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Development of an Initial Concept and Prototype for a Neuromuscular Assistive Stimulation System

Master's thesis

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Tallinn 2021

TALLINNA TEHNIKAÜLIKOOL
Infotehnoloogia teaduskond

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Neuromuskulaarse abistimulatsiooni süsteemi esimese kontseptsiooni ja prototüübi arendamine

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Author’s declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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30.12.2021

Abstract

This Master thesis work is related to an ongoing project (PRG424) in Thomas Johann Seebeck Department of Electronics in Tallinn University of Technology and is focused on the research and creation of an initial concept and first prototype of a possible neuromuscular assistive stimulation system to support patients with neurodegenerative diseases. To fulfil this goal, it was required to solve a variety of different problems.

As a first step, three main issues were reviewed: neuromuscular stimulation principles, the effect of long-term stimulation, and the market of neuromuscular stimulation devices. Based on this, the selection of a suitable neuromuscular stimulation device for conducting initial tests in the first prototype was carried out.

During the second step it was needed to review and find a suitable method for analysing the human movement data and detect abnormalities. Different filtering and machine learning methods were researched and tested; to find the most suitable one. As a result, it was decided to proceed with neural network solutions.

In the third step, based on the selected neuromuscular stimulation device, which was connected to a separate controller and set of solid-state relays, the initial prototype of externally-controlled stimulation system was built. Using the previously selected data analysis method, pre-recorded human movement data was analysed. In case of detected abnormalities, the algorithm (running on a PC) sent a control signal via wireless Bluetooth communication to the stimulation prototype and neuromuscular stimulation was activated.

The resulting prototype consists of both hardware and software elements that implement the developed concept. It successfully fulfils the objective of this MSc thesis, i.e. it combines and implements researched theory onto a real prototype of a stimulation device, which based on recorded human movement data can decide whether the person has a problem with his movement and needs auxiliary stimulation.

This thesis is written in English and is 97 pages long, including 6 chapters, 74 figures and 8 tables.

Annotatsioon

Neuromuskulaarse abistimulatsiooni süsteemi esimese kontseptsiooni ja prototüübi arendamine

Käesolev magistritöö on seotud Tallinna Tehnikaülikooli Thomas Johann Seebecki elektroonikinstituudis jooksva projektiga (PRG424) ning keskendub neurodegeneratiivsete haigustega patsientide toetamiseks vajaliku neuromuskulaarse abistimulatsiooni süsteemi esialgse kontseptsiooni ja prototüübi uurimisele ja loomisele. Selle eesmärgi saavutamiseks oli vaja lahendada erinevaid probleeme.

Esimese sammuna vaadati üle kolm põhiküsimust: neuromuskulaarse stimulatsiooni põhimõtted, pikaajalise stimulatsiooni mõju ja neuromuskulaarse stimulatsiooni seadmete turg. Sellest lähtuvalt valiti esialgses prototüübis esmaste testide läbiviimiseks sobiv neuromuskulaarse stimulatsiooni seade.

Teise etapi käigus oli vaja üle vaadata ja leida sobiv meetod inimese liikumisandmete analüüsimiseks ja kõrvalekallete tuvastamiseks. Sobiva lahenduse leidmiseks uuriti ja katsetati erinevad filtreerimis- ja masinõppe meetodid. Sellest tulenevalt otsustati edasi minna närvivõrgu lahendustega.

Kolmandas etapis ehitati esialgne väliselt juhitav prototüüp, milles kasutati eelnevalt valitud neuromuskulaarse stimulatsiooni seadet, mille külge oli ühendatud kontoller ja pooljuhtreleede moodulid. Kasutades eelnevalt valitud andmeanalüüsi meetodit, analüüsiti eelsalvestatud inimeste liikumisandmed. Avastatud kõrvalekallete korral saatis algoritm (arvutis töötav) juhtmevabalt Bluetooth-side kaudu prototüübile stimulatsiooni juhtsignaali ja neuromuskulaarne stimulatsioon sai aktiveeritud.

Saadud prototüüp koosneb nii riist- kui ka tarkvaraelementidest, mida implementeeriti väljatöötatud konspetsioonis. See täidab edukalt käesoleva magistritöö eesmärki, st. see ühendab ja rakendab uuritud teooriat reaalsele stimulatsiooniseadme prototüübile, mis saab salvestatud inimese liikumisandmete põhjal otsustada, kas inimesel on liikumisprobleemid ja kas ta vajab abistimulatsiooni.

Lõputöö on kirjutatud inglise keeles ning sisaldab teksti 97 leheküljel, 6 peatükki, 74 joonist, 8 tabelit.

List of abbreviations and terms

AI	Artificial Intelligence
BLE	Bluetooth Low Energy
BT	Bluetooth
CPS	Cyber Physical Systems
EEC	European Economic Community
EMG	Electromyography Sensor
EU	European Union
FES	Functional Electrical Stimulation
HDMI	High Definition Multimedia Interface
IoT	Internet of Things
IT	Information Technology
KNN	K-Nearest Neighbours
LED	Light Emitting Diode
LVQ	Learning Vector Quantization
M2M	Machine to Machine
MPC	Model Predictive Control
MQTT	Message Queuing Telemetry Transport
NDD	Neurodegenerative Diseases
PCB	Printed Circuit Board
RPi4	Raspberry Pi4
SMD	Surface Mounted Device
SVM	Support Vector Machine
TENS	Transcutaneous Electrical Nerve Stimulation
WPAN	Wireless Personal Area Network
Wi-Fi	Wireless Fidelity
WSANs	Wireless Sensor-Actuator Networks

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1 Introduction

Since this thesis deals with cyber-physical systems, it is worth to start by defining what there are. A cyber-physical system refers to an information technology concept that implies the integration of computing resources into physical entities of any kind, including biological and man-made objects. In cyber-physical systems, the computing component is distributed throughout the entire physical system, which is its carrier, and is synergistically linked with its constituent elements [1].

1.1 Evolution steps of technologies

Our current days are called the information and telecommunication age (also referred to as the Information and Communication (ICT) or Information Technology (IT) age) and this has been going on for several decades. Historically, the information age was preceded by the industrial era, which began with the industrial revolution in England at the end of the 18th century (Figure 1) [2].

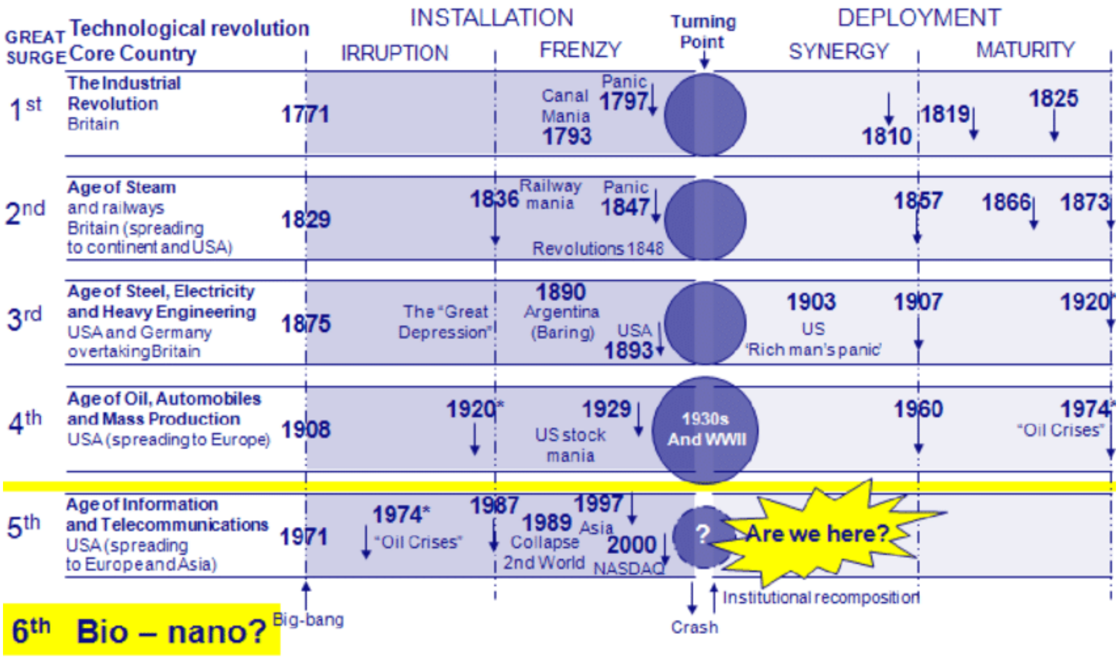


Figure 1. Technological Revolutions and the Age of Information and Telecommunications [2].

But no matter how great the importance of IT is, IT does not produce a variety of material objects - everything that ultimately constitutes the humans’ environment. Also shifting public attention to the IT does not mean stop of production of goods, i.e. manufacturing only moved (was outsourced) to so called “developing” countries. As a result, a certain dependence on the "factory countries" has arisen, and to restore independence, a process is needed that is the opposite of outsourcing. But it must be at a qualitatively different level - and cyber physical systems (CPS) play an essential role in that process. Of course, the scope of the CPS is much broader as these systems allow to create conditionally new level of objects, services, and infrastructure.

1.2 Concepts of cyberphysical systems

The concepts of CPS and also the Internet of Things (IoT) are undoubtedly intertwined. The IoT includes several phenomena at once. These are the devices themselves that go online and interact with each other using the machine-to-machine (M2M) communication, without human intervention. In addition, the connected devices generate data. Data that can (and should) be collected, analysed and further used for verification [3]. A CPS implements the difficult combination and coordination between the computational and physical elements of that system. As a next step, the aspect of real-time capability starts to play a significant role. Here comes the need to exchange possibly huge amount of data, analyse it, having effective algorithms and need to be energy-efficient (e.g. low power and low energy consumption in case of battery-powered devices, also the need to be efficient from an environmental point of view etc.).

1.3 Examples of cyberphysical systems

One of the most rapidly developing examples of the practical application of CPS is industry and so-called “Industry 4.0” where the main goal is the work and cooperation of all systems with global data collection, their analysis in real time and their processing, aimed at optimization (for example activating some machines and systems synchronized with others taking into account state of the whole batch of systems, not every single device or subsystem separately). Here it is important to take into account many aspects, also the data transmission of connected machines can be divided into two groups, wired and wireless [4].

Another prime area of application of CPS is healthcare. As shown in Figure 1, there are already many pre-requisites and many experts believe that the next revolution will be in the cooperation of engineering and biology. Wireless sensor-actuator networks (WSANs) are intensively implemented in many areas of the industry and daily life [4]. But the development of modern wireless technologies, in addition to the production sphere, gives tremendous opportunities in systems that society needs. Namely people with different health problems, for whom cooperation with devices would help to compensate their physical disabilities. Also monitoring the state or changes of the human body or real time physical performance tracking can improve the speed of response and determination of the need for hospitalization. Of course, non-industrial protocols and methods are used for these purposes, for example the IEEE 802.15 group is working on the international standards for Wireless Personal Area Network (WPAN) [5] [6]. At the same time, there are two main categories of systems for receiving a signal from a human; the first ones are wearable devices (sensors and devices located on or in the human body) and the second ones are non-wearable (visual camera or picture analysis, radio frequency reflection and return and radiation solutions etc.) [7].

1.4 Technology and human health related problems

How to implement and optimally use this significant variety of different technologies to solve human problems? The solution should always be as simple, effective, low cost, safe and reliable as possible (not to create false signals about the human condition, not create any radiation, overheating etc.). Today, such devices as smart watches or smartphones have already reliably entered our lives, in which the collection of physical data about a persons and their activity has already been partially implemented. But this is only a small part of what should be implemented. The information collected by these devices may have a delay or errors and at most this will not have any detrimental effect since these systems are more about entertaining the end user and they do not affect their health or safety even.

At its core, any wearable system can be composed of fairly simple sensors (accelerometers, gyroscopes, magnetometers etc.) and other elements such as microcontrollers and have a simple circuit on the board, which indicates the possibility of a rather cheap implementation of the device itself. The main challenge for creating a device will be its programming and analyse of the collected data to create reasonable system output. For this purpose, it is possible to use both traditional ("manual" - using statistics, filtering, and so on), but also rapidly developing and very popular machine learning ("automated") algorithms. At the same time, living in the world or periodical lack of initially planned assembly hardware components it is necessary to predict the need for device upgrade and revision change capabilities, for example the possibility of expanding memory, the ability to quickly connect additional systems, different methods of transferring data, or replacing some parts of the device with whole blocks in easy way in new revisions of the device without any big production, software and certification change. This approach is quite widespread within many development teams nowadays [8].

1.5 Master thesis' focused issues and challenges

The aim of this MSc thesis is to develop an initial concept and prototype for neuromuscular assistive stimulation system to support and contribute to the progress of the project PRG424 "Closed-Loop Communication System to Support Highly Responsive Neuromuscular Assistive Stimulation" [9] that is ongoing in Thomas Johann Seebeck Department of Electronics in Tallinn University of Technology.

The project goal is to control the stimulation of neuromuscular activity based on the human body's position and movement dynamics (context awareness). The novelty of the project is in the controlled stimulation, meaning how to bring intelligence into wearable devices such as functional electrical stimulation (FES) electrodes to react depending on the context awareness. In another words, the stimulation strength and frequency should not be constant during different physical activities [10].

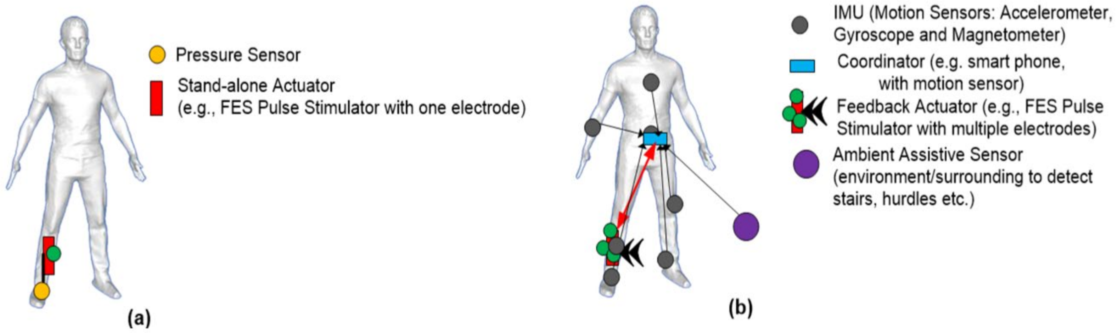


Figure 2. (a) Functional electrostimulation system solution based on pressure sensor and stimulating electrodes; (b) Closed-loop auxiliary solution with different sensors system, multiple electrodes and signal processing [10].

The development of wearable closed-loop tactile feedback systems is an open topic for research. This project examines an FES case study for patients with partially disabled neurodegenerative diseases (NDD). In Figure 2 it is shown some proposed (in PRG424 project) neuromuscular actuator and accessory systems for life support. The first proposal (Figure 2 part a) is a based on a pressure transducer and one pair of stimulation electrodes solution [11] [12]. It does not adapt to nervous conditions or changes in skin conductance, requiring constant manual adjustment of signal strength and device position. It also does not include the functions of the surrounding intelligence, for example, to activate different muscle groups during more complex movements [11]. The second proposal is a closed-loop auxiliary system (Figure 2 part b) which brings several advantages because it:

- allows smart monitoring (via different wearable sensors) and significantly improves quality (i.e. user experience) through the collected information;
- gives possibility to perform more complex neurostimulation of certain muscles group using several electrodes;
- provides real-time feedback to which helps to analyse the previously activated stimulation and trigger new stimulation in case needed.

The second proposed system (Figure 2 part b) motivates and arouses the greatest interest for research and creation of a concept and the first real prototype of such a system.

1.6 Research Statement

The development of a closed-Loop communication system to support highly responsive neuromuscular assistive stimulation raises a lot of challenges. At the current stage of progress there are many different issues and one of them is the development of the concept itself and building an initial prototype of the corresponding system. This sets the main research objectives and goals for this work.

The first goal is to study the market of existing devices for neurostimulation to be able to perform first stage stimulation concept testing. The main selection criterion should be the ability to control the device by third-party methods and modify the control signals. The challenge is that in order to make any test on humans, the device must be certified in the European Union (EU). Based on that, it is also necessary to study device limits and to compare the hardware and software parameters for possible changes and external control provided by different vendors and also take into account existing and similar solutions.

The second goal is to perform the research of different suitable data analysis solutions for the project specific topic. In the framework of the project, there is a need for finding a method for human movements detection using sensors installed on the human body. Using this approach, the received data will be converted to detect different movement types (normal and abnormal movement) and the decision of activating neuromuscular stimulation will take place based on that data.

The third goal is to combine the results of the previous two goals, and in combination with additional hardware, to implement a prototype which is able to perform neuromuscular stimulation based on the movement signal received. A working prototype will provide opportunities for further research and improvement in the indicated direction.

Given the above, the research statement of this MSc thesis is expressed as:

- **Perform the selection of a suitable neuromuscular stimulation device for conducting initial tests;**
- **Review methods for detecting human movement abnormalities and select a suitable one;**
- **Based on the selected neuromuscular stimulation device and data analysis method, build the initial prototype of the stimulation system.**

To achieve the above, the tasks of this thesis are:

- Review of transcutaneous electrical nerve stimulation, working principles and different stimulation parameters;
- Market analysis of available and used in similar applications stimulation devices and selection suitable for the initial prototype;
- Review and selection of filtering and machine learning solutions;
- Example test of selected machine learning solution to detect human movement abnormalities in pre-recorded data;
- Building a hardware solution with selected stimulation device to activate stimulation only when needed (i.e. when an abnormality is detected);
- Test of prototype hardware setup and developed logic structure based on pre-analysed human measurement file reading;
- Summarizing results achieved and review for possible future improvements.

1.7 Thesis work structure

The rest of this MSc thesis is organized as follows.

Chapter 2 presents background information related to transcutaneous electrical nerve stimulate. Review of stimulation types, limits and some devices available on the market.

Chapter 3 reviews principals and methods to analyse signals of human movement and create main concept of an algorithm for processing data of a person with some movement disabilities.

Chapter 4 is focused on the creating hardware prototype and establish wireless communication to the prototype.

Chapter 5 Takes result of all previous chapters and tests the abilities of the prototype to perform stimulation based on the results of movement data analyse (from movement pre-recorded file)

Finally, in chapter 6 the results of the whole work are reviewed ad summarized and future developments proposed.

2 Transcutaneous electrical nerve stimulation

This chapter gives a high-level description of the features of electrical nerve stimulation, their parameters and possible ways to apply them. Since within the framework of the project there was a fundamental decision made to use a ready-made stimulation signal generator, it is necessary to choose a device suitable for this area of application. To make this selection, it is necessary to study the existing parameters and features of the devices as a whole and how they affect the human body. Based on the results of this study, the selection of a suitable stimulation device for the first physical prototype of the project can be carried out.

2.1 Working principle

TENS - transcutaneous electrical nerve stimulation is non-invasive method based on the usage of electrical current generated by a specific medical device to stimulate nerves. TENS refers to the entire range of transcutaneous currents used to stimulate nerves, but very often this term is used to describe devices that only provide stimulation specifically to relieve pain or massage muscles[13].

Typical device available for the end consumer on the market is a battery equipped gadget, which has buttons on its body for selecting a program preset by the manufacturer or setting manually the stimulation parameters such as current level, frequency, width and type of outgoing pulses. As shown in Figure 3, a standard TENS device uses at least two electrodes (positive “cathode” and negative “anode”), which are connected to the human skin using special medical adhesive contacts with a gel layer, which ensure tight contact with the skin surface and good electrical conductivity.

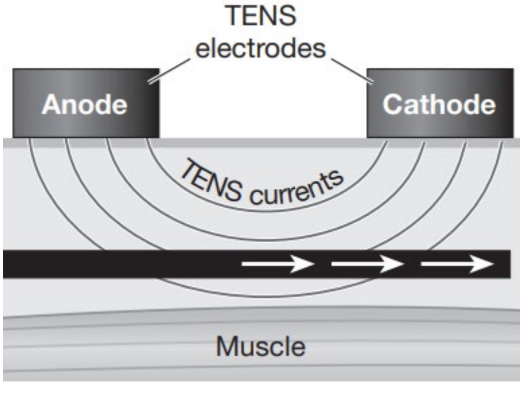


Figure 3. TENS electrodes connected to human skin and stimulation currents passing through the human body [13].

There are also options with metal contacts, which do not require periodic replacement (comparing to adhesive contacts) and are easy placeable but require special cuffs to fix contacts on the human body, and also in some cases may have worse conductivity than contact with a helium layer.

2.2 Stimulation performance defining parameters

There are various factors and parameters that determine the final effect of electrical stimulation (represented graphically in Figure 4), the main ones being the amount of the electric current flowing through the human body; the duration of its effect on the body; the magnitude of the voltage acting on the body; type and frequency of current; the path of current flow in the human body; electrical resistance of the human body; psychophysiological state of the organism and its individual properties; condition and characteristics of the environment (air temperature, humidity, gas pollution, dustiness), etc.

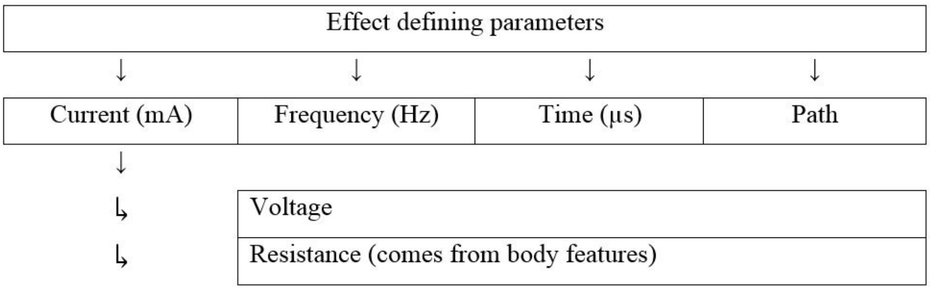


Figure 4. Graphical way of representing stimulation performance defining parameters [14].

2.3 Currents

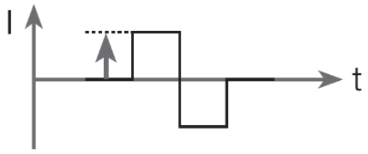


Figure 5. Current (I, on the y axis) direction change in TENS device during the time (t on the x axis) [15].

Current direction during TENS can be changed various times (Figure 5). To consider the aspect of the current strength, then most often, for the end user, it is displayed on the device’s screen, similar to the sound volume control in other devices. Due to the different characteristics of each person, the required current level must be selected individually, because the resistance of tissues and body surfaces of even one person may differ depending on the part of the body (Figure 6) [16]. Knowing the resistivity parameters of various gaps of the human body, it is easy to calculate also currents or voltages through the Ohm law (Equation 1):

$$I = U/R \tag{1}$$

where

R – resistance of human body

U – voltage applied to human body

I – current flowing in between two contacts on stimulator

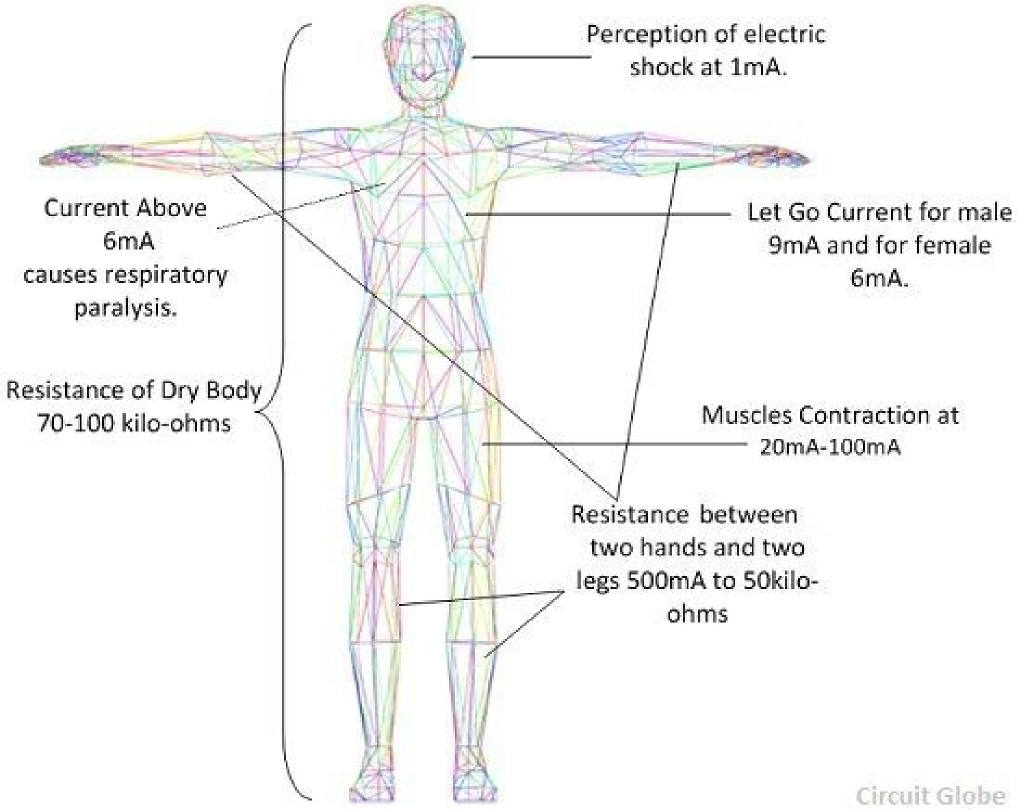


Figure 6. Human body resistivity parameters [16].

At the same time, at a low current level, the sensations will be comfortable, but the stimulation effect is hardly noticeable, and vice versa, at higher currents, a strong result can be clearly obtained, but also a markable discomfort for the patient. Behind this lies the property of the human body and the difference in response to alternating (AC) and direct (DC) currents, so in Table 1 it can be seen that the influence of AC (60 Hz in US and 50 Hz in Europe available in domestic conditions, but at maximum values this does not have much effect numerically) with a lower current it is capable produce more damage on a human than a DC, and the higher the frequency of the alternating current, the higher currents the human body can carry. In the devices considered in the framework of this work the output signal can consist of both DC and AC components (combination of changing directions signals). Here is important to note that AC at the low frequencies, when the current is still low enough to disrupt the functioning of the human heart, can already cause muscle contraction, which can bring the "can't let go" effect; this is due to the fact that the compression muscles are stronger than the expansion muscles, and for this very reason, a person grabbing an alternating current wire very often cannot let go of it [17].

It is also important to consider that statistically there are also noticeable differences in that the male body can withstand higher currents than the female one. In case of AC the higher the frequency the bigger currents amounts can the human resist.

Table 1. Influence of DC and AC currents on human body [17].

Body effect	Gender	DC	60 Hz AC	10 kHz AC
Slight sensation at point(s) contact	Men	1 mA	0,4 mA	7 mA
	Women	0,6 mA	0,3 mA	5 mA
Threshold of bodily perception	Men	5,2 mA	1,1 mA	12 mA
	Women	3,5 mA	0,7 mA	8 mA
Pain with voluntary muscle control maintained	Men	62 mA	9 mA	55 mA
	Women	41 mA	6 mA	37 mA
Pain, with loss of voluntary muscle control	Men	76 mA	16 mA	75 mA
	Women	51 mA	10,5 mA	50 mA
Severe pain, difficulty breathing	Men	90 mA	23 mA	94 mA
	Women	60 mA	15 mA	63 mA
Possible heart fibrillation after three seconds	Men	500 mA	100 mA	N/A
	Women	500 mA	100 mA	N/A

For comparison, the current level of a stun gun can be considered. The current directly affecting a person varies in the range from 2 to 5 mA. It is important to note that in stun guns used for example by the police, the voltage is about 1200 V [18].

2.4 Frequency

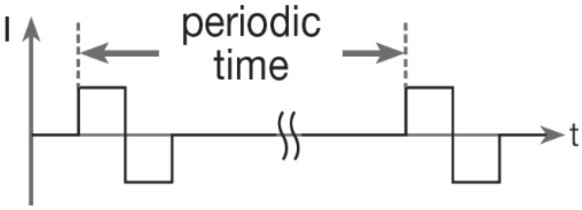


Figure 7. Frequency of current switching in TENS device [15].

Current switching in TENS can be performed with configured frequency during time period (Figure 7). Frequency describes the number of stimulation pulses in one second and measured in Hertz (Hz). The Table 2 describes the observed effects of the most commonly used frequency ranges for stimulation.

Table 2. Effects in different ranges of frequency used by stimulation [19].

1-10Hz	generates warming up of muscles, hardly causes fatigue, suitable for strongly atrophied muscles
20-60Hz	enough for joint movement and tetanic muscle contraction (applicable for functional exercises)
>60Hz	Muscle contraction decreases and sensory response changes to be dominating (sensations in the area of the electrodes can be painful)

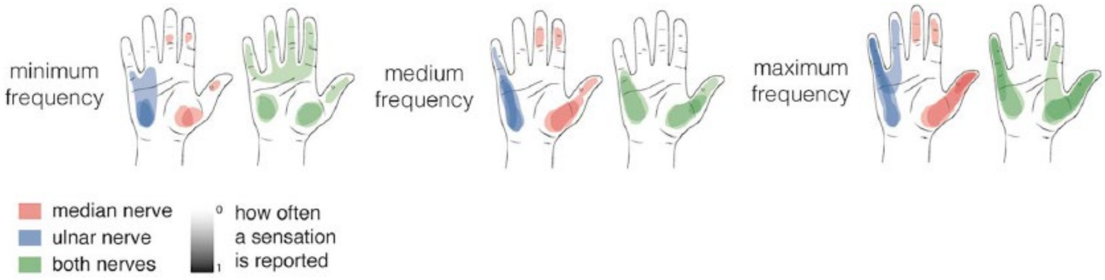


Figure 8. Result of different frequency stimulation on the example of hand [20].

Figure 8 shows the effect of sensing an increasing frequency on the example of stimulation of the nerves of the hand (median and ulnar nerves): the darker the zone, the greater and brighter the feeling of stimulation in the patient’s hand. Here it is important to note that the effect on both nerves stimulated simultaneously would not be similar if simply adding the zones of sensations from the stimulation of each nerve separately, that is, at the same frequencies, the blue zone (ulnar nerve) and the red zone (median nerve) together do not form a green zone (both nerves) [20].

2.5 Pulse width

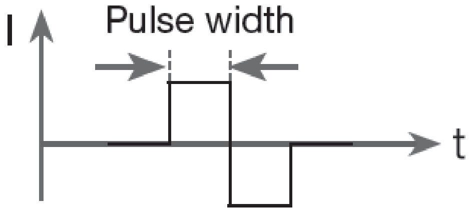


Figure 9. Pulse width parameter in TENS device [15].

Pulse width (see Figure 9) describes the duration of the pulse (in other words, when the pulse is on); it is the time between the rise and fall of the produced pulse or signal. The wider the impulse, the longer the stimulation is maintained in the muscles and thus can cause a greater torque in the moving limb. But at the same time, long-term stimulation can cause the current to overflow into neighbouring tissues that were not supposed to be stimulated. A lot of research done on this topic advise to still remain in the range of 300-350 μs in standard applications [21]. More detailed descriptions of the effects of changing the pulse width and possible gaps are presented in Table 3.

Table 3. Effects in different ranges of pulse width used by stimulation[19].

0-200 μs	Used for small groups of muscles, provides mild superficial muscle contraction, low intensity and least likely to create overflow
200-350 μs	Possible overflow effect, stronger contractions of motor muscles
350-500 μs	Used for large groups of muscles, produces, abundant muscle contraction with a deep and pronounced effect. Possibility of overflow starts to be high

2.6 Pulse shapes

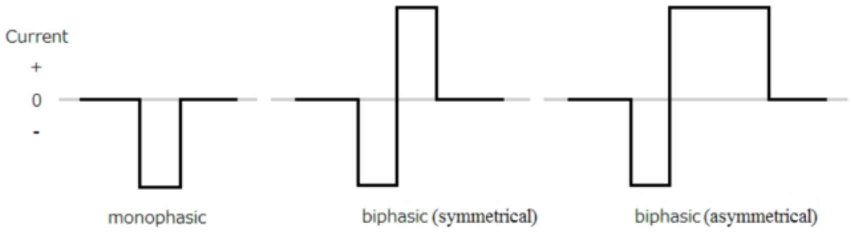


Figure 10. Different pulse shape options in TENS devices [22].

The pulse shapes can be monophasic and biphasic (see Figure 10). With monophasic pulses, the direction of the current flow is always in the same direction, whereas in the case of biphasic pulses, each subsequent stimulation changes the direction of the current flow; also, biphasic stimulation can be asymmetric, which means that duration of pulses in one direction has another length than in reverse direction [15].

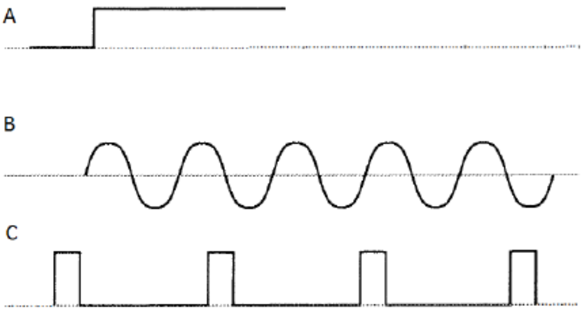


Figure 11. TENS pulse waveforms [22].

Moreover, the waveforms can be direct current, alternating and pulsating (Figure 11). The signal waveform can be either square, sinusoidal, or have a specific waveform that is separately set for the needs of the application. The most commonly used standard stimulators available are biphasic with square pulsating waveforms [22].

2.7 Fatigue caused by electrical stimulation

Despite the fact that electrostimulation has many advantages and there is a lot of experience in its use in the rehabilitation of people with movement problems (i.e. it became possible to stimulate movement, train and relax muscles and relieve pain), there is also a clear problem that after 30-60 minutes of active stimulation fatigue of muscles and tissues begins [23].

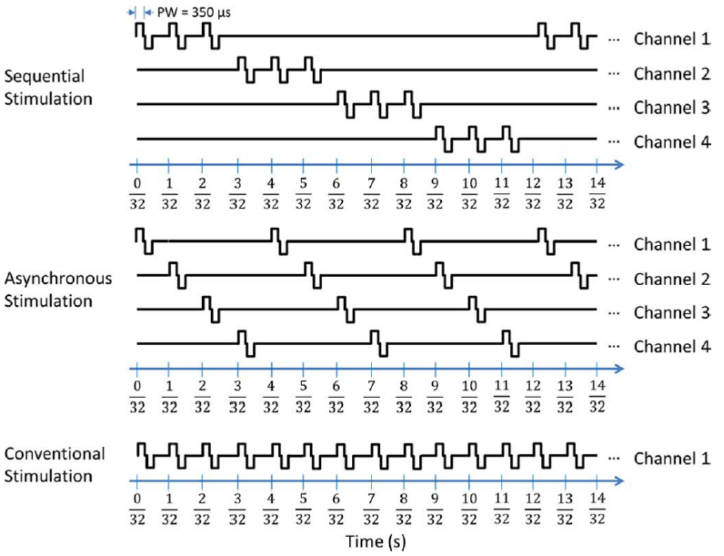


Figure 12. Sequential and Asynchronous stimulation methods[23].

In Figure 12 are shown three methods to stimulate: conventional, asynchronous and sequential. The conventional method uses only one channel and as it was described previously causes fatigue. One of the approaches to eliminate this and decrease fatigue is to apply the stimulating signal to different channels using different signal distribution methods. In sequential stimulation, muscle stimulation pulses are alternately delivered through different channels, which allows the muscle to rest while using another channel. Asynchronous stimulation uses the fragmentation of the impulse between different channels, which allows to reduce the frequency of stimulation on each of the channels and, as follows from many studies, also reduce muscle fatigue [23]. In addition, combined stimulation through different channels also improves blood circulation [24].

2.8 TENS device selection

For a system that regulates human movements and performs neuromuscular stimulation, there is a need for devices that are able, under external control, to provide impulses through contacts installed on the human’s body. For this purpose, it is most rational to use (at least at the stage of initial development of prototype) already existing devices of low complexity. For example, devices that massage people through neurostimulation are distinguished by their simplicity, widespread use, and low cost. But since there are almost an infinite number of such devices on the market, certain criteria are needed for the selection of such devices.

In particular, in this project, we apply criteria for choosing medical equipment:

- the presence of certification to European standards;
- the reasonable price and not infinitely long delivery time;
- the ability to control the device from outside (can be ‘hacked’).

After the technical selection process, confirmation of a consulting clinical specialist is also required and performed as part of this project.

2.9 Similar devices used in other projects and approaches

Since this is not the first existing project in which external control of transcutaneous electrical nerve stimulation is used, then those devices that have been used in other projects of different researchers are also taken into account.

There exist several approaches to accomplish this kind of task. For example, it is possible to assemble a completely independent scheme for pulse signal generator, which consists of microchip (IC 7555), transistors (two BC-327), resistors, variable resistors and capacitors [25]. This circuit can be completely controlled by an Arduino board. Although this is a fairly common approach, the creation of this kind of circuit, be it on a bread board or even on a specially made printed circuit board, does not meet the first search criterion, i.e. this device will not be certified and any experiments with it on humans may be unsafe. But the main advantage of projects with similar schemes is the complete decomposition into stages and phases of the entire stimulation process, which allows to well understand how this process approximately occurs in already certified devices. Certified devices, on the other hand, most often do not have open information about how they work and for any actions to modify them require so-called reverse engineering to understand the working principals.

It is also quite common that an existing stimulator is taken as a base device, and additional control is added to the wires going to the contacts installed on the body. The stimulator is set to constant stimulation mode, and an additional controller on the wires turns on or off the stimulation depending on the requirements of the running algorithm. The main advantage of this approach is its simple implementation and the fact that the impulse is completely created by a certified device and it is only turned on or off by a third-party circuit. In such cases and projects, devices from the company Sanitas are often used (see Figure 13 for an example).

Figure 13. 3D Virtual Hand Pointing with EMS and Vibration Feedback [26] as an example of a project using a stimulation device from Sanitas.

Also, a device from the same manufacturer is used in University of Hannover project, where the is implemented so-called «cruise control of a person» by stimulating movements by TENS [27] (Figure 14).

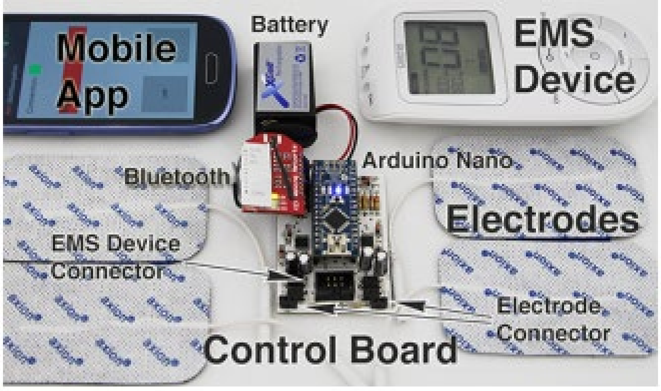


Figure 14. Hardware prototype of TENS device based system for cruise control of a person [27] as a second example of a project using a stimulation device from Sanitas.

Finally, it is also possible to connect to a stimulator in such a way that the wire between the device itself and the contacts on the body is not even damaged. To do so, an external device is connected to the control buttons, which is programmed to simulate the user's mode selection using the existing interface. This leaves the certified stimulator system completely intact from the factory.

2.10 Devices and projects with a similar idea and logic behind

IDC (Industrial Design Consulting, UK) and iFLYTEK have collaborated on foot drop walking aids to allow people with specific neurological conditions walk again. The electrode is fully integrated into the bandage. This type of design is unheard of in identical items, indicating a significant leap forward in technology [28].

Research in this area has been carried out by the company since 2009 and by now the fourth generation of the device has already been developed. The principle of operation lies in patented artificial intelligence (AI) algorithms that constantly monitor human behaviour and movements. The device has built-in conveniently maintained metal electrodes as well as a display with a small amount of information and the ability to connect to a smartphone using the application [29].

Figure 15. XFT-2001E view from body and outside [29].

This 4th generation of Muscle and Nerve Stimulator (Figure 15) has the trade name: XFT-2001E Foot Drop System and has similar goals and application area as the planned end device of the ongoing PRG424 project. However, at the time of writing this MSc thesis, there is only promotion and datasheet info available and no clear data whether is it produced already or only developed on the concept level (comparison of this device datasheet parameters will be done at the chapter 2.12.3).

2.11 Variety of different possible device variants

Since the Sanitas SEM 43 device has already been used in many projects and was originally also one of the examples that the clinical advisor of the project cited in the recommendation, it was one of the first choices. But since the project was at that time in its initial phase, it was decided not be limited with the choice of only one device, because certain technical limitations or difficulties might have arisen in the future, thus additional devices were also selected for ‘reserve’.

As a result, in addition, some of the available TENS devices on the market were also selected which met all the previously defined criteria for choosing. As an additional selection strategy, the principle was also added that the device should be fairly simple in terms of its design and operation. The presence of conventional buttons obviously simplifies the possibility of external control of the device (rather than control of a device with a touch screen).

So, the following devices met the previously defined criteria:

- Sanitas SEM 43
- Premier TENS
- Salmue EMS Massager
- LTK545
- TENStem eco Basic
- Beurer EM 29

Based on the study of the parameters performed in this chapter and in accordance with the use of a reasonable price and quick availability of the devices, two devices were initially selected to conduct the first experiments on the prototype: Sanitas SEM43 and Beurer EM29. The capabilities of these two devices are discussed in more details in following subchapters.

2.12 Capabilities of the two selected devices

After purchasing the necessary devices, a detailed study was carried out on both devices to find out how they are built in order to identify the most convenient of the two for further experiments.

2.12.1 Sanitas SEM43

The Sanitas SEM43 device has two stimulation channels and a variety of programs (50 in total), the purpose of which is massage (10 programs), muscle warming and training (30 programs) and pain relief (10 programs). The most interesting feature of the device is the possibility of custom programs (possible to make them default), where it is possible to select the operating frequency from 1 to 100 Hz, and the pulse width from 50 μs to 320 μs. Those custom programs are possible in pain relief mode (TENS mode on display as on Figure 16) with program numbers 8-10 and in muscle warming mode with program numbers 28-30 (EMS mode on display). The device also has the ability to adjust the current, but the exact data is not given in the user's guide; the user sees only the scale on the device display corresponding to the intensity of stimulation (0-50 levels), it is known that the maximum output value can be no more than 13.6 mA.

Figure 16. Device view and interface description.

It is also important to note that this device assumes the use of adhesive contacts, which means that there are cables with connectors which can be easily modified based on the needs of the project: 2.35mm shielded plug on the device side and 3.9 mm stud connectors on the electrode side (Figure 17).

Figure 17. Sanitas cable connectors (1 – body connector side, 2 – device connector side) and body contact adhesive pad (3).

To turn on the device and select any program, there is needed to press the buttons, which are (as can be seen in Figure 16 and Figure 19 of PCB views) micro push momentary SMD type buttons. That means that having an external controller, it is possible to simply connect to these buttons (solder additional wire) and to send a pre-programmed signal to select the desired program. This is the second main advantage of this device.

Figure 18. Sanitas SEM43 PCB back view.

Figure 19. Sanitas SEM43 PCB front view.

2.12.2 Beurer EM 29

The Beurer device has only a 4 programs without the possibility of changing the frequency and pulse lengths, but has a cuff system (Figure 20) that allows to make a simple and fast installation of contacts on the human body. This was the main reason for selecting this device, because it is also possible to connect its cuffs to another device and make fast setups during experiments.

Figure 20. Beurer EM 29 device (left) and cuff with contacts (right).

From the point of view of the design of the board of the device itself, it is much compact (Figure 20) in comparison to Sanitas', but it is not so convenient for modifications, since capacitive buttons on PCB are used (Figure 21, Figure 22), to which it is more difficult to connect, and due to the presence of only 4 programs, it is most likely that only the periphery (cuff with contacts) of this device can be used in prototyping goals, but not the device itself.

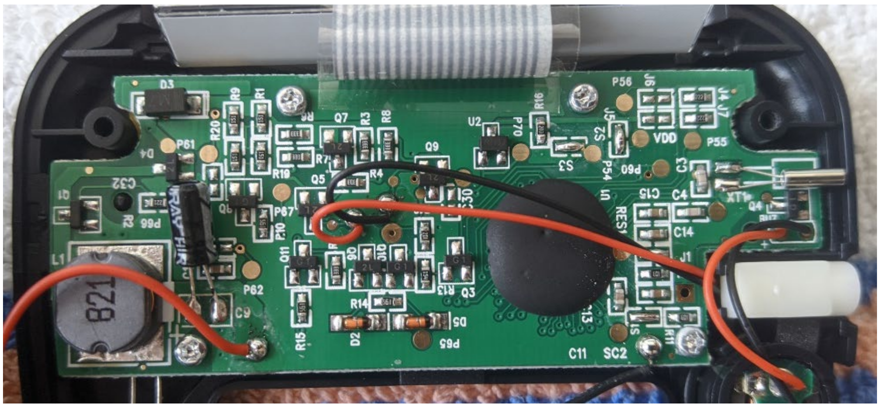


Figure 21. Beurer EM 29 PCB front view.

Figure 22. Beurer EM 29 PCB back view with buttons.

2.12.3 Comparison of technical possibilities and limits

Table 4 shows the parameters of the two purchased stimulation devices, as well as the parameters of the XFT-2001E device that was found later in the course of the project and which is very similar in design to what is ultimately planned to be obtained within the framework of the project. All devices are certified and have similar values of pulse length intervals, the most noticeable difference is in frequencies at which signals can be issued; Sanitas SEM43 has the widest range and XFT-2001E the smallest one. As discussed earlier, the higher the frequency, the larger currents a person can feel painlessly, so this parameter can be considered very important, especially in the case of a prototype. Among the advantages of XFT-2001E, the presence of a rechargeable battery can be noted (although it may be easier for a person with problems of the head to have batteries that he can buy in a store) and the possibility of communication with the outside world, which is missing in the other devices. It is also critical to note that at the time of writing, the XFT-2001E device only had a technical description and was not yet available for purchase in the EU, hence it is listed here for comparison purposed and not as a potential device for prototyping activities in the project.

Table 4. Comparison of parameters of purchased and similar to the project end goal device.

Parameter	**Sanitas SEM43** [15]	**Beurer EM 29** [30]	**XFT-2001E** [31]
Frequency	1-150Hz	2-110Hz	16-50Hz
Output voltage	max. 100 Vpp / 7.3V rms (500 Ω)	max. 50 Vpp / 5.5 V rms (500 Ω)	-
Output current:	max. 200 mApp / 13.6mA rms (500 Ω)	max. 100 mApp / 11 mArms (500 Ω)	0-90mA (500 Ω)
Pulse length (per phase)	50 – 450 μs	60 – 220 μs	50-300μs
Initial curve shape	Biphase square-wave pulse	Symmetric, biphasic rectangular pulse	Asymmetric biphasic balanced wave
Power source	3x1.5V (AAA)	3x1.5V (AAA)	3.7V rechargeable lithium battery
Communication	NA	NA	Bluetooth 4.0
Working current	-	-	≤120mA
Certification	CE 0483*	CE 0483*	CE 0123

* complies with directive 93/42/EEC for medical equipment

2.13 Conclusion of the transcutaneous electrical nerve stimulation part

The research carried out in this chapter allows to consciously select Sanitas SEM43 as device for the first prototype of the project, it has a wide range of customizable characteristics, is available on the market, and projects in similar area have already been carried out with this device. The study of TENS devices made it possible not only to choose a device for a prototype but give an understanding of the relevant parameters and how they may be modified and used in framework of the prototype project.

In the next chapter, it will be studied what solutions can be applied to analyse and create an algorithm for processing data of a person with disabilities in the correct movement.

3 Data analysis and algorithm concept

This chapter will consider initial for data analysis and concepts of possible prototype working algorithms.

3.1 Description of the algorithm needed

To create an algorithm for the operation of the final system, it is necessary to indicate the goals of its operation. The system will receive data measured by sensors placed on the human body, which will provide information about body position and movement dynamics. Based on these data, the system must determine whether the movement of a person in an independent mode is sufficient or whether an abnormality was detected which should trigger a stimulation (Figure 23). When stimulation is performed, feedback in the form of continuous real time movement measurement is also needed to understand what result is achieved.

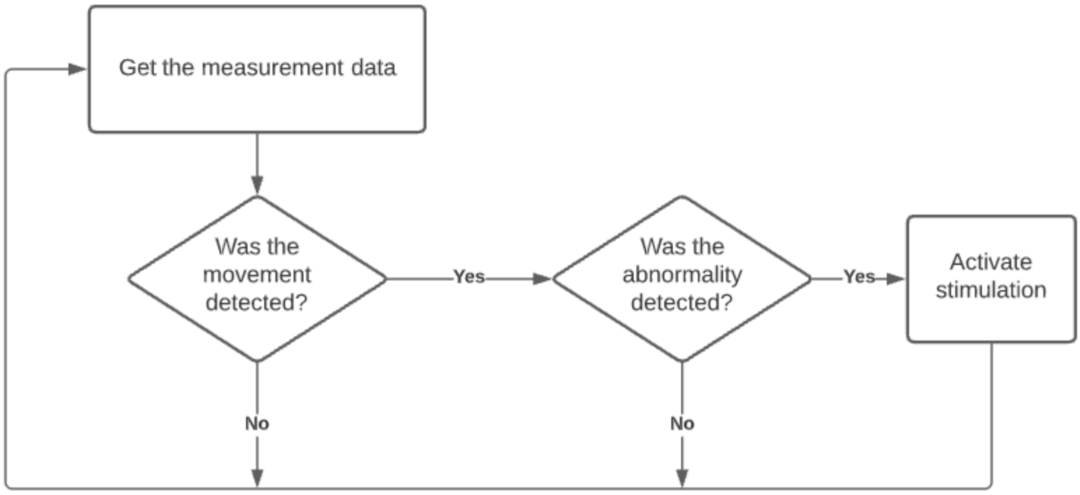


Figure 23. Algorithm needed to activate stimulation system.

3.2 Possible algorithmic approaches

There can be several different approaches to build the working system based in variable input data.

3.2.1 Closed loop

To implement the algorithm, it is necessary to use a so-called closed-loop system (Figure 24) where the system changes the output values based on the current state, adjusting it to the desired one. However, feedback is needed to take into account the resulting change. But there are also drawbacks, i.e. it is necessary to take into account that if there are errors in the sensors supplying information to the input, an error may accumulate, which in turn will affect the deviation of the final output signal.

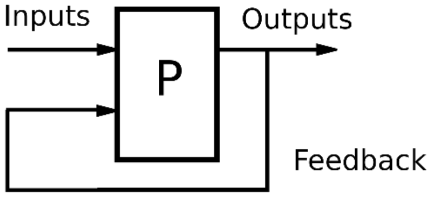


Figure 24. Principle of a closed loop system, wherein information about the output, via a feedback loop, is used to continuously try to correct the difference between the ideal and actual output values [32].

3.2.2 Modelling and Identification Approaches

To obtain the model of any system there are 3 approaches [33]**:**

White Box modelling (also known as First Principles modelling). The structure of the model is known, and the model originates from physical laws.

Grey Box modelling. The model is partially derived from physical laws. Certain parts of the model are approximated such that they these approximations have no direct physical interpretation but are suitable for modelling goals.

Black Box modelling. No information about the physical structure of the system is given a priori. The model is obtained by fitting experimental data to a randomly chosen mathematical model type and structure.

3.2.3 Model predictive control

Model predictive control (MPC) uses model of the system to predict possible states and control the system adjusting it based on the model[34].
This control system assumes a fully prescribed model of the system, but since when a person moves, the variability of combinations of behaviour and possible movements is very large, and there also may happen unexpected situations; it is not possible to manually prescribe all possible situations in the source code. Therefore, it is necessary to come to a more universal solution; one of the way to solve this problem can be implementing some elements of machine learning.

3.2.4 Machine learning

Machine learning (ML) is a branch of artificial intelligence. In more detail, it is a data analysis technique that allows a machine, robot, or any analytical system to independently learn by solving an array of similar problems. To simplify, machine learning technology is a search for patterns in the array of information presented and the choice of the best solution without human intervention [35].

3.2.5 Summary of possible data analyses approaches

The methods discussed above have different advantages and the most rational would be to use a combination of all of them. That is, it is the determination of the measured data using machine learning methods, but in the final system it is necessary that the entire system has the closed loop feedback, and the most likely approach to solving the problem will be when we consider the system as a black box, as to describe the movement of a person with functions or equations may be too complicated. In addition, it is important to filter the incoming data measured by the sensors, different filtering methods will be discussed in the next subsection.

3.3 Filtering signals

Any implemented algorithm will work using the data measured from the sensors. No matter how well any measuring sensor is working, there always can appear the noise during values acquisition process. To learn how to reduce the spread of values caused by noise from the sensor, different sine wave and square signals were simulated, to which a uniform constant noise and a rare random noise in the form of large spikes were added. To reduce the effect of noise, the following filters were tested to be applied:

3.3.1 Arithmetic mean filter (average)

To calculate arithmetic mean filter the following equation need to be used:

$$A = \bar{x} = \frac{1}{n}(x_1 + \cdots + x_n) \tag{2}$$

where:

A – filtered arithmetic mean value (output)

$\bar{x}$ – filtered arithmetic mean value

n – amount of filtered elements

x_1, x_n – first and last filtered element (input) [36]

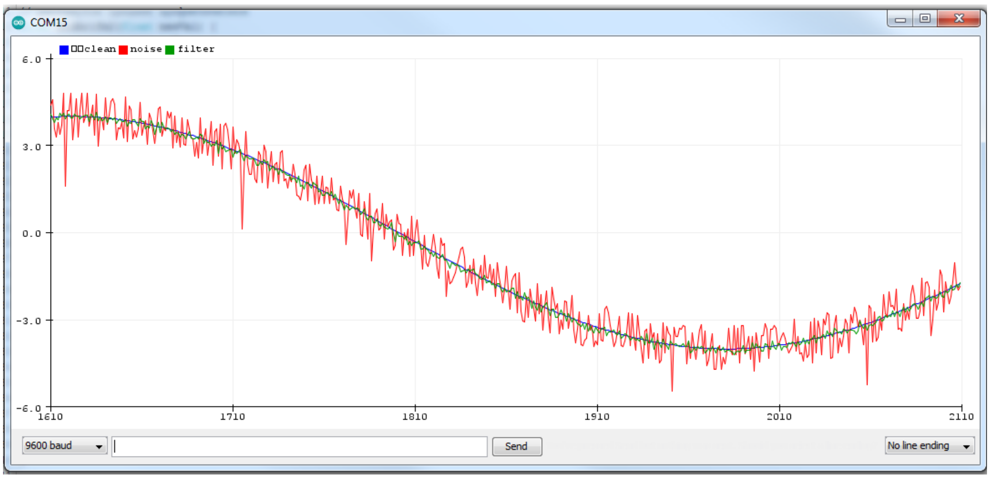


Figure 25. Arithmetic mean filter result, blue - initial signal (clear), red – noise, green – filtered resulting signal.

The filtered resulting signal (Figure 25) is calculated by adding the values of all (n number) measurements divided by their total number. This method takes n number of values into account and gives the result, the next result will be given by the filter when a new n number of values is received. This takes multiple measurements in one go, which can be time-consuming. It is recommended to use it where the time of one measurement is negligible or the signal changes slowly, because due to the extended sampling time, the signal may already have time to change.

3.3.2 Running arithmetic mean (moving average)

To calculate running arithmetic mean filter the following equation need to be used:

$$MA_n = \frac{1}{k}\sum_{i=n-k+1}^{n} x_i \qquad (3)$$

where:

MA – moving average value (output)

k – amount of points in the average

n – number of point to be filtered

x_i –filtered element (input) [37]

The logic of the moving average filter is similar to the previous filter (equation 2), but it allows to shift the averaging window in increments of +1. That essentially gives it the ability to work on the principle of a FIFO buffer, where the oldest value is removed and only one newest value is added. This gives opportunity to simplify the formula and reduce calculation power using the formula:

$$MA_n = MA_{n-1} + \frac{1}{k}(x_n - x_{n-k}) \qquad (4)$$

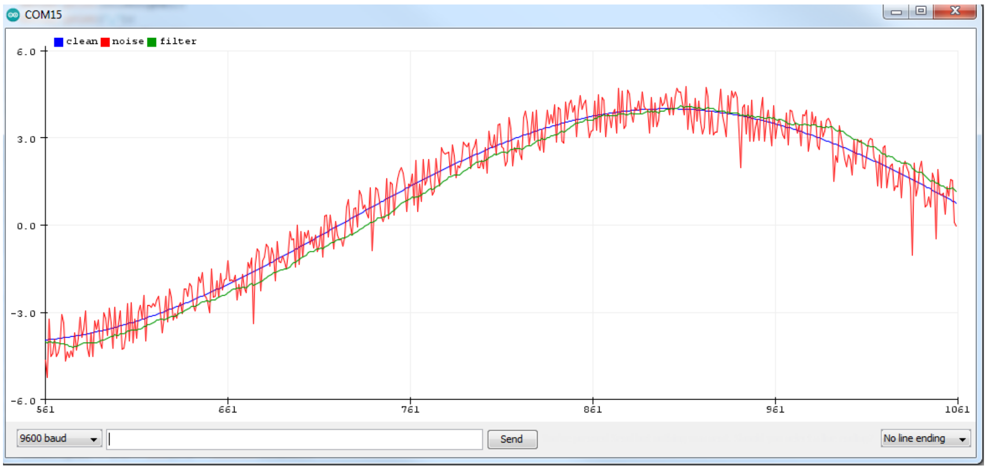


Figure 26. running arithmetic mean result, blue - initial signal (clear), red – noise, green – filtered resulting signal.

The filter takes only one measurement at a time and does not block the code for a long period. One of the drawbacks is that it averages the last n measurements, due to which the value is lagging (as can be seen in Figure 26). It also needs fine tuning of the polling rate and sample size.

3.3.3 Exponential moving average

To calculate Exponential moving average filter the following equation need to be used:

$$S_n = S_{n-1} + \alpha(x_n - S_{n-1}) \tag{5}$$

where:

S_n – exponential moving average value (output)

S_{n-1} – previous exponential moving average value

α – smoothing coefficient (0< α <1).

n – number of point to be filtered

x_n –filtered element (input) [38]

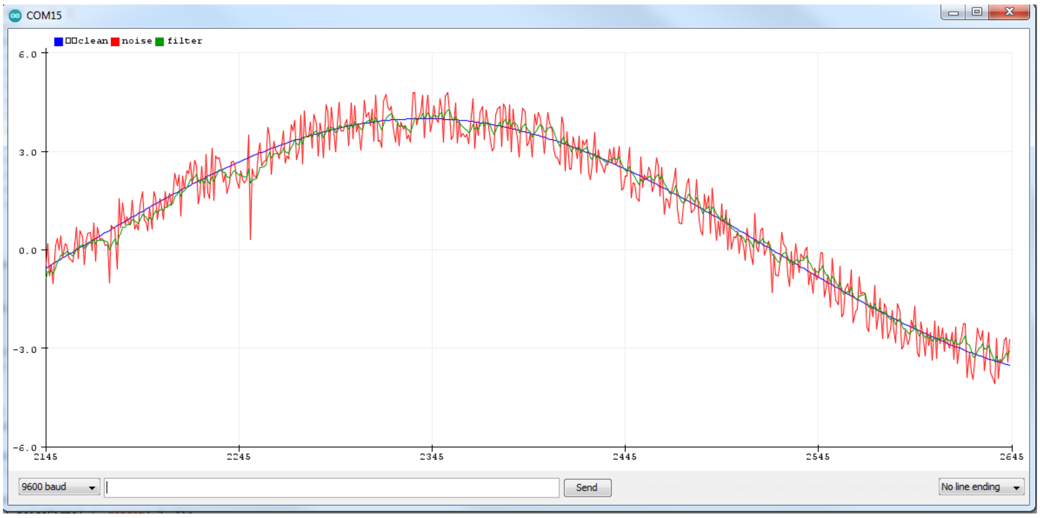


Figure 27. exponential moving average result, blue - initial signal (clear), red – noise, green – filtered resulting signal.

The exponential moving average filter is the lightest, fastest and easiest algorithm to calculate. It takes only one measurement at a time and does not block the code for a long period. The coefficient allows to rig the smoothness of the filter, the less the coefficient, the smoother, the greater, the less the peaks are smoothed (Figure 27).

3.3.4 Exponential moving average adaptive

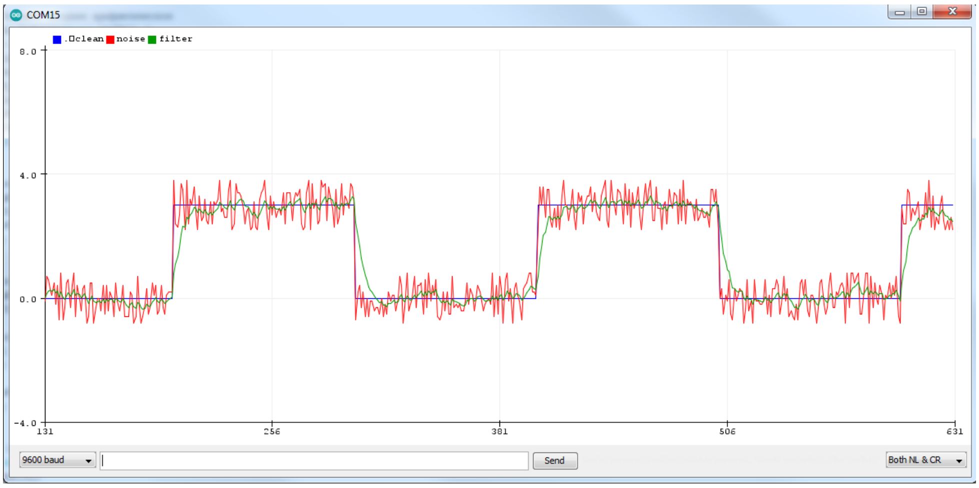


Figure 28 exponential moving average result, blue - initial signal (clear), red – noise, green – filtered resulting signal

The previous filter works extremely well on smoothly changing signals (Figure 27), but for example, in the case of a square signal, delays may already be observed (Figure 28), since a sharp change in the signal level will be smoothing out.

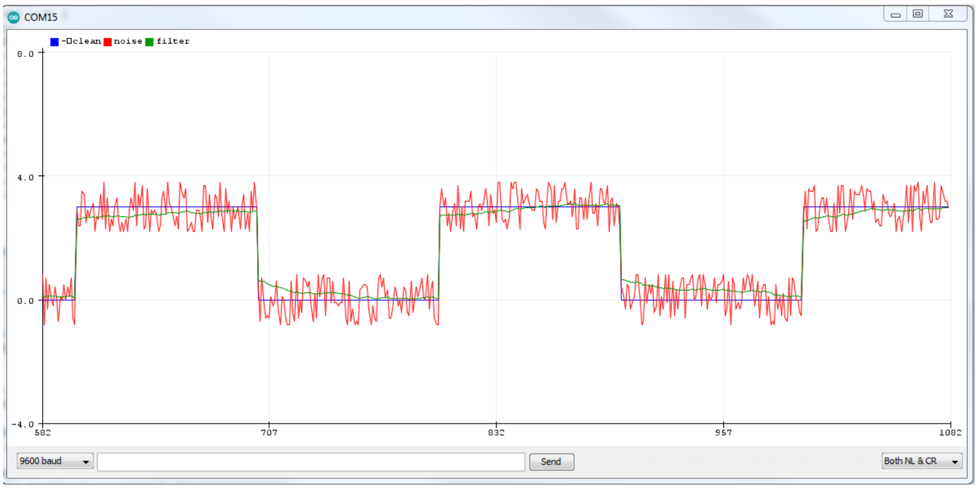


Figure 29. Exponential moving average adaptive result, blue - initial signal (clear), red – noise, green – filtered resulting signal.

To eliminate this smoothing problem, it can be used the Equation 5, but programmatically the filtering coefficient can be changed on each iteration, depending on the comparison of current and previous signal difference (different ranges) corresponding smoothing coefficient (in this case adaptive coefficient) can be applied. As a result, in case of square signal (or any rapidly changing signal) filter will have no markable delay (Figure 29).

3.3.5 Median

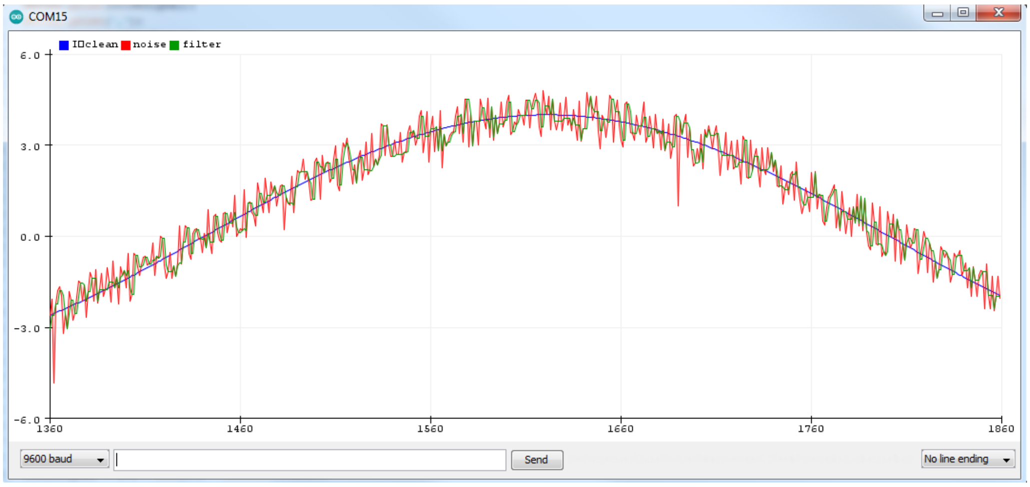


Figure 30. Median result, blue - initial signal (clear), red – noise, green – filtered resulting signal.

The median method is good to filter out some huge random noise peaks (Figure 30). The median filter also finds the average value, not by averaging but by choosing it from the presented ones. that is, in the case of five values (or any n number of values), all values will be arranged in ascending order and the average will be chosen, that is, the value that is bigger than 50% of other values and smaller than also 50% of other values. [39]

Example:

values= (1, 70, 50, 3, 15)

rearranged values = (1, 3, 15, 50, 70)

median value = 15

3.3.6 Simple Kalman

To calculate simple Kalman filter the following equation need to be used:

$$x_n = x_{n-1} + K_n \cdot (z_n - x_{n-1}) \tag{6}$$

where:

x_n - current estimated state (output)

x_{n-1} – last estimated state

z_n - new value (input)

K_n- Kalman Gain ($0 \leq K_n \leq 1$) [40]

Kalman gain is calculated:

$$K_n = \frac{p_{n-1}}{p_{n-1} + r} \tag{7}$$

where:

p_{n-1} – error estimate (extrapolated estimate uncertainty, adjusts itself during the filter operation)

r - error in measurement (expected measurement noise, set manually, can be taken as square of standard deviation)

Error estimate (Covariance Update after x_n calculation)

$$p_n = (1 - K_n) \cdot p_{n-1} + (x_{n-1} - x_n) \cdot r \tag{8}$$

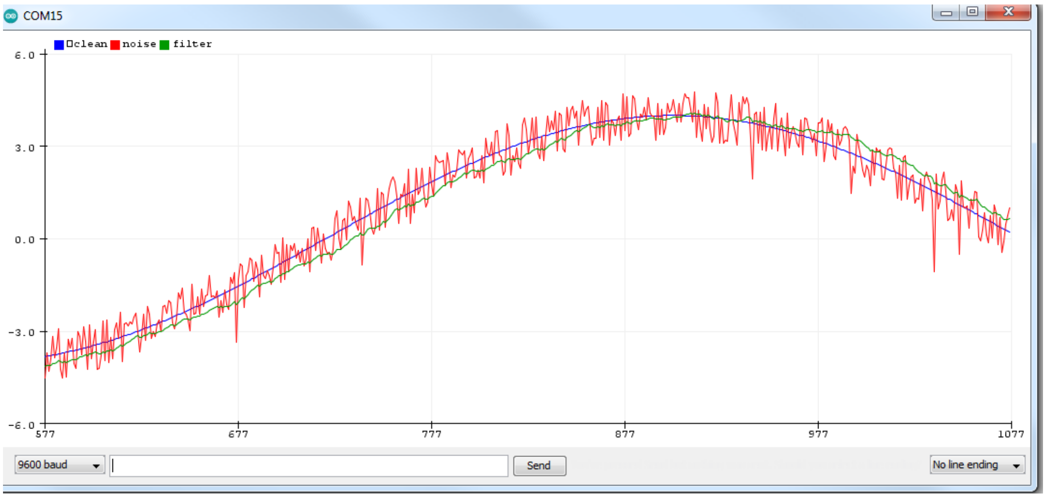


Figure 31. Simple Kalman result, blue - initial signal (clear), red – noise, green – filtered resulting signal.

The Kalman filter copes well with constant noise and sharp peaks. It takes only one measurement at a time and thus does not block the code, and has a slight delay (Figure 31) like the running average filter. The more often it measures, the better the result, but the calculation algorithm is not the simplest one, so one must take into account the possible time delay in case of low computational power processing unit..

3.3.7 ABfilter (AlphaBetaFilter)

ABfilter is derivative of the Kalman filter, where simplification of coefficient calculation is replaced by fixed coefficients or they vary only in some pre-programmed cases (similar logic as in adaptive running average). [41]

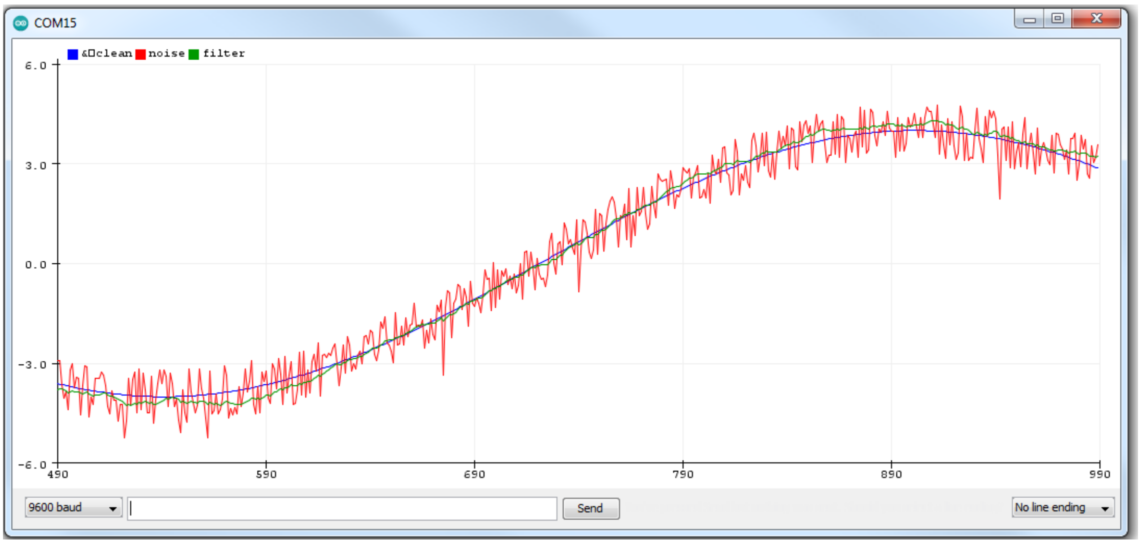


Figure 32. ABfilter result, blue - initial signal (clear), red – noise, green – filtered resulting signal.

A good filter, when properly tuned, does not have the same apparent delay (Figure 32) as the original Kalman filter. With fixed coefficients, it has a similar complexity, but if one lets them vary, then it has a rather large need for computing resources (for derivative, etc.).

3.3.8 Summary of filters

The choice of a filter depends on the type of signal and filtering time constraints. Arithmetic mean - well suited if filtering is performed infrequently and the time of one measurement of a value is short. A running average is fine for most situations, it is quite fast and gives good results when set up correctly. The 3rd order median filter is also very fast, but it can only filter out outliers, it will not flatten the signal itself. A higher order median is a rather cumbersome and time-consuming algorithm, but it works better. The median filter of the 3rd order + running average works very well, a smoothed signal with filtered outliers is obtained (first filtered by the median, then by the running average). The AB filter and Kalman filter are excellent filters, they cope with a noisy signal no worse than the median + running average combination, but they need fine tuning, and they are also quite cumbersome in terms of code computing power. Filters of linear approximation were not considered, since human walking has a completely non-linear character, and this method assumes finding a straight line that can be drawn between all measurement points. For the same reason, a least square filter was also not used, as it already tries to find the function describing the behaviour, but this will be the part of the other algorithm, not at the input filtering stage.

Finally, despite the fact that median filter of the 3rd order and running average filter combination were decided to be most suitable for the application, it was determined not to use currently any of the above filters, and instead, to investigate a ML-based approach implementing and testing filters at later stages of the development (possibly more at the stage of dataset preparation, during real-time data reading or reading back the feedback signals). This decision was done because the raw data can have some useful inputs for the movement analysing system and they can be lost during the filtration process. As a result there will be missing the ability to identify the problem of human at an early stage of the movement.

3.4 Machine learning methods

A further goal after studying standard solutions with filters is to study ML algorithms. Any ML algorithm (model) is essentially a mathematical description of a problem based on data. In the initial phase it is needed to understand the principles and use cases; how, for example, to restore the damaged shape of a sinusoid or square signal. After the overall performance on a simple signal will be researched, there will be clearer how a detailed algorithm can be applied to a signal coming from human motion measurements. ML methods can be divided into two groups. Supervised learning - giving examples with known inputs and outputs (data with label or classified) and unsupervised learning – the system has provided only sets of inputs and need to classify or find some pattern by itself. The following methods are most popular currently:

3.4.1 Regression

Regression methods can vary but they fall under the concept of supervised ML. In case of simplest linear regression, a straight line is selected that best describes the behaviour of the set of available data and, in accordance with the existing model (equation of the straight line $y = b*x$), having the input value «x», it is possible to predict the output value «y» along this line by multiplying the value by the obtained coefficient «b» (Figure 33). [42]

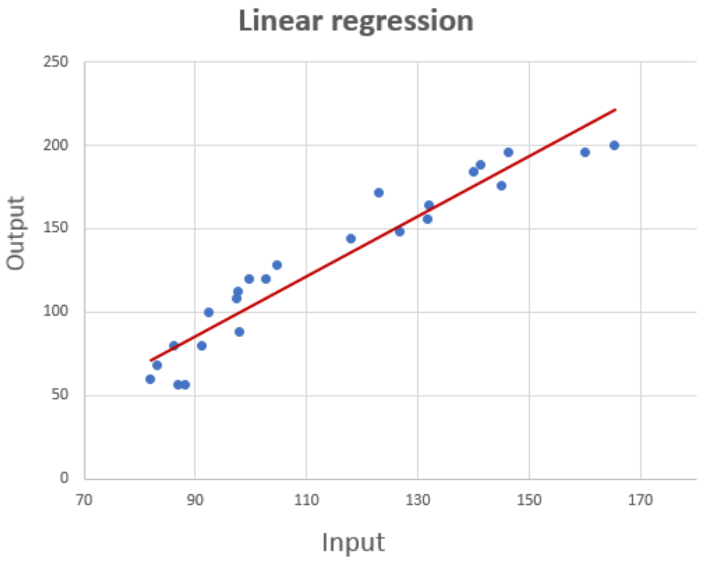


Figure 33. Linear regression example.

Regressions can also be polynomial, logarithmic, etc., in this case we are dealing in a pure form with statistical data analysis.

3.4.2 Classification

Classification is a supervised method where the input or combination of inputs data are provided to the system and an unambiguous answer is given to which group the object belongs (Figure 34).

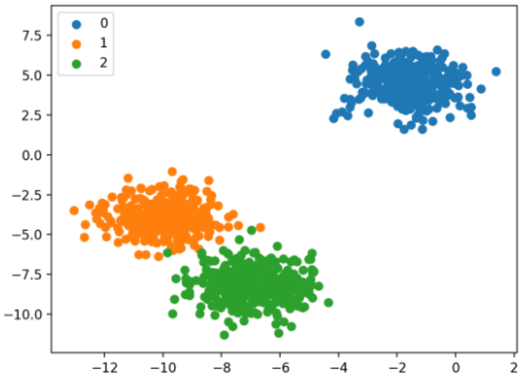


Figure 34. Class Classification [43].

Logistic regression is classification method that can be used to train systems to determine a binary answer like yes or no (Figure 35). An example here can be teaching a child by showing her/him many pictures of dogs, then a lot of pictures of cats, etc., thereby showing many examples of each class [44].

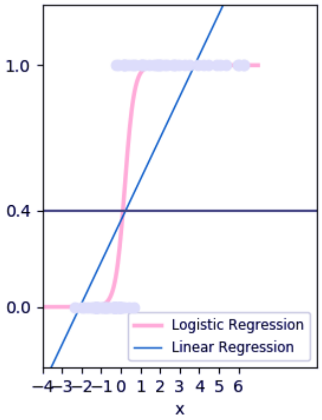


Figure 35. Logistic regression (classification method) VS linear regression (regression method) [45].

3.4.3 Decision trees

A decision tree (supervised method) can be represented as a binary tree (Figure 36) which is familiar to many from algorithms and data structures. Each node represents an input variable and a split point for that variable (variable is a number). Leaf nodes are an output variable that are used for prediction. Predictions are made by traversing the tree to a leaf node and printing the output value or class at that node [46].

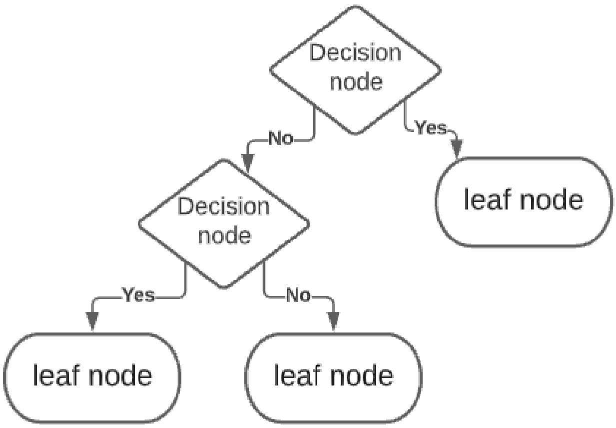


Figure 36. Decision tree example.

Trees learn quickly and make predictions. In addition, they are accurate for a wide range of tasks and do not require special data preparation. Ensemble of decision trees can create random forest algorithm (or begging)[45].

3.4.4 Naive Bayesian classifier

Naive Bayes is not complex and strong predictive algorithm. The system calculates two types of probabilities (calculated using the training data, Figure 37):

- the probability of each class.
- conditional probability for each class for each value of x.

After calculating the probabilistic model, it can be applied to make predictions with new inputs using Bayes' theorem. In case of real data, then, assuming a normal distribution, it is not too difficult to calculate these probabilities [47].

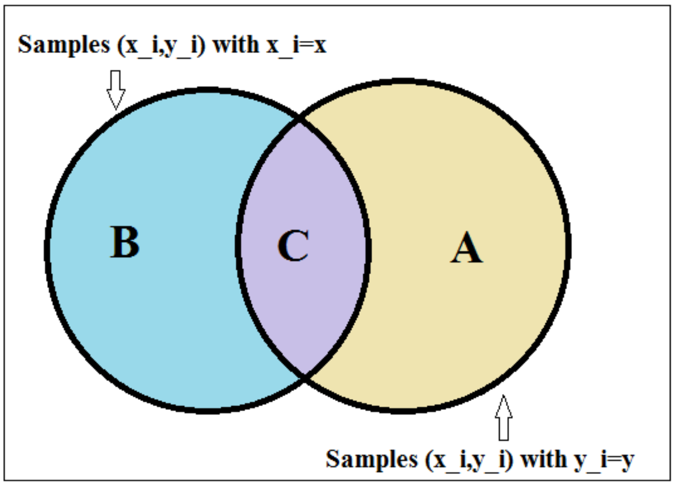


Figure 37. Naive Bayesian classifier example.

Naive Bayes is called naive because the algorithm assumes that every input is independent. This assumption does not match the actual data, however, this algorithm is very effective for a number of complex tasks such as, for example, classifying spam or recognizing handwritten numbers [45].

3.4.5 K-Nearest Neighbours

The K-nearest neighbours (KNN) supervised model is represented by the entire training dataset and is a simple and very efficient algorithm. A prediction for a new point is done by looking for the K nearest neighbours in the dataset (Figure 38) and summing the output variable. [44] [46]

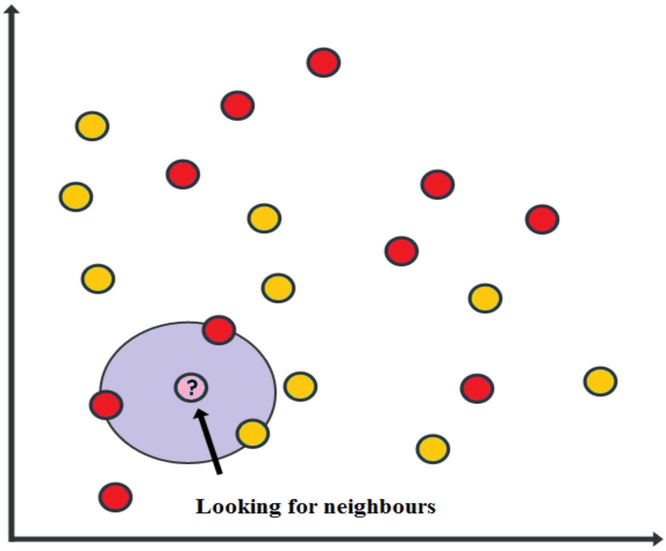


Figure 38. KNN working principle.

Of course, difficulties may arise in determining the similarity criteria for different data, determining the radius of taking the closest neighbours, etc. Also, in the case of multidimensional data (where data is not on 2-3 dimensional planes), processing by this method can take up a lot of memory, since it is necessary to constantly analyse a very large amount of data located nearby and in certain cases this can be a big loss in time. Here the solution can be a comparison only based on a part of the data, and not all available inputs.

3.4.6 Neural networks (Learning vector quantization)

Even in case of successful working, the KNN method in any case requires storing the entire dataset, what means large amount of memory and can be considered as a huge disadvantage. If the KNN worked successfully, then there is possible to use the learning vector quantization (LVQ) method or, under the more widespread naming, neural networks (NN). NN has no disadvantage associated with memory [47].

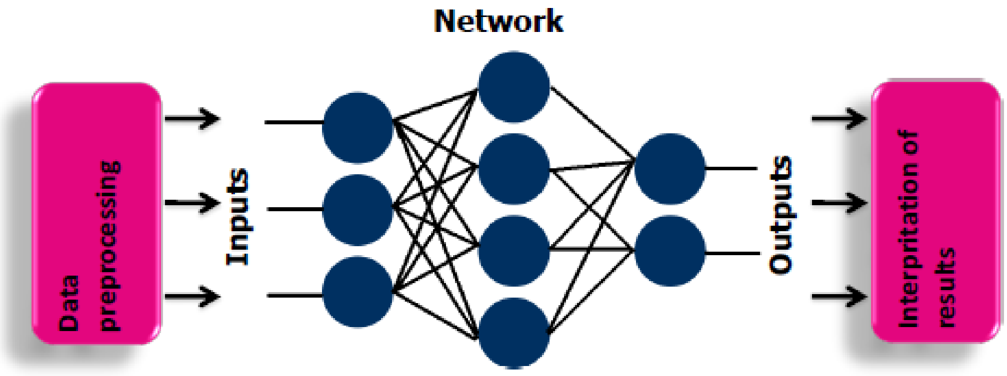


Figure 39. Neural network structure [48].

In this scheme (Figure 39), the first layer with the number of input parameters and the output layer with the number of output parameters can be selected, between them there is a hidden layer (there may be more than one). At the beginning of training, the vector algorithm inside the system has random values, but each time data is passed through them, their weight coefficients are edited and thereby the most optimal values of weight coefficients (for vectors) are achieved. After the successful network training when new data arrives, the algorithm as in KNN searches the most suitable vectors (neighbours in KNN) for the input data, but in this case, it is applied to vectors, not the dataset, after that the algorithm will be able to predetermine the output value. This method can be used both as a supervised and unsupervised. This method is believed to be particularly good for defining two-way outputs (yes or not).

3.4.7 Support vector machine

Support vector machines (SVM) is a type of supervised classifier method. Having on a plane a set of values of different classes, as a result, their zones can be limited by hyperplanes (green line in Figure 40), which will separate areas with most optimal way.

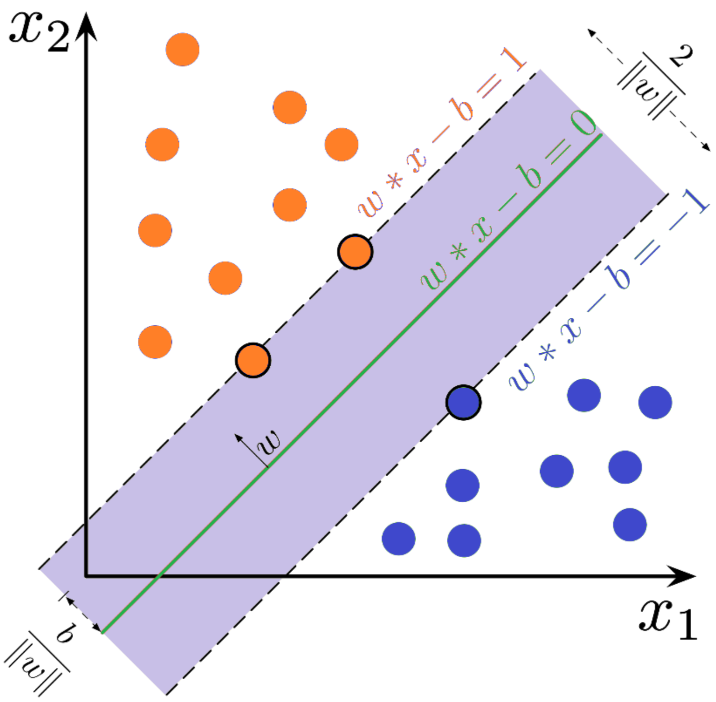


Figure 40. Support vector machine example [45].

The points that are closest to the hyperplane are called support vectors (points located on a dashed line in Figure 40), and the distance from these vectors to the hyperplane is called the gap. The further the support vectors are from the hyperplane, the more likely it is to correctly classify. It may happen that several points of the 1st class lie in the area of the 2nd. Then the gap will be small, and overfitting may occur. To prevent this, SVM ignores such cases by counting them based on cross-validation. Thus, points inside the gap are ignored (considered incorrectly classified) [49] [45].

3.4.8 Summary of machine learning methods

Despite the fact that each of the considered methods has good classification abilities, the method using neural networks seems to be the most suitable for use within the framework of a prototype for processing human movement data, since having a lot of input (measured) data, it is possible give the network a large amount of inputs (datasets) and train by examples. Trained NN after receiving new unseen before signal will be able to give answer whether it was expected or unexpected signal (normal or abnormal step). It is important to note here that a NN is trained at a certain interval of data values and can provide the solution only in the trained range. If there will be inputs outside the rage on training data set, then the behaviour of NN can be unpredictable.

3.5 Signal segmentation and neural network training

The analysis of human movement is supposed to be done based on the measurement data of steps by the means of motion sensors located on the patient's leg. For this purpose, a Shimmer3 Wireless Sensor Unit was used to measure movement data along three axes and recorded data at a frequency of 250 Hz to the separate file (measurements performed by another Master student).

Next, it is necessary to determine, based on measurements, which step was correct and which was not, to be able to assess at which moment a person had problems with movement. For this purpose, it is necessary to first investigate on which of the axes the signal for this is best suited, then select the patterns of correct and incorrect steps. Further, with the help of training a neural network (subchapter 3.5.3-3.5.4), it is necessary to train it to determine correct and incorrect steps based on the provided examples. Since studying different types of steps and movement problems will require studying a very large amount of data, only at the initial stage all steps will be given to the system manually, then an algorithm will be thought out that independently reads the entire data array[1].

3.5.1 Measuring the data

To collect and record the data, several patient passes were done, where the person walked normally and then at some point walked with an abnormal gait (measurements performed by another Master student). The following gait abnormalities were reproduced and recorded [50]:

- antalgic - pathology caused by pain, most often manifested as lameness
- ataxic - staggering, slow and unsteady gait. With unilateral lesion of the cerebellum, patients will deviate in the direction of the lesion
- hemiplegic - spastic flexion of the upper limb and extension of the lower limb
- diplegia - similar to hemiplegic but has bilateral character
- parkinsonian - with slow start and resting tremor, reduced arm swings
- and some others (can be seen more detailed in other thesis work focused on this topic [51])

---

[1] I obtained the following results as part of the course IAS0031 MODELING AND IDENTIFICATION which I took specially to support the implementation of the work presented in this MSc thesis.

The result of data collection was CSV files (where, while making a circle around the room, the patient made specially one or two steps typical for an abnormal gate). Each run resulted in two files: one from the sensor which was placed on knee and one from a sensor placed on the foot. Each file contained data with time, acceleration for 3 axes (m/(s^2)), gyroscope for 3 axes (deg/s) and EMG (electromyography sensor) [52].

3.5.2 Measured data overview and sample selection (Hemiplegic gait)

Hemiplegic gait measured with sensor placed on the knee was taken as a data set to be analysed. It is important to note here that although the manufacturer declared the sampling frequency was 250 Hz, based on the measurement files, each sampling took place on average every 3.91 ms, which ultimately leads to the fact that the actual sampling frequency changes from 250 to 256 Hz in real life.

The duration of this hemiplegic gait measurements was 56 seconds (approximately 40 steps with one leg). It is the interval from the first to the last step. In order to identify the moment of the beginning of steps a “hit” to the sensor followed, which stood out clearly from the general background of the measured data (marked in Figure 41). In addition, a video recording was also used, where it was possible to accurately observe what was happening at what moment and combine the measured data of activity on the chart with real actions seen on the video.

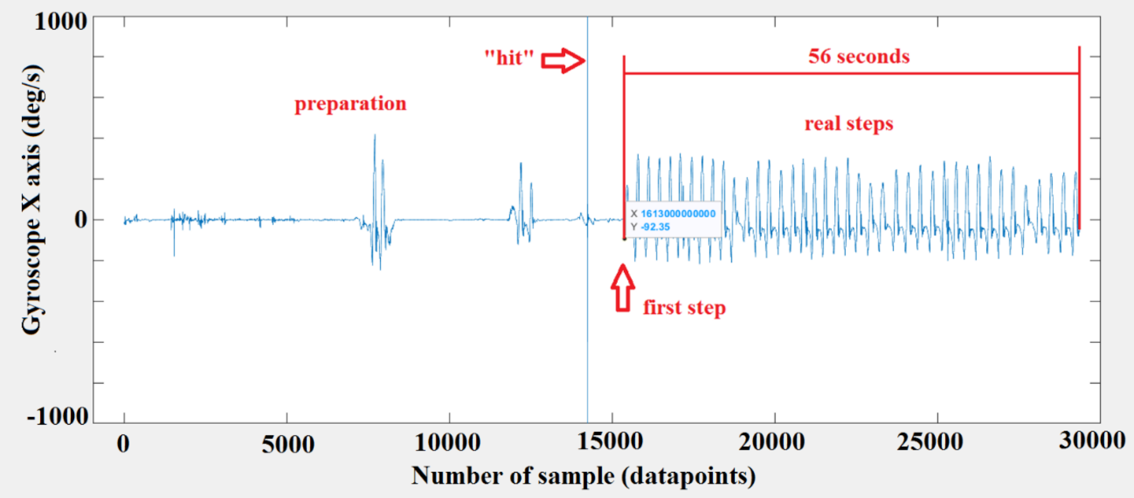


Figure 41. Gyroscope X axis of knee sensor (initial plotting of measured data).

The data measured from the gyroscope on the knee along the x-axis turned out to be the most periodic of all the measured signals (Figure 42), the amplitude of the signal of each “normal” step was very similar, which was not observed so clearly in the case of other axes and the sensor on the foot.

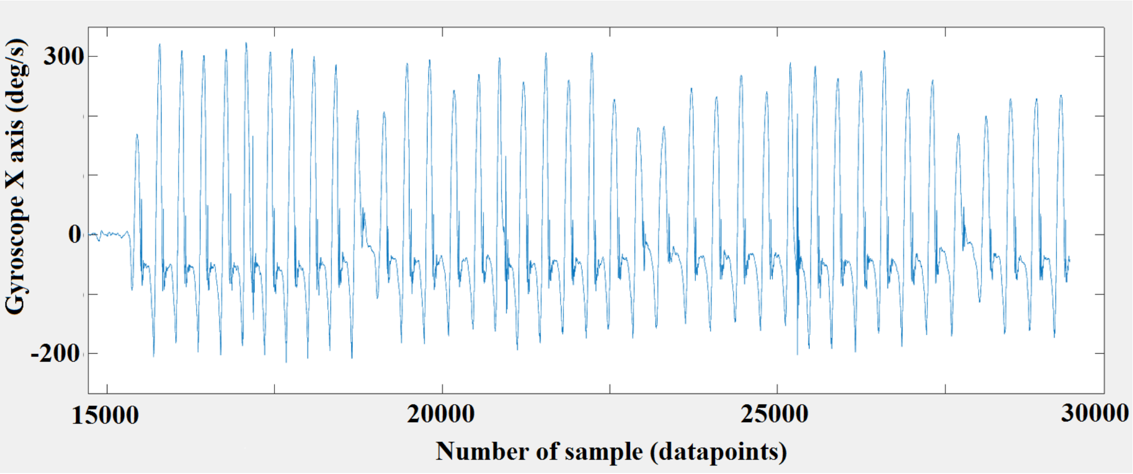


Figure 42. Gyroscope X axis of knee sensor (gait measurement).

Examples of normal and abnormal steps signal are shown in Figure 43. It is even visually noticeable that normal steps have a very similar shape, while the abnormal one has a bigger angle of slope at the beginning and sharper shape of following signal part.

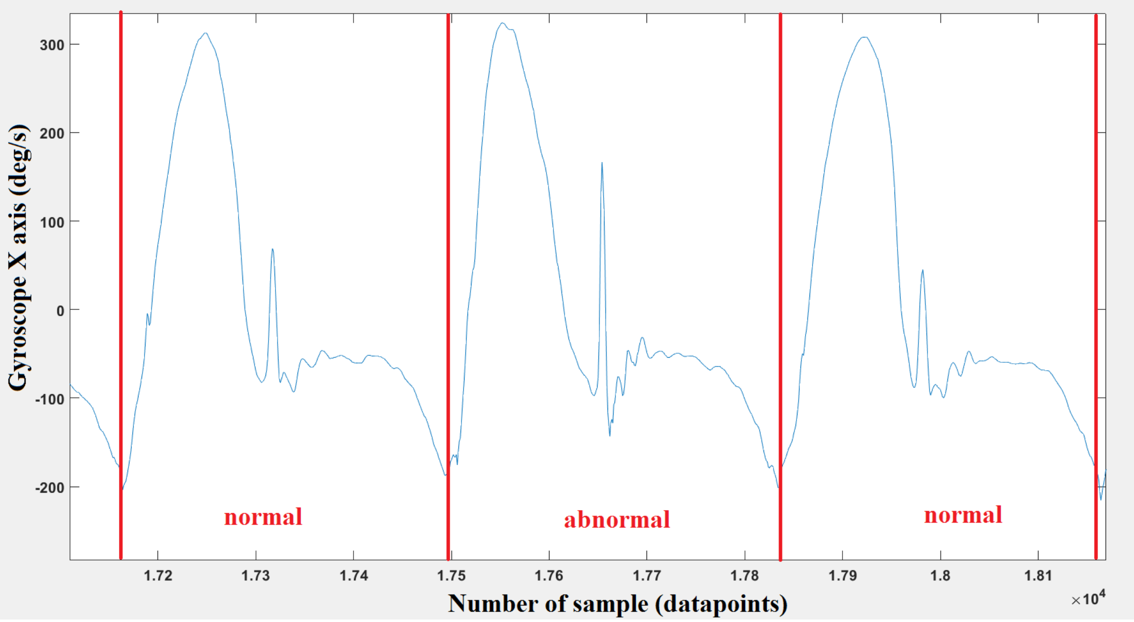


Figure 43. Examples of normal and abnormal steps signal at hemiplegic gait. (zoomed part of Figure 42)

It is difficult to determine the steps along other axes (where is the beginning and where is the end of the step), nevertheless, at the instant an incorrect step occurs on these axes, a spike is clearly visible that stands out from the general signal behaviour (Figure 44).

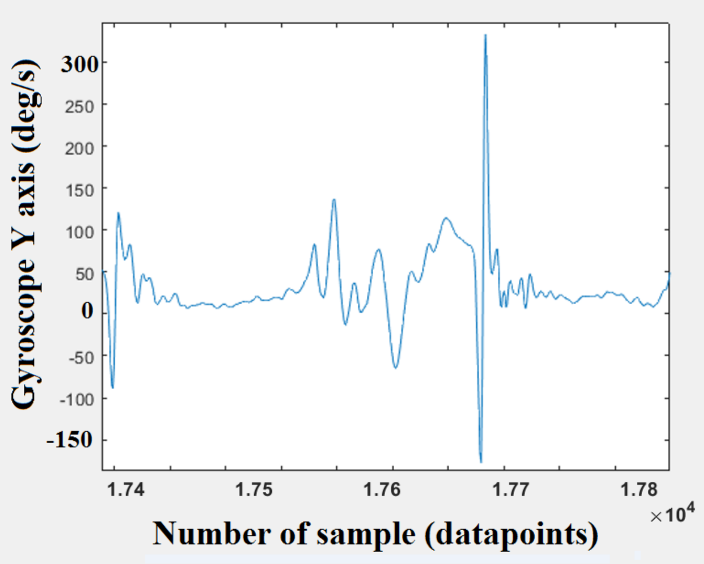


Figure 44. Signal "splash" at Y axis at the moment of abnormal step.

Finally, there were manually selected examples (from gyroscope X axis and knee sensor) for training a neural network, samples of correct and incorrect steps (similar to those displayed in Figure 43).

3.5.3 Supervised network in Matlab for step type detection (full step data)

For training, the NN Matlab software (version 2020a) with Deep Learning Toolbox, Optimization Toolbox, and Statistics and Machine Learning Toolbox were used. The data from the measurement file was read into Matlab and in the region of interest, normal and abnormal steps were selected, respectively (manual selection at this stage). The neural network was trained using supervised method (feed forward) providing to the system examples of inputs and known output value.

Initially, for the system training, a full steps sets were given: normal and abnormal. After training the network for verification, there were inserted several measured steps data that the network had not seen before (test set with normal and abnormal steps). After this test, the system gave the answer that the step was normal (normal test step) with a probability of around 60%. At this point, an understanding came about the need for normalizing the measured human step data (between 0 and 1). After that, the network was retrained and testing it with normal steps improved the probability to detect normal steps to between 70-75%.

But accuracy turned out to be insufficient, since difficulties arose when trying to determine an abnormal step. To deal with this, the system was fed with more examples of correct and incorrect steps and during training, variations with the addition of noise were also used.

Table 5 shows the 7 steps used to test the trained neural network. Accordingly, steps 1,3,5,6 were examples of normal steps and steps 2,4,7 were examples of abnormal steps. The output result of the neural network varies from 0 to 1, respectively. As an example, if the neural network outputs 1 opposite to "detected normal" then the neural network determined that the step was normal, the more the number differs from 1, the more uncertainty in the neural network response. As a result, after this test, the system could give an answer whether it was a normal or abnormal step in all 7 selected test step cases (correct answers marked with green) with a rather small uncertainty in cases of step5 and step6.

Table 5. Test of trained NN with validation step set with full step.

Detected step by NN	Test set						
	Step1*	Step2**	Step3*	Step4**	Step5*	Step6*	Step7**
normal	1	0	1	0	0.9985	0.9888	0
abnormal	0	1	0	1	0.0015	0.0112	1

* normal step inserted for detection
** abnormal step inserted for detection

(As some parts during training process of neural network are random and not configurable, later using the exact same parameters of neural network it is possible to get the slightly other output results)

3.5.4 Supervised network in Matlab using first part of the step

So, the determination of the type of step began to occur successfully, but in a real system, after measuring the full step, it will be too late to determine that the step was wrong, because in this case, we will be able to state that the person has already either fallen or did the previous step incorrectly.

So, before that, each full step was described by 330 points (in average), after which the next step began; now it will be tried to determine the type of the step in the first half or third of the full step, that is, 165 and 110 points, respectively. For that goal, the starting points of steps remain the same, but the endpoint will be changed.

But it turned out to be quite interesting that when using half a step unknown patterns (steps) to the system were determined correctly only in 4 of 7 cases (Table 6 shows wrong recognitions marked in red and correctly recognized with green).

Table 6. NN system test after training with half step.

Detected step by NN	Test set						
	Step1*	Step2**	Step3*	Step4**	Step5*	Step6*	Step7**
normal	1	0	1	0	0.0001	0.0022	1
abnormal	0	1	0	1	0.9999	0.9978	0

* normal step inserted for detection
** abnormal step inserted for detection

To understand the reason for this error, visualizing graphs were considered, which showed how the used half of the steps looked like (Figure 45). And here an assumption can be done that these pieces have a certain similarity, and if we take into account that the network was trained with samples with the addition of small noise, then the system, most probably, began to perceive the existing differences as noise.

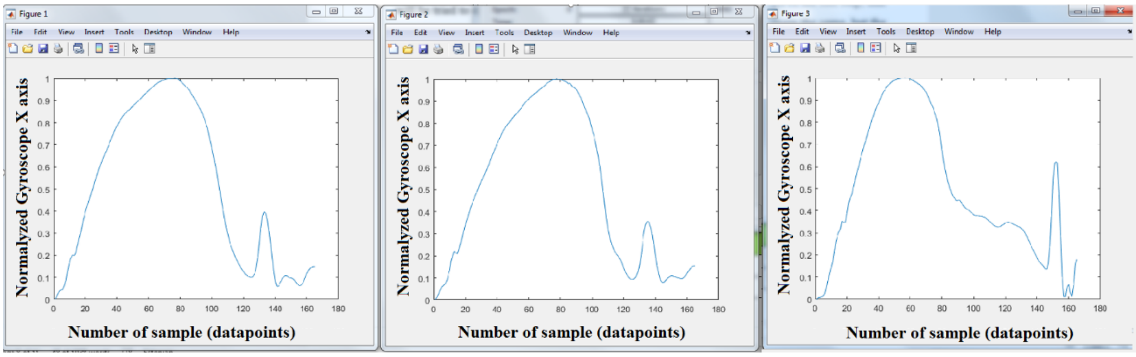


Figure 45. Normalized between 0 and 1 first half step data shape comparison (from left to right: normal, normal, abnormal).

When taking one third of a step and retraining the NN, it turned out that the NN always identifies the steps correctly (see Table 7, green cells are correctly identified steps). So, this approach seems to be the more effective and rational, as it can predict the type of the step already at first third of ongoing movement step signal.

Table 7. NN system test after training with one third of step.

Detected step by NN	Test set						
	Step1*	Step2**	Step3*	Step4**	Step5*	Step6*	Step7**
normal	1	0	1	0	1	0.9241	0
abnormal	0	1	0	1	0	0.0759	1

* normal step inserted for detection
** abnormal step inserted for detection

If, again, considering the separately plotted part of the step (Figure 46), then it can be seen that it is probably easier for the system to identify the differences on a particular segment since the slope in the abnormal step is larger and also the graph ends noticeably differently than in the normal step.

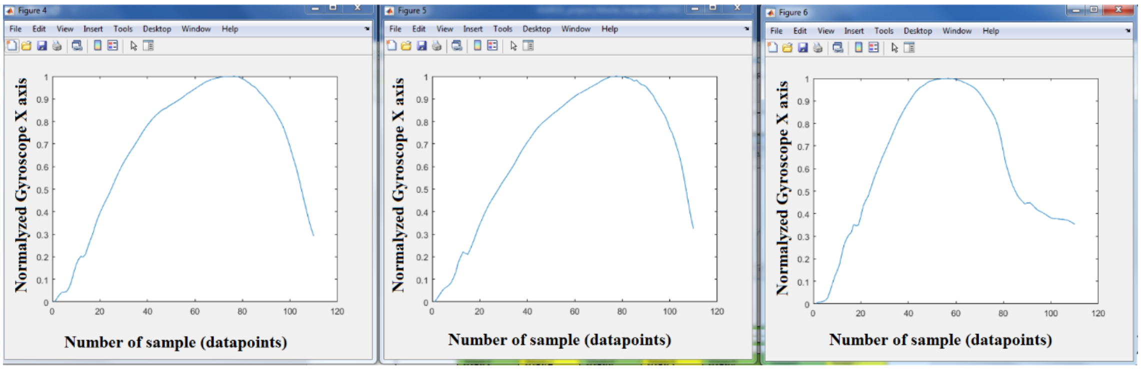
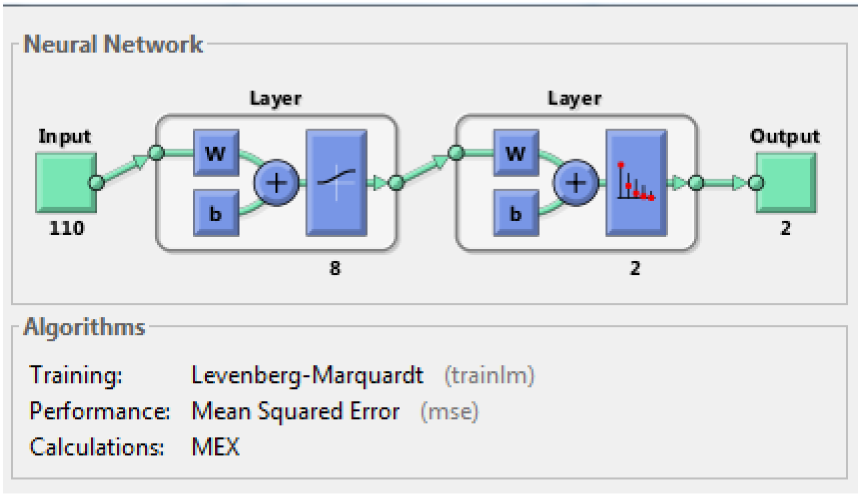


Figure 46. Normalized between 0 and 1 first third part of step data shape comparison (from left to right: normal, normal, abnormal).

3.5.5 Structure of tested NN



Training: Levenberg-Marquardt (trainlm)
Performance: Mean Squared Error (mse)
Calculations: MEX

Figure 47. Structure of NN tested in paragraph 3.9.

The neural network used in the previous paragraphs (3.5.3-3.5.4) is shown on Figure 47 or in code can be defined as:

```
net=newff(minmax(steps),[8 2],{'logsig','softmax'},'trainlm')
```

The network has 110 input neurons (minmax(steps) - each step first third of points is in average 110 datapoints), 8 neurons in hidden layer and 2 output neurons in output layer (the answer comes from output neuron was normal or abnormal step), transfer functions used are Log-sigmoid (logsig) and Soft max (softmax), backpropagation network training function is Levenberg-Marquardt (trainlm).

The selected combination of parameters and functions may not be ideal, the choice was based on tests of various examples offered inside the Matlab Deep Learning Toolbox, as well as on the basis of the proposed examples of solving similar problems within the framework of the IAS0031 course. The goal of the training NN was not to find ideal solution, but rather to prove the concept, that the problem can be solved using NN.

3.5.6 Automated step detection for more training data

The previously used manual approach can be automated to detect the steps. For example, it seems to be rational to write a script that would automatically determine steps in a long series of signals. The logic of the script should be such that maximums and minimums are determined among the data array in known ranges, and based on them, it is determined where the step is done (in fact, like a person does it by looking at the graph). This idea is illustrated in Figure 48.

