

## CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the ACUSON Sequoia ultrasound systems with VA11A software:

Dear Valued Customer:

This letter is to notify you of a safety issue found with the VA11A software.

### What is the issue and what is the potential risk to health?

The ultrasound system averages the Mean Sac Diameter (MSD) and Gestational Sac Diameter (GSD) into the Estimated Date of Delivery (EDD) calculation. This may result in an incorrect EDD.

The American College of Obstetrics and Gynecology (ACOG), World Federation for Ultrasound in Medicine and Biology (WFUMB), and the Society for Maternal-Fetal Medicine (SMFM) recommend excluding the MSD and GSD from estimation of fetal growth. Evaluation of the gestational sac is primarily used to validate fetal viability. Prior to five weeks gestation, MSD or GSD may be used for fetal age, but as soon as a fetal pole with a heartbeat is visible, the MSD or GSD is no longer a valid measurement and should be excluded from an US EDD (ultrasound-derived estimated date of delivery).

An incorrect EDD may influence patient management decisions regarding induction of labor and elective caesarean delivery, which may result in premature births.

### What steps can the user take to avoid the possible risks associated with this issue?

To avoid this issue, delete any MSD or GSD values from the patient report if other biometric parameters are measured.

Siemens Healthineers recommends a review of any early obstetric or gynecology ultrasound results for current pregnancies which produced a gestational age using MSD or GSD as an input.

### How will the issue finally be resolved?

Siemens Healthineers will correct this issue with an update to the VA11A software.

Your Customer Service Engineer from Siemens Healthineers will contact you to schedule a facility visit to update the software or updates will be issued via the Remote Update Handling process.

### Dissemination of the content of this notice

We appreciate your cooperation with this product advisory and ask you to instruct your personnel accordingly.

Sincerely yours,

Electronically signed by: .....  
Reason: I am approving this document  
Date: Jan 12, 2021 19:36 EST

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