URGENT FIELD SAFETY NOTICE

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

<Date of Letter Deployment>

GEHC Ref# 32047-2

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

RE: Infant Warmer System (IWS) Hot "Heater Head" Screw could Fall onto theb ed

This is a correction to a previous notification that you could have received and adds two additional model numbers to the Affected Product Details section; see bold underlined model numbers below.

GE Healthcare has recently become aware of a potential safety issue related to loose screws in the "Heater Head" of certain Infant Warmer System (IWS) 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

Hot screws from the "Heater Head" of the IWS could fall onto the bed if the "Heater Head" assembly has been improperly serviced. This situation can be clinically hazardous because thermal injury to a patient could result. Two injuries have been reported as a result of this issue.

Safety Instructions

The potential for this issue to occur is only present if the "Heater Head" assembly has been improperly serviced.

As a result, if "Heater Head" service has been performed in the past, check to ensure that the screws are tightened as soon as the unit becomes available.

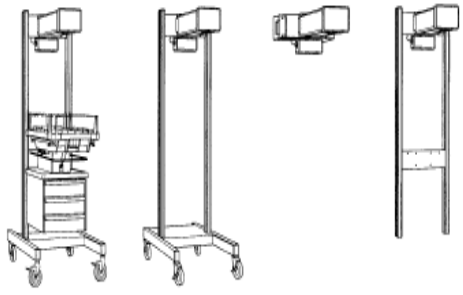
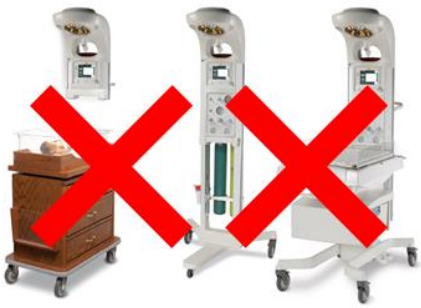
If the "Heater Head" assembly has not been serviced, check to ensure that the screws are tightened as part of your next regularly scheduled annual Preventive Maintenance check.

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: All IWS Models (Model 2001 IWS (International), 3000 IWS, 3050 IWS, **3051 IWS**, 3100 IWS, 3150 IWS, 3300 IWS, **3400 IWS**, 3500 IWS, 4000 IWS, 4300 IWS, 4400 IWS, 5000 IWS.)

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, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare

MEDICAL DEVICE CORRECTION CONFIRMATION GE REF: 32047-2
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 will perform 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
2. **Take photo of completed form and send via SMS text to +1-410-972-8096**
   Note: QR code can be used to text the form: click QR code, attach photo to text, click Send
3. **Fax completed form to Fax Number: +1-410-630-5938**

QR (text) QR (email)

32047-2 – XXXX