Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 18 / 2023

07 -07-1444 H

29 -01-2023

Recall of Liko M220, Liko M230 from Liko AB.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15998
Product	Liko M220, Liko M230.
Description	Mobile patient lifting system, battery-powered.
Manufacturer	Liko AB.
Local agent	Taiba Medserv.
The affected products	Liko M220 and M230 Models: 2050010 & 2050015 Manufactured between 2016-DEC-27 and 2021-SEP01.
Reason	Missing bushing on Liko M220 and M230 causing wear and potential for falls.
Action	1. Identify and quarantine affected products. Periodically inspect your Liko device for damage or wear. Report visible wearing or damage to Liko Technical Support Team. A representative will be in contact with the costumers to provide and install a replacement slingbar with the bushing. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Directorate General of Pharmaceutical
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سلطنة عُمان
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To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 18 **dated** 29/01/2023 **Regarding NCMDR Recall of Liko M220, Liko M230 from (mfr: Liko AB).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Hillrom Hillrom Luleå Nedre Vägen 100, 975 92 Luleå, Sweden	Field Safety Notice	FA 2021-010-002-LUL-001

Type of Action: Field Safety Notice

Field Action Identifier: FA 2021-010-002-LUL-001

Subject: Missing bushing on Liko M220 and M230 causing wear and potential for falls.

Commercial name of affected product: Liko M220, Liko M230

Affected Models: 2050010 & 2050015 manufactured between 2016-DEC-27 and 2021-SEP-01.

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

Description of the problem:

Hillrom has received customer complaints whereby a Slingbar had detached from the upper bracket of the sling bar attachment. Investigations indicated that a bushing was missing on the product. The missing bushing causes wear on the Slingbar attachment, which in turn can potentially cause the sling bar to detach from its attachment. If the slingbar detaches from the upper bracket, this has the potential for patient falls.

Background:

The sling bar on the Liko M220 and M230 mobile lift is locked into its position onto the lifting arm through two link plates, see figure 1. These two link plates are attached to each other through a bolt and a locking plate that allows for a rotation of the sling bar in one direction relative to the upper link plate.

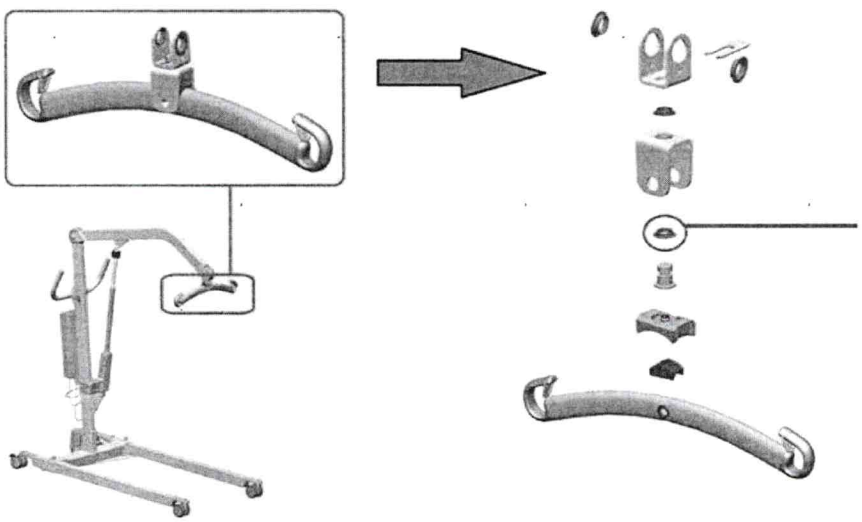

Figure 1: Mechanism and parts included in the sling bar for M220/M230. Bushing marked in red.

Hillrom investigation determined that the root cause of the slingbar detachment is caused by wearing at the slingbar attachment due to the missing of a plastic bushing (see red markings in Figure 1) as part of the assembly during manufacturing of the device. It was determined that assembly of this device has the potential to not contain this plastic bushing on devices manufactured between 2016-DEC-27 and 2021-SEP-01.

Potential Risk:

A missing plastic bushing on the device can cause wearing on the slingbar attachment. Over time, this wearing can cause the slingbar to detach from the lift, which may result in a patient fall. Hillrom can confirm there have been no death or serious injuries reported from this failure.

Actions to be taken by Customer:

1. Review the product label on your Liko M220/M230 to determine if it is impacted by this field action by identifying the manufacturing date of the device (i.e. Manufacturing date between 2016-DEC-27 and 2021–SEP-01). See figure 2.

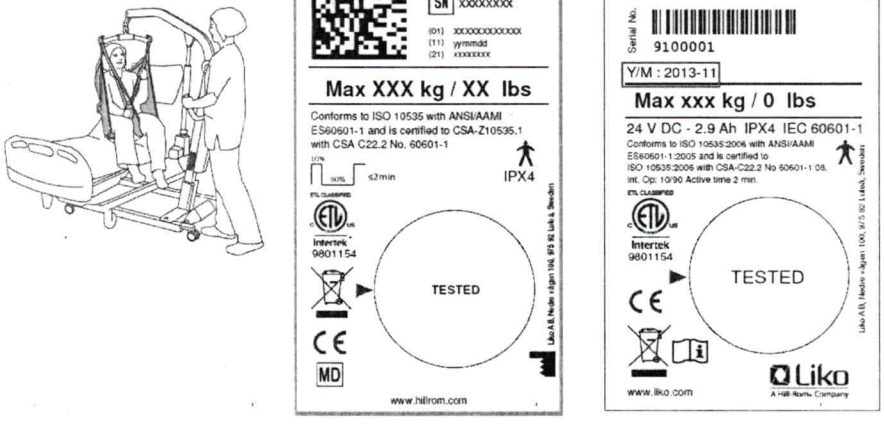

Figure 2: Placement of the label and its designs. Left: New design. Right: Old design.

2. Please periodically inspect your Liko device for damage or wear. Report visible wearing or damage to your Technical Support Team – do not use the device until Technical Support can inspect and repair where necessary.

3. Please fill out the attached response form and return it to Hillrom hillromLUL001OUS@sedgwick.com within two weeks.

Action to be taken by the Distributor:

Please share this Field Safety Notice with your end users and complete the attached response form and return to hillromLUL001OUS@sedgwick.com within two weeks. Contact hillromLUL001OUS@sedgwick.com to receive an electronic copy of this notification and response form for onward distribution.

Action to be taken by the Hillrom:

Upon receipt of the response form, identifying potentially impacted devices, Hillrom or an official Hillrom distributor/representative will be in contact to schedule inspection of your device to confirm presence of the bushing. Where it is confirmed that the device is missing the bushing, a replacement slingbar with the bushing will be installed.

Contact Reference Person:

For any questions or concerns regarding this Field Safety Notice and field corrective action, please contact Hillrom Technical Support, using the email or number below.

Market /Region/ Country	Phone Number	Technical Support Email
Austria	(+ 43) 2 243 285 50	service.dach@hillrom.com
Germany	(+ 49) 2 0149869500	service.dach@hillrom.com
Switzerland	(+ 41) 8 48 811530	service.dach@hillrom.com
Netherlands	(+ 31) 347 323 532	service.nl@hillrom.com
Spain	(+ 34) 9 36856000	asistencia@hillrom.com
Italy	(+ 39) 02 950541	assistenza.tecnica@hillrom.com
France	(+ 33) 0 820 012345	sav@hillrom.com
Sweden	(+ 46) 20-781030	ordernordic@hillrom.com
UK/Ireland	(+ 44) 1530 562176	UKTechSupport@hillrom.com
Eastern Europe Countries	Contact your Local Hillrom Distributor	
Middle East & Africa	Contact your Local Hillrom Distributor	
India Sub-Continent	Contact your Local Hillrom Distributor	

The undersign confirms that this notice has been communicated to the appropriate Regulatory Agencies.

If you have any questions regarding this safety notice, please contact Hillrom Technical Support, your distributor, or your local Hillrom representative.

Sincerely

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

Swissmedic Recall

Back

Reference Number: mdprc 016 01 22 000
Date submitted: 1/13/2022

Manufacturer:	Liko AB
Device Type:	Liko M220, Liko M230
Description:	Mobile patient lifting system, battery-powered
Medical Device Identifier:	Liko M220 and M230 Models: 2050010 & 2050015 Manufactured between 2016-DEC-27 and 2021-SEP01.
Reason of Field Safety Corrective Action:	Missing bushing on Liko M220 and M230 causing wear and potential for falls.
Remedy Action:	Identify and quarantine affected products. Periodically inspect your Liko device for damage or wear. Report visible wearing or damage to Liko Technical Support Team. A representative will be in contact with the costumers to provide and install a replacement slingbar with the bushing.
Athorized Representative/Importer/Distributor:	Medical regulations gate
Report Source:	Swissmedic
Source Ref. Number:	Vk_20211216_20
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	Liko AB.pdf

View History