Patient Therapy Controller (PTC®) Guide

For use with Prometra® Programmable Infusion Systems

MR Unsafe

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

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.

FCC Information

The following is communications regulation information on the Prometra® Patient Therapy Controller.

FCC ID: A3LYPGI1

FCC ID: T7V1315

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and

(2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Changes or modifications to this product not authorized by Infusyn Therapeutics, could void the FCC Certification and negate your authority to operate this product.

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.

Table of Contents

Glossary

Bolus or Drug Bolus – supplement drug dose prescribed by your doctor. This drug dose has a set amount and is delivered in a set amount of time.

PTC® – Patient Therapy Controller

Dose per Bolus – the amount of medication that will be delivered by your pump.

Drug Bolus Duration – the length of time that it will take to deliver your bolus.

Allotted Boluses per day – The maximum number of boluses allowed to be delivered within 24 hours.

Lockout Duration – The length of time that you must wait between bolus deliveries.

Date of Next Refill – the date in which the anticipated reservoir volume will reach 3.0 mL. This refill date makes the assumption that all allotted boluses per day will be delivered. The PTC calculates the refill date at the start of each bolus.

Patient Therapy Controller

Software Revision: 2.01.2

PTC® Description

The Patient Therapy Controller is an accessory to the Prometra® Programmable Infusion System that allows you to periodically deliver additional doses of Infumorph® (a drug bolus) as prescribed by your doctor. When you activate the delivery of a drug bolus with the Patient Therapy Controller, it communicates with the implanted Programmable Pump and tells it to deliver the drug bolus. 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.

Purpose of the PTC®

(FDA approved 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.

Potential Benefits

Your doctor may have prescribed the use of the Patient Therapy Controller if you need additional doses of Infumorph® to treat your symptom variations, intolerable side effects or your current treatment regimen is not decreasing your symptoms. The use of the Patient Therapy Controller may help you better manage your drug delivery therapy from your Programmable Pump.

Potential Risks

The possible risks of using the Patient Therapy Controller include the potential side effects from receiving additional doses of Infumorph®.

The potential side effects of Infumorph® are as follows:

- If nausea occurs, consult your doctor or pharmacist for ways to decrease it (such as taking antihistamines, lying down for 1 to 2 hours with as little head movement as possible).
- This medication may cause dependence, especially if it has been used regularly for a long time or in high doses. In such cases, withdrawal reactions (such as restlessness, watery eyes, widened pupils, sweating, and runny nose) may occur if you suddenly stop this drug. To prevent withdrawal reactions, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details, and report any withdrawal reactions immediately.
- When this medication is used for a long time, it may not work as well. Your doctor may need to increase your dose or change your medication. Talk with your doctor if this medication stops working well.
- Along with its benefits, this medication may rarely cause abnormal drug-seeking behavior (addiction). This risk may be increased if you have abused alcohol or drugs in the past. Use this medication exactly as prescribed to lessen the risk of addiction.
- Tell your doctor if your pain persists or worsens.

Patient Therapy Controller

Potential Risks (continued)

- Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, increased sweating, or dry mouth may occur. Pain, redness, or swelling at the injection site may occur if this medication is given into a muscle or under the skin. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.
- To prevent constipation, maintain a diet adequate in fiber and drink plenty of water, if not contraindicated. If necessary, consult your doctor for help in selecting a laxative (such as a stimulant type with stool softener).
- Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.
- Tell your doctor immediately if any of these rare but very serious side effects occur: severe stomach or abdominal pain, change in the amount of urine
  or seizures.
- A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including rash, itching/swelling (especially of the face, tongue or throat), severe dizziness or trouble breathing.
- This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor.

Radio Signals

Radio signals sent by your Patient Therapy Controller could interfere with other medical devices. Tell your doctor if you use any other devices (such as a pacemaker, insulin pump, or pain-relief device).

How to use your PTC®

Before you use your Patient Therapy Controller, please complete the following steps to help ensure your system continues to function properly:

- Read the Patient Guide for the Prometra® Programmable Infusion System that was provided with the Programmable Pump.
- Read this Patient Therapy Controller Guide.
- Do not use your Patient Therapy Controller until your physician has trained you
  on its use.
- Handle your Patient Therapy Controller with care – see the **Handling and Care** section (page 22).
- Ensure your Patient Therapy Controller's rechargeable battery is charged before 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.

How the PTC® Works

Your Patient Therapy Controller is linked to your specific Programmable Pump; it cannot be shared amongst other pump patients. This feature prevents unintended Infumorph® delivery. Your physician sets the limits on the amount of Infumorph® dosage that can be delivered and when it can be delivered. If you activate the Patient Therapy Controller and your request is within the physician's prescription, the pump will deliver the dose of Infumorph® (or drug bolus).

Patient Therapy Controller

How the PTC® Works (continued)

Your doctor programs the parameters that control your bolus dose. Your doctor programs the following information into your Patient Therapy Controller:

- **Dose per Bolus:** the amount of medication that will be delivered by your pump.
- **Drug Bolus Duration:** the length of time that it will take to deliver your bolus.
- **Allotted Boluses per day:** The maximum number of boluses allowed to be delivered within 24 hours.
- **Lockout Duration:** The length of time that you must wait between bolus deliveries.

If you have any questions concerning the use of your Patient Therapy Controller, call Infusyn Therapeutics' Technical Support Department at 855-356-9665 or contact your physician.

PTC® Overview

The Patient Therapy Controller has 2 buttons, a power button and a prescription button, and color touchscreen to allow you to initiate a bolus. The Patient Therapy Controller communicates with the Programmable Pump via a wireless signal (referred to as telemetry).

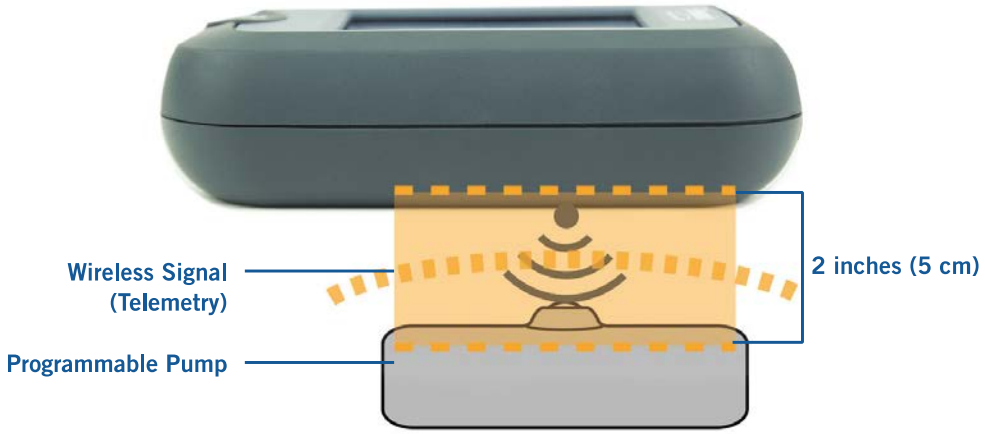
The Patient Therapy Controller consists of four main components:

1. LCD Touchscreen
2. Power Button
3. Prescription Button
4. Internal wireless transmitter used for communication with your implanted Programmable Pump.

Patient Therapy Controller

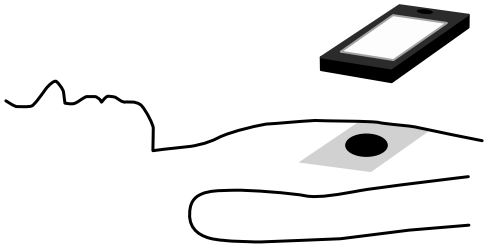
PTC® Orientation

The signal used to program the Programmable Pump **can travel up to 2 inches (5 cm)**. If the Patient Therapy Controller is not positioned close enough to the pump or is not oriented correctly over the pump, the Patient Therapy Controller will not be able to communicate with the pump.



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

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



Position of the Patient Therapy Controller over the Programmable Pump

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

Patient Therapy Controller

PTC® Orientation (continued)

3. Hold the Patient Therapy Controller steady until the tone stops and the message changes on the device's screen. The Patient Therapy Controller's tone lasts up to approximately ten seconds. Once connection is complete, the Patient Therapy Controller sounds a confirmation tone.

Note: If a bolus cannot be confirmed, it may be due to interference or the communication distance being out of range during inquiry or programming. Refer to the Troubleshooting section (page 15) if there is difficulty with wireless communication.

Warnings

- 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, please avoid contact with water.
- Only use the Patient Therapy Controller after receiving training specific to this device. Use of this device by non-qualified or untrained personnel could lead to serious consequences involving under- or over-dosage of Infumorph®. In the event of over-dosage, refer to the approved Infumorph® labeling for appropriate treatment.
- Clinicians programming implanted Programmable Pumps must comply with the instructions for use. Technical errors may result in a return of underlying symptoms, drug withdrawal symptoms, or clinically significant or fatal over-dose.
- The handheld Patient Therapy Controller uses electromagnetic energy to program the Programmable Pump. The device's electromagnetic field may affect other medical devices. Use or interference with other medical devices has not been established.
- Schedule regular refill visits to avoid reservoir depletion and possible discomfort. Contact your physician if you experience changes in your symptoms.
- Potential communication problems between the Programmable Pump and the 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.
- Use of a power source other than those provided by Infusyn could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- To avoid the risk of shock, when using the AC adapter to charge the Patient Therapy Controller, it must be connected to a grounded AC power outlet.
- The Patient Therapy Controller is not intended to be functional and used while it is charging. All inquiring and programming functionality is disabled.
- Use of the 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 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 Patient Therapy Controller including cables specified by Infusyn. Otherwise, degradation of the performance of this equipment could result.
- Patient Therapy Controllers with software versions prior to 2.01.1 are not compatible with Prometra II 40 mL pumps. Contact Infusyn Therapeutics' Technical Support at (855) 356-9665 for more information on software upgrades.
- **MRI Safety:** The Patient Therapy Controller is 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.
- The wireless communication signal used to inquire and program the Programmable Pump (referred to as telemetry) can travel about 2 inches (5 cm). If the Patient Therapy Controller is not positioned closely enough to the pump or is not oriented correctly over the pump, the Patient Therapy Controller may not be able to initialize a connection with the pump.
- Do not disassemble the Patient Therapy Controller. Disassembling the Patient Therapy Controller may damage it or cause it to malfunction.
- Certain electronic equipment may cause interference with the Patient Therapy Controller. Interference may also occur near equipment marked with the symbol shown below. Move away from the suspected source of interference. Examples of equipment that may cause interference include cathode ray tube (CRT) monitors and large electric motors.
- Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Programmable Pump and Patient Therapy Controller.

How to Initiate a Bolus using the PTC®

1. Your health care professional will set up your Patient Therapy Controller before you can use it. Until it is setup, the Patient Therapy Controller will indicate, “Your physician must setup programmer before use”.

How to Initiate a Bolus using the PTC®

2. Prior to using, ensure your Patient Therapy Controller is charged. To charge, plug in your included Micro USB Charger into the USB port located at the bottom of the Patient Therapy Controller. Then, connect it to an AC outlet. When charging, the Patient Therapy Controller is disabled and cannot be used. Once it is charged, you can unplug it and it will be ready to use.

Connect the USB Charger into the USB port located at the bottom of the Patient Therapy Controller.

How to Initiate a Bolus using the PTC®

Note: While the battery is charging, the Patient Therapy Controller does not indicate the amount of charge. To determine the percentage of battery charged, simply unplug the device from the charger and press the power button. You will feel and hear a “click” when it is pressed. The amount of charge will be displayed at the top of the screen.

Note: Charge will need to be above 5% to deliver bolus.

Power Button

Battery Charge Indicator

3. Once your Patient Therapy Controller is setup, it 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 for the pump 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.

Rx Button

How to Initiate a Bolus using the PTC®

4. After you Press the “Rx” button on your Patient Therapy Controller, the screen will display “Place Programmer over Pump to deliver bolus”. 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”.

5. If you have not positioned the Patient Therapy Controller properly over the pump, then the pump will not activate the bolus delivery. The message on the screen will say, “Bolus not Delivered. Pump Not found. To try again, Press OK”
as shown below.

6. If this occurs, simply press “OK” and then go back to step 3 above and press the “Rx” button. Then reposition the Patient Therapy Controller over the pump as described in the **Patient Therapy Controller Orientation Section** (page 9) and follow steps 4 and 5.

How to Initiate a Bolus Using the PTC®

7. Once you have successfully activated your bolus, the screen will indicate that the bolus was delivered. Press "OK" to continue to the next screen which will show 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:

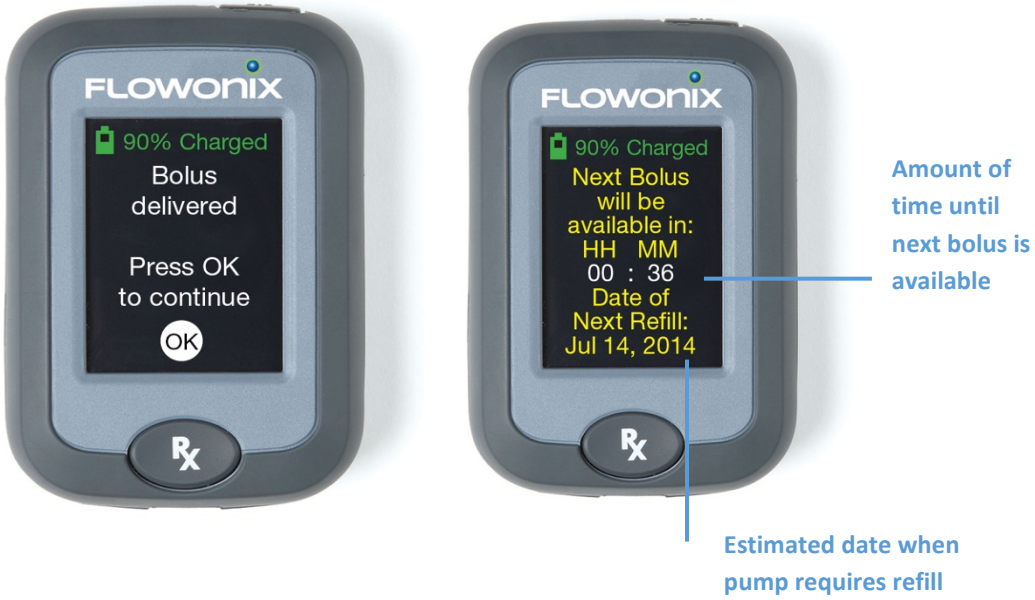
   Drug Bolus Duration: **30 minutes**

   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.

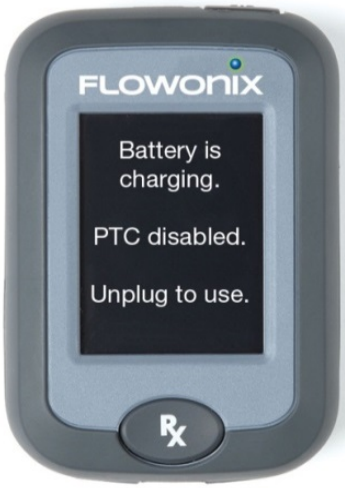


Troubleshooting

If assistance is needed at any time during use, please contact your physician or Infusyn Therapeutics' Technical Support Department at 855-356-9665.

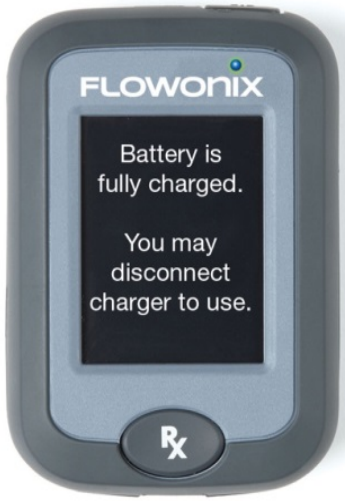
PTC® Battery Messages

The following messages may be displayed on the Patient Therapy Controller depending on the charge level of your device.



This message reminds the user that the device cannot be operated at the same time it is charging.

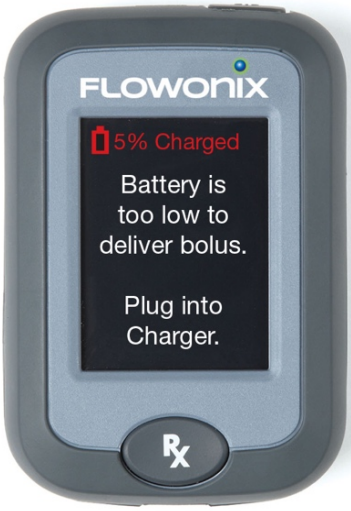
The patient does not need to wait for a full charge to deliver a bolus. *If a bolus is desired: disconnect the programmer from the charger and check on the battery charge level.*
Charge will need to be above 5% to deliver bolus.



The Patient Therapy Controller has received a full charge of the battery.

To use the Patient Therapy Controller, unplug from the charger.

At 10% battery, the charged icon will turn red. The Patient Therapy Controller has enough battery to complete the current task, but you should charge your battery following this use and before your next use.



Once the battery charge reaches 5% or lower, the Patient Therapy Controller will not be able to deliver a bolus. You must charge your battery before your next use.

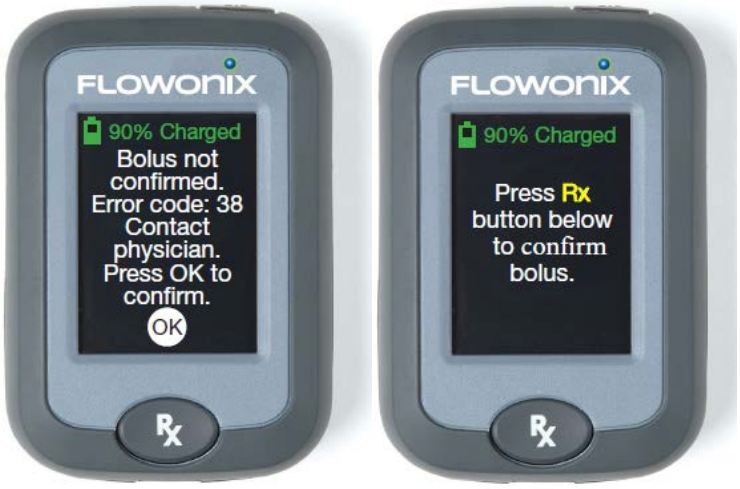
PTC® Wireless Communication Troubleshooting

The Patient Therapy Controller interacts with the Programmable 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, it may not be able to communicate with the pump and the bolus delivery may fail. See the **Patient Therapy Controller Orientation** section (page 9) for positioning information.

Additionally, certain electronic equipment, such as MRI systems, may interfere with the system's wireless communication. Moving away from the suspected source of interference should resolve the problem. If there are problems connecting to the pump, refer to the **Patient Therapy Controller Orientation** section (page 9) 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 Infusyn Therapeutics' Technical Support 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".

PTC® Wireless Communication Troubleshooting (continued)

Touchscreen Troubleshooting

If the touchscreen button presses become unresponsive, contact your physician to troubleshoot the device.

Troubleshooting

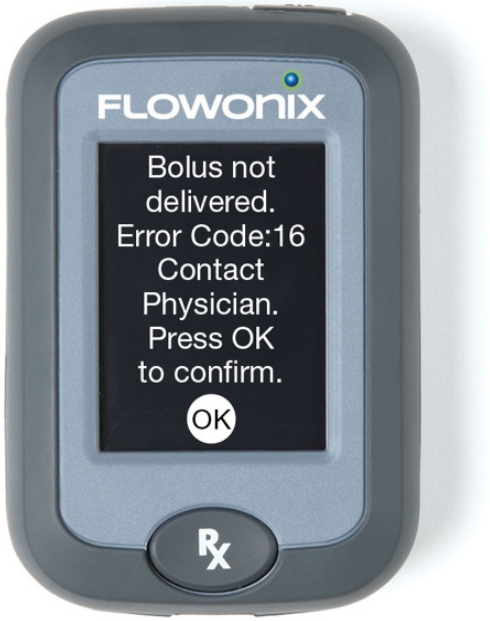
Messages that might Appear on Your PTC's Screen

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.	The Patient Therapy Controller was unable to communicate with your implanted 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 your implanted pump as described in the "Patient Therapy Controller Orientation section" (page 9). If problems persist, contact your physician for further assistance.
Bolus not delivered. Contact physician for pump refill.	There is not enough drug in your pump to deliver a bolus. Your pump must be refilled by your physician.	Contact your physician to refill your Programmable 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" (page 9). If problems persist, contact your physician for further assistance.
PTC not currently set to this pump. Contact physician. Press OK to continue.	Your Programmable Pump is not setup with your Patient Therapy Controller.	Contact physician to setup your Patient Therapy Controller with your implanted pump. Your Patient Therapy Controller cannot be used until it is properly setup.
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 your current bolus is complete before trying to deliver another bolus.
Low Battery on PTC. Charge battery after use. Press OK to Continue.	The Patient Therapy Controller's rechargeable batteries are low.	Recharge the Patient Therapy Controller's batteries.
Battery is too low to deliver bolus. Plug into charger.	The Patient Therapy Controller's rechargeable batteries are critically low and the Patient Therapy Controller is disabled.	Recharge the Patient Therapy Controller's batteries.
Battery charging. PTC disabled. Unplug to use.	The Patient Therapy Controller is charging. Your Patient Therapy Controller cannot be used while charging.	Allow recharging to complete on the device. Unplug your Patient Therapy Controller from the charger in order to use.

