Shenzhen Hawk Medical Instrument Co., Ltd.

Safety and Performance Information Relevant to The User or Other

（SYRINGE PUMP）

Model: HK-400 HK-400I HK-400II

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

CE 0197

057-00683-00

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-400, HK-400I, HK-400II SYRINGE PUMP

Version No.	Compile date
V1.0.0	2025-11-01

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 pump has small improvement: In order to better using the pump, 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 pump 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 extension tube. It is required to inspect the infusion status regularly to prevent above problems.

Don't spill fluid on the pump.Rinsed fluid may corrode the internal electrical components.

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 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 moment. In addition, the occlusion alarm is not given maybe because the actual occlusion pressure not large enough to reach the occlusion alarm threshold value, therefore, to check the insertion area regularly is needed. If the insertion area seems abnormal, please take proper treatments such as re-inserting the needle.

d) Infusion flow blockage that caused by infusion tubing knotting, filter or needle blocking, or needle occurring thrombosis etc, may lead to pressure increase inside the extension tube. During dismissing such blockage, it may cause temporary large-volume infusion. The correct method is to clamp the tube near the insertion area tightly before releasing the pressure. Then get rid of the occlusion problem, release the tube and restart operation.

e) Please use disposable sterile syringes which meet the requirements of relevant rules and standards and with valid medical device registration certificate. 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.The syringe should be replaced after being used for 24 hours.

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

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

o) Please use to meet the relevant laws and regulations, with a valid medical device registration certificate of the infusion tubing, or cannot guarantee the accuracy of infusion and normal detection alarm.

p) Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

r) Do not position me equipment to make it difficult to operate the disconnection device.

s) Unauthorized modifications to this equipment are not permitted,that may result in serious injury o patients.

t) Loss of power may result in unacceptable risks. The equipment must be connected to a suitable power supply.

u) The device must be connected to a certified DC power supply that conforming to IEC 60950-1/IEC 62368-1 or other relevant safety standards when powered by DC power source.

v) To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

w) When the power loss duration does not exceed 30s, the alarm setting before the power loss can be automatically restored.

x) When this device is connected to the same infusion port as other infusion systems, backflow may occur due to mutual influence between the infusion tubes, or the response duration for blockage may be extended. Therefore, when connections to other infusion systems are required, a One-Way valve should be used at the end of the infusion line or done under the guidance of the local hospital.

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, 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 tubing 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 Syringe Pump must be operated by or under the guidance of clinically trained and qualified technicians who have received a training related to the use of this device.

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.

o) The maximum infusion pressure created by syringe pump is 180Kpa.

p) the pump is contraindicated for use with drugs or solutions that have not been labeled for administration.

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 Intended use

It is used in conjunction with an syringe to administer intravenous medication to patients. This syringe pump is suitable for adult, pediatric and neonatal patients in all clinical departments. The syringe pump is used in hospitals, clinics and other medical institutions.

Contraindication: None.

2.3 Type and specifications

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

The CF applied parts are disposable syringes sets that are not included in the system. The maximum temperature of applied part is 45℃according to IEC60601-1 standard,and the duration of PATIENT with skin is a time ≥1min and ＜10min.

2.4 Operating conditions

a) Temperature: 5℃-40℃

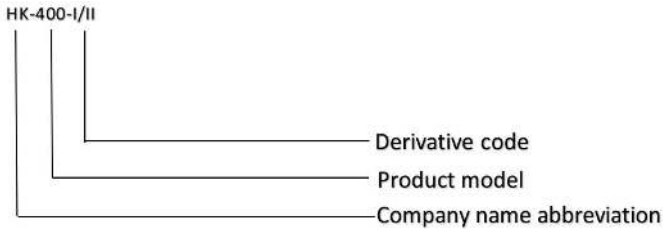
b) Relative humidity: 10%-95% (no frosting)

c)Atmosphere pressure: 86.0kPa～106.0kPa

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 The components of each model and definitions



Model	Infusion modes
HK-400	1. Rate mode 2. Time mode 3.Body Weight Mode (Weight Mode)
HK-400I	1. Rate mode 2. Time mode
HK-400II	1. Rate mode 2. Time mode 3. Body Weight Mode(Weight Mode) 4. Intermittent mode 5.Dose Mode

2.7 Date of manufacture & life span

The life span of the syringe pump (battery is not included) and its cable is 8 years. Please refer to label for date of manufacture.

