ACOUSTICS 2012

Study of the emissive properties of ultrasound systems for physiotherapy and aesthetic treatments

C. Giliberti[a], P. Calicchia[b], A. Bedini[a], R. Palomba[a] and S. De Simone[b]

[a]INAIL ex ISPESL, Via Urbana 167, 00184 Rome, Italy
[b]Institute of Acoustics and Sensors, Via del Fosso del Cavalliere,100, 00133 Rome, Italy
sara.desimone@idasc.cnr.it

The widespread use of ultrasound in physiotherapy and recently in aesthetics (medical and non medical) and the variety of devices based on ultrasonic emission at relatively low cost and available to a wide range of users, requires a deep knowledge of the emissive mode of these equipments. In order to provide a contribution for improving the quality and safety of treatments, a study on the technical performance and emissive characteristics of few devices available on the market was carried out, according to the international standard CEI EN 61689:2007. Emissive properties were assessed for two systems working at 1 MHz and 3 MHz, respectively, used for physiotherapy and aesthetics; the characterization of the ultrasonic pressure fields of these devices was related to the electronic characteristics of their controls. The results highlighted few critical aspects related to the non perfect accord between control and US transducer, to the effects of internationally-defined parameters values, when they are found out of range, according to the definition of an acceptable systems' quality, and to the need of extensively describe such systems including a suitable set of measurements aiming at their characterization as a whole.

1 Introduction

Among the physical agents potentially harmful for human health, ultrasounds (US) present new issues related to their increasing use in medical applications, from diagnostics to physiotherapy, up to aesthetics (medical and non-medical).

From clinical efficacy studies, the use of US in the field of physiotherapy, shows increased soft tissue extensibility, decreased levels of pain and faster repair of tendon injuries [1]. In aesthetics, US are typically used for the treatment of wrinkles and localized fat.

The easy availability of tools that use US for physiotherapy and aesthetics on the market, at relatively low cost and thus accessible to a wide range of users, requires a thorough understanding of the ultrasonic output characteristics of these devices and the effects that may have been induced.

The literature points out great attention to the performance evaluation of US devices for physiotherapy treatments [2-6]; some papers show that, very often, the output of these systems show variability respect to the tolerance limits set by international standards, with possible impact on the patients health. Machines that are out of calibration and have very high outputs, can produce excessive exposures, with possible impact on patient health, subjected to unknown risk levels; on the contrary, machines that are out of calibration, with very low outputs, will result in ineffective treatments and devoid of their clinical benefit, resulting in an unnecessary exposure of patients to a physical agent [7]. In this regard, an author argues that crucial points are the non-existence of a "*metrology culture*" among users, due to the restricted number of items of measuring equipment available [8], and lack of guidelines and standards that clearly define the need for a periodic calibration of the equipments, including explicit timing in relation to their functioning mode.

In this context, it should be noted the lack of standards and guidelines for aesthetics, medical and non medical.

In order to provide a contribution to improving the quality and safety of the treatments, technical performances and emission characteristics of two US equipments, according to the international standard IEC 61689-2007 [9] for physiotherapy treatments, have been carried out. The US transducers work at the characteristic frequency of 1 MHz and 3 MHz, employed for physiotherapy and aesthetics.

2 Material and methods

Two US devices, consisting of circular transducers (diameter 6 cm) with their controls, working in continuous and pulsed mode, with maximum power ranging from 10% to 100%, were characterized. According to information provided by the manufacturer, both systems provide a maximum intensity of 2.0 W/cm^2 in continuous and 2.5 W/cm^2 in pulsed mode.

Emission characterization of the two transducers were performed at CNR Institute of Acoustics and Sensor IDASC, Rome, according to the standard CEI EN 61689-2007. Additional total power measurements were carried out by using a radiation force balance.

The above mentioned standard defines parameters and procedures for evaluating the emitting performances of a US device for physiotherapy treatments; in particular *Effective Radiating Area* (ERA), that is the area, next to the face of the transducer, where the majority of the emitted ultrasonic power is distributed; *Beam Non-Uniformity Ratio* (BNR), that defines the relationship between the spatial-maximum intensity and the spatial-average intensity. These parameters identify the quality of the device output and can reveal possible creation of hot spots and inhomogeneities. In particular, the higher the value of BNR, the worse the beam pattern of the device: BNR values from 3 to 7 discriminates transducers operating under acceptable conditions from poor quality transducers operating in unsafe conditions, with BNR values greater than 8. From literature, it is noted that US physiotherapy devices have provided BNR values up to 14 [10].

As regards the aesthetic treatments device, the physical quantities that describe the energy emitted from the transducers (ERA and BNR) are the same as the physiotherapy one. In absence of specific technical reference standards, it was decided to extend the application of the standard IEC 61689-2007 to the transducer used for aesthetics.

The experimental set up involved the use of a tank 1.2 x 0.3 x 0.3 m filled with distilled water, in order to reduce reverberation. Hydrophone and the transducer under study were immersed in the water up to about half of its depth, with their major axes aligned in a horizontal position; a suitable procedure was realized assuring the alignment of their symmetry axes.

The measurements were performed in *echo-free* conditions by using a tone burst mode. The transducers were connected to a RF power amplifier driven by the Agilent mod 33220A function generator, producing a sinusoidal tone-burst with peak-to-peak voltage set to 2.3 V and burst length between 80 and 120 cycles, depending on the transducer, repetition period equal to 0.001 s, ensuring a stationary portion of the acquired signal.

A Precision Acoustics needle hydrophone, with 0.5 mm piezoelectric element, and relative preamplifier, having a sensitivity of 29 mV/MPa at 1 and 3 MHz, connected to a 12-bit acquisition board (10 Msamples/s) was employed. A dedicated procedure, developed in LabView environment, provided the amplitude rms average value on 100 acquisitions. Proper filtering of the signals has been performed.

According with IEC 61689-2007 standard, the following steps were carried out for both the transducers:

a) research of the working frequency f_{awf}, by means of the transducers frequency response, calculated as the arithmetic mean of the two frequencies in correspondence of which the amplitude of the sound pressure is 3 dB below the peak;

b) research of the position of: the last maximum z_N of the pressure field, by means of the scan along the z horizontal axis of the transducers in steps of 2 mm starting from 0.3 cm faced the transducer; research of the maximum of the pressure field p_{max} and the pressure peak position z_P in the acoustic field;

c) raster scan of the ultrasonic pressure in 2 planes perpendicular to the main axis of the transducers at the distances 0.3 cm and at z_N;

d) calculation of ERA by: total mean square acoustic pressure *pmst*; beam cross sectional area A_{BCS}, the minimum area in one of the two specified planes, for which the sum of the mean square acoustic pressure is 75% of the *pmst*, extrapolated to the front face of the treatment head, by a dimensionless factor (1,354);

e) calculation of BNR, as the ratio of the square of the maximum rms acoustic pressure to the spatial average of the square of the rms acoustic pressure, where the spatial average is taken over the effective radiating area.

3 Results

3.1 Transducer at 1 MHz

Feeding the transducer with a sinusoidal tone burst at its "nominal" frequency of 1 MHz, the beam axis has been determined. Through a scan along this central axis, the position of the last maximum z_N has been detected at about 130 mm from the transducer's surface. Here, the frequency response measurement of the transducer has been performed, between 900 kHz and 1.4 MHz to 10 kHz steps, in order to identify the frequency that maximizes the acoustic signal. The results are shown in Figure 1; the frequency response does not show a well defined peak, but presents a trend with different local maxima, including the one at about 1.3 MHz that has the maximum rms voltage.

The calculation of f_{awf} for this transducer gives its optimum frequency at 1.320 MHz. It should be emphasized that this frequency is different from that to which the transducer works when it is driven by its control; in fact, from the output signal analysis of its control, results a working frequency centered at 1.040 MHz, corresponding to a relative maximum in Figure 1.

