

Shenzhen Hawk Medical Instrument Co., Ltd.

**Safety and Performance Information Relevant
to The User or Other**

(SYRINGE PUMP)

Model: hawk-s1

CE 0197

057-00684-00

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Revision Notes:

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

This document is applicable to hawk-s1 Syringe Pump.

Revision	Date of revision
V1.0.0	2025-11-01

Document version upgrade notes:

V X.Y.Z

V: means version, stating the version number of the information.

X: indicates the major function update that corresponds to change or upgrade of the document in case of a major change of software, hardware or structure.

Y: indicates a slight enhancement update that corresponds to an update of the specification in case of a minor change in hardware, software, or structure to better use the enteral feeding pump (no need to re-register the test after evaluation).

Z: indicates the corrective update to correct text errors or better describe the change or upgrade in the document without any changes to software and hardware. For example, text, illustrations correction, new illustrations, text descriptions.

1. Warnings and 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 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 ISO 7886-1. When choosing an infusion tube, 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 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)** This syringe pump cannot be directly powered by vehicle power supply.
- N)** Medical staffs should have regular patrol inspection, instead of relying on alarm system only, so as to prevent accidents.
- O)** Under single failure state, the maximum infusion quantity should be the remaining fluid (Max. 50mL) in syringe. Keep monitoring the operation state of system during infusion and check the syringe and infusion loop, instead of relying on alarm function of this system.
- P)** Operator should not start infusion unless the infusion parameters of syringe pump are conforming to the medical advices. Any nonconforming setting of parameters may lead to invalid operation.
- Q)** Accuracy is not guaranteed in case of unstable network voltage and abnormal temperature, relative humidity and atmospheric pressure.
- R)** 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.
- S)** Do not position me equipment to make it difficult to operate the disconnection device.
- T)** Unauthorized modifications to this equipment are not permitted,that may result in serious injury o patients.
- U)** Loss of power may result in unacceptable risks. The equipment must be connected to a suitable power supply.

V) 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.

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

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

Y) 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.

Z) During normal use, the maximum temperature of the application part can reach 42.4 °C.

Cautions

Personal injury or property loss may occur if violating these precautions.

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 3.5 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 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.

2. Overview

2.1 Features

- ✧ User friendly interface, easy operation
- ✧ 8 occlusion level adjustable
- ✧ Auto recognize of 5, 10, 20, 30 and 50(60)ml syringes
- ✧ Multiple infusion modes to meet clinical requirements
- ✧ Double CPU for safe infusion
- ✧ Stackable feature to save space

2.2 Intended Use

It is used in conjunction with an infusion line 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.

Contraindications: None.

2.3 Type and Specification

This product is Category I and CF type continuously operated device with internal batteries. It cannot be carried by patients, or used in places with mixed gas of flammable gas and air, or mixed gas of oxygen with nitrous oxide.

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

2.4 Product Model

hawk-s1

2.5 Operation conditions

- (1) Temperature: 5°C-40°C
- (2) Relative humidity: 10%-95% (no frost)
- (3) Atmospheric pressure: 86.0kPa -106.0kPa

2.6 Impacts on Environment and Energy

This syringe pump may have certain electromagnetic radiation and interference on other devices. Such interference, if occurred, should be alleviated by adopting certain measures, such as rearranging position of syringe pump or inducing mains supply from different positions. For more information, please see Appendix – “Electromagnetic Compatibility (EMC) Information” of this Manual.

2.7 Production date and service life

The normal service life of the complete Syringe pump (without batteries) and the power cord is 8 years. Please refer to the product label for the production date.

2.8 Software version

This manual corresponds to the V01 release version of the infusion pump software.

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:



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3. Constituent Parts

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4. Technical Characteristics, Parameters and Explanations of Nouns

Technical and parameters	
Applicable syringe	5, 10, 20, 30, 50/60ml disposable sterile syringes
Infusion mode	Multi-mode Rate mode, Time mode, Weight mode, Intermittent mode, Programmable mode Micro Mode Drug library mode
Volume to be Infused(VTBI)	0-9999.9 ml
KVO rate	0.1-5 ml/h, preset by the user; default: 0.1ml/h
Infusion rate	5ml syringe: 0.1-150 ml/h 10ml syringe: 0.1-300 ml/h 20ml syringe: 0.1-600 ml/h 30ml syringe: 0.1-900 ml/h 50ml(60ml) syringe: 0.1-1800 ml/h
Bolus	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: 100.0-1800.0 ml/h
Purge	5ml syringe: 150 ml/h 10ml syringe: 300 ml/h 20ml syringe: 600 ml/h 30ml syringe: 900 ml/h 50 (60ml) syringe: 1800 ml/h
Accuracy	Infusion rate accuracy : $\pm 5\%$ for Infusion rate ≤ 5 ml/h, $\pm 2\%$ for Infusion rate > 5 ml/h Bolus accuracy : $\pm 10\%$ or ± 0.25 ml is the maximum value
Occlusion pressure	8 levels available: 10~160kPa Default level: level 4 Level 1: 10 ~50kPa Level 2: 25 ~ 65kPa Level 3: 40 ~80kPa Level 4: 55 ~ 95kPa Level 5: 70 ~110kPa Level 6: 85~ 125kPa Level 7: 100 ~140kPa Level 8: 115 ~ 160kPa
Low battery alarm limit	The voltage of the internal battery < 7.3 V
Battery exhausted alarm limit	The voltage of the internal battery < 6.9 V
SPL (sound pressure level) of alarm	No lower than 45dB(A) when setting is low level No lower than 65dB (A) when setting is high level

Single failure infusion volume	≤0.5ml
Water Proof Level	IP34
AC power	100-240V, 50/60Hz
Battery	Li_Polymer 7.4V 1900mAh; Recharge time: 10h with power on, 3.5h with power off. Running time: more than 7h at rate of 5ml/h, environment temperature 25°C after being fully charged.
Power consumption	35VA
DC	DC12 ± 1.2V, 1.5A
Fuse	Slow fuse Specification: 250V 2A (Maximum fusing time is 10 seconds when current is 5.5A)
Dimensions	258x160x79 (LxWxH) mm (Pole clamp excluded)
Weight	1.8kg
Compliant Standards	EN60601-1:2006/A2:2021 Medical electrical equipment-Part 1 : General requirements for basic safety and essential performance EN 60601-2-24:2015 Medical electrical equipment-Part 2-24: Particular requirements for the safety of syringe pump and controllers EN60601-1-2:2015+A1:2021 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests EN 60601-1-8:2007+A1:2013+A11:2017+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
Glossary	
Bolus	The amount of fast infusion
Anti bolus	Diminishes the volume of unwanted Bolus after removal of the occlusion.
Infusion tubing	Syringe and extension tube

5. Installation and Adjustment

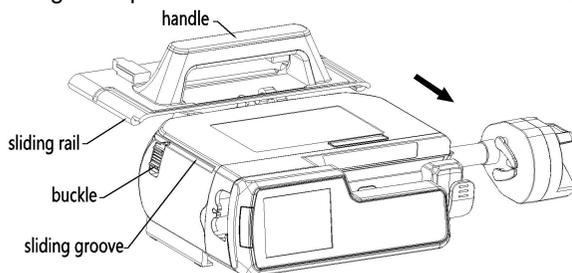
5.1 Installation conditions and technical requirements

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

5.2 Assembly/ Disassembly of Handle

5.2.1 Installation of handle

Hold the syringe pump with one hand, hold the handle with another hand, push the sliding rail of handle into the sliding groove of syringe pump straightly, when it reach the designated position the buckle will bounce automatically to lock it.



5.2.2 Remove the Handle

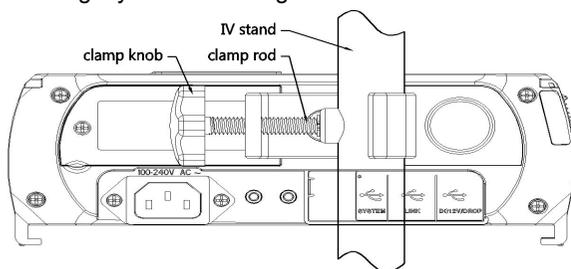
Pull down the buckle with one hand, push backwardly the handle from sliding groove with another hand to remove the handle.

5.3 Installation method and cautions

Method 1: Put the syringe pump on stable platform

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

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



6. Appearance Introduction

6.1 Front View

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6.2 Keypad

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6.3 Screen Display

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6.4 Rear view

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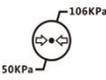
6.5 Label

6.5.1 Product label (on the back shell)

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

6.5.2 Symbols and significance

Symbols	Description	Symbols	Description
	Production batch No.		Protective Earthing
	Serial number	IP34	The enclosure is protected against solid objects larger than 2.5 mm in diameter. The enclosure is protected against splashing water from any direction.
	Prohibition		AC power
	Defibrillation-proof type CF applied part		DC power
	Date of manufacture and Country of manufacture, CN: China		Dispose in environmental-friendly way
	manufacturer		Start/stop

	Bolus		Turn on/off
	Clear		Audio Paused
	Please refer to this Manual		Fragile. Handle with care!
	Caution Against Wet		5 layers at most of the same package
	Keep upright during transport		Unique device identifier
	Medical device		Model number
	Importer		EU Authorised representative
	This device is provided with a CE marking in accordance with the regulation 2017/745. 0197 is the Notified Body number.		EU distributor
	Humidity limitation		Temperature limit
	Atmospheric pressure limitation		

7. Preparation and inspection

7.1 Preparation and Inspection before Use

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) Set and check system time and make sure the history records are correctly recorded.
- (7) When turn on machine, the self-test result displays "OK", which means the system is normal.
- (8) Please carefully read the warnings, cautions and operation steps of this Manual.

7.2 Operation Precautions

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

8. Operation Method

8.1 Operation

8.1.1 Fix the machine and connect the power cord

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

8.1.2 Switch on/off

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

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

8.1.3 Install the syringe

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8.1.4 Set the parameters

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8.1.5 Purge

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8.1.6 Start infusion

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8.1.7 Bolus (Fast infusion)

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8.1.8 Stop infusion

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8.1.9 Infusion complete

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8.1.10 Replace syringe

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8.2 Alarms and Solutions

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8.3 Syringe Setting

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8.4 System Setting

8.4.1 Set alarm sound volume

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8.4.2 KVO rate setting

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8.4.3 Occlusion level setting

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8.4.4 Key Sound setting

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8.4.5 Key Lock setting

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8.4.6 Bolus setting

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8.4.7 Back light setting

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8.4.8 Night mode setting

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8.4.9 Forget Operate Alarm Setting

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8.4.10 “Almost Done” alarm setting

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8.4.11 Infusion Log Setting

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8.4.12 Date and Time setting

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8.4.13 Auto shutdown setting

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8.4.14 Language setting

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8.4.15 Patient Info setting

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8.4.16 Admin setting

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8.4.17 Purge setting

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8.4.18 Standby setting

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8.4.19 Pre-occlusion setting

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8.4.20 Near Empty setting

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8.4.21 Dislocated

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8.4.22 Pause setting

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8.4.23 WiFi setting

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9.Troubleshooting

Failure	Cause Analysis	Solutions
Accuracy discrepancy	The syringe edge did not install into the syringe fixed groove	Please install it correctly
	The syringe currently used does not match default brand	Select the correct brand of syringe or self-defined syringe
	Certain parts of the machine may be defective	Contact 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 distributor or 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 works with malfunctions may incur unpredictable damage.

