# Medical Device Alert

Ref: MDA/2011/092 Issued: 18 August 2011 at 15:00

## Device

Eleganza Standard (model prefix 1GS) and Deluxe (model prefix 1GL) beds manufactured by Linet prior to December 2005.

Affected serial numbers:
Standard: 1739003 – 20053049650
Deluxe: 1752144 – 20053022252

## Problem

The manufacturer issued a Field Safety Notice (FSN) for this device on 15 July 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 using, managing and maintaining hospital beds. In particular: nurses, 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: 19 September 2011

Action complete: 18 November 2011

## Contact

**Supplier**
Rowena King
Linet UK Service Dept
Tel: 02392 322135
Fax: 02392 389540
Email: rking@linet.uk.com

# 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)
- Health and Safety Executive
- 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 and clinical departments
- EBME departments
- Equipment store managers
- Maintenance staff and contractors
- Medical directors
- Nursing executive directors
- Risk managers

### Primary care trusts

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

- Community hospitals
- Community nurses
- Equipment store managers
- Maintenance staff and contractors
- Risk managers

### Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Equipment store managers
- Maintenance staff and contractors
- Risk 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

Please note: CQC 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

**Supplier**
Rowena King
Linet UK Service Department
Linet House
17 Murrills Estate
Portchester
Hampshire
PO16 9RD

Tel: 02392 322135
Fax: 02392 389540

Email: rking@linet.uk.com

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/092** or **2011/001/018/401/006**

Jonathan Smith or David Small
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

### 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.iric@nhs.net

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

## 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

# Appendix

LINET® UK

## FIELD SAFETY NOTICE

FSN-A0025
Issue Date: 15-07-2011

**FIELD SAFETY NOTICE**

**LINET ELEGANZA STANDARD & DELUXE MODEL BEDFRAMES (PREFIX 1GS... & 1GL...)**

**Type of action: Inspection & fitting of weld strengthening brackets.**

**Attention:**

Users and maintenance personnel of bedframes manufactured by our parent company Linet Spol. s.r.o. based in the Czech Republic.

**Details of affected devices:**

Eleganza Standard bedframes within the serial no. range 1739003 – 20053049650
(Bedframe models commencing 1GS.....)

Eleganza De-Luxe bedframes within the serial no. range 1752144 – 20053022252
(Bedframe models commencing 1GL.....)

All bedframe are CE marked in accordance with the Council Directive 93/42/EEC for Medical Devices.

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# FIELD SAFETY NOTICE

FSN-A0025
Issue Date: 15-07-2011

**Description of the problem:**

Recent reports have identified a number of bedframes that have reported cracked or damaged welds in one particular area of the bedframe. The fault is related to a sporadic occurrence of cracking or breaking welds connecting the patient surface (frame) to the main lifting column assembly. The two column assemblies are connected to the frame, each by two brackets. The cause of the damage is possible vibration during transport or stressing of the device during possible overloading conditions experienced over time. The design is compliant to the relevant standards for Hospital bedframes and although an update to the bedframe was undertaken in December 2005 (Standard & Deluxe models) so bedframes manufactured after this date are unaffected. However, there remains the possibility that bedframes manufactured until December 2005 may experience failures. The risk to safety is considered to be minimal and there are no reported incidences as a result of this issue.

**Action to be taken:**

Following further investigation by the manufacturer there is the possibility that other bedframes may experience cracking or failure of the weld in the same area as those previously reported. To eliminate this risk the manufacturer has developed strengthening brackets that can easily be fitted to affected bedframes. The strengthening brackets are available from Linet UK Ltd and can be fitted by suitably experienced maintenance and service personnel.

- Trace all beds identified within the serial no. ranges contained within this Field Safety Notice.
- The Model & Serial number plate is located on the underside of the main frame (foot end) on the left hand side as you face the footend of the bedframe.
- Users are requested to contact their maintenance personnel or maintenance providers to arrange inspection of their bedframes.
- Maintenance personnel are requested to examine all brackets for signs of cracking in the areas shown in Appendix 1.
- If evidence of any cracking welds is identified, we would recommend that the bedframe be removed from service at the earliest opportunity for the fitment of the strengthening brackets.
- If evidence of any broken welds is identified, we would recommend that the bedframe is removed from service at the earliest opportunity and you contact Linet UK for technical advice. Please see *'Technical Reference Person'* below for technical advice.
- We recommend that all bedframes are fitted with these brackets in due course but priority should be placed upon any bedframes showing any evidence of defect.
- The Strengthening brackets will be supplied free of charge in kit form for both the foot and headend of the bedframe and should be fitted as per the instructions supplied with each kit.
- Strengthening brackets should be ordered directly from Linet UK. Please see *'Contact Reference Person'* section below for the ordering of kits.
- Non-standard repairs/modifications outside the scope of this Field Safety Notice will not be endorsed by Linet and we will not be held responsible for any subsequent problems or failures as a result of such unauthorised modifications to the bedframes. In such cases a frame replacement may be required

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# FIELD SAFETY NOTICE

FSN-A0025
Issue Date: 15-07-2011

**Transmission of this Field Safety Notice:**

This notification needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially 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.

**Corrective Action**

Linet UK will contact all known customers, and will advise these customers of this Field Safety Notice and respective corrective action.

**Contact reference person:**

Rowena King
Linet UK Service Department
Linet House
17 Murrills Estate
Portchester
Hampshire
PO16 9RD
Tel: 02392 322135 Fax: 02392 389540 E-mail: rking@linet.uk.com

**Technical reference person:**

Richard Westbrook
Linet UK Service Department
Linet House
17 Murrills Estate
Portchester
Hampshire
PO16 9RD
Tel: 02392 322134 Fax: 02392 389540 E-mail: rwestbrook@linet.uk.com

LINET® UK

# FIELD SAFETY NOTICE

FSN-A0025
Issue Date: 15-07-2011

**Appendix 1**

**Bedframe Headend Inspection**

1. Using the Supervisor Control Panel / Patient handset raise the Backrest to its full working height.
2. Inspect the weld joints as detailed in fig 01 below. Ensure the paint surrounding the welds is not flaking, showing signs of rust and the weld joints are intact. Inspect both the RH and LH weld fillets, above and below the Mattress Platform.
3. We would recommend that Bedframes displaying the above symptoms are removed from service at the earliest opportunity for the fitment of the strengthening brackets.

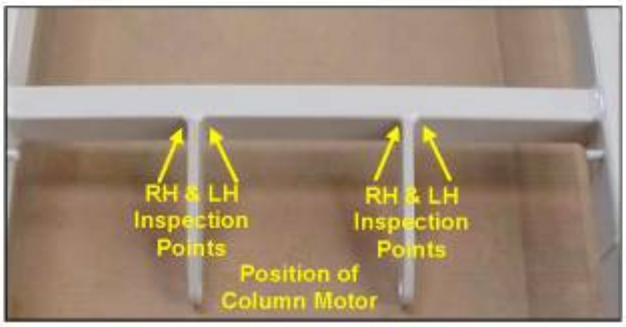


**Fig 01**

**Bedframe Footend Inspection**

1. Using the Supervisor Control Panel / Patient handset raise the Kneebreak together with the mechanical Legrest Ratchet, to its full working height.
2. Inspect the weld joints as detailed in fig 02 below. Ensure the paint surrounding the welds is not flaking, showing signs of rust and the weld joints are intact. Inspect both the RH and LH weld fillets, above and below the Mattress Platform.
3. We would recommend that Bedframes displaying the above symptoms are removed from service at the earliest opportunity for the fitment of the strengthening brackets.

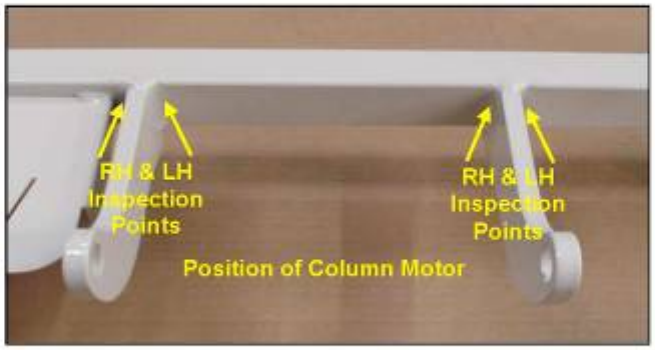


**Fig 02**