Graseby™

Syringe Pump Instruction Manual

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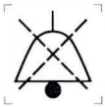
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1 Symbols, Graphics and Warnings

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
IP24	Ingress Protection Grade 24	~	AC (Alternating Current)
⎓ 15V	DC (Direct current)		Non-ionizing electromagnetic

			radiation
	Mute		Lithium battery
	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.

- The Syringe Pump is intended for clinical intravenous infusion. It must either be used with a syringe that is from the list of the recommended brands or with one from other brands after calibration is performed on the device.
- 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.
- To prevent fire or explosion, do not use this equipment in an environment where flammable or explosive matters are present.
- 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.
- 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.
- 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.
- The installation height of this equipment should not be more than 1 meter above or below the patient's heart.
- Do not reuse the same IV infusion set on another infusion device.
- This device cannot be used as a portable device.

- Do not use sharp objects to press on the buttons or the touch screen.
- 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.
- Please make sure to use only the parts and accessories provided by MDK.
- When hit hard or dropped, the pump should not be used until it has been checked by trained technical staff.
- 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.
- During the use of the equipment, the equipment should be placed smoothly and fixed firmly.
- 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.
- Operator should set the infusion parameters strictly based on the doctor's prescriptions. Mistakes in infusion parameter settings may cause harm to patients.
- After setting infusion parameters, the operator must ensure that the infusion set is properly stuck to the device before starting infusion.
- 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.。

- To maintain high infusion accuracy, the pump needs to be re-calibrated when there is a significant change in ambient temperature.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- For different types of patients, different occlusion pressure Level should be set. For details, please refer to the doctor's advice.
- 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.

- Please follow the instructions for consumables to use the liquid stop clamp and other components on the infusion line correctly.
- 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.
- IV infusion set needle is the application part of this product.
- 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.
- 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.
- 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 1500, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, 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.

- 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.
- The ME EQUIPMENT or ME SYSTEM is suitable for professional healthcare facility environments.
- 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.
- 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.
- 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.
- 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.

- 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.
- 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.
- 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.
- 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.
- 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.
- The MS33, S20 and S20 Plus syringe pump have verified the accuracy of the mathematical model and injection accuracy.
- In order to avoid accidental use of TCI, please exit the TCI mode in time after the target-controlled infusion is completed.

- 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.
- When using the diluted anesthetic drug, the drug concentration should be set to the diluted concentration.
- Continuous target-controlled infusion is not allowed for the same patient and same drug.
- 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 5.00 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.

3 Brief Introduction and Scope

3.1 Brief Introduction

The Graseby™ S20 Plus, S20, and MS33 (hereinafter referred to as S20 Plus) are infusion devices primarily 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).

3.2 Intended Purpose

Intended use: The MS33, S20, and S20 Plus syringe pumps are designed for intravenous therapy in clinical settings. They are intended for use in both adults and pediatric patients, delivering drug solutions or medications intermittently or continuously through clinically accepted routes of administration. These syringe pumps regulate the flow rate and are used in conjunction with syringes.

Indication for use: N/A.

Contraindications: None.

4 Important Features

- **Compatible syringe sizes:** A wide range of syringe types can be automatically identified, including 2/3 mL, 5 mL, 10 mL, 20 mL, 30mL and 50/60 mL.
- **Accuracy:** The accuracy for infusion rate and volume both are kept within 1.5%.
- **Infusion rate:** Infusion rate can be adjusted from 0.01 mL/h to 2300mL/h in a continuous manner, which makes syringe pump capable of meeting various Infusion rate requirements in different infusion situations.
- **Touchscreen interface:** Infusion parameters can be set by using the touch screen on the device, even with gloves on.

- **Electric Drive head:** Use electric drive head to eliminate the mechanical gap when the device is started, so that the first drop of liquid medicine can be injected into the patient's body as soon as possible.
- **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.
- **Battery capacity:** The rechargeable internal high-capacity Lithium battery can support normal operation for 8 hours, which is conveniently helpful during patient transport or power outage.
- **Display:** LCD touch screen display offers high contrast and great visibility. Clearly visible from 5 meters away.
- **Occlusion removal:** When the infusion line is occluded, the stepper motor will rotate reversely to release the pressure accumulated in the infusion line.

5 Specifications

5.1 Basic Specifications

MS33

Dimensions	280mm×130mm×118mm (width x depth x height)
Weight	1.6Kg
Power supply	Network power supply: ~ 100V-240 V, 50/60 Hz Internal battery: ⎓ 7.4 V rechargeable Lithium

	battery
Rate of work	55 VA
Syringe requirements	Refer to Section 11 Precautions for Using Disposable Syringes
Maximum Infusion Rate	2100.00mL/h

S20

Dimensions	277mm×136mm×72mm (width x depth x height)
Weight	1.43 Kg
Power supply	Network power supply: ~ 100V-240 V, 50/60 Hz Internal battery:⎓7.4 V rechargeable Lithium battery
Rate of work	55 VA
Syringe requirements	Refer to Section 11 Precautions for Using Disposable Syringes
Maximum Infusion Rate	2300.00mL/h

S20 Plus

Dimensions	277mm×136mm×72mm (width x depth x height)
Weight	1.43 Kg
Power supply	Network power supply: ~ 100V-240 V, 50/60 Hz Internal battery:⎓7.4 V rechargeable Lithium battery
Rate of work	30 VA
Syringe requirements	Refer to Section 11 Precautions for Using Disposable Syringes
Maximum Infusion Rate	2300.00mL/h

5.2 Main Performance

MS33

Infusion Rate range	2/3 mL syringe: 0.01 ~ 100.00 mL/h; 5 mL syringe: 0.01 ~ 150.00 mL/h; 10 mL syringe: 0.01 ~ 400.00 mL/h; 20 mL syringe: 0.01 ~ 600.00 mL/h; 30 mL syringe: 0.01 ~ 1000.00 mL/h; 50/60 mL syringe: 0.01 ~ 2100.00 mL/h; resolution is 0.01 mL/h.
VTBI range	0 ~ 9999.99 mL with resolution of 0.01 mL

Infusion accuracy	±1.5%
Purge Rate / Bolus Rate	2/3 mL syringe: 1 ~ 100 mL/h; 5 mL syringe: 1 ~ 150 mL/h; 10 mL syringe: 1 ~ 400 mL/h; 20 mL syringe: 1 ~ 600 mL/h; 30 mL syringe: 1 ~ 1000 mL/h; 50/60 mL syringe: 1 ~ 2100 mL/h; resolution is 1 mL/h.
Purge VTBI / Bolus VTBI	0.10mL ~ 50.00mL 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 velocity is lower than the user-defined KVO velocity, KVO velocity = infusion velocity.
Infusion Time range	00:00:00~99:59:59, with resolution of 1 s.
Occlusion threshold	9 levels, with the lowest being 26kPa ± 20 kPa, and the highest being 130 kPa ± 20 kPa.
Syringe brand	6 brands of syringes are recommended, including Kangjin、Wego、KDL、BD、Xinhua、B.Braun.

	10 brands can be user-defined.
Supported Infusion modes	8 modes, RVT mode, Drug Library mode, Loading Dose mode, Micro mode, Dose mode, RTM mode, Sequence mode, Intermittent mode.
Syringe sizes	2/3mL、5mL、10mL、20mL、30mL、50/60mL
Battery running time at intermediate speed	When fully charged, the battery can run continuously for more than 8 hours.
Wi-Fi connectivity	The device has WiFi function, which can transmit data with the "InfuseDirect" APP.
Maximum infusion pressure generated by the device	150kPa
Occlusion alarm trigger time and	When operated at minimum Infusion rate: < 1 h when the occlusion alarm pressure threshold is

Bolus dosage	set to the lowest pressure; or < 3 h 30 min when the occlusion alarm pressure threshold is set to the highest pressure. When operated at intermedium speed: < 15 min when occlusion alarm pressure threshold is set to the lowest pressure, and the Bolus produced during occlusion is < 0.20 mL; < 45 min, when the occlusion alarm pressure threshold is set to the highest pressure, the Bolus during occlusion is not more than 0.50 mL. (Tested when an occlusion was created 1 meter away from the syringe outlet)
Alarm Mute Time	2min ± 10s
Call Back Time	1min~60min ± 10s
Classification	Type II CF continuous operating volumetric syringe pump with internal power supply; Grade IP24.

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	MS33_V1
Service lifetime	8 years

S20

Infusion Rate range	2/3 mL syringe: 0.01 ~ 100.00 mL/h; 5 mL syringe: 0.01 ~ 150.00 mL/h; 10 mL syringe: 0.01 ~ 400.00 mL/h; 20 mL syringe: 0.01 ~ 600.00 mL/h; 30 mL syringe: 0.01 ~ 1000.00 mL/h; 50/60 mL syringe: 0.01 ~ 2300.00 mL/h;

	resolution is 0.01 mL/h.
VTBI range	0 ~ 9999.99 mL with resolution of 0.01 mL
Infusion accuracy	±1.5%
Purge Rate / Bolus Rate	2/3 mL syringe: 1 ~ 100 mL/h; 5 mL syringe: 1 ~ 150 mL/h; 10 mL syringe: 1 ~ 400 mL/h; 20 mL syringe: 1 ~ 600 mL/h; 30 mL syringe: 1 ~ 1000 mL/h; 50/60 mL syringe: 1 ~ 2300 mL/h; resolution is 1 mL/h.
Purge VTBI / Bolus VTBI	0.10mL ~ 50.00mL 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 velocity is lower than the user-defined KVO velocity, KVO velocity = infusion velocity.
Infusion Time range	00:00:00~99:59:59, with resolution of 1 s.
Occlusion threshold	9 levels, with the lowest being 26kPa ± 20 kPa, and the highest being 130 kPa ± 20 kPa.

Syringe brand	6 brands of syringes are recommended, including Kangjin、Wego、KDL、BD、Xinhua、B.Braun. 10 brands can be user-defined.
Supported Infusion modes	9 modes, RVT mode, Drug Library mode, Loading Dose mode, Micro mode, Dose mode, RTM mode, Sequence mode, Intermittent mode, Relay mode.
Syringe sizes	2/3mL、5mL、10mL、20mL、30mL、50/60mL
Battery running time at intermediate speed	When fully charged, the battery can run continuously for more than 8 hours.
Wi-Fi connectivity	The device has WiFi function, which can transmit data with the "InfuseDirect" APP.
Maximum infusion pressure generated by	150kPa

the device	
Occlusion alarm trigger time and Bolus dosage	When operated at minimum Infusion rate: < 1 h when the occlusion alarm pressure threshold is set to the lowest pressure; or < 3 h 30 min when the occlusion alarm pressure threshold is set to the highest pressure. When operated at intermedium speed: < 15 min when occlusion alarm pressure threshold is set to the lowest pressure, and the Bolus produced during occlusion is < 0.20 mL; < 45 min, when the occlusion alarm pressure threshold is set to the highest pressure, the Bolus during occlusion is not more than 0.50 mL. (Tested when an occlusion was created 1 meter away from the syringe outlet)
Alarm Mute Time	2min ± 10s
Call Back Time	1min~60min ± 10s

Classification	Type II CF continuous operating volumetric syringe pump with internal power supply; Grade IP24.
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	Graseby S20_V1
Service lifetime	8 years

Infusion Rate range	2/3mL：0.01~100.00mL/h； 5mL：0.01~150.00mL/h； 10mL：0.01~400.00mL/h； 20mL：0.01~600.00mL/h； 30mL：0.01~1000.00mL/h； 50/60mL：0.01~2300.00mL/h； step by 0.01mL/h。
VTBI range	0.01~9999.99mL，step by 0.01mL
Infusion accuracy	±1.5%
Mechanical accuracy	±1%
Purge Rate / Bolus Rate	2/3mL：1~100mL/h； 5mL：1~150mL/h； 10mL：1~400mL/h； 20mL：1~600mL/h； 30mL：1~1000mL/h； 50/60mL：1~2300mL/h； step by 1mL/h。
Purge VTBI / Bolus VTBI	0.10mL~100.00mLcontinuous adjustable，step by 0.01mL。
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 velocity is lower than the user-defined KVO velocity, KVO velocity = infusion velocity.
Time setting range	00:00:00～99:59:59， step by 00:00:01.
Occlusion threshold	12 levels，with the lowest being 26kPa ± 20 kPa, and the highest being 130 kPa ± 20 kPa.
Maximum infusion pressure generated by the device	150kPa
Syringe brand	6 brands of syringes are recommended, including Kangjin、Wego、Kindly、BD、Shinva、B.Braun. 10 brands can be customized.
Supported infusion modes	11 modes ; RVT mode, Drug Library mode, Loading Dose mode, Micro mode, Dose mode, RTM mode, Sequence mode, Intermittent mode, Relay mode, TCI mode, TIVA mode.
Syringe sizes	2~60mL

Battery life	When fully charged, the battery can run continuously for more than 8 hours.
WIFI	The device has WiFi function, which can transmit data with the "InfuseDirect" APP.
Triggering time of occlusion alarm and Bolus	When operated at minimum flow rate(1.00mL/h): < 1 h when the occlusion alarm pressure threshold is set to the lowest pressure; or < 3 h 30 min when the occlusion alarm pressure threshold is set to the highest pressure. When operated at intermedium speed(5.00mL/h): < 15 min when occlusion alarm pressure threshold is set to the lowest pressure, and the Bolus produced during occlusion is < 0.20 mL; < 45 min, when the occlusion alarm pressure threshold is set to the highest pressure, the Bolus during occlusion is not more than 0.50 mL. (Tested when an occlusion was created 1 meter away from the syringe outlet)
Alarm Mute Time	2 min ± 10s
Call Back Time	1 min ~ 60 min ± 10s
Classification	Type II CF continuous operating volumetric syringe pump with internal power supply; Grade IP24, Non AP、APG
Ambient temperature and humidity	Ambient temperature of transportation and storage: -20 ℃ ~ + 55 ℃ Ambient temperature for operation: 5℃ ~ + 40 ℃

	Ambient humidity for transportation, storage and operation: 20% ~ 90% Ambient pressure for transportation, storage and operation: 800 kPa ~ 1060 kPa
Software version	S20 Plus_V1
Service lifetime	8 years

5.3 Main Functions and Common Functions

- Automatic identification for syringe size
- Set infusion flow rate, injection volume preset and real-time data display function
- Displays the function of remaining injection volume and remaining injection time
- Purge/Bolus
- Alarms;
- The flow rate will be automatically changed to KVO flow rate after the VTBI complete alarm is activated
- Temporary mute for alarm sound and timer for alarm sound recovery
- Displays the accumulated quantity injected and supports clearance
- A variety of brands for syringes are supported
- Built-in battery, Display battery remaining
- External power adapter
- Wi-Fi connectivity
- Contains Dose-Error Reduction Software
- Support manual installation, automatic installation, manual-auto installation of syringes

6 Structure and Operation Interface

6.1 Structural Composition

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

Names for parts and components：

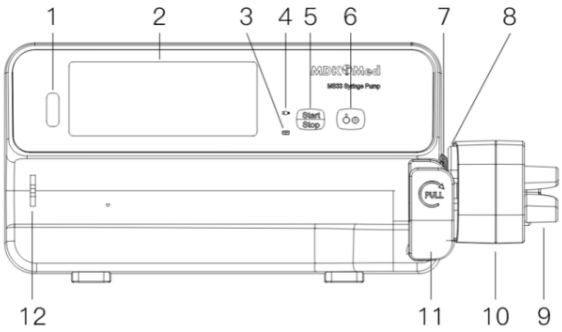


Figure 6-1-1 MS33Front view

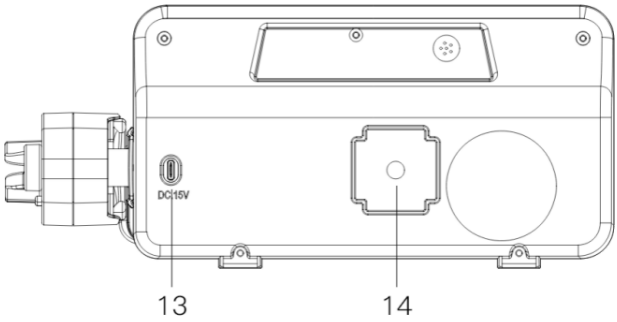


Figure 6-1-2 MS33 Rear view

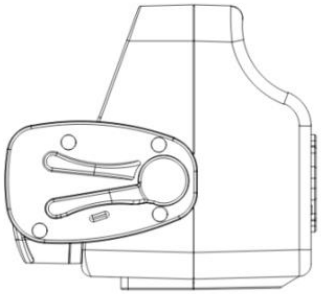


Figure 6-1-3 MS33 Side view

1	Operation status indicator	8	Swing arm
2	Touch screen display	9	Finger grips
3	Charging indicator	10	Drive head
4	External power indicator	11	Syringe clamp
5	Start/Stop key	12	Infusion line clamp
6	Power On/Off key	13	DC Power port
7	Syringe pressure plate	14	Locking screw

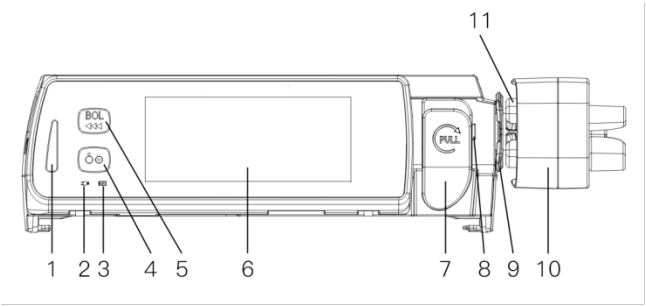


Figure 6-1-4 S20 Front view

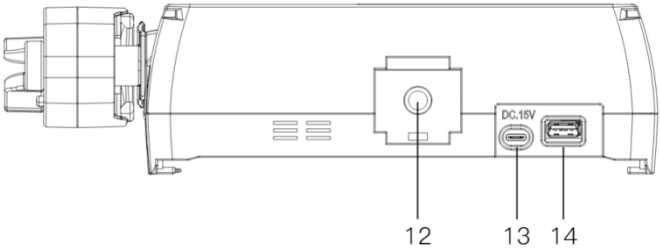


Figure 6-1-5 S20 Rear view

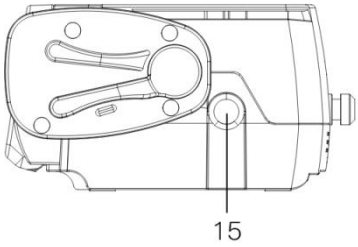


Figure 6-1-6 S20 Side view

Figure 6-1-7 Side view

1	Operation status indicator	9	Syringe pressure plate
2	External power indicator	10	Push hand seat
3	Charging indicator	11	Swinging arm
4	Power On/Off key	12	Locking screw
5	Purge/Bolus key	13	Power interface
6	Touch screen display	14	Data Communication port
7	Syringe clamp	15	Stack slot
8	Syringe in-place detection		

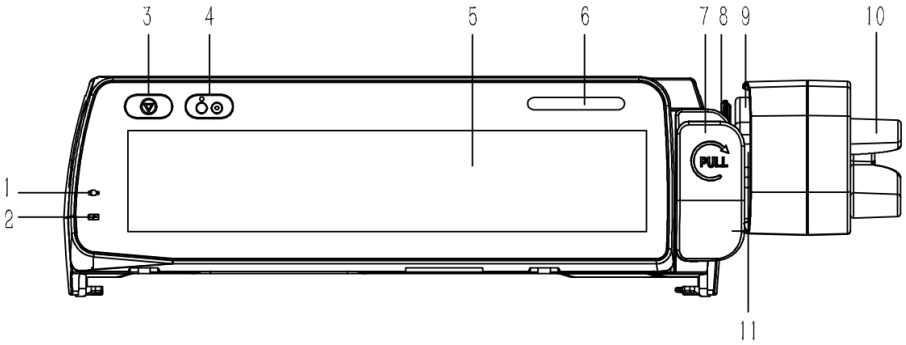


Figure 6-1-8 S20 Plus Front view

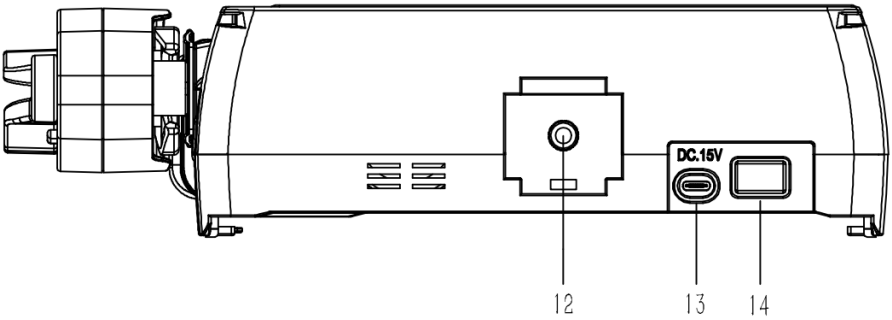


Figure 6-1-2 S20 Plus Rear view

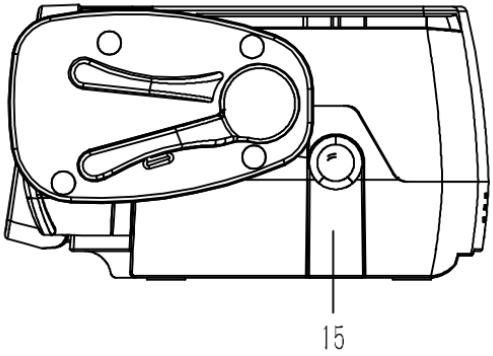


Figure 6-1-3 S20 Plus Side view

1	External power indicator	2	Charging indicator	3	Start-Stop key
4	Power On/Off key	5	Touch screen display	6	Operation status indicator
7	Syringe clamp	8	Syringe in-place detection	9	Swinging arm
10	Swinging arm button	11	Syringe pressure plate	12	Locking screw

13	Power interface	14	Data Communication port	15	Stack slot

6.2 Display and Operation Interface

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

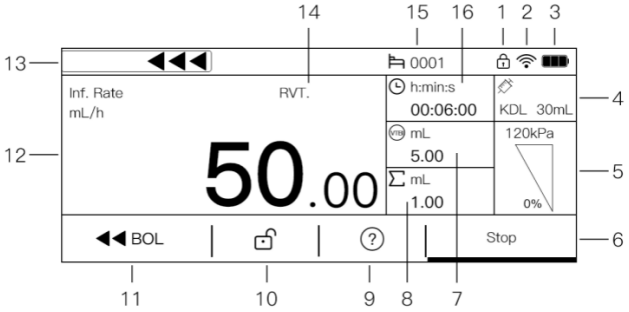


Figure 6-2-1 MS33 Operation interface on the screen

1	Lock screen	9	more information
2	Wi-Fi	10	Unlock
3	Battery	11	Purge/Bolus
4	Brand	12	Rate
5	Occlusion pressure	13	Infusion stater
6	Start/Stop button	14	Infusion mode
7	Remaining volume	15	Bed number

8	Infused volume	16	Time remaining

S20

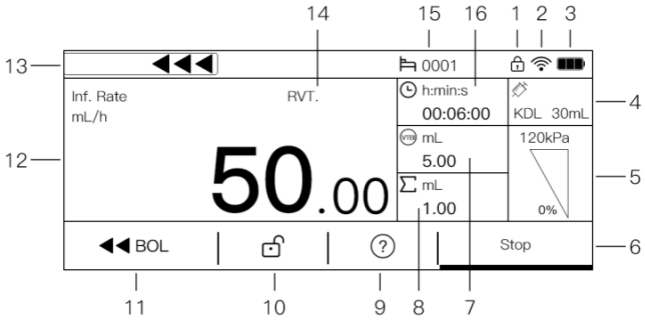


Figure 6-2-2 Operation interface on the screen

1	Lock screen	9	more information
2	Wi-Fi	10	Unlock
3	Battery	11	Purge/Bolus
4	Brand	12	Rate
5	Occlusion pressure	13	Infusion stater
6	Start/Stop button	14	Infusion mode
7	Remaining volume	15	Bed number
8	Infused volume	16	Time remaining

S20 Plus

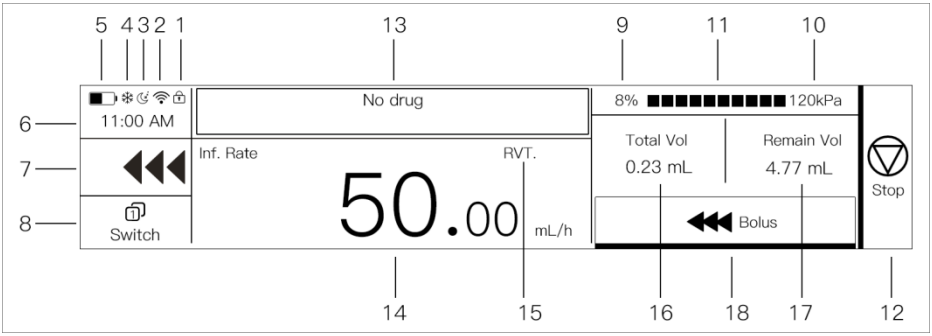


Figure 6-2-3 S20 Plus Operation interface on the screen1

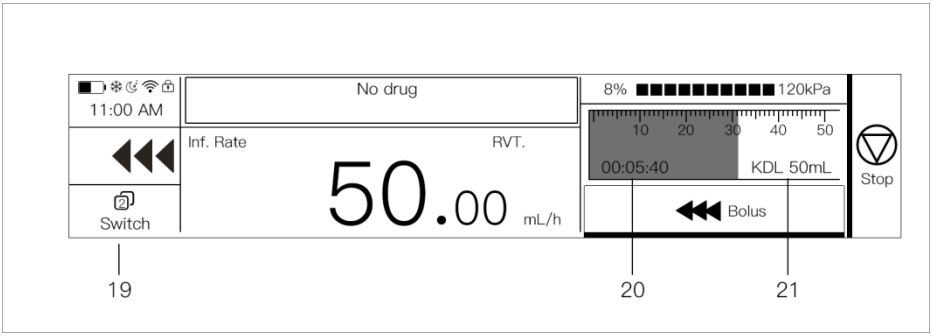


Figure 6-2-4 S20 Plus Operation interface on the screen2

1	Screen lock	2	WIFI	3	Night mode
4	Low temperature	5	Battery	6	Time
7	Infusion status	8	Switch	9	Current occlusion pressure percentage
10	Upper occlusion pressure limit	11	Occlusion pressure bar	12	Start/Stop button
13	Drug name	14	Infusion rate	15	Infusion mode
16	Infused volume	17	Remaining volume	18	Purge/Bolus

19	Switch	20	Time remaining	21	Syringe size

7 Operation Instructions

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

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

7.1 Installation of Syringe Pump

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

7.2 Power on and Device Safety Self-test

7.2.1 Power on and off

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

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

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

Please remove the syringe before turning the device off.

7.2.2 Device safety self-test

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

7.3 Quick Use Guide

7.3.1 Install / Replace syringe

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

Open the syringe pump door, pull the syringe clamp out and turn it clockwise for 90° to the horizontal position, place the syringe barrel flange in the slot between the pump casing and the syringe press plate, pull the syringe clamp out again and turn it counterclockwise for 90° to the upright position, release it to clamp the syringe tight in position; straighten the syringe extension line, place it inside the hook behind the pump door to prevent it from being pressed, then close the pump door. When the device detects that

the syringe clamp pressed the syringe, the drive head automatically moves from right to left to the place where the syringe presses the hand.

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

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

7.3.2 Select syringe

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

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

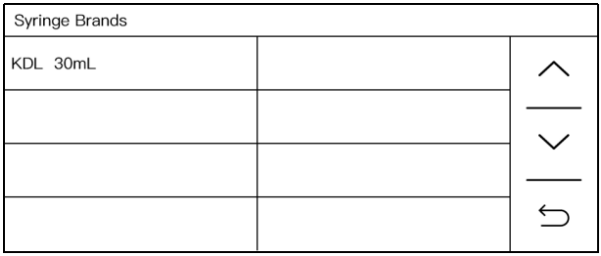


Figure 7-3-2-1 MS33 Syringe brand confirmation

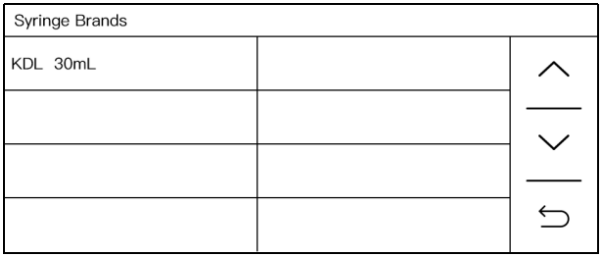


Figure 7-3-2 S20 Syringe brand confirmation



Figure 7-3-2 S20 Plus Syringe brand confirmation

7.3.3 Set infusion parameters

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

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

the parameters.

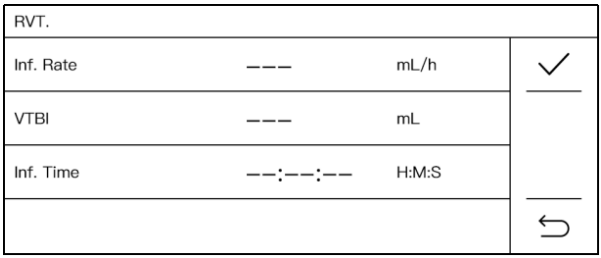


Figure 7-3-3-1 MS33 Set infusion parameters

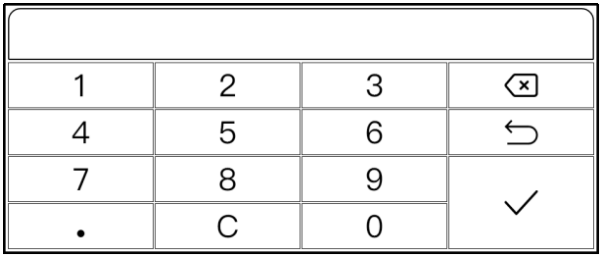


Figure 7-3-3-2 MS33 Input values using keypad

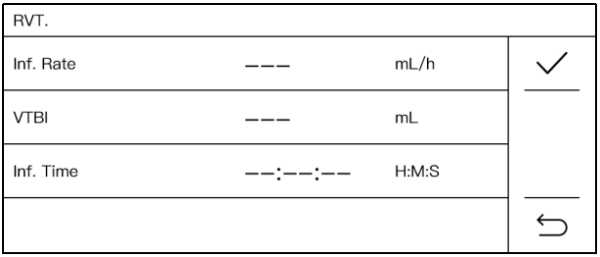


Figure 7-3-3-3 S20 Set infusion parameters

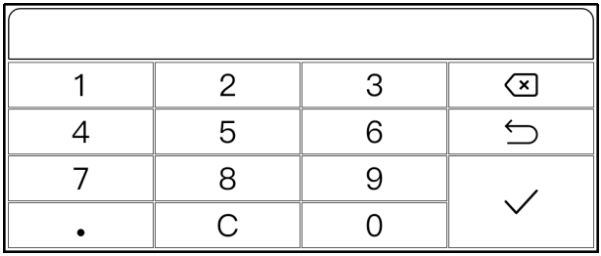


Figure 7-3-3-4 S20 Input values using keypad

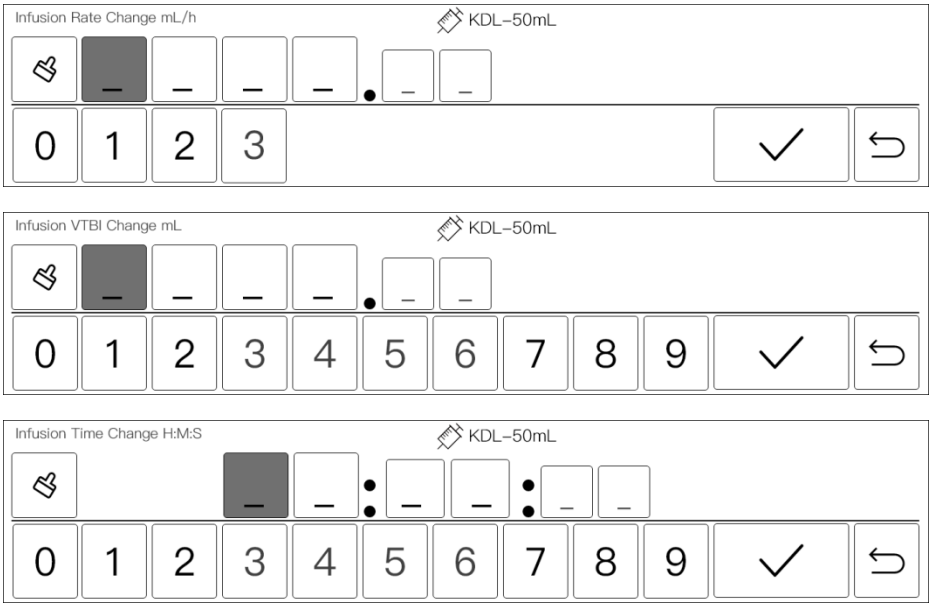


Figure 7-3-3-5 S20 Plus Set infusion parameters

7.3.4 Purge

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

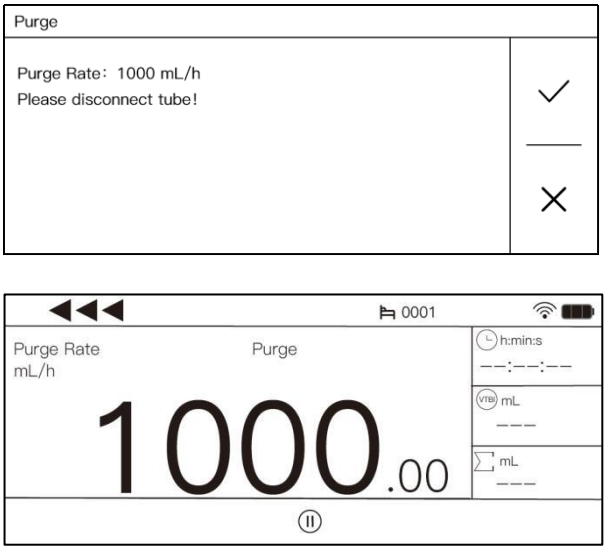
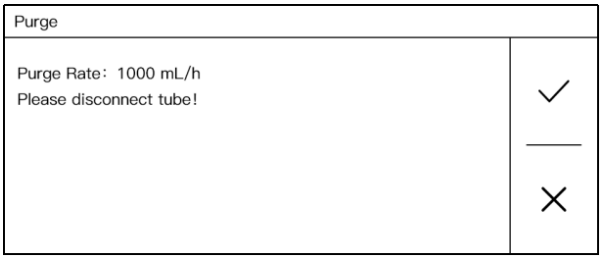


Figure 7-3-4-1 MS33 Purge syringe



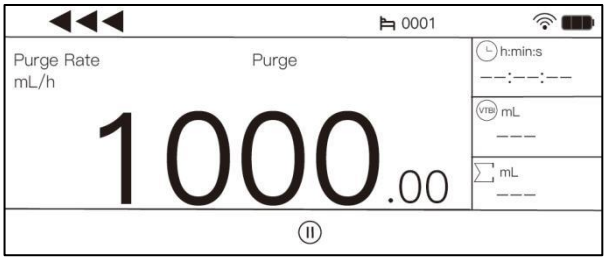


Figure 7-3-4-2 S20 Purge syringe

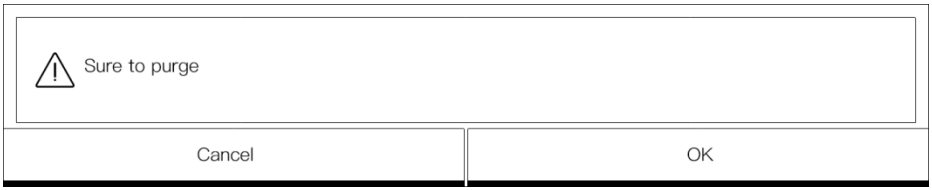


Figure 7-3-4-3 S20 Plus Confirm to purge

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

The purge volume is not included in the Infusion accumulation.

7.3.5 Start infusion

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

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

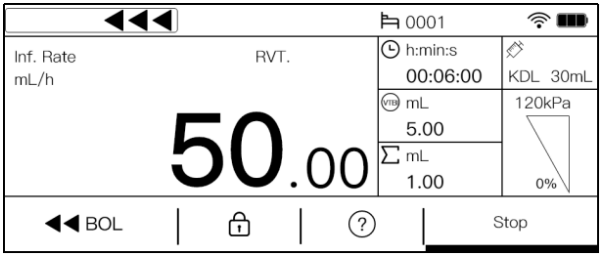


Figure 7-3-5-1 MS33 Infusion operation interface

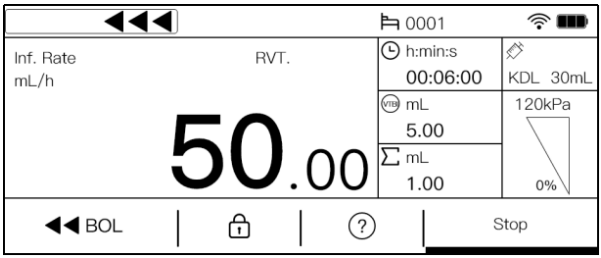
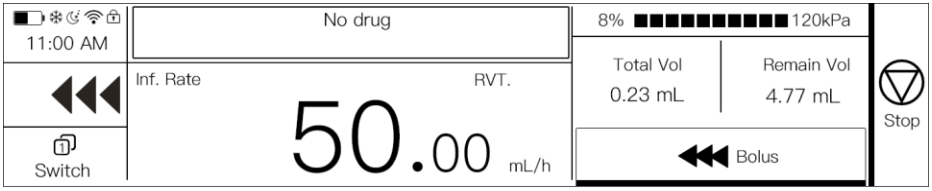


Figure 7-3-5-2 S20 Infusion operation interface



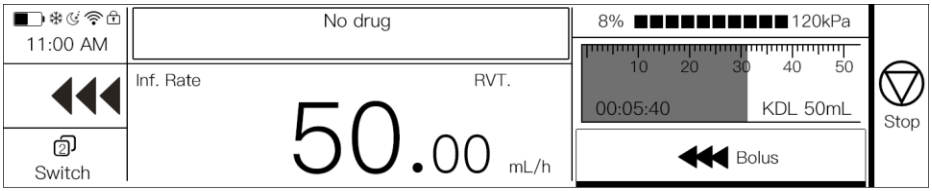


Figure 7-3-5-3 S20 Plus Infusion operation interface

7.3.6 Infusion completed

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

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

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

7.4 Pause or Stop Infusion

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

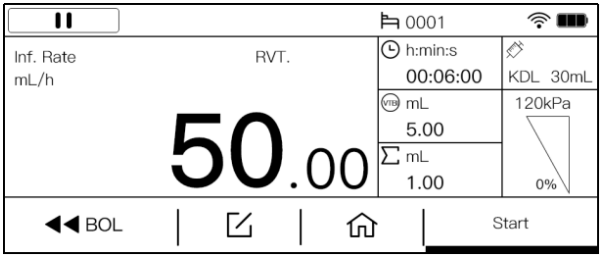


Figure 7-4-1 MS33 Infusion pause

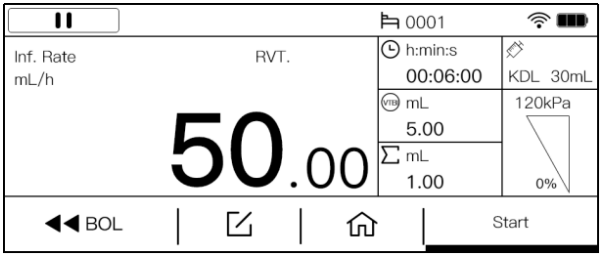


Figure 7-4-2 S20 Infusion pause

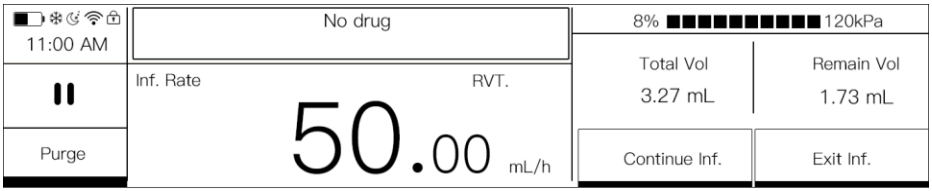


Figure 7-4-3 S20 Plus Infusion pause

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

7.5 Bolus

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

syringe pump returns back to the normal infusion state to continue infusion, and the bolus dose is included in the infusion accumulation.

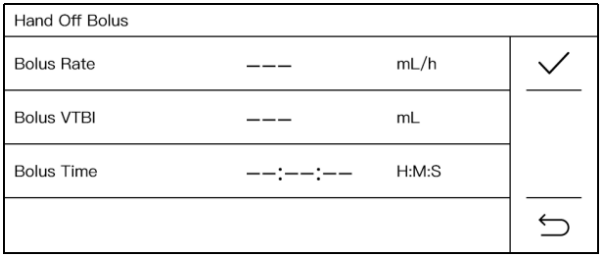


Figure 7-5-1-1 MS33 Bolus Settings interface

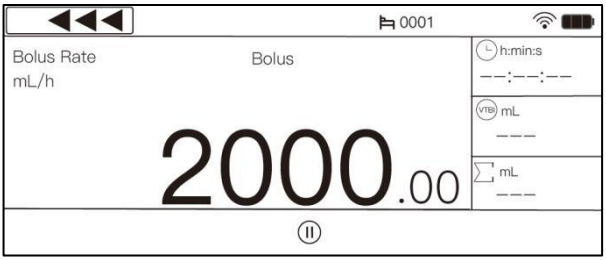


Figure 7-5-1-2 MS33 Bolus Settings interface

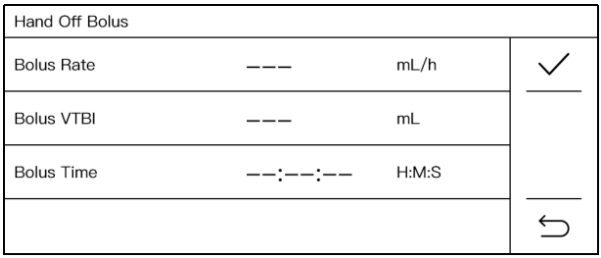


Figure 7-5-1-3 S20 Bolus Settings interface

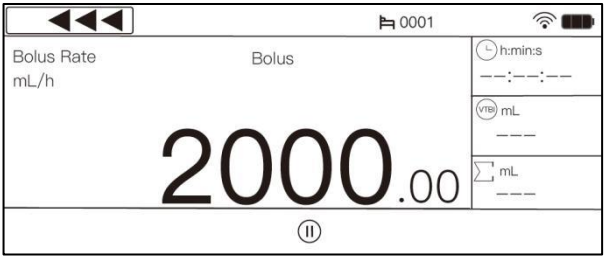


Figure 7-5-1-4 S20 Bolus Settings interface

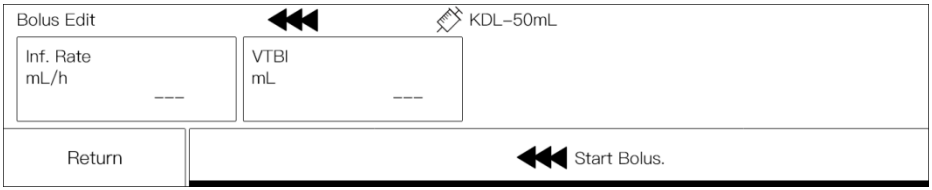


Figure 7-5-1-5 S20 Plus Bolus Settings interface

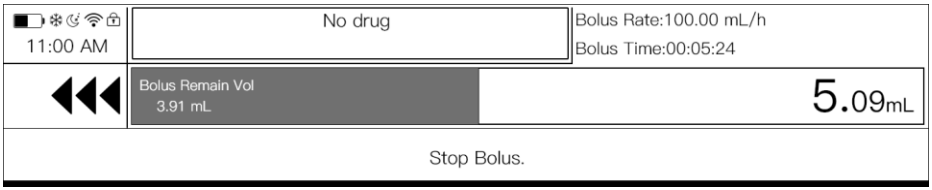


Figure 7-5-2 S20 Plus Bolus Settings interface

7.6 Lock and Unlock Screen Function

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

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

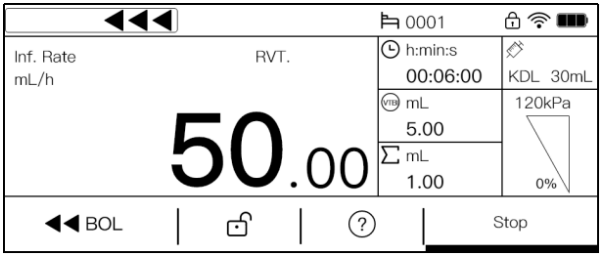


Figure 7-6-1 MS33 Lock Screen

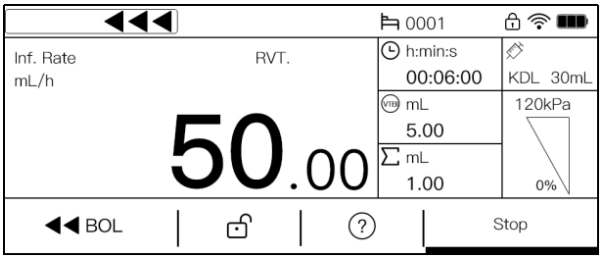


Figure 7-6-2 S20 Lock Screen

7.7 Infusion Mode Selection and Setting

Beside for the RVT mode on the home screen, there are 9 infusion modes on the Infusion mode - Other mode page: Dose mode, Drug Library mode, RTM mode, Sequence mode, Loading Dose mode, Intermittent mode, Micro mode, Relay mode, TIVA mode.

In the RVT setting page, the infusion rate, VTBI and infusion time can be set in a variety of combinations, forming the following four combinations of infusion mode: rate + volume (R+V) Mode , rate + time (R+T) Mode, volume + time (V+T) Mode, rate (R) Mode. Therefore, there are 13 different infusion modes for the device in total.

The setting of the RVT mode should follow the instructions in

the "Quick Use Guide" above. The settings for the other modes are outlined in that section.

7.7.1 Dose mode

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

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

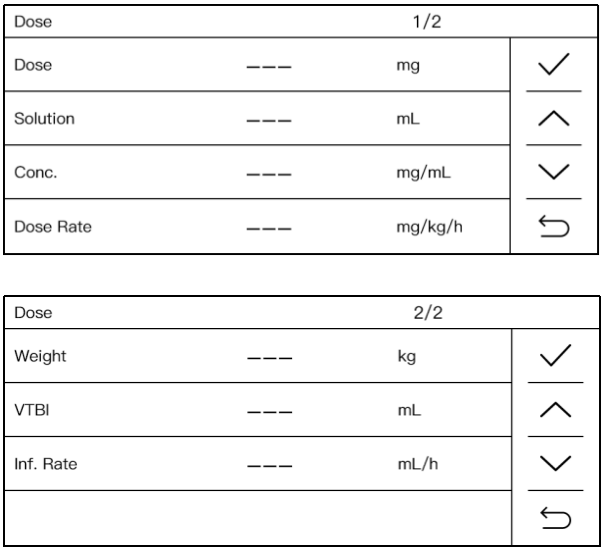


Figure 7-7-1-1 MS33 Dose mode setting

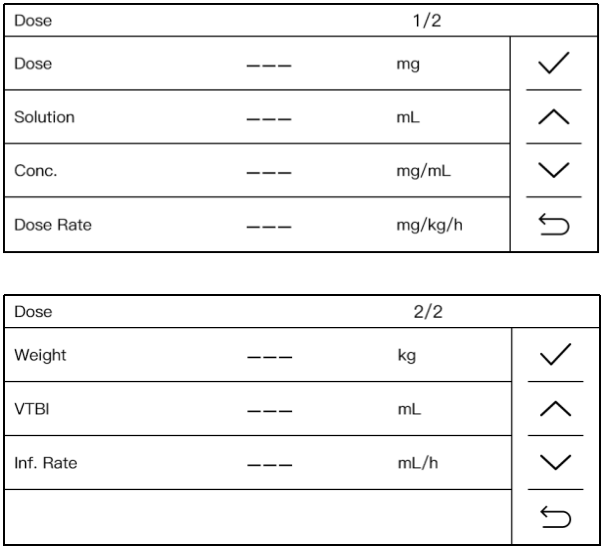


Figure 7-7-1-2 S20 Dose mode setting

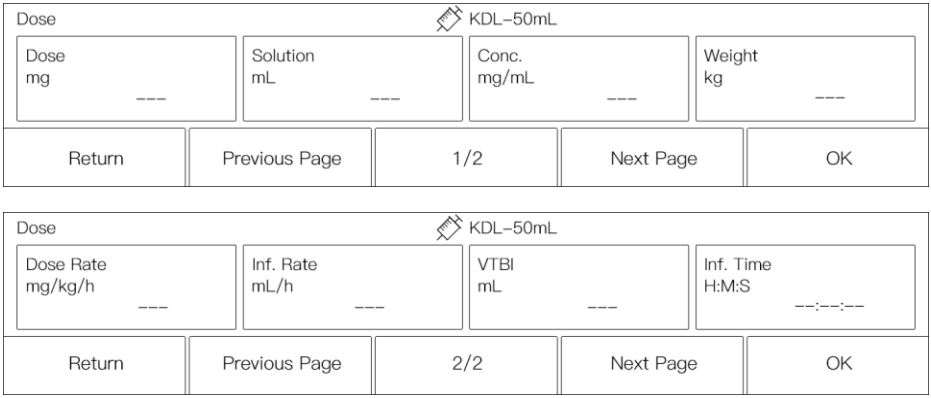


Figure 7-7-1-3 S20 Plus Dose mode setting

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

Concentration and Infusion Rate are calculated as follows:
Concentration calculation formula:

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

Infusion rate calculation formula:

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

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

7.7.2 Drug Library mode

Enter the drug library mode settings interface.

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

ADREnaline	1/2		
Conc.	---	mg/mL	✓
Weight	---	kg	∧
Dose Rate	---:--	mg/kg/mL	∨
Inf. Rate	---	mL/h	⮌

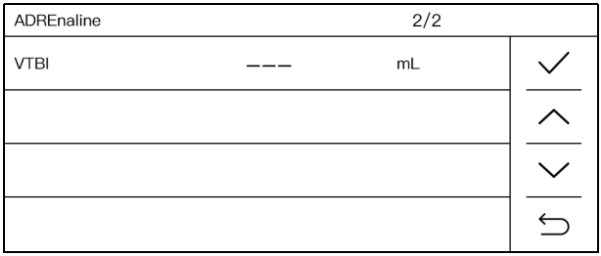
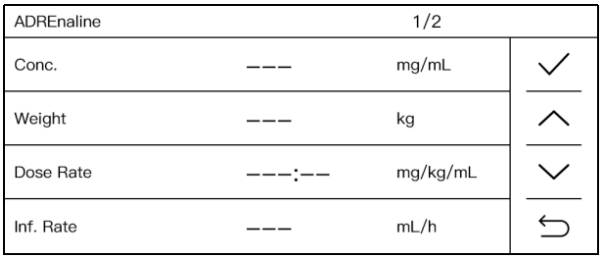


Figure 7-7-2-1 MS33 Drug library mode setting



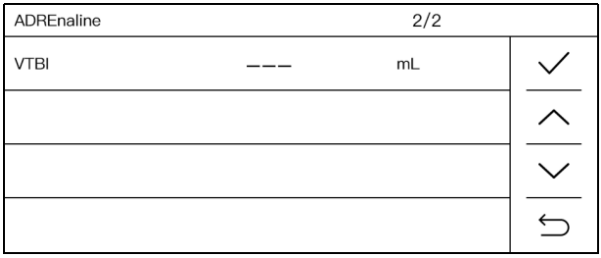


Figure 7-7-2-2 S20 Drug library mode setting





Figure 7-7-2-3 Drug library mode setting

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

7.7.3 RTM mode

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

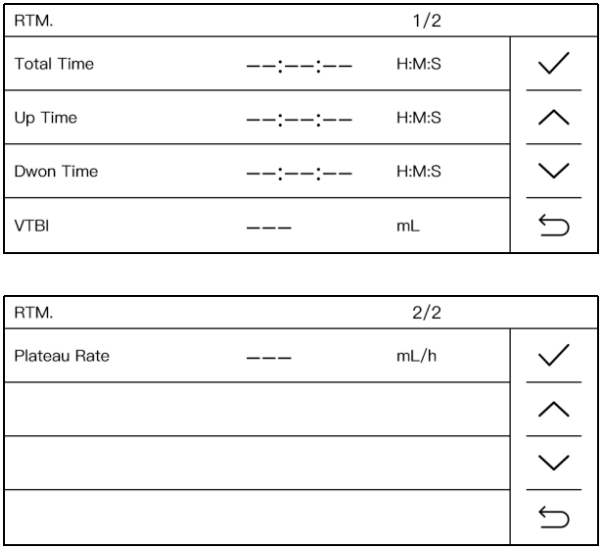


Figure 7-7-3-1 RTM mode setting

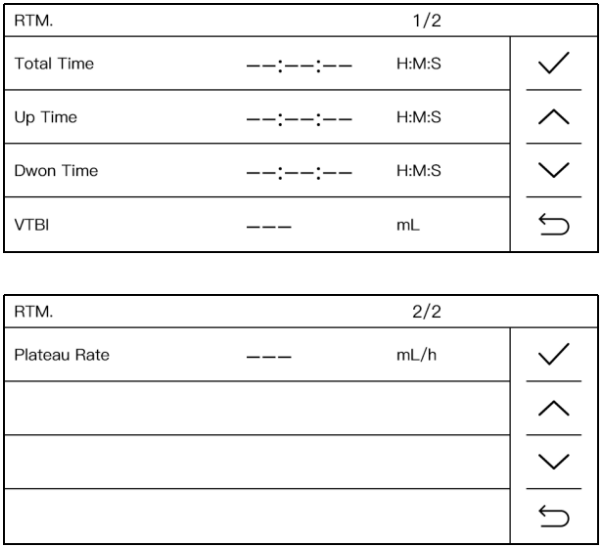


Figure 7-7-3-2 RTM mode setting

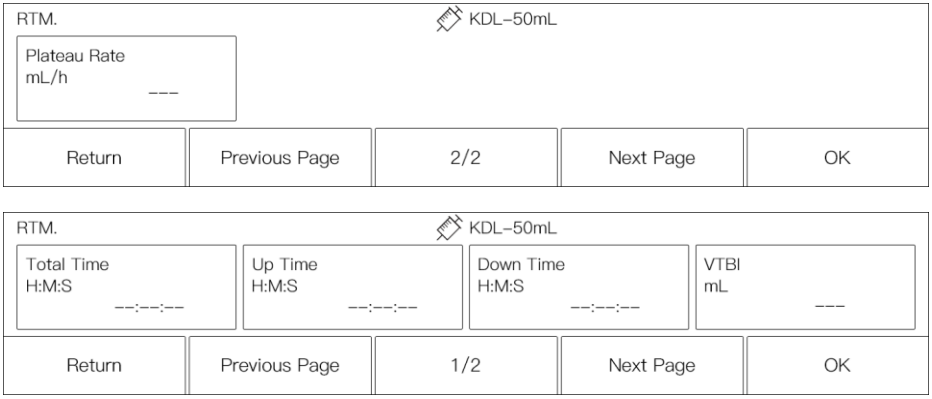


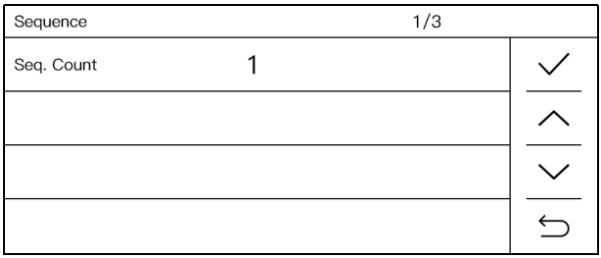
Figure 7-7-3-3 RTM mode setting

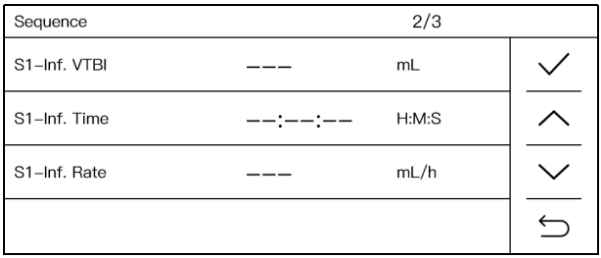
In the RTM mode parameters, VTBI, Up Time, and Down Time must be set. After setting one of the two parameters of Plateau rate or Total Time, the other parameter will be calculated automatically. After setting the parameters, click " √ " to confirm the parameters.

When the device is started, the infusion rate gradually increases from 0 to Plateau Rate during the Up Time and then maintains the rate. When the remaining time is equal to the Down Time, the infusion rate gradually decreases until it reaches 0 and the infusion is completed.

7.7.4 Sequence Mode

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





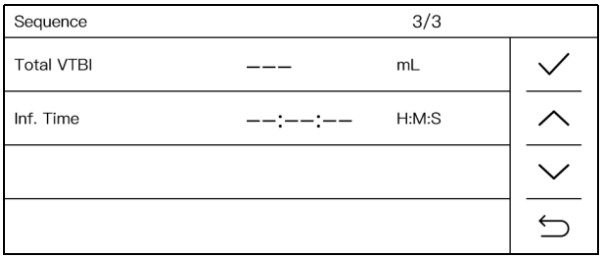


Figure 7-7-4-1 MS33 Sequence Mode Setting

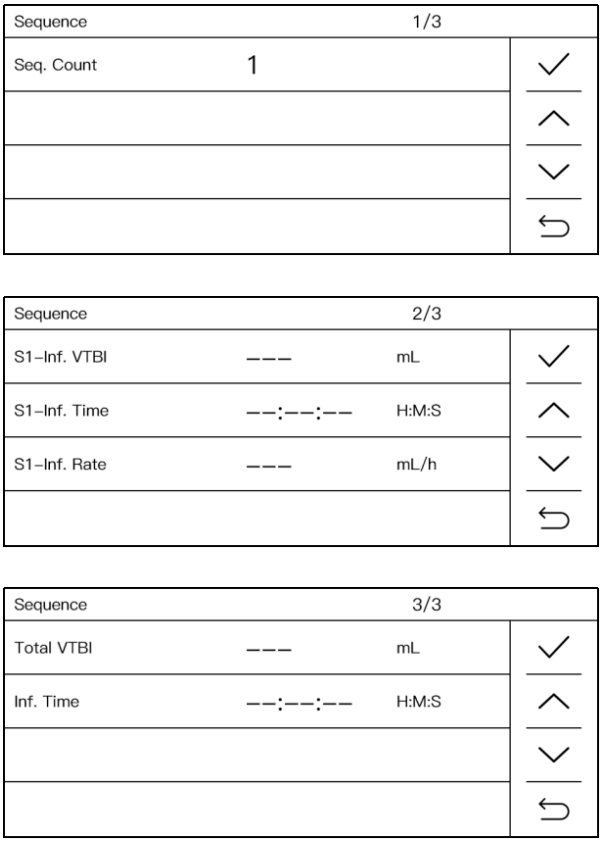


Figure 7-7-4-2 S20 Sequence Mode Setting



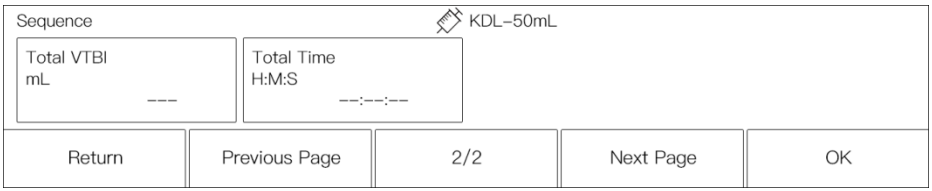


Figure 7-7-4 S20 Plus Sequence Mode Setting

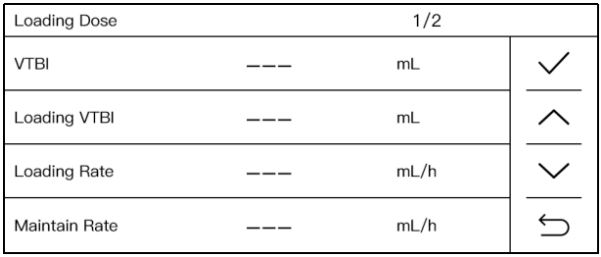
As shown in the figure, set any two of the Infusion VTBI, Infusion Rate, Infusion Time, the device will automatically calculate another parameter.

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

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

7.7.5 Loading Dose Mode

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



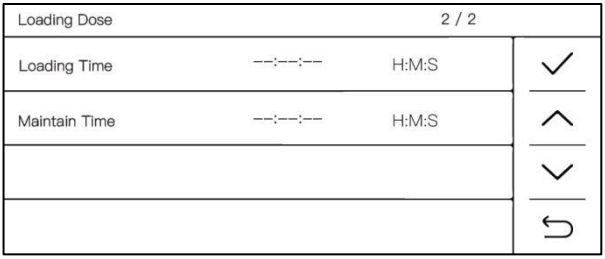


Figure 7-7-5-1 MS33 Loading Dose mode setting

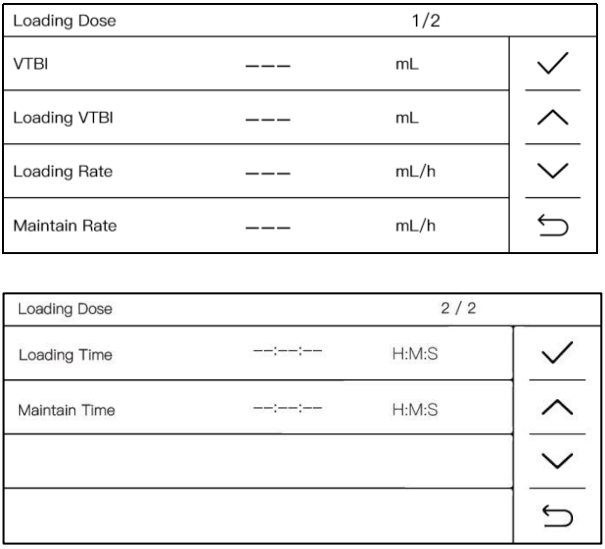
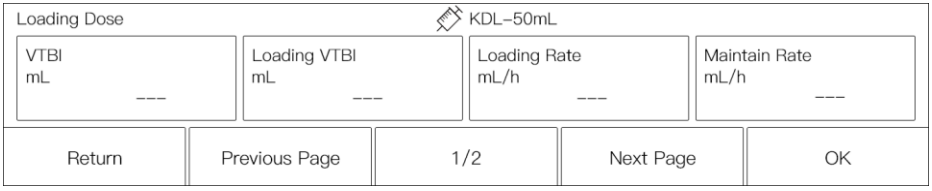


Figure 7-7-5-2 S20 Loading Dose mode setting



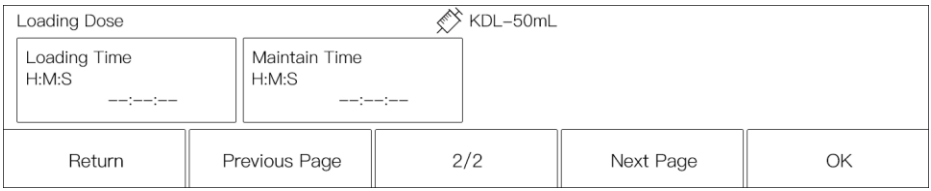


Figure 7-7-5-3 S20 Plus Loading Dose mode setting

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

7.7.6 Intermittent mode

Enter intermittent mode settings interface.

As shown in the figure, set the Single VTBI, Single Rate, Intermittent Time and Maintain Rate, and click the "√" button to confirm the infusion parameters. After the device is started, the infusion will start at the Single Rate. When the infused volume is equal to the single VTBI, the device will automatically continue infusion according to the Maintain Rate. When the Maintain Rate is set to 0, the device will run at 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.

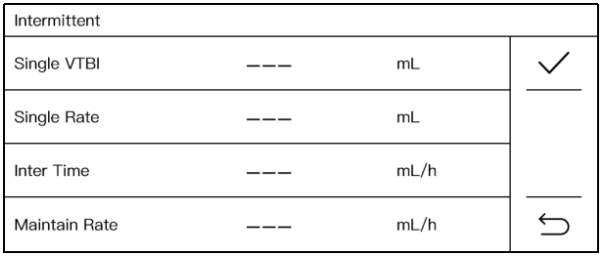


Figure 7-7-6-1 MS33 Intermittent mode

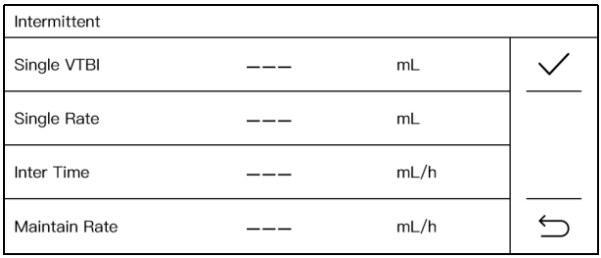


Figure 7-7-6-2 S20 Intermittent mode

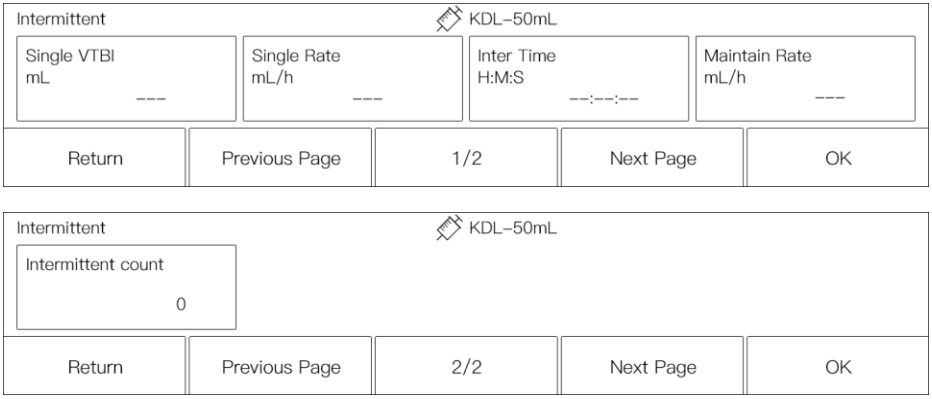


Figure 7-7-6-3 S20 Plus Intermittent mode setting

7.7.7 Micro mode

Enter Micro mode settings interface, as shown in the following

figure.

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

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



Figure 7-7-7 S20 Plus Micro mode setting

7.7.8 Relay mode

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

7.7.9 TCI mode

Only S20 Plus has this feature

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 S20 Plus syringe pump is based on the algorithm of the three-compartment pharmacokinetic model to calculate the infusion speed needed to achieve and maintain the target concentration. V1 is the central chamber (the chamber where drugs are injected), V2 is the chamber with a fast exchange rate with the central chamber, and V3 is the chamber with a slow exchange rate with the central chamber. Drug transport (distribution) between chambers was expressed by velocity constant (k12, k21, k31, and k13) or clearance rate cl1, cl2, cl3.

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

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

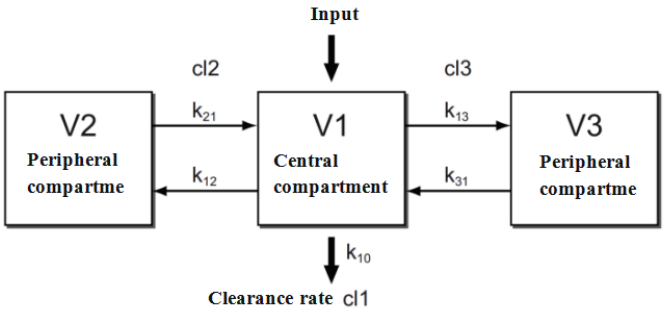


Figure7-7-9-1 Plasma target control model

When the effect-compartment target control mode is selected, the user can set the effect-compartment target concentration, and then obtain the infusion speed required to reach the set concentration through the pharmacokinetic model. The corresponding model diagram is as follows:

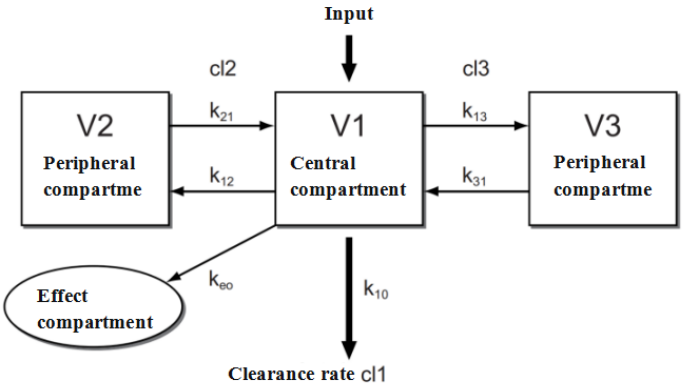


FIG.7-7-9-2 Effect location-based control model

To set the TCI mode, perform the following steps:

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

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



Figure7-7-9-3 TCI parameter setting page 1



Figure7-7-9-4 TCI parameter setting page 2

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

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

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

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

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

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

During operation, the target concentration can be modified. After modifying the target concentration, the TCI will recalculate and

update the parameter information.

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

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

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

Table 1 Drug model and target control mode supporting TCI infusion

Drug names	Model Name	Plasma target control	Effect chamber target control
Propofol	Marsh	◯	×
	Schnider	◯	◯
	Kataria	◯	×
	Paedfusor	◯	×
	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

7.7.10 TIVA mode

Only S20 Plus has this feature

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

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



Figure 7-7-10 S20 Plus TIVA mode setting

7.8 View Log

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

recorded time, Alarm time, etc.

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

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

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

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

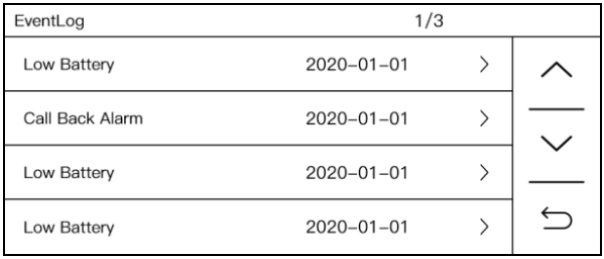


Figure 7-8-1 Event Log

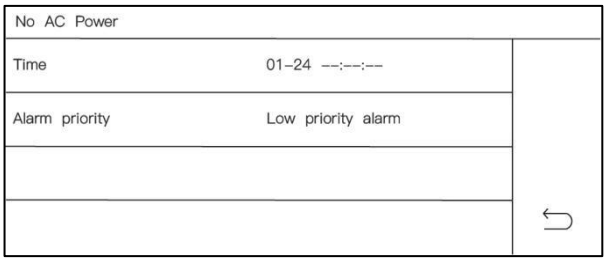


Figure 7-8-2 Alarm priority



Figure 7-8-3 View logs

8 Alarms

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

Alarm classification prompts of the equipment:

No.	Alarm	Priority	Alarm category	Alarm condition
8.1	No syringe	High	Latching	1. Syringe fall off . 2. The syringe rear barrel ear is not mounted between the syringe pump housing and the syringe pressure plate.
8.2	OCCL (Occlusion)	High	Latching	When the infusion line is occluded.
8.3	Empty Of Syringe	High	Latching	When the syringe is pushed to the end.
8.4	End Of Infusion	High	Latching	When the infused volume reaches to the VTBI.

8.5	Pusher Setup Fail	High	Latching	When pump is running, the syringe push handle without touch the pressure conduction block.
8.6	Battery empty	High	Latching	When the internal battery is running out.
8.7	Battery & External Power disconnect	High	Unlatching	When the device is running, the battery and external power is disconnected at the same time.
8.8	Motor Err.	High	Latching	when motor failure
8.9	Pusher Position Error	High	Latching	The infused volume exceeded the expected volume during the machine is running.
8.10	Battery error	High	Latching	The device does not detect battery signal or battery disconnect when plug in the external power.
8.11	KVO	High	Latching	The infusion is complete with KVO is enabled.

8.12	KVO end	High	Latching	KVO status run for 30 minutes until the KVO task is complete.
8.13	Standby End	High	Latching	When standby is end.
8.14	Com. Err. (Communication error)	High	Latching	Monitor the CPU for communication handshake errors.
8.15	Call Back	Low	Unlatching	The device is ready to start the infusion, but the device is not started and the device is placed without operation for the set time.
8.16	Low battery	Low	Unlatching	When the internal battery power is low.
8.17	Near Empty Of Syringe	Low	Unlatching	When the remaining time is less than or equal to the set near end of infusion time.
8.18	Near Empty Of Syringe	Low	Unlatching	The remaining volume of the syringe is less than 10% or the time from emptying is

				less than 3 minutes.
8.19	No AC Power	Low	Unlatching	When the device is disconnected from the external power and operated with batteries.

The MS33,S20 and S20 Plus device alarm indicator characteristics：

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

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

After powering on, the status indicator lights up, and the device automatically conducts a safety check. After passing the self-check, you will hear two short beeps of "DiDi", which means that the alarm system is normal. If the status indicator does not light up or you hear a continuous alarm sound or no prompt sound after booting, it means that the alarm system is faulty and the 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 No Syringe Alarm

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

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

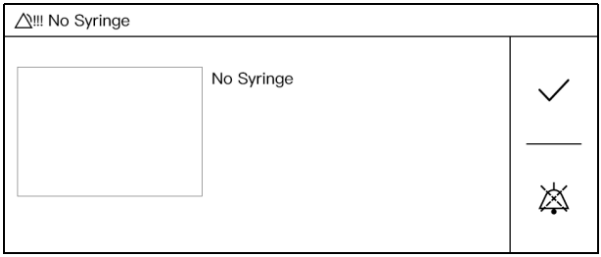


Figure 8-1-1 MS33No Syringe Alarm

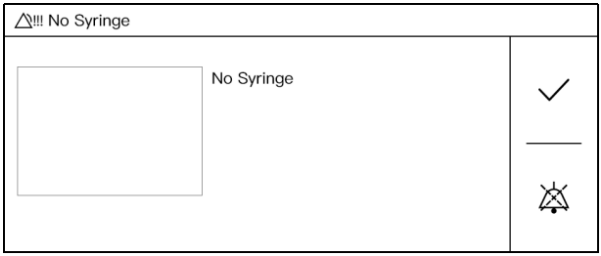


Figure 8-1-2 S20 No Syringe Alarm

8.2 Occlusion Alarm

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

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

Solution:

1)Click the "Confirm" button on the screen to clear the alarm and the message " OCCL " disappear.

2)Check whether the syringe extension line is kinked, whether the patient presses into the syringe extension line and other issues, eliminate the problem and restart the infusion.

3)If there is still an occlusion alarm, remove the syringe, replace the syringe and restart the infusion.

8.3 Empty Of Syringe Alarm

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

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

8.4 End Of Infusion Alarm

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

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

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

8.5 Pusher Setup Fail Alarm

Cause: When the syringe pump is running, the finger grips of the drive head was accidentally pinched and pulled out, result in the syringe push handle without touch the pressure conduction block, the device will trigger an alarm, stop running, make a high priority

alarm sound, the screen appear with the message "Pusher Setup Fail" and the operation status indicator flash red at the same time.

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

8.6 Battery Empty Alarm

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

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

8.7 Battery & External Power Disconnect Alarm

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

Solution: Use external power supply or battery supply, and restart the device after power supply.

8.8 Motor Error Alarm

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

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

8.9 Pusher Position Error Alarm

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

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

8.10 Battery Error Alarm

Cause: When the external power is inserted on the device, the device does not detect the battery signal or the battery is disconnected unexpectedly, the device will trigger an alarm, stop running, make a high priority alarm sound, the screen appear with

the message "Battery Error" and the operation status indicator flash red at the same time.

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

8.11 KVO alarm

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

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

8.12 KVO end alarm

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

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

8.13 Standby End Alarm

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

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

8.14 Communication Error Alarm

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

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

8.15 Call Back Alarm

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

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

8.16 Low battery Alarm

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

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

8.17 Near End of Infusion Alarm

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

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

8.18 Near Empty of Syringe Alarm

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

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

8.19 No AC Power Alarm

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

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

9 System Parameter setting

9.1 Bed number

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

9.2 Brightness

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

9.3 Alarm Sound Volume

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

9.4 Occlusion Pressure Level

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

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

9	100±20kPa
10	110±20kPa
11	120±20kPa
12	130±20kPa

9.5 Bolus Setting

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

9.6 Purge Setting

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

9.7 Call Back Time Setting

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

9.8 Auto Screen Lock Time

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

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

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

9.9 Prime prompt switch

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

9.10 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.

9.11 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.

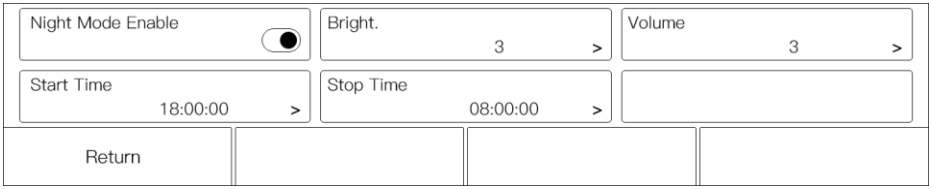


Figure 9-11 Night mode setting

9.12 Near End of Infusion Time Setting

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

9.13 Maintenance

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

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

9.14 Date/Time Setting

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

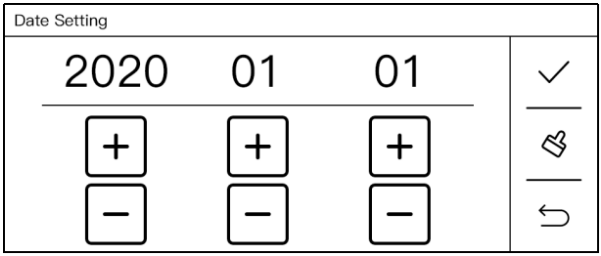


Figure 9-14-1 MS33 Date Setting

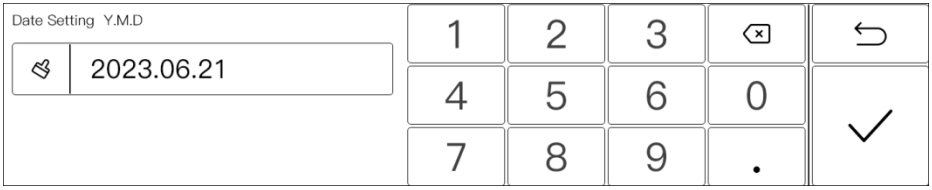


Figure 9-14-2 Date Setting

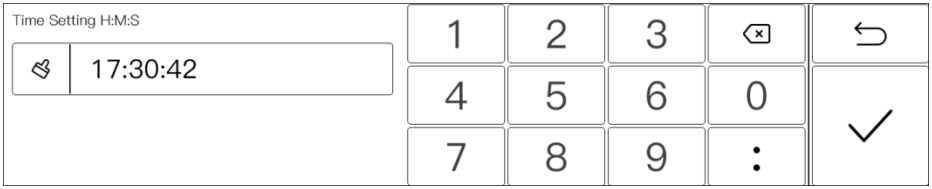


Figure 9-14-3 Time Setting

9.15 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 syringe

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

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

10.1 Automatic Accuracy Calibration for syringe

1) Pull the empty syringe that needs to be calibrated to the maximum range and install it to the device.

2) Click "Home - Setting - Maintenance - Consumables maintenance - Calibration Consumable" to enter the consumables calibration page.

3) Click Auto Calibration Start/Stop and wait for the device to run until the syringe is pushed empty.

4) Turn to the next page and click OK to save the current calibration value.

10.2 Manual Accuracy calibration for Syringe

1) Fill the syringe that needs to be calibrated with liquid, connect it to the balance or measuring cylinder through the extension tube, and install it to the device.

2) Prime/Purge until the extension tube is filled with liquid and stop.

3) Click "Home - Setting - Maintenance - Consumables maintenance - Calibration Consumable" to enter the consumables calibration page.

4) Click the brand and select the consumables brand that needs to be calibrated.

5) Click the Specification and select the specification for this calibration.

6) Pour out the water in the measuring cylinder or clear the balance.

7) Click the calibration Start/Stop, the calibration remaining amount will be displayed on the right side, and wait for the remaining amount to displayed ---.

11 Precautions for Using Disposable syringe

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

The recommended Syringes are listed in the table below:

MS33

No.	Brand	Infusion accuracy	Ambient temperature
1	Kangjin	±2%	+5℃～＋40℃
2	Wego	±2%	+5℃～＋40℃
3	KDL	±2%	+5℃～＋40℃

4	BD	±2%	+5℃～+40℃
5	Xinhua	±2%	+5℃～+40℃
6	B.Braun	±2%	+5℃～+40℃

S20 Plus

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

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

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

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

compromised.

12 Technical Specification

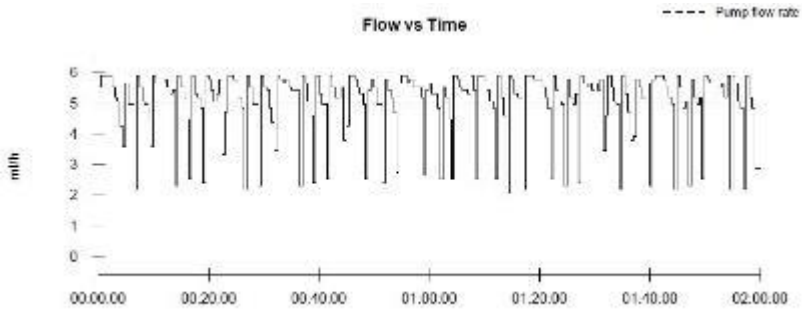
1)The methods of controlling Bolus volume before occlusion: The pressure in the occlusion pipeline is released to control the bolus volume by controlling the inversion of the stepper motor.

2)Storage time for the electronic memory after power off: same as the product lifetime.

3)The maximum volume that the pump can deliver under a single fault condition：0.3mL

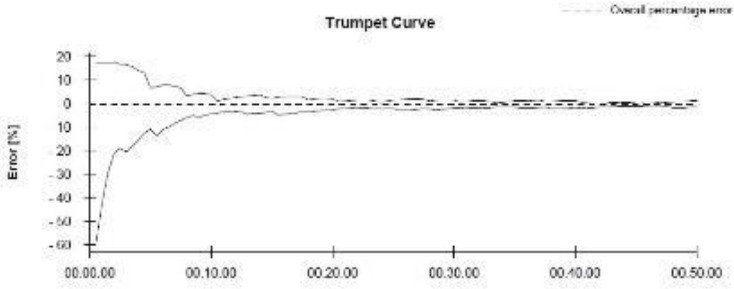
4)Device calibration is measured in ml.

5)A graph of rising curves for the first two hours of the intermediate rate.



The dashed part of the figure above represents the set Infusion rate (in the figure the intermediate Infusion rate of 5mL/h). The solid part is a continuous cable with the average Infusion rate value over the sampling period.

6)Horn graph for the 2nd hour of intermediate rate.



7)The dashed line of the horn curve is the precision error value of the device's final approach, the solid part of the dotted line is the maximum positive deviation curve in the second hour, and the solid part of the lower part of the dashed line is the maximum negative deviation curve in the second hour.

13 Restore to factory setting

Default factory setting as below:

No.	Parameter	Factory presets
1	Brightness level	Level 3
2	System sound level	Level 3
3	Night mode sound level	Level 3
4	Night mode brightness level	Level 3
5	Occlusion pressure level	120 kPa
6	Night mode	Close
7	WIFI	Close
8	Infusion mode	Rate mode
9	KVO	Constant KVO
10	KVO rate	1.00 mL/h

11	Call Back Time	2 min
12	Near End Of Infusion time	5 min
13	Auto screen lock time	5 min
14	Night mode start time	19:00:00
15	Night mode end time	09:00:00
16	Bolus rate	1200.00 mL/h
17	Purge rate	1200.00 mL/h
18	Bolus volume	5.00 mL
19	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:

1) 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.

2) The device works at a maximum selectable speed (2300.00mL/h) and runs for up to 4 hours on battery to facilitate patient transport and unexpected power outages.

3) Contact the customer service immediately if the internal battery cannot be charged or cannot work normally. Do not disassemble it by yourself.

4) The device has a internal disposable button battery designed to last longer than 8 years, when the set time is exceeded, need to be

disposed with the device in accordance with the instructions for waste disposal in this manual 16.

15 Service and Maintenance

Check the pump before use：

1）Check whether there are foreign objects inside the power outlet (such as drug solution residue), and confirm that the device startup self-test is normal.

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

During use：

1）To avoid giving an incorrect dosage of drug to a patient, please disconnect the pump from the patient before changing a device.

2） Please make sure that the infusion line is not kinked. Insert the needle to the vein on a part of the patient's body where it is not likely to be squeezed or pressed.

3）To prevent the spilled drug solution on the pump surface from getting into the inside of the device, wipe it dry immediately if there is a spill.

Storage and daily maintenance：

1）To keep the device clean, wipe it clean for at least once a month, which can prevent the corrosion caused by the drug solution and avoid the mobility of the mechanical parts being affected by the dried solution.

2）Use a clean and damp cloth or an alcohol pad to wipe clean the device. Take caution to avoid any liquid from entering the device. If disinfection is required, commonly used disinfectants can be used.

After using the disinfectant, after wetting with a soft cloth in water, wring out the soft cloth for scrub treatment. When using disinfectants, follow their instructions.

3）Check the Low battery Alarm time of the device at least once a month. Make the device standby when the battery is low in non-clinical use, start timing when you hear the alarm of "low battery", and the alarm time should be more than 30 minutes.

Disinfection method:

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

16 Waste Disposal

16.1 Battery

Please follow local regulations to dispose of used batteries.

16.2 Syringe

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

16.3 Syringe pump

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

17 Electromagnetic Compatibility

Special precautions regarding Electromagnetic Compatibility (EMC) are required for this 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:：

The name of the cable	Length
The power adapter	2.9 m

In addition to cables (transdicators) sold as spare parts for internal components, the use of accessories and cables (transdicators) other than specified may result in an increase in 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	Specific Description
The network power supply (including the internal battery) is connected to run	At the intermediate rate of 5.00mL/h and the VTBI of ≥10mL, start to operation, infusion accuracy error less than ±1.5% and the operation is normal during the process, there should be no abnormal phenomena and failures.

Guidance and manufacture's declaration – electromagnetic emission

Guidance and manufacture's declaration – electromagnetic emission

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such and environment.：

Emissions test	Compliance	Electromagnetic environment - guide
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function, so its RF emission is low and there is little chance of interference with nearby electronics
RF emissions CISPR 11	Class A	The device is suitable for use in all facilities that are not domestic and are not directly connected to the public low-voltage power supply network of domestic residences
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity

Guidance and manufacture's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guide
Electrostatic discharge (ESD) IEC 61000-4-2	±8KV contact ±15 KV air	±8KV contact ±15KV air	The ground should be made of wood, concrete, or ceramic tiles. If the ground is covered with synthetic materials, the relative humidity should be at least 30%
Electrical fast transient/burst	±2KV for power supply lines	±2 KV for power supply lines	The network power supply should have

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

Guidance and manufacture's declaration – electromagnetic immunity			
The 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） 10V（Valid value） 150 kHz～80MHz （ISM bands between） 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. Recommande 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 distance between portable and mobile RF communication equipment and infusion pumps

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

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

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

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

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

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

18 Antistatic Precautions

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

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

The operator should be aware of the following things:

a) Unless appropriate preventive measures have already been taken, do not use hand or hand tool to touch connectors with electrostatic discharge warning signs. Preventive measures include: 1) Methods for preventing electrostatic charge accumulation (such as air conditioning, air humidification, floor conductive coating or non-synthetic clothing); 2) Discharge electrostatic charge from human body to the framework of 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 Network 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)Network security feature configuration

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.

4)Data backup and disaster recovery

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

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

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

Software environment: Embedded software system;

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

6)Security Software compatibility list (if applicable)

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

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

Not applicable, not updated

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

No other off-the-shelf software;

20 Packaging and Accessories

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

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



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Manual book preparation date: 07-12-2023

EC REP

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Technical Specifications

1. Important Features

Free combination: IW200/IW200LED infusion workstation is flexible to assemble, and the number of infusion pumps and/or syringe pumps can be freely selected for use.

Quick installation: Infusion pumps (V20 and V20 plus) and/or syringe pumps (S20 and S20 plus) can be quickly installed on the IW200/IW200LED infusion workstation.

Plug and play: Infusion pumps (V20 and V20 plus) and/or syringe pumps (S20 and S20 plus) can be turned on and used after being plugged into IW200/IW200LED infusion workstation, without configuration. There is no requirement for the installation slot of the pump.

Relay infusion: Any infusion module has an online function to meet the user's relay continuous infusion function requirements.

Centralized display: Collect and centrally display infusion status information on the infusion workstation, with good visual effects.

Centralized power supply: Multiple pumps are powered on an infusion workstation to reduce cluttered power cords.

Connect to HIS: IW200/IW200LED infusion workstation can be connected to the hospital information system by wire or wireless, supporting medical information applications.

HL7 protocol: IW200/IW200LED infusion workstation supports standardized health information transmission protocol.

2. Size

The size of IW200/IW200LED (including variants) is shown as below:

Maximum dimensions of IW200/IW200LED infusion workstation Unit:mm

Serial no.	Model	Channel no.	Size(Height*Width*Depth)	
			Without pumps installed	With pumps installed
1.	IW200/IW200LED-4	4	360*243*120	360*243*165
2.	IW200/IW200LED-6	6	514*243*120	514*243*165
3.	IW200/IW200LED-8	8	668*243*120	668*243*165

3.Technical specifications

The technical specifications are mainly described in the below table:

IW200/IW200LED Technical specifications

No.	Specification	Details
1.	Type of unit	Infusion workstation
2.	MDR class	IIb
3.	Protection type	IPX1
4.	Rated voltage	A.C：100V～240V
5.	Rated frequency	50Hz/60Hz
6.	Applicable syringe pump	Graseby syringe pump
7.	Applicable infusion pump	Graseby infusion pump
8.	Infusion unit combination	4/6/8
9.	Max. Weight(Kg) (without pumps installed)	4 channels: 1.89kg; 6 channels: 2.48kg; 8 channels: 3.06kg
10.	Networking	Wireless WIFI/wired networking

11.	Maximum power (VA)	200VA
12.	Environmental temperature and humidity	Transport and storage environment temperature: -20℃~+60℃; Ambient temperature for use: +5℃~+40℃ Transportation, storage and use environment humidity: 20%~90% Working atmospheric pressure: 700hPa~1060hPa
13.	Software release version	IW200-V1.0.0
14.	Life span	8 years

The recommended accessories for use with one single IW200/IW200LED are shown as below:

IW200/IW200LED accessories

Accessories	Quantity	Unit
IFU	1	volume
Fixation clamp	2	piece
Power cable	1	piece
Carts(Optional)	1	set
For other accessories, please see the packing list.		

3. Main functions:

1) Power supply for each channel: Provide DC15V power supply for each pump;

2) Record the cumulative amount of infusion of each channel: After each channel is inserted with pump, the cumulative amount generated by the infusion is uploaded, and the total cumulative amount is displayed at the cumulative amount;

3) View the connection status and alarm status of each pump: After the infusion pump is installed on the workstation, the connection status and alarm status of the infusion pump can be observed;

4) Log recording function: The workstation log records the disconnection of pumps and the workstation alarm log;

5) Multi-channel pump relay function: IW200/IW200LED can have multiple relay modes for multi-channel pumps, including relay in sequence, relay in any sequence, and multi-channel pump cycle relay function; two sets of independent relay infusion can be run at the same time;

6) Power-on login function: IW200/IW200LED needs to enter a dedicated account and password to log in when it is turned on;

7) Wifi related

a）IW200/IW200LED has WiFi and wired network connection functions:

- The infusion workstation can be connected to the hospital network via Wifi.
- The infusion workstation can be connected to the hospital network via a wired network.

b) IW200/IW200LED has the following network security capabilities:

- Audit (AUDT):capable of providing the ability to audit user activities.
- Authorization (AUTH):capable of determining that the user is authorized.
- Node Authentication (NAUT): capable of identifying network nodes.
- Personnel Authentication (PAUT): capable of identifying the capabilities of authorized users.

- Connectivity (CONN): capable of ensuring that the connected network is secure and controllable.
- Data Backup and Disaster Recovery (DTBK): capable of recovering data, hardware, or software after it is damaged or destroyed.

c) Wireless transmission distance: greater than or equal to 20 meters without obstruction indoors.

8）Support hot-swap connection function for pumps on the device;

9) Alarm function:

- Low battery alarm: Alarm when the battery is low
- Exhausted battery alarm: Alarm when the battery is exhausted
- No external power alarm: Alarm when the device is not connected to an external power source and is powered by a battery
- Battery failure alarm: Alarm when the device does not detect a battery signal or the battery is accidentally disconnected when the device is powered on
- Ethernet disconnect alarm: Alarm when the device Ethernet communication is disconnected
- WiFi disconnect alarm: Alarm when the device WiFi is disconnected