

FLOWONIX

URGENT FIELD SAFETY NOTICE

Prometra® Programmable Pump System

RECIPIENTS: Health Care Providers using Prometra® Programmer Software 1.06.1 or prior with Prometra® and Prometra® II Programmable Pumps

August 12, 2019

Product Name: Prometra® Pump

Catalog No.: Prometra® Programmer - REF 91828 (Software Versions 1.03, 1.06, 1.06.1)
Prometra® Pump - REF 91827
Prometra® II Pump - REF 93827

Dear Healthcare Provider,

The purpose of this letter is to advise you of a software anomaly associated with the Prometra® Programmer with Software Versions 1.03, 1.06, 1.06.1. This software anomaly has the ability to unexpectedly shut down the pump if a certain extended programming sequence is used with the pump while in Periodic Flow or Multiple Rates flow mode, leading to abrupt cessation of drug therapy.

In this case, the pump sounds a one-beep alarm, displays "Error Code 115", and shuts down. This behavior differs from the Instructions for Use, which state the pump will sound three long (1/2 second) beeps every 30 minutes for all critical errors. Patients abruptly deprived of morphine sulfate or baclofen may suffer a significant reduction in pain relief or withdrawal syndrome due to lack of drug therapy.

To date, Flowonix has received zero (0) reported events related to the Error Code 115 issue from the EU or other countries outside of the USA. In the USA, Error Code 115 events have occurred, however these events were caused by a different US-only version of Programmer and software. Flowonix has conducted non-clinical bench-top testing which demonstrates that pumps programmed with the CE-Marked Prometra Programmer (REF 91828) could abruptly stop during specific programming sequences as described below. Flowonix is providing this notification to help clinicians avoid an unexpected pump stop that could lead to cessation of therapy for patients.

Prometra® Programmer Software Versions 1.03, 1.06, or 1.06.1:

The software anomaly may cause the pump to shut down if a Healthcare Provider programs a lengthy Demand bolus while the pump is set to either a Periodic Flow or Multiple Rates flow mode. In this case, the programmer displays "Error Code 115" and the pump will need to be explanted. However, this pump stop will only occur after the Demand Bolus is complete, which could take up to seventy-two (72) hours. Accordingly, it is likely that such a shut-down would occur after a patient has left the Healthcare Provider's office and returned home. Patients whose pumps have been programmed with Constant Flow Therapy are not susceptible to errors of this kind.

Approval Date: July 2019
CC FSN2019-035-02 Rev. B

FLOWONIX

Prometra Pump Error Code 115 Alarm:

In the event of any cause of a Prometra pump Error Code 115, the pump sounds a one-beep alarm and then shuts down. This behavior differs from the Instructions for Use, which state the pump will sound three long (1/2 second) beeps every 30 minutes for all critical errors. As it is unlikely that the patient will notice the single beep, there may be a significant delay in the patient becoming aware that the pump has stopped delivering therapy which may in turn delay resumption of drug therapy.

Actions to be Taken by the Healthcare Provider

All Healthcare Providers should take these steps:

1. STOP using the Demand Bolus feature for patients in a Periodic Flow or Multiple Rates flow mode, as this programming sequence has been determined to be a potential cause of a 115 error and pump stoppage.

In the event that a Demand Bolus is needed, convert the patient to Constant Flow Mode, then program the Demand Bolus as needed (instructions for use PL-81797-04, page 21). Once the bolus is complete, revisit the patient or have them return to your clinic for programming back to their desired Periodic Flow or Multiple Rates flow mode.

2. IDENTIFY and CONTACT all patients who have had a Demand Bolus programmed while in Periodic Flow or Multiple Rates flow mode. These patients are at high risk of a pump shutdown due to Error Code 115. PERFORM a clinical assessment to determine if they have suffered any harm. ADVISE the patient that if they experience withdrawal symptoms at a later time to immediately contact your office (if during business hours) or call 112.
3. SCHEDULE the patient to have their pump reprogrammed as soon as possible, if a Demand Bolus has been programmed while in Periodic or Multiple Rates flow mode. COUNSEL the patient that if they experience withdrawal symptoms or a significant reduction in pain relief, to immediately contact your office (if during business hours) or call 112.
4. Be aware of and inform patients regarding the one-beep pump alarm for an Error Code 115.
5. Review an excerpt of the Prometra Programmer IFU provided with this Field Safety Notice that provides track changes to the instructions, See Attachment A. The Programmer IFU has been updated to include a warning regarding the programming sequence that should be avoided to prevent the risk of pump shutdown. Note: the complete Prometra Programmer IFU (PL-81797-04) is available on the Flowonix website at www.flowonix.com.

