

# Safety Notice

## Medical Devices

---

### Ceiling Mounted Rail Systems for all Liko Stationary Lifts - Likorall, Multirall and Masterlift

#### Priority 2 – Warning

HPRA Safety Notice: SN2015(27)

Issue Date: 20 October 2015

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Liko / Hill-Rom	V16769

#### ISSUE

Hill-Rom has identified that there is a risk of stress corrosion cracking of the fasteners securing all overhead rail lift systems that are installed in highly chlorinated indoor environments, such as swimming pools.

The manufacturer has advised that there is no concern for traditional care facility installations of rail systems, including wet areas such as bath applications.

Hill-Rom issued a Field Safety Notice in November 2012 and requested that users perform periodic inspections of devices and to pay close attention to any signs of corrosion. If signs of corrosion are noted, users should suspend the use of the lift until repairs are made by a qualified technician. 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 advise that users:

- 1 Determine if you have affected devices which are installed in a highly chlorinated indoor environment, such as a swimming pool area.
- 2 Follow the actions outlined by Hill-Rom in the Field Safety Notice with regard to periodic inspections of devices. In particular, note that if corrosion is visible on any part of the rail system or hardware, suspend the use of the lift until repairs are made by a qualified technician.
- 3 Complete the customer reply form provided by Hill-Rom immediately and return it to Hill-Rom.
- 4 Forward a copy of the Hill-Rom Field Safety Notice 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	Physiotherapists
Clinical Engineers	Procurement Managers
Community Care Managers	Public Health Nurses
Community Therapists	Rehabilitation Centres
HSE Offices	Risk Managers
Nursing Homes	Sports Centres
Occupational Therapists	

## BACKGROUND

Hill-Rom issued a Field Safety Notice (FSN) in November 2012 but has not received responses from all affected customers for this field safety corrective action on the Irish market. This field safety corrective action has been ongoing since that time. There are three lifts on the Irish market used with the Liko Overhead Rail System. A number of these Overhead Rail Systems were supplied to the Irish market by KCI Medical, who is no longer a distributor for these products.

The HPRA has not received any complaints in relation to this issue. Full details of the field safety corrective action can be found in the attached field safety notice issued by Hill-Rom.

## MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

Hill-Rom	Telephone: +46 (0) 920 47 47 00
Nedre Vägen 100	Fax: +46 (0) 920 47 47 01
975 92 Luleå	E-mail: <a href="mailto:se.quality@hill-rom.com">se.quality@hill-rom.com</a>
Sweden	Website: <a href="http://www.liko.com/se/Sverige/">http://www.liko.com/se/Sverige/</a>

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: <a href="mailto:service-uk@hill-rom.com">service-uk@hill-rom.com</a>
Dublin 22	Website: <a href="http://www.hill-rom.ie/ie/">http://www.hill-rom.ie/ie/</a>
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: <a href="mailto:devicesafety@hpra.ie">devicesafety@hpra.ie</a>
Earlsfort Terrace	Website: <a href="http://www.hpra.ie">www.hpra.ie</a>
Dublin 2	