Ultrasound Safety

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Ultrasound Imaging
How do you know it’s SAFE?

EFSUMB Safety Committee
Why are we concerned about safety?

• The range of clinical applications is becoming wider
• The number of patients undergoing ultrasound examinations is increasing
• New techniques with higher acoustic output levels are being introduced.

What are bio-effects?

The result of ultrasound interacting with biological molecules as it passes through tissue
Safety

Is a bioeffect likely to cause a problematic change (e.g. cell, gene or DNA damage) ?

Mechanisms of Action

Heat (Ispta)

Cavitation (P-)

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**Attenuation**

\[ \text{Attenuation} = \text{Absorption} + \text{Scatter} \]

**INCIDENT BEAM**

**IMAGE**

**Absorption**

60-80%

**HEAT**

**Scatter**

20-40%

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**HEATING (Absorption)**

Increases with: frequency, exposure duration, pulse repetition frequency

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Transducer Self Heating:

Temperature distribution due to probe self-heating for diagnostic devices (maximum):

**B-Mode**

- \( I_{sptb} = 11 \text{ mW cm}^2, \text{MI} = 0.5 \)

**Pulsed Doppler**

- \( I_{spta} = 533 \text{ mW cm}^2, \text{MI} = 0.9 \)

**Colour Doppler**

- \( I_{spta} = 606 \text{ mW cm}^2, \text{MI} = 0.3 \)

International limits for probe surface temperature due to self-heating:

- \( T < 41^\circ C \) (in a water bath 2 l / 10 min)  \( \text{IEC 601-2-5} \)
- \( T < 43^\circ C \) (coupled to skin)  \( \text{IEC 60601-2-37} \)
- \( T < 50^\circ C \) (emitting into air)
Biological consequences of heat depend on temperature rise and duration.

Tissues containing a large component of actively dividing cells are most sensitive to the effects of heat.
ACOUSTIC CAVITATION

Cavitation
Acoustic Cavitation

- Formation/activity of gas filled bubbles in an ultrasound exposed medium
- At MHz frequencies bubble radius ~1 µm
- Stable cavitation – bubbles oscillate
- Inertial cavitation – bubbles expand too far then collapse very rapidly, releasing enough energy to damage tissue

STABLE CAVITATION
How does the risk of heating & cavitation change with imaging conditions?
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- Contact time: Increase
- Output power: Increase
- Frequency: Decreasing importance
- Sector format: Heating
- Deeper/more focal zones: Heating
- Narrow sector format: Heating

Increase importance

Decreasing importance
Other Factors which may influence Heating and cavitation

Range Gate Width
(pulse length may vary with gate width)

Range Gate Depth
(power may increase with depth)

Doppler Velocity Range
(pulse repetition frequency may increase)

Receiver Gain
has **NO** effect on heating or cavitation

So ..... Maximise it!
Thermal Effects

A diagnostic exposure that produces a maximum \textit{in situ} temperature rise of no more than 1.5°C above physiological levels (37°C) may be used clinically without reservation on thermal grounds.

WFUMB 1992

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Thermal Effects

A diagnostic exposure that elevates embryonic and fetal \textit{in situ} temperature above 41°C (by 4°C) for \geq 5 \text{ min} should be considered to be potentially hazardous.

WFUMB 1992

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“On Screen” Labelling

Designed to provide safety related information

AIUM/NEMA Output Display Standard

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THERMAL INDEX (TI)

The Thermal index (TI) is an on-screen guide to the user of the potential for tissue heating.

Estimate of the tissue temperature rise in °C which might be possible under "reasonable worst-case conditions"
THERMAL INDEX

\[ TI = \frac{\text{Acoustic Power Output}}{(\text{Acoustic Power to produce a } 1^\circ \text{C rise})} \]

Soft tissue index

TIS

Bone

TIB

TIC - bone near transducer
The Mechanical index (MI) is an on-screen guide of the likelihood and magnitude of nonthermal effects.

\[ MI = \frac{p}{\sqrt{f}} \]

- **P**: in situ pressure
- **f**: frequency
Power setting

High power
low gain

Lower power
high gain

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From scientific evidence of ultrasound-induced biological effects to date, there is **NO REASON** to withhold diagnostic scanning during pregnancy, provided it is 

1. medically indicated
2. used prudently by fully trained operators.

**This includes routine scanning of pregnant women.**

**Ultrasound exposure during pregnancy**

With increasing mineralisation of fetal bones, the possibility of heating sensitive tissues such as brain and spinal cord increases. **So .... extra vigilance is advised**
3D imaging

No additional safety considerations (particularly if there are significant pauses during scanning to study or manipulate the reconstructed images)

4D imaging (real-time 3D)

Involves continuous exposure

Guard against prolonging examination times unduly to improve the recorded image sequence beyond that necessary for diagnostic purposes.
Doppler probes are associated with the greatest risk of heating.

Doppler - greatest cavitation risk (but still insignificant due to “high” frequency)
SAFETY OF ULTRASOUND CONTRAST AGENTS (UCAs)

Ultrasound contrast agents

Non-acoustic safety considerations
Toxicity of carrier medium
Size of micro-bubbles
Ionic composition, osmolarity, viscosity of carrier
Immunological or allergic reactions
**Ultrasound Contrast Agents (UCAs)**

- UCAs are not licensed for pregnancy
- Caution should be exercised when using in tissues for which damage to microvasculature may be important (e.g. eye, brain, neonate)
- Exercise caution when using UCAs in patients with severe coronary artery disease and pulmonary hypertension.

**Keep MI low, and avoid long exposure times**

Refer to EFSUMB CEUS guidelines (2011)

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**Recent developments**

**Elastography:**
1. Strain imaging
2. Shear wave imaging
3. ARFI
   (Acoustic Radiation Force Imaging)

New Contrast agents
Elastography Imaging (breast)

**Strain elastography** - stress applied by manual palpation

**Shear wave elastography** - stress applied by acoustic radiation force

Elastography safety

**Mechanical push:**
*No* safety concerns beyond those of B-mode imaging

**Acoustic radiation force (≤ 300 μs):**
~ 30 pulses per image
Ispta up to 100 mW/cm²
Thermocouple measurements of transducer heating of four consecutive ARFI acquisitions into a layer of ultrasonic transmission gel.

Between these the scanner is B-mode imaging. Temperature drop due to cessation of B-mode for ~500 ms.

**Elastography Conclusions**

Push pulses used in ARFI may lead to significant temperature rises

Displayed indices may be an underestimate
**Epidemiological safety studies**

Recent systematic reviews:

- Torloni MR. WHO systematic review of the literature and meta-analysis. UOG 2009;33:599-608
- Salvesen KÅ. Ultrasound in pregnancy and non-right handedness: meta-analysis of randomized trials. UOG 2011;38:267-71

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**Only one controversial issue**

Prenatal ultrasound is associated with left-handedness

Published studies

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**Meta-analysis**

Forrest plot from Salvesen UOG 2011;38:267-71

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**We should worry - why?**

- 5 epidemiological studies demonstrate an increased risk of left-handedness of 15-30%
- No other epidemiological study on ultrasound and handedness has been published
- Experimental studies indicate effects on the brain in some animal models
- Modern scanners produce higher outputs
We should not worry - why?

• Being left-handed is normal (10-15% of population)
• A statistical association does not imply a causal relationship
• The biological plausibility of this association is questionable

Safety Statements

European Committee for Medical Ultrasound Safety
www.efsumb.org/ecmus

British Medical Ultrasound Society
www.bmus.org

World Federation for Ultrasound in Medicine & Biology
wwwwfumb.org
Key principles for the safe use of ultrasound  
BMUS 2010

• 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 effect of machine settings on power levels.
Key principles for the safe use of ultrasound
BMUS 2010

- 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 (ALARA) 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.

http://www.bmus.org/policies-guides

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(ECMUS)
THE SAFE USE OF ULTRASOUND IN MEDICAL DIAGNOSIS

Available from BIR, BMUS and on the EFSUMB website.