

Urgent Field Safety Notice

Subject: Affinity® Four Bed—Brake Upgrade

FSCA-identifier: Mod 471

Type of action: Device Modification

Date: April 10, 2012

To: Chief Executive

Facility Administrator
Facility Engineer
Vigilance Manager
Biomedical Engineering

Medical Device Liaison Officer

Affected Devices:

Models: Affinity® Four Birthing Bed (P3700B/C/D)

Range of serial numbers affected: H331AA4785 thru N081AA7966

Production Dates: prior to March 21, 2012

Background:

Hill-Rom has found that some of our Affinity® Four Birthing Beds, manufactured between the dates specified above, may experience problems with the brakes. This may result in unwanted bed movement.

Action to be taken:

We have developed an enhanced braking system for these beds, and we will come to your facility to modify your affected beds.

Until we visit your facility, we ask that you do as follows:

- Locate the affected beds listed in this notice.
- Test the brakes:
 - After you set the brakes, push and pull on the bed from opposite corners to make sure the brakes are holding.
 - When you release the brakes, make sure the brake lever is either in the flat (neutral) or transport position, and the bed rolls easily.
- If you still can not get the brakes to hold or operate as normal, take the bed out of service until we can do the modification.
- To make sure the brakes operate as designed, do the annual Preventive Maintenance (PM) on your Affinity® beds as specified in the Service Manual. A regular PM program is essential to maintain proper operation of your Hill-Rom beds.



Transmission of this Field Safety Notice:

Please forward a copy of this letter to any other facility personnel you deem appropriate.

Contact reference person:

If you have any questions concerning this request or the procedure as outlined, please contact Hill-Rom Technical Support using the attached listing for your geographic region.

Regards,

Hill-Rom Technical Support

Attachment: DS119RD



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.

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United States: Tel: 800-445-3720 (8 am – 5 pm ET (New York time))

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