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PAPER

A Design and Construction of the Vibration Perception Threshold Measurement Device for Diabetes

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ABSTRACT

The purpose of this study was to design and build a mechanical vibration assessment tool for diabetic patients' peripheral nervous systems. There is a substantial correlation between peripheral sensory neuropathy and vibration perception threshold (VPT). Peripheral sensory neuropathy has been identified by VPT determination utilizing the VPT measurement instrument built for that purpose. The designed device can assist in determining the threshold and tracking any progressive changes or trends. This designed device consists of two main components: hardware and software. The hardware part includes a DC power supply circuit, an Arduino NANO, a display, an isolation MOSFET driver for the electrical isolation circuit, a transducer driver, and a transducer head. The software part uses C programming on the Arduino to generate signals and display the transducer supply voltage. The testing results consist of 1) the voltage settings results (5–30 volts) comparing the voltage values on the display between the designed device and a digital multimeter, which has an average error of 0.75%, 2) According to the transducer head pressing test results, the Vibrotest Digital Biothesiometer and the proposed device had different pressing weights of ±0.02 g, and 3) the electrical safety testing results of the designed device is in the standard of IEC60601-1. (IEC: International Electrotechnical Commission).

KEYWORDS

vibration perception threshold measurement device, diabetes, peripheral sensory neuropathy

1 INTRODUCTION

The most prevalent metabolic illness in the world is diabetes. IDF and WHO reported rising incidence globally, particularly in developing countries [1]. Nerve disease, also known as neuropathy, is a common complication of diabetes that significantly impacts the quality of life and disability of affected patients [2], [3]. A diabetes management and supporting clinical treatment application were developed [4], [5]. Diabetic neuropathy is marked by significant morbidity and pain, as well as a loss of sensory function that starts distantly in the lower limbs. Diabetic neuropathy affects at least 50% of people with diabetes throughout time [6]. The severities of

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diabetic peripheral neuropathy (DPN) and diabetic retinopathy (DR) are significantly correlated [7], [8], [9]. DPN can occasionally lead to other health issues such as blood circulation issues, cardiac rhythm abnormalities, and foot ulcers [10].

One of the most frequent side effects of individuals with poorly managed diabetes mellitus is diabetic foot ulcers [11], [12], therefore treating and diagnosing DPN at an early stage is vital. Screening for DPN is an important aspect of diabetes care. Early detection allows for timely intervention to prevent complications. DPN screening typically involves clinical assessments, patient history, and various neurological tests [13]. The impact of diabetic peripheral neuropathy and foot ulcers on a patient's quality of life is measured by a questionnaire developed by Vileikyte et al. [3]. The instrument's psychometric qualities are evaluated in a sample of patients with different degrees of the disease's severity and symptomatology.

To increase the accuracy of DPN detection, many straightforward neurological tests have been reported to be utilized for screening [14], [15]. Some of these tests have also been integrated into composite scoring systems [3]. The assessments of large-fiber function, including tendon reflex, pressure/touch sensation, vibratory sensation, and protective feeling, are the focus of these tests [16]. Practically, there are popular techniques for identifying and assessing DPN, including the Semmes-Weinstein monofilament test (SWMT), tendon reflex testing, tuning fork, vibration perception, and others [16]. To increase the rate and precision of DPN identification, these techniques should be paired with certain nerve function scoring systems [17].

Monofilament testing is a portable, low-cost, and user-friendly test for determining the loss of protective feeling. Use monofilament, a thin, flexible filament, to evaluate a person's capacity to feel touch at particular locations on the foot. When questioned if they can feel the touch, the patient reports [18]. The diagnostic accuracy of monofilament tests for the detection of diabetic peripheral neuropathy was reviewed and meta-analyzed by Wang F. et al. [19]. Based on the data available at the time of the study, the 5.07/10 g Semmes-Weinstein monofilament appeared to be a screen with limited sensitivity for DPN in primary care settings.

The C 128-Hz tuning fork has been utilized to evaluate peripheral neuropathy; typically, this involves comparing the patient's vibration detection time to that of the examiner. The examiner's perception of vibration is reduced if they experience it for a longer period than the patient [13], [20].

Many VPT measurements measure the patient's ability to perceive vibrations like Biothesiometer and Neurothesiometer [21]. Elevated VPT indicates reduced sensitivity to vibration, which can be a sign of neuropathy.

