



FIELD SAFETY NOTICE

Issue Date: 24/10/2011

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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 1710057 - 20070015143
(Bedframe models commencing 1GS.....)

Eleganza De-Luxe bedframes within the serial no. range 1725419- 20070020578
(Bedframe models commencing 1GL.....)

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

Description of the problem:



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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 design is compliant to the relevant standards for hospital beds and although an update to the bedframe was undertaken in December 2005 (Standard & Deluxe models) and in October 2007 (Standard & Deluxe models with X-Ray Backrest only) so bedframes manufactured after these dates are unaffected. However, there remains the possibility that bedframes manufactured until December 2005 and until October 2007 (models with X-Ray Backrest only) may experience failures. The risk to safety is considered to be minimal and there are no reported incidences of injury 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 Wissner-Bosserhoff and can be fitted by suitably experienced maintenance and service personnel.

- Trace all beds identified within the serial no. ranges contained within this FSCA 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.
- For bedframes not covered by a maintenance agreement please contact Wissner-Bosserhoff Service Department where arrangements will be made for an engineer to visit.
- Maintenance personnel are requested to examine all brackets for signs of cracking in the areas shown in Appendix 1.
- If evidence of any cracking or broken welds is identified, we would recommend that the bedframe be removed from service at the earliest opportunity for the fitment of the strengthening brackets.
- We would 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 are supplied free of charge.



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Transmission of this Field Safety Corrective Action Notice:

This notice 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

Wissner-Bosserhoff will contact all customers, who we are aware that have these bedframes accordingly and make arrangements to have their bedframes inspected and modified.

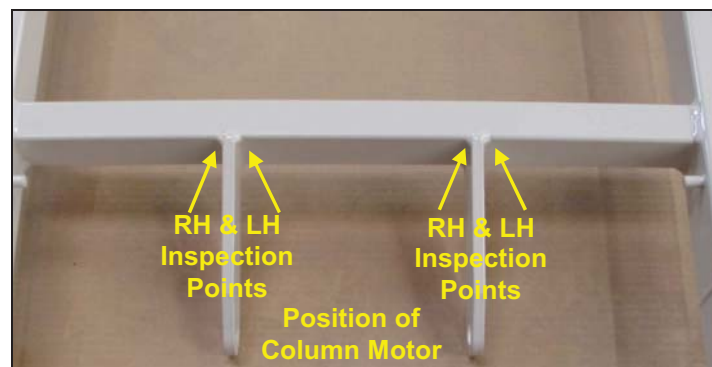
Contact reference person:

Markus Klappholz
Wissner-Bosserhoff
Hauptstrasse 6
Wickede – Ruhr
58739 – GERMANY

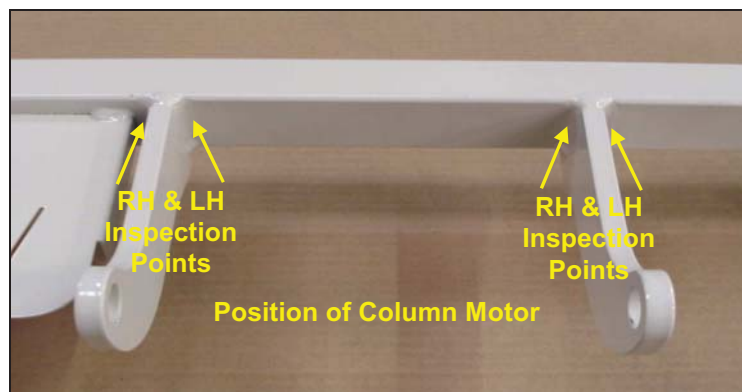
Tel: Fax: +49-(0)2377-784-204 E-mail: klappholz@wi-bo.de

Appendix 1**Bedframe Headend Inspection**

1. Using the Nurse/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 Nurse/Patient handset raise the Legrest 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**