User Manual

Syringe Pump

UniFusion SP50/Pro/Neo/TIVA/SE

Version:V4.1

CE 0197

Preface

I. Application Scope

Applicable to UniFusion SP50 series syringe pumps of our company.
This User Manual describes the product's most complete configuration, the accessories and functions may not be existed in the product of the user, for more detailed information, please contact manufacturer.

II. Applicable Object

It is applicable to the professional trained nurse, anesthetist, and maintenance technician of this equipment.

III. Use Instructions

This User Manual covers the basic information on the safety and effectiveness of the product for guiding the operator to correctly install, test, operate, use and maintain the product. Please read this manual thoroughly before use.
Our company is responsible for the reliability and performance of the equipment only all following conditions are met:

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

IV. Paraphrase

【】 means mechanical button
『』 means touch button
( ) further Information
- means inapplicable
√means accordant
→means operation steps

Bolus: Infuse large volume liquid in a short time.
KVO: Keep the vein open, prevent blood back to the syringe extension line and needle to be blocked.
Anti-bolus: Motor automatically reverse while the syringe extension line needle with high pressure.
Warning /Attention: it may possibly cause physical injury or death if the cautions covered in the Warning are not obeyed.
Caution: it may possibly cause physical injury or property loss if the cautions are not obeyed.
Note: in case fails to follow the supplementary or prompt information on the operation instructions may possibly cause physical injury the equipment fault or property loss if it is not obeyed.
Accessories: the optional components which are necessary and (or) suitable for using with the equipment in order to achieve the expected purpose, or provide convenience for achieving the expected purpose, or improve the expected purpose, or increase the additional functions of the equipment.

V. Description on Revision of User Manual

This User Manual will be revised subject to product improvement, laws updating or instructions improving basing on the preconditions of meeting related laws and regulations, and all revised records will be stated in the new version.

Version	Revising Date	Revised Content
V1.0	2018.9.20	First edition
V2.0	2020.3.20	Add CE mark
V3.0	2020.7.2	Adjust Order of Content
V4.0	2022.7.22	Updated the applicable standards in Section 2.5 and the content of Sections 8.2.7 and 8.2.9
V4.1	2023.7.21	Update/change the address of the EU REP as well as update the content of section 6.2.5etc

Content

Chapter 1 Safety Instructions

1.1 Warnings

⚠

- Before using, please check the equipment, connecting wire and accessories to ensure that it can work normally and safely. If there's anything abnormal, immediately stop working and contact our after sale service department. Additionally, the adhesion or intrusion of fluid/drug may possibly cause the equipment fault and malfunction. Therefore, please clean the equipment after use, and store it correctly.

- This equipment must be operated by trained professional medical care personnel (Operator).

- This equipment is not applicable to blood transfusion.

- It is not allowed to put and use the equipment in the environment with anesthetic and other inflammable or explosive articles to avoid fire or explosion.

- It is not allowed to store or use the equipment in the environment with active chemical gas (including gas for disinfecting) and moist environment since it may influence the inside components of the syringe pump and may possibly cause performance drop or damage of the inside components.

- The operator (trained professional medical care personnel) shall guarantee that the inputted infusion parameters of this equipment are the same as the medical advice before starting infusion.

- Please do not only depend on alarm system during use, please periodically check it to avoid accident.

- If the sound level of the alarm signal is lower than the environmental noise, the operator will be effected to identifying the alarm status.

- Tightly fix this equipment on the infusion stand and ensure the stability of the infusion stand. Be careful when moving the infusion stand and this equipment to avoid the equipment dropping and infusion stand falling or knocking the surrounding objects.

- If the syringe extension line is twisted, or the filter or needle is obstructed, or blood in the needle which may obstruct the syringe, the pressure in the syringe will rise. When removing such occlusion, it may possibly cause "bolus infusion" (temporary excess infusion) to the patient. The correct method is to tightly hold or clamp the extension line near the puncturing position, then loosen the syringe, solve the reason of occlusion, and restart infusion. If infusion is restarted when the occlusion reason exists, then it may cause occlusion alarm persistently, and the pressure in the syringe may keep rising, and may break or cut off the connection, or hurt the patient.

- This equipment has the occlusion detection function for detecting and alarming when the syringe needle deviates the position in the vein or the needle is not correctly punctured in the vein. However, it only alarms when the occlusion pressure has reached certain numerical value, and the puncturing part

may possibly have become reddish, swelling or bleeding, additionally, it is possible that the device doesn't alarm for a long period if the actual occlusion pressure is lower than the alarm threshold value, therefore, please periodically check the puncturing part. If there's any abnormal phenomenon for the puncturing part, please timely take suitable measures, such as puncturing again.

- Only those sterile hypodermic syringes for single use and other medical components that meet the local laws and regulations and the requirements covered in and this User Manual can be adopted, it is suggested to adopt the syringe with same brand as defaulted in this equipment. It can't ensure the infusion accuracy if the unsuitable syringe line is adopted. Please use the syringe and the extension line with luer taper, or may be because of the extension line pop off to cause damage to the patient.

- It is not allowed to disassemble or refit this equipment or use it for other purposes except normal infusion.

- No one is allowed to repair this equipment except our company or the authorized repair technician of our company.

- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protecti ve earth

- If you have other batteries which you want to insert them together in one pump, Please remember to charge these batteries at single pump separately at full capacity firstly.

1.2 Cautions

⚠

- Before its first use after purchase, or this equipment is not used for a long period, please charge the equipment with AC power supply. If it is not fully charged, under power failure, the equipment can't continue working with built-in battery power supply.

- This equipment can't be used in the places with radiological installation or magnetic resonance equipment as well as the places with high pressure oxygen therapy.

- Other devices near this equipment must meet corresponding EMC requirements, otherwise, it may influence the performance of this equipment.

- Under general conditions, please use AC power supply as much as possible since it can prolong the service life of the battery at a certain degree. When using AC power supply, ensure that the grounding wire is reliably connected with the ground, and only the AC power cord attached with this equipment shall be adopted, please pay attention to the plug position of the power cord to ensure that you can disconnected it at any time. The built-in battery can only be used as the assistant power supply when the AC power supply can't reliably connect with the ground and is not under normal conditions (power failure or in-transport infusion).

- Before connecting this equipment with power supply, please keep the power socket and plug dry, and the power voltage and frequency meet the requirements listed in the equipment label or this User Manual.

- The equipment is equipped with the audible and visual alarm system, the red and yellow alarm indicators will light on by turn to check if the alarm system can work normally, and the speaker makes the "beep" sound.

- Please keep the equipment away from the AC power socket for a certain distance to avoid fluid/drug splashing or dropping in the socket, otherwise, it may possibly cause short circuit.

- Please use the fluid/drug after it has reached or nearly reached room temperature. When the fluid/drug is used at low temperature, the air which is dissolved in the fluid/drug may cause more air bubbles.

- It is not allowed to press and operate the button with sharp object (such as pencil tip and nail), otherwise, it may possibly cause early damage to button or surface film.

- Under the condition of low flow rate infusion, please pay special attention on occlusion. The lower the infusion flow rate, the longer the time of detecting occlusion, and it in turn may possibly cause a long time infusion stop during this period.

- If the equipment suffered from dropping or impacting, please stop using it immediately, and contact our after sale service department, because the inside components of the equipment may be possibly damaged even the appearance is not damaged and abnormality is not occurred when working.

- When using the pump, other infusion control equipment should not be installed on the same infusion Tube. Otherwise, it may cause danger.

1.3 Dialogue window

Dialogue window mainly content include operation select, operation confirm etc. tips information.

1.4 Symbols

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

Table:1.4-1

Marks	Description	Marks	Description
	Lot Number		Protective earth
	Serial Number	IP34	Ingress Protection(Prevent solid objects larger than 2.5mm in diameter and water intrusion from splashing in all directions)
	Caution		Alternating Current
	Both direct and alternating current		Input and output
	Defibrillation proof type CF applied Part		Handle with harmless method
	Date of Manufacture		Manufacturer
	Bell, cancel temporary		Selection; affirmative acknowledgement; success; ACK
	environment-friendly use period (20 years)		Non-ionizing radiation
	Authorized Representative in the European Community		Please refer to User Manual /Handbook
	Notified Body		Importer

Chapter 2 Overview

2.1 Application Scope

2.1.1 Expected Purpose

This product can be used by hospitals for intravenous infusion of medicine liquid for patients in an adjustable way. The syringe pump is intended for infuse cardiovascular drugs, vasoactive drugs and antibiotics. And used for physiological maintenance and micro infusion of premature and newborn. Other liquids can also be injected according to clinical needs.

2.1.2 Expected Working Environment

Including but not limiting to: hospital ICU (intensive care unit), operating room, neonate intensive care unit (NICU).

2.1.3 Suitable Object

Adult, child or neonate.

2.1.4 Intended User

Medical professionals, clinical nurses

2.2 Contraindications

No

2.3 Working Principle

It is controlled to move into a linear motion from a microcontroller based on system which drives a step motor, allowing a wide range of pumping rates configured to the inside diameter of the loaded syringe. The syringe plunger is driven from a lead screw and drive-nut mechanism, infusing the drugs into the patient.

2.4 Structure and Performance

2.4.1 Structure and Performance

The syringe pump mainly composes of the main unit and built-in battery. This equipment provides several infusion modes, such as rate mode, time mode, body weight mode, drug library mode, ramp up/down mode, loading dose mode, sequence mode, and TIVA mode. Additionally, it also has functions such as history records, drug library, Anti-bolus, and alarm and so on.

2.4.2 Accessories

Optional accessories include a protective cover, the protective cover is used to protect the Slider box.

2.4.3 Description on Model

This equipment has five models: UniFusion SP50, UniFusion SP50 Pro, UniFusion SP50 SE, UniFusion SP50 TIVA, UniFusion SP50 Neo, the main function differences are shown in table below.

Model	UniFusion SP50	UniFusion SP50 Pro	UniFusion SP50 SE	UniFusion SP50 TIVA	UniFusion SP50 Neo
Syringe specifications	5ml、10ml、20ml、30ml、50/60ml	2/3ml、5ml、10ml、20ml、30ml、50/60ml	5ml、10ml、20ml、30ml、50/60ml	5ml、10ml、20ml、30ml、50/60ml	2/3ml、5ml、10ml、20ml、30ml、50/60ml
drug library mode	-	√	-	√	√
loading dose mode	-	√	-	√	√
TIVA mode	-	√	-	√	√
sequence mode	-	√	-	√	√
ramp up/down mode	-	√	-	√	√
Occlusion pressure levels	3 levels	12 levels	3 levels	12 levels	12 levels

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

2.5 Product Specification

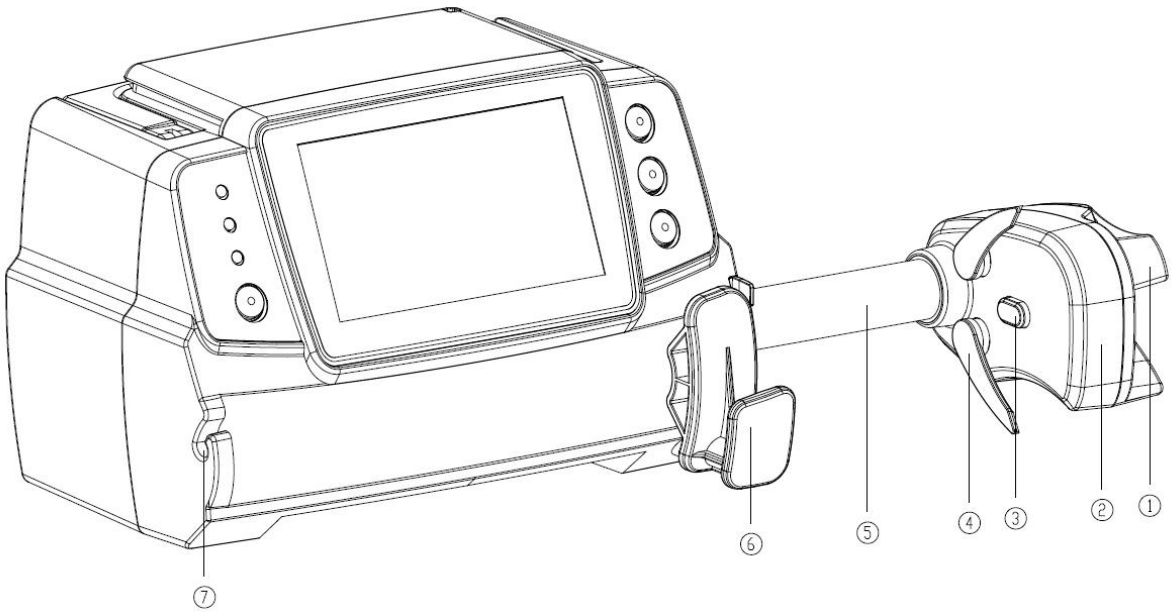
Safety Classification	
Electric protection Type	Class I
Electric protection Level	Defibrillation proof type CF applied Part Device recovery time is 10S after application of defibrillation voltage
Applied Parts	The applied Parts is the infusion tube (Note: the infusion tube is used as a supporting accessory and is not provided by the company）
Ingress Protection	IP34 (Prevent solid objects larger than 2.5mm in diameter and water intrusion from splashing in all directions)
Working mode	Continuous
Classification	Portable equipment, non-portable syringe pump
Specification Parameters	
Compatible Syringes	2/3ml, 5ml, 10ml, 20ml, 30ml, 50/60ml
System Accuracy	≥1ml/h, ±2% ＜1ml/h, ±5%
Infusion Rate	Syringe size 2/3ml: (0.1-100) ml/h Syringe size 5ml: (0.1-150) ml/h Syringe size 10ml: (0.1-300) ml/h Syringe size 20ml: (0.1-600) ml/h Syringe size 30ml: (0.1-900) ml/h Syringe size 50ml: (0.1-1500)ml/h
Bolus Rate	Syringe size 2/3ml: (0.1-100) ml/h Syringe size 5ml: (0.1-150) ml/h Syringe size 10ml: (0.1-300) ml/h Syringe size 20ml: (0.1-600) ml/h Syringe size 30ml: (0.1-900) ml/h Syringe size 50ml: (0.1-1500) ml/h
Bolus preset value	Min: 0.1ml Max: max rate of accordingly loaded syringe size
KVO Rate	0-5.00ml/h
Micro mode setting range	Syringe size 2/3ml: (100-100) ml/h Syringe size 5ml: (100-150) ml/h Syringe size 10ml:(100- 300) ml/h Syringe size 20ml: (100-600) ml/h Syringe size 30ml: (100-900) ml/h Syringe size 50ml: (100-1500) ml/h
Flow rate increment	0.01ml/h(0.01-99.99ml/h) 0.1ml/h(100-999.9ml/h) 1ml/h(1000-1500ml/h)
VTBI	0-9999.99ml, minimum step is 0.01ml

Total Volume Infused	0-9999.99ml, minimum step is 0.01ml
Time Range	1min-99hrs59min
Fuse Type	slow fuse 2A 250V
Dimensions	242.5(W)*111(D)*126.5(H) mm
Weight	1.7kg
Power Supply	
AC power supply	100-240V 50/60Hz
Input power	50VA (power consumption within 25W)
DC power supply	12V，2A; DC chargers conforming to IEC 60950-1/IEC 62368-1 or other relevant safety standards shall be used.
Battery Specifications	Specification: 7.4V 2500mAh Single battery: Charging time is less than 2hrs, working time is over 5.5 hrs(after completely charging battery, when the environment temperature is 25℃， flow rate is 25ml/h and 1500ml/h, the constantly working time). The remaining time or the percentage of remaining battery power of a single battery is displayed in white. Two batteries: Charging time is less than 4hrs, working time is over 5.5 hrs (after completely charging batteries, when the environment temperature is 25℃, flow rate is 25ml/h and 1500ml/h, the constantly working time) . The remaining time or the percentage of remaining battery power of the dual batteries is displayed in blue.
Alarm	
Alarm signal sound pressure level	When the sound is set at lowest level, alarm signal sound pressure level ≥45dB(A) When the sound is set at highest level, alarm signal sound pressure level ≤80dB(A)
Alarm information	VTBI near end, Syringe near empty, VTBI infused, Syringe empty,Pressure high, Battery nearly empty, Battery empty, No battery inserted, No power supply, Check syringe, Pump idle alarm, Standby time expired, KVO finished
Environment	
Non AP/APG type equipment	Do not use it in the environment with inflammable anesthetic gas mixed with air, and inflammable anesthetic gas mixed with oxygen or nitrous oxide
Operating	(1) temperature: 5-40℃ (2) humidity: 15-95%, non-condensable (3) atmospheric pressure: 57-106kPa

Transport & Storage	(1) temperature: -20-55℃ (2) humidity: 10-95%, non-condensable (3) atmospheric pressure: 50-106kPa
Safety Standard	
Main Safety Standards	IEC 60601-1:2005+A1:2012+A2:2020 Medical Electrical Equipment, Part 1: General Requirements for basic safety and essential performance IEC 60601-2-24:2012 Medical electrical equipment – Part 2-24: Particular requirements for the safety of syringe pumps and controllers IEC 60601-1-8:2006+A1:2012+A2:2020 Medical electrical equipment –Part 1-8: General requirements for basic safety and essential performance –Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-2:2014+A1:2020 Medical Electrical Equipment - Part1-2: General requirements for basic safety and essential performance-Collateral standard:Electromagnetic compatibility-Requirements and tests

Chapter 3 Appearance

3.1 Front View



①Handle

Control syringe pump push-pull sliding box and clip.

②Slider box

③Pressure sensor

Detect the pressure of the syringe

④Syringe clip

Clamp the syringe plunger

⑤Lead-screw

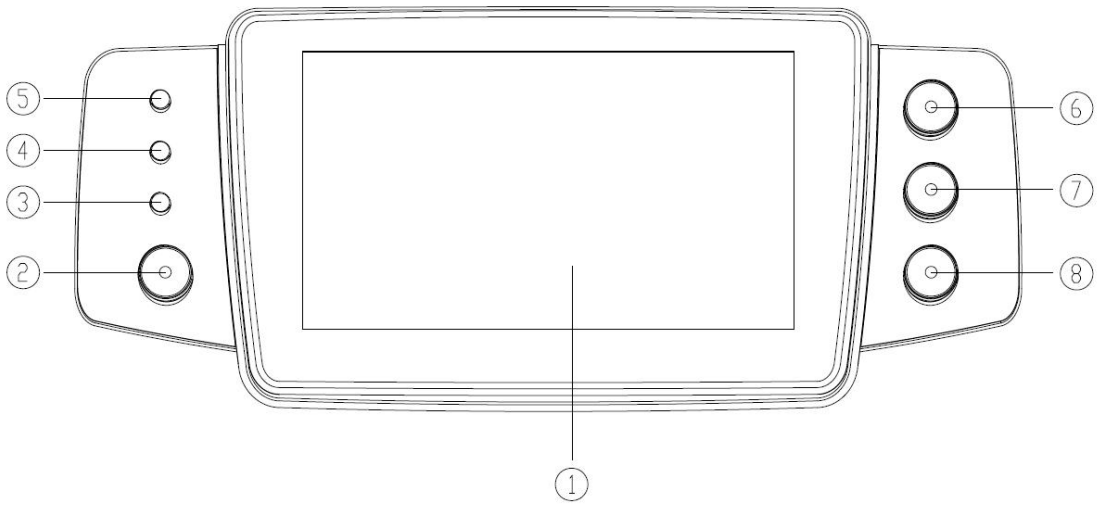
⑥Syringe fixture lever

Pull forward then turn 90° right or left , install the syringe into the slot.

⑦Extension line Clamp

Keep the extension line in line and neat

3.2 Operation Panel



①Touch Screen: 4.3 inches full color LCD (TFT) touch screen

②【Power】

Pump power switch, press and hold for 3 seconds, pump power off. Standby selection button.

③AC indicator light

When connecting with AC power supply, AC indicator lights on.

④Alarm indicator light

While pump alarms, indicator light glitter, different level different frequency and color, more information please **refer to Chapter 10.1**.

⑤Running lights

⑥【Start/stop】

⑦【Bolus/Purge】

⑧【Home】

Enter system home page.

3.3 Display Screen

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

3.3.1 Title Bar

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

Table3.4.1-1: Title Bar Icon

Icon	Paraphrase	Description
	Syringe apparatus indication icon	Syringe apparatus indication icon
	Lock screen indication icon	Unlock state icon is 
	WIFI indication icon	Indicate WIFI connection state.
	Battery charging indication icon	Display the current battery charging state
	Battery status indication icon	The percentage numerical value at the left side of the icon displays the remained battery. Since the remained battery may change, it may possibly show the following states: 

3.3.2 Typical Interface

During pre-infusion and infusion, the typical interface will display the following: main interface, working interface, alarm interface, prompt interface, control panel, parameters setting, input method, standby interface etc.

3.3.2.1 Typical Interface Icon Paraphrase

Table: 3.4.2.1-1

Icon	Paraphrase	Description
	Running indicator	When the machine is running infusion, this light will be on and green.
	Alarm indicator	When the machine alarms, this light will be on. A red light flashes indicates a high-level alarm, a yellow light flashes for an intermediate-level alarm; a steady yellow light indicates a low-level alarm.
	ON/OFF	Power ON/OFF button: Power on: long press; Power off: long press or short press to display the power off interface (You can choose standby)
	Start	Click this icon, start infusion
	Stop	Click this icon, infusion stop
	Bolus/Purge	1. During infusion, it is『Bolus』function, click it to start fast infusion 2. Before infusion starting, it is『Purge』function, click it to exhaust air from the Infusion set
	Home	Click this icon, return to the main interface

3.3.2.2 Input Method Interface

The input method interface composes of the title bar, input box, editing box.

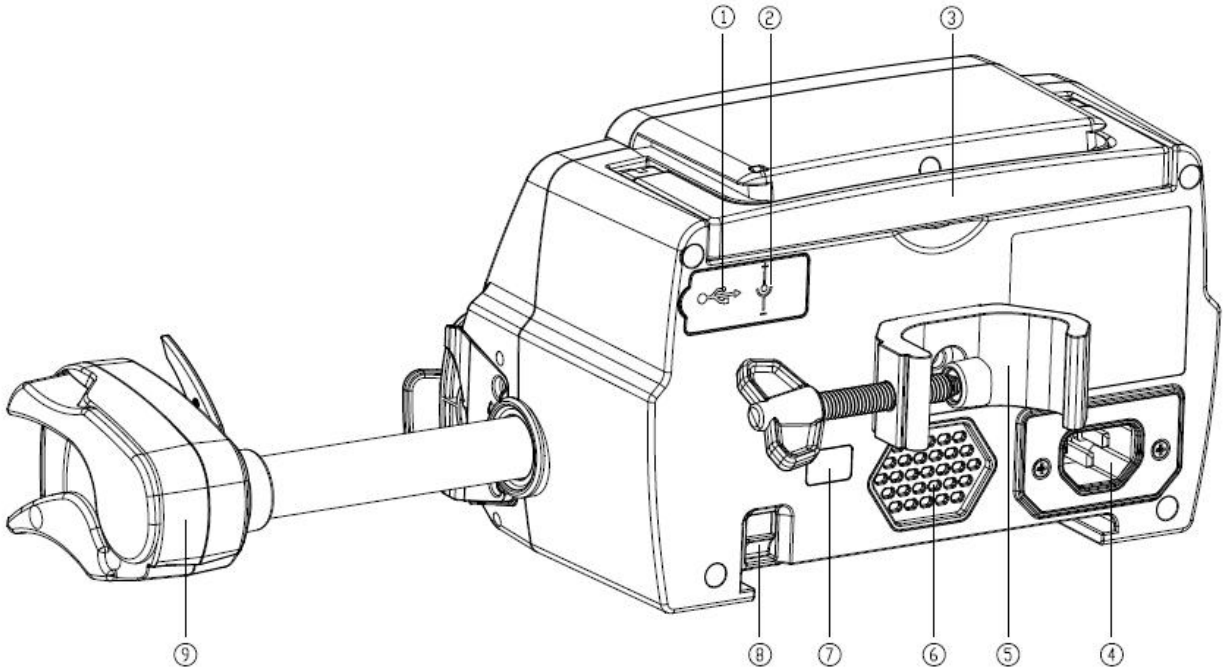
1) Title bar: display the name of current editing parameter.
2) Input box: real-time display the input content.
3) Editing box: Divided into a main key area and a function key area.

The main key area consists mainly of numeric, alphabetic and symbolic keys, which are switched in sequence by successive clicks.

The function button area composes of 『 』 『 』, 『Cancel』, 『Confirm』 and 『A/a』.

Icon	Paraphrase	Description
	Clear key	After clicking it, the input will be cleared
	Backspace button	Click it to backspace delete
	Cancel button	Click it to cancel editing and exit
	OK button	Click it to save editing and exit
	Case switch key	Click it to switch the capital and lowercase English letters

3.4 Rear View



① USB Port

The USB Port can used for:

- Software upgrade. Turn off the pump and connect it to the computer with a USB cable ,then upgrade the pump software using a dedicated upgrade tool (PC software).
- Data export. The USB port is converted into RS232 standard interface through a dedicated conversion cable supplied by Medrena, and can be connected to the computer through RS232.

⚠ Caution: It is necessary to purchase a computer that has passed relevant security verification through formal channels for software upgrade and data export. Otherwise, it may introduce dangerous voltages exceeding 5V and cause harm to the Syringe pump or human body.

- Nurse call realizing. The connection requirements for realizing the nurse call function is: 3.3V, 25mA.

② DC Input Port

External 12V DC power supply

③ Handle

④ A/C Adapter Port

External 100-240V 50/60Hz AC power supply

⑤ Pole Clamp

Using for fixing the equipment on the infusion stand

⑥ Loudspeaker

⑦ IrDA

Using for communicating with infusion docking station (Optional)

⑧ Latch for stackable function

⑨ Slider box

Chapter 4 Installation

4.1 Unpacking and Checking

1) Please check the appearance before unpacking, if broken, please contact the transportation company or our after-sale service department quickly.

2) Please carefully open the package to avoid damaging the equipment and relevant accessories.

3) After unpacking, please check the objects according to the packaging list, if there is insufficient or damaged accessories, please contact our company as soon as possible.

4) Please keep relevant accessories, warranty card and User Manual.

5) Please keep the packing case and packing materials for future transportation or storage.

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

4.2 Installation

⚠ Warning:

- This equipment shall be installed by the designated technicians of our company.
- All devices that connect with this equipment must pass the designated IEC standards (for example: IEC 60950 information technology equipment safety and IEC 60601-1 medical electric device safety) certification, and all devices must be connected according to the valid version of IEC 60601-1 system. The technician who takes charge of connecting to additional devices with the equipment interface is responsible for meeting the IEC 60601-1 standard. Please contact our company if you have any enquiry.
- When connecting this equipment with other electric devices to form the combination with special function, if the combination can't be confirmed dangerous or not, please contact our company or the electric expert of hospital to ensure that the necessary safety of all devices in the combination won't be destroyed.
- This equipment must be used and stored in the environment regulated by our company.

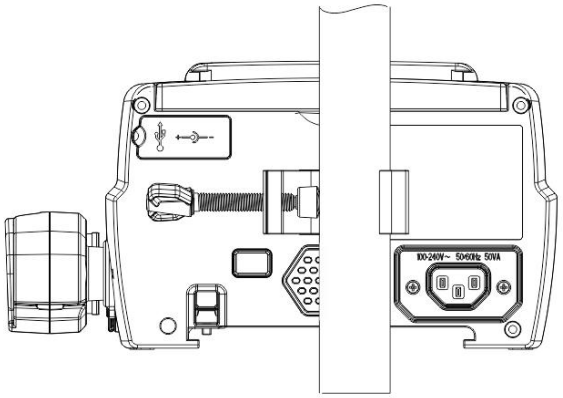
Install the syringe Pump

(1) Rotate the pole clamp screw (knob) and

unscrew to leave the space.

(2) Lock the Pole Clamp on the infusion stand, adjust the position of the syringe pump, tighten the pole clamp to fix the syringe pump on the infusion stand (shown in drawing right). Hold the syringe pump when tightening the fixing clamp; loose it after tightening to avoid falling.

(3) The pole clamp supports the vertical pole at default state. To adjust the pole clamp direction, please remove the bolt from the pole clamp screwdriver, take out the pole clamp and adjust the direction, then tighten the bolt.



Chapter 5 Use Preparation and Cautions

5.1 Use Preparation

The new equipment, or reusing after storing for a period, or reusing after repair, please check it to ensure before use:

- The equipment appearance is clean and under good condition without crack and leakage.
- The moving components are smooth and effective; the button is effective.
- The touch screen can be operated smoothly and effectively.
- The power cord is installed tightly and won't be easily damaged when pulling.
- Set and check the system time to ensure that the history records will be correctly recorded.
- In case only built-in battery is adopted for supplying power, please charge it to full before using, and ensure that the battery keeps at the effective working conditions.
- Carefully read the Warnings, Cautions and Operation Steps listed in this User Manual.

5.2 Operation Cautions

⚠ Cautions:

- Avoid direct sunlight, high temperature or high humidity.
- The equipment shall be put at the position less than 0.65m (both up and down) to the heart of the patient.
- The parameters can only be set or changed by the trained and professional personnel.
- Avoid the equipment working with fault so as to avoid medical negligence, which may hurt the health and even life of the patient.
- It may possibly drop the infusion accuracy or abnormal work of the equipment if the working environment temperature exceeds the designated range.
- The viscosity and specific gravity of infusion fluid will influence the infusion accuracy.
- Before operation, the syringe pump should be placed in a relatively open location to ensure that there is no debris around the syringe pump.

Chapter 6 Basic Operation

6.1 Operation Flow

1) Mount the syringe pump on the IV stand: **refer to Chapter 4.2**
2) Power on: press  two seconds, Power on equipment, **refer to Chapter 6.2.2**
3) Install syringe: **refer to Chapter 6.2.3**
4) Confirm syringe brand and size: select syringe brand or add new brand
5) Remove air bubble in the line: **refer to Chapter 6.2.5**
6) Select infusion mode: select infusion modes according to requirement
7) Set infusion Parameters: set infusion parameters according to requirement
8) Connect infusion line with patient
9) Start infusion: press  , start infusion
10) Infusion finish **refer to Chapter 6.2.9**
11) Remove syringe **refer to Chapter 6.2.11**
12) Power off or Standby **refer to Chapter 6.2.12**

6.2 Infusion Operation

6.2.1 Equipment Installation

Mounting the device on the infusion stand according to **Chapter 4.2**, connect with AC power supply, check the AC indicator lights. Battery will start to charge once AC power connected.

6.2.2 Starting and Self-test

1) Press  two seconds，power on the equipment
2) After power on, the system will automatically check the motor, sensor, battery, memorizer, CPU communication, alarm indicator.
3) After passing self-test, pump enters into rate mode interface.

⚠Warning: ● If self-test failed, pump cannot operate properly or damaged, it cannot used for patient infusion, please contact the company.

6.2.3 Install Syringe

(1) Hold the clutch and pull the slider to the right side.
(2) Pull the syringe fixture lever, turn 90° right or left.
(3) Insert the syringe flange into slot, turn syringe fixture lever 90° spring back to tight the syringe.
(4) Hold the clutch and push leftward, release after it touched the plunger firmly.
(5) Put extension line of syringe into the extension line hook.
(6) Click『Setting』→『Commonly used Syringe brand』to choose syringe brand.

⚠Warning:

- Recommend to use syringe brand defaulted in this syringe pump.
- Make sure syringe brand and size in display screen is accordant with the one in use.
- Although self defined syringe brand function is available, to ensure infusion accuracy and safety, highly suggest to contact our company and ask the professional technician to set and test the user-defined syringe.

⚠Caution：

- Check to ensure no air bubble in syringe.
- Make sure syringe is correctly installed, otherwise accuracy will not assured and may do harm to patient due to no infusion or large dose output due to siphon.

6.2.4 Set Infusion Parameters

refer to Chapter 7.

6.2.5 Remove Air bubble

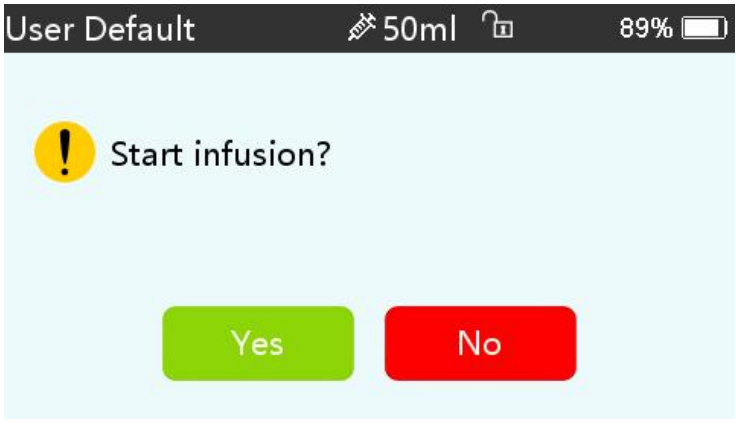
There are two ways to set parameters: manual purge and automatic purge. Users can choose the method according to their needs, and the purge total volume is not calculated in the Total Volume Infused.

(1) Manual purge: Long pressing [Bolus] button, the device will purge air according to the default flow rate of the system, release it and return to the setting parameter interface.
(2) Automatic purge: Under the parameters setting interface, Press 【Bolus】 button on the display and select "Yes" in the pop-up prompt box, until the air bubble in the infusion line is eliminated, click "Stop".

6.2.6 Start Infusion

(1) Connect syringe extension line with patient, confirm infusion parameters, Press【Start】button, click 『Yes』in the pop-up prompt interface, start infusion.

(2) After starting the infusion, the cumulative infusion volume is displayed on the infusion interface.

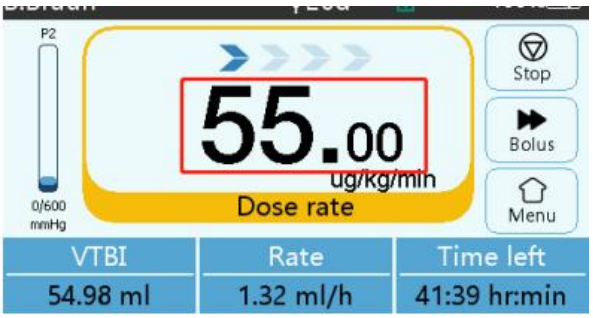


⚠Warning:

- When the pump is running, the lead-screw should be avoided by external force.

6.2.7 Change the Rate during Infusion

During the infusion process, select a mode, click the value of rate/dose rate/drip rate on the running interface, the flow rate can be changed online, and the infusion can continue at the changed flow rate.



⚠Note:

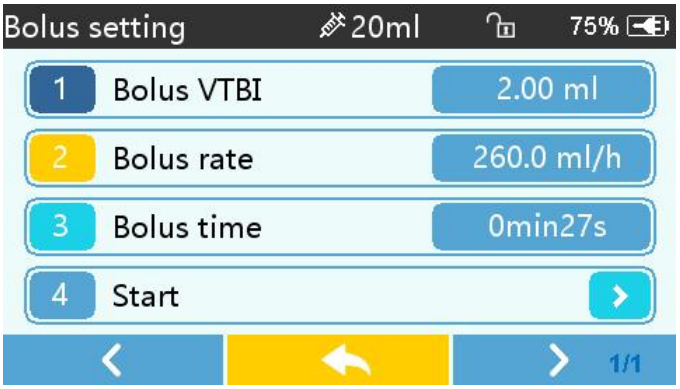
- Only **Rate mode** , **Time mode**, **Body-weight mode**, **Drip rate mode** and **drug library mode** support online changes to the flow rate.

6.2.8 Bolus Application

In operation, Bolus functions have two operation modes: Manual bolus and Automatic bolus.

(1) **Manual bolus**: press and hold the 【Bolus】 button on product panel, pump will work at the max flow rate of current syringe size, or set max bolus rate under setting interface. (syringe flow rate range please. refer to **Chapter 2.5**), release the button, pump will back to the previous setting infusion rate.

(2) **Automatic bolus**: Under the running interface, click『Bolus』 on touch screen, set two parameters among bolus infusion volume, rate and time, click『Start』.The device will make a sound of beep at every 1ml infused. After bolus infusion finished, the equipment goes back to the previous infusion rate.



6.2.9 Infusion Completion

When remaining infusion time is near preset volume to be infused completion time, pump will alarm. If ignore it, the system will keep alarming until complete VTBI infusion, for more information please **refer to Chapter 8.1.9**.

After VTBI completed, it activates VTBI infused alarm, if KVO function is ON, the equipment automatically starts KVO function, click 『OK』 in the alarm interface to stop KVO and eliminate alarm.

The default working time of the KVO system is 30min, after reaching the time, it will activate KVO completion alarm and stop infusion.

Please refer to **Chapter 8.1.2** for setting KVO rate.

6.2.10 Stop Infusion

During infusion or after infusion, click , infusion stop. It will return to the parameter setting interface display Total Volume Infused and adjustable parameters.

6.2.11 Remove the syringe

Disconnect the extension line from the patient, then remove the syringe.

Replace syringe, please follow the steps of **Chapter 6.2.3**.

6.2.12 Power OFF or Standby

Method 1: hold the 【Power】Button till the screen is OFF, the equipment is OFF.

Method 2: press the 【Power】Button to enter into OFF interface.

(1) Turn off the equipment: click 『Power off』icon, the equipment is turned OFF.

(2) Standby: click 『Standby』icon to enter into standby time setting interface, set the standby time. Under standby state, the screen brightness will be lowest, after standby, the screen brightness will be recovered.

(3) Cancel: click『Cancel』, return to the interface before OFF setting.

⚠Note: ●The equipment has standby function only under the non-working state.

Chapter 7 Set Infusion Parameters

7.1 Introduction to Infusion Parameters Setting

(1) The drug information can be displayed in the infusion running interface only when the drug library is under active state.

Click『Settings』 icon in the main interface to enter sub-menu, find 『Drug Library』menu item, click to enter then set the ON/OFF state of drug library and select drug. Please refer to this User Manual **Chapter 8.1.1** for details.

(2) For both the rate set in infusion parameter and the rate calculated by the system, the range is the system default flow rate of the current working syringe specification.

(3) If didn't set VTBI (Volume to be infused), which means to complete the fluid/drug in the syringe.

7.2 Infusion Parameters Setting Range

Infusion Parameter	Parameter Range
VTBI	0-9999.99ml
Rate	(0.1-100)ml/h for 2/3ml syringes (0.1-150)ml/h for 5ml syringes (0.1-300)ml/h for 10ml syringes (0.1-600)ml/h for 20ml syringes (0.1-900)ml/h for 30ml syringes (0.1-1500)ml/h for 50ml syringes
Time	1min-99hrs59min
Weight(Body weight)	0.1-300kg
Acti agentia (Drug mass)	0.01-99999.99
Conc. unit(Concentration unit)	ug/ml, mg/ml, g/ml, U/ml, KU/ml, IU/ml, EU/ml, mmol/ml, mol/ml, kcal/ml
Volume(Fluid amount)	0.01-9999.99ml
Dose rate	0.1-9999.99
Dose rate unit	ng/min、ng/h、ng/kg/min、ng/kg/h、μg/min、μg/h、μg/kg/min、μg/kg/h、mg/min、mg/h、mg/kg/min etc.

7.3 Infusion Mode Setting

After starting the equipment and self-test, the equipment automatically enters into the rate mode parameters setting interface, to select other mode, click『Menu』icon to enter into the main interface, click『Modes』icon to enter into the mode selection menu interface, and select preset

infusion mode.

7.3.1 Rate Mode

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

7.3.2 Time Mode

Under this mode, it allows to set VTBI (Volume to be infused) and Time, the system will automatically calculate the speed, speed = Volume(ml) /time(min).

7.3.3 Body Weight Mode

Under this mode, can select the dose unit,set the Weight (body weight), Conc. Unit (concentration unit), Acti agentia (drug mass),Volume (fluid volume), Dose rate, Dose unit, VTBI.
The system will automatically calculate the flow rate from the specified dose rate (ug/kg/min, mg/kg/min, ug/kg/h, mg/kg/h…etc) according to related formula {dose rate × weight}/{Acti agentia (drug mass) / Volume (fluid volume)}, and automatically calculate the time according to (VTBI) /(flow rate).

7.3.4 Drug library mode

Under this mode, set the Weight(body weight), Conc.(concentration), Dose and VTBI, the speed will automatically calculated according to this parameter.

7.3.5 Ramp up/down mode

Ramp up/down mode means to automatically increase the flow rate till reaching stable flow rate within the set rise time of the equipment through setting the rise time and fall time, after holding for a period, it automatically drops the flow rate within the set fall time. The rising or dropping stage is implemented in multiple stages.
Under this mode, set VTBI, rate in the stable stage, rise time and fall time, the system will automatically calculate the rising and dropping rate.

7.3.6 Loading dose mode

The Loading dose mode means to infusion with the Loading flow rate according to the Loading time, after reaching the Loading time, it works at the Maintain rate till complete the VTBI(Volume to be infused).
Loading VTBI=Rate*RiSe time
Maintain time =(VTBI -Loading VTBI) /Maintain rate

Under this mode, set the VTBI, Maintain rate, Loading rate, Loading time, system automatically calculate Loading dose VTBI and Maintain time.

⚠Note: ● VTBI must be greater than the Loading dose VTBI otherwise, when setting exceeds the limit, the excess part can't be set.

7.3.7 Sequence Mode

Sequence mode means to infuse according to the set sequence after setting the rate and time of different sequence groups. This pattern supports setting up multiple sequences,, it can set up to 5 sequences

7.3.8 TIVA mode

Under this mode, firstly, set the basic parameters of the Conc. unit(concentration unit), Acti agentia (drug mass), Volume(fluid volume), Weight, and then set the Loading stage: set Loading dose rate, Loading time. Set maintenance stage: set Maintaining dose and units, the system will automatically calculate the fluid rate, start running, first run the Loading dose rate after the end of the Loading time change to works at the Maintaining dose which automatically calculate by system until manually stop or stop with alarm.

Chapter 8　System Setting

8.1 Settings

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

8.1.1 Drug Library

Click on the preset drug name, the selected drug will be reflected in infusion mode parameters.
This feature can be turn on and off.
（1）UniFusion SP50 Pro\TIVA\Neo no less than 2000 drugs, can be imported through external tools, with upper and lower limit, concentration configuration, color configuration and other functions.
（2）UniFusion SP50\SE support 32 drugs, without upper and lower limit.

8.1.2 KVO Rate

Click『KVO rate』, input the numerical value, after confirming, click『OK』.
Please refer to **Chapter 2.5** for the adjustable KVO range.

8.1.3 Bolus Rate

Set the default Bolus rate. Please refer to **Chapter 2.5** for the range of bolus rate.

8.1.4 Syringe brands

For the built-in syringe brand of the system, after installing the syringe, click『Syringe brands』to enter into the syringe brand selecting interface, and click the preset brand option. The system built-in syringe brand: User Default (Double Dove), B. Braun, BD, Terumo. Users can also add other syringe models by creating new brands, and re-calibrating as described in section 12.3.

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

8.1.5 DPS

DPS, Dynamic pressure detection can be carried out after opening, alarm can be triggered when the pressure continues to rise or suddenly falls, this function is optional.

8.1.6 Occlusion Pressure

Click『Occlusion pressure』to enter into occlusion level setting interface, move the long box to the preset level, after confirming, click 『OK』.
The higher the level, the higher the occlusion level, it is suggested to select suitable occlusion pressure according to actual requirement.

⚠Warning:

- When adopting fluid/drug of high viscosity and the occlusion pressure is set at low level, it is possible that the system will report occlusion alarm even when the line is not obstructed, under this condition, please carefully observe the pressure indication icon in the display screen and infusion line, and rise the occlusion pressure if needed.

- When the occlusion pressure is set to high grade, the big pressure inside the pipeline is likely to pop out the extension line connected to the syringe. Please confirm that the extension line is securely attached to the syringe.

- When the occlusion pressure is set at high level, it may possibly cause the patient uncomfortable, after rising the occlusion pressure, please carefully observe the condition of the patient, and immediately take measure if there's any abnormality.

- Under the equipment fault state, the max pressure generated by the Syringe is 300kPa. Under single fault state, the max infusion volume is 2/3ml.

(Table 8.1.2-1 Relation of Occlusion level and Pressure)

Applicable Model: UniFusion SP50\SE Occlusion Pressure Level: 3 levels					
Level	Pressure Intensity (mmHg)	Level	Pressure Intensity (mmHg)	Level	Pressure Intensity (mmHg)
1	300	2	600	3	900

Applicable Model: UniFusion SP50 Pro\TIVA\Neo Occlusion Pressure Level: 12 levels					
Level	Pressure Intensity (mmHg)	Level	Pressure Intensity (mmHg)	Level	Pressure Intensity (mmHg)
1	75	2	150	3	225
4	300	5	375	6	450
7	525	8	600	9	675
10	750	11	825	12	900

8.1.7 Pressure Unit

Click 『Pressure unit』to enter into pressure unit select setting interface, four units are available: mmHg, kPa, bar, PSI, click the preset unit option.

⚠ Note: ● Please carefully confirm when changing the current pressure unit.

Unit Mark	Unit Conversion
kPa	1 kPa=7.5mmHg=0.145psi=0.01bar
PSI	1psi=51.713mmHg=6.895kpa=0.069bar
Bar	1bar=787.5mmHg=15.225psi=105kPa

8.1.8 Pump Idle Alert

Click『Pump idle alert』to enter into the time for reminder alarm setting interface, click the preset time option to set the reminder alarm time.

Pump Idle Alert refers to the alarm that will be prompted if there is no key operation within the preset idle alert time when the device is in the non-infusion and non-alarm state.
Pump idle alert time Settable: 2min、5min、10min、15min、20,min、30min.

8.1.9 Finish Pre-alarm

Click『Finish pre-alarm』to enter into the time for pre-alarm setting interface, click the preset time option, to set the finish pre-alarm time.
Time for pre-alarm refers to the time of activating near completion alarm when the fluid/drug infused volume is nearly reaching the preset value. Finish pre-alarm time Settable: 2min、5min、10min、15min、20min、30min.

8.1.10 Micro Mode

Click 『Micro mode』 to enter into micro mode setting interface. ON/OFF is optional in this function Optional. Under the ON mode, set the rate limit, then the infusion rate under any infusion mode is not allowed to exceed this limit. Micro mode setting:100~1500ml/h, minimum step is：1ml/h.

Syringe Size	Max Rate Range
2/3ml	100-100ml/h
5ml	100-150ml/h
10ml	100-300 ml/h
20ml	100-600 ml/h
30ml	100-900 ml/h
50ml	100-1500 ml/h

8.1.11 Reset Total Volume

Click『Reset total volume』, the interface displays the operation confirming prompt box, click『Yes』to confirm reset, otherwise, please click『No』.

8.2 General

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

8.2.1 Date& Time

Click『Date &Time』to enter into the date and time setting interface. It allows to set the date, time and format in this interface.

When setting date and time, directly input the numerical value in the input method interface. For example, to preset one date “2018-08-31”, input “20180831”; to preset the time “12: 34”, input “1234”.

The time is displayed in 24h format or 12h format, the date is displayed in British type, American type or Chinese type, please set according to the requirement.

8.2.2 Brightness

Click『Brightness』to enter into display brightness setting interface. The brightness has 10 levels.

8.2.3 Sound

Click『Sound』 to enter into the sound parameters setting interface, the volume has 10 levels. The lowest volume is ≥45 dB, and the highest volume is ≤80 dB. Move the long box to the preset value, after confirming, click『OK』

8.2.4 Screen Lock

Click『Screen lock』to enter into automatic lock screen setting interface, select ON or OFF.

Automatic lock screen time can be set at 15s, 30s, 1min, 2min, 5min, 10minor 30min and so on, which means that the equipment will automatically lock the screen if it is not touched or the button is pressed within corresponding time after starting.

Unlock: directly click『Cancel』in the lock screen interface.

⚠Note: The equipment will automatically unlock if there’s high Level alarm.

8.2.5 Night Mode

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

8.2.6 Battery capacity display

Turn it on to show the battery life in the upper right corner of the screen, and turn it off to show the percentage of remaining battery life.

8.2.7 Nurse Call

Connection steps:

(1) Connect the syringe pump to the special nurse call cable;

(2) Click『Nurse call』to select function ON ;

(3) Set the nurse call alarm level.

Click『Nurse call』to select function ON and OFF.

⚠Note: ● The nurse call function must be used with special cable.

● The user shall not only depend on the nurse call function as the main alarm notice mode, and shall identify according to the equipment alarm and the patient state.

8.2.8 Nurse call alarm level

By selecting the nurse call alarm level, when the alarm level reaches the selected level, the nurse call alarm is conducted.

8.3 System

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

8.3.1 Language

This equipment supports simplified Chinese, English, Spanish, Portuguese, etc.

8.3.2 Factory Default

Click『Factory default』to clear the User defined option, and this function is open to the user.

8.3.3 Version

8.3.3.1 SN (Serial Number)

Check the serial number of the equipment, and user can't modify the serial number.

8.3.3.2 Software version

Check the software version in this interface. Software version:2.0 .

8.3.4 Maintenance

More detail pleases refer to **Chapter 11**

Chapter 9　Other Functions

9.1 Patient Information System

Click『Patient』in the main interface to enter into setting interface.

9.1.1 Patient Information

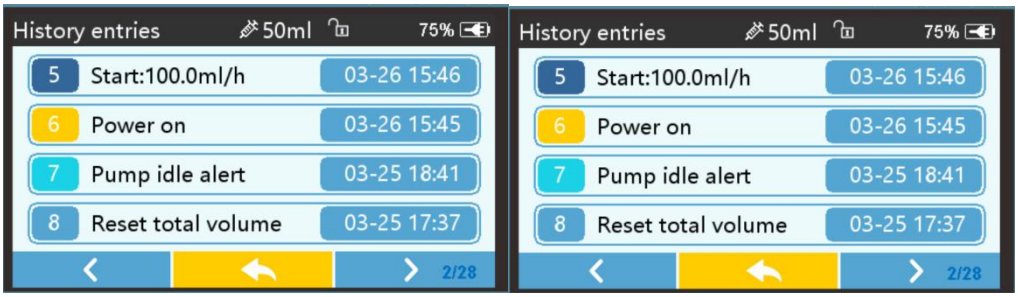
Click『Patient』to enter into the patient information setting interface and set bed number, MRN, name, gender, age, body weight, height.

9.1.2 Prescription

Click『Patient』to enter into the patient information setting interface and enter the end of the sub menu, find menu item 『Prescription』and enter to set the medical advice ID, medical advice information, start time and state.

9.2 History entries

Click 『Records』in the main interface to enter submenu, click the "History entries" menu item into history records query interface. The equipment supports to save over 5000 history records, and can display the event name, event date and time (permanent preservation). When it is full, the new records will cover the old records with first in first out principle.



9.3 Last therapy

Click『Last Therapies』in the main interface to enter therapy records query interface.

(1) This interface displays the last 20 treatment records. Users can directly select it as the infusion plan at this time, and start infusion after confirming the parameters.

(2) The system can store up to 20 treatment records. When the records are full, the new records will overwrite the old records in turn.

9.4 Anti-bolus

Motor automatically reverse while the syringe with high pressure. Automatic drop line pressure to reduce bolus impact after occlusion.

9.5 Electronic memory function

After power off, the electronic memory function can save no less than 10 years.

9.6 Dose Error Reduction System (DERS)

This system uses predetermined dosing information stored in the pump's configured Drug Library to control the dose, rate and concentration for specific drugs. Programming using this method may reduce the risk of programming errors.

Chapter 10 IT Network Description

10.1 Device data

The Syringe pump is connected to the PC via a USB data cable to form a point-to-point IT-network. Data is simply transferred between the networks in the form of point-to-point routing. The types of data transferred include: history, program codes that need to be upgraded.

10.2 IT- Networking characteristics

IT-Network characteristics include:

(1) Reliability The Syringe pump and PC are connected via USB cable to form a point-to-point short-distance transmission IT-network, which can effectively guarantee the integrity of data and the stability of the transmission rate.

(2) Safety For IT-network security, it is recommended that the PC be configured with: 4G or more RAM; 200G or more free space on the hard disk; Windows 7 or Windows 10 system; CPU 1.0Ghz or more, and firewall and anti-virus software installed.

The PC runs on windows 10 and supports common security software (e.g. 360 security guards, 360 antivirus, qq computer butler, Kingsoft antivirus, etc.), the security software should be a valid version that can ensure the security of the computer system.

10.3 IT- Network technical specifications

Secure data transmission: Checksum fields are added to the transmitted data to guarantee data integrity.

Security Vulnerability Scanning: Regularly conduct security vulnerability scanning on PCs to discover and repair system and application vulnerabilities in a timely manner.

10.4 IT- Network-related risks

The following risks may be introduced during data transfer from the Syringe pump to the computer:

1）The downloadable software on the PC does not work properly;

2）Data leakage caused by illegal physical intrusion into the embedded software;

3）Third-party interception/data tampering during data transmission;

The corresponding control measures that can be taken to address the risks that may be introduced are as follows:

1） Installation of firewall and antivirus software on PC

2） Data reading can only be operated by internal professional technicians, and software maintenance can only be carried out by specialized technicians on a regular basis to prevent illegal intrusion and the risk of data loss.

3） A checksum field is added to determine whether the received data is complete or not. If the data checksum is incorrect, it will discard the received data and apply for re-transmission to

reduce the risk of receiving incorrect data.

When it is necessary to use the equipment for data export or software upgrading, the above possible risks should be identified, analyzed, evaluated and appropriate control measures should be taken.

10.5 IT Web update notes

This software does not have remote network update. In the course of subsequent use, if the software network security risks occur during the use of the product, the security measures of the system can be upgraded, and the user or maintenance personnel can submit an application。

It is described below that some of the possible change items for IT-Network, the corresponding cause analysis and treatment measures:

Changes	Cause Analysis	Treatment Measures
IT-Network Configuration Changes	Protection software is uninstalled or real-time protection is turned off, resulting in data being tampered with when transmitted to the pump side	Before connecting the PC to the pump, check if the protection software is correctly configured or the protection is turned on.
Items with broken IT-network connections	Incomplete or unplugged cable, failed to upgrade the pump software version, or incomplete data exported to the PC.	Check if the data cable is intact or if the device is plugged in at both ends.
Updating of equipment connected to the IT-network	Software update tool and data export tool do not work properly on updated devices	The update of the equipment needs to ensure that the upgrade tool and the data export tool work properly.
Upgrading of equipment connected to the IT-network	Failure to install the system correctly on the PC results in the upgrade tool and data export tool not functioning properly. No protection software is installed on the PC, resulting in tampering of the transmitted data.	Safeguard equipment is upgraded with WINDOWS operating system installed. Installation of the latest protection software.

Chapter 11 Alarm Prompt and Troubleshooting

11.1 Introduction to Alarm Level

During infusion preparation and infusion, this equipment will alarm when reaching or exceeding the set alarm threshold value and prompt with sound, light and text. According to the importance of alarm information as well as the emergency and safety, the alarm is divided into three levels: high, middle and low. Please refer to table below for details:

Alarm Level	Sound Signal Interval	Light color /flash frequency
High alarm	10s	Red indicator flashes /2.0±0.6Hz
Middle alarm	15s	Yellow indicator flashes / 0.6±0.2Hz
Low alarm	20s	Yellow indicator lights on

If there's alarm, the system will display the alarm interface, if the alarm level is high, click 『OK』, stop the alarm, and exit the alarm interface, if the alarm level is middle or low, click 『OK』, the sound signal will stop, and exit the alarm interface.
Click『Mute』to mute, if alarm is not eliminated, the alarm sound will be sent out 2min later.

⚠ Warning: ●Some alarm threshold values of this equipment can be set by the user, for example: occlusion pressure, pump idle alarm, VTBI infused pre-alarm, alarm sound volume and so on, the user shall confirm the parameters when set the alarm threshold value, otherwise, it may possibly influence the alarm function or infusion safety.

11.2 Multilevel Alarm Rules

When there're several alarms, the system will alarm according to the following rules:

Table10.2-1

Multilevel Alarm	Rules
Several alarms of different levels generate simultaneously	Display the alarms of highest level with sound, light and text, report middle alarm after eliminating all alarms of highest level
Several alarms of same level generate simultaneously	Alarm circularly by turns, the time interval is 1s

when alarming, the corresponding alarm information will display on the title of the screen. Refer to Appendix C for more information.

11.3 Alarm Treatment

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

Please refer to Appendix C for the alarm solution.

11.4 Fault Analysis and Solution

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

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

Chapter 12 Maintenance

12.1 Cleaning

⚠ Warning:

● Please cut off power supply and unplug the DC /AC power cord before cleaning the equipment.
● During cleaning and disinfecting, please keep the equipment horizontal and upwards to protect the equipment and accessories from fluid.
● Please disinfect the equipment with common disinfecting agent such as 50% sodium hypochlorite, cidex 2% glutaraldehyde + activating agent, 70% ethanol, 70% isopropyl alcohol and so on.

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

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

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

12.2 Periodical maintenance

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

12.2.1 Check the Appearance

(1) The appearance of the equipment shall be clean and under good condition without crack and water leakage.
(2) The buttons are flexible and effective without invalid phenomenon; the sensitivity of the touch screen is normal,
(3) The slider of the syringe pump is flexible in movement, and the clamp is ok.
(4) The power cord is under good condition and could be installed tightly.

(5) After connecting with external power supply, check whether AC indicator light is on.
(6) Adopt the accessories designated by our company.
(7) The environment meets the requirements.

12.2.2 Performance Check

(1) Self-test and infusion function works.
(2) Alarm function works well.
(3) Battery performance.

12.2.3 Maintenance Plan

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

Maintenance Items	Cycle
Safety check according to IEC60601-1	Once every 2 years, please check after replacing the printed circuit board assembly or the equipment is dropped or knocked.
Preventive system maintenance items (pressure calibrate, sensor calibrate, pump)	Once every 2 years, when the occlusion alarm, or infusion accuracy is doubt to be abnormal
Brand of user-defined syringe, infusion accuracy calibration	Using the equipment for the first time, syringe brand using for the first time, reusing the equipment after stopping for a very long period.

12.3 Calibration

In the 『System』submenu, click『Brand maintenance』 to enter into brand setting interface, user can add new brand, delete and calibrate the brand.

⚠Warning: ●It is suggested to contact our company or local dealer, to customize or calibrate it by professional technician, otherwise, it may can't guarantee the infusion accuracy.

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

(1) Add new brand

If the actual using syringe brand is not listed in the system built-in brand, please add the new syringe brand in this interface.

Set syringe brand name and brand information.

(2) Delete brand

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

(3) Calibration

⚠Note

- When first time use pump need calibration
- When added new brand need calibration

- When accuracy is not good need calibration.

The following materials shall be prepared before calibration:
A set of new syringe include 2/3ml、5ml、10ml、20ml、30ml、50/60ml.

Calibrating Steps:

1) Select syringe brand.
2) Select syringe size.
3) Install syringe, pull the syringe piston beyond size scale line a little, press and hold on [bolus], push the piston to the corresponding size line.
4) Press [start], begin calibration.
5) Calibration completed.
6) Exit calibration, the calibrated brand was selected as the current brand, syringe size is detected automatically after each calibrated size loaded, and the infusion accuracy was verified at 5ml/h and 100ml/h flow rates, respectively. The measured infusion accuracy shall conform to the accuracy value specified in Table 2.5 of this manual.

12.4 Repair

12.4.1 Normal Repair Process

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

12.4.2 Maintenance for Long Term Store

If the equipment won't be used for a long period, please take out the battery, and pack it with the equipment in the package, and store it in the shade, cool and dry place without direct sunlight.
The following operations are necessary for using it again:

(1) Verify the flow rate accuracy to avoid nonconformity between the syringe apparatus parameters in the equipment and the actual parameters after it hasn't be used for a long period or caused by other reasons, otherwise, it may cause infusion error, influence the therapeutic effects and even cause medical negligence.
(2) Perform occlusion alarm test.
(3) Test the battery discharging and charging duration to confirm that the battery is also usable.

12.5 Equipment Components/Accessories

⚠ Warning: ● Only the components and accessories designated by our company shall be adopted, otherwise, it may possibly damage the equipment or drop the equipment performance.

Variety	Name	Code
Equipment Components	Pole clamp	63-000001-00
	power cord	13-000024-00
	protective cover (optional)	24-000060-00

12.6 Production Date

Please refer to the label of the product.

12.7 Recycling

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

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

Chapter 13 Battery

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

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

⚠ Warning: ● Only the batteries that meet the requirements of standard 62133-2 and designated by our company can be used.

●When changing from single battery to dual-battery, please follow the guidance from our company or distributor; otherwise, it may cause danger.

13.1 Check the Battery Performance

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

(1) Disconnect the equipment from the patient, and stop all infusion.
(2) Supply AC power to the equipment to charge the battery for 5h at least.
(3) Supply power for the syringe pump only with battery, infusion at the rate of 5ml/h, test the time till the battery runs down and the equipment is turned off.

- If the infusion time exceeds 10h, the battery keeps at good state.
- If the infusion time exceeds 7h but less than 10h, the battery starts deterioration, but it can be used temporarily.
- If the infusion time is less than 7h, the battery is reaching the service life, please replace the battery.

13.2 Replaced the Battery

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

The steps of replacing battery are shown as below:

(1) Cut off the power supply of the equipment, disconnect the power cord. Open the shells and take out the battery.
(2) Push the new battery into the battery chamber, and insert in the battery fastener.
(3) After replacing the battery, close the shells, and check the battery.

⚠ Warning: ● When replace the battery, please do not touch the 12V DC plug inside of the batter Chamber.

● Replacing batteries with untrained personnel may result in the risk of overheating, fire or explosion.

Chapter 14 After Sale Service

This product enjoys 1 year free warranty after purchase. The warranty period starts from the date the customer purchases the product.
If any serious incidents related to the device occur while the device is in use, the user should report them to the competent authority of the manufacturer and/or the patient's member State.

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

(1) Fault caused by incorrect operation, unauthorized refitting or repair.

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

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

For the damages or faults mentioned above, our company provides repair services but chargeable according to the repair cost.

Manufacturer: Shenzhen MedRena Biotech Co., Ltd.
702, Block A, Youlitong Technology Industrial Park, No. 56 Qingsong Road, Laokeng Community, Longtian Street, Pingshan District, 518122 Shenzhen, P.R. China
TEL: +86 755 28500025

Authorized representative in the European Community:
SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands.
TEL:+31(0)10 3034500; +31(0)2021 11106

Chapter 15 Appendix

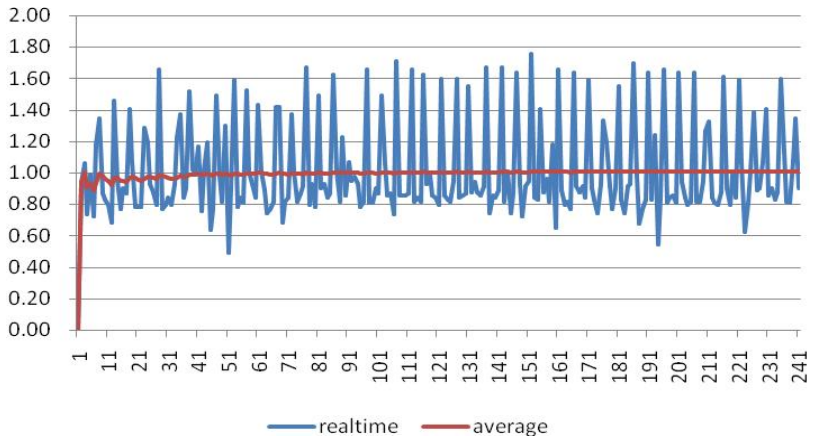
Appendix A Start Up Graphs and Trumpet Curves

Accuracy Test Sample Information:

1. Brand and specification of syringe: Double-Dove Size:50ml
2. Number of syringes: 2 (1 each at 1 ml/h and 5 ml/h test flow rate)

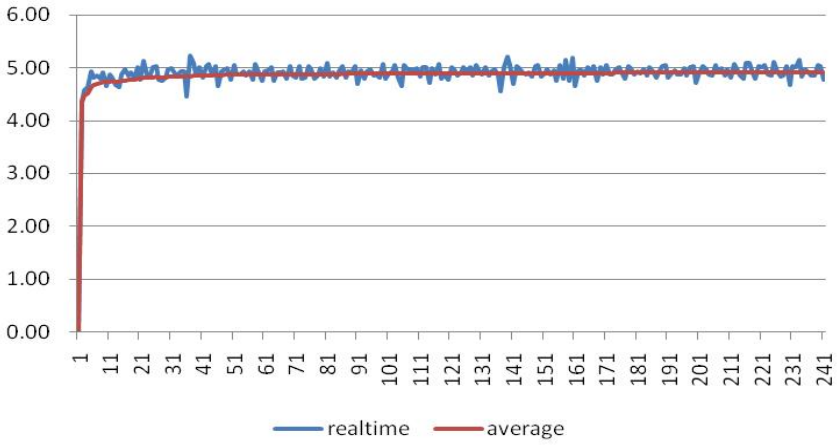
Appendix A.1 Start-up Graphs

Brand: Double-Dove Size:50ml
Flow Rate: 1ml/h
Measurement Interval: Δ t = 0.5min
Measurement duration: T = 2h



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

Brand: Double-Dove Size:50ml
Flow Rate: 5ml/h
Measurement Interval: Δ t = 0.5min
Measurement duration: T = 2h



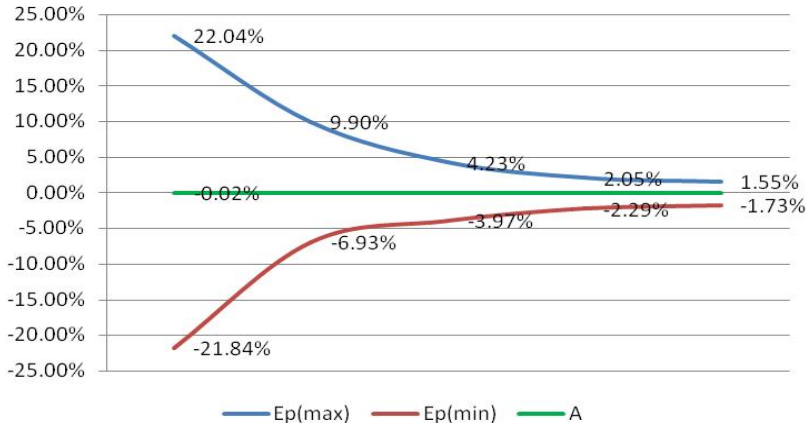
Appendix A.2 Trumpet Curves

Brand: Double-Dove Size:50ml

Flow Rate: 1ml/h

Measurement Interval: Δ t = 0.5min

Measurement duration: T = 2h

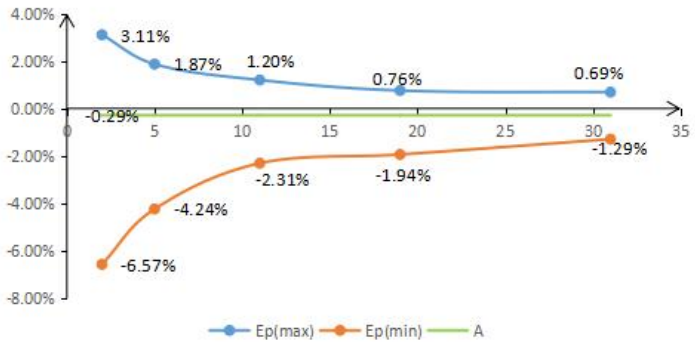


Brand: Double-Dove Size:50ml

Flow Rate:5ml/h

Measurement Interval: Δ t = 0.5min

Measurement duration: T = 2h



Appendix B Occlusion Response Property

When a occlusion alarm is triggered, the system will automatically processed Anti-bolus, withdraw according to the current pressure level to reduce the amount of blocking pills.

UniFusion SP50 Pro\Neo\TIVA occlusion time and bolus relation:

Flow Rate (ml/h)	Occlusion Pressure (mmHg)		Time to occlusion alarm(min)	Max bolus (ml)
1	Low	75	0h18min40sec	0.039
	High	900	2h17min0sec	0.102
5	Low	75	0h6min15sec	0.043
	High	900	0h30min43sec	0.079

UNIFUSION SP50\SE occlusion time and bolus relation:

Flow Rate (ml/h)	Occlusion Pressure (mmHg)		Time to occlusion alarm (min)	Max bolus (ml)
1	Low	300	0h49min30sec	0.037
	High	900	2h08min25sec	0.079
5	Low	300	0h13min40sec	0.038
	High	900	0h28min23sec	0.069

Notes: The alarm pressure intensity error is ±20% or ±125mmHg, the higher value shall be taken;

⚠Notes: ●Conditions for testing above data: Syringe Brand: Double-Dove Size:50ml

- The occlusion alarm pressure, alarm delay time and bolus are influenced by the test conditions.
- The above data is the typical value under the test conditions, please see the test data of the product for the actual data, the data may be different if the test conditions are different.

Appendix C Alarm and Solution

No.	Alarm Type	Alarm Level	Reason	Solution
1	VTBI near end	Low	During infusion, the remaining time of preset value reaches or is less than the set nearing completion time	This alarm can't be eliminated, and waits till infusion completes
2	Syringe near empty	Low	The syringe is near empty status which is calculated by checking the liquid medicine remaining in the syringe by current flow rate.	This alarm cannot be eliminated, waiting to syringe empty.
3	VTBI infused	High	The preset value infusion Completion	Press【Stop】button to stop alarm
4	Syringe empty	High	The liquid medicine in the syringe is empty.	Press 【Stop】button to stop the alarm can be eliminated
5	Pressure near threshold	Middle	Pipeline pressure increases close to the preset blocking level.	Check the connection of the pipeline, press 『OK』button to continue infusion
6	Pressure drop	Middle	When the pipeline pressure is high, the pressure suddenly decreases.	Check the connection of the infusion pipeline, press 『OK』button to continue infusion
7	Pressure high	High	1. Line occlusion during infusion	Click『Mute』to silence, Manually remove the reason of occlusion, Press 【Start】button to continue infusion
			2. Fluid/drug in the actual infusion line has high viscosity, but the system occlusion level is set too low	Rise the alarm Level, Press【Start】button to continue infusion
			3. The pressure sensor is damaged	Please contact the dealer or manufacturer for repair
8	Battery nearly empty	Low	1. When power is supplied only with the built-in battery, under low battery, the alarm duration is >30min	The alarm automatically eliminates after connecting the external power supply.
			2. Battery ageing or the equipment charging circuit is fault.	Please contact the dealer or manufacturer for repair.
9	Battery empty	High	1. When only the internal battery is used for power supply and the battery power is close to exhaustion, the alarm duration is not less than 3 minutes	Immediately connect with external power supply.
			2. Battery ageing or the equipment	Please contact the dealer or

			charging circuit is fault.	manufacturer for repair.
10	No battery inserted	Low	Battery is removed	Keep connecting with external power supply, reinstall the battery
11	Battery in use	Low	Under ON state, AC power supply is adopted, but the AC power cord is dropped during the process	The alarm automatically eliminates after connecting the external power supply.
12	No battery and No power supply	High	Battery is removed and the AC power cord is dropped	reinstall the battery or connect the power supply
13	Check syringe	High	Syringe drop off during infusion	Reinstall the syringe
14	Pump idle alert	Low	After installing syringe, under non-working or alarm state, it is not operated within the set time of the system	Click any button to stop
15	Standby time expired	Middle	During standby, after reaching the standby time	Press 【Stop】button to stop alarm
16	KVO finished	High	KVO working time reaches 30min, syringe pump stops working	Press 【Stop】button to stop alarm
17	System Error (NO.: 1-15)	High	Internal failure or software exception	Turn off and Restart, if the alarm still exist, please contact the dealer or manufacturer for repair

Note: 1)When alarm rings, click the 『Mute』 icon on the screen to temporarily stop sound alarm for 2min.

2) Among the above alarms, except 1, 3, 14 and 15, other alarms can be classified as technical alarms.

Appendix D Electro Magnetic Compatibility declaration

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

⚠Caution:

- This unit has been thoroughly tested and inspected to assure proper performance and operation!
- This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

⚠Warning:

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

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

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

Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	400A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity

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

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Syringe pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.167 $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 

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 Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Syringe pump is used exceeds the applicable RE compliance level above the Syringe pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Syringe pump.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the Syringe pump .

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

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

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

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

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

Appendix E Factory Default Data Set

Parameters	Default Setting	Parameters	Default Setting
KVO rate	1ml/h	Sound	10%
Occlusion pressure	450mmHg	Screen lock	1min
Finish pre-alarm	2min	Brightness	100%
Reminder alarm	2min	Night mode	OFF
Pressure unit	mmHg	Nurse call	OFF
Micro mode	OFF	Drug Library	OFF
Commonly used syringe brand	Double Dove	Relay mode	OFF

34-000044-00