

Field Safety Notice, December 19, 2008

Subject: Liko mobile patient lifts; Uno, Viking S, Viking XS, LikoLight

Affected products, serial numbers (sequential):

 Uno 100 EM/EE:
 s/n 7090001 - 7096199
 Viking S:
 s/n 7300301 - 7301299

 Uno 101:
 s/n 10001 - 11000
 Viking XS:
 s/n 7400301 - 7400749

 Uno 102:
 s/n 20001 - 21300
 LikoLight:
 s/n 2500001 - 2505899

Uno 102 EM/EE/ES: s/n 30001 - 48099

Dear customer,

Liko AB has initiated a field correction program for the Liko Uno, Viking S, Viking XS and LikoLight mobile patient lifts (according to list above), due to a potential safety hazard.

Background:

The actuator of the lift has the potential to separate when the upper arm is fully extended. If this happens when a patient is being lifted the lift will fail, resulting in a patient fall.

To date, Liko has received 18 reports of actuator failures, out of which one report of a death from complications associated with a hip fracture, and one report of a fractured femur.

Corrective measures:

All affected lifts in use on the market shall be equipped with the patented accessory "OuterTube" which will prevent the actuator from collapsing in the unlikely event that it should malfunction. Liko or our local Liko representatives will contact all affected customers to arrange the assembly of the OuterTube.

Actions to be taken:

While awaiting the addition of the OuterTube, Liko has developed an inspection that can allow the lifts to stay in service. The inspection is described on page 2 in this document. If the lift passes the inspection it is in compliance with specifications and is safe to use. However, if you are unable to perform the inspection or if the lift does not pass inspection it must IMMEDIATELY be put out of service. If this is the case, please contact your Liko representative to arrange a solution.

Please make sure that all affected persons receive this information.

Should you have any questions, please contact the Liko product distributor in your country. Contact information is found at www.liko.com/int/distributors.asp.

Your country's medical product regulatory agency has been informed by Liko AB about this Field Safety Notice.

Thank you for your attention and cooperation in this matter. We sincerely apologize for any inconvenience this may cause you.

Best regards,

Liko AB

Quality Department



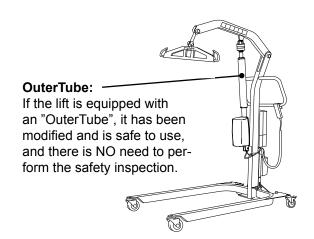


Uno 100 EM/EE, Uno 101, Uno 102, Uno 102 EE/ES/EM, Viking S, Viking XS, LikoLight

Safety Inspection

Before use, at least once per day, inspect all affected lifts without OuterTube according to instructions below:

- 1. Using the handcontrol, move the actuator all the way to the bottom until the red emergency lowering starts to spin.
- 2. Measure the distance between the emergency lowering and the top of the collar on the actuator, using the enclosed paper tool (Max 0.4 inch / 10 mm). Alternative methods of measuring such as a ruler or scale are allowed as long as the distance between the metal surface under the red emergency lowering and the top of the collar on the actuator is measured.





Max 0.4 inch / 10 mm





If the distance is <u>less</u> than 0.4 inch / 10 mm, the lift is Ready to use according to the Instruction Guide (the line on the paper tool is below the top of the collar on the actuator).

Never move the lift by pulling the actuator! Be careful not to run the lift into a bed or other objects.



If the distance is <u>greater</u> than or equal to 0.4 inch / 10 mm, the lift must be put out of service (the line of the paper tool is above or aligned with the top of the collar on the actuator). If this is the case, please contact your Liko repre-

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