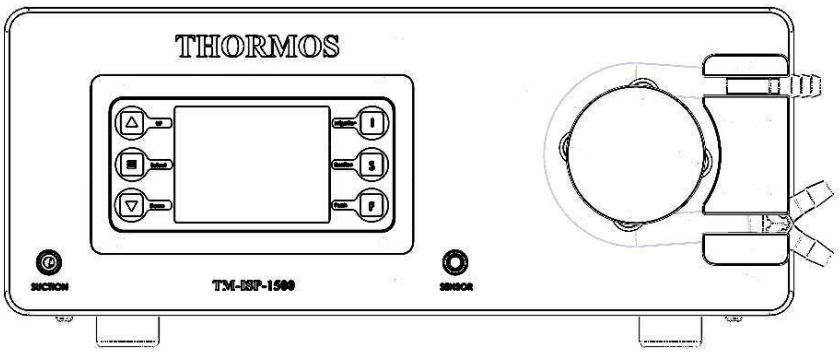
ESC®
MEDICAMS



USER MANUAL

Suction Irrigation Pump

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1 ABBREVIATIONS

This section provides a list of abbreviations used throughout this manual along with their corresponding full terms.

1. ISP – Irrigation Suction Pump
2. LCD - Liquid Crystal Display
3. TURP - Transurethral Resection of the Prostate
4. IEC - International Electrotechnical Commission
5. CEC - Canadian Electrical Code
6. NEC - National Electrical Code
7. AC - Alternating Current
8. EMC - Electromagnetic Compatibility
9. IPXO - Ingress Protection Rating for Ordinary Equipment
10. VA - Volt-Ampere
11. ISO - International Organization for Standardization
12. DEHP - Di(2-ethylhexyl) phthalate
13. RoHS - Restriction of Hazardous Substances
14. IFS - Foot Switch
15. IV - Intravenous
16. AHP - Accelerated Hydrogen Peroxide
17. FDA - Food and Drug Administration
18. QA/QC - Quality Assurance/Quality Control

2 ABOUT THIS MANUAL

Welcome to the Suction irrigation pump user manual! This guide is designed to help you understand and effectively use the PUMP for various surgeries. Please read the manual thoroughly before use and ensure proper training and safety protocols are followed.

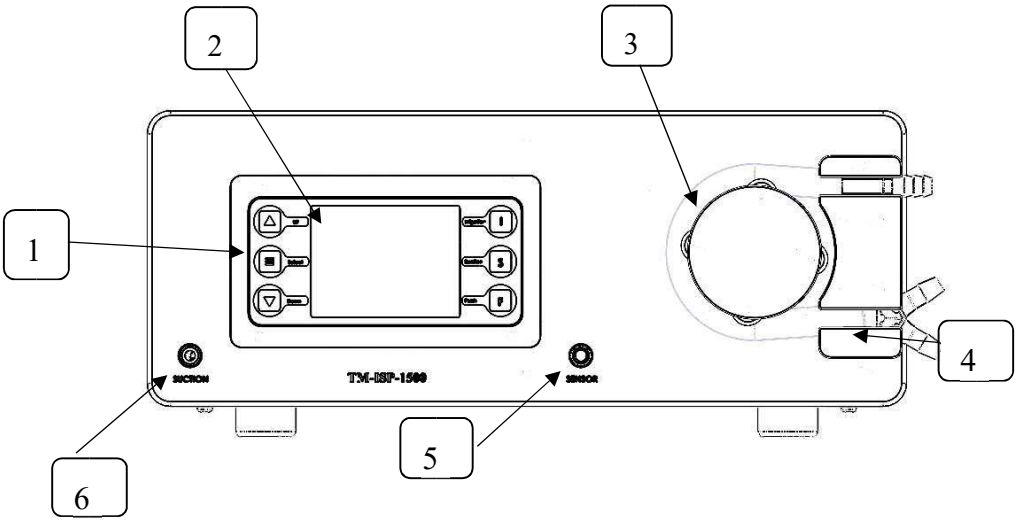
Inside, you'll find essential safety instructions, a detailed breakdown of the pump’s components and features, and step-by-step setup and operation guides. We also provide

cleaning and maintenance procedures to keep your pump in top condition, as well as troubleshooting tips for common issues.

At Seller, we are committed to innovation and user satisfaction. If you have any questions or need assistance, our support team is here to help. Thank you for choosing Seller, and we look forward to supporting your medical practice.

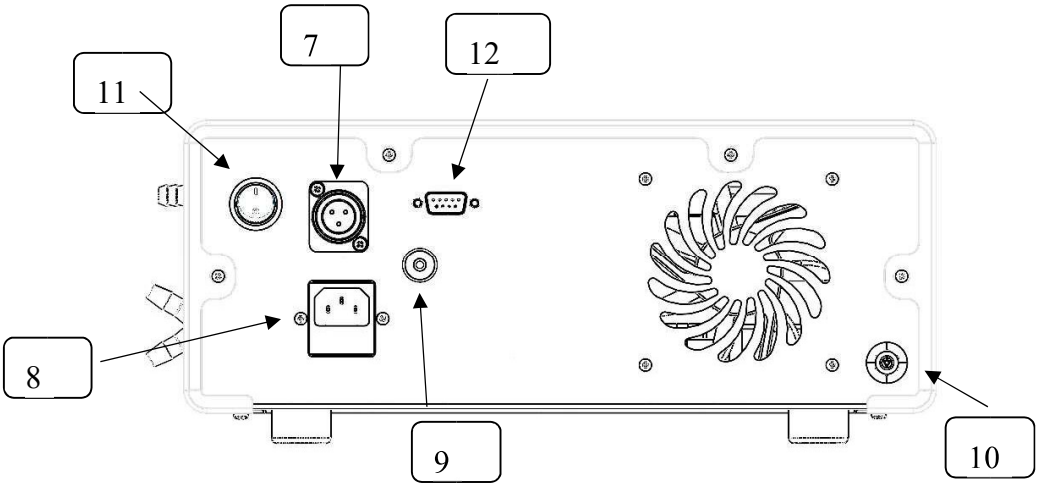
3 INTRODUCTION

The PUMP is a versatile, essential device for medical applications, specifically tailored for surgical and diagnostic procedures. Known as an Irrigation & Suction pump, it manages fluid flow for procedures like Laparoscopy and Hysteroscopy, ensuring clear operative fields by delivering irrigation fluids and suctioning excess materials. It also functions as a Saline Pump for wound irrigation, hydration therapy, and maintaining organ function. Its precise fluid management makes the PUMP a crucial tool for achieving optimal surgical outcomes and diagnostic accuracy.



ISP Front View

1. Operation Button
2. Display
3. Pulley
4. Y-Block
5. Pressure Sensor Nozzle
6. Suction Inlet



ISP Rear View

7. Foot Switch connector
8. Power Cable Socket
9. Suction Outlet
10. Earthing Pin
11. On/Off Switch
12. Serial Port

1. Operation button: The Operation button is used to control the function of the device. We operate parameters such as irrigation rate & irrigation pressure, allowing users to monitor the progress of the irrigation.
2. Display: The display interface of the Suction irrigation pump provides essential information and settings for operating the device effectively. It shows parameters such as irrigation rate irrigation pressure and suction pressure, allowing users to monitor the progress of the irrigation or suction.
3. Pulley: The Pump utilizes a pulley system to ensure optimal performance during operation. The pulleys securely hold the infusion tubing in place. As the motor drives the rollers, the pulleys create a smooth, continuous rotation that compresses the tubing. This compression creates the suction that draws fluid through the tubing and into the patient. The pulley system also helps to maintain consistent pressure on the tubing, preventing leaks and ensuring accurate fluid delivery.
4. Y-block: The Y-block in the Suction irrigation pump serves as a pivotal component for holding irrigation tubing securely during medical procedures.
5. Pressure Sensor Nozzle: The Pressure Sensor Nozzle integrated into the Suction irrigation pump plays a vital role in accurately measuring and maintaining irrigation pressure during medical procedures. This nozzle is specifically designed to detect variations in pressure levels within the irrigation system, ensuring precise control and delivery of fluids to the patient.
6. Suction Inlet: The suction inlet, a crucial component of the Suction irrigation pump, serves to establish negative pressure within the system for effective fluid suction during medical procedures. This inlet is designed to connect securely to the suction jar, creating a vacuum environment essential for extracting fluids from the patient's body.
7. Foot Switch Connector: The connector integrated into the Suction irrigation pump enables remote operation of suction procedures, allowing surgeons to control the device via a footswitch even at a distance from the pump. This remote operation capability minimizes disruptions during procedures, optimizing efficiency and maintaining a sterile surgical environment.
8. Power Cable Socket: The power cable socket is designed to receive the plug of the power cable, enabling the PUMP to draw electrical power from an AC power source.

It ensures a secure and stable connection, allowing the device to operate reliably and efficiently during medical procedures.

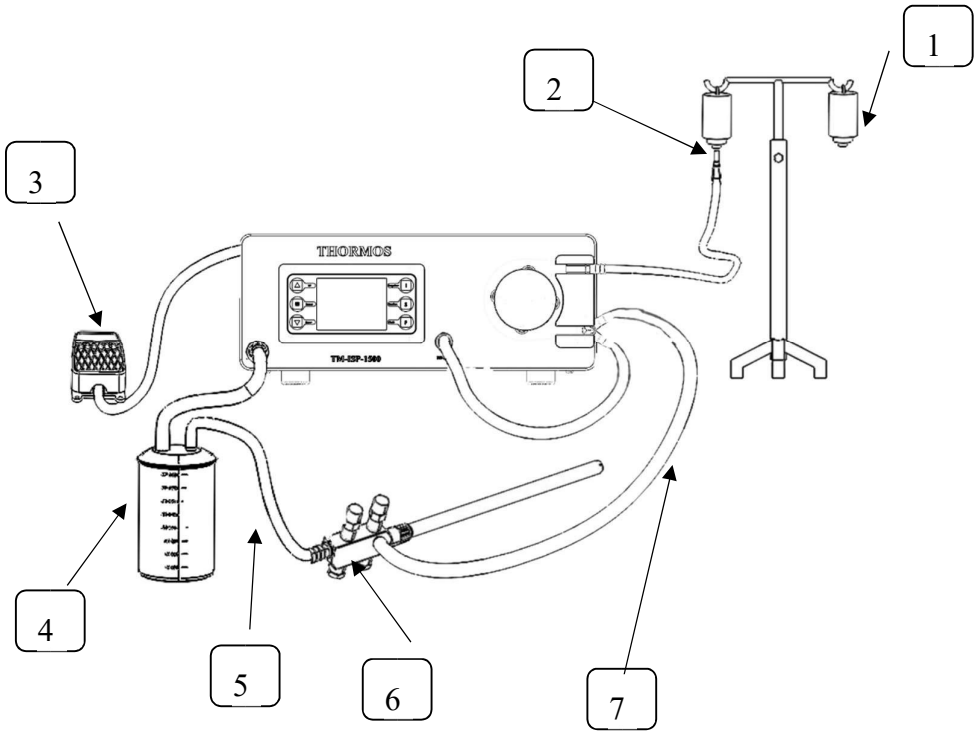
9. Suction Outlet: The suction outlet integrated into the Suction irrigation pump is a critical component responsible for generating negative pressure or vacuum, essential for suction procedures during medical interventions.
10. Earthing Pin: The earthing pin, a crucial safety feature of the Suction irrigation pump, is designed to ensure electrical grounding for the device, minimizing the risk of electric shock and promoting safe operation It serves as a protective measure to prevent electrical hazards and maintain the integrity of the Pump's electrical system.
11. On/Off button: The On/Off button is used to control the power status of the device. To turn the device on, press the On/Off button firmly and to turn the device off, press the On/Off button again until the device powers down completely.
12. Serial Port: The Serial port is used for programming device.

4 SYMBOLS & DEFINITION

Symbol	Definition
	Caution, consult accompanying documents.
	Warning
	Consult Instruction for use
	Follow instruction for use
	Indicates compliance with the Medical Device Directive.
	Catalogue Number
	Serial Number

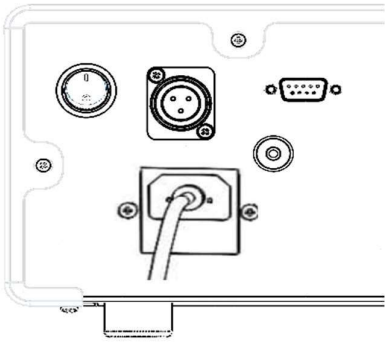
	Date of Manufacture
	Manufacturer
	Medical Device
	Do not dispose with household waste
	Keep dry
	Temperature Limit
	Humidity Limitation
	Packaging Unit
	Warning Electricity
	DEHP Free
	China RoHS (Reduction of hazardous substances)

5 SETUP AND DEVICE CONFIGURATION



1. IV Fluid
2. Piercer
3. Footswitch
4. Suction Jar
5. Suction Tube
6. Trumpet Valve Suction Irrigation Cannula
7. Irrigation Tube

5.1 Connect to AC Power.



- Plug the designated hospital power cord into the AC inlet situated on the rear side of TM-ISP1500.
- Connect the other end to hospital-grade power outlet.

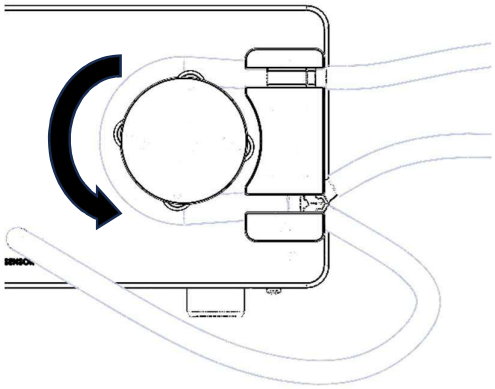
WARNING:

- Check the power cord assembly periodically for damaged insulation or connectors.
- To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

CAUTION

- When connecting or disconnecting a cable, hold the cable by its connector (its plug, not the cord). Failure to comply may result in damage to the cable or pump.
- Connect the power cords directly to the AC inlet or outlet. Do not connect any of the power cords together.

5.2 Connect Irrigation tubing with Y-connector and Roll-over the pulley.

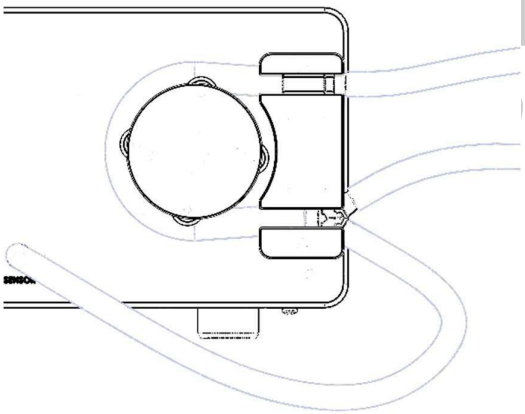


with y-connector and roll it

 Attach the Irrigation tubing

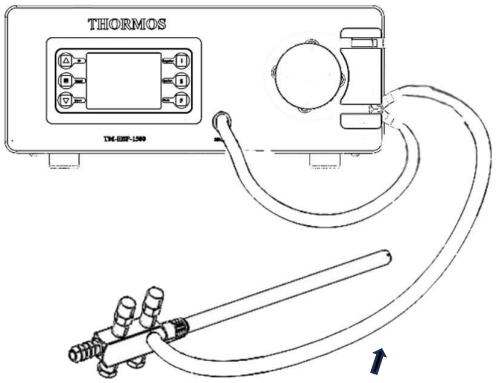
over the pulley as demonstrated in the fig.

5.3 Connect irrigation tubing from y-connector to pressure sensor nozzle.



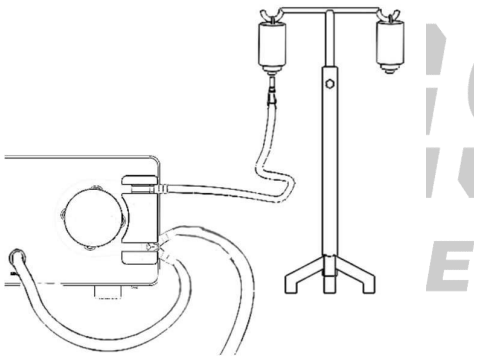
 Connect the one end of y-connector irrigation tubing with the pressure sensor nozzle.

5.4 Connect irrigation tubing to trumpet valve suction irrigation cannula



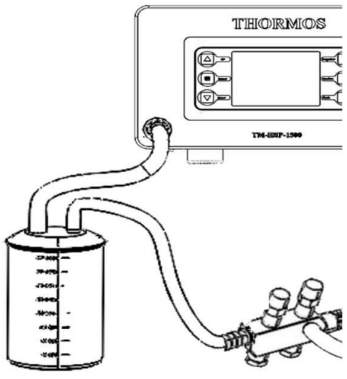
- Gently insert the other end of y-connector irrigation tubing to the side port (L-shaped port) of trumpet irrigation suction cannula.

5.5 Connect the IV fluid to irrigation tubing.



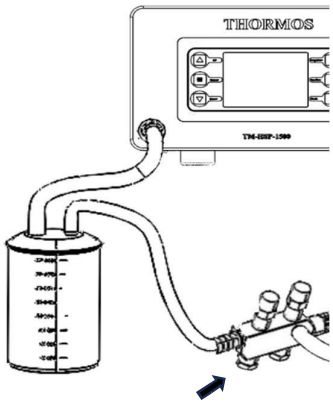
- Connect the IV fluid to the irrigation tubing using the piercing spike by inserting it into the IV fluid container's rubber stopper. Then, attach the irrigation tubing to the Y-connector, ensuring a secure fit. This setup allows for seamless fluid transfer between the IV fluid container and the irrigation system

5.6 Connect Suction nozzle to Suction Jar



- Gently insert the suction tubing with one end on the suction nozzle inlet of the pump while another end into the designated port on the lid of suction jar.

5.7 Connect the suction jar to trumpet suction irrigation cannula.



Connect the other port on the lid of suction jar to the straight valve of trumpet suction irrigation cannula.

6 PUMP USER INTERFACE:

6.1 Starting a procedure:

To initiate the procedure, follow these steps:

1. Start the pump by pressing ON button.
2. Prime the irrigation tubing before operate the pump
3. Select the pressure and flowrate of irrigation.

Start the pump by pressing On button

1. Press button located at the top of right corner of rare panel to power on the pump. The pump will display a splash screen while the software is loading.
2. To power off the system, press again

WARNING:

The selection of irrigation fluid should be determined by the physician, considering the surgical technique to be utilized.

Prime the irrigation tubing before operate the pump

1. Press and Hold "Flush" to remove all air from the tube.
2. Keep it pressed till solutions comes out from the tube outlet.
3. Confirm no air bubble in the tube and Release button.
4. If you want to skip press down button

NOTE: This step is performing each time when we power on the pump, without this step we cannot proceed to next step.

Irrigation Mode:

For Irrigation process, click on Irrigation button, a green light will flash behind suction. It shows that Irrigation motor is on.

Suction Mode:

For suction process, click on suction button, a green light will flash behind suction. It shows that suction motor is on.

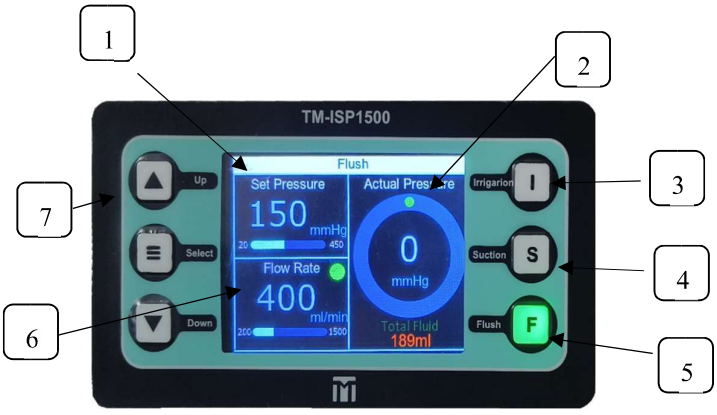
You can also initiate suction by just pressing footswitch.

NOTE: For the first time, suction motor will take 30 seconds to generate negative pressure inside the suction jar.

Flush Mode:

After surgery to remove all the remaining fluid inside the tube, press and hold flush button.

User Interface Reference:



1. Set Pressure
2. Actual Pressure
3. Irrigation
4. Suction
5. Flush
6. Flow rate control
7. Adjust pressure increase or decrease.

A green light flash beside Flush button. It shows that Flush button is on.

Note: You can use  button to increase or decrease the set pressure value or flowrate value.

7 TECHNICAL SPECIFICATION:

1. FEATURES & PERFORMANCE : The display indicates the total fluid consumed to prevent fluid overloading into the Cavity. User-friendly interface– easy-to-use operation. Upto 1500 ml/min irrigation performance. Suction pressure -0.65 bar Efficient procedural flow – fast and accurate pressure control. Factory fixed preset pressure. Optimal visualization – provides clear visualization during a procedure.

Voltage range (V)	100 - 240 V~
Supply frequency (Hz)	50/60 Hz
Protection	IP21
Operating conditions	+10 to +40 °C 30 to 75 % rel. atmospheric humidity 70 to 106 kPa air pressure 3000 m max. operating altitude above sea level
Storage, transport and shipping conditions	-20 to +60 °C 10 to 90 % rel. atmospheric humidity 70 to 106 kPa air pressure
Nominal flow range	Hysteroscopy: 200 - 1500 ml/min (max. flow)
Pressure	20 - 450 mmHg
Dimensions (W x H x D)	330 mm x 140 mm x 410 mm
Weight	
Irrigation tube Set	10 kg
Power cable	3 m length, with Y-piece, with luer-lock connector.
Foot Switch	Cable length: 3 m Cable length: 3 m

8 MAINTENANCE

8.1 Importance of cleaning, disinfection, and sterilization.

The medical reports shows that incidents of cross-contamination are resulting from improper cleaning, disinfection, or sterilization. It is strongly recommended that all individuals

engaged in reprocessing closely observe all instruction given in this manual and have a thorough understanding of the following items:

- Professional health and safety policies of your hospital.
- Instruction manuals for the endoscope, hysteroscope, laparoscope accessories and all the other reprocessing equipment.
- Handling of pertinent chemicals.

When selecting appropriate methods and conditions for cleaning and disinfection and sterilization, follow the policies at your institution, applicable national laws and standards, and professional society guidelines and recommended practices, in addition to the instructions given in this manual.

WARNING

- DO NOT spray disinfectant directly on the electrical Pump, or immerse the Pump in any type of liquid. This could result in a severe electrical hazard.
- Do not allow fluid to seep inside the pump (especially through the sensor nozzle, suction nozzle or rear case multipin connector) severe damage may occur.
- All disinfection should be done using a “hospital-grade” disinfectant registered with the Environmental Protection Agency (EPA).
- When disinfecting is required, check manufacturer’s instructions before use, and use disinfectant in accordance with the manufacturer’s instructions.

Suggested Disinfectants

1. Quaternary Cleaners
2. Chlorinated Bleach Solution (5.25% bleach diluted 1 part bleach to 10 parts water)
3. 70% Isopropyl Alcohol
4. Accelerated Hydrogen Peroxide (AHP)

CAUTION

- Always wear gloves when cleaning the pump and pump accessories.
- Only use Seller specified compatible cleaning fluids.

- Do not spray solutions directly onto the pump and pump accessories.
- Do not autoclave or use EtO (ethylene oxide) to sterilize pumps or pump accessories.
- Do not immerse any part of the pump in cleaning agents or other liquid.
- Do not use phenol-based cleaners/disinfectants. Phenols degrade plastics and membrane switches.
- Do not use abrasive cleaners.
- Do not use rigid cleaning instruments.
- Disinfect the Pump, Power Cord, and Hosing Assembly between patient installations and when servicing, utilizing standard hospital protocol and disinfectants. Failure to disinfect may risk cross-contamination and infection.
- Unplug Pump from its source prior to cleaning.

NOTE: Do not use damaged equipment. Send to Seller for repair.

- Senor can be damaged if cleaning is not performed in a careful manner.
- Prior to performing any maintenance on the Pump, read each maintenance procedure completely.

8.2 Cleaning the pump

8.2.1 To clean the front and sides of the pump:

1. Unplug the main supply cord from the backside of the pump
2. Place the pump in an upright position (means on its feet).
3. Apply the compatible cleaning agent to a lint-free cloth.

NOTE: Use dilution ration per the cleaning agent's manufacturer's instructions.

NOTE: Do not spray solutions directly onto the pump.

4. Wring out any excess cleaning solution from the lint-free cloth.

NOTE: Make sure the cloth is damp, not dripping. This prevents fluid from seeping into component areas of the pump.

5. Wipe down the front and sides of the pump.

NOTE: Disinfectants should remain on the pump's surface in an even, but not dripping, film for the recommended contact time for the compatible cleaning agents. A minimum of two wipes will be required to keep the surface visibly wet for the duration of the contact time.

6. Wipe the pump dry and allow too fully air-dry.

8.2.2 To clean the back of the pump.

NOTE: Do not allow moisture to permeate the terminal pins.

7. Apply cleaning solution to a lint-free, foam tipped swab (do not use a cotton swab). Blot the swab onto a dry lint-free towel to remove excess cleaning solution
8. Carefully wipe down the multipin connector, earthing pin, suction nozzle inlet and the power supply pin.

8.3 Drying the pump:

NOTE: Keep the pump powered off, the AC Power Adaptor unplugged from a power source until all cleaning liquids have completely evaporated from the entire pump.

9. Allow the pump to air dry.
10. Allow additional drying time when in a cold or humid environment.
11. Allow the cleaning liquids to completely evaporated from the pump.
12. Allow time for fluids that may have seeped into or between pump components to dry.

WARNING

Proper Disposal Required

To dispose of this device or the associated administration sets, adhere to local, state, federal and/or other governing regulations.

8.4 Pump Handling, Transport and Storage

1. Do not handle, transport or store pumps in a manner in which any heavy or sharp objects could impact the keypad.
2. Use care when handling, transporting and storing pumps to prevent physical damage.

9 WARRANTY AND SERVICES

Limited Warranty:

1. Seller Warrants to the original purchaser ("Customer") that this newly manufactured enteral feeding pump, will be free of defects in materials and workmanship, under normal use, for two (2) years from the date of shipment from Seller This Limited Warranty is not applied to pump accessories.
2. This Limited Warranty does not cover regular maintenance tasks like cleaning or performance tests, which are outlined in this manual. It's the sole responsibility of Customer. If the customer doesn't follow these instructions and something goes wrong with the pump then the warranty might not cover the repairs.
3. All products should be returned to Seller for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Seller unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Seller, and product repair and part replacement must be done in strict conformance with Seller specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Seller for that part.
4. Delivery by Seller of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Seller instruments and other products should never be modified or altered under any circumstances.
5. Contact Seller if you have any question (1) whether replacement of a part or a repair is authorized by Seller, or (2) whether you have complete instructions and specifications for part replacement or repair.
6. This Limited Warranty does not cover any pump, product or part that:
    a) has been operated in an unsuitable environment or used for purposes other than intended;
    b) has been subjected to unauthorized or non-Seller repair or use of non-Seller supplied parts;
    c) has been altered, misused, abused or neglected;

d) has been subjected to fire, casualty or accident;
e) suffer damage caused by Customer's negligent acts or omissions
f) suffers damage beyond normal wear and tear.

7. For purposes of this Limited Warranty, "damage beyond normal wear and tear" includes without limitation:
    a) Damage to housing, LCD, display overlay or power supply;
    b) Use of non-qualified power supply
    c) Use of unauthorized cleaning fluids
8. If a pump does not operate as warranted during the applicable warranty period, Seller may, at its option and expense,
    a) repair or replace the defective part or pump;
9. Dated proof of original purchase is required to process warranty claims. Removal, defacement or alteration of serial lot number voids this Limited Warranty.
10. Shipping costs for pumps being returned to Seller shall be borne by Customer. Customer is responsible for proper packaging for return shipment. Loss or damage in return shipment to Seller shall be at Customer's risk.
11. Seller disclaims all other warranties, expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose or application other than

as expressly set forth in the product labeling. In no event shall Seller be liable for any incidental, indirect or consequential damages in conjunction with the purchase or use of the pump, even if advised of the possibility of the same.