Operator's Manual

Flo-Gard® 6301 Dual Channel Volumetric Infusion Pump

Baxter

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Introduction

The Flo-Gard[®] 6301 Dual Channel Volumetric Infusion Pump from Baxter can deliver a wide variety of fluids over a broad range of infusion rates. The device's features include:

- Uses only standard Baxter[®] solution administration sets.
- Two separate pump channels allow it to do the work of two conventional pumps, resulting in space savings.
- Configurable settings allow the device to be customtailored to best suit the hospital's needs.
- Computer control capability allows remote control or monitoring of the device via a standard RS-232C interface.
- Infuses a wide variety of fluids, including blood and fat emulsions.
- Suitable for use in epidural administration.
- Safety clamp automatically occludes the tubing when the pump door is opened.
- Occlusion sensors detect both upstream and downstream restrictions. Sensitivity of the downstream occlusion sensor is selectable through the device's configuration.
- Flow check display shows resistance to flow.
- Ultrasonic air-in-line detectors. Sensitivity of the air detectors is selectable through the device's configuration.
- Each pump channel features a Programmed Delivery Profile that enables programming of up to 10 sequential infusion programs for situations where ramping of medications are indicated.

- Slide clamp loading option provides flow shut-off when I.V. set is removed from the pump.
- Locking control panel helps prevent patient tampering.
- Each pump channel features an independent secondary medication program. The channel automatically switches over to the primary program upon completion.
- Volume-Time programming automatically calculates flow rate.
- Automatic self-test routine checks for proper function before use.
- Five-hour memory retains infusion data after power-off.
- Easily replaceable fuse, battery, and power cord.
- Access to test points and internal program simplifies servicing and software upgrades.
- Device can be configured to display a hospital area designator, such as "ONCOLOGY" or "CARDIAC ICU," upon power-up.

Physical Description

Items 1 through 9 are associated with Pump 1 and are described below. The controls associated with Pump 2 are identical and function in exactly the same manner. Items 10 through 28 are common to the operation of both pumps. All front panel items are shown in Figure 1.

| | Front Panel | | | | |
|----|------------------------------|--|--|--|--|
| | ITEM | FUNCTION | | | |
| 1. | Pump 1 ON- OFF/CHARGE key | Turns Pump 1 on and off. The internal battery charger re- mains on regardless of the ON-OFF/CHARGE key as long as the device is plugged in. | | | |
| 2. | Pump 1 door latch | Opens and closes pump door for I.V. set loading and removal. | | | |
| 3. | Pump 1 STOP key | Stops Pump 1 until further instructions are given. The mes- sage STOPPED appears when the key is pressed. An alert sounds if Pump 1 is stopped for more than two minutes. Clears all programming alerts while pump is running. | | | |
| 4. | PUMP 1 key and indicator | Allows keypad and other controls common to both pumps to accept data for Pump 1 programming. Yellow LED lights to in- dicate that Pump 1 is selected. | | | |
| 5. | Pump 1 main dis- play | Shows rate, volume to be infused (VTBI), and total volume in- fused for Pump 1 primary and secondary infusion programs. The decimal point is displayed as an underscore (example: 99_9). | | | |
| 6. | Pump 1 message display | Shows all Pump 1 messages and messages that apply to the device as a whole. | | | |
| 7. | Pump 1 ALARM LED | Red LED that blinks on and off during a Pump 1 or general alarm, accompanied by a message display and a repeated se- quence of three tones. An alarm indicates that Pump 1 or the device as a whole requires immediate attention. | | | |
| 8. | Pump 1 PUMPING LED | Green LED which is constantly lit while Pump 1 is pumping. | | | |
| 9. | Pump 1 ALERT LED | Yellow LED which lights during Pump 1 and general alerts, accompanied by a message display and a repeated single tone. An alert indicates that Pump 1 or the device as a whole needs timely attention. | | | |

| Front Panel | | | |
|----------------------------------|--|--|--|
| ITEM | FUNCTION | | |
| 10. BACK LIGHT key | Backlights the displays when pressed. Pressing the key again turns the backlight off. If the device is operating on battery power, the backlight remains on for 60 seconds when the BACK LIGHT key is pressed. | | |
| 11. SILENCE key | Temporarily silences an audible alarm or alert for two min- utes, unless another alarm or alert occurs on either pump within the two-minute silence period. All messages remain displayed. | | |
| 12. NEXT legend | Lights when the TOT VOL STATUS key is functioning as the NEXT key. | | |
| 13. TOT VOL/STATUS key | Displays total volume delivered for each pump. The key is also used to advance to the next step when programming a delivery profile. (See NEXT legend, item 12 above.) | | |
| 14. CLEAR TOT VOL key | Resets the total volume delivered by the selected pump to zero if pressed when the pump is stopped. | | |
| 15. TIME key | Enters the time over which an infusion is to take place during Volume-Time programming. | | |
| 16. PRI RATE key | Allows programming of the primary infusion rate for the se- lected pump. | | |
| 17. PRI VTBI key | Allows programming of the primary VTBI for the selected pump. | | |
| 18. PRI START key | Starts the primary infusion for the selected pump. | | |
| 19. Plug icon | Always lit while the device is plugged in and the battery is charging. | | |
| 20. MONITOR legend | Lights when the device is being queried by the computer dur- ing computer monitoring. | | |
| 21. Battery icon | Lights when the device is operating on battery power. | | |
| 22. COMPUTER CON- TROL legend | Lights when the device is being controlled by a remote computer. | | |
| 23. CLR key | Clears any programming values currently being entered. | | |
| 24. SEC START key | Starts the delivery of the secondary infusion for the selected pump. | | |



Figure 1. Front View

| Front Panel | | |
|----------------------|--|--|
| ITEM | FUNCTION | |
| 25. SEC VTBI key | Allows programming of the secondary VTBI for the selected pump. | |
| 26. SEC RATE key | Allows programming of the secondary infusion rate for the se- lected pump. | |
| 27. Numerical keypad | Programming values and decimal point are entered with these keys. | |
| 28. OPTIONS key | Allows the device to enter an enabled optional mode. These may include the Programmed Delivery Profile (PDP) or Com- puter Control modes. If Programmed Delivery Profile and/or Computer control is available, the OPTIONS key is lit. | |

Figure 2 shows Pump 2 only. Pump 1 has identical features, which function in the same manner.

| | Pump Head Features | | |
|----|--------------------------------|--|--|
| | ITEM | FUNCTION | |
| 1. | Upstream occlusion sensor | Detects a tubing restriction upstream of the pump. | |
| 2. | Pumping fingers | The linear peristaltic pump mechanism consists of cam-driven pumping fingers which succes- sively manipulate the tubing against the back- plate, resulting in fluid movement in a downward direction. | |
| 3. | Downstream occlusion sensor | Detects tubing restrictions downstream of the pump. The sensitivity level can be adjusted to suit the needs of the hospital through the de- vice's configuration. | |
| 4. | Air sensor | Detects air bubbles in the tubing. The sensitivity is adjustable via the device's configuration. | |
| 5. | Safety clamp | Prevents accidental fluid flow by automatically occluding the tubing whenever the pump door is opened. | |
| 6. | Slide clamp slot | The slide clamp loading option is selectable through the configuration. When the slide clamp loading option is enabled, the I.V. set's slide clamp must be inserted into this slot. The opera- tor must push the slide clamp into the slot to oc- clude the tubing before the I.V. set can be removed from the pump. | |
| 7. | Slide clamp spring retainer | If your hospital has not selected the slide clamp loading option, this spring retainer is inserted into the slide clamp slot, preventing the insertion of the slide clamp. | |



Figure 2. Pump 2 With Door Open

| Rear Panel Features | | |
|---------------------|---------------------|--|
| | ITEM | FUNCTION |
| 1. | I.V. pole clamp | Secures the device to the I.V. pole. |
| 2. | Power cord strap | Stores the power cord. |
| 3. | Audio speakers | For generation of alarm and alert tones. |
| 4. | Battery compartment | Allows easy access to the battery. (For use by authorized service personnel only.) |
| 5. | Fuse | Fuse compartment is located behind the power cord cover. |
| 6. | Power cord | Supplies AC power when plugged into a hospital-grade earth-grounded outlet. Remov- able by authorized service personel only. |
| 7. | PANEL LOCK switch | Disables all front panel keys except BACK LIGHT and TOT VOL/STATUS when pressed. |
| 8. | COMMUNICATIONS PORT | Standard RS-232C port that allows the device to communicate with a computer and provides the nurse call signal when enabled. |
| 9. | VOLUME knob | Adjusts volume of alert and alarm tones. The tones cannot be turned completely off. |

The following items are located on the rear of the device and are shown in Figure 3.



Figure 3. Rear View

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Operating Instructions

Precautions

General

- DANGER—Possible explosion hazard if used in the presence of flammable anesthetics.
- Operate device from 115 V, 60 Hz, hospital-grade earth-grounded outlet only.
- Though the factory-supplied configuration settings are suitable for most therapies, the operator and hospital professionals should verify that the device's settings are appropriate for their clinical applications.
- Use only with standard Baxter[®] soft tubing administration sets with an "s" designation.
- Read and understand this manual before using this device.
- When infusing fluid through a central line catheter, Baxter recommends that sets with a Luer lock adapter be used.
- If using a filter set, use only filters which are suitable for use with infusion pumps. Read and follow instructions of the filter to be used.
- To use the automatic piggyback function, use only Continu-Flo[®] sets from Baxter as the primary line with a compatible secondary set for the secondary line.
- As with all medical electronic equipment, care must be exercised to avoid exposing this device to powerful sources of electromagnetic interference. This device design has been tested to the requirements of

MDS-201-004, and applicable portions of MIL-STD-461C, which are voluntary test guidelines for electromagnetic susceptibility and emissions. This device was not found to be adversely affected by the susceptibility tests in these specifications, and will perform safely. The device's emissions were also found to be acceptable.

Epidural Administration

- 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.
- Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.
- To prevent infusion of drugs that are not indicated for epidural use, do not use administration sets that incorporate injection sites during epidural delivery.
- It is strongly recommended that pumps used for epidural drug delivery be clearly differentiated from pumps used for other routes of administration.
- WARNING—Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.

Loading the Pumps

1. Plug the device in. Plug power cord into a 115 V, 60 Hz grounded outlet, unless temporary battery power is required. The plug icon lights whenever the device is plugged in.

When the device is not plugged in and is on battery power, the battery icon lights.

Note: The procedure for preparing and loading the administration set (steps 2 through 9) is the same for Pump 1 and Pump 2.

2. Prepare solution. Prepare fluid container and administration set according to the directions accompanying the products. Prime the set. Ensure all air is expelled from the set.

- **3.** Close set regulating clamp.
- **4.** Open pump door. Raise pump door latch to horizontal position and pull door open.
- **5.** Load the I.V. set.



a. Press SAFETY CLAMP to open position.

b. If your hospital has enabled the slide clamp loading feature, insert the slide clamp on the I.V. set fully into the slot, so that it is flush with the pump housing. (See Figure 4.) If the slide clamp loading feature is not enabled, a black spring retainer occupies the slide clamp slot and the slide clamp cannot be inserted. Proceed to step c.

Note: During an emergency, in the alert mode, the pump can be operated without inserting the slide clamp. An alert tone sounds until the slide clamp is inserted or SILENCE is pressed. In the alarm mode (software versions later than 1.08), the pump will NOT start and an alarm tone will sound if the slide clamp is not loaded.

Slide clamp

in slot

Figure 4. I.V. Set Loading Diagram

- **c.** Load the tubing through the guide channel from bottom to top as shown in Figure 4.
- **d.** Ensure that the I.V. tubing is loaded straight through the pump mechanism tubing guides and safety clamp.
- e. Ensure that the tubing is touching the pumping fingers before closing the pump door.
- **6.** Close pump door. If resistance is felt when closing the door, check for a misloaded I.V. set.
- 7. Open set regulating clamp completely.
 a. Verify that no drops are falling in drip chamber. If flow is observed, close regulating clamp, recheck I.V. set loading, and verify that the proper administration set is being used.
 - **b.** If flow is again observed, do not use the pump. Have it inspected by service personnel.

Note: Always close the administration set regulating clamp(s) before opening pump door and removing set.

- 8. Attach set to I.V. access site.
- 9. Turn pump(s) on by pressing appropriate ON/OFF CHARGE key(s).
 Verify that the following self-test occurs when you turn on the first pump:
 a. All segments of the Pump 1 and Pump 2 message displays appear momentarily. All segments of the powered-on pump appear momentarily.
 - **b.** Three separate audible tones sound.

- **c.** If a Hospital Area Designator (HAD) has been programmed into the device, it is displayed for three seconds in the Pump 1 message display.
- d. The occlusion detection level is momentarily displayed in the Pump 1 message display (*LEVEL 1, 2, or 3*), followed by *AUDIBLE SWITCHOVER* if the Audible Switchover option is enabled.
- e. If Auto Restart and Flow Check are both enabled, *AUTO RESTART* appears for one second in the Pump 1 message display.
- **f.** If the device is plugged into an AC outlet, the plug icon is lit. If the device is operating on battery power, the battery icon is lit.
- g. If the message *INSERT SLIDE CLAMP* appears when you close the door, the slide clamp loading option is enabled. Close the I.V. set's regulating clamp, open the door, and insert the I.V. set's compatible slide clamp fully into the slide clamp slot located below the safety clamp. Close the door and open the regulating clamp.
- **10.** Set **VOLUME** knob on the rear of the device to the desired level.

Starting a Primary Infusion

The procedures for programming Pump 1 and Pump 2 Note: are identical.

- **1.** Select the pump you Press PUMP 1 or PUMP 2 as appropriate. wish to program. The yellow LED on the **PUMP** key lights to indicate that the pump is selected.
- 2. Set primary flow rate. a. Press PRI RATE.
 - **b.** Program desired flow rate (in mL/hr) on keypad. Zero cannot be entered as the first digit.
 - c. A selected flow rate higher than the allowable maximum results in the message *Hi* appearing in the PRI RATE display. To correct a mistake, press CLR or PRI RATE again and reenter correct rate. The flow rate is displayed in the main display of the selected pump.
- **3.** Set primary volume to a. Press PRI VTBI. be infused.

 - b. Program desired VTBI (in mL) on keypad. Set VTBI equal to the amount of fluid in the container or less if desired.
 - c. To correct a mistake, press CLR or PRI VTBI again and re-enter the correct VTBI. The VTBI is displayed in the main display of the selected pump.
- Press TOT VOL/STATUS key. VOLUME IN-4. Review infusion settings and/or read total volume **FUSED** is displayed first, followed by infused. RATE and VTBI.

5. If necessary, reset the volume previously infused on the selected pump to zero.

Press the CLEAR TOT VOL key.

Note: Always verify programmed information prior to starting the selected pump.

- **6.** Start the pump.
- a. Press **PRI START**. The green **PUMP**-**ING** LED lights and a moving bar appears next to the appropriate flow rate setting.
- b. If the alarm (software versions later than 1.08) or the alert tone sounds with the message INSERT SLIDE CLAMP when you press PRI START, the slide clamp loading option is enabled and the slide clamp has not been loaded into the slide clamp slot. Close the I.V. set's regulating clamp, open the door, and insert the I.V. set's slide clamp into the slide clamp slot located below the safety clamp. Close the door, then open the regulating clamp.
- **c.** Confirm flow by checking for drops in the I.V. set drip chamber.
- d. If Auto Restart is enabled and Flow Check is not enabled, AUTO RE-START is displayed in the Pump 1 message display.
- e. If you wish to program the other pump, press its **ON-OFF/CHARGE** key and repeat steps 1 through 6.
- 7. To stop an infusion bef- a. Pres ore it is complete:
 - **a.** Press the appropriate **STOP** key.

- **b.** The selected pump's **PUMPING** LED goes out and **STOPPED** appears in the message display.
- **c.** If the pump is not restarted or powered off within two minutes, an audible alert sounds.
- 8. To restart an infusion: **a.** Press the PUMP 1 or PUMP 2 key as appropriate.
 - **b.** Press the appropriate **START** key.

9. When the infusion completes: When a pump has delivered the selected volume, it sounds an alert tone and switches to a KVO (Keep Vein Open) rate of 5 mL/hr or the current rate setting, whichever is lower.

- 10. Remove set(s) from a. Press the appropriate STOP key. pump(s) as follows:
 - **b.** Close administration set regulating clamp.
 - **c.** Open appropriate pump door.
 - **d.** If the slide clamp loading option is enabled, press the slide clamp fully into its slot.
 - e. Press the SAFETY CLAMP to the open position.
 - **f.** Check that no fluid is flowing in set, then remove set from pump.
 - **g.** To turn a pump off, press the appropriate **ON-OFF/CHARGE** key.

Starting a Secondary Infusion

Note: The procedures for programming a secondary infusion are identical for Pump 1 and Pump 2.

- 1. Prepare secondary fluid container and administration set.
- **a.** To perform automatic piggybacking, a Continu-Flo[®] set from Baxter must be used as the primary set.
- **b.** Follow directions accompanying the products.
- **c.** Ensure all air is expelled from the secondary set.
- 2. Attach the secondary set to the injection site of the primary set above the device.
- **3.** Lower primary container with the hanger accompanying the secondary set.
- **4.** Set secondary flow rate. **a.** Press **PUMP 1** or **PUMP 2** as appropriate to select the desired pump.
 - **b.** Press **SEC RATE** key. The right-hand side of the selected pump's main display now shows secondary infusion data.
 - **c.** Enter desired flow rate (in mL/hr) for the secondary solution.
 - **d.** To correct a mistake, press **CLR** or **SEC RATE** again and re-enter the correct value.
- **5.** Set secondary volume to **a.** Press the **SEC VTBI** key. be infused.

| b. | Enter the desired fluid amount (in mL) on the keypad. Set VTBI equal to the volume of fluid in the con- tainer. |
|----|--|
| c. | To correct a mistake, press CLR or SEC VTBI again and re-enter the correct value. |

- 6. Open secondary set Check also that the primary set regulatregulating clamp. Check also that the primary set regulat-
- 7. Press SEC START to begin a. Verify that drops begin falling in the secondary set drip chamber only.
 - **b.** Verify that the secondary program is displayed.
 - c. When the VTBI of the secondary program reaches zero, the pump will revert to the primary program. When this happens, if the primary flow rate is set above 999 mL/hr, be sure to close the secondary set regulating clamp.

Using Volume-Time Programming

Volume-Time Programming allows you to select a VTBI and the amount of time over which the infusion is to take place. The device automatically calculates the required flow rate. If the calculated rate is outside of the device's capabilities, the message *Hi* or *Lo* appears as appropriate. Volume-Time Programming can be used for primary and secondary infusions. In the procedure below, the keys to press for secondary programming are shown in parentheses.

Note: The Volume-Time Programming procedures are identical for Pump 1 and Pump 2.

| 1. | Turn on and select the pump. | a. | Press the appropriate ON-OFF/CHARGE key. |
|----|--|----|---|
| | | b. | Press PUMP 1 or PUMP 2 as appropriate to select the desired pump. |
| 2. | Enter a VTBI. | a. | Press the PRI VTBI key (or SEC VTBI , if you are programming a secondary infusion). |
| | | b. | Program the desired VTBI on the keypad. |
| | | c. | To correct a mistake, press the CLR key and re-enter the correct VTBI. |
| 3. | Enter a time. | a. | Press the TIME key. Enter the amount of time (up to 99 hours and 99 minutes) over which you wish the infusion to take place. |
| | | b. | To correct a mistake, press the CLR key or TIME key again and re-enter the correct time. |
| 4. | Press the PRI RATE (or SEC RATE) key. | a. | The device calculates the flow rate required to deliver the desired VTBI in the specified time period. |

- b. If the calculated flow rate is higher than the device's capabilities, the message *Hi* is displayed. To correct a *Hi* message, repeat the procedure from step 2 and enter a longer time period if appropriate.
- c. If the calculated rate is too low, the message *Lo* is displayed. To correct a *Lo* message, repeat the procedure from step 2 and enter a shorter time period if appropriate.

5. Check the rate, then start the pump.

Verify that the calculated rate is acceptable before pressing **PRI START** (or **SEC START**) to begin the infusion.

Changing the Flow Rate While the Pump Is Running

To change the primary or secondary flow rate during the course of an infusion, follow the procedure given below. The keys to press for a secondary infusion are shown in parentheses.

- **1.** Select the pump. Press **PUMP 1** or **PUMP 2** as appropriate to select the desired pump.
- 2. Press PRI RATE (or SEC **NEW RATE** appears in the selected pump's message display and an alert tone sounds periodically.
- 3. Enter the new flow rate on the keypad.a. If the primary rate is changed above 999 mL/hr, ensure that the secondary set regulating clamp is closed.
 - **b.** If a new rate higher than the allowable maximum is entered, *Hi* appears in the appropriate rate display.
- 4. Press PRI START (or SEC START).
 The pump begins delivering fluid at the new rate, the alert tone stops, and the NEW RATE message disappears.

The OPTIONS Key

The **OPTIONS** key is used to place the device into Computer Control mode and to set a Programmed Delivery Profile (PDP). The **OPTIONS** key is active only when at least one of these two features has been made available in the device's configuration. Pressing the **OPTIONS** key with neither pump selected selects Computer Control (if enabled). Selecting a pump and then pressing **OPTIONS** puts the pump into PDP mode (if enabled). The PDP mode allows you to program an infusion with up to 10 different steps.

NOTE: If the word OPTIONS is not visible when a pump is powered on, you cannot use computer control or PDP. Consult qualified hospital biomedical personnel regarding the appropriateness of the device's settings.

Using the Programmed Delivery Profile Feature

Each pump channel has a Programmed Delivery Profile (PDP) that allows you to program an infusion which changes over time. This feature, which can be made available through the device's configuration, lets you program an infusion of up to 10 different steps. The pump automatically changes to the next programmed rate once the VTBI of a step has been delivered. To use a PDP:

- Verify that the OPTIONS key is lit.
 If OPTIONS is not lit, your device is not configured for PDP. Consult with authorized hospital personnel if you have questions regarding the appropriateness of your device's configuration settings.
 Select a pump.
 Press PUMP 1 or PUMP 2 as appropriate.
 - p.Press PUMP 1 or PUMP 2 as appropriate.
The yellow LED on the PUMP key lights
to indicate that the pump is selected.

- **3.** Place the pump into PDP mode by pressing the **OPTIONS** key.
- **4.** Review previous PDP settings.

The message **PGM DELIV** appears and the **NEXT** legend over the **TOT VOL/STATUS** key lights. The pump is now in PDP mode.

- **a.** If a previously set PDP is stored in the pump's memory, **STEP 1** appears in the message display and the rate and VTBI of the first programmed step appear in the main display.
- b. If you wish to clear the stored PDP, press the CLR key. The message CLEAR ALL? appears. Press the CLR key again to actually clear the PDP. The CLEAR ALL? message disappears.
- c. If you wish to use the stored PDP, continue pressing the NEXT key to scroll through all steps of the PDP until the first step is again displayed. Review each step to ensure that the PDP is appropriate.
- d. To begin the PDP, press PRI START. The message *REVIEW PDP* appears if you have not completed reviewing the stored PDP. After you have reviewed all steps and pressed PRI START, the pump begins delivering fluid.

Note: If you enter PDP mode and then try to start the pump without first entering a PDP, the message ENTER PGM appears on the second line of the message display. The message disappears once you start to enter a PDP.

5. Modify previous PDP settings.a. After completing steps 1 through 3 above, press the NEXT key to reach the PDP step you wish to modify.

- **b.** Press the key for the infusion parameter you wish to modify (PRI VTBI or PRI RATE).
- **c.** Enter the new value on the keypad.
- **d.** Press the **NEXT** key to enter the new value.
- e. Modify additional PDP steps if desired. After reviewing or changing the last step, press NEXT again, until the first step is displayed.
- f. To begin the PDP, press PRI START. The pump begins delivering fluid.
- a. After completing steps 1 through 3 above, enter the desired values using one of the following methods:
 - Entering rate and VTBI—Use • PRI RATE, PRI VTBI and the numeric keypad exactly as if programming a primary infusion. You may enter rate and volume in either order.
 - VTBI Entering and time-First press PRI VTBI and enter a value. Then press TIME and enter a time span for this step (up to 99 hours and 99 minutes). Finally, press PRI RATE. The device calculates and displays the resulting flow rate. If the display reads *Hi* or *Lo*, the calculated rate is outside the device's capabilities. Re-enter the VTBI and the time and press PRI RATE again.
 - Entering rate and time—First • press **PRI RATE** and enter a value.
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6. To program a new PDP:

Then press TIME and enter a time span for this step (up to 99 hours and 99 minutes). Finally, press PRI VTBI. The device calculates and displays the resulting volume. If the display reads *Hi* or *Lo*, the calculated VTBI is outside the device's capabilities. Re-enter the rate and the time and press PRI VTBI again.

- **b.** Press the **NEXT** key to lock in the programmed values and advance to the next step.
- c. Program all remaining steps (up to 10) in the same manner. After entering settings for the last step, press
 NEXT again, until the first step is displayed.
- **d.** To begin the PDP, press **PRI START**. The pump begins delivering fluid.

To pause during a PDP, press the pump's **STOP** key. To resume from the point at which you left off, select the pump (with **PUMP1** or **PUMP2**) and press **PRI START**.

To drop out of PDP, select the pump and then press **OP-TIONS**, **PRI RATE**, **SEC RATE**, or **SEC VTBI**.

In PDP mode, the pump switches to the KVO rate when it reaches a step that has a rate and VTBI of zero or when it finishes the tenth step.

Computer Control

The Computer Control option allows the device to be controlled by a remote computer. Computer Control is an option made available through the configuration.

When the device is under computer control, the **COM**-**PUTER CONTROL** legend on the front panel is lit.

Pressing any enabled key (other than SILENCE, TOT VOL/STATUS, BACK LIGHT, PANEL LOCK, or the key combination for the Flow Check display or the Alarm Log display) causes the device to drop out of computer control, allowing you to clear alarms and/or change infusion data.

Computer Monitoring

When the device is set up for computer monitoring, information is gathered by a remote computer via the **COMMUNI-CATIONS PORT**. The computer connected to the device does not control it; it simply monitors infusion data. The **MONI-TOR** legend on the front panel lights whenever the computer queries the device for information. The device is operated in exactly the same manner as if it were not connected to the computer.

Locking the Front Panel

The front panel keys can be locked during pumping to prevent tampering. They can be unlocked at any time. The **TOT VOL/STATUS** and **BACK LIGHT** keys are not affected by the lockout. This allows routine infusion data checks while the front panel is still locked. If either pump is stopped due to an infusion alarm or an opened door, the panel must be unlocked to restart the infusion.

| 1. | To lock the panel: | With all powered-on pumps running, |
|----|----------------------|---|
| | | press the PANEL LOCK switch on the rear |
| | | of the device for at least one second. The |
| | | message <i>Loc</i> appears in the main dis- |
| | | play of pumps that are powered on. |
| 2. | To unlock the panel: | Press the PANEL LOCK switch again. The |
| | | <i>Loc</i> message disappears. |

Battery Powered Operation

The device automatically switches to battery operation when the AC power is interrupted or the device is unplugged. When operating on battery power, the battery icon on the front panel is lit. The battery automatically recharges whenever the device is plugged in. It is recommended that the device be plugged into an AC outlet during storage to help maintain batteries at full charge.

FLOW CHECK Information Display

The Flow Check feature displays the resistance to flow. There is a separate display for each pump. As shown in Figure 5, the **FLOW CHECK** display is a dashed line that stretches from left to right as the resistance to flow increases. The left side of the display is labeled **norm** and corresponds to the pressure when the infusion was initially started or manually restarted after an alarm. The right side of the display is labeled **occ** and corresponds to the next occlusion threshold. Selecting the Flow Check option in the configuration results in the **FLOW CHECK** display appearing whenever the pump is running. Whether or not the Flow Check option is selected, the display may be momentarily viewed whenever the front panel is unlocked by pressing the decimal point and **TOT VOL/STATUS** simultaneously.



Figure 5. Flow Check Display

Cleaning and Storage

The exterior of the device may be cleaned with a soft cloth, sparingly dampened with any of the cleaners listed below. Follow manufacturers' dilution instructions for concentrated cleaners. Used devices should be cleaned/disinfected with an agent from the list below before use on another patient. If spillage into either pump mechanism occurs, clean the mechanism immediately by wiping with a soft cloth dampened with any of the cleaners listed below.

| Cleaner | Manufacturer |
|------------------------------------|---------------------|
| LpH, Septisol | Vestal Labs |
| Cidex 7 | Surgikos |
| Super Edisonite | Edison Chemical Co. |
| TOR, Hi-Tor Plus | Huntington Labs |
| Bafix | Hysan Corp. |
| A solution of 10% bleach and water | |
| Soapy water | |
| Isopropyl alcohol up to 95% | |

Note: 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. Do not use the following chemicals on the device, as they will damage the front panel: acetone, ammonia, benzene, hydroxytoluene, methylene chloride, n-alkyl dimethyl ethylbenzyl ammonium chloride, and ozone.

> It is recommended that the pump be plugged in during storage to help maintain the batteries at full charge. Do not store the device with either **ON-OFF/CHARGE** key ON. The battery may discharge completely.

Alerts and Alarms

The following chart describes alarm and alert messages for each pump along with the cause of each.

| Message | Flow Status | Condition |
|---|--|---|
| | | Alert Messages |
| STOPPED | No flow | Pump has been in STOPPED mode for two minutes. |
| KVO PRI VTBI = 0 | KVO | Primary VTBI has been delivered or the PDP has finished. The pump has switched to a KVO rate of 5 mL/hr or pro- grammed rate, whichever is less. This alert also occurs if you start the pump without first entering a non-zero value for the primary VTBI. |
| INSERT SLIDE CLAMP | No effect | The slide clamp loading option is enabled and the slide clamp is not loaded into the slide clamp slot. Close the regulating clamp, open the pump door, and insert the slide clamp fully into the slot, so that it is flush with the pump housing. Close the door, open the regulating clamp, and restart the pump. |
| NEW RATE | No change until proce- dure is complete | Flow rate is being changed while pump is running. Pump remains in NEW RATE alert condition until the appropri- ate START key is pressed. Pressing STOP or TOT VOL/STATUS displays the current flow rate. |
| PRI RATE = 0 | No flow | A primary flow rate of zero has been entered. The pump remains in this alert condition until a non-zero primary flow rate is entered and the appropriate START key is pressed. |
| BATTERY LOW with intermittent alert tone | No change | Battery needs recharging. Pump will stop operating in approximately fifteen minutes unless it is plugged into an AC outlet. |
| SEC COMPLETE | No change | The SEC COMPLETE alert option is enabled and the pump has completed its secondary program and has switched to primary. Press any enabled key to exit from this alert. |

| Message | Flow Status | Condition | | |
|-------------------------|----------------|--|--|--|
| SEC PROGRAM | No change | Secondary program data is being entered while pump is running. Pump remains in alert condition until you press SEC START or STOP . | | |
| SEC RATE = 0 | No flow | An attempt has been made to start the secondary program with a secondary flow rate of zero. The pump remains in this alert condition until you enter a non-zero secondary flow rate and press SEC START , or start the primary pro- gram. | | |
| SEC VTBI = 0 | No flow | A secondary VTBI of zero has been entered. The pump re- mains in this alert condition until you enter a non-zero secondary VTBI and press SEC START , or start the pri- mary program. | | |
| FLOW RATE | No flow | During Volume-Time Programming, if a flow rate outside the pump's capabilities is calculated, the message <i>Hi</i> or <i>Lo</i> appears in the rate display. If an attempt is made to start the pump with either of these messages displayed, a FLOW RATE alert is triggered. To exit this alert condi- tion, reprogram the pump for a rate within the range set in the configuration and press the appropriate START key. | | |
| CHECK VTBI | No flow | A VTBI outside the acceptable range has been entered. To exit this alert condition, enter a VTBI within the range set in the configuration and press the appropriate START key. | | |
| PGM DELIV ENTER PGM | No flow | The pump is waiting for a Programmed Delivery Profile. Either enter the profile (as described on p. 24), or press OPTIONS to leave PDP mode. | | |
| PGM DELIV REVIEW PGM | No flow | An attempt has been made to start a Programmed Deliv- ery Profile before reviewing all the steps. Either press NEXT until the first step is again displayed, or press OP- TIONS to leave PDP mode. | | |
| PGM DELIV CLEAR ALL? | No flow | The pump is asking for confirmation that all steps of the existing Programmed Delivery Profile should be erased. Do one of the following: press CLR to erase the profile; press NEXT to begin reviewing the rest of the profile; press PRI RATE or PRI VTBI to modify this step; or press OPTIONS to leave PDP mode. | | |

| Message | Flow Status | Condition | |
|---|----------------|--|--|
| COM TIMEOUT | No change | There has been no communication between the device and the computer for the specified time period. Check for a dis- connected cable or computer problem. To clear this alert, press the OPTIONS key to return the device to computer control, or press SILENCE or PUMP 1 or PUMP 2 to use the pump(s) without the computer. | |
| EXT COMM ERROR | No change | The controlling or monitoring computer is sending multiple questions or instructions to the device without waiting for the device's replies. The condition has been caused by the computer, not the device. To clear the alert, press OP-TIONS to return the device to computer control (if appropriate), or press SILENCE or PUMP 1 or PUMP 2 to control the pump(s) manually. Notify the technical personnel responsible for the computer. If the alert recurs, disconnect the cable from the communications port. Reprogram the pump(s) for manual operation. | |
| Alarm Messages | | | |
| CHECK SET LOADING | No flow | I.V. set is not loaded properly. Close the regulating clamp, open the pump door, and verify that the set is loaded prop- erly against the pumping fingers and through the up- stream and downstream occlusion sensors. Close the door, open the regulating clamp, and restart the pump. | |
| AIR | No flow | a. Air bubble at detector b. Empty fluid container c. No I.V. set in pump | |
| OCCLUSION | No flow | Closed distal clamp, stopcock, clogged filter or other block- age downstream of the pump. <i>Note:</i> The pump can be set up to restart itself automati- cally when the occlusion is removed. If you want to prevent the pump from restarting automatically, press any enabled key (such as SILENCE) during the alarm. | |
| INSERT SLIDE CLAMP Note: This alarm option is available only on pumps running software versions later than 1.08. | No flow | The slide clamp loading option is enabled and the slide clamp is not loaded in the slide clamp slot. To clear this alarm, open the pump door and insert the slide clamp into the slot. Close the door. | |

| Message | Flow Status | Condition | |
|--|----------------|---|--|
| UPSTREAM OCCLUSION | No flow | Closed clamp or other blockage upstream of the pump. | |
| DOOR OPEN | No flow | Pump door not fully closed. The door latch must be fully lowered to a vertical position. | |
| BATTERY LOW with rapid three-tone alarm | No flow | Battery power has been exhausted. Plug device into AC outlet to restore operation and recharge battery. | |
| FAILURE in message display with code number in main display | No flow | Pump-specific failure. Press appropriate ON-OFF/CHARGE key twice to reset. If <i>FAILURE</i> does not clear, record the failure code number, remove the device from use and have it serviced. | |
| COMMON FAILURE in left message display and code number in right SEC VTBI display | No flow | General failure. Press each ON-OFF/CHARGE key in turn until both pumps are powered off. Power one or both pumps on again. If COMMON FAILURE does not clear, rec- ord the failure code number, remove the device from use, and have it serviced. | |
| COM TIMEOUT | No flow | There has been no communication between the device and the computer for the specified time period. Check for a dis- connected cable or computer problem. To clear this alarm, press the OPTIONS key to return the device to computer control, or press SILENCE or PUMP 1 or PUMP 2 to use the pump(s) without the computer. | |
| EXT COMM ERROR | No flow | The controlling computer is sending multiple questions or instructions to the device without waiting for the device's replies. The condition has been caused by the computer, not the device. To clear the alarm, press OPTIONS to re- turn the device to computer control, or press SILENCE or PUMP 1 or PUMP 2 to control the pump(s) manually. No- tify the technical personnel responsible for the computer. If the alarm recurs, disconnect the cable from the commu- nications port. Reprogram the pump(s) for manual opera- tion. | |

Note: The last ten alarm codes are stored in memory for each pump. You can review these codes when the pump is powered on and stopped. To recall the stored alarm codes, press SILENCE and TOT VOL/STATUS simultaneously. The alarm code that occurred most recently for each powered-on and stopped pump appears in that pump's message display. To scroll back through the other stored alarm codes, press CLEAR TOT VOL within one second. Alarm Recall is exited automatically if the CLEAR TOT VOL key is not pressed within one second. The alarm codes are date and time stamped. They are detailed in the Service Manual.

Technical Specifications

| ITEM | SPECIFICATION | | |
|------------------------------|--|--|--|
| Catalog Code Number | 2M8064 | | |
| Description | Dual Channel Linear Peristaltic Volumetric Infusion Pump | | |
| Administration Set | Baxter [®] "s" designated sets | | |
| Keep Vein Open (KVO) Rate | 5 mL/hr or programmed rate, whichever is less | | |
| Nurse Call | Available through the COMMUNICATIONS PORT | | |
| Battery | 12 volt, 3.2 ampere-hour sealed lead-acid | | |
| Battery Life | -Approximately 6 hours with one pump running at a rate from 1 to 1400 mL/hr -Approximately 4 hours with both pumps running at rates from 1 to 1400 mL/hr | | |
| Battery Recharge | 8 hours for more than 80% recharge | | |
| AC Power Requirements | 110/120 V, 60 Hz | | |
| Power Cord | $2.9\ m$ (9.5 ft) long, with Hospital Grade plug | | |
| Fuse | 0.8 A, 250 V, SB, 5.2 mm $({}^{13}\!\!\!/_{64}$ in.) $\times20$ mm $({}^{25}\!\!\!/_{32}$ in.) | | |
| Leakage Current | Less than 50 microamps (using UL-544 specified test methods) | | |
| Weight | 8.1 kg (17.9 lbs) | | |
| Dimensions | 33 cm W \times 13 cm D \times 29 cm H (13" W \times 5.1" D \times 11.4" H) | | |
| Flow Rate Range | Primary program for each pump: 1.0–99.9 mL/hr in 0.1 mL increments or 1–1999 mL/hr in 1 mL increments. Upper limit can be reduced by authorized service personnel. Secondary program: 1.0–99.9 mL/hr in 0.1 mL increments or 1–999 mL/hr in 1 mL increments, subject to the upper limit that also applies to the primary program. | | |
| VTBI Range | 1.0–99.9 mL in 0.1 mL increments or 1–9999 mL for both primary and secondary of each pump. Upper limit can be reduced by authorized service personnel. | | |

| ITEM | SPECIFICATION |
|-----------------------|--|
| Air-in-Line Detection | Factory set to NORM, which causes the device to alarm on air bubbles approximately 75 μL or larger. The MIN setting causes the device to alarm on air bubbles approximately 50 μL or larger. |

Configurable Options

The device has several features which can be selected to best suit the needs of the hospital. The settings for these features are referred to as the configuration. The configuration applies to the device as a whole unit, and thus to both pumping channels.

To see your device's configuration settings:

- a. Both pumps must be stopped. Press TIME and TOT VOL/STATUS simultaneously, and hold for one second. The message *REVIEW CONFIG* appears in the left message display. The first option and its current setting appear in the right message display.
- **b.** To view the next option, press the **NEXT** or **SEC START** key.
- **c.** To stop viewing the configuration, again press **TIME** and **TOT VOL/STATUS** simultaneously.
- Note: If there is any question regarding the device's current configuration or applicability for a particular clinical application, the operator and hospital professionals should verify that the settings are appropriate. The configuration can be changed only by designated personnel.

The following table shows all of the configurable items, their available settings, and the way they are set when the device leaves the factory.

| Configurable Options | | | | |
|---|----------------------|---|--------------------|--|
| Item | Descriptor | Options | Factory Setting | |
| Occlusion Alarm Level (Pressure increments which trigger an OC- CLUSION alarm. This setting is displayed for one second after the self- test when the pump is turned on.) | OCCLUSION LEVEL n | 1 = LEVEL 1 (approximately 7 psig) 2 = LEVEL 2 (approximately 12 psig) 3 = LEVEL 3 (approximately 17 psig) | LEVEL 1 | |
| Audible Switchover from secondary to primary program. When ON, AUDIBLE SWITCHOVER is displayed for 1 second after the self-test when the pump is turned on. | AUDIB SWI | 1 = OFF 2 = ON | OFF | |
| Number of Automatic Re- starts The number of times the pump will restart auto- matically after a down- stream occlusion occurs and is then relieved. When ON, AUTO RE- START is displayed while the pump is running. If Flow Check is also en- abled, AUTO RESTART is displayed for one second after the self-test when the pump is turned on. | AUTO RES | 0 to 9 | 3 | |
| Door Open Required | DOOR OPEN | 1 = OFF 2 = ON (door must be opened after a downstream occlusion alarm.) | OFF | |
| Air Bubble Alarm Size | AIR SIZE | $\begin{array}{l} 1 = MIN \; (25 85 \; \mu L) \\ 2 = NORM \; (50 110 \; \mu L) \end{array}$ | NORM | |
| Alarm Off Interval | ALARM INT | 1–7 seconds | 1 sec. | |
| Alert Off Interval | ALERT INT | 1–7 seconds | 7 sec. | |

| Configurable Options | | | | |
|---|---------------|---|--------------------|--|
| Item | Descriptor | Options | Factory Setting | |
| Maximum Flow Rate | MAX RATE | 1–1999 mL/hr | 1999 mL/hr | |
| Maximum VTBI | MAX VTBI | 1–9999 mL | 9999 mL | |
| Flow Check Display | FLOW CHECK | 1 = OFF (The decimal point & TOT VOL/STATUS keys must be pressed to view the Flow Check display) 2 = ON (Flow Check display visible whenever pump is running) | OFF | |
| Baud Rate (The rate of information exchange between the de- vice and the computer when in computer control or computer monitoring) | BAUD RATE | 1 = 300 2 = 1200 3 = 2400 4 = 4800 5 = 9600 | 9600 | |
| Computer Control (Selects the type of com- puter control available at power-up) | COMP CONT | 1 = DISABLED (computer control not avail- able) 2 = OFF W ALRM (device drops out of computer control when an alarm occurs) 3 = ON W ALRM (device re- mains in computer control during an alarm) | DIS- ABLED | |
| Hospital Area Designator (displayed for 3 seconds after self-test. Custom designators can be cre- ated using a computer.) | HAD | 0 = No message 1 = NICU 2 = PICU 3 = MED/SURGICAL 4 = TRAUMA/BURN UNIT 5 = OPER ROOM 6 = CARDIAC/ICU 7 = SURGICAL/ICU 8 = ICU 9 = ONCOLOGY | No mes- sage | |

| Configurable Options | | | |
|--|------------|---|-----------------------------|
| Item | Descriptor | Options | Factory Setting |
| Close Clamp Message (<i>CLOSECLAMP</i> appears with <i>DOOR OPEN</i> mes- sage to remind the user to close the I.V. set regu- lating clamp when the pump door is open.) | CLOSE CLMP | 1 = OFF 2 = ON | ON |
| Slide Clamp Loading Op- tion Note: The alarm option is available only on pumps running software ver- sions later than 1.08. | INS CLAMP | 1 = OFF 2 = ON for software versions earlier than 1.09, or ALERT for software versions later than 1.08 (An audible alert oc- curs and the message <i>INSERT</i> <i>SLIDE CLAMP</i> is displayed if the pump is used without first loading the set's slide clamp into the slide clamp slot.) 3=ALARM (An audible alarm occurs and the message <i>IN-</i> <i>SERT SLIDE CLAMP</i> is dis- played. The pump will not operate.) | OFF |
| Programmed Delivery Profile | PDP | 1 = DISABLED (No PDP allowed) 2 = FIVE HOUR (profile can be entered from front panel and is saved in 5-hour memory) 3 = SEMI PERM (profile can be entered from front panel; pump remembers the most recent profile) 4 = PERM (Profile is saved in permanent memory. If a new PDP is entered, the pump will revert to the PDP in permanent memory after the current run.) | DIS- ABLED |
| Time Setting | TIME SET | Real time entered in hours and minutes | Central Standard time |

| Configurable Options | | | |
|----------------------|------------|----------------|--|
| Item | Descriptor | Options | Factory Setting |
| Date Setting | DATE SET | Month/Day/Year | Current date for Central Standard Time |

Warranty and Service Information

Warranty

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

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

THERE ARE NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY AND ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PAR-TICULAR PURPOSE WHICH EXTEND BEYOND THE DESCRIPTION OF THE PRODUCT AND THOSE EX-PRESSLY SET FORTH IN ITS LABELING. UNLESS USED ACCORDING TO THE DIRECTIONS ACCOM-PANYING THE PRODUCT, ALL WARRANTIES ARE SPECIFICALLY EXCLUDED. In no event shall Baxter Healthcare Corporation be responsible for incidental, consequential or exemplary damages. Modification, alteration, recalibration or abuse, and service by other than a Baxter Healthcare Corporation authorized representative may void the warranty.

Service Information

While under Baxter Healthcare Corporation Warranty, Service Agreement (optional), or lease agreement, the instrument must not be opened by unauthorized personnel.

To contact Baxter Healthcare Corporation Customer Service Division for service and repair information for all instruments, call 1-(800) THE PUMP.

Shipping costs for all units returned to Baxter Healthcare Corporation shall be paid 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 Product Service representative must be notified before shipping any unit for repair. When calling Baxter Product Service, please be prepared to provide code number and serial number of the unit. A service request number will be issued and should accompany all communications. A brief written description of the problem should be attached to the instrument when it is returned for service.

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



Baxter Healthcare Corporation Deerfield, IL 60015 USA

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