All-In-One Sensory Diagnostic Tool

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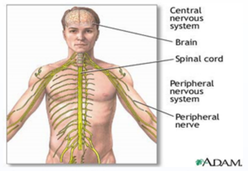
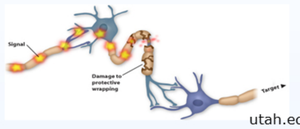
University of Minnesota – 2010 Biomedical Engineering Design Show

Background

A neurological disorder is defined as a disorder of the body's nervous system. Biochemical, electrical, or structural abnormalities within the brain or spinal cord, or within the nerves leading to or from the central nervous system, can result in loss of sensation, muscle weakness, and paralysis.



Neurological disorders stem from problems in the transmission or reception of signals between neurons within the nervous system.



Neurological disorders are revealed during a neurological examination in which the neurologist uses an array of instruments to test for the presence or absence of sensation ability. Neurologists screen for a variety of sensations including the following: audition, gustation, nociception, olfaction, proprioception, touch, and vision. However, for several of these sensation screenings, there is currently no standard method for testing. The current techniques are subjective and highly dependent upon the neurologist and therefore, the methods tend to differ between patient screenings. AIO Medical directly addresses these current issues by designing and manufacturing an all-in-one sensory diagnostic tool for neurological screening. The device not only integrates the key sensory testing tools, but through its electrical components, it provides methods to conduct reproducible tests. AIO Medical can provide a standard procedure for neurological examinations and thus revolutionize the clinical industry.

Purpose

Our mission is to develop a compact, all-in-one alternative to the current array of neurological examination tools used today. Current instruments used during neurological examinations are highly dependent upon the user and thus yield subjective results. Our device will provide methods for conducting reproducible tests and thus eliminate this subjectivity.

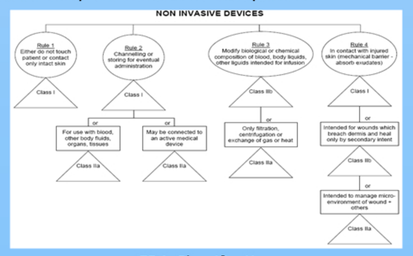
Market Analysis

A variety of instruments are currently used during a neurological examination. The AIO diagnostic tool is an integrative device that is marketed primarily toward resident neurologists and practicing neurologists. Currently there are approximately 13,500 practicing neurologists in the United States alone. However, AIO Medical designed the device so that it is simple and easy to use, allowing physicians the possibility to conduct preliminary sensory examinations effectively in a minimal amount of time. Therefore, the secondary customers include physiatrists, internists, and family practice physicians and residents.

Due to its potential to enter wide-range of customer segments, the AIO diagnostic tool is expected to flourish in the current market. With the predicted growth and its potential to standardize neurological examinations and thus revolutionize the clinical industry, the device will become more prevalent in hospitals and private practices.

Device Classification

The All-In-One (AIO) Sensory Diagnostic Tool is classified as a medical device since it is intended for use in the diagnosis of potential neurological pathologies in human patients. Specifically, it is a Class I medical device since it is simple in design and manufacture, presents minimal potential harm to the user and patient, and it contacts only intact skin of the patient.



FDA Classification

Methods

Light Touch/Pressure Sensation

AIO Medical implemented a retractable monofilament to test for light touch sensation and pressure sensation. In order to touch for light touch sensation, the neurologist utilizes the monofilament in a horizontal manner to lightly move individual hairs upon the patient's limbs. For pressure sensation, the neurologist presses the monofilament against the patient's skin with increasing force.

Olfaction Sensation

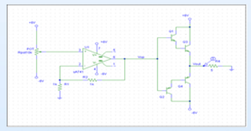
Three essential oils (lemon, peppermint, and pine) were implemented to test for olfaction sensation. Three small sponges were soaked in the essential oils and then placed within three separate eppendorf tubes.

Pain Sensation

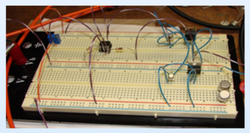
A retractable pin was implemented to test for pinprick pain sensation. The pin has a built-in safety mechanism that causes the pin to move in an opposite manner when being pressed against the patient's skin. The pin component also includes a removable cap for additional prevention of accidental injury.

Temperature Sensation

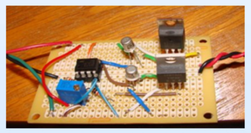
A Peltier device coupled to a circuit for temperature regulation is used for temperature sensation testing. The circuit amplifies the current to achieve effective changes in temperature, and through an external switch, allows current to run in both directions. Reversing the polarity of the circuit allows the exposed side of Peltier device to switch between hot and cold temperatures. The following figures chronicle the process of transforming a circuit schematic to a printed circuit board.



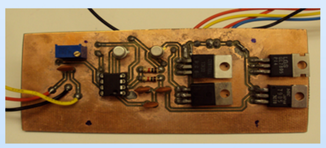
PSpice Circuit Schematic



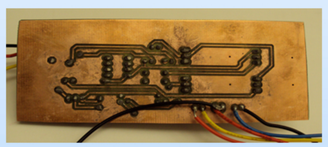
Breadboard



Soldered Circuit Board



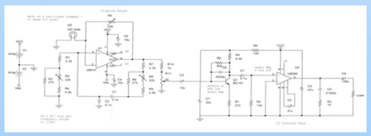
Printed Circuit Board



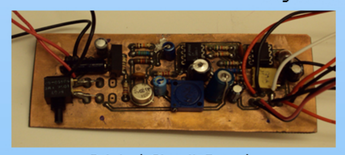
Printed Circuit Board

Vibration Sensation

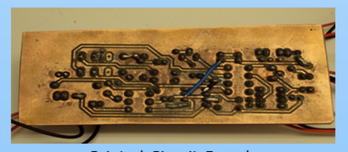
A Wein-Bridge oscillator circuit and an amplifier circuit in series is used to for vibration sensation testing. The W-B oscillator circuit produces the 128 Hz frequency that is expressed as mechanical energy in a solenoid. The amplifier circuit amplifies the oscillator output voltage to yield a constant and effective amplitude of vibration. The printed circuit board, including the W-B oscillator and amplifier circuits, is shown in the figures below.



Eagle Circuit Schematic



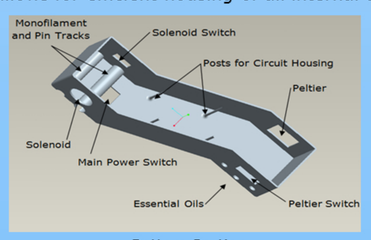
Printed Circuit Board



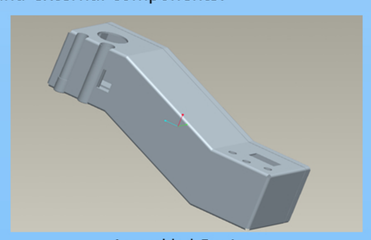
Printed Circuit Board

PRO/E Prototype

The external casing provides an ergonomic shape, professional appearance, and allows for efficient housing of all internal and external components.



Bottom Portion



Assembled Device

Results

Requirements Verified/Not Addressed

Requirements	Test(s)	Results
Light Touch/Pressure Sensation (Monofilament)	Test on 5 volunteers	Light touch and pressure sensations induced without causing pain
Olfaction Sensation (Essential oils)	Test on 5 volunteers – blind scent detection	Scents easy to distinguish and do not linger in air
Pain Sensation (Pin)	Test on 5 volunteers – pain induction and safety mechanism	Pinprick pain induction without causing harm due to safety mechanism
Temperature Sensation (Peltier device + circuit)	Test on 5 volunteers – effective and safe temperature changes	Hot/cold sensations induced, temps. remained in safety range
Vibration Sensation (Solenoid + circuit)	Test on 5 volunteers – side-by-side comparison with tuning fork	Very representative of tuning fork, stimulates vibration sensation
Reproducible Tests	Quantify circuit reproducibility	Solenoid: 128 Hz, constant amplitude Peltier: 40F – 70F
Professional Appearance	Demonstrate to potential users – comparison with current instruments	N/A due to time constraints
Lightweight & Durable	Manufacture device out of aluminum	N/A due to monetary and time constraints

[redacted]

Insert picture of fully assembled device

Conclusions

Conclusion

The components of this device, especially those that allow for the conduction of reproducible tests, will assist neurologists in revealing potential problems with the transmission and/or reception of signals within the neurons of the nervous system. Unearthing such problems will allow neurologists to diagnose and subsequently treat neurological disorders in order to restore partial or fully sensory perception.

Future Directions for Device

The next generation of the device will include a laser diode, smaller and more poser efficient circuits, and an LCD display screen. A laser diode would provide a non-invasive, non-contact method of inducing pinprick pain and thus testing for pain sensation. Working closely with electrical engineers and outsourcing the circuits to fulfill modifications would allow for a more handheld and lightweight device. Incorporating a 7-Segment LCD display screen in conjunction with modifications to the circuits would allow for temperature and vibration output.

Acknowledgements

First and foremost, the members of AIO Medical would like to thank their advisor Dr. Steve Saliterman. Without his direct guidance and support, the work presented in this project would not have been possible. The team would also like to thank Dr. Shai Ashkenazi and Dr. Andrew Rys, as well as Dillon and Lucas from the Medical Device Center. Their support and assistance were invaluable throughout this project. The team would further like to acknowledge the neurologists interviewed for providing their time and expressing their customer needs. Finally, the team would like to thank ABC Electronics for donating parts.

References

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