

# Medical Device Alert

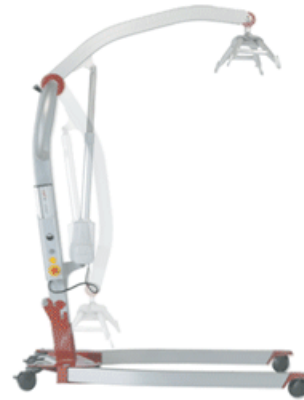
Ref: MDA/2011/050 Issued: 18 May 2011 at 14:30

## Device

Smart 150 mobile hoists manufactured by Molift Group AS, distributed in the UK by Meditec Medical Ltd.

Model number: 0920008

Specific serial numbers affected.



## Problem

The manufacturer issued a Field Safety Notice (FSN) for this device on 30 March 2011, but has not had sufficient confirmation from users that they have received and acted on this information.

A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.

This alert has been issued in support of the manufacturer's actions.

## Action by

All those involved in the maintenance and use of these hoists. In particular: equipment store managers, nursing home managers, moving and handling co-ordinators, nurses, occupational therapists, care staff, and maintenance staff and contractors.

## Action

- Ensure that relevant members of staff are aware of the problem.
- Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.

## CAS deadlines

Action underway: 03 June 2011

Action complete: 22 August 2011

## Contact

### UK Supplier

Beverley Thompson  
Meditec Medical Ltd

Tel: 0844 800 4236

Fax: 0844 800 4237

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- OFSTED (Directors of Children's Services) for information
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

#### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All wards
- Equipment store managers
- Health and safety managers
- Maintenance staff and contractors
- Moving and handling co-ordinators
- Nurses
- Nursing executive directors
- Occupational therapists
- Physiotherapists
- Risk managers

#### Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community hospitals
- District nurses
- Equipment store managers
- Maintenance staff and contractors
- Moving and handling co-ordinators
- Occupational therapists
- Palliative care teams
- Physiotherapists
- Risk managers

#### Social services

Liaison officers for onward distribution to all relevant staff including:

- Back care/manual handling advisors
- Care at home staff
- Care management team managers
- Community care staff
- Equipment store managers
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Occupational therapists

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Nursing agencies

### **Establishments registered with OFSTED**

This alert should be read by:

- Children's services
- Educational establishments with facilities for the disabled
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## **Contacts**

### **UK Supplier**

Meditec Medical Ltd  
Unit 1 Woodrow Business Centre  
Woodrow Way  
Irlam  
Manchester  
M44 6NN

Tel: 0844 800 4236

Fax: 0844 8004237

## **England**

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/050** or **2011/003/024/081/011**

Ed Ball or James McVeigh  
Medicines & Healthcare products Regulatory Agency  
Centre for Assistive Technology  
241 Bristol Avenue  
Bispham  
Blackpool FY2 0BR

Tel: 01253 596 000

Fax: 01253 596 177

Email: [bav@mhra.gsi.gov.uk](mailto:bav@mhra.gsi.gov.uk)

### **How to report adverse incidents**

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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## Appendix



*field safety notice*

### Field Safety Notice (FSN) 01-2011

March 30<sup>th</sup> 2011

<i>Product type:</i>	Molift Smart 150 (Article number 0920008)
<i>Manufactured between</i>	Feb. 2 <sup>nd</sup> 2010 – Feb. 4 <sup>th</sup> 2011
<i>Serial number</i>	From 20941 to 27299
<i>Other products:</i>	None
<i>Action to be taken:</i>	Upgrade of all affected lifting devices with two new locking clamps
<i>Valid from:</i>	March 30 <sup>th</sup> 2011
<i>Manuals updated / Rev. no:</i>	None
<i>Solution developed by:</i>	Morten Harald Lie, CTO
<i>Approved by:</i>	Geir Olav Farstad, CEO

#### Field Safety Notice related to a potential safety hazard of Smart hoist

Molift Group AS is issuing this Field Safety Notice due to a potential safety hazard related to varying level of quality of a series of locking clamps used in the leg opening mechanism of the Smart 150 patient hoist. We have received reports on three incidents, none with serious injury to the patient. In these incidents a locking clamp in the leg spreader mechanism has failed, resulting in a situation where one of the legs can move outside the operating area. When the leg is outside the operating area, the hoist can become unstable and tip over, leading to potential injury of a patient.

The locking clamp is located behind the grey foam cover on each side of the chassis on the hoist (see picture 1, 2 and 3 below).



Picture 1 – Smart 150



Picture 2 – chassis with foam covering the mechanism



Picture 3 – locking clamp

Based on the incident reports and internal testing we have found that the hardening of the locking brackets for a specific batch is of varying quality. An insufficient level of hardening can result in a potential failure / breakage of the locking clamp which again will lead to a potentially unstable hoist.



*field safety notice*

**Corrective action**

All affected hoists (in the serial number range as specified above) shall be upgraded with two new locking clamps. Our local Molift representatives will attempt to contact all affected customers to arrange the upgrade. The upgrade will include the replacement of the foam and the locking clamp on each side.

**What actions are to be taken to the Smart hoists that are already in use?**

Pay particular attention by checking the leg spreader mechanism on all affected hoists thoroughly before every use. Before every use, the operator must check that the legs are moving only within the working position as specified in the Operator manual. It shall not be possible to move the legs outside the outer stop position or inside the inner stop position. The hoist is safe to use if the legs stops at the outer and inner stop positions.

If it is possible to move one or both legs substantially outside the outer stop position or inside the inner stop position, or if you are not sure how to measure the inner and outer stop positions, the affected hoists must IMMEDIATELY be put out of service. To ensure a swift replacement of the components, please contact your Molift representative as soon as possible to arrange a solution. The hoist must be upgraded by a service technician accredited by Molift Group or a local Molift representative.

Please make sure that all affected persons receive this information, and encourage to increased attention until the product has been upgraded. We kindly ask you to provide us with contact details for organisations to which the products may have been transferred and forward this safety notices to those organisations. Please fill in the list below and return to [groupsales@molift.com](mailto:groupsales@molift.com).

Should you have any questions, please contact your Molift representative in your country. If you need assistance to get in contact with your local Molift representative, please contact Molift Group AS' Customer Service at: [groupsales@molift.com](mailto:groupsales@molift.com).

Your country's medical product regulatory agency has been informed by Molift Group AS about this Field Safety Notice and regarding the adjusted safety measure on the market.

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

Best regards,

Molift Group AS

***Molift contact details:***

Molift Group AS  
Customer service  
Hadelandsveien 2  
N-2816 Gjøvik  
NORWAY  
E-mail: [groupsales@molift.com](mailto:groupsales@molift.com)  
Switchboard: +47 4000 1004  
Fax: +47 4000 1006



*field safety notice*

**Contact details for organisation to which one or several products may have been transferred**

(Send this to Molift Customer Service, e-mail: [groupsales@molift.com](mailto:groupsales@molift.com) or fax to +47 4000 1006)

Organization:

Address:

Country:

Contact persons:

E-mail:

Phone number

Serial number/ List of hoist: