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SpO_2 Cihazlarında Ölçüm Bandına Göre Lineer Regresyon ile Tolerans Değeri Önerilmesi

Özge ÜSTÜNER[1*], Cafer BUDAK[2]

[1,2]Elektrik-Elektronik Mühendisliği, Fen Bilimleri Enstitüsü, Dicle Üniversitesi, Diyarbakır, Türkiye.
[1]ozgeustuner96@gmail.com, [2]cafer.budak@dicle.edu.tr

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Öz

Kandaki oksijen değerinin izlenebilmesi,bronşit, zatürre, KOAH gibi çeşitli solunum yolu hastalıklarının ve COVID-19 hastaları da dahil olmak üzere kritik bakım hastalarının takibi için hayati önem taşımaktadır. SpO_2 cihazları, parmak ya da kulak memesi dokusundan alınan ölçümlerle kandaki oksijen yüzdesini hesaplayan tıbbi cihazlardır. Yapılan saha çalışmalarında edinilen izlenimler; cihaz kullanıcılarının, düşük oksijen satürasyonuna sahip hastalardan alınan ölçümlerde yüksek sapma görüldüğünü ve SpO_2 cihazı ölçümlerinin kusurlu olduğu izleniminde olduklarını sıklıkla belirtmeleri göz önünde bulundurularak, ölçümlerin doğru yorumlanabilmesi için bu çalışma gerçekleştirilmiştir. Bu çalışmada SpO_2 cihazlarının farklı ölçüm bantlarındaki % SpO_2 oranları makine öğrenmesinde lineer regresyon algoritması ile yorumlanarak kalite sınıflandırması yapılmış ve kullanıcılara her ölçüm bandı için tolerans değerleri ve göz önünde bulundurulması gereken sapma değerleri önerilmiştir. Ayrıca lineer regresyon yöntemi ile daha az veri kullanılarak sonuç tahimini ile kullanıcıya ve test uzmanına zaman kazandırarak daha çok cihazın izlenmesi ve cihazların daha sık test edilebilmesi hedeflenmiştir. Tahmin sonuçlarının gerçek değere çok yakın sonuçlar verdiği gözlemlenmiş ve bu çalışmanın testin sahada daha sık uygulanabilmesine ve hızlı yorumlanabilmesine katkı sağlayacağı öngörülmüştür. Çalışmada 80601-2-61 sayılı Avrupa standardının 201.12.1.101 sayılı maddesinde önerilen yöntem kullanılarak farklı üç marka pulse oksimetre cihazından; Contec marka MS100 model simülatör kullanılarak %70-79 SpO_2,%80-89 SpO_2,%90-100 SpO_2 olmak üzere üç ölçüm bandında ölçümler alınmıştır. Her ölçüm için lineer regresyon ile A_{rms} eğrisi grafiği oluşturulmuş, ortalama hata değerlerinin karesi (MSE) ve Arms değerleri hesaplanarak iki değer arasındaki ilişkinin yorumlanmasıyla cihazların değerlendirilmesi gerçekleştirilmiştir. Sonuç olarak düşük oksijen satürasyonu seviyelerinde sapma oranının arttığı gözlemlenmiş ve her ölçüm bandı ve farklı kalitede cihazlar için göz önünde bulundurulması gereken %spo2 sapma değeri önerilmiştir.

