BARD

INFUS O.R.™ Pump

Bard® *INFUSO.R.*™ Pump
USER'S MANUAL

Bard MedSystems Division
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WARNING: AN ISSUE DATE FOR THESE INSTRUCTIONS IS INCLUDED FOR THE USER'S INFORMATION. IN THE EVENT TWO YEARS HAVE ELAPSED BETWEEN THIS DATE AND PRODUCT USE, THE USER SHOULD CONTACT BARD MEDSYSTEMS TO SEE IF ADDITIONAL PRODUCT INFORMATION IS AVAILABLE.

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

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CONTENTS

I. General Introduction

The Bard ***INFUSO.R.*** Pump is a syringe infusion device that will aid in the administration of many intravenous agents given during anesthetic procedures. In conjunction with the Bard Smart Label System, it provides for the convenient delivery of narcotics, muscle relaxants, vasoactives and other drugs routinely given during anesthesia. The Bard Smart Label System is a set of drug specific labels that attach to the front of the Bard ***INFUSO.R.*** Pump. Each Bard Smart Label converts the ***INFUSO.R.*** Pump into a specific delivery system for the indicated drug with appropriate rate selections and delivery units. By simply changing the specially coded Smart Label, the Bard ***INFUSO.R.*** Pump is automatically changed to a specific delivery system for a particular intravenous agent.

The Bard ***INFUSO.R.*** Pump is easy to set up and use. Each Smart Label is clearly marked with drug dilution instructions and the required syringe size. The pump accepts B–D® or Monoject® 20 cc and 60 cc plastic disposable syringes which attach to Bard tubing sets for connection to the patient's primary intravenous line. Drug delivery choices are easily selected and changed using front panel rotary switches. The selections are made directly in drug dosing units and, where appropriate, are related to patient body weight, thus eliminating tedious calculations. Total volume of drug delivered is displayed for both patient management and record keeping needs.

This lightweight battery operated pump is provided with a versatile mounting bracket that securely fastens

the pump and provides good pump accessibility during use. The Bard *INFUSO.R.* Pump and Smart Label System combine the flexibility of a general infusion device with the convenience of a drug specific infusion device to meet many intravenous delivery needs during anesthetic procedures.

U.S. Patent No. 4,804,368

B-D is a registered trademark of Becton-Dickinson and Company.

Monoject is a registered trademark of Sherwood Medical, Inc.

II. Principles of Operation

The Bard *INFUSO.R.* Pump is a battery operated device that holds and empties disposable syringes in a controlled manner. A plastic holder accepts the syringe barrel. The syringe plunger is held and moved by a pusher assembly. The pusher engages a threaded leadscrew which is rotated by a reliable, efficient motor that is controlled and monitored by a microcomputer system. Magnetically coded labels attach to the pump front panel and are read by the microcomputer. The coded label tells the microcomputer the delivery rate selections available when that specific label is used with the pump. Rotary input switches, set by the user, select the drug delivery rate. Calculations are then performed by the microcomputer so that the drug is delivered as indicated. A force sensing system responds to overpressure in the fluid pathway and a position detector determines when the syringe needs refilling. The microcomputer controls the indicator lights and alarms and also displays the volume of drug delivered. The batteries are electronically monitored for a low power condition.

III. The Bard Smart Label System

The convenience and flexibility of the Bard *INFUSO.R.* Pump is provided by the Bard Smart Label System. The Bard Smart Label System is designed exclusively for use with the Bard *INFUSO.R.* Pump and allows the pump to deliver many intravenous agents routinely administered during anesthetic procedures. The Smart Label System has the ability to redefine the rotary input switches of the *INFUSO.R.* Pump so that delivery rates appropriate to a given agent are available. In addition, the delivery functions of the switches may also be redefined by the Smart Label so that only delivery modes applicable to the agent are available. Your Bard MedSystems Sales Representative can provide you with a complete list of available Smart Labels.

The Bard Smart Labels are each color coded by drug class according to the ASTM Drug Label Color Standard. The class and color designations are as follows:

Narcotics	Light Blue
Muscle Relaxants	Fluorescent Red
Vasopressors	Violet
Hypotensive Agents	Violet/White Stripes
Induction Agents	Yellow
Other Agents	White

The Smart Label System provides for three different operating configurations of the front panel input switches depending on the drug being delivered. These three operating configurations are:

- Bolus and infusion delivery
- Infusion delivery without bolus
- Infusion delivery that is not based on body weight

Bolus and Infusion

For agents that are given as a loading or supplemental bolus and a continuous infusion, the Smart Label panel appears as shown in Figure 1. The top switch selects the pump infusion rate in units of mcg/kg/min. The middle switch provides Body Weight input for scaling the infusion rate. The third switch selects Bolus settings that are also scaled by body weight, given in units of mcg/kg. Examples of Smart Labels in this configuration are:

1. Alfentanil 500 mcg/mL
2. Atracurium 10 mcg/mL
3. Vecuronium 1 mg/mL
4. Esmolol 10 mg/mL

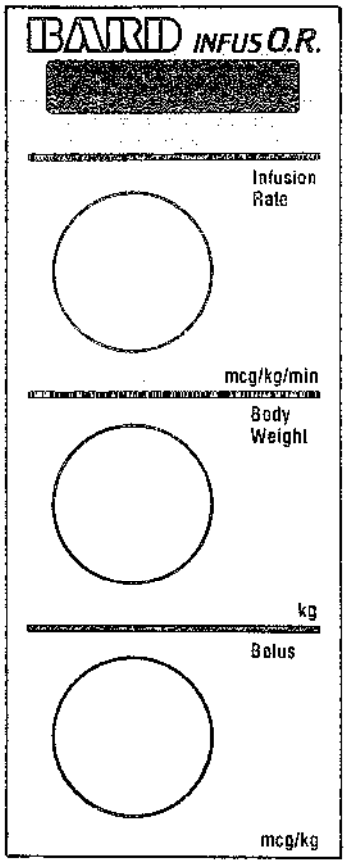

BARD INFUS O.R.
Infusion Rate
mcg/kg/min
Body Weight
kg
Bolus
mcg/kg

Figure 1

Infusion Delivery without Bolus

For agents that are given solely as a continuous infusion, the Smart Label panel appears as shown in Figure 2. The top switch selects the High Infusion Rate in mcg/kg/min. The middle switch selects Body Weight for scaling the infusion rate. The third switch selects Low Infusion Rate. In this configuration, **only one infusion rate switch is active at any time.** The other switch must be set to the zero position or a warning alarm will sound. Examples of Smart Labels in this configuration are:

1. Dopamine 4000 mcg/mL
2. Dobutamine 5000 mcg/mL
3. Nitroprusside 1000 mcg/mL
4. Nitroglycerin 1000 mcg/mL

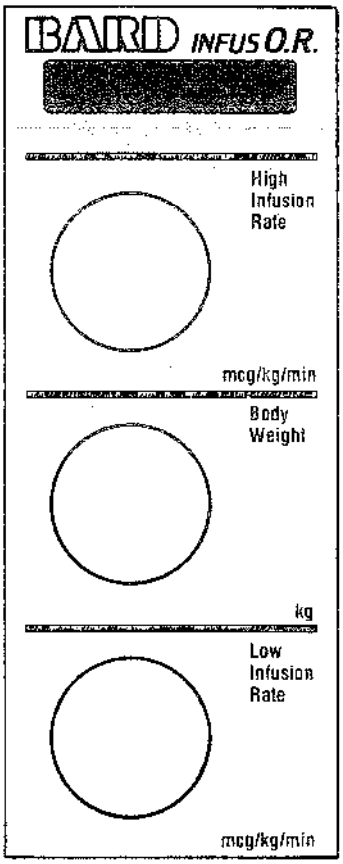

BARD INFUS O.R.
High
Infusion
Rate
mcg/kg/min
Body
Weight
kg
Low
Infusion
Rate
mcg/kg/min

Figure 2

Infusion Delivery not Based on Body Weight

For agents that are given as a continuous infusion not based on body weight, the Smart Label panel appears as shown in Figure 3. The top switch selects High Infusion Rates usually in mcg/min. The middle switch is labelled "Not Active" and has no effect on pump rate delivery. The third switch selects Low Infusion Rates. Examples of Smart Labels in this configuration are:

1.	Epinephrine	20 mcg/mL
2.	Isoproterenol	20 mcg/mL
3.	General	mL/hr

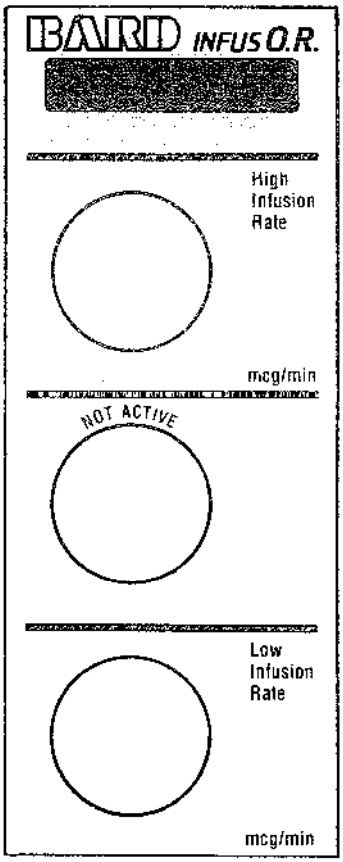

BARD INFUS O.R.
High
Infusion
Rate
mcg/min
NOT ACTIVE
Low
Infusion
Rate
mcg/min

Figure 3

Drug Concentration and Syringe Size

Each Smart Label lists the drug concentration for use in the *INFUSO.R.* Pump along with dilution instructions for obtaining this concentration. The dilution instructions are printed on the back of the Smart Label. In addition, the syringe size to be used with the Smart Label is also listed on the label.

WARNING: THE PROPER DRUG CONCENTRATION AND SYRINGE SIZE MUST BE USED FOR EACH SMART LABEL OR INACCURATE DOSING WILL OCCUR.

Refer to the Bard Smart Label Instruction Sheet provided with each Smart Label for the dilution and syringe size information. The rate settings for each input switch position are also discussed in the Smart Label Instruction Sheet. It is recommended that the Instruction Sheet for each Smart Label be kept in the Smart Label section of this Manual for convenient reference.

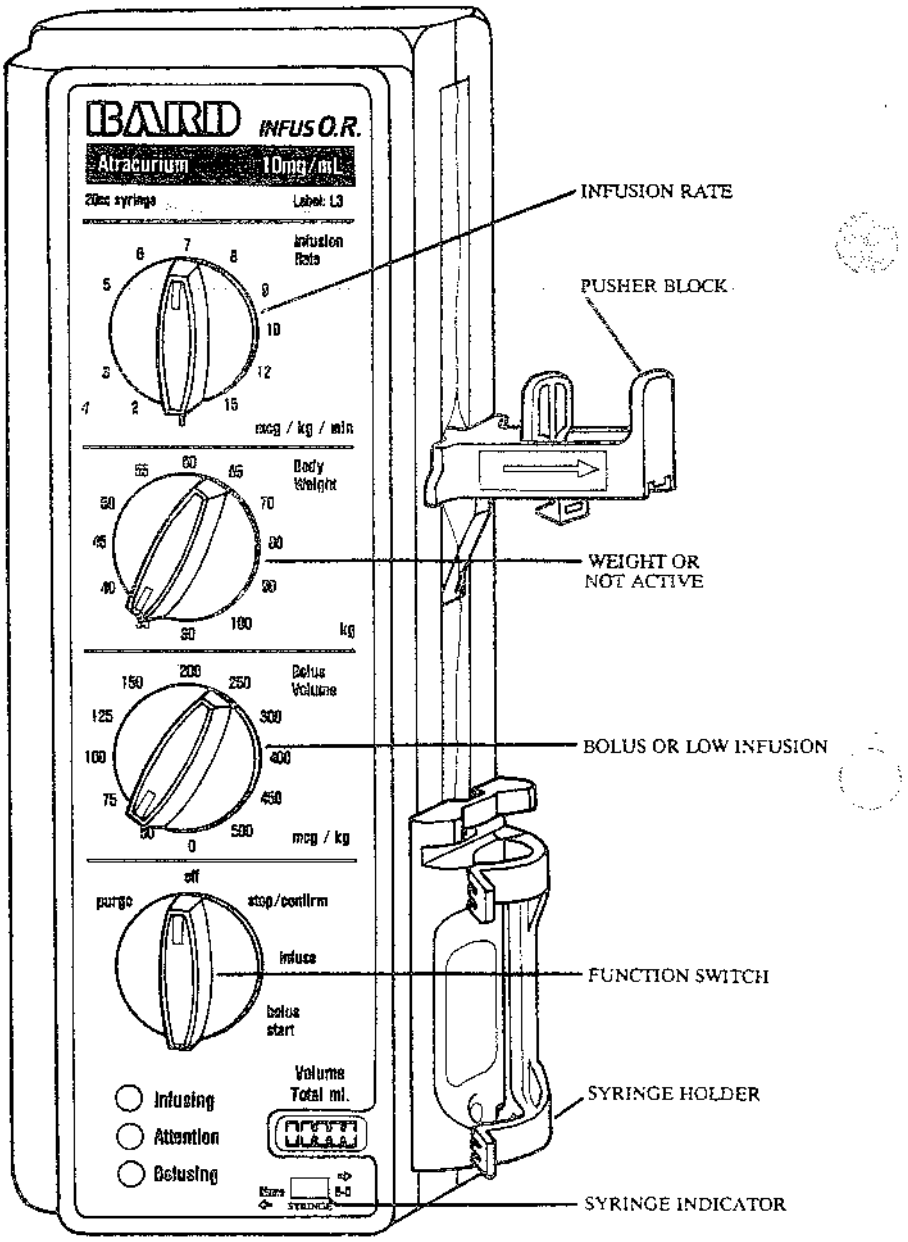

BAIRD INFUS O.R.
Atracurium 10mg/mL
20cc syringe Label: L3
Infusion Rate
mcg / kg / min
Body Weight
kg
Bolus Volume
mcg / kg
off
purge
stop/confirm
infuse
bolus start
Volume Total ml.
Infusing
Attention
Occlusing
Bore
SYRINGE
INFUSION RATE
PUSHER BLOCK
WEIGHT OR NOT ACTIVE
BOLUS OR LOW INFUSION
FUNCTION SWITCH
SYRINGE HOLDER
SYRINGE INDICATOR

FIGURE 4

IV. Description of Features

Smart Label

The Smart Labels allow delivery of a variety of narcotic, muscle relaxant, and vasoactive drugs. Applicable bolus volume, body weight, and infusion rate settings for each drug are noted on the label. Each label bears a unique identification code and defines the appropriate drug concentration and syringe size to be used. A Smart Label must be attached to the face of the pump for pump operation to commence.

Function Switch

The Function switch is used to choose among five operating states. **WHEN THE SWITCH IS MOVED TO "OFF", ALL POWER IS OFF AND ALL INTERNAL MEMORY IS LOST.** When held in PURGE, the pump will deliver at approximately three (3) or six (6) milliliters/minute with a 20 cc or 60 cc syringe, respectively. The position is "momentary" so that, upon release, the switch returns to OFF. When moved to STOP/CONFIRM the infusion is suspended and any initiated bolus is permanently terminated. Total dose memory is retained. In the INFUSE position, the pump will infuse at the rate indicated by the Infusion Rate switch.

If moved to the BOLUS START position and held for one second, a short audible tone will be heard after which a bolus is delivered at the appropriate rate. The BOLUS START position is also "momentary" and the switch will return to INFUSE when released.

Once initiated, the bolus selected will be given even if the Bolus switch is changed to a different selection.

Infusion Rate Switch

The Infusion Rate switch sets the infusion rate in micrograms per kilogram per minute to be infused when the Function switch is in INFUSE. Available settings are identified on the Smart Label for the drug to be infused.

Body Weight Switch or Not Active

The Body Weight switch selects the weight adjustment factor in kilograms used for both the infusion rate and bolus calculations. The choices are 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90 and 100 kilograms (kg). For drugs that are not given as a function of body weight, the Smart Label defines this switch as NOT ACTIVE.

Bolus Switch or Low Infusion Rate Switch

The Bolus switch selects the bolus that will be infused when initiated. Available settings are identified on the Smart Label for the drug to be infused. For drugs that are not indicated for bolus delivery, this switch is redefined by the Smart Label as a Low Infusion Rate switch. This Low Infusion Rate switch works similarly to the Infusion Rate switch.

Infusing Light

The Infusing Light will flash when an infusion rate other than "0" is chosen and the Function switch is in INFUSE. This light indicates that a normal infusion is occurring.

Bolusing Light

The Bolusing Light will flash during the time that a bolus is being delivered.

Attention Light

The Attention Light will flash when an attention condition occurs. The attention conditions are low battery, end of syringe, occlusion, and internal fault. The Digital Display will show which condition exists.

Digital Display

The Digital Display gives important information about the ***INFUSO.R.*** pump's status. When the Function switch is first set to STOP/CONFIRM, the Display shows the label identification code for the applied Smart Label. When bolusing, the Display will progress upward from zero to the selected bolus in mL increments as the delivery occurs. During normal infusion, the Display gives the total amount of drug in mL delivered since the pump was last turned "on". Turning the Function switch to OFF clears the Digital Display.

NOTE: When the function switch is moved to OFF, all power is off and all internal memory is lost.

During an attention condition, the Display will show which condition exists as shown below.

Display	Condition Description
LO BA	Low Battery
EOS	End of Syringe
OCC	Occlusion

Refer to Section VIII for additional information on these attention conditions.

Syringe Manufacturer Selector Switch

The Syringe Manufacturer Selector switch is set to identify use of either B–D or Monoject syringes.

Audio Indicators

Audio Indicators signify several pump conditions. These are occlusion, end of syringe, internal fault, bolus initiation, improper switch position, and missing Smart Label.

Both the Occlusion and End of Syringe Alarms are identical pulsating audible beeps. Nonetheless, they are independently sensed. An Occlusion Alarm occurs when the pump cannot overcome excessive flow path resistance such as closed stopcocks or other obstructions. An End of Syringe alarm occurs when approximately one milliliter remains in the syringe. The existing condition can be determined by reading the Digital Display. An Internal Fault causes the audio alarm and all lights to come on continuously and simultaneously. A single short audible beep occurs

upon each successful bolus initiation. If any switch is improperly placed between active positions, three short audible beeps will occur. Refer to Section VIII of this Manual for additional information on each audible alarm condition.

Mounting Bracket

The pump is supplied with a mounting plate pre-assembled to the rear face. It is recommended that this plate be used in conjunction with the Mounting Bracket, also supplied, for maximum convenience, safety, and security. The Mounting Bracket will attach to most IV poles.

V. INSTRUCTIONS FOR USE - GENERAL

Accepted principles and practices of IV therapy should be followed for all administrations. The rate and bolus selections on the Pump's Smart Label System should allow convenient, appropriate drug delivery regimens. Actual dose requirements must be carefully determined by the physician based on the individual response of each patient. Careful review of these instructions and thorough familiarization with both the Pump and the drug is recommended before use with patients.

WARNING: **USE ONLY B-D OR MONOJECT 20CC OR 60CC PLASTIC DISPOSABLE SYRINGES AS INDICATED ON THE SMART LABEL. USE OF OTHER SYRINGES OR THE WRONG SIZE SYRINGE WILL RESULT IN INACCURATE DOSING.**

WARNING: **THE BARD *INFUSO.R.* PUMP IS DESIGNED FOR THE OPERATING ROOM DELIVERY OF PARENTERAL FLUIDS UNDER CONSTANT SURVEILLANCE BY INDIVIDUALS TRAINED IN THE ADMINISTRATION OF THESE AGENTS. BARD MEDSYSTEMS DIVISION DOES NOT RECOMMEND THE USE OF THIS PUMP WHEN SURVEILLANCE IS NOT CONTINUAL.**

WARNING: **ALL DRUG WARNINGS, PRECAUTIONS, AND CONTRAINDICATIONS SHOULD BE CONSIDERED WHEN USING THIS PUMP.**

WARNING: **USE OF THE BARD *INFUSO.R.* PUMP NEAR ELECTRIC FIELDS, MAGNETIC FIELDS, OR RADIATION (E.G. ELECTROSURGICAL UNITS, MAGNETIC RESONANCE IMAGING MACHINES, X-RAY MACHINES) IS NOT RECOMMENDED. SUCH USE MAY RESULT IN DEVICE MALFUNCTION. THE BARD *INFUSO.R.* PUMP HAS PASSED ESD/EMI/EMISSION TESTING PER TEST SPECIFICATION #MDS – 201 – 0004 OF THE U.S.**

DEPARTMENT OF HEALTH AND HUMAN SERVICES. IT HAS ALSO PERFORMED SATISFACTORALLY DURING ESU TESTING. CONTACT YOUR BARD MEDSYSTEMS DIVISION SALES REPRESENTATIVE IF ADDITIONAL INFORMATION IS REQUIRED.

VI. INSTRUCTIONS FOR USE - SYSTEM SETUP

When setting up the Bard *INFUSO.R.* Pump:
(refer to Figure 4)

1. Install the Smart Label for the drug to be infused. Set the Function switch to the STOP/CONFIRM position. Confirm that the label identification code shown on the Digital Display matches the code on the Smart Label. The code is located in the upper section of the Smart Label.

WARNING: IF THE LABEL IDENTIFICATION CODE ON THE DISPLAY DOES NOT MATCH THE CODE ON THE SMART LABEL, DO NOT OPERATE THE PUMP.

2. Fill a 20cc or 60cc Monoject or B–D syringe with the amount of drug required. The syringe size to be used for each Smart Label is shown on the upper section of the label. See the Instruction Sheet for the specific Smart Label for proper drug dilution information. Confirm that the concentration of the infusate matches the drug concentration noted on the Smart Label.

WARNING: CONCENTRATION OF THE INFUSATE MUST MATCH THE DRUG CONCENTRATION NOTED ON THE SMART LABEL OR INACCURATE DOSING WILL RESULT.

3. Attach an appropriate Bard infusion set to the syringe.

WARNING: USING SETS OTHER THAN THOSE RECOMMENDED BY BARD MEDSYSTEMS DIVISION MAY RESULT IN NUISANCE ALARMS OR REQUIRE EXCESS PRIMING VOLUME. THIS EXCESS VOLUME COULD CAUSE SIGNIFICANT EFFECTS DURING SYRINGE CHANGES OR OTHER MANIPULATIONS.

4. Attach a port puncturing needle to the distal end of the set, if required.

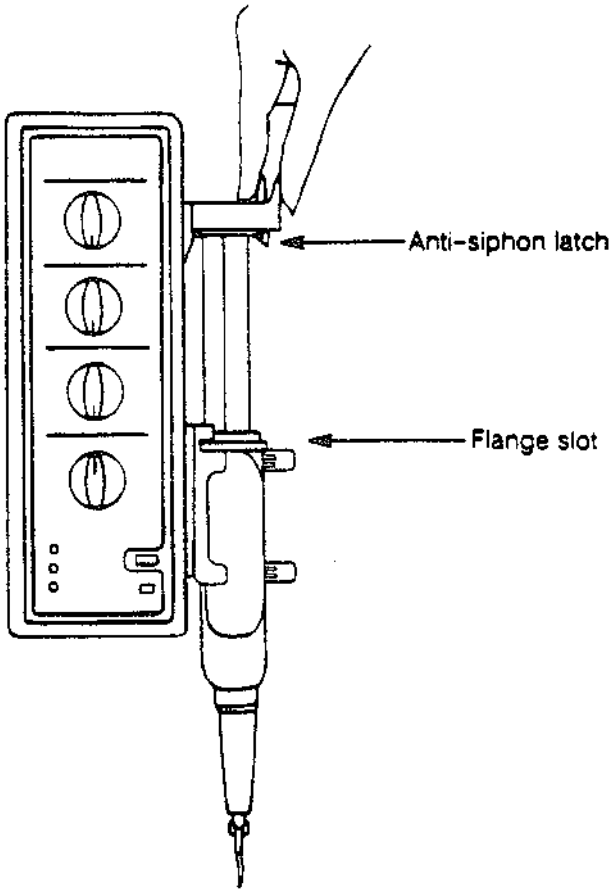
5. Eliminate all air from the fluid path.

NOTE: Refer to Figure 5 for steps 6–8.

6. Reset the Pusher block to the pump's top end by moving the Pusher block upward while squeezing the Release Lever with thumb and forefinger.

NOTE: Squeeze the Release Lever fully prior to movement for smoothest operation.

7. Place the syringe barrel into the Syringe Barrel Holder.



WARNING: ASSURE THE SYRINGE BARREL FLANGE IS PROPERLY INSERTED INTO THE HOLDER'S NOTCH OR UNCONTROLLED EMPTYING MAY OCCUR.

FIGURE 5

8. Move the Pusher downward until it touches the syringe plunger, then release the Lever so that the Anti-Siphon Latch engages the syringe plunger flange.

WARNING: IF THE PLUNGER FLANGE IS NOT PROPERLY ENGAGED BY THE ANTI-SIPHON LATCH, UNCONTROLLED SYRINGE EMPTYING MAY RESULT.

9. While observing the fluid outlet, turn the Function switch to PURGE until fluid flow occurs.

WARNING: DO NOT USE PURGE POSITION WHILE CONNECTED TO THE PATIENT.

10. Connect the fluid outlet to the patient's primary IV line or catheter.

WARNING: WHEN INFUSING INTO PRIMARY LINE PORTS, THE PRIMING VOLUME DOWNSTREAM OF THE PORT MAY CAUSE "DELAY EFFECTS" AND "BOLUS EFFECTS" IN DRUG DELIVERY. USE THE PORT OR FLASHBALL SITE NEAREST THE PATIENT TO MINIMIZE THESE EFFECTS.

VII. INSTRUCTIONS FOR USE - PUMP OPERATION

The Bard Smart Label System defines the *INFUSO.R.* Pump input switch configuration and the specific settings for each switch. Once the system is properly prepared, as outlined by the Smart Label Instruction Sheet and Section VI of these instructions, the Pump is operated as described below.

