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Original Research Article

A Calibration Study of Electro-Physical Agents Used in Physiotherapy Clinics and Academic Institutions in India

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ABSTRACT

Physiological effects of electrophysical agents are dependent on the intensity output and duration of application of any electrophysical agent. The purpose of this study was to test Electrophysical agents used in clinical settings for proper calibration of time and output parameters.

Methods: Measurements of power output and timer accuracy were obtained from a total of 158 electrophysical agents comprising solid state therapeutic Ultrasound (US), Diagnostic Stimulator (DMS), Interferential Current therapy (IFCT); used in clinical and academic institutions. This study was preceded by a survey undertaken to assess the awareness of calibration techniques used to test the various electrophysical agents in use amongst professional physiotherapists in both clinical as well as academic institutions. The US machines were tested at 4 intensity settings (1, 1.5, 2, and 2.5 W/cm^2) using a continuous waveform and a 1-MHz frequency, 3- MHz frequency.. DMS was tested for Faradic currents, Interrupted Galvanic Current, Surged Faradic Current, and Direct Current using an Oscilloscope. Also, IFCT was tested for beat high frequency of 10 Hz and sweep frequencies of 20, 40, & 80 Hz. The measured intensities and frequencies were converted to percentages of error and compared with the20% standard

Results: A total of 158 EPA's were tested comprising, 57 Solid state Ultrasound, 66 diagnostic Stimulators, and 35 Interferential Current Therapy units, 29 (50.8%) of the 57 US units were not within the 20% standard of calibration. 38 (57.58%) DMS units were found to be not within standards of calibration, while only 2 (5.7%) IFT units were not within standard of calibration. Digital timers were more within standard of calibration as compared to the analogue timers.

Discussion and Conclusion: More than one third of the EPA's 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, DMS and IFCT calibration are needed.

Keywords: US, DMS, IFCT, EPA's, Calibration, Oscilloscope, Power-meter.

INTRODUCTION

In Physiotherapy the combination of electrotherapy and manual techniques has been responsible for uplifting the quality and influence the pace of output in the world of physiotherapy.

Electrotherapy has marked its spot in the treatment options over the years. In India

like in the foreign countries, the ongoing techniques are modifying the views towards the role of these modalities and their application. However in this era of evidence based practice, there is dilemma regarding the presence and use of electrical modalities within the boundaries of mediocre physiotherapeutic treatment.

Continuing efforts to implement higher quality standards in hospitals are essential to provide a healthy lifestyle and to resolve health-related problems of people. In health care facilities, one of the most important factors that has to be considered is to ensure the safety of diagnostic and therapeutic devices that are directly exposed to the patients. [1] The safety of all medical devices used in health care should be emphasized because the mistakes that can be experienced in the field of healthcare may cause casualties. [2] The safety and the performance of medical devices can be controlled by medical calibration measurements.

Calibration measurement is the process of detection of the correlation between the value measured by the test device and the value shown by the medical device. By answering many questions arising in mind about whether the device works with desired accuracy or not, and whether the device gives damage to patients or not, the medical calibration measurements stands out in the foreground. The calibration procedures are carried out with the measurement systems with at least ten times more sensitive features than the medical devices that will be tested. The test devices certificated by national or international standards under the standard conditions, are used for this process. So that, under a known uncertainty, the measurement result of the test device is compared to the adjusted or measured value of medical devices. [3,4]

Evaluation of physiotherapy practices including use of electrophysical agents (EPA's) demonstrates the growing importance of measurement. Continuing efforts to implement higher quality standards in hospitals and academic institutions are essential to provide a healthy lifestyle, to resolve health-related problems of people and to impart sound knowledge in use Electrotherapy.

In a Physiotherapy clinic, it has great importance that the devices using electrical current extensively must be under control and must be also tested by using the calibration measurement procedures. With calibration measurements performed at regular intervals, it is possible to control whether the current that is given to the patient has the set value as displayed on the equipment or not.

Researchers in various parts of the world have reported that a large number of therapeutic US machines used clinically were not within the standard. In previous studies [5,6] US calibration accuracy was assessed using the 20% standard. The Canadian Government [7] had set calibration standards of $\pm$ 30%. A study described in 1974 showed that 49 (85%) of the 58 US machines tested were not within this standard. A 1981 study demonstrated that 21 (81%) of 26 machines tested were outside the standard. [6] There is however no Indian studies regarding safety and calibration of EPA's used in clinics or academic institutions. A Turkish study [4] assessed varied types of EPA's and determined that the devices that are not within limits of the calibration measurements, in other words, inappropriate devices according to the international standards, were old equipments used in the treatment for many years and these devices have to be sent to their technical services for repair.

The purpose of calibrating EPA's is to minimize risk, to reduce costs, to minimize user problems and to ensure compliance with international standards.

With regular and programmed control of medical devices, accurate measurements of the device is provided, consequently, problems before they arise and delays in response are prevented; besides, the life of the device is extended.

In physiotherapeutic practice, it has great importance that the devices using electrical current extensively must be under control and must also be tested by using calibration measurement procedures. With calibration measurements performed at regular intervals, it is possible to control the quality of physiotherapy treatment and to ascertain whether the physical energy that is given to the patient is appropriate enough to bring about the desired effects in the body so as to correct the pathological status of the tissues. The same principles need to be followed while teaching the fundamentals and application of various EPA's both theoretically and in clinical practice. In academic institutions (timely) calibration of EPA's will help academicians check the quality as well the precision of teaching clinical skills to the physiotherapy students. Calibration of EPA's will enable us ensure that the academicians deliver appropriate guidelines while teaching the application of EPA's to physiotherapy students. Electrodiagnosis definitely requires the EPA's to be calibrated such that it permits us to report the neurophysiologic responses of the nerves and muscles to current of wide range of pulse durations and current intensities.

Therefore, the main purpose of our study was to perform the calibration measurements of the devices in fully equipped physiotherapy clinics and Physiotherapy colleges in and around Navi Mumbai. The EPA's inclusive of solid state therapeutic Ultrasound (US), Diagnostic Stimulator (DMS), and Interferential Current therapy (IFCT) were tested for calibration

MATERIALS AND METHODS

Calibration measurement is the process that must be done in various time periods according to the production type or the utilization of the device to ensure the safety of device and to obtain reliable results.

The calibration measurements are determined by experienced users by considering the device features and the usage conditions. Hence we did this study in collaboration with an engineering company, Biotech, India, where the procedure was carried out by expert engineers from Biotech and reporting was solicited by the Director of the same company.

Prior to beginning this research we conducted a survey in the initial phases of our PhD thesis. The results of this study gave a clear understanding as to where all do we need to probe in while carrying the calibration study; to determine which EPA's to include in the calibration study we utilised the findings of our survey done in the initial phases wherein, on the basis of widespread use of Electrophysical agents in physiotherapy clinics and colleges we meticulously selected Solid state Ultrasound therapy (US), Diagnostic Stimulators (DMS) used both for therapy as well as Electrodiagnosis in clinics and college inclusive of Faradic currents, Surged faradic currents Interrupted Galvanic current and Direct current. We also included Interferential Current Therapy (IFCT) units. Each of the EPA's in the scope of our study was separately handled and the points for all devices were calculated. 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. Physiotherapists in the facilities were unaware of the 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 colleges and clinics. Measurements of output and timer accuracy were obtained from all EPA's and compared with the American standard[8] (Due to lack of availability of Indian standards) of 20% for power output and 10% for timer accuracy. EPA's from three different Academic colleges and two Clinical hospitals were selected to be calibrated.

Calibration Procedure and Equipments

Calibration of all the equipments was conducted in collaboration with Mr. Deepak Shah, Director of Biotech, India. Expert engineers from this company were assigned to perform calibration of EPA's included in the study.

Calibration of Solid-state Ultrasound

An Ultrasound Power Meter, Model UPM-DT-10 AV from Ohmic instruments co. was used to test the power output (Fig. 1). The Company got the Instrument calibrated prior to the start of testing and certified the device to be accurate for a period of 1 year under normal use.

The components of the device are as follows:

- ✓ Test Tank with Rubber
- ✓ Positioning Clamp Assembly
- ✓ Cone Assembly
- ✓ 120 VAC to 12VAC 500 mA power adapter # 12102320

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 transducer head's effective radiation area, in order to convert the readings to watts per square centimeter. The UW-2 has a resolution of 0.1 W and an accuracy of10%.

Figuer-1: Ultrasound Power Meter

Figuer-2: Stop Watch

A 12 jewel Diamond Brand (Mechanical) stopwatch was used to test the accuracy of the timers. Prior to testing, this stopwatch was checked against the IST to ensure its calibration. It consist of stainless steel, single metallic balance nickel based alloy hairspring, anchor escapement and with 12 jewels fixed in the structure.

Following were the specifications of the stopwatch:

* Minimum Calibration of Sec Regs (s): 0.1
* Running Time (h): 6
* Time for 1 Rev of Sec Regs (s): 30

* Time for 1 Rev of Min Regs (m): 15

Calibration of Diagnostic Muscle Stimulator (DMS) and Interferential Current Therapy IFCT

A Tektronix TBS 1022 Digital Storage Oscilloscope was used for calibration of DMS and IFCT. The waveform, amplitude of current intensity, and frequency was observed and measured on the digital Oscilloscope by the engineer from Biotech, India Company.

Figuer-3: Digital Oscilloscope

Procedure

Solid state Ultrasound

The transducer well of the UW-2 was filled with 55 ml of degassed water for the coupling medium.

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. 4). In an effort to decrease testing error, the same engineer positioned the US head in the transducer well for all machines tested.

Four intensity settings (1, 1.5, 2, and 2.5 W/cm^2) were tested on each US unit using a continuous waveform. Machines tested had one of the following transducer's effective radiation area sizes: 4/ 5 cm^2

Figuer-4: Calibration of Ultrasound

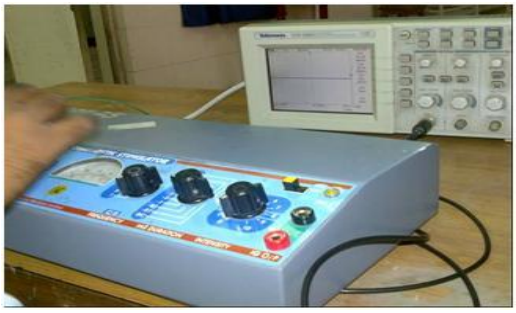


Figure 5: Use of Digital Oscilloscope

Diagnostic Muscle Stimulator/IFCT

DMS was tested for TENS, Interrupted Galvanic current, Direct Current, Faradic and Surged faradic current. The reporting was done for DMS taking all the current types into consideration. All the currents were checked for intensities and frequencies, using the oscilloscope as seen in Figure 5. Interrupted Direct current was checked for Pulse duration (ms) and intensities in voltage.

IFCT

IFCT was tested IFCT was tested for beat high frequency of 10 Hz and sweep frequencies of 20, 40, & 80 Hz.

All the measured intensities and frequencies were converted to percentages of error and compared with the20% standard.

A complete list of manufacturers, models, and numbers of machines tested is presented in Table 1.

Table 1. Details of Electrophysical agents Assessed in the Study

Make	Total Number of US	Total Number of DMS	Total Number of IFT	
Bionics	3	4	0	
Electromedicare	3	29	1	
Biotech/Striker	15	2	9	
Ronak Surgicals	3	0	0	
Ami Surgicals	6	3	0	
Sai Meditech	1	2	0	
Combo Healer- Striker	26	26	25	
Total	57	66	35	**158**

The procedures for all EPA's is summarised and can be seen in Table 2

Table 2 : Calibration measurement procedures for Electrophysical Agents

Device	**Measured Parameter**	**Used Test**	**Device Explanation**
Ultrasound Device	Power (1, 1.5, 2, 2.5 W/cm2)	Ultrasound Power-meter (Ohmic instruments co.)	For each transducer head, output power was measured
	Time	Stopwatch (Mechanical)	Timer setting was tested.
Diagnostic Muscle Stimulator			
TENS	Frequency (1, 50, 100, 150 Hz)	Oscilloscope (Tektronix TBS 1022)	For each channel, all current modes (Burst, continuous, modulated current modes..) was observed.
			The frequency was measured.
Interrupted Galvanic	Frequency (1 Hz)	Oscilloscope (Tektronix TBS 1022)	The frequency was measured as <10 Hz
	Pulse durations (0.1,3 & 100, msec)	Oscilloscope (Tektronix TBS 1022)	Short and Long pulse durations were tested
	Current intensities/ amplitude (Volts)	Oscilloscope (Tektronix TBS 1022)	Intensity output was measured
Galvanic	Current intensities (Volts)	Oscilloscope (Tektronix TBS 1022)	Intensity output at various 'knob' levels and at specified intensities was measured along with the type of waveform
Faradic Current	Current intensities (Volts)	Oscilloscope (Tektronix TBS 1022)	Intensity output at various 'knob' levels and at specified intensities was measured along with the type of waveform
Surged Faradic	Current intensities (Volts)	Oscilloscope (Tektronix TBS 1022)	Intensity output at various 'knob' levels and at specified intensities was measured along with the type of waveform
	Surging duration (msec)		Surged duration measured against the 'knob' positions
Interferential Current therapy	Frequency	Oscilloscope (Tektronix TBS 1022)	Beat high frequency of 10 Hz and sweep frequencies of 20, 40, & 80 Hz were measured.

Calculations

The difference between the power output registered on the Power-meter (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]X100.

This percentage of error also called as tolerance was calculated at each intensity setting and recorded for each US unit tested. The tolerance or percentage of error for DMS was calculated using the formula

[(observed value of intensity/actual value of intensity) X 100]- 100

Similarly, percentage of error was calculated using

[(observed value of frequency/actual value of frequency) X 100]- 100

Each EPA was classified as being within limits of calibration, if the tolerance values were within limits of ±20% of standard for power output and 10% for standards of time accuracy.

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:

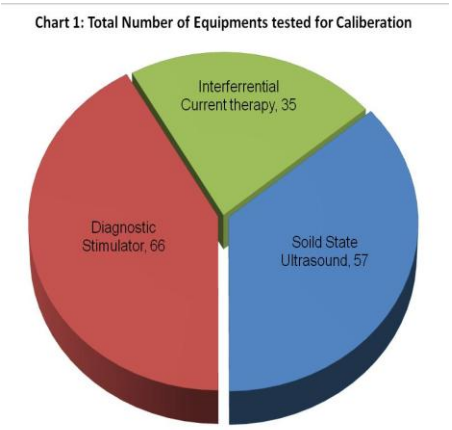
[(measured time-indicated time)/indicated time] X100

RESULTS

A total of 158 EPA's were tested comprising, 57 Solid state Ultrasound, 66 diagnostic Stimulators, and 35 Interferential Current Therapy units (Refer chart 1)

Power Output for Solid state Ultrasound

The results showed that 29 (50.8%) of the 57 machines were not within the 20% standard of calibration at one or more of the tested settings. US frequency of 1 MHz, 3MHz and a combination of both were assessed.



There was a mix of US equipments displaying power digitally as well as on an analogue meter in Watts/cm^2 Table- 3 lists the brand names of the US machines tested and the numbers of machines within and outside the standard.

18 (31.58%) of US machines worked on a frequency of 1 MHz, 5 (8.8%) of the US machines worked on 3 MHz and 8 (14.03%) of the US machines had an availability of both 1 MHz as well as 3 MHz frequencies. (Refer Table 3)

Table 3- Number of Ultrasound Machines Outside the Standard and the Number of Machines Within the Standard for Each Brand Name Tested

Make	Total Number	WNL	N-WNL	1 MHz	1 & 3MHz	3 MHz
Bionics	3		3	3		
Electromedicare	3		3	2	1	
Biotech/Striker	15	3	12	3	7	5
Ronak Surgicals	3		3	3		
Ami Surgicals	6		6	6		
Sai Meditech	1		1	1		
Combo Healer- Striker	26	25	1			
Sum total	**57**	**28**	**29**	**18**	**8**	**5**
Percentage		49.12	50.88	31.58	14.0358	8.778

Timers

Of the 57 US machines tested, 30 (52.63%) had digital timers and 27 (47.36%) had mechanical timers. All of the digital timers were within the 10% calibration standard. Eight (29.6%) of the 27 mechanical timers were outside the standard when evaluated for 7 minute interval and 4 (14.8%) were outside the standard at the 10-minute interval.

Output for Diagnostic Muscle Stimulator

A total of 66 DMS were assessed for calibration. 28 (42.2%) were found to be within standards of calibration and 38 (57.58%) were found to be not within standards of calibration. The Number of DMS units within standard of calibration and their make are displayed in Table 4.

Table 4: Number of Diagnostic Muscle Stimulator Outside the Standard and the Number of Machines Within the Standard for Each Brand Name Tested

Make	Total Number	WNL	N-WNL
Bionics	4		4
Electromedicare	29		29
Biotech/Striker	2	2	
Ami Surgicals	3		3
Sai Meditech	2		2
Combo Healer- Striker	26	26	
Sum total	**66**	**28**	**38**
Percentage		**42.42424**	**57.57576**

Timers

Only 28 (42.42%) DMS out of a total of 66 had an option of setting application time while using therapeutic currents.

Output for Interferential current Therapy

35 IFCT machines were tested for calibration. 33 (94.2%) were within standards of calibration while only 2 (5.7%) were not within standard of calibration. Refer Table 5 for the number of IFT machines and their make within limits of calibration..

Table 5: Number of Interferential current Therapy Outside the Standard and the Number of Machines Within the Standard for Each Brand Name Tested

Make	Total Number	WNL	N-WNL
Electromedicare	1	1	
Biotech/Striker	9	7	2
Combo Healer- Striker	25	25	
Sum total	**35**	**33**	**2**
Percentage		94.28571	5.714286

Timer

All the IFCT units had digital timer and all were within standard of calibration when compared to 7 minutes and 10 minutes time interval. It was observed that the physiotherapists used lesser number of IFCT's in clinical set ups, and surprisingly lesser number of the same in academic institutes.

Survey

A survey was undertaken prior to resuming the present research. It was evident from the survey that Ultrasound therapy, Faradic Currents, Conventional TENS and interferential Current therapy were the top ranked EPA's used in physiotherapeutic practice.

All 158 Electrophysical agents assessed in the present study were reported to be "checked" at least annually. Physiotherapists surveyed reported that they "did not know" the variables (i.e., power output, electrical supply and safety) tested on US machines. Power output was reported to be "checked" on almost all of the EPA's, and electrical supply and safety were the only variables reported to be "checked" of the machines. In clinical hospitals and clinics it was evident that all the EPA's were routinely 'calibrated' as per norms set up by the hospital authorities; however no certificate was produced mentioning the various parameters evaluated and the technique of evaluation. A few claimed their EPA's were calibrated

using a multimeter. There was a scarce knowledge of the need of the EPA's used in academic institutions to be calibrated.

DISCUSSION

Almost in all physiotherapy clinics and academic institutes commonly used EPA's are Therapeutic Ultrasound, Diagnostic Muscle Stimulator and Interferential Current therapy units. Considering this fact, our study was focused on these devices. Calibration measurement procedures have not been developed previously for physiotherapy devices. Even if seldom done, both calibration measurement procedures and a specific test device have been used for several years for only ultrasound therapy device. However, the rest of the physiotherapy devices were not considered in a periodic calibration measurement system.

One of the observations made during the current study was that most of the physiotherapy clinics and institutions used Electromedicare equipments in large number, there were a few institutes where not very well known brands and make of EPA's were in use. Biotech and Combo Healer stood out as very reliable in terms of accuracy of equipments. However not many were used in practice in the physiotherapy clinics. The previous survey we undertook gave us the answer for this kind of observation. It is the cost of the EPA's that matters to Indian Physiotherapists and that could be one of the factors where Indian Physiotherapist lose out on quality in use of EPA's used as adjuncts in clinical practice.

4 major brand names of the US machines, DMS and IFCT tested were compared with the number of machines outside the standard. However, as indicated in Table 6 &7, Biotech and Combo Healer/ Striker had a greater number of machines within the standard than other brands. (Refer Chart 2.) Table 6 and 7 summarises the number of EPA s within the standard of calibration for 4 popular brands tested.

Table 6: Number of EPA's Outside the Standard and the Number of Machines Within the Standard for 4 popular Brand Name Tested

EPA's	Electromedicare	Biotech/Striker	Combo Healer-Striker	Bionics
US- WNL	0	3	25	0
US- N-WNL	3	12	1	3
DMS- WNL	0	2	26	0
DMS- N-WNL	29	0	0	4
IFCT- WNL	1	7	25	
IFCT- N- WNL	0	2	0	

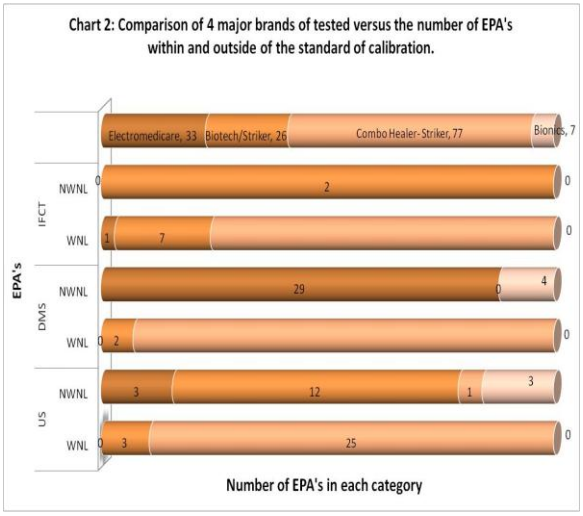
Table 7: 4 Leading Brands -The Number And Percent Of EPA's Within Limits Of Calibration

	US	DMS	IFCT	Total EPA's tested	Percent
	WNL	WNL	WNL		
Electromedicare	0	0	1	33	3.03
Biotech/Striker	3	2	7	26	46.15
Combo Healer- Striker	25	26	25	77	98.7
Bionics	0	0		7	nil

In physiotherapy clinics, patients are usually treated by means of electrical currents which could be harmful to the patient. Therefore, to provide an effective and safe treatment on patients, calibration measurements of EPA's are very essential. Hence, the calibration measurements of these EPA's operating under the required standards are very important.

It is very sad state of affair that there are no standards put-forth by the health officials in India. The annexure from the

officials procured during the course of the study mentions technical specification required for electrophysical agents to be used in any physiotherapy set up which mentions about parameters like frequency, output modes, display, safety class etc, but there are no norms laid down for calibration of any of the EPA's. Therefore we followed the United States standards. Several operational standards for EPA's have been published. The US Department of Health, Education, and Welfare [8] specify that the output should be within ±20% of the intensity indicated on the US machine. Many studies are conducted in other parts of the world. 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. [9] Another report published in 1992 showed that 59 (69%) of the 85 US machines tested were not within this standard. [10] A study published in 1997 showed that, out of 31 machines, "almost all" of the Ultra Sound machines tested were outside of this standard. [11]



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

The clinicians assumed that technicians, either in-house personnel or outsource vendors, were conducting periodic "checks" on the EPA's to ensure proper power output, electrical safety, and timer accuracy. Most of the therapists are not aware that the concept of calibration they hold onto is incorrect. There has to be more awareness regarding these concepts and improvement in standards of electrical modalities that are being currently used for treatment purposes. There are certain rules and regulations pertaining to the calibration procedure and importance, which are essential to maintain standards. Quality assurance is really not given utmost importance; even if it were to be given there are no appropriate quality checks to ensure quality assurance in turn.

Because therapists are responsible for safe delivery of dosage of EPA to the patient, it should be believed that they need to be more aware of the variables that are to be tested to ensure safe delivery of EPA. Therapists and others could benefit from systematic training in their education curricula on specific variables of EPA (e.g., power output, frequency, time) in need of periodic checks. Continuing education programs need to be available to educate therapists and academicians on this topic.

CONCLUSION

It would be appropriate to propose that the therapist should be aware that the intensity displayed on EPA's is not always a direct indication of the actual output being emitted. In addition, although most new EPA's have digital timers, we strongly recommend when purchasing used equipment that the machines have digital timers.

More than half 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 EPA's calibration is needed. Clinicians should not hesitate to request that EPA's 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 dosages and, therefore, safe and appropriate treatment

EPA's are also used in academic institutions where students learn the skill and the theory of using varied types of EPA's in clinics. These EPA does therefore need to be giving the actual output and enable them to learn effectively. And, if the knowledge of calibration and appropriate output is imparted in academic institutions it would definitely impart and improve the awareness regarding the technical errors and the mode of assessing them.

Evidence Based practice has taken precedence in every field of health care. Physiotherapists too, fall in the purview of this spectrum. At this point, development of a routine of calibration of EPA's used in physiotherapy clinics and its introduction in the curricula does form an important part. Knowledge of calibration procedures for physiotherapy devices becomes crucial and will enable therapists to imbibe the working of EPA's used as adjunct in entirety and be able to impart holistic and efficient treatment to their patients during their practice.

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***Conflict of Interest**:* None.

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