URGENT FIELD SAFETY NOTICE UPDATE

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

<Date of Letter Deployment>

GEHC Ref# FMI32079

To: Nurse Manager / Director of NICU and Labor and Delivery / Director of Neonatology
Hospital Administrator
Director of Biomedical Engineering

RE: **All Giraffe Incubator and Giraffe Incubator Carestation, and Giraffe OmniBed and Giraffe Omnibed Carestation Devices**

IMPORTANT REMINDER - Actions to Avoid Risk of Patient Falls - Previously communicated Urgent Medical Device Correction (Ref: FMI32070-2/FMI32070-2A), and new information about updated latches

Information

GE Healthcare (GEHC) is sending this letter to ensure continued awareness of the previously communicated safety instructions related to FMI32070-2/FMI 32070-2A. As stated in the previous device safety letter:

- 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.

The recall (FMI32070-2) and customer communication were launched in November 2019. However, we recently received 3 complaints of infant falls/injuries related to the bedside panels not being latched. **It is critical to ensure the bedside panels and portholes are properly latched to avoid the risk of patient falls.**

Please review the Instructions for Customers/Users below and in the previously communicated letter attached.

Actions to be taken by Customers / Users

It is important to ensure that your staff continues to be aware of the serious risks if the bedside panels and portholes are not securely latched. All users must follow the important safety instructions provided with GE Healthcare Field Action Ref# FMI32070-2/FMI32070-2A.

You can continue to use your device by strictly following the labeling and instructions to properly secure the bedside panels and portholes.

For your reference, the previously provided Urgent Medical Device Safety letter is attached to this package.

Actions:

- Ensure previously provided "Giraffe Incubator/OmniBed Risk of Patient Fall" posters are placed in prominent clinical locations for your staff and ensure they remain displayed for the lifetime of the devices.
- Ensure that the safety information from the previously provided safety letter and User Addendum are properly disseminated to all users that handle the devices.
- Ensure all users who interact with these devices are fully aware of, understand, and always follow these instructions.

Additional Resources:

- Additional resources including a video demonstration of the safe operation of bedside panels and portholes, and Patient Safety infographics can be accessed at:

  http://supportcentral.ge.com/*giraffesafetyresourcesR2

If you have any questions or would like any additional support from GE Healthcare, please contact your local GE Healthcare Service Representative.

Confirm, by completing the attached acknowledgement form, that all users who interact 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.

Product Details

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

Intended Use:

The Incubator is an enclosed neonatal intensive care microenvironment developed through a philosophy of extensive user input to best define products that meet the needs of clinicians, patients, and families. Several unique features provide a developmentally appropriate environment for the infant, while decreasing stress for family and simplifying procedures for the clinician.

The OmniBed is a combination of an infant incubator and an infant warmer. The device can be operated as an incubator or as a warmer and can transition from one mode to the other on user's demand. It cannot be operated in both modes at the same time. Incubators and warmers provide heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. Incubators provide an enclosed, temperature-controlled environment and warmers provide infrared heat in an open environment.

Product Action

In addition to resources described above, GE Healthcare will be providing updated latch designs for bedside panels and portholes for the Giraffe Incubator/OmniBed products. These updated latches are designed to help further address certain situations in which the walls or portholes might look closed but not be latched. GE Healthcare will be issuing replacement latches for all Giraffe Incubator/OmniBed devices owned by your facility, in the coming months. GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction. Additionally, if any support is required with installation, this will be provided at no cost to you.

Contact Information

If you have any questions or concerns regarding this notification or need any additional labels, posters (which were previously provided) including training materials, please contact GE Healthcare Service or your local Service Representative.

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

GE Healthcare is committed to continuous product improvements and customer satisfaction. If you have any questions, please contact us per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT RESPONSE REQUIRED

GEHC Ref# 32079

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# 32079.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

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 safety letter is properly disseminated to all users that handle the Incubators and OmniBeds.

Customer Actions:

- Ensure previously provided "Giraffe Incubator/OmniBed Risk of Patient Fall" posters are placed in prominent clinical locations for our staff and ensured they remain displayed for the lifetime of the devices.
- Ensure that the safety information from the previously provided safety letter and User Addendum are properly disseminated to all users that handle the devices
- Ensure all users who interact with these devices are fully aware of, understand, and always follow these instructions.

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

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MMM/YYYY): _____

Please return completed form scanning or taking a photo of the completed form e-mailing to: MIC.FMI32079@ge.com

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