AbstractID: 8389 Title: Ultrasound Bioeffects and NCRP on Needed US Exposures
:
Effects of Increased Outputs of Medical Diagnostic Ultrasound Equipment on Diagnostic Performance

It is argued that improvements should be possible in diagnostic capabilities of ultrasound systems due to an increase in acoustic power limits beyond the current FDA 510k guidelines for maximum SPTA intensity and MI (720 mW/cm^2 and 1.9, respectively). Many of the arguments are detailed in [1].

Anticipated performance benefits are:

1) Increased useable frequency for a given penetration in many imaging/measurement modes. This is particularly true for harmonic imaging and imaging with coded excitation, as well as all Doppler modes. In many or all anatomical situations this enhancement will be constrained by increased aberration effects at higher frequencies.
2) At fixed frequency and penetration some of the possible gains are: somewhat higher frame rates; higher numbers of transmit focal zones; higher number of view angles in compound gray scale; or greater signal averaging in Doppler modes.

Not all of these performance improvements may be available with today's systems. However, developments that lead to these improvements should not be overly discouraged by the presence of limits if they are judged to be unnecessary. There are many proposed and potential imaging and measurement techniques that would not be permitted under current limits. This includes, for example, techniques involving the use of radiation force effects for tissue motion as well as techniques for generating imageable bubbles.

In the various engineering/scientific literature there are also many detailed developments of methods to improve the quality of ultrasound images and other signals. Much less common, however, are meaningful studies and summaries of the ways in which safety concerns about acoustic outputs may be in conflict with output needs for image quality or other diagnostic information. It should be cautioned that the imaging improvements would be apparent only in selected cases and would not be universal in the entire patient population. No substantial experimental work has been published on the number of cases in which diagnostic benefits might be derived at current maximum levels. The topic of potential diagnostic improvements from increased outputs, and changes from reduced outputs is worthy of organized study.

There are some "win-win" approaches to equipment design and features for improving <u>both</u> safety and efficacy, although these can involve increased development and production costs. Users can control this safety/efficacy balance very strongly by use of high outputs only as needed.

1) Intensity and Power Needed in Diagnostic Ultrasound, Section in: Exposure Criteria for Medical Diagnostic Ultrasound--Part 1: Exposure Criteria Based on Thermal Mechanisms, NCRP Report 113, National Council on Radiation Protection and Measurements, Bethesda, MD, August, 1992, 278 pp.
A similar section will be in NCRP Report 140, in press.