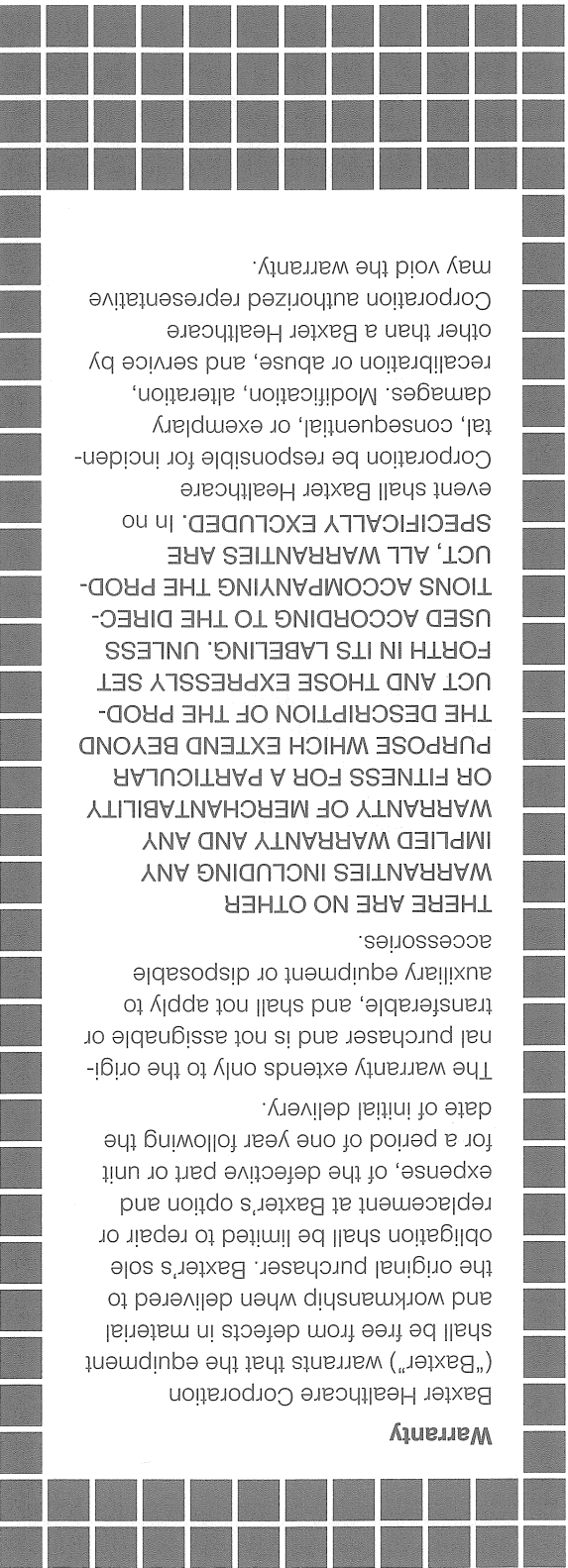




Warranty

Baxter Healthcare Corporation
("Baxter") warrants that the equipment
shall be free from defects in material
and workmanship when delivered to
the original purchaser. Baxter's sole
obligation shall be limited to repair or
replacement at Baxter's option and
expense, of the defective part or unit
for a period of one year following the
date of initial delivery.

The warranty extends only to the origi-
nal purchaser and is not assignable or
transferable, and shall not apply to
auxiliary equipment or disposable
accessories.

**THERE ARE NO OTHER
WARRANTIES INCLUDING ANY
IMPLIED WARRANTY AND ANY
WARRANTY OF MERCHANTABILITY
OR FITNESS FOR A PARTICULAR
PURPOSE WHICH EXTEND BEYOND
THE DESCRIPTION OF THE PROD-
UCT AND THOSE EXPRESSLY SET
FORTH IN ITS LABELING. UNLESS
USED ACCORDING TO THE DIREC-
TIONS ACCOMPANYING THE PROD-
UCT, ALL WARRANTIES ARE
SPECIFICALLY EXCLUDED. In no
event shall Baxter Healthcare
Corporation be responsible for inciden-
tal, consequential, or exemplary
damages. Modification, alteration,
recalibration or abuse, and service by
other than a Baxter Healthcare
Corporation authorized representative
may void the warranty.**

For additional information, call Baxter Healthcare
Corporation at 1-800-343-0366.

To report problems, call 1-800-437-5176.

