

# **Volumetric Infusion Pump**

## **Operation Manual**

**C** **€**<sub>0197</sub>

**ISO 13485**

**ISO 9001**

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## **GENERAL INFORMATION**

BEFORE USING THE PUMP, BE SURE TO READ CAREFULLY AND UNDERSTAND ALL SECTIONS OF THIS USER MANUAL. FAILURE TO READ AND UNDERSTAND THE INSTRUCTIONS MAY LEAD TO MISUSE OF THE PUMP, WHICH COULD RESULT IN HARM TO THE PATIENT.

### **HEADINGS USED IN THIS MANUAL**

THIS GUIDE CONTAINS WARNINGS, PRECAUTIONS, AND IMPORTANT INFORMATION TO HELP CALL YOUR ATTENTION TO THE MOST IMPORTANT SAFETY AND OPERATIONAL ASPECTS OF THE PUMP. TO HELP IDENTIFY THESE ITEMS WHEN THEY OCCUR IN THE TEXT, THEY ARE SHOWN USING THE FOLLOWING HEADINGS:

#### **WARNING**

STATEMENTS THAT DESCRIBE SERIOUS ADVERSE REACTIONS AND POTENTIAL SAFETY HAZARDS.

#### **PRECAUTION**

STATEMENTS THAT CALL ATTENTION TO INFORMATION REGARDING ANY SPECIAL CARE TO BE EXERCISED BY THE PRACTITIONER FOR THE SAFE AND EFFECTIVE USE OF THE DEVICE.

#### **IMPORTANT**

STATEMENTS THAT CALL ATTENTION TO ADDITIONAL SIGNIFICANT INFORMATION ABOUT THE DEVICE OR A PROCEDURE.

# WARNINGS AND PRECAUTIONS

**IMPORTANT:** USER SHOULD READ THIS ENTIRE MANUAL BEFORE OPERATING THIS VOLUMETRIC INFUSION PUMP.

## WARNINGS OVERVIEW

CRITICAL! EXPLOSION HAZARD. DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS!

### WARNINGS:

1. DO NOT USE A PUMP, INFUSION SET, OR ACCESSORY THAT SHOWS ANY SIGN OF DAMAGE.
2. THE PUMP DOES NOT DETECT AIR BUBBLES OR OCCLUSION WHEN PRIMING. WHEN PRIMING, DO NOT CONNECT THE INFUSION SET TO THE PATIENT.
3. DO NOT SUBMERGE THIS PUMP IN WATER OR OTHER LIQUID.
4. BEFORE STARTING AN INFUSION, WITH THE IV SET INSTALLED IN THE PUMP AND THE FLOW-PROTECTION CLAMP OPEN, VERIFY THAT THERE IS NO FLOW OF FLUID FROM THE INFUSION SET. ALSO CHECK THAT THE PROGRAMMED INFORMATION IS CORRECT.
5. CLOSE THE INFUSION SET'S FLOW-PROTECTION CLAMP BEFORE AND AFTER REMOVING THE INFUSION SET FROM THE PUMP TO PREVENT UNRESTRICTED FLOW.
6. BEFORE CONNECTING THE IV SET TO THE PATIENT, USER MUST PRIME THE INFUSION SET TO PREVENT AIR TO THE PATIENT.
7. TO PREVENT ELECTRIC HAZARDS, UNPLUG THE PUMP BEFORE CLEANING. DO NOT SPRAY CLEANSERS INTO THE IV SET OR POWER CORD RECEPTACLES. DO NOT SUBMERGE THE PUMP IN ANY LIQUID.
8. DO NOT USE ANY INFUSION SET IF ITS PACKAGING APPEARS TO BE DAMAGED OR OPENED.

## PRECAUTIONS OVERVIEW

1. TO AVOID A MALFUNCTION CAUSED BY ELECTROMAGNETISM DISTURBANCE, PUMP SHALL OPERATE AWAY FROM DEVICES SUCH AS ELECTROCOAGULATOR AND DEFIBRILLATOR WHICH MAY CREATE A STRONG ELECTROMAGNETIC FIELD. DURING OPERATION, PLEASE NOTICE THAT THE

PUMP:

- i. MUST KEEP ENOUGH DISTANCE FROM ELECTROCOAGULATOR AND/OR DEFIBRILLATOR;
  - ii. DO NOT SHARE SAME POWER OUTLET WITH ELECTROCOAGULATOR AND/OR DEFIBRILLATOR;
  - iii. DO NOT USE THE PUMP IN THE MRI ROOM OR HIGH PRESSURE ROOM THAT CREATES A STRONG ELECTROMAGNETIC FIELD.
  - iv. MUST OPERATE UNDER SUPERVISION.
2. **DO NOT CONNECT UNSPECIFIED GRAVITY-CONTROLLED IV SET OR OTHER UNSPECIFIED BRAND PUMP-USED IV SET WITH THIS PUMP, AS THIS MAY AFFECT THE ACCURACY OF INFUSION AND MAY TRIGGER FALSE ALARMS, WHICH WILL CAUSE DANGER TO PATIENT. CONTACT YOUR DISTRIBUTOR FOR THE AUTHORIZED IV SETS TO WORK THIS INFUSION PUMP.**
  3. WHILE PUMP IS USING AC POWER, PLEASE ENSURE THE POWER OUTLET IS PROPERLY GROUNDED.
  4. DISPOSABLE INFUSION SETS USED IN THE PUMP SHOULD COMPLY WITH THE GOVERNMENT REGULATIONS.
  5. USED INFUSION SETS SHOULD BE STORED IN A SAFE PLACE, AND DISPOSED ACCORDING TO REGULATIONS.
  6. THE CIRCUIT DIAGRAM AND PARTS LIST WILL ONLY BE PROVIDED TO MANUFACTURER ASSIGNED TECHNICIANS.
  7. THE ACCESSORIES INCLUDE A DROP SENSOR. THE DROP SENSOR IS AN ACCESSORY USED TO DETECT WHETHER THERE IS FLUID LEFT IN THE RESERVOIR. REMINDER: IF THE DETECTOR IS NOT USED, PLEASE UNPLUG THE DETECTOR FROM THE PUMP; OTHERWISE THE COMPLETION AND OCCLUSION ALARMS WILL BE TRIGGERED SIMULTANEOUSLY.
  8. IF YOU CHOOSE TO USE THE DROP SENSOR, INSTALL WITH CARE. THE DETECTOR IS VERTICAL TO THE RESERVOIR BOTTLE. SOLUTION SURFACE HAS TO BE BELOW THE MID-LINE OF THE DRIPPING CHAMBER. IF "COMPLETE" AND "OCCLUSION" ALARMS ARE SET OFF RIGHT AFTER THE PUMP STARTS RUNNING, CHECK THE CONNECTION SOCKETS AT THE BACK OF THE PUMP TO SEE WHETHER THE DETECTOR HAS BEEN INSTALLED PROPERLY OR NOT.
  9. WHEN RELOCATING THE PUMP, PLEASE AVOID AN EXCESSIVE SWING OF FLUID BAG (AND DRIP DETECTOR).
  10. THE PUMP CAN BE USED ON A HORIZONTAL PLATFORM OR ON THE IV STAND WITH THE IV POLE CLAMP. BEFORE SECURING THE PUMP ON THE IV POLE,

PLEASE MAKE SURE THAT THE IV STAND IS SOLID VERTICALLY AND WON'T FALL WITH THE WEIGHT OF THE PUMP.


