



A Hill-Rom Company

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

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