PROMETRA®

CLINICIAN PROGRAMMER (REF 12828)

For use with Prometra® Programmable Infusion Systems
Software Version - 2.01.6

PTC®

PATIENT THERAPY CONTROLLER (REF 12860)

For use with Prometra® Programmable Infusion Systems
PTC® Software Version – 2.01.2

MR Unsafe

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

Symbols used in Labeling

Explanation of Symbols:
Refer to the package and product labeling to see which symbols apply to this product.

	Catalog number
	Serial number
	Date of manufacture
	Non-sterile
	Caution, consult accompanying documents
	Consult instructions for use
	MR Unsafe
	Keep dry
	Non-ionizing electromagnetic radiation
	Electrical Safety Type BF Applied Part
	Waste must be controlled according to local regulation and collection schemes for disposal of Batteries
Latex-Free	No patient or fluid contact with latex components
PVC-Free	No patient or fluid contact with polyvinyl chloride components
DEHP-Free	No patient or fluid contact with di(2-ethylhexyl)phthalate components
Nonpyrogenic	Non-pyrogenic
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
R	Refurbished Device

FCC Information

The following is communications regulation information on the Patient Therapy Controller and Clinician Programmer.

Clinician Programmer: FCC ID: A3LYPGI1, T7V1315
Patient Therapy Controller: FCC ID: T7V1315

These devices comply with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) these devices may not cause harmful interference and (2) these devices must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Changes or modifications to these products not authorized by Flowonix Medical, Inc., could void the FCC Certification and negate your authority to operate these products.

NOTE: "Harmful interference" is defined by the FCC as follows: Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

Software Version Information

Clinician Programmer Software Version: 2.01.6
Release Date: October 2020

To view the Clinician Programmer software version information on the Clinician Programmer:

1. From the main menu, select Setup.
2. From the Setup menu, select Administration.
    a. Then select Version Information.
    b. The screen will indicate the Clinician Programmer software Build version, Wand Revision, and UI (User Interface) Revision.

Patient Therapy Controller Software Version: 2.01.2
Release Date: March 2021
To view the Patient Therapy Controller software version information on the Clinician Programmer:

1. From the Main menu, select Setup.
2. From the Setup menu, select Patient Therapy Controller Setup
3. From the Patient Therapy Controller Setup menu, select PTC Administration.
    a. Then select PTC Version Information.
    b. The screen will indicate the Patient Therapy Controller software version, and serial number.

Software Version Compatibility Information

See tables below for information on Pump Model Compatibility with Clinician Programmer and PTC Software Versions and "Pump Model" Information Displayed on Inquiry Screen for Clinician Programmer Software Versions. Contact Flowonix Technical Solutions at 855-356-9665 if you require access to a Flowonix Clinician Programmer or PTC with upgraded software.

Pump Compatibility with Clinician Programmer and PTC Software Versions				
	Clinician Programmer software version 2.01.5 and higher	Clinician Programmer software versions 1.02.1, 1.03.2, 1.04.10, 2.00.29, 2.00.30	PTC software version 2.01.1 and higher	PTC software versions 1.00, 1.02, 2.00.10
Prometra 20 Ml (REF 11827	✓	✓	✓	✓
Prometra II 20Ml (REF 13827)	✓	✓	✓	✓
Prometra II 40 Ml (REF 16827)	✓	Not compatible, programmer displays "Communication Failed. Please try again"	✓	Not compatible, PTC will display "Bolus not delivered. Contact physician for pump refill. "

"Pump Model" Information Displayed on Inquiry Screen for Clinician Programmer Software Versions		
	Clinician Programmer software version 2.01.5 and higher	Clinician Programmer software versions 1.02.1, 1.03.2, 1.04.10, 2.00.29, 2.00.30
Prometra 20 Ml (REF 11827	Prometra 20 Ml	Prometra
Prometra II 20 Ml (REF 13827)	Prometra II 20 Ml	Prometra II
Prometra II 40 Ml (REF 16827)	Prometra II 40 Ml	Programmer displays "Communication Failed. Please try again." The Inquiry Screen is not displayed.

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Clinician Programmer General Information
Software Revision: 2.01.6

Clinician Programmer Description
The Clinician Programmer is a handheld, menu driven device external to the implanted pump, which enables wireless programming of the Prometra® System Programmable Pump[1].

The Clinician Programmer is also used to configure the Prometra® System Patient Therapy Controller (PTC®) for use with a single Prometra® Programmable Pump.

Indications
The Prometra® Clinician Programmer is indicated for use with the Prometra® Programmable Infusion Systems. It is intended to provide close-range wireless communication with the pump. The Clinician Programmer also enables the physician to program the parameters of the Patient Therapy Controller to deliver patient-activated supplemental doses of Infumorph®. The PTC should not be prescribed to a patient when the pump is administering intrathecal baclofen.

Contraindications
There are no known contraindications.

Warnings
WARNING: USE OF UNAPPROVED DRUGS (e.g., DRUG COCKTAILS, PHARMACY-COMPOUNDED DRUGS, MORPHINE WITH PRESERVATIVES, ETC.) WITH THE PROGRAMMABLE PUMP COULD RESULT IN PUMP FAILURE AND/OR SERIOUS ADVERSE EVENTS SUCH AS SEVERE UNDERDOSE, OVERDOSE OR DEATH.

- Always select and program approved drug dosages consistent with the drug labeling to prevent improper drug administration.
- To avoid electric shock or damage to the Patient Therapy Controller or Clinician Programmer, please avoid contact with water.
- Only use the Clinician Programmer and Patient Therapy Controller after receiving training specific to these devices. Use of these devices 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 approved drug labeling for appropriate treatment.
- Clinicians programming implanted programmable pumps and Patient Therapy Controllers 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 over-dose.
- 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 Clinician Programmer and Patient Therapy Controller use electromagnetic energy to communicate with the Programmable Pump. Their electromagnetic fields may affect other medical devices. Use or interference with other medical devices has not been established.

[1] The “Programmable Pump” refers to the Flowonix Medical Programmable Pumps, such as the Prometra Pump and the Prometra II Pump.

- 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.
- The Patient Therapy Controller cannot be used if the Daily Dose Limit for the implanted pump has been disabled. The Daily Dose Limit must be enabled prior to setup of the Patient Therapy Controller. Please refer to Pump Setup, More Options selection using the Clinician Programmer to enable the Daily Dose Limit.
- Patient Therapy Controllers with software versions prior to 2.01.1 and Clinician Programmers with software versions prior to 2.01.5 are not compatible with Prometra II 40 Ml pump. Contact Flowonix Technical Solutions at (855) 356-9665 for more information on software upgrades.
- Potential communication problems between the pump and Clinician Programmer and/or the pump and Patient Therapy Controller 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. If problem persists, contact Flowonix Technical Solutions at (855) 356-9665.
- Use of a power source other than those provided by Flowonix could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The Clinician Programmer and Patient Therapy Controller are not intended to be functional and used while they are being charged. All communication and programming functionality is disabled while charging.
- Use of the Clinician Programmer or Patient Therapy Controller adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Clinician Programmer or Patient Therapy Controller including cables specified by Flowonix. Otherwise, degradation of the performance of this equipment could result.
- **MRI Safety:** The Patient Therapy Controller and Clinician Programmer are MR Unsafe.

MR Unsafe

Precautions

- Carefully read and follow all instructions prior to use.
- Use of the equipment by untrained or non-qualified personnel could lead to serious harm to the patient.
- When finished programming a patient's pump, always turn off and then restart the Clinician Programmer prior to programming a new patient's pump. This practice avoids Clinician Programmer error messages should the user inadvertently attempt to program one patient's pump with data from another patient's prescription.
- The wireless communication signal used by the Patient Therapy Controller and Clinician Programmer to communicate with the implanted pump (referred to as telemetry) can travel about 2 inches (5 cm). If the Patient Therapy Controller or Clinician Programmer are not positioned closely enough to the pump or are not oriented correctly over the pump, they may not be able to communicate with the pump.
- Do not disassemble the Patient Therapy Controller or Clinician Programmer. Disassembling these devices may damage them or cause them to malfunction.
- Do not sterilize the Patient Therapy Controller or Clinician Programmer. Sterilization could damage the Clinician Programmer and/or Patient Therapy Controller.
- The Clinician Programmer is not intended to be disinfected by cleaning solutions or detergents. Exposure to disinfection procedures could damage the Clinician Programmer.
- As the Clinician Programmer is not intended to be sterilized or disinfected, precautions should be used to avoid cross-contamination when handling the Clinician Programmer.

- If it becomes necessary to use the Clinician Programmer within a sterile environment, such as a surgical field, ensure that a sterile barrier is established between the Clinician Programmer and the patient. Always use standard sterile technique as to avoid cross contamination.
- Certain electronic or electromagnetic equipment may cause interference with the programming procedure. Interference may also occur near equipment marked with the symbol shown at right. Move the patient from the suspected source of interference and attempt to reprogram. Examples of equipment that may cause interference include MRI equipment, 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 Clinician Programmer and Patient Therapy Controller.

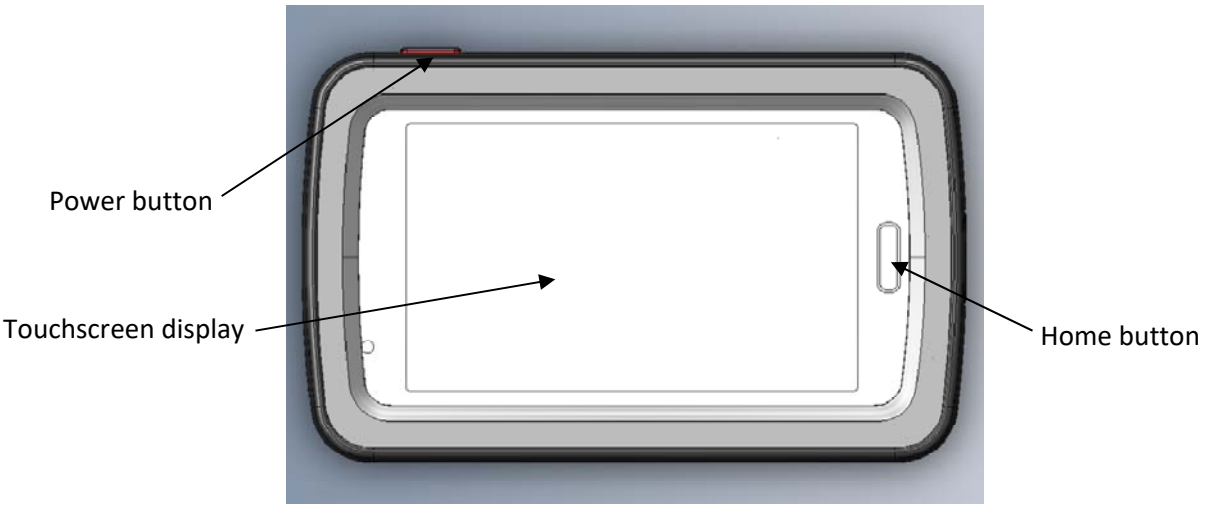
Potential Adverse Events

- Inability to program the implanted pump due to Clinician Programmer or Patient Therapy Controller failure or loss of telemetry.

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

Clinician Programmer Features

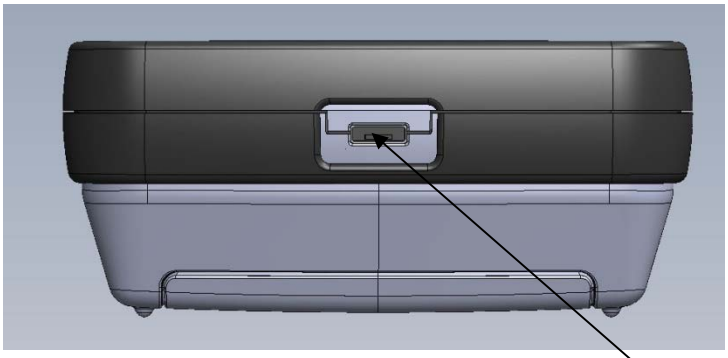
- Inquire the Programmable Pump to read the pump's current settings.
- Program the Programmable Pump to adjust pump settings including: flow regimens, patient and drug information, refill data, and emergency pump stop.
- A real-time clock on the Clinician Programmer, which is used to synchronize the pump to the appropriate date and time.
- A log of inquiry and programming events (reviewable and printable).
- Printer connectivity for printing inquiry and programming events.
- Bluetooth wireless communication to configure parameters of the Patient Therapy Controller
- Access to historical data and error logs stored on the Patient Therapy Controller



Front View

Clinician Programmer Front

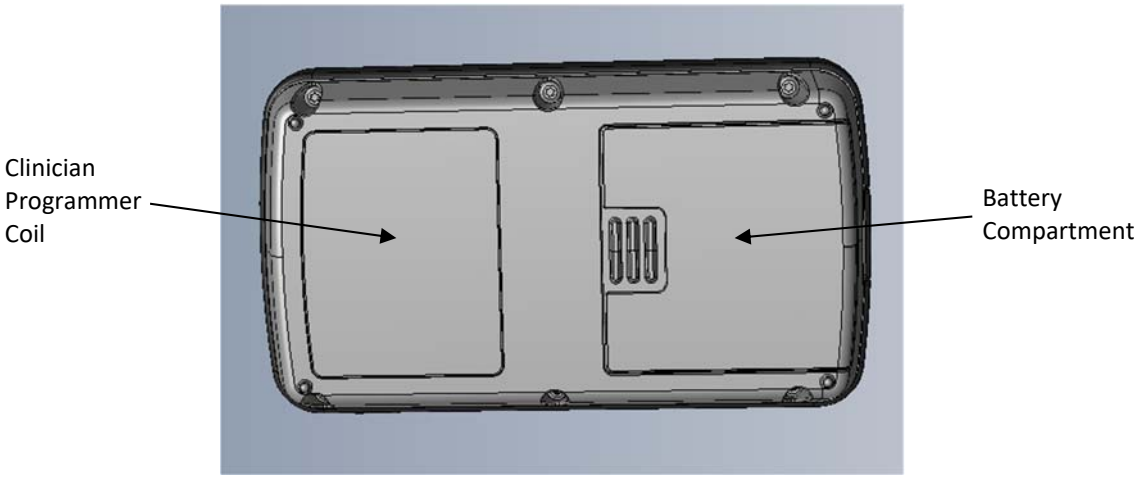
Component	Description
Touchscreen display	Allows user to interact with a menu-driven interface.
Power Button Usage	**Press and hold** the power button to turn the Clinician Programmer on. A short vibration will be felt upon successful activation shortly followed by the Flowonix Medical logo. Allow the system to power on and after five seconds, the main screen shall appear. If the Clinician Programmer does not respond, the internal battery may need to be recharged. If the device still does not respond after charging, please contact **Flowonix Technical Solutions: (855)-356-9665.** To turn the Clinician Programmer off, the power button must be held down for approximately two seconds; a menu will then appear with the choice to select: "Silent Mode", "Flight Mode", or "Power Off". Select "Power Off". The device will produce a short vibration to confirm that it has been successfully powered down and the screen will go blank. If the Clinician Programmer is on, pressing the power button a single time illuminates the LCD panel's backlight. Note: The Clinician Programmer automatically turns off after about fifteen minutes of inactivity and the screen will go blank.
Home Button	The Home button allows the user to go back to the main screen from any location screen.



Bottom View

Clinician Programmer Bottom

Component	Description
USB Port	The micro USB Port is used to charge the Clinician Programmer (via micro-USB to standard-USB cable). An AC adapter is supplied with the system. It also allows for connection to a PC to transfer data records.



Back View

Clinician Programmer Back

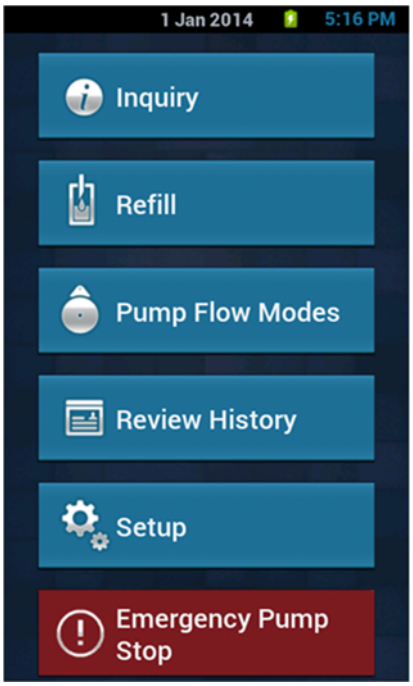
Component	Description
Clinician Programmer Coil	The Clinician Programmer coil emits the wireless communication signal used to interact with the pump. This coil must be placed directly above the pump to successfully send and receive data.
Battery Compartment	The telemetry coil is powered by three replaceable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

Clinician Programmer Principals of Operation

The Clinician Programmer performs three basic types of transactions: Clinician Programmer transactions (or adjustments of the Clinician Programmer's settings), pump transactions, and Patient Therapy Controller transactions. Clinician Programmer transactions only involve the Clinician Programmer; they do not affect the pump. Pump transactions transfer information between the Clinician Programmer and the pump. Patient Therapy Controller transactions transfer information between the Clinician Programmer and the Patient Therapy Controller.

Clinician Programmer Home Screen

When the Clinician Programmer is turned on, or the Home button is pressed, the home screen is displayed.



This screen allows users to easily navigate into any of the five main functions of the Clinician Programmer:

- Inquiry
- Refill
- Pump Flow Modes
- Review History
- Setup

In addition, there is an Emergency Pump Stop key located at the bottom of the home screen.

Status Bar

At the top of every screen, a status bar displays:

- Date
- Rechargeable Battery Status
- Clinician Programmer Internal Communication Icon
- Time

Main Menu Keys

At the bottom of each screen, except the home screen and the Emergency Stop screens, there is a main menu shortcut bar with five touch-buttons, which enables the user to quickly navigate to the five main functions found on the home screen.

Configuring the Clinician Programmer

Clinician Programmer functions can be accessed under the Setup function and its submenus. These features include:

- Language
- Date
- Time
- Brightness/Volume

Pump Transactions: Communication with the Pump

Clinician Programmer to pump communication falls into two categories:

- Inquiry transactions (downloading information ***from*** the pump)
- Programming transactions (writing information ***to*** the pump)

Inquiring the Pump

During an Inquiry transaction, the Clinician Programmer initializes a connection with the pump and receives the pump's current information via telemetry. Inquiring information from the pump does not change its settings; it simply downloads, stores and displays the pump's current information. The Clinician Programmer uses the information obtained during an Inquiry to perform calculations and provide values for other programming transactions. The Clinician Programmer must complete an Inquiry of the pump before any additional pump programming can be performed.

After the Clinician Programmer inquires the pump, it displays this information in the Pump Status screens. Inquiry information is displayed as a set of pages; these pages can be scrolled through by using the arrow keys at the top left and right corners.

On Page 1:

Field Name	Description
Patient	The last name followed by the First Name and Middle Initial of the patient currently stored in the pump. The patient name is programmed through the Pump Setup Menu.
Pump Model and Volume	The pump model number and volume (Prometra® 20Ml, Prometra® II 20 Ml, or Prometra® II 40 Ml). The pump model number and volume is programmed at the factory and cannot be changed.
Pump S/N	The pump serial number. The pump serial number is programmed at the factory and cannot be changed.
Pump Version	The pump software version number loaded in the pump. The pump version is programmed at the factory and cannot be changed.
Accumulator	The volume of drug in microliters delivered during each pump accumulator cycle. The pump accumulator is an intermediary chamber in the pump that meters out small amounts of drug. The Clinician 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.
Battery	The pump battery status. This information comes from the pump and cannot be changed.
Drug	The drug name entered by the user during a Refill operation and can be modified through the Refill Menu.
Concentration	The concentration of the drug entered by the user during a Refill operation and can be modified through the Refill Menu.
Reservoir Volume	The amount of medication that is currently computed to be in the pump reservoir based on the last programmed refill and flow regimen settings since the last refill.
Flow Mode	The pump's current basal mode regime. If the Flow Mode is constant, and the PTC is enabled, this field will be populated with "Const. & PTC".
Daily Dose	The medication dosage the pump is programmed to deliver based on the basal mode delivery over a 24-hour period. This value does not include any bolus dosages.
Max Daily Dose	The medication dosage the pump is programmed to deliver based on the Constant Flow daily dose and the maximum dose from the PTC over a 24-hour period. This field replaces the Daily Dose field when the Flow Mode is "Const. & PTC". Note: Max Daily Dose is used interchangeably with Total Maximum Daily Dose displayed on Page 2 of Inquiry when in Const. & PTC mode.
Low Reservoir Alarm	The Low Reservoir Alarm status. Either this option is "Disabled" or when "On", displays the reservoir volume that triggers the pump's Low Reservoir Alarm.
Daily Dose Limit	The Daily Dose Limit Status. Either this option is "Disabled" or when "On" displays the maximum allowed dose that the pump is allowed to deliver per day; including PTC boluses. The demand bolus cannot be greater than the Daily Dose Limit.

On Page 2:

Field Name	Description
Flow Mode Details	The basal mode that is programmed on the pump including the total daily dose regime and the next refill date. If the basal mode is Constant Flow and the PTC is enabled, the Maximum PTC Daily Dose, and the Total Maximum Daily Dose will be listed. The next refill date is the date when the reservoir volume is anticipated to have a volume of 3 Ml. The next refill date takes into account all flow mode programming and is calculated each time the pump is inquired or programmed with the Clinician Programmer.

On Page 3:

Field Name	Description
Pump Errors	If there are any errors currently occurring with the pump
Catheter Information	The catheter length in cm, catheter volume in Ml, or catheter information unknown as entered by the user in the Catheter Information menu
Physician Name	The first and last name of the physician as entered by the user in the Pump Setup menu
Physician Phone	The phone number of the physician as entered by the user in the Pump Setup menu
Patient Birthday	The birthday of the patient as entered by the user in the Pump Setup menu

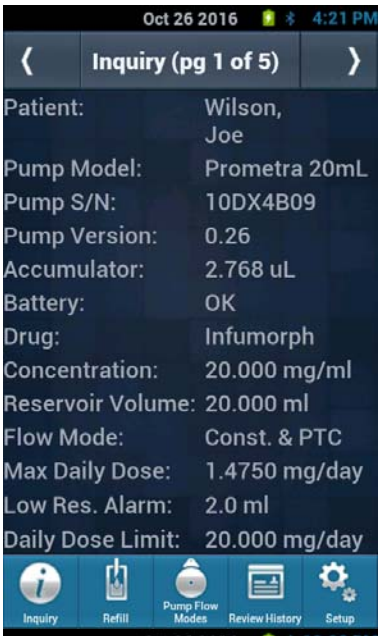
On Page 4:

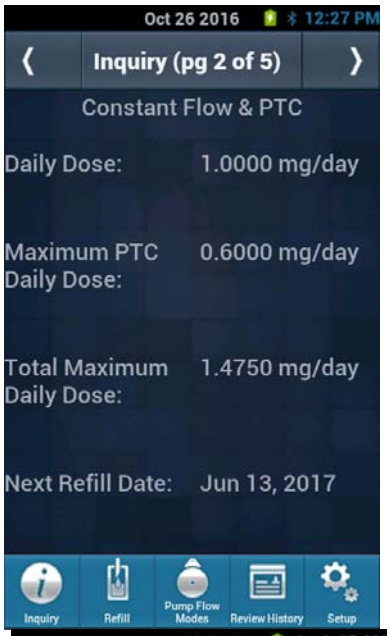
Field Name	Description
Drug log	The information for the drug inputted in the drug log under the Refill menu screen

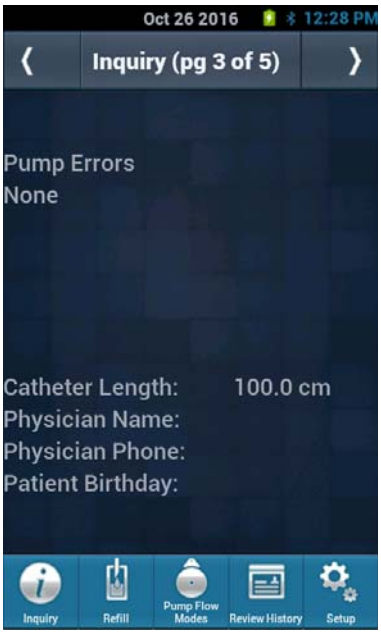
On Page 5:

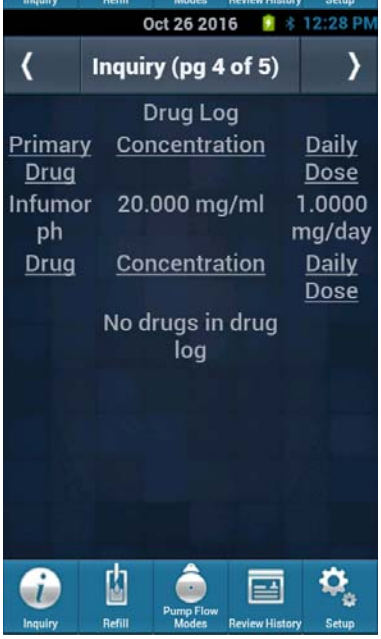
Field Name	Description
Note: The Following fields will appear only if a PTC is linked to the pump, otherwise “No PTC Linked to Pump” will be displayed.	
Serial Number	The serial number of the PTC linked to the pump. Note: If the PTC linked to the pump has a software version earlier than 2.00.10, then the serial number will be listed as Unknown
PTC Status	Enabled or Disabled. If Disabled, one or more of the following reasons would be provided: - Not in const. flow - Daily Dose Limit is too low - No daily dose limit - Bolus dose must exceed the const. flow
PTC Settings	The following PTC settings are provided for PTCs with software version 2.00.10 or later: - Dose per bolus - Duration - Lock-out Duration Post-Bolus - Allotted Boluses Per Day - Maximum PTC Daily Dose

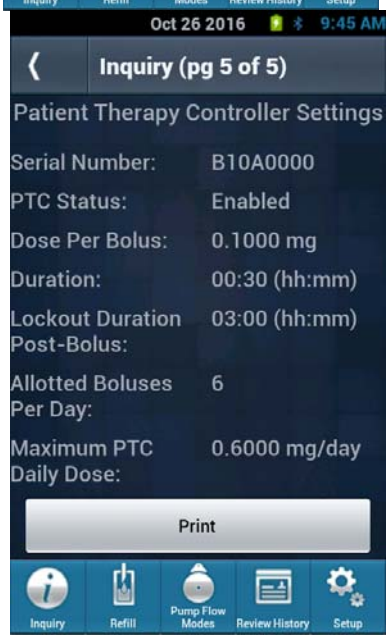
When the flow mode is Constant Flow & PTC, information related to both the basal dose and the PTC boluses are displayed on inquiry. Information related to the PTC boluses include the Maximum PTC Daily Dose, which is the maximum amount of medication the patient will receive in the form of PTC boluses if they were to use all of their allotted bolus per day. The Total Maximum Daily Dose is the maximum amount of medication the patient will receive in an entire day including the daily basal dose from the constant flow (Daily Dose) and the Maximum PTC Daily Dose. As shown on page 2 on the inquiry screens below, the Total Maximum Daily Dose is not equal to the Daily Dose and the Maximum PTC Daily Dose added together. Since the Daily Dose is interrupted while the PTC boluses are delivered, the Total Maximum Daily Dose will always be less the addition of the two doses.











Programming the Pump

Programming transactions write information to the pump. The following functions are pump program transactions:

- Refill
- Constant Flow
- Multiple Rates
- Periodic Flow
- Priming Bolus
- Bridge Bolus
- Demand Bolus
- Patient Information
- Physician Information
- Catheter Information
- Daily Dose Limit
- Low Reservoir Alarm
- Drug/Dosage Units

Clinician Programmer Audible Cues

The following table describes the Clinician Programmer's audible tones.

Tone	Occurrence
Touchscreen Entry	Every time a key is pressed, the Clinician Programmer sounds a short beep.
Pump Search	When the Clinician Programmer is searching for the pump's signal, it sounds a series of rapid clicks.
Telemetry Initialization	When the Clinician Programmer finds the pump and initializes the connection, it sounds a steady tone.
Confirmation	When the Clinician Programmer finishes inquiring or programming the pump, it sounds a quick multi-tone.
Error	When the communication is unsuccessful, a sound of rapid click is sounded by the Clinician Programmer

Instructions for Use of the Clinician Programmer

Inquiring and Programming the Pump

Receiving the stored information from the pump is called an Inquiry. Sending messages to the pump is called programming .

To perform an Inquiry, select the Inquiry button on the main menu or the Inquiry sub menu key and follow the instructions under Clinician Programmer Orientation section below. An inquiry can be performed at any time and is a critical step at the beginning and end of a programming session to verify and confirm the information in the pump.

Programming the pump is done after new data is entered into the Clinician Programmer. This process sends the new information to the pump so that it is stored and implemented.

To communicate with the pump, the Clinician Programmer directs the user to orient the Clinician Programmer close to the pump by displaying a message that says, “Place Programmer Over Pump.” Instructions for positioning the Clinician Programmer are detailed in the next section under Clinician Programmer Orientation.

Clinician Programmer Orientation

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

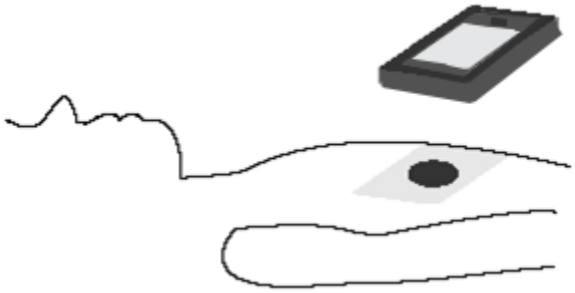
“Place Programmer Over Pump” is displayed prior to the start of an Inquire or Programming of the Pump.

“Inquire In Progress” is displayed when the programmer is communicating with the pump during an Inquiry.

“Programming In Progress” is displayed when the programmer is communicating with the pump during Programming.

When prompted by the above screen to place the Clinician Programmer over the pump, follow these steps:

1. Horizontally position the Clinician Programmer up to 2 inches (5cm) above the pump. The top of the Clinician Programmer should be parallel to the top of the pump as shown in the figure below.



Position of the Clinician Programmer over Pump

2. Slowly move the Clinician Programmer toward the pump. As it tries to locate the pump, the Clinician Programmer sounds a series of rapid clicks. Once it locates the pump, the Clinician Programmer sounds a steady tone. The Clinician Programmer screen will indicate if an Inquire or Programming is in Progress.

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

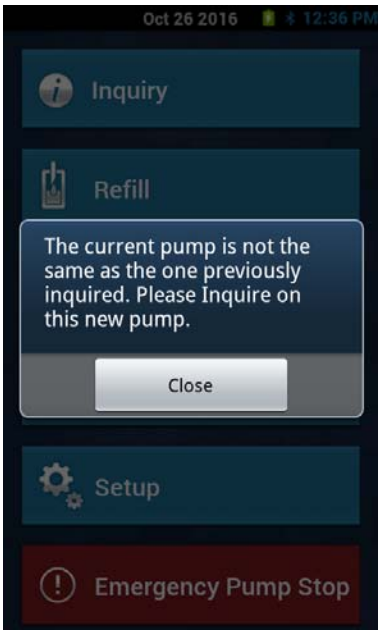
3. Hold the Clinician Programmer steady until the tone stops and the message changes on the Clinician Programmer screen. The Clinician Programmer tone lasts up to approximately ten seconds. Once the transaction is complete, the Clinician Programmer sounds a confirmation tone and the inquiry status or program confirmed screen appears.

   Note: If a transaction fails, it may be due to interference, the communication distance being out of range during inquiry or programming, or if the pump is conducting its daily diagnostic test.

   - **If this occurs during inquiry, the following message will appear:**
     "Pump Communication failed. Please try again"

   - **If a transaction fails during programming, you will see:**
     "Programming failed. Please re-enter values and try again."

4. The programming or inquiry step is now complete.

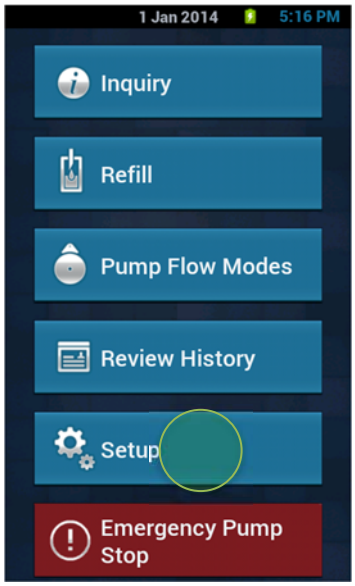


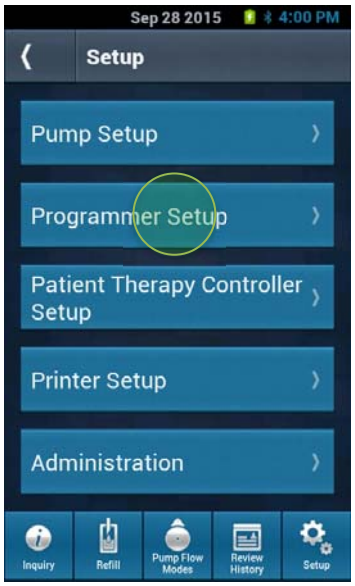
Warning: It is not possible to inquire and program more than one pump simultaneously, if this is attempted a warning will appear on screen to alert the user that the serial number does not match the initial inquired pump.

Clinician Programmer Setup

Setup Screen:

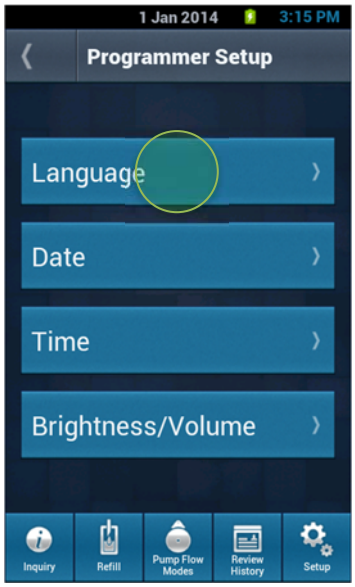
Select Setup from the Main Menu, and then select Programmer Setup.





Language

1. From the Clinician Programmer Setup Menu, select Language.



2. Select the desired language on the Clinician Programmer screen.

3. Confirm the language and all subsequent messages will be displayed in the selected language.

Date

1. From the Clinician Programmer Setup Menu, select Date.
2. Set the date and/or date format (mm/dd/yyyy or dd/mm/yyyy)

3. After entering date values and/or changing date format, select Confirm then Proceed
4. The Clinician Programmer updates the date and/or date format.
5. The Clinician Programmer displays the new date on the status bar.

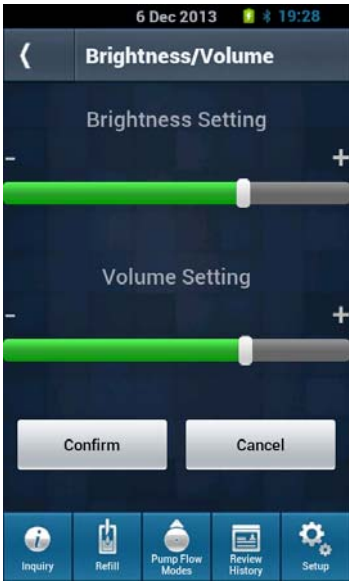
Time

1. From the Clinician Programmer Setup Menu, select Time.
2. Set the time and/ or time format (12 or 24 hour)

3. After entering the time and/or time format, select Confirm then Proceed.
4. The Clinician Programmer updates the time/time format.
5. The Clinician Programmer displays the new time/time format on the status bar.

Brightness/Volume

1. From the Clinician Programmer Setup Menu, select Brightness/Volume.
2. Set the brightness and/or volume level by using the slider bar. Left is the lowest value and right is the highest value.
   Note: The brightness and volume cannot be set to an OFF value.



3. After setting the brightness and/or volume setting, select Confirm then OK.
4. The Clinician Programmer saves the new value.
5. The Clinician Programmer updates the brightness and/or volume with the new setting.

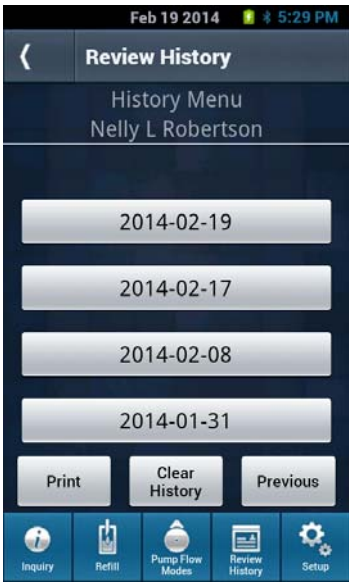
Review History

The Clinician Programmer History is a record of pump transactions. Pump transactions are listed under their affiliated patient name or date. Under the patient name, records are sorted by date (in reverse chronological order), and transaction type.

To view the Clinician Programmer history:

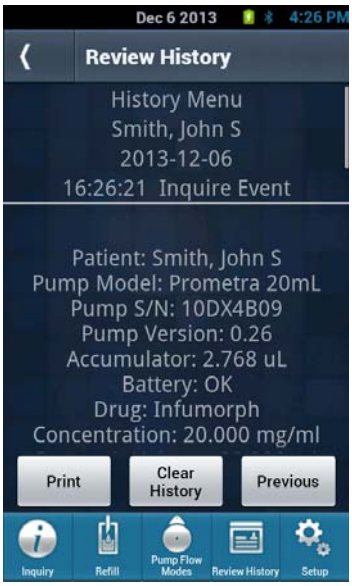
1. From the main menu, select Review History.

2. The records are displayed with a list of patient records in alphabetical individual order.
3. The records can be displayed by date by selecting Sort by Date.
4. Select the patient to view all of the date records for the patient.



5. Select the date to view all of the patient records for that day.

6. Select the event to view the details for the date.



7. Use the Previous key to view the data from the prior selection.
8. Use the Print key to print the current screen selection.

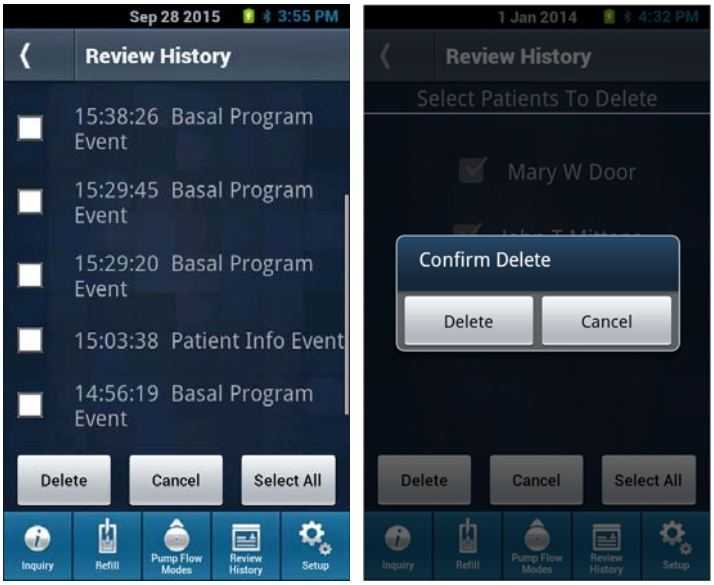
Clear History

The Clear History function allows the user to erase individual, multiple or all history records in the Clinician Programmer's memory. The Clinician Programmer History is a record of all pump transactions.

Warning: Deletions cannot be recovered once confirmed.

To clear the Clinician Programmer history:

1. From the Review History Menu
2. Select patients, dates, or events desired for deletion (select all to erase the entire range of records).
3. Select Clear History
4. Confirm Deletion prior to action taking place.



Pump Setup

It is recommended to set up the pump prior to it being implanted in the operating room. During the pump setup, the following information can be programmed into the pump:

- Patient Information including full name and date of birth
- Physician Information including full name and phone number
- Catheter length information (this information is required in order to perform a bridge bolus)
- Daily Dose Limit (Maximum amount of drug allowed in one day; including PTC boluses. The demand bolus is also limited by the Daily Dose Limit)
- Low Reservoir Alarm setting and volume (Ml)
- Drug/Dosage units (Programming can be performed in units of milligram or microgram)

The Pump Setup Menu:

Select Setup from the Main Menu and then select Pump Setup.

Patient Information

1. From the Pump Setup menu, select Patient Information. If an Inquiry function was performed, the Clinician Programmer displays the Patient Name Menu.
2. If an Inquiry was not performed, the system will prompt the user to place Clinician Programmer over pump. Review all of the inquired information and select Continue to enter the Patient Information.

3. Enter patient name: first name, middle initial and last name in separate lines.
4. Select the checkbox to enable Birth Date and enter the Date of Birth.
5. Select the Program key.
6. Confirm the Patient Information Programming.
7. Follow the screen instructions to program the Patient Information. Hold the Clinician Programmer steady until the tone stops. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with the programmed information.

Physician Information

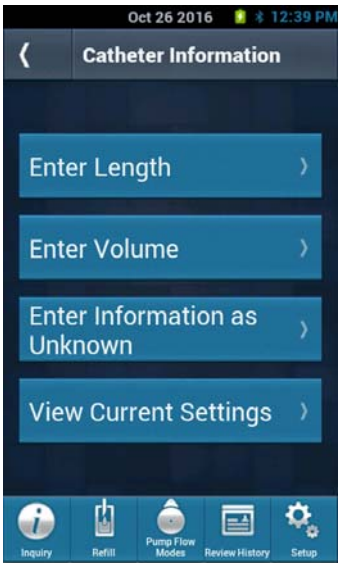
1. From the Pump Setup menu, select Physician Information. If an Inquiry function has already been performed, the Clinician Programmer displays the Physician Name Menu.
2. If an Inquiry has not been performed, the system will prompt the user to perform an Inquiry. Review all of the inquired information and select Continue to enter the Physician Information.

3. Enter physician name: first name and then last name in the same line.
4. Enter the physician's phone number including area code.
5. Select the Program key.
6. Confirm the Physician Information Programming.
7. Follow the screen instructions to program the Physician Information. Hold the Clinician Programmer steady until the tone stops. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with the programmed information.

Catheter Information

The Catheter Information must be set before programming any basal or bolus flow mode. If the catheter information is entered as Unknown, Catheter Priming Bolus (Prime Catheter, Prime Stem and Catheter, Prime Pump and Catheter) and Bridge Bolus (with and without aspiration) features will be disabled. The Catheter Information is mutually exclusive. If the Catheter Information is entered as a length, Catheter Length will be displayed on Page 3 of Inquiry. If the Catheter Information is entered as a volume, Catheter Volume will be displayed on Page 3 of Inquiry.

1. From the Pump Setup menu, select Catheter Information. If an Inquiry function has already been performed, the Clinician Programmer displays the Catheter information screen.
2. If an inquiry has not been performed, the system will prompt the user to perform an Inquiry.

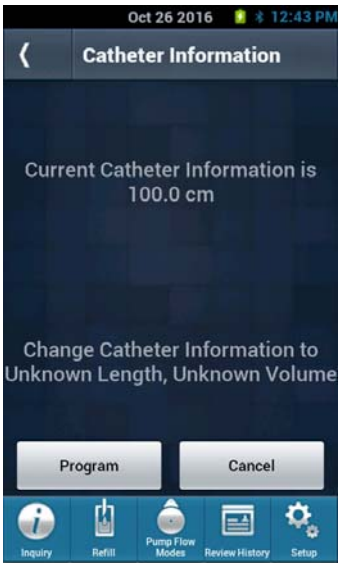


3. Select Enter Length, Enter Volume, Enter Information as Unknown, or View Current Settings.
    a. Entering Length
        i. Enter the total implanted catheter length in cm.
        ii. The Clinician Programmer will automatically calculate the catheter volume and the catheter + fluid pump pathway volume in Ml. (**Warning: These calculations are only valid when using a Prometra® Catheter**)
        iii. If the catheter length is less than 50 cm, a warning message will be displayed.
        iv. Select the Program key.
        v. Confirm the new catheter length.
        vi. Follow the screen instructions. Hold the Clinician Programmer steady until the tone stops. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with programmed information.

b. Entering Volume:
   i. Enter the total implanted catheter volume in Ml. The Clinician Programmer will automatically calculate catheter + fluid pathway volume in Ml.
   ii. If the catheter volume is less than 0.130 Ml, a warning message will be displayed.
   iii. Select the Program key.
   iv. Confirm the new catheter volume.
   v. Follow the screen instructions. Hold the Clinician Programmer steady until the tone stops. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with programmed information.

c. Entering Catheter Length/Volume Unknown:
   i. View the existing catheter information. (**Note: The catheter length and volume information will be cleared when the catheter information in set to unknown**).
   ii. Select the Program Key.
   iii. Confirm the new catheter information unknown (**Note: Priming Functions and Bridge Bolus functions will be disabled**).

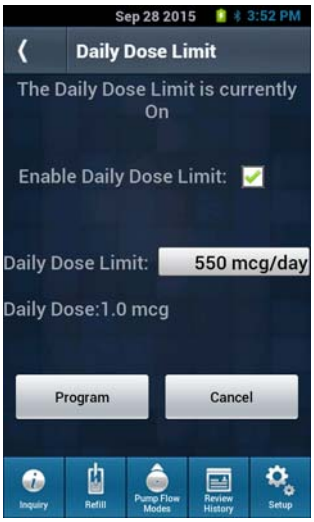
iv. Follow the screen instructions. Hold the Clinician Programmer steady until the tone stops. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with programmed information.



Pump Setup Menu (More Options selection)

Daily Dose Limit

The daily dose limit specifies the maximum amount of drug allowed to be delivered in a 24-hour period. This includes all basal flow mode programming and PTC boluses. Demand Boluses cannot exceed the Daily Dose Limit. Follow on screen direction to program.



The Daily Dose Limit screen displays the Daily Dose when in Constant, Periodic, or Multiple Rate Flow Mode (No PTC)

The Daily Dose Limit screens displayed the Daily Dose, Maximum PTC Daily Dose, and Total Maximum Daily Dose when in Constant & PTC Mode.

Note: The daily dose limit is disabled as default. In order to be used it must be enabled and an appropriate (physician selected) value programmed in the pump. A daily dose limit is required to allow the Patient Therapy Controller (sold separately) to function.

Low Reservoir Alarm (Low Res. Alarm)

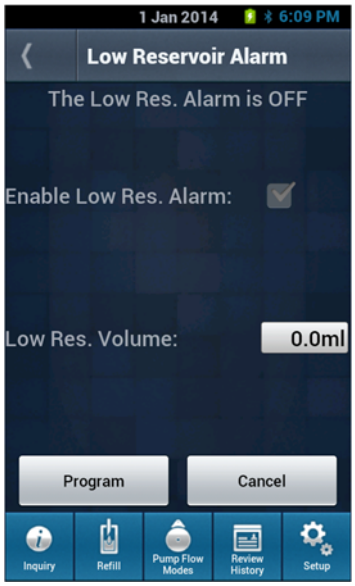
The Low Reservoir Alarm warns patients when the medication in the pump reservoir gets below a certain pre-defined volume. The pump signals a low volume condition by sounding two short (1/4 second) beeps every 30 minutes. The alarm continues to sound until the pump is refilled using the Refill function on the Clinician Programmer, 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. By default, the Low Reservoir Alarm is set to OFF.

If the Low Reservoir Alarm is OFF, make sure to schedule regular refill visits for the patient to avoid reservoir depletion and possible patient discomfort. The 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, More Options select the Low Reservoir Alarm. If an Inquiry function has already been performed, the Clinician Programmer displays the Alarm Level Menu.
2. If an Inquiry has not been performed, perform an Inquiry and select Next Page (>) on the Pump Status Screen until the Continue button is displayed to access the Low Reservoir Alarm screen.



Toggle the Low Reservoir alarm to either Off or On.

3. Enter the Low Reservoir Volume that has a range of 0.1 to 20.0 Ml for Prometra 20 Ml and Prometra II 20Ml pumps and a range of 0.1 to 40.0 Ml for Prometra II 40 Ml pumps.
   Note: When shipped from the factory, the Low Reservoir Volume is set to 2.0 Ml.
4. To program the Low Reservoir settings into the pump, select Program and confirm the Low Reservoir Alarm settings following the prompts on screen.
   Note: If a value above 3.0 Ml is entered, a prompt will appear indicating that the alarm may sound before the Next Refill Date.
5. Hold the Clinician Programmer steady until the tone stops. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with the programmed values.

Drug/Dosage Units

1. From the Pump Setup menu, More Options select the Drug/Dosage Units.
2. Toggle between milligrams and micrograms for the Drug Concentration and Dosage by using the "Yes" key to switch from the current setting to the alternate.
3. Confirm the change by pressing the Proceed button and program the pump.

After programming is complete, the new drug units are displayed in the program confirmation screen, press Continue to proceed. Thereafter all units for the Drug Concentration and Dosage shall be displayed in these programmed units.

Programming Pump Flow Modes

The Clinician Programmer always verifies the pump's information (i.e. patient name/code, serial number, etc.) before programming any information to the pump. If attempting to program one patient's pump with the previous patient's information, the Clinician Programmer returns a "Wrong Patient" error. To prevent this, it is good practice to turn the Clinician Programmer off in between different patients. Programming of the Pump Flow Modes is not complete until the Program Confirmed screen appears. It is good practice to perform a final inquiry to confirm that the Flow Mode was programmed properly. All programming steps can also be printed out from the Review History screens.

Constant Flow Regimen

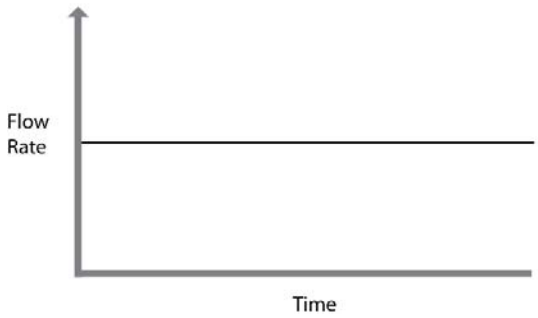
The Constant Flow regimen delivers medication at a constant flow rate. Program the daily medication dosage within the following limits:

Description	Value Limit	
Daily Dose	Min	0.0000 mg/day or 0.0 mcg/day
	Min (non-zero value)	0.0010 mg/day or 1.0 mcg/day
	Max	99.9999 mg/day or 99999.9 mcg/day
Pump Delivery Rate (For Reference Only)	Min	0.0 Ml/day (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 value based on average pump accumulator volume*

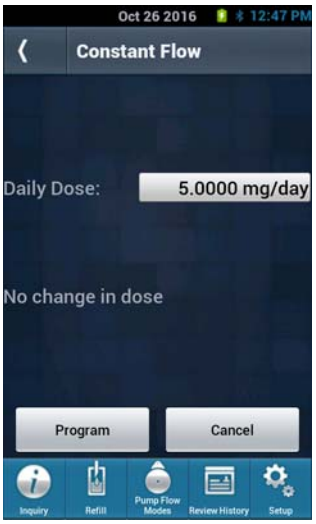
Notes:

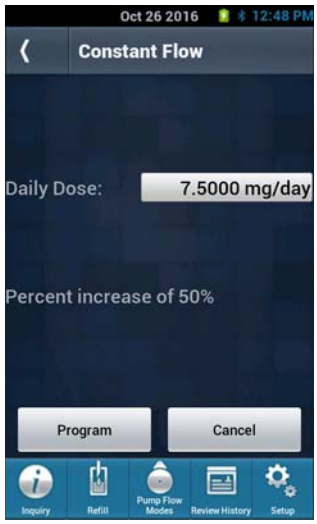
- The Clinician Programmer will not allow the entry of values outside of its allowable range.
- Setting the Daily Dose to 0.0 mg/day can be used to stop the pump delivery.
- The drug type and concentration value are entered in the Refill Menu.



To program a Constant Flow Regimen:

1. From the Main Menu, select Pump Flow Modes then select Constant Flow. If an Inquiry function has already been performed, the Clinician Programmer displays the Constant Flow Menu.
2. If an Inquiry has not been performed, the system shall prompt user to place Clinician Programmer over pump. Complete the inquiry and select Continue to enter the constant flow.
3. Enter the Daily Dose amount in either mg/day or mcg/day.
   (Note: Unit type is selected in Pump Setup -> More Options -> Drug/Dosage Units).
4. A warning will appear when a dose is changed from the previous programmed Daily Dose. The percentage change of the dose shall be displayed after the new Daily Dose has been entered.





5. Select the Program key and confirm the new Daily Dose.
6. Follow the prompts on the Clinician Programmer's screen to program the Constant Flow Dose into the pump.
7. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with the old and new settings. In addition, the next refill date is displayed.

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:

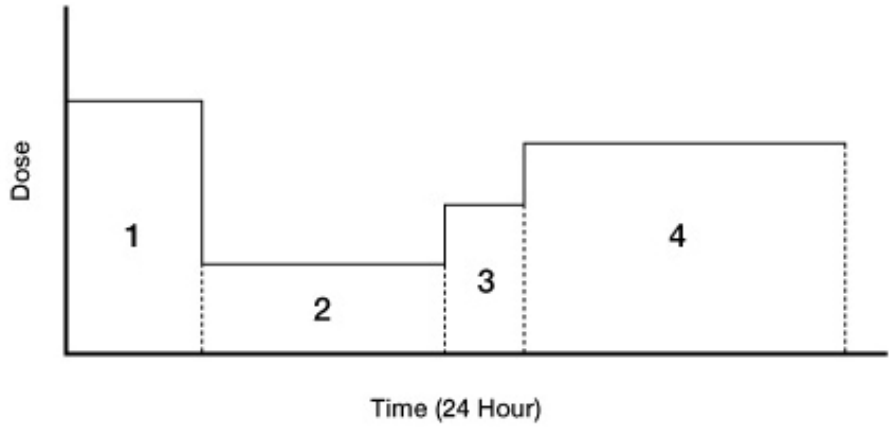
Description	**Value Limit**	
Dose	Min	0.0000 mg or 0.0 mcg
	Min (non-zero value)	0.0010 mg or 1.0 mcg
	Max	99.9999 mg or 99999.9 mcg
Pump Delivery Rate (For Reference Only)	Min	0.0 Ml/day (The pump accuracy has not been tested and is unknown for flow rates 0-0.045 Ml/day)
	Max*	28.8 Ml/day, or 1.2 Ml/hr, or 20 mcL/min
Single Duration	Min	1 min
Sum of all doses	Max*	28.8 Ml/day, or 1.2 Ml/hr, or 20 mcL/min
Sum of all rate durations	=	24 hr

**approximate value based on average pump accumulator volume*

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

Caution: Time should be entered in 24-hour periods and midnight is 00:00.

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

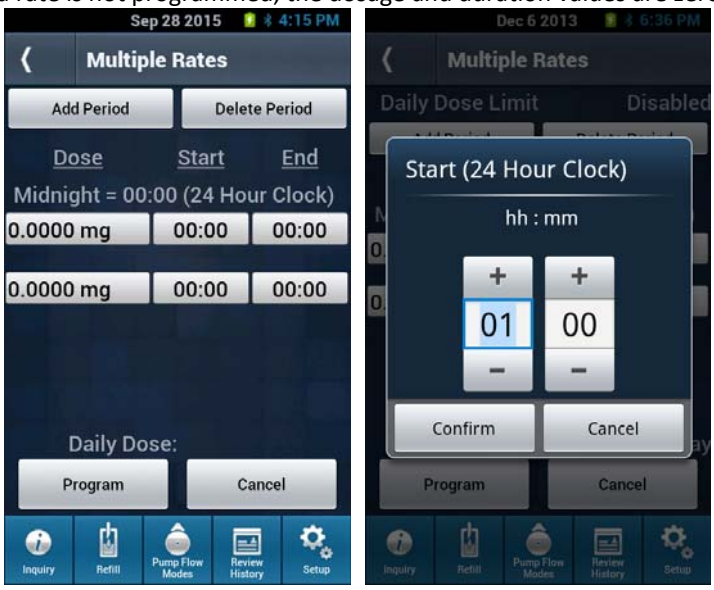


Example of a Multiple Rate Program

A Multiple Rates regimen can have up to four (minimum of two) programmed rates that repeat daily. Each line lists the medication dosage and duration for the current rate.

To program a Multiple Rates Regimen:

1. From the Main Menu, select Pump Flow Modes then Multiple Rates. If an Inquiry function has already been performed, the Clinician Programmer displays the Multiple Rates Menu.
2. If an Inquiry has not been performed, the system shall prompt user to place Clinician Programmer over pump. Complete the inquiry and select Continue to enter the Multiple Rates regime.
3. Enter the first period followed by the second period. Enter the dose and the start and stop time for the period. If a rate is not programmed, the dosage and duration values are zero.



Note: If the pump was previously programmed to a Multiple Rates regimen, the programmed start and end time will be displayed.

3.1. To adjust the Rate for period 1 dose, select the dose field and and enter the dose in mg or mcg.
3.2. Once the dose is entered, enter the Start time.
3.3. Once the Start time is entered, enter the End time.

Note: The start and end time is set based on a **24 hour clock, add 12 to all pm times (ie. 9pm = 9+12 = 21:00)**; **Midnight is indicated as 00:00.**

4. Select Add Period to enter a third period regime. Select the remaining fields to modify; enter 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.
   Note: Select cancel to clear all entries that have not yet been programmed.
5. To remove and clear a dose rate row from the multiple rate regimen, select the Delete Period.
6. When all required values have been entered, select Program. All of the rate durations must add up to 24 hours. (The Daily Dose will be calculated in real-time and displayed within this screen)
7. Once the values are confirmed, follow prompts on the Clinician Programmer's screen to program pump with new settings. The values to be programmed shall be shown on the screen for confirmation.
8. Hold the Clinician Programmer steady until the tone stops. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with the Old and New Settings.

Periodic Flow Regimen

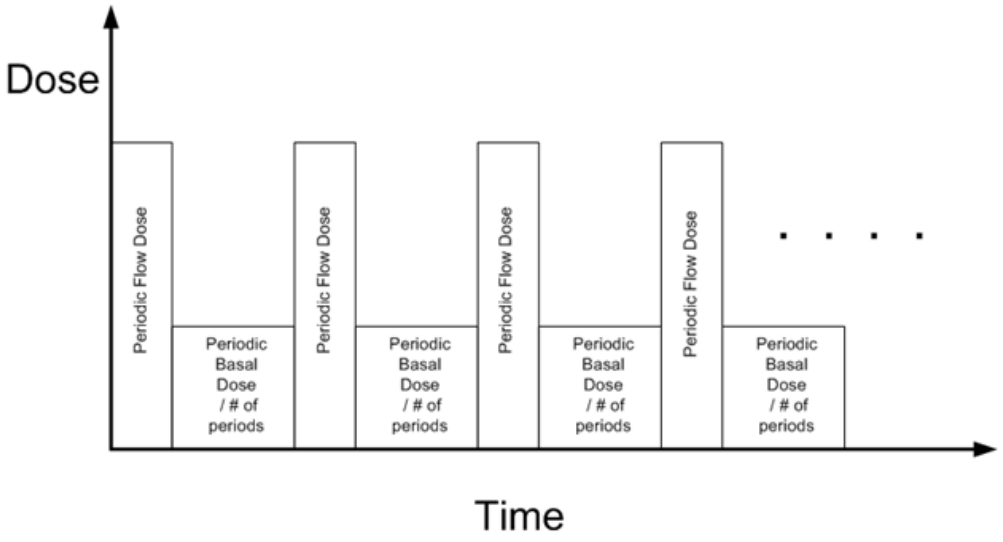
The Periodic Flow regimen delivers medication in a sequence of periodic infusions with a basal dose. The first period starts immediately upon programming. When the periodic infusion is not active, medication will be delivered according to the basal dose setting. Program the medication dosage, the duration of the dose, and the interval at which the dosage is repeated, within the following limits:

Description	**Value Limit**	
Daily Basal Dose	Min	0.0000 mg/day or 0.0 mcg/day
	Min (non-zero value)	0.0010 mg/day or 1.0 mcg/day
	Max	99.9999 mg/day or 99999.9 mcg/day
Periodic Dose	Min	0.0000 mg or 0.0 mcg
	Min (non-zero value)	0.0010 mg or 1.0 mcg
	Max	99.9999 mg or 99999.9 mcg
Pump Delivery Rate	Min	0.0 Ml/day (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 hh:mm
Repeat	Max	1 Hour (24 Periods)
Sum of all doses	Max*	Daily Dose Limit (if programmed) OR 28.8 Ml/day, if no Daily Dose Limit
Sum of all rate durations + intervals	=	24 hr

**approximate value based on average pump accumulator volume*

Caution: Attempting to enter a value outside these limits will cause the Clinician Programmer to return an error message.

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



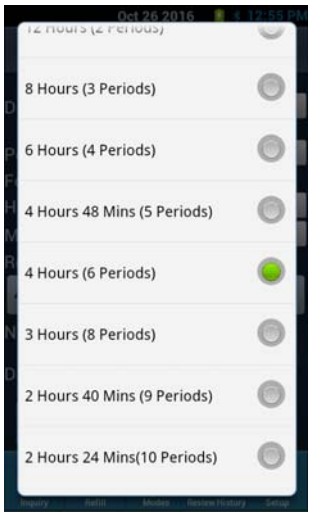
Example of Periodic Flow Regimen

To program a Periodic Flow regimen:

1. From the Main Menu, select Pump Flow Modes then Periodic Flow. If an Inquiry function has already been performed, the Clinician Programmer displays the Periodic Flow Menu.
2. If an Inquiry has not been performed, user will be prompted to place Clinician Programmer over pump. Complete the inquiry and select Continue to enter the Periodic Flow regime.
3. Enter the dose amount in mg or mcg. Next, enter the duration of the doses in hours and minutes separately (note for 90 minutes, enter 1 hour and 30 minutes) and select the number of dose periods based on the drop down menu. The amount of time between doses (dose period) must exceed the dose time otherwise an error will be displayed.

Field Name	Description
Daily Basal Dose	The dose amount for the entire day to be delivered between active intervals
Periodic Dose	The dose amount for that period
Duration of Dose	The total length of the period dose in hours and minutes
Repeat every	The number of dose periods over a 24 hour period

In the following example, the periodic dose of 0.25mg is delivered over 1 hour, six times a day. One sixth of the daily basal dose (0.1667 mg) is delivered over the remaining three hours in the four hour period. As a result, the total amount of medication that the patient will receive is equal to the perodic dose multiplied by the number of dose periods plus the daily basal dose (0.25mg x 6 dose periods + 1 mg = 2.5 mg/day).



4. When all required values have been entered, the Clinician Programmer will display the Daily Dose to be delivered. Note: This value cannot exceed the Daily Dose Limit.
5. Once the values are confirmed, follow prompts on the Clinician Programmer's screen to program pump with new settings.
6. Hold the Clinician Programmer steady until the tone stops. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with the Old and New Settings.

Demand Bolus Regimen

The Demand Bolus regimen temporarily replaces the current regimen to deliver an immediate or one-time infusion of medication. The Demand Bolus regimen can only be delivered when the pump is in Constant Flow mode.

The Clinician Programmer always verifies the pump's information (i.e. patient name/code, serial number, etc.) before programming any information to the pump. If attempting to program one patient's pump with the previous patient's information, the Clinician Programmer returns a "Wrong Patient" error. To prevent this, it is good practice to turn the Clinician Programmer off in between different patients. Programming of the Demand Bolus is not complete until the Program Confirmed screen appears. It is good practice to perform a final inquiry to confirm that the Bolus was delivered. All programming steps can be printed out from the Review History screens to confirm the correct prescription was programmed onto the pump

Program the medication dosage and duration, within the following limits:

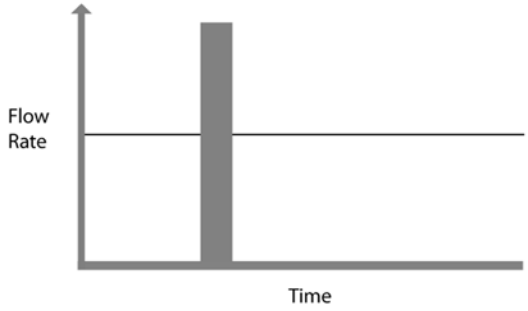
Description	**Value Limit**	
Dose	Min	0.0000 mg or 0.0 mcg
	Min (non-zero value)	0.0010 mg or 1.0 mcg
	Max	99.9999 mg or 99999.9 mcg
Pump Delivery Rate	Min	0.0 Ml/day (The pump accuracy has not been tested and is unknown for flow rates 0-0.045 Ml/day)
	Max*	28.8 Ml/day, or 1.2Ml/hr, or 20 mcL/min
Duration	Min	01 min
	Max	71:59 hh:mm

**approximate value based on pump's accumulator volume*

Warning: The bolus dosage is LIMITED by the Daily Dose Limit; therefore, it is NOT possible to program a bolus prescription that exceeds the Daily Dose Limit. When this occurs, the Clinician Programmer will issue a warning.

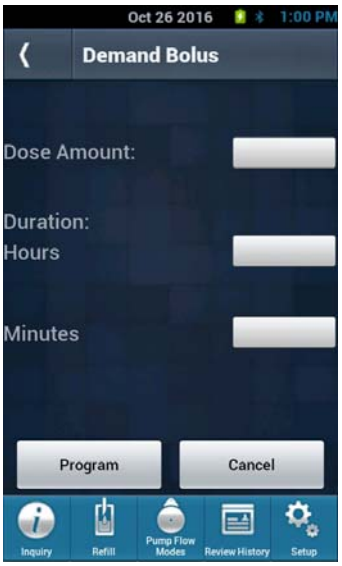
Note: It is not possible to run two Demand Bolus regimens simultaneously. Therefore, if another bolus is currently running, the Clinician Programmer will display a prompt to cancel the current bolus before allowing a new bolus to be initiated.

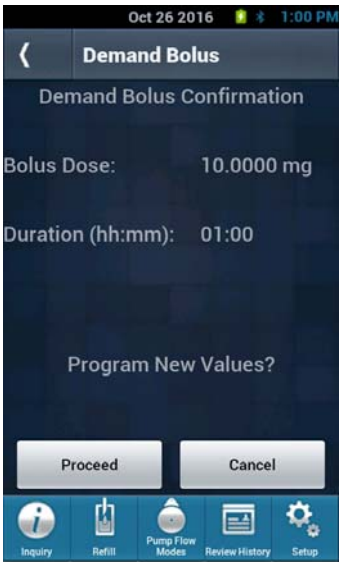
When the bolus is complete, the pump returns to its regularly scheduled Constant Flow regimen. The following diagram illustrates a Demand Bolus that was programmed while a Constant Flow regimen was running. As indicated in the diagram, the bolus interrupts the pump's current medication regimen; however, the pre-existing medication regimen immediately resumes its schedule once the bolus is complete.



To program a Demand Bolus regimen:

1. From the Main Menu, select Pump Flow Modes, Bolus Menu and Demand Bolus. If an Inquiry function has already been performed, the Clinician Programmer displays the Demand Bolus Menu.
2. If an Inquiry has not been performed, the Clinician Programmer will prompt user to place Clinician Programmer over pump. Complete the inquiry and select Continue to enter the Demand Bolus.
3. Enter the dose amount in either mg or mcg and next enter the duration of the demand bolus in the hours and minutes input boxes.





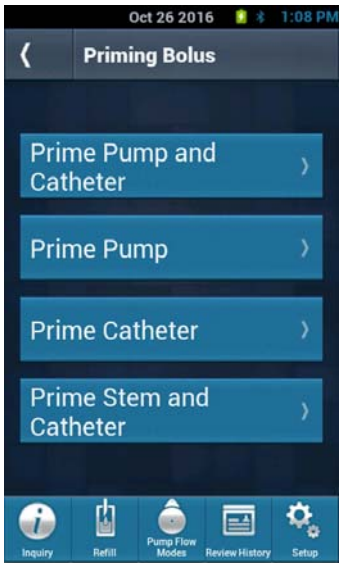
4. Select Program and confirm the new settings.
5. Program the pump by following the prompts on screen.
6. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with programmed demand bolus.

   Note: The time remaining for the demand bolus is displayed on page 3 of the Inquiry screen.

Priming Bolus

The Clinician Programmer allows for the choice of four different types of priming boluses for the pump. Selection must be carefully chosen to reflect the type of priming required.

The Clinician Programmer always verifies the pump's information (i.e. patient name/code, serial number, etc.) before programming any information to the pump. If attempting to program one patient's pump with the previous patient's information, the Clinician Programmer returns a "Wrong Patient" error. To prevent this, it is good practice to turn the Clinician Programmer off in between different patients. Programming of the Priming Bolus is not complete until the Program Confirmed screen appears. It is good practice to perform a final inquiry to confirm that the Bolus was delivered. All programming steps can be printed out from the Review History screens to confirm the correct prescription was programmed onto the pump.



a) Prime Pump and Catheter
b) Prime Pump
c) Prime Catheter
d) Prime Stem and Catheter

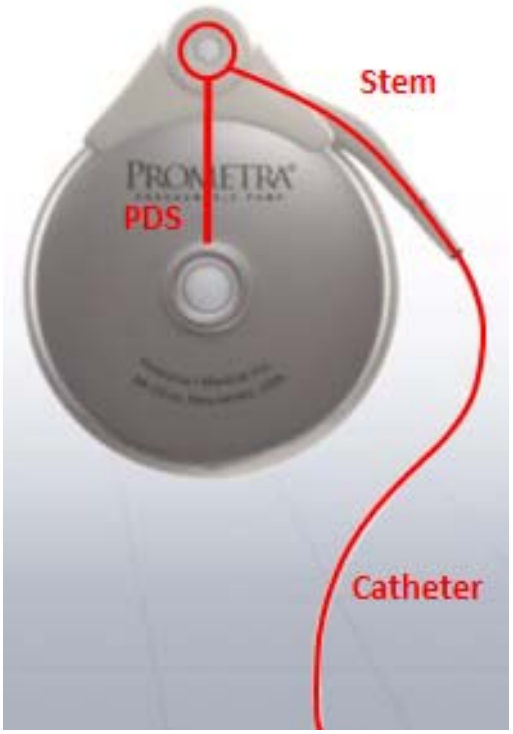
Note: This feature uses automatic calculations. To perform this function without using automatic calculations, manually calculate the corresponding bolus parameters by using the appropriate Supplementary Calculations Guide, and enter the results using the Demand Bolus menu option.

Warning: It is imperative that the correct priming bolus type is selected; each choice delivers a different amount of fluid.
When priming the pump, both the Precision Dosing System (PDS) and the Stem pathways are primed. The definitions for the PDS and Stem are as follows:

Precision Dosing System (PDS) : This is the pathway from filter to after the chamber between the two valves. It includes the accumulator and some other fluid pathways. This volume is 0.137 Ml for the Prometra® Pump and 0.153 Ml for the Prometra® II Pump

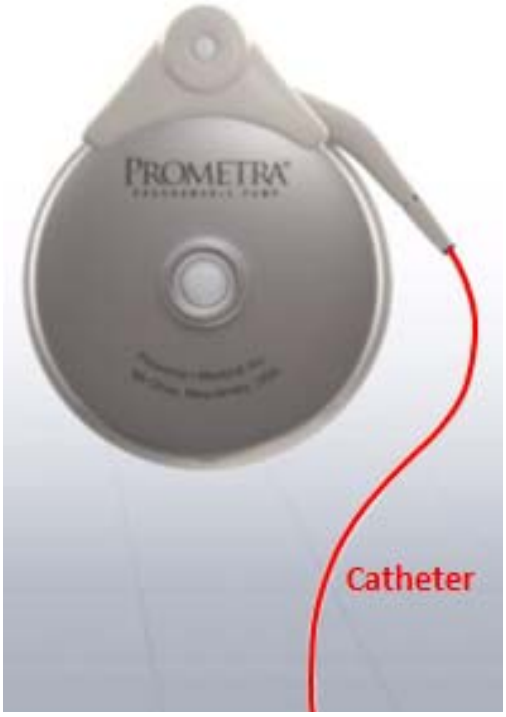
Stem: This is a short piece of tube that runs from the Drug Metering Controller to the catheter. The catheter plugs into the end of the T-stem. This volume is 0.068 Ml for both the Prometra® and Prometra® II pumps.

Graphics depicting the fluid pathway that is primed for each of the priming bolus options are shown below.

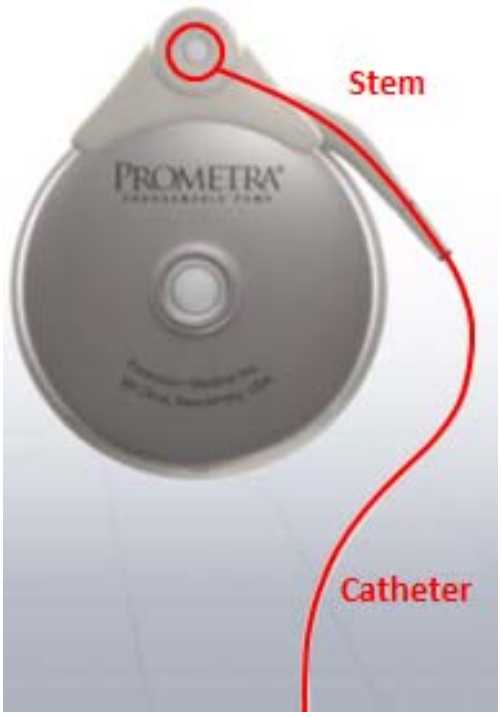


Prime Pump and Catheter

Prime Pump



Prime Catheter



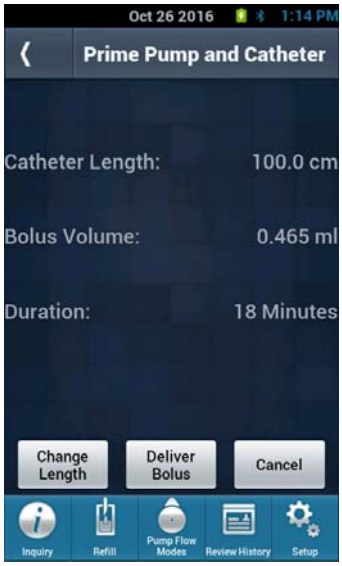
Prime Stem and Catheter

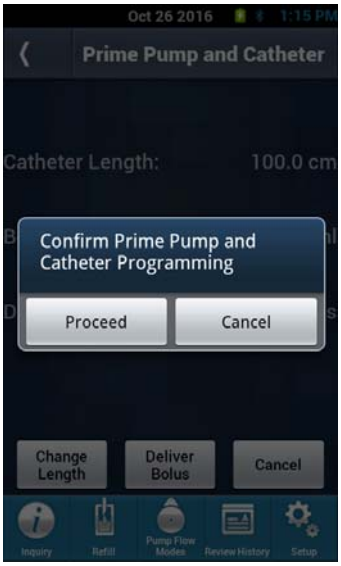
Prime Pump and Catheter

When the user selects Prime Pump and Catheter, the Clinician Programmer warns the user that they are priming both the pump and catheter. The user should verify that the **catheter is attached** to the pump.

The Clinician Programmer displays the catheter length, or catheter volume along with the total volume to be delivered along with the duration of bolus. The user must confirm the programming of the bolus and place the Clinician Programmer over the pump to start delivery. Confirm that the catheter length or catheter volume is correctly programmed into the pump prior to starting this function.

Note: This is an automatic calculation. The catheter length or catheter volume must be entered prior to the start of this function. To perform this function without using automatic calculations, manually calculate the corresponding bolus parameters by using the appropriate Supplementary Calculations Guide, and enter the results using the Demand Bolus menu option.





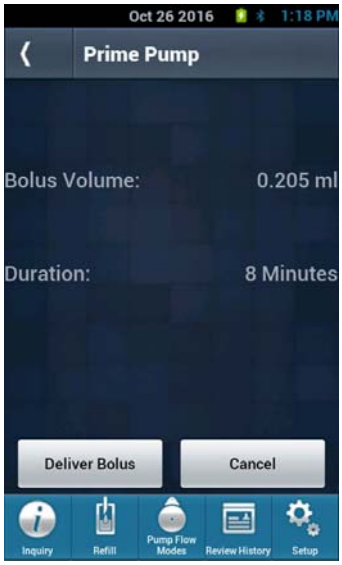
Note: The remaining time of a priming bolus is displayed on the Inquiry screen on page 3.

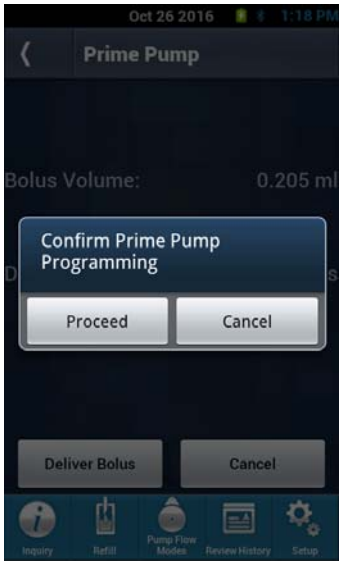
Prime Pump

When the user selects Prime Pump, the Clinician Programmer warns the user that they are priming the pump only and to verify that the **catheter is not attached** to the pump.

The Clinician Programmer displays the volume to be delivered along with the duration of bolus. The user must confirm the programming of the bolus and place the Clinician Programmer over the pump to start the delivery.

Note: This is an automatic calculation. To perform this function without using automatic calculations, manually calculate the corresponding bolus parameters by using the appropriate Supplementary Calculations Guide, and enter the results using the Demand Bolus menu option.





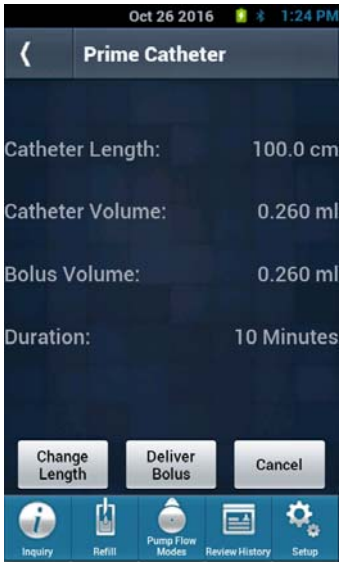
Note: The remaining time of a priming bolus is displayed on the Inquiry screen on page 3.

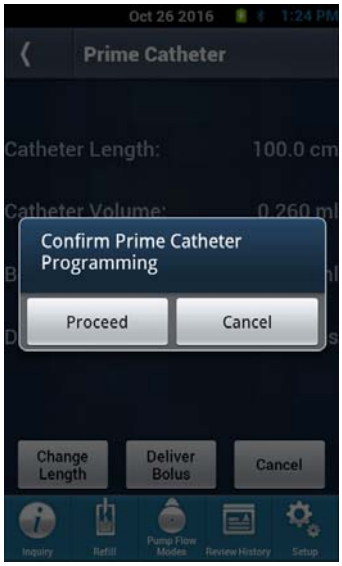
Prime Catheter

When the user selects Prime Catheter, the Clinician Programmer warns the user that they are priming the catheter only. The user is to verify that the pump is already primed, that the **catheter is attached** to the pump being primed, and that the catheter does not contain medication.

The Clinician Programmer displays the catheter length and/or catheter volume, bolus volume, and the duration of bolus. Confirm the correct catheter length or catheter volume prior to starting this function. The user must confirm the programming of the bolus and place the Clinician Programmer over the pump to start the delivery.

Note: This is an automatic calculation. The catheter length or catheter volume must be entered prior to the start of this function. To perform this function without using automatic calculations, manually calculate the corresponding bolus parameters by using the appropriate Supplementary Calculations Guide, and enter the results using the Demand Bolus menu option.



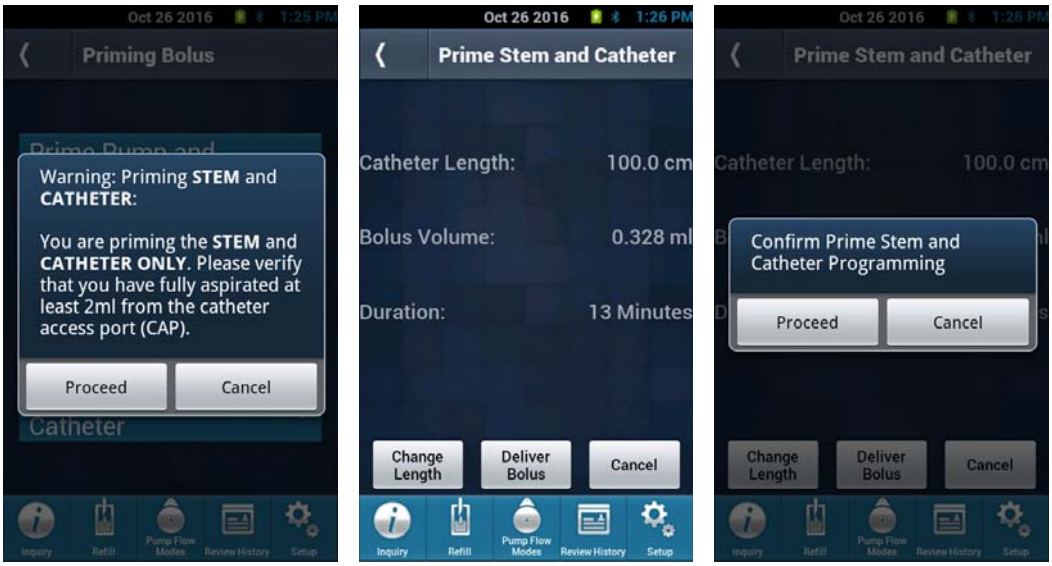


Note: The remaining time of a priming bolus is displayed on the Inquiry screen on page 3.

Prime Stem and Catheter
When the user selects Prime Stem and Catheter, the Clinician Programmer warns the user that they are priming both the stem and catheter. The user should verify that the **catheter is attached** to the pump.

The Clinician Programmer displays the catheter length or catheter volume along with the volume to be delivered and the duration of bolus. The user must confirm the programming of the bolus and place the Clinician Programmer over the pump to start delivery. Confirm that the catheter length is correctly programmed into the pump prior to starting this function.

Note: This is an automatic calculation. The catheter length or catheter volume must be entered prior to the start of this function. To perform this function without using automatic calculations, manually calculate the corresponding bolus parameters by using the appropriate Supplementary Calculations Guide, and enter the results using the Demand Bolus menu option.



Note: The remaining time of a priming bolus is displayed on the Inquiry screen on page 3.

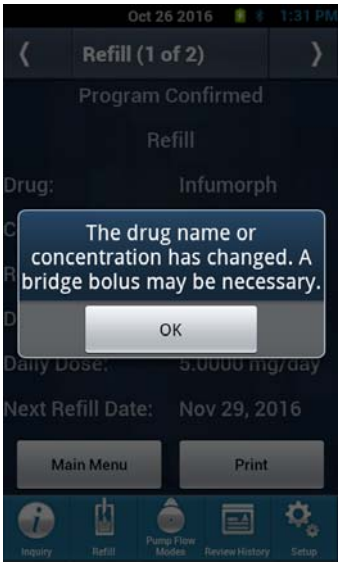
Bridge Bolus Regimen

The Bridge Bolus regimen is used when drug name or concentrations are changed in the pump reservoir. In this situation there will be a specific volume of the old drug still remaining in the catheter and fluid pathway. This type of bolus "bridges" the drug change by flowing the quantity of old drug at a rate and period, which matches the bridge daily dose rate. The bolus will temporarily replace the current regimen. The Bridge Bolus can only be delivered when the pump is in Constant Flow mode. When the bolus finishes, the pump continues with its regularly scheduled Constant Flow regimen.

The Clinician Programmer always verifies the pump's information (i.e. patient name/code, serial number, etc.) before programming any information to the pump. If attempting to program one patient's pump with the previous patient's information, the Clinician Programmer returns a "Wrong Patient" error. To prevent this, it is good practice to turn the Clinician Programmer off in between different patients. Programming of the Bridge Bolus is not complete until the Program Confirmed screen appears. It is good practice to perform a final inquiry to confirm that the Bolus was delivered. All programming steps can be printed out from the Review History screens to confirm the correct prescription was programmed onto the pump.

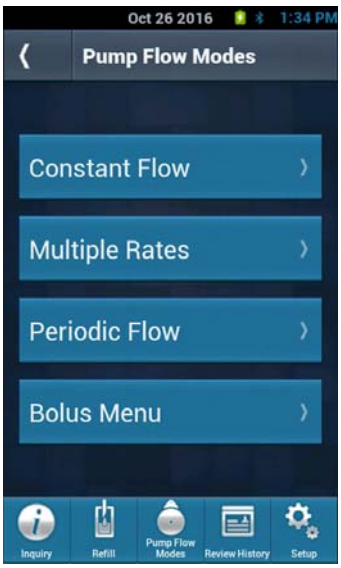
Note: This is an automatic calculation. The catheter length or catheter volume must be entered prior to the start of this function. To perform this function without using automatic calculations, manually calculate the corresponding bolus parameters by using the appropriate Supplementary Calculations Guide, and enter the results using the Demand Bolus menu option.

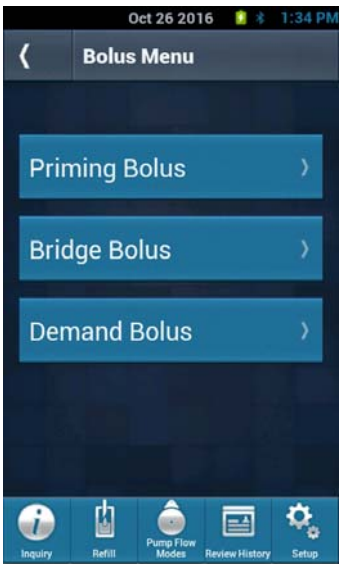
Note: A change in concentration or drug name in the Refill function must have been entered for a Bridge Bolus function to be allowed. A reminder is provided to the user after a refill with a change in concentration or drug name has been programmed.



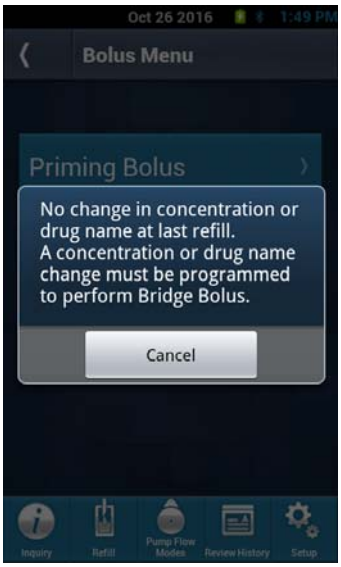
Note: The Bridge Bolus regimen can be used to deliver the old drug concentration at the newly programmed daily dose rate or deliver the old drug at the prior daily dose rate. The automatic calculation is based on the user entered Bridge Daily Dose for which the old drug or old drug concentration will be delivered during the Bridge Bolus duration. For questions, please contact Flowonix Technical Solutions at (855) 356-9665.

After programming a refill, select Pump Flow Modes from the Main Menu, select Bolus Menu and then select Bridge Bolus.



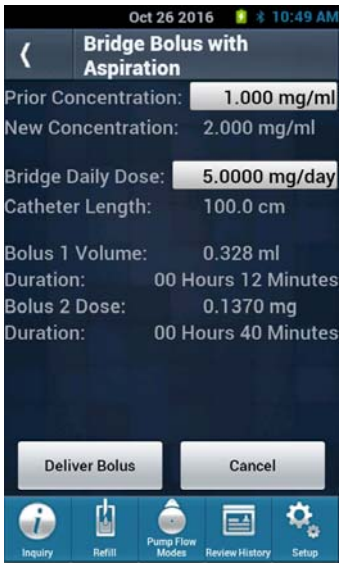


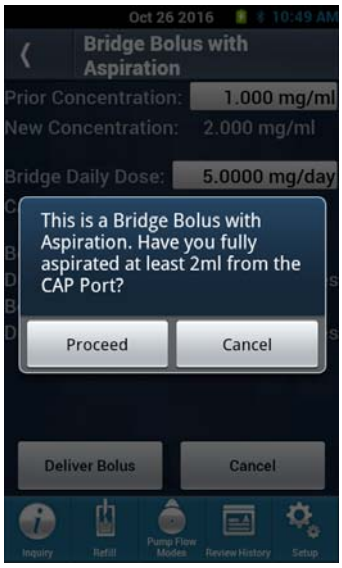
A concentration or drug name change must be programmed first to allow a Bridge Bolus. If a refill with a concentration or drug name change is not done beforehand, the message shown in the following figure will be displayed when attempting to access the bridge bolus menu.



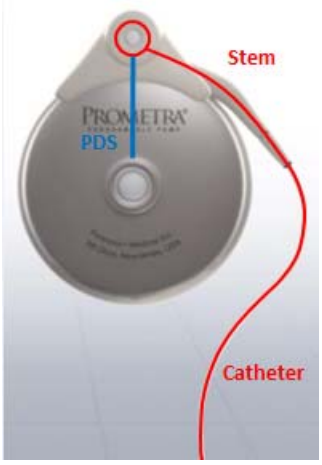
To program a Bridge Bolus (Aspirating the Catheter)

1. After performing the refill, and programming refill information and any new flow information, proceed to the Main Menu.
2. From the Main Menu, select Pump Flow Modes, Bolus Menu, then Bridge Bolus with Aspiration.
3. It is important to have the prior concentration and bridge daily dose noted as it needs to be entered prior to the start of the bridge bolus. Once complete select the deliver the bolus key and follow the prompts on screen.
4. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen.
5. The time remaining for the bolus is displayed on page 3 of the Inquiry screen.
6. Once the Bridge Bolus (catheter aspiration) is complete, the pump resumes its normal basal mode flow regimen.





The Bolus 1 Volume is the volume required to fill the aspirated fluid pathway (stem and catheter). Bolus 2 Dose is the amount of old drug remaining in the PDS that has not been aspirated. After Bolus 1 Volume has been delivered at the maximum flow rate, Bolus 2 Dose will be delivered at the Bridge Daily Dose rate until the entire amount of the old drug has been delivered.



Note: Flow modes cannot be changed after a Bridge Bolus has started. Be sure to make any mode changes before starting a Bridge bolus.

To program a Bridge Bolus (Without Aspirating the Catheter)

1. After performing the refill, and programming refill information and any new flow information, proceed to the Main Menu.
2. From the Main Menu, select Pump Flow Modes, Bolus Menu, and then Bridge Bolus without Aspiration.
3. Enter required data and program the pump by following the prompts on screen.
4. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen.
5. The time remaining for the bolus is displayed on page 3 of the Inquiry screen.
6. Once the Bridge Bolus (without aspiration) is complete, the pump resumes its normal regimen.

The bolus dose is the amount of old drug remaining. The bolus dose will be delivered at the Bridge Daily Dose rate until entire amount of the old drug has been delivered.

Note: Flow modes cannot be changed after a Bridge Bolus has started. Be sure to make any mode changes before starting a Bridge bolus.

Programming a Refill

Prior to refilling, inquire the Programmable Pump to verify patient and pump information.

After refilling the Programmable Pump, 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.

The Clinician Programmer always verifies the pump's information (i.e. patient name/code, serial number, etc.) before programming any information to the pump. If attempting to program one patient's pump with the previous patient's information, the Clinician Programmer returns a "Wrong Patient" error. To prevent this, it is good practice to turn the Clinician Programmer off in between different patients. Programming of the Refill is not complete until the Program Confirmed screen appears. It is good practice to perform a final inquiry to confirm that the proper refill information was entered. All programming steps can be printed out from the Review History screens to confirm the correct prescription was programmed onto the pump.

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

Refill Data

After refilling the pump, enter the following data in the Clinician 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 Clinician 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 Clinician Programmer also reprograms the current medication regimen to maintain the currently prescribed dose. 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. 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 0.0 Ml Max (Prometra 20Ml) 20.0 Ml Max (Prometra II 20Ml) 20.0 Ml Max (Prometra II 40Ml) 40.0 Ml
Drug	The name of the drug put into the pump.	Only one drug may be entered
Concentration	The concentration of the drug put into the pump. The Clinician Programmer uses the 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 Log*	Opens the Drug Log Menu in which the names and concentrations of up to four drugs may be entered.	This is an information only field

***WARNING: USE OF UNAPPROVED DRUGS (e.g., DRUG COCKTAILS, PHARMACY-COMPOUNDED DRUGS, MORPHINE WITH PRESERVATIVES, ETC.) WITH THE PROGRAMMABLE PUMP COULD RESULT IN PUMP FAILURE AND/OR SERIOUS ADVERSE EVENTS SUCH AS SEVERE UNDERDOSE, OVERDOSE OR DEATH.**

How to Program Refill Data

1. From the Main Menu, select Refill. If an Inquire function has already been performed, the Clinician Programmer displays the Refill Menu.
2. If an Inquiry has not been performed, the Clinician Programmer will require an Inquiry. Complete the inquiry and select next page (>) to scroll through the information screens then press Continue to enter the Refill.

The Refill screen displays the Daily Dose when in Constant, Periodic, or Multiple Rate Flow Mode (No PTC)

The Refill screen displayed the Total Maximum Daily Dose when in Constant & PTC Mode.

3. Select Drug to enter or change the name of the medication (up to 10 alphanumeric characters is allowed).
4. Select Concentration to change the concentration in either mg/ml or mcg/ml.
5. Select Refill volume to enter the volume added to the pump.
6. If the medication consists of multiple drugs, select Drug Log to display the Drug Info Menu.
    a. Enter the information in the drug, concentration (mg or mcg) and volume fields
    b. Once complete, select Enter.

WARNING: USE OF UNAPPROVED DRUGS (e.g., DRUG COCKTAILS, PHARMACY-COMPOUNDED DRUGS, MORPHINE WITH PRESERVATIVES, ETC.) WITH THE PROGRAMMABLE PUMP COULD RESULT IN PUMP FAILURE AND/OR SERIOUS ADVERSE EVENTS SUCH AS SEVERE UNDERDOSE, OVERDOSE OR DEATH.

7. When all fields have been completed, select Enter.
8. Confirm the refill information by selecting Program.
9. If the drug concentration is changed, the Clinician Programmer will allow the option to perform a bridge bolus following the refill (If desired by the physician).
   Note: If the new concentration entered results in a flow rate outside the pump's range, the Clinician Programmer returns an error message and then displays the medication regimen menu so the prescription can be re-entered.
10. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen. The Clinician Programmer displays a confirmation screen with the new information along with the next refill date.
11. **Note: If the refill results in a change in drug concentration or drug name, a message will appear indicating that a bridge bolus may be necessary.**

Pump Shutdown

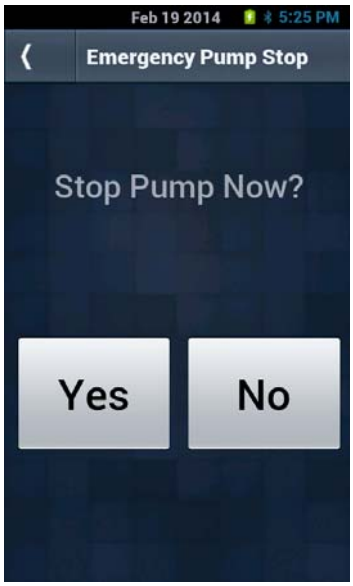
Emergency Pump Stop

This is for a temporary emergency shutdown only.

To Program the Emergency Pump Stop:

1. From the Main Menu, select Emergency Pump Stop.

   Note: An inquiry is not required prior to executing an Emergency Pump Stop.



2. Select No to abort the process and return to the previous menu.
   Note: An emergency pump shutdown bypasses the normal inquiry process; therefore, the Clinician Programmer only sounds one or two clicks before stopping the pump. This operation takes less than a second to complete.

3. Select Yes to shut down the pump. The Clinician Programmer will prompt to “Place Clinician Programmer Over Pump.”

4. Once the pump is stopped, the Clinician 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.

   The Pump function remains suspended until the Pump is reprogrammed.

5. Select Continue to return to Main Menu.

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. If long-term shut down is expected, it is recommended to program a dose of 0.2 mg/day (after filling the pump with saline: 1 mg/Ml) to maintain catheter patency.

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

Pump Restart after Shutdown

To restart a stopped pump: The pump will need to be reprogrammed with a desired flow mode and non-zero dose. An example would be programming a constant flow regime with a dose value other than 0.0 mg:

1. From the Main Menu, select Pump Flow Modes then select Constant Flow. If an Inquiry function has already been performed, the Clinician Programmer displays the Constant Flow Menu.
2. If an Inquiry has not been performed, the system shall prompt user to place Clinician Programmer over pump. Complete the inquiry and select Continue to enter the constant flow.
3. Enter the Daily Dose amount in either mg/day or mcg/day.
   (Note: Unit type is selected in Pump Setup -> More Options -> Drug/Dosage Units).
4. A warning will appear when a dose is changed from the previous programmed Daily Dose. The percentage change of the dose will be displayed after the new Daily Dose has been entered.
5. Select the Program key and confirm the new Daily Dose.
6. Follow the prompts on the Clinician Programmer's screen to program the Constant Flow Dose into the pump.
7. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with the old and new settings. In addition, the next refill date is displayed.

Printing Clinician Programmer Data

The Clinician Programmer can output Pump Status, Program Confirmation, and History records to a printer by means of Bluetooth communications. The following is a list of devices, which are compatible for printing with the Clinician Programmer. Pairing with any other devices is not recommended:

- HP Officejet 100 Mobile Printer

Note:

- Selecting "Print" prints the entire record, not just the current screen. Therefore, it is NOT necessary to select "Print" on every screen.
- Pump transactions may be printed when initially displayed, or when reviewed in the History Menu.

Setting up a Bluetooth Printer

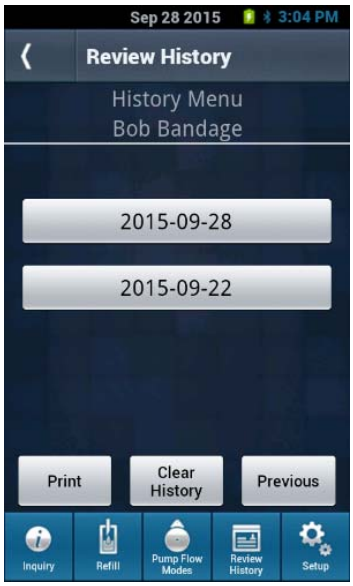
1. Click the "Setup" button to get to the Setup Screen
2. Click the "Printer Setup" button to get to the Printer Setup Screen
3. Click the "Bluetooth Scan" button to get to the Bluetooth Connection Screen
4. Click the "Scan" button to begin scanning for nearby Bluetooth devices
5. When you see your Bluetooth Printer appear in the list, click the button with your printer's information on it
6. A confirmation box will appear, click "Yes" to pair
7. You may be asked to enter a pin number (typically 000000 or 1234). Enter the pin number associated with your printer and click "OK"
8. Once connection is successful you should be put back on the Printer Setup Screen
9. Click the "Register Printer" button, a popup with a list of all connected devices will appear
10. Click on the printer you want to use and then hit "Confirm"
11. A confirmation popup will appear telling you registration was successful, click "Close"
12. The Clinician Programmer is now ready to print to the registered printer

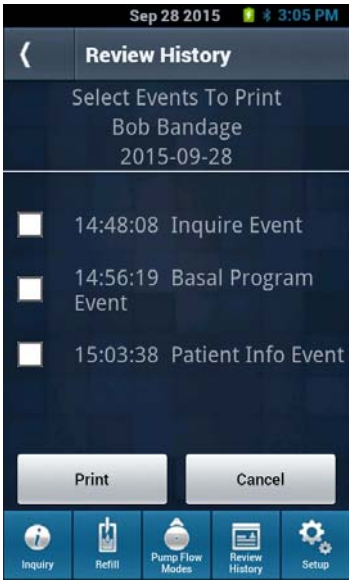
Printing During a Pump Transaction

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

Printing from the History Menu

1. From the Clinician Programmer's Main Menu, select Review History.
2. Select the name of the patient whose records are to be printed.
3. Records can be printed by the date of visit, select events within a given date or as an individual event. The print option will be displayed at the bottom of each screen that allows printing after the patient name screen.





4. Select the record(s) desired for printing. The Clinician Programmer displays the record's opening screen.

5. On the screen, select Print.

Connecting and Sending Records to the Clinician Print Tool

1. Connect the Clinician Programmer to the PC using a USB to micro USB cable, and ensure that the Clinician Print Tool application is running on the PC. If the Clinician Print Tool is not running or loaded, refer to the Print Tool IFU.
2. From the Clinician Programmer's Main Menu, select Setup, then Printer Setup.
3. On the Printer Setup menu select the "Connect to Print Tool" key, and select "Connect" at the Ready to Connect prompt.
4. Acknowledge the "Record Upload Complete" prompt.
5. Follow the Clinician Print Tool instructions for selecting and printing the downloaded log data.

Clinician Programmer Calculations

Please refer to the appropriate Supplementary Calculations Guide to manually calculate the bolus parameters for priming procedures.

Troubleshooting Clinician Programmer

Clinician Programmer Error Messages

Clinician Programmer-generated error messages interrupt the current procedure to notify the user of a problem. Some error messages provide on screen information and programming can continue after displayed. Other messages require that the issue be resolved before continuing the procedure. In a few rare instances, such as a critically low battery error, the Clinician Programmer shuts down. All critical error codes are displayed with a unique numeric code. Non-critical errors do not have unique error codes associated with them.

NOTE: The fault log is stored in a separate administration area. This information can only be accessed by Flowonix personnel and is used for troubleshooting purposes if necessary. Once an error is cleared it cannot be restored.

The following table lists the Clinician Programmer-generated error messages with descriptions and suggested solutions. If error messages are encountered or the Clinician Programmer is not functioning properly or is unresponsive, please contact **Flowonix Technical Solutions: (855) 356-9665.**

Clinician Programmer Non-Critical Error Messages

Clinician Programmer Message	Description	Suggested solution for resolution
Amount too large for allotted time	The prescribed dose and duration require a flow rate that is faster than the pump is capable of delivering.	Reprogram with either a smaller dose or a longer duration.
Amount too small for allotted time	The prescribed dose and duration require a flow rate that is slower than the pump is capable of delivering.	Reprogram with either a larger dose or a shorter duration.
Programmed Daily Dose exceeds the Daily Dose Limit	Attempted to program a dose delivery above the programed daily dose	Either disable or increase the Daily Dose Limit or prescribe a lower dosage.
Duration too large for interval	This message is specific to Periodic Flow regimens. The regimen's duration is greater than its repeat value.	Re-enter the duration so it is less than the repeat value.
Daily Basal Dose too large for Dose Period	This message is specific to Periodic Flow regimens. The regimen's basal rate is greater than the periodic rate.	Re-enter the Daily Basal Dose and the Periodic Dose so that the basal rate is less than the periodic rate.
Warning: The entered Daily Basal Dose is greater than zero. The Daily Basal dose is divided intermittently between the periodic flow dose. The entire Daily Basal Dose will be infused in a 24 hour period. Do you wish to proceed?	This message is specific to Periodic Flow regimens. The regimen has a non-zero Daily Basal Dose. The entire Daily Basal Dose will be delivered in a 24 hour period during the times the periodic dose is not active.	Check the dose amount to make sure the correct value is entered.
Warning: The entered Daily Dose is 0 mg/day. Do you wish to proceed?	This message is specific to Constant and Multiple Rates Flow regimens. The regimen's Daily Dose is zero.	Check the dose amount to make sure the correct value is entered.
Low Battery: Recharge your battery.	The Clinician Programmer's rechargeable batteries are low.	Recharge the Clinician Programmer's batteries.
Low Battery: Replace the AA batteries	The Clinician Programmer's AA batteries are low.	Replace the Clinician Programmer's batteries or call Flowonix Technical Solutions at (855) 356-9665 if the message persists.
Pump communications failed. Please try again.	The pump did not respond to the Clinician Programmer signal. Interference, communication distance, or the pump performing its daily diagnostic test may cause this. The Clinician Programmer may not recognize the pump model.	Re-attempt to communicate with the pump or if issue continues, contact Flowonix Technical Solutions at (855) 356-9665.

Clinician Programmer Message	Description	Suggested solution for resolution
Time 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.
Bolus operation not allowed as there is a bolus already in progress. Cancel running bolus?	The pump is already delivering a demand bolus.	Either cancel running demand bolus or wait until bolus is complete.
Warning: You have set a zero value for the demand bolus which should only be used during a soft reset. Do you wish to proceed?	A demand bolus of 0 mg has been entered.	Check the dose amount to make sure the correct value is entered.
Warning: The entered Demand Bolus is less than the current daily flow rate. Do you wish to proceed?	The Demand Bolus flow rate is less than the current flow rate for Constant Flow regimens and less than the average rate over the course of the day for Periodic and Multiple Rate Flow regimens.	Check the dose amount to make sure the correct value is entered.
Warning: Bolus dose higher than the daily dose.	The Demand Bolus dose is higher than the Daily Dose for the Constant, Periodic, of Multiple Rates regimen.	Check the dose amount to make sure the correct value is entered.
Delivering the requested Demand Bolus will exceed the Daily Dose Limit.	Attempted to program a Demand Bolus greater than the Daily Dose Limit	Update the Demand Bolus dose amount below the Daily Dose Limit or change the Daily Dose Limit
A Bridge Bolus is running. Flow modes cannot be changed until bolus is complete.	There is a Bridge Bolus and the user attempted to change the flow mode without cancelling the running bolus.	Allow bridge bolus to complete or cancel running bridge bolus and reprogram the running flow mode.
A Demand Bolus is running. Flow modes cannot be changed until bolus is complete	There is a Demand Bolus and the user attempted to change the flow mode without cancelling the running bolus.	Allow bridge bolus to complete or cancel running bridge bolus and reprogram the running flow mode.
Bolus cannot be delivered. Insufficient reservoir volume. Confirm any changes with prescribing physician prior to programming settings! Press OK to Continue	The volume to be delivered during the Demand Bolus duration is greater than the volume in the reservoir.	Check the dose amount to make sure the correct value is entered.
Bridge Bolus is unavailable. Flow Mode must be Constant Flow to perform this operation.	The user attempted to enter the bridge bolus menu when not in Constant Flow mode.	Change the flow mode to Constant Flow prior to programming a bridge bolus.
Demand Bolus is unavailable. Flow Mode must be Constant Flow to perform this operation.	The user attempted to enter the Demand Bolus screen when not in Constant Flow mode.	Change the flow mode to Constant Flow prior to programming a demand bolus.
A value must be entered for all inputs before programming.	All values required for programming were not entered.	Check all fields to make sure that the values are entered.

Clinician Programmer Message	Description	Suggested solution for resolution
Could not connect to registered printer. Please make sure it is turned on and in range of the Clinician Programmer	An error occurred while trying to print to the printer.	Check that printer is ON and it is connected to the Clinician Programmer.
An unknown error has occurred	Clinician Programmer has detected an unknown error.	Repower Clinician Programmer and if error continues contact Flowonix Technical Solutions at (855) 356-9665.
Cannot change catheter information while a bolus is running	Attempted to change the catheter length, catheter volume, or catheter information as unknown while the bolus mode is underway.	Wait until bolus is complete and then reprogram the catheter information or cancel running bolus and reprogram catheter information.
Daily Dose Limit cannot be below current Daily Dose	Attempted to program a Daily Dose Limit less than the current Daily Dose	Change the Daily Dose Limit or Update the programmed dose below the daily dose limit.
Each row must have a value entered for all inputs before programming.	In multiple rates all values have not been entered.	Review Multiple Rates values and Enter all of the values
Bluetooth device not found	Attempted to connect to a Bluetooth printer that is not turned on	Turn on printer and reattempt to connect.
Export Error. Please try again	Unable to export data to PC	User error occurred.
Failed to backup EEPROM	During program upgrade, an error occurred.	Start the upgrade procedure again.
Failed to restore EEPROM	During program upgrade, an error occurred.	Start the upgrade procedure again.
Failed to update firmware	During program upgrade, an error occurred.	Start the upgrade procedure again.
Failed to upload firmware	During program upgrade, an error occurred.	Start the upgrade procedure again.
No change in concentration or drug name at last refill. A concentration or drug name change must be programmed to perform Bridge Bolus.	During last refill no drug concentration or drug name change was done so Bridge Bolus operation is not allowed.	Confirm drug or concentration change to determine if bridge bolus is required.
No patient name set. A name must be set before continuing.	A patient name has not been stored in the pump.	Set the patient name to continue use of the pump and Clinician Programmer.
Clinician Programmer is currently plugged in. Please disconnect cable before continuing.	The Clinician Programmer is charging and it cannot be used for inquiry or programming while charging.	Disconnect the charger and use the Clinician Programmer.
Programming Failed. Please re-enter values and try again.	During programming of the pump, communication issue occurred.	Reprogram the pump or if issue continues contact Flowonix Technical Solutions at (855) 356-9665.
Pump Refill Information Error. A new refill and flow prescription must be programmed.	Issue with data read from pump.	Reprogram pump with new refill and flow mode prescription.
Refill not allowed as there is a bolus already in progress. Cancel running bolus?	Attempted to perform a refill while a running bolus is undergoing.	Allow bolus to complete and then perform refill or cancel running bolus and then perform refill.

Clinician Programmer Message	Description	Suggested solution for resolution
The batteries need to be replaced. Please consider replacing batteries before programming the pump.	The AA batteries need to be replaced.	Remove and replace the AA batteries.
The implanted catheter information must be set before performing this operation	There is no value stored for the catheter information. Enter value length, volume, or information unknown to continue.	Enter catheter length, volume or catheter information as unknown using Clinician Programmer in Pump Setup.
The implanted catheter information must be set before performing any operation	There is no value stored for the catheter information. Enter value length, volume, or information unknown to continue.	Enter catheter length, volume or catheter information as unknown using Clinician Programmer in Pump Setup.
The implanted catheter length or volume must be set before performing this operation.	There is no value stored for the catheter length or volume. Enter value to continue.	Enter catheter length or volume using Clinician Programmer in Pump Setup.
There is currently an error in the pump data. Leaving this screen will leave the pump data incorrect and unusable .	There is an issue with the current pump information.	Reprogram pump prescription values.
Warning: The entered catheter length is 50 cm or less. Do you wish to proceed?	This message is specific to the Catheter Information. The entered Total Implanted Catheter Length is 50 cm or less.	Check the Total Implanted Catheter Length to make sure the correct value is entered.
Warning: The entered catheter volume is 0.130 ml or less. Do you wish to proceed?	This message is specific to the Catheter Information. The entered Total Implanted Catheter Volume is 0.130 Ml or less.	Check the Total Implanted Catheter Volume to make sure the correct value is entered.
The Clinician Programmer needs to be recharged. Plug in power adapter.	The Clinician Programmer is at a critical level and needs to be recharged.	Recharge the Clinician Programmer.
Warning: The pump's low reservoir alarm may sound before the Next Refill Date. Do you wish to proceed?	The Next Refill Date is defined as when the reservoir volume will reach 3 Ml. The low reservoir alarm will sound before the reservoir volume reaches 3 Ml.	Set the low reservoir alarm to 3 Ml or lower.
No export key installed	The decryption key for Print Tool records is missing. Patient records cannot be exported to the Print Tool.	Connect to the Bluetooth Printer to print records and contact Flowonix Technical Solutions.
Firmware image not found	The PTC firmware is not properly loaded onto the Clinician Programmer and the connected PTC cannot be upgraded.	Connect the PTC to a different Clinician Programmer if available to upgrade and contact Flowonix Technical Solutions.

Pump Critical Error Messages

If during an Inquire or programming function the Clinician Programmer receives an error message from the pump, the Clinician Programmer will display the pump critical error message before displaying the standard programming screens. Each error message will be associated with a unique numeric code that will be displayed along with the error message. The numeric code helps Flowonix Technical Solutions identify the issue with the pump.

The following table lists the pump-generated status messages with descriptions. If these critical errors are encountered the pump will not allowed to be programmed.

Clinician Programmer Message	Error Code from Pump	Description of Error
Warning: The pump has stopped because it has detected a potential internal error (100). Contact Flowonix Medical Technical Support.	100	The pump is in a critical error.
Warning: The pump has stopped because it has detected a potential internal error (101). Contact Flowonix Medical Technical Support.	101	The ADC test failed High. The pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (102). Contact Flowonix Medical Technical Support.	102	The ADC test failed Low. The pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (103). Contact Flowonix Medical Technical Support.	103	The capacitor test failed. The pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (104). Contact Flowonix Medical Technical Support.	104	The battery open voltage test failed high. The pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (105). Contact Flowonix Medical Technical Support.	105	The battery low voltage test failed low. The pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (106). Contact Flowonix Medical Technical Support.	106	The Outlet POC is out of acceptable bounds. The Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (107). Contact Flowonix Medical Technical Support.	107	The Inlet POC is out of acceptable bounds. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (108). Contact Flowonix Medical Technical Support.	108	The outlet valve HOC is out of acceptable bounds. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (109). Contact Flowonix Medical Technical Support.	109	The inlet valve HOC is out of acceptable bounds. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (110). Contact Flowonix Medical Technical Support.	110	The outlet valve is out of acceptable bounds. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (111). Contact Flowonix Medical Technical Support.	111	The inlet valve is out of acceptable bounds. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (112). Contact Flowonix Medical Technical Support.	112	The oscillator in the pump is too slow. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (113). Contact Flowonix Medical Technical Support.	113	The oscillator in the pump is too fast. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (114). Contact Flowonix Medical Technical Support.	114	The redundant clock in the pump disagrees with the pump clock. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (115). Contact Flowonix Medical Technical Support.	115	The watchdog timeout failed. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (116). Contact Flowonix Medical Technical Support.	116	The check timer test failed. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (117). Contact Flowonix Medical Technical Support.	117	The sleep timer test failed. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (118). Contact Flowonix Medical Technical Support.	118	The basal buffer is corrupted. Pump is shutdown.

Clinician Programmer Message	Error Code from Pump	Description of Error
Warning: The pump has stopped because it has detected a potential internal error (119). Contact Flowonix Medical Technical Support.	119	The bolus buffer is corrupted. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (120). Contact Flowonix Medical Technical Support.	120	The valve check failed (short). Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (121). Contact Flowonix Medical Technical Support.	121	The valve check failed (long). Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (122). Contact Flowonix Medical Technical Support.	122	The soft reset flag was set. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (123). Contact Flowonix Medical Technical Support.	123	The data read/write test failed. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (124). Contact Flowonix Medical Technical Support.	124	The code CRC test failed. Pump is shutdown.
Warning: The pump has stopped because it has detected a potential internal error (125). Contact Flowonix Medical Technical Support.	125	The RAM transient upset failed. Pump is shutdown.
Pump Resetting	N/A	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.
Pump Is Stopped	N/A	The pump has shut down.
Software Error	N/A	The pump's internal software check failed. This critical error shuts down the pump.
Pump Information Error	N/A	The pump's information was corrupted, causing the pump to fail its integrity check.
Pump refill information error	N/A	The pump's refill information was corrupted, causing the pump to fail its integrity check. When this error occurs, the Clinician Programmer cannot program a new prescription.

Reset Procedures to Resolve Pump Critical Error Messages

If during an Inquire or programming function the Clinician Programmer receives a critical error message from the pump, the pump has stopped. The physician must determine if the patient can be safely deprived of medication until the pump restarts. If medication is needed, then alternative means of drug delivery (such as I.V. administration or analgesic patch) should be employed. Contact Flowonix Technical Solutions at (855) 356-9665 to determine if the pump can be restarted through a series of programming steps known as a soft reset. If the soft reset procedure is not successful, Flowonix Technical Solutions will schedule an appointment for a hard reset of the pump which will reinitialize the pump's memory, microprocessor and data registers. If successful, at the end of the hard reset procedure, the pump will be restored with all errors cleared. The basal and bolus flow rates will be at 0 mg/day. Reprogram the pump's flow mode to resume infusion.

Warning: A period of observation should follow the Reset Procedure to closely monitor patients for clinical symptoms of underdose or overdose based upon the prescribing information of the drug.

Clinician Programmer Critical Error Messages

The table below summarizes the critical issues associated with the Clinician Programmer.
Each error message will be associated with a unique numeric code that will be displayed along with the error message. The numeric code helps Flowonix Technical Solutions identify the issue with the Clinician Programmer.

Clinician Programmer Message	Error Code from Clinician Programmer	Description of Error
Warning: The pump has detected a potential Clinician Programmer error (200). Attempt to reprogram or contact Flowonix Medical Technical Support.	200	Pump information CRC
Warning: The pump has detected a potential Clinician Programmer error (201). Attempt to reprogram or contact Flowonix Medical Technical Support.	201	Pump refill CRC
Warning: The pump has detected a potential Clinician Programmer error (202). Attempt to reprogram or contact Flowonix Medical Technical Support.	202	Basal prescription mismatch
Warning: The pump has detected a potential Clinician Programmer error (203). Attempt to reprogram or contact Flowonix Medical Technical Support.	203	Basal prescription bad
Warning: The pump has detected a potential Clinician Programmer error (204). Attempt to reprogram or contact Flowonix Medical Technical Support.	204	Bolus prescription mismatch
Warning: The pump has detected a potential Clinician Programmer error (205). Attempt to reprogram or contact Flowonix Medical Technical Support.	205	Bolus prescription bad
Warning: The pump has detected a potential Clinician Programmer error (206). Attempt to reprogram or contact Flowonix Medical Technical Support.	206	Unknown software error
Warning: The Clinician Programmer has a critical low battery: Recharge the Clinician Programmer.	207	The Clinician Programmer's recharging battery is critically low. This critical error shuts down the Clinician Programmer.
Warning: The Clinician Programmer has a critical low battery: Replace all three AA batteries.	No code, Text Message "Warning: The Clinician Programmer has a critical low battery: Replace all three AA batteries"	The Clinician Programmer's AA batteries are critically low. This critical error does not allow programming of the pump.
Warning: The system has detected a potential Clinician Programmer error (210). Attempt to reprogram or contact Flowonix Medical Technical Support.	210	The Analog to Digital Converter (ADC) failed its self-diagnostic test. The ADC is an electronic device that measures battery voltage. The Clinician Programmer will still function but may not be able to determine when its batteries are low.
Warning: The system has detected a potential Clinician Programmer error (211). Attempt to reprogram or contact Flowonix Medical Technical Support.	211	The Vcc power test has failed. The Clinician Programmer cannot communicate with the pump.
Warning: The pump has detected a potential Clinician Programmer error (212). Attempt to reprogram or contact Flowonix Medical Technical Support.	212	The telemetry test circuitry failed. The Clinician Programmer cannot communicate with the pump.
Replace all AA batteries or contact Customer Service for further support	No code, Text Message "Replace all AA batteries or call Customer support"	The OTS device cannot communicate with the PCB assembly.

Wand Critical Error Messages

The messages below are a list of the critical issues associated with the wand hardware. These errors are associated with a unique numeric code that will be displayed along with the error message. The numeric code helps Flowonix Technical Solutions identify the issue with the wand hardware. These error codes are only accessible via the wands diagnostic serial port interface.

Wand Error Code	Description of Error
-1	POST failure due to incorrect Vcc supply voltage.
-2	POST failure due to incorrect Vdd supply voltage.
-3	POST failure due to incorrect battery supply voltage.
-4	POST failure due to incorrect Vee supply voltage.
-5	POST failure due to incorrect Bluetooth System supply voltage.
-6	POST failure due to incorrect PVcc supply voltage.
-7	POST failure due to hardware error in telemetry circuitry.
-8	POST failure due to inability to initialize Bluetooth Module.
-9	POST Failure due to hardware error in flash memory interface.

Telemetry Troubleshooting

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

Service and Maintenance of the Clinician Programmer

Battery Installation and Replacement

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

Batteries for coil (Replaceable AA)

To install or replace the AA batteries:

1. Turn the Clinician Programmer off.
2. Slide the cover of the battery compartment on the back of the unit open.
3. If replacing the batteries, remove and discard the old batteries.
4. Insert three AA alkaline batteries as shown in the Clinician Programmer's battery compartment. (Line up the plus sign of the battery with the plus sign picture shown in the battery compartment. When this is done, the minus sign on the battery will be lined up with the minus sign in the battery compartment)

   Warning: All batteries should be disposed of according to local and federal regulation.

   - Please abide by the disposable battery manufacturer's shelf life limitation. To protect natural resources and to promote material reuse, please separate batteries from other types of waste and recycle them through your local, free battery return system.

   - If the Clinician Programmer is no longer going to be used, it should be returned to Flowonix Medical. Please contact Flowonix Technical Solutions at (855) 356-9665 to arrange shipment or disposal.

Batteries for device (Rechargeable/Internal)

- Use the supplied USB charger (AC adapter) to charge the internal battery for the touchscreen using a UL approved power source.
- The charging port is located at the bottom of the device.
- When the device is fully charged (100%) it will produce a short vibration to notify the user.
- When the battery reaches approximately 15% of its charge, a message will appear on the screen indicating that the battery needs to be recharged.
- The user cannot replace the rechargeable battery inside the Clinician Programmer. If the battery is no longer charging, then contact Technical Customer Service.
- The charging of device shall be outside of the patient vicinity.
- Over time, unused batteries will discharge and must be recharged before use.

Service

The Clinician Programmer has no serviceable parts. For technical issues or questions about the Clinician Programmer, please contact Flowonix Technical Solutions at (855) 356-9665.

Proper Care and Handling

- Do not drop the Clinician Programmer or subject it to severe shock. If Clinician Programmer becomes damaged, contact Technical Customer Service at (855) 356-9665.
- Keep the device dry; humidity and all types of liquids may damage device parts or electronic circuits.
- Do not turn on the device if it is wet. If the device is already on, turn it off. In addition, remove the batteries immediately (if the device will not turn off or you cannot remove the batteries, leave it as-is). Then, dry the device with a towel and call Technical Customer Service at (855)-356-9665. Caution: Do not use as there is a possible electrical shock hazard.
- Do not store the device in hot or cold areas. Only use the Clinician Programmer between **20 °C and 40 °C,** The device can explode if left inside a closed vehicle, as the inside temperature can reach up to 80°C.
- Do not expose the device to direct sunlight for extended periods of time (such as on the dashboard of a car).
- Storage temperature should be between 0 °C and 40 °C.
- Do not store the device near magnetic fields. The device may malfunction or the battery may discharge from exposure to magnetic fields.
- Do not use carrying cases or accessories with magnetic closures or allow the device to come in contact with magnetic fields for extended periods of time. This includes avoiding exposure to MRI machines.

Sterilization and Disinfection

- Do not sterilize the Clinician Programmer or Patient Therapy Controller. Sterilization could damage the unit.
- The Clinician Programmer and Patient Therapy Controller are not intended to be disinfected by cleaning solutions or detergents. Exposure to disinfection procedures could damage the unit.
- As the Clinician Programmer and Patient Therapy Controller are not intended to be sterilized or disinfected, precautions should be used to avoid cross-contamination when handling the units.
- If it becomes necessary to use the Clinician Programmer or Patient Therapy Controller within a sterile environment, such as a surgical field, ensure that a sterile barrier is established between the unit and the patient or pump. Always use standard sterile technique as to avoid cross contamination.
- If the Clinician Programmer or Patient Therapy Controller becomes dirty:
  - Wipe your unit or charger with a towel or cloth. Do not spray any liquids on the unit or allow droplets to enter the charging port.
  - Clean the terminals of the battery with a cotton ball or a towel.
  - Do not use chemicals or detergents.
  - Do not immerse the Clinician Programmer or Patient Therapy Controller in any type of liquid.

Device Software Updates and Upgrades

Your sales representative will inform you when upgrades are available and will schedule a convenient time for this service.

Security of the Clinician Programmer

Safeguards are in place to maintain the integrity of the Clinician Programmer and protect patient data. Safeguards include the disabling of the Clinician Programmer's WiFi and/or cellular capability and restricting access to the system's Bluetooth and serial port. All Personal Health Information (PHI) and Personal Identifying Information (PII) are encrypted. It is recommended to maintain strict physical control of the Clinician Programmer. If it is suspected that the device has been tampered with by physical or remote access, please contact Flowonix Technical Solutions at (855) 356-9665.

Clinician Programmer Specifications

Height	6.50 inches (16.51 cm)
Width	3.50 inches (8.89 cm)
Depth	1.45 inches (3.68 cm)
Weight	350 grams with batteries 250 grams without batteries
Telemetry Range	Approximately 2 inches (5.08 cm) above the pump Interference may occur in the vicinity of equipment marked with the following symbol: 
Power Source	Rechargeable battery powers the touchscreen part of the Clinician Programmer. 3 AA alkaline batteries are used to power the telemetry coil
Use Environment*	Store between 0 °C and 40 °C Use the device between 20 °C and 40 °C Relative Humidity: 60+/-15% Atmospheric Pressure: 860 hPa to 1,060 hPa Rated to operate to an altitude of 2000 m.
Timeout	The Clinician Programmer will automatically time out after 15 minutes of no operation on the Clinician Programmer.
Voltage Rating	5 VDC
Regulatory	i. Degree of electrical insulation: Type BF (body floating) ii. Protection against water ingress: Ordinary equipment (IP20) iii. Mode of operation: Continuous iv. Power source: Model ETA0U60JBE Rated Input: 100-240 Vac, 50-60 Hz, 0.15 A Rated Output: 5 VDC, 0.7 A v. Protection against electric shock: Class II power supply used vi. Anesthetic Warning: This equipment not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXED WITH AIR or OXYGEN or NITROUS OXIDE. vii. Means of Operator Protection (MOOP) for Power Supply and Means of Patient Protection (MOPP) for Clinician Programmer. viii. Standards used for Clinician: Clinician Programmer: MEDICAL GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008), and IEC 60601-1-2 (2007) Charger standards: UL 60950-1, 2nd Edition (2007-03); CSA C22.2 No. 60950-1-07 2nd Edition (2007-03)

*See Appendix 1 for additional information regarding Electromagnetic Compatibility

Clinician Programmer Peripherals

The following peripherals are used with the Clinician Programmer:

- Printer -The Clinician Programmer is a standalone accessory to the device.
- Printer Power Cord – The power cord is used to connect the printer to a wall supply.

Patient Therapy Controller General Information
Software Revision: 2.01.2

PTC® Description
The Patient Therapy Controller (PTC®) is a handheld touchscreen device, which allows a patient to initiate a pre-configured supplemental bolus of Infumorph® from their implanted Programmable Pump. The patient requests a bolus by pressing the Rx button on the PTC and then placing it over their implanted pump. The Patient Therapy Controller communicates with the implanted pump initiating the supplemental bolus delivery. The settings for the bolus delivery are programmed into the Patient Therapy Controller by a healthcare certified professional (HCP) using the Clinician Programmer. The PTC can only be used to deliver patient controlled boluses of Infumorph®. The PTC CANNOT be used to administer patient controlled boluses of intrathecal baclofen.

Indications
The Patient Therapy Controller is indicated for use with the Prometra® Programmable Infusion Systems. It enables the patient to activate delivery of supplemental doses of Infumorph® (preservative-free morphine sulfate sterile solution) from the Programmable Pump as prescribed by a physician. The Patient Therapy Controller is not indicated for delivery of supplemental doses with intrathecal Baclofen.

Contraindications
There are no known contraindications.

Intended Patient Population
The intended user population for the Patient Therapy Controller is comprised of:

- Adults age 22 and older (lay users) who would be prescribed the Programmable Pump
- Patients deemed suitable to use the Patient Therapy Controller by the prescribing healthcare professional for managing their pump and:
  - Show the ability to work with hand held devices, including acuity to use a cell phone or similar handheld device
  - Understand the training and IFU
  - Are psychologically competent, as determined by the physician

Warnings
WARNING: USE OF UNAPPROVED DRUGS (e.g., DRUG COCKTAILS, PHARMACY-COMPOUNDED DRUGS, MORPHINE WITH PRESERVATIVES, ETC.) WITH THE PROGRAMMABLE PUMP COULD RESULT IN PUMP FAILURE AND/OR SERIOUS ADVERSE EVENTS SUCH AS SEVERE UNDERDOSE, OVERDOSE OR DEATH.

- Always select and program dosages consistent with the Infumorph® labeling to prevent improper drug administration.
- To avoid electric shock or damage to the Patient Therapy Controller or Clinician Programmer, please avoid contact with water.
- Only use the Clinician Programmer and Patient Therapy Controller after receiving training specific to these devices. Use of these devices by non-qualified or untrained personnel could lead to serious consequences involving under- or over-dosage of Infumorph. In the event of over-dosage, refer to the approved Infumorph labeling for appropriate treatment.
- Clinicians programming implanted programmable pumps and Patient Therapy Controllers 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 over-dose.
- The handheld Clinician Programmer and Patient Therapy Controller use electromagnetic energy to communicate with the Programmable Pump. Their electromagnetic fields 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.

- The Patient Therapy Controller cannot be used if the Daily Dose Limit for the implanted pump has been disabled. The Daily Dose Limit must be enabled prior to setup of the Patient Therapy Controller. Please refer to Pump Setup, More Options selection using the Clinician Programmer to enable the Daily Dose Limit.
- Patient Therapy Controllers with software versions prior to 2.01.1 and Clinician Programmers with software versions prior to 2.01.5 are not compatible with Prometra II 40 Ml Pumps. Contact Flowonix Technical Solutions at (855) 356-9665 for more information on software upgrades.
- Potential communication problems between the pump and Clinician Programmer and/or the pump and Patient Therapy Controller 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. If problem persists, contact Flowonix Technical Customer Service.
- Use of the Clinician Programmer or Patient Therapy Controller adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Clinician Programmer or Patient Therapy Controller including cables specified by Flowonix. Otherwise, degradation of the performance of this equipment could result.
- Use of a power source other than those provided by Flowonix could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The Clinician Programmer and Patient Therapy Controller are not intended to be functional and used while they are being charged. All communication and programming functionality is disabled while charging.
- **MRI Safety:** The Patient Therapy Controller and Clinician Programmer are MR Unsafe.

MR Unsafe

Precautions

- Carefully read and follow all instructions prior to use.
- Use of the equipment by untrained or non-qualified personnel could lead to serious harm to the patient.
- When finished programming a patient's pump, always turn off and then restart the Clinician Programmer prior to programming a new patient's pump. This practice avoids Clinician Programmer error messages should the user inadvertently attempt to program one patient's pump with data from another patient's prescription.
- The wireless communication signal used by the Patient Therapy Controller and Clinician Programmer to communicate with the implanted pump (referred to as telemetry) can travel about 2 inches (5 cm). If the Patient Therapy Controller or Clinician Programmer are not positioned closely enough to the pump or are not oriented correctly over the pump, they may not be able to communicate with the pump.
- Do not disassemble the Patient Therapy Controller or Clinician Programmer. Disassembling these devices may damage them or cause them to malfunction.
- Do not sterilize the Patient Therapy Controller or Clinician Programmer. Sterilization could damage the Clinician Programmer and/or Patient Therapy Controller.
- The Clinician Programmer is not intended to be disinfected by cleaning solutions or detergents. Exposure to disinfection procedures could damage the Clinician Programmer.
- As the Clinician Programmer is not intended to be sterilized or disinfected, precautions should be used to avoid cross-contamination when handling the Clinician Programmer.
- If it becomes necessary to use the Clinician Programmer within a sterile environment, such as a surgical field, ensure that a sterile barrier is established between the Clinician Programmer and the patient. Always use standard sterile technique as to avoid cross contamination.

- Certain electronic or electromagnetic equipment may cause interference with the programming procedure. Interference may also occur near equipment marked with the symbol shown at right. Move the patient from the suspected source of interference and attempt to reprogram. Examples of equipment that may cause interference include MRI equipment, 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 Clinician Programmer and Patient Therapy Controller.

Potential Adverse Events

- Inability to program the implanted pump due to Clinician Programmer or Patient Therapy Controller failure or loss of telemetry.

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

PTC® Features

- Linked to and configured with a single Implantable Programmable Pump
- Initiates a pre-configured bolus with a button press and placement over the Implantable Programmable Pump
- Real time clock for post bolus lockout periods
- Maintains a historical record of patient bolus requests that can be accessed by the Clinician Programmer
- 2.7 inch screen size (diagonal measurement)
- Touchscreen interface
- Color LCD
- Hand held design (4.31 inch length x 3.12 inch width x 1.26 inch height)

Each Patient Therapy Controller is linked to one specific pump; it cannot be shared amongst patients. This feature prevents unintended patient therapy bolus delivery. The Patient Therapy Controller settings are configurable, including bolus dose amount, duration, post-bolus lockout period, and allotted boluses per day. The Patient Therapy Controller determines when a bolus can be delivered, and the delivered dose, based on the programmed limits.

The Patient Therapy Controller records a diagnostic log of bolus activity, which can only be accessed by healthcare professionals using the Clinician Programmer.

Instructions for Use of the Patient Therapy Controller

Prior to initial use, ensure the rechargeable batteries of the Patient Therapy Controller (PTC) and the Clinician Programmer are fully charged. See Service and Maintenance section for additional information.

PTC® Interface

The Patient Therapy Controller's user interface consists of a touchscreen LCD, power button and Rx button. The PTC communicates with the pump via a wireless signal referred to as telemetry. The PTC communicates with the Clinician Programmer via a Bluetooth wireless signal.

The Patient Therapy Controller consists of four main components shown above:

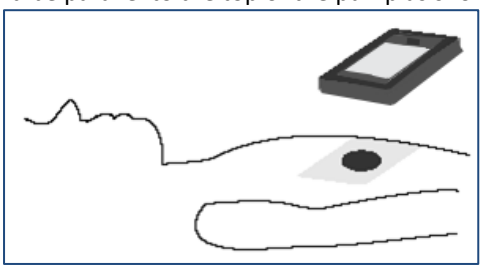
1. Touchscreen LCD screen
2. Power Button
3. Prescription Button (Rx Button)
4. Internal wireless transmitter used for programming commands between the Patient Therapy Controller and implanted pump.

PTC® Programming Orientation

The signal used to program the pump can travel up to 2 inches (5 cm). If the Patient Therapy Controller is not oriented correctly over the pump or if it is too far away, it will not be able to communicate with the pump.

When prompted to place the Patient Therapy Controller over the pump, follow these steps:

1. Horizontally position the Patient Therapy Controller up to 2 inches (5cm) above the pump. The top of the PTC should be parallel to the top of the pump as shown in the figure below.



Position of the Patient Therapy Controller over Pump

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

   Note: Do not position the Patient Therapy Controller too close to the pump. The signal requires at least 0.5 inches (1.27 cm) to initialize the connection.

3. Hold the Patient Therapy Controller steady until the tone stops and the message changes on the PTC touchscreen. The programming tone may last up to ten seconds or more. Once connection is complete, the Patient Therapy Controller sounds a confirmation tone.

   Note: If a programming fails, it may be due to interference or the communication distance being out of range during inquiry or programming. Refer to the Troubleshooting Section if there is difficulty with wireless communication.

Setting up the PTC®

1) In order to program a Patient Therapy Controller to deliver supplemental prescribed bolus doses, the following conditions must be met for the patient's implanted Programmable Pump:
   - Pump's drug delivery must be in Constant Flow Mode.
   - Daily Dose Limit is enabled

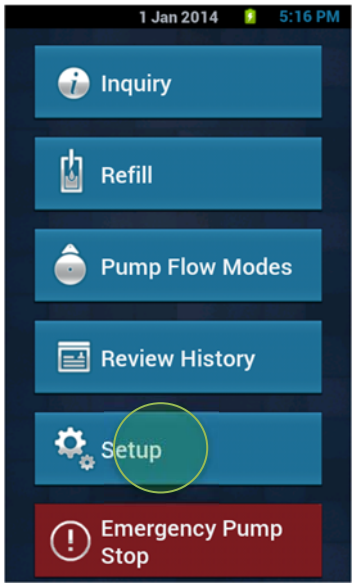
   Refer to the Programming Pump Flow Modes section under Constant Flow Regime details on programming in Constant Flow Mode and Pump Setup section under Daily Dose limit for details on setting a daily dose limit.
2) To setup the Patient Therapy Controller, it must be wirelessly connected (paired) with the Clinician Programmer. Turn on the Clinician Programmer by holding the power button for 2-5 seconds (until the Flowonix splash screen appears).
3) Turn on the Patient Therapy Controller by pressing the power button. A message will appear indicating that the device must first be setup before use.

4) Once you see the screen above, plug the Patient Therapy Controller into its charger. Plug the Patient Therapy Controller charger into an AC outlet and verify that the charging message appears on the screen as shown below.

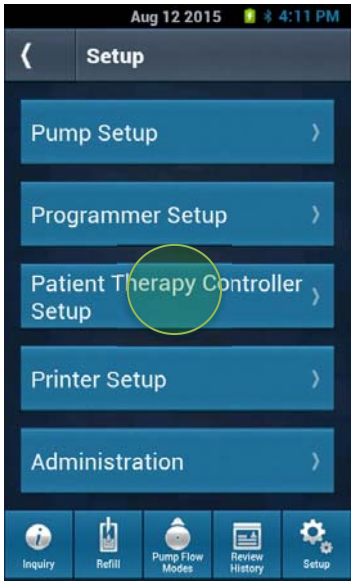
Note: The PTC's wireless connection is turned "on" for the first 5 minutes of charging. This enables it to be paired with the Clinician Programmer. It is turned "off" if not paired within 5 minutes.

Note: The message stating "Battery Charging. PTC disabled." Applies to the bolus delivery functionality. The PTC can still be setup using the Clinician Programmer.

5) On the Clinician Programmer, select the **"Setup"** button.
6) On the Clinician Programmer, select the **"Patient Therapy Controller Setup"** button.



