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

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Abstract. 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 present European (EC) project is an ongoing attempt to improve the quality of the treatment of patients being treated with ultrasonic physical-therapy. A Portable Ultrasound Power Standard (PPS) is being 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.

1. Introduction
This paper describes work undertaken to develop an ultrasound power standard for use at physical therapy levels, 0.1 to 15 W. This ultrasound power standard will consist of a Portable Power Standard (PPS) and a Cavitation Detector (CD). Four PPS’s and CD’s will be produced, providing each partner with a unit on which to base regulatory work in their respective countries. The paper describes the progress made within the first 26 months of the project which is supported financially by the 5th Framework programme of GROWTH from the European Community (EC) and a grant from the Innovation Access Program administered by the Australian federal government agency DEST.

1.1. Background
Physiotherapy ultrasound is widely applied to patients. However, many ultrasound devices do not comply with the relevant standard: actual output shall be within ±20% of that indicated [1]. Extreme cases have been reported where devices in use are delivering no ultrasound or operating at maximum power at all powers indicated. This can potentially lead to patient injury as well as mistreatment.

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A previous EC project [2] resulted in primary standards of radiation force balances. Measurement errors caused by cavitation and perturbations in absorption or reflection of ultrasound were identified. A useful method for the detection of cavitation has been developed. What has been missing from the standards infrastructure, is a therapy-level acoustic source which can be used to calibrate power measurement systems ‘in the field’, e.g. in hospitals, manufacturers or test-houses. Those which have been produced require specialist handling and are incapable of generating more than 1 W output. The need for a Portable Power Standard (PPS) has been addressed within the present EC project.

2. Rationale behind the development of the PPS

The project is an ongoing attempt to improve the quality of the treatment of patients being treated with ultrasonic physical therapy. A Portable ultrasound Power Standard (PPS) is being developed and accurately calibrated. It will enable the user to perform traceable calibration of an ultrasonic power measurement system and provide a mechanism by which they can check their ability to do this. The PPS needs to fulfil the requirements appropriate for such a standard device – e.g. have good long and short-term stability, be representative of actual systems etc. The total setup comprise a set of five ultrasound transducers (including one exhibiting an unusual output) such that the range of treatment heads seen in clinical use is bracketed. The driver includes software-driven proficiency test protocols. Furthermore, a Cavitation Detector (CD) will inform users about the presence of gas bodies within the propagation medium, providing a diagnostic tool which will identify and thus avoiding inappropriate measurement conditions.

The PPS and CD will be subject to a round of travel journeys with tests by potential users. The European partners will contact parties interested using the PPS as an ‘in-house’ quality tool.

The motivation for commercial testers including manufacturers to be accredited and for the clinical users to request a traceable calibration will be different for each country. A common feature is the key information clinical users should demand from their commercial testers or manufacturers.

3. The radiation force measurement

A general outline of measurement of ultrasound power including the radiation force balance principle can be found in [3]. Essentially a set-up consists of a target, immersed in a water bath, which intercepts the ultrasound radiated from a source. The apparent mass difference, ∆m, of the target between the setting where no ultrasound is radiated and that where ultrasound is radiated, is derived and is converted into the measured ultrasonic power, \( P_m \), using the following expression:

\[
P_m = \Delta m \cdot g \cdot c(T)
\]

(1)

where \( g \) is the gravitation acceleration and \( c(T) \) is the speed of sound in the water as a function of temperature [4]. The formula for \( P \) is based on the assumption that the ultrasonic beam behaves as a plane wave field. In practice that is mostly not the case. A correction method for this [5] has been refined in [2,6]: corr \( C_1 \). A second correction (corr \( C_2 \)) is applied because measurement takes place at a finite distance from the transducer but is to be known at the transducer surface [2,6]. This correction automatically accounts for attenuation in the water path. So the formula is rewritten as:

\[
P_i = corr C_1 \cdot corr C_2 \cdot P_m
\]

(2)

where \( P_m \) is the measured power, \( P_i \) is the power corrected to the transducer surface, corr \( C_1 \) is the correction for non-plane waves and corr \( C_2 \) is the correction for distance dependence.

3.1. Some major measurement errors associated with power measurements.

Figure 1 shows that the size of the reflecting target is not large enough to intercept all of the generated ultrasound leading to large underestimates in the power. Even when the target-transducer distance...
becomes smaller the target will not intercept all ultrasound. Figure 2 shows that this effect can be distance dependent and can also be evident for absorbing targets.

Another common error is due to inappropriate treatment of the water used. Figure 3 shows the effect that O₂ content of the water had on the measured power (2000 V² ∶ 10 W acoustic power).

4. Transducers selected for the PPS
Commercially available ultrasound transducers have been selected, modified and tested by TNO. Five heads comprise a set for each PPS such that the range seen in clinical use is bracketed, see Figure 4. The basic beam characteristics of the transducers were measured following IEC 61689 [7]. A typical example is given in Figure 5. The characteristics include the working frequency, the effective radiating area (AER), the beam type and the radiation conductance and its temperature dependence. The transducers should show stability with time and should be robust for travel.

4.1. Results for the transducers selected
The temperature dependencies of the radiation conductance G (ratio of ultrasonic power and rms driving voltage squared) and the ultrasonic power P were determined for a set of 4 typical transducers. Due to temperature variation the transducer impedance varies a little. As a result P and G will vary. The maximum variation observed was 1.1% in G and 0.5% in P.

Over a period of about 8 months the stability of the transducers has been determined from
measurements of G. Figure 6 shows the results of the large ($A_{ez}: 5 \text{ cm}^2$) 1 MHz transducers and the small ($A_{ez}: 0.8 \text{ cm}^2$) 3 MHz transducers. These results are typical for all four types of transducers tested, showing a maximum variation of 3% over the 8 month period and a final measurement after 2 years. From the results after 2 years it seems that the drift for the 3 MHz transducer has stopped.

The project has mixed success in producing a negative control transducer to reveal the known deficiencies in some commercial power meters. Only one successful negative control has been produced. It has identified four defective power meters in routine use. Other transducers to be used are under investigation.

Figure 6. Variation of the radiation conductance over a period of 2 years, for a single large 1 MHz (A) and a small 3 MHz (B) transducer. In upper part the temperature of the water during the measurement is shown.

5. The Cavitation Detector
The formation of bubbles within the test medium (usually water), some of which may not be readily apparent to the operator, can scatter the ultrasound field generated by the transducer, leading to under-estimates in the measurement of power of up to 30%, and may indeed be responsible for some of the differences reported in the literature. The design specification for a cavitation detector (CD) generated during the previous EC project [2,6], has been refined by NPL to produce detectors which can be used to monitor the onset of cavitation within the propagation medium, through detecting acoustic emissions from bubbles oscillating under the influence of the incident acoustic field.

![Diagram of cavitation detector and hydrophone](image)

Figure 7. The principle set-up to detect the onset of cavitation and the Cavitation Detector and hydrophone, presented as part of the Portable Power Standard.

Figure 7 shows the way an angled hydrophone will measure the ultrasonic radiation that has been converted in direction as well as in frequency content due to the existence of bubbles in the ultrasound beam. The figure also shows the CD with the detector (a needle hydrophone). The electronics module is directly coupled to the Portable Power Standard. Monitoring takes place in such a way that power measurements are not disturbed. The design of the CD, and its performance are described in a companion paper [8].
6. The driving unit of the Portable Power Standard

The microprocessor controlled driving unit, produced by CSIRO, see Figure 8, combines three major tasks: It drives the transducers connected to it, communicates with the user who performs the calibration and proficiency tests and logs the measurement conditions and responses of the tester. The measurement conditions monitored in the background are: input from a thermometer in the tester’s power meter water, the Cavitation Detector alarm, the internal temperature of the driver (calibration state during use and freight), how many times the transducers were used and whether they were immersed at all times, and finally whether the tester required an excessively long time for a measurement or exceeded the total session time.

![Figure 8. The driving unit of the Portable Power Standard.](image1)

![Figure 9. Block diagram showing the basic features of the Portable Power Standard.](image2)

The basic features are shown in Figure 9 and comprise a

- **Tutorial Sub-Program**: enables the tester to check the calibration of their power meter against all the transducers and to become familiar with the PPS.
- **Proficiency Test Sub-Program**: the blind test of the tester with their power meter. They are required to measure a number of unknown powers with five different transducers.
- **Super User Sub-Program**: a LabView interface between the laboratory computer and the Driver. It is used for setting various values in the Driver and downloading logged data from the Driver.
- **Cavitation Detector Interface** to the Driver.

7. Fundamental power measurement

Ultrasonic power measurements were performed at PTB with an electronic mass balance under computer control in the same arrangement as that used to perform the international CIPM key comparison [9] and in accordance with IEC 61161 [10]. Figure 10 shows the arrangement used: the target is hanging under the balance, the water tank is not in contact with the balance pan, the transducer radiates upwards through a hole in the bottom of the water tank, see [11].

![Figure 10. Power measurement system](image3)

The nominal power values used in the calibration are 100 mW, 500 mW, 3 W and 15 W for the "large" transducers, and 100 mW, 300 mW, 1 W and 3 W for the "small" transducers. Each transducer was excited by the PPS in continuous-wave mode and using a particular driving frequency. The excitation amplitude has provided to the PPS in the form of a dimensionless number.
7.1. Results of the fundamental power measurement
Almost all transducer – PPS combinations have been measured three times in an independent process. Only one transducer failed to survive the whole process. A complete evaluation of the results has not yet been discussed within the project group, but the first results look promising. Table 1 shows the overall stability during the measurements. It is expressed as the maximum percentage of difference between the highest and lowest values obtained with all transducers on their PPS for the driving voltage, the measured ultrasonic power and the radiation conductance for each transducer.

|        | device | driving voltage | measured power | radiation conductance |
|--------|--------|-----------------|----------------|-----------------------|
| PPS01  | 0,28   | 1,09            | 0,62           |
| PPS02  | 0,50   | 0,48            | 0,83           |
| PPS03  | 0,81   | 1,82            | 1,57           |
| PPS04  | 0,54   | 1,44            | 1,78           |

8. Conclusions and future work
The project is on target to develop transfer standard devices for ensuring the accurate calibration of ultrasonic therapy machines in clinical use. However the work has taken longer than expected due to a number of unexpected technical challenges.

The project has come into a phase of travel trials with tests by potential users. This phase of work is currently being executed in Australia and New Zealand. The European laboratories will soon start a trial of their PPS in their respective country. Before that, each laboratory will perform power measurements using their individual primary radiation force measurement systems to compile reference material. After this work it is expected that the PPS will be suitable for conducting in-the-field accreditation (involving proficiency testing and calibration). Guidance material for the user and draft supplement(s) to international standards to be submitted to IEC TC87 will be prepared.

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