SIEMENS

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of ACUSON SC2000™ ultrasound system

Dear Valued Customer,

This letter is to notify you of a malfunction concerning the V5M transducer on the ACUSON SC2000 system. This malfunction was detected during internal quality testing at Siemens and has not been reported at any clinical facility or lab outside of Siemens.

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

When using the V5M transducer, the display of the temperature on the ACUSON SC2000 system can be *lower* than the actual temperature of the V5M transducer. This occurs only if the system hardware contains revision 4 of the MPI Board.

If this condition occurs when scanning a febrile or hyperthermic patient using maximum system power settings (0 db), the actual lens surface temperature could exceed 43ºC (109ºF) while the system temperature display continues to show a value under 43ºC.

There is a potential to cause esophageal burns in patients with body temperatures greater than 40º C (104ºF).

This malfunction is an ACUSON SC2000 system hardware issue and is not due to a defect in the V5M transducer. Your other transducers (4Z1c, 4V1c, 8V3, 9L4, 10V4, ACUSON AcuNav™ ultrasound catheters, ACUSON AcuNav V ultrasound catheter and CW2) on the ACUSON SC2000 system are not affected by this issue.

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

To avoid potential risk of this malfunction, it is recommended to use the V5M transducer with the ACUSON SC2000 system at the following power levels in all modes (B-mode, M-mode, Color Doppler, CW and PW Doppler):

- If the patient has normal body temperature, no system power reduction is needed (you may use 0 dB power)
- If the patient has an elevated body temperature of < 40ºC (104ºF), then reduce system power to -3dB power
- If the patient temp is > 40ºC (104ºF), then use -6dB system power

How will this issue be resolved?

Siemens has identified an upgrade for the ACUSON SC2000 system hardware that will correct this issue.

Your local Customer Service Engineer will install new hardware on your system as soon as it becomes available. You will be contacted to schedule a time for the hardware modification. 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.

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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]

Vice President, Quality Regulatory Affairs, EH&S and Compliance Officer
Siemens Medical Solutions USA, Inc.
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