

State of California—Health and Human Services Agency

California Department of Public Health



Food and Drug Branch - Drug Recalls

CALIFORNIA DRUG RECALL INFORMATION SHEET

Siemens Medical Solutions Recalls Acuson Ultrasound Imaging System and Software for Calculation Error during 2D Manual Trace

Recall Date	Product Description	Recalling Firm	Recall Reason
11/12/2021	ACUSON Sequoia Ultrasound Imaging System with Software Version VA25A/B	Siemens Medical Solutions USA, Inc. Issaquah, Washington	Due to a calculation error in the measurement when using 2D trace (manual trace) tool. The trace circumference value is overestimated and may potentially result in misdiagnosis of a patient's condition.

Recall Class	Product Identification	Distribution	Affected Dates
II	System Serial Numbers: 800101- 802972	47 Units in California	November 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

