

Dear Sir/Madam,

This letter is a reminder to follow the Instruction Guide when using a Liko® Multirall™ 200 and S65 carriage. You are receiving this letter since you are potentially a user of these products per our records.

If you have any questions concerning this Field Safety Notice please contact Hill-Rom Technical Support, your distributor or your Hill-Rom representative.

Thank you in advance for your attention on this matter.

Regards,

Hill-Rom Technical Support

Urgent Field Safety Notice

Subject: Liko® Multirall™ 200 and S65 carriage proper attachment reminder

FSCA-identifier: MOD1267

Type of action: Reminder to follow the Instruction Guide when using a Multirall™ 200 and S65 carriage together

Date:

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

Affected Device: Multirall™ 200 (3130001) and S65 carriage (3136011)

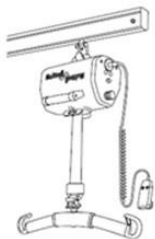
Description

Hill-Rom has become aware of a user-error that could result in a potential safety issue when attaching the Multirall™ 200 to the S65 carriage. Since the introduction of this combination in 2007, 26 events have been reported where an improper connection of the Multirall™ 200 to S65 carriage was not identified by the user prior to use and a disconnect occurred, resulting in the unit falling. Eleven (11) of these cases have alleged injuries to the caregiver or patient. We have evaluated the potential risk and determined the likelihood of occurrence to be less than 27 per 1 billion (1 000 000 000) lifting experiences, or less than 0.000003%.

Hill-Rom would like to reinforce that instructions for proper connection, including verification of proper attachment prior to use, must be followed when attaching the Multirall™ 200 to the S65 carriage. The instructions for proper connection are included in the Instruction Guide provided with your product.

Proper Connection

The S65 carriage is intended for use with a Multirall™ 200 lift motor only. Attachment of the Multirall™ to the S65 carriage can be accomplished in two different methods (illustrated below), depending on intended use.

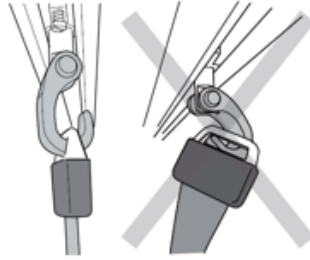


Method 1: Multirall™ 200 mounted on the S65 Carriage



Method 2: Q-link (strap) mounted on the S65 Carriage

Most of the improper connection related events have occurred when the Q-link (lift strap) is mounted to the S65 Carriage (Method 2 above).



. Correct vs. incorrect mounting of the Q-link to the S65 Carriage.

The instruction guide states that the user shall make sure, before use, that the Q-link is properly positioned into the carriage hook. The lift strap must hang vertically before the lifting begins.

Additionally, Hill-Rom has created training material (Quick Reference Guide) with the same information as the instruction guide, but gives emphasis on how to properly connect the Multirall™ 200 to the S65 carriage.

Action to be taken by user:

Share this notification with your staff as a reminder to follow the instructions for the proper attachment of the Multirall™ 200 to the S65 carriage. Included with this notification is the Quick Reference Guide.

Please note the Quick Reference Guide refers to a web address with a video on proper installation/use of the Multirall™ 200 and S65 carriage. Please review these additional resources with your staff and pay careful attention to the instruction on how to secure the Multirall™ 200 to the S65 carriage correctly. When used in accordance with the instruction guide, the Multirall™ 200 and S65 carriage are safe for use.

As an alternative option to the S65 carriage we would like to remind you that Hill-Rom offers the S50 carriage (product number 3136010) which has a locking mechanism.

Contact reference person:

If you have any questions concerning this Field Safety Notice, please contact Hill-Rom Technical Support, your distributor, or your Hill-Rom representative.

Transmission of this Field Safety Notice:

Please transfer this notice to other organizations as appropriate. Please maintain awareness of this notice and additional resource for an appropriate period to ensure effectiveness.

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

Regards,

Hill-Rom Technical Support

Attachment: Quick Reference Guide- 204886

Liko™ Multirall™ and S65 carriage

Quick Reference Guide

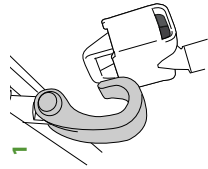
- Connect the Q-link to the S65 carriage with the help of the extension arm (Images 1+2)

Before each transfer, systematically inspect the connection to ensure that:

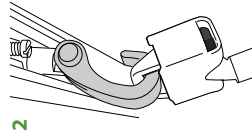
- The Q-link is properly positioned all the way into the carriage hook and that the lift strap is safely attached to the hook (Image 3)
- The lift strap must hang vertically before lifting (Image 4)

It is essential to thoroughly read both the assembly instruction for the extension arm as well as the user manual for the Liko Multirall before use.

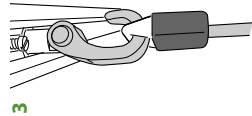
The illustration and instructions below should be considered a quick guide, intended to ensure that the Q-link accessory is placed in the correct position within the carriage hook.



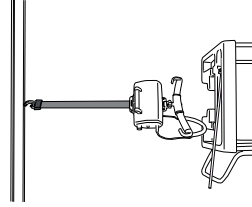
1



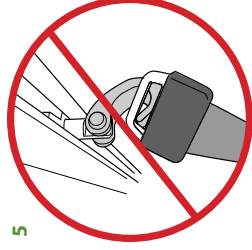
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3



4



5

- Simply pulling and exerting force to the strap is not a guarantee that the Q-link is properly connected! Image 5 illustrates an improper connection. If this happens, lower the Q-link to the original position and begin again.

Go to www.hill-rom.com/MultirallInfo/ for a training video on the application of the S65 carriage.

Enhancing outcomes for patients and their caregivers.

204886 REV 1

Multirail is appropriate for use in all common lift and transfer situations.

Class I

Manufacturer: Liko AB, Nedre vägen 100, SE-975 92 Luleå, Sweden

This medical device is a regulated health product which, pursuant to such regulation bears a CE mark. Hill-Rom recommends that you carefully read the detailed instructions for safe and proper use included in the documents accompanying the medical devices. The personnel of healthcare establishments are responsible for the proper use and maintenance of these medical devices.

Hill-Rom reserves the right to make changes without notice in design, specifications and models. The only warranty Hill-Rom makes is the express written warranty extended on the sale or rental of its products.

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