

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the ACUSON SC2000 ultrasound systems with software versions VB10B and lower

Dear Valued Customer:

This letter is to notify you of potential for data loss on your ACUSON SC2000™ ultrasound system.

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

The ACUSON SC2000 ultrasound system considers uppercase/lowercase differences in the same patient name as unique patient instances when registered on the same ultrasound system. The system recalls the case sensitivity even if the original study has been removed from the hard drive. If these differences are not corrected at the time of registration, the system does not capture images or clips.

The potential risk is the study data, including measurements, may not be captured and the study will need to be re-performed.

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

To avoid this issue, correct the uppercase/lowercase differences in the patient name at the time of registration.


How will this issue be resolved?

This issue will be resolved in a future software release. If you have any questions, please contact your customer care center 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 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.



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