

Safety Notice

Medical Devices

Liko Bathing Chair

Priority 2 – Warning



HPRA Safety Notice: SN2015(28)

Issue Date: 20 October 2015

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Liko / Hill-Rom	V15947

ISSUE

Hill-Rom has identified a fall hazard associated with improper use of the safety belt on the Liko Bathing Chair.

Hill-Rom has updated the product labels and labeling on the device to remind users to secure the patient with the safety belt. Hill Rom has created a label reminding users to secure the patient with the safety belt and has also published a new user instruction guide on how to safely use the chair.

Hill-Rom issued a field safety notice (FSN) in September 2012 to communicate this issue to end users, provide a copy of the user instruction guide, and to provide safety decals to be applied to affected devices. Hill Rom has not received confirmation that this action has been completed for all affected devices on the Irish market.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Follow the instruction communicated by Hill-Rom in the attached FSN. Pay careful attention to the instruction on how to secure the patient with the safety belt.
- 2 If you are in possession of affected devices, contact Hill-Rom or your local distribution agent in order to arrange implementation of this action for all devices within your possession.
- 3 Complete and return the Response Form included with the FSN.
- 4 Forward a copy of the Hill-Rom FSN and this HPRA Safety Notice to all those who need to be notified of this issue in your organisation and to all those to whom affected product may have been transferred.
- 5 Report any adverse events / incidents associated with this device to the manufacturer and the HPRA.

TARGET GROUPS

Carers	Occupational Therapists
Clinical Engineers / Biomedical Engineer	Physiotherapists
Community Care Centres	Private Hospital Staff
Community Care Managers	Purchasing Managers
Health Visitors	Relevant Wards
Hospital Chief Executive Officers	Risk Managers
HSE Hospital Staff	Supplies Managers
Nursing Home Staff	Swimming Pools

BACKGROUND

Hill-Rom has updated the product label and labeling of the device in an effort to clarify the proper use of the Liko Bathing Chair.

This action affects all Liko Bathing Chairs, model number 3156025, manufactured from 1998 up to communication of this field safety corrective action in September 2012.

Included with the FSN 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.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Liko AB	Telephone: +46 (0)920 474 700
Nedre vagen 100	Fax: +46 (0)920 474 701
975 92 Lulea	E-mail: se.quality@hill-rom.com
Sweden	Website: http://www.liko.com/se/Sverige/

Enquiries to the **distributor** should be addressed to:

Hill-Rom Limited	Telephone: +353 (0) 1 413 6005
Unit 1 Kilcarbery Business Park	Fax: N/A
Nangor Road	E-mail: service-uk@hill-rom.com
Dublin 22	Website: http://www.hill-rom.ie/ie/
Ireland	

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority	Telephone: +353-1-6764971
Kevin O'Malley House	Fax: +353-1-6344033
Earlsfort Centre	E-mail: devicesafety@hpra.ie
Earlsfort Terrace	Website: www.hpra.ie
Dublin 2	