume up to ensure the alarm sound can be heard.
22) Pump or accessories may not be usable if their lifetime for use has expired (the lifetime for pump is 8 years). Contact manufacturers to upgrade to new products.
23) The device has a internal rechargeable lithium battery and its lifetime is 2 years.
24) Please check the voltage of the internal battery before using it for pump operation. The battery must be replaced and maintained by trained technical personnel in accordance with Section 14 Use, Maintenance and Removal of the Internal Batteries in this manual.

Replacing the battery by personnel without sufficient training will lead to risks such as over temperature, fire or explosion.

25) Please do not connect any other device to the USB and Type-C port other than the included DC power adapter shipped with the pump. Do not put the AC/DC adapter above the patient.
26) For different types of patients, different occlusion pressure Level should be set. For details, please refer to the doctor's advice.
27) Healthcare professional should check on the device during operation on a regular basis, and he/she should also pay attention to medication solution in the infusion set before starting the device to make sure the right medicine is in the right infusion channel.
28) When using this device, please do not place the power plug or other independent plug in a difficult place when it is used as a disconnecting measure.
29) The needle on the syringe extension line is the application part of this product.
30) While in normal operation, an alarm will be triggered if the pump door is opened. Please contact company for service if this alarm fails to appear.
31) If the sticker on the screw hole is removed, then consider the fact that the pump has been tampered with, and discontinue use.
32) The product is not AP or APG type device and should not be used in flammable gas environment.
33) Don’t near active HF SURGICAL device and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
34) Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such

use is necessary, this device and the other device should be observed to verify that they are operating normally.

35) Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

36) Portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Graseby S20 Plus, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

37) The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the device.

38) The ME device or ME SYSTEM is suitable for professional healthcare facility environments.

39) If the device needs to be used on the move (transport within the hospital): make sure the device is securely fixed and placed. If the device is changed in position, or the pump is severely shaken, the accuracy of the infusion may be affected.

40) Do not use unapproved cleaners, materials or chemicals as they may damage device surfaces, labels, or cause device failures.

41) Do not route LVP supply bag or administration set right above the

pump.

42) Do not route the administration set in a way that presents tripping hazard and administration set break off.

43) Do not change the height of pump during infusion, otherwise the infusion accuracy may be affected.

44) When the device is powered by the internal battery, the charging indicator light is blue; When the device is powered through the net power supply, the external power indicator light will turn green. At this time, if the battery is not fully charged, the charging indicator light will turn green at the same time, and the charging indicator light will not turn on when the battery is fully charged.

45) Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

46) Do not modify this device without authorization of the manufacturer.

47) If this device is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the device.

48) If necessary, please contact the company's customer service staff to provide the relevant information of maintenance.

49) The operator of TCI mode must be an anesthesiologist who fully understands the principles of TCI and has actually operated the TCI pump, and has received training from our company.

50) The default values of target controlled infusion parameters in this device cannot be guaranteed to be applicable to all patients, and the corresponding parameter values must be adjusted according to the actual condition of the patients during use.

51) When TCI mode needs to be used, the operator must read and

understand the prescription information of the drug in advance, and known its clinical characteristics. The drug parameters set must comply with the regulations of the country/region and be consistent with the prescribing information.

52) When using this device for target-controlled infusion, the operator is responsible for the infused drug, and must also be familiar with the blood drug concentration-effect relationship of the selected drug. If necessary, learn and understand the clinical data related to drug parameters, refer to physician prescriptions related to flow rate and infusion volume limitations.

53) Operators need to aware that the interactions between the pharmacokinetics and pharmacodynamics of anesthetic drugs is not considered when calculating plasma and effect compartment concentrations.

54) Compared with plasma targeting, the equilibrium time of using a unified drug for effect chamber targeting is shorter and induction is faster. However, the load of target control in the effect chamber is relatively large. Therefore, for drugs with large side effects and elderly and weak patients, it is recommended to choose plasma concentration as the target concentration.

55) To select TCI mode based on the specific situation of the patient, it is necessary to confirm whether the patient's characteristics, target concentration, and infusion volume are consistent with the prescription information before use.

56) When the TCI mode is activated, it will automatically infuse the pre-calculated infusion volume, and then infuse continuously to reach the set target concentration.

57) In order to avoid accidental use of TCI, please exit the TCI mode in

time after the target-controlled infusion is completed.

58) The plasma concentration and effect chamber concentration displayed on the TCI mode infusion operation interface of this device are predicted values and are only for reference.

59) When using the diluted anesthetic drug, the drug concentration should be set to the diluted concentration.

60) Continuous target-controlled infusion is not allowed for the same patient and same drug.

61) During the operation, if the device crashes or shuts down unexpectedly, after the device is restarted, it is forbidden to re-infuse the drug before the restart.

2 Terms and definitions

Operator: A professionally trained and qualified member of medical staff.

Keep vein open (KVO): After infusion is completed based on the preset parameters, the pump will automatically switch to a mode with extremely low Infusion rate and continue to run (this mode virtually does not have any treatment effect), which is to keep the IV push set and vein unobstructed and to avoid the blood flowing backwards.

Intermediate rate: An infusion rate of 5.00mL/h.

Minimum rate: An infusion rate of 1.00mL/h.

Free-flow: Drug solution is flowing out in an uncontrolled manner under the effect of gravity.

VTBI: Volume to be infusion.

3 Brief Introduction and Scope

3.1 Brief Introduction

Graseby S20 Plus (hereinafter referred to as S20 Plus) is a kind of infusion device, it is mainly consisted of pump housing, motor drive system, input system, storage system, control system, display system, sensor monitoring system, alarm system and power system (adapter).

3.2 Intended Purpose

Intended use: By controlling the flow rate, the syringe pump is intended to be used for intravenous therapy at clinical service facilities on adults, pediatrics for the intermittent or continuous delivery of drug solution, medications via IV infusion route. Light and sound alarms help the users use the pumps properly.

Indication for use: N/A.

Contraindications: None.

Intended patient population: The target population is adults, pediatrics who need intravenous therapy, no other specific requirements.

Intended users of the device: The device is intended to be used by trained healthcare professionals in medical institution environments.

3.3 Benefits

Expected clinical benefit: Syringe pumps provide a variety of advantages compared to manual IV push, such as:

Automated delivery

Precision dosage

Avoiding medication errors

Reducing the workload of nursing staff

Syringe pumps can deliver much smaller amounts of medicine than a manual IV push.

Thus, the use of syringe pumps could provide reliable, automated, contact-free dosing to patients with severe cases, and this helped to ease the burden on ICU nurses and other clinicians without compromising care quality,

3.4 Risks

Syringe pumps appear to enhance overall safety and care quality compared to manual IV administration, they are not without risk. Design issues, software bugs, and user errors continue to compromise patient safety.

We have carry out risk management throughout the design and development stage.

3.5 Side effects

The unintended bolus of medication might cause possible inflammation and pain at the infusion site and potential source of infection.

4 Important Features

1) **Compatible syringe sizes:** A wide range of syringe types can be automatically identified, including 2/3, 5, 10, 20, 30, 50/60mL.
2) **Accuracy:** The accuracy for infusion rate and volume both are kept within 1.5%.
3) **Infusion rate:** Infusion rate can be adjusted from 0.01mL/h to 2300mL/h in a continuous manner, which makes syringe pump

capable of meeting various Infusion rate requirements in different infusion situations.

4) **Touchscreen interface:** Infusion parameters can be set by using the touch screen on the device, even with gloves on.
5) **Electric Drive head:** Use electric drive head to eliminate the mechanical gap when the device is started, so that the first drop of liquid medicine can be injected into the patient's body as soon as possible.
6) **External power supply:** An external power adapter is used, which not only removes the safety concerns of using an internal switching power source but also makes the device lighter and smaller in size.
7) **Battery capacity:** The rechargeable internal high-capacity Lithium battery can support normal operation for 8 hours, which is conveniently helpful during patient transport or power outage.
8) **Display:** LCD touch screen display offers high contrast and great visibility. Clearly visible from 5 meters away.
9) **Occlusion removal:** When the infusion line is occluded, the stepper motor will rotate reversely to release the pressure accumulated in the infusion line.

5 Specifications

5.1 Basic Specifications

Dimensions	277mm×136mm×72mm (width x depth x height)
Weight	1.43 Kg
Power supply	Network power supply: ~ 100V-240 V, 50/60 Hz Internal battery:⎓7.4 V rechargeable Lithium battery
Rate of work	45 VA

Syringe requirements	Refer to Section 11 Precautions for Using Disposable Syringes
Maximum Infusion Rate	2300.00mL/h

5.2 Main Performance

Infusion Rate range	2/3mL: 0.01~100.00mL/h; 5mL: 0.01~150.00mL/h; 10mL: 0.01~400.00mL/h; 20mL: 0.01~600.00mL/h; 30mL: 0.01~1000.00mL/h; 50/60mL: 0.01~2300.00mL/h; step by 0.01mL/h
VTBI range	0.01~9999.99mL, step by 0.01mL
Infusion accuracy	±1.5%
Purge Rate / Bolus Rate	2/3mL: 1~100mL/h; 5mL: 1~150mL/h; 10mL: 1~400mL/h; 20mL: 1~600mL/h; 30mL: 1~1000mL/h; 50/60mL: 1~2300mL/h; step by 1mL/h
Purge VTBI / Bolus VTBI	0.10mL~100.00mL continuous adjustable, step by 0.01mL
KVO Rate	This syringe pump provides two KVO modes to ensure venous patency while guaranteeing infusion safety: **1.Constant KVO Mode** (V_{KVO} rate setting range: 0.10-5.00 mL/h, minimum step value 0.01 mL/h) -When the infusion rate is >V_{KVO} : After the infusion task is completed, the pump

	automatically runs at the V_{KVO} rate to maintain venous patency. -When the infusion rate is ≤ V_{KVO}: After the infusion task is completed, the pump continues to run at the infusion rate to maintain venous patency. **2.Variable Speed KVO Mode** (V_{KVO} rate setting range: 0.10-5.00 mL/h, minimum step value 0.01 mL/h) Users need to set the V_{KVO} rate separately for three scenarios: (a) V_{KVO}(>10) rate for infusion rates > 10 mL/h, (b) V_{KVO}(1-10) rate for infusion rates between 1-10 mL/h, and (c) V_{KVO}(≤1) rate for infusion rates ≤ 1 mL/h. The system will automatically matches the KVO rate based on the infusion rate: -When the infusion rate is > 10 mL/h: After the infusion task is completed, the pump automatically runs at the V_{KVO}(>10) rate to maintain venous patency. -When the infusion rate is between 1-10 mL/h: After the infusion task is completed, the pump automatically runs at the V_{KVO}(1-10) rate to maintain venous patency. -When the infusion rate is ≤ 1 mL/h and the infusion rate is > V_{KVO}(≤ 1) rate: After the infusion task is completed, the pump continues to run at the V_{KVO}(≤1) rate to maintain venous patency.

	-When the infusion rate is ⩽ 1 mL/h and the infusion rate is ⩽ V_{KVO}(⩽ 1) rate: After the infusion task is completed, the pump continues to run at the infusion rate to maintain venous patency.
Time setting range	00:00:00~99:59:59, step by 00:00:01.
Occlusion threshold	12 levels, with the lowest being 20kPa ± 20 kPa, and the highest being 130 kPa ± 20 kPa.
Maximum infusion pressure generated by the device	150kPa
Triggering time of occlusion alarm and Bolus	When operated at minimum flow rate(1.00mL/h): < 1 h when the occlusion alarm pressure threshold is set to the lowest pressure; or < 3 h 30 min when the occlusion alarm pressure threshold is set to the highest pressure. When operated at intermediate speed(5.00mL/h): < 15 min when occlusion alarm pressure threshold is set to the lowest pressure, and the Bolus produced during occlusion is < 0.20mL; < 45 min, when the occlusion alarm pressure threshold is set to the highest pressure, the Bolus during occlusion is not more than 0.50mL. (Tested when an occlusion was created 1 meter away from the syringe outlet)
Syringe brand	6 brands of syringes are recommended, including Kangjin, Wego, Kindly, BD, Shinva, B.Braun. 10 brands can be customized.
Supported infusion modes	11 modes; RVT mode, Drug Library mode, Loading Dose mode, Micro mode, Dose mode,

	RTM mode, Sequence mode, Intermittent mode, Relay mode, TCI mode, TIVA mode.
Syringe sizes	2/3mL, 5mL, 10mL, 20mL, 30mL, 50/60mL
Battery life	When fully charged, the battery can run continuously for 8h10min in maximum rate(2300.00mL/h).
WIFI	The device has WiFi function, which can transmit data with the "InfuseDirect" APP.
Alarm Mute Time	2 min ± 10s
Call Back Time	1 min ~ 60 min ± 10s
Classification	Type II CF continuous operating volumetric syringe pump with internal power supply; Grade IP44, Non AP, APG.
Ambient temperature and humidity	Ambient temperature of transportation and storage: -20 ℃ ~ + 55 ℃ Ambient temperature for operation: 5℃ ~ + 40 ℃ Ambient humidity for transportation, storage and operation: 20% ~ 90% Ambient pressure for transportation, storage and operation: 700 hPa ~ 1060 hPa
Software version	S20 Plus_V1
Service lifetime	8 years

5.3 Main Functions and Common Functions

1) Automatic identification for syringe size
2) Set infusion flow rate, injection volume preset and real-time data display function
3) Displays the function of remaining injection volume and remaining injection time
4) Purge/Bolus

5) Alarms
6) The flow rate will be automatically changed to KVO flow rate after the VTBI complete alarm is activated
7) Temporary mute for alarm sound and timer for alarm sound recovery
8) Displays the accumulated quantity injected and supports clearance
9) A variety of brands for syringes are supported
10) Built-in battery, Display battery remaining
11) External power adapter
12) Wi-Fi connectivity
13) Contains Dose-Error Reduction Software
14) Support manual installation, automatic installation, manual-auto installation of syringes
15) TCI infusion mode

6 Structure and Operation Interface

6.1 Structural Composition

The structure of the device consists of a pump casing, a motor drive system, an input system, a storage system, a control system, a display system, a sensing and monitoring system, an alarm system and a power supply system.

Names for parts and components:

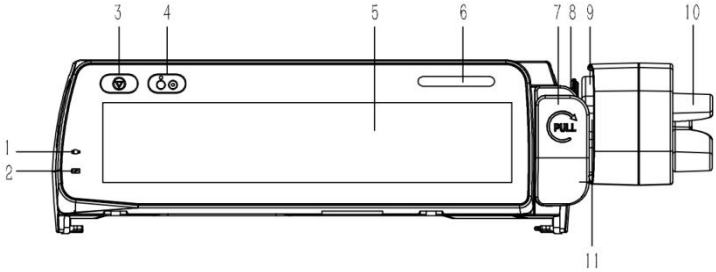


Figure 6-1-1 Front view

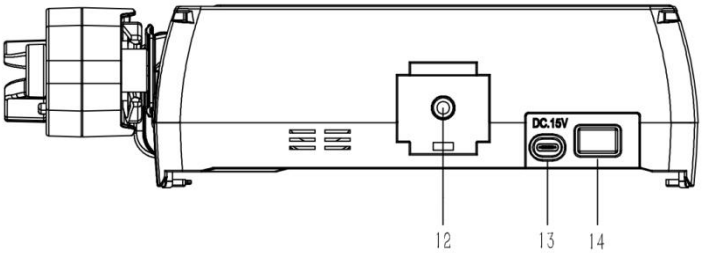


Figure 6-1-2 Rear view

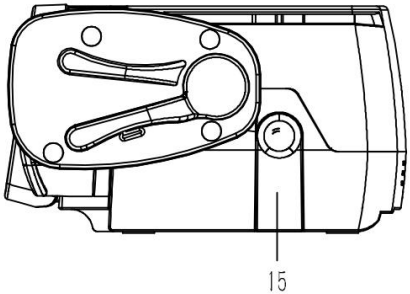


Figure 6-1-3 Side view

1	External power indicator	2	Charging indicator	3	Start-Stop key
4	Power On/Off key	5	Touch screen display	6	Operation status indicator
7	Syringe	8	Syringe in-place	9	Swinging arm

	clamp		detection		
10	Swinging arm button	11	Syringe pressure plate	12	Locking screw
13	Power interface	14	Data Communication port	15	Stack slot

6.2 Display and Operation Interface

Operation interface is as below, click "switch" icon to switch to different screens

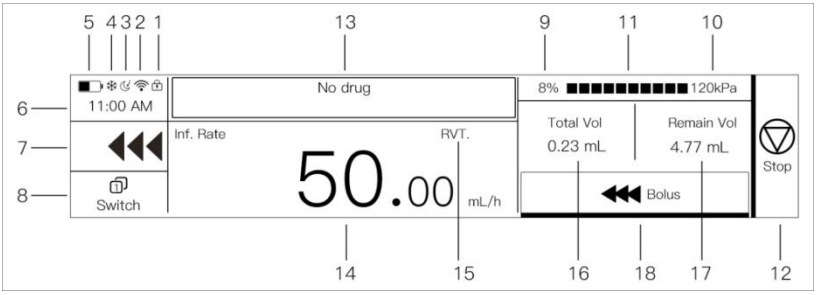


Figure 6-2-1 Operation interface on the screen1

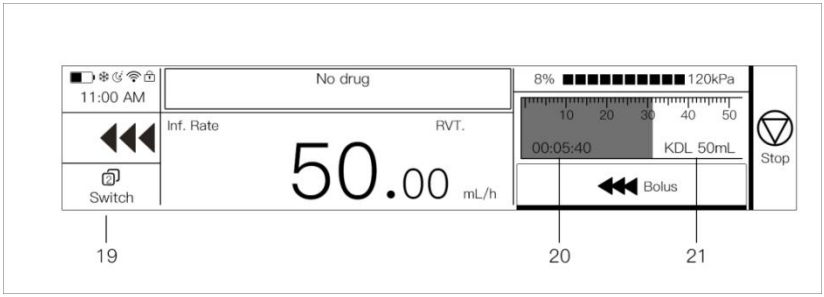


Figure 6-2-2 Operation interface on the screen2

1	Screen lock	2	WiFi	3	Night mode
4	Low temperature	5	Battery	6	Time
7	Infusion status	8	Switch	9	Current occlusion

					pressure percentage
10	Upper occlusion pressure limit	11	Occlusion pressure bar	12	Start/Stop button
13	Drug name	14	Infusion rate	15	Infusion mode
16	Infused volume	17	Remaining volume	18	Purge/Bolus
19	Switch	20	Time remaining	21	Syringe size

7 Operation Instructions

Install syringe pump → Power on → Device safety self-test → Install syringe → Select syringe brand → Parameters setting → Prime / Purge → Start infusion → Infusion completed → Remove accessories → Power off.

The brand of syringe used in this device for the first time must be calibrated before being used.

7.1 Installation of Syringe Pump

First loosen the locking screw, install the clamp to the pole of the infusion stand, adjust the height of the clamp, and then tighten the locking screw.The operator must make sure that the syringe pump is positioned in a secure, stable and reliable manner.

7.2 Power on and Device Safety Self-test

7.2.1 Power on and off

Before connecting to the mains power, check if there is any foreign matter inside the power outlets (such as drug solution residue).

Connect to the mains power, check the power indicator on the pump front panel. If the indicator is not lit up, check the connection of power cable and the pump, or check if there is a power outage. Then press the power Key on the front panel to turn the device on.

After infusion therapy is completed, press the power key and click Power-Off button to turn the device off. Do not power off when the device is in operation mode, otherwise the infusion therapy will be stopped.

Please remove the syringe before turning the device off.

7.2.2 Device safety self-test

The pump will perform an automatic safety self-test after powered on, if the test is passed then there will be two short beeps and the operation status indicator will be lit up in stable green color. If a continuous alarming sound is initiated or there is no any sound at all, then the device cannot be used, please contact the customer service immediately.

7.3 Quick Use Guide

7.3.1 Install / Replace syringe

After the device is power on, the electric drive head will automatically move to the far right to facilitate the next step of loading the syringe.

Open the syringe pump door, pull the syringe clamp out and turn it clockwise for 90° to the horizontal position, place the syringe barrel flange in the slot between the pump casing and the syringe press plate, pull the syringe clamp out again and turn it counterclockwise for 90° to the upright position, release it to clamp

the syringe tight in position; straighten the syringe extension line, place it inside the hook behind the pump door to prevent it from being pressed, then close the pump door. When the device detects that the syringe clamp pressed the syringe, the drive head automatically moves from right to left to the place where the syringe presses the hand.

As disposables, syringes must be replaced after being used for once.

When replacing the syringe, the device should be in the stopped state. Pinch and hold the finger grips on the drive head, slide it to the right and release the finger grips, pull the syringe clamp out and rotate it 90° clockwise, remove the syringe and the extension line.

7.3.2 Select syringe

After the syringe pump is powered on and the safety self-test is passed, Syringe specifications will be monitored continuously. When the syringe is properly installed, the syringe brand confirmation page will be entered. The brand and model of the syringe will be identified and displayed on the screen. You can also click the Brand button in the upper right corner to enter the syringe brand selection page.

It is possible that the syringes from the same brand may have different characteristics if they are from different lots, which will affect their infusion accuracy if they are not calibrated before use. In that case, calibration of the syringe is recommended, which is described in Section 10.2 Accuracy Calibration for Syringes.

Figure 7-3-2 Syringe brand confirmation

7.3.3 Set infusion parameters

Click "Infusion rate" on the screen to enter the infusion rate change page. After entering the flow rate, click " √ " button.

Setting the preset amount and total time is the same as setting the infusion rate above. After setting, click the " √ " button to confirm the parameters.

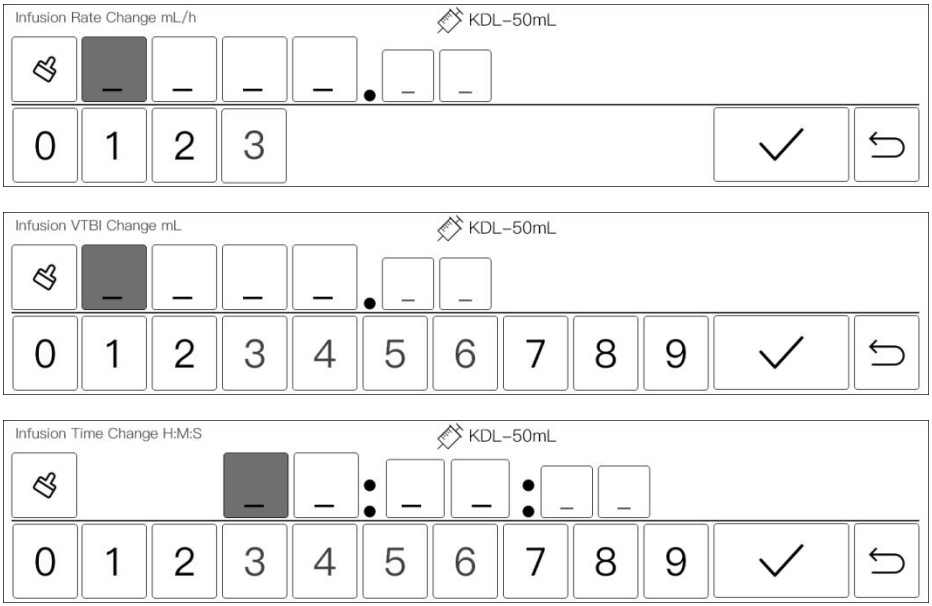


Figure 7-3-3 Set infusion parameters

7.3.4 Purge

After setup the infusion parameters, click the "Start infusion" button, the device will pop up a page to confirm purge, click the "Confirm" button on the screen, the device will purge at the set amount, and quickly empty the air in the infusion line (click the "Stop purge" button to stop).

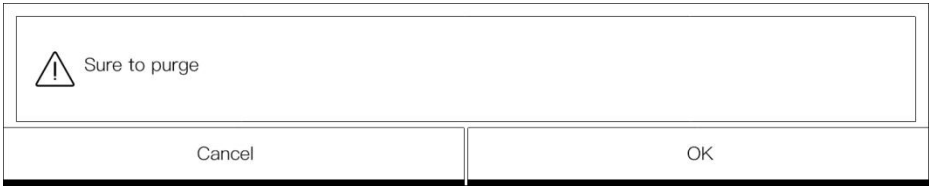


Figure 7-3-4 Confirm to purge

After complete the purge, the infusion pause screen will be displayed. If there are still air bubbles in the infusion line, click the "Purge" button to purge again and repeat the above operations until there are no air bubbles.

The purge volume is not included in the Infusion accumulation.

7.3.5 Start infusion

In the infusion pause interface, click the "Continue infusion" button, and the device will run according to the set infusion parameters, as shown in the figure below.

When the device is running, once the flow rate is revised, the electric motor synchronously changes the voltage to increase the motor speed, so that the pump synchronously reaches the revised flow rate.

Figure 7-3-5 Infusion operation interface

7.3.6 Infusion completed

The infusion is completed when the infusion accumulation volume reaches the VTBI set for the infusion task, the device triggers the "infusion complete" alarm and emits an alarm sound at the same time. Click the "Confirm" button to eliminate the alarm.

If KVO is enabled, the device will convert to the KVO Rate to continue running automatically and trigger the "Enter KVO" high priority alarm at the same time, make an alarm sound. Click the " √ " on the screen to exit the KVO infusion status.

After the infusion is completed, remove the infusion accessories that are no longer used following the steps described in Section 7.3.1. Press the power on/off key, click power-off button to turn off the device. Pull the ring on the base of the mounting clamp upward and pull the syringe pump body outward to remove it.

7.4 Pause or Stop Infusion

Press the Start/Stop key during infusion operation can pause

the operation, as shown in the following figure.

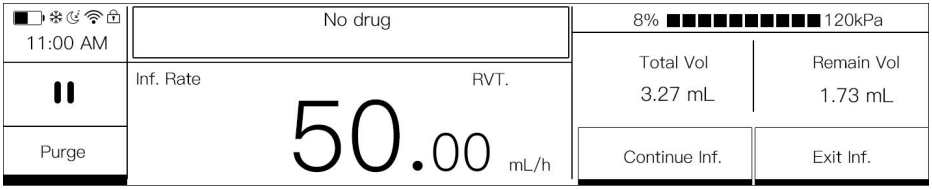


Figure 7-4 Infusion pause

On the Infusion pause page, press the Start/Stop key again can start the device operation, and the device will will continue to infuse the remaining volume based on the set Infusion rate. If click the "Exit Infusion" button, the device will be back to the infusion mode selection interface, then you can reset the infusion parameters and start a new infusion task.

7.5 Bolus

In the infusion operation state, click the "BOL" button, enter the Bolus page. If select "Last bolus", the device will start bolus according to the last bolus parameters; If select "Automatic bolus", the device will switch to the bolus parameter setting page. After setting and confirming the bolus parameters, click the "Start bolus" button, and the syringe pump will enter the bolus state. When the bolus dose reaches the set value, the bolus will be stopped, and the syringe pump returns back to the normal infusion state to continue infusion, and the bolus dose is included in the infusion accumulation.

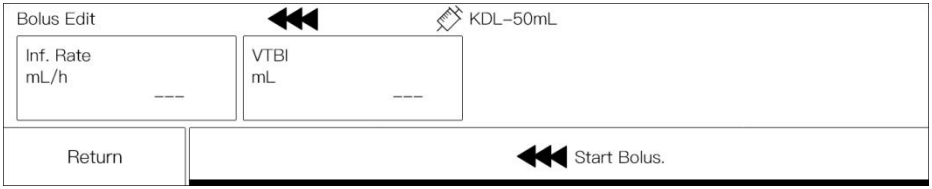


Figure 7-5-1 Bolus Settings interface

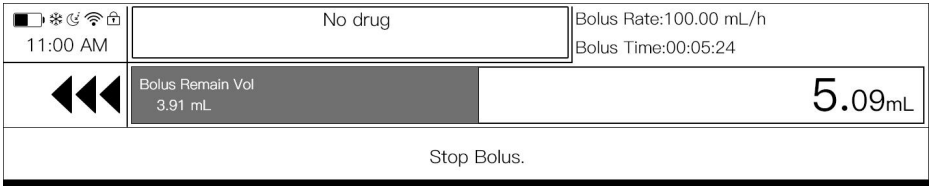


Figure 7-5-2 Bolus Start interface

7.6 Lock and Unlock Screen Function

The device automatically locks the screen after running for a period of time. When the device is in the lock screen, click the screen and a prompt will pop up asking whether to unlock the screen, click to unlock the screen.

Auto Lock time settings See Home - Setting - Auto Screen Lock.

7.7 Infusion Mode Selection and Setting

Expect for the RVT mode on the home screen, there are 10 infusion modes on the Infusion mode - Other mode page: Dose mode, Drug Library mode, RTM mode, Sequence mode, Loading Dose mode, Intermittent mode, Micro mode, Relay mode, TCI mode, TIVA mode.

In the RVT setting page, the infusion rate, VTBI and infusion time can be set in a variety of combinations, forming the following

four combinations of infusion mode: rate + volume (R+V) Mode, rate + time (R+T) Mode, volume + time (V+T) Mode, rate (R) Mode. Therefore, there are 13 different infusion modes for the device in total.

The setting of the RVT mode should follow the instructions in the "Quick Use Guide" above. The settings for the other modes are outlined in that section.

7.7.1 Dose mode

Enter the Dose mode settings interface, as shown in the following figure.

Set the dose, solution, concentration, weight, dose rate, infusion rate, preset VTBI, and total time respectively. Click the "Confirm" button to confirm the infusion parameters.

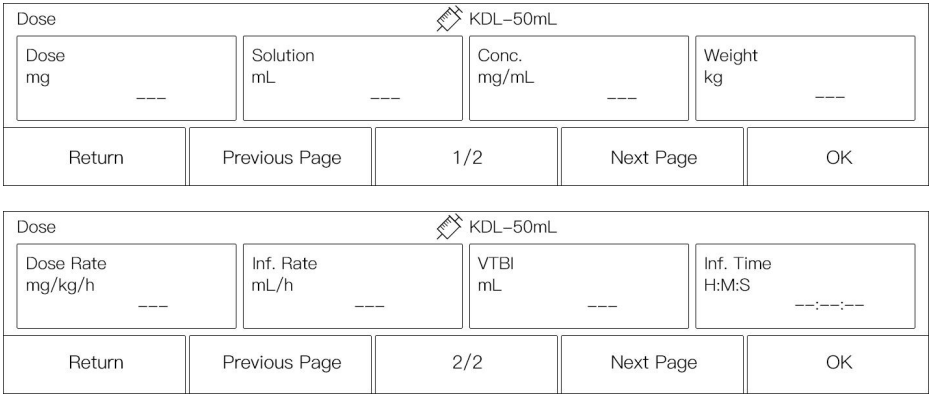


Figure 7-7-1 Dose mode setting

In the Dose Mode Settings interface, click "Unit" to the right of any parameter in "Dose", "Concentration" and "Dose Rate" to select different unit expression modes, and the other two corresponding units will be automatically adjusted.

Concentration and Infusion Rate are calculated as follows:

Concentration calculation formula:

$$\text{Concentration (mg/mL)} = \frac{\text{Dose（mg）}}{\text{Solusion（mL）}}$$

Infusion rate calculation formula:

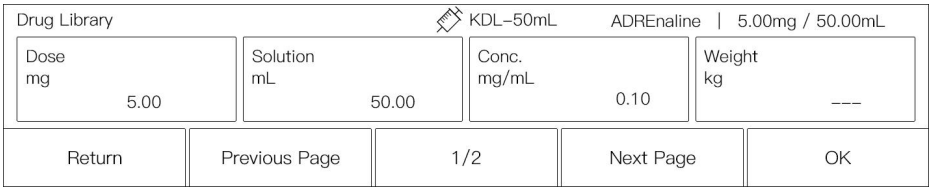
$$\text{Infusion rate(mL/h)} = \frac{\text{Dose rate（mg/kg/h）} \times \text{weight（kg）} \times \text{solution（ml）}}{\text{Dose（mg）}}$$

$$\text{Infusion rate(mL/h)} = \frac{\text{Dose rate（mg/h）} \times \text{solution（ml）}}{\text{Dose（mg）}}$$

7.7.2 Drug Library mode

Enter the drug library mode settings interface.

Select the name and the specific specifications of the drug that requires infusion. The device will enter the drug library mode settings page and automatically brings in the drug-related parameters. At this point, the drug name and drug specifications are displayed in the title bar of the parameter settings page. After setting the parameters, click "Confirm" to confirm the parameters.



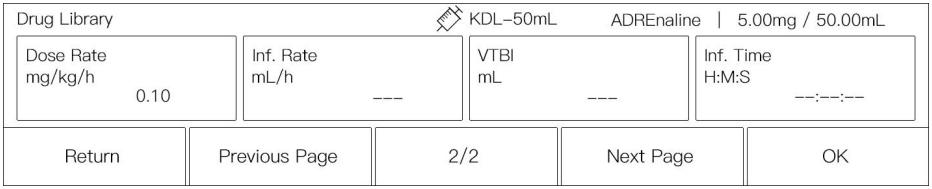


Figure 7-7-2 Drug library mode setting

The Drug library mode has built-in DERS (Dose-error Reduction Software) functionality to reduce medication errors and improve infusion safety.

7.7.3 RTM mode

Enter the RTM mode(Ramp and Taper Mode) settings interface, as shown in following Figure.

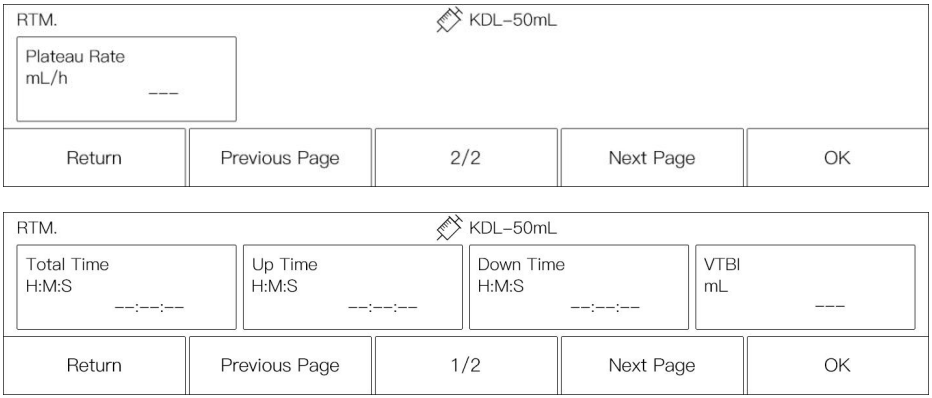


Figure 7-7-3 RTM mode setting

In the RTM mode parameters, VTBI, Up Time, and Down Time must be set. After setting one of the two parameters of Plateau rate or Total Time, the other parameter will be calculated automatically. After setting the parameters, click " √ " to confirm the parameters.

When the device is started, the infusion rate gradually increases from 0 to Plateau Rate during the Up Time and then

maintains the rate. When the remaining time is equal to the Down Time, the infusion rate gradually decreases until it reaches 0 and the infusion is completed.

7.7.4 Sequence Mode

Enter the Sequence Mode settings interface to set the number of sequences (up to 10 groups), click the "∨" button to enter the infusion parameter settings interface, as shown below.

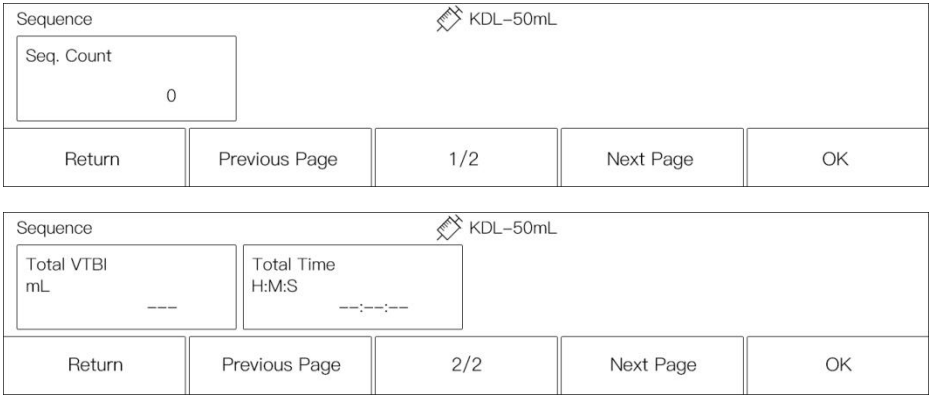


Figure 7-7-4 Sequence Mode Setting

As shown in the figure, Set any two of the Infusion VTBI, Infusion Rate, Infusion Time, the device will automatically calculate another parameter.

Click the "Next page" button, set 1 to 9 different infusion parameters according to clinical needs, view the total preset amount and total time, and click the "Confirm" button to confirm the infusion parameters.

After the device completes the first set of infusion parameters, it automatically switches the flow rate to complete the second set of parameters until all set parameters are completed and infusion

ends.

7.7.5 Loading Dose Mode

Enter the Loading Dose mode settings interface as shown in below picture.

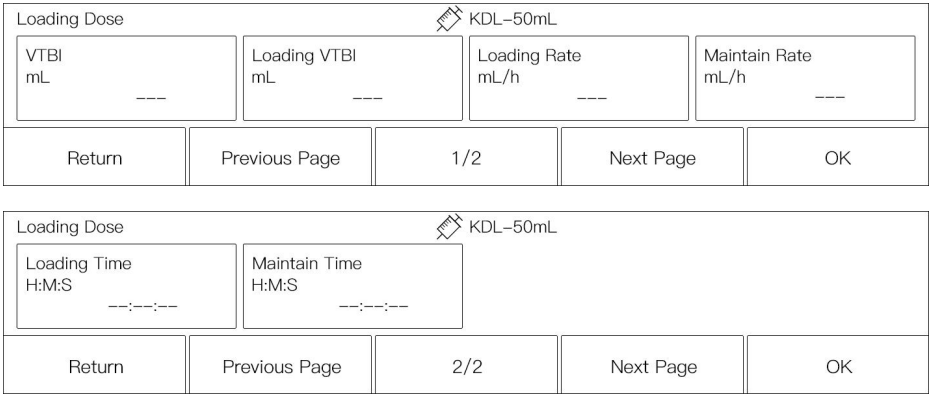


Figure 7-7-5 Loading Dose mode setting

As shown in the figure, After setting the VTBI, Loading VTBI, Loading Rate, and Maintain Rate, the device automatically calculated the Loading Time and Maintain Time, and click the "Confirm" button to confirm the infusion parameters. After the device is started, infusion starts according to the induced flow rate. When the cumulative infusion amount reaches the induced preset amount, it automatically continues infusion according to the maintained flow rate. When the cumulative infusion amount equals the preset amount, infusion is completed.

7.7.6 Intermittent mode

Enter intermittent mode settings interface.

As shown in the figure, set the Single VTBI, Single Rate,

Intermittent Time and Maintain Rate, and click the "√" button to confirm the infusion parameters. After the device is started, the infusion will start at the Single Rate. When the infused volume is equal to the single VTBI, the device will automatically continue infusion according to the Maintain Rate. When the Maintain Rate is set to 0, the device will run at 0mL/h. The device runs at Maintain Rate until the time is equal to the Intermittent Time, the device automatically switches to the Single Rate to continue the infusion, so as to cycle.

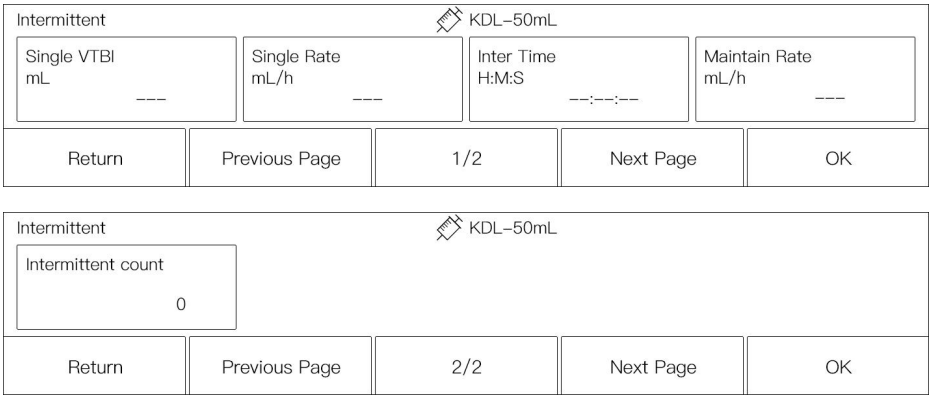


Figure 7-7-6 Intermittent mode setting

7.7.7 Micro mode

Enter Micro mode settings interface, as shown in the following figure.

Set any two of the Infusion Rate, VTBI, and Infusion Time, the device will automatically calculate another parameter. The Infusion Rate should not exceed 100mL/h. After the device is started, the infusion starts at the preset Infusion Rate. When the infused volume is reached to the VTBI, the infusion will be stopped

automatically.

When the user only sets the Infusion Rate, the device runs at the Infusion Rate until the operator stops the infusion or the device triggers a high priority alarm to stop the infusion.

Figure 7-7-7 Micro mode setting

7.7.8 Relay mode

The Syringe Pumps can be installed on our infusion workstation for advanced functions such as relay infusion and drug library management through the Infusion Information Collection System.

7.7.9 TCI mode

TCI mode is an auxiliary drug administration function developed based on the pharmacokinetic model. Anesthesia professionals select the pharmacokinetic model and set the target concentration of anesthetic drugs, and adjust the target concentration according to the clinical drug effect during the drug administration process to achieve clinical drug administration.

Pharmacokinetic models (PK models) are mathematical models used to predict changes in blood drug concentration after a single injection or continuous infusion over a period of time.

After the drug is injected intravenously into the blood, it will

spread, and the targeted space for diffusion is called the compartment. The syringe pump is based on the algorithm of the three-compartment pharmacokinetic model to calculate the infusion speed needed to achieve and maintain the target concentration. V1 is the central chamber (the chamber where drugs are injected), V2 is the chamber with a fast exchange rate with the central chamber, and V3 is the chamber with a slow exchange rate with the central chamber. Drug transport (distribution) between chambers was expressed by velocity constant (k12, k21, k31, and k13) or clearance rate cl1, cl2, cl3.

According to the target concentration setting site, TCI mode can be divided into two infusion modes: plasma target control and effect-ventricular target control.

When the plasma target control mode is selected, the user can set the plasma drug concentration and then calculate the infusion speed required to achieve the set concentration through the pharmacokinetic model. The corresponding model is shown below:

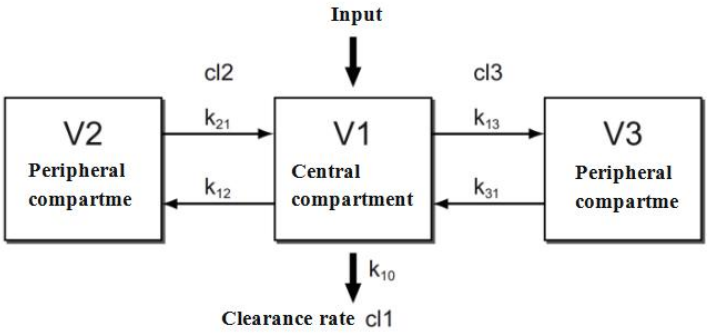


Figure 7-7-9-1 Plasma target control model

When the effect-compartment target control mode is selected, the user can set the effect-compartment target concentration, and

then obtain the infusion speed required to reach the set concentration through the pharmacokinetic model. The corresponding model diagram is as follows:

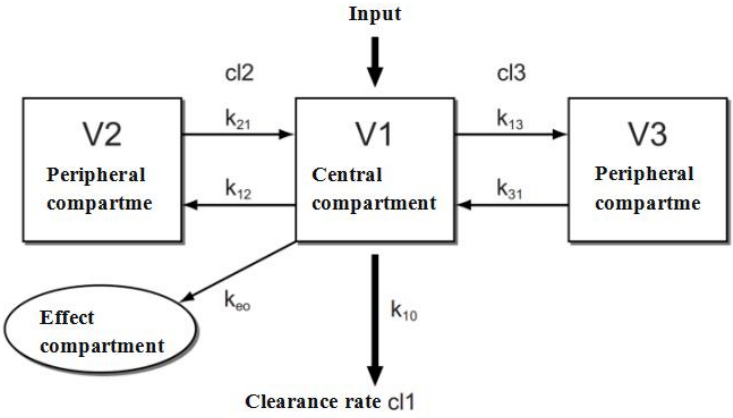


Figure 7-7-9-2 Effect location-based control model

To set the TCI mode, perform the following steps:

Select the TCI mode setting screen, as shown in the following figure:

Select the drug and specification, and the device enters the TCI parameter setting interface, as shown in the figure:

Figure 7-7-9-3 TCI parameter setting page 1

Figure 7-7-9-4 TCI parameter setting page 2

Select the target control model and method, set parameters such as concentration, height, weight, age, target concentration, maximum flow rate and P-Limit, and then click "√" to enter the parameter calculation result interface.

Note: Target-P refers to plasma Target control and target-e refers to effector ventricular Target control. Only effect-room target control has the P-Limit parameter setting option.

After confirming that the parameters of induction dose, induction preset amount and induction time are correct, click "Back" to enter the main infusion interface.

Note: In the plasma target control mode, the induction time is the time when the plasma concentration reaches the target concentration.

In effect-chamber target control mode, the induction time was the time when the effect-chamber concentration reached the highest concentration and the infusion was suspended.

Click the "Start and Stop" button on the device to start TCI infusion. After entering the infusion operation interface, you can view the drug name, target concentration, real-time infusion speed, Cp (plasma concentration) /Ce (effector chamber concentration), time accumulation and other parameters.

During operation, the target concentration can be modified.

After modifying the target concentration, the TCI will recalculate and update the parameter information.

After clicking " " in the middle during infusion, you can view the TCI curve, where x axis represents time and y axis represents target concentration.

Click the "Start and Stop" button on the device to suspend the infusion. Pause the infusion screen and click the HOME button or Edit button on the screen. "Do you want to exit TCI mode?" will appear. On the prompt screen, click "√" to exit TCI mode.

The drug model and parameter setting range supported by the device for TCI infusion are as follows:

Table 1 Drug model and target control mode supporting TCI infusion

Drug names	Model Name	Plasma target control	Effect chamber target control
Propofol	Marsh	○	×
	Schnider	○	○
	Kataria	○	×
	Paedfusor	○	×
Remifentanil	Minto	○	○
Sufentanil	Gepts	○	○
Alfentanil	Maitre	○	○
"○" means yes, and "×" means no.			

Table 2 Drug models supporting TCI infusion and parameter Settings

Drug names	Model Name	Set up parameters
Propofol	Marsh	concentration:5.00-20.00mg/mL Age:⩾16 Target concentration: 0.01-15.0ug/mL Max Rate: Same as 5.2 rate setting

		range
	Schnider	concentration:5.00-20.00mg/mL Height:130-220cm Gender:Male/Female Age:25–81 Target concentration: 0.01-15.0ug/mL Max Rate:Same as 5.2 rate setting range P-Limit:100-999%
	Kataria	concentration:5.00-20.00mg/mL Age:3-16 Weight: 15.00-61.00Kg Target concentration: 0.01-15.0ug/mL Max Rate: Same as 5.2 rate setting range
	Paedfusor	concentration:5.00-20.00mg/mL Age:1-16 Weight: 5.00-61.00Kg Target concentration: 0.01-15.0ug/mL Max Rate: Same as 5.2 rate setting range
Remifentanil	Minto	concentration:20.00-50.00ug/mL Height:130-220cm Gender:Male/Female Age:20–85 Target concentration: 0.01-20.0ng/mL Max Rate: Same as 5.2 rate setting range P-Limit:100-999%
Sufentanil	Gepts	concentration: 0.20-5.00ug/mL Age: 14–68 Weight: 47-94 Kg

		Target concentration: 0.01-5.00ng/mL Max Rate: Same as 5.2 rate setting range P-Limit: 100-999%
Alfentanil	Maitre	concentration:100.00-500.00ug/mL Age: 19-91 Weight: 46-102 Kg Gender: Male/Female Target concentration: 0.01-500.00ng/mL Max Rate: Same as 5.2 rate setting range P-Limit: 100-999%

7.7.10 TIVA mode

TIVA (total intravenous anesthesia) is a mode of intravenous anesthesia administration. It controls the infusion rate of intravenous anesthesia drugs via a computer to maintain the concentration of the drug in the plasma or effect chamber within a preset target range. This mode can precisely control the depth of anesthesia, reduce drug waste, and improve the safety of surgery.

TIVA mode is widely used in various surgeries requiring precise control of the depth of anesthesia, such as neurosurgery, heart surgery, etc. Due to its ability to provide a stable anesthetic effect and reduce drug fluctuations, the TIVA model has significant advantages in improving surgical success rates.

Select to enter the TIVA mode setting interface, as shown below.

Set the weight, induction dose, and any two parameters of dose,

solution, and concentration to automatically calculate the left parameter value; Setting any of the induction time and induction flow rate parameters can automatically calculate the left parameter value; By setting any of the parameters for maintaining dose rate and flow rate, another parameter value can be automatically calculated.

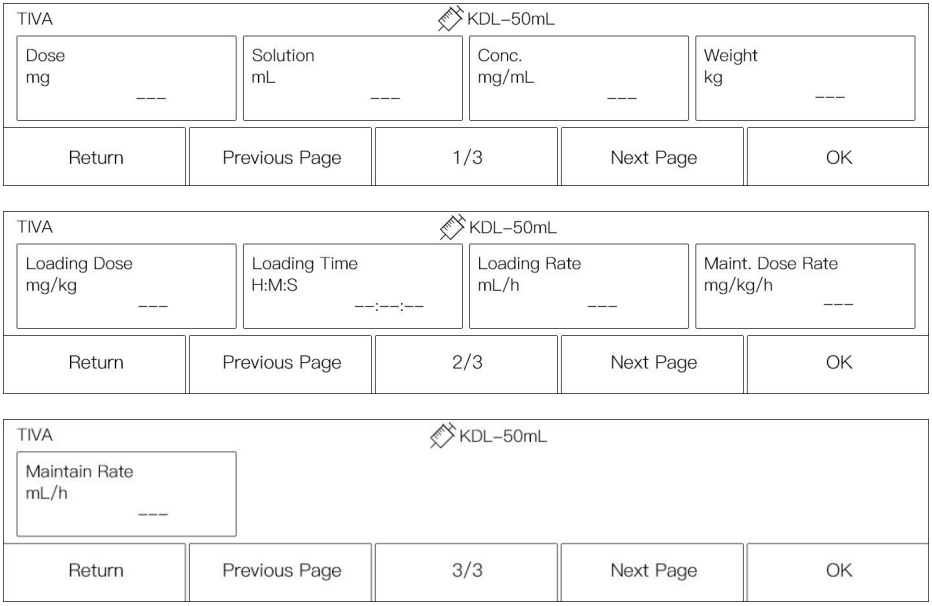


Figure 7-7-10 TIVA mode setting

7.8 View Log

In the Home Menu - Event log page, you can view the device infusion status and alarm log information. Click the log to view the detailed information. Example: infusion rate, infusion volume, recorded time, Alarm time, etc.

When the pump log storage reaches the upper limit of the pump capacity, the oldest log will be overwritten by the new log.

Through the infusion workstation, all infusion and alarm logs can be stored and queried without limitation, and the logs can be printed out once needed.

Once the alarm system is powered off, the log still exists.

Once the alarm system loses internal and external power (battery and network power are disconnected at the same time) for a limited time, the logs will not change.

Figure 7-8 View logs

8 Alarms

Alarm refers to the infusion changes caused by the abnormal infusion circuit or the failure of the syringe pump itself, which leads to the failure of the infusion to the patient. The syringe pump prompts the medical staff through sound, light, screen signs and other ways.

Alarm classification prompts of the device:

No.	Alarm	Priority	Alarm category	Alarm condition
8.1	No syringe	High	Latching	1. Syringe fall off. 2. The syringe rear barrel ear is not mounted between the syringe pump housing and the syringe

				pressure plate.
8.2	OCCL (Occlusion)	High	Latching	When the infusion line is occluded.
8.3	Empty Of Syringe	High	Latching	When the syringe is pushed to the end.
8.4	End Of Infusion	High	Latching	When the infused volume reaches to the VTBI.
8.5	Pusher Setup Fail	High	Latching	When pump is running, the syringe push handle without touch the pressure conduction block.
8.6	Battery empty	High	Latching	When the internal battery is running out.
8.7	Battery & External Power disconnect	High	Unlatching	When the device is running, the battery and external power is disconnected at the same time.
8.8	Motor Err.	High	Latching	when motor failure
8.9	Pusher Position Error	High	Latching	The infused volume exceeded the expected volume during the machine is running.
8.10	Battery error	High	Latching	The device does not detect battery signal or battery disconnect when plug in the external power.

8.11	KVO	High	Latching	The infusion is complete with KVO is enabled.
8.12	KVO end	High	Latching	KVO status run for 30 minutes until the KVO task is complete.
8.13	Standby End	High	Latching	When standby is end.
8.14	Com. Err. (Communication error)	High	Latching	Monitor the CPU for communication handshake errors.
8.15	Call Back	Low	Unlatching	The device is ready to start the infusion, but the device is not started and the device is placed without operation for the set time.
8.16	Low battery	Low	Unlatching	When the internal battery power is low.
8.17	Near Empty Of Syringe	Low	Unlatching	When the remaining time is less than or equal to the set near end of infusion time.
8.18	Near Empty Of Syringe	Low	Unlatching	The remaining volume of the syringe is less than 10% or the time from emptying is less than 3 minutes.
8.19	No AC Power	Low	Unlatching	When the device is disconnected from the

				external power and operated with batteries.

The device alarm indicator characteristics:

Alarm priority	Indicator color	Flicker frequency		Rate
High priority	Red	2Hz	0.7Hz (Battery & External Power Disconnect)	50%
Medium priority	/	/		/
Low priority	Yellow	Normally turned on		100%

High-priority and low-priority alarms are distinguished in sound and light according to standard requirements. When an alarm occurs, the operator can accurately detect it at 1m away from the alarm system. The delay time of triggering the alarm signal is not more than 2s.

After powering on, the status indicator lights up, and the device automatically conducts a safety check. After passing the self-check, you will hear two short beeps of "DiDi", which means that the alarm system is normal. If the status indicator does not light up or you hear a continuous alarm sound or no prompt sound after booting, it means that the alarm system is faulty and the device cannot be used normally. It can be put into use after being repaired.

The sound pressure range of the audible alarm signal is 60-95dB.

Note that this device prohibits access to the change or storage change alarm function. In the process of adjusting the alarm limit or alarm preset, the operation of the alarm system still runs according to the last setting. This device alarm is a technical alarm state.

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Caution

Latching alarm signal: The alarm signal that continues to be generated after the trigger event no longer exists, and does not stop until the operator deliberately acts (click the " √ " button);

Unlatching alarm signal: When the related trigger event is no longer When it exists, automatically stop the alarm signal generated.

Device alarm announcement sequence:

High priority alarm sound priority principle, that is, when the device is in the low priority alarm sound state, when a high priority alarm is generated, the original low priority alarm sound is interrupted, the high priority alarm sound is broadcast, and the high priority alarm sound is displayed at the same time Level alarm prompt information.

The device is in a high priority alarm. When a low priority alarm is generated, the high priority alarm continues to broadcast without being interrupted.

The device is in low priority alarm. When a low priority alarm is generated, it still reports a low priority tone and displays the latest alarm prompt information.

The device detects that a visual alarm and an audible alarm appear immediately.

When the power loss time is less than 5 seconds, the alarm settings before the power loss will automatically restore.

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8.1 No Syringe Alarm

Cause: When the syringe clamp is accidentally pulled open while the device is running, or when the syringe rear clamp is not installed between the syringe pump casing and the stopper plate, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "No syringe" and the operation status indicator flash red at the same time.

Solution: Click the "Confirm" button on the screen to eliminate the alarm, the message " No syringe " disappears, and returns to the infusion pause interface. Check the syringe clamp and reinstall the syringe to continue using.

8.2 Occlusion Alarm

Cause: When the infusion line is occluded, occlusion sensor detects that it is exceeding the set value, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "OCCL" and the operation status indicator flash red at the same time.

At the same time, as a infusion safety protection mechanism, the motor reverses back to pump a small amount of liquid medicine to reduce the dose of the bolus before occlusion relief.

Solution:

1) Click the "Confirm" button on the screen to clear the alarm and the message " OCCL " disappear.
2) Check whether the syringe extension line is kinked, whether the patient presses into the syringe extension line and other issues, eliminate the problem and restart the infusion.
3) If there is still an occlusion alarm, remove the syringe, replace the syringe and restart the infusion.

8.3 Empty Of Syringe Alarm

Cause: When the remaining liquid amount of syringe is 0, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Empty Of Syringe" and the operation status indicator flash red at the same time.

Solution: Click the "Confirm" button on the screen to clear the alarm and the message "Empty Of Syringe" disappears. After reinstalling a new syringe with enough of the same drug, press the Start/Stop key or click the start button to complete the remaining infusion tasks.

8.4 End Of Infusion Alarm

Cause: If KVO is disabled, When the infused volume reaches the VTBI, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "End Of Infusion" and the operation status indicator flash red at the same time.

As a security mechanism, If KVO is enabled, the device will automatically convert to KVO Rate to continue the infusion.

Solution: Click the "Confirm" button on the screen to clear the alarm and the message "End of Infusion" disappears. The device can be set up and used again.

8.5 Pusher Setup Fail Alarm

Cause: When the syringe pump is running, the finger grips of the drive head was accidentally pinched and pulled out, result in

the syringe push handle without touch the pressure conduction block, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Pusher Setup Fail" and the operation status indicator flash red at the same time.

Solution: Click the "Confirm" button on the screen to clear the alarm sound and the message "Pusher Setup Fail" disappears. Check the drive head, reinstall the syringe to continue using.

8.6 Battery Empty Alarm

Cause: When the internal battery is running out, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Battery Empty" and the operation status indicator flash red at the same time, and the device will stop running and power off after 3 minutes.

Solution: The external power supply should be used immediately. When plugged in the external power supply, the battery charge light goes on and the battery starts charging. When the battery is fully charged, the battery charge indicator goes out.

8.7 Battery & External Power Disconnect Alarm

Cause: When the syringe pump is running, the external power is disconnected, and the device does not detect the battery signal or the battery is disconnected unexpectedly, the device will trigger an alarm, the screen is black, the operation status indicator flash red at the same time, and the sound and light continue to alarm for 3 minutes before the device automatically power off.

Solution: Use external power supply or battery supply, and

restart the device after power supply.

8.8 Motor Error Alarm

Cause: When an error is detected in the motor feedback signal (too slow or too fast, or wrong direction of motor operation etc.), or the sensor detection of push handle position does not match the cumulative amount of infusion, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Motor Error" and the operation status indicator flash red at the same time.

Solution: Click the "Confirm" button on the screen to clear the alarm. Start the infusion again, still report the fault alarm, please contact our service personnel.

8.9 Pusher Position Error Alarm

Cause: When the syringe pump is running, the infused volume exceeded the expected volume, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Pusher Position Error" and the operation status indicator flash red at the same time.

Solution: Click "Confirm" button on the screen to clear the alarm sound. Check the drive head and syringe specifications, reinstall the syringe to continue using.

8.10 Battery Error Alarm

Cause: When the external power is inserted on the device, the device does not detect the battery signal or the battery is

disconnected unexpectedly, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Battery Error" and the operation status indicator flash red at the same time.

Solution: Click "Confirm" button on the screen to clear the alarm sound. Press the Power on/off key to shut down the device and restart the device. If the fault alarm is still reported, please contact our service personnel.

8.11 KVO alarm

Cause: When KVO is enabled and the infusion is complete, the device will automatically convert to the KVO Rate to continue operation. At the same time, the device will trigger high priority alarm and sound alarm, the screen appear with the message "KVO" and the operation status indicator will flash red at the same time.

