Artigo Original

Revista Brasileira de Física Médica (2023) 17:709

How reliable are the ultrasonic output power values realized by therapeutic ultrasound devices used in physiotherapy?

Quão confiáveis são os valores de potência acústica emitidos por equipamentos de ultrassom em fisioterapia?

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Abstract

Therapeutic ultrasound is one of the most utilized electrophysical devices in physiotherapy. Despite their importance and widespread application, therapeutic ultrasound devices (TUSDs) may operate outside the acoustic power range recommended by the International Standard IEC 61689:2013, and thus, may not contribute to the treatment (if the ultrasonic output power, UOP, used in clinical practice is lower than the nominal power, NP) or even aggravate the pre-existing injury (if the UOP used is higher than the NP). This study aimed to verify whether the UOP values realized by four TUSDs from the Physiotherapy Section of the Grupo de Saúde de Pirassununga ($TUSD_1$, $TUSD_2$, $TUSD_3$, and $TUSD_4$) were following the IEC 61689:2013 standard. In addition, statistical tests were employed to assess the repeatability of the UOP measurements realized using the TUSDs on three different days. An acoustic radiation force balance was used to measure the UOP values realized by the TUSDs in the three days of testing using each equipment, which were configured to operate in a continuous mode. In addition, 10 UOP measurements were obtained for each NP value using all available frequencies and effective radiation area. The TUSDs, even with up-to-date maintenance, presented several instances in which UOP values had a relative error greater than that specified by the IEC 61689:2013 standard (81.39% of 1800 UOP measurements with $TUSD_1$, 58.67% of 1800 UOP measurements with $TUSD_2$, 75.25% of 1200 UOP measurements with $TUSD_3$, and 3.17% of 600 UOP measurements with $TUSD_4$). Thus, companies that manufacture TUSDs or perform maintenance on TUSDs must maintain the power values within the range specified by the IEC 61689:2013l standard. Additionally, the professionals responsible for monitoring the maintenance and/or calibration of this equipment should be able to identify, the reports prepared by the companies that provide maintenance/calibration services, whether the tested power values are within the range recommended by the IEC 61689:2013 standard.

Keywords*: therapeutic ultrasound; power; accuracy; maintenance; physiotherapy.*

Resumo

O ultrassom terapêutico é um dos métodos de tratamento de lesões musculoesqueléticas mais empregados em fisioterapia. Entretanto, quando os aparelhos de ultrassom terapêutico (AUST) operam fora da faixa preconizada pela Norma Internacional IEC 61689:2013, podem não contribuir com o tratamento (se os valores de potência acústica emitida, PAE, usados na prática clínica forem inferiores aos valores das potências nominais, PN) ou até mesmo agravar a lesão na região tratada (se a potência empregada for superior à PN). A IEC 61689:2013 estabelece que o erro máximo admissível para os valores de PAE seja de ± 20%. Então, o objetivo desse estudo foi verificar se os valores da potência emitida por quatro equipamentos de ultrassom da Seção de Fisioterapia do Grupo de Saúde de Pirassununga, GSAU-YS, (chamados de $AUST_1$, $AUST_2$, $AUST_3$ e $AUST_4$) estavam de acordo com o estabelecido pela IEC 61689:2013. Além disso, foram utilizados testes estatísticos para avaliar a repetibilidade das medições realizadas com os equipamentos em 3 dias distintos. Uma balança de força de radiação acústica foi empregada para medir a potência emitida pelos equipamentos em três dias de testes por equipamento, os quais foram configurados para operar no modo contínuo. Além disso, foram realizadas 10 medições da PAE para cada valor PN com todas as frequências disponíveis e área de radiação efetiva. Os aparelhos, mesmo estando com as manutenções em dia, apresentaram vários valores de PAE com erro relativo superior ao determinado pela IEC 61689:2013 (81,39% de 1800 medições com aparelho $AUST_1$, 58,67 % de 1800 medições com $AUST_2$, 75,25 % de 1200 medições com $AUST_3$ e 3,17% de 600 medições com $AUST_4$). Assim, é importante que as empresas que fabricam ou realizam manutenção em AUSTs, mantenham os valores de potência acústica dentro da faixa determinada pela norma internacional. Além disso, os profissionais que acompanham a manutenção e/ou a calibração desses equipamentos devem ser capazes de identificar, nos relatórios elaborados pelas empresas que prestam serviços de manutenção/calibração, se os valores de potência testados estão dentro da faixa recomendada pela norma IEC 61689:2013.

Palavras-chave*: ultrassom terapêutico; potência; exatidão; manutenção; fisioterapia.*

1. Introduction

The use of therapeutic ultrasound devices (TUSDs) under a continuous operating mode is among the most used diathermy options for treating musculoskeletal injuries. The acoustic energy emitted by TUSDs is absorbed by the tissue being treated, increasing its temperature and, realizing increased blood flow in the treated region, reduced muscle spasm, increased extensibility of collagen fibers, and reduced inflammation (1). According to Prentice (1),

to achieve therapeutic effects, the temperature of the treated region must be maintained between 40°C and 45°C for a minimum timespan of 5 min. Generally, treatments are not performed with therapeutic ultrasound alone; that is, other therapeutic treatments (kinesiotherapy, transcutaneous electrical nerve stimulation [TENS], and/or isolated vector interferential current) can be used in combination with therapeutic ultrasound (2, 3). A recent study showed that the electrophysical treatments most used by orthopedic and sports physiotherapists in Brazil are TENS, therapeutic ultrasound, pulsed current excitomotor electrotherapy, and cryotherapy, with therapeutic ultrasound being the most used in clinical practice (61% of the 376 respondents reported that they use it for treating >50% of their patients) (4). In addition, TUSDs can be used in a pulsed mode, so named for its mechanical effects, which are beneficial in the treatment of acute and subacute inflammation, neuropathic pain, and edema (5). TUSDs operating within the recommended range and appropriate irradiation dosage selected by the physiotherapist contributes to the reduction of treatment time globally.

In general, in many private clinics, professionals are concerned with the use of TUSDs when they are unable to observe the presence of steam, which forms during the so-called cavitation test. Nevertheless, it is important to ensure the safety and proper functioning of this equipment in a clinical setting (parameters within the ranges established by the International Electrotechnical Commission International Standard IEC 61689:2013) (6). However, this does not occur very often, perhaps owing to a lack of a metrological culture associated with accuracy verification, the limited or nonexistent number of available calibration equipment, or even a lack of an infrastructure to carry out these tests. Meanwhile, some companies provide calibration and/or maintenance services for these types of equipment. Training in courses in the health services field is not focused on in the development of skills and competencies related to ultrasonic metrology. Furthermore, the Brazilian Air Force Academy (AFA) does not have the necessary instruments to perform inspections on ultrasonic equipment. However, the Grupo de Saúde de Pirassununga (GSAU-YS) of AFA is concerned with the proper functioning of its equipment and has requested that an external company perform preventive maintenance and calibration services on the TUSDs every six months. Services are also provided whenever a device stops functioning or indicates that it is overheating.

The correct and safe operation of a TUSD can be verified by measuring the acoustic parameters of the equipment. The manufacturers provide a nominal value for the effective radiation area (ERA), as well as a nominal scale of intensities and/or powers, which is shown on the equipment display. Equipment that is not calibrated cannot reliably reveal its effective intensities (ultrasonic output intensity, or even, the ratio between the ultrasonic output power [UOP] and ERA) with certainty. Some studies have verified that a substantial difference exists between the nominal and measured values of UOP, ERA, and the effective intensity of TUSDs (7-9). Such variability can contribute to the absence of or reduction in the intended therapeutic effects, which can result in ineffective treatments or even injuries (10, 11). Therefore, professionals should be alerted against the indiscriminate use of this technology and be informed about the importance of maintaining and calibrating this equipment, commonly used during rehabilitation. In addition, the person responsible for monitoring the maintenance and/or calibration of TUSDs appointed by an external company (contract inspector within the scope of the AFA) should be prepared to inspect the maintenance/calibration reports provided by the company.

Previous studies have also demonstrated disparities between the measured and nominal UOP, as many TUSDs were outside the acoustic range recommended by the International Standard (11-14). For example, Pye and Milford (12) analyzed 85 TUSDs, of which 59 devices had at least one UOP reading with relative error (RE) exceeding the range of ±30%. Meanwhile, the IEC 61689:2013 standard (6) recommends a maximum RE of ±20%. In all the studies mentioned previously, the majority or even totality of the TUSDs evaluated had some discrepancy between the nominal and ultrasonic values of output power, even in the case of new devices or devices having undergone corrective maintenance and/or calibration.

According to the GSAU-YS, in 2018, the Physiotherapy Section performed 6437 treatments using therapeutic ultrasound (as one of the treatment modalities) on military personnel and their dependents. Some of these treatments were performed in the continuous mode, whereas others were conducted in the pulsed mode, based on the type of injury. Therefore, the objective of this study was to perform a test examining the accuracy of the UOP readings of the four TUSDs from the Physiotherapy Section of the GSAU-YS. We assess whether the operating TUSD output values have errors greater than the maximum permissible error of 20% and verify the repeatability of the failed equipment. This information allows us to answer the question asked in the title of this study.

2. Methods

2.1. International Standard - IEC 61689:2013

The safety requirements, methods of measuring and characterizing the output parameters, and acceptance criteria for the TUSD output are indicated by the IEC 61689:2013 standard.

According to IEC 61689:2013 (6), UOP emitted by TUSDs outside the range of ±20% of the nominal power (NP) is considered outside of the tolerance limit, requiring that the equipment be sent for corrective maintenance/calibration. In addition, the device must be tested with the maximum average power, which can be obtained during an operation in the continuous mode. This International Standard recommends the UOP to be determined using a radiation force balance. The principle of radiation

force measurement consists of positioning a target in the trajectory of the acoustic beam, which results in the application of a force on it owing to the moment associated with the pressure exerted by the beam. The target is reflective and generally has a conical shape and is composed of a thin metallic membrane, with a rear layer filled with air. This provides an acoustic approximation of the ideal water–air interface (15).

The repeatability of instrument failure is vital for guiding its maintenance. Repeatability is the capability to provide the same output when the same operator makes repeated measurements based on the same parameters, with the same procedure, using the same instruments, under the same conditions, and in the same place over a short period of time (16). According to Werkema (17), a measurement system may have inadequate repeatability owing to TUSD defects (e.g., wear, poor quality, poor maintenance, inadequate design), operator errors (e.g., unsatisfactory technique, lack of experience, inadequate handling skills/training, fatigue), or the environmental factors (e.g., fluctuations in temperature/humidity, vibration).

2.2. Experimental Setup

An acoustic radiation force balance (UPM-DT-1; Ohmic Instruments, Easton, MD, USA) was used to measure the UOP of four TUSDs purchased from Ibramed (Amparo, SP, Brazil) from the Physiotherapy Section of GSAU-YS ($TUSD_1$, $TUSD_2$, $TUSD_3$, and $TUSD_4$). These TUSDs were set to operate in the continuous mode. A digital thermometer (MT-455A; Minipa do Brasil Ltda, São Paulo, SP, Brazil) was employed to measure the temperature of the room and water in the balance reservoir. $TUSD_1$ and $TUSD_2$ (Sonopulse model) contain an ergonomic dual function head, which allows the user to select a transducer with a nominal ERA of 3.5 cm^2 (T_1) or 1.0 cm^2 (T_2). When T_1 is used, the device operates at the frequency of 1.0 or 3.0 MHz, with a maximum UOP of 7 W. Meanwhile, T_2 allows operation at a frequency of 1 MHz and a maximum UOP of 2 W. $TUSD_3$ (Sonopulse II model) has an ergonomic head that contains a transducer with a nominal ERA of 10 cm^2. This equipment can be set to operate at 1 or 3 MHz, with a maximum UOP of 20 W. Finally, $TUSD_4$ (Sonopulse III model) contains an ergonomic head with a transducer with a nominal ERA of 7 cm^2. In addition, this device can be set to operate at 1 or 3 MHz, with a maximum UOP of 21 W.

The experiment setup is illustrated in Figure 1. The devices shared the same location on a stable and fixed bench in the Physics and Chemistry Laboratory of the Brazilian AFA. The doors and windows of the laboratory were kept shut, and the air conditioning units were kept off during the experiments, to avoid any disturbance (airflow) over the water contained in the balance reservoir. In addition, the absence of bubbles between the balance cone and transducer was constantly verified. The TUSD head was fixed to a balance support, such that the metal face that emits radiation was approximately 0.5 cm below the water level in the balance reservoir, which contained 950 mL of degassed water. The central axis of the transducer was aligned with the center of the metal cone of the balance. After 30 s of the activation of each ultrasound device, the operator recorded the UOP displayed on the radiation balance display in an electronic database (Excel, Microsoft Corp., Redmond, WA).

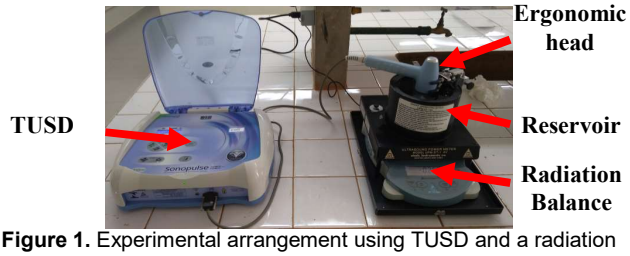

Figure 1. Experimental arrangement using TUSD and a radiation balance to measure the UOP values.

2.3. Calibration and Programming Test of the Radiation Balance

Every day, the initial stage of the experiments was performed using a radiation balance consisting of the assembly of the entire experimental setup to measure the UOP of the TUSDs. Then, the system was let to rest for at least 30 min to guarantee balance stability and achieve thermal equilibrium. Finally, a test was conducted to verify the calibration and programming of the acoustic radiation balance. This test consisted of recording the power value displayed on the balance display as a result of the placement of a 1 g aluminum disk (supplied by the balance manufacturer) at a specific location on the balance. According to the manufacturer, this mass corresponds to an ultrasonic power output of 14.650 W and may vary by ± 1%, that is, from 14.504 to 14.796 W. Five measurements of the power related to the mass of the 1 g disk were performed by removing and repositioning the object on the balance support five times. Carrying out the procedure described above is important to verify that the calibration and programming of the radiation balance follow the recommendations of the manufacturer. If the results of the tests described in this section are outside the range recommended by the manufacturer (from 14.504 to 14.796 W), the acoustic radiation balance must be sent for corrective maintenance and calibration. This test indicates whether the equipment used to measure the output acoustic power is in a proper working condition.

2.4. UOP Measurement

The ultrasonic power output from the TUSDs was measured over the entire NP range of the equipment. For $TUSD_1$ and $TUSD_2$, 10 UOP measurements were performed for each value of NP (0.3, 0.7, 1.0, 1.4, 1.7, 2.1, 2.4, 2.8, 3.1, 3.5, 3.8, 4.2, 4.5, 4.9, 5.2, 5.6, 5.9, 6.3, 6.6, and 7.0 W) at the frequencies of 1.0 and 3.0 MHz for T_1 and 10 measurements for each NP value (0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, and 2.0 W) for T_2. For $TUSD_3$, 10 UOP measurements were performed for each NP value (from 1 to 20 W, with steps of 1 W)

at the frequencies of 1.0 and 3.0 MHz. For $TUSD_4$, 10 UOP measurements were made for each NP value (from 0.7 to 21.0 W, with steps of 0.7 W) at the frequencies of 1.0 and 3.0 MHz. Each configuration of equipment was analyzed three times on different days (during consecutive weekends). For convenience, the days were named A, B, C, D, E, F, G, H, I, and J.

The test for repeatability consists of a procedure, in which the measurement system, experimental protocol, operator, and location are the same, over a short time period (16). This study considered all these items, and the repeatability of UOP measurements was statistically evaluated by comparing the measurements made over three days by the same operator, in the same measurement system, on the bench of the Physics and Chemistry Laboratory, and using the same experimental protocol.

The Shapiro–Wilk test was applied to assess the normality of the distribution of the data obtained from each subgroup using $TUSD_1$ and $TUSD_2$ (10 measurements obtained over 3 days for each NP value, totaling 180 subgroups), considering the use of T_1 (1 and 3 MHz) and T_2 (1 MHz), and each subgroup data obtained using $TUSD_3$ (10 measurements obtained over 3 days, for each NP value, totaling 120 subgroups). This normality test was chosen because it is more robust than the Kolmogorov–Smirnov, Lilliefors, and Anderson–Darling tests (18). Then, the Levene test was employed to assess the homogeneity of variances of the data that demonstrated normal distribution because these are the necessary conditions for the use of the one-way analysis of variance (ANOVA) for repeated measures. In situations where using ANOVA is not possible, the Kruskal–Wallis test was employed. Statistical analyses were performed using the Action Stat 3.7 software (ESTATCAMP, Campinas, SP, Brazil) with a significance level of 5%.

2.5. Calculation of Relative Error (Accuracy Test)

The accuracy test consisted of calculating the relative error (RE) (%) between the nominal and the measured UOP emitted by the TUSD. This error is related to the accuracy of the UOP measurements. This value is obtained using Equation (1),

$$\mathrm{RE}\ (\%) = \left[\frac{(\mathrm{NP}-\mathrm{UOP})}{\mathrm{NP}}\right] \cdot 100. \qquad (1)$$

Negative values indicate an alert, as they represent the scenario where the UOP is higher than the NP.

3. Results

$TUSD_4$ was used only once in this study because it was sent by the Physiotherapy Section for corrective maintenance and calibration. In the only experiment performed with this device, extreme temperature values were displayed several times; this information emerged from the first 5 min of the experiment on day J.

3.1. Calibration and Programming Test of the Radiation Balance

The mean and standard deviation of the UOP obtained with the calibration and programming test of the radiation balance are presented in Table 1. These results indicate that the balance functions properly because the acoustic power corresponding to the 1 g disk is 14.650 W, and according to the manufacturer, it can vary in the range of 14.504 to 14.797 W. The greatest difference between the measured and NP values was 0.04%.

Table 1. Mean and standard deviation values of acoustic power corresponding to a mass of 1 g.

Devices	Day	Acoustic Power (W)
$TUSD_1$	D	14.652 ± 0.003
	E	14.652 ± 0.001
	F	14.652 ± 0.002
$TUSD_2$	A	14.653 ± 0.003
	B	14.652 ± 0.003
	C	14.652 ± 0.002
$TUSD_3$	G	14.652 ± 0.001
	H	14.646 ± 0.012
	I	14.656 ± 0.005
$TUSD_4$	J	14.656 ± 0.006

Source: The Author (2023).

3.2. Assessment of Room and Water Temperatures

At the beginning and end of the UOP measurements for each of the 10 days of the experiments, the room and water temperatures were measured. Table 2 shows the mean and standard deviations with respect to the temperature measurements before and after the experiments on each day.

Table 2. Mean and standard deviation values of room and water temperature over the 10-day experiments.

Devices	Day	Water Temperature (°C)	Room Temperature (°C)
$TUSD_1$	A	26.1 ± 0.9	25.1 ± 1.5
	B	25.9 ± 0.4	25.4 ± 1.3
	C	25.5 ± 0.7	24.7 ± 0.3
$TUSD_2$	D	24.8 ± 2.7	25.0 ± 0.8
	E	25.9 ± 2.5	26.2 ± 0.5
	F	26.5 ± 2.1	25.7 ± 0.2
$TUSD_3$	G	29.7 ± 7.8	27.2 ± 2.1
	H	29.5 ± 5.2	27.0 ± 0.9
	I	28.3 ± 7.1	28.3 ± 2.5
$TUSD_4$	J	23.9 ± 3.0	22.2 ± 1.2

Source: The Author (2023).

3.3. Measurement Repeatability of UOP Emitted by TUSD

The measurement repeatability corresponding to the UOP was analyzed via statistical tests using the ActionStat software at a significance level of 5% (p-value = 0.05). The Shapiro–Wilk test was applied to the data from $TUSD_1$, revealing that 38.3% and 40.0% of the UOP values obtained with T_1 at 1 and 3 MHz (60 subgroups per frequency), respectively, did not follow normal distribution. In addition, 31.7% of the 60 subgroups of T_2 did not follow normal distribution. Furthermore, the application of this test to the data from $TUSD_2$ demonstrated that 30.0% and 26.7% of

the UOP values obtained with T_1 at 1 and 3 MHz, respectively, did not follow normal distribution. Finally, the test applied to the data from $TUSD_3$ revealed that 43.3% and 18.3% of the 60 subgroups of T_1 at 1 and 3 MHz, respectively, did not follow normal distribution.

Then, the Levene test was employed to assess the homogeneity of the group variances with the UOP values that were normally distributed and obtained in the experiment. This test was applied to only 15 groups of the $TUSD_1$ power outputs (2.1, 3.5, 3.8, 4.2, 5.6, and 7.0 W with T_1 at 1 MHz; 0.3, 2.4, 2.8, and 6.3 W with T_1 at 3 MHz; and 0.5, 1.0, 1.3, 1.5, and 2.0 W with T_2), 21 groups of the $TUSD_2$ power outputs (0.7, 2.4, 3.5, 4.5, 4.9, 5.9, and 7.0 W with T_1 at 1 MHz; 1.4, 1.7, 2.4, 3, 5, 3.8, 4.5, 4.9, 5.6, and 6.3 W with T_1 at 3 MHz; and 0.3, 0.4, 1.2, 1.3, and 2.0 W with T_2), and 13 groups of the $TUSD_3$ power outputs (2 and 19 W at 1 MHz and 2, 3, 9, 10, 11, 12, 13, 16, 17, 18, and 19 W at 3 MHz). The Levene test indicated that 40.0%, 47.6%, and 53.8% of the groups related to $TUSD_1$, $TUSD_2$, and $TUSD_3$, respectively, did not demonstrate the homogeneity of variance, that is, $p < 0.05$.

ANOVA and the Kruskal–Wallis test were employed to assess whether the UOP measurements obtained over the three experimental days were statistically different for each NP value and piece of equipment. ANOVA was used in groups presenting normal distribution and showing the homogeneity of variance, that is, when the results of the Shapiro–Wilk and Levene tests provided a p-value ≥ 0.05 ($TUSD_1$: 9 groups; $TUSD_2$: 11 groups; and $TUSD_3$: 6 groups). Meanwhile, the Kruskal–Wallis test was employed to assess the data that did not follow normal distribution and/or demonstrate the homogeneity of variance. The ANOVA demonstrated a significant difference between all groups compared, regardless of equipment or NP value. Virtually all results of the Kruskal–Wallis test were significantly different (exceptions were the NP values of $TUSD_1$ for T_2: 0.2 and 1.9 W with p-values of 0.20 and 0.13, respectively).

3.4. Accuracy Test

Tables 3 and 4 show the mean and standard deviations of the RE values obtained over the three days of testing (A, B, and C) using T_1 (Table 3) and T_2 (Table 4) and the entire range of NP for $TUSD_1$.

The mean and standard deviations of the RE values obtained over the three days of testing (D, E, and F) using T_1 (Table 5) and T_2 (Table 6) and the entire range of NP for $TUSD_2$ are presented in Tables 5 and 6.

Table 7 presents the mean and standard deviations of the RE values obtained over the three test days (G, H, and I) at 1 and 3 MHz and the entire range of NP for $TUSD_3$.

Regardless of the ultrasonic physiotherapy equipment employed, the percentage change for measurements with REs greater than 20% and 30% for each day of the experiment can be verified (see Table 8).

Table 3. Mean and standard deviation of the RE values obtained over 3 test days (A, B, and C) using the head face with T_1 and the entire range of NP of $TUSD_1$.

Freq. MHz	NP W	A	B	C
1	0.3	2.01 ± 8.41	1.62 ± 6.08	-1.21 ± 4.06
	0.7	41.29 ± 0.24	36.97 ± 0.69	16.69 ± 0.47
	1.0	38.36 ± 0.18	33.88 ± 0.17	12.50 ± 0.11
	1.4	39.76 ± 0.12	35.09 ± 0.14	14.40 ± 0.41
	1.7	35.34 ± 0.21	25.18 ± 13.81	8.38 ± 0.28
	2.1	34.08 ± 0.24	28.28 ± 0.21	7.03 ± 0.44
	2.4	29.54 ± 0.28	23.08 ± 0.22	0.58 ± 0.21
	2.8	27.64 ± 0.18	21.16 ± 0.60	-1.28 ± 0.23
	3.1	22.85 ± 0.16	15.88 ± 0.23	-7.03 ± 0.15
	3.5	24.18 ± 0.15	17.02 ± 0.19	-4.34 ± 0.19
	3.8	24.29 ± 0.11	16.69 ± 0.24	-3.48 ± 0.57
	4.2	25.75 ± 0.16	18.21 ± 0.13	0.00 ± 0.45
	4.5	25.15 ± 0.14	17.16 ± 0.30	1.40 ± 0.62
	4.9	25.98 ± 0.12	18.31 ± 0.18	4.76 ± 0.62
	5.2	25.07 ± 0.09	32.34 ± 5.29	6.25 ± 0.65
	5.6	25.34 ± 0.26	38.03 ± 1.04	9.36 ± 0.73
	5.9	24.04 ± 0.23	39.47 ± 0.50	10.51 ± 0.74
	6.3	23.81 ± 0.21	40.97 ± 0.49	13.01 ± 1.39
	6.6	22.75 ± 0.25	40.59 ± 0.33	13.19 ± 1.06
	7.0	22.72 ± 0.23	40.23 ± 0.15	13.94 ± 0.36
3	0.3	4.07 ± 1.19	20.67 ± 2.74	-2.87 ± 2.44
	0.7	38.86 ± 0.40	49.11 ± 0.46	35.46 ± 1.50
	1.0	40.68 ± 0.21	50.44 ± 0.41	37.62 ± 0.58
	1.4	44.31 ± 0.48	53.04 ± 0.24	40.87 ± 0.43
	1.7	41.93 ± 0.43	51.19 ± 0.30	38.22 ± 1.55
	2.1	41.70 ± 0.10	51.79 ± 0.73	37.45 ± 0.12
	2.4	40.54 ± 0.71	48.53 ± 0.69	34.03 ± 0.45
	2.8	38.84 ± 0.34	46.50 ± 0.37	32.63 ± 0.08
	3.1	35.03 ± 0.17	43.94 ± 1.62	28.74 ± 0.21
	3.5	38.80 ± 0.29	46.94 ± 0.30	32.85 ± 0.05
	3.8	39.11 ± 1.64	47.04 ± 0.14	32.68 ± 0.11
	4.2	39.87 ± 0.16	47.85 ± 0.16	34.50 ± 0.62
	4.5	39.22 ± 0.20	46.94 ± 0.29	34.22 ± 0.05
	4.9	39.83 ± 0.14	42.76 ± 3.22	35.09 ± 0.16
	5.2	39.27 ± 0.17	40.24 ± 0.22	34.11 ± 0.17
	5.6	39.77 ± 0.14	40.82 ± 0.14	34.37 ± 0.20
	5.9	39.03 ± 0.09	40.33 ± 0.22	31.92 ± 0.10
	6.3	39.29 ± 0.14	40.39 ± 0.22	32.27 ± 0.24
	6.6	38.50 ± 0.31	39.38 ± 0.32	31.67 ± 0.22
	7.0	41.31 ± 0.19	38.69 ± 0.45	34.69 ± 0.45

Source: The Author (2023).

The coefficient of variation (CV) of the UOP values obtained for $TUSD_1$ (T_1 and T_2), $TUSD_2$ (T_1 and T_2), and $TUSD_3$ were measured. In general, the devices present excellent precision and the CV is <5% and no subgroup had a CV >10%.

Table 4. Mean and standard deviation of the RE values obtained over 3 test days (A, B, and C) using the head face with T_2 and the entire range of NP of $TUSD_1$.

NP W	A	B	C
0.1	-5.00 ± 3.56	-10.80 ± 1.93	-9.00 ± 2.87
0.2	24.40 ± 1.07	25.10 ± 6.14	23.40 ± 1.51
0.3	31.93 ± 0.80	31.20 ± 2.08	35.53 ± 1.94
0.4	35.10 ± 0.66	33.90 ± 0.88	36.28 ± 0.71
0.5	36.72 ± 0.49	35.04 ± 0.8	38.00 ± 0.42
0.6	36.57 ± 0.22	35.23 ± 0.99	39.20 ± 0.39
0.7	37.37 ± 2.94	34.91 ± 0.66	36.31 ± 9.04
0.8	35.43 ± 0.17	34.75 ± 0.85	37.00 ± 1.43
0.9	34.20 ± 0.13	33.78 ± 0.54	37.36 ± 0.40
1.0	34.24 ± 0.49	34.20 ± 0.62	37.66 ± 0.19
1.1	34.80 ± 0.21	41.16 ± 17.49	38.45 ± 0.30
1.2	35.50 ± 0.30	36.10 ± 0.20	38.92 ± 0.37
1.3	36.12 ± 0.37	36.62 ± 0.45	38.95 ± 0.14
1.4	36.23 ± 0.27	36.76 ± 0.34	38.74 ± 0.18
1.5	36.33 ± 0.13	36.76 ± 0.53	38.57 ± 0.15
1.6	36.29 ± 0.18	36.43 ± 1.15	38.13 ± 0.08
1.7	36.28 ± 0.28	31.94 ± 14.53	37.89 ± 0.24
1.8	36.32 ± 0.21	36.12 ± 0.42	37.43 ± 0.11
1.9	36.48 ± 0.21	36.79 ± 0.68	36.71 ± 0.17
2.0	38.20 ± 0.37	37.23 ± 0.28	37.62 ± 0.18

Source: The Author (2023).

Table 6. Mean and standard deviation of the RE values obtained over 3 test days (D, E, and F) using the head face with T_2 and the entire range of NP of $TUSD_2$.

NP W	D	E	F
0.1	-68.80 ± 3.79	-87.80 ± 7.97	-101.40 ± 5.66
0.2	-17.10 ± 1.79	-21.70 ± 9.10	-34.20 ± 5.92
0.3	-1.67 ± 1.52	-11.20 ± 1.66	-10.93 ± 1.23
0.4	5.70 ± 0.75	-3.20 ± 1.40	-4.15 ± 0.91
0.5	9.92 ± 4.83	0.72 ± 0.84	1.80 ± 0.69
0.6	9.53 ± 0.79	2.37 ± 0.78	4.17 ± 0.45
0.7	8.86 ± 0.40	3.23 ± 0.87	5.57 ± 0.49
0.8	8.73 ± 0.22	3.70 ± 0.37	5.75 ± 0.49
0.9	7.96 ± 0.47	3.11 ± 0.47	5.67 ± 0.32
1.0	16.68 ± 0.34	13.38 ± 0.38	14.78 ± 0.24
1.1	18.75 ± 0.41	14.18 ± 0.36	16.49 ± 0.36
1.2	19.97 ± 0.20	15.75 ± 0.36	17.82 ± 0.23
1.3	21.06 ± 0.27	16.69 ± 0.35	18.54 ± 0.20
1.4	21.11 ± 0.52	17.66 ± 0.34	19.64 ± 0.32
1.5	21.71 ± 1.00	18.00 ± 0.29	21.47 ± 0.56
1.6	20.36 ± 0.82	18.58 ± 0.17	21.59 ± 0.10
1.7	19.94 ± 0.33	19.28 ± 1.03	21.89 ± 0.71
1.8	19.78 ± 1.92	19.11 ± 0.28	22.33 ± 0.20
1.9	18.53 ± 1.21	19.42 ± 0.25	22.49 ± 0.14
2.0	15.29 ± 0.41	17.01 ± 0.23	19.92 ± 0.20

Source: The Author (2023).

Table 5. Mean and standard deviation of the RE values obtained over 3 test days (D, E, and F) using the head face with T_1 and the entire range of NP of $TUSD_2$.

Freq. MHz	NP W	D	E	F
1	0.3	0.73 ± 3.79	24.53 ± 1.47	0.92 ± 3.53
	0.7	23.29 ± 0.91	42.26 ± 0.85	31.57 ± 0.72
	1.0	19.12 ± 0.55	39.24 ± 1.04	28.88 ± 1.35
	1.4	20.63 ± 0.68	40.94 ± 0.27	29.54 ± 0.28
	1.7	14.53 ± 0.88	37.42 ± 0.29	24.18 ± 0.68
	2.1	12.65 ± 0.39	36.72 ± 0.26	23.63 ± 0.41
	2.4	7.35 ± 0.27	32.74 ± 0.16	18.19 ± 0.37
	2.8	5.74 ± 0.24	31.79 ± 0.52	16.51 ± 0.28
	3.1	0.88 ± 2.02	27.94 ± 0.39	10.37 ± 0.78
	3.5	5.48 ± 0.46	30.09 ± 0.23	12.40 ± 0.51
	3.8	6.80 ± 0.23	29.15 ± 1.57	10.55 ± 0.62
	4.2	13.09 ± 3.75	32.12 ± 4.66	10.96 ± 0.16
	4.5	20.88 ± 0.35	29.59 ± 0.4	9.65 ± 0.13
	4.9	21.51 ± 0.29	29.63 ± 0.24	10.04 ± 0.13
	5.2	24.18 ± 0.40	27.99 ± 0.25	8.49 ± 0.24
	5.6	23.36 ± 0.84	26.95 ± 1.75	8.67 ± 0.15
	5.9	20.70 ± 0.17	25.96 ± 0.11	7.26 ± 0.29
	6.3	19.67 ± 0.49	25.15 ± 0.24	7.05 ± 0.40
	6.6	18.76 ± 2.55	23.32 ± 0.10	5.65 ± 0.15
	7.0	21.63 ± 0.30	27.46 ± 0.13	11.37 ± 0.20
3	0.3	8.27 ± 2.14	4.93 ± 4.04	4.93 ± 2.42
	0.7	38.26 ± 0.68	36.03 ± 1.14	37.91 ± 2.21
	1.0	39.00 ± 0.49	35.84 ± 1.65	40.26 ± 0.83
	1.4	42.40 ± 0.42	38.20 ± 0.44	42.00 ± 0.55
	1.7	38.04 ± 0.17	35.09 ± 0.24	39.14 ± 0.36
	2.1	37.86 ± 0.48	34.01 ± 0.09	37.10 ± 0.15
	2.4	32.63 ± 0.19	29.36 ± 0.18	31.35 ± 0.93
	2.8	31.51 ± 0.22	27.14 ± 0.15	28.29 ± 0.54
	3.1	28.34 ± 2.34	22.94 ± 0.26	22.33 ± 0.36
	3.5	32.13 ± 0.16	28.67 ± 0.47	28.19 ± 0.68
	3.8	32.13 ± 0.27	28.41 ± 0.09	27.37 ± 0.74
	4.2	34.19 ± 0.42	29.66 ± 0.17	27.79 ± 0.28
	4.5	33.87 ± 0.47	28.77 ± 0.98	27.04 ± 0.41
	4.9	35.80 ± 0.80	28.82 ± 0.21	28.35 ± 0.71
	5.2	34.66 ± 0.85	27.57 ± 0.19	30.12 ± 3.71
	5.6	35.55 ± 0.71	27.48 ± 0.26	27.56 ± 0.30
	5.9	35.38 ± 0.12	26.39 ± 0.51	25.32 ± 0.28
	6.3	35.18 ± 0.27	27.10 ± 0.48	26.17 ± 0.94
	6.6	34.49 ± 1.39	25.90 ± 0.27	26.33 ± 0.99
	7.0	37.59 ± 0.42	30.27 ± 0.48	29.79 ± 0.16

Source: The Author (2023).

4. Discussion

Although the devices had undergone up-to-date preventive and/or corrective maintenance, electrical safety inspection, and calibration, discrepancies were observed in the UOP values measured on the three days of the experiment, regardless of the NP utilized. In addition, many values of the RE of the UOP were outside the range specified by IEC 61689:2013 (6).

ANOVA showed that there was a statistical difference between the UOP values measured on three different days, regardless of the NP or TUSD used. The Kruskal–Wallis test also indicated a significant difference between the compared subgroups (same NP value measured over three separate days) regardless of the group (NP), equipment used, or the device configuration (except when $TUSD_1$ was used with T_2 with an NP of 0.2 and 1.9 W, which represents 1.25% of the 160 evaluated groups).

Table 7. Mean and standard deviation of the RE values obtained over 3 test days (G, H, and I) in the frequencies of 1 and 3 MHz and the entire range of NP of the $TUSD_3$.

Freq. MHz	NP W	G	H	I
1	1.0	-5.57 ± 1.25	-0.64 ± 5.79	-1.23 ± 5.20
	2.0	-54.32 ± 1.01	23.51 ± 0.73	18.84 ± 0.44
	3.0	-117.04 ± 1.76	29.73 ± 0.85	24.64 ± 0.23
	4.0	-181.72 ± 3.14	30.97 ± 0.46	26.90 ± 5.60
	5.0	27.41 ± 0.75	29.68 ± 0.73	22.53 ± 0.59
	6.0	25.76 ± 1.49	27.37 ± 0.63	18.87 ± 0.61
	7.0	23.15 ± 0.28	23.88 ± 0.60	14.92 ± 0.38
	8.0	20.91 ± 0.35	20.67 ± 0.44	11.06 ± 0.68
	9.0	18.10 ± 0.61	17.60 ± 0.84	6.72 ± 0.19
	10.0	12.81 ± 0.27	9.96 ± 0.24	1.66 ± 1.47
	11.0	15.71 ± 3.40	10.58 ± 0.34	3.39 ± 0.68
	12.0	25.03 ± 1.16	11.16 ± 0.68	8.80 ± 1.88
	13.0	25.36 ± 0.69	21.30 ± 3.57	12.83 ± 0.52
	14.0	25.78 ± 0.43	26.01 ± 0.53	13.71 ± 1.49
	15.0	21.66 ± 2.90	27.51 ± 0.63	24.47 ± 2.29
	16.0	20.04 ± 6.31	28.10 ± 0.20	26.73 ± 0.83
	17.0	31.48 ± 6.47	26.47 ± 0.33	25.68 ± 0.74
	18.0	36.76 ± 0.60	24.29 ± 0.76	22.83 ± 0.78
	19.0	35.53 ± 0.37	23.47 ± 0.67	23.55 ± 2.01
	20.0	33.11 ± 1.57	18.97 ± 0.61	17.67 ± 1.81
3	1.0	14.68 ± 3.61	-12.42 ± 4.56	-2.84 ± 2.52
	2.0	41.34 ± 2.20	21.48 ± 0.93	27.54 ± 0.32
	3.0	44.20 ± 0.58	29.10 ± 0.31	33.82 ± 0.30
	4.0	44.84 ± 0.48	30.11 ± 0.63	34.66 ± 0.35
	5.0	45.18 ± 3.31	28.97 ± 0.68	32.69 ± 0.40
	6.0	42.71 ± 0.24	27.45 ± 2.30	30.56 ± 0.10
	7.0	40.80 ± 0.76	24.51 ± 0.36	28.34 ± 0.36
	8.0	39.91 ± 0.69	22.26 ± 0.41	26.50 ± 0.47
	9.0	38.23 ± 0.35	19.73 ± 0.49	24.11 ± 0.50
	10.0	35.03 ± 0.36	15.54 ± 0.55	20.38 ± 0.70
	11.0	37.23 ± 0.25	18.39 ± 0.50	23.72 ± 0.42
	12.0	38.76 ± 0.22	20.30 ± 0.54	25.91 ± 0.27
	13.0	40.00 ± 0.35	21.62 ± 0.19	27.17 ± 0.41
	14.0	40.84 ± 0.18	22.63 ± 0.08	29.65 ± 0.34
	15.0	41.94 ± 0.62	23.39 ± 0.13	30.31 ± 0.14
	16.0	43.09 ± 0.36	23.65 ± 0.21	30.81 ± 0.16
	17.0	43.71 ± 0.07	23.41 ± 0.10	31.00 ± 0.19
	18.0	44.17 ± 0.33	24.54 ± 0.58	30.83 ± 0.46
	19.0	44.76 ± 0.22	25.41 ± 0.38	30.10 ± 0.21
	20.0	46.70 ± 15.88	21.94 ± 0.40	26.95 ± 0.79

Source: The Author (2023).

Table 8. Number, in %, of relative error modulus measurements greater than 20 and 30%, on each day of the experiment

Device	Day	|RE| > 20 %	|RE| > 30 %
$TUSD_1$	A	95.17	70.17
	B	85.83	75.83
	C	63.17	59.83
$TUSD_2$	D	55.33	31.83
	E	68.15	26.67
	F	52.50	16.17
$TUSD_3$	G	85.75	64.25
	H	74.00	6.75
	I	66.00	22.25
$TUSD_4$	J	3.17	1.67

Source: The Author (2023).

The result of the calibration and programming test of the radiation balance show that the balance functions according to what is recommended by the manufacturer (Table 1). As shown in Table 2, no great variation in temperature (both room and water) from one day to the next can be observed for the same equipment. The standard deviation of the temperature values indicates that there was no great variation in temperature throughout the experiment. As operator training was performed before the experiments were performed, the results of the Kruskal–Wallis and ANOVA tests seem to indicate that the TUSD is not functioning properly.

In this study, 600 UOP measurements were performed per day with $TUSD_1$ and $TUSD_2$, totaling 1800 UOP measurements per equipment. $TUSD_3$ has only one transducer; thus, 400 UOP measurements per day were performed, totaling 1200 UOP measurements. $TUSD_4$ also has only one transducer and operates at frequencies of 1 and 3 MHz; therefore, 600 UOP measurements were performed per day (this equipment did not perform properly and, thus, was sent for corrective maintenance and calibration after the first day). The RE associated with the corresponding NP was calculated. For $TUSD_1$, 81.39% (of 1800) of the RE values calculated from the UOP were >±20%, and 68.61% of the RE values were >±30%. For $TUSD_2$, 58.67% and 24.89% of the RE values were >±20% and ±30%, respectively. For $TUSD_3$, 75.25% and 31.08% (of 1200) of the RE values calculated from the UOP were >±20% and ±30%, respectively. Finally, 3.17% and 1.67% (of 600) of the RE values calculated from the UOP for $TUSD_4$ were >±20% and ±30%, respectively. Despite the good accuracy for this equipment, 26.5% of the RE measurements showed negative values and the ultrasound emission was paused several times owing to the head temperature being ≥41°C, which resulted in extreme temperature outputs.

From Table 3, 75.00% of the average values of the RE of the UOP for $TUSD_1$ presented values outside the range specified by IEC 61689:2013 (6). In addition, some RE values were negative, implying that the measured power is greater than the NP, which could damage the biological tissue. When $TUSD_1$ was operated with T_1 at 3 MHz, the RE values indicated that the electronics of this equipment should be adjusted because 96.67% of the RE values were above the IEC 61689:2013 standard (6) regardless of the NP value utilized. In addition, 93.33% of the RE values were outside the ±30% range. When T_1 was used with a frequency of 1 MHz, only 53.33% of the 60 mean values of the UOP were above the ±20% limit. Finally, 23.33% of the mean values of the UOP were outside the ±30% range.

Considering the use of T_2 in $TUSD_1$, 95% of the average values of the RE presented in Table 4 were outside the range established by the International Standard (6). In addition, 90% of the average RE values were >±30%, which indicates the need for corrective maintenance of the equipment.

Table 5 shows that 75.00% of the average values of the RE of the UOP measured from $TUSD_2$ were outside of the range recommended by IEC 61689:2013 (6). The use of T_1 at 3 MHz demonstrated that this equipment needed to undergo corrective maintenance and calibration because 95.00% of the RE values were above the standard established by IEC 61689:2013 (6), regardless of the NP value used.

In addition, 51.67% of the RE values were outside the ±30% range. When T_1 was used with a frequency of 1 MHz, only 55.00% of the 60 average values of the RE were >±20%. Finally, 16.67% of the average values of the RE were >±30%.

The use of T_2 for $TUSD_2$ showed that 23.33% of the average values of RE shown in Table 6 were outside the range of ±20%. In addition, the UOP values corresponding to NP of 0.1, 0.2, 0.3, and 0.4 W were higher, which may represent a risk of tissue injury. Nevertheless, the Physiotherapy Section of GSAU-YS mentioned that these values are not used in the treatment of musculoskeletal injuries.

The RE associated with $TUSD_3$ is presented in Table 7. Moreover, 76.67% of the average RE values of the UOP measured over the three days presented values outside the range specified by the IEC 61689:2013 standard (6). In addition, 30.83% of the RE values are outside the range of ±30%.

Pye and Milford (12) showed that the vast majority of TUSD presented errors greater than ±20% in UOP. They evaluated 85 TUSD, of which 59 devices (approximately 69.4%) had at least one UOP value outside the range of ±30%. They further observed that, after repair and calibration, all UOP measurements made with 76 of the TUSD had RE less than ±30% of the NP value, and 95% of the UOP measurements were within the range of ±20%. According to the reports provided by the company contracted to perform the corrective maintenance and calibration of the TUSDs, four devices were not repaired and thus were not calibrated. Furthermore, two were not returned before this article was submitted (12). The results obtained in this study show that there was no improvement in the accuracy of the equipment after maintenance and calibration were performed, which differs from the results of the study conducted by Pye and Milford (12). A plausible explanation for the discrepancy between the measured power values before and after preventive or corrective maintenance and calibration may be the quality of the preventive or corrective maintenance and calibration services provided.

Guirro and Santos (13) evaluated eight TUSDs produced in Brazil and found that five models (Sonamed I, Sonacel, Sonacel Plus, Sonacel III, and Avatar I) presented errors above ±30% of the nominal intensity in more than the measured ultrasonic intensity. The results obtained in that study were surprising, considering that the devices with a corrective maintenance/calibration problem were new. Ishikawa *et al*. (11) analyzed the performance of 33 TUSDs manufactured in Brazil and abroad, comprising different brands and models and used in public and private services in the city of Rio de Janeiro. Only 18.89% of the ultrasonic intensity measurements were within the tolerance range. Ferrari *et al*. (19) evaluated 33 TUSDs and noted that two were not working; thus, in practice, they analyzed the UOP of 31 devices across 13 different models. These devices were used for the routine treatment of patients. The results indicated that only 32.3% of the TUSDs had UOP and ERA values within the International Standard recommendations. In general, Health professionals generally believe that, after maintenance, a device operates correctly; however, this study refutes that belief.

Researchers from three Australian universities evaluated the UOP of 64 TUSDs from private clinics and hospitals (14). They performed a total of 249 UOP measurements, considering the combinations of 3 NP (2, 5, and 8 W) and two frequency values (1 and 3 MHz) in the continuous mode. They found that approximately 56% of the UOP measurements were outside the range recommended by IEC 61689:2013 (6). When the pulsed mode was used, maintaining the same combinations described above, approximately 62% of 242 UOP measurements were outside the ±20% range of the NP. In summary, 13 devices required corrective maintenance and/or calibration because they presented values outside the recommended range for all evaluated combinations; meanwhile, only 3 devices had values within the ±20% range for all combinations. Although this study evaluated ultrasound equipment only in the continuous mode, devices produced in other countries also have similar problems regarding the emitted acoustic power. In addition, the devices used in the study by Schabrun *et al*. (14) were calibrated annually, and 90.6% of the devices were found to be up to date. The average time before calibration was 11 months.

When analyzing the daily data obtained using each equipment, we observed that they have good precision because only 2.22% and 1.67% of the subgroups had a CV >10% for $TUSD_1$ and $TUSD_3$, respectively. In addition, the CV was >5% in only 5.00% of the subgroups, regardless of equipment or configuration.

Considering UOP values higher than NP, that is, the scenario that could potentially cause damage to biological tissue represent 5.39% of all measurements performed with $TUSD_1$, 7.35% of all measurements performed with $TUSD_2$, 5.75% of all measurements performed with $TUSD_3$, and 26.5% of all measurements performed with $TUSD_4$. Of the 97 measurements with negative values (UOP > NP) obtained using $TUSD_1$ (5.39%), 47.42% were recorded in the range of 2.8–4.2 W and a frequency of 1 MHz (T_1), and 50.52% were recorded for NP of 0.1 and 0.3 W (T_2 and T_1, respectively). Of the 119 measurements with negative values obtained using $TUSD_2$ (7.35%), 90.76% fell in the range of 0.1–0.5 W with T2, and 8.40% were observed for NP 0.3 W (T_1). Considering the negative measurements obtained using $TUSD_3$ (5.75%), 72.46% of the measurements were in the range of 1–4 W and frequency of 1 MHz and 27.54% were observed for NP of 1 W and frequency of 3 MHz. Finally, of the 159 negative values obtained using $TUSD_4$ (26.50%), 12.58% were obtained with NP of 0.7 and 10.5 W and frequency of 1 MHz, and 62.89% were obtained with NP in the range from 0.7–7.0 W (10 values of NP) and frequency of 3 MHz.

In view of these results, the report supplied by the company providing the service was consulted, and we

observed that they performed only three measurements for three NP values for $TUSD_1$ and $TUSD_2$. Therefore, contract inspectors for this type of service must be instructed to highlight the power range and configurations that must be evaluated by the company. Ideally, inspectors should consult the Physiotherapy Section of GSAU-YS to verify the configuration of the TUSDs and the power range used in clinical practice. In nonmilitary units, health professionals who are responsible for requesting and monitoring this type of service can specify the range of ultrasonic power that should be assessed, which would be established based on the frequency of NP used in clinical practice.

Musculoskeletal injuries are usually treated with TUSDs and other therapeutic resources, such as lasers, short waves, TENS, and Russian currents. In addition, most treatments are performed with the equipment operating in the pulsed mode; however, care must be taken in avoiding UOP values above the NP values as this may compromise patient safety.

Because operator training with respect to the TUSD devices was conducted before the experiments were performed, we believe that the values of the RE obtained (in many situations the values were greater than ±20%) indicate that the devices are not functioning properly. This is because all measurements showed excellent precision (most CV values were below 5%, regardless of NP or equipment used), the experiments were conducted in the same place, room temperature was within the range recommended by the ultrasonic equipment manual from the manufacturer, calibration and programming test of the radiation balance was excellent, and degassed water was used in all experiments. In addition, the operator constantly checked for bubbles in the reservoir. However, the radiation balance manual recommends that the tests be performed at a room temperature in the range of 21 to 27 ºC to avoid the formation of bubbles in the water of the reservoir. In this study, the UOP measurements performed at a frequency of 3 MHz for $TUSD_3$ were outside the temperature range indicated by the radiation balance manual.

Durando and Guglielmone (20) showed decay in the values of the acoustic power emitted by TUSDs as a function of time, indicating that the power does not remain constant throughout the treatment. This reduction can be owing to the increase in temperature in the piezoelectric ceramic over time (20).

In this study, TUSDs from the Physiotherapy Section of the Brazilian AFA were used; thus the number of devices evaluated was a limitation of this study. In future studies, more devices of different models and manufacturers will be evaluated. In addition, other TUSD parameters such as ERA and intensity must be evaluated.

The results of this study provide important recommendations regarding experimental procedures to be followed, which are based on the IEC standard and acoustic radiation balance manual. Herein, we present these suggestions for a measurement protocol for accuracy tests of the acoustic power emitted by ultrasound equipment:

1. Visually inspect the integrity of the head and connection of the ultrasound applicator head.
2. Mount the radiation balance in a place free from drafts (open windows/doors or in the direction of air conditioner) and without excessive vibration, temperature, and humidity variations.
3. Fill the balance reservoir to 0.6 cm below the top of the rubber liner with degassed water (for UPM-DT-1AV and UPM-DT-10AV models).
4. Place the radiating face of the head 0.3 to 0.6 cm below the degassed water level, parallel to the water surface, and directly above the center of the cone (for UPM-DT-1AV and UPM-DT-10AV models).
5. Perform the tests at a water temperature of 22 ± 3°C, as recommended by the International Standard.
6. Test the operation of the treatment timer over a period of 5 to 10 min. This test also makes it possible to verify the general operation of the equipment, as it may indicate excess temperature, which occurred with the application of $TUSD_4$ on day two of the experiment.
7. Verify the calibration and programming of the acoustic radiation balance.
8. Take at least five measurements of each acoustic power used in clinical practice. This procedure drastically reduces the total duration of testing and assesses the clinical range of interest.
9. Prepare a report detailing the results of measurements taken during calibration and clearly indicate the RE, highlighting whether these errors are outside the recommended range of ±20%.

In general, companies that provide maintenance and/or calibration services should check the acoustic power emitted by the TUSD for different NP values at one of the head-operating frequencies. However, replacing the head or transducer is sometimes necessary; thus, it would be interesting for companies to provide test results with ERA and/or intensity as recommended by the IEC.

5. Conclusions

This study evaluated the UOP emitted by the four TUSDs from the Physiotherapy Section of the Grupo de Saúde de Pirassununga. In addition, the repeatability of measurements made with each device was examined on three different days. The devices, even with up-to-date maintenance, presented many values of UOP with a RE higher than that suggested by the IEC 61689:2013 standard (81.39% of 1800 measurements with $TUSD_1$, 68.61% of 1800 measurements with $TUSD_2$, 75.25% of 1200 measurements with $TUSD_3$, and 3.17% of 600 measurements with $TUSD_4$). These results indicate that even when the maintenance and/or calibration of the equipment is up to date, maintenance and/or calibration should be reperformed to ensure patient safety is not compromised. The study developed by Pye and Milford in 1994 showed that over 20 years since the generation of the IEC 601-2-5 standard in 1984, minimal improvement in the performance of

ultrasound equipment was achieved. Almost 40 years later, this study indicates that despite updating the standards governing this type of equipment (IEC 61689:2013), the performance of some TUSDs needs improvement. Therefore, manufacturers and maintenance and calibration service providers need be aware of the necessity to provide acoustic power values with greater accuracy. In addition, those responsible for monitoring the maintenance of this equipment must closely observe the effects of corrective or preventive maintenance, particularly in the NP range and with the equipment configuration used most widely in clinical practice.

Acknowledgments

The authors would like to thank the Biomedical Engineering Program of the Federal University of Rio de Janeiro for the trust and helpfulness in the loan of the acoustic radiation power balance; the Physiotherapy Section of the Grupo de Saúde de Pirassununga, which enthusiastically supported us in the loan of therapeutic ultrasound devices; and the Brazilian Air Force Academy, for the financial support and for making this research possible.

References

1. Prentice WE. Therapeutic Modalities for Physical Therapists. New York: McGraw-Hill Education; 2001.
2. Kesiktas N, Karakas S, Gun K, Gun N, Murat S, Uludag M. Balneotherapy for chronic low back pain: a randomized, controlled study. Rheumatol Int. 2012; 32: 3193–99. http://dx.doi.org/10.1007/s00296-011-2163-9
3. Ricci AN, Dias KNC, Driusso P. The use of electrothermal and phototherapeutic methods for the treatment of fibromyalgia syndrome: a systematic review. Braz J Phys The. 2010; 14:1-9. https://doi.org/10.1590/S1413-35552010000100002
4. Silva FP, Severo-Silveira L, Plentz RDM, Durigan JLQ, Baroni BM.Electrophysical agents in clinical practice of orthopedic and sports physical therapists in Brazil. Fisioter. Pesqui. 2020; 27: 202-9. https://doi.org/10.1590/1809-2950/19019727022020
5. Agne JE. Eu sei eletroterapia. São Paulo: Pallotti; 2009.
6. IEC 61689:2013. Ultrasonics – physiotherapy systems – field specifications and methods of measurements in the frequency range 0,5 MHz to 5 MHz. International Electrotechnical Commission (IEC). 2013.
7. Merrick MA, Bernard KD, Devor ST, Williams MJ. Identical 3-MHz ultrasound treatments with different devices produce different intramuscular temperatures. J Orthop Sports Phys Ther. 2003; 33: 379-85. https://doi.org/10.2519/jospt.2003.33.7.379
8. Johns LD, Demchak TJ, Straub SJ, Howard SM. The role of quantitative Schlieren assessment of physiotherapy ultrasound fields in describing variations between tissue heating rates of different transducers. Ultrasound Med. Biol. 2007; 33: 1911-17. https://doi.org/10.1016/j.ultrasmedbio.2007.06.012
9. Straub SJ, Johns LD, Howard SM. Variability in effective radiation area at 1 MHz affects ultrasound treatment intensity. Phys. Ther. 2008; 88: 50-7. https://doi.org/10.2522/ptj.20060358
10. Baker KG, Robertson VJ, Duck FA. A review of therapeutic ultrasound: Biophysical effects. Phys Ther. 2001; 81: 1351–58.
11. Ishikawa NM, Alvarenga AV, Paes LFC, Pereira WCA, Machado JC. Análise do Desempenho de Equipamentos de Ultra-Som para Fisioterapia, operando na Cidade do Rio de Janeiro, Conforme a Norma NBR/IEC 1689 da ABNT. Rev Bras Fisioter. 2002; 6: 63-9.
12. Pye SD, Milford C. The performance of ultrasound physiotherapy machines in Lothian Region, Scotland, 1992, Ultrasound Med Biol. 1994; 20: 347-59. https://doi.org/10.1016/0301-5629(94)90003-5
13. Guirro R, Santos SCB. Evaluation of the acoustic intensity of new ultrasound therapy equipment. Ultrasonics. 2002; 39: 553-7. https://doi.org/10.1016/s0041-624x(02)00251-2
14. Schabrun S, Walker H, Chipchase L. How accurate are therapeutic ultrasound machines? Hong Kong Physiother J. 2008; 26: 39-44. https://doi.org/10.1016/S1013-7025(09)70006-5
15. Shaw A, Hodnett M. Calibration and measurement issues for therapeutic ultrasound. Utrasonics. 2008; 48: 234-52. https://doi.org/10.1016/j.ultras.2007.10.010
16. Inmetro, Vocabulário Internacional de Metrologia (VIM 2012): Conceitos Fundamentais e termos associados. Brasília: INMETRO; 2012.
17. Werkema C. Avaliação de sistemas de medição. Rio de Janeiro: Elsevier Brasil; 2013.
18. Razali NM, Wah YB. Power comparisons of Shapiro-Wilk, Kolmogorov-Smirnov, Lilliefors and Anderson-Darling tests. J. Stat. Model. 2011; 2: 21-33.
19. Ferrari CB, Andrade MAB, Adamowski JC, Guirro RRJ. Evaluation of Therapeutic Ultrasound Equipments Performance. Ultrasonics. 2010; 50: 704-9. https://doi.org/10.1016/j.ultras.2010.02.006
20. Durando G, Guglielmone C. Ultrasound physiotherapy devices: how to measure them. IEEE Instrum. Meas Mag. 2016; 19: 15-48. https://doi.org/10.1109/MIM.2016.7579065.

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