URGENT FIELD SAFETY NOTICE

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

<Date of Letter Deployment>

GEHC Ref# 32075

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

RE: **Certain Giraffe Shuttle Devices – Battery emitting odor during charging (sulfur odor)**

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.

Safety Issue

GE Healthcare has become aware that when the Giraffe Shuttle is being charged the batteries could potentially emit low concentrations of gases (outgassing) producing a strong sulfur odor. The outgassing stops when the shuttle is unplugged from the wall socket. Inhalation of these gases in rare cases could cause bronchoconstriction potentially requiring medication in susceptible individuals such as asthmatic users. This issue could also cause minor headaches, irritation of the eyes and throat. There have been no serious injuries reported as a result of this issue.

Safety Instructions

To minimize the opportunities for outgassing during charging of the Giraffe Shuttle until the correction is available, it is recommended in order to continue use of the Giraffe Shuttle to follow the below instructions. If at any time you smell a gas odor during charging, disconnect the Giraffe Shuttle from the wall power outlet. **Discontinue use** of the Giraffe Shuttle and contact a GE Healthcare Representative.

1) **DO NOT** charge the Giraffe Shuttle while connected to Giraffe or Panda beds. In the rare case where charging is required when connected, **DO NOT** charge more than 5 minutes and ensure a caregiver is nearby the Giraffe Shuttle with patients in the Giraffe or Panda bed.

2) The Giraffe Shuttle should always be plugged in to a wall outlet when not in use:
   - with power ON/OFF switch in ON position; and
   - in a well-ventilated area away from patients.

3) When not in transport the locking/unlocking pedals should be in the position shown in Figure 1. The STOP (red) and GO (green) indicators should not be illuminated.

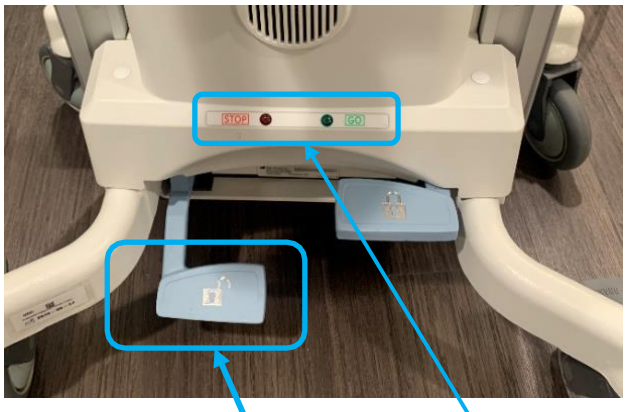

Figure 1: Undocked - Unlock Pedal Pressed and STOP/GO LED Lights OFF

4) **DO NOT** use the Giraffe Shuttle for transport if the battery charge display shows only one yellow light or a single flashing RED light as shown in Figure 2. Ensure the Giraffe Shuttle is adequately charged for the transport before use.

Figure 2: Battery charge display

Affected Product Details	Certain Giraffe Shuttle Devices serial listed below and Giraffe Shuttle devices which have received Upgrade kits with part number 2109672-001 and 2109673-001 GTIN: 00840682110808 with serial numbers: GSHW60086; GSHX60001; GSHX60014; GSHY70002; GSHY70003; GSHY70004; GSHY70005; GSHY70006; GSHY70007; GSHY70008; GSHY70009; GSHY70012; GSHY70013; GSHY70014; GSHY70015; GSHY70016; GSHY70017; GSHY70018; GSHY70019; GSHY70020; GSHY70021; GSHY70022; GSHY70023; GSHY70024; GSHY70025; GSHY70026; GSHY70027; GSHY70028; GSHY70029; GSHY70030; GSHY70031; GSHY70032; GSHY70033; GSHY70034; GSHY70035; GSHY70036; GSHY70037Q; GSHY70038; GSHY70039; GSHY70040; GSHY70041; GSHY70042; GSHY70043; GSHY70044; GSHY70045; GSHY70046; GSHY70047; GSHY70048; GSHY70049; GSHY70050; GSHY70051; GSHY70052; GSHY70053; GSHY70054; GSHY70055; GSHY70056; GSHY70057; GSHY70058; GSHY70059; GSHY70060; GSHY70061; GSHY70062; GSHY70063; GSHY70064; GSHY70065; GSHY70066; GSHY70067; GSHY70068; GSHY70069; GSHY70070; GSHY70071; GSHY70072; GSHY70073; GSHY70074; GSHY70075; GSHY70076; GSHY70077; GSHY70079; GSHY70080; GSHY70081; GSHY70084; GSHY70085; GSHY70086; GSHY70087; GSHY70088; GSHY70089; GSHY70090; GSHY70091; GSHY70092; GSHY70093; GSHY70094; GSHY70095; GSHY70096; GSHY70097; GSHY70098; GSHY70099; GSHY70100; GSHY70101; GSHY70102; GSHY70103; GSHY70104; GSHY70105; GSHY70106; GSHY70107; GSHY70108; GSHY70109; GSHY70110; GSHY70111; GSHY70113; GSHY70114; GSHY70115; GSHY70116; GSHY70117; GSHY70118; GSHY70119; GSHY70120; GSHY70121; GSHY70122; GSHY70123; GSHY70124; GSHY70125; GSHY70126; GSHY70127; GSHY70130; GSHY70131; GSHY70132; GSHY70133; GSHY70134; GSHY70135; GSHY70136; GSHY70137; GSHY70138; GSHY70139; GSHY70140; GSHY70141; GSHY70142; GSHY70143; GSHY70144; GSHY70145; GSHY70146; GSHY70147; GSHY70148; GSHY70149; GSHY70150; GSHY70151; GSHY70152; GSHY70153; GSHY70154; GSHY70155; GSHY70156; GSHY70157; GSHY70158; GSHY70159; GSHY70160; GSHY70161; GSHY70162; GSHY70163; GSHY70165; GSHY70166; GSHY70167; GSHY70168; GSHY70169; GSHY70170; GSHY70172; GSHY70173; GSHY70174; GSHY70175; GSHY70176; GSHY70177; GSHY70178; GSHY70179; GSHY70180; GSHY70181; GSHY70182; GSHY70183; GSHY70184; GSHY70185; GSHY70186; GSHY70187; GSHY70188; GSHY70189; GSHY70192; GSHY70193; GSHY70194; GSHY70195; GSHZ70101; GSHZ70102; GSHZ70103; GSHZ70104; GSHZ70105; GSHZ70106; GSHZ70107; GSHZ70108; MAAP50034; MAAQ50170; MAAR50021; MAAT50013; MAAT60045; MAAU61029; MAAU61040; MAAV60059;
Product Correction	GE Healthcare will correct all affected products at a later date 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,

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GE Healthcare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

GEHC Ref# 32075

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# 32075.

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.Recall32075@ge.com
You may obtain this e-mail address through the QR code below: