



Medicines and Healthcare products  
Regulatory Agency

# Medical Device ALERT

Ref. MDA/2005/024

Issued: 18 April 2005

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION REQUEST	

	Further Information										
<b>DEVICE:</b> Mobile electric patient hoists - various manufacturers.											
<b>PROBLEM:</b> Potential for electric actuators to fail without warning, causing sudden dropping of the hoist boom, leading to the serious injury of the patient and/or carer.	▶										
<b>ACTION BY:</b> All those involved in the supply, maintenance or use of these devices.											
<b>ACTION:</b> <ul style="list-style-type: none"> <li>Identify mobile patient hoists with electric actuators.</li> <li>Assess whether the rate of usage (lifts per day) and age indicate that the electric actuator is due for replacement. Repeat this assessment at each inspection and service of the hoist.</li> </ul>	▶										
<b>DISTRIBUTED to:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">NHS Trusts (England)</td> <td style="width: 50%;">– Chief Executives*</td> </tr> <tr> <td>Commission for Social Care Inspection (CSCI)</td> <td>– Headquarters</td> </tr> <tr> <td>Healthcare Commission (CHAI)</td> <td>– Headquarters</td> </tr> <tr> <td>Primary Care Trusts (England)</td> <td>– Chief Executives*</td> </tr> <tr> <td>Social Services (England)</td> <td>– Directors*</td> </tr> </table> <p style="text-align: right; margin-top: 5px;">* via CE Bulletin</p>	NHS Trusts (England)	– Chief Executives*	Commission for Social Care Inspection (CSCI)	– Headquarters	Healthcare Commission (CHAI)	– Headquarters	Primary Care Trusts (England)	– Chief Executives*	Social Services (England)	– Directors*	▶
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<b>CONTACTS:</b> Details of MHRA contacts for technical and clinical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.	▶										

▶ Further information supplied in the following pages.

The full text of this notice is on our website: <http://www.mhra.gov.uk>

## **PROBLEM:**

Electric actuators have failed suddenly and without warning. All the reported failures have involved hoists with inclined electric actuators.

These failures have caused sudden, uncontrolled dropping of the hoist boom and, on some occasions, serious patient injury.

Investigations have shown that failures are most influenced by usage i.e. number of lifting cycles performed, rather than the age of the actuator.

Note: One lifting cycle = raising then lowering the patient.

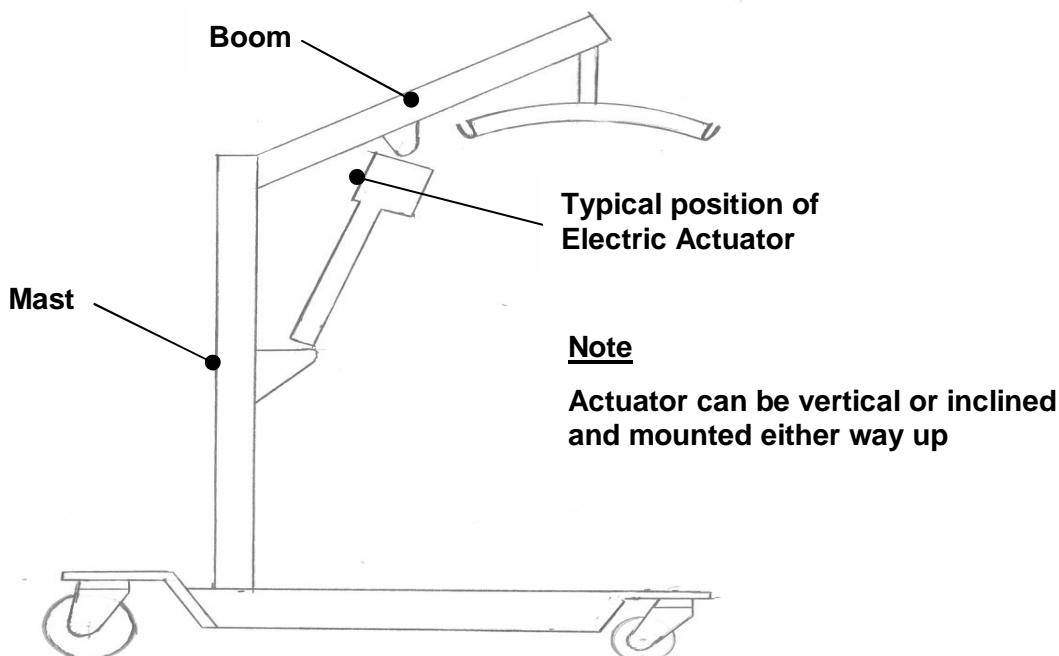
There is also a risk of damage and material fatigue failures caused by inappropriate handling, abnormal use and lack of proper servicing of the actuator mounting points. Excessive wear of the actuator mounting points can also lead to sudden failure of the actuator.

Establishing the 'life' of an actuator is difficult because hoists do not have counters fitted to record the number of lifting cycles.

Patient hoists must be tested and inspected under the Lifting Operations and Lifting Equipment Regulations (LOLER) which detail the interval and requirements for thorough examination. However, the sealed design of electric actuators prevents internal examination of components for faults or excessive wear within the actuator, caused by long term or high usage. Thus, wear may go undetected until sudden failure occurs.

## **ACTION:**

Identify mobile hoists with electric actuators, using the sketch below for guidance if necessary.



## Action (continued):

- Contact the hoist manufacturer, quoting the model and serial number, together with its rate of usage and age, to determine if the actuator is due for replacement.
- If the manufacturer cannot be contacted, for example because the hoist is unidentifiable or the manufacturer is no longer trading, a risk assessment should be carried out to determine if the electric actuator needs replacement. For guidance on how the rate of usage of a hoist relates to the life of the actuator in terms of years (for hoists conforming to BS EN ISO 10535:1998), please refer to the graph shown in the Appendix. In cases where the rate of usage and age indicate that the actuator is due for replacement, the actuator should be replaced unless the manufacturer states that the actuator has a longer design/service life than 10,000 cycles.
- As part of all future inspections and servicing of the hoist review the need for the electric actuator to be replaced.

### **ACTION DEADLINES FOR THE SAFETY ALERT BROADCAST SYSTEM (SABS)**

**Trust managers should ensure that measures to implement the 'Actions' specified above are planned and completed in line with the following SABS deadlines.**

**Deadline (Action underway): 25 April 2005**

Action plan to be agreed and actions started.

**Deadline (Action complete): 23 May 2005**

All actions to be completed.

Further information about SABS can be found at [www.info.doh.gov.uk/sar/cmopatie.nsf](http://www.info.doh.gov.uk/sar/cmopatie.nsf)

## DISTRIBUTION:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution by:

### **TRUSTS to:**

- Liaison officers (for onward distribution)
- Accident & emergency departments
- Adult & paediatric intensive care units
- All wards
- Backcare/manual handling advisors
- Clinical governance leads
- Day hospitals
- Equipment stores
- Health & safety officers
- Maintenance departments
- Medical directors
- Nursing executive directors
- Occupational therapists
- Physiotherapists
- Risk managers

### **SOCIAL SERVICES to:**

- Liaison officers (for onward distribution)
- Backcare/manual handling advisors
- Care at home staff
- Day centres
- Equipment stores
- Occupational therapists
- Schools with hoists

### **COMMISSION FOR SOCIAL CARE INSPECTION (CSCI) to:**

- Headquarters (for onward distribution)
- Care homes providing nursing care
- Care homes providing personal care
- Domiciliary care providers
- Hospices
- Residential schools
- Staff undertaking care home inspection

### **HEALTHCARE COMMISSION (CHAI) to:**

- Headquarters (for onward distribution)
- Clinics
- Hospices
- Hospitals in the independent sector
- Mental health hospitals

### **PRIMARY CARE TRUSTS to:**

- Liaison officers (for onward distribution)
- Backcare/manual handling advisors
- Clinical governance leads
- Community hospitals
- Directors of public health
- District nurses
- Equipment stores
- Health visitors
- Lead nurses
- Occupational therapists

## **CONTACTS:**

Enquiries to the MHRA should quote reference number **2003/012/010/121/006** and be addressed to:

### **Technical aspects:**

John Ward or Andy Marsden  
Medicines & Healthcare products Regulatory Agency  
Hannibal House  
Elephant and Castle  
London SE1 6TQ

Tel: 020 7972 8232 / 8205

Fax: 020 7972 8106

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[andy.marsden@mhra.gsi.gov.uk](mailto:andy.marsden@mhra.gsi.gov.uk)

### **Clinical aspects:**

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E-mail: [jonathan.plumb@mhra.gsi.gov.uk](mailto:jonathan.plumb@mhra.gsi.gov.uk)

## **Change of address or removal from address list for CSCI and Healthcare Commission:**

CSCI Customer Service Unit  
St Nicholas Building  
St Nicholas Street  
Newcastle-upon-Tyne  
NE1 1NB

Tel: 0845 015 0120

E-mail: [enquiries@csci.gsi.gov.uk](mailto:enquiries@csci.gsi.gov.uk)

Healthcare Commission  
Finsbury Tower  
103-105 Bunhill Row  
London  
EC1Y 8TG

Tel: 020 7448 9054

E-mail: [contacts@healthcarecommission.org.uk](mailto:contacts@healthcarecommission.org.uk)

### **HOW TO REPORT ADVERSE INCIDENTS**

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre  
Medicines and Healthcare products Regulatory Agency  
Hannibal House, Elephant and Castle, London SE1 6TQ  
Telephone 020 7972 8080 or Fax 020 7972 8109  
or e-mail: [aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk)

(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the MHRA website:** <http://www.mhra.gov.uk>

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## APPENDIX TO MDA/2005/024

BS EN ISO 10535:1998 'Hoists for the transfer of disabled persons – Requirements and test methods' requires hoists conforming to this standard to achieve a minimum of 10,000 lifting cycles. The graph below shows how the rate of usage relates to the life of the electric actuator for a hoist conforming to this standard.

Note: Not all hoists in service conform to BS EN ISO 10535:1998.

### How to use the graph

The graph can be used to determine the lifetime of an actuator with a design life of 10,000 lifting cycles.

Example [1] (see graph) If a hoist is used for an average of five lifts per day and is two years old, the electric actuator is within its design/service life.

Example [2] (see graph) If a hoist is used for an average of 25 lifts per day and is three years old, the electric actuator has exceeded its design/service life and requires replacement.

