



رقم المحفوظات: ٢٠١٢
رقم الصادر: ١٤/١٢٥٢٢١
بيروت، في: ٢١ نزيلا ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Sapphire Multi Therapy Pump with software Rev09Ver07

الجهاز المعنى بالمتابعة:

- Sapphire Multi Therapy Pump with software Rev09Ver07
- Trade Mark: Hospira Inc
- Local Representative:

بناء على التقرير الصادر عن الوكالة الأسترالية TGA والذي يشير الى وجود خلل في عمل

الصنف الوارد أعلاه ، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن الوكالة الأسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد أعمار



Recall detail

Type of Productⁱ	Medical Device
TGA Recall Referenceⁱⁱ	RC-2013-RN-01041-1
Product Name/Descriptionⁱⁱⁱ	Sapphire Multi Therapy Pump with software Rev09Ver07 (Infusion Pump) Hospira List Number: 163113601 ARTG Number: 201499
Recall Action Level^{iv}	Hospital
Recall Action Classification^v	Class I
Recall Action Commencement Date^{vi}	10/10/2013
Responsible Entity^{vii}	Hospira Pty Limited
Reason / Issue^{viii}	<p>The manufacturer, Q Core, has received three similar reports from a customer, who experienced deviations from the duration of treatment, as programmed. The incidents occurred while using the Multi Step mode. While no patient injuries or deaths have been reported, the issue may result in incorrect therapy.</p> <p>Specifically, the issue only occurs when the following conditions are met simultaneously:</p> <ul style="list-style-type: none"> - Multi-step mode is used, and - The pump is not plugged into an AC power outlet and is operating on battery power only, and - The pump backlight is turned OFF. <p>The factory default for the backlight configuration in the Sapphire Multi Therapy pump is ON; therefore unless the pump backlight is turned OFF, the issue will not occur.</p>
Recall Action^{ix}	Recall for Product Correction
Recall Action Instructions^x	<p>Q Core has developed a software solution (Rev09Ver08) to address the issue. Until the Sapphire Multi Therapy pumps have been updated with the new software, users are required to:</p> <p>(i) Use the Sapphire Multi Therapy pump plugged into an AC power outlet; and/or</p> <p>(ii) Use the Sapphire Multi Therapy pump with the backlight configuration set to ON or PARTIAL.</p> <p>It is recommended to check all pumps that are in current operation in order to ensure correct setting of the backlight. Please note that in pumps configured with backlight OFF the screen will darken completely after 1 minute of screen inactivity. The pumps configured to have the backlight OFF require reconfiguration of the backlight setting to ON.</p>
Contact Information^{xi}	1300 046 774 (Option 1) - Hospira Customer Service