2.8 Version of software

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

2.9 Statement

This device is compliant with the Medical Devices Regulation 2017/745. According to this regulation, it is a class IIb device. This model carries the marking:

CE 0197

In accordance with the requirements of the Medical Device Regulation 2017/745, the enteral feeding pump is compliant with the following standards:

No.	Standard No.	Standard Description
1	EN ISO 13485:2016+A1:2021	Medical devices – Quality management systems – Requirements for regulatory purposes
2	EN 60601-1:2006+A1:2013+ A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3	EN 60601-1-8:2007+A1:2013+ A2:2021	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
4	EN 60601-1-2:2015+A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
5	EN 60601-1-6:2010+A1:2015+ A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
6	EN 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
7	EN 60601-2-24:2015	Medical electrical equipment - Part2-24: Particular requirements for the safety of infusion pumps and controllers
8	EN 62304:2006+A1:2015	Medical device software-Software life cycle processes

9	EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
10	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
11	EN ISO 20417:2021	Information supplied by the manufacturer with medical devices
12	EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
13	EN IEC 81001-5-1:2022	Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle
14	ISTA 2A:2011	Packaged-Products 150 lb (68 kg) or Less
15	EN IEC 62506:2023	Methods for Product Accelerated Testing

3. Working Principle & components

3.1 Working Principle

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

3.2 Components

This page intentionally left blank.

4. Technical specifications

Technical parameters	
Applicable syringe	5, 10, 20, 30, 50(60) ml disposable sterile syringes
Applicable syringe brand	BOON
Volume to be infused (VTBI)	0.1-9999.9ml, increment at 0.1ml
KVO rate	0.1-2.0ml/h, increment at 0.1ml/h, default: 0.1ml/h
infusion rate	5ml syringe: (0.1-150.0) ml/h 10ml syringe: (0.1-300.0) ml/h 20ml syringe: (0.1-600.0) ml/h 30ml syringe: (0.1-900.0) ml/h 50ml(60ml) syringe: (0.1-1200.0)ml/h Increment at 0.1ml/h
Bolus rate	5ml syringe: (100.0-150.0) ml/h 10ml syringe: (100.0-300.0) ml/h 20ml syringe: (100.0-600.0) ml/h 30ml syringe: (100.0-900.0) ml/h 50ml(60ml) syringe: (100.0-1200.0)ml/h Increment at 0.1ml/h
Purge	5ml syringe: 150.0 ml/h 10ml syringe: 300.0 ml/h 20ml syringe: 600.0 ml/h 30ml syringe: 900.0 ml/h 50(60ml) syringe: 1200.0 ml/h Increment at 0.1ml/h
Accuracy	Infusion rate accuracy : ±2% Bolus accuracy : ±10% or ±0.05ml is the maximum value

Occlusion pressure	3 ranges (adjustable): low, middle, high; Low(40-100kPa) Middle(70-130kPa) High(100-160kPa) default: middle After calibration, the occlusion pressure is ≤180kPa.
Single failure infusion volume	≤0.5ml
Ingress protection Level	IP24
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 25ml/h. Environment temperature 25℃, after being fully charged.
Power consumption	35VA
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	300mm(L)×130mm(H)×125mm (W, not including pole clamp)
Net weight	1.7kg
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
Intermittent mode	To control infusion by setting the flow rate, intermittent infusion volume, interval time and KVO rate

5. Installation

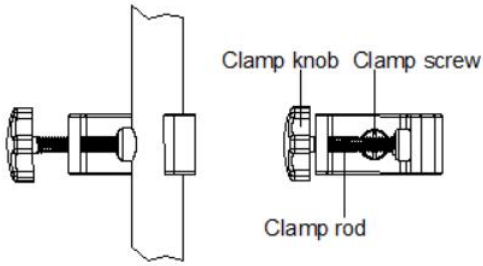
5.1 Installation conditions and technical requirements

The syringe pump can be fixed to a vertical IV pole or horizontal bar with diameter of 12-35mm, or placed on platform with slope angle no more than 5°.

5.2 Installation method and cautions

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

Loose the clamp screw, rotate the pole clamp 90° clockwise or counterclockwise, and tighten the fixing clamp screw, screw the clamp knob to fix the pump.



6. External Features

6.1 Front panel

This page intentionally left blank.

6.2 Rear panel

This page intentionally left blank.

6.3 Label

6.3.1 Product label (on the back housing)

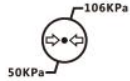
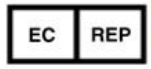
The label includes information such as manufacturer, date of production, product serial No., classification, waterproof level, etc.

6.3.2 Symbols and significance

Table 1 Symbol in accompanying document

Symbols	Descriptions
	Production batch No.
	Product serial No.
	Prohibition
	Please refer to manual
	Type CF
	Protective Earthing
IP24	the pump against ingress of solid foreign objects ≥12.5mm diameter and splashing water
	AC power
	DC power

	Dispose in environmental-friendly way
	Date of manufacture and Country of manufacture, CN: China
	Manufacturer
	Authorized European representative
	Medical device
	Recycle: Electronic Equipment
	Caution Against Wet
	Fragile. Handle with care!
	Keep upright during transport
	The same package can be stacked up to 5 layers.
	Humidity limitation

	Temperature limit
	Atmospheric pressure limitation
	Medical device
	Model number
	EU Authorised representative
	This device is provided with a CE marking in accordance with the regulation 2017/745. 0197 is the Notified Body number.
	Audio paused
	Unique device identifier
	EU Importer
	EU distributor

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.

(6) In addition to the built-in six syringe brands, user must calibrate the syringe pump when using the other brand of syringe.

8. Operation Method

8.1 Operation

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 for a few seconds, the pump will be switched on and do self-test, and shows Self-testing on the display, it will test: Communication Info, Pressure sensor, Dedicated IV set, AC Info and Battery Info. If the test result is unqualified, the corresponding alarm message will be displayed after the pump is turned on. If qualified, no alarm message will be displayed.

Attention:

1.If the power-on detects that a syringe is installed, the message "Do you use this syringe?" will display. Please confirm whether the syringe brand is correct or not. If correct, select YES. If not correct, select NO and then enter automatically the syringe brand selection screen.

2. Please keep an eye on the self-test, if any abnormal condition occurs, do not use the syringe pump and contact supplier or manufacturer immediately for after service support.

Press and hold POWER key  for about 2 seconds to turn off the pump.

8.1.3 Install the syringe

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

(2) Insert the syringe filled and with extension tube connected, remove air from infusion line and place the syringe plunger in right position, ensure that syringe flanges is put in the groove.

(3) Turn the pull handle left 90° to fasten the syringe.

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

Attention:

(1) Make sure there's no air bubble in the syringe and its extension tube.

(2) Please make sure push handle grip the end of syringe plunger, otherwise infusion accuracy cannot be guaranteed.

8.1.4 Set the parameters

This page intentionally left blank.

8.1.5 Purge

This page intentionally left blank.

8.1.6 Start Infusion

This page intentionally left blank.

8.1.7 Bolus Infusion

This page intentionally left blank.

8.1.8 Stop Infusion

This page intentionally left blank.

8.1.9 Infusion completion

This page intentionally left blank.

8.1.10 Replace Syringe

This page intentionally left blank.

8.2 Alarms and Solutions

This page intentionally left blank.

8.3 System Setting and Accuracy Calibration

This page intentionally left blank.

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.
- The Syringe Pump has occlusion detection function. It gives occlusion alarm when the infusion set is blocked that produce under-infusion.
- The Syringe Pump has malfunction detection function. It gives high priority alarm when the pump is fault that produce over-infusion.

9. Malfunctions Analysis and Solutions

Problems	Causes	Solutions
Accuracy discrepancy	The Syringe edge does not install into the syringe edge 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 pump may be defective	Contact the distributor or manufacturer for repair
Push handle can not move freely	There is 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 a short circuit or any other malfunction occurs, the fuse shall cut off circuit in advance.

(2) DC input: built-in fuse. When a 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, overheating or short circuiting, etc.

10.2 Troubleshooting

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

(2) If the syringe pump catches 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 housing and pump body. Clean it with a damp soft cloth. Do not use solvents such as xylene or acetone or other similar solvents which may corrode the syringe Pump.

Disinfect the infusion pump according to your hospital's disinfection protocols. Should cleaning pump before disinfection. Follow the manufacturer's instructions for diluting and using the disinfectant. The recommended disinfectant is: Ethanol 75%.

Disinfection steps：

1) Using a soft cloth, dip it in an appropriate amount of water or 75% ethanol and squeeze it dry

2) Wipe the display screen.

3) Wipe the surface of the pump or accessories, taking care to avoid interfaces and metal parts.

4) Using dry cloth to wipe off the cleaning agent on the pump or accessory surface, and air it dry in a cool, ventilated environment.

Note: To avoid damage to the pump or accessories by improper disinfection, please disinfect them only when necessary according to your hospital's system

11.2 Maintenance during operation

The maintenance 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 fingers, therefore clean the syringe Pump every time after infusion completion. The device shall not be serviced and maintained during while in use with the patient.

11.3 Periodic Inspection

11.3.1 Inspect infusion accuracy (once every 2 years)

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

In order to obtain an accurate infusion, the following should be noted:

1) perform the injection under a background pressure of 13.33kPa (100mmHg);

2) calibrate the Syringe Pump before use the infusion set first.

3)use infusion set that meets relevant laws and regulations and has a valid medical device registration certificate.

11.3.2 Inspect Internal Battery

The battery shall reduce in performance due to prolonged usage, please check the battery capacity every 2 years.

(1) First recharge the battery fully (10 hours with power on, or 3 hours with power off).

(2) Let syringe pump work on battery only and set flow rate at 5ml/h. Record the operating period until the battery is exhausted.

—If the syringe pump operates for more than 360 minutes, the battery is in good condition.

—If the syringe pump operates for more than 240 minutes but less than 360 minutes, the battery starts low quality but still can be used.

—If the syringe pump operates for less than 180 minutes, the battery has reached 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 is not squashed by the battery cover. Then install battery cover. After replacing new battery, please check its working condition.

11.4 Normal repair procedures

Repair should be performed by authorized service personnel. It needs to make a complete inspection on machine after maintenance. If necessary, contact the manufacturer for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.

11.5 Maintenance for long-time storage

If the syringe pump is not being used for long time, it should be placed in a packing carton, not stored in direct sunlight and kept in a cool and dry place. Refer to 12.2 for detailed storage conditions.

When using a syringe pump after a long time in 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 service life of this product is 8 years. After the equipment reaches the service life, it should be disposed according to local laws and regulations.(For more information, please contact manufacturer or our distributors.)

WARNING: Disposal of parts, batteries, packaging materials and accessories must comply with local laws, regulations or the hospital's waste disposal system.

12. Transport and storage

12.1 Precautions during transport

(1) Place the product as per No. of layers indicated on packing carton.

(2) Temperature: --20℃～60℃;

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

(4) Atmosphere pressure: 50.0kPa～106.0kPa

12.2 Storage conditions.

Storage temperature:-20℃～+45℃(With battery);-20℃～+60℃(Without battery)

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

Atmosphere pressure: 50.0kPa～106.0kPa

13. Packing list

13.1 Standard configuration in a package:

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

13.2 Replaceable Parts

Name	Model	Specification
Power cord	KC-015	AC250V, 10A
Lithium battery (power)	AEC903466	7.4V,1900mAh
Lithium battery (alarm)	GSP422025	3.7V/DC,180mAh

The replacement should comply with the product standards,and contact the manufacturer for replacement.

For all the components replaced by dismantling the shell with a tool, should be operated by authorized maintenance personnel.

14. Open-package Inspection

Cautions for Open-package inspection:

(1) Open the packing carton carefully to avoid damaging the pump or its accessories.

(2) Handle all items with care.

(3) Keep all accessories, warranty card and User Manual safe for future use and reference.

(4) Retain packing cartons for use to return defective items.

(5) If there is any accessory missing or damaged, please contact the supplier.

15. After Sales Service

The warranty for the syringe pump is two years.

Note: The warranty does not cover:

(1) Malfunctions resulting from improper operation, or modification / repair of the syringe pump without supplier's knowledge and permission.

(2) 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.

After-sales service provider:

Shenzhen Hawk Medical Instrument Co. ,Ltd.

1st-5th Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen,518109 Guangdong, P.R.China

Tel.: 0086 755-83151901

Fax: 0086 755-83151906

Email: szhk@hawkmedical.cn

Website: http://www.hawkmed.com.cn

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
Disengaged	High priority	Red/2Hz
Syringe Off	High priority	Red/2Hz
Occlusion	High priority	Red/2Hz
LowBattery	Low priority	Yellow, consistent
B.Exhaust	High priority	Red/2Hz
Empty	High priority	Red/2Hz
Near Empty	Low priority	Yellow, consistent
AlmostDone	Low priority	Yellow, consistent
Finished	High priority	Red/2Hz
On Battery	Low priority	Yellow, consistent
AC Fail	Low priority	Yellow,consistent
No Operate	Low priority	Yellow,consistent
Battery fail	Low priority	Yellow,consistent
Pressure Error	High priotiry	Red/2Hz
Standby end	Low priority	Yellow, consistent
Malfunction	High priotiry	Red/2Hz
Shutdown timer	Low priority	Yellow,consistent

