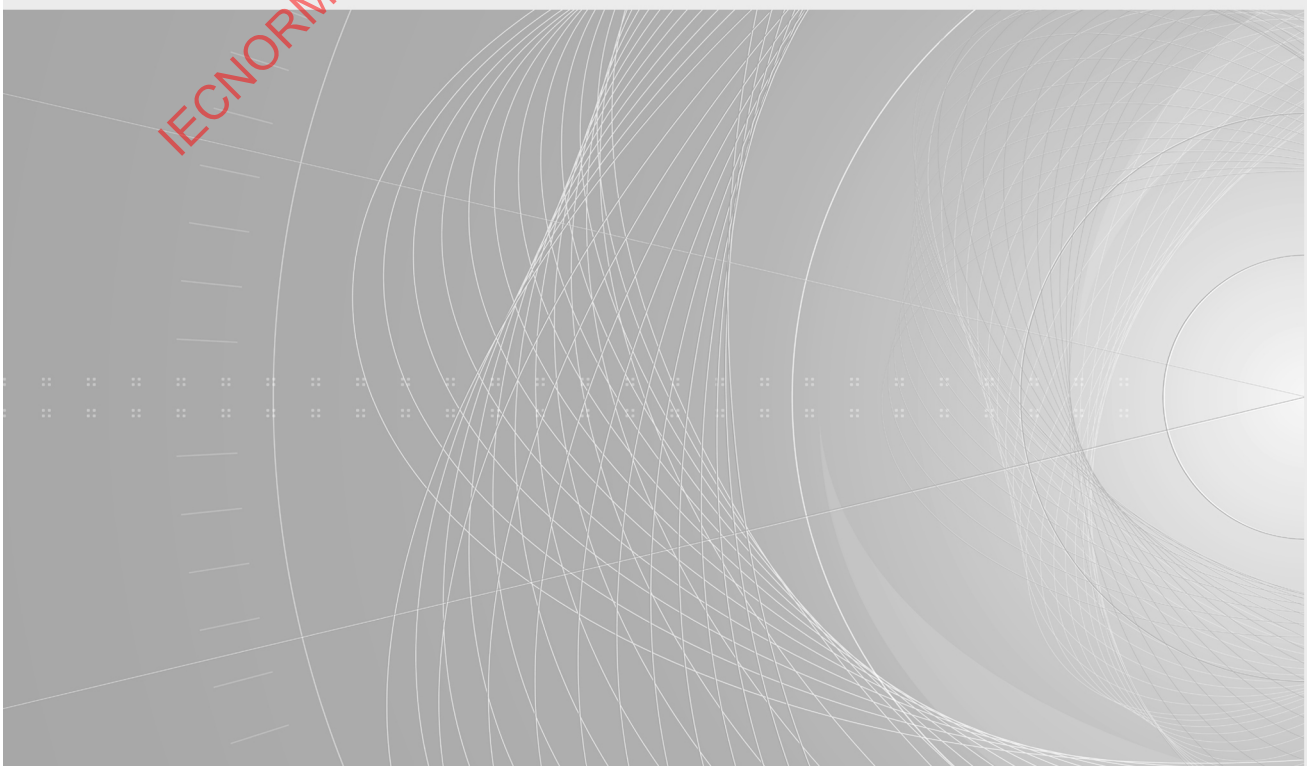
IEC TS 62462

Edition 2.0 2017-07

TECHNICAL SPECIFICATION

colour inside

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



IEC TS 62462:2017-07(en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

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

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing 20 000 terms and definitions in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
65 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

IEC TS 62462

Edition 2.0 2017-07

TECHNICAL SPECIFICATION

colour inside

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.60;17.140.50

ISBN 978-2-8322-4561-3

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

ULTRASONICS – OUTPUT TEST – GUIDANCE 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 itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
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 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.

1) Numbers in square brackets refer to the Bibliography.

5.1.6 Recording of results of acceptance test

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

5.1.7 Requirements and recommendation

Patterns obtained by performing 5.1.5, 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 5.1.2, 5.1.3, 5.1.4, 5.1.5, the manufacturer should be consulted to check the device.

5.2 Weekly testing

5.2.1 General

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

5.2.2 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.

5.2.3 Relative ultrasonic output test

The ultrasonic output should be measured using the same method described in 5.1.4 c) and at the same settings as used during the acceptance test.

The result should not deviate by more than 25 % of the value determined during the acceptance test.

5.2.4 Beam uniformity and output test

The beam uniformity should be tested using the same method described in 5.1.5.

5.2.5 Recording of results of weekly testing

The results of the weekly test should be recorded. Annex F gives an example of a weekly test report.

5.2.6 Requirements and recommendation

Patterns obtained by performing 5.2.4, which are not circularly symmetric and/or have sharp peaks, indicate that the **treatment head** may not be performing appropriately and could be unsafe. Unexpected patterns may identify future failure.

In case of non-conformance of any of the tests listed in 5.2.2, 5.2.3, 5.2.4 the manufacturer should be consulted to check the device.

5.3 Annual testing

5.3.1 General

The purpose of the test for evaluating beam uniformity is that it gives the healthcare professional some guidance as to whether the **treatment head**s are beginning to deviate significantly from the desired norm.

The equipment used to perform the annual testing shall be calibrated traceably to a higher standard; see Annex G.

5.3.2 Output power test

For each **treatment head** and at the intended frequencies of operation, the actual **ultrasound output power** shall be measured in accordance with IEC 61161.

The **ultrasound** power should be measured at the indicated values (or as close as possible for machine settings) which are 10 %, 25 %, 50 % and 100 % of the maximum. This is done at least twice with the **treatment head** being removed from the **ultrasound** power meter and then reattached for the second series of readings. Annex G gives an example of the annual **ultrasound** power calibration test report. The results obtained are directly plotted onto the appropriate graph of the report.

The power measured shall be within ±20 % of that indicated on the device.

Check that a power output value setting of 0 W or intensity output value setting of 0 W/cm^2 does not deliver any **ultrasound**.

5.3.3 Effective radiating area

Most therapeutic treatments are based on the **effective intensity**. This intensity is equal to the ratio of the ultrasonic power over the **effective radiating area**. So apart from calibrating the ultrasonic power, the size of the **effective radiating area** is also of importance. Possible changes of this area can be observed using the beam uniformity test in 5.1.5.

5.3.4 Beam uniformity test

The annual beam uniformity test is performed in the same manner as the weekly test for beam uniformity; see 5.1.5.

5.3.5 Pulse duty factor accuracy test

5.3.5.1 General

The performance of the pulse regime is not expected to change significantly from year to year. The test can be with an **ultrasound** power meter or an oscilloscope using a non-invasive current probe. For all measurements The **treatment head** shall be immersed in water. For a given machine, it is sufficient to test a single **treatment head** and only at full power.

NOTE The test is optional as it is not expected that the pulse duty factor will change over time.

5.3.5.2 Using an ultrasound power meter

The power at continuous wave mode operation (100 % duty) should be measured and then compared with the power obtained for the range of pulsing regimes available on the machine.

The power measured under the pulsing regime should be within ±5 % of that calculated using the corresponding pulse duty factor with the continuous power value.

5.3.5.3 Using an oscilloscope

Confirmation is needed that the amplitude is the same as for continuous wave mode (to within ±5 %) and that the pulse duty factor is as indicated on the machine, to within ±5 %.

NOTE A way of performing the measurement is to clamp a current probe around the cable to the **treatment head** and then observe the corresponding pulse regime on the oscilloscope.

5.3.6 Timer accuracy test

The performance of the timer accuracy is not expected to change significantly from year to year.

The test can be performed using a stopwatch. The **ultrasound** machine's timer should be accurate to within ±10 %.

NOTE The test is optional as it is not expected that this parameter will change over time. For this reason the test is also simplified from the test described in IEC 60601-2-5.

5.3.7 Recording of results of annual testing

The results of the annual test should be recorded. Annex G gives an example of an annual test report.

If possible, the measurement uncertainty should be estimated using ISO/IEC Guide 98-3:2008 [5].

The test report should record the following:

a) identification of the **treatment head** and machine tested. Serial numbers (S/N) are important;

b) date of the maintenance test;

c) name of the accredited **tester**;

d) calibration date of the **ultrasound** power meter;

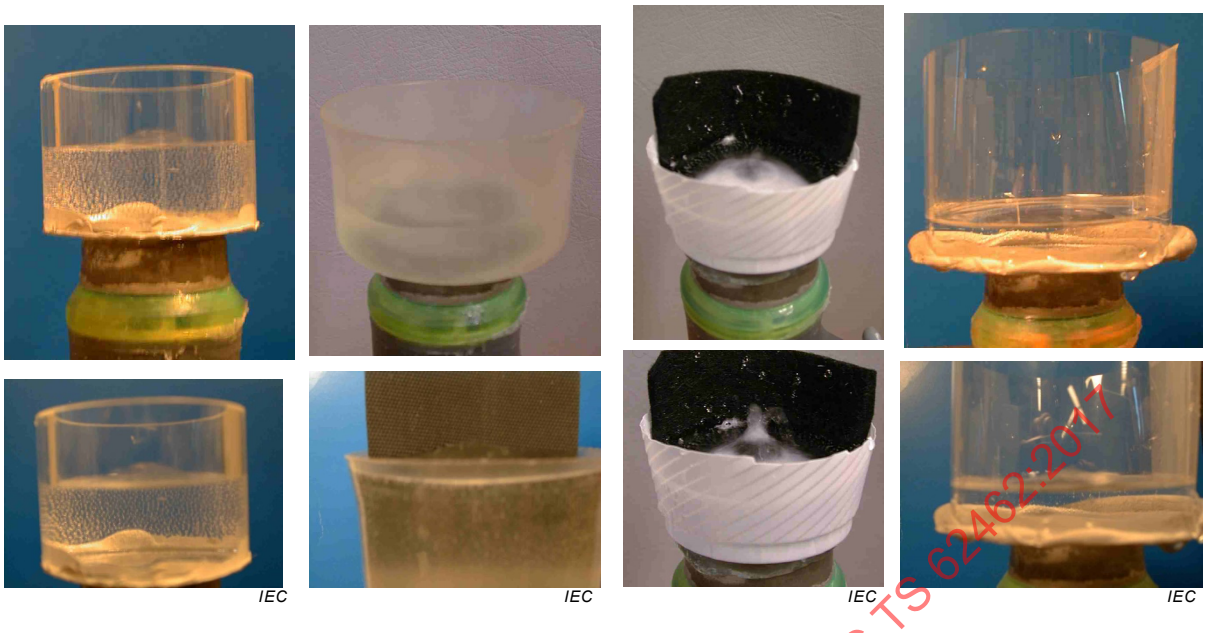
e) beam uniformity test result;

f) power calibration shown as a graph with the ±20 % limits for a pass. There are separate graphs for large (to 15 W) and small (to 3 W) **treatment head**s. Although the total power radiated for large and small heads is quite different, the intensity is often similar. The intensity is the physical quantity which most strongly relates to the therapeutic benefit of the treatment. It is therefore important to maintain the accuracy of calibration by using graphs of different scales for large and small heads.

NOTE Examples of such graphs are given in Figures G.1 and G.2.

5.4 Service requirement

If any of the parameters listed in 5.3 do not function within the listed uncertainty, the device should not be used for treating patients until the non-conformity is resolved.



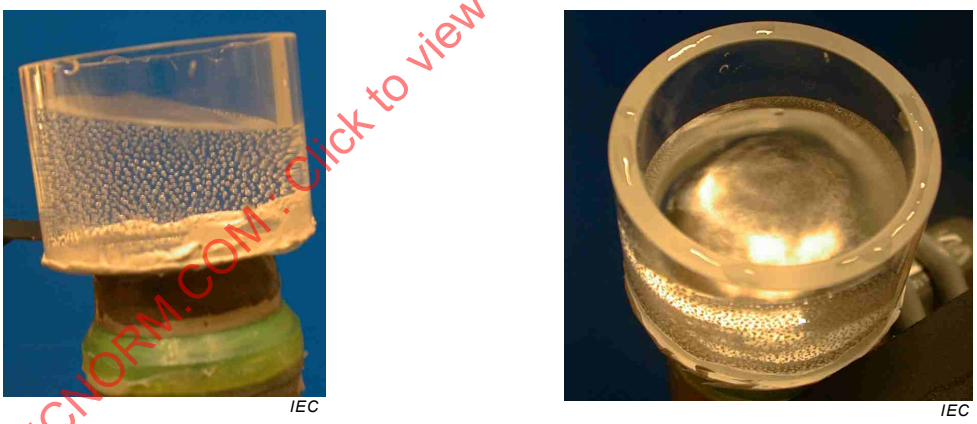
a)
A clear plastic pipe closed at the bottom using a piece of a sheet used for an overhead projector transparency

b)
A small container made from polyethylene

c)
The bottom of a plastic coffee cup is used as container, the black material is used to produce better camera image

d)
The container is made from a sheet used for an overhead projector

Figure 1 – Several examples of how to prepare a set-up to check the distortion on the water surface due to ultrasound



A

B

Especially in image B the circular distortion can well be observed.

