



CUSTOMER ADVISORY NOTICE

To users of the ACUSON X150™ and SONOLINE G40™ ultrasound systems

Dear Valued Customer:

This letter is to notify you of a potential issue when using the manual trace tool to measure fetal biometry on the ACUSON X150 software version 1.0 and the SONOLINE G40 software versions 1.0 and 2.0.

When does this malfunction occur and what is the potential risk?

Using the manual trace tool to measure circumference lengths for fetal biometry may cause an overestimation by up to 10%. This overestimation could potentially lead to a misdiagnosis.

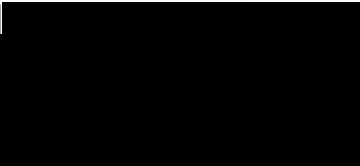
What steps can the user take to avoid potential risk of this issue?

To avoid the potential for misdiagnosis Siemens recommends using the ellipse measurement tool and NOT the manual trace tool when measuring circumference.

Please pass this notice on to all those within your organization who need to be aware of this issue.

We are always concerned about patient safety issues and strive to alert customers of product issues. No patient injury has been reported. This problem was discovered as a part of our ongoing quality process.

We sincerely regret any inconvenience this condition may cause in your daily operations.

Sincerely, 

Senior Director, Quality and Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Ultrasound Business Unit