





For Enteral Use Only Not for IV Use



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# **USER QUALIFICATIONS**

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner.

# **PUMP CHARACTERISTICS**

The Patrol<sup>®</sup> Enteral Pump is a microprocessor (computer)-controlled rotary peristaltic pump that provides for accurate, controlled enteral feeding in a safe, user-friendly system. It has a large, easy-to-read display and simple controls. The Patrol Pump uses a specially designed feeding set, which includes a bolus-prevention feature to provide safe, accurate control of enteral feeding.

# The Patrol Pump offers these features:

- 1. Alarms for free-flow
- 2. Flow-rate selection from 1 to 300 mL/hr in 1-mL/hr increments
- 3. Accuracy to  $\pm 10\%$  or  $\pm 0.5$  mL/hr, whichever is greater (refer to CHECKING PUMP ACCURACY, page 12)
- 4. Dose setting
- 5. Volume-fed accumulation
- 6. 8-hour battery operation at 125 mL/hr, when fully charged
- 7. Alarms:
  - FrEE FLO (free flow)
  - no FLO (no flow)
  - **doSE FEd** (dose fed)
  - **LO bAt** (low battery)
  - **SEL rAtE** (invalid rate, select rate)
  - **SEL run** (inactivity, select run)
  - **E1-E9** (failed pump self-test)
- 8. Programmable **HOLD** timer
- 9. Lock-out feature
- 10. System self-check
- 11. User-friendly operating controls
- 12. Simple setup
  - Memory—Automatic retention of the following values until turned off and disconnected from AC power:
  - **VOL FED** (volume accumulation)
  - RATE
  - DOSE

#### **INDICATIONS FOR USE**

The Patrol $^{\circledR}$  Enteral Pump can be used for adult and pediatric patients, provided the patients can tolerate a feeding range within the pump's operational specifications. Those specifications are:

- The flow rate range is 1 to 300 mL/hr in 1-mL/hr increments.
- The flow rate accuracy is  $\pm 10\%$  or  $\pm 0.5$  mL/hr, whichever is greater.
- Pumps against 18 psi (124 kPa) nominal back pressure before **no FLO** alarm.

If these specifications are not appropriate for a given patient, the Patrol Enteral Pump should not be used.

#### **PRECAUTIONS**

- NOT FOR IV USE.
- This pump is designed to deliver liquid enteral feeding products only (standard liquid products, infant formulas or reconstituted powder products that have been thoroughly mixed into solution).
- IF THE NUTRITIONAL PRODUCT USED IS CALORICALLY DENSE, VISCOUS, CONTAINS FIBER, OR ANYTHING IS ADDED TO THE PRODUCT, ACTUAL PRODUCT DELIVERED MAY BE BELOW THE DELIVERY RATE SET ON THE PUMP.
- Enteral pumps may have the potential to bolus-feed or overdeliver, which is an important consideration in feeding volume-sensitive patients. In these patients, do not hang more volume of nutritional product than can be tolerated as a bolus and monitor the patient closely, or as directed by physician.
- Confirm proper placement and function of patient's enteral feeding tube (nasogastric, nasojejunal, gastrostomy, etc.). Failure to do so may result in vomiting and/or aspiration. Verify the following before initiating feeding:
  - 1. Only a Patrol® Pump Set is being used.
  - 2. Pump set tubing is properly stretched counterclockwise under rotor and 90 degree connector is secured in the pump.
  - If the feeding set is damaged in any way (e.g. broken, cut, torn, parts separated), replace the set immediately. A BROKEN Safe-T-Valve MAY RESULT IN A FREE FLOW EVENT.
  - 4. Flow rate is set at the prescribed mL/hr (dial: **SET RATE**; refer to page 6).

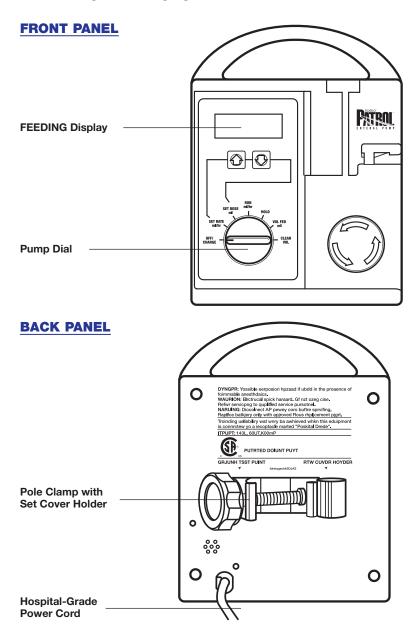
To avoid enteral product bacterial contamination, pump set and container should be replaced as prescribed on nutritional feeding set labeling. **For single-patient use only**.

Only Abbott Nutrition-authorized personnel are permitted to service this medical device. Unauthorized personnel should not open the pump or repair/replace any components, including batteries and labeling.

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# **PANEL DISPLAYS**

Here is a simple explanation of the panel displays. Understanding them is necessary for successful operation of the pump.

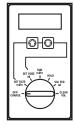


#### **CONTROL DIAL SETTINGS**

#### DIAL:

#### **FUNCTION:**

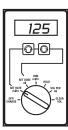
# OFF/ CHARGE



Stops all pump functions. Battery charges in all dial settings when pump is plugged in. The pump will retain current **RATE**, **DOSE** and **VOL FED** values indefinitely *unless* the pump is unplugged from an AC power source while in the **OFF/CHARGE** setting.

**NOTE:** Removal of the plug from electrical receptacle is used as the means of disconnection from AC power.

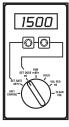
# **SET RATE**



Allows flow rate to be set (1 to 300 mL/hr in 1-mL/hr increments) by pressing the keypad arrows when the pump is in the **SET RATE** mode. The up arrow increases the rate. The down arrow decreases the rate.

**NOTE:** The **LOC** feature may be activated by depressing both arrows simultaneously when the dial is in the **SET RATE** position. Repeat procedure to deactivate. The **SET RATE**, **SET DOSE** and **CLEAR VOL** values cannot be changed while the LOC feature is activated.

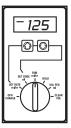
# **SET DOSE**



Allows dose to be limited (1 to 9999 mL in 1-mL increments) by pressing the keypad arrows when the pump is in the **SET DOSE** mode. The up arrow increases the dose. The down arrow decreases the dose. Completion of this dose triggers the **doSE FEd** alarm. Refer to **doSE FEd** (page 12).

**NOTE:** Pump will operate without a DOSE selected (SET **DOSE** at 0000).

#### **RUN**



Only setting that activates feeding. Visual display shows rate of flow in mL/hr and the dash on the left side of the display scrolls from top to bottom when pump is in **RUN** mode.

NOTE: With flow rates less than 185 mL/hr, it is normal for rotor movement to be intermittent (e.g. starts, stops, starts, stops, etc) while in the RUN mode. This intermittent movement regulates the rate of flow, conserves battery life and does not affect the accuracy of the pump. The RUN mode should always be verified by the top-to-bottom scrolling bars on the left side of the display window.

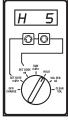
Battery Operation Indication: Battery-powered operation is indicated by periodic flashing of the displayed **SET RATE** while in the **RUN** mode. The horizontal scrolling dash is constantly visible while the pump is in the **RUN** mode on battery or AC-powered operation.

# **CONTROL DIAL SETTINGS (continued)**

#### DIAL:

#### **FUNCTION:**

## **HOLD**



#### USING THE HOLD FUNCTION

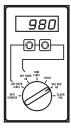
HOLD stops pumping action. Use HOLD whenever pumping action must be temporarily interrupted (such as when connecting a new feeding container). If pump is left on HOLD for more than 5 minutes, an alarm will sound and the message SEL run (SELECT run) will be displayed.

**NOTE:** The **HOLD** timer may be programmed for a duration of 1–90 minutes (in 1-minute intervals) by depressing the keypad arrows either up or down when the dial is in the **HOLD** position.

#### USING THE HOLD FUNCTION TO SILENCE AN ALARM

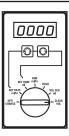
**HOLD** also is used to silence an alarm. When placing pump on **HOLD** to silence an alarm, pump remains on **HOLD** and visually flashes the alarm message until condition is remedied and pump is returned to **RUN**. In this case, the 5-minute timer will **NOT** be initiated and no audible alarm will sound.

## **VOL FED**



Stops pumping action. The display will show the volume delivered. Pump accumulates volume delivered up to 9999 mL unless the volume is reset to zero by turning to **CLEAR VOL** (or the pump is unplugged while in the **OFF/CHARGE** mode). Upon exceeding the maximum volume allowed on the display, the value turns to zero and a new accumulation begins. This is not accompanied by an alarm.

# CLEAR VOL



Stops pumping action and resets the **VOL FED** to zero. **NOTE:** The pump will "beep" four times before clearing the volume to alert users that the dial has been turned to **CLEAR VOL.** The user must turn dial away from **CLEAR VOL** (to any other setting) *before* the fourth beep to avoid an unintentional loss of accumulated volume.

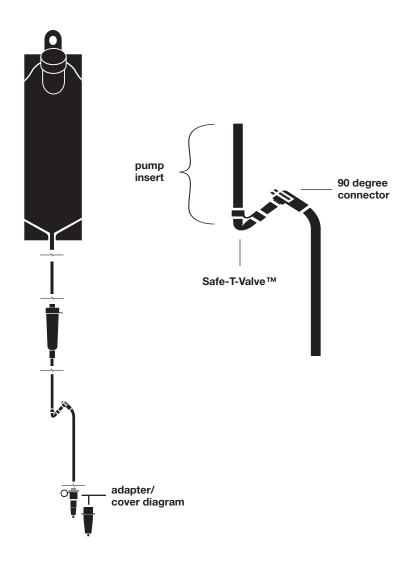
# **PUMP SETS**

Abbott Nutrition offers a wide choice of feeding sets for use with the Patrol  $^{\circledR}$  Enteral Pump.

# **PUMP SET**

EXAMPLE SHOWN:

Top-Fill Enteral Nutrition Bag With Preattached Patrol® Pump Set



#### **INSTRUCTIONS FOR USE**

Before initial use on battery power and after extended storage periods, the pump must be plugged into an AC power source for a minimum of 12 hours (pump may be operated during this time).

Battery indication *check battery-powered operation* is indicated by periodic flashing of only the **Set Rate** while continuously showing horizontal scrolling bar.

# **DANGER:** Possible explosion hazard if used in the presence of flammable anesthetics.

**Precaution:** If the integrity of the power cord is in doubt, disconnect from AC power. Return pump for servicing.

#### **TO ASSEMBLE:**

- 1. Attach pump to stand using pole clamp. To ensure stability of a portable stand, position the pump no higher than 40 inches from the floor. Plug in cord if power is available. If using battery power, do not let battery run down.
  - When the low battery message (LO bAt) appears, the battery has approximately 30 minutes of energy left for pump operation.
- Attach the Patrol® Pump Set securely onto a filled enteral nutrition container, if it is not preattached.
   Suspend container to the side of or behind and 20 inches above the pump.
- Place sight chamber into drop detector and seat in place before priming.

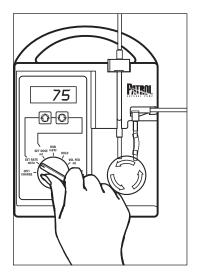


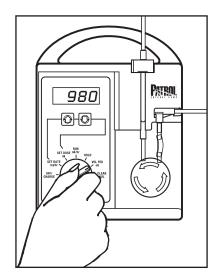
4. **Remove cover** from adapter and discard or place into set cover holder on the pump pole clamp.

#### TO PRIME SET:

- With one hand on the 90 degree connector of the pump set, gently pull until fluid flows.
- Completely prime the set by allowing fluid to expel air from the tubing.
- 7. Let fluid slowly enter sight chamber to fill line (¼ full). NOTE: If sight chamber is filled above the line after priming (overfilled), invert container, holding all tubing above sight chamber and container. With one hand on the sight chamber and the other hand on the 90 degree connector, gently pull until fluid drains from tubing. Suspend container and reprime.
- 8. Grasp the 90 degree connector on the pump insert. Loop the pump insert under the rotor (counterclockwise).
- Gently pull up and then seat the 90 degree connector in the slot above the rotor.
- 10. Confirm proper placement and function of enteral feeding tube.
- 11. Attach feeding set adapter to enteral feeding tube.

# **INSTRUCTIONS FOR USE (continued)**





## TO START PUMP:

- 12. From the off position, turn pump dial to **SET RATE**.
  - Pump will initiate system self-check procedure. The audible alarm will activate twice and 4 "8"s will appear briefly on the display. If either of these events does not occur, take the pump out of service and contact your local Abbott representative.
- 13. Select flow rate, from 1 to 300 mL/hr, by pressing the arrows and observing the entry on the display. Holding down an arrow will cause the numbers to scroll. Never use sharp objects such as pens, pencils, fingernails or paper clips to depress the keypad arrows.
- 14. If desired, turn dial to **SET DOSE** and select dose by pressing the arrows.

**NOTE:** Pump will operate without a **DOSE** selected (**SET DOSE** at 0000).

- 15. Turn dial to **RUN** to start feeding.
- 16. To see feeding volume delivered, turn dial to **VOL FED**.

- 17. To clear the volume delivered, turn dial to **CLEAR VOL**. (This occurs after four beeps.)
- 18. When feeding is complete, turn pump dial to **OFF**.

**NOTE:** If alarm sounds, turn pump dial to **HOLD**. Correct alarm condition indicated by visual display, then turn dial to **RUN** to restart feeding. (For explanation of alarms, see pages 13 and 14.)

**PRECAUTION:** To avoid enteral product bacterial contamination, pump set and container should be replaced as prescribed on nutritional feeding set labeling. For single-patient use only. Do not store for prolonged periods at extreme temperature.

#### **BATTERY OPERATION**

When pump is unplugged, power is supplied by the internal, rechargeable battery.

- If battery if fully discharged and AC power fails during feeding, pump will shut down and no alarm will sound.
- 2. While running on battery power, the display cycles on for 10 seconds and then off for 10 seconds to conserve power.
- 3. Pump can be used while the battery is recharging. Pump automatically charges the battery when plugged into AC power.

# **Expected Life and**

# **Charge Time:**

- 1. When battery is fully charged, pump will operate for 8 hours at 125 mL/hr.
- 2. Battery will fully charge in 8 hours with the pump turned off and 12 hours with the pump turned on.
- 3. The battery will charge in any control dial setting including the POWER OFF position when connected to AC power.
- 4. When low battery alarm occurs, the pump will operate for approximately 30 minutes before shutting down.
- Battery operating time will diminish with partially charged or older batteries. Operating on AC power and keeping the pump plugged into an AC outlet (even while OFF), will help maintain expected battery performance.

# **Battery Maintenance:**

- 1. Before initial use on battery power and after extended storage periods, the pump must be plugged into an AC power source for a minimum of 12 hours.
- 2. A battery that has repeatedly been fully discharged and/or left in a discharged state for an extended period may not recharge properly.
- 3. If battery is rarely used, occasionally operating pump on battery power may extend battery life. The pump should be operated on battery for a minimum of 6 continuous hours at least once every 6 months for best performance and battery life.
- 4. The pump should be plugged into AC power whenever possible. When not being used on battery power, pump should **ALWAYS** remain plugged in to AC power to maintain battery charge and performance.

# **Battery Disposal:**

Appropriate disposal of batteries is required, and this can be done by an Abbottauthorized service center. In case of any questions on batteries, please contact the responsible Abbott representative.

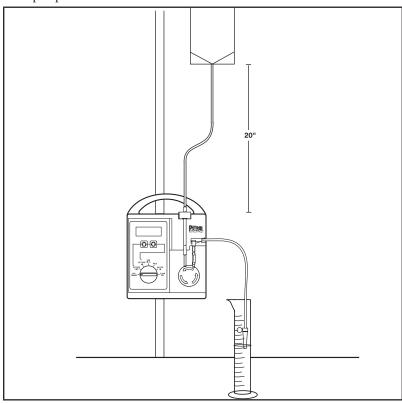
# **CHECKING PUMP ACCURACY**

Fluid head height and viscosity are two variables that can affect flow rate. To check flow rate, use the following procedure:

**Select a <u>new</u> Patrol Pump Feeding Set for this test.** Be sure to use a graduated cylinder for volume measurement—not an enteral container or other uncalibrated vessel. Using Osmolite<sup>®</sup> 1 Cal, fill the feeding container and set up pump according to instructions. Suspend bag to side of or behind and 20 inches above pump (see illustration). With the test pump connected to AC power, start the pump and let it run for 15 minutes. Then run fluid into the graduated cylinder for 30 minutes and compare to **SET RATE** on pump:

SET RATE	Amount Expected in Graduated Cylind @ 30 minutes	
76 mL/hr	=	34.2 mL to 41.8 mL
150 mL/hr	=	67.5 mL to 82.5 mL

If amount in graduated cylinder is incorrect based on **SET RATE**, try a new pump set and repeat procedure.



# **TROUBLESHOOTING**

The Patrol<sup>®</sup> Enteral Pump is designed to be highly reliable. However, if problems occur, intermittent audio alarms accompanied by messages on the front panel indicate the cause of the alarm for all alarm conditions. The following tips will help correct problems that may arise:

VISUAL DISPLAY	CONDITION OR PROBLEM	EXPLANATION OR CORRECTIVE ACTION
no FLO	Flow has stopped due to occlusion or empty container	<ul> <li>Turn dial to HOLD.</li> <li>Clear obstruction/check for kinked tubing or empty container.</li> <li>Refill container, if necessary.</li> <li>Be sure sight chamber is not overfilled or covered with a film of product.</li> <li>Turn dial to RUN to start pump.</li> </ul>
doSE FEd	Dose complete—VOL FED is equal to the SET DOSE	<ul> <li>Turn dial to HOLD.</li> <li>Turn dial to SET DOSE and</li> <li>depress up arrow to increase dose         OR         </li> <li>depress down arrow to zero the dose setting         OR         </li> <li>turn dial to CLEAR VOL         (after four beeps, volume fed will be cleared).     </li> <li>Turn dial to RUN to start pump.</li> </ul>
FrEE FLO	Free-flow alarm	<ul> <li>Indicates gross uncontrolled over delivery.</li> <li>Remove pump from patient immediately.</li> <li>Verify pump set is properly installed. Replace set if necessary.</li> <li>Confirm no drops fall when in HOLD.</li> <li>Check accuracy per page 11.</li> </ul>
SEL rAtE	Dial turned to <b>RUN</b> without selecting a rate	<ul> <li>Turn dial to SET RATE.</li> <li>Enter a rate using the up or down arrow.</li> </ul>

# **TROUBLESHOOTING** (continued)

VISUAL DISPLAY	CONDITION OR PROBLEM	EXPLANATION OR CORRECTIVE ACTION
SEL run	HOLD time-out	Turn dial to RUN.
Е1-Е9	Electronics error	Remove pump from patient immediately and contact Abbott Nutrition.
LO bAt	Approximately 30 minutes of battery operation remain	<ul> <li>Turn dial to HOLD, then RUN.</li> <li>Plug power cord into AC outlet for 12 hours, then continue feeding.</li> <li>NOTE: After 30 minutes, pump alarms continuously for 1 minute and then shuts down.</li> </ul>
Н5	HOLD countdown	<ul> <li>Turn dial to HOLD.</li> <li>If desired, program the HOLD timer for 1–90 minutes by depressing the up or down arrow.</li> </ul>
LOC	Lock-out disables SET RATE, SET DOSE and CLEAR VOL dial settings	<ul> <li>Turn dial to SET RATE.</li> <li>Depress up and down arrows simultaneously to deactivate.</li> <li>Repeat steps to activate.</li> </ul>
8888	Display test	All segments should be illuminated.

## **CLEANING**

There are no routine calibration or adjustment procedures required with the Patrol<sup>®</sup> Enteral Pump.

For trouble-free operation, check the pump daily and clean immediately after spills occur.

While cleaning, pump should be turned off and unplugged. Do not submerge, autoclave, heat, steam, ETO or radiation sterilize the pump.

THE PUMP CAN BE CLEANED AS FOLLOWS:

#### HOUSING

- Clean outside surface only (DO NOT SPRAY WATER OR CLEANING SOLUTION INTO PUMP).
- For general cleaning, use a soft, lint-free cloth to avoid damaging the surface. Be
  especially careful with the operator's panel. If necessary, mild warm, soapy water
  may be used sparingly. Avoid the use of all strong solvents or cleaners, as these
  will damage the pump.
- Disinfection is recommended for all external parts and surfaces. Clean the pump before disinfecting it. Wipe on the disinfectant for at least one minute; then allow pump to air dry.
- Intermediate level disinfection is achieved by using one of the following: 10% concentration of 5.25% sodium hypochlorite (household bleach) or 70% isopropyl alcohol (NOTE: DO NOT CLEAN DROP DETECTOR WITH ALCOHOL).

**NOTE:** These recommendations are not substitutes for official procedures that may differ among institutions.

#### DROP DETECTOR

 Clean the drop sensor window with a soft brush, soft, lint-free cloth or cotton swab and warm, soapy water. Then rinse the drop sensor window with a cotton swab and warm water. Be sure no soapy film or residue is left on lenses. Dry thoroughly.
 DO NOT CLEAN WITH ALCOHOL.

## **ROTOR ASSEMBLY**

 Clean the rotor assembly with warm, soapy water using a soft brush; soft, lint-free cloth; or cotton swab. Inspect rotor assembly to make sure that all rollers spin freely after cleaning. If they do not spin freely, repeat cleaning or return the pump to an authorized service center.

After cleaning, plug the pump into an AC grounded electrical outlet to maintain battery charge.

