GRASEBY™

CE
2862

Graseby V20 Plus Infusion Pump User Manual

Version: 1.0

MDKMed Medical Technology Co., Ltd.
2024.7.5

Content

1 Symbols, Graphics and Warnings

1.1 Descriptions of Graphics and Symbols

	Caution		Read the User Manual
	Defibrillation prevention Type CF equipment	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)
	DC (Direct current)		Non-ionizing electromagnetic

			radiation
	Mute		Lithium battery
EC REP	European Representative		Manufacturer

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 infusion pumps are intended for the intermittent or continuous delivery of parenteral fluids, enteral fluids, medications, blood and blood products through clinically accepted routes of administration. The devices can be used together with liquid storage devices /IV infusion sets /Blood transfusion sets /Enteral feeding sets.
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 equipment in an environment where flammable or explosive matters are present.
4) Do not use it with other devices that generate external radio frequency interference or electromagnetic radiation that may affect the safe operation of the device.
5) The operator must use the recommended IV infusion set calibrated in accordance with the requirements described in Section 10

Accuracy Calibration for IV infusion set in this guide, and ensure that the correct IV infusion set brand and type are selected.

6) The IV infusion set that is not recommended should never be used for infusion, otherwise it may lead to large infusion inaccuracy and even to become unusable.
7) The installation height of this equipment should not be more than 1 meter above or below the patient's heart.
8) It is forbidden to reuse the same IV infusion set 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 Infusion Pump must be serviced and calibrated by trained professional technicians. Before maintenance, make sure to unplug the power cable that supplies power to the equipment. Untrained personnel are strictly prohibited from opening the equipment casing, otherwise the eligibility for warranty of the equipment will be lost.
12) Please make sure to use only the parts and accessories provided by MDK.
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 equipment according to Section 15 Service and Maintenance in this manual, no other part of the equipment shall be serviced or maintained by users. If there is any abnormality in the equipment, please contact the customer service of MDK.
15) During the use of the equipment, the equipment should be placed

smoothly and fixed firmly.

16) After loading the IV infusion set, the operator is required to check whether the liquid medicine in the IV infusion set leaks. If there is leakage, stop using the IV infusion set and notify the customer service of MDK.
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) After setting infusion parameters, the operator must ensure that the infusion set is properly stuck to the device before starting infusion.
19) In order to maintain a high infusion accuracy, the contacting spot of compression on an IV infusion set should be changed every 8 hours.When the MDK IV infusion set is used, the IV infusion set should be changed every 48 hours to maintain a high accuracy of infusion.
20) To maintain high infusion accuracy, the pump needs to be re-calibrated when there is a significant change in ambient temperature.
21) The pump will stop operation automatically when there is an alarm. Press the Start-Stop key or click the start button to resume operation after the alarm causing condition is removed.
22) To avoid failure or false alarm caused by a dirty occlusion sensor or air- in-line sensor, operator should wipe clean the pump on a regular basis to keep it clean.
23) 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.

24) Pump or accessories may not be usable if their lifetime for use has expired (the lifetime for pump is 8 years). Contact MDK to upgrade to new products.
25) The device has a internal rechargeable lithium batter and its lifetime is 2 years.
26) 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 Battery in this manual. Replacing the battery by personnel without sufficient training will lead to risks such as over temperature, fire or explosion.
27) 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.
28) For different types of patients, different occlusion pressure Level should be set. For details, please refer to the doctor's advice.
29) Healthcare professional should check on the equipment during operation on a regular basis, and he/she should also pay attention to medication solution in the IV infusion set before starting the equipment to make sure the right medicine is in the right infusion channel.
30) Please follow the instructions for consumables to use the liquid stop clamp and other components on the infusion line correctly.
31) When using this equipment, please do not plug the power to somewhere that is difficult to plug or unplug. Use an independent power outlet as a measure in case quick disconnection is needed.
32) IV infusion set needle is the application part of this product.
33) While in normal operation, an alarm will be triggered if the pump

door is opened. Please contact MDK for service if this alarm fails to appear.

34) Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

35) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Graseby V20 Plus, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

36) Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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

38) The EMISSIONS characteristics of this equipment 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 equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

39) The ME EQUIPMENT or ME SYSTEM is suitable for professional

healthcare facility environments.

40) Do not use unapproved cleaners, materials or chemicals as they may damage device surfaces, labels, or cause equipment 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) For different types of patients, different occlusion pressure Level should be set. For details, please refer to the doctor's advice.
45) When the equipment 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.
46) 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.
47) 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.
48) 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.

49) When using this device for target-controlled infusion, the operator is responsible for the injected 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 injection volume limitations.

50) 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.

51) 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.

52) 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 injection volume are consistent with the prescription information before use.

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

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

time after the target-controlled infusion is completed.

55) 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.

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

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

58) 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 infusion set and vein unobstructed and to avoid the blood flowing backwards.

Intermediate rate: An Infusion rate of 25.00 mL/h.

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

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

VTBI: Volume to be infusion.

Piggyback： Piggyback infusion.

3 Brief Introduction and Scope

3.1 Brief Introduction

Graseby V20 Plus(hereinafter referred to as V20 Plus) is a kind of infusion equipment, 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 Use

Intended Use: The Infusion pump is intended for the intermittent or continuous delivery of parenteral fluids, enteral fluids, medications, blood and blood products through clinically accepted routes of administration. It is used together with liquid storage devices /IV infusion sets/ Blood transfusion sets /Enteral feeding sets.

Indication for use: N/A.

Contraindications: not known.

Intended patient population: The target population is adults, pediatrics (including newborns) who need intravenous therapy, blood transfusion and enteral nutrition, 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

Since the infusion pumps do not come into contact with patient directly, they don’t have direct clinical benefit to patients. So the

clinical benefit of the infusion pump is that the device enables the precisely administration of intravenous fluid /blood /blood product /enteral fluid procedure to be undertaken, and realizes the monitoring of the infusion processing (the device is able to send alarms during infusion process when occlusion or other circumstances), which can greatly increase the infusion safety.

4 Important Features

1) **Accuracy:** The accuracy for infusion rate and volume both are kept within 4%.
2) **Flow rate:** The Infusion rate can be adjusted from 0.01 mL/h to 2000.00 mL/h in a continuous manner, which makes the infusion pump capable of meeting various flow rate requirements in different infusion situations.
3) **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.
4) **Battery capacity:** The rechargeable internal high-capacity Lithium battery can support normal operation for 6 hours, which is conveniently helpful during patient transport or power outage.
5) **Display:** LCD touch screen display offers high contrast, great visibility and user friendly usability.
6) **Occlusion Alarm:** Both upstream and downstream occlusion alarms are available, 10 pressure level is adjustable.
7) **Air-in-line alarm:** Based on ultrasonic technology, the device is capable of detecting air bubble sizes down to 25 μL and initiating air-in-line alarm.

5 Specifications

5.1 Basic Specifications

Dimensions	216 mm×131 mm×72 mm (WxDxH)
Weight	1.26 kg
Power supply	Network power supply: ~ 100 V-240 V, 50/60 Hz Internal battery:⎓7.4 V rechargeable Lithium battery
Rate of work	45 VA
Consumable requirements	Refer to Section 11 Precautions for Using Disposable Consumables
Maximum Infusion Rate	2000.00(mL/h)

5.2 Main Performance

Infusion Rate range	0.01 ~ 2000.00 mL/h with resolution of 0.01 mL/h
VTBI range	0.01 ~ 9999.99 mL with resolution of 0.01 mL
Infusion accuracy	±4.0%; ±3.0%(MDK consumable)
Purge Rate	1 mL/h ~ 2000 mL/h, with resolution of 1 mL/h
Bolus rate/volume	Bolus rate: 1 mL/h ~ 2000 mL/h, with resolution of 1 mL/h; bolus volume: 0.10mL ~ 100.00mL with resolution of 0.01 mL
KVO rate	Constant KVO: Infusion rate 0.10mL/h ~ 5.00mL/h, step by 0.01mL/h

	When the Infusion rate is greater than the user-defined KVO Rate, the system runs at the user-defined KVO Rate. When the Infusion rate is less than the user-defined KVO Rate, KVO Rate = Infusion rate. Variable speed KVO: Infusion rate 0.10mL/h ~ 5.00mL/h, step by 0.01mL/h When the Infusion rate is > 10 mL/h, run at the user-defined KVO Rate > 10 mL/h. When 1 mL/h < Infusion rate ≤10 mL/h, the user-defined KVO Rate of 1 mL/h < Infusion rate ≤10 mL/h is used. When the Infusion rate is ≤1mL/h, the KVO Rate defined by the user is ≤1mL/h. When the infusion rate is lower than the user-defined KVO rate, KVO rate = infusion rate.
Infusion Time range	00:00:00~99:59:59, with resolution of 1s
Occlusion threshold	10 levels, with the lowest being 30 kPa ± 20 kPa, and the highest being 120 kPa ± 20 kPa.
Maximum infusion pressure generated by the device	140 kPa
Occlusion alarm trigger time and Bolus dosage	When operated at minimum Infusion rate(1.00mL/h): < 1h when the occlusion alarm pressure threshold is set to the lowest pressure;

	or < 3h when the occlusion alarm pressure threshold is set to the highest pressure. When operated at intermediate rate(25.00mL/h): < 1min30s when occlusion alarm pressure threshold is set to the lowest pressure, and the Bolus produced during occlusion is < 0.20 mL; < 2min30s, when the occlusion alarm pressure threshold is set to the highest pressure, the Bolus during occlusion is not more than 0.50 mL. (Tested with the Hanaco IV infusion set when an occlusion was created 1 meter away from the pump outlet for testing purpose at 20 ℃)
Consumable brand	IV infusion set: 6 brands are recommended, and the default brand is Hanaco, JR, Kindly, Kang Jin, Shinva, MDK. 10 brands can be customized. enteral feeding set: MDK blood transfusion set: Terumo
Supported Infusion modes	15 modes, RVT mode, Drug Library mode, Dose mode, Drop speed mode, RTM mode, Sequence mode, Loading Dose mode, Intermittent mode, Relay mode, Micro mode, TIVA mode, Piggy back mode, Feeding mode, Transfusion mode, TCI mode.
Battery running time	Intermediate speed: When fully charged, the battery can run continuously for 6h30min. Maximum speed: When fully charged, the battery can run continuously for 6h10min.

WIFI connectivity	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 Infusion pump with internal power supply; Grade IP44, non AP/APG type equipment.
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	V20 Plus_V1
Service lifetime	8years

5.3 Main Functions and Common Functions

1) Set infusion rate, infusion VTBI and real-time data display function;
2) Display of completed infusion volume;
3) Purge / Bolus;
4) Alarms;
5) The Infusion rate will be automatically changed to KVO Rate after the VTBI complete alarm is activated
6) Temporary mute for alarm sound and timer for alarm sound

recovery;

7) Automatic free-flow stopping function;

8) Displays the accumulated quantity infusion and supports clearance

9) A variety of brands for IV infusion set are supported;

10) Built-in battery;

11) External power adapter;

12) Wi-Fi connectivity;

13) Closed-loop infusion protection safety function

14) Contains Dose-Error Reduction Software

15) Electric infusion pump door

16) TCI infusion mode

6 Structure and Operation Interface

6.1 Structural Composition

The device is composed of a pump housing, motor drive system, input system, storage system, control system, display system, sensor monitoring system, alarm system and power system (adapter).

Names for parts and components:

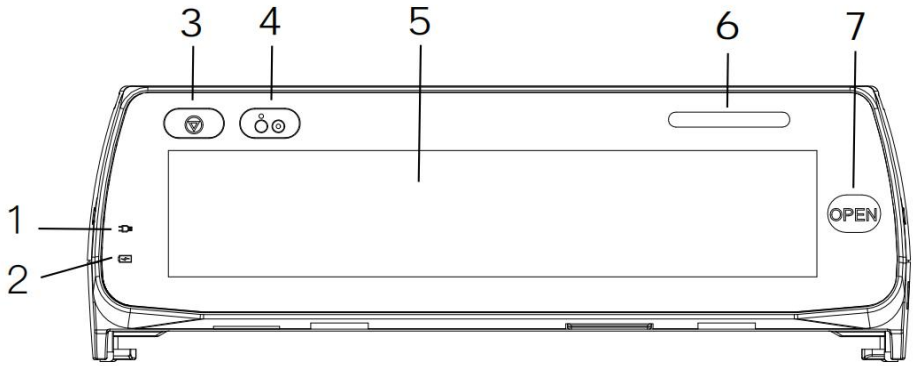


Figure 6-1-1 Front view

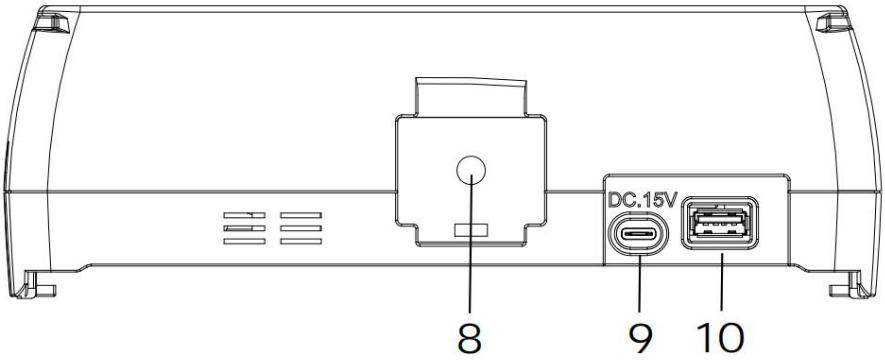


Figure 6-1-2 Back view

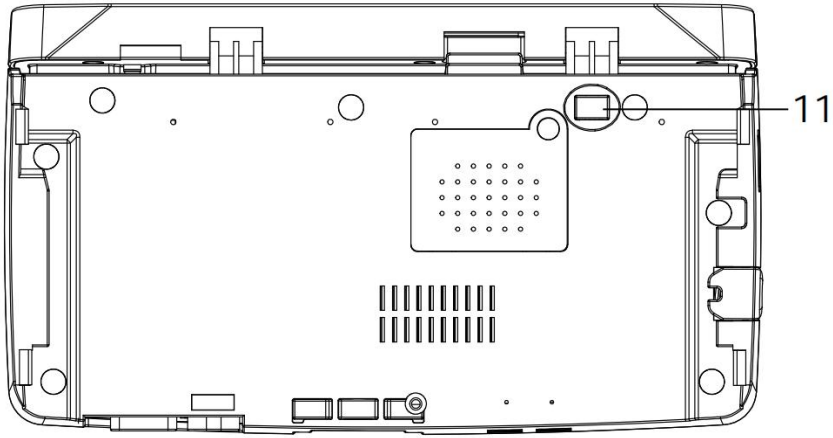


Figure 6-1-3 Upward view

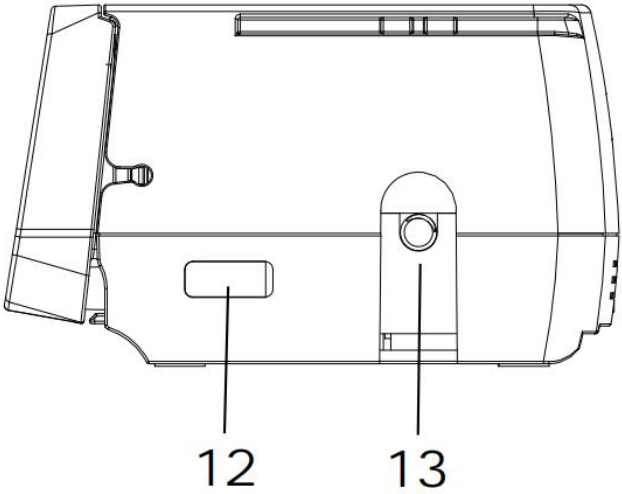


Figure 6-1-4 Side view

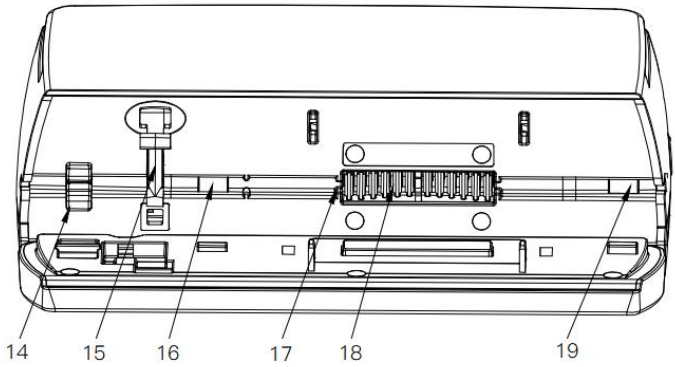


Figure 6-1-5 Pump door open diagram

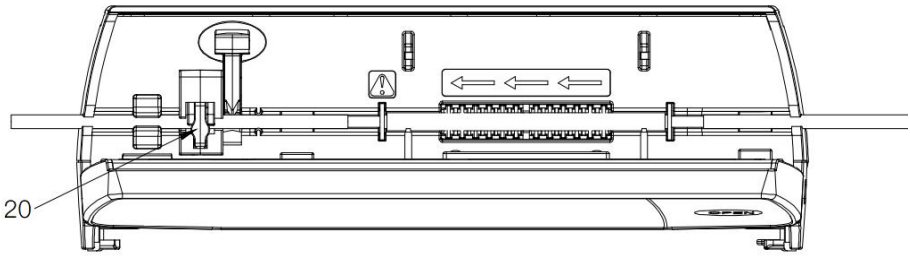


Figure 6-1-6 MDK infusion set installation diagram

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	Electric pump door switch	8	Fixed pole	9	Power Port
10	Data Communication port	11	Manual pump door switch	12	Drop sensor port

13	Stack slot	14	Air in line sensor	15	Liquid stop clamp
16	Down stream occlusion sensor	17	Positioning groove for IV infusion set	18	Pump disc
19	Upper stream occlusion sensor	20	Clamp for MDK IV infusion set (Optional)		

6.2 Display and Operation Interface

The display interface is shown below. Click the "Switch" button to switch the interface display.

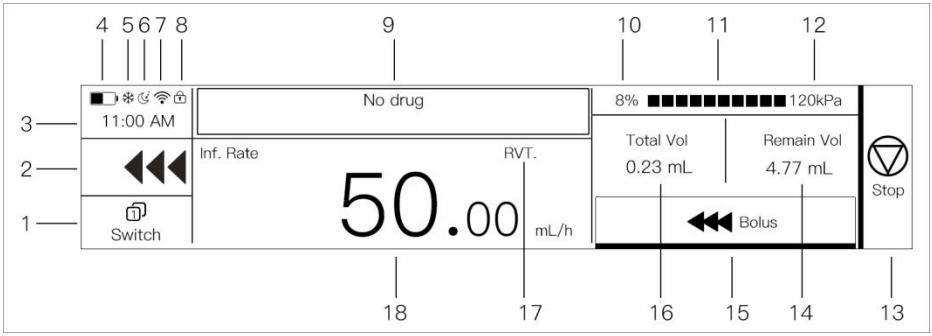


Figure 6-2-1 Operation interface on the screen 1

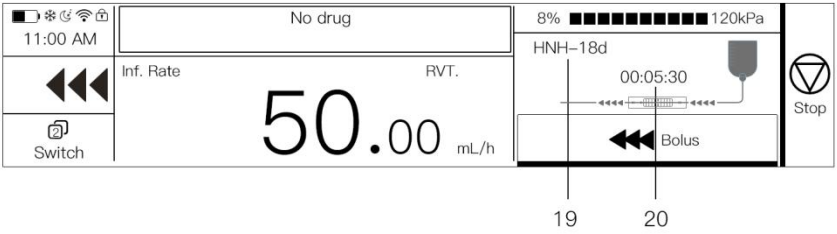


Figure 6-2-2 Operation interface on the screen 2

1	Switch	2	Infusion status	3	Time
4	Battery	5	Low temperature	6	Night mode
7	WiFi	8	Lock screen	9	Drug name
10	Current pressure ratio	11	Pressure accounts for progress	12	Upper occlusion pressure limit
13	Start/Stop button	14	Remaining volume	15	Bolus button
16	Total volume infused	17	Infusion mode	18	Infusion rate
19	Brand	20	Time remaining		

7 Operation Instructions

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

Before infusion starts, please confirm that the IV infusion set in

use matches the current IV infusion set setting selected in the menu. Any IV infusion set which brand is not included in the list of recommended brands must be calibrated before being used.

7.1 Installation of Infusion 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 Infusion 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.

7.2.2 Device safety self-test

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 IV infusion set

First, press the electric pump door switch to open the pump door, press the clamp shown in Figure 6-1-5 18 upward to make the clamp open. Straighten the infusion line below the drip chamber and place it into the positioning groove. Then close the pump door, adjust the roller clamp on the IV infusion set to its open position. The installation of IV infusion set is completed.

As above, when installing the MDK IV infusion set, it is necessary to insert the stop liquid piece for MDK IV infusion set into the clamp for MDK IV infusion set shown in Picture 6-1-6 23, straighten the IV infusion set so that the IV infusion set is in the positioning groove, and then close the pump door.

Before changing IV infusion set or changing drug solution, the roller clamp on the IV infusion set has to be turned to the closed position to prevent free flow of the medication solution.

As disposables, IV infusion set must be replaced after being used for once.

To change or re-install the IV infusion set, first open the pump door, push the clamp inside pump door upward to open it and to release the infusion line. Install the IV infusion set back into the pump again, and adjust the roller clamp on the set to the open

position after the IV infusion set installation is done.

If the electric pump door cannot be opened by pressing the electric pump door switch in standby mode, press the "manual pump door switch" at the bottom of the device to open the pump door in an emergency, replace the IV infusion set and re-check whether the pump door is normal before use.

7.3.2 Select IV infusion set

After the infusion pump is powered on and the safety self-test is passed, the parameter setting page will show up. Click the Brand button in the upper right corner to enter the IV infusion set brand selection page. Figure 7-3-2.

After clicking an IV infusion set brand to make a selection, the system will automatically return to the parameter setting page. Please check if the IV infusion set displayed on the right side of the screen matches the set that is being used.

It is possible that the IV infusion set 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 IV infusion set is recommended, which is described in Section 10 Accuracy Calibration for IV infusion set.

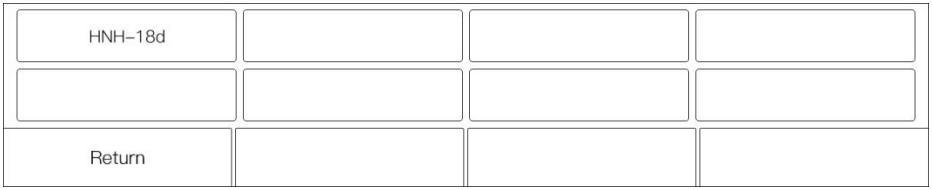


Figure 7-3-2 Select IV infusion set

7.3.3 Install drip sensor(optional)

Connect the drip sensor to the drip transfer interface of the device, and install the drip sensor on the drip pot. If you need to replace the infusion set, remove the drip rate sensor, pull out the interface, and reinstall it.

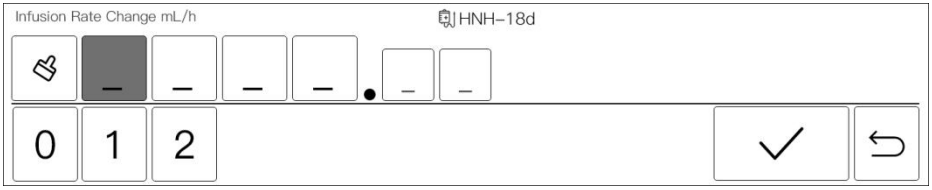
To ensure reliable and accurate drop count detection, the drop count sensor should be installed as close to the liquid level as possible, and the liquid level height should be 1/3 of the drop pot. During the infusion process, it is necessary to avoid tilting the drop count sensor, direct sunlight, and strong light.

For the cleaning of the drop count sensor, please refer to the instruction manual "15 Product Maintenance" to wipe the outer surface of the drop count sensor.

7.3.4 Set infusion parameters

Click on "Infusion Speed" on the screen to enter the infusion speed change page. Enter the flow rate value to be set, and click the "√" button to complete the input.

The method for setting the preset amount and total time is the same as the method for setting the infusion speed mentioned above. After setting, click the "√" button to confirm the parameters.



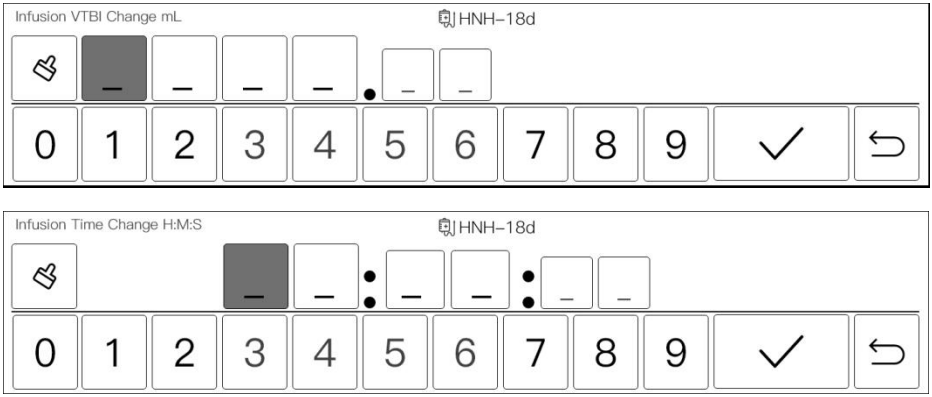


Figure 7-3-4 Set infusion parameters

7.3.5 Purge

After the infusion parameters are set, click the "Start Infusion" button and the device will pop up an exhaust confirmation page. Confirm that the pipeline is disconnected from the patient. Click the "Confirm" button on the screen, and the device will run at the purge rate and total amount set by the system to quickly empty the gas in the infusion pipeline (click the "Stop Purge" button to stop purge).

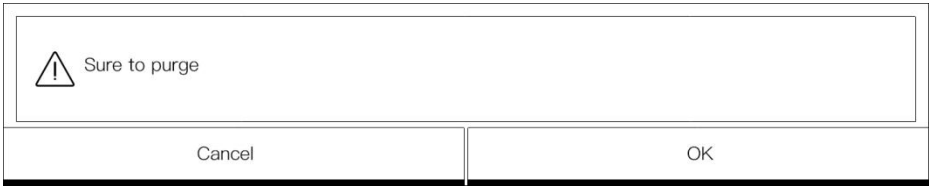


Figure 7-3-5 Confirm to purge

After the purge, enter the infusion pause interface. If there are still air bubbles in the infusion line, click the "purge" button to purge again, and repeat the above operation until there are no air bubbles.

The purge volume is not included in the Infusion accumulation. When the Purge is running, the Air-in-line alarm is not suppressed, and the other alarms are normal.

7.3.6 Start infusion

Press the Start/Stop key or click the start button and the pump will start to run according to the set infusion parameters, as shown in the following figure.

When the device is working, after revising the infusion flow rate in real time, the motor will synchronously change the voltage to increase the motor speed, so that the pump can synchronously reach the changed flow rate.

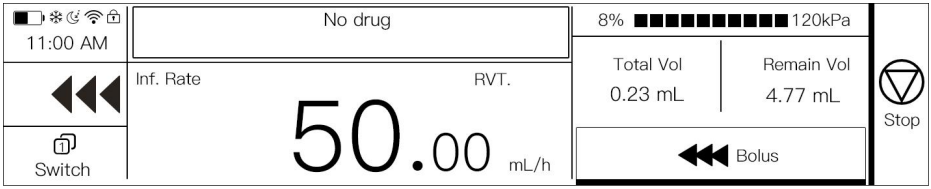


Figure 7-3-6 Infusion interface

7.3.7 Infusion completed

The infusion is completed when the infusion accumulation volume reaches the VTBI set for the infusion task.

If KVO is enabled, the device will convert to the KVO Rate to continue running automatically and trigger the "KVO" high priority alarm at the same time. Click the "Stop" button or press the "Stop" button to enter the infusion pause interface. Click "Exit Infusion" to enter the infusion mode selection interface. At this time, you can reset the infusion parameters and start a new infusion task.

After the infusion task is completed, remove the infusion attachment, follow the method of replacing the infusion set, remove the infusion set that is no longer in use, press the "Power" button, and click "Shutdown" to turn off the device. Pull the circular ring on the fixed clamp base upwards and remove the infusion pump by pulling it outward.

7.4 Pause or Stop Infusion

Press the Start/Stop key or click the stop button during infusion operation can pause the operation, as shown in the following figure.

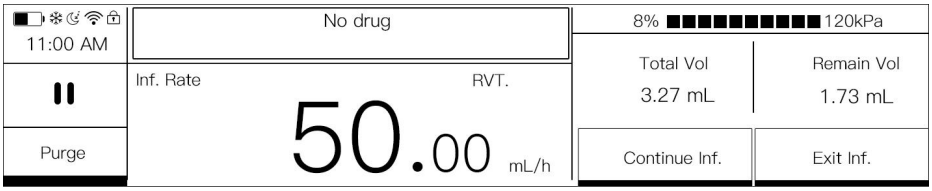


Figure 7-4 Infusion pause

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

7.5 Bolus

In the infusion state, click the "Bolus" button to enter the bolus selection page. If "Last Bolus" is selected, the device will take the bolus according to the parameters of the previous bolus; If

"Automatic Bolus" is selected, the device will enter the bolus parameter setting page. After setting and confirming the bolus parameters, click the "Start Bolus" button, and the infusion pump will enter the pill infusion state. After the bolus dosage reaches the set value, stop the infusion of the bolus, and the infusion pump returns to the normal infusion operation state before entering the bolus infusion to continue infusion. The bolus dosage is included in the accumulated infusion volume.

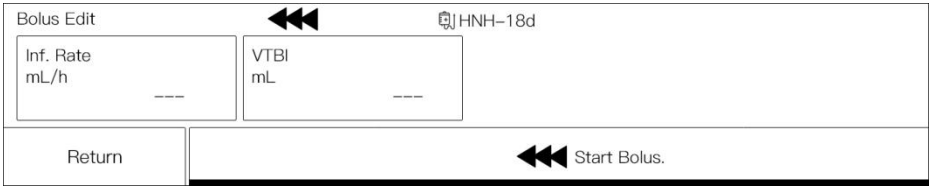


Figure 7-5-1 Bolus setting interface

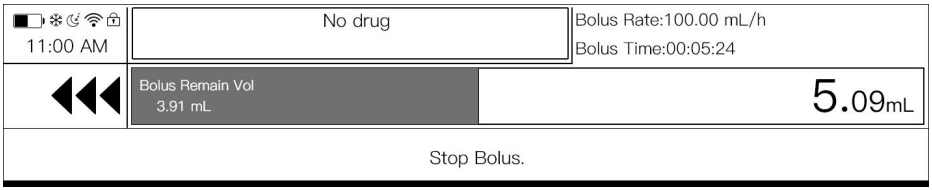


Figure 7-5-1 Bolus running interface

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 the "Confirm" button to unlock the screen.

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

7.7 Infusion Mode Selection and Setting

Except for the RVT mode on the home screen, there are other infusion modes on the Infusion Mode page: Dose mode, Drug Library mode, Drop speed mode, RTM mode, Sequence mode, Loading Dose mode, Intermittent mode, Micro mode, Relay mode, TIVA mode, Piggyback mode, Feeding mode, Transfusion mode.

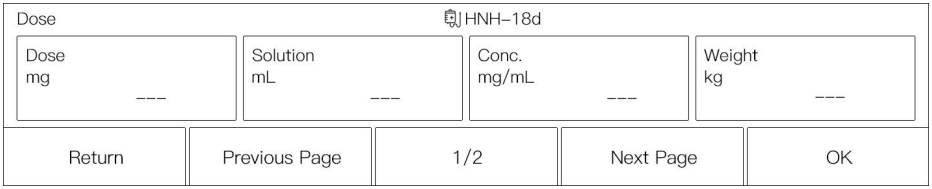
In the RVT setting page, the infusion rate, VTBI and infusion time can be set in a variety of combinations, forming the following four combinations of infusion mode: rate + volume (R+V) Mode , rate + time (R+T) Mode, volume + time (V+T) Mode, rate (R) Mode. Therefore, there are 17 different infusion modes for the device in total.

Please follow the instructions in the "Quick Use Guide" above for setting the speed mode. The following is a brief introduction to the settings of other modes.

7.7.1 Dose mode

Enter the Dose mode settings interface, as shown in Figure 7-7-1.

Set the dosage, solution volume, concentration, body weight, dose rate, infusion rate, preset amount, and total time separately. After setting the parameters, click the "Confirm" button to confirm the infusion parameters.



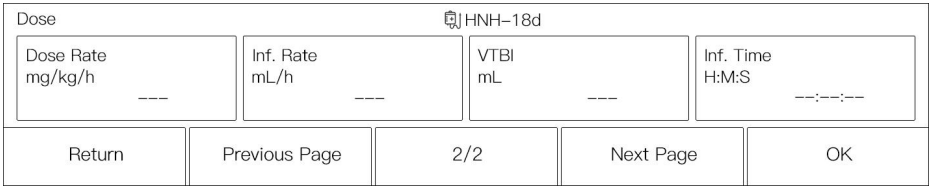


Figure 7-7-1 Dose mode setting

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:

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

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,Figure 7-7-2.

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.

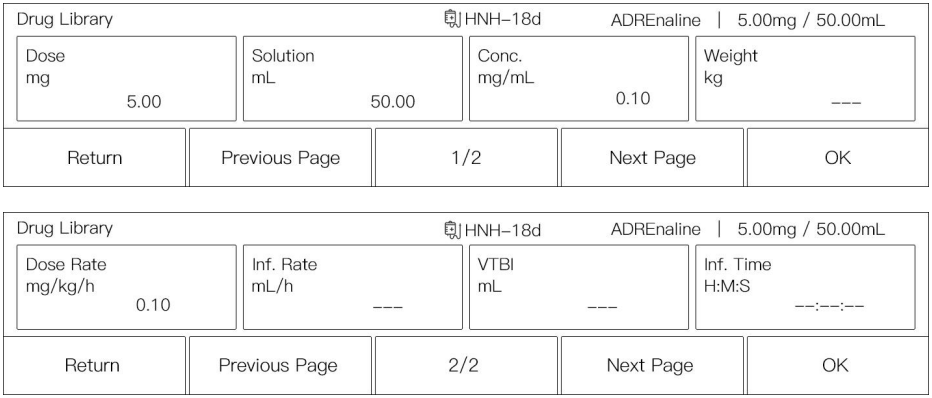


Figure 7-7-2 Drug Library mode setting

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

7.7.3 Drop Speed mode

Enter the system maintenance interface and open the drip transfer function.

This infusion pump can be used in conjunction with the matching drop count sensor to monitor the flow rate in the infusion pipeline. When the deviation between the drop rate and the set infusion rate exceeds 50%, an alarm prompt will be triggered.

Select to enter the drip rate mode setting interface, as shown in the following figure. After setting the infusion infusion rate parameter, it is automatically converted to a speed parameter display, and other operations are the same as the speed mode

introduced in the Quick Use Guide section.

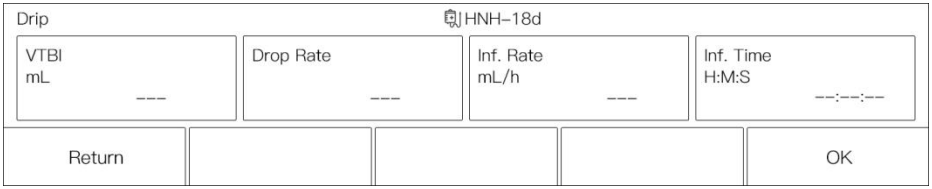


Figure 7-7-3 Drop Speed mode setting

7.7.4 RTM mode

Enter the RTM mode(Ramp and Taper Mode) settings interface, as shown in Figure 7-7-4.

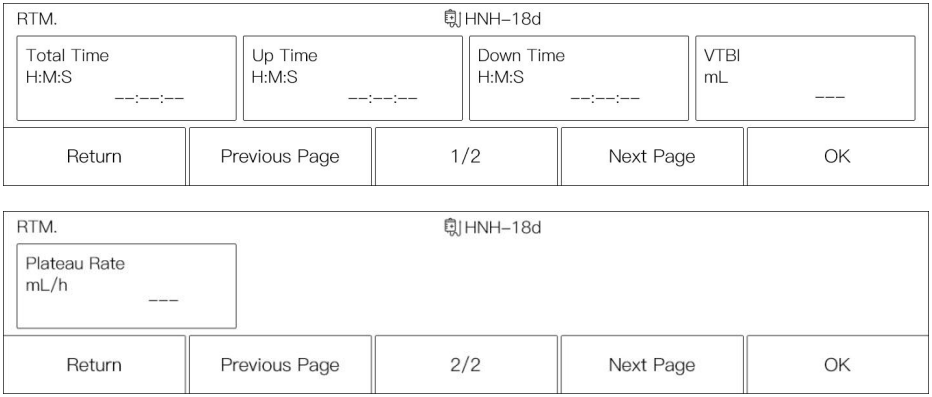


Figure 7-7-4 RTM mode setting

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 "Confirm" 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.

7.7.5 Sequence Mode

Select to enter the sequence mode setting interface and set the number of sequences (up to 10 groups), Click the "Next" button at the bottom right to enter the infusion parameter settings, as shown in the following figure.

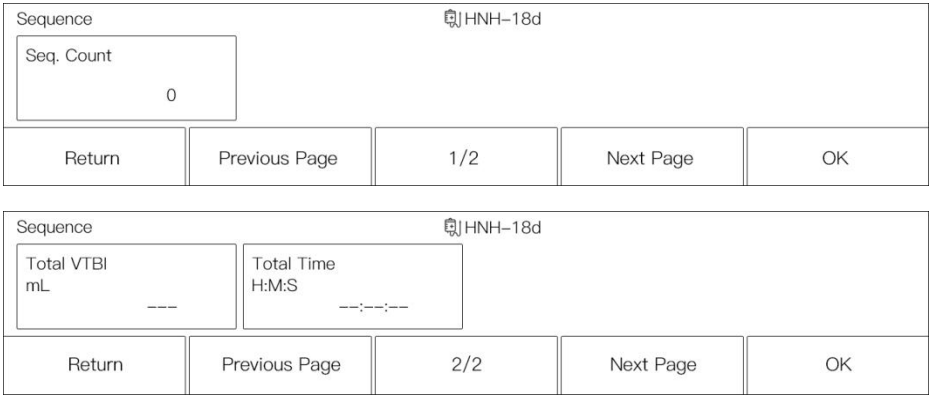


Figure 7-7-5 Sequence mode setting

As shown in Figure, if any two of the three parameters are set, including preset amount, total time, and infusion speed, the device will automatically calculate another parameter.