Figure 2 – Set-up where the slight angle of the treatment head to the vertical may improve the image

Annex A
(informative)

Rationale for testing

A.1 Acceptance testing

The acceptance test is important because it records the performance of the device that has not been used before or the device that has returned from a repair. The test will encourage manufacturers to perform traceable calibrations of the device before delivery. For the user it will form an important first step in the quality assurance programme.

A.2 Weekly testing

Treatment heads can suddenly fail entirely, or can partially fail, giving either reduced output or **hot spot**s of more intense **ultrasound** across the face of the head. For these reasons, it is highly desirable to perform a weekly qualitative check of **ultrasound** output.

By testing the performance of a device the user can demonstrate good practice.

A.3 Annual testing

A quantitative test of the power calibration of the transducer is performed to ensure reliability of the transducer.

Beam uniformity testing is performed to assess any **hot spot**s on the transducer head and whether the machine is outputting any **ultrasound** power.

Pulse duty factor and machine timer are tested for their accuracy. Output accuracy can otherwise be affected due to inaccuracy of the pulse duty factor.

Annual testing will also record the conformance with the standard which was originally used to state the specifications.

Annex B
(informative)

Guidance for testers

B.1 Ultrasound power meter specifications

An introduction to the physical principles of **ultrasound** power measurement and the mechanisms of the most common types of meter can be found in IEC 61161. It is valuable to read the literature which describes the way in which the measurement set-up itself affects the measurement result [1], [6], [7], [8]. The important features of an **ultrasound** power meter, which should be considered before purchasing, are as follows:

- conformance to the principles in IEC 61161;
- a resolution of at least 0,1 W and a measurement range of up to 15 W;
- a calibration of the force measurement mechanism that can be checked by the **tester**, without sending the **ultrasound** power meter to a service agent;
- ease of use when in the laboratory and when travelling to physiotherapy practices.

The most common **ultrasound** power meter style has a target consisting of a convex, 45°, metal-skinned air-backed cone. The target sits in a water bath, the walls of which are lined with an **ultrasound** absorbing rubber. The force on the cone is measured by a digital mass balance, which can be calibrated with masses which are of the same order as the **ultrasound** force ($F = mg$, where F is the force acting on the cone, m is the correspondent mass informed by the balance, and g is the local gravity acceleration).

Especially in the case of diverging ultrasonic beams, it is advisable to use an absorbing target instead of a reflecting target. See [7].

IEC 61161 gives guidance on the use of different **ultrasound** power meters.

Ultrasound power meters can be found using a web search engine with appropriate use of keywords.

Ultrasound power meter styles that can often give irregular performance are as follows:

a) Targets that have a rounded tip at the apex of the cone. The tip of the cone should be sharp so that the target geometry is constant over the full extent of the **ultrasound** beam; otherwise there will be a dependence on the radiating area of the **treatment head**. The cone should have an apex with an area of less than 0,1 mm^2.

b) Conical reflector targets or targets that consist of a 45° plate. These may cause difficulty dealing with asymmetrical ultrasonic beam due to the radiation force measurement mechanism.

c) **Ultrasound** power meter equipped with reflecting target. These always need lateral absorber; see IEC 61161.

d) Targets with concave geometry. These targets can reflect **ultrasound** energy back into the **treatment head**. Most modern **ultrasound** therapy machines will cut off (power down) if the **treatment head** is subjected to high levels of reflected **ultrasound**. A bad acoustic load, such as removing the **treatment head** from the water or the patient, will also give the same response. Even if the machine does not cut off, the power result may be incorrect and may differ from the free-field power, due to the reflected **ultrasound** arriving at the transducer surface if the concave reflector is too close.

e) Absorbing targets whose acoustic properties do not conform to IEC 61161.

f) Targets with anti-streaming membranes. Membranes often have frequency-dependent transmission properties in the range of interest. Their properties also tend to vary with time and wetting. The nature and quality of the coupling between the **treatment head** and the membrane may also affect the generated power.

