ACOUSTICS2008/3385 On the need for basic theoretical, numerical, and experimental research in the development of useful standards for focused ultrasound therapy

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High Intensity Focused Ultrasound (HIFU) is rapidly gaining widespread clinical use in China, and is undergoing regulatory evaluation in Europe and the US for many target diseases. There is rising concern within the HIFU community that no standards exist for measuring or reporting of HIFU fields, inhibiting broad clinical adoption of HIFU. This paper addresses current technical gaps for the development of such standards. High power and strong focusing combine to make accurate measurements of focal fields difficult. No simple way exists to extrapolate in-water field measurements directly to patients, and thus to calculate temperature rise and therapeutic dose in tissue. To arrive at a set of characteristic parameters for HIFU systems that are both clinically relevant and are practical to measure reliably, we believe several avenues of research are needed. Numerical models that include nonlinear acoustic propagation must be carefully validated with experiments, and both numerics and experimental methods must be standardized for broad dissemination. Mechanisms of enhanced tissue heating due to nonlinear effects must be experimentally quantified, and robust accurate models developed. These advances in understanding must be transitioned into practical recommendations for standard metrics and methodologies to facilitate industrial development and regulatory oversight.