SIEMENS

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the ACUSON S1000™ ultrasound systems and the Advanced SieClear™ spatial compounding feature

Dear Valued Customer:

This letter is to notify you of a possible synchronization error with software version VC10A which can cause a mismatch between the image and the depth scale.

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

The synchronization error can only occur under the following conditions:

1. Activate Advanced SieClear.
2. During live imaging, activate exam review (either using the **REVIEW** key on the control panel or double-clicking a thumbnail on the image screen).
3. Exit exam review and then change the image depth.

There is a potential the image will not update to match the depth scale, which can cause measurement errors in 2D-mode only. The measurement discrepancy could result in misdiagnosis.

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

To avoid this error, *always* freeze the system prior to entering exam review (either using the **REVIEW** key on the control panel or double-clicking a thumbnail on the image screen).

If the user exits exam review and then changes the image depth, take precautions to ensure the image updated appropriately.

If the synchronization error occurs, use one of the following methods to reset the image:

- Activate and then deactivate one of the following modes: color, pulsed wave Doppler, or M-mode.

OR

- Press **TEQ** key on the control panel.

How will this issue be resolved?

Siemens is in the process of releasing a software update that will correct this issue. Your local Customer Service Engineer will install it on your system as soon as it becomes available. You will be contacted to schedule a time for the software modification. Should you have any questions regarding this notification, you may contact your local service support person.

Please pass this notice on to all those within your organization who need to be aware of this issue until the corrective action is completed.

We are always concerned about patient safety issues and strive to alert customers of product concerns. No patient injury has been reported.

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
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