



**URGENT: DEVICE RECALL**  
**LIST No. 16026 Symbiq™ One-Channel Infuser**  
**LIST No. 16027 Symbiq™ Two-Channel Infuser**  
(This Notification is an Update to a Clinical Bulletin dated March 2010)

September 13, 2010

Dear Healthcare Professional and Valued Hospira Customer:

Hospira, Inc. is conducting a recall of the 16026 Symbiq™ One-Channel Infuser and the 16027 Symbiq™ Two-Channel Infuser because we have received reports of free flow administration of medication and/or fluid during use of these Symbiq™ infusers. If the Symbiq™ Administration Set (cassette) is removed while the cassette carriage is not completely open, and the roller/slide clamp is not engaged, there is a potential for unrestricted flow. Unrestricted flow of medication and/or other therapy has the potential to cause life-threatening effects and/or critical patient injury, especially in specific patient groups such as critically ill patients, patients with congestive heart failure and/or neonates. The "Check Flow Stop" alarm, intended to warn users of free-flow conditions, may not consistently operate as intended and may not reliably provide appropriate warning. This recall does not require the removal or return of any Symbiq™ devices at this time, however this letter is intended to re-emphasize the need to confirm the infuser is in the "Stop" mode and to close the roller/slide clamp before removing the cassette from the infuser.

This letter is an update to the March 2010 Clinical Bulletin in which Hospira intended to reinforce the proper technique for removing the cassette. Despite the March 2010 notification, Hospira is aware of an incident where a user removed the cassette improperly, resulting in a free flow condition. Therefore, Hospira is reinforcing that it is imperative that all clinicians using Symbiq™ devices should be notified of the importance of this issue, and should be reminded to adhere to the operating instructions for removing the cassette from the infuser, in order to mitigate the risk of free flow, until a final correction is implemented:

1. Confirm the infusion pump is in Stop mode, and close the administration set roller clamp and/or slide clamp prior to removing the cassette from the infuser.
2. Press "Load/Eject" to open the cassette carriage. **Ensure the cassette carriage is fully opened. Do not remove the administration set until the movement of the cassette carriage has stopped.**
3. Grasp the tubing above and below the cassette. Slide the cassette upward and out of the cassette carriage.
4. The cassette carriage will close automatically in approximately 10 seconds. Alternatively, press Load/Eject to close the cassette carriage sooner.
5. To discontinue use of the device, press and hold the "On/Off" button for one second to power down.
6. Discard the administration set and fluid container per Centers for Disease Control, hospital or healthcare provider guidelines.

The Symbiq™ cassette carriage was designed to assure the cassette is properly inserted into the pump and to prevent inadvertent dislodging of the cassette during use. There is a safety feature that automatically closes the flow-stop during the closing of the carriage. This safety feature is circumvented when the cassette is pulled from the carriage before the door is fully opened. The "Check Flow Stop"

Alarm was subsequently added to signal an alarm when premature cassette removal occurs prior to fully opening the cassette door. However, further evaluation has shown that the 'Check Flow Stop Alarm' may not be triggered depending on how quickly the cassette is being removed. Therefore, the alarm cannot be considered a reliable alarm notification to clinicians of a potential unrestricted flow condition.

Hospira is evaluating a software correction for the malfunctioning "Check Flow Stop" Alarm. Once available, a Hospira representative will contact you to make arrangements to upgrade the software at no charge.

Please remind healthcare professionals in your organization to follow the instructions on the pump and in the product literature. For additional information or technical assistance contact Hospira Technical Support Operations at 1-800-241-4002. (8 a.m.-6 p.m. CT, M-F)

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. On September 7, 2010, the FDA classified this action as a Class 1 recall.

Please report a product problem any time and use the chart provided below for questions and support.

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 Technical Support Operations	1-800-241-4002 (8am-6pm CST, M-F)	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](http://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

**PLEASE PROMPTLY COMPLETE THE ATTACHED REPLY FORM IN ITS ENTIRETY AND FAX IT TO HOSPIRA AT FAX NUMBER 262-577-6921.**

Sincerely,



Ileana Quinones  
Vice President,  
Device Quality Operations

**Device Recall Notification Reply Form- RESPONSE REQUIRED**

**Hospira September 2010 URGENT: Medical Device Recall Notification- Symbiq™ Unrestricted Flow**

**Complete the information and fax the completed form to Hospira at (Fax: 262-577-6921)**

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**The following action has been taken:**

**I have received the Recall Notification and distributed it to users throughout the facility:**

**YES \_\_\_**

**NO \_\_\_**

**If NO, state reason:**

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**General Required Information**

\_\_\_\_\_  
**Business Name**

\_\_\_\_\_  
**Phone Number**

\_\_\_\_\_  
**Address/City/State/Zip**

\_\_\_\_\_  
**Hospira Customer Number (ship to #)**

\_\_\_\_\_  
**Completed by: Printed Name/Signature/Date**