Ipump™ Pain Management System Operator's Manual

Product Code: 2L3107

Note: Before operating this pump, the user should carefully read this manual to fully understand how the pump functions and to ensure its safe and proper operation.

Change Record

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Page Revision Levels

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Front cover (inside blank)	0
Title page III	0
Change Record page IV — V	A
VII — X	0
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1-1 — 1-20	0
2-1 — 2-12	0
3-1 — 3-30	0
4-1 — 4-8	0
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7-1 — 7-10	0

Page Revision Levels — continued

Page or Range	Revision
8-1 — 8-4	0
9-1 — 9-16	0
Glossary-1 — Glossary-10	0
Index-1 — Index-12	0
Back cover (inside blank)	A

Notice

There are risks associated with using anything other than the recommended sets with this device. Sets designated for use with this device are listed in "Accessories and Recommended Sets, 8-1". Baxter's warranty on this device will be null and void, and Baxter will assume no responsibility for incidents that may occur if the product is not used in accordance with product labeling.

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* Where X represents the current revision level of the manual.

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This product has been designed for Year 2000 compliance. Roll over between all significant time demarcations (for example, days, months, years, centuries), special dates, and leap years, will be performed correctly. Neither the performance nor the functionality is affected by dates prior to, during and after the year 2000 up to the year 2098.

Warranty

Baxter warrants that.the equipment shall be free from defects in materials and workmanship when delivered to the original purchaser. Baxter's sole obligation shall be to repair or replace the product (excluding batteries), at Baxter's option and expense, for a period of one year following the date of initial delivery.

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Table of Contents

Key Features

The pump's key features include:

- Upstream and downstream occlusion detectors
- Air sensor
- Ability to transfer configuration data via a serial port to another pump
- Multilanguage interface
- Preventive maintenance alert
- Detailed history display and printout capability
- Year 2000-compliant software
- Programmable limits for Patient Controlled Analgesia (PCA) doses

Chapter 1. Product Overview

The Ipump™ Pain Management System (hereafter referred to as the "pump") is designed for the epidural, subcutaneous, or intravenous administration of parenteral fluids. Because the pump can be used as a portable or stationary unit, this advanced pain management product will enable patients to become ambulatory as quickly as possible.

The lightweight, compact pump can be battery operated for portability or attached to a standard IV pole and connected to an AC power source for stationary use. A specially designed optional pole-mounting clamp allows the pump to be unlocked and easily removed for placement in a comfortable carrying case. An optional AC adapter can be used when the pump is mounted.

Programming Options

The pump can be programmed to provide:

- PCA, basal and PCA (BASAL+PCA), or continuous infusions
- Infusion rates in mL, mg, and µg
- Physician-prescribed values for the desired therapy
- Clinician- or institution-selected operating limits

When the pump is programmed for PCA, the patient has the option of self-administering analgesic medications on an as-needed basis. The BASAL+PCA programming option combines this patient-controlled method with a minimum continuous dose.

Record Management

The pump tracks the programming, time, and history of each infusion. If no power is available, all of this data will be retained in the memory of the pump's microprocessor.

The pump is equipped with a real-time clock that provides the correct date and time for record management. Both the date and time are displayed on the screen and included on any hard copy printout generated by using the optional printer.

Security

For patient security, the pump may be configured to require the:

- Insertion of a key in the cover lock (KEY ONLY)
- Entry of a security code before programming or changing the prescription (CODE ONLY)
- Both key insertion and code entry (KEY+CODE) – the factory default configuration

Note: If the pump is configured to require only the entry of a security code, the cover that holds the IV bag is optional.

Note: Use of security features, such as KEY+CODE, should be governed by individual care site policies and regulations regarding the use of controlled substances.

Organization of This Manual

This manual is designed for the health care professionals or home-based patients required to use the pump on a daily basis. The following sections are organized to provide you with the following information:

- "Ipump™ Pain Management System Description, 2-1" – covers what is included in the shipping package and the components of the pump.
- "Setting Up the Pump, 3-1" – describes how to install the pump battery, load and prepare the tubing set, mount the pump on a pole, set up connections, and remove the cover.
- "Configurable Options, 4-1" – lists the factory-set options and how to reset these values.
- "Using the Pump, 5-1" – contains step-by-step instructions for setting up prescriptions, starting and stopping infusions, and accessing and reviewing a patient's prescription history.
- "Alerts and Alarms, 6-1"– provides an alphanumeric list of the alert and alarm messages that may occur and how to resolve them.
- "Preventive Maintenance, 7-1" – contains references on conducting functional checks and storage procedures and authorized service center contacts.

- "Accessories and Recommended Sets, 8-1" – contains a list of accessories, including bags and sets, that can be used with the pump.

In addition, "Technical Specifications, 9-1" and a glossary are included to assist you in using this manual.

Anesthesia Business

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General Information

Although the pump has been designed and manufactured to exacting specifications, it is not intended to replace trained personnel in the supervision of pain management infusions.

This product is classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1, Second edition, and CAN/CSA C22.2 No. 601.1. In accordance with these documents, this equipment is classified as:

- Class 1, internally powered
- Type CF
- Drip-proof (IPX1)
- Not suitable for use with flammable anesthetic mixtures with air, oxygen, or nitrous oxide
- Continuous operation

Before operating this pump, the user should carefully read this manual to understand fully how the pump functions and to ensure its safe and proper operation. This manual has been developed with consideration of the requirements in the Collateral Standard IEC 60601-2-24, First Edition 1998-02, Medical Electrical Equipment, Part 2-24: Particular Requirements for the Safety of Infusion Pumps and Controllers.

When disposing of this device or the sets designed for use with device, adhere to local regulations and guidelines.

SERIAL NUMBER DESCRIPTION

To determine the year and month of manufacture, refer to the first three digits of the device serial number.

Example: 908XXXAA

9 = Year of manufacture 1999
08 = Month of manufacture August

Label Definitions

Label	Description
IPX1	Drip-proof equipment: enclosed equipment protected against dripping fluids.
	Connection port for the AC to DC converter/adapter.
	This product is classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1, Second edition, and CAN/CSA C22.2 No. 601.1.
	Type CF in accordance with UL2601-1.

Warnings, Cautions, and Notes

The safety and information labels included in this manual are defined as follows:

- **Danger** messages indicate an immediate hazard that, if not avoided, will result in severe personal injury or death.
- **Warning** messages indicate a possible hazard that, if not avoided, could result in severe personal injury or death.
- **Caution** messages indicate a problem or unsafe practice that, if not avoided, could result in minor or moderate personal injury or product or property damage.
- **Note** messages provide information that supplements the accompanying text.

Warnings

! WARNING ! **Always read and follow the instructions that accompany the source container and administration sets. Carefully follow the instructions for loading, removing, and reloading the set.**

! WARNING ! **Baxter will assume no responsibility for incidents that may occur if the product is not used in accordance with product labeling.**

! WARNING ! **Do not use in the presence of flammable anesthetics.**

! WARNING ! **To reduce the risk of stored fluid being infused after an occlusion occurs, relieve the pressure by disconnecting the system above the occlusion before freeing the occlusion.**

! WARNING ! **The tubing set MUST NOT be connected to the patient while priming.**

! WARNING ! **Do not use any pump that has readily apparent defects or damage, including missing or misaligned components, missing display segments, or missing audio.**

! WARNING ! **Clamp tubing distal to the pump before opening the tubing door or troubleshooting any pump connected to a patient.**

! WARNING ! **If the tubing is pinched by the closed tubing door, resistance to flow may increase and fluid delivery to the patient may be compromised. If this occurs, open the bag cover, reseat the tubing and check the tubing door for proper closure, close the bag cover, then restart the pump.**

! WARNING ! **If the pump detects an upstream occlusion, the clinician must identify the source and relieve the occlusion without turning off the pump. If the occlusion is not relieved and the pump is turned off, the pump may not detect the existing occlusion when the pump is turned back on.**

! WARNING ! **Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.**

! WARNING ! **This pump should be used only with the Baxter accessories specified for it. There are risks associated with using anything other than the recommended accessories with this pump. Accessories designated for use with this pump are listed in "Accessories and Recommended Sets, 8-1"**

! WARNING ! **Failure to latch the tubing door properly may result in a no flow condition.**

! WARNING ! **You must change the administration set after 2,000 mL of infusion or every seven days, depending on which event occurs first.**

! WARNING ! **The air sensor will detect and measure accumulated amounts of air over an amount of fluid delivered. However, the pump may not detect all instances of micro or "champagne" air bubbles.**

! WARNING ! **While the pump can operate in temperatures from 50-104°F, if used in temperatures below 50°F or if cold solutions are used, air sensor functionality may be compromised. For maximum safety, move the pump to an environment above 50°F and allow cold solutions to warm to appropriate operating temperatures before use.**

! WARNING ! **Avoid getting any liquids on the tubing set, inside the tubing door, or in the tubing channel. Air sensor functioning could be compromised or permanent damage may result.**

Cautions

CAUTION Use of this pump is restricted to sale or use by, on the order of, or under the supervision of a qualified physician.

CAUTION There are no internal user serviceable parts or adjustments.

CAUTION When using the optional AC adapter, use earth-grounded AC outlets only. When grounding reliability is in doubt, the equipment should be powered by its battery.

CAUTION Hospital protocol for the management of critical drugs must be followed with this device.

CAUTION Variations in epidural catheter sizes can cause occlusion alarms. If an occlusion alarm occurs with no visible occlusion, change to a larger diameter and/or shorter catheter. If occlusion alarms continue, contact your nearest authorized service center. Contact the Andover Service Center at 1-800-343-0366, extension 1.

CAUTION Only use sets manufactured by Baxter as specified in "Accessories and Recommended Sets, 8-1".

CAUTION Do not use sharp objects to press keys.

CAUTION Do not use zinc-air, ni-cad, or any other rechargeable batteries with the Ipump™ Pain Management System.

CAUTION All luer-lock connections must be properly tightened. Over tightening of a connection may crack the luer and cause leakage.

CAUTION The Ipump™ Pain Management System is not waterproof and should not be immersed. Avoid getting liquids inside the pump. Air sensor functioning could be compromised or permanent damage may result. Do not use alcohol for cleaning.

CAUTION Do not clean, disinfect, or sterilize any part of the device by autoclaving or with ethylene oxide gas. Doing so may damage the device and void the warranty. Only external parts of the device should be disinfected.

CAUTION Follow the cleaning schedule and methods defined in "Preventive Maintenance, 7-1" to ensure the proper maintenance of the pump.

CAUTION This pump has configurable options. Operating modes and input parameter selections may vary as a function of the selected configuration.

CAUTION Epidural administration of anesthetics is limited to short-term infusion (not to exceed 96 hours) with indwelling catheters specifically indicated for short-term anesthetic epidural drug delivery.

CAUTION Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for analgesic epidural delivery.

CAUTION To prevent the infusion of drugs not indicated for epidural use, do not use IV administration sets incorporating injection sites during epidural delivery.

CAUTION It is strongly recommended that the pumps programmed for epidural drug delivery be clearly differentiated from those programmed for other routes of administration.

CAUTION As with all medical electronic equipment, exercise care to avoid exposing this pump to powerful sources of electromagnetic interference. This device design has been tested to current U.S. and European standards and guidelines for medical devices. The pump was not found to be affected adversely by these susceptibility tests and will perform safely. The pump's emissions also were found to be acceptable. Using the pump near operating equipment that radiate high-energy radio frequencies (such as electrosurgical/cauterizing equipment, two-way radios, or cellular telephones) may cause false alarm conditions. If this happens, reposition the pump away from the source of interference or turn off the pump.

CAUTION Use only accessory equipment complying with the pump's safety requirements; failure to do so may lead to reduced safety levels of the resulting system. Consideration relating to accessory choice shall also include the use of the accessory in the patient vicinity, and evidence that the safety certification of the accessory has been performed in accordance with the appropriate UL2601-1 or IEC 601-1 and/or IEC 601-1-1 harmonized national standard.

CAUTION Use this product for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer. If interconnection with other infusion systems and/or parallel infusion is desired, make sure a recommended anti-reflux y-set (2L3506) is used to prevent back flow.

CAUTION Any equipment connected to the pump through the PRINTER/COMM port must conform to the electrical safety requirements of IEC 601-1.

CAUTION When attaching the pump to an IV pole or other mounting locations, ensure that it has been clamped securely.

CAUTION If the pump is attached to an IV pole, ensure that the device is mounted where the main body is easily accessible and the IV administration set can be installed in the loading mechanism without stretching or kinking the tubing.

CAUTION To avoid personal injury, ensure that the IV pole is stable and secure. Ensure that the pole can support the pump, along with any other devices, without tipping or falling. The pole diameter should be between 0.5" and 1.25".

Notes

Note: Grounding reliability can be achieved only when this equipment is connected to an earth-grounded receptacle marked "Hospital Grade." When grounding reliability is in doubt, the equipment should be battery powered.

Note: The pump may be configured to the specific needs of the operator or institution. See the Configuration Manual for further information.

Note: U.S. Law requires the tracking of this device. Parties acquiring this device must:

- Promptly report the receipt of this device to the manufacturer
- Report the sale of this device to any home patient
- Maintain patient and physician information for short-term home patient placements
- Report the device's purchase, receipt in trade, return after sale, loss, destruction or retirement

Note: If this is an initial purchase from the manufacturer, you may return a signed copy of the packing list to the manufacturer in order to comply with these requirements. For additional information, contact the Andover Service Center at 1-800-343-0366, extension 1.

Chapter 2. Ipump™ Pain Management System Description

This section will acquaint you with the various components of the pump, including the:

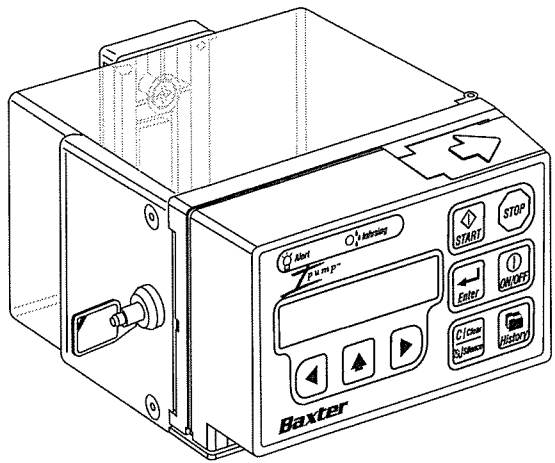
- Ipump™ Pain Management System Package Contents
- Pump Components
- Pump Key Pad
- Action Keys
- Pump Symbols
- LCD Symbols

Ipump™ Pain Management System Package Contents

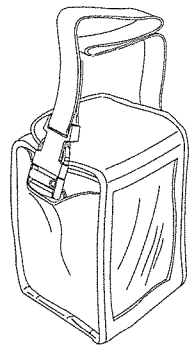
When the pump arrives, check to make sure that you have all the required parts, which should include the:

- Ipump™ Pain Management System
- 250E Cover
- Key(s)
- Patient Control Cable with PCA Button
- Pump Carrying Case
- Operator's Manual(s)
- Configuration Manual

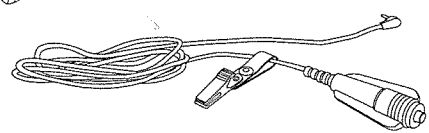
If you need to connect the pump to an electrical power source, you will also need a Baxter AC adapter, which is sold separately. (See "Accessories and Recommended Sets, 8-1".)



Ipump™ Pain Management System



Carrying Case



PCA Cord and Button

Figure 2-1 Ipump™ Pain Management System Package

Pump Components

The pump is a linear peristaltic pump that consists of a:

- Key pad for programming
- Container (cover) that holds the fluid bag in place and can be locked
- Tubing cover that holds the tubing in place and protects it
- Battery compartment to hold the battery
- AC Power port
- Printer port
- PCA port

Pump Key Pad

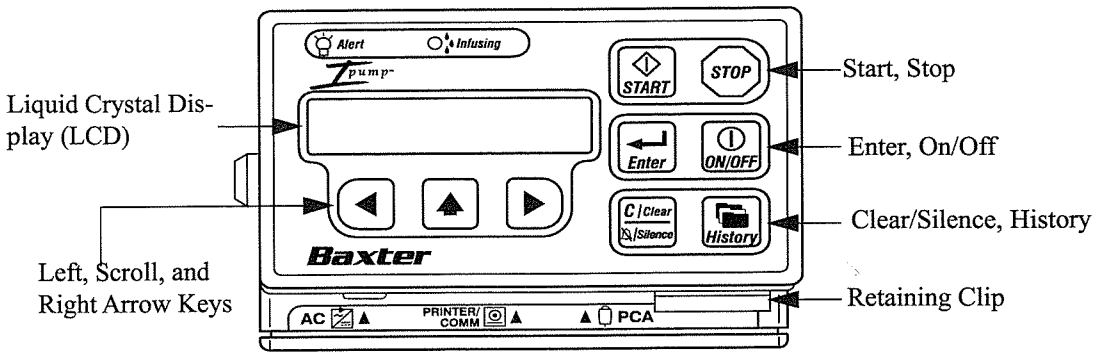


Figure 2-2 Pump Key Pad

Action Keys

Table 2-1 Action Keys

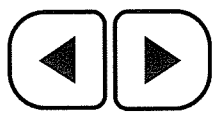
Action Key	Description
	The ON/OFF key powers up and powers down the pump. Press this key once to power on the pump. Press this key twice to power off the pump. For more detailed information, see "Turn on the Pump, 5-7" and "Turn off the Pump, 5-8".
	The left (⇐) and right (⇒) arrow keys move the cursor (↑) on the LCD to the left and right.

Table 2-1 Action Keys — continued

Action Key	Description
	The scroll (⇑) key displays the next available option or scrolls through the digits 0-9 at the cursor's (↑) current position on the LCD. Press and hold the key to increase the scrolling speed.
	The ENTER key sets the value displayed on the LCD.
	The START key begins the operation of the pump and can also be configured to act as a PCA button. If all of the required programming values have been entered, the START key initiates the infusion. Following the resolution of certain alerts or alarms, pressing the START key resumes the infusion if the condition no longer exists.

Table 2-1 Action Keys — continued

Action Key	Description
	The STOP key must be pressed twice in 1 second to stop the operation of the pump. After you press the STOP key, you can press the ON/OFF key to turn the pump off.
	The HISTORY key displays the infusion history on the LCD.
	The Clear/Silence key either clears the data shown on the LCD or silences an alert or alarm signal generated by the pump.

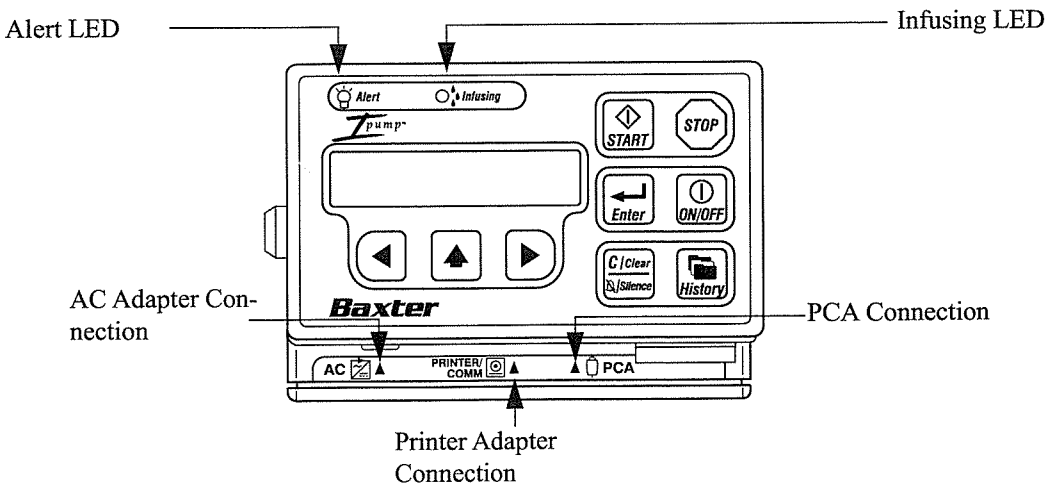


Figure 2-3 Pump Labels

Pump Symbols

Table 2-2 Pump Symbols

Symbol	Description
	The ALERT Light Emitting Diode (LED) flashes red if it is activated by an alert or an alarm.
	This green INFUSING LED flashes intermittently when the pump is operating normally.
PRINTER/ COMM 	The printer/communication port is an RS232-compatible port (connection) for a printer adapter.

Table 2-2 Pump Symbols — continued

Symbol	Description
AC 	This AC adapter port must be used to plug the pump into a Baxter AC adapter approved for use with the pump.
 PCA	The PCA port must be used to connect the PCA cord, which is attached to the PCA button.

LCD Symbols

Table 2-3 LCD Symbols

Symbol	Description
	When the 9-volt battery appears on the screen, it is the primary power source.
	If an electrical plug is displayed, the pump is connected to an AC adapter.

Chapter 3. Setting Up the Pump

The steps required to set up and use the pump include:

- Installing and changing the battery
- Connecting the AC adapter
- Installing the PCA button
- Connecting the PCA button
- Removing or changing the cover
- Preparing, loading, and changing the fluid bag and tubing set
- Attaching or removing the pump from a pole (optional)

The following sections contain step-by-step procedures for completing these tasks. To obtain information, refer to "Accessories and Recommended Sets, 8-1".

Installing and Changing the Battery

When you use the pump, you should install a 9-volt alkaline battery to:

- enable patients to carry the portable pump, and
- ensure that the pump continues to operate during a power outage.

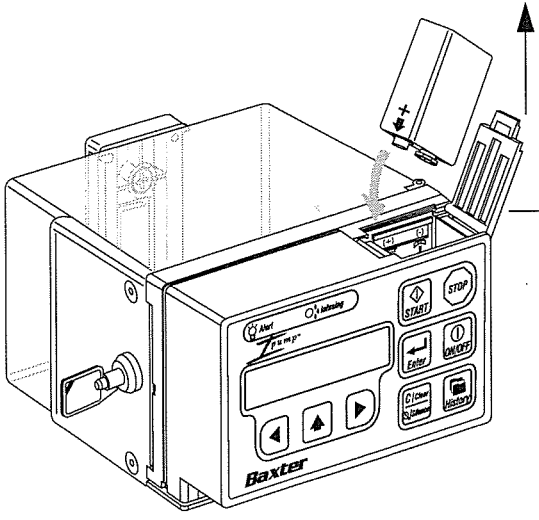
This section covers how to install the battery and how to replace it when necessary.

Note: If all power sources have been disconnected or are not functioning, the pump will emit a chirping sound and the red LED will flash for a short period of time to notify the user that no power source is available. To silence the chirp, press the Clear/Silence key.

Install the 9-volt Alkaline Battery

CAUTION Do not use zinc-air, ni-cad, or any other rechargeable batteries with the Ipump™ Pain Management System.

1. Open the battery compartment by sliding the battery latch door on the top of the pump in the direction of the arrow.
2. Then, lift the latch door.
3. Check the (+) and (-) labels inside the battery compartment to determine the correct placement of the battery.
4. Insert the battery with the poles down into compartment, close the battery door, and slide it back to the original position.



② Lift up the latch door.

① Slide the battery door to the right.

Insert the Battery

As you insert the battery, make sure that the poles are facing downward.

Then, close the battery door securely by sliding the cover back over the battery.

Figure 3-1 Inserting the Battery

Change the Battery

The 9-volt alkaline battery should be changed regularly. If battery voltage drops below the required level:

- A LOW BATTERY alert will appear on the pump's screen,
- The red Alert and green INFUSING LEDs will flash, and
- An audible alert will sound.

After you replace the battery, dispose of the old one according to the manufacturer's recommendations and applicable environmental regulations.

To change a battery, you must complete one of the following procedures in addition to the same tasks described in "Install the 9-volt Alkaline Battery, 3-3".

- If the pump is powered by the AC adapter, remove and replace the battery at any time without interrupting operation. During the battery change, the pump will issue the PCA message and the BATTERY MISSING alert, but will not interrupt service.
- If the pump is battery-operated and the infusion has not been started, press ENTER to acknowledge the alert, turn off the pump and replace the battery. Then, turn on the pump and re-enter the

prescription as described in "Using the Pump, 5-1".

- If the pump is battery-operated and the infusion has been started, turn off the pump as described in "Using the Pump, 5-1" and replace the battery.

In this case, the pump will turn off, but it will retain the prescription and therapy history. When the battery is replaced and the pump is turned on, the pump will display PUMP READY PRESS START or PUMP READY START OR CLEAR. Restart the pump as indicated in "Using the Pump, 5-1".

Change the Battery

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- A LOW BATTERY alert will appear on the pump's screen,
- The red Alert and green INFUSING LEDs will flash, and
- An audible alert will sound.

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- If the pump is battery-operated and the infusion has not been started, press ENTER to acknowledge the alert, turn off the pump and replace the battery. Then, turn on the pump and re-enter the

Connecting the AC Adapter

The AC adapter must be used to plug the pump into an AC electrical power source. The 9-volt alkaline battery should be inserted in the battery compartment as a backup power source in the event of AC power interruption and to allow patient ambulation.

Attach the Adapter

1. Find the red dot on the adapter connector and on the connector port on the pump (see Figure 3-2).
2. Rotate the adapter cord so that the red dot on the base of the connector is aligned with the red dot on the connector port. If these dots are not lined up, the connector will not seat firmly in the port.
3. Insert the connector of the adapter into the port on the bottom panel of the pump labeled with the AC symbol.
4. Make sure that the 9-volt alkaline battery is inserted in the battery compartment as a backup power source in the event of AC power interruption and to allow patient ambulation. See "Insert the Battery, 3-4".
5. Plug in the AC adapter into an AC electrical power source.

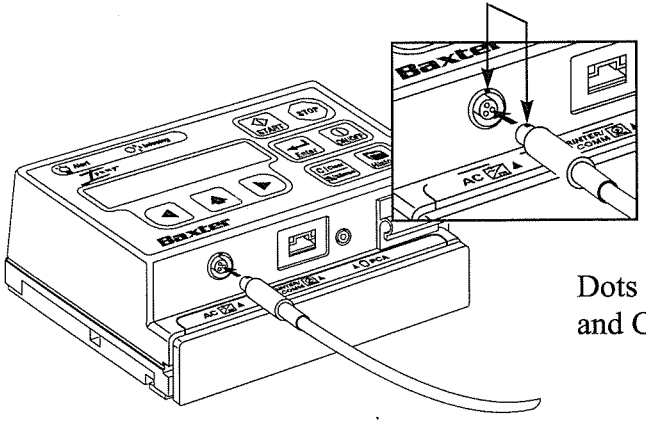


Figure 3-2 AC Adapter Connection

Installing the PCA Button

The PCA button is attached to the PCA cord, which can be installed as described under "Connecting the PCA Cord, 3-10". The pump can be configured to start a PCA infusion by using:

- Only the PCA button, or
- Either the PCA button or the START key.

If the pump is configured for use only with the PCA button, failure to connect the PCA cord after programming for the PCA or BASAL+PCA mode will generate the alarm message PCA BUTTON NOT CONNECTED when the infusion is started.

The PCA cord is **not required** if the pump is programmed to operate in Continuous mode.

The PCA cord is **required** if the pump is programmed to operate in the PCA or BASAL+PCA mode with a non-zero PCA dose.

The PCA cord is **not required** if the pump is programmed to operate with a 0.0 mL PCA dose in the BASAL+PCA mode.

Connecting the PCA Cord

Placing the PCA cord through the retaining clip provides additional strain relief for the PCA cord.

1. Plug the PCA cord into the PCA outlet on the pump and gently bend the cord into a "hump" shape.
2. Gently pull the cord through the clip until the "hump" straightens out.

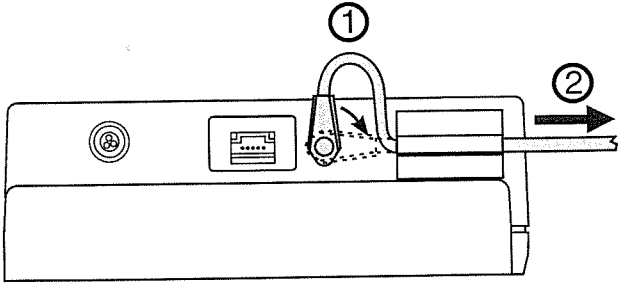


Figure 3-3 PCA Cord Connection Through the Retaining Clip

3. Make sure the PCA cord and plug are installed as shown in Figure 3-4

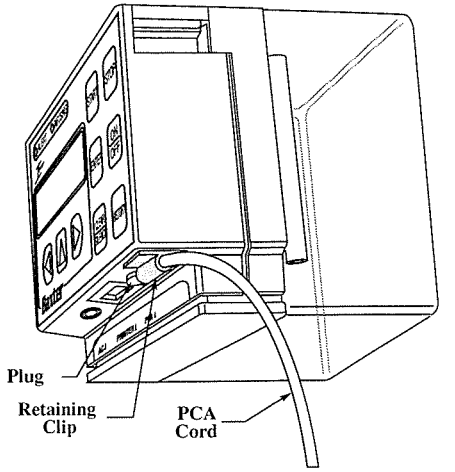


Figure 3-4 Connected PCA Cord and Plug

Removing or Changing the Cover

The highest level of drug security is attained with programming the combination of KEY+CODE and using the cover. However, if the pump is configured for CODE ONLY, the cover may be removed completely.

1. To remove or change the cover, unlock the cover if necessary, and open it (see Figure 3-5).
2. Place the pump face down (see Figure 3-5).
3. Detach the current cover from the pump by removing the three screws on the hinge assembly (see Figure 3-6).
4. Attach the new cover by aligning the hinge assembly and replacing the three screws.

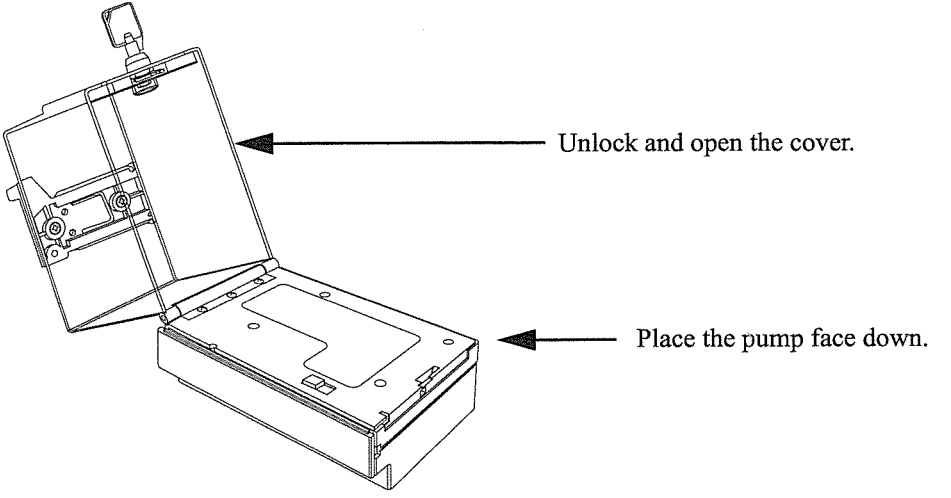
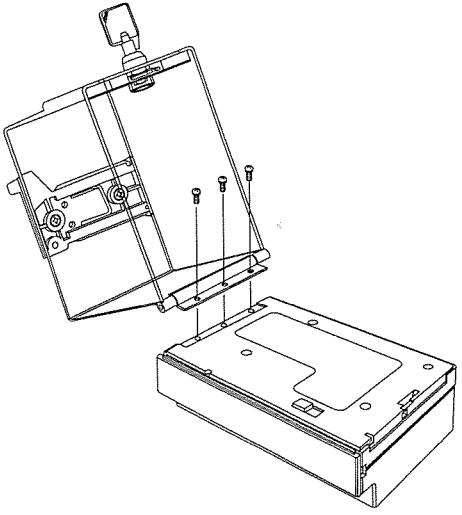


Figure 3-5 Opening the Pump Cover



Remove the three screws that connect the hinges.

Make sure that you line up the hinges when you reconnect the cover.

Figure 3-6 Removing the Bag Cover

- Load Viaflex®, IntraVia® container, or similar fluid bags
- Change the Fluid Bag

More specific information about the types of required bags is provided in "Accessories and Recommended Sets, 8-1".

Preparing, Loading, and Changing the Tubing Set and Fluid Bag

During the preparation of the fluid bag and tubing set, you must use aseptic techniques, follow hospital guidelines for changing bag sets, and follow the directions for the fluid bag provided by the manufacturer. The pump may be used with several types of fluid bags, including:

- Baxter 100 mL or 250 mL bags, or
- Viaflex®, IntraVia® container, or similar fluid bags up to 500 mL

! WARNING ! **This pump should be used only with the Baxter accessories specified for it. There are risks associated with using anything other than the recommended accessories with this pump. Accessories designated for use with this pump are listed in "Accessories and Recommended Sets, 8-1".**

The following directions are provided to assist you in using the different types of bags in the pump. These directions cover how to:

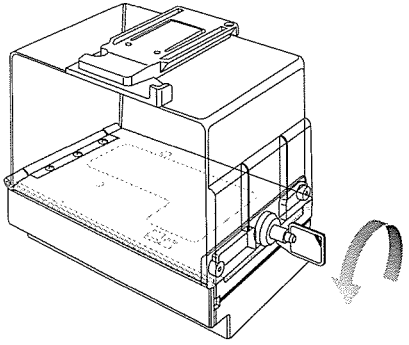
- Unlock the Cover
- Load the Tubing Set
- Load Baxter 100 mL or 250 mL Bags

Unlock the Cover

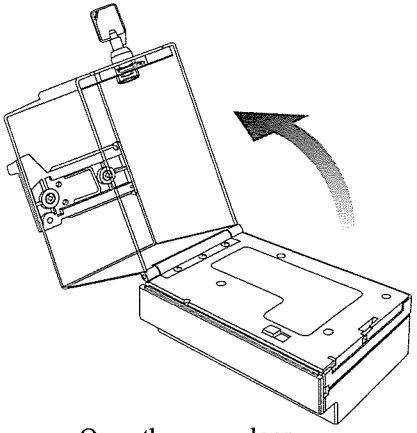
CAUTION Only use sets manufactured by Baxter as specified in "Accessories and Recommended Sets, 8-1".

1. If the pump is attached to a pole, remove it as described in "Remove the Pump from the Pole, 3-29".
2. Turn the pump over so that the programming keys are face down.
3. If the cover is locked, insert the key, and rotate it one-quarter turn counter clockwise. Then, open the cover. The key will remain in the lock whenever the cover is unlocked. To remove the key, close and lock the cover.

   If the pump is configured for CODE ONLY, no cover is necessary.



Unlock the cover door.



Open the cover door
with the pump face down.

Figure 3-7 Unlocking and Opening the Cover Door

Load the Tubing Set

To load the tubing set:

1. Release the tubing door latch by moving it away from the hinge.
2. Open the tubing door by pulling it down.
3. Load the tubing set into the groove in the tubing door.
4. Ensure that the set's longer tubing segment exits the side of the pump. The shorter segment must follow the curved groove, exiting behind the pump for attachment to the bag (see Figure 3-9).

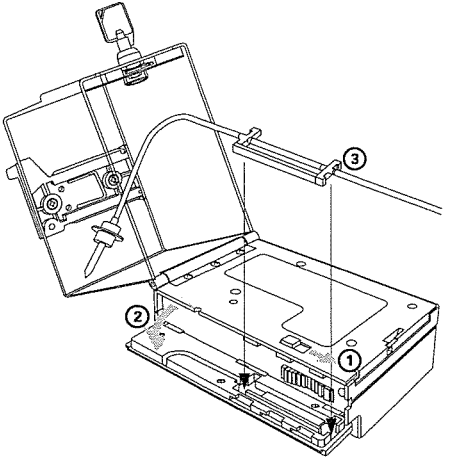


Figure 3-8 Tubing Set

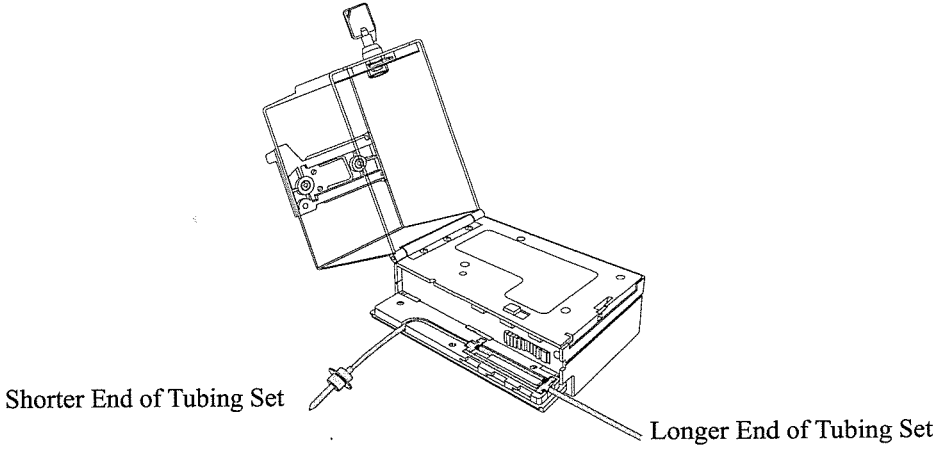


Figure 3-9 Tubing Set Position

5. Close and latch the tubing door as follows. Move the latch away from the hinge, close the tubing door, and release the latch so that it returns to its original position.

   To avoid pinching the tubing, do not let the tubing fall out of the groove when you are closing the tubing door. Failure to latch tubing door will prevent the cover from closing.

! WARNING ! **Failure to latch the tubing door properly may result in a no flow condition.**

! WARNING ! **If the tubing is pinched by the closed tubing door, resistance to flow may increase and fluid delivery to the patient may be compromised. If this occurs, open the bag cover, reseat the tubing and check the tubing door for proper closure, close the bag cover, then restart the pump.**

! WARNING ! **Avoid getting any liquids on the tubing set, inside the tubing door, or in the tubing channel. Air sensor functioning could be compromised or permanent damage may result.**

Note: The pump automatically closes off the tubing whenever the device is stopped to reduce the risk of a free flow condition. When the tubing is removed from the pump, the anti-siphon valve on the set reduces the risk of a free flow condition when used in accordance with the set's instructions.

Load Baxter 100 mL or 250 mL Bags

CAUTION All luer-lock connections must be properly tightened. Over tightening of a connection may crack the luer and cause leakage.

1. Open the package and carefully remove the bag.

Note: Do not confuse the nonvented cap (which is supplied in its own package) with the cap attached to the outlet tubing. The cap attached to the outlet tubing is not airtight and will not prevent fluid leakage.

2. Fill a sterile syringe with the solution to be placed in the bag.
3. Remove and discard the cap from the outlet tubing of the bag.
4. Connect the syringe to the female luer-lock fitting on the bag's outlet tubing. (Do not use a needle.)
5. Inject the solution into the bag. If necessary, refill the syringe and repeat the process. (The bag will hold approximately 100 mL or 250 mL, depending on the bag selected.)
6. Remove all air from the bag by aspirating with the syringe, and then remove the syringe.

7. • If the bag is being used immediately do not use the nonvented cap. Connect the luer-lock fittings between the bag and the pump tubing set. (The bag must be connected to the shorter segment of the tubing set.)

   • If the bag is being stored for later use connect the nonvented cap to the bag after the bag is filled.

8. Remove the air from the remainder of the tubing set by following the priming procedure described in "Prime the Pump, 5-23".

! WARNING ! **The tubing set must NOT be connected to the patient while priming.**

9. Connect the distal end (longer segment) of the pump tubing set to the patient's access site, making certain that the luer-lock connection is properly tightened.

Note: To prevent upstream occlusions, open any optional clamp on the bag before starting the infusion.

! WARNING ! **You must change the administration set after 2,000 mL of infusion or every seven days, depending on which event occurs first.**

End of Steps

Load Viaflex®, IntraVia®, or Similar Fluid Bags

CAUTION Follow any directions provided by the manufacturer of the fluid bag being used.

1. Open the package and carefully remove the bag.
2. Add any additional drug to the bag using an appropriate syringe and needle for the injection port of the bag. Mix or shake the bag to dilute the drug and solution appropriately.
3. Remove all air from the bag by aspirating with the syringe, and then remove the syringe.
4. Insert the tubing set spike into the outlet port of the bag.

! WARNING ! **The tubing set must NOT be connected to the patient while priming.**

5. Remove the air from the remainder of the tubing set by following the priming procedure described in "Prime the Pump, 5-23"
6. Connect the distal end (longer segment) of the pump tubing to patient's access site, making certain that the luer-lock connection is properly tightened.

Note: To prevent upstream occlusions, open any optional clamp on the bag before starting the infusion.

7. After connecting the bag to the pump tubing, place the bag inside the cover and place the tubing in the groove in the tubing door ("Load the Tubing Set, 3-19")

8. Verify that the tubing door is properly closed and latched.

9. Close the cover, taking care not to pinch the pump tubing. If the tubing is pinched, an alarm will sound after the pump is started.

! WARNING ! **If the tubing is pinched by the closed tubing door, resistance to flow may increase and fluid delivery to the patient may be compromised. If this occurs, open the bag cover, reseat the tubing and check the tubing door for proper closure, close the bag cover, then restart the pump.**

! WARNING ! **Failure to latch the tubing door properly may result in a no flow condition.**

! WARNING ! **Avoid getting any liquids on the tubing set, inside the tubing door, or in the tubing channel. Air sensor functioning could be compromised or permanent damage may result.**

10. If a cover is attached to the pump, lock it. If the cover cannot be closed and locked, check the tubing cover to be certain it is closed completely.

End of Steps

Change the Fluid Bag

1. Follow the "Load Baxter 100 mL or 250 mL Bags, 3-22" or "Load Viaflex®, IntraVia®, or Similar Fluid Bags, 3-24" to prepare and install the bag and tubing set.
2. Complete the tasks described in the "Changing the Prescription During Infusion, 5-42", making sure to select PRIME at the SELECT ACTION prompt.
3. Enter the correct fluid volume, and prime the set, if required, as indicated in "Preparing, Loading, and Changing the Tubing Set and Fluid Bag, 3-15".
4. When the pump displays the PUMP READY prompt, press START to restart the infusion.

End of Steps

Attaching or Removing the Pump From a Pole (Optional)

Attach the Pump to a Pole

1. Align the pole-mounting clamp below the slide bracket on the back of the pump.
2. Slide the clamp toward the top of the pump until it stops. Make sure that the two holes on the clamp align with the two smaller holes on the bracket.
3. To keep the clamp attached to the pump, insert the two enclosed screws through the clamp and into the holes in the bracket.

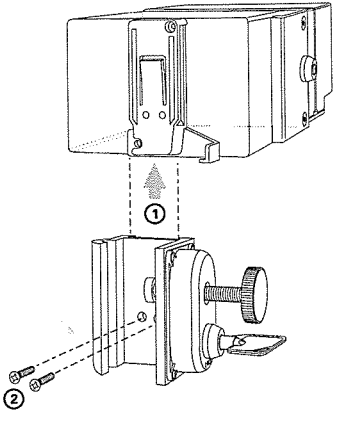


Figure 3-10 Attaching the clamp

4. Mount the clamp to a stable pole or vertical rail that is 0.5" to 1.25" in diameter and tighten it. If the clamp is detached from the pump, make certain the arrow on the clamp is pointing up.

5. Lock the clamp by inserting the key, pushing it in, and rotating it clockwise to the locked position.

Note: The pump must be in the clamp before locking the clamp. Failure to do so makes it possible for the pump to be removed without using a key.

Although the clamp may be tightened when it is locked, it cannot be loosened enough to remove it.

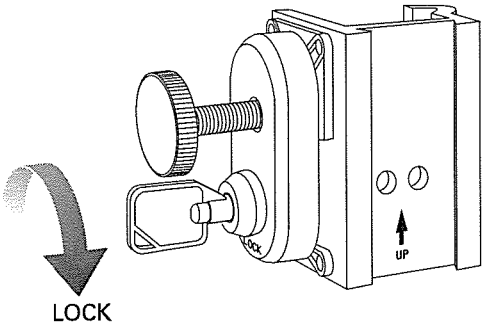


Figure 3-11 Locking the Clamp

Remove the Pump from the Pole

1. Unlock the clamp by inserting the pole-mounting clamp key into the lock on the housing, pushing the key in, and rotating it counter clockwise to the unlocked position.
2. If the clamp has not been screwed onto the pump, slide the pump up and out of the clamp to remove the pump from the pole. If the clamp has been screwed onto the pump, loosen the clamp by turning the knob counter clockwise to remove both the clamp and the pump from the pole.

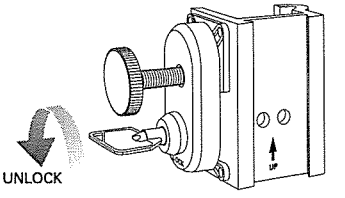


Figure 3-12 Unlocking the Clamp

Chapter 4. Configurable Options

This section lists the configurable features and the initial factory settings available for this device. The factory-set defaults can be modified by authorized personnel to meet customer-specific needs as described in the Configuration Manual. The pump's configurable features are categorized as:

- **Preferences** – for a particular language, date format, clock type, decimal mark, security method, security code, and identification label (see "Configurable Options - Preferences, 4-2").
- **Limits** – for the infusion mode, units, dose limit type, max (maximum) PCA Dose, max continuous rate, and max bolus dose (see "Configurable Options - Limits, 4-4").
- **Controls** – for restarting the pump after the bolus and setting the alert silencing time, low-volume alert time, PCA Button status, preventive maintenance alert, upstream occlusion detection, and air detection (see "Configurable Options - Controls, 4-6").

Table 4-1 Configurable Options - Preferences

Preferences	Available Settings	Factory Settings
Language	ENGLISH SPANISH FRENCH JAPANESE GERMAN DANISH/SWEDISH ITALIAN NONE	NONE
Date Format	MM/DD/YY DD/MM/YY YY-MM-DD	MM/DD/YY

Table 4-1 Configurable Options - Preferences — continued

Preferences	Available Settings	Factory Settings
Time Setting	12 HOUR 24 HOUR	12 HOUR **Note:** AM or PM will be displayed when the pump is configured for a 12-hour clock.
Decimal Mark This setting is used in countries that use decimal points instead of commas.	POINT (decimal point) COMMA	POINT (decimal point)
Security Method This setting determines the security requirements for operating the pump.	KEY+CODE CODE ONLY KEY ONLY	KEY+CODE
Security Code	001 – 999	123

Table 4-1 Configurable Options - Preferences — continued

Preferences	Available Settings	Factory Settings
Identification Label The Identification Label is a user-defined message that is displayed following the Power On Self Test.	Up to 16 characters (A-Z, 0-9, blank, dash and characters and accents for specific languages such as Japanese characters, German Ä, Ö, Ü, the Danish Ä, Å, Ö, and the Spanish Ñ)	None

Table 4-2 Configurable Options - Limits

Limits	Available Settings	Factory Settings
Infusion Modes	PCA BASAL+PCA CONTINUOUS	All modes enabled

Table 4-2 Configurable Options - Limits — continued

Limits	Available Settings	Factory Settings
Infusion Units	mL mg µg	All infusion units types enabled
Dose Limit Type	1 HOUR 4 HOUR PCA DOSES/HR	1 HOUR
Maximum PCA Dose	0.2 to 9.9 mL	9.9 mL
Maximum Basal Rate	0.2 to 19.9 mL/hr	9.9 mL/hr
Maximum Continuous Rate	0.2 to 90.0 mL/hr	19.9 mL/hr
Maximum Bolus Dose	0.2 to 49.9 mL	9.9 mL

Table 4-3 Configurable Options - Controls

Controls	Available Settings	Factory Settings
Restart After Bolus This setting determines whether the pump will begin infusion automatically after completing initial bolus delivery, or whether the operator must press START to begin infusion.	AUTO RESTART MANUAL RESTART	AUTO RESTART
Alert Silencing Time	2, 15, 30 or 60 MIN	2 MIN
Low Volume Alert Time	30, 60, 90 or 120 MIN	120 MIN

Table 4-3 Configurable Options - Controls — continued

Controls	Available Settings	Factory Settings
PCA Button Status	REQUIRED OPTIONAL	REQUIRED **Note:** In PCA and BASAL+PCA modes, the REQUIRED setting requires use of a PCA button to request PCA doses. The OPTIONAL setting allows the use of the START key as an alternative for requesting PCA doses.
Preventive Maintenance Alert	0 (no alert) to 12 MONTHS	0 (no alert)
Upstream Occlusion Detection	ON OFF	ON

Table 4-3 Configurable Options - Controls — continued

Controls	Available Settings	Factory Settings
Air Detection This setting controls the sensitivity of the Air Detection feature.	OFF LOW = 500 µL within 800 µL of fluid HIGH = 100 µL within 160 µL of fluid	OFF The air sensor will measure the accumulated amount of air detected over an amount of fluid delivered. The amounts of delivered fluid depend on the programmed air bubble size. The air alarm is triggered for a single air bubble greater than the set threshold or an accumulation of air greater than the threshold. **! WARNING !** **The air sensor will detect and measure accumulated amount of air over an amount of fluid delivered. However, the pump may not detect all instances of micro or "champagne" air bubbles.**

Chapter 5. Using the Pump

This chapter covers all of the tasks associated with programming and using the pump based on the messages displayed on the screen. Because the pump stores patient data, the sequence of the messages displayed on the pump will depend on whether you are programming an infusion for the first time or restarting a pump. To help you use the pump quickly and effectively, this chapter contains basic procedures for the pump, including examples of the "Messages Displayed." The chapter is organized as follows:

- Preliminary Information
- Basic Pump Procedures
- Programming the Prescription
- Start, Stop, Restart the Infusion
- Changing the Prescription During Infusion
- Reviewing the Therapy History

! WARNING ! **Do not use any pump that has readily apparent defects or damage, including missing or misaligned components, missing display pixels, or missing audio.**

Select Settings and Enter Values

1. Press the left (⇐) and right (⇒) keys to position the cursor (↑) under the required digit or selection.

Table 5-1 Cursor Movement

Cursor Position	Action
far-left value	press the ⇐ key to move (wrap) the ↑ to the far right.
far-right value	press the ⇒ key to move (wrap) the ↑ to the far left.

2. Press the scroll key (⇑) to select a different value or scroll through available options. To increase the speed of the scrolling, you can:
   - Press and hold ⇑ key for more than 1 second to scroll to other options at a rate of 2 characters/second.
   - Release ⇑ key and press it again to reset the scroll rate to the previously set lower rate.
3. Press the ENTER key to accept the selected value.
4. Press the Clear/Silence key to reset numerical values to zero.

Turn on the Back Light

When the pump is powered through the AC adapter, the display and back light will remain on constantly. If the pump is operated by using a battery, both the display and back light are turned off during infusions to save energy. To turn the screen lighting back on, press any key except the START key. If the pump is set up for a PCA dose, pressing the START key will initiate a PCA dose, but will not turn on the back light.

Retain Programming Data

The pump automatically saves the prescription settings and tracking information in memory. This information will not be lost if the pump is turned off. If a pump is restarted, the previous prescription can be accessed as described in "Reviewing the Therapy History, 5-44".

Display the Power Status

The power status of the pump is shown in the upper right hand corner of the display by:

- A battery symbol to show that the pump is operating on battery power, or
- A plug to indicate that the pump is powered through the Baxter AC adapter.

See "Pump Symbols, 2-10" for graphic examples.

Basic Pump Procedures

Because the pump stores patient data, the sequence of the messages displayed on the pump varies, depending on whether you are setting up an infusion for the first time or restarting a pump. All of these procedures are generic and apply to PCA, BASAL+PCA, and CONTINUOUS infusions. The following procedures include specific instructions and *examples* that cover how to:

- Turn on the Pump
- Turn off the Pump
- Select the Language
- Wait for the Software to Load
- Accept or Modify Date and Time Settings
- Unlock and Lock the Cover
- Enter the Security Code
- Use the Previous Prescription
- Select the Mode and Units

- Set the Concentration
- Prime the Pump
- Set the Fluid Volume in the Reservoir

Before the pump is put in service, it should be configured as necessary to reset any of the default values described in "Configurable Options, 4-1".

Turn on the Pump

When the pump is turned on, it begins a series of self-diagnostic tests. During these tests, the LEDs flash, and the alarm tone sounds briefly. If the pump fails to display the entire display screen, flash both LEDs, sound a brief alarm tone, or fails the self-test, contact the service center listed in "Authorized Service Center, 7-1".

Action	Message Displayed
1. Press the ON/OFF key to turn on the pump.	PERFORMING POWER ON SELF TESTS
2. Wait for the self-diagnostic tests to complete. End of Steps	

Turn off the Pump

Turn off the pump to reset or modify a prescription during programming or administration of a bolus or infusion. If the pump is turned off, prescription data will be saved in memory. When the pump is turned back on, the previous prescription can be resumed or other options may be selected. See "Restart the Infusion, 5-40".

Action	Message Displayed
1. If an infusion is in progress, press **STOP** twice within 1 second. This will stop the infusion but will not turn off the pump.	KEY+CODE and KEY ONLY: PUMP READY PRESS START CODE ONLY: PUMP READY START OR CLEAR

Action	Message Displayed
2. Press the ON/OFF key twice within 1 second. End of Steps	

Select the Language

If the pump is not configured for a particular language, the pump will default to a NONE option, which will allow the user to cycle through and select the appropriate language as English, Spanish, French, Japanese, German, Danish/Swedish, or Italian. To avoid having to scroll through these languages, properly set a language as indicated in the Configuration Manual.

Action	Message Displayed
1. Wait for the correct language to appear on the screen. Press ENTER to accept the language OR Wait for the list to scroll through again if you missed the required entry. End of Steps	**Example:** PRESS ENTER FOR ↑ ENGLISH

Wait for the Software to Load

After the pump completes the self-test, the software is loaded, and the software version is displayed. The sequence of this message will vary, depending on how the pump is configured and whether a previous prescription has been programmed.

Action	Message Displayed
1. Wait for the pump to load the software and complete the self-test. Result: The software version is displayed.	**Example:** SOFTWARE VERSION X.XX.XX
2. If an identification label is defined for the pump, it is briefly displayed. End of Steps	**Example:** CARDIOLOGY 12

Accept or Modify Date and Time Settings

The date may appear as MM/DD/YY, DD/MM/YY, or YY-MM-DD, depending on the configured date format. AM or PM is:

- displayed if the pump is configured for a 12-hour clock or
- omitted if the pump is set up for a 24-hour clock (military time)

Action	Message Displayed
1. Wait for the software to load. When the date and time appear: Press ENTER to accept the values, and go to the next required procedure. OR Press Clear to modify the values; then go to Step 2.	**Example:** 06/30/99 08:55PM ENTER OR CLEAR

Action	Message Displayed
2. Press the ⇐ or ⇒ key to position the ↑ under the number that you want to change.	**Example:** 06/30/99 08:35PM ↑ SET MONTH
3. Press the ⇑ key to select the correct digit.	**Example:** 07/30/99 08:35PM ↑ SET MONTH
4. If you make a mistake, press the: ⇑ key again until the correct value appears. OR ⇐ or ⇒ key to reposition the cursor (↑). OR Clear/Silence key to reset the previous values.	**Example:** 76/70/99 08:35PM ↑ SET MONTH 06/30/99 08:35PM ↑ SET MONTH 06/30/99 08:35PM ↑ SET DAY

Action	Message Displayed
5. Repeat the preceding steps until you have set the month, day, year, hour, and minute. When the values are correct, press ENTER. End of Steps	UNLOCK THE COVER

Unlock and Lock the Cover

If the pump is configured for the KEY+CODE or KEY ONLY security method, the pump prompts you to UNLOCK THE COVER. When you unlock and then open the cover, the message LOCK THE COVER is displayed on the screen and the pump produces a beeping sound.

Action	Message Displayed
1. Place the key inside the lock, twist it one-quarter turn counter clockwise, and open the back cover of the pump.	UNLOCK THE COVER

Action	Message Displayed
2. When the cover is unlocked, the pump displays the LOCK THE COVER prompt while sounding a repeating alert tone.	LOCK THE COVER
3. Lock the cover by turning the key clockwise one-quarter turn. End of Steps	

Enter the Security Code

If the pump is configured for the KEY+CODE or CODE ONLY, you will be prompted to enter the security code before you can program the prescription.

Note: The pump has a factory-default security code of "123". See the Configuration Manual for directions on how to customize this code.

Action	Message Displayed
1. Press the ⇑ key to enter the first number of the security code for the pump.	000 ENTER CODE ↑
2. Press the ⇒ key to position the ↑ under the second number.	100 ENTER CODE ↑
3. Press the ⇑ key to display the second number. If you make a mistake, use the ⇑, ⇐ or ⇒ keys to enter the correct value.	120 ENTER CODE ↑
4. Repeat the preceding steps until all of the numbers are entered correctly. Then, press ENTER. End of Steps	123 ENTER CODE ↑

Use the Previous Prescription

Action	Message Displayed
1. At the USE PREVIOUS Rx? prompt, press ENTER to select YES. If a YES response is entered, the pump will display the previous prescription settings as default values during programming. You can choose to modify the prescription by re-entering different values (for example for the mode, unit, and/or bolus). If a NO response is selected, the pump will display zeroes for the initial prescription settings.	USE PREVIOUS Rx? ↑Yes

Action	Message Displayed
2. If necessary, press HISTORY to review the previous therapy history as described in the "Reviewing the Therapy History, 5-44". The pump will return to the USE PREVIOUS Rx? prompt following the history review. End of Steps	

Set the Concentration

The units displayed on the pump's LCD are determined by the selected programming unit and mode. If the previous prescription settings are being used, that concentration setting is displayed instead of zeroes. If mL units are selected, you do not have to enter the concentration entry.

Action	Message Displayed
1. Use the ⇐ or ⇒ keys and ⇑ key to set the correct concentration.	00.0 mg/mL SET ↑ CONC.
2. If you make a mistake, press the: ⇑ key again until the correct value appears. OR ⇐ or ⇒ key to reposition the ↑. OR Clear/Silence key to reset the previous value to 0.	000 µg/mL SET ↑ CONC.

Select the Mode and Units

Unless the pump is configured for a single mode or a single type of unit, you will be prompted to select the infusion mode and/or units.

Action	Message Displayed
1. If prompted, press ENTER to select the current mode displayed or use the ⇑ key to display the desired mode (BASAL+PCA or CONTINUOUS), then press ENTER.	**Example:** SELECT MODE ↑ PCA
2. Select the units currently displayed, or use the ⇑ key to display the required units (mL, mg or µg), then press ENTER.	**Example:** SELECT UNITS ↑ mL
3. If you make a mistake, press the ⇑ key again until the correct selection appears.	
4. When the correct selection is displayed, press ENTER. End of Steps	

Set the Fluid Volume in the Reservoir

Before continuing with prescription entry, you must set the fluid volume in the reservoir.

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
1. Press the ⇐ or ⇒ key to position the ↑.	✔	✔	✔	0000 mL SET ↑FLUID VOLUME
2. Press the ⇑ key as necessary to set the volume.	✔	✔	✔	
3. Press the Clear/Silence key to reset the values to zero or the previous setting.	✔	✔	✔	
4. Press the ENTER key to set the value. End of Steps	✔	✔	✔	

Action	Message Displayed
3. Press ENTER when the desired value is displayed. End of Steps	**Example:** 10.0 mg/mL SET ↑ CONC. 100 µg/mL SET ↑ CONC.

Prime the Pump

The pump must be disconnected from the patient before you prime the pump. As a security measure, you will not be allowed to prime the pump more than 10 times without entering a security code. While priming is in progress, the pump displays the amount being delivered. After priming is completed, the pump shows the total priming volume.

! WARNING ! **The tubing set MUST NOT be connected to the patient while priming.**

Note: When the pump is priming, the air-in-tubing alarm is disabled.

Note: To skip priming, press ENTER.

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
1. Press the START key to prime the pump, or press the HISTORY key to display the current priming total.	✔	✔	✔	START TO PRIME ENTER TO PROCEED
2. Wait for the pump to prime. The priming continues until 0.5 mL is delivered or STOP is pressed.	✔	✔	✔	**Example:** PRIMING 00.2 mL
3. Observe the PRIMING TOTAL message.	✔	✔	✔	**Example:** PRIMING TOTAL 01.5 mL

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
4. Wait a few seconds until the pump returns to the START TO PRIME / ENTER TO PROCEED prompt.	✔	✔	✔	START TO PRIME ENTER TO PROCEED
5. Repeat priming as many times as necessary until the tubing set is fully primed. **Note:** After 10 priming steps (that is, when 5 mL is delivered), the clinician must enter the security code.	✔	✔	✔	
6. Press ENTER to continue prescription entry. End of Steps				

Programming the Prescription

These procedures cover how to program PCA, BASAL+PCA, and CONTINUOUS prescriptions. After you select PCA, BASAL+PCA, or CONTINUOUS, follow the checks provided in the procedures to determine the screen messages applicable to each mode, and then complete all applicable tasks. The tasks covered in this section include:

- Program PCA Dose
- Set the PCA Delay Period
- Program the Basal Rate
- Set the Dose Limit
- Program the Bolus Dose
- Program Continuous Rate
- Program a Supplemental Bolus

All of the units presented in this section are provided only as examples. The actual units displayed are determined by the selected programming units (mL, mg, or µg). If the previous prescription settings are being used, those values will be displayed instead of zeroes.

Program the PCA Dose

The PCA dose is the programmed volume of the drug to be injected when requested by the patient.

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
1. Use the ⇐ and ⇒ keys and ↑ to program the PCA dose.	✔	✔		0.0 mL SET ↑ PCA DOSE
2. If necessary, press the **Clear/Silence** key to reset the displayed value to zero.	✔	✔		
3. Press **ENTER** when the desired value is displayed. End of Steps	✔	✔		

Program the Basal Rate

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
1. Use the ⇐ and ⇒ keys and ↑ to program the basal rate.		✔		000.00 mg/hr SET ↑ BASAL RATE
2. If necessary, press the Clear/Silence key to reset the displayed value to zero.		✔		
3. Press ENTER when the desired value is displayed. End of Steps		✔		

Set the PCA Delay Period

The delay period begins with the start of delivery of each PCA dose. The initial delay is measured from the start of infusion. During the delay period, another PCA dose may not be started even if a PCA dose is interrupted.

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
1. Use the ⇐ and ⇒ keys and ↑ to set the PCA delay period.	✔	✔		000 MINUTES ↑ SET DELAY
2. If necessary, press the **Clear/Silence** key to reset the displayed value to zero.	✔	✔		
3. Press **ENTER** when the desired value is displayed. End of Steps	✔	✔		

Set the Dose Limit

The pump will display a 1-hour, 4-hour, or maximum dose limit, depending on the configuration of the pump. If the1-hour or 4-hour dose limit is reprogrammed, a new time period is started and the dosage delivered is restarted from zero. If the maximum dose limit per hour is reprogrammed, a new time period is started, but the dose that was stopped before the delivery was completed will be counted towards the dose per hour limit in the new time period.

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
1. Use the ⇐ and ⇒ keys and ↑ to set the dose limit.	✔	✔		000.0 mg SET ↑1 HR LIMIT 000.00 mg SET ↑4 HR LIMIT 00 SET MAX PCA ↑ DOSES/HR

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
2. If necessary, press the **Clear/Silence** key to reset the displayed value to zero.	✔	✔		
3. Press ENTER when the desired value is displayed. End of Steps	✔	✔		**Example:** 010.0 mg SET ↑ 1 HR LIMIT 010.00 mg SET ↑ 4 HR LIMIT 01 SET MAX PCA ↑ DOSES/HR

Program the Bolus Dose

The programmed bolus dose is either delivered automatically at the start of therapy, or initiated by the clinician during the course of therapy. If a programmed bolus dose has not been started, the pump will display the programmed dosage instead of zeroes.

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
1. Use the ⇐ and ⇒ keys and ↑ to program the bolus dose. **Note:** If no bolus is desired, enter zero.	✔	✔	✔	0000.0 mg SET ↑ BOLUS
2. If necessary, press the Clear/Silence key to reset the displayed value to zero.	✔	✔	✔	
3. Press ENTER when the desired value is displayed.	✔	✔	✔	0100.0 mg SET ↑ BOLUS

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
4. Connect the pump tubing set to the patient's access device.	✔	✔	✔	START BEGINS Rx ENTER REVIEWS Rx
5. Press START to begin the bolus.	✔	✔	✔	
6. Wait until the bolus starts. Result: The INFUSING LED will flash green. **Note:** If a bolus has been programmed, the bolus dose will be delivered first.	✔	✔	✔	**Example:** BOLUS INFUSING 1000.0 mg
7. Wait until the bolus delivery is completed, or press STOP twice in 1 second to stop the infusion. End of Steps	✔	✔	✔	**Example:** BOLUS DONE 1000.0 mg

Program the Continuous Rate

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
1. Use the ⇐ and ⇒ keys and ↑ to program the continuous rate.			✔	000.00 mg/hr SET ↑ CONTINUOUS RATE
2. If necessary, press the Clear/Silence key to reset the displayed value to zero.			✔	
3. Press ENTER when the desired value is displayed. End of Steps			✔	

Program a Supplemental Bolus

If a bolus is interrupted, it cannot be restarted automatically. To administer additional bolus volumes, you must reprogram the bolus.

Action	Message Displayed
1. At the SET BOLUS prompt, use the ⇐ and ⇒ keys and ⇑ key to set the desired bolus dose. Press Clear/Silence to make the displayed value zero. Press ENTER when the desired value is displayed.	00.0 mL SET ↑ BOLUS
2. Press ENTER to review or change the prescription. See "Review the Prescription, 5-45" or "Change the Prescription, 5-42". OR Press START to begin infusing the supplemental bolus.	START BEGINS Rx ENTER REVIEWS Rx

Action	Message Displayed
3. If you pressed START, the pump resumes the infusion, and the pump displays BOLUS INFUSING. The bolus delivery will continue until the bolus dose is delivered or STOP is pressed twice in 1 second.	**Example:** BOLUS INFUSING 0001.3 mg
4. When the bolus delivery is completed, the pump displays a BOLUS DONE message.	**Example:** BOLUS DONE 002.0 mg
5. Press START to resume the infusion. **Note:** If the pump configuration specifies automatic start after bolus, infusion will resume automatically in approximately 10 seconds. End of Steps	PCA BASAL+PCA

Start the Infusion

Action	PCA	BASAL+PCA	CONTINUOUS	Message Displayed
1. Press START to begin the infusion. **Note:** If the pump is configured for an automatic start after bolus, the infusion will begin immediately after the delivery of the bolus if one has been programmed. End of Steps	✔	✔	✔	PCA BASAL+PCA CONTINUOUS 00.0 mg/hr

Stop the Infusion

Action	Message Displayed
1. Press STOP twice to interrupt the infusion or bolus. End of Steps	KEY+CODE or KEY ONLY: PUMP READY PRESS START CODE ONLY: PUMP READY START OR CLEAR

Restart the Infusion

Action	Message Displayed
1. If the pump is configured as KEY+CODE or KEY ONLY, unlock and lock the fluid bag cover. If the pump is configured as CODE ONLY, press Clear/Silence. If the pump is configured as KEY+CODE or CODE ONLY, input the correct security code at the ENTER CODE OR START prompt, and press ENTER.	PUMP READY PRESS START PUMP READY START OR CLEAR 000 ENTER CODE ↑ OR START

Action	Message Displayed
2. When the pump displays the SELECT ACTION prompt, use the ⇑ key to select: PRIME to prime the tubing set after changing the fluid reservoir. Then press ENTER and go to "Prime the Pump, 5-23". OR SET BOLUS to program a supplemental bolus dose, then press ENTER. See "Program a Supplemental Bolus, 5-36". OR CHANGE Rx to modify the prescription, then press ENTER. See "Changing the Prescription During Infusion, 5-42". OR START INFUSION to restart the infusion. End of Steps	SELECT ACTION ↑ PRIME SELECT ACTION ↑ SET BOLUS SELECT ACTION ↑ CHANGE Rx SELECT ACTION ↑ START INFUSION

Changing the Prescription During Infusion

The prescription and units cannot be changed unless the pump has been reprogrammed. If it is necessary to retain a patient's history information, you can review and record the history data on the patient's chart or print a hard copy before turning off the pump. See "Reviewing the Therapy History, 5-44".

To change the prescription during an infusion, you must complete the following procedures to:

- "Stop the Infusion, 5-39"
- "Program a Supplemental Bolus, 5-36"

Change the Prescription

Action	Message Displayed
1. At the SELECT ACTION prompt, use the ⇑ key to display the CHANGE Rx prompt, then press ENTER.	SELECT ACTION CHANGE Rx

Action	Message Displayed
2. Use the ⇐ and ⇒ keys and ↑ to program the new prescription. See "Programming the Prescription, 5-26".	
3. Press START to begin the infusion. End of Steps	START BEGINS Rx ENTER REVIEWS Rx

Reviewing the Therapy History

The pump retains a record of the previous prescription and therapy history in memory until it is modified or the pump is reconfigured. The type of information provided in this section includes how to:

- "Review the Prescription, 5-45"
- "Access a Patient's History, 5-47"
- "History Not Available Message, 5-58"

All of the totals displayed reflect current information at the time that they are displayed. The date and time formats are determined by the configuration of the pump, and the units displayed are the programmed units in mL, mg, or µg.

Review the Prescription

To review a prescription, you can view the patient's prescription details as described in "Access a Patient's History, 5-47" or as part of the bolus entry procedure. The procedure below describes prescription review as part of programming a bolus.

Action	Message Displayed
1. At the SET BOLUS prompt, use the ⇐ and ⇒ keys and ↑ to program the bolus dose.	00.0 mL SET ↑ BOLUS
2. Press ENTER when the desired values are displayed.	START BEGINS Rx ENTER REVIEWS Rx

Access a Patient's History

Action	Message Displayed
1. Press HISTORY during an infusion or whenever one of the messages shown in the next column is displayed. 2. If a patient's history is available, the date and time of the start of infusion appears on the screen. Go to Step 4. 3. If a patient's history is not available, see "History Not Available Message, 5-58".	PUMP READY PRESS START PUMP READY START OR CLEAR REVIEW HISTORY OR PRESS ENTER ENTER CODE ENTER CODE OR START USE PREVIOUS Rx? ↑ YES

Action	Message Displayed
4. The pump records the total, dates, number, and amount of each patient's prescription. The type and sequence of the messages are directly dependent on the programmed prescription. When the THERAPY STARTED message appears: 4.1 Press the ⇒ key to scroll through the history review screens. 4.2 Press the ⇐ key to go back to the previous history screen or the start of the previous group of screens. 4.3 Press the HISTORY key again to exit the history review at any time.	**Example:** THERAPY STARTED 03/10/99 08:11AM

Action	Message Displayed
5. As you scroll, the following messages are displayed: 5.1 TOTAL GIVEN, including any PCA, BASAL+PCA, CONTINUOUS, and bolus infusions.	XXXX.X mL TOTAL GIVEN **Example:** 53.3 mg TOTAL GIVEN
5.2 For PCA infusions, the recorded number of total injections (TOTAL INJ) administered and total dose attempts (TOTAL ATT). Partial PCA doses are included in the TOTAL INJ count. A partial dose can occur when a dose is interrupted by an occlusion, or when the dose is interrupted because the 1-hour limit or 4-hour limit has been reached.	XXXX TOTAL INJ XXXX TOTAL ATT **Example:** 0008 TOTAL INJ 0010 TOTAL ATT

Action		Message Displayed
5.3	For bolus infusions, the total of the initial and supplemental bolus infusions.	XXXX.X mL BOLUS INFUSED **Example:** 0012.0 mL BOLUS INFUSED
5.4	The FLUID VOLUME REMAINING.	XXXX.X mL FLUID VOLUME REMAINING **Example:** 0039.3 mL FLUID VOLUME REMAINING

Action	Message Displayed
6. The SHIFT HISTORY group messages provide specific pump infusion information for a particular shift. A new shift is started whenever the operator clears the shift totals. After reviewing the information, you can delete the data and initiate a new shift. At the SHIFT HISTORY message: 6.1 Press the ⇒ key to scroll through the history review screens. 6.2 Press the ⇐ key to go back to the previous history screen or group of screens. 6.3 Press the HISTORY key again to exit the history review at any time.	SHIFT HISTORY

Action	Message Displayed
7. As you scroll, the following messages are displayed: 7.1 The date and time of the start of the shift. [A new shift is started whenever the operator clears the shift totals.]	SHIFT STARTED MM/DD/YY HH:MMAM **Example:** SHIFT STARTED 03/17/99 12:00AM
7.2 For PCA doses only, the total injections (TOTAL INJ) administered and total attempts (TOTAL ATT) recorded per shift.	XXXX TOTAL INJ XXXX TOTAL ATT **Example:** 0004 TOTAL INJ 0004 TOTAL ATT
7.3 The SHIFT TOTAL for any PCA, BASAL+PCA, CONTINUOUS, or bolus infusions.	XXXX.X mL SHIFT TOTAL **Example:** 0031.5 mL SHIFT TOTAL

Action	Message Displayed
8. After you view the SHIFT TOTAL screen, you may (as an option) choose to: 8.1 Press Clear/Silence to clear the totals and begin a new shift. 8.2 Wait for the INITIAL SETTINGS of the prescription to appear on the screen. **Note:** Pressing Clear/Silence will reset the total infused and the "injections versus attempts" to zero and set the time and date of the new shift as the time/date that the pump was cleared.	SHIFT TOTALS CLEARED
9. Press the ⇒ key to view the following prescription details:	PRESCRIPTION DETAILS
9.1 Concentration	**Example:** 05.0 mg/mL CONCENTRATION

Action	Message Displayed
9.2 Dose	**Example:** 6.0 mg PCA DOSE
9.3 Delay	**Example:** 003 MINUTES DELAY
9.4 Rate settings	**Example:** 004.00 mg/hr BASAL RATE
10. The HOURLY HISTORY group of screens is displayed only if PCA doses were allowed at some time during the therapy. For each 24-hour period, three screens per hour are generated. At the HOURLY HISTORY message, press the ⇒ key to scroll through the following screens:	HOURLY HISTORY

Action	Message Displayed
10.1 The hour of the dosage.	**Example:** 11:30 - 12:00AM
10.2 The number of PCA doses administered and the number requested during the hourly period.	**Example:** 0004 INJECTIONS 0004 ATTEMPTS
10.3 The cumulative total infused at the end of the hourly period, including any bolus, PCA and BASAL+PCA infusions.	**Example:** 0031.5 mL GIVEN AS OF 12:00AM
11. The EVENT HISTORY group displays a chronological list of events that occurred during the therapy. This group begins with the message EVENT HISTORY and ends with the message END OF HISTORY.	EVENT HISTORY
12. Press the ⇒ key to display the following types of events:	

Action	Message Displayed
12.1 Date and time cover was unlocked.	**Example:** COVER UNLOCKED 03/17/99 12:15PM
12.2 Date and time infusion was started.	**Example:** START INFUSION 03/17/99 01:20PM
12.3 Date and time infusion was stopped.	**Example:** STOP INFUSION 03/18/99 02:20PM
12.4 Date and time bolus was started.	**Example:** START BOLUS 03/17/99 12:20AM
12.5 Total bolus infused.	**Example:** 008.0 mg BOLUS DONE

Action	Message Displayed
12.6 Date and time 1-hour limit, 4-hour limit or max doses per hour limit was reached.	**Example:** DOSE LIMIT 03/16/99 11:58PM
12.7 Date and time and type of alarm.	**Example:** AIR IN TUBING 03/17/99 09:30AM
12.8 Change to prescription value.	**Note:** This information is only displayed in the printout of the Patient History. See"Optional History Printout, 5-58".
12.9 Date and time when the infusion ended.	**Example:** THERAPY ENDED AT 03/17/99 09:30AM
12.10 End of the patient's history review. End of Steps	END OF HISTORY

History Not Available Message

When the HISTORY key is pressed and the pump displays HISTORY NOT AVAILABLE, the history may have been erased if:

- A new prescription that was not started, was entered for a PCA, BASAL+PCA, or CONTINUOUS mode infusion

OR

- The configuration of the pump was modified

Optional History Printout

The therapy history data can be printed using an optional printer and printer adapter. Some information, such as changes made to prescription values, can only be viewed in a printout. Contact your local Baxter Service Center for details.

Chapter 6. Alerts and Alarms

Audible signals for alerts and alarms can be silenced by pressing the **Clear/Silence** key. These audible signals will return after the time period defined by the Alert Silencing Time setting (see "Configurable Options, 4-1").

An alarm, unlike an alert, requires immediate attention because it stops the motor on the pump. Both alerts and alarms are signalled by a:

- Flashing red light on the **Alert** indicator
- Audible tone consisting of:
  - an alert signal (a single or repeating tone of one long beep followed by three short beeps)
  - an alarm signal (a repeating tone of one long beep followed by three short beeps)
- Specific message in the LCD screen that describes the cause of the alert or alarm.

Note: If the pump is battery operated, the alert or alarm message will not be displayed until you press a key.

Alerts

Each alert message that could be displayed in the pump's LED is described in this section with step-by-step procedures for resolving the alert. These alert messages are organized numerically and then alphabetically.

Table 6-1 Alert Messages and Responses

Alert Message	Situation/Action
1 HOUR LIMIT REACHED	**Situation:** The total basal and PCA dose delivered over the past 60 minutes has reached the programmed **1-hour limit**. As a result, the pump will stop the infusion until the total basal and PCA dose volume falls below the 1-hour limit. **Action:** 1. Press Clear/Silence to cancel the alert. 2. If the patient requires an additional drug dosage after the infusion has been interrupted by the 1-hour limit, then: ■ administer a bolus dose (see "Program the Bolus Dose, 5-33") or ■ reprogram an increased 1-hour limit. 3. If the 1-hour limit is reprogrammed, the pump starts a new 1-hour accounting period.

Alert Message	Situation/Action
4 HOUR LIMIT REACHED	**Situation:** The total basal and PCA dose volume has reached the programmed maximum **4-hour limit**. As a result, the pump will stop the infusion until the total basal and PCA dose volume falls below the 4-hour limit. **Action:** 1. Press Clear/Silence to cancel the alert. 2. If the patient requires an additional drug dosage after the infusion has been interrupted by the 4-hour limit, then: ■ administer a bolus dose (see "Program the Bolus Dose, 5-33") or ■ reprogram an increased 4-hour limit. After the 4-hour limit is reprogrammed, the pump starts a new 4-hour accounting period.

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
BATTERY IS MISSING Or BATTERY MISSING	**Situation:** The pump is powered by the AC adapter and no battery is inserted. If another action is occurring at the same time, the pump displays the message BATTERY MISSING on the second line of the screen. **Action:** 1. Follow the directions for replacing the battery under "Installing and Changing the Battery, 3-2".

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
BATTERY VOLTAGE IS LOW	**Situation:** The pump has just completed the power on self-test and the battery power is low. Three short tones are sounded. **Action:** 1. Press Clear/Silence during the alert to silence the audio for 2 minutes, regardless of the Alert Silencing Time configuration setting. 2. Replace the battery as soon as possible as specified in "Installing and Changing the Battery, 3-2".

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
BOLUS DONE	**Situation:** A bolus has completed, the pump is configured for manual start after bolus, and neither the START or the ENTER key has been pressed for 1 minute. **Action:** Press ENTER or START to start the infusion.
CODE INCORRECT	**Situation:** An invalid security code has been entered. **Action:** 1. Enter the correct code.

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
FLUID VOLUME IS LOW	**Situation:** The remaining fluid volume will be delivered within two hours at the current rate of infusion, or the volume remaining is less than 5 mL. **Action:** 1. Prepare to replace the fluid bag if necessary.

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
LOW BATTERY	**Situation:** The battery power is low. A repeating alert tone is sounded. Remaining battery life is approximately 24 hours or less when running the pump at 1 mL/hr. The message is displayed in Run mode on the second line of the screen. **Action:** 1. Press Clear/Silence during the alert to silence the audio for 60 minutes, regardless of the Alert Silencing Time configuration setting. 2. Replace the battery as soon as possible as specified in "Installing and Changing the Battery, 3-2".

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
PCA BUTTON NOT CONNECTED	**Situation:** A PCA button is required to continue the pump's operation. **Action:** 1. Connect the PCA button to the pump. 2. If the pump is configured to use START, you will not receive this message.

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
PUMP LEFT IN PROGRAMMING MODE	**Situation:** The programming mode time period has elapsed. **Action:** 1. Press the ENTER key to cancel the alert and restart the programming mode time period. **Note:** The pump retains all prescription data entered prior to the timeout.

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
PREVENTIVE MAINTENANCE DUE	**Situation:** The configured preventive maintenance period has elapsed. **Action:** 1. Perform the preventive maintenance procedures as described in "Preventive Maintenance, 7-1". **Note:** After its initial occurrence, the PREVENTIVE MAINTENANCE DUE message will appear each time the pump is turned on—until the preventive maintenance is reset.

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
RELEASE THE <key name> KEY	**Situation:** A key on the key pad has been pressed continuously for 3 minutes, or the key is stuck. **Action:** 1. Release the stuck key. 2. If this alert occurs and the key is not being pressed intentionally, there may be a mechanical or electronic fault in the key. Contact your local Baxter authorized service personnel concerning the replacement of the key.

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
RELEASE PCA BUTTON	**Situation:** The PCA button has been pressed continuously for 3 minutes. **Action:** 1. Release the PCA button. 2. Advise the patient to press the PCA button briefly when making a PCA dose request. 3. If this alert occurs and the PCA button is not being pressed intentionally, there may be a mechanical or electronic fault in the PCA button. Contact your local Baxter authorized service personnel concerning the replacement of the PCA button.

Alarms

Each alarm message that could be displayed in the pump's LCD screen is described in this section in alphabetical order with step-by-step procedures for their resolution.

Table 6-1 Alert Messages and Responses — continued

Alert Message	Situation/Action
REPLACE BATTERY	**Situation:** The pump does not sound a tone for this alert. The pump is running on AC and the battery power remaining is too low to power the pump. The message is displayed in Run mode on the second line of the screen. **Action:** 1. Replace the battery as described in "Installing and Changing the Battery, 3-2".

Table 6-2 Alarm Messages and Responses — continued

Alarm Message	Situation/Action
AIR IN TUBING PRESS ENTER ! WARNING ! **The air sensor will detect and measure accumulated amounts of air over an amount of fluid delivered. However, the pump may not detect all instances of micro or "champagne" air bubbles.**	**Situation:** The pump has detected air in the tubing set. The infusion is stopped. **Action:** 1. Press ENTER. The pump will display the START TO PRIME, ENTER TO PROCEED prompt. ! WARNING ! **The tubing set MUST NOT be connected to the patient while priming.** 2. Disconnect, check, and possibly aspirate the tubing set. See "Preparing, Loading, and Changing the Tubing Set and Fluid Bag, 3-15" and "Prime the Pump, 5-23". Press START to begin priming. OR 3. Press ENTER to continue if air does not need to be purged.

Table 6-2 Alarm Messages and Responses

Alarm Message	Situation/Action
AC ADAPTER FAILURE Or AC FAILURE	**Situation:** The AC adapter is not functioning properly. In Run mode, AC FAILURE is displayed in the second line of the screen. If another action is occurring at the same time, the pump displays the message AC FAILURE in the second line of the screen. **Action:** 1. Check the AC adapter connector to make sure it is inserted properly. 2. If the alarm condition persists, replace the AC adapter.

Table 6-2 Alarm Messages and Responses — continued

Alarm Message	Situation/Action
BATTERY IS DEPLETED	**Situation:** The pump is running on battery power and the battery power remaining is too low to continue. **Action:** 1. Replace the dead battery as soon as possible as described in "Installing and Changing the Battery, 3-2". 2. If necessary, connect the pump to the AC adapter (see "Connecting the AC Adapter, 3-7".

Table 6-2 Alarm Messages and Responses — continued

Alarm Message	Situation/Action
CODE INCORRECT	**Situation:** Three invalid security codes have been entered. **Action:** 1. If the pump is configured as KEY+CODE, unlock the cover, lock it again, and enter the security code. 2. If it is configured as CODE ONLY, turn off the pump and turn it on again.
COVER IS UNLOCKED	**Situation:** The cover is unlocked while the pump is active and the pump is configured for KEY+CODE or KEY ONLY. **Action:** 1. Lock the cover, and press the START key to resume the infusion.

Table 6-2 Alarm Messages and Responses — continued

Alarm Message	Situation/Action
DOWNSTREAM OCCLUSION	**Situation:** The pump has detected an occlusion or blockage between the pumping mechanism and the patient that is preventing fluid flow. The infusion stops. **Action:** 1. Check the tubing set for closed clamps and kinks. 2. If no closed clamps or kinks are found, disconnect the patient from the pump before opening the tubing door to check for tubing obstructions. 3. Check the injection site. 4. When the pump detects that the occlusion has been cleared, it will resume operation automatically or press the START key to resume the infusion after the occlusion has been cleared.

Table 6-2 Alarm Messages and Responses — continued

Alarm Message	Situation/Action
EMPTY	**Situation:** The fluid bag is empty. **Action:** 1. Replace the fluid bag with a filled fluid bag. 2. Reprogram the fluid volume and prime as described in "Set the Fluid Volume in the Reservoir, 5-22" and "Prime the Pump, 5-23".

Table 6-2 Alarm Messages and Responses — continued

Alarm Message	Situation/Action
RELEASE PCA BUTTON	**Situation:** The PCA button is being pressed continuously for 6 minutes. **Action:** 1. Release the PCA button. 2. Advise the patient to press the PCA button briefly when making a PCA dose request. If this alarm occurs and the PCA button is not being pressed intentionally, the PCA button may have a mechanical or electronic fault. Contact your local Baxter authorized service personnel concerning the replacement of the button.

Table 6-2 Alarm Messages and Responses — continued

Alarm Message	Situation/Action
SOFTWARE VERSION ERROR-RECONFIG	**Situation:** The software version does not match the pump configuration. **Action:** 1. Turn off the pump, and then turn it on again. 2. Reconfigure the pump as described in the Configuration Manual.

Table 6-2 Alarm Messages and Responses — continued

Alarm Message	Situation/Action
SYSTEM ERROR XX SERVICE PUMP	**Situation:** A system error has been detected by the microprocessor and the pump is inoperable. The two-character code (XX) refers to a specific malfunction. Refer to the Service Manual for further information about this error code. **Action:** 1. Record the alarm code. 2. Turn off the pump, and then restart the pump. 3. If the same code or a new code is displayed after the restart, return the pump for service. 4. If no system error code is displayed, continue to use the pump.

Table 6-2 Alarm Messages and Responses — continued

Alarm Message	Situation/Action
UPSTREAM OCCLUSION	**Situation:** The pump has detected an occlusion or blockage between the fluid bag and the pumping mechanism that is preventing fluid flow. The infusion stops. **Action:** **! WARNING !** **If the pump detects an upstream occlusion, the clinician must identify the source and relieve the occlusion without turning off the pump. If the occlusion is not relieved and the pump is turned off, the pump may not detect the existing occlusion when the pump is turned back on.** 1. Open the cover and check the tubing and bag for closed clamps and kinks. 2. If no closed clamps or kinks are found, disconnect the patient from the pump before opening the tubing door to check for tubing obstructions. 3. After clearing the occlusion, press START to resume the infusion.

Chapter 7. Preventive Maintenance

Baxter recommends performing preventive maintenance every six months and cleaning after every use. If the device cannot be cleaned using the methods described previously or components are missing or damaged, discontinue use and notify the appropriate authorized service personnel.

Authorized Service Center

To contact Baxter for authorized service or repair, call the Andover Service Center at 1-800-343-0366, extension 1.

Cleaning the Pump

The pump must be cleaned by using one of the recommended cleaners listed in the following table.

Note: Some of the listed cleaners may not be available at your location. Use any of the available listed cleaners.

Table 7-1 Recommended Cleaners

Recommended Cleaner	Manufacturer
Soapy water	n/a
A solution of 10% bleach and water	n/a
LpH®	Vestal Labs
Septisol	Vestal Labs
Cidex 7®	Surgikos
Super Edisonite	Edison Chemical

Table 7-1 Recommended Cleaners — continued

Recommended Cleaner	Manufacturer
TOR® or Hi-Tor® Plus	Huntington Labs
Bafix®	Hysan Corporation

As you clean the pump, be careful that you:

- Do not spray the cleaner directly into the pumping mechanism or the area where the AC adapter enters the device.
- Do not use hard instruments for cleaning. Follow manufacturer's dilution instructions for concentrated cleaners.

Always clean/disinfect the device after each use as follows:

Type of use	Action
If the device has been in an Isolation Area	select those agents from the list that both clean and disinfect.
If the device has been used	clean/disinfect the pump with an agent from the recommended list of cleaners before use on another patient.
If spills occur or the unit is dirty	clean the pump as quickly as possible.

Caution The Ipump™ Pain Management System is not waterproof and should not be immersed. Avoid getting liquids inside the pump. Air sensor functioning could be compromised or permanent damage may result. Do not use alcohol for cleaning.

Caution Do not clean, disinfect, or sterilize any part of the device by autoclaving or with ethylene oxide gas. Doing so may damage the device and void the warranty. Only external parts of the device should be disinfected.

Fluid Spillage

The product design safeguards against fluid spillage into the pump module. However, if fluid enters the tubing channel, contact your local Baxter Service Center.

This should be done immediately to minimize any potential difficulties with the solutions pooling and drying on the mechanism.

Caution The Ipump™ Pain Management System is not waterproof and should not be immersed. Avoid getting liquids inside the pump. Air sensor functioning could be compromised or permanent damage may result. Do not use alcohol for cleaning.

Preventive Maintenance Checklist

The following Preventive Maintenance Checklist contains a schedule of basic maintenance tasks that should be performed on the device.

Cleaning and Inspection	
Perform as required, but recommended after every use. **Note:** Cleaning must be performed by using one of the recommended cleaners listed in Table 7-1, "Recommended Cleaners, 7-2".	
Check	Action
Housings	Clean housing and front panel as recommended in the cleaning instructions in this section. Check for cracks or large dents.
Labels	Clean as recommended in the cleaning instructions. Check for scratches, cuts, or obliterated words.
AC adapter	Verify that the optional AC adapter is undamaged over the entire length of the cord and the molded plugs.

Cleaning and Inspection	
Cover	Clean as recommended in "Cleaning the Pump, 7-2". Ensure that the cover is intact, fits properly when closed and locked, and has no obvious cracks or fractures.
Pole clamp	Operates freely throughout range of motion. Check that the pump stays on IV pole.
Functional Testing	
Perform as required, but recommended every 6 months.	
Check	Action
Entire device	Schedule functional test by qualified biomedical personnel or authorized service personnel as specified in the Service Manual.

Transporting and Storing the Pump

When unpacked, store the pump in a clean and dry environment without the battery to safeguard against prolonged exposure to dust and moisture. This storage area should meet the following environmental guidelines:

- Ambient temperature: 50°F to 104°F
- Relative humidity: 30% to 75% (non-condensing)

If conditions fall outside these limits, Baxter recommends that the device be repackaged in the original shipping materials. When storing the pump for long periods of time, such as longer than seven days, remove the 9-volt battery from the pump.

Repair and Troubleshooting

The pump must be serviced only by authorized personnel who have completed the manufacturer's technical training program. Service documentation, including circuit diagrams, is available to approved service organizations upon request. Alternatively, the pump should be returned to Baxter for service.

While under Baxter's warranty, Service Agreement (optional), or lease agreement, the pump must not be opened by unauthorized personnel. Use an authorized Baxter service provider for service and repair. For service and repair information for this product, contact your local Baxter Service Center.

Shipping costs for all units returned to Baxter shall be paid for by the customer. The unit must be packed in its original container or in another Baxter-approved container that will provide adequate protection during shipment. To ensure prompt return, a Baxter authorized service representative must be notified before shipping any unit for repair. When calling for service, please be prepared to provide the code number and serial number of the unit. A brief written description of the problem should be attached to the pump when it is returned for service.

Baxter will not be responsible for unauthorized returns or for units damaged in shipment due to improper packaging.

Chapter 8. Accessories and Recommended Sets

Component	Description	Product Number
Bags	100 mL bag	2L3256
	250 mL bag	2L3257
	Empty IntraVia® Container with PVC Ports 50mL 150mL 250mL 500mL	 2B8019 2B8011 2B8012 2B8013
Administration Sets **Note:** Sets' maximum pressure is 2326 mmHg.	7.9" Anti-Reflux Y-Set	2L3506
	72" Anti-Siphon Pump Set	2L3510

Component	Description	Product Number
Administration Sets, continued **Note:** Sets' maximum pressure is 2326 mmHg.	101" Anti–Siphon Pump Set	2L3511
	101" Epidural Pump Set	2L3512
	108" Air Eliminating Spike Set	2L3513
	108" Air Eliminating Anti-Siphon Set	2L3520
	117" Epidural Spike Set for 500 mL Bag Cover	2L3522
	122" Air Eliminating Spike Set for 500 mL Bag Cover	2L3523
Printer Accessories	Printer Adapter	2L3400
	Printer Adapter Cable	2L3402
Miscellaneous Options	Patient Controlled Analgesia Button	6465388

Component	Description	Product Number
Miscellaneous Options, continued	Locking Pole Mount Clamp	2L3211
	Non-locking Pole Mount Clamp	2L3212
	Pump Carrying Case (250 mL)	2L3219
	AC Adapter (100–120V)	2L3210
	Configuration Transfer Cable	2L3112
Covers	100 mL Cover	2L3218
	250 mL Cover	2L3220
	250E mL Cover	2L3217
	500 mL Cover	2L3221

Chapter 9. Technical Specifications

Component	Description
AC Power Requirements (when used with optional AC adapter)	100 to 120 VAC 50/60 Hz or 220 to 240 VAC 50/60 Hz, 700mA
DC Power Requirements	9V alkaline battery Typical operating time when operating at an intermediate rate of 1 mL/hr is approximately 140 hours.
Leakage Current	Less than 300 μA earth leakage (tested per UL 2601-1)
AC Adapter Cord (120 V)	Approximately 5.9 feet long
Range of Programmable Flow Rates	0.1 to 90.0 mL/hr in 0.1-mL/hr increments
Maximum Infusion Under Single Fault Conditions	0.5 mL

Component	Description
Operational Features	PCA Dose Volume Selections: 0.0 to 9.9 mL Bolus Volume Selections: 0.0 to 9.9 mL Reservoir Volume Selections: 1 to 1999 mL One-hour Limit Selections: 0.1 to 60.0 mL/hr Delay Time Selections: 1 to 240 minutes History/Prescription Recall
Security Features	Locking cover 3-digit programmable security code Latched tubing door
Indicators	Alphanumeric description via LCD display Red Alert light Green Infusing light Audible tones
Battery	9-volt alkaline

Component	Description
Drive Mechanism	DC Motor, microprocessor-controlled, precision linear peristaltic pumping mechanism
Printer Port	1200 Baud, 8 data bits, no parity and 1stop bit
Housing	Shock- and vibration-resistant ABS
Size	4.9" x 3.4" x 1.8" without cover
Weight	17.5 ounces (with 250E mL bag cover and without a battery)
Environmental Operating Limits	Temperature: 50°F to 104°F Humidity: 30% to 75% relative humidity, non-condensing Barometric Pressure: 700 to 1060 hPa

Component	Description
Environmental Storage and Transport Limits (packaged)	Temperature: -4°F to 140°F Humidity: 20% to 95% relative humidity (non-condensing, unpackaged) Barometric Pressure: 500 to 1060 hPa
Options and Accessories	100 and 250 mL Bags Empty 50 mL, 150 mL, 250 mL, 500 mL IntraVia® Containers with PVC Ports 7.9" Anti-Reflux Y–Set 72" Anti–Siphon Pump Set 101" Anti–Siphon Pump Set 101" Epidural Pump Set 108" Air Eliminating Spike Set 108" Air Eliminating Anti–Siphon Set 117" Epidural Spike Set for 500 mL Bag Cover 122" Air Eliminating Spike Set for 500 mL Bag Cover Printer Adapter Printer Adapter Cable Patient Controlled Analgesia Button

Component	Description
Options and Accessories, continued	Locking Pole Mount Clamp Non-locking Pole Mount Clamp AC Adapter (100-120V) Pump Carrying Case Configuration Transfer Cable 100, 250, 250E, and 500 mL Covers

Flow Rate Accuracy of the System

The Ipump™ Pain Management System, using the appropriate Baxter® administration sets as identified in Chapter 8, maintains flow rate accuracy with delivery errors not exceeding ±8% for available flow rates.

Note that flow fluctuations can be caused by unusual conditions or combinations of conditions that may involve, but are not limited to, the following: fluid density, positive and negative pressure and the environment. Flow fluctuations are most likely to occur when the conditions mentioned above are exacerbated or when the device is operated in conditions outside of its normal limits. See "Environmental Operating Limits", 9-4. The accuracy figures as stated are based upon operation at a room temperature of 72°F (22°C).

Recommended Practices

Connections of this pump to the same patient line with other infusion systems or accessories may alter the performance of the pump. Consult the manufacturer's instructions for use of the systems or accessories before proceeding.

To ensure that pump performance is maintained, annual inspections should be performed by authorized service personnel in accordance with the Joint Commission on Accreditation of Healthcare Organizations procedure. Service personnel should refer to the Ipump™ Pain Management System Service Manual for information on procedures.

Startup Graph Description

The Startup Graph was developed in accordance with IEC60601-2-24. The Startup data shown in the graph illustrates the startup performance of the Ipump™ Pain Management System during the first 24 hours of operation with a sampling period of 15 minutes.

A Startup Graph of flow versus time (Figure 9-1) illustrates initial stability with time. Even with proper components and set up, the flow of any manufacturer's pump may be erratic during the initial startup period. Therefore, we have included the startup, or stabilization data. It should be noted that as the time interval over which accuracy is measured is lengthened, all pumps show considerable improvement in flow accuracy

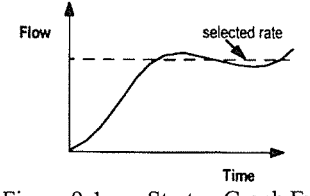


Figure 9-1 Startup Graph Example

How Trumpet Graphs are Interpreted

The Trumpet Curve graph (Figure 9-2) provides a graphical view of the maximum deviation in flow rate from the programmed delivery rate for specific segments of delivery time. The horizontal axis does **not** represent elapsed delivery time, but rather acts as a graphical reference for selecting specific observation time intervals. The widest area of the trumpet curve (greatest deviation) reflects the smallest sampling intervals or observation windows. As the sizes of the sampling intervals increase (in minutes), the deviations in flow from the programmed delivery rate are reduced as the deviations are spread out over the longer periods of time. This results in the narrowing of the trumpet curve giving a more realistic representation of the device's average flow rate accuracy over longer intervals of time.

For example, if you were to look at the maximum and minimum percentage error points corresponding to the 60-minute interval point on the Observation Interval axis, you would be looking at the average flow variance for any 60-minute period throughout the infusion.

How Trumpet Graphs are Created

The Trumpet Curve graphs were developed in accordance with data collection and manipulation methods defined in IEC60601-2-24.

The Trumpet Curve graphs were created in the following manner.

- Fluid from the device is collected at the set flow rates over 25 hours.
- Every 15 minutes, the cumulative weight of the fluid is recorded.
- The data from the collection period are divided into observation or time windows and the flow rate accuracy is determined for each window.
- The maximum and minimum deviations from the set flow rate for various window sizes (15, 60, 150, 330, 570, and 930 minutes) are plotted on a graph.
- These plotted points are connected to form the trumpet-shaped lines.

How Trumpet Graphs Can be Used

Trumpet Curve graphs can be important sources of information for the medical professional who must decide whether a certain infusion pump can be used with a particular medication. For example, when delivering a medication with a short half-life, very small deviations in flow over the course of an infusion would be desirable to ensure that the deviations in plasma level also remained small. The device's ability to deliver very closely to the programmed rate would ensure that the medication's efficacy was being maintained. In this example, the medical professional would be wise to select a device whose trumpet curve indicated a small or narrow range of deviations in flow rate.

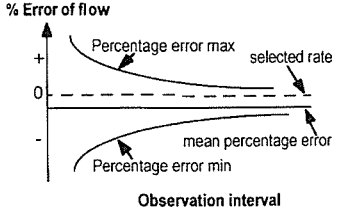
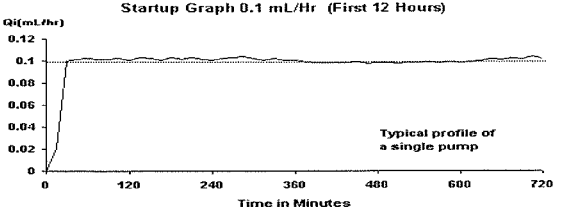
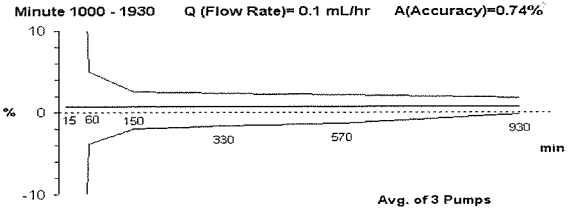


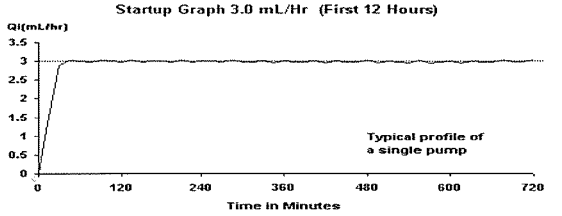
Figure 9-2 Trumpet Graph Example

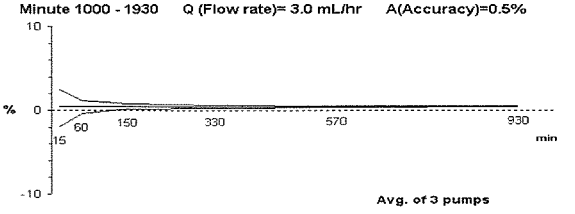
Startup and Trumpet Graphs at 0.1 mL/hr





Startup and Trumpet Graphs at 0.3 mL/hr





List of Materials

Type	Tradename/Description
ABS	Cycolac
PC	Lexan
ACETAL/PTFE	Thermocomp
Polyester	Mylar
Nylon	Zytel

Type	Tradename/Description
Buna-N	Synthetic rubber
Brass	Nickel plated
Zinc	Die cast
Aluminum	n/a
Stainless steel	n/a

Glossary.

AC

Alternating Current

alarm

An event, marked by a flashing Alert LED, repeating alert tone, and specific display message that signals a condition requiring a response by the operator and stops any motor movement (see also: system alarm).

alarm log

A record of pump system alarms by date and time, maintained in non-volatile memory even though the power is turned off.

alert

An event, marked by a flashing Alert LED, repeating alert tone, and specific message (unless otherwise indicated), that provides important status information or signals a condition requiring a response by the operator.

attempt

The patient action (either the depression of the PCA button or START button) intended to initiate a PCA dose.

basal rate

The programmed continuous infusion rate when the pump is operating in BASAL+PCA mode.

bolus

The programmed quantity of drug either delivered automatically at the start of therapy, or initiated by the clinician during the course of therapy.

concentration

The programmed amount of drug in milligrams or micrograms per milliliter of fluid.

configuration group

A collection of functionally related configuration settings contained in the configuration record.

configuration record

A data block, maintained in nonvolatile memory, that consists of settings that enable, disable, control, or limit specific pump features and functions. The configuration record can be modified by the operator in a special mode accessible by a security code.

continuous rate

The programmed continuous infusion rate when the pump is operating in CONT mode.

critical data

Data that are critical to the operation of the pump, including prescription, configuration, and historical data.

delay

The programmed time interval that must elapse between the start of therapy and the initial PCA dose or between the start (of delivery) of one PCA dose and the start of the next PCA dose.

Doses per Hour Limit

The programmed maximum number of PCA doses that may be delivered in a one-hour period.

event log

A record of significant operator actions that occur during a single therapy, and related data; each action entry is date- and time-stamped, and the event log is maintained in non-volatile memory.

fluid volume

Programmed initial amount of fluid in the reservoir.

Four Hour Limit

The programmed maximum volume of a drug that may be delivered in a four-hour period.

Ipump™ Device or System

Ipump™ Pain Management System

initial bolus

The bolus dose delivered automatically at the start of therapy.

INJ/ATT shift total

The total number of injections and attempts since the start of therapy or since the operator last cleared the total for the current shift.

LCD

Liquid Crystal Display

LED

Light Emitting Diode

mg

Milligram

mL

Milliliter

One Hour Limit

The programmed maximum volume of drug that may be delivered in a one-hour period.

operator, user

A professional healthcare person (clinician or biomedical engineer).

PCA

Patient Controlled Analgesia

PCA dose

The programmed volume of drug to be injected when requested by the patient.

Prescription Rx

The complete set of program data including infusion mode, units, and, where applicable, concentration, PCA dose size, delay, dose limit, infusion rate and bolus size.

run time

The mode of operation of the pump other than System Configuration. Run time includes the programming mode, history review and printout, and run mode (infusion).

shift total

The calculated volume of fluid given since the start of therapy or since the operator last cleared the shift total.

system alarm

An event, marked by a flashing Alert LED, system alarm tone, and error message, generated by the pump in response to an unrecoverable system failure.

volume remaining

The calculated amount of fluid left in the reservoir.

therapy

A course of treatment using a programmed prescription and initiated by a START key press, during which a patient may receive one or more bolus doses, one or more PCA doses, and/or a continuous infusion.

therapy history

A collection of data, maintained in nonvolatile memory, that relates to the most recent or current therapy, consisting of the prescription data, current alarm status, and infusion totals (hourly, by shift, and for the entire therapy).

total given

The calculated volume of fluid given since the start of therapy.

µg

Microgram

Index.

Numerics

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