Follow-up Action by Flowonix Medical

Clinician Programmers: We are developing a solution to address all concerns associated with this issue in a new version of the Programmer. This will take some time. In the interim, the key safeguard is to stop using Demand Bolus features while a patient is in a Periodic Flow or Multiple Rates flow mode, as this programming sequence has been determined to be a potential cause of this error.

FLOWONIX

Serious Risk to Health

Patients whose pumps stop will have their medication abruptly discontinued.

Patients on INFUMORPH may experience withdrawal syndrome. Some or all of the following can characterize this syndrome: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other signs and symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate. (Reference: Infumorph Package Insert REF ID 4027903, Section 9.3, Recent Changes/Updates 12/2016.)

Patients on baclofen who experience abrupt cessation of the therapy may experience sequelae that include high fever, altered mental status, exaggerated rebound spasticity and muscle rigidity that in rare cases progressed to rhabdomyolysis, multiple organ-system failure, and death. (Reference: Gablofen Package, section 5.5 Insert REF ID MKT-GAB-002-01-JUL-2017, Recent Changes/Updates 03/2017)

Other Information

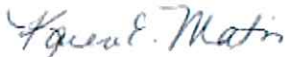
The appropriate Competent Authorities have been notified of this Field Safety Corrective Action.

This Safety Notification should be distributed to all those who need to be aware within your organization or to any organization where Prometra® Programmers with Software Version 1.03, 1.06, 1.06.1 are used.

Should you have concerns or require further clarification, please contact your Flowonix Representative.

Thank you for your cooperation.

Sincerely,



Karen E. Matis, RAC, CCRA
Senior Vice President
Clinical, Quality & Regulatory Affairs
Flowonix Medical, Inc.

Attachments:

Attachment A: An excerpt of the Prometra Programmer IFU (PL-81797-04)

Attachment A – Excerpt from Prometra Programmer (REF 91828) IFU


Programmer Instructions for Use revised text to address Error Code 115

Instructions for Use Reference:

PL-81797-04 Prometra Programmer (REF 91828) IFU

Pages 16 and 19 -

Added the following Warning to the Multiple Rates and Periodic Flow Regimen Sections:

 WARNING: DO NOT PROGRAM A DEMAND BOLUS WHILE IN PERIODIC OR MULTIPLE RATE FLOW MODE. PROGRAMMING A DEMAND BOLUS WHILE IN MULTIPLE RATE OR PERIODIC FLOW MODE HAS A HIGH RISK OF PUMP SHUTDOWN.

Page 20 - Edits to the Demand Bolus Regimen Section as follows:

Demand Bolus Regimen

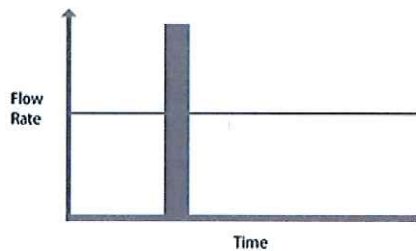
The Demand Bolus regimen temporarily replaces the current regimen to either deliver an immediate, one-time infusion of medication, prime the implanted pump, or clear the fluid pathway for a new drug or drug concentration (bridge bolus). Program the medication dosage and duration, within the following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


	Value Limit	
Dose	Min	00.0000 mg
	Max	99.9999 mg
Pump Delivery Rate	Min	0.0 mL/day for emergency pump stop
		0.1 mL/day to maintain catheter patency
	Max*	28.8 mL/day, or 1.2mL/hr, or 20 uL/min
Duration	Min	20 min
	Max	71 hours and 59 minutes

**approximate based on pump's accumulator volume*

Warning: The bolus dosage is NOT limited by the Daily Dose Limit; therefore, you can program a bolus prescription that exceeds the Daily Dose Limit

When the bolus finishes, the pump continues with its regularly scheduled flow regimen. The following diagram illustrates a Demand Bolus that was programmed while a **Multiple Rates/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 finished.



 WARNING: DO NOT PROGRAM A DEMAND BOLUS WHILE IN PERIODIC OR MULTIPLE RATE FLOW MODE. PROGRAMMING A DEMAND BOLUS WHILE IN MULTIPLE RATE OR PERIODIC FLOW MODE HAS A HIGH RISK OF PUMP SHUTDOWN.
