

EFSUMB CLINICAL SAFETY STATEMENT FOR DIAGNOSTIC ULTRASOUND

AN OVERVIEW

Diagnostic ultrasound has been widely used in clinical medicine for many years with no proven deleterious effects. However, investigations into the possibility of subtle or transient effects are still at an early stage. Biological effects (such as localized pulmonary capillary bleeding) have been reported in mammalian systems at diagnostically relevant exposures, but the clinical significance of such effects is not yet known. Consequently, diagnostic ultrasound can be considered safe only if used prudently. Ultrasound examinations should be performed only by competent personnel who are trained and updated in safety matters. It is also important that ultrasound devices are appropriately maintained. The range of clinical applications is becoming wider, the number of patients undergoing ultrasound examinations is increasing and new techniques with higher acoustic output levels are being introduced. It is therefore essential to maintain vigilance to ensure the continued safe use of ultrasound.

AVAILABLE SAFETY INFORMATION DURING CLINICAL SCANNING

Ultrasound produces heating, pressure changes and mechanical disturbances in tissue. Diagnostic levels of ultrasound are capable of producing temperature rises that may be hazardous to sensitive organs and the embryo/fetus. Biological effects of nonthermal origin have been reported in animals, but to date, no such effects have been demonstrated in humans, except when a microbubble contrast agent is present. The thermal index (TI) is an on-screen guide to the user of the potential for tissue heating.* The mechanical index (MI) is an on-screen guide of the likelihood and magnitude of nonthermal effects.* Users should remain aware of both indices while scanning, especially when changing scan modes, and should adjust the machine controls to keep them as low as reasonably achievable (ALARA principle) without compromising the diagnostic value of the examination. Where low values cannot be achieved, examination times should be kept as short as possible.

Scanners should be set up so the default (switch-on) power for a given examination is no greater than the minimum level necessary for that type of examination. In obstetric applications, this default power should result in a thermal index no higher than 0.7. The output should be increased during the examination only if this is necessary to produce a satisfactory diagnostic result. Some modes are more likely than others to produce significant acoustic outputs, and when these modes are used, particular care should be taken to regularly check the thermal and mechanical indices. Spectral pulse wave Doppler and Doppler imaging modes (color flow imaging and power Doppler imaging), in particular, can produce more tissue heating and hence higher thermal indices, as can B-mode techniques involving coded transmissions. Since the algorithms used to calculate thermal index for most imaging modes are not appropriate for elastography, it should be noted that the TI displayed for these applications may represent an underestimate of the temperature rises to be expected. Tissue harmonic imaging mode can sometimes involve higher mechanical indices. Three dimensional imaging does not introduce any additional safety considerations, particularly if there are significant pauses during scanning to study or manipulate the reconstructed images. However, four-dimensional (real-time three-dimensional) scanning involves continuous exposure, and users should guard against the temptation to prolong examination times unduly in an effort to improve the recorded image sequence beyond that which is necessary for diagnostic purposes.

ULTRASOUND EXPOSURE DURING PREGNANCY

The embryo/fetus in early pregnancy is known to be particularly sensitive. In view of this and the fact that very little information is currently available regarding possible subtle biological effects of diagnostic levels of ultrasound on the developing human embryo or fetus, care should



be taken to limit the exposure time and the thermal and mechanical indices to the minimum commensurate with an acceptable clinical assessment, particularly when the thermal index exceeds 0.7. It is recommended that thermal indices less than 3.0 are used.*

Temperature rises are likely to be greatest at bone surfaces and adjacent soft tissues. With increasing mineralization of fetal bones, the possibility of heating sensitive tissues such as brain and spinal cord increases. Extra vigilance is advised when scanning such critical fetal structures, at any stage in pregnancy. Based on scientific evidence of ultrasound-induced biological effects to date, there is no reason to withhold diagnostic scanning during pregnancy, provided it is medically indicated and is used prudently by fully trained operators. This includes routine scanning of pregnant women. However, Doppler ultrasound examinations should not be used routinely in the first trimester of pregnancy. The power levels used for fetal heart rate monitoring (cardiotocography) are sufficiently low that the use of this modality is not contraindicated on safety grounds, even when it is to be used for extended periods.

SAFETY CONSIDERATIONS FOR OTHER SENSITIVE ORGANS

Particular care should be taken to reduce the risk of thermal and nonthermal effects during investigations of the eye and when carrying out neonatal cardiac and cranial investigations.

ULTRASOUND CONTRAST AGENTS

These usually take the form of stable gas-filled microbubbles, which can potentially produce cavitation or microstreaming, the risk of which increases with mechanical index. Data from small animal models suggest that microvascular damage or rupture is possible. Caution should be considered for the use of ultrasound contrast agents in tissues where damage to microvasculature could have serious clinical implications, such as the brain and the eye, and in the neonate. As in all diagnostic ultrasound procedures, the mechanical and thermal indices should be continually checked and kept as low as possible. It is possible to induce premature ventricular contractions in contrast-enhanced echocardiography when using high mechanical indices and end-systolic triggering. Users should take appropriate precautions in these circumstances. The use of contrast agents should be avoided 24 hours prior to extracorporeal shock wave therapy. Since a rare allergic response to these agents has been seen (1:10000), it is recommended that an “Allergy Kit” be readily available at all times during these procedures*.

*Please see EFSUMB tutorial articles on these topics.