

## **URGENT MEDICAL DEVICE CORRECTION**

## **GE Healthcare**

9900 Innovation Drive Wauwatosa, WI 53226 USA

<Date of Letter Deployment>

GEHC Ref# 32041

- To: Nurse Managers, Labor & Delivery/NICU Bio-Medical Engineering Department Managers Risk Management Directors
- RE: Giraffe Shuttle Shortened Battery Life

GE Healthcare has become aware of a potential safety issue with the shortened battery life of the Giraffe Shuttle products. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue	Shortened battery life can lead to a loss of power to devices plugged into the Shuttle. Power loss during transport most reasonably expected to occur from this battery issue may lead to a minor delay in the transport time, which may result in a minor decrease in body temperature (mild hypothermia). There have been no injuries reported as a result of this issue.
Safety Instructions	You can continue to use the device. Follow these instructions to ensure that batteries do not get over-charged:
	<ul> <li>a. Charging time should not exceed the time needed to turn the top LED segment green. This will happen after approximately 8 to 12 hours. Do not exceed 12 hours.</li> </ul>
	b. To stop charging, turn off Shuttle Mains power switch.
Affected Product Details	All Giraffe Shuttles shipped prior to July 1, 2015. Giraffe Shuttles with serial number MAAU61001 or higher are not affected by this issue and do not require correction.
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 correction.
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.

Sincerelv.



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



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