CE 0123

INFUSION PUMP

HX-801D

OPERATOR MANUAL

Guangzhou Huaxi Medical Science Technology Co., Ltd.

Please read this manual completely prior to using the device!

Version: V1.1

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Chapter 1 Safety Precautions

Thank you for choosing the HX-801D infusion 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. HX-801D must be operated by medical professional staff, such as doctors, nurses, etc.
2. HX-801D 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.

Chapter 2 Introduction

2.1 Application

HX-801D infusion pump is intended to provide accurate and continuous intravenous infusion.

2.2 Specifications

Product name:	Infusion pump
Model:	HX-801D
Applicable IV set:	10, 15, 20 and 60 d/mL (with outer diameter 3.4 ~ 4.5mm)
Pumping mechanism:	Peristaltic finger pump
Infusion mode:	Volumetric
Maximum flow rate:	1200 mL/h
Flow rate accuracy:	±5% (after calibration)
Volume infused display:	0 ~ 9999 mL & >9999 mL
Volume limit:	1 ~ 9999 mL
KVO (keep vein open):	1 mL
Air-in-line detection:	Ultrasonic, 50 ~ 1000 μL, 8 sensitivities setting
Occlusion pressure:	40 ~ 140 KPa, 8 sensitivities setting
Sound volume:	8 levels setting
Max. power consumption:	≤25VA
Peristaltic finger pump:	Detachable
Tube clamp:	Detachable
Display:	Blue LCD with high brightness
AC power:	AC100V ~ 240V, 50Hz/60Hz
Internal battery:	Rechargeable Ni-MH battery, DC12V, 2000mAh, life: approximately 4 hours at 25mL/h

Net weight:	2.3 kg
Dimensions:	150mm x 150mm x 235mm
Audio and visual alarms:	Air-in-line, Door open, Upstream occlusion, Downstream occlusion, Infusion finished, No operation, Bottom empty, Battery low, Pump error, Motor reverse, AC power lost, etc.

2.3 Working conditions

Temperature:	+5 ℃ ~ +40 ℃
Relative Humidity:	20% ~ 90%
Atmospheric Pressure:	70KPa ~ 106KPa

2.4 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.

2.5 Features

1. HX-801D is with a full function of audio and visual alarm and exact infusion-controlled function. It is used widely, safely and reliably.
2. HX-801D can control the flow rate automatically. It is not just available for the intravenous infusion of normal brine and dextrose, but also for the infusion of high surface tension.
3. Standard IV sets of 10, 15, 20 and 60 d/mL are applicable.
4. The battery supply system can guarantee the continue infusion when move the patient or the AC power is disconnected.
5. Easy switch between mL/h and volume/time units.
6. The finger pump is detachable and can be washed in water.

7. The tube clamp is detachable and can be washed in water.
8. Easily operate with single hand by using the side handle.

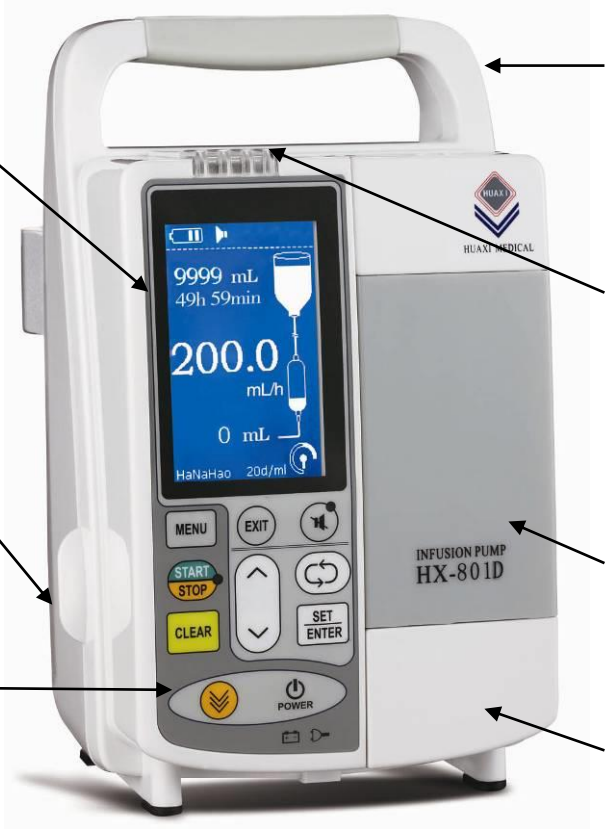
2.6 Components and functions

HX-801D is made of housing, peristaltic finger pump, air sensor, display and battery, etc.

LCD: All essential information is displayed.

Side handle: Easy operate with single hand.

Keyboard: Allow data entry.



Handle for carrying

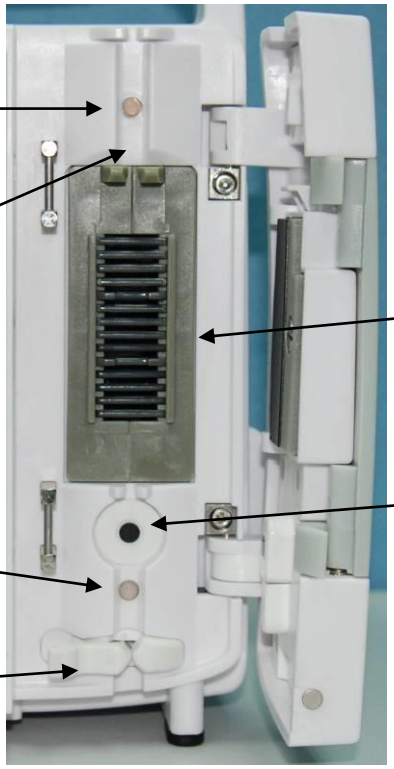
Alarm light: Lights up during an alarm.

Pump door handle: Pull it to open the door.

Pump door

Occlusion pressure sensor on top

Fluid path



Peristaltic finger pump

Occlusion pressure sensor at bottom

Air sensor

Tube clamp

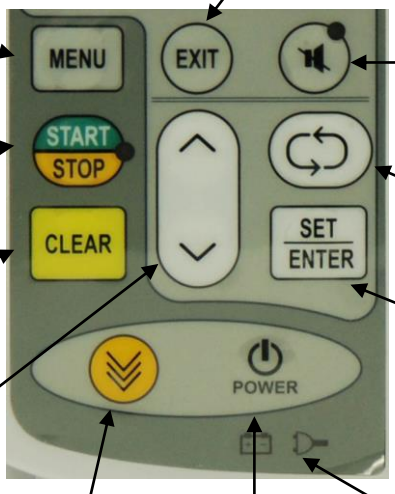
Knob: To attach the pump to an IV pole.

Label: To show the product information.

AC power socket

LCD information

Keyboard



Menu key: To enter the menu or return to the main screen.

Exit key: To return to the previous menu.

Start/Stop keys

Alarm silence key: Silence alarm for 2 minutes.

Switch key: To shift the cursor.

Clear key: To clear the alarm or parameter.

Set/Enter keys: To activate and confirm the parameter.

Up/Down keys: To plus or minus the number and choose the character.

Prime key

Power key

: Battery indicator light

: AC power indicator light

Chapter 3 Operation Guidance

3.1 Operation flowchart

Infusion Pump Installation
↓
IV set Installation
↓
Programmation
↓
Priming
↓
Connect IV Set To Patients
↓
Starting The Infusion

3.2 Infusion pump installation

1. Attach the pump to an IV pole by turning the knob on the back of the pump clockwise, or place the pump on flat, stable surface.
2. Plug the pump's power cord into an electrical outlet.
3. Press 

to turn on the machine, listen for the beep.

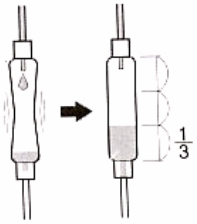
Note:

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.

3.3 IV set installation

1. Close the roller clamp of IV set and insert it into the solution container. Gently press the drip chamber to fill it up to 1/3 full.

Turn the roller clamp left to close it



2. Open the roller clamp. Once the IV set is completely primed, close the roller clamp and check if there is air bubble in the set.
3. Open the pump door. Thread the IV set down the fluid path, making sure it is threaded the air sensor and pressure sensor. Then open the clamp at the bottom of the fluid path, insert the IV set and release clamp.
4. Close the pump door and open the roller clamp. Check that no drops are falling in the drip chamber.

3.4 Infusion parameter setting

3.4.1 IV set selection

1. Press MENU , system will enter into main menu.
2. The cursor positions on “Infusion”, press SET ENTER ∧ ∨ to position the cursor on “IV Set”.
3. Press SET ENTER ∧ ∨ SET ENTER to select the brand and size of IV set.
4. Return to previous menu by pressing EXIT and main screen by pressing MENU.

3.4.2 Infusion volume setting

Method 1:

1. Press MENU , system will enter into main menu.
2. The cursor positions on “Infusion”, press SET ENTER ∧ ∨ to position the cursor on “Volume Limit”.

3. Press [SET ENTER] [▲] [▼] [↻] [SET ENTER] to select the desired volume.
4. Return to previous menu by pressing [EXIT] and main screen by pressing [MENU].

Method 2:

1. On the main screen, press [SET ENTER] to enter into “Quick Menu”, the cursor positions on “Limit”.
2. Press [SET ENTER] [▲] [▼] [↻] [SET ENTER] to select the desired volume.
3. Return to main screen by pressing [EXIT] or [MENU] .

3.4.3 Infusion rate setting

Method 1:

1. Press [MENU] , system will enter into main menu.
2. The cursor positions on “Infusion”, press [SET ENTER] [▲] [▼] to position the cursor on “Infuse rate”.
3. Press [SET ENTER] [▲] [▼] [↻] [SET ENTER] to select the desired rate.
4. Return to previous menu by pressing [EXIT] and main screen by pressing [MENU].

Method 2:

1. On the main screen, press [SET ENTER] to enter into “Quick Menu”, and press [▲] [▼] to position the cursor on “Rate”.
2. Press [SET ENTER] [▲] [▼] [↻] [SET ENTER] to select the desired rate.
3. Return to main screen by pressing [EXIT] or [MENU] .

Infusion rate and volume setting range are as follows:

IV set	mL/h	Volume limit
10 d/mL	1.0 ~ 1200	1 ~ 9999 mL
15 d/mL	1.0 ~ 1200	1 ~ 9999 mL
20 d/mL	1.0 ~ 1200	1 ~ 9999 mL
60 d/mL	1.0 ~ 1200	1 ~ 9999 mL

From 0.1 mL/h to 99.9 mL/h, 0.1 mL increment; ⩾100 mL/h, 1 mL increment.

3.4.4 Infusion time setting

It is allowed to set the volume limit and infusion time, then the pump will calculate the flow rate automatically, detail steps as follow:

1. On the main screen, press SET ENTER to enter into “Quick Menu”, and press ∧ ∨ to position the cursor on “Time”.
2. Press SET ENTER ∧ ∨ ⟳ CLEAR SET ENTER to select the desired infusion time.
3. Return to main screen by pressing EXIT or MENU .

3.4.5 Total infused volume

How to clear the total infused volume:

Method 1:

1. Press MENU , system will enter into main menu.
2. The cursor positions on “Infusion”, press SET ENTER ∧ ∨ to position the cursor on “Total Volume”.
3. Press SET ENTER CLEAR to clear the total infused volume.
4. Return to previous menu by pressing EXIT and main screen by pressing MENU.

Method 2:

1. On the main screen, press SET ENTER to enter into “Quick Menu”, and press ∧ ∨ to position the cursor on “Total”.
2. Press SET ENTER CLEAR to clear the total infused volume.
3. Return to main screen by pressing EXIT or MENU .

3.4.6 Bolus mode

1. Press MENU , system will enter into main menu.
2. Press ∧ ∨ SET ENTER to enter into “Bolus Mode”.
3. Press SET ENTER ∧ ∨ ⟳ SET ENTER to set the desired volume limit.
4. Press SET ENTER ∧ ∨ ⟳ SET ENTER to set the desired flow rate.
5. Press START STOP to start infusion

3.5 Priming

1. Check and confirm that the IV set is disconnected to the patient.
2. Press  to prime until all the air bubbles are removed.

Note:

The volume of priming will not be cumulated with the total infused volume.

Flow rate for purging: 600 mL/h

3.6 Start the infusion

1. Connect IV 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.

3.7 Stop infusion

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

.
2. To resume the infusion, press 

.

3.8 Infusion finish

1. When the infused volume reaches the volume limit, the device will give an audio and visual alarm “Finished. KVO” and infuse at KVO rate.
2. Press 

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

3.9 Power off

Stop the infusion and keep pressing 

until the device turns off.

3.10 System management

3.10.1 Occlusion sensitivity setting

1. Press MENU , system will enter into main menu.
2. Press ∧ ∨ SET ENTER to enter into “System”.
3. Press ∧ ∨ SET ENTER to enter into “Pres. -Top” or “Pres. - Bottom”.
4. Press ∧ ∨ SET ENTER to set the desired sensitivity.

From level 1 to level 8, the pressure limit is increasing.

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

Occlusion alarm response time and possible infused volume based on 20 d/mL IV set:

	1 mL/h	25 mL/h	Volume
Level 1	28 minutes 01 second	1 minute 18 seconds	0.55 mL
Level 8	59 minutes	2 minute 18 seconds	0.99 mL

3.10.2 Air-in-line sensitivity setting

1. Press MENU , system will enter into main menu.
2. Press ∧ ∨ SET ENTER to enter into “System”.
3. Press ∧ ∨ SET ENTER to enter into “Air Sens.”.
4. Press ∧ ∨ SET ENTER to set the desired sensitivity.

From level 1 to level 8, the threshold for alarm is increasing.

3.10.3 Sound volume setting

1. Press MENU , system will enter into main menu.
2. Press ∧ ∨ SET ENTER to enter into “System”.
3. Press ∧ ∨ SET ENTER to enter into “Sound Volume”.
4. Press ∧ ∨ SET ENTER to set the desired sound volume.

3.11 Unit convert

This function is for operator to convert the infusion rate, if it is known any of d/min and mL/h, the other will be calculated automatically.

1. Press MENU , system will enter into main menu.
2. Press ∧ ∨ SET ENTER to enter into “Unit Convert”.
3. Press SET ENTER ∧ ∨ ⟲ SET ENTER to input the desired rate, d/min or mL/h.
4. The other rate will be calculated automatically.

3.12 Manage IV set

3.12.1 Calibration value setting

1. Press MENU, system will enter into main menu.
2. Press ∧ ∨ to position the cursor on “Manage IV set”.
3. Press SET ENTER ∧ ∨ to position the cursor on “Edit Adj Value”.
4. Press SET ENTER ∧ ∨ SET ENTER to select the desired IV brand.
5. Press ∧ ∨ to position the cursor on the desired size of IV brand.
6. Press SET ENTER ∧ ∨ SET ENTER to select the desired calibration value.
7. Return to previous menu by pressing EXIT and main screen by pressing MENU.

3.12.2 Add new brand of IV set

1. Press MENU, system will enter into main menu.
2. Press ∧ ∨ to position the cursor on “Manage IV set”.
3. Press SET ENTER ∧ ∨ to position the cursor on “Add a Brand”.
4. Press SET ENTER ∧ ∨ ⟲ SET ENTER to set the brand name.
5. Return to previous menu by pressing EXIT and main screen by pressing MENU.

3.12.3 Auto calibration

The accuracy of infusion will be affected by the below factors, therefore it is necessary to calibrate for each type of IV set before putting into use in order to ensure the accuracy.

1. Difference of IV set diameters for various brands.
2. Different surface tension of various concentration solutions.

Preparation:

A measurement cup to measure the actual volume of the solution.

A container filled with 200 mL (or above) 0.9% standard physiological brine or pure water.

Process:

1. Install and prime the IV set.
2. Press MENU , system will enter into main menu.
3. Press ∧ ∨ SET ENTER to enter into “Manage IV Set”.
4. Press ∧ ∨ SET ENTER to enter into “Adjust IV Set”.
5. Press ∧ ∨ SET ENTER to select the IV brand.
6. Press ∧ ∨ SET ENTER to select the IV size.
7. Press ∧ ∨ ↻ SET ENTER to input the flow rate.
8. Press ∧ ∨ ↻ SET ENTER to input the volume.
9. Place the end of IV set into measurement cup and start infusion.
10. Once the pump stop running and alarming for finish calibration, it will ask to input the actual volume infused. Press ∧ ∨ ↻ SET ENTER to input the volume from the measurement cup.
11. Repeat step 2 to 10, calibrate for another time to ensure the high accuracy. The calibration process is finished.

Note:

1. The default flow rate and volume for calibration is 50 mL/h and 10 mL respectively, operator can change them as they want, and it is

recommended to set the volume as 1/5 of the rate.

2. **It is recommended to make a record for the calibration result in order to avoid negligence during the operation.**

   Here is the example for operator reference.

IV Brand	IV Size	Calibration Finished?
A	20 d/mL	Yes
A	15 d/mL	Yes
B	20 d/mL	Yes

3.12.4 Calibration by manual

Preparation: The same as auto calibration.

