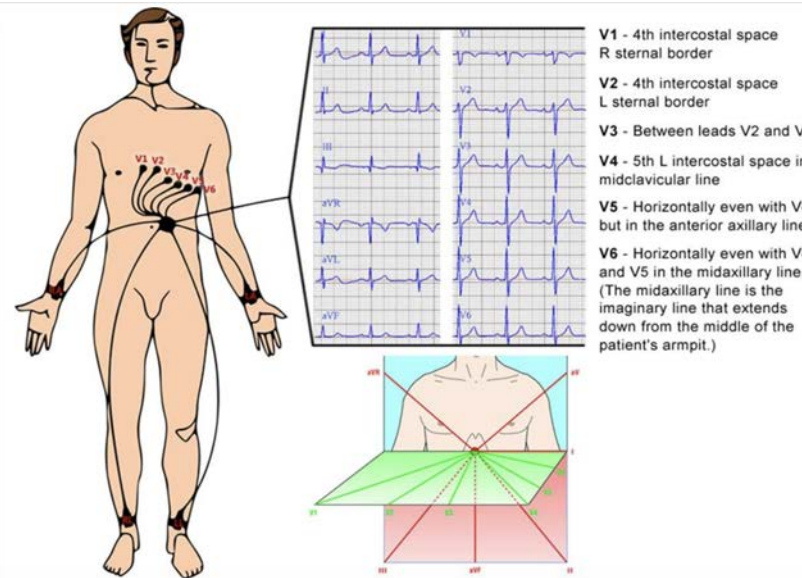


Pocket Electrocardiogram [ECG]

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Liz McCullough - Mechanical Engineering, Biomedical Engineering; Julia Salerno - Chemical Engineering, Biomedical Engineering
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The Problem



- ECGs are used worldwide in hospitals for **cardiac imaging** & disease detection.
- 12** connection points gives the clearest voltage signal but it is **time consuming**.
- In ER: **~90 uses per day** (5 min setup time) => **~8 work hrs a day**.

Background

- 300 million ECGs conducted annually in the US; **arrhythmias** affect over **4 million** and approximately **half a million die** as a result.
- Existing solutions:
 - Implantable** - reliable but requires surgery
 - Holter monitor** - portable but still need to attach all of the leads and can't get wet
 - CardioTech One Patch technology** - not reliably developed and still expensive
 - Bluetooth & smart watch-adapted technologies** - expensive, not fully developed, and catered toward personal



Needs Statement

"A compact, lightweight, and easily-transportable ECG device for use by healthcare professionals to simplify and ease transition between patients and save time and energy throughout the ER/hospital floor."

- Problem:** Current ECGs are large, difficult to transport, and limited, taking valuable time from healthcare workers to move them around.
- Population:** Healthcare workers spend a lot of time transporting and administering ECGs. Therefore, patients suffer too if they need a quick ECG measurement for diagnosis
- Outcome:** A small, transportable ECGa device that can be easily moved in hospitals and even taken home by patients.

Proposed Solution

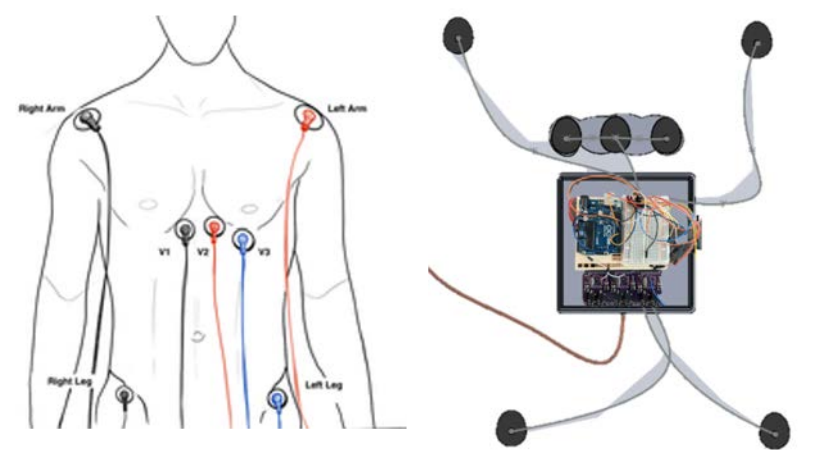


Figure 1: Sketch Representation of electrode placement on patient for data collection

Figure 2: CAD Model Visualization of electrical component. Small rectangular housing negates the need for the bulky cart.

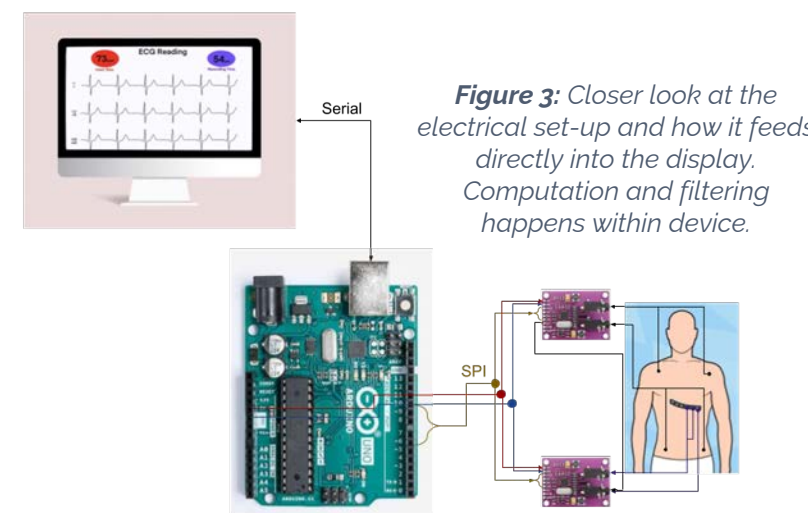


Figure 3: Closer look at the electrical set-up and how it feeds directly into the display. Computation and filtering happens within device.

The solution is a **"9-lead" system**. It follows the clinical application standards of a 5-lead as well as all the data a 5-lead provides. This solution also includes an additional two signal leads also found in a 12-lead.

Reimbursements, Cost, Patents, & Pathway

Reimbursement

- ECG Monitoring processes are covered by Medicaid programs when medically necessary
- Medicare covers ECG Monitoring to detect or monitor a cardiovascular disease.

Cost

Factoring in the Dev Board, QFN, Electrical housing, electrodes, the electrode patch ad wiring, adhesives, and the arduino, the anticipated cost per functional ECG device is **\$209.95**

Patents

The Pocket ECG is an electromechanical system patentable as a machine. The novelty of our device is where it will differ from current ECG technology:

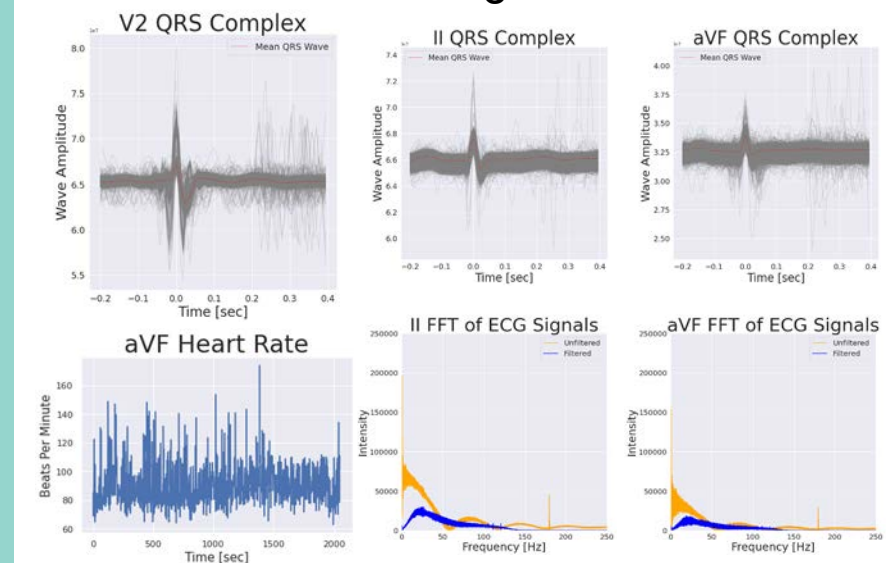
- Basic electrodes & leads but **changing the orientation and connection** between electrodes as a way of innovating