



**URGENT: DEVICE FIELD CORRECTION**  
**LIST No. 16026 Symbiq™ One-Channel Infuser**  
**LIST No. 16027 Symbiq™ Two-Channel Infuser**

February 22, 2010

Dear Healthcare Professional and Valued Hospira Customer:

Hospira, Inc has identified two new hardware component design changes to help reduce complaints related to the Symbiq product family.

The first design improvement is a new pole clamp design that provides a vulcanized rubber pad to eliminate the potential for the Symbiq infusion pump to slip down an IV pole during transit. This new pole clamp design will significantly improve the mechanical security of the Symbiq pump mounting interface with standard IV pole. Hospira will be replacing all original pole clamps with this new design. A Hospira representative will contact your facility to arrange delivery of new pole clamps to your facility as inventory is available.

The second component design is the next generation pumping motor encoder to reduce Sx21 motor malfunctions during infusion therapy. Hospira has received reports regarding Symbiq pumps experiencing an increased frequency of S321/S421 alarm codes. When an S321/S421 alarm code is triggered, the infusion will stop; the pump will alarm to alert the clinician. These alarm codes are associated with a monitoring algorithm, used to detect hardware issues related to the pumping motor mechanism. Motor performance characteristics such as motor encoder failures may trigger the monitoring algorithm to post a malfunction code Sx21 to alert the clinician of a potential motor encoder malfunction. Sx21 alarm codes can affect all Symbiq pumps affected by this field correction.

Hospira has identified a hardware replacement for impacted pumps with motor encoder malfunctions caused by an erroneous encoder signal. Until Hospira can replace all device pumping mechanisms that contain affected motor encoders, we recommend the following actions for continued use of your Symbiq

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pump. Avoid use of this device on patients in which a delay of therapy would not be tolerated. Respond appropriately to any alarm or warning displayed by the device.

Please remind healthcare professionals in your organization to follow the instructions on the pump and in the product literature including possibly returning the unit to Hospira for service. If you experience an Sx21 alarm on a particular device you should follow normal hospital protocol, remove the device from service and contact Hospira Global Product Safety and Complaints at 1-800-441-4100. For additional information or technical assistance contact Hospira Technical Support Operations at 1-800-241-4002.

A Hospira representative will contact you to make arrangements to implement the appropriate enhancements.

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation, and we regret any inconvenience this action may cause.

This correction is being made with the knowledge of the U.S. Food and Drug Administration.

Please forward this notice to all departments within your facility that use these devices.

Sincerely,

A handwritten signature in blue ink, appearing to read "JK", is positioned above the typed name.

Jessie Kirklan  
Director, Global Electromechanical Device Quality

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