URGENT
FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 78099

To: Head of Ultrasound Department
Head of Emergency / Critical Care Department
Head of Musculoskeletal Department
Head of Anesthesia Department
Hospital Administrator / Risk Managers
Biomedical Engineering

RE: **Venue Go Standard Cart**

Safety Issue

GE HealthCare has become aware that some Venue Go Standard Carts can develop an internal failure of the vertical/horizontal tilt adjustment mechanism which can result in the Venue Go system detaching from the cart and falling.

Actions to be taken by Customer/ User

You can continue to use your Venue Go system by following the instructions below.

Check the vertical/horizontal tilt adjustment mechanism on the Venue Go Standard Cart (see Figure 1, marked by red oval) on a weekly basis to ensure it is secure:

1. Lock the wheels.
2. Raise the up/down adjustment column to its highest position.
3. Observe the tilt mechanism during side-to-side rocking as shown in Figure 2.

Note: Slight movement of the up/down adjustment column is normal and not related to the vertical/horizontal tilt adjustment mechanism (see Figure 3, marked by the green box).

Figure 1

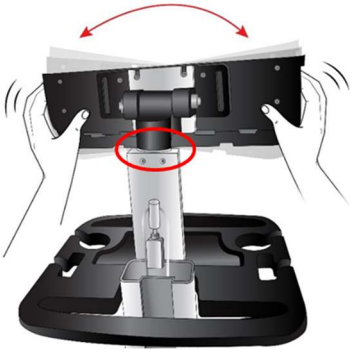

Figure 2

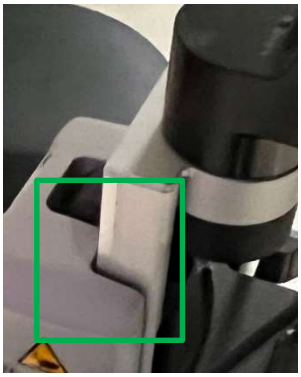

Figure 3

If the vertical/horizontal tilt adjustment mechanism is loose:

- Remove the Venue Go system from the Cart cradle and place on a tabletop using the adjustable rear support stand.
- Do not use the Venue Go Standard Cart until the corrective action is performed by GE HealthCare.

Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to POCUS.Recall@ge.com.

Affected Product Details

Venue Go Standard Carts (see Figure 4) (H45181VC and H45103VCW) used with Venue Go R2, R3, R4 systems (GTIN 0084068213884, 00840682190503, and 00195278516510) that were manufactured 2022-08 and before are impacted. See Figure 6 for how to identify the manufacture date on the Venue Go Standard Cart.

Note: Venue Go Simple Carts are not affected (Figure 5).

Venue Go Standard Cart

Figure 4

Venue Go Simple Cart

Figure 5

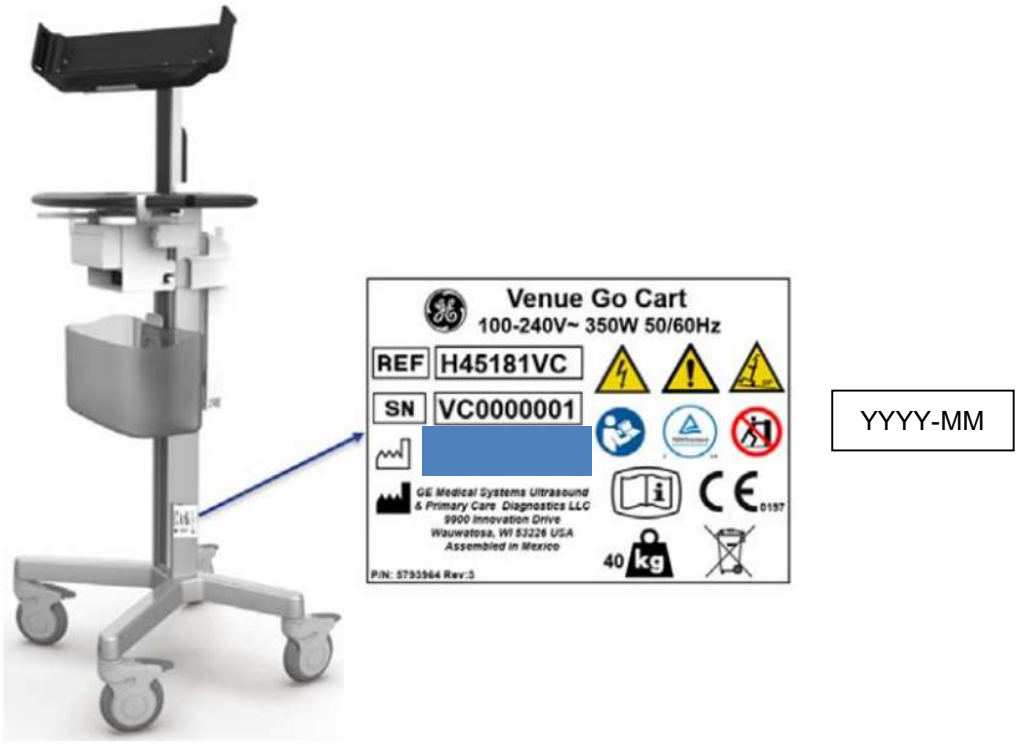

Figure 6

Intended use:
The Venue Go is a general purpose diagnostic ultrasound system for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid. Venue Go is intended to be used in a hospital or medical clinic.

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 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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

GE HealthCare

GE HealthCare Ref. # 78099

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.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

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