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## Urgent Field Safety Notice

### Subject: AvantGuard® Beds—Brake Correction

FSCA-identifier: Mod 1219

Type of action: Device Modification

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**Date:**

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

**Affected Devices:**

Models: AvantGuard® 800 (CS800A1, PRS800A1)  
AvantGuard® 801 (CS801A1, CS801A2, PRS801A1)

Production Dates: August 26, 2011 to May 19, 2013

**Background:**

Hill-Rom has found that some of our AvantGuard® Beds, manufactured between the dates specified above, may experience problems with the brakes. If potentially the brake system is not fully engaged upon activation, the brakes may become disengaged when the bed is shaken. This can result in unwanted bed movement, and possible patient or user injury.

**Action to be taken:**

We have developed a correction for the braking system, and we will come to your facility to modify your affected beds.

Until we visit your facility, we ask that you continue to follow the User Manual instructions:

**Warning:** *Always place the brake bar in the stop position when the bed is occupied, except during patient transport. To make sure the bed will not move, push and pull on the bed to check it after the brake bar has been placed in the stop position. Failure to do so could result in patient injury or equipment damage.*



Use your foot to step down on the brake/steer bar until it stops.



If after testing you can not get the brakes to hold, take the bed out of service until we can do the modification.

Please complete and **return the attached Customer Response Form/Receipt** within 10 days.

**Important:** The *Customer Response Form/Receipt* provides Hill-Rom with the means to monitor the progress of Field Corrective Actions. It is imperative that you return this form/receipt for our records.

**Transmission of this Urgent Field Safety Notice:**

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

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action

Hill-Rom confirms that the relevant Competent Authorities have been informed of this Field Safety Corrective Action

**Contact reference person:**

If you have any questions concerning this Urgent Field Safety Notice, please contact Hill-Rom Technical Support, your distributor, or your Hill-Rom representative.

Regards,

Hill-Rom Technical Support

Attachments: Customer Response Form/Receipt



## Customer Response Form/Receipt

**Subject: AvantGuard® Beds—Brake Correction (Mod 1219)**

It is imperative that you return this form/receipt for our records.

Please complete and **return this form/receipt within 10 days**. See specific instructions at bottom of page. Thank you.

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Hill-Rom account number: \_\_\_\_\_

Name of the facility: \_\_\_\_\_

Address of the facility: \_\_\_\_\_

City: \_\_\_\_\_ Country: \_\_\_\_\_

Facility Authorized Name: \_\_\_\_\_

*Please print legibly*

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Title: \_\_\_\_\_ Phone: \_\_\_\_\_

Email: \_\_\_\_\_ Fax: \_\_\_\_\_

Check applicable box(es):

1.  We acknowledge receipt of this notification and it has been forwarded to all users.
2.  We do not have any affected beds.
3.  Other: \_\_\_\_\_

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Return this form to: