

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the ACUSON S1000, ACUSON S2000, or ACUSON S3000 ultrasound systems with software version VC30A, VC30B, VC30C, or VC31A

Dear Valued Customer:

This letter is to notify you of potential measurement error on your ACUSON S Family ultrasound system.

When does this issue arise and what is the potential risk?

We have recently discovered a potential miscalculation when using the Doppler manual trace measurement tool in a full screen display format. The manual trace tool may incorrectly calculate the Time Average Velocity (TAV) and subsequently incorrectly calculate the Pulsatility Index (PI).

The potential risk is a misdiagnosis.

The probability is low that a misdiagnosis will result.

What steps can the user take to avoid potential risk of this issue?

To avoid this issue, do not perform measurements utilizing the manual Doppler trace tool in a full screen display format.

How will this issue be resolved?

This issue will be resolved in a future software release. If you have any questions, please contact your Siemens Service for more information.

Until the necessary repairs have been completed on your system, please share this information with all personnel within your organization who need to be aware of this issue.

As always, patient safety issues are a high priority. To date, no patient injury has been reported. This problem was discovered as part of our ongoing quality process.

We sincerely regret any inconvenience this condition may cause in your daily operations.

Sincerely,



Sheila Pickering, Ph.D.
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