TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144784 0001

Report No.: 17054694 001

Manufacturer: Shenzhen Hawk Medical Instrument
Co., Ltd.
5/F, Building No.2, Lijincheng Industrial Park
East Gongye Road, Longhua District
Shenzhen
518109 Guangdong
China

Products:
- Infusion Pumps
- Syringe Pumps
- Enteral Feeding Pumps
- Fluid Warmers

Replaces the Certificate No CN13/30894

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-27

Notified Body TÜV Rheinland LGA Products GmbH

Digitally signed by Jighili Tatiana
Date: 2021.04.16 18:08:52 EEST
Reason: MoldSign Signature
Location: Moldova

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Jiangxi Hawk Medical Supplies Co., Ltd.
Torch Road, High tech park, Fengcheng City
Yichun City
331100 Jiangxi
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Disposable Infusion Enteral Giving Sets, Disposable Feeding Bags, Disposable High-Pressure Angiographic Syringes, Disposable Infusion Sets for Infusion Equipment Use, Disposable Infusion Sets

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-03-20
Certificate Registration No.:	SX 60148251 0001
An audit was performed. Report No.:	15096361 002
This Certificate is valid until:	2022-04-30

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Herbert Zhong

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date 2020-03-20

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Shenzhen Hawk Medical Instrument Co., Ltd.

USER MANUAL

Please read the manual before using the product;

Please keep the manual for reference !

CE 0197

057-00084-02

Table of Contents

Revision Notes:

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-100, HK-100I, HK-100II infusion pump.

Version No.	Date of Preparation
V1.0.0	2021.01.07

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 Infusion Pump uses peristaltic mechanism 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 dripping as well as the residual liquid inside the infusion bag/bottle to ensure correct performance of the infusion. The Infusion Pump does not directly measure quantity of fluid so it may not detect certain free flow in extremely special case. Even equipped with drop sensor, the Infusion Pump may not detect free flow that smaller than certain volume due to tolerance.

c) The Infusion 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) The user must install the infusion set straight and properly along the peristaltic fingers from left to right. Otherwise, infusion may not reach expected performance.

e) Make sure the IV set is properly installed to the location of air bubble sensor and the occlusion sensor (pressure detector). Air Bubble alarm or Occlusion alarm may not be given due to incorrect installation of IV set.

f) 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 opening the pump door to release the pressure. Then release the clamping of IV set, get rid of the occlusion problem and restart operation. If infusion restarting with blockage remaining, 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.

g) Recommended that keep the flow clip of IV set in downstream position of the Infusion Pump. In case of Air Bubble alarm, it is convenient for the user to clamp the flow clip and then squeeze the air bubble back into the drip chamber.

h) Fix the Infusion Pump well to infusion stand/bar and also ensure the stability of the stand/bar. Be cautious when moving the stand/bar and the Infusion Pump to prevent the Infusion Pump falling off or the stand collision with surrounding objects.

i) The Infusion Pump cannot parallel use with gravity infusion device, as the machine can't detect downstream occlusion or empty of gravity infusion set.

j) The Infusion Pump cannot use with possible large negative or positive pressure piping such as extracorporeal circuit. As in such case, the Infusion Pump cannot ensure infusion accuracy and correct alarm functions.

k) The Infusion Pump cannot use for blood transfusion.

l) Please install the IV set in correct direction (from left to right). If installing in a wrong direction, patient's blood may be sucked out..

m) Do not use the Infusion Pump near inflammable liquid or gas.

n) Do not store or use the Infusion Pump in humid environment or environment with chemically active gases (including gas for sterilization). Such environments may have impact on internal electronic parts and thus bring degradation or damage to their functions.

o) It can be used for ambulance with DC: 12V by working with a voltage stabilizer.

P) Please use to meet the relevant laws and regulations, with a valid medical device registration certificate of the infusion tube, or can not guarantee the accuracy of infusion and normal detection alarm.

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

a) Inspect the Infusion 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 Infusion Pump. Therefore please clean the Infusion Pump and store it properly after each use.

b) When use the Infusion 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 Infusion Pump with enough power in case of AC power failure.

c) If using near electric cautery equipment, the Infusion Pump may result in wrong operation due to the high frequency wave of electric cautery equipment. If the Infusion Pump has to be used with electric cautery equipment, please take proper measures as follows:

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

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

(3) The Infusion 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 Infusion Pump. Otherwise the high frequency noise/signal may cause wrong performance of the Infusion Pump. Make sure the Infusion Pump has ground connection and do not use the same power socket with that for the above-mentioned devices.

e) The Infusion 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 Infusion Pump. Otherwise, the keys or the mask may suffer premature damage.

g) Keep the infusion bag, IV set and the Infusion 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. If infusion with low temperature fluid, the air dissolution inside the tube evaporate to many air bubbles, which cause frequent Air Bubble alarms.

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 Infusion Pump. Just use battery when there is difficulty in ground connection or without AC power (such as AC power failure or

mobile infusion).

j) Do not use the same segment of infusion set for over 6 hours. The IV set may be out of shape due to long-hour squeeze by the peristaltic fingers and thus cause accuracy error. It is suggested to move to a new section (15 cm upward or downward) after every 6 hours of usage, and then start operation again. Or replace the IV set with a new one.

k) To prevent free flow after door open please make sure to close the flow clip of IV set before taking it out of the Infusion Pump.

l) 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.

m) 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.

n) If Infusion 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.

o) The Infusion Pump must be operated by well-trained professionals such as doctor, nurse and medical device expert.

p) Do not disassembly or modify the Infusion Pump or use it for other purposes other than normal infusion. Otherwise, the manufacturer takes no responsibility.

q) the maximum volume infused following a single fault condition is:1ml

r) Monitor the operation status of the device during infusion, check the infusion pipeline, and don't rely solely on the alarm function of the device.

2. Introduction

2.1 Features

Compact and light weight

User-friendly interface, easy parameters setting

2.8 inch colorful LCD with detailed menu

Peristaltic system, better accuracy.

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

Apply to vertical pole or horizontal bar

Removable pump body for easy cleaning.

Product models

Model/Description		HK-100	HK-100I	HK-100II
Infusion modes	Rate mode	√	√	√
	Drip mode	√	√	√
	Time mode	X	X	√
	Body weight mode	X	X	√
	Intermittent mode	X	X	√
Functions	Almost Done	√	√	√
	Keypad lock	√	√	√
	Display of real time	√	√	√
	Anti bolus	√	√	√
	Night mode	√	X	√
	Key sound ON/OFF	√	X	√
	Review/ transfer history record	√	X	√
	Number of history record	1600	X	⩾30000
Remark: √ means with the function， X means without the function				

2.2 Intended use

The device is intended for use in hospitals where patient need intravenous infusion at preset infusion rate and volume limit. It is used for adults, children and newborns.

Indications

The device is indicated for infusion of medications for infusion therapy. The medications for infusion therapy including: cardiovascular, respiratory system, antibiotic, antifungale, antiviral, alimentary system, nervous system, urinary system, hematologic, endocrine system, muscle relaxants, metabolics, antitumour, amino acidfluid, fat emulsion etc.

Contraindications

The device is contraindicated for blood transfusion, insulin, analgesia and epidural anesthesia drugs.

2.3 Type and specifications

This product belongs to class I, type CF. It is volumetric Infusion Pump 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 Operating conditions

a) Temperature: 5°C-40°C

b) Relative humidity: 10%-95% (non-condensing)

c) Atmosphere pressure: 86kPa～106kPa

2.5 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 Infusion Pump, or using AC power from a different source.

2.6 Date of manufacture & life span

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

2.7 Version of software

The version of the user manual for infusion pump's software is V02.

3. Components

The Infusion 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,

squeezing medical liquid forward along peristaltic fingers driven by step motor.

Detection device: mainly containing sensors, such as ultrasonic sensor (for detecting air in line) 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

Infusion accuracy	±5%
Applicable infusion set	Various brand of infusion set 15, 20, 60 drops/ml, Infusion set diameter: 3.4~4.5mm. Optional brand: Boon infusion set
Infusion modes	Rate Mode, Drip Mode, Time Mode, Body Weight Mode, Intermittent Mode
Flow rate range	0.1-1200ml/h increment select-able: 0.01ml/h, 1ml/h, 10ml/h or 100ml/h
Drip rate range	1-400 drips/min increment select-able: 1drips/min, 10drips/min, 100drips/min
Volume to be infused (VTBI)	0.1-9999ml,or 0 (no limit on VTBI) increment select-able: 0.01ml/h 1ml/h, 10ml/h, or 100ml/h
Volume infused	0.0-36000ml

Alarm functions	Visual and audible alarms: Door open, Air Bubble, Occlusion, Infusion completion, infusion near over, No operate, Low Battery, Battery exhausted, malfunction etc.
KVO rate	0.1-10ml/h, preset by the user; default: 1ml/h Accuracy：±（5%+0.1ml）
Bolus rate	0.1-1200ml/h, preset by the user; default: 1000ml/h Accuracy：±（10%+0.1ml）（1-1200ml/h）
Purge rate	0.1-1200ml/h, preset by the user; default: 600ml/h Accuracy：±（10%+0.1ml）（1-1200ml/h） Minimum Purge Volume ≥1.2ml（Minimum distance from patients）
Air Bubble detector	4 adjustable alarm triggering levels: 1 level: 50ul, 2 level:100ul, 3 level: 200ul, 4 level: 300ul. Accumulated bubbles: Each single bubble level corresponds to the cumulative bubble within 1 hour, the limit is 800ul. Default: 1 level (50ul)
Occlusion pressure	10-130kpa, 13 adjustable levels (10Kpa, 20Kpa, 30Kpa, 40Kpa, 50Kpa, 60Kpa, 70Kpa, 80Kpa, 90Kpa, 100Kpa, 110Kpa, 120Kpa, 130Kpa.) Default: 8 level (80Kpa) Accuracy: 1-5levels: ±5kPa; 6-13 levels: ±10kPa Available Unit: kpa, bar, mmHg, psi. Progress bar displays pressure intensity and present pressure value.
Maximum infusion pressure	(250-280) kPa
Anti-bolus function	Diminishes the volume of unwanted Bolus injected to the patient after removal of the occlusion cause.
RS-232 port (optional)	RS-232 port enables user to check infusion/alarm record in computer terminal.

Water Proof Level	IP24
AC power	100-240V 50/60Hz
Battery	Lithium Polymer 7.4V 1900mAh. Recharge time: 10h with power on, 3h with power off. Running time: more than 3h at rate of 25ml/h, environment temperature 25℃ after being fully charged.
Power consumption	35VA
DC	DC 12V ±1.2V NOTE: It cannot be used for ambulance.
Fuse	Slow fuse, 250V 2A
Operating conditions	Environment temperature: 5℃～40℃ Relative humidity: 10%～95% (non-condensing) Air pressure: 86kPa～106kPa
Dimensions	145(L)x 120(H)x 100(W, not including pole clamp)mm
Net weight	≤1.4kg

5. Installation

5.1 Installation conditions and technical requirements

The Infusion 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°.

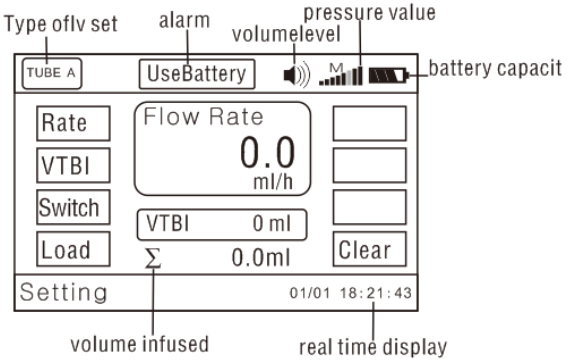
5.2 Installation method and cautions

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.

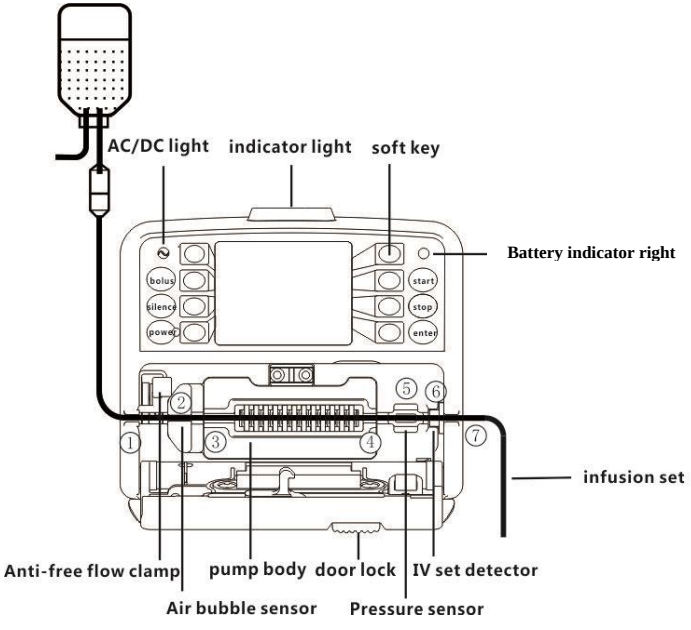
When fixing the pole clamp to IV stand or bar, use the other hand to hold the Infusion Pump until the clamp is well fixed.

6. External Features

6.1 Front panel (diagram 1)



(LCD display)



(diagram 1)

Description	Functions
BOLUS key	In 'stop' status, press & keep finger on 'bolus' key, the pump starts purging (default purge rate: 600ml/h). 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.
SILENCE key	Press this key to silence the alarm signal
POWER key	Switch on / off the Infusion Pump. In 'power off' status, press this key until LCD screen displays, which means the pump is switched on. In 'power on' & 'stop' status, or in 'alarm' case, press this key for about 2 seconds, the pump shall be switched off.
START key	In 'stop' status, press this key to start infusion.
STOP key	Press this key to stop infusion.
ENTER key	Press this key to confirm / save the parameter newly setting
Soft key	The soft keys have various functions. Pressing the key next to the text displayed in the LCD, the text will be highlighted for further parameters setting by pressing soft keys again.
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 on top of the pump indicates operating status/alarms cases. If the IV set is correct installation and with no air in line, the indicator light shall be green after the door is closed, which also indicating the pump is ready for operation. The green indicator light flashes when the infusion is in normal progress. If high-priority alarm occurs during operation, 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
Battery indicator light	This indicator light on means the battery is used.
Door lock	Pressing the door lock, the door shall pop open automatically. Press the door with a bit force to close the door. A 'click' sound indicates the door is well closed.
IV set detector	It can identify the dedicated IV set, or prevent the IV set from being installed in wrong direction. This function is optional.

6.2 Rear panel (diagram 2)

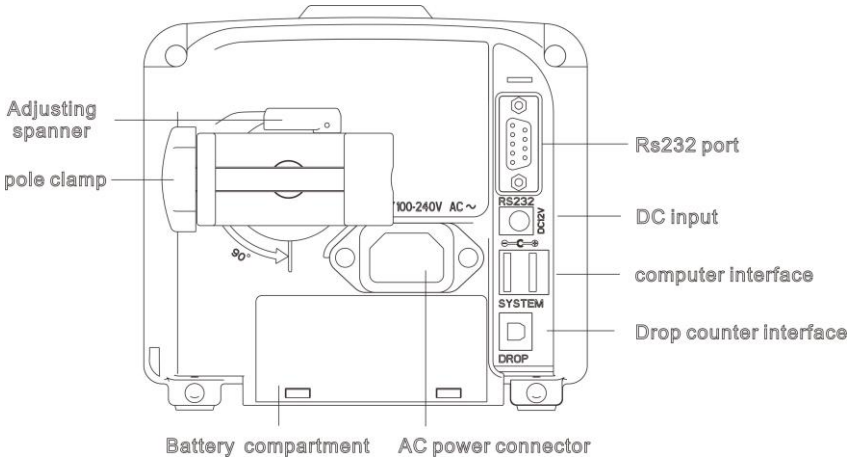


diagram 2 Rear Panel

Description	Functions
Pole clamp & adjusting spanner	It is used to fix the Infusion Pump on IV stand. Draw the adjusting spanner outward or upward; then rotate clamp for 90°for horizontal bar or vertical stand; then draw the spanner back in place to fix the clamp.
Adjusting spanner	Rotate 180° , used to adjust the clamp direction.
Battery compartment	Battery location. Open it from the bottom of machine.
AC power connector	The socket for connecting to AC power source.
RS-232 port	It is used to connect infusion pump to standard PC to transfer infusion history records. **Note: This process must be carried out when machine in non-infusion state.**
DC input	It can be connected to exterior DC power supply (12V±1.2V). Must use the adapter that in accordance with EN 60601-1.
computer interface	This socket is for upgrading program

Drop counter interface	This interface is for connecting to exterior drop sensor, to detect the drop rate. The drop sensor cannot be exposed to sunshine, and when using drop sensor, squeeze the drip chamber to fill it with 1/2 of the liquid. (This function is optional)

6.3 Label

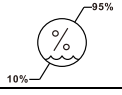
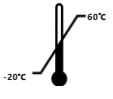
6.3.1 Product label (on the back shell)

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
	Batch code
	Serial number
	Caution
	Refer to instruction manual/booklet
	Type CF applied part
	Protective earth; protective ground
IP24	The device against ingress of solid foreign objects ≥12.5mm diameter and splashing water
	Infusion liquid flow direction identification: the infusion liquid flows from left to right.

Symbols	Descriptions
	Alternating current
	Direct current
	Battery and waste electrical and electronic device must be disposed of in accordance with the locally applicable regulations, not with domestic waste.
	Date of manufacture
	Manufacturer
	Keep away from rain
	Fragile; handle with care
	This way up
	Stacking limit by number
	Humidity limitation
	Temperature limit

EC REP	Authorized Representative in the European Community
CE 0197	This device is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC

7. Preparation and inspection

Whether the Infusion 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) The door opens agilely and can be closed tight.

(4) The power cord can be plugged in tight, not easy to loose.

(5) If Infusion Pump worked on internal battery only, charge it fully before use and also make sure the battery is still valid for use.

Attention: The infusion pump only stores one brand of infusion sets: BOON. Other brand of infusion sets are not recommended. If users want to use other brands, Please calibrate it before using by manufacturer.

8. Operation Method

In order to ensure the accuracy of infusion, it is recommended to use the pump built-in infusion tube brand (Boon A2 (1ml = 20 drops)

8.1 Operation

The whole infusion operation contains the following processes:

1) Fix the Infusion Pump and connect it to AC power.

2) Switch on / off.

3) Dedicated infusion set function(optional): If you use a dedicated infusion set for the first time, you need to enter "System Settings" --> "DedSet" --> "DedicatedSet" to “ON” state and then shut down and restart. If it is already set before, after switch on, please follow the indications displayed on device to install the dedicated infusion set.

4) Fill the IV set with medical liquid and install it in the Infusion Pump.

5) Set infusion parameters.

6) Purge the air in line.

7) Clear Σ (volume infused).

8) Start infusion.

9) Bolus infusion.

10) Stop infusion.

11) Infusion completion.

12) Replace IV set and infusion bag/bottle.

8.1.1 Adjust the pole clamp to fix the Infusion Pump properly to a stand/bar/cage and connect it to AC/DC power. The AC/DC indicator light (on upper left corner) shall be on.

8.1.2 Switch on/off.

Press Power key few seconds, the pump will be switched on and do self-test, and shows Self-testing on the display, it will test: Communication Info, Press sensor, Air bubble sensor, Dedicated IV set, AC Info and Battery Info. The test result (OK or FAIL) will be displayed on LCD.

Pump self-test information after switching on:

(1) Communication information: OK indicates CPU normal; FAILED indicates CPU abnormal;

(2) Battery information: OK indicates internal battery normal; FAILED indicates internal battery abnormal

(3) AC information: OK indicates AC connected well; FAILED indicates AC fail;

(4) Pressure sensor: OK indicates normal pressure detection; FAILED indicates: abnormal pressure detection;

(5) Air bubble sensor: OK indicates normal air bubble sensor; FAILED indicates abnormal air bubble sensor or IV set was installed in the pump already;

(6) Dedicated IV set: OK indicates normal dedicated IV sensor; FAILED indicates: abnormal installation of dedicated IV set or IV set is installed in the pump already;

Attention: 1. If Air bubble sensor test FAIL, system will show "Is the infusion set installed?", please choose the answer according to the facts, the system will predicate per your choice.

2. If not connect with AC power, but use battery, it will show FAIL, in this situation the pump is working on battery.

3.Please keep an eye on the self-test, if any abnormal, please contact our company, DO NOT force to use it.

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

8.1.3 Fill the IV set and install the IV set properly.

(1) Put the flow clip downstream of the Infusion Pump and close the flow clip tight. Connect IV set to infusion bag/bottle and then squeeze the drip chamber to fill with 1/2 of liquid. Open the flow clip and let the fluid flow to the tip of the needle. Then close the flow clip again.

(2) Install the IV set

Press door lock and the door shall pop open. Upward the anti-free flow clamp and place it at top of right side plastic block. Then pull the IV set straight and install it in correct direction as shown in Diagram 1 (from left to right), making sure the IV set is properly inserted in all positions from ① to ⑦. Press the door to close it (A 'click' sound indicates the door is well closed). If the air detector detects no air inside the tube, the indicator light on top of the machine shall be on, which indicates the pump is ready for operation. If the green indicator light is not on, follow "Step 8.1.5 Purge" to purge all the air inside the tube. Then the green indicator light shall be on.

8.1.4 Infusion mode selection

The default infusion mode is Rate Mode, press "Switch" key to choose the other infusion modes. The machine will sequentially display Rate Mode, Drip Mode, Time Mode, Body Weight Mode, Intermittent Mode after pressing "Switch" key.

Attention:

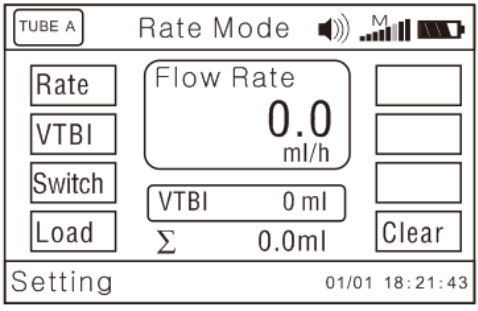
1. Different infusion modes need to set different parameters.
2. Under Time Mode, when flow rate (result from volume limit divided by infusion time) more than maximum flow rate of system 1200ml/h, the system will display the infusion time （result from volume limit divided by 1200ml/h）.
3. Under Body Weight Mode, if flow rate (result from entering parameters) more than system default maximum rate, the system will alert flow rate out of range and users

need to reset parameters.

Parameters under each infusion mode		
Parameters		Setting range
Rate Mode	Flow rate	0.1-1200ml/h
	VTBI	0-9999.99ml
Drip Mode	Drip rate	0-400drop/min
	VTBI	0-9999.99ml
Time Mode	VTBI	0-9999.99ml
	Time	0-99h59min
Body Weight Mode	Dose	0.1-2000
	VTBI	0-9999.99ml
	Weight	0.1-300kg
	Concentration	0.1-2000
	Unit	mg/kg/h, mg/kg/min, ug/kg/h, ug/kg/min
Intermittent Mode	VTBI P. (VTBI Per time)	0-9999.99ml
	Inter. (Interval time)	0-99h59min
	Rate	0.1-1200ml/h
	KVO	0.1-5ml/h

8.1.5 Set infusion parameters

1) Rate Mode

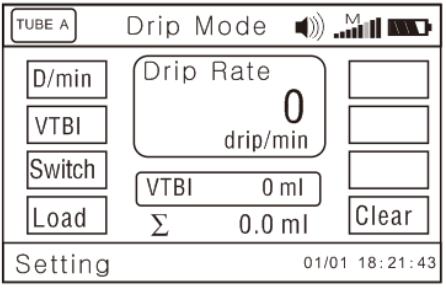


Rate Mode: Press for 'Rate' and input rate value. Press ENTER key to save the value and exit to the previous menu.

VTBI: Press for 'VTBI' and input volume to be infused. If you are to infuse all the liquid inside the bottle, do not input VTBI value (just leave it as '0ml'). Press ENTER key to save the value and quit to the previous menu.

Switch: Pressing for 'Switch', it can switch between Rate mode and Drip mode, Time mode, Body Weight mode, Intermittent mode.

2) Drip Mode



Drip Mode: After switching to drip rate mode, please set parameters as follows:

(1) Press and hold on STOP key first, then press (1st soft key on top left), entering 'parameter setting interface'. Press for 'D./ml' and input the number of drops equivalent to 1ml as specified on the package of IV set selected for use. Press ENTER key to save/exit. Press and hold on STOP key first, then press (1st soft key on top left) to return to previous menu.

★ Regarding drip rate mode, it must input the number of drops equivalent to 1ml as specified on the package of the IV set. (e.g. For "Boon" brand of IV set, it specifies 20 drops/1ml ±0.1ml. You then input the value '20' in 'D./ml'.)

(2) After setting the D./ml value, check and calibrate it.

Set drop rate as 50 drop/min and VTBI as 5ml. Start infusion and count with your eyes the actual number of drops within the 5ml. If the actual number of drops counted is too different from the pre-set D./ml value, you need to adjust the D./ml value according to the actual D./ml value measured by counting. (e.g. Set D./ml value of 'Boon' IV set as 20, drop rate as 50 drop/min and VTBI as 5ml. The actual number of drops counted should be supposedly 100 drops. If there are only 75 drops within 5ml, you then need

to enter ‘parameter setting interface’ to adjust D./ml value as 15.)

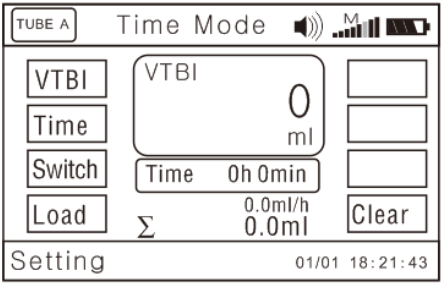
(3)Drop rate: Press for 'D/min', input drop rate needed, press ENTER key to save and quit to previous menu.

VTBI: Press for 'VTBI' and input VTBI value. If it needs the whole bottle of medical liquid, please leave it as 0. Press ENTER key to save and quit to previous menu.

Load: Press for 'Load'. It can directly load the rate and VTBI of last infusion.

★ After pressing 'Load', please check and calibrate if the rate and VTBI are the ones you need for this infusion, otherwise you need to reset the rate and VTBI.

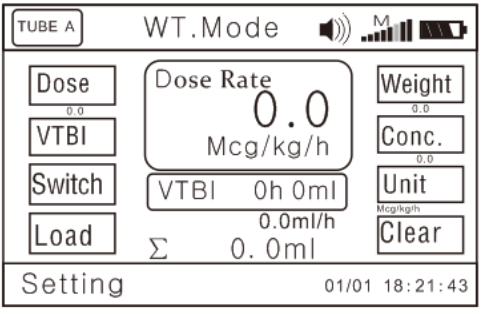
3) Time Mode



Time Mode: Press for ‘Time’ and input time value. Press ENTER key to save the value and exit to the previous menu.

VTBI: Press for ‘VTBI’ and input volume to be infused. Press ENTER key to save the value and quit to the previous menu.

4) Body Weight Mode (WT. Mode)



Body Weight Mode (WT. Mode): Press for ‘Dose’ and input Dose Rate (0.1-2000).

Press ENTER key to save the value and exit to the previous menu.

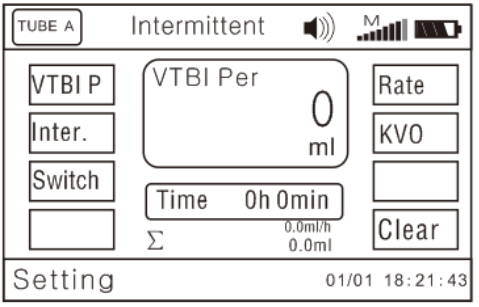
VTBI: Press for 'VTBI' and input volume to be infused. If you are to infuse all the liquid inside the bottle, do not input VTBI value (just leave it as '0ml'). Press ENTER key to save the value and quit to the previous menu.

Press for 'Weight' and input value (0.1-300 kg). Press ENTER key to save the value and exit to the previous menu.

Press for 'Conc.' (Concentration) and input value (0.1-2000). Press ENTER key to save the value and exit to the previous menu.

Press for 'Unit' and select the unit (mg/kg/h, mg/kg/min, ug/kg/h, ug/kg/min). Press ENTER key to save the value and exit to the previous menu.

5) Intermittent Mode



Intermittent Mode: Press for 'Rate' and input flow rate value. Press ENTER key to save the value and exit to the previous menu.

VTBI Per: Press for 'VTBI P' and input volume to be infused per time. Press ENTER key to save the value and quit to the previous menu.

Press for 'KVO.' and input KVO rate value (0.1-5ml/h). Press ENTER key to save the value and exit to the previous menu.

Press for 'Inter.' (interval time) Press ENTER key to save the value and exit to the previous menu.

Eg: input 'Rate':10ml/h, 'VTBI P': 10ml, 'KVO': 0.1ml/h, 'Inter.': 30min, after infused 10ml at rate 10ml/h, it will stop infusion for 30min and start KVO at 0.1ml/h. After 30 min, it will start infusion for 10ml at flow rate 10ml/h again.

8.1.6 Purge

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

8.1.7 Clear the volume infused

Press for 'clear' to clear Σ (volume infused) as '0.0ml'.

★ If Σ (volume infused) is not cleared after VTBI completion, when the next VTBI less than the previous Σ (volume infused), the pump shall give FINISH alarm and this FINISH alarm can only be eliminated by clearing the previous Σ (volume infused).

8.1.8 Start infusion

Confirm the top indicator light turning green and the IV set clipper is open, press START key to start infusion. Flow rate and VTBI shall display in the middle and Σ (volume infused) shall display in the lower right corner.

During infusion, only BOLUS key and STOP key shall function.

8.1.9 Bolus infusion

There are two methods to purge. They are manual bolus and auto bolus. Please follow by the following procedures:

1)Manual bolus: During infusion process, press bolus key and hold on. The pump will purge at preset bolus rate. It will return to previous infusion rate after releasing your finger.

2)Auto bolus: After setting bolus rate, it will purge at bolus rate by single clicking bolus key.

Note: Different sizes of infusion sets may have different Bolus rate. Bolus rate can be set in setting interface. Please look up 8.3.2.

8.1.10 Stop infusion

During infusion, press STOP key to stop infusion. Press START key to re-start infusion.

8.1.11 Infusion completion

After VTBI completion or Σ (volume infused) reaching 36000ml, the pump shall start KVO function automatically. Press STOP key to stop infusion.

★ KVO function means keep patient's vein open by infusing at a pre-set low rate.

8.1.12 Replace IV set and infusion bottle

★ If you need to replace IV set, please follow steps below:

Close the flow clip of IV set. Open the pump door and take out the IV set.

As per instructions of 8.1.3, fill the new IV set with medical fluid and install it properly. Restart infusion as required.

★ The IV set may be out of shape due to long-hours squeeze by the peristaltic system and which can cause accuracy error. It is suggested that change the section of the infusion set that is against peristaltic chips or replace a new infusion set after continuously working for 6 hours.

★ If need to replace infusion bottle, please follow steps below:

Close the flow clip of IV set. Open the pump door and take out the IV set.

Disconnect IV set from infusion bottle

Reconnect the IV set to a new infusion bottle.

Fill in and install the IV set as per instructions of 8.1.3.

Restart infusion as per infusion instructions of 8.1.

8.2 Alarms and solutions

During infusion preparation and infusion process, alarms may occur as follows. Please treat them as per instructions below. Table 2（Refer to Annex Table1,2&3 for corresponding alarm parameters）

Name of alarms	Cause for alarms	Solutions
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. ★ This alarm function can adjust from 1-5min, but it can't be closed (See 8.3.14)
Door Open alarm	The pump door is opened during infusion.	Pressing SILENCE key can pause the alarm sound 2 mins. Close the pump door to eliminate the alarm.

AlmostDone alarm (infusion near over)	Three (3) minutes before VTBI completion	Pressing SILENCE key can pause the alarm sound 2 mins. ★ This alarm function can be set as 'OFF' if there is no need. (See 8.3.15)
Finished alarm	1. The VTBI is completed. 2. Volume infused reaches 36000ml.	Pressing SILENCE key can pause the alarm sound 2 mins. Press STOP key to clear the alarm. Press for 'clear' to clear Σ (volume infused) as '0'.
Empty alarm(This alarm is only available with drip sensor)	When the infusion volume in the container is exhausted	Press SILENCE key to clear the alarm.
Air Bubble alarm	1. Air bubble inside the tube,Single bubble or accumulated bubble reaches the limit	Pressing SILENCE key can pause the alarm sound 2 mins Open the door to get rid of air bubble in the tube and then press START key to start infusion again.
	2. The IV set is improperly installed.	Install the IV set in correct way as instruction in 8.1.3.
	3. The air sensor is defective.	Contact distributor / manufacturer for repair.
AC Fail alarm	Power failure or AC power plug off after switch on.	Pressing SILENCE key can pause the alarm sound 2 mins Connecting the network power supply can eliminate the alarm
Occlusion alarm	1. The infusion set is blocked.	Pressing SILENCE key can pause the alarm sound 2 mins Open the door to clear the occlusion properly and press START key to start infusion again.
	2. The occlusion sensitivity is too high.	Adjust occlusion level of the Infusion Pump as per instructions of 8.3.12.

	3. The pressure sensor is defective.	Contact distributor / manufacturer for repair.
Use Battery alarm	1. AC power is not plugged in.	Pressing SILENCE key can pause the alarm sound 2 mins. Connecting the network power supply can eliminate the alarm
	2. The Infusion Pump's electric circuit has problem.	Contact distributor / manufacturer for repair.
Low Battery alarm (when battery has to be used during power failure or mobile infusion)	1. Thirty (30) minutes before the battery capacity is exhausted.	Pressing SILENCE key can pause the alarm sound 2 mins. If AC power cord is not plugged in, the alarm keep on ringing . Connecting the network power supply can eliminate the alarm
	2. The battery is aging or the Infusion Pump's charging circuit is defective.	Contact distributor / manufacturer for repair.
B. Exhaust alarm (battery depleted alarm. when battery has to be used during power failure or mobile infusion)	1. Three (3) minutes before the battery capacity is exhausted.	Pressing SILENCE key cannot pause the alarm sound. In this case ,we must stop infusion and connect to AC power to charge the battery fully.
	2. The battery is aging or the charging circuit of the Infusion Pump is defective.	Contact distributor / manufacturer for repair.
Check tube	IV set is not the brand dedicated infusion set	Pressing SILENCE key can pause the alarm sound 2mins. Install the IV set in correct way. ★ NOTE: It is applicable to the infusion pump that has special infusion set recognition function.

Heat error alarm	Failure of heating part of infusion pump	Pressing SILENCE key can pause the alarm sound 2 mins. Contact distributor / manufacturer for repair.
0xE0,0xE1 0xE2,0xE3	1.0xE0: data communication error.	Pressing SILENCE key can pause the alarm sound 2 mins. 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 Infusion Pump's driving system has problem.	Pressing SILENCE key can pause the alarm sound 2 mins. 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.	Pressing SILENCE key can pause the alarm sound 2 mins. Reboot the pump 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 system has problem.	Pressing SILENCE key can pause the alarm sound 2 mins. Reboot the pump to try operation again. If problem occurs again, try to restore default setting to try again. If problem still occurs, contact distributor / manufacturer for repair. ★ After restoring factory default setting, you need to calibrate the IV set parameters again.

8.3 Parameters Setting and Accuracy Calibration

This chapter illustrates how to set infusion parameters.

Press and hold on STOP key first, then press (1st soft key on top left) to enter 'parameter setting interface'. If the first page has no parameters for setting, press (4th soft key on the right) to skip to 'next' page for setting. For any parameter setting, press ENTER key to save the value. After all parameters are well setting, press and hold on STOP key first, then press (1st soft key on top left) to quit to main menu.

8.3.1 Set KVO rate

After entering 'parameter setting interface', press for 'KVO' and set required KVO rate. Then press ENTER key to save the value and exit.

8.3.2 Set bolus rate

There are two methods for Bolus, manual Bolus and auto Bolus, operation as below:

Manual Bolus: After power on the pump, press STOP+ left 1st soft key to enter Settings, select Bolus, set Bolus rate and VTBI: 0, press ENTER to save the value. During infusing, keep pressing BOLUS key then it will run at Bolus rate; if release the BOLUS key, it will run at original rate, not Bolus rate.

Auto Bolus: After power on the pump, press STOP+ left 1st soft key to enter Settings, select Bolus, set Bolus rate and VTBI >0, press ENTER to save the value. During infusing, press BOLUS and release, it will run at Bolus rate until finishing the VTBI, then run at original rate.

8.3.3 Set occlusion sensitivity level.

After entering 'parameter setting interface', press for 'Occl.' and select required occlusion level (13 level). Then press ENTER key to save the value and exit. Recommended setting for low occlusion alarm level for elderly or pediatric patients.

Occlusion level	Alarm pressure	Occlusion level	Alarm pressure
1	10±10kPa	8	80±10kPa(Default)
2	20±10kPa	9	90±10kPa

3	30±10kPa	10	100±10kPa
4	40±10kPa	11	110±10kPa
5	50±10kPa	12	120±10kPa
6	60±10kPa	13	130±10kPa
7	70±10 kPa		

8.3.4 Set air bubble size for detection

After entering 'parameter setting interface', press  for 'Air L' and select required air bubble size for detection (4 level). Then press ENTER key to save the value and exit.

level	Air bubble size
1	50ul±20%(Default)
2	100ul±20%
3	200ul±20%
4	300ul±20%

8.3.5. Select IV set brand

After entering 'parameter setting interface', press  for 'Tube' and select a brand/type of IV set (A, B, C ~ J). Then press ENTER key to save the value and exit.

★ After selecting a brand of IV set, its corresponding accuracy which has been calibrated shall be automatically effective.

★ The Infusion Pump uses IV set under brand of Boon for factory setting (default setting). Using the other brand of IV set needs calibrating the accuracy of that IV set, otherwise accuracy can't be ensured.

8.3.6 Set drop/ml

After entering 'parameter setting interface', press  for 'D./ml' and input the actual value of drops/ml as shown on the package of IV set. Then press ENTER key to save the value and exit.

8.3.7 Accuracy calibration of IV set

Install the IV set as per instructions in 8.1.3, and prepare a measuring cup for flown-out liquid. After entering 'parameter setting interface', press  for 'Accu.' to enter IV set

calibration mode.

Press START key, the Infusion Pump shall start operation at 150ml/h. After it finishes VTBI (10ml), measuring the flown-out liquid in measuring cup, input this actual flown-out volume on “real” text of calibration interface. Then press ENTER key to save the value and exit. The calibration of this brand/type of IV set is completed.

The accuracy calibration is directly related to the measurement of the actual flown-out fluid/quality. Please use high-precision electronic scale or other measuring instrument.

Test method in detail refer to Annex Ⅱ.

8.3.8 Set alarm sound level

After entering ‘parameter setting interface’, press for ‘Next’ to turn to next page. Press for ‘Sound’ and select desired sound level (L1~L10). Then press ENTER key to save the value and exit.

Attention:

——The default sound level: L8

——alarm sound pressure range：45-80dB；

——The adjust in L1-L8 need high level of authority。

8.3.9 Set LCD backlight level

After entering ‘parameter setting interface’, press for ‘Back L’ and press “+1” to select 1min, 2min, 3min, 4min, 5min (i.e. dark after 1min etc), DARK or press “-1” to select BRIGHTNESS. Then press ENTER key to save the value and exit.

★ Selecting ‘1min’ means the LCD shall automatically darken in 1 minute if no operation on keys.

8.3.10 Set key tone

After entering ‘parameter setting interface’, press for ‘Key S’ and select ON or OFF. Then press ENTER key to save the value and exit.

8.3.11 Set real date and time

After entering ‘parameter setting interface’, press for ‘Time’ and input value for year/month/day/hour/minute/second. Press ENTER key to save the value and exit.

8.3.12 Adjust occlusion alarm pressure value

This parameter needs to be calibrated with a pressure scale. User should adjust the parameter according to the selected IV set.

The occlusion alarm pressure has 13 levels that are respectively 10-130kPa. If the actual pressure is out of setting level, the occlusion alarm pressure value needs adjusting.

After entering 'parameter setting interface', press for 'Press.' and adjust the value accordingly. Then press ENTER key to save the value and exit.

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

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

8.3.13 View the event logs/alarm records

After entering 'parameter setting interface', press 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 1500 infusion / alarm information. Select '3 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 Infusion Pump to a computer with RS-232 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 232 port).

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 an infusion pump serial number on the computer, and then click "Start."

e. Press 1 soft key, upload infusion 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 infusion pump returns to superior menu interface automatically.

(2) 2 View Log: Select “2 View log” to view latest 1500 pieces of infusion / alarm information. Press ‘Prev.’ to check the previous records or ‘Next’ for next records. Press ‘Back’ to return to ‘Log’ interface. Select “3.Back” to return to parameter setting interface.

Log format

Time(y-m-d-h-m-s)	Mode
status information Including: ——alarming — — Setting parameters（flow、VTBI、time、weight etc.）	Record No./total

Attention :

Log is kept continue, not affected by power interruption.

Maximum number of preservation: ＞30000

8.3.14 “No Operate” alarm on and off setting

After entering ‘parameter setting interface’, press ◯ for ‘Next’ to turn to next page. Press◯ for ‘No Op’ and select ON or OFF. Then press ENTER key to save the value and exit.

“No Operate” alarm setting as on: in ‘stop’ status, “No Operate” alarm shall sound when no operation on keys in 2 minutes.

8.3.15 “Almost Done” alarm on and off setting

After entering ‘parameter setting interface’, press for “Almost Done” and select ON or OFF. Then press ENTER key to save the value and exit.

If setting as ON, “Almost Done” alarm shall sound 3 minutes before VTBI is complete.

8.3.16 NIGHT mode on and off setting

After entering ‘parameter setting interface’, press for ‘NIGHT’ and select ON or OFF. Then press ENTER key to save the value and exit.

If setting as ON,  shall display on LCD. Key sound 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 indicator light shall be on.)

8.3.17 “KLock” on and off setting

After entering ‘parameter setting interface’, press for ‘KLock’ and press “+1” key for 1min, 2min, 3min, 4min or 5min, or press “-1” key to select OFF. Then press ENTER key to save the value and exit.

Setting as 1min means all keys shall be locked (except POWER key) after 1minute if no operation on keys. This icon  shall display on LCD.

To unlock the panel, press ENTER key + (2nd soft key on top left) together.

8.3.18 Select language and restore default

Press and hold on STOP key first, then press (2nd soft key on top left) to enter language setting interface. select ‘1.Chinese’ or ‘2. English’. If selecting ‘3. Restore Default’, all factory settings shall be restored.

★ After selecting ‘Restore Default’, the IV parameters need re-calibration.

