

Syringe pump

User information



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- The contents of this manual should be correct. If, for some reason, there are any questionable points, please do not hesitate to contact our service center.
- The manual will be replaced if any pages are missing or collation is incorrect.

Warranty

- Please contact your local distributor about the warranty period.
- Device failure or damage related to the following situations during the guarantee period is not covered by this warranty:
- Installation, transfer installation, maintenance, and repairs by any person other than an authorized Covetrus employee or technician specified by Covetrus.
- Damage sustained to the Covetrus product(s) caused by product(s) from another company excluding products delivered by Covetrus.
- Damage – caused by mishandling and/or misuse – is the responsibility of the user.
- Maintenance and repairs utilizing maintenance components that are not specified by Covetrus.
- Device modifications or use of accessories not recommended by Covetrus.
- Damage caused by accidents or natural disasters (earthquakes, flooding, etc.).
- Damage resulting from usage where caution statements and operating instructions shown in this manual have not been followed.
- Damage due to neglect of specified maintenance checks.

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Precautions

Note:

This operating manual provides a detailed introduction to the use, functioning and operation of the device. Read the manual completely prior to using this device. Carry out pump inspection and maintenance periodically according to the manual in order to avoid patient/user injury.

The manual contains the most complete function and features. Please refer to the relevant model, functions, and features. Should you have any question, please contact us.

Keep the operating manual near the device for easy reference.

Operator

The operating manual is only used by well-trained clinical nurse or doctors.

Others

The figures in the operating manual are only for reference. The settings and data used in the figures may not correspond exactly to those under actual use.

Safety precautions

- (1) The device is not portable and is not to be used on a patient bed.
- (2) This device is used for intravenous infusions, NOT external and intragastric infusion. It should only be used by well-trained clinical nurses or doctors.
- (3) Steady the syringe pump on the IV stand. Make sure the device is securely installed before use.
- (4) Use a three-plug socket and make sure the plug is completely inserted. Do not touch the socket with wet hands.
- (5) No voltage other than that specified on the product label may be used, at the risk of damage or even fire.
- (6) Check the device and the accessories completely before use to make sure all are in working order.
- (7) Do not rely solely on the device alarm. Pay attention to the remaining volume or any occlusion alarm during injection.
- (8) Set the alarm value based on the patient's condition and keep a close eye on the patient rather than relying exclusively on the alarm.
- (9) Stop using the device when an alarm sounds.
- (10) If there are any abnormal circumstances, stop using the device immediately.
- (11) The device may work improperly in a hyperbaric environment.
- (12) Installing other infusion control devices in the same injection line could be hazardous and is not recommended.
- (13) Connecting another brand of infusion system or accessories could be hazardous and is not recommended.
- (14) Keep the IV line smooth; a crimped line can lead to occlusion, malfunction, underflow, etc.
- (15) Use the device within 120 cm of the patient's heart.
- (16) Do not operate this device in environments where there are flammable gases such as anesthetics, oxygen, oxidized ammonia, etc.
- (17) Do not operate this device under conditions of strong sunlight, cold, and hot air currents or dust.
- (18) Microwaves will influence the device's functioning; equipment must conform to EMC standards. Mobile phones, X-rays, and MRI devices may cause malfunctioning due to high frequency radiation.
- (19) The device must be operated by professional medical staff, such as doctors, nurses, etc. Do not permit patients to operate the device.
- (20) Dismantling or modifying the device is prohibited. Opening the housing of the device may lead to severe electric shock. Maintenance and upgrades of the device must be done by the staff trained or authorized by Covetrus.
- (21) Do not throw the heat or incinerate the battery or there will be leakage and possibly fire or explosion.
- (22) Do not remove the battery cover, or there may be explosion or chemical burns.
- (23) To avoid patients being injured by overflow or underflow, set parameters correctly and use the standard well-calibrated syringe, or the accuracy will not be assured and may reach more than $\pm 40\%$.
- (24) Check the device daily and check that all functions are operable if it is not used for long period.
- (25) Clean the surface of the device with the soft cloth and warm water.
- (26) Obey the local or hospital regulations with regard to disposal of the packing material and keep it away from children.
- (27) Please stop using the device if there are abnormal or failed functions and contact the supplier right away; otherwise, the manufacturer and supplier will not be responsible for any loss, harm or injury caused by it.
- (28) The maximum injection volume is 0.7 ml in a single failure.

Symbol key

List of symbols used in the instruction

Symbol	Significance
	CAUTION: These notes must be observed to prevent any damage to the device
	Type CF part without defibrillation discharge effect (degree of protection against electrical shock)
	AC POWER indicator: When illuminated, the pump is connected to an AC power supply and the battery is being charged
	BATTERY indicator - When illuminated the pump is running on the internal battery. When flashing the battery power is low with less than 30 minutes of use remaining
IPX4	Protected against falling water drops
	Date of manufacture
	Manufacturer
	MUTE button - Press to silence alarm for (approximately) 2 minutes. The alarm will resound after this time
	ON/OFF button - Press once to switch the pump ON. Press and hold down for approximately 3 seconds to switch the pump OFF
	THE OPERATING MANUAL MUST BE READ
	Authorized Representative in the European Community
	COMPLIES WITH MDD 93/42/EEC REQUIREMENTS
	Serial number
	Non-ionizing radiation
	ENVIRONMENT PROTECTION - Waste electrical products should not be disposed of with household waste. Please recycle where possible. Check with your local authority or retailer for recycling advice.
	This way up
	Fragile! Handle with care
	Keep dry: A medical device that needs to be protected from moisture
	Keep away from sunlight
	Atmospheric pressure limit
	Humidity limit
	Temperature limit
	Stacking layer limit

Chapter 1. Introduction

1.1 Application

The syringe pump is intended to provide continuous injection with an accurate flow rate and to monitor the injection process at a constant rate to the patient under clinical treatment for a period.

1.2 Main components and functions

The device consists of an LCD, front shell module, back shell module, main control board, driving module, plunger head module, barrel clasp module, battery, etc., including the circuit control system, alarm detection system, input and output system, and mechanical driving system.

Main component and function:

- Main control system: It is core of the whole system. It can intelligently control, manage and process the system signals. The double CPUs monitor and backup each other. When one CPU has a problem, the other will sound an alarm and stop the power supply and operation to ensure the patient's safety.
- Mechanical drive system: It is the driving force of injecting the fluid. The step motor pulls the plunger head, which pushes the fluid injection.
- Detection system: mainly various sensors to detect size, pressure (in the syringe), etc.
- Alarm system: Consists of audio and visual alarms to call the operator's attention to anomalous situations, and thus avoid harm to the patient.
- Input and display: To enter the infusion parameters: VTBI, flow rate, etc. Displays the injection parameters and alarm messages.

1.3. Technical specifications

1.3.1 Compliance

Protection against electric shocks: Class I, include the internal power supply

Leakage current protection: Type CF, the part without defibrillation discharge effect

Splashing fluid protection: IPX4

Working Mode: Constant infusion

1.3.2 Operating, Transportation and storage conditions

Temperature: +5°C~ +40°C

Relative humidity: 20~90%, not condensation

Atmospheric pressure: 70 kPa~106 kPa

Transportation and storage temperature: -20°C +55°C

Transportation and storage humidity: 10~95%, not condensation

Transportation and storage atmospheric Pressure: 55 kPa~106 kPa

Transportation and storage condition: No corroded air and good ventilated environment

