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## Medical Device Notification

**Subject:** TotalCare® Bariatric Bed—Potential Bed Instability When Applying Lateral Forces During Patient Turning

**FSCA-identifier:** Mod 478

**Type of action:** Device Modification

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**Date:**

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

**Affected Devices:**

**Models:** TotalCare® Bariatric Bed (P1830)  
TotalCare® Bariatric Plus Therapy System (P1840)

**Range of serial numbers affected:** All

**Production Dates:** January 13, 2003 through November 15, 2012

**Background:**

Hill-Rom has received a few complaints regarding bed casters rising off the floor when turning patients on the TotalCare® Bariatric Bed. No reports of a bed tipping over have been received.

Hill-Rom's investigation into these complaints concluded that multiple factors could contribute to the potential for the casters to lift off the floor:

- Factors such as patient mobility, patient girth, height of the bed, direction of the casters, and the number of caregivers helping perform the manual patient turn were assessed.
- In situations where multiple caregivers are pushing/pulling during a manual patient turn, the bed is subjected to lateral forces that may, in combination with the other contributing factors, cause some instability in the TotalCare® Bariatric bed.
- In scenarios where the TotalCare® Bariatric bed became unstable, most commonly only one caster (not both) on one side of the bed lifted slightly off the floor.
- This unstable condition is readily recognizable and easy for caregiver(s) at the bedside to take immediate corrective action.



All TotalCare® Bariatric beds are safe to use and meet current UL stability standards and all specifications.

**Action to be taken:**

Included with this notification is a **Response Form/Receipt**. Please determine the number of affected beds that you have, **complete and return the form to Hill-Rom as soon as possible (within 30 days)**, and we will send an applicable number of retrofit kits and one copy of the newly revised User Manual to you at no cost.

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

After you receive your kits, please apply the labels to your TotalCare® Bariatric beds as soon as possible.

**Transmission of this Medical Device Update:**

Please forward a copy of this letter to any other facility personnel you deem appropriate.

Hill-Rom confirms that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.

**Contact reference person:**

If you have any questions concerning this request or the procedure as outlined, please contact Hill-Rom Technical Support, your distributor, or your Hill-Rom representative.

Regards,

Hill-Rom Technical Support

Attachment: Customer Response Form/Receipt



## Customer Response Form/Receipt

**Subject: TotalCare® Bariatric Bed—Instability Warning Labels Kit (Mod 478)**

It is imperative that you return this form/receipt for our records, and to enable us to meet our obligations to notify the appropriate Competent Authority of non-responders.

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: \_\_\_\_\_

Title: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_ Phone: \_\_\_\_\_

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

Check action(s) taken:

- We do not have any affected products.
- We need \_\_\_\_\_ kits to retrofit all affected products in our facility.
- We have loaned/sold/donated affected units to: \_\_\_\_\_

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