Process:

1. Install and prime the IV set
2. Set the volume limit as 10 mL according to section 3.4.3.
3. Set the flow rate as 50 mL/h according to section 3.4.4.
4. Clear the total infused volume according to section 3.4.6.
5. Place the end of IV set into measurement cup and start infusion.
6. Once volume limit is finished, measure the actual volume in the cup, and calculate the calibration value (**Value A**) by the below formula.

$$\text{Calibration value (Value A)} = \frac{\text{Total infused volume} - \text{Actual Volume}}{\text{Actual Volume}} \times 100\%$$

7. Input Value A into the pump according to section 3.12.1. The calibration process is finished.

Note:

The calibration value should be -30% ~ +30%, or else it means some mistakes occur during infusion, and it needs to re-perform the calibration.

3.12.5 Adjust calibration value for high concentration solution

It should be add a calibration value (Value B) for the high concentration solutions showed in the below form, since its high surface tension will affect the accuracy.

Note: If it is already used the corresponding high concentration solution for calibration, it is not necessary to add Value B.

Solutions	Calibration values (Value B)
Common solution	0%
Dextrose (10%)	+5%
Dextrose (50%)	+10%
TPN(Total Parental Nutrition)	+5 ~ +10%
TPN+ fat-soluble vitamin	+10 ~ +20%

1. If it is already calibrated by auto calibration based on section 3.12.3, input Value B directly to the device according to section 3.12.1.
2. If it is calibrated by manual based on section 3.12.4, input total calibration value to the device as below according to section 3.12.1.

   Total calibration value = Value A + Value B

3.12.6 Delete a brand of IV set

1. Press MENU, system will enter into main menu.
2. Press ∧ ∨ to position the cursor on “Manage IV Set”.
3. Press SET ENTER ∧ ∨ to position the cursor on “Delete a Brand”.
4. Press SET ENTER ∧ ∨ SET ENTER to select the IV brand.
5. Press SET ENTER to confirm, or EXIT to return to previous menu.

3.13 Others

3.13.1 Change of container

1. Press START STOP to hold infusion.
2. Close roller clamp.
3. Disconnect set from the old container.
4. Connect set to new container according to good clinical practices.
5. Check fluid level in drip chamber (around 1/3 of its capacity).
6. Program new infusion parameters: flow rate, volume, …
7. Open roller clamp.
8. Press START STOP to start infusion.

3.14 Alarms and errors

3.14.1 Alarms

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

Alarms	Possible cause	Actions
Door open	Door is open.	Close the door.
Finish! KVO	Infusion finished.	1. Change solution container and restart infusion. 2. Remove IV set.
Air in line	IV set is not installed or IV set is installed incorrectly.	Install the IV set properly and make sure it thread the air sensor.
	Air bubble in the IV set.	Remove air from IV set.
	Air inlet cap is closed.	Check where the air inlet is open and make sure it is not blocked.
No operation	No operation for 2 minutes.	Press or CLEAR .

Alarms	Possible cause	Actions
Upstream occl. (occlusion)	IV set kinked.	Correct kinks.
	Air inlet cap is closed.	Check where the air inlet is open and make sure it is not blocked.
	Bottle empty.	Check solution container.
Downstream occl. (occlusion)	IV set kinked.	Correct kinks.
	Roller clamp closed.	Open roller clamp.
	Needle blocked.	Check if the needle is blocked.
	IV set is too hard or its diameter exceeds the acceptable limit.	Change another IV set or increase the occlusion pressure limit.
Parameter err! (Error)	Infusion parameter incorrect.	Check and reset parameter.
Battery low	Battery voltage is low.	Connect pump to AC power.
Battery ran out	Battery is nearly used up.	Connect pump to AC power.
Battery lost	Battery disconnected.	Connect battery properly.
	Battery damaged.	Change another battery.
AC power lost	AC power is lost.	Connect pump to AC power.
Top / Bottom pressure sensor error	Top / Bottom pressure sensor is not working properly.	Stop using the device and contact with after-sales service.
Air sensor error	Air sensor is not working properly.	Stop using the device and contact with after-sales service.
Pump error	Pump is blocked due to serious pollution.	Clean the pump.
	Pump is blocked due to improperly installation of IV set.	Reinstall the IV set.
Motor reverse	Motor is running reversely.	Stop using the device and contact with after-sales service.
System failed	Internal error.	Stop using the device and contact with after-sales service.

Note: The possible infused volume in a single failure is less than 0.7 mL.

3.14.2 Other errors

Check as follows firstly by yourself before contact with after-sales service:

Phenomena	Possible Cause	Actions
The device can not be turned on.	Are AC power and battery properly connected?	Connect the AC power and battery properly.
Can not infuse, strange sound emitted from finger pump cassette.	Is there anything stuck on the finger pump cassette?	Clean the finger pump cassette.

3.15 Daily check

Checking points	Procedures
Check if the housing is flawed, cracked or distorted.	Check the housing of the device.
Check if the power cord is damaged	Check the power cord.
Check finger pump cassette.	Open pump door and take away the finger pump cassette. Rotate gear and check if it revolves smoothly.
Check air sensor.	Before installing the IV set, the pump will alarm for “Air in line” when start infusion.
Check door sensor.	Open the door, the pump will alarm for “Door open”.
Note: If any problem can’t be solved by operator, please stop to use and contact with after-sales service.	

Chapter 4 Maintenance

4.1 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.

4.1.1 Clean the housing

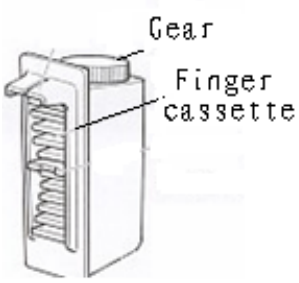
Clean the pump with a soft lint-free cloth or swab dampened with detergent and water.

4.1.2 Clean the air sensor

Gently wipe the sensor surface with wet cotton, and dry it well.
Do not damage the sensor surface.

4.1.3 Clean the finger pump cassette

Take away the finger pump cassette and wash it, then wipe with dry cotton and install.



4.1.4 Clean the tube clamp

1. Loosen screw and remove the tube clamp.
2. Wash the tube clamp.
3. Dry it well with dry cotton and install it.

4.2 Battery

4.2.1 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: 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.

4.2.2 Replace battery

1. Loosen screw to remove battery cover at the bottom of the device.
2. Disconnect the battery and move it out.
3. Place and connect new battery, then install the cover.

Note:

1. Do not place the battery close to fire or heat source.
2. Use the specified battery provided by the manufacturer only.

4.3 Periodical replacement for accessories

The following accessories should be replaced periodically.

Accessories	Recommended replacement period
Battery	2 years
Finger pump cassette	3 years

The warranty for the battery is one year.

4.4 Transportation and storage conditions

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

Chapter 5 Appendix

5.1 Trumpet curve

Trumpet curve indicates the trend of the max and min deviations of the infusion 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 Hanahao IV set in the test; and it is considered as only one basis of the overall performance of the infusion pump. For more related information, contact the supplier.

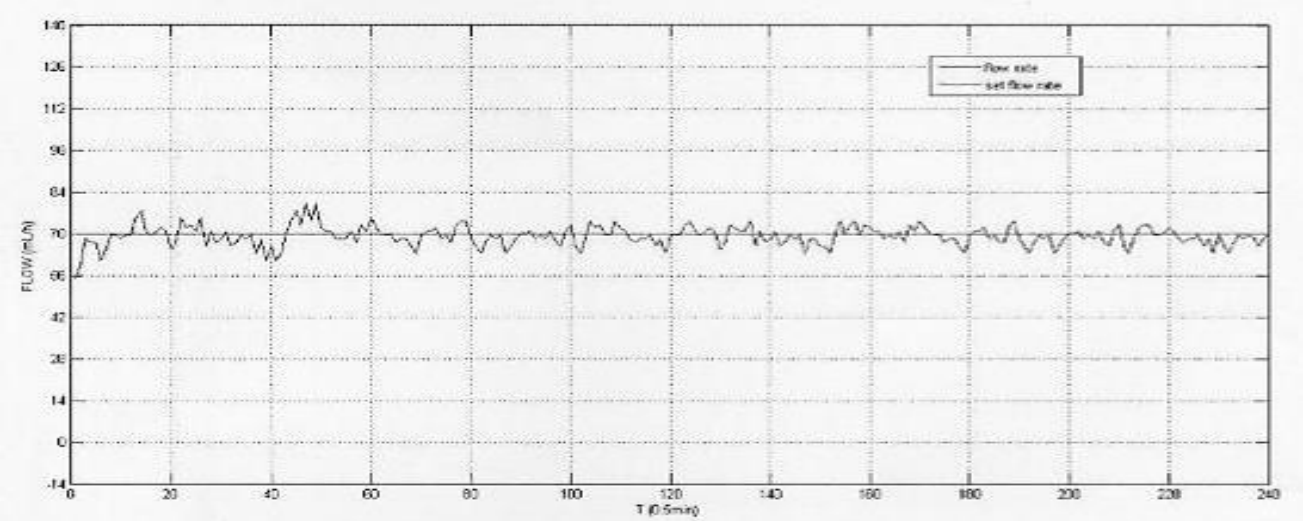


Figure 1- Start-up graph plotted from data gathered during the first 2h of the test period

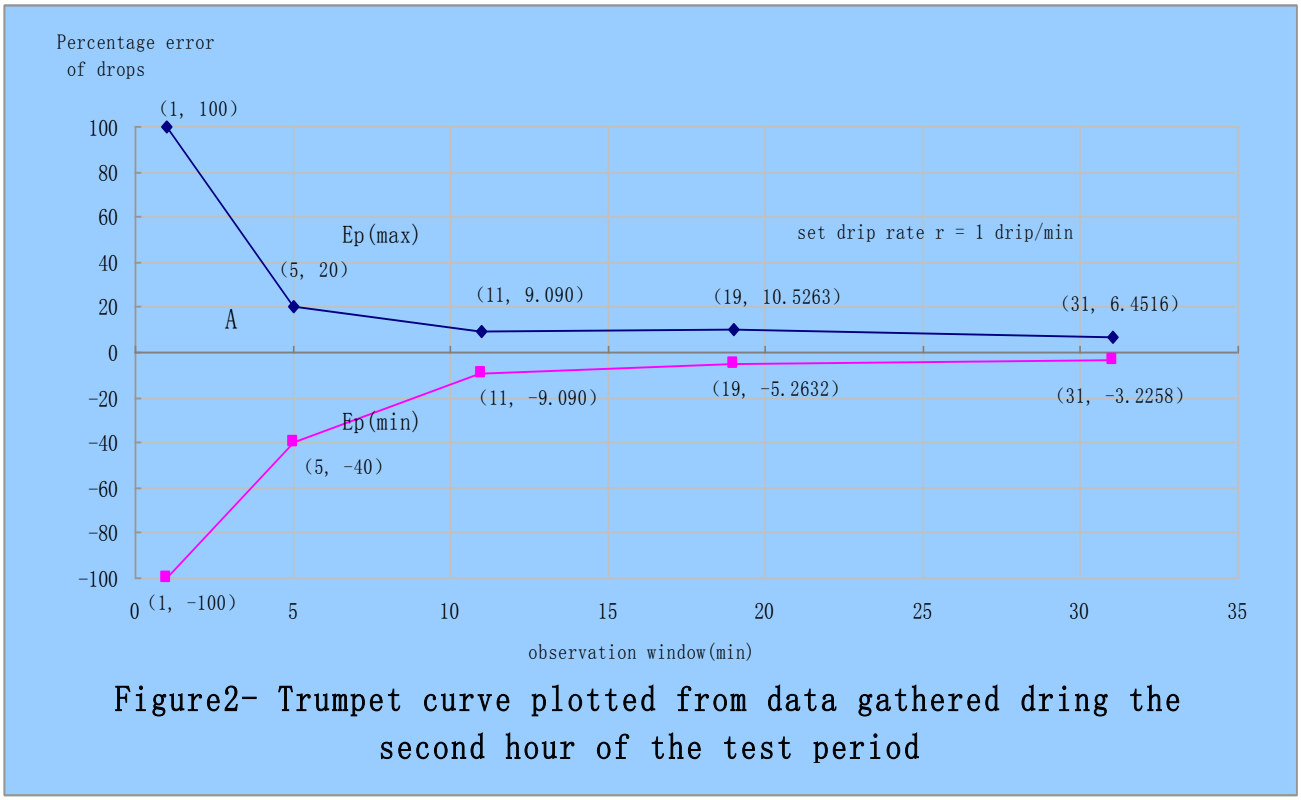


Figure2- Trumpet curve plotted from data gathered dring the second hour of the test period

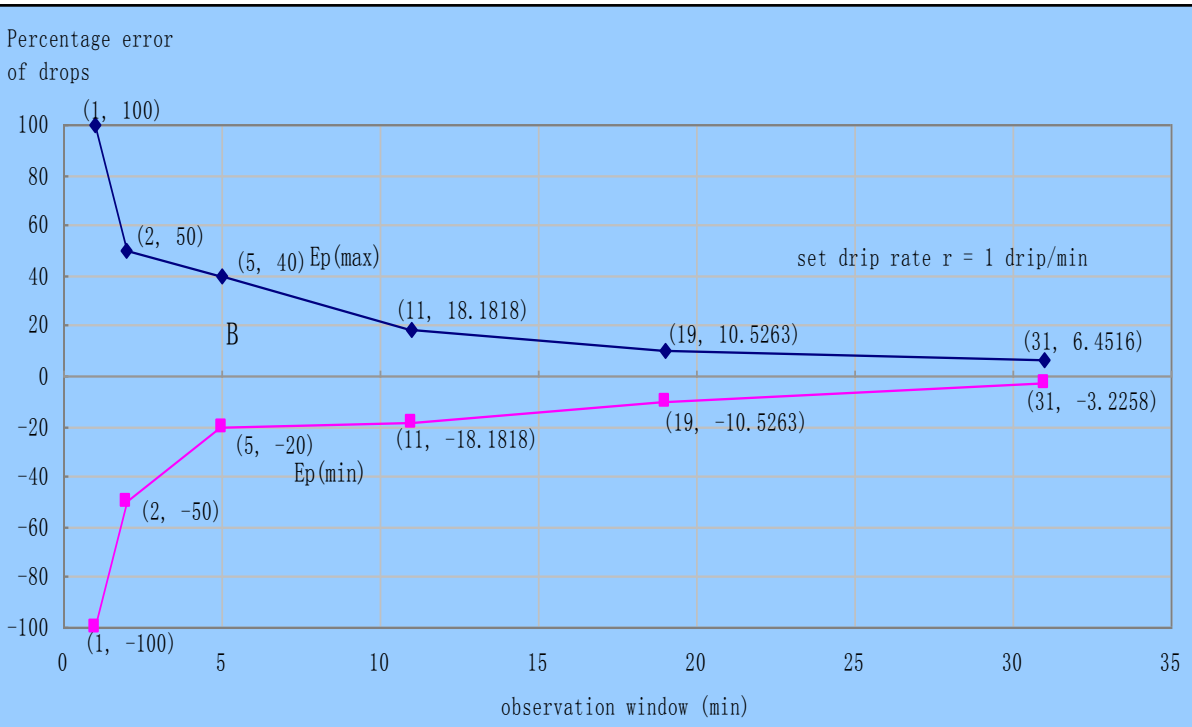


Figure3-trumpet curve plotted from data gathered during the last hour of the ADMINISTRATION CHANGE INTERVAL

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 ±15kV Air	±8kV Contact ±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 ±1kV Input/output	±2kV Power cord ±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 ±2kV Common mode	±1kV Differential mode ±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 (>95% dips in Ut) 0.5 cycle 40% Ut (60% dips in Ut) 5 cycle 70% Ut (30% dips in Ut) 25 cycle <5% Ut (>95% dips in Ut) 5 seconds	<5%Ut (>95% dips in Ut) 0.5 cycle 40% Ut (60% dips in Ut) 5 cycle 70% Ut (30% dips in Ut) 25 cycle <5% Ut (>95% dips in Ut) 5 seconds	Mains power quality should be that of a typical domestic, commercial or hospital environment. 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.		

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

<table>
<tr><th colspan="4">Guidance and manufacturer's statement on anti-electromagnetic interference:
applicable to all the non-living device and systems</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment guidelines</th></tr>
<tr><td>Conducted RF IEC 61000-4-6

Radiation, RF, electromagnetic field IEC 61000-4-3</td><td>3Vrms
150KHz
to 80 MHz

3V/m
80MHz
to 2.5 GHz</td><td>3V

3V/m</td><td>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.
Recommended Separation Distance
$d=[\frac{3,5}{V_1}]\sqrt{P}$
$d=[\frac{3,5}{E_1}]\sqrt{P}$ 80MHz to 800 MHz
$d=[\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.5 GHz
If p is the maximum rated output power (w) provided by the RF device manufacturers, d will be the recommended separation distance (m). (b)
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)
Device marked with the following tag would interfere with the nearby substances:  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

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!

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