Patient Safety: reducing Ultrasound ‘Doses’

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Prudent use of Ultrasound

US is non-ionising BUT since many bioeffects of ultrasound have not yet been studied fully, ‘prudent’ use is recommended

ALARA – as low as reasonably achievable (exposure)

In practice ‘prudent’ = justification + optimisation

Multiple Societies have issued Safety Statements (ISUOG, AIUM, BMUS, SOGC)

- No commercial demos on human subjects
- No training on students
- No ‘see baby just for fun’ or excessive screening in obstetrics

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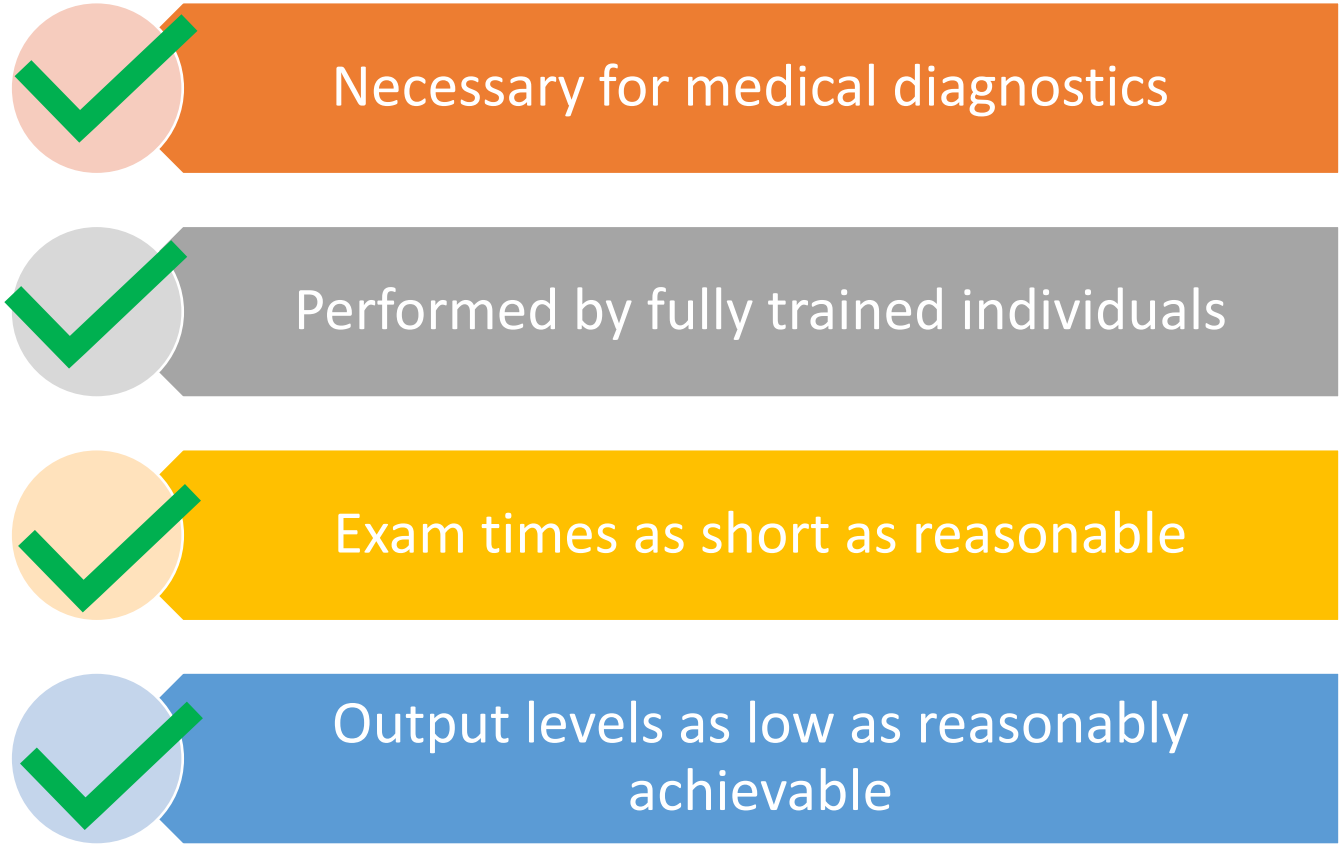


From BMUS “Guidelines for the Safe Use of Diagnostic Ultrasound Equipment”

Early Human Development

Gestation From LMP	Gestation from Conception/ fertilisation	Title of Conceptus	Major relevant events
0-14 days	Nil	-	-
14-28 days	0-14 days	Zygote	Rapid cell multiplication
29-70 days 4.1-10 weeks	15-56 days 2.1-8 weeks	Embryo	Organogenesis
10-11 weeks	8-9 weeks	Fetus	Ossification of spine starts
13-14 weeks	11-12 weeks	Fetus	Ossification of skull and long bone starts

Biological Effects

- Possible bioeffects: inactivation of enzymes, altered cell morphology, internal haemorrhage, free radical formation …
- Mechanisms of bioeffects:
  - Mechanical effects
    - Displacement and acceleration of biomolecules
    - Gas bubble **cavitation** (stable and transient) – see the lecture on biological effects of ultrasound
  - Thermal effects
    - absorption of ultrasound and therefore increase in temperature
    - high in lungs, less in bone, least in soft tissue
- All bioeffects are deterministic with a threshold (cavitation) or without it (heating)

Output Power from Transducer

- varies from one machine to another
- Increases as one moves from real-time 2D imaging to colour flow Doppler to spectral Doppler
- M-mode output intensity is low but dose to tissue is high because beam is stationary

Risk Indicators

- To avoid potentially dangerous exposures, two indices were introduced. Their values (different for different organs) are often displayed on device screens and should not be exceeded routinely
- Thermal Index (TI): TI = possible tissue temperature rise if transducer is kept stationary
  - TIS: soft tissue path
  - TIB: bone near focus of beam
  - TIC: Cranium (near surface bone)
- Mechanical Index (MI): measure of possible mechanical bioeffects

More on the TI and MI

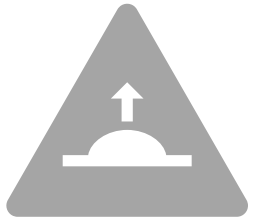
- **Thermal index** – device power divided by the power that would increased the temperature by one degree Celsius under conditions of minimum heat loss (without perfusion).

- **Mechanical index** (for assessment of cavitation-conditioned risk, increased danger when using echocontrast agents):

$$MI = I_{UZ} / \sqrt{f} \quad [W.cm^{-2}, MHz]$$

MI: Mechanical index

Rarely an issue



Relates to threshold for cavitation

Thought to be due to rarefaction during propagation of US wave

0.7 is the value chosen for cavitation in situations where contrast agents might be present

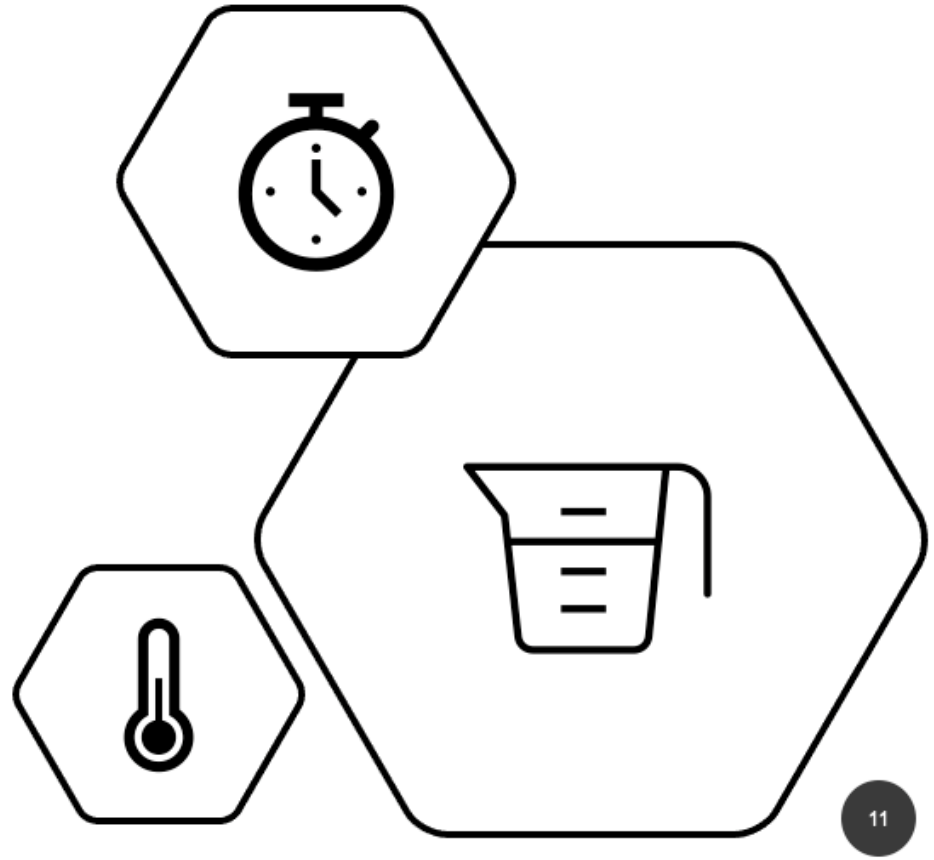
Otherwise, the possibility of cavitation is thought to be only a *theoretical* possibility

0.3 is the value for capillary bleeding in tissues of gas-containing organs (lung, bowel)

TI: Thermal index

- Ratio of emitted power to the power required raise the temperature of tissue by 1 ^{o}C

- Dependent on tissue insonated and the time exposed
  - TIS soft tissue and fetus <10wks
  - TIB most OB scanning
  - TIC

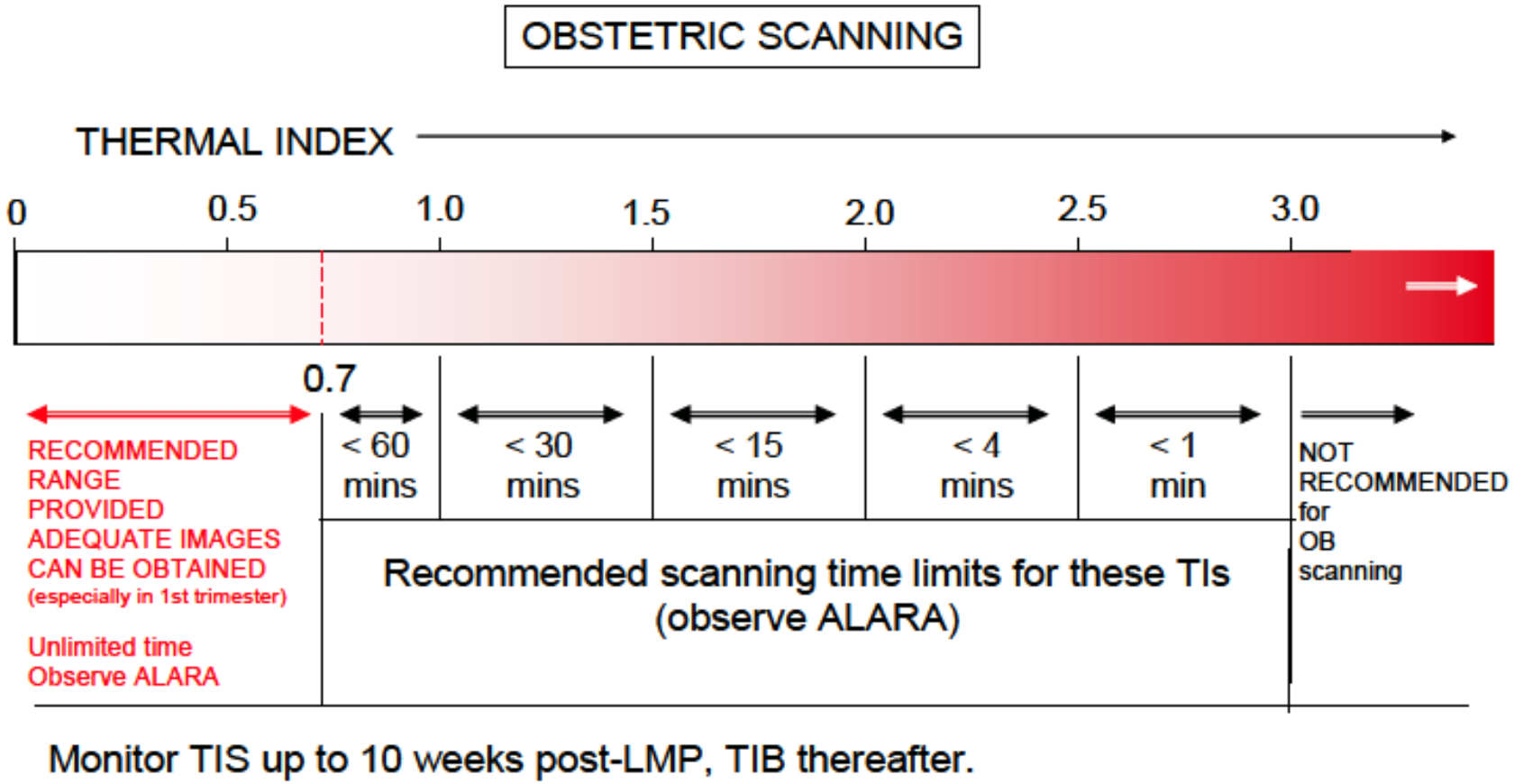


Theoretical tissue damage with elevation in temperature

Temperature elevation (°C)	Maximum exposure time (minutes)
5	1
4	4
3	16
2	64
1	256

But the extent to which the temperature is raised depends on scanning mode, exposure duration, and the tissue being scanned

TI Guidelines



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

General guidelines for both

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

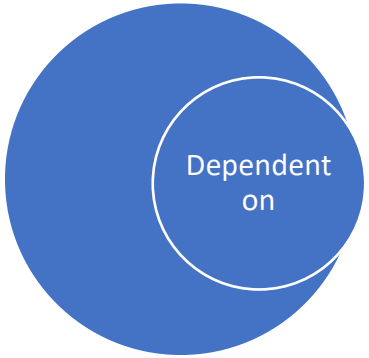
Application	Values to monitor (A)	Thermal Index value			Mechanical Index value		
		0 - 0.7	0.7 - 3.0	>3.0	0 - 0.3	>0.3	>0.7
Obstetrics up 10 weeks after LMP (and gynaecology when pregnancy is possible)	TIS and MI	✓	(B) restrict time to 0.7<TIS≤1.0 : 60 min 1.0<TIS≤1.5 : 30 min 1.5<TIS≤2.0 : 15 min 2.0<TIS≤2.5 : 4 min 2.5<TIS≤3.0 : 1 min	Scanning of an embryo or fetus is not recommended, however briefly	✓	✓	(E) risk of cavitation with contrast agents
Obstetrics more than 10 weeks after LMP	TIB and MI	✓	(B) restrict time to 0.7<TIB≤1.0 : 60 min 1.0<TIB≤1.5 : 30 min 1.5<TIB≤2.0 : 15 min 2.0<TIB≤2.5 : 4 min 2.5<TIB≤3.0 : 1 min	Scanning of an embryo or fetus is not recommended, however briefly	✓	✓	(E) risk of cavitation with contrast agents

mWatts/cm2: 720 limit

Used to be 94 mW/cm2 for OB scanners

Changed to 720 in 1992 ***BUT***

Vendors are now required to make machines able to display the MI and TI



- Operating mode
  - B mode
  - Color Doppler
  - Spectral Doppler
- Power output
- PRF
- Frequency

"Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" or ODS

Initial power setting	• Should be low
Exposure time	• As short as is reasonable
Probe position	• Should not be fixed if not acquiring information
Use of Doppler	• Monitor TI and use for only necessary, short times

Optimisation of ‘Dose’

Minimise	Check	Use	Start
Minimise TI and MI and use appropriate index (TIS, TIB, TIC), care in cases when these underestimate	Check acoustic power outputs on manual	Use high receiver gain when possible as opposed to high transmit power	Start scan with low transmit power and increase gradually

Optimisation of ‘Dose’

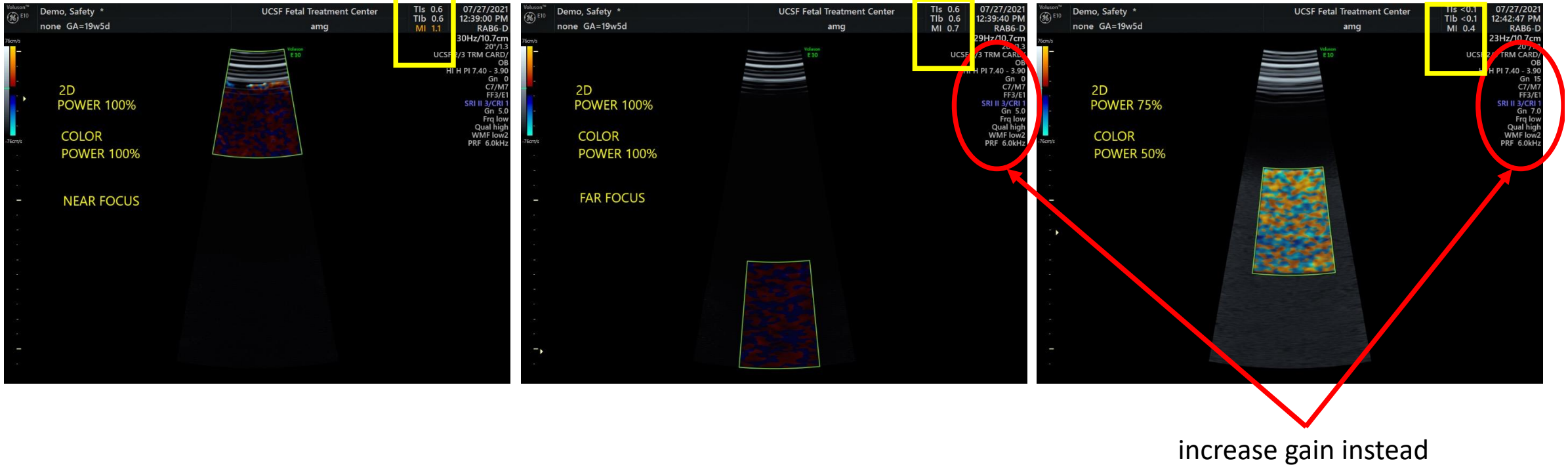
Avoid repeat scans and reduce exposure time

