

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.



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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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

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

Contact reference person:

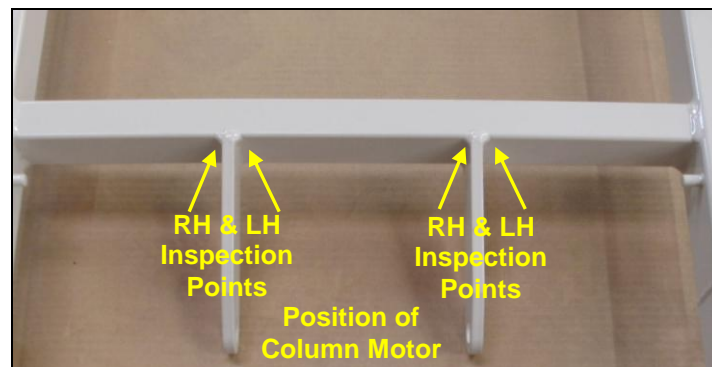
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Technical reference person:

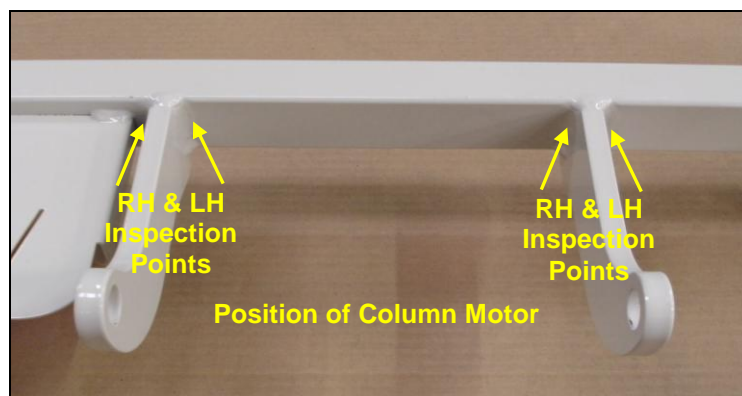
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Appendix 1**Bedframe Headend Inspection**

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**