11. THERE MAY BE A LOW BATTERY ALARM WHEN THE PUMP IS POWERED ON WITH BATTERY POWER FOR THE FIRST TIME AFTER A LONG PERIOD OF TIME. WHEN THE LOW BATT ALARM SETS OFF, THE PUMP HAS TO BE CONNECTED TO THE ELECTRICAL OUTLET TO CONTINUE TO OPERATE. THE PUMP CAN OPERATE WITH AC POWER AND CHARGE THE BATTERIES AT THE SAME TIME. AFTER A CONTINUOUS CHARGE OF 8 HOURS, THE BATTERY CAN SUPPORT RUNNING AT A RATE OF 25 ML/H UP TO 3 HOURS.
12. PERIODICALLY THE PUMP AND DROP SENSOR NEED TO BE CLEANED. USE A DAMP (NOT WET) CLOTH OR SPONGE; GENTLY WIPE OFF THE SHELL AND CONTROL PANEL OF PUMP. DO NOT IMMERSE PUMP OR POWER CABLE INTO WATER OR OTHER CLEANING SOLUTIONS.
13. TO ENSURE THE BATTERY WORKS WELL WITHIN ITS LIFE-SPAN, OPERATE WITH BATTERY POWER OCCASIONALLY TO EXAMINE WHETHER THE BATTERY WORKS PROPERLY. IF THE BATTERY IS NOT USED FOR A PERIOD OF TIME, CHARGE THE BATTERY AT LEAST EVERY THREE MONTHS.
14. DISCONNECT THE PUMP WITH AC POWER WHILE CHANGING THE FUSE.
15. THIS INFUSION PUMP IS NOT INTENDED TO REPLACE TRAINED PERSONNEL IN THE SUPERVISION OF INFUSIONS.
16. ONLY AUTHORIZED SERVICE PERSONNEL SHOULD REPAIR THIS PUMP. MANUFACTURER ASSUMES NO RESPONSIBILITY FOR INCIDENTS THAT OCCUR IF THE PUMP IS NOT REPAIRED ACCORDING TO MANUFACTURER-AUTHORIZED PROCEDURES.
17. CAREFULLY READ AND FOLLOW THE INFUSION SET INSTRUCTIONS.
18. ONLY APPROVED ACCESSORIES SHOULD BE USED WITH THIS PUMP
19. WHEN INFUSING THROUGH A CENTRAL LINE CATHETER, LUER LOCK CONNECTORS SHOULD BE USED.
20. DO NOT CLEAN, DISINFECT OR STERILIZE ANY PART OF THE PUMP WITH ETHYLENE OXIDE GAS OR BY AUTOCLAVING. THIS MAY DAMAGE THE PUMP AND WILL VOID THE WARRANTY; DISINFECT THE PUMP'S EXTERNAL PARTS ONLY, USING APPROVED CLEANSERS OR DISINFECTANTS.
21. THESE CHEMICALS MAY DAMAGE THE PUMP'S FRONT PANEL: ACETALDEHYDE, ACETONE, AMMONIA, BENZENE, HYDROXYTOLUENE, METHYLENE CHLORIDE,

OR OZONE. DO NOT USE THOSE CHEMICALS OR CLEANSERS CONTAINING N-ALKYLDIMETHYLBENZYLAMMONIUM CHLORIDE.

22. PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT CAN AFFECT THIS INFUSION PUMP. IF THIS PUMP DOES NOT APPEAR TO BE WORKING NORMALLY TRY TO RELOCATE OR REORIENT THE PUMP.
23. THE USE OF NON-RECOMMENDED ACCESSORIES MAY RESULT IN INCREASED EMC EMISSIONS OR DECREASED EMC IMMUNITY OF THIS INFUSION PUMP.
24. WHEN USING THIS INFUSION PUMP WITH LIFE-SUSTAINING MEDICATIONS, ENSURE THERE ARE BACKUP PUMPS AND INFUSION SETS.
25. THE TUBE PLACED ON PERISTALIC PART OF THE PUMP COULD BE ALTERED AFTER 24 HOURS RUNNING; IT'S SUGGESTED REPLACING THE IV SET OR CHANGE THE TUBE AREA PLACED ON THE PUMP'S PERISTALIC PART TO ENSURE ACCURATE INFUSION.

# SPECIFICATIONS

## SIGNS AND SYMBOLS

- |  |  |
|--|--|
| a) Category:                                       | <b>Type I Internal Power Supplied</b>  |
| b) Type of Protection Against Electric Shock:      |  <b>Type BF</b> |
| c) Mode of Operation:                              | <b>Continuous</b>  |
| d) Degree of Protection Against Ingress of Fluids: | <b>Drip-Proof IPX1</b>   |
| e) Application:                                    | <b>I.V infusion set</b>  |

## TECHNICAL SPECIFICATIONS

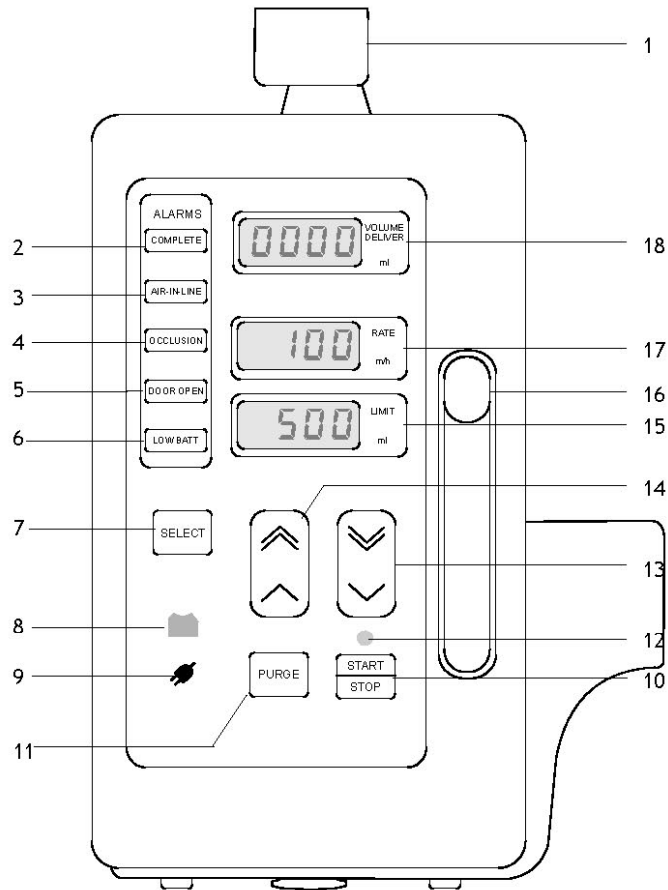
<b>Flow Rate Range</b>	1-1000 ml/h in 1 ml/h increments
<b>Total Volume Infused Display</b>	1-9999ml
<b>KVO Flow Rate</b>	1ml/h
<b>Accuracy</b>	± 2% (pump only)
<b>Compatible I.V set</b>	Can be calibrated to major brands (Pump use IV set Only)
<b>Display</b>	Bright large LED screens
<b>Alarms, Audible and Visual</b>	"COMPLETE", "OCCLUSION", "AIR-IN-LINE", "DOOR OPEN" and "LOW BATT"
<b>Pumping Mechanism</b>	Linear Peristaltic
<b>Power Source</b>	220VAC±10% 50Hz or 12VDC 110VAC±10% 60Hz or 12VDC
<b>Coating</b>	Durable rust proof Aluminium alloy
<b>Battery Capacity</b>	Approximate 4 hours continuously operation at 50 ml/hr with built-in rechargeable Ni-MH battery
<b>Net Weight</b>	4.25 kg / 9.35 lb
<b>Dimension</b>	125(W) × 250(H) × 190(D) mm

### Environment :

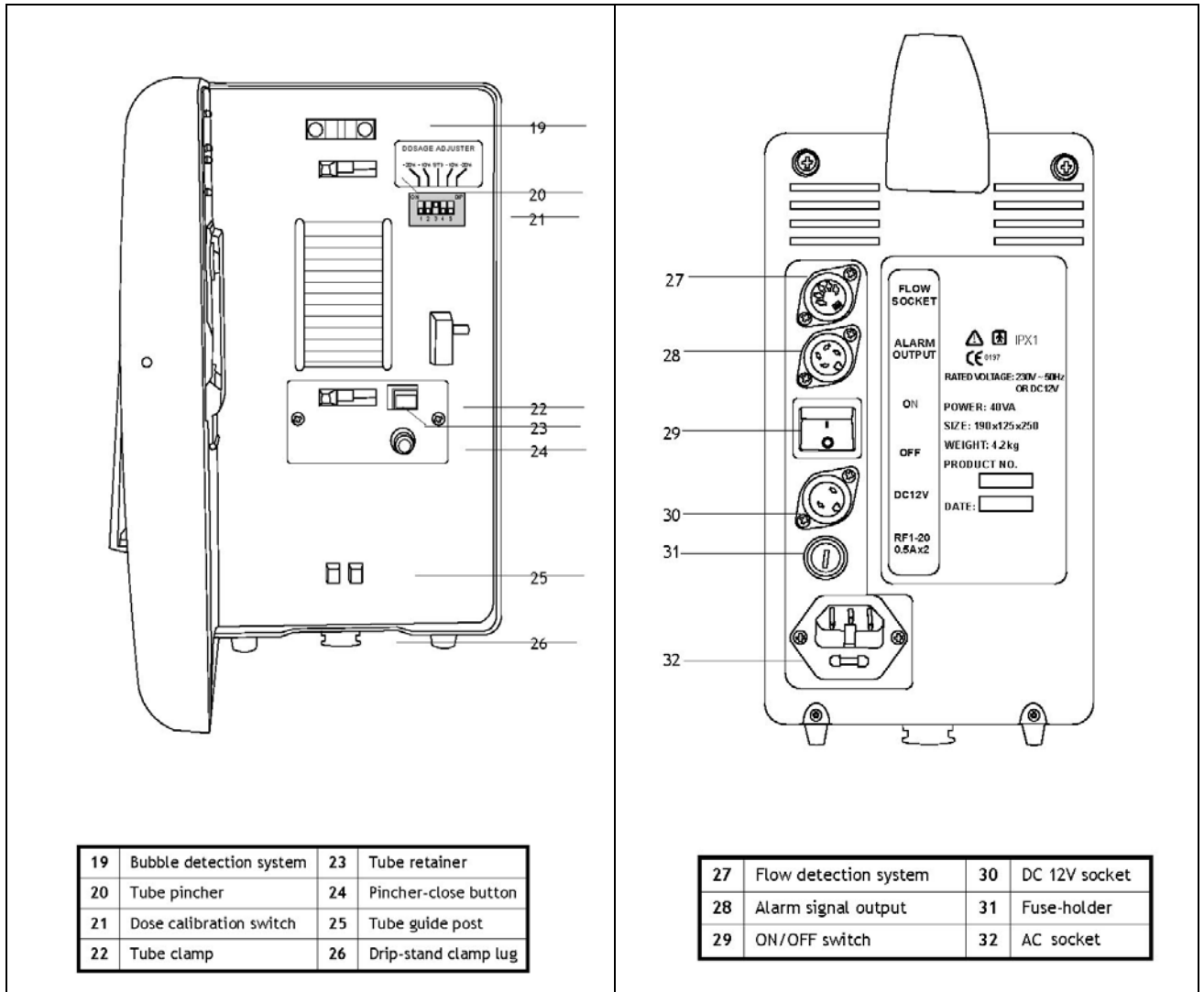
<b>Condition</b>	<b>Operating</b>	<b>Transportation / Storage</b>
Relative humidity (non-condensing)	≤80 %	≤93 %
Temperature	10°C to + 30°C 50°F to + 86°F	-10°C to + 55°C 14°F to + 131°F
Atmospheric	700 to 1060 hPa	500 to 1060 hPa

# KEYPAD DESCRIPTION








## CONTROL PANEL (refer to fig.1-3)



1	Handle	10	Start/Stop
2	Complete alarm	11	Purge button
3	Bubble alarm	12	Infusion indicator
4	Occlusion alarm	13	Increase rate
5	Door open alarm	14	Decrease rate
6	LOW BATT alarm	15	Door latch
7	Select	16	Dosage limit display
8	Battery power indicator	17	Flow rate
9	AC power indicator	18	Volume delivered



## KEYPAD DESCRIPTION

	Select between ml/h or ml.	
		The displayed value is increased or decreased. Hold the button for continuous operation.
	For purging infusion, block, or expelling bubbles from infusion tube.	
	Start or stop operation.	
	In RED when the battery is used as main power source.	
	In green while the pump is connected to AC power. The internal battery will be charged when connected to AC.	

## OPERATION PROCEDURES

- 1) Infusion pump should be hold on the frame by clamp and other accessories. (See figure 4)
- 2) Connect to AC 220V, the battery must be charged more than 10 hours if internal battery is used.
- 3) According to operation procedure, prepare dosage bottle and sterile disposable infusion device fluid full, ensure the flow to have half space air.
- 4) Connect flow testing device to infusion pump and clamp suitable Testing position so that it must be installed vertically. (See figure 5)
- 5) Ensure pump maintain better operating condition, the designated Infusion device should be used. The soft flexible infusion tube should be used and the infusion fluid is compensated by dosage adjustable key.
- 6) Dosage adjustable key should be set on standard position while designated infusion device is used. (See figure 6)
- 7) Open the door and press clamp button, then put infusion tube into "bubble testing", "Tube pincher", "tube clamp" and "tube guidepost", the tube clamp will be automatically closed while the door is closed. (See figure 7)
- 8) Release adjustable clamp of dosage infusion device and open power supply's switch on the back of pump, the pump enters into original status through self-testing. At this time, numeric display shows "0000" ml, infusion rate shows "1" ml/h and number flashes, the dosage limitation is 50ml.
- 9) Set infusion rate by pressing numeric display button, then press "SELECT" button, the numeric shows '50" ml and number flashes, the infusion procedure is finished after above operation.
- 10) The pump start to infuse by pressing "start/stop" button, infusion indicator lights up.

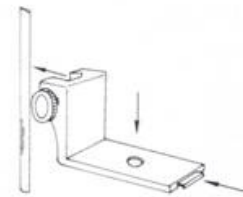


Fig. 4

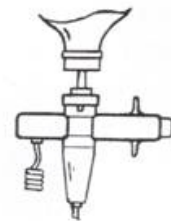


Fig. 5

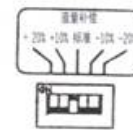


Fig. 6

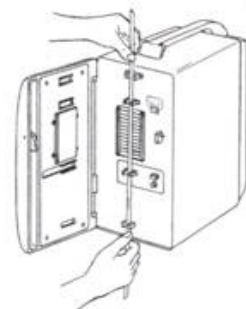


Fig. 7

Note: reasons for failing to start running may be one of the following,

- (1) Door is not closed properly.
- (2) The programmed infusion volume is equal or less than volume infused.
- (3) While "Complete" and "Occlusion" alarms set off simultaneously, check the Dripping Chamber Detector.
- (4) The alarm of "Occlusion" or "Air in Line" is not cleared.

## ALARMS

- “COMPLETE” alarm: Infusion dosage has reached its limit. The pump stops automatically and enters KVO state with rate of 1 ml/h.
- “AIR IN LINE” alarm: There is air in the tube. The pump stops automatically and enters KVO state.
- “OCCLUSION” alarm: The infusion tube is pinched or the infusion device is blocked, the pump stops automatically.
- “COMPLETE” and “OCCLUSION” alarm together: The infusion bag is empty, the pump will stop automatically and enter KVO state.
- “DOOR OPEN” alarm: The door has been opened during infusion. The pump stops automatically.
- “LOW BATT” alarm: The internal battery charge is low. The pump should be connected to 230V AC mains as soon as possible. The alarm clears after the battery has been charging for several minutes.

The alarm functions can be sent to an authorized technician using the "alarm signal plug" on the back of pump. The alarm buzzer can be silenced using the "SELECT" button.

The above mentioned alarm functions are provided for system supervision through "alarm signal plug" which is designed on the back of pump. The alarm buzzer can be closed by "SELECT" key. (See figure 8 )

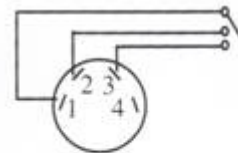


Fig. 8

## ACCESSORIES

The accessories come with each pump are as follows:

1) Standard power cable:	one piece
2) Dripping Chamber Sensor:	one piece
3) Infusion Pole Clamp	one piece
4) Signal plug, 2-pin and 4-pin	one piece each
5) Operation manual	one piece
6) QC certificate	one piece

## LIMITED 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 date of purchase by the original purchaser.

Manufacturer's obligation, or that of its designated representative under this Limited 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 Limited Warranty shall not extend the above mentioned Warranty period.

All repairs under this Limited 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 Limited 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 Limited 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 limited warranty are purchaser's sole and exclusive remedies with respect to any claim of purchaser arising under this Limited Warranty.