An easy-to-build transcutaneous electrical stimulator for spinal cord stimulation therapy

Monzurul Alam (md.malam@connect.polyu.hk)
UNSW Sydney

Method Article

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Abstract

Transcutaneous electrical spinal cord stimulation, a non-invasive, reversible spinal cord neuromodulation method holds tremendous promise and hope for the people with paralysis resultant of spinal cord injury (SCI) and other neurological conditions. Yet, there are not many options of such stimulation device compared to other successful electrical stimulators such as neuromuscular electrical stimulator (NMES) and functional electrical stimulator (FES), especially for most people around the world. In this report, a simple design and step-by-step prototyping of a transcutaneous electrical stimulator (TES) is presented to facilitate anyone with the modest technological knowledge to develop their own stimulator for the spinal cord stimulation treatment. It is, however, warned to handle the stimulator with highest caution and care as it can generate high voltage which can have adverse health effects, if not handled carefully. The entire design and source-code are shared online on GitHub repository: https://github.com/OpenXstim/OpenVstim

Background

Transcutaneous electrical spinal cord stimulation (TESCS) is a non-invasive technique that uses electrical current though the skin to neuromodulated the targeted spinal cord region. For the stimulation, cathodal electrodes are generally placed paraspinally with large anodal electrodes placed anterior to the spinal cord. [1] Typically, a disk electrode is placed over the spinous process and a large reference electrode is sticked on the abdomen. The anodal electrodes often placed bilaterally on the bony surface of the iliac crest. [2] TESCS can be utilized for both exploratory (mechanistic) as well as therapeutic applications. A single rectangular pulse or burst of TESCS with 0.1-1ms stimulation duration at motor-threshold elicits evoked potentials to the muscles though different synaptic pathways. [3] Previous study has demonstrated that, with a moderate stimulation intensity, posterior root afferents can also be depolarized by TESCS. [4] In healthy human, by applying a single stimulus of mean intensity of 28.6V through TESCS electrodes placed over the T11-T12 vertebrae, bilateral monosynaptic reflexes can be simultaneously elicited in quadriceps, hamstrings, tibialis anterior, and triceps surae muscles by depolarization of lumbosacral posterior root fibers. It was further demonstrated that monosynaptic posterior root reflexes in extensor and flexor muscles of thigh and leg can also be elicited by stimulating L2-S1 spinal segments in upright standing position, and can be modulated during the execution of postural maneuvers. [5]

Tonic TESCS utilizes charge-balanced, symmetric, biphasic rectangular pulses at sub-threshold strengths to modulate the spinal cord circuits. The frequency of this tonic stimulation generally ranges from 5 to 100 Hz. A recent design includes modulated TESCS with 10kHz career frequency to minimize the perceived pain of the subjects. [6] This modulated tonic TESCS has shown successful activation of spinal rhythm generator circuits in healthy human. [2] Recent studies found that, in case of a disruption of the connection between the brain and the spinal cord, resulting from an injury or disease, motor tasks can be enabled by TESCS to the cervical and/or lumbosacral segments of the spinal cord. [7,8] Modification of spasticity by tonic TESCS was also demonstrated in individuals with spinal cord injury. [9] In a recent study, it has also been demonstrated that TESCS can induce rhythmic activities of legs in robotic orthosis driven body-weight support system in upright position in people with complete spinal cord injury. [10] Furthermore, repetitive gait training along with TESCS promotes long term functional recovery. [11] Thus, neuromodulation via TESCS essentially restores or improves functions in patients with neurological conditions including brain injury, [12] spinal cord injury, [13] and cerebral palsy. [14]

Despite all the success of TESCS on restoring functions in several neurological patients, there are very few commercially available stimulators capable of stimulating the spinal cord with the required stimulation parameters, specially the relatively high 10kHz modulating stimulation. Hence, in the present report, a step-by-step prototyping of an easy-to-build transcutaneous electrical stimulator (TES) is presented to allow everyone to develop their own TES system for spinal cord stimulation therapy. Special care has been given to minimize the complexity of the design and to use most commonly available off-the-shelf (OTS) components so that one can build the stimulator from anywhere in the world.

Design Methods

For easy prototyping, the transcutaneous electrical stimulator (TES) was built from commonly available off-the-shelf components. Functional block diagram of the stimulator is shown in Fig. 1. The stimulator contains 3 primary modules: a DC-DC boost converter, a Full H-bridge driver, and a Microcontroller unit. Operation of each of these modules are explained in detail in the following.

Module 1: Voltage boost by DC-DC converter

Due to the high skin impedance (~ 500Ω at 10kHz), transcutaneous stimulation requires high compliance voltage to be able to deliver necessary current for stimulation. But, for safety and the ease of use, these stimulators are commonly powered by a single NiCd/NiMH battery. The presented stimulator is powered by a common 9V battery. A DC-DC boost converter module (XL6009) is used in the stimulator to covert + 9V DC to a High Voltage (+ HV) DC output. XL6009 is capable of converting 3.6-36V DC to up to 42V DC voltage by it’s built-in switching capabilities. Figure 2 shows the schematics of XL6009 boost converter circuit.

An on-board variable resistor (Rv) is used to vary the output voltage of the DC-DC boost module. The output voltage of the module is determined by the following equation:

+HV = 1.25*(Rv/Rf)

If the maximum resistance of the variable resistor (Rv) is 10kΩ and the feedback resistor (Rf) value is fixed to 330Ω, the output voltage (+ HV) will be 1.25×(10/0.33) = 37.88V DC. In some modules, these values are 50kΩ and 1.5kΩ, resulting a maximum output voltage of 1.25×(50/1.5) = 41.67V DC. It is important to note that the voltage rating of the output regulating capacitor, C2 must be above the maximum output voltage. A 100μF bipolar capacitor of 50V voltage rating is used in the module.

In the presented stimulator, the 10kΩ on-board trimmer potentiometer is replaced with a 10kΩ linear single gang potentiometer with integrated on/off switch to allows varying the output voltage as well as to turn on and off the stimulator. The details procedure of this is explained in the Assembly section.

Module 2: Biphasic pulse generation by Full H-bridge driver

The output voltage of the DC-DC boost converter is still monopolar (only positive). To create a biphasic stimulation, a switching polarity or a bipolar supply (both positive and negative) is needed. This is achieved by a full H-bridge driver module (DRV8871) (Fig. 3*).* The H-bridge circuit in the driver module switches the polarity based on the binary control commands as shown in Table 1. The output voltage is measured in between OUT2 and OUT1. For the positive polarity output, IN1 is set to 0 and IN2 is set to 1, while for negative, the pins are toggled (IN1 is set to 1 and IN2 is set to 0). The DRV8871 is supplied with the high volage, +HV from the XL6009 boost converter. This setup allows in generating a maximum ± 42V output voltage for biphasic stimulation.

Table 1
H-bridge control logics of DRV8871 driver module.

IN1	IN2	OUT1	OUT2	Description
0	0	High Impedance	High Impedance	H-bridge disabled
0	1	LOW	HIGH	OUT2 + OUT1 -
1	0	HIGH	LOW	OUT2 – OUT1 +
1	1	LOW	LOW	Low-side slow decay

The maximum output current of the DRV8871 H-bridge driver module can be set by the on-board R1 resistor. By default, this value is 20kΩ to generate maximum 3.2A output current based on the following equation:

$$I_{LIM} = V_{LIM}/R1$$

V_{LIM} is a constant value of 64kV. To set the I_{LIM} to, say, 2A, R1 resistor value needed to be 32kΩ. The minimum allowed R1 value is 15kΩ.

Module 3: Logic control by microcontroller unit

Two logic (HIGH/LOW) inputs, LOGIC1 and LOGIC2 are needed to operate the H-bridge circuit of DRV8871 driver module to generating biphasic stimulation. This is achieved by Arduino Uno, one of the simplest and most accessible Microcontroller board in the market (Fig. 4). Two general purpose input/output (GPIO) pins, D9 and D10 of Arduino Uno microcontroller are connected to the DRV8871 module’s two input pins, IN1 and IN2. Arduino board is also powered by the common + V supply from the battery.

Assembly: Prototyping the stimulator

Step 1: Replace the potentiometer of XL6009 DC-DC boost converter module

To have easier access for varying the stimulation intensity and to power on/off the stimulator, on-board trimmer potentiometer (ex. 10kΩ) needed to be replaced with an external linear single gang potentiometer of the same value. For easier prototyping, the on-board trimmer is removed (de-soldered), and 3 pin headers are soldered as shown in the following image (Fig. 5). Two pairs of input-output pin headers also soldered into the input and output terminals of the XL6009 module.

Step 2: Solder all components and connections on the Arduino Uno Shield board

Next, to complete the circuit between the XL6009 DC-DC converter, DRV8871 H-bridge driver and the Microcontroller, an Arduino Uno Shield prototyping board is used. Connectors (PCB receptacles), connecting wires, the 10kΩ linear single gang potentiometer with build-in on/off switch and a 9V battery snap are soldered onto the shield board as shown in following image (Fig. 6). Since, the Arduino Uno Shield comes with PCB tracks, carefully disconnecting any unwanted track to the modules and connections are needed. The connections were carefully tested for any short-circuits using a multimeter before powering up the board.

Step 3: Program the Arduino Uno Microcontroller to generate biphasic stimulation

To program the Microcontroller, the Arduino Uno board is connected to a PC via an USB cable. After successfully selecting Arduino Uno board from the menu of Arduino IDE, the Microcontroller is programmed for GPIO 9 and 10 to logic control (HIGH/LOW) the DRV8871 H-bridge driver to generate biphasic stimulation. The program flowchart and it's corresponding Arduino code is shown in Fig. 7. After the start, two stimulation parameters (Hz and burst) are defined. Hz is the stimulating frequency and the burst is the number of biphasic pulses inside the stimulation burst. User should initiate values to these parameters. Here, 20Hz and 10 pulses are initiated to these parameters. Next, the three GPIO pins are set to output mode for the microcontroller. GPIO pins D9 and D10 are for logic control of DRV8871 H-bridge drive and GPIO pin D13 is for Arduino Uno on-board LED. Then, in a loop of 10, 10 biphasic stimulation pulses are being generated by controlling the GPIO logic pins and microseconds delays. This is essentially the active burst of the stimulation. To allow, tonic stimulation, a delay is being added after the active burst period. It is calculated by the wavelength of the stimulation frequency. Finally, to visualization that the stimulation is in operation, the Arduino Uno on-board LED is being toggled for the entire loop. The program runs in a continuous loop until it is powered off. The flushing rates of LED represents the stimulation frequency.

Results And Discussion

OpenVstim is a low-cost open-source transcutaneous voltage stimulator capable of spinal cord electrical stimulation. Figure 8 shows the prototyped stimulator powered with a common 9V battery. The stimulator contains standard Electronic Muscle Stimulation (EMS) or Transcutaneous Electrical Nerve Stimulation (TENS) lead wires to connect stimulation electrodes. On-board linear potentiometer allows the user to control the stimulation intensity as well as turn on and off the stimulator. A minimum 3.6V DC is needed to power the entire stimulator. Stimulation parameters are listed in Table 2.

Table 2
Specifications of the Transcutaneous voltage stimulator (OpenVstim).

Channel	**1 (can be expanded to more channels)**
Waveform	Biphasic square wave
Pulse Intensity	0-128mA peak into 500Ω load
Output Voltage	maximum 64V peak-to-peak
Pulse duration	50 μs (can be reprogrammed)
Interpulse Interval	1μs (can be reprogrammed)
Stimulation Frequency	20Hz (can be reprogrammed)
Carrier Frequency	10kHz (can be reprogrammed)
Power	One 9V battery

OpenVstim is a single channel voltage stimulator. However, the channel numbers can be easily increased by having more DC-DC boost converter and H-bridge driver modules. The stimulation parameters are all reprogrammable through the Arduino Uno microcontroller board. Since this is a voltage stimulator, the stimulation intensity depends on the electrode-tissue impedance. Peak intensity can be as high as 128mA for a typical 500Ω electrode-tissue impedance. Figure 9 illustrates the 10kHz biphasic burst stimulation. A 330kΩ resistive load is used to mimic the electrode-tissue impedance.

The biphasic stimulation burst generated by the OpenVstim stimulator contains few microseconds of inter-pulse interval (see Fig. 9). This is due to the slow activation of the Microcontroller's GPIO logic pins. To standardize the stimulation, a faster activation of the logic pins is needed. This can be achieved by replacing the digitalWrite function with the following binary code:

```
PORTB = B00000XY0; // faster digitalWrite operation for Arduino Uno
```

The XY are the binary value for the GPIO pins 9 and 10. Replacing XY with 00 will send logic 0 to GPIO pins 9 and 10, and 11 send logic 1. When the code is implemented, OpenVstim generates faster stimulation burst with undetectable inter-pulse interval as shown in Fig. 10.

Components and modules used to build the OpenVstim stimulator are all listed in Table 3. Total cost of building the stimulator was only AU$66.65; however, can vary based on the market and supplies of the items. Reference prices and sources of all the components are also listed in the table. Special care is given to choose the most commonly available items so that anyone can build the stimulator in anywhere in the world. One should, however, check with their local market and supplier for the availability of the components and modules. In case of unavailability, a similar module can be used, but care must be given to connect appropriate circuit and power.

Table 3
Bill of Materials (BOM) of OpenVstim with itemized cost and source link.

Item no.	Item name	Model number	Description	Key feature	Units	Price (AU$)	Example source
1	M1	Arduino Uno	Microcontroller unit (MCU)	8 bits	1	18.95	www.ebay.com.au/ itm/402150942592
2	M2	XL6009	DC-DC converter module	50 V 1.5 A max output	1	6.85	www.ebay.com.au/ itm/273707870769
3	M3	DRV8871	Full H bridge module	45 V 3.5 A max output	1	17.68	www.ebay.com.au/ itm/363862724775
4	SP1	50kΩ	Linear pot with on/off switch	5 terminals	1	5.35	www.ebay.com.au/ itm/152893232674
5	J1	Battery clip	9 V battery clip connector	T type	1	2.92	www.ebay.com.au/ itm/284538269404
6	P1	PCB board	Arduino Uno Shield board	For easy Prototyping	1	6.99	www.ebay.com.au/ itm/392331016225
7	W1	TENS cable	Electrotherapy Lead wires	To connect electrodes	1	2.46	www.ebay.com.au/ itm/254783965300
8	B1	Battery	9V	550 mAh	1	5.45	www.ebay.com.au/ itm/ 384397462542
Total cost:						AU$ 66.65	

Table 4 shows the list of transcutaneous electrical stimulators used for non-invasive spinal cord stimulation therapy in patients with neurological injuries. Most TES system utilizes constant biphasic current pulses for neuromodulation. The design presented in the report, however, utilizes constant biphasic voltage pulses. An in-depth study on constant voltage vs constant current stimulation is warranted to take full advantage of TESCS therapy on functional recovery after neurological injuries.

Table 4
List of transcutaneous electrical stimulators used by the spinal cord stimulation research groups around the world.

Name	Company	Country	Approval	Mode	Channel	Power	Price
Biostim-5 [15]	Cosyma Inc.	Moscow, Russia	N/A	Current	5	Battery	N/A
NeoStim-5 [16]		Louisville, USA	N/A	Current	5	Battery	N/A
ARC_{EX} [17]	ONWARD Medical Inc	Eindhoven, Netherlands; Lausanne, Switzerland	FDA Breakthrough Device	Current	4	Battery	N/A
Stimulette r2x [18]	Dr Schuhfried Medizintechnik GmbH	Vienna, Austria	N/A	Current	2	Line	N/A
SCONE™ [19]	SpineX Inc.	Los Angeles, USA	FDA Breakthrough Device	Current	2	Battery	N/A
SCiP [20]				Current	2	Battery	N/A
DS8R [3]	Digitimer Ltd	UK, USA and Hong Kong	CE	Current	1	Line	£8,335
OpenXstim	Present report	Australia	Un-approved	Voltage	1	Battery	A$66.65

The presented stimulator (OpenXstim) provides an easy-accessible tool for non-invasive spinal cord stimulator to arguably for most communities around the world. However, the stimulator needed to be tested in TESCS settings to examine the efficacy of spinal cord neuromodulation. In future design, a voltage-to-current converter circuit will be added in the stimulator to generate constant biphasic current stimulation. This may require dynamic monitoring of load impedance to adjust the output compliance voltage of the stimulator. For the safety of unprofessional general users, however, constant voltage TES over constant current TES is advised.

Declarations

The author declares no conflict of interests associated with this publication.

References

1. Hofstoetter, U.S., Danner, S.M. & Minassian, K. Paraspinal Magnetic and Transcutaneous Electrical Stimulation. in *Encyclopedia of Computational Neuroscience* (eds. Jaeger, D. & Jung, R.) 1–21 (Springer New York, New York, NY, 2013).
2. Gerasimenko, Y., *et al.* Transcutaneous electrical spinal-cord stimulation in humans. Annals of Physical and Rehabilitation Medicine **58**, 225–231 (2015).
3. Alam, M., *et al.* Reversing 21 years of chronic paralysis via non-invasive spinal cord neuromodulation: a case study. Annals of Clinical and Translational Neurology **7**, 829–838 (2020).

4. Minassian, K., *et al.* Posterior root–muscle reflexes elicited by transcutaneous stimulation of the human lumbosacral cord. Muscle & nerve **35**, 327–336 (2007).
5. Hofstoetter, U.S., *et al.* Modification of Reflex Responses to Lumbar Posterior Root Stimulation by Motor Tasks in Healthy Subjects. Artificial Organs **32**, 644–648 (2008).
6. Gorodnichev, R.M., *et al.* [Transcutaneous electrical stimulation of the spinal cord: non-invasive tool for activation of locomotor circuitry in human]. Fiziol Cheloveka **38**, 46–56 (2012).
7. Rahman, M.A., Tharu, N.S., Gustin, S.M., Zheng, Y.-P. & Alam, M. Trans-Spinal Electrical Stimulation Therapy for Functional Rehabilitation after Spinal Cord Injury: Review. Journal of Clinical Medicine **11**, 1550 (2022).
8. Martin, R. Utility and Feasibility of Transcutaneous Spinal Cord Stimulation for Patients With Incomplete SCI in Therapeutic Settings: A Review of Topic. Frontiers in Rehabilitation Sciences **2**(2021).
9. Alashram, A.R., Padua, E., Raju, M., Romagnoli, C. & Annino, G. Transcutaneous spinal cord stimulation effects on spasticity in patients with spinal cord injury: A systematic review. The Journal of Spinal Cord Medicine, 1–8 (2021).
10. Minassian, K., *et al.* Spinal Rhythm Generation by Step-Induced Feedback and Transcutaneous Posterior Root Stimulation in Complete Spinal Cord-Injured Individuals. Neurorehabil Neural Repair **30**, 233–243 (2016).
11. Estes, S., Zarkou, A., Hope, J.M., Suri, C. & Field-Fote, E.C. Combined Transcutaneous Spinal Stimulation and Locomotor Training to Improve Walking Function and Reduce Spasticity in Subacute Spinal Cord Injury: A Randomized Study of Clinical Feasibility and Efficacy. J Clin Med **10**(2021).
12. Qian, Q., Ling, Y.T., Zhong, H., Zheng, Y.-P. & Alam, M. Restoration of arm and hand functions via noninvasive cervical cord neuromodulation after traumatic brain injury: a case study. Brain Injury, 1–10 (2020).
13. Megía García, A., Serrano-Muñoz, D., Taylor, J., Avendaño-Coy, J. & Gómez-Soriano, J. Transcutaneous Spinal Cord Stimulation and Motor Rehabilitation in Spinal Cord Injury: A Systematic Review. Neurorehabil Neural Repair **34**, 3–12 (2020).
14. Solopova, I.A., *et al.* Effects of spinal cord stimulation on motor functions in children with cerebral palsy. Neurosci Lett **639**, 192–198 (2017).
15. Grishin, A.A., Moshonkina, T.R., Bobrova, E.V. & Gerasimenko, Y.P. A Device for the Rehabilitation Therapy of Patients with Motor Pathology Using Mechanotherapy, Transcutaneous Electrical Stimulation of the Spinal Cord, and Biological Feedback. Biomedical Engineering **53**, 227–230 (2019).
16. Parhizi, B., Barss, T.S. & Mushahwar, V.K. Simultaneous Cervical and Lumbar Spinal Cord Stimulation Induces Facilitation of Both Spinal and Corticospinal Circuitry in Humans. Frontiers in neuroscience **15**(2021).
17. Samejima, S., *et al.* Multisite Transcutaneous Spinal Stimulation for Walking and Autonomic Recovery in Motor-Incomplete Tetraplegia: A Single-Subject Design. Phys Ther **102**(2022).
18. Hofstoetter, U.S., Freundl, B., Lackner, P. & Binder, H. Transcutaneous Spinal Cord Stimulation Enhances Walking Performance and Reduces Spasticity in Individuals with Multiple Sclerosis. Brain Sciences **11**, 472 (2021).
19. Kreydin, E., Zhong, H., Lavrov, I., Edgerton, V.R. & Gad, P. The Effect of Non-invasive Spinal Cord Stimulation on Anorectal Function in Individuals With Spinal Cord Injury: A Case Series. Frontiers in neuroscience

16(2022).

20. Gad, P., *et al.* Transcutaneous Spinal Neuromodulation Reorganizes Neural Networks in Patients with Cerebral Palsy. Neurotherapeutics **18**, 1953–1962 (2021).

Figures

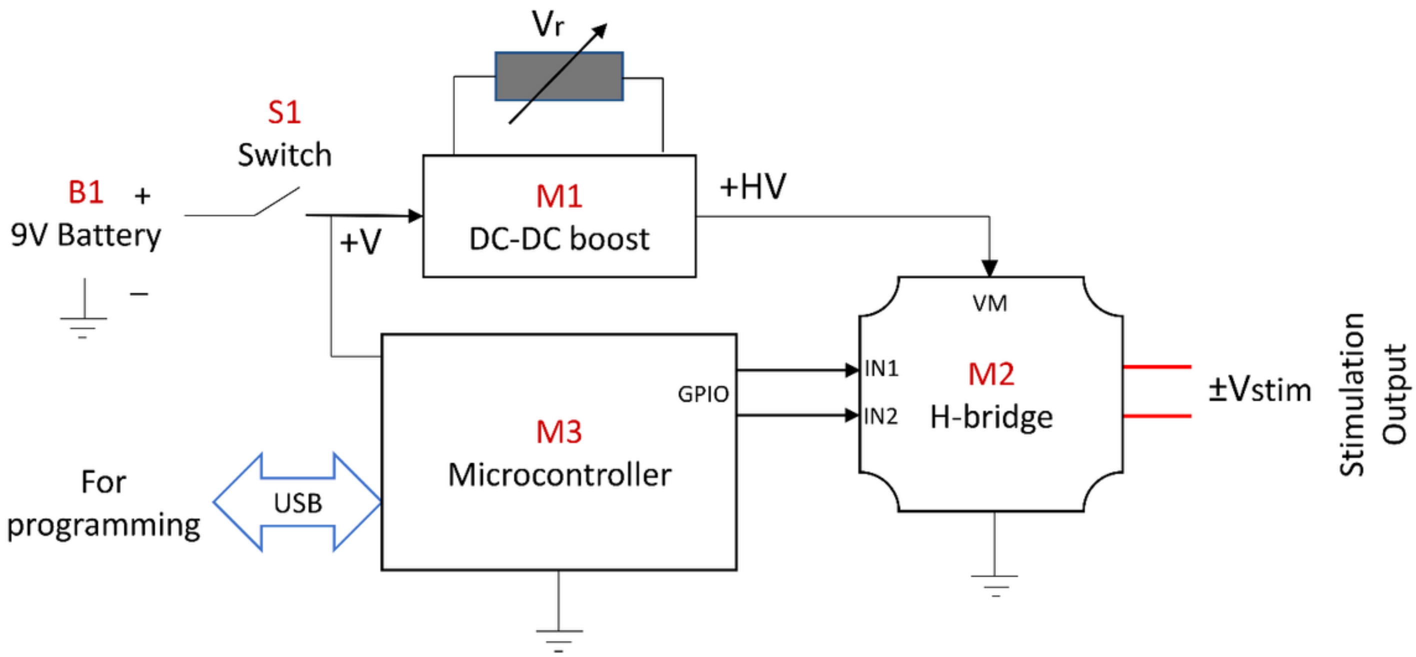

Figure 1

Block diagram of a transcutaneous voltage stimulator (OpenVstim) for spinal cord stimulation. The stimulator is built with 3 stand-alone modules, a linear potentiometer and a 9V battery. The potentiometer is used to vary the stimulation intensity as well as power on and off the stimulator.

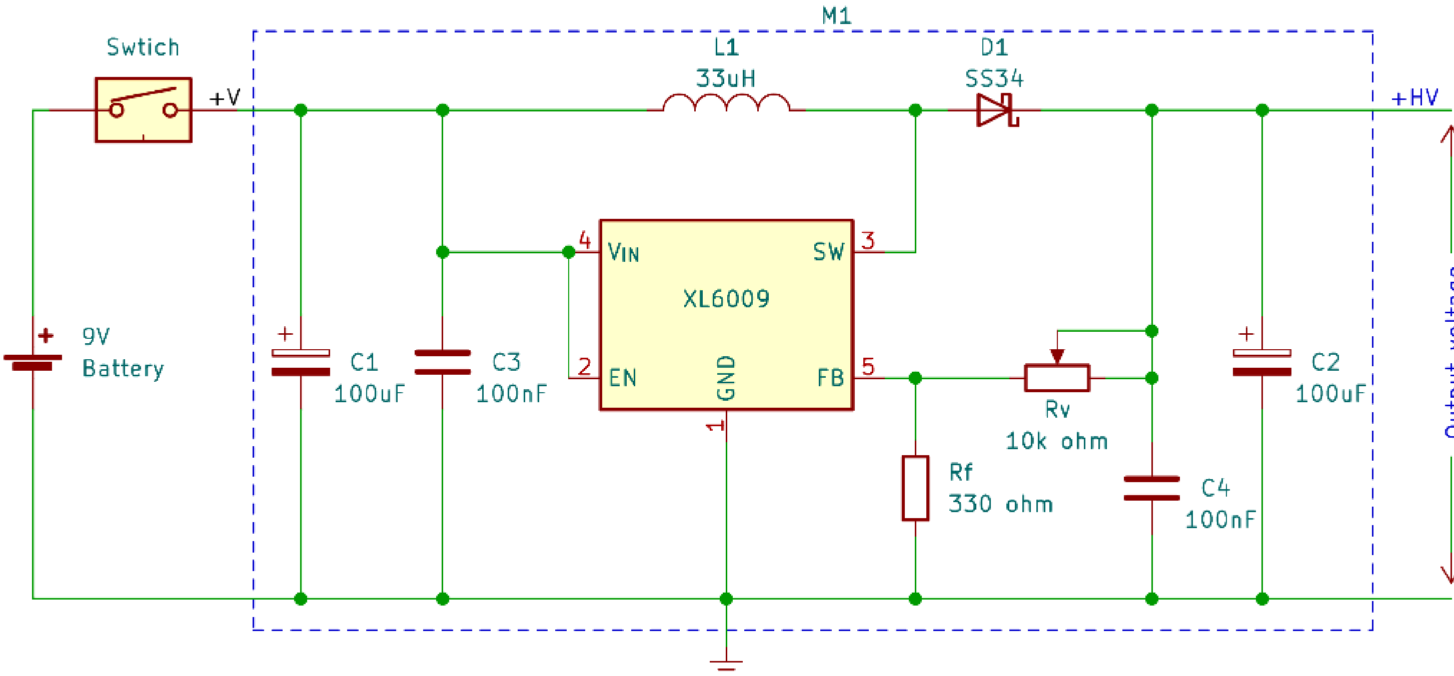

Figure 2

Schematic diagram of XL6009 DC-DC boost converter powered by a 9V battery and power switch. The dotted area indicates the off-the-shelf XL6009 module.

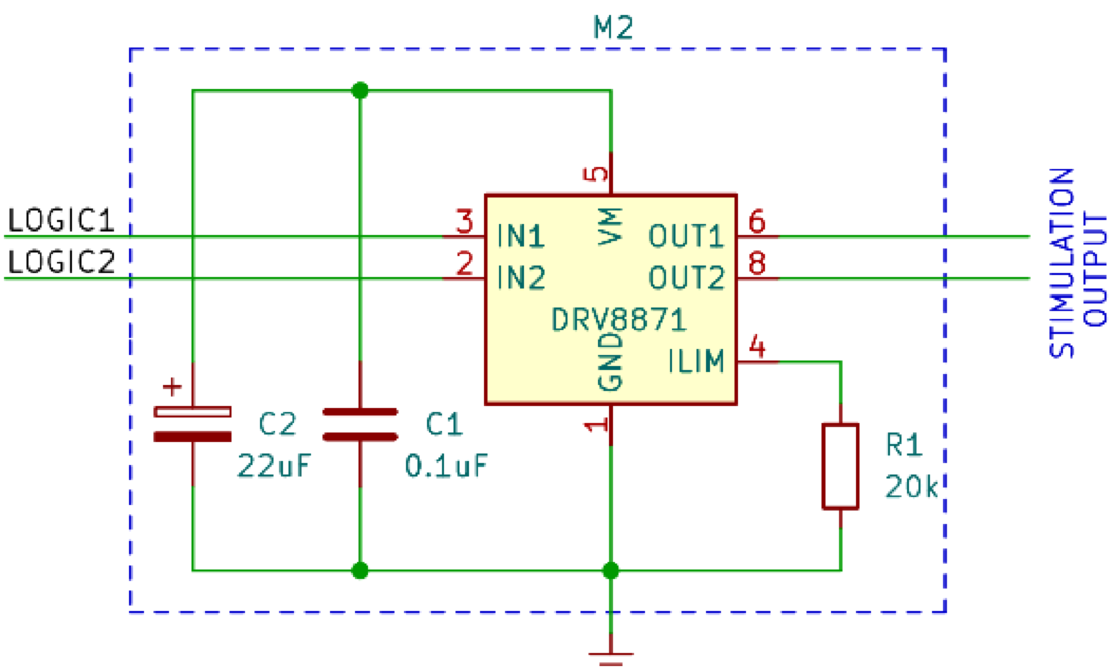

Figure 3

Schematic diagram of DRV8871 H-bridge driver controlled by two logic inputs (LOGIC1 and LOGIC2). The stimulation electrodes are connected to the output terminals: OUT1 and OUT2.

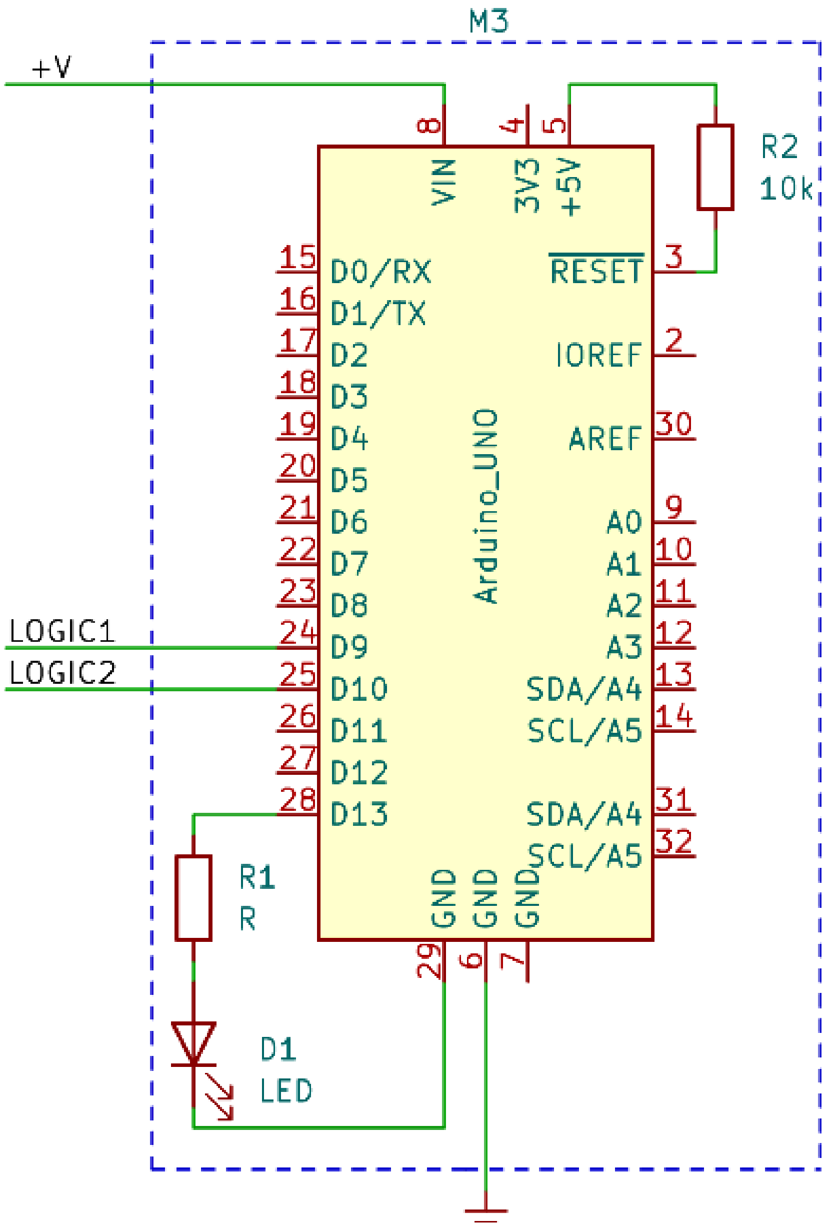

Figure 4

Arduino Uno microcontroller board. Two GPIO pins (D9 and D10) are used for logic control of the H-bride driver circuit (see *Figure 3*). The Arduino Uno has an on-board LED connected to pin D13.

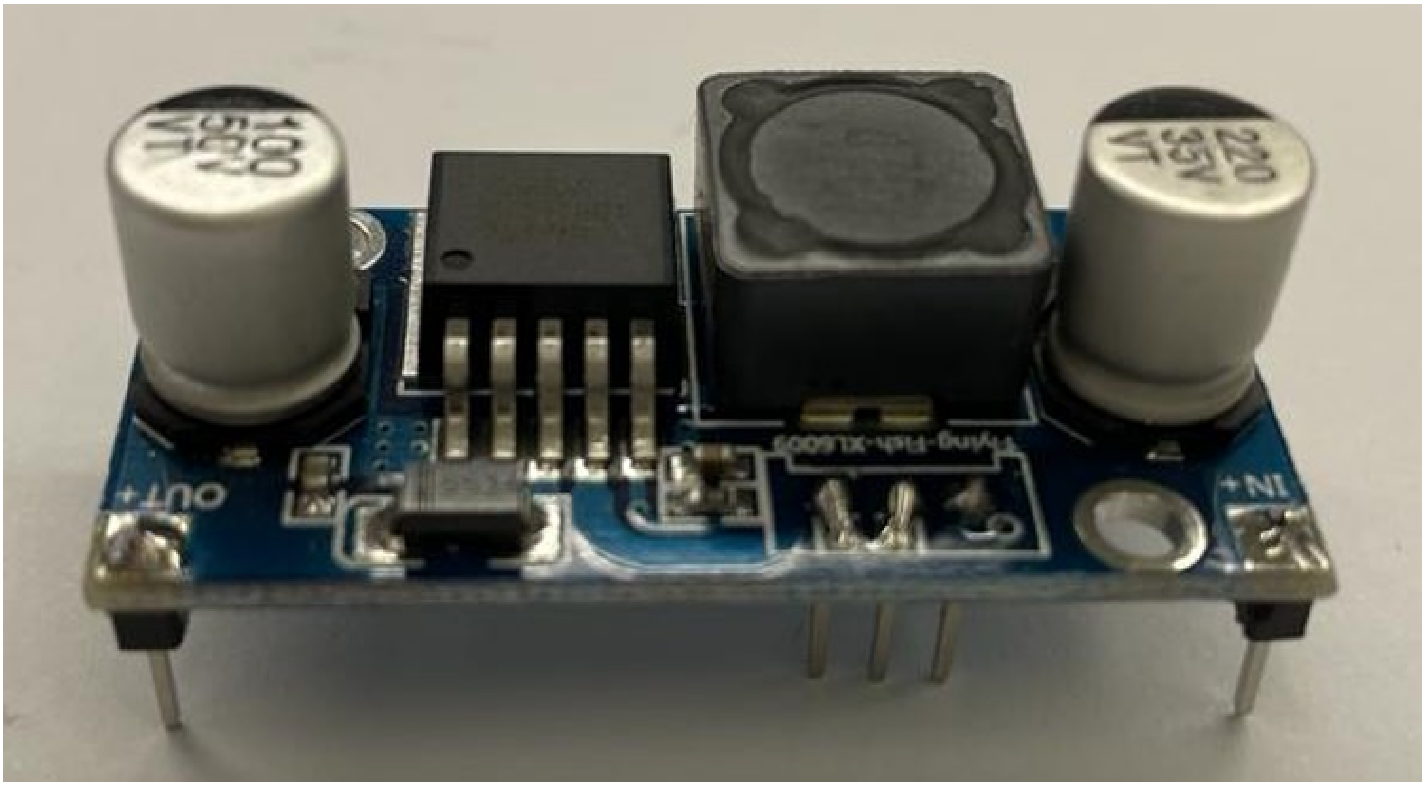

Figure 5

Modified XL6009 DC-DC converter module. On-board trimmer potentiometer is replaced with 3 pin headers.

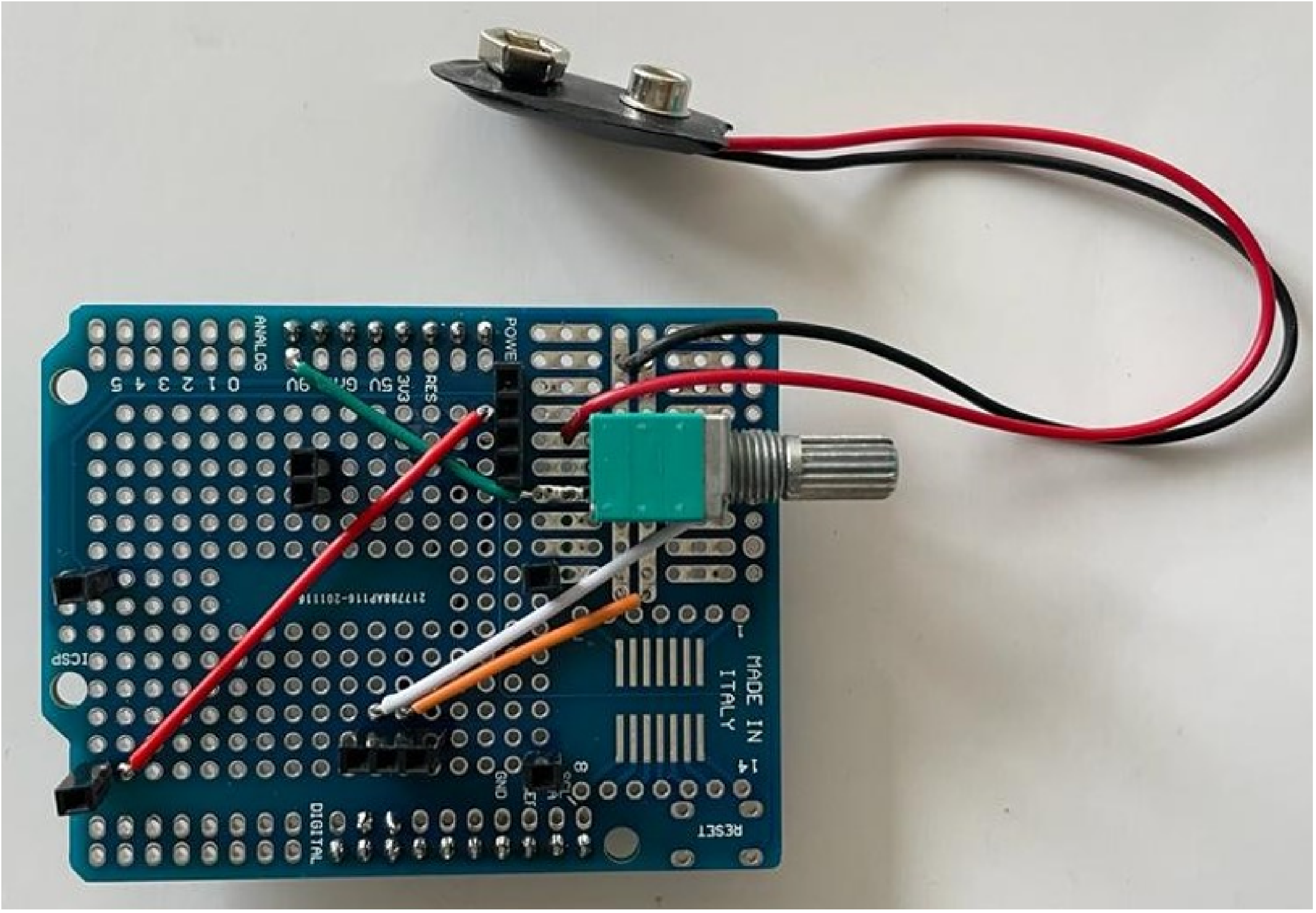

Figure 6

Arduino Uno Shield board containing connecting wires, PCB receptacles, a 10kΩ linear single gang potentiometer with built-in on/off switch and a 9V battery snap connector.

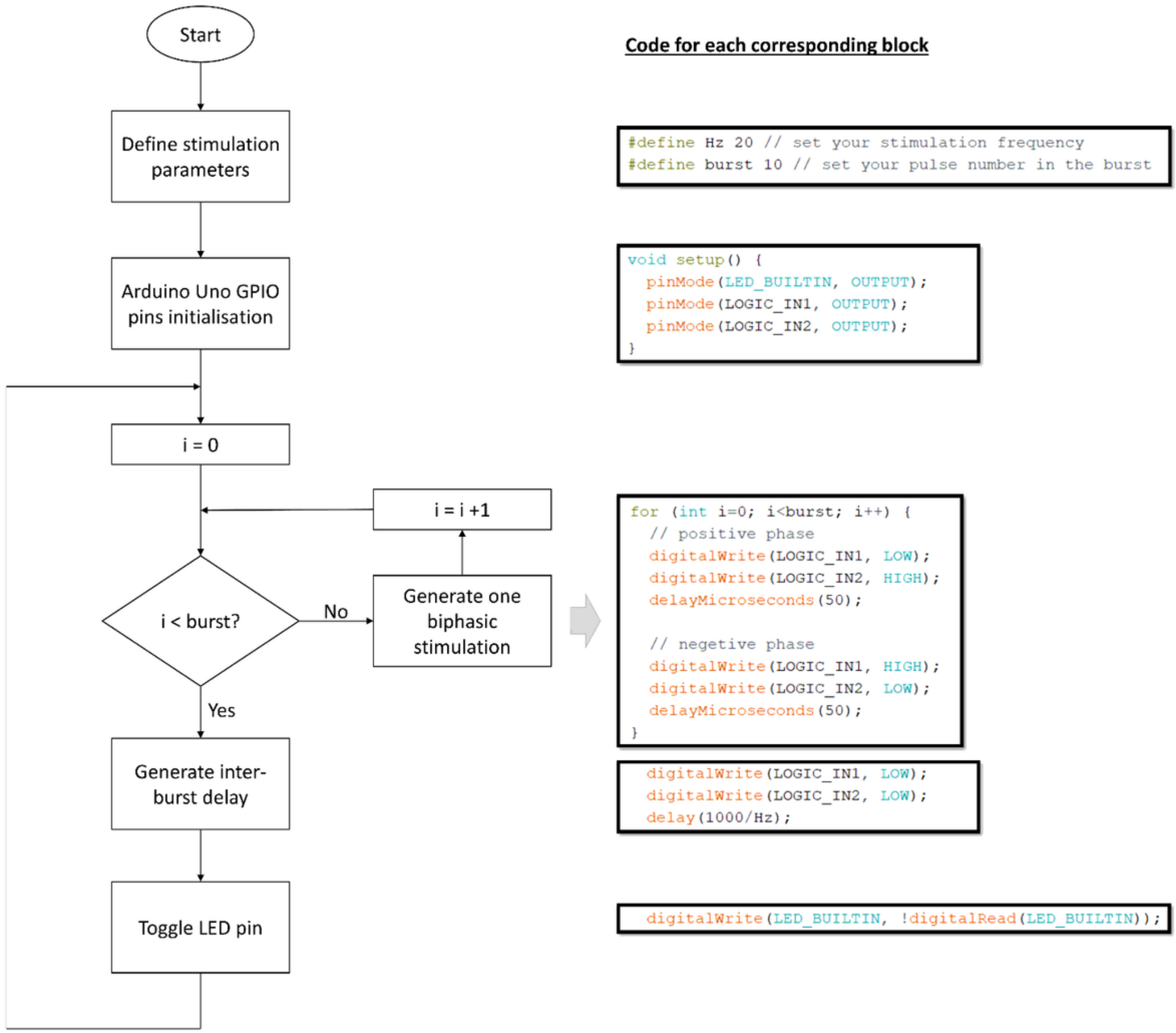

Figure 7

Program flowchart (left) and corresponding code (right).

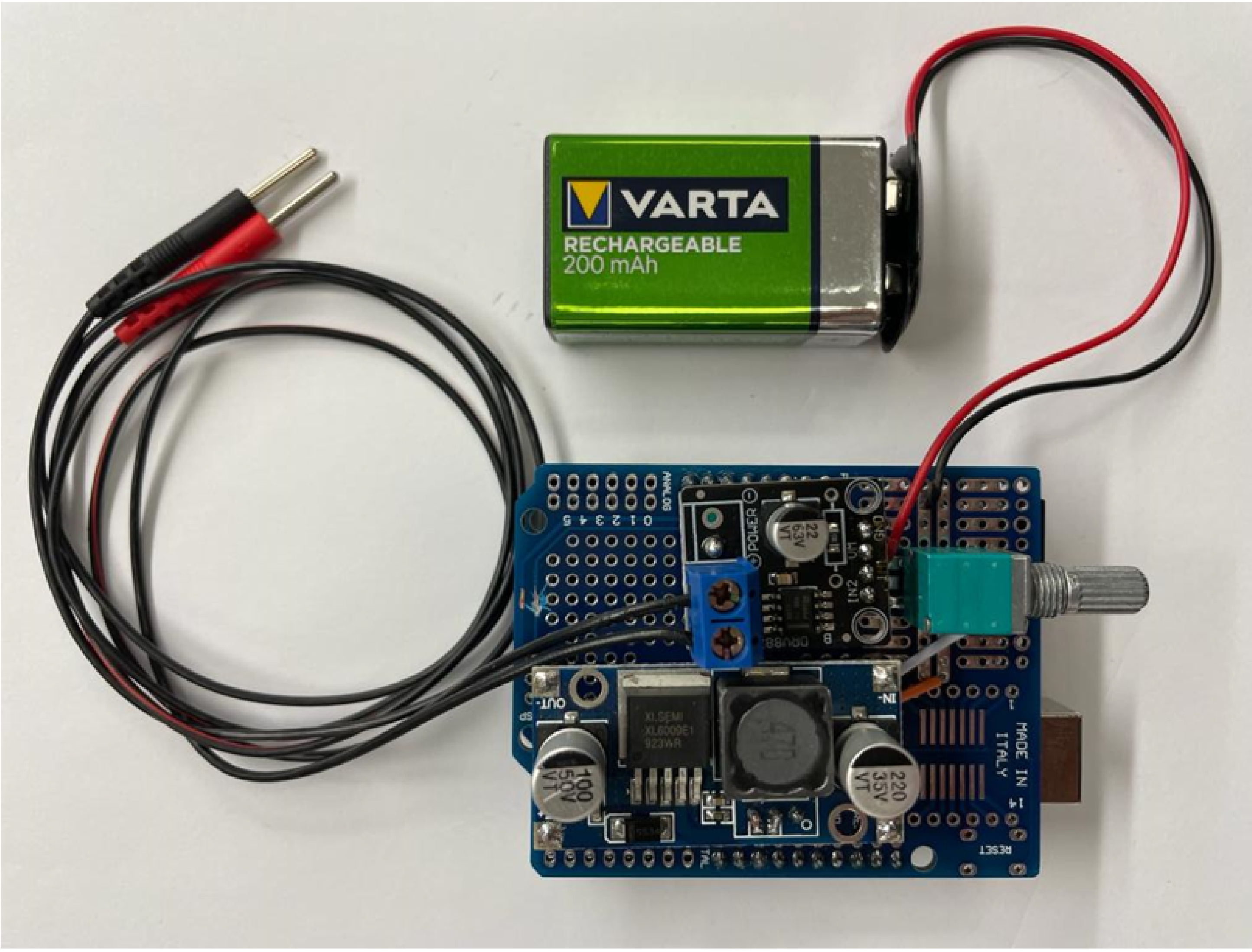

Figure 8

OpenVstim, open-source transcutaneous electrical stimulator with standard EMS/TENS lead wires to connect stimulation electrodes. The linear potentiometer controls the intensity of the stimulation as well as switches on and off the stimulator. A 9V battery is used to power the stimulator.

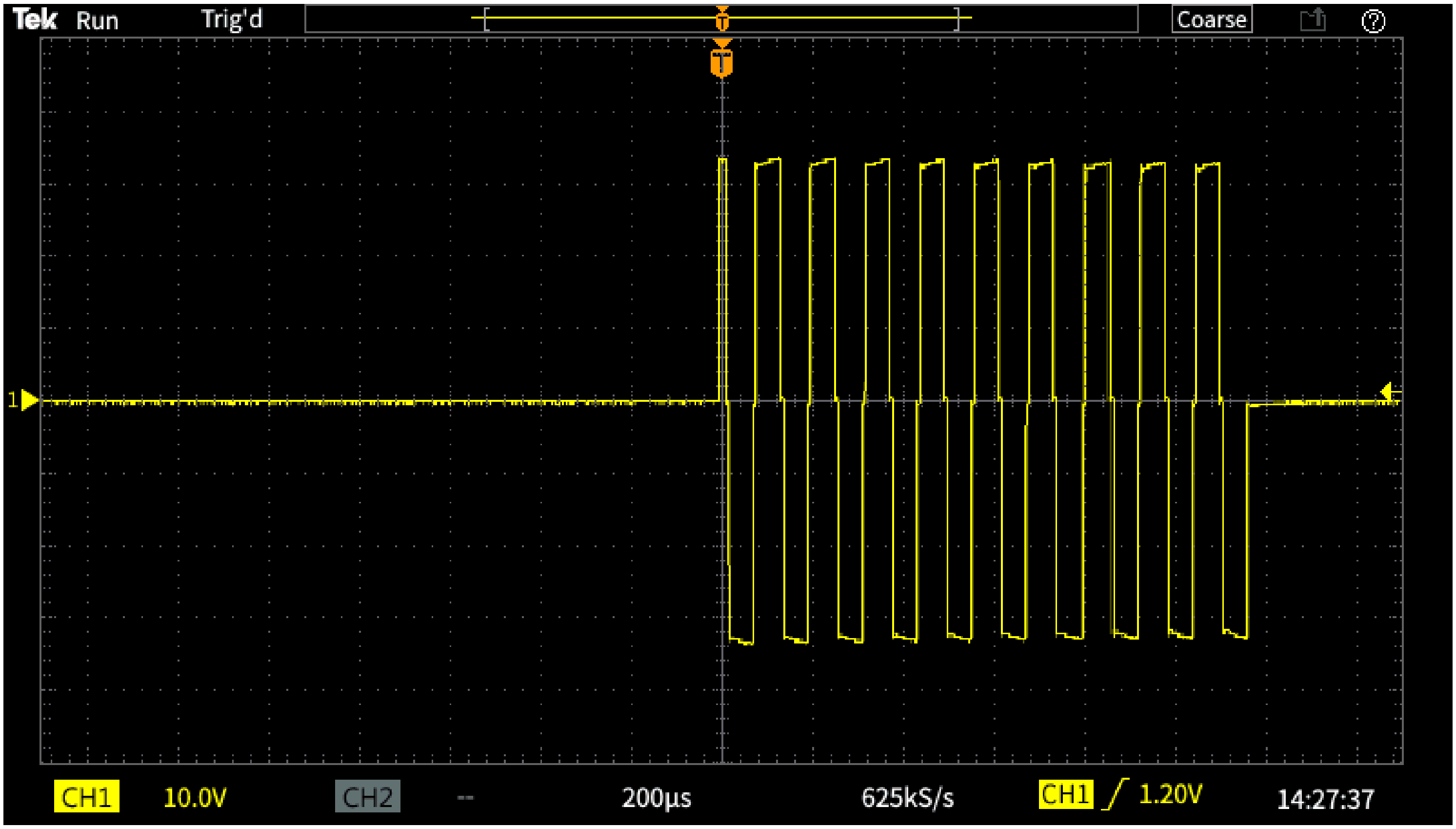

Figure 9

Biphasic stimulation (10kHz burst of 10 biphasic pulses) with peak-to-peak voltage of 64V.

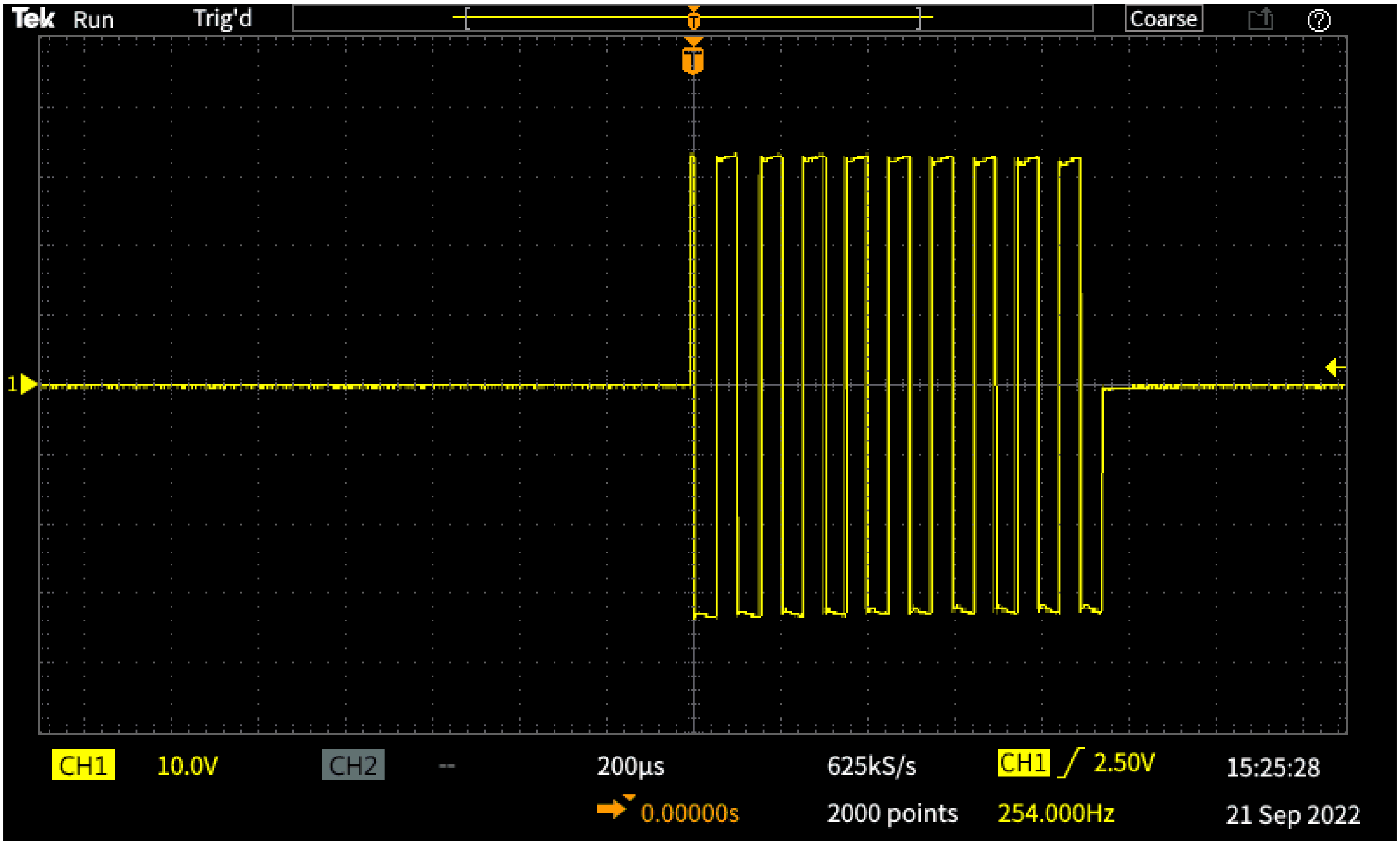

Figure 10

Fast biphasic stimulation with non-traceable inter-pulse interval.