Troubleshooting

PTC® Pump Error Messages

If the Patient Therapy Controller receives an error message from the Programmable Pump, the Patient Therapy Controller will display the pump 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 the Technical Solutions Department identify the issue with the pump. Below is an example of what an error message would look like. In all cases, contact your physician or Technical Solutions Department for further assistance.



Service and Maintenance

The following applies to the Patient Therapy Controller.

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

- If you are no longer going to use the Patient Therapy Controller, you should return it to your physician. Your physician will arrange to have it to returned to Infusyn Therapeutics.

Batteries for PTC® (Rechargeable/Internal)

- Use the supplied Micro USB Charger (AC adapter) to charge the internal battery for the touchscreen using a UL approved power source.
- The charging USB 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 is low and needs to be recharged.
- You cannot replace the rechargeable battery inside the device.
- If the battery is no longer charging, then contact your physician.
- Over time, if you do not use your Patient Therapy Controller, the battery will deplete and must be recharged before use.

The life of the Patient Therapy Controller's battery will vary depending on use. If there is a suspected issue with the battery, contact your physician to coordinate getting a replacement.

Service

The Patient Therapy Controller has no serviceable parts. For technical issues or questions about the programmer, please contact your physician or contact Infusyn Therapeutics' Technical Support Department.

Handling and Care

- Do not drop the Patient Therapy Controller or subject it to severe shock. If the device becomes damaged, contact your physician.
- Keep the device dry; humidity and all types of liquids may cause damage.
- Do not turn on the device if it is wet. If the device is already on, turn it off (if the device will not turn off, leave it as-is). Then, dry the device with a towel and contact your physician.

  Caution: If device becomes wet, 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 **68° F and 104° F**. The device can explode if left inside a closed vehicle, as the inside temperature can reach up to 176° F.
- 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 32° F and 104° F.**
- 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 encounter magnetic fields for extended period of time, including exposure to MRI machines.

If the Patient Therapy Controller becomes dirty:

- Wipe your device or charger with a towel or cloth. Do not spray any liquids on the device or allow droplets to enter the charging port.
- Do not use chemicals or detergents.
- Do not allow excessive moisture to enter the device. Do not immerse the device in any type of liquid.

Sterilization

Do not sterilize the Patient Therapy Controller. If a sterile barrier is desired, place the device in a clear sterile bag or sleeve.

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 32° F and 104° F Use the device between 68° F and 104° F Relative Humidity: 60+/-15% Atmospheric Pressure: 860 hPa to 1,060 hPa Rated to operate to an altitude of 2000 m
Timeout	The programmer 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

*See Appendix 1 for additional information regarding Electromagnetic Compatibility.

Legal Notices

Infusyn Therapeutics (“Infusyn”) makes no representations or warranties with respect to Prometra® Patient Therapy Controller, any software, or the contents of this documentation, or use of same, and specifically disclaims any express or implied warranties of merchantability or fitness for any particular purpose. Further, Infusyn reserves the right to revise the Patient Therapy Controller, any software and/or this publication and to make changes to its design or content, at any time, without obligation to notify any person or entity of such revisions or changes except as required by law or governing regulatory agencies. This product may require
export authorization from the U.S. Department of Commerce prior to exporting from the U.S.

Warranty

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

To the extent allowable by applicable law, this limited product warranty is in lieu of all other warranties, whether express or implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. In no event will Infusyn be liable for any incidental or consequential damages resulting from handling or use of this product.

Some states and/or countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state and/or country.

General Disclaimer

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

Trademarks are the property of their respective owners.

US and Foreign patents issued and pending. Please consult www.infusyn.com for the most up-to-date information.

Appendix

Technical Specifications and EMC Tables

The Patient Therapy Controller is intended for use in the electromagnetic environment specified in the following EMC tables. The user of the device should assure that it is 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 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.		
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	

Appendix

Technical Specifications and EMC Tables (continued)

Table 2: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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	± 6 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 % UT for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle and 70 % UT for 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle and 70 % UT for 25/30 cycles Single phase: at 0° 0 % UT; 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: UT is the AC Mains voltage prior to application of the test level.			

Appendix

Technical Specifications and EMC Tables (continued)

Table 3 – 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 or the user of this equipment should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test 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	

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An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Infusyn Therapeutics to see if additional product information is available.

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