



URGENT FIELD SAFETY NOTICE

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 32069

To: Director of Biomedical Engineering
Director of Neonatology/ L and D/ Nurse
Manager Risk Manager/Hospital Administrator

RE: **Stop Use** of specific Giraffe™ OmniBed™ Carestation - Under Torqued Fasteners on Canopies

***This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.
Please retain this document for your records.***

Safety Issue

GE Healthcare has become aware that specific Giraffe™ OmniBed™ Carestation systems were manufactured with eight fasteners torqued to a value less than the specified value. In the unlikely event that under torqued fasteners loosen to the point of coming off, the canopy could become detached and fall. A canopy fall onto an infant could result in a life-threatening injury. In addition, there is a potential that a loose fastener could fall and cause a thermal injury or fall into the infant's mouth blocking airflow. There have been no injuries reported as a result of this issue.

Safety Instructions

Stop use and segregate the affected Giraffe™ OmniBed™ Carestation immediately.

Affected Product Details

Giraffe™ OmniBed™ Carestation:
GTIN: 00840682116862 with serial numbers:
TABY70672, TABY70673, TABY70675, TABY70676, TABY70677, TABY70678, TABY70686, TABY70688,
TABY70689, TABY70690, TABY70692, TABY70693, TABY70694, TABY70695, TABY70697, TABY70698
TABY70699, TABY70703, TABY70704, TABY70705, TABY70706, TABY70707, TABY70708, TABY70709,
TABY70719, TABY70722, TABY70723, TABY70724, TABY70725, TABY70726, TABY70727, TABY70728,
TABY70729, TABY70730, TABY70731, TABY70732, TABY70733, TABY70734, TABY70737, TABY70747,
TABY70748, TABY70753, TABY70755

Product Correction

GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

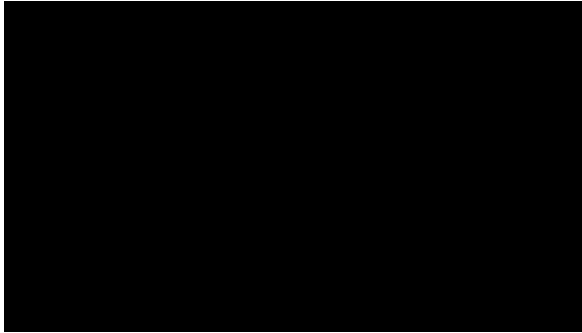
Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

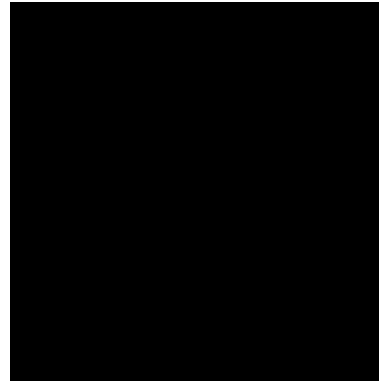
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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,



GE Healthcare



GE Healthcare



**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice and required actions to be taken Ref# 32069.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have stopped use and taken out of service all affected devices in accordance with that Notification.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form scanning or taking a photo of the completed form e-mailing to:

MIC.Recall@ge.com

You may obtain this e-mail address through the QR code below:

