Tele-tDCS: A Novel Tele-neuromodulation Framework using Internet of Medical Things

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Abstract: As part of the Internet of Medical Things (IoMT) within Biomedical Engineering, telehealth is an emerging field. Due to the recent events surrounding COVID-19, it has become obvious that Telehealth treatments must be developed as a means of protecting vulnerable patients in hospitals by reducing the need to visit and therefore reducing risk to physicians. This paper investigates the feasibility of developing a non-invasive remote neuro-stimulation system using internet-based transcranial Direct Current Stimulation (tDCS). A hardware-based prototype tDCS device has been developed to be controlled using a remote command-line interface over the internet. As a result, a physician can remotely set the parameters for the tDCS treatment and monitor the treatment in real-time to ensure patient safety. In this study, the feasibility of a Tele-tDCS system was investigated, as well as the capabilities a Tele-tDCS system should offer to patients.

1 INTRODUCTION

Telehealth is an evolving field, a part of the Internet of Medical Things (IoMT) within Biomedical Engineering. In current society, it is of growing significance to develop such systems, as it allows patients to be treated remotely by physicians. However, models must be in place to ensure that the treatments may be performed appropriately, taking into consideration the security risks associated with the IoMT (Hall *et al.*, 2014). Recent events involving COVID-19 make it clear that there is a need for telehealth treatments to be developed because of the benefits of protecting vulnerable patients by reducing the need for visits to hospitals and other clinical settings, and also reducing risk to physicians through less physical patient contact (Smith *et al.*, 2020).

Transcranial Direct Current Stimulation (tDCS) has been used in neurorehabilitation for many years to effectively increase or decrease mental function and learning (Bucur *et al.*, 2018) and it is considered to safe and widely accepted (Bikson *et al.*, 2016). The use of tDCS for treating neurological disorders such as Parkinson's disease and other movement-related disorders has been considered in several studies (Boggio *et al.*, 2006; Lefaucheur *et al.*, 2017). It has been demonstrated that such treatments are effective in a wide range of patients with neuro disorders, where tDCS treatment has improved quality of life (QoL) in patients who would otherwise suffer significantly (Leite *et al.*, 2014). In order to obtain the desired results with tDCS systems, researchers typically need to work with patients. This is because these types of systems are required to precisely target and focus on specific areas of the brain for stimulation (Park *et al.*, 2011). In addition, tDCS systems can be very expensive, limiting their use to specialist units with facilities where they exist (Zaghi *et al.*, 2009). Consequently, new approaches to performing tDCS have been developed for improving patient outreach. As an example, the methods mentioned by Sourav (2017) are built on open source framework to provide the same therapies, ultimately benefiting more patients. However, such systems are still under development and susceptible to certain limitations, such as the accuracy of actual output currents and the efficacy of the system.

As tDCS treatments require specialised clinician supervision, treatment monitoring and delivery are essential features of any novel tDCS system. By

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providing remote and cloud-based services for such treatment, more patients could be reached. This study will explore how tDCS could be utilised by doctors remotely using cloud-based applications. A system like this must take into consideration legal and ethical implications, including the need for safe testing and development prior to clinical trials. As a result, these automated remote solutions have to be secure and must pose no risk to patient privacy or abuse or misuse of tDCS treatments. In order to keep costs down and make the device more affordable for patients, this study will explore use of off-the-shelf components in the hardware design.

The remainder of the paper is organised as follows: Section 2 discusses the optimal conditions reported in the literature for tDCS treatments, Section 3 discusses the effects of tDCS on patients from previous studies, Section 4 presents the proposed framework and use cases for evaluating the system, Section 5 explains the development of the remote software interface, Section 6 describes the hardware components of the system, Section 7 reports the results of the evaluation of the system, and Section 8 concludes the paper and suggests directions for future work.

2 TRANSCRANIAL DIRECT CURRENT STIMULATION

The tDCS is a non-invasive brain stimulation technique, used to modulate the excitability of the central nervous system in humans (Woods *et al.*, 2016). The aim of stimulating the central nervous system is to change the discharge of neurons in the brain. The effects of the altered neurons have effects that may be potentially positive or negative for a patient. There have been a number of studies investigating optimum testing parameters for patients undergoing a tDCS treatment. These parameters include session durations (minutes), current doses (mA) and session timelines. The aim is to discover the optimum conditions to produce the greatest long-term cognitive plasticity improvement (Fertonani *et al.*, 2014).

