URGENT MEDICAL DEVICE CORRECTION

Date of Letter Deployment

GE HealthCare Ref. # 32089

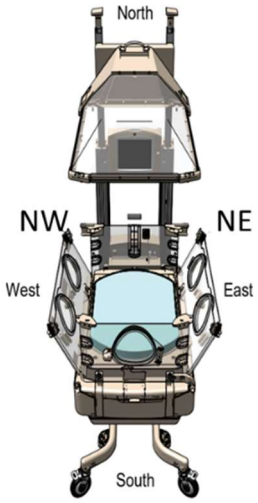
To: Director of Biomedical Engineering/Environmental Services
Director of Neonatology/Labor and Delivery/ Nurse Manager
Hospital Administrator

RE: Giraffe OmniBed and Giraffe OmniBed Carestation potential incorrect secondary latch installed on certain bedside panels.

Safety Issue

GE HealthCare has become aware of the potential that an incorrect type of secondary latch could have been installed on the northeast (NE) and/or northwest (NW) bedside panels for certain Giraffe OmniBed and Giraffe OmniBed Carestation devices (see figure 1).

Figure 1. Bedside Panels showing Northeast (NE) and Northwest (NW) latches



The Giraffe OmniBed and Giraffe OmniBed Carestation devices have primary and secondary latch mechanisms.

The primary latches are present and operate correctly.

The secondary latch mechanism serves two functions: (1) acts as a “catch” and reduces the potential for the bedside panel to fall if the user does not latch the primary latch mechanism correctly and (2) keeps the north wall in place when the canopy is raised.

For devices that have the incorrect type of secondary latch installed, the north wall can potentially become disengaged when the canopy is raised. However, the device

is designed such that the panels will stay closed and function as intended, even if only the primary latches on the south end are properly engaged.

There has been no customer complaints of this issue and no patient injuries.

Actions to be taken by Customer /User

Inspect the device bedside panels as instructed in **Appendix A.** If the device has the correct latches, continue to use the device. If the device does not have the correct latches, follow the instructions in Appendix A prior to clinical use.

Please complete and return the attached acknowledgement form to MIC.FMI32089@ge.com.

Affected Product Details

All Giraffe OmniBeds*
Giraffe OmniBed Carestation (2082844-001-XXX) [GTIN – 0100840682116862 21]
Bedside panel FRU Kits: 5865384-01 to 5865384-34, 5865385-01 to 5865385-34, 5865386-01 to 5865386-34 and 5865387-01 to 5865387-34

*NOTE: Some products were shipped prior to the implementation of UDI and may not contain a Global Trade Item Number (GTIN)

INTENDED USE:

The Giraffe OmniBed Carestation 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. They may also be used for short periods of time to facilitate the neonate's transition from the uterus to the external environment. This device may incorporate a Servo Controlled Oxygen Delivery System. This is indicated to provide stable oxygen concentration within the infant compartment at the value set by the operator (21-65%).

Product Correction

GE HealthCare will replace all affected latches at no cost to you.
A GE HealthCare representative will contact you to arrange for replacing any incorrect latches.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service 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,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

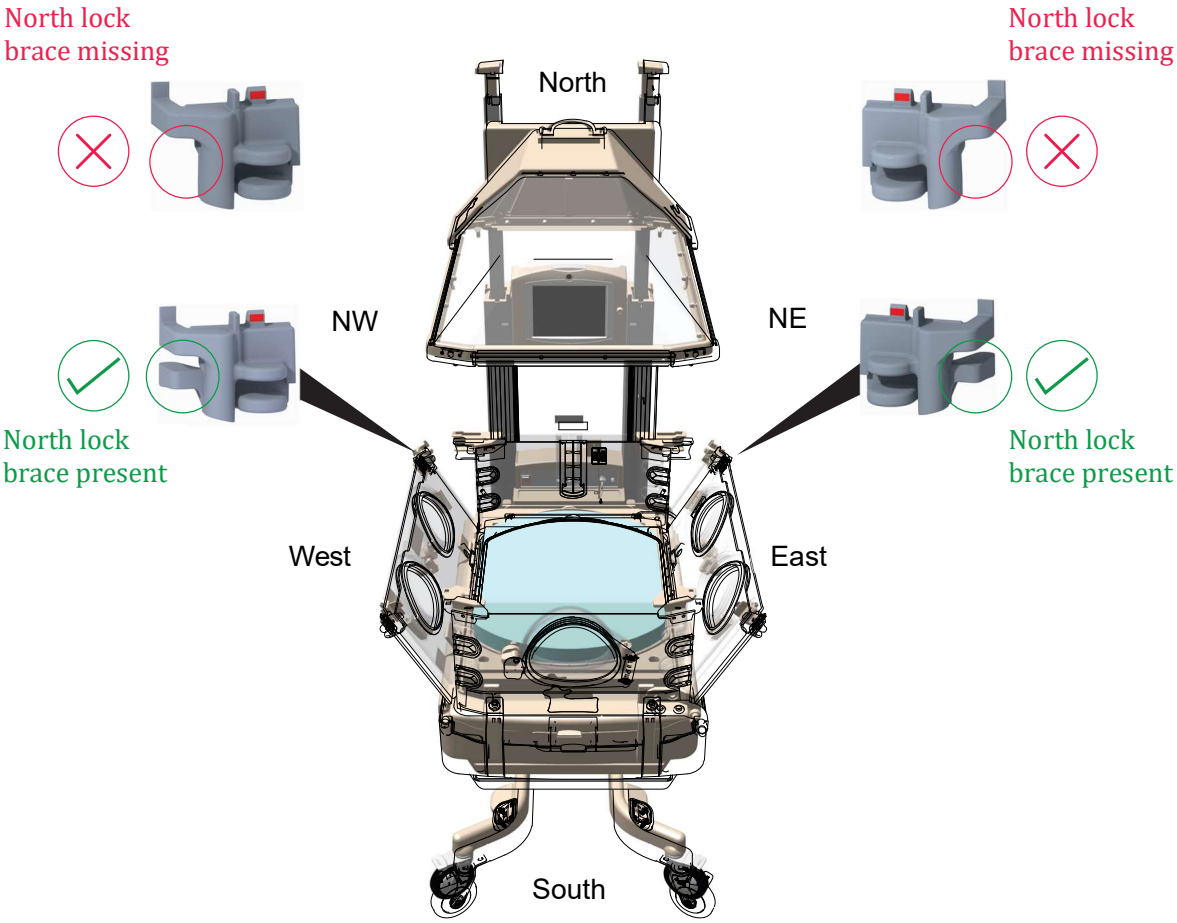
Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

Appendix A

Northwest (NW) and Northeast (NE) bedside panel latch Inspection

1. Visually inspect the NW and NE bedside panel latch assemblies on all Giraffe OmniBeds and Giraffe OmniBed Carestations to ensure the correct latches are present (See Figure 2).

Figure 2. North end bedside panel latch locations



2. If an incorrect latch is found quarantine the device.
3. Inspect any field replaceable bedside panel stock at your facility per Figure 2 for the parts #'s listed below to ensure the correct latches are present and quarantine any field replaceable bedside panels with incorrect latches.
    - 5865384-01 to 5865384-34,
    - 5865385-01 to 5865385-34,
    - 5865386-01 to 5865386-34 and
    - 5865387-01 to 5865387-34
4. Record the results of the inspections on the provided Medical Device Notification Acknowledgement Response Form and send this form to GE HealthCare at MIC.FMI32089@ge.com
5. GE HealthCare will contact you to arrange for shipment of replacement latches. These will be provided free of charge to you.

6. Once correct latches are received, replace the incorrect latches with the correct latches and dispose of the incorrect latches.

   If you need help with the above, please contact GE HealthCare Service at 1-800-437-1171.

GE HealthCare Ref. # 32089

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

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. GE HealthCare needs this completed form to process shipment of replacement latches to you. These replacement latches will be provided free of charge.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

We acknowledge receipt and understanding of the Medical Device Correction Notice and have executed the instructions as provided in this notification. We have inspected all of our **Giraffe OmniBed and Giraffe OmniBed Carestations and Field Replacement Stock and provided the results below:**

Giraffe OmniBed and Giraffe OmniBed Carestation Serial Number or Field Replacement Stock Part Number	Latches are correct Yes or No

Please list every serial number and part number individually in the table above. If you need additional space to include serial numbers or part numbers, please copy this page and provide as many pages as necessary to include all devices.

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

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: (MIC.FMI32089@ge.com**)**