Team Project: Developing and testing a MCT device simulator[1]

Due Sun Apr 18th at 11:59pm

Team work submitted individually on cuLearn as a tar or zip file named teamX.tar or teamX.zip, where X is your team number. **Mandatory demos** will be **individual** Thu **Apr 15th** and Fri **Apr 16th** for early birds, and then Mon **Apr 19th**, Tue **Apr 20th** and Wed **Apr 21st**. If these days are not possible, demos can also be done on Thu Apr 22nd and Fri Apr 23rd.The demo times will be arranged between you and your assigned TA. You are encouraged but not required to submit a deliverable for comment by your assigned TA by Wed Apr 7th and to check your progress on a weekly basis with myself and the TAs. Do not wait until the last minute.

The goal of this project is to develop and test a simulator for embedded software used in microcurrent biofeedback devices similar to the DENAS and Avazzia products described below. Both are examples of a noninvasive medical device that delivers modulated electrical signals via an electrode through the skin to communicate with the peripheral nervous system for the purpose of therapeutic intervention. The implementation and testing are to be in C++ using the Qt framework preferably on the COMP3004-F19 VM which has the Qt Creator IDE installed.

The DENAS device

https://www.youtube.com/watch?v=TfUFfYtS3jQ

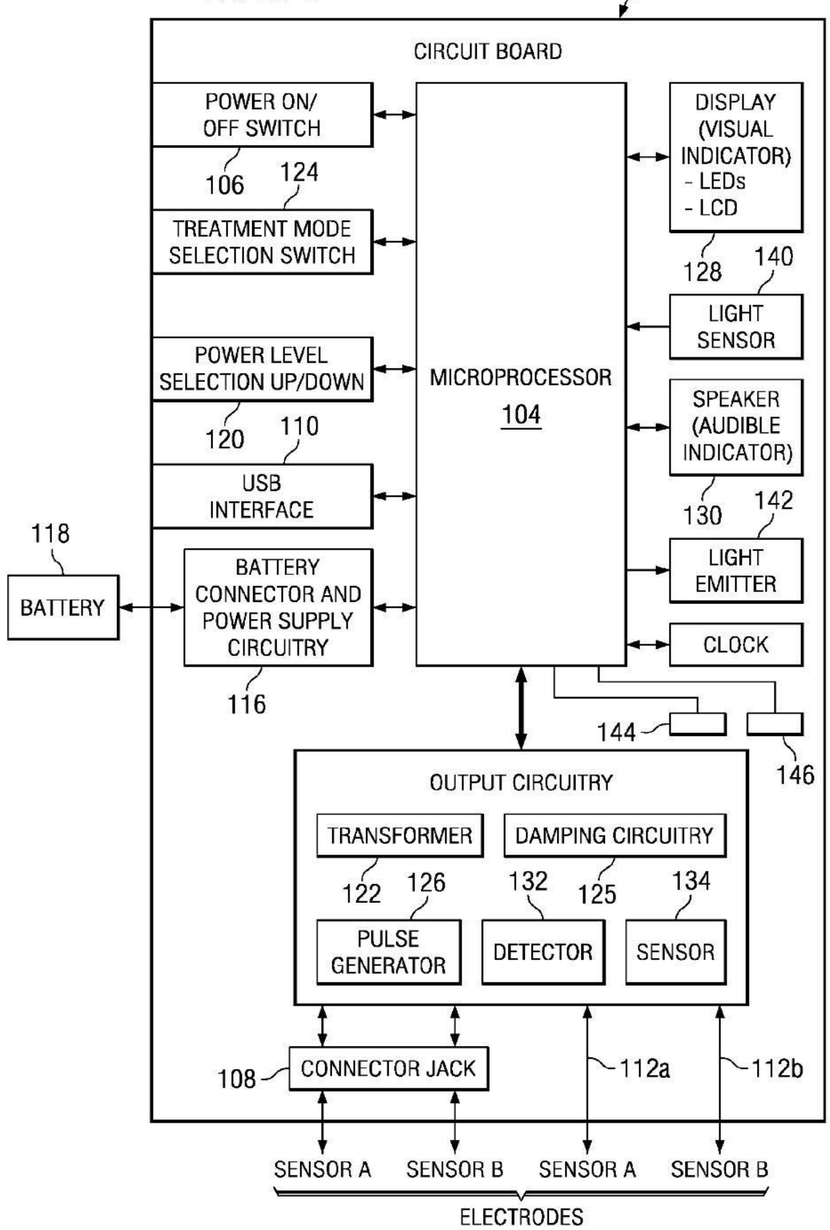
https://www.youtube.com/watch?v=vQyy-AKeKGk

[1] This project has been inspired by conversations with Igor Radonjić who wrote the background material.

For purposes of this project you can assume a hardware layout similar to that of Avazzia [2] though it is a somewhat more complex device than Denas. An example of Avazzia waveforms in action are also included.

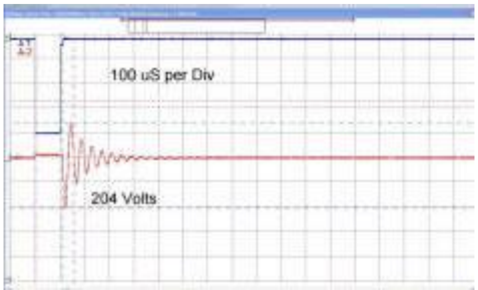
Avazzia Hardware Block Diagram [2]

FIG. 1

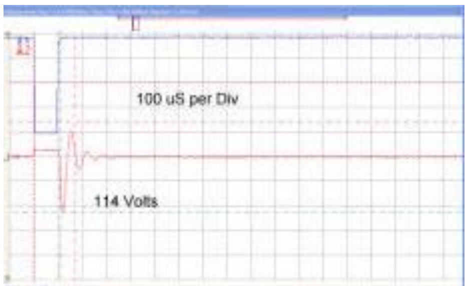


The three charts below show an example of Avazzia waveforms when (1) electrode is not on tissue, (2) when first placed on tissue and (3) as treatment continues.

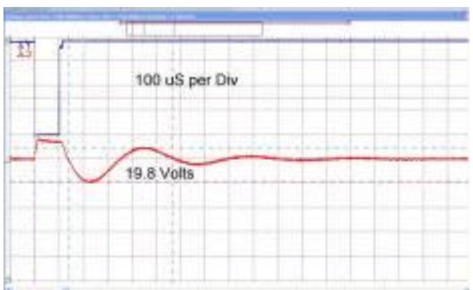
1. In the air, the output signal waveform appears as shown



2. The device immediately detects when the electrodes are first placed on reactive tissue



3. The device continues treatment reaching optimum electrical characteristics



What needs to be simulated?

1. The interface: buttons, display and electrodes
2. Battery level: dependent on time and power level of therapy
3. Time of therapy: displayed and advanced only during skin on, paused during skin off
4. Power level: 0-100
5. Electrodes: output and input (skin on/off)
6. Therapies: frequency (4 of your choice), programmed (4 of your choice)
7. Recording: user can choose to record a therapy and add to history of treatment. Assume only a single user.

Your deliverable should include the following:

1. A use case model based on given information about microcurrent biofeedback devices using the provided videos and manuals. A use case model includes use cases and the use case diagram. Name each use case, e.g. UC1, UC2, so that it can be referred to.
2. An OO Design model using UML Class, Sequence, Activity (if applicable) and State (if applicable) diagrams. For each design diagram identify which use case or use cases it is intended to realize. Your design models should include the Qt elements you used.
3. Source files for your implementation.
4. Tests and traceability matrix from use cases to tests.

For all of the above diagrams refer to the agile modeling link on cuLearn (http://agilemodeling.com/), specifically “Artifacts -> Introduction to UML 2.x”.

Background on Microcurrent Technology

Microcurrent Technology (MCT) represents a major breakthrough in the treatment of chronic and intractable pain and holds promise for a variety of other conditions. This new wave of therapeutic agents that utilize electrical impulses, dubbed electroceuticals, has been called by many the future of medicine.

History

MCT that features biofeedback or neuromodulation capabilities was first developed for the Russian space program under the acronym SCENAR (Self Controlled Energo Neuro Adaptive Regulator) as an all in one medical device for astronauts to use on space missions, hence its nickname, ‘Star Trek medicine.’ It was so successful in clinical trials that it became widely adopted for general use and once declassified spawned a family of commercial devices, such as the popular DENAS (Dynamic Electro Neuro Adaptive Stimulation) line of products, that employ SCENAR Technology. The Russian Ministry of Health has approved SCENAR for a wide range of medical conditions.

In the United States, the leading manufacturer of microcurrent devices is a company called Avazzia, founded by engineer Tim Smith. Tim Smith was a leading engineer for Texas Instruments and designed the logic chips used on the Apollo moon missions, and later in F-14 and F-15 fighter jets. This further links the technology to space exploration initiatives. In addition, NASA is currently developing its own in house version.

TENS vs MCT

Conventional TENS units widely available on the market today are the forerunner of next generation electro-stimulation devices.

TENS units — Transcutaneous Electrical Nerve Stimulation — use electrical currents passed through the skin to stimulate nerves for temporary pain relief.

There are key differences between conventional TENS units and microcurrent biofeedback technology (MCBT). TENS units use much stronger electrical currents in the milliampere range, whereas microcurrent technology, as the name suggests, uses electrical currents in the micro ampere range which is thousands of times weaker. Published medical research has found the micro current range to be far more effective, as the electrical currents in the human body function in the micro current range.

The major difference with microcurrent biofeedback devices is that they are responsive to the body and prevent habituation to the signals sent, whereas other units do not. Habituation or accommodation is a major problem, as the body becomes non responsive to received signals, therefore preventing the changes necessary for therapy.

How does it work?

Microcurrent biofeedback devices generate and modulate specific electrical signals that vary in response to changes in the electrical impedance on the surface of skin tissue which functions as a terminal access point to interact with the human body's bio-electrical system.

This has various beneficial health effects, which are beyond the scope of this project outline, but include the following to assist the students understanding.

The first is the concept of neuromodulation which is fairly easy to understand. Neuro means nerve and modulation means varying the property of a wave or signal. Therefore, put together, it means changing the signals of nerves. Nerve signals, in the case of debilitating pain, can become pathological and repetitive fixed signals which fail to change in response to environmental stimuli. Neuromodulation can disrupt this pattern and restore the nerve signal to a normal state in order to eliminate pain.

Medical research has identified many of the electrical signal characteristics of nerves and how to target them for therapeutic stimulation. These electrical signal properties can be incorporated into algorithms that produce specific patterns of output pulses for specific applications. However, this is not a part of the project requirements and is merely mentioned as a point of interest.

Another major benefit of micro current technology is that it can provide bioavailable electrical energy to the body. It is a basic fact of biology that every cell membrane requires a certain electrical potential or voltage to function properly. Microcurrent can help recharge biological cells and restore their electrical potential.

Additionally, when tissue as a whole is in an injured or diseased state, there is a drop in electrical impedance which is reflected as a drop in electrical impedance on the surface of the skin.

The onboard electrodes can detect (via reaction readings) the electrical impedance of the skin by gliding across it. The areas with low electrical impedance will be ‘sticky’ (dramatic increase in friction) and may indicate underlying inflammation.

Inflammation has been implicated in almost every medical condition, including debilitating pain and chronic disease. It is characterized by a deficiency of electrons caused by free radicals. Popular anti-oxidants marketed as nutritional supplements effectively neutralize these free radicals by providing extra electrons. These microcurrent devices can directly provide these extra electrons at the injury site.

By placing the devices electrode at a correct spot for treatment, it is able to detect and autocorrect electrical impedance and abnormal electrical patterns in nerve and connective tissue in the body. In the process, the redox (reduction-oxidation) potential of the body is recharged and inflammation greatly reduced.

To further explain and repeat in more detail, the system establishes a cybernetic feedback loop between the analog output of the device and the body tissue. The body’s response is measurable by a high-speed microprocessor, creating information for the loop. When a signal is emitted and penetrates into the tissue, the impedance of the tissue modulates the next waveform. Impedance is the effective resistance of an electric circuit or component to alternating current, arising from the combined effects of ohmic resistance and reactance.

The degree of modulation is based upon the changes of impedance of skin. This sets up a constantly changing interactive bio-loop processing non-repeating signals. Eventually the change in impedance diminishes in significance until a plateau occurs.

General technical specifications of micro current Biofeedback devices

- Emits high voltage pulsed current signals referred to as HVPC
- They are short duration pulses of high voltage amplitude and very low duty cycle
- Voltage range: 20-650 volts
- Amperage range: Microamps (10-6 amps)
- Signals, frequency range: 1Hz to 500Hz
- High-voltage, pulsed current, damped, asymmetrical, biphasic, sinusoidal waveform
- Uses two AA batteries.

References:

[1] “Nasa signs deal … “
https://www.dailymail.co.uk/sciencetech/article-2555731/Star-Trek-device-heals-skin-instantly-soon-used-astronauts-ISS.html

[2] Avazzia Patent (cuLearn)

[3] Denas manuals (Denas-part1 and Denas-part2 on cuLearn)

[4] Avazzia links
https://www.youtube.com/watch?v=28_OzWYO2xY
https://www.avazzia.com/professionals/why-avazzia-works/
https://www.avazzia.com/Assets/PDFs/TENS_Comparison_2013.pdf
https://www.avazzia.com/Assets/PDFs/Tech_Sheets/MKT-070906-04-BEST-RSI-tech-sheet.pdf

[5] Scenar patents
http://www.scenar-revenko.ru/en/scenar/patents.htm