FIELD SAFETY NOTICE
Q CORE MEDICAL - SAPPHIRE INFUSION PUMP

Sapphire Multi-Therapy Pump – Hospira L/N and 163113601/Q Core P/N 15031-000-0001 Sapphire Epidural Pump – Hospira L/N and 163123601/Q Core P/N 15032-000-0001

26 October 2015

Dear Valued Customer,

Q Core Medical has received complaints from a small number of customers that there may be a delay in delivery of pain medication when using Epidural mode with patient bolus on Sapphire Multi-Therapy and Sapphire Epidural pumps that have Software version 11.07 or lower installed. On these pumps, this delay can only occur if the user attempts to start the infusion without first opening the clamp.

Cause

Under specific conditions, if a treatment that is programmed in Epidural mode is started by the user without the user opening the clamp, the pump may not detect an occlusion.

This resultant potential delay in therapy may happen, if, and only if, all of the following conditions occur concurrently:

A. The **clamp is left closed** at the "start" of the treatment; and
B. The treatment is set at **Epidural mode**; and
C. The programmed treatment is set to "**bolus only**", i.e the basal rate=0;

This specific combination of conditions may only occur with pumps that have Software version 11.07 or lower.

Risk to Health

Though no patient injuries or deaths have been reported as a result of this issue, there is a potential risk of harm due to the potential delay in the pain therapy.

Action Taken by the Company

Q Core has a software upgrade that includes a correction for this issue. This version also includes additional functionality enhancements. You will be contacted by Hospira, Q Core's distributor, to coordinate the upgrade of the software as soon as possible. Until the software is upgraded, please remind the hospital team to be certain to open the clamp when starting an infusion.

Actions to be taken by the user

1. **Inform**: Inform the healthcare professionals in your organization about this notification and provide them with a copy of this notification.
2. **Remind**: Until the software is upgraded, remind the hospital team to open the clamp when starting an infusion.
3. **Upgrade**: Coordinate the pump software upgrade as soon as you are contacted by your Hospira representative. If you wish to upgrade the pump yourself, Hospira will provide you with the necessary tools and documentation subject to scheduling availability of training. The upgrade process must be completed by November 30th, 2015.

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4. Complete the attached form:

a. Complete the attached reply form; and

b. Return the form via the fax number or e-mail address on the form or by providing the Hospira representative with the completed form.

Inquires and Support

For questions regarding this Field Safety Notice, please contact Hospira customer service at 0800 028 7304.

Tally Eitan

President
Q Core Medical Ltd.

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RESPONSE IS REQUIRED

Fax the completed form to 0800 028 7305 **or email it to** customerservice.uk@uk@hospira.com. If you have questions about this form, please call 0800 028 7304.

Customer Information

_____

Business Name Hospira Customer # (If applicable)

_____

Address/City/State/Zip

_____

Contact Name/Phone/Email Address

_____

Completed by: Printed Name/Signature/Date

Actions to be taken, confirm the following:

- I have received and read the 26 October, 2015 letter and have provided a copy to all relevant stake holders: YES ☐ NO ☐
  - If NO, state reason: _____
- I have coordinated the software upgrade with Hospira YES ☐ NO ☐
  - If YES, identify the date when the upgrade is scheduled to occur. _____
  - If No, state reason: _____