



Promoting Excellence In Ultrasound

Policies and Statements

A4

Safety Statement On Thermal Biological Effects

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Safety Statement On Thermal Biological Effects

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A significant body of information is available on thermal bioeffects, including those on the fetus. Although many questions remain, current knowledge permits a number of conclusions to be drawn on the thermal mechanism of production of biological effects of ultrasound.

In general, Doppler examinations (excluding cw Doppler fetal monitoring) present the highest risk of inducing biological effects that are thermally mediated. This follows from the use of longer pulses and higher pulse repetition rates than those used in grey scale imaging.

Data from animal experiments have shown that some Doppler equipment can produce biologically significant temperature rise, especially at bone/soft tissue interfaces, such as in fetal examinations in the second and third trimester.

The risk of adverse effects of heating increases with the duration of exposure.

The current FDA regulatory limit for obstetric ultrasound applications is 720 mW/cm² intensity (I_{SPTA}), estimated at the tissue of interest, i.e. attenuated according to the beam path length in tissue. For this intensity, it has been estimated that the maximum temperature in the conceptus can exceed 2°C.

RECOMMENDATIONS

- A diagnostic exposure that produces a maximum temperature rise of 1.5°C above normal physiological levels (37°C) may be used without reservation in clinical examinations.
- A diagnostic exposure that elevates embryonic or fetal temperature above 41°C (i.e. 4°C above normal body temperature) for 5 minutes or more should be considered potentially hazardous.
- The effects of heating should be reduced by minimising the duration of exposure.
- Due to the possible influence of potentiating factors, duplex/Doppler ultrasound in febrile patients might present an additional embryonic and fetal risk.
- Care should be taken to use the minimum output consistent with obtaining the required diagnostic information and to minimise the duration of pulsed Doppler examinations in pregnancy.

WFUMB (1998) World Federation for Ultrasound in Medicine and Biology Symposium on Safety of Medical Ultrasound; Conclusions and Recommendations regarding thermal and non-thermal mechanisms for biological effects of ultrasound. ed. Barnett S. Ultrasound in Medicine and Biology, 24: S1; 1-55.



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