Diagnostic Ultrasound

How do you know it’s SAFE?

EFSUMB Safety Committee
https://efsumb.org/safety-committee-ecmus/
Why are we concerned about safety?

- The range of clinical applications is expanding.
- The number of patients undergoing ultrasound examinations is increasing.
- New techniques with higher acoustic output levels are being introduced.
What are bio-effects?

The effects seen when ultrasound interacts with biological molecules as it passes through tissue.
Is a bio-effect likely to cause a problematic change (e.g. cell, gene or DNA damage)?
Mechanisms of Action

Heat ($I_{\text{spt}a}$, $P$)

Cavitation ($p_-$)

$I_{\text{spt}a}$ - spatial peak temporal average intensity (mW/cm$^2$)

$P$ - acoustic power (mW)

$p_-$ - peak-rarefractional acoustic pressure (kPa or MPa)
Interaction of Ultrasound with Tissue

Attenuation = Absorption + Scatter

INCIDENT BEAM

Absorption 60-80%

HEAT

Scatter 20-40%

IMAGE
Heating (Absorption)

Increases with:

- frequency
- exposure duration
- pulse repetition frequency
Shear Wave Elastography

Ultrasound modes and Heating potential

- Pulsed Doppler
- Colour Doppler
- Harmonic imaging
- M-mode
- B-mode 2D, 3D

Heating potential

Power
Transducer Self-Heating

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

- **B-Mode**
  - $I_{spta} = 11 \text{ mW/cm}^2$, $MI = 0.5$

- **Pulsed Doppler**
  - $I_{spta} = 533 \text{ mW/cm}^2$, $MI = 0.9$

- **Colour Doppler**
  - $I_{spta} = 606 \text{ mW/cm}^2$, $MI = 0.3$

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

- $T < 43 \, ^\circ\text{C}$ (for tissue contact & for invasive probes)  
  IEC 60601-2-37
- $T < 50 \, ^\circ\text{C}$ (emitting into air)  
  IEC 60601-2-37
Thermal Effects

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

- Formation/activity of gas filled bubbles in an ultrasound exposed medium
- At MHz frequencies bubble radius $\sim 1 \, \mu m$
- **Stable cavitation** – bubbles oscillate
- **Inertial cavitation** – bubbles expand too far then collapse very rapidly, releasing enough energy to damage tissue
Effects of inertial cavitation
How does the risk of heating & cavitation change with imaging conditions?

<table>
<thead>
<tr>
<th>Imaging conditions</th>
<th>Heating</th>
<th>Cavitation</th>
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</thead>
<tbody>
<tr>
<td>Contact time increase</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Output power increase</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Frequency increase</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Wide Sector format</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Narrow sector format</td>
<td>+</td>
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<tr>
<td>Deeper/more focal zones</td>
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</tbody>
</table>
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)
Gain

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

So … **Optimize** it!
Thermal Effects

A diagnostic exposure that produces a maximum *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 1997
Thermal Effects – embryo and foetus

A diagnostic exposure that elevates embryonic and fetal in situ temperature above 41°C (by 4°C) for ≥ 5 min should be considered to be potentially hazardous.
“On Screen” labelling

Designed to provide safety related information

AIUM/NEMA: Output Display Standard
The Thermal index ($TI$) is an on-screen guide to the user of the potential for tissue heating.

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

Estimate of the tissue temperature rise in $^\circ\text{C}$ which might be possible under "reasonable worst-case conditions".
Tissue specific THERMAL INDEX

Soft tissue:
soft tissue index \( TIS \)

Bone:
bone in the focus \( TIB \)
bone near transducer \( TIC \)
The Mechanical index \((MI)\) is an on-screen guide of the likelihood and magnitude of non-thermal effects.

\[
MI = \frac{p - f_{awf}}{\sqrt{f_{awf}}} \cdot C
\]

- \(p\): *in situ* peak-rarefractional pressure [MPa]
- \(f_{awf}\): acoustic working frequency [MHz]
- \(C\): factor \(C = \text{MHz}^{1/2}/\text{MPa}\)
Power setting

High power
low gain

Lower power
high gain
Diagnostic scanning during pregnancy

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 (as frequently as needed),
2. used prudently by fully trained operators.
Ultrasound exposure during pregnancy

With increasing mineralisation of foetal bones, the possibility of heating sensitive tissues such as brain and spinal cord increases.

So .... extra vigilance is advised!
Obstetric scanning

**THERMAL INDEX**

- **RECOMMENDED RANGE**: Provided adequate images can be obtained (especially in 1st trimester)
- **Not recommended** for OB scanning

**Recommended scanning time limits for these TIs (obey ALARA)**

- Monitor TIS up to 10 weeks post-LMP, TIB thereafter.

http://www.bmus.org
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.
Epidemiological safety studies

Why we should be worried:

- there are epidemiological studies indicating different associations on gestation or later development
- experimental studies indicate effects in some animal models
- new techniques often involve innovative pulsing regimes producing higher outputs
- modern scanners that are mobile, light and small are sometimes used by personnel with insufficient training
- the public or media interpret some outcomes of these studies wrongly or imprecisely and attract an audience
Epidemiological safety studies

Why we should not be worried:

- a statistical association does not imply a causal relationship in general
- some of these studies show statistical flaws or methodological errors
- from most of the studies the biological plausibility of this association is questionable
- some studies contain experimental settings and exposure durations not commonly used by skilled personnel
- safety committees regularly evaluate these studies
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.

- Guidelines and Good Clinical Practice Recommendations for Contrast Enhanced Ultrasound (CEUS) in the Liver–Update 2020
- The EFSUMB Guidelines and Recommendations for the Clinical Practice of Contrast-Enhanced Ultrasound (CEUS) in Non-Hepatic Applications: Update 2017
Safety Statements & Tutorials

European Committee for Medical Ultrasound Safety

www.efsumb.org

World Federation for Ultrasound in Medicine & Biology

www.wfumb.org

British Medical Ultrasound Society

www.bmus.org