CE 0123

# SYRINGE PUMP

# HX-901A

# OPERATOR MANUAL


**Guangzhou Huaxi Medical Science Technology Co., Ltd.**

**Please read this manual completely prior to using this device!**

**Version: V3.2**

# Table of contents

# Chapter 1 Introduction

Product Name: Syringe Pump

Model: HX-901A

Thank you for choosing the HX-901A Syringe pump produced by Huaxi. Please read this operator manual completely prior to using this device. Please carry out inspection and maintenance to the pump periodically according to the manual in order to avoid patient/user injury.

## 1.1 Application

HX-901A syringe pump is for micro and continuous infusion, specially used for intravenous infusion of drugs.

## 1.2 Precautions

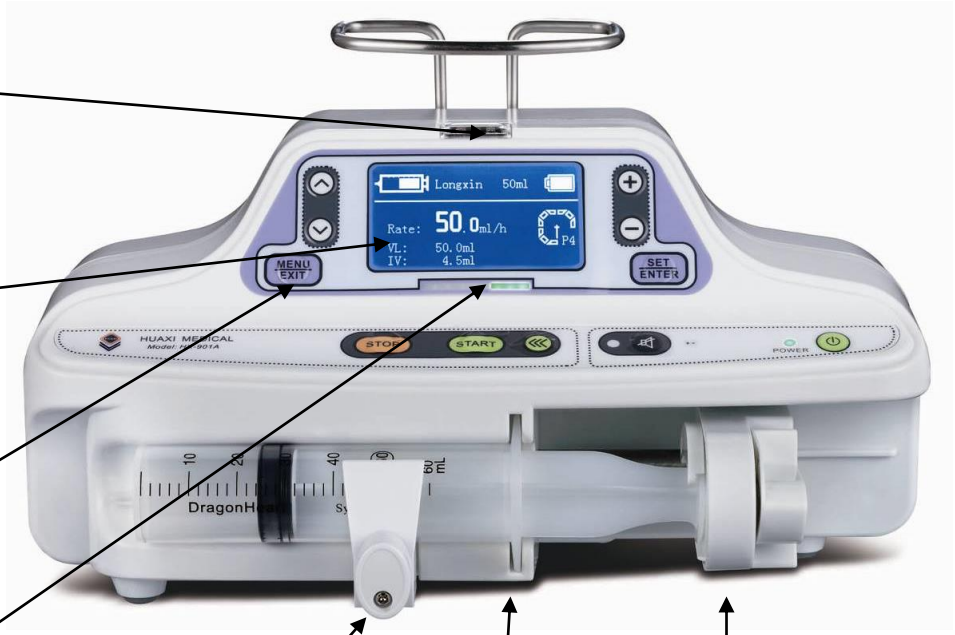
1. HX-901A must be operated by medical professional staff, such as doctors, nurses, etc.
2. HX-901A is not explosion-proof or portable device.
3. Do not operate this device in environments where there are gas mixtures of flammable anesthetic, oxygen and oxidize ammonia, etc.
4. To avoid patients being injured by over-flow or under-flow, please set infusion parameters correctly and calibrate before using a new IV set.
5. If anything abnormal is found, stop using this device at once.
6. To avoid malfunctions, maintain the recommended protective distances for the devices that cause strong electromagnetic wave or noise, such as nuclear magnetic resonance device, microwave generating device and radiological device (X-ray machine or CT machine).
7. To avoid malfunctions, keep this device at least 25 meters away from high-frequency surgical instruments, such as knife holder, knife cable, electrode feeder board, and keep this device at least 1 meter away from mobile phone.

8. It is not allowed to use voltage other than that specified on the product label, or else it might cause damage or even fire.
9. The battery should not be heated or throw into fire, otherwise it might cause leakage, fire or even explosion.
10. Do not tear off the battery sheath, otherwise it might cause explosion or chemical burns.
11. Hold the plug tightly when plugging in or unplugging the AC electric wire. Don't touch the plug with wet hands.
12. It's better not to share a socket with other devices.
13. It's not allowed to dismount or modify the device without permission.
14. The device should be checked daily, and all functions should be checked prior to use if the device has not been used for a long time.
15. If any abnormality or absence of any function, please stop using the device and contact the supplier as soon as possible. Otherwise the manufacturer/seller will assume no responsibility for the loss, damage or injury.
16. Do not shake or crash the device. Keep away from direct sunlight or strong light.
17. Do not exposure to hot or wet air coming from heating installation, furnace and humidifier.
18. Do not operate this device in environments where there are chemical materials, dust, and humidity.
19. Do not reuse or re-sterilize disposable syringe.
20. Operate, transport, and store the device in the conditions stipulated in this manual.
21. Monitoring of the patient and infusion status is necessary to ensure the infusion is being delivered as anticipated.

# 1.3 Main components

HX-901A is made of housing, motor, display, and battery, etc.

# 1.4 Exterior features




**Alarm light:** Lights up during an alarm.

**Display:** All essential information is displayed.

**Keyboard:** Allow data entry.

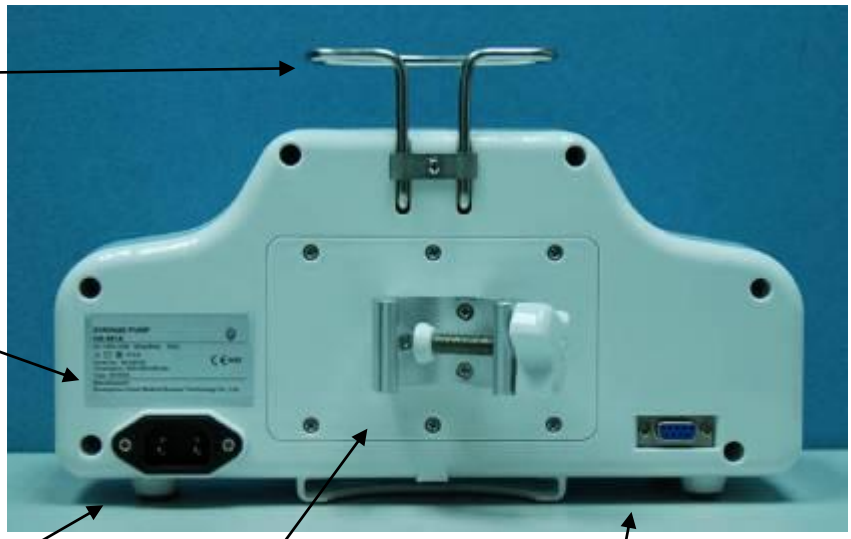
**Infusing light:** Indicates pump is infusing.

**Syringe barrel clasp**

**Syringe flanges cradle:**
For placing the flanges of syringe.

**Syringe plunger head:**
To fix the head of syringe drive.

**Handle for Carry as well as Stack-mounted**



**Label:** To show the product information.

**Power cord socket**

**Knob:** To attach the pump to an IV pole.

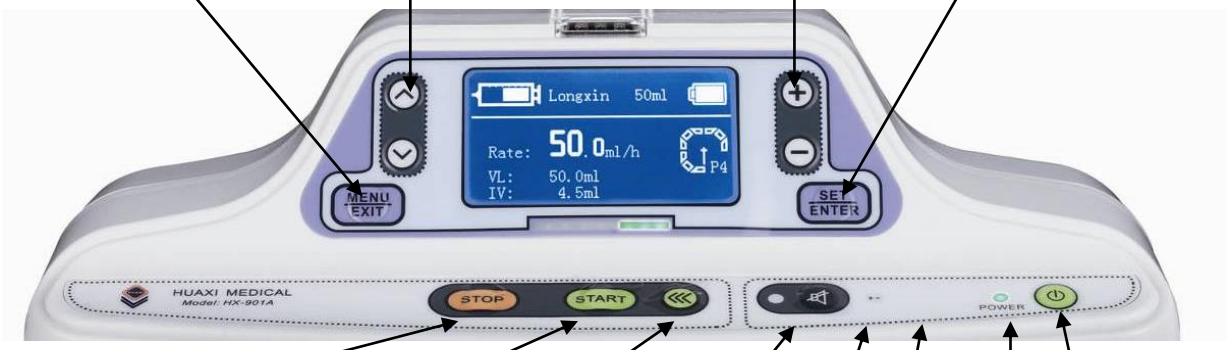
**RS-232 communication port:** To connect the pump to computer.
(Remark: This function will be applicable in the future)

**Switch keys:** To shift the cursor.

**Plus/Minus keys:** To plus or minus the number.

**Menu/Exit keys:** To enter the menu or return to the previous menu.

**Set/Confirm keys:** To activate and confirm the parameter.




**Stop key**

**Start key**

**Bolus key**

**Alarm silence key:**
Silence alarm for 2 minutes

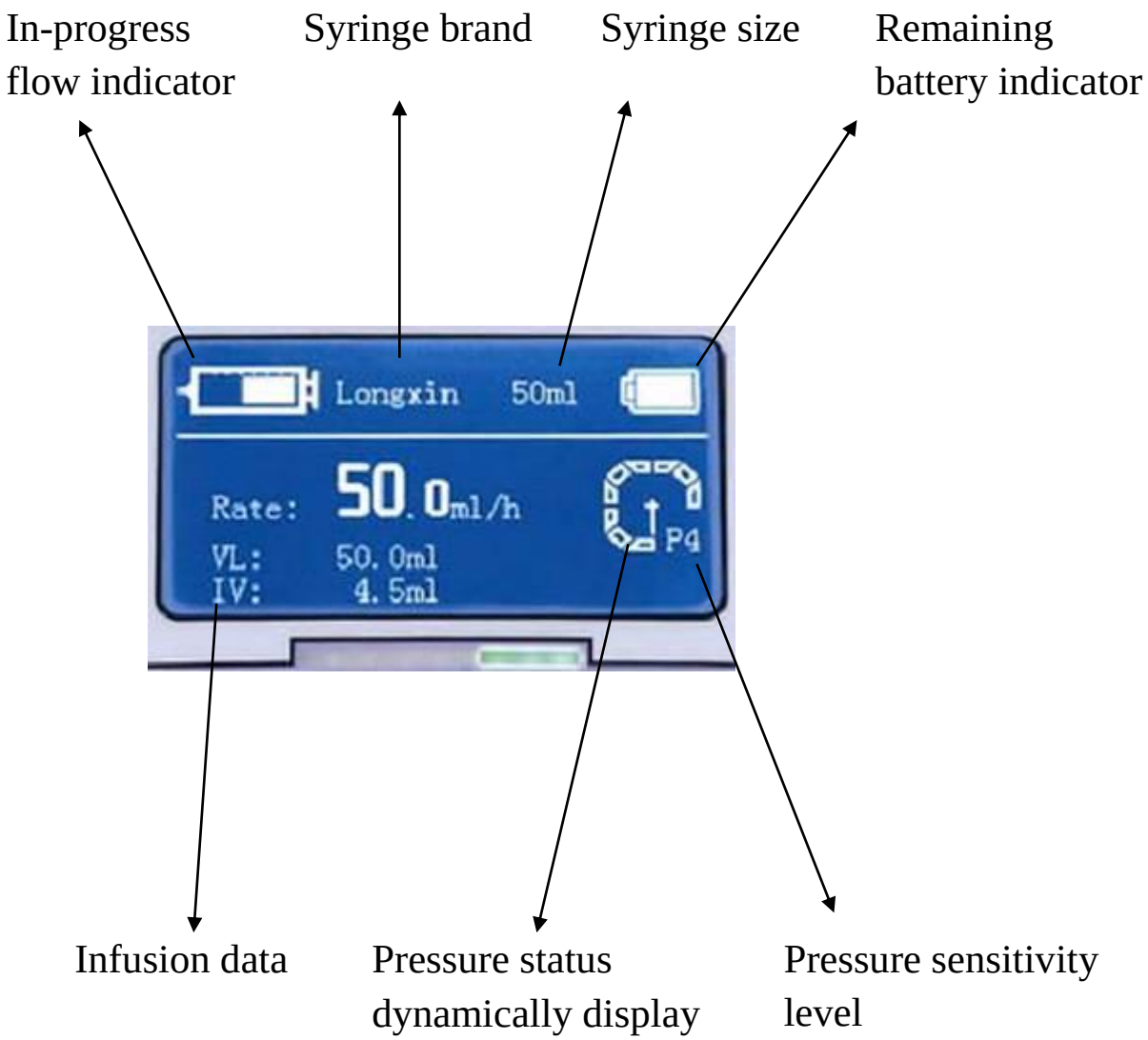
**Battery indicator light**

**AC Indicator Light**

**Power indicator light**

**Power key**

# 1.5 Information during infusion



# Chapter 2 Operation Guidance

## 2.1 Operation flowchart

| |
|---|
| Syringe Pump Installation |
| ↓ |
| Syringe Installation |
| ↓ |
| Programmation |
| ↓ |
| Priming |
| ↓ |
| Connect Infusion Set To Patients |
| ↓ |
| Starting The Infusion |

## 2.2 Syringe pump installation

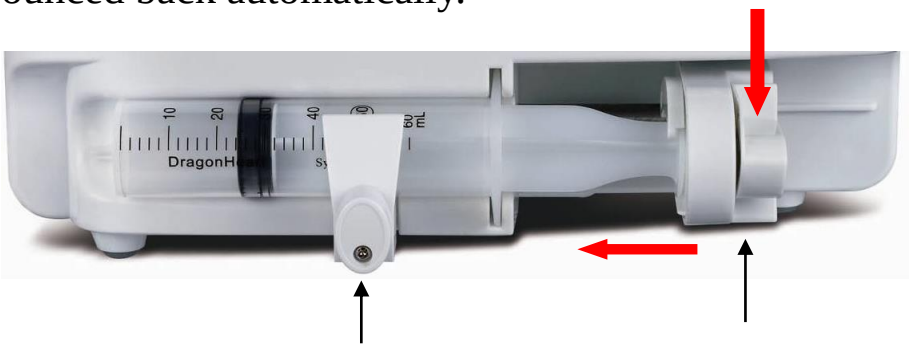
1. Attach the pump to an IV stand by turning the knob on the back of the pump clockwise. Particular attention should be paid to the stability of the device before it is put into use.
2. Plug the pump's power cord into an electrical outlet.
3. Press  to turn on the machine, listen for the beep, the AC indicator lights up  .

Note:

1. The device has a continuous inspection which functions as soon as the pump is in use.
2. Connect the device to AC power as often as possible to recharge battery.

# 2.3 Syringe installation

1. Connect the infusion set to the syringe according to proper practices.
2. Pull out the barrel clasp and turn horizontally for holding it. Place syringe in its cradle, the flanges correctly in the provided slot.
3. Turn the syringe barrel clasp into the closed position.
4. Press down and release the button of the plunger head on the right side and move it forward the end of syringe by engaging the small button on the left side of the plunger head, then the button on the right side will be bounced back automatically.



Syringe barrel clasp  Syringe plunger head

# 2.4 Infusion parameter setting

## 2.4.1 Syringe brand setting

### 1) Select syringe brand preset in the pump

1. Press MENU EXIT , system will enter into main menu.
2. The cursor positions on “Brand”, press SET CONFIRM .
3. Press SET CONFIRM ▲ ▼ SET CONFIRM to select the desired brand.
4. Then the cursor positions on “Enter”, press SET CONFIRM .
5. Return to main screen by pressing MENU EXIT .

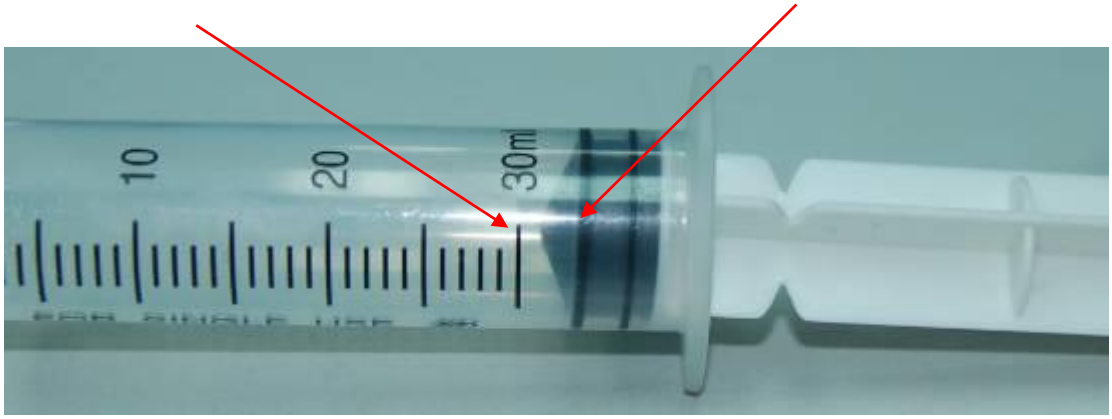
## 2) Self-define syringe brand (Calibration)

When the syringe brand is not preset in the pump, operator should calibrate for this new brand before it is put into use.

### Method 1 Auto calibration

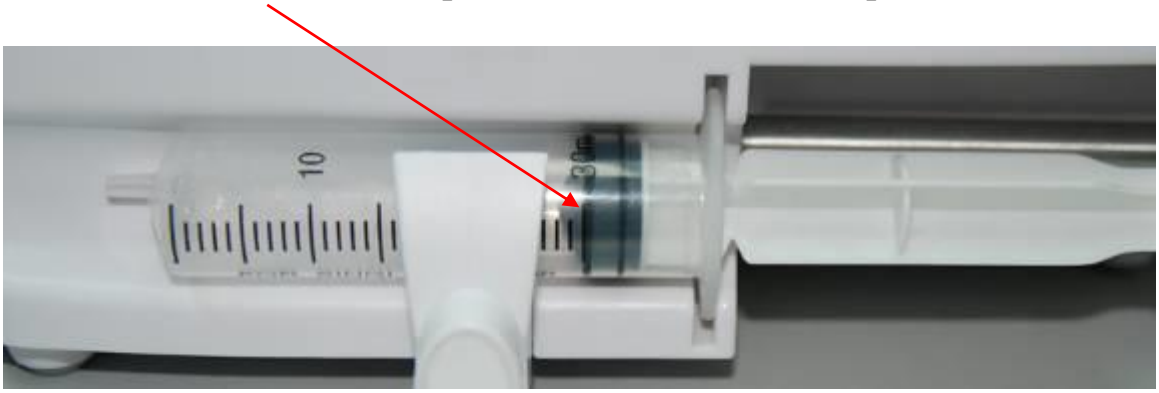
1. Pull the push rod until the head of push rod is out of the maximum scale (more than 5mm), then install the syringe.

Maximum scale Head of push rod




2. Press  to prime until the head of push rod **reaches** the maximum scale.

Maximum scale and head of push rod are at the same position.




3. Press 

, system will enter into main menu.
4. The cursor positions on “Brand”, press 

to position the cursor on “Set User Brand”.
5. Press 

, system will enter into the “User Brand Setting” screen,

the cursor positions on “Size”.

6. Press  to enter into the “AutoCorrect User Brand Length” screen.
7. The cursor positions on “Start”, press  to start AutoCorrect process.
8. After the AutoCorrect process finished, press  to confirm the length of scale.
9. Double check the syringe size and length of scales, press  .
10. Return to main screen by pressing  .

Note:

The pump can store one brand for 10 mL, 20 mL, 30 mL and 50/60 mL syringe, please define these four size syringes at the same time if possible. If new brand of syringe will be used, please define for it again and the memory of the device will be changed accordingly.

## Method 2 Calibration by manual

1. Press  , system will enter into main menu.
2. The cursor positions on “Brand”, press  to position the cursor on “Set User Brand”.
3. Press  , system will enter into the “User Brand Setting” screen, the cursor positions on “Size”.
4. Press  to select the syringe size.
5. Press  to input the length of the syringe scale.
6. Then the cursor positions on “Enter”, press  , self-define is finished.
7. Return to main screen by pressing  .

Note:

1. The length of the scale of syringe means: the length between the scale of 0 mL to the maximum scale, which can be obtained from syringe

manufacturer.

2. The pump can store one brand for 10 mL, 20 mL, 30 mL and 50/60 mL syringe, please define these four size syringes at the same time if possible. If new brand of syringe will be used, please define for it again and the memory of the device will be changed accordingly.

## 2.4.2 Infusion rate setting

Method 1:

1. Press 

, system will enter into main menu.
2. Press  to position the cursor on “Rate”.
3. Press 

, system will enter into the “Rate Setting” screen, the cursor positions on the digit.
4. Press 

to select the desired rate. (Keep pressing  to speed up change for the digit)
5. Return to main screen by pressing 

.

Method 2:

1. On the main screen, press 

, the cursor positions on “Rate”.
2. Press 

to select the desired rate.

## 2.4.3 Infusion volume setting

Method 1:

1. Press 

, system will enter into main menu.
2. Press  to position the cursor on “Volume Limit”.
3. Press 

, system will enter into the “Volume Limit” screen, the cursor positions on the digit.
4. Press 

to select the desired volume. (Keep pressing  to speed up change for the digit)
5. Return to main screen by pressing 

.

Method 2:

1. On the main screen, press    to position the cursor on “VL”.
2. Press       to select the desired volume.

**Note**:

1. Volume limit (show as “VL” on the screen) must be larger than the total infused volume (show as “IV” on the screen).
2. If user wants to infuse all the solution in the syringe, keep pressing  until the “VL” goes to “Empty”.

## 2.4.4 Total infused volume

Total infused volume is accumulated from starting up the device until it is turned off.

How to clear the total infused volume:

1. Press  , system will enter into main menu.
2. Press   to position the cursor on “Infused Volume”.
3. Press  , system will enter into the “Infused Volume” screen, the pump asks: CLEAR?
4. Press  , the pump asks: OK?
5. Press  .
6. Return to main screen by pressing  .

## 2.4.5 Bolus

Method 1:

Press  , the pump will infuse at a fix rate according to different size syringe, details as below.

10mL syringe: 300mL/h

20mL syringe: 400mL/h

30mL syringe: 600mL/h

50/60mL syringe: 600mL/h

The volume will be accumulated on the existing infused volume.

Method 2:

1. Press MENU EXIT , system will enter into main menu.
2. Press ▲ ▼ to position the cursor on “Bolus”.
3. Press SET CONFIRM , system will enter into the Bolus screen, the cursor positions on “Bolus Rate”.
4. Press SET CONFIRM ⊕ ⊖ ▲ ▼ SET CONFIRM to select the desired rate.
5. Press SET CONFIRM ⊕ ⊖ ▲ ▼ SET CONFIRM to select the desired volume.
6. Press START to start infusion.

When the bolus volume finished, the pump will alarm for finish and is still running at KVO rate.

## 2.4.6 Drug mode

1. Press MENU EXIT , system will enter into main menu.
2. Press ▲ ▼ to position the cursor on “Drug Mode”.
3. Press SET CONFIRM , system will enter into the “Drug Mode” screen, the cursor positions on infusion unit. There are 6 selectable infusion units: μg/h, mg/h, μg/kg/min, mg/kg/min, μg/kg/h, and mg/kg/h.
4. Press ▲ ▼ SET CONFIRM to select the desired unit, then the cursor locates on “Dose”.
5. Press SET CONFIRM ⊕ ⊖ ▲ ▼ SET CONFIRM to select the desired dose rate, then the cursor locates on “Solu.Vol” (Solution volume).
6. Press SET CONFIRM ⊕ ⊖ ▲ ▼ SET CONFIRM to select the desired solution volume, then the cursor locates on “Drug Vol” (Drug volume).
7. Press SET CONFIRM ⊕ ⊖ ▲ ▼ SET CONFIRM to select the desired drug volume. If infusion unit is μg/h or mg/h, the pump asks user to confirm: ENTER. Please skip to step 9. If infusion unit is μg/kg/min, mg/kg/min, μg/kg/h or mg/kg/h, the cursor locates on “Weight”.

8. Press  to select the patient's weight. The pump asks user to confirm: ENTER.

Note: The pump will calculate the concentration (show as "Conc.") and flow rate automatically.

9. Press  .
10. Return to main screen by pressing  .
11. Set the volume limit according to the step 2.4.3.
12. Press  to start infusion.

### 2.4.7 Timing mode

1. Press  , system will enter into main menu.
2. Press  to position the cursor on "Timing Mode".
3. Press  , system will enter into the "Timing Mode" screen, the cursor positions on VL (Volume limit).
4. Press  to select the desired volume, then the cursor locates on "Time".
5. Press  to select the desired infusion time, then the cursor locates on "Enter".
6. Double check the parameters, and confirm them by pressing  ,
7. Return to main screen by pressing  .
8. Press  to start infusion.

## 2.5 Start the infusion

1. Connect infusion set to patient site and check general installation.
2. Check and make sure all the parameters showed on main screen are correct.
3. Press  to start infusion.

# 2.6 Stop infusion

1. At any time, the infusion can be stopped by pressing 

.
2. To resume the infusion, press 

.

# 2.7 Infusion finish

1. When the volume limit is set “Empty”, the device will alarm for finish and stop running once the syringe is empty.

   When the total infused volume reaches to the volume limit, the device will alarm for finish and infuse at KVO rate.
2. Press 

to stop infusion.
3. Disconnect infusion set from patient site.

# 2.8 Power off

Stop the infusion and keep pressing  until the device turns off.

# 2.9 Others

## 2.9.1 Pressure sensitivity setting

1. Press 

, system will enter into main menu.
2. Press  to position the cursor on “Pressure”.
3. Press 

, system will enter into the “Pressure Sensitivity” screen, and the cursor positions on pressure level.
4. Press  to select the desired pressure level.
5. Return to main screen by pressing 

.

## 2.9.2 Silence the sound when pressing keys

Press  to silence the sound when pressing keys for 2 minutes.

# 2.10 Alarms and errors

## 2.10.1 Alarms

When the alarm occurs, it is with visual and audible signal. The audible signal can be switched off for 2 minutes by pressing  . To clear the alarm, press  .

| Alarm | Possible Cause | Action |
|---|---|---|
| AC power lost | AC power disconnection during infusion. | Silence the alarm by pressing  and the device keeps infusing.<br>Connect AC power. |
| Barrel clasp | Syringe incorrectly positioned. | Check barrel clasp and position the syringe correctly. |
| Plunger head | Drive system not engaged. | Connect the syringe correctly to plunger head by engaging the small button on the left side. |
| Finish. KVO | Infusion finished and the device keeps infusing at KVO rate. | Stop infusion. |
| Near empty | End of infusion pre-alarm, 10% of total syringe capacity remaining. | Silence the alarm by pressing  and the device keeps infusing. |
| Empty | Total syringe empty. | Stop infusion. |
| Occlusion | Pressure threshold reached. | Correct kinks.<br>Check patient site.<br>Increase pressure sensitivity level. |
| No operat. | No operation for 2 minutes. | Set parameter.<br>Start infusion. |
| Low battery | Battery voltage low. | Connect pump to AC power. |
| Bat. ran out | Battery ran out. | Connect pump to AC power. |

| | | |
|---|---|---|
| Battery lost | Battery disconnected or damaged. | Check whether the battery is connected correctly or not.<br>If battery is damaged, change another one. |
| Motor plug | Problem in motor. | Stop to use and contact with after-sales service. |

### 2.10.2 Other errors

| Phenomena | Possible Cause | Action |
|---|---|---|
| The device can not be turned on. | Are AC power and battery properly connected? | Connect the AC power and battery properly. |

# Chapter 3 Maintenance

## 3.1 Daily maintenance

Disconnect the AC power cord before cleaning the device.

EOG sterilization; Ultrasonic sterilization.

Attention: Do not wash the device by diluents, alcohol and other organic liquid.

## 3.2 Cleaning the housing

Clean the pump with a soft lint-free cloth or swab dampened with detergent and water.

## 3.3 Battery operation

### 3.3.1 General guidance

1. When AC power disconnected, the pump will alarm and be powered by internal battery, user can press  to silence the alarm.
2. To recharge battery, just connect the device to AC power supply. Recharging of the battery is visualized by the indicator  when the pump is turned off and  when the pump is turned on.

3. The device will alarm when the battery is low, then stop infusion about 27 minutes later and turn off about 30 minutes later automatically.
4. Charge battery on initial use approximate 16 hours.

   After several times of charging and consuming process, the maximum battery capacity can be achieved.

   If the charging and consuming cyclic process keeps increasing and the battery is charged repeatedly without full discharge, the battery capacity will decrease concomitantly. If the device will not be put into used for long time, it is suggested that the internal battery is used every half year.

**Note:**

1. Deal with the wastes (batteries, electrical and electronic device) according to the local regulations, and try to make the wastes recovered. The wastes can not be handled as daily garbage.
2. The warranty for the battery is one year.

### 3.3.2 Replace battery

Battery replacement should be handled by qualified technicians.

1. Loosen screw of the battery cover from rear housing, and remove the cover, and the battery will be seen.
2. Loosen screw of the rear housing and the front housing, and dismantle the device.
3. Pull out the connector JN9 and take out the battery.
4. Put the new battery in, inert the connector JN9, install the front and rear housing, and tighten the screw; then cover the battery cover and finally tighten the screw.

**Note:**

1. Do not place the battery close to fire or heat source.
2. Use the specified battery provided by the manufacturer only.
3. The battery service life is two years; it is recommended to replace it earlier.

## 3.4 LCD contrast

Press and hold down  , and press  one after the other to increase contrast, or press  one after the other to decrease contrast.

# Chapter 4 Technical Specifications

## 4.1 Mains power

AC power: AC 100~240V, 50/60Hz.

Maximum power consumption: 25VA

## 4.2 Battery

Please prevent short-circuit of the positive pole and negative pole.

Characteristic: Rechargeable Ni-MH battery, 9.6V, 2000mAh.

Battery working time: approximately 4.0 hours at 5mL/h (on the condition that the battery is entirely new and fully charged).

Battery charging time: ≤ 16 hours.

## 4.3 Applicable syringe

Applicable syringes: 10mL, 20mL, 30mL and 50/60mL syringe.

It recognizes the size of the syringe automatically. The last syringe is offered when the device is switched on.

Two brands of the syringe are stored: B-D and Yusheng.

Note: Application of the syringe of “User-defined” brand may decrease accuracy due to inaccurate measurement of syringe.

## 4.4 Flow rate range

| | Syringe size (mL) | | | |
|---|---|---|---|---|
| | 10 | 20 | 30 | 50/60 |
| Rate (mL/h) | 0.1 ~ 300 | 0.1 ~ 400 | 0.1 ~ 600 | 0.1 ~ 1200 |
| Bolus rate (mL/h) | 0.1 ~ 300 | 0.1 ~ 400 | 0.1 ~ 600 | 0.1 ~ 600 |

0.1 mL/h increment

KVO (Keep vein open) rate: 1 mL/h

# 4.5 Infusion volume range

**0.1 ~ 9999.9 mL**

The volume limit can be set as “Empty”, which indicates that the solution in the syringe will be completely infused.

**0.1 ~ 5.0 mL (For Bolus)**

# 4.6 Flow rate accuracy

Infusion accuracy: ±2%

(Including the device accuracy ±1%)

# 4.7 Volume infused display

**0 ~ 9999.9 mL**

# 4.8 Occlusion pressure

Occlusion pressure sensitivity can be switched among the following eight levels:

Level 1: 20 ~ 60 KPa  Level 2: 30 ~ 70 KPa

Level 3: 40 ~ 80 KPa  Level 4: 50 ~ 90 KPa

Level 5: 60 ~ 100 KPa  Level 6: 70 ~ 110 KPa

Level 7: 80 ~ 120 KPa  Level 8: 90 ~ 140 KPa

The higher the pressure limit, the less sensitive the pump is to changes in fluid resistance.

# 4.9 Response time and bolus release after occlusion alarm

The data provided here is based on clinical trial measurements and used as reference.

| Syringe specifications | Flow rate | Pressure threshold | | | |
|---|---|---|---|---|---|
| | | Level 1 | | Level 8 | |
| | | Longest response time | Possible infused bolus volume | Longest response time | Possible infused bolus volume |
| 10 mL | 1 mL/h | 3 min | 0.05 mL | 7 min | 0.12 mL |
| | 5 mL/h | 2 min | 0.2 mL | 3 min | 0.25 mL |
| 20 mL | 1 mL/h | 10 min | 0.17 mL | 15 min | 0.25 mL |
| | 5 mL/h | 3 min | 0.3 mL | 10 min | 0.85 mL |
| 30 mL | 1 mL/h | 10 min | 0.17 mL | 30 min | 0.5 mL |
| | 5 mL/h | 5 min | 0.45 mL | 10 min | 0.85 mL |
| 50 mL | 1 mL/h | 30 min | 0.5 mL | 240 min | 4 mL |
| | 5 mL/h | 6 min | 0.5 mL | 25 min | 2.1 mL |

Remarks: The test bases on Yusheng syringe. The longest delay time and bolus volume depends on the test conditions.

# 4.10 Net weight

Approximate 2.0 kg

# 4.11 Dimensions

305 x 165 x 185 mm

# 4.12 Working conditions

Temperature: +5 ℃ ~ +40 ℃
Relative humidity: 20% ~ 90%
Atmospheric pressure: 70 KPa ~ 106 KPa

# 4.13 Transportation and storage conditions

Temperature: -20 ℃ ~ +55 ℃
Relative humidity: 10% ~ 90%
Atmospheric pressure: 70KPa ~ 106KPa

# 4.14 Compliance

Compliance with Medical Device Directive 93/42 EEC.

