Is Ultrasound Safe for My Baby?

Third WHO Global Forum on Medical Devices
Geneva, May 11, 2017
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University of Chicago and WFUMB
I have no conflict of interest with respect to any of the material presented in this lecture. I will not discuss off-label or unapproved uses of drugs or devices.
World Federation for Ultrasound in Medicine and Biology

WFUMB helps bring sustainable ultrasound programs to the underserved areas of the world to improve global healthcare through collaboration, communication, and education.

AFSUMB  Asian Federation of Societies for Ultrasound in Medicine and Biology
AIUM    American Institute of Ultrasound in Medicine
ASUM    Australasian Society for Ultrasound in Medicine
EFSUMB  European Federation of Societies for Ultrasound in Medicine and Biology
FLAUS   Federación Latinoamericana de Sociedades de Ultrasonido en Medicina y Biología
MASU    Mediterranean and African Society of Ultrasound

6 Member organizations
89 Countries
51,155 Individual members
WFUMB runs 13 COEs

Bangladesh Society of Ultrasonography (BSU), Bangladesh, established in 2004
Uganda Association of Sonography (UGASON), Uganda, established in 2004
Sociedad Venezolana de Ultrasonido en Medicina (AVUM), Venezuela, established in 2005
Romanian Society of Ultrasound in Medicine and Biology, Romania, established in 2007
Indonesian Society of Ultrasound in Medicine, Indonesia, established in 2011
Kenya Society of Ultrasound in Medicine and Biology (KESUMB), Kenya, established in 2013
Mongolian Society of Diagnostic Ultrasound (MSDU), Mongolia, established in 2013
Nigerian Society of Ultrasound Practitioner (NSUP), Nigeria, established in 2013
Societe Togolaise D'Ultrasonographie Medicale, Togo, established in 2013
Ethiopian Ultrasound Society, Ethiopia, established in 2014
Sociedad Paraguaya de Ecografia, Paraguay, established in 2015
Khartoum, Sudan, accepted to establish in 2017
Chisinau, Moldavia, accepted to establish in 2017
WHY DO WE SPEAK ABOUT SAFETY OF ULTRASOUND?

Questions about Prenatal Ultrasound and the Alarming Increase in Autism

by Caroline Rodgers

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[Editor’s note: This article first appeared in Midwifery Today Issue 80, Winter 2006.]
Should the practitioner worry?
Should the Mom (and Dad) worry?
Should the fetus worry?
Why is there even a talk about this at the 2017 WHO Global Forum on Medical Devices?

We all know ultrasound is safe
Ultrasound is not Thalidomide
Ultrasound is not X-Rays
Ultrasound = Energy

Ultrasound = waveform with positive and negative pressures
Acoustic energy is transformed into heat
## NON-THERMAL EFFECTS (DIRECT)

<table>
<thead>
<tr>
<th>Positive pressure</th>
<th>Negative pressure (mostly) can cause cavitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation stress</td>
<td>Inertial (a.k.a. transient): growth and violent collapse of the bubble</td>
</tr>
<tr>
<td>Acoustic streaming</td>
<td>Non-inertial: back and forth motion of bubbles</td>
</tr>
<tr>
<td>Nerve ending stimulation</td>
<td>?Release of free radicals</td>
</tr>
<tr>
<td>?Release of free radicals</td>
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</tbody>
</table>
Manufacturers may increase maximal output (from 94 mW/cm² up to 720 mW/cm² for fetal use) on the condition that two indices appear on-screen:

- Thermal index (TI) for thermal effects
- Mechanical index (MI) for non-thermal (a.k.a. mechanical) effects
- AND: a particular effort is to be made to educate the end-users about bioeffects, safety and TI and MI
THERMAL INDEX (TI)

Unitless estimate of possible tissue temperature rise in 0°C under "reasonable worst-case conditions"

\[ TI = \frac{\text{total acoustic power}}{\text{acoustic power needed to raise temperature by } 1^\circ C} \]

Predicts potential for temperature increase

Not a real temperature measurement

No time (duration of exposure) information
<table>
<thead>
<tr>
<th>MI expresses potential to induce inertial cavitation: bubbles must be present</th>
</tr>
</thead>
<tbody>
<tr>
<td>No bubbles in fetal lungs or bowels</td>
</tr>
<tr>
<td>Hence, mechanical risk appears to be low</td>
</tr>
</tbody>
</table>
Manufacturers must display TI and MI on screen.

What are these?

But what do end-users know about these indices?

Co to jest?
Ye Sub Cheese kya he?
3D6-2/0B Gen

Que son estos?

Was ist das?

Hva er dette?

Mitä tämä on?

Hva er dette?

Che cosa questo?

Vad ar detta?

Mitä tämä on?

Vad ar detta?

Hva er dette?

Mitä tämä on?

Hva er dette?

Mitä tämä on?
The output display standard has it missed its.

Knowledge of the bio-effects of ultrasound among physicians conducting clinical ultrasonography: Results of a survey performed by the Italian Society for Ultrasound in Medicine and Biology (SIIUMB)

What Ultrasound Operators Know in the Ultrasound Regardwire Survey

About 25% of end-users know what TI and MI stand.

Houston et al.: JUM 2011
Akhtar et al.: JUM 2011

This true for physicians, sonographers, residents, fellows in the USA, Europe and Asia...
But how can it get?

HEAT IS TERATOLOGICAL

Ultrasound animal experiments
Maternal fever in early pregnancy
External factors (e.g. sauna, hot bath)
<table>
<thead>
<tr>
<th>Maximum exposure (minutes)</th>
<th>TI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1.5</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>2.5</td>
<td></td>
</tr>
</tbody>
</table>

BMUS, 2000, 2011
Output is mode dependent (Doppler>>B-mode)

Output is under examiner control

Output is altered by manipulating certain controls, apparently not related (focus, gate sample etc…)

Every machine behaves differently
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<tr>
<td><strong>B-Mode</strong></td>
<td>No contraindication (see exposure).</td>
<td>No reason to withhold B-Mode or M-Mode</td>
<td>No contraindication.</td>
<td>Not contraindicated on thermal grounds.</td>
<td>Exercise prudent use.</td>
</tr>
<tr>
<td><strong>Doppler</strong></td>
<td>&quot;If the clinician judges it as essential to scan the fetus or embryo with pulsed Doppler, or color flow Doppler, the output parameters should be kept as low as possible.&quot;</td>
<td>Use only with clear indication.</td>
<td>Use when indicated. Keep exposure level and time to minimum required.</td>
<td>Use only with clear indication.</td>
<td>Use only with clear indication.</td>
</tr>
<tr>
<td><strong>Exposure levels</strong></td>
<td>Use lowest available power for shortest time possible to obtain diagnostic information (ALARA).</td>
<td>Detailed instructions regarding T1 levels and time of exposure.</td>
<td>Keep exposure level and time at minimum to obtain adequate diagnosis.</td>
<td>Exposures resulting in temperature &lt; 38.5°C can be used without reservation</td>
<td>Pay attention to indicator of risk (TI or MI)</td>
</tr>
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</table>

**WHO NON-IONIZING RADIATION GUIDELINES**

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<tr>
<td><strong>Contrast agents</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Produces a maximum temperature rise of 1.5°C above normal physiological levels may be used clinically without reservation on thermal grounds.</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>First trimester exposure</strong></td>
<td>Use Doppler with caution. Do not use routinely. Keep T1 &lt; 1</td>
<td>Use caution, particularly with pulsed and color Doppler.</td>
<td>Use Doppler with caution. Keep T1 &lt; 1</td>
<td>Do not use Doppler routinely. Keep T1 &lt; 1</td>
<td>Minimize power. Keep T1 &lt; 1</td>
</tr>
</tbody>
</table>
Concerns have been raised in the past related to

- Autism
- Abnormal hearing, vision or language development
- Intrauterine growth restriction
- Childhood cancer
- Increase in non-right handedness

Abramowicz JS, UOG 29:363, 2007
Perform exam if indicated
Keep output as low as possible
Keep exam as short as possible
Watch TI (MI) and keep <1

Compatible with accurate diagnosis

Thank you for your attention