

Statement on Mammalian Biological Effects of Ultrasound In Vivo

Information from experiments using laboratory mammals has contributed significantly to our understanding of ultrasonically induced biological effects and the mechanisms that are most likely responsible. Adverse biological effects have been observed in some animal studies under conditions that may be achieved by using diagnostic scanners (see associated specific statements). The following statement summarizes observations relative to minimal diagnostic ultrasound parameters and indices.

In the low-megahertz frequency range, there have been no independently confirmed adverse biological effects in mammalian tissues exposed in vivo under experimental ultrasound conditions, as follows:

1. Thermal Mechanisms

- a. No effects have been observed for an unfocused beam having free-field spatial-peak temporal-average (SPTA) intensities* below 100 mW/cm^2 , a focused** beam having intensities below 1 W/cm^2 , or temperature increases of less than 1.5°C .
- b. For fetal exposures, no effects have been reported for a temperature increase above the normal physiologic temperature, ΔT , when $\Delta T < 4.5 - (\log_{10} t)/0.6$, where t is exposure time ranging from 1 to 250 minutes, including off time for pulsed exposure.
- c. For postnatal exposures producing temperature increases of 6°C or less, no effects have been reported when $\Delta T < 6 - (\log_{10} t)/0.6$, including off time for pulsed exposure. For example, for temperature increases of 6.0°C and 2.0°C , the corresponding limits for the exposure durations t are 1 and 250

minutes.

d. For postnatal exposures producing temperature increases of 6°C or higher, no effects have been reported when $\Delta T < 6 - (\log_{10} t)/0.3$, including off time for pulsed exposure. For example, for a temperature increase of 9.6°C, the corresponding limit for the exposure duration is 5 seconds (=0.083 minutes) (see AIUM "[Statement on Mammalian Biological Effects of Heat](#)").

2. Nonthermal Mechanisms

a. For diagnostic ultrasound exposure by actual medical devices or laboratory equipment, no adverse effects have been observed in tissues containing naturally occurring gas bodies for in situ peak rarefactional pressures below approximately 0.4 MPa (estimated mechanical index [MI] values less than ≈ 0.4) (see AIUM "[Statement Regarding Mammalian Biological Effects in Tissues With Naturally Occurring Gas Bodies](#)").

b. For contrast-enhanced diagnostic ultrasound, no adverse effects in mammalian tissue in vivo have been reported and independently confirmed for an MI below about 0.4 (see AIUM "[Statement on Mammalian Biological Effects in Tissues With Gas Body Contrast Agents](#)").

c. In tissues that do not contain well-defined gas bodies, no adverse nonthermal bioeffects have been observed for MI values below 1.9: the upper limit for diagnostic ultrasound (see AIUM "[Statement on Mammalian Biological Effects in Tissues Without Gas Bodies](#)").

*Free-field SPTA intensity for continuous wave and pulsed