Solution: Click the "√" button on the screen to clear the alarm. The message "KVO" disappear. The device can be reset according to operating steps.

8.12 KVO end alarm

Cause: When the KVO state runs for 30 minutes until KVO task is completed, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "KVO End" and the operation status indicator flash red at the same time.

Solution: Click the "√" button on the screen to clear the alarm.

The message "KVO End" disappear. The device can be reset according to operating steps.

8.13 Standby End Alarm

Cause: When the device is in standby and the standby is over, the device will trigger high priority alarm and sound alarm, the screen appear with the message "Standby End" and the operation status indicator flash red at the same time.

Solution: Click the "Confirm" button on the screen to clear the alarm.

8.14 Communication Error Alarm

Cause: When the communication of the device monitoring CPU is incorrect, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Communication Error" and the operation status indicator flash red at the same time.

Solution: Click "Confirm" button on the screen to clear the alarm sound. Press the Power on/off key to shut down the device and restart the device. If the fault alarm is still reported, please contact our service personnel

8.15 Call Back Alarm

Cause: The device is ready to start the infusion, but the device is not started and the device is placed without operation for the set time, the device will trigger an alarm, make a low priority alarm sound, the screen appear with the message "Call Back" and the operation status indicator steady on yellow at the same time.

Solution: Click the "Confirm" button on the screen to clear the alarm.

8.16 Low battery Alarm

Cause: When the internal battery is low, the device will trigger an alarm, make a low priority alarm sound, the screen appear with the message "Low Battery" and the operation status indicator steady on yellow at the same time. If the syringe pump is infusing, the device will not stop infusing.

Solution: The external power supply should be used immediately. When plugged in the external power supply, the battery charge indicator lights up, the battery starts charging, and the message "Low battery" disappears, the battery icon shows the dynamic effect of charging. When the battery is fully charged, the battery charge light goes out.

8.17 Near End Of infusion Alarm

Cause: When the remaining time is less than or equal to the preset parameter, the device will trigger an alarm, make a low priority alarm sound, the alarm indicator area at the top of the screen appear with the message "Near End Of Infusion" and the operation status indicator states on yellow at the same time, and the syringe pump continues to infusion does not stop.

Solution: Click the "Mute" button on the right of the alarm prompt area or click the “Confirm” button to suspend the alarm sound. Focus on the amount of fluid remaining in the syringe pump and the time remaining, and wait for the syringe pump infusion to complete.

8.18 Near Empty Of Syringe Alarm

Cause: If the device is running at the current Infusion Rate, when the remaining volume of the syringe should be less than 10% or the time from emptying should be less than 3 minutes, the device will trigger an alarm, make a low priority alarm sound, the alarm indicator area at the top of the screen appear with the message "Near Empty Of Syringe" and the operation status indicator steady on yellow at the same time, and the syringe pump continues to infusion without stopping.

Solution: Click the "Mute" button on the right of the alarm prompt area to suspend the alarm sound. Focus on the amount of remaining liquid in the syringe and replace the syringe in time

8.19 No AC Power Alarm

Cause: When the device is powered on without the network power and use battery power supply, the device will trigger an alarm, make a low priority alarm sound, the screen appear with the message "No AC Power" and the operation status indicator steady on yellow at the same time.

Solution: Click the "Confirm" button on the screen or connect to an external power supply to clear the alarm.

9 System Parameter setting

9.1 Bed number

The Bed number can be set on the Home-Setting- Bed number page.

9.2 Brightness

On the Home- Setting- Brightness page, brightness of the display can be adjusted between 1 and 10 level by clicking on the + or – sign. After brightness setting is completed, click the "Confirm" button to return to the previous page.

9.3 Alarm Sound Volume

On the Home- Setting- Volume- page, alarm sound volume can be adjusted between 1 and 5 level by clicking on the + or – sign. After sound volume setting is completed, click the "Confirm" button to return to the previous page.

9.4 Occlusion Pressure Level

The occlusion pressure Level can be set on the Home- Setting- Level Setting page. Click + or - sign on the screen to choose a pressure level. Click the "Confirm" button to return to the previous page.

Level	OCCL value and error
1	20±20kPa
2	30±20kPa
3	40±20kPa
4	50±20kPa
5	60±20kPa
6	70±20kPa
7	80±20kPa
8	90±20kPa
9	100±20kPa

10	110±20kPa
11	120±20kPa
12	130±20kPa

9.5 Bolus Setting

The Bolus Rate and Bolus VTBI can be set on the Home- Setting- Bolus page. Click the corresponding parameter value to set. After the Settings are complete, click the Back button to return to the previous page.

9.6 Purge Setting

The Purge Rate and Purge VTBI can be set on the Home- Setting- Purge page. Click the corresponding parameter value to set. The values set in the Purge setting will not affect the Bolus Rate and Bolus VTBI.

9.7 Call Back Time Setting

On the Home- Setting- Call Back Time page, can set the Call Back Alarm time when the device is placed without operation and not running.

9.8 KVO setting

On the Home- Setting - KVO page, set the KVO Mode and KVO Rate after the End Of Infusion.

Select the Constant KVO mode and the device will operate according to the currently set KVO Rate.

Select the Adaptive KVO mode, the device will automatically determine the KVO Rate level according to the current Infusion rate

of the infusion operation, and run according to the KVO Rate of the currently set Infusion rate level.

Constant KVO Mode (V_{KVO} rate setting range: 0.10-5.00 mL/h, minimum step value 0.01 mL/h)

-When the infusion rate is >V_{KVO}: After the infusion task is completed, the pump automatically runs at the V_{KVO} rate to maintain venous patency.

-When the infusion rate is ≤ V_{KVO}: After the infusion task is completed, the pump continues to run at the infusion rate to maintain venous patency.

Variable Speed KVO Mode (V_{KVO} rate setting range: 0.10-5.00 mL/h, minimum step value 0.01 mL/h)

Users need to set the V_{KVO} rate separately for three scenarios:

(a) V_{KVO}(>10) rate for infusion rates > 10 mL/h,

(b) V_{KVO}(1-10) rate for infusion rates between 1-10 mL/h, and

(c) V_{KVO}(≤1) rate for infusion rates ≤ 1 mL/h.

The system will automatically matches the KVO rate based on the infusion rate:

-When the infusion rate is > 10 mL/h: After the infusion task is completed, the pump automatically runs at the V_{KVO}(>10) rate to maintain venous patency.

-When the infusion rate is between 1-10 mL/h: After the infusion task is completed, the pump automatically runs at the V_{KVO}(1-10) rate to maintain venous patency.

-When the infusion rate is ≤ 1 mL/h and the infusion rate is > V_{KVO}(≤ 1) rate: After the infusion task is completed, the pump continues to run at the V_{KVO}(≤1) rate to maintain venous patency.

-When the infusion rate is ≤ 1 mL/h and the infusion rate is ≤ V_{KVO}(≤1) rate: After the infusion task is completed, the pump continues to run at the infusion rate to maintain venous patency.

9.9 Auto Screen Lock Time

On the Home- Setting- Auto Screen Lock page, set the Lock time for the screen and keys of the device during infusion operation.

If the screen lock time is set to 0, the Auto Screen Lock function is disabled.

When the screen is locked, other buttons and screen areas are unavailable except the power button and the Unlock button on the screen.

9.10 Near End Of Infusion Time Setting

The near end of infusion time can be set on the Home- Setting- NEOI page.

9.11 Prime prompt switch

On the Home- Setting- Prime prompt switch page, can choose whether to enable the Prime prompt, if this function is enabled, the "Prime" prompt page will appear when a new infusion task starts after each syringe change.

9.12 Night mode Setting

On the Setting- Maintenance- Night Mode page, can set the brightness or sound volume for daytime or nighttime, the setting method is the same as that for brightness and sound level.

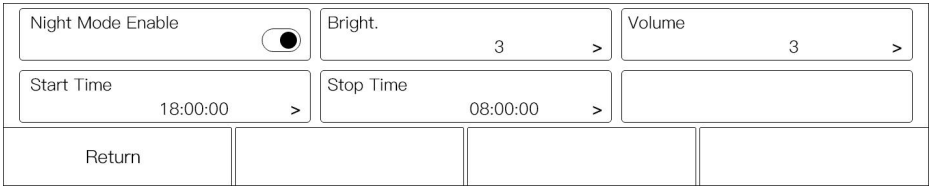


Figure 9-12 Night mode setting

9.13 Date/Time Setting

The device of Time and date can be set on the Setting - Maintenance- Date/Time page.

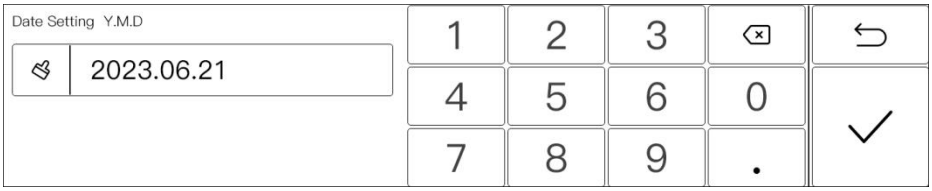


Figure 9-13-1 Date Setting

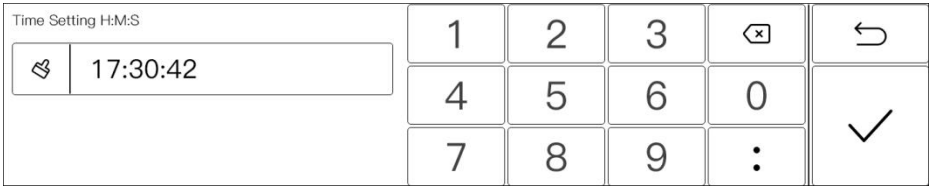


Figure 9-13-2 Time Setting

9.14 WIFI setting

After configuring the Wi-Fi network connection parameters on the device in Setting - Maintenance - Wi-Fi Setting page, you can establish a data communication connection with IT systems such as Infusion Monitoring APP, Infusion Information System, System HIS, etc. Please complete the parameter setting under the guidance of our sales and service staff.

9.15 Maintenance

Maintain the device in “Setting - Maintenance”, Including the calibration of syringe accuracy, system time settings, system language settings, factory resets, etc. Entering the Maintenance interface requires entering the engineer's maintenance password, password please consult the company's sales and service personnel.

Syringe precision calibration operation instructions see Section 10 of this manual.

10 Accuracy Calibration for syringe

The brand and specification syringes that have not been calibrated, or syringes belonging to different production lots with the calibrated syringes, need to be calibrated before use. In normal use, the syringe should be re-calibrated every 6 months.

Calibrate the syringe accuracy in "Setting- System Maintenance - Consumables maintenance".

10.1 Automatic Accuracy Calibration for syringe

1) Pull the empty syringe that needs to be calibrated to the maximum range and install it to the device.
2) Click "Home - Setting - Maintenance - Consumables maintenance - Calibration Consumable" to enter the consumables calibration page.
3) Click the Brand and select the consumables brand that needs to be calibrated.
4) Click the specification and select the specification for this calibration.

5) Click Auto Calibration Start/Stop and wait for the device to run until the syringe is pushed empty.
6) Turn to the next page and click OK to save the current calibration value.

10.2 Manual Accuracy calibration for Syringe

1) Fill the syringe that needs to be calibrated with liquid, connect it to the balance or measuring cylinder through the extension tube, and install it to the device.
2) Prime/Purge until the extension tube is filled with liquid and stop.
3) Click "Home - Setting - Maintenance - Consumables maintenance - Calibration Consumable" to enter the consumables calibration page.
4) Click the brand and select the consumables brand that needs to be calibrated.
5) Click the Specification and select the specification for this calibration.
6) Pour out the water in the measuring cylinder or clear the balance.
7) Click the calibration Start/Stop, the calibration remaining amount will be displayed on the right side, and wait for the remaining amount to displayed.
8) Turn to the next page, click the Volume Output, input the actual volume read from the balance or measuring cylinder, click OK, and save the current calibration value.

11 Precautions for Using Disposable syringe

It’s suggested to use the recommended Syringes. The ambient temperature should be kept at least at 5℃ or above when a

recommended Syringe is used. The infusion accuracy will be compromised if ambient temperature is lower than 5℃.