B.2 Room and water temperature

This should generally be in the range 19 °C to 25 °C. Working beyond this range may require attention to the specifications of the **ultrasound** power meter and the use of correction factors to the measurements it makes.

B.3 Water

Detailed methods for the preparation of **degassed water** can be found in IEC TR 62781 and [9]. Any method can be used that ensures that the oxygen content stays below the basic required value listed in IEC TR 62781.

B.4 Environmental considerations

Drafts of air can affect the performance of some **ultrasound** power meters. Common sources of drafts are overhead fans, open windows, doors, and people walking past and/or the close proximity of an air-conditioning outlet. A large cardboard box over the **ultrasound** power meter and the **treatment head** will eliminate the effect of drafts. A plastic window in the cardboard box is necessary so that the display of the **ultrasound** power meter can be read.

Ultrasound power meters are also susceptible to variabilities related to environmental vibration, due to the small forces being measured. The surface on which the **ultrasound** power meter is placed should therefore be level, and situated away from sources of vibration.

B.5 Ultrasound power meter checks

The **ultrasound** power meter specification, including calibration and traceability, should be in accordance with IEC 61161. Furthermore, the following should be checked:

a) The validity of the calibration, e.g. has it been done in the past year? Does the **ultrasound** power meter have a standard set of masses to check for? Does the calibration depend on the frequency and radiating area of the **treatment head**?

b) The water level reservoir, if present, is topped up, if necessary.

c) For those **ultrasound** power meters with obliquely orientated membranes in front of the target to ensure that the membrane is flat and in good condition.

d) Whether the **ultrasound** power meter can be levelled, if recommended by the manufacturer.

e) Whether an independent solid bench for mounting the **treatment head** has been used to reduce the effect of vibration from equipment with fans, etc.

B.6 Ultrasound power meter testing technique

The technique is as follows:

a) Obtain a small paint brush and bend the end to a right angle. The brush can be used to brush the face of the immersed **treatment head**. A small inspection mirror (like a dental mirror or mechanic's inspection mirror) with a small torch light is useful for checking for bubbles on the face of the **treatment head**.

b) If the **ultrasound** power meter's target is open to access, it should also be brushed down lightly once it has been immersed. Brush the upper and lower surfaces to ensure all bubbles are removed.

c) If the **ultrasound** power meter is a sealed system with a membrane in front of the target, ensure that the membrane is lightly brushed down after immersing it in water.

d) It is desirable to have the **treatment head** face close to the **ultrasound** power meter target. In the case of reflecting targets 5 mm to 10 mm might be appropriate (see IEC 61161 for considerations about reflecting targets); in the case of absorbing targets a larger distance should be chosen to avoid heating of the treatment surface by the absorption of **ultrasound** in the target. This may not be possible for **ultrasound** power meters that supply positioning rings for the **treatment head** or have a membrane in front of the target. If this is the case, then endeavour to have a reproducible distance, within 2 mm from the target.

e) Tape or clamp the cable of the **treatment head** to the bench.

f) In the case of a convex conical target the transducer faceplate should be centralized over the target apex to within ±2 mm. This can be performed by visual inspection, and is adequate for transducers conforming to IEC 61689. When using an absorbing target balance, it is good measurement practice to similarly align the central axis of the transducer faceplate with the centre of the balance target.

g) The reproducibility of a measurement and the accuracy of the final (averaged) result can be affected by measurement conditions in general, including, but not limited to the distance between the **treatment head** and the target in the **ultrasound** power meter. Probably, the most time efficient technique is as follows:

   1) set up a **treatment head** in the **ultrasound** power meter;

   2) run through all the desired power levels once;

   3) remove the **treatment head** from the **ultrasound** power meter and place it back again, readjusting the distance between the **treatment head** clamping mechanism and the **ultrasound** power meter, if possible; and

   4) repeat steps 1) to 3) three to five times, for a **treatment head**. There should be a reasonable time between the measurements to assure the stability of the power meter reading. For a high quality **ultrasound** power meter, the typical repeatability from repositioning might lie in the range 3 % to 5 %. If there are much larger differences, then it is likely that reflections impinging on the **treatment head** face are affecting its **output power**. This might come, for example, from the use of absorbing materials whose acoustic properties are inadequate. The most accurate result is then obtained from the average of a number of measurements, e.g. 3 to 5.

h) The technique of raising the **treatment head** out of the water whilst it is running, to 'clear the head' of an adverse reading, should be avoided. Such a practice can reduce the lifetime and change the calibration of the **treatment head**. Modern **ultrasound** therapy machines have automatic cut offs (power down) when the **treatment head** has insufficient contact with the patient or is not immersed.

Annex C
(informative)

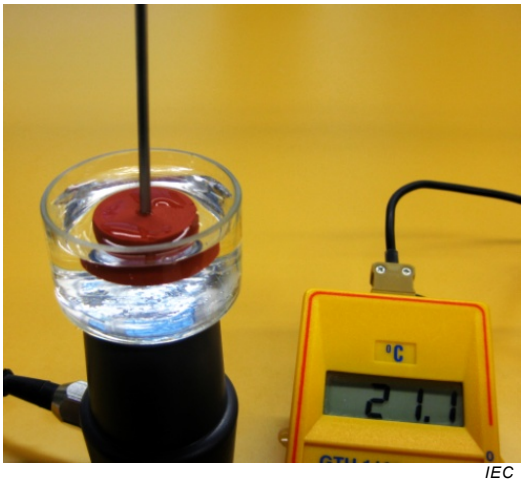
Quantitative relative ultrasonic output test using temperature rise

When **ultrasound** is radiated into absorbing material its energy will be transferred into heat. The temperature rise due to this heat can easily be measured. To be able to use this method for quality assurance purposes, the measurement has to be reproducible. This will be the case with the following guidance.

The materials needed for a typical measurement set-up are as follows.

a) The set-up given in 5.1.5 and Figure 1 can be used:
   1) a piece of high absorbing material (an amplitude reflection factor of less than 3,5 % and an acoustic energy absorption within the target of at least 99 %). Its size should be not smaller than the size of the front of the **treatment head** under test (use the same size for small **treatment head**s as for the larger heads);
   2) a thermometer. This could be an ordinary thermometer, an electronic one (thermistor), or a thermocouple.

b) The measurement set-up is as follows:
   1) The thermometer should be mounted in a hole in the absorbing material. The distance between the tip of the thermometer and the surface of the absorber should be greater than 3 mm. The thermometer has to fit tightly in that hole. If necessary, some coupling gel will improve the heat transfer from the absorber to the thermometer. See Figure C.1.
   2) The absorber should be placed at a distance between 1 cm to 2 cm from the face of the **treatment head** (the distance used should be equal for all the measurements with this **treatment head** in future).
   3) Wait about 5 min to allow the absorber, the water and the thermometer to reach an equilibrium temperature.
   4) Set the physiotherapy device at the preferred output (for this test an I_{eff} of 1 W/cm^2 should be sufficient).
   5) Note the temperature from the thermometer.
   6) Switch the physiotherapy device on and note the time.
   7) Usually there is a reasonable temperature rise in 5 min, but if necessary take more time.
   8) Note the temperature in the absorber and note the time **ultrasound** was on to raise the temperature in the absorber. The difference between this temperature and that at the start of the measurement should be noted as the temperature rise under that specific device setting in the specified time.
   9) It is important that all device settings and distances are the same for all measurements in future.



IEC

Figure C.1 – Example of a measurement set-up to measure the temperature rise due to ultrasound in absorbing material

Annex D
(informative)

Quantitative relative ultrasonic output test using calorimetry

The following test outlines a protocol for using the simple calorimeter, based on reference [4]. The test is very similar to that described in Annex C, except that an absorber is not used and the acoustic power is transferred to heat through absorption within water, and the material used in the manufacture of the recipient, which holds the fluid.

Equipment required to complete the test is: a plastic recipient and cone and a thermometer; see Figure D.1. The aim of the test is to return a single number (the temperature rise generated under specific operating conditions) which is representative of the power being generated by the **treatment head** under test. If the output changes with time, this temperature rise will also change.

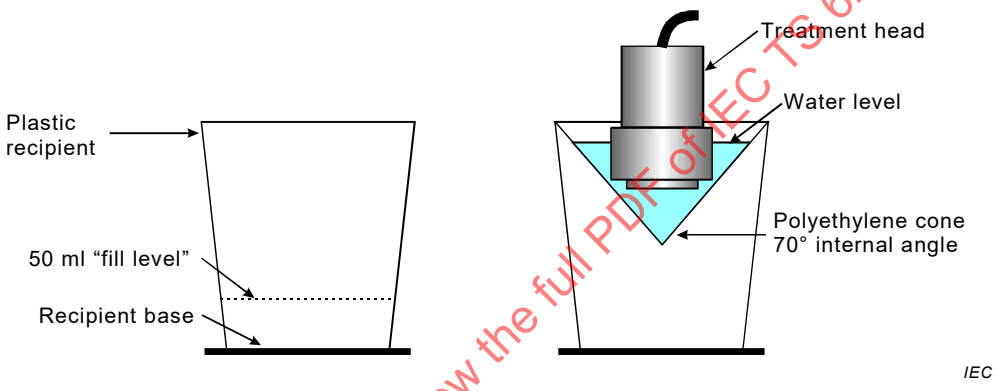


Figure D.1 – Schematic of equipment used within the calorimeter method for monitoring power output of therapy treatment heads

This simple check therefore enables the **output power** of therapy units to be monitored and to enable changes in acoustic power of greater than about 20 % to be detected. This test does not give an absolute measure of the output in watts or W/cm^2. More details of the method may be found in reference [10]. Although the test is straightforward, it should be exactly as described in a) and b), to obtain consistent results. Each frequency of **ultrasound** should be tested separately, even if the same **treatment head** produces the two frequencies. The test results should be reported in a log sheet, which is to be preserved with the equipment during its lifetime. The first test should be undertaken at acceptance test and used as reference for future tests.

a) For large **treatment head**s:

1) Fill the plastic recipient with tap water between 20 °C and 25 °C up to the "fill level" and place the **treatment head** in this recipient, for at least 5 min, to allow the head and water to reach the same temperature.
2) Thoroughly stir the water in the recipient with the **treatment head**. Using the syringe, transfer exactly 20 ml of this water to the plastic cone.
3) Remove the **treatment head** from the recipient and immediately immerse it in the cone so that the final position of the head is vertical and resting gently on the walls of the cone. Take care to slide the face of the head underwater so as not to trap any air underneath.
4) Run the head for 60 s on continuous wave (CW) at 1,0 W/cm^2. Move the **treatment head** gently up and down in the water.

5) Remove the head and place it in its holder on the physiotherapy equipment. Stir the water in the cone with the thermometer. Make sure that the tip of the thermometer is immersed, but do not allow it to touch the bottom of the cone. Record the maximum temperature that is reached in the cone.

6) Stir the remaining water in the recipient with the thermometer. Measure and record the temperature on the log sheet.

7) Subtract the temperature of the water in the recipient from that in the cone, and record the temperature rise on the log sheet.

   The acceptable temperature range is ±20 % about the mean temperature rise recorded on the log sheet. If the measured temperature rise is not within this range, repeat the procedure again immediately as a double check. If the second temperature rise is still out of the specified range, it can indicate that the physiotherapy equipment may not be performing appropriately and could be unsafe.

b) For small **treatment head**s:

   Follow the instructions for large **treatment head**s, but use 5 ml of water from a 5 ml syringe instead of 20 ml and run the head for 60 s on CW at 1,5 W/cm^2. Remember to move the **treatment head** gently up and down in the water.

Annex E
(informative)

Qualitative test to assess changes of effective radiating area

A quick test to qualitatively assess changes of the **effective radiating area** can be performed using phantoms cooked with thermochromic material. The technique uses the **ultrasound** emitted by the **treatment head** to heat the phantom and create a heating pattern correlated with the **treatment head** radiating area. This pattern can be recorded at acceptance test and used as reference for future tests. The material needed is as follows:

a) a thermochromic phantom sensitive to temperature in the range of 42 °C to 45 °C [11];

b) a small plastic pipe or cylindrical bowl of sufficient depth to be filled with water to a maximum of 25 mm. This bowl should be connected on one side to the **treatment head** and on the other side to the thermochromic phantom. See Figure E.1 for an assemblage example;

c) water (tap water is adequate for this qualitative and quick test).

The procedure is as follows.

a) Hold the **treatment head** so that the face is pointing upwards. Connect the pipe to the face of the **treatment head**.

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

c) Put the thermochromic phantom at the top of the pipe and make sure that there are no air bubbles under the phantom (for instance, use a transparent pipe).

d) Turn on the **ultrasound** to 1,0 W/cm^2 and wait until a stable pattern appears. The effect that can be seen is shown in Figure E.2 a). The time necessary until the thermochromic phantom presents a stable pattern depends on the material used to cook it. It is known that thermochromic phantoms made of silicone or epoxy need approximately 30 s to show a stable pattern (see reference [11] for details).

e) Record the observed pattern (a digital camera can be used).

The features of the heating pattern to note since the last time it was checked are as follows:

1) the circular symmetry of the pattern;

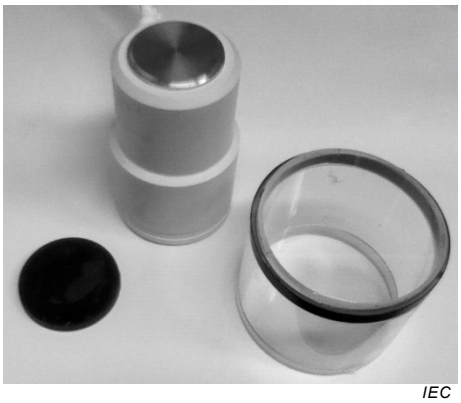
NOTE 1 Changes in the circular symmetry can be an indication of changes in the **effective radiating area**.

2) whether the pattern changed in symmetry (Figure E.2 b);

3) whether the pattern decreased in size (Figure E.2 c).

NOTE 2 Size decreasing could be related to the reduction in **ultrasound** power.

Changes in the circular symmetry can indicate that the **treatment head** may not be performing appropriately and could be unsafe.



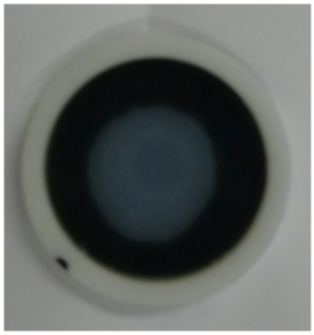
IEC

a) Material need to perform the test

IEC

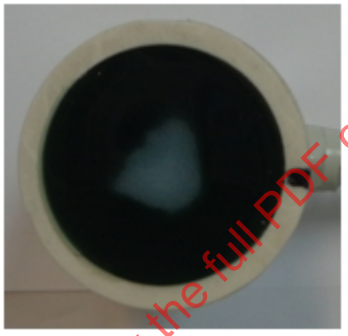
b) Example of possible set-up

Figure E.1 – Assessing changes of the effective radiating area using a thermochromic phantom



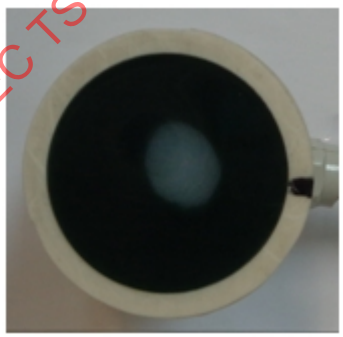
IEC

a) Circular symmetry



IEC

b) Changed in symmetry



IEC

c) Decreased in size due to reduction in ultrasound power

Figure E.2 – Examples of different patterns observed during an experiment using a thermochromic phantom made of silicon

Annex F
(informative)

Example of weekly test report

Acceptance test for device, date: .....

Manufacturer: ..... Model: ..... Serial no.: .....

Treatment head – Frequency: ..... Nominal radiating area:

Serial no.: .....

Results visual inspection: .....

Device traceably calibrated? .....

Setting for relative ultrasonic output test: Mode: ..... Intensity or power: .....

Method used for relative ultrasonic output test: ..... Relative value .....

Beam uniformity • Circularly symmetric? ..... • Sharp peaks? .....

• General comments? .....

Weekly test

Date	Visual inspection	Pattern symmetry	No sharp peaks	Comment	Result relative power measurement	Tester Name and signature

Describe the measurement protocol in details (container dimensions, water level etc.):.....

.....