AMENDED -
URGENT MEDICAL DEVICE RECALL

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

<Date of Letter of Deployment>

GEHC Ref# 32070-2

To: Director of Biomedical Engineering
Director of Neonatology/ L and D/ Nurse Manager
Risk Manager/Hospital Administrator
Chairman Medical Board
Relevant Head of Departments for hospital

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 is a supplement to a previous notification you received and provides additional Safety instructions and materials.

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 can look closed but not be 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 instructions below:

Note: 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.

1. Every time the bedside panel is closed, you must pull on the bedside panel to make sure the bedside panel is latched, and 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.

UNLATCHED

LATCHED

Figure 2: LATCHED bedside panel
When the red tab is not visible, it is latched.

2. You must pull on the porthole doors every time the bedside panel or porthole is closed to make sure the porthole door is latched (see Figure 3).

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

FMI Kit Contents

3. You have been provided with the following items:

Part	Qty.
Giraffe Incubator and OmniBed Bedside Panel and Porthole Letter	1
Giraffe Incubator and OmniBed Bedside Panel and Porthole Poster	3
Giraffe Incubator and OmniBed User Manual Bedside Panel and Porthole Addendum	1 per device
Bedside Panel Latch Label Set	1 set of 4 labels per device*
Bedside Panel and Porthole Warning Label	3 per device*

*Additional labels will be provided in case of loss or damage.

4. Apply Safety labels included in this mailing to the Incubator/OmniBed using the following instructions:

Label 1: Latch Label

Label 2: Warning Label

a. Wipe the areas where labels will be applied with a soft, lint-free cloth dampened with water.

b. Make sure the label area is dry and visibly clean.

c. Before applying the label, make sure the label edges do not overlap the edge of the bedside panel or touch the latches.

d. Make sure the label is flat and fully adhered to the surface.

e. Refer to Figures 4 – 6, below, for label placement locations.

Label Placement Locations

f. Each Incubator or OmniBed has 2 bedside panels. Attach the Bedside Panel Latch Labels (Label 1, above) and Warning Labels (Label 2, above) at the locations shown in Figures 4 and 5 on each bedside panel.

Figure 4: Giraffe Incubator

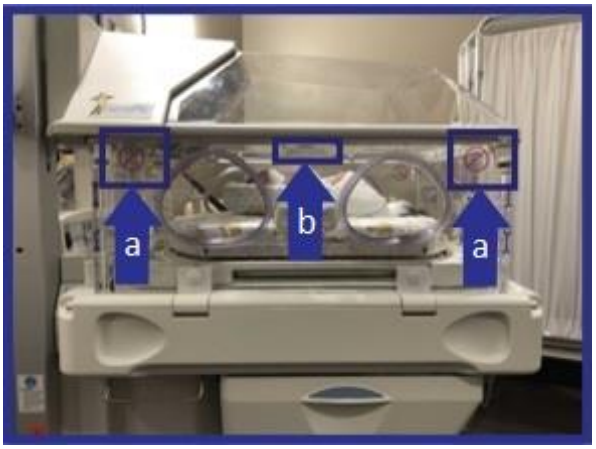

Figure 5: Giraffe OmniBed

a Latch Labels (Label 1) Place beside each bedside latch as shown above. **b Warning Label (Label 2)** Center near the top of the bedside panel as shown above	**a Latch Labels (Label 1)** Place beside each bedside latch as shown above. **b Warning Label (Label 2)** Center near the top of the bedside panel as shown above. The labels should be visible when the canopy is closed.

g. If your device has an additional porthole on the end panel, attach a Warning Label (Label 2, above) as shown:

Figure 6: Giraffe OmniBed with Porthole End Panel

b Warning Label (Label 2)

Center the label over the porthole latch near the top of the wall as shown above. The label should be visible when the canopy is closed.

Additional Instructions

5. Review the attached Addendum and place it with your Incubator/OmniBed User Manual.
6. Place all (3) of the provided "Giraffe Incubator/OmniBed Risk of Patient Fall" posters in prominent clinical locations for your staff and ensure they remain posted for the lifetime of the Incubator/OmniBed(s).
7. Confirm that the information from this recall letter and attached Addendum is properly disseminated to all users that handle the Incubator/OmniBed.
8. Make sure that all hospital staff and non-clinical individuals who open panels or portholes or otherwise come into contact with the device understand these instructions.
9. You have been provided extra labels in this mailing. If you have any spare bedside panels or end panels that are not installed on units, please ensure they are appropriately labeled as per the instructions above. If you need additional labels, please contact your local GE representative.
10. Confirm, by completing the attached reply form, that all hospital staff who come into contact with the device are trained on the proper closing and latching of the Incubators and OmniBeds and that appropriate actions in accordance with this Notification have been taken.

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 is including with this notice, an additional user manual addendum, labels, and wall posters.
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 at the contact information above.

Sincerely,

Laila Gurney
Senior Executive, Quality & Regulatory
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

[redacted]

[redacted]

GE Healthcare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

GEHC Ref# 32070-2

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# 32070-2.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address/Phone Number: _____ _____

Affected Device Serial Numbers (attach additional sheets if needed):

Please read the following section and check the box to confirm acknowledgement and completion:

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification and confirm that the information from this recall letter and addendum is properly disseminated to all users that handle the Incubators and OmniBeds.

Customer Actions:

- Ensure that all Giraffe OmniBed and Giraffe Incubators are fully labeled per the labeling instructions:
  - 3 labels for each bedside panel, and
  - 1 label for any end panel with porthole (if applicable);
- Ensure that any spare bedside panels or end panels that are not installed on units, are appropriately labeled;
- Place the provided Addendum in your Incubator/OmniBed User Manual;
- Post the provided 3 Posters in clinical areas; and
- Ensure all hospital staff who open panels or portholes or otherwise come into contact with the device are trained on the proper closing and latching of the Incubators and OmniBeds.

Please provide the name of the individual with responsibility who 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.Recall32070-2@ge.com
You may obtain this e-mail address through the QR code below: