Safety and Bioeffects of Diagnostic Ultrasound

“A don’t care if bungee jumping is faster than the aerial lift. Around here it’s against safety rules!”

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Introduction

Safety of diagnostic ultrasound is an important consideration for obstetric scanning, particularly in the first trimester and when using pulsed Doppler. There is a small risk of causing thermal or mechanical damage.

There are also non-obstetric applications (e.g. the eye and neonates, the use of contrast agents) where ultrasound should be used with caution.

As with all modalities, the principle of ALARA should be used. The on-screen thermal and mechanical indices (TI, MI) help achieve this.

A full safety statement and guidelines can be found on the British Medical Ultrasound Society website: www.bmus.org
How do we respond to patients who have read such articles?
About Chris

My name is Chris Kresser, and I'm a licensed acupuncturist and practitioner of integrative medicine. I've been interested in health and wellness since I was a kid. My high school basketball coach had our whole team on a special diet, and while most of my teammates couldn't stand it, I actually loved the way I felt when I ate healthy food.

I did my undergraduate work at UC Berkeley. There I was introduced to Eastern spirituality and a wide range of health modalities and practices, from nutrition to meditation to tai qi to kundalini yoga to massage.
Evidence - Epidemiology

Several studies published on the possible effects of ultrasound exposure *in utero* e.g.:

- Childhood malignancies – no association
- Birthweight – conflicting evidence
- Neurological development – most have no association. For dyslexia–possible associations but small and not repeated.

- Speech development – conflicting evidence
- Non-right handedness – small but statistically significant association
Evidence - Epidemiology

- i.e. no conclusive epidemiological evidence to suggest that ultrasound exposure \textit{in utero} causes an alteration in the growth and development of a foetus.

\textbf{BUT}

- We do know that ultrasound can “change” tissue … \textit{BIOEFFECTS}
Evidence - BioEffects

- Animal and in vitro studies show that it is possible to cause damage to cells and embryos using ultrasound.

- Therapeutic ultrasound – physiotherapy, HIFU, hyperthermia, lithotripsy, liposuction!

- Sonochemistry, sonophoresis, sonolysis

- In the NEWS ….  
  - Ultrasound may disrupt fetal brain development,  
    07 August 2006  
    NewScientist.com news service

- Bioeffects work is useful for determining exposure thresholds
More Evidence


Health Effects of Exposure to Ultrasound and Infrasound RCE 14, Advisory Group on Non-ionising Radiation, Health Protection Agency, February 2010
Using the Evidence

Bio-effects studies tell us that it is possible to cause damage using ultrasound.

Epidemiology studies tell us that no-adverse effects have yet been found using diagnostic ultrasound.

Ultrasound can be used with confidence but with caution.

Understanding the physics and technology of the ultrasound we are using can help us use it safely.

Use common sense … and the BMUS guidelines!
Possible Mechanisms for Ultrasound Damage – Bioeffects
(What happens to tissue exposed to ultrasound and does it matter?)

- Thermal Effects
- Non Thermal Effects
Thermal Effects

**Heating** i.e. the absorption of ultrasound by tissue. A potential for thermal damage - related to the intensity of the ultrasound.

Remember that heating is the largest component of attenuation. Also higher frequencies are attenuated more.
Non-Thermal Effects

Cavitation or “gas-body activation” - the expansion, resonance and collapse of small gas cavities within tissue. A potential cause of mechanical damage - related to the peak negative pressure of the ultrasound (& frequency).

- Stable Cavitation
- Inertial Cavitation
Non-Thermal Effects

- **Stable Cavitation** – resonating microbubbles – can be ok but shear stresses can represent a “tearing force” to adjacent cells.

- **Inertial or Transient Cavitation** – Higher pressures and short pulses give large size variations and violent collapse. Intense “microstreaming” occurs with large local changes in pressure and temperature causing damage to cells - more violent effect than for stable cavitation.
What is the output of our ultrasound machine?

....can we measure it?

In theory – YES
...but it’s not easy!
Acoustic Output Parameters

Peak negative pressure

\[ P^- \]
Acoustic Output Parameters

- Intensity and Power

Intensity = Power / Area (W cm$^{-2}$)

- Isppa – spatial peak pulse average
- Ispta – spatial peak temporal average

Ispta – most often used
Acoustic Output Parameters

- Spatial Peak
- Spatial Average
- Temporal Peak
- Temporal Average

Intensity (W/cm²) vs. Distance across beam

Intensity (W/cm²) vs. Time
Has anyone measured outputs from ultrasound scanners?

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**Figure 3.11.** Manufacturer declared values of peak rarefaction pressure (\(p_r\)) in 2010 compared to 3 previous surveys in B-mode, pulsed Doppler and colour Doppler (from Martin, 2010).
Figure 3.12. Manufacturer declared values of spatial-peak temporal-average intensity ($I_{spa}$) in (2010) compared to 3 previous surveys in B-mode, pulsed Doppler and colour Doppler mode (from Martin, 2010).

Increasing Acoustic Output – why?

- Penetration vs. Resolution
- Harmonic Imaging
- Higher density of elements
- Longer pulses
- More use of Doppler

- Contrast agents!
What should these parameters be?  
... are there any rules?

"Thanks a bunch. I'll just run these by our committee and pass them along."
At present, there is no statutory limit on the acoustic output of ultrasound scanners.

- European Medical Devices Directive – no specific limits on ultrasound output

- IEC 60601-2-37 - manufacturers must provide acoustic output information unless
  \[ p- < 1\text{MPa} \text{ and } I_{\text{spta}} < 100 \text{ mWcm}^{-2} \]
Manufacturers Responsibility

Manufacturers must apply the standards required by the Medical Devices Directive (MDD) in Europe and the Food and Drug Agency (FDA) in the USA.

<table>
<thead>
<tr>
<th>Applications</th>
<th>Derated $I_{\text{pt}}$ (mW cm$^{-2}$)</th>
<th>Derated $I_{\text{ap}}$ (W cm$^{-2}$)</th>
<th>MI</th>
<th>TI</th>
</tr>
</thead>
<tbody>
<tr>
<td>All except ophthalmology</td>
<td>720</td>
<td>190</td>
<td>1.9</td>
<td>(6.0)$^*$</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>50</td>
<td>NS</td>
<td>0.25</td>
<td>1.0</td>
</tr>
</tbody>
</table>

The upper limit of 6.0 for TI is advisory. At least one of the quantities MI and $I_{\text{ap}}$ must be less than the specified limit. NS: Not specified.

Table 13.1: The upper limits of exposure required by the US FDA.

IEC 60601-2-37, Medical electrical equipment, Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment, effectively implements the AIUM/NEMA ODS methods and requires calculation and display of TI and MI values subject to the same conditions as the ODS. In addition, it places upper limits for the temperature of the transducer surface which is in contact with the patient.
Standards and Guidance

User Responsibility

Users must ensure that their training and knowledge is up to date with changing technology and practices. They must be able to choose scanners and transducers appropriate for the type of examination and the condition of the patient. They must follow good practice for minimising any risk to the patient.
Ultrasound professional bodies - BMUS, AIUM, EFSUMB, WFUMB provide safety statements. E.g “A temperature elevation of 4°C maintained for 5 minutes or more is considered to be potentially hazardous to a fetus or embryo”

But – how can we tell what the acoustic exposure to the patient is?
Standards and Guidance

To help the user …

AIUM in conjunction with NEMA (the manufacturers) introduces the **Output Display Standard (ODS)** in an attempt to make it easier to interpret the standards and apply ALARA using on screen indicators of the likelihood of causing damage.

BMUS have interpreted the ODS to provide guidance on how to use the indices.
The ODS provides an on-screen method of monitoring and limiting the ultrasound exposure.

The **Thermal Index, TI**, relates to the possibility of thermal damage.

\[ TI = \frac{W}{W_{\text{deg}}} \]

(W is acoustic power and \( W_{\text{deg}} \) is the acoustic power required to generate a temperature rise of 1°C)

It has three parts,

**TIS** – soft tissue scanning (e.g. before 8 weeks gestation)
**TIB** – bone thermal index (fetal scanning after 8 weeks)
**TIC** – cranial thermal index (scanning close to bone e.g. transcranial applications)
**Fig. 13.4** Diagram showing conditions for TIS for scanning (these conditions are also assumed to apply for the calculation of TIB for scanning).

**Fig. 13.5** Diagram showing the conditions for TIB.

**Fig. 13.6** Diagram showing the conditions for the TIC.
The **Mechanical Index, MI**, relates to the possibility of cavitational damage

\[ MI = p^{-0.3} \div \sqrt{f} \]

*Where* $p^{-0.3}$ *is peak negative or rarefractional pressure, derated by 0.3 dB/cm/MHz*

*f is the acoustic frequency*
The BMUS Safety Statement and Guidance

http://www.bmus.org/

Key principles for the safe use of ultrasound

Medical ultrasound imaging should only be used for medical diagnosis.

Ultrasound equipment should only be used by people who are fully trained in its safe and proper operation. This requires:

- an appreciation of the potential thermal and mechanical bio-effects of ultrasound
- a full awareness of equipment settings
- an understanding of the effects of machine settings on power levels.
**Key principles - continued**

- Examination times should be kept as short as is necessary to produce a useful diagnostic result.

- Output levels should be kept as low as is reasonably achievable whilst producing a useful diagnostic result.

- The operator should aim to stay within the BMUS recommended scan times (especially for obstetric examinations).

- Scans in pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs.

FRCR/MSC - Safety
The BMUS Safety Statement and Guidance

Guidelines for probe and system use

- Initial power setting – low as possible

- Exposure time - minimise

- Stationary probe – minimise

- Probe self-heating – endo probes, febrile patient

- Doppler modes – use with caution!

FRCR/MSC - Safety

AJW - 2014
The BMUS Safety Statement and Guidance

- **Hazard and risk factors**

  - Awareness of scanner factors influencing hazard

  - Sensitive tissues.
    - an embryo less than eight weeks after conception;
    - the head, brain or spine of any foetus or neonate;
    - an eye (in a subject of any age).

  - Pre-existing temperature elevation.

  - Thermal and Mechanical Indices.

### Application-specific guidelines – obs & neo

<table>
<thead>
<tr>
<th>Application</th>
<th>Values to monitor (A)</th>
<th>Thermal Index value</th>
<th>Mechanical Index value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetrics up 10 weeks after LMP (and gynaecology when pregnancy is possible)</td>
<td>TIS and MI</td>
<td>0.7 - 1.0: 60 min</td>
<td>Scanning of an embryo or fetus is not recommended, however briefly</td>
</tr>
<tr>
<td>Obstetrics more than 10 weeks after LMP</td>
<td>TIB and MI</td>
<td>0.7 - 1.0: 60 min</td>
<td>Scanning of an embryo or fetus is not recommended, however briefly</td>
</tr>
<tr>
<td>Neonatal – transcranial and spinal</td>
<td>TIC and MI</td>
<td>0.7 - 1.0: 60 min</td>
<td>Scanning of the central nervous system is not recommended, however briefly</td>
</tr>
<tr>
<td>Neonatal - general and cardiac imaging</td>
<td>TIB and MI recommended</td>
<td>1.0 - 1.5: 120 min</td>
<td>(D) Possibility of minor damage to lung or intestine. Minimise exposure time</td>
</tr>
<tr>
<td>Fetal Doppler heart monitoring</td>
<td>TI or MI are not usually available for dedicated fetal heart monitors.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Table 1. Recommended exposure time and index values for obstetric and neonatal ultrasound.**

- **Thermal Index value:**
  - 0.7 - 1.0: 60 min
  - 1.0 - 1.5: 30 min
  - 1.5 - 2.0: 15 min
  - 2.0 - 2.5: 4 min
  - 2.5 - 3.0: 1 min

- **Mechanical Index value:**
  - 0.3: 1 min
  - 0.7: 4 min
  - >0.7: Scanning of an embryo or fetus is not recommended, however briefly

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**Notes:**

- (B) restrict time to 0.7 - 1.0: 60 min
- (C) restrict time to 1.0 - 1.5: 120 min
- (D) Possibility of minor damage to lung or intestine. Minimise exposure time
- (E) risk of cavitation with contrast agents
# Application-specific guidelines - general

## Table 2. Recommended exposure time and index values for non-obstetric and non-neonatal ultrasound.

<table>
<thead>
<tr>
<th>Application</th>
<th>Values to monitor (A)</th>
<th>Thermal Index value</th>
<th>Mechanical Index value</th>
</tr>
</thead>
<tbody>
<tr>
<td>General abdominal</td>
<td>TIB and MI</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Peripheral vascular</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unlisted applications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye</td>
<td>TIS and MI recommended</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Adult transcranial (imaging and stand-alone) (D)</td>
<td>TIC and MI</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Peripheral pulse monitoring</td>
<td>TI or MI are not usually available for dedicated peripheral pulse monitors.</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

### Thermal Index value

- **0 - 1.0**
- **> 1.0**

### Mechanical Index value

- **0 - 0.3**
- **> 0.7**

- **(B) restrict time to**
  - $0.7 < TIC \leq 1.0$ : 60 min
  - $1.0 < TIC \leq 1.5$ : 30 min
  - $1.5 < TIC \leq 2.0$ : 15 min
  - $2.0 < TIC \leq 2.5$ : 4 min
  - $2.5 < TIC \leq 3.0$ : 1 min

- **(C) risk of cavitation with contrast agents**

- **The output from CW Doppler devices intended for monitoring peripheral pulses is sufficiently low that their use is not contra-indicated, on safety grounds.**
Applying ALARA

• Minimise exposure to sensitive tissue

• Exercise particular care when using Doppler modes (particularly spectral Doppler and deep colour boxes)

• Be aware of TI and MI on-screen values - observe any changes due to scan controls

• Minimise TI and MI as far as possible - use lowest possible output setting

• Move the transducer to minimise exposure times
Useful Safety Related Websites:

www.bmus.org/Safety_of_Ultrasound.htm - British Medical Ultrasound Society safety statements and guidance particularly relating to use of the ODS, foetal and ophthalmic scanning, volunteer scanning


www.efsumb.org/ecmus.htm – European Federation of Societies for Ultrasound in Medicine and Biology. Safety statements and useful tutorial articles on e.g. minimising acoustic output

www.aium.org – American Institute of Ultrasound in Medicine – various safety statements. Clinical standards PDF files

www.ob-ultrasound.net - follow the links in the safety section
"With all these lectures and safety manuals, I'm about ready for a trip to where I can lie down and forget about all these rules and regulations!"