

CUSTOMER ADVISORY NOTIFICATION

To users of the ACUSON SC2000 ultrasound systems with software versions VB10A, VB10B, VB10D, VB10E that have PRIME and eSie PISA software licenses

Dear Valued Customer:

This letter is to notify you of a potential issue on your ACUSON SC2000 ultrasound system.

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

The 3D eSie PISA volume analysis application quantifies valvular regurgitation. While imaging with the Z6Ms volume transesophageal echocardiography transducer, this application may underestimate the EROA (Effective Regurgitant Orifice Area) in comparison to the same patient results obtained with the 4Z1c volume transthoracic echocardiography transducer.

There is an extremely low risk of misdiagnosis occurring from underestimating the patient's mitral regurgitation severity when using the eSie PISA analysis application with the Z6Ms volume transesophageal echocardiography transducer.

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

Users should continue to rely on a combination of several quantitative parameters for evaluation of mitral regurgitation rather than solely on the EROA derived from eSie PISA analysis with the Z6Ms transducer.

If you have any further questions, please contact your Customer Care Center.

Please share this information with all personnel within your organization who need to be aware of this issue.

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,

Mazi Kiani
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