

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the ACUSON S Family ultrasound systems utilizing the 18L6 HD and/or 6C1 HD biopsy guidelines

Dear Valued Customer:

This letter is to notify you of a recent finding on the ACUSON S Family systems regarding needle guides. Both the **6C1 HD** and **18L6 HD** transducers demonstrate a misalignment while utilizing the on-screen guidelines.

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

This issue occurs when using the CIVCO biopsy attachments in combination with the ACUSON S Family on-screen guidelines. The biopsy needle may traverse outside the on-screen guidelines. This occurs on the 6C1 HD and 18L6 HD transducers. The potential risk is the tissue of interest may not get sampled.

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

To avoid this issue, do not use the 6C1 HD and 18L6 HD with the CIVCO biopsy attachments for guided biopsy procedures.

For guided procedures with other transducers, please perform the instructions below.

As instructed in the Chapter 5 of the Instructions for Use manual, before performing any patient procedure using a needle guide, you must verify that the path of the needle is accurately indicated by the on-screen guidelines. The needle guide is ready for patient use **only after the path of the needle has been verified.**

Checklist of Items Required for Needle Path Verification:

- Transducer with attached needle guide
- Water-based coupling agent (gel)
- Sterile transducer sheath
- New, straight, biopsy needle
- Sterilized container of sterilized and degassed water

To verify the path of the needle:

WARNING: The biopsy guidelines that display on the system monitor are not intended as an absolute reference. It is the user's responsibility to verify correct positioning of the needle during a biopsy or puncture procedure.

WARNING: Do not use a needle guide if the path of the needle is not accurately indicated by the on-screen guidelines. The path of the needle must display within the guideline. Contact your Siemens service representative if the needle path is not accurately indicated.

1. Attach the needle guide to the transducer.
2. Connect the transducer to the system and activate the transducer.
3. Set the system to the depth of the intended puncture procedure.
4. Select **Biopsy A** or **Biopsy B** from the image menu to display the guidelines on the image screen. Ensure the selected angle (**Biopsy A** or **Biopsy B**) corresponds to the needle guide attached to the transducer.
5. Immerse the head of the transducer into the degassed water and insert the needle into the needle guide.
6. Verify that the path of the needle displays according to the guidelines shown on the image screen.

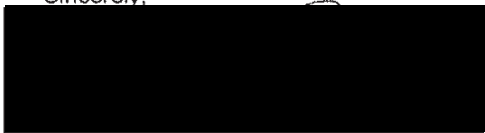
After verification, the needle guide is ready for use.

How will this issue be resolved?

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,



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English