

MEDICAL DEVICE SAFETY CORRECTION

To users of ACUSON Sequoia ultrasound systems with the following software version:

Sequoia 1.2 (VA25A/VA25B)

Dear Valued Customer:

This letter is to notify you of an error identified in the manual trace measurement tool on the ACUSON Sequoia ultrasound system.

What is the issue?

In Sequoia 1.2, there is a calculation error in the measurement when using the 2D trace (manual trace) tool. The trace circumference value is overestimated; however, the area value is accurate.

What is the potential risk to patient health?

The primary risk associated with utilizing the 2D trace circumference and 2D open trace distance tools is overestimated measurements may potentially result in misdiagnosis of a patient's condition.

Scenario 1: Utilizing 2D trace circumference measurements for obstetric imaging (abdominal circumference and head circumference) can result in an overestimation of gestational age and estimated fetal weight (EFW) leading to the potential of reporting inaccurate fetal age and growth, which may affect patient care management.

Scenario 2: Utilizing the 2D open trace distance tool to measure cervical length can result in an overestimation of cervical length, therefore potentially reporting an erroneous result of cervical competence, which may affect the predictive value of preterm delivery stratification and associated risk.

Should an adverse reaction or quality problem be experienced with the use of this product, please report the incident to your local regulatory authorities.

What can I do to avoid the overestimation until the problem is resolved?

To avoid overestimation of circumference measurements, use the default ellipse tool for all circumference measurements. The ellipse measurement is accurate.

To avoid overestimation of distance measurements, use the default distance tool for all distance measurements. The distance measurement is accurate.

Recommendations for previous studies

If you use 2D trace as the primary method for measuring AC and HC, we recommend reviewing previous patient results or initiate patient follow up.

How will the issue finally be resolved?

Siemens Healthineers will correct this issue with a free-of-charge update to your ACUSON Sequoia ultrasound system with a new software version.

Your Customer Service Engineer from Siemens Healthineers will contact you to schedule a facility visit to update the system or inform you of a remote update.

Please ensure all users of the affected products within your organization and others who may need to be informed will receive the safety-relevant information provided with this notice and will comply with the recommendations.

We apologize for any inconvenience this may cause your institution.

If you have further questions regarding this safety correction, please send all inquiries to:

Siemens Healthineers USD Complaints
usd-complaint.team@siemens-healthineers.com

Sincerely yours,



Khalil Thomas
Head of Quality & Regulatory