



URGENT MEDICAL DEVICE RECALL

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

October 11, 2019

GEHC Ref# 32070

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

RE: Giraffe Incubator, Giraffe OmniBed, Giraffe Incubator Carestation, and Giraffe OmniBed Carestation – Bedside panels and portholes can appear closed without being latched - Potential patient fall

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

- The bedside panels of Giraffe Incubator, Giraffe OmniBed, Giraffe Incubator Carestation, and Giraffe OmniBed Carestation can be upright and look closed but not be latched.
- The portholes also can look closed when not latched.
- If a canopy cover is used, it can hold the bedside panel or porthole door closed without being latched.

If a bedside panel or porthole that is not latched falls open, it will no longer protect the patient from falling.

Safety Instructions

You can continue to use your Giraffe Incubator, Giraffe OmniBed, Giraffe Incubator Carestation and Giraffe OmniBed Carestation by following the four instructions below:

- Each time the bedside panel is closed, make sure the red tab is no longer visible (see Figures 1 and 2).

Figure 1. UNLATCHED bedside panel
The red tab shows the latch is **not** engaged.



Figure 2. LATCHED bedside panel
The red tab no longer visible shows the bedside panel is latched

- Each time the porthole doors are closed, manually check the porthole latches to make sure the porthole door latches are secure (see Figure 3).

Figure 3. LATCHED (left) and UNLATCHED (right) portholes



- You must pull on the porthole door every time the bedside panel or porthole is closed to make sure the porthole door is latched.
- The device is intended to be used by healthcare professionals. If a non-healthcare professional comes into contact with the device, you must check the latches every time to ensure that panels and portholes are closed.

**Affected
Product
Details**

All Giraffe Incubators and Giraffe OmniBeds*
Giraffe Incubator Carestation (2082844-002-XXX) [GTIN – 010084068211685521]
Giraffe OmniBed Carestation (2082844-001-XXX) [GTIN – 010084068211686221]

*NOTE: Some products were shipped prior to implementation of UDI and may not contain a Global Trade Item Number (GTIN).

**Product
Correction**

GE Healthcare will provide a user manual addendum, labels for the device, and instructional posters materials in a future mailing at no cost to you.

**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.

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,

Laila Gurney
Senior Executive, Quality & Regulatory
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
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# 32070.

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 taken and will take appropriate actions 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 to FAX NUMBER: +1-410-630-5579, or scanning or taking a photo of the completed form e-mailing to: MIC.Recall32070@ge.com
You may obtain this e-mail address through the QR code below:**