Table 2 Alarm conditions and alarm signal delay

Names of alarm	Alarm condition delay	Alarm signal delay
Handle Off	10ms	100ms
SyringeOff	10ms	100ms
Occlusion	840s@1ml/h 27s@25ml/h	100ms
LowBattery	10ms	100ms
B.Exhaust	500ms	100ms
Empty	10ms	100ms
Near Empty	10ms	100ms
AlmostDone	10ms	100ms
Finished	10ms	100ms
On Battery	10ms	100ms
AC Fail	10ms	100ms
No Operate	120ms	200ms
Battery fail	10ms	200ms
Pressure Error	10ms	100ms
Standby end	10ms	100ms
Malfunction	10ms	100ms
Shutdown timer	10ms	100ms

Table 3 Characteristic parameters of alarm signals

Alarm level	Intervals	Alarm information
High	8s±2s	Black on red
Low	25s±2s or no repeating	Black on yellow

Note: 1.Only the three alarms "Near Empty" ,"No Operate", "AlmostDone" and "LowBattery" sound three tones at intervals of 25s±2s, all other Low Priority alarms sound one tone and are not repeated.

2.The alarm volume is between 45dB and 85dB,Alarm volume measurement radius is 1 meter.

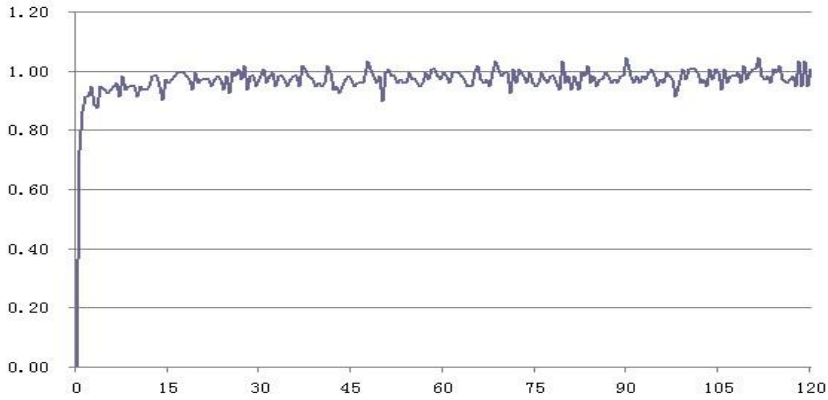
Table 4 Occlusion response characteristic

Flow Rate (ml/h)	Occlusion alarm level	Occlusion pressure(KPa)	Occlusion alarm time	Unintened bolus volume(ml)
0.1	Low	40-100	-	-
	High	100-160	-	-
1	Low	40-100	≤1h	≤0.6
	High	100-160	≤4h	≤1.2
5	Low	40-100	≤25min	≤0.6
	High	100-160	≤40min	≤1.2

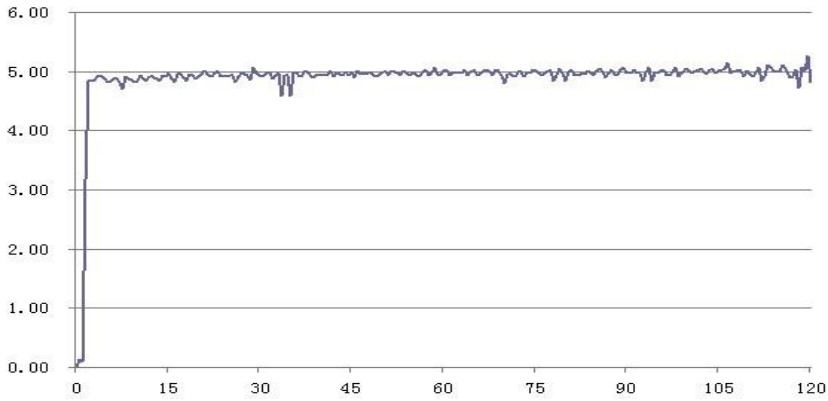
The above test uses ‘BOON’ brand of 5ml syringe. All the data are obtained by using ‘BOON’ brand syringe.

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 Start-up Curves

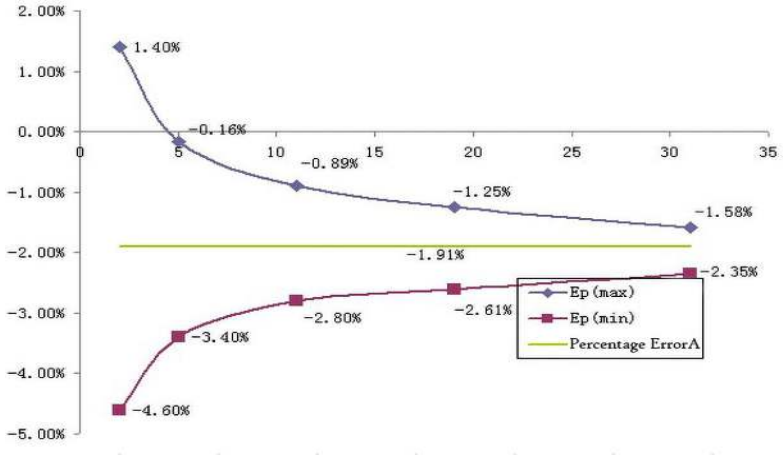


1ml Start-up curve

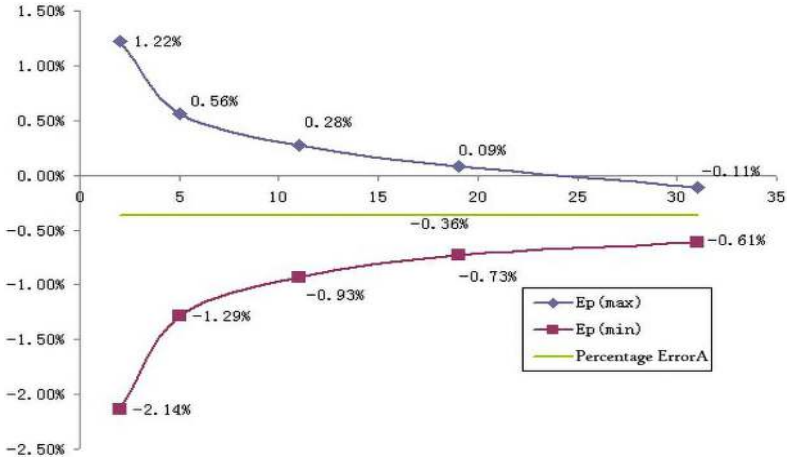


5ml Start-up curve

Table 6 Trumpet Curves



1ml Trumpet Curve



5ml Trumpet Curve

The above results are based on the data obtained through tests conducted according to the IEC 60601-2-24:2012 standard and our company's product standards, representing the test results of 1 syringe pump unit sample and syringe (Boon brand 10ml) used during the experiment. For more information, please contact our after-sales service department.

Annex II

Information related to Electromagnetic Compatibility (EMC)

 **Attention：**

- Syringe pump HK-400 series meet the electromagnetic compatibility requirements of IEC60601-1-2 Clause 201.17.202. The Essential Performance of devices are defined as:

  1) Infusion rate accuracy :±2%

  Bolus accuracy : ±10% or ±0.05ml is the maximum value

  2) Protection against unintended bolus volumes and occlusion

  3) Correct alarm signal of high-priority

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

 **Warning:**

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

Please see enclosed Guideline and manufacturer's statement:

<table>
<tr><td colspan="3">Guidance and manufacture's declaration – electromagnetic emission</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment–guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class B</td><td rowspan="3">The Infusion pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacture'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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Infusion pump requires continued operation during power mains interruptions, it is recommended that the Infusion pump be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	400A/m	400A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The 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
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.5 GHz	3 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Infusion pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d=2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Infusion pump.

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

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

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

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

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

Shenzhen Hawk Medical Instrument Co., Ltd

1st-5th Floor, Building C, Jianyetai Industrial Zone,

No.11 Minhuan Road, Fukang Community,

Longhua Street, Longhua District, Shenzhen,

518109 Guangdong, P.R.China

Tel: 0086-755-83151901

Fax: 0086-755-83151906

Email: szhk@hawkmedical.cn

http://www.hawkmed.com.cn

Umedwings Netherlands B.V.

Treubstraat 1, 2288EG, Rijswijk, the Netherlands

Tel.: + 31(0)642758955

Fmail: ar@umedwings.en