BIOLIGHT

P600 Infusion Pump
used for intravenous infusion administration

User's Manual

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CONTENTS

1 INTRODUCTION

1.1 Explanation of symbols

• Warning is used to indicate the presence of a hazard, which can cause severe personal injury, death or substantial property damage if the warning is ignored.

• Caution is used to indicate the presence of a hazard, which will cause minor personal injury or property damage if the warning is ignored.

NOTE

• Note is used to notify the user of installation, operation or maintenance information, which is important but not hazard-related.

Thank you for choosing our **P600 Infusion Pump used for intravenous infusion administration (hereinafter referred to as Infusion Pump)**.

In order to use this pump correctly and safely, read this manual carefully before operating the Infusion Pump. If you have any questions as you are reading through this manual, call the local authorized dealer in your country. Retain this manual together with the unit for future reference.

This device is designed for high flow rate accuracy and ease of handle in the infusion of solutions with the equipped peristaltic finger system.

• The Infusion Pump is not intended for the infusion of chemicals such as anti-cancer drugs, oxytocic, nutrition, blood, and drug for chemotherapy medication.

1.2 Features

• Compact in design, light in weight and small in size.
• Compatible with universal IV set.
• Low motor driving noise.
• Ultrasonic bubble sensor.
• Easy to set VTBI (volume to be infused) by [INCR] or [DECR] key on the front panel.
• Accurate setting of flow rate for patients.
• Flow rate accuracy with the equipped peristaltic finger system.
• The infused volume can be cleared by pressing [CLEAR] key without switching off the power.
• Audio-visual alarms for added safety.
• The reminder alarm sounds repeatedly if no action is taken within 2 minutes after the alarm was switched off.
• The flow rate can be set in 0.1ml/h increments.
• After delivering the VTBI, the pump continues running with keep vein open (KVO rate) mode.
• When door is open, the tube is automatically locked by tube clamp.
• The rechargeable built-in battery allows the pump to be transported with the patient without ceasing normal pump operation.

1.3 Revision history

The following revision history table summarizes changes contained in this document.

The right is reserved to change or discontinue this product without notice.

Revision No.	Revision Date	Document number	Description of Revisions
1.0	04/03/2016	J/P600CE-A-004	Initial version

1.4 CE mark

CE 0123

EC Representative Name:

Shanghai International Holding Corp. GmbH (Europe)

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2 DESCRIPTION OF PUMP

2.1 Front view

1) LCD display

	Wireless communication (optional function).
	Pump powered by alternate current.
	Pump powered by built-in battery. Flashing indicates battery under charging.
	Silence the alarm.
	Indicate occlusion level.
	Indicate pump under calibration
	Alternate flash to indicate pump is running.
	Light on when air bubble is in the IV tubing.
	Light on when the IV tubing is occluded.
	Light on when low battery.

FLOW RATE	Light on when speed abnormal detected.
DOOR	Light on when the door is open.
DROP	Light on when drop abnormal detected (This pump does not have this function).
FINISH	Light on when VTBI is completely delivered.
KVO	Pump run at KVO mode.
UNATND	Light on when the pump standby for 2 minutes.
FLOW RATE	Flow rate area.
mL/hr	Flow rate mode
drop/min	drop/min mode.
	Time-based mode.
VOLUME mL	Volume area.
	Infused volume.
VTBI	Volume to be infused.
BOLUS	Bolus volume (optional function).

2) Keys

	[INC] KEY: Increase.		[START/STOP] KEY: start or stop infusion, also act as a silence key.
	[DEC] KEY: Decrease.		[PURGE] KEY: Remove air in the IV tubing.
	[SET]KEY: Parameter settings.		[CLEAR] KEY: Clear the infused volume. Work under when pump stops.
		Simultaneously press the two keys to change infusion mode: ml/h, drop/min and time-based.	

3) Flow LED: Flash when infusion.

4) DIP switch: IV set selection.

5) Bubble sensor: Detects air bubble in the IV tubing.

6) Tension plate: Press on the tubing to generate pressure.

7) Fingers: Peristaltic press on the tubing to drive down the solution.

8) Door lever: Pull up this lever and close the door. Just push the door to lock it.

9) Tubing guider: Guide the IV tubing.

10) Pressure sensor: Detects the occlusion of the IV tubing.

11) Tubing clamp: Automatically clamps the IV tubing when the door is open.

12) Pump door.

2.2 Rear view

1) Pole clamp
2) Grounding terminal
3) Pump handle
4) Power switch
5) AC power inlet

2.3 Power cord


AC power cord

3 PRIOR TO USE

3.1 Warnings

• If this pump is used in the vicinity of the surgical operation equipment which generates a high frequency current such as mobile (cellular) phone, radio, or defibrillator, the pump may malfunction since electrical interference.
Please carefully check for any sources of electrical interference in the vicinity before use.

• When using the pump concurrently with the surgical operation equipment, please note the following:
- Do not use the pump together with any surgical operation equipment that generates high noise level.
- Be sure that the pump is kept a sufficient distance from the surgical operation equipment.
- The pump and such device should not be powered from the same outlet.
- Check and confirm the normal operation of the pump periodically.

• In case of malfunction, turn off the power immediately, and remove IV set from the pump and from the patients. After this action, please contact your local authorized dealer at once.

• Avoid using the pump in presence of flammable gases and flammable anesthetic mixture with air, oxygen or nitrous oxide.

• The use of any mobile (cellular) phone near the pump is not allowed since the high frequency noise during the conversation could cause malfunction of the pump.

• The use of the pump in MRI rooms such as high-pressure rooms or places where high electromagnetic radiation is generated is not allowed.

• In case of using an IV set of your local brand, contact your local authorized dealer for compatibility of IV set with this pump before use. If an improper IV set is used, the accuracy of flow rate and alarm functions cannot be guaranteed.

• Be sure that the IV tubing is properly fit in the tubing slots of bubble sensor and occlusion sensor. If not, those alarms will not function normally.

• Be sure that the IV tubing runs straight over the peristaltic finger section. If not, an accurate flow rate cannot be guaranteed.

• During infusion, regularly check the drop rate to make sure that the solution is being infused at the selected rate.

• Do not connect the IV set administered from an Infusion Pump to another IV set administered only by the roller clamp because this may cause inaccuracy of flow rate and alarm functions.

• When the same site of the IV tubing has been set at peristaltic finger section for a long time (over 12 hours), use it after moving the IV tubing connected to this pump at a distance of more than 10 cm. Deformation of IV tubing arising from long time (over 12 hours) use can affect the accuracy.

• The pump does not detect damage to the IV set such as a leak in the line or a rupture in the filter due to pressure exertion. Therefore, regularly check for any damage to the IV set during infusion.

• When the flow is obstructed due to kinking of the IV tubing or clogging of the needle or filter, it can cause the pressure increment in the IV set and cause the IV tubing to be inflated with the solution. Complete removal of the obstruction will allow the solution to be delivered to the patient. If the flow is obstructed, take appropriate actions after completely closing the roller clamp of IV set.

• The pump is connected to an AC power outlet to be operated. If there is no available AC power outlet, the pump can be operated with only its built-in battery.

• The spill of the solution on the AC power inlet may cause a short circuit.

• In case of malfunction, do not try to take the unit apart or attempt to repair by yourself. Please contact your local authorized dealer immediately. If the user does not comply with these warnings, System cannot be held liable and the warranty does not apply.

3.2 Precautions

• The pump does not detect if the solution is infused out of the blood vessel. Please check the puncture site and monitor the patient's condition carefully.
• Do not try to use the pump for other purposes such as blood transfusion.
• The pump is not portable equipment, Fix the pump securely to a pole stand and check its stability.
• The pump must be used in accordance with this instruction manual by trained medical personnel.
• Be sure to use components including power cord, provided or recommended in this manual.
• When alarm sounds, please take corrective actions. (Refer to troubleshooting)

3.3 Cleaning and disinfection

Before cleaning the pump, make sure to power off the pump and disconnect the AC power cord. Do not immerse the pump in any liquid nor allow any liquid to leak into the pump. If spillage into the pump mechanism occurs, clean immediately by wiping with a soft cloth.

• Do not use drier to dry the unit.
• Used pumps should be disinfected before use on another patient.
• Do not clean, disinfect or sterilize any part of the pump by autoclaving or with ethylene oxide gas. Doing so may damage the pump and void the warranty.
• Do not use the following chemicals on the pump, as they will damage the front panel.
• Acetone, ammonia, benzene, hydroxytoluene, methylene chloride, n-alkyl dimethyl ethylbenzyl ammonium chloride, and ozone.

NOTE

• If cleansers or disinfectant solutions used, Follow manufacturers' dilution instructions for concentrated cleansers or disinfectant solutions.

• Cleaning procedures:

Open pump door, use cloth sparingly dampened with any cleanser list in List 3.1. Wipe the split of bubble sensor. Wipe peristalsis fingers. Wipe the occlusion sensor, tension plate and other surface in it. Close pump door, wipe enclosure surface. Ensure that clean cloths do not become contaminated. Allow surfaces to remain wet for 30 seconds.

• Disinfection procedure:

Open pump door, use cloth sparingly dampened with any infectant solution list in List 3.2. Wipe the split of bubble sensor. Wipe peristalsis fingers. Wipe the occlusion sensor, tension plate and other surface in it. Close pump door, wipe enclosure surface.

List 3.1 recommended cleanser

A solution of 10% bleach and water
Soapy water
Isopropyl alcohol up to 75%
Distilled water

Lists 3.2 recommend disinfectant solution and manufacture

Super Edisonite	Edison Chemical Co.
Cleaner	Manufacturer
LpH, Septisol	Vestal Labs
Cidex 7	Surgikos
TOR or Hi-Tor Plus	Huntington Labs
Super Edisonite	Edison Chemical Co.
Bafix	Hysan Corp.

3.4 Storage

• Avoid the following environment for storage and transport of the Infusion Pump
- Where the unit is exposed to dirt or heavy dust.
- Where the unit is exposed to salty atmosphere.
- Where the unit is exposed to severe vibration or corrosive gas.
- Where the unit is exposed to rough handling.
- Where the unit is exposed to direct sunlight or UV light.
- Where the unit is exposed to water.
- Where the unit is exposed to extreme temperature and humidity.

3.5 Maintenance and repair

• If any irregularity and failure are detected, stop operation of the pump immediately and contact your local authorized dealer to repair or replace by supplying the details of the situation. Never try to disassemble or repair by yourself because it could cause further serious failure.

• Make sure that there is any damage with the pump and components. In case that the unit and components were shocked; do not use them even if visible damages are not observed. Please contact your local authorized dealer.

• Contact your local authorized dealer for periodical inspection of the pump for safety and longer product life.

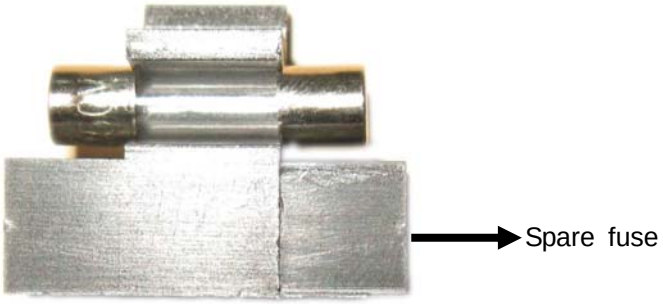
• The pump can keep working for at least 3 hours at 25ml/h when powered by fully charged built-in battery. If the battery is low, the pump will stop running in 30 minutes if there is no way to connect the pump to an AC power outlet. After that pump will keep alarm until battery is exhausted.

• Operate the pump with the built-in battery once a month to check its performance because the built-in battery is subject to aging. If the operation time is getting short after it is normally recharged, contact your local authorized dealer to replace with a new battery. Please be sure that your local authorized dealer checks it annually.

• Please recharge the built-in battery fully for more than 8 hours by connecting the pump to an AC power outlet before the pump is used for the first time or after a long interval.

3.6 Replace a fuse

Pull the fuse holder out. Replace a fuse as the figure showed. Push the fuse holder to its position.



The fuse must be F0.25AL250V.

3.7 Packing list

No.	Description	Qty.
1	Infusion Pump	1
2	Power Cord	1
3	User's Manual	1
4	Certificate	1
5	IV Set	1

3.8 Alarm testing

Self-checking when pump starts	Switch on the pump, system program will check itself automatically: all lights will be on, along with a beep.
Bubble testing	Switch on the pump, when there is no IV set in bubble sensor slot, AIR should display; set up the IV set in bubble sensor slot after making sure IV set is full of liquid, AIR should be off.
Occlusion testing	Switch on the pump, set up the flow rate and VTBI. The pump alarms and OCCL displays when IV set is blocked for a while.
Opened-door testing	Switch on the pump, when the door is opened, DOOR should display; when the door is closed, DOOR should be off.

3.9 Disposal of waste product

• Waste product should be disinfected and sterilized before disposal. After that, please handle it refer to local laws.

- When battery reaches the end of life, do not throw it into fire or water; do not disassemble, recharge, or short it. Please handle it refer to local laws.

4 OPERATION

Caution

• When to press buttons or watch LCD, operator must face to pump front panel, with a distance about 50 cm.

4.1 Install the pump on a pole stand

• Fix the pump securely on a pole stand, using the pole clamp at the rear of the pump.

• Referring to right figure, put the pole into the pole clamp, and fasten the screw as the arrow direction to fix the pump.

4.2 Connect to AC power

• Connect the provided AC power cord to the AC power inlet at the back of the pump and to an AC power outlet.

NOTE

• Alternatively, the pump may be operated by built-in battery.

4.3 Switch on the pump

• When switch on the pump, the built-in battery will automatically come into being recharged.

NOTE

• When turn on the power switch, all LCD will be flashing for 500ms, and give a beep. Then pump enters standby mode. Please confirm the actions to make sure all LCD and speaker can work properly.

• After flashing, as in the drawing below, [AC] LCD will automatically keep on.

NOTE

• In standby status, LCD of volume display "Ln *"  , shows the number of IV set selected. LCD of rate alternate display "Oc **" and "dr **", shows the occlusion sensitivity setting and drop/ml setting. Refer to IV set calibration.

4.4 Press [START/STOP] key

• When pump in standby mode, press [START/STOP] key to let pump enter stop mode. In stop mode, pump displays last successful infusion setting parameter of flow rate and VTBI... Flow rate and VTBI can be set in stop mode. Infused volume can be cleared by pressing [CLEAR] key.

4.5 Prime an IV set

1. Connect IV set to the infusion (fluid) bag or solution container.
2. Fill the solution into the drop chamber up to one third.
3. By opening the roller clamp of the IV set, make a few drops of solution out of the hypodermic needle.
4. When priming is completed, close the roller clamp.

NOTE

Do not put the container 1.3m above or 0.5m below patient's heart, otherwise rate precise can't

assurance.

4.6 Install an IV set

1. Open the door set the IV tubing properly in place, make sure that the tubing sits in the bubble sensor and keeps straight through the peristaltic finger and the occlusion sensor.

2. Push the tubing clamp and clamp the IV set.

Caution

• If the IV set does not keep straight over the Peristaltic finger section, the desired flow rate may not be achieved.
• When the same site of the tubing has been set at peristaltic finger section for a long time (over 12 hours), use it after moving the IV tubing connected to this pump at a distance of more than 10 cm. Deformation of IV tubing arising from long time (over 12 hours) use can affect the accuracy.
• The tube should be replaced with a new one every 24 hours.

NOTE

• If there is a need to replace IV set with a new one while using the pump, follow the below procedure.

1）Stop the operation

2）Open the door, close the roller clamp, and remove IV set

3）Replace IV set and prime the IV set

4）Set IV set back properly in place

5）Close the door and open the roller clamp

6）Restart infusion

4.7 Close the door

• Close the door.

Caution

• Make sure the IV set is not clamped by the door.

4.8 Set flow rate (ml/h, drop/min and time-based)

1. Simultaneously press [DEC] [SET] key to select flow rate mode.

Caution

• The flow rate area will toggle display 'ml/h' , 'drop/min' and time-based, make sure the unit of flow rate displays properly. Wrong unit will cause big error.

2. Press [INCR] or [DECR] key at flow rate area to increase or decrease the flow rate.

NOTE

• Keep pressing [INCR] or [DECR] key, the digital will increase or decrease continuously.

• Keep pressing [INCR] or [DECR] key for several seconds, the digital will change faster.

• The flow rate range is as follows

1~1100 ml/h (in 0.1 ml/h increments)

1~366 drop/min (in 1 drop/min increments)

NOTE

• This is a volumetric Infusion Pump. Both drop/min and time-based are calculated as ml/h and start at that rate.

4.9 Set VTBI (volume to be infused) (ml)

• The VTBI can be set from 1 to 9999ml in 1ml increments.

• The pump initially displays the infused volume of last operation.

• Press [INCR] or [DECR] key to increase or decrease the VTBI.

NOTE

• Keep pressing [INCR] or [DECR] key, the digital will increase or decrease continuously.

• Keep pressing [INCR] or [DECR] key for several seconds, the digital will change faster.

• The flow rate range is as follows

1~9999 ml (in 1ml increments)

• Make sure that the VTBI should be set slightly lower than the amount of solution in the solution container so that the pump can continue the infusion at the lowest rate (KVO rate) after the infusion completion.

NOTE

• Infusion will not start in case that the VTBI is set at 0000 ml

• After starting infusion, the LCD displays infused volume in about 3 seconds.

4.10 Open roller clamp of an IV set

• Open roller clamp of an IV set.

• Make sure that the solution neither comes into the drop chamber nor comes out of the needle. If solution does, please confirm that IV set is of a recommended type, that the IV tubing is set properly, and IV set is in good condition. When none of the above is found, the pump fault may be suspected. Stop the operation of the pump and contact your local authorized dealer

4.11 Insert a hypodermic needle into a patient

• Insert a hypodermic needle into a patient.

• The pump is not designed to detect if the solution is infused out of blood vessel. Please regularly check the puncture site and monitor the patient's condition carefully.

4.12 Press [START/STOP] key to start infusion

NOTE

• Before operating the pump, make sure to check flow rate, VTBI, "drop/ml" and the IV set again.

• Press [START/STOP] key to start infusion, pump enters run mode.

• [FLOW] LED on top of the pump door flickers. This means the pump is running.

• Check the drop rate of the solution to make sure that it is being delivered at the selected flow rate.

• If any irregularity is observed, immediately stop the pump and contact your local authorized dealer.

4.13 Infusion completion

• When the infused volume reaches the VTBI, the "FINISH" indicator will be on, along with alarm sound. The pump continues the infusion at the following KVO rate.

Flow rate setting	KVO rate
>= 4ml/h	4 ml/h
< 4ml/h	Same as flow rate setting

• Pressing [START/STOP] key to stop KVO mode.

• Before opening the door of the pump in order to release the tubing clamp and remove the IV set, make sure to close the roller clamp completely.

• Free flow will occur if the IV set is removed or the tubing clamp is released without completely closing the roller clamp.

5 SPECIAL FUNCTIONS

5.1 System memory of infused volume & flow rate

• Switch on pump, the infused volume and flow rate that were set previously are shown on the LCD. The infused volume & flow rate can be kept for 8 years in the internal memory.

• The new value can be set by pressing [INCR] or [DECR] key.

5.2 Reminder alarm function

• When pump in stop mode, if no corrective action is taken within 2 minutes the alarm will sound. Press any key to silence the alarm.

5.3 Temporarily stop infusion

• Press [START/STOP] key, pump stops and enters stop mode.

• Before restarting the infusion, make sure to check the flow rate, VTBI and "drop/ml" that were set and then press [START/STOP] key.

5.4 Purge

• When [PURGE] key is double pressed and held, the pump delivers the solution at a flow rate of 700 ml/h.

NOTE

• In "STOP" mode, Purge function can be used for removing air in IV set.

• In "RUN" mode, The volume infused by purging is added to the value of total infused volume

Warning

Alarms will not work while purging. Make sure the pump is in normal condition after purging.

5.5 Clear infused volume

• In stop mode, if the [CLEAR] key is pressed, the infused volume will become "0".

Caution

• Before restarting the infusion, make sure that the parameters of flow rate, VTBI and "drop/ml" are set correctly. If different, set flow rate, VTBI and "drop/ml" again.

NOTE

• In case of restarting infusion after clearing the infused volume, the pump will start to deliver the solution newly from "0" to the VTBI specified previously if the new VTBI setting is not taken.

5.6 Run the pump with built-in battery

• The pump is automatically switched to the built-in battery and [LOW BATT] LCD lights on when the AC power is not supplied.

• The built-in battery is recharged by connecting the pump to an AC power outlet when pump is stwitched on.

• The pump can be operated on the built-in battery for about 3 hours at 30ml/h.

NOTE

• When the battery is new, it should be recharged for more than 8 hours.

• During infusion, if [LOW BATT] LCD light on with the alarm sound, the built-in battery should be recharged by connecting the pump to an AC power outlet without pressing any key, otherwise the pump may stop running because it means the voltage of the built-in battery will be depleted in 30 minutes

• When the voltage of the built-in battery is depleted the pump will stop running with the alarm.

• The battery is subject to aging. Please have your local authorized dealer check it annually.

• To keep the battery in good condition, fully recharge it at least once a month even if it is not used for a long time.

• Please confirm if the built-in battery works properly by turning on the Infusion Pump without connecting to an AC power outlet once a month.

• When using the pump for the first time, or if it is used after a long interval, recharge the built-in battery fully by connecting the pump to an AC power outlet for more than 8 hours.

6 TROUBLE SHOOTING

Take the following actions if any trouble occurs. When the troubles could not be solved with the following actions, Please contact your local authorized dealer immediately.

NOTE • Whenever alarm sounds, the pump will stop infusion and indicator on LCD is flickering.

Symptom	Cause	Action
Pump cannot be switched on.	• AC power cord is not inserted properly	Check the AC power cord connection.
	• Built-in battery has deteriorated.	Stop the operation of the pump and replace with a new battery through your local authorized dealer.
	• The voltage of the built-in battery is low.	Recharge the battery fully for more than 8 hours by connecting the pump to an AC power outlet and turn it on.
The [AIR] LCD light on and alarm sounds continuously	• Air bubble in IV set. • IV set is not properly placed. • Bubble sensor is stained.	1. Turn the alarm off by pressing [START/STOP] key. Pump enters "stop" mode. 2. Close the roller clamp of the IV set 3. Take the IV set from the pump and tap the tube to make the air bubble gather into the drop chamber. 4. In case that bubble sensor is stained, clean it with a gauze cloth or similar, moistened with cold or tepid water. 5. Set the IV set backs properly in place. 6. Close and lock the door securely. 7. Open the roller clamp of the IV set. 8. Make sure that the parameters of flow rate, VTBI and "drop/ml" are set correctly. 9. Restart infusion by pressing [START/STOP] key.
	• IV set is not compatible with this pump.	Check the compatibility of IV set with your local dealer.
The [OCCLUSION] LCD light on and alarm sounds continuously	• The roller clamp is closed.	1. Turn the alarm off by pressing [START/STOP] key. Pump enters "stop" mode. 2. Open the roller clamp on IV set. 3. Make sure that the parameters of flow rate, VTBI and "drop/ml" are set correctly. 4. Restart infusion by pressing [START/STOP] key.
	• IV set is not compatible with this pump.	Check the compatibility of IV set with your local dealer.

Symptom	Cause	Action
	• IV Tubing is kinked or twisted • IV set is not properly placed • IV Tubing is stretched or shrunk	1. Turn the alarm off by pressing [START/STOP] key. Pump enters "stop" mode. 2. Close the roller clamp on IV set. 3. Open the door and take the IV set from the pump, check the IV set and take a corrective action like untwisting or replacing with a new one to solve the problem of occlusion. 4. Set the IV set back properly in place.
All red LCD flash and alarm sounds continuously. "Er-1" or "Er-2" show on the LCD.	• Battery is depleted, when pump powered by built-in battery	1. Turn off power switch at the back of pump. 2. Plug in AC power cord, if it isn't plugged in. 3. Turn on power switch at the back of pump. 4. LCD should flash, if not stop the operation of the pump and replace with a new battery through your local authorized dealer. If battery be charged normally go to next step. 5. Make sure that the parameters of flow rate, VTBI and "drop/ml" are set correctly. 6. Restart infusion by pressing [START/STOP] key. If this symptom happens again and again, please contact your local authorized dealer to replace the battery.
	• Peristaltic finger system out of work.	1. Turn the alarm off by pressing [START/STOP] key. Pump enter "stop" mode. 2. Restart infusion by pressing [START/STOP] key. 3. Listen close to peristaltic finger system, if there isn't any noise; contact your local authorized dealer.
All red LCD flash and alarm sounds continuously.	• The setting of "drop/ml" is not correct.	1. Set the correct "drop/ml". (Refer to IV set calibration).
	• The same site of the tubing has been set at peristaltic finger section for a long time (over 12 hours). • IV tubing is not properly placed	1. Turn the alarm off by pressing [START/STOP] key. 2. Close the roller clamp on IV set. 3. Open the door. Either move the IV tubing connected to this pump at a distance of more than 10cm to reset or replace IV set with a new one. 4. Set the IV set back properly in place. 5. Close and lock the door securely. 6. Open the roller clamp of IV set. 7. Make sure that the parameters of flow rate, VTBI and "drop/ml" are set correctly. 8. Restart infusion by pressing [START/STOP] key.
	• IV set is not compatible with this pump.	Check the compatibility of IV set with your local dealer.
"Er-P"" shows on the LCD. Cannot start the pump.	• Occlusion sensor is abnormal	Follow the steps for shift IV set. Try to dismount IV set and mount it again. If this symptom happens again and again, please contact your local authorized dealer to replace the battery.

Symptom	Cause	Action
All red LCD flash and alarm sound continuously.	• Program is abnormal.	Check if there exists some strong interfere, or failure of power system, or pump very close to a heavy load. Try to use pump at a stable environment. Power cycle the pump and use it. If this symptom happens again and again, please contact your local authorized dealer.

• Before restarting infusion, Make sure that the parameters of flow rate, VTBI and "drop/ml" are set correctly.

• After restarting infusion, check flow rate to confirm the delivery of the solution at the selected rate.

TROUBLE SHOOTING - OTHERS

In this pump, flow rate is not controlled by drop sensor. Therefore, to correct the fluctuations of volume of a drop caused by viscosity of solution, flow rate and VTBI should be compensated. Please refer to IV set calibration.

• Without the above compensation, the actual flow rate might be lower than intended but the pump could not detect it.

7 SPECIFICATIONS

7.1 Infusion

FLOW RATE	1 ~ 1100ml/h (1ml/h increments)
ACCURACY WITH APPROVED IV SET	ml/h control mode: ±5%
VOLUME TO BE INFUSED	1 ~ 9999ml (1ml increments)
VTBI RANGE	1 ~ 9999ml
SENSITIVITY OF THE AIR DETECTOR	<=40μL
KVO RATE	4ml/h when flow rate setting >= 4ml/h Keep the same rate when flow rate setting < 4ml/h
COMPATIBLE IV SET	Can be calibrated to major brands (see Section 9). IV set with external diameter 3.8±0.2mm, inner diameter 2.8±0.2mm is recommended. HANACO H-06APD IV set is recommended.

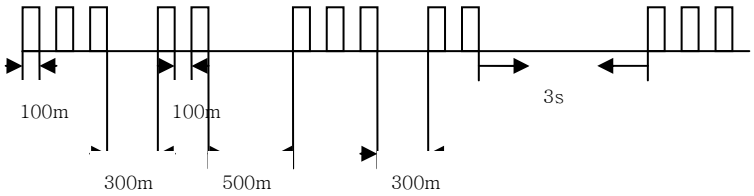
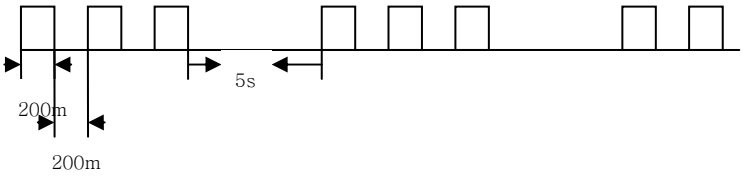
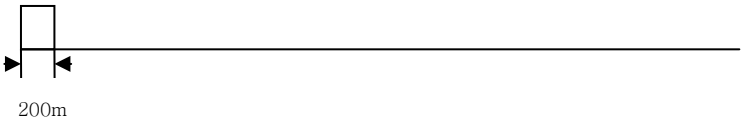
7.2 Mechanical

PUMPING MECHANISM	Linear peristaltic finger
DIMENSIONS (W×D×H)	174×126×215 (mm) without pole clamp
WEIGHT	Approximately 2.5kg
WATER PROOF CLASSIFICATION	IPX3

7.3 Alarm condition

Alarms	Priority	Alarm condition
AIR IN LINE	high	when an air bubble is in the IV tubing
OCCLUSION	high	when the IV tubing is obstructed
DOOR OPEN	high	when the door is open
FLOW RATE ABNORMAL	high	When flow rate faster or slower 20% than setting rate.
INFUSION COMPLETION	Middle	When VTBI is delivered.
LOW BATTERY	Middle	when battery capacitor is low
REMINDER ALARM	Middle	No operation and pump in standby mode in 2 minutes
AC FAILURE	low	AC source accidentally off
All alarms are TECHNICAL alarm.		

7.4 Alarm sound parameters

High priority	
Middle priority	
Low priority	

7.5 Delay of alarms

Alarms	Alarm condition delay	Alarm signal generation delay
AIR IN LINE	125ms	75ms
OCCLUSION	20S	200ms
LOW BATT	1S	200ms
DOOR OPEN	1S	200ms
FLOW RATE ABNORMAL	2160S @ 1ml/h 90S @ 25ml/h	200ms
FINISH	10ms	200ms
AC FAILURE	1S	200ms
REPEAT ALARM	120S	200ms

7.6 Features

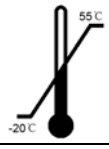
PURGE RATE	700 ml/h
VOLUME MEMORY, TEMPORARY STOPPING, CLEAR INFUSED VOLUME, OCCLUSION PRESSURE CONTROL	

7.7 Other parameters

POWER REQUIREMENTS	230V AC, 50/60Hz 8*AA Ni-MH battery 9.6 VDC
POWER CONSUMPTION	20VA
ALARM SOUND PRESSURE	Over 65db @ 1m distance
CLASSIFICATIONS	Class I / built-in power supply / Type CF
BATTERY / OPERATION / CHARGING	Ni-MH / 3 hours (at 30ml/h) / more than 8 hours
BATTERY LIFE	1 year
OPERATION CONDITIONS	10~30℃, 30~75% RH (no condensation)
STORAGE CONDITIONS	-20~55℃, ≤93% RH (no condensation)
WARRANTY PERIOD	1 year

※*Specifications and design are subject to change for improvement without prior notice*

8 SYMBOLS

Symbol	Description
	Caution, consult accompanying documents
	Manufacturer
	Refer to instruction manual / booklet
	Lot number
	Serial number
IPX3	Waterproof level
	AC
	Grounding terminal
	Do not throw it into wastebin
	Type CF equipment (protection against electrical shock)
	Stack products not exceed 3 packages
	Keep dry
	Storage conditions: -20~55℃

9 IV SET CALIBRATION

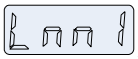
9.1 IV set calibration

• Use Infusion Pump for the first time or change a new brand of IV set, Calibration is needed. If infusion accuracy get worse or work Condition changed for example temperature, humidity changed. Calibrate the IV set can get a better infusion accuracy.

• Infusion accuracy can not be guaranteed if non-calibrated or non-compatible (as mentioned in Chapter 7) IV sets are used.

Please follow the steps below to calibrate an IV set.

Materials required but not provided: 10 ml cylinder / syringe.

1. Open pump door, there are six DIP switches for each specific IV set, located at the top right corner of the pump. Select one switch for the new IV set brand and keep a record. Close pump door.
2. Keep pressing [INCR] key and simultaneously switch on the pump, "FLOW RATE" area displays "1111" (see Figure 1).
3. Press [DECR] key, "FLOW RATE" area displays  . "VOLUME" area displays "0.0". The pump will calibrate the IV set at a low flow rate.
4. Put the hypodermic needle in the cylinder / syringe. Open roller clamp.
5. Press [START/STOP] key to start calibration.

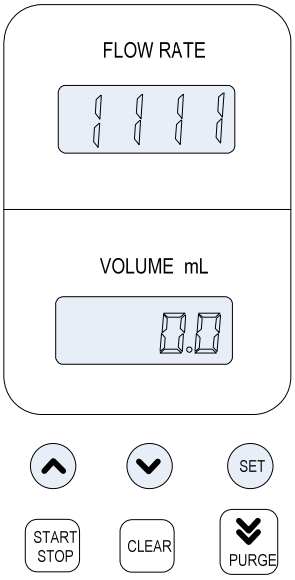
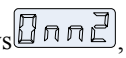
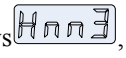


Figure 1 IV set calibration

6. The pump stops when "VOLUME" area displays "5.0". Read the real value of the infused liquid in the cylinder / syringe. Enter the real value in the "VOLUME" area by pressing [INCR] or [INCR] key. Press [START/STOP] key to save the calibration data of the low flow rate. Remove the infused liquid from the cylinder / syringe.
7. It is strongly recommended to repeat "STEP 5-6" twice to get a better accuracy, at least get a real value of "5.0".
8. Press [DECR] key, "FLOW RATE" area displays  , the pump will calibrate the IV set at a medium flow rate. Repeat "STEP 5-7".
9. Press [DECR] key, "FLOW RATE" area displays  , the pump will calibrate the IV set at a high flow rate. Repeat "STEP 5-7".

