

Urgent Field Safety Notice

Subject: Affinity™ Four Birthing Bed—Lift-Off Foot Section

FSCA-identifier: Mod 1224

Type of action: Customer Safety Notification

Date:

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

Affected Devices:

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

Production Dates: October 2006 through June 2014



Lift-Off Foot Section

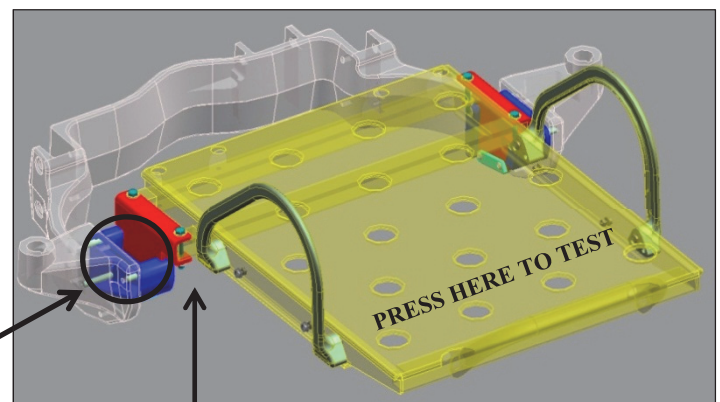
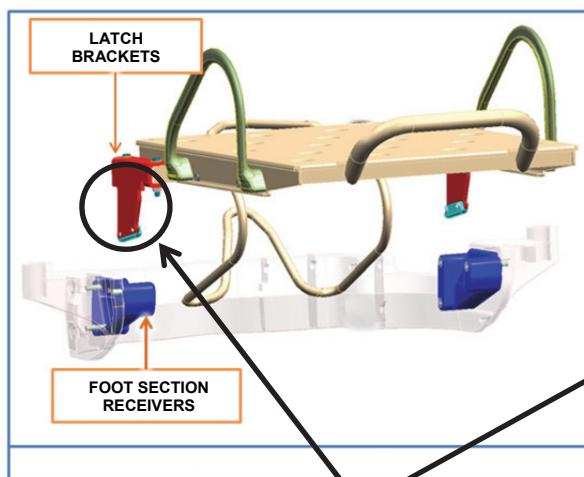
Background:

Hill-Rom would like to remind users of proper handling of the Lift-Off foot section per the Affinity™ Four Birthing Bed manual. Improper handling, such as allowing the foot section to be dropped repeatedly, could cause the attachment latch mechanism to become bent. If the latch mechanism is bent badly enough, it could potentially cause the installed foot section to be improperly engaged onto the bed. If the damaged foot section should disengage during use, this could result in injury to the user due to a fall. Again, this is a rare condition (from our data, 2.8 times per million usages) and can be avoided by properly handling the foot section and not allowing it to repeatedly drop onto the floor. The product is safe to use as long as it is not damaged.

Action to be taken:

Upon receipt of this notification, we recommend that you verify the Lift-Off foot section on your beds has enough engagement. **Before you do these steps be aware that the foot section has the potential to fall if the brackets are bent.** Refer to the graphics below for the following 8 steps.

1. Following the procedures in the User Manual, remove the Lift-Off foot section and place it on the perineal stand.



Placenta Basin REMOVED

The latch brackets (red in photos) can be bent if the section is dropped. Make sure they are straight, not bent to the side, and fit into the receivers (blue) securely.

2. Unsnap and remove the top cushion from the Lift-Off foot section.
3. Remove the placenta basin.
4. Install the Lift-Off foot section without the cushion back onto the bed frame. Make sure the latches engage before applying weight or moving around the section.
5. Next, push the Lift-Off foot section all the way to either the left or right.
6. If the foot section remains engaged, then move on to the next step; if not, contact Hill-Rom Technical Support.
7. Before step 8, verify that the foot support brackets are still solidly engaged in the receivers.

CAUTION: Take steps to avoid injury to your lower extremities in case the foot section should fall.

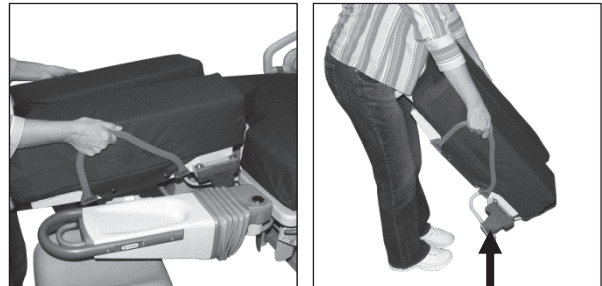
8. Use two hands and press down firmly on the foot section where indicated by “PRESS HERE TO TEST” in the graphic above. It should not slip or fall.

If the Lift-Off foot section fails to meet the inspection criteria, take the Lift-Off foot section and/or bed out of service until a qualified Hill-Rom technician can make the necessary correction.

Until we contact you again:

Hill-Rom is currently working on a way to mitigate this risk through a change to the Lift-Off foot section. In the meantime, when using this product please caution your users (caregivers, housekeeping, etc.) to continue to follow the instructions from the User Manual:

1. **Grasp both handles**, and hold the foot section as close to the body as possible.
2. Lift and slide the foot section toward you (bending your knees) while taking a step backward.
3. With the knees bent, place it on the floor with the perineal stand down to hold it upright.



AVOID DROPPING ON THE LATCH MECHANISM!

Please complete and **return the attached Customer Response Form/Receipt** within 30 days.

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.

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

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

Attachment: Customer Response Form/Receipt



Customer Response Form/Receipt

Subject: Affinity™ Four Birthing Bed—Lift-Off Foot Section (Mod 1224)

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

Please complete and **return this form/receipt within 30 days**. See specific instructions at bottom of page. Thank you.

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):

We acknowledge receipt of this notification and it has been forwarded to all users.

We do **not** have any affected products.

Other: _____

Return this form to: