

 <p>Hillrom™ Hillrom Luleå Nedre Vägen 100, 975 92 Luleå, Sweden</p>	<p>Field Safety Notice</p>	<p>FA 2021-010-002-LUL-001</p>
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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.

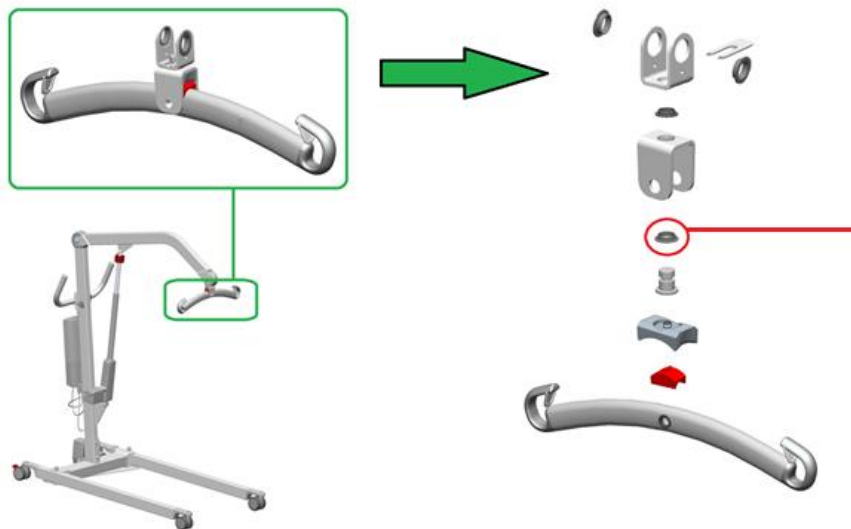


Figure 1: Mechanism and parts included in the sling bar for M220/M230. Bushing marked in red.

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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.

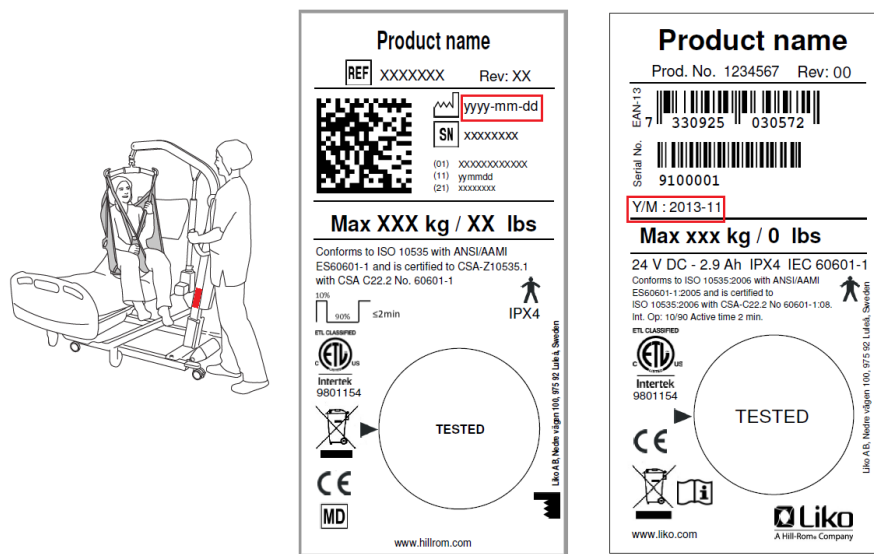


Figure 2: Placement of the label and its designs. Left: New design. Right: Old design.

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.



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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) 1 530 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.

Signature



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Field Safety Notice

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Response Form

Subject: Missing bushing on Liko M220/M230 (FA 2021-010-002-LUL-001)

It is important that you return this form/receipt as acknowledgement of your receipt and provide us with the necessary information.

Please complete the following with the correct information and return this Response Form within two weeks.

Upon receipt of this Response Form, Hillrom will contact you to assess your device and arrange for replacements where needed. Thank you!

Hillrom account number (if known): _____

Name of the facility: _____

Address of the facility: _____

City: Zip: Country: _____

Facility Contact Person Name: (print) _____

Signature: Date: ____/____/____

Title: Phone: _____

Email: _____

Check actions taken:

We have reviewed and understand the attached Field Safety Notice Yes No

Results from the review of our product inventory show:

- We do not have any potentially affected products.
- We have potentially affected products. Quantity _____

Please identify all serial numbers manufactured between 2016-DEC-27 and 2021-SEP-01 per product label on your Liko M220/M230 in the table below

Serial Number	Serial Number	Serial Number

Response form shall be returned to hillromLUL001OUS@sedgwick.com within 2 weeks.