

Dear Sir, Madam

As part of its policy of continuous improvement, Hill-Rom has developed a partnership with Docapost (La Poste Group in France) for the distribution of the safety instructions or information related to the Hill-Rom® medical devices.

You will find enclosed the regulatory document and the response form which must be returned to attest to the confirmation of receipt.

Once completed, your response form must be returned to our partner Docapost via mail, email or fax, who will process the document management responses.

Thank you to fill in the form clearly and legibly and check the proposed options. This will allow our local coordinator to manage the necessary elements and to follow up in a timely manner.

Response form to be returned to:

*DOCAPOST BPO IS
HILL ROM MODS
Energy Park
150 Boulevard de Verdun
92400 Courbevoie – France*

Or, Fax: +33(0)1 46 35 97 98

Or, Email: hill-rom.mods@docapost-bpo.com

Best Regards

Regulatory Affairs Department
Hill-Rom.

Urgent Field Safety Notice

Subject: Liko® Viking® L, Viking® M, Viking® XL , and Viking® 300 Mobile Lifts – Potential Actuator Damage

FSCA-identifier: Mod 1228

Type of action: Corrective Action Notification

Date:

To: Hill-Rom Authorized Distributor

Affected Models and Serial numbers:

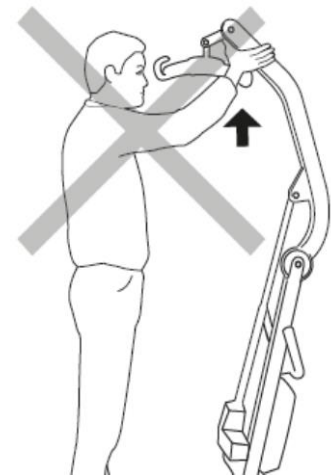
- Viking® M Lift
 - Model 2040035 (S/N 9 200 000 – 9 203 000)
 - Model 2040015 (S/N 7 500 401 – 7 570 000)
 - Model 2040005 (S/N 7 100 101 – 7 200 200)
- Viking® L Lift
 - Model 2040004 (S/N 7 200 201 – 7 300 300)
- Viking® XL or Viking® 300 Lift
 - Model 2040003 (S/N 800 001 – 804 999)

Background:

Hill-Rom has received 9 complaints where it is alleged that the lift arm drifted down suddenly on certain Viking® Mobile Lifts.

This issue is preceded by users who lift the lift arm assembly manually, as shown in the illustration to the right.

The lift arm assembly is intended to only be lifted by the actuator (lift motor). If the lift arm assembly is manually lifted, the actuator can become damaged and get stuck in the highest position. When the actuator is stuck, the lift cannot be raised/lowered by the lift motor. If a patient is lifted into the sling while the actuator is stuck, there is a potential risk of a free fall of the patient. This hazard could cause minor or potentially catastrophic injuries to a patient if the free fall encompasses the entire stroke of the actuator.



Hill-Rom is sending a customer notification requesting customers not to raise the lift arm manually since the lifting actuator can become stuck and/or become damaged. Customers will be instructed to always use the hand controls or the control box to operate the lift. There are no hazards when using the device as intended. Hill-Rom is updating the product labelling to address this hazard with the attached customer notification we expect you to forward to your customers.

Hill-Rom is concerned that the actuator may have become damaged from manually lifting, therefore, is more susceptible to becoming stuck in the highest position if manually lifted again. To reduce the risk of this occurring, Hill-Rom is announcing a correction that will include an inspection of all potentially affected Viking® lifts. If there is damage to the actuator, it will be replaced.

Action to be taken:

Hill-Rom is conducting a correction in two phases. Phase 1 will launch immediately and phase 2 will commence as you confirm which customers have potentially affected products to correct. Information about which customers have potentially affected products will be obtained from

executing phase 1. Phase two activity should be completed as soon as possible from receipt of the consignee response from phase 1. You do not need to complete phase 1 of the correction to begin phase 2.

Phase 1 will be to mail the customer letter we provide as part of this notification to customer in your area. The letter includes information to enable your customers to update the Instruction Guides. Included in the customer notification is a return form that documents they received the notification, updated the applicable Instruction Guides and identifies what lifts need to be inspected at each customer site.

Please add your contact information to the Response Form on the applicable language customer letter; then forward the customer letter to your accounts that have affected product. A Hill-Rom coordinator has or will supply you with a list of affected models and serial numbers that according to our records have been shipped to you.

Send to us weekly the number of accounts that have responded to you as completing the action. The response should indicate the % of responses received and the % of responses outstanding. You must continue to report weekly until you have received 100 % response or you have contacted your accounts up to three times without response. This information is to be supplied to your Retrofit Coordinator.

Phase 2 will include the physical inspection of potentially affected devices. Hill-Rom expects you to schedule appointments with your customers to perform an inspection per the instructions on each potentially affected product. Direction on how to document the inspection and order the required parts will be included in the forthcoming instructions, supplied by your retrofit coordinator. Please note that all inspected lifts should have an informative sticker applied, those stickers will be supplied via your local retrofit coordinator.

Contact your coordinator for reimbursement details.

If you have any questions concerning this notification, please contact your local retrofit coordinator.

Please complete and return the *Distributor Response Form/Receipt* within 15 days of receipt.

Important: The *Distributor Response Form/Receipt* provides Hill-Rom with the means to monitor the progress of Field Corrective Actions. It is imperative that you return this form/receipt for our records.

Regards,

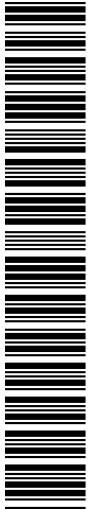
Hill-Rom Technical Support

Attachment: Urgent Field Safety Notice in the applicable language

Distributor Response Form / Receipt

Subject: Potential Actuator Damage on Viking® M, L, XL, or Viking® 300 Mobile Lifts (ref: MOD1228)

Please complete and return this Response Form within 15 days. See instructions at bottom of page.



9999123456789

Hill-Rom account number: _____

Name of the facility: _____

Address of the facility: _____

City: _____ Country: _____

Facility Authorized Name: (print) _____

Signature: _____ Date: ____/____/____

Title: _____ Phone: _____

Email: _____ Fax: _____

The delivery address indicated in the cover page is not my current address. Use above details for future correspondence.

Check action(s) taken:

We acknowledge receipt of this letter, have added our contact information on the customer letter and have forwarded it to the appropriate accounts.

Our customers do not have any affected products.

We want to be contacted by Hill-Rom for further information.

We have loaned/sold/donated affected units to: _____

Response form to be returned to:

*DOCAPOST BPO IS
HILL ROM MODS
Energy Park
150 Boulevard de Verdun
92400 Courbevoie – France*

*or Fax: +33(0)1 46 35 97 98
or Email: hill-rom.mods@docapost-bpo.com*

Urgent Field Safety Notice

Subject: Liko® Viking® L, Viking® M, Viking® XL, and Viking® 300 Mobile Lifts – Potential Actuator Damage

FSCA-identifier: Mod 1228

Type of action: Corrective Action Notification

Date:

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

Affected Models and Serial numbers:

- Viking® M Lift
 - Model 2040035 (S/N 9 200 000 – 9 203 000)
 - Model 2040015 (S/N 7 500 401 – 7 570 000)
 - Model 2040005 (S/N 7 100 101 – 7 200 200)
- Viking® L Lift
 - Model 2040004 (S/N 7 200 201 – 7 300 300)
- Viking® XL or Viking® 300 Lift
 - Model 2040003 (S/N 800 001 – 804 999)

Background:

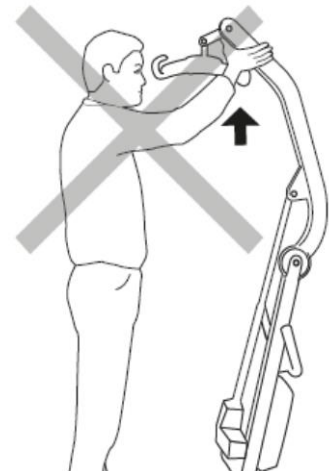
Hill-Rom has received 9 complaints where it is alleged that the lift arm drifted down suddenly on certain Viking® Mobile Lifts.

This issue is preceded by users who lift the lift arm assembly manually, as shown in the illustration to the right.

The lift arm assembly is intended to only be lifted by the actuator (lift motor). If the lift arm assembly is manually lifted, the actuator can become damaged and get stuck in the highest position. When the actuator is stuck, the lift cannot be raised/lowered by the lift motor. If a patient is lifted into the sling while the actuator is stuck, there is a potential risk of a free fall of the patient. This hazard could cause minor or potentially catastrophic injuries to a patient if the free fall encompasses the entire stroke of the actuator.

Hill-Rom requests customers not to raise the lift arm manually since the lifting actuator can become stuck and/or become damaged. Always use the hand controls or the control box to operate the lift. There are no hazards when using the device as intended. Hill-Rom is updating the product labelling to address this hazard.

Hill-Rom is concerned that the actuator may have become damaged from manually lifting, therefore, is more susceptible to becoming stuck in the highest position if manually lifted again. To reduce the risk of this occurring, Hill-Rom is announcing a correction that will include an inspection of all potentially affected Viking® lifts. If there is damage to the actuator, it will be replaced.



Action to be taken:

Hill-Rom is conducting a correction in two phases.

Phase 1 will be this letter and information to enable you to update the Instruction Guides.

Phase 2 will include the physical inspection of potentially affected devices. A part of the inspection is to apply an informative sticker to the lift.

If your lift is already equipped with the sticker (see example to the right), it is already inspected and no further action is required.

**Phase 1: Labelling update**

This letter shall serve as the labelling update to warn against manually lifting the lift arm assembly.

Please use the insert attached to this letter to update the following Viking® Mobile Lift instruction guides. Complete instruction guides with the updated labelling incorporated in the document are available from Hill-Rom.

7EN137105

7EN137106

7EN137102

7EN136102

7EN135104

7EN135102

Please fill in the attached response form and return to Hill-Rom. This will provide us with the necessary information to plan the inspection in Phase 2.

