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TECHNICAL SPECIFICATION

colour inside

Ultrasonics – Output test – Guidance for the maintenance of ultrasound physiotherapy systems

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FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- the subject is still under technical development or where, for any other reason, there is the future but no immediate possibility of an agreement on an International Standard.

Technical specifications are subject to review within three years of publication to decide whether they can be transformed into International Standards.

IEC TS 62462, which is a Technical Specification, has been prepared by IEC technical committee 87: Ultrasonics.

This second edition cancels and replaces the first edition published in 2007. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- addition of a novel method for periodic testing regarding possible changes of the **effective radiating area** using thermochromic absorbers in a new Annex E;

The text of this Technical Specification is based on the following documents:

Enquiry draft	Report on voting
87/640/DTS	87/647A/RVDTS

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

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

In this document, the following print types are used:

- requirements: in roman type;
- notes: in small roman type;
- words in **bold** in the text are defined in Clause 3.

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

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

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The purpose of this document is to establish standard methods for a qualitative check of the performance of **ultrasound** physiotherapy devices during their lifetime, and to provide guidance on calibration requirements and techniques.

To ensure that the **ultrasound** physiotherapy equipment is in an appropriate condition for use, a regular quality check can be performed. This document defines acceptance, weekly and annual checks. The acceptance test checks the delivery of the device and its performance at the start of its lifetime. The weekly check is a simple qualitative check of device operation. In the annual check, in addition to a qualitative check, a quantitative check is defined. Examples are provided of weekly and annual test reports.

This document also gives guidance to the **tester**s concerning the measurement of acoustic output.

Annual testing may be performed by a skilled **tester**, e.g. biomedical engineer, medical physicist, medical device service agent, commercial **tester**, test house, national measurement institute or manufacturer.

ULTRASONICS – OUTPUT TEST – GUIDANCE FOR THE MAINTENANCE OF ULTRASOUND PHYSIOTHERAPY SYSTEMS

1 Scope

This document, which is a Technical Specification, describes methods meant to assist users of **ultrasound** physiotherapy systems in checking the performance of such systems. It is applicable primarily to physiotherapists, general medical practitioners, chiropractors, osteopaths, beauty therapists, sports professionals, biomedical engineers, medical physicists, medical device service agents, commercial **tester**s, test houses or manufacturers. Typical **ultrasound** physiotherapy systems operate in the range from 0,5 MHz to 5 MHz. Long-wave **ultrasound** therapy machines operating in the frequency range 30 kHz to 0,5 MHz are not covered by this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

NOTE The titles of all publications referred to informatively in this document are listed in the Bibliography.

IEC 60601-2-5:2009, *Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment*

IEC 61161:2013, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC 61689:2013, *Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE Most of the definitions in Clause 3 are taken from existing IEC standards. They have been simplified for the purposes of this document.

3.1
acoustic working frequency
rate at which the **treatment head**'s contact face is vibrating

[SOURCE: IEC 61689:2013, 3.7, modified – The definition has been simplified.]