

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the ACUSON P300 ultrasound systems

Dear Valued Customer:

This letter is being sent to notify you of a potential malfunction with your ACUSON P300™ ultrasound system when utilizing the PA230 transducer. If not addressed, this issue could lead to an unsafe imaging condition.

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

Using the PA230 transducer with a user-defined preset which includes the 100% setting for output power could cause the transducer surface temperature to exceed the maximum allowable limit.

The potential risk is a patient burn.

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

To avoid this scenario, it is recommended to only utilize the factory-defined presets for imaging with the PA230 transducer.

How will this issue be resolved?

A new version of software resolving this error will be provided free of charge. Your local Customer Service Engineer will contact you to schedule an appointment to make the necessary repairs on your system. If you have any questions, please contact your local service support person 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.

Sincerely,



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

English

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