AP II
INFUSION PUMP
OPERATOR'S
MANUAL

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

NOTE: An issue date for these instructions is included on the title page for the user's information. In the event 2 years has elapsed between this date and product use, the user should contact Baxter Healthcare Corporation at 800-343-0366 to see if additional information is available.

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Issue Date: 12/94

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INTRODUCTION

The AP II Pump is an advanced pain management product designed to help patients become ambulatory as soon as possible. It is lightweight, compact and battery operated for portability. A specially designed optional pole-mounting clamp allows the Pump to be unlocked and easily removed for placement in a comfortable carrying case. The AP II Pump can also be connected to AC power for stationary use.

This operator's manual has been organized for easy reference with tab dividers for quick identification of the most-used sections. In addition, we have included a separate small-sized programming guide for your convenience.

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Anesthesia Division

Baxter

1. DESCRIPTION OF AP II PUMP

Typical use

The AP II Pump is indicated for epidural, subcutaneous or intravenous delivery of parenteral fluids.

Ambulatory use with carrying case or pole mount

The AP II Pump is a small, lightweight linear peristaltic pump that may be operated by battery or AC power. Specifically designed to allow patient ambulation, it comes complete with a convenient carrying case for enhanced patient comfort. The Pump can also be easily attached to a standard IV pole using the optional pole mounting clamp.

Customized configuration

The Pump is capable of continuous infusions and patient-requested dosing, with or without a basal rate. The health care professional can program the Pump with physician prescribed values for the therapy desired. The Pump can also be configured with clinician or institution-selected operating limits.

Microprocessor controlled

The AP II Pump utilizes a DC motor, linear peristaltic pumping head and custom tubing set. Motor speed, indicators, alarms and prescription entry are controlled by a microprocessor.

Control panel

The control panel consists of a liquid crystal display (LCD), red and green status lights, and a nine-function keypad. The keypad contains the following keys: ON/OFF, START, STOP, ENTER, CLEAR/SILENCE, HISTORY, two cursor control keys and one scroll key.

Security

A key is required to unlock the Pump's fluid bag cover and to change the prescription, providing appropriate drug security and device accessibility. An operator-defined security code prevents unauthorized prescription changes.

Record management

The Pump has a real-time clock that provides the correct date and time for record management. Date/time is displayed on screen and, when using the optional printer adapter, on the hard copy printout.

Power source

The AP II Pump is powered by either a 9-volt alkaline battery or its AC adapter. When no power source is available, programming, time and history will be retained by the microprocessor's back-up power source.

2. PRECAUTIONS

WARNING: Do not use in the presence of flammable anesthetics.

WARNING: To reduce the risk of stored fluid being infused after an occlusion occurs, the pressure must be relieved prior to freeing the occlusion. Do this by disconnecting the system above the occlusion.

WARNING: Failure to latch the tubing cover door properly and completely may result in uncontrolled flow of administered fluids and subsequent patient overdose.

WARNING: Patient MUST NOT be connected while priming the pump tubing set.

WARNING: Do not use any Pump which 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 cover door or trouble-shooting any Pump connected to a patient.

WARNING: Tubing pinched by a closed fluid bag cover may prevent fluid delivery to the patient.

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

CAUTION: Use only under the direction of a qualified physician.

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

CAUTION: There are no internal user serviceable parts or adjustments.

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.

CAUTION: Only use sets manufactured by Baxter for the AP II Pump (see Section 4).

CAUTION: To stop Pump operation, press the STOP key twice within one second. To turn the Pump OFF, unlock the bag cover and press the ON/OFF key twice within one second (the prescription data will be moved from the programming, and patient history will be retained for review).

CAUTION: Use grounded AC outlets only.

CAUTION: Do not use with medications that are incompatible with silicone or PVC or are unstable under infusion conditions.

CAUTION: Do not use sharp objects to actuate keys.

CAUTION: Improper battery orientation may result in Pump damage.

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

CAUTION: The AP II Pump and AC adapter is not waterproof and should not be immersed. Avoid getting liquids inside the Pump or permanent damage may result. Do not use alcohol for cleaning. Sterilization via ETO, steam, etc. should not be attempted.

CAUTION: This Pump is configurable. Operating modes and input parameter selections may vary as a function of the configuration selected. See Configuration Manual for more information on configuration.

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

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

CAUTION: To prevent infusion of drugs that are not indicated for epidural use, do not use administration sets that incorporate injection sites.

CAUTION: It is strongly recommended that the Pumps used for epidural drug delivery be clearly differentiated from Pumps used for other routes of administration.

PRODUCT TRACKING

This Pump Is Subject To Tracking

Pursuant to Title 21 of the U.S. Code of Federal Regulations, Part 821, "Medical Device Tracking Requirements," customers within the United States have certain obligations in furthering the tracking of infusion pumps.

You should verify equipment serial numbers against those listed on the packing slip. If correct, indicate this on the packing slip by signing and dating the slip. Should any of the information be incorrect, please contact us at 1-800-THE-PUMP. To facilitate future communications, in addition to your signature, please print your name, title and telephone number on the packing slip. Return a copy of the packing slip to Baxter Healthcare, I.V. Systems Division.

Any format of verification that provides the required level of information is acceptable.

Infusion pump tracking within the hospital (or other types of user facilities) is not required. Please refer to the rule for further information. However, should you allocate any of your facility's infusion pumps for home patient use, you have additional tracking requirements. You must maintain a current patient and physician registry, by serial number, in a format that can be provided to the manufacturer within 5 working days. Should you sell a pump to a patient, you must promptly provide us with the patient and physician information.

The final rule on device tracking clarifies the responsibility of hospitals and other user facilities within the United States. The following fact sheet summarizes these requirements. We would recommend that you develop written procedures that outline your operation's device tracking compliance plan.

Pump Medical Device Tracking Fact Sheet

1. Scope

   Per 21 CFR Part 821, infusion pumps have been categorized by the FDA as devices which must be tracked. If used within a device user facility, tracking **to the user facility** is required. If the infusion pump is used outside a device user facility, tracking within the user facility is not required. The distributor who provides the device to a patient must keep records of the pump's location and subsequently report this information to the manufacturer.

2. Effective Date

   August 29, 1993

3. Definitions

User Facility	Hospital, Nursing Home, Ambulatory Surgical Facility, or Diagnostic Facility
Distributor	Any entity who furthers the distribution of a device from the original place of manufacturer to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does not repackage or otherwise change the container, wrapper or labeling of the device or device package.
Final Distributor	Any entity who distributes a tracked device intended for use by a SINGLE patient over the useful life of the device.
Multiple Distributor	Any entity who distributes a tracked device intended for use by MORE THAN ONE patient over the useful life of the device.

4. Distributors (consignees) are required to **REPORT TO THE MANUFACTURER** the purchase, receipt in trade, return of sale, loss, destruction or retirement of any tracked medical device.

   Required Information:
   - Name and address of the distributor (consignee)
   - Model and serial or lot number of the device
   - Date the device was received
   - From whom the device was received
   - Date of permanent distribution, i.e., loss, destruction, retirement

5. Upon **DISTRIBUTION OF A TRACKED DEVICE FOR USE IN OR BY THE HOME PATIENT**, the following record must be maintained by the distributor (final or multiple distributor who places the device in the home environment) for the useful life of the tracked device. Note useful life is defined as the time a device is in use or in distribution channels for use.

   Required Information:
   - Model and serial or lot number of the device
   - Patient's name, address and telephone
   - Date the device was provided to the patient
   - Prescribing physician's name, address and telephone
   - Attending physician's name, address and telephone

6. Reporting Requirements

   The following information must be reported:

DATA	TIME FRAME ALLOWED TO OBTAIN INFORMATION
Manufacturer's distribution/ inventory records	3 working days
Final distributor's patient and physician records	Reported to the manufacturer promptly following distribution to the patient
Multiple distributor's patient and physician records	Upon request, reported to the manufacturer within 5 working days
Manufacturer's patient records	**A** 10 working days (for multiple patient use devices such as Infusion Pumps) i.e., multiple distributor's registries **B** Promptly for single patient use devices

7. Audit Requirements

   In addition, a statistically revelant sample of the manufacturer's consignees must be audited every 6 months for the first three years, then annually, to ensure compliance with tracking regulations. Customers who are not complying with this regulation must be reported to the FDA.

BAXTER HEALTHCARE CORPORATION LIMITED WARRANTY

Baxter Healthcare Corporation warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of 1 year from the date of its shipment from Baxter Healthcare Corporation to the original purchaser. If this product proves to be defective, purchaser may return same to Baxter Healthcare Corporation for repair or replacement at Baxter Healthcare Corporation's option. All returns must be authorized in advance in accordance with Baxter Healthcare Corporation's Returned Goods Policy found in its then current price list. The liability of Baxter Healthcare Corporation under this limited product warranty does not extend to any misuse or abuse of this product or its repair by anyone other than an authorized Baxter Healthcare Corporation representative.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, SUITABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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

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3. SETTING UP THE AP II PUMP

3.1 Unpacking the AP II Pump

In addition to the pump, your AP II Pump box should contain the following:

AC Adapter
250E Fluid Bag Cover
Patient Control Button
Pump Carrying Case
Operator's Manual
Configuration Manual
Quick Programming Guide

AC Adapter

250E Fluid Bag Cover

Patient Control Button
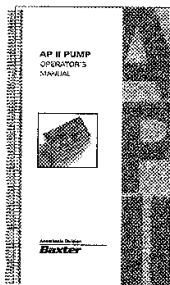
Operator's Manual
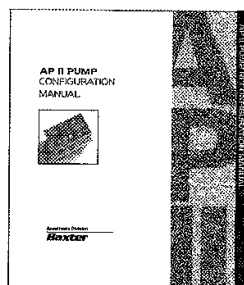
Configuration Manual
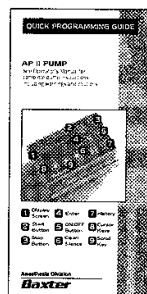
Quick Programming Guide

Pump Carrying Case

3.2 Installing the 9-Volt Alkaline Battery

NOTE: Do not use zinc-air or ni-cad batteries with the AP II Pump.

A. To open the battery compartment, slide the battery door in the direction of the arrow and lift door by pulling up at the opening in back of arrow.
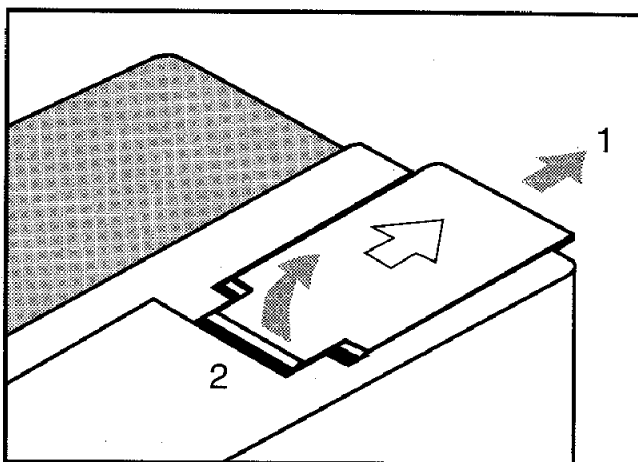
B. Observing battery polarity, insert battery into compartment and return battery door to original position.
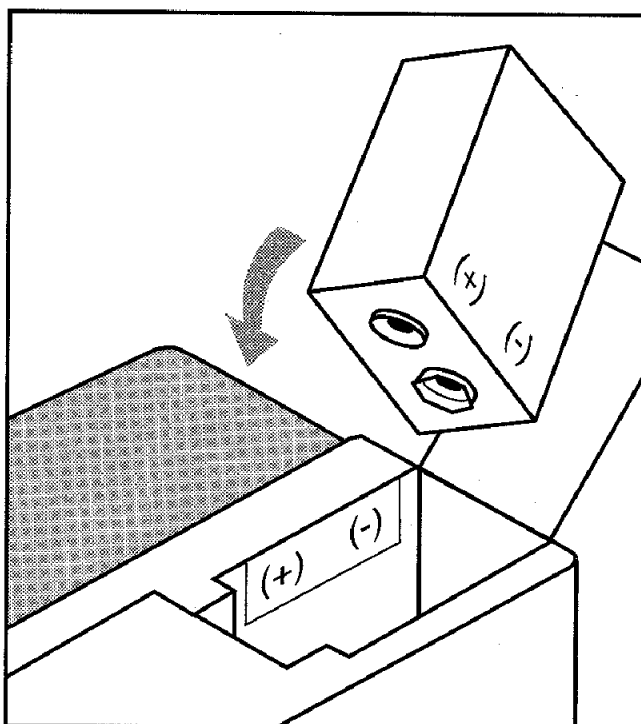
CAUTION: Improper battery orientation may result in pump damage.

3.3 Attaching the AC Adapter

Use the AC adapter to operate the Pump with AC power. Insert the connector of the adapter into the receptacle on the bottom panel of the pump being certain to line up the red dots. A 9-volt alkaline battery should be installed as a backup power source in the event of AC power interruption and for patient ambulation.

3.4 Loading the Pump Tubing Set

CAUTION: Only use sets manufactured by Baxter for the AP II Pump. (See Section 4)

A. Turn Pump over so keyboard is face down. If the fluid bag cover is locked, push in and rotate key one-quarter turn counterclockwise as shown.

NOTE: The key will be retained in the lock whenever bag cover is unlocked. To remove key, close and lock bag cover.
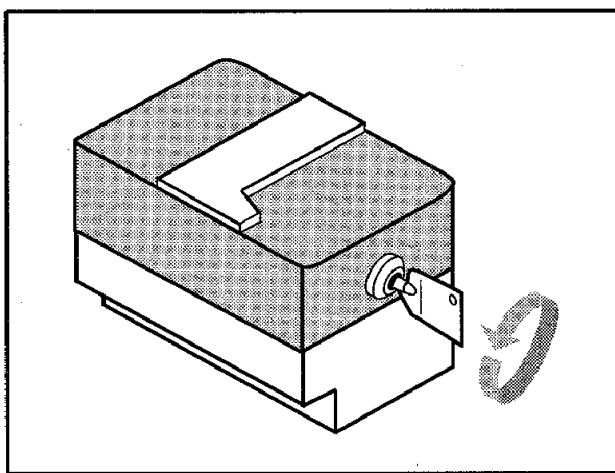
B. Open fluid bag cover.
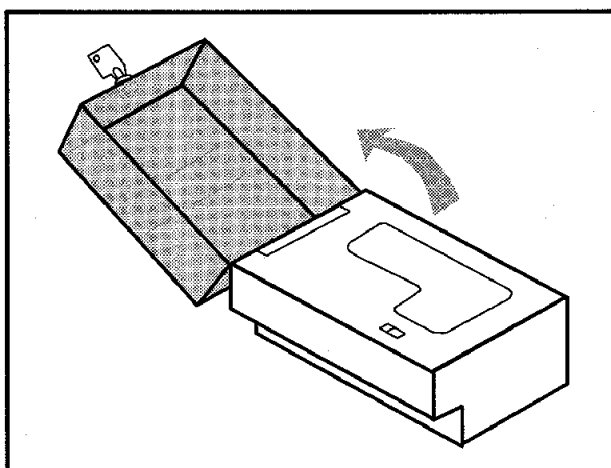
C. Open tubing cover door by moving the latch away from the hinge and pulling down on the door as shown below.
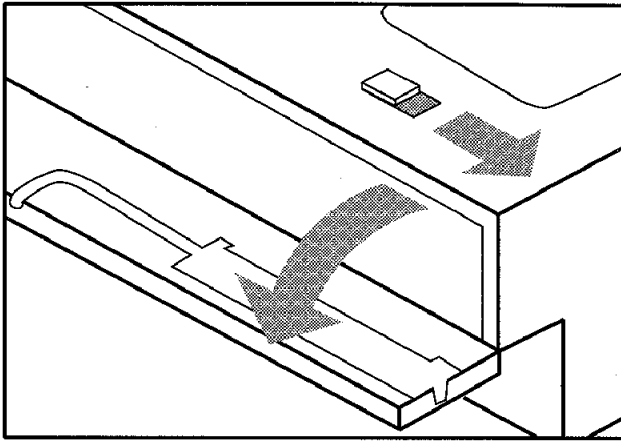
D. Load the tubing set into the groove in the tubing cover door as shown. The longer segment of the tubing set must exit to the side of the Pump and the shorter segment must exit to the back of the Pump for attachment to the bag.
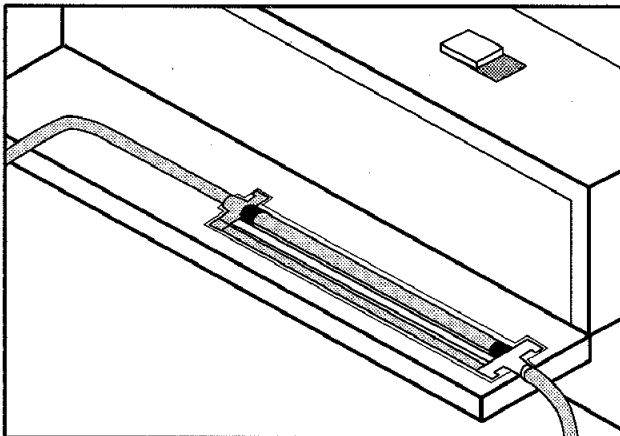
E. Close and latch the tubing cover door by moving the latch away from the hinge and returning the tubing cover door to the closed position. Be sure latch returns to original position. To avoid pinching the tubing, be careful not to let the tubing fall out of its groove when closing the tubing cover door.

NOTE: Failure to latch tubing cover door will prevent the closure of the bag cover.

WARNING: Failure to latch the tubing cover door properly and completely may result in uncontrolled flow of administered fluids and subsequent patient overdose.

3.5 Preparing the Fluid Bag and Tubing Set

NOTE: Use aseptic technique in the following procedures.

NOTE: The AP II Pump may be used with two types of fluid bags:

- Baxter 100 mL or 250 mL bags
- Viaflex® container or similar pre-filled diluent bag up to 250 mL

Be certain to follow directions for the fluid bag you are using.

Directions for 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.

A. Open the package and carefully remove the bag.

B. A nonvented cap is supplied in its own package. It must not be confused with the cap attached to the outlet tubing, since that cap is not airtight and will not prevent fluid leakage.

C. Fill a sterile syringe with the solution to be placed in the bag.

D. Remove and discard the cap from the outlet tubing of the bag.

E. Connect the syringe to female luer-lock fitting on the bag's outlet tubing (do not use a needle).

F. Inject the solution into the bag. Refill the syringe and repeat the process if necessary. The bag will hold approximately 100 mL or 250 mL depending on the bag selected.

G. Remove all air from the bag by aspirating with the syringe. Remove the syringe when completed.

H. If the bag is to be stored for later use, connect the nonvented cap to the bag after bag is filled.

I. For immediate use of the bag, do not use the non-vented 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.

J. Force the air from the remainder of the tubing set by following the priming procedure in Section 6.10.

WARNING: Patient must not be connected while priming the pump tubing set.

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

Directions for Viaflex® or Similiar Fluid Bags

NOTE: Please follow any directions provided by the manufacturer of the fluid bag to be used.

A. Open the package and carefully remove the bag.

B. Add any additional drug to the bag using an appropriate syringe and needle for the injection port of the bag.

C. Remove all air from the bag by aspirating with the syringe. Remove the syringe when completed.

D. Insert the tubing set spike into the outlet port of the bag.

E. Force the air from the remainder of the tubing set by following the priming procedure in Section 6.10.

WARNING: Patient must not be connected while priming the pump tubing set.

F. Connect the distal end (longer segment of the pump tubing) to patient access making certain that the luer-lock connection is properly tightened.

3.6 Installing the Fluid Bag

A. After connecting the bag to the pump tubing, place the bag in the bag cover. Verify that the tubing cover door is properly closed and latched. Close the bag cover taking care not to pinch the pump tubing.

WARNING: Tubing pinched by a closed bag cover may prevent fluid delivery to the patient.

B. Lock the bag cover. If the bag cover cannot be closed and locked, check the tubing cover door for complete closure.

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3.7 Attaching the Pump to a Pole (Optional)

A. Align the pole mounting clamp below the slide bracket on the back of the Pump. Slide the clamp toward the top of the Pump until it stops. The two holes on the clamp should align with the two smaller holes on the bracket.
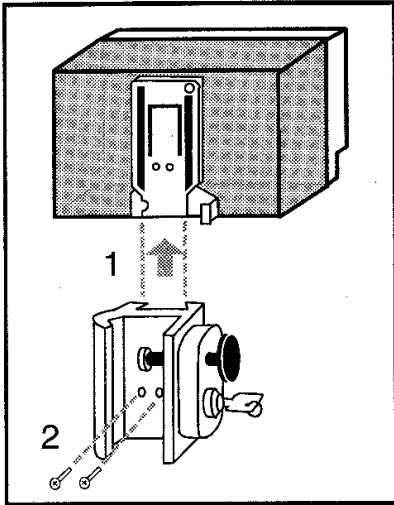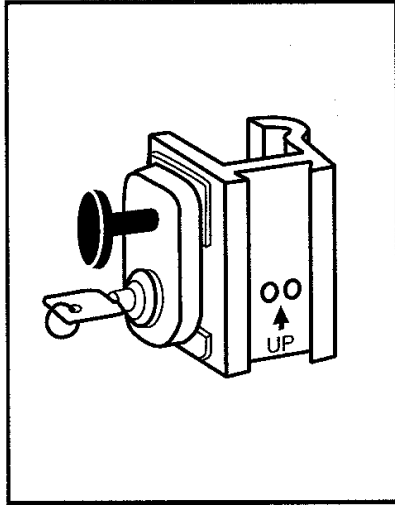
Slide Bracket   Pole Mounting Clamp

To keep the clamp attached to the Pump, insert the two enclosed screws through the clamp and into the holes in the bracket.

The pole mounting clamp can easily be attached or removed from the pole. Unlock the clamp by inserting the pole-mounting clamp key into the lock on the housing, push key in and rotate it counterclockwise to the unlocked position. In this position (if the Pump has not been secured to the clamp), the Pump may be removed from the clamp by pulling it upwards and the clamp may be loosened and pulled up and off of the pole.
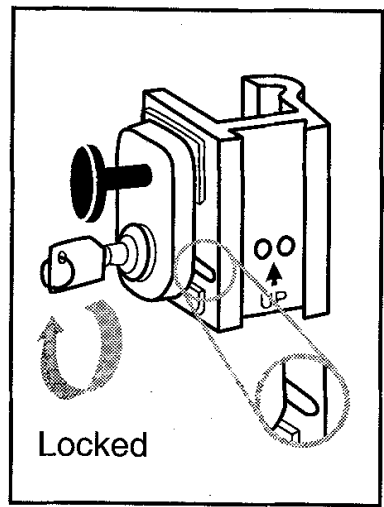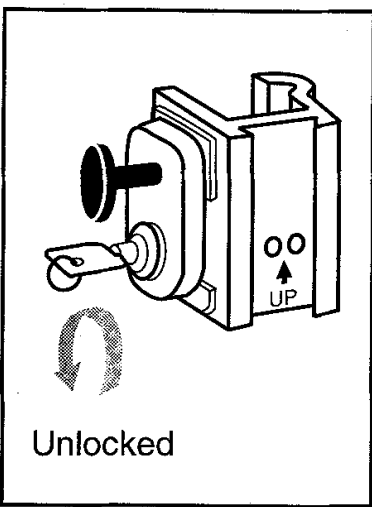
Unlocked

Locked

Mount the clamp to a pole or rail (0.5" to 1.25" diameter) and tighten it. If the clamp is detached from the Pump, make certain the arrow on the clamp is pointing up.

Lock the clamp by inserting the key, pushing in and rotating clockwise to the locked position. The clamp may be tightened when it is locked, but it cannot be loosened enough to remove it.

NOTE: The Pump must be in the clamp before locking the clamp. Failure to do so allows removal of the Pump without the use of a key.

3.8 Installing the PCA Cord for Patient Control

A. When the AP II Pump is programmed to operate in the PCA or BASAL + PCA mode, the PCA cord must be attached to allow patient requests.

NOTE: If a 0.0 mL PCA dose is programmed in the BASAL + PCA mode, the PCA cord does not need to be attached.

B. Insert the connector of the PCA cord into the labelled jack on the bottom panel of the Pump.

C. Failure to connect the PCA cord will result in an alarm message "PCA CONNECTOR NOT INSERTED," when the infusion is started.

4. FACTORY DEFAULT SPECIFICATIONS OF THE AP II PUMP

NOTE: The AP II Pump can be configured for specific modes, units, and prescription limits. The Pump as delivered from the manufacturer, is capable of operating within the following factory-default specifications. Please refer to the Configuration Manual for available configuration options.

Modes of Operation
- PCA, BASAL + PCA, and CONTINUOUS

Flow Rate Accuracy
- ± 10%

Flow Rates
- Basal Rate: 0.1 - 9.9 mL/hr
- Continuous Rate: 0.1 - 19.9 mL/hr
- PCA Dose, Bolus, and Priming Rate: 90 mL/hr

Occlusion Detection
- 22 ± 10 psi measured immediately distal of the pumping mechanism

Operational Features
- PCA Dose Volume Selections: 0.0 - 9.9 mL
- Bolus Volume Selections: 0.0 - 9.9 mL
- Reservoir Volume Selections: 1 - 1999 mL
- One-Hour Limit Selections: 0.1 - 60.0 mL/hr
- Delay Time Selections: 3 - 240 minutes
- History/Prescription Recall

Front Panel Controls
- Back-lighted dot matrix, 16 characters per line, 2 line LCD Screen
- Sealed tactile and audible feedback membrane switches:

START	STOP
ENTER	ON/OFF
CLEAR/SILENCE	HISTORY
One Scroll Control	Two Cursor Controls

Security Features
- Locking Fluid Bag Cover
- 3-Digit Programmable Security Code
- Latched Tubing Cover

Indicators
- Alphanumeric Description via LCD Display
- Red Alert Light
- Green Infusing Light
- Audible Alert

Alarms
- Bag Cover is Unlocked
- Bag Volume is Low
- Battery Voltage is Low
- Check for AC Adapter Failure
- Check Tubing Placement
- Code Incorrect
- Configuration Has Been Reset
- Downstream Occlusion
- End of Bag
- 1-Hour Limit Reached
- Low Battery
- No Battery
- PCA Connector Not Inserted
- Replace the Low Battery
- Release Key
- Release PCA Button
- Remove Dead Battery
- System Error

Battery

- 9-Volt Alkaline (NEDA 1604A)

Drive Mechanism

- DC Motor, Microprocessor Controlled, Precision Linear Peristaltic Pumping Mechanism

Printer Port

- 600 Baud, 7 data bits no parity

Housing

- Shock and Vibration Resistant ABS

Size

- 4.9" x 3.4" x 1.8" without Fluid Bag Cover

Weight

- 16 ounces

Options and Accessories

- 100 and 250 mL Bags
- 72" and 101" Anti-Siphon Pump Set
- Anti-Reflux Y-Set
- Air Eliminating Spiked Pump Set
- Epidural Pump Set
- Optional 100, 250, and 250E* Fluid Bag Covers
- Optional Locking Pole Mount Clamp
- Patient Control Button*
- AC Adapter*
- Printer Adapter
- Pump Carrying Case*

*Included with the Pump

5. CONTROLS

Begins therapy or prime.

Provides selection of data to be entered.

Allows movement of cursor arrow left or right on display.

```
┌──────────────────────────────────────────┐
│  ⊙ ALERT    ○ INFUSING                     │
│  ┌────────────────────────┐  ┌─────┐ ┌─────┐
│  APII                     │  │START│ │STOP │
│  │                        │  └─────┘ └─────┘
│  │                        │  ┌─────┐ ┌─────┐
│  │                        │  │ENTER│ │ ON  │
│  └────────────────────────┘  └─────┘ │ OFF │
│                                       └─────┘
│   ◀   ▲   ▶                  ┌─────┐ ┌───────┐
│                              │CLEAR│ │HISTORY│
│   Baxter                     │SILENCE│└───────┘
└──────────────────────────────────────────┘
```

Stops therapy or prime.

Applies or removes power to pump.

Allows review of history and prescription.

Clears all data on the screen, clears shift totals, silences alarms (when permitted), resets configuration to factory defaults.

Enters the displayed data into pump.

NOTE: **Security Feature** – To prevent interruption of therapy, the Pump must be unlocked and ON/OFF key *pressed twice* within one second to turn off the Pump. This action will move all programming parameters currently entered into the Pump's history memory. The Pump cannot be operated until this history is cleared.

ON/OFF
Applies or removes power to the Pump.

START
Begins therapy or prime.

STOP
Stops therapy or prime.

NOTE: To stop therapy, STOP key must be pressed twice within one second. To stop prime, STOP key must be pressed once.

ENTER
Enters the displayed data into the Pump.

HISTORY
Allows review of history and prescription.

CLEAR

SILENCE
Clears all data on the screen, clears shift totals, silences alarms (when permitted).

SCROLL KEY

Provides selection of data to be entered.

CURSOR KEYS

Allows movement of cursor arrow left or right on display.
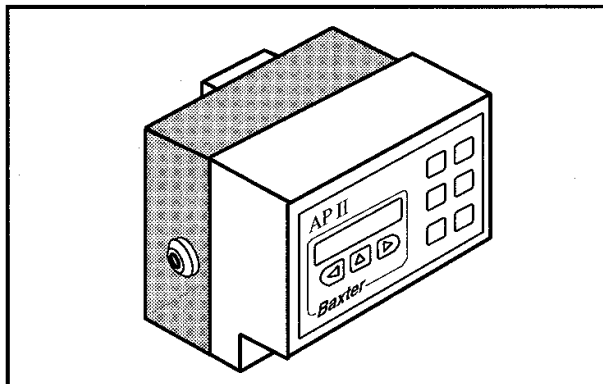
FLUID BAG COVER LOCK
Key operated, 2 positions (lock and unlock).
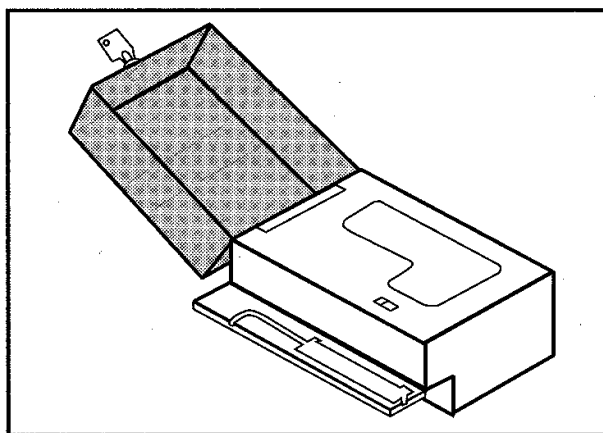
TUBING COVER DOOR
Allows access to pumping mechanism.
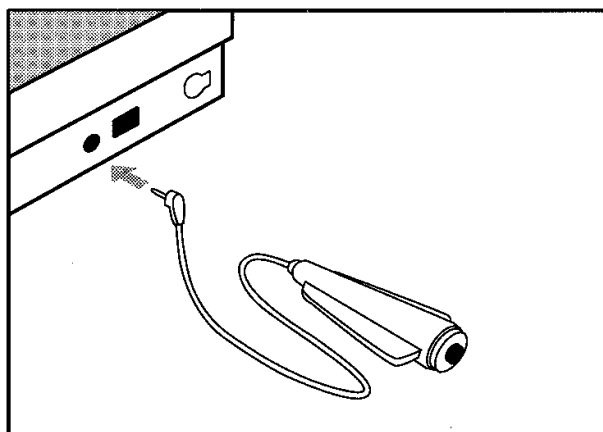
PATIENT CONTROL BUTTON
Allows remote activation in PCA modes.

