ONDA

Putting Confidence in Ultrasound

Field characterization of HIFU / HITU devices

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What is HIFU / HITU?

High **I**ntensity **F**ocused **U**ltrasound and/or

High **I**ntensity **T**herapeutic **U**ltrasound

•Intensities / Pressures typically higher than diagnostic or physiotherapy limits, e.g.:

FDA diagnostic limits: $I_{spta.3} < 720\ mW/cm^2$, MI < 1.9

IEC limit on effective intensity: $I_{eff} < 3.0\ W/cm^2$

•Usually designed to create long-lasting changes to biological tissue

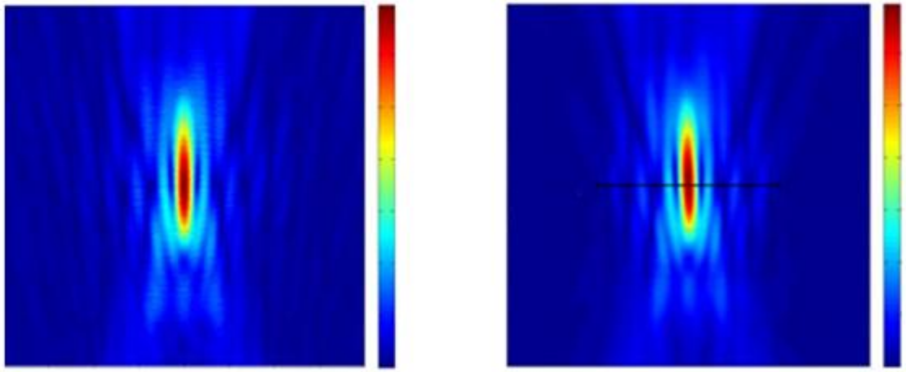
Why Measure HITU Fields

- Determine effectiveness at the targeted treatment site (e.g. treatment planning for thermal or cavitation dose)
- Assess safety (e.g. pre-focal maxima or sidelobes)
- Show compliance with a standard, like

IEC 60601-2-62 Medical Electrical Equipment, Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment.

Why is HIFU / HITU difficult to Measure?

- High pressures/intensities are often damaging to hydrophones
- High pressures/intensities may create cavitation screening
- High pressures lead to high nonlinearities in water
  - errors due to artificially high nonlinearity of water compared to tissue (i.e. nonlinear loss and acoustic saturation)
  - errors due to hydrophone bandwidth and size



Solution: Extrapolate from low-level measurement (IEC 62556)

- **Method 1 (Linear Scaling)**: Measure field intensities at low levels and scale linearly with output power, which can be measured by RFB at low and high powers.

- **Method 2 (Mathematical Modelling)**: Measure field at pre-focal plane (where levels are low) and use math to predict the field in the focal plane, sidelobes, etc.

IEC 62556 Extrapolation Protocol

- Make measurements at safe levels for hydrophones, at nonlinearity $\sigma_q < 0.5$, and with decreased duty factor to avoid cavitation screening
- Use an intensity metric that is robust to extrapolation: $I_{SAL} = P_6 / A_{b,6}$

$A_{b,6}$ = -6 dB beam area at beam maximum ($z = z_p$)

P_6 = power contained within $A_{b,6}$

$A_{b,6}$ determined from $A_{b,6,q}$ via either transaxial hydrophone scans or from numerical projection

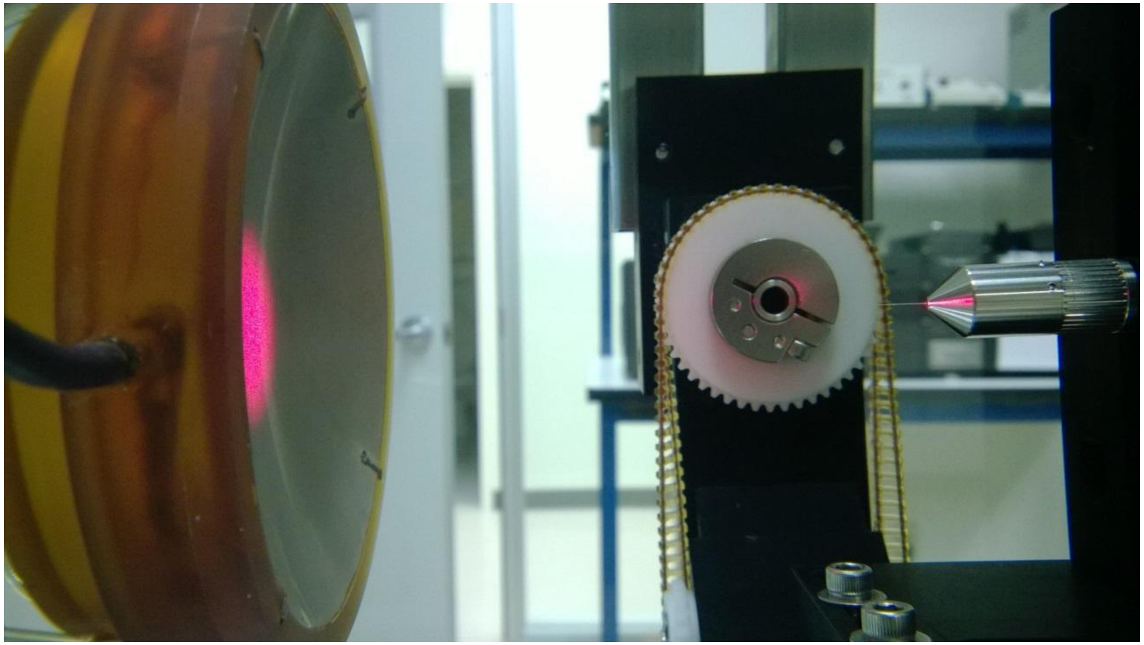
P_6 should be determined for actual clinical driving levels from RFB measurements

Ref: C.R. Hill, I. Rivens, M.G. Vaughan, and G. R. ter Haar, Lesion Development Focused Ultrasound Surgery: a General Model. Ultrasound in Med & Biol. 20,3 (1994) pp. 259-269

Example

Source: 100mm focus F/1, 1.45 MHz

Pressures P+ ~ 60 MPa / P- ~10 Mpa



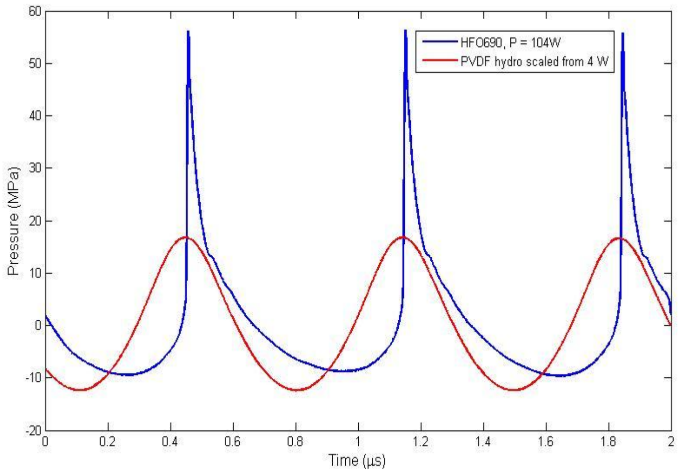
Example: I_{SAL} from Scaling

Planar scans:
conventional PVDF hydrophone at 17 V_{RMS} yields:
Local distortion σ_q = 0.37
$A_{b,6,q}$ = 1.76 mm^2
$P_{q,6} / P_q$ = 0.69

Radiation force balance measurements:
At 17 V_{RMS} => P_q = 4.18 W
At 98 V_{RMS} => P_c = 104.5 W

$$I_{SAL} = (P_{q,6} / P_q) * P_c / A_{b,6,q} = 3962 \text{ W / cm}^2$$

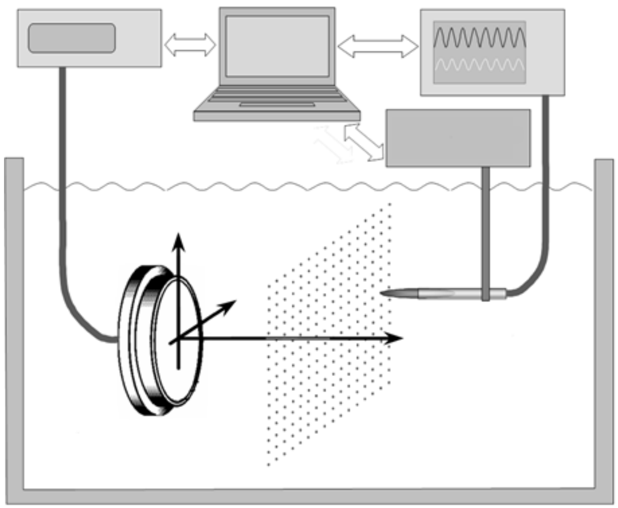
Comparison of methods to Direct Measurement with Optical Hydrophone



	Scaling	HFO690	% diff
P^+ (Mpa)	16.7	56.3	-70%
P^-(Mpa)	12.4	9.67	28%
I_{spta} (W/cm^2)	7092	9575	-26%
I_{sal} (W/cm^2)	3962	4490	-12%

- High nonlinearity at 104 W: $\sigma_q = 4.2$
- Although peak values are off, agreement is not bad for I_{SAL} , which is the emphasis for IEC TS 62556

Projection Method



- Select pre-focal plane satisfying safety and linearity criteria
- Perform planar scan, capturing magnitude and phase
- Calculate field by either
- (i) Rayleigh Integral $p(x,y,z>z_0) = -\frac{1}{2\pi}\iint p(x',y',z_0)\frac{\partial}{\partial n}\left(\frac{e^{ikR}}{R}\right)dx'dy'$
- (ii) Fourier Projection $p(x,y,z) = \frac{1}{(2\pi)^2}\iint F(k_x,k_y)e^{ik_z(z-z_0)}e^{i(k_x x+k_y y)}dk_x dk_y$
- ***Linear Projection only is currently well-established —full non-linear projection is under development.***

Sidelobes and Pre-focal Maxima
Options from IEC 62556

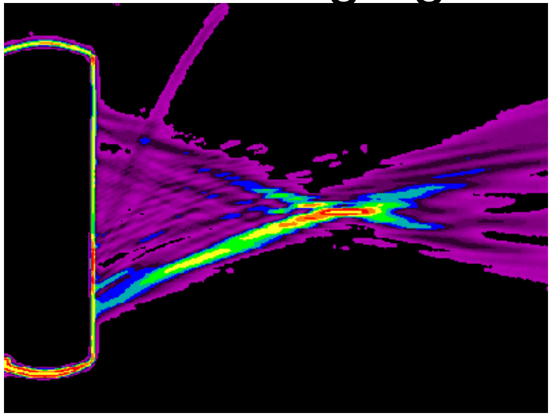
- Numerical Projection
- Detailed Hydrophone Search

  - search transaxial planes from beam entry point to focus

  - planes should capture -20 dB contour

  - planes separation < one wavelength

    => *time consuming!*
- Other Means: optical, thermal imaging—Example: Schlieren imaging to find location of sidelobes:



--Use image to identify location and quantify sidelobe levels with hydrophone

Future Developments at IEC

- Nonlinear Projection

  Make measurements at pre-focal plane, use as input to full non-linear simulation of the field to predict field values *in tissue* (this is a new work proposal in IEC TC 87).

- Direct Measurements

  Compliment non-linear modelling with measurements with new robust hydrophones (such as **fiber-optic** probe) at clinical pressure levels in water, at least to validate non-linear modelling (this is also a new work proposal in IEC TC 87).

Thank you !