Shenzhen Hawk Medical Instrument Co., Ltd.

Safety and Performance Information Relevant to The User or Other

（SYRINGE PUMP）

Model: InnoFusion IF-70, 806 S

Please read the manual before installing and using the product.
Please keep the manual for reference！

CE 0197

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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 user manual is applicable to InnoFusion IF-70, 806 S syringe pump.

Version No.	Date of Preparation
V1.0.0	12-11-2025

User manual version updating instructions:

V X.Y.Z

V: indicates version No. of the user manual.

X: indicates the major function update that corresponds to change or upgrade of the Manual 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 syringe 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 Manual 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 is not large enough to reach the occlusion alarm boundary, therefore, it is needed 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 cause 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 the relevant standard and regulatory. When choosing an infusion line, it is advised to use the syringe with threaded Luer connector 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 repeating using 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 be used 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) Do not use the Syringe Pump near inflammable liquid or gas.

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

L) This syringe pump cannot be directly powered by vehicle power supply.

M) Medical staffs should have regular patrol inspection, instead of relying on alarm system only, so as to prevent accidents.

N) 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.

O) Operator should not start infusion unless the infusion parameters of syringe pump are conforming to the medical devices. Any nonconforming setting of parameters may lead to invalid operation.

P) Accuracy is not guaranteed in case of unstable network voltage and abnormal temperature, relative humidity and atmospheric pressure.

Q) Please use the syringe that meets the requirements of this manual, otherwise, the infusion accuracy and normal detection alarm cannot be guaranteed.

R) Please do not connect the other infusion system or accessories to the equipment and the patient's IV set, other than those specified in this user manual. Otherwise, it will incur danger, and will not ensure the infusion accuracy and correct alarm functions

S) When in doubt about the protective grounding, the internal power supply should be used.

T) 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.

U) Please do not place the power plug where it is difficult to operate the disconnecting device.

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 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.

O) During the complete loss of power supply (power supply network and internal power supply) of the alarm system, the log stored in the system will not be affected, but this complete loss of power will not be recorded in the log as an alarm.

P) If the same or similar equipment used in any independent area uses different alarm presets, there will be potential dangers, such as: intensive care units, cardiac operating rooms, etc.

Q) In order to prevent the loss of patient data and alarm settings when the syringe pump is suddenly powered off, the syringe pump provides data and alarm settings for power-down storage. If the syringe pump suddenly loses power, after the syringe pump is restarted, the patient's last infusion parameters, alarm information, etc., remain the same as before the power loss, and can be reloaded.

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

S) Before using the syringe pump, check whether the current alarm preset is applicable to each patient.

T) Before installing the syringe, please confirm that the IV set is closed; if the push handle leaves the syringe or the push handle clip needs to be opened when infusion completes or infusion alarm begins, please confirm that the IV set is closed to avoid the risk of overdose accidents!

U) Before the infusion, please confirm IV set is open to avoid insufficient fluid and delay the treatment.

2 Introduction

2.1 Features

✧ User friendly interface, detailed menu display, 5-inch IPS full-view display, capacitive touch screen, mobile phone-like operating experience, easy operation and setting

✧ Auto/Manual, safe and reliable, more convenient and quick to load the syringe, and realize the rapid infusion function

✧ IrDA communication, realize wireless stackable function

✧ U dusk upgrade, easy to operate

✧ 13 occlusion levels adjustable

✧ Support multiple syringe brands and self-define syringe brands

✧ Auto recognize of 1ml、2/2.5ml、5ml、10ml、20ml、30ml、50/60ml syringes

✧ Various infusion modes for user’s option, convenient for clinical use

✧ Visual & audible alarms and double CPU system ensure stable and safer infusion

✧ Arc shape, ergonomic design, easy for clean

Remarks: The optional functions in the corresponding technical requirements can be selected by customers.

2.2 Intended use and contraindications

The syringe pump is intended for use for the delivery of medications, solutions, parenteral nutrition, lipids indicated for infusion therapy through an intravenous or intra-arterial route.

Warning: The device is not used for infusion of analgesic drugs, chemotherapy drugs or insulin.

2.2.1 Indication

Syringe pumps are for patients who need receive various types of medications, solutions, parenteral nutrition, lipids in controlled amounts through an intravenous or intra-arterial routes.

2.2.2 Intended Users

1) Clinical operators: This user group refers to the authorized and well-trained medical personnel allowed to operate this syringe pump in clinical situations.
2) Reprocessing personnel: This user group refers to those who clean and disinfect the Syringe Pump and its accessories.
3) Service personnel: This user group refers to the authorized customer service engineers who are responsible for calibrating its components, and for service or modifications to the syringe pump as permitted.

2.2.3 Intended Patient Population

This syringe pump is suitable for adults, children, and newborns(<28days and premature babies>0.1kg) in such locations as the delivery room, ICU, NICU, emergency room, general ward, high dependency wards, and departments.

2.2.4 Intended conditions of use

The Syringe Pump is intended to be used in medical institutions, such as hospitals and clinics.

2.2.5 Contra-indications

None.

2.2.6 Side-effects

None.

2.2.7 Clinical Benefit

The syringe pump allows administration of medications, solutions, parenteral nutrition, lipids accurately, evenly and continuously through an intravenous or intra-arterial routes.

2.3 Type and Specifications

This product belongs to class I and defibrillation-proof type CF application. It is a continuous operation device equipped with internal batteries. Carrying of the device by patients or the use of the device in environments where gas mixtures of flammable gas and air or oxygen with nitrous oxide is not allowed.

Note: The recovery time of defibrillation prevention application part is 1 second.

2.4 Product model

InnoFusion IF-70, 806 S

Model	InnoFusion IF-70, 806 S	Characteristics
Infusion mode	1. Rate Mode 2. Time Mode 3. Multi Mode 4. Weight Mode 5. Dose Mode 6. Intermittent Mode 7. Sequential Mode 8. Program Mode 9. Ramp Mode 10. Micro Mode 11. Loading Dose Mode	It can directly stack maximum 4 units syringe pumps for cascade connection

2.5 Operation conditions

(1) Temperature: 5℃-40℃

(2) Relative humidity: 10%-95% (no frost)

(3) Atmospheric pressure: 57.0kPa-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 (batteries and power cords excluded) is 10 years. Please refer to the product tag for the production date. In case of aging, damage or poor contact of AC power cables, contact the manufacturer or dealer.

2.8 Statement

The syringe pump is compliant with Medical Devices Regulation 2017/745. According to this regulation, it is a class IIa device.

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3 Components

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4 Technical Characteristics, Parameters and Explanations of Nouns

Technical and parameters (InnoFusion IF-70, 806 S)	
Applicable syringe	1ml、2/2.5ml、5ml、10ml、20ml、30ml、50/60ml disposable sterile syringes that meet the requirements of relevant regulations and standards and having a valid CE certificate.
Infusion accuracy	1. At the standard operating condition, injection rate Accuracy ≤ ±1.8% 2. At the standard operating condition, Bolus volume Accuracy ≤ ±2%
Infusion mode	Rate Mode, Time Mode, Multi Mode , Weight Mode, Dose Mode, Intermittent mode , Sequential mode ,Program Mode, Ramp Mode, Micro Mode, Loading Dose Mode
Volume to be infused (VTBI)	（0.10-9999.99）ml
KVO rate	（0.10-5.00）ml/h preset by the user: can be on/off
Infusion rate	1ml syringe：（0.10～50.00）ml/h；

	2/2.5ml syringe：（0.10～150.00）ml/h； 5ml syringe：（0.10～300.00）ml/h； 10ml syringe：（0.10～800.00）ml/h； 20ml syringe：（0.10～1200.00）ml/h； 30ml syringe：（0.10～1500.00）ml/h； 50/60ml syringe：（0.10～1800.00）ml/h； Minimum increment: 0.01ml/h.
Bolus rate	1ml syringe：（0.10～50.00）ml/h； 2/2.5ml syringe：（0.10～150.00）ml/h； 5ml syringe：（0.10～300.00）ml/h； 10ml syringe：（0.10～800.00）ml/h； 20ml syringe：（0.10～1200.00）ml/h； 30ml syringe：（0.10～1500.00）ml/h； 50/60ml syringe：（0.10～1800.00）ml/h Minimum increment: 0.01ml/h.
Bolus VTBI	1ml syringe：(1.00～1.00) ml； 2/2.5ml syringe：(1.00～2.50) ml； 5ml syringe：(1.00～5.00) ml； 10ml syringe：(1.00～10.00) ml； 20ml syringe：(1.00～20.00) ml； 30ml syringe：(1.00～30.00) ml； 50/60ml syringe：(1.00～60.00) ml； Minimum increment: 0.01ml.
Purge	50%-100% of the maximum flow rate of the current syringe specification
Occlusion pressure	(10.0-130.0)kPa （13 levels available, refer to 8.5.5）
Waterproof Level	IP44
Electrical classification	Class I and Defibrillation-proof Type CF
AC power	100-240V~ 50/60Hz
Built-in battery	DC11.1V, Rechargeable Li-ion Polymer, 4400mAh Under standard testing conditions: Medium rate running time: greater than 10 hours Maximum rate running time: greater than 5 hours Charging time: 8 hours with power off
Power consumption	35VA

