

Medical Device Alert

Ref: MDA/2013/031 Issued: 10 May 2013 at 13:00

Device
<p>Hospital beds: Dynamis and Gerialit with Dewert electrical control systems.</p> <p>Manufactured by Hill-Rom.</p> <p>Specific models numbers manufactured from October 1995 to June 2001 inclusive.</p>

Problem	Action
<p>Risk of serious injury to patients, staff and visitors.</p> <p>Unintentional movement, including sudden collapse to its lowest position, can occur when the bed is connected to the mains supply.</p> <p>A Field Safety Notice (FSN) was published on 01 March 2012. However, the manufacturer has since advised that these beds should be fixed to their lowest position and the control system deactivated to remove the risk of injury.</p>	<p>Identify affected beds.</p> <p>Consider removing affected beds from use if alternatives are available.</p> <p>If an alternative is not available:</p> <ul style="list-style-type: none"> - consider whether continuing to use the beds at their fixed, lowest position is acceptable - if acceptable, fix the beds to their lowest position and contact the manufacturer for instructions on how to deactivate the Dewert control system.
Action by	<p>Confirm with the manufacturer your actions when completed.</p>
<p>Those responsible for the use, service and maintenance of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 24 May 2013</p> <p>Action complete: 21 June 2013</p> <p>Note: These deadlines are for systems to be in place to seek alternative beds or to fix the beds to the lowest position and deactivate the control systems.</p>	<p>Manufacturer Yvonne Powell Hill-Rom Tel: 01530 562 167 Email: yvonne.powell@hill-rom.com</p>

Device

Dynamis and G erialit beds were manufactured with electrical control systems supplied by either Dewert or SKF.

This notification applies only to **Dewert** systems, which are easily recognizable by the design of the lockout unit, as shown in the manufacturer's Field Safety Notice, MOD 466.

Affected model numbers: LI146B1—LI146BI, LI146D1—LI146DI, LI147B1—LI147D1, LI150A0—LI150B0, LI163B1—LI163C1, PRS0128, PRS0199, PRS0201, PRS2001.

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)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- NHS England area teams 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
- All clinical area
- Community hospitals
- Community nurses
- EBME departments
- Equipment libraries and stores
- Maintenance staff
- Medical directors
- Medical libraries
- Nursing executive directors
- Risk managers

NHS England local area teams

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

- Risk managers

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Equipment stores
- Equipment supplies managers
- Maintenance staff
- Risk managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers

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)
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

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 and requesting this facility.

Contacts

Manufacturer

Yvonne Powell
Hill-Rom
Clinitron House
Ashby Park
Ashby de la Zouch
LE65 1 JG

Tel: 01530 562 167
Fax: 01530 441 555
Email: yvonne.powell@hill-rom.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/031** or **2012/004/005/081/005**

Technical aspects

Andy Marsden or Emma Rooke
Medicines & Healthcare products Regulatory Agency
Floor 4, 151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7205 / 6609
Fax: 020 8754 3965
Email: andy.marsden@mhra.gsi.gov.uk
emma.rooke@mhra.gsi.gov.uk

Clinical aspects

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Medicines & Healthcare products Regulatory Agency
Floor 4, 151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 6648
Fax: 020 8754 3965
Email: jonathan.plumb@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

<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

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

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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