SIEMENS Healthineers

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the ACUSON NX2, ACUSON NX2 Elite, ACUSON NX3, and ACUSON NX3 Elite ultrasound systems with the following software versions:

Ultrasound System	ACUSON NX3 ACUSON NX3 Elite		ACUSON NX2 ACUSON NX2 Elite	
Software Version	VA10A VA10B VA10C VA10D VA10E VA10F	VB20A VB20B	VA10A VA10B	VA11A VA11B
Software Version Resolving the Following Issue	VA10G	VB20C	VA10C	VA11C

Dear Valued Customer:

This letter is to notify you of an issue on your ACUSON NX2, ACUSON NX2 Elite, ACUSON NX3, and ACUSON NX3 Elite ultrasound system.

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

As part of our ongoing quality initiatives, internal testing revealed a situation where under specific imaging conditions during pulsed wave Doppler, there is a possibility for transducers to exceed the acoustic output power (AOP) values defined in Track 3 of the *FDA Guidance for Industry and Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* and the Output Display Standard in IEC 60601-2-37.

The probability of occurrence of this issue is remote. During routine clinical use, input values to the calculations for acoustic output power are updated each time the user presses the **UPDATE** key for real-time acquisition. If the issue were to occur, there is an extremely remote likelihood these imaging conditions could result in a burn or tissue damage from cavitation.

We have no reports of injuries or adverse events due to this issue.

What steps can the user take to avoid potential risks associated with this issue?

To avoid a situation where incorrect acoustic output power values are used during pulsed wave Doppler, always press the **UPDATE** key prior to acquiring a real-time (live), pulsed wave Doppler spectrum. The ultrasound system updates the acoustic output power values to the correct values after each press of the key.

Also, do not use a simultaneous format for continuous acquisition. You must press the **UPDATE** key prior to acquiring a real-time (live), pulsed wave Doppler spectrum. For additional information on simultaneous format, refer to Chapter A4 in your Features and Applications Reference manual.

Observe the following instructions provided for acoustic output power in Chapter 2 of your Instructions for Use.

Acoustic Output — Mechanical and Thermal Indices

WARNING: Ultrasound procedures should be used for valid reasons, for the shortest period of time, and at the lowest mechanical/thermal index setting necessary to produce clinically acceptable images.

The ultrasound system incorporates an output display of Mechanical and Thermal Indices to allow you to monitor, and to limit, the amount of ultrasound energy that is transferred to the patient.

Note: For systems distributed in the United States of America, refer to the *Medical Ultrasound Safety* ultrasound education program brochure produced by the AIUM that is shipped with the ultrasound system.

How will this issue be resolved?

A software update which will address this issue is currently being developed. When this software becomes available, a Siemens Healthineers customer service representative will contact you to schedule your system update. 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.

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

Sincerely,

[redacted]

Siemens Medical Solutions USA, Inc.
Ultrasound Business Area
English