

## CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the ACUSON S2000 and ACUSON S3000 ultrasound systems with the Virtual Touch IQ option

Dear Valued Customer:

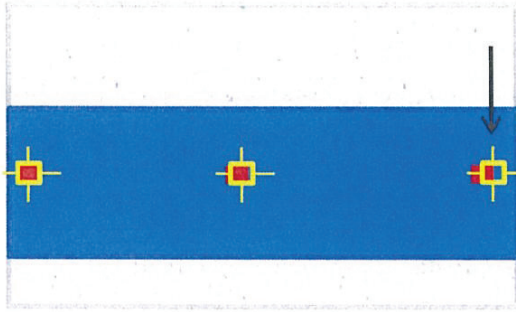
This letter is to notify you of potential measurement error on your ACUSON S Family ultrasound system.

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

When you reposition the Virtual Touch IQ region of interest from the original (default) location, the lateral position of the measurement tool (indicated in yellow) may not align with the lateral position of the shear velocity data (indicated in red), as shown below.

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

To avoid this issue, do not reposition the Virtual Touch IQ region of interest from the original (default) location.



The maximum error in position between the measurement tool and shear velocity data is 3.8 mm. The potential risk of misdiagnosis associated with this issue is low.

Please review previously performed studies to ensure the results are as expected.

**How will this issue be resolved?**

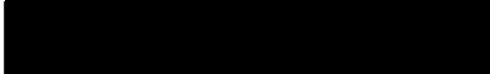
This issue will be resolved in a future software release. If you have any questions, please contact your Siemens Service for information.

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.  
Senior Director, Quality and Regulatory Affairs  
Siemens Medical Solutions USA, Inc.  
Ultrasound Business Unit

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