



A Hill-Rom Company

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## Urgent Field Safety Notice

**Subject:** Liko® Bathing Chair—Safety Belt Label and Instructions

**FSCA-identifier:** Mod 494

**Type of action:** Label Installation and Update of Instructions for Use

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**Date:** September 14, 2012

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

**Affected Devices:**

Models: 3156025, P3156025

Range of serial numbers affected: All

**Background:**

In an effort to clarify the proper use of the Liko Bathing Chair, Hill-Rom is updating the product labels and labeling on the device. We have created a label reminding users to secure the patient with the safety belt and a new user instruction guide on how to safely use the chair. There are no potential hazards associated with the continued use of the device without installing the label, but there is a fall hazard associated with improper use of the safety belt.

**Action to be taken:**

Included with this letter is a kit that includes two labels that should be installed on the chair. Instructions are included on how and where to install the labels. Also included in the kit is the new user instruction. Please read and understand this instruction. Please pay careful attention to the instruction on how to secure the patient with the safety belt.

For regulatory reporting purposes, it is required that you **complete and return the attached Customer Response Form**.

**Transmission of this Field Safety Notice:**

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

**Contact reference person:**

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

Regards,

Hill-Rom Technical Support



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# Customer Response Form

**Subject: Liko® Bathing Chair Safety Belt Labels**

Please complete the following with the correct information, and **return this Response Form** without delay to your distributor. See specific instructions at bottom of page. Thank you.

Liko account number: \_\_\_\_\_

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

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

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

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

*Please print legibly*

Signature: \_\_\_\_\_

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

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

Check action taken:

- We **have installed** the labels on all of our affected products, have studied the new user instructions, and understand how to secure the patient with the safety belt.
- We have a **plan to install** the labels on all of our affected products, have studied the new user instructions, and understand how to secure the patient with the safety belt.
- We do not have any affected products.
- We need \_\_\_\_\_ more labels to retrofit all affected products in our facility.
- Other *please describe*: \_\_\_\_\_

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

**Fax: +46 (0)920 47 47 01**

**or**

**E-Mail: [se.quality@hill-rom.com](mailto:se.quality@hill-rom.com)**