

TECHNICAL REPORT

Models for evaluation of thermal hazard in medical diagnostic ultrasonic fields



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Models for evaluation of thermal hazard in medical diagnostic ultrasonic fields

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

FOREWORD.....	4
1 Scope.....	6
2 Normative references	6
3 Terms and definitions	6
4 Background	10
4.1 General.....	10
4.2 Limitations of the existing standard	11
4.2.1 Linear display	11
4.2.2 Equilibrium temperature.....	12
4.2.3 Tissue parameters	12
4.2.4 Transducer self-heating	12
4.2.5 Safety limits.....	12
5 Options for improvement of the existing standard	13
5.1 General.....	13
5.2 Exponential display of the current <i>TI</i>	13
5.2.1 Theory.....	13
5.2.2 Illustrative results for the new thermal index display	15
5.2.3 Advantages of the new display	15
5.2.4 Shortcomings of the new display.....	16
5.3 Replacement of the <i>TI</i> with the thermally equivalent time index (<i>TETI</i>)	16
5.3.1 Theory.....	16
5.3.2 Illustrative results for the <i>TETI</i>	20
5.3.3 Advantages of the <i>TETI</i>	22
5.3.4 Shortcomings of the <i>TETI</i>	22
5.4 Replacement of the <i>TI</i> with the time to threshold (<i>TT</i>).....	23
5.4.1 Theory.....	23
5.4.2 Illustrative results for the <i>TT</i>	24
5.4.3 Advantages of the <i>TT</i>	27
5.4.4 Shortcomings of the <i>TT</i>	27
5.5 Replacement of the <i>TI</i> with the safe use time (<i>SUT</i>)	28
5.5.1 Theory.....	28
5.5.2 Illustrative results for the <i>SUT</i>	30
5.5.3 Advantages of the <i>SUT</i>	33
5.5.4 Shortcomings of the <i>SUT</i>	33
5.6 Replacement of the <i>TI</i> with the thermally equivalent time displayed (<i>TETD</i>)	34
5.6.1 Theory.....	34
5.6.2 Illustrative results for the <i>TETD</i>	35
5.6.3 Advantages of the <i>TETD</i>	38
5.6.4 Shortcomings of the <i>TETD</i>	39
6 Summary.....	40
7 Recommendations	41
7.1 General.....	41
7.2 Thermally equivalent time index.....	41
7.3 Other models	41
Bibliography.....	42

Figure 1 – Comparison of the values of thermal index that would be displayed under the proposed definition, TI_{new} , with that displayed currently, TI_{cur}	15
Figure 2 – Expanded view of the comparison of Figure 1 for smaller values of TI_{cur}	15
Figure 3 – Thermal-equivalent core temperature elevations vs time	18
Figure 4 – Temperature-time curve (solid line) that represents a conservative boundary for non-foetal exposure durations, particularly for exposure durations of less than 5 s	19
Figure 5 – Thermally equivalent time index (solid curves) vs foetal exposure duration for $TI = 1, 2, 3$ and 4	21
Figure 6 – Temperature rise for distance ($z_0 > 3$ cm) for four models as a function of US exposure time	25
Figure 7 – Relation between TT (time to threshold) and power parameters that give a temperature rise of $\Delta T_{\text{thr}} = 4$ °C.....	26
Figure 8 – The ratio of temperature rise to acoustic absorption coefficient, $\Delta T/\mu$, vs exposure duration for the non-scanning soft tissue model with $P_a = 100$ mW.....	27
Figure 9 – A typical example of temperature rise due to diagnostic ultrasound.....	29
Figure 10 – Values of temperature rise as a function of insonation time	31
Figure 11 – The thermal load as a function of time and f-number	32
Figure 12 – A comparison of thermally equivalent times (t_{43}) for the temperature profiles shown in Figure 6	36
Figure 13 – Probability of birth defect or kidney necrosis as a function of thermally equivalent time (t_{43})	37
Figure 14 – Probabilities of kidney necrosis estimated for the thermally equivalent times (t_{43}) shown in Figure 12.....	38
Figure 15 – Probabilities of birth defect estimated for the thermally equivalent times (t_{43}) shown in Figure 12	39
Table 1 – Thermally equivalent time thresholds for chronic damage in various tissues, t_{43} ; see [21].	20
Table 2 – Foetal exposure durations for a thermally equivalent time index value of 1	22
Table 3 – Non-foetal exposure durations for a thermally equivalent time index value of 1	22
Table 4 – SUT values when including and ignoring the contribution of temperatures lower than ΔT_{max} for the four exposure conditions and the corresponding values of ΔT_{max}	32
Table 5 – Values of W , W_a , and ΔT_{max} for the case of $SUT = 500$ s.	33
Table 6 – Comparison of significant characteristics of the possible replacements for the TI	40

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