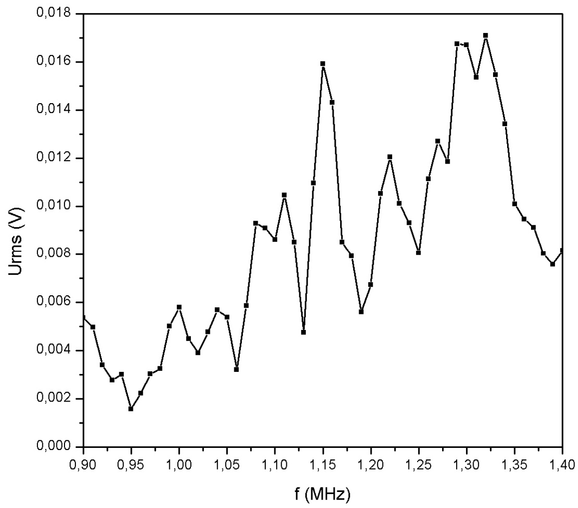


Figure 1: Transducer 1 MHz: frequency response, in z_N.

To confirm this result, the impedance of the transducer (amplitude and phase) using an HP 4194A Impedance/Gain Phase Analyzer, was measured, showing the correspondence with the hydrophone measurements.

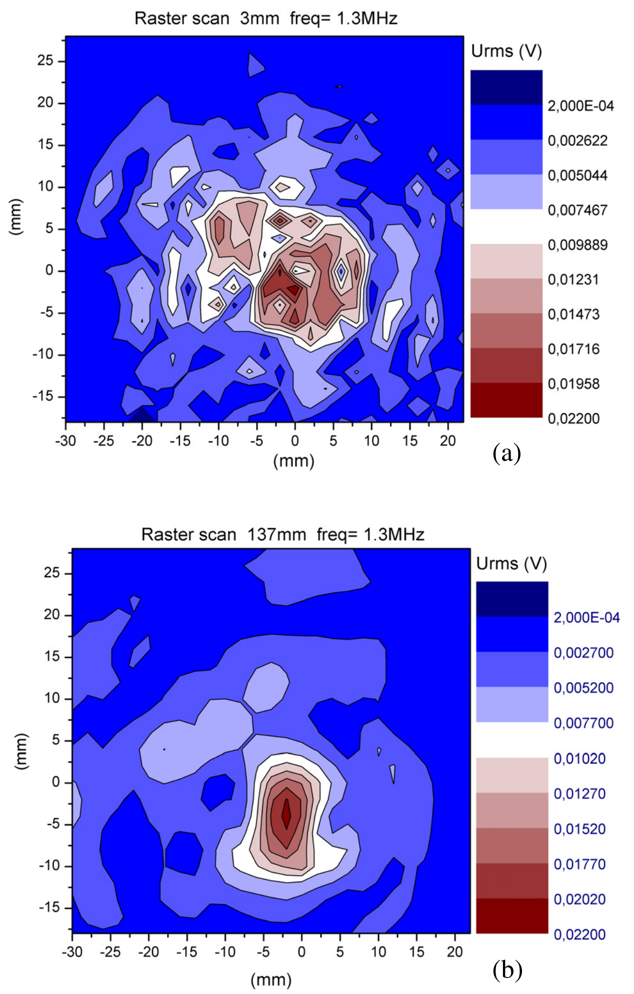


Figure 2: Raster scan performed in two planes orthogonal, at z = 0.3 cm from the transducer (a), at z_N = 13.7 cm (b), at the working frequency = 1.320 MHz.

The measurement of the pressure field along the z axis of the transducer, which allows to check the positions of the maxima and minima with those predicted by the theory, has disclosed that z_N is slightly marked; then it has been settled at the theoretical datum, that is 13,7 cm from the transducer for f=1.320 MHz. Furthermore, the rms value of the maximum voltage was determined (U_{max}=0.028329 V), at approximately 33 mm from the transducer's surface.

Figures 2a)-b) show the raster scan, displaying the voltage, U_{rms}, measured in two planes orthogonal to the z axis of the transducer, at 0.3 cm (a) and at z_N=13.7 cm (b), for an excitation frequency of the transducer equal to 1.320 MHz.

In order to evaluate the behaviour of the transducer in its operating conditions, i.e. when it is connected to its control, the above procedure was repeated by exciting the transducer with a sinusoidal burst at 1.040 MHz; the results are reported in table 1.

Table 1: Results for the transducer at 1 MHz, for frequencies of the excited signal 1.320 MHz and 1.040 MHz

Frequency	1.320 MHz	1.040 MHz
z_N	13,7 cm	9,6 cm
A_{BCS}	4,28 cm^2	6,44 cm^2
ERA	5,8 cm^2	8,72 cm^2
BNR	7,06	36,85
Power	6,6 W	
Effective intensity	1,14 W/cm^2	0,76 W/cm^2
Max effective intensity by the manufacturer 2,5 W/cm^2		

When the transducer works at 1.040 MHz, the ERA and BNR values show an anomalous behaviour of the system, with output parameters outside the range specified by the standard (ERA = 8.72 cm^2, BNR = 36.85). In particular, the transducer at 1 MHz presents optimum values according with IEC parameters, only for a frequency different from that provided by its control. The consequence is to increase the values of ERA and BNR, which are larger than those allowed by the standard; it is therefore evident that the frequency is a crucial parameter for determining the operating conditions of these devices. Considering the use of such devices for physiotherapy, these results show that particular attention has been paid to assessing the health effects of a frequency mismatch between the transducer and its control, in terms of possible production of excessive heat in specific regions of the treated tissue or ineffective treatments.

Figure 3 shows the comparison of the two raster scans at 0.3 cm from the face of the transducer, obtained feeding the transducer with signals at 1.040 MHz a) and 1.320 MHz b). A greater irregularity of the pressure field produced at the frequency of 1.040 MHz can be observed, accompanied, however, by lowering the overall values of pressure. This could be linked to a reduced efficacy of the treatment itself, obtained by operating the diffuser at a frequency different from the resonance one of the piezoelectric transducer.

On this device, total power measurements with radiation force balance was carried out; it is then possible to compute the *effective intensity* generated by the transducer, as the ratio between output power and ERA. The results obtained by using the two different values of ERA, obtained by operating the transducer respectively at its resonance frequency and at the frequency of its control, are reported in Table 1. The calculated *effective intensity* would seem well below the maximum stated by the manufacturer (2.5 W/cm^2), for both the frequencies investigated. These results raise doubts about the effectiveness of the treatment performed in the experimental conditions described above.

