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Ultrasound Physiotherapeutic Devices: How to measure them

Giovanni Durando, Claudio Guglielmono

Ultrasound machines are frequently used by physiotherapists. Ultrasound, US, physiotherapy devices are widely used for the treatment of chronic inflammation, degenerative rheumatic disorders, ankle distortions and post-traumatic diseases, such as lateral epicondylitis and acute soft tissue injuries [1]. At lower power (less than 3 W), US effects could produce stable cavitation in biological tissues, which in turn could affect the permeability of cell membranes. At high power settings (up to 12 W), the absorption of ultrasound energy by tissues causes a temperature increment, with an increase in the blood flow. In order to ensure safe and effective treatments, it is important that the adopted ultrasound therapeutic devices are accurate. The use of uncalibrated systems could in general produce inefficient or even harmful treatments results on the patients. In this context, the objective of this work was to evaluate the performance of the ultrasound devices that are commonly used in Physical-therapy departments [3].

Quality Control

A verification programme of the medical apparatuses adopted in therapies that use ultrasound beams is essential to maintain an acceptable quality standard of the performances in time.

Planning a quality control programme may lead to a decrease in the number of therapy sessions, an increase in the effectiveness of the treatment and a reduction in the need for other methods to complete the therapy.

Moreover, it is possible, through the use of precautions to eliminate or at least reduce the effect of the operator, to compare different devices and probes when taking a decision on purchasing a device and checking its correspondence with the manufacturer's declared characteristics.

After the initial setup, the need for quality verifications stems from the physical decay of the apparatus (signs of wear may be found in particular in cables and transducers). This decay is due to the wear of electronic and electric components, and may also cause electrical safety problems. It depends on the quality of the components, on the total working time and on the characteristics of the environment in which the device operates. The resulting degradation of therapy effectiveness is a slow and progressive process that is normally not detected by the operator who uses the same device again and again and technical assessment procedures that are able to give objective and reproducible measurement of the parameters are therefore necessary [4].

On the basis of these considerations, the verification of the correct operation of therapeutic ultrasound devices should start with an initial acceptance test, in co-operation with the manufacturer's technicians.

At a later point in time, it is advisable to plan periodic verifications of the device status, in order to sketch a maintenance plan of the therapeutic device, on the basis of a specified number of quality control parameters. In order to take into account the variability of the set-up configurations and conditions of use, the evaluation of the technical parameters should be compared with the initial values of the acceptance test for the same individual device.

From a practical standpoint, the periodicity of the verification test should be constant and should depend on the workload and on the previous history of the device, in agreement with the physicians and medical physics experts. However, the test should be carried out at least once a year for devices used daily, although additional verification tests should be conducted if the operator believes that it is appropriate [5]. The age of the device, if it has been maintained properly, is not a criterion that should influence the periodicity of the tests [6]. The quality controls test, according to the procedures, should be performed by a technician with verified expertise, and the conformance should be stated by a physician with experience in the field [7].

Some years ago (1992), Pye and Milford tested eighty-five ultrasound therapy machines that were used in the Lothian region (Scotland). The most important parameter reported was Ultrasound Power. It resulted that around 69% of the tested devices had an ultrasonic power that differed by more than 30 % from the expected values. A total of 29 out of 85 machines required some form of major repairs, and could not simply be calibrated by adjusting their internal power or

frequency controls. A total of 9 required crystal replacements [8].

Ultrasonic Power Measurement

The most important parameter necessary to define the ultrasound field is the output ultrasound power, P , emitted by the transducer. The standardized method is based on the radiation force balance method, which is defined as the time-averaged force exerted by an acoustic field (that is, a second-order effect of wave propagation in fluids [9]) on a target that intercepts the ultrasonic beam. Under the assumption that the target is much larger than the lateral dimensions of the acoustic beam, the ultrasound power, P , can be related to the resultant radiation force, F , or, in other terms, the variation of mass induced by the US field, by means of the simple equation:

$$P = u(T)F = u(T) g \Delta m \quad (1)$$

where $u(T)$ is the speed of sound in a medium (ultra-pure in water), g , is the gravity acceleration and Δm is the mass variation. From this equation, it is possible to determine that the sensitivity of the measurement method is 69 mg for 1 W of power, and very sensitive and accurate balances are therefore required [10]. Equation (1) is valid for a plane-wave assumption and, for this reason, it is a very good equation to approximate the real fields that are encountered in medical practice, see Figure 1.

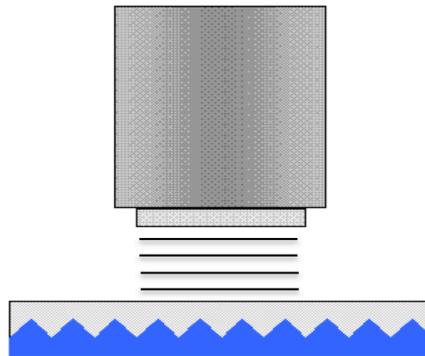


Figure 1, US transducer - plane wave mode

The radiation force method is the internationally accepted method that is generally used to characterize ultrasonic power, and it specifies a procedure that can be used to determine the total emitted acoustic power of ultrasonic transducers, based on the use of a radiation force balance [11], in order to evaluate the ultrasonic parameters that are related to physiotherapy systems. This procedure can be applied to ultrasonic equipment designed for physiotherapy that contains an ultrasonic transducer which generates continuous or quasi-continuous wave ultrasounds in the 0.5 MHz to 5 MHz frequency range [12]. There are many high-quality commercially available power balances, the sensitivity of which is fully compatible with the physiotherapy output power levels (100mW–15W). There are many types of power measurement systems, but in practice the radiation force is usually determined by measuring the apparent change in weight of an initially buoyant target.

An absorbing target is preferred in a radiation force balance for the realization of primary instruments [13] (especially for NMIs, National Metrological Institutes), and conical reflecting targets, designed to totally reflect incident ultrasound laterally, are commonly used for commercial instruments, which are usually called “ultrasound wattmeters”. Radiation force balances are cheap and easy to use instruments, and for these reasons represent the first step in establishing a measurement infrastructure within a hospital, device manufacturer or test laboratory [14]. A system based on an absorbing target is shown in Figure 2, while a system based on a reflecting target is shown in Figure 3.

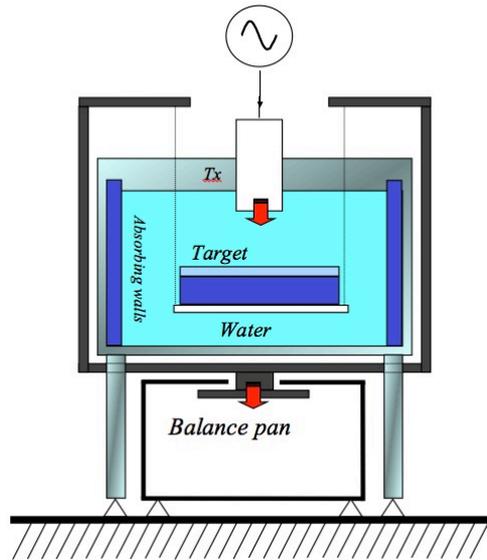


Figure 2, Measuring system based on an absorbing target

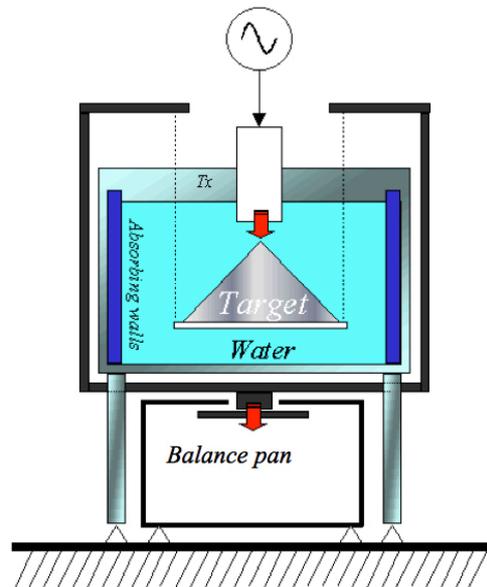


Figure 3, Measuring system based a reflecting target

Ultrasound Power Measurements at INRIM

INRIM (Italian National Metrological Institute) has developed two different systems for ultrasound power measurements.

The first system, the Radiation Force Balance system (RFB), see Figure 4, is based on a commercial METTLER TOLEDO model SAG-285 balance, which is able to measure ultrasound power from 50 mW to 20 W, with a greater insonation time than 10 s [15].

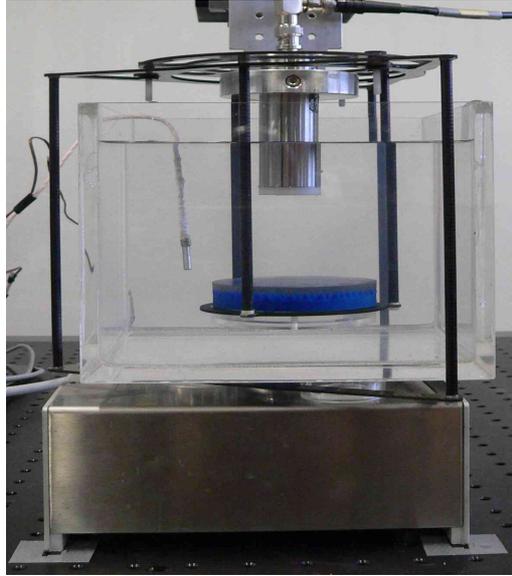


Figure 4, the RFB system

The second system, the Submersible Load Cell system (SLC), see Figure 5, is based on a HONEYWELL model 31 submersible load cell, which takes the place of the balance, and is able to measure ultrasonic power from 0.5 W to 200 W, with an insonation time of less than 2 s [16]. The target, whether absorbing or reflecting, is connected closely to the sensing element of the load cell through a screw. The signal produced by the load cell passes through a HONEYWELL model UV-10 strain gauge amplifier, and is then measured by an AGILENT model 34420A voltmeter.

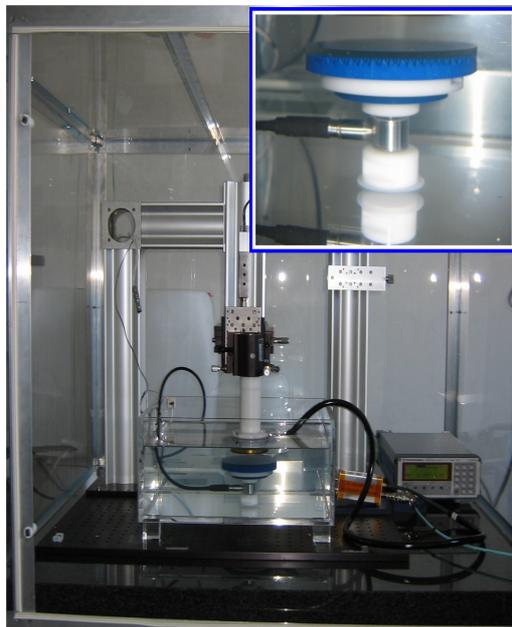


Figure 5, the SLC system

This solution, compared with a system based on a commercial balance, essentially offers two advantages. The first, of an electrical nature, concerns the possibility of reducing the insonation time (the ON period of the electric driving signal to the HIFU transducer) to less than 2 s, and this is obtained from the faster response of the force transducer. The second one is relevant to the fact that the target is connected rigidly to the force transducer, thus eliminating unwanted target motion at high power.

Both measuring set-ups are based on targets (see Figure 6, the absorbing target is on the left and the reflecting one is on the right), and are immersed in water tank that intercept the radiated ultrasonic field from the transducer [17].