Literally, the Biothesiometer is a diagnostic instrument for a variety of neurological conditions. It's an "electrical tuning fork" whose amplitude can be adjusted to any desired level or raised gradually until the vibratory feeling threshold is achieved [22]. On the other hand, the amplitude can be decreased until the vibration is not noticeable. Under all circumstances, the amplitude may be precisely determined at any level. VPT is measured by the new Neurothesiometer, intended to replace the Biothesiometer in the screening process for diabetic peripheral neuropathy. When used in normal clinical settings, the Neurothesiometer produces results that closely match those of the Biothesiometer and has a good coefficient of variance. This self-contained, battery-powered gadget is more costly than its predecessor, but it is still a valuable tool for diabetes screening programs and community epidemiological surveys [21].

VPT testing is indeed commonly used as a part of screening for DPN. The purpose of this testing is for early detection, monitoring progression, and assessment of intervention efficacy [23]. VPT is a valuable tool, a diagnosis of diabetic peripheral neuropathy is typically made based on a combination of clinical signs, symptoms, and various neurological tests. Healthcare professionals, especially those specialized

in diabetes care and neurology, can provide more specific guidance on the interpretation of VPT results and the overall assessment of diabetic peripheral neuropathy.

There are many kinds of research comparing vibration sensation among each tool. Tuning fork (128 Hz) versus Neurothesiometer were compared in assessing vibration sensation in patients with diabetes mellitus [13]. Ahsan H. et al. made a study comparing the efficacies of neurological physical examination, Neurothesiometer, and PainDETECT questionnaire in detecting diabetic neuropathy in patients [24] and showed that Neurothesiometer is a better diagnostic tool for diabetic neuropathy in patients. VPT measurements have been shown in the literature to be a useful tool for quickly and reliably identifying patients with diabetes who are at risk, including those who have early neuropathic impairments [25]. The study of Dash et al. aimed to determine whether VPT testing might be used as a preliminary diagnostic technique in diabetic neuropathy and discovered that VPT testing ought to be performed on all diabetic patients, regardless of whether they exhibit clinical neuropathy symptoms. Identifying the at-risk group for diabetic peripheral neuropathy using VPT detection will be beneficial. It's also a reasonably priced process [26].

A proprietary smart point-of-care testing (POCT) system [27] for the diagnosis and grading of peripheral neuropathy at the patient's home or care center is intended to detect changes or worsening of a patient's neuropathy. Their technique detects sensation decrease in vibration sensitivity threshold (VST) by using the vibration motor within a smartphone, which is administered via a 3D printed probe attachment. A smartphone app presents the user with various neuropathy questionnaires to identify and monitor changes in their condition. They compare their smart device and the gold standard Neurothesiometer and indicate that POCT performs similarly in terms of vibration frequency and amplitude.

To assess diabetic neuropathy, it is critical to have a method that can indicate risk. Thus, the goal of this research is to construct a device whose oscillation amplitude is dependent on the applied voltage. The cost of this technology is suitable for usage in local health promotion hospitals.

2 MATERIALS AND METHODS

2.1 Medical concepts

This paper is composed of two concepts: 1) the electrical circuit of the machine generates a high potential pulse signal (0–30 V) with a frequency of 100 Hz and transmits it to the transducer head and 2) the transducer head converts electrical energy into mechanical energy, also known as vibrations, transmitted through the soles of the feet with diabetes. Each concept will be described as shown in Figure 1.

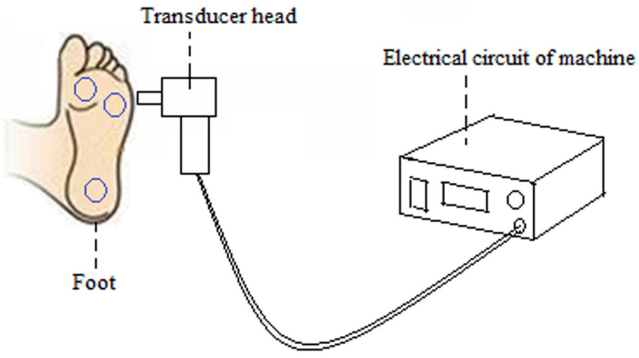

Fig. 1. Device appearance and medical applications

2.2 Hardware and software designs

The block diagram of the designed device for VPT measurement with diabetes is shown in Figure 2. It consists of two main parts: the electrical circuit of the machine and the transducer head.

