URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref# 32049

To: Nurse Managers, Labor & Delivery/NICU
Bio-Medical Engineering Department Managers
Risk Management Directors

RE: Lullaby Warmer "Heater Head" Screw could fall onto the bed

GE Healthcare has recently become aware of a potential safety issue related to loose screws in the "Heater Head" of certain Lullaby warmer devices. **Please ensure that all potential users, as well as those servicing these units, in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

Screws from the "Heater Head" of the Lullaby Warmer may come loose over time and could fall onto the bed. This situation can be clinically hazardous because potential thermal injury to a patient could result.

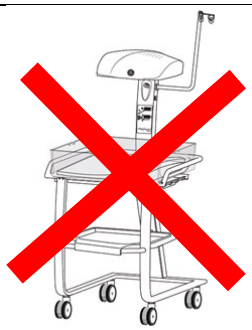
Safety Instructions

Check to ensure that the screws are tightened as soon as the unit becomes available and there is no patient in the bed.
The attached Service Manual Addendum provides instructions for checking and tightening the screws. During each annual Preventive Maintenance check, continue to ensure that the screws are tight.

Affected Product Details

Refer to Product Images below for images of Affected and Not affected products.

Affected model numbers: Lullaby warmer 230 V, Lullaby warmer 115 V
Lullaby warmer part numbers: 2041599-001, 230 V and 2060092-001, 230 V
2050878-001, 115 V and 2061755-001, 115 V

Affected Products	Not Affected Products
	

Product Correction	Attached to this letter, we provide instructions as part of a Service Manual Addendum on how to correct the issue. Please add this new Addendum to the Service Manual of your device(s) and train the affected users accordingly. Please acknowledge that you have received this letter and that you understand that an action needs to be taken on your part to correct this issue by filling out and returning the attached "Customer Response" form.
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,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare

MEDICAL DEVICE CORRECTION CONFIRMATION GE REF: 32049
CUSTOMER RESPONSE REQUIRED
We request that you PLEASE COMPLETE and return this form to GE Healthcare within two (2) weeks.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

It is important that we confirm our customers have received this correction notice. Please check one of the following and complete the requested information and send back via one of the methods below.

☐ We acknowledge receipt and understanding of the Medical Device Correction Notice and have alerted the appropriate personnel at our facility regarding the safety issue and instructions. We **have performed** the actions as requested in the attached Medical Device Correction Notice on all potentially affected systems.
List all Device/System Serial Number(s) known (attachment can be used): _____

_____

_____

☐ We acknowledge receipt and understanding of the Medical Device Correction Notice and no longer have a system affected by this Medical Device Correction Notice. (Please check appropriate disposition. If multiple systems or further information, attachment can be used.)

☐ Sold ☐ Returned ☐ Scrapped ☐ Other: _____

Device/System Serial Number(s): _____

New Owner, if known: _____

Contact Name: _____

Street Address: _____

City/State/Country: _____

Contact (i.e. Email, Phone): _____

Please provide the name of the individual with responsibility for risk and compliance.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return this form using one of the following methods:

1. **Scan or take photo of completed form and email to MIC.Recall@ge.com**
   Note: QR code can be used to email the form: click QR code, attach photo to email, click Send

QR (email)

2. **Fax completed form to Fax Number: +1-410-630-5938**

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