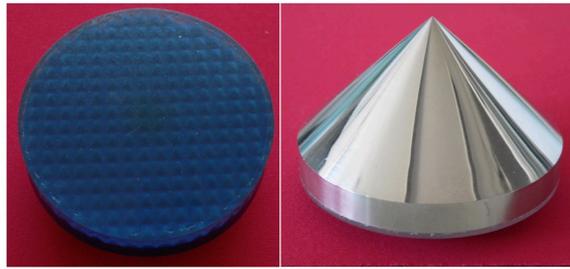


Figure 6, Left: Absorbing target; Right: Reflecting target

Ultrasonic Power Measurements of Therapeutical Devices

Three different devices currently used in in the Physical Medicine & Rehabilitation Department of the University Hospital have been measured in this work.

Table 1 shows the list of devices that have been tested.

Table 1 - List of tested devices		
Name	Model	Probe 1MHz
Device 1	SONOPLUS 434	X
Device 2	COSMOGAMMA F230	X
Device 3	ENRAF NONIUS SONOPLUS 490	X

The experiment consisted of two separate measurements on each apparatus. First, the device was set up at its nominal output level and the ultrasound power emitted by the probe was measured $n = 5$ times in order to evaluate the repeatability of the ultrasound emission. The short time of the single measurements allowed the RFB system to be used in the absorbing target configuration. The second measurement was aimed at evaluating the stability of the output in time: with the same device set up, the power was measured over a 300 s period, that is, the typical time of a clinical treatment [18]. In this case, it was not possible to use the absorbing target, as the absorbed energy would have led to an excessive heating and thermal dilatation, with an increase in the buoyancy, and therefore to a measurement error [19]. A reflecting target was used instead, and it should be pointed out that the SLC system allows the use of this kind of target at high power levels without unwanted movements, because the target is connected closely to the sensing element.

Measurements

The measurements on the devices listed in Table 1 are reported in Figures 7, 8 and 9.

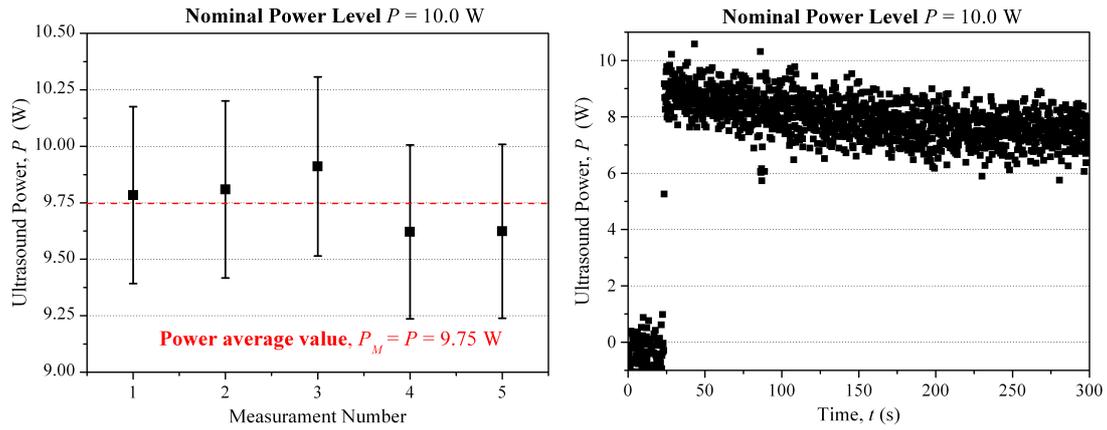


Figure 7, Left: US Power emitted from Device 1 Probe 1 MHz; Right US Power vs. time Device 1 Probe 1 MHz

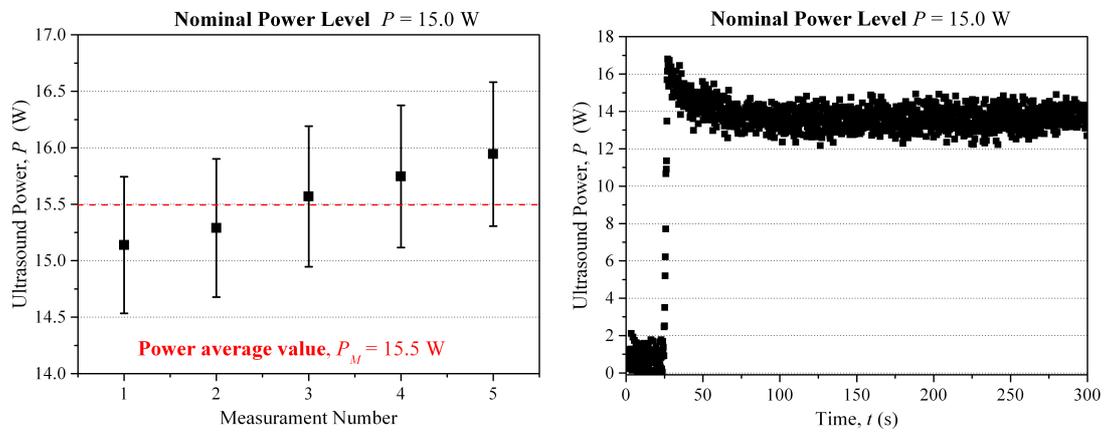


Figure 8, Left: US Power emitted from Device 2 Probe 1 MHz; Right: US Power vs. time Device 2 Probe 1 MHz

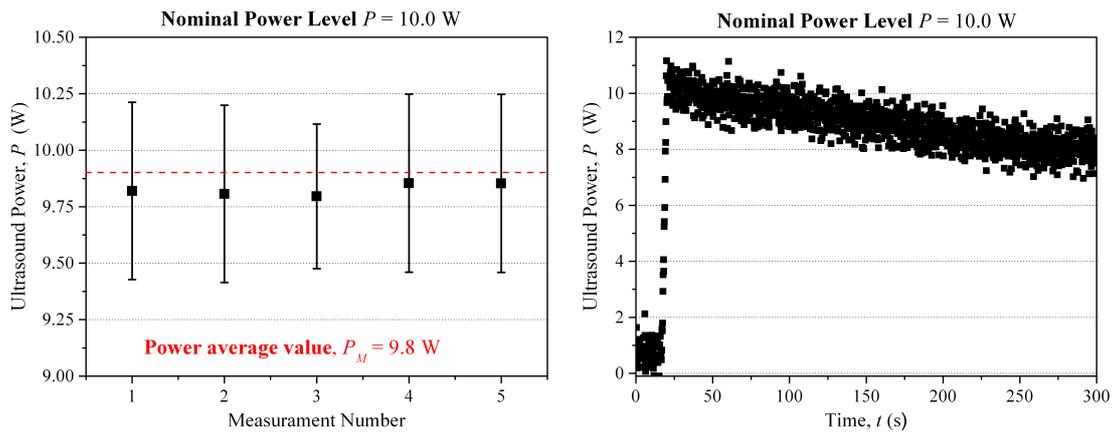


Figure 9, Left: US Power emitted from Device 3 Probe 1 MHz; Right: US Power vs. time Device 3 Probe 1 MHz

Conclusion

Even though the measurement check was not based on a large number of devices, it is possible to conclude that, unlike what had happened in the past, the tested devices were inside the recommended $\pm 20\%$ standard limits [20]. As a result of these verifications, it has been found that the level of the emitted US power decays with time, that is, it does not remain constant during the treatment.

Assuming an average US treatment time equal to 5 minutes, the difference between the US power emitted at the beginning and the end of the treatment is still less than 30 %.

The cause of the decay is probably due to the increase in the temperature of the piezoelectric part of the transducer and to a subsequent change in the working point of the internal amplifier [21].

This data could be used by the manufacturers of physiotherapeutic systems to feed back the electrical characteristics in order to obtain constant emissions during the treatments.

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Claudio Guglielmono received his master degree in Electrical Engineering at the Politecnico di Torino. He worked in the field of computerized measuring systems for industry before joining IEN, the Italian National Metrology Institute (which

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He participated in the setting up of the Ultrasound measurement capabilities at INRiM. Eng. Gugliemone is chair of the Italian CT 29/87 Electroacoustics and Ultrasound, a member of IEC TC 29, a convenor of the “sound in air” committee of the EURAMET TC AUV technical committee on acoustics, ultrasound and vibration, and an Italian delegate in the CIPM CCAUV consultative committee.