



URGENT FIELD SAFETY NOTICE

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 32076

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

RE: **Certain Giraffe Incubators and Giraffe OmniBeds – Oxygen sensor compatibility with Giraffe Systems**

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 has become aware that certain Giraffe Incubators and Giraffe OmniBeds manufactured before 2012 can deliver a different environmental oxygen level than what is displayed by the device, if a certain optional component referred to as the Servo Oxygen Module is installed in your device. The Servo Oxygen Module automatically regulates oxygen that is provided internally by the device. Standard pulse oximetry monitoring will detect patient oxygen level changes and therefore this issue should only result in temporary hypoxia or hyperoxia. There have been no injuries reported as a result of this issue.

Safety Instructions

If the Giraffe Incubator or Giraffe OmniBed device is manufactured before 2012 **AND** has the **oxygen sensor part number M-43GE** installed, the **Servo Oxygen feature will need to be disabled or the device will have to be taken out of service**. Follow the instructions below for more information regarding product configurations impacted along with the detailed safety instructions.

1. Locate the serial number on the back of your Giraffe Incubator or Giraffe OmniBed (see Figure 1). Check the 4th letter of the serial number.



Figure 1: Serial number label, 4th letter location

- a. If the 4th letter is in the range of **R** through **Z**, the device can be used, no further action.
- b. If the 4th letter is in the range of **A** through **Q**, proceed to step 2.

2. Visually check to see if the Servo Oxygen module is installed in your Giraffe Incubator or Giraffe OmniBed (see Figure 2). Look under the power cord inlet to see if the metal box and fittings, indicative of the presence of the Servo Oxygen module, are present.



Figure 2: Servo Oxygen module is installed



Figure 3: Servo Oxygen module is NOT installed

- a. If the Servo Oxygen module is NOT installed, (per Figure 3) **the device can be used, no further action.**
 - b. If the Servo Oxygen module is installed (per Figure 2), proceed to step 3.
3. Determine whether Servo Oxygen software revision needs to be checked:
 - a. If the 4th letter of the bed serial number (see Figure 1) is in the range from **A** through **M**, proceed to step 4.
 - b. If the 4th letter of the bed serial number (see Figure 1) is in the range of **N** through **Q**, turn the device power off and then back on and watch the screen to determine the Servo Oxygen software revision (see Figure 4). Note this screen will appear for 3 to 5 seconds.

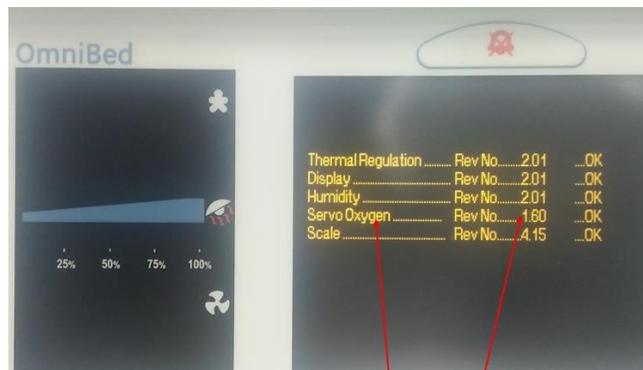


Figure 4: Servo Oxygen software revision location

- i. If the software revision identified is 1.60, **the device can be used, no further action.**
 - ii. If the software revision is 1.51 or lower, proceed to step 4.
4. Remove the oxygen sensor by following the instructions in the service manual to check the oxygen sensor part number. Refer to the Giraffe OmniBed service manual (P/N 6600-0343-000) Section 5.14.1 or Giraffe Incubator service manual (P/N 6600-0356-000) section 5.8.1 for instructions on how to remove the oxygen sensor. Note: Manuals can be downloaded from <http://customer-doc.cloud.gehealthcare.com/> (type manual P/N into search box)

Note: Oxygen sensors are sensitive to electrostatic discharge (ESD). Follow your hospital ESD control procedures to prevent damage to the oxygen sensors.

- a. If the oxygen sensor part number is 6600-1278-600, (see Figure 5), reinstall the oxygen sensors. **The device can be used, no further action.**

Note: Ensure that during future Planned Maintenance, these 6600-1278-600 oxygen sensors **DO NOT** get replaced with M-43GE oxygen sensors until a GE Healthcare Representative corrects your device.

- b. If the oxygen sensor part number is M-43GE (see Figure 6), do not reinstall the oxygen sensors. Proceed to step 5.



Figure 5: Oxygen sensor part number: 6600-1278-600 Figure 6: Oxygen sensor part number: M-43GE

- 5. Disable the Servo Oxygen feature by removing the oxygen sensors from the device, prior to returning the device to service. Removed sensors should be paired together in a non-airtight package, labeled with device serial number and stored in a dust-free environment until a GE Healthcare representative visits the site for the correction.

Affected Product Details

Certain Giraffe Incubators and Giraffe OmniBeds **manufactured before 2012** with **Servo Oxygen module installed**:

Serial numbers starting with the letters:

Giraffe Incubator: HDHA through HDHQ

Giraffe OmniBed: HDGA through HDGQ

Servo Oxygen board spare part kits: 6600-0233-850

Servo Oxygen Upgrade Kits: 6600-0678-800,6600-0678-801,6600-0678-802,6600-0678-803,6600-0849-800,6600-0849-801,6600-0849-802,6600-0849-803,6600-0866-800,6600-0866-801,6600-0867-800,6600-0867-801, M1142293 or M1142295.

Product Correction

GE Healthcare will correct all affected products when the correction is available at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

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
Executive, Quality & Regulatory
GE Healthcare

Jeff Hersh, PhD MD Senior
Chief Medical Officer
GE Healthcare



**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 and required actions to be taken Ref# 32076.

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.Recall32076@ge.com

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