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

11. Maintenance, Inspection, Repair and Recycling

Note: 1) ME equipment shall not be serviced and maintained during while in use with the patient

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

11.1 Routine maintenance

Daily maintenance includes the cleaning of outer shell and pump body. Clean it with wet soft cloth and natural drying. Do not use solvents like xylene or acetone or other similar solvents which may corrode the infusion 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 during operation mainly concerns the cleaning of 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 timely after infusion completion.

11.3 Regular Inspection

11.3.1 Appearance inspection

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

11.3.2 Check infusion accuracy (check once every 2 years)

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

11.3.3 Check internal battery

The battery shall reduce the performance due to prolonged usage, please check the battery capacity every 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 whole working time till the battery is exhausted.

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

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

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

Replace internal battery

It is better to replace the battery every year. It is advised to contact the supplier once battery is expired because they are not easy to be replaced.

Battery replacement steps are listed as follows:

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

11.4 Normal maintenance procedure

The repair job should be performed by supplier or distributor. It needs to make a complete inspection on machine after maintenance. If necessary, contact the manufacturer for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment 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 after long-time storage, please refer to following steps before use:

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

11.6 Recycling

The 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: $-20^{\circ}\text{C} \sim 60^{\circ}\text{C}$;
3. Relative humidity: 10~95% (no frosting)
4. Atmosphere pressure: 50.0kPa~106.0kPa

12.2 Storage conditions.

Storage temperature: $-20^{\circ}\text{C} \sim 60^{\circ}\text{C}$;

Relative humidity: 10~95% (no frosting)

Atmosphere pressure: 50.0kPa~106.0kPa

13. Package list

13.1 Standard configuration in a package:

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

13.2 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. Opening the packing carton carefully to avoid damaging the machine or its accessories.
2. Handle with care all items inside the package.
3. Keep all accessories, warranty card and User Manual well for future use and reference.
4. Keep some packing cartons in case of using them to deliver defective machines.
5. If there is any accessory lacking or damaged, please contact the supplier at the earliest.

15. After Sales Service

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

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

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

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

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>

16. EMC Information



Note:

- The syringe pump conforms to relevant requirements of IEC60601-1-2 standard EMC. The Essential Performance of devices are defined as:
 - 1) Infusion rate accuracy : Infusion rate accuracy : $\pm 5\%$ for Infusion rate $\leq 5\text{ml/h}$, $\pm 2\%$ for Infusion rate $> 5\text{ml/h}$
Bolus accuracy : $\pm 10\%$ or $\pm 0.25\text{ml}$ is the maximum value
 - 2) Protection against unintended bolus volumes and occlusion
 - 3) Correct alarm signal of high-priority
- 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 syringe pump, strong electromagnetic 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:

- syringe 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 syringe pump, it may be difficult to ensure EMC in other environment;
- The application of accessories and cables, other than the cables sold by syringe pump manufacturer as the spare parts of its internal components & parts, can increase pump emission or reduce interference immunity.
- Use of cables other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

List below the cables information:

No.	Cable name	Length(m)	specification	Shield or not	Remark
1	Power cord	2.5m	KC-015+KC-003+ H05VV-F	No	Standard configuration
2	Signal cable	0.3m	hawk-s1-JL	No	Selectable

Please see enclosed Guideline and manufacturer's statement:

Guidance and manufacture's declaration – electromagnetic emission		
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
RF emissions 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.
RF emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
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	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	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.

	(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	
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

			<p>equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.167 \sqrt{P}$ $d = 1.167 \sqrt{P}$ <p>80 MHz to 800 MHz</p> $d=2.333 \sqrt{P}$ <p>800 MHz to 2.5 GHz</p> <p>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).</p> <p>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:</p> 
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NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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.

