

Urgent Field Safety Notice

Subject: Reminder for Product Safe Use—Dynamis[™] and Gerialit[™] Beds manufactured between October 1995 and June 2001 with DEWERT electrical system (not applicable to beds manufactured between June 2001 and January 2009 with SKF electrical system)

FSCA-identifier: Mod 466

Type of action: Notification

Date: March 1, 2012

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

Affected Devices:

Models:

LI146B1—LI146BI, LI146D1—LI146DI, LI147B1—LI147D1, LI150A0—LI150B0, LI163B1—LI163C1, PRS0128, PRS0199, PRS0201, PRS2001

Production Dates:

Dynamis[™] and Gérialit[™] beds manufactured from October 1995 to June 2001

Background:

Hill-Rom wants to make your aware of a potential safety issue regarding Dynamis and Gerialit beds manufactured and shipped from October 1995 to June 2001 that have Dewert control boxes. It is possible for there to be unintentional movement of the bed when it is plugged in, including sudden collapse to the lowest position. This important safety announcement is being issued to remind you and your staff to not place their hands or limbs under the bed, or allow individuals to climb under the beds.

WARNING:

Make sure that staff, patients, caregivers, and visitors do not work or crawl under any bed or other areas where unintended quick return to lowest position or collapse of the bed could cause entrapment. Serious injury or death could occur.



Dewert / SKF product identification :

As Dynamis[™] and Gérialit[™] beds have been manufactured with electrical systems manufactured by two different suppliers (Dewert or SKF), be advised that this notification applies **only** to **Dewert** (easy recognizable by the Lockout Unit Functions – see below).



Action to be taken:

- 1. In an effort to mitigate the potential for injury, Hill-Rom requests that the enclosed labels be applied to both sides of the bed as a reminder where a hand should not be placed, and to not climb under the bed. (See Label Attachment Locations on next page.)
- 2. Complete and **return the attached form** to confirm receipt of this Field Safety Notice and of your actions taken.



Label Attachment Locations



Transmission of this Field Safety Notice:

Please pass this notice on to all those who need to be aware within your organization and/or to any organization 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 concerning this safety notice, please contact Hill-Rom Technical Support using the attached listing for your geographic region.

Regards,

Hill-Rom Technical Support

Attachment: Confirmation of Receipt, DS119RD