Product Warranty Card

NAME:	DATE OF PURCHASE:
ADDRESS:	PURCHASE FROM:
ITEM PURCHASED: **TMS INFUSION PUMP (TI-600)**	REGISTRATION DATE:

Inmed Corporation warrants this product to be free from defects in material or workmanship within 1 year from date of purchase under normal use. If fault is found, please return the equipment, freight prepaid, in its original packaging along with the purchase receipt to the address below. Inmed Corporation will repair or replace any defective parts free of charge subject to the terms and conditions stated herein.

For service, the unit is to be returned freight prepaid to:

Inmed Corporation

5 Calle Industria, Bagumbayan,
Quezon City 1110, Philippines
Tel: 857.11888

Please register your unit online at www.inmed.com.ph

Distributed by:

TMS® Infusion Pump
TI-600

User's Manual

APPENDIX B Bolus, duration, pressure value

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

Flow rate	Pressure value	Duration (h/m/s)	Bolus (ml)
1ml/h	≦0.085 MPa	≦1/0/0	≦0.64
	≦0.0115 MPa	≦1/15/0	≦0.94
	≦0.1155 MPa	≦2/30/0	≦1.86
25ml/h	≦0.085 MPa	≦0/1/30	≦0.43
	≦0.0115 MPa	≦0/2/23	≦0.87
	≦0.1155 MPa	≦0/5/0	≦1.85
1100ml/h	≦0.085 MPa	≦0/0/3	≦0.41
	≦0.0115 MPa	≦0/0/5	≦0.86
	≦0.1155 MPa	≦0/0/15	≦1.88

NOTE Only a reference, data will vary when IV set or test condition is changed.

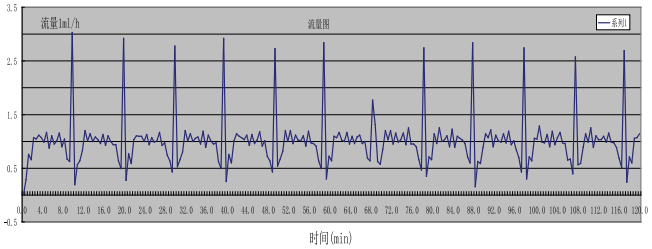
The duration in Single fault condition and bolus value

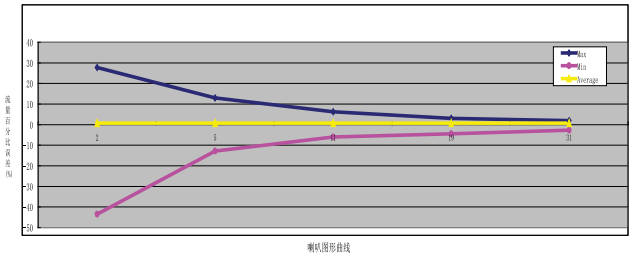
Flow rate	Single default condition	Duration (h/m/s)	Bolus (ml)
1ml/h	Rate abnormal	≦0/39/36	≦0.66
25ml/h		≦0/1/35	≦0.66
1100ml/h		≦0/0/3	≦0.66

CONTENTS

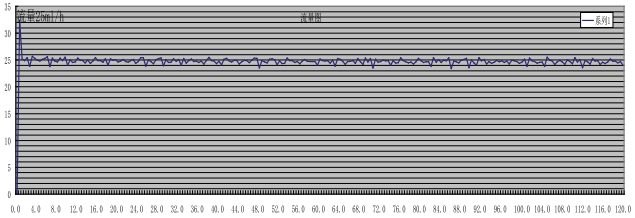
APPENDIX A Chart of flow rate VS time

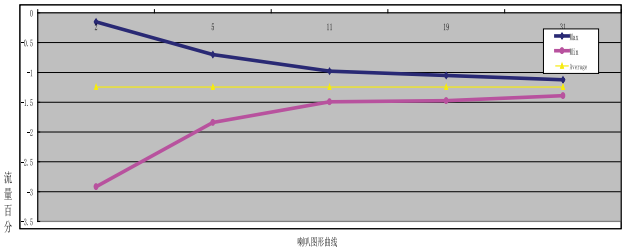
1. 1ml/h chart





2. 25ml/h chart





NOTE Charts for reference, data will vary when IV set or test condition is changed.

11. WARRANTY

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

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.

All repairs under this Warranty should be undertaken only by qualified, trained service personnel. 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. Material returned should be properly packaged to avoid pump 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.

Revision history

The following revision history table summarizes revisions contained in this document. The right is reserved to change or discontinue this product without notice.

Revision No.	Revision Date	Description of Changes
1.0	07/2011	Initial verison
1.1	17/06/2014	Update of European representative
1.2	25/08/2014	Update of Registration Information

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

Thank you for choosing our **Infusion Pump**.
In order to use this pump correctly and safely, read this manual carefully before operating 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 liquid with the equipped peristaltic finger system and the use of a drop senor control.

This 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.
- Compatibility with a variety of IV set.
- Low motor driving noise.
- Ultrasonic Bubble sensor.
- Easy to set the VTBI by up or down key on the front panel.
- Accurate setting of flow rate for patients.
- Flow-rate accuracy with the equipped peristaltic finger system and the use of a drop sensor control.
- The delivered volume reading can be cleared in menu 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 1ml/h increments.
- After delivering the VTBI, the pump enter KEEP VEIN OPEN (KVO rate) function,
- When door is open, the tube is automatically clamped.
- The rechargeable built-in battery will keep the pump working if AC power disconnects accidentally.

Rated maximum output power of transmitter	Seperation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
W	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$
0.01	0.12	0.12	0.07
0.1	0.37	0.37	0.22
1	1.17	1.17	0.70
10	3.69	3.69	2.21
100	11.67	11.67	7.00

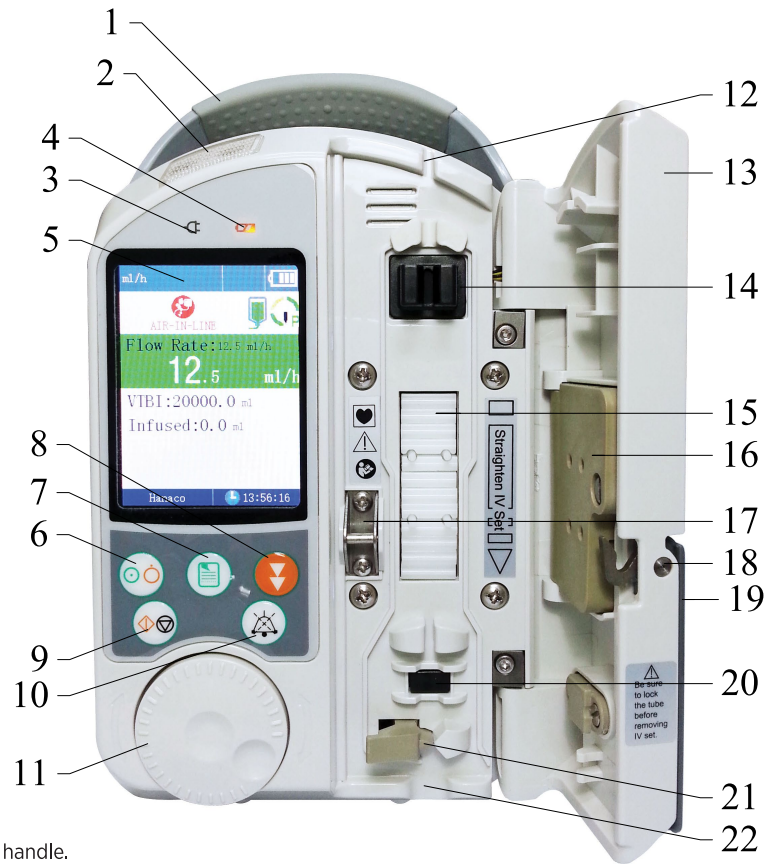
For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

	80 MHz to 2,5 GHz	80 MHz to 2,5 GHz	equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 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: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the field strength measured where the PUMP is used exceeds the applicable RF compliance level mentioned above, the PUMP should be observed to verify normal operation. If abnormal performance is found, additional measures should be taken, such as re-orienting or relocating the PUMP. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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

2. DESCRIPTION OF PUMP

2.1. Front view



1) Pump handle.
2) Alarm indicator and running indicator:
   Flash in red when pump in alarm condition. Flash in green in running condition.
3) POWER STATUS LED: Indicate pump powered by alternate current.
4) BATT and CHARGE LED: Flashing indicates battery under charging. On indicates pump powered by battery.
5) LCD: Display information.
6) [ON/OFF] KEY: Keep pressing this key to turn on or turn off pump.
7) [MENU] KEY: Press this key to enter main menu.
8) [PURGE] KEY: Remove air in the IV tubing.
9) [START/STOP] KEY: start or stop infusion, also act as a mute key.
10) [SILENCE] KEY: Press this key to mute the alarm sound.
11) Shuttle KEY.

11) Shuttle KEY.
12) Up position slot: guide IV set.
13) Pump door.
14) Bubble sensor: detect air bubble in the IV tubing.
15) Peristalsis fingers: Press the IV tubing to deliver the liquid.
16) Tension plate: press the IV tubing to generate pressure.
17) Door lock lever.
18) Door magnet.
19) Pump hook: Pull up this hook to close the door, then push it to lock the door.
20) Pressure sensor: Detect the occlusion of the IV set.
21) Tubing clamp: Automatically clamp the IV tubing when the door is open.
22) Down position slot: guide IV set.

Guidance and manufacturer's declaration – electromagnetic immunity			
The PUMP is intended for use in the electromagnetic environment specified below. The customer or the user of the 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PUMP requires continued operation during power mains interruptions, it is recommended that the PUMP be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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 PUMP is intended for use in the electromagnetic environment specified below. The customer or the user of the PUMP should assure that it is used in such an electromagnetic environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m	3 Vrms 150 kHz to 80 MHz 3 V/m	Portable and mobile RF communications equipment should not be used closely to any part of the PUMP, including cables, not closer than the recommended separation distance calculated from the

10. EMC DECLARATION

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

Portable and mobile RF communications equipment can affect the PUMP.

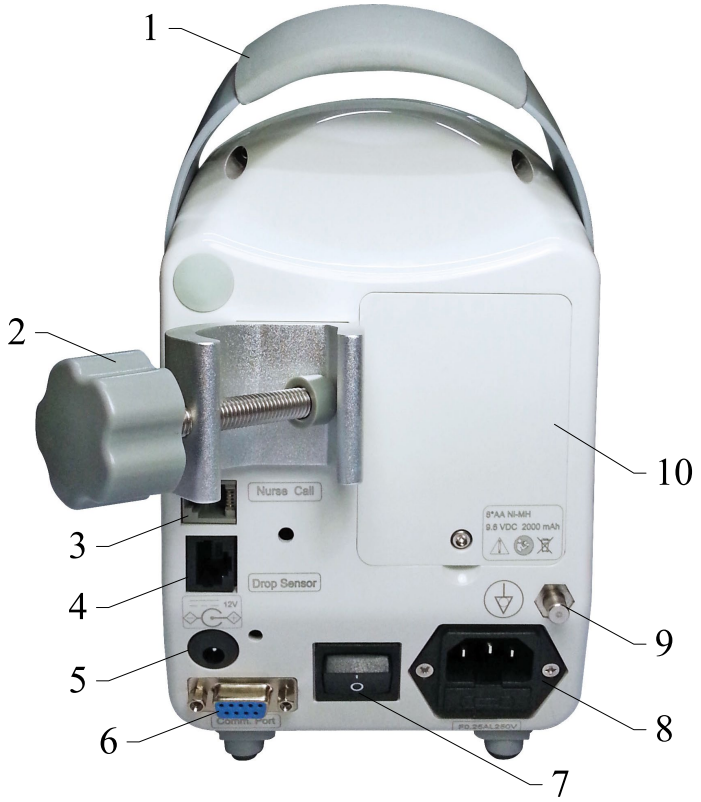
All cables and maximum length of cables, Transducers and other accessories with which the manufacturer of the PUMP claims compliance with the requirements, Accessories that do not affect compliance with the requirements of these sub clauses need not be listed. Accessories, transducers and cables may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

NOTE Transducers and cables sold by the manufacturer of the PUMP as replacement parts for internal components need not be listed.

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The PUMP is intended for use in the electromagnetic environment specified below. The customer or the user of the PUMP should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The 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	The PUMP is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This PUMP is intended to be used by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It is necessary to take mitigation measures, such as re-orienting or relocating the PUMP or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

2.2. Rear view



1) Pump handle.
2) Pole Clamp.
3) Nurse Call System connector:
   NOTE connect to Nurse Call System.
4) Drop sensor Connector:
   NOTE connect to drop sensor.
5) Vehicle power connector: Run the pump in a vehicle (ambulance).
6) Communicate port:
   NOTE For vendor use, or connect to medical equipments assigned by vendor.
7) Switch
8) AC Power inlet
9) Ground: Equipotential point.
10) Battery cover: Hex screwdriver needed to open it.

2.3. Components

Drop sensor

AC power cord

NOTE Drop sensor is optional.

3. Change the value of drop/ml.
4. Focus [SET] button and confirm by shuttle key, the IV set parameters will be saved after a beep.

NOTE Drop/ml value is limit between 10~30.

9.3. Occlusion sensitivity setting

1. Use shuttle key to select IV set brand as required.
2. Change the item value to “Occlusion”.
3. Mount the IV set with reference to Section 4 OPERATION. Connect IV set output to a manometer.
4. Press [START/STOP] key to run the pump, and observe the manometer, once the value reaches 0.04Mpa, press [START/STOP] key again to stop the pump.
5. Press [START/STOP] key to run the pump, and observe the manometer, once the value reaches 0.14Mpa, press [START/STOP] key again to stop the pump.
6. Read values of “@ 0”,”@ 0.04Mpa” and “@0.14Mpa”, if the values are increased, focus [SET] button and confirm by shuttle key, after a beep, the IV set parameters will be saved. Otherwise, Focus [Restart] button and confirm by shuttle key, release IV set pressure by open the door and IV tubing clamp, close the door, repeat 4-6 to calibrate again.

Figure 9.2 drop/ml setting

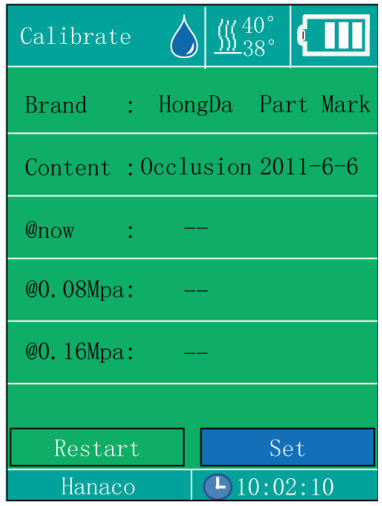


Figure 9.3 Occlusion calibration

9. IV SET CALIBRATION

Caution

Use Infusion Pump at first time or change a new brand of IV set, calibration is necessary.
If infusion accuracy get worse or work condition is changed, such as temperature and humidity change. Calibrate the IV set can get a better accuracy.
It is recommended doing calibration annually.

Refer to chapter 5 to Enter calibration window. There are 3 functions in this window: precise calibration, drop/ml setting and occlusion calibration. Refer to figure 9.1.

9.1. IV set calibration

Follow the steps below to calibrate the IV set.

1. Use shuttle key to select IV set brand as required.
2. Change the item value to “Flow rate”.
3. Select Rate value to Low.
4. Prepare a measuring cylinder of 10ml. Install the IV set with reference to Section 4 OPERATION.
   Put the IV set needle into the cylinder.
5. Press [START/STOP] key, pump starts with a beep and estimated VTBI will be displayed. When estimated volume arrives 5ml, pump stops with a beep. It takes about 2 minutes for this process.
6. Read the liquid volume in the measuring cylinder, change ‘Real vol’ value to the same as what you read by shuttle key.
7. Focus [SET] button and confirm by shuttle key, after a beep, the IV set parameters will be saved.
8. Empty liquid in measuring cylinder, repeat step 5~8 to improve accuracy.
9. Select Rate value to Medium or High, Pump will start to examine parameters of IV set at medium or high flow rate. Repeat step 5~8. To calibrate IV set in medium or high rate.
10. Please repeat steps 1~10 to calibrate other brand of IV sets.

NOTE

If the brand not be saved in the system, please define it by UserDef1 or 2; please do remember the correlative UserDef number of each brand.

Following blank is provided for recording the information after calibration.

No	IV set	Note
User Def1		
User Def2		

9.2. “drop/ml” setting

NOTE

Drop/ml vary from IV set, it is recommend to set drop/ml.
1. Use shuttle key to select IV set brand as required.
2. Change the item value to “Drop”.

3. PRIOR TO PUMP 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 because of 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.

Warning

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 the use of any other IV sets which is not recommended in this manual, contact your local authorized dealer for compatibility of IV sets with this pump before use. If an IV set with no compatibility is used, the accuracy of flow rate and alarm functions can not be guaranteed.
- Be sure that the IV tubing is properly fit in the tubing slots of Bubble sensor and Pressure 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 can not be guaranteed.
- During infusion, regularly check the flow rate to make sure that the liquid 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 manual 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 in the IV set to increase and cause the IV tubing to be inflated with the liquid. Complete removal of the obstruction will allow the liquid to be delivered to the patient. If the flow

obstructed, take appropriate actions after completely closing the manual roller clamp on 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 liquid 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 can not be held liable and the warranty does not apply.

NOTE Pump is optimized with HANACO IV set (from Tianjin China), if other IV set is used, please refer to chapter 9 to do calibration first. Otherwise, infusion accuracy can not be guaranteed.

3.2. Precautions

- The pump does not detect if the liquid 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.
- 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 switch off the pump and disconnect the AC power cord. Do not immerse the pump in any liquid or allow any liquid to leak into the pump. Before cleaning / disinfecting the drop sensor, make sure to disconnect the drop sensor from the pump. If leakage happens, clean immediately by wiping with a soft cloth.

Caution

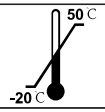
Do not use drier to dry the unit.
Used pump should be disinfected before reusing.
Do not clean, disinfect or sterilize any part of the pump by autoclaving or with ethylene oxide gas. It may damage the pump and void the warranty.
Do not use the following chemicals on the pump, as they will damage the 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 procedure:

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 pressure sensor, tension plate and other surface in it. Close pump door, wipe enclosure surface. Ensure that clean cloths are not contaminated. Allow surfaces to remain wet for 30 seconds.

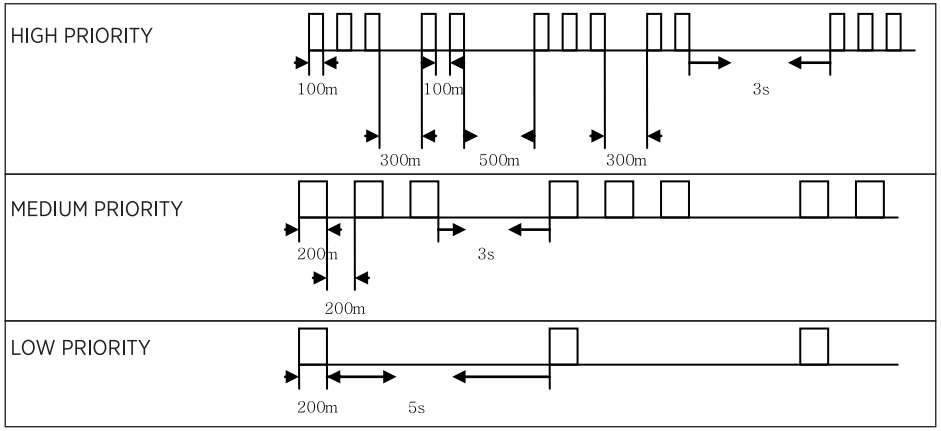
8. SYMBOLS

Symbol	Description
	Caution, consult accompanying documents
	Manufacturer
	Consult instructions for use.
	Lot number
	Device serial number
	Waterproof level
	AC
	Do not throw it into wastebin
	Type CF equipment (protection against electrical shock)
	Stack product not exceed 3 packages.
	Keep dry
	Authorized representative in the European Community.
	Temperature limitation for storage. The highest value is 50°C and the lowest value is -20°C

Alarm condition

Alarms	Priority	Lamp color & frequency	Alarm condition
AIR IN LINE	high	Red 2Hz	When air bubble is in the IV tubing
OCCLUSION	high	Red 2Hz	When the IV tubing is obstructed
LOW BATTERY	high	Red 2Hz	When low battery
DOOR OPEN	high	Red 2Hz	When the door is open
FLOW RATE ABNORMAL	high	All Red lamp on 2Hz	When flow rate is 20% faster or slower than set rate.
DROP	high	Red 2Hz	When drop pulse rate is 30% faster or slower than set rate.
INFUSION COMPLETION	medium	Yellow 0.5Hz	When infusion of VTBI is completed
AC FAILURE	low	Yellow light on	AC source is accidentally off
REPEAT ALARM	low	No lamp on	No operation and pump in standby mode in 2 minutes
All alarms are TECHNICAL alarm.			

Alarm sound parameters



Delay of alarms

Alarms	Alarm Condition Delay	Alarm Signal Generation Delay
AIR IN LINE	125ms	75ms
OCCLUSION	20S	200ms
LOW BATT	1 S	200ms
DOOR OPEN	1 S	200ms
FLOW RATE ABNORMAL	2160S @ 1ml/h 90S @ 25ml/h	200ms
DROP	20S	200ms
FINISH	10ms	200ms
AC FAILURE	1 S	200ms
REPEAT ALARM	120S	200ms

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

For the drop sensor, Wipe the main body with cloth sparingly dampened with any cleanser list in List 3.1, Push the case to find infrared windows and wipe them.

• 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 pressure sensor, tension plate and other surface in it. Close pump door, wipe enclosure surface.

For the drop sensor, Wipe the main body use cloth sparingly dampened with any infectant solution list in List 3.2, Push the case to find infrared windows and wipe them.

List 3.1 Recommended cleansers

A solution of 10% bleach and water
Soapy water
Isopropyl alcohol up to 95%
Distilled water

List 3.1 Recommended cleansers

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 for the 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 or 1hour at 1100ml/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 fuses

Pull the fuse holder out. 2 fuses in the holder replace the fuse; Push the fuse holder to its position. Please refer to figures below. The fuse must be F0.25AL250V.

3.7. Disposal of waste product

- Waste product should be disinfected and sterilized before disposal. After that, please refer to local laws to dispose it.
- When battery reaches the end of life, do not throw it into fire or water; do not disassemble, recharge, or short it. Please refer to local laws to dispose it.

7. SPECIFICATIONS

INFUSION

FLOW RATE	1 ~ 1200ml/h (in 0.1ml/h increments)
ACCURACY WITH CALIBRATED IV set	ml/h control mode: ±5%
VTBI	1 ~ 20000ml (in 0.1ml increments)
INFUSED VOLUME	1 ~ 20000ml
KVO RATE	Preset KVO rate : when flow rate setting >= preset KVO rate Same as flow rate: when flow rate setting < preset KVO rate
Compatible IV set	Can be calibrated to major brands in the market (see Sec. 9) IV set must meet ISO 8536-4:2004 Infusion equipment for medical use Part 4: Infusion sets for single use, gravity feed, MOD

MECHANICAL

PUMPING MECHANISM	Curvilinear peristaltic finger
DROP SENSOR	External (optional)
DIMENSIONS (W×D×H)	140×120×230 (mm) (no pole clamp).
WEIGHT	Approximately 2.5kg

ALARM

AIR IN LINE, OCCLUSION, DOOR OPEN, INFUSION COMPLETION, LOW BATTERY, REPEAT ALARM, DROP ERROR RATE ABNORMAL

FEATURES

PRUGE RATE	500, 800 or 1000ml/h
NURSE CALL	Short circuit
VOLUME MEMORY, TEMPORARY STOPPING, CLEAR DELIVERED VOLUME, IV SET CALIBRATION, OCCLUSION PRESSURE CONTROL, DROP/ML SETTING	

OTHER PARAMETERS

POWER REQUIREMENTS	110/230VAC (Optional), 50Hz 8 * AA size NIMH battery 9.6VDC
POWER CONSUMPTION	≤ 20VA
CLASSIFICATIONS	Class I / Internal power supply / Type CF
BATTERY / OPERATION / CHARGING	Ni-MH / 3 hours (at 25ml/h) / more than 8 hours
WATERPROOF LEVEL	IPX1
BATTERY LIFE	1 year
OPERATION CONDITIONS	10~40°C, 30~85% RH (no condensation)
STORAGE CONDITIONS	-20~55°C, ≤93% RH (no condensation)
WARRANTY PERIOD	1 year

Symptoms	Cause	Action
	• IV set is not compatible with this pump.	Check the compatibility of IV set with your local dealer.
	• Drop sensor is not securely attached on the drop chamber on IV set.	1. Turn the alarm off by pressing [START/STOP] key. Pump enter “STAND-BY” mode. 2. Attach the drop sensor securely on the drop chamber. Make sure that the surface of drop chamber and drop sensor is dry. 3. Make sure the flow rate, VTBI and drop/ml are set. 4. Restart infusion by pressing [START/STOP] key.
	Battery is exhaust when pump is 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. [CHAG] LED 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 the flow rate and VTBI are set. 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 closely to peristaltic finger system, if there isn’t any noise; contact your local authorized dealer.
BUZZER beep continuously and all keys lost function.	Program abnormal.	Check if there are some strong interfere, power failure, or mechanical failure. Try to use pump at a stable environment. Restart the pump. If this symptom happens again and again, please contact your local authorized dealer.

Caution

- Before restarting infusion, make sure the flow rate and VTBI are set.
- After restarting infusion, check the flow rate to confirm the delivery of the liquid at the selected rate.

4. OPERATION

4.1. Install the pump to a pole stand

- Fix the pump securely on a pole stand, using the pole clamp on the back of the pump.

4.2. Connect to AC power

- Connect the AC power cord provided to the AC power inlet on the back of the pump and an AC power outlet.

NOTE

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

4.3. Switch on the pump

- When turns on the pump, the built-in battery is automatically be recharged. Pump enters standby mode.

NOTE

When turns on the pump, [AC] LED will on, if the battery is under charged, the BATT LED will flick.

4.4. Pressing [ON/OFF] key

Press and hold [ON/OFF] for more than 1 second, pump will turn on, and enter into self-checking before operation. Self-checking contains:

1) LCD checking.
2) Power supply checking, voltage of DC and AC will be displayed.
3) Motor checking: to see if motors can running normally and detect rotate direction and position.
5) LED flick checking.
6) Pressure sensor checking.
7) System time checking.

After self-checking, by default, pump enter infusion interface. Refer to figure 4.1.

4.5. Prime an IV set

1. Connect IV set to the liquid container.
2. Fill the liquid into the drop chamber up to one third.
3. By opening the manual roller clamp on IV set, make a drop of liquid formed on the tip of needle.
4. When priming is completed, close the manual roller clamp.

NOTE

- Liquid surface should higher than patient’s heart and not exceed 1m.
- Also can use purge key to remove air bubbles in the IV tubing.

4.6. Install an IV set

1. Open the door and set the IV tubing properly, be sure that the IV tubing through the bubble sensor and keep straight through the Peristaltic finger and the Pressure sensor. Be sure that the Pressure sensor moves smoothly when it is pushed by a finger.
2. Push the tubing clamp to clamp the IV set.

Caution

If the tubing does not keep straight over the peristaltic finger section, the desired flow rate may not be achieved.

When the same section of the tubing has been set at peristaltic finger section

for a long time (over 12 hours), use it after moving the tubing connected to this pump at a distance of more than 10 cm. Deformation of tubing arising from long time (over 12 hours) use can affect the accuracy.
The IV set 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 manual roller clamp, and remove IV set
③ Replace IV set and prime the IV set
④ Set IV set properly
⑤ Close the door and open the manual roller clamp
⑥ Restart infusion

4.7. Close the door

• Close the door and lock the door lock lever.

Caution

• Make sure the tubing not to be caught by the door.

4.8. Install a drop sensor

• Attach the drop sensor vertically on the drop chamber of IV set, by squeezing the drop sensor with fingers.

Caution

Only drop sensor mentioned at section 3 can be used. Otherwise, the function of the drop sensor could not be guaranteed.

NOTE

Please check the flicker of the lamp on the drop sensor whenever the liquid drops. If there is no flicker, please contact your local authorized dealer.

Caution

The drop sensor should be located between the drop nozzle of drop chamber and the surface of the liquid to avoid any incorrect detection.
When the drop sensor is attached on the drop chamber, make sure that the drop sensor should be positioned vertically. If the drop sensor is attached obliquely, the expected flow rate may not be achieved.
Avoid strong light straight into drop sensor, especially the infrared windows. It may cause malfunction.

NOTE

Drop sensor is an optional device.

4.9. Set flow rate (ml/h or drop/min, time-based) and VTBI.

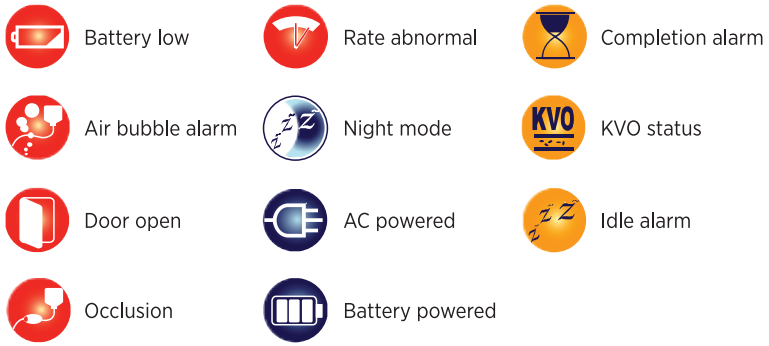
Flow rate and VTBI can be set in infusion window, refer to figure 4.1.
At infusion window, rotate the shuttle key to select rate item or volume item until the item gets focused. Press shuttle key to change the item value, the item value will flick, rotate the shuttle key to change the value as required. Press shuttle key to confirm setting.

Symptoms	Cause	Action
Pump cannot be switched on		7. Open the manual roller clamp on IV set. 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.
The [OCC] icon displays on and alarm sounds continuously.	• The manual roller clamp is closed.	1. Turn the alarm off by pressing [START/STOP] key. Pump enters “stop” mode. 2. Open the manual roller clamp on IV set. 3. Make sure the flow rate; VTBI and drop/ml are set. 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.
	• Tubing is kinked or twisted • IV set is not properly placed • Tubing is stretched or shrunk	1. Turn the alarm off by pressing [START/STOP] key. Pump enter “stop” mode. 2. Close the manual 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.
	• Pressure sensor abnormal	Follow the steps for reinstall 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.
Rate abnormal icon display on	• The setting of drop/ml is not correct.	1. Set the correct drop/ml. (Refer to IV set calibration).
	• The same site of the IV tubing has been set at peristaltic finger section for a long time (over 12 hours). • Tubing is not properly placed.	1. Turn the alarm off by pressing [START/STOP] key. Pump enter “stop” mode. 2. Close the manual 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 manual roller clamp on IV set. 7. Make sure the flow rate and VTBI are set. 8. Restart infusion by pressing [START/STOP] key.

6. TROUBLE SHOOTING

6.1. Alarm or Status Icons

Icons will display on infusion window, when pump change status or encounter alarm events. Refer to list 6.1.



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 stops infusion and [STATUS] icon display on the top LCD in red. That is, alarm sounds only in error situation during infusion.

Symptoms	Cause	Action
Pump cannot be switched on	• AC power cord isnot connected properly	Check the AC power cord connection.
	• End of built-in battery life	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] icon display on and alarm sounds continously	• Air bubble is in the IV tubing • IV set is not properly placed • Bubble sensor is stained	1. Turn the alarm off by pressing [START/STOP] key. Pump enter “stop” mode. 2. Close the manual roller clamp on IV set. 3. Take the IV set from the pump and tap the tube to make the air bubble gather into the drop chamber. (In case that bubble sensor is stained, clean it with a gauze cloth or similar, moistened with cold. 4. Set the IV set back properly in place. 5. Close and lock the door securely. 6. Open the manual roller clamp on IV set.

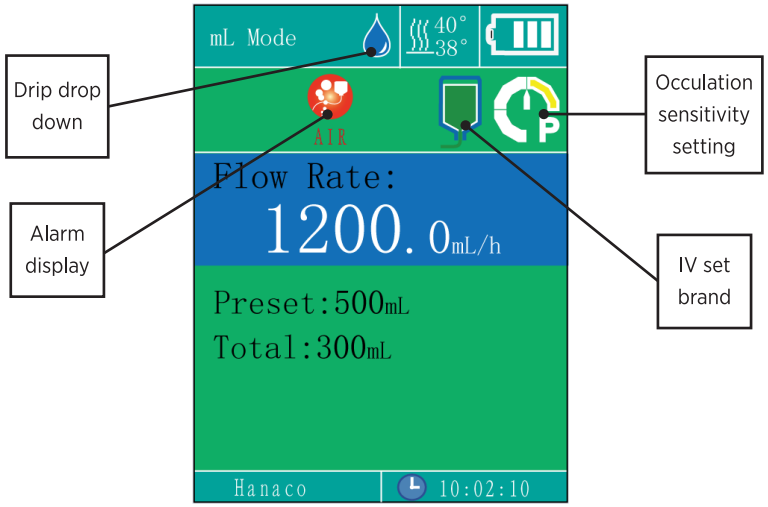


Figure 4.1 Infusion window

- The flow rate range is as follows
  1~1200ml/h (in 0.1ml/h increments)
  1~400 drop/min (in 1drop/min increments)
- The flow rate range is as follows
  1~20000ml (in 0.1ml increments)

Caution Make sure that the VTBI should be set slightly less than the amount of liquid in the liquid 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 the VTBI is set at 0000ml.
- After starting infusion, the LCD displays delivered volume in bigger font.

4.10. Open roller clamp of an IV set

- Open the roller clamp of the IV set.

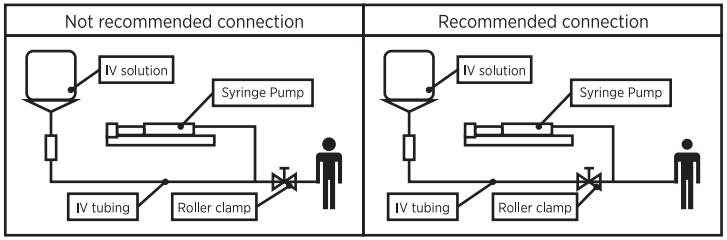
Caution Make sure that the liquid neither comes into the drop chamber nor comes out of the needle. If liquid does, please confirm that IV set is of a recommended type, that the IV tubing is set properly, and IV set is in good condition. When none of the above is found, the pump fault may be suspected.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

4.11. Insert hypodermic needle into a patient

- Insert the needle into the patient.

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

Caution Once a patient need to be infused by both gravity infusion and Syringe Pump. Please kindly refer to the following figures.



4.12. Press [START/STOP] key to start infusion

NOTE Before operating the pump, make sure to check the flow rate, VTBI and IV set again.

- Press [START] key to start infusion. Pump enters run mode.
- LCD display animation of the drop. This means the pump is working normally. At the bottom of LCD shows total volume infused in ml unit with an enlarged font. Refer to figure 4.2.

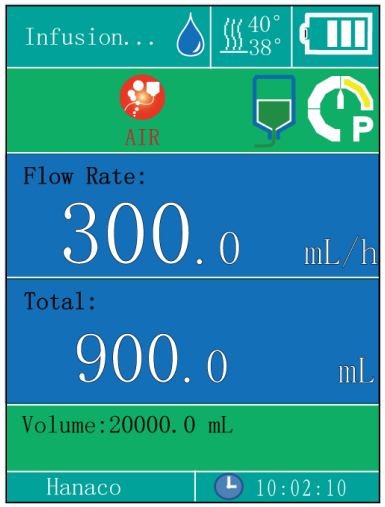


Figure 4.2 Pump running

Caution

Check the flow rate to make sure that it is being delivered at the selected rate.
If any irregularity is observed, immediately stop the pump and contact your local authorized dealer.

4.13. Infusion completion

- When the total delivered volume reaches the VTBI, The "COMP" lamp light on, along with alarm sound. The pump continues the infusion at the following KVO rate.

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

- Pressing [START/STOP] key to stop the KVO mode.
- Before opening the pump door in order to release the IV tubing clamp and remove IV set, make sure the manual roller clamp is closed.
- Free flow will occur if IV set is removed or the IV tubing clamp is released without closing the manual roller clamp.

4.14. Cleared Infused Volume

Refer to figure 4.1, rotate shuttle key to make [Clr Total] get focused, then press shuttle key to clear the total infused volume.

NOTE In case of restarting infusion after clearing the total delivered volume, the pump starts to deliver the liquid newly from "0" to the VTBI specified previously if the new setting is not active.

- To keep the battery in good condition, 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.
- Before 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.

5.12. Connecting the pump to nurse call

- Attach the alarm terminal cord (option) to the nurse call connector at the back of the pump and to a nurse call.

When any alarm is activated, error message is shown on the display and a signal (short circuit) is sent to the nurse call continuously.

5.7. Repeat Alarm Function

• When pump in stop mode, if no action is taken within 2 minutes, the alarm sounds. Press any key can release this alarm.

5.8. Drop Sensor Control

Caution

To start infusion, it is necessary to attach the drop sensor on the drop chamber on IV set. Make sure set the drop/ml of IV set correctly. The drop sensor detects the flow rate can be used only to monitor empty container or flow error, not to control the infusion.

Only drop sensor provide along with the pump can be used. Otherwise, the function of the drop sensor could not be guaranteed.

5.9. Temporarily Stopping Infusion

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

• Before restarting the infusion, make sure to check the flow rate and VTBI and press [START/STOP] key.

5.10. Purge

When [PURGE] key is double pressed and held, the pump delivers the liquid at the rate of 500ml/h.

NOTE

• In “stop” mode, purge function can be used for removing air in IV set.

• In “run” mode, the purged volume is counted to the total VTBI.

Warning

Alarms can not be detected in purge function. Make sure pump is in normal condition after purging.

5.11. Running the pump with the built-in battery

The pump switches to the built-in battery and [CHAG] LED lights on in yellow when the AC power absence.

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

• The battery is recharged regardless of the pump status.

• The pump can be operated for about 3 hours at 25ml/h with the built-in battery.

NOTE

When the battery is new, it should be recharged for more than 8 hours. During charging the battery, [CHAG] LED is flicker. When battery full charged, [CHAG] LED turn off.

Caution

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

Caution

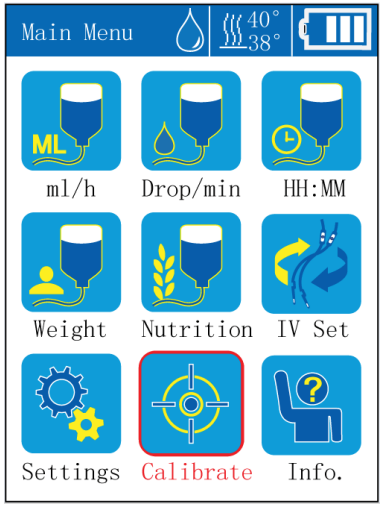
When the voltage of the built-in battery is depleted the pump stops running with the alarm without a previous notice.

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

5. OTHER FUNCTIONS

5.1 Enter Main Menu

Press [MENU] key can enter main menu except pump in run mode. Refer to figure 5.1. There are 9 icons on main menu, each icon relates to a function. Rotate shuttle key can select one icon, if the icon gets focused, the icon will be red framed and associated function show on the window title bar.



5.2 Enter Infusion Window

At main menu, switch to the infusion icon, press shuttle key to enter infusion window.

5.3 IV set Selection Window

At IV set selection window, rotate the shuttle key to select one brand as required, press shuttle key to confirm selection. Refer to figure 5.2.

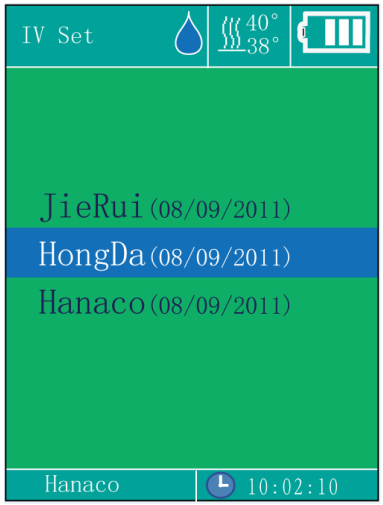


Figure 5.2 Select IV set

NOTE When enter Select IV set menu, current selected IV set will get focused. If no valid IV set data exist, the window will blanked.

5.4 Settings

Infusion parameters can be set, such as occlusion sensitivity, KVO rate, Bolus rate and thermostat temperature And so on .Refer to figure 5.3.

Occlusion sensitivity can be set at 3 levels: Low, Medium and High. Each level relates to a range of pressure value, refers to list 5.1, pump will give alarm when IV set is occluded and the pressure exceeds the value.

List 5.1 Occlusion Sensitivity VS Pressure Range

Low	0.155Mpa ± 0.025MPa
Medium	0.115Mpa ± 0.025MPa
High	0.085Mpa ± 0.025MPa

Bolus rate can be set at 500ml/h, 800ml/h or 1200ml/h.

KVO Rate can be set at 1~5ml/h in 0.1ml/h increments.

Thermostat temperature can be set at 30 ~ 45°C. Turn off thermostat by set temperature to OFF.

In system config window can set LCD backlight intensity, alarm volume, time and data. Refer to figure 5.5

LCD backlight intensity can be set at 1~5, when change the value, the LCD backlight change intensity simultaneously.

Alarm volume can be set at 1~3, with alarm volume from low to high.

Time and date can be set as required.

This pump support 2 languages, simplified Chinese and English. Once language is selected.

NOTE

- Thermostat is an optional function, if not exist; set thermostat temperature has no affection.
- Time and date can set refer to the local time. Pump use the time and date settings as a base for system log recording.

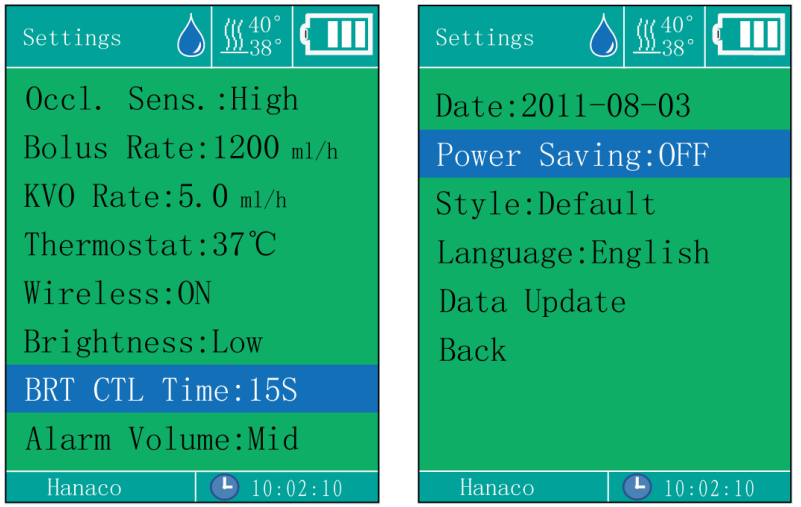


Figure 5.3 settings

5.5. Calibration

Use calibration window can calibrate IV set, please see detail in chapter 9.

5.6. Information

Information window display the vendor, pump serial number, software version. Refer to figure 5.4.

Figure 5.3 Information