Press and hold on STOP key first, then press (2nd soft key on top left) to exit.

8.4 Operation Precautions

- After the IV set is continuously used for 6 hours, please change the section of IV set that is against the peristaltic chips, or replace a new one. Meanwhile pay attention to the length of the IV set. Use extension lines if necessary in case the IV set is

stretched out of position when patient turns his body.

- 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 Infusion 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.
- When infusion at high rate (≥800ml/h), large-sized needle (size 7 or above) should be used, otherwise it shall influence infusion accuracy.
- The Infusion Pump should be placed within 1.2 meters above or below patient's heart.
- The damaged front panel (mask) needs to be replaced in time to prevent leakage.
- Infusion 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 IV set used on this Infusion Pump should get valid Medical Device Registration Certificate.
- The Infusion Pump uses 'Boon' brand A2 IV set for factory settings. If users use the other brands of IV set, please calibrate its accuracy on machine before use. system setting

9. Malfunction Analysis and Solutions

Problems	Causes	Solutions
Frequent Air Bubble alarm	The IV set too soft or too thin.	replace IV set
	Small air bubble in the IV set.	Select a higher level air bubble filter.
Accuracy discrepancy	The IV set is not calibrated.	Calibrate the accuracy of IV set

	The IV set currently used does not match the default brand.	Select the correct brand of IV set.
	Due to variation in weather and temperature, the internal parameters of the pump incompatible with that of the IV set actually used.	Re-calibrate the accuracy of IV set.
	certain parts of the machine may be defective.	Contact distributor or manufacturer for repair

Beside 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 Infusion 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. Infusion Pump working with malfunctions may incur unpredictable damage.

(2) If the Infusion 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

water or alcohol soft cloth. Do not use solvents like xylene or acetone or other similar solvents which may corrode the Infusion Pump.

11.2 Maintenance during operation

The maintenance during operation mainly concerns the cleaning of the pump body and surrounding areas. Medical liquid may drip into the Infusion Pump during infusion process. Certain medical fluid may corrode the pump body and certain may stick on the peristaltic chips, therefore clean the Infusion Pump every time after infusion completion.

11.3 Periodic Inspection

11.3.1 Inspect anti-free flow clamp (once every 2 months)

Check if the anti-free flow clamp can stop the free flow effectively.

(1) Install IV set on the Infusion Pump. Close the door and open the flow clip of IV set.

(2) Keep pressing BOLUS key until liquid drops from the tip of needle.

(3) Open the pump door.

(4) Observe and confirm no liquid drips from the needle and no liquid drops into drip chamber.

11.3.2 Check the alarm function of occlusion sensor (once every 2 months)

Check if the Occlusion alarm is given within 2-10 seconds.

(1) The testing conditions: The Infusion Pump should be 20cm away from the flow clip of IV set and 30cm away from the filter, flow rate at 150 ml/h, volume to be infused as 200ml, and occlusion level as middle.

(2) Install IV set in the Infusion Pump. Close the door and open the flow clip of IV set.

(3) Upon pressing START key, use a stopwatch to measure the time taken for occlusion alarm.

11.3.3 Check the alarm function of air bubble sensor (once every 2 months)

Testing method:

(1) Install IV set in the Infusion Pump and set flow rate at 150ml/h, volume to be infused as 200ml, air bubble detection level as OFF and then start infusion.

(2) Reverse the drip chamber to let in some air flow into the tube. Use finger to flip the

tube to create an air bubble.

(4) When the Infusion Pump gives Air Bubble alarm, opening the door and check if there is any air bubble in the tube near the air bubble sensor.

★ When air bubble detection level setting as OFF, Air Bubble alarm shall be given upon detection the size of air bubble as 4mm.

11.3.4 Calibrate delivery accuracy (once every 2 months)

The Infusion Pump built in mechanism driving system which may suffer abrasion during usage. Frequently use of the machine and variation on temperature may cause accuracy error. It requires check infusion accuracy periodically.

(1) Install IV set in the Infusion Pump. Close the door and open the flow clip of IV set.

(2) Calibrate the accuracy as per instructions of 8.3.7.

(3) After calibration, setting flow rate at 150ml/h and volume to be infused as 10ml to test delivery accuracy. The delivery accuracy should be within ±3%.

11.3.5 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 25ml/h. Record the whole working time when the battery is exhausted.

---If infusion time more than 90 minutes, the battery is in good condition.

---If Infusion time more than 45 minutes but less than 90 minutes, the battery starts low quality but still can be used.

---If infusion time less than 45 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 Infusion 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 Infusion Pump of long time storage, please refer to following steps before use:

(1) Calibrate the Infusion Pump to ensure infusion accuracy and avoid possible medical accident.

(2) Test Air Bubble and Occlusion alarm.

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

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 Infusion 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. EMC Information

Note:

- The infusion pump conforms to EMC relevant requirements of IEC 60601-1-2 standard;
- Users should install and use the product according to the EMC information provided by random documents;
- Since portable and mobile RF communication device may affect the performance of

infusion pump, strong electromagnet interference should be avoided, for example, do not use it close to mobile phone or microwave;

- See attachments for the guidance and manufacturer's declaration.


Warning:

- The infusion pump should not be put close to or stacked on other devices. If it has to be put close to or stacked on other device, it should be observed and verified that if it can operate normally under its application configuration;
- Class A device is planned to be used in industrial environment. Due to the conducted disturbance and radiated disturbance of infusion pump, it may be difficult to ensure EMC in other environment;
- To use cables not provided by infusion pump manufacturer, which may increase emission or reduce interference immunity of the pump.

Attachments:

Guidance and Manufacturer's Declaration		
The infusion pump is intended for use in the electromagnetic environment specified below. The customer of the user of the Infusion pump should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment – Guidance**
Radio frequency (RF) emission CISPR 11	Group 1	The infusion pump use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Radio frequency (RF) emission CISPR 11	Class A	The infusion pump is suitable for use in all establishments, other than domestic establishments and buildings used for domestic purposes that are connected to the public low-voltage power supply network.
Harmonic emission IEC 61000-3-2	Not applicable	
Voltage fluctuation/Flicker emission IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

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

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±6 kV, ±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	±2 kV, ±4 kV, ±6 kV, ±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	The floor should be wood, concrete or ceramic tile. If it is covered by synthetic materials, then the relative humidity level should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power line	±2 kV for power line	The network power should be of a standard quality suitable for application in commercial

			environments or hospitals.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1kV, ±2 kV line to ground	The network power should be of a standard quality suitable for application in commercial environments or hospitals.
Voltage dips, short interruption and voltage variation on power input line IEC 61000-4-11	<5 % U_T, continuing for 0.5 cycle (On U_T, >95% temporary drop) 40 % U_T, continuous for 5 cycles (On U_T, 60% temporary drop) 70 % U_T, continuous for 25 cycles (On U_T, 30% temporary drop) <5 % U_T, continuous for 5s (On U_T, >95% temporary drop)	<5 % U_T, continuing for 0.5 cycle (On U_T, >95% temporary drop) 40 % U_T, continuous for 5 cycles (On U_T, 60% temporary drop) 70 % U_T, continuous for 25 cycles (On U_T, 30% temporary drop) <5 % U_T, continuous for 5s (On U_T, >95% temporary drop)	Network power should have the quality that is typical for application in commercial environment or hospital. If users of the infusion pump need to operate it continuously during power interruption, it is suggested to adopt UPS or battery for power supply.
Power frequency magnetic field (PFMF) (50/60 Hz) IEC 61000-4-8	30 A/m, 50/60 Hz	30 A/m, 50/60 Hz	PFMF should have the PFMF characteristics of typical places in commercial environment or hospital.
Note: U_T refers to the AC network voltage before applying test voltage.			

Guidance and Manufacturer's Declaration- Electromagnetic Immunity

The infusion pump is expected to be used in the following electromagnetic environment. Purchasers and users should ensure that they will use the product in the following electromagnetic environment:

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment – Guidance
RF conduct IEC 61000-4-6	3 Vrms 150 kHz-80 MHz 6 Vrms ISM band	3 Vrms 150 kHz-80 MHz 6 Vrms ISM band	Portable and mobile RF communication device should not be closer to any part of infusion pump than the recommended isolation distance while using, including cables. This isolation distance should be calculated with the formula corresponding to transmitter frequency. **Recommended isolation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz~800 MHz $d = 2.3\sqrt{P}$ 800 MHz~2.7 GHz P —the maximum rate output power of transmitter provided by transmitter manufacturer, in W; *d*—recommended isolation distance, in m . The field strength of fixed RF transmitter is determined by the survey[a] of electromagnetic field. *d* should be lower than Compliance level
RF radiation IEC 61000-4-3	3 V/m 80 MHz-2.7 GHz	3 V/m	

			in each frequency range[b]. There may be interference around the devices with the following symbol. 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: This guidance may not apply to all situations, electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

a Fixed transmitter, such as the base stations of wireless (cell/cordless) phones and ground mobile radio, amateur radio, amplitude modulation, FM radio broadcast and TV broadcast, etc., its field strength cannot be forecasted accurately in theory. Survey of electromagnetic fields should be taken into consideration in order to evaluate the electromagnetic environment of fixed RF transmitter. If it is measured that the field strength of the location of the infusion pump is higher than the applicable RF **Compliance level**, the infusion pump should be observed to calibrate if it can operate normally. If abnormal performance is observed,then supplementary measures might be necessary, for example, readjustment of the direction or location of the infusion pump.

b Field strengths should be lower than 3 V/m within the whole frequency range of 150KHz~80MHz.

Recommended Isolation Distance between Portable and Mobile RF Communication Device and the infusion pump

The infusion pump is expected to use in the electromagnetic environment where RF radiated disturbance is under control. According to the maximum rated output power of communication device, purchasers or users can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication device (transmitter) and the infusion pump.

Rated maximum output power of transmitter **W**	**Isolation Distance Corresponding to Different Frequencies of Transmitter/m**		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	**80 MHz ~ 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz~ 2.7 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 the Rated maximum output power of transmitter not listed in the table above, isolation distance *d*, in m, is recommended. It can be determined with the formula in the frequency column of corresponding transmitter. *P* here is the maximum rated output power of transmitter, in W, provided by transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the formula of higher frequency range applies.

Note 2: This guidance may not apply to all situations, electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

13. Transport and storage

13.1 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% (non-condensing)

(4) Atmosphere pressure: 50.0kPa～106.0kPa

13.2 Storage conditions.

Storage temperature: -20℃～45℃;

Relative humidity: 10～95% (non-condensing)

Atmosphere pressure: 50.0kPa～106.0kPa

14. Package list

Standard configuration in a package:

①Infusion Pump 1unit

② AC power cord 1set

③User Manual 1 pc

④Warranty card 1pc

⑤Product qualification certificate 1 pc

15. Open-package Inspection

Cautions for Open-package inspection:

(1) Opening the packing carton carefully to avoid damaging the machine.

(2) Handle with care all items inside the package.

(3) Keep all 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.

16. 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 Ⅰ

Table 1 Classification of alarms and color of alarm indicator light

Classification of alarms	Alarm priority	Color and frequency of alarm indicator light	Technical alarm physiological alarm	Non-latching or latching alarm signals
Door Open alarm	High priority	Red/ 2Hz	Technical	Non-latching
Air Bubble alarm	High priority	Red/ 2Hz	Technical	latching
Occlusion alarm	High priority	Red/ 2Hz	physiological	Non-latching
Low battery alarm	High priority	Red/ 2Hz	Technical	Non-latching
B. Exhaust alarm	High priority	Red/ 2Hz	Technical	Non-latching
Check tube alarm	High priority	Red/ 2Hz	Technical	latching
Finished alarm	High priority	Red/ 2Hz	Technical	latching
Empty bottle alarm	High	Red light /2Hz	Technical	latching
Abnormal dripping rate alarm	High priority	Red/ 2Hz	Technical	latching
AlmostDone alarm	Low priority	Yellow,steady	Technical	latching
AC Fail alarm	Low priority	Yellow,steady	Technical	Non-latching
Use Battery alarm	Low priority	Yellow,steady	Technical	Non-latching
No operate alarm	Low priority	Yellow,steady	Technical	Non-latching
Attention: 1.Time of auditory alarm signal pause： 120s				

Table 2 Alarm conditions and alarm signal delay

Names of alarms	Alarm condition delay	Alarm signal delay
Door Open alarm	10ms	100ms
Air Bubble alarm	110ms	100ms
Occlusion alarm (Middle（8 level）_	12min 5sec @1ml/h, 29s@25ml/h	100ms
LowBattery alarm	10ms	100ms

B. Exhaust alarm	500ms	100ms
Check tube	10ms	100ms
Abnormal dripping rate alarm	10ms	200ms
AlmostDone alarm	10ms	200ms
Finished alarm	10ms	200ms
AC Fail alarm	10ms	200ms
UseBattery alarm	10ms	200ms
No Operate alarm	120 ms	200ms
Heat error alarm （only for heating function）	10ms	100ms

Table 3 Characteristic parameters of alarm signals

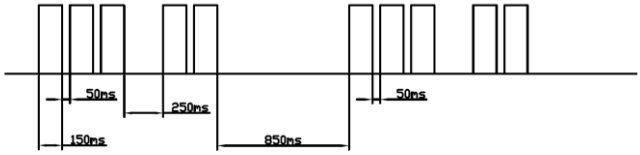
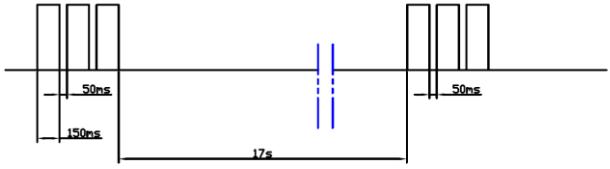
Alarm priority level	Characteristic parameters of alarm signals
Hihg priority	
Low priority	

Table 4 Occlusion response characteristic

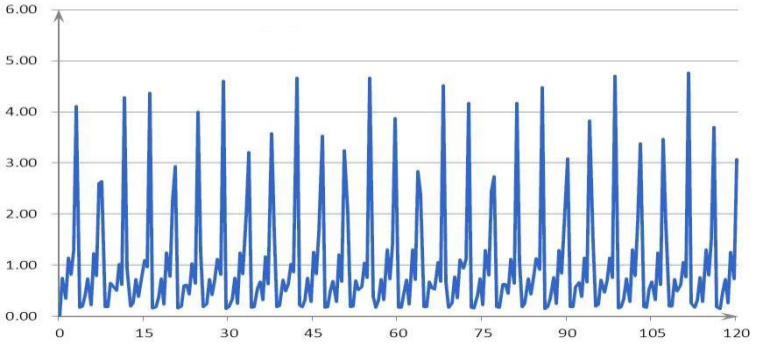
Flow Rate (ml/h)	OCCL alarm level	Occlusion pressure(kPa)	OCCLUSION alarm time	Dosage (ml)
1	Low（1 level）	10	10min	0.03
	Middle（7 level ）	70	1h	0.74
	High（13 level）	130	2h	1.43
25	Low（1 level）	10	30sec	0.04
	Middle（8 level ）	70	3min	0.66
	High （13 level ）	130	5min	1.23

★ The above test uses 'Boon' brand IV set. All the data are obtained by following conditions: The flow clip of IV set is 20cm away from the Infusion Pump; the filter 30cm away from the Infusion Pump; two operations at rate of 1ml/h and 25ml/h respectively.

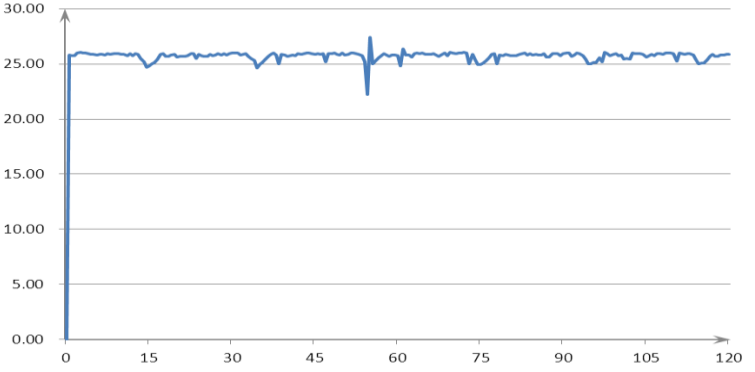
★ The Infusion Pump has anti-bolus function: pressure inside the tube shall release

automatically after giving occlusion alarm.

Table 5 Starting Curves

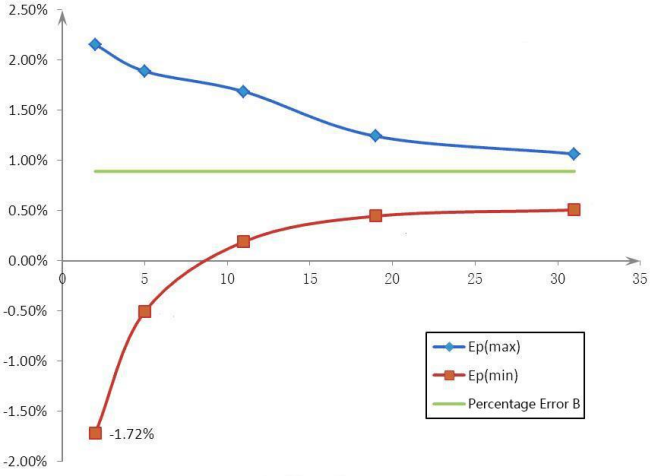


1ml Starting Curves



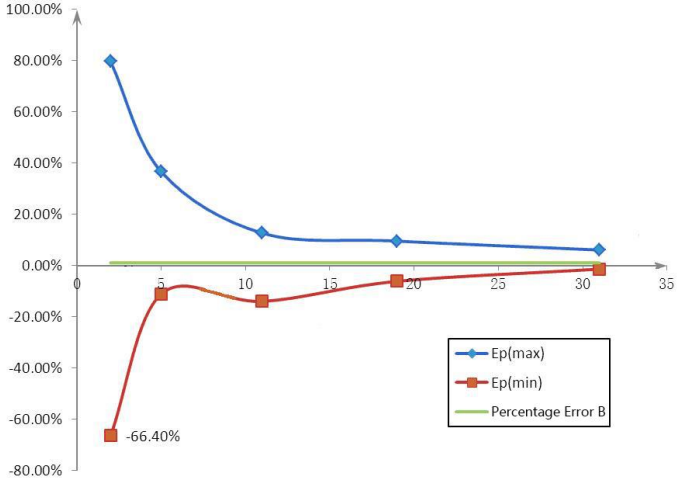
25ml Starting Curves

Table 6 Trumpet Curves



1ml Trumpet Curves

Infusion sets: BOON A2 (1ml=20d)



25ml Trumpet Curves

Infusion sets: BOON A2 (1ml=20d)

Table 7 circuit diagram

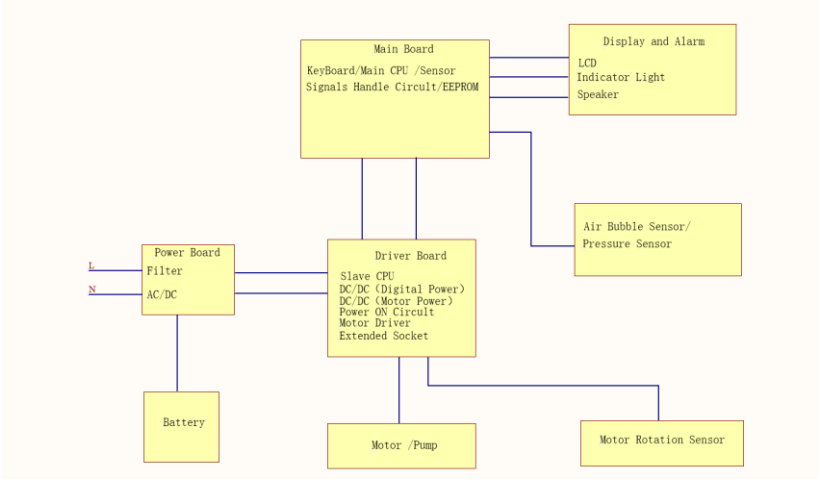


Table 8 component part list

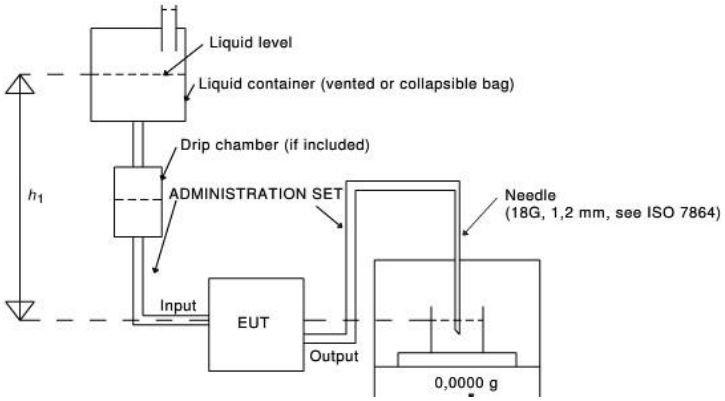
Comment	Designator	Quantity	Supplier
7.4V 1900mAH	AEC903466	1	Apower Electronics
AC power cord	H05VV-F	1	Kenic Electric Mfg. Co. Ltd.
2 phase1.8°42 motor	17HD2422-01N	1	SHANGHAI MOONS' ELECTRIC CO,,LTD
HK-100_Main	PCBA1	1	Interchangeable
HK100_Driver	PCBA2	1	Interchangeable
HK-100_Power	PCBA3	1	Interchangeable
HK-100_YLDB	PCBA4	1	Interchangeable
LCD_2.8	LCD1	1	TianMa
Pres_Sensor	SNR4	1	Measurement
16ohm 1w	SPK1	1	XinFeng elec

Appendix II Infusion pump flow volume accuracy test methods

1. Test method: gravimetric method

2. Principle

Gravimetric method uses electronic balance as the calibration test equipment. Connect calibration system as per diagram 2-1. Put certain volume of fluid into container (Container should add lid. If without lid it should add certain amount of paraffin oil to prevent evaporation). Injection needle should be under surface of fluid. This method uses electronic balance to collect the total output volume of the infusion pump during test period. The error calculated by differences between preset volume and actual weighing weight.



(diagram 2-1)

3. Test Environment

3.1 Temperature: 20±2°C

3.2 Relative humidity: 60±15%

3.3 Atmospheric pressure: 860hpa~1060hpa (645mmHg~795mmHg) (note: A standard atmospheric pressure:760mmHg)

4. Test instruments and reagents:

4.1. Calibrated electronic balance（Requires precision to more than three decimal places）

4.2 Injection needle（18G,1.2mm, refer to ISO 7864）

4.3 Infusion set(infusion set for pump use or infusion set under Boon brand）

4.4 Connecting components (connecting pipe and injection needle)

4.5 Collector (beaker + anti-volatile paraffin oil)

5 Test procedures

5.1 Connect infusion pump, infusion set, electronic balance and container as diagram 2-1 (among it h is 50cm±20cm)

5.2 The balance is placed in suitable fixed position; the collector is placed in the balance. Put certain amount of water to beaker and certain drops of Anti-volatile oil. (Record the readings of electronic balance. Confirm weight change of collector per hour less than 0.001g / h before testing)

5.3 Connect a brand new infusion set as per instruction, immerse injection needle below the surface of fluid in collector and keep hanging. Ensure injection needle holder is relatively higher enough than fluid surface. (Prevent fluid level rises so immerse the injection needle holder).

5.4 The infusion pump is placed in proper position. Ensure infusion pump input terminal and the collector fluid surface at the same level height. Turn on the machine after connecting power cable.

5.5 Fix the pipe and ensure no deformation of tubing due to movement or other reasons during testing.

5.6 Press and hold on STOP key first, then press  (1st soft key on top left) to enter 'parameter setting interface', press  for 'Accu.' to enter IV set calibration mode.

Press START key, the Infusion Pump shall start operation at 150ml/h. After it finishes VTBI (10ml), measuring the flown-out liquid (the balance reading after infusion finish – balance reading before infusion), input this volume on "real" text of calibration interface. Then press ENTER key to save the value and exit. The calibration of infusion set is complete.

5.7 After calibration, set flow rate at 150ml/h, volume limit as 10ml. The flow rate accuracy should be +3%.

6. Supplements

6.1 The consistency of infusion set

The infusion set used in test procedure, the pipeline cross-sectional area of the size, the diameter consistency, resilience have a greater effect on accuracy of infusion pump. Usually require calibration prior to use.

6.2 Stability of connecting components

Output terminal of infusion set and collector used in test procedure, shaking and deformation of infusion set will affect the total volume of liquid output.

6.3 The change of testing environment

The piping material is high polymer; the changes in the environment, especially temperature will change piping volume, thus affecting the amount of the output fluid.

6.4 Effect by other factors

As per the effect by environmental of solution, it needs to check infusion liquid filter blockage after testing. When a blockage occurs, the test should be repeated.

6.5 High-quality dedicated infusion set:

a) Material: (only used within the length of the peristaltic pump) platinum cured processing medical grade silicone tube.

b） Silicone tube working length: 320mm5mm

c） Tensile strength: 9.01.4N/mm²

d） Hardness: 562 Shore hardness A

e） Silicone tube wall manufacturing error: 0.0254mm

Note: Accuracy testing can also use infusion set that has similar performance as an alternative for peristaltic pump, such as Boon brand infusion set.

Manufacturer : Shenzhen Hawk Medical Instrument Co., Ltd.

Address: 1st Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community，Longhua Street, Longhua District, Shenzhen, 518109, Guangdong, P.R.China

Postal code: 518109

Tel: +86-755-8315 1901

Fax: +86-755-8315 1906

Email: szhk@hawkmedical.cn

Web: www.hawkmedical.cn

EU Representative: Wellkang Ltd

Address: The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

Tel: +353 (1) 4433560

Web: www.CE-marking.eu

Email: AuthRep@CE-marking.eu

SYRINGE PUMP

USER MANUAL

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

057-00034-03

Table of Contents

Revision Notes:

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.

Version No.	Date of Preparation
V1.0.0	2012.03.17
V1.1.0	2017.07.14
V1.2.0	2017.08.16
V1.0.0	2020.06.18

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) 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 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

n) Please use to meet the relevant laws and regulations, with a valid medical device registration certificate of the infusion tube, or can not guarantee the accuracy of infusion and normal detection alarm.

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 classI, 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 Operating conditions

a) Temperature: 5℃-40℃

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

2.5 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.

2.6 Date of manufacture & life span

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

2.7 Version of software

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

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, drug library
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°.

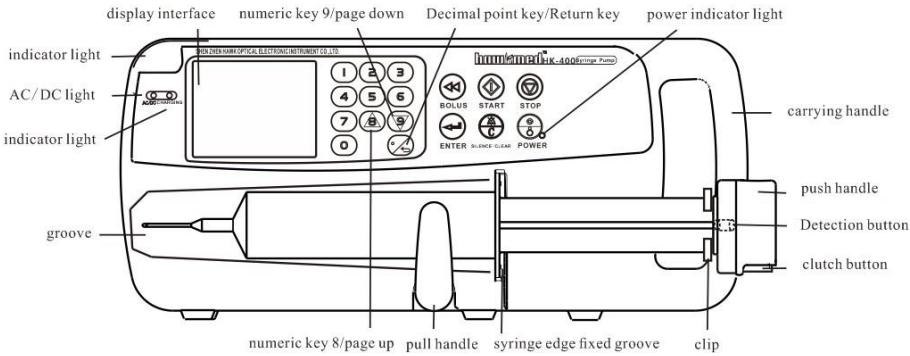
5.2 Installation method and cautions

If the pole clamp is in the same direction with that of IV stand or bar, rotate 90° 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

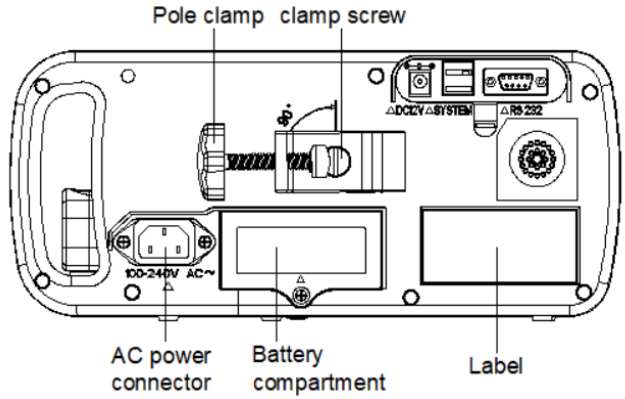


Description	Functions
BOLUS key	In 'stop' status, press & keep finger on 'bolus' key, the pump starts purging. After releasing the finger, purging stops. During operation, press & keep finger on 'bolus' key, the pump starts bolus infusion (bolus rate preset by the user). Release the finger, bolus infusion 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).
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. Loosen the clamp screw to change the direction of pole clamp. (Horizontal or vertical optional)
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)

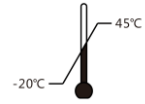
The label contains information such as manufacturer, date of production, product serial No., classification, waterproof level, etc.

6.3.2 Symbols and significance

(Table 1)

Symbols	Descriptions
LOT	Production batch No.
SN	Product serial No.
	Caution， consult accompanying documents
	Consult instruction for use
	Type CF
	Protective Earthing

IP24	The device against ingress of solid foreign objects ≥12.5mm diameter and splashing water
	AC power
	DC power
	Dispose in environmental-friendly way
	Date of production
	manufacturer
	Caution Against Wet
	Fragile. Handle with care!
	Keep upright during transport
	5 layers at most of the same package
	Transport package humidity 10～95%

	Transport package temperature -20°C～45°C

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.

Switch on: Press Power key ⏻ few seconds, the pump will be switched on and do self-test, and shows Self-testing on the display, it will test: Communication Info, Press sensor, Potentiometer, Dedicated IV set, AC Info and Battery Info. The test result (OK or FAIL) will be displayed on LCD.

Pump self-test information after switching on:

(1) Communication information: OK indicates CPU normal; FAILED indicates CPU abnormal;

(2) Battery information: OK indicates internal battery normal; FAILED indicates internal battery abnormal;

(3) AC information: OK indicates AC connected well; FAILED indicates AC fail;

(4) Pressure sensor: OK indicates normal pressure detection; FAILED indicates: abnormal pressure detection;

(5) Potentiometer: OK indicates normal Potentiometer; FAILED indicates: abnormal Potentiometer;

(6) Dedicated IV set: OK indicates normal dedicated IV sensor; FAILED indicates: abnormal installation of dedicated IV set or IV set is installed in the pump already;

Attention: 1. If the potentiometer is abnormal, the system will ask "Is the syringe installed?", please choose the answer according to the facts, the system will predicate per your choice.

2.Please keep an eye on the self-test, if any abnormal, please contact our company, DO NOT force to use it.

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

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.

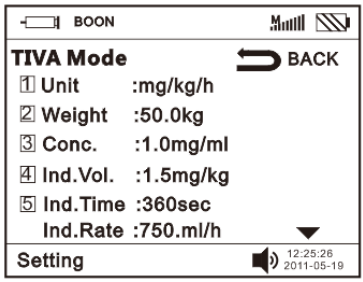
(4) Press the clutch button on push handle tightly; move the push handle to the end of syringe handspike, release the clutch button, the clip will grip the end of syringe handspike automatically. Meanwhile, the size of syringe will be displayed on LCD.

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

1. 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.

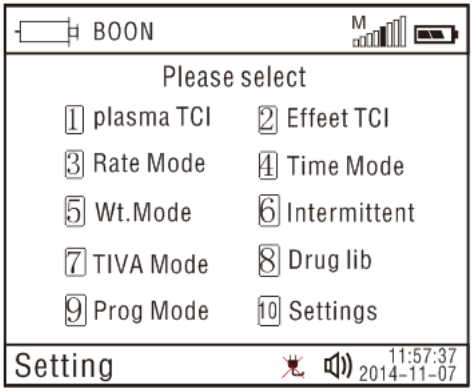
（2）If setting weight, input the number directly after the white text appearing, press ENTER key to save it. If input wrong number, press CLEAR key to remover and reset.

Attention:

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

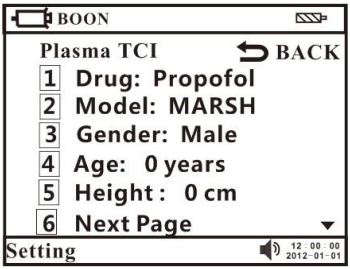
(2) If the setting value out of system default limit, the system will only display the minimum or maximum default value. Take body weight for example, if system default value is 3-150 kg, input 2, it will only display 3; input 160, it will only display150.

2. Submenu (Infusion Mode) Selection

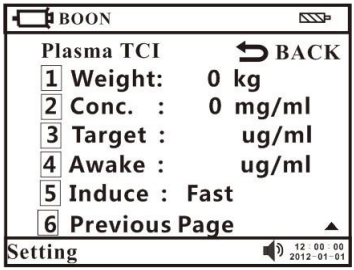


（Diagram 3）

（1）Plasma TCI mode

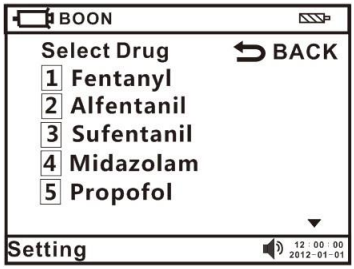


（Diagram 4）

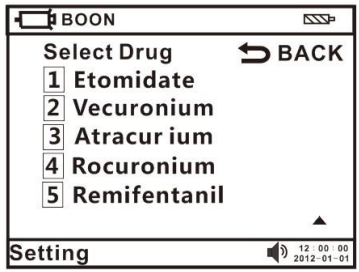


（Diagram 5）

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**）



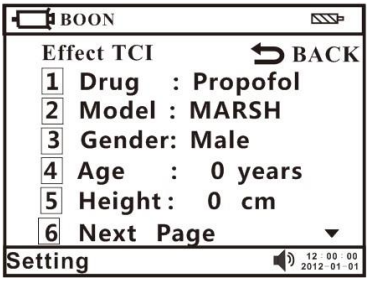
（**Diagram 7**）

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.

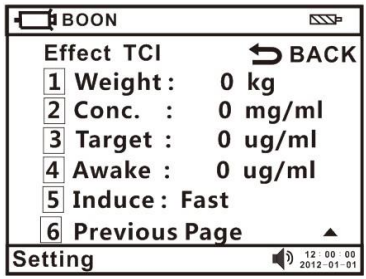
Set the other parameters as per above methods, press ENTER key to save value and exit.

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.

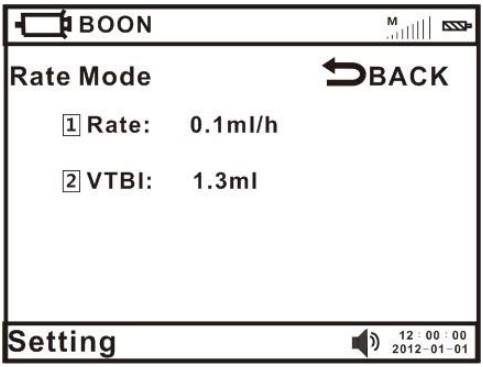
Drug: Press numeric key "1" entering the drug selection interface (Diagram 6). If there is no required drug, press numeric key "9" entering the next page (Diagram 7). Select the drug according to initial number.

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）

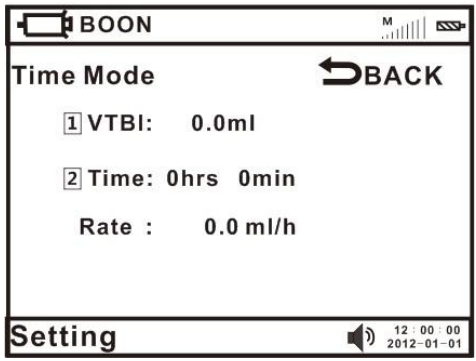
On syringe pump main menu (Diagram 3), press corresponding number key of rate mode enter the parameter setting interface (Diagram 10). Flow rate and volume to be infused (VTBI) can be setting.

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.

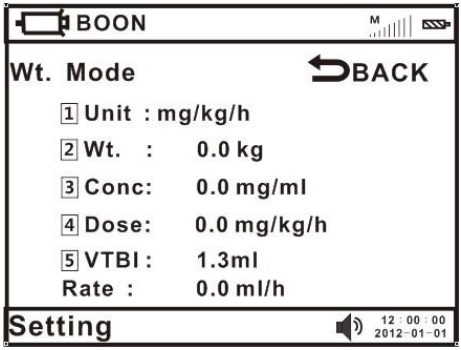
VTBI: Press numeric key "1", input the VTBI (volume limit) in white text. If input wrong value, press CLEAR key to remove and reset. Press ENTER to save value and exit.

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.

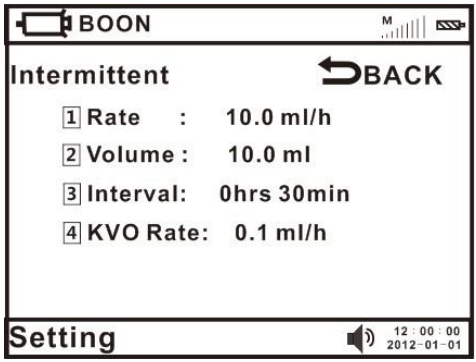
Set the other parameters in the same way.

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



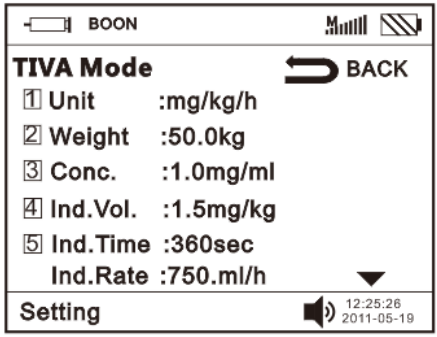
(Diagram 13)

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.

Eg: as Diagram 13 shows, after infused 10ml at rate 10ml/h, it will stop infusion for 30min and start KVO at 0.1ml/h. After 30 min, it will start infusion for 10ml at flow rate 10ml/h again.

Return: Press RETURN key back to main menu.

（7）TIVA mode

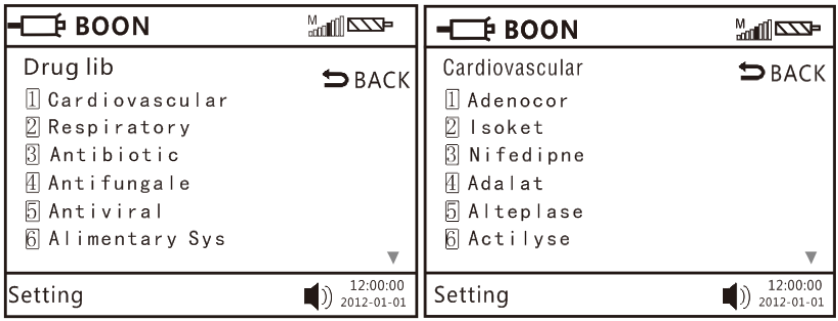


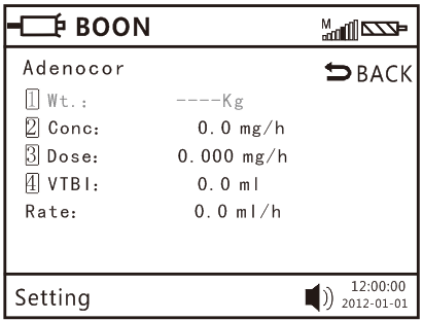
(Diagram 14）

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）Drug lib

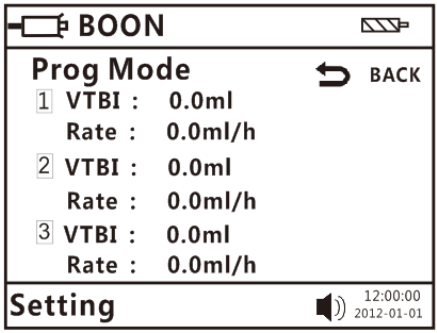




(Diagram 15）

press the corresponding number key to enter the parameter setting interface, according to the demand to select the drug category, enter the drug name menu, set the parameters correct, press the Enter key to save.

(9) Prog Mode



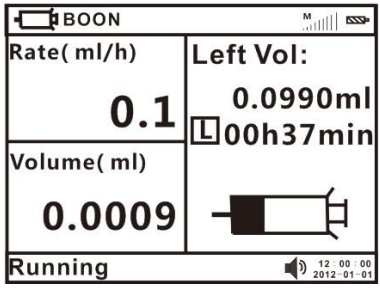
(Diagram 16）

This mode can be used up to three stages for infusion. Each mode has two sets of parameters to be set, that is, the infusion volume and infusion time. The machine will automatically calculate the infusion flow rate in this phase according to the input of this two sets of parameters for drug infusion. When the first stage of the pre-set infusion is completed, the machine will run for the second stage of the infusion, and so on until the completion of all three stages of the preset amount of the set. User can also select one or two of the stages to set the parameters and then run, the machine will automatically identify which stage has parameter settings and run this stage.

8.1.5 Purge

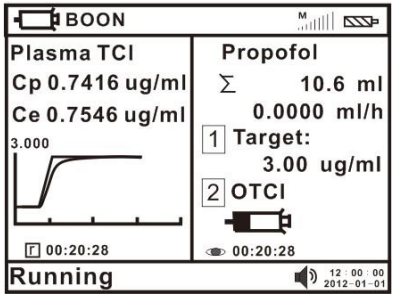
In 'stop' status, press & hold on BOLUS key until all air inside the tube is purged.

8.1.6 Start Infusion



(Diagram17 Constant Flow Rate mode running interface）

（Diagram18 Reminding interface before TCI mode running）



（Diagram 19 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

There are two methods to purge. They are manual bolus and auto bolus. Please follow by the followi ng procedures:

1)Manual bolus: During infusion process, press bolus key and hold on. The pump will purge at preset bolus rate. It will return to previous infusion rate after releasing your finger.

2)Auto bolus: After setting bolus rate, it will purge at bolus rate by single clicking bolus key.

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 “Endinjection” 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.

8.1.11 to change infusion rate during infusion

When the pump is working, press numeric key“5”to enter into the interface of changing infusion rate.

Setting procedure: Infusion rate: Press numeric key “1”to make it editable.Then enter infusion rate value you want to set. If any error, press “SILENCE/CLEAR”key to clear and enter correct one.

Preset: Press numeric key “2”to make it editable.Enter into preset value.If any error, pls press “SILIENCE/CLEAR”key to enter again.Save the value after confirmation.

Return to infusion interface: after setting infusion rate and preset volume,press “start”key to return to infusion interface.But pls note:

(1) Infusion rate should be more than “0”.

(2) Preset volume should be more than real time total volume.

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.
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

Press the corresponding number key in the main menu interface to enter the system setting interface. In order to ensure the accuracy of infusion, it is recommended to use the pump built-in syringe brand (Boon, Jie Rui, Long heart, double pigeon, Hongda, Hongda-B, Kandelai, Fuli, Bailang)

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-define syringe

(1) Brand name setting procedure.

Select “Settings”to enter into setting interface.Then select “2 Set Syringe Para”.Then select “1 Set the brand name”to set brand name.

Setting methods：

please press one of the numeric keys 1-5 to make it editable.

Press numeric keys 1or2 or3 or 4 or5 or 6 or7 to enter into wanted letters.

Note:1=A,B,C,D

2=E,F,G,H

3=I,J,K,L

4=M,N,O,P

5=Q,R,S,T

6=U,V,W,X

7=Z,Y

Pls press 8 (up) 9(down) to shift from one to another letter

For for example, I f I need to set brand name “Hawkmed”,I shall press key 2 to choose its “H”,then key 1 to choose its “A”, then key 6 to choose its “W”, then key 4 to choose its “M”,then key 2 to choose its “E”, then key 1 to choose its “D”. When finished, press “Enter” key to confirm it.

（2）Self calibration procedure:

Take 50ml syringe for example, pull the plunger(handspike) to 50ml scale and install it correctly.

Enter into settings interface. Press numeric key “2 Set Syringe Para”to enter into self calibration interface. In the “Set the Syringe Para” interface, select “2 Set the Parameters”and then choose one brand name like Brand B.In this brand setting interface, choose corresponding syringe like 50 ml syringe.There are two calibrating Methods.

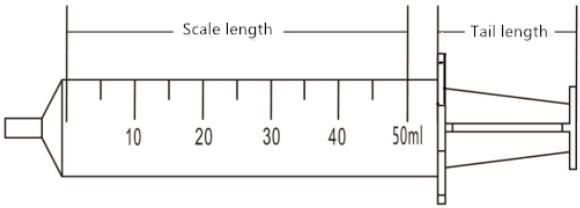
Method 1: auto calibration

Select “1 Auto measure syringe”.A popup menu will show “Pull syringe handspike to 50ml scale, install it to machine”. Select “1 Yes” to start calibration.After finish, select”3”to confirm it.

Method 2: manual calibration

Select “2 Manual measure syringe”. Then measure the length of scale(from 0-50ml) and the length of tail.Select “1 Length: ml” to enter into scale length and select “2 Tail: ml”to enter into tail length.Then press Key “3”to confirm it.Now the manual calibration is done.

Attention: Pls choose correct brand name before using the pump in order to avoid alarm and make it more accurate.



（**Diagram** 19）

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

There are two methods for Bolus, manual Bolus and auto Bolus, operation as below:

Manual Bolus: After power on the pump, press STOP+ left 1st soft key to enter Settings, select Bolus, set Bolus rate and VTBI: 0, press ENTER to save the value. During infusing, keep pressing BOLUS key then it will run at Bolus rate; if release the BOLUS key, it will run at original rate, not Bolus rate.

Auto Bolus: After power on the pump, press STOP+ left 1st soft key to enter Settings, select Bolus, set Bolus rate and VTBI >0, press ENTER to save the value. During infusing, press BOLUS and release, it will run at Bolus rate until finishing the VTBI, then run at original rate.

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 WIFI configuration and WIFI module (optional)

The pump supports connection to fluid management system wirelessly, it works through WIFI module (optional) and router (optional). Steps as below:

WIFI configuration: After entering Settings, select WIFI, set it ON, then active the WIFI function. It will connect with the WIFI network which connected successfully last time.

WIFI module configuration: Connect with monitoring system system wirelessly, send the infusion data, alarms, reminders etc to monitoring system system.

Attention: The configuration must be set by the engineers we admit, or the servicer we appointed.

8.3.18 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.

8.3.19 Maintenance reminder

This function is mainly to remind the user to maintain the machine on a regular basis, set the parameters of the maintenance interval, when the machine detects that the setting of maintenance time has reached, it will remind user to maintain.

8.3.20 About this machine

This option is mainly to display the machine model, software burning version, release version and the machine's SN code.

8.3.21 User-define drug library

This function provides user-defined drugs (up to 30 drugs can be user-defined) for injecting drugs in

the Drug library mode. User-define drug can enter the drug name (up to 10 letters) and set the drug infusion mode (three modes are optional, the dose mode, body weight mode, flow rate mode)etc.

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 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℃～45℃;

(3) Relative humidity: 10～85% (no frosting)

(4) Atmosphere pressure: 50.0kPa～106.0kPa

12.2 Storage conditions.

Storage temperature: −20℃～+45℃(With battery);

−20℃～+60℃(Without battery)

Relative humidity: 10～85% (no frosting)

Atmosphere pressure: 50.0kPa～106.0kPa

13. Package list

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

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	Red/2Hz

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

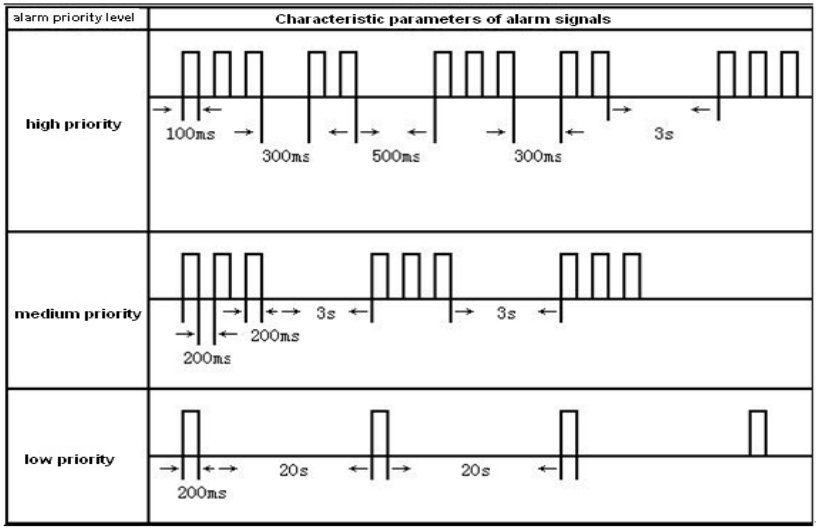


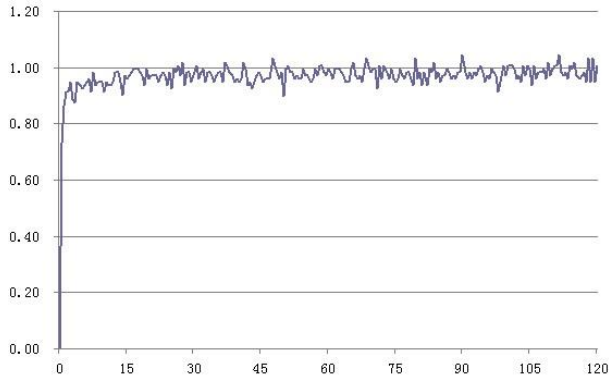
Table 4 Occlusion response characteristic

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

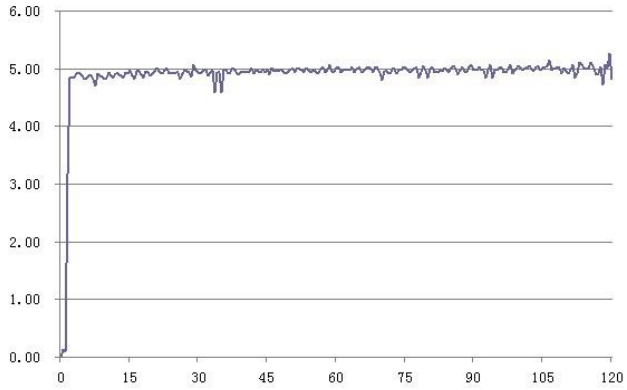
The above test uses ‘Boon’ brand of 5ml syringe. All the data are obtained by using ‘Boon’ brand syringe.

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

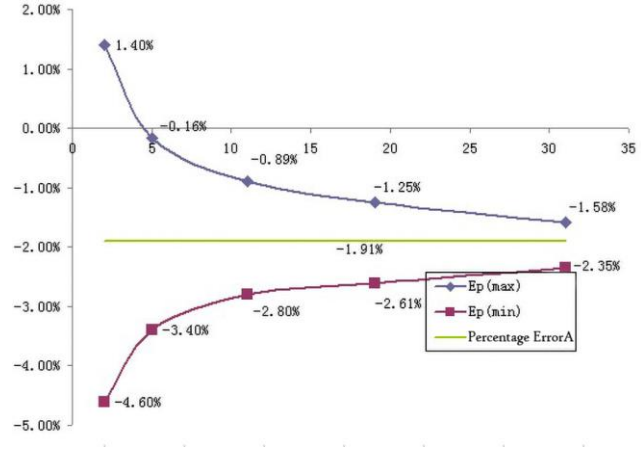


1ml starting curve

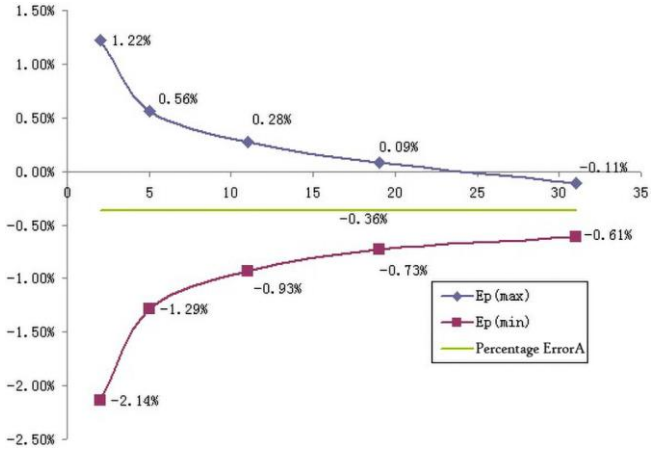


5ml starting curve

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.

浙江升升医疗器械有限公司

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MEDICAL DEVICE BROCHURE

医疗器械宣传手册

升升醫療器械

SS Medical

浙江升升医疗器械有限公司

ZHEJIANG SHENGSHENG MEDICAL EQUIPMENT CO. LTD

一次性使用肠内营养输注器

生产许可证编号：赣食药监械生产许 20190273 号
注册证 / 产品技术要求编号：赣械注准 20192140035

【使用方法】

- 拆开初包装，取出本产品，关闭止液夹和流量调节器。
  A 型：打开营养袋上盖子，向袋内注入配置好的营养制剂，然后将盖子盖紧，摇均匀后展挂在输液架上
  B 型：打开营养袋旋盖，向袋内注入配置好的营养制剂，用配套旋盖盖上旋紧，摇均匀后悬挂在输液架上，
- B 型拔掉瓶塞穿部保护，拉开营养裂旋盖页端拉环，将瓶塞穿刺器插入旋盖穿刺接口内
  C 型；拔掉瓶塞穿刺器保护套，将瓶塞穿刺器插入另已配置好营养制剂的营养瓶 / 袋内
- 打开止液夹和流量调节，拔掉接头保护套，使整个管路充满营养制剂，并确保管路无气泡，关闭流量调节器
- 对于重力给养输注
  将接头与鼻胃、肠管等连接
  根据需要的流速调节流量调节器，进行管饲喂养；
  冲洗管路或给药时，旋开三通护帽进行冲洗或给药，完毕后立即旋紧三通护帽
- 对于配套泵用输注
  将硅胶泵管嵌入营养输液泵的簧型固定槽内；
  根据需要设定营养输液泵的流速，再将流量调节器调制最大流量，启动营养输液泵，进行管饲喂养
  冲洗管路或给药时，旋开三通护帽进行冲洗或给药，完毕后立即旋紧三通护帽。

【注意事项】

- 使用前检查初包装是否完整，包装破损、内有异物、保护套脱藩禁止使用
- 本品仅供肠内营养输注用，不得用于其它输注场合。
- 本品仅供单一患者使用，为避免污染，使用时间建议不超过 24 小时
- 本品经环氧乙烷灭菌，无菌，在规定的失效日期前使用
- 本品仅限一次性使用，用后销毁。
- 生产日期 / 批号、失效日期、型号规格见封口处。
  STERILEJEO STERI 目
- 其他内容详见说明书。

一次性使用输液延长管

国械注准 20153660831
浙食药监械生产许 20100216 号
通过 ISO9001&ISO13485 质量体系认证

【注意事项】

- 包装破损，保护套脱落禁止使用。
- 仅供一次性使用，用后销毁。
- 环氧乙烷灭菌，无菌，无热原。
- 其他内容详见说明书。

【使用说明】

- 检查小包装是否破损，是否有异物，如有此情况不得使用。
- 撕开小包装，去除输液延长管，上紧输液延长管内圆锥接头与输液器具 6:100 圆锥接头；然后将
- 输液针或注射针与输液延长管外圆锥接头连接紧密。