Consider avoiding scanning febrile gravidas

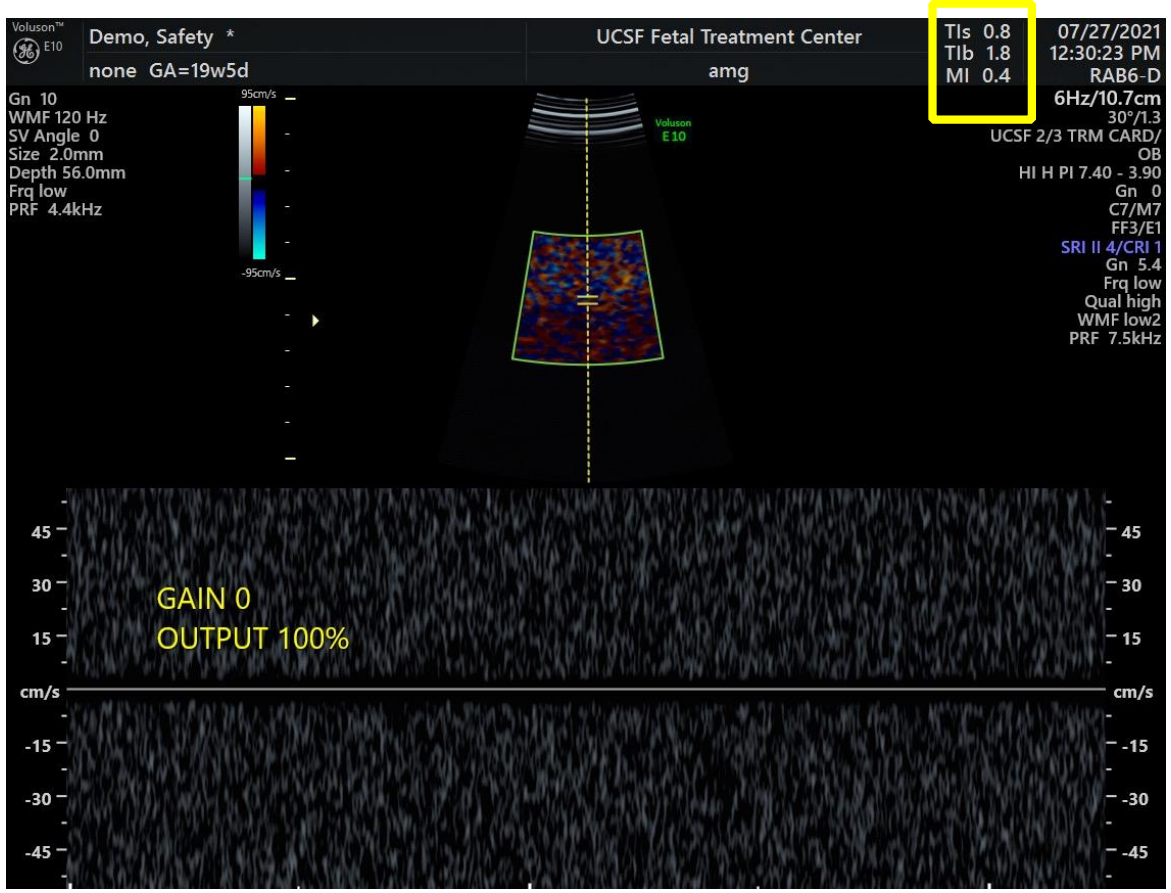
Do not hold transducer stationary

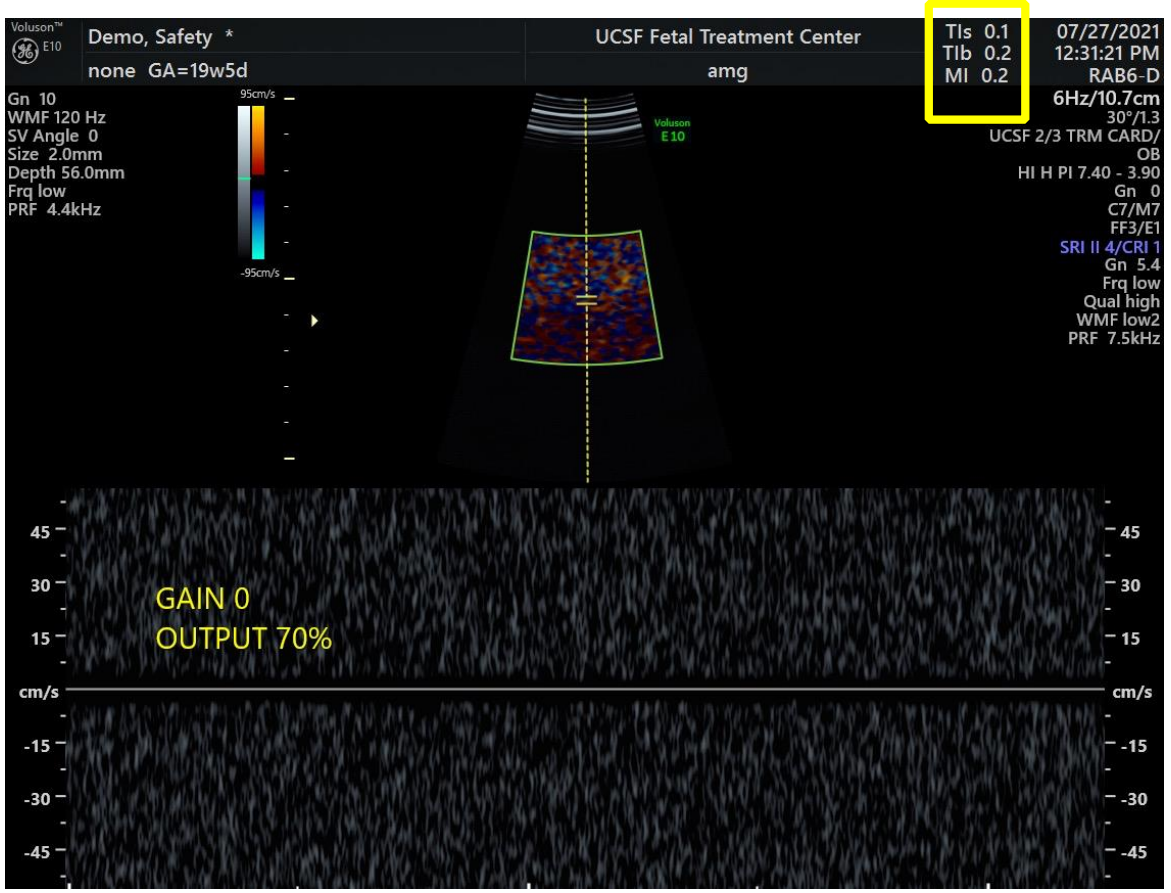
Greater care when using contrast agents as these increase the possibility of cavitation

Exceptional care must be taken in applying pulsed Doppler in obstetrics



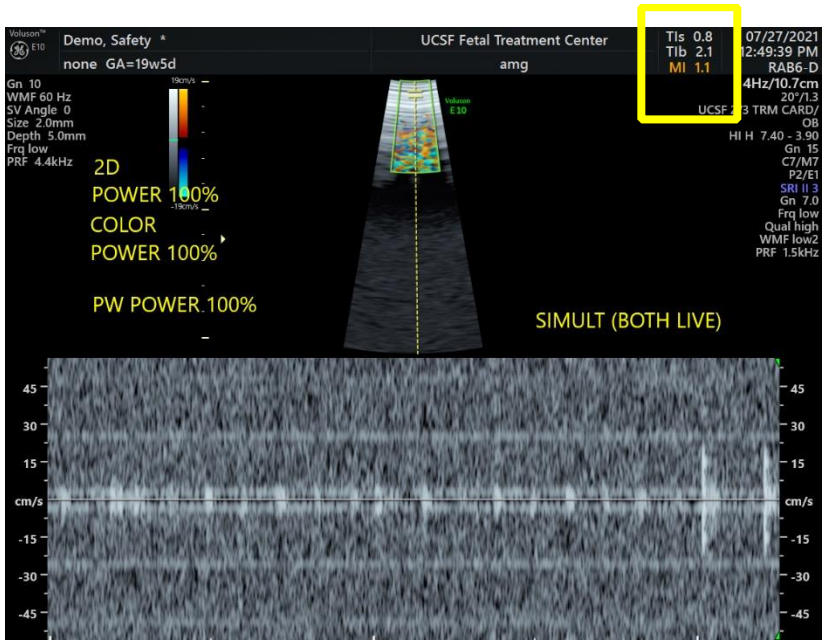
MI and effect of 2D focus and power output
TIb and power output-- use gain instead

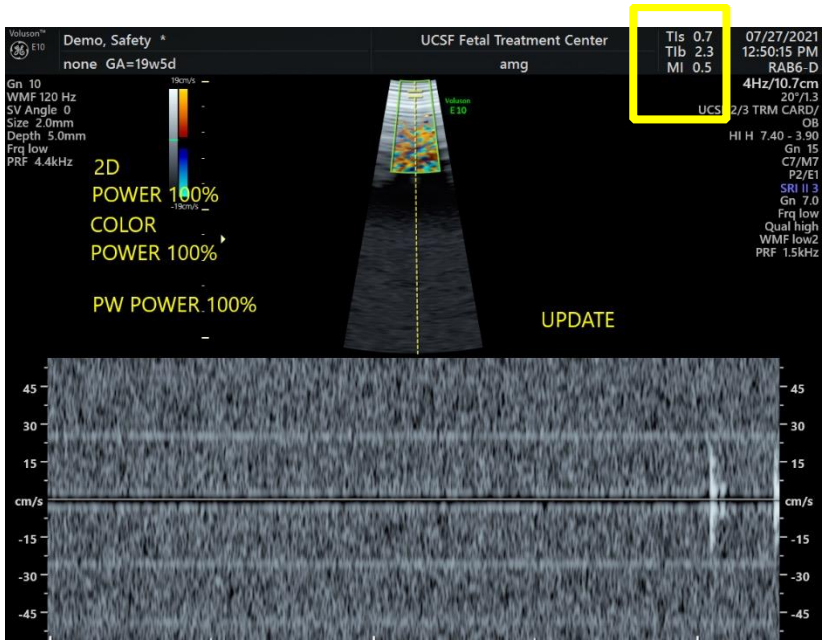




TIb and PW output

Use update to freeze reference image power down





Summary

- Application of ALARA
- Scans must be medically necessary
- MI should be kept as low as possible without compromising image; ideally <0.7
- TI </= 1.0-1.5 is preferable; over 3.0 should not be used
- If TI is 1.0-3.0, scan time should be kept as short as is reasonable (5-10 min suggested)

Summary

The recommendations are for theoretical situations based on modeling and animal work

There is no epidemiologic support for a causal relationship between medical diagnostic ultrasound and adverse effects on the fetus

References

Ultrasound Biosafety Considerations for the Practicing Sonographer and Sonologist *Thomas R. Nelson, PhD, J. Brian Fowlkes, PhD, Jacques S. Abramowicz, MD, Charles C. Church, PhD.* J Ultrasound Med 2009; 28:139–150

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