



A Hill-Rom Company

Urgent Field Safety Notice

**SUBJECT: Liko® Sabina® and Capella™ Sit-to-Stand Mobile Lifts—
Hook Retrofit Kit Delivery**

FSCA-identifier: Mod 448

Type of action: Field Corrective Action

Date: September 28, 2012

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

Affected Devices: Manufactured before 31-May-2012

All Liko® Sabina® EE, Sabina® EM, Sabina® II EE, Sabina® II EM,
Sabina® Comfort, and Sabina® 200 Sit-to-Stand Mobile Lifts.

All Capella™ 201 Sit-to-Stand Mobile Lifts

Background:

In a previous letter, Hill-Rom informed you of an issue related to the Sabina® and Capella™ Sit-to-Stand mobile lifts. In certain situations, a patient, caregiver, or bystander could fall against the lift in a way that the sling hook on the end of the SlingBar™ could cause injury.

Please find **included with this notification** a specific number of Hook Retrofit Kits (either requested by you after our previous letter, or based on our shipping records), plus the installation instructions to upgrade your Sabina® and Capella™ lifts.

Action to be taken by user:

1. Immediately **install the parts** included with this notification on all affected lifts and slingbars you may have, and discard all old parts.
2. Complete the attached **Kit Install Response Form** and **return** it to Hill-Rom as soon as possible. (This form is necessary for review by the Competent Authorities.)
 - The Hook Retrofit kit, spare part number 20290046, is intended to be installed on the main SlingBar™ only. Do **not** install kits on the **optional SeatStrap SlingBar™** if so equipped.
 - If you have additional SlingBars™ for use with Sabina® lifts that are not currently installed on your lifts, please make sure they are updated with the new Hook Retrofit Kit as well.



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Continue to follow safe lifting practices, such as:

- When assisting a patient with the lift, use extra care and support them to prevent falling forward or to the side.
- Do not allow unauthorized persons, especially children, to play around or operate the lift.

If you did not receive enough kits, contact Hill-Rom and request the number of additional kits for main SlingBars™ that you need, and we will send them to you at no cost.

Transmission of this Field Safety Notice:

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.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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

Contact reference person:

If you have any questions concerning this request or the procedure as outlined, please contact Hill-Rom Technical Support using the attached listing for your geographical region.

Regards,

Hill-Rom Technical Support

Attachment: Response Form, DS119RD



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Kit Install Response Form

Subject: Liko® Sabina® and Capella™ Sit-to-Stand Mobile Lifts Retrofit Kit (Mod 448)

Please complete the following with the correct information, and **return this Response Form** without delay to Hill-Rom Technical Support. 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 Hook Retrofit Kit on all of our affected products and **discarded all old parts.**
- We have a plan to install the Hook Retrofit Kit on all of our affected products.
- We do not have any affected products.
- We need _____ more kits to retrofit all affected products in our facility.
- Other *please describe*: _____

As soon as possible, please
FAX or email this form to the applicable Technical Support Contact location according to the attached listing.

Technical Support Contact Information

Important: This is a comprehensive list of Technical Support contact information for Hill-Rom offices worldwide. If this is attached to another document or letter, it does **not** mean that every country listed below is affected by that document.

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|--|---|
| Austria: | Tel: 0810 00 10 23 – Fax: + 43 (0)224 32 85 50 - 19 e-mail: germany.customer.care@hill-rom.com |
| Belgium | Tel: +32 2761 96 42 – Fax: +32 (0) 2 761 96 41 e-mail: services-belgium@hill-rom.com |
| Canada: | Tel: 800-267-2337 (8 am – 5 pm ET (New York time)) |
| Central & Eastern European Region: | Tel: +971 (0) 4 450 3530 – Fax: +971 (0) 4 450 3621 e-mail: trescilla.dsouza@hill-rom.com |
| France: | Tel: +33 (0)820 01 23 45 – Fax: +33 (0)2 56 37 30 20 e-mail: services-france@hill-rom.com |
| Germany: | Tel: +49 (0)2152 144 255 – Fax: +49 (0)2152 144 105 e-mail: germany.customer.care@hill-rom.com |
| Ireland: | Tel: +353 (0)1 413 6005 – Fax: +353 (0)1 413 6030 e-mail: dublin.sales@hill-rom.com |
| Italy: | Tel: +39 02 950542 95 – Fax: +39 02 950543 26 e-mail: giuseppe.sanna@hill-rom.com |
| Middle East & Africa Region: | Tel: +971 (0) 4 450 3530 – Fax: +971 (0) 4 450 3621 e-mail: trescilla.dsouza@hill-rom.com |
| Netherlands: | Tel: +31 (0)347 32 35 43 – Fax: +31 (0) 347 32 35 00 e-mail: jos.vanschie@hill-rom.com |
| Nordic Region: (Sweden, Norway, Denmark, Finland, Iceland) | Tel: +46 (0)920 47 48 22 – Fax: +46 (0)920 47 47 01 e-mail: karl-henrik.dagman@hill-rom.com |
| Portugal and Spain: | Tel: +34 (0)902 193 423 – Fax: +34 (0)93 666 55 70 e-mail: matteo.montesano@hill-rom.com |
| Switzerland: | Tel: 0848 81 15 30 – Fax: + 41 (0)21 7062132 e-mail: germany.customer.care@hill-rom.com |
| United Kingdom: | Tel: +44 (0)1530 411000 – Fax: +44 (0)1530 411555 e-mail: uk.customer.care@hill-rom.com |
| United States: | Tel: 800-445-3720 (8 am – 5 pm ET (New York time)) |
| All other countries for support of products manufactured in the US: | Tel: 812-934-1348 (8 am – 5 pm ET (New York time)) e-mail: gary.lakes@hill-rom.com |
| All other countries for support of products manufactured outside the US: | Tel: +33 (0)2 97 50 92 45 e-mail: leny.rodriquez@hill-rom.com |