HEDY
Healthy Every Day

HealFusion

Infusion Pump User Manual

(i7, ip-3)

Product Information

Congratulations on your purchase of HealFusion Infusion Pump. Before using this product, please read this manual carefully for proper use of the product. Please keep this manual after reading so that you can access at any time when needed.

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Contents

Preface

Statement

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Manufacturer's Responsibility

The manufacturer should be responsible for the safety, reliability and performance of this machine only under the following conditions, i.e.:

- The assembling operation, extension, readjustment, improvement and maintenance are done by the qualified personnel approved by the manufacturer.

- The related electrical devices conform to national standards.

- The machine is used according to the conditions and requirements described in this manual.

User Notice

- To ensure operation safety and long-term stable performance of the system, it's strongly recommended reading this manual to get a full knowledge on the function, operation and maintenance before operating the system.

- Pay special attention to contents of "Warning", "Caution" and "Note" in this manual.

- The manufacturer takes no responsibility for any damage or harm caused by incorrect operation or maintenance inconsistent with instructions of the manufacturer or its agent thereof.

- The Dosage Mode, Drugs, WiFi and some other functions are optional, the user can choose to have these functions or not.

Warranty

- The manufacturer guarantees 12 months of warranty for the main unit and its material and technology. During warranty period, the manufacturer provides free repairing and damaged part replacement.

- The warranty only applies to faults occurred in operation under conditions specified by this manual. So, please make sure the system is used within the application scope recommended by this manual.

- The warranty doesn't apply to damage caused by accidents, misuse, abuse, falls, modification or alteration to any part or component of the system.

- Surface damage is not included in the free repair or replacement range. Battery replacement, training material supply, etc. are not free, either.

- The manufacturer takes no responsibility for any damage caused by other system or unauthorized connection to other systems.

- The manufacturer takes no responsibility for any loss, damage or harm caused by delayed service request.

- Please report to the manufacturer after-sale service department if the system has any malfunction. Model number, series number and a brief description of the malfunction are supposed to be provided in the report.

Chapter 1 Safety Precaution

1.1 Safety Signs

The following messages can be read throughout this manual, they are supposed to be paid special attention to.

 **WARNING!**	A **WARNING** label applies to information that may cause severe personal injury, death or actual property loss if neglected.

 **CAUTION !**	A **CAUTION** label applies to information that may cause mild personal injury or property loss if neglected.

NOTE !	A **NOTE** label applies to information on installation, operation or maintenance, which is very important but poses no risk potential.

Table 1-1 Equipment Symbols

Num.	Symbol	Description
1		Defibrillation-proof type CF applied part
2		Refer to the instruction manual/booklet
3		Labeling of electric and electronic devices according to directive 2002/96/EC(WEEE)

4		Serial number
5		Manufacture date
6		Manufacture information
7		European community representative
8		General warning sign
9		Flow direction arrow
10		Non-ionizing radiation
11	IPX3	Waterproofing grade

1.2 Safety Information

Safety of the operator or the examinee, and reliability of the system are generally considered during designing and manufacturing. However the following safety preventive instructions should be followed.

1. The system should be operated by qualified personnel or under the guidance of qualified personnel.

2. The system belongs to type CF, class I system，defibrillation recovery time for 5s.

3. When there is any equipment failure, please turn off the pump and contact the manufacturer or its authorized agent immediately.

4. Avoid operation or storage in the following environments:

- Sharp temperature variance.
- Rather high humidity, poor ventilation.
- Water vapor exposure, do not operate the system with wet hands.
- Near heat-emitting systems.
- Direct solar irradiation.
- Violent shakes or vibration.
- Near chemical materials or explosive gas.
- Do not let dust or metal articles fall into the system.
- Do not disassemble or open the system. the company won't shoulder any responsibility for any result caused thereby.
- Take the plug rather than the wire for pulling out the power line.

5. Environmental specifications

- Transport & Storage Temperature: -30℃～70℃.
- Transport & Storage Relative Humidity: 10％～90％.
- Transport & Storage Atmospheric Pressure: 22kPa～106kPa.
- Operating Temperature: 5℃～40℃.
- Operating Relative Humidity: 10％～90％.
- Operating Atmospheric Pressure: 70kPa～106kPa.
- Maximum elevation of 3000 meters.

6. Power supply

- AC: 100-240VAC 50/60Hz 35VA.
- DC: 10-15VDC 2.5A.

7. Pump mobile condition

- When handling equipment (especially the stairs), care must be taken.

- If the pump fall or bump, it must be inspected and tested by service personnel.

- After selecting the location to place the equipment, before installing this system, please make sure the power supply is normal.

8. The emergency measure and corrective action during use

- If there are any errors or equipment failure during use, the user should immediately stop operation and take care of the wounded. Contact the manufacturer or its authorized agent immediately.

- Users are not permitted to repair any components of the equipment without authorization. Please put all the maintenance tasks to qualified maintenance personnel.

 **WARNING!**	The Infusion pump is not a raw material, and the device is not supposed to be used as a portable device.

 **WARNING!**	The hospital & agent which have the right to use the pump, are responsible for the proper use of the system, otherwise it may cause abnormal fault and damage the patients' life.

1.3 Electric Safety Preventive Measurements

The pump meets the requirement of IEC 60601-1:2005，IEC 60601-2-24:2012，IEC 60601-1-8:2007. In addition, the following points should be paid attention to.

- The power cable should conform to the power cable of the system. The system should be well grounded (otherwise, noise may be produced).

 **WARNING!**	To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

- Do not open the enclosure without permission. Do not change any other parts of the pump without permission.
- In case of any equipment failure, cut off the power supply immediately and contact the manufacturer or its authorized agent.
- The fuse is manufactured by Littelfuse, Inc. The specification is 392 T1 AL 250 V.

1.4 Contraindications

/

1.5 EMC

The EMC-limits (electro-magnetic compatibility) according to IEC/EN 60601-1-2 and IEC/EN 60601-2-24 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.) maintain the recommended protective distances from these devices.

- Refer to Appendix B for more information.

1.6 Environment Safety Preventive Measurements

- The waste must be treated follow the local laws timely (especially the disposable infusion device).

- Equipment and accessories probably cannot be normal used at the end of life, ensure to replace the equipment or accessories timely to decrease the risk to the minimum. The battery inside the device is not replaceable.

- Harmful substances and the content in the product:

Table 1-2 Harmful Material and Its Content

Component	Hazardous Substance					
	Pb	Hg	Cd	Cr^{6+}	PBB	PBDE
Host	○	○	○	○	○	○
Cable	○	○	○	○	○	○

○ indicates that the concentration of the hazardous substance in all homogeneous materials in the parts is below the relevant threshold of the RoHS Directive (2011/65/EU Directive), the system is fully in compliance with RoHS requirements in terms of component selection and application, production process control, overall testing, appearance and labeling.

╳ indicates that the concentration of the hazardous substance in all homogeneous materials in the parts is beyond the relevant threshold of the RoHS Directive (2011/65/EU Directive), the system is fully in compliance with RoHS requirements in terms of component selection and application, production process control, overall testing, appearance and labeling.

Chapter 2 Brief Introduction

2.1 Brief Introduction of the User Manual

- This User manual introduced the HealFusion Infusion Pump. It applies enough information for the user to operate and storage the pump. Please read it carefully before using.

- This User manual applies enough information for the user to operate the pump safety. It contains the system's basic function, security features, operate mode, how to care and maintenance the pump. Please read it carefully before using.

- In daily operations, we can refer to fast operation card to make quick access.

- This manual consists of several independent chapters. Partial contents in some chapters are identical. All chapters are compiled to provide the user with reading convenience and content consistency.

- Any query on operation of this system, please turn to the manufacturer's service engineer or its authorized distributor for support.

NOTE！	**The User manual describes the operation of the pump, before using, the user must be familiar with the operation and precautions, in order to avoid unnecessary losses.** **Also, medical equipment used in the room must conform to the relevant regulations (such as IEC, VDE0100 or VDE0107).**

2.2 Brief Introduction of the Pump

- Product name: Infusion Pump
- Product type: i7/ip-3, The differences between two types are as follows:
  - i7 has gray panel, and can support up to 2000 logs.
  - ip-3 has purple panel, and can support up to 1500 logs.
- This system consists of the following parts: Infusion pump enclosure, drive system, input system, storage system, control system, display system, sensor monitoring system, alarm system, internal rechargeable battery.
- Congratulations on your purchase of HealFusion Infusion Pump. This system is a high quality system which is stable and convenient to operate. It is suitable for all qualified doctors, this pump consists of the following modes:
  - Rate Mode
  - Time Mode(include V-T Mode and R-T Mode)
  - Dosage Mode(optional)
  - Trapezia Mode(optional)
  - Intermittent Mode(optional)
  - Loading Dose Mode(optional)
  - Sequence Mode(optional)

Note: Mean Time to power down from fully charged @ 5ml/h under normal conditions is more than 6 hours, @ 2000ml/h more than 1.5h, and need less than 4 hours to be charged full.

- Classification
  - Class I / Internally powered equipment;
  - Type CF applied part;
  - IPX3– Protected against vertically falling drops of water;
  - No sterilization requirement;
  - Not Category AP / APG equipment;

- Mode of operation: Continuous;

2.3 Device Features and Intended Use

- Intended use: working with the infusion set. The pump is suitable for the hospital operating room, ICU, outpatient and general wards and other places, which is used to control the flow of liquid infused into the patient. The injection site support for intravenous.

- The pump is an advanced device for treatment, which is used for infusion. It can accurately control the infusion velocity, and input the liquid to the patient timely and accurately. It can guarantee the accuracy of the dose rate and work safely into the patient, making it especially suitable for the situation that requires liquid flow rate and dosage controlled strictly.

NOTE！	**Since the infusion pump is a kind of life support equipment, ensure to enter the correct infusion rate and volume, otherwise it may damage the patients' life.**

2.4 Overview

1. **Features of the Pump**

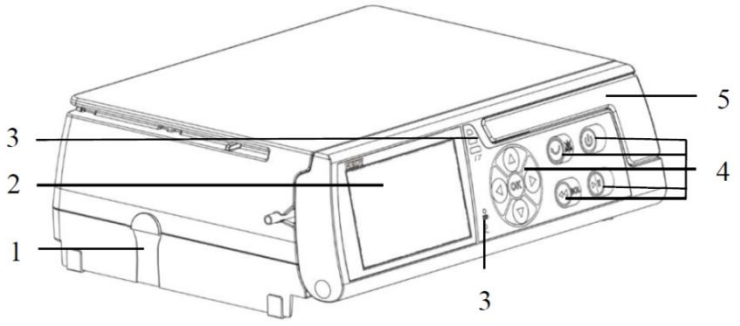


Figure 2-1 Pump Closed

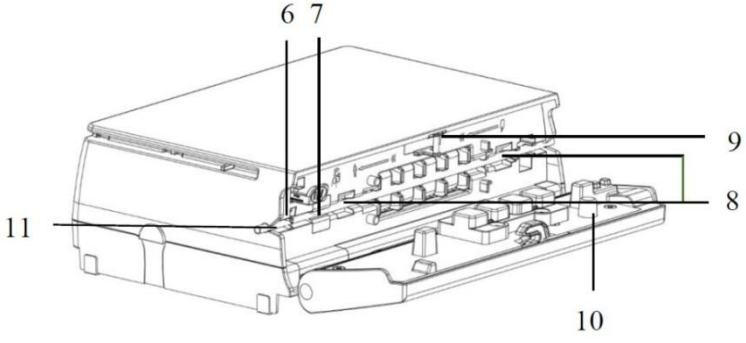


Figure 2-2 Pump Open

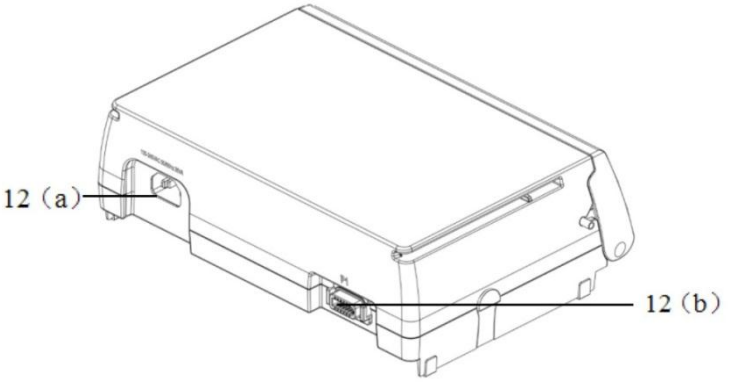


Figure 2-3 Rear View

Table 2-1 Equipment Parts Description Table

Num.	Symbol	Description
1	Connect button	Fixed stacked Infusion pump and syringe pump
2	3.5 inch color display	Display menus and submenus, can be operated by touching
3	Indicator	ALARM indicator indicates the alarm status, POWER indicator indicates the power status
4	Operation panel	ON/OFF button, RUN/STOP button, MUTE/BACK button, PUSH/ BOLUS button, Arrow keys, ENTER/OK button, indicators
5	Door handle	Open/close the door
6	Safety clamp	Prevent the infusion liquid from flowing when the door open
7	Air sensor	Detect air bubbles in the infusion tube(note: the infusion tube between pump and patient cannot be detected, it must be artificial ruled out)
8	Pressure sensor	Detect the pressure in the infusion tube

9	Door fixed shaft	Fixed the door
10	Door sensor	Detect the door's state
11	Infusion tube slot	Fixed the infusion tube
12	Back interface	AC power connector(12(a)), RS232 Connector(12(b))

- SIP/SOP function

12(b) is RS232 Connector, it provides:

External DC voltage input function.

RS232 Connector: RS232 interface can be used with a two-way communication, please ask our Customer Service Department to obtain an interface protocol if necessary, RS232 communication cable need to use shielded cable. The device which is connected to the RS232 interface should conform to the standard of IEC60950.

Staff call: RS232 Connector generated high.

 **WARNING!**	**The plug is used as disconnect to the mains supply, do not to position the pump to make it difficult to operate the disconnection device when an appliance coupler or mains plug or other separable plug is used as isolation.**

2. Operation Panel

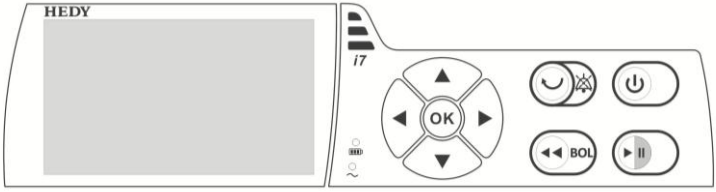
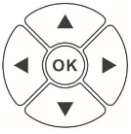


Figure 2-4 Operating Panel Diagram

Table 2-2 Description Table

Symbol	Name	Description
	**ON/OFF** button	Press to turn pump **ON/ OFF**.
	**RUN/STOP** button	Press to start/stop infusion.
	**MUTE/BACK** button	Press to silence alarm for two minutes (configurable). Or cancel the operation and return to the previous menu.
	**PUSH/BOLUS** button	Press to access **PUSH** or **BOLUS**.
	Arrow keys	Press to access optional features. The backlight of the Arrow keys alternately lit counterclockwise during infusion.
	ENTER/OK button	Open certain functions and press to confirm values/settings/alarms.

	**ALARM** indicator	Flashing red: high level alarm. Yellow: low level alarm.
	**BATTERY** indicator	Flashing green: battery charged. Steady green: battery full. Steady red: battery error.
	**AC POWER** indicator	Lit up when the pump is connected to an AC power supply.

Note: BOLUS function details.

- Press **PUSH/ BOLUS** button twice（within 1s）

1. At the very beginning of infusion, enter manual PUSH.
2. During an infusion, or already have an infusion, enter manual BOLUS.
3. Bolus will continue until the button released in the second long-press. The volume is displayed.

- Press **PUSH/ BOLUS** button once

1. At the very beginning of infusion, enter Automatic PUSH. Press  to start PUSH.
2. During an infusion, or already have an infusion, enter Automatic BOLUS, Press  to confirm BOLUS dose and time.

3. Screen Interface

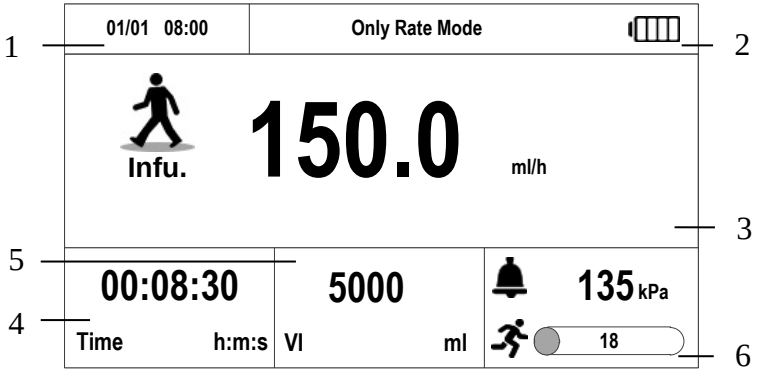


Figure 2-5 Screen Interface

Table 2-3 Screen Interface Description Table

Number	Description
1	Display system time, Format: “MM/DD HH:MM”
2	Display infusion mode alternately, display charging status / battery remaining capacity
3	Display infusion status (through doll’s states), rate, and can press MENU to enter the submenu: MENU button hidden during infusion
4	Display Time and Volume during infusion alternately, others VTBI
5	Display total volume, press to clear
6	Display current pressure, press to set pressure class

Details

- Charging status / battery remaining capacity:

A battery icon displayed when only battery-powered. A battery charging animation icon displayed when there is an external power supply and the battery is not fully charged. A fully charged battery icon displayed when there is an external power supply and the battery is full.

- Display VTBI in the infusion pause status, Time and the Volume displayed alternately during infusion.

- Doll status: conventional infusion walking, BOLUS running, KVO walking slowly, standing scratching in a pause. Press the doll, enter the standby time setting interface, set standby time, confirmed and enter standby mode, the interface shows standby time countdown.

- Pressure status box displays obstruction pressure icon, occlusion pressure and real-time pressure, when real-time pressure accounting for less than 70% occlusion pressure, 71% -90%, 91%-100%, the color of the real-time pressure were green, yellow, red. Press the box to enter the pressure class setting interface, the user can set the current pressure class and its unit.

Simple operation

- To select an option, the user can press directly on the screen to enter (the background changes to yellow when selected), or press the arrow keys and OK button to enter (appear yellow box when selected).

- Set infusion rate: press directly on the screen, or press the arrow keys and OK button to set infusion rate in the submenu.

- VTBI: press directly on the screen, or press the arrow keys and OK button to set VTBI in the submenu.

- Clear accumulated volume: press directly on the screen, or press the arrow keys and OK button to choose whether to clear accumulated volume or not in the submenu.

- Set pressure class: press directly on the screen, or press the arrow keys and OK button to select pressure class in the submenu.

- Press MENU on the screen directly, or press the arrow keys and OK button to select MENU and enter the submenu.

- Change infusion rate: press the rate displays on the screen directly to input new infusion rate in the submenu.

Note: The above operations can be taken place only when there is a response pressing the screen, if no response, this parameter cannot be set.

4. Submenu

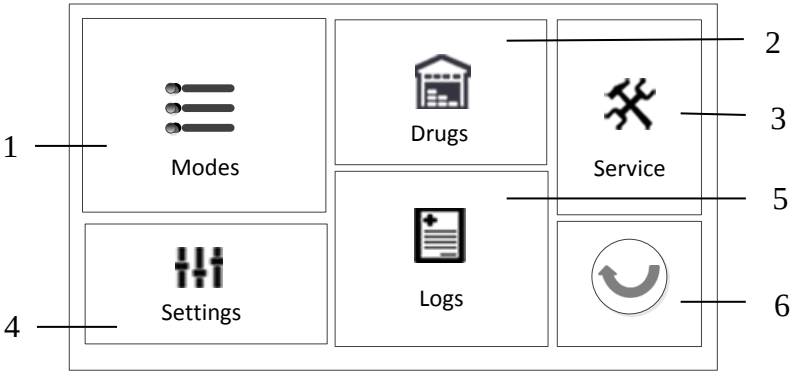


Figure 2-6 Submenu

Table 2-4 Submenu Description Table

Num.	Name	Description
1	Modes	Select different modes

2	Drugs	Select Drug's name
3	Service	Maintenance the equipment（password needed）
4	Settings	Select and set user parameters（password needed）
5	Logs	Include Operation Logs, Alarm Logs, Infu. Logs
6	return key	Back to the previous menu

1、 Press **MENU** to enter.

2、 Use Arrow keys and **ENTER/OK** button to select and enter the submenu, or press directly on the screen to enter.

3、 If the option is still under the submenu, then repeat the above steps 2.

4、 Repeat steps 2 and 3 to adjust other parameters. The user can press CLR or press on the display to return to the previous submenu.

2.5 Daily Use Procedures

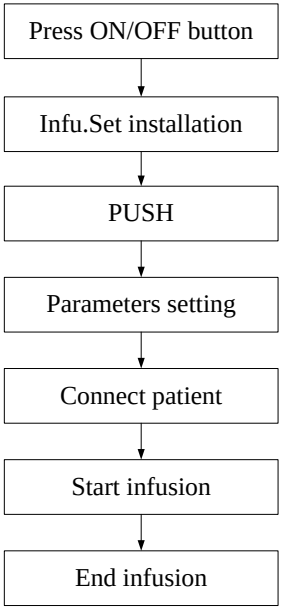


Figure 2-7 Conventional Procedures

1. Press **ON/OFF** button to turn the pump on.

2. Select proper Infu. Set and discharge air bubbles in the infusion tube (an alternative way is using the PUSH function).

NOTE！	**Please choose the accurate Infusion Set produced by the Provide manufacturers, the use of other company's Infusion Set may cause inaccurate infusion rates, pressure false alarm and so on. For a given Infusion Set, we only consider its form factor size, biochemistry, physics, metrology and other indicators get the relevant supervision departments' Testing Approval.**

3. Infu. Set installation

Refer to the dynamic installation prompts figure to install the Infusion Set.

Note: Refer to 3.2.2 for more information.

4. PUSH

Press  to start PUSH,  to stop PUSH, or automatically stop after the pre-set volume completed.

Note: Refer to 3.2.2 for more information.

5. Use last settings

The user can choose “Yes” or “No”.

Choose “Yes”, enter the Screen Interface which has last parameters.

Choose “No”, enter the Screen Interface which has no parameters. Different mode has different parameter setting interface. Please refer to the 3.2.3 Mode Selection for more information.

NOTE！	**The parameters like Infusion fluids, volume and rate should be set by medical professionals.**

6. Discharge air bubbles inside the Infusion Set, until there is liquid flowing from the needlepoint.

Note: Please use PUSH to discharge air bubbles inside the Infusion Set.

7. Connect the patient

NOTE！	**Only after turning on the pump can patient be connected. In order to prevent inaccurate value input, please interrupted the connection during the parameter setting period.**

8. Make sure the rate is correct, press **ON/OFF** button to start infusion.

9. Replace the Infusion Set

9.1. Press **ON/OFF** button to stop infusion.

9.2. Disconnect the patient.

9.3. Open the pump door, remove the Infusion Set.

9.4. Replace the Infusion Set, install a new one and discharge the air bubbles inside it.

9.5. Connect the patient.

9.6. Make sure the rate is correct.

9.7. Press **ON/OFF** button to start infusion.

NOTE！	**Infusion Set and disposable components should be replaced every 8 hours. Be sure to replace within the required time interval, to ensure its performance.**

10. Stop infusion

10.1. Press **ON/OFF** button to stop infusion. Disconnect the patient.

10.2. Remove the Infusion Set. Close the pump door.

NOTE！	**Please take good care of the infusion rate and the patient's response, if there are any abnormal situations, treat timely.**

11. Turn off the pump

Press **ON/OFF** button long, to turn the pump off.

11.1 Before the countdown reach 1, loosen the **ON/OFF** button, return to the previous interface.

11.2 After the countdown reach 1, the system turned off.

Note: More information, refer to the following chapters.

FOR YOUR NOTE

Chapter 3 Operation

3.1 Before the Operation

- Ensure the pump is properly positioned and secured（a maximum of 3 pumps can be stacked together）. The pump must be positioned on a level surface if used in combination with the short stand. Do not position the pump above the patient. And the pump should place in front of the operator.

- Prior to administration, visibly inspect the pump for damage, missing parts or contamination. If staff call is used we recommend checking the equipment carefully after connecting the pump.

- Make sure the power cord can be used normally.

3.2 Operation Procedure

3.2.1 Turn On

- Press **ON/OFF** button to turn the pump on.

Note: If the pump fails to start and display “Device Failure!”, please turn the pump off and connect our service.

3.2.2 Basic Settings

For the first time using the pump, after boot animation, the pump enters the touch calibration interface automatically.

3.2.2.1 Touch calibration

The Infusion pump has four calibration points, respectively press on the screen according to the instructions, until the calibration is successful.

Note: Once enter the touch calibration interface, only after successful calibration can the user skip this interface.

3.2.2.2 Power initialization

After the calibration, the pump enters power initialization automatically and checks audible and visible alarms during self-test.

In the process of self-test， the horn and buzzer rang, the alarm light first on a red, and then light yellow. If the above function is normal, the alarm self-test finished and function normal.

Figure 3-1 Power initialization

3.2.2.3 System Time Setting

After the power initialization, the pump enters system time setting automatically:

Note: more information, please refer to 3.5.12.

After system time setting, users can press the return key to reset date, or press **OK** to enter the following steps.

3.2.2.4 Door status

After system time setting, the user can install infusion set according to the following steps:

1. Hang the infusion bottle/bag on medical support, infusion bottle (bag) should be higher than the patient heart 20-80 cm.

2. Choose the appropriate infusion set after the user hang up the infusion bottle (bag). Inserted the infusion needle into the bottle/bag in vertical direction.

3. Fill the bottom part of the drop chamber by max. 2/3. Fill the infusion line from bottom to top, then close the roller clamp.

4. Open the door. Insert the line follow the line guide.

Note: The roller clamp can continuous increase/decrease the infusion liquid flowing through the infusion set. The safety clamp can prevent the infusion liquid from flowing under gravity conditions when the door is open.

Note !	**The extrusive infusion line cannot be installed between two ultrasonic sensors, otherwise false bubble pass alarm may occur.**

5. Ensure the infusion line placed correctly, close the door.

 **Warning !**	**Make sure the door handle connected the door fixed shaft, otherwise it may cause functional module fails, and damage the patient's life.**

Note: To reinstall the Infusion set, repeat the above steps.

3.2.2.5 Push

If this is not the first time using the pump, and in the "**Settings-Default Settings**" interface, "**Pop up push UI**" is selected, then after the Infusion installation, the pump enters PUSH interface automatically.

PUSH Rate is 500ml/h, it can be set in "**MENU-Settings-Manual Bolus Rate**".

PUSH Volume can be set in "**MENU-Settings- Push Volume Setting**", four values are optional: 1.0 ml, 2.0ml, 3.0ml, 5.0ml.

Note: The blocking alarm and bubbles alarm are disabled when the PUSH is operated. The maximum blocking threshold alarm value automatically to the P11 during bolus, more than the threshold will trigger alarm.

Press ◀◀ to start PUSH:

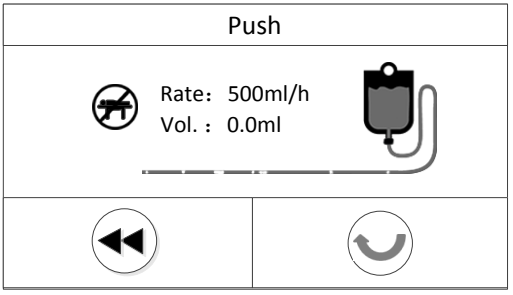


Figure 3-2 PUSH 1

Press ⏸ to stop PUSH during PUSH:

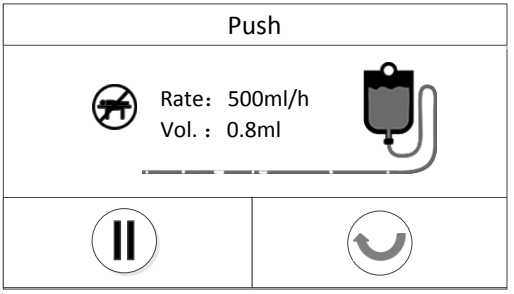


Figure 3-3 PUSH 2

Or it will stop automatically after the pre-set volume completed.

The PUSH volume will be reset when next PUSH process starts.

3.2.2.6 Use last settings

If it is not the first time using the pump, and in "**Settings-Default Settings**" we select "**Pop up Last Setting UI**" option, then after PUSH, press, the pump enters "**Use last settings**" interface automatically:

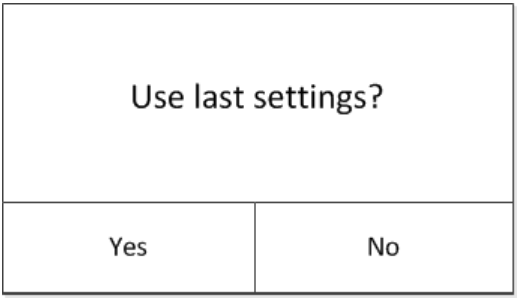


Figure 3-4 Use last settings

The user can choose "**Yes**" or "**No**".

In addition to involving parameters, other parameters which are within range (such as BOLUS rate) will follow the previous value.

Note: No matter whether the user use last parameter or not, the mode is the same as the last infusion mode.

Note: It will not appear for the first time.

Till now, all the basic settings completed, enter screen interface.

3.3 Modes

The Default Setting mode is Rate Mode.

Press "**MENU-Modes**" to enter mode selection interface.

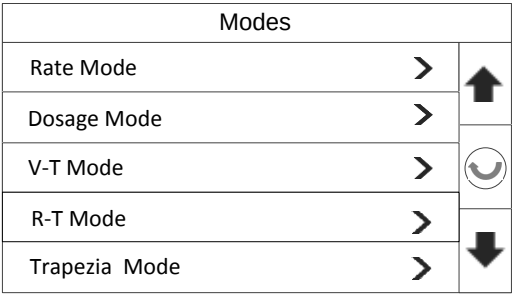


Figure 3-5 Modes 1

The user can press ▼ to enter the next page.

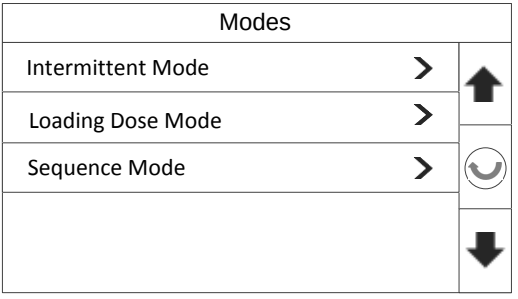


Figure 3-6 Modes 2

3.3.1 Rate Mode

Press "**Rate Mode**", enter Rate setting interface. Or press the rate at the middle of main interface. According to whether the "Enable Drip Rate Display" is selected or not, the interface is different.

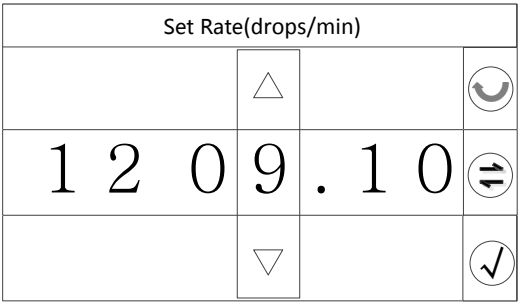


Figure 3-7 Set Rate (Enable Drip Rate Display)

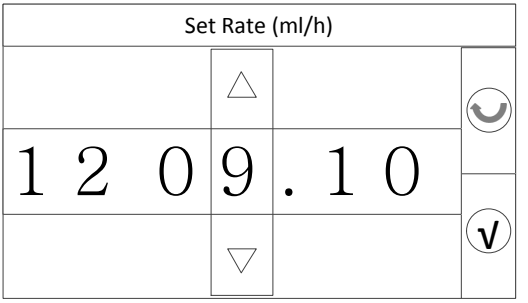


Figure 3-8 Set Rate (Close Drip Rate Display)

- Press △ to Increase values, ▽ to decrease values.
- Or press arrow keys to select and increase / decrease values.
- Press √ to confirm.

Press **START/STOP** button, the pump work in the certain rate.

3.3.2 Dosage Mode

Press "**Dosage Mode**", enter the following interface:

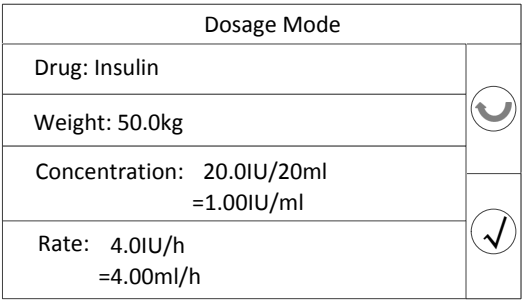


Figure 3-9 Dosage mode

The Drug, Weight, Concentration, rate are adjustable. Press the corresponding item, input the correct data and press  to confirm. The relevant parameters of dosage mode are as follows:

- Drug: select from drugs;
- Weight: 0.1~ 300kg;
- Concentration: Dose Unit Setting, Dose Setting and Dilution Volume Setting are adjustable. The adjustable range of Dose Setting is 0.1~99999.9, the Solvent Setting is 1~9999;
- Rate: Dose Rate Unit and Dose Rate Setting are adjustable. The adjustable range of Dose Rate Setting is 0.1~9999.9.

Note: There was a "Parameters Error" prompt character when the parameter is out of range.

The formula: Rate=Dose Rate/Concentration.

The detail steps to set concentration are as follows:

1) Press Concentration item, enter the Dose Unit Setting interface:

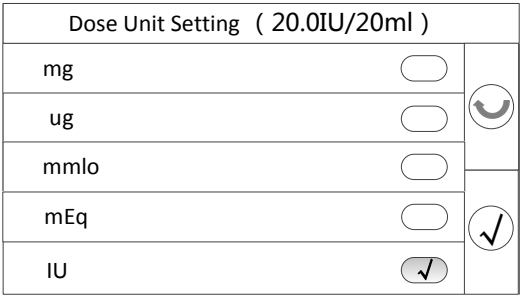


Figure 3-10 Dose Unit Setting

2) Click the target unit, such as the virtual box back of “mg” to select mg, then press √ to enter Dose Setting and Dilution Volume Setting interface:

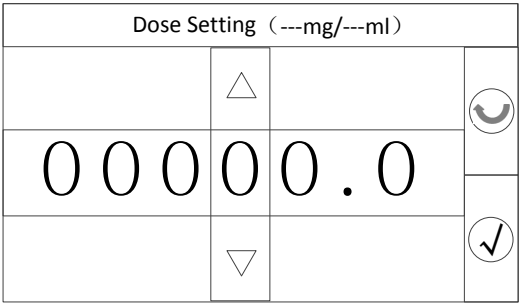


Figure 3-11 Dose Setting

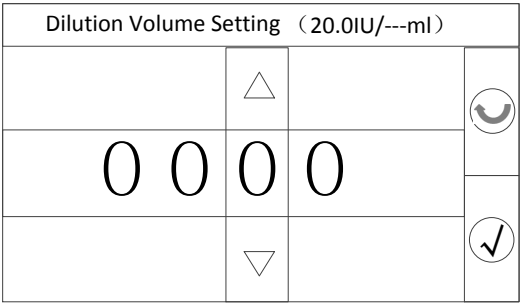


Figure 3-12 Solvent Setting

3) Click other dosage units will enter the above Settings interface, only the unit is different. Press  to confirm and return the dosage mode interface.

The detail steps to set rate are as follows:

1) Press Rate item, and enter the Dose Rate Unit interface. The different dosage units corresponding to different dose rate unit, such as the dosage units for mg, press the Rate enter into the following interface:

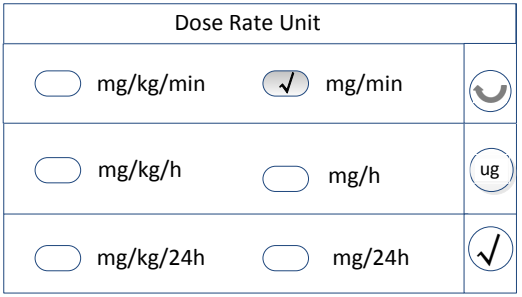


Figure 3-13 Dose Rate Unit

2) Press  to enter Dose Rate Setting interface. Note shall not exceed limit setting rate, otherwise there will be "Out of Range" prompt character. Click the return key  will not save this set and return previous interface. Click the  key can select other dose rate unit, such as ug.

Press the  key in the dose mode interface after finished setting, and return the screen interface, and then work with this rate.

3.3.3 V-T Mode

Press "**V-T Mode**", enter the following interface:

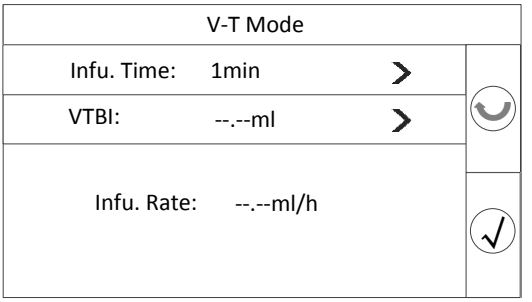


Figure 3-14 V-T Mode

Press the corresponding item, enter Infusion Time setting and VTBI setting interface.

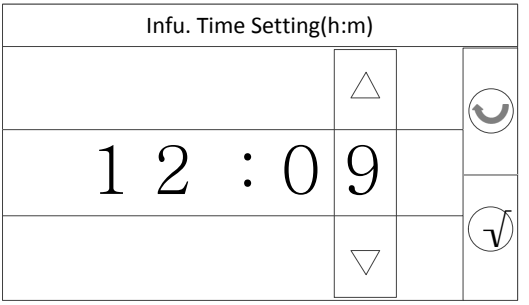


Figure 3-15 Set Infusion Time

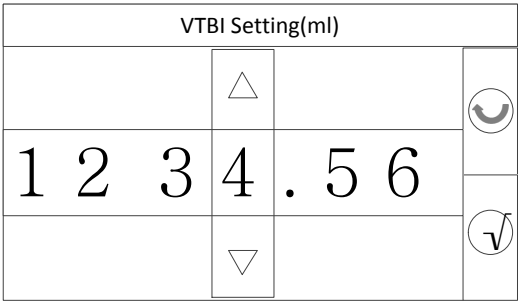


Figure 3-16 Set VTBI

- Press △ to Increase values, ▽ to decrease values.
- Or press arrow keys to select and increase / decrease values.

- Press √ to confirm, enter V-T mode.

Press √ key in the V-T Mode interface, then enter VIBI Finished Entry interface. The user can select Continue, Stop or Enter KVO Mode after finished.

After confirmed, enter the screen interface, the system can work under V-T Mode.

The user can enter Preset volume setting and Time setting interface directly by press VTBI in the screen menu.

3.3.4 R-T Mode

Press "**R-T Mode**", enter the following interface:

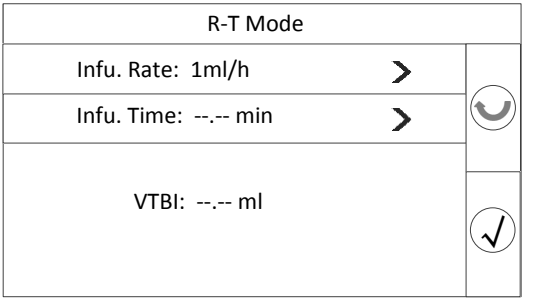


Figure 3-17 R-T Mode

Press the corresponding item, enter Infusion Rate setting and Infusion Time setting interface. The detail setting steps can refer to V-T Mode.
The user can enter Infusion Rate setting and Infusion Time setting interface directly by press the rate in the screen menu.

3.3.5 Trapezia Mode

Press "**Trapezia Mode**"（gradient model）, enter the following interface:

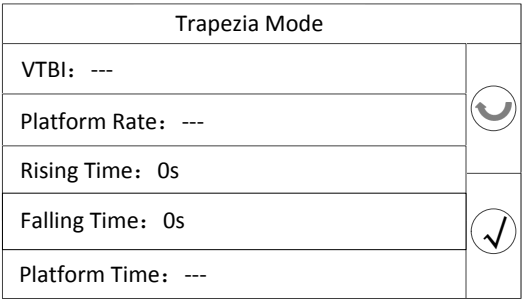


Figure 3-18 Trapezia Mode

The VTBI, Platform Rate, Rising Time and Falling Time are adjustable, Press the corresponding item, input the correct data and press √ to confirm. The Platform Time will update and display according to each parameter. The relevant parameters of gradient mode are as follows:

- VTBI: 0.01~9999.99ml;
- Platform Rate: 0.01~9999.99ml/h;
- Rising Time: 0.01s~99h59min59s;
- Falling Time: 0.01s~99h59min59s;

Note: There was a "Parameters Error" prompt character when the parameter is out of range.

The detail setting steps can refer to Dosage Mode. After confirmed, enter the Trapezia Mode ,the interface shows as follows:

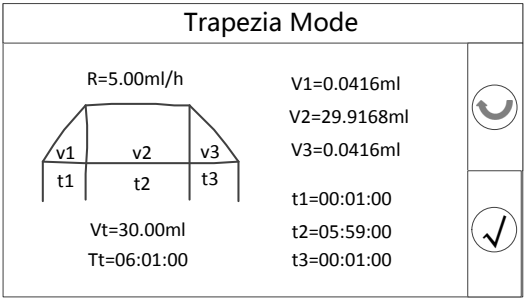


Figure 3-19 Trapezia Mode Infusion

Note: v: VTBI, t1: Rising Time, t2: Maintain Time, t3: Falling Time.

Check formula: （t1+t2）/2 < V/R，(R: maintenance rate).

Press  to confirm, return the main infusion interface, enter into Trapezia Mode.

NOTE！	1. It is forbidden for any Bolus during Trapezia Mode process. 2. Rising and falling stages are not allowed to change the rate, only in the maintenance phase rate of change and change to follow the principle. The fulling time and residual fluid volume remains the same, no more than the limits of the pump (department, the drug library, etc.). 3. If occur alarm lead to motor stalling during process, remove after the alarm, press start again, and then continue the last time breakpoint running. The rest of the alarm does not affect the infusion. Returns the last regular mode after the end of three stages.

3.3.6 Intermittent Mode

Press "**Intermittent Mode**" (discontinuous model), enter the following interface:

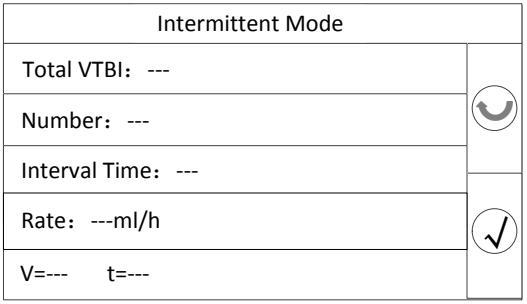


Figure 3-20 Intermittent Mode

The Total VTBI, Number, Interval Time and Rate are adjustable, Press the corresponding item, input the correct data and press  to confirm. The

Single VTBI will update and display according to each parameter. The relevant parameters of gradient mode are as follows:

- Total VTBI: 0.01~9999.99ml;
- Number: 1~50;
- Interval Time: 1s~99h59min59s;
- Rate: 0.01~9999.99ml/h;

Note: There was a "Parameters Error" prompt character when the parameter is out of range.

The detail setting steps can refer to Dosage Mode. After confirmed, enter the Intermittent Mode, start infusion.

Change rate during infusion process, it will effective immediately, and the VTBI remain unchanged, the infusion time adjustment. In the interval adjustment rate, the next sequence to take effect.

NOTE！	1. It is forbidden for any Bolus during Intermittent Mode process. 2. If occur alarm lead to motor stalling during process, remove after the alarm, press start again, and then continue the last time breakpoint running. The rest of the alarm does not affect the infusion.

3.3.7 Loading Dose Mode

Press "**Loading Dose Mode**", enter the following interface:

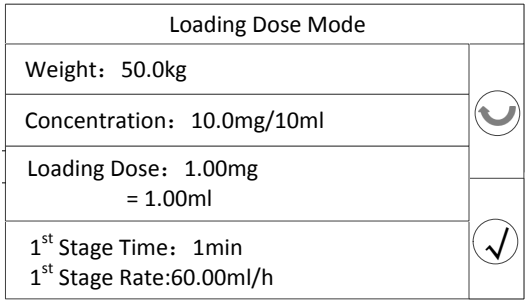


Figure 3-21 Loading Dose Mode

The Weight, Concentration, Loading Dose, 1st Stage Time and 1st Stage Rate are adjustable, Press the corresponding item, input the correct data and press √ to confirm. The relevant parameters of loading dose mode are as follows:

- Weight: 0.1~300kg；
- Concentration: Dose Unit Setting, Dose Setting and Dilution Volume Setting are adjustable. The adjustable range of Dose Setting is 0.1~99999.9, the Dilution Volume Setting is 1~9999;
- Loading Dose: Loading Dose Unit and Loading Dose Setting are adjustable. The adjustable range of Loading Dose Setting is 0.1~9999.99ml;
- 1st Stage Time and 1st Stage Rate : 1st Stage Time is adjustable.
- 2nd Stage Rate: Dose Rate Unit and Dose Rate Setting are adjustable. The adjustable range is 0.1~9999.99ml;
- 2nd Stage Dose: Dose Rate Unit and Dose Rate Setting are adjustable. The adjustable range is 0.1~9999.99;

Note: There was a "Parameters Error" prompt character when the parameter is out of range.

The detail setting steps can refer to Dosage Mode. After confirmed, enter the following interface:

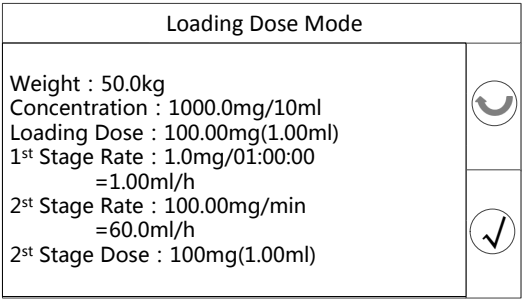


Figure 3-22 Loading Dose Mode

Press √ to confirm, enter loading dose mode.

NOTE！	1. It is forbidden for any Bolus during loading dose phase. Can manual end of 1st Stage ahead of time. Access to 2nd Stage directly, at this stage can change rate for Bolus or

	online. 2. If occur alarm lead to motor stalling during process, remove after the alarm, press start again, and then continue the last time breakpoint running. The rest of the alarm does not affect the infusion.

3.3.8 Sequence Mode

Press "**Sequence Mode**" (sequence mode), enter the following interface:

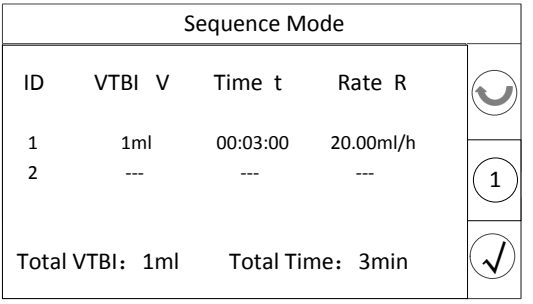


Figure 3-23 Sequence Mode

The VTBI and Time are adjustable, Press the corresponding item, input the correct data and press  to confirm. The Rate, Total VTBI and Total Time will update and display according to each parameter. The next sequence will automatically arrange after setting up a sequence. The relevant parameters of sequence mode are as follows:

- VTBI: 0~9999.99ml;
- Time: 1s~99h59min59s;

Note: There was a "Parameters Error" prompt character when the parameter is out of range.

Click the sequence can change its VTBI and time, the whole period of sequence mode can change rate. Change of rate effective immediately during infusion process. Can only change the rate at which the current sequence, do not affect other rate.

After confirmed, in the case of setting the VTBI and time for each sequence can enter sequence mode infusion.

NOTE！	1. It is allowed for manual Bolus during Sequence Mode process. The quantity of Bolus calculation to the infusion quantity. 2. If occur alarm lead to motor stalling during process, remove after the alarm, press start again, and then continue the last time breakpoint running. The rest of the alarm does not affect the infusion.

3.4 Relay Mode

Press "**Relay Mode**", enter the following interface:

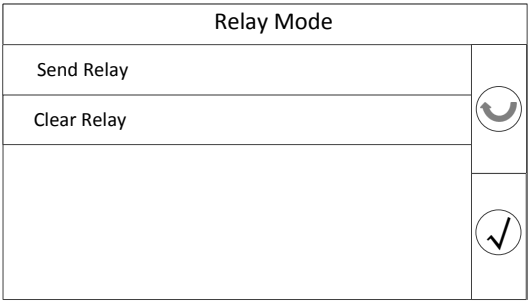


Figure 3-24 Relay Mode

The equipment can continuously launch relay. This mode needs to be used with infusion information collection system manufactured by HEDY Medical Device Co., Ltd.

3.5 Settings

Press "**MENU-Settings**", enter user setting interface.

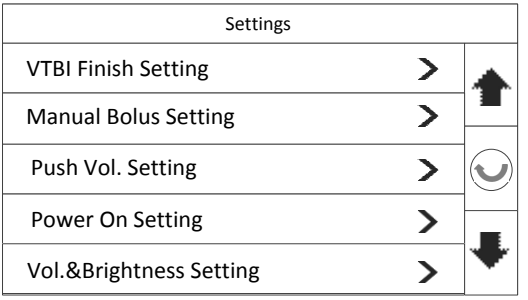


Figure 3-25 Settings 1

The user can press ▼ to enter the next page.

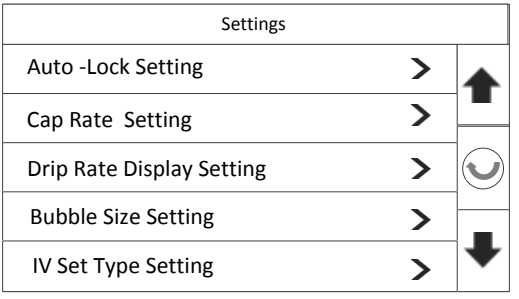


Figure 3-26 Settings 2

Press each individual in the menu, the user can enter the submenu to set all the parameters in user setting.

We have set the password for Settings of some items to improve the safety of device, the password is: 520512, please enter the password into the corresponding interface when you need.

WARNING!	**Setting alarm limits to extreme values that can render the alarm system useless.**

3.5.1 VTBI Finish Setting

Press "**VTBI Finish Setting**", enter the submenu, the user can choose any one of the next three ways to continue working after the VTBI is completed.

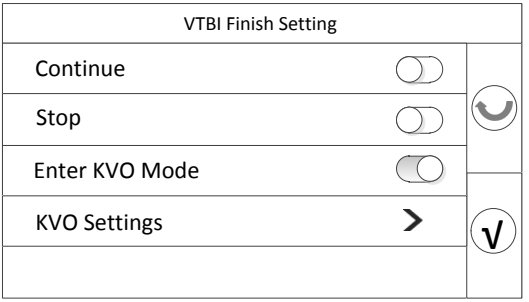


Figure 3-27 VTBI Finish Setting

If Enter KVO Mode is selected, the user should set the KVO Rate, KVO Rate must be limited in 0.10-5.00ml/h.

If the user choose 2 or 3 of the options, after the preset value is set, the "After VTBI Completed Entry" interface will pop up, the user can choose a way to continue(You can choose only one option).

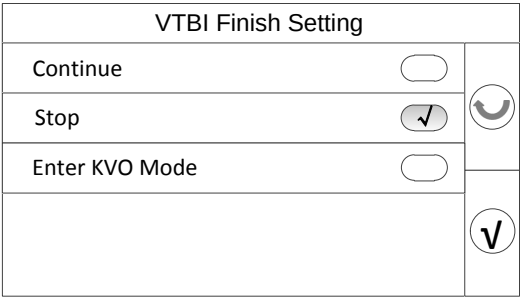


Figure 3-28 Continue working options

Note: During operation, after the user make a choice in the pop up, the next pop will contain only the ways the user selected last time, if the user select only one way, the next time will not pop up.

3.5.2 Manual Bolus setting

Press "**Manual Bolus Setting**" to enter the Bolus Rate setting interface.

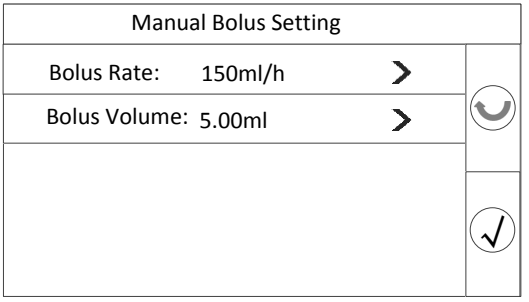


Figure 3-29 Manual Bolus Setting

The Bolus Rate and Bolus Volume are adjustable, Press the corresponding item, input the correct data and press √ to confirm.

- Bolus Rate: 0.10-2000.00ml/h;
- Bolus Volume: 0.01~100ml.

Note: There was a "Parameters Error" prompt character when the parameter is out of range.

Manual BOLUS Rate limit is the same as the infusion rate limit, and related to the type of the Infusion.

3.5.3 Push Vol. Setting

Press "**Push Vol. Setting**", enter push Volume setting interface. There are four parameters can be set: 1.0 ml. 2.0 ml. 3.0 ml. 5.0 ml (You can choose only one option).

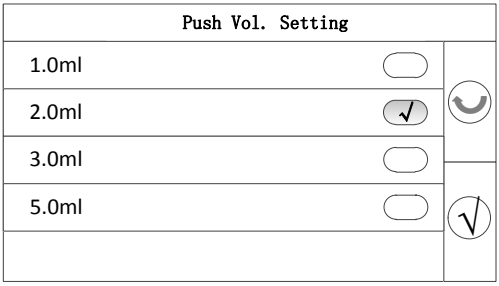


Figure 3-30 Push Volume Setting

3.5.4 Power On Settings

Press "**Power On Setting**", enter "**Please Enter Password**" interface.

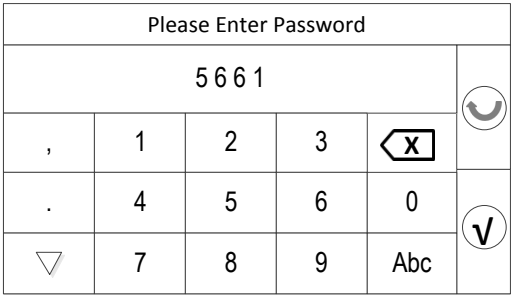


Figure 3-31 Enter Password

If the password is incorrect, there will be a reminder "**Password Error**".

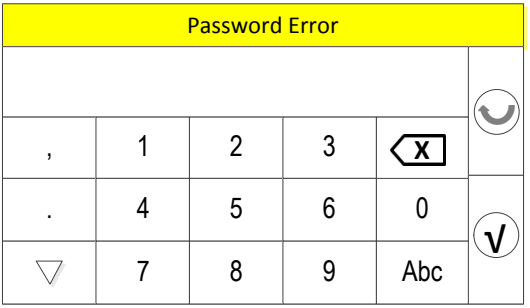


Figure 3-32 Password Error

Please contact the manufacturer to obtain the password.

If the password is correct, enter "**Power On Setting**" interface. If the password is correct, enter "**Power On Setting**" interface. The user can choose to pop up these UIs:

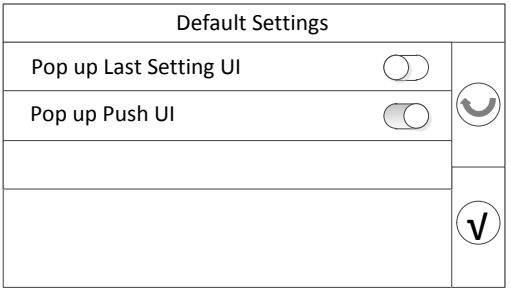


Figure 3-33 Default Settings

Press the virtual key to turn on/off the options, if this option is turned on, it will pop up automatically when the pump turned on, otherwise it will not.

Note: These options above are optional, the user can choose none, one or all of them.

3.5.5 Vol. & Brightness Setting

Press "**Vol. & Brightness Setting**", enter "**Please Enter Password**" interface. If the password is correct, enter Volume & brightness setting interface.

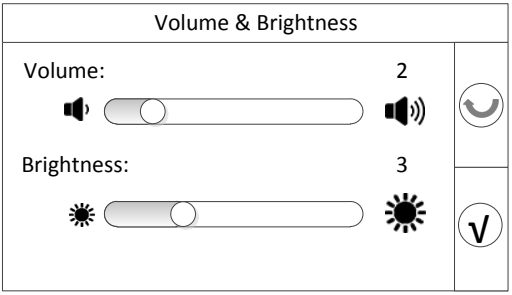


Figure 3-34 Volume & Brightness

1. Alarm volume has 5 grades, press to decrease the volume, to increase the volume, when adjust the volume, it is accompanied with voice prompt.

2. Screen brightness has 9 grades, press on the left side to weaken screen brightness, on the right side to enhance screen brightness, when adjust the screen brightness, it is accompanied with brightness display prompt.

3. Press to confirm the setting.

WARNING!	**The auditory alarm signal sound pressure levels, which are less than ambient levels, can impede operator recognition of alarm conditions and the alarm system provides.**

3.5.6 Auto-Lock Setting

Press the up key on the panel + CLR more than 1s at the same time, the panel and the screen can be locked or unlocked. When it is locked, there has no response pressing the screen or pressing the panel, after unlocking, their functions recovery. When an alarm occurs, the lock canceled automatically (except Remainder Alarm).

The user can choose to auto-lock or not, and can set auto-lock time, the pump provide four auto-lock time: 2min, 5min, 10min, 20min (You can choose only one option).

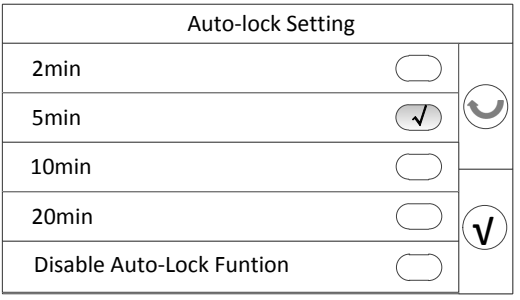


Figure 3-35 Auto-Lock Setting

Note: Auto-lock time represent how long will the pump auto-lock without operation, it will not auto-lock if the pump continue being operated.

WARNING!	**The auditory alarm signal sound pressure levels, which are less than ambient levels, can impede operator recognition of alarm conditions and the alarm system provides.**

3.5.7 Cap Rate Setting

Press "**Cap Rate Setting**" enter "**Please Enter Password**" interface. If the password is correct, enter the Cap Rate setting interface.

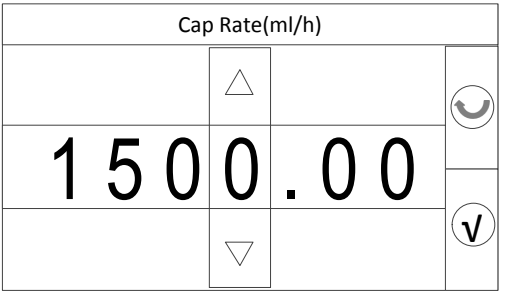


Figure 3-36 Set Cap Rate

- Press △ to Increase values, ▽ to decrease values.
- Or press arrow keys to select and increase / decrease values. If the parameter is out of range, there will be a reminder "?**Out of range**".

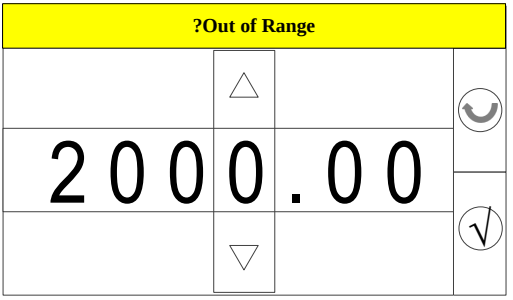


Figure 3-37 Out of Range

- Press √ to confirm.

Note: Rate upper limit can be set in the range of 0.10-2000.00ml / h, the default value is 2000.00ml / h, in the trace mode this value can be set to 100.00ml / h.

3.5.8 Drip Rate Display Setting

Press "**Drip Rate Display Setting**", enter drip rate display setting interface.

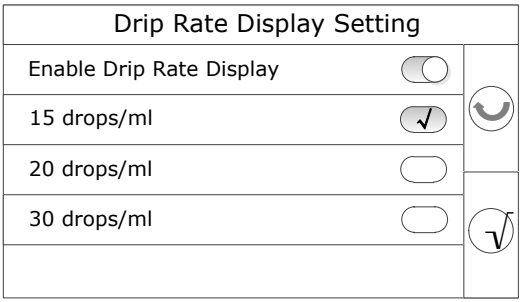


Figure 3-38 Drip Rate Display Setting

If “Enable Drip Rate Display” is selected, after the infusion rate set, the user can change its unit from ml/h to drop/min by pressing . The screen interface displays both of them.

3.5.9 Bubble Size Setting

Press “**Bubble Size Setting**” enter “**Please Enter Password**” interface. If the password is correct, enter Bubble Class setting interface.

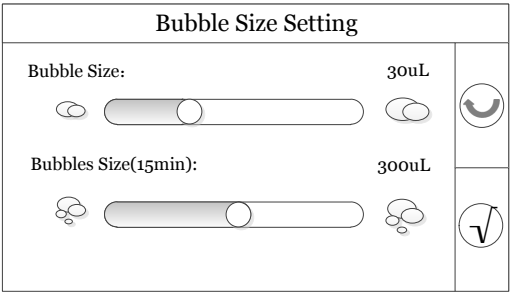


Figure 3-39 Bubble Class

1.Air Bubble Class has 3 levels: 30ul, 100ul, 300ul, press on the left side and on the right side to adjust the air bubble class level.

2. Air Bubble Class (15min) has 2 levels: 300ul, 500ul, press on the left side and on the right side to adjust the air bubble class (15min) level.

3. Press √ to confirm the setting.

Note: In the process of transfusion, the cumulative size of the bubbles (each more than 10ul) exceeds the limit size within 15min. It will occur "Bubble Pass" alarm.

3.5.10 IV Set Type Setting

Press "**IV Set Type Setting**", enter IV set type setting interface.

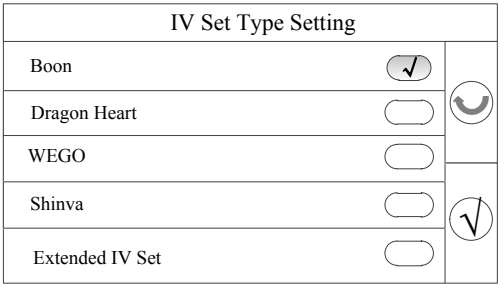


Figure 3-40 Infusion type setting

If the extended infu. Set has not been calibrated, the extended infu. Set is not optional. The infu. Set recommended by the manufacturer displays here:

- Boon: Type-A1, A2, A3, B1, B2, B3 (transfusion needle: 0.45, 0.5, 0.55, 0.6, 0.7, 0.8, 0.9).

The specifications list of Boon infusion set has been tested. And the accuracy has been evaluation.

The administration set (including needle and pipe) are treated as the applied part, which are not intended to deliver heat, during normal user, the maximum temperature at applied part maybe up to 41 ℃.

3.5.11 Day & Night Setting

Press "**Day & Night Setting**", enter "**Please Enter Password**" interface. If the password is correct, enter Day & Night setting interface. The user can set

the start time of the day, and the volume & brightness during the day, the start time of the night, the volume and brightness during the night.

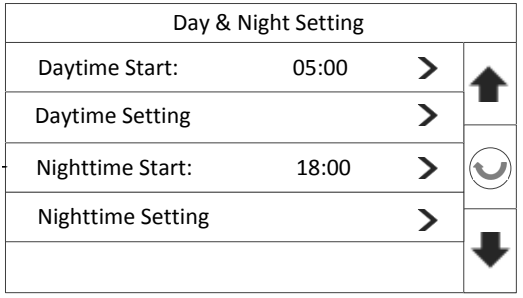


Figure 3-41 Day & Night Setting

The start time of the day and night can be set freely, press the virtual key to enter submenu.

The volume & brightness during the day and night can be set freely according to users' own habits. The volume & brightness change according to the mode.

The user can also choose to close Day & Night mode.

3.5.12 System Time setting

Press "**System Time Setting**", enter time setting interface.

1. Date setting, format: "YY-MM-DD":

- Press △ to Increase values, ▽ to decrease values.
- Or press arrow keys to select and increase / decrease values.
- Press √ to confirm.

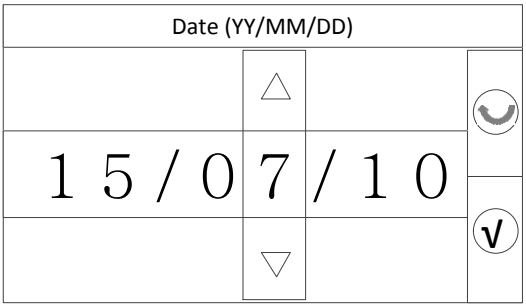


Figure 3-42 Date Setting

2. After confirm date setting, enter time setting interface.

3. Time setting format “HH:MM:SS”, refer to date setting procedures to set values.

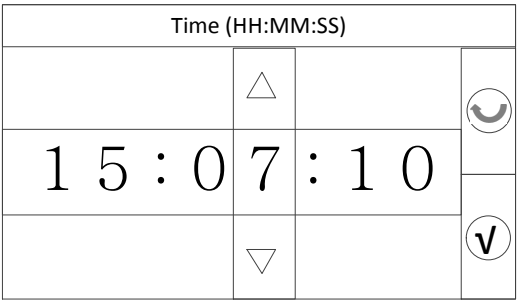


Figure 3-43 Time Setting

4. Time setting completed, press ⟲ to reset date, or √ to return to the user setting menu interface.

3.5.13 Extended IV Set Calibration

Press “**Extended IV Set Calibration**”, enter extended IV Set calibration interface.

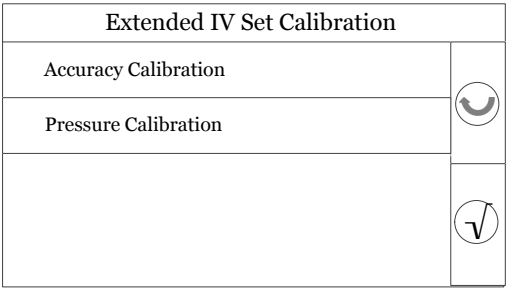


Figure 3-44 Extended IV Set Calibration

Press “Accuracy Calibration”.

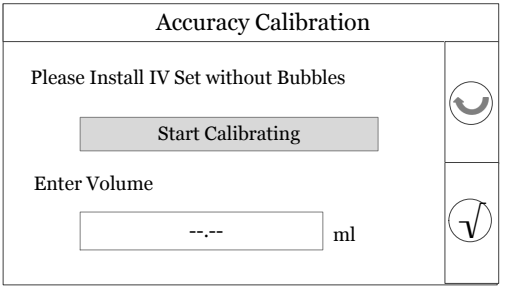


Figure 3-45 Accuracy Calibration

1. Install IV Set without Bubbles, put the liquid outlet in the measuring cup(25ml) or the container on the balance. Press “Start Calibrating” to calibrate, it needs 6min.

Note: during calibrating, the screen displays “Calibrating”, the screen and the panel locked (except ON/OFF button).

2. The screen displays “Calibration Completed”, read the value of the measuring cup/ balance(unit ml, g is equal to ml). Input the value in ”Enter Volume”. Press √ to confirm.

Press “Pressure Calibration”.

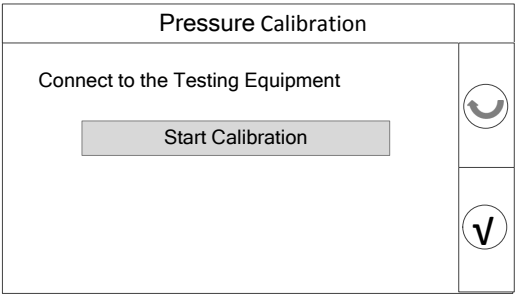


Figure 3-46 Pressure Calibration

1. Connect the iv Set to the testing equipment (such as pressure gauge), press" Start Calibrating".

2. Press "Mark 30kPa" when the pump displays "Mark 30kPa", Press "Mark 100kPa" when the pump displays "Mark 100kPa".

3. The screen displays "Calibration Completed", Press √ to confirm and return to the previous menu.

4. Extended IV Set calibrated successful.

3.5.14 System Version

Press "System Version" to view system version. The version is V02.00.00.

3.6 Logs

If the user needs to check operation logs, alarm logs, infusion logs. Press "**MENU-Logs**" to enter the interface.

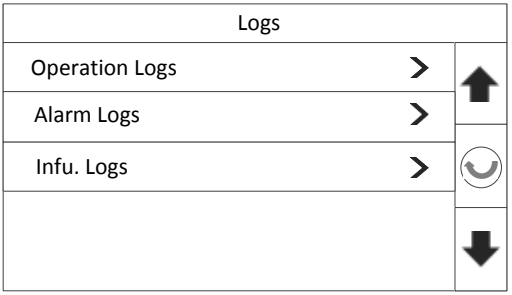


Figure 3-47 Logs

The contents of the log are not going to disappear after the alarm system has experienced a total loss of power for a finite duration.

The pump will eliminate the earliest log as it reaches capacity.

3.6.1 Operation Logs

Operation log shows the operate time and date, and what the user set.

Press "**Operation Logs**" to enter the interface.

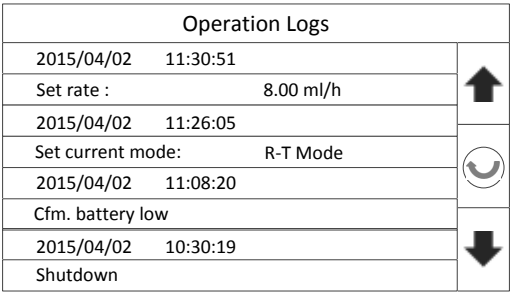


Figure 3-48 Operation Logs

The format is:

Date and time [yyyy/mm/dd hh:mm:ss]

Operation string: **value** [optional]+**unit/auxiliary string**[optional]

3.6.2 Alarm Logs

Alarm log shows the time and date when alarm occurs, and why the alarm occurred.

Press "**Alarm Logs**" to enter the interface.

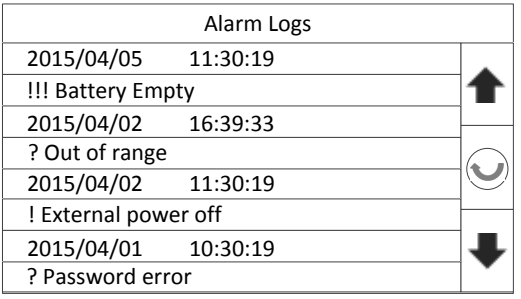


Figure 3-49 Alarm Logs

The format is:

Date and time [yyyy/mm/dd hh:mm:ss]

Alarm string

3.6.3 Infusion Logs

Infusion log shows the start and stop time of each infusion, and the rate during this time.

Press "**Infu. Logs**" to enter the interface.

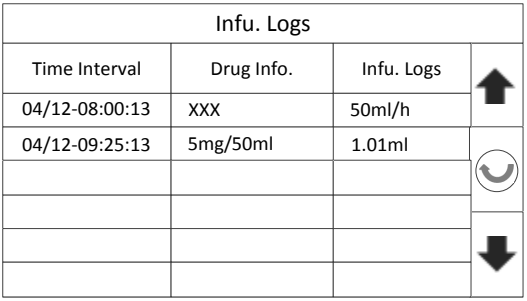


Figure 3-50 Infusion Logs

The format is:

time	Drug information	Log
Start time Stop time	—— ——	Rate (ml/h) Volume (ml)

3.7 Drugs

Press "**MENU-Drugs**", enter the drugs interface:

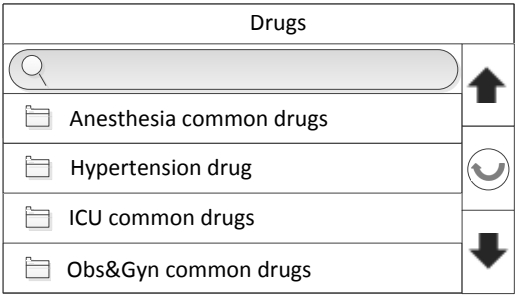


Figure 3-51 Drugs

The user can press the drugs folder to enter drug list, select the target drug. Or click the search box and input keyword to search.

Press the drug's name to enter the following interface view drug information after searched the target drug.

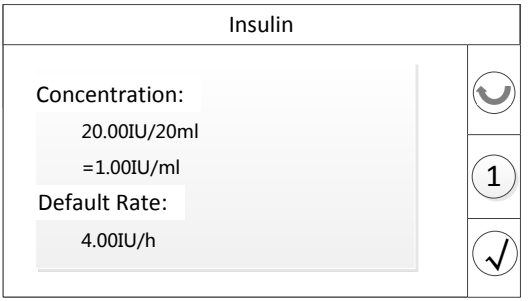


Figure 3-52 Drug's information

Press the number key on the right, such as 1 to check out other information page. All the information parameters including Concentration, Default Rate, Dose Rate Hard Limit, Manual Bolus Vol. , Manual Bolus Vol. Hard Limit, Default Manual Bolus Rate, Bolus Rate Hard Limit, Code.

Press back key to return previous interface, press √ to confirm drug information.

Note: this function is optional.

3.8 Service

Press "**MENU-Service**", enter "**Please Enter password**" interface. Contact the manufacturer to obtain the password.

Please use the Infu. Set the manufacturer recommended. When the Infusion pump leave factory, it has default calibration coefficients corresponding the Infu. Set inside. Under normal circumstances, it doesn't need re-calibrated. In case of other factors, the user can enter "**Accuracy Calibration**" interface to enter Calibration factor.

Note: Set a target VTBI, using standard measuring instruments to measure the actual infusion quantity. The quotient of the two is the calibration factor.

Chapter 4 Technical Data

4.1 Infusion Accuracy

- The maximum capacity flowing through under single fault condition is less than 1ml.

- Under normal circumstances, the infusion precision of the Infusion pump is as the following:

Table 4-1 Infusion Control Parameters

Infusion Control Parameter		Rate Range
Rate		0.1 ~ 2000 ml/h
Infusion Rate Step Resolution	0.1-99.99ml/h	0.01ml/h
	100.0-999.9ml/h	0.1 ml/h
	1000-2000 ml/h	1 ml/h
VTBI		0.1-9999ml
VTBI Step Resolution	0.1-99.99ml	0.01ml
	100.0-999.9ml	0.1ml
	1000-9999ml	1ml

Note: the infusion precision(Solution: Ⅲ grade water, Test temperature:23±2℃) is ±5%. It means that, infusion after the rate and the VTBI is set, the liquid error range is less than ±5%.

Under the single fault condition, the system has over-infusion and under-infusion caused precision error range is ±10%.

 **WARNING!**	**If the Infu. Set used is untested varieties, or used under other unusual circumstances, such as too short circle time, abnormal transfusion characteristic, Inadequate protection under harsh environmental conditions, tube plugging and backflow, the pump may unable to maintain the accuracy.**

- The Bolus infusion Performance meets the following requirements:

Table 4-2 Bolus Infusion Control Parameters

Bolus Infusion Control Parameter	Parameter Range
Bolus Rate	0.1 ~ 2000 ml/h

- The infusion pump has air bubble detection function.

4.2 KVO Mode

KVO mode can switch on/off, the system can switch automatically when there is a trigger, others can be switched via an infusion pause.

- KVO（keep vein open）Mode

  In the end of the pre-set time, or when the VTBI completed, the Infusion pump will transfuse automatically with a very low rate, in order to prevent the blood from blocking the needle. KVO rate is a minimum rate to keep vein open.

- When the infusion completed, the pump enters KVO mode automatically, KVO can be turned off.

- KVO protection performance meets the following requirements:

Table 4-3 KVO Protection Performance

KVO Protection Control Parameters	Parameter Range
KVO Rate	0.1 ~ 5.0 ml/h

4.3 Blocking Threshold

In order to ensure the safety of the patients, the pump has Occlusion alarm function, when the pressure in the infusion tube is greater than the blocking threshold, it will alarm.

- Under the condition of patients' pipe end completely blocked, the maximum injection pressure generated by the pump is 560kPa.
- The blocking alarm threshold means the physical quantity value when the blocking alarm is triggered. The blocking alarm threshold is highly affected by the environment temperature, infusion pipe quality. The test temperature is 23±2℃ and the length of infusion connective tube is less than 0.5 meters.
- The pump will release pressure automatically to entrapped unintended bolus before occlusion release.

- The following table shows the typical values for time to alarm (Boon):

Table 4-4 Typical Values for Time to Alarm

Rate（ml/h）	Pressure Class	Occlusion Pressure（kPa）	Time to Alarm（s）	Blous （ml）
200	P1	16.3	00:00:01	0.003
	P6	58.94	00:00:06	0.106
	P11	130.27	00:00:12	0.293

25	P1	12.67	00:00:05	0.01
	P6	62.4	00:00:44	0.16
	P11	137.87	00:07:41	0.33
1	P1	16.93	00:04:43	0.015
	P6	69.83	00:25:11	0.171
	P11	136.83	03:25:23	0.358
0.1	P1	11.33	00:12:37	0.023
	P6	66.4	2:02:55	0.19
	P11	138.8	11:09:03	0.416

Note: the Occlusion pressure and Occlusion alarm time are related to the Infusion brand, infusion tube, pressure calibration coefficients and the test equipment. So the data above are only for reference.

- due to equipment's pressure release function, when the pump operate in the middle speed, and the pressure up to maximum occlusion alarm threshold, the pump will release the system pressure automatically, therefore the liquid flowing through after the release is negligible.
- The liquid flowing through under single fault conditions is 0.54ml (Pressure class is P11).

  Press the pressure blocking box in the lower right corner of the interface, enter submenu to set the pressure class.

Chapter 5 Alarm and Tips

5.1 Alarm Function

1. Alarm function's operating environment is the same as the equipment's operating environment.

2. Alarm Silence: the user can press CLR to silence the alarm for 2 minutes.

3. Alarm Acknowledge: All the alarms can be confirmed by pressing OK. Only after acknowledging alarm can message be cleared and back to the previous interface (except the Install Infu. Set interface).

4. Audible alarm will exist in all alarm conditions. Alarm meets the following requirements: Audible alarm can produce sound levels, the sound pressure produced by the maximum sound level is more than 65dB(A) when the user stand 1m away from the source, by the minimum is more than 45dB(A).

5. The device has real-time detection through encoder and hardware circuit, and produce device fault alarm to prevent the patient from over-infusion and under-infusion.

6. The alarm produced by the system can output through nurse call. The alarm delay no more than 10ms. Associated with the alarm Settings, such as blocking alarm threshold, automatic save by hardware permanently.

5.2 Alarm Priority

Alarm is sound and light alarm that has sound and light signals. Infusion pump's alarms in priority order are divided into: high-level alarm,

intermediate-level and low-level alarm. Different priority alarms have different sound and light signals. All alarms are technical type.

This section will detail the cause of the alarm and the corresponding solutions. If there is more than one alarm occurring at the same time, high priority Alerts appear first depending on the alarm priority.

5.2.1 High-level Alarm

Device failure and cannot work properly when the high-level alarm occurs. At this moment the infusion immediately stopped and the device will emit the high alarm sound, the red alarm light is blinking and the screen displays relevant information. High-level alarm includes the following types:

High-level Alarm	Alarm Cause	Solution
!!! Device Fault	Caused by the hardware and etc.	Please turn the pump off and connect our service.
!!! Door Unclosed	In the process of transfusion, the pump door open is detected.	Infusion pump automatically stop infusing, press OK to confirm the alarm, close the door.
!!! Battery Empty	In the case of no external power supply, the remaining capacity can support the pump continue working only 3 more minutes.	First, press OK to confirm the alarm. Second, connect the external power supply.

!!! Bubble Pass	In the process of transfusion, the size of the single bubble, or the size of the bubbles (15min) exceeds the limit size.	Infusion pump automatically stop infusing. Press OK to confirm the alarm.
!!! Rate Out of Range	The velocity /BOLUS rate exceed the limit value of the new infusion set when a new infusion set reloaded, and the user chose to use last parameter.	Press OK to confirm the alarm. The velocity/BOLUS rate automatically changes to the maximum value of the new infusion set.
!!! Infu. Finished	In the process of infusion, when the pre-set infusion time come to an end, or VTBI completed, including KVO finished, is detected (When the preset value is reached, select to stop infusion), this alarm occurs.	Infusion pump automatically stop infusion, please press OK to confirm the alarm.
!!! IV set Occluded	In the process of infusion, infusion tube pressure exceeds the limit value.	First, press OK to confirm the alarm. Second, anti - bolus to pressure back to

		normal.
!!! Near Empty	In the infusion process, the IV set will soon be empty is detected.	Press OK to confirm the alarm. The infusion will be continued. The user can stop the infusion after confirming the alarm.

5.2.2 Intermediate-level Alarm

The intermediate-level alarm occurs when there are some bad effects in the normal work, it means that the device's work has been done, and the medical personnel need to do the next step. When the intermediate-level alarm occurs, the device will emit the medium alarm sound, the yellow alarm light is blinking and the screen displays relevant information. Intermediate-level alarm includes the following types:

High-level Alarm	Alarm Cause	Solution
!!! KVO Actived	In the process of infusion, the VTBI completed is detected (select to enter KVO when VTBI completed).	Press OK to confirm the alarm. The infusion continues. The user can stop the infusion after confirming the alarm.

5.2.3 Low-level Alarm

The low-level alarm refers to the alarm which does not affect the normal work and does not require the medical personnel to do the next step. Its main function is to prompt the medical personnel prepare to enter the next operation. In addition, the low-level alarm won't interrupt the infusion. When the low alarm occurs, the device will emit the low alarm sound, the yellow alarm light

is on and the screen displays relevant information. Low-level alarm includes the following types:

High-level Alarm	Alarm Cause	Solution
! Battery Low	In the case of no external power supplied, and the remaining capacity can support the pump continue working only 30 more minutes.	First, press OK to confirm the alarm. Second, connect the external power supply.
! Infu. Near Finished	In the infusion process, the infusion time or the VTBI is nearly completed.	Press OK to confirm the alarm. The infusion continues. You can stop the infusion after confirming the alarm.
! Forget Operation	When the screen unlocked, and the user has no operation staying on the main screen or the setup interface for more than 2 minutes.	Press OK to confirm the alarm.
! External power supply interruption	The status of external power supply changes from connected to disconnected.	Press OK to confirm the alarm. If no human factors, reconnect the external power supply.
! VTBI Finished，Continue Infu.	In the process of transfusion, VTBI completed is detected	Press OK to confirm

	(select to continue infusion when VTBI completed).	

Note: The following alarms are non-latching alarm signal, and others are latching alarm.

- Battery Low
- External power supply interruption
- Infu. Near Finished

5.2.4 Alarm acknowledgement reference table

Alarm Type	Audible signal	optical signal			Staff call	User confirmation
		Red LED	Yellow LED	Text		
High Alarm	Yes	Blink	Off	Such as "!!! Battery Empty"	Yes	Press CLR to silence the alarm. Press OK to confirm.
Low Alarm	Yes	Off	Blink	Such as "! Remainde r Alarm"	Yes	Press CLR to silence the alarm. Press OK to confirm.

Note: If the current alert was not lifted, touch screen and hardware buttons (except the button of OK/CLR/POWER ON) shall be void.

5.3 Tips

In addition to the alarm, in order to facilitate user action, the Infusion pump has some relevant tips. The contents of tips mainly refers to the input parameter is incorrect. Such as the velocity exceeds the allowed range, cannot change the parameters, and so on. When then tips appear, does it make a sound. Tips including the following types:

1. VTBI completed, Continue Infusing.

- Cause: In the process of transfusion, VTBI completed is detected (select to continue infusion when VTBI completed).

2. Out Of Range

- Cause: In the parameter setting interface, the value is set out of the allowed range.

3. Password Error

- Cause: the password input is not correct, including service password, user password and WiFi password.

4. Parameter Error

- Cause: Parameters cannot be changed.

5. Please Unlock

- Cause: Success to lock the device.

6. No Infusion Set

- Cause: When the infusion set is not detected to do some operations such as infusion, PUSH or BOLUS.

7. Screen Locked

- Cause: Success to lock the device.

8. Screen Unlocked

- Cause: Success to unlock the device.

Note: If the user does not have operations, the above tips will disappear automatically.

FOR YOUR NOTE

Chapter 6 Maintenance

6.1 Cleaning/Disinfection

 **CAUTION!**	**Power off and unplug the system before cleaning the equipment.**

The system should be wiped with the following liquids dipped soft cloth at least once every month for cleaning.

- 50% NaClO
- 10% HClO
- 3% H_2O_2
- 70% Alcohol
- 70% Isopropyl Alcohol in water
- 10% NaCl and water
- T-Spary I (Pharmaceutical Innovations)
- T-Spary I (Pharmaceutical Innovations)
- PROTEXTM DISINFECTANT SPRAY
- MetriZyme

After equipment cleaning / disinfection completed, store in a cool dry place. Please refer to the equipment component's User manual to get the limit of temperature, pressure, humidity and time that the equipment components can withstand in detail.

Never:

- Let any liquid enter the device.
- Sterilize the equipment by heating or with gas.

6.2 Maintenance

- Equipment should store at the specified temperature, humidity and other external conditions.
- Observe the pump's statue to find and solve problems timely.

 **WARNING!**	No modification of this equipment is allowed.

 **WARNING!**	This equipment shall not be serviced or maintained while in use with the patient.

6.3 Safe Use and Maintenance of the Rechargeable Batteries

- Rechargeable batteries cannot be replaced.
  Battery Type: KMP-BAT-01.
  Size: 7.4V-2600mAh.
- Ensure the safety of the battery, please avoid overcharge and keep the battery maintains a certain amount of electricity all the time.
- Under the suitable external condition, if the device will be stored for longer than six months, please charge the device.

Appendix A Start-up Curves and Trumpet Curves

The following are the Start-up Curves and Trumpet Curves @different infusion speeds (infusion time: 2h).

Solution: Ⅲ grade water.

Test temperature: 23±2℃.

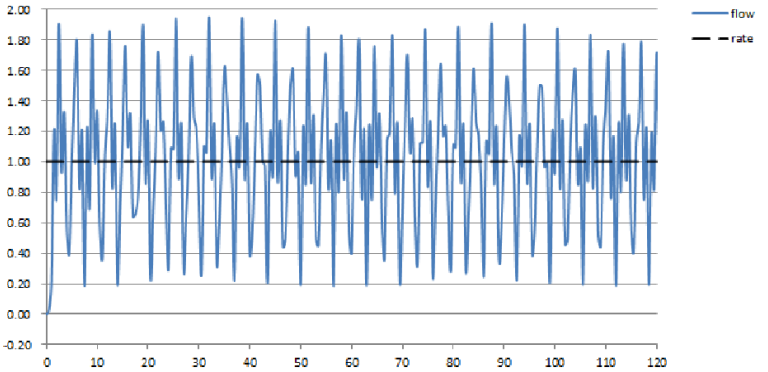


Figure A-1 Start-up Trend. @1ml/h

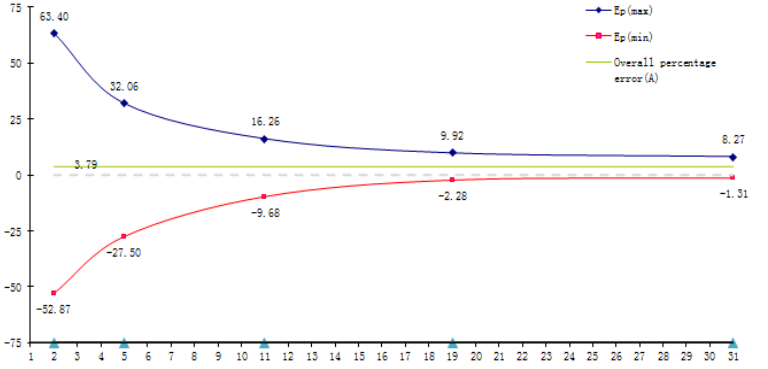


Figure A-2 Trumpet Curve. @1ml/h

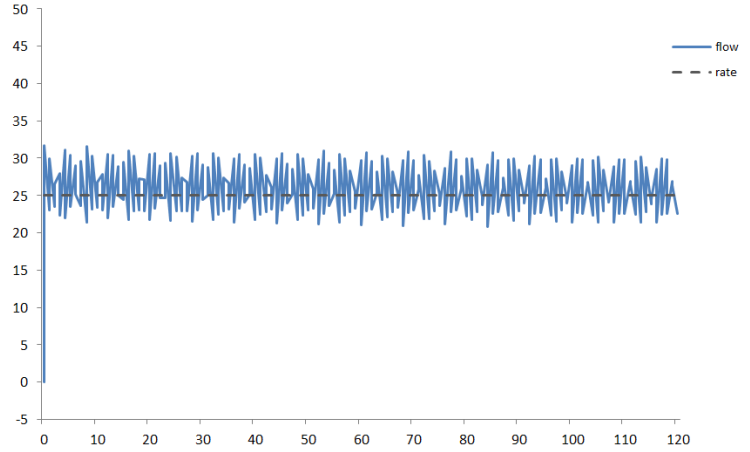


Figure A-3 Start-up Trend. @25ml/h

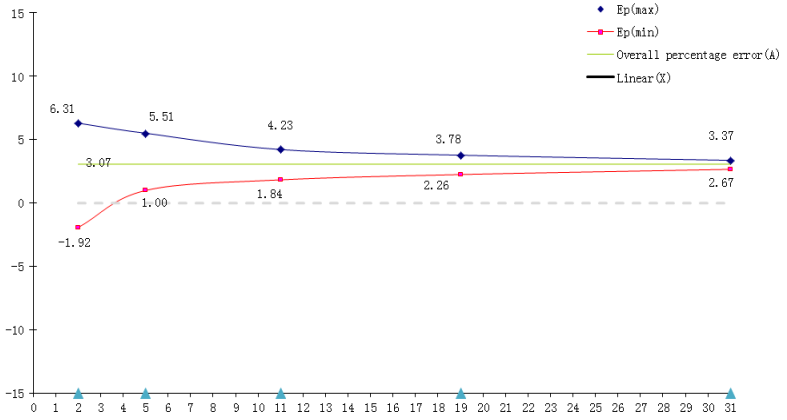


Figure A-4 Trumpet Curve. @25ml/h

The graphs show the accuracy/uniformity of flow in relation to time. They allow for the following:

The delivery behavior or delivery precision is essentially influenced by the type of the disposable used. Deviations from the technical data of the pump cannot be excluded if lines (disposables) other than those stated in the order data are used.

The above graphs show the test's results, which can be used as an important symbols of comprehensive characteristic of the pump.

The above data is tested by the same infusion pump, and each test using new infusion set, a total of 2 infusion set.

- **Trumpet Curves**

All measured values for second hour in each case.

Measurement interval $\Delta t = 0.5$ min

Observation interval $p \times \Delta t$ [min]

- **Start-up Curves**

Measurement interval $\Delta t = 0.5$ min

Measurement duration $T = 120$ min

Flow Q_i (ml/h)

FOR YOUR NOTE

Appendix B EMC Information

Accompanying Documents:

1. Instructions for use

- Model i7/ip-3 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;
- Portable and mobile RF communications equipment can affect model i7/ip-3.

2. Technical description

- **Warning** that the use of accessories, transducers and cables other than those specified with the exception of transducers and cables sold by the manufacturer of the model i7/ip-3 as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the model i7/ip-3.
- **Warning** that the model i7/ip-3 should not be used adjacent to or stacked with other equipment.

3. Normative references:

Guidance and manufacturer's declaration – electromagnetic immunity			
The model i7/ip-3 is intended for use in the electromagnetic environment specified below. The customer or the user of the model i7/ip-3 should ensure 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 ±15 kV air	±8kV 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	±2 kV 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) and neutral ± 2 kV line(s) to earth	±1 kV line(s) and neutral ± 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	<5 % U_T (>95 % dip in U_T) for 0,5 cycle	<5 % U_T (>95 % dip in U_T) for 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model i7/ip-3

variations on power supply input lines IEC 61000-4-11	40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	requires continued operation during power mains interruptions, it is recommended that the model i7/ip-3 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

4. Normative references (Continued)

Guidance and manufacturer's declaration – electromagnetic immunity			
The model i7/ip-3 is intended for use in the electromagnetic environment specified below. The customer or the user of the model i7/ip-3 should ensure 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the model sp-3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** **d=1.2√P** **d=1.2√P 80MHz to 800MHz** **d=2.3 √P 800MHz 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 metres (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 model i7/ip-3 is used exceeds the applicable RF compliance level above, the model i7/ip-3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model i7/ip-3.

b

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

5. Normative references (Continued)

Guidance and manufacturer's declaration – electromagnetic emissions		
The model i7/ip-3 is intended for use in the electromagnetic environment specified below. The customer or the user of the model i7/ip-3 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The model i7/ip-3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The model i7/ip-3 is suitable for use in all establishments, but if used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, whatever additional measures are necessary.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the model i7/ip-3

The model i7/ip-3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model i7/ip-3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model i7/ip-3 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E1}]\sqrt{P}$
0,01	**0.12**	**0.12**	**0.23**
0,1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

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 C Abbreviations

AC	Alternating Current
Cap Rate	The upper limit of the rate
CLR	Clear
DC	direct current
EMC	Electromagnetic Compatibility
Infu.	Infusion
KVO	Keep vein open
RF	Radio frequency
RS232	recommend standard 232
R-T Mode	Rate-Time Mode
SIP /SDP	Session Initiation Protocol/Session Description Protocol
UI	User Interface
VTBI	Volume To Be Infused
V-T Mode	VTBI-Time Mode
WEEE	Waste Electrical and Electronic Equipment