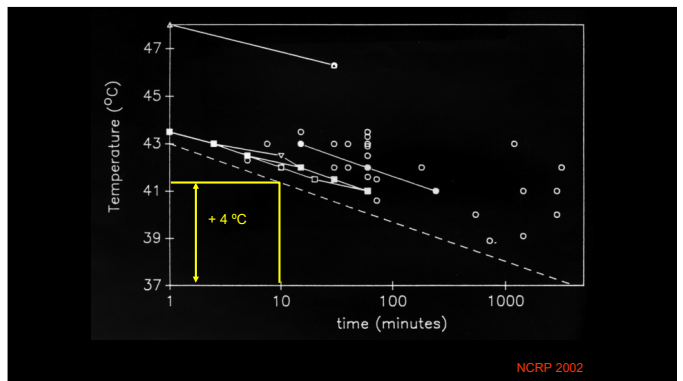
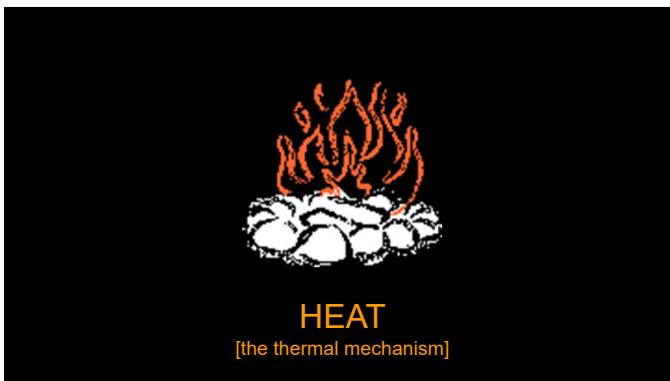
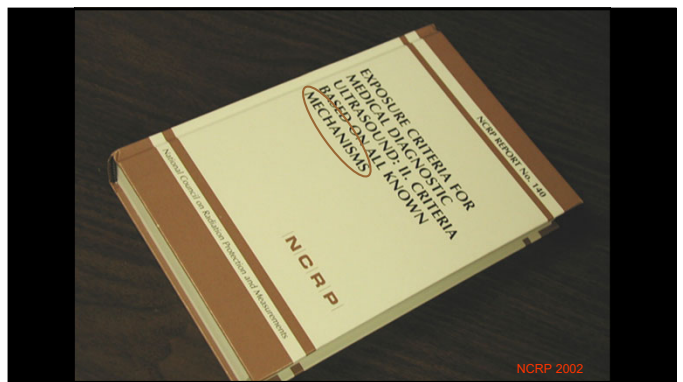
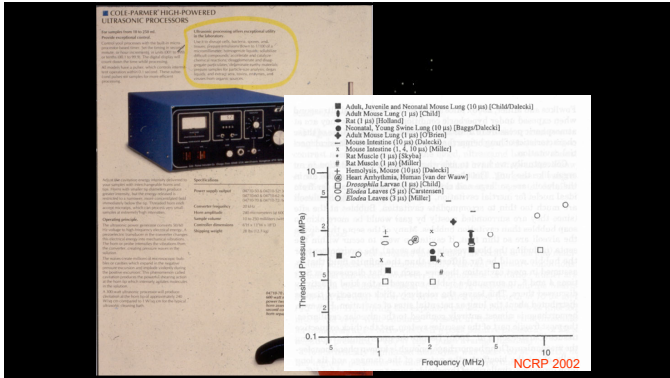


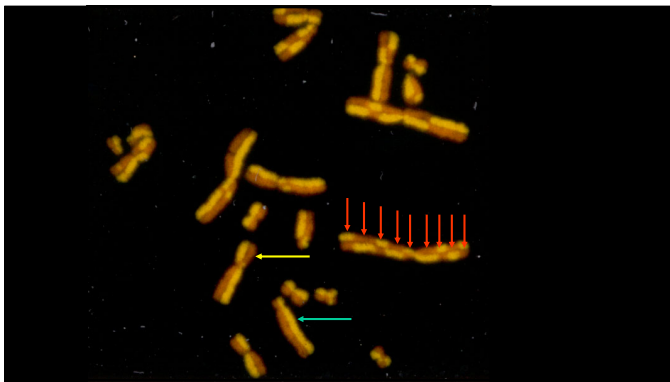
- Heating
- Cavitation
- Cellular Effects
- Mammalian Effects
- Epidemiology
- Prudent Use
- ALARA Principle
- Output-Display Standard





Experimental Studies

- Cells
- Plants
- Animals
- Humans



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In Vitro Biological Effects

It is often difficult to evaluate reports of ultrasonically induced in vitro biological effects with respect to their clinical significance. An in vitro effect can be regarded as a real biological effect. However, acoustic exposures^{1,2} and predominant physical and biological interactions and mechanisms involved in an in vitro effect may not pertain to the in vivo situation. Results from in vitro experiments suggest new end points and serve as a basis for design of in vivo experiments. In vitro studies provide the **capability to control experimental variables that may not be controllable in vivo and thus offer a means to explore and evaluate specific mechanisms and test hypotheses.** Although they may have limited applicability to in vivo biological effects, such studies can disclose fundamental cellular or extracellular effects of ultrasound. Although it is valid for authors to place their results in context and to suggest further relevant investigations, extrapolations to clinical practice should be viewed with caution.

References
 1. Edmonds PD, Abramowitz JS, Carson PL, Carstensen EL, Sandstrom KL. Guidelines for *Journal of Ultrasound in Medicine* authors and reviewers on measurement and reporting of acoustic output and exposure. *J Ultrasound Med* 2003; 24:1173-1179.
 2. ter Haar G, Shaw A, Dye G, et al. Guidance on reporting ultrasound exposure conditions for bioeffects studies. *Ultrasound Med Biol* 2011; 37:177-183.

Approved: 03/19/2007; Reapproved: 04/01/2012, 04/07/2019

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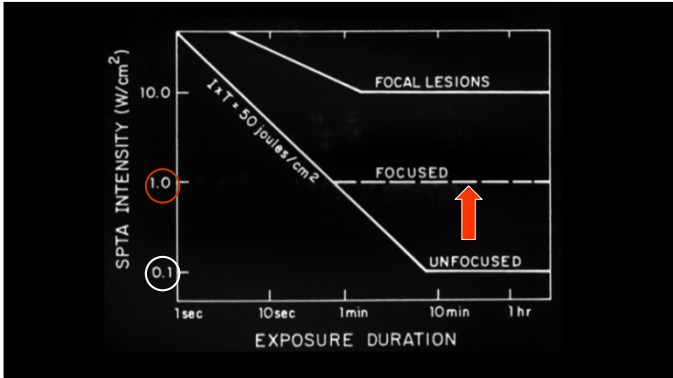
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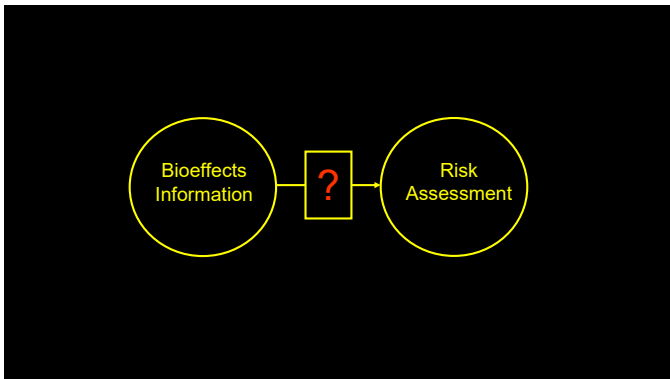
Statement on Mammalian Biological Effects of Ultrasound in Vivo

Information from experiments using laboratory animals has contributed significantly to our understanding of ultrasonically induced biological effects and the mechanisms that are most likely responsible. Adverse biological effects have been observed in some animal models under conditions that may be achieved by using diagnostic scanners (see associated specific statements). The following statement summarizes observations relative to mammalian diagnostic ultrasound parameters and indices.

In the low-mechanical frequency range, there have been no independently confirmed adverse biological effects to mammalian tissues exposed to in vivo under experimental ultrasound conditions, as follows:

- Thermal Mechanisms**
 - No effects have been observed for an unfocused beam having free field spatial peak temporal average (SPTA) intensities¹ below 100 mW/cm², a focus² beam having intensities below 10W/cm², or temperature increases of less than 1.0 °C.
 - For field exposures, no effects have been reported for a temperature increase above the normal physiological temperature, 37 °C, when 2.7-4.3 (Diagnostic Ultrasound) index 1 exposures (see range from 1 to 200 minutes, including off time for pulse exposures).
 - For point-of-exposure producing temperature increases of 0.5°C or less, no effects have been reported when 2.7-6 (Diagnostic Ultrasound) including off time for point exposures, for research, for temperature increases of 0.5°C and 2.0°C, the corresponding index 1 to 200 minutes, including off time for pulse exposures.
 - For point-of-exposure producing temperature increases of 0.5°C or higher, no effects have been reported when 2.7-6 (Diagnostic Ultrasound) including off time for point exposures, for research, for a temperature increase of 0.5°C, the corresponding index 1 to 200 minutes, including off time for pulse exposures [See AIUM "Statement on Mammalian Biological Effects of Ultrasound"]
- Nonthermal Mechanisms**
 - For diagnostic ultrasound exposures by actual medical devices in laboratory equipment, no adverse effects have been observed in tissues containing naturally occurring gas bodies that in some cases mechanical pressure before approximately 0.2 MPa (estimated mechanical index [MI] values less than 0.4) (see AIUM "Statement on Mammalian Biological Effects of Ultrasound")
 - For contrast-enhanced diagnostic ultrasound, no adverse effects in mammalian tissue in vivo have been reported and independently confirmed for in vivo below:





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Prudent Use and Safety of Diagnostic Ultrasound in Pregnancy

Based on the epidemiologic data available and on current knowledge of interactive mechanisms, there is insufficient justification to warrant conclusion of a causal relationship between diagnostic ultrasound and recognized adverse effects in humans...

Fetal Heart Rate Evaluation
Doppler Ultrasound During 11- to 14-Week Scans (or Earlier in Pregnancy)
Keepsake Fetal Imaging
References

Approved: 05/19/2020;

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WFUMB Safety Statement on Doppler Ultrasound in Pregnancy
 On January 27, 2011, the World Federation for Ultrasound in Medicine and Biology (WFUMB) Administrative Council approved the following statement on the safe use of Doppler ultrasound during 11- to 14-week scans (or earlier in pregnancy):
 Pulsed Doppler (spectral, power, and color flow imaging) ultrasound should not be used routinely.
 Pulsed Doppler ultrasound may be used for clinical indications such as to refine risks for trisomies.
 When performing Doppler ultrasound, the displayed thermal index (TI) should be less than or equal to 1.0, and exposure time should be kept as short as possible (usually no longer than 5-10 minutes) and not exceed 60 minutes.
 When using Doppler ultrasound for research, teaching, and training purposes, the displayed TI should be less than or equal to 1.0, and exposure time should be kept as short as possible (usually no longer than 5-10 minutes) and not exceed 60 minutes. Informed consent should be obtained.
 In educational settings, discussion of first-trimester pulsed or color Doppler should be accompanied by information on safety and bioeffects (eg, TI, exposure times, and how to reduce the output power).
 When scanning maternal uterine arteries in the first trimester, there are unlikely to be any fetal safety implications as long as the embryo/fetus lies outside the Doppler ultrasound beam.

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Prudent Clinical Use and Safety of Diagnostic Ultrasound

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use. No independently confirmed adverse effects caused by exposure from present diagnostic ultrasound instruments have been reported in human patients in the absence of contrast agents. Biological effects (such as localized primary bleeding) have been reported in experimental mammalian systems at diagnostically relevant exposures, but the clinical relevance of such effects is either not significant or is not yet known. Increased outputs and time of exposure can increase the likelihood of bioeffects. Ultrasound should be used only by qualified health professionals to provide medical benefit to the patient.

References

1. American Institute of Ultrasound in Medicine, Official Statements: As Low As Reasonably Achievable (ALARA) Principle. American Institute of Ultrasound in Medicine website. <https://www.aium.org/officialStatements/39>. Reapproved April 2, 2014.
2. American Institute of Ultrasound in Medicine, Official Statements: Recommended Maximum Scanning Times for Displayed Thermal Index (TI) Values. American Institute of Ultrasound in Medicine website. <https://www.aium.org/officialStatements/50>. Approved October 30, 2016.

Approved: 03/19/2007; Reapproved: 04/01/2012, 05/20/2019

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As Low As Reasonably Achievable (ALARA) Principle

The potential benefits and risks of each examination should be considered. The as low as reasonably achievable (ALARA) principle should be observed when adjusting controls that affect the acoustic output and by considering both the transducer dwell time and overall scanning time. Practicing ALARA requires that users do all of the following:

1. Apply correct examination presets if built into the diagnostic ultrasound device. The review of manufacturer default presets for appropriateness is encouraged.
2. Adjust the power to the lowest available setting that provides diagnostic-quality images. If appropriate, reduce power at the end of each examination so the next user will start with the lowest acoustic output setting.
3. Monitor the mechanical index (MI) and thermal index (TI), and related duration limitations for the type of examination being performed.^{1,2}
4. Move/tilt the transducer when stationary imaging is not necessary to reduce the dwell time on a particular anatomic structure. When possible, avoid fields of view that include sensitive tissues such as the eye, gas-filled tissues (lung and intestines), and fetal calcified structures (skull and spine).
5. Minimize the overall scanning time to that needed to obtain the required diagnostic information.

