URGENT FIELD SAFETY NOTICE

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

<Date of Letter Deployment>

GEHC Ref# 32081

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

RE: **Mounting issue for Lullaby™ Resus Plus/Prime dovetail mounts onto Lullaby™ Warmer side rails**

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 (GEHC) has become aware that the dovetail mount accessory used to mount the Lullaby™ Resus Plus/Prime device onto the side rails of the Lullaby™ Warmer could potentially have a defect. This issue could cause the Resus device to fall when an external force is applied, potentially causing an injury to a caregiver or, in an extremely rare case, the patient.
There have been no injuries reported as a result of this issue.

Actions to be taken by Customer / User

You can continue to use the device by following the below instructions:

A. Locate the dovetail mount accessory on the Lullaby™ Warmer.
B. Check for proper installation of the dovetail mount accessory on the Lullaby™ Warmer rail.

Note - Please follow the below steps of proper installation checks in every use of the dovetail mount of the Lullaby™ Resus Plus/Prime devices with Lullaby™ Warmer.

A. Location of the dovetail mount accessory on the Lullaby™ Warmer:

The Lullaby™ Resus Plus/Prime dovetail mount is located on the side dovetail rails of the Lullaby™ Warmer. Refer to **Fig 1** for details.

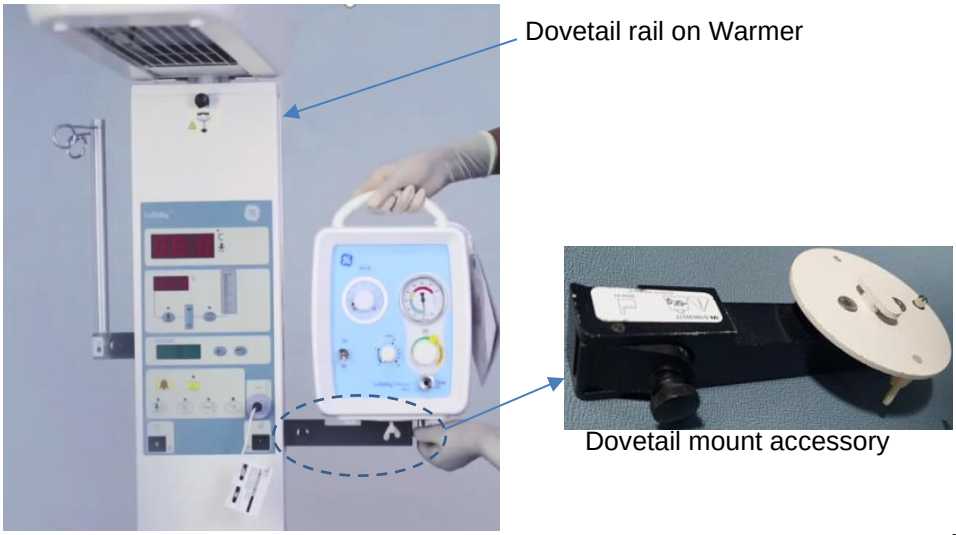

Fig 1. Location of the Lullaby™ Resus Plus/Prime dovetail mount on the Lullaby™ Warmer

B. Check for proper installation of the dovetail mount accessory on the Lullaby™ Warmer rail:

1. Lock wheels of the Lullaby™ Warmer.
2. Disconnect Air/Oxygen hoses of the Lullaby™ Resus Plus/Prime device (If they are connected).
3. Disconnect the Lullaby™ Resus Plus/Prime from the dovetail mount accessory. See Fig **2** for details.

Fig 2. Disconnect and remove Lullaby™ Resus Plus/Prime from the dovetail mount

4. Check for the proper installation of the dovetail mount with the dovetail rail. See **Fig 4** for the correct installation condition.

Gap between the dovetail mount and the rail

Fig 3 Incorrect installation due to defective dovetail mount accessory (gap or opening presence)

No Gap between the dovetail mount and the rail

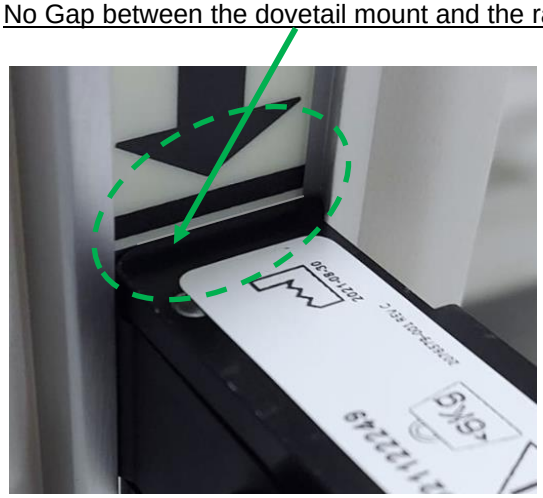

Fig 4 Correct installation (full contact with no gap) of the dovetail mount with the dovetail rail

5. If you find the incorrect installation as shown in the **Fig 3**, disconnect the dovetail mount, remove the mount from use, and destroy it.

6. If the **Fig 4** conditions are observed, ensure that dovetail mount is firmly fixed by tightening the mounting screws. In the event the dovetail mount needs to be installed on a different Lullaby™ Warmer device, ensure to recheck for proper installation of the dovetail mount.

Affected Product Details

Lullaby™ Resus Plus/Prime Dovetail mount accessory Part number 2070349-001 (part number is not labelled on the part, refer to Fig 1 for identification) that is used to mount Lullaby™ Resus Plus/Prime devices on to Lullaby™ Warmers.

Intended Use:
Dovetail accessory is mountable on the Lullaby™ Warmer using a dovetail-rail system and combines vital capabilities in a single, compact unit that is designed for high risk deliveries, intrahospital transport and bedside caregiving.

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 new dovetail mount accessory.

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,

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# 32081

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# 32081.

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 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 by scanning or taking a photo of the completed form e-mailing to: MIC.FMI32081@ge.com

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