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Development of transfer standard devices for ensuring the accurate calibration of ultrasonic therapy machines in clinical use

Guide for the maintenance of ultrasound physiotherapy systems

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E-mail: kristiaan.larsen*@ec.europa.eu*

Contact: Kristiaan LARSEN

European Commission
Office CDMA 04/100
B-1049 Brussels

Tel. (32-2) 29-60764
Fax (32-2) 29-64299

EUROPEAN COMMISSION

Guide for the maintenance of ultrasound physiotherapy systems

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R.T. Hekkenberg([1]), K.Beissner([2]), B. Zeqiri([3]), A.Richards([4]),
R.A.Bezemer([1]) and M. Hodnett([3])

([1]) Netherlands Organisation for Applied Scientific Research (TNO), NL

([2]) Physikalisch-Technische Bundesanstalt (PTB), DE

([3]) National Physical Laboratory (NPL), UK

([4]) Commonwealth Scientific and Industrial Research Organisation (CSIRO), AU

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Annex H

Guide for the maintenance of ultrasound physiotherapy systems

CONTENTS

Guide for the maintenance of ultrasound physiotherapy systems

FOREWORD

Physical therapy ultrasound is widely applied to patients. However, many devices do not comply with the relevant standard stating that the actual power output shall be within ±20% of the device indication. Extreme cases have been reported: from delivering effectively no ultrasound or operating at maximum power at all powers indicated. This can potentially lead to patient injury as well as mistreatment.

The European Commission (EC) has funded a number of projects as an ongoing attempt to improve the quality of the treatment of patients being treated with ultrasonic physical-therapy.

- In 1992: Hekkenberg R T, Reibold R, Zeqiri B, *Development of standard measurement methods for essential properties of ultrasound therapy equipment*, BCR 3377/1/0/132/90/3-NL(30), June 1992.
- In 2000: Hekkenberg R T, Beissner K, Zeqiri B, *Therapy-level ultrasonic power measurement*, Final Technical report SMT4-CT96-2139, 2000, *European Commission, BCR Information, Report EUR 18828 ISSN*
- In 2005: R T Hekkenberg, A Richards, K Beissner, B Zeqiri, G Prout, M Hodnett, R A Bezemer and Ch Cantrall, *Development of transfer standard devices for ensuring the accurate calibration of ultrasonic physical therapy machines in clinical use,* project G6RD-CT-2001-00600, to be published late 2005.

During the last project a Portable ultrasound Power Standard (PPS) has been developed and accurately calibrated. The PPS includes: Ultrasound transducers (including one exhibiting an unusual output) and a driver for the ultrasound transducers that has calibration and proficiency test functions. Also included with the PPS is a Cavitation Detector to determine the onset of cavitation occurring within the propagation medium.

The PPS will be suitable for conducting in-the-field accreditation (proficiency testing and calibration). In order to be accredited it will be important to be able to show traceability of the calibration, the calibration process and qualification of testing staff. The clinical user will benefit from traceability because treatments will be performed more reliably.

The purpose of this Guidance is to establish standard methods of qualitative and quantitative checks of the performance of ultrasound physiotherapy devices during their lifetime, and to provide guidance on calibration requirements and techniques.

It will provide basic guidance for the maintenance of physio-therapy systems at two levels: one for weekly use and the other for annual use.

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.

§ The numbers in square brackets refer to annex **[……….]** – Bibliography

INTRODUCTION

The purpose of this Guidance is to establish standard methods of qualitative and quantitative checks 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 needed. This Guidance defines an acceptance, weekly and annual check. The acceptance test is to check 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 a weekly and annual test reports.

This report gives also 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.

Guide for the maintenance of ultrasound physiotherapy systems

1 Scope

This Guidance:

- is intended to assist users of ultrasound therapy machines in checking the performance of these machines.

- 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 1 – The titles of all publications referred to in this Guidance are listed in annex G.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Guidance. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this Guidance are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 61689, Ed2: 200x, ULTRASONICS - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz

IEC 61161, Ed2: 200x, draft standards, ULTRASONICS – Power measurement – Radiation force balances and performance requirements up to 1 W in the frequency range 0,5 MHz to 25 MHz and up to 20 W in the frequency range 0,75 MHz to 5 MHz

3 Definitions

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

3.1
Acoustic Working Frequency
The rate at which the treatment head's contact face is vibrating.
(simplified definition, for original IEC 61689)

NOTE: Typical ultrasound physio-therapy machines operate in the range 0,7 MHz – 3,3 MHz. The long-wave ultrasound therapy machines operating in the frequency range 30kHz 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.
(**simplified definition, for original** IEC 61689)

3.3
Degassed water
Water with a low dissolved gas content.
(See IEC 61161 and Annex B3)

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

3.4
Effective Radiating Area (A_{ER})
The area of the front of the treatment face from which ultrasound is being emitted/radiated. (simplified definition, for original see IEC 61689)

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
Acoustic intensity
The amount of ultrasonic energy flowing per second through an area and divided by that area.

3.7
Output Power
A measure of how much ultrasonic energy is flowing out of the treatment head per second. (simplified definition, for original see IEC 61161)

3.8
Tester
The 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 at 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 manufacturers 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. Are all items delivered and do they look undamaged.

5.1.2 Manufacturers statement

On delivery of either a new device or after repair of an existing device check the written manufacturer's statement that the device performs following the specification. From this statement it should follow that the device is traceably calibrated following the IEC 61689 and IEC 60601-2-5 standards.

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 case 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 following 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 Clause 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 will be used in the weekly test, see Clause 5.2.2.

5.1.4 Beam uniformity and output test

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 the water in a container. The equipment needed is as follows:

a) A small container of sufficient depth to be filled with water till 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 shut down 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].

5.1.4.1 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 up with 5 mm - 20 mm water. (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. (A circular 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:

(i) The circular symmetry of the pattern.

(ii) Whether there are any sharp peaks (hot spots) showing (see Figure 1(c)).

(iii) Whether the appearance of the disturbance changed in height or symmetry since the last time the check was carried out.

(iv) Whether the pattern remained the same but decreased in height with reduction in ultrasound power.

(v) Especially changes of the circular symmetry can be an indication of changes in the effective radiating area.

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

In case one of the events listed in Clause 5.1.1, 5.1.2, 5.1.3, 5.1.4 are not satisfied, 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 like cable damage.

5.2.1 Visual inspection

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

5.2.2 Relative ultrasonic output test

The ultrasonic output should be measured relatively using the same method described in Clause 5.1.3.c and at the same settings as used during the acceptance test.

The result should not deviate more than 25 % from the value determined during the acceptance test

5.2.3 Beam uniformity and output test

The beam uniformity can be tested using the same method as described in Clause 5.1.4.

5.2.4 Recording of results of weekly testing

The results of the weekly test should be recorded. Annex E gives an example of a Weekly Test Report.

5.2.5 Requirements / Recommendation

Patterns obtained by performing Clause 5.2.3, which are not circularly symmetric and/or have sharp peaks, indicate that the treatment head may not performing appropriately and could be unsafe. Unexpected patterns may identify future failure.

In case one of the events listed in Clause 5.2.1, 5.2.2, 5.2.3 are not satisfied, the manufacturer should be consulted to check the device.

5.3 Annual testing

The purpose of the test for evaluating beam uniformity is that it gives the healthcare professional some guidance as to whether the treatment heads 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 F).

5.3.1 Output power test

For each treatment head and at the intended frequencies of operation the actual ultrasound output power shall be measured following the IEC 61161 standard [5].

The ultrasound power should be measured at the indicated values (or as close as possible for the 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 power meter and then re-attached for the second series of readings. Annex F 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 agree to within ±20 % of that indicated on the device.

It shall also be checked that a power setting of 0 Watt does not deliver any ultrasound.

5.3.2 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. Eventual changes of this area can be observed using the beam uniformity test in Clause 5.1.4.

5.3.3 Beam uniformity test

The annual beam uniformity test is performed in the same manner as the weekly test for beam uniformity, see Clause 5.1.4.

5.3.4 Pulse regime accuracy test

The performance of the pulse regime is not expected to change significantly from year to year. The test can be done with an ultrasound power meter or an oscilloscope using a non-invasive current probe. All measurements need to be done with the treatment head 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 this parameter will change over time.

5.3.4.1 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 agree to within ±5 % of that calculated using the pulse regime factor with the continuous power value.

5.3.4.2 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 cycle is as indicated on the machine, again 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 observing the pulse regime on the oscilloscope.

5.3.5 Timer accuracy test

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

NOTE: The test is optional as it is not expected that this parameter will change over time.

The test can be performed using a stopwatch. The ultrasound machine's timer should be accurate to within ±1 %.

5.3.6 Recording of results of annual testing

The results of the annual test should be recorded. Annex F gives an example of an Annual Test Report

The measurement uncertainty shall be estimated using [6]

5.3.6.1 Test report format

The Test Report should record the:

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,

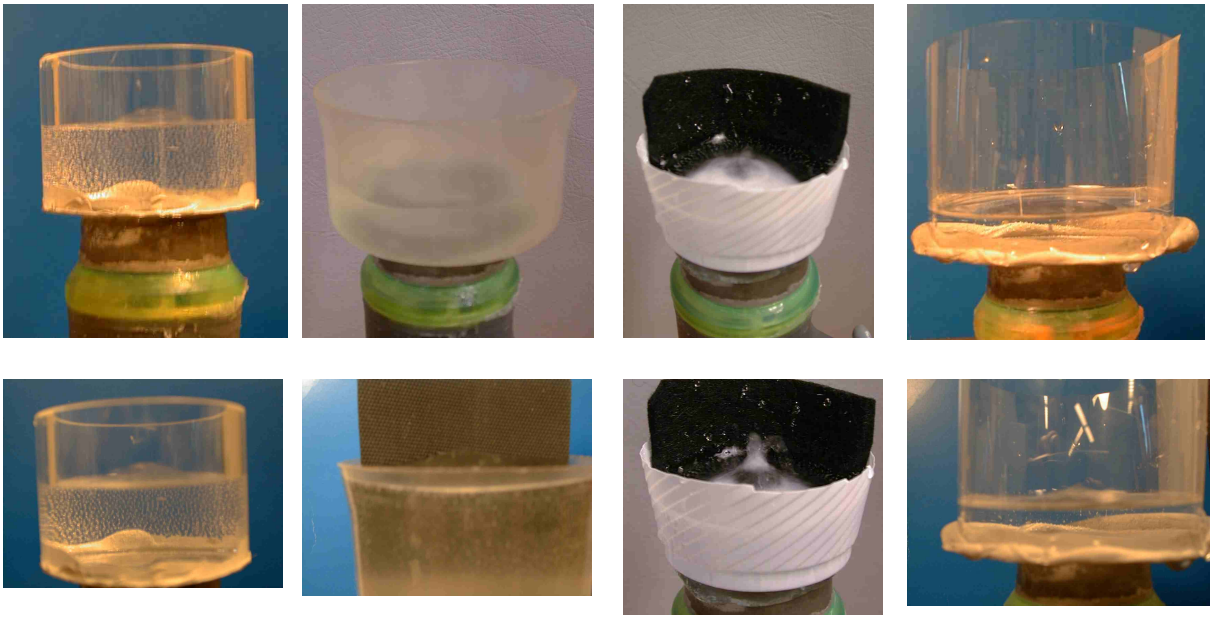
d) calibration date of the power meter,

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 heads. 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 dose and 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.

5.4 Service requirement

If any of the parameters listed in Clause 5.3 does not function within the listed uncertainty the device should no longer be used for treating patients until the unconformity has been resolved.



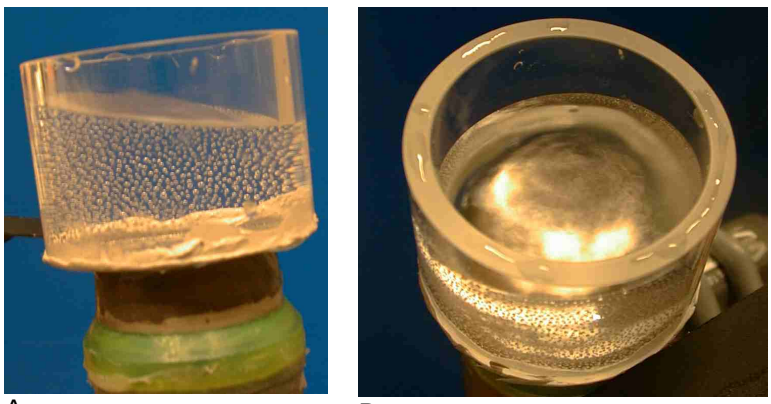
A.
A clear plastic pipe at the bottom close with a piece of a sheet used for an overhead projector transparency

B.
A small container 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 how to prepare a set-up to check the distortion on the water surface due to ultrasound.



A B

Figure 2 Set-up where the slight angle of the treatment head to the vertical may improve the image. Especially in image B the circular distortion can well be observed.

