

MEDICAL DEVICE SAFETY CORRECTION

To users of the ACUSON Juniper ultrasound systems with the following serial numbers:

550975	552770	553629	553951	555060
555601	555602	555603	555604	555605
555606	555607	555610	555611	555612
555613	555626			

Dear Valued Customer:

This letter is to notify you of a potential failure of the power supply in the ACUSON Juniper ultrasound system.

What is the issue?

There are intermittent failures of the power supply in the ACUSON Juniper ultrasound system. This renders the ultrasound system inoperable. When an ultrasound system experiences this failure, cycling the power does not recover system functionality.

What is the potential risk to patient health?

The risk to the patient is the lack of ultrasound guidance due to ultrasound system unavailability for interventional procedures (e.g., biopsy, guidance during surgery, patients under sedation) that rely on real-time ultrasound imaging to guide or complete the procedure.

The likelihood of this failure causing harm is improbable.

There have been no reports of adverse events associated with this failure.

Should an adverse reaction or quality problem be experienced with the use of this product, please report the incident to your local regulatory authorities.

How will the issue finally be resolved?

Siemens Healthineers will correct this issue with a free-of-charge update to your ACUSON Juniper ultrasound system with a new power supply.

Your Customer Service Engineer from Siemens Healthineers will contact you to schedule a visit to your facility to update the system shortly after receiving this letter.

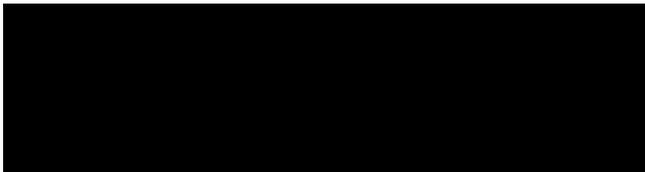
Please ensure all users of the affected products within your organization and others who may need to be informed will receive the safety-relevant information provided with this notice and will comply with the recommendations.

We apologize for any inconvenience this may cause your institution.

If you have further questions regarding this safety correction, please send all inquiries to:

Siemens Healthineers USD Complaints
usd-complaint.team@siemens-healthineers.com

Sincerely yours,



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