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Safety Statement, 2000 (reconfirmed 2002)

International Society for Ultrasound in Obstetrics and Gynecology (ISUOG)

ISUOG Bioeffects and Safety Committee (J.S. ABRAMOWICZ, G. KOSSOFF, K. MARSAL and G. TER HAAR)
on behalf of the Executive Board of the International Society of Ultrasound in Obstetrics and Gynecology

STATEMENTS

The thermal index (TI) and the mechanical index (MI) are not perfect indicators of the risks of thermal and nonthermal bioeffects, but currently they should be accepted as the most practical and understandable methods of estimating the potential for such risks.

B-mode and M-mode

Acoustic outputs are generally not high enough to produce deleterious effects. Their use therefore appears to be safe, for all stages of pregnancy.

Doppler ultrasound

Significant temperature increase may be generated by spectral Doppler mode, particularly in the vicinity of bone. This should not prevent use of this mode when clinically indicated, provided the user has adequate knowledge of the instrument's acoustic output, or has access to the relevant thermal index. Caution is recommended when using color Doppler mode with a very small region of interest, since this mode produces the highest potential for bioeffects.

When ultrasound examination is clinically indicated, there is no reason to withhold the use of scanners that have received current Food and Drug Administration clearance in tissues, which have no identifiable gas bodies. Since ultrasound contrast agents are mostly gas-carriers, the risk of induction and sustenance of inertial cavitation is higher in circumstances when these agents are employed.

Pregnancy

Based on evidence currently available, routine clinical scanning of every woman during pregnancy using real-time B-mode imaging is not contraindicated.

The risk of damage to the fetus by teratogenic agents is particularly great in the first trimester. One has to remember that heat is generated at the transducer surface when using the transvaginal approach. Spectral and color Doppler may produce high intensities and routine examination by this modality during the embryonic period is rarely indicated. In addition, because of high acoustic absorption by bone, the potential for heating adjacent tissues must also be kept in mind.

Exposure time and acoustic output should be kept to the lowest levels consistent with obtaining diagnostic information and limited to medically indicated procedures, rather than for purely entertainment purposes.

Education

Education of ultrasound operators is of the utmost importance since the responsibility for the safe use of ultrasound devices is now shared between the users and the manufacturers, who should ensure the accuracy of the output display.

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