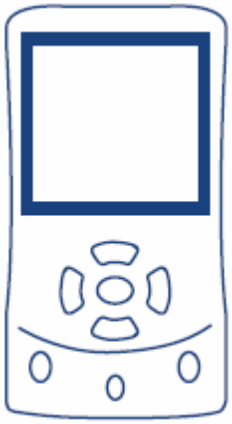
PROMETRA®

PROGRAMMER (REF 11828)

For use with Prometra® Programmable Infusion Systems



MR Unsafe

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

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Device Description

The Prometra Programmer is a handheld, menu driven device external to the implanted pump that enables remote programming of the Pump. Features of the Prometra Programmer include:

- Real-time clock
- LCD display
- Non-volatile memory that automatically stores all pump programming and diagnostic history and which retains the information when power is removed
- USB port and cable for interfacing with a computer or printer
- Three (3) standard AA alkaline batteries (Lr6 for IEC) power the programmer.

Prometra Programmer Front

Component	Description
LCD Panel	The LCD panel displays the programmer's text-based, menu-driven interface.
Navigation Keys	The navigation keys allow you to move between menu options. Once a menu option is selected, the ◀ and ▶ keys move the cursor within a field or between fields. The ▲and ▼ keys increase or decrease the highlighted value.
Select Key	Pressing the Select key selects the currently highlighted field or menu option. Selecting a field within a menu puts the field in edit mode so you can modify its value. Selecting a menu option performs the corresponding action.
Clear Button	The Clear button returns you to the previous menu. Clears a rate row in the Multiple Rates Menu
Power Button	A quick depression of the power button turns the programmer on. To turn the programmer off, the power button must be held down for approximately two seconds. If the programmer is on, pressing the power button a single time illuminates the LCD panel's backlight. Note: The programmer automatically turns off after about fifteen minutes of inactivity.
Inquire Button	The Inquire button initializes an Inquire transaction. The pump's current information displays in the Pump Status screens when the Inquire process is complete.

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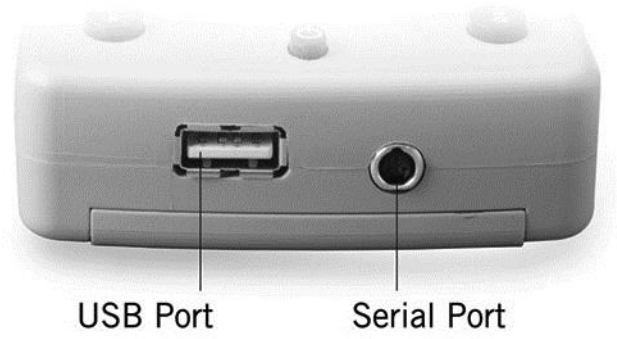
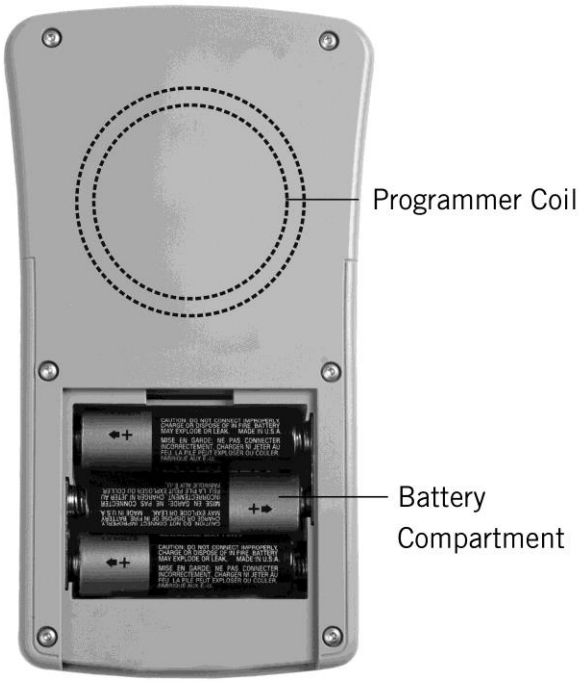


Prometra Programmer Bottom

Component	Description
USB Port	The programmer can output Pump Status, Program Confirmation, and History records to a printer via its USB port.
Serial Port	History records can be transferred to a PC via the programmer's serial port.



Prometra Programmer Back

Component	Description
Programmer Coil	The programmer coil emits the wireless communication signal used to interact with the pump. This coil must be placed directly above the pump to successfully send or receive data.
Battery Compartment	The batteries are located beneath a sliding cover. To remove the cover, press down on the top center portion of the cover and gently slide downward.

For Indications, Contraindications, Warnings, Precautions and potential adverse events related to the Programmable Pump, refer to the appropriate Prometra Programmable Pump Physician's Manual.

Indications

The Prometra Programmer is indicated for use with Prometra Programmable Infusion Systems. It is intended for use in remote communication with the pump.

Contraindications

None known.

Warnings

- Always select and program dosages consistent with the drug labeling to prevent improper drug administration.
- Only use the Prometra Programmer after receiving training specific to this device. Use of this device by non-qualified or untrained personnel could lead to serious consequences involving under- or over-medication. In the event of over-dosage , refer to the approveddrug labeling for appropriate treatment.
- Clinicians programming implanted programmable pumps must comply with the instructions for use. Technical errors may result in a return of underlying symptoms, drug withdrawal symptoms, or clinically significant or fatal overdose.
- Physicians must be familiar with the drug stability information in the product insert and must understand the dose relationship to drug concentration and pump flow rate before prescribing pump infusion.
- Inform patients of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention.
- If suspected that all or part of the drug was injected into the pocket during the refill procedure, monitor the patient closely for signs and symptoms of overdose.
- The handheld programmer uses electromagnetic energy to program the pump. The programmer's electromagnetic field may affect other medical devices. Use or interference with other medical devices has not been established.
- If the Low Reservoir Alarm has been disabled, carefully monitor the reservoir volume. Schedule regular refill visits to avoid reservoir depletion and possible patient discomfort. Patients should be advised to contact their physician if changes in their symptoms occur.
- Potential communication problems between the pump and programmer may occur after exposure to other therapies or procedures, which may include, but are not limited to: magnetic resonance imaging, diathermy, electrosurgical cautery, radiofrequency ablation and lithotripsy.
- **MRI Safety:** The Prometra Programmer is MR Unsafe.

MR Unsafe

Precautions

- Carefully read and follow all instructions prior to use.
- When finished programming a patient’s pump, always turn off and then restart the programmer prior to programming a new patient’s pump. This practice avoids programmer error messages should you inadvertently attempt to program one patient’s pump with data from another patient’s prescription.
- The wireless communication signal used to inquire and program the pump (referred to as telemetry) can travel about 2 inches (5 cm). If the programmer is not positioned closely enough to the pump or is not oriented correctly over the pump, the programmer may not be able to initialize a connection with the pump.
- Always perform a final inquiry at the completion of each visit that the programmer was utilized.
- The programmer is designed for use at temperatures above 10ºC and below 40ºC. If the programmer is stored or transported in temperatures outside of this range, allow its temperature to stabilize within the specified operating range before use.

- Do not disassemble the programmer. Disassembling the programmer may damage it or cause it to malfunction.
- Do not sterilize the programmer. For use where a sterile barrier is desired, place the programmer in a clear sterile bag or pouch.
- Certain electronic equipment may cause interference with the programming procedure. Interference may also occur in the vicinity of equipment marked with the symbol shown at right. Move the patient from the suspected source of interference. Examples of equipment that may cause interference include cathode ray tube (CRT) monitors and large electric motors.

- Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Prometra Programmable Pump and Programmer.

Potential Adverse Events

- Inability to program the device due to programmer failure or loss of telemetry.

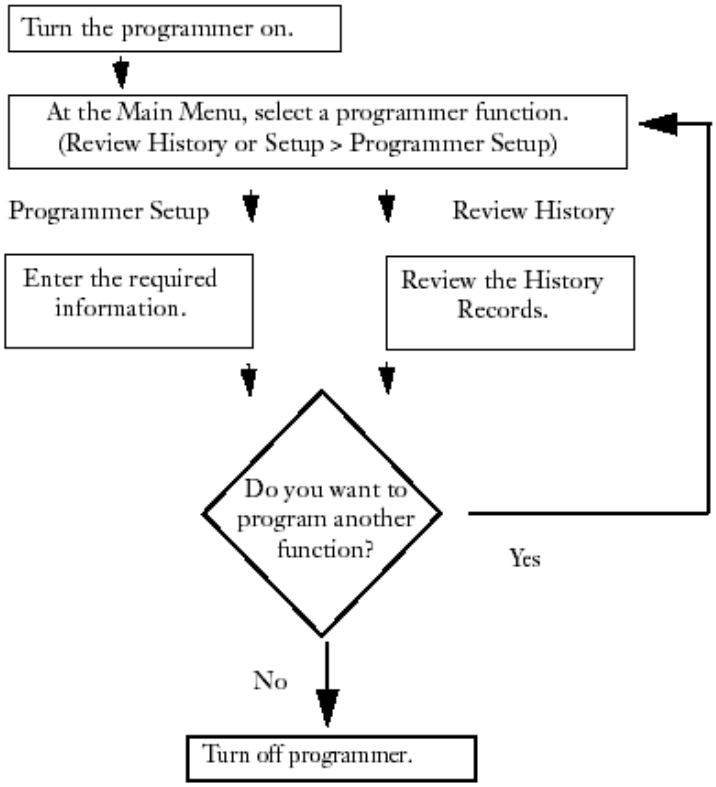
Programmer Operation

The Prometra Programmer system performs two types of transactions: programmer transactions and pump transactions. Programmer transactions are performed independently and do not affect the pump. Pump transactions transfer information between the programmer and the pump.

Programmer Transactions

The following functions are programmer transactions:

- Programmer Setup
- Language
- Set Time/Date
- Clear History
- Review History



Programmer Transaction Sequence Flowchart

Pump Transactions

There are two types of pump transactions:

- Inquire information from the pump
- Program information to the pump

Inquire Transactions

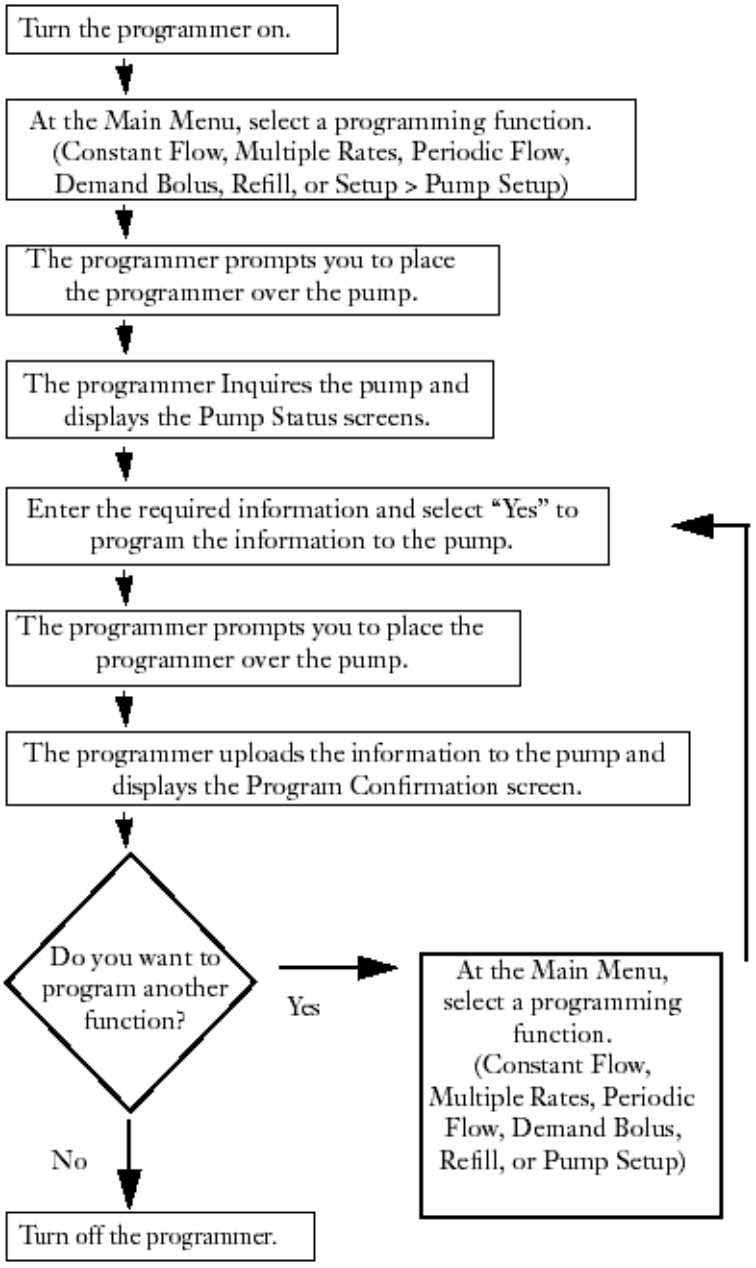
During an Inquire transaction, the programmer initializes a connection with the pump and receives the pump's current information. This information displays in the Pump Status screens when the Inquire is complete. The programmer uses the information obtained during an Inquire session to calculate pump flow rates, determine flow accuracy, and provide default values for programming transactions. By default, the programmer only performs an Inquire of the pump before the first programming operation. To review the pump's current information without performing a programming operation, press the INQ button.

Program Transactions

Program transactions transfer information to the pump. The following functions are pump program transactions:

- Constant Flow
- Multiple Rates
- Periodic Flow
- Demand Bolus
- Refill
- Pump Setup
- Patient Name (code)
- Low Reservoir Alarm
- Set Daily Dose Limit

The sequencing of events for pump transactions is:



Pump Transaction Sequence Flowchart

Programmer Audible Cues

The following table describes the programmer's audible tones.

Tone	Occurrence
Keyboard Entry	Every time a key is pressed, the programmer sounds a short beep.
Error	When an incorrect key is pressed or an error displays, the programmer sounds a long beep.
Pump Search	When the programmer is searching for the pump's signal, it sounds a series of rapid clicks.
Telemetry Initialization	When the programmer finds the pump and initializes the connection, it sounds a steady tone.
Confirmation	When the programmer finishes inquiring or programming the pump, it sounds a quick multi-tone.

Instructions for Use

Programming and Inquiring the Pump

Sending messages to the pump is called programming and recieving the current information from the pump is called an Inquire.

Programming the pump is done after new data is entered into the programmer. This sends the new information to the pump so that it can be stored and carried out. The programmer informs you of when to program the pump by displaying a message that says, “Place Programmer Over Pump”. Then follow the instructions below under programmer orientation.

To perform an Inquiry, press the INQ button and follow the instructions below. An inquiry can be performed at any time and is particularly useful at the beginning and end of a programming session to verify/confirm the information in the pump.

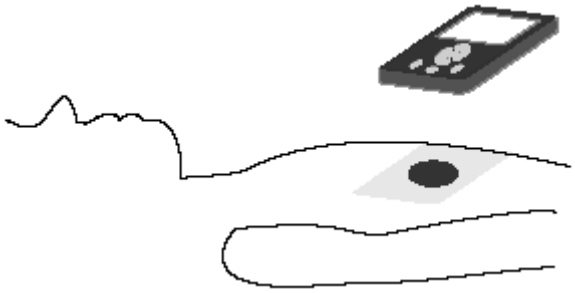
Both of these functions require that you place the programmer over the patient and pump in a specific manner, which is outlined below.

Programmer Orientation

The signal used to inquire and program the pump can travel about 5 cm (2 inches). If the programmer is not positioned close enough to the pump or is not oriented correctly over the pump, the programmer will not be able to communicate with the pump.

When prompted to place the programmer over the pump, follow these steps:

1. Horizontally position the programmer about 10 cm (4 inches) above the implanted pump. The programmer coil beneath the LCD panel should be parallel to the top of the pump.



Position of the Programmer over Pump

2. Slowly move the programmer toward the pump. As it tries to locate the pump, the programmer sounds a series of rapid clicks. Once it locates the pump, the programmer sounds a steady tone.

   Caution: Do not position the programmer too close to the pump. The signal requires at least 1.27 cm (0.5 inches) to initialize the connection.

3. Hold the programmer steady until the tone stops. The programmer tone lasts approximately 5 seconds. Once the transaction is complete, the programmer sounds a confirmation tone and a status screen appears.
4. The programming or inquiry is now complete.

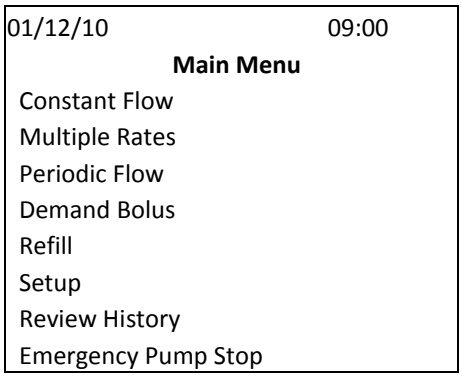
Data Entry

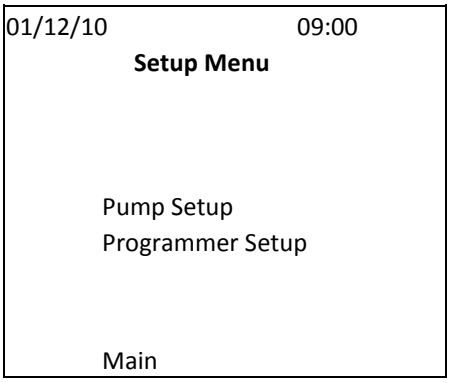
To	Do This
Put field in edit mode	Move cursor to highlight field and press SEL
Select menu option	Move cursor to highlight option and press SEL
Return to previous menu	Press CLR
Move cursor	Press ◀ and ▶ to move left and right Press ▲, and ▼to move up and down
Increase highlighted value	Press ▲
Decrease highlighted value	Press ▼

Programmer Setup

To reach the Setup Menu:

Select Setup from the Main Menu, then select Programmer Setup.

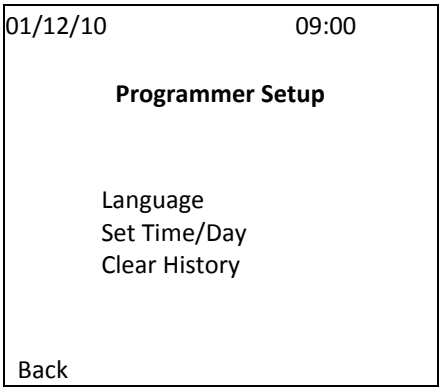




Set Language

To set the language:

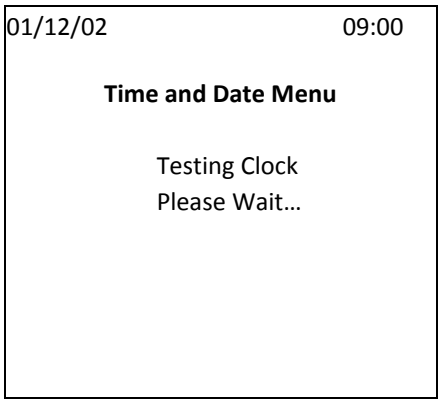
1. From the Programmer Setup Menu, select Language.
2. Use the arrow keys to select the language to be displayed on the programmer screen.
   Note: All subsequent screens will be displayed in the selected language.
3. You may now return to the Programmer Setup Menu or turn the programmer off.



Set Date and Time

To set the date and time:

1. From the Programmer Setup Menu, select Set Time/Day.
2. Select the field you want to change.
3. Use the keys to move the cursor to the number you want to change.
4. Use the arrow keys to change the values. Note that time values are based on a 24-hour clock.
5. After entering date and time values, press SEL.
6. The programmer saves the time and date and verifies that the clock is functioning properly. The screen displays a Testing Clock message during this process.
7. After about 2 seconds, the programmer displays the Programmer Setup Menu with the new date and time.



Clear History

The Clear History function allows you to purge all history records currently in the programmer's memory. The Programmer History is a record of all pump transactions and programmer-generated error messages. The programmer can store over 400 records.

Warning: When the programmer memory is full, the oldest records are automatically deleted as new records are added. The programmer does not display any warnings when the programmer memory is full.

To clear the programmer history:

1. From the Programmer Setup Menu, select Clear History.
2. Use the arrow keys to select Yes or No. The programmer returns to the Programmer Setup Menu.

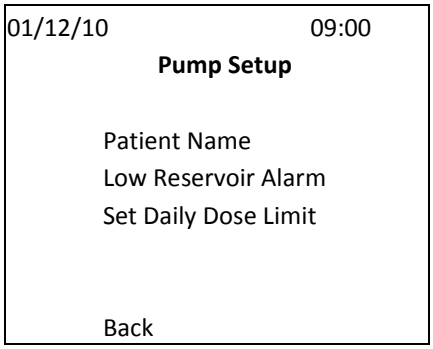
Pump Setup

The pump setup is typically done before the pump is implanted in the operating room. During the pump setup the following information can be programmed into the pump:

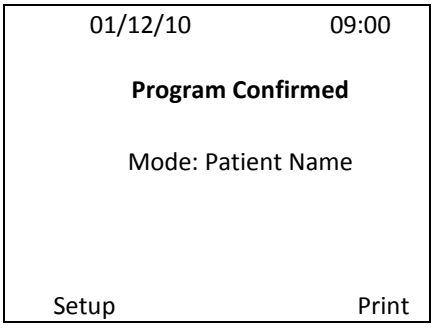
- Patient Name and/or Code
- The low reservoir alarm data
- Daily Dose Limits
- Refill Information
- Drug Information

To reach the Pump Setup Menu:
Select Setup from the Main Menu and then select Pump Setup.

Patient Name/Code



1. From the Pump Setup menu select Patient Name. If an Inquire function has already been performed, the programmer displays the Patient Name Menu.
2. If an inquiry has not been performed, perform an inquiry and select Next on the Pump Status Screen until the Daily Dose Limit Menu is displayed.
3. Enter patient name or code using the arrow keys to move through the alphabet, then press SEL.
4. To program a name into the pump, select YES and program the pump by following the on screen prompts.
5. Hold the programmer steady until the tone stops. Once the programming process is complete, the programmer sounds a confirmation tone and displays the Program Confirmation screen.



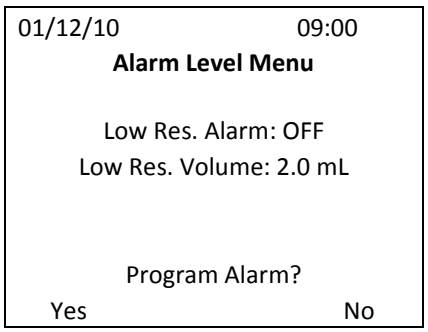
Low Reservoir Alarm

The Low Reservoir Alarm warns patients when the medication in the pump reservoir gets below a certain volume. The pump signals a low volume condition by sounding two short (1/4 second) beeps every 30 minutes. The alarm continues to sound until the pump is refilled, the Low Reservoir threshold volume is changed, or the alarm is disabled.

Warning: The Low Reservoir Alarm must be turned ON and the threshold volume programmed. When pumps are shipped from the factory, the Low Reservoir Alarm is set to OFF.

If the Low Reservoir Alarm is OFF, schedule regular refill visits to avoid reservoir depletion and possible patient discomfort. Patient should be advised to contact their physician if changes in their symptoms occur.

Programming the Low Reservoir Alarm



1. From the Pump Setup menu select Low Reservoir Alarm. If an Inquire function has already been performed, the programmer displays the Alarm Level Menu.
2. I If an inquiry has not been performed, perform an inquiry and select Next on the Pump Status Screen until the Alarm Level Menu is displayed.
3. Press SEL to edit Low Res. Alarm
4. Use the arrow keys to turn the low reservoir alarm ON and Press SEL to end editing.

5. Use the arrow keys to navigate to Low Res. Volume field
6. Press SEL to edit the Low Reservoir Volume set at the factory.
7. When shipped from the factory, the Low Reservoir Volume is set to 2.0 mL. Use the arrow keys to change the value.
8. To program the Low Reservoir settings into the pump, select YES and program the pump by following the prompts on screen.
9. Hold the programmer steady until the tone stops. Once the programming process is complete, the programmer sounds a confirmation tone and displays the Program Confirmation screen.

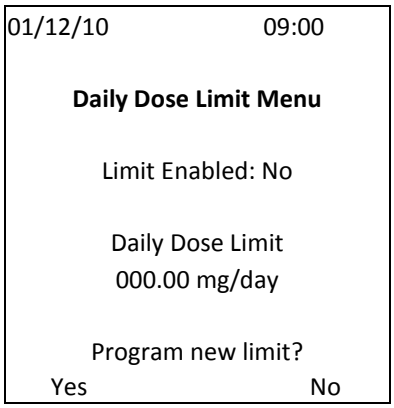
Daily Dose Limit

The Daily Dose Limit Menu allows you to impose limits on the medication dose that may be released in a 24-hour period in the **Constant Flow, Multiple Rates, and Periodic Flow regimens.**

Warning: The Daily Dose Limit does NOT limit Demand Bolus regimens.

Programming the Daily Dose Limit

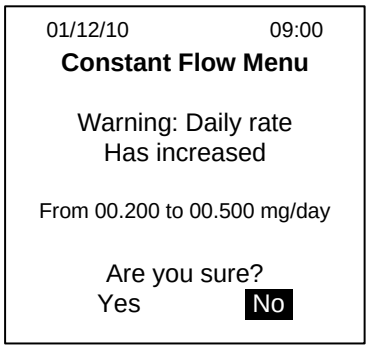
1. From the Pump Setup menu select Set Daily Dose Limit. If an Inquire function has already been performed, the programmer displays the Daily Dose Limit Menu.
2. If an inquiry has not been performed, perform an inquiry and select Next on the Pump Status Screen until the Dose Limit Menu is displayed.
3. To program the Daily Dose Limit settings into the pump, press SEL to edit and use the arrow keys to enable or disable the Daily Dose Limit.
4. Press SEL to enter and exit edit mode.
5. When shipped from the factory, the Daily Dose Limit is set to 0.000 mg. Use the arrow keys to navigate to Daily Dose Limit field and press SEL to edit.



6. Use the arrow keys to change the value and press SEL to enter.
7. To program the Daily Dose Limit settings into the pump, select YES and program the pump following the prompts on the programmer screen.

Note: Separate from the daily dose limit, a warning will appear when a dose is changed from the previous programmed dose. An example of a warning screen is shown below:

If values are confirmed, then use the arrow keys to highlight YES and press SEL. Follow prompts on the programmer's screen.



Programming Medication Regimens

The programmer always verifies the pump's information (i.e. patient name/code, serial number, etc.) before programming any information to the pump. If you attempt to program one patient's pump with the previous patient's information, the programmer returns a "Wrong Patient" error. To prevent this, it is good practice to turn the programmer off in between different patients.

Constant Flow Regimen

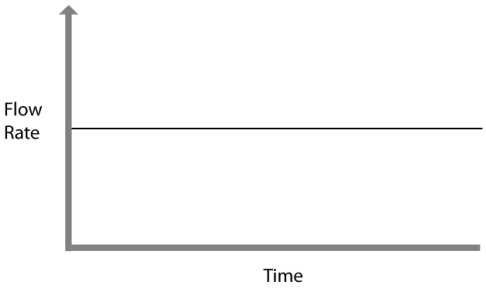
The Constant Flow regimen delivers medication at a constant rate. Program the daily medication dosage within the following limits:

	Value Limit	
Dose	Min	0.0 mcg 2.0 mcg to maintain catheter patency
	Max	999.999 mcg
Pump Delivery Rate	Min	0.0 mL/day 0.1 mL/day to maintain catheter patency (The pump accuracy has not been tested and is unknown for flow rates 0-0.045 mL/day)
	Max*	28.8 mL/day, or 1.2 mL/hr, or 20 mcL/min

**approximate based on pump's accumulator volume*

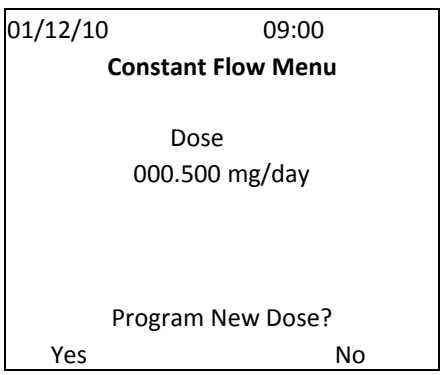
Caution: If you attempt to enter a value outside these limits, the programmer returns an error message.

Note: The drug type and concentration are entered in the Refill Menu.

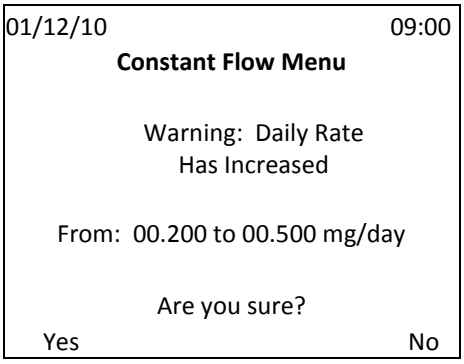


To program a Constant Flow Regimen:

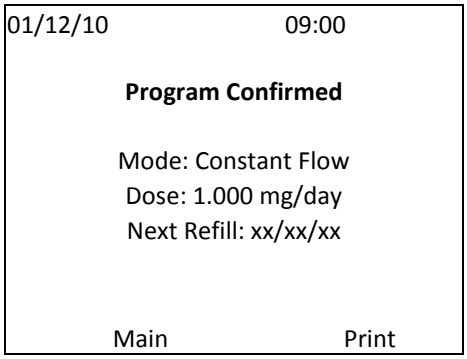
1. From the Main Menu, select Constant Flow. If an Inquire function has already been performed, the programmer displays the Constant Flow Menu.
2. If an inquiry has not been performed, perform an inquiry and select Next on the Pump Status Screen until the Constant Flow Menu is displayed.
3. Press SEL to select the Dose field, use the arrow keys to change the value, and press SEL to enter the information into the programmer.
4. Separate from the daily dose limit, a warning will appear when a dose is changed from the previous programmed dose. An example of a warning screen is shown below:



5. If values are confirmed, then use the arrow keys to highlight YES and press SEL. Follow prompts on the programmer's screen to program the Constant Flow Dose into the pump



6. Once the programming process is complete, the programmer sounds a confirmation tone and displays the Program Confirmation screen.



Multiple Rates Regimen

The Multiple Rates regimen delivers medication using one to four rates that repeat daily. For each prescribed rate, program the medication dosage and the time over which the dosage is delivered, within the following limits:

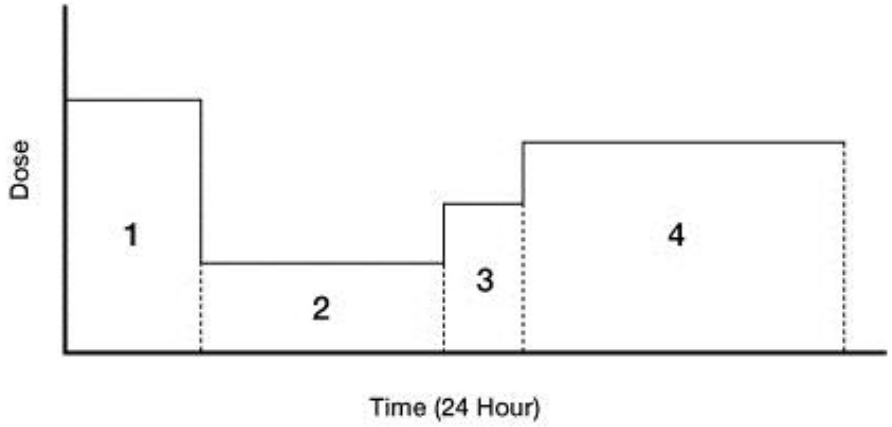
	Value Limit	
Dose	Min	000.000 mg
	Max	999.999 mg
Pump Delivery Rate	Min	0.0 mL/day during emergency pump stop 0.1 mL/day to maintain catheter patency (The pump accuracy has not been tested and is unknown for flow rates 0-0.045 mL/day)
	Max	28.8 mL/day, or 1.2 mL/hr, or 20 mcL/min
Single Duration	Min	1 min
Single Rate	Max	1.2 mL/hr
Sum of all rates	Max*	Daily Dose Limit, if programmed, OR 28.8 mL/day, if no Daily Dose Limit
Sum of all rate durations	=	24 hr

**approximate based on pump's accumulator volume*

Warning: To accurately synchronize a multiple rates regimen to real time, the programmer's real-time clock must be properly set. **Refer to *Programmer Setup* Section.**

Caution: If you attempt to enter a value outside these limits, the programmer returns an error message.

The drug type and concentration are entered in the **Refill Menu**.



To program a Multiple Rates regimen,

1. From the Main Menu, select Multiple Rates. If an Inquire function has already been performed, the programmer displays the Multiple Rates Menu.
2. If an inquiry has not been performed, perform an inquiry and select Next on the Pump Status Screen until the Multiple Rates Menu is displayed.
3. Use the arrow keys to navigate to the field to edit, then press SEL to enter edit mode.

01/12/10					09:00
Multiple Rates Menu					
	Dose		Start		End
1:	002.000	mg	00:00	to	06:00
2:	000.500	mg	06:00	to	09:00
3:	001.000	mg	09:00	to	00:00
4:	000.000	mg	—:—	to	—:—
003.500 mg			**24 hr 00 mn**		

Note: If the pump was previously programmed to a Multiple Rates regimen, the default start and end time is received from the pump during the initial Inquire process. Otherwise, the default start and end times are the current time.

3.1. To adjust the Rate 1 dose, press SEL to select the dose field, use the arrow keys to change the value, and press SEL to enter into programmer.

3.2. Once the dose is entered, use the arrow keys to navigate to the Start time field. Press the select key to enter edit mode and use the arrow keys to change the value, and press SEL to enter into programmer.

3.3. Once the Start time is entered, use the arrow keys to navigate to the End time field. Press the select key to enter edit mode and use the arrow keys to change the value, and press SEL to enter into programmer.

Note: The start and end time is set based on a 24 hour clock.
Note: If a time is entered that is greater than 23:59, the programmer will issue an error message that an invalid clock time was entered and not allow the user to exit without entering a valid clock time between 00:00 and 23:59.

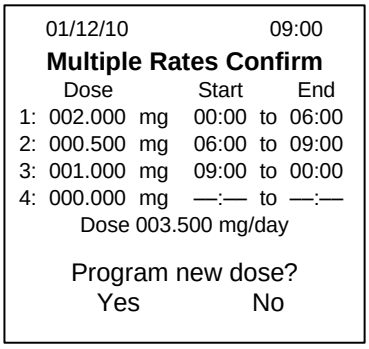
4. Press SEL to select the remaining fields you want to modify and use the arrow keys to change the dose and end time values for each prescribed rate.

Note: The Start time for Rates 2-4 will be automatically set based on the previous Rate's End time. The start time is not automatically populated until an end time for the new rate is entered.

5. When you have entered all the required values, press SEL to enter into programmer. All of the rate durations must add up to 24 hours. The start time of the first rate should be the same as the end time of the final rate.

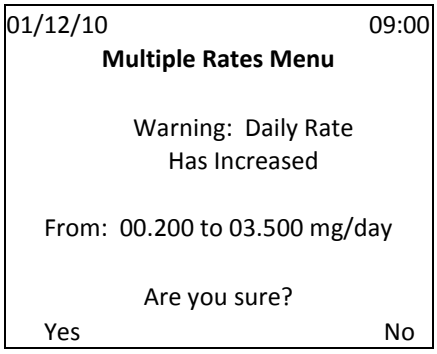
6. Use the arrow keys to move past forth rate line or the last field till the programmer displays the final Multiple Rates Confirm screen.

7. Confirm the start time, end time and dose information are correct in the multiple rate confirm screen. To program the Multiple Rates regimen into the pump, select YES.

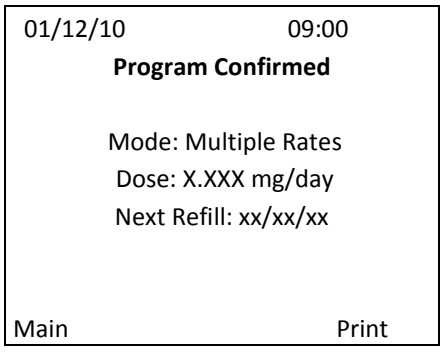


8. Separate from the daily dose limit, a warning will appear when a dose is changed from the previous programmed dose. An example of a warning screen is shown below:

9. If the values are confirmed, then use the arrow keys to highlight YES and press SEL. Follow prompts on the programmer's screen to program pump with new settings.



10. Hold the programmer steady until the tone stops. Once the programming process is complete, the programmer sounds a confirmation tone and displays the Program Confirmation screen.



11. To remove and clear a dose rate row from the multiple rate regimen, use the arrow keys to navigate to the row number which is to be removed. Press SEL to select the row number (edit mode) and then press CLR. A confirmation message asks you whether you want to clear the rate. Select YES to confirm.

Note: Cleared or blank rate rows cannot preceed other completed rate rows. The programmer will issue error messages that the end time or start times are not valid.

Periodic Flow Regimen

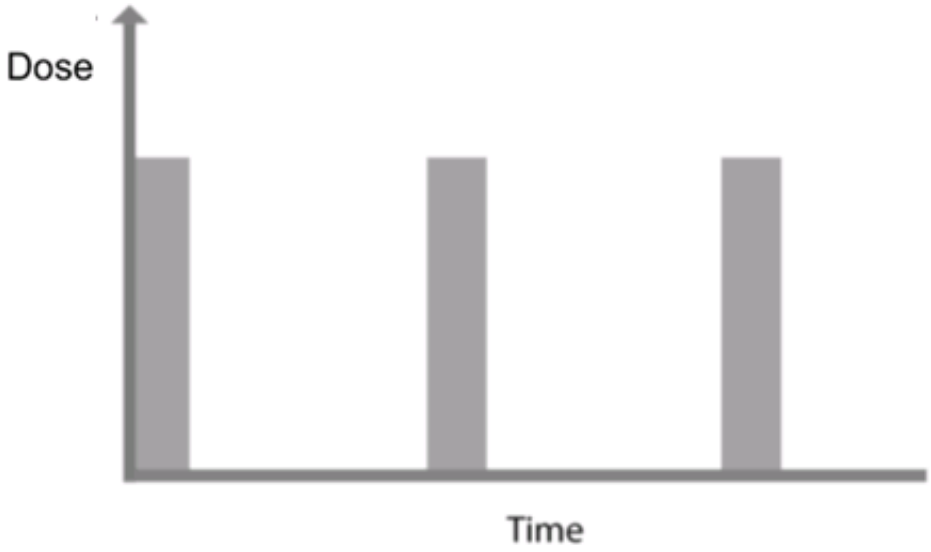
The Periodic Flow regimen delivers medication in a sequence of periodic infusions. Program the medication dosage, the time over which the dosage is delivered, and the interval at which the dosage is repeated, within the following limits:

	Value Limit	
Dose	Min	000.000 mg
	Max	999.999 mg
Pump Delivery Rate	Min	0.0 mL/day during emergency pump stop 0.1 mL/day to maintain catheter patency (The pump accuracy has not been tested and is unknown for flow rates 0-0.045 mL/day)
	Max	28.8 mL/day, or 1.2mL/hr, or 20mcL/min
Duration	Min	1 min
	Max	23:59
Repeat	Max	24:00
Single rate	Max	1.2 mL/hr
Sum of all rates	Max*	Daily Dose Limit (if programmed)OR 28.8 mL/day, if no Daily Dose Limit
Sum of all rate durations	=	24 hr

**approximate based on pump's accumulator volume*

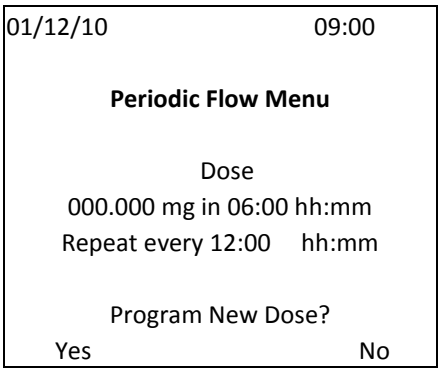
Caution: If you attempt to enter a value outside these limits, the programmer returns an error message.

The drug type and concentration are entered in the **Refill Menu**.



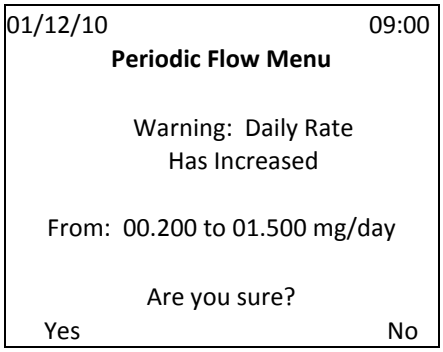
To program a Periodic Flow regimen:

1. From the Main Menu, select Periodic Flow. If an Inquire function has already been performed, the programmer displays the Periodic Flow Menu.
2. If an inquiry has not been performed, perform an inquiry and select Next on the Pump Status Screen until the Periodic Flow Menu is displayed.
3. Press SEL to select the field you want to modify and use the arrow keys to change the dose, duration and repeat values.
4. When you have entered all the required values, press SEL to enter into programmer.

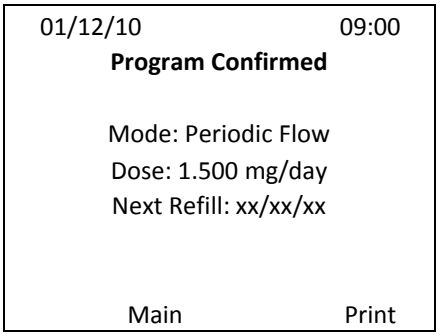


5. Separate from the daily dose limit, a warning will appear when a dose is changed from the previous programmed dose. An example of a warning screen is shown below:

6. If the values are confirmed, then use the arrow keys to highlight YES and press SEL. Follow prompts on the programmer's screen to program pump with new settings.



7. Once the programming process is complete, the programmer sounds a confirmation tone and displays the Program Confirmation screen.



Demand Bolus Regimen

The Demand Bolus regimen temporarily replaces the current regimen to either deliver an immediate, one-time infusion of medication, prime the implanted pump, or clear the fluid pathway for a new drug or drug concentration (bridge bolus). Program the medication dosage and duration, within the following limits:

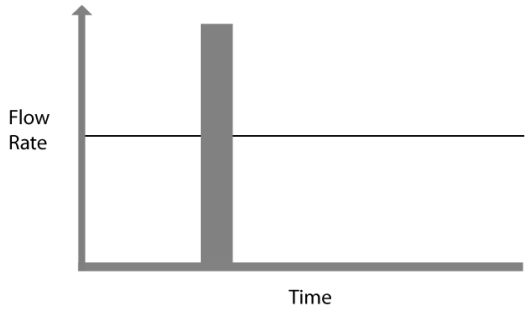
	Value Limit	
Dose	Min	000.000 mg
	Max	999.999 mg
Pump Delivery Rate	Min	0.0 mL/day for emergency pump stop 0.1 mL/day to maintain catheter patency (The pump accuracy has not been tested and is unknown for flow rates 0-0.045 mL/day)
	Max*	28.8 mL/day, or 1.2mL/hr, or 20 mcL/min
Duration	Min	20 min
	Max	23:59

**approximate based on pump's accumulator volume*

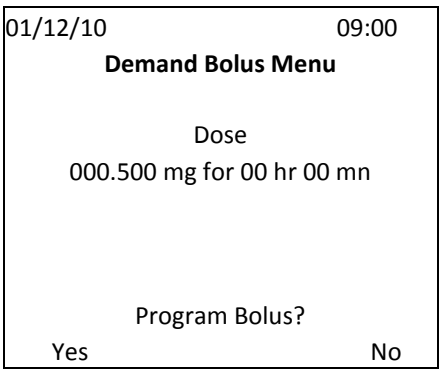
Note: the table below lists limits in addition to those listed above for all flow rates.

Warning: The bolus dosage is NOT limited by the Daily Dose Limit; therefore, you can program a bolus prescription that exceeds the Daily Dose Limit and the programmer will not issue a warning.

When the bolus finishes, the pump continues with its regularly scheduled flow regimen. The following diagram illustrates a Demand Bolus that was programmed while a Multiple Rates regimen was running. As indicated in the diagram, the bolus interrupts the pump's current medication regimen; however, the pre-existing medication regimen immediately resumes its schedule once the bolus is finished.



Caution: It is not possible to run two Demand Bolus regimens simultaneously. Therefore, if another bolus is currently running, the programmer will display a prompt to cancel the current bolus before allowing a new bolus to be programmed.

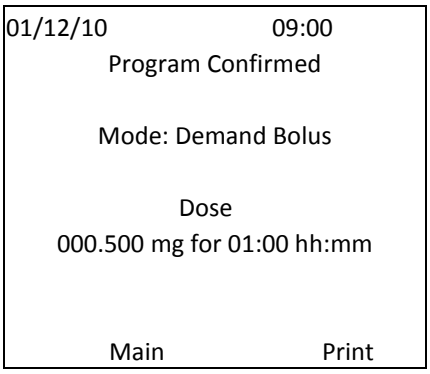


To program a Demand Bolus regimen:

1. From the Main Menu, select Demand Bolus. If an Inquire function has already been performed, the programmer displays the Demand Bolus Menu.
2. If an inquiry has not been performed, perform an inquiry and select Next on the Pump Status Screen until

the Demand Bolus Menu is displayed.

3. Press SEL to select the field you want to modify, use the arrow keys to change the dose and duration values. Press SEL to enter into programmer.
4. To program the Demand Bolus regimen into the pump, select YES and program the pump by following the prompts on screen.
5. Once the programming process is complete, the programmer sounds a confirmation tone and displays the Program Confirmation screen.
6. Once the Demand Bolus regimen is complete, the pump resumes its normal regimen.



Programming Refill Data

After refilling the Programmable Pump, you must enter information related to the procedure including the refill drug concentration and the volume of medication put into the pump. Additional information such as the name of the drug may also be entered.

Warning: Always carefully calculate refill concentration and bridge bolus dosages altering drug concentration or when changing solutions to prevent over- or under-medication. Always program a bridge bolus to clear all medication from the fluid pathway. Rinse the pump reservoir two times to clear it of any residual drug.

Consult the separate Calculations Guide for all calculations. For instructions on programming a bridge bolus, see the Demand Bolus Regimen section.

Refill Data

- After refilling the pump, enter the following data in the programmer:
- The volume of medication put into the pump.
- The name of the drug (if it has changed).
- The concentration of the drug (if it has changed).

The programmer uses this information to calculate the flow rate necessary for the pump to accurately deliver the patient's prescribed dosage.

When the Refill data is programmed to the pump, the programmer also reprograms the current medication regimen. This ensures that any changes that may affect the amount of medication being infused to the patient (such as drug concentration) are properly communicated to the pump. However, reprogramming the pump also restarts the current medication regimen. This means that Periodic Flow regimens always restart when a refill is programmed and Multiple Rate regimens resynchronize their schedule as per the start time entered for Rate 1. Constant Flow regimens are essentially unaffected because their schedule is fixed.

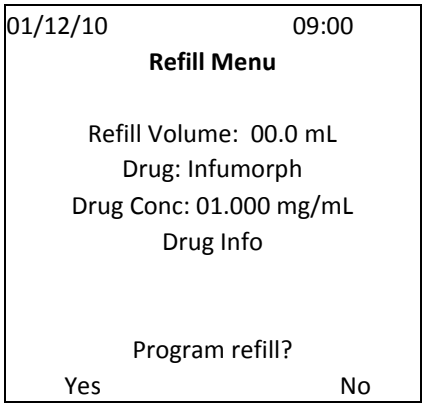
Refill Menu Field Definitions

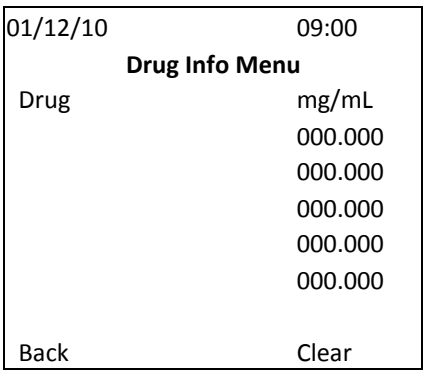
Field	Definition	Limits
Refill Volume	The volume of medication put into the pump.	Min 00.0 mL Max 20.0 mL
Drug	The name of the drug put into the pump.	Only one drug may be entered
Drug Conc.	The concentration of the drug put into the pump. The programmer uses the primary drug concentration to determine the flow rate necessary for the pump to accurately deliver the patient's prescribed dosage.	Only one drug concentration may be entered Max resulting flow rate 20 mcL/min, 1.2 mL /hr, or 28.8 mL/day
Drug Info	Opens the Drug Info Menu in which you may enter the names and concentrations of up to five drugs.	This is an information only field

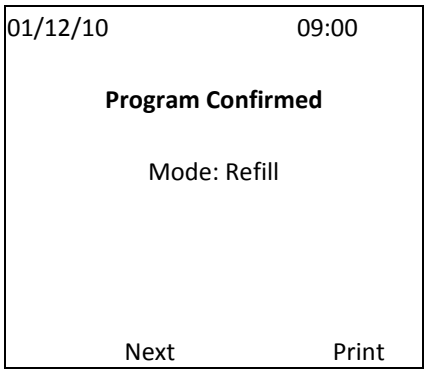
How to Program Refill Data

1. From the Main Menu, select Refill. If an Inquire function has already been performed, the programmer displays the Refill Menu.
2. If an inquiry has not been performed, perform an inquiry and select Next on the Pump Status Screen until the Refill Menu is displayed.
3. Press SEL to select the field you want to modify, use the arrow keys to change the Refill volume, drug and drug concentration values, and press SEL to enter into programmer.
4. If the medication consists of multiple drugs, select Drug Info to display the Drug Info Menu.
5. Press SEL to select a Drug field and enter the drug name using the arrow keys to move through the alphabet.
6. Select a concentration field and use the arrow keys to change the value.
7. When you have entered all the necessary information, select Back.
8. To program the Refill Information into the pump, select YES and program the pump by following the prompts on screen.

   Note: If the drug concentration was changed, the programmer also reprograms the refill prescription. If the new concentration entered results in a flow rate outside the pump's range, the programmer returns an error message and then displays the medication regimen menu so the prescription can be re-entered.

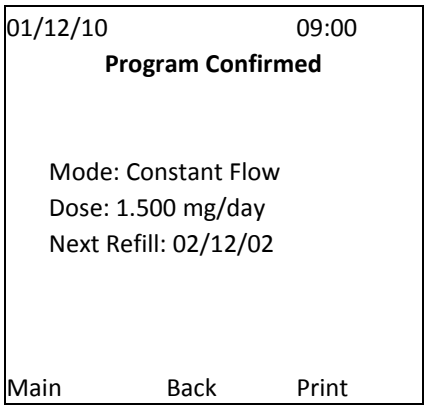






9. Once the programming process is complete, the programmer sounds a confirmation tone and displays the Program Confirmation screen. The programmer displays two Program Confirmation screens, one for the refill data and one for the medication regimen.

   Note: Periodic Flow regimens always restart after a refill is programmed. Multiple Rate regimens resynchronize their schedule as per the start time entered for Rate 1. Constant Flow regimens are unaffected.



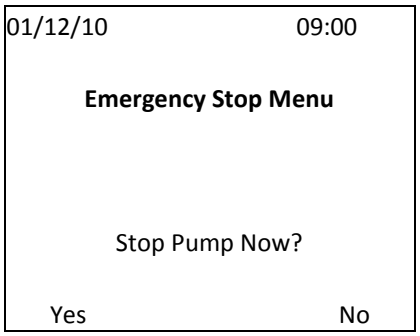
Pump Shutdown

Emergency Pump Stop

This is for temporary or emergency shut down only.

To Program the Emergency Pump Stop:

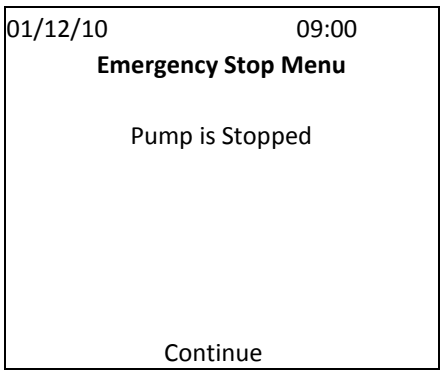
1. From the Main Menu, select Emergency Pump Stop.
2. Select No or press CLR to abort the process and return to the previous menu.
3. Select Yes to shut down the pump. The programmer prompts you to "Place the Programmer Over Pump."
4. Now do one of the following:
   a. To cancel the pump shutdown and return to the Main Menu, select Cancel.
   b. To execute the pump shutdown, hold the programmer approximately 5 cm (2 in.) above the implanted pump as if you are programming it.



   Note: An emergency pump shutdown bypasses the normal beaconing process; therefore, the programmer only sounds one or two clicks before stopping the pump. This operation takes milliseconds to complete.

5. Once the pump is stopped, the programmer returns the message "Pump is Stopped."

   Note: The pump will sound the critical alarm and will continue to do so about every 30 minutes. To prevent this, follow the instructions below if the pump is being shut down permanently.



6. The Pump function remains suspended until the Pump is reprogrammed.
7. Now do one of the following:
   a. Select Continue to return to Main Menu.
   b. Turn the programmer off.

When using the Emergency Pump Stop option, the pump will continue to set off the Critical Alarm until reprogrammed. To prevent this if the pump is permanently shut off, program the pump to a constant flow regimen at 0.0 mg/day.

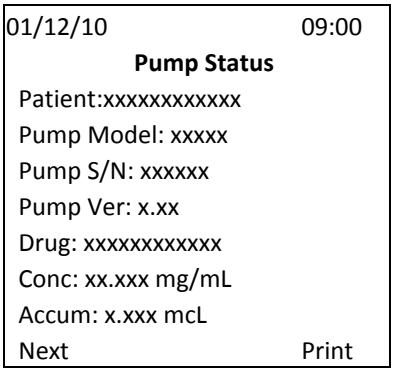
Note: For instructions on how to program a constant flow regimen refer to the Programming Medication Regimens section.

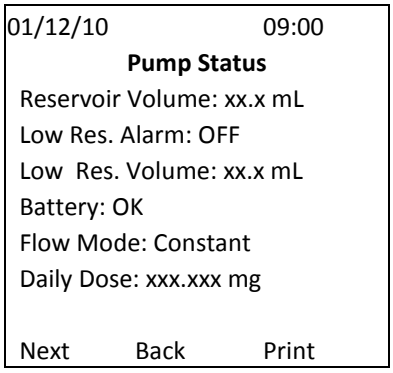
Pump Status Screens

During the Inquire process, the programmer retrieves the pump's current information. After the programmer Inquires the pump, it displays this information in the Pump Status screens.

The Pump Status screens vary according to the pump's current medication regimen. The following sections display the corresponding Pump Status screens for the Constant Flow, Multiple Rates, Periodic Flow, and Demand Bolus regimens with accompanying explanations of the information in each screen.

All flow regimens use the following Pump Status screens. For the constant flow regimen, these are the only two status screens.

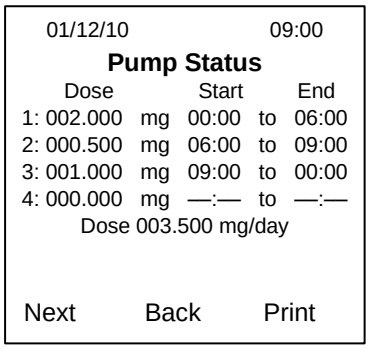


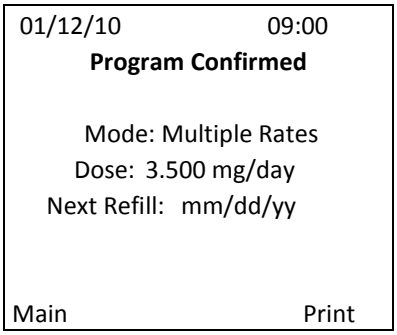


Field Name	Description
Patient	The patient name/code stored in the Prometra Programmable Pump. The patient name/code is programmed through the Pump Setup Menu.
Pump Model	The pump model number. The pump model is programmed at the factory.
Pump S/N	The pump serial number. The serial number is programmed at the factory.
Pump Ver	The version number of the software loaded in the pump.
Drug	The drug currently in the pump reservoir. The drug name is programmed through the Refill Menu.
Conc	The concentration of the drug currently in the pump reservoir. The drug concentration is programmed through the Refill Menu.
Accum	The volume of drug delivered during each pump accumulator cycle. The pump accumulator is an intermediary chamber in the pump that meters out small amounts of drug. The programmer uses the accumulator volume to calculate the expected flow of medication between Refill procedures. This pump accumulator volume is unique to each pump and is programmed at the factory.
Reservoir Volume	The amount of medication the pump thinks is currently in the pump reservoir.
Low Res. Alarm	The Low Reservoir Alarm status. This option is either "ON" or "OFF."
Low Res. Volume	The threshold volume at which the Low Reservoir Alarm is triggered.
Battery	The pump battery status.
Flow Mode	The pump's current medication regimen.
Daily Dose	The medication dosage the pump delivers over a 24-hour period for the current Constant Flow regimen. This value does not include any bolus dosages.

Multiple Rates Regimen

In addition to the pump status screens shown above, the Multiple Rate Regimen also uses the following screens.

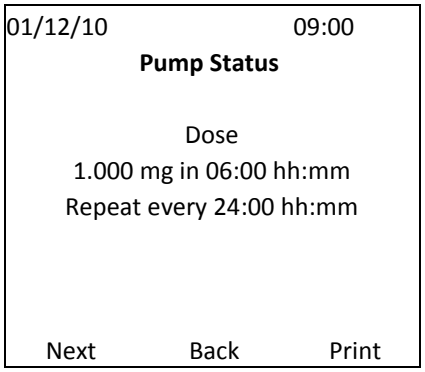




Field Name	Description
1-4	The rates programmed for the current Multiple Rates regimen. A Multiple Rates regimen can have up to four programmed rates that repeat daily. The currently active rate is highlighted. Each line lists the medication dosage and duration for the current rate. If a rate is not programmed, the dosage and duration values are zero.

Periodic Flow Regimen

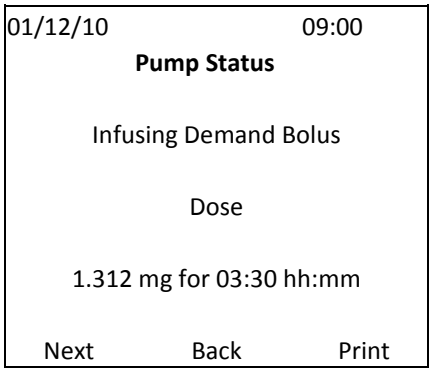
In addition to the pump status screens listed above, the Periodic Flow Regimen uses the following screen.



Field Name	Description
Dose	The medication dosage and duration for the current Periodic flow regimen.
Repeat Every	The interval at which the dosage is repeated.

Demand Bolus Regimen

Because a Demand Bolus only temporarily overrides the pump's default medication regimen, the programmer first displays the default regimen's pump status screens and, following the standard pump status screen, it displays a single screen indicating a Demand Bolus is currently active.



Field Name	Description
Infusing Demand Bolus	The pump is currently executing a Demand Bolus.
Dose	The medication dosage and duration for the current Demand Bolus regimen.

Accessing Programmer Data

Every time the Prometra Programmer performs an Inquire function or programs information to the pump, it returns a series of Pump Status or Program Confirmation screens. This information may be reviewed in the Programmer History or printed. A log of all programmer error messages is available in the Programmer History.

Programmer History

The Programmer History is a record of both pump transactions, pump error messages and programmer error messages.

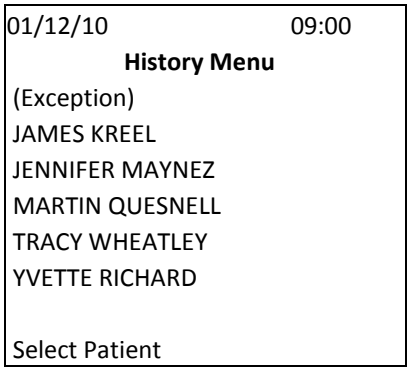
Pump transactions and pump errors are listed under their affiliated patient name/code. Under the patient name/code, records are sorted by date (in reverse chronological order) and transaction type.

Programmer error messages are found under the "Exception" entry. Programmer error messages are sorted first by date (in reverse chronological order) and second by record type.

The programmer can store over 400 records. When the programmer memory is full, the oldest records are automatically deleted as new records are added. Print programmer data at frequent intervals to archive these data records.

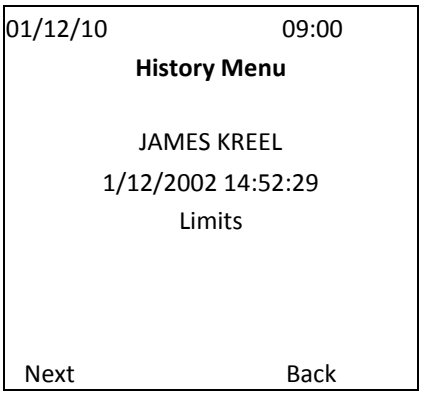
To View Programmer History:

1. From the Main Menu, select Review History. The programmer displays the History Menu.
2. To see a list of programmer messages, select Exception. The programmer lists programmer error messages in reverse chronological order.
3. To view the history of pump transactions for a particular patient, select the patient's name or code. The programmer lists the patient's pump transactions in reverse chronological order.
4. Select the record you would like to review using the arrow keys. The programmer displays the record's opening screen.



5.

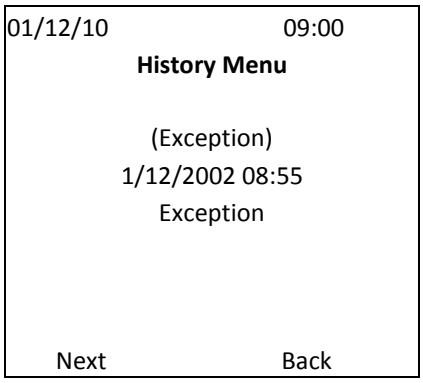
   a. Each pump transaction record begins with the patient name/code, the date and time of the transaction, and the record type.



b. Error message records begin with the error date, time and the record type (i.e. “Exception”).

6. Select Next to view the record data. This screen will indicate what the error is.

   Note: Once you reach the end of a record, selecting “Next” brings up the next record. The total number of screens in each record varies depending on the type of pump transaction or error message.

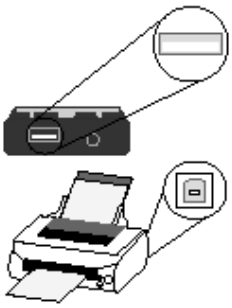


7. To return to the previous screen, select Back or press CLR.

8. To print a record, select Print.
9. Once the record has been reviewed, do one of the following:
   a. Select Next to continue through the history records in reverse chronological order. At the end of the last history record, the programmer returns to History Menu’s list of transactions or error messages.
   b. Press CLR to return to the previous menu.
   c. Turn the programmer off.

Printing Programmer Data

The programmer can output Pump Status, Program Confirmation, and History records to a printer by means of its USB port. Due to rapid changes in technology, please verify that the programmer interfaces with your printer first. If you need a list of compatible printers, please consult your sales representative or call Flowonix Medical. .



Pump transactions may be printed when initially displayed or when reviewed in the History Menu.

Using a USB cable, connect the programmer's USB port to the USB port located on the printer.

Note: Selecting “Print” prints the entire record, not just the current screen. Therefore, you do NOT need to select “Print” on every screen.

Printing During a Pump Transaction

In any one of the Pump Status or Program Confirmation screens, select “Print”.

Printing from the History Menu

1. From the programmer’s Main Menu, select Review History.
2. Select the name of the patient whose records you want to print.
3. Select the record you would like to print. The programmer displays the record’s opening screen.
4. Select Next to display the record data.
5. In the data screen, select Print.

Canceling a Print Job

To cancel the current print job, press the programmer’s CLR button. The printer has a memory buffer; therefore, if you cancel a print job, the printer may continue printing until the buffer is empty.

Troubleshooting

Programmer Error Messages

Programmer-generated error messages interrupt the current procedure to notify you of a problem. Some error messages provide information and you may immediately resume the procedure. Other messages require that you resolve the problem before you may continue the procedure. In a few rare instances, such as a critically low battery error, the programmer shuts down.

Programmer error messages are displayed as “Exceptions” on the programmer screen and History Menu.

Error messages include a unique numeric code. The numeric code helps Customer Service identify the exact nature of the problem.

The following table lists the programmer-generated error messages with descriptions and suggested solutions.

If programmer displays	It means	You should
ADC Electronics Error	The Analog to Digital Converter (ADC) failed its self-diagnostic test. The ADC is an electronic device that measures battery voltage. The programmer will still function but may not be able to determine when its batteries are low.	If the problem persists, contact Customer Service.
Amount entered with zero time	“0” was entered for the rate duration. The Multiple Rates, Periodic Flow, and Demand Bolus regimens require a duration that is greater than zero.	Enter a duration that is greater than zero.
Amount too large	The prescribed dose and duration require a flow rate that is faster than the pump is capable of delivering.	Reprogram the pump with either a smaller dose or a longer duration.
Amount too small	The prescribed dose and duration require a flow rate that is slower than the pump is capable of delivering.	Reprogram the pump with either a larger dose or a shorter duration.
Backup Battery Low	The programmer’s backup battery is low. The programmer will still function normally; however, it may periodically lose its time, date, and History information.	If the problem persists, contact Customer Service.
Critically Low Battery	The programmer’s primary batteries are critically low. This critical error shuts down the programmer.	Replace the programmer’s batteries.
Drug Concentration out of range	The drug concentration value entered during the pump refill operation exceeds the drug concentration allowed by the programmer.	Verify the drug concentration value is entered correctly.
Drug dose over limit	The prescribed drug dosage exceeds the Daily Dose Limit.	Either disable or increase the Daily Dose Limit or prescribe a lower dosage.
Duration too large for interval	This error message is specific to Periodic Flow regimens. The regimen’s duration	Re-enter the duration so it is less than the repeat value.

If programmer displays	It means	You should
	is greater than its repeat value.	
End time for rate X is not valid	Specific to the multiple rates menu. The start and end time of a rate are equal to each other or the user attempts to adjust a rate following a cleared row.	Re-enter the rate's end time so that it does not equal the start time or check all of the rates to ensure they total 24 hours and no cleared rows are in between rates.
Electronics Error	An electronics component in the programmer failed its self-diagnostic test.	If the problem persists, contact Customer Service.
History format error History records lost	The Programmer History files were corrupted; therefore, the programmer reformatted the history, erasing all existing records.	If the problem persists, contact Customer Service.
Invalid time was entered	The entered clock time in the multiple rates menu is greater than 23:59 and not a valid entry	Enter a clock time between 00:00 and 23:59.
Low Battery Replace Batteries	The programmer's primary batteries are low. The programmer will still function normally.	Replace the programmer's batteries.
Memory corruption History records lost	The memory storing the Programmer History was corrupted. The programmer reformatted the memory, erasing all existing records. Memory corruption may occur if the batteries fail while the programmer is trying to write a record.	If the problem persists, contact Customer Service.
No response from pump	The pump did not respond to the programmer signal.	Re-attempt to communicate with the pump. If the problem persists, contact Customer Service.
Out of Memory	The program requirements exceeded the available memory.	If the problem persists, contact Customer Service.
Prescription rejected by pump	The pump rejected the medication regimen. The pump may not accept the prescription if there is some error with the pump or if there is an error with the information being sent to the pump. Note: There is a minute possibility that electrical interference may corrupt data being sent to the pump. The system's multi-level integrity checking ensures the pump does not accept any erroneous data.	Reprogram the regimen. Reposition programmer and/or relocate patient to eliminate potential electronic interference then reprogram the regimen. If the problem persists, contact Customer Service.
Print job canceled	The current print job was cancelled by the user.	Press the CLR button on the programmer to return to the previous screen. Press Print again.
Printer error	The printer has encountered an error.	Turn the printer off and then on again to clear the error.
Printer not found	The programmer was unable to locate the printer.	Make sure the printer is connected to the programmer using a USB cable.

If programmer displays	It means	You should
		Make sure the printer is plugged in and turned on.
Printer out of paper	The printer is out of paper.	Add paper to the printer.
Printer Timeout	The printer is not responding.	Make sure the printer is connected to the programmer using a USB cable. Make sure the printer is plugged in and turned on.
Pump Information Error	The pump's information was corrupted, causing the pump to fail its integrity check.	Use the Emergency Pump Stop function to shut down the pump and contact Customer Service.
Start time for rate 1 is not valid	Specific to multiple rates menu. The start time of rate 1 has been cleared and the rate following the cleared row is adjusted	Enter a dose, start and end time for rate 1 and ensure the durations of all rates add to 24 hours.
Pump refill information error	The pump's refill information was corrupted, causing the pump to fail its integrity check. When this error occurs, the programmer cannot program a new prescription.	Use the Emergency Pump Stop function to shut down the pump and contact Customer Service.
Pump Stopped	The pump has stopped. This may be due to a critical pump error or the Emergency Pump Stop function.	If the pump has been stopped using the Emergency Pump Stop function, reprogram the pump. If the error is a result of a critical pump error, contact Customer Service.
Pump transfer interrupted	The programmer's transfer of information to/from the pump was temporarily interrupted.	Reposition the programmer over the pump and select "Yes" again.
Pump temporarily busy	The pump is currently accessing the memory the programmer wants to write to. The programmer is not allowed to write to the memory until the pump is done.	Retry the function until the error goes away. If the problem persists, contact Customer Service.
Real-Time Clock Not Set	The programmer's system clock contains invalid information.	Set the programmer's date and time. If the problem repeats contact Customer Service.
Software Error	The programmer detected an incorrect execution of the software.	Return the programmer to Customer Service for repair or replacement.
Times must add to 24 hours	This error is specific to Multiple Rates regimen. The cumulative rate duration is not 24 hours.	Re-enter the rate durations so they total 24 hours. Note: The duration total displays at the bottom of the Multiple Rates Menu.
Unknown Printer	The printer is not supported by the programmer.	Use a printer that the programmer supports.
USB Electronics Error	The USB port that connects the programmer to a printer failed its self-diagnostic test. The programmer will still function but will not print.	If the problem persists, contact Customer Service.

If programmer displays	It means	You should
Wrong patient	The patient information contained in the pump is different from the patient information that was received by the programmer during the Inquire process.	Prior to performing a programming operation, push INQ to update the programmer's patient information. If the problem persists, contact Customer Service.

Pump Error Messages

If during an Inquire or programming function the programmer receives an error message from the pump, the programmer displays the pump status before displaying the standard programming screens.

Each error message has a unique numeric code that displays in parentheses to the right of the status message. The numeric code helps Customer Service identify the exact nature of the problem.

The following table lists the pump-generated status messages with descriptions and suggested solutions.

If programmer displays	It means	You should
Battery Depleted	The pump's battery is depleted. This critical error shuts down the pump.	Contact Customer Service.
Electronics Error	An electronics component in the pump failed its self-diagnostic test. This critical error shuts down the pump.	Contact Customer Service.
Inlet Valve Failed	The electrical current consumed by the inlet valve is out of acceptable bounds. This critical error shuts down the pump.	Contact Customer Service.
Outlet Valve Failed	The electrical current consumed by the outlet valve is out of acceptable bounds. This critical error shuts down the pump.	Contact Customer Service.
Prescription Error	To ensure prescriptions are accurately implemented, both the programmer and the pump validate prescriptions before they are implemented by the pump. In the event the programmer check fails, the pump will reject any faulty prescription.	Change the prescription and reprogram the pump. If you get this error, report it to Customer Service with the exact prescription you tried to enter.
Pump Resetting	The Emergency Pump Stop function stops the pump by executing one of the pump's reset modes. If an Inquire is performed as the pump is resetting, the pump returns this error message.	Wait until the pump shuts down before attempting to inquire or program the pump. If the problem persists, contact Customer Service.
Pump Is Stopped	The pump has shut down.	Contact Customer Service.
Software Error	The pump's internal software check failed. This critical error shuts down the pump.	Contact Customer Service.

Telemetry Troubleshooting

The programmer interacts with the pump using a 2-way wireless communication link. The signal used to inquire and program the pump can travel about 5 cm (2 inches). If the programmer is not positioned close enough to the pump or is not oriented correctly over the pump, telemetry may fail. See the "Programmer Orientation" section.

Additionally, certain electronic equipment, such as MRI systems, may interfere with the system's telemetry. Moving the patient from the suspected source of interference should resolve the problem. If you are having problems connecting to the pump, refer to the Programmer Orientation section.

Calculations

Please refer to the appropriate supplementary **Calculations Guide**.

Service and Maintenance

Battery Installation and Replacement

Do not use rechargeable batteries. Rechargeable batteries have a lower current capacity and voltage than non-chargeable alkaline batteries and may fail due to the relatively high and instantaneous current loads required by the programmer.

To install or replace the batteries:

1. Turn the programmer off.
2. Remove the cover on the battery compartment.
3. If you are replacing the batteries, remove and discard the old batteries.
4. Insert three AA alkaline batteries as shown in the programmer's battery compartment.

The programmer also includes two permanent, lithium coin cell batteries that maintain the programmer's memory and real time clock. These batteries are designed to last for the expected life of the programmer; however, if you receive an error message indicating the programmer's backup battery is low, contact Customer Service for repair or replacement.

Service

The Prometra Programmer has no serviceable parts. For technical issues or questions about the programmer, please contact customer service.

Proper Care and Handling

- Do not drop the programmer or subject it to severe shock.
- Use at room temperature (operating temperature: 10 to 40°C).
- Store between +5 to 57°C.

Cleaning

If the programmer becomes dirty, clean with a slightly moist cloth and a mild soapy solution. Do not allow excessive moisture to enter the programmer. Do not immerse the programmer in any type of liquid.

Sterilization

Do not sterilize the programmer. If a sterile barrier is desired, place the programmer in a clear sterile bag or sleeve.

Specifications

Programmer Specifications

Height	15.49 cm (6.1 inches)
Width	8.382 cm (3.3 inches)
Depth	2.54 cm (1 inch)
Weight	• 311 g (10 oz) with batteries • 202.2 g (6.5 oz) without batteries
Telemetry Range	4.4 to 5.7 cm above the pump (2 ± 0.25 inches) Interference may occur in the vicinity of equipment marked with the following symbol:
Power Source	3 AA alkaline batteries
Operating Temperature	10º- 40º C (50º- 104º F) If the programmer is stored or transported in temperatures outside this range, allow it to return to the specified temperature range before use. Do not expose the programmer to freezing temperatures.
Storage Temperature	+5ºC to +57ºC Do Not Freeze.
Relative Humidity	The programmer is designed to operate in humidity conditions between 10-85% relative humidity without condensation.
Use Environment	The Programmable Pump and Prometra Programmer are suitable for use in all establishments.
Timeout	The programmer will automatically time out after 15 minutes of no communication or operation with the programmer.

Peripherals

The following peripherals are used with the programmer:

- Printer. The Prometra Programmer may be attached to a printer.
- Printer Cable. The printer cable is a standard USB peripheral cable. The cable length is 2 meters (6 feet).
- Printer Power Cord. The power cord is used to connect the printer to a wall supply. It is not supplied by Flowonix Medical.

Glossary

Accumulator: an intermediary chamber in the pump that meters out small amounts of drug. This volume of the accumulator chamber is used to calculate the expected flow of medication between Refill procedures.

Bridge Bolus: a Demand Bolus regimen that is used when changing drug concentrations or solutions. The bridge bolus prevents under- or over-medication of the patient while the old drug concentration is cleared from the fluid pathway.

Catheter Access Port: a port in the Programmable Pump that allows direct accesses to the catheter

Constant Flow Regimen: a programmable medication regimen that delivers medication at a constant rate. Program the dosage that is delivered every 24 hours.

Daily Dose Limit: the maximum dosage that may be prescribed in the Constant Flow, Multiple Rates, and Periodic Flow regimens.

Demand Bolus Regimen: a programmable regimen that temporarily replaces the default flow regimen to deliver an immediate, one-time infusion of medication. Program the medication dosage and the time over which the dosage is delivered. When the bolus finishes, the pump continues with its regularly scheduled flow regimen.
Exception: A programmer-generated error message. Exceptions are archived in the Programmer History.
Flow Rate: the rate at which the pump releases medication.
Fluid Pathway: the pathway the medication follows from the pump reservoir to the intrathecal space. The "Total" Pump Fluid Pathway includes the pump reservoir, the pump accumulator chamber and the implanted catheter. For measurements refer to the pump and catheter IFUs.
Inquire: a specialized transaction in which the programmer receives the pump's current information.
Low Reservoir Alarm: a pump alarm that warns the patient when the medication in the pump reservoir falls below a certain volume. Through the programmer's Pump Setup Menu, one can enable or disable the Low Reservoir Alarm and also set the threshold volume at which the alarm is triggered.
Multiple Rates Regimen: a programmable medication regimen that delivers medication using one to four rates that repeat daily.
Periodic Flow Regimen: a programmable medication regimen that delivers medication in a sequence of periodic infusions.
Programmer: a device that allows clinicians to conveniently and non-invasively interrogate and program the implanted Prometra Programmable Pump.
Programmer History: a record of all pump transactions.
Programmer Transaction: an operation that does not require interaction with the Programmble Pump; that is, the transaction only impacts the programmer.
Programming: any pump transaction that requires the programmer to send information to the pump. The following are programming functions: Constant Flow, Multiple Rates, Periodic Flow, Demand Bolus, Refill, and Pump Setup.
Pump Status Screens: display of the information received by the programmer during the Inquire process once the process is complete.
Pump Transaction: an operation in which the programmer sends or receives information from the pump.
Refill Volume: the volume of medication put into the pump during refill.
Telemetry: the process of transmitting and receiving data by wireless signals. The programmer interacts with the pump using telemetry.
USB Port: a high-speed port that transmits data between a computer and external peripherals using bi-serial transmission. The programmer has a USB port that allows printing of the programmer's history data to a printer.

Legal Notices

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Warranty

Flowonix warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase. Liability under this limited product warranty will be limited to repair or replacement of the defective product, at the sole discretion of Flowonix, or a refund of the net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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General Disclaimer

The examples of Prometra programmer screens shown in this manual are simulations, not exact reproductions of the programmer's screens. Every effort has been made to ensure that the contents of these sample screens are complete and accurate; however, there may be variations in appearance (text spacing, character font face, etc.) and default settings (default numbers and amounts) between the sample screens in this manual and the actual screens in the programmer.

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