

Philips Medical Systems

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## URGENT – Medical Device Correction

September XX, 2006

RE: Philips iE33 Diagnostic Ultrasound System and S12-4 transducer

Dear Philips Ultrasound System User:

Philips Ultrasound has recently identified an acoustic output intensity and contact surface heating condition with the iE33 ultrasound system and S12-4 transducer. The acoustic output intensity may exceed the maximum specified limit and the patient contact temperature may exceed 43°C when using this system-transducer combination in CW-mode. No other combinations of transducers, systems and imaging modes are affected.

If you have an S12-4 transducer, please do not use it in CW-mode on the iE33 ultrasound system.

Philips Ultrasound is releasing new software that corrects the problem. This software modification will be available starting in November, 2006. If our records indicate that your facility is affected by this situation, your local field service representative will be in contact with you to arrange for the installation of the new software to correct this issue. Until your iE33 system has been upgraded, please avoid the use of CW-mode on the S12-4 transducer as described above.

We apologize for any inconvenience that this situation may present. Please forward this information to the appropriate individuals within your organization. If you have any questions, please contact your local field service representative.

Sincerely,

[Redacted Signature]

[Redacted Name]  
Director, Quality & Regulatory  
Philips Ultrasound