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 delivering. For the user it will form an important first chain in the Quality Assurance program

A.2 Weekly testing

Treatment heads can suddenly fail entirely, or can partially fail, giving either reduced output or 'hot spots' 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 in order to ensure reliability of the transducer.
Beam uniformity testing is performed to assess any 'hot spots' on the transducer head and whether the machine is outputting any ultrasound power.
Pulse regime and machine timer are tested for their accuracy. Accuracy of dosage can otherwise be affected due to inaccuracy of the pulse regime.

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

Annex B
(informative)

GUIDANCE FOR TESTERS

Considerations for use by the testers are as follows:

B.1 Purchase of power meter

An introduction into the physical principles of ultrasound power measurement and the mechanisms of the most common types of meter can be found in the IEC 61161 standard. It is worth reading the literature about the way the measurement set-up itself affects the measurement result [1,7,8,9]. The features, which should be considered before purchasing, are as follows:

(i) Compliance with the principles in IEC 61161.

(ii) A resolution of at least 0,1 W and a measurement range of up to 15 W.

(iii) A calibration check of the force measurement mechanism that can be done by the tester, without sending the power meter to a service agent.

(iv) Ease of use when in the laboratory and when travelling to physiotherapy practices.

The most common 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 of the ultrasound force (F=mg).
Especially in the case of diverging ultrasonic beams it is advised to use an absorbing target instead of a reflecting target. See [5,8]
IEC61161 give guidance on the use of different power meters.

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

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

a) The target has 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 no larger than <0,1 mm^2

b) Conical reflector targets or targets that consist of a 45° plate/s may have difficulty dealing with less than ideal beam cylindrical symmetry due to the radiation force measurement mechanism.

c) A power meter equipped with a reflecting target always needs lateral absorbers, see IEC61161.

d) Concave geometry targets that 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 will also give the same response, such as removing the treatment head from the water or the patient.

e) Absorber targets that do not comply to the requirements given in IEC 61161.
Absorbers are theoretically very attractive but can be highly variable in performance. It is important to ensure that the acoustic properties comply with the specification given in IEC 61161.

f) The use of membranes in front of the target or coupled to the front face of the treatment head. 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.

g) Poor electromagnetic screening within the power meter. Some dual frequency (1 MHz and 3,3 MHz) treatment heads have slightly higher electromagnetic radiation levels which can interact with the electronics in some power meters.

B.2 Room and water temperature

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

B.3 Water

Tap water is *not* advisable since it will have a high dissolved gas content from being cold and under pressure in the water supply. High dissolved gas content will cause problems due to the formation of bubbles when ultrasound at higher powers is applied to the water. Tap water may also have fine particles, which can act as nucleation points for cavitation. For measurements of ultrasonic power > 5 W the water need to be degassed.

Detailed methods for the preparation of degassed water can be found in IEC 61161 and [10]. Any method can be used that ensures that the oxygen content stays below the basic required value listed in the IEC 61161 standard.

Some techniques, in order of ease of use, that are suitable in a simple testing environment are as follows:

(i) *Chemical Additive.* Sodium sulphite (Na_2SO_3) at $4gl^{-1}$ will efficiently scavenge the dissolved oxygen, and it has been found that this is sufficient to ensure a significant suppression in the cavitation activity. A sodium sulphite solution of approximately 1 litre will remain usable for at least one day. A sealed vessel with no air bubbles present will remain satisfactory for two to three days. The solution should be prepared using distilled water which has been allowed to stand at room temperature and at atmospheric pressure overnight.

(ii) *Boiling.* Boil the water for 15 min at atmospheric pressure, and then cool the boiling vessel in a water bath to an acceptable temperature for storage.

(iii) *Vacuum.* Use a vacuum vessel at <4 kPa for at least 3 h. The use of a magnetic bar stirrer can considerably reduce the time under vacuum. After the degassed water has been prepared, it should be stored in containers that are gastight and with no bubbles. Plastic bottles that are used for carbonated beverages are ideal. Once the degassed water is open to the air, it will remain satisfactory for 1 to 2 hours, depending on the open surface to volume ratio. The use of sodium sulphite (see i above) will prolong the period and is thus the most convenient technique.

NOTE 1: Clean tap water can be used to be degassed. It is however preferred to use distilled water to prevent oxidation of metals used.

NOTE 2: No other gas should be used to lower the dissolved oxygen content in the water

NOTE 3: Equipment should be rinsed with distilled water after use with sodium sulphite solution

NOTE 4: Dissolved oxygen in water forms the far most contribution to incorrect measurements compared to other dissolved gasses.

B.4 Environmental considerations

Drafts of air can affect the output of some ultrasound power meters. Common sources of drafts are overhead fans, open windows, doors, people walking past and/or the close proximity of an air-conditioning outlet. A large cardboard box over the power meter and the treatment head will eliminate the effect of drafts. A plastic window in the cardboard box is needed so that the display of the 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 power meter is placed should therefore be level, and situated away from sources of vibration.

B.5 Power meter checks

Having read the manufacturer's instructions, the following checks should be carried out:

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

(ii) The water level reservoir, if present, and topped up, if necessary.

(iii) Those power meters with membranes in front of the target to ensure that the membrane is flat and in good condition. A weak membrane can form a lens and can results in incorrect measurement.

(iv) Whether the power meter is levelled, if required by the manufacturer.

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

B.6 Power meter testing technique

The technique is as follows:

(i) 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.

(ii) If the 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.

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

(iv) It is desirable to have the treatment head face close to the power meter target. In case of reflecting targets 5 mm -10 mm will be appropriate; in 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 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.

(v) Tape or clamp the cable of the treatment head down to the bench.

(vi) In the case of a convex conical target the transducer faceplate should be centralised over the target apex to within ± 2 mm. This can be performed with the naked eye, and is adequate for transducers complying to the IEC 61689 standard. 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.

(vii) The reproducibility of a measurement and the accuracy of the final (averaged) result can be affected by the distance between the treatment head and the target in the power meter. Probably, the most time efficient technique is to

(A) set up a treatment head in the power meter;

(B) run through all the desired power levels once;

(C) remove the treatment head from the power meter and place it back again, readjusting the treatment head clamping mechanism to the power meter; and

(D) repeat Steps (A) to (C) three to five times, for a treatment head. For a high quality power meter, typical repeatability form repositioning, will 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 absorber 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.

(viii) The technique of raising the treatment head out of the water whilst it is running in order to ‘clear the head’ for 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 when the guidance below is followed.

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

- The set-up given in Clause 5.1.4 and Figure 1 can be used,
- A piece of high absorbing material. (absorption > 40 dB/cm at the frequency of interest) Its size should be not smaller than the size of the front of the treatment head under test. (use for small treatment heads the same size as for the larger heads)
- A thermometer. This could be an electronic one, a simple mercury thermometer or with a thermocouple.

The measurement set-up is as follows:

- The thermometer shall 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 > 3 mm. The thermometer has to fit tightly in that hole. If needed some coupling gel will improve the heat transfer from the absorber to the thermometer. See Figure C.1.
- The absorber shall be placed at a distance 1 to 2 cm from the face of the treatment head. (the distance used shall be equal for all the measurements to be carried out with this treatment head in future)
- Wait about 5 minutes to allow the absorber, the water and the thermometer to reach an equilibrium temperature.
- Set the physiotherapy device at the preferred output. (for this test an I_{eff} of 1 W/cm^2 should be sufficient)
- Note the temperature from the thermometer.
- Switch the physiotherapy device on and note the time
- Usually there is a reasonable temperature rise in 5 minutes, but if needed take more time.
- Note the temperature in the absorber and note the time ultrasound was on to rise 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.
- It is important that all device settings and distances are the same for all measurements in future.

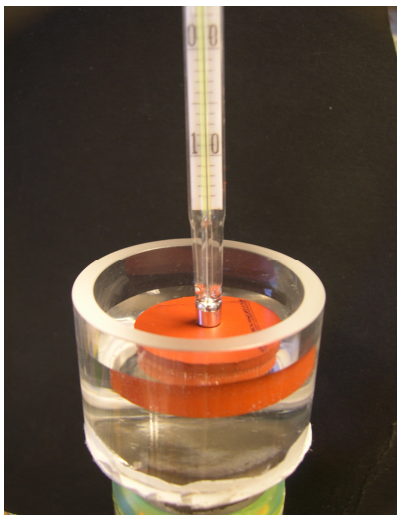


Figure C.1. Example of a measurement set-up to measure the temperature rise due to ultrasound in absorbing material.

Annex D
(informative)

QUANTITATIVE RELATIVE ULTRASONIC OUTPUT TEST USING CALORIMETRY

The following test outlines a protocol for using the simple calorimeter, based on 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 cup which holds the fluid.

Equipment required to complete the test is: a plastic (drinking) cup and cone and a thermometer. 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.

