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Models for evaluation of thermal hazard in medical diagnostic ultrasonic fields

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee EPL/87, Ultrasonics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MODELS FOR EVALUATION OF THERMAL HAZARD IN MEDICAL DIAGNOSTIC ULTRASONIC FIELDS

FOREWORD

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IEC 62799, which is a technical report, has been prepared by IEC technical committee 87: Ultrasonics.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
87/510/DTR	87/537/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

Terms appearing in bold print in the text are defined in Clause 3 of this technical report.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

MODELS FOR EVALUATION OF THERMAL HAZARD IN MEDICAL DIAGNOSTIC ULTRASONIC FIELDS

1 Scope

This technical report provides background information for users of IEC 62359 to understand the relative merits of several of the potential replacements for the thermal index (TI) as described in IEC 60601-2-37 and IEC 62359.

The report discusses:

– parameters related to thermal aspects of diagnostic ultrasonic fields;
– methods for the determination of an exposure parameter relating to temperature rise in theoretical tissue-equivalent models, resulting from absorption of ultrasound.

The report is intended to be used by:

– those involved in the development and maintenance of IEC 62359;
– manufacturers of medical electrical equipment for risk assessment;
– health care regulatory authorities, test houses and other organizations responsible for implementing standards for medical electrical equipment.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-2-37:2007, *Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*

IEC 62127-2, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

IEC 62359:2010, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*

3 Terms and definitions

For the purposes of this technical report, the terms and definitions given in IEC 60601-2-37, IEC 62127-1, IEC 62127-2 and IEC 62359, some of which are repeated below for convenience, and the following terms and definitions apply.

3.1
acoustic absorption coefficient
μ
quantity intended to account for loss of ultrasonic energy to tissue at a specified point by mechanisms other than scattering