



Urgent Field Safety Notice

Subject: Hi/low Adjustment Lowering Risk

FSCA-identifier: MOD 400

Type of action: Maintain medical bed in lowest position before hi/low column replacement

Date: October 13, 2008

To: Chief Executive
Facility Risk Manager
Facility Administrator
Facility Engineer
Vigilance Manager
Biomedical Engineering
Medical Device Liaison Officer

Affected devices:

Models: AvantGuard™ 1600 (Li160A), 1200 (Li158B), XT (Li165B)

Serial number: See attached list

Background:

Our records indicate that your facility purchased one or more AvantGuard™ beds mentioned above.

During an internal performance test, we experienced an uncontrolled bed lowering during a hi/low sequence, and subsequently identified a supplier defect in a load-bearing part. In the worst case, the defect could occur while the bed is in the highest position, and result in the bed's uncontrolled movement (head or foot or both) until it stops in the lowest position. The failure (excessive wear on hi/low gears) is expected to occur at the beginning of the bed's life, depending on how much weight is put on the bed.

Action to be taken by the user:

Although we have had only one event reported with no injury, considering the potential risk we strongly recommend that you immediately put and keep these beds (only those in the attached list) in the lowest position and lock out the hi/low function. A Hill-Rom representative will be contacting you to make an appointment to replace the affected parts of the hi/low mechanism.

We are well aware that this recommendation may be inconvenient in the short term. However, we are convinced that this product modification is essential for patient and user safety.

Transmission of this Field Safety Notice:

Please pass this notice on to all those who need to be aware within your organisation and/or to any organisation where the 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.



In cases where customers opt to not comply with this recommendation, Hill-Rom can not accept any responsibility for safety related issues or legal liabilities caused by the failure to respond.

Contact reference person:

If you have any questions regarding this safety notice, please contact Hill-Rom Technical Support using the attached listing for your geographical area.

Yours sincerely,

Hill-Rom Technical Support

Attachments: DS119RD

Ref: Mod 400

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Technical Support Contact Information

Important: This is a comprehensive list of Technical Support contact information for Hill-Rom offices worldwide. If this is attached to another document or letter, it does **not** mean that every country listed below is affected by that document.

Austria:	Tel: 0810 00 10 23 – Fax: + 43 (0)224 32 85 50 - 19 e-mail: austria@hill-rom.com
Canada:	Tel: 800-267-2337 (8 am – 5 pm ET (New York time)) e-mail: jeff.moorehead@hill-rom.com
Central & Eastern European Region:	Tel: +48 (0)692 414 826 – Fax: +44 (0)870 137 1872 e-mail: karolina_fenicka@hill-rom.com
France:	Tel: +33 (0)4 73 86 92 05 – Fax: +33 (0)4 73 86 92 05 e-mail: claude_martin@hill-rom.com
Germany:	Tel: +49 (0)2152 144 255 – Fax: +49 (0)2152 144 105 e-mail: germany.customer.care@hill-rom.com
Ireland:	Tel: +353 (0)1 413 6005 – Fax: +353 (0)1 413 6050 e-mail: dublin.sales@hill-rom.com
Italy:	Tel: +39 02 950542 95 – Fax: +39 02 950543 26 e-mail: assistenza_tecnica@hill-rom.com
Middle East & Africa Region:	Tel: +9714 (0)4-8816818 – Fax: +9714(0)4-8812357 e-mail: trescilla_dsouza@hill-rom.com
Netherlands:	Tel: +31 (0)347 32 35 32 – Fax: +31 (0) 347 32 35 00 e-mail: info_nl@hill-rom.com
Nordic Region: (Sweden, Norway, Denmark, Finland, Iceland)	Tel: +46 (0)8 564 353 60 – Fax: +46 (0)8 564 353 61 e-mail: se.marketing@hill-rom.com.se
Spain:	Tel: +34 (0)902 193 423 – Fax: +34 (0)93 666 55 70 e-mail: asistencia@hill-rom.com
Switzerland:	Tel: 0848 81 15 30 – Fax: + 41 (0)21 7062132 e-mail: swiss_hotline@hill-rom.com
United Kingdom:	Tel: +44 (0)1530 411000 – Fax: +44 (0)1530 562029 e-mail: uk.customer.care@hill-rom.com
United States:	Tel: 800-445-3720 (8 am – 5 pm ET (New York time))
All other countries for support of products manufactured in the US:	Tel: 812-934-1348 (8 am – 5 pm ET (New York time)) e-mail: gary.lakes@hill-rom.com
All other countries for support of products manufactured outside the US:	Tel: +33 (0)2 97 50 92 45 e-mail: leny.rodriquez@hill-rom.com