References

1. American Institute of Ultrasound in Medicine, Recommended maximum scanning times for displayed thermal index (TI) values. American Institute of Ultrasound in Medicine website. <https://www.aium.org/resources/statements.aspx>. Approved October 30, 2016.
2. American Institute of Ultrasound in Medicine, Medical Ultrasound 3rd ed. Laurel, MD: American Institute of Ultrasound in Medicine; 2014.

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Recommended Maximum Scanning Times for Displayed Thermal Index (TI) Values

The following two tables contain recommended maximum times for the duration of an ultrasound exposure at a given setting of the Thermal Index (TI). These recommendations for maximum scanning time vs. TI are intended to provide reasonable assurance that an ultrasound examination can be conducted without risk of producing an adverse effect due to a thermal mechanism under any scanning conditions. If it is necessary to exceed the recommendations, the occurrence of an adverse thermal effect is still unlikely under most scanning situations due to mitigating factors such as transducer movement and perfusion. However, the principle of ALARA should be followed for the examination times as only as long as necessary to produce a useful diagnostic result. See the AIUM Statement "As Low as Reasonably Achievable (ALARA) Principles".

Table 1. Recommended maximum scanning time and TI ranges for obstetric (including gynecologic when pregnancy is possible), neonatal, transcranial, and neonatal spinal examinations. For obstetric exams, scanning the TIS is recommended up to 10 weeks from the last menstrual period (LMP) and TIB thereafter.

TI range	Max Scanning Time (minutes)
3.0 < TI	Not recommended
2.0 < TI <= 3.0	<15
1.5 < TI <= 2.0	<45
1.0 < TI <= 1.5	<90
0.7 < TI <= 1.0	<60
TI <= 0.7	No time limit

1/31/2021 Official Statement https://www.aium.org/official-statements/01_31_2021_t1_max_scanning_time

Table 2. Recommended maximum scanning time and TI ranges for adult transcranial, general abdominal, peripheral vascular, neonatal (except head and spine), and other scanning examinations (except the eye).

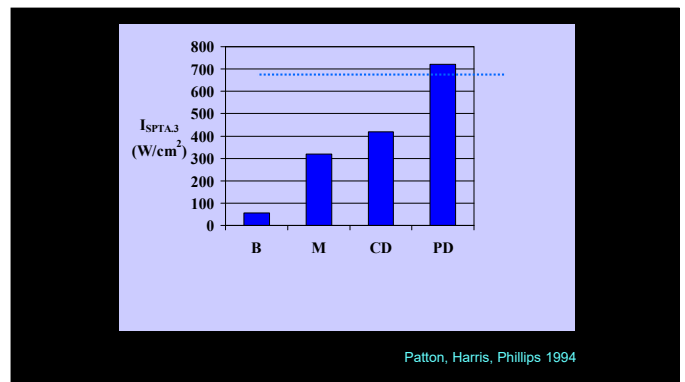
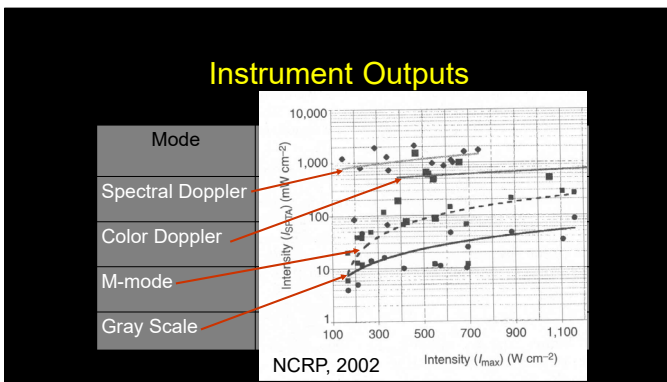
TI range	Max Scanning Time (minutes)
6.0 < TI	Not recommended
5.0 < TI <= 6.0	<15 (15 s)
4.0 < TI <= 5.0	<15
3.0 < TI <= 4.0	<45
2.0 < TI <= 3.0	<15
1.5 < TI <= 2.0	<60
1.0 < TI <= 1.5	<120
TI <= 1.0	No time limit

Harris GR, Church CC, Dalacki D, Ziskin MC, Bagley JE. Comparison of thermal safety practice guidelines for diagnostic ultrasound exposures. *Ultrasound Med Biol* 2015; 42:345-357.

Approved: 06/20/2016
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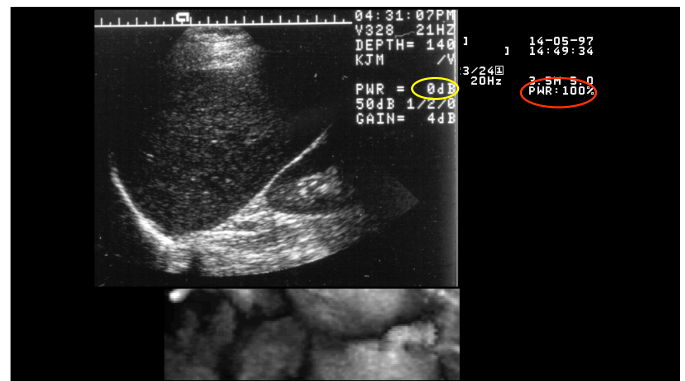
ALARA
As Low As Reasonably Achievable

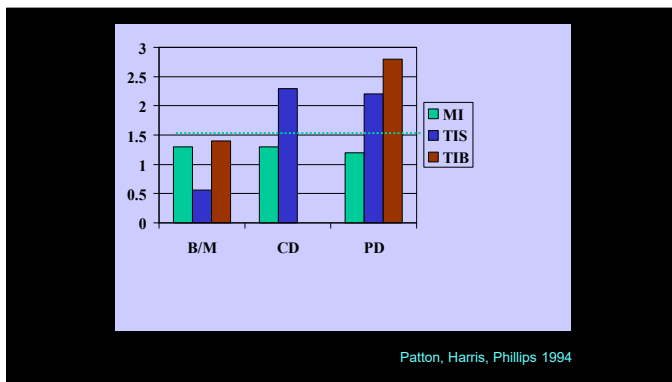
DOP



FDA LEVELS

USE	I _{spta} (mW/cm²)	I _{sppa} (W/cm²)
PV	720	190
cardiac	430	190
fetal/other	94	190
ophthalmic	17	28





A Heating
L Cavitation
A Cellular Effects
R Mammalian Effects
A Epidemiology
R Prudent Use
A ALARA Principle
A Output-Display Standard

THE WALL STREET JOURNAL

Pregnant Women Get More Ultrasounds, Without Clear Medical Need

Experts say frequent fetal scans in low-risk pregnancies aren't medically justified

By KEVIN HELLERER
 Updated July 11, 2015 at 9 p.m. ET

During her pregnancy, Melissa Skowrosky estimates she underwent a dozen fetal ultrasounds. "I was just happy to get my pictures," she says of the scans. "I just kept them in my little album."

Her experience isn't uncommon. American women have been getting fetal ultrasound scans at a higher rate than before, and parents have turned to the images of their unborn love for comfort and reassurance.

In 2014, scans in the U.S. of the most common fetal ultrasound procedures averaged a 3-year delivery, up from 2006, according to an analysis of data compiled for The Wall Street Journal by FAIR Health Inc., a nonprofit aggregator of insurance claims. Some women report getting scans at every doctor visit during pregnancy.

But medical experts are now warning that frequent scans in low-risk pregnancies aren't medically justified. A joint statement in May 2014 from several medical societies, including the American College of Obstetricians and Gynecologists, calls for one or two ultrasounds in low-risk, uncomplicated pregnancies.

"Ultrasound should be used only when clinically indicated, for the shortest amount of time," the statement said, referring to ultrasound scans, "and with the lowest level of acoustic energy compatible with an accurate diagnosis."

	AIUM	BMUS (FUSMB)	ISUOG	WFUMB	ASUM
B-Mode	No contraindication (see exposure).	No reason to withhold B-Mode or M-Mode.	No contraindication. Use only with clear indication.	Not contraindicated on thermal grounds.	Exercise prudent use.
Exposure levels	Use lowest available power for shortest time possible to obtain diagnostic information (ALARA).	Detailed instructions regarding T1 levels and time of exposure.	Keep exposure level and time at minimum to obtain adequate diagnosis.	Exposures resulting in temperature < 38.5°C can be used without reservation.	Pay attention to indicator of risk (T1 or MI).
Thermal effects	Only when using contrast agents.			Diagnostic exposure that produces a maximum temperature rise of 1.5°C above normal physiological levels may be used clinically without reservation on thermal grounds.	Same as WFUMB.
Non-Thermal (mechanical) effects		Caution with contrast agents.		Caution with contrast agents.	Caution with contrast agents.
First trimester exposure	Use Doppler with caution. Do not use routinely. Keep T1 < 1.	Use caution, particularly with pulsed and color Doppler.	Use Doppler with caution. Keep T1 < 1.	Do not use Doppler routinely. Keep T1 < 1.	Minimize power. Keep T1 < 1.

Courtesy Jacques Abramowicz, MD, Univ. Chicago

