

# DRAFT 09-APR-2013

Hill-Rom

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## Urgent Field Safety Notice

**Subject:** Evolution™ Bed—Right Side-rail Cable Damage with Replacement Parts

**FSCA-identifier:** Mod 1211

**Type of action:** Parts Replacement Recall

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**Date:** April 8, 2013

**To:** Chief Executive, Facility Administrator, Facility Engineer, Vigilance Manager,  
Biomedical Engineering, Medical Device Liaison Officer

### Affected Devices:

Models: Evolution™ Beds (L1156)

Parts affected: **Side-rail spare parts kits:** 156ANB04,  
156ANBC01, 156CDE01, 156CDE08

Production/Distribution Dates: July 3, 2012 to January 29, 2013

### Background:

Hill-Rom has become aware of an issue with a batch of side-rail spare parts kits supplied for the Evolution™ bed. A number of right-hand side-rail kits include a nonconforming part which can cause internal cable damage after a short period of time. When the cable becomes damaged, there could be unexpected bed movement, including:

- Inability to move bed to best working height, creating potential for caregiver strain and inefficiency
- Greater risk of patient falls due to bed stuck at high position
- Possible respiratory and pulmonary issues if the backrest is not at the correct angle (the mechanical backrest lowering is not affected and can be used)
- General delay of care

### Action to be taken:

A Hill-Rom technician will contact you to make arrangements to visit your facility to replace the kits that have been installed on your beds. Before that, we ask that you do as follows:

- Locate any beds that have had affected right-hand side-rail spare parts kits installed, and if possible take those beds out of service. If that is not possible, make sure your staff is aware of the issue with those beds and advise them to raise/lower the patient right side-rail as little as possible.

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- Consider **locking out the side-rail controls** using the lock-out panel located at the foot end of the bed, under the footboard. Doing this will prevent unwanted bed movement in the event that the wire becomes damaged in the right side-rail.
- Locate any affected right-hand side-rail spare parts kits in your inventory and permanently **discard** those kits.
- Complete and **return the attached Customer Response Form/Receipt** within 30 days of receipt.

**Important:** The *Customer Response Form/Receipt* provides Hill-Rom with the means to monitor the progress of Field Corrective Actions, and to enable us to meet our obligations to notify the appropriate Competent Authority of non-responders. It is imperative that you return this form/receipt for our records.

#### **Transmission of this Medical Device Correction:**

Please pass this notice on to all those who need to be aware within your organization and/or to any organization where the affected devices have been transferred.

If you have sold/loaned any affected kits, or are otherwise no longer in your possession, we kindly ask that you forward this safety notice to the new owner.

#### **Contact reference person:**

If you have any questions concerning this Urgent Field Safety Notice, please contact Hill-Rom Technical Support, your distributor, or your Hill-Rom representative.

Regards,

Hill-Rom Technical Support

Attachment: Response Form/Receipt



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Customer Response Form/Receipt

Subject: Evolution™ Bed—Right Side-rail Cable Damage (Mod 1211)

It is imperative that you return this form/receipt for our records.

Please complete and return this Response Form within 30 days to Hill-Rom. See specific instructions at bottom of page. Thank you.

Hill-Rom account number: \_\_\_\_\_

Name of the facility: \_\_\_\_\_

Address of the facility: \_\_\_\_\_

City: \_\_\_\_\_ Country: \_\_\_\_\_

Facility Authorized Name: \_\_\_\_\_

Please print legibly

Signature: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Title: \_\_\_\_\_ Phone: \_\_\_\_\_

Email: \_\_\_\_\_ Fax: \_\_\_\_\_

Check all action(s) taken or that apply:

- checkbox We have a service contract with Hill-Rom. Number: \_\_\_\_\_
checkbox We acknowledge receipt of this notification and it has been forwarded as needed.
checkbox We have located and permanently discarded affected kits from our inventory.
checkbox We have installed affected kits on to \_\_\_\_\_ beds in our facility.
checkbox We need side-rail spare parts kits to replace our inventory. (note quantity each)
\_\_\_\_\_ 156ANB04 side-rail spare parts kits
\_\_\_\_\_ 156ANBC01 side-rail spare parts kits
\_\_\_\_\_ 156CDE01 side-rail spare parts kits
\_\_\_\_\_ 156ANB08 side-rail spare parts kits

As soon as possible, please FAX or email this form to: