# Operating Manual Infusion Pump

#### Rev.No.0.01

This manual has been compiled to users of the Infusion Pump in Installation, operation & routine maintenance.

Specifications and Operating Characteristics are subject to change without notice for improvement.

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# **Chapter 1: Features and Specifications**

#### Introduction

The advanced infusion system "Infusion Pump" is a compact and comprehensive drop and volume infusion pump which can infuse fluids, medication or nutrients into a patient's circulatory system, and it has power packed features, and provides accurate and reliable delivery over the whole range of delivery rates.

Infusion pump can control the infusion rate automatically by detecting the drops of liquid medicine in IV drop chamber in a minute and controlling the speed of the stepper motor that drives the peristaltic pieces that make the liquid medicine flow.

The infusion pump could be widely used in various departments of hospitals, such as department of medicine, pediatrics, gynecology and obstetrics, oncology, neurology, ICU, CCU etc., but not for blood transfusion

#### **Features**

- Can be used for all standards of Sterile burette type infusion set for single use (Correspond ISO 8536-4:2007 standard).
- Automatic Calibration for IV sets.

- Three working modes: Rate control mode,
   Time control mode and volumetric mode.
- Built in rechargeable battery (Li battery).
- 5 hours internal battery backup.
- Alarm functions: occlusion, empty bottle, low battery, rate error, end of infusion, door open, air in line etc
- Three levels of the occlusion limited pressure: high, middle and low.
- Three levels of alarm sound: high, middle and low.
- The infusion pump goes into KVO mode automatically as infusion is completed.
- Purge and Bolus functions

### **Technical Specification**

- Flow range : 1.0∼1200ml/h in 0.1ml/hr steps
  Or 1∼400drops/min 1drop/min steps
- Flow precision :

±2% for ≤25d/min (In rate & time setting modes) ±3% for >25d/min (In rate & time setting modes) ±5% (in volumetric mode).

- Purge : >600 ml/h.
- Bolus

Adjustable from 10-1200ml/hr, in steps of 0.1ml/hr (if flow rate < 100ml/hr) and 1ml/hr (if flow rate > 100ml/hr)

 KVO rate : if the flow rate ≤10 ml/h, KVO is 1ml/h.Otherwise KVO is 3ml/h.

Power supply : AC100~240V±10%, 50/60Hz,

Internal Li battery: DC 11.1V 2000mAh. The battery Backup is approx. 5 hours (when using a, fully charged Battery and running at 20drops/min with any standard IV Set).

• Power consumption : ≤25VA

Class : IType : BF

• Size : 130mm(W)×230mm(H)×200mm(D)

• Net weight: approx . 3kg

Operating condition :

Ambient temperature: 5~40 degree C,

Relative humidity : 20~90%

Storage condition

Ambient temperature: -10~55degree C

Relative humidity : 10~90%.

There should not be corrosive gas and harmful substance in the air and avoid pressing and drenching by rain and snow in the state of transportation

# **Chapter 2: Installation and Familiarization**

#### Installation

Before installing check the instrument for any external damage or broken connectors. If damage is found contact the authorized sales dealer for guidance.

Initial charging

Keep the unit plugged to AC mains for charging the built in battery for about 16 to 18 hours before actual use.

#### Warnings:

The instrument should be away from vibrations, dust, corrosive or explosive atmosphere, extreme temperature or excessive humidity & all large electrical appliances/ X-ray equipments/ RF transmitters.

The instrument is designed to operate at all ambient temperatures between 5°C to 40°C. Temperatures beyond this range could affect the accuracy & cause damage to the equipment

Connect AC power using the three-pin power cord, supplied with the product and ensure a reliable ground.

Do not touch the power plug with wet hands.

Please contact qualified service engineer for replacing the

fuses when the fuse fails. There are two fuses inside the infusion pump.

Keep the infusion pump dry. When the liquid medicine flows into the pump, turn off the power and pull out the plug immediately. The infusion pump can only be used again only after verification by qualified service engineer.

Please confirm the infusion pump stability in fixation and make sure not to fall off after fixing.

Please calibrate the IV set if it is used for the first time so as to assure the accuracy of the flow. To calibrate the IV set follow the following steps.

- 1. Keep the "**Purge/Bolus**" key pressed and switch on the unit. Now the unit is in calibration mode.
- 2. Use a 100ml or 250ml full IV bottle. Install the IV set, to be calibrated. Select the volume as 100ml or 250ml,

#### 3. Start infusion.

The number of drops will be counted and displayed on the panel.

4. When the bottle becomes empty, immediately press the "SELECT/CONFIRM" key.

Now the calibration is completed. The drops/ml will be calculated and stored in the pump automatically

Please deal with alarms immediately. The infusion pump can continue to work only after getting out of the alarms.

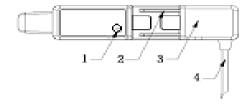
Please use AC power as often as possible as the internal battery is charged at the same time. When AC power fails unit automatically will switch to battery mode.

Please connect the instrument to AC power immediately on

indication of "Low battery" on the display, when the internal battery is used.

#### **Product Familiarization**

#### **Drop sensor**



1—drops Indicator

2—detect clamp

3—drops sensor

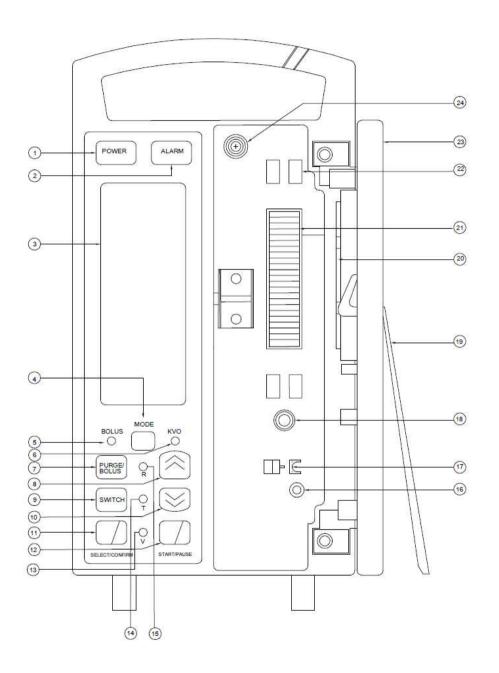
4-sensor leads wire

**Drop Indicator:** LED flashes against the fall of each drop in the IV chamber.

**Detect clamp:** To hold the drop chamber.

**Drops sensor:** Detect the drop falling in the IV chamber.

Sensor leads wire: Wire from the sensor to the unit.



1. Power AC indicator

3. Display

5. Bolus LED

7. Purge/Bolus Key

9. Switch Key

11. Select/Confirm Key

13. Volumetric Mode indicating LED

15. Rate mode indicating LED

17. Anti flow clamp

19. Door lever

21. Peristalsis fingers

23. Door

2. Alarm indicator

4. Mode key

6. KVO LED

8. Increment Key

10. Decrement Key

12. Start/Pause Key

14. Time mode indicating LED

16. Close clamp button

18. Pressure sensor

20. Extrusion plate

22. Air detector

24. Door open indicating light

# **Description of Keys**

**MODE Key** — By using this key, along with switch key, it is possible to switch among three different working modes (**Rate mode**, **Time mode** and **Volumetric mode**) in a cyclic manner.

**SELECT/ CONFIRM Key** — There are two purposes for this key. One, to switch among different parameters which are to be set before the infusion starts, and for Second, to clear the alarm as the pump alarms.

Increment Key — To increase the value of any

parameter. If the key is kept pressed the value of the parameter will increase quickly, otherwise increase in the minimum steps. It is also used to vary the occlusion pressure from low to high.

Decrement Key —To decrease the value of any parameter. If the key is kept pressed the value of the parameter will decrease quickly, otherwise decrease in the minimum steps. It is also used to vary the occlusion pressure from high to low

**SWITCH Key** — To switch between the two different types of infusion rates, drops/min and ml/h. It is also used to unlock "IV set" for selecting proper IV set, in drops/ml interface. Press this key combined with PURGE/BOLUS key to switch to bolus rate setting interface.

**PURGE/BOLUS Key** — To Purge the extension line during set up while the pump is stopped. Press the key once and release. Press and hold it again within in 5 seconds. The pump will start purging in the predetermined accelerated rate. The pump will be in the purge mode as long as the key is kept pressed and comes out of purge mode when the key is released.

Caution: Never try to purge if the pinhead is connected to patient.

**START/PAUSE Key** -- To start infusion after setting the parameters, and to stop infusion when the infusion is over.

#### **Description of Indicators**

Alarm indicator is lit whenever any alarm occurs, along with audio and visual indications

**Power** is lit as AC power is connected and the unit is ON

**Drop indicator:** The indicator flashes when the pump detects a drop in the IV chamber in the normal working condition.

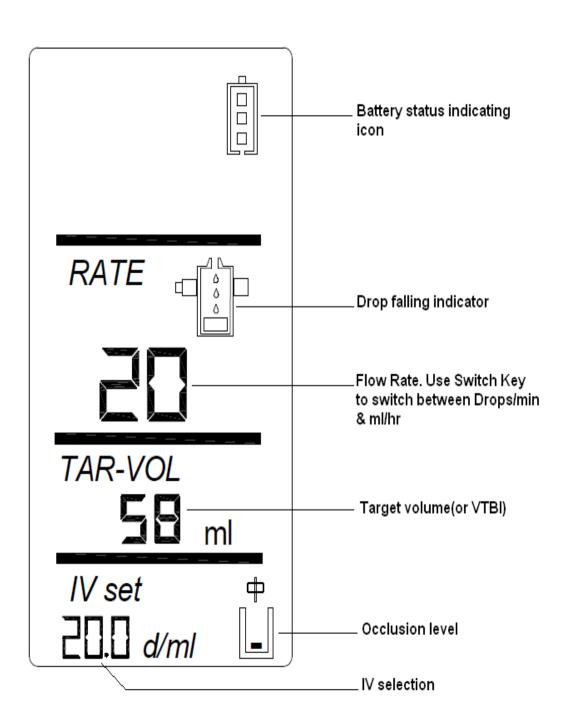
**Bolus LED:** Will be "ON" when the unit is in bolus rate setting interface and "Blinking" when in bolus operation.

**KVO LED:** Blinks when the unit switches to KVO mode.

**R, T, V LEDs**: Indicates the modes (Rate, Time and Volumetric respectively) in use.

**Door open light**: ON when the door is open.

Display



# **Chapter 3: Operation.**

#### **Pump installation:**

Place the infusion pump on the table or fix to the infusion pole by tightening the screw handle.

Connect AC power with the special three-pin plug power cable supplied with the product. And use the internal battery only in case of AC power failure.

#### IV installation

Position the IV bottle properly. Fix the drop sensor on the IV drop chamber. Make sure that the drop detector comes between the orifice and the liquid level in the IV chamber. Ensure that the drop sensor is hanging horizontally and away from direct light as much as possible.

#### **Tube routing**

Keep the manual lock, provided along with the IV set in the locked position to prevent the free flow of the liquid. Open the door by pulling the door lever upwards. See figure 3.1.

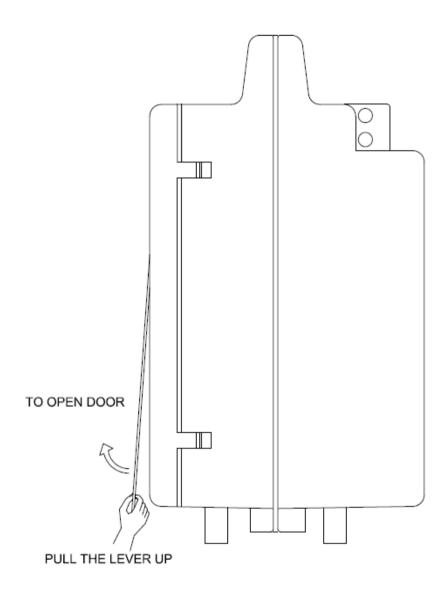


Figure 3.1 Route the tube as shown in the figure 3.2.

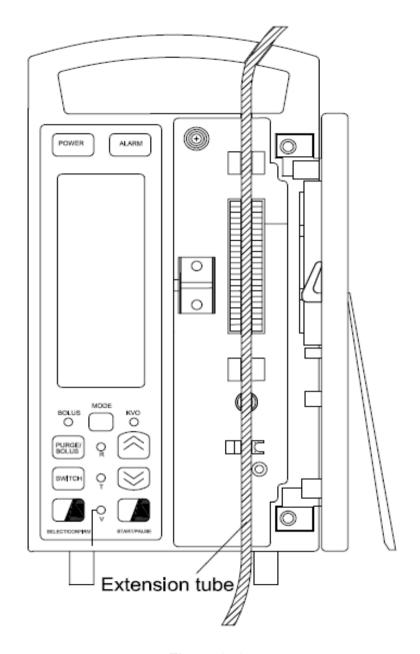


Figure 3..2

Close the door by following the steps as shown in the figures 3.3 & 3.4 given below.

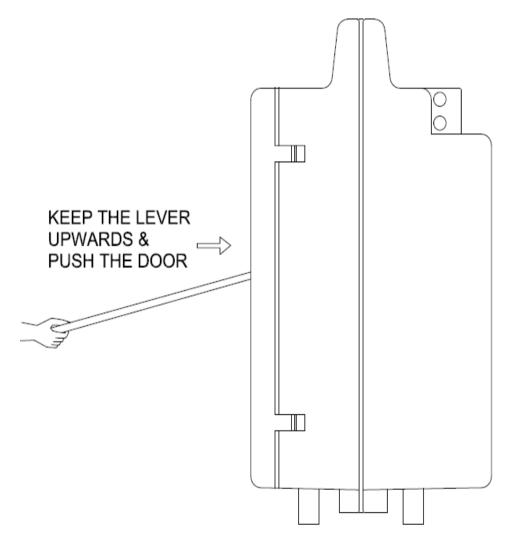


Figure 3.3.

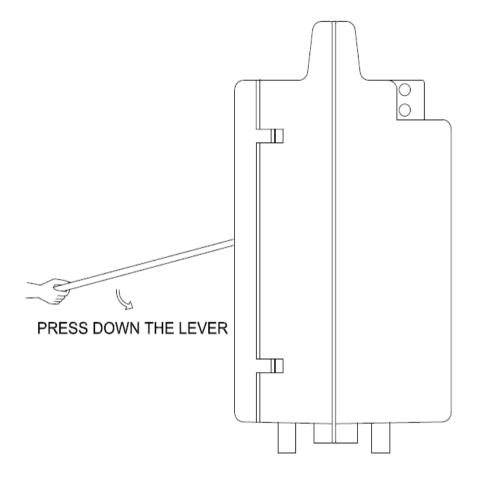


Figure 3.4

#### **Purge**

Unlock the manual lock of the IV set. To fill the extension tube (if required) press the Purge / Bolus key once. Within 5 seconds, press and hold the key again. "**Purge**" is displayed. The pump starts purging in the predetermined accelerated

rate. The pump will be in the purge mode as long as the key is kept pressed and comes out of purge mode when the key is released. The pump will return to the set parameter interface automatically.

Caution: Ensure that the pinhead is not connected to the patient.

#### **Mode setting**

Switch on the unit using the on-off switch provided at the back of the unit. The AC power indicator will be ON if the AC power is used, and will black out when the internal battery is used. Select the required mode by pressing the "mode" and "switch" keys simultaneously.

#### Rate mode

#### 1. Setting Parameters:

Flow rate: In the rate mode, when the power is on, automatically "RATE" starts blinking. Use "SWITCH" key to switch between "ml/hr" and "drops/min". Set the flow rate (ml/h or drops/min) using the ", ", "keys.

Target Volume: Press the Select key to switch to target volume. Then "Tar. Vol" (target volume i.e. Volume to Be Infused) starts blinking. Set target volume using the "A", "keys.

"IV SET": Press the Select key to switch to "IV set". The value can be changed by pressing "", "" keys only after unlocking it by pressing the "SWITCH" key.

**Occlusion limit:** Press the Select key to switch for setting "**Occl. Lt**" (H,M,L). As it flashes, set the level as High, Medium or Low as required, using " ", " weys.

Alarm Sound volume: Press the "SELECT" key to set "Vol." (H,M,L).

As it flashes, set the level as High, Medium or Low as required, using """ keys.

- 2. **Start Infusion:** Press the start/pause button to start the infusion. Icon "**Infusing**" on the display panel starts blinking.
- 3. **Stop infusion:** To stop infusion press start/pause button.

#### Time mode

Set the "Tar. Vol." (ml), "IV SET", "Occl Lt" (high, middle, low) and alarm sound volume (high, middle, low), as mentioned above in the Rate Mode, on the basis of various kinds of clinical treatment required in time setting mode. To switch among various parameters use the button "SELECT"

on the panel. For setting the "Time", refer below for the procedure.

**Target Time:** Press the Select key to switch to set target time. Then "Time" starts blinking. Set target time using the "", "" keys.

In the time mode, flow rate will be decided by the machine itself

Press "START/PAUSE" key to start infusion

#### Volumetric mode

Set the flow "Rate." (ml/h or drops/min), "TAR VOL", "IV SET", "ACCURACY ADJUST", "OCCL. LIMIT" (high, middle, low) and alarm sound volume (high, middle, low), as mentioned above in the Rate Mode, on the basis of various kinds of clinical treatment required in volumetric mode. To switch among various parameters use the button "SELECT" on the panel. For setting the "ACCURACY ADJUST", refer below for the procedure.

The "ACCURACY ADJUST" can be used to compensate for the wide tolerances in the IV Set. Some of the IV sets may not be very accurate and the drops per ml may vary much beyond the specified limits. For such IV sets to obtain accurate flow and volume, adjust the accuracy.

For e.g. if the infused volume is less by 10% than the Displayed volume, then increase the flow rate by varying the "ACCURACY ADJUST" 10% in the positive direction. The

accuracy can be changed by pressing " , " only

after pressing the "SWITCH" key.

Press "START/PAUSE" key to start infusion

#### **Bolus function**

Maximum Bolus volume is 100 ml

#### **Bolus Flow Rate Setting Mode**

In the stop condition, press both "Mode" and "Purge/Bolus" keys simultaneously, to switch to the Bolus Flow Rate Setting Mode. The Bolus LED in the panel will be ON. The default Bolus Flow rate of 200ml/hr will be displayed. Bolus flow rate is adjustable in minimum steps of 0.1ml/hr if the flow rate < 100ml/hr and in steps of 1ml/hr if the flow rate > 100ml/hr. Bolus flow rate is adjustable from 10 to 1200ml/hr.

To adjust the rate, use the ", ", ", " keys.

Press confirm key to store the Bolus rate.

Bolus LED will be OFF and the pump will return to normal, stopped condition.

#### **Bolus operation**

While infusion is in progress, press and hold **Purge/Bolus** key to switch to bolus operation mode.

