SIEMENS

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the 18L6 HD transducer on the ACUSON S Family ultrasound systems with software versions VD10A or VD10C

Dear Valued Customer:

This letter is to notify you of a potential issue with the 18L6 HD transducer on the ACUSON S Family™ systems with software versions VD10A or VD10C.

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

When scanning with the 18L6 HD transducer on the ACUSON HELX™ Evolution with Touch Control, the ultrasound system may display a triple image or an image with a dark band. For the triple image issue, the system repeats one-third of the aperture, but does not display the full field of view.

This issue occurs intermittently when connecting the 18L6 HD transducer to the ultrasound system or when selecting the touch screen control to activate the transducer.

The potential risk is specific to breast exams and the possibility of not visualizing lesions when acquiring images of breast tissue which may result in a misdiagnosis.

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

To avoid the potential risk associated with this issue, perform the following recommended test before using the 18L6 HD transducer:

- Connect the 18L6 HD transducer to the ultrasound system and then place a fingertip coated with gel on the transducer face. Drag the finger along the entire face of the transducer. If the echo from the finger displays in triplicate, disconnect and reconnect the transducer, and then repeat the test.

Additionally, it is recommended to review any previous breast studies performed with the 18L6 HD transducer and software versions VD10A or VD10C to confirm no triple images were used as part of a diagnosis.

How will this issue be resolved?

We have taken steps to resolve this issue in the VE10A software release. If you have any questions, please contact your Siemens Service organization for information.

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, and we alert customers of product concerns which may occur under various conditions. 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,

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11288102-691-001-02 AXSC 1/31

English

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