Shenzhen Hawk Optical Electronic Instrument Co.,Ltd.

SYRINGE PUMP USER MANUAL

V1.0

Please read the manual before using the product;
Please keep the manual for reference !

CE 0120

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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) Infusion flow blockage that caused by infusion set knotting, filter or needle blocking, or needle occurring thrombosis etc. may lead to pressure increase inside the infusion set. Solving such blockage may be followed by temporary large-volume infusion. The correct method is to clamp the IV set near the insertion area tight before releasing the pressure. Then release the IV set, get rid of the occlusion problem and restart operation. If infusion restarting with blockage remains, occlusion alarm shall sound again and the pressure inside the tube may keep increasing, which may result in disconnection or crack of the tube and further bring harm to the patient.

e) Use the disposable sterilized syringe consistent with GB15810-2001. 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.

f) The user must install the syringe correctly. Otherwise, infusion may not reach expected performance.

g) Avoid repeated use or re-sterilizing of disposable syringe. After using, the syringes should be handled in accordance with the appropriate guidelines.

h) 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.

i) 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.

j) The Syringe Pump can not use for blood transfusion.

k) Do not use the Syringe Pump near inflammable liquid or gas.

l) 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.

m) The syringe pump can not be powered by the vehicle-mounted power supply. If the vehicle-mounted power supply is used, please add the voltage stabilizer or the power inverter complying with the safety regulations so as to let power supply output become the stable voltage complying with the input power of the syringe pump; if not, the syringe pump may be damaged seriously.

n) At any time when conducting the target-controlled infusion, please provide the all-around monitoring for the patient; user must be only the experienced and trained anesthetist, and he/she must know about the respiratory tract and breathing of the patient, and has been trained in sense of the cardio-pulmonary resuscitation skill.

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 electric cautery equipment, please take proper measures as follows:

(1) Avoid using the Syringe Pump along with old-fashioned electric cautery apparatus (open vacuum tube).

(2) The distance between Syringe Pump and the body of electric cautery apparatus or its power source should be more than 25cm.

(3) The Syringe Pump shall not use the same electric cabinet as that of electric cautery apparatus, 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 or DC 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 electric cautery apparatus, 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 Infusion Pump must be operated by well-trained professionals such as doctor, nurse and medical device expert.

n) Do not disassembly 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.

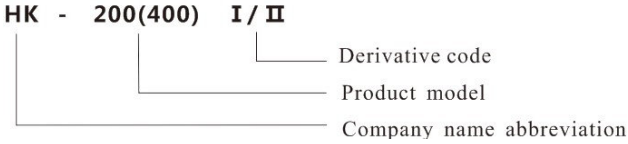
2.2 Application scope

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 can not 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℃-40℃
b) Relative humidity: 10-95% (no frosting)

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.

3. 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（60）ml disposable sterile syringes
Volume to be infused (VTBI)	（0-1000）ml
KVO rate	（0.1-2）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：(0.1-1500)ml/h Infusion accuracy：±2%
Bolus rate	5ml syringe：(100-150)ml/h 10ml syringe：(100-300)ml/h 20ml syringe：(100-600)ml/h 30ml syringe：(100-900)ml/h 50ml(60ml) syringe：(100-1500)ml/h
Purge	5mlsyringe：150 ml/h 10mlsyringe：300 ml/h 20mlsyringe：600 ml/h 30mlsyringe：900 ml/h 50（60ml）syringe： 1500 ml/h
Occlusion pressure	(40.0-160.0)kpa;3 levels (adjustable): low, middle, high; default: middle
Water Proof Level	IPX3
AC power	100-240V 50/60Hz
Battery	Li_Polymer 7.4V 1900mAh； Recharge time: 10h with power on, 3h with power off. Running time: more than 6h at rate of 5ml/h, environment temperature 25℃ after being fully charged.
Power consumption	25VA
DC	DC 12V ±1.2V
Fuse	Slow fuse Specification:250V 2A

Operating conditions	Environment temperature 5℃～40℃ Relative humidity: 10-95% (no frosting) Air pressure: 86kPa～106kPa
Dimensions	300(L)x 130(H)x 125(W, not including pole clamp)mm
Net weight	1.8kg
Glossary	
KVO	Keep vein open
Bolus	The amount of fast infusion
Purge	Rinse
anti bolus	Diminishes the volume of unwanted Bolus after removal of the occlusion.
Infusion tubing	Syringe and extension tube
Constant rate mode	Including rate mode、time mode、body weight mode、Intermittent mode、TIVA mode
TCI mode	Plasma TCI mode、Effect TCI mode
Intermittent mode	To control infusion by setting the flow rate, intermittent infusion volume, interval time and KVO rate
Plasma TCI mode	In population pharmacokinetic-with pharmacodynamic theory as a guide, it controls and adjusts the depth of anesthesia by directly controlling and maintaining the concentration of drug in the plasma at the desired value
Effect TCI mode	In population pharmacokinetic-with pharmacodynamic theory as a guide, it controls and adjusts the depth of anesthesia by directly controlling and maintaining the concentration of drug in onset body part at the desired value

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 12-35mm, or on platform with slope angle not exceeding 5°.

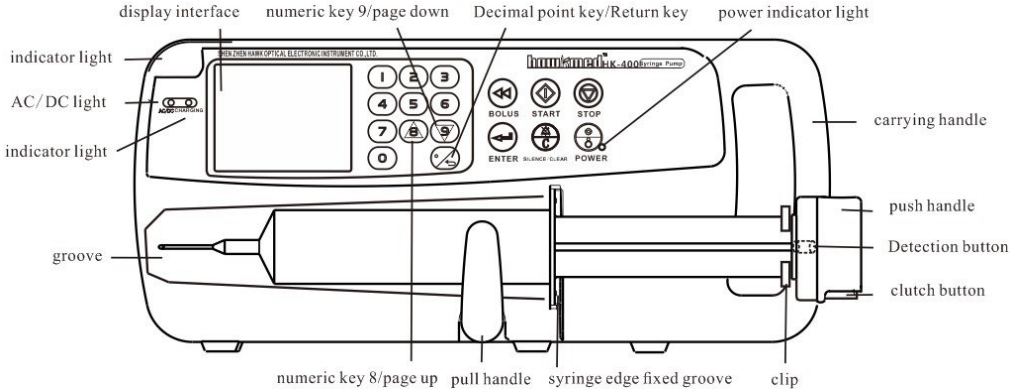
5.2 Installation method and cautions

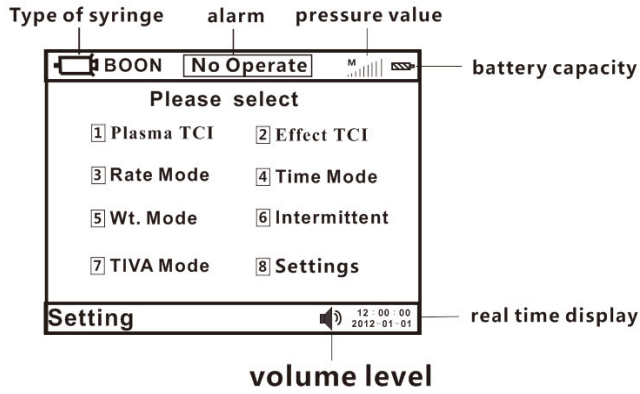
If the pole clamp is not in the same direction with that of IV stand or bar, adjust it to suit the direction of the IV stand or bar.

When fixing the pole clamp to IV stand or bar, use the other hand to hold the Syringe Pump until the clamp is well fixed.

6. External Features

6.1 Front panel



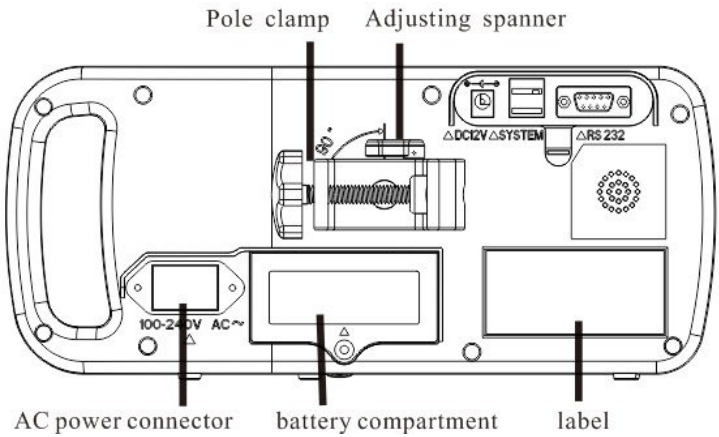


(Diagram1 LCD display)

Description	Functions
BOLUS key	In 'stop' status, press & keep finger on 'bolus' key, the pump starts purging. After releasing the finger, purging stops. During operation, press & keep finger on 'bolus' key, the pump starts bolus infusion (bolus rate preset by the user). Release the finger, bolus infusion stops and the pump continues infusion at original rate.
START key	In 'stop' status, press this key to start infusion.
STOP key	Press this key to stop infusion.
SILENCE /CLEAR key	1.Press this key to silence the alarm signal 2 clear value when inputting parameters
POWER key	Switch on / off the Syringe Pump. 1.In 'power off' status, press this key until LCD screen displays, which means the pump is switched on. 2.In 'stop' status, or in 'alarm' case, press this key and the pump shall be switched off.
ENTER key	Make the parameters adjustable or save the parameter newly setting
AC / DC indicator light	If on, it indicates there's AC/DC input; if off, it indicates there's no AC/DC input.
Indicator light	Indicator light indicates operating status/alarms cases. The green indicator light flashes when the infusion is in normal progress. If high-priority alarm occurs, the indicator light shall turn red and flash. If middle-priority alarm occurs during operation, the indicator light shall turn yellow and flash. If low-priority alarm occurs during operation, the indicator light shall turn yellow but not flash. * Please refer to Annex Table I for priority of alarm classification.
Charging indicator light	This indicator light on means the battery is recharging. This indicator light off means the battery is not charging.
numeric 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).

Description	Functions
numeric 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.
Display interface	Display Settings/ parameters/ working status etc.
groove	Syringe installation location
Pull handle	Used for fixation the syringe and avoid it disengage.
Syringe edge fixed groove	Used for fixation the syringe edge.
Push handle	Press and move clutch button on push handle, which drive the syringe pump screw moving
Detection button	To detect whether the syringe handspike is installed in place.
Clutch button	Keep pressing clutch button and move push handle freely.
clip	Use to fix the syringe handspike and avoid syringe handspike disengage

6.2 Rear panel



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 connector	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 when machine in non-infusion state. The RS232 communication line must use shielded wire.
DC12V input	It can be connected to DC power supply (12V±1.2V).
SYSTEM interface	Used for joint control with the other devices of our company.

6.3 Label

6.3.1 Product label (on the back shell)

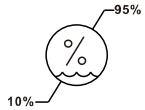
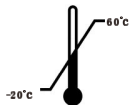
The label contains information such as manufacturer, date of production, product serial No., classification, waterproof level, etc.

6.3.2 Symbols and significance

(Table 1)

Symbols	Descriptions
	Production batch No.
	Product serial No.
	Caution， consult accompanying documents
	Consult instruction for use

Symbols	Descriptions
	Type CF
	Protective Earthing
IPX3	Waterproof level: dripping water by slope angel 60°
	AC power
	DC power
	Dispose in environmental-friendly way
	Date of production
	manufacturer
	Caution Against Wet
	Fragile. Handle with care!
	Keep upright during transport

Symbols	Descriptions
	5 layers at most of the same package
	Transport package humidity 10～95%
	Transport package temperature -20°C～60°C
EC REP	Authorized Representative in the European Community

7. 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 push handle could move freely.
(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.

8. Operation Method

8.1 Operation

The whole infusion operation contains the following processes:

1) Fix the Syringe Pump and connect it to AC/DC power.

2) Switch on / off

3) Install the Syringe

4) Set infusion parameters

5) Purge the air in line

6) Start infusion

7) Bolus infusion

8) Stop infusion

9) infusion completion

10) Replace Syringe

8.1.1 Fixed the syringe pump, connect it to AC/DC line

Adjust the pole clamp to fix the Syringe Pump properly to a stand/bar/cage and connect it to AC/DC power. At this time, the AC/DC indicator light ○ (on upper left corner) shall be on.

8.1.2 Switch on/off.

Press POWER key ⏻ until LCD displaying to turn on the machine.

Press POWER key ⏻ for about 2 seconds to turn off the machine.

Attention: The battery is being charged automatically when battery icon flashes.

8.1.3 Install the syringe

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

(2) Full the syringe with medical liquid, connect it to extension tube and scalp needle, purge the air in line, then install the syringe in groove and syringe edge fixed groove.

(3) Turn the pull handle right 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. Meanwhile, the size of syringe will be displayed on LCD.

Attention: (1) Make sure there's no air bubble in the syringe.

(2) Please make sure the end of syringe handspike is fixed on push handle groove, otherwise they will be no liquid output.

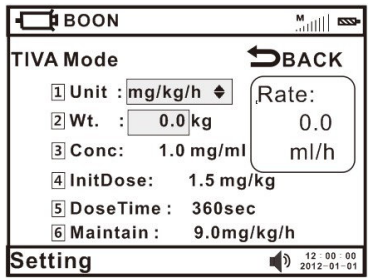
8.1.4 Set infusion parameters

8.1.4.1. Infusion Mode Parameter Table

Model	Infusion modes
HK-200	1.Plasma TCI mode 2.Effect TCI mode 3.Rate mode 4. Time mode 5.Body weight mode 6. Intermittent mode 7. TIVA mode
HK-200 Ⅰ	1.Plasma TCI mode 2. Effect TCI mode 3. Rate mode 4. Time mode

HK-400	1. Rate mode	2. Time mode 3.Body Weight Mode
HK-400 Ⅰ	1. Rate mode	2. Time mode
HK-400 Ⅱ	1. Rate mode 4. Intermittent mode	2. Time mode 3.Body Weight Mode 5. TIVA mode
mode	**parameters**	range
Rate Mode	Rate	0.1-1500ml/h
	VTBI	0-1000ml
Time Mode	VTBI	0-1000ml
	Time	1min-99hrs59min
Wt, Mode	Unit	mg/kg/h , ug/kg/min, ug/kg/h, mg/kg/min
	Wt.	0-300kg
	Conc	0-2000mg/ml
	Dose	0-2000
	VTBI	0-1000ml
Intermittent	Rate	0.1-1500ml/h
	Volume	0-1000ml
	Interval	1min-99hrs59min
	KVO Rate	0.1-2ml/h
TIVA Mode	InitDose	0.1-2000
	DoseTime	1-3600s
	Maintain	0.1-2000

8.1.4.2. Numerical value input method



（Diagram 2）

（1）As above diagram show, e.g. Setting “Unit”, its corresponding numerical value is 1, so press

numeric key “1”. “Unit” displays in a white text and that means it can be editing. When  displays on the right, press numeric key “8” or “9” to set the parameters. Press ENTER key to save the value newly setting, then the white text disappears.

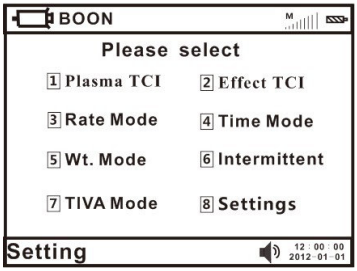
（2）If setting weight, input the number directly after the white text appearing, press ENTER key to save it. If input wrong number, press CLEAR key to remover and reset.

Attention:

(1) It can only continue to set other parameters after pressing ENTER key to save the value newly setting.