When reporting problems, please be prepared
with the following information:

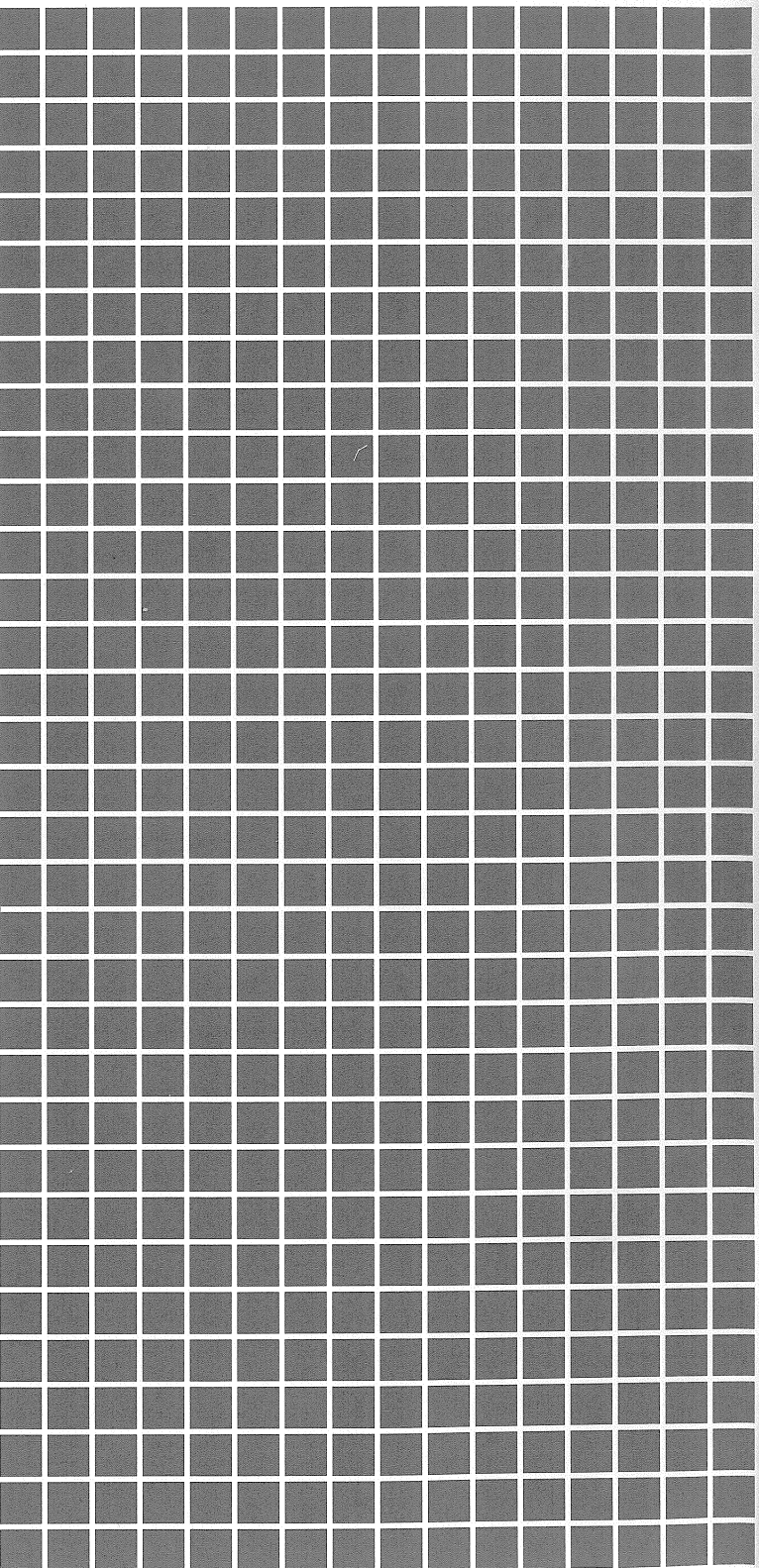
- Your name and title
- The name, address and phone number of the
user facility
- Product catalog number(s)
- Serial or lot number(s)
- Was product in use on a patient when problem
was detected?
- Was there any injury to the patient? (If yes, FDA
user reporting may be required).
- Date of event
- Description of event (please include pump set-
up, programming, configuration, and any alarms
prior to or at the time of the event).



Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

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**Operator's
Manual**

**Mini-Infuser™
System**



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Introduction

The **Mini-Infuser™** System is designed for controlled intermittent administration of intra-venous medication. The system includes standard disposable syringes, Microbore extension sets, and the **Mini-Infuser™ 150XL** or **Mini-Infuser™ 300XL** syringe pump. These battery operated devices provide ultimate control over both drug dosage and rate of administration. The **Mini-Infuser™** System provides reproducible, defined drug infusion rates and, when used properly, is safe, dependable and practical.

The **Mini-Infuser™** System accepts B-D®¹ and Monoject®² disposable syringes of various sizes(5-60cc).

Warnings

— An issued or revision date for these instructions is included for the user's information. If a period of two years has elapsed between this date and product use, the user should contact Baxter Healthcare Corporation to learn if additional product information is available.

— Use only under the direction of a qualified physician. Hospital protocol for management of drugs to be used must be followed with this device.

— Federal law (USA) restricts this device to sale by or on the order of a physician.

— The **Mini-Infuser™** System may malfunction if used near electric fields, magnetic fields, radiation sources, such as electrosurgical units, magnetic resonance imaging machines, or x-ray machines.

— This equipment is not suitable for use in the presence of flammable anesthetics.

¹ Becton Dickinson
² Sherwood Pharmaceutical Co.

Operating Principles

The **Mini-Infuser™ 150XL** and **Mini-Infuser™ 300XL** are syringe pumps that will hold and empty a standard plastic syringe at a constant, continuous rate. The syringe barrel is secured in a holder and the syringe plunger is moved by a pusher.

1. As an intermittent infusion system in combination with a heparin lock.
2. As a piggyback in combination with a gravity flow primary I.V. The primary line flow rate is not interrupted but is operated continually to deliver maintenance fluids or drug diluents. The Microbore extension set should be attached to the primary line at the lower injection port or flashback site.
3. As a piggyback in combination with an I.V. controller or I.V. pump. No change to the pump extension set should be attached to the primary line at an injection port or flashback site downstream from the infusion device.
4. As a piggyback in combination with a volume control chamber (burette). The flow rate for the burette is not interrupted. The Microbore extension set should be attached to the primary line at either the lower injection port or the flashback site.

Principles

The **Mini-Infuser™** System is a method of administering intermittent I.V. therapy. Select the drug for intermittent administration, then dilute to the concentration that will yield the desired delivery time. In many cases an isotonic solution is desired. The total dose will be infused accurately over the desired time period.

Infusion Methods

The **Mini-Infuser™** System may be used for intermittent infusions as follows:

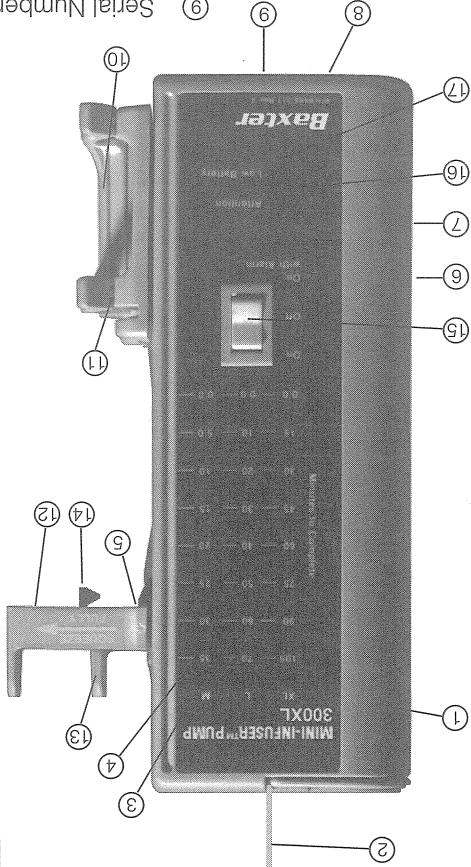
When using the **Mini-Infuser™** System as a piggyback into a running primary line, the syringe contents are further diluted by the primary solution. The equivalent dilution of the syringe contents may be calculated as follows:

$$\text{Total Volume (ml)} = [\text{Volume in Syringe}] \times \left[\frac{\text{Primary Rate (ml/hr)}}{\text{Mini-Infuser Rate (ml/hr)}} + 1 \right]$$

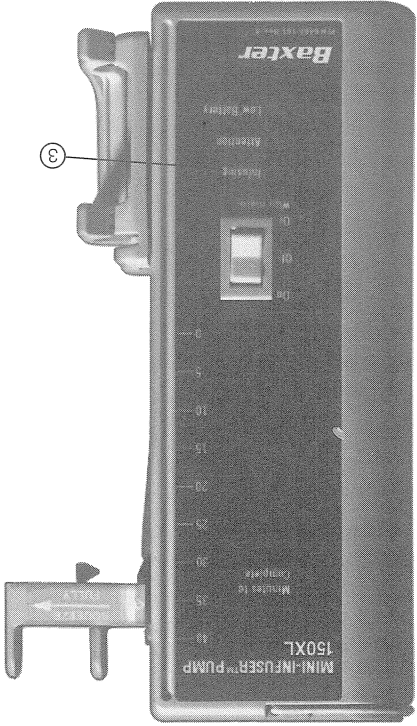
The "total volume" calculated represents the total volume into which the dose is effectively dissolved. This information is particularly important when delivering medications that require additional dilution.

Features:

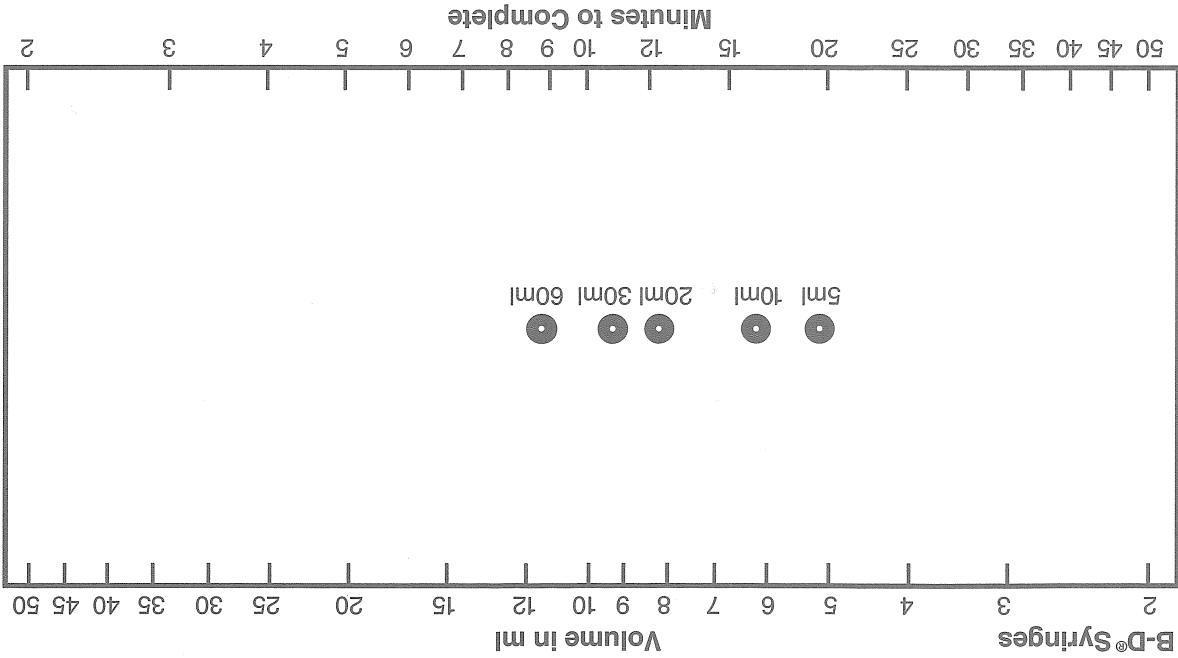
- ① Impact-Resistant ABS Molded Case
- ② I.V. Pole Attachment Loop
- ③ Infusing Lights—Flashing green light. On 300XL pump, the light also indicates the active time scale.
- ④ Time Scale(s)—Indicate Minutes to Complete.
- ⑤ Indicating Mark—Aligns with the time scale.
- ⑥ Rate Selector Switch (not shown; Model 300XL only)—Sets the rate of the pump.
- ⑦ Instructions (not shown)—Brief operating instructions are provided on the rear label.
- ⑧ Battery Door (not shown)—Slide for battery access.
- ⑨ Serial Number—(inside battery housing).



- ⑩ Syringe Barrel Holder
- ⑪ Notch—Retains barrel flange.
- ⑫ Pusher—Pushes syringe plunger.
- ⑬ Release Lever—Squeeze to release Pusher and Anti-Syphon Latch.
- ⑭ Anti-Syphon Latch—Captures syringe plunger to prevent syphoning.
- ⑮ On-Off/Switch—Up for "On" (visible alarm only), Middle for "Off", Down for "On" (with audible alarm).
- ⑯ Attention Light—Flashing red light.
- ⑰ Low Battery Light—Flashing yellow light.
- ⑱ Audible Alarm—Beeping alarm.
- ⑲ Mounting Bracket (not shown)—Allows pump to be secured to various surfaces (i.e., I.V. pole, bed headboard,...).



Nomographs—Mini-Infuser™ 150XL/300XL Pump



1. Rate determined at M speed setting. For calculation at XL or L settings, note relationship as follows:
Minutes to Complete at L = 2 times Minutes to Complete at M.
Minutes to Complete at XL = 3 times Minutes to Complete at M.

Instructions for Use

Accepted I.V. Therapy principles and techniques should always be followed for all intravenous administrations.

1. Connect the infusion system together including filled syringe, tubing set, and delivery devices as required.

2. Purge the entire system of air and replace the distal cover.

3. Reset the Pusher of the **Mini-Infuser™ 150XL** or **300XL** pump to its upper end by fully squeezing the Release Lever until the Pusher is free to move.

4. Snap the syringe barrel into the Syringe Holder of the **Mini-Infuser™ 150XL** or **300XL** pump. Make sure that the barrel flange fits into the Notch of the Holder.

5. Move the Pusher downward until it touches the syringe plunger, then release the lever.

Warning

Ensure that the plunger flange is engaged by the Anti-Syphon Latch or uncontrolled emptying of the syringe may result.

6. For Model 300XL only, set the desired rate using the Rate Selector Switch located on the back.

7. Check the Time Scale and Indicating Mark to determine the infusion duration.

8. Secure the **Mini-Infuser™ 150XL** or **300XL** pump in a convenient location using the optional Mounting Bracket or hang it from an I.V. pole using the Pole Loop.

9. Attach the primed tubing set to the appropriate infusion site, such as a heparin lock or a primary administration set. When attached to a primary set, the flashback site or the lower infusion "Y" site are the recommended infusion sites.

Warning

When infusing into a "Y" site, the volume capacity of the primary set may cause either a delay of

10. To start the infusion, turn the **Mini-Infuser™ 150XL** or **300XL** pump to the "On with Alarm" position for an audible as well as visual alarm at end of syringe. The "On" position provides a visual alarm only.
11. When infusion is complete, turn the **Mini-Infuser™ 150XL** or **300XL** pump to the "Off" position. Fully squeeze the Release Lever, reset the Pusher, and remove the syringe.

Note

When the flashing red light occurs, the **Mini-Infuser™ 150XL** or **300XL** pump will not restart until the pusher is reset or released and the switch is cycled through the off position.

Alarms and Indicators

—Flashing green light indicates normal operation. The green light also indicates the active Time Scale for the **Mini-Infuser 300XL** pump.

—Flashing red light indicates end of syringe or occlusion.

Warning

To reduce the risk of a bolus being infused after an occlusion occurs, the pressure must be relieved prior to freeing the occlusion by resetting the Pusher and/or disconnecting the system. To minimize the bolus volume, Microbore Extension Sets may be used.

—Beeping audio alarm mimics the flashing red light if the switch is in the "On with Alarm" position.

—Flashing yellow light indicates low battery. When the yellow light occurs, the infusion may safely be continued to completion before replacing the batteries with four "C" alkaline cells. There are typically 4 hours of battery life remaining.

Routine Maintenance

General

The **Mini-Infuser™ 150XL** and **300XL** pumps are designed to provide many years of reliable service with only minor routine maintenance. A periodic functional check of the **Mini-Infuser™** System should be made at least every six months. At that time it should be cleaned and disinfected if required, lubricated, and inspected as described below.

Functional Inspection

Check for proper function as follows:

1. Squeeze the Release Lever and check for free movement of Pusher.

2. Release and check for reengagement.

3. Check condition and holding ability of Syringe Holder Spring.

4. Turn switch to "On" and check for:

—Flashing (2-3Hz) green light

—Slightly audible motor noise

—Pusher movement (check over time)

5. Place the Pusher near the end of syringe position and allow it to move the Syringe Holder until the infusion stops. Check for:

—Flashing (2-3Hz) red light

—No noise or movement

6. Turn switch to "Off" then back to "On". **Mini-Infuser™** System should not restart, but remain in attention mode.

7. Reset Pusher with Release Lever and turn **Mini-Infuser™** System mode to "On with Alarm".

8. Repeat 4, 5, and 6 in "On With Alarm" mode and check as above except that an audible alarm should mimic the flashing red light.

9. Repeat 4 through 8 for each speed (300XL only).

10. Flashing yellow light (2-3Hz) can be inspected during routine use when the batteries run down. If battery life is less than specified, pump malfunction should be suspected.

Note
Battery life will be slightly affected by backpressure and audible alarm duration.

Cleaning and Disinfecting

The exterior surfaces may be cleaned using a cloth dampened with water or a mild detergent, then wiped dry. A mild germicide may be used as a disinfectant.

Caution

The **Mini-Infuser™ 150XL** and **300XL** pumps are not waterproof, and should not be immersed. Avoid getting liquids inside the **Mini-Infuser™ 150XL** and **300XL** pumps; permanent damage may result. Do not spray liquid at the pump for cleaning.

Sterilization via ETO, steam, etc., should not be done.

Lubrication

To ensure maximum life of the **Mini-Infuser™ 150XL** and **300XL** pumps, the lead screw should be lubricated at least every six months using General Electric Versilube G-322L grease. Using the nozzle applicator supplied with the grease, squeeze a small amount onto the entire length of the lead screw. Do this by carefully inserting the nozzle straight into the case channel thereby spreading the rubber seal. Use care to avoid damage.

Caution

Use only the recommended lubricant; use of a substitute may cause permanent damage.

Repair and Troubleshooting

Since specialized equipment is necessary to adjust the mechanisms and electronics inside the **Mini-Infuser™ 150XL** and **300XL** pumps, it is recommended that the defective unit be returned to the manufacturer for troubleshooting and repair. Should the **Mini-Infuser™ 150XL** or **300XL** pump appear to be malfunctioning, check for:

— Proper switch location
— Proper battery orientation (i.e., negative end

in first)

— Dead battery or batteries

— Proper Pusher location (i.e., not at end of syringe)

For those customers wanting to do their own repairs, an in-hospital repair program is available. Contact your Baxter Sales Representative for details.

Calibration

If calibration checks are to be made, the following parameters and methods should be used:

Rate

150XL 5.48 ±0.164 inches/hr
300XL 5.48 ±0.164 inches/hr

(Medium speed)
2.74 ± 0.082 inches/hr

(Low speed)
1.83 ± 0.055 inches/hr

(XLow speed)

Occlusion Force

150XL 8.0 ± 1.0 lbs.

300XL 8.0 ± 1.0 lbs.

These forces applied to the Syringe Holder in a downward direction should cause the **Mini-Infuser™ 150XL** or **300XL** pump to alarm.

Battery

Low Battery Level 4.00 ± 0.2 volts.

How to Obtain Warranty Service

A. To obtain warranty service, call the following toll-free telephone: 1-800-343-0366 (Alaska and Hawaii call collect: (508) 664-5900).

B. Give the following information to the Baxter Technical Service Representative (TSR):

1. Customer name and address.

2. Contract P.O. number which validates the warranty.

3. Serial number of each "problem pump" to be returned.

Non-Warranty Service

If all conditions for warranty coverage have expired, non-warranty service may be obtained for a service charge as follows:

A. To obtain non-warranty service, call 1-800-343-0366. (Alaska and Hawaii call (508) 664-5900.)
B. The Baxter Technical Service Representative will provide an address for you to ship the pumps for service.

C. Include a purchase order with the pump(s) authorizing the repair.

D. Baxter will initiate the repair if the estimate is under \$150.00. If repairs exceed \$150.00, our TSR will call for authorization to repair. (If you wish us to call for authorization of repairs *under* \$150.00, please note this on your "repair purchase order").

E. After your pump(s) are repaired, Baxter will return them via UPS or other qualified carrier.

F. Invoicing will be mailed separately through normal channels.

G. There is a *minimum* one hour labor service charge for repair of a **Mini-Infuser™ 150XL** or **300XL** pump.

Return Shipments and Invoicing

In all cases of in-warranty and out of warranty repair, it is important that the following information be correctly stated:
— Correct customer "ship to" address
— Correct customer "bill to" address
— The name and telephone number of the person to contact for repair authorization
— A tracking P.O. number