The recommended Syringes are listed in the table below:

No.	Brand	Accuracy	Ambient temperature
1	Kangjin	±1.5%	+5℃~+40℃
2	Wego	±1.5%	+5℃~+40℃
3	Kindly	±1.5%	+5℃~+40℃
4	BD	±1.5%	+5℃~+40℃
5	Shinva	±1.5%	+5℃~+40℃
6	B.Braun	±1.5%	+5℃~+40℃

The syringe used must have a medical device product registration certificate, and the syringe specifications are selected in the same specification as the recommended syringe brand. Syringe Installation Methods Seethe section Install/replace syringe.

In order to ensure infusion accuracy, when the ambient temperature changes significantly, the device needs to be re-calibrated, calibration method See Section 10 Accuracy Calibration for Syringe.

Please strictly follow the requirements described in Section 10 to calibrate and use the Syringe when change to a new Syringe from a different manufacturer. Otherwise, the infusion accuracy may be compromised.

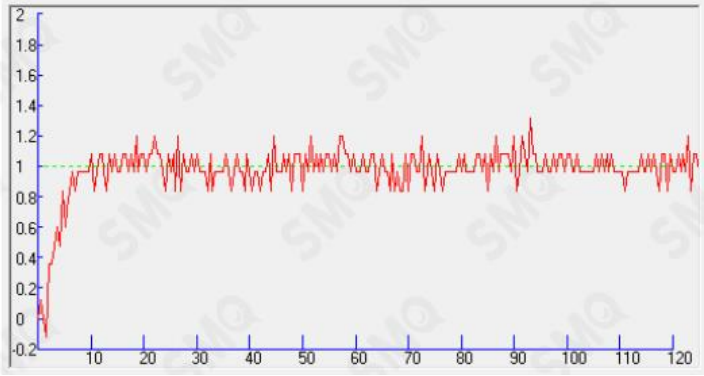
12 Technical Specification

According to IEC 60601-2-24 standard, we tested and obtained the trumpet and flow rate graphs under the conditions of 1mL, 5mL, positive and negative back pressure, etc. The specific

data are reflected in the IEC 60601-2-24 test reports, and the relevant graphs will update in this section accordingly.

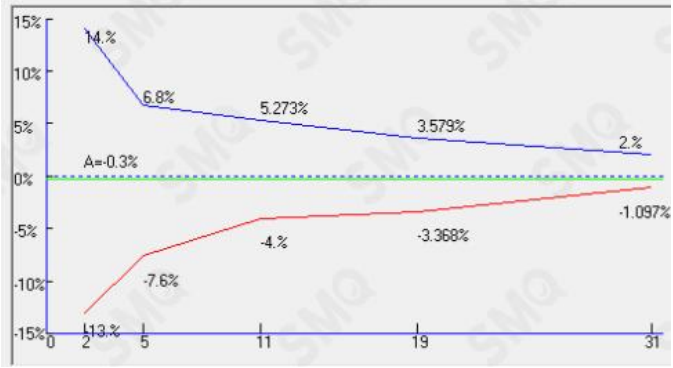
1) The methods of controlling Bolus volume before occlusion: The pressure in the occlusion pipeline is released to control the bolus volume by controlling the inversion of the stepper motor.
2) Storage time for the electronic memory after power off: same as the product lifetime.
3) The maximum volume that the pump can deliver under a single fault condition: 0.3mL
4) Device calibration is measured in ml.
5) Minimum flow rate performance curve (1 mL/h)

a. The rising curve for KDL syringe with the minimum flow rate during the first two hours of operation.



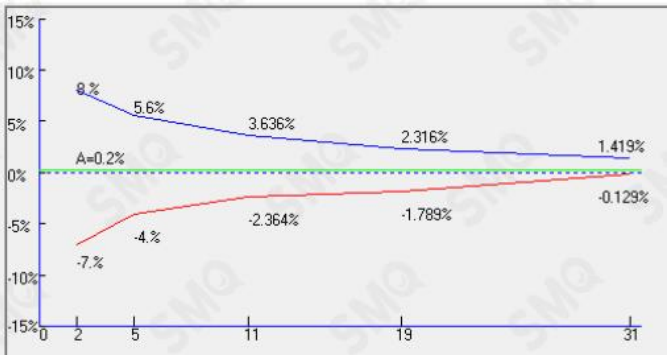
In the above figure, the dashed line shows the set flow rate (1 mL/h in this figure), and the solid line is the continuous connection line for the average flow rate during a sampling period.

b. The trumpet curve for KDL syringe with the minimum flow rate during the second hour of operation.



The dashed line in green color is the final value that the infusion error of the device is eventually converging to. The solid blue line above the dashed line is the maximum positive deviation during the second hour of operation. The solid red line below the dashed line is the maximum negative deviation during the second hour of operation.

c. The trumpet curve for KDL syringe with the minimum flow rate during the last hour of the run.

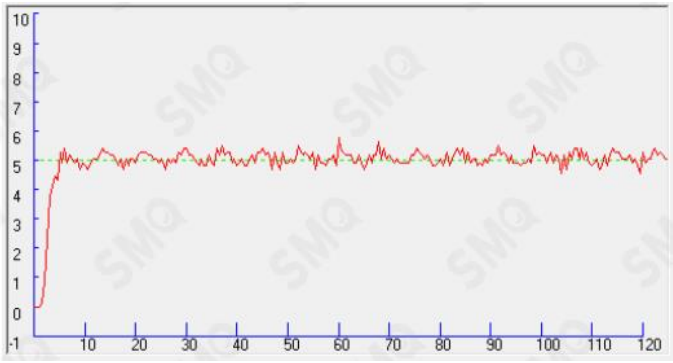


The green dashed line is the value where the device perfusion error finally converges. The solid blue line above the dashed line is the maximum positive deviation within the hour of the run. The solid red line below the dashed line is the maximum negative deviation

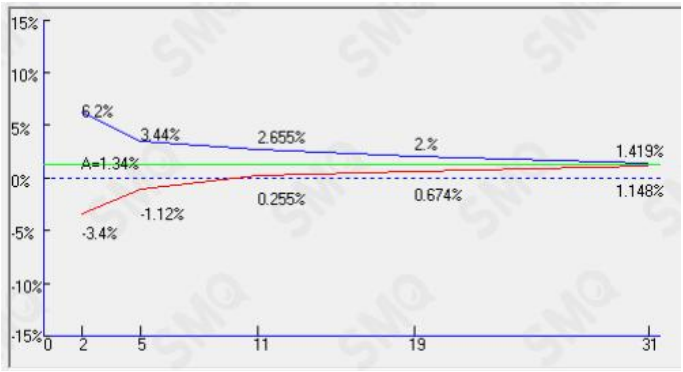
within the last hour.

6) Intermediate flow rate performance curve (5 mL/h)

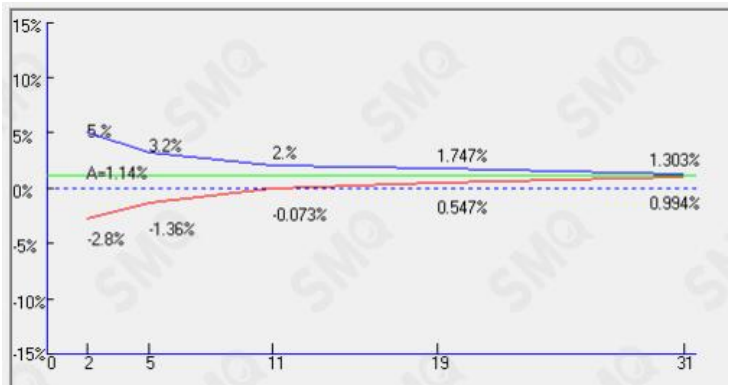
a. The rising curve for KDL syringe with the intermediate flow rate during the first two hours of operation.



b. The trumpet curve for KDL syringe with the intermediate flow rate during the second hour of operation.

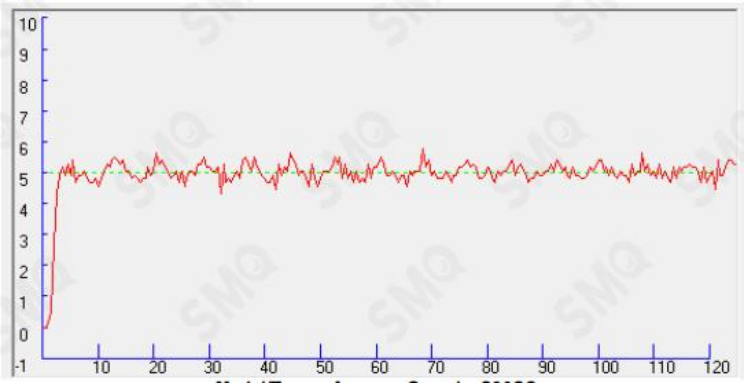


c. The trumpet curve for KDL syringe with the intermediate flow rate during the last hour of the run.



7) Intermediate flow rate and back pressure +13.33kPa performance curve

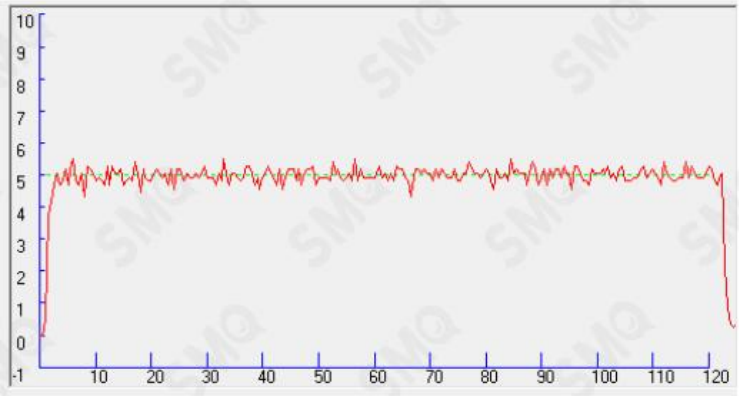
a. The rising curve for KDL syringe with the Intermediate flow rate and back pressure +13.33kPa during the first 2h of the test period.



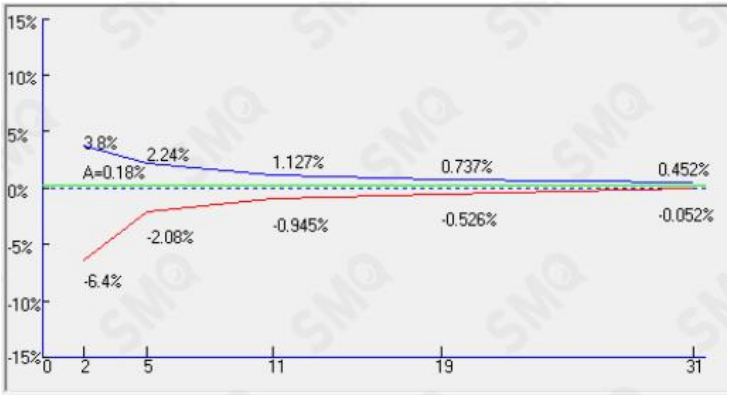
b. The trumpet curve for KDL syringe with the Intermediate flow rate and back pressure +13.33kPa during the second hour of the test period.

8) Intermediate flow rate and back pressure -13.33kPa performance curve.

a. The rising curve for KDL syringe with the Intermediate flow rate and back pressure -13.33kPa during the first 2h of the test period.



b. The trumpet curve for KDL syringe with the Intermediate flow rate and back pressure -13.33kPa during the second hour of the test period.



13 Restore to factory setting

Default factory setting as below:

No.	Parameter	Factory presets
1	Brightness level	Level 3
2	System sound level	Level 3
3	Night mode sound level	Level 3
4	Night mode brightness level	Level 3
5	Occlusion pressure level	120kPa
6	Night mode	Close
7	WIFI	Close
8	Infusion mode	Rate mode
9	KVO	Constant KVO
10	KVO rate	1.00mL/h
11	Call Back Time	2 min
12	Near End Of Infusion time	5 min
13	Auto screen lock time	5 min
14	Night mode start time	19:00:00

15	Night mode end time	09:00:00
16	Bolus rate	1200.00mL/h
17	Purge rate	1200.00mL/h
18	Bolus volume	5.00mL
19	Purge volume	15.00mL

14 Use, Maintenance and Removal of the Internal Battery

The device has an internal rechargeable lithium battery with the following specification: 21700/4800mAh*2PCS.

Daily maintenance of the battery:

When the pump is not used for a long time, the internal battery should be fully charged at least once for every 3 months by connecting the device to the mains power to help saving the battery life.

Contact the customer service immediately if the internal battery cannot be charged or cannot work normally. Do not disassemble it by yourself. For the healthcare providers who have the ability to repair a device, we will provide training to the related personnel from these facilities.

The battery is maintained and replaced as shown in the figure below.

The device has a internal disposable button battery designed to last longer than 8 years, when the set time is exceeded, need to be disposed with the device in accordance with the instructions for waste disposal in this manual 16.

15 Service and Maintenance

Check the pump before use:

1) Check whether there are foreign objects inside the power outlet

(such as drug solution residue), and confirm that the device startup self-test is normal.

2) Select the correct syringe specification, check the battery power, and charge it in time when the power is low.

During use:

1) To avoid giving an incorrect dosage of drug to a patient, please disconnect the pump from the patient before changing a device.
2) Please make sure that the infusion line is not kinked. Insert the needle to the vein on a part of the patient's body where it is not likely to be squeezed or pressed.
3) To prevent the spilled drug solution on the pump surface from getting into the inside of the device, wipe it dry immediately if there is a spill.

Storage and daily maintenance:

1) To keep the device clean, wipe it clean for at least once a month, which can prevent the corrosion caused by the drug solution and avoid the mobility of the mechanical parts being affected by the dried solution.
2) Use a clean and damp cloth or an alcohol pad to wipe clean the device. Take caution to avoid any liquid from entering the device. If disinfection is required, commonly used disinfectants can be used. After using the disinfectant, after wetting with a soft cloth in water, wring out the soft cloth for scrub treatment. When using disinfectants, follow their instructions.
3) Check the Low battery Alarm time of the device at least once a month. Make the device standby when the battery is low in non-clinical use, start timing when you hear the alarm of "low

battery", and the alarm time should be more than 30 minutes.

Disinfection method:

If disinfection is required, commonly used disinfectants can be used. After using the disinfectant, after wetting with a soft cloth in water, wring out the soft cloth for scrub treatment. When using disinfectants, follow their instructions.

16 Waste Disposal

16.1 Battery

Please follow local regulations to dispose of used batteries.

16.2 Syringe

After use, please dispose of the syringe in accordance with the relevant medical waste disposal regulations.

16.3 Syringe pump

This device is designed to last 8 years and should be scrapped after it has exceeded the lifetime. End-of-life syringe pumps can be sent back to the dealer who sold the product or to the Company for proper recycling.

17 Electromagnetic Compatibility

Special precautions regarding Electromagnetic Compatibility (EMC) are required for this device. Must install and use in accordance with the electromagnetic compatibility information specified in this instruction.

Portable and mobile RF communication devices may have an impact on this device.

Must use the cables and accessories provided by this device,

and the cable information as follows:

The name of the cable	Length
The power adapter	2.9 m

In addition to cables (transdicators) sold as spare parts for internal components, the use of accessories and cables (transdicators) other than specified may result in an increase in device or system emission or a decrease in immunity.

Devices or systems should not be used close to or stacked with other devices, and if they must be accessed or stacked, observe to verify that they can run normally in the configuration they are using.

The basic performance is to operate on a network power supply (including an internal battery) connection.

Name	Specific Description
The network power supply (including the internal battery) is connected to run	At the intermediate rate of 5.00mL/h and the VTBI of ≥10mL, start to operation, infusion accuracy error less than ±1.5% and the operation is normal during the process, there should be no abnormal phenomena and failures.

Guidance and manufacture's declaration – electromagnetic emission The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such and environment.:		
Emissions test	**Compliance**	Electromagnetic environment - guide
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function, so its RF emission is low and there is little chance of interference with nearby electronics
RF emissions	Class A	The device is suitable for use in all

CISPR 11		facilities that are not domestic and are not directly connected to the public low-voltage power supply network of domestic residences
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 device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guide
Electrostatic discharge (ESD) IEC 61000-4-2	±8KV contact ±15 KV air	±8KV contact ±15KV air	The ground should be made of wood, concrete, or ceramic tiles. If the ground is covered with synthetic materials, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2KV for power supply lines ±1 KV signal input/output	±2 KV for power supply lines Not applicable	The network power supply should have the quality used in typical commercial or hospital environments

Surge IEC 61000-4-5	±1 KV line to line ±2 KV line to ground	±1 KV line to line Not applicable	The network power supply should have the quality used in typical commercial or hospital environments
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5%U_T, 0.5 cycle (>U_T, >95% voltage dips) 40%U_T, 5 cycle (> U_T, 60% voltage dips) 70%U_T, 25 cycle (>U_T, 30% voltage dips) <5%U_T 5 s (>U_T, >95% voltage dips)	<5%U_T, 0.5 cycle (>U_T, >95% voltage dips) 40%U_T, 5 cycle > U_T, 60% voltage dips) 70%U_T, 25 cycle (>U_T, 30% voltage dips) <5%U_T, 5s (>U_T, >95% voltage dips)	The network power supply should have the quality suitable for typical commercial or hospital environments. If the user of the device needs to operate continuously during a power outage, it is recommended to use an uninterruptible power supply or battery power supply for the device.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	400A/m	400 A/m	The power frequency magnetic field should have the horizontal characteristics of the power frequency magnetic field in

			typical commercial or hospital environments
Note: U_T is the a.c. mains voltage prior to application of the test level.			

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 syringe pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conduced RF IEC61000-4-6	3 V(Valid value) 150 kHz~ 80MHz (expect the ISM bands between [a])		Portable and mobile RF communication devices should not be used closer to any part of the device, including cables, than the recommended isolation distance. The distance should be calculated using a formula corresponding to the transmitter frequency. Recommended isolation distance
	10V(Valid value)	10V	$d = 1.2\sqrt{(P)}$ 150kHz-80MHz
			$d = 1.2\sqrt{(P)}$ 80MHz-800MHz
Radiated RF IEC61000-4-3	150 kHz~ 80MHz (ISM bands between [a])	10V/m	$d = 2.3\sqrt{(P)}$ 800MHz-2.5GHz Note: P——According to the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W); d ——Is the recommended isolation distance in meters (m).[b]
	10V /m 80MHz~2.5GHz		The field strength of a fixed RF

			transmitter is determined by surveying the electromagnetic field c, and should be lower than the corresponding level in each frequency range d. Interference may occur near devices marked with the following symbols 

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

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

a The ISM bands between 150kHz and 80MHz means 6.765MHz~6.795 MHz, 13.553MHz~13.567 MHz, 26.957MHz~27.283 MHz 和 40.66MHz~40.70MHz.

b The ISM bands between 150kHz~80MHz and 80M Hz~2.5GHz compliance level, is used to reduce the possibility of interference caused by mobile/portable communication devices accidentally brought into the patient's area. For this purpose, an additional factor of 10/3 is used to calculate the recommended isolation distance of the transmitter within these frequency ranges.

c Fixed transmitter. For example, the field strength of base stations for wireless (cellular/wireless) telephones and ground mobile radios, business radios, AM and FM radio broadcasts, and television broadcasts cannot be accurately predicted in theory. To evaluate the electromagnetic environment of fixed RF transmitters, consideration should be given to the investigation of electromagnetic sites. If the measured field strength of the location where the syringe pump is located is higher than the applicable RF compliance level mentioned above, the syringe pump should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be

necessary, such as adjusting the direction or position of the syringe pump.

d In the entire frequency range of 150kHz to 80MHz, the field strength should be less than 3V/m.

Recommended isolation distance between portable and mobile RF communication device and syringe pumps

The device is expected to be used in an electromagnetic environment with controlled radio frequency radiation disturbance. Based on the maximum rated output power of communication devices, buyers or users can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication devices (transmitters) and devices as recommended below.

Maximum rated output power of the transmitter W	Isolation distance corresponding to different frequencies of the transmitter/m			
	150kHz ~ 80MHz expect the ISM bands) d = 1.2 $\sqrt{P}$	150kHz ~ 80MHz (ISM bands) d = 1.2 $\sqrt{P}$	80MHz~800MHz d = 1.2 $\sqrt{P}$	800MHz~2.5GHz d = 2.3 $\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For the maximum rated output power of transmitters not listed in the above table, it is recommended to isolate the distance d in meters (m), which can be determined by the formula in the corresponding transmitter frequency column. Here, P is the maximum rated output frequency of the transmitter provided by the transmitter manufacturer, in watts (W).

Note 1: At the frequency points of 80 MHz and 800 MHz, the formula for the higher frequency band is used.

Note 2: The power frequency medical frequency band between 150 kHz and 80 MHz refers to 6.765 MHz to 6795 MHz, 13.553 MHz to 13567 MHz, 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.70 MHz.

Note 3: The additional factor of 10/3 is used to calculate the recommended isolation distance for transmitters in the engineering and medical frequency bands of 150 kHz to 80 MHz and the frequency range of 80 MHz to 2, 5 GHz, in order to reduce the possibility of interference caused by portable/mobile communication devices accidentally brought into the patient's area.

Note 4: These guidelines may not be suitable for all situations. Electromagnetic propagation is influenced by the absorption and reflection of buildings, objects, and the human body.

18 Antistatic Precautions

The device has been tested and comply with medical device standard IEC 60601-1-8.

When using this device, the user should not touch the pins of connectors marked with an electrostatic discharge warning symbol and should not connect to these connectors unless electrostatic discharge precautions are used.

The operator should be aware of the following things:

a) Unless appropriate preventive measures have already been taken, do not use hand or hand tool to touch connectors with electrostatic discharge warning signs. Preventive measures include: 1) Methods for preventing electrostatic charge accumulation (such as air conditioning, air humidification, floor conductive coating or Non-synthetic clothing); 2) Discharge electrostatic charge from human body to the framework of device, or to the ground, or to a large piece of metal; 3) Use a wrist band to connect human body to the device or to the ground.

b) All staff who may be in contact with connectors with electrostatic discharge warning signs should receive training,

including all clinical/biomedical engineering and healthcare personnel.

c) Electrostatic discharge training should include the introduction of static charges in the theory of physics, the voltage that may be produced in normal practice, and the damage to the electronic components caused by the electrostatic charge from an operator. Further, methods for how to prevent electrostatic charge accumulation should be provided, as well as how and why to discharge the electrostatic from human body to the framework of device or to the ground, and how to use wrist band to connect someone's body to the device or to the ground.

19 CyberSecurity Notes

1) User access control mechanism

The user access control of this device adopts the account and password system, and illegal login is rejected.

2) Electronic interfaces (including network interfaces, electronic data interchange interfaces) and their data types and technical characteristics.

The communication interface between the product and the outside is Wi-Fi network communication interface, and the data transmission is encrypted according to the internal data interface protocol defined by the company. The data transmission protocol is TCP protocol.

The data type was device data and did not contain personal patient information.

3) CyberSecurity feature configuration

When connecting to the incoming LAN, the user should configure the appropriate firewall, intrusion prevention device, anti-ddos attack system, Internet behavior analysis system, vulnerability scanner, log audit system and other security reinforcement facilities for the LAN to ensure the CyberSecurity.

4) Data backup and disaster recovery

System Settings stored in FLASH can be saved for hundreds of years. The system log is recommended that users regularly download and save it to the computer system using the supporting infusion monitoring information system for subsequent audit.

5) Operating environment (including hardware configuration, external software environment, network environment, if applicable)

Hardware configuration: The company's electronic circuit based on the ARM architecture chip processor;

Software environment: Embedded software system;

Network conditions: Wi-Fi wireless communication module based on 802.11b/g/n;

6) Security Software compatibility list (if applicable)

This device does not involve anti-virus software, firewall and other security software;

7) External software environment and security software updates (if applicable)

Not applicable, not updated

8) Off-the-shelf Software Inventory (SBOM, if applicable)

No other off-the-shelf software;

20 Packaging and Accessories

The list of recommended accessories for use with this device (single unit) is as follows:

Attachment	Quantity	Unit
User manual	1	Book
Power adapter	1	Set
Other accessories can be found in the packing list.		

GRASEBY

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