Appendix 1

Table 1 Classification of alarms and color of alarm indicator light

Alarm classification	Alarm priority	Color and frequency of alarm indicator light
Handle off alarm	High priority	Red light/2Hz
Syringe off alarm	High priority	Red light/2Hz
Roll hem abnormality alarm	High priority	Red light/2Hz
Syringe push off	High priority	Red light//2Hz
Occlusion alarm	High priority	Red light//2Hz
Low battery alarm	Low priority	Yellow, steady
Battery exhausted alarm	High priority	Red light//2Hz
Empty	High priority	Red light//2Hz
Almost empty	Low priority	Yellow, steady
Almost Done alarm	Low priority	Yellow, steady
Finished alarm	High priority	Red light//2Hz
AC fail alarm	Low priority	Yellow, steady
No operation alarm	Low priority	Yellow, steady

Table 2 Alarm conditions and alarm signal delay

Alarm classification	Alarm Condition Delay	Alarm Signal Delay
Handle off alarm	10ms	100ms
Syringe off alarm	10ms	100ms
Roll hem abnormality alarm	10ms	100ms
Syringe push off	10ms	100ms
Occlusion alarm	840s@1ml/h 27s@25ml/h	100ms
Low battery alarm	10ms	100ms
Battery exhausted alarm	500ms	100ms
Empty	10ms	100ms
Almost empty	10ms	100ms
Almost Done alarm	10ms	200ms
Finished alarm	10ms	200ms
AC fail alarm	10ms	200ms
No operation alarm	120ms	200ms

Table 3 Alarm sound interval time

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

Note: Only the four alarms "No operation", "Almost empty", "Almost Done" and "Low Battery" sound three tones at intervals of 25s ± 2s, all other Low Priority alarms sound one tone and are not repeated.

Table 4 Occlusion response characteristic

Flow rate (ml/h)	Occlusion alarm level	Occlusion pressure (kPa)	Occlusion alarm time
1	Level 1	41	12min59sec47s
	Level 8	144	42min53sec
5	Level 1	54	4min37sec69s
	Level 8	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 Curve

