TECHNICAL SPECIFICATION

IEC TS 62462

First edition
2007-05

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

Reference number
IEC/TS 62462:2007(E)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Customer Service Centre: www.iec.ch/webstore/custserv

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: csc@iec.ch
Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00

TECHNICAL SPECIFICATION

IEC TS 62462

First edition
2007-05

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

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE U

For price, see current catalogue

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. In exceptional circumstances, a technical committee may propose the publication of a technical specification when

- the required support cannot be obtained for the publication of an International Standard, despite repeated efforts, or
- 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*

3 Terms and definitions

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

NOTE Most of the definitions described are taken from existing IEC standards. For use in the present guide such definitions are simplified.

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

[IEC 61689:2007, definition 3.3, simplified]

NOTE Typical ultrasound physio-therapy machines operate in the range from 0,7 MHz to 3,3 MHz. Long-wave ultrasound therapy machines operating in the frequency range 30 kHz to less than 1 MHz are not covered by the present document. Usually the boundary between sound and ultrasound is 20 kHz.

3.2
beam non-uniformity ratio
***R*$_{BN}$**
a measure of the range of non-uniformity in the ultrasound beam produced by the treatment head, calculated from the ratio of the acoustic intensity measured at the most intense part of the ultrasound beam to the spatial average acoustic intensity measured for that treatment head

[IEC 61689:2007, definition 3.9, simplified]

3.3
degassed water
water with a low dissolved gas content (see IEC 61161 and Clause B.3)

NOTE For ultrasound physiotherapy fields it is sufficient to decrease the oxygen content below 4 ppm.

3.4
effective radiating area
A_{ER}
area of the front of the treatment face from which ultrasound is being emitted/radiated

[IEC 61689:2007, definition 3.19, simplified]

3.5
hot spot
a localized peaking of the pressure distribution above values that normally can be expected when the ultrasonic beam has been emitted from a piston source. It is called a **hot spot** when the **beam non-uniformity ratio** (**R_{BN}**) > 4

3.6
effective intensity
amount of ultrasonic energy flowing per second through an area and divided by that area

[IEC 61689:2007, definition 3.17, simplified]

3.7
output power
a measure of how much ultrasonic energy is flowing out of the treatment head per second

[IEC 61161:2006, definition 3.3, simplified]

3.8
tester
person who does performance testing on, or calibration of, therapy machines

3.9
treatment head
assembly comprising one **ultrasonic transducer** and associated parts for local application of **ultrasound** to the patient

(see IEC 60601-2-5)

4 Testing regimes

4.1 Acceptance testing

After the device has been delivered to the user a first test should be performed to record the performance at the start of the device's lifetime.

4.2 Weekly testing

Weekly qualitative testing is performed by the therapy machine user, e.g. physiotherapist, general medical practitioner, chiropractor, osteopath, beauty therapist, sports professional.

4.3 Annual testing

Annual testing is performed by an accredited tester, e.g. biomedical engineer, medical physicist, medical device service agent, commercial tester, test house, national measurement institute, manufacturer.

5 Performance testing

5.1 Acceptance testing

The purpose of the test is to record the performance of a device before clinical use, or of a device that has been repaired. The test involves a manufacturer's statement, a visual inspection and a quantitative relative ultrasonic output test.

5.1.1 Visual inspection

The first visual inspection should concentrate on the delivered items. All items should have been delivered in accordance with the purchase specification, and they should look undamaged.

5.1.2 Manufacturer's statement

On delivery of either a new device or after repair of an existing device check the written system manufacturer's statement that the device performs in accordance with the manufacturer's device specifications. From this statement it shall follow that the device is traceably calibrated in accordance with IEC 61689 and IEC 60601-2-5.

5.1.3 Quantitative relative ultrasonic output test

a) To prepare a starting point for future simple quantitative output testing, either the effective intensity or the ultrasonic output power of the device should be recorded for at least one output setting, e.g. continuous wave, effective intensity: 1 W/cm^2.

b) In cases where the manufacturer has stated the traceability of the calibration there is no need for an absolute output measurement. In all other cases the ultrasonic output should be calibrated in accordance with IEC 60601-2-5 and IEC 61161.

c) Once confidence is established in the calibration of the device, a prescribed method should be used to relate the device output setting as recorded in 5.1.3 a) to a reading of a related performance. This method could be a determination of temperature rise following Annex C or Annex D, or using a wattmeter. The method used should be described in the record and should be used in the weekly test, see 5.2.2.

5.1.4 Beam uniformity and output test

5.1.4.1 General

The test is a quick check of whether the machine is outputting any ultrasound power, and of any '**hot spots**' or asymmetry present in the beam produced by the treatment head. It is not a power calibration. The technique uses the ultrasound emitted by the treatment head to disturb the surface of water in a container. The equipment needed is as follows:

a) a small container of sufficient depth to be filled with water to a maximum of 25 mm. This container should have a bottom thickness of <0,3 mm. See Figure 1 for a number of examples;

b) coupling gel.

NOTE Common, undesirable techniques which have been used in the past to check ultrasound output are as follows:

(a) placing a few drops of water on the upturned treatment head, then timing how long it takes for the water to boil off.

(b) making a small well of water about the treatment head using some tape, and observing the disturbance of the water surface by the ultrasound.

Modern physiotherapy units have automatic cut-offs (power down) when the treatment head has insufficient contact with the patient or is not immersed. Techniques such as those described in Items (a) and (b) above will often trigger the automatic shutdown of the head and thus give a false indication that the ultrasound therapy machine is faulty.

Subjecting a treatment head to poor patient contact or poor water immersion will shorten the lifetime of the device. For these reasons, using a container of water to see the effect of the ultrasound on a surface of water is highly advisable.

Further valuable reading can be found in [1],[2],[3],[4] [1)].

5.1.4.2 Procedure

The procedure is as follows.

a) Hold the treatment head so that the face is pointing upwards. Apply coupling gel to the face of the treatment head. Place the container on the face of the treatment head and make sure that all coupling gel is properly distributed without air bubbles. See Figure 1.

b) Fill the container with water to a depth of 5 mm to 20 mm. (Tap water is adequate for this qualitative and quick test.)

c) A slight angle of the treatment head to the vertical may improve the image. See Figure 2.

d) Turn on the ultrasound to full power, or less if this is sufficient to observe a disturbance of the water. (A disturbance of the water will be observed when looking from the side, and it may be necessary to move the treatment head around a little and to also change the angle to the surface to see the disturbance. The effect which can be seen is shown in Figure 1.) If the treatment head is <5 mm below the surface and/or exactly parallel to it, then the ultrasound may turn off due to an automatic safety sensor, as damage to the ultrasound therapy machine may otherwise occur.

   The features of the water disturbance to note are as follows:

   1) the circular symmetry of the pattern;

   NOTE Changes in the circular symmetry can be an indication of changes in the effective radiating area.

   2) whether there are any sharp peaks (hot spots) showing (see Figure 1(c));

   3) whether the appearance of the disturbance changed in height or symmetry since the last time it was checked;

   4) whether the pattern remained the same but decreased in height with reduction in ultrasound power.

5.1.5 Recording of results of acceptance test

The results of the acceptance test shall be recorded. Annex E gives an example where the results of the acceptance test can be recorded as a start of the weekly test report.

5.1.6 Requirements / Recommendation

Patterns obtained by performing 5.1.4, which are not circularly symmetric and/or have sharp peaks, indicate that the treatment head may not be performing appropriately and could be unsafe.

In case of non-conformance with one of the events listed in 5.1.1, 5.1.2, 5.1.3, 5.1.4, the manufacturer should be consulted to check the device.

5.2 Weekly testing

Weekly testing involves a simple and quick procedure for testing the ultrasonic output relatively and visual inspection of aspects such as cable damage.

5.2.1 Visual inspection

The ultrasound therapy machine should be inspected visually on aspects that could affect proper safe functioning, such as a damaged mains or treatment head cable or connector.

---

1) Figures in square brackets refer to the Bibliography.