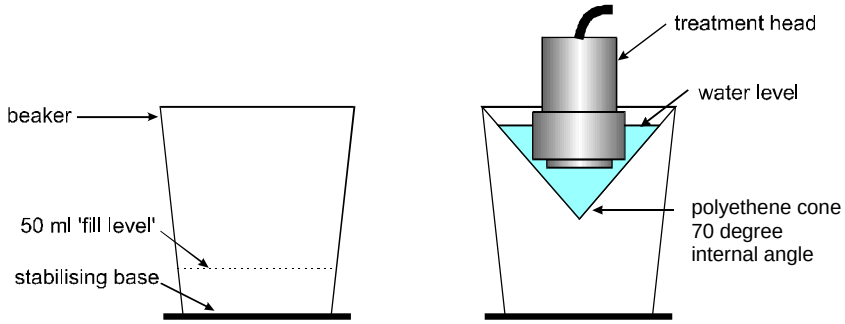


Figure D.1: Schematic of equipment used within the calorimeter method for monitoring power output of therapy treatment heads.

This simple check therefore enables the output power of therapy units to be monitored and to allows **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 Wcm^{-2}.
More details of the method may be found in publication [11]

Please read this instruction sheet carefully. Although the test is straightforward, it should be carried out exactly as described below in order to obtain consistent results. Each frequency of ultrasound must be tested separately, even if the two frequencies are produced by the same treatment head.

For large treatment heads:

1. Fill the plastic cup with tap water between **20 and 25 °C** up to the `fill level` and place the treatment head in this cup, for at least one minute, to allow the head and water to reach the same temperature.

2 Thoroughly stir the water in the cup 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 cup 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 seconds on CW at 1,0 Wcm^{-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 machine. 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 cup with the thermometer. Measure and record the temperature on the log sheet

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

8. If the measured temperature rise is not within the range specified on the log sheet for that treatment head and frequency, repeat the procedure again immediately as a double check. If the second temperature rise is still outside the specified range, contact should be made with the organisation that calibrates the equipment, who will test the calibration of the machine. (The acceptable temperature range is ±20-25 % about the mean temperature rise recorded as soon as the head has had its annual calibration.)

For small treatment heads:

Follow the instructions for large treatment heads, but use 5 ml of water from a 5 ml syringe instead of 20 ml and run the head for 60 seconds on CW at 1,5 Wcm^{-2}. Remember to move the treatment head gently up and down in the water.

Annex E
(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 —circular	No sharp peaks	Appearance has not changed since last test	Comment	Result relative power measurement

Annex F
(informative)

EXAMPLE OF ANNUAL TEST REPORT

CLIENT: .....

Location of Testing: .....

DEVICE FOR TEST

Manufacturer: .....

Model: .....

Serial No.: .....

Treatment Head - Frequency: .....

Serial No.: .....

Nominal Radiating Area: .....

A separate report sheet is to be used for each treatment head.

POWER METER

Manufacturer: .....

Model: .....

Serial No.: .....

Calibration Date: ..... <1 year .....

Calibration Method: .....Portable power standard (PPS) proficiency test by WA or SA?.....

BEAM UNIFORMITY

- Circularly Symmetric? .....
- Sharp Peaks? .....
- General Comments? .....

POWER REPORT GRAPH

- See this Appendix .....

POWER CALIBRATION COMMENTS

- Pass / Fail, within ±20 % .....
- General .....

Comments and action:.....

Failed and requires recalibration so that reading within ±20 %?

OPTIONAL TESTS

- Pulse Regime Accuracy: .....
- Timer Accuracy: .....

GENERAL COMMENTS

- Condition of device and treatment head? .....
- Any other? .....

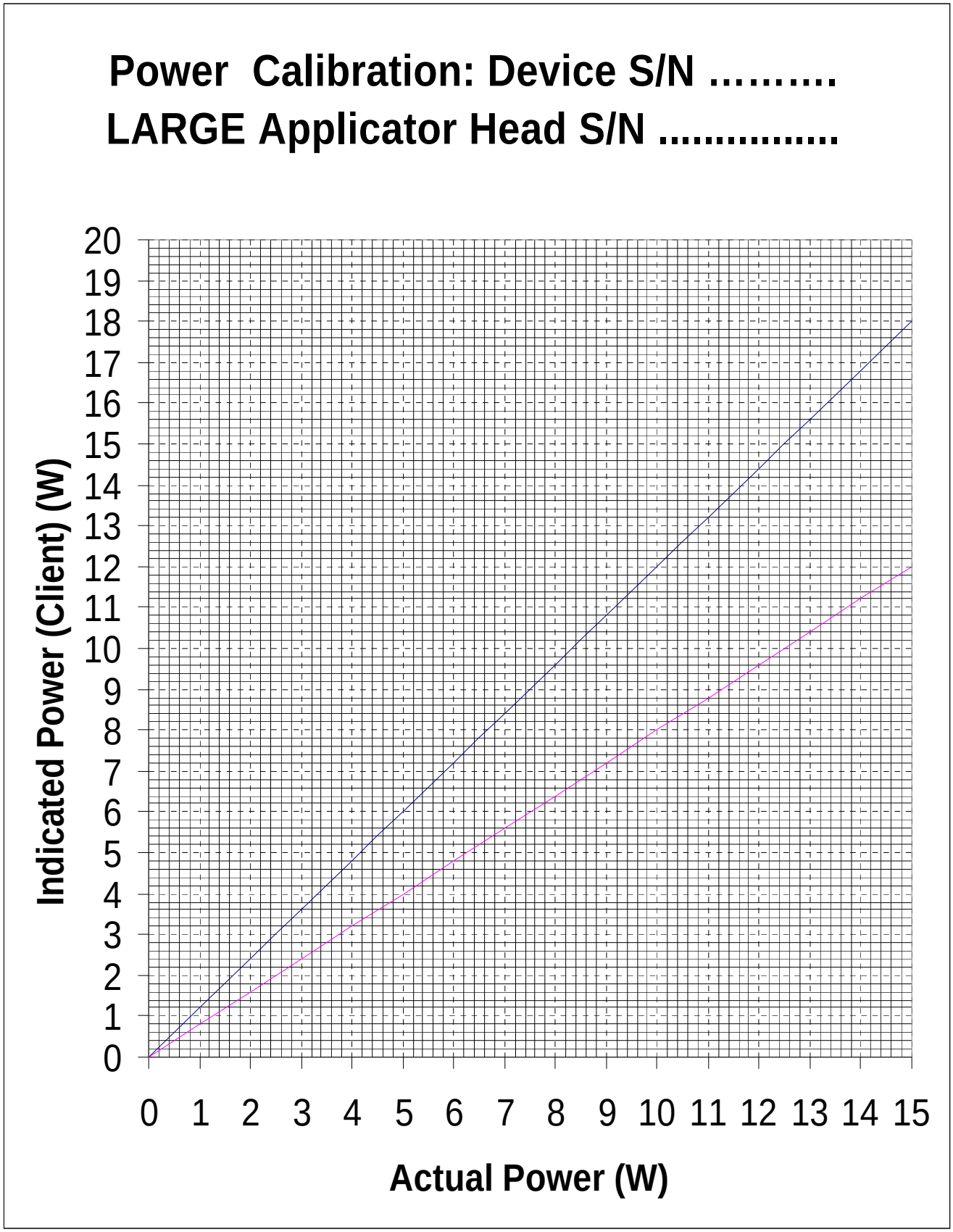
Name of Testing Officer (print) .....

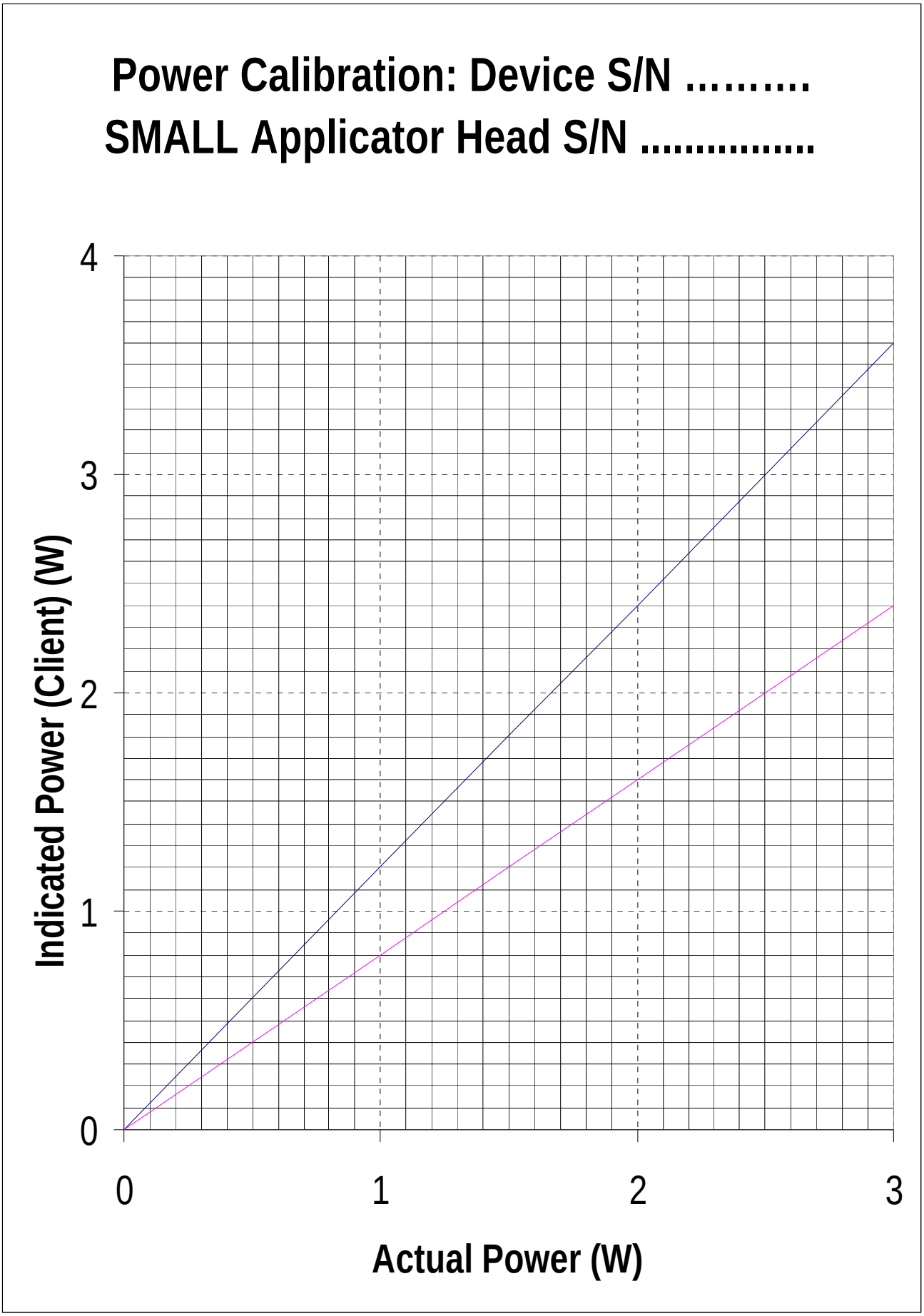
Signature of Testing Officer: .....

Date of Test: .....

Note: .....

The original report remains with the client. A copy is retained by the tester


Power Calibration: Device S/N .....
LARGE Applicator Head S/N .....
Indicated Power (Client) (W)
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Actual Power (W)


Power Calibration: Device S/N .....
SMALL Applicator Head S/N .....
Indicated Power (Client) (W)
0
1
2
3
4
Actual Power (W)
0
1
2
3

Annex G
(informative)

ULTRASOUND PORTABLE POWER STANDARD

G.1 Introduction

Any device that emits energy to treat a patient has to be calibrated and maintained regularly. This rule should be a part of the quality assurance program of the user of this medical device to protect patients.

There are several ways to achieve that goal.

a) The output can be calibrated by a calibration service provider who maintains a higher calibration level.

b) The output can be calibrated by a comparison with another device that has been calibrated at a higher level.

Also the reference to a higher calibration level can be organised in different ways:

a) The output can be calibrated directly at the institute holding the primary standard.

b) The calibration service proves their ability for ultrasonic output calibration by taking part in key-comparisons or using a device like the Portable Power Standard.

The Portable Power Standard (PPS) is a controlled standard. It provides a stable and reproducible source of ultrasound power in addition to providing the tester with a means to demonstrate his/her efficiency in using the power meter. The PPS uses calibrated ultrasound power transducers (treatment heads) which can be used to calibrate a user's power meter. There is a range of transducers available, intended to be representative of what is seen in clinical application. In addition, there is a transducer which is designed to test the immunity of the power meter to electromagnetic radiation interference and its robustness in measuring asymmetric ultrasound beams. The proficiency test function involves measuring a number of unknown powers from each transducer with the ultrasound power meter. The power meter should determine the correct power to within ±20 %. A complete calibration and proficiency test for five treatment heads should only take half a day.

Presently this Portable Power Standard is in use in European countries. As it is a relatively simple way to organise traceability, the use of such equipment should be promoted.

Annex H

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