Set the Syringe Manufacturer Selector switch to the proper selection. The switch is located below the digital display.

WARNING: DUE TO DIFFERENCES IN SYRINGE DIAMETERS, THE VOLUME DELIVERY IS AFFECTED BY CHOOSING EITHER B-D OR MONOJECT SYRINGES. THIS DIFFERENCE IS MOST PRONOUNCED (13%) WHEN USING 20 CC SYRINGES AND IS NEGLIGIBLE WITH 60 CC SYRINGES. FOR PROPER DELIVERY, ASSURE CORRECT SWITCH POSITION.

NOTE: Changing the Syringe Manufacturer Selector switch during pump operation will cause the pump to alarm. The pump must be turned off to clear the alarm.

Smart Label Verification

If not already confirmed, verify that the identification code on the display matches the label identification code shown below the Smart Label drug name.

WARNING: **IF THE LABEL IDENTIFICATION CODE ON THE DISPLAY DOES NOT MATCH THE SMART LABEL IDENTIFICATION CODE, DO NOT USE THE PUMP.**

Body Weight Selection

For drugs that are delivered as a function of body weight, select the body weight to be used by the Pump's computer for dosage calculations. Rotate the Body Weight switch to the value closest to the patient's weight.

Infusion Rate Selection

To deliver a constant infusion of the drug rotate the Infusion Rate switch to the desired rate and move the Function switch to INFUSE. The green infusion light will flash to show that a normal infusion is occurring. The digital display will begin incrementing in milliliters the amount of drug delivered. To change the rate, simply rotate the infusion rate switch to a new setting.

For Smart Labels that have a High Infusion Rate setting and a Low Infusion Rate setting, only one rate setting is allowed at any time. Therefore, if a Low Infusion Rate is set, the High Infusion Rate switch must be set to zero or the pump will give a warning alarm.

The same applies to the Low Infusion Rate when setting a High Infusion Rate delivery. To stop an infusion, turn the active rate switch to "0", or turn the function switch to the STOP/CONFIRM position.

Loading or Supplemental Bolus Administration

To administer a loading or supplemental bolus dose, choose the desired dose on the Bolus switch and rotate the Function switch to the BOLUS START position. When a short audible beep is heard, release the Function switch. The audible beep indicates successful bolus initiation. The bolusing light will flash to indicate normal bolus delivery. The digital display will begin incrementing in milliliters as the bolus is delivered to show the status of the present bolus.

To stop a bolus delivery, rotate the Function switch to the STOP/CONFIRM position. This will permanently terminate the current bolus. Once a bolus is initiated, the Bolus switch may by changed to a new setting in anticipation of future need. The current bolus will be unaffected and will be delivered as initially selected. Changes to the Body Weight switch will also not affect a bolus in progress.

For drugs that are not given as loading or supplemental boluses, the Smart Label redefines the Bolus switch as a Low Infusion Rate switch, therefore preventing bolus delivery of these agents. Rotating the Function switch to the BOLUS START position will have no affect on pump operation for delivery of these agents.

VIII. WARNING INDICATORS

The following actions should be taken when audible warnings occur.

1. End of Syringe or Occlusion

A delivery system occlusion or an empty syringe is indicated by a pulsating audible alarm and flashing attention light. The display will indicate which condition exists.

If the display reads EOS, the syringe is nearly empty and must be refilled or replaced. To do so, turn the Function switch to STOP/CONFIRM, then clamp the tubing set.

WARNING: ASSURE THAT THE EXTENSION SET IS CLAMPED BEFORE DISCONNECTING THE SYRINGE. IF THE EXTENSION SET IS NOT CLAMPED, THE VOLUME IN THE TUBING SET MAY BE DELIVERED INTO THE PATIENT BY GRAVITY. THIS COULD RESULT IN SIGNIFICANT ADVERSE EFFECTS.

Remove the syringe by first resetting the Pusher then removing the syringe barrel from the Holder. Disconnect the syringe from the tubing set and reconnect a properly prepared syringe. Repeat the system set-up steps for reinserting the syringe. Unclamp the tubing set, then return the Function switch to INFUSE to resume the infusion.

If the display reads OCC, an occlusion in the delivery system exists. Turn the Function switch to STOP/ CONFIRM, then determine the cause and location of the occlusion.

WARNING: TO REDUCE THE RISK OF STORED FLUID BEING INFUSED AFTER AN OCCLUSION OCCURS, THE PRESSURE MUST BE RELIEVED PRIOR TO FREEING THE OCCLUSION. DO THIS BY RESETTING THE PUSHER AND/OR DISCONNECTING THE SYSTEM ABOVE THE OCCLUSION.

Correct the occlusion, then return the Function switch to INFUSE to resume the infusion.

NOTE: If an Occlusion or End of Syringe alarm occurs while bolusing, the bolus delivery will be permanently terminated. To resume and complete the current bolus, note the digital display setting before turning the Function switch to STOP/CONFIRM. After rectifying the alarm condition, initiate a new bolus for the balance of the dose.

2. **Low Battery**

If the attention light flashes without an audible alarm, then a low battery condition exists. Check the display for LO BA to verify this condition, then replace the

batteries with four C–size alkaline cells before the next procedure. The present administration may usually be safely completed since the batteries should last several hours after the alarm is first indicated.

NOTE: When the batteries are removed, all internal memory is lost.

