Diagnostic Ultrasound

How do you know it's SAFE?

EFSUMB Safety Committee

https://efsumb.org/safety-committee-ecmus/

European Committee for Medical Ultrasound Safety

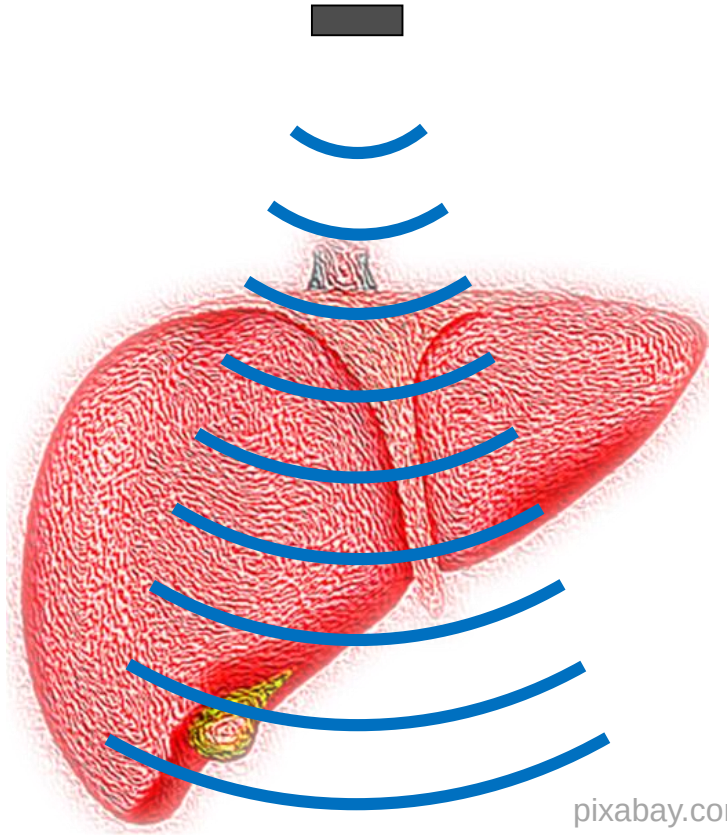
Version 03-2022

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.



pixabay.com

Safety

Is a bio-effect likely to cause a problematic change (e.g. cell, gene or DNA damage)

?

Mechanisms of Action

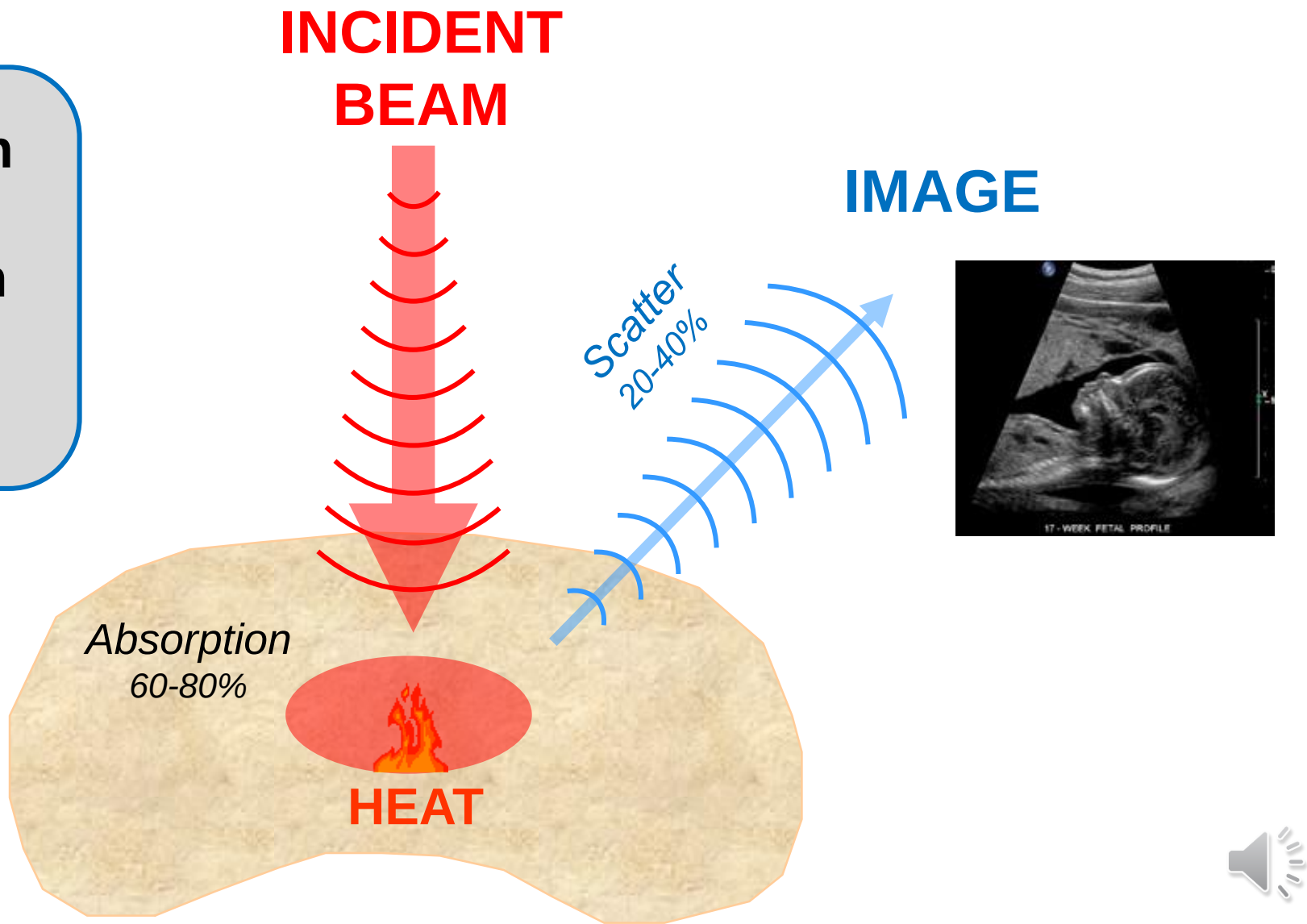
Heat (I_{spta}, P)

Cavitation (p_-)

I_{spta} - spatial peak temporal average intensity (mW/cm²)
P - acoustic power (mW)
p_- - peak-rarefactional acoustic pressure (kPa or MPa)

Interaction of Ultrasound with Tissue

Attenuation
=
Absorption
+
Scatter

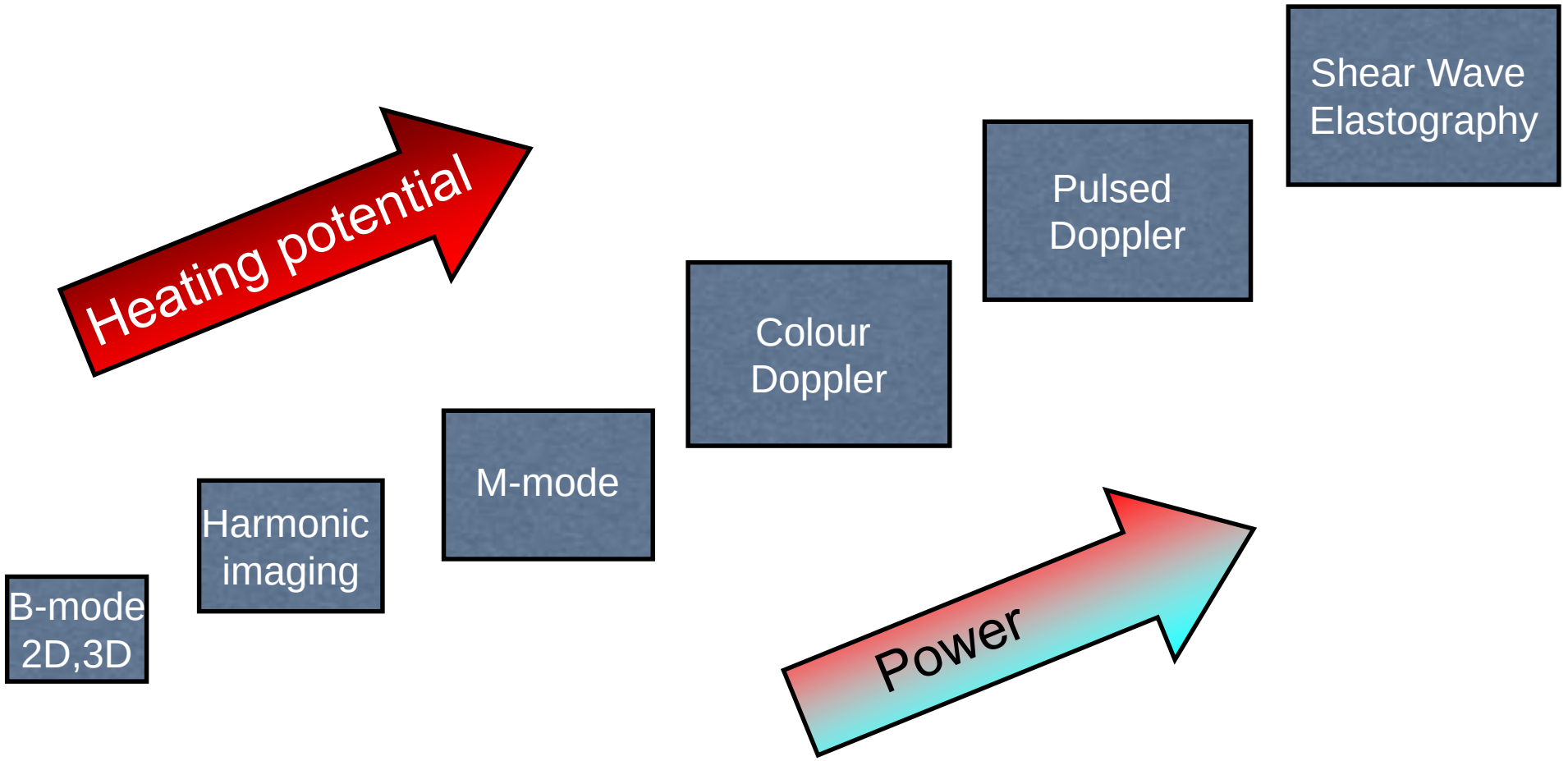


Heating (Absorption)

Increases with:

- frequency
- exposure duration
- pulse repetition frequency

Ultrasound modes and Heating potential



Heating

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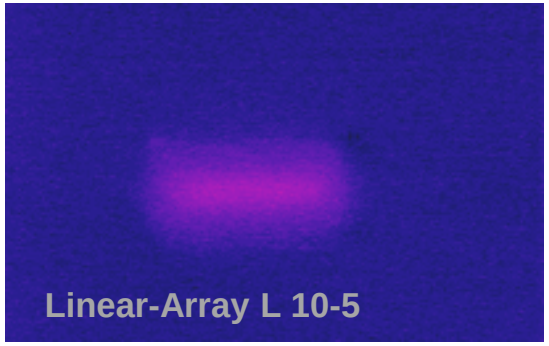
Transducer Self-Heating

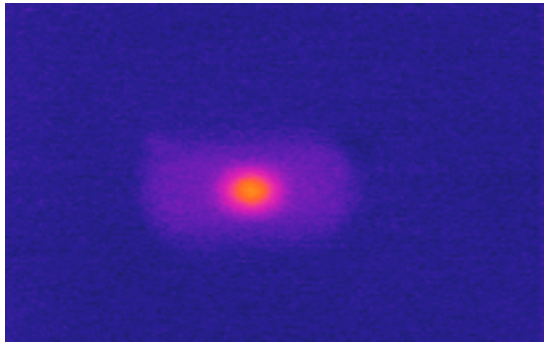
Temperature distribution due to probe self-heating for diagnostic devices (maximum) :

B-Mode



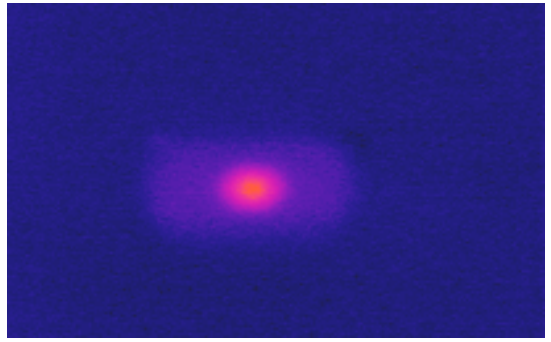
I_{spta} = 11 mW/cm², MI = 0,5

Pulsed Doppler

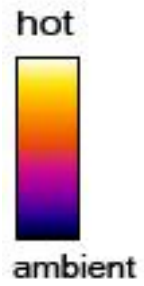


I_{spta} = 533 mW/cm², MI = 0,9

Colour Doppler



I_{spta} = 606 mW/cm², MI = 0,3



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

T < 43 °C (for tissue contact & for invasive probes)	IEC 60601-2-37
T < 50 °C (emitting into air)	IEC 60601-2-37

Thermal Effects

Heating

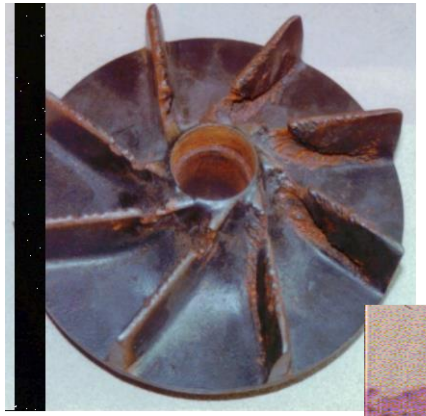
Biological consequences of heat depend on temperature rise and duration.

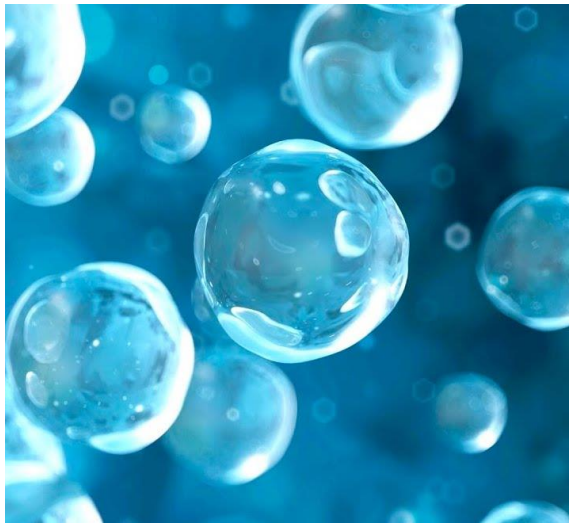
Tissues containing a large component of actively dividing cells are most sensitive to the effects of heat.

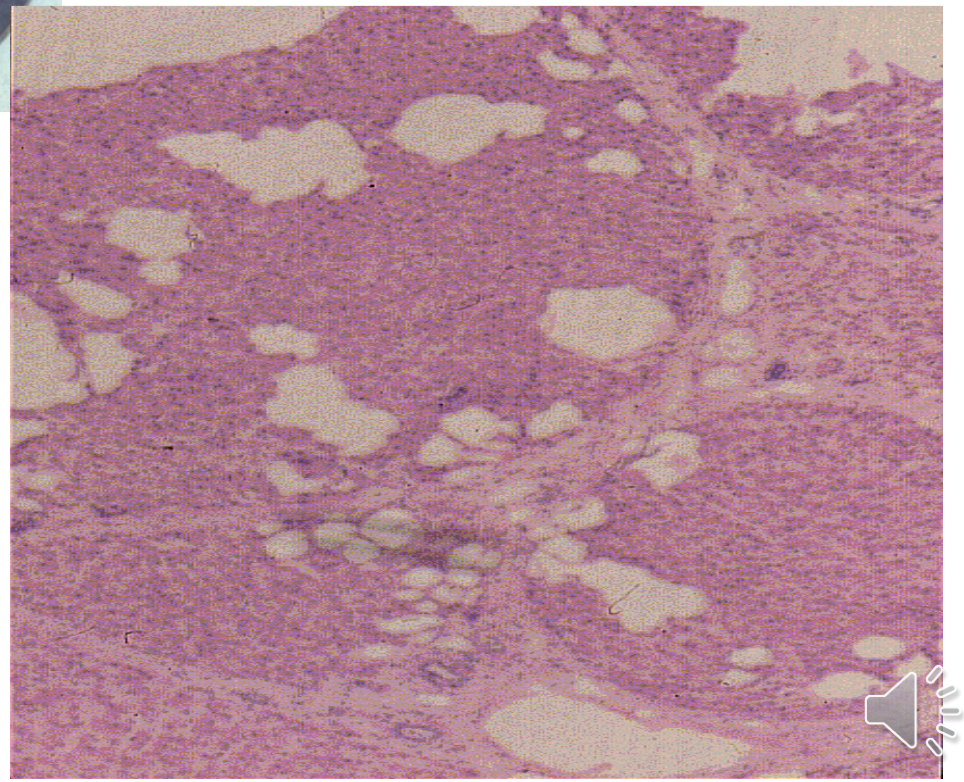
Acoustic Cavitation

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

Effects of inertial cavitation







Cavitation

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How does the risk of heating & cavitation change with imaging conditions?

Imaging conditions and risk

Contact time increase

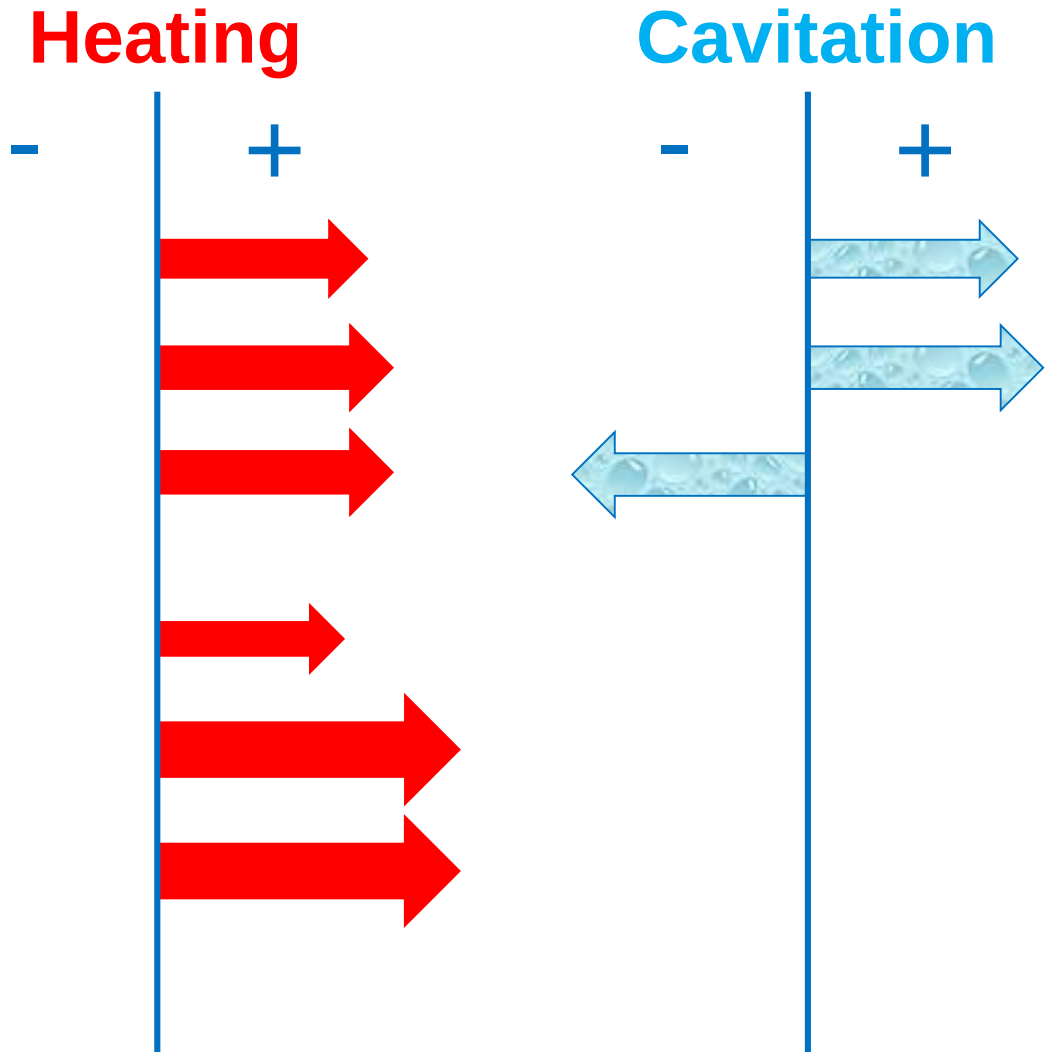
Output power increase

Frequency increase

Wide Sector format

Narrow sector format

Deeper/more focal zones



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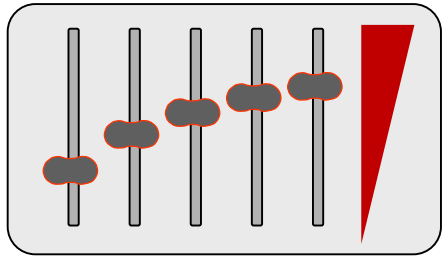
Factors which may influence heating and cavitation

- **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 …

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

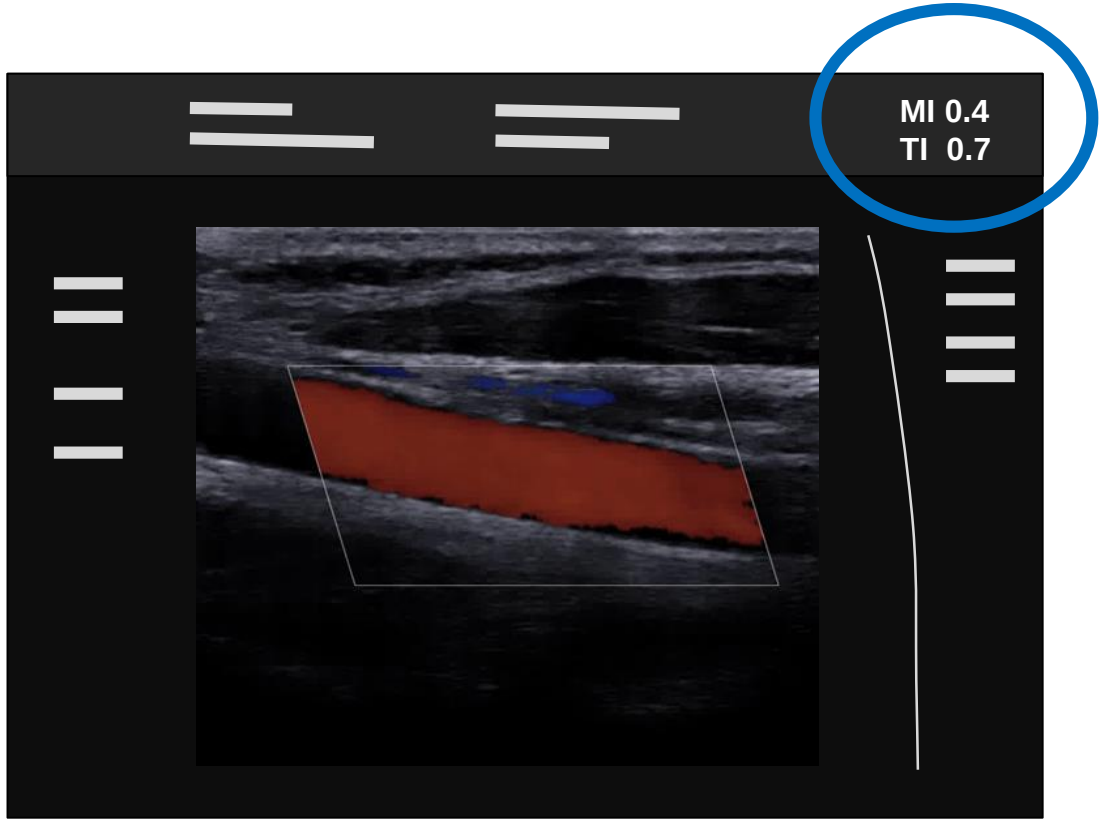
above 41°C (by 4°C) for ≥ 5 min

should be considered to be potentially hazardous.

pixabay.com

WFUMB 1997

“On Screen” labelling



Designed to provide safety related information

AIUM/NEMA:

Output **D**isplay **S**tandard

Output Display Standard - ODS

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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.

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

Estimate of the tissue temperature rise in ºC 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***

MECHANICAL INDEX (*MI*)

The Mechanical index (*MI*) is

an on-screen guide of the likelihood and magnitude of non-thermal effects.

$$MI = \frac{p_-}{\sqrt{f_{awf}}} \cdot C$$

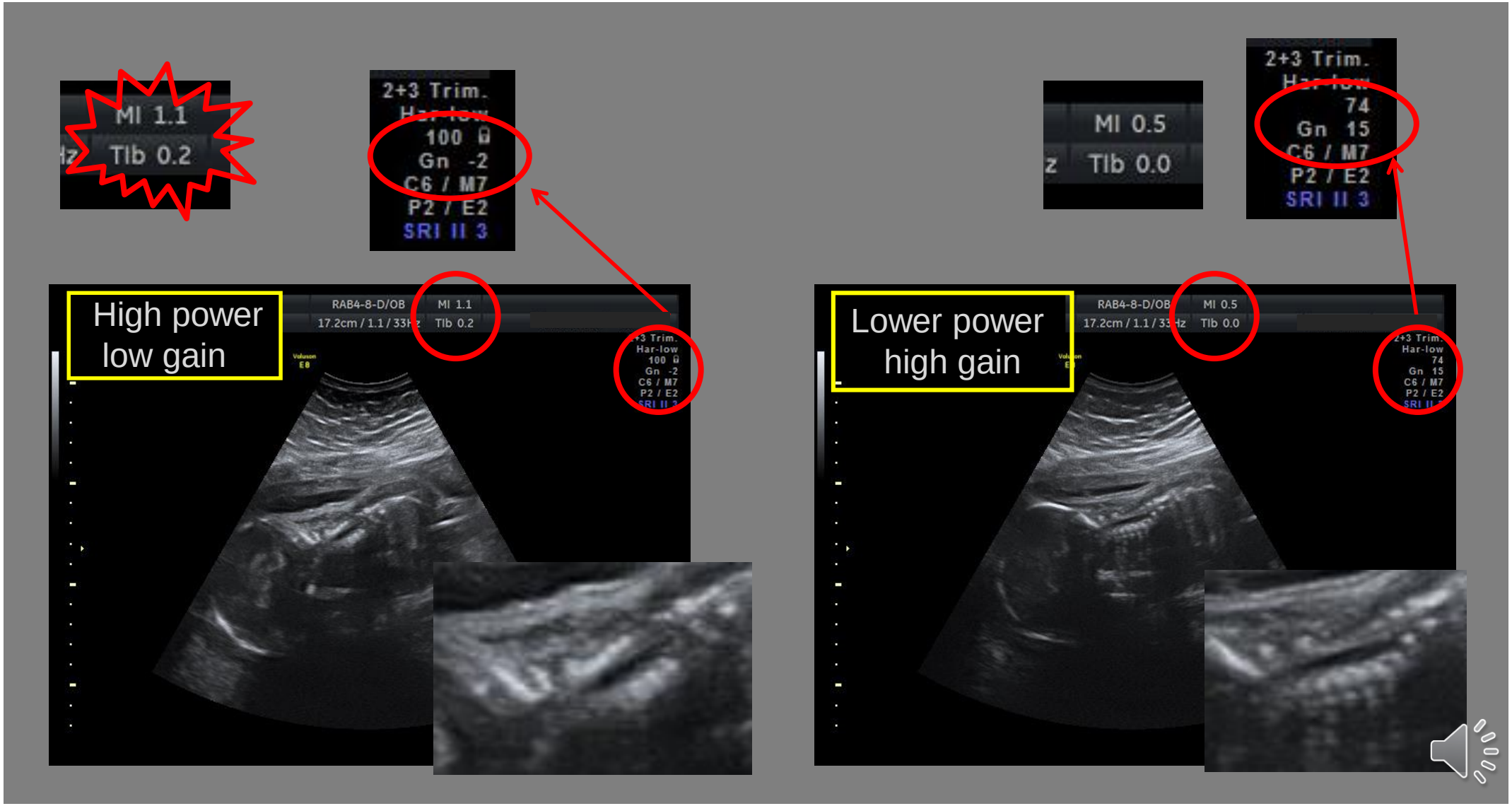
p_- : *in situ* peak-rarefactional pressure [MPa]

f_{awf}: acoustic working frequency [MHz]

C: factor C = $MHz^{1/2}$/MPa

Power setting

Output Display Standard - ODS



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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:

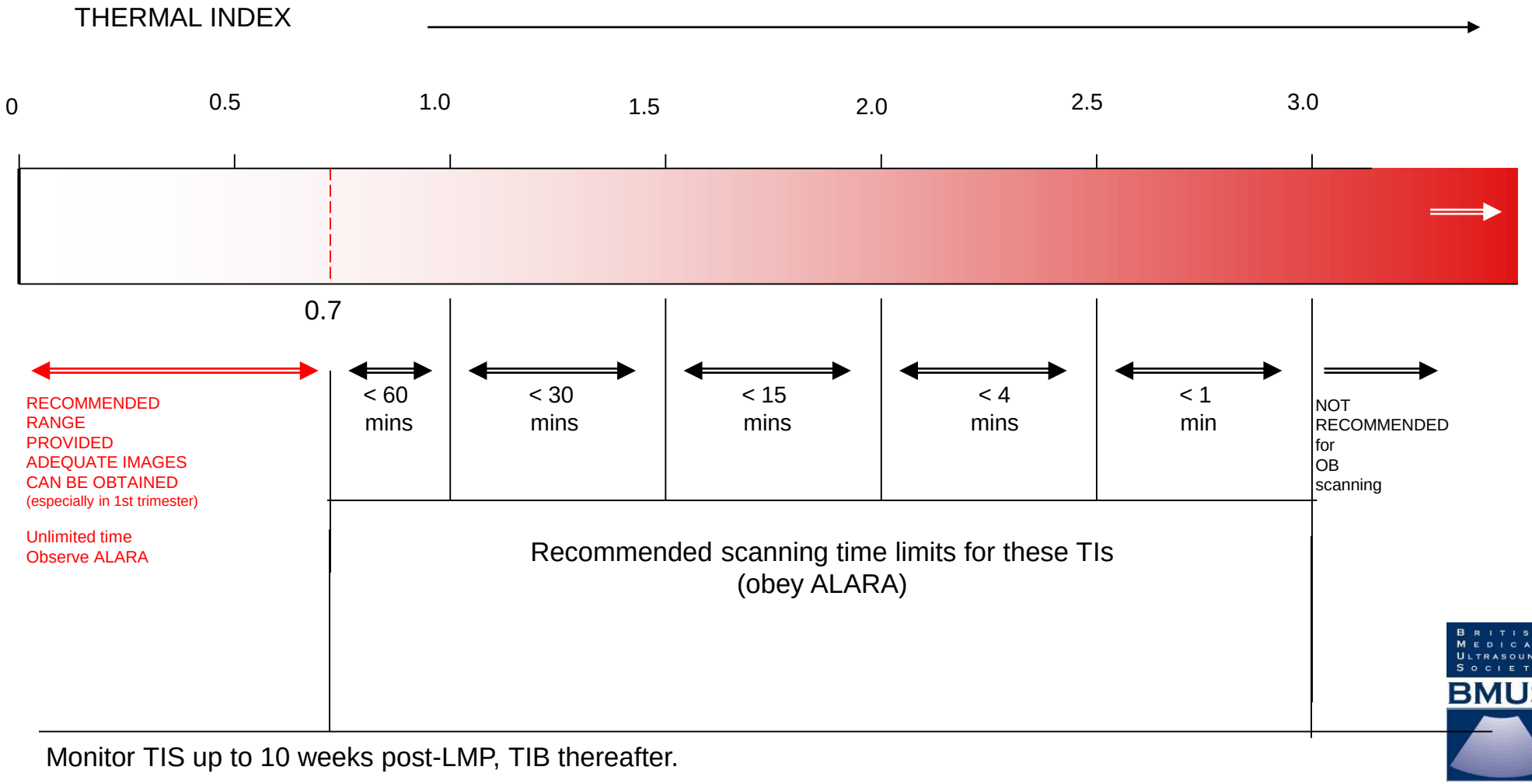
1. **medically indicated (as frequently as needed),**
2. **used prudently by fully trained operators.**

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



Ultrasound and pregnancy

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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 epidemological 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

Further information

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