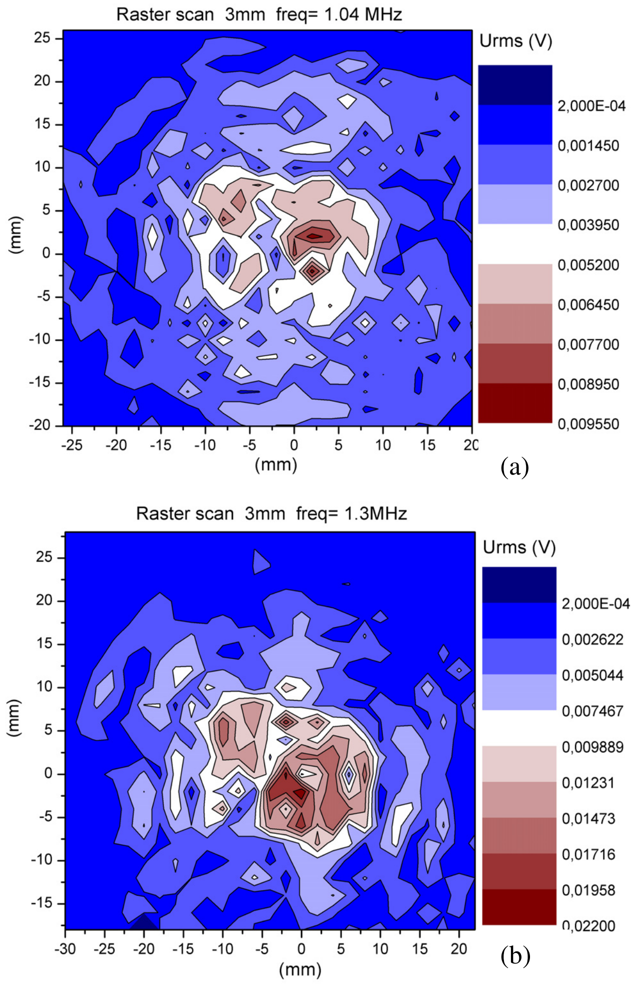


Figure 3: Comparison of raster scans at 0.3 cm for a) 1.040 MHz and b) 1.320 MHz.

3.2 Transducer at 3 MHz

The same procedure was followed in the characterization of the transducer operating at 3 MHz. The frequency response, reported in figure 4, shows a well-shaped peak centred at f_{awf}=3.158 MHz; also in this case, the resonance frequency of the transducer is slightly different from that obtained when the transducer is driven by its control, working at 3.1 MHz.

In Table 2, the results for the transducer fed with signals at 3.158 MHz and 3.1 MHz are shown; despite the slight difference in frequency, a variation of ERA and BNR values was observed. When the transducer is excited by a signal at the working frequency of the whole system transducer-control (3.1 MHz), BNR is within the values set forth in standard (BNR = 4.92), but the *effective radiating area* ERA shows an inconsistent value (14.79 cm^2) compared to its structural features (area of the piezoelectric=5,7 cm^2).

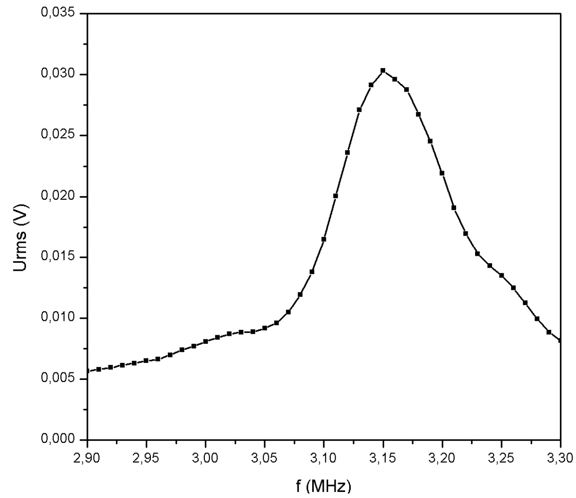


Figure 4: Transducer 3 MHz: frequency response, in z_N.

Considering the use of such devices for aesthetic treatments, what experimentally observed requires special care to assess any adverse health effects and/or efficacy of the treatment itself.

Table 2: Results for the transducer at 3 MHz, for frequencies of the excited signal 3.158 MHz and 3.1 MHz

Frequency	3.158 MHz	3.1 MHz
z_N	38,5 cm	33,0 cm
A_{BCS}	3,52 cm^2	10,92 cm^2
ERA	4,77 cm^2	14,79 cm^2
BNR	2,20	4,92
Power	4,61 W	
Effective intensity	0,96 W/cm^2	0,31 W/cm^2
Max effective intensity by the manufacturer 2,5 W/cm^2		

Figures 5a)-b) show the raster scan, displaying the voltage, U_{rms}, measured in two planes orthogonal to the z axis of the transducer, at 0.3 cm (a) and at z_N=38.5 cm (b), for an excitation frequency of the transducer equal to 3.158 MHz.

Finally, figure 6 shows the comparison of the two raster scan at 0.3 cm from the face of the transducer, at the two investigated frequencies; a greater irregularity of the pressure field produced at 3.1 MHz accompanied, however, by an overall lowering of the pressure, even if not as clear as in the case of the transducer at 1 MHz, can be observed.

As already specified for the transducer at 1 MHz, this could be due to a reduced efficacy of the treatment itself.

Also on this device, total power measurements with radiation force balance were carried out. In this case, the calculated effective intensities, obtained by using ERA values in table 2, are below the maximum stated by the manufacturer (2.5 W/cm^2).

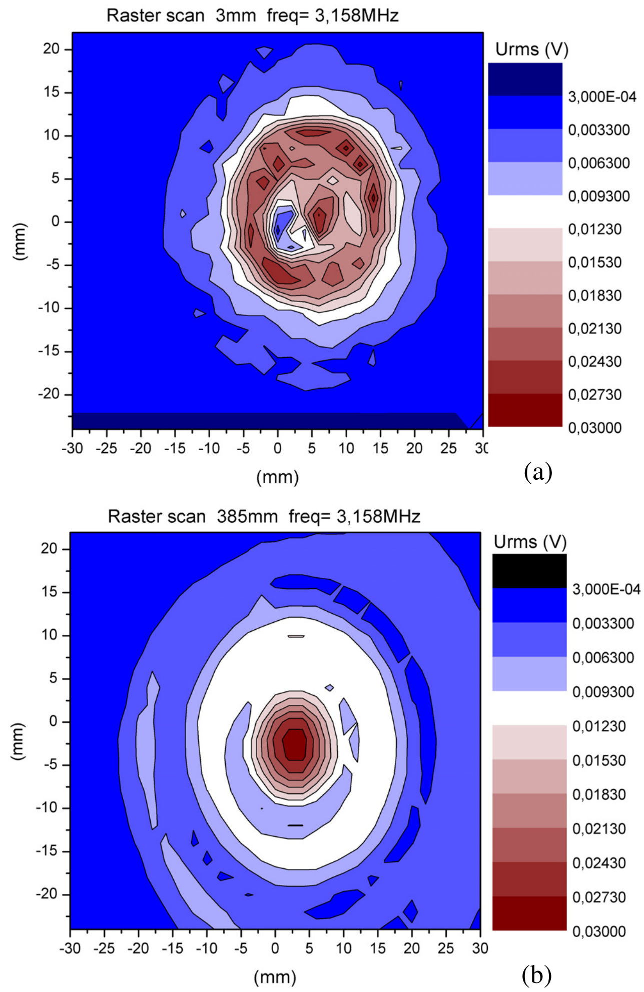
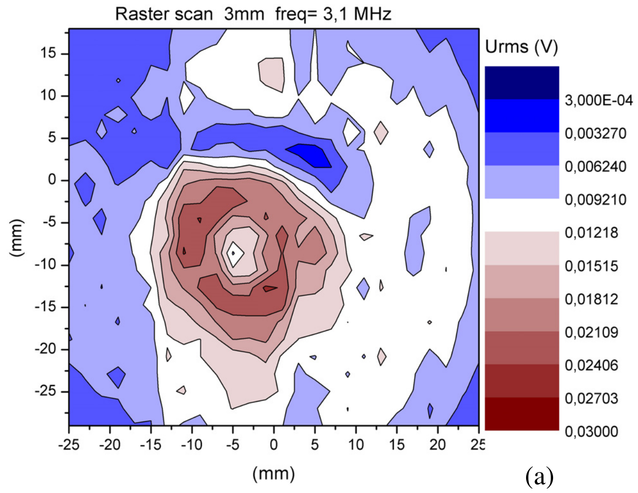


Figure 5: Raster scan performed in two planes orthogonal, at z = 0.3 cm from the transducer (a), at z_N = 38.5 cm (b), at the working frequency = 3.158 MHz.



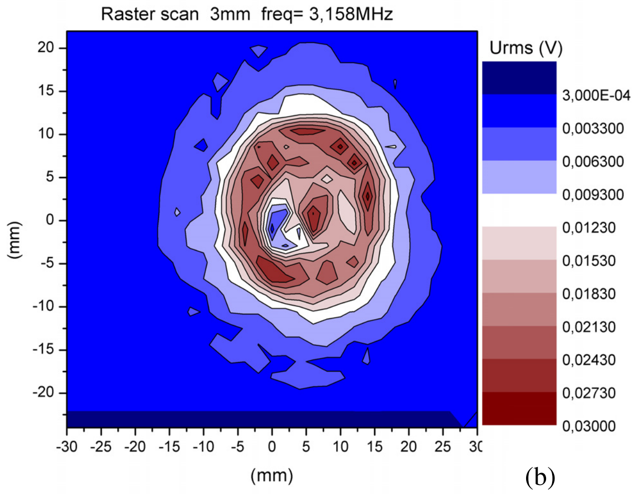


Figure 6: Comparison of raster scans at 0.3 cm for a) 3.1 MHz and b) 3.158 MHz.

4 Conclusion

From the experimental results of the output measurements performed on the two transducers working at 1 MHz and 3 MHz, respectively used for physiotherapy and aesthetic treatments, a certain variability in the frequency response as well as in the emission characteristic, clearly emerges. Moreover the values of the significant parameters, ERA and BNR, are quite different if the transducer alone is characterized or the whole system (transducer plus control unit) is taken into account.

Furthermore, the characterization of the control unit allows to complete the knowledge of the system. An examination of the frequency response of the ultrasonic emitter more extensive than the standard demands, can provide a more in-depth analysis on the performance of such devices, which were not provided by the technical specifications of the product.

From the results obtained not at the optimal working frequency of the two transducers, but equal to the working frequencies of their related control units, emerged significant deviations of the indicators ERA and BNR values specified by the standard. An extension of the study is highly recommended in order to focus on the main critical aspects in this type of devices currently on the market, or otherwise available to a wide target users group, and to relate these data to the level of performance of such equipments in terms of risks/benefits and effectiveness of treatments.

Reference

[1] Speed C.A. Therapeutic ultrasound in soft tissue lesions, Rheumatology, 2001; 40:1331-1336

[2] Ferrari C.B., Andrade, JC Adamowski, RRJ Guirro Evaluation of therapeutic ultrasound equipments performance, Ultrasonics 50 (2010) 704-709.

[3] Fyfe M., Bullock M. Acoustic output from therapeutic ultrasound units, The Australian Journal of Physioterapy , vol 32 n.1 1986, 13-16.

[4] Artho P.A.,. Thyne J.G, Warring B.P., Willis C.D., Brismée J.-M., Latman N.S., A calibration study of therapeutic ultrasound units, Phys. Ther. 82 (3) (2002) 257–263.

[5] Johns L.D., Straub S.J., Howard S.M., Analysis of effective radiating area, power, intensity, and field characteristics of ultrasound transducers, Arch. Phys. Med. Rehabil. 88 (1) (2007) 124–129.

[6] Schabrun, Walzer, Chipchase, How accurate are therapeutic ultrasound machines? Hong Kong Physiotherapy Journal, Volume 26, 2008.

[7] Pye S. Ultrasound therapy equipment-does it perform? Physioterapy, January 1996, vol. 82, n.1, 39-44.

[8] Guirro, R. S Britshcy Dos Santos Evaluation of the acoustic intensity of the new ultrasound therapy equipment, Ultrasonics 39 (2002) 553-557.

[9] CEI EN 61689-2007 - Ultrasound-physiotherapy-specific systems for field and method of measurement in the frequency range between 0.5 MHz and 5 MHz (first version 1996).

[10] Hekkenberg, R T, Reibold, R and Zeqiri, B (1994). 'Development of standard measurement methods for essential properties of ultrasonic therapy equipment', Ultrasound in Medicine and Biology 20, 1, 83-98.