Bolus LED on the panel will start blinking synchronously with the "**infusing**" on the display panel and the pre-set bolus flow rate will be displayed instead of normal flow rate. The infusion will be done at the bolus flow rate.

This will continue as long as the "**Purge / Bolus**" key is kept pressed provided no alarm occurs in between or the maximum bolus limit of 100ml is not reached.

When the "**Purge / Bolus**" key is released, automatically pump comes out of the bolus mode and go back to continue infusion prior to the bolus operation.

It is possible to infuse 100ml for every entry into the bolus mode.

If the bolus volume reached the limit it will stop infusing immediately with audio alarm and visual changes in the panel.

The bolus rate will go back to its default value of 200ml/h if the unit is switched off.

The total volume infused displayed is inclusive of the bolus volume.

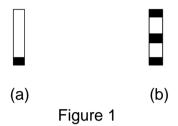
#### KVO:

During infusion, when the infused volume reaches the target volume, the pump will alarm and switch to KVO. The LED of KVO starts blinking. Press the confirm key, only the alarm sound will be cleared, but KVO will continue. The KVO will continue until the stop / pause key is pressed or any alarm interrupts.

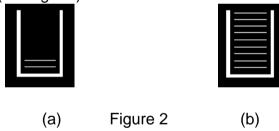
#### Other icons on the display panel:

a) Battery: It indicates the remaining capacity of the battery. If there is only one block (see fig 1.a) in the icon, means battery is near to empty and is to be re-charged

immediately. Three blocks (see fig 1.b) in the icon means battery is full. While charging, the blocks seem to be moving.



**b)** Occlusion pressure level: The pressure inside the tube is indicated in display panel as in Figure 2. And the white lines stand for the level of the pressure inside the infusion line. The larger the number of white lines, the more the infusion pressure (see fig 2.b) exists.



#### **Alarms and Disposition**

Whenever the alarm occurs, press the "**Select / Confirm**" key to clear the alarms and it will return to the set parameter interface automatically. The causes and how to get out of them are given below.

**Occlusion** — when "occlusion" alarm occurs, the pump will stop working automatically.

**Empty** — the infusion pump gives alarm when the IV bottle becomes empty (or if no drop is falling) and stops infusion. Clear the alarm by pressing the "**Select / Confirm**" key and the unit will return to the set parameter interface.

**Air bubble** --- The infusion pump gives alarm and stops infusion whenever air bubble is formed inside the IV tube during infusion.

**Door open ---** The infusion pump gives alarm and stops infusion whenever the door is opened during **infusion**.

Low battery — if the capacity of the battery is below a certain level, low battery alarms (battery icon on the display starts blinking). Connect AC mains immediately. But the battery low alarm will not disturb the infusion. i.e., if the battery low alarm happens during infusion, it won't stop infusion. Clear the alarm using "Select / Confirm" key and it will work for sometime, till the battery becomes empty (if mains is not connected).

**End of infusion** — the infusion pump will stop working and gives alarm when the infused volume reaches the target volume. Clear the alarm by "**Select / Confirm**" key. Automatically the pump switches to "**KVO**".

**Rate error** --- Whenever this alarm occurs check for correct settings of drop sensor and manual lock.

# **Chapter 4: Maintenance.**

Once unpacked, keep the unit for charging the internal battery at least for 16 to 18 hours before putting the equipment for actual use.

The equipment uses Lithium rechargeable battery. Though the equipment can be operated for few more minutes even after the battery low indication, it is recommended to keep the unit for charging the battery immediately on low battery indication.

When using the infusion pump in conjunction with any other pumps or devices requiring vascular access, extra care is advised. Adverse delivery of fluids or medication can be caused by the substantial variation in pressures created within the local vascular system by such pumps.

Keep the pump dry and clean.

Voltages present inside the instrument are potentially dangerous. If there is a problem with the instrument, the power cord should be removed until the instrument is repaired by qualified service personnel. This is to prevent anyone from inadvertently using the instrument, thus causing possible harm to themselves, or damage to the instrument itself.

Adequate protection including clothing and ventilation must be provided if dangerous liquids are used. In case of incidental spillage, carefully wipe with a dry cloth, taking into account the nature of the spilled liquid and necessary safety precautions.

Cleaning, dismantling, maintenance, adjustment and repair should only be performed by a qualified personnel trained in such work, and who are aware of the possible dangers involved.

Clean the instrument with a soft cloth lightly moistened with soapy water. Do not use abrasive or chemical cleaning agents.

This instrument must not be sterilized, using an autoclave, or any other mechanical device.

If the instrument does not appear to function correctly, first verify electrical connections are correct and that the instrument is switched ON. Contact your Company dealer for technical advice or an eventual service visit. Any service required will be given within the warranty conditions assured by your Company dealer.

If the pump is dropped, subjected to excessive moisture, fluid spillage, humidity or high temperature or otherwise suspected to have been damaged, remove it from service for inspection by qualified service personnel.

When transporting or storing, use original packaging where possible, and adhere to temperature, humidity and pressure ranges stated in the specifications section.

# **Chapter 5: Trouble shooting guidelines.**

Please contact the dealer or the Authorized service agent of Company, for any defect in the pump. Never disassemble the pump without authorization. Anyone who disassembles the pump without authorization does so at his / her own risk.

Some of the possible faults and the remedies are given below.

Faults	Possible causes	Possible remedies
NO response after switch-on	<ol> <li>Low battery</li> <li>No AC power</li> <li>Fuse blown</li> <li>The broken LCD</li> </ol>	<ol> <li>Connect power AC</li> <li>Checkup the connection of power AC</li> <li>Contact authorized agent</li> </ol>
"DOOR OPEN" in the display even though door is closed	<ol> <li>Door open</li> <li>Door close / open sensor not working</li> </ol>	<ol> <li>Close the door properly</li> <li>Contact authorized agent</li> </ol>

"ERR"in	1. Not installed the	1. Install the drops
display	drop sampling	sampling clamp as
	clamp as per the	told in the user
	instruction	manual.
	2. The drop sensor	2. Shake IV drop
	cannot detect the	chamber so as to
	drops of some	clear the drops on
	medicine, drops	the wall.
	spilled on the wall	3. Contact authorized
	of the IV drop	agent
	chamber	
	3、The drops sensor	
	failure	
	1、Mistake of the IV	1. Try to install the
	set installed in the	IV set again
	infusion pump.	2. Unlock manual
	2、The manual flow	flow adjustor or
	adjustor locked or	unfold extension
	the extension line	line
	folded	3、Connect the
	3. The pinhead is	pinhead correctly
Alarms	not connected	4. Select the proper
	properly	pressure limit
	4. Pressure set limit	(H,M,L)
	is too low	5. Contact authorized
	5、Pump fault	agent
	1. Battery not	1、Charge the battery
	charged	2. Contact authorized
	2. The battery can	agent
	not be charged	<b>J</b> - 1

## **WARRANTY CERTIFICATE**

Warrants to the purchaser of the instrument that it is free from all defects in material and workmanship. Provides One year warranty to the following instrument as per the warranty Terms & Condition given overleaf:

OWNER/INSTRUMENT DETAILS

MODEL NO:	SI	ERIAL NO:
INV/BILL NO:	D	ATE OF PURCHASE:
NAME OF THE OWNER AND ADDRESS:		
PHONE:	OFFICE:	CELL:
NAME OF THE	DEALER:	SIGNATURE AND STAMP:
IMPORTANT N	 OTE:	

The warranty registration card is enclosed. The warranty will be strictly as per the warranty Terms & Conditions given overleaf. The Dealer will get your signature in warranty certificate and forward to us. In case Dealer does not do so within one month of the date of purchase, you are requested to send it to the company address given below. This is to ensure that the service provider is in touch with you. Hence, properly secure the warranty card.

DEALER ADDRESS:

#### **WARRANTY TERMS & CONDITIONS**

Warrants that each instrument distributed by company and sold by an authorised Company dealer will be free, from any defects in material and workmanship at the time of manufacture subject to the following conditions:

- 1. To qualify for this warranty:
  - a) The instrument must be purchased directly from authorised dealer and serviced by Company authorised dealer/service center.
- b) The warranty certificate given overleaf must be completed by the dealer at the time of delivery of the instrument (Read important Note overleaf).
- 2. The term of the warranty shall be one year from the date of purchase to the first owner or 13 months from the date of manufacturing, whichever is earlier. The warranty will be valid only on receipt of warranty registration cards.
- 3. If any defect(s) should be found in the instrument within the terms stipulated above Trvitron will repair or replace at its sole discretion any part found to be defective, with a new part or the equivalent at no cost to the owner for parts or labour. The owner is responsible for any repair or replacements which are not covered by this warranty under clause 7 `Limitation'.
- 4. This warranty is the entire written warranty given by Trvitron for Company instruments and no dealer or his agent or employee is authorized to alter any terms of this warranty and no dealer or his agent or employee is authorized to make any oral warranty on Company's behalf.

Company reserves the right to add any improvements or change of design of any model at any time with no obligation to make the same changes on units previously sold.

- 5. To obtain warranty service, the complete instrument with accessories must be presented at the owner's expenses to any authorized Company service centre.
- 6. Owner's warranty responsibility:

- a) Make certain that the warranty certificate is completed in all respect at the time of delivery of the instrument.
- b) Present the warranty registration card to the service centre whenever requesting for warranty service.

#### Limitation:

This warranty shall not apply:

- a) To the Battery, Power cord and other accessories (they are warranted for only 3 months from the date of purchase).
- b) To any defects caused by misuse, negligence or insufficient care.
- c) To repairs or replacement required as a result of accidents or fluctuations in AC mains supply voltage.
- d) If the instrument has been modified or altered by anyone other than Company service center/ authorised dealer.
- e) If the instrument has not been operated in accordance with the operating instructions.
- f) If the instrument has been assembled, disassembled, adjusted or repaired by anyone other than an Company Service center/authorised dealer.
- g) If damage or deterioration has been caused by insect droppings or rat bite.
- h) To insignificant defects which do not affect the function of the instrument.
  - i) To body scratches or asaethetic defacing.

#### 8. Force Majeure;

Neither the purchaser nor Company shall be liable to the other for any delay in or failure of performance of their respective obligations under this Agreement caused by occurrences beyond the control of purchaser or company (as the case may be) because of Fire, Floods, Power failures or reductions, acts of God, acts of public enemy, wars, insurrections, riots, strikes, lock-outs, go-slows, sabotage, accidents to the machinery.

- 9. This warranty is issued subject to the jurisdiction of Chennai court.
- 10. Disclaimer of consequential damage:

Company assumes no responsibility for loss of business, loss of time, inconvenience or any other direct or indirect incidental or consequential damage resulting from instrument not being available to the owner because of any delay in repairs.

**Note:** Warranty valid only if returned with seal & signature. Refer warranty terms & conditions.

# WARRANTY REGISTRATION CARD <u>CUSTOMER COPY</u>

MODEL NO :

SL NO :

INV / BILL NO :

DATE OF PURCHASE :

PERIOD OF WARRANTY

FROM:

TO:

RECEIVED WARRANTY

CARD

BY :DEALER NAME

SIGNATURE & STAMP

# WARRANTY REGISTRATION CARD **COMPANY COPY** MODEL NO SL NO INV / BILL NO DATE OF PURCHASE PERIOD OF WARRANTY FROM: TO: NAME & ADDRESSS OF CUSTOMER E-MAIL PHONE RESIDENCE: OFFICE: CUSTOMER NAME & SIGNATURE DEALER NAME, SIGNATURE & STAMP :

**NOTES:**