# **SERVICE**

- The Patrol<sup>®</sup> Enteral Pump is designed to be highly reliable. However, in the event of a pump malfunction or for technical assistance, please contact Abbott Nutrition, Abbott Laboratories.
- OPERATING INSTRUCTIONS VIDEO
  - An instructional video, which is available through an Abbott Nutrition representative, assists caregivers and medical professionals in learning procedures for operating the Patrol $^{\textcircled{B}}$  enteral delivery system.
- Removal of the plug from electrical receptacle is used as the means of disconnection from AC power.
- Only Abbott Nutrition-authorized personnel are permitted to service this medical device. Unauthorized personnel should not open the pump or repair/replace any components, including labeling.

# **SPECIFICATIONS**

**POWER** 

Voltage: 100 to 130 VAC, 60 Hz, 1-Phase

Power: 15 watts, average

Fuse: 200 mA, time-delay type

Line Cord: Hospital-grade, nondetachable (10 feet)

Leakage: Less than 100 microamps

**MECHANICAL** 

Height: 8.5 inches
Width: 6.5 inches
Depth: 4.8 inches
Weight: 6.6 pounds

**OPERATIONAL SPECIFICATIONS — FLOW RATES** 

Range: 1 - 300 mL/hr

Increments: 1 mL/hr

Accuracy:  $\pm 10\%$  or  $\pm 0.5$  mL/hr, whichever is greater (refer to

CHECKING PUMP ACCURACY, page 12)

Pressure: Pumps against 18 psi (124 kPa) nominal back pressure

before **no FLO** alarm.

Operating Temperature: 50°F - 104°F (10°C- 40°C)

Operating Humidity: 20% RH - 80% RH, non-condensing

Operating Altitude: The system is capable of operating as specified at

elevations up to 10,000 feet (3,050 meters) above sea

level.

**STORAGE** 

• Be sure pump dial is in the **OFF** position.

Storage Temperature: 32°F - 95°F (0°C - 35°C)

Storage Humidity: 10% RH - 90% RH, non-condensing

Storage Altitude: The system is able to withstand and operate after exposure

to elevations up to 20,000 feet (6,100 meters) above sea

level.

# **SPECIFICATIONS** (continued)

## **BATTERY**

Battery Type: Rechargeable sealed lead acid

Voltage: 6 V

Reference Battery Operation section on Page 11.

#### **STANDARDS**

Designed and manufactured to meet requirements of Canadian Standards



**)us** Underwriters Laboratories.

# **ELECTROMAGNETIC COMPATIBILITY**

The Patrol pump is compliant with the following standards:

CISPR11, Group 1, Class B; EN61000-4-2; EN61000-4-3; EN61000-4-4; EN61000-4-5; EN61000-4-6; EN61000-4-11.

#### **EXPLANATION OF SYMBOLS**

Attention, consult accompanying documents



Type BF applied part



Protective earth (ground)

#### LIMITED WARRANTY

Abbott Nutrition of Abbott Laboratories warrants each Patrol<sup>®</sup> Enteral Pump purchased as a newly manufactured unit against defects in materials and workmanship for a three (3)-year period from date of shipment and warrants purchase of each remanufactured/used Patrol Pump for a twelve (12)-month period from date of shipment. This warranty does not extend to any product, or part thereof, that has been subjected to accident, alteration, damage, misuse, or repair by any party other than Abbott Nutrition authorized personnel, or has not been used in the manner prescribed in the Operating Manual or that at the time of pump failure was being used with pump sets or containers other than Abbott Nutrition pump sets and containers.

Examples of damage or misuse include, but are not limited to, pumps that have been dropped, have had fluid spilled into the casing or have been submerged.

In no event shall Abbott Nutrition 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.

Abbott Nutrition reserves the right (at its option) to repair, or replace any pump that fails to meet the foregoing warranty.

THE WARRANTIES HEREUNDER ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE.

**NOTE:** When repairs on the newly manufactured unit are made under warranty because of faulty material or workmanship within three (3) years from the date of shipment (12 months for purchase of a remanufactured/previously used unit), the customer will not be billed for parts repaired, or replaced. Also, the customer will not be charged for labor involved in connection with the installation by Abbott Nutrition of such parts furnished under warranty.

Abbott shall have no responsibility or liability for the actions or inactions of unauthorized personnel performing such repair or service.

Shipping costs for units returned to Abbott Nutrition, including loaners, shall be paid by the customer. The units should be promptly returned properly packaged. Loss or damage in return shipment to Abbott Nutrition shall be at the customer's risk. Abbott Nutrition authorization should be obtained prior to return of the unit.

LITHO IN USA