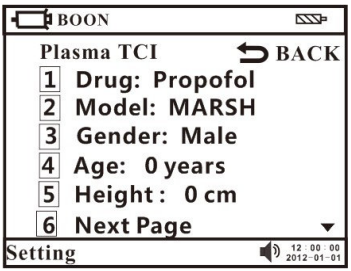
(2) If the setting value out of system default limit, the system will only display the minimum or maximum default value. Take body weight for example, if system default value is 3-150 kg, input 2, it will only display 3; input 160, it will only display150.

8.1.4.3. Submenu (Infusion Mode) Selection

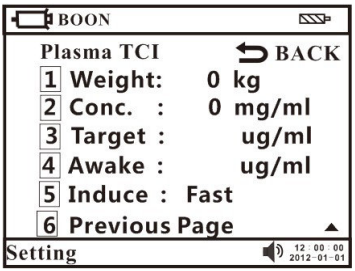


（Diagram 3）

（1）Plasma TCI mode

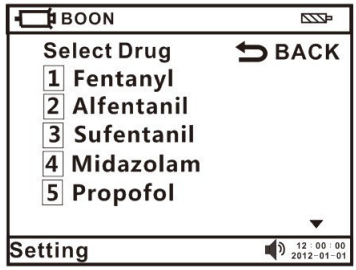


（Diagram 4）

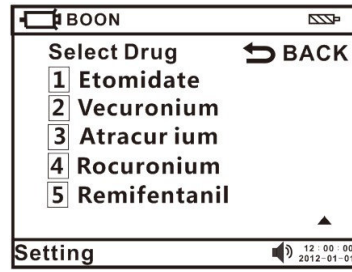


（Diagram 5）

On syringe pump main menu (Diagram 3), press corresponding number of Plasma TCI mode entering parameter setting interface (Diagram 4). At the bottom of LCD shows “next page”, press numeric key “6” entering the next page for parameter setting (body weight, drug concentration, target concentration, recovery concentration, induce method). After setting all parameters, the flow rate will be calculated automatically.



（**Diagram 6**）



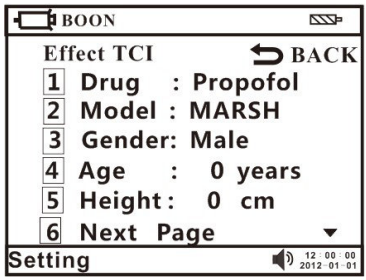
（**Diagram 7**）

Drug: Press numeric key “1” entering the drug selection interface (Diagram 6). If there is no required drug, press numeric key “9” entering the next page (Diagram 7). Select the drug according to initial number. Press numeric key “8” back to previous page.

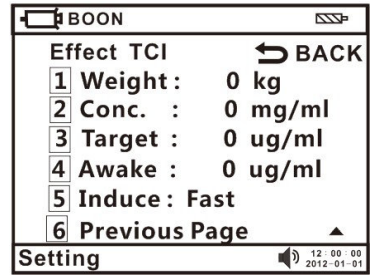
Set the other parameters as per above methods, press ENTER key to save value and exit.

Return: Press RETURN key ⮌ back to main menu (Diagram3) if want to reset the infusion mode.

（2）Effect TCI mode



（**Diagram 8**）



（**Diagram 9**）

On syringe pump main menu (Diagram 3), press corresponding number of Effect TCI mode entering the parameter setting interface (Diagram 8). At the bottom of LCD shows “next page”, press numeric key “6” entering the next page for parameter setting(body weight, drug

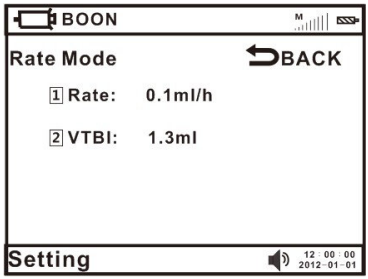
concentration, target concentration, recovery concentration, induce method).
After setting all parameters, the flow rate will be calculated automatically.

Drug: Press numeric key “1” entering the drug selection interface (Diagram 6). If there is no required drug, press numeric key “9” entering the next page (Diagram 7). Select the drug according to initial number. Press numeric key “8” back to previous page.

Set the other parameters as per above methods, press ENTER key to save value and exit.

Return: Press RETURN key back to main menu (Diagram3) if want to reset the infusion mode.

（3）Rate mode



（Diagram 10）

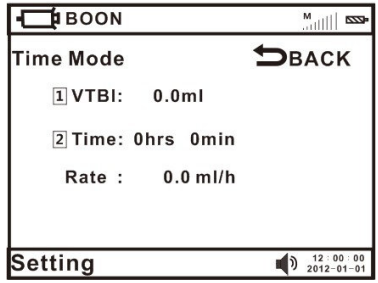
On syringe pump main menu (Diagram 3), press corresponding number key of rate mode enter the parameter setting interface (Diagram 10). Flow rate and volume to be infused (VTBI) can be setting.

Flow rate: Press numeric key “1”, input the flow rate in white text. If input wrong value, press CLEAR key to remove and reset. Press ENTER to save value and exit.

Setting VTBI parameter as per above methods.

Return: Press RETURN key back to main menu (Diagram3) if want to reset the infusion mode.

（4）Time mode



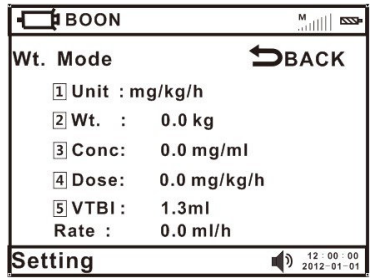
（Diagram 11）

On syringe pump main menu (Diagram 3), press corresponding number key of time mode entering the parameter setting interface (Diagram 11). VTBI and time can be setting.
VTBI: Press numeric key "1", input the VTBI (volume limit) in white text. If input wrong value, press CLEAR key to remove and reset. Press ENTER to save value and exit.
Setting **TIME** parameter as per above methods. After setting all parameters, the flow rate will be calculated automatically.

Attention: When the setting flow rate is more than the maximum limit, it will remind "Rate: >1500ml/h". Then please reset as above steps.

Return: Press RETURN key back to main menu (Diagram3) if want to reset the infusion mode.

5）Body Weight Mode



（Diagram12）

On syringe pump main menu (Diagram 3), press corresponding number key of Body weight mode entering parameter setting interface (Diagram 12). Unit, Body weight, concentration, dose, VTBI can be adjustable. The flow rate will be calculated automatically after setting the other parameters.

Unite: Press numeric key "1", there are 4 optional units "mg/kg/h、mg/kg/min、ug/kg/h、ug/kg/min". Press numeric key "8" or "9" to choose the required unit, press Enter key to save value and exit.

Body weight: press numeric key "2", input the weight in the white text. If input wrong value, press CLEAR key to remove and reset. Press ENTER to save value and exit.

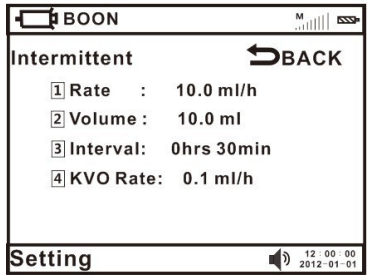
Set the other parameters in the same way.

Return: Press return key ⮌ back to main menu (Diagram3) if want to reset the infusion mode.

Attention: The flow rate will be changed when switch the Unit.

1. If there is parameter forgotten to set, it will remind "Parameters haven't been set" when start infusion. Press Return key ⮌ back to parameter setting interface, check and set it.
2. When the setting flow rate is larger than the maximum limit of syringe pump, it will remind "Rate out of range" when start infusion. Press Return key ⮌ back to parameter setting interface, check and set it.

（6）Intermittent Mode

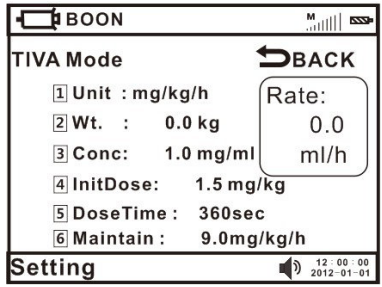


(Diagram 13)

On syringe pump main menu (Diagram 3), press corresponding number key of Intermittent mode entering parameter setting interface (Diagram 13). Flow rate, volume limit each time, interval time and KVO rate can be setting. Press Enter key to save value and exit.

Return: Press RETURN key ⮌ back to main menu (Diagram3) if want to reset the infusion mode.

（7）**TIVA mode**



(Diagram 14）

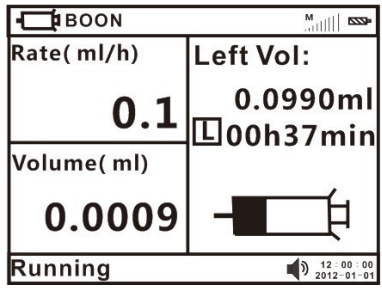
On syringe pump main menu (Diagram 3), press corresponding number key of TIVA mode entering parameter setting interface (Diagram 14). Unit, Body weight, concentration, induction volume, dose time and maintaining rate can be setting. Press Enter key to save value and exit.

Return: Press return key ⮌ back to main menu (Diagram3) if want to reset the infusion mode.

8.1.5 Purge

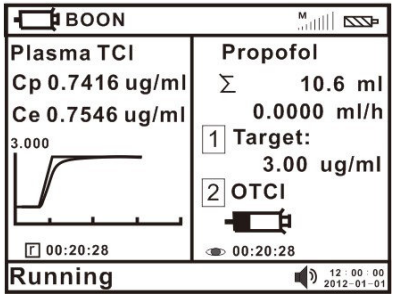
In ‘stop’ status, press & hold on BOLUS key until all air inside the tube is purged.

8.1.6 Start Infusion



(Diagram15 Constant Flow Rate mode running interface）

（Diagram16 Reminding interface before TCI mode running）



（Diagram 17 TCI mode running interface）

（1）Press START key after setting all the parameters correctly. During infusion, only purge key and stop key shall function. And it will show “operating” on the left bottom.

（2）When working under plasma / effect TCI mode, the target concentration can be adjustable; the operator can adjust it as the practical situation.

8.1.7 Bolus Infusion

During injection, press & keep finger on BOLUS key, the pump shall start bolus infusion at pre-set bolus rate. Releasing the finger, the pump shall continue infusion at original rate.

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, press STOP key to stop infusion. It will show the Σ (volume infused) and other adjustable parameters, set them as required, press START key to work again. Choose “End injection” back to setting menu; the Σ (volume infused) will clear to 0 automatically.

8.1.9 Infusion completion

After VTBI completion or Σ (volume infused) reaching 9999.9ml, the pump shall start KVO Function automatically and give over 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 alarm	The end of syringe handspike is not correctly installed into push handle groove / not gripped by clip.	Press SILENCE key to clear the alarm signal. Reinstall the syringe correctly.
syringe off alarm	During operation, take out the syringe or pull handle does not compress on syringe.	Press SILENCE key to clear the alarm signal. Reinstall the syringe correctly.
Empty Alarm	The VTBI is complete .	Press Clear key to clear the alarm.
Occlusion alarm	The infusion line is blocked	Press SILENCE key to clear the alarm signal.
Battery exhaust alarm	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 alarm	Battery icon shows only 1 grid when operate only on battery	Press SILENCE 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 alarm	The syringe will be empty soon.	Press SILENCE key to clear the alarm signal, but will still display on the interface.
Almost Done alarm (infusion near over)	The VTBI is almost completed	Press SILENCE key to clear the alarm signal, but will still display on the interface
Finished alarm	The VTBI is completed	Press SILENCE key to clear the alarm signal.

Name of alarms	Cause for alarms	Solutions
Use Battery alarm	AC power cord is not plugged in.	Press SILENCE key or connect to AC power to clear alarm signal.
AC fail alarm	Power failure or AC power plug off after switch on.	Press SILENCE key or connect to AC power to clear alarm signal
No Operate alarm	If there is no operation on machine for 2 minutes after switch on, it shall give 'no operate' alarm.	Press any key to clear the alarm
0xE0，0xE1 0xE2，0xE3	1 0xE0:data communication error.	Reboot the machine and load the 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 Setting and Accuracy Calibration

On main menu, press numeric key entering system setting.

8.3.1 Select Syringe brand

Press numeric key "1", when it become white text, press numeric key "8" or "9" 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.

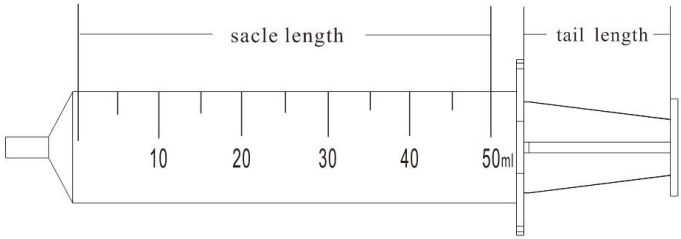
8.3.2 Self-Defined Syringe

Press numeric key "2" entering syringe self-defined interface, then select a brand entering parameters setting interface, setting parameters of the syringe, press enter key to save the value newly setting. Press numeric key "3" or ⮌ key return to previous menu.

Self-defined syringe method: e.g.: choose a 50ml syringe. Install this syringe to syringe pump as per instruction 8.1.3. Select **"Brand A"**, select 50ml syringe, input the actual scale length and tail length (Diagram 18), press enter key to save the value newly setting. Press numeric key "3" or ⮌ key return to previous menu.

Back to system setting main menu, Press numeric key "1",select **"Brand A"**, press enter key to save the setting.

Attention: If select Brand B for syringe self-defined, it must choose brand B under item 1 "syringe" on main menu of system setting. Meanwhile, top left corner of LCD shows "brand A".The machine then works under parameter setting of Brand B. Otherwise, the machine will work under previous default brand setting.



（**Diagram** 18）

8.3.3 Set occlusion Alarm level.

This parameter should be calibrated by pressure scale. Users should adjust this parameter according to the selected syringe.

Occlusion value is range from 40Kpa to 160Kpa.

Press numeric key "3", appear white text box, press numeric key "8" or "9" to select "High"/ "Middle"/ "Low" as per real situation. Press Enter key to save value and exit.

If the actual pressure value measured upon Occlusion alarm is higher, adjust occlusion alarm level to a smaller one. Otherwise, adjust occlusion alarm level to a larger one.

After setting, re-measure the actual pressure value to ensure actual pressure value is within occlusion alarm level range.

8.3.4 Bolus Rate Setting

Press numeric key "4" entering the bolus rate setting interface, set the bolus rate according to practical situation. Press Enter key to save.

8.3.5 KVO Rate Setting

Press numeric key "5" to set the KVO rate, input the value and press enter key to save.

8.3.6 Key Lock setting

Press numeric key “6” to set key Lock. Press numeric key “8” or “9” 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.

Remark: Setting as “After 5 min” “After 4 min” “After 3 min” “After 2 min” “After 1 min” means all keys shall be locked (except POWER key) “After 5 min” “After 4 min” “After 3 min” “After 2 min” “After 1 min” if no operation on keys. This icon shall display on LCD.

To unlock the panel, press ENTER key and numeric key “2” together.

Press numeric key “9” **to enter the next page of system setting.**

8.3.7 Alarm Volume Setting

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

8.3.8 LCD backlight level setting

After entering ‘parameter setting interface’, press numeric key “2”, then press numeric 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.

Remark: Selecting “5min” “4min” “3min” “2min” “1min”etc. means select the corresponding backlight level. The LCD shall automatically darken in “5min” “4min” “3min” “2min” “1min”etc if no operation on keys.

8.3.9 Key Sound Setting

After entering ‘parameter setting interface’, Press numeric key “3”, select ON or OFF。

8.3.10 Set Date and Time

After entering ‘parameter setting interface’, press numeric key “4” for year/Month/day/hour/minute /second setting. Press ENTER key to save the value and exit.

8.3.11 Set pressure base value

After entering ‘parameter setting interface’, press numeric key “5”, then input pressure value and press ENTER key to save the value . The smaller the pressure base value, the more sensitive the pressure alarm.

8.3.12 View the event logs/alarm records

After entering ‘parameter setting interface’, press numeric key “6” for ‘Log’. 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 syringe pump to a computer with RS232 cable.
Computer (in power-on status)-click “start” (left bottom corner)-click “programs”-click “accessories”-click

"communication"-click "hyper terminal"-click disconnect icon  . Then in "file" menu, select "properties" and set COM interface (according to actual 232port).

b. In 115200 properties interface, click "configure" and set "baud rate" as 115200 and data flow control as Xon / Xoff.

c. After setting is complete, click call icon  to connect to terminal.

d. In Hyper Terminal interface to select "Transfer - Capture Text" , recommending set up a txt named after a syringe pump serial number on the computer, and then click "Start".

e. Press numeric 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 numeric key "2" to view latest 1500 pieces of infusion records/alarm information. Press 'Prev' to check the previous records or 'Next' for next records. Press 'Back' to return to previous menu.

(3) Return ： Press "Back" to return to parameter setting interface

(4) After shutdown, the electronic memory is five years.

8.3.13 "No Operate" alarm setting

After entering 'parameter setting interface' press numeric key "1" to select "ON" or" OFF" . "No Operate" alarm setting as on: in 'stop' status, "No Operate" alarm shall sound when no operation on keys in 2 minutes.

8.3.14 Almost Done alarm

After entering 'parameter setting interface 'press numeric key "2" to select ON or OFF. If setting as ON, "Almost Done" alarm shall sound 3 minutes before VTBI is complete.

8.3.15 Night mode on and off setting

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

If setting as ON,  shall display on LCD. Key shall be off; the screen shall turn dark after 1 minute if no operation on keys; the top indicator light shall be off during infusion. (If there is any alarm, the light shall be on.)

8.3.16 Select language

After entering 'parameter setting interface' Press numeric key "4" to enter language setting interface .Select "Chinese", "English" or "Cancel".

8.3.17 Restore default

After entering 'parameter setting interface', press numeric key "5" to turn to restore default

interface, select “YES” or “NO”.
Attention: After selecting ‘Restore Default’ the syringe parameter need re-calibration.

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 dose 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 can not 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 caught fire or displays any other malfunction, please disconnect the power immediately and contact the sales agent /manufacturer.

11 Maintenance, Inspection, Repair and Recycling

11.1 Routine 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 Inspect infusion accuracy (once every 2 months)

Inspect periodically, if it is inaccurate please contact the sales agent /manufacturer.

11.3.2 Inspect 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 Infusion 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 more than 360 minutes, the battery is in good condition.

---If Infusion time more than 240 minutes but less than 360 minutes, the battery starts low quality but still can be used.

---If infusion time less than180 minutes, the battery reaches the end of its life and needs to be replaced.

Replace internal battery

(1) Unscrew the screws at the bottom of machine; remove the battery cover.

(2) Unplug the battery cable and take out 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 repair procedures

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) Test occlusion alarm.

(3) Test the working time and recharging time of battery to ensure the battery can still be used.

11.6 Recycling

The normal working life of the Syringe Pump is five (5) years. The usage frequency and maintenance property level shall affect working life of machine. When exceeding the normal working life, the syringe pump needs to be well scrapping. Please contact the manufacturer or distributor for more info.

(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℃～60℃;

(3) Relative humidity: 10～95% (no frosting)

(4) Atmosphere pressure: 50.0kPa～106.0kPa

12.2 Storage conditions.

Storage temperature: --20℃～45℃;

Relative humidity: 10～95%　(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 accessory

Nurse call interface

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 Infusion 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 Infusion 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.

Annex

Table 1 Classification of alarms and color of alarm indicator light

Classification of alarms	Alarm priority	Color and frequncy of alarm indicator light
Handle off alarm	High priority	Red/2Hz
Syringe off alarm	High priority	Red/2Hz
Occulusion alarm	High priority	Red/2Hz
Low battery alarm	High priority	Red/2Hz
B.Exsaust 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

Names of alarm	Alarm condition delay	Alarm signal delay
Handle off alarm	10ms	100ms
Syring off alarm	10ms	100ms
Occlusion alarm	840s@1ml/h 27s@25ml/h	100ms
LowBattery alarm	10ms	100ms
B.Exhaust alarm	500ms	100ms
empty alarm	10ms	100ms
Almost empty	10ms	100ms
AlmostDone alarm	10ms	200ms
Finished alarm	10ms	200ms
Use battery alarm	10ms	200ms
AC fail alrm	10ms	200ms
No Operation alarm	120ms	200ms

Table 3 Characteristic parameters of alarm signals

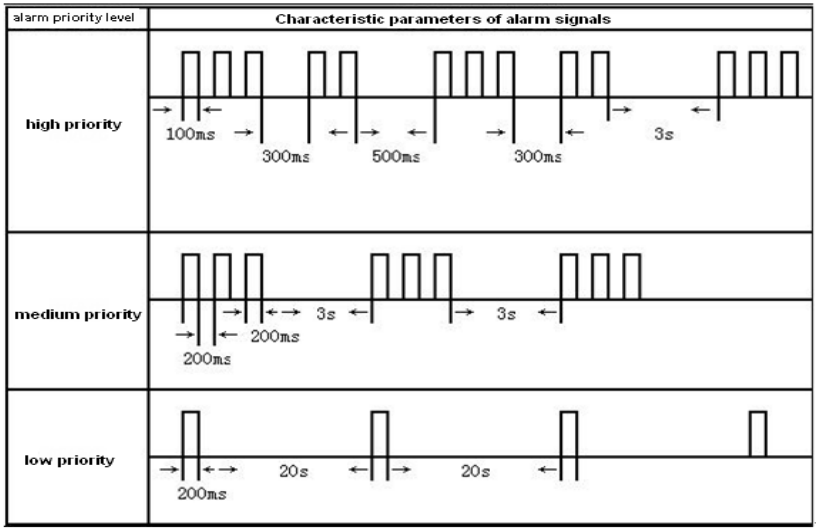


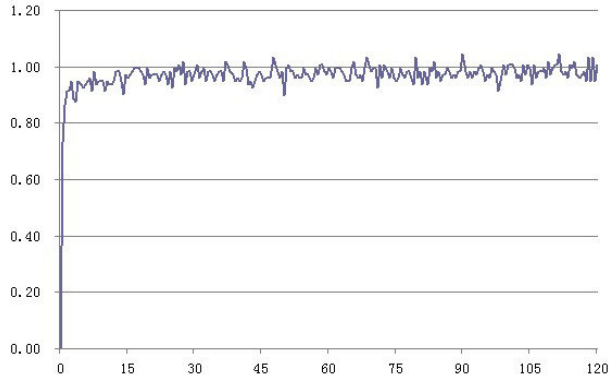
Table 4 Occlusion response characteristic

Flow Rate （ml/h）	OCCl 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

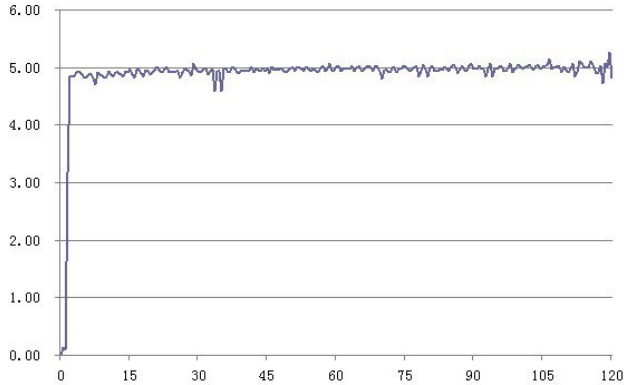
The above test uses ‘Boon’ brand of 5ml syringe. All the data are obtained by using ‘Boon’ brand syringe.

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

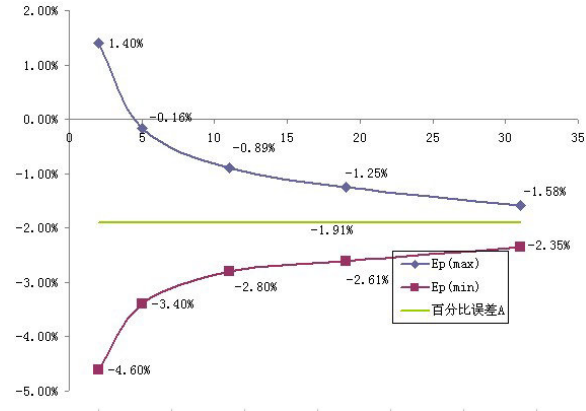


1ml starting curve

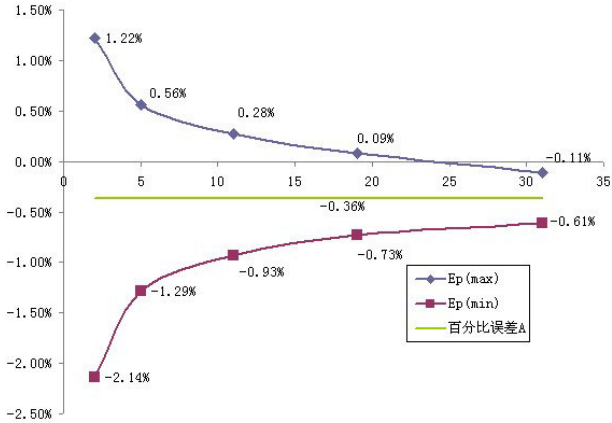


5ml starting curve

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.

Manufacturer : Shenzhen Hawk Optical Electronic Instrument Co.,Ltd.

Address: 2B, Building No.2, Aerospace Science & Industry factory areas, Yousong community, Longhua street, Bao'an District, Shenzhen, China.

Postal code: 518109

Tel: 0086-755-8315 1901

Fax: 0086-755-8315 1906

Email: szhk@hawkmedical.cn

Web: www.hawkmedical.cn