

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 original 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 PRODUCT AND THOSE EXPRESSLY SET FORTH IN ITS LABELING. UNLESS USED ACCORDING TO THE DIRECTIONS ACCOMPANYING THE PRODUCT, ALL WARRANTIES ARE SPECIFICALLY EXCLUDED. In no event shall Baxter Healthcare Corporation be responsible for incidental, 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).

The Baxter logo consists of the word "Baxter" in a bold, italicized, sans-serif font.

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www.Ardusmedical.com

**Mini-Infuser™
System**

**Operator's
Manual**

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Introduction

The **Mini-Infuser™ System** is designed for controlled intermittent administration of intravenous 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, or 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. This pusher is moved by the engagement of a nut on a threaded lead screw. The lead screw is rotated, through appropriate gearing, by a reliable, efficient direct current motor. The motor speed is electronically controlled to keep it constant regardless of syringe back pressure or battery voltage. A force sensing system is included as part of the syringe holder, and is used to detect end of syringe and occlusion. Electronic circuitry is used to control the indicators, alarms and infusion modes, and to sense the condition of the batteries.

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:

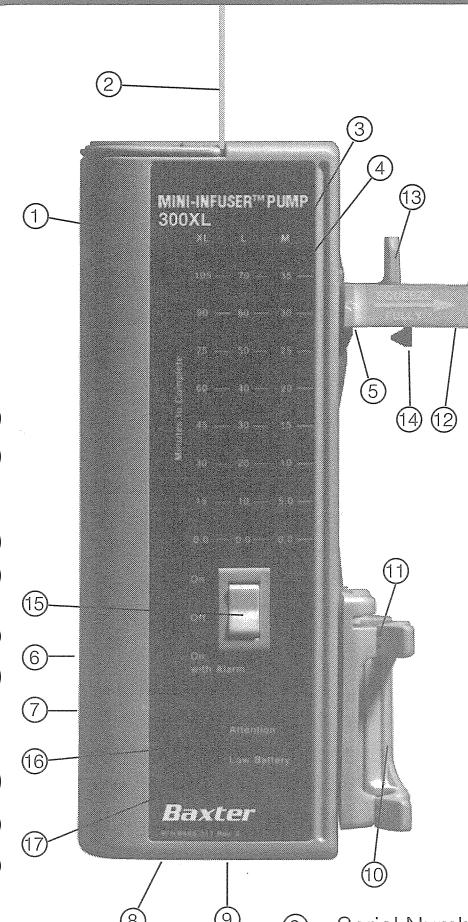
1. As an intermittent infusion system in combination with a heparin lock.
2. As a piggyback in combination with a gravity flow primary I.V. The primary line flow rate is not interrupted but is operated continually to deliver maintenance fluids or drug diluents. The Microbore extension set should be attached to the primary line at the lower injection port or flashball site.
3. As a piggyback in combination with an I.V. controller or I.V. pump. No change to the pump or controller is required. The Microbore extension set should be attached to the primary line at an injection port or flashball 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 flashball site.

When using the Mini-Infuser™ System as a piggy-back 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:

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

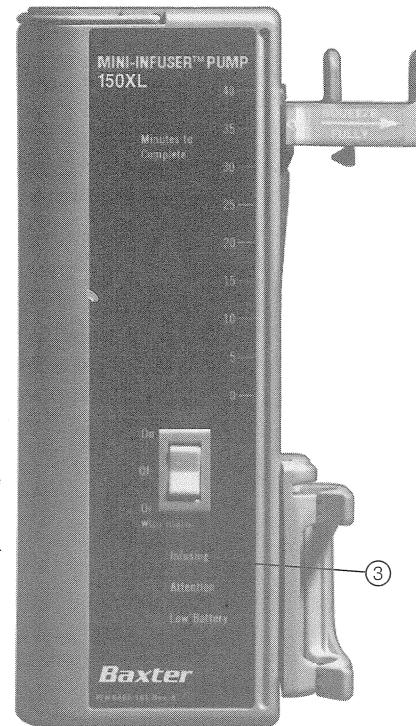
The "total volume" calculated represents the total volume into which the dose is effectively dissolved. This information is particularly important when delivering medications that require additional dilution.

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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,...).



Mini-Infuser™ Syringe Pump Specifications:

Accuracy (travel)	±3%
Battery Life	400 hours typical 4 hours typical minimum at low battery
Batteries	Four C-size alkaline cells (NEDA 14A)
Flow Profile	Continuous flat
Rate (travel)	XLow 1.8 in/hr Model 300XL Low 2.7 in/hr Model 300XL Med. 5.5 in/hr Model 300XL/150XL Consult Flow Rate Chart to determine flow rates with specific syringes.
Occlusion Detection Time*	70 seconds
Occlusion Force	8 lb. Consult Flow Rate Chart to determine occlusion pressure with specific syringes.
Stored Volume on Occlusion*	0.9 ml
Back Pressure Effect on Accuracy	None to occlusion pressure
Size	8.5" X 4.5" X 1.6"
Weight	1 lb. 12 oz. with batteries
Catalog Code Numbers	Model 150XL — 2M8170 Model 300XL — 2M8171

*With 60" Baxter Extension Set (catalog #2C9201), a 20 ml syringe and the Mini-Infuser™ 150XL or 300XL pump set at the "Medium" rate.

Operational Precautions

- 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, or 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.
- Make sure the flange on the syringe barrel is properly placed in the slot of the syringe holder.
- Use only recommended sets and syringes for best performance. Use of other syringes may cause incorrect flow rates and dosage.
- Make sure the plunger flange is engaged by the anti-syphon latch, otherwise uncontrolled emptying of the syringe may occur. Uncontrolled emptying of the syringe may result in patient injury.
- Improper installation may cause batteries to leak.
- When the Mini-Infuser™ System is used with a primary I.V. line, use of an appropriate Y-Set is highly recommended. Failure to properly use a Y-Set may result in retrograde flow into the primary line during a partial or complete downstream occlusion. This may subsequently result in inadvertent bolus to the patient when the occlusion is cleared.
- To reduce the risk of bolus being infused after an occlusion has occurred, the pressure must be relieved by resetting the pusher block and/or disconnecting the system prior to freeing the occlusion. To minimize the bolus volume, use disposable sets specifically designed for the Mini-Infuser™ System.

Drug Preparation

The implementation of a syringe infusion system for intermittent drug therapy will require some advance preparations. A standard dilution chart for the specific medications delivered via syringe system is available from Baxter. Drugs which are compatible with the delivery set up, and which meet the dose/rate/volume requirements can be successfully infused with the Mini-Infuser™ System.

A protocol for the aseptic filling and labeling of syringes should also be prepared.

The steps listed below may be followed as a guide in preparing syringes for the Mini-Infuser™ System.

1. Determine the proper dilution, syringe size, volume, and time combination for the drug/dose prescribed from your standard dilution chart.
2. Reconstitute the drug using 5% dextrose, 0.9% sodium chloride, sterile water, or other appropriate diluent. Use of sterile water in concentrated dilution may result in an osmolarity level closer to isotonic than a solution similarly reconstituted with D5W or normal saline.
3. Using standard aseptic procedures, fill the syringe to the required volume of drug. Cap and label the syringe appropriately.
4. Secure all syringes for delivery to patients.

Compatibility of I.V. Solutions

In the event an I.V. additive is incompatible with the primary line solution, hospital policy should be followed to prevent or correct the problem.

Nomograph Use

The accompanying nomographs are supplied as a convenient means of calculating proper dose. There are two different graphs to give every combination of Mini-Infuser™ System pump and syringe types. Make sure the proper graph is used.

To use the nomographs first choose a syringe type. Then, choose either the desired time to deliver, or the desired volume, and find it on the appropriate scale. Draw a straight line through the correct syringe dot to the opposite scale, and read the volume or time, respectively.

Example:

Model: 150XL
Syringe: Monoject® 20cc
Volume: 15cc
The delivery time is 20 minutes as read from the lower scale.

The infusion time for a full syringe is also provided in the following chart.

Infusion Times and Flow Rates

Mini-Infuser™ 300XL Pump									
B-D®	MONOJECT®	Infusion Times			Flow Rates			Nominal Occlusion Pressure* (psi)	
		Syringe Size (ml)			Infusion Time (min) for Full Syringe				
		XLow	Low	Medium	XLow	Low	Medium		
5	57	38	19	5.31	7.96	15.9	45		
10	78	52	26	7.67	11.5	23.0	31		
20	90	60	30	13.3	20.0	40.0	18		
30	105	70	35	17.2	25.7	51.5	14		
60 ¹	115	77	38	26.0	39.0	78.1	9.2		
6 ²	51	34	17	5.87	8.80	17.6	41		
12 ³	65	44	22	9.17	13.8	27.5	26		
20	80	53	27	15.0	22.6	45.1	16		
35 ⁴	87	58	29	20.7	31.0	62.0	12		
60 ¹	116	78	39	25.8	38.7	77.4	9.3		

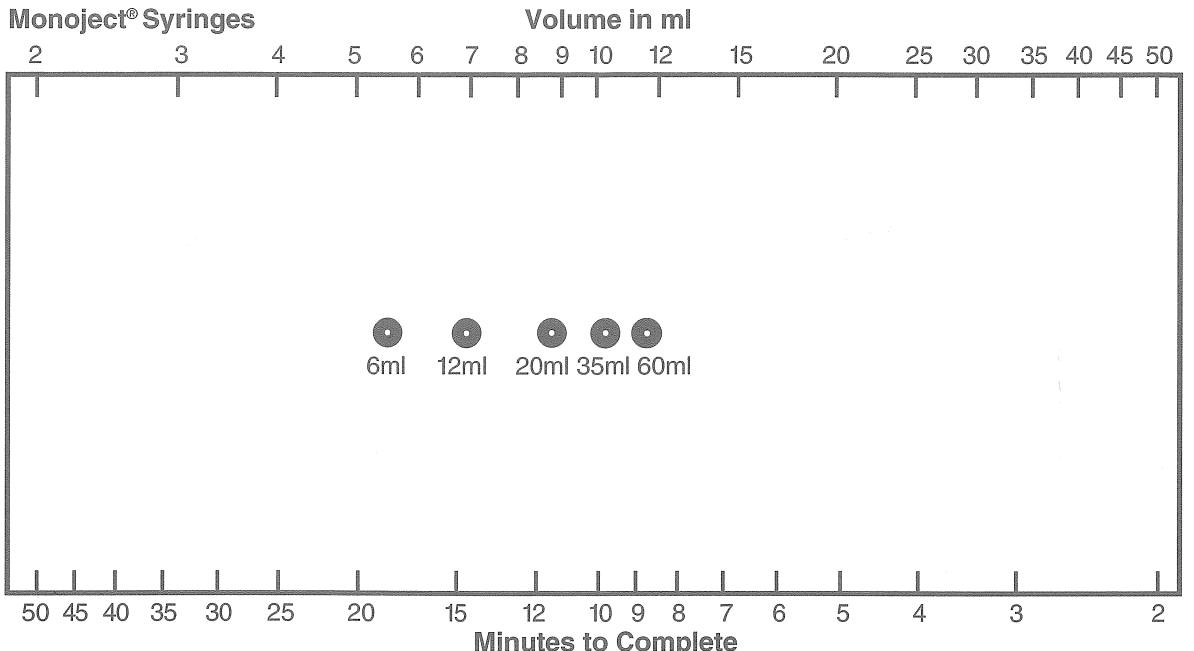
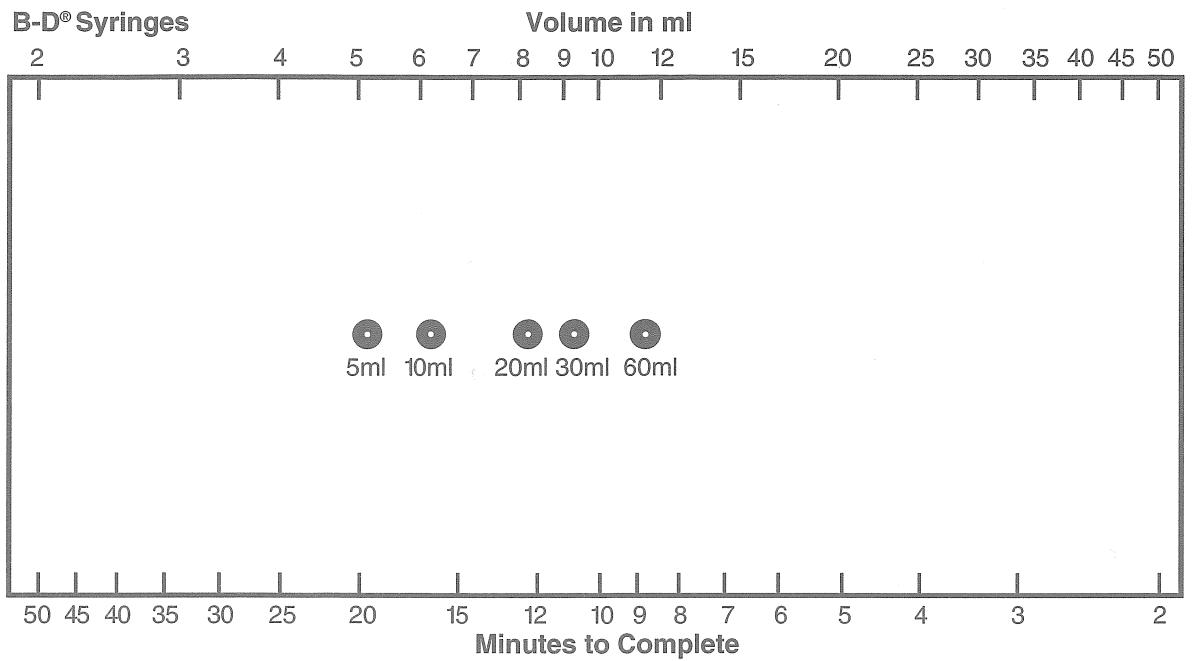
Mini-Infuser™ 150XL Pump			
Infusion Times/ Flow Rates			Nominal Occlusion Pressure* (psi)
Syringe Size (ml)	Infusion Time (min)	Flow Rate (ml/hr)	
B-D®	5	19	15.9
	10	26	23.0
	20	30	40.0
	30	35	51.5
	60 ¹	38	78.1
	6 ²	17	17.6
MONOJECT®	12 ³	22	27.5
	20	27	45.1
	35 ⁴	29	62.0
	60 ¹	39	77.4
	6 ²	17	17.6
	12 ³	22	27.5

1) for 50cc 2) for 5cc 3) for 10cc 4) for 30cc

B-D is a trademark of Becton-Dickinson & Co.; Monoject is a trademark of Sherwood Pharmaceutical Co.

* Determined by calculation. Actual pressure may differ due to syringe characteristics.

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 flashball site or the lower injection "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

drug infusion when starting the **Mini-Infuser™ 150XL** or **300XL** pump or a "bolus effect" if the primary flow is increased. The flashball site or the lower "Y" site should be used to minimize these effects.

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.

4. Tracking P.O. number.

C. The Baxter Technical Service Representative will provide an address for you to ship the pumps for service.

D. Upon receipt of the pump(s), Baxter, after verifying the warranty, will service the pump(s) and will return them to your institution by UPS or other qualified carrier.

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