Click the "Next" button, set 1 to 10 different infusion parameters according to clinical needs, view the total preset volume and 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 the infusion is completed.

7.7.6 Loading Dose Mode

Enter the Loading Dose mode settings interface, as follows.

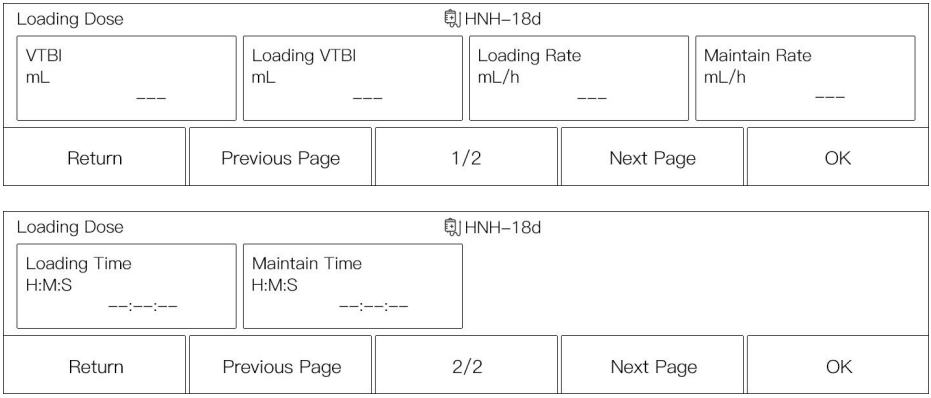


Figure 7-7-6 Loading dose mode setting

As shown in the figure, set the preset amount, loading amount, loading rate, and maintain rate. The device automatically calculates 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 loading rate. When the cumulative infusion amount equals the preset loading amount, the infusion automatically continues according to the maintain rate. When the cumulative infusion amount reaches the preset amount, the infusion is completed.

7.7.7 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 "Confirm" 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 0 mL/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.

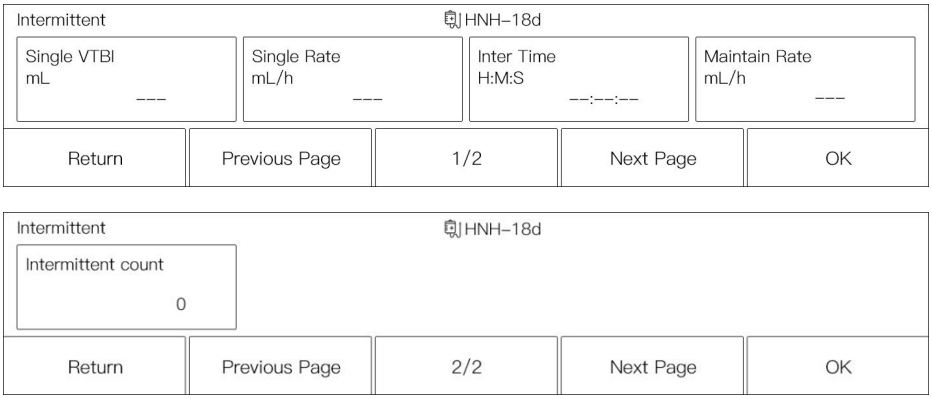


Figure 7-7-7Intermittent mode setting

7.7.8 Micro mode

Enter Micro mode settings interface.

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 Infusion Rate. When the infused volume is equal to the VTBI, the infusion will be stopped automatically.

When 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.

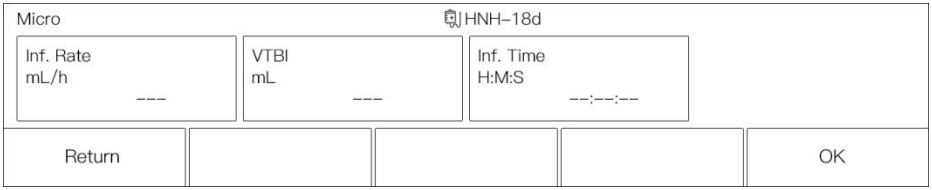


Figure 7-7-8 Micro mode setting

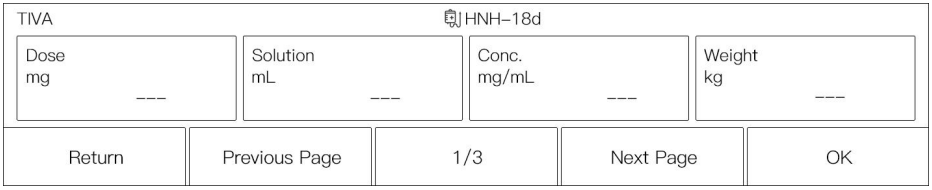
7.7.9 Relay mode

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

7.7.10 TIVA mode

Enter the TIVA mode setting interface.

Set body weight, loading dose, and any two parameters in dose, solution volume, and concentration to automatically calculate another parameter value; Setting any parameter in the loading time and loading rate can automatically calculate another parameter value; Setting any parameter in maintain rate or flow rate can automatically calculate another parameter value.



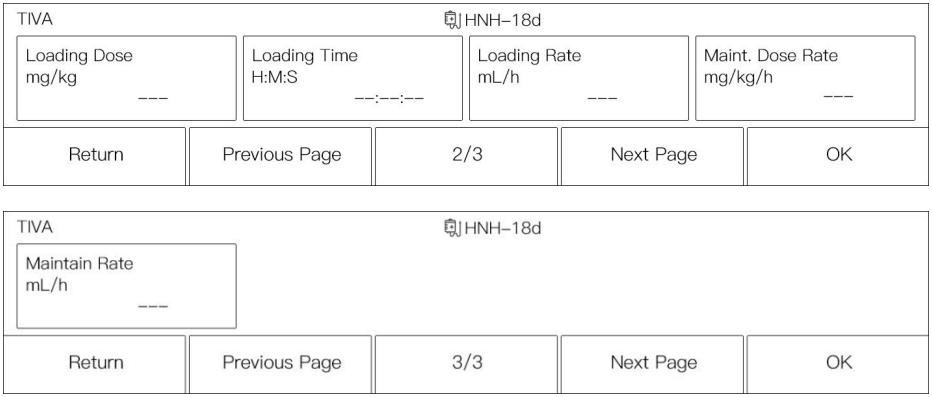


Figure 7-7-10 TIVA mode setting

7.7.11 Piggyback mode

1) Install the infusion set and purge it according to the instructions for the use of piggyback consumables.

2) On the infusion mode page, select the piggyback mode, click the Primary button to select the infusion mode, set the infusion parameters as described in the above chapter, and click OK. The Secondary button appears in the bottom right corner of the page.

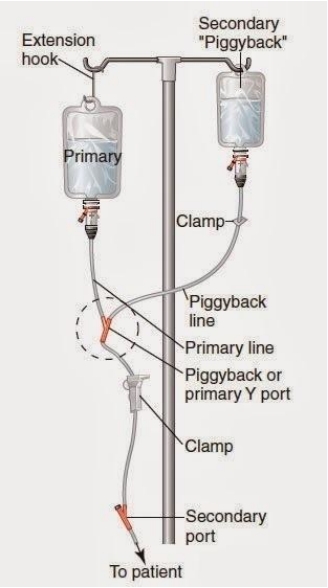
3) Click on the Secondary button to set the same settings as the Primary. After setting up, click "Start Infusion" to start normally.

4) After starting the operation, due to the high liquid level in the secondary bag, it will flow down first; Until the liquid in the secondary bag is completely infused, it will automatically switches to the primary bag flowing downwards.

5) In step 3), if you do not select the Secondary button, you can directly click Start to start the infusion, and the device runs according to the infusion parameters of the Primary; During infusion operation, you can click the pause button, click the secondary

button on the pause page, and follow step 3 to start the second bag of liquid infusion.

6) After the device completes the second bag of liquid infusion, it automatically switches to the first bag of liquid infusion until the primary preset amount is completed or when the infusion is empty, an alarm stops infusion.



7.7.12 Feeding mode

Install the special nutrition tube according to 7.3.1 Operation instructions, and select the consumables as the special nutrition tube according to the operation instructions in Section 7.3.2. Click Home-Infusion Mode-Feeding Mode to enter the page of mode parameter setting.

According to the method of 7.3.3, set two of the three

items of feeding flow rate, feeding quantity and feeding time, and the equipment will automatically calculate the third item. When the feeding flow rate is set, and the feeding quantity and feeding time are set to 0, the set speed will be run until the liquid bag is empty. After setting feeding parameters and removing Air Bubbles from Infusion Line according to 7.3.4, press the Start-Stop button or click the Start button to start the infusion.

7.7.13 Transfusion mode

Install the special blood transfusion tube according to 7.3.1 Operation instructions, and select the consumables as the special blood transfusion tube according to the operation instructions in Section 7.3.2. Click Home-Infusion Mode-Transfusion Mode to enter the page of mode parameter setting.

The method for setting transfusion mode parameters is the same as that for RVT mode. The three parameters of flow rate, infusion volume and infusion time can be set to form the following four combination modes: flow rate + total volume mode, flow rate + time mode, total volume + time mode, and RVT mode (without total volume and time).

After setting transfusion parameters and removing Air Bubbles from Infusion Line, press the Start-Stop button or click the Start button to start the infusion.

7.7.14TCI 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 volume of the diffusion is called the atrioventricular. The infusion 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:

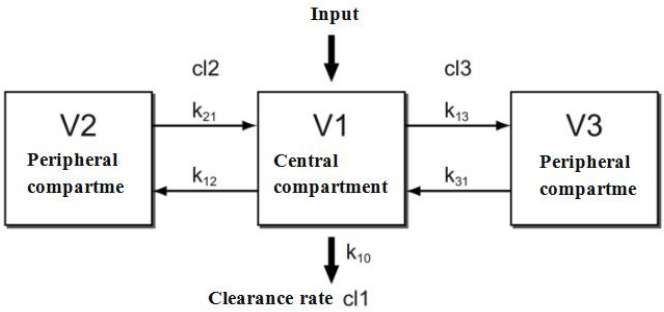


Figure7-7-14-1 Plasma target control model

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:

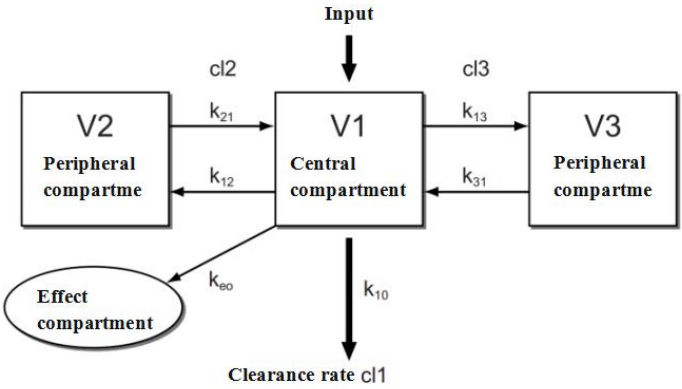


FIG.7-7-14-2 Effect location-based control model

To set the TCI mode, perform the following steps:

Select the TCI mode setting screen, as shown in Figure7-7-9-3:

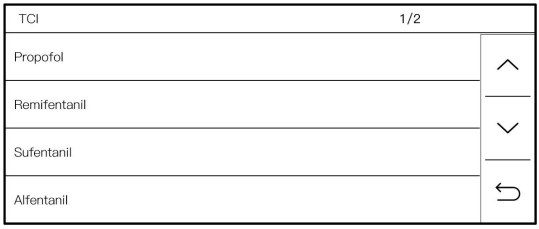


Figure7-7-14-3 TCI model drug interface

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

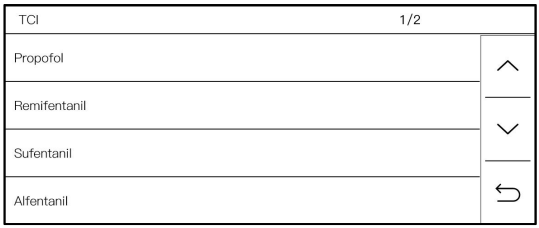


Figure7-7-14-4 TCI parameter setting page 1

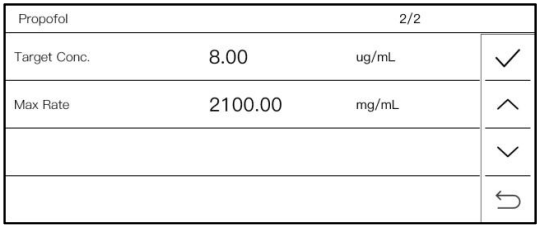


Figure7-7-14-5 TCI parameter setting page 2

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.

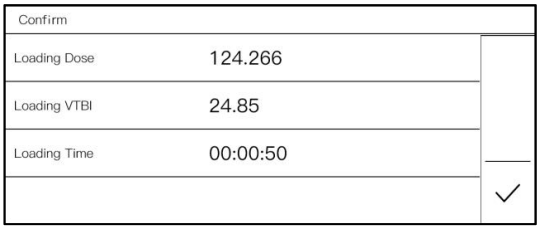


Figure7-7-14-6 Confirming parameters

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

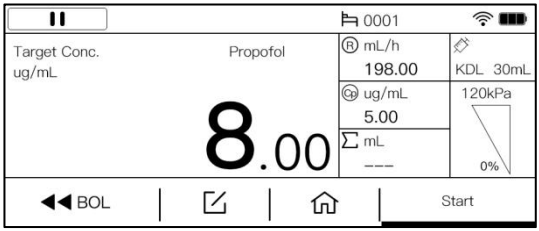


Figure7-7-14-7 Infusion screen

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, as shown below:

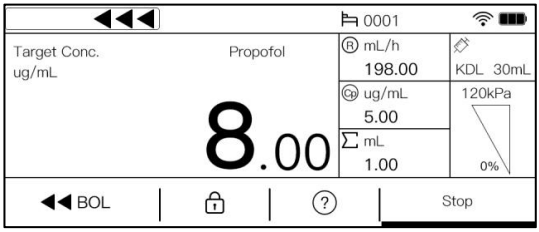


Figure7-7-14-8 Running screen

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. As shown in the picture:

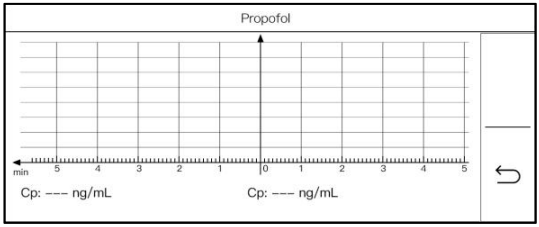


Figure7-7-14-9 Infusion curve

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	◯	×
	Eleveld	◯	◯
Remifentanil	Minto	◯	◯
Sufentanil	Gepts	◯	◯
	Bovill	◯	◯
Alfentanil	Maitre	◯	◯
Fentanyl	Shafer	◯	◯
Dexmedetomidine	Dyck	◯	×
"○" 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 Weight:30.00-200.00Kg Target concentration: 0.01-15.0ug/mL

		Max Rate: Same as 5.2 speed setting range
	Schnider	concentration:5.00-20.00mg/mL Height:130-220cm Gender:Male/Female Weight:30.00-200.00Kg Age:16-100 Target concentration: 0.01-15.0ug/mL Max Rate:Same as 5.2 speed setting range P-Limit:100-999 %
	Kataria	concentration:5.00-20.00mg/mL Age:2-16 Weight:15.00-99.99Kg Target concentration: 0.01-15.0ug/mL Max Rate: Same as 5.2 speed setting range
	Paedfusor	concentration:5.00-20.00mg/mL Age:1-18 Weight:15.00-99.99Kg Target concentration: 0.01-15.0ug/mL Max Rate: Same as 5.2 speed setting range
	Eleveld	concentration:5.00-20.00mg/mL Height:130-220cm Gender:Male/Female Weight:5.00-200.00Kg Age:2-90

		Target concentration: 0.01-15.0ug/mL Max Rate: Same as 5.2 speed setting range P-Limit:100-999 %
Remifentanil	Minto	concentration:20.00-50.00ug/mL Height:130-220cm Gender:Male/Female Weight: 30.00-200.00Kg Age:16-100 Target concentration: 0.01-20.0ng/mL Max Rate: Same as 5.2 speed setting range P-Limit:100-999 %
Sufentanil	Gepts	concentration: 0.20-5.00ug/mL Weight: 30.00-200.00Kg Target concentration: 0.01-5.00ng/mL Max Rate: Same as 5.2 speed setting range P-Limit:100-999 %
	Bovill	concentration: 0.20-5.00ug/mL Weight: 30.00-200.00Kg Target concentration: 0.01-5.00ng/mL Max Rate: Same as 5.2 speed setting range P-Limit:100-999 %
Alfentanil	Maitre	concentration: 100.00-500.00ug/mL

		Gender: Male/Female Weight: 15.00-200.00Kg Age:18-95 Target concentration: 0.01-500.00ng/mL Max Rate: Same as 5.2 speed setting range P-Limit: 100-999 %
Fentanyl	Shafer	concentration: 1.00-5.00ug/mL Age: 2-100 Weight: 5.00-200.00Kg Target concentration: 0.01-500.00ng/mL Max Rate: Same as 5.2 speed setting range P-Limit: 100-999 %
Dexmedetomidine	Dyck	concentration: 1.00-10.00ug/mL Weight: 15.00-300.00Kg Height: 130-220cm Target concentration: 0.01-500.00ng/mL Max Rate: Same as 5.2 speed setting range

7.8 View Log

On the Home - Event Log Page, event logs such as device infusion status and alarm can be displayed. Click this event can view the detailed event information such as Infusion Rate, VTBI, time, Alarm priority and time.

When the pump log store 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 log information can be stored and queried in unlimited, and the log information can be printed out on the Internet to facilitate the needs of medical management.

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

Figure 7-8 Log view

8 Alarms

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

Alarm classification prompts of the equipment:

No.	Alarm	Priority	Alarm category	Alarm conditions
8.1	Door open	High	Latching	The pump door is not closed during infusion or purge.
8.2	IV-Set Setup Fail	High	Latching	IV-Set are not properly installed.
8.3	OCCL (Occlusion)	High	Latching	When the infusion line is occluded.

8.4	Upstream occlusion	High	Latching	When the upstream infusion line is occluded.
8.5	End Of Infusion	High	Latching	When the infused volume is equal to the VTBI.
8.6	Air-in-line	High	Latching	Air bubbles are detected in the line.
8.7	Battery Empty	High	Latching	When the internal battery is running out.
8.8	Battery&External Power Disconnect	High	Unlatching	When the device is running, the battery and external power is disconnected at the same time.
8.9	Motor Err.	High	Latching	In the event of a motor failure.
8.10	Com. Err. (Communication error)	High	Latching	Monitor the CPU for communication handshake errors.
8.11	Battery Error	High	Latching	The device does not detect battery signal or battery disconnect when plug in the external power.
8.12	KVO	High	Latching	The infusion is complete with KVO is enabled.
8.13	KVO end	High	Latching	KVO status run for 30 minutes until the KVO task is complete.

8.14	Standby End	High	Latching	When standby is end.
8.15	No AC Power	Low	Unlatching	When the device is disconnected from the external power and operated with batteries.
8.16	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.
8.17	Low battery	Low	Unlatching	When the internal battery power is low.
8.18	Near End Of Infusion	Low	Unlatching	When the remaining time is less than or equal to the set near end of infusion time.
8.19	Drip rate error	High	Latching	When used in conjunction with a drop count sensor, when the deviation between the drop rate and the set infusion flow rate exceeds 50%

The device alarm indicator characteristics：

Alarm type	Indicator color	Flicker frequency		Ratio
High	Red	2 Hz	0.7 Hz(Battery &	50%

priority			External Power Disconnect alarm)	
Medium priority	/	/		/
Low priority	Yellow	Normally open		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 equipment 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 equipment alarm is a technical alarm state.

==========

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.

Equipment 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.

==========

8.1 Door Open Alarm

Cause: When the infusion pump is running, if the pump door is not closed, or the pump door is opened by accident, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Door Open" and the

operation status indicator flash red at the same time.

Solution： Click the “Confirm” on the screen to clear the alarm, the word " Door Open " disappears, and returns to the infusion pause interface. Check the pump, close pump door and continue to operate.

8.2 IV-Set Setup Fail Alarm

Cause: When operation is started without an IV infusion set being installed on the pump, the device triggers an alarm, stops running, make a high priority alarm sound, the screen appears with the message "IV-Set Setup Fail" and the operation status indicator flashes red at the same time.

Solution: Click the “Confirm” button on the screen to clear the alarm, the word "IV-Set Setup Fail" disappears, and returns to the infusion pause interface. Open the pump door and install the IV infusion set before continuing.

8.3 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 IV infusion set line is kinked, whether the patient presses into the infusion line and other issues, eliminate the problem and restart the infusion.

3)If there is still an occlusion alarm, shut off the roller clamp on the IV infusion set, open the pump door, pull out the IV infusion set, check whether the filter or the needle on IV infusion set is occluded, change to a new IV infusion set if necessary and restart infusion.

8.4 Upstream Occlusion Alarm

Cause: When the roller clamp between the bag and the pump is left closed by mistake, the infusion line will become flat when the infusion gets started. The device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Upstream Occlusion" and the operation status indicator flash red at the same time.

Solution:

1)Click the “Confirm”button on the screen to clear the alarm and the message "Upstream Occlusion" disappear.

2)Check whether the tube of the IV infusion set it kinked, whether the stop pulley is opened, whether the bag has the liquid medicine, etc., and restart the infusion after troubleshooting.

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

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

8.6 Air-in-line Alarm

Cause: When the infusion pump is running, if the air-in-line sensor detects that the size of air bubble is larger than that of the preset limit, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with the message "Air-in-line" and the operation status indicator flash red at the same time.

Solution:

1)Click the “Confirm” button on the screen to clear the alarm and the message "Air-in-line" disappears.

2)To remove air bubbles from the infusion line, close the roller clamp, open pump door, take IV infusion set out, check whether there is air bubbles in the line, shake and move the air bubbles to the drip chamber by hands if there is, reinstall the IV infusion set, close the pump door, open the roller clamp, press the Start/Stop key or click the Start button to restart infusion.

3)Check if the air-in-line sensor is clean. If sensor probe is dirty,

uninstall the IV infusion set, wipe clean the sensor probe with alcohol, reinstall the IV infusion set, and restart infusion.

4)If there is still an Air-in-line alarm, change to a new IV infusion set, install the IV infusion set and restart.

5)The air-in-line alarm will be activated too if the infusion line between the infusion bag and the pump is occluded. Remove the occlusion in infusion line and restart infusion.

8.7 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.

8.8 Battery & External Power Disconnect Alarm

Cause: When the Infusion 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.

8.9 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.

8.10 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.

8.11 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.

8.12 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 "Confirm" button on the screen to clear the alarm. The message "KVO" disappear. The device can be reset according to operating steps.

8.13 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 "Confirm" button on the screen to clear the alarm. The message "KVO End" disappear. The device can be reset according to operating steps.

8.14 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.

8.15 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.

8.16 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.

8.17 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 Infusion 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.

8.18 Near End Of infusion Alarm

Cause: When the remaining time is less than or equal to the set near end of infusion time, 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 steady on yellow at the same time, and the Infusion pump continues to infusion does not stop.

Solution: Click the "Mute" button on the right of the alarm prompt area to suspend the alarm sound. Focus on the amount of fluid remaining in the Infusion pump and the time remaining, and

wait for the Infusion pump infusion to complete.

8.19 Drip rate error alarm

Cause: When the device is used in conjunction with a drip rate sensor, when the deviation between the drip rate and the set infusion flow rate exceeds 50%, the device emits a high priority alarm sound, stops operation, the screen displays the word "Drip rate error", and the status indicator light flashes red at the same time.

Solution: Click the "Confirm" button on the screen to clear the alarm. Check if the installation of the drop count sensor is normal, and restart the infusion after troubleshooting the problem.

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

In the "Home - Settings - Pressure Settings" section, the blocking pressure alarm level can be set by clicking the corresponding level number button to complete the setting. After setting up, click the "Confirm" button to return to the previous page.

Occlusion pressure level	Occlusion pressure and error value
1	30 ± 20 kPa
2	40 ± 20 kPa
3	50 ± 20 kPa
4	60 ± 20 kPa
5	70 ± 20 kPa
6	80 ± 20 kPa
7	90 ± 20 kPa
8	100 ± 20 kPa
9	110 ± 20 kPa
10	120 ± 20 kPa

9.5 Air Bubble Detection Sensitivity

Set the bubble level in "Home - Settings - Bubble Settings", and the smaller the bubble level, the more sensitive it is. Click the

corresponding level number button to complete the setting. After setting up, click the "Confirm" button to return to the previous page.

9.6 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.

9.7 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.

9.8 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.

9.9 Screen Lock Time

Set the time for the display screen and device buttons to enter the locked state during device infusion operation in "Home - Settings - Automatic Lock Screen Settings".

If the lock screen time is set to 0, the automatic lock screen function can be turned off.

In the locked screen state, except for the power button, all other buttons and screen areas are not operable.

9.10 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 IV infusion set change.

9.11 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.

KVO example: When the device selects the Constant KVO, the Constant KVO rate is 2mL/h. When the actual flow rate is ≥2mL/h, the KVO flow rate after infusion is 2mL/h. When the actual flow rate is ＜2mL/h, the KVO running rate after infusion is equal to the actual running rate.

When the device selects variable speed KVO, the variable KVO rate: “Flow Rate > 10” is 3mL/h, “Flow rate ≤10” is 2mL/h, and “Flow rate ≤1” is 0.5mL/h. When the actual flow rate is ＞ 10mL/h, the KVO flow rate after infusion is 3mL/h. When 2mL/h≤ the actual flow rate≤ 10mL/h, the KVO running flow rate after infusion is 2mL/h. When 1mL/h < the actual flow rate< 2mL/h, the KVO running flow rate after infusion is equal to the actual running

rate. When 0.5mL/h ⩽ the actual flow rate ⩽ 1mL/h, the KVO running flow rate after infusion is 0.5mL/h. When the actual flow rate is ＜0.5mL/h, the KVO running rate after infusion is equal to the actual running rate.

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.

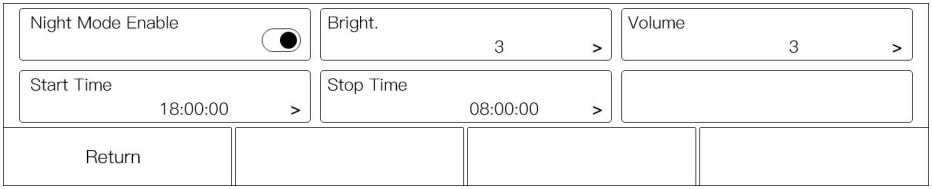


Figure 9-12 Night mode Setting

9.13 Near End Of Infusion Time Setting

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

9.14 Maintenance

Maintain the device in “Setting - Maintenance”, Including the calibration of IV infusion set 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.

IV infusion set calibration operation instructions see Section 10

of this manual.

9.15 Date/Time Setting

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

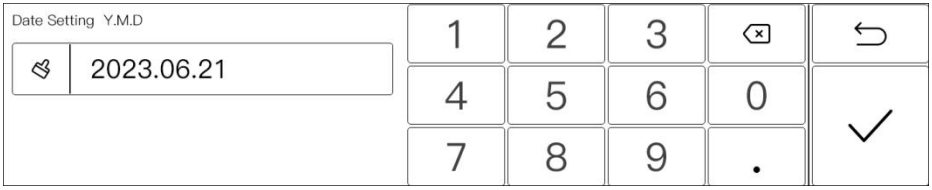


Figure 9-15-1 Date/Time Setting

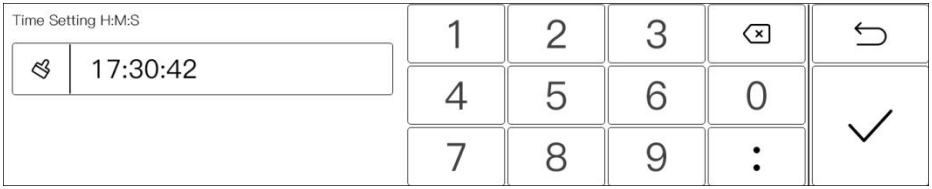


Figure 9-15-2 Date/Time Setting

9.16 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.

10 Accuracy Calibration for IV infusion set

The brand and specification IV infusion sets that have not been calibrated, or IV infusion sets belonging to different production lots

with the calibrated IV infusion sets, need to be calibrated before use. In normal use, the IV infusion set should be re-calibrated every 6 months.

10.1 Enter infusion set accuracy calibration interface

Calibrate the accuracy of the infusion device in the "Home - System Maintenance - Consumables Maintenance" section.

