

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of ACUSON S2000 Automated Breast Volume Scanner

Dear Valued Customer:

This letter is to notify you of a potential malfunction with your ACUSON S2000 Automated Breast Volume Scanner (ABVS) with serial numbers 250157 to 250190. If not addressed, this issue could lead to an unsafe mechanical condition.

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

We have recently discovered there is potential for the lateral scanner arm on the ABVS to work itself loose and possibly become detached.

There is a very low probability the scanner arm will become completely detached from the scanner column. The arm would still remain attached to the system due to the design of the cabling and plastic housing.

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

Immediately discontinue use of your ABVS.

How will this issue be resolved?

Your local Customer Service Engineer will contact you to schedule an appointment to make the necessary repairs on your system. If you have any questions, please contact your local service support person for information regarding timelines and status.

Until the necessary repairs have been completed on your system, 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 very 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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