# A hand-held electro-mechanical exciter for multi-frequency peripheral neuropathy assessment

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**Abstract.** Diabetes is becoming alarmingly common worldwide and is associated with long-term complications. One of the major and common complications of the disease is peripheral neuropathy, which causes loss of sensation in the patient's limbs due to the degeneration of sensory nerves. Loss of sensation often allows injuries to get unnoticed, which increases the risk of infections that may lead to ulcers and amputation. Several tests are used as part of peripheral neuropathy screening, one of which is the vibration perception threshold (VPT) test. Most of the existing instruments for VPT testing apply a stimulus at a single frequency while gradually increasing the vibration acceleration until the stimulus is felt and reported by the subject. Nevertheless, recent studies have shown that performing VPT at several frequencies offers a comprehensive VPT assessment. Moreover, the literature indicates that VPT evaluation is affected by excessive pressure that may be applied by the operator while the vibrator's head is in contact with the skin. In this work, we describe the design of a hand-held exciter instrument capable of applying multifrequency stimuli in the range 4 Hz – 500 Hz and that prevents excessive pressure from being applied by the operator to the subject's skin.

**Keywords:** Diabetes, Peripheral Neuropathy, Quantitative Sensory Testing, Vibration Perception Threshold, Multi-Frequency Assessment.

## 1. Introduction

Diabetes, also known as diabetes mellitus, is a persistent medical condition that results in the elevation of blood sugar levels beyond normal limits. This occurs due to lack of or inadequate production of insulin [1]. The International Diabetes Federation (IDF) reports that diabetes affects 537 million people globally, while the UAE has an estimated 990,900 known cases (approximately 10% of the population) and 634,200 cases that are undiagnosed as of 2021 [2].

The long-term complications of diabetes are known to increase the risk of mortality and morbidity. Among these complications, peripheral neuropathy (PN) is a significant concern, as it often leads to the loss of sensation in the limbs due to the degeneration of sensory nerves [3]. This complication is prevalent in patients with type II diabetes, and it is particularly concerning for the feet, as injuries can go unnoticed. When left untreated, these injuries can lead to infections, which may result in amputation [4]. Peripheral neuropathy affects roughly half of all diabetic patients at some point.

The International Diabetes Federation (IDF) recommends that the diagnosis of PN should involve an assessment of the degree of sensorimotor nerve damage. This assessment should include a thorough investigation of the patient's medical history, comprehensive physical examinations, laboratory tests, nerve conduction studies (NCS), electromyography (EMG), and quantitative sensory testing (QST) [2]. By considering the presence of specific symptoms and signs, as well as the exclusion of other possible causes, the diagnosis of peripheral neuropathy can then be achieved [3].

A consensus conference on diabetic neuropathy recommended QST as a screening method for PN [5]. It involves several tests designed to evaluate both small and large myelinated and unmyelinated nerve fibers. These tests consist of thermal sensation, light-touch sensation, and vibration sensation, each of which is associated with assessing a specific type of nerve fiber [6]. The nature of these tests is subjective and relies on the full cooperation of the patient.

The work described in this paper is concerned with assessing vibration sensation. This is achieved by measuring the vibratory perception threshold (VPT), which refers to the minimum level of vibration that can be perceived. Clinical neurology suggests that a decrease in the ability to sense vibration may indicate early signs of PN [7]. To conduct the test, a vibration stimulus is applied to the patient's limb, and the acceleration of the vibration is increased gradually until the subject can feel and report the sensation.

Over time, various instruments have been developed to evaluate VPT, which can be classified based on how they are applied to the subject's skin. These instruments can be categorized as either hand-held, where the operator controls the application of the vibrator's head on the skin, or stationary, where the subject places their finger or foot on the vibrator's head, which is incorporated into a stationary base. Some of the available instruments in the market include tuning forks with different vibration frequencies (hand-held, 64 Hz, 128 Hz, and 256 Hz) [8], the Bio-thesiometer (hand-held electromagnetic vibrator vibrating at 100 Hz) [9], the Vibrameter (improved version of Bio-thesiometer, hand-held, 100 Hz) [10], the Neurothesiometer (Arnold Horwell, London, UK) (hand-held, 56 Hz), the CASE IV vibrator stimulator (stationary, 125 Hz) (WR Medical Electronics Co., Maplewood, Minnesota), the Vibratron II (stationary, 120 Hz) [11], the Vibratory Sensory Analyzer (hand-held and stationary, 100 Hz) [12], and the VibroSense Meter (VibroSense Dynamics AB, Malmo, Sweden) that can perform multi-frequency VPT assessment (stationary, 4 Hz to 500 Hz).

Campbell [13] suggests that the skin's mechanoreceptors have a sensitivity range of 10 Hz to 400 Hz, with the highest sensitivity being between 100 Hz and 200 Hz, which is why most clinical VPT instruments produce vibration stimuli at a fixed frequency within this range. However, recent studies have indicated that multi-frequency VPT instruments, such as the VibroSense Meter (4 Hz – 500 Hz), which can also generate low-frequency stimuli (4 Hz and 8 Hz), offer a more comprehensive assessment [14, 15]. Additionally, hand-held VPT instruments have a potential challenge, as the operator cannot control the pressure applied when placing the vibrator's head on the skin [16]. It has been reported that higher pressure leads to lower VPT, resulting in measurement variability and incorrect diagnoses [17]. The same issue may occur with stationary instruments since subjects may unknowingly apply excessive pressure during VPT examinations.

Considering the aforementioned, we present here the design of a hand-held exciter instrument that is capable of producing multi-frequency VPT measurements, and that prevents the application of excessive pressure by the operator on the patient’s skin. The implementation of the instrument was achieved using mainly off-the-shelf components and a few 3D-printed parts.

## 2. Materials and methods

### *2.1. Instrument overview*

The developed hand-held exciter is presented in Figure 1. The dimensions of the instrument are 19.3 cm (L) × 6.8 cm (W) × 14.9 cm (H) and it weighs 229 g. Moreover, it is powered by an AC/DC adapter (AC input: 100-240 V, 1.2 A, 50/60 Hz – DC output: 12 V, 2.0 A) via a DC power jack (Figure 1-a) and regulated down to 5 V using the L7805 regulator.

The instrument allows the user to select the vibration frequency using the yellow push-button depicted in Figure 1-a. There are eight frequency values, 4 Hz (default frequency when the instrument is switched on), 8 Hz, 16 Hz, 32 Hz, 64 Hz, 128 Hz, 256 Hz, and 500 Hz. Each press of the button moves the frequency to the next value (8 Hz, 16 Hz, 32 Hz, etc.). When the frequency is at 500 Hz (highest value) and the yellow button is pressed, it moves back to 4 Hz.

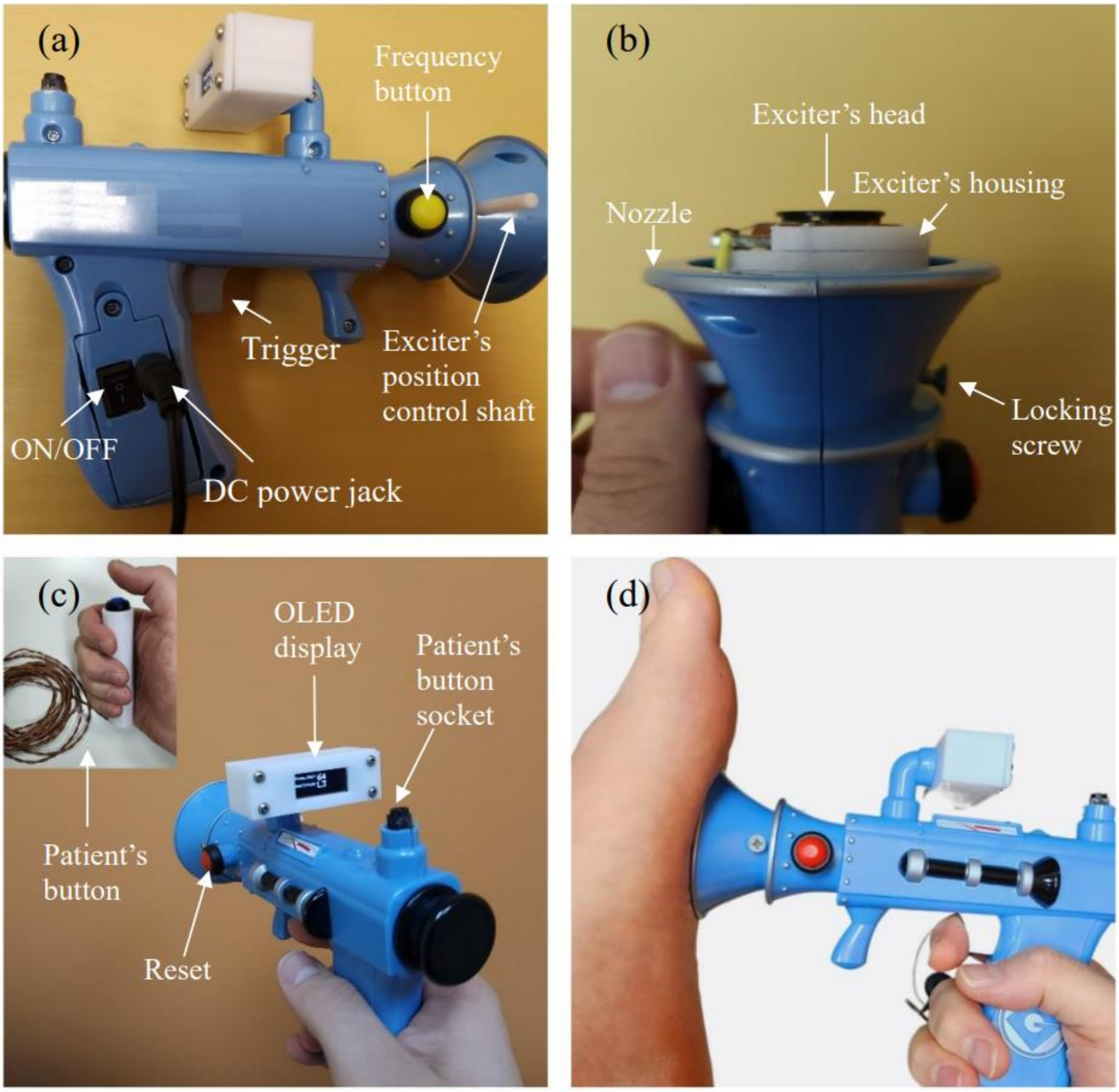

**Figure 1.** Overview of the hand-held exciter showing the different views and features of the instrument.

The vibrations are generated by an exciter (speaker), which is located in a custom-made housing (Figure 1-b) and mounted on a movable stage. This arrangement allows the user to adjust the position of the exciter vertically by rotating the exciter's position control shaft (Figure 1-a). More specifically, the surface of the exciter's head (Figure 1-b) can move vertically between -2 mm to +9 mm with respect to the surface of the nozzle (Figure 1-b). The desired vertical position can then be locked by turning the locking screw shown in Figure 1-b. The presence of the nozzle in the instrument improves stability when holding the instrument and minimizes any excessive pressure that the operator may unwillingly apply.

Nevertheless, due to the presence of the nozzle, it was necessary to allow the exciter to move vertically so that the operator can apply stimuli to areas of the foot where there is curvature. To use the instrument, the operator would have to (1) pull the exciter's head all the way back below the nozzle's surface (i.e. at -2 mm) using the position control shaft, (2) apply the nozzle at the desired foot area (Figure 1-d), (3) advance the exciter's head until resistance is encountered (i.e. the exciter's head touches the foot), (4) turn the locking screw to fix the exciter's position, and (5) pull the trigger (Figure 1-a) to carry out the VPT assessment.

When the trigger is pulled, the exciter's head begins to vibrate at the selected frequency. The frequency is kept constant while the acceleration of the exciter is automatically and gradually increased from 80 dB to 110 dB in steps of 3 dB, with each stimulus lasting for 3 seconds. The selected frequency and acceleration are both displayed on the 0.91-inch OLED display (Figure 1-c). During this time, if the subject senses the vibration, they can press the patient's button (inset of Figure 1-c) to indicate this. The VPT at the selected frequency is then displayed.

### 2.2. *Instrument design*

The housing of the exciter instrument is a toy gun that was purchased and modified by integrating the system shown in Figure 2. At the heart of the system is an Arduino Nano board with an ATmega328P microcontroller. The signal that drives the exciter is a square wave generated by the microcontroller via one of its digital I/O pins. The frequency of the signal is varied by making the value of the output pin 'high' and 'low' alternately at selectable periods that will produce the eight frequencies mentioned in section 2.1. The desired period is selected using the yellow push button. Since the amplitude of the signal is 5 V (default), a digital potentiometer (X9C103S, Renesas, Japan) is used to attenuate it and produce varying acceleration levels. The selected frequency and acceleration are both displayed on a 0.91-inch OLED display. The exciter is then driven by the amplifier shown in Figure 2. The amplifier comprises an op-amp (TL071) configured as a non-inverting amplifier with a gain of 2 and an NPN BJT transistor (BC140) to boost the current delivered to the exciter (E-3304, Soberton Inc.), which has an impedance of 4 Ω.

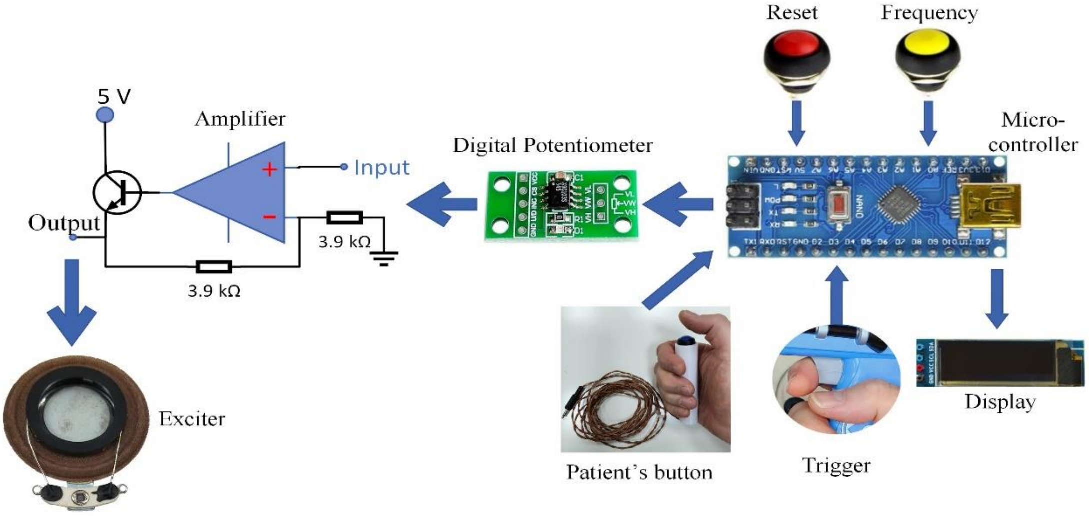

**Figure 2.** Diagram of the system that was integrated into the toy gun to implement the exciter instrument.

All the components used in the design of the instrument are off-the-shelf apart from the OLED display housing, the patient's button grip and the stage mechanism that holds the exciter and allows it to move vertically (Figure 3-a). These components were custom designed and 3D-printed in order to fit the dimensions of the exciter and the toy gun. Figure 3-b shows the mechanism that was implemented in order to convert the rotational movement of the position control shaft into vertical movement.

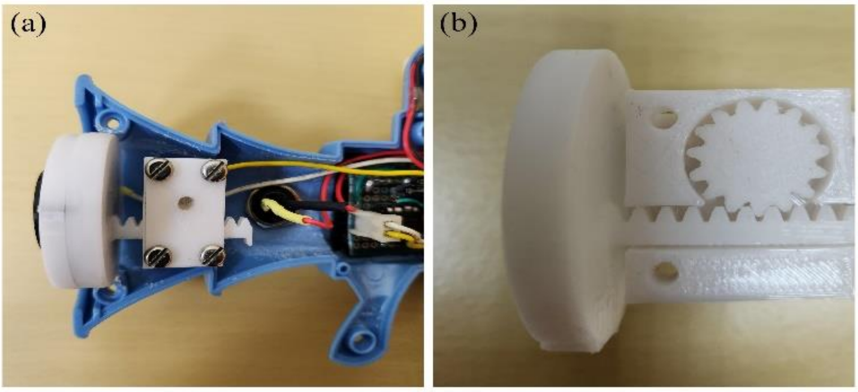

**Figure 3.** (a) The 3D-printed stage that holds the exciter and allows its vertical movement. (b) The mechanism that converts the rotational movement of the control shaft into vertical movement.

## 3. Testing and calibration

To measure the actual vibration frequencies of the instrument, the setup shown in Figure 4 was used. The exciter's head was positioned against a fixed custom-made frame. The surface of the frame and that of the exciter were each covered with a piece of conductive tape and the tapes were connected to a 5 V DC supply and an oscilloscope as illustrated. During vibration, as the exciter's head is displaced, it touches the conductive surface of the fixed frame, which shorts the supply causing the voltage on the oscilloscope to alternate between zero and five volts at the same frequency as that of the vibration. The measured frequencies were (the expected values are inside the brackets): 3.97 (4), 8.1 (8), 16.7 (16), 31.3 (32), 62.5 (64), 125.0 (128), 250.0 (256), and 500.3 (500) yielding errors between 0.1% and 4.2 %, which are acceptable according to ISO 13091-1, which suggests a tolerance of ±10%.

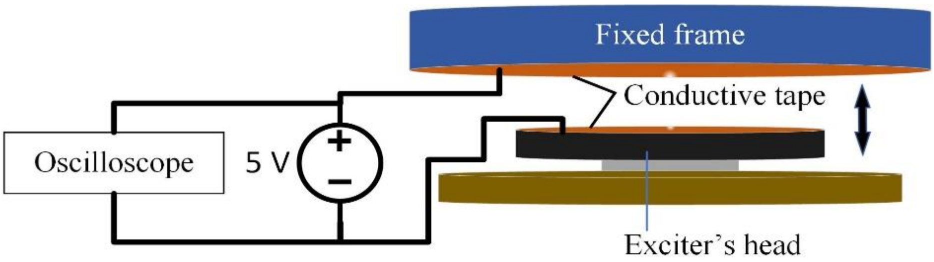

**Figure 4.** Experimental setup to measure the vibration frequencies of the exciter.

The different acceleration values that the instrument can generate (determined by the driving voltage that the digital potentiometer controls) were measured using the LSM6DSO accelerometer (STMicroelectronics), which is integrated into an S22+ Samsung smartphone. Data were recorded using the Physics Toolbox Suite application (Vieyra Software). Measurements were made by placing the phone on the nozzle of the instrument with the exciter's head touching the back of the phone and initiating the vibrations by pulling the trigger. Figure 5 presents such a recording at 16 Hz where the acceleration (measured in $m/s^2$ and converted to dB later) is gradually increasing until the patient's button is pressed. Using these data, we calibrated the digital potentiometer to vary the acceleration between 80 dB and 110 dB.

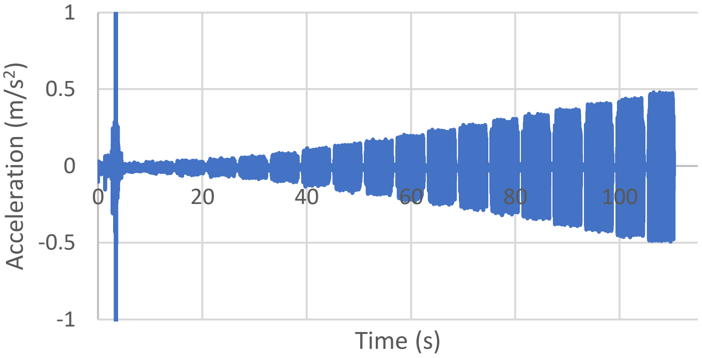

**Figure 5.** Accelerometer data showing the gradual increment of acceleration during the operation of the instrument. The large spike in the beginning is an artifact due to the pulling of the trigger.

Finally, a force sensor was used to measure the effectiveness of the nozzle method in preventing the application of excessive pressure. The gun was positioned vertically on the foot of a volunteer (the subject was lying face down with one of his knees bent) with the nozzle facing down and the exciter's head in contact with the force sensor, thus utilizing the weight of the instrument (229 g) for this experiment. We measured the force both with the nozzle being in contact with the surface around the force sensor and with nozzle lifted up by advancing the exciter's head. The force measured when the nozzle was in contact with the surface of the skin was approximately three times smaller.

## 4. Conclusion and future work

In the current phase of our work, we have successfully implemented an instrument capable of generating stimuli at eight different frequencies with variable acceleration in order to determine VPT. We have also managed to devise a method for preventing excessive pressure being applied while the operator handles the device. Our instrument is, however, not yet fully compliant with international standards (ISO 13091-1), therefore, we are now in the process of programming the microcontroller in order to execute the protocol indicated by the standards. Moreover, we are currently applying for approval to use the exciter on healthy human subjects. This will enable us to establish a baseline for healthy subjects and fine tune the performance of the instrument before we proceed to use it on neuropathic patients.

## Acknowledgements

The authors would like to thank Dr. Konstantinos Aidinis and Mr. Maher Samha for their valuable help. This work was supported by Ajman University (grant agreement IRG-2018-A-EN-02).

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