10.2 Accuracy Calibration for IV infusion set

1) Same as the normal infusion operation, install the IV infusion set first, put the scalp needle into the beaker, place the beaker on the balance and clear the indicator to zero, and enter the page of "Setting- System Maintenance- Consumable Maintenance-Calibration Consumable".

2) Click Brand, select the brand of the IV infusion set to be calibrated, and return to the Calibration Consumable page.

3) Click Calibration range, select the high Rate interval or the low Rate (the calibration Rate of the low Rate is 200mL/h, and the output volume is 10mL; the calibration Rate of the high Rate is 1000mL/h, and the output volume is 50mL), return to the Calibration Consumable page, and pay attention to the selection of the scalp needle specifications that match the rate.

4) Click Calibration Start/Stop, the infusion pump will output a certain amount of solution according to the current calibration interval. When the infusion was completed, the infusion pump automatically stopped running.

5) Check the balance reading, convert it to the actual solution

volume, and input the actual solution volume in the Volume Output;
6) Turn to the next page and click OK to save the current calibration value.

11 Precautions for Using Disposable Consumables

It's suggested to use the recommended consumables. The ambient temperature should be kept at least at 5 ℃ or above when a recommended consumable is used. The infusion accuracy will be compromised if ambient temperature is lower than 5 ℃.

The recommended consumables are listed in the table below:

No.	Brand	Model	Accuracy	Ambient temperature
1	Hanaco	H-06APD-8	±4%	+5℃~+40℃
2	JR	Automatic Vent Type With Needle	±4%	+5℃~+40℃
3	Kindly	Ordinary type with needle	±4%	+5℃~+40℃
4	Kangjin	IS-F-C3F	±4%	+5℃~+40℃
5	Shinva	Ordinary type with needle	±4%	+5℃~+40℃
6	MDK	P-B-11	±3%	+5℃~+40℃
7	MDK(enteral feeding)	EF-BS1-P1	±4%	+5℃~+40℃
8	Terumo		±4%	+5℃~+40℃

The consumable used must have a medical device product registration certificate, and the consumable specifications are

selected in the same specification as the recommended consumable brand. consumable Installation Methods See 7.3.1 Install/replace consumable.

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

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

Consumables should be used in accordance with the IFU, and the following points should be noted:

— infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and

— physical hazards such as from sharps.

12 Technical Specification

This product is numbered according to the technical requirements of medical devices:

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.

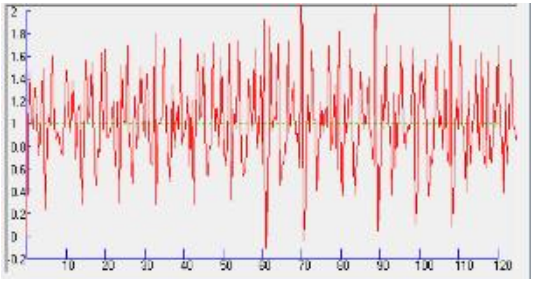
3) The maximum volume that the pump can deliver under a single

fault condition: 0.5 mL.

4) Device calibration is measured in ml.

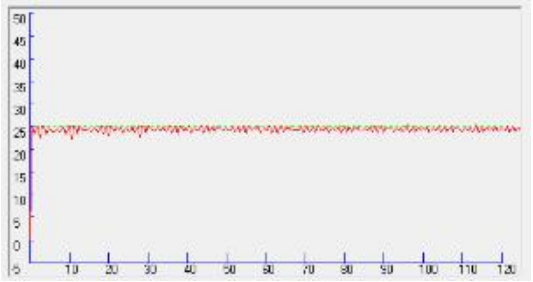
5) The methods used to avoid overflow or underflow due to device failure: to prevent overflow or underflow by using drop speed sensor to measure flow rate.

6) The rising curve for HANACO IV infusion set with the minimum flow rate during the first two hours of operation.



In the above figure, the dashed line shows the set flow rate (1.00 mL/h in this figure), and the solid line is the continuous connection line for the average flow rate during a sampling period.

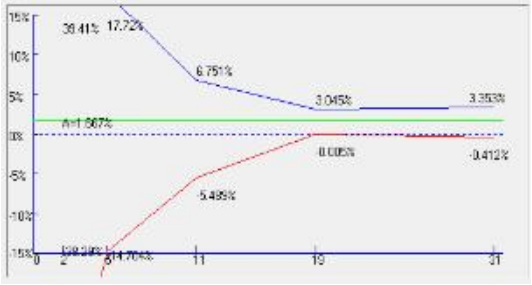
7) The rising curve for HANACO IV infusion set with the intermediate flow rate during the first two hours of operation



In the above figure, the dashed line shows the set flow rate (25.00 mL/h in this figure), and the solid line is the continuous

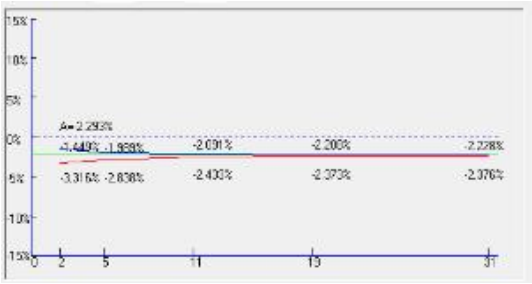
connection line for the average flow rate during a sampling period.

8) The trumpet curve for HANACO IV infusion set with the minimum flow rate during the two hour of operation, which was plotted based on the test data gathered during the two hours 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.

9) The trumpet curve for HANACO IV infusion set with the intermediate flow rate, which was plotted based on the test data gathered 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.

The rising curve chart and horn curve chart can be used to understand the performance of the infusion pump after the start of infusion and the changes in infusion status during a period of time when it reaches normal infusion rate.

13 Restore to factory setting

Default factory setting as below:

No.	Item	Default
1	Brightness level	level 3
2	System sound level	level 3
3	Bubble level	level 3
4	Night mode sound level	level 3
5	Night mode brightness level	level 3
6	Occlusion pressure level	120 kPa
7	Night mode	Close
8	WIFI	Close
9	Infusion mode	RVT mode
10	KVO	Constant KVO
11	KVO rate	1.00 mL/h
12	Call Back Time	2 min
13	Near End Of Infusion time	5 min
14	Auto screen lock time	5 min
15	Night mode start time	19:00:00
16	Night mode end time	09:00:00
17	Bolus rate	1200.00 mL/h

18	Purge rate	1200.00 mL/h
19	Bolus volume	5.00 mL
20	Purge volume	15.00 mL

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.

1) 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 IV infusion set 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 bolus.

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.

4)Keep the surface of the air bubble sensor probe clean. A dirty probe will reduce the sensor's sensitivity in air bubble detection or cause false alarm. Take caution when cleaning the probe to avoid causing any damage.

16 Waste Disposal

16.1 Battery

Please follow local regulations to dispose of used batteries.

16.2 Consumable

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

16.3 Infusion pump

This device is designed to last 8 years and should be scrapped after it has exceeded the lifetime. End-of-life Infusion 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 equipment. 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:

Product name	Length
Power adapter	2.9m

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 equipment 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	Description
The network power supply (including the internal battery) is connected to run	At the intermediate rate of 25.00mL/h and the VTBI of ≥10mL, start to operation, infusion accuracy error less than ±4% and the operation is normal during the process, there should be no abnormal phenomena and failures.

Guidance and manufacture's declaration – electromagnetic emission

Guidance and manufacture's declaration – electromagnetic emission The device is expected to be used in the following specified electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Emission test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The device only uses RF energy for its internal functions, so its RF emission is very low and the possibility of interference to nearby electronic devices is very low

RF emissions CISPR 11	Class A	The device is suitable for use in non household and all facilities that are not directly connected to the public low-voltage power supply network of household residential areas.
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

Guidance and manufacture's declaration – electromagnetic immunity The Infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of Infusion pump should assure that it is used in such an environment.:			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±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	±1 KV line to line	±1 KV line to line	The network power

IEC 61000-4-5	±2 KV line to ground	Not applicable	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 cycle (>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， 5 cycle (>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： UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration - electromagnetic

immunity - For life support equipment and systems

Guidance and manufacture's declaration – electromagnetic immunity			
The Infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of Infusion 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 Radiated RF IEC61000-4-3	3 V(Valid value) 150 kHz~ 80MHz (expect the ISM bands between[a]) 10V(Valid value) 150 kHz~ 80MHz (ISM bands between[a]) 10V /m 80MHz~2.5GHz	10V 10V/m	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 d =1.2$\sqrt{(P)}$ 150kHz-80MHz d =1.2$\sqrt{(P)}$ 80MHz-800MHz 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] 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 infusion pump is located is higher than the applicable RF compliance level mentioned above, the infusion 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 infusion pump.

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

Recommended isolation distances between portable and mobile radio frequency communication devices and devices or systems——For life support equipment and systems

Recommended isolation distance between portable and mobile RF communication equipment and infusion 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 Anti static Precautions

The Infusion pumps have 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 equipment, or to the ground, or to a large piece of metal; 3) Use a wrist band to connect human body to the equipment 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 equipment or to the ground, and how to use wrist band to connect someone's body to the equipment or to the ground.

19 Cyber Security 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） Cyber security feature configuration

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

5） 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.

6） 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;

7） Security Software compatibility list (if applicable)

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

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

Not applicable, not updated

9） 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:

Accessories	Qty	Unit
IFU	1	pcs
Power adapter	1	set
Other accessories can be found in the packing list.		

Legal manufacture: MDKMed Medical Technology Co., Ltd.

Address: 502A, Building 7, No. 22, Xinyan Road, Donghu Street, Linping District,Hangzhou City, Zhejiang Province, P. R China 311323

After sale service: MDKMed Medical Technology Co., Ltd.

Tel: 400-880-8392

Email: sales@graseby.com

Web: http://www.graseby.com

European Authorized Representative:
MedNet EC-REP C IIb GmbH
Borkstrasse 10

48163 Münster, Germany