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Development and Implementation of Calibration Measurement Methods for Physical Therapy Devices

Fizik Tedavi Cihazları için Kalibrasyon Ölçüm Metodlarının Geliştirilmesi ve Uygulanması

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Summary

Objective: In this study, calibration measurement methods for physical therapy devices were developed to ensure the accuracy of the devices, and therefore to use the device on patients efficiently and safely with the aim of increasing the quality of physical therapy. Although the calibration measurements have been performed for emergency, operation and intensive care devices for many years, physical therapy calibration measurement methods that might be used in the periodic controls of equipments except ultrasound have not yet included in national or international standards.

Materials and Methods: TENS, galvani farad, ultrasound, electrotherapy, diadynami, traction, shortwave diathermy, infrared, treadmill, paraffin and hot pack devices are within the scope of this study. In order to develop the calibration measurement procedures, the adjustable and measurable parameters of the devices that might be tested were defined and the appropriate test devices were selected for each parameter. By using the procedures developed in this study, the devices in a sample clinic (Physical Medicine and Rehabilitation Department of Istanbul Medical Faculty, Istanbul University) have been tested for accuracy.

Results: Many devices in physical therapy unit were within limits of the calibration measuremens that are stated in each device's technical manual. It has been determined that the devices that are not within limits of the calibration measurements, in other words, inappropriate devices according to the international standards, are old equipments used in the treatment for many years and these devices have to be sent to their technical services for repair.

Conclusion: The recommended calibration procedures in this study can help to determine the reliability and the accuracy of the physical therapy devices. *Turk J Phys Med Rehab 2012;58:47-51.*

Key Words: Physical therapy, calibration measurements

Özet

Amaç: Bu çalışmada, fizik tedavi kalitesinin arttırılması amacıyla, fizik tedavi cihazlarının doğruluğundan emin olunması, dolayısıyla cihazın hasta üzerinde verimli ve güvenli kullanımının sağlanması için, kalibrasyon ölçüm teknikleri geliştirilmiştir. Ameliyathane, acil ve yoğun bakım cihazları için kalibrasyon ölçümlerinin uzun yıllardır gerçekleştiriliyor olmasına rağmen, ultrason dışındaki fizik tedavi cihazları için periyodik kontrollerde kullanılabilecek kalibrasyon ölçüm yöntemleri ulusal veya uluslar arası normlarda henüz ortaya konmamıştır.

Gereç ve Yöntem: TENS, ultrason, galvani faradi, elektroterapi, diadinami, traksiyon, kısa dalga diatermi, infraruj, treadmill, parafin ve hot pack kazanı, bu çalışmanın kapsamındaki cihazlardır. Kalibrasyon ölçüm prosedürlerinin geliştirilmesi için, çalışılan cihazların ayarlanabilen ve ölçülebilen parametreleri belirlenmiş ve her bir parametre ölçümü için uygun test cihazları seçilmiştir. Çalışmamızın sonucunda oluşturulan kalibrasyon ölçüm prosedürleri ile örnek bir klinikteki (İstanbul Üniversitesi, İstanbul Tıp Fakültesi, Fiziksel Tıp ve Rehabilitasyon Birimi) fizik tedavi cihazlarının doğrulukları kontrol edilmiştir.

Bulgular: Fizik tedavi ünitesinde çalışılan birçok cihazın, teknik kitapçıklarında belirtilen kalibrasyon ölçüm sınır değerlerinin içinde olduğu ve bu cihazların da genellikle yeni cihazlar olduğu görülmüştür. Kalibrasyon ölçüm sınırları içinde olmayan cihazların, başka bir deyişle uluslar arası standartlara uymayan cihazların uzun senelerdir kullanılan eski cihazlar olduğu ve sözkonusu cihazların teknik servislerine gönderilmesi gerektiği anlaşılmıştır.

Sonuç: Bu çalışmada önerilen kalibrasyon ölçüm prosedürleri, fizik tedavi ünitelerindeki cihazların güvenilirliğinin ve doğruluğunun tespitinde yardımcı olacaktır. *Türk Fiz Tıp Rehab Derg 2012;58:47-51.*

Anahtar Kelimeler: Fizik tedavi, kalibrasyon ölçümleri

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Introduction

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 factor 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).

The purpose of the calibration measurement 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 physical therapy unit, 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 setted value or not, whether the ultrasound treatment on is effective or not, whether the temperature in hot therapy is within the desired range or not.

Therefore, the main base of our study was to perform the calibration measurements of the devices in fully equipped physiotherapy unit including TENS, therapeutic ultrasound, Galvani Farad devices, electrotherapy equipment, diadynami device, traction, shortwave diathermy device, infrared, treadmill, paraffin and hot pack devices by developing the calibration measurement procedures, and to interpret the calibration measurement results.

Material 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 measurement periods are determined by experienced users by considering the device features and the usage conditions.

Calibration measurement period of devices in the physical therapy unit was calculated with the "Device Management Coefficient" which is used in "Clinical Equipment Management" standards in the "Technology & Safety Management" series developed by the Joint Commission (5). The equation of the "Device Management Coefficient" is shown below.

Device Management Coefficient =	**Device**	**Function**	**Point**	**+**
	Device	**Risk**	**Point**	**+**
	Device	**Preventive**	**Maintenance**	**Point**

According to the standards, device management coefficient can be maximum of 20 and the devices with 12 or more coefficients are incorporated into the plans of calibration and preventive maintenance of medical devices (5). In this manner, to determine which devices are taken into the calibration measurement system, each physical therapy device in the scope of our study were separately handled and the points for all devices were calculated. For the calculation of the "device management coefficient" of the physical therapy devices, firstly, all devices' function scores were defined as 8 points because each device is used only for treatment not for operation, diagnosis or intensity care. The risk score for each device was defined as 4 points because patient injury will be resulted if the device is corrupted or malfunctioning. Finally, the score of the equipment preventive maintenance requirements was accepted as 3 points by considering the usage frequency of the devices and the risk of breakdown. With the total 15 points, it has been decided that the calibration measurements of these devices in the physical therapy unit should be done in 12 months. Subsequently, the physical therapy equipments whose measurement periods were specified, have been taken to review in terms of adjustable parameters on them. For each device, the adjustable and measurable parameters were determined, and the calibration measurement procedures have been established. The procedures can be seen in Table 1.

After the calibration measurement procedures were developed, each procedure was applied to one of the every kind of device in the Physical Medicine and Rehabilitation Department of Istanbul Medical Faculty in Istanbul University that was selected as the sample clinic. In there, the performance tests of the devices were performed and the measurement results were evaluated.

For the calibration measurements of the shortwave diathermy and the infrared devices, the plexiglass phantom, whose size is known and filled with water, was used. The output power was calculated by using the technique of heat energy transferring (6,7).

The heat applied by device to the water in calori unit:

$Q(cal) = m.C.\ \Delta T$ [2]

Here, m is the weight of the water in gram, C is the specific heat in Cal/gr °C that is 1 for water and ΔT is the difference between the temperatures in °C.

If the heat is transferred to the energy in joule and the weight of the water is written in the multiplication of the surface area, height and specific weight that is 1 gr/cm^3 for water, the energy formula can be writen as below.

$E\ (Joule)=m\times4,18\times\Delta T=Surface\ Area\times Height\times4,18\times\Delta T$ [3]

Power can be calculated from the energy by dividing the time difference (Δt) in seconds.

$P(Watt)=E / \Delta t$ [4]

Finally, power density (S);

$S=(Surface\ Area\times Height\times4,18\times\Delta T) / (\Delta t\times Surface\ Area)$ [5]

$S=Height\times4,18\times\Delta T/\Delta t$ [6]

is obtained from above equation. Here, the unit of height is centimeter.

Results

In the calibration measurements of the TENS device, the frequency of 61Hz was measured as 60.23 Hz and it was decided that the deviation was within the expected 10% limits (8). The limit was determined from the frequency accuracy value documented in the technical manual of the device (8). It was seen that each frequency value set in each channel on the device was close to the measured frequency values on the oscilloscope. Additionally, the signal accuracy of the current modes has been investigated and it was observed that this TENS device was appropriate to the international standards.

On the therapeutic ultrasound, different power values were set and the measurements were performed for the two different probes. Although it was seen that the first probe gave the more correct values than the second probe, the measurement results obtained from the second probe were also found within calibration limits (9). 3 watts of power values set in the ultrasound device was seen as 3.6 watts in the ultrasound wattmeter, and the power value set to 3.5 watts was seen as 4.4 watts in the ultrasound wattmeter. The result showed that the deviation increased by increasing the power.

The current value set to 100 mA on the Galvani Farad device, was seen as 84.4 mA for F1 faradic current mode and seen as 56.68 mA for F2 faradic current mode and seen as 70 mA for E1 exponential current mode. These values are outside the 10% limits of the device documented in its technical manual and it demonstrated the necessity of care for this device (10). In other side, the current value set in the device as 100 mA were measured in galvanic current and E2 current mode as 92 mA and the measurement result were found to be within the 10% limits of the calibration measurements (10).

For the calibration measurements of the shortwave diathermy device, the phantom filled with water was used to observe temperature increase. From the data obtained from the measurements, the power density was calculated by using the heat energy transfer formula (6). Although the first temperature of water in phantom (3 cm height) was 22 ^{o}C, after the diathermy application of 15 minutes the temperature was measured as 35.8 ^{o}C. By setting out from heat energy transfer formula (6), the power density (S) was calculated as 11.553 watts/ cm^2. According to the knowledge obtained via the manufacturer, the device has 1000 watts of power and when the power is divided by the surface area, the power density is found to be 13.33 watts/cm^2. When the two values that are the production power density of the device and the calculated power density from the measurement results were compared; it was seen that the device is within 20% calibration limits which is expected to be (11). By measuring the temperatures in three different levels, power density calculations were made and the results for each level were compared. The result was the increasing deviation with increasing temperature level.

In diadynami device, all diadinamic currents were measured in each diadynami modes. The adjusted value of 50 mA has been measured as 46.34 mA in galvanic current mode and it was proven that the deviation in the galvanic current mode was within the accepted limit value (12). But, 50 mA current was measured in single-phase fixed current mode as 34.84 mA, in difaze fixed current mode as 36.52 mA, in rhythm syncope current mode as 35.08 mA, in short-circuit current module as 38.42 mA, and in the long-circuit current module as 36.86 mA. From these results, it was observed that the other current modes except galvanic current modes were not within the calibration limits (12). Because of this, the device were sent to the technical service for the repair.

For electrotherapy devices, three different frequency values were set at six channels and these values were obtained correctly at each channel output. The three values set to 30-60-90 Hz were measured at the first channel as 31-59-62 Hz, respectively. These measurements were repeated for each channel and it was noticed that the deviation of the measurement results were appropriate to the international standards (13). Moreover, on the oscilloscope it was seen that the different current modes in the device gave the signals accurately.

For the calibration measurement of the traction device, three different standard masses (5,10,15 kg) were used. When the device was connected to 5, 10 and 15 kg respectively, it was also measured as 5, 10, 15 kg, respectively and it was determined that the traction device supports the desired strength (14). It was observed that the strength values of the device increased gradually.

During the power measurement of the infrared light, a phantom with a height of 3 cm was used. It was seen that the first temperature (19 ^{o}C) increased to 22 ^{o}C after 20 minutes by applying the infrared light to the water in phantom. Afterward, the temperature growth was calculated. According to the temperature increase, the power density was calculated as 1.8837 watt/ cm^2 by using the heat energy transfer formula [6]. Normally, the power of the light is 250 watts. When the power is divided to the surface area, the power density is calculated as 2.033 watt/cm^2. As a result of this measure, the light power was within the calibration measurement limits, as expected.

For the treadmill, the speed was measured by using the tachometer that shows how much distance has been taken in an hour. It has been observed that the device had true values by comparing the data on the tachometer and the km/h values on treadmill. It was determined that the set value of 1 km/h on device was equivalent to 16.66 m/min and by comparing the value that has been measured in the tachometer as 15 m/min, it was seen that the device was suitable to 10% limitation (15). Other speed values of the device were also found to be within the calibration measurement limits (15).

The temperature measuring for paraffin device were taken from three different points which are right point, left point and midpoint. The temperature measurement results were 53.7 ^{o}C at the right point, 54.10 ^{o}C at the left point and 54 ^{o}C at the midpoint. Because the device's temperature value was expected to be 55 ^{o}C, the measured temperature values were found to be in compliance with standards (16).

For hot-pack device, the temperature measurements were taken from five different points. The temperatures at the lower-right, upper-right, lower-left, upper-left point have been measured and the same temperatures were measured as 74 ^{o}C. The value of the midpoint was the warmest point with 74.40 ^{o}C. Because the temperature of the device was expected to be 75 ^{o}C, the calibration measurement results were obtained within the error boundaries (17).

Discussion

Almost in all physical therapy units, commonly used devices are TENS unit, physical therapy ultrasound device, diadynami device, Galvani Farad device, electrotherapy, paraffin machine, hot-pack, treadmill, infrared lamp, short wave diathermy device and traction devices. Considering this fact, our study was focused on these devices.

Calibration measurement procedures have not been developed previously for physical therapy devices. Both calibration measurement procedures and a specific test device have being used for several years for only ultrasound therapy device. However, the rest of the physical therapy devices were not considered in a periodic calibration measurement system.

In physical therapy units, the treatments are usually made by means of electrical currents which could be harmful to the patient. Therefore, to provide an effective and safe treatment on patients, the calibration measurements of devices are very essential. In addition, some burning accidents frequently occur when paraffin and hot-pack device that have high temperature, are used without control. Hence, the calibration measurements of these devices operating under the required standards are very important.

At this point, development of the calibration measurement procedures for physical therapy devices becomes crucial.

By using the proposed calibration measurement prosedures, the reliability of therapy devices can be determined which could not be done earlier extensively.

As a result of the measurements, it was observed that some devices in the physical therapy unit operate in accordance with the international standards and these devices are relatively new products. It was concluded that the devices which are not within the calibration limits are usually old devices that have intensively been used for many years.

By using the prepared calibration measurement procedures developed in this study, the devices in these units can be tested and can be checked for compliance to the standards.

As a result, the recommended calibration procedures in this study can help to determine the reliability and the accuracy of the physical therapy devices.

Table 1. The calibration measurement procedures for physical therapy devices.

Device	Measured Parameter	Used Test Device	Explanation
TENS	Frequency Current Modes Time	Oscilloscope (GW Instek) Oscilloscope (GW Instek) Chronometer (Oregon Scientific)	For each channel, all current modes (Burst, continuous, modulated current modes..) must be observed. The frequency and time should be measured.
Physical Therapy Ultrasound Device	Power Time	Ultrasound Wattmeter (Fluke UV-5) Chronometer (Oregon Scientific)	For each probe, output power must be measured. Timer should be controlled.
Galvani Farad Device	Current Time	Multimeter (Fluke 179 True SMS) Chronometer (Oregon Scientific)	Galvanic, discrete galvanic, exponential and faradic current must be measured. Timer should be controlled.
Short Wave Diathermy Device	Output Power	Phantom Temperaure Probe (Fluke DPM4)	The increase of water temperature in phantom should be measured and the output power should be obtained from the heat transfer formula.
Diadinami Device	Current Time	Multimeter (Fluke 179 True SMS) Oscilloscope (GW Instek) Chronometer (Oregon Scientific)	Current value should be measured with multimeter and the accuracy of the current modes should be checked with oscilloscope. Timer should be verified with oscilloscope.
Electrotherapy Device	Current Modes Frequency Time	Oscilloscope (GW Instek) Oscilloscope (GW Instek) Chronometer (Oregon Scientific)	By using oscilloscope, the accuracy of the current modes should be checked, frequency must be measured. Timer should be verified by chronometer.
Traction	Force	Standard Mass (Acuweigh Corporation)	Device should be tested by using calibrated standard mass. Intermittent traction must be observed to work correctly.
Infrared Lamp	Power	Phantom Temperature Probe (Fluke DPM4)	By using the phantom with water that is placed under the lamp, the increase of water temperature should be measured and the output power should be calculated from the heat energy transfer formula.
Treadmill	Speed	Tachometer (Lutron DT 2268)	Rate of speed of each level should be measured.
Paraffin Device	Temperature	Temperature Probe (Fluke DPM4)	Temperature measurements should be taken from three different points as left, right and central point.
Hot-pack Device	Temperature	Temperature Probe (Fluke DPM4)	Measurements should be taken from right bottom, right upper, left bottom, left upper and midpoint.

Conclusion

In this study, calibration measurement procedures have been developed for widely used medical devices in a physical therapy unit, such as TENS unit, physical therapy ultrasound device, diadynami device, Galvani Farad device, electrotherapy, paraffin machine, hot-pack, treadmill, infrared lamp, shortwave diathermy device and traction device. The visible and adjustable parameters on these medical devices were determined, and according to these parameters the necessary measurement instruments and test systems have been designed. Moreover, according to the established calibration meaurement procedures, the measurements were carried out on 11 devices in the Physical Medicine and Rehabilitation Department of Istanbul Medical Faculty in Istanbul University.

Experimental studies show that most of the devices are compatible with the international standards.

Conflict of Interest:

Authors reported no conflicts of interest.

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