



## URGENT MEDICAL DEVICE CORRECTION

August 18, 2006

**SUBJECT: P3700 Affinity® Three Birthing Beds distributed after October 2000 and equipped with the 12VAC Accessory Outlet option**

To: Facility Administrator or Biomedical Engineering

Our review process has determined that a potential overheating hazard may exist affecting the low-voltage transformer for the accessory outlet. It is possible for the thigh section of the bed to overrun its stops during articulation and come into contact with a wire connected to the low-voltage transformer. Over time, it is possible to wear through the insulation causing a short that can lead to overheating of the transformer.

Hill-Rom has received reports of overheating with the release of smoke and, in at least one case, heat deformation of the transformer and the plastic shroud.

Hill-Rom has determined that the potential overheating hazard can be eliminated by disconnecting the power to the low-voltage transformer. This will have no impact on the operation of the Affinity® Three Birthing beds, as there are currently no accessories that operate using the low-voltage accessory outlet.

In order to minimize disruption to your facility and to your patients, Hill-Rom is requesting that **this corrective action be implemented immediately** by your biomedical department. Instructions for disconnecting the transformer are enclosed. When this corrective action has been completed on all Affinity® Three Birthing Beds in your facility(ies), please complete the response card and return the card to Hill-Rom.

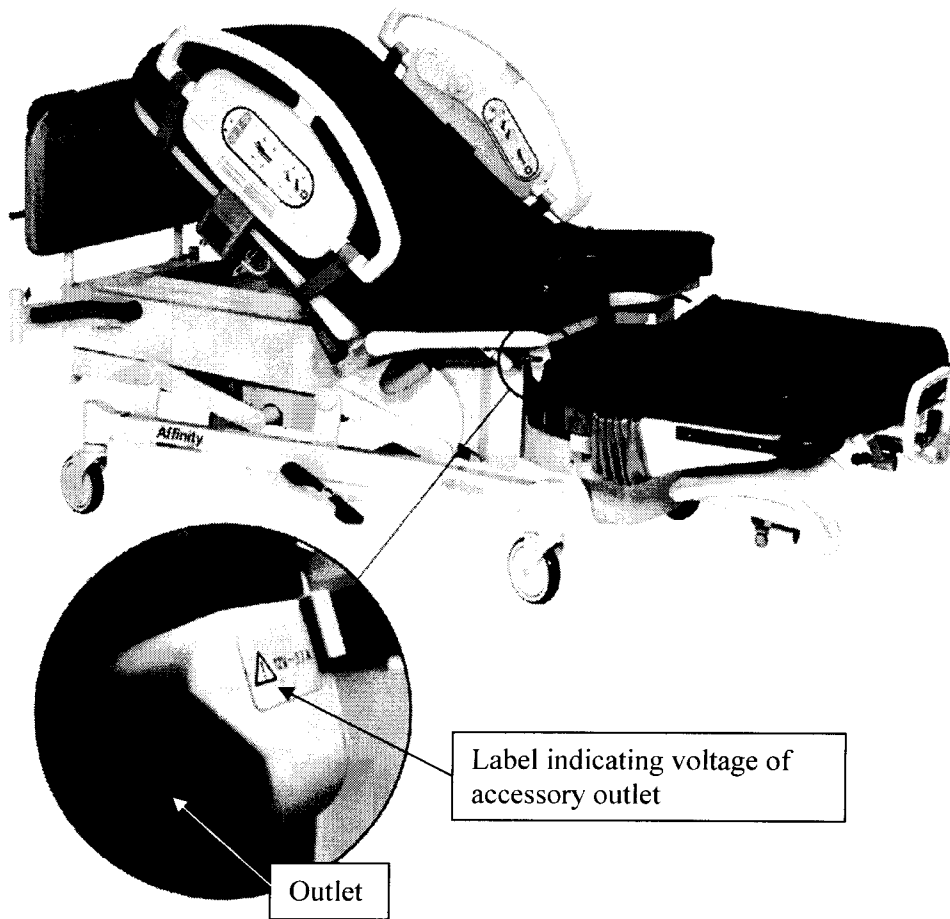
Please forward a copy of this letter to any other personnel or facility that you deem to be appropriate, and to any facility to whom you have loaned or sold this device.

This device correction is being conducted with the knowledge of the Food and Drug Administration.

We believe that your personnel can easily perform this correction at a time that is most convenient for your facility. However, if you have questions or desire assistance performing this correction, contact Hill-Rom Technical Support using the attached listing for your geographic region to arrange a time when the bed can be removed from service for the correction to be performed.

The affected units can easily be identified by viewing either the right or left side of the bed for the attachment of the optional 12VAC outlet. If your device has the outlet as indicated in the "Location of Optional Outlet," the Correction **must** be completed. If the outlets are not visible, then no transformer exists and no additional action is required for that bed.

**Location of Optional Outlet**





We apologize for any inconvenience this may cause your facility, and we are willing to work toward meeting your needs regarding this matter. We understand that our products and services are an integral part of many medical facilities. Additionally, we are aware of the impact that any disruption may have on the facility and its caregivers' ability to care for their patients. Be assured that our top priority is to provide you with high quality, safe, and reliable products that you have come to expect from us.

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

Thank you for your cooperation.

Regards,

Hill-Rom Technical Support

Reference: mod360  
Attachment: ds119rd, 144469 REV 1

143893 REV 1



**URGENT MEDICAL DEVICE CORRECTION**

**P3700 Affinity® Three Birthing Bed**

Please complete the following with the correct information, and return this response card by fax to (812) 931-2410 by September 18, 2006.

Thank you.

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

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

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

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ *Please print legibly*

Title: \_\_\_\_\_ Date: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Check action taken:

- Affinity® Three Birthing Bed cable disconnection has been completed on all beds at our facility(ies)
- A plan is in place to complete the Affinity® Three Birthing Bed cable disconnection on all beds at our facility(ies)
- Other *please describe*: \_\_\_\_\_

Fax to: **Hill-Rom Co., Inc.**  
**812-931-2410**  
**Attention: ASG**  
**Reference: MOD360**



## 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.

United States: 800-445-3720 (8:00 a.m. to 5:00 p.m. ET\*)

Canada: 800-267-2337 (8:00 a.m. to 5:00 p.m. ET\*)  
or [REDACTED]@hill-rom.com

Austria: 02243 28550

France: 0820 01 23 45

Germany: 02152 144 222

Ireland: 01 413 6005

Italy: 02 950541

Netherlands: 0347 323532

Nordic Region: +46 (0)8 564 353 60  
(Sweden, Norway, Denmark, Finland, Iceland)  
or se.marketing@hill-rom.com

Spain: 902 193 423

Switzerland: 0848 81 15 30

United Kingdom: 01530 411000

All other countries  
requesting support for  
products manufactured in  
the U.S.: 812-934-1348 (8:00 a.m. to 5:00 p.m. ET\*)  
or [REDACTED]@hill-rom.com

All other countries  
requesting support for  
products manufactured  
outside the U.S.: +33 (0) 2 97 50 92 45  
or [REDACTED]@hill-rom.com

\* ET = New York time

**Subject: Affinity® Three Birthing Bed—Auxiliary Transformer Disabling  
Instructions**

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Tools required: T25 Torx®<sup>1</sup> head bit/ratchet or T25 screwdriver  
Wire cutters

Parts required: (1) 19124 Wire tie, 8.5", nylon  
(included with customer mailing)

**Procedure**

1. Set the brake/steer pedal to the brake position.
2. Make sure the bed is out of the Trend-Like position.
3. Use the hilow function to raise the bed to the high position.
4. Use the head function to raise the head section to the high position.

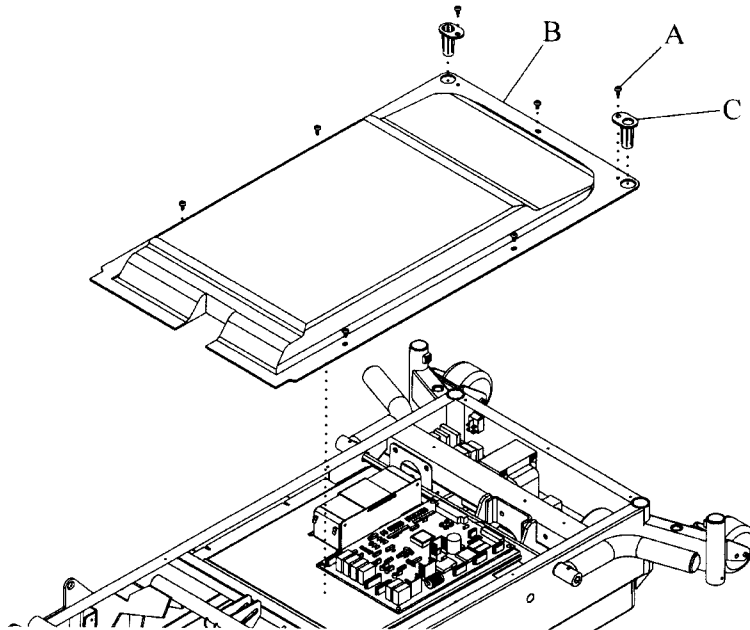


**SHOCK HAZARD:**

Unplug the unit from its power source. Failure to do so could result in personal injury or equipment damage.

5. Unplug the bed from its power source, and engage the lockout control.
6. Remove seven screws (A) that secure the top motor cover (B) (see figure 1 on page 1).

**Figure 1. Top Motor Cover Removal**

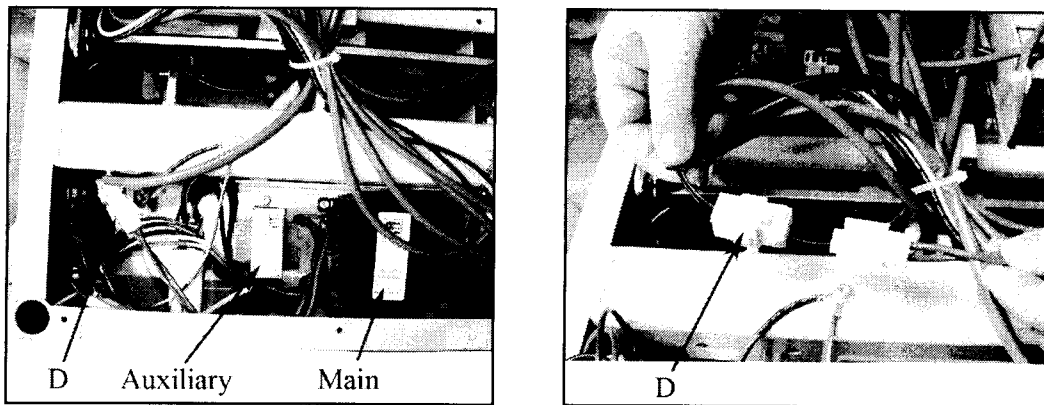


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1. Torx® is a registered trademark of Textron Innovations, Inc.

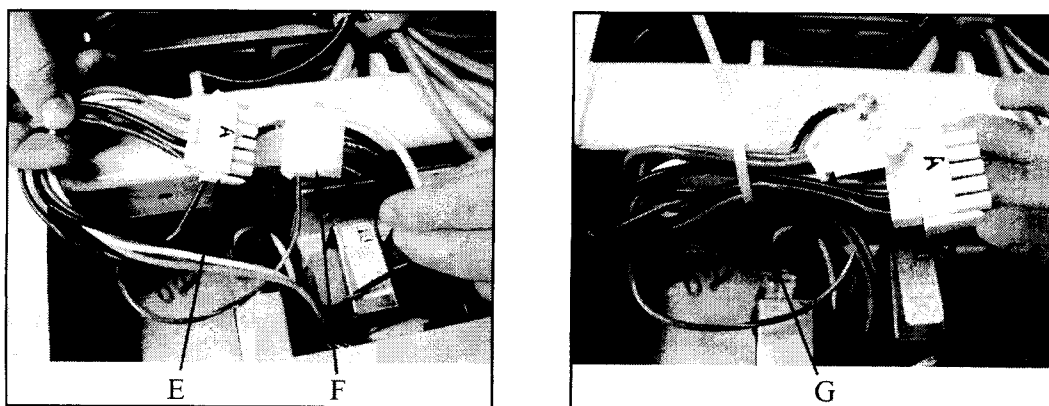
7. Remove the two headboard bushings (C) from the top motor cover (B).
8. Remove the top motor cover (B) from the bed.
9. From the head end, locate the auxiliary and main transformers (see figure 2 on page 2).
10. Disconnect the small auxiliary transformer plug (two red wires) from the outlet connector (D) (red and black wire).

**Figure 2. Transformer Locations and Auxiliary Outlet Disconnection**



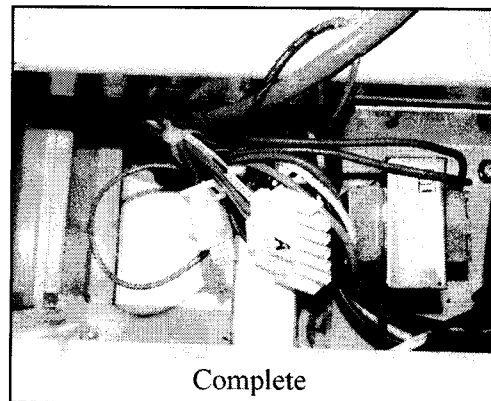
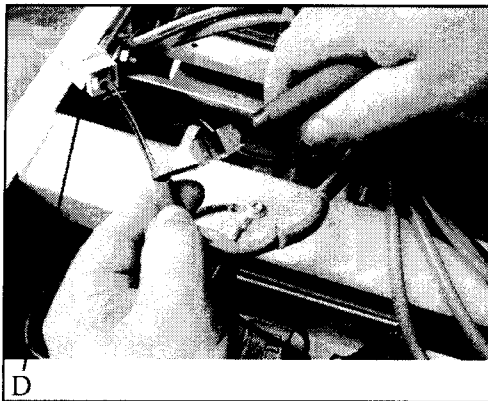
11. Disconnect the auxiliary transformer from the large main transformer connector (E) (multiple, colored wires) (see figure 3 on page 2).
12. Move the loose main transformer wire (F) back to its original location.
13. Use a wire tie (G) to bundle together the loose connectors from the auxiliary transformer, tighten, and cut off any excess wire tie.
14. Stuff the tied bundle back into an open area to the left of the auxiliary transformer.

**Figure 3. Main to Auxiliary Disconnection and Wire Tie**



15. At the outlet connector (D)—the only loose wire remaining, which comes from the wire bundle leading towards the foot end of the bed—pull back the sheathing to expose as much of the red and black wires as possible (see figure 4 on page 3).
16. Cut the red and black wires (no power is present, as they are disconnected from the transformer) as close to the sheathing as possible, and dispose of the connector (D). Allow the sheathing to extend back over the ends of the cut wires.

**Figure 4. Cutting Auxiliary Outlet Connector and Final View**



17. Tuck the end of the cut wire down into the bed frame housing (see “Complete” photo).
18. Do steps 6 thru 8 in reverse order to install the top motor cover (B).
19. Plug the bed into its power source.
20. Do the “Function Checks” in the *Affinity® Three Birthing Bed Service Manual* (MAN272).





**NOTES:**

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