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Novel Non-Invasive Device to Diagnose and Monitor Fibromyalgia

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KATZ Diagnostics

Background

- Fibromyalgia is a disease that manifests in widespread physical and mental pain. It affects **4 million US adults or 2% of the population** [1]
- Current diagnostic tools are purely qualitative and therefore diagnosis is subjective. We aim to develop a quantitative metric for diagnosis
- **Muscle pressure** has been shown to correlate with severity of fibromyalgia symptoms. [2] It is correlated to muscle oxygenation; high muscle pressure leads to capillary restriction and result in hypoxia [3].
- This device seeks to obtain a **quantitative measurement** of muscle oxygenation to **diagnose and monitor** fibromyalgia
- Our proposed device will utilize **Near-Infrared Spectroscopy (NIRS)** to obtain a muscle oxygenation reading
- Light will be emitted into the skin and absorbance will be measured via a photodiode after backscattering

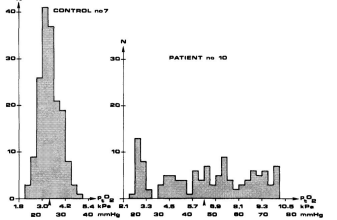

Figure 1. Histogram showing muscle oxygenation measurements among a control (left) and fibromyalgia patient (right). Results are statistically significant. [2]

Design Criteria

Priority	Design Needs	Specific Criteria	Validation
1	**Safe**	Device is non-penetrative to prioritize **patient comfort**. Device has a thermal limit of 37ºC.	Cytotoxicity, Sensitivity and Irritation testing per ISO 10993 IEEE 360 Wearable Dev Standards
2	**Physician Friendly**	Device is **portable** and can be held with a single hand. Output is easily interpretable.	Smaller than 4 x 7 inches Output is in percentage of muscle oxygenation
3	**Cost Effective**	Device is affordable and accepted by insurance agencies.	Manufacturing cost less than $1000
Priority	**Goals**	**Validation**	
1	**Accuracy**	Device output matches the output of the Moxy muscle monitor	
2	**Develop a Validation Test**	Hemoglobin model must have a concentration between 12-18 g/dL Animal muscle tissue must have minimum depth of 15 mm	

Prototype

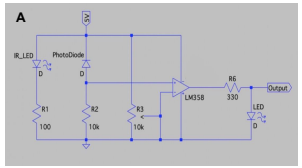

Figure 2. (A) Circuit diagram for the first prototype iteration **(B)** Circuit diagram for the current prototype **(C)** First prototype iteration. **(D)** Current prototype in testing configuration.

Standards

Standard	Application
ASTM F3357-19 Standard Guide for Designing Reusable Medical Devices for Cleanability.	Reusability and cleanability
ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part I: Evaluation and Testing within Risk Management Process	Biological risk management
ISO 14971:2019 Medical Devices - Application of Risk Management to Medical Devices	Physical and software risk management
ISO 16142-1:2016 Recognized Essential Principles of Safety and Performance of Medical Devices	General essential safety measures
IEC 80601-2-71:2015 Medical Electrical Equipment	Electrical and NIRS safety standard
IEEE 360 Standard for Wearable Consumer Electronic Devices	Wearability, reliability, and safety

Testing

	Subject 1	Subject 2	Subject 3
Baseline	406 mV	382 mV	317 mV
Hypoxia	337 mV	313 mV	273 mV
% Change	16.9%	18.0%	13.9%

Table 1. Photodiode voltage outputs for light absorbance at 820 nm through hypoxic forearm muscle tissue induced by 10 minutes of muscle constraint with a rubber band.

Cuvette Hemoglobin Testing

- Several controlled tests have been performed using our device on hemoglobin samples via a cuvette. Experimental configuration seen in Figure 3.
- Goal: to better understand device response to concentration and percent Hb oxygenation. Can we accurately predict changes to these variables?
- Concentration and oxygenation was varied
- More data must be collected to draw any conclusions

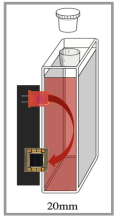

Figure 3. Schematic of the light path in our cuvette testing

Future Plans

- Incorporate **microcontroller** for signal transm. & power management and implement modeling to **convert V readings into useful data** in real-time
- **Increase resolution** with **2 more wavelengths** & implementing deconvolution measures
- Improve **testing conditions** with the help of a darkroom

Acknowledgments

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References

[1] Marques et al., "Prevalence of Fibromyalgia."
[2] Lund, Bengtsson, and Thorborg, "Muscle Tissue Oxygen Pressure in Primary Fibromyalgia."
[3] Katz et al., "Intramuscular Pressure Is Almost Three Times Higher in Fibromyalgia Patients."