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6. INSTRUCTIONS FOR USE - PROGRAMMING THE AP II PUMP

WARNING: Do not use any Pump which has readily apparent defects or damage, including missing or misaligned components, missing display segments or missing audio.

NOTE: The AP II Pump may be configured to the specific needs of the operator or institution. See the Configuration Manual for further information. This manual describes the factory default programming mode as listed in Section 4.

6.1 Cursor Control and Value Entry

A. All value entries and selections are made using the left and right cursor control keys to move the cursor arrow under the desired digit or selection and the scroll key to increase the value or change the selection displayed. To scroll through values or selections, press and hold the scroll key. To stop scrolling, release the key. When the cursor arrow is under the far left value or selection, pressing the left cursor control key will cause the cursor arrow to move to the far right value or selection. When the cursor arrow is under the far right value or selection, pressing the right cursor control key will cause the cursor arrow to move to the far left value or selection.

```
┌─────────────────────────┐
│   0000 mL/HR SET         │
│   ↑  BASAL RATE          │
└─────────────────────────┘
```

◀   ▲   ▶
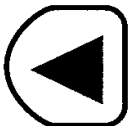
Left cursor   Up scroll key   Right cursor
control key   control key

B. When the appropriate entry or selection is displayed, press "ENTER" to accept that parameter. "CLEAR" may be pressed at any time to reset the screen to zero.

6.2 Liquid Crystal Display

The AP II Pump utilizes a 2-line, 16-characters-per-line, dot matrix liquid crystal display (LCD). This display is back lit for improved visibility in all lighting situations. The display and the back light may turn off during infusion modes dependent upon the power status. Note display and back light characteristics described below.
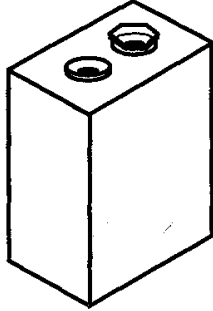
When using 9-Volt Alkaline Battery:

In Infusion Modes (includes history review during infusion modes) Display and back light will turn off after 15 seconds without a key press. To turn on the display and back light, press any key. (NOTE: The first key press will only relight the display. A second key press will be necessary to take any action on the Pump.)

In Programming and Configuration Modes
The display and back light will stay on until exiting these modes.

In Pump Ready, Alarm, and Idle Pump Modes
Display and back light will turn off after 15 seconds without a key press. To turn on the display and back light, press any key. (NOTE: The first key press will only relight the display. A second key press will be necessary to take any action on the Pump.)
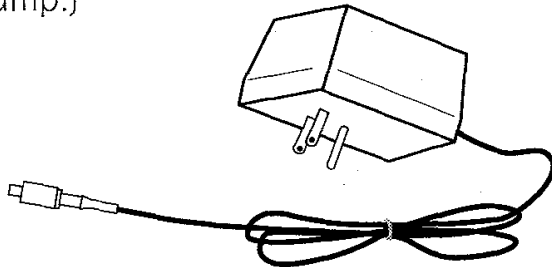
When On AC Power:

In All Modes
The display and back light will remain on at all times.

6.3 Power Options and Power Status

NOTE: The AP II Pump uses an internal power supply to retain programming memory during battery changes or when the primary power source is not available.

A. The AP II Pump may be operated using a 9-volt alkaline battery or an AC adapter as the primary power source. When operating on AC, a 9-volt alkaline battery should be used as a back-up power system.

B. The power status of the Pump will be reported during infusion modes by a symbol in the upper right hand corner of the display. A battery symbol denotes 9-volt primary source. An AC plug denotes AC as the primary power source.
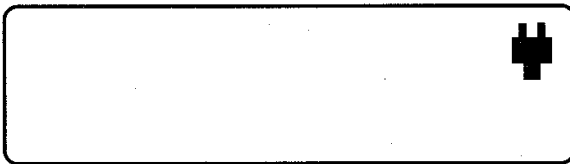
C. Battery status with programming and operating modes – When operating on a 9-volt alkaline battery, the software will measure the battery voltage on power up and prior to entering programming or operating modes. If the voltage is low, the message "BATTERY VOLTAGE IS LOW" will be displayed for 3 seconds, then the programming sequence will continue automatically. See Chapter 8, Alarms.

D. Battery status with configuration mode – When operating on a 9-volt alkaline battery, the software will measure the battery status prior to entering the configuration mode.

During power up, if voltage is low, the message "REPLACE THE LOW BATTERY" will be displayed. The alarm may be silenced by pressing "CLEAR", but will resound after 3 minutes. Configuration will not be allowed until a fresh battery is installed.

During operation, the message "LOW BATTERY" stays on at the bottom of the screen and audible alarm sounds.

E. When operating on AC power without a 9-volt alkaline battery, the message "NO BATTERY" will be displayed on power up. If the operator wishes to continue programming and subsequent operation without a 9-volt for back up, press "ENTER." If a back up power source is desired, install a 9-volt alkaline battery.

6.4 Turning the Pump "ON"

A. Press the "ON/OFF" key once.

B. Once on, the Pump will begin to perform a self-diagnostic test. During this test all segments of the screen will appear for 5 seconds, the alert lights will flash, and the audible alarm will sound briefly.

```
▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓
▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓
```
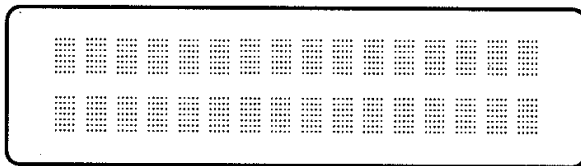
C. The self-diagnostic test screen will display as the test continues.

```
PERFORMING POWER
UP SELF TESTS
```

D. The software revision number will display as the test ends.

```
SOFTWARE
VERSION X.X
```

E. If the Pump fails to display all segments of the LCD, fails to light the alert lights, fails to sound a brief audible alarm, or fails the self-test, contact an authorized service center (see Section 9.5) or your local representative.

WARNING: Do not use any Pump which has readily apparent defect or damage, including missing or misaligned components, missing display segments or missing audio.

G. After approximately 30 seconds, the test will be complete and the time entry screen will display.

6.5 Confirming and Setting the Real Time Clock

A. The date and time will be displayed. To accept the displayed date and time, press "ENTER" once and see Section 6.6. To reset the date and time, press "CLEAR" once.

```
MM/DD/YY HH:MMAM
ENTER OR CLEAR
```

B. The cursor arrow will appear below the left digit of the month (MM). Use the scroll key to display the correct month.

```
MM/DD/YY HH:MMAM
↑  SET MONTH
```

C. Use the cursor keys to position the cursor arrow under the day (DD) and then use the scroll key to display the correct day of the month.

```
MM/DD/YY HH:MMAM
↑  SET DAY
```

D. Repeat this step for the year (YY), hour (HH), minute (MM), and AM or PM. Press "ENTER" after displaying the correct date and time to accept the display and exit this mode.

E. If the Pump has been operated prior to this sequence and the prescription cleared (by pressing "OFF" twice while the bag cover is unlocked) and the history retained, the review or clear history screen will be displayed. See Section 7 for directions on reviewing or clearing history. If no old history is retained, as in the initial set up of the Pump, this screen will not appear.

```
REVIEW OR
CLEAR HISTORY
```

6.6 Accessing the Security Code Screen

A. The fluid bag cover lock must be unlocked, then locked, to access the security code entry screen. During the start up sequence, the programming screens will prompt you on this action if no pre-scription is available.

```
UNLOCK THE
BAG COVER
```

B. Insert the key, push in, and rotate one-quarter turn counterclockwise to unlock the fluid bag cover.

```
LOCK THE
BAG COVER
```

C. Press in on the key and rotate one-quarter turn clockwise to relock the bag cover. The security code entry screen will display.

```
000 ENTER CODE
↑
```

NOTE: If the Pump has been programmed and is ready to run, the words "OR START" will appear on the bottom line of the screen. See Section 7.2 for directions on reviewing this programming. Press "START" to initiate therapy.

D. Use the cursor and scroll keys to display the security code, then press "ENTER" to accept the code and proceed with the programming.

NOTE: The AP II Pump has a factory-default security code of "123." See the Configuration Manual for directions on customizing the security code.

```
123 ENTER CODE
↑
```

E. If an incorrect code is entered, the audible alert will sound and the message "CODE INCORRECT" will be displayed on the screen for 3 seconds. A new code entry attempt can be made. Three incorrect codes will cause the Pump to go into audible alarm and display the message "CODE INCORRECT". Unlock then lock the bag cover to clear this screen (see Section 8, Alarms, for more information).

6.7 Selecting the Operating Mode

A. Select the operation mode of the Pump by using the cursor control key to place the cursor arrow below the desired mode. The modes available for selection are the PCA, the BASAL+PCA, and the CONTINUOUS. Press "ENTER" to accept the mode.

> **PCA BAS+PCA CONT**
> ↑ **SELECT MODE**

6.8 Selecting the Programming Units

A. Select the programming units using the same method as the mode selection. The units available are mL, MG, and µG. Press "ENTER" to accept the units.

> **mL MG µG**
> ↑ **SELECT UNITS**

B. If MG or µG are selected, a concentration for the drug must be set at this time. Use the keys to display the concentration of the drug to be infused, then press "ENTER" once.

> **0.0 MG/mL SET**
> ↑ **CONC.**

C. If mL was selected, no concentration entry will be requested.

6.9 Setting the Fluid Bag Volume

A. Use the keys to display the volume of the fluid in the bag. Press "ENTER" when the correct volume is displayed.

```
0000 mL SET
       BAG VOLUME
```

6.10 Priming the Set

A. To prime the set through the Pump, press "START" as prompted by the display. If you do not desire to prime, press "ENTER."

```
START TO PRIME
ENTER TO PROCEED
```

B. While priming, the display will indicate the amount being delivered. This volume will count up until 0.5 mL is delivered or until "STOP" is pressed.

```
PRIMING
00.0 mL
```

Followed by

```
PRIMING COMPLETE
00.0 mL
```

After approximately 3 seconds, the display will return to the prime screen.

```
START TO PRIME
ENTER TO PROCEED
```

This sequence should be repeated until the tubing set is fully primed.

C. To review the amount primed press "HISTORY". The amount primed will be displayed for 3 seconds.

D. When priming is completed, or if no priming is desired, press "ENTER" to proceed. If programming in the BASAL+PCA or the PCA modes, go to Section 6.11. If programming in the CONTINUOUS mode, go to Section 6.12. If the priming sequence was part of bag change, go to Section 6.13.

6.11 Programming in the BASAL+PCA or PCA Modes

NOTE: The values described in this section are in mL. If MG or µG has been programmed, the equivalent value in those units would be displayed.

A. Set the PCA Dose using the keys. Press "ENTER" when the prescribed PCA Dose is displayed.

```
0.0 mL SET
↑      PCA DOSE
```

B. Set the Delay Time using the keys. Press "ENTER" when the prescribed Delay Time is displayed.

```
000 MINUTES
↑   SET DELAY
```

C. If programming in the BASAL+PCA mode, set the Basal Rate using the keys. Press "ENTER" when the prescribed Basal Rate is displayed. This screen will not appear in the PCA mode programming.

```
00.0 mL/H SET
↑     BASAL RATE
```

D. Set the 1 HR LIMIT using the keys. Press "ENTER" when the prescribed 1 HR LIMIT is displayed.

```
┌─────────────────────────────┐
│  00.0 mL SET                │
│  ↑     1 HR LIMIT           │
└─────────────────────────────┘
```

E. The optional Bolus may now be set using the keys. Press "ENTER" when the prescribed Bolus is displayed. The Bolus will be delivered prior to the initiation of the therapy.

```
┌─────────────────────────────┐
│  00.0 mL SET                │
│  ↑        BOLUS             │
└─────────────────────────────┘
```

F. When the programming is complete, press "START" to initiate therapy or "ENTER" to review or change the prescription.

NOTE: If a Bolus has been programmed, that volume will be delivered prior to initiating therapy.

```
┌─────────────────────────────┐
│  START BEGINS RX            │
│  ENTER REVIEWS RX           │
└─────────────────────────────┘
```

6.12 Programming in the CONTINUOUS Mode

NOTE: The values described in this section are in mL. If MG or μG has been programmed, the equivalent value in those units would be displayed.

A. Set the Continuous rate using the keys. Press "ENTER" when the prescribed Continuous rate is displayed.

```
┌─────────────────────────────┐
│  00.0 mL/H SET              │
│  ↑     CONTINUOUS           │
└─────────────────────────────┘
```

B. The optional Bolus may now be set using the keys. Press "ENTER" when the prescribed Bolus is displayed. The Bolus will be delivered prior to the initiation of the therapy.

```
┌─────────────────────────────┐
│                             │
│   00.0 mL SET               │
│   ↑       BOLUS             │
│                             │
└─────────────────────────────┘
```

C. When the programming is complete, press "START" to initiate therapy. Press "ENTER" to review or change the prescription.

NOTE: If a Bolus has been programmed, that volume will be delivered prior to initiating therapy.

```
┌─────────────────────────────┐
│   START BEGINS RX           │
│   ENTER REVIEWS RX          │
└─────────────────────────────┘
```

6.13 Initiating Therapy

A. After connecting the pump tubing set to the patient's access device, press "START" to initiate therapy. If a Bolus has been programmed, that volume of fluid will be delivered first. See section 6.16 for information on the Bolus delivery.

The current mode of operation will display and the green LED will light. If the CONTINUOUS mode has been programmed, the Continuous Rate will also display.

```
┌─────────────────────────────┐
│   PCA                       │
│                             │
└─────────────────────────────┘
```

or

```
┌─────────────────────────────┐
│   BASAL+PCA                 │
│                             │
└─────────────────────────────┘
```

or

```
CONTINUOUS
0.0 mL/H
```

B. Press "STOP" twice when the display is lighted to interrupt therapy.

6.14 Changing the Prescription During Therapy

A. To change the prescription during therapy, press "STOP" twice to interrupt the infusion. The PUMP READY screen will display.

```
PUMP READY
PRESS START
```

B. Unlock and lock the fluid bag cover. The code-entry screen will appear. Enter the security code as described in Section 6.6.

C. To set a new Bolus, press "ENTER" and follow the steps in Section 6.16. To change the prescription, press "CLEAR" and follow the steps in Section 6.11 if programming in the BASAL+PCA or PCA modes, or Section 6.12 if programming in the CONTINUOUS mode.

```
ENTER SETS BOLUS
CLEAR CHANGES RX
```

D. To change the mode or units as well as the prescription, press "STOP" twice to interrupt the infusion, unlock the fluid bag cover, and press "OFF" twice. Lock the bag cover and press "ON" to restore power to the Pump. See Section 6.4 for information on turning on the Pump.

E. After completing the power up sequence, the REVIEW OR CLEAR HISTORY screen will be displayed. Press "HISTORY" to review the history retained in the Pump memory. Press "CLEAR" to

erase the retained history. After review, press "CLEAR" to continue.

```
┌─────────────────────────────┐
│                             │
│  REVIEW OR                  │
│  CLEAR HISTORY              │
│                             │
└─────────────────────────────┘
```

NOTE: It is not possible to retain the history stored in the Pump beyond this screen. If it is necessary to retain this information, record the data on the patient chart or print a hard copy. See Section 7.3 for directions on printouts.

F. Follow the directions beginning in Section 6.7 to program the Pump.

6.15 Changing the Prescription Prior to Initiating Therapy

To change the prescription prior to initiating therapy, press enter when the START BEGINS RX, ENTER REVIEWS RX screen is displayed.

```
┌─────────────────────────────┐
│                             │
│  START BEGINS RX            │
│  ENTER REVIEWS RX           │
│                             │
└─────────────────────────────┘
```

Follow the steps beginning in Section 6.7

6.16 Programming Additional Bolus Doses

A. Press "STOP" twice to interrupt therapy.

B. Unlock, then lock the bag cover to access the security code screen and enter security code.

```
┌─────────────────────────────┐
│                             │
│  0.0 mL SET                 │
│  ↑  BOLUS                   │
│                             │
└─────────────────────────────┘
```

C. Press "ENTER" to set the new Bolus Volume.

```
0.0 mL SET
↑   BOLUS
```

D. The new Bolus Volume may now be set using the keys. Press "ENTER" when the prescribed Bolus is displayed. This Bolus will be delivered prior to the initiation of the therapy.

```
START BEGINS RX
ENTER REVIEWS RX
```

6.17 Initiating Additional Bolus Doses

A. To initiate the Bolus, press "START" when the Pump displays "START" BEGINS RX, "ENTER" REVIEWS RX. The display will show the increasing volume of fluid being delivered.

```
BOLUS INFUSING
00.0 mL
```

B. At the completion of the Bolus or if interrupted by pressing "STOP" twice, the volume delivered will be displayed. Three short beeps will sound and the red alert LED will flash upon completion or interruption of the Bolus. After one minute, a continuous alarm will sound. This alarm may be silenced for one minute by pressing "CLEAR/SILENCE."

```
BOLUS DONE
00.0 mL
```

NOTE: If a Bolus is interrupted, it cannot be restarted. To give additional Bolus Volumes, reprogram the Bolus as described in Section 6.16.

C. To return to the prescribed therapy, press "START." If no action is taken, the Pump will alarm in approximately one minute.

6.18 Changing the Fluid Bag

A. Follow the directions for preparing the bag and tubing set, (see Section 3.5) and installing the fluid bag (see Section 3.6).

B. Press "STOP" twice to interrupt therapy and unlock the bag cover. Press "SILENCE" to silence the alarm.

C. After locking the bag cover, the security code entry screen will display. Press "ENTER" while 000 is the code displayed. It is not necessary to reenter security code.

```
┌─────────────────────────────┐
│                             │
│ 000 ENTER CODE              │
│ ↑  OR START                 │
│                             │
└─────────────────────────────┘
```

D. Set the fluid bag volume as instructed in Section 6.9 and prime the set, if required, as instructed in Section 6.10.

E. The PUMP READY screen will display. Press "START" to restart the therapy.

6.19 Changing the Battery

A. The 9-volt alkaline battery should be changed on a regular basis. If battery voltage drops below required level, the low battery alarm will display, the red and green LED lights will flash and an audible alert will sound every 60 minutes.

B. To change the battery, press "STOP" twice to interrupt the infusion.

C. Open the battery compartment and replace battery, making certain to observe correct polarity.

D. Press "ON" to power up the Pump. See Section 6.4 for information on power up.

E. When the PUMP READY screen appears, press "START" to resume the infusion.

7. REVIEWING HISTORY

7.1 Reviewing or Clearing Old History

A. The AP II Pump retains a record of the previous prescription and therapy history. The user can choose to review this history by pressing "HISTORY." The history can be cleared by pressing "CLEAR."

> # REVIEW OR
> # CLEAR HISTORY

B. To complete the review, press "HISTORY" until the review or clear screen displays. To exit the review at any time, press "START." After the review is complete, press "CLEAR" to proceed with programming.

NOTE: The history record retained in the Pump should be recorded prior to clearing.

NOTE: If the history is cleared and the Pump is turned off prior to entering a new program, this screen will not appear in the next programming sequence.

7.2 Reviewing Therapy History and Prescription Data

A. Therapy history and prescription data may be reviewed by pressing "HISTORY." If history cannot be accessed or is not available, the message "HISTORY NOT AVAILABLE" will be displayed. If history can be accessed, the fluid remaining in the bag will be displayed. To scroll through the available history, continue to press "HISTORY." To exit the history review at any time, press "START."

> # 00.0 mL BAG
> # VOLUME REMAINING

B. The time from the beginning of therapy or from the last time the shift totals were cleared is displayed. Press "HISTORY" to continue.

```
TOTALS SINCE
MM/DD/YY HH:MMAM
```

C. In all operating modes the top line of the shift total screen reports the amount of fluid infused from the beginning of therapy or from the last time the shift totals were cleared.

If the Pump is programmed in the BASAL+PCA or PCA modes, the bottom line reports the total injections and attempts from the beginning of therapy or from the last time the shift totals were cleared (this line will be blank if the Pump is programmed in the CONTINUOUS mode).

```
0 mL
0 INJ 0 ATT
```

If the operator wants to clear the shift totals and reset the shift time, press "CLEAR." The message "SHIFT TOTALS CLEARED" will be displayed for 3 seconds, then the display will return to the current shift totals screen.

NOTE: Clearing the shift totals does not affect the total volume delivered or the 24-hour history of injections and attempts. It is recommended that all shift history be recorded on the patient record prior to clearing.

If the operator wants to continue history review, press "HISTORY."

D. The total volume given from the beginning of therapy is displayed. Press "HISTORY" to continue the review.

```
0 mL
TOTAL VOL GIVEN
```

E. The prescription information follows the total volume given. These screens will vary by the mode of the Pump, but include all the values entered during programming.

F. If the pump is programmed in the BASAL + PCA mode or the PCA mode, the prescription values will be followed by an hour-by-hour history of the most recent 24 hours for injections and attempts.

The injection attempt history reports from the most current hour (or portion of an hour) to the most distant hour (up to 24 hours prior to the current hour). When 24 hours of history are recorded, the most distant hour will be dropped as a new hour is added.

If the Pump is programmed in the CONTINUOUS mode, this screen will not appear.

```
0 INJ 0 ATT
HH:MM - HH: MM
```

At the beginning of therapy, the first hour recorded will be the time from the start of therapy to the top of the hour. Each hour after that time will be the full clock hour. For example, the first hour is 12:15 PM to 12:59 PM. The second hour is 1:00 PM to 1:59 PM.

G. When all history has been reviewed, the message "END OF HISTORY" will be displayed. Press "START" to exit history review or press "HISTORY" to restart the review. If the Pump is left in the history mode for 3 minutes, the display will automatically revert to the current operating screen.

7.3 Printer and Printouts

A. The AP II Pump can print the history and prescription of the Pump via the printer adapter (Baxter product #6464850), the AP II Printer Adapter Cable (Baxter product #6464852), and a compatible printer (e.g. Seiko DPU-411 thermal printer).

B. Please refer to the directions included with the printer adapter and specifications in Section 4 for operating instructions and compatible printers.

C. The information printed is mode dependent and may include:
- volume remaining in bag
- total volume delivered
- shift totals
- prescription parameter
- injection/attempt history for up to 24 hours
- any current alarm conditions

8. ALARMS

All audible signals (except system errors) can be silenced by pressing "SILENCE." Audible signals will return after a defined time period.

LCD Messages are listed in alphabetical order.

When Screen Reads:

**BAG COVER
IS UNLOCKED**

Audible Signal:

▬▬▬ ▬ ▬ ▬

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound.

Visual Signal: ®

Red Flashing LED

Situation: The bag cover is unlocked. Pump operation is not allowed.

Action: Lock the bag cover.

When Screen Reads:

**BAG VOLUME
IS LOW**

Audible Signal:

▬▬▬ ▬ ▬ ▬

1 Long beep and 3 short beeps, until silenced. To silence audible signal and clear screen, press "CLEAR". Audible signal will not resound.

Visual Signal: ® ©

Red & Green Flashing LEDs

Situation: The calculated fluid volume remaining in the bag equals or is less than the amount required for two hours of operation. Pump operation continues.

Action: Prepare new bag and plan to change bag within two hours.

When Screen Reads:

> **BATTERY VOLTAGE
> IS LOW**

Audible Signal:

No Audible Signal.

Visual Signal:
Red Flashing LED

Situation: Prior to programming the Pump, this screen will appear for 3 seconds indicating an estimated 4 hours of battery life is remaining. Programming sequence may be continued.

Action: Replace battery.

When Screen Reads:

> **CHECK FOR AC
> ADAPTER FAILURE**

Audible Signal:

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal:
Red Flashing LED

Situation: The AC adapter is not operating correctly. Pump operation is stopped.

Action: Check for proper insertion of the AC adapter connector. Replace adapter if error continues.

When Screen Reads:

CHECK TUBING
PLACEMENT

Audible Signal:

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal:
Red Flashing LED

Situation: The tubing set is not properly installed or the tubing cover door is not closed. Pump operation is not allowed.

Action: Correctly place the tubing in the tubing cover and fully close and latch the cover.

When Screen Reads:

CODE
INCORRECT

Audible Signal:

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal:
Red Flashing LED

Situation: Three incorrect codes were entered. Pump operation is not allowed.

Action: Unlock then lock the Pump and enter the correct security code.

When Screen Reads:

CONFIGURATION HAS BEEN RESET

Audible Signal:

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal:
Red Flashing LED

Situation: The configuration of the Pump has been reset to factory default since last operation. Pump operation is not allowed.

Action: Re-enter the desired configuration prior to operating the Pump.

When Screen Reads:

DOWN STREAM OCCLUSION

Audible Signal:

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal:
Red Flashing LED

Situation: There is an occlusion or blockage in the system that is preventing fluid flow. Pump operation is interrupted.

Action: Check tubing set for clamps or kinks. Assess patency of vascular device.Operation may continue upon relief of occlusion.

When Screen Reads:

> **END OF BAG**

Audible Signal:

■■■■ ■ ■ ■

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal: **R**
Red Flashing LED

Situation: The calculated fluid remaining in the bag equals zero. Pump operation is interrupted.

Action: Prepare new bag and change bag immediately, and reprogram bag volume.

When Screen Reads:

> **1 HOUR**
> **LIMIT REACHED**

Audible Signal:

■■■■ ■ ■ ■

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal: **R**
Red Flashing LED

Situation: The programmed volume for the 1-hour limit has been reached and further fluid delivery has been stopped.Pump operation is interrupted.

Action: Check the prescription and verify that the correct parameters have been entered. Evaluate the current prescription. Pump operation will resume when either "START" is pressed or a PCA request is made and the volume delivered in the last hour does not exceed the programmed limit.

When Screen Reads:

> ## LOW BATTERY

Audible Signal:

▬▬ ▬ ▬ ▬

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 60 minutes.

Visual Signal: Ⓡ Ⓖ

Red/Green Flashing LED

Situation: An estimated 4 hours of battery life is remaining. Pump operation continues.

Action: Prepare to change the battery.

When Screen Reads:

> ## NO
> ## BATTERY

Audible Signal:

▬▬ ▬ ▬ ▬

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal: Ⓡ

Red Flashing LED

Situation: Pump has been powered up, is operating on AC power and has no 9-volt alkaline backup. Pump is not operating.

Action: To operate without battery, backup, press "ENTER." To operate with battery backup, install battery and press "ENTER."

When Screen Reads:

PCA CONNECTOR
NOT INSERTED

Audible Signal:

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal:
Red & Green Flashing LEDs

Situation: The Pump is in the PCA mode and the PCA cord is not connected. Basal infusion, if programmed, will continue, but no patient activated doses can occur.

Action: Connect the PCA cord to the Pump. If a PCA cord is currently connected, change to a new one.

When Screen Reads:

PUMP LEFT IN
PROGRAMMING MODE

Audible Signal:

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal:
Red Flashing LED

Situation: The Pump was left in a programming screen for three minutes without any key press activity. Pump operation is not allowed.

Action: Press "ENTER" and re-enter the security code to complete programming.

When Screen Reads:

> **REPLACE THE**
> **LOW BATTERY**

Audible Signal:

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal: Red Flashing LED

Situation: Battery voltage is low. Configuration will not be allowed until fresh battery is installed.

Action: Replace the battery.

When Screen Reads:

> **REALEASE THE**
> **"   " KEY**

Audible Signal:

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal: Red & Green Flashing LEDs

Situation: A key on the keypad is being depressed constantly. Pump operation continues.

Action: Advise patient to release key. If no key is being held this alarm will convert to a system error after 3 additional minutes.

When Screen Reads:

RELEASE PCA
BUTTON

Audible Signal:

■■■■ ■ ■ ■

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal: Ⓡ Ⓖ
Red & Green Flashing LEDs

Situation: The PCA button is being depressed constantly. Pump operation continues.

Action: Advise patient to release the PCA button after making the request.

When Screen Reads:

REMOVE THE
DEAD BATTERY

Audible Signal:

■■■■ ■ ■ ■

1 Long beep and 3 short beeps until silenced. To silence audible signal, press "CLEAR". Audible signal will resound every 2 minutes.

Visual Signal: Ⓡ
Red Flashing LED

Situation: The battery voltage is too low to allow proper infusion rates. Pump operation is not allowed.

Action: Replace the battery.

When Screen Reads:

> **SYSTEM ERROR XX**
> **SERVICE PUMP**

Audible Signal:

■ ■ ■ ■ ■ ■

Constant repeating beep alarm, cannot be silenced.

Visual Alert: Ⓡ

Red Constant LED

Situation: A system error has been detected by the microprocessor and therapy has been stopped. XX will be a two digit code referring to a specific malfunction. Pump operation is not allowed.

Action: Record alarm code. Turn the Pump off by pressing "OFF" once.

9. ROUTINE MAINTENANCE

The AP II Pump is designed to provide reliable service with only routine maintenance. A periodic functional check of the Pump by qualified personnel should be made at least every six months. The Pump should also be cleaned and disinfected, as required, depending on the frequency of use and hospital protocol.

9.1 Cleaning and Disinfecting

The exterior surfaces of the AP II Pump may be cleaned with a cloth, sparingly dampened with any of the cleaners listed below. Follow manufacturers' dilution instructions for concentrated cleaners. Used Pumps should be cleaned/disinfected with an agent from the list below before use on another patient. Spills and dirt should be cleaned off the Pump as quickly as possible.

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
TOR or Hi-Tor Plus	Huntington Labs
Bafix	Hysan Corporation

CAUTION: The AP II Pump and AC adapter are not waterproof and should not be immersed. Avoid getting liquids inside the Pump or permanent damage may result. Do not use alcohol for cleaning. Sterilization via ETO, steam, etc. should not be attempted.

9.2 Storing the Pump

When storing the Pump for long periods of time, e.g. longer than 7 days, remove the 9-volt battery from the Pump.

9.3 Repair and Troubleshooting

Since specialized equipment is required to adjust the mechanism and electronics of the Pump, it is recommended that a defective device be returned to an authorized service center.

9.4 Complaints

For complaints, please contact the Baxter Healthcare Corporation, I.V. Systems Division, Quality Management Department 1-800-437-5176 with the following information:

- Name and Title
- Institution, Address, Telephone
- Product
- Serial Number/Lot Number
- Will product sample be returned? (Yes or No.)
- Was product in use on a patient when problem detected? (Yes or No.)
- Was there any injury to the patient? (Yes or No. If yes, FDA user-reporting may be required.)
- Date of event
- Description of event (Please include Pump programming, configuration, and any alarms prior to or at the time of the event.)

9.5 Authorized Service Centers

Baxter Healthcare Corporation
Anesthesia Division
(800) 343-0366 (United States Only)

Anesthesia Division

Baxter

Baxter Healthcare Corporation
Deerfield, IL 60015

(800) 343-0366 (United States Only)

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