Anahtar kelimeler: SpO_2, Pulse oksimetre, Oksijen satürasyonu, A_{rms}, Lineer regresyon

*Yazışılan yazar

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Şikayet: fujece@firat.edu.tr

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Recommending Tolerance Value for SpO_2 Devices with Linear Regression Based on Measuring Tape

Özge ÜSTÜNER[1*], Cafer BUDAK[2]

[1,2]Electrical and Electronics Engineering, Institute of Science and Technology, Dicle University, Diyarbakır, Turkey.
[1]ozgeustuner96@gmail.com, [2]cafer.budak@dicle.edu.tr

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Abstract

Monitoring blood oxygen levels is vital for tracking various respiratory diseases like bronchitis, pneumonia, COPD, and critical care patients, including those with COVID-19. SpO_2 devices, calculating oxygen percentage via finger or earlobe tissue, play a crucial role. Field studies have revealed concerns regarding the accuracy of SpO_2 measurements due to high deviations, particularly in patients with low oxygen saturation, prompting the initiation of this study to ensure accurate interpretation of the device's measurements. Using a linear regression algorithm, SpO_2 values from different bands were classified for quality. Tolerance values and deviation thresholds for each band were recommended. Additionally, linear regression aimed to save time by making result estimations with less data, facilitating more device monitoring and frequent testing. Results closely matched actual values, suggesting contributions to more frequent application and rapid interpretation. Following the European standard 80601-2-61, measurements were taken from three pulse oximeter brands (Contec MS100 model simulator) in three bands: 70-79%, 80-89%, and 90-100% SpO_2. For each measurement, an Arms curve graph was generated using linear regression, and the mean square error (MSE) and A_{rms} values were calculated to evaluate devices. In conclusion, deviation rates increase at low oxygen saturation levels, and recommended % SpO_2 deviation values were proposed for each band and device quality.

Keywords: SpO_2, Pulse oximetry, Oxygen saturation, A_{rms}, Linear regression

*Corresponding author

1. Introduction

Oxygen saturation is an important measure for understanding the working capacity of the lung and for early detection of oxygen deficiency.The lungs first transfer oxygen to the capillaries, the oxygen mixed into the blood is sent to the heart and from the heart it is distributed to all organs that are supplied with oxygen. Since disruption in this cycle affects organs and therefore vital functions, monitoring oxygen saturation is extremely important. In a healthy person, oxygen saturation is between 95% and 100%. a drop in oxygen levels causes hypoxemia. Oxygen levels below 90% are considered low, and when they fall below 80%, they indicate severe hypoxemia, i.e. respiratory failure. Oxygen saturation is monitored during the diagnosis and treatment of many respiratory and chest diseases such as respiratory failure, pneumonia, bronchitis, covid-19, pneumothorax, smoking-related chest diseases [6-8, 19, 20, 29]. Pulse oximetry devices, which have started to be used for instant monitoring of oxygen saturation and pulse rate in surgical interventions, have been used for the last decade in monitoring the treatment processes of respiratory diseases, general condition monitoring of intensive care patients, and monitoring of patients treated in emergency and general wards [1, 3, 22, 23, 24, 27]. Due to the Covid-19 outbreak, the use of pulse oximetry devices has become widespread since the World Health Organization declared a pandemic in March 2020. Pulse oximetry devices are devices that examine oxygen saturation by recording the absorption rate of 600nm red light and 940nm infrared light by hemoglobin in the blood [10, 28]. The use of a non-invasive (non-surgical) measurement method and its low cost have made pulse oximetry devices easily accessible to users and easily usable for home care [19, 20]. However, despite the ease of use, clinical competence and knowledge of the technical features of the device are required for correct interpretation of the measurement results [2].

In Thomas Paul Walters' study of the impact of pulse oximeters in clinical practice, he conducted a literature review between 1980 and 2006 and found that nurses and physicians lacked the necessary level of knowledge about using pulse oximeters. Walters assessed the adequacy of the information obtained by speed reading and suggested that future research should be conducted to evaluate this information for clinical competence [3].In a similar study, Malcom Elliott et al. reported that nurses, physicians and allied health personnel who frequently use the device have significant knowledge gaps and, worryingly, there are senior and experienced clinicians among them [4]. Bader conducted a questionnaire study with 50 participants, including nurses, physician assistants and respiratory therapists, and as a result of the analysis, the participants stated that there was a lack of knowledge in general principles, and as a result of the study, he stated that healthcare professionals need training on the basic working principles of pulse oximetry [26]. Kiekkas et al. observed that intensive care nurses had more correct answers compared to emergency nurses in their survey study with 207 participants and associated pulse oximetry device knowledge with longer experience and being an intensive care worker [23]. Jamieson et al. applied a questionnaire to healthcare personnel working in the neonatal service and stated that the participants had a significant lack of knowledge about the use of pulse oximetry and therefore, there was a need for continuous training on pulse oximetry devices [5]. Since the oxygen saturation value will affect the planning of the treatment process, it is very important to interpret it correctly. In case of low oxygen level, drug therapy, oxygen therapy, ventilation and mechanical ventilation methods may need to be applied depending on the patient's condition in order to provide the required oxygen level to the blood. For this reason, health personnel should not be in conflict with the oxygen saturation value during the diagnosis and treatment process [12].

In 2022, at a medical conference in Canada, M. Blanchet and colleagues shared the results of their research on 6 different brands of SpO_2 devices, but the results only contain summary information and are based on measurements taken from patients. In 2023, Giuliano et al. examined SpO_2 results in 28 healthy adult volunteers with 3 different brands of spo2 devices under motion dysfunction and low perfusion. The fact that the results were not obtained with a reference device of known accuracy and were not obtained according to an international standard reduces the reliability rate [9, 17].

In order to evaluate the accuracy and effectiveness of pulse oximetry devices, the use of which has become more frequent with the Covid-19 pandemic; "Anesthesiology and Respiratory Therapy Devices Panel Medical Devices Advisory Board Meeting" was held on November 1, 2022 by the Food and Drug Administration (FDA) of the United States Ministry of Health. As a result of the panel, where experts in the

field took part and gave opinions and suggestions; FDA recommended to comply with the standard ISO 80601-2-61:2017 for the evaluation of the effectiveness of pulse oximetry devices [15, 16, 18].

Since the application of the tests included in the European Standard recommended by the FDA is not possible to be performed by healthcare personnel in the field due to the lack of technical competence and equipment required for the test, in this study, the % SpO_2 ratios of oxygen saturation measurement devices in the 70-79% SpO_2, 80-89% SpO_2, 90-100% SpO_2 measurement bands were examined and the deviation values to be considered for each measurement band were suggested to the device users. It is aimed to eliminate the uncertainties caused by user interpretation by predicting the results with linear regression. In the experimental phase of the study, Contec brand, MS100 model simulator device, which can perform SpO_2 and pulse rate simulation, was used in accordance with the test applications specified in the standard. Measurements were taken from three different brands of pulse oximeters that are widely used, these measurements were recorded and a measurement graph was created for each measurement by the method specified in the standard, and Arms and MSE values were recorded by applying linear regression algorithm to the measurements. As a result, in addition to the known factors such as dark skin and skin pigmentation, dark nail polish and artificial nails, probe placement, signal quality, medical residues such as blood etc. remaining on the sensor, the effect of the range of measurement results and the differences that may arise from sensor quality on the measurement accuracy was emphasized.

2. Materials and Methods

The basic physical property of the pulse oximeter is based on the Beer-Lambert law. According to Beer-Lambert's law, light passing through a solution is logarithmically inversely proportional to the path of light through the solution and the concentration of the solution, and directly proportional to the amount of light absorbed. For the two wavelengths of light of the pulse oximeter, red and near infrared light, the absorption rates of oxygenated hemoglobin and non-oxygenated hemoglobin are different. In general, pulse oximetry devices consist of an LED diode emitting light at two different wavelengths and a light detector (sensor) that senses the light in the opposite direction. Oxygen saturation is measured through a translucent region of the human body placed between the led light region and the sensor region [19, 20, 10].

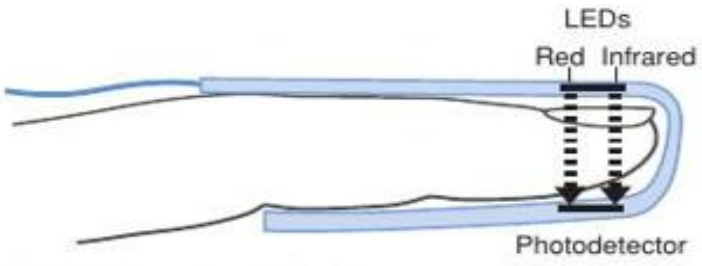

Figure 1. Finger-type pulse oximetry sensor [10]

One of the two LED diodes on the pulse oximeter device has red light at 660 nm wavelength and the other has infrared light at 940 nm wavelength. The absorption rates of these two different wavelengths of light by oxyhemoglobin (oxygenated hemoglobin) and deoxyhemoglobin (deoxygenated hemoglobin) are very different. The ratio of the difference in absorption between oxyhemoglobin and deoxyhemoglobin is calculated and compared with direct measurement of arterial oxygen to estimate peripheral oxygen saturation [19, 10].

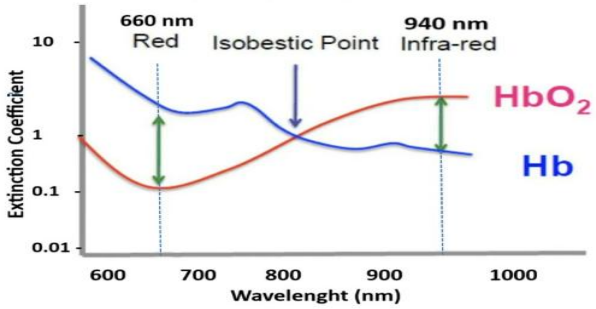

Figure 2. Hemoglobin light spectroscopy curve. (Black curve represents oxyhemoglobin, blue curve represents deoxyhemoglobin. The two vertical sections mark the wavelength points used in LEDs.) [10]

To apply the measurement accuracy test recommended in clause 201.12.1.101 of the European standard 80601-2-61 to the pulse oximetry device, a Contec, MS100 model SpO_2-pulse simulator with a SpO_2 range of 35-100% and a SpO_2 resolution of 1% was used.

Figure 3. Experiment-measurement setup

With the simulator device, which has four different light interference options: daylight, 50 Hz interference light, 60 Hz interference light and normal light source and has an amplitude setting in the range of 0.000-20.000%, measurements were made in the range of 70-100% SpO_2 with normal light source interference and 3.000% automatic amplitude setting [13].

With the test setup shown in Figure 3, the " SpO_2 accuracy test" in clause 201.12.1.101 of the ISO 80601-2-61:2017 standard recommended by the FDA was applied to three different brands of commonly used pulse oximetry devices. For the test setup described in the standard, the measurement points should consist of 31 measurement points ranging from 70% SpO_2 to 100% SpO_2 in 1% SpO_2 steps. At each measurement point set on the simulator device, the actual measurement results from the pulse oximeter device should be recorded and the deviation between the value set on the simulator (reference) device and the measurement value from the tested (pulse oximeter) device should be calculated and recorded. Arms values were calculated using the recorded deviation values and the accuracy value calculation equation [18].

$$Arms = \sqrt{\frac{\sum_{i=1}^{n}(SpO2i - SRi)^2}{n}} \quad (1)$$

The A_{rms} (accuracy.root-mean-square difference) value calculated for the equation given in CC.2.5 of the standard should be $\leq 4\%$ SpO_2 and the measurement results should form a linear curve as stated in CC.2.2 of

the standard under the heading 'effects of offset linearity errors'.[18] Considering the requirement that the measurement results should form a linear curve according to the standard, it is observed that the measurement results are suitable for the evaluation of the machine learning to be estimated with the linear regression algorithm application.

Linear regression is one of the machine learning algorithm methods that predicts the dependent variable by modeling the relationship between a dependent variable and an independent variable.[11] In the model, the set values in the measurements represent the independent variable and the actual measurement values represent the dependent variable to be predicted.

An example of the measurement records is given in figure 4 and examples of the obtained measurement results and linear curve graphs for 3 different devices of high, medium and low quality are given in figure 6, figure 7 and figure 8 under the heading "Experimental Results".

3. Experimental Results

Table 1. Example of measurement record

	First Measuring Band %70-79										Second Measuring Band%80-89										Third Measuring Band %90-100										
SET value (simulator device)	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
measurement value (pulse oximeter)	64	65	66	68	69	70	71	73	73	75	76	77	79	79	81	81	83	84	85	87	87	89	90	92	93	94	96	97	98	99	100
Deviation value	-6	-6	-6	-5	-5	-5	-5	-4	-5	-4	-4	-4	-3	-4	-3	-4	-3	-3	-3	-2	-3	-2	-2	-1	-1	-1	0	0	0	0	0

Table 1 shows a sample record of the measurements taken in the SpO_2 accuracy test application. By calculating the deviation values for each measurement value, the accuracy value expressed in the Arms equation was calculated and it was seen that the Arms value was 3.58 SpO_2 for the measurement values given in Table 1. It is seen that the Arms value obtained meets the ≤4% SpO_2 requirement for SpO_2 accuracy. When the accuracy curve of the measurement records is examined, it is seen that the linear curve condition required in the standard is also met. The graph of the Spo2 accuracy curve of the measurements in Table 1 is given in Figure 4.

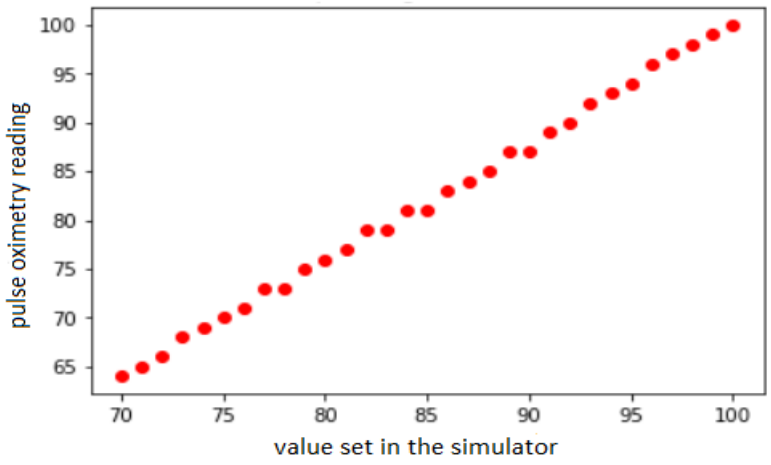

Figure 4. Linear curve plot of measurement data

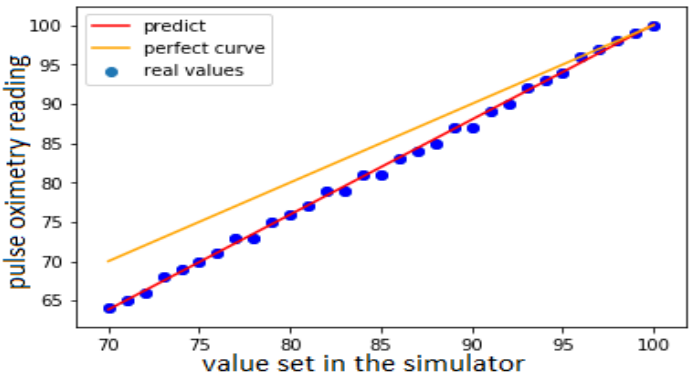

Figure 5. Example graph from a low quality device

A comparison of the curve of the predictions obtained by linear regression, the actual measurement values and the perfect curve in the absence of drift for the low quality device, for which the measurement record example is given in table 1, is given in Figure 5.

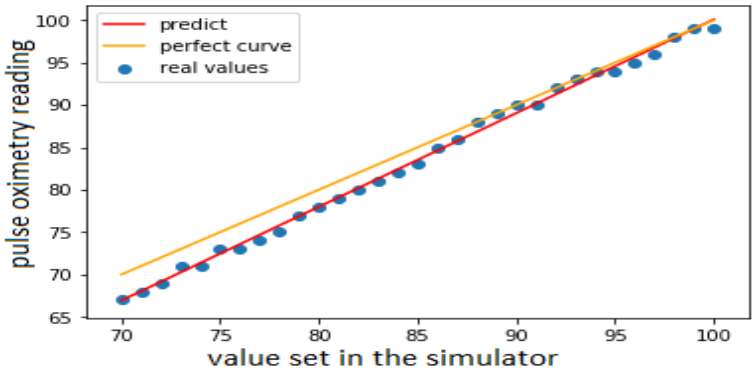

Figure 6. Example graph from a medium quality device

A comparison of the curve of predictions obtained by linear regression for a measurement from a medium quality device, the actual measurement values and the perfect curve in the absence of drift is given in Figure 6.

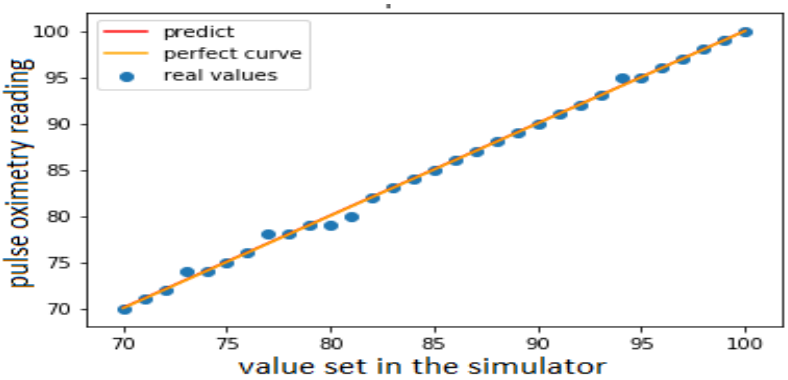

Figure 7. Example graph from a high quality device

A comparison of the curve of predictions obtained by linear regression for a measurement from a high quality instrument, the actual measurement values and the perfect curve in the absence of drift is given in Figure 7.

Table 2. Example of measurement record

	Low Quality Device (standard measurement)	Medium Quality Device (standard measurement)	High Quality Device (standard measurement)	Low Quality Device (10 Point measurement)
MSE Value	0,567	0,224	0,160	0,218
Arms Value	3,583	1,849	0,402	3,580

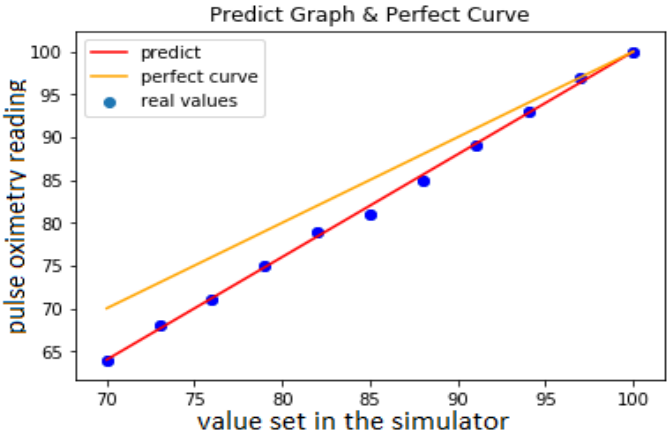

Figure 8. Prediction curve obtained with measurements from only 10 points

For the measurement results given in Table 1 (measurement from low quality device), only 10 measurement points were measured and the measurement results and prediction curve in Figure 8 were obtained. The comparison of the MSE values obtained for the 10 measurement points shown in Figure 8 with the MSE values obtained with the standard measurement is given in Table 2.

4. Results

When the measurement results were evaluated over different measurement bands in the measurements taken from three different brands of commonly used devices, it was observed that the deviation values in the lowest measurement band (70-79% SpO_2) found ~ 6% SpO_2 values, while the deviation values in the middle level measurement band (80-89% SpO_2) found ~ 4% SpO_2 values. In the measurement band with high oxygen saturation levels (90-100% SpO_2), it was observed to be less than 2% SpO_2. These results are the maximum values that can be tolerated in devices that comply with the standard observed in low quality devices with maximum deviation values.

It was observed that each device may show different deviation values depending on the sensor quality of the device and linear regression method was applied to predict the device measurement results in order to predict this by the user and to interpret the results correctly. In this study, by estimating the sensitivity of the device according to the MSE value calculated in the measurement results, the results that can be distributed according to the order of importance within the hospital, reduce the user's margin of error by estimating the deviation values of the devices and help the user to make healthier evaluations have been tracked. Although the sensitivities of different brands of devices make a difference in the measurements, the user will be able to make a healthier evaluation by considering the response of the devices under different measurement conditions by getting to know the devices more closely with the evaluation of the measurement results. When devices are classified according to sensor quality and MSE ratios are taken into account, it is predicted that the possibility of misdiagnosis of the monitored patient, such as severe hypoxemia instead of low saturation caused by the device, will be greatly reduced. Apart from the differences between the devices, the user will be able to make a healthier evaluation process by monitoring the points where the deviation from the actual

value increases with the change in the measurement values (change in the measurement bands) in the same device.

When the prediction values made with the measurement results taken from only 10 points for the same device are compared with the actual measurement values, it is observed that the predictions made with the linear regression method give very close values with fewer measurements. This study will provide an advantage in terms of monitoring more devices and testing devices more frequently by saving time for the user or tester while measuring the devices used in the field.

5. Discussion

A literature review of the studies conducted between 2006 and 2023 on the use of pulse oximetry device and its effects on diagnosis and treatment shows that healthcare professionals do not have sufficient knowledge about the use of pulse oximetry device, while the FDA has directed users to the ISO 80601-2-61 standard, which covers certain features for the required performance and basic safety of the pulse oximetry device in order to know the accuracy of the pulse oximetry device. The studies conducted do not provide efficient results for informing healthcare personnel working in the field and using the pulse oximetry device effectively. Observations made during field studies also revealed that health personnel were unable to correctly interpret the measurement differences between different brands of devices, and that there was a need for training on the use of devices and interpretation of results.

With the development of technology and the spread of epidemics, the usage area and need for SpO_2 devices are increasing and the variety of different brands is increasing in this direction. It is very important to check the accuracy of the devices used in the sector in certain periods and to inform the users regularly according to the classification and tolerances proposed in this study. Informing the health personnel in the field about the effects of the result of this test, which can be applied by an expert with the necessary equipment during the periodic maintenance-measurement of pulse oximetry devices, on the measurement performance of the device will increase the effective use of the pulse oximetry device. In this study, the accuracy test of the pulse oximeter device of the European Standard ISO 80601-2-61 was applied with the necessary equipment and in line with the experimental results, the deviation values that the device users can tolerate in different measurement bands while analyzing the measurement data were suggested and the applicability of the test was increased by making predictions close to the actual values with less data.

6. Author Contribution Statement

In the study, Author 1 contributed to forming the idea, making the design ,literature review, analysis of the results, provision of the materials and examination of the results; Author 2 contributed to checking the spelling and checking the article in terms of content.

7. Ethics Committee Approval and Conflict of Interest

There is no need for an ethics committee approval in the prepared article

8. References

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