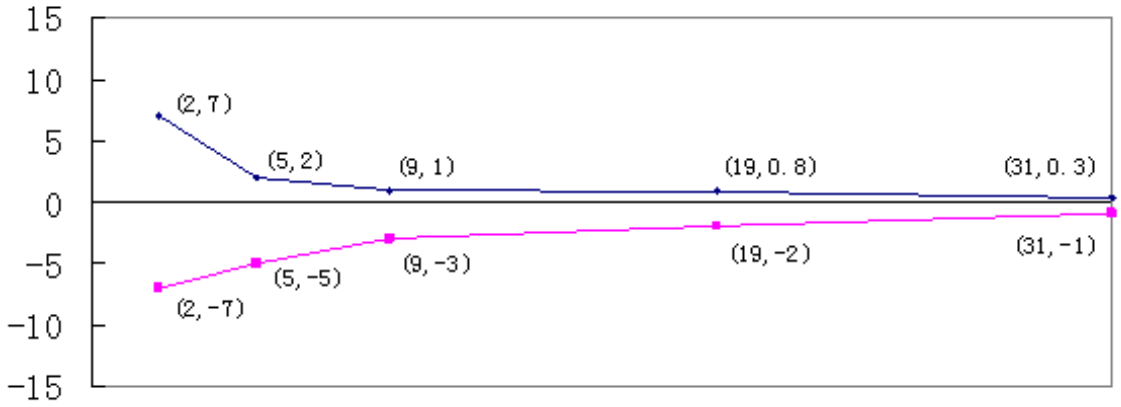
 : Please read the operator manual prior to using this device!
 : Protection against leakage current: Type CF equipment.
IPX4 : Protection against splashing fluid.

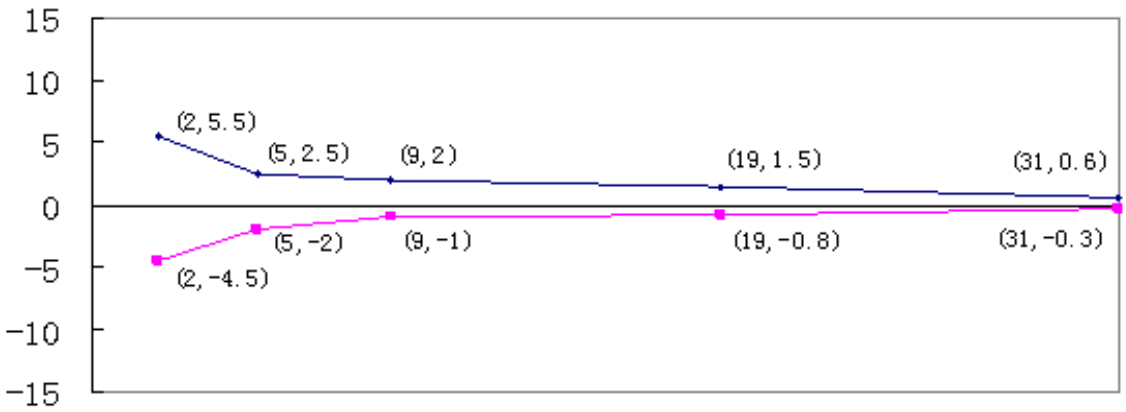
# Chapter 5 Appendix

## 5.1 Trumpet curve

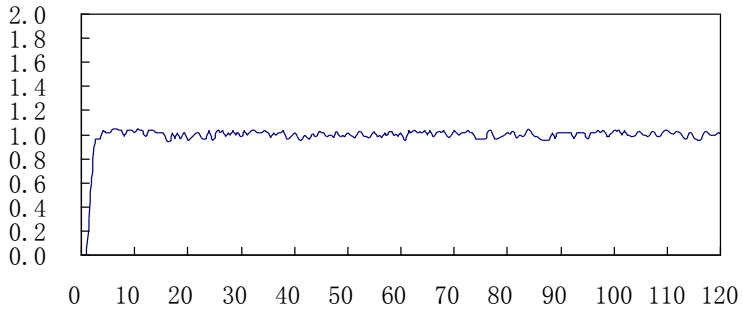
Trumpet curve indicates the trend of the max and min deviations of the syringe and pump. The detection proposals introduced for obtaining results in this aspect are based on EN60601-2-24. For more detailed information, please refer to this publication.
The following curve represents the results after using Yusheng syringe in the test; and 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

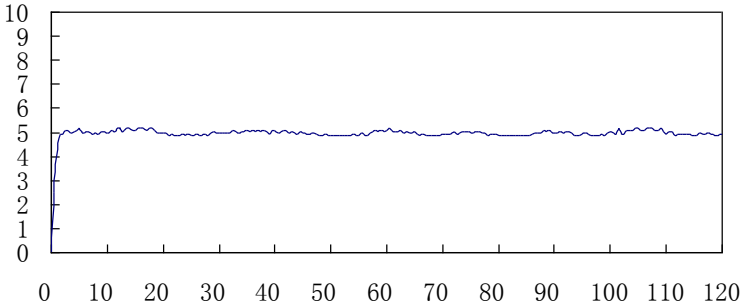
| Variance (%) | Flow Rate=1 mL/h |
|---|---|
| |  |
| | Observation windows (min) |

| Variance (%) | Flow Rate=5 mL/h |
|---|---|
| |  |
| | Observation windows (min) |

(2)Start-up and Real-time Curve (Startup Curve)

| | |
|---|---|
| Flow rate (mL/h) | Flow Rate=1 mL/h |
| |  |
| | Time (min) |



| | |
|---|---|
| Flow rate (mL/h) | Flow Rate=5 mL/h |
| |  |
| | Time (min) |



# 5.2 Guidance and manufacturer's statement on anti-electromagnetic interference Ⅰ

**Applicable to all the devices and systems**

| | | | |
|---|---|---|---|
| 1 | **Guidance and manufacturer's statement on anti-electromagnetic interference** | | |
| 2 | This device is predicted to be used in following electromagnetic environment. The buyer or user of the device should make sure to use it in this electromagnetic environment. | | |
| 3 | Emissions test | Compliance | Guidelines on the electromagnetic environment |
| 4 | RF emissions CLSPR 11 | Group 1 | RF energy of this device is only applicable to the inner part. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |

| | | | |
|---|---|---|---|
| 5 | RF emissions CISPR 11 | Class B | |
| 6 | Harmonic current IEC 61000-3-2 | Class A | |
| 7 | Voltage fluctuation and flicker IEC 61000-3-3 | Complies | |

| **Guidance and manufacturer's statement on anti-electromagnetic interference** | | | |
|---|---|---|---|
| This device is predicted to be used in following electromagnetic environment. The buyer or user of the device should make sure to use it in this electromagnetic environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Guidelines on the electromagnetic environment** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8kV Contact<br>±15kV Air | ±8kV Contact<br>±15kV Air | The ground should be made of wood, concrete, or ceramic. If the ground is covered by composite materials, the RH of the air should be not lower than 30%. |
| Electrical fast Transient burst IEC61000-4-4 | ±2kV Power cord<br>±1kV Input/output | ±2kV Power cord<br>±1kV Input/output | Mains power quality should be that of a typical domestic, commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1kV Differential mode<br>±2kV Common mode | ±1kV Differential mode<br>±2kV Common mode | Mains power quality should be that of a typical domestic, commercial or hospital environment. |
| Voltage dips, Short interruptions and voltage variations IEC 61000-4-11 | <5%Ut<br>(>95% dips in Ut)<br>0.5 cycle<br>40% Ut<br>(60% dips in Ut)<br>5 cycle<br>70% Ut<br>(30% dips in Ut)<br>25 cycle<br><5% Ut<br>(>95% dips in Ut)<br>5 seconds | <5%Ut<br>(>95% dips in Ut)<br>0.5 cycle<br>40% Ut<br>(60% dips in Ut)<br>5 cycle<br>70% Ut<br>(30% dips in Ut)<br>25 cycle<br><5% Ut<br>(>95% dips in Ut)<br>5 seconds | Mains power quality should be that of a typical domestic, commercial or hospital environment.<br>If the users need to continue the operation during power failure; therefore, the uninterruptible power supply or battery power supply are recommended. |
| Power frequency (50/60Hz) Magnetic field IEC 61000-4-8 | 3 A/m | 3A/m | Electric power frequency magnetic fields should comply with the standards of the commercial or hospital usage. |
| Note | Ut is the AC mains voltage prior to application of test level. | | |

# 5.3 Guidance and manufacturer's statement on anti-electromagnetic interference Ⅱ

**Guidance and manufacturer's statement on anti-electromagnetic interference: applicable to all the non-living device and systems**

This device is predicted to be used in following electromagnetic environment. The buyer or user of the device should make sure to use it in this electromagnetic environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment guidelines |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 | 3Vrms 150KHz to 80 MHz | 3V | Portable and mobile RF communications device should not be placed closer to any parts of the device than the recommended separation distance. The separation distance should be calculated by the formula corresponding to the transmitter frequency.<br>**Recommended Separation Distance**<br>$d=[\frac{3,5}{V_1}]\sqrt{P}$<br>$d=[\frac{3,5}{E_1}]\sqrt{P}$ 80MHz to 800 MHz<br>$d=[\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.5 GHz<br>If *p* is the maximum rated output power (w) provided by the RF device manufacturers, *d* will be the recommended separation distance (m). (b)<br>The field strength of fixed RF transmitters is determined by the investigation of the electromagnetic fields. Each band should be lower than compliance level. (a) (b)<br>Device marked with the following tag would interfere with the nearby substances: |
| Radiation, RF, electromagnetic field IEC 61000-4-3 | 3V/m 80MHz to 2.5 GHz | 3V/m | |

Note 1. If the frequency of the communications device is 800MHz or higher, formula for the high band should be used.

Note 2. The proposed guidelines may not be applicable to all conditions. Electromagnetic spread can be affected by absorption and reflection of buildings, substances, and human bodies.

a) Field strength of the fixed transmitters (such as Wireless (cordless / cellular) telephones and ground mobile radio station, amateur radio, AM FM radio and television broadcasting) can not be predicted theoretically.

In order to evaluate the electromagnetic environment of the fixed RF transmitters, the investigation of electromagnetic field should be taken into consideration. If the field strength of the place near to the device is higher than the RF compliance level, the pump should be observed and checked to assure whether it can work normally. If abnormal performance is observed, the compensation measures may be necessary, for example, re-orientate and re-position the device.

b) When the frequency range is between 150kHz and 80MHz, the field strength should be less than 3V/m.

| **Maximum rated output power of the communications device (W)** | **Separation distance determined by the frequency of the communications device (m)** | | |
|---|---|---|---|
| | 150KHz to 80MHz $d=[\frac{3,5}{V_1}]\sqrt{P}$ | 80MHz to 800MHz $d=[\frac{3,5}{E_1}]\sqrt{P}$ | 800 MHz to 2.5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$ |
| 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 maximum rated output power of the transmitter not listed in the above table, the recommended separation distance *d* (unit: m) can be determined by the formula in the corresponding column of the transmitter frequency. Here, *p* is the maximum rated output power rating provided by the manufacturer (unit: w).

Note 1. If the frequency of the communications device is above 80MHz-800MHz, the formula for high brand should be applied.

Note 2. The proposed guidelines may not be applicable to all conditions. Electromagnetic spread can be affected by absorption and reflection of buildings, substances, and human bodies.

**Recommended separation distance between portable / mobile RF communications device and syringe pumps**

This device is expected to be used in the electromagnetic environment where the radiation RF disturbance is controlled. Based on the maximum output power of the communication device, the buyers or users can prevent electromagnetic interference through maintaining the minimum distance between the portable/mobile RF communications device (transmitters) and the infusion pump.

# Keep your patients safer
# Make your job easier!

**Guangzhou Huaxi**
Medical Science Technology Co., Ltd.
6F, Building A8, No.11, Kaiyuan Avenue, Science City, Guangzhou Hi-tech Industrial Developments Zone, Guangzhou. China.
Tel: 0086-20-32290298, 32290268
Fax: 0086-20-32053080
Postal code: 510530
Website: http://www.gzhuaxi.com