  按常规操作，排除输液器具、输液延长管及输液针或注射针内的气泡，进行正常输液。

注射器类
SYRINGES

京环医疗

一次性使用
无菌注射器 带针
Disposable syringe with needle

型号规格 /Specification
1ml、2.5ml、5ml、10ml、20ml、30ml、50ml

京环医疗

一次性使用
无菌配药器 带针
Disposable dosage syringe with needle

型号规格 /Specification
10ml、20ml、30ml、50ml

京环医疗

一次性使用
微量注射器
Disposable Microsyringe

京环医疗

一次性使用
输液器 带针
Disposable infusion set with needle

Va

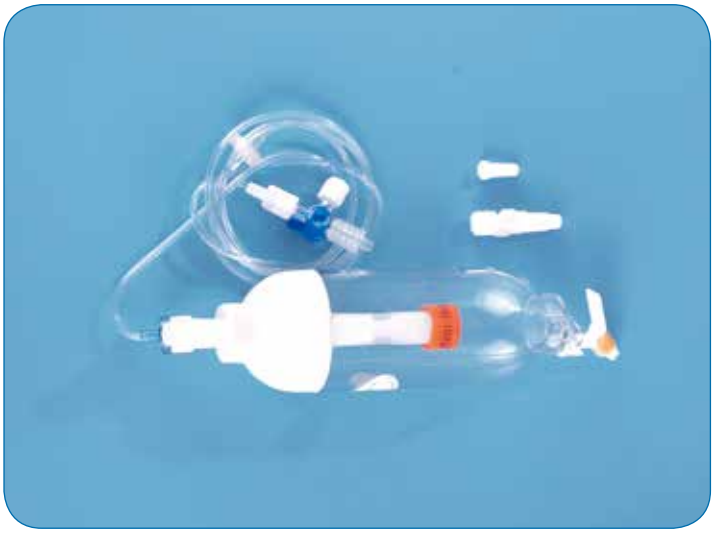
京环医疗

一次性使用
精密过滤输液器 带针
Disposable precise infusion set with needle

PF-5.0-Va

京环医疗

一次性使用
输血器
Disposable blood transfusion set



一次性使用

输注泵

Disposable antalgic infusion set/pump

康健医疗

一次性使用

无菌阴道扩张器

Disposable vaginal speculum

1037

康健医疗

一次性使用

妇科冲洗器

Vaginal washer

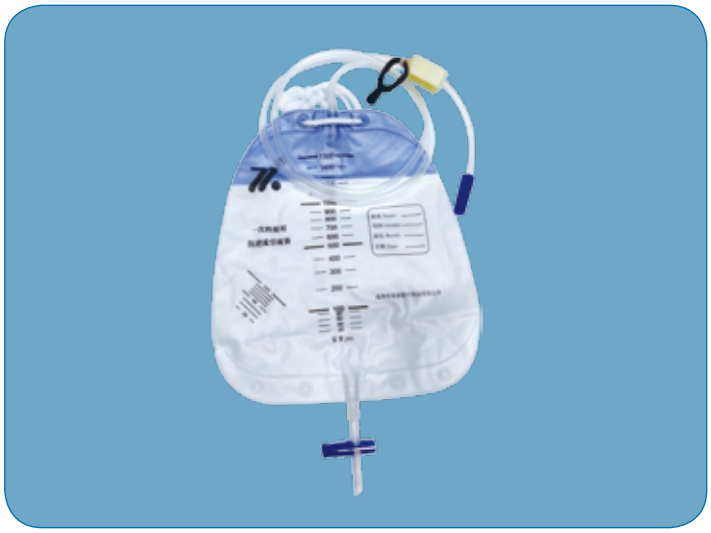
1035

引流袋类
DRAINAGE BAG

双美医疗

一次性使用
引流袋
Drainage bag

推拉阀 1000ML



双美医疗

一次性使用
引流袋
Drainage bag

1500ML

双美医疗

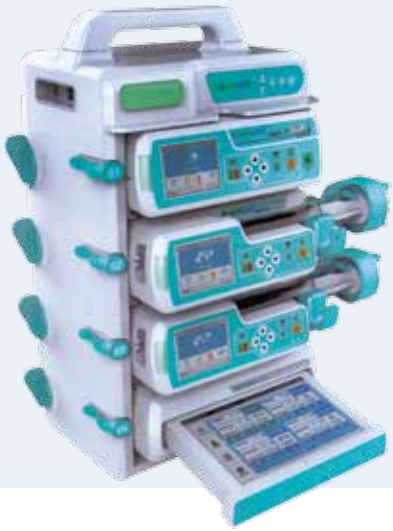
一次性使用
引流袋
Drainage bag

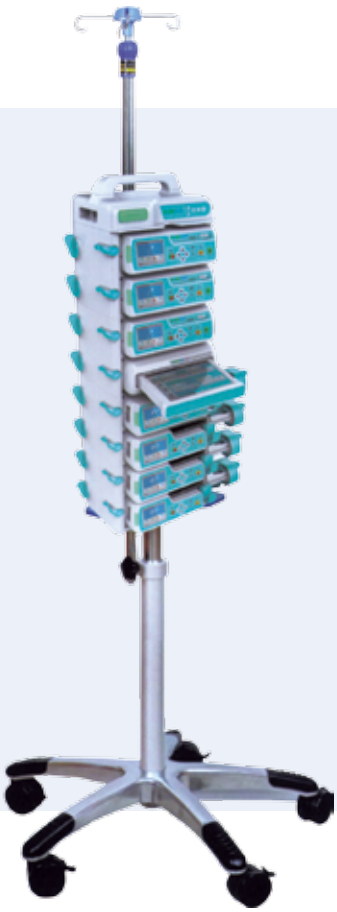
十字阀 1000ML

HAWK-WS1 工作站

HAWK – WS1 workstation

好克医疗





插件式、模块化组合方式、可以根据临床需求，组合成多通道注射泵、多通道输液泵、多通道注射输液混合泵，输注泵之间实现级联输液功能，满足患者静脉输注各种需要。

产品特点

- 多通道组合：多至 5 个组合箱，可组成 15 通道输注泵；
- 级联输液：输注泵之间级联输液，自动连续输液；
- 插件式、模块化设计：简单快捷实现多通道输注泵组合（无需拆装单台泵固定夹）
- 输液管路整理夹：让多通道输注管路及延长管理有序整理达到清晰、整洁的效果
- 整体供电：只需一根电源线，可满足组合箱内所有单泵的充供电。

HK-M1000 输注监护管理系统

HK-M1000 Infusion Monitoring Management System

产品特点

- 可靠的 WIFI 组网
- 实现远程的无线监护
- PC 端显示输注信息，输注状态一览无余
- 精准的数据反馈显示实时的输注信息
- 完整记录输液信息和患者信息

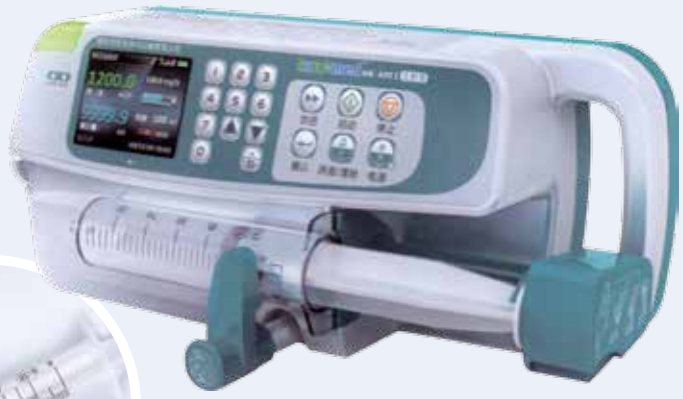
注：不对联网的注射泵、输液泵、多道泵进行控制操作，确保输液的安全。

HK-400 系列注射泵

Hk-400 Series Syringe pump

好克医疗

- 全方位报警指示灯
- 固定夹 90° 可调可水平或垂直
- 大屏幕彩色液晶菜单显示详情
- 支持无线维护功能



特点功能

- 独特的智能识别注射器功能，自动识别注射器规格；
- 支持 5、10、20、30、50、60ml 等多种规格注射器；
- 支持符合国标的任何厂家的一次性使用无菌注射器；
- 实时时钟显示，保证患者输液信息被正确记录；
- 阻塞档位三档可调，实时显示输注管路压力情况

HK-50F6/SN-50F66(R) 微量注射泵

HK-50F6/SN-50F66(R) micro syringe pump

CE 0123

HK-50F66R 具有无线通讯联网功能

好克医疗

国际一流品质的注射泵

更精确：注射器精度校准，适配所有品牌注射器以更高精度注射
更安全：专利技术，注射时针头脱落自动报警
更续航：电池充满电后可持续工作 7 小时以上 (5mL/h)
更易用：多方向固定夹，可任意方向安装
更节电：每通道可独立设置成休眠模式
更机动：支持车载，可使用车内 12V 电源
更智能：提供无线通讯联网功能，管理更智能 (SN-50F66R)
更兼容：支持 5(SN-50F66R)、10、20、30、50(60)ml 等多种规格注射器，方便临床应用

双通道
双色系设计，容易区分，互不干扰

通道休眠模式
省电，不干扰另一通道工作

HK-1600V(R)/HK-1700V(R) 输液泵
HK-1800V(R)/HK-1900V(R) 输液泵

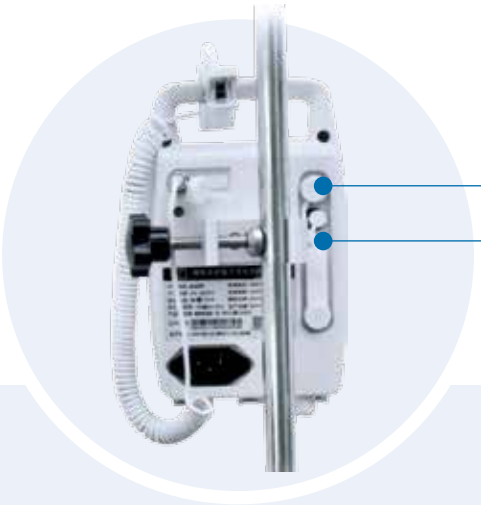
SN－1600V(R)/SN－1700V(R) infusion pump
SN－1800V(R)/SN－1900V(R) infusion pump

安全易用的输液泵

CE 0123

更精确：智能脉动补偿，低速输液流速更均匀
更安静：高品质电机驱动，功耗小，噪音低
更安全：双 CPU 实时监控。安全性高
更易用：支持流速、点滴、体重、时间、预设方案五种输液模式，功能强大
更续航：可续航 8 个小时以上 (25ML/H 运行)
更灵活：支持输液器 10 滴、15 滴、18 滴、20 滴、60 滴多种选择
更智能：提供无线通讯联网功能，管理更智能 (SN-1600VR/SN-1700VR/SN-1800VR/SN-1900VR)

好克医疗



1. 运行状态灯，方便观察机器状态
2. 泵内夜间照明传感器
3. 数码管显示关键信息
4. 液晶屏显示详细参数设置
5. 数字键盘快捷输入
6. 底部防滑垫设计，便于平放使用
7. 流线型精巧设计，整机仅 1.8KG

注：以上特性同时适用于立式输液泵

HK-600N(R) 肠内营养泵

SN-600N(R) enteral nutrition pump

全透明泵门，输液全程可视

CE 0123

好克医疗

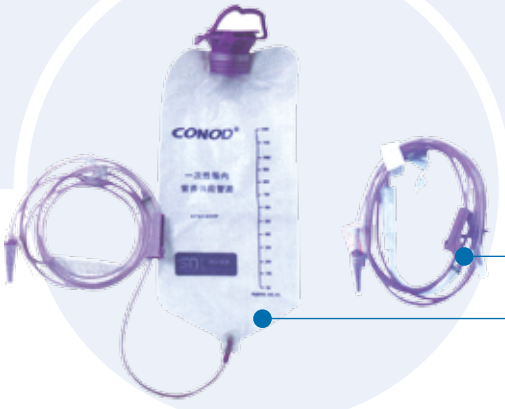
更方便：全透明泵门设计，凸轮可拆卸冲洗

更精巧：整机仅 1.3KG, 优雅的流线造型

更安全：泵顶大状态灯，速度可校准，电源插座防水

更智能：仿生间断输出，无线联网功能，报警音可调

1. 大状态灯更醒目
2. 紫色外观，流线造型，更优雅美观
3. 间断仿生输出，速度可校准，运行功耗低
4. 可拆卸冲洗结构，更便捷
5. 全程透明式输送，清晰可见
6. 防水插座设计



G-0
一次性肠内营养供应管路

E-1200
一次性肠内营养供应管路

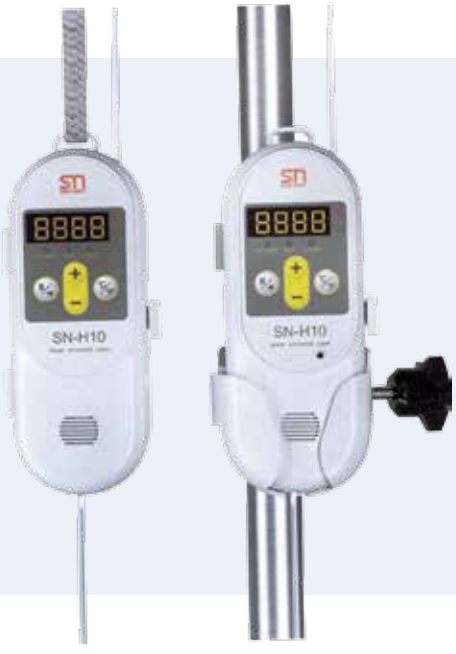
HK-H10 输血输液加温器

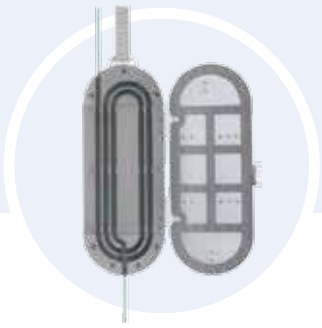
SN-H10 blood transfusion and infusion heater

好克医疗

智能控制、温度精确、2 种悬挂方式

- 采用智能控制技术，温度控制精确，提供故障报警，确保安全
- 两组独立温度传感器，实时显示温度





CT 高压注射器（SinoPower 系列）

CT high-pressure syringes (SinoPower series)

全球独创的“直接压力传感器”专利设计

（专利号 zL2009201290059）

- 实时压力显示
- 当实际压力超过限定压力系统会自动报警停机
- 有效减少药液渗漏造成的肿胀（见应用案例）

SinoPower-D

SinoPower-S

近远端控制台大尺寸真彩色液晶触摸屏同步显示

- 远端：预案编制与执行注射动作，同步显示近端的所有操作
- 近端：可以执行所有动作，同步显示远端的所有操作

机头尾部 LED 旋转指示灯

- 在吸药过程中 LED 灯顺时针旋转显示
- 在注射过程中 LED 灯逆时针旋转显示

高压造影注射器及附件

High-pressure Angiographic Syringes and Accessories For Single Use

200 适用于 CT100200A

包含 /CONTAINS

(压力不要超过 300PSi 或 2100Kpa)

200ml 注射器
150cm 单通连接管 / 多通道连接管
1 支 管式吸药器 –J 型 / 管式吸药器 – 直型 / 穿式吸药器 – 塑插针 / 穿式吸药器 – 刚针

Attention: See instructions for use packaged each carton
使用前请参考说明书

Do not reuse
一次性使用

STERILE EO
Sterilized with Ethylene Oxide
环氧乙烷灭菌

LATEX
Latex
含天然橡胶

NON-PYROGENIC
DO NOT USE IF PACKAGE IS OPENED OR DAMAGED
STERILE

无菌、无热原。单包装如有破损严禁使用
环氧乙烷灭菌。天然橡胶过敏者禁用，
其它内容详见说明书。

进口 / 国产
自助胶片打印机
Imported/domestic self-service film printer

进口 / 国产
胶片打印机
Imported/domestic film printer

进口 / 国产医用胶片

Medical infrared laser film

国外进口激光胶片

国内胶片