



Urgent Field Safety Notice

Subject: Evolution series beds until manufacturing date December 31, 1999

FSCA-identifier Mod 388a

Type of action Verification of the side-rail gaps

Date: 18th December 2007

To: Facility Risk Manager and Administrator
Vigilance Manager
Biomedical Engineering

Affected devices:
Evolution series beds until manufacturing date December 31, 1999

Background:

There have been a number of adverse incidents involving side rails that have led to injury and in some cases death. In 2001 Hill-Rom informed you how to prevent incidents on the beds in question. On top of this the highest regional authorities published in May 2001 a bulletin about the risks of siderail entrapments on hospital and nursing home beds. This information contained a checklist in the appendix 2 with the accepted gap measurements on siderails referring to the latest standard DIN EN 60601-2-38 A1:2000 (DIN EN 1970) . For the old stock in the field the regional authorities accepted a tolerance of 10% on the gap measurements.

Our records indicate that you still operate with Evolution hospital beds manufactured prior to December 31, 1999. The side rails of these beds are in all likelihood not compliant to the latest standards and regulations.

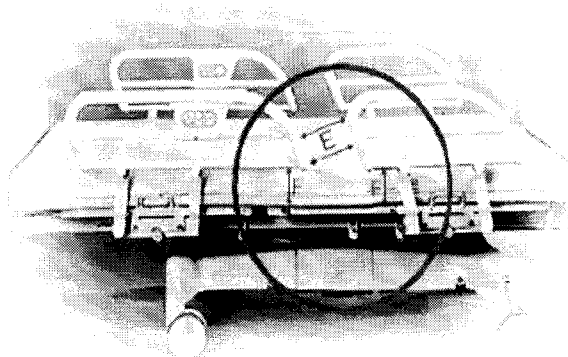
Of particular importance is the gap "E" between the two siderails and gap "F" between lower side rail bar and sleep surface.

The accepted guidelines for this gap measurement are:

- **Gap E \geq 235 mm**
- **Gap F \leq 60 mm**

Any bed that has not been refitted by an appropriate siderail kit will not meet the essential requirements of the § 7 MPG and must be removed from service.

Please consider that non compliant siderails can cause high risks for entrapments. A Patient with a small size and/or weight is small enough to pass through the space and to become trapped between the siderails - with potential serious injury or death.



Action to be taken by the user:

- Please check the side rail gaps against the above mentioned details and the safety advice from the highest regional authorities (Medical device bulletin 1/2001; Check list Appendix 2)
- In order to meet the legal requirements Hill-Rom will provide retrofit kits which fit precisely to the different side rail versions.
- Please contact Hill-Rom in any case in order to inform us about the results of your side rail verification.
- If you have moved your beds to another location, or if any beds have been sold or removed from service, please advise us immediately so that we take appropriate steps to complete this action.

In order to facilitate your response, Hill-Rom has attached a form in the appendix.

Please ensure that enclosed form will be sent back in any case.

Hill-Rom assumes no liability resulting from your failure to comply with your obligations. Liability claims are expressly excluded.

Transmission of this Field Safety Notice: (if appropriate)

This safety advice is being conducted with the knowledge of the competent authority and of the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM).

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.

Contact reference person:

If you have any questions regarding this safety notice, please contact Hill-Rom Technical Support , telephone 02152 -144 -222.

Yours sincerely

Hill-Rom Technical Support



Please send response-form back to following fax-number 02152 144 105

Response-Form

**Evolution series beds until manufacturing date December 31,
- Verification of the siderail gaps**

Please tick off and complete as applicable

- I have checked the siderail gaps per your information and I confirm hereby with my name/signature that the siderails meet all regulatory requirements of the highest competent regional authorities.
- Evolution series beds not compliant to the regulatory requirements of the highest competent regional authorities are:
(Please tick off as applicable)
 - Moved to an other location or sold or removed from service
 - Temporarily removed from service
 - Still in our location and under service .
Please provide solutions for retrofitting.

Address: _____

Contact Person: _____

Street Address: _____

Post-Code: _____

Telefon _____

Date: _____

Signature: _____