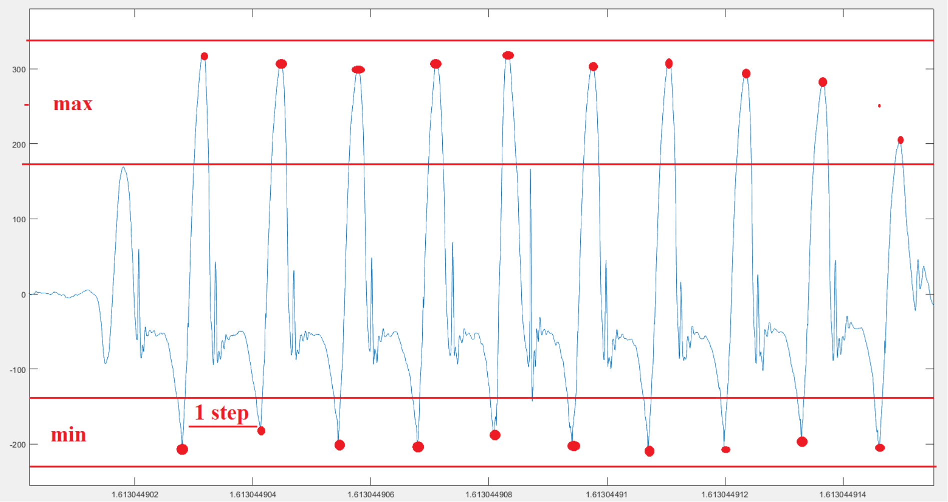


Figure 48. Idea of more advanced data preparation algorithm for step recognition.

For non-manual selection of steps, an algorithm was derived that takes three acceleration axes parameters (x, y, z) which, after summation, are slightly smoothed by a filter. As a result, the beginning of each step (red points marked in Figure 49) were detected by calculating stationary points of the movements. Having the coordinates of each this point (saved to separate matrix) it is possible to take the predefined zone of interest in different directions from this point.

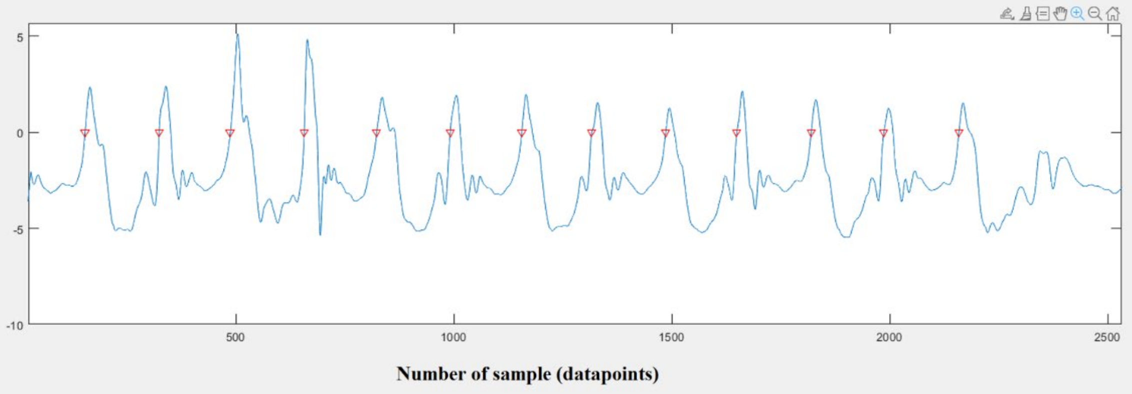


Figure 49. Step starting point (all accelerations 0) Problem of detection the steps for the training sets is solved.

3.5.7 Conclusion of Matlab part

This part turned out to be the most time-consuming of all that was done in this thesis. At a first glance, it seemed quite simple, but in reality, it took a lot of time and effort. The first and most difficult task was to determine which of the huge set of measured data is most suitable for initial and almost manual analysis. The last and simpler one was to give the selected data to the system. The main difficulty was the lack of experience in collecting and analysing data, perhaps, this could have been done faster. But it was even mentioned in all literature of machine learning, that the preparation of data and its collection takes the largest part of the time in any kind of such project.

In general, the goal has been achieved. But in theory as there are also other measured human movement files it is also possible to add different definitions of additional action (not only normal and abnormal step), for example, when a person turns around on place (for example rotation of person in Figure 49 region between 2200 and 2500 in data sample axis). The system makes currently nothing when a signal is not detected as a step. Since many types of abnormal walking have been measured, it is possible to make a determination of different types of abnormal steps, but this is a question to be discussed, because it is good to have all possible error types in one system; however, in this case the system gets to be more complex and it is unlikely that there will be a patient who will have all possible variations problems of walking and system need to be adjusted to every person separately.

It can be concluded that the planned recognition of steps was performed adequately, but as it already can be seen, maybe not in the most efficient way and some aspects could be optimized and added in the developed program (detecting different abnormalities for example).

3.6 Conclusion of data analysis and algorithm concept part

Within the framework of this chapter, it was considered what methods of filtering incoming signals can be, and which of them can give the desired effect without requiring very large computational capabilities (a combination of a running average with a third-order median filter). Also, various machine learning methods were considered. The neural network approach was tested on the one type of measured gait abnormality. For a good training of a neural network, the set of a large number of examples is necessary, but even using a small number of samples and creating their variations adding the noise to them it was possible to get the initial and desired results.

4 Hardware solutions

This chapter considers the application of the learned theory and certain software solutions onto real devices and components.

4.1 Wireless system and initial experiments

For initial first testing, a Raspberry Pi4 (RPi4) board was used to test the system in which the algorithm will operate. In order to track the data exchange flow, adapters from micro HDMI to standard HDMI were used and the system was connected to a monitor. An additional cooling system was also added, since even during normal operation the RPi4 began to overheat.

Within the framework of the project, it is assumed that the prototype system will be worn by a person at all times. As already at the stage of the very first tests, the structure of a RPi4 with cooling and a sensor connected to it turned out to be very cumbersome, it was decided to try to implement a scheme where the RPi4 acts as an intermediary/broker (Mosquito local broker was used), and the sensor sends it data over a wireless channel (Wi-Fi). For these purposes, the message queuing telemetry transport (MQTT) protocol was used, where it is possible to send information on a specific topic and subscribe needed devices to it [53].

For the first test of the system's operations, a rather simple scheme was implemented (Figure 50), where instead of a body position and movement sensor, a temperature and humidity sensor (dht11) was used, and a module with a relay played the role of a stimulator that turns on and off according to the logic of the algorithm. Both the temperature sensor and the relay were connected to the esp8266 modules each, which allowed them to be controlled wirelessly and they would only need to be supplied with power (5V).

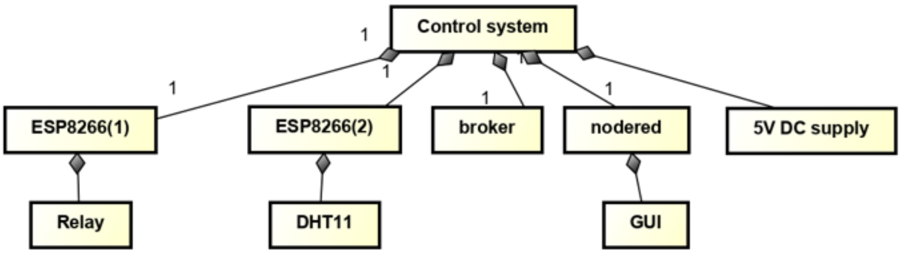
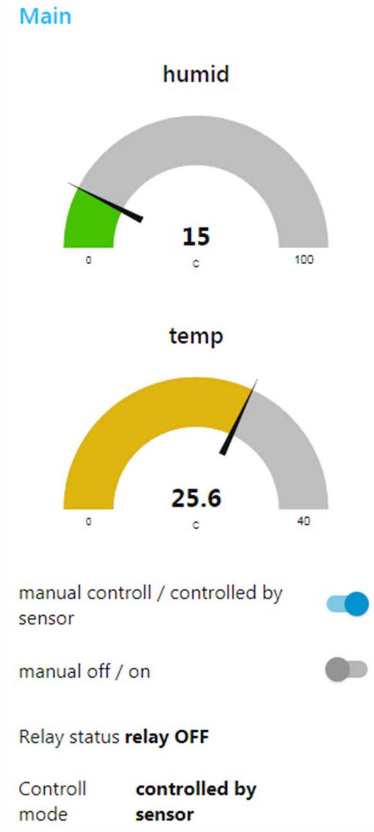


Figure 50. Structure of the system.

To track the current temperature (in next steps this will be replaced by human position data) and see the state of the relay (in next steps, the state of the TENS device) NodeRed was installed on the RPi4, in addition to the broker. This gives the possibility to see in real time the data flow, to let the system work using some algorithm, and also to implement some simple graphical user interface (GUI) where it is also possible to switch between different modes and get feedback from the system (Figure 51).



manual controll / controlled by sensor

manual off / on

Relay status **relay OFF**

Controll mode **controlled by sensor**

Figure 51. GUI for fist test setup.

The logic of exchanging messages through the broker can be seen in Figure 52. In the MQTT scheme, any receiving or sending device is considered a client, and the broker is the place where the last value is stored and the place through which all messages pass. Accordingly, there are 3 clients in this system, one sends data from the sensor, the second receives on or off commands and gives feedback whether the system (next step TENS device) is turned on or not, and the third client is a NodeRed interface in which it is possible monitor the data on the screen and also control either using an algorithm or in manual mode. In the future, the client NodeRed will be replaced by an algorithm with the previously trained neural network, and it will be the client which will already receive real movement data and send commands.

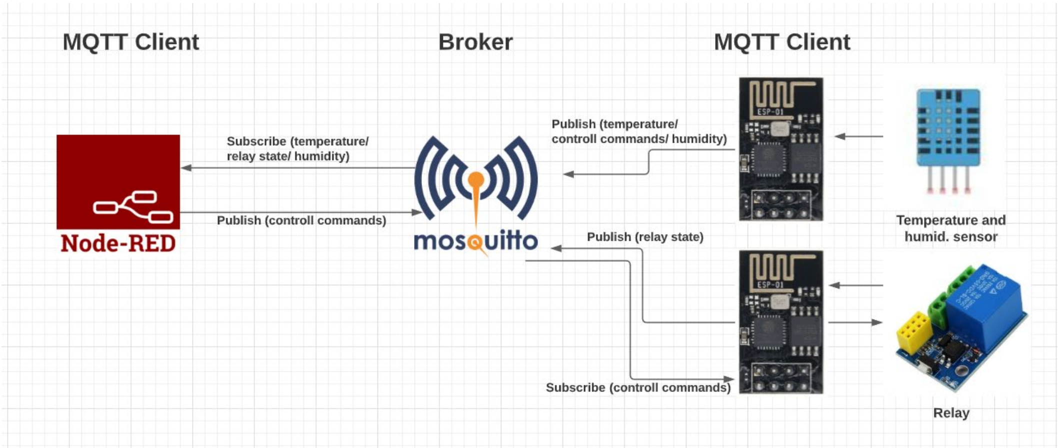


Figure 52. Initial wireless system structure.

Since at this stage of the prototyping, there were already existing measured data on the basis of which it was possible to make some analytics, it was decided to replace the temperature sensor with a program running in Windows PC that reads data from a CSV file with recorded movements and turns on the device for the some time during each human step (Figure 53).

This made it possible to already send some defined signals based on the results of the pre-processed data. The system was working, but this way of data exchange is more suitable for home automation (turning on heating for example) and has practical drawbacks in terms of significant delays, which is not acceptable in real-time systems. So, the concept and structure worked, but needed some improvement to satisfy real-time system requirements. One of the ways to solve it is transition from ESP8266 to some another controller.

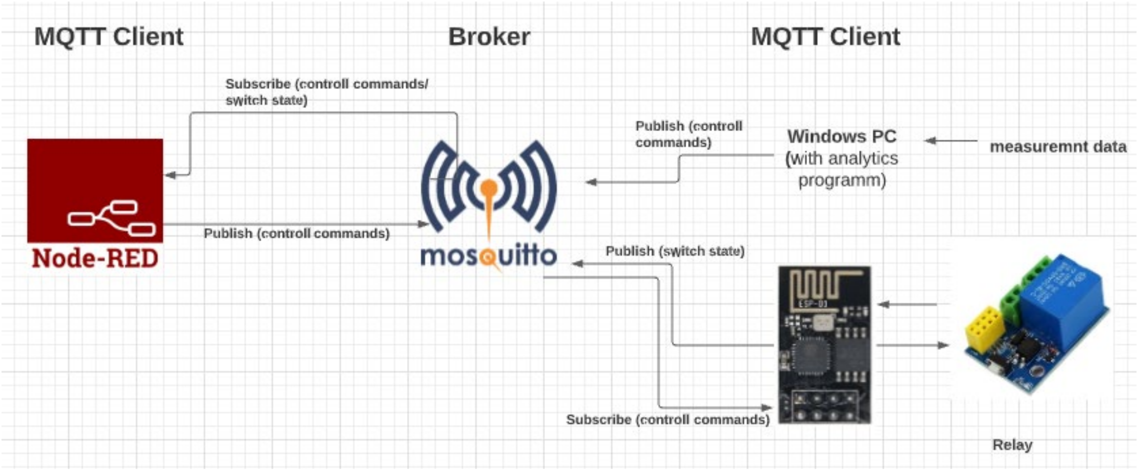


Figure 53. Wireless system with first movement based signal sending algorithm.

4.2 Esp32 and Bluetooth implementation

Since the main need for the transition from ESP8266 is to increase the speed of data exchange, it was decided to take the next step from communication not through Wi-Fi and MQTT, but by means of Bluetooth and the simplest and most economically feasible was to conduct tests with esp32 chip-based board, which has additionally to Wi-Fi also Bluetooth Low Energy (BLE) interface [54]. So, the whole logic remained similar but changed the board and communication type. Also, in the circuit the relay module was replaced with a transistor key, since in reality it is hardly possible to use a bulky relay block in the prototype of wearable device. To test the setup with Bluetooth (BT) on esp32 the circuit with IRF520 MOSFET transistor (Figure 54) and external power source was tested, in this case LED (light emitting diode) strip with built-in resistors was in the role of "contact" on the human body.

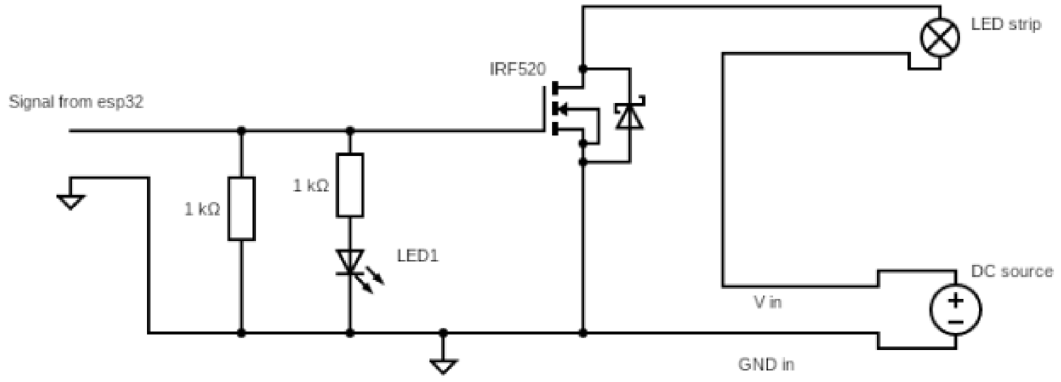


Figure 54. Circuit with IRF520.

Communication in this case is carried out quickly (esp32 has BLE 4.2 which regarding the measurements should be below 46 ms [55]) and can be controlled both from the Bluetooth module of the computer and for debugging purposes, it can also be connected from a phone.

4.3 Bluetooth communication

The logic of the code inside the esp32 controller board was as simple as possible, so that it had the minimum complexity and the minimum possible places for generating delays in the process (Figure 55). The controller is programmed to receive three types of messages:

- on - the switch is activated, which enables the passage of the stimulator signal directly to the patient;
- off - the stimulator signal switches to the resistance simulating the resistance of the human body (the need for this was investigated in Section 4.4);
- test - mode for debugging, when receiving a blinking signal, the device will alternate once a second, stimulation will go to the body, once a second, stimulation will go to deceiving resistance (this mode was necessary for debugging work and can be used further when working out other algorithms).

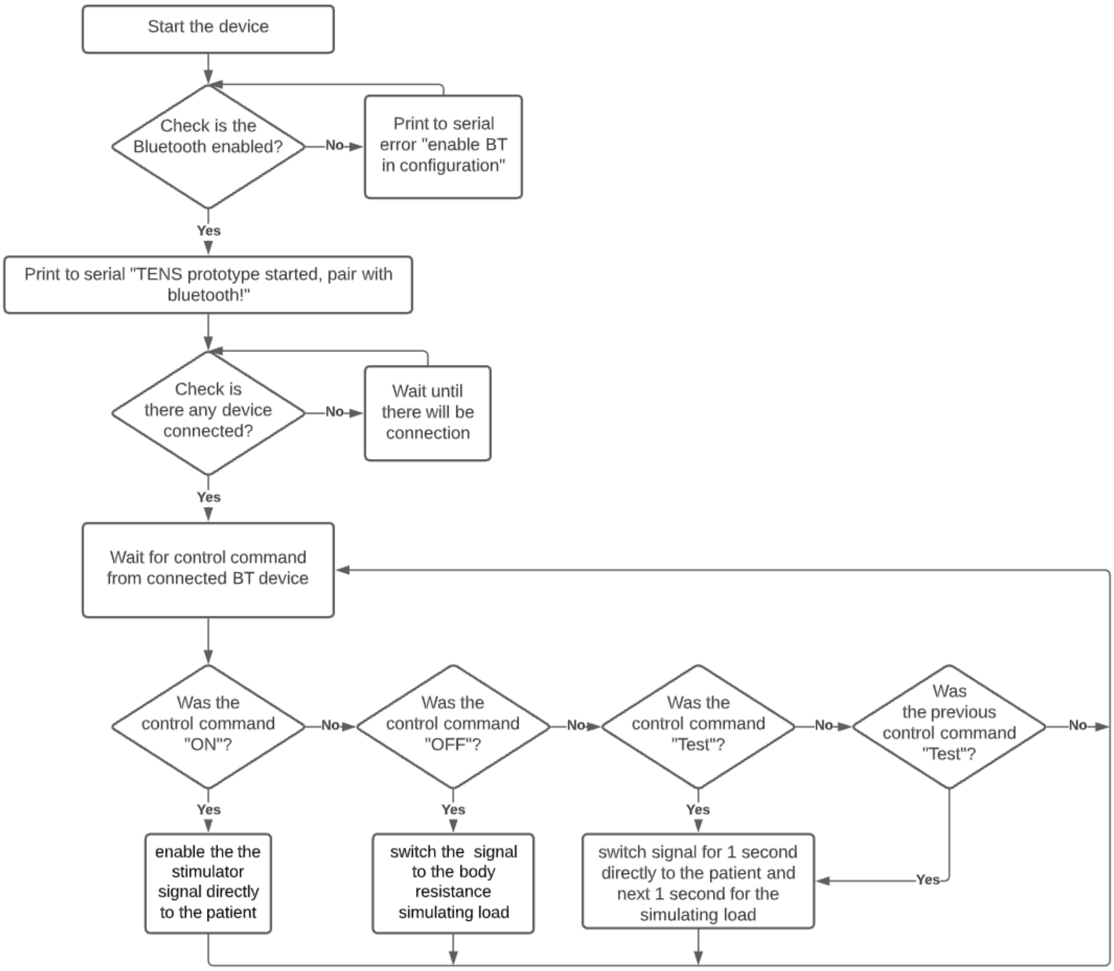
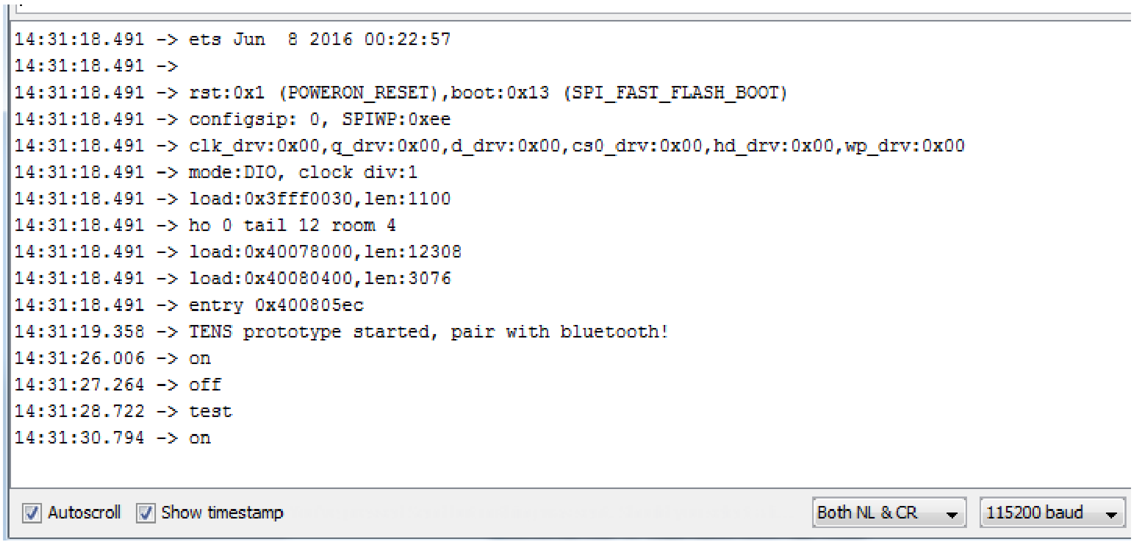


Figure 55. Algorithm of the communication and performance logic inside of esp32.

For communication via BT, a ready-made open library "BluetoothSerial.h" was used, which has the most stable and well-functioning communication with esp32 based controller. Code was developed (Appendix 2) based on the logic described in the algorithm shown in Figure 55 and adding some additional features for debug possibilities. There are functions that allow to return a received BT command message from the device to the esp32 serial interface (Figure 56), send back the BT message to the control device, depending on what state the device currently has (in Figure 57, state response messages indicated in green). Since at the later stages of development this function can be needed again, it is temporarily only commented out.

Initially, to check the performance of the code, a smartphone program named "Serial Bluetooth Terminal" (available for Android and iOS smartphones) was used for communication (Figure 57). In addition to connecting to BT devices, the program also allows to send and receive messages from the connected BT devices, and also has the ability to save fixed commands. In Figure 57, under the buttons M1, M2 and M3, are saved control commands “on”, off” and “test”, respectively.



```
14:31:18.491 -> ets Jun  8 2016 00:22:57
14:31:18.491 ->
14:31:18.491 -> rst:0x1 (POWERON_RESET),boot:0x13 (SPI_FAST_FLASH_BOOT)
14:31:18.491 -> configsip: 0, SPIWP:0xee
14:31:18.491 -> clk_drv:0x00,q_drv:0x00,d_drv:0x00,cs0_drv:0x00,hd_drv:0x00,wp_drv:0x00
14:31:18.491 -> mode:DIO, clock div:1
14:31:18.491 -> load:0x3fff0030,len:1100
14:31:18.491 -> ho 0 tail 12 room 4
14:31:18.491 -> load:0x40078000,len:12308
14:31:18.491 -> load:0x40080400,len:3076
14:31:18.491 -> entry 0x400805ec
14:31:19.358 -> TENS prototype started, pair with bluetooth!
14:31:26.006 -> on
14:31:27.264 -> off
14:31:28.722 -> test
14:31:30.794 -> on
```

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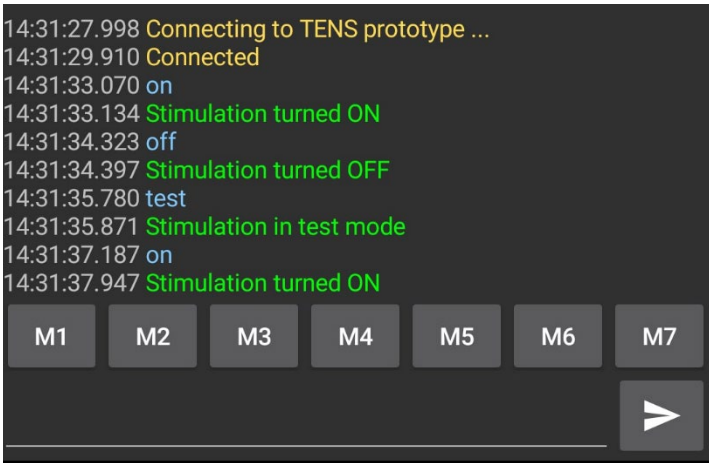
Both NL & CR

115200 baud

Figure 56. Serial communication with esp32 based prototype.



```
14:31:27.998 Connecting to TENS prototype ...
14:31:29.910 Connected
14:31:33.070 on
14:31:33.134 Stimulation turned ON
14:31:34.323 off
14:31:34.397 Stimulation turned OFF
14:31:35.780 test
14:31:35.871 Stimulation in test mode
14:31:37.187 on
14:31:37.947 Stimulation turned ON
```

Figure 57. Bluetooth communication from smartphone using program “Serial Bluetooth terminal”.

4.4 Prototype with TENS setup measurements

Since only theoretical aspects were previously studied, the practical experiment with TENS device can give extremely useful and illustrative results.

Already from the initial try to implement the TENS device to the circuit it was found out that the stimulator measures the resistance between the contacts every moment; as soon as there is no resistance, the stimulation stops and the device enters a waiting mode until resistance appears back and the stimulation activation button is released again. To fulfil the requirement of continuous resistance present during all stages of the test, changes were made to the circuit (Figure 58) where in a situation where it is necessary to stimulate a person (ON state), a load 1 (resistor 1kOhm instead of real person) is connected, and in a situation where a person walks smoothly and there is no need to send any stimulating signal (OFF state), the connection goes to load 2, which in turn makes it possible to "deceive" the stimulator so that it looks like contact with the body always present.

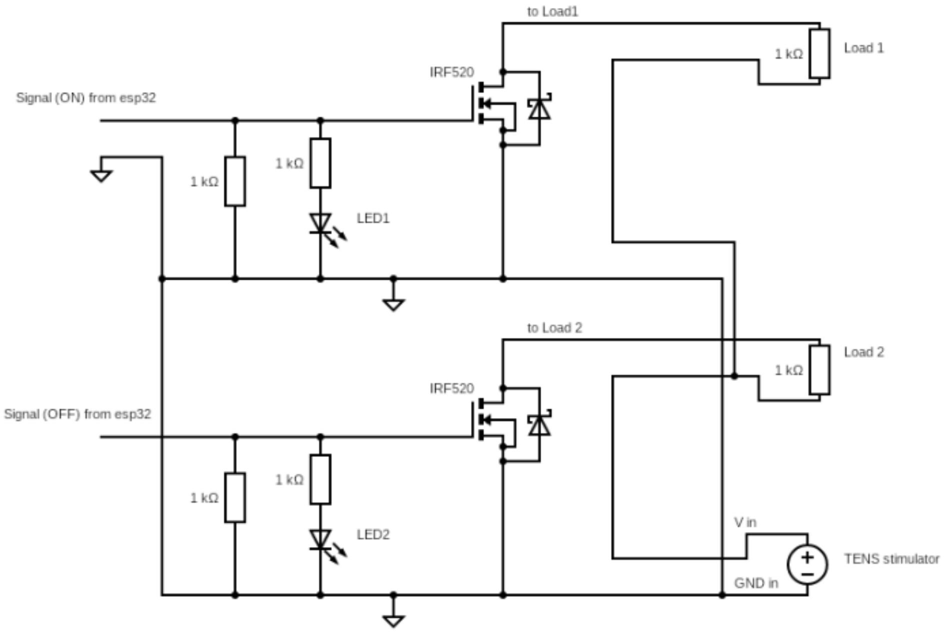
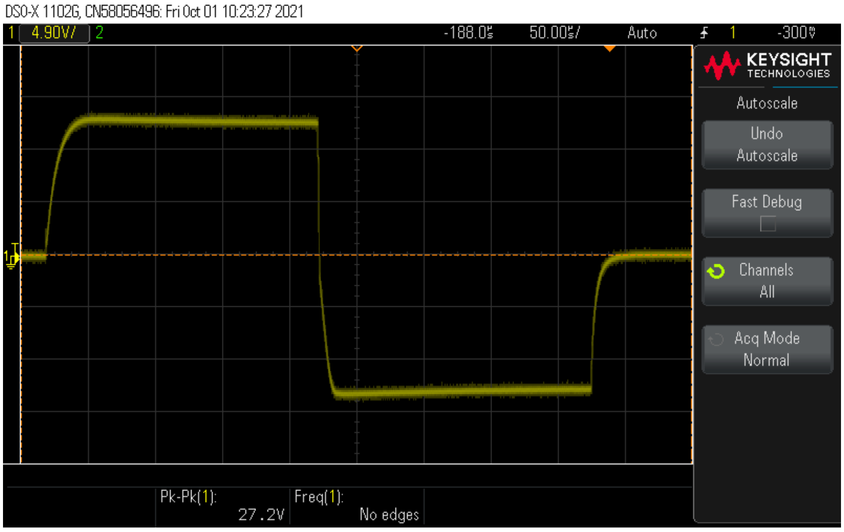


Figure 58. Prototype proposed schematic with TENS and resistors to simulate human body.

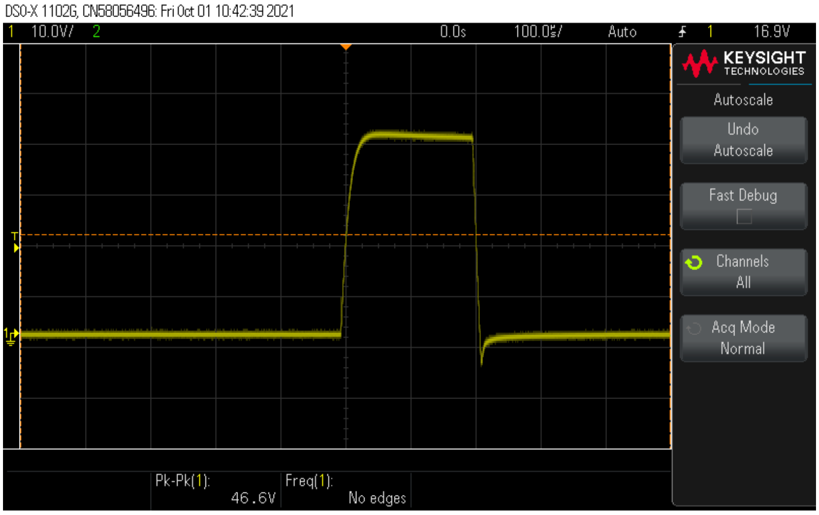
To make sure how the real output of prototype works, the contacts (outputs to load 1) were measured with an DSOX1102G oscilloscope. In fact, the stimulator produces both direct and alternating current components seen on the oscilloscope's display (Figure 59) and it is not possible to control it by connecting and disconnecting the one line with a single transistor; the current direction is changing during second part of each pulse. MOSFETS are cutting only one side of this so kind of "AC" (Figure 60) signal, so this circuit is only suitable for DC as it was used in DC setup (Figure 54) schematic.


DSO-X 1102G, CN58056496: Fri Oct 01 10:23:27 2021

Pk-Pk(1): 27.2V

Freq(1): No edges

Figure 59. Signal shape when stimulation is on.


DSO-X 1102G, CN58056496: Fri Oct 01 10:42:39 2021

Pk-Pk(1): 46.6V

Freq(1): No edges

Acq Mode Normal

Channels All

Figure 60. Signal shape when stimulation is turned off with one transistor.

4.5 Solutions to switch AC components of the signal

To solve the problem identified in the previous section, it makes sense to look at solutions applicable to control the standard AC available in building grids. In case of standard AC it is possible to solve this problem using a setup with an optocoupler (for example MOC3020) what isolates optically the switching circuit and controller system from each other and next the signal coming from the optocoupler can switch the gate of triac (for example BTA12-600).

But this solution is not applicable directly to the existing system as in triac in addition to the control current, there is such a parameter as the holding current - this is the minimum anode current to keep the thyristor open and this also can bring to additional power consumption. But this triac setup has used an optocoupler which is of more interest for consideration, for example, an optocoupler MOC3060 with zero detection will switch the on and off state only at the moment the sinusoid (or any signal) crosses the zero line (Figure 61). Using MOC3020 as in this setup allows sparks and noise to appear in the case of a standard AC devices (Figure 62). In the case of a stimulator, the option where zero crossing is expected to happen is not satisfactory since in this case a part of the signal may be lost, which could already stimulate the patient.

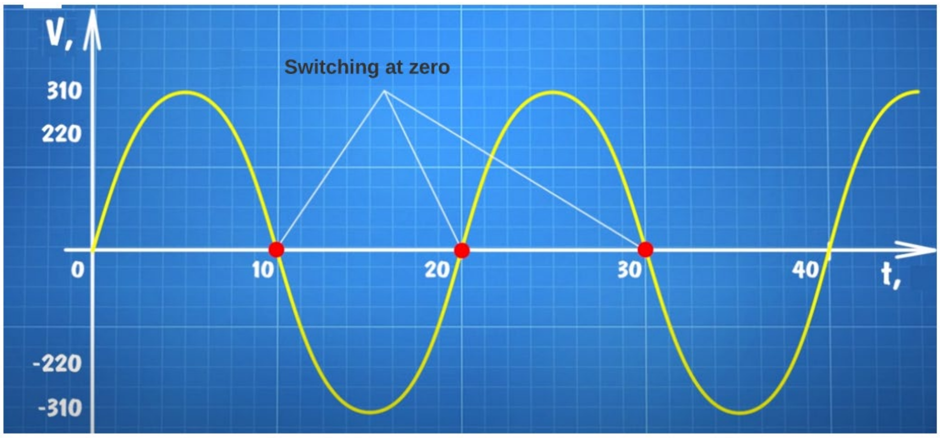


Figure 61. Optocoupler switching with zero detection.

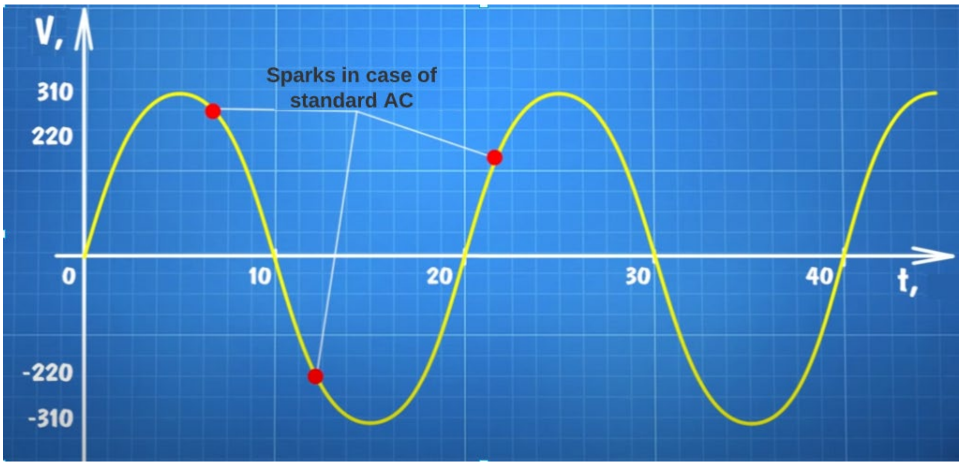


Figure 62. Optocoupler switching without zero detection.

Adding a separate zero-crossing sensor may allow additional functions to be introduced into the system.

So, if in a normal AC network, detecting zero allows to adjust the power of the operating device, this kind of dimmer is obtained by cutting off a part of the sinusoid counting every time the moment when to switch after zero crossing (t 1 moment on the Figure 63) . In the case of a stimulator, this feature can reduce the length of the stimulation pulse set to the TENS device, but will not require switching physically buttons to set the pulse duration on the device itself (Figure 64).

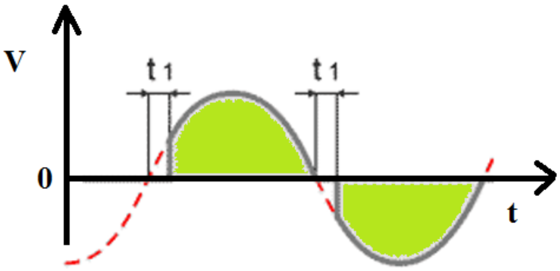


Figure 63. Power dimmer using separate zero crossing detector (green - signal changed, red intermittent – original signal).

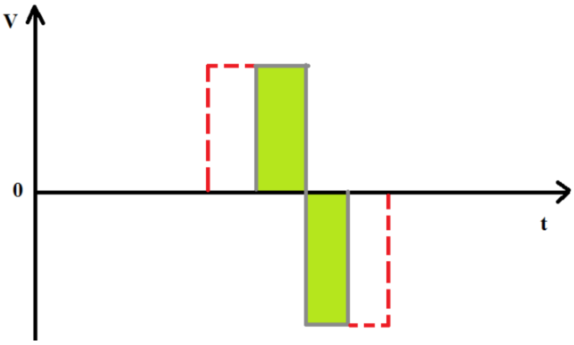


Figure 64. Possible solution for changing pulse width with zero detection setup (green - signal changed, red intermittent - signal original).

4.6 Solid state relay

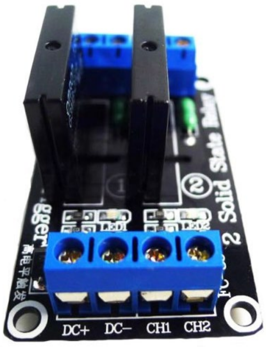


Figure 65. Solid state relay module [56].

For the applications of standard AC there are existing solid state relays almost with the same logic inside as discussed in Section 4.5. Using the factory-made modules with this solid state relays (Figure 65) gives the opportunity to build a setup with good contacts and fast change options (in next developments it is feasible to use solid state relays for PCB). Replacing mosfets with solid state relays in the circuit (Figure 66) a solution is obtained that can completely disable signals consisting of direct and alternating current components, and also completely isolate the connected loads from the circuit, when they are deactivated by control signal.

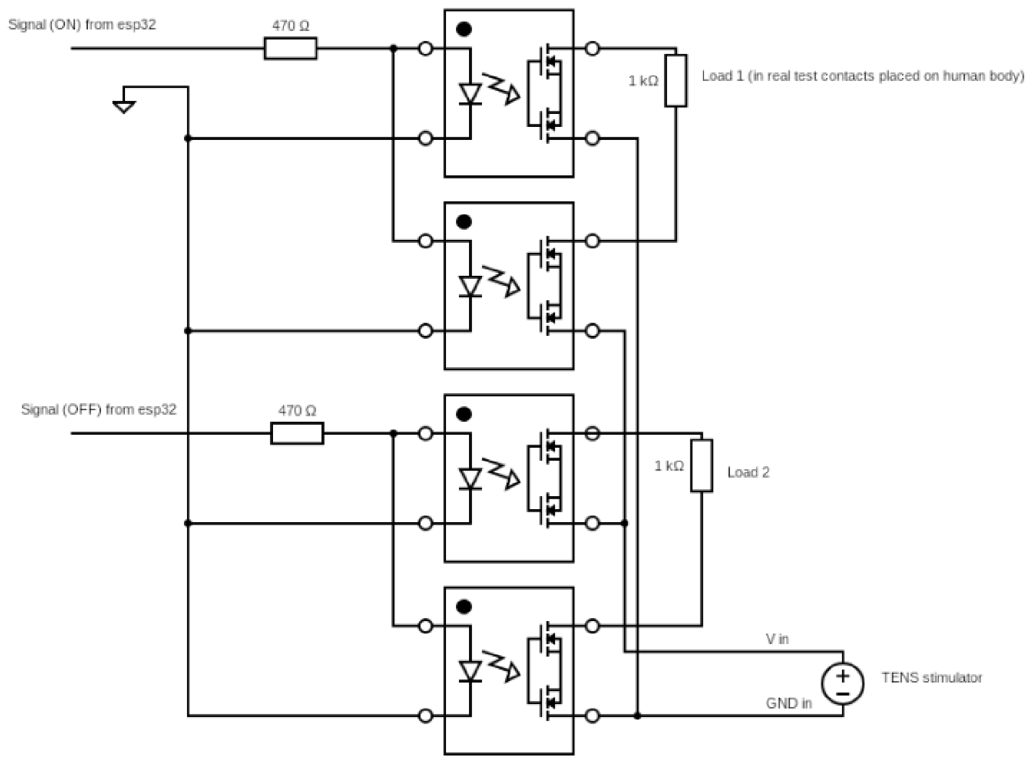


Figure 66. Switching stimulation circuit with solid state relays for prototype

As can be seen from Figure 67, the desired effect of completely switching off the signal on the contacts going to the patient is achieved, while the device also switches to a simulating resistance and continues to function.

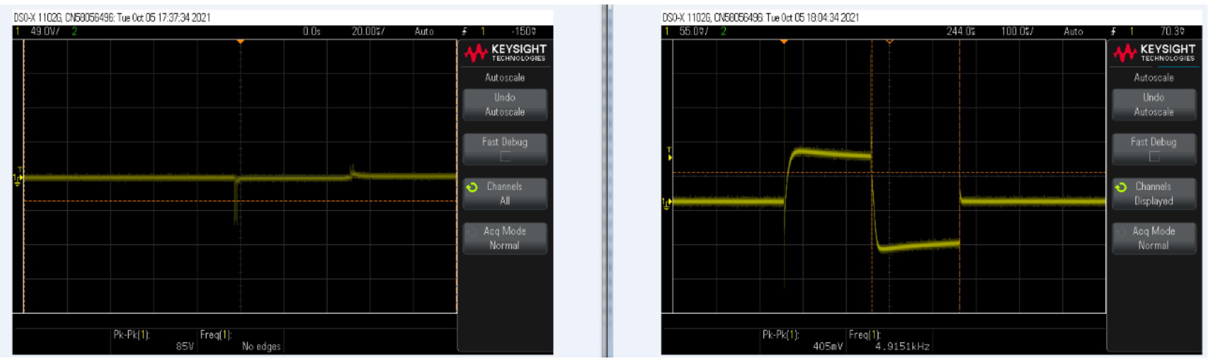


Figure 67. Verification of new schematic performance on the oscilloscope.

4.7 Signal and consumption measurements

Since the device allows to set in some modes both the pulse length and the stimulation frequency, it was possible to check how much the set value corresponds to the output. Setting the value to 50, 100 and 150 Hz, as well as the pulse lengths from 50 µs to 450 µs (checked in 50 µs steps) were clearly visible and determined on the oscilloscope (DSOX1102G) in the auto scale mode. This gave a complete understanding of the existence of a correspondence between the initially assumed signal and functionality in the real purchased device.

In order to have at least an approximate representation of the current consumption of the assembled prototype, the current consumption of both the control board with components and the stimulator itself was measured (Table 8). Measurements based on laboratory E36312A 80W Triple Output Power Supply readings.

All readings were performed on 1 channel which was set to 5,0 V. The accuracy of voltage is 0.04% +2 mV, in low range current 0-20 mA 0.25% +80 µA and in higher ranges 0.04% +3 mA [57].

Table 8. Setup element current consumption.

State for current measurement	**Current [mA]**
Tens at stand by with display LED turned on	≈15-16
Tens at stand by with display LED turned off	≈0,85-1,0
Tens working in program #8 100Hz 200µs stimulation level 1 of 50 display LED turned off	≈1,1
Tens working in program #8 100Hz 200µs stimulation level 50 of 50 display LED turned off	≈51
esp32 consumption	≈50

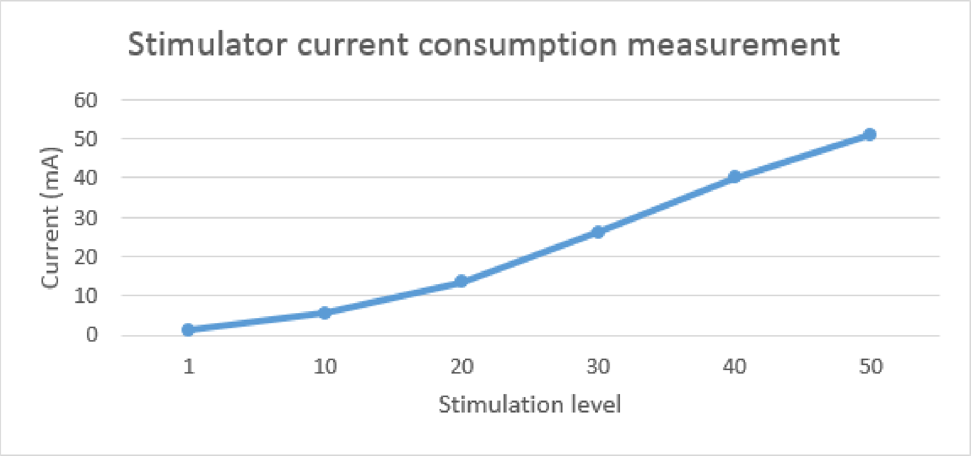


Figure 68. TENS device current consumption in relation to selected stimulation level.

In general, it can be stated (Figure 68) that the current consumption, depending on the selected intensity level, has an almost linear relationship between each other. Since currently the most widespread cells are type 18650 2500 mAh Li-On batteries, it is possible to make very approximate calculations of how long one such battery will actually last in the most maximum modes of this prototype use. In total, the maximum consumption of setup is 100 mA (esp32 + TENS at maximum power), which means:

2500 mAh /100 mA = 25 hours

but this implies a complete discharge of the battery, which is not practical: firstly, a completely zero value is unattainable (cell internal protection will stop the discharge) secondly, during the last stages of discharge, the voltage will already drop, which will no longer allow the devices to work as expected. To deal with this, the most common practice is to multiply the obtained value by a factor of 0.8-0.9, which as a result gives 25*0.8 = 20 hours, which is still acceptable for device use during the whole day.

4.8 Conclusion of hardware prototype part

In this chapter, it was considered how to get a prototype from different components that would satisfy the task specified. The resulting solution allows to have a wireless connection with the prototype through Bluetooth and also allows to turn on and off TENS stimulation of human in accordance with the command received. The next chapter will consider how hardware setup and data signal processing solutions reviewed previously can work together.

5 Current prototype

In the previous sections, stimulation devices, data processing techniques, and external control of a stimulation device have been discussed. Having data from different measurements, a trained algorithm and a prepared prototype system, the prototype setup can be tested.

5.1 Prototype setup

The current assembly (Figure 69) consists of a stimulator (Sanitas sem43), controller (esp32) responsible for communication through Bluetooth, a set of solid state relay modules, resistors to simulate the human body and wiring connecting it all into a single system.

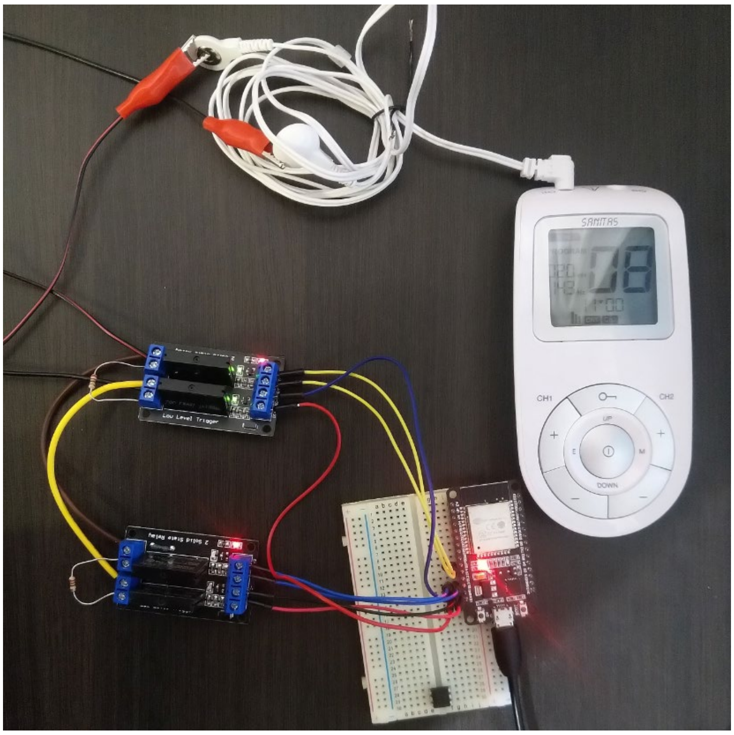


Figure 69. Current prototype assembly.

In the prototype system one resistor can be replaced to the cables to connect it with adhesive pads to human body. Prototype system is ready to receive stimulation activating and deactivating commands. In current stage system was tested with pre-recorded movement data, but prototype is capable to work in pair with any connected Bluetooth device which will send commands working in real time.

5.2 Logic of working prototype system

Logic of the current prototype working system can be seen in Figure 70.

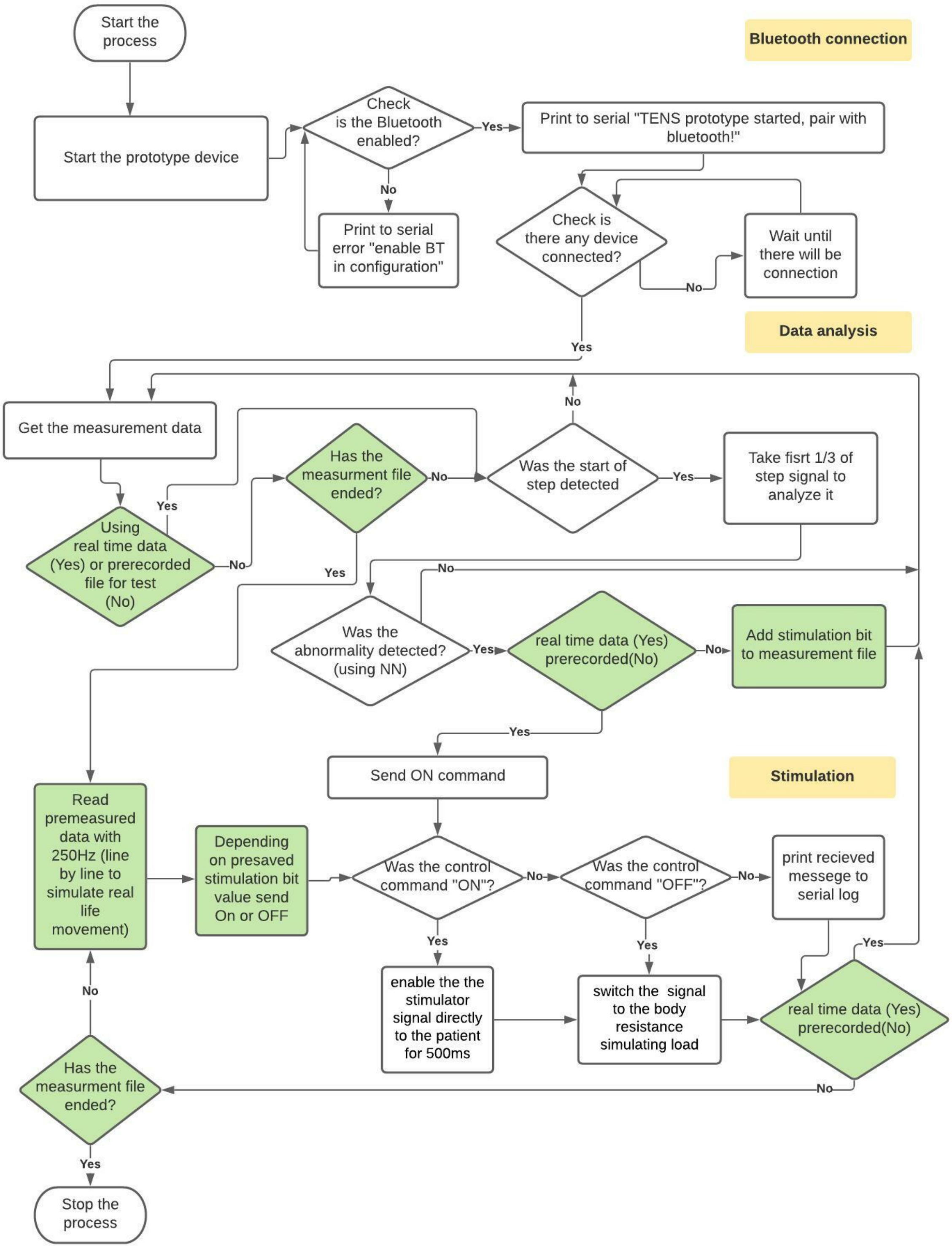


Figure 70. Current prototype flowchart (in real time system green parts can be removed).

In the flowchart (Figure 70) there is combined logic of the system working with real time data and pre-saved data. At the current development stage data analyse was performed on separately standing PC connected via BT to the prototype and sending activating commands, but implementing NN working with real time data flowchart blocks highlighted with green can be skipped (following the logic of the "yes" arrow coming from the green block) and the system will work. The hardware setup on Figure 69 is prepared to operating with real time data as its program follows the logic listed in Figure 70.

5.3 Data readings and analysis in prototype system

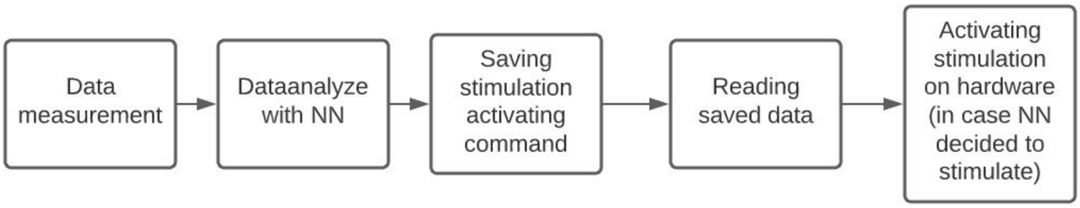


Figure 71. Current prototype work steps.

In the current prototype system work steps (Figure 71) there is a trained neural network that reads data from a previously saved file and determines the beginning of the step (as shown in subchapter 3.5.6) and according to its first one third part decides was it normal or abnormal (problematic) human step. In case of problematic one, the value that activates stimulation is written to the file during second third of the step (Figure 72), which will be send as a command via Bluetooth to prototype hardware setup during file reading.

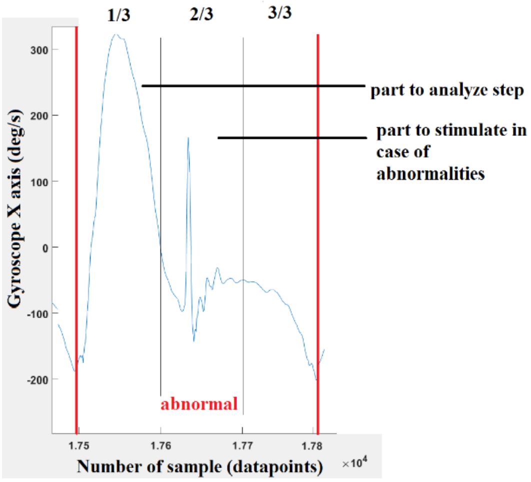


Figure 72. Step data flow segmentation explained.

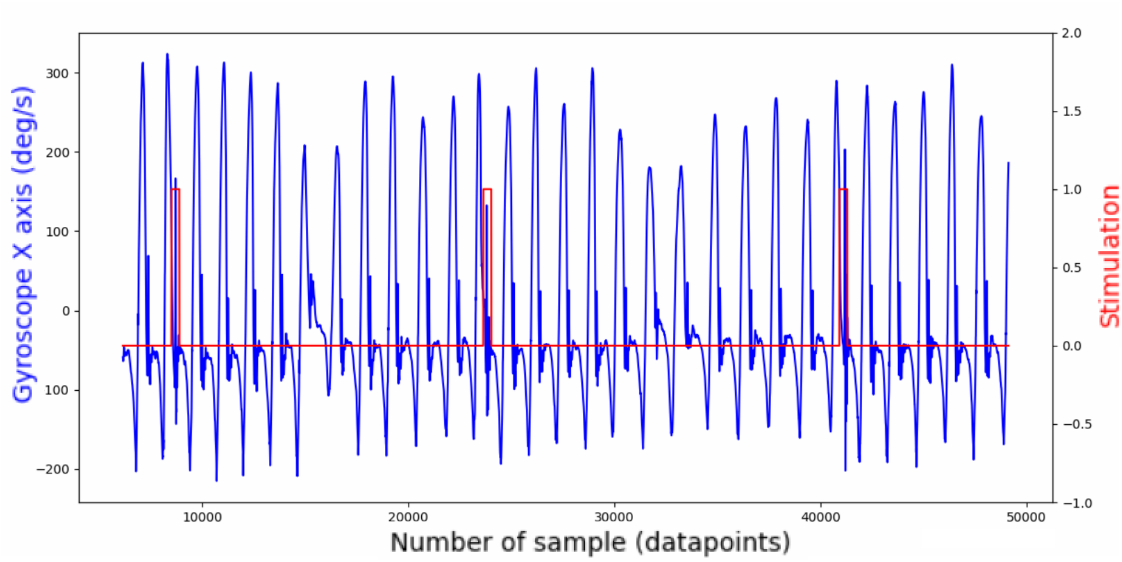


Figure 73. Data flow of long movement during file reading to activate stimulation (red – stimulation activation signal, blue – movement data) (zoomed view in figure 74).

If we consider the reading (by the prototype system) of the entire movement measurement file analysed by NN, then it is clearly visible how in the final file, in cases where the NN determined that the step was abnormal, stimulation is activated (red signal in the Figure 73). This result can be considered an achieved goal, so based on the analysed data, the system is able to activate or deactivate the stimulation of a person at the beginning of his incorrect movement analysing first third of the step (Figure 74).

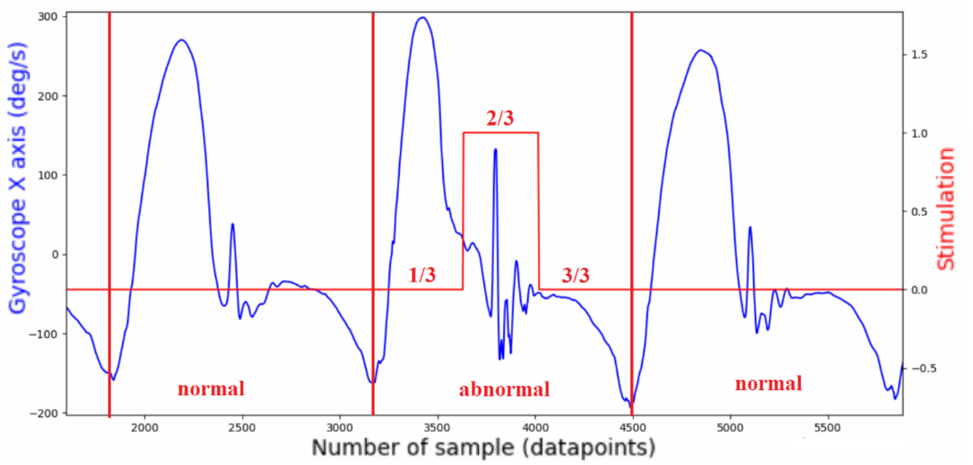


Figure 74. Zoomed example of 3 steps, where after the analyse of 1/3 of step the abnormality was detected and on the second third of the step stimulation was activated (red line)

5.4 Conclusion of current prototype part

This chapter has brought together all the topics discussed in one place. As a result, a prototype of a device was obtained that can turn on and off neurostimulation, depending on the correctness of human movements. This prototype has not yet been tested in real-time data output, but it already fulfils its main task, it clearly outlines the functionality and the necessary features for the further development of an already more advanced device on the next stages of the research.

6 Conclusion

6.1 Summary

The goal of this Master thesis work was to research and create an initial concept idea of a possible neuromuscular assistive stimulation system and build its first prototype. To accomplish this, several problems have been researched and solved.
As a first step, the main stimulation principles and the market of neuromuscular stimulation devices were reviewed. The selection of a suitable neuromuscular stimulation device for conducting initial tests in the prototype system was also conducted and the Sanitas SEM43 was selected.
Next, methods for detecting human movement abnormalities were reviewed and a suitable one was selected. It was tested out that using trained neural network system it is possible to detect human step abnormalities even based on only the first third of the step signal.
Lastly, based on selected neuromuscular stimulation device, which connected to the esp32 microcontroller and set of solid-state relays, the initial prototype of the stimulation system was built. Using the previously selected data analysis method, a pre-recorded human movement file was analysed; the results show that when abnormalities are detected, the control signal is sent to the prototype via Bluetooth communication and neuromuscular stimulation is activated.

This work on studying all the important aspects for creating the first prototype can be considered successful. As a result, there is a functioning prototype that performs the task initially defined for this MSc thesis, i.e., perform neurostimulation based on the measured data of the movement of a person, which in turn could be used to prevent a person from falling or to support making correct movements. The resulting prototype has working hardware and software and implements the developed concept. At the same time, it uses stimulation emanating from a certified medical device, which in case of new discoveries and ideas can be easily replaced by another device with a similar logic during next prototyping phases of the research project at the university. The same applies also to the other functional elements of the system.

Another value of this work is the fact that now there is a clear understanding of the main elements of the prototype system, as well as more narrowly specialized areas for further study within the framework of this topic.

6.2 Future work

All previous experiments have shown the convenience of the developed concept, but currently the system consists of separately standing blocks to measure, analyse, and stimulate. Future developments need to be focused to get a final product prototype. It will be necessary to bring all the blocks together in one device but still maintain the communication with possible external devices to track the real-time state of the system. All this leads for example to the concept of edge computing (Edge computing - distributed computing that is carried out within the reach of end devices, reduces network response time, as well as use of network bandwidth) [58]. So, all functions and calculations can and need be done onboard a wearable device, which will send already precomputed information and will be able to execute several tasks in (near) real-time. For this purpose, there exist a variety of different edge devices having an architecture suitable for that kind of set of functions, for example (but not necessarily) the Kendryte K family [59]. Such device stands out by its small size and low power consumption, and most importantly, it is designed specifically for edge computing and for machine learning thanks to its embedded hardware accelerators. These kind of devices provide high performance with small physical dimensions and are designed to run artificial intelligence algorithms [60].

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Appendix 2

In the following repository can be found different Python, Arduino and Matlab code files used and created during prototype development process (more detailed described in readme file):

https://bitbucket.org/grigorjevnikolai/code-files-used/src/master/

The most important code to setup and test the prototype hardware and communication are also presented below:

Code used in esp32 controller to receive signals and activate stimulation

```
#include "BluetoothSerial.h"

const int Pin1 =  13;

const int Pin2 =  27;

int blinkvalue =  0;

String message = "";

char incomingChar;

#if !defined(CONFIG_BT_ENABLED) || !defined(CONFIG_BLUEDROID_ENABLED)

#error Bluetooth is not enabled! Please run `make menuconfig` to and enable it

#endif

BluetoothSerial SerialBT;


void setup() {

  pinMode(Pin1, OUTPUT);

  pinMode(Pin2, OUTPUT);

  digitalWrite(Pin1, LOW);

  digitalWrite(Pin2, LOW);

  Serial.begin(115200);

  SerialBT.begin("TENS prototype");

  Serial.println("TENS prototype started, pair with bluetooth!");

}

void loop() {

  if (SerialBT.available()){

    char incomingChar = SerialBT.read();

    if (incomingChar != '\n'){
```

```
    message += String(incomingChar);
    //blinkvalue =  0;
  }
  else{
    message = "";
  }
  Serial.write(incomingChar);
}
else if (blinkvalue ==  1 ){
    //Serial.write("blink again");
    message = "test";
    }
// Check received message and control output accordingly
if (message =="on"){
  digitalWrite(Pin1, HIGH);
  digitalWrite(Pin2, LOW);
  SerialBT.println("Stimulation turned ON");
  blinkvalue =  0;
  delay(1);
}
else if (message =="off"){
  digitalWrite(Pin1, LOW);
  digitalWrite(Pin2, HIGH);
  SerialBT.println("Stimulation turned OFF");
  blinkvalue =  0;
  delay(1);
}
else if (message =="test"){
  SerialBT.println("Stimulation in test mode");
  digitalWrite (Pin1, HIGH);
  digitalWrite (Pin2, LOW);
  delay(1000);
  digitalWrite (Pin1, LOW);
```

```
    digitalWrite (Pin2, HIGH);
    blinkvalue =  1;
    delay(980);
  }
  delay(20);
}
```

Code used in PC to send signals based on pre-analysed file reading

```
import serial
import time
from csv import DictReader
import pandas as pd
import matplotlib.pyplot as plt
active = '1'
prev_mode = 0
with serial.Serial() as ser:
    ser.baudrate = 9600
    ser.port = 'COM5'
    ser.open()
    with open('outdemo.csv', 'r') as read_obj:
        measured_data = DictReader(read_obj)
        print("lets start stimulation")
        for row in measured_data:
              time.sleep(0.004) # Delay for 0.004 sec (measurement frq 250 -
>1/250).
            if row['Stimulation'] == active :
                if prev_mode == 0:
                    ser.write(b'on\r\n')
                    input_data=ser.readline()#This reads the incoming data
                    print(input_data.decode())
                    prev_mode = 1
                else:
                    prev_mode = 1
            else:
```

```
                if prev_mode == 1:
                    ser.write(b'off\r\n')
                    input_data=ser.readline()#This reads the incoming data
                    print(input_data.decode())
                    prev_mode = 0
                else:
                    prev_mode = 0


    ser.close()
print("stimulation stopped, draving nice chart")
df = pd.read_csv('outdemo.csv')
fig, ax1 = plt.subplots()
ax2 = ax1.twinx()
ax2.set_ylim([-1, 2])
ax1.plot(df['Shimmer_CB64_Timestamp_Unix_CAL'], df['Shimmer_CB64_Gyro_X_CAL'],
'b', label="gyroscope x")
ax2.plot(df['Shimmer_CB64_Timestamp_Unix_CAL'],     df['Stimulation'],     'r',
label="stimulation")
ax1.set_xlabel('Number of sample (datapoints)')
ax1.set_ylabel('Gyroscope X axis (deg/s)', color='b')
ax2.set_ylabel('Stimulation', color='r')
#plt.legend()
plt.show()
print("File reading ended")
```