URGENT MEDICAL DEVICE CORRECTION UPDATE

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

<Date of Letter Deployment> GEHC Ref# 32083

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

RE: **All Giraffe Bedded Warmer & Panda iRes Warmer Devices**

IMPORTANT REMINDER - Actions to Avoid Risk of Patient Falls - Previously communicated Urgent Medical Device Correction (Ref: FMI32067/A & 32071)

Information

GE Healthcare (GEHC) is sending this letter to ensure continued awareness of the previously communicated safety instructions related to FMI32067/A & 32071.

The field action (FMI 32067/A & 32071) and customer communication were launched in March 2019 and July 2020, respectively. However, we recently received one complaint of a patient fall related to the bedside panels not being latched as instructed. It is critical to ensure the bedside panels are properly latched to avoid the risk of patient falls.

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 are not securely latched. All users must follow the important safety instructions provided with GE Healthcare FMI32067/A.

It is important to strictly follow labeling and instructions for use before and while using your device As a reminder, these instructions are provided below and additional safety posters are included in this package.

- Ensure the bedside panels are **securely latched** following each opening/closing of the bedside panels during patient care by **pulling gently on the walls** to ensure proper latching.
- Inspect the operation of all three bedside panels and **confirm that they lock securely** in the upright position. Lowering a bedside panel should be possible only by pulling up, and then pulling the top edge away from the bed.
- Ensure previously provided **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, User Addendum, and Posters are **properly disseminated to all users** that handle the devices.
- **Ensure users** who interact with these devices are fully aware of, understand, and **follow these instructions**.

Additional Resources:

- Additional resources including a video demonstration of the safe operation of bedside panels can be accessed at:

https://rebrand.ly/gewarmerbedsidepanels

Note:

To enable closed captions (subtitles) select the closed caption icon. If your preferred language is not displayed, select language under YouTube™ settings.

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 devices and that appropriate actions in accordance with this Notification have been taken.

Product Details	Giraffe Bedded Warmers (GTIN:00840682103923), Panda iRes Warmers (GTIN:00840682103893) (All serial numbers starting with GBW, PBW and HDJ)
Product Action	No product actions 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.

Please be assured that maintaining a high level of safety and quality is our highest priority. 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# 32083

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# 32083.

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.

Customer Actions:

- Ensure the three "Giraffe and Panda iRes Warmers" posters provided in this mailing are placed in prominent clinical locations for our staff and ensured they remain displayed for the lifetime of 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.FMI32083@ge.com

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