

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 78101

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 / Venue Fit Ultrasound systems**

Safety Issue

GE HealthCare has become aware that the battery for certain Venue Go and Venue Fit ultrasound systems with software versions R2, R3, and R4 (see Affected Products List in this letter) can potentially develop an internal failure which could result in smoke or fire.

There have been no injuries reported to GE HealthCare as a result of this potential issue.

Actions to be taken by Customer/ User

You can continue to use your Venue Go and Venue Fit system after following the actions below:

- 1) Turn the system 'Off' and unplug the system from the wall socket.
- 2) Remove the system batteries by following instructions provided in the User Manual Chapter 3. These instructions are also provided in this letter in Appendix A for Venue Go and in Appendix B for Venue Fit.
- 3) Check the date of manufacture of the system batteries by looking at the label on the bottom of each battery (See Figure 1). The date of manufacture is displayed as YYYY-MM for year and month of manufacture.

NOTE: Venue Go has two batteries and Venue Fit has one battery



Figure 1. Battery label showing date of manufacture (YYYY- MM) (Red Circle)

- 4) Calculate the age of each of the system batteries.
- 5) If any of the batteries are more than 2 years old:
 - a. With the system unplugged, re-insert batteries, turn the system 'On' and leave the system 'On' to discharge the batteries.
 - b. Once the battery capacity indicator shows two segments or less (See Figure 2), turn the system 'Off' and remove the batteries per step 2.



Figure 2: Battery capacity indicator on the system monitor showing 2 segments (Red Circle)

- c. Dispose of batteries according to local regulations.

NOTE: After battery removal, you can continue to use the system with use of AC power cord. The system is fully functional without the battery.

- 6) If the batteries are less than 2 years old, you may continue to use the battery until the battery reaches 2 years old, at which point, repeat instructions in step 5.

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 **recall.78101@gehealthcare.com**.

**Affected
Product
Details**

Venue Go R2 system (GTIN 00840682138840)
Venue Go R3 system (GTIN 00840682190503 / GTIN 00195278358011)
Venue Go R4 system (GTIN 00195278516510 / GTIN 00195278516527)
Venue Fit R3 system (GTIN 00195278194275 / GTIN 00195278361400)
Venue Fit R4 system (GTIN 00195278516497 / GTIN 00195278516503)

China ONLY market systems:

Venue Go R3 Surgery for China (GTIN 00195278547866)
Venue Go R3 PeriOP for China (GTIN 00195278548344)
Venue Go R3 Expert for China (GTIN 00195278547262)
Venue Go R3 Pro for China (GTIN 00195278547828)
Venue Go R3 Performance for China (GTIN 00195278547842)
Venue Go R3 Intervention for China (GTIN 00195278548061)
Venue Fit R3 Surgery for China (GTIN 00195278552488)
Venue Fit R3 PeriOP for China (GTIN 00195278552501)
Venue Fit R3 Expert for China (GTIN 00195278552402)
Venue Fit R3 Pro for China (GTIN 00195278552419)
Venue Fit R3 Performance for China (GTIN 00195278552440)
Venue Fit R3 Intervention for China (GTIN 00195278552495)

Intended Use:

The Venue Go/Venue Fit 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/Venue Fit 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.

After the correction has been implemented, please be sure to destroy the installation media for affected software at your site.

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

**FIELD SAFETY NOTICE 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 Field Safety Notice.

There are two options for your convenience:

- 1) Electronic response form (this page)

OR

- 2) Manual filled and scanned response form (next page)

Please scan the QR code or follow the link below to complete the workflow

[https:// app.sc.ge.com/esurveys/takesurvey/18446744073711873812](https://app.sc.ge.com/esurveys/takesurvey/18446744073711873812)



Alternatively, if the workflow on the previous page is not possible, 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 Field Safety Notice.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Field Safety Notification, and that we have informed all potential users 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: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: recall.78101@gehealthcare.com
You may obtain this e-mail address through the QR code below:



Appendix A – Battery removal for Venue Go systems (excerpt from User Manual Chapter 3)

Battery Replacement

The following instructions describe how to replace the rechargeable battery on your Venue Go system.

Preparing system for battery removal

1. Shut the system down and disconnect the AC/DC power cord.
2. Place the system facing down on a flat horizontal surface covered by a blanket or any thick soft cloth.
3. Lift the flap and turn the battery switch OFF (Figure 3-5, item 1).
4. Remove the probe from the lower probe connector (Figure 3-5, item 2).
5. Lift the rear support backwards as shown in Figure 3-5, item 5.
6. Slide the battery cover latch to the left (Figure 3-5, item 3), and lift up the battery cover.



1. Battery switch, covered by flap
2. Lower probe connector
3. Battery cover latch
4. Battery cover
5. Rear support folded up

Figure 3-5. Preparing Venue Go for battery replacement

NOTE: *Graphics are for reference purposes only.*

7. Grasp the flexible flap on the left side (attached to the battery) and pull the battery up (Figure 3-6).



Figure 3-6. Replacing a battery

8. Remove the second battery in the same way (Figure 3-7).



Figure 3-7. Removing the second battery

9. Place the new batteries with labels facing down (Figure 3-6).
10. Close the battery cover.
11. Turn the battery switch back ON (Figure 3-5, item 1).

Appendix B – Battery removal for Venue Fit systems (excerpt from User Manual Chapter 3)

Preparing system for battery removal

1. Shut the system down and disconnect the AC/DC power cord.
2. Place the system facing down on a flat horizontal surface covered by a blanket or any thick soft cloth.
3. Lift the flap and turn the battery switch OFF (Figure 2-2, item 10).
4. Locate the battery cover (Figure 2-2, item 16, Figure 3-5, item 1).
5. Slide the cover latch (Figure 3-5, item 2).
6. Slide out the battery cover (Figure 3-5, item 1) and remove it.
7. Pull out the battery and replace with a new one.
8. Slide the battery cover and snap into place.
9. Turn battery switch back ON.

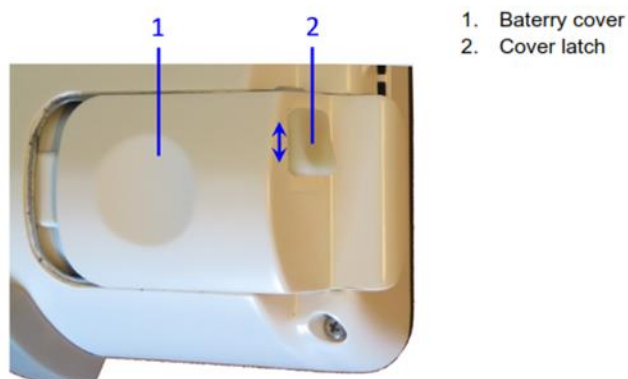
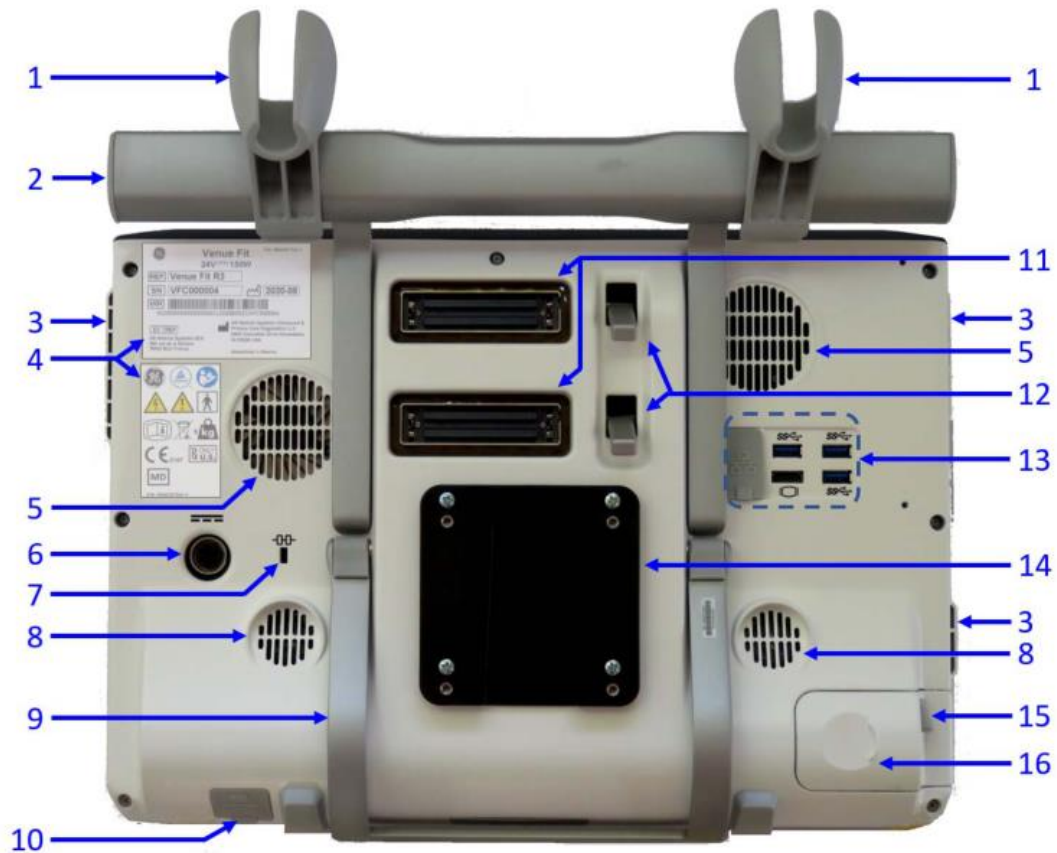


Figure 3-5. Battery cover removal



Venue Fit battery

Patient Environmental Devices



- | | |
|--|--|
| <ol style="list-style-type: none"> 1. Probe holder accessory 2. System carrying handle 3. Air ventilation outlet 4. System labels 5. Air ventilation inlet 6. Power supply plug connector 7. Anti-theft cable connector 8. Speaker grid 9. Adjustable rear support stand (kickstand)
- optional | <ol style="list-style-type: none"> 10. Battery switch with rubber cover 11. Two probe connectors 12. Probe connector latches 13. Rear panel including: <ul style="list-style-type: none"> • One HDMI port • One network port • Three USB ports 14. Mounting bracket – Standard VESA 75x75 15. Battery cover latch 16. Battery compartment cover |
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Figure 2-2. Patient Environmental Devices

NOTE: Graphics are for reference purposes only.