

HK-400III SYRINGE PUMP

USER MANUAL

Version: V1.0.0

Shenzhen Hawk Medical Instrument Co. Ltd.

Please read the manual before using the product.

Please keep the manual for reference !



20180821-01

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Revision Notes:

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On the premise of comply with relevant laws and regulations, we'll revise the manual timely according to the improvement of products or update of laws and regulations.

This Manual applies to HK-400III SYRINGE PUMP

Version No	Date of Preparation
V1.0.0	2018.08.17

User manual version upgrade instructions:

V X.Y.Z

V means version No. of user manual.

X means device has big upgraded: When software, hardware and construction of device have big modified, the user manual should be upgraded accordingly.

Y means the device has small improvement: In order to better using the device, the software, hardware and construction of device have been tiny improved (it is not necessary for re-registration after evaluation), the user manual should be upgraded accordingly.

Z means correcting information of user manual while the device has no changed. It only correct the wrong word/ diagram/explanation and so on.

1. Warnings & Cautions

Warning: Failure to follow precautions below may result in the risk of death or injury to patients.

- a) The Syringe Pump uses motor-driven screw for medical fluid infusion, but cannot detect leakage caused by disconnection or crack of infusion set. It is required to inspect the infusion status regularly to prevent above problems.
- b) During infusion process, please regularly check the status of the residual liquid inside the disposable sterilized syringe (Hereinafter referred to as the syringes) to ensure correct performance of the infusion.
- c) The Syringe Pump has occlusion detection function. It gives occlusion alarm when the infusion needle fails to insert into intravenous vein properly or the needle deviates from its position inside the vein during infusion. As occlusion alarm is given only after the occlusion pressure reaching a certain value, the area around the needle may already become swollen or bleeding at this time. In addition, the occlusion alarm is not given maybe because the actual occlusion pressure not large enough to reach the occlusion alarm gate, therefore, it needs to check the insertion area regularly. If the insertion area seems abnormal, please take proper treatments such as re-inserting the needle.
- d) Please use disposable sterile syringes which meet the requirements of relevant rules and standards and with valid medical device registration certificate. Accepted syringes include brands of Boon, RJ, Dragon Heart, double dove, HD, KDL. When choosing an infusion line, it is advisable to use the syringe with screw and extension tube. Otherwise, it may do harm to patients when the IV tubing is stretched.
- e) The user must install the syringe correctly. Otherwise, infusion may not reach expected performance.
- f) Avoid repeated use or re-sterilizing of disposable syringe. After using, the syringes should be handled in accordance with the appropriate guidelines.
- g) Fix the Syringe Pump well to infusion stand and also ensure the stability of the stand. Be cautious when moving the stand and the Syringe Pump to prevent the Syringe Pump falling off or the stand collision with surrounding objects.
- h) The Syringe Pump cannot use with possible large negative or positive pressure piping such as extracorporeal circuit. As in such case, the Syringe Pump cannot ensure infusion accuracy and correct alarm functions.
- i) The Syringe Pump cannot use for blood transfusion.
- j) Do not use the Syringe Pump near inflammable liquid or gas.
- k) Do not store or use the Syringe Pump in humid environment or environment with chemically active

gases (including gas for sterilization). Such environments may have an impact on internal electronic parts and thus bring degradation or damage to their functions.

- l) The syringe pump cannot be directly used vehicle power supply. It needs the support of inverse appliances to let car output becomes stable voltage before use. If exceeding the allowable voltage of syringe pump DC interface, the syringe pump will be burned.
- m) Please do not rely on the alarm system only; the medical staff should inspect the infusion regular to avoid accident.
- n) Under single fault condition, the maximum volume infused is the remaining volume in the syringe. It should inspect the infusion situation and check the syringe and tube regular.
- o) The operator should make sure the parameters setting in the pump are the same with the doctor's instruction and then start infusion. Any parameters excess the limited setting of system will lead to invalid operation.
- p) Please use syringe that meets relevant regulations and has a valid medical product registration certificate. Otherwise, infusion accuracy and detection alarm will be affected.

Cautions:

Failure to follow cautions below may lead to injury of operator/patient or loss of property.

- a) Inspect the Syringe Pump before use, making sure it can work normally. If any malfunction is found, stop operation immediately and contact the distributor or the manufacturer. Besides, adhesion or leakage of medical liquid may lead to malfunction of the syringe pump. Therefore please clean the Syringe Pump and store it properly after each use.
- b) When use the Syringe Pump the first time after purchasing or after long-time of storage, please connect it to AC power source and charge it for at least 10 hours with power on, or 3 hours with power-off. If not fully recharged, the internal battery can't support the Syringe Pump with enough power in case of AC power failure.
- c) If using near electric cautery equipment, the Syringe Pump may result in wrong operation due to the high frequency wave of electric cautery equipment. If the Syringe Pump has to be used with HF surgical equipment, please take proper measures as follows:
 - (1) Avoid using the Syringe Pump along with old-fashioned HF surgical equipment (open vacuum tube).
 - (2) The distance between Syringe Pump and the body of HF surgical equipment or its power source

should be more than 25cm.

(3) The Syringe Pump shall not use the same electric cabinet as that of HF surgical equipment, and having reliable ground connection.

- d) Do not use mobile phone, wireless device or cardiac defibrillator within 1 meter near the Syringe Pump. Otherwise the high frequency noise/signal may cause wrong performance of the Syringe Pump. Make sure the Syringe Pump has ground connection and do not use the same power socket with that for the above-mentioned devices.
- e) The Syringe Pump cannot use in area with radiotherapy equipment or magnetic resonance (MR) equipment or hyperbaric oxygen therapy.
- f) Do not use pointed object like pen-tip or finger nail (etc) to press on keys of the Syringe Pump. Otherwise, the keys or the mask may suffer premature damage.
- g) Keep the infusion set and the Syringe Pump a certain distance from the AC power source and DC socket to prevent the medical liquid from splashing or dropping onto the socket to incur shortage of circuit. In addition, make sure the power plug and socket are dry before connecting to power source.
- h) Try to use the medical liquid when it reaches or near room temperature.
- i) In normal conditions, try to use AC power source to extend battery service life. When use AC power source, making sure it is well connected to ground and please use the power cord that is standard configuration with the Syringe Pump. Just use battery when there is difficulty in ground connection or without AC power (such as AC power failure or mobile infusion).
- j) Pay more attention to occlusion when infusion at low rate. The lower the rate, the more time needed for detecting occlusion, thus there may be a long interval of infusion interruption.
- k) When using computer port, it may suffer interference from devices such as HF surgical equipment, mobile phone, wireless device or cardiac defibrillator etc. Please try to keep away from the above-mentioned devices.
- l) If the Syringe Pump falling off or suffering collision, stop using it immediately and contact the distributor or the manufacturer. Even there is no damage on appearance or no malfunction alarm, the internal parts may have damaged.
- m) The syringe Pump must be operated by well-trained professionals such as doctor, nurse and medical device expert.
- n) Do not disassemble or modify the Syringe Pump or use it for other purposes other than normal infusion. Otherwise, the manufacturer takes no responsibility.

2. Introduction

2.1 Features

User-friendly interface, easy operation.

2.8 inch colorful LCD with detailed menu.

Internal multiple reliable design and alarm functions, more stable and safer infusion.

Arc shape and easy cleaning.

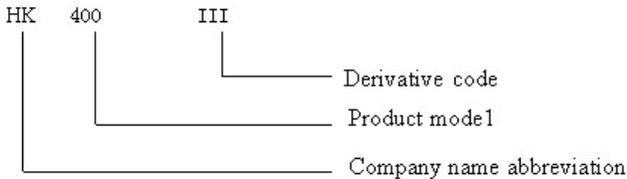
2.2 Application scope

It is used in hospitals where patient need intravenous infusion.

2.3 Type and specifications

This product belongs to class I , type CF. It is on continuous operation and with internal battery. It cannot be carried by patient for mobile use. It can't be used in mixed gases of flammable anesthetic gas with air, or of oxygen or nitrous oxide with flammable anesthetic.

2.4 The components of each model and definitions



2.5 Operating conditions

a) Temperature: 5°C-40°C

b) Relative humidity: 10-85% (no frosting)

c) Atmosphere pressure: 86.0kPa ~106.0kPa

2.6 Affection on environment and energy

This product may have certain electromagnetic radiation which may influence other devices. In such case, please take proper measures to reduce the interference such as re-locating the Syringe Pump, or using AC power from a different source etc.

2.7 Date of manufacture & life span

The life span of the syringe pump (battery is not included) and its cable is 5 years. Please refer to label for date of manufacture.

2.8 Version of software

The version of the user manual for infusion pump's software is V01.

3. Working Principle & components

3.1 Working Principle

Syringe pump is medical equipment that use motor driving screw and make rotary motion become linear motion, pushing syringe piston to deliver medical fluid to patients.

3.2 Components

The Syringe Pump is mainly composed of 5 parts: microcomputer system, pump body, detection device, alarm system and input & display part.

Microcomputer system: the brain of the whole system, giving an intelligent control and management to the whole system and processing signals detected, adopting double CPU.

Pump body: the heart of the whole system and the driving force of transfusing medical liquid. It uses step motor driving screw to push the syringe plunger forward.

Detection device: mainly containing sensors, such as ultrasonic sensor (for detecting motor running and reversing) and pressure sensor (for detecting occlusion) etc. They can detect corresponding signals, which after being amplified and transferred to microcomputer system for signal processing and thus incur control instruction for corresponding operation.

Alarm system: The signals detected by the sensor, after being processed by the microcomputer, shall incur alarm control signal and then at the response of alarm system, which alert the user for immediate correct operation. It contains mainly photoelectric alarm (light emitting diode) and audible alarm (loudspeaker and buzzer) etc.

Input & display part: Press keypad to set all parameters such as infusion volume and flow rate. LCD displays all parameters and present operation status.

4. Technical and specifications

Technical and parameters	
Applicable syringe	5, 10, 20, 30, 50/60ml disposable sterile syringes
Volume to be infused (VTBI)	0-9999.99 ml
Infusion mode	1. Rate mode 2. Time mode 3. WT. mode (Body weight mode) 4. Intermittent 5. TIVA mode 6. Drug lib (Drug library) 7. Programmable 8. TPN mode 9. Shift mode (Sequential) 10. Dose mode
KVO rate	0.1-10 ml/h, preset by the user; default: 0.1ml/h
infusion rate	5ml syringe: 0.1-150 ml/h 10ml syringe: 0.1-300 ml/h 20ml syringe: 0.1-600 ml/h 30ml syringe: 0.1-900 ml/h 50ml(60ml) syringe: 0.1-1800 ml/h Infusion accuracy: $\pm 2\%$
Bolus rate	5ml syringe: 0.1-150 ml/h 10ml syringe: 0.1-300 ml/h 20ml syringe: 0.1-600 ml/h 30ml syringe: 0.1-900 ml/h 50ml(60ml) syringe: 0.1-1800 ml/h

5. Installation

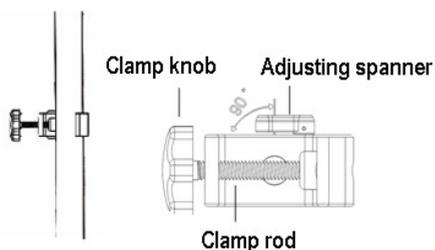
5.1 Installation conditions and technical requirements

The Syringe Pump can be fixed to a vertical IV pole or horizontal bar with diameter of 12-35 mm, or on platform with slope angle not exceeding 5°.

5.2 The Method of Adjusting Pole Clamp

The factory default setting of pole clamp is for vertical pole. If for horizontal bar, please follow the below steps:

- (1) counter-clockwise rotate adjusting spanner 180°.
- (2) counter-clockwise rotate pole clamp 90°.
- (3) Then rotate the adjusting spanner clockwise 180°.



5.3 Installation method and cautions

Method 1: Put the syringe pump on stable platform.

Method 2: Fix the syringe pump to IV Pole as per below steps:

- (1) Rotate the clamp knob screw out the clamp rod, leave space for IV pole.
- (2) Clamp the IV pole, screw down the knob to fix the position of syringe pump. Should hold the infusion pump during the installation; only release the hand after screwed tightly to avoid falling.

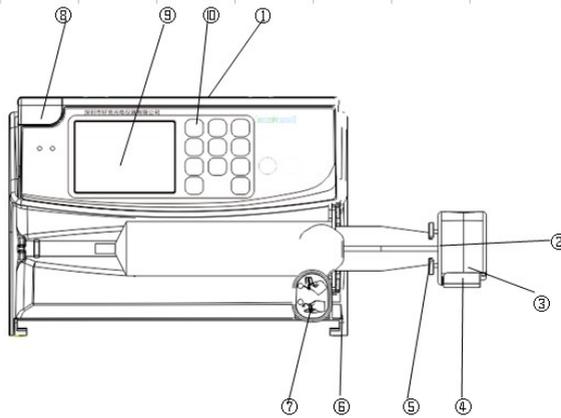
Make the syringe pumps stackable:

HK-400III has groove at top of device. Push another HK-400III into the groove, until hear a “da” sound which means two syringe pumps are well stackable together. Press the buckle at back of syringe pump to take out a single pump.

Maximum stackable quantity is 6 unit syringe pumps. Under stackable condition, temperature at top of device is relatively high; user should avoid to touch it.

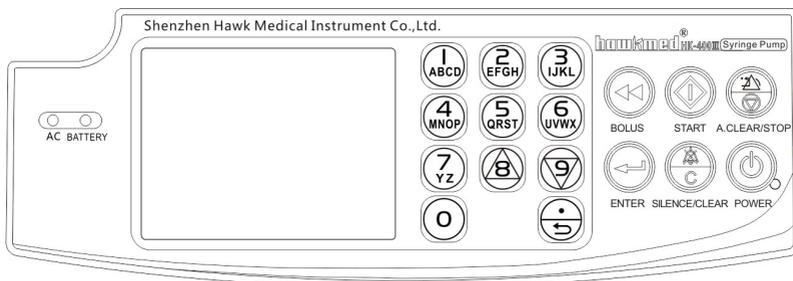
6. External Features

6.1 Front Appearance



- | | | |
|--------------------|---------------------|------------------------------|
| ①--carrying Handle | ②--detection button | ③--push handle |
| ④--clutch button | ⑤--clip | ⑥--syringe edge fixed groove |
| ⑦--pull handle | ⑧--Indicator light | ⑨--Display interface |
| ⑩--keypad | | |

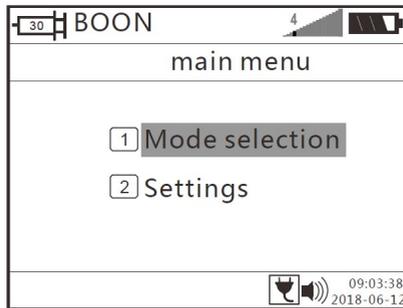
6.2 Keypad



describe	function
Indicator light	<p>Indicator light indicates operating status/alarms cases. The green indicator light flashes when the infusion is in normal progress.</p> <p>If high-priority alarm occurs, the indicator light shall turn red and flash.</p> <p>If middle-priority alarm occurs during operation, the indicator light shall turn yellow and flash.</p> <p>If low-priority alarm occurs during operation, the indicator light shall turn yellow but not flash.</p> <p>* Please refer to Annex Table I for priority of alarm classification.</p>
BOLUS key	There are manual bolus and auto bolus. Please refer to “8.1.7 Bolus infusion” for more info.
START key	In ‘stop’ status, press this key to start infusion.
STOP key	Press this key to stop infusion.
ENTER key	Make the parameters adjustable or save the parameter newly setting.
SILENCE /CLEAR key	<p>1.Press this key to silence the alarm signal.</p> <p>2 clear value when inputting parameters.</p>
POWER key	<p>Switch on / off the Syringe Pump.</p> <p>1.In ‘power off’ status, press this key until LCD screen displays, which means the pump is switched on.</p> <p>2.In ‘stop’ status, or in ‘alarm’ case, press this key and the pump shall be</p>

	switched off.
AC indicator light	If on, it indicates there's AC/DC input; if off, it indicates there's no AC/DC input.
Charging indicator light	This indicator light on means the battery is recharging. This indicator light off means the battery is not charging.
number key 8/ page up	1. In the numerical input status, it is digital key to enter the value of 8. 2. In the menu selecting status, press this button to turn the page (upturning).
number key 9/ page down	1. In the numerical input status, it is digital key to enter the value of 9. 2. In the menu selecting status, press this button to turn the page (Page Down).
Decimal point key/ Return key	1. Decimal point key works in the numerical input status. 2. In the menu selecting status, press this button to return to the last operation interface.

6.3 Screen Display



Battery icon

- 1). Red-yellow-green wave alternately appearing indicates the battery is charging.
- 2). The battery icon indicates status of battery remaining capacity.

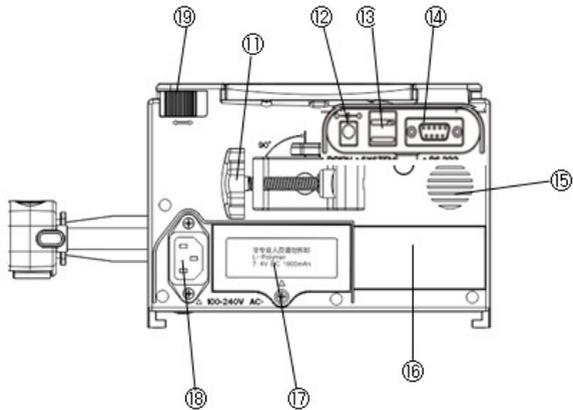
Pressure indicating icon

- 1). Red vertical line indicates the occlusion level setting in the system.
- 2). With the changing of pressure in infusion tube, pressure indicating icon will appear green surge wave. When the green wave reaches or passing the red vertical line, the syringe pump will give occlusion alarm.

AC power supply icons:

- 1). This icon "❌" means that the power cord is not connected.
- 2). This icon "🔌" means that the power cord is connected.

6.4 Rear Appearance



- | | | |
|------------------------|------------------|-------------------------|
| ⑪-- Pole clamp | ⑫--DC power port | ⑬--Expansion port (USB) |
| ⑭--RS232 port | ⑮--Speaker | ⑯--Label |
| ⑰--Battery Compartment | ⑱--AC power port | ⑲--Buckle |

Description	Functions
Pole clamp	It is used to fix the syringe Pump on IV stand.
Adjusting spanner	Draw the adjusting spanner outward or upward 180°; then rotate clamp for 90°for horizontal bar or vertical stand; then draw the spanner back in place to fix the clamp.
Battery compartment	Battery location. Open it from the bottom of machine.
AC power port	AC power connector.
RS232 port	It is used to connect syringe pump to standard PC to transfer infusion history records. Note: This process must be carried out

	<p>when machine in non-infusion state.</p> <p>The RS232 communication line must use shielded wire.</p>
DC power port	<p>It can be connected to DC power supply (10.8---13.2V 1.25A).</p> <p>Other external power source connected to the device must meet the standards of IEC60950 / IEC 60601-1. (10.8-13.2 V, 1.25A)</p>

6.5 Label

6.5.1 Product label (on the back shell)

The label contains information such as manufacturer, date of production, product serial No., classification, waterproof level, etc.

6.5.2 Symbols and significance

(Table 1)

Symbols	Description	Symbols	Description
	Production batch No.		Protective Earthing
	Product serial No.	IPX3	Waterproof level: dripping water by slope angel 60°
	Caution, consult accompanying documents		AC power
	Type CF		DC power
	Date of production		Please refer to usermanual

	<p>manufacturer</p>		<p>Dispose in environmental -friendly way</p>
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7. Preparation and Precautions before Use

7.1 Preparation and Inspection

Whether the Syringe Pump is a new one, or it has been stored for a period of time, or it just has been repaired, please check the following terms before use:

- (1) The outlook remains good, clean, no crack and no leakage.
- (2) All keys are responsive, no invalid key or stuck key.
- (3) Syringe pump pull handle, push handle, lead screw and clutch are flexible moving.
- (4) The power cord can be plugged in tight, not easy to loose.
- (5) If Syringe Pump worked on internal battery only, charge it fully before use and also make sure the battery is still valid for use.
- (6) Check or set the system time to ensure that infusion history is recorded correctly.
- (7) Carefully read the warning, precautions and operation procedures in this manual.

7.2 Operation Precautions

- (1) Avoid direct sunlight, high temperature or high humidity.
- (2) Avoid the syringe pump working with problem, so as to avoid medical malpractice and the harm to patients.
- (3) Setting or changing the parameters of the syringe pump should be under the trained professionals.
- (4) The syringe pump should be placed within 1.2 meter up or down the patient's heart.
- (5) If the panel is damaged, please replace the panel to avoid liquid entering into the syringe pump.
- (6) The syringe pump works under environment temperature that exceeding the predetermined range, which will reduce accuracy or even work abnormal.
- (7) The infusion fluid viscosity and proportion will affect the infusion precision.
- (8) In addition to the built-in six syringe brands, user must calibrate the syringe pump when using the other brand of syringe.

8. Operation Method

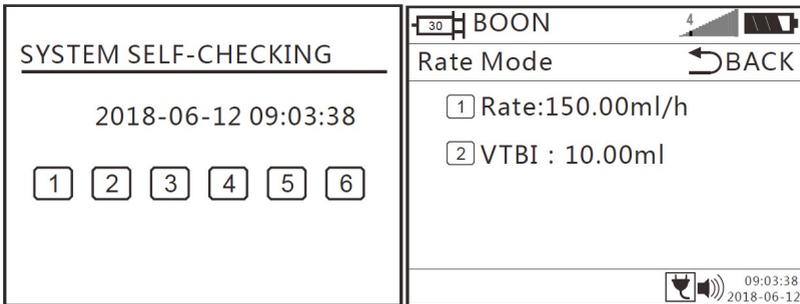
8.1 Operation

8.1.1 Fix the machine and connect the power cord.

Install the syringe pump and connect it to AC power according to Step 5.3. AC/DC indicator light will be on. The battery will start charging when connect to external power.

8.1.2 Switch on/off

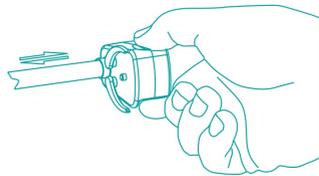
Switch on: Press POWER key for about 2 seconds, the pump will be switched on and do self-testing. After self-testing, it will display last used infusion mode.



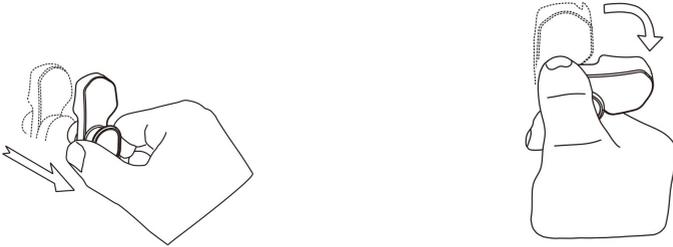
Press POWER key for about 2 seconds to turn off the machine. After the machine turn off, the accumulated volume will become 0ml.

8.1.3 Install the syringe

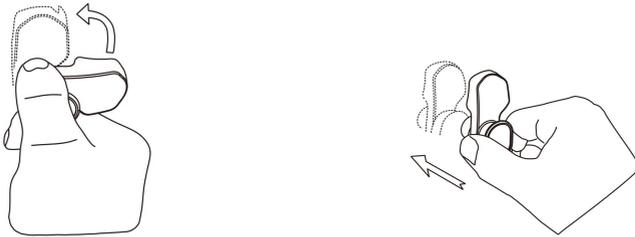
(1) Press the clutch and move the push handle right forward, release it when it reaches the end.



(2) Pull the pull handle of syringe pump to the end, then turn right 90° and fix it.



(3) Fill the syringe with medical liquid, connect it to extension tube and scalp needle, purge the air bubble in line, install the syringe in groove and syringe edge fixed groove. Turn the pull handle left 90°. It will rebound and compress the syringe.



(4) Press the clutch button on push handle tightly; move the push handle to the end of syringe handspike, release the clutch button, the clip will grip the end of syringe handspike automatically.



After correct installation, syringe pump will recognize the syringe size automatically, and displays the size on top left corner of LCD. Please make sure the size displayed on LCD is the same as the using syringe. Otherwise, it will affect the infusion accuracy and alarm functions.

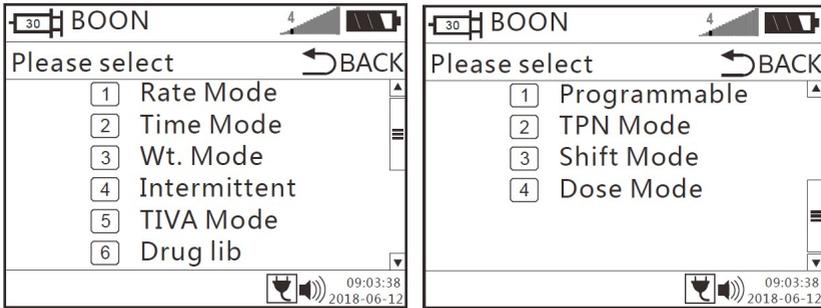
There are 6 brands of syringe built in the system: Boon, JR, LX, SG, HD, KDL. Please enter the setting menu to choose the correct brand. If you use another brand, please self-defined the syringe firstly accordingly to instruction 8.3.

Note: (1) Make sure there's no air bubbles in the syringe.

(2) Please make sure the end of syringe handspike is fixed on the groove of push handle, otherwise no liquid flowing out may cause harm to patients.

8.1.4 Set the parameters

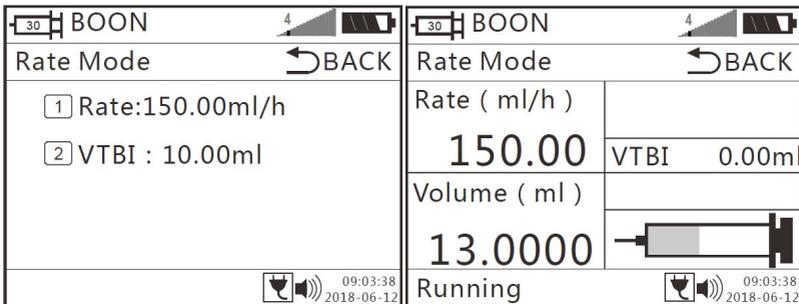
(1) On the main menu of the syringe pump, press the corresponding number key to select the infusion mode, eg: press number key 1 to select Rate mode.



(Diagram 814-1 syringe pump infusion modes)

Infusion modes:

1) Rate Mode:



Rate: Press number key 1 to select rate, input the rate value, press ENTER key to save the value and exit.

If the value entered is wrong, press CLEAR key and re-enter the value.

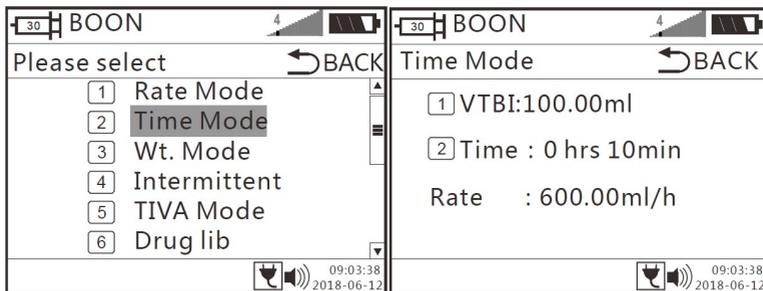
VTBI: Press number key 2 to select VTBI, input the value, press ENTER key to save the value and exit. If the value entered is wrong, press CLEAR key and re-enter the value.

Press return key  to main menu to select the other infusion mode.

It could change flow rate and VTBI without stopping infusion. During infusion, press ENTER key, press number key 1 to select rate, change rate value, press Enter key to save the value. Press number key 2 to select VTBI, change value, press Enter key to save the value. Press START key, the device will work under new parameters.

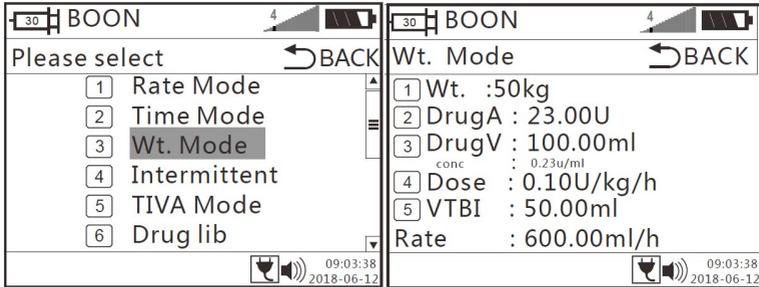
When infusion finished, press "STOP" key to eliminate "Finished" alarm, then press number key 3 for "End injection", the machine will return to rate mode parameter setting interface.

2) Time Mode:



Press number key 2 to enter time mode. Input VTBI and time by number keys, press ENTER key to save the value. The flow rate will be calculated automatically after setting the VTBI and time.

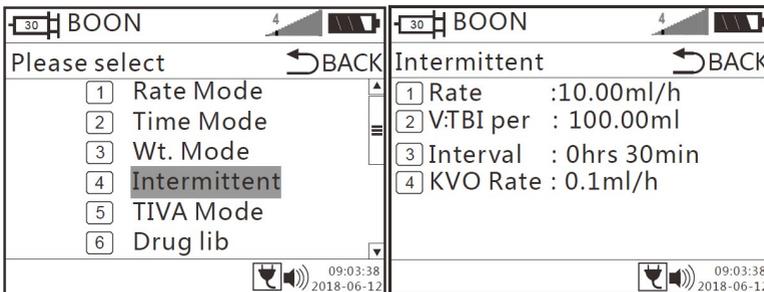
3) Body Weight mode (Wt. Mode):



Press number key 3 to enter body weight mode. Input weight, Drug A (Drug amount), Drug V (drug volume), dose rate & VTBI by number keys. The flow rate will be calculated automatically after setting the parameters.

It could change dose rate without stopping infusion. During infusion, press ENTER key, change the dose value, press ENTER key to save the value. The device will work under new parameters.

4) Intermittent Mode:



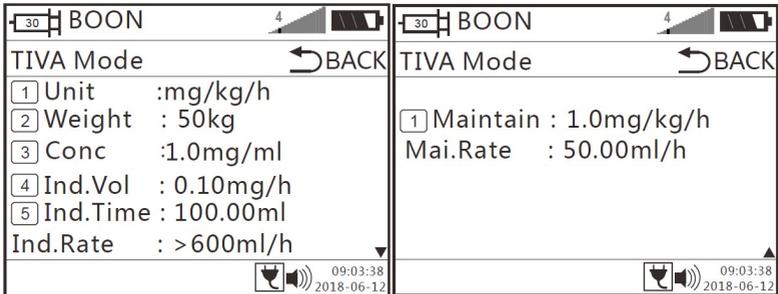
Press number key 4 to enter Intermittent mode.

Under intermittent mode, the infusion will be paused by interval time.

Input parameters of Rate, VTBI Per (VTBI Per time), interval time, press START key for infusion.

For example, VTBI Per=30ml, Interval time = 10mins, rate=100ml/h, when syringe pump finished infusion of 30ml medication, it will pause for 10mins and then start another 30ml.

5) TIVA mode:

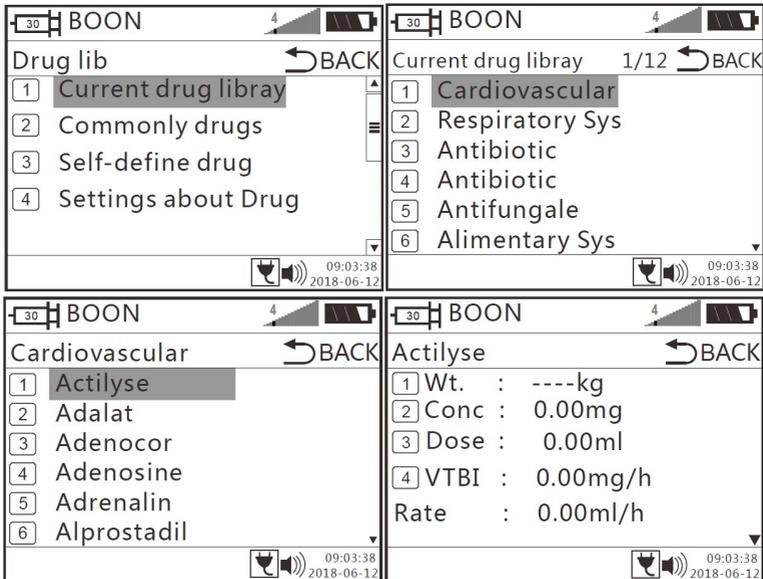


Press number key 5 to enter TIVA mode.

Input Unit, weight, concentration, induction volume, induction time and maintain dose, induction rate and maintain rate will be calculated automatically.

Press ▼ to next page to set Maintain dose.

6) Drug library Mode:



Press number key 6 to enter drug library mode.

1) Current drug library

Press number key 1 to select “Current drug library”, press ▼ to review the rest drug categories. There are total 3 pages.

Press number key to select specific drug category, press number key to select the specific drug. Press ▼ to review the rest drugs. Total pages of drugs under this category will be displayed at top of screen. After selecting the specific drug, the machine will display drug library infusion mode. Drug name will be displayed at top right of screen. Input infusion parameters and press START key to start infusion.

2) Commonly drugs

It needs manually set the commonly used drug under “4 Setting about drug”. After setting, “Commonly drugs” will display selected drug names.

It could store 30 mostly used drugs.

3) Self-define drug

Press number key 3 to enter “Self-define drug”.

Press corresponding number key to select drug and enter drug library infusion mode.

It has to enter drug name under “4 Setting about drug”.

4) Setting about drug

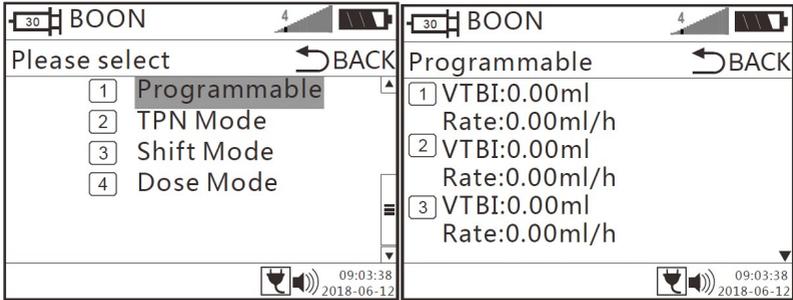
Press number key 4 to enter “Setting about drug”.

Press number key 1 for “Commonly drugs”, press corresponding number key to select drug category and drug name. After selected the drugs, press Return key ↩ twice to drug lib main menu. Under “Commonly drugs”, it will display the drugs selected.

Press number key 2 for “Self-define drug”. Press number key (1, 2, 3...), enter the alphabet(A,B,C.....Z) by letter keys. Press ▼ key to switch to next letter. Press ENTER key to save the drug name. Press ▼ key to select infusion mode: Rate mode, dose mode, weight mode, press ENTER key to save the mode. Press ▼ key to select dose unit (no need for rate mode), press ENTER key to save the unit. Press Return key ↩ twice to drug lib main menu. Under “Self-define drug”, it will display the self-defined drugs.

Under infusion mode main menu, press ▼ key to next page for the rest infusion modes.

1) Programmable

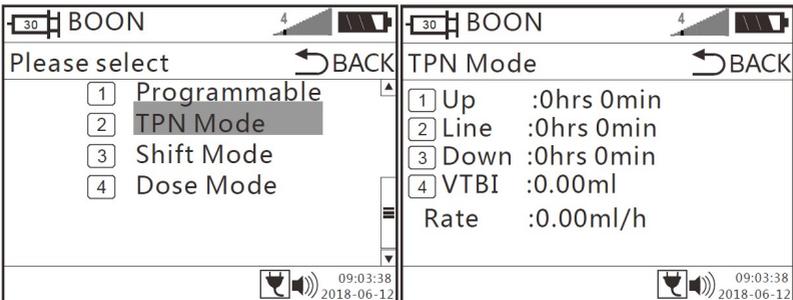


Press number key 1 to enter programmable mode.

Under programmable mode, the infusion is going under 3 sections/phases. When the first phase finished, the second phase will start automatically. When second phase finished, the third phase will start automatically. It allows to use only one or only two phases.

Input VTBI & Time for each phase. The flow rate of each phase will be calculated automatically.

2) TPN mode



Press number key 2 to enter TPN mode.

Input VTBI, up time, line time & down time, the flow rate will be calculated automatically for each phase.

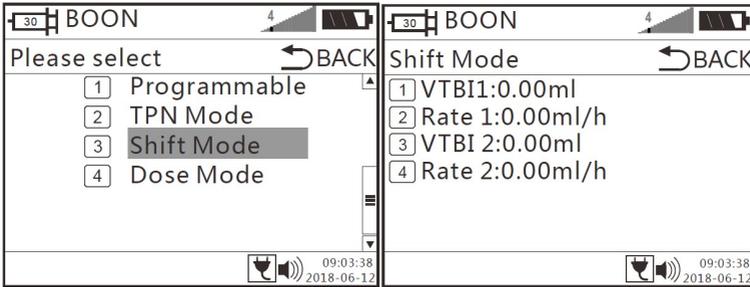
Press START key to start infusion.

During up time, flow rate keeps increasing.

During line time, flow rate is uniform/constant.

During down time, flow rate keeps decreasing.

3) Shift mode (Sequential)



Press number key 3 to enter shift mode.

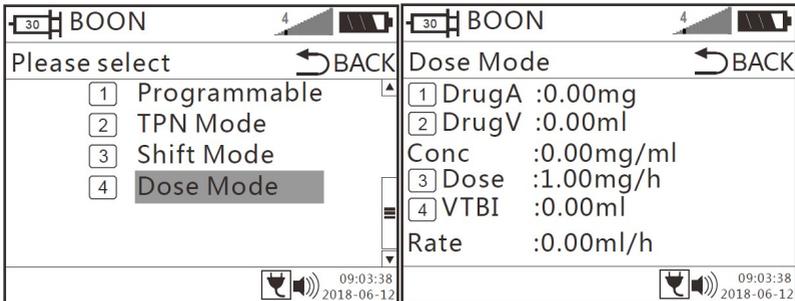
Under shift mode, the infusion is going under 2 sections. When the first section finished, the second section will start automatically.

Input VTBI 1 & Rate 1 for first section.

Input VTBI 2 & Rate 2 for second section.

Press START key to start infusion.

4) Dose Mode



Press number key 4 to enter dose mode.

Input parameters of Drug A (Drug amount), Drug V (drug volume), dose & VTBI, the Conc (Concentration) & flow rate will be calculated automatically. Press START key to start infusion.

It allows to change dose value without stopping infusion. During infusion, press ENTER key, change the value, press ENTER key to save the value. The syringe pump will work under new parameters.

8.1.5 Purge

In 'stop' status, when purge VTBI is 0ml, press & hold on BOLUS key until all air bubble inside the tube is purged out. When purge VTBI >0ml, press BOLUS key (one touch), the machine will start purge function automatically. The volume of purge is not included into volume infused.

Attention: Purge only works in 'stop' status and the syringe is not connected to patient.

8.1.6 Start infusion

Press START key after setting all the parameters correctly. During infusion, only BOLUS key and STOP key shall function. And it will show "Running" on the bottom of LCD, the indicator light flashes in green.

8.1.7 Bolus infusion

There are manual bolus and auto bolus.

1) Manual bolus:

When Bolus VTBI is 0ml, during infusion process, press bolus key and hold on, the pump will work at preset bolus rate. It will return to previous infusion rate after releasing your finger.

2) Auto bolus: After setting bolus rate & bolus VTBI>0ml, press Bolus key (one touch), the pump will start auto bolus function. It will return to previous infusion rate after reaching the target bolus volume.

During infusion, press number key 6 for fast setting of Bolus rate and Bolus VTBI. Press number key (1-5) to select Bolus of corresponding syringe, change the bolus rate, press ENTER key to save the setting. Press number key 6 to change Bolus VTBI value, press ENTER key to save the setting. Press Return key to working interface, press Bolus key (one touch) for fast infusion.

Attention: Different syringes have different bolus rate. Bolus rate can be setting on the system menu, please refer to 8.3.4 in user manual.

8.1.8 Stop infusion

During infusion or infusion completed, press STOP key to stop infusion. It will show Stop on the bottom of LCD, the indicator light is OFF. The Σ (volume infused) and other adjustable parameters are showed on LCD.

(1) If want to adjust the parameters, set them as required, press START key to infusion again.

(2) If want to end this infusion, choose “End injection” back to setting menu; the Σ (volume infused) will clear to 0 automatically.

8.1.9 Infusion completion

After VTBI completed or Σ (volume infused) reaching 9999.99ml, syringe pump shall start KVO Function automatically and give Finished alarm. Press STOP key to stop infusion.

★ KVO Function means keep patient’s vein open by keep infusion at a pre-set low rate.

8.1.10 Replace Syringe

(1) Pull the pull handle to the end then turn left 90°; keep pressing clutch button and take out the syringe.

(2) install syringe as per 8.1.3 in user manual.

8.2 Alarms and Solutions

During infusion preparation and process, alarms may occur as follows. Please treat them as below instructions.

Table 2 Refer to Annex Table1 for corresponding alarm parameters

Name of alarms	Cause for alarms	Solutions
Handle off	The end of syringe handspike is not correctly installed into push handle groove / not gripped by clip.	Press “A. CLEAR/STOP” key to clear the alarm signal. Re-install the syringe correctly.
Syringe off	During operation, take out the syringe or pull handle does not compress on syringe.	Press “A. CLEAR/STOP” key to clear the alarm signal. Re-install the syringe correctly.
Empty	The VTBI is complete.	Press Clear key to clear the alarm.
Occlusion	The syringe is blocked.	Press “A. CLEAR/STOP” key to clear the alarm signal.
	Occlusion alarm is too sensitive.	Adjust syringe pump occlusion pressure level as per 8.3.11
	Pressure sensor is defective.	Please contact distributor /manufacturer for

		repair.
Battery exhaust	Battery icon shows blank when operate on battery.	Plug AC power cord to clear the alarm. If AC power cord is not plugged in, the alarm shall cannot clear (will continue to alarm for 3mins at least).
Low Battery	Battery icon shows only 1 grid when operate only on battery.	Press “A. CLEAR/STOP” key to clear the alarm. If AC power cord is not plugged in, the alarm shall not clear (in this case, it can infuse at least 30min at medium flow rate).
Near empty	The syringe will be empty soon.	Press “A. CLEAR/STOP” key to clear the alarm signal, but will still display on the interface.
Almost Done (infusion near over)	The VTBI is almost completed.	Press “A. CLEAR/STOP” key to clear the alarm signal, but will still display on the interface.
Finished	The VTBI is completed.	Press “A. CLEAR/STOP” key to clear the alarm signal.
Use Battery	AC power cord is not plugged in.	Press “A. CLEAR/STOP” key or connect to AC power to clear alarm signal.
AC fail	Power failure or AC power plug off after switch on.	Press “A. CLEAR/STOP” key to clear alarm sound, please re-install the syringe correctly. Press STOP key to clear alarm(sound, signal and indicator light).
No Operate	If there is no operation on machine for 2 minutes after switch on, it shall give ‘no operate’ alarm.	Press “A. CLEAR/STOP” key to clear alarm sound, please re-install syringe correctly, Press STOP key to clear alarm(sound, signal and indicator light). If alarm source is not excluded, it will alarm again when reboot machine.
0xE0, 0xE1	1. 0xE0:data communication	Reboot the machine and load the

0xE2, 0xE3	Error.	parameters of last infusion to try operation again. If problem still occurs, contact distributor /manufacturer for repair.
	2. 0xE1: The syringe Pump's driving system has problem.	Reboot the machine and load the parameters of last infusion to try operation again. If problem still occurs, contact distributor /manufacturer for repair.
	3. 0xE2: The Infusion Pump's motor has problem.	Reboot the machine and load the parameters of last infusion to try operation again. If problem still occurs, contact distributor /manufacturer for repair.
	4. 0xE3: The Infusion Pump's data storage has problem	Reboot the machine and load the parameters of last infusion to try operation again. If problem still occurs, contact distributor /manufacturer for repair ★After restoring factory default setting, you need to calibrate the syringe parameters again.

8.3 System Parameters Setting

Press number key 2 in the main menu to enter the system parameters setting interface.

8.3.1 Select Syringe brand

The system has some brands of syringe: Boon, Terumo, BD, BBraun, HuaFu, FL, KDL, HD-B, HD, SG (Double dove), LX, JR(Jie Rui).

Press number key "1", it shows white editable frame, press "down arrow key 9" or "up arrow key 8" to choose the syringe brand. Press Enter key to save and exist.

Attention: The syringe pump only stores a few brands of syringe. When brand of syringe being used is not found here, please turn to instruction **8.3.2** to customize the brand and make calibration.

8.3.2 Syringe calibration

Press number key 2 to enter syringe calibration interface.

a. Set the brand name

Press number key 1 to enter “set the brand name” interface.

Press the corresponding number key to choose Brand A, or Brand B.....for self-define. Press letter keys (number keys) to enter the wanted alphabet, press “down arrow key 9” to switch to next editing letter and enter the wanted alphabet. During brand name editing, it could press “up arrow key 8” to switch to previous letter for editing. Press ENTER key to save new brand name.

Press Return key to last menu.

Detail instruction as follows:



As per above diagram, number key 1 for ABCD, number key 2 for EFGH, number key 3 for IJKL, number key 4 for MNOP, number key 5 for QRST, number key 6 for UVWX, number key 7 for YZ. Press number key “0” to enter numbers 0~9. Press CLEAR key if input wrongly.

Take “BrandB” self define to “BBRAUN” for example: “Settings” -> 2 “Syringe calibration” -> 1 “Set the brand name” -> 2 “BrandB”.

The first letter no need to change, press “down arrow key 9”
Press number key 1 twice to get B, press “down arrow key 9”,
press number key 5 twice to get R, press “down arrow key 9”,
press number key 1 once to get A, press “down arrow key 9”,
press number key 6 once to get U, press “down arrow key 9”,

press number key 4 twice to get N, press ENTER key to save the brand.

Note: Brand A~T can be self-defined, the maximum letters of each brand is 6. If want to use Brand A~T, press ENTER to set the syringe values directly.

b. Make calibration

Press number key 2 to enter “syringe calibration” interface. Press corresponding number key to choose the new brand. Press corresponding number key to choose the size of syringe needing calibration.

There are two options:

- 1) Auto measure syringe
- 2) Manual measure syringe

1) Auto measure syringe

Take 50ml syringe for example, press number key 1 to select “Auto measure syringe”.

A pop-up window display “make sure to install the 50ml syringe and stretch to 50ml mark”. If the syringe handspike was pulled to 50ml scale, and the syringe was well installation on the machine, press number key 1 to confirm yes. Otherwise, press number key 2 to select “No”.

When select yes, the machine will start auto measuring...When infusion finished (syringe handspike was pushed to the end), the screen display “Press confirm then take off the syringe”. Press number key 4 to confirm. Auto calibration finished.

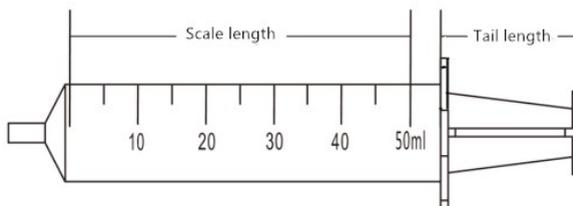
2) Manual measure syringe

Press number key 2 to select “Manual measure syringe”.

When syringe is installed to machine, input the scale length and tail length of syringe, press ENTER key to save the values. The machine will measure diameter of syringe automatically. Press number key 4 to confirm all the settings. Manual measure syringe finished.

When syringe is not installed to machine, input the scale length, tail length and diameter of syringe, press ENTER key to save the values. Press number key 4 to confirm all the settings. Manual measure syringe finished.

The following diagram is reference for measuring scale length and tail length of syringe. When measuring tail length of syringe, please push handspike of syringe to the end.



(Diagram 832-1)

C. Select Syringe brand that just calibrated

Press  back to settings main menu, press number key 1 "Syringe brand"- choose brand of syringe that just calibrated (8.3.1). The brand & size of syringe will display on the top left of LCD.

8.3.3 Set occlusion pressure level

The occlusion pressure has 13 levels (10kPa-130kPa)

Under system parameters setting interface, press number key 3 to enter occlusion level setting interface. Press number key 1, occlusion pressure level text become editable, press "up arrow key 8" or "down arrow key 9" to select the occlusion pressure level. Press ENTER key to save the setting.

Press number key 2 "Unit", press "up arrow key 8" or "down arrow key 9" to select the pressure units: kpa, psi, bar, mmHg . Press ENTER key to save the setting.

Attention: 1. When using a high viscosity liquid and the occlusion pressure level is setting to a low level, there is possible occlusion alarm even there is no block in infusion tube. Please carefully check the infusion tube and the pressure level indicated on top of LCD screen. If necessary, please increase the occlusion pressure level.

2. When the setting is high occlusion level, the pressure inside the syringe too large may flush away the extension line, please make sure the line is connected well with syringe.

8.3.4 Bolus setting

Under system parameters setting interface, press number key 4 to enter Bolus setting interface.

Press number key (1-5) to select Bolus of corresponding syringe, change the bolus rate, press ENTER key to save the setting. Press number key 6 to change Bolus VTBI value, press ENTER key to save the setting.

Set Bolus rate, keep VTBI as 0ml, the machine will work with manual bolus.

Set Bolus rate and VTBI >0ml, the machine will work with auto bolus.

Please refer to “8.1.7 Bolus infusion” for fast setting of Bolus during infusion.

8.3.5 KVO rate setting

Press number key 5 to enter KVO setting interface, press number key 1 to set this function on or off. Press number key 2 to change KVO rate. KVO means keep vein open.

8.3.6 Key lock setting

Press number key 6 to select key lock parameter. Press “down arrow key 9” or “up arrow key 8” to select “never”, “After 5 min” “After 4 min” “After 3 min” “After 2 min” “After 1 min”. Then press ENTER key to save the value and exit.

E.g.: If select “after 3 min”, when no operation for 3 minutes on machine, the machine will lock all the keys automatically.

To unlock the keypad, press Enter key + number key 2 together.

Press “down arrow key 9” to enter next page.

8.3.7 Alarm volume setting

Press number key “1” to enter the sound level setting. Press number key “8” or “9” to select “High” or “Low”, Press Enter key to save value and exit.

8.3.8 Back light Setting

Press number key “2”, then press number key “9” to select “Bright”, “Dark” or “5 min”, “4 min”, “3 min”, “2 min”, “1 min”, press ENTER key to save the value and exit. The LCD shall automatically darken in “5min” “4min” “3min” “2min” “1min”etc if no operation on keypad.

8.3.9 Key Sound Setting

Press number key “3”, select ON or OFF.

8.3.10 Set Date and Time

Press number key “4” for year/month/day/hour/minute/second setting. Press ENTER key to save your setting and exit.

8.3.11 Set pressure base value

Press number key 5 for “Press” to enter pressure base value setting interface.

The smaller the pressure base value, the higher sensitivity of the occlusion alarm. It should be calibrated by a pressure gauge. Select occlusion pressure level (8.3.3), test actual pressure value by pressure gauge, then adjust pressure base value.

When actual pressure value is lower than pressure value displayed on the pump (for example, Level: 40 Kpa), increase pressure base value; when actual pressure value is higher than pressure value displayed on the pump (for example, Level: 40 Kpa), decrease the pressure base value.

When the syringe being used is large than 5ml, press number key 1 to adjust pressure base value and press ENTER key to save the value.

When the syringe being used is 5ml, press number key 2 to adjust pressure base value and press ENTER key to save the value.

8.3.12 Infusion log setting

Syringe pump could store more than 1000 pcs history records, including turn on/off, start, stop and alarms during operation. When records are full, the new record will overwrite the old one. The records will not be lost even the device has been placed for a long time. The content of the records cannot be modified.

Select ‘1 Upload log’, all infusion records can be viewed on computer (only available when connect the pump to computer by RS232 interface). Select ‘2 View log’, the pump can directly display the latest infusion/alarm information. Press “Back” the pump shall return to ‘parameter setting interface’.

(1) Upload log: upload infusion records to computer. Please refer to steps as follows:

a. Connect the computer with 232 serial port line.

Open the super terminal (if there is no, pls open the computer main menu - program - Annex - Communication - super terminal, establish the super terminal named 115200 on the desktop. Click

disconnect icon , Disconnect the terminal connection. In the file menu, select "properties", set the COM port (according to actual 232port)

b. In 115200 property box, click on the "configuration". Set the baud rate: as 115200, Data flow controls as Xon/Xoff.

c. After the setting, click call Icon , Connect the terminal.

d. In the hyper terminal interface, select the "transfer - capture text". Establish a txt file named after a syringe pump serial number and then click "start".

e. Press number key "1", upload records to computer terminal. Press "transfer - capture text " after finishing uploading. And all infusion/alarms records can be reviewed on the txt that setting previously. After finishing uploading, the syringe pump returns to previous menu automatically.

(2) View Log: Press number key "2" to view latest infusion records/alarm information. Press 'Prev' to check the previous records or 'Next' for next records. Press 'Back' to return to previous menu. The system will not record the alarm that it is closed by the system.

(3) When the pump is power off, the history records are still kept inside. After shutdown, the electronic memory is 5 years.

8.3.13 "No Operation" alarm setting

After entering 'parameter setting interface', press number key "1" to select "OFF" or "10-1min", press ENTER key to save the setting.

"No Operate" alarm setting as "1-10mins": in 'stop' status, "No Operate" alarm shall sound when no operation on keypad in 1-10 minutes.

8.3.14 "Almost Done" alarm setting

After entering 'parameter setting interface' press number key "2" to select OFF or "10-1min". If set it as "1-10mins", "Almost Done" alarm shall sound "1-10mins" minutes before VTBI is complete.

8.3.15 Night mode setting

After entering 'parameter setting interface', press number key "3" for 'NIGHT mode' and select ON or OFF.

If set it as on, the LCD screen appears Night mode icon . If set it as on, the screen shall turn dark immediately. The top indicator light shall be off during infusion. However, if there is any alarm, the light shall be on.

8.3.16 Language setting

After entering 'parameter setting interface', press number key "4" to enter the language settings interface. Press corresponding number key to select the language. Press "down arrow key 9" to review the rest language.

8.3.17 Restore default setting

After entering 'parameter setting interface', press number key 5 to enter restore default setting interface, select "YES" or "NO". The default parameters at the factory are shown in this table:

Parameters	Factory default setting	Parameters	Factory default setting
KVO	0.1ml/h	Backlight	On
Occlusion level	40Kpa	Key sound	ON
Syringe	Boon Brand	Pressure base value	30
Key lock	never	No Operation	OFF
Volume	high	Almost Done alarm	OFF
Night mode	OFF		
Purge/Bolus	5ml Syringe: 100ml/h 10ml Syringe: 200ml/h 20ml Syringe: 400ml/h		

	30ml Syringe: 600ml/h 50/60ml Syringe: 1200ml/h
--	--

Note: restore the factory settings, please calibrate the syringe again.

8.3.18 WIIF

The syringe pump supports connection to HK-M1000 infusion monitoring system wirelessly, it works through WIFI module (optional) and router (optional).

Start WIFI function: After entering 'parameter setting interface', press number key 6 for "WIFI", set it ON to active the WIFI function. It will connect to the WIFI network which connected successfully last time.

WIFI functions: send the infusion status and alarms to HK-M1000 infusion monitoring system. For more information please refer to User manual of HK-M1000 Infusion monitoring system.

Attention: The configuration should be setting by the authorized engineer.

8.3.19 Inspection remind time

After entering 'parameter setting interface', press number key 1 for "Inspection", set the function off as 0 or 1-12 months. This function will remind user make inspection of device as per setting time.

8.3.20 Anti-Bolus

After entering 'parameter setting interface', press number key 2 for "Anti-Bolus", set the function as on, the machine will diminish the volume of unwanted Bolus after removal of the occlusion.

8.3.21 Purge VTBI

After entering 'parameter setting interface', press number key 3 for 'Purge VTBI', set the purge volume, press ENTER key to save and exit.

8.3.22 Near Empty

After entering 'parameter setting interface', press number key 4 for 'Near empty', set the function as off or 1-10mins. When setting the time 1-10mins, the machine will give near empty alarm 1-10mins before the syringe reaches to the end.

8.3.23 System check

After entering 'parameter setting interface', press number key 5 for "system check", set the function on or off. When the setting is on, the syringe pump will make self-testing when turn on the device. When the setting is off, the syringe pump will not make self-testing when turn on the device.

8.3.24 Auto shutdown

After entering 'parameter setting interface', press number key 6 for "Auto shutdown".

When set the time as 0, which will close this function.

When set the time 1-120min, if the machine doesn't work for 1-120 min, the infusion pump will turn off automatically.

8.3.25 Developer mode

It needs password to enter. It is for technical engineer only.

8.3.26 Machine info

It displays the machine software version, release version & SN.

8.4 Operation Precautions

- Avoid direct sunlight, high temperature and high humidity.
- If the pump work on battery only, please check battery capacity before operation and make sure it has enough power. Otherwise, recharge the battery fully.
- Avoid using the syringe pump with problems, which may cause medical accidents and bring harm to patient's health and even life.
- Only well-trained professionals are permitted to set or adjust infusion parameters.
- The Syringe Pump should be placed within 1.2 meters above or below patient's heat
- The damaged front panel (mask) need to be replaced in time to prevent leakage.
- Syringe Pump works under conditions that exceed the prescribed range may influence infusion accuracy or even cause malfunction.
- The degree of viscosity and ratio of medical liquid may influence infusion accuracy.
- The Syringe Pump uses 'Boon' brand syringe for factory setting. If users use the other brands of syringe, please calibrate its accuracy on machine before use.

8.5 Contraindications

No findings so far.

9. Malfunctions Analysis and Solutions

Problems	Causes	Solutions
Accuracy discrepancy	The Syringe edge did not install into the syringe edge fixed groove	Please install it correctly
	The syringe currently used does not match the default brand	Select the correct brand of syringe or self-defined syringe
	Certain parts of the machine may be defective	Contact the distributor or manufacturer for repair
Push handle cannot move freely	There are liquid on the screw	Wipe with a wet clean soft cloth

Besides the problems mentioned in 8.2, please contact the sales agent/manufacturer for repair.

10. Safety Invention and Troubleshooting

10.1 Safety Invention and precautions

- (1) AC power: built-in double fuses. When short circuit or any other malfunction occurs, the fuse shall cut off circuit in advance.
- (2) DC input: built-in fuse. When short circuit or any other malfunction occurs, the fuse shall cut off circuit in advance.
- (3) Battery protection: The battery contains protective devices against excessive pressure, over heat or short circuit, etc. to avoid overheating or burnt.

10.2 Troubleshooting

(1) If the syringe Pump gives system error alarm, stop the operation and contact the sales agent for repair. It can be used again only after it is well repaired and tested. Syringe Pump working with malfunctions may incur unpredictable damage.

(2) If the syringe Pump catch on fire or displays any other malfunction, please disconnect the power immediately and contact the sales agent /manufacturer.

11. Maintenance, inspection, repair and recovery

Shutdown and disconnect the DC / AC power cord before cleaning.

11.1 Daily maintenance

Routine maintenance includes the cleaning of outer shell and pump body. Clean it with wet soft cloth. Do not use solvents like xylene or acetone or other similar solvents which may corrode the syringe pump.

11.2 Maintenance during operation

The maintenance during operation mainly concerns the cleaning push handle and surrounding areas. Medical liquid may drip into the Syringe Pump during infusion process. Certain medical fluid may corrode the pump body; therefore clean the Syringe Pump every time after infusion completion.

11.3 Periodic inspection

11.3.1 check its appearance

- (1) all the machines look good, clean, no crack, no leakage.
- (2) each button is flexible and effective, no invalid or adhesive phenomenon.
- (3) press the clutch to push the handle to move back and forth. Check whether the screw rod is flexible or not.
- (4) power cord appearance is in good condition, fastening and not easy to pull off.

11.3.2 Check infusion accuracy (check once every 2 months)

Inspect periodically (refer to 8.3.2), if it is inaccurate please contact the sales agent /manufacturer.

11.3.3 Check internal battery

The battery shall reduce the performance due to prolonged usage, please check the battery capacity every other month.

- (1)First recharge the battery fully (10 hours with power on, or 3 hours with power off).
- (2) Let Syringe Pump work on battery only and set flow rate at 5ml/h. Record the whole working time when the battery is exhausted.

---If infusion time is more than 360 minutes, the battery is still in good condition.

--- If infusion time is more than 240 minutes but less than 360 minutes, the battery has begun to deteriorate, but still can be used.

--- If infusion pump is less than 180 minutes, the battery has reached the end of its life, it needs to be replaced.

Replace internal battery

It has better to replace the battery every year. It is advised to contact the supplier once battery is expired because they are not easy to be replaced. Battery replacement steps are listed as follows:

- (1) loosen the bottom shell screws and remove the battery cover.
- (2) unplug the battery cable lug and remove the battery.
- (3) Install the new battery. Please make sure the battery cable won't be squeezed by the battery cover. Then install battery cover. After replacing new battery, please check its working condition.

11.4 normal maintenance procedure

The repair job should be performed by supplier or distributor. It needs to make a complete inspection on machine after maintenance. If necessary,our company can offer circuit diagram and components list to authorized maintenance personnel.

11.5 Maintenance for long-time storage

If the Syringe Pump will not be used for long time, it should be placed in packing carton and avoid direct sunlight and keep it in cool and dry place. Refer to 12.2 for detailed storage conditions.

When using an Syringe Pump of long time storage, please refer to following steps before use:

- (1) Calibrate the Syringe Pump to ensure infusion accuracy and avoid possible medical accident.
- (2) Occlusion alarm testing.
- (3) Test the working time and recharging time of battery to ensure the battery can still be used.
- (4) Must be charged and discharged every three months to ensure battery life span.

11.6 Recycling

The machines and its cable which have been used over its life span should be scrapped. For more information, please contact manufacturer or our distributors. (Whether it is used frequently or not and whether it is repaired properly or not will impact infusion pump's life span.)

- (1) The scrapped syringe pump can be sent back to manufacturer or distributor.
- (2) The used battery can be sent back to manufacturer or distributor, or can be scrapped according to

legally proper way.

12. Transport and storage

12.1 Precautions during transport

- (1) Place the product as per No. of layers indicated on packing carton.
- (2) Temperature: $-20^{\circ}\text{C} \sim 45^{\circ}\text{C}$;
- (3) Relative humidity: 10~85% (no frosting)
- (4) Atmosphere pressure: 50.0kPa~106.0kPa

12.2 Storage conditions

Storage temperature: $-20^{\circ}\text{C} \sim +45^{\circ}\text{C}$ (With battery)

$-20^{\circ}\text{C} \sim +60^{\circ}\text{C}$ (Without battery)

Relative humidity: 10~85% (no frosting)

Atmosphere pressure: 50.0kPa~106.0kPa

13. Package list

13.1 Standard configuration in a package:

① Syringe pump	1 unit
② AC power cord	1 set
③ User Manual	1 pc
④ Product qualification certificate	1 pc
⑤ Warranty card	1 pc

13.2 Optional

Wifi module

14. Open-package Inspection

Cautions for Open-package inspection:

- (1) Opening the packing carton carefully to avoid damaging the machine or its accessories.
- (2) Handle with care all items inside the package.
- (3) Keep all accessories, warranty card and User Manual well for future use and reference.

- (4) Keep some packing cartons in case of using them to deliver defective machines.
- (5) If there is any accessory lacking or damaged, please contact the supplier at the earliest.

15. After Sales Service

The warranty for the syringe pump is one (1) year.

Note: The following situation is not within the range of free maintenance and repair.

- (1) Malfunctions resulting from improper operation, or modification / repair of the syringe pump without supplier's knowledge and permission.
- (2) Bruise or damage caused by improper handling during transport.
- (3) Malfunction or damage caused by fire, salt, poisonous gas, earthquake, hurricane, flood, abnormal electric voltage or any other natural disaster.

For all the malfunctions and damage due to above reasons, the manufacturer can offer repair but charge for the cost.

Appendix I

Information related to Electromagnetic Compatibility (EMC)



Attention:

- Syringe pump HK-400III meet the requirements of YY0505 standards related to Electromagnetic Compatibility;
- User should install and use according to the Electromagnetic Compatibility information provided by random file.
- Portable and mobile RF communication equipment may affect the performance of HK-400III syringe pump, please avoid strong electromagnetic interference during usage, such as near mobile phone, microwave oven, etc.
- Please see enclosed Guideline and manufacturer's statement



Warning:

- Syringe pump HK-400III should not be used nearby or stacked with other device. If it must be used nearby or stacked with the other devices, user should observe and verify it can work fine under its current configuration.
- Class A device is intended for use in Industrial environment, because Syringe pump HK-400III conduct and radiate Harassment, it may be difficult to ensure electromagnetic compatibility in other environments.
- Except the power cables provided by manufacturers of syringe pump HK-400III, using accessories and cables that is excluded in regulation may cause the increase of emission and decrease of noise immunity.

Annex:

Guidance and manufacture's declaration – electromagnetic immunity			
The syringe pump is intended for use in the electromagnetic environment specified below. The users of 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 GB/T 17626.2	±8 kV Contact discharge ±15 kV Air discharge	±8 kV Contact discharge ±15 kV Air discharge	The ground should be wood, concrete or ceramic tile, and if the ground is covered with synthetic material, the relative humidity shall be at least 30%

electrical fast transient GB/T 17626.4	$\pm 2\text{kV}$ for power line $\pm 1\text{kV}$ For input / output lines	$\pm 2\text{kV}$ for power line	Network power supply should have the quality used in typical commercial or hospital environment.
Surge GB/T 17626.5	$\pm 1\text{ kV}$ Line to line $\pm 2\text{ kV}$ Line to ground	$\pm 1\text{ kV}$ Line to line $\pm 2\text{ kV}$ Line to ground	Network power supply should have the quality used in typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on the power supply input wire GB/T 17626.11	$<5\% U_T$, last for 0.5 cycle (On UT, $>95\%$ of Voltage dips) 40% UT, last for 5 cycle (On UT, 60% of Voltage dips) 70% UT, last for 25 cycles (On UT, 30% of Voltage dips) $<5\%$ UT, last for 5S(On UT, $>95\%$ of Voltage sag)	$<5\% U_T$, last for 0.5 cycle (On UT, $>95\%$ of Voltage sag) 40% UT, last for 5 cycle (On UT, 60% of Voltage sag) 70% UT, last for 25 cycles (On UT, 30% of Voltage sag) $<5\%$ UT, last for 5S(On UT, $>95\%$ of Voltage sag)	Network power supply should have the quality that can be used in typical commercial or hospital environment. If user require syringe pump HK400III to run constantly during the power interruption, It is recommended to use uninterrupted power supply for Syringe pump HK-400III
Power frequency magnetic field (PFMF) (50/60Hz) GB/T 17626.8	400A/m	400A/m/50Hz/60Hz	PFMF should have the level and characteristic of PFMF used in typical commercial or hospital environment.
Note: "UT" refers to the AC power network voltage before applying test voltage			

Guidance and manufacture's declaration – electromagnetic immunity

The syringe pump is intended for use in the electromagnetic environment specified below. The users of syringe pump should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Radio frequency transmission GB/T 17626.6</p> <p>Radio frequency radiation GB/T 17626.3</p>	<p>3 V (Effective value) 150 kHz~80 MHz</p> <p>3 V/m 80 MHz~2.5 GHz</p>	<p>3 V (Effective value)</p> <p>3 V/m</p>	<p>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.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ <p>$d = 1.2\sqrt{P}$ 80 MHz ~ 800 MHz</p> $d = 2.3\sqrt{P}$ <p>$d = 2.3\sqrt{P}$ 800 MHz ~ 2.5 GHz</p> <p>In formula:</p> <p>“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).</p>

			<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, “c” should be less than the compliance level in each frequency range “d”</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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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 10 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	Separation distance according to frequency of transmitter(m)
-------------------------------	--

	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
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 II

Table 1 Classification of alarms and color of alarm indicator light

Alarm classification	Alarm priority	Color and frequency of alarm indicator light
Handle off alarm	High priority	Red / 2Hz
Syringe off alarm	High priority	Red / 2Hz
Occlusion alarm	High priority	Red / 2Hz
Low battery alarm	High priority	Red / 2Hz
Battery exhausted alarm	High priority	Red / 2Hz
empty	Middle priority	Yellow / 0.5Hz
Almost empty	Middle priority	Yellow / 0.5Hz
Almost Done alarm	Middle priority	Yellow / 0.5Hz
Finished alarm	Middle priority	Yellow / 0.5Hz

Use battery alarm	Low priority	Yellow, steady
AC fail alarm	Low priority	Yellow, steady
No operation alarm	Low priority	Yellow, steady

Table 2 Alarm conditions and alarm signal delay

Alarm classification	Alarm condition delay	Alarm signal delay
Handle off alarm	10ms	100ms
Syringe off alarm	10ms	100ms
Occlusion alarm	840s@1ml/h 27s@25ml/h	100ms
Low battery alarm	10ms	100ms
Battery exhausted alarm	500ms	100ms
Empty alarm	10ms	100ms
Almost empty	10ms	100ms
Almost done alarm	10ms	200ms
Finished alarm	10ms	200ms
Use battery alarm	10ms	200ms
AC fail alarm	10ms	200ms
No operation alarm	120ms	200ms

Table 3 Characteristic parameters of alarm signals

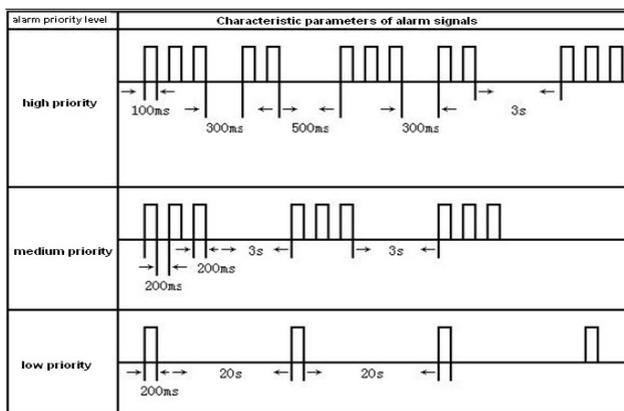
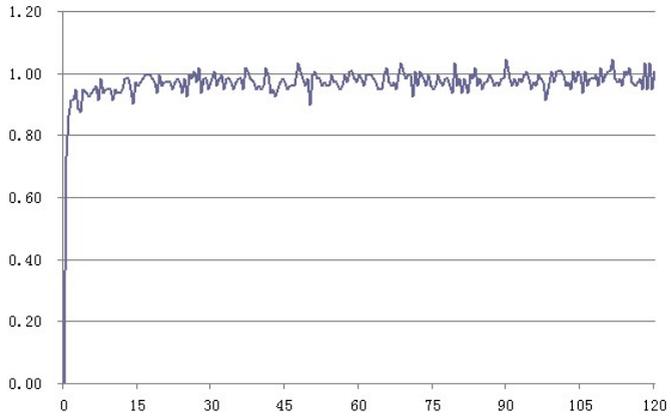


Table 4 Occlusion response characteristic

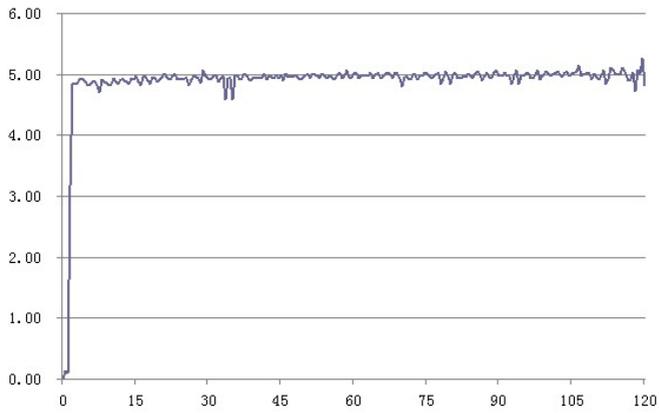
Flow Rate (ml/h)	OCCI alarm level	Occlusion pressure (KPa)	Occlusion alarm time
1	Low	41	12min59sec47s
	Middle	104	35min29sec
	High	144	42min53sec
5	Low	54	4min37sec69s
	Middle	90	7min09sec
	High	153	9min50sec

The above test uses 'Boon' brand of 5ml syringe. All the data are obtained by using 'Boon' brand syringe. The syringe pump has pressure release function. When occlusion alarm sounds, the pressure in the infusion line system will release automatically, so the bolus volume could be neglected when occlusion block release.

Table 5 Starting Curves

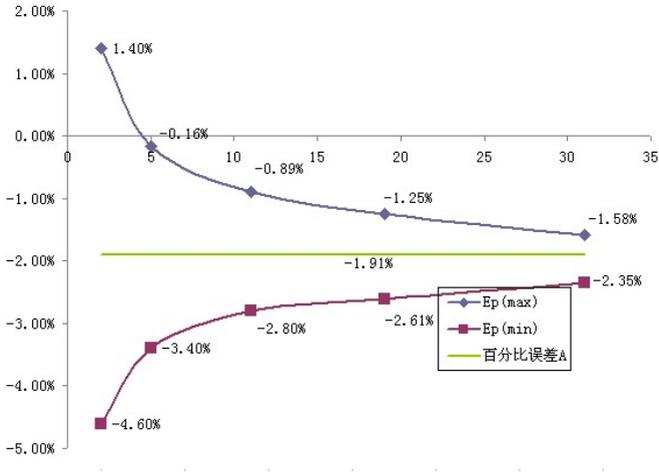


1ml starting curve

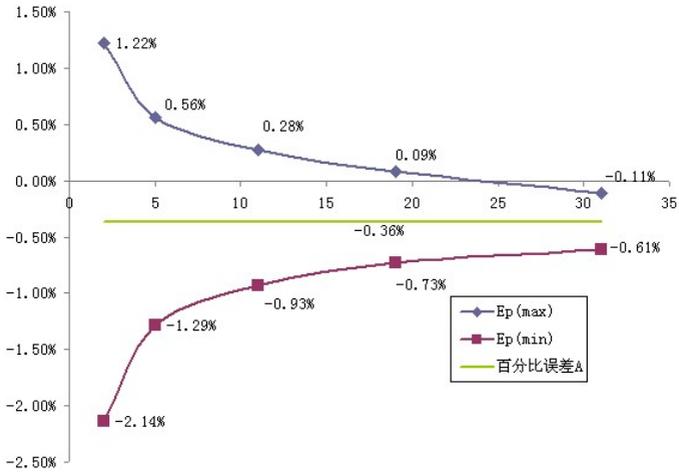


5ml starting curve

Table 6 Trumpet Curves



1ml Trumpet Curves



5ml Trumpet Curves

These data are testing result according to GB9706.27-2005 and the company's products standard. It use syringe pump and 10ml syringe under Boon brand.

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