



# Promoting Excellence In Ultrasound

## **Policies and Statements**

# **A5**

Safety Statement On Acoustic Output And Equipment Output Display

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#### **Safety Statement On Acoustic Output And Equipment Output Display**

*September 1998, Revised February 2000 Revised July 2008*

The equipment Output Display allows the user to determine the risk/benefit ratio of ultrasound procedures based on information provided on the equipment. Most modern equipment includes a form of display of output.

The FDA approved AIUM/NEMA\* real-time output display standard (ODS) incorporates indicators of possible bioeffects;

- Thermal Index (TI) estimates the potential for producing thermally-induced biological effects in soft tissue and bone.
- Mechanical Index (MI) estimates the potential for producing nonthermal/mechanical biological effects in tissue.

It is necessary to understand that these indices have some limitations. Due to the difficulties of estimating tissue conditions, the indices (TI, MI) provide indicators of risk rather than quantifiable values. They also do not take account of extraneous factors such as dwell time, examination time, patient temperature or presence of contrast agents.

#### **RECOMMENDATIONS**

- Users of ultrasound diagnostic equipment should pay attention to any indicator of output, or of risk, displayed by the equipment to ensure that acoustic exposure is minimised to that necessary to obtain clinical diagnostic information.
- Use the ODS as indicators of risk rather than as quantifiable values.
- Users should appreciate that equipment that provides an output display can produce high intensities. For example, the embryo or fetus can be exposed to intensities as high as 720 mW/cm<sup>2</sup> under the FDA regulations. Equipment that has no output display is generally limited to intensities that do not exceed 94 mW/cm<sup>2</sup>.

\* AIUM/NEMA, American Institute of Ultrasound in Medicine/National Electrical Manufacturers Association.



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