

INTERNATIONAL STANDARD

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Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

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CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
1 Scope.....	6
2 Normative references	6
3 Terms and definitions	6
4 List of symbols	15
5 Test methods for determining the mechanical index and the thermal index	16
5.1 General.....	16
5.2 Determination of mechanical index.....	17
5.3 Determination of thermal index – general	17
5.4 Determination of thermal index in non-scanning mode.....	17
5.5 Determination of thermal index in scanning mode.....	19
5.6 Calculations for combined-operating mode.....	19
5.7 Summary of measured quantities for index determination.....	20
Annex A (informative) Relationships with other standards.....	22
Annex B (informative) Guidance notes for measurement of output power in scanning mode.....	23
Annex C (informative) Rationale and derivation of index models	27
Annex D (informative) Guidance on the interpretation of <i>TI</i> and <i>MI</i>	40
Bibliography.....	41
Figure B.1 – Suggested 1 cm-wide aperture mask	25
Figure B.2 – Suggested orientation of transducer, mask slit and RFB target	25
Figure B.3 – Suggested orientation of transducer and 1 cm RFB target	25
Figure C.1 – Focused transducer with a large aperture	35
Figure C.2 – Focused transducer with smaller aperture ($\geq 1 \text{ cm}^2$).....	35
Figure C.3 – Focused transducer with a weak focus ($A_{\text{eq}} > 1 \text{ cm}^2$).....	36
Figure C.4 – Weakly focused transducer.....	36
Table 1 – Summary of combination formulae for each of the THERMAL INDEX categories.....	20
Table 2 – Summary of the acoustic quantities required for the determination of the indices ..	21
Table C.1 – THERMAL INDEX categories and models	29
Table C.2 – Thermal index formulae	33

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FIELD CHARACTERIZATION –
TEST METHODS FOR THE DETERMINATION OF THERMAL
AND MECHANICAL INDICES RELATED TO
MEDICAL DIAGNOSTIC ULTRASONIC FIELDS**

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International Standard IEC 62359 has been prepared by IEC technical committee 87: Ultrasonics

The text of this standard is based on the following documents:

FDIS	Report on voting
87/300/FDIS	87/305/RVD

Full information on the voting for the approval of this standard 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.

This standard may be used to support the requirements of IEC 60601-2-37.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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 standard may be issued at a later date.

INTRODUCTION

Medical diagnostic ultrasonic equipment is widely used in clinical practice for imaging and monitoring purposes. Equipment normally operates at frequencies in the low megahertz frequency range and comprises an ultrasonic transducer acoustically coupled to the patient and associated electronics. There is an extremely wide range of different types of **systems** in current clinical practice.

The ultrasound entering the patient interacts with the patient's tissue and this interaction can be considered in terms of both thermal and non-thermal effects. The purpose of this International Standard is to specify methods of determining thermal and non-thermal exposure indices which can be used to help in assessing the hazard caused by exposure to a particular ultrasonic field used for medical diagnosis or monitoring. It is recognised that these indices have limitations and a knowledge of the indices at the time of an examination is not sufficient in itself to make an informed clinical risk assessment. It is intended that these limitations will be addressed in future revisions of this standard and as scientific understanding increases.

Under certain conditions specified in IEC 60601-2-37 these indices are displayed on medical ultrasonic equipment intended for these purposes.

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1 Scope

This International Standard is applicable to medical diagnostic ultrasound fields.

This standard establishes

- parameters related to thermal and non-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;
- methods for the determination of an exposure parameter appropriate to certain non-thermal effects.

NOTE In this standard where multiples or submultiples of SI units are used this is clearly stated and the usage is self-consistent.

2 Normative references

The following referenced documents are indispensable for the application of this document. 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, *Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment*

IEC 61102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz*

IEC 61157:1992, *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*

IEC 61161:1992, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz* ¹⁾
Amendment 1 (1998)

¹⁾ A consolidated edition (1.1) exists, including IEC 61161:1992 and its Amendment 1 (1998).