Ultrasound Bioeffects and NCRP On Needed US Exposures: INTENSITY AND POWER NEEDED IN DIAGNOSTIC ULTRASOUND

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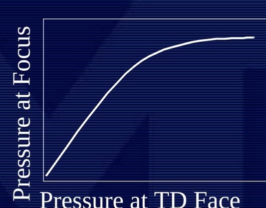
Question :

- Are improvements are possible in diagnostic capabilities of ultrasound systems due to an increase in acoustic output beyond the $\sim 1^0$ bioeffects threshold and the FDA 510(k) guidelines for maximum SPTA intensity (720 $mWcm^{-2}$) and MI (1.9)?
- Most arguments are detailed in NCRP Report 113, NCRP, Bethesda, 1992 and NCRP Report 140, 2002, in press.

Acoustic Waveform after linear and nonlinear propagation



Expected Image or Doppler Signal Improvements from Increased Ultrasonic Output

A. Maximum Depth of Imaging or of Doppler Signal Acquisition *(effective penetration)*

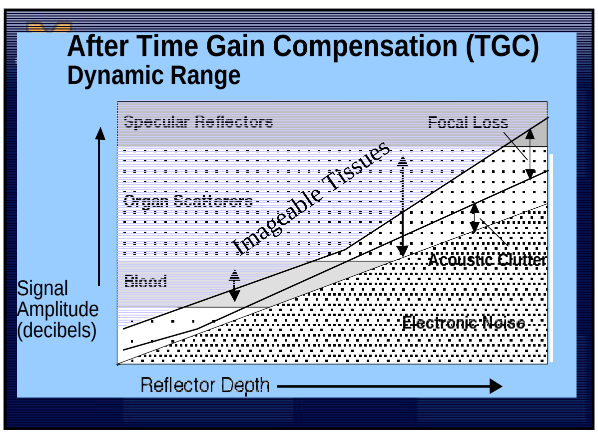
B. Possible change in *effective penetration* from an increase in output power.

C. Effects of Increased Power and Intensity on Other Image and Signal Quality Measures

D. Conditions in which Increased Power Will Not Yield Improved Diagnostic Information

Expected Image or Doppler Signal Improvements from Increased Ultrasonic Output

A. Calculation of maximum Depth of Imaging or of Doppler Signal Acquisition *(effective penetration)*



Reflecting interface	Amplitude R= (P_r/P_i)	Energy Ratio (R^2)
Muscle-blood	0.03	0.0007
Soft tissue-water	0.05	0.0023
Fat-muscle	0.10	0.01
Skin and bone	0.64	0.41
Soft tissue-air	0.9995	99.9

Normal incidence

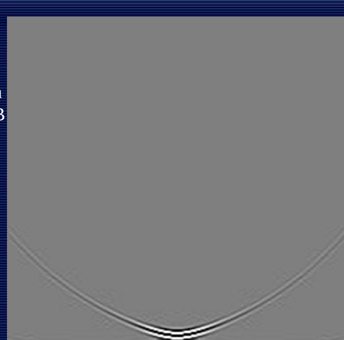
Backscatter from Tissues

- Backscatter coefficient $S=c_1+c_2f^n$
- Backsc. factor S_r(dB) = 10 log(S(cm^{-1}sr^{-1}) LΩ)
  - 1980's-typical, 19 mm diameter, 8 cm focal length transducer, 3 MHz.

Quantity	Blood	Brain	Liver	Spleen
S (cm/sr)	1.8 x 10-6	7.2 x 10-5	8.7 x 10-4	6.6 x 10-4
c1	0	.23 x 10-4	3.3 x 10-4	1.2 x 10-4
c2	2.2 x 10-8	0.6 x 10-6	0.2 x 10-4	0.2 x 10-4
n	4	4	3	3
S_r (dB)	-81	-65	-54	-55

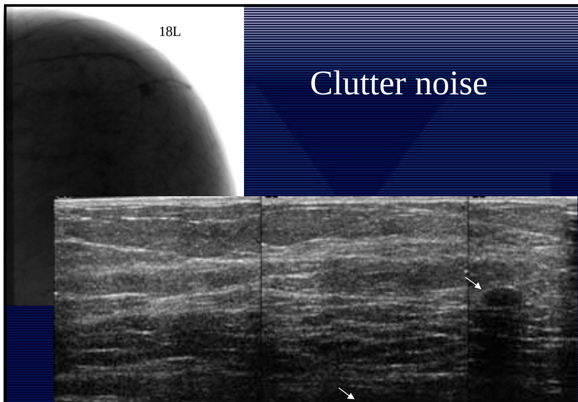
Amplitude attenuation coef., a
Attenuation of A=-2afz$_m$ in dB

D = loss in sensitivity at depths away from focal point



ATTENUATION COEFFICIENTS, a, at 1 MHz

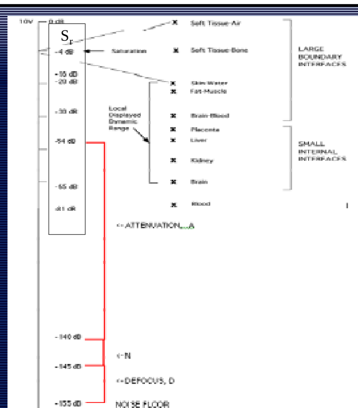
Lung	40
Bone, Cortical	13-26
Liver	0.4-0.7
Smooth Muscle	0.2-0.6
Tendon	~1.0



Clutter noise

Revised Dynamic Range Summary

Revised 2002, from Kossoff, 1976.



Total Dynamic Range, R_o

- Sum (in dB) over all loss mechanisms:
  - attenuation, A,
  - the signal loss from weak scattering (relative to a perfect reflector), S_r,
  - correction for transducer response off-focus, D
  - ratio of the minimum detectable signal under ideal noise conditions, to that typical at max imageable depth, N
- = - *total dynamic range*, $-R_o$
- $R_0 = -(A + S_r + D + N)$.

- With $A = e^{-2afz} = 2afz_m$ (dB)
- The *effective penetration* is
  - $Z_m = (R_0 + D + N + S_r)/(2af)$
- Given known data, one can estimate the maximum imaging distance in various tissues.

Depth of Penetration, z_m

- $Z_m = (R_0 + D + N + S_r)/(2af)$
- $a = -.5$ dB $cm^{-1}MHz^{-1}$, assumed global dynamic range $R_0 = 120$ dB, N = 12 dB

Quantity	Blood	Brain	Liver	Spleen
S_r (dB)	-81	-65	-54	-55
z_m	9	12	15	14
D (dB)	0	-6	-10	-10

Measured *effective penetration* for Doppler & pulse echo US scanners

Frequency (MHz)	Doppler Penetration Depth, z_m (cm)	Pulse Echo Penetration Depth, z_m (cm)
	0.5 dB cm^{-1} MHz^{-1}	0.7 dB cm^{-1} MHz^{-1}
2.5	14.0-15.5	11.5-16.5
3	9.7-12.0	12.8-13.5
3.5		11.0-14.0
5 high I	7.3-10.0	6.0-11.5
5 low I	4.3-6.5	
7.5		3.6-4.7

Boote and Zagzebski (1988) and Carson (1986)

B. ~ change in *effective penetration* from increased peak output power

Increase in power and intensity by an amount ΔI (dB) the global dynamic range, R, could be R + ΔI. Then:

$$\Delta z_m = \Delta I / (2\ a\ f) .$$

For 0.5 dB $cm^{-1}MHz^{-1}$ one way liver attenuation, 3 MHz frequency and a doubling of intensity (3 dB increase),

Δz_m = 3 (dB) / (1 (dB $cm^{-1}MHz^{-1}$) x 3 (MHz)) = 1 cm .

For a maximum imaging depth of 14 cm, the percent change in imaging depth is 7%.

C. Effects of Increased Peak Power and Intensity on Other Quality Measures

⇑ intensity can ⇑ resolution from higher frequency. The global dynamic range is ⇑ to $R = R_o + \Delta I$,
Then f, goes to f + Δf, and S_r is ⇑ by much larger ΔS_r by it's strong frequency dependence of

$$S_r + \Delta S_r = 10 \log [L\ \Omega\ \ (c_1 + c_2(f + \Delta f)^n]$$

When solve for Δf given ΔI,

$$(2\ a\ z_m)\ \Delta f - (\Delta I - S_r) = 10 \log [L\ \Omega\ \ (c_1 + c_2(f + \Delta f)^n)]$$

Effects of ⇑ frequency

At ΔI = 3 dB, at 3 MHz
and a = 0.5 dB cm^{-1}MHz^{-1}

Δf	Organ	Beam Width	Res Vol
8%	liver	- 8%	-22%
26%	blood	-26%	-59%

⇑ f can ⇑ contrast between many tissues, because of enhanced attenuation shadows and differing frequency dependencies of scattering.

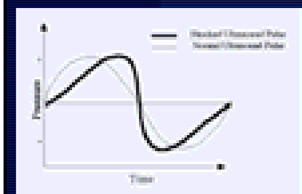
⇑ TA output power instead of peak intensity or pressure

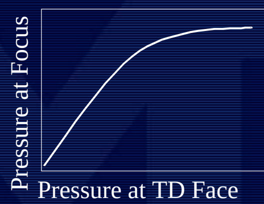
- Can use as proportionate increase in:
  - frame repetition rate (shorter exam times or capture of faster motions, more complete coverage, visual avg'g)
  - No. of transmit focal zones
  - No. of pulses averaged over a line (improved SNR)

D. Conditions where ⇑ Power Don't Yield ⇑ Dx Information

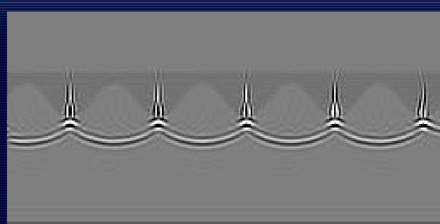
- Limit on useful peak power and intensity:
  - From unnecessary scanner limits. E.g., feed through of output power produces a corresponding increase in noise
  - Body-produced, output-dependent noise sources, e.g., echoes from strong reflectors not in expected beam path, from reverberation, multiple scattering, phase aberration and refractive and diffractive beam dispersal
  - Pressure saturation from nonlinear propagation

Acoustic Waveform after linear and nonlinear propagation





Beam Dispersal by Phase Aberration



Artifactual echoes from dispersed beam hitting wrong targets not ameliorated by increased peak output.
Phase aberration and other beam dispersal also produces signal loss which <u>can</u> be compensated by increased output, nonlinear effects not as bad with dispersed, (lower pressure) beams.

II. Observations Concerning the Intensities and Powers Needed to Obtain Certain Image Quality or Diagnostic Accuracy

A. Comparisons Between Maximum Outputs of Existing Systems and Calculations of Intensities Expected to Achieve a Given Performance at the Focal Planes of Those Systems

DIAGNOSTIC ULTRASOUND OUTPUT DATA -- AIUM, 2002

- Reports on equipment specifications
  - To the AIUM from individual manufacturers.
  - From U.S. FDA, CDRH 510(k) applications, approved
- 1100 tables for specified combinations of transducer and operating mode, up to 393/ scanner model

Calculated, needed intensity, from equation 9.8 of NCRP Report 113 (1992)

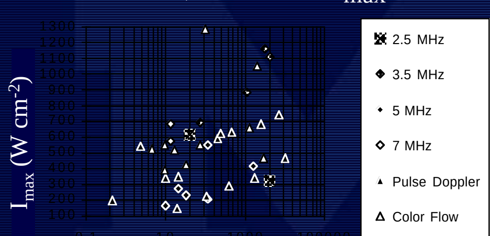
$$I_{calc} \propto K \frac{F^2}{d^2 f^2} e^{+4aFf}$$

I_{calc} is needed inten. in H_2O
K is a constant
F is focal length
d is beam diameter
f the frequency
a the assumed atten. coef.

For constant f No. (~ true in this system), d^2 = a constant/f, so:

$$I_{calc} \propto F^2 e^{+4aFf}$$

Reported I_{max} *vs*. Calculated (or "Needed") relative I_{max}



Calculated Relative I_{max}

Equipment Features for Reduction of Intensity and Power
A. **One Knob Recommendation**
B. **Multiple Receive Lines on a Single Transmit Pulse - Explososcan.**

Conclusions:

- In many circumstances, with well designed equipment, an increase in acoustic output will lead to increased capability for acquiring diagnostic information.
- Thus, a ceiling on exposure parameters at or near current maximum levels should result in a loss of future diagnostic capability.
- Not known is the fraction of images or diagnoses affected by changes in maximum outputs.

Conclusions/Observations

- ***While much damage could be done by denying patients the best possible diagnosis by unnecessary limits on acoustic output, there is also a desire by much of the medical community for a class of ultrasound equipment that can be presumed to be quite safe under essentially any operating conditions.***
- ***High speed 3D cardiac imaging, e.g., will place demands on surface heating limits.***

Conclusions:

- ***The improvement in resolution with increased power can be significant, while the improvement in penetration is a small percentage of the increase in power. In some cases, the improved performance will be worth some risk. This suggests that at least some classes of ultrasound systems should be allowed higher output settings, even above an expected 1 - 2°C rise, but with a clear indication of the risks.***

References

- AIUM (1993, 2002). Acoustical data for diagnostic ultrasound equipment. Laurel, Maryland, American Institute of Ultrasound in Medicine.
- Boote, E.J. and Zagzebski, J.A. (1988). "Performance Tests of Doppler Ultrasound Equipment with a Tissue and Blood-Mimicking Phantom", J. Ultrasound Med., 7, 137-147.
- Carson, P. L. and Zagzebski, J. A. (1981). Pulse Echo Ultrasound Imaging Systems: Performance Tests and Criteria. AAPM Report No. 8. New York, American Association of Physicists in Medicine. 10, 26-36.
- NCRP (1992). Exposure criteria for medical ultrasound. Part 1: Exposure based on thermal mechanisms., Report 113, NCRP, Bethesda, MD.
- NCRP (2002) Exposure Criteria for Medical Diagnostic Ultrasound: II. Criteria Based on All Known Mechanisms, Report 140, NCRP, Bethesda, MD.

Typical Output Summary Table

Trans.	Op. Mode	MI	TIB	TIC	Pr.3
LP13 10MHz	B Mode	1275	0.489	0.589	3.08
LP13 10MHz	CFM +B	0,578	1,378	1,423	1,51
Wo(TIB)	**Wo(TIC)**	**zsp(MI)**	**deq**	**fc**	**Ap Dim**
17.5	17.5	1.15	0.14	5.87	0.43
42,33	47,45	1,60	0,35	6,88	0,54