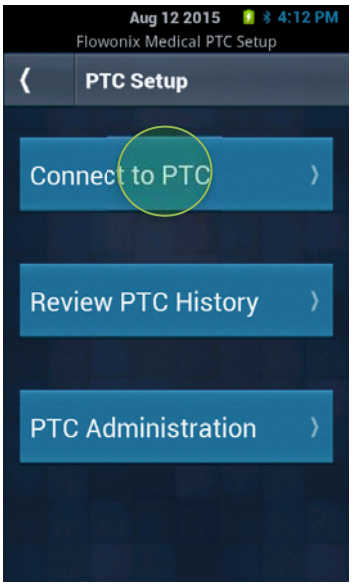
Main Menu Clinician Programmer



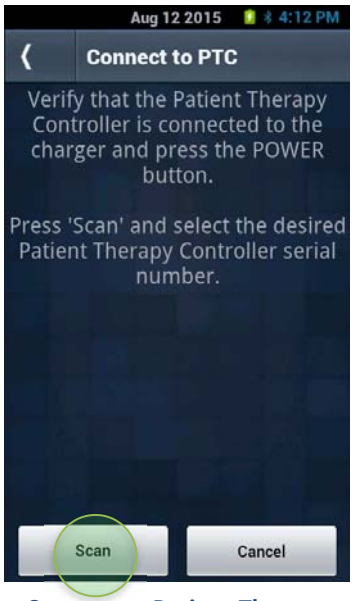
Setup Menu Clinician Programmer

7) On the Clinician Programmer, select the **"Connect to PTC"** button.

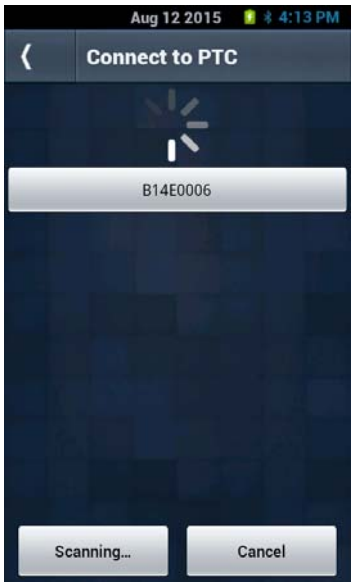
Note: The Clinician Programmer uses the term "PTC" to refer to the Patient Therapy Controller. Press "Scan" on Connect to PTC screen and the scanning indicator will appear.



Main Menu PTC Setup

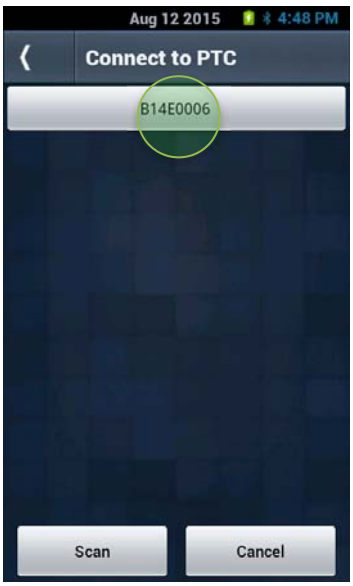


Connect to Patient Therapy Controller Screen

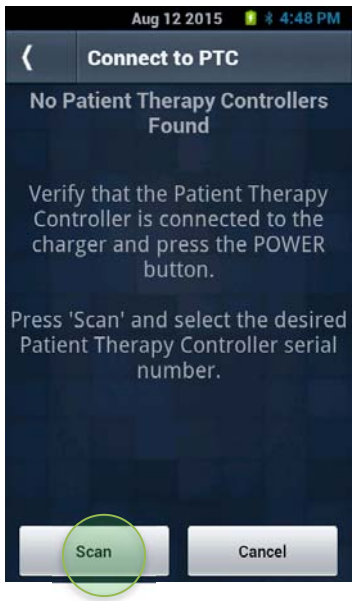


Scanning Indicator Screen

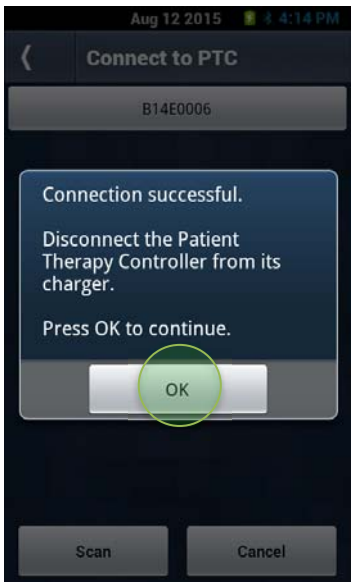
8) Each Patient Therapy Controller has a serial number on the back. The first time the PTC is set up the serial number will display on the screen once it is found. If the PTC has already been linked to a pump using the same clinician programmer, the patient's name will be displayed on screen. Select the serial number or patient name desired.



Scan Successful



Scan Unsuccessful



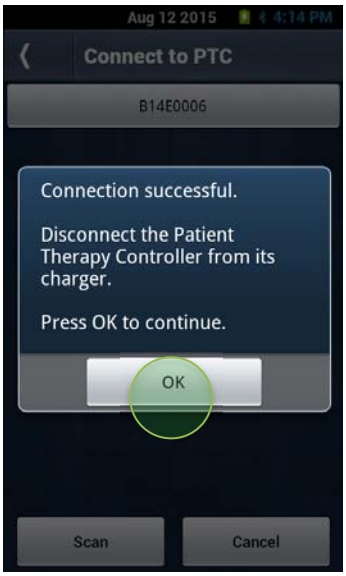
Confirmation screen

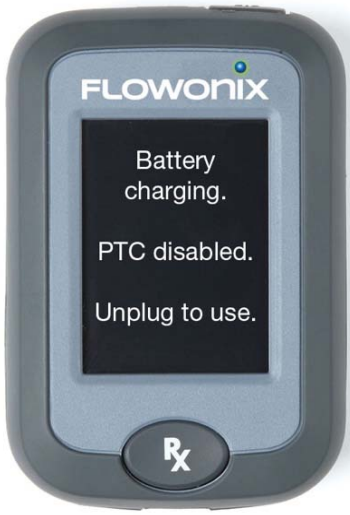
9) Select the Patient Therapy Controller serial number to configure then confirm by selecting "Yes".

Note: The PTC's wireless connection is "on" for the first 5 minutes of charging. If the Clinician Programmer does not find the PTC, then the 5 minutes may have been exceeded. Unplug PTC for 10-15 seconds and repeat the connection process (step 2).

10) A prompt on the Clinician Programmer will appear to "Press the power button on the Patient Therapy Controller". Press the power button on the PTC and "OK" on the Clinician Programmer.

11) Upon successful connection to the Patient Therapy Controller, a prompt on the Clinician Programmer will confirm a successful connection and the Patient Therapy Controller can be unplugged from the charger. Remove the charger from the Patient Therapy Controller.

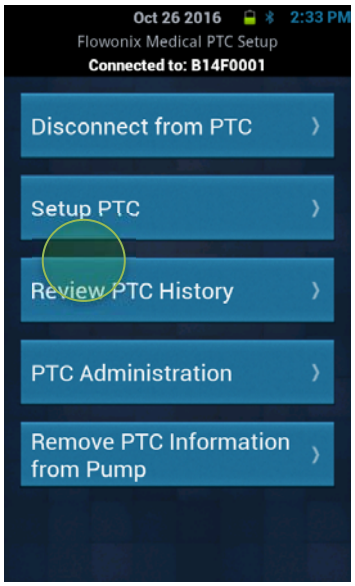




Note: While the battery is charging, the Patient Therapy Controller does not indicate the amount of charge. To determine the amount the battery is charged, simply unplug from the charger and press the power button. The amount of charge will be displayed at the top of the screen.

Note: If the Clinician Programmer is unsuccessful connecting to the Patient Therapy Controller, unplug PTC for 10-15 seconds and repeat the connection process (step 2).

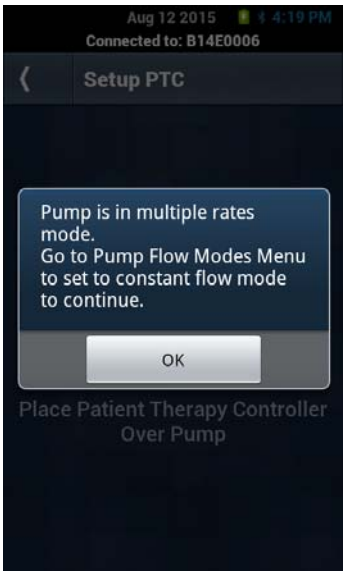
12) Press “OK” on the Clinician Programmer and you will now be on the Patient Therapy Controller Setup menu with the ability to Setup the Patient Therapy Controller or disconnect from the Patient Therapy Controller.
13) Select “Setup PTC”.



14) It will now ask you to place the PTC over the pump.
15) Place the Patient Therapy Controller over pump as described in the Patient Therapy Controller Orientation section.
16) The Patient Therapy Controller will run a Pump Link mode.
17) Hold the Patient Therapy Controller over the implanted pump until Patient Therapy Controller says “Pump link successful.”

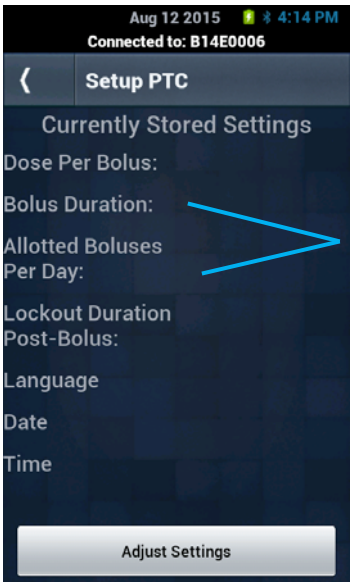
Note: If the pump is not in Constant Flow Mode or other conditions as discussed in step 1 above are not met, an error message will appear and the Clinician Programmer will not be able to complete programming. Press the OK button and then return to the Programmer Main Menu and the Setup Pump menu in order to place the pump in Constant Flow Mode.

Successful link with Pump

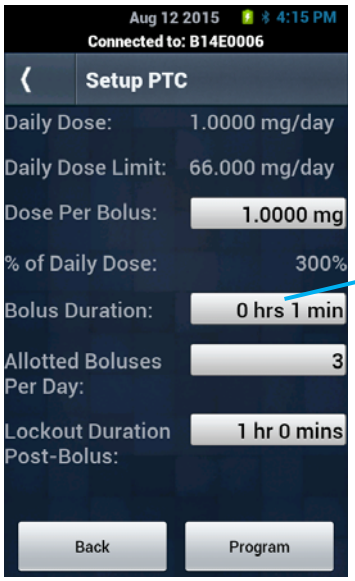


Unsuccessful link with Pump due to pump not being in Constant Flow Mode

18) The Clinician Programmer screen will show the set-up screen and the Currently Stored Settings. When the Patient Therapy Controller is setup for the first time, the values for the currently stored settings will be blank.

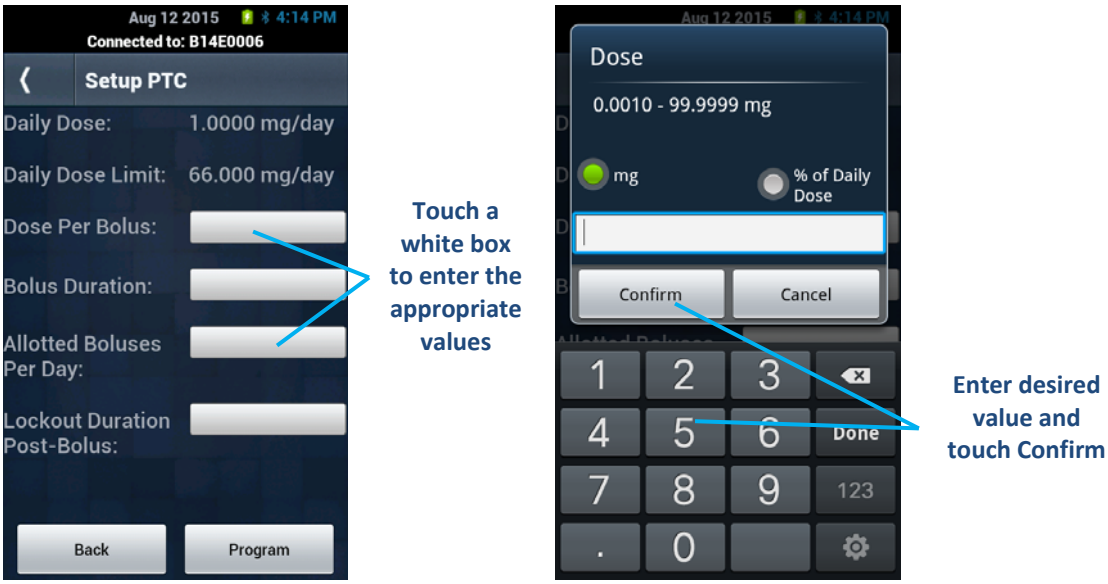


For first time setup, current bolus settings values are blank



After first setup, current bolus settings are displayed following successful pump link

19) Press “Adjust Settings” button on the screen to display a screen to enter bolus information, as well as display pump info (daily dose and daily dose limit).
20) Enter desired information: dose per bolus, bolus duration, allotted boluses per day and lockout duration post-bolus. The bolus dose may be entered in mg or as a percentage of the daily dose.



21) After each field has been completed, select “Program”.
22) The next screen is a confirmation screen displaying all programmed values and calculating the dose amount per day if the user runs the max number of boluses.
23) If the information on the confirmation screen is correct, select “Confirm”.
24) It will now ask you to place the PTC over the pump.
25) Place the Patient Therapy Controller over pump as described in the Patient Therapy Controller Orientation section.
26) The Patient Therapy Controller will run a Pump Link mode.
27) Hold the Patient Therapy Controller over the implanted pump until Patient Therapy Controller says “Pump link successful.”
28) The confirmation screen now displays that the values are set in the Patient Therapy Controller; it is now ready to deliver a bolus when needed.

How to initiate a bolus using the PTC®

1) Follow all steps included in the previous section: “Setting up the Patient Therapy Controller”.
2) After setup is complete, the Patient Therapy Controller will display “Press Rx button below to deliver bolus” along with the Date of Next Refill when the device is powered on. The estimated Date of Next Refill is the date in which the reservoir volume is anticipated to reach 3 Ml based on current flow settings and the maximum possible number of PTC bolus activations.

3) Press the “Rx” button on the device.
4) The device will display “Place PTC over Pump to deliver Bolus”.
5) Place and hold the Patient Therapy Controller over pump until the display reads that bolus delivery was successful and success tone is heard. During this process, the device will display “Programming in progress” to make you aware it has found the pump and it is running its checks and initiating the bolus.

6) If the Patient Therapy Controller is not positioned properly over the pump or if the pump is performing its daily diagnostic test, then the pump will not initiate bolus delivery. The screen will say, “Bolus Not Delivered. Pump Not Found. To Try Again, Press OK.” The PTC has a touchscreen, press the OK button on the touchscreen.

7) The screen following a successful programming will include a countdown timer to indicate how long until the next bolus will be available; this screen will also indicate the estimated next refill date for the pump. The countdown timer is dependent upon the Drug Bolus Duration, Lockout Duration, and the Allotted Boluses per day. If the number of boluses delivered in the past 24 hours is less than the maximum number allowed, the countdown timer will start at the Drug Bolus Duration plus the Lockout Duration. However, if the maximum number of boluses allowed has been reached, the countdown timer may display an extended lockout period. For example:

   Drug Bolus Duration: 30 minutes
   Lockout Duration: 2 hours
   Allotted Boluses per day: 4

   When the first, second, and third boluses are delivered at 9 AM, 12 PM and 3 PM respectively, the countdown timer will start at 02:30 (HH:MM) after each bolus is delivered. However, when the fourth bolus is delivered at 6 PM, the countdown timer will read 15:00 (HH:MM) as all four allotted boluses have been delivered. The PTC will not allow another bolus until hour 24, which would be 9 AM the following day.

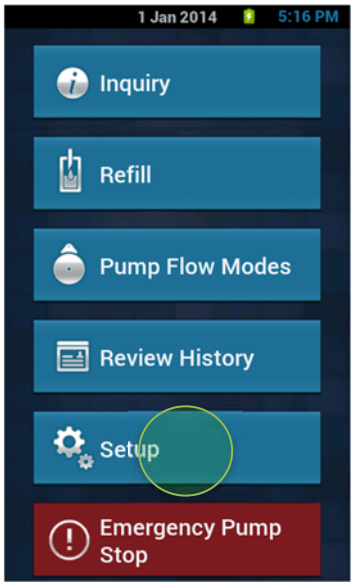
   The Date of Next Refill is calculated each time a bolus is delivered. If boluses are often skipped, the Date of Next Refill may move to a later date the next time a bolus is delivered.

How to view PTC® history using the Clinician Programmer

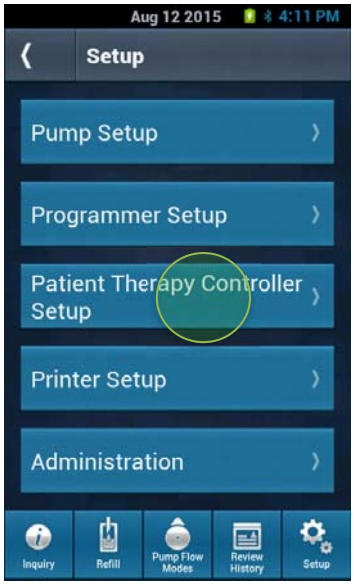
1) If the Patient Therapy Controller is already linked to the Clinician Programmer then skip to Step 17. Otherwise continue onto Step 2.
2) Turn on the Clinician Programmer by holding the power button for 2-3 seconds (until the device vibrates).
3) Wake up the Patient Therapy Controller by pressing the power button.
4) Once booted up, plug the Patient Therapy Controller into its charger.
5) On the Clinician Programmer, select the “Setup” button.
6) On the Clinician Programmer, select the “Patient Therapy Controller Setup” button.
7) On the Clinician Programmer, select the “Connect to PTC” button.
8) Read the steps on-screen.
9) Select the “Scan” button.
10) If no Clinician Programmers were found, try again. If none are found after 2-3 times, unplug the Patient Therapy Controller from its charger for 2 seconds and plug it back in.
11) Once the desired Clinician Programmer is found, select it.
12) Read the next step and select “OK”. There will be a pop up saying “Attempting to connect…”
13) On the Patient Therapy Controller, the display will now read “Press power button to connect to Configuration Device”.
14) Press the power button on the Patient Therapy Controller. Once selected, the Patient Therapy Controller will display “Clinician Programmer Connection Successful”. A few seconds later, the Clinician Programmer will also confirm that the Patient Therapy Controller has successfully connected.
15) Press “OK” on the Clinician Programmer and you will now be in the Patient Therapy Controller Setup menu with the ability to disconnect from the Patient Therapy Controller and Setup the Patient Therapy Controller.
16) Every time the Clinician Programmer connects with a Patient Therapy Controller, it downloads all the history.
17) Select “Review PTC History”.
18) There is a list of all stored Patient Therapy Controllers, with the ability to erase all history from the Clinician Programmer.
19) Select desired Patient Therapy Controller.
20) There is a list of all dates that an event occurred on, with the ability to erase all history from that device from the Clinician Programmer.
21) Select desired date.
22) You can view all the events that occurred on that specific date, with the ability to erase all history from that date on that Patient Therapy Controller from the Clinician Programmer.

How to Remove Patient Therapy Controller Settings from the Pump

1) On the Clinician Programmer, select the **"Setup"** button.
2) On the Clinician Programmer, select the **"Patient Therapy Controller Setup"** button.

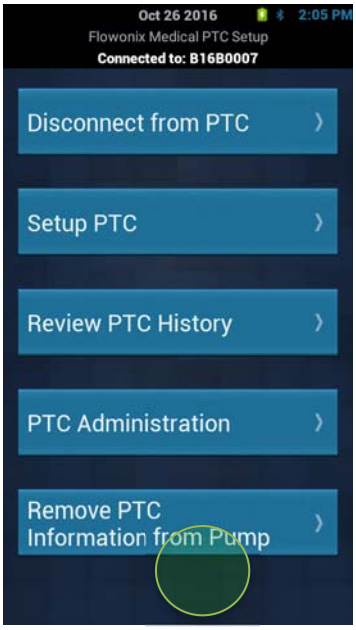


Main Menu Clinician Programmer

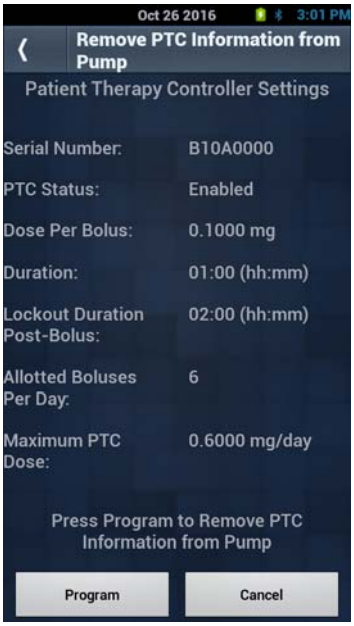


Setup Menu Clinician Programmer

4. On the Clinician Programmer, select the "**Remove PTC Information from Pump**" button. If an Inquiry function has already been performed, the Clinician Programmer displays the Remove PTC Information from Pump screen.
5. If an inquiry has not been performed, the system will prompt the user to perform an Inquiry.



PTC Setup Menu



Remove PTC Information from Pump

6. Select the Program key.
7. Confirm removal of the PTC setting.

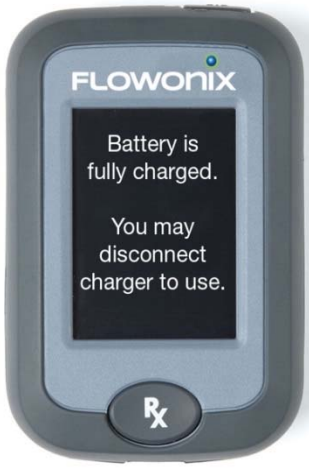
8. Follow the screen instructions. Hold the Clinician Programmer steady until the tone stops. Once the programming process is complete, the Clinician Programmer sounds a confirmation tone and displays the Program Confirmation screen with programmed information.

Troubleshooting Patient Therapy Controller

If assistance is needed at any time during the programming process, please contact **Flowonix Technical Solutions: (855) 356-9665.**

Patient Therapy Controller Battery Messages

The following messages may be displayed on the Patient Therapy Controller depending on the charge level of the device. Once the battery charge reaches 10% or less, the battery indicator message will change from green to red.



Notifies the user that the device has received a full charge of the battery.

Note: The patient does not need to wait for a full charge to deliver a bolus.

Device has enough battery to complete the current task but will need to be charged following use.

Battery of PTC is too low to program a bolus, charge the device above 5% for use.

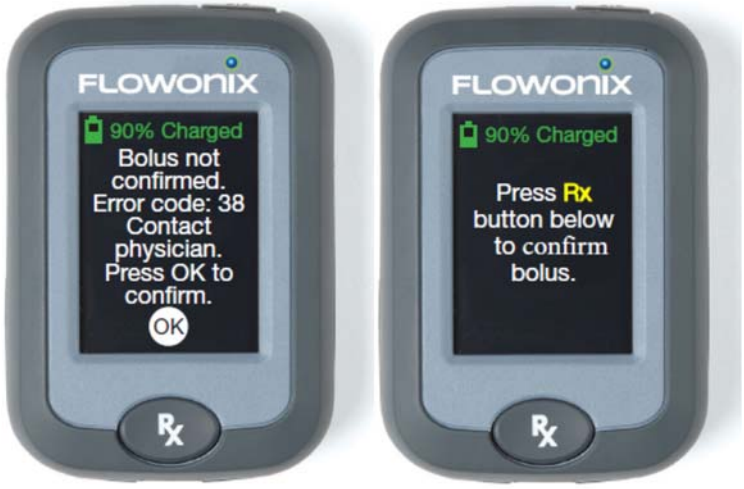
Patient Therapy Controller Wireless Programming Troubleshooting

The Patient Therapy Controller interacts with the pump using a 2-way wireless communication link. The signal used to inquire and program the pump can travel about 2 inches (5 cm). If the Patient Therapy Controller is not positioned properly over the pump, programming may fail. See the "Patient Therapy Controller Programming Orientation" section for positioning graphic and instructions.

Additionally, certain electronic equipment, such as MRI systems, may interfere with the system's wireless communication. Moving the patient from the suspected source of interference should resolve the problem. If there are problems connecting to the pump, refer to the Patient Therapy Controller Programming Orientation section for further troubleshooting sections.

If Patient Therapy Controller communication is interrupted after the pump has activated the bolus delivery, but before the Patient Therapy Controller is able to confirm delivery of the bolus, the message on the screen will say, "Bolus not delivered. Error Code 38. Contact Physician. Press OK to Confirm" as shown below. After pressing "OK", the PTC will display the message "Press Rx button to confirm bolus".

Note: The occurrence PTC communication being interrupted after the pump has activated the bolus delivery is unlikely. Follow the messages on screen to allow the PTC to self-correct by checking if the bolus was delivered. If Error Code 38 continues to appear call Flowonix Medical's Technical Solutions Department at 855-356-9665 or contact your physician.



After you Press the "Rx" button on your Patient Therapy Controller, the screen will display "Place PTC over Pump". Place and hold the Patient Therapy Controller over the Programmable Pump until the display reads that bolus delivery was successful and success tone is heard. During this process, the device will display "Programming in progress". Upon confirmation of the bolus, the PTC will display, "Bolus Delivered Press OK to continue".

Clinician Programmer Wireless Programming Troubleshooting

The Clinician Programmer uses Bluetooth to program the Patient Therapy Controller. If there is a suspected issue with communication or assistance is needed for setup, please call Technical Customer Service.

Touchscreen Troubleshooting

If touchscreen button presses become unresponsive, call Flowonix Technical Solutions at (855) 356-9665 to troubleshoot the device.

Clinician Programmer Error Messages associated with the Patient Therapy Controller

Error messages that could occur with the Clinician Programmer are shown in the table below:

Clinician Programmer Message	Description	Suggested solution for resolution
Connection Failed. Press OK to try again.	Failed to connect with Patient Therapy Controller	Ensure Patient Therapy Controller is powered on. Ensure Patient Therapy Controller is plugged in.
Daily Dose Limit must be enabled. To set Daily Dose Limit go to: Main Menu → Setup → Pump Setup → More Options → Daily Dose Limit	Daily Dose limit is not set for the pump	Use the Clinician Programmer to set the Daily Dose Limit.
Pump Not Found. Press 'Setup PTC' to try again.	Patient Therapy Controller cannot connect to pump.	Ensure Patient Therapy Controller is powered on and within range of the pump.
Disconnect the Patient Therapy Controller from its charger to continue.	Patient Therapy Controller is connected to charger and pump link cannot be performed.	Ensure Patient Therapy Controller is connected to charger.
Pump is in multiple rates mode. Go to Pump Flow Modes menu to set constant flow mode to continue.	Pump is in incorrect flow mode.	Use the Clinician Programmer to set pump to constant flow.
Pump is in periodic flow mode. Go to Pump Flow Modes menu to set constant flow mode to continue.	Pump is in incorrect flow mode.	Use the Clinician Programmer to set pump to constant flow.
Pump is in an unknown mode. Go to Pump Flow Modes menu to set constant flow mode to continue.	Pump is in incorrect flow mode.	Use the Clinician Programmer to set pump to constant flow.

Clinician Programmer Message	Description	Suggested solution for resolution
Data failed to send (after setup when sending data over to Patient Therapy Controller)	Clinician Programmer cannot send data to Patient Therapy Controller for configuration.	Ensure Patient Therapy Controller is powered on.
Dose per bolus is too small for the pump to deliver. Increase dose per bolus Confirm any changes with prescribing physician prior to programming settings! Press OK to Continue.	Bolus parameters were entered at range not allowed by pump.	Check and reenter bolus parameters.
Bolus rate is too fast for the pump to deliver. Decrease dose per bolus Or Increase bolus duration Confirm any changes with prescribing physician prior to programming settings! Press OK to Continue.	Bolus parameters are set at range not allowed by pump.	Check and reenter bolus parameters.
Bolus not accepted. The bolus needs to be greater than the constant flow amount delivered which is x mg/mcg Adjust the bolus amount or duration to try again. Press OK to Confirm.	Bolus is less than constant flow mode.	Update bolus parameters to be greater than the programmed constant flow,
Bolus settings exceed 24 hrs. Please modify.	Bolus parameters were entered at range not allowed by pump.	Check and reenter bolus parameters.
Amount entered would exceed daily dose limit of x mg/mcg	Bolus is larger than the daily dose limit.	Check and reenter bolus parameters that must be less than the programmed flow rate.

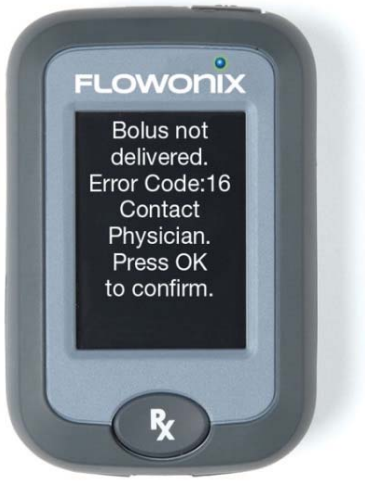
Error Messages Occurring on Patient Therapy Controller

Error messages that could occur with the Patient Therapy Controller are shown in the table below:

Message on Patient Therapy Controller	Description of Message	What you should do if this message appears
Bolus Not Delivered. Pump Not Found. To Try Again, Press OK.	Patient Therapy Controller was unable to communicate with the pump after the Rx button was pressed. This may be due to signal interference, distance between PTC and pump being out of range, or the pump performing its daily diagnostic test.	Press OK. If you want to deliver a bolus, press Rx and then position the Patient Therapy Controller over the implanted pump as described in the Patient Therapy Controller Orientation section. If problems persist, patient should contact physician for further assistance. If problem persists, contact Flowonix Technical Customer Service.
Bolus not delivered. Contact physician for pump refill.	There is not enough drug in the pump to deliver a bolus. The pump requires to be refilled by your physician.	The patient should contact physician to refill pump.
Press Rx Button to Confirm Bolus	The Patient Therapy Controller was unable to communication with your implanted pump after the pump has activated the bolus delivery. This may be due to signal interference or distance between PTC and pump being out of range,	Press Rx and then position the Patient Therapy Controller over your implanted pump as described in the "Patient Therapy Controller Orientation section." If problems persist, contact your physician for further assistance.
PTC not currently set to this pump. Contact physician. Press OK to continue.	Pump not setup with the Patient Therapy Controller.	Patient should contact physician to setup their Patient Therapy Controller.
Your physician must setup the PTC before use.	Your Patient Therapy Controller has not yet been setup or the PTC has reset.	Contact physician to setup your Patient Therapy Controller with your implanted pump. Your Patient Therapy Controller cannot be used until it is properly setup.
Pump is already delivering a bolus. Press OK to continue.	Pump is already in the process of delivering a bolus.	A bolus cannot be initiated if there is already a bolus in process. Wait until the current bolus is complete until trying to deliver another bolus.
Low Battery in PTC. Charge battery after use. Press OK to Continue.	The Patient Therapy Controller's rechargeable batteries are low.	Recharge the Patient Therapy Controller.
Battery is too low to deliver bolus. Plug into charger.	The Patient Therapy Controller's rechargeable batteries are critically low and the PTB is disabled.	Recharge the Patient Therapy Controller batteries.
Battery charging. PTC disabled. Unplug to use.	The device is charging.	Allow recharging to complete on the unit. Unplug the charger from the device to use.

Patient Therapy Controller Pump Critical Error Messages

If during communication the Patient Therapy Controller receives an error message from the pump, it will display the pump critical error message before displaying the standard programming screens. Each error message will be associated with a unique numeric code displayed along with the error message. The numeric code helps Technical Customer Service identify the issue with the pump.



The following table lists the pump-generated status messages with descriptions. If these critical errors are encountered the pump will not allow programming. Contact Technical Customer Service for Assistance.

Error Code	Description of Error
1	POST failure due to low Vcc supply voltage.
2	POST failure due to low Vdd supply voltage.
3	POST failure due to low battery supply voltage.
4	POST failure due to low Vee supply voltage.
5	POST failure due to incorrect Bluetooth System supply voltage.
6	POST failure due to low PVcc supply voltage.
7	POST failure due to hardware error in telemetry circuitry.
8	POST failure due to inability to initialize Bluetooth Module.
9	POST Failure due to hardware error in flash memory interface.
10	POST – Current too high (> 300Ma)
11	Pump stopped
12	Data acquisition circuits are out of tolerance – too high
13	Data acquisition circuits are out of tolerance – too low
14	Battery error – Internal charging circuit charges valve drive too slowly
15	Battery Error – Battery terminal voltage too low to operate valves
16	Battery Error – Battery terminal voltage, with additional load indicates battery EOL
17	Outlet valve pull-open current out of limits
18	Inlet valve pull-open current out of limits
19	Outlet valve hold-open current out of limits
20	Inlet valve hold-open current out of limits
21	Current detected in outlet valve while driving inlet valve
22	Current detected in inlet valve while driving outlet valve
23	Oscillator test failed – slow (measured value too high)
24	Oscillator test failed – fast (measured value too low)
25	Redundant Real Time Clocks in disagreement
26	Watchdog timeout error
27	Check counter Failed POST – count long
28	Check counter Failed POST – count short
29	Basal prescription buffer is corrupted

Error Code	Description of Error
30	Bolus prescription buffer is corrupted
31	Prescription check count failed (short)
32	Prescription check count failed (long)
33	A Soft Reset has been asserted (Non-Maskable)
34	The active area of memory has failed read/write test
35	CRC of code memory has failed
36	Number of memory correction cycles has exceeded error limit
37	Pump Unknown Error
38	Failed to confirm bolus
39	Pump not found
40	Pump is not linked to Patient Programmer
41	Pump is in bolus mode
42	Pump has bad software version (doesn't match what is linked in Patient Programmer)
43	Pump not in constant flow mode
44	Bolus dose less than constant flow over bolus duration
45	Bad RTC (invalid date/time)
47	Sanity (parameter/prescription) or CRC error when trying to delivering bolus
48	Dose will exceed daily dose limit
49	Dose too small
50	Dose with no time
51	Dose too large
52	Allotted bolus too large – triggered if programmed max bolus per day is 0 or total minutes of bolus (bolus duration + lockout period) exceeds programmed max bolus per day
53	Daily dose limit disabled
63	Failed to deliver bolus

Service and Maintenance of the Patient Therapy Controller

The following applies to the Patient Therapy Controller.

Warning: All batteries should be disposed of according to local and federal regulation.

- If the Patient Therapy Controller is no longer going to be used, it should be returned to Flowonix Medical. Please contact Technical Customer Service to arrange shipment or disposal.

Batteries for Patient Therapy Controller (Rechargeable/Internal)

- The rechargeable battery will need to be fully charged prior to initial use. The Patient Therapy Controller will indicate when the battery is fully charged.
  Note: It may take up to 9 hours to fully charge the battery.
- Use the supplied USB charger (AC adapter) to charge the internal battery for the touchscreen using a UL approved power source.
- The charging port is located at the bottom of the device.
- When the battery reaches approximately 10% of its charge, a message will appear on the screen indicating that the battery needs to be recharged.
- The user cannot replace the rechargeable battery inside the Patient therapy Controller. If the battery is no longer charging, then contact Technical Customer Service.
- The charging of device shall be outside of the patient vicinity.
- Over time, unused batteries will discharge and must be recharged before use.
- The shelf life of the device's battery will vary depending on use. If there is a suspected issue and a replacement is needed, contact Technical Customer Service.

Service

The Patient Therapy Controller has no serviceable parts. For technical issues or questions about the Patient Therapy Controller, please contact Technical Customer Service at (855)-356-9665.

Proper Care, Handling, and Shipping

- Do not drop the device or subject it to severe shock. If Patient therapy Controller becomes damaged, contact Technical Customer Service at (855)-356-9665
- Keep the device dry; humidity and all types of liquids may damage device parts or electronic circuits.
- Do not turn on the device if it is wet. If the device is already on, turn it off and remove the batteries immediately (if the device will not turn off or you cannot remove the batteries, leave it as-is). Then, dry the device with a towel and call Technical Customer Service at (855) 356-9665. Caution: Do not use as there is a possible electrical shock hazard.
- Do not store the device in hot or cold areas. Only use the Patient therapy Controller between **20 °C and 40 °C,** the device can explode if left inside a closed vehicle, as the inside temperature can reach up to 80°C.
- Do not expose the device to direct sunlight for extended periods of time (such as on the dashboard of a car).
- **Storage temperature should be between 0 °C and 40 °C.**
- Do not store the device near magnetic fields. The device may malfunction or the battery may discharge from exposure to magnetic fields.
- Do not use carrying cases or accessories with magnetic closures or allow the device to be exposed to magnetic fields for extended periods of time, including exposure to MRI machines.
- If the devices become dirty:
    - Wipe your device or charger with a towel or cloth. Do not spray any liquids on the devices or allow droplets to enter the charging port.
    - Do not use chemicals or detergents.
    - Do not allow excessive moisture to enter the devices. Do not immerse the devices in any type of liquid.

Sterilization and Disinfection

- Do not sterilize the Clinician Programmer or Patient Therapy Controller. Sterilization could damage the unit.
- The Clinician Programmer and Patient Therapy Controller are not intended to be disinfected by cleaning solutions or detergents. Exposure to disinfection procedures could damage the unit.
- As the Clinician Programmer and Patient Therapy Controller are not intended to be sterilized or disinfected, precautions should be used to avoid cross-contamination when handling the units.
- If it becomes necessary to use the Clinician Programmer or Patient Therapy Controller within a sterile environment, such as a surgical field, ensure that a sterile barrier is established between the unit and the patient or pump. Always use standard sterile technique as to avoid cross contamination.
- If the Clinician Programmer or Patient Therapy Controller becomes dirty:
    - Wipe your unit or charger with a towel or cloth. Do not spray any liquids on the unit or allow droplets to enter the charging port.
    - Clean the terminals of the battery with a cotton ball or a towel.
    - Do not use chemicals or detergents.
    - Do not immerse the Clinician Programmer or Patient Therapy Controller in any type of liquid.

Device Software Updates and Upgrades

Your sales representative will inform you when upgrades are available and will schedule a convenient time for this service.

Patient Therapy Controller Specifications

Height	4.60 inches (11.69 cm)
Width	3.20 inches (8.13 cm)
Depth	1.20 inches (3.05 cm)
Weight	Approximately 190 grams
Telemetry Range	Approximately 2 inches (5.08 cm) above the pump Interference may occur in the vicinity of equipment marked with the following symbol: 
Power Source	Rechargeable Lithium ion battery
Use Environment*	Store between 0 °C and 40 °C Use the device between 20 °C and 40 °C Relative Humidity: 60+/-15% Atmospheric Pressure: 860 hPa to 1,060 hPa Rated to operate to an altitude of 2000 m.
Timeout	The Patient Therapy Controller will automatically time out after 1 minute of no operation.
Voltage Rating	5 VDC
Regulatory	i. Degree of electrical insulation: Type BF (body floating) ii. Protection against water ingress: Ordinary equipment (IP22) iii. Mode of operation: Continuous iv. Power source: Model v. Protection against electric shock: Class II power supply used vi. Anesthetic Warning: This equipment not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXED WITH AIR or OXYGEN or NITROUS OXIDE. vii. Means of Operator Protection (MOOP) for Power Supply and Means of Patient Protection (MOPP) for Patient Therapy Controller. viii. Standards used for Patient Therapy Controller: MEDICAL GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008), and IEC 60601-1-2 (2014) Charger standards: UL 60950-1, 2nd Edition (2007-03); CSA C22.2 No. 60950-1-07 2nd Edition (2007-03)

*See Appendix 1 for additional information regarding Electromagnetic Compatibility.

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.

Bolus Dose: prescribed dose, given in a set amount of time.

Bridge Bolus: 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 Pump that allows direct access 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: the dosage prescribed in the Constant Flow, Multiple Rates, and Periodic Flow regimens.

Daily Dose Limit: the maximum dosage that may be prescribed in the Constant Flow, Multiple Rates, and Periodic Flow regimens and PTC Boluses. The demand bolus dosage is LIMITED by the Daily Dose Limit; therefore, it is NOT possible to program a bolus prescription that exceeds the Daily Dose Limit.

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 Constant Flow regimen.

Exception: a Clinician Programmer-generated error message. Exceptions are archived in the Clinician 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” Fluid Pathway includes the pump reservoir, the pump accumulator chamber and the implanted catheter. For measurements refer to the appropriate pump and catheter IFUs.

Inquiry: a specialized transaction in which the Clinician 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 Clinician 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 with an optional daily basal dose to be delivered intermittently between the periodic infusions.

Clinician Programmer: a device that allows clinicians to conveniently and non-invasively interrogate and program the implanted Programmable Pump.

Clinician Programmer History: a record of all pump transactions.

Clinician Programmer Transaction: an operation that does not require interaction with the Pump; that is, the transaction only affects the Clinician Programmer.

Programming: any pump transaction that requires the Clinician Programmer to send information to the pump. The following are programming functions: Constant Flow, Multiple Rates, Periodic Flow, Demand Bolus, Bridge Bolus, Prime Bolus, Refill, and Pump Setup.

PTC: Patient Therapy Controller

Maximum PTC Daily Dose: maximum dose the patient will recieve in the form of PTC boluses if maximum alloted boluses are delivered.

Total Maximum Daily Dose: maximum dose the patient will recieve in the form of the constant flow (Daily Dose) and the Maximum PTC Daily Dose. Since the Daily Dose is interrrupted while the PTC boluses are delivered, the Total Maximum Daily Dose will always be less than the sum of the Daily Dose and Maximum PTC Daily Dose.

Max Daily Dose: see Total Maximum Daily Dose

Pump Status Screens: display of the information received by the Clinician Programmer during the Inquire process once the process is complete.

Pump Transaction: an operation in which the Clinician Programmer sends or receives information from the pump.

Refill Volume: the volume of medication put into the pump during refill.

Refill Date: the date in which the anticipated reservoir volume will reach 3.0 mL. This refill date takes into account all basal flow modes, Maximum PTC Daily Dose, demand, bridge, and priming boluses. The refill date is calculated each time the punp is programmed or inquired on the Clinician Programmer and at the start of each bolus on the PTC.

Telemetry: the process of transmitting and receiving data by wireless signals. The Clinician Programmer interacts with the pump using telemetry.

Wand Hardware: custom printed circuit board that interfaces with the telemetry coil for reading and writing data to the pump.

Appendix 1: Technical Specifications and EMC Tables

The Patient Therapy Controller and Clinician Programmer are intended for use in the electromagnetic environment specified in the following EMC tables. The customer and/or user of these devices should assure that they are operated in such an environment.

Essential Performance of the Clinician Programmer and PTC®
Medical Equipment Performance Criteria - unacceptable operating conditions / responses are:
When charging in standby mode the Clinician Programmer or PTC does not go into operating mode.
When in wireless link mode, the Clinician Programmer or PTC does not stop communication with the pump. It is acceptable for the Clinician Programmer or PTC to be temporarily unable to communicate with the pump during the period it is exposed to sources of electromagnetic interference, provided that the programmer resumes communication once the exposure period has ended. Electromagnetic interference has been classified as a minor risk and does not have an impact on safety.

Specification of RF Frequency Bands
Bluetooth is the only RF Frequency used by the Clinician Programmer and PTC for transmission and reception. Bluetooth frequency is 2400 MHz.

Table 1 – Guidance and Manufacture's declaration – Electromagnetic Emissions – for all ME Equipment and ME Systems

The Patient Therapy Controller and Clinician Programmer are intended for use in the electromagnetic environment specified below. The customer and/or user of these devices should assure that they are operated in such an environment.

RF emissions CISPR 11	Group 1, Class B	These components use RF energy only for their internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	These components are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 2: Guidance and Manufacturer's Declaration - Electromagnetic Immunity for the Clinician Programmer

The Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer and/or the user of this device should assure that it is operated in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential Mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95 % dip in U_T) For 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) <5 % U_T (>95 % dip in U_T) For 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of this equipment requires continued operation during power mains interruptions, it is recommended that this equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	10 A/m	10 A/m 60 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC Mains voltage prior to application of the test level.			

Table 3: Guidance and Manufacturer's Declaration - Electromagnetic Immunity for the Patient Therapy Controller

The Patient Therapy Controller is intended for use in the electromagnetic environment specified below. The customer and/or the user of this device should assure that it is operated in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	The home healthcare environment can be assumed to be uncontrolled with respect to relative humidity and the use of anti-static (or low static) flooring and material. The relative humidity can be quite low in some locations, as low as 5 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical home healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	0 % U_T for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of this equipment requires continued operation during power mains interruptions, it is recommended that this equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC Mains voltage prior to application of the test level.			

Table 4 – Guidance and Manufacturer's declaration – Electromagnetic Immunity – for Clinician Programmer

The Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer and/or the user of this device should assure that it is operated in such an environment.

Immunity Test	IEC 60601Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of this equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey **a**, should be less than the compliance level in each frequency range **b**. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection form structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this equipment is used exceeds the applicable RF compliance level above, this equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this equipment.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 5 – Guidance and Manufacturer's declaration – Electromagnetic Immunity – for Patient Therapy Controller

The Patient Therapy Controller is intended for use in the electromagnetic environment specified below. The customer and/or the user of this device should assure that it is operated in such an environment.

Immunity Test	IEC 60601Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of this equipment, including cables, should be used no closer than 30 cm (12 inches) to any part of the Patient Therapy Controller or Clinician Programmer. Otherwise, degradation of the performance could result. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	

Note: The Patient Therapy Controller has been tested in accordance with the 4th Edition of IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. The recommended separation distance between portable and mobile RF communications equipment and the Patient Therapy Controller is 30 cm (12 inches).

Table 6 – Recommended separation distance between portable and mobile RF communications equipment and the Clinician Programmer

Recommended separation distances between portable and mobile RF communications equipment and the Clinician Programmer			
These devices are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer and/or the user of these devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.7	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1**: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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