
Urgent Field Safety Notice

Subject: Affinity® Four Bed—Brake Upgrade

FSCA-identifier: Mod 424

Type of action: Device Modification

Date: November 16, 2009

To: Facility Risk Manager/Facility Administrator

Affected Devices:

Models:	Affinity® Four Birthing Bed
Range of serial numbers affected:	H331AA4785 thru J170AA9123
Production Dates:	November 27, 2006 to June 18, 2008

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, and possible patient or caregiver injury.

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, and, if possible, remove the affected beds from service.
- If it is not possible to remove a bed from service, do a test of 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 semi-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.



Included with this letter is a Correction supplement for your Affinity® Service Manual. Please attach it to your manual, as it contains updated technical information related to the enhanced braking system, along with other changes.

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, 154182 REV 1

Reference: MOD 424