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Book Review

EXPOSURE CRITERIA FOR MEDICAL DIAGNOSTIC ULTRASOUND: II. CRITERIA BASED ON ALL KNOWN MECHANISMS

(NCRP Report No. 140) National Council on Radiation Protection and Measurements (NCRP), 2002

This Report was generated by Scientific Committee 66 of the NCRP, under the chairmanship of Wesley Nyborg. The Committee's remit was to address the topic of biological effects of ultrasound (US) and exposure criteria, and this is the third in a series that includes NCRP Reports No. 74 (1983), Biological effects of Ultrasound: Mechanisms and Clinical Implications and No. 113 (1992), Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria based on Thermal Mechanisms. The work's primary objective is to reassess the issue of medical diagnostic US safety, partly due to advances in our own knowledge of the way US interacts with tissue, but also due to the growth of new applications, procedures and equipment being used clinically.

The Report is well structured, comprising 14 Chapters dealing with well-identified topics. With over 1100 references, the work stands as a valuable reference work, that will undoubtedly be put to practical use by researchers in the area of bioeffects, standardisation and safety assessment. A particularly useful feature is that each Chapter ends with a concise local Summary, making key points easy to absorb. The Summaries are brought together in Chapter 13, which forms a *précis* of the whole Report.

NCRP Report No. 113 dealt primarily with thermal effects of US, and the current status of our knowledge of US induced temperature increase and its influence on tissue, are reviewed in Chapter 11, which covers temperature elevation and its biological effects. This Chapter highlights important advances made in the computation of *in situ* temperature rise, temperature rise measurement within tissue-mimicking phantoms and our knowledge of the biological impact of temperature increase in tissue.

The main thrust of the Report is its treatment of nonthermal effects, with Chapters 3 to 8 devoted to the topic. Chapter 3 deals with biological effects in the absence of cavitation, highlighting the effects of radiation force and acoustic streaming. The major nonthermal effect considered within the Report is acoustic cavitation, and the physical and biological consequences of bubbles activated or driven by an externally applied acoustic field are assessed. Chapter 4 covers noninertial cavitation, arising from stabilised gas bubbles present in a biological medium. The oscillation of these bubbles is restricted, but its key feature is that the response to a sound wave is not governed by a threshold, and may result from any non zero applied pressure level. Although stable gas bodies are unlikely to exist within tissue, the growing importance of contrast agents (CAs) means that there is an urgent need to understand the physics and biology of their response within an acoustic field. The Report describes the physics of CA excitation and their ability to enhance bioeffects.

Chapter 5 deals with the nonlinear bubble response, in particular the severe conditions resulting from inertial cavitation, cavitation collapse and the resultant effects that might be sonochemical, erosive or sonoluminescent. Special emphasis is placed on assessing the potential effects of pulsed US at MHz frequencies. The background behind the $f^{0.5}$ dependence of the mechanical index, used within safety assessment, is described. Chapter 6 covers bioeffects of inertial cavitation *in vitro*, with cell lysis being the most studied effect. The literature pertaining to the bioeffects of acoustic cavitation in mammalian tissues is reviewed in Chapter 8, which includes a summary of threshold pressure data. Special care needs to be taken when air-tissue interfaces are insonated, particularly lung and CAs.

Of ultimate interest in assessing the safe use of diagnostic US are the acoustic levels at specific sites within tissue, and Chapter 9 reviews models for exposure to human beings. NCRP Report 113 (1992) introduced the thermal and mechanical indices that become part of the AIUM/NEMA Output Display Standard (ODS). A critique is presented of the applicability and limitations of the various models of exposure, which utilise acoustic parameters determined in water. Appendix B provides very useful background information covering the ODS.

Chapter 10 presents an interesting discussion of the sound pressures utilised within diagnostic systems, and contrasts this with the levels required for effective operation of equipment. Chapter 12 reviews the epidemiological evidence for bioeffects, critically analysing the most recent studies, such as the RADIUS, Newnham and Campbell studies. Although the epidemiological findings remain very encouraging regarding the safety record of diagnostic US, the Report adds the important *caveat* that data was gathered before 1991, prior to the introduction of the FDA 510(k) Track 3, that allowed an eight-fold increase in the thermal index. The Report also states that this increase in output levels has resulted in improved equipment capability.

The Report ends by making a number of key recommendations (Chapter 14) relating to the areas of exposure quantity determination and safety criteria, aimed at both manufacturers and users. For users, the Report emphasises that the thermal index should be regarded only as very crude measures of the risk. The final risk benefit assessment must be applied by the user, and imposes a significant requirement on their knowledge of dosimetry and bioeffects. Consequently, the Report calls for improved training and educational material.

As its predecessors, this Report represents an important contribution to the technical literature and is strongly recommended for all those interested in the safety of diagnostic US: users, manufacturers and bioeffect researchers. It is very readable, and its use of numerous worked examples makes it useful to new researchers or students of the field.

National Physical Laboratory, U.K. BAJRAM ZEQIRI

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