NOTE: Battery life will be significantly affected by bolus duration,backpressure required, and audible alarm duration.

3. **Internal Fault**

An Internal Fault alarm is signified by the audible alarm, all lights coming on continuously, and all pumping operation stops. This alarm is caused by three different conditions: Syringe Manufacturer Selector switch moved, Smart Label removed, or internal electronic failure. Which of these conditions exists must be determined and the appropriate action taken.

If the Syringe Manufacturer Selector switch was changed during operation, turn the Function switch to OFF, set the switch to its proper position and resume operation.

Should the Smart Label become detached during use, turn the Function switch to OFF, reattach the label and resume operation.

If the cause of the alarm cannot be determined, the pump should be taken out of service and returned for repair.

NOTE: The pump should be left off for a few seconds before resuming operation to allow all internal memory to clear. Otherwise, the internal fault alarm may occur.

4. **Improper Switch Position**

If any switch is left in or held in a position between actual selections for over one-half second, the pump will alarm with three short audible beeps. The pump will continue to infuse at the previously chosen rate. Reposition the switch to the proper location to terminate the alarm.

5. **Missing Smart Label**

In order for the ***INFUSO.R.*** Pump to operate, a Smart Label must be attached to the pump face. If a label is not attached and the pump is turned "on", an internal fault will occur. Also, if the label is removed during pump use, an internal fault alarm will occur.

6. **Two Infusion Rates Set**

For Smart Labels that have High Infusion Rate and Low Infusion Rate switches, only one switch can be set. The other must remain in the zero position.

If two infusion rates are set, the pump will stop delivery and sound an audible alarm. To clear the alarm, return the undesired infusion rate setting to zero. The pump will then begin delivery at the set rate.

IX. Flow Rates

The following equations may be used to determine the relationship among volumetric flow rate, body weight, and infusion rate in the Bard ***INFUSO.R.*** Pump:

$$\text{Infusion flow (mL/min)} = \frac{\text{Infusion Rate (mcg/kg/min) x Body Weight (kg)}}{\text{Drug Concentration (mcg/mL)}}$$

To determine total volume (in mL) for bolus settings, use the following:

$$\text{Total Bolus Volume (mL)} = \frac{\text{Bolus Dose (mcg/kg) x Body Weight (Kg)}}{\text{Drug concentration (mcg/mL)}}$$

To determine bolus duration (in minutes), use the following:

$$\text{Bolus duration (min)} = \frac{\text{Bolus dose (mcg/kg)}}{\text{Bolus Delivery Rate for Drug (mcg/kg/min)}}$$

X. ROUTINE MAINTENANCE

The Bard *INFUSO.R.* pump is designed to provide many years of reliable service with only minor routine maintenance. A periodic functional inspection of the pump should be made at least every six months, or more frequently depending on use. The pump should also be cleaned and disinfected, as required, depending on frequency of use and hospital protocol.

Functional Inspection

To assure proper pump operation, the following items should be checked:

1. Pusher Block – Squeeze the release lever of the pusher block and check for free movement of the pusher over the complete travel range. Release the lever and check for engagement of the pusher block assembly.

2. Syringe Holder – Check the condition and holding ability of the syringe holder. Assure that 60 cc and 20cc plastic syringes sit firmly in the holder and are retained by the barrel notch. Also, check that the anti–siphon latch of the pusher captures the syringe plunger to prevent siphoning.

3. End of Syringe Alarm – The End of syringe Alarm occurs when approximately 1 mL is remaining in the syringe. To check the alarm, place a syringe with the plunger located at approximately 3 mL in the pump. Initiate an infusion and check for:

- Flashing Infusion Light with the LCD incrementing in milliliters.

- Audible Alarm when End of Syringe occurs. The pumping operation should cease and the Attention light should flash. The display should flash EOS.

- Turn the pump OFF, then back to INFUSE. The alarm condition should resume when the pump is set to INFUSE.

4. Occlusion Alarm - The Occlusion Alarm occurs when the pusher encounters 8 ±1 lbs. of force. To check the alarm, move the syringe holder downward while the pump is infusing (8 ±1 lbs. force required). Check for:

   - Audible Alarm and flashing Attention Light with pumping operation discontinued. The display should also flash OCC.

5. Input Switches - The front panel input switches should be checked for proper rotation and function. Check as follows:

   - The three input switches should rotate through 12 discrete positions. Rotation directly from the highest to the lowest switch setting should not occur.

   - Rotate the Function switch through 5 discrete positions. The two end positions are momentary and should return to the previous switch location upon release.

6. Syringe Manufacturer Selector Switch – The Syringe Selector switch should be checked to assure proper function. To check the switch, set the pump to any infusion rate setting and turn the Function switch to INFUSE. Change the Syringe Manufacturer Selector switch while the pump is infusing. An internal fault alarm should occur when the switch is changed.

7. Flow Rates and Delivery Volumes – The Bolus and Infusion Rates should be checked for delivery accuracy within ±3%. For checking infusion rates, the following table provides the linear rate of the pusher for different Smart Labels. These rates span the dynamic operating range of the pump.

NOTE: When measuring these linear rates, the Syringe Manufacturer Selector switch MUST be in the B–D position.

Bard *INFUSO.R.* Infusion Rates

Label #	Infusion Rate	Body Weight	Linear Rate
1	0.25 mcg/kg/min	30 kg	0.063 ± 0.002 in/hr
2	300 mcg/kg/min	100 kg	12.66 ± 0.38 in/hr
3	8 mcg/kg/min	40 kg	0.262 ± 0.008 in/hr
4	1.2 mcg/kg/min	50 kg	0.492 ± 0.015 in/hr
5	14 mcg/kg/min	60 kg	0.711 ± 0.021 in/hr
6	1 mcg/kg/min	70 kg	0.074 ± 0.002 in/hr
7	2 mcg/min		0.418 ± 0.013 in/hr
8	160 mcg/kg/min	80 kg	5.39 ± 0.16 in/hr
9	3 mcg/kg/min	90 kg	1.140 ± 0.034 in/hr
10	0.8 mcg/kg/min	50 kg	0.109 ± 0.003 in/hr

For checking Bolus distances, the following table provides the linear travel of the pusher block for different

Smart Labels. These distances span the dynamic operating range of the pump.

NOTE: When measuring the Bolus travel, the Syringe Manufacturer Selector switch MUST be in the Monoject position.

Bard *INFUSO.R.* Bolus Travel

Label #	Bolus	Body Weight	Linear Travel
1	15 mcg/kg	30 kg	0.063 ±0.002 in
2	3000 mcg/kg	100 kg	2.115 ±0.063 in
3	200 mcg/kg	50 kg	0.121 ±0.004 in
4	100 mcg/kg	70 kg	0.850 ±0.025 in
8	2000 mcg/kg	90 kg	1.269 ±0.038 in
10	1.5 mcg/kg	40 kg	0.146 ±0.004 in

8. Batteries – The pump batteries should be checked for a low battery condition. Check as follows:

   – Turn the Function switch to INFUSE. Check the Attention light and digital display.

   – If the Attention light flashes and the display shows LO BA then replace the pump batteries with four alkaline C-cells.

Cleaning and Disinfecting

The exterior surfaces of the pump and Smart Labels 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. Bard MedSystems recommends Vestal® LPH® or equivalent.

CAUTION: The Bard *INFUSO.R.* pump and Smart Labels are not waterproof and should not be immersed. Avoid getting liquids inside the pump or permanent damage may result. Do not use alcohol for cleaning. Sterilization via eto, steam, etc., should not be attempted.

Lubrication

The leadscrew 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 leadscrew. 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. A substitute lubricant may cause permanent damage.

Technical Maintenance

Since specialized equipment is necessary to adjust the mechanisms and electronics inside the pump, it is recommended that a defective unit be returned to the factory for troubleshooting and repair. Should the pump appear to be malfunctioning, check for:

- Proper switch location
- Proper battery orientation (i.e., negative end first)
- Dead battery or batteries
- Proper Pusher location (i.e., not at end of syringe)
- Proper attachment of a Smart Label and that rear surface of Smart Label is clean and free of debris.

Before returning the pump, contact your Bard MedSystems sales representative for information on return authorization.

Storage

When the pump is placed in storage or is not in use for extended periods, the four C-cell batteries should be removed.

BARD MEDSYSTEMS DIVISION
LIMITED WARRANTY

Bard MedSystems Division warrants to the original purchaser that this Bard MedSystems product will be free from defects in material and workmanship for a period of ninety (90) days from the date of its shipment from Bard MedSystems to the original purchaser. If this product proves to be so defective, purchaser may return same to Bard MedSystems for repair or replacement, at Bard MedSystems' option. All returns must be authorized in advance in accordance with the Bard MedSystems Returned Goods Policy found in its then current Price List. The liability of Bard MedSystems under this limited product warranty does not extend to any abuse or misuse of this product or its repair by anyone other than an authorized Bard MedSystems representative.

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THE LIABILITY AND REMEDY STATED IN THIS PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BARD MEDSYSTEMS AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND BARD MEDSYSTEMS WILL NOT BE LIABLE TO PURCHASER FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGE ARISING OUT OF ITS HANDLING AND USE.

SPECIFICATIONS

Device Name	Bard *INFUSO.R.* Pump	
Accuracy	Infusion:	Linear Rate ±3%
	Bolus:	Linear Displacement±3%
Battery Life	Typical Use:	150 hours
	At Low Battery and Typical Use:	4 hours
Batteries	Four "C"-size Alkaline Cells (NEDA 14A)	
Operating Voltage	4.5 – 7 Volts	
Operating Current	20 mA	
Low Battery Voltage	4.75 Volts	
Flow Rates	0 to 600 mL/hr	
Flow Profile	Bolus:	Continuous
	Infusion:	Pulsed intermittently
Occlusion Force	8 ± 1 lbs.	
Maximum Occlusion Pressure	11 psi w/ 60 cc syringe 20 psi w/ 20 cc syringe	
Occlusion Detection Time* (Inversely related to flow rate)	120 seconds at 36 mL/hr	
Volume Stored on Occlusion*	1.1 mL Approximate	

* Using a Bard Microbore Anesthesia Set and a 60 cc syringe.

Back Pressure Effect on Accuracy	None to Occlusion Pressure
Size	9.2 x 4.5 x 2.0
Weight	2 lbs. with Batteries
Syringes	Monoject® or B-D® 60 cc Monoject® or B-D® 20 cc

- Drip proof equipment: prevents entry of falling liquids. Product is not watertight, do not immerse in liquid or expose to possible splash or sprayed liquids.

Type BF Equipment: internal power source (batteries) with an isolated (floating) applied part.