DC	DC 15V±10%　2.5A; DC power supply to the pump by Infusion Pump Management Unit
Fuse	Slow fuse Specification: 250V 2A (Maximum fusing time is 10 seconds when current is 5.5A)
Dimensions	258 * 160 * 83（L*W*H ）mm(Pole clamp excluded)
Weight	Around 2.0kg（net weight of the syringe pump，battery included, accessories excluded）
Glossary	
Bolus	The amount of fast infusion
Anti-Bolus	Diminishes the volume of unwanted Bolus after removal of the occlusion
KVO	Refers to the purpose of keeping the patient's veins open. After the infusion task is completed, the syringe pump will automatically infuse at a very low flow rate to prevent blood from returning and blocking the needle.
Infusion line	Syringe and extension tube
Standard test condition	The ambient temperature is 23°C±2°C, the screen brightness is set to 20% and the default volume, WIFI and key light off.
Main safety standard	EN 60601-1:2006+A1:2013+A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-8:2007+A1:2013+A11:2017+A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 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 EN 60601-2-24:2015 Medical electrical equipment - Part2-24: Particular requirements for the safety of infusion pumps and controllers

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

Installation：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 till the end by the side of screen.

Remove the handle: Pull down the buckle with one hand, push backwardly the handle from sliding groove with another hand to remove the handle from the syringe pump. (1: handle 2: lock buckle)

Note: The recommended number of load-bearing pumps for the handle is two. If you want to lift multiple pumps, please hold the bottom of the pumps with your hands and lift them.

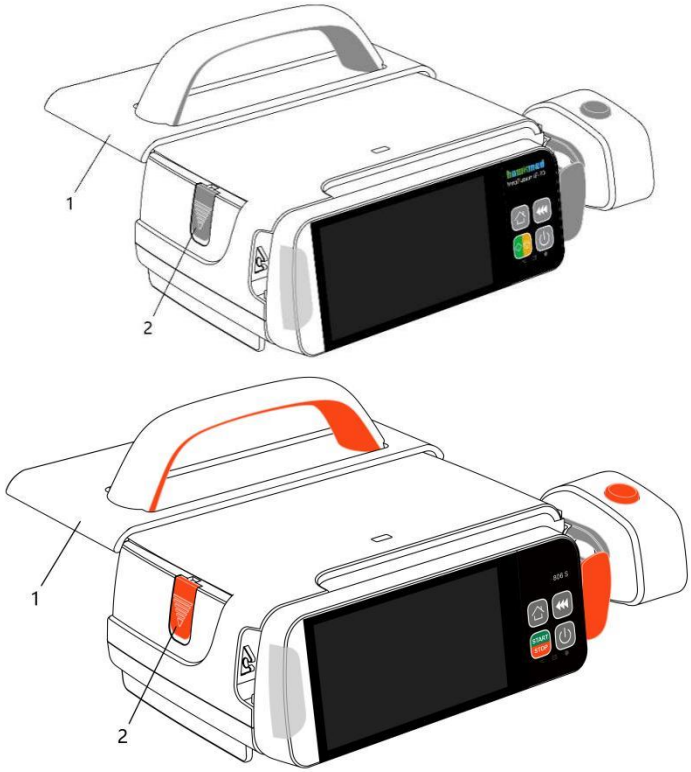


Figure 521-1. InnoFusion IF-70, 806 S

5.2.2 Installation of pole clamp

Installation ways: vertical and horizontal.

Vertical: slide the pole clamp along the slot from left to right.

Horizontal: slide the pole clamp along the slot from bottom to top.

Disassembly: Turn the knob to exit the screw rod of the pole clamp, press the bump in the center of the pole clamp and slide it out in the opposite direction to the installation method to complete the disassembly of the pole clamp.