1.3.3 Power supply

Volt: 100~240 V

Current: 0.6~0.3 A

Frequency: 50Hz/60Hz

1.3.4 Battery

Quantity: 1

Type: Rechargeable Lithium battery

Capacity: 3000mAh

Rated voltage: DC 11.1 V

Max. power: 50 VA

Operation time: ≤ 9 hr at 5 ml/h after fully charged

Recharging time: 14-16 hrs

1.3.5 Physical specifications

Device dimension: 275 mm×145 mm×160 mm

Weight: ≈ 2.1 kg

LCD type: LCD with high brightness

LCD size: 3.5 inch

1.3.6 Basic parameters

Syringe size:	5 ml, 10 ml, 20 ml, 30 ml, 50/60 ml, auto-detection
Injection modes:	Constant mode, Volume/Time Mode, Drug Weight Mode, Micro Mode, Programmable Mode and Drug Library Mode
Flow rate:	5ml: 1.0 ml/h~60.00 ml/h 10ml: 0.10~300.00 ml/h 20 ml: 0.10~400.00 ml/h 30 ml: 0.10~600.00 ml/h 50/60 ml: 0.10~1200.00 ml/h
Increment:	0.01 ml/h
VTBI:	0.10-9999.9 ml or OFF
Time:	1s~99 h 59 min59s
Deviation:	$\leq \pm 2\%$ (including mechanical deviation $\pm 1\%$)
KVO:	0.10~5.00 ml/h adjustable (keep vein open)
Purge rate:	Purge Rate: 5 ml:30~60 ml/h 10 ml: 150~300 ml/h 20 ml: 200~400 ml/h 30 ml: 300~600 ml/h 50/60 ml: 600~1200 ml/h
Occlusion pressure:	Detection Range: 20 kPa~150 kPa, 8-level sensitivity adjustment, with dynamic pressure value display
Volume:	Standard medical alarm voice with mute function, 8-levels adjustment
Screen brightness:	10 levels adjustable
Keypad:	User-friendly numeric keypad
BOLUS rate:	5 ml:0.10~60.00 ml/h 10 ml:0.10~300.00 ml/h 20 ml:0.10~400.00 ml/h 30 ml:0.10~600.00 ml/h 50/60 ml:0.10~1200.00 ml/h
Syringe management:	20 preset syringe brands, can add or edit brands, accept all brands after calibration
Anti-motor reverse:	Monitor the step motor to avoid reverse injection
Self-testing:	Self-Testing during loading and injection
Audio and visual alarms:	Occlusion, Battery Exhausted, Near Complete, Completed, Syringe Fall-Off, Battery Lost, No Operation, Low Battery, Completed! KVO, Near Empty, Completed, Net Power Fall, Infusion Error, Parameter Error, Start Failed, Syringe Fault, Communication Error, Infusion Fault
Syringe management:	Can add or edit brands, accept all brands after calibration
Communication port:	USB, for future use, Ethernet Port
Event history:	10,000 history records, can be transmitted to PC with USB
Language:	Chinese or English
Note:	Specifications are subjected to change without prior notice.

1.4 Function description

- 1.4.1** The device has fully functional acoustic and visual alarms and an accurate injection-control system with high safety and reliability. It can give alarms, for finished, occlusion, low battery, abnormal injection, etc.
- 1.4.2** The device is available for the intravenous injection of normal brine and dextrose, is also for the injection of high surface tension.
- 1.4.3** It can accept exclusive and standard single-use syringes.
- 1.4.4** The battery power system can guarantee continuous injection when the patient needs to be moved or the AC power is disconnected. Battery life can be more than 10 hrs at the speed of 5 ml/h after it is fully charged.

1.5 Components and functions

The device consists of an LCD, front shell, back shell, main control board, driving module, plunger head module, barrel clasp module, battery, etc. including the circuit control system, alarm detection system, input and output system and mechanical driving module.

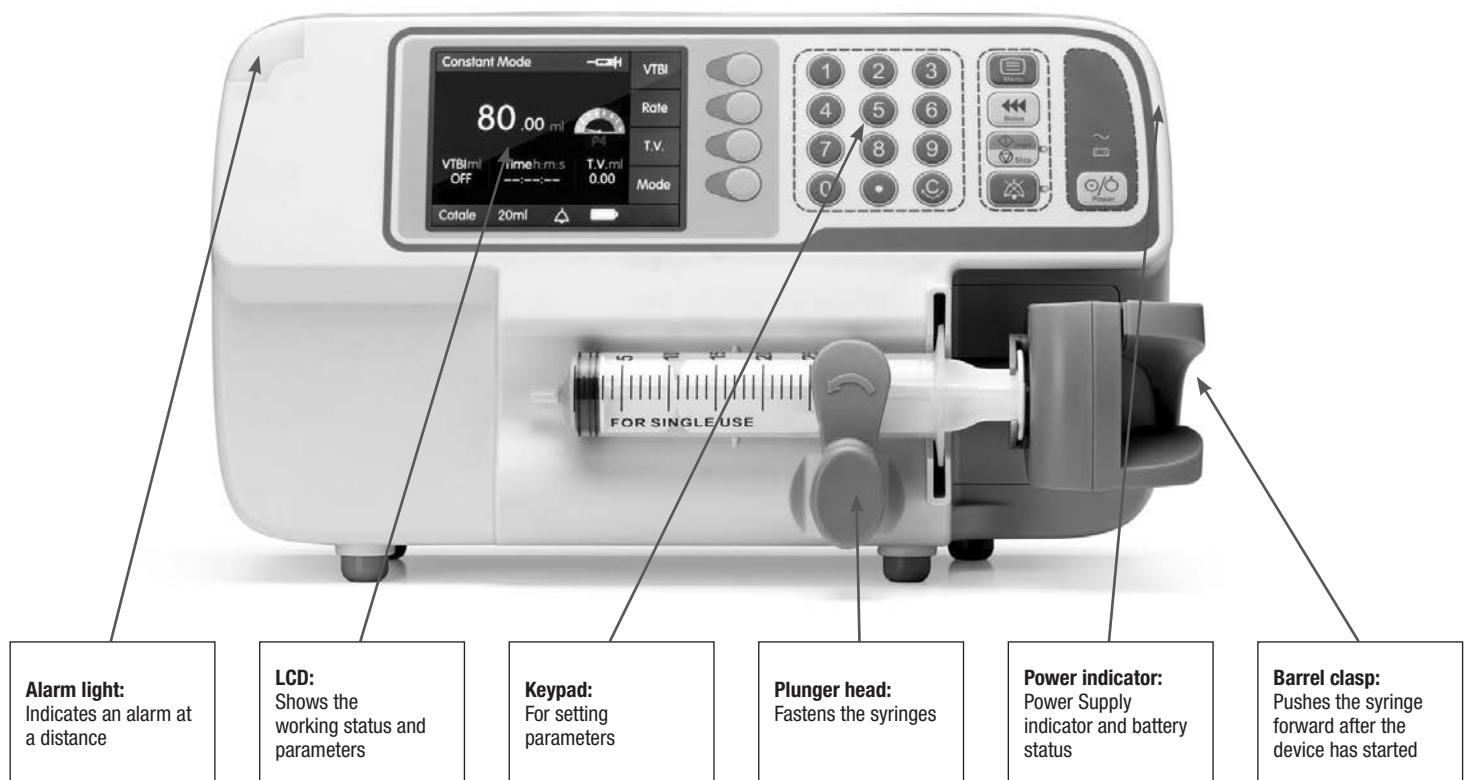
The circuit system consists of a mother board, display control board, power board and other types of transfer boards.

The input & output system includes an LCD and keypad, etc.

The alarm detection system consists of a speaker, alarm light, sensors, etc.

The motor driving system consists of a motor driving system, front and back shell, plunger head, barrel clasp, etc.

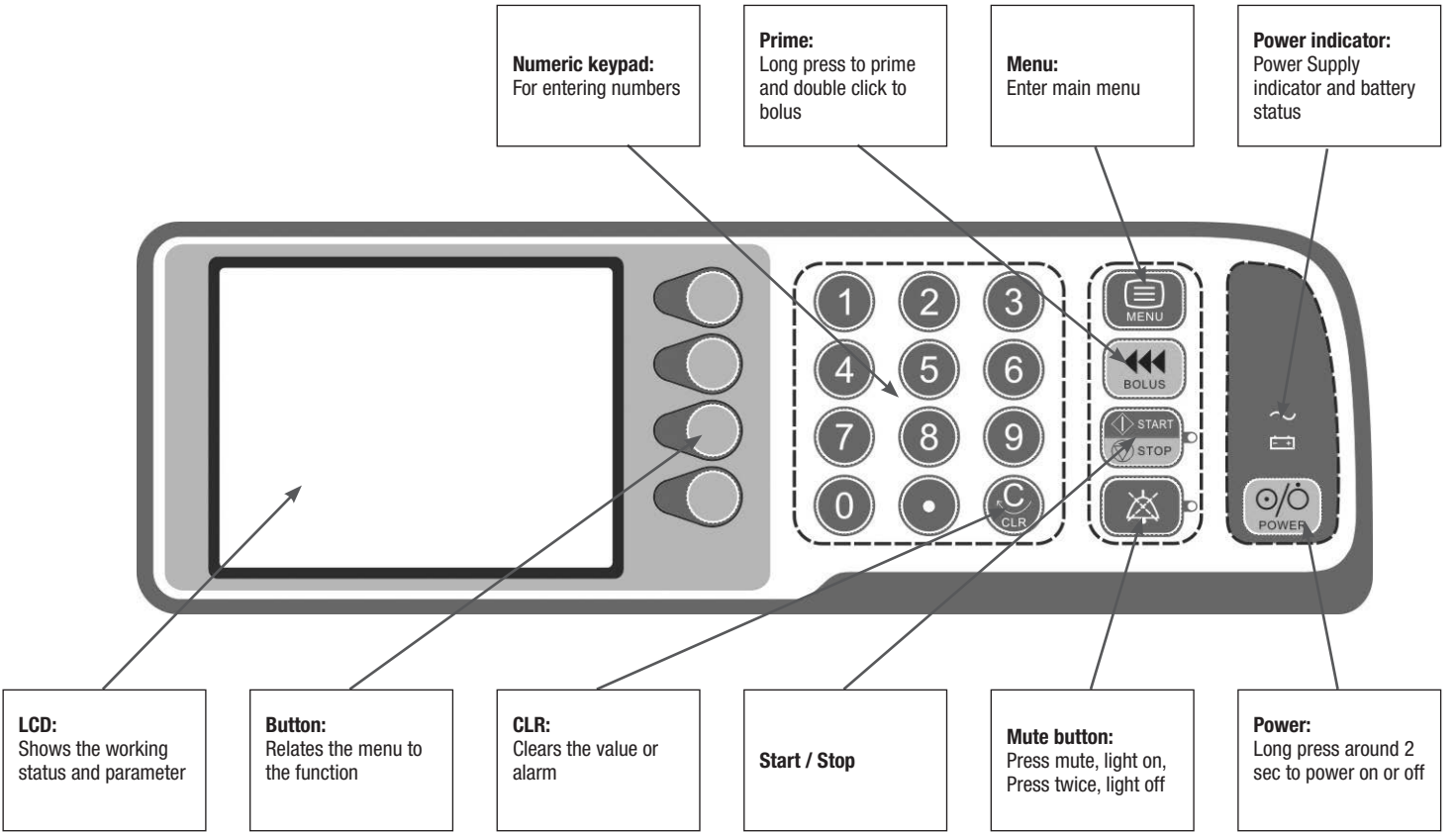
1.5.1 Front shell components



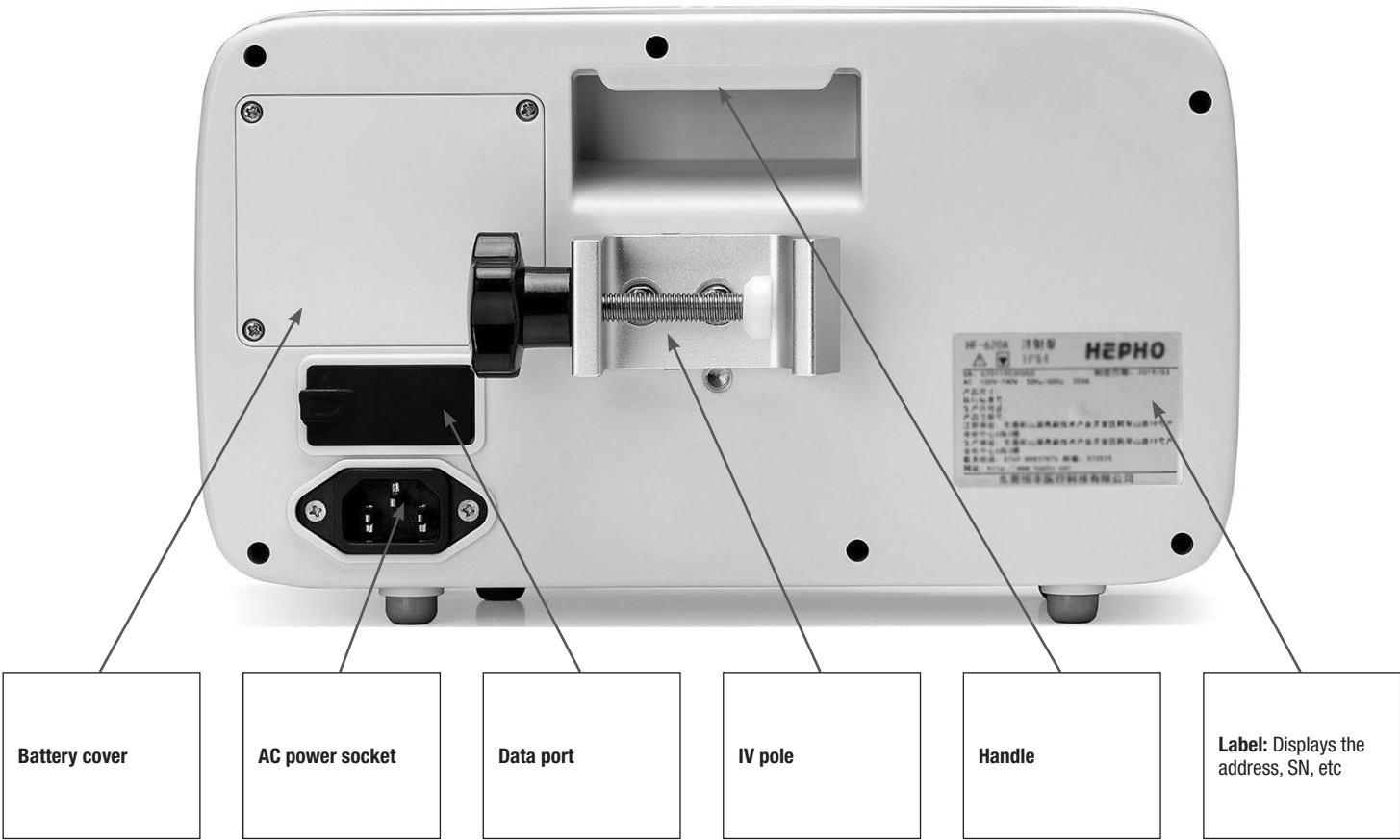
1.5.2 Infusion fluid path module



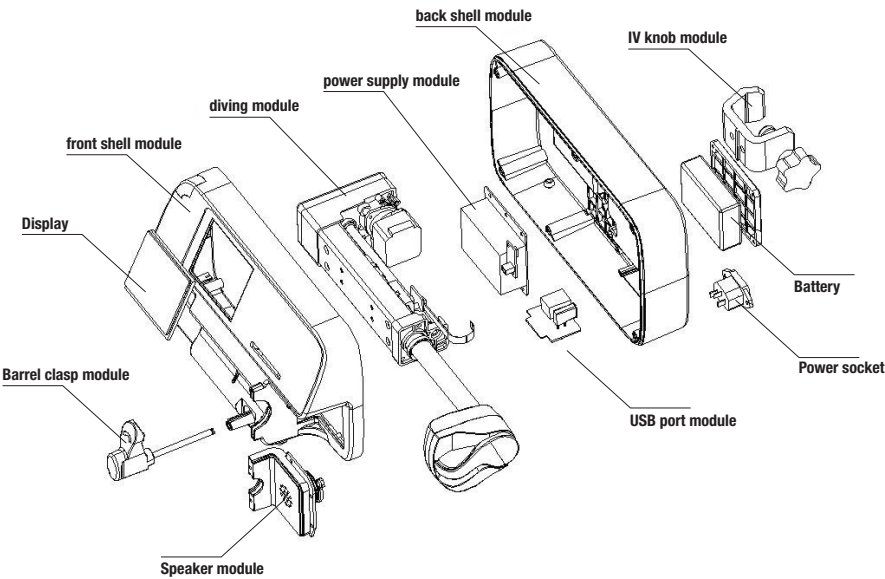
1.5.3 Button function



1.5.4 Back shell components



1.5.5 Main unit component



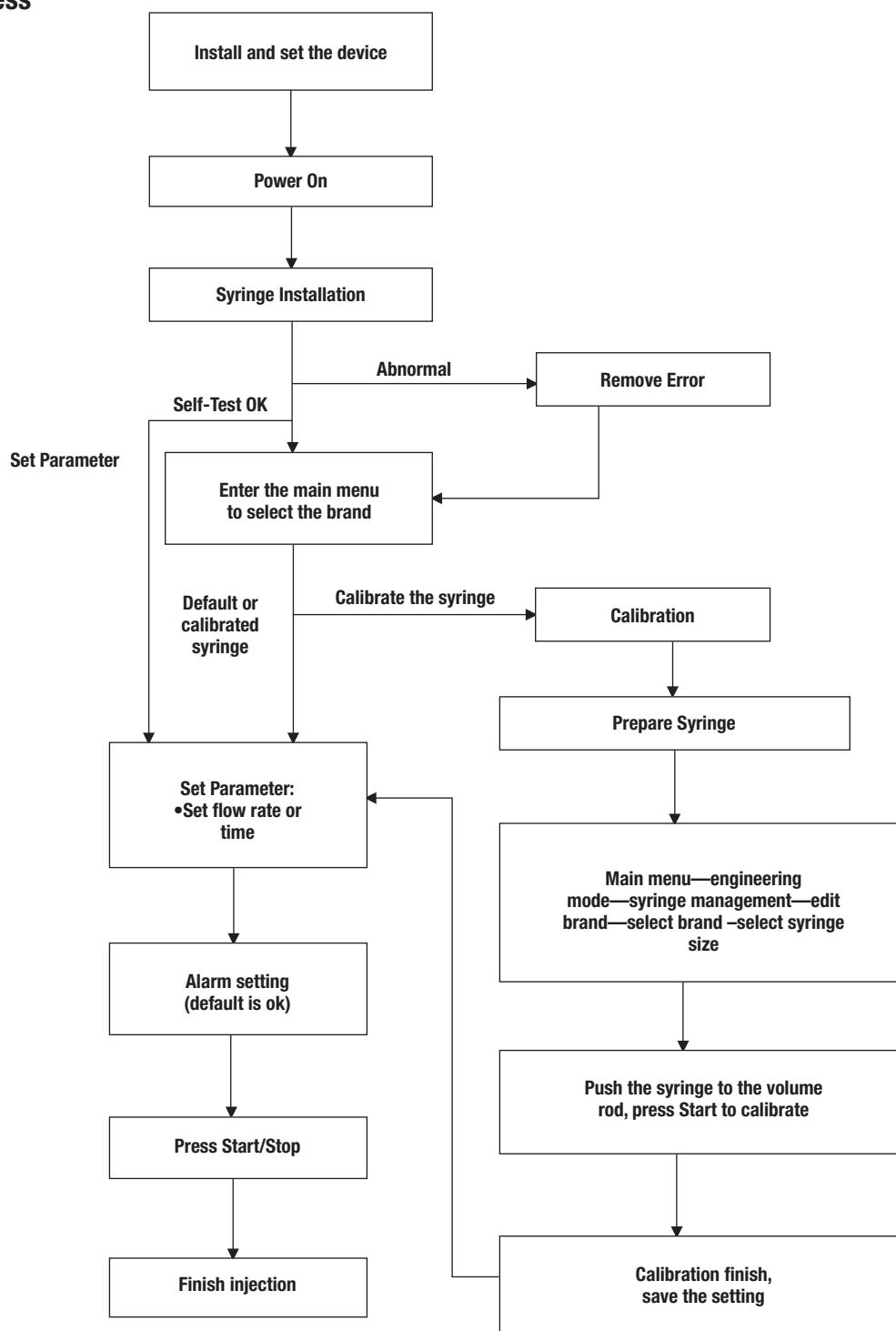
Chapter 2. Packing list and operating process

2.1 Packing list

The following parts are included:

- (1) Syringe pump 1pc
- (2) Power cord 1pc
- (3) Operating manual 1pc
- (4) Quick operation guide..... 1pc
- (5) Quality inspection certificate..... 1pc

2.2 Operating process



Note!

- If the injection unit is the same as last injection, the flow rate, time, VTBI and other parameters can be set directly; the injection mode, syringe brand selection, and alarm setting steps may be skipped.
- The last parameters (except Total Volume, which will be cleared) will be kept in memory after the device is powered off.

Chapter 3. Operating guide

3.1 Preparation

3.1.1 Package open/inspection

Before opening the package, please check it carefully for damage. If there is damage, contact the forwarder or supplier immediately.

If all is ok, then open it carefully and remove the device and other items. Check the parts list and make sure everything has been included. If you have any questions, kindly contact us.



Note!

- **Keep the packing material out of reach of children. Follow local or hospital regulations for the packing material.**
- **Keep the packaging on hand for future use.**

3.1.2 Environmental standards

Keep the device away from the noisy, shaking, dusty, corrosive, flammable, explosive environments. Please maintain a clearance of at least 5 cm distance around the device and ensure proper ventilation.

When the device is moved to another location, there may be condensation due to temperature difference, in which case, please do not start the device until the condensation is gone.

Keep the device away from mobile phones, X-rays, or MRI equipment, as they may interfere with the device's operation or cause damage due to electromagnetic interference.

3.1.3 AC power supply standard

Please run the device under the AC power range on the label only.



Note!

- **Use the proper AC power supply based on the power voltage setting, or there will be a risk of damage and fire.**
- **Power feed spec: 5*20 mm, ceramic tube high breaking fuse, model: 5H, 2A, 250V.**

3.1.4 Power cord installation

Connect the power cord into the socket on the back of the device and connect to the AC power. The  will be flashing on the keypad; the battery will start charging at the same time.  Flashing indicates battery is charging.



Note!

Make sure the power cord is completely connected.

- **AC power voltage range is 100~240V, 50/60Hz.**
- **Make sure the power cord is completely connected.**
- **Make sure the power cords are placed out of the way.**

3.2 Installation and settings

3.2.1 Installation and power on

3.2.1.1. Install the device straightly and tightly on the IV stand. Connect to AC power and  will be flashing on the keypad.

3.2.1.2. Press the Power button for around 2 seconds and the device will start self-testing. If anything is wrong, it will display an alarm on the screen (e.g., AC power lost)

3.2.1.3. The device will manage the battery automatically.



Note!

- **The device will switch to battery power automatically if AC power disconnected or lost.  will be flashing and the acoustic and visual AC power lost alerts will remind the operator. Alarms can be removed by pressing CLR on the keypad.**
- **It is advisable to switch the device first and then install the syringe and set the parameter.**

3.2.2 Syringe installation

3.2.2.1. Install the syringe correctly and prime the bubble in it.

3.2.2.2. Pull the barrel clasp and install it on the device.

3.2.2.3. Pull the syringe handle to the end and put it on the device.

3.2.2.4. Place the syringe in its cradle, with the flanges correctly positioned in the provided slot.

3.2.2.5. Press down and release the button of the plunger head on the right side and move it forward to the end of the syringe by engaging the small button on the left side of the plunger head, then the button on the right side. It will be bounced back automatically.

3.2.2.6. Check that the syringe is installed correctly.



Note!

- **Make sure to move the plunger head handle to the end of the device when moving the plunger head, or there may be mechanical damage to the device.**

3.2.3 Parameter setting

3.2.3.1. In standby mode, VTBI, flow rate, total volume and mode will on the right side of the LCD.

3.2.3.2. Press the function button to enter into the setting.

3.2.3.3. Select VTBI, flow rate and input the value; press OK to proceed.

3.2.3.4. Press Total Volume to clear the value.

3.2.3.5. Select Mode, press  or  to proceed.



Note!

- Total volume is only for the current injection and will be cleared after the device is powered off.
- If VTBI is set to OFF, the injection will keep pushing until all the fluid in the syringe has been injected.
- Confirm that the current syringe brand is the same as the one selected before setting the parameter.
- The function button is different for different modes.
- The default is the constant rate mode.
- There will be a “Parameter error” alarm if the VTBI, flow rate, etc. are out of the range.

3.2.4 Start injection

3.2.4.1. Check that the syringe is installed correctly.

3.2.4.2. Check that the parameter is set correctly.

3.2.4.3. Check that there is no air inside the syringe.

3.2.4.4. Make the venous puncture on the patient.

3.2.4.5. Press Start/Stop to proceed in standby mode and the syringe icon in the LCD will keep moving.



Note!

- Remaining VTBI will be decreasing during the injection.
- The time on the LCD is the remaining injection time if the VTBI is set correctly during injection.
- It is advisable not to use one syringe for more than 24 hrs.
- Prime the air inside the syringe or the extended tube by long pressing the Bolus button until all the air removed.
- It is advisable to prime the air before the venous puncture, especially in the low-rate injection, which can make the plunger head and the syringe handle connect completely.
- Hospital staff should check on the injection from time to time and not rely exclusively on the device's alarms.

3.2.5 Near empty

If VTBI is set to OFF, it will give acoustic and visual alarm and show Near Empty on the LCD when the syringe is approaching empty; press the Clear button to clear the alarm and get back to the injection interface.



Note!

- When there is a Near Empty alarm, the injection will not stop, but will keep going until all the fluid is ejected.

3.2.6 Injection finish

3.2.6.1. When the total volume reaches the set volume, VTBI will show 0 ml and the Finish! KVO alarm. The injection will stop and enter into KVO mode to keep the vein open.

3.2.6.2. When VTBI is more than the fluid volume inside the syringe, it will show a Syringe Emptied alarm when the fluid is finished and it will stop injection.

3.2.6.3. Press the Start/Stop button and stop injection.

3.2.6.4. Remove the needle.

3.2.6.5. Press the Power button for about 2 seconds to shut power off.

3.2.6.6. Press the plunger head handle and pull out the syringe by rotating the barrel clasp 90 degrees counterclockwise and remove the syringe.

3.2.6.7. Remove the AC power plug and take away the device.



Note!

- Set the parameters correctly and press Start/Stop to continue with a new injection.
- The last injection parameters (except total volume) will keep in memory after the device is powered off.

3.3 Main menu

3.3.1 Select mode

3.3.1.1. Press Menu to enter the main menu.

3.3.1.2. Press  or  to select “1. Select Mode” and press OK to proceed.

3.3.1.3. Press  or  to select the injection mode and press OK to proceed.

- 3.3.1.4. The menu contains the Constant Mode, Volume/Time Mode, Drug Weight Mode, Micro Mode and Drug Library Mode. Press  or  to select the mode and press OK to proceed.
- 3.3.1.5. Constant Mode: injection with the unit ml/h.
- 3.3.1.6. Volume/Time Mode: Injection with VTBI and time and flow rate calculated automatically.
- 3.3.1.7. Drug Weight Mode: Input dose, solution, drug, weight and calculation, etc. The flow rate is calculated automatically.
- 3.3.1.8. Micro Mode: The maximum rate is less than 99.9 ml/h.
- 3.3.1.9. Drug Library Mode: select the drug for injection
- 3.3.1.10. Programmable Mode: Select flow rate or time for injection, max. 5 step for injection.
- 3.3.1.11. Press OK to proceed.



Note!

- **Programmable Mode: flow rate or time is programmable.**

3.3.2 Parameter Setting

- 3.3.2.1. Press Menu to enter the main menu.
- 3.3.2.2. Press  or  to select “2. Parameter Setting” and press OK to proceed.
- 3.3.2.3. Parameter settings include: select brand, KVO Setting, blocking pressure level, prime, near empty. Press  or  to select and press OK to proceed.
- 3.3.2.4. Select Brand: there are well-calibrated default syringe brands in the menu; press the number to select.
- 3.3.2.5. KVO setting: Set KVO VTBI with range: 0.1-5.00 ml; KVO flow rate with range: 0.01-5.00 ml/h. Press Save after setting and press OK to proceed.
- 3.3.2.6. Blocking Pressure setting: Press  or  to select Level 1 – Level 8. (the lower the level, the more sensitive); press OK to proceed.
- 3.3.2.7. Prime Setting: Auto Prime and Manual Prime. Select to calculate the prime volume into total volume or to not set the flow rate; press OK to proceed.
- 3.3.2.8. Near Empty setting: Select the Near Empty alarm with time or volume. Set time as the Near Empty alarm (time range: 30-900 seconds); set remaining volume as Near Empty alarm: around 10% volume remaining; press OK to proceed.



Note!

- **Maximum Auto Prime Volume is 5 ml, range: 0.10-5.00ml**
- **Select remaining volume as Near Empty alarm, either time or remaining volume will trigger the alarm when the value is reached.**

3.3.3 System setting

- 3.3.3.1. Press Menu to enter the main menu.
- 3.3.3.2. Press  or  to select “3. System Setting” and press OK to proceed.
- 3.3.3.3. System Setting includes: set date/time, LCD brightness, System Info. Press  or  to select and press OK to proceed.
- 3.3.3.4. Set Date/Time: Press  or  to set the date and time and press OK to proceed.
- 3.3.3.5. Set LCD brightness: Press  or  to select 1-10 level brightness (level 10 > level 1) and press OK to proceed.
- 3.3.3.6. System Info: Check device model, version, etc. and press Exit to proceed.



Note!

- **If the system time is incorrect, the history time will also. be incorrect.**

3.3.4 History records

- 3.3.4.1. Press Menu to enter the main menu.
- 3.3.4.2. Press  or  to select “History Record” and press OK to proceed.
- 3.3.4.3. The menu includes View Event Log, search Event Log. Press  or  to select and press OK to proceed.
- 3.3.4.4. Check View Event Log: Press  or  to check the log and press OK to read it and press Exit to proceed.
- 3.3.4.5. Search Event Log: Press  or  to select the date and press OK to read and press Exit to proceed.

3.3.5 Engineer Mode

- 3.3.5.1. Press Menu to enter the main menu.
- 3.3.5.2. Press  or  to select “5. Engineer Mode” and press OK to input the password to proceed.
- 3.3.5.3. Engineer Mode includes the function check System Log, Drug Library, Brand Management, Alarm Volume, Language Setting, Pump back Setting, Pressure Error Level, Device Calibration, Restore factory setting, and software upgrade. Press  or  to select and press OK to proceed.
- 3.3.5.4. System Log: Clear History Records, export History Records. Press  or  to select and press OK to check or clear the log. Connect USB to export the History Records and press OK to proceed.

- 3.3.5.5. Drug Library: Select drug, add drug, delete drug, import drug, export drug. Press  or  to select and press OK to proceed.
 Select drug: Press  to select the drug and the drug will be displayed in the Drug Library menu.
 Add drug: Input the drug name using the soft keypad.
 Delete Drug: Delete the drug in the system.
 Import Drug: Import the drug from USB data.
 Export Drug: Export the drug to USB.
- 3.3.5.6. Brand Management: Select brand, edit brand, add brand, delete brand, import brand, export brand. Press  or  to select and proceed.
 Select brand: Press  to select and “Parameter Setting” will be displayed in the “Select brand” menu.
 Edit Brand: change the syringe length, diameter, empty length and other parameters to improve accuracy.
 Add brand: enter the brand using the soft keypad.
 Delete brand: delete the brand in the system.
 Import brand: Import the brand from USB data.
 Export brand: Export the brand data to USB.
- 3.3.5.7. Alarm volume: Press  or  to select the level, alarm volume: Level 1 < Level 8
- 3.3.5.8. Language: Press  or  to select Chinese or English and press OK to proceed.
- 3.3.5.9. Pumpback Setting: enter volume 0.1-0.5 ml using the numeric keypad and press OK to proceed.
- 3.3.5.10. Pressure Error Level: Press  or  to select the level: 1-8 (the lower the level, the more sensitive).
- 3.3.5.11. Device Calibrationg: Press  or  to select the parameter to be calibrated and press OK to proceed.
- 3.3.5.12. Restore Factory Setting: Set the brand data, drug library data, and History Records into factory setting and press OK to proceed.
- 3.3.5.13. Software upgrade: Press  or  to select a software upgrade, press OK to continue, and select KEY or MAIN to proceed

 Note!

- **Reverse Volume is the motor reverse pressure release volume in the syringe.**
- **The History Records is 10,000 logs. A cleared log cannot be checked after it is cleared; please pay attention to this step.**
- **Get the password from the manufacturer or supplier.**

3.4 Other operations

3.4.1 Pause

- 3.4.1.1. During injection, press Start/Stop to pause (the injection icon will stop in the LCD and injection indicator will also stop flashing)
- 3.4.1.2. Press Start/Stop to restart the injection.

3.4.2 Mute

Press the Mute button to stop an active alarm; the mute button will be on for about 2 minutes.

 Note!

- **Mute is only to stop the alarm; the alarm is not cleared.**

3.4.3 Prime

In standby mode, long press Bolus button to prime with the set flow rate and display the prime total volume.

3.4.4 Change parameter without stopping injection

During the injection, change the flow rate and VTBI without stopping the injection. Press Change Parameter in injection mode and press VTBI to change and press Flow Rate to change and press OK to proceed.

3.4.5 Bolus Setting

After starting injection, press Bolus to enter Bolus parameter set, press VTBI, press Rate, and then press Start to confirm Bolus starting.

Bolus volume: 0.10 ml-5.00 ml

Bolus rate: 5 ml: 0.10~60.00 ml/h

10 ml: 0.10~300.00 ml/h

20 ml: 0.10~400.00 ml/h

30 ml: 0.10~600.00 ml/h

50 (60) ml: 0.10~1200.00 ml/h

Accuracy of bolus $\pm 2\%$

 Note!:

- **A beep will sound after bolus is finished and the previous injection will continue.**

3.4.6 Battery supply

- 3.4.6.1. The device will work under battery power in the following case:

- when AC power is not connected
- when AC Power is disengaged.

3.4.6.2. Under battery power

- When AC power is disengaged, the device will work normally under battery power (AC power indicator will be off, battery indicator will be on, and alarm light will keep flashing, low level alarm will be on).
- The device work under battery power. The battery capacity will be decreasing from full to be 1 until 0 capacity.
- When the battery is low, it will alarm "Battery Low" and  keep flashing with acoustic and visual alarm. The device will keep working for about 30 minutes to remind the operator to connect the AC power.
- When the battery is empty, it will stop the injection until it is totally empty and power off automatically 3 minutes after the Battery Empty alarm.



Note!

- When the battery is fully charged and the injection rate is 5 ml/h, the power time is not less than 9 hrs.

Chapter 4. Alarm and solution

4.1 Alarm

The alarm will be given when there is an anomaly in the injection circuit or device error that will lead to injection failure. The device alarm will alert the hospital staff to take action acoustically and visually and with a message. The standard is following:

- The volume can be heard; the lowest volume 45 db within 1m.
- The default mute time is around 2 minutes.
- The device should keep working during the 2 minute mute time.
- Stop working when there is error.

4.2 Alarm level and type

4.2.1 Alarm level

There are two alarm levels: high and low. See the details below.

Level	High	Occlusion, Battery Exhausted, Completed, Syringe Fall-Off, Battery Lost, Completed Infusion Error, Parameter Error, Start Failed, Syringe Fault, Communication Error, Infusion Fault
	Low	Near Complete, No Operation, Low Battery, Near Empty, Completed! KVO, Net Power Fall

4.2.2 Alarm methods

The device will emit visual, audio and message alarms when it is necessary to alert the operator to a situation requiring action. Distinguish the alarm in different way as following standard:

Table 1:

Level	Alarm light	Alarm light flashing frequency	Percentage	Period	Volume (dB)
High	Red	2.0±0.6Hz	20%-60% on	2-15 seconds	Not less than 45 dB in 1 meter distance
Low	Yellow	Always on	100% on	>15 seconds	Not less than 45 dB in 1 meter distance

Table 2:

Level	Volume	Light color			Nurse call	Operator confirm
		Red light	Yellow light	Message		
High	Yes	Flashing	Occlusion, etc.	Air, etc.	No	Press Mute button, and Enter to confirm
Low	Yes	Off	Flashing	No operation, etc.	No	Press Mute button, and Enter to confirm

4.2.3 Alarm responses

When there is alarm, check the patient first.

When there is alarm, take the following actions:

1. Check the patient.
2. Confirm the alarm type.
3. Find the reason for the alarm.
4. Find a way to clear the alarm.
5. Confirm clearing the alarm.

4.2.4 Alarm and Solution

Alarm message	Cause	Solution
Completed	Infused volume equal to VTBI	Remove the device once completed. Reset VTBI to continue the injection.
Nearly empty	Remaining volume is less than 10% of the VTBI.	Press any button to clear the alarm.
Nearly Completed	Less than 30-900 seconds to finish.	Press any button to clear the alarm.
Completed	VTBI more than real volume, all fluid is gone from the syringe.	Remove the device once finished. Reset VTBI to continue the injection.
Occlusion	The occlusion reaches the maximum occlusion value.	Remove the occlusion and press Clear to remove the alarm and press Start to proceed.
Syringe Fall-Off	a. Syringe is not installed well; the plunger head cannot detect the syringe. b. Syringe is not installed or not in the right position. c. Fixed button disengaged in the syringe during injection.	a. Syringe handle not fixed on the plunger head. b. The distance between the syringe handle and the plunger head is too great. c. The button on the plunger head is not pressed well by the syringe handle. d. The fixed button may not be in good condition.
No operation	No operation more than 2 minutes.	a. Press Clear button to remove the alarm. b. Press Start/Stop to proceed after parameter set. c. Power off if no injection.
Parameter error	Parameter is out of range or syringe is not installed	Set the parameter correctly or install the syringe correctly.
Syringe Fault	The syringe size is incorrect.	Install the correct size syringe.
Low Battery	Battery level is near empty.	Connect to AC power.
Battery Lost	Battery is unconnected or damaged.	Connect or replace the battery.
Battery Exhausted	Battery is about to lose power.	Connect to AC power or power off.
Net Power Fall	AC power is disconnected	1. Reconnect to AC power. 2. Press Clear to remove the alarm and work on battery power.
Infusion Fault	Motor error	Contact the manufacturer or distributor for maintenance.
Communication error	Mother board error	Contact the manufacturer or distributor for maintenance.



Note!

- The maximum injection volume is not more than 0.7 ml in a single failure.
- The maximum hydraulic pressure cannot be more than 140 kPa in a single failure.
- Injection will stop when there is an alarm (except for battery low or AC power disengaged) to remind the operator to take action to avoid harm to the patient. from overcurrent.
- Check the patient first after the alarm to avoid any harm.

4.3 Other errors

Check the device as following before contact the supplier.

Problem	Possible cause	Solution
Cannot switch on the device.	Battery installed correctly?	Install the battery correctly.
	Is AC power connected correctly?	Connect the AC power correctly.
Deviation too big	Is the selected syringe the same as the one in use?	a. Select the same syringe as the one in the settings.
	Is the syringe installed correctly?	b. Calibrate the syringe correctly.

4.4 Occlusion pressure

a. Occlusion pressure threshold, occlusion alarm real value and postponed alarm time reference chart:

Level	Occlusion pressure threshold	Real detection pressure value (kPa)					Postponed alarm time (sec)				
		5 ml	10 ml	20ml	30 ml	50 ml	5 ml	10 ml	20 ml	30 ml	50 ml
L1	20 kPa	25 kPa	28 kPa	30 kPa	31 kPa	34 kPa	70 s	151 s	246 s	300 s	456 s
L2	30 kPa	35 kPa	34 kPa	40 kPa	45 kPa	47 kPa	140 s	300 s	401 s	452 s	600 s
L3	40 kPa	55 kPa	48 kPa	58 kPa	60 kPa	57 kPa	260 s	464 s	555 s	603 s	750 s
L4	60 kPa	66 kPa	78 kPa	69 kPa	72 kPa	80 kPa	411 s	620 s	704 s	760 s	902 s
L5	80 kPa	70 kPa	75 kPa	81 kPa	84 kPa	90 kPa	588 s	777 s	859 s	937 s	1050 s
L6	100 kPa	90 kPa	88 kPa	100 kPa	92 kPa	101 kPa	690 s	920 s	911 s	1088 s	1230 s
L7	120 kPa	100 kPa	110 kPa	112 kPa	115 kPa	109 kPa	800 s	1070 s	1066 s	1233 s	1435 s
L8	140 kPa	120 kPa	123 kPa	119 kPa	134 kPa	131 kPa	910 s	1190 s	1203 s	1367 s	1655 s

b. The longest time between the alarm pressure value from the occlusion threshold at the minimum and maximum rate and trigger alarm time during device operation (for reference):

Syringe	Alarm threshold	Alarm pressure value (kPa)	Trigger alarm time (min)
5 ml	L1 (20 kPa)	35 kPa	30:21 m
	L8 (140 kPa)	135 kPa	50:12 m
10 ml	L1 (20 kPa)	37 kPa	38:23 m
	L8 (140 kPa)	125 kPa	68:12 m
20 ml	L1 (20 kPa)	40 kPa	45:40 m
	L8 (140 kPa)	133 kPa	85:12 m
30 ml	L1 (20 kPa)	35 kPa	48:31 m
	L8 (140 kPa)	129 kPa	97:12 m
50 ml	L1 (20 kPa)	41 kPa	55:28 m
	L8 (140 kPa)	131 kPa	115:12 m

c. The bolus volume from the alarm threshold at the middle rate and minimum rate during device operation, reference chart:

Syringe size	Alarm threshold (kPa)	Bolus (g)
5 ml	L1 (20 kPa)	0.08 g
	L8 (140 kPa)	0.20 g
10 ml	L1 (20 kPa)	0.10 g
	L8 (140 kPa)	0.22 g
20 ml	L1 (120 kPa)	0.13 g
	L8 (140 kPa)	0.26 g
30 ml	L1 (20 kPa)	0.14 g
	L8 (140 kPa)	0.30 g
50 ml	L1 (20 kPa)	0.15 g
	L8 (140 kPa)	0.40 g

! Note!

- The test syringe brand is Kangdelai.
- The occlusion alarm pressure value and the longest postpone time depend on the test condition.
- Occlusion pressure value deviation: ± 25 kPa
- The test rate is 25 ml/hr and minimum rate is 1 ml/h.

Chapter 5. Product daily check, storage, and transportation condition

For the product maintenance requirement, Covetrus can provide the board circuit, components, reference chart, calibration instructions or other technical instructions. Please use the materials and methods below to clean or sterilise the device. Covetrus will be not responsible for the damage or accidents caused by other materials and methods of cleaning or sterilising. The listed chemicals and methods are only for infection control. Covetrus will not bear any responsibility for their validity.

Please ask the hospital infection prevention department or local epidemiological expert about infection control methods.

5.1 Daily check

Ethylene oxide sterilisation or ultrasonic sterilisation can be used.

! Note!

- Do not clean the device with diluent, alcohol, etc.

5.1.1 Shell clean

Clean the shell with a soft cloth and warm water or diluted neutral detergent and wipe dry afterwards.

5.1.2 Daily check of the syringe fixed clip, plunger head, and barrel clasp

Clean the syringe fixed clip, plunger head, and the barrel clasp with soft damp cloth and dry.

5.1.3 LCD and keypad daily check

Clean the LCD and keypad with soft damp cloth and dry.

! Note!

- Do not let the fluid flow onto the keypad.

5.1.4. Daily check for syringe guides and guide port

Clean the syringe guides and guide port with soft wet cloth and dry.

! Note!

- Power off and disconnect the AC socket and power cord before cleaning.
- Use the recommended dilute detergent and disinfectant or use as low a concentration as possible.

- Do not soak the device in liquids or pour liquids on the device or components or allow fluids to enter the device.
- Do not use abrasive materials (such as steel balls or silver polish) and solvents similar to xylene or acetone, to avoid damage to the shell.
- Optional detergents and disinfectants: warm water, diluted soapy water, diluted ammonia, sodium hypochlorite (bleaching powder for washing), hydrogen peroxide (3%), ethanol (70%), isopropanol (70%), etc.
- Stop the device and contact the manufacturer or distributor if water has entered the device or its components, which may lead to operating failure.

5.2 Battery

The internal rechargeable battery ensures that the device continues working normally during transport or without an external power supply. It will charge automatically when connected to AC power. It will work under battery power when there is no AC power. Please take out the battery if it is not used for long period; the battery can discharge automatically, the life of the battery will decrease if not charge it every three months especially in high temperature.

5.2.1 Charge battery

1. Connect to AC power to charge when there is a battery low alarm.
2. Charge the battery before first-time use or it has been in storage for long period.
 - a. Before powering off the device, the indicator  will be on and LCD will show the charging icon and the indicator on the keypad will be flashing after connecting to AC power.
 - b. Press Power button for about 2 seconds to switch the device,  will be on the keypad,  flashing,  moving on the LCD.
 - c. Press the Power button for about 2 seconds to switch off the device. It will keep charging and  will be turn off when fully charged (about 16 hours).



Note!

- If the device is in storage for a long period, charge the battery every 3 months to avoid damage.
- It takes 16 hours to fully charged the battery from empty.
- The battery is only for backup use; connect to AC power during injection.

5.2.2 Battery performance inspection

Disconnected from AC power, the battery can run for about 10 hours at 5 ml/h. The performance of the battery will degrade over time; please check the performance regularly. Check the battery as follows:

- a. Connect the device to AC power and charge it for 16 hours.
- b. Disconnect the AC power, run the injection at 5 ml/h until the battery runs down and the device powers off automatically.
 - If it can work for more than 120 minutes, it means battery is in good condition.
 - If it can work for 60-120 minutes, it means the battery is near the end of its lifetime.
 - If it works for less than 60 minutes, it means the battery is at the end of its lifetime.
- c. Please recharge the battery for the next use after checking it.



Note!

- If the battery has obvious damage (swollen bag, deformation, leakage) or cannot hold power, it should be replaced and properly recycled.

5.2.3 Replacing the battery

Battery life depends on the frequency of use frequency and the operating environment. The lifetime is around 2 years if it is used properly. It is advisable to replace the battery every two years. If the battery has obvious damage (bulk bag, deformation, leakage) or the battery cannot store power, it should be replaced in time and properly recycled. Please follow local regulations concerning battery disposal.

To replace the battery, take off the battery cover, and pull out the connector, remove and replace the battery, then reconnect it well.

- a. Loosen the battery cover screw on the back of the device and remove the port to get to the battery.
- b. Insert the new battery, connect to power, and replace the battery cover well. Tighten the screw well.



Note!

- Do not disassemble, incinerate or short-circuit the battery. Battery burning, explosion, or leakage will cause injury.
- The battery should not be disposed of as domestic waste.
- The battery is consumable; please replace it when it no longer can hold a current.
- Use only an original battery from the manufacturer or distributor.
- The device can only accept the specified battery from the manufacturer. There is a risk of damage or fire from using unspecified batteries.
- Please replace the battery if is damaged or leaking.
- Do not use a damaged battery in the device.

5.3 Regular maintenance

5.3.1 Check for deviations of the device

Please calibrate the syringe every 3 months or when changing the brand.

5.3.2 Routine maintenance

Interval period	Step
Follow hospital cleaning rules	Clean the surface completely after or before long-term storage.
Check at least once yearly	1. Test the AC power socket and cable. 2. Run the device until the battery low alarm sounds and charge the battery to confirm it is working normally. 3. Check whether the device can recognize the syringe size.

5.4 Replace the components routinely

The device has exclusive components. The battery can be replaced regularly, depending on the actual use conditions. The battery is consumable and replacement every two years is recommended.

5.5 Transportation and storage

Store the device in the following conditions after cleaning:

Temperature: -20°C-55°C, relative humidity: 10%~93%, atmospheric pressure: 70kPa~106 kPa.

Do not store the device where it will be exposed to:

- a. Direct sunlight or strong light
- b. Hot or humid air coming from heating, boilers, or humidifiers
- c. Chemicals, dust, and humidity
- d. Water, vibration, or uneven surfaces

Do not stack the devices more than 5-high.

5.6 Compliance



Please read the operating manual prior to using this device!



Protection against electric shock: Class I with protective ground conductor.



Protection against leakage current: Type CF equipment.

IPX4 Protection against splashing fluid.

Chapter 6. Appendix

6.1 Electromagnetic compatibility



Note!

- The device meets Electromagnetic Compatibility Standard YY0505-2012.
- Please install and operate the device based on the electromagnetic compatibility information in the device packaging.
- Portable and mobile RF communication equipment may affect the performance of the syringe pump. Avoid using the device near strong electromagnetic interference from mobile phones, microwave ovens, etc.
- Please read the instructions and the manufacturer's statement in the attachment.



Note!

- The device or system should not be used close to or stacked with other devices. If it must be used close to or stacked with other devices, monitor that it is working normally under the configuration.
- Class A equipment is intended for use in industrial environments. Due to conducted disturbances and radiated disturbances by the syringe pump, it may be potentially difficult to ensure electromagnetic compatibility in other environments.
- In addition to the transducers and cables sold by the manufacturer of the device or system as spare parts for internal components, the use of additional accessories, transducers, and cables may result in increased emissions or immunity to the device or system.
- Use of accessories, transducers, or cables outside of the regulations with equipment and systems may result in increased emissions or immunity to emissions from equipment or systems.



Note!

- Use of accessories, transducers, or cables outside of the regulations with equipment and systems may result in increased emissions or immunity to emissions from equipment or systems.
- The device or system should not be used close to or stacked with other devices. If it must be used close to or stacked with other devices, monitor that it is working normally under the configuration.
- Special EMC protection for syringe pumps is required and installation and maintenance are required in an environment as described in the following EMC information.
- Avoid using the syringe pump with MRI or similar equipment, to prevent malfunction or failure due to electromagnetic interference.
- Even if other equipment meets the CISPR emission requirements, it may still interfere with the syringe pump.
- When the input data is lower than the minimum specified in the technical specifications, the measurement may be inaccurate.
- Portable and mobile RF communication equipment may affect the performance of the syringe pump.

SN	ITEM	Length (m)	Hide or not	Note
1	Power cord	3.0	no	/

6.2 Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [A]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

6.3 Guidance and manufacturer's declaration - electromagnetic Immunity I

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not Applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0% UT; 250/300 cycle	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0% UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
NOTE UT is the AC mains voltage prior to application of the test level.		

6.4 Guidance and manufacturer's declaration - electromagnetic Immunity II

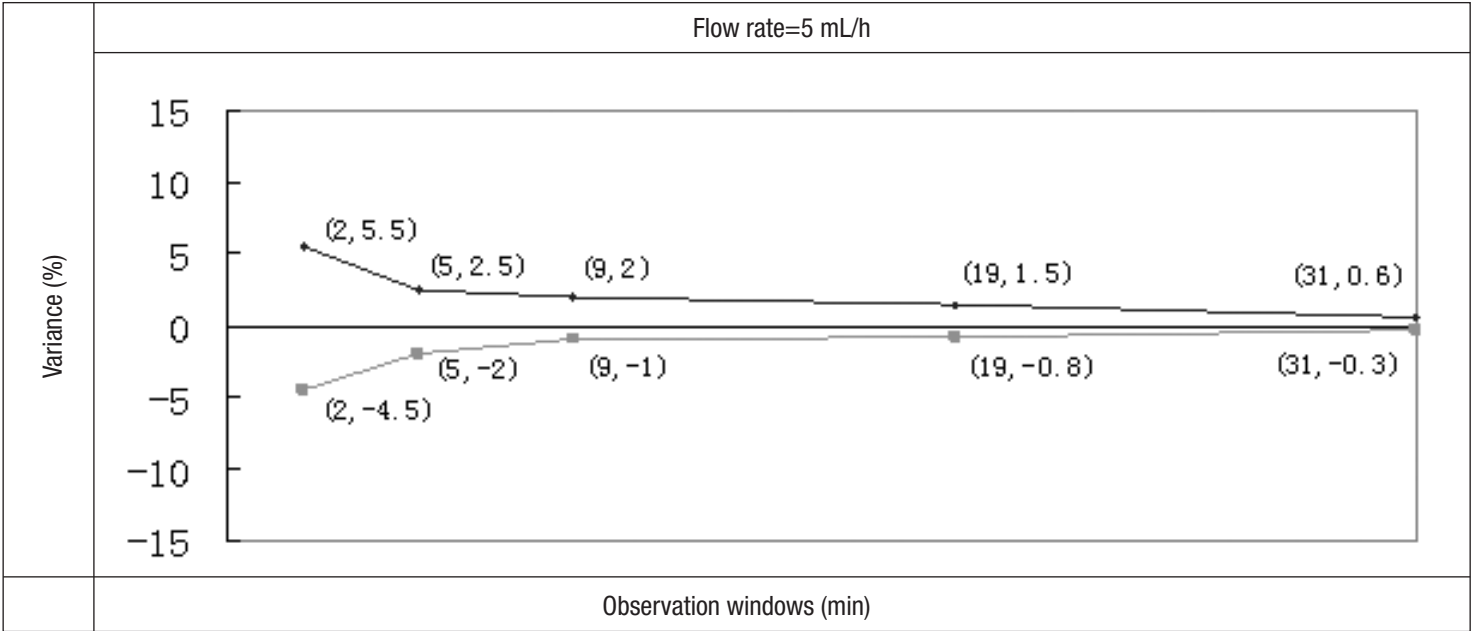
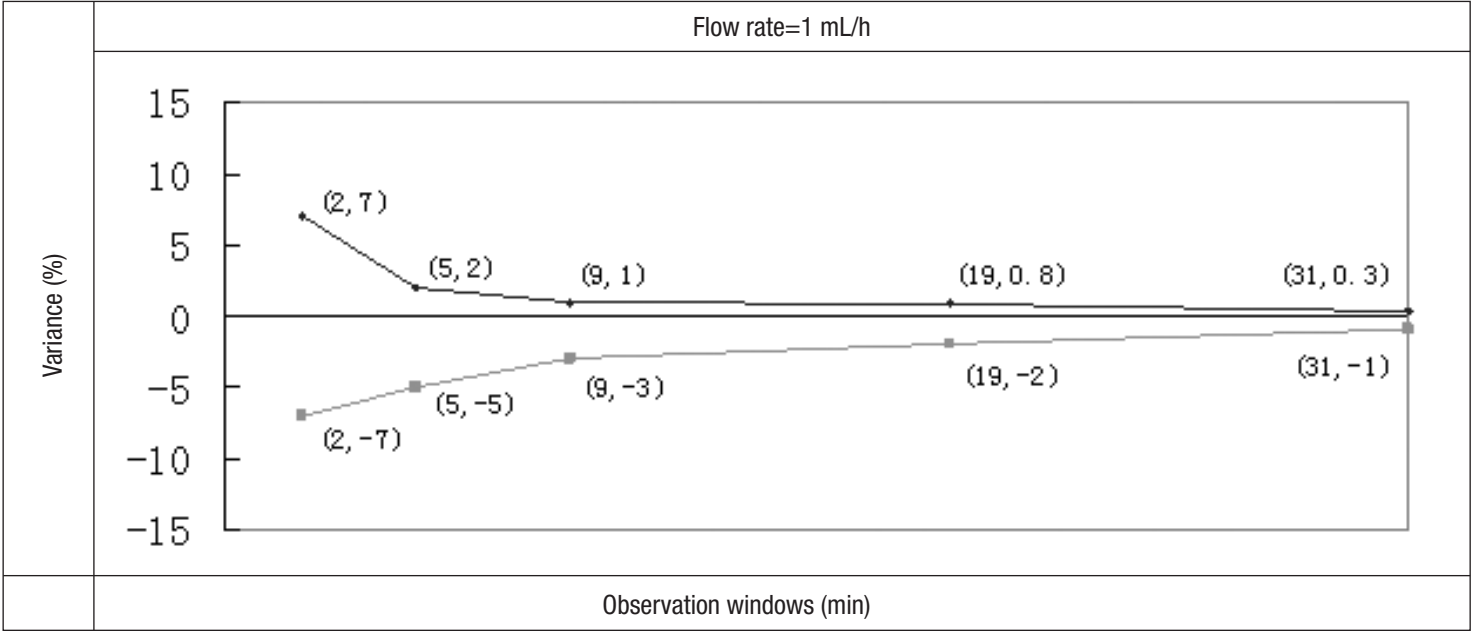
Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	Immunity test level (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
	450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						

6.5 Trumpet curve

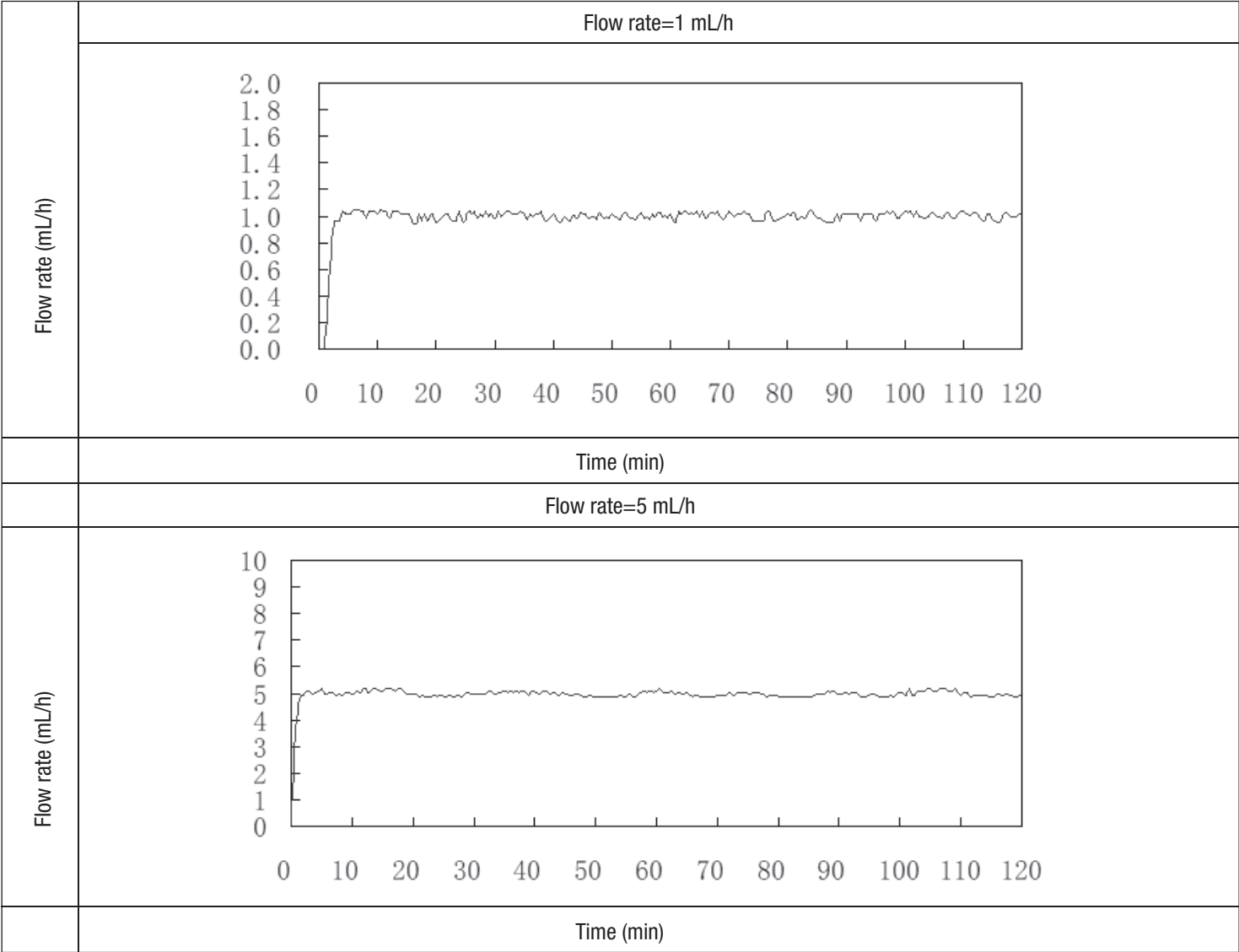
Trumpet curve

Trumpet curve indicates the trend of the max and min deviations of the syringe and pump. The detection proposals introduced for obtaining results in this aspect are based on EN60601-2-24. For more detailed information, please refer to this publication.
The following curve represents the results after using a Yusheng syringe in the test. It is considered as only one basis of the overall performance of the syringe pump. For more related information, contact the supplier.

(1) Trumpet curve



(2) Start-up and real-time curve (start-up curve)



6.6 Symbol and terms

Unit reference sheet

Abbreviation	English
Min	Minute
H	Hour
Hz	Hertz
Mg	Milligrams
G	Gram
Kg	Kilogram
kPa	Kilopascal
ml	Milliliter

Unit reference sheet

Abbreviation	English
MRI	Magnetic resonance imaging
AC	Alternating current
DC	Direct current
EMC	Electromagnetic compatibility
KVO	Keep vein open
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
LED	Light emitting diode
CPU	Central processing unit
RAM	Random access memory
ROM	Read-only memory
ETO	C2H4O
BOLUS	Bolus

