A Cost-Effective IoT-based Transcutaneous Electrical Nerve Stimulation (TENS): Proof-of-Concept Design and Evaluation

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***Abstract*—Transcutaneous electrical nerve stimulation (TENS) systems have been extensively used as a noninvasive and non-pharmaceutical approach for pain management and rehabilitation programs. Moreover, recent advances in telemedicine applications and the Internet of Things (IoT) have led to an increased interest in developing affordable systems that facilitate the remote monitoring of home-based therapeutic programs that help quantify usage and adherence, especially in clinical trials and research. Therefore, this study introduces the design and proof of concept validation of an IoT-enabled, cost-effective, single-channel TENS for remote monitoring of stimulation parameters. The presented prototype features programmable software that supports manipulating the stimulation parameters such as stimulation patterns, pulse width, and frequency. This flexibility can help researchers substantially investigate the effect of different stimulation parameters and develop subject-specific stimulation protocols. The IoT-based TENS system was built using commercial-grade electronic components controlled with open-source software. The system was validated for generating low-frequency (10 Hz) and high-frequency TENS stimulation (100 Hz). The developed system could produce constant biphasic pulses with an adjustable compliance voltage of 5–32 V. The stimulation current corresponding to the applied voltage was quantified across a resistive load of 1 kΩ, resulting in a stimulation current of approximately 4.88–28.79 mA. Furthermore, synchronizing the TENS system with an IoT platform provided the advantage of monitoring the usage and important stimulation parameters, which could greatly benefit healthcare providers. Hence, the proposed system discussed herein has the potential to be used in education, research, and clinics to investigate the effect of TENS devices in a variety of applications outside of the clinical setup.**

Keywords—Electro-stimulator; Internet of Things; TENS; pain management; smart health; IoT; telemedicine

I. Introduction

Chronic pain, lasting over three months, is considered one of the critical public health issues worldwide, with approximately 20% of the world's population estimated to suffer from chronic pain [1, 2]. Several studies have reported that the prevalence of chronic pain in adults is approximately 33% and 56% in the elderly in middle-income and low-income countries [3]. Moreover, pain and pain-related illnesses are the primary cause of disability worldwide [4]. Thus, there is a continuous need to develop and implement therapeutic interventions and medical technologies to enhance the quality of pain management.

Pain management is essentially managed via two main approaches: pharmacological and non-pharmacological interventions [5]. Pharmacological intervention has been shown to have some limitations and risks, such as opioid dependency, tolerance, and hyperalgesia [6, 7]. In comparison, non-pharmacological pain management strategies often refer to interventions and techniques used to reduce pain sensation without medicine. Non-pharmacological interventions such as physical and occupational therapy, psychological approaches, and neurostimulations have been previously shown to be effective in acute and chronic pain management [5].

One of the most widely used neurostimulation techniques for pain management is transcutaneous electrical nerve stimulation (TENS) [8]. TENS is a non-pharmacological, noninvasive, and inexpensive stimulation procedure in which pulses of electrical currents are delivered across the skin via pairs of electrodes that stimulate peripheral nerves to alleviate pain [9]. The analgesic effects of TENS have been shown to be effective in mediating pain sensation through peripheral and central neurological mechanisms [10]. Moreover, several studies have demonstrated the efficiency of various TENS protocols in alleviating neuropathic pain in multiple sclerosis [11], cancer [12], postherpetic [13], spinal cord injury [14], and stroke populations [15].

TENS devices can be configured with various stimulation parameters depending on the case. Therefore, the clinical settings for TENS can be classified into three main paradigms. In the conventional TENS protocol, low-intensity electrical pulses are delivered at a high frequency (50–100 Hz) with a pulse width adjustable between 50 and 200 µs, while in the intense TENS protocol, high-intensity electrical pulses are delivered at a low frequency (<10 Hz). Moreover, acupuncture-like TENS is configured to provide high-intensity electrical pulses at low frequencies (<10 Hz) with a more extended pulse width of 100–400 µs [16].

The physiological mechanism of conventional TENS is believed to be based on the Gate-Control theory of pain, where the activation of large-diameter mechanoreceptive nerve fibers with a low threshold level leads to impeding the transmission of action potentials generated by small-diameter nociceptive fibers [8, 9]. Essentially, the touch-related nerves can prevent the pain-related nerves from sending signals to the brain by blocking their transmission through the spinal cord. Moreover, an acupuncture-like TENS paradigm is intended to cause muscle twitches by engaging the motor afferents with a small diameter to induce extrasegmental analgesia, whereas the intense TENS paradigm causes extrasegmental analgesia and peripheral nerve blockade via the activation of small-diameter noxious afferents [17].

Several previous studies have investigated the feasibility of developing nerve and muscle microcontroller-based stimulation systems that can be used in educational, clinical, or research setups. For instance, Cornman et al. [18] proposed a portable, inexpensive, low-power consumption stimulation apparatus capable of producing ±150 V monophasic or biphasic pulses. Additionally, Trout et al. [19], implemented and further developed a proposed TENS electrical design of the stimulator proposed in [18] and validated its use for cutaneous and transcutaneous nerve stimulation. The results of Trout et al. show that nerve and muscle stimulation generated comparable forces with no significant effect of stimulation timing when applied to nerves or hand muscles.

Advances in smart technology applications in healthcare have gained attention in recent years as they provide the benefit of remote monitoring of patients' conditions and can be utilized as a tool to monitor patients' adherence, particularly for self-administered therapeutic interventions. Therefore, various medical applications have been developed to support the integration of IoT technology to support remote monitoring and reduce the daily time clinicians need for patient follow-ups. For instance, Ursache et al. [20] developed a low-cost smart TENS system that can be programmed and controlled via an Android application that can digitally adjust the stimulation parameters. Their proposed system was developed from commercial, low-cost electronic hardware and could deliver up to 100 V of monophasic pulses with an adjustable pulse duration. Additionally, Ortiz et al. [21] designed a knee orthosis with an embedded Bluetooth-connected TENS system controlled by a mobile application with customizable electrical muscle stimulation parameters suitable for osteoarthritis treatment.

To the best of our knowledge, no study has investigated the ability to develop an open-access, programable, and inexpensive TENS system incorporating the IoT application and its importance in enhancing the remote monitoring of systems designed to be operated by end users out of clinical setups with minimal training. Therefore, this paper presents and discusses the design and development of a low-cost and Internet of Things (IoT)-based TENS system. The use of an IoT-enabled neurostimulation system could facilitate the remote monitoring of patients' use of the TENS system and provide accurate information regarding adherence to prescribed daily usage.

The rest of this study is structured as follows: Section II provides an overview of the primary hardware elements of the proposed IoT-based TENS system along with details about the software structure and interface. Section III presents the proposed system's integration and validation. Lastly, Section IV discusses the study's conclusions, outlining its objectives and offering suggestions for future advancements.

II. Materials and Methods

The development of the IoT-based TENS system consists of identifying effective and inexpensive low-power consumption electronic hardware and tailored software to control the stimulation parameters. An IoT platform containing individual channels is also needed to record and monitor patient usage and the most critical protocol parameters, such as stimulation frequency and duration. The block diagram of the IoT-TENS system is shown in Fig. 1.

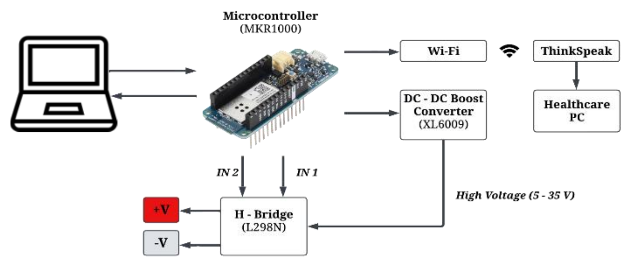

Fig. 1. Block diagram of the proposed IoT-based TENS unit.

A. Hardware Design

The electrical hardware components used in the study were selected based on their efficiency to provide an effective compliance voltage and the required amount of direct current stimulation. Hence, the IoT-based TENS was constructed using the following main consumer-grade components:

1) Microcontroller: A low-cost consumer-grade microcontroller (MKR 1000, Arduino LLC, Boston, MA) with internet connectivity via the integrated Wi-Fi shield. The IoT-enabled microprocessor is crucial for transmitting session information to the cloud.

2) Notebook: The proposed TENS system must be connected to a computer or notebook to power the system via the universal serial bus and establish serial communication with the microcontroller to send commands through a simple, user-friendly interface.

3) DC-DC step-up voltage transformer: A voltage boost converter was used to increase the output voltage of the microcontroller. The DC-DC voltage boost converter (XL 6009) used in this study can increase the essential 5-V-supplied input voltage to an output voltage between 5 and 32 V. The desired output voltage can be adjusted via an incorporated potentiometer.

4) Full H-Bridge module: TENS protocols could be administered through mono- or biphasic pulses. However, biphasic symmetrical TENS was found to achieve better clinical results [22]. Therefore, a dual H-Bridge (L298N) driver module was used in this prototype to switch the polarity of the monopolar pulses generated by the microcontroller and amplified by the boost converter. The H Bridge allows for generating positive and negative pulses with a maximum voltage of 5–35 V and a maximum current of 1 mA per channel.

5) Surface electrodes: A pair of adhesive 5 × 5-cm reusable surface electrodes were used.

B. Internet of Things Platform

The ThingSpeak platform was used in the IoT-based TENS device. A private channel was established to capture, track, and retrieve real-time information on the chosen stimulation type and duration. This information is critical for healthcare providers to track the patient's adherence to protocol and frequency of use [23].

C. Software Architecture

An open-access C++-based Arduino Integrated Development Environment (IDE; Version 2.1.1) was used to design custom-made software to control and activate the IoT-based TENS system. The software initiated the connection to the wireless network to feed the session's information to the IoT cloud at the start and finish of the stimulation. In addition, the healthcare provider could adjust the stimulation parameters, such as pulse width, frequency, and interpulse interval, to suit patients' needs. The stimulation pattern can be modified to be mono- or biphasic as needed. However, the work presented here was based on symmetric biphasic stimulation pulses as monophasic stimulation may lead to adverse effects such as excessive accumulation of charge and skin irritation [24, 25].

Therefore, various settings were implemented as a proof of concept for the IoT-based TENS system demonstrated in this study. Two distinct biphasic stimulation montages were programmed. First, the low-frequency stimulation, which has a stimulation frequency of 10 Hz and a pulse width of 400 µs, and the high-frequency stimulation protocol, where the stimulation was delivered at 100 Hz with a pulse width of 200 µs. The custom-made algorithm was designed based on the switch statement approach, where a set of discrete stimulation options are preconfigured based on the two types of stimulation (low frequency or high frequency) and the stimulation duration (5, 10, 15, 20, and 30 min).

The flowchart of the proposed algorithm is shown in Fig. 2. Users are prompted to enter a predefined code of the required stimulation frequency and duration, as shown in Table I. Upon entering the correct session code, the stimulation would begin by sending activation pulses from the microcontroller digital pins to produce the amplified biphasic stimulation pulses (pin 6 for the positive phase and pin 11 for the negative phase). Furthermore, the session information (frequency and duration) would be fed to the IoT Thinkspeak cloud at the beginning and end of each session.

TABLE I. STIMULATION SETTINGS

Stimulation type	Predefined session code	Duration [a] (minutes)	Pulse width [a]
Low Frequency (default: 10 Hz[a])	a	5	400µs
	b	10	
	c	15	
	d	20	
	e	30	
High Frequency (default: 100 Hz[a])	f	5	200µs
	g	10	
	h	15	
	i	20	
	j	30	

[a.] adjustable parameters.

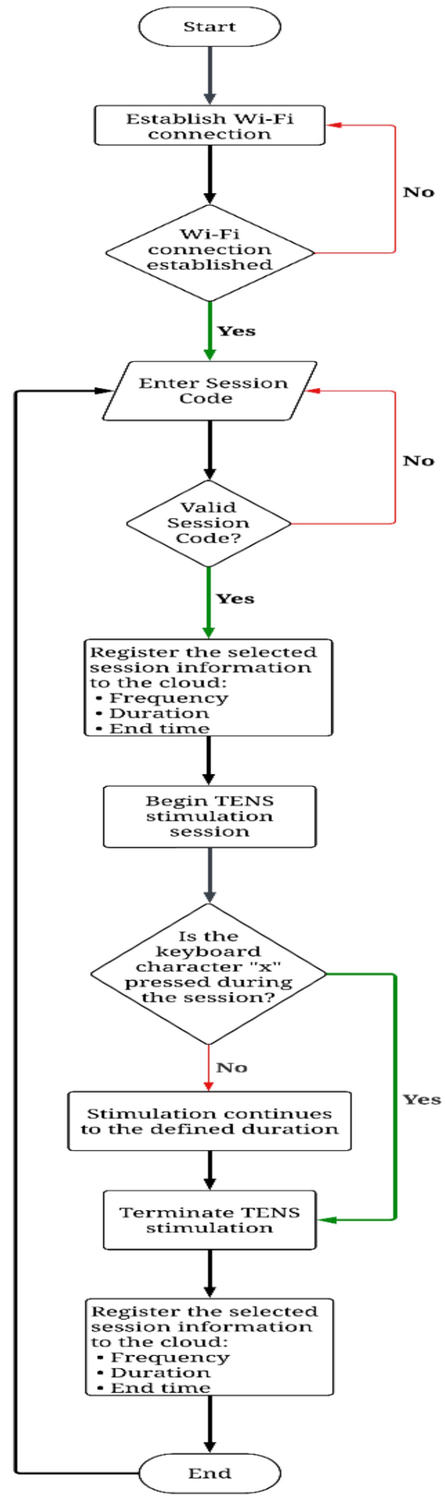

Fig. 2. Flowchart of the IoT-based TENS software.

D. System Functionality Testing

To evaluate the performance of the IoT-based TENS, the generated biphasic square pulses were monitored via an oscilloscope. The resulting frequency, current, and voltage range were recorded using a digital multimeter (GDM-451, GW Instek) across a resistor with a resistance of 1000 Ω to represent human skin resistance [26]. The stimulation durations were also monitored and recorded to confirm the accuracy of each selected duration option. Moreover, the successful real-time synchronization of the session information was validated, including the stimulation type and the duration of the session between the proposed IoT-TENS system and the Thinkspeak cloud.

III. Results

A. System Integration

The prototype of the constructed IoT-based TENS system is shown in Fig. 3. The system components can be secured in a compact portable box with approximate dimensions of 16 × 10 × 8 cm. The proposed system successfully generated square pulses originating from the pulse-width modulation pins of the microcontroller and amplified by the DC-DC converter. The monophasic pulses were then converted into biphasic pulses via the H-bridge module (see Fig. 4). The resulting output peak-to-peak voltage of the system is adjustable between approximately 10–60 V (peak-to-peak) via the DC-DC converter voltage adjust potentiometer. The potentiometer allows users to alter the current intensity of the stimulation by increasing or decreasing the compliance stimulation voltage. Notably, the cost of developing the single-channel IoT-based TENS system was $58.72.

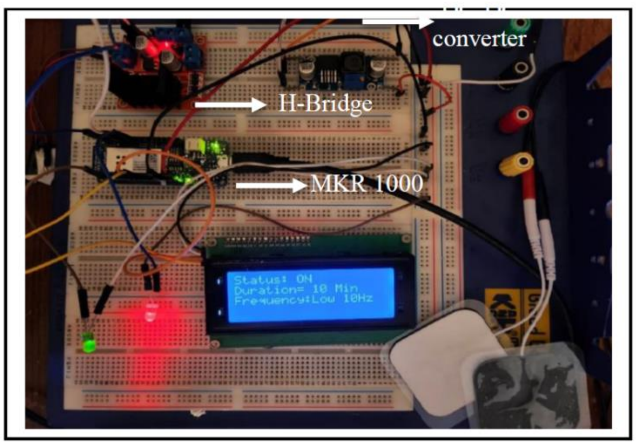

Fig. 3. Photograph of the proposed IoT-based TENS circuit.

B. System Validation

The noninvasive IoT-based TENS system operation was validated by visualizing the output waveform across the electrode leads. The low-frequency stimulation program generated biphasic stimulation waveforms, as shown in Fig. 4. Using a load of 1 kΩ, the stimulation current amplitude can be changed between 4.88 mA and 28.79 mA for compliance voltage between 5 and 30 V, respectively, with a variation of stimulation current between −0.90 % and −4.03% (see Table II). Moreover, testing the system's internet connectivity revealed that maintaining connectivity was achievable with a mobile hotspot. Two data points recorded the selected session's information on start time, stimulation duration and frequency, and the end time, upon which the stimulation was completed across all the predefined settings and uploaded to the system's private channel, accordingly (see Fig. 5).

TABLE II. Comparison Between Calculated and Measured Current Intensity

Applied peak voltage (V_p)	Calculated current across a resistive load of 1kΩ ($I_p = V_{IN}/R_L$)	Measured Current	Error
5 V	5 mA3	4.88 mA	−2.4 %
10 V	10 mA	9.91 mA	−0.90 %
20 V	20 mA	19.23 mA	−3.85%
30 V	30 mA	28.79	−4.03 %

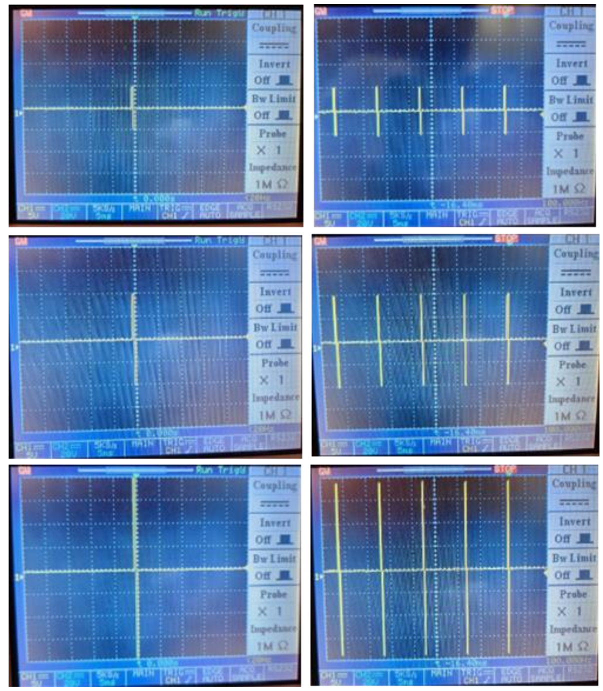

Fig. 4. Demonstrates the testing of the IoT-based biphasic output voltage with an oscilloscope, showcasing different compliance voltages and stimulation frequencies. The left column shows low-frequency stimulation. pulses (10 Hz) with 10, 20, and 40 V peak-to-peak voltage amplitudes, respectively. The right column displays high-frequency stimulation pulses (100 Hz) with 10, 20, and 40 V peak-to-peak voltage amplitudes, respectively.

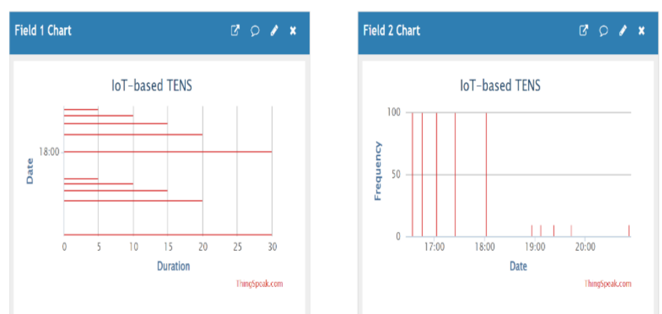

Fig. 5. ThinkSpeak private channel information in which the session duration in minutes (left) and frequency in Hertz (right) were updated and validated for each predefined setting.

IV. Conclusion

The IoT-based TENS system presented in this study demonstrates the feasibility of constructing an affordable single-channel TENS system with IoT capabilities that can be used in research laboratories and studies requiring users' adherence to the stimulation protocols. Moreover, the data derived from the IoT-based TENS can be critical in evaluating the effect of the TENS system, especially in cases where users are instructed to employ the stimulation system as a treatment for pain. Additionally, the stimulation waveforms and properties of most of the available TENS systems in the market cannot be customized [19]. Thus, using a microcontroller-based system and the associated software has the advantage of designing tailored stimulation patterns, durations, and frequencies to target different clinical or research purposes and facilitate the customization of stimulation parameters for each end user.

The proposed system has an additive value of incorporating the IoT feature that can automatically save vital information regarding system usage compared with the previously developed TENS systems [19-21]. Although the IoT-based TENS system incorporated a single stimulation channel and biphasic stimulation patterns were presented, this can be expanded to two or more channels, and monophasic or biphasic stimulation can be generated, as in [18, 19]. Furthermore, although the generated compliance voltage capabilities of the presented system (±30 V) are commonly used in battery-powered TENS systems, this can be further enhanced and upgraded directly by replacing the DC-DC boost converter and the H-bridge modules with other models that have higher power ratings as used in [18, 19]. However, as TENS systems are often available as over-the-counter options, operating high-voltage instruments of ±300V is hazardous and requires those systems to be only used in a well-controlled environment.

Further studies are required to validate the efficacy of the proposed IoT-based TENS systems on the human population to evaluate their ability to stimulate nerves and muscles. Additional research can discern whether the proposed system has the potential to be used in clinical treatment programs to reduce the sensation of pain.

Data Availability Statement

The data supporting this study's findings are available within the text.

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