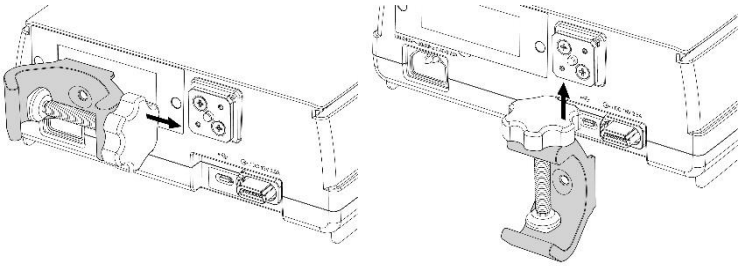


Figure 522-1

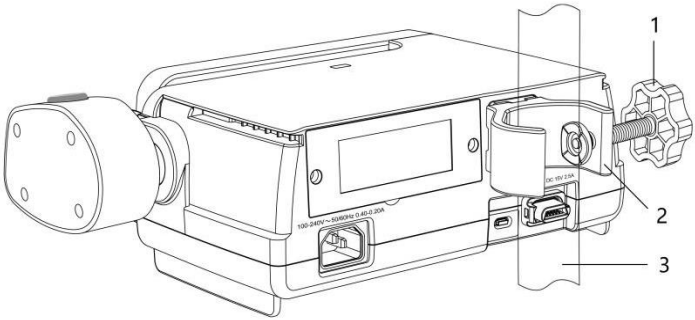
5.3 Installation method and cautions

Method 1: Put the syringe pump on stable platform.

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

Rotate the clamp knob of fixation screw out the rod, leave space for IV pole, 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.

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. 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, only release the hand after screwed tightly to avoid falling.



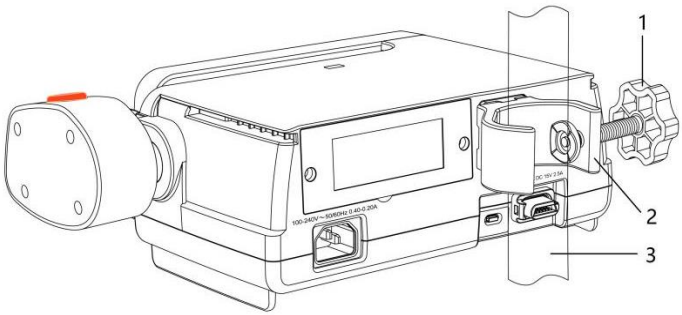


Figure 53-1. InnoFusion IF-70, 806 S

1：Clamp knob of fixation screw

2：Pole clamp

3：IV pole

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 rear shell)

According to the relevant standard, this label contains information regarding manufacturer, date of manufacture, product Lot number, classification, waterproof level etc.

6.5.2 Symbols and significance

Symbols	Descriptions	Symbols	Descriptions
 InnoFusion IF-70  806 S	Start/Stop		Bolus
	Switch on/off		Home key
	Start		Stop
	Return		Back
	In connection		Connection failure
	Confimed		Indicate that the alarm status is confirmed
	Bell, cancel temporary		Attention
	WIFI		Battery
	AC power		DC power
	USB interface		DC/AC
	Multifunctional interface		Protective earthing
	Model number		Production batch number

SN	Product serial number		Defibrillation-Proof Type CF
IP44	Ingress Protection Rating: Protected against splashing water		Non-ionizing radiation
	Please refer to the instruction manual		Prohibition
	Waste Electrical and Electronic Equipment (WEEE)	CN 2022-10	Date of manufacture and Country of manufacture, CN: China
MD	Medical device		Manufacturer
UDI	Unique device identifier		Importer
EC REP	EU Authorised representative	CE 0197	This device is provided with a CE marking in accordance with the Medical Device Regulation 2017/745. 0197 is the Notified Body number.
	Fragile. Handle with care!		Keep product dry
	This way up	5	Stacking limit (5)
70℃ -30℃	Temperature limit	95% 10%	Humidity limitation
106KPa 50KPa	Atmospheric pressure limitation		

7 Precautions for Preparation and Operation

7.1 Preparation and Inspection before use

Whether the syringe pump is new, has been stored for a period of time, or has been recently repaired, please check the following before use:

(1) The appearance is still good, clean, no visible cracks and leakages.

(2) All keys are responsive, and none of the keys are invalid or stuck.

(3) Syringe pump push handle could be moved in a smooth manner.

(4) The power cord should be attached securely to ensure that it does not easily become loose.

(5) If syringe pump is operating on internal battery alone, charge it fully before use and make sure the battery is in good condition for use.

(6) Set and check the system time to make sure that the event histories are recorded correctly.

(7) Please read the warnings, precautions and operation steps of this user manual carefully.

7.2 Operation Precautions

(1) Avoid exposing to direct sunlight, high temperature or high humidity.

(2) If the syringe pump is unable to carry out its functions as described in this manual for unknown reasons, stop the operation and report the details of the pump (including SN, photo or video about the malfunctions) to your local representative.

(3) The syringe pump must be operated by trained healthcare professionals.

(4) The syringe pump should be placed within 0.5 meter above or below the patient's heart level.

(5) If the touchscreen display is damaged, please ensure timely replacement of the panel to protect the syringe pump from damage by leaked liquids.

(6) If the operating environment temperature is not within the specified range, the injection will be less accurate and abnormal operation may result as a consequence.

(7) The injection fluid viscosity and proportion will affect the infusion accuracy.

(8) The device should be calibrated before a new brand of syringe is used.

(9) Disposable accessories can only be used once. Repeated use may lead to performance degradation or cross infection.

8 Operation Method

8.1 Operation

8.1.1 Fix the syringe pump and connect to AC power source

Fix the syringe pump properly onto an IV stand and connect it to an AC power source. The AC indicator light  (bottom right corner) will light up. The battery will start charging as soon as it is connected to an external power source.

8.1.2 Switch on/off

Press and hold POWER key  for few seconds, the pump will be switched on and perform system Self-Check.

Self-Checking includes: Communication, Press sensor, Potentiometer, AC power, Battery etc.

Press POWER key  and release to enter Power off interface, clicking Power off to switch off the pump.

When the push rod extends more than 28mm from the left end, it will automatically retract to a position 28mm from the left end.

Note: Turning off the power switch will not cut off the AC power supply of this device. To completely disconnect the power supply, please unplug the power plug.

8.1.3 Install the syringe

There are 3 methods to install the syringe:

a. Manual installation (the default setting)

b. Automatic installation

c. Auto-manual

8.1.4 Infusion Modes & 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

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8.1.8 Stop infusion

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8.1.9 Infusion completed

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8.1.10 Replace a syringe

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8.2 Alarms and solutions

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8.3 Syringe setting

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8.4 UserInfo Settings

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8.5 System setting

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8.6 Dock Settings

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9 Troubleshooting and Analysis

Failure	Cause Analysis	Solutions
Accuracy discrepancy	The syringe edge did not install into the syringe pump 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

Except for 8.2 common alarms and any other malfunctions, 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 to repair. It can be used again only after it is well repaired and tested. Syringe pump works with malfunctions may incur unpredictable damage.

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

11 Maintenance, Inspection, Repair and Recycling

In order to maintain the pump's performance, a preventive maintenance inspection must be carried out at least once every 3 years. Shutdown and disconnect the DC / AC power cord before cleaning.

11.1 Routine Maintenance and Disinfection

Daily maintenance includes the cleaning of outer shell. 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 syringe pump.

Disinfect the main unit according to hospital's disinfection protocol. Should clean it before disinfection. Follow the manufacturer's instruction and use regular disinfectant. The recommend disinfectant is: Ethanol 75%.

Disinfection steps：

1. Remove the syringe and fixing clip of the pump, soak the water with a dust-free cloth and squeeze it dry, wipe the pump shell until the surface is free of dust, stains and fiber residues.
2. Using a soft cloth, dip it in an appropriate amount of water or 75% ethanol and squeeze it dry.
3. Wipe the display screen.
4. Wipe the surface of the pump or accessories, taking care to avoid interfaces and metal parts.
5. 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.

Instructions	
Warnings	1. Before cleaning or disinfecting equipment or accessories, you must shut down the machine and unplug the power cord 2. Do not immerse equipment or accessories in liquids 3. Do not pour liquids onto equipment or accessories or into the enclosure
Preparation before cleaning	1. Turn off the power and disconnect the power cord 2. Remove the syringe 3. Wipe off any residual liquid on the surface with a lint free cloth
Cleaning	Method: Surface wiping Reagent: Water Operation: Dip a soft cloth in cleaning agent and wipe the shell, focusing on addressing the gaps between the buttons Rinse: Dry with a lint free cloth and wipe dry
Disinfection	Method: Wipe and disinfect Reagent: 75% ethanol Contact time: ≥ 1 minute Attention: Avoid liquid infiltration into the interface
Drying	Natural air drying or drying with a lint free cloth; Disable heating equipment for drying

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.

During operation of the syringe pump, maintenance, disassembly, or adjustment of patient contact parts is strictly prohibited.

11.3 Regular Inspection

It is recommended that a technical safety check of the equipment be carried out every two years, including verification that the alarm system is functioning.

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 easily to be pulled off.

11.3.2 Check Infusion Accuracy

Inspect method please refer to 8.5.9, It is recommended to contact the distributor for maintenance.

11.3.3 Check Internal Battery

The battery shall reduce the performance due to prolonged usage, please check the battery every 3 months or when the runtime of the battery is significantly reduced.

(1) First recharge the battery fully (8 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 10 hours, the battery is still in good condition.

--- If infusion time is more than 8 hours but less than 10 hours, the battery has begun to deteriorate, but still can be used.

--- If syringe pump is less than 5 hours, the battery has reached the end of its life, it needs to be replaced.

11.3.4 Replace Internal Battery

The battery is better to be replaced once three years, the battery must be replaced by trained professionals, it is recommended to contact the distributor or manufacturer to replace the battery once battery is expired. Battery replacement steps are listed as follows:

(1) Loosen the rear shell screws and remove the battery cover.

(2) Unplug the battery cable 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.

Note: if the replacement is not carried out according to the manufacturer's instructions, it may cause equipment failure, electric shock, fire or explosion risk.

11.4 Normal Maintenance Procedure

If pump is to be found abnormal, please do not disassemble and repair the machine by yourself, 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 13.2 for detailed storage conditions.

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

1. Calibrate the syringe pump to ensure infusion accuracy and avoid possible medical accident.

2. Occlusion alarm testing.

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

4. Must be charged and discharged every three months to ensure battery life span.

11.6 Recycling

The service life of this product is 10 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: -30℃～+70℃ ;
3. Relative humidity: 10%～95% (no frosting)
4. Atmosphere pressure: 50.0kPa～106.0kPa

12.2 Storage Conditions.

Storage temperature: -30℃～+70℃ ;

Relative humidity: 10～95% (no frosting)

Atmosphere pressure: 50.0kPa～106.0kPa

13 Package List

13.1 Standard Configuration in a Package:

Name	Number
Syringe pump	1unit
AC power cord	1set
User Manual	1 pc
Product qualification certificate	1 pc
Warranty card	1 pc
Pole clamp	1 pc

13.2 Standard optional accessories

Accessory	Model/Specification
Power cable	KC-015+KC-003
Handle	HK-HL50
Multi-functional interface cable	/

Above are specific accessories for the device. Use above accessories should follow manufacturer's instruction. To replace the above accessories, please contact manufacturer to get

original accessories. If non-special accessories are used, it will lead to abnormal functions such as non-recognition of equipment, incorrect accuracy, alarm and so on.

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 syringe pump.
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 spare parts and repair service 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

Appendix I: EMC Information

 Note:

- InnoFusion IF-70, 806 S syringe 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 InnoFusion IF-70, 806 S syringe 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:

- InnoFusion IF-70, 806 S 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 InnoFusion IF-70, 806 S syringe pump, it may be difficult to ensure EMC in other environment;
- The application of accessories and cables, other than the cables sold by InnoFusion IF-70, 806 S syringe pump manufacturer as the spare parts of its internal components & parts, can increase InnoFusion IF-70, 806 S syringe pump emission or reduce interference immunity.

Attachments:

Guidance and Manufacturer's Declaration - EME		
InnoFusion IF-70, 806 S syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of the syringe pump should ensure that it is used in such an environment:		
Emission Test	**Conformance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	InnoFusion IF-70, 806 S syringe pump uses 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 emissions CISPR 11	Class A	InnoFusion IF-70, 806 S syringe pump is suitable for being used 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.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration- Electromagnetic Immunity			
InnoFusion IF-70, 806 S syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of syringe pump should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Conformance Level**	**Electromagnetic Environment – Guidance**
Electrostatic transient / burst IEC 61000-4-4	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The floor should be covered with wood, concrete or tiles; if it is covered by composite materials, then the relative humidity should be at least 30%.
Surge IEC 61000-4-5	±2kV to power line ±1kV to input/output line	±2kV to power line	Network power should have the quality that is typical for application in commercial environment or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Network power should have the quality that is typical for application in commercial environment or hospital.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	<5 % U_T, continuing for 0.5cycle (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 0.5cycle (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 InnoFusion IF-70, 806 S syringe pump need to operate it continuously during power interruption, it is suggested to adopt uninterruptible power supply or battery for power supply.

Electrostatic discharge (ESD) IEC 61000-4-2	400A/m	400A/m/50Hz/60Hz	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			
InnoFusion IF-70, 806 S syringe pump is expected to be used in the following electromagnetic environment. Purchasers or 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**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	10 V(effective value) 150 kHz~80 MHz 10 V/m 80 MHz~2.5 GHz	10 V (effective value) 10 V/m	Portable and mobile RF communication device should not be closer to any part of InnoFusion IF-70, 806 S syringe 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~2.5 GHz P—the maximum rate output power of transmitter provided by transmitter manufacturer, in W; d—recommended isolation distance, in m [b]. The field strength of fixed RF transmitter is determined by the survey[c] of electromagnetic field. Should be lower than Compliance level in each frequency range[d]. 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 InnoFusion IF-70, 806 S syringe pump is higher than the applicable RF Compliance level, syringe pump should be observed to verify 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 InnoFusion IF-70, 806 S syringe pump.

b Field strengths should be lower than 10 V/m within the whole frequency range of 150KHz~80MHz.

Recommended Isolation Distance between Portable and Mobile RF Communication Device and InnoFusion IF-70, 806 S syringe pump

InnoFusion IF-70, 806 S syringe pump is expected to be used 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 InnoFusion IF-70, 806 S syringe 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～2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For 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.

Appendix II

Table 1 Alarm classification and color of alarm indicator light

Alarm classification	Alarm priority	Color and frequency of alarm indicator light
Syringe Off	High priority	Red light/2Hz
Occlusion	High priority	Red light/2Hz
Dedicated tube error	High priority	Red light/2Hz
Connection failure	High priority	Red light/2Hz
Battery exhausted	High priority	Red light/2Hz
Finished	High priority	Red light/2Hz
Push-empty	High priority	Red light/2Hz
System error	High priority	Red light/2Hz
No external power	Low priority	Yellow light long bright
Abnormal battery power supply	Low priority	Yellow light long bright
Near empty	Low priority	Yellow light long bright
Low battery	Low priority	Yellow light long bright
Pre-occlusion	Low priority	Yellow light long bright
Almost done	Low priority	Yellow light long bright
No operation	Low priority	Yellow light long bright

Note：The inherent delay of the alarm is less than 100ms.

Table 2 Characteristic parameters of alarm signals

Alarm classification	Interval time	Alarm information
High alarm	8s±2s	Red background with white letters
Low alarm	25s±2s or not repeat	Blue background with white letters

Note:

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

Table 3 Occlusion Response Characteristic

Occlusion alarm trigger time

Flow rate (ml/h)	Occlusion alarm level	Occlusion alarm time (min)
1.00	1 level (Lowest)	<60
	13 level (Highest)	<300
5.00	1 level (Lowest)	<10
	5 level of 2ml/2.5ml syringe (Lowest)	<10
	13 level (Highest)	<60
0.10	1 level (Lowest)	<180
	13 level (Highest)	<2400

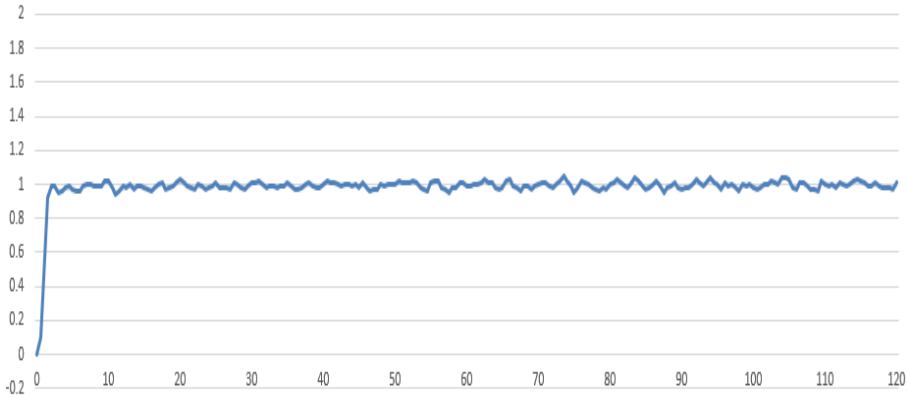
Unintended bolus volume

Flow rate (ml/h)	Occlusion alarm level	Unintended bolus volume (ml)
5.00	1 level (Lowest)	<0.9
	5 level of 2ml/2.5ml syringe (Lowest)	<0.9
	13 level (Highest)	<2.0

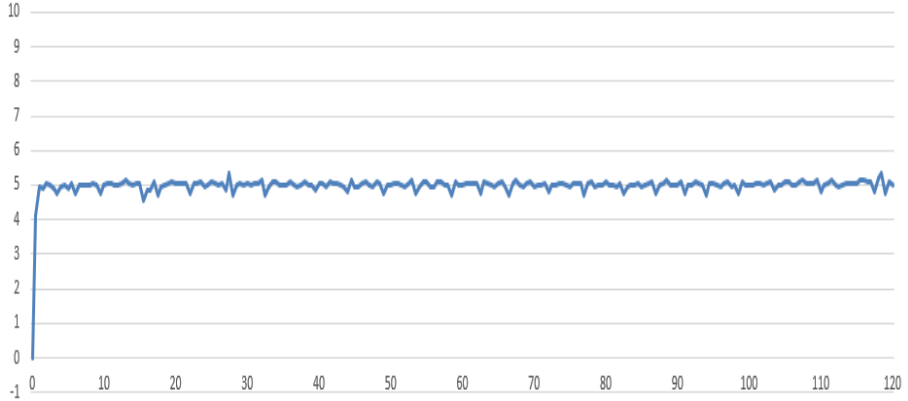
This experiment uses 50ml and 2ml Jierui brand syringe, and the following data only represent the conclusions obtained from the syringe used in the experiment. The test temperature is 20℃±2℃, and the pipeline length is 1m.

Note: The occlusion alarm pressure, trigger time, and unintended bolus volume are all affected by experimental conditions, temperature, and pipeline length.

Table 4 Starting Curve

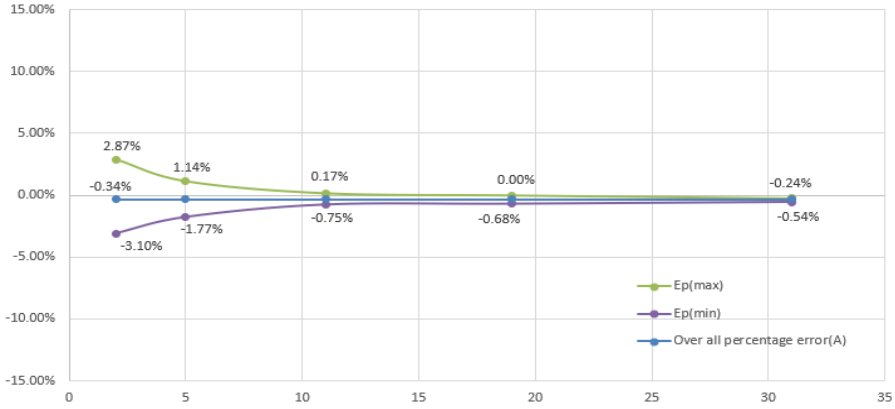


1ml/h Starting Curve

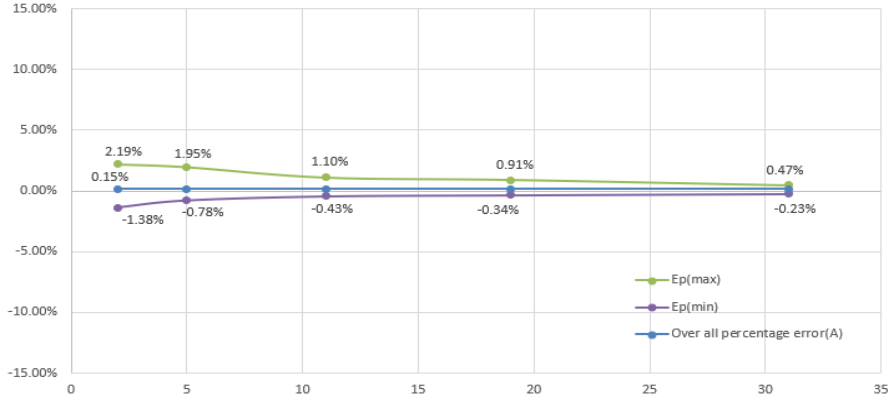


5ml/h Starting Curve

Table 5 Trumpet Curves



1ml/h Trumpet Curves



5ml/h Trumpet Curves

These data are testing result according to IEC 60601-2-24:2012 and the company's products standard. It uses 1 syringe pump unit sample and 10ml syringe under Jierui brand. For more information, please contact with our After-sales Service Department.

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EC REP

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