10. Restart the pump and ready for infusion.

Please repeat "STEP 1-10" to calibrate other IV sets.

NOTE • To get good performance, carefully measuring and operation are recommended.

A List is provided; customs can fill the list after calibration.

No.	IV set	Note
1		
2	Hanaco	Calibrated
3	JieRui	Calibrated
4		
5		

9.2 Flow rate testing

1. Prepare tools: IV set, 10 ml cylinder / syringe, chronograph.

2. Refer to Chapter 4, Set up IV set, Set VTBI to 5 ml, Set flow rate to 25ml/h, put hypodermic needle in the cylinder / syringe, press [START/STOP] key and start chronograph simultaneously.

3. Wait for infusion completion, and stop the chronograph. Check infused volume in the cylinder, it should be 5 ml ±5%. Check infusion time, it must be 12 min ±1%. Otherwise, recalibration is recommended.

9.3 "drop/ml" setting

NOTE • drop/ml varies with different IV set, it is recommended to set drop/ml for the IV set to be used.

1. Open pump door, there are six DIP switches for each specific IV set, located at the top right corner of the pump. Select one switch for the new IV set brand and keep a record. Close pump door.
2. Keep pressing [INCR] key and simultaneously switch on the pump, "FLOW RATE" area displays "1111" as figure 1.
3. Press [INCR] key again, "FLOW RATE" area displays "2222" (see Figure 2).
4. Press "SET" key, "20" will be flickered. Enter the expected drops by pressing [INCR] or [DECR] key. Press [START/STOP] key to save the data of drop/ml setting.
5. Restart the pump and ready for infusion.

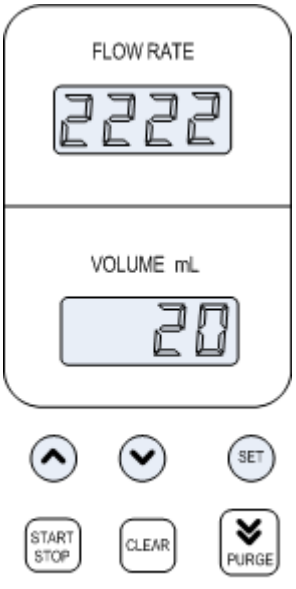


Figure 2 drop/ml calibration

NOTE • drop/ml value is limited between 10~30.

NOTE • After setting drop/ml, rate convert change to ml/h = drop/min / (drop/ml) * 60.

9.4 Occlusion sensitivity setting

When high flow rate or high concentration liquid is required, the occlusion sensitivity can be adjusted to an appropriate value. The default value is 2.

1. Open pump door, there are six DIP switches for each specific IV set, located at the top right corner of the pump. Select one switch for the new IV set brand and keep a record. Close pump door.
2. Keep pressing [INCR] key and simultaneously switch on the pump, "FLOW RATE" area displays "1111" (see Figure 1).
3. Press [INCR] key again, until "FLOW RATE" area displays "4444". Press [DECR] key twice, until the pump displays "Pr-2" (see Figure 3).
4. Press [SET] key. Select the expected sensitivity level (level 1, 2, 3) by pressing [INCR] or [DECR] key. Press [START/STOP] key to save occlusion sensitivity.
5. Restart the pump and ready for infusion.

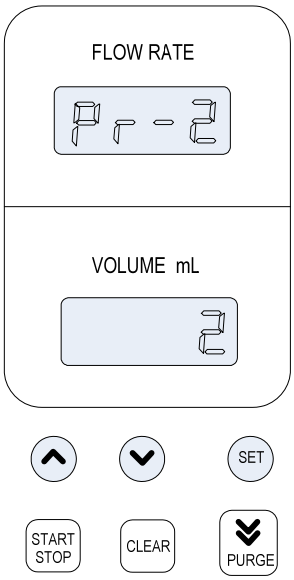


Figure 3 Occlusion Sensivity Setting

NOTE The maxim infusion pressure is set at 0.3~0.4MPa.

Highest sensitivity is limited to 1 and lowest sensitivity is limited to 3. The list below is occlusion alarm threshold.

1: 0.06 ~ 0.10 MPa

2: 0.10 ~ 0.14 MPa

3: 0.14 ~ 0.18 MPa

10 EMC DECLARATION

The Infusion Pump needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents;

Portable and mobile RF communications equipment can affect the Infusion Pump.

All cables and maximum length of cables and other accessories with which the manufacturer of the Infusion Pump claims compliance with the requirements, Accessories that do not affect compliance with the requirements of these sub clauses need not be listed. Accessories and cables may be specified either generically or specifically.

NOTE • Cables sold by the manufacturer of the Infusion Pump as replacement parts for built-in components need not be listed.

The use of accessories and cables other than those specified, with the exception of cables sold by the manufacturer of the Infusion Pump as replacement parts for built-in components, may result in increased emissions or decreased immunity of the Infusion Pump.

Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS		
The Infusion Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Infusion Pump should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Infusion Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Not Comply	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Comply	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Infusion Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Infusion Pump should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 2,4, 6, 8 kV contact ± 2,4,8,15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Infusion Pump requires continued operation during power mains interruptions, it is recommended that the Infusion Pump be powered from an uninterruptible power supply or a battery.

	(30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	(30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	400 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The Infusion Pump is intended for use in the electromagnetic environment specified below.
The customer or the user of the Infusion Pump should assure that it is used in such an environment.

IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bandsa	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Infusion Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10V/m	

Recommended separation distances between portable and mobile RF communications equipment and the Infusion Pump

The Infusion Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Infusion Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Infusion Pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output powerof transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0.117	0.117	0.233
0,1	0.36999	0.36999	0.73681
1	1.17	1.17	2.33
10	3.69986	3.69986	7.36811
100	11.7	11.7	23.3

11 WARRANTY

The Infusion Pump has been carefully manufactured from the highest quality components. The pump is guaranteed against defects in material and workmanship for twelve (12) months from the date of shipment.

Manufacturer's obligation, or that of its designated representative under this Warranty, shall be limited, at our option, to repairing or replacing the pump, which upon examination, is found to be defective in material or workmanship. The repair or replacement of any product under this Warranty shall not extend the above mentioned Warranty period.

Only qualified, trained service personnel should undertake all repairs under this Warranty. In the event that a pump is found to be defective during the warranty period, the purchaser shall notify manufacturer or its designated representative within thirty (30) days after such defect is discovered.

The defective pump should be sent immediately to manufacturer or its designated representative for inspection, repair or replacement. Returned pump should be properly packaged to avoid damage.

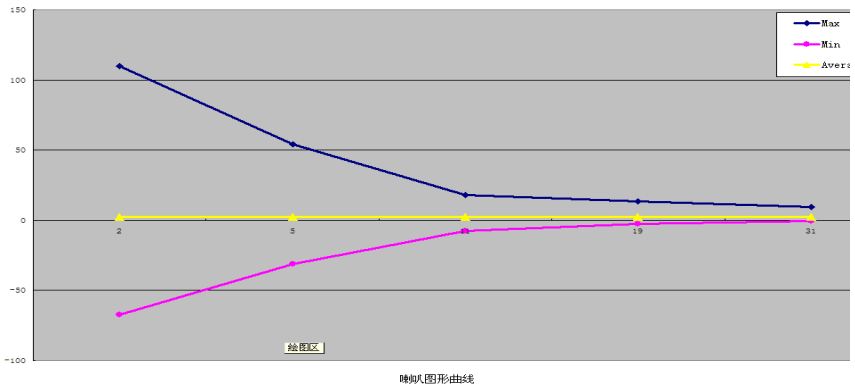
This Warranty shall not apply to defects or damage caused, wholly or in part, by negligence, spilt fluids, dropping of the pump, misuse, abuse, improper installation or alteration by anyone other than qualified, trained personnel; or to damage resulting from inadequate packaging in returning the pump.

This Warranty is the sole and entire warranty pertaining to manufacturer's products and is in lieu of and excludes all other warranties of any nature whatsoever, whether stated, or implied or arising by operation of law, trade, usage or course of dealing, including but not limited to, warranties of merchantability and warranties of fitness for a particular purpose.

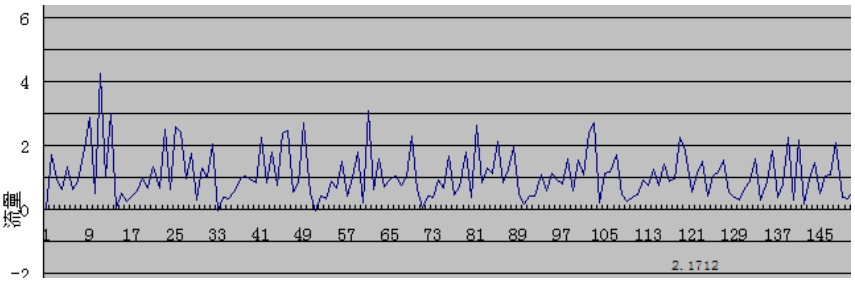
Purchaser expressly agrees that the remedies granted to it under this Warranty are purchaser's sole and exclusive remedies with respect to any claim of purchaser arising under this Warranty.

APPENDIX A Chart of flow rate VS time

1. 1ml/h chart

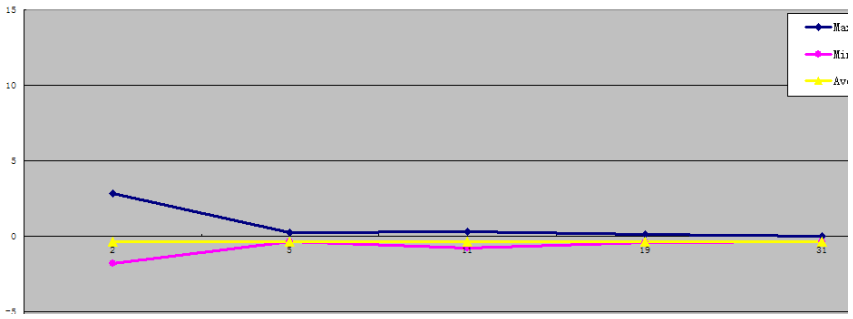


1ml/h bugle shape chart

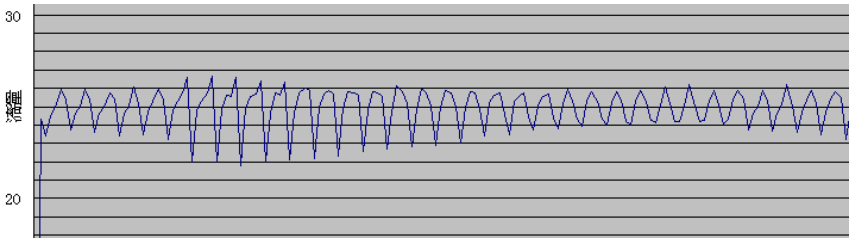


1ml/h flow rate chart

2. 25ml/h chart



25ml/h bugle shape chart



25ml/h flow rate chart

NOTE • Charts for reference, Data will vary when change IV set or test condition.

APPENDIX B Bolus, duration, pressure value

The duration of giving an alarm, pressure value and bolus value when IV tubing occluded.

Flow rate	Pressure value	duration (h/m/s)	Bolus (g)
1ml/h	≦0.08 MPa	≦1/15/0	≦0.94
25ml/h	≦0.08 MPa	≦0/2/23	≦0.87
1100ml/h	≦0.08 MPa	≦0/0/5	≦0.86

NOTE • Only a reference, data varies when change IV set or test conditions.

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