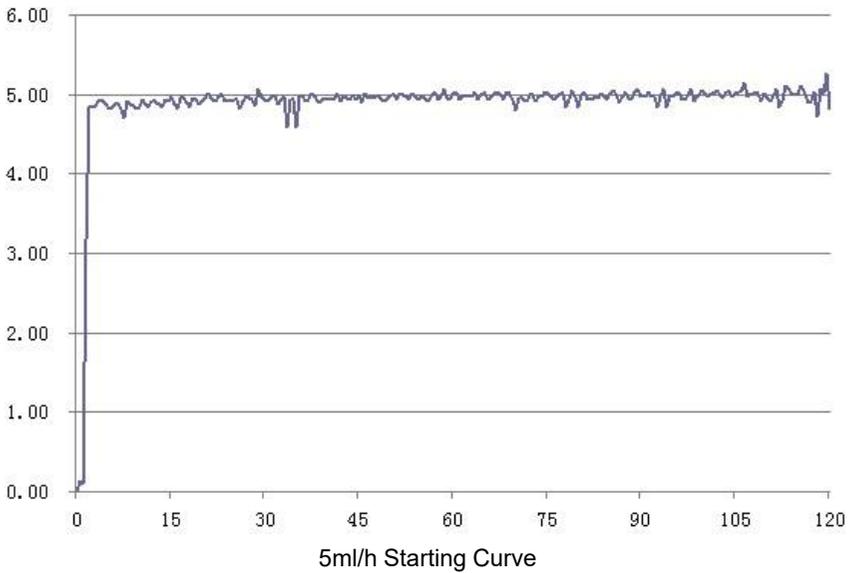
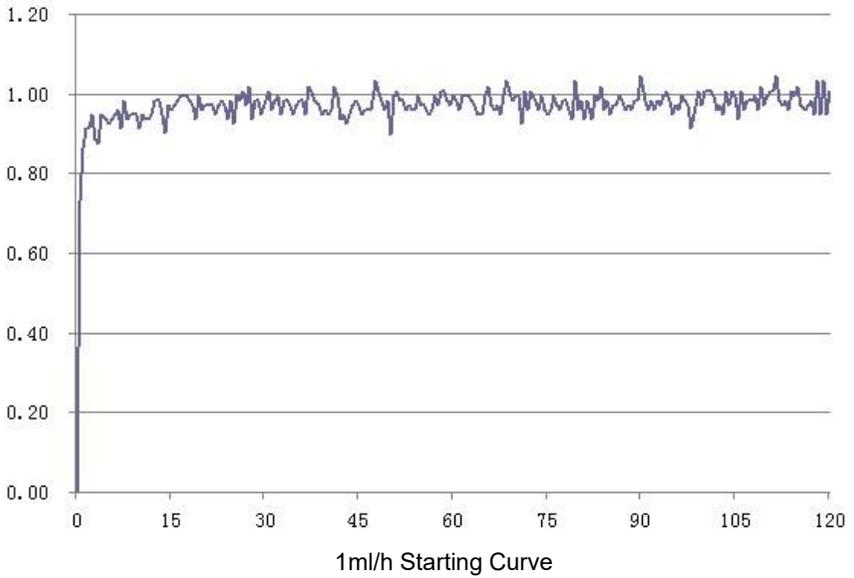
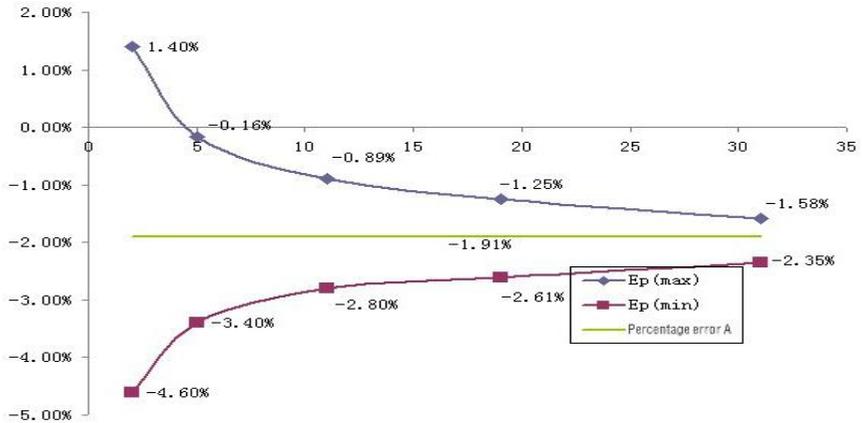
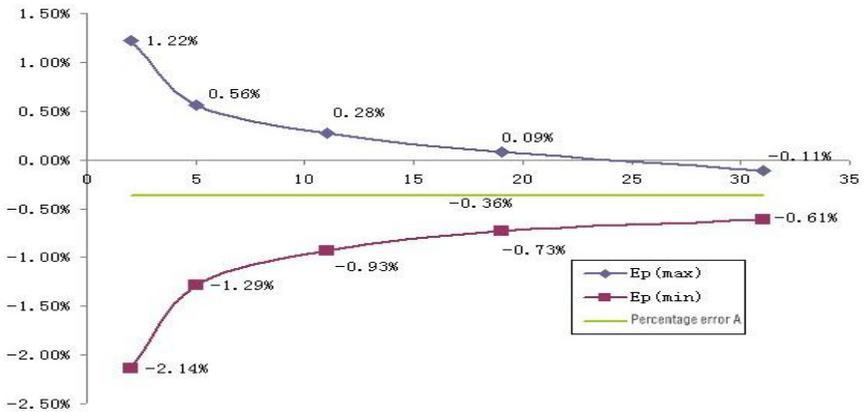


Table 6 Trumpet Curves



1ml/h Trumpet Curves



5ml/h Trumpet Curves

These data are testing result according to GB9706.27-2005 and the company's products standard. It uses syringe pump and 10ml syringe under Boon brand. For more information, please contact with our After-sales Service Department.



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