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# TECHNICAL SPECIFICATION

# IEC TS 62462

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## Ultrasonics – Output test – Guide for the maintenance of ultrasound physiotherapy systems



Commission Electrotechnique Internationale  
International Electrotechnical Commission  
Международная Электротехническая Комиссия

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

# ULTRASONICS – OUTPUT TEST – GUIDE FOR THE MAINTENANCE OF ULTRASOUND PHYSIOTHERAPY SYSTEMS

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

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

Enquiry draft	Report on voting
87/350/DTS	87/362/RVC

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

NOTE The following print types are used:

- requirements: roman type;
- notes: in small roman type;
- words in **bold** in the text are defined in Clause 3.
- numbers in square brackets refer to the Bibliography.

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

- transformed into an International standard,
- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

## INTRODUCTION

The purpose of this technical specification 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 is necessary. This technical specification 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 report also gives guidance to the testers concerning the measurement of acoustic output.

Annual testing is to 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 – GUIDE FOR THE MAINTENANCE OF ULTRASOUND PHYSIOTHERAPY SYSTEMS**

### **1 Scope**

This technical specification describes methods meant to assist users of ultrasound therapy machines in checking the performance of such machines. It is applicable primarily to physiotherapists, general medical practitioners, chiropractors, osteopaths, beauty therapists, sports professionals, biomedical engineers, medical physicists, medical device service agents, commercial testers, test houses or manufacturers.

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

### **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 61689:2007, *Ultrasonics – Physiotherapy systems – Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

IEC 61161:2006, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

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

BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML, *Guide to the expression of uncertainty in measurement*