



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 32063

To: Director of Biomedical Engineering
Risk Manager/Hospital Administrator
Director of Clinical/Radiology

RE: **Giraffe OmniBed – Canopy seals not cleaned properly on systems with original seal design, potential contamination.**

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

GE Healthcare has become aware of a potential safety issue that can occur if the canopy seals are not cleaned appropriately per Giraffe OmniBed cleaning and care guidelines on systems with original seal design. Reported buildup of debris around the edge of the canopy seal can lead to a source of infection.

Safety Instructions

You can continue to use your Giraffe OmniBed systems in open Bed warmer mode and incubator mode. Care should be taken to achieve visible cleanliness during the cleaning process. Design of the Giraffe OmniBed allows for your facilities normal cleaning to be performed, following the step by step procedure to remove the canopy seal to reach visible debris accumulation. Contact your Biomedical department to perform the removal and reassembly of the original seal fasteners, per the attached addendum, prior to performing the cleaning procedure. Attention to cleaning technique by personnel involved in the cleaning process will reduce the likelihood of occurrence of the mentioned condition.

- Carefully follow the additional instructions provided in the attached addendum to ensure continued safe use of the device and place the addendum with your User Manual.
- Always follow your facility guidelines for cleaning and infection control.

Affected Product Details

Giraffe OmniBeds shipped from 2000 to 2011 with Serial Numbers starting from HDGD00001 to HDGQ50183.

Product Correction

GE Healthcare will provide a Giraffe OmniBed Cleaning & Care Guidelines poster for display by your system. No other correction is required.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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SaudiArabiaServiceCenter@ge.com

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



ADDENDUM FOR REMOVAL AND CLEANING OF SEALS

Identify the type of canopy seal on the Giraffe OmniBed

Two types of canopy seals are available. Determine which type you have:

- a. The original canopy seals, which are attached with fasteners (you cannot unsnap the corner covers by hand).
- b. The enhanced canopy seals can be removed by hand by unsnapping the corner covers as shown in the *Figure 1*.
- c. If you have enhanced canopy seals, this addendum is not applicable – Refer Giraffe OmniBed Cleaning and care guidelines (GE PN M1131904)

Note: If the original canopy seals are present, and if necessary to achieve visible cleanliness, you may contact your Biomedical Department or GE Healthcare service personnel for canopy seal disassembly and reassembly



Figure 1 Enhanced Canopy Seal

Steps to follow for disassembly and reassembly of original canopy seals

- a. Remove the canopy from the Giraffe OmniBed, refer Giraffe OmniBed service manual (GE PN 6600-0343-000) or Contact GE Healthcare Service personnel.
- b. Remove the 4 corner pins using M2.5 hex key – refer *Figure 2*
- c. Remove the north side seal by removing the 4 hex nuts using M11 socket / wrench – refer *Figure 3*
- d. Unsnap the west side seal cover to expose the 5 screws holding the seal – refer *Figure 4*
- e. Remove the west side seal by removing the 5 screws using a M2.5 hex key and M7 socket / wrench – refer *Figure 5*
- f. Remove the east side seal similar to west side seal by removing the 5 screws using a M2.5 hex key and M7 socket / wrench
- g. Remove the south side seals by removing the 4 screws using a M2.5 hex key
- h. Store all disassembled parts for reassembly post cleaning

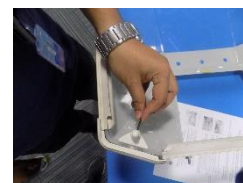


Figure 2



Figure 3



Figure 4

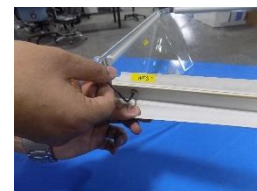


Figure 5

Cleaning Instructions

Soak the seals in the recommended cleaning agent. Refer User Manual (GE PN 6600-0342-000) section “Cleaning and Disinfection” for list of recommended cleaning agents.

Reassembly

Assemble the parts by following the above steps in reverse order



Warning: The OmniBed must be properly reassembled as per these guidelines. Improper assembly of the OmniBed may result in unsafe operation of the unit

(Optional) You may order the enhanced canopy seals released by GE. Part number to be ordered is M1208286

