



Promoting Excellence In Ultrasound

Policies and Statements

F1

Statement on the Appropriate Use of Diagnostic Ultrasound Equipment for Non-Medical Entertainment Ultrasound

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July 2005 (Reaffirmed September 2006)

The Australasian Society for Ultrasound in Medicine, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Royal Australian and New Zealand College of Radiologists are committed to ensuring the maintenance of the highest standard of medical care for pregnant women.

Diagnostic medical ultrasound technology offers enormous benefits in terms of the provision of useful diagnostic information so that pregnancy may be better assessed and managed, with optimum outcomes for mothers and babies achieved.

The use of diagnostic medical ultrasound equipment requires regulation such that its primary use is for the purpose of medical diagnosis. Such regulation should require that the diagnostic ultrasound equipment usage be restricted to appropriately qualified health care professionals.

Usage of such equipment should conform to the guidelines produced by the Australasian Society for Ultrasound in Medicine.

We urge that appropriate regulation regarding the sale, distribution and use of diagnostic ultrasound equipment be formulated with a view to ensuring that this technology continues to assist clinicians in the management of pregnancy, thereby optimizing outcome for mothers and babies.

The Australian Sonographers Association also supports the ASUM Position Statement as of June 2007

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Background/Preamble

Since its introduction to medical practice and the biological sciences in the 1950s, ultrasound has grown from being a subject of minor curiosity to probably the most widely used imaging modality throughout the world across dozens of clinical disciplines.

A major initial clinical application was in the discipline of obstetrics and this has continued through to the current day where modern diagnostic ultrasound plays a major role in the clinical management of pregnancy. The use of diagnostic ultrasound in pregnancy has been underpinned by a large volume of research into issues concerning bioeffects and safety in human tissue. For many years most of the learned bodies worldwide, concerned with imaging and obstetrics, have encouraged the appropriate and safe use of diagnostic medical ultrasound equipment.

The recent widespread availability of good quality real time three dimensional diagnostic ultrasound equipment has seen the proliferation of businesses offering ultrasound examinations during pregnancy for the purpose of producing "keep sake" images of fetuses. This has been most prevalent in the United States where much effort is currently being directed toward regulating this phenomenon and restoring the use of diagnostic medical ultrasound equipment to the area of medical diagnosis as opposed to entertainment (see websites of United States Food and Drug Administration, American

Medical Association). Confining the use of diagnostic Medical ultrasound equipment in pregnancy to examinations for the purpose of providing medical information useful to the management of pregnancy is based on the following principles:

1. Bioeffects and safety.

It is widely accepted that diagnostic ultrasound when used as per guidelines promoted by bodies such as the World Federation for Ultrasound in Medical and Biology, the American Institute of Ultrasound in Medicine and the Australasian Society for Ultrasound in Medicine has not been demonstrated to be associated with the deleterious effects in human tissue. Such statements do not guarantee the absolute safety of diagnostic ultrasound but rather emphasises that the long term effects and the possibility of subtle effects are not completely known. Prudent use is therefore recommended in order to minimise the chance of significant bioeffects. It should be noted that recommended power output levels have been significantly increased in recent years and much of the safety data relating to the use of diagnostic ultrasound precedes the increased permitted power outputs for different ultrasound imaging modalities. In terms of exposure to diagnostic ultrasound, all learned bodies emphasize the ALARA (as low as reasonably achievable) principle. This principle emphasizes that diagnostic medical ultrasound equipment be used by trained individuals to seek relevant diagnostic information with the minimum of exposure, thereby minimising the potential for bioeffects and tissue damage.

2. The Trivialisation of Diagnostic Medical Technology.

Trivialising diagnostic medical technology and the role of trained technical and medical professional will inevitably erode the significant relationship between health care providers and patients that currently exists. This will ultimately be to the significant detriment of the maintenance of the high standard of practice upon which optimum medical outcomes are based.

3. Potential for Misdiagnosis.

The potential clearly exists for not detecting significant diagnoses. Pregnant women may believe that this form of examination is an adequate substitute for a properly conducted examination involving appropriately trained sonographers and medical practitioners. A potential problem is also created where the abnormalities are incorrectly diagnosed or doubt regarding normality is created, thereby producing significant patient anxiety.

4. General Note

There needs to be community discussion regarding the entitlement of a fetus to particular rights, including the right not to be exposed to a source of potential harm where no health benefit exists.



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