# Brief report about on-site measurement study of ultrasonic power from physiotherapy devices

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**Abstract.** The objective of this work is to show some results on the total emitted acoustic power of ultrasound physiotherapy devices measured in a recent field study in Mexico. A total of 87 ultrasound physiotherapy devices took part in this study. A portable radiation force balance with a convex-conical reflecting target, operating in the range from 10 mW to 30 W, was used as a reference standard. The output power emitted by each ultrasound physiotherapy device at four nominal values was measured: 1 W, 5 W, output power corresponding to 1.5 W/cm$^2$, and maximum power. In each case, the ultrasound device was set to operate in a continuous-wave mode and at a fixed frequency (1 MHz or 3 MHz). Although variations of the actual output power within ± 20 % are considered as acceptable values by an international standard [1]. In this study it was found that nearly 24 % of the measured ultrasound devices (with deviations >40 %) can potentially lead to placebo treatments or mistreatments. This study remarks the importance of periodic calibration programs for the ultrasound physiotherapy devices, besides the actual maintenance service that is regularly given to these equipments.

## 1. Introduction

Ultrasound for physiotherapy purposes is widely applied to patients as part of a physical rehabilitation treatment. Since one of the properties of ultrasound is its thermal effect, higher dosages can cause tissue damage, while at lower dosages it may become a placebo. Therefore, the safety and effectiveness of the treatment with ultrasonic physical therapy may be compromised if the equipment used does not deliver the prescribed doses to patients with a reasonable degree of accuracy. In Mexico, every year more than 2.6 million of physical therapies are performed in the public sector [2]; it is estimated that at least a similar amount are performed in the private sector. Being ultrasonic therapy one of the most used techniques nowadays.

Since usually calibration of ultrasound physiotherapy devices is not included as part of its periodic maintenance program, the correct operation of the ultrasound physiotherapy equipment may lack of measurement evidence. That is, users may not have enough objective information to assure that their ultrasonic physiotherapy devices operate

correctly. Fact is, at August 2010, there are not secondary laboratories in Mexico, accredited by the mexican accreditation body (EMA), to calibrate ultrasound equipment used in physiotherapy.

Thus, in order to know the current operation status of ultrasound infrastructure for physical therapy available in the State of Queretaro, a field study was done; focusing in hospitals, clinics and physical rehabilitation centers that provide treatments with ultrasonic physical therapy, in both public and private sectors. The main goals were to measure the total emitted acoustic power of ultrasound physiotherapy equipments, and to determine the error between nominal values indicated in the display of each device and the actual measured acoustic power. A second goal was to promote the use of traceable measurement standards among physiotherapists that use ultrasonic equipment; as a key aspect to assure safe and effective treatments to patients. Information regarding amount, geographic distribution and manufacturing date of ultrasound physiotherapy equipments, was also gathered during the study. To the authors' knowledge, this is the first field study on ultrasound metrology of its kind and scope in Mexico; including results of total acoustic power measurements from 87 ultrasonic physiotherapy devices belonging to 34 medical centers.

## 2. Methodology

Measurement of acoustic power emitted by ultrasound physiotherapy equipments is very useful to ascertain whether such equipment is performing satisfactorily, and to ensure that exposure doses applied to patients indeed correspond to the expected levels and avoid possible harms on healthy tissue.

The phenomenon of radiation force, where ultrasonic waves propagating in water cause a transfer of momentum to a target located in the beam path, is the basis used to perform total acoustic power measurements addressed in this study. The target experiments a force along the direction of propagation, if the target is large enough to intercept the whole beam, then the experienced force is proportional to the total acoustic power of the beam.

It is known that for a perfectly reflecting target, assuming plane waves, the ultrasonic power, P, is directly proportional to the radiation force, F, as shown in (1)

$$P = cF/2\cos^2\theta \qquad (1)$$

where c is the wave speed in the medium, usually water, and θ is the angle between the propagation direction of the incident beam and the normal to the reflecting surface of the target.

For a 45° cone angle, θ = 45°, the expression simplifies to

$$P = cF \qquad (2)$$

In practice, the treatment head is positioned facing the apex of the cone and is aligned perpendicularly to the base of the cone, so that the incident ultrasound is reflected away from the acoustic beam axis.

The reference standard used in the study was a portable radiation force balance with operating range from 10 mW to 30 W, having an expanded uncertainty of 5 % (coverage factor k=2) at ultrasonic power values near 1 W [3]. A computer interface was developed to automatically acquire the ultrasonic power (W) readings from the radiation force balance.

Only ultrasonic physiotherapy equipment employing a single plane unfocused circular transducer per treatment head were considered. All measurements were performed using the ultrasonic equipment operating in a continuous wave mode. The preferred operating frequency was 3 MHz, however, there were some cases were this frequency was not available in the equipment, and an operating frequency of 1 MHz was used instead.

The radiation force balance has a convex-conical reflecting target of 82.3 mm diameter, with a cone half-angle of 45º. Since the target size affects the force that is measured, a general requirement is that the target diameter shall be at least 1.5 times the diameter of the ultrasonic transducer under test [4]; thus, the maximum diameter of an ultrasonic transducers that could be measured with the radiation force balance used in the study is 55 mm. Diameters of ultrasonic transducers ranged from (8 to 35.7) mm, according to their nominal effective radiating area, thus the requirement of diameter ratio between target and transducer was fulfilled in all cases.

In this study, the *ka* values of ultrasonic transducers operating at 1 MHz range from 44.5 to 75.2, while for transducers operating at 3 MHz the ka values range from 44.5 to 228.7.

In the on-site measurements, each ultrasound physiotherapy equipment was configured to four different nominal values of ultrasonic power: 1 W, 5 W, output power corresponding to 1.5 W/cm$^2$, and maximum power. Such values were selected to obtain enough information about its operating behavior from a low power to the highest power that could be selected in the equipment. Then, deviations of actual output power from selected nominal values were determined.

It was not possible to control some important variables in the radiation force balance set up that are usually accounted for in the laboratory; such as use of degassed water, draughts and vibration, to mention some; mainly because of the short time given to the research group to set up the system and performed measurements. Distilled water without additional degassing was used to fill the radiation force balance tank; care was taken to remove any bubbles that occasionally formed on the target's surface and transducer by softly sweeping them away. The ultrasonic transducer was held as close as possible over the apex of the cone target. Visual alignment of the position and orientation of each transducer was also made. Measurements were repeated at least twice, removing and realigning the ultrasonic transducer between measurements. An uncertainty contribution due to misalignment of the ultrasound transducer was certainly considered in the uncertainty budget as indicated in [4]. The effects from draughts were reduced by using an

acrylic enclosure surrounding the radiation force balance. Whenever possible, a location with limited movement from persons and objects was provided by the visited physiotherapist, in order to avoid vibration influences. Figure 1 shows the radiation force balance used in the study, and a treatment head (ultrasonic transducer) positioned above the target.

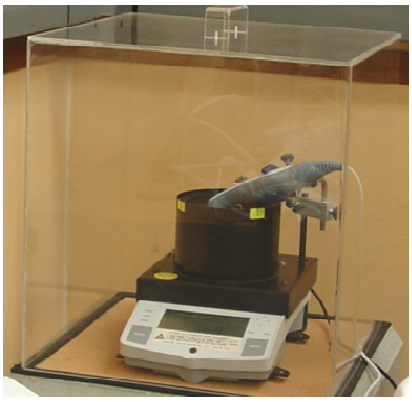


**Figure 1**. Radiation force balance used as reference standard.

Acoustic power emitted by the ultrasound physiotherapy device is determined from the force difference exerted on the target by switching the ultrasound device ON and OFF [1]. The acoustic power was measured in a sequence of OFF-ON-OFF events. For nominal power values of 1 W, 5 W and 1.5 W/cm$^2$, the ultrasound was ON and OFF, for 10 s each. At maximum power values, the ON event lasted 15 s and the OFF event 20 s. The total acoustic power was determined from the average of balance readings corresponding to the two transitions of ultrasound, OFF-ON and ON-OFF, for each sequence.

Considering that four nominal power values were measured on each ultrasound physiotherapy device; the criterion taken to determine if its operating condition may compromise effectiveness of a given treatment, is that deviations between nominal values and actual power emitted, be larger than 40 %, in at least 3 of the 4 nominal values selected. That is, when deviation in three output power measurement levels is twice the tolerance indicated in IEC 61689 [1], the ultrasound equipment is considered as not apt to assure effective physiotherapy treatments.

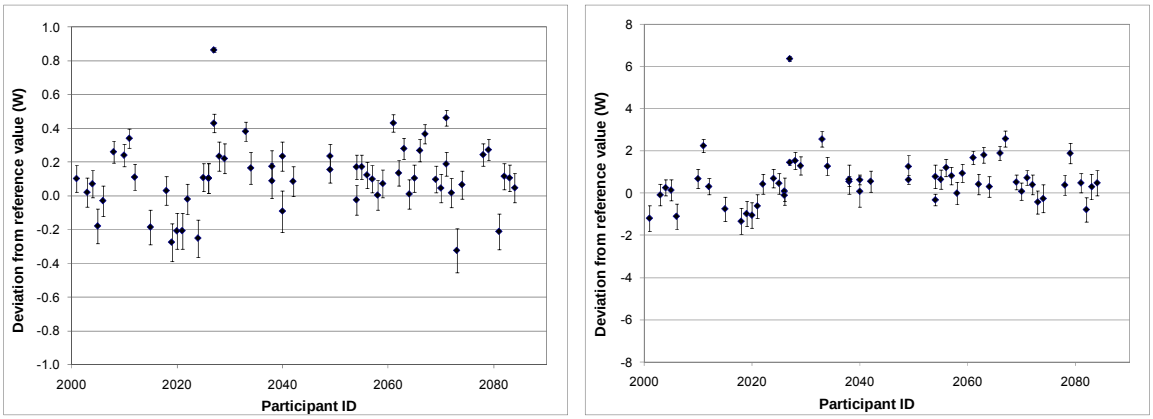
In order to preserve confidentiality of participants, an identification number was assigned to each combination of ultrasound physiotherapy equipment and medical center.

### 3. Results

A total of 87 ultrasonic devices were measured, such equipments were located in 34 medical units, from public and private sectors.

Operating frequency in 52 out of 87 ultrasound physiotherapy equipments was set at 3 MHz. Seven on those ultrasound equipments had a treatment head with double

ultrasonic transducer on opposite sides and with different nominal effective radiating area. Figure 2 shows the deviations between nominal values (1 W and 1.5 W/cm$^{2)}$ and emitted acoustic power for equipment operating at 3 MHz. At a nominal power of 1 W, it can be observed that most of the participants have a deviation value within ± 0.4 W, and ± 2 W at 5 W/cm$^2$.




(a) (b)

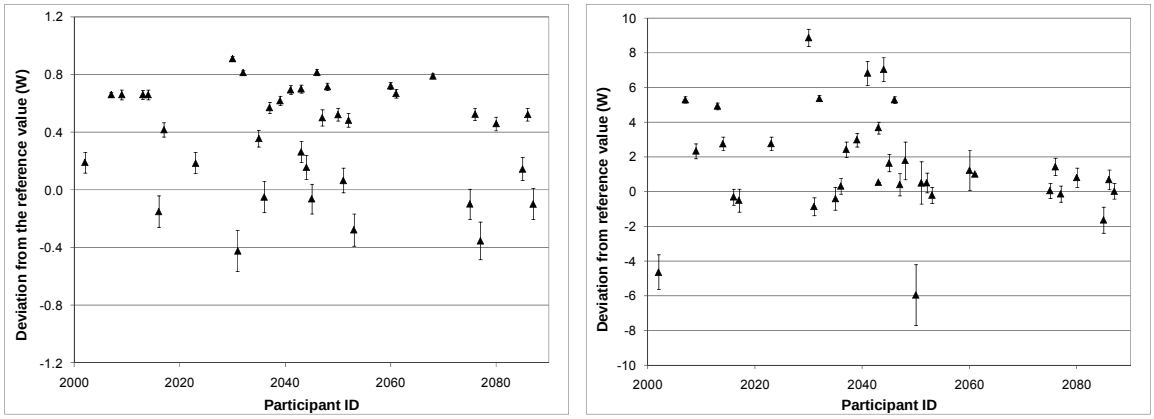
**Figure 2.** Deviations between nominal values and actual power emitted for (a) 1 W and (b) 1.5 W/cm$^2$ at 3 MHz

In general, a large percent of measurements taken (using an operating frequency of 3 MHz) presented deviations of the emitted acoustic power less than 40 %, results are summarized in Table 1. Applying the criterion adopted for this study, 13.6 % of the ultrasonic devices measured at 3 MHz presented deviations > 40 % in 3 of the 4 power values measured.

**Table 1.** Summary of measurement results for ultrasonic devices operating at 3 MHz.

| Nominal output power | 1 W | 5 W | @ 1.5 W/cm$^2$ | Maximum |
|---|---|---|---|---|
| Number of ultrasonic devices measured | 59 | 52 | 56 | 59 |
| Number of ultrasonic devices deviations ≤ 40 % | 52 | 43 | 48 | 48 |

In addition, a total of 36 ultrasound phystiotherapy equipments were measured at an operating frequency of 1 MHz. Deviations in the output power measurement levels for 1 W and 1.5 W/cm$^2$ at 1 MHz are presented in Figure 3. It can be observed that at 1 W, most of the participants have a deviation in the range from -0.4 W to 0.8 W; and from -2 W to 6 W for a nominal intensity value of 1.5 W/cm$^2$.




(a) (b)

**Figure 3.** Deviations between nominal values and actual power emitted for (a) 1 W and (b) 1.5 W/cm$^2$ at 1 MHz

For ultrasonic devices operating at 1 MHz, 41.7 % of the measurements corresponding to an output power of 1 W, showed deviations less than 40 % respect to the nominal value; in the other output power values, nearly 60 % of measurements showed also deviations less than 40 %, see Table 2.

**Table 2.** Summary of measurement results for ultrasound devices operating at 1 MHz.

| Nominal output power | 1 W | 5 W | @ 1.5 W/cm$^2$ | Maximum |
|---|---|---|---|---|
| Number of ultrasonic devices measured | 36 | 34 | 35 | 36 |
| Number of ultrasonic devices deviations ≤ 40 % | 14 | 21 | 21 | 21 |

Although a natural thought would tend to relate larger deviations of the actual emitted power from the nominal power value, to the age of the ultrasound physiotherapy equipment as well as the lack regular maintenance program; it was a surprise to find ultrasound equipments recently acquired by physiotherapists that showed large deviations (> 40 %). This shows the relevance of incorporating the calibration of physiotherapy devices using a reference standard with traceability to national standards as part of the maintenance. It was found that in many cases a maintenance program is followed on a regular basis but the aspects of a systematic calibration and traceability are missing.

## 4. Conclusion

Acoustic power measurements were taken in 87 ultrasound physiotherapy equipments, belonging to 34 medical centers. The results show that, in general, 1 in 4 ultrasound equipments presented deviations, between nominal power value and actual power emitted, higher than expected.

It was recommended to include calibration of these equipments as part of their maintenance programs and to make sure that traceable reference standards were used to determine the total acoustic power emitted. Otherwise, physiotherapists would lack objective information regarding actual operation of their ultrasound physiotherapy devices, putting at risk treatment effectiveness or its safe usage.

Metrological concepts like reference standard and calibration were clarified to participants during this study, as well as how a regular calibration of their equipment using a reference standard may help them to know the operation status of their ultrasound equipment.

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## References

[1] IEC 61689 Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz

[2] http://dif.sip.gob.mx/discapacidad/

[3] CENAM, Internal calibration procedure 510-AC-P.052: “Medición de potencia acústica de un haz ultrasónico (Incluye estimación de incertidumbre y validación de método)”.

[4] IEC 61161 Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz