

URGENT DEVICE FIELD CORRECTION



<i>Product</i>	<i>Version Number</i>	<i>List Number</i>	<i>Lot Numbers</i>
GemStar™ SP Infusion Suite Database (PC Application)	1.0	13092-01	71-494-G1 72-613-G1 84-832-G1

March 23, 2011

Dear Valued Customer:

Hospira, Inc. has identified that the GemStar devices utilizing the PC application identified above are capable of being programmed for a Bolus Lower Lockout Limit interval less than the programmed hard limit value stored in the GemStar SP Infusion Suite Database PC application. This could potentially result in the infuser granting more frequent bolus delivery requests than intended in programming the hard limit potentially causing over-delivery of medication to the patient.

The cause is software related. If the Lower Hard Limit for bolus lockout time programmed into the PC application is greater than 15 minutes, the value stored on the GemStar device is the remainder of the value on the PC application divided by 16, e.g. a value of 20 minutes entered into the PC application is stored on the GemStar device as 4 minutes (20 minutes divide by 16 equals 1 with a remainder of 4). This allows the clinician to program the device with a Bolus Lockout Limit outside (below) the programmed hard limit value. Please note that this software issue does not cause a programming mistake, but it does allow a program to be entered that is outside the Lower Hard Limit for Bolus Lockout time when the limit is greater than 16 minutes.

We are finalizing software enhancements which will resolve this situation and will contact you when the update is available. Until the software can be upgraded, **the maximum Bolus Lockout Lower Hard Limit that should be programmed on the GemStar SP Infusion Suite Database is 15 minutes.**

Hospira has not received any reports of patient involvement, adverse events or delays in therapy as a result of this issue. This field correction is being conducted as a precautionary measure. The U.S. Food and Drug Administration has been notified.

Please complete the attached Reply Form and return it via fax to the number on the form, even if you no longer are using this software.

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Product Safety and Complaints	1-800-441-4100 (8am-5pm CST, M-F) (ProductComplaintsPP@hospira.com).	To report adverse events or product complaints
Hospira Advanced Knowledge Center	1-800-241-4002, option 4 (Available 24 hours a day/7 days per week)	Additional information Technical Assistance



Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Linking to the MedWatch website at www.fda.gov/medwatch
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Mailing to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787

Hospira is committed to providing our customers with the highest level of service and product quality. We regret any inconvenience this action may cause and ask your cooperation in this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Ileana Quinones".

Ileana Quinones
Vice President, Device Quality Operations

**Urgent Device Field Correction Effectiveness Check
Response Required**



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COMPLETE THE INFORMATION AND FAX THE COMPLETED FORM TO 262-577-6921.

The following action has been taken:

Healthcare professionals who utilize the GemStar SP Infusion Suite Database PC Application have been made aware of this letter: Yes _____ No _____

If NO, provide reason:

Customer Information

Business Name

Address/City/State/Zip

Hospira Customer Number (if applicable)

Contact Name

Contact Phone/e-mail Address

Completed by: Printed Name/Signature/Date