Phase 2: Inspection

If you have affected units and you have returned the response form, you will be contacted by Hill-Rom or one of Hill-Rom's distributors, to schedule an inspection of your potentially affected devices. If there is damage to the actuator consistent with manually lifting, the actuator will be replaced by Hill-Rom.

Transmission of this Field Safety Notice:

Please pass this notice on to all those who need to be aware within your organization and/or to any organization where the affected devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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

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.

Regards,

Hill-Rom Technical Support



Response Form / Receipt

Subject: Potential Actuator Damage on Viking® M, L, XL, or Viking® 300 Mobile Lifts (ref: MOD1228)

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

Please complete the following with the correct information, and **return this Response Form without delay**. See specific instructions at bottom of page. Thank you!

Hill-Rom account number: _____

Name of the facility: _____

Address of the facility: _____

City: _____ Zip: _____

Facility Authorized Name: (print) _____

Signature: _____ Date: ____/____/____

Title: _____ Phone: _____

Email: _____ Fax: _____

Check action taken:

- We **do not have** any potentially affected products.
- We **have potentially affected products** and have inserted the new instruction into the Viking® M, L, XL, or 300 Mobile Lift Instruction Guide.

Note the potentially affected products, only include the serial number ranges of the devices in the customer notification header:

____ Unit/units of Viking® M Mobile Lifts

____ Unit/units of Viking® L and Viking® XL/300 Mobile Lifts

- We have **forwarded the letter** to the following consignees that we have distributed the potentially affected lift to: (make copies as needed)

Name / Contact: _____

Address: _____

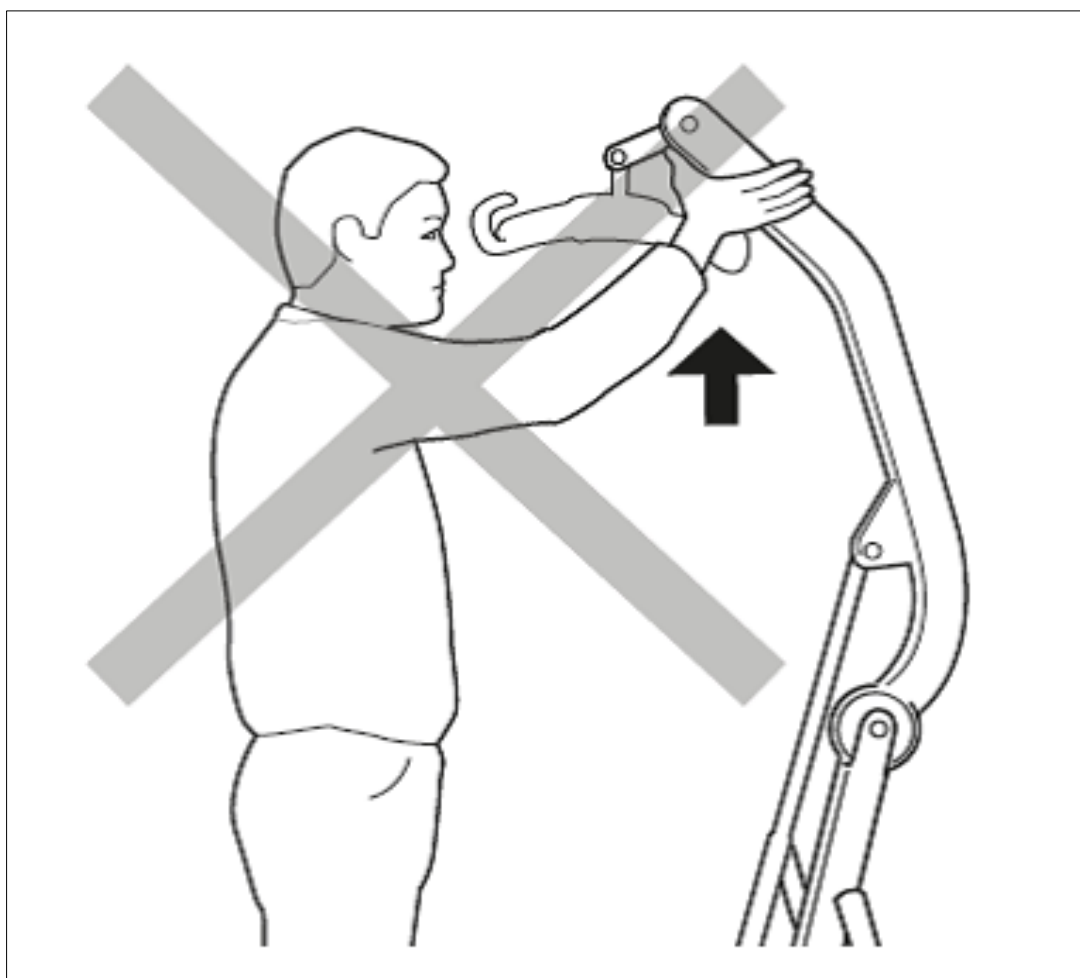
City / State: _____

Phone: _____

Return this Form to:



Insert for your Viking® Lift Instruction Guide



**△ Do not raise
the lift arm
manually!**