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Requirements for measurement standards for high intensity therapeutic ultrasound (HITU) devices

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CONTENTS

FOREWORD 4
INTRODUCTION 6
1 Scope 7
2 Background 7
3 Limitations of existing standard methods 10
3.1 General 10
3.2 Very high pressures 11
3.3 Very high intensities 11
3.4 Strong focusing 12
3.5 Nonlinear harmonics 12
3.6 Acoustic saturation and nonlinear loss 12
3.7 Relevant parameters 13
4 Survey of experts 13
5 Existing literature for measurement of HITU fields 18
6 Discussion 26
6.1 General 26
6.2 Measurement of power 26
6.3 Specification of field parameters related pressure and intensity distribution 27
6.4 Robust methodology for measuring pressure at a point 27
6.5 Direct measurement of intensity 28
6.6 Measurement of temperature rise and temperature distribution 28
6.7 Thermal dose 28
6.8 Cavitation activity 30
6.9 Registration of the HITU field with the targeting system 30
6.10 Tissue-mimicking material for QA/engineering evaluation 30
6.11 Electrical properties of the transducer 31
6.12 Treatment monitoring 31
6.13 Equipment safety and essential performance 31
6.14 Tissue properties 31
7 Recommendations 32
7.1 Items for immediate development 32
7.1.1 General 32
7.1.2 Measurement of total output power as an International Standard or as an amendment to IEC 61161 Ed.2 in TC 87 32
7.1.3 Specification and measurement of field parameters as a Technical Specification (TS) in TC 87 32
7.1.4 Equipment safety and essential performance as a Particular Standard in the 60601 series in TC 62. 32
7.2 Items for development within 5 years 32
7.2.1 General 32
7.2.2 Robust method of measuring pressure 32
7.2.3 Measurement of temperature. 33
7.2.4 Electrical properties of therapeutic transducers 33
7.2.5 Registration of the HITU field with the targeting system 33
7.2.6 Tissue-mimicking material for QA/engineering evaluation 33
7.3 Items requiring extensive further research 33

Annex A (informative) Detailed responses to questionnaire....34
Annex B (informative) Definitions in selected ultrasound standards....54
Annex C (informative) Chinese national standard....67
Bibliography....87

Figure 1 – Radiation force balance system using absorbing target (upward beam)....77
Figure 2 – Radiation force balance system using different measuring system (downward beam)....78
Figure 3 – Hydrophone scanning configuration for measuring HIFU acoustic field (upward beam)....78
Figure 4 – Hydrophone scanning measurement configuration for measuring HIFU acoustic field (downward beam).....79
Figure 5 – Correction factor of plane wave for the acoustic field of a circular plane piston ultrasonic transducer....82

Table 1 – General characteristics of ultrasound used for different therapeutic applications....8
Table 2 – International standards and related documents for the measurement of medical ultrasound fields....9
Table 3 – Questions and summarised answers....14

INTERNATIONAL ELECTROTECHNICAL COMMISSION

REQUIREMENTS FOR MEASUREMENT STANDARDS FOR HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) DEVICES

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IEC 62649, which is a technical report, has been prepared by committee TC 87: Ultrasonics.

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

Enquiry draft	Report on voting
87/420/DTR	87/428/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.

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.

INTRODUCTION

This Technical Report is concerned with standards for high intensity therapeutic ultrasound (HITU) and concentrates on applications that destroy tissue by heating which may or may not be accompanied by acoustic cavitation and other mechanisms. The purpose of the report is to identify topics where there is a consensus that the development of international standards would benefit the industries and/or patients involved with these forms of therapeutic ultrasound. The shortcomings of existing standards as they may be related to the applications of interest are reviewed. It is not its purpose to propose or evaluate specific alternative measurement methods which may be more reliably applied to HITU or other therapeutic equipment. Physiotherapy and lithotripsy are excluded as there are existing standards for these established uses. Lower intensity applications such as enhanced bone healing or ultrasound-induced gene therapy are not explicitly considered.

The use of HITU has advanced to the point where systems have achieved clinical approval for general use in several countries. Medical applications and product development are continuing rapidly. The corresponding products of many companies have been approved for marketing and clinical applications. Fast development in preclinical medicine, clinic medicine, and product manufacture has created an urgent need to standardize measurements of the basic acoustic parameters and the field characteristics of HITU. In order to promote the further development of HITU and to ensure its safe and effective use, international standards are required.

REQUIREMENTS FOR MEASUREMENT STANDARDS FOR HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) DEVICES

1 Scope

This technical report is relevant to the measurement and specification of ultrasound fields intended for medical therapeutic purposes. Lithotripsy and physiotherapy are excluded, since there are existing International Standards for these applications.

It establishes:

- topics where there is a consensus that the development of International Standards would benefit the industries and/or patients;
- topics where the writing of standards should start immediately;
- topics where the writing of technical specifications should start immediately in order to gain practical experience and establish consensus prior to standardisation;
- topics which require future standardisation but where further research is required before initiating the writing of standards or technical specifications.

This report addresses primarily the requirements for measurement standards related to high intensity therapeutic ultrasound (HITU) [also known as high intensity focused ultrasound (HIFU)] fields which are both high intensity and focused and where the main mechanism for action is thermal. However, aspects of the discussion, conclusions and any resulting standards or technical specifications may also be relevant to therapeutic applications which are either focused or high intensity or where the main mechanism is not thermal.

Scientific literature has been reviewed and responses to a questionnaire which was sent to experts around the world are reported.