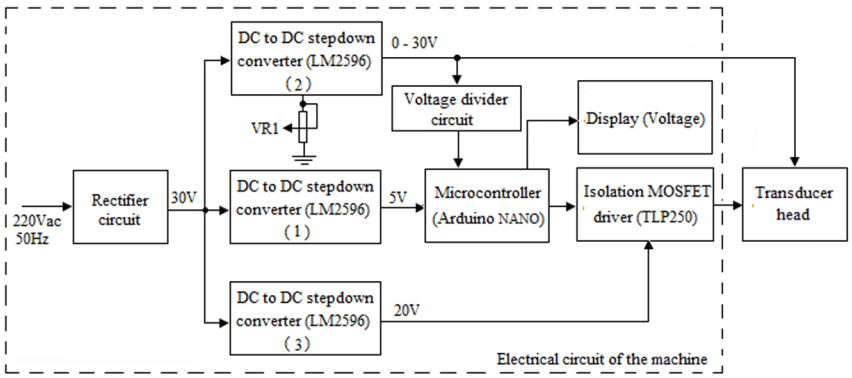

Fig. 2. Block diagram of the prototype

1) The electrical circuit of the machine consisted of 5 parts: DC power supply circuit, microcontroller, voltage divider circuit, isolated MOSFET driver, and display can be explained as follows:

1.1 DC power supply circuit, shown in Figure 3, converts 220ac/50Hz alternating current to direct current and supplies it to Arduino, Isolated MOSFET driver, and transducer head, respectively.

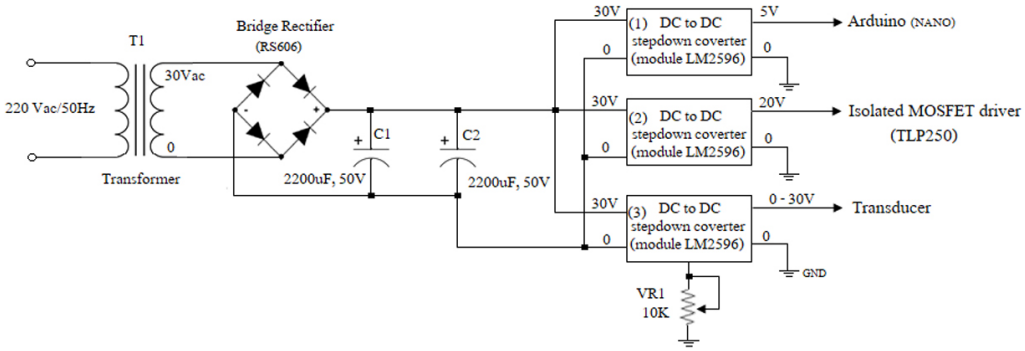

Fig. 3. DC power supply circuit

From Figure 3, the design used a transformer (T1) to reduce the voltage from 220Vac/50Hz to 30 Vac/50Hz, 2 A. The bridge rectifier (RS606) was used to change the alternating current 30 Vac/50Hz to DC electricity. Capacitors C1 and C2 (2200uF, 50 V) serve to store electrical charge, making this power supply into DC electricity smoother. After that, pass it to the 3 parts of the DC to DC Stepdown Converter (LM2596), which serves to reduce the DC voltage from 30 V to 5 V, and is supplied to Arduino, 20 V is supplied to the Isolated MOSFET driver (TLP250) and range 0–30 V was supplied to the transducer head, respectively.

1.2 Microcontroller part, we used Arduino written with C language to generate a pulse signal with a frequency of 100 Hz and send it to the output port (D3), after which it is fed to the Isolated MOSFET driver (TLP250), and the resistance (VR2) used to adjust the duty cycle of the pulse signal to 50% as shown in Figure 4.

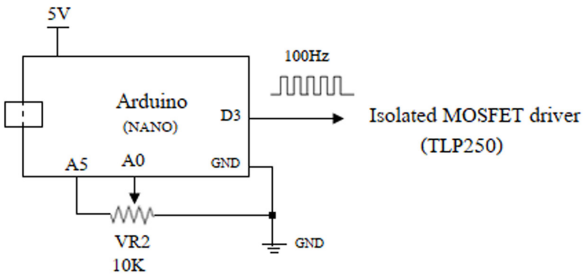

Fig. 4. The microcontroller was used as a pulse signal generator with a frequency of 100 Hz

1.3 Isolated MOSFET driver is used to separate the power supplies from each other. The objective is to isolate different high and low voltage levels from the same power supply for hazard prevention to the electronic devices during operation faults in the electrical circuit that uses a higher voltage. We use a TLP250 (Isolated MOSFET driver) to separate the Arduino, which uses 5 V electricity to work, and the transducer head, which uses electricity in the range of 0–30 V to prevent Arduino from being damaged by the operation of the transducer head.

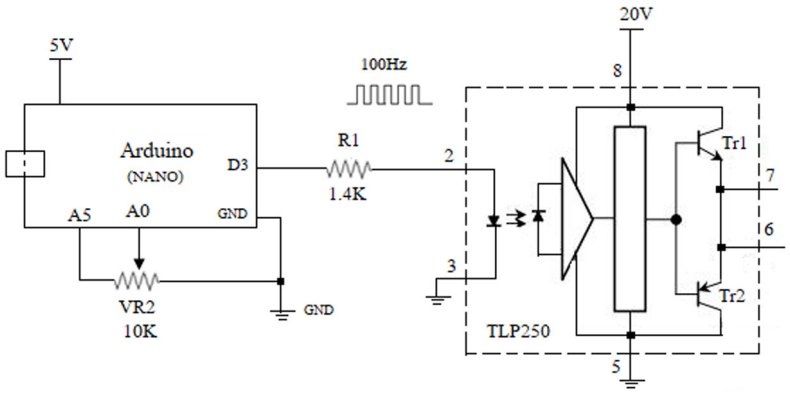

Fig. 5. Connecting Arduino (NANO) to TLP250

The Arduino serves as a signal generator of 100 Hz and is supplied to pin 2 of the TLP250 as shown in Figure 5. In the design, the value of R1 was calculated, which determines the bias point in the operation of the TLP250 as follows. From the datasheet of the TLP250, the maximum bias current or maximum forward current (I_{Fmax}) was set to be 5 mA. In the design, we chose 3 mA. The R1 value can be calculated from Equation 1.

$$R1 = \frac{V_{CC} - V_F}{I_F} \tag{1}$$

Given $I_F = 3$ mA.
$V_{CC} = 5$ V (pulse signal voltage)
$V_F = 0.8$ V (voltage drop across the LED bulb insideTLP250)
Substitute the values in Equation 1

$$R1 = \frac{5\ V - 0.8\ V}{3 \times 10^{-3}\ A} \tag{2}$$

$$R1 = 1.4\ K\Omega \tag{3}$$

Transducer head drive circuit is shown in Figure 6. This circuit design used TLP250 and IRF3415 to drive the transducer head, therefore, the determination of the bias point in the operation of both devices was as follows.

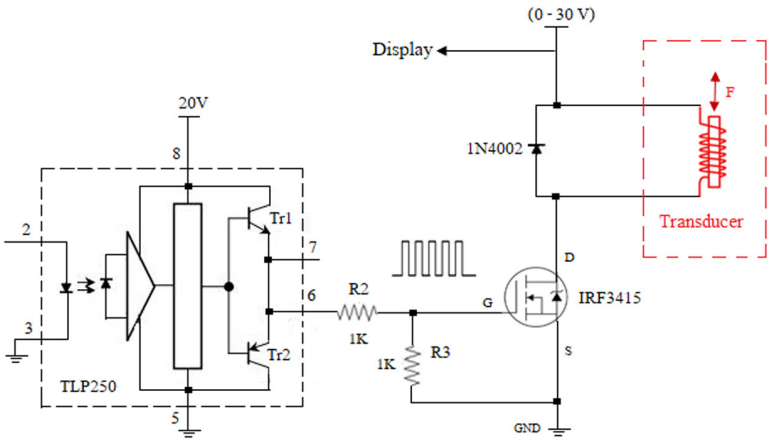

Fig. 6. Transducer head drive circuit

From the datasheet of TLP250, the maximum voltage at terminal 6 of TLP250 is set to be 20 V(max) and Imax is 10 mA. In the design, the bias point V_{GS} of the IRF3415 was selected at 10 V. Calculate the resistance R2 and R3 (R2 = R3) from equation 4.

$$R2 + R3 = \frac{V}{I} \tag{4}$$

Given V = 20 V, I = 10 mA
Substitute the values in equation (4)

$$R2 + R3 = \frac{20\ V}{10 \times 10^{-3}\ A} \tag{5}$$

$$R2 + R3 = 2\ K\Omega \tag{6}$$

Therefore, R2 = R3 = 1 KΩ will get the bias point of IRF3415 at 10 volts.

1.4 Display (voltage) is used to display the DC voltage supplied to the transducer head in the range of 0–30 V. This circuit is composed of 2 parts: a voltage divider circuit and a voltage measurement circuit.

1.5 The voltage divider circuit, as shown in Figure 7, serves to reduce the DC voltage from the transducer head in the range of 0–30 volts to 0–5 Voltage. After that, it is fed into the input port (A1) of the microcontroller. The calculation of the resistance values R4 and R5 is as follows.

$$V_{out} = V_{in} \times \frac{R5}{R4 + R5} \tag{7}$$

Given V_{in} = 30 V, V_{out} = 5 V and R4 = 100 kΩ.
From the equation 7

$$5 = 30 \times \frac{R5}{R4 + R5} \tag{8}$$

$$5(R4 + R5) = 30 \times R5 \tag{9}$$

$$5R4 + 5R5 = 30R5 \tag{10}$$

$$5R4 = 25R5 \tag{11}$$

$$5 \times 100\ k = 25R5 \tag{12}$$

$$25R5 = 500\ k \tag{13}$$

$$R5 = \frac{500\ k}{25} = 20\ k\Omega \tag{14}$$

Therefore, we will get R2 = 20 kΩ

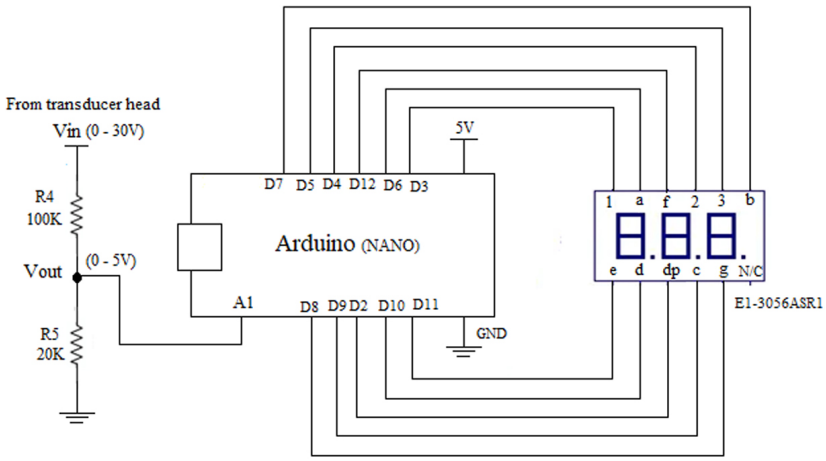

Fig. 7. Voltage measurement circuit and display (voltage)

1.6 Voltage measurement circuit. A microcontroller programmed in C to measure and display the voltage level applied to the transducer head. We used Arduino (NANO) connected to a 3-digit 7-Segment Display (E1-3056ASR1) and voltage divider circuit as shown in Figure 7.

2) The software for generating a 100 Hz pulse signal, measuring DC voltage, and displaying were programmed with C-language, main flowchart as shown in Figure 8.

