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TECHNICAL SPECIFICATION

colour inside

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

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

FOREWORD

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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- withdrawn,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.]

3.2
beam non-uniformity ratio
R_{BN}
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**

[SOURCE: IEC 61689:2013, 3.15, modified – The definition has been simplified.]

3.3
degassed water
water with a low dissolved gas content

Note 1 to entry For **ultrasound** physiotherapy fields it is sufficient to decrease the oxygen content below 4 mg/l.

Note 2 to entry Methods for the degassing of water are described in IEC TR 62781.

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

[SOURCE: IEC 61689:2013, 3.23, modified – The definition has been simplified.]

3.5
effective intensity
I_{eff}
ratio of the ultrasonic power over the **effective radiating area**

3.6
hot spot
a localized peaking of the pressure distribution above values that normally can be expected indicated by a **beam non-uniformity ratio** (R_{BN}) being larger than 4

3.7
output power
measure of how much ultrasonic energy is flowing out of the **treatment head** per unit time

[SOURCE: IEC 61161:2013, 3.3, modified – The definition has been 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

[SOURCE IEC 60601-2-5:2009, 201.3.214]

3.10
ultrasound
acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01]

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. See Annex A for rationale.

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. See Annex A for rationale.

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. See Annex A for rationale.

5 Performance testing

5.1 Acceptance testing

5.1.1 General

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. See Annex B for guidance for **tester**s.

5.1.2 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.

5.1.3 Manufacturer's statement

On delivery of 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 follows that the device shall be traceably calibrated in accordance with IEC 61689 and IEC 60601-2-5.

5.1.4 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 5.1.4 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 an **ultrasound** power meter. For qualitative test to assess changes of **effective radiating area**, follow Annex E. The method used should be described in the record and should be used in the weekly test, see 5.2.3.

5.1.5 Beam uniformity and output test

5.1.5.1 General

The test is a quick check of whether the machine is outputting any **ultrasound** power, and of any '**hot spot**s' 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: for instance, a cylinder bottom covered with a membrane made of polyester film, polyvinylidene difluoride (PVDF), or other similar thin plastic material. 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:

- placing a few drops of water on the upturned **treatment head**, then timing how long it takes for the water to boil off;
- 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 within this note 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 can avoid this.

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

5.1.5.2 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 less than 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.

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1) Numbers in square brackets refer to the Bibliography.