SIEMENS

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of ACUSON SC2000™ volume imaging ultrasound systems

Dear Valued Customer:

This letter is to notify you of an issue when using the 8V3c transducer on the ACUSON SC2000 system. The error is described below.

When does this malfunction occur and what is the potential risk?

When using the 8V3c transducer in Color M-mode, there is an imaging condition affecting the derated $I_{SPTA.3}$ (Spatial Peak-Temporal Average Intensity) limit stated in the Instructions for Use. The imaging condition occurs when you are using the transducer under the following operating conditions:

- Color M-mode frequency of 5 MHz
- Color ROI (region of interest) focus at 40 mm
- Color velocity scale at the highest setting of 0.59 m/s

In this specific imaging scenario, derated $I_{SPTA.3}$ may exceed the stated limit of 720 mW/cm^2 by up to 15%.

In addition, there are certain imaging conditions when the displayed MI (Mechanical Index) and TI (Thermal Index) are outside the stated display accuracy of +/- 15% and +/- 30%, respectively. However, the MI never exceeds the limit of 1.9, nor does the TI exceed 6.

The largest deviation may occur when the displayed MI value is 1.4, with an actual value of 1.66, and the displayed TIB value is 1.8, with an actual value of 2.95.

Please note that specific biological effects cannot be determined due to variable scanning conditions, which include the mode of operation, scanning duration time, and scanning dwell time (time duration of holding the transducer in one place). Refer to your country-specific recommendations, such as: AIUM, *Ultrasound Biosafety Considerations for the Practicing Sonographer and Sonologist*, Journal Ultrasound in Medicine 2009; 28: 139-150.

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

This issue is a software issue and is not due to a defect in the 8V3c transducer.

We recommend not using the 8V3c transducer until the software issue is fixed.

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How will this issue be resolved?

Siemens is intensively working to release a software update as soon as possible that will correct this issue. You can continue to use your other transducers (4Z1c, 4V1c, V5M, and CW2).

Your local Customer Service Engineer will install new software on your system as soon as it becomes available. We will be updating the local Siemens organizations on a weekly basis, until the software resolution is deliverable to you. If you have any questions, please contact your local service support person for information regarding timelines and status.

Please share this information with all personnel within your organization who need to be aware of this issue.

We are always concerned about patient safety issues and strive to alert customers of product concerns. 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,

[redacted]

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