Technical Report

A Calibration Study of Therapeutic Ultrasound Units

Background and Purpose. Physiological effects of therapeutic ultrasound (US) are dependent on the intensity and duration of application. The purpose of this study was to test US machines used in clinical settings for proper calibration of time and power output. Methods. Measurements of power output and timer accuracy were obtained from 83 US units in clinical use. The machines were tested at 4 intensity settings (0.5, 1.0, 1.5, and 2.0 W/cm^2) using a continuous waveform and a 1-MHz frequency. The measured intensities were converted to percentages of error and compared with the ±20% standard. Results. Of the machines tested, 32 (39%) were outside the calibration standard for at least one output setting. Of these machines, 15 (18%) were above the +20% standard, and 17 (21%) were below the −20% standard for at least one output setting. Of the 32 machines outside the standard, 26 (31%) were outside the standard for 2 or more settings, and 3 (4%) produced no output at any of the settings. Of the mechanical timers tested, 7 (28%) were outside of the ±10% standard for timer accuracy at the 5-minute interval, and 6 (24%) were outside of the standard at the 10-minute interval. All digital timers tested were within the standard. Discussion and Conclusion. More than one third of machines tested in this study were outside the standard for power output, and approximately one fourth of the mechanical timers were outside the standard. Therefore, further improvements in the accuracy of US machine calibration are needed. [Artho PA, Thyne JG, Warring BP, et al. A calibration study of therapeutic ultrasound units. *Phys Ther.* 2002;82:257–263.]

Key Words: *Calibration, Physical agent, Standards, Ultrasound.*

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Therapeutic ultrasound (US) is a frequently used modality in the practice of physical therapy.[1,2] Much research has been conducted on the effects of US on living tissue, and both positive and negative effects have been reported. These effects are dependent on the intensity and frequency of the US applied to the tissue. For example, an increase in intracellular calcium, which leads to faster tissue healing, was shown to occur in human tissue in cultured medium at intensities of 0.5 to 0.75 W/cm^2 with a pulsed frequency of 20%.[3] Other beneficial effects such as increased soft tissue extensibility,[4,5] decreased pain levels,[6,7] and faster and stronger repair of tendon injuries[8–11] have also been reported.

Not all effects of US on tissue are beneficial. Ultrasound delivered at 1 W/cm^2 (energy in watts divided by the size of the soundhead's effective radiation area in centimeters squared) and a 1-MHz frequency has been shown to increase the temperature in the human gastrocnemius muscle by 0.2°C per minute.[12] Although the rise in tissue temperature can be beneficial, such as for pain reduction, addition of excessive energy to the tissue poses potential risks. For example, bone damage, including inhibition of bone growth[13] and damage to bone marrow[14] has been shown to occur in dogs at intensities above 3 W/cm^2.

Due to its potential beneficial and deleterious effects, which depend on the intensity and duration of application, the US soundhead output should be what is expected. The effects of US on tissue are intensity-dependent; too low a dose will have no clinical effect, whereas too high a dose can be damaging.[15] Ultrasound used inappropriately may be at best ineffective or at worst damaging to the patient.[16]

In order to help ensure that US equipment is properly calibrated, several operational standards for US machines' outputs have been published. The US Department of Health, Education, and Welfare[17] specifies that US output should be within ±20% of the intensity indicated on the US machine. The Canadian government[18] and the International Electrotechnical Commission[19] have set calibration standards of ±30%. All 3 standards specify that timers be accurate to within ±10%.

Researchers have reported that a large number of therapeutic US machines used clinically were not within the standard. In 2 studies,[20,21] US calibration accuracy was assessed using the ±20% standard. A study described in 1974 showed that 49 (85%) of the 58 US machines tested were not within this standard.[20] A 1981 study demonstrated that 21 (81%) of 26 machines tested were outside the standard.[21]

In the most recent studies, the less stringent ±30% calibration standard was used. A report in 1987 showed that 24 (56%) of the 43 machines tested were outside of this calibration standard.[22] Another report published in 1992 showed that 59 (69%) of the 85 US machines tested were not within this standard.[23] A study published in 1997 showed that, out of 31 machines, "almost all" of the US machines tested were outside of this standard.[24]

Results from previous research dating back to the early 70s indicate that a number of US machines had outputs that were outside the standard. The purpose of our study was to ascertain whether therapeutic US machines were within the ±20% standard for power output and the ±10% standard for timer accuracy.

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Mr Brismée provided concept/research design. Mr Warring and Mr Willis provided writing. Mr Artho and Mr Thyne provided data collection, Mr Thyne provided data analysis and facilities/equipment. Mr Artho and Mr Willis provided project management. Mr Warring provided fund procurement, and Mr Artho and Mr Warring provided clerical support. Dr Latman provided consultation (including review of manuscript before submission). The authors thank Lanny Traves from Baptist St Anthony's Hospital, Amarillo, Tex, for the use of the Bio-Tek Digital Ultrasound Wattmeter (model UW-2). They also thank Steve Sawyer, PT, PhD, Assistant Professor, Texas Tech University Health Sciences Center, Lubbock, Tex, for assistance with statistical programs and problem solving.

This study was approved by the Amarillo Institutional Review Board of Texas Tech University Health Sciences Center.

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Figure 1.
Illustration of Bio-Tek Digital Ultrasound Wattmeter (model UW-2) used to test power output.

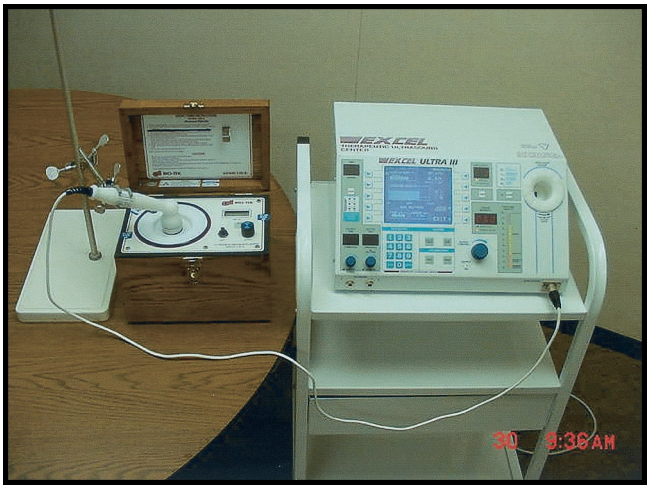

Figure 2.
Illustration of the power output testing procedure. Soundhead placed in UW-2 transducer well containing degassed/deionized water and held in place by clamp attached to a ring stand.

Method

We evaluated 83 US machines used in clinical facilities in 10 counties of northwest Texas over a period of 3 months, from May until August 2000. The inclusion criteria required the machines to be in use in a rehabilitation facility and to be considered by the staff as appropriate for patient treatment. Personnel in the facilities were unaware of the US variables to be evaluated.

A short letter was sent to potential participants explaining the study and inviting their participation. The clinics were later contacted via phone to confirm participation and schedule appointment times. Testing occurred at the participating rehabilitation facilities. Measurements of power output and timer accuracy were obtained from all US units and compared with the American standard of ±20% for power output and ±10% for timer accuracy.

Equipment

A Bio-Tek Digital Ultrasound Wattmeter (model UW-2)* was used to test the power output (Fig. 1). Bio-Tek Instruments Inc calibrated the UW-2 the week prior to the start of testing and certified the device to be accurate for a period of 1 year under normal use. This device measures output through a linear variable differential transmitter (LVDT). Deflection of a spring-and-cone assembly in the fluid is measured by the LVDT through means of a movable core. This deflection is a measurement of the amount of ultrasonic energy applied to the cone. The UW-2 measures watts only, so the actual measured readings from the wattmeter were divided by each soundhead's effective radiation area, as specified by the manufacturer, in order to convert the readings to watts per square centimeter. The UW-2 has a resolution of 0.1 W and an accuracy of ±10%.

A digital stopwatch was used to test the accuracy of the timers. Prior to testing, this stopwatch was checked against the US atomic clock to ensure its calibration.

Procedure

A pilot study was conducted prior to data collection to determine the number of trials needed for reliable measurements. Based on a test-retest protocol, a perfect correlation coefficient (r) of 1.0 was obtained, with zero variance for any repeated measurements. Therefore, based on those results, one measurement per intensity setting and timer interval was sufficient to obtain reproducible readings.

Clinicians filled out a brief questionnaire providing general information about each US unit tested. This information included each machine's brand name, age, most commonly used intensities, and how often the machine was used per week. In addition, the survey included how often the machine was checked and which variables were tested.

The transducer well of the UW-2 was filled with 55 mL of degassed water for the coupling medium. A dissolved oxygen test kit was used to test each container of degassed water prior to use to ensure that the oxygen content was less than 2 ppm. More than 4 ppm of oxygen reduces the accuracy of the power output measurements by interfering with the transmission of the ultrasonic energy.[21]

* Bio-Tek Instruments Inc. Highland Park, Box 998, Winooski, VT 05404.

Particular care was used to ensure that the transducer head was properly placed into the transducer well. The transducer head was held in place in the well with a clamp attached to a ring stand (Fig. 2). In an effort to decrease testing error, the same researcher positioned the US head in the transducer well for all machines tested. Four intensity settings (0.5, 1.0, 1.5, and 2.0 W/cm^2) were tested on each US unit using a continuous waveform. A complete list of manufacturers, models, and numbers of machines tested is presented in Table 1. Machines tested had one of the following soundhead's effective radiation area sizes: 4, 5, 6, 8.5, or 10 cm^2.

Calculations

The difference between the power output registered on the UW-2 (measured power output) and the intensity output indicated on the US unit (indicated power output) was expressed as a percentage of error using the formula: [(measured power output − indicated intensity output)/indicated intensity output] × 100. This percentage of error was calculated at each intensity setting and recorded for each US unit tested.

Each machine's timer was tested for accuracy after the output measurements were taken. Timers were tested at 5- and 10-minute intervals after placing the transducer heads into beakers of water. The difference between the time registered on the US unit (indicated time) and the actual time recorded on the stopwatch (measured time) was recorded for every US unit tested using the formula: [(measured time − indicated time)/indicated time] × 100.

Results

Power Output

The results showed that 32 (39%) of the 83 machines were not within the ±20% standard of calibration at one or more of the tested settings. Of these machines, 15 (18%) were above the ±20% standard and 17 (21%) were below the −20% standard for at least one output setting. Of these 32 machines, 26 (81%) were outside the standard at 2 or more settings. Three (9%) of the 32 machines had no output at any setting. Of the 51 machines that were considered to be inside the calibration standard, 8 (16%) were exactly 20% away from the expected output for at least one setting. Table 2 lists the brand names of the US machines tested and the numbers of machines within and outside the standard.

The correlation between the percentage of error for each US machine versus the age of each machine was examined. A statistically significant correlation was found between percentage of error for each US machine and age of each machine only for an intensity of 2.0 W/cm^2 (r=.29, P=.01). No statistically significant

Table 1.
Details of Ultrasound Machines Assessed in the Study

Manufacturer	Model	No. of Machines Tested
Amrex[a]	Synchrosonic 54	2
Bosch[b]	Sonomed 4	1
Chattanooga[c]	Forte 200 Combo	5
	Forte 400 Combo	4
	Intellect Legend Combo	5
	Intellect 700	11
	Intellect 240	1
	Intellect 225P	1
	Forte CB	1
	Intellect 200	1
	Vectra	1
	Forte US	1
	Intellect US	1
Dynatronics[d]	Dynatron 950	9
	Dynatron 800	1
Enraf-Nonius[e]	Sonopuls 434	8
	Sonopuls 464	4
	Sonopuls 590	3
Excel[f]	Ultra IV	1
Linquist[g]	Chronosonic Ultrasound	1
Mettler[h]	Sonicator 706	4
	Sonicator II	2
	Sonicator 730	1
	Sonicator 720	1
Mid-Canada Medical[i]	Medisound	1
PTI[j]	Omnisound 2500C	1
Rich-Mar[k]	Rich-Mar VI	2
	Rich-Mar X	2
	3P	2
	Thera-touch	1
	Rich-Mar V	1
	Rich-Mar 2060	1
	510	1
	HV-II	1

[a] Amrex Electrotherapy Equipment, 641 E Walnut St, Carson, CA 90746.
[b] Bosch Corp, 2800 S 25th Ave, Broadview, IL 60155.
[c] Chattanooga Group Inc, 4717 Adams Rd, Hixson, TN 37343.
[d] Dynatronics Corp, 7030 Park Centre Dr, Salt Lake City, UT 84121.
[e] Enraf-Nonius BV, Röntgenweg 1/PO Box 810, 2600 AV Delft, the Netherlands.
[f] Excel Tech Ltd, 2892 Portland Dr, Oakville, Ontario, Canada L6H 5W8.
[g] Linquist, address unavailable.
[h] Mettler Electronics Corp, 1333 S Claudina St, Anaheim, CA 92805.
[i] Mid-Canada Medical, 6200A Tomken Rd, Mississauga, Ontario, Canada L5T 1X7.
[j] Power Technologies Inc, 1482 Erie Blvd, PO Box 1058, Schenectady, NY 12301-1058.
[k] Rich-Mar Corp, PO Box 879, Inola, OK 74036.

Table 2.
Number of Ultrasound Machines Outside the Standard at Only One Setting and at Two or More Settings and the Number of Machines Within the Standard for Each Brand Name Tested

Brand Name[a]	Total No. of Machines	Mean Age (y)	No. Out at Only One Setting	No. Out at Two or More Settings	No. Within Standard
Chattanooga	32	7.3		15	17
Enraf-Nonius	15	11.3	1		14
Rich-Mar	11	8.4	2	4	5
Dynatronics	10	3.4		2	8
Mettler	8	10.8	2	3	3
Amrex	2	5.5	1		1
Bosch	1	14.0		1	
Excel	1	2.0			1
Lindquist	1	20.0		1	
Mid-Canada Medical	1	5.0			1
PTI	1	6.0			1
Total	83	8.1	6	26	51

[a] See Table 1 footnotes for manufacturers' addresses.

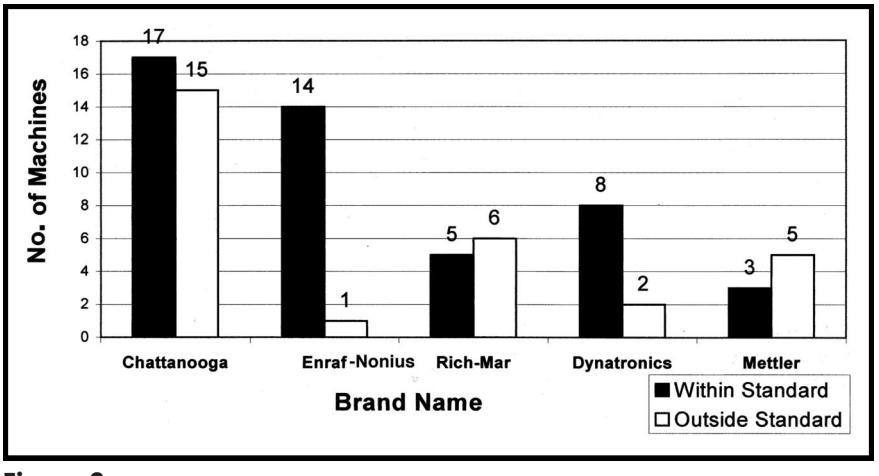

Figure 3.
Comparison of 5 major ultrasound machines (n>8) tested versus the number of ultrasound machines within and outside of the standard. See Table 1 footnotes for manufacturers' addresses.

correlation was found for intensities of 0.5, 1.0, and 1.5 W/cm^2. The correlations between how often each US machine was checked and how often it was used versus the percentage of error for each machine also were examined. No statistically significant correlation was found.

No difference was found when the 5 major brand names of the US machines tested were compared with the number of machines outside the standard using a chi-square test with a Yates correction. However, as indicated in Figure 3, some brands had a greater number of machines within the standard than other brands.

Timers

Of the 83 US machines tested, 25 (30%) had mechanical timers and 58 (70%) had digital timers. All of the digital timers were within the ±10% calibration standard. Seven (28%) of the 25 mechanical timers were outside the standard at the 5-minute interval, and 6 (24%) were outside the standard at the 10-minute interval (Fig. 4).

Survey

The most commonly used intensities were reported as 1.1 to 1.5 W/cm^2 (75%). The ages of the US machines ranged from 1 to 20 years, with a mean age of 8.1 years (SD=5.5). Table 2 shows the mean age of the US machines for each brand. The frequency of use for the US machines was as follows: 4.1 to 5.0 hours per week=6%, 3.1 to 4.0 hours per week=8%, 1.1 to 2.0 hours per week=17%, 0 to 1.0 hour per week=22%, greater than 5.0 hours per week=23%, and 2.1 to 3.0 hours per week=24%. All 83 machines were reported to be "checked" at least annually. Clinicians surveyed reported that they "did not know" the variables (ie, power output, electrical supply and safety, and timer accuracy) tested on 38% of the US machines. Power output was reported to be "checked" on 46% of the US machines, and electrical supply and safety were the only variables reported to be "checked" on 14% of the machines.

Discussion

The clinicians assumed that technicians, either in-house personnel or outsource vendors, were conducting periodic "checks" on the US machines to ensure proper power output, electrical safety, and timer accuracy. Actually, all 3 variables, just one variable, or a combination of variables might have been "checked."

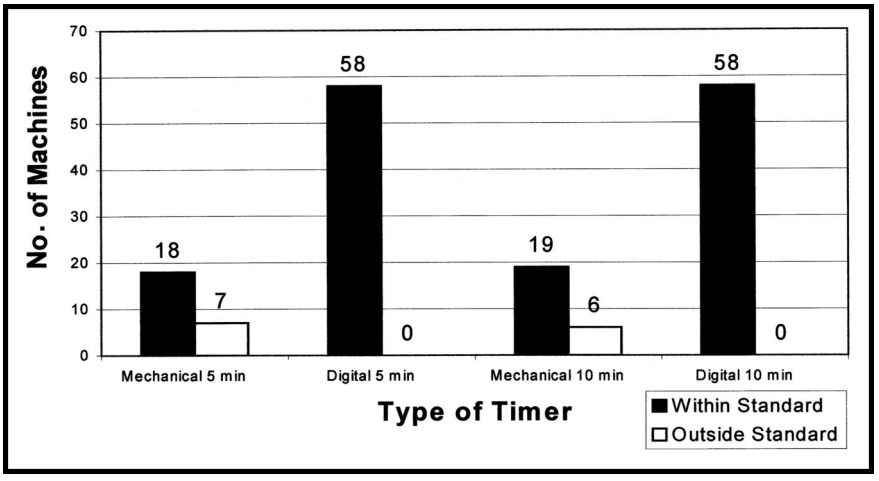

Figure 4.
Comparison of mechanical versus digital timers within and outside the standard.

We found that 32 (39%) of the tested US machines had variables outside the standard for at least one setting. Of these machines, 15 (18%) were above the +20% standard and 17 (21%) were below the −20% standard for at least one output setting. The 17 US machines below the −20% standard may only be denying the patient effective treatment. However, the 15 US machines above the +20% standard could be a potential harm to the patient. An additional 8 (10%) of the US machines were within the ±20% standard but on the borderline. These results indicate that the percentage of US machines outside the standard has decreased over the last 3 decades when compared with results previously published. This finding could be due to a greater awareness by clinicians of the importance of periodic "checks." No tests were run to identify the source of the problem for the US machines outside the standard. These results indicate that clinicians should request in-house technicians (eg, biomedical services) or outsource vendors to check the US machine annually for correct power output. If the US machine is found not to be within the ±20% standard, the machine should be calibrated by the technician or sent back to the manufacturer for calibration. Whether this matters in terms of clinical effectiveness is not known.

With the exception of one weak correlation coefficient between the age of the machines and the percentage of error at 2 W/cm^2 (r=.29, P=.01), there was no statistically significant association among the amount of time the machines were used per week, their age, and the percentage of error of power output. This finding indicates that age and usage of US machines are not good predictors of the machines' correct output. Results also indicated no significant correlation between how often the machines were "checked" and the percentage of error of power output. Because all machines tested were reported to be "checked" at least annually, an assumption cannot be made in this study as to whether frequency of testing has an effect on power output being within the standard.

A relationship regarding the output accuracy of certain brands of US machines was also observed. In our study, Enraf-Nonius[†] and Dynatronics[‡] brands exhibited a greater percentage of machines that were within the standard (n=25; >85%) than Chattanooga,[§] Rich-Mar,[‖] and Mettler[#] brands (n=51; <50%) (Fig. 3).

All digital timers were within the standard at both time intervals tested, whereas approximately one fourth of the mechanical timers were outside the standard (Fig. 4). This finding suggests that machines with digital timers are preferable to ensure correct treatment duration.

Our survey revealed that a large number of clinicians were unaware of the variables checked for each machine. Because clinicians are responsible for safe delivery of US dosage to the patient, we believe they need to be more aware of the variables that are to be tested to ensure safe delivery of US. Therapists and others, in our view, could benefit from systematic training in their education curricula on specific variables of US machines (eg, power output) in need of periodic checks. Continuing education programs need to be available to educate clinicians on this topic.

We suggest that further studies in US calibration should involve testing US units at different frequencies (1 MHz versus 3 MHz), because frequency is important in regard to the depth of the tissue targeted. Evaluating the differences in machine accuracy when using pulsed versus continuous waveforms could also be investigated. Calibration studies could also be conducted throughout the country to determine whether there is a consistent trend in accuracy of calibration in different regions.

Conclusion

We believe that clinicians should be aware that the intensity displayed on US units is not always a direct indication of the actual output being emitted. In addition, although most new US units have digital timers, we

[†] Enraf-Nonius BV, Röntgenweg 1/PO Box 810, 2600 AV Delft, the Netherlands.
[‡] Dynatronics Corp, 7030 Park Centre Dr, Salt Lake City, UT 84121.
[§] Chattanooga Group Inc, 4717 Adams Rd, Hixson, TN 37343.
[‖] Rich-Mar Corp, PO Box 879, Inola, OK 74036.
[#] Mettler Electronics Corp, 1333 S Claudina St, Anaheim, CA 92805.

strongly recommend when purchasing used equipment that the machines have digital timers.

According to our data, improvement has been made regarding the accuracy of therapeutic US when compared with past research findings. This improvement may be due to several factors. One factor may have been an increase in awareness by US technicians and manufacturers of the importance of machine accuracy. The differences may also have been attributable to testing machines in a different region than previous studies. However, more than one third of machines tested in this study were outside the standard for power output, as were almost one fourth of mechanical timers. Thus, further improvement in the accuracy of US machine calibration is needed. Clinicians should not hesitate to request that US machines be checked for power output and timer accuracy, which would benefit the safety of the patient and decrease the liability of the institution. Proper calibration would help ensure that patients receive a more accurate US dosage and, therefore, safe and appropriate treatment.

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