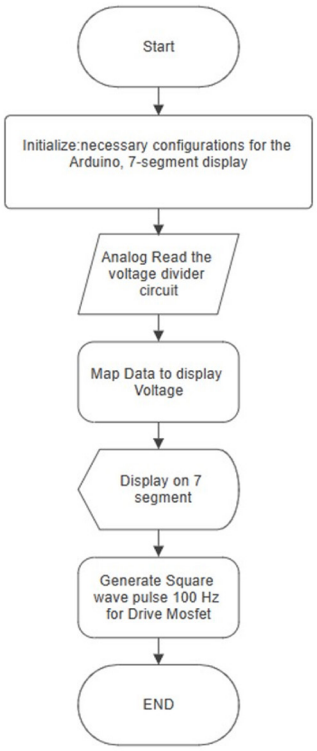

Fig. 8. Main flow chart of generating a 100 Hz pulse signal, measuring DC voltage and display

3) The transducer head converts electrical energy into mechanical energy (vibration). The design used a No. 26 copper coil wound on a 9.4 mm diameter cylindrical insulator with air as the medium, inside there is an iron core as shown in Figure 9. When an electric current flows through the coil, it creates an electromagnetic field that moves through the iron core inside, causing an electric current to flow in the iron core. As the electric current flows in the iron core, an electromagnetic field is created. One set which has opposite polarity to the original set creates a force of attraction. As a result, the steel shaft moves downward to overcome the force of the spring. When the electric current stops supplying the coil (the electromagnetic field does not occur), the spring pushes the steel core to its original position. Therefore, when electricity is supplied to the pulse transducer head, (supplying and stopping the supply of electric current alternately) causes the iron shaft to move up and down alternately according to the frequency of the electrical signal supplied to the head transducer.

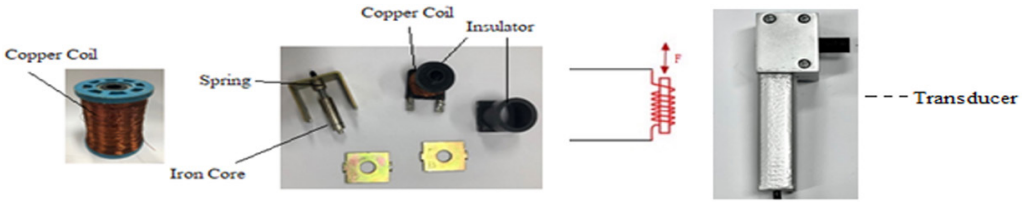

Fig. 9. Components inside of transducer head

The complete prototype for vibrations in the soles of the feet with diabetes was designed and constructed as shown in Figure 10.

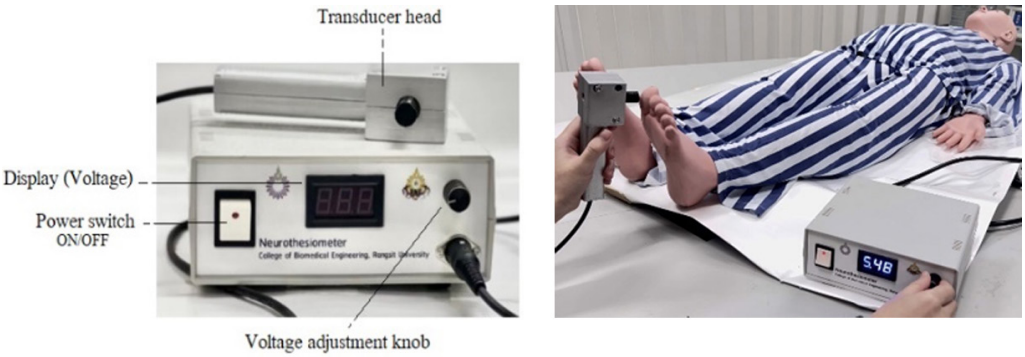

Fig. 10. The designed device and medical application

3 RESULTS AND DISCUSSION

The experiment is to test the efficiency of the designed prototype. It can be divided into 2 sections: qualitative test and quantitative test, as follows:

3.1 Qualitative test

This part tested the functionality of the designed device which consists of the power switch ON/OFF, machine operation, vibration adjustment, display, and the operation of the transducer head, respectively as presented in Table 1.

Table 1. Shown qualitative test of the designed device

Test Item	Test Result
Power switch ON/OFF	Pass
Machine operation	Pass
Voltage adjustment	Pass
Display on screen	Pass
Operation of transducer head	Pass

3.2 Quantitative tests

The quantitative tests consisted of voltage settings, transducer head pressure testing, and electrical safety testing.

1) Voltage settings, we used a Model 289 (Fluke) digital multimeter to measure the voltage applied to the transducer head. After that, we compared the voltage values on the display between the designed device and a digital multimeter as shown in Figure 11. The results of measuring the voltages applied to transducer heads at each value are shown in Table 2.

Fig. 11. Measuring the voltage supplied to the transducer head with a digital multimeter

Table 2. Comparing the voltage value between the designed device display and digital multimeter display

Adjusted Voltage Level of the Designed Device (Volt)	Measured Voltage Level of Digital Multimeter (Volt)			Average (Volt)	Error (%)
	Test 1	Test 2	Test 3		
5	5.09	5.09	5.09	5.09	1.83
10	10.18	10.22	10.14	10.16	1.67
12	12.13	12.07	12.08	12.09	0.78
15	15.1	15.08	15.09	15.09	0.6
17	17.1	17.09	17.07	17.08	0.5
19	19.16	19.12	19.11	19.13	0.68
21	21.09	21.12	21.1	21.1	0.49
23	23.10	23.14	23.11	23.11	0.50
25	25.19	25.12	25.16	25.15	0.62
27	27.11	27.12	27.17	27.13	0.49
30	30.01	30.12	30.01	30.04	0.15

From testing the accuracy of each voltage display of the designed device compared to the display of the digital multimeter, the voltage values obtained were percentage error in the range of 0–1.83 with an average error of 0.75%.

2) Transducer head pressing test. We designed this test based on [28], which used a digital weighing device (BONITA model DNB 3002A) to measure the pressing force of the transducer head during operation as shown in Figure 12 and compare the result obtained from the designed device and the Vibrotest Digital Biothesiometer (EN: ISO13485:2016 Certified), which is the standard device. The result of this test was reported in Table 3.

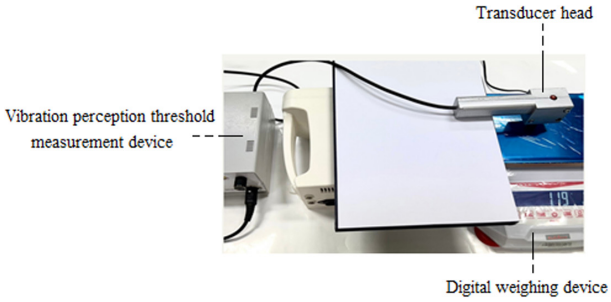

Fig. 12. Digital weighing device measures vibrations at the transducer head of the designed device

According to the result of Table 3, the pressing test result of the designed device was different from the pressure of Vibrotest Digital Biothesiometer (standard device) within ±0.02 g. Results of the transducer head pressing test when voltage levels range from 0 to 30 V, comparing the Vibrotest Digital Biothesiometer with the designed device, was shown in Figure 13.

Table 3. The adjusting voltage and the force that presses on the digital weighting device of the standard device (Vibrotest digital Biothesiometer) and the designed device when the transducer head area is equal

Voltage (V)	The Standard Device (Vibrotest Digital Biothesiometer)				The Designed Device				Diff Weight (g)
	1st Weight (g)	2nd Weight (g)	3rd Weight (g)	Avg Weight (g)	1st Weight (g)	2nd Weight (g)	3rd Weight (g)	Avg Weight (g)	
0	0	0.05	0	0.02	0	0	0	0.00	–0.02
5	0.09	0.06	0.09	0.08	0.15	0.06	0.09	0.10	0.02
10	0.09	0.13	0.09	0.10	0.09	0.1	0.11	0.10	0
12	0.19	0.18	0.22	0.20	0.19	0.18	0.2	0.19	–0.01
15	0.28	0.27	0.28	0.28	0.27	0.27	0.28	0.27	–0.01
17	0.3	0.29	0.34	0.31	0.32	0.33	0.3	0.32	0.01
19	0.37	0.34	0.43	0.38	0.36	0.38	0.37	0.37	–0.01
21	0.42	0.42	0.51	0.45	0.45	0.44	0.44	0.44	–0.01
23	0.52	0.52	0.58	0.54	0.53	0.54	0.53	0.53	–0.01
25	0.63	0.59	0.59	0.60	0.61	0.62	0.61	0.61	0.01
27	0.7	0.66	0.74	0.70	0.68	0.7	0.67	0.68	–0.02
30	0.75	0.76	0.73	0.75	0.73	0.73	0.74	0.73	–0.02

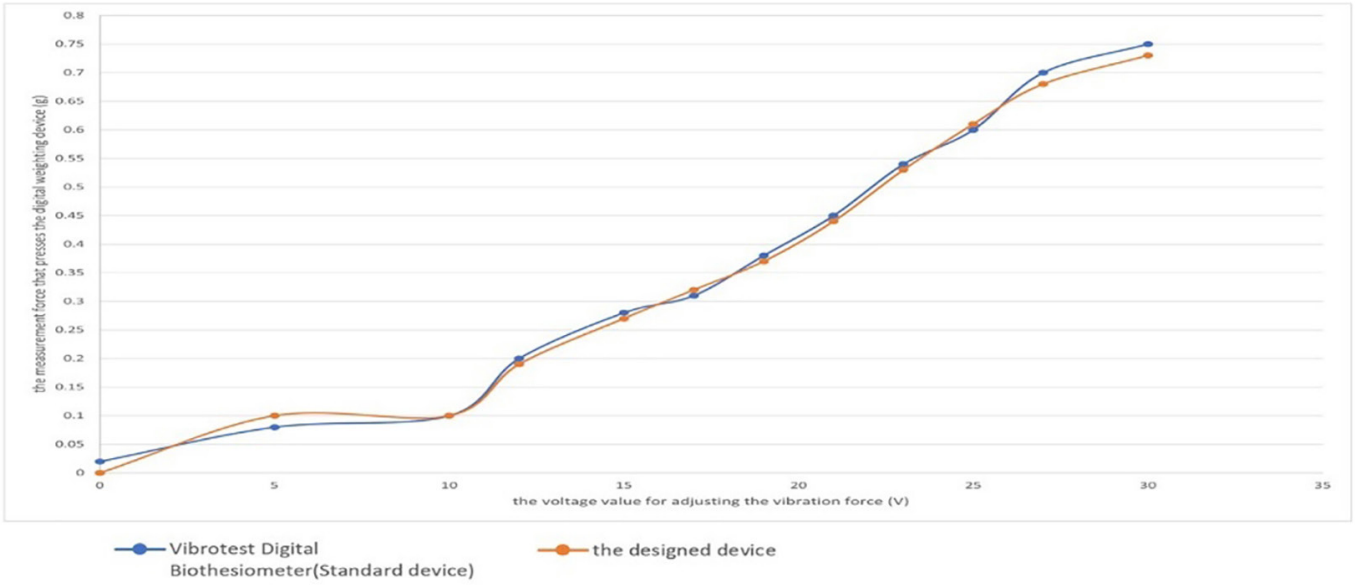

Fig. 13. Results of the transducer head pressing test when voltage levels range from 0 to 30 V, comparing the Vibrotest Digital Biothesiometer (Standard device) with the designed device

3) Electrical safety testing. Electrical safety was tested with the Fluke ESA 612 Electrical Safety Analyzer as in Figure 14. We used the Fluke ESA 612 to measure the protective earth continuity, insulation resistance – mains part of the case, earth leakage current, and enclosure leakage current of the designed device. The results are presented in Table 4.

Fig. 14. Electrical safety test with the Fluke ESA 612 Electrical Safety Analyzer

Table 4. Electrical safety testing results of the designed device

Test Item	Set Values (Standard)	Measured Values	Test Result
Protective Earth Continuity	0.2 Ω	0.164 Ω	Pass
Insulation Resistance – Mains Part of Case	> 2 MΩ	99,999 MΩ	Pass
Earth Leakage Current	< 500 μA	11.7 μA	Pass
Enclosure Leakage Current	< 100 μA	0.3 μA	Pass

The electrical safety testing results of the designed device, as shown in Table 3, which is in the IEC60601-1 standard, can be accepted.

4 CONCLUSION

In this paper, we focused on the design and construction of a prototype VPT measurement device. This device is composed of 2 main parts: the electrical circuit of

the machine and the transducer head. The testing results consist of three main parts: 1) the voltage settings results compared the voltage values on the display between the Neurothesiometer and a digital multimeter, which has an average error of 0.75%, 2) According to the transducer head pressing test results, the Vibrotest Digital Biothesiometer and the proposed device had different pressing weights of 0.02 g. and 3) the electrical safety testing results of the designed device is in the standard of IEC60601-1.

5 ACKNOWLEDGMENT

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