A study conducted by Bikson *et al.* (2009) established the safety limits for tDCS treatments and suggested the average treatment time to be 20 minutes, at a range of 5-30 minutes. The duration of treatment depends on the neurophysician's prescription for each session, as confirmed by Thair *et al.* (2017). Therefore, any tDCS system being developed would need to have the capability of

performing optimally throughout the treatment duration, potentially 30 minutes (Bikson *et al.*, 2009; Thair *et al.*, 2017). Additionally, studies have been conducted to determine whether current tDCS doses are both safe for patients and provide a sufficient level of stimulation to see positive results. Research from Parazzini *et al.* (2014) found that 1 mA had no brain-stem interference, so is an appropriate dose for prolonged tDCS treatment up to 30 minutes. An earlier study by Parazzini *et al.* (2013) found a dose below 2 mA did not affect the heart, indicating a safe current range of 1 to 2 mA. Once again, a doctor would prescribe a precise amount for the patient (Parazzini *et al.*, 2014; Parazzini *et al.*, 2013).

Finally, the number of sessions needed to achieve the optimum neurological and cognitive improvement is also an integral part of the treatment. Studies from Castillo-Saavedra *et al.* (2015) showed that five sessions per week were the optimal number. These results were mirrored by Loo *et al.* (2010) with treatments lasting between two and eight weeks. However, no further improvements were observed after week six. In cases where the number of sessions were exceeded, there was a risk of minor negative effects on the patients (Loo *et al.*, 2010). Therefore, the platform must support a scheduling or control mechanism to protect the patient in accordance with the physician's instructions.

In order to prove any tDCS system is successful in treating a patient, there have been randomised sham tDCS studies, where the device suggests to the patient that the system is providing the current to the patient. However, in reality no current is administered – this is called a sham or placebo tDCS trial (Palm *et al.*, 2013; Palm *et al.*, 2012). While such studies describe methodologies to perform sham tDCS trials, they don't discuss a device specific method that would allow the hardware platform to automate the process by providing both fake and real treatments to the patients. Previous studies only suggest a random cross-over mechanism during the middle of the trial by swapping patients between sham or real tDCS treatments (Palm *et al.*, 2012). Therefore, further investigations are needed to automate the integration of placebo and real treatments into the hardware platform.

3 EFFECTS OF tDCS ON PATIENTS

Several studies have been conducted on the benefits of tDCS for treating a variety of health conditions,

from relatively simple cognitive improvements (cognitive neuroplasticity) to treating depression, Parkinson's disease, dyslexia, and fibromyalgia with the goal to improve patient QoL (Fregni *et al.*, 2006; Boggio *et al.*, 2006). Figure 1 illustrates how tDCS significantly improved cognitive reaction times of patients with Parkinson's disease. It shows improvement in both 1 mA and 2 mA doses. With up to 15% increase in response time to some patients, tDCS has the potential to improve QoL for many patients. While the studies show direct improvements in patients, they do not examine in detail the exact varying parameters of treatment, even if this is a relatively minor variation in current, due to varying load resistance (through the patient's head), device output voltage or overall power output. From patient to patient, the head size and skull thickness will vary, which means that there is a wide variance in head resistance, with the average being 7560 +/- 4130 Ohm-cm (Law, 1993). To account for physiological differences, additional studies need to be undertaken to explore more precise parameter values, including the variations in load output during tDCS treatments for a wide range of patients.
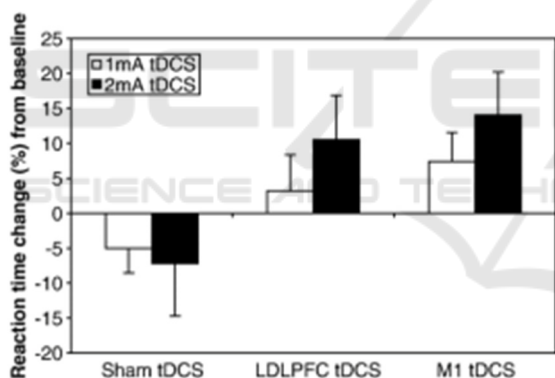

Figure 1: Response time improvements from patient's with Parkinson's Disease (Boggio *et al.*, 2006).

As discussed previously, research has been conducted to explore the suggested parameter ranges for patients and define treatment durations (Bikson *et al.*, 2009; Bikson *et al.*, 2016). Yet little is known about the design of tDCS devices. Specifically, the design decisions that have been made to ensure that patients receive their treatment safely. This may involve safety-net systems that work both autonomously or manual overrides to stop incorrect treatment current doses or durations. To put such a system into the hands of a large and possibly unrestricted group of patients, it must be explored how the tDCS devices can be controlled with a high degree of precision.

4 PROPOSED Tele-tDCS FRAMEWORK

The cloud communication is an important element of a Tele-tDCS platform to protect both patients and physicians. Studies have demonstrated the use of Tele-tDCS devices where patients are treated remotely after receiving the specialist device, and doctors work remotely with patients via video conferencing (Cucca, *et al.*, 2019). Although this framework provided a mechanism for delivering a patient's required dose in line with current tDCS safety regulations and guidelines (Bikson *et al.*, 2009; Bikson *et al.*, 2016), it did not provide a mechanism for collecting real-time data about individual treatment parameters or details regarding patient's conditions. Additionally, it does not discuss further safety mechanisms that allow the device to deliver the correct dose to the patient or the ability for the doctor to remotely control it. In this paper, a novel IoMT device is presented that facilitates bi-directional communication between a patient's tDCS device held remotely (such as at their home) and a physician's software interface.

Figure 2 demonstrates the treatment process in the Tele-tDCS framework. Each element of the process is indicated with a change of colour in the figure. The first phase (blue), is checking the device is online. If confirmed, the Command Line Interface (CLI) of the system provides the option to set the tDCS treatment parameters. Once set, the treatment is considered authorised and waits for the patient starting the treatment through a button press on the device. The confirmation triggers a start signal to be sent from the tDCS device to the CLI. Once received, the CLI enters a loop for the duration of the treatment, where it regularly polls the tDCS device to collect the real-time treatment values. This looping mechanism also contains a treatment abort loop, which checks for connection loss between the CLI and the device, as well as checking to see whether the physician or patient has stopped the treatment.

For the prototype system a publicly available secure platform, Particle Cloud (Particle, 2020), was used as the data hub for the framework. However, clinic's private cloud system would be the obvious choice when the device is manufactured after the validation stage for trust and security reasons. Particle have released a white paper that contains a security checklist for all applications on their network (Particle, 2020). API requests sent between the device and the remote software interface utilise a 2048-bit TLS certificate which uses HTTPS as a required protocol.
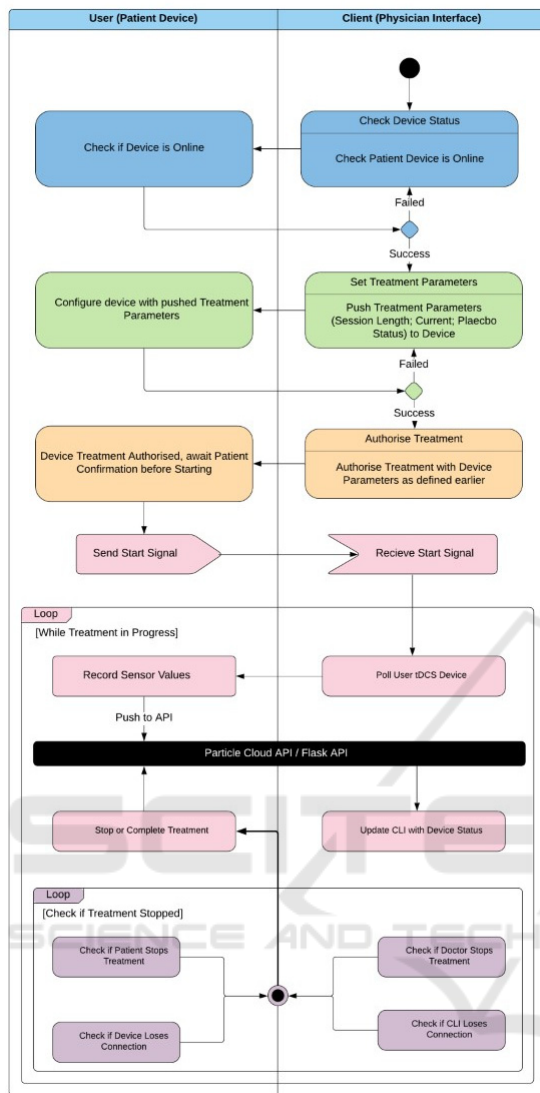
Figure 2: Tele-tDCS data flow diagram.

4.1 Use Case 1: Set Treatment Parameters

The first use case of the framework is the ability to set treatment parameters in the tDCS device. There are three variables of interest: session length, current status, and placebo status. In this scenario, the doctor will access the client and define these parameters within the acceptable safety ranges for tDCS treatments. In this case, they stand for 1-60 minutes, 1-2 mA, and True/False for duration, current state, and placebo status, respectively. This range falls within the standard practice guidelines for tDCS treatments (Bikson *et al.*, 2009; Bikson *et al.*, 2016; Thair *et al.*, 2017). Consequently, only appropriate treatment values will be allowed to be entered via the physician's interface while parsing the inputs at the point of data entry.

4.2 Use Case 2: Monitor Treatment Progress in Real-time

Another use case of the framework is to record sensor data in real-time during treatments. The objective is to emulate the ability of a doctor to be part of a patient's care in real-time. Monitoring can be performed for all treatment parameters as well as incoming parameters from sensors using the I2C Protocol (SparkFun, 2020).

4.3 Use Case 3: Patient Treatment Safety Mechanisms

Safeguarding patients is one of the most important aspects of Telehealth devices. Tele-tDCS systems must ensure patient safety throughout the treatment period (Riggs *et al.*, 2018). Although there are systems that provide remote monitoring so that a physician can monitor the patient before tDCS delivers the dose, this remote monitoring does not provide the ability to abort a treatment by physicians remotely if necessary. Similarly, the patient or caregiver may need to end the treatment at any time. The proposed Tele-tDCS device will implement this through a regular polling mechanism between the physician's CLI and the user's tDCS device. This is a passive safety mechanism that can be operated manually; however, real safety mechanisms should be a combination of active and passive safety mechanisms. The proposed tDCS device overcomes these flaws by providing active safety systems on-board that enable tracking and monitoring of the output current and other treatment parameters. A parameter deviation will immediately stop the dose

In addition to the secure API calls, the device uses the OAuth 2.0 Standard for secure device login when creating tokens for User to Client Communications. These standards used for the proposed prototype IoMT Tele-tDCS system ensure that all data on the device, inbound and outbound are secure and users are not at risk being compromised by unauthorised actors during a treatment. In the future, as medical needs evolve, this framework allows for more functional safety-oriented Tele-treatments, in contrast to closed proprietary systems that cannot be modified (Cucca *et al.*, 2019). In addition to architectural descriptions for secure operational features, following use cases were considered to evaluate system's behaviour from user's point of view.

from being delivered to the patient, and an alert will immediately be sent to the physician's CLI.

5 REMOTE INTERFACE

Remote CLI was developed to provide a reliable connection to the Particle Platform using secure API requests and OAuth tokens. Among the variables stored on this platform are the treatment parameters (Current, Session Length, Placebo Status) as well as the device status and a selection of other relevant variables. At device start-up configuration, a particle class specific to each device is called (as shown in Figure 3), revealing its status. These variables are made publicly accessible via the Particle Class.

```
1.  Particle.variable("ping", ping);
2.
3.  Particle.variable("actualCurrent", actualCurrent);
4.  Particle.variable("busVoltage", busVoltage);
5.  Particle.variable("powerOutput", powerOutput);
6.  Particle.variable("relayClosed", relayClosed);
7.
8.  Particle.variable("deviceMode", deviceMode);
9.  Particle.variable("targetCurrent", targetCurrent);
10. Particle.variable("sessionLength", sessionLength);
11. Particle.variable("placeboStatus", placeboStatus);
12.
13. Particle.function("setMode", setDeviceMode);
14. Particle.function("setCurrent", setCurrentTarget);
15. Particle.function("setLength", setSessionLength);
16. Particle.function("setPlacebo", setPlaceboStatus);
```

Figure 3: Particle microcontroller setup code.

Figure 4: Tele-tDCS physician's CLI login.

Using the Click Library, the CLI was written in Python 3.7. The library provides all the necessary error handling for parameters (Pallets, 2020). In order to run the CLI, the physician will need to install a Python 3.7 emulator and Click, with all its dependencies installed. To use the Tele-tDCS System, the physician connects to the tDCS Controller's CLI as shown in Figure 4. This interface allows the physician to define the tDCS treatment parameters within the expected safe ranges. The system also checks input data to ensure the requested parameters are within an acceptable range and

suggests help texts where incorrect parameters have been entered (Figure 5).

Figure 5: System checks incorrect inputs.

Figure 6: Help page option for each of the treatment.

In the CLI, parameters will be passed to the device that are safe for the majority of patients, although the final parameter values are determined by the physician. The system also includes a doctor's name, as well as a password access to the system to be used for both security and for logging treatment information. In the event of any ambiguities, or if the physician is using the utility for the first time, they may refer to the CLI's inbuilt help page which defines the system's permitted parameters, as shown in Figure 6, to allow successful setting of the treatment parameters

6 Tele-tDCS DEVICE HARDWARE

6.1 Tele-tDCS Device Circuit

In Figure 7, the detailed breadboard schematic of the proposed Tele-tDCS device circuit is shown. Power for the current dose is supplied by a Li-ion battery, which powers both the microcontroller of the Particle Argon as well as the Adafruit Power Boost 1000B IC.
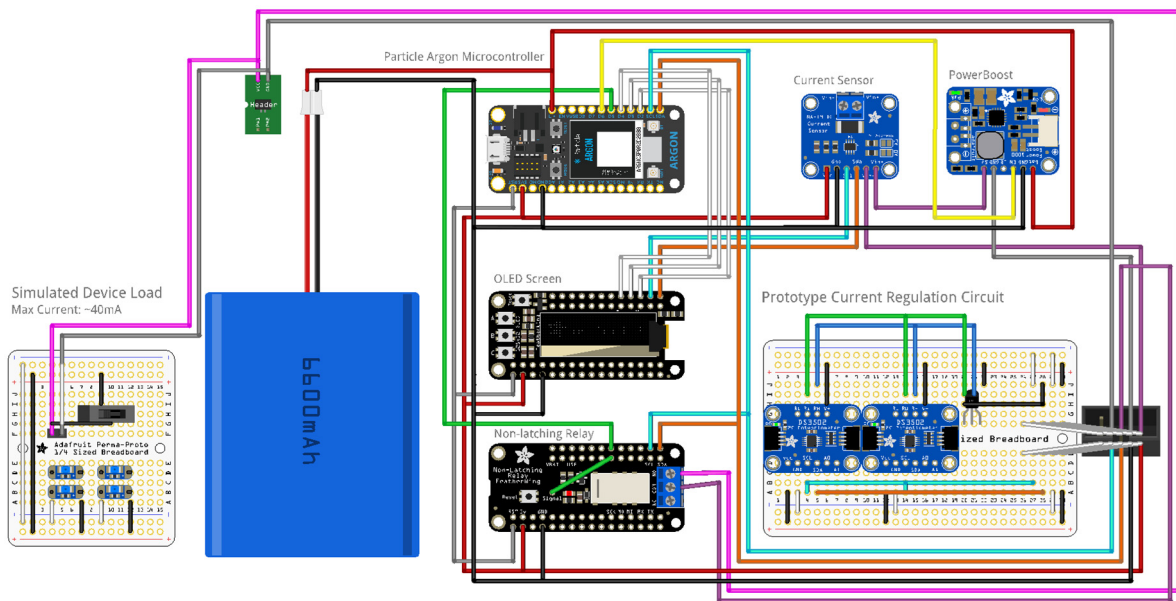
Figure 7: Tele-tDCS graphical breadboard schematic.

It is important to note that the microcontroller's power supply and the power boost supply are fully isolated. This ensures that as the load from the microcontroller changes in usage, there will not be any potential interference with the patient's DC load.

The current dose the patient requires is of low amplitude, so an acceptable error range is very small, with the prototype having a minimum resolution of $\pm$ 0.1mA. The microcontroller can control the Power Boost by pulling the 'EN' pin low from the D6 pin; this can be seen as a yellow line in Figure 7. Therefore, in placebo scenarios, the power can be turned off without the patient's knowledge, removing potential bias in the trials.

Upon powering up the Power Boost, its 5V output is directly connected to the current sensor (via the Vin pin), allowing the microcontroller to monitor the current output from the Power Boost. Sensor readings are then polled by the system through the SCL and SDA pins. These allow sensor data to be shared via an I^2C Protocol connection between the two ICs. Vout from the current sensor connects to Vin from the current regulation prototype circuit, which provides a set current value out to the patient.

In Figure 7, the purple connection indicates the Vin pin connection. One of the circuit's active safety mechanisms is implemented through a Non-Latching Relay, which acts as a safety barrier between the patient and the device. There are two features in this,one controlled by the microcontroller and the other controlled by the non-latching relay. First, if a deviation occurs from the prescribed treatment

parameters, the microcontroller will immediately cease administering the treatment. Also, the relay shares Vcc (power lines) with the microcontroller. As a result, if the microcontroller loses power, the relay will automatically open, stopping any dose from being delivered to the patient.

6.2 Current Regulator Circuit

In comparison to other tDCS systems (Sourav *et al.*, 2017), the current regulation circuit provides a variable current that can be digitally controlled in real-time. By knowing the precise current measurement, the microcontroller dynamically adjusts the digital potentiometers wiper values to provide the required current to the patient. Through a dynamic adjustment process the current sensor calculates the required resistance needed from the Digital Potentiometers (Digi Pots) for the LM344 Current Regulator. The logic to dynamically adjust the wiper values is shown in Figure 8, where first the sensor for current is being read and then compared with the target value. If the actual current is greater than the target value, then the Digi Pot wiper value is increased.

Figure 9 shows the Digi Pots with the required connections for LM344. The default values of the Digi Pots were 64 and 32, respectively. After experimentation, these values were found to provide the required target current of 1mA. Using two Digi pots in series, resistance values were varied for the LM344 Circuit Regulator. The values of 64 and 32
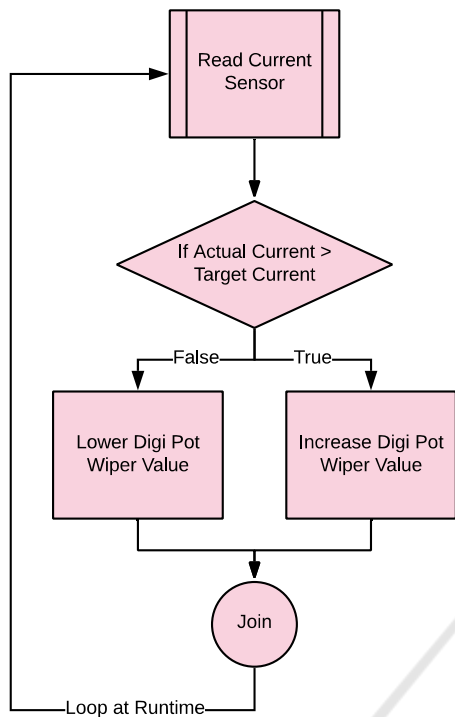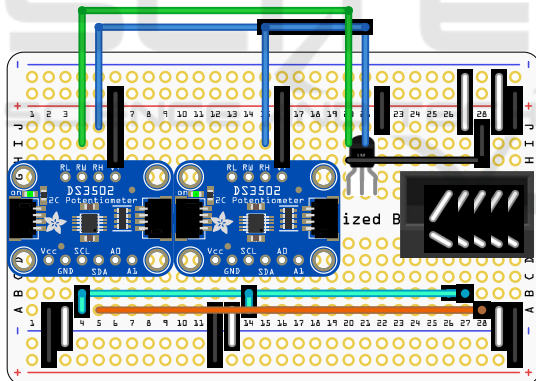
Figure 8: Dynamic adjustment of Wiper values.

Figure 9: Current regulator breadboard schematic.

are set to DS3502_0 and DS3502_1, respectively. They are set within the 7-bit wiper register, seen in the datasheet of the Digi Pots (Figure 10). This allows the device an approximate current output of 1 ± 0.5mA, calculated through trials with the device. However, these Digi Pots would also allow for a higher current should the tDCS treatment require alternative current values.
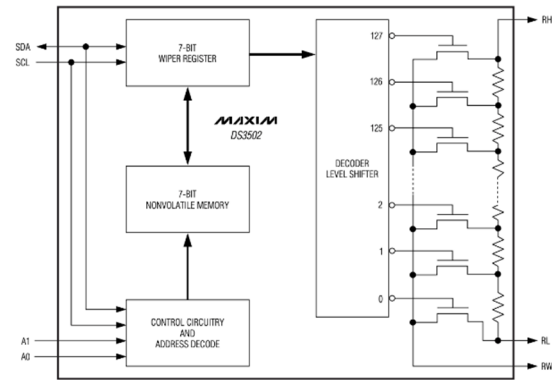

Figure 10: DS3502 datasheet (Maxim, 2009).

Once the device is turned on, during configuration, it is possible to configure it to reach a more precise current output within 0.1mA by adjusting the Digi Pot Wiper Values. Changing wiper values would take less than five seconds, Alternatively, wiper settings can be adjusted for specific current values during calibration, such that during operation the device skips the wiper setting time to deliver the same current.

6.3 Tele-tDCS Device Interface

Upon turning on the Tele-tDCS device, it will perform basic configuration and setup, which includes connecting to the Wi-Fi network, or other available web platforms in the vicinity. The system will then enter an "Awaiting Physician Configuration" mode, shown in Figure 11, when it awaits for the treatment parameters to be sent from the physician's CLI (as shown in Figure 12).
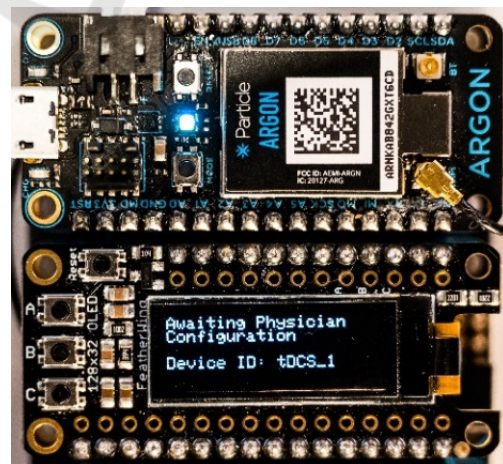

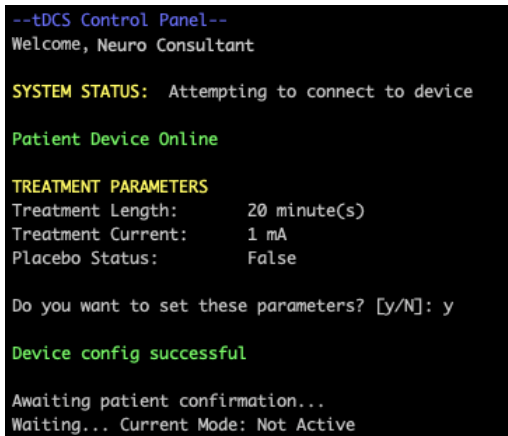Figure 11: Tele-tDCS device interface.

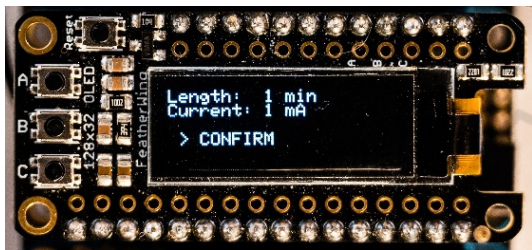Figure 12: CLI setting device's treatment parameters.
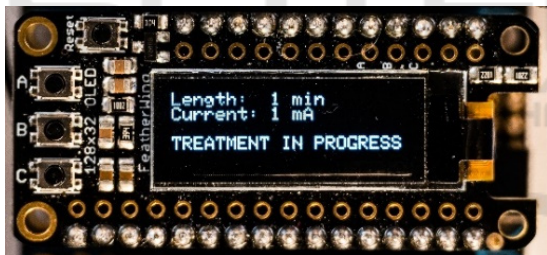

Figure 13: CLI prompting the user to confirm.

Figure 14: Device status during treatment.

The RGB Status LED is shown in Figure 11 as being a blue colour, indicating that the device is connected to the Particle Cloud. Once the parameters have been pushed by the physician using CLI control panel (Figure 12), the patient should have the final confirmation to start the treatment when they are ready. Figure 13 demonstrates device interface prompting the user to confirm the treatment parameters and begin the treatment. Once confirmed, Tele-tDCS Device Interface shows the user the 'TREATMENT IN PROGRESS' in Figure 14. As the treatment starts, the real-time monitoring also begins, and the device will push the sensor readings to the Particle Cloud API, ready to be received by the CLI.

7 EVALUATION OF THE SYSTEM

Experiments were conducted to evaluate the system for all three use cases outlined in the framework, described in Section 4. A dummy load was used to test the operation and functionality of the Tele-tDCS system without any human presence. This was done to verify the circuit functionality and safety. Upon receiving ethical approval in the future, human trials will be carried out.

In the first use case, framework's ability to manage tDCS treatment parameters was tested. This test was necessary to ensure usability of the system, as well as simplicity and clarity of use. Furthermore, it is important to verify that the communication between the physician and the device is in real-time, without any delays that could impair the safe administration of doses or stop treatments in the event of problems. Experiment was conducted to test whether the parameters of a simulated treatment, which are tDCS session length, current state and placebo status, could be delivered to the tDCS device successfully. The tDCS device screen showed 'Awaiting Physician Configuration". The three parameters were then set, and once this was confirmed the treatment was able to commence, and the GUI stated, 'Treatment in Progress'. Once the current was administered over the prescribed time the GUI stated, 'Treatment Stopped'. The GUI then confirmed 'Treatment Completed.' Each of these stages required confirmation from the Physician's CLI. The physician's interface ensured that only appropriate treatment ranges were used by parsing the parameters at the point of data entry.
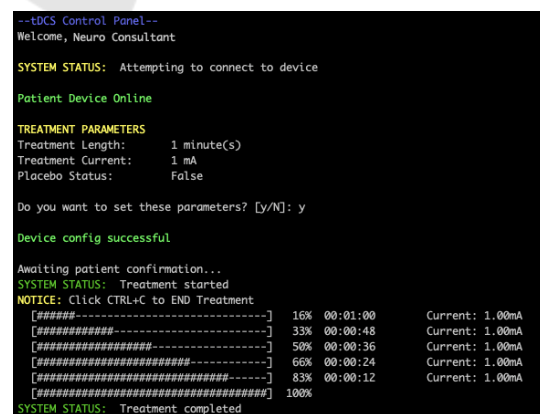

Figure 15: CLI monitoring Live a simulated treatment.

Figure 15 shows demo of the treatment phase, which also shows the status when the treatment was

completed. The interface provided a clear and concise information to the tDCS device remotely throughout the experiment's simulated treatment process. Additionally, the ability to stop the treatment at any time by the tDCS device was very simple through a button push. In real use, some patients may find the technology stressful, so it has been kept simple to minimise difficulties and to aid physicians in reassuring and guiding patients during remote consultations.

In Use Case 2, the treatment progress was monitored in real time. The device was tested to ensure that the tDCS device's treatment parameters were continuously monitored, including any additional parameters that can be sent to the device from a sensor using the I^{2}C Protocol. The experimental use of the CLI and device indicated that a doctor could have the same level of control that can be achieved during face to face contact. The systems provided constant feedback from the device regarding its status both operationally and regarding its treatment output.

Figure 16: Treatment being halted by the CLI.

Final experiment was conducted to testify the third use case of the framework to examine the safety of the device. The remote monitoring in this instance would allow the physician to monitor the patient in real time. It was possible to abort a treatment anytime either by the remote CLI or by using tDCS device's own control. Figure 16 demonstrates how inputs from the CLI (in real, use by a doctor) can halt the treatment taking control of the device remotely. The treatment can be also aborted from the device and this was implemented using a regular polling mechanism between the physician's CLI and the tDCS device. When the treatment was halted, not only the power boost was turned off, but also the relay was opened, preventing any residual power within the circuit from reaching to the simulated electrical load acting as a patient's head. In the case of deviations from a set current value during the treatment, onboard tracking systems could alert the remote CLI. Overall, this experiment demonstrated a sound safety mechanism of the hardware during simulated treatments.

8 CONCLUSIONS

While the device has been shown to function, further testing and ethical approval must be obtained before it can be used for human trials. At present, there is a short time delay for the device to calculate the resistance values needed for the Digi Pots to provide the required current output. With enhanced PCB-based prototypes, future research should aim for faster current adjustments almost instantly. Current ranges can be extended outside the 1-2mA range and preliminary investigations have shown that this is possible using the prototype model.

The prototype should be further refined in the future, so that it can be used successfully in clinical trials and can also provide a more seamless experience for physicians. An NFC smart card system should be supported on the device interface so that physicians can access the device using an institution's smart card system to configure treatment parameters for patients. Moreover, the CLI should be extended to automatically log the treatment data. These logs can then be used to generate patient reports that can be uploaded to a healthcare system, such as the advanced Patient Administration System (SystemC, 2020). In the long run, the CLI should be developed into a graphical mobile or web-based application, enabling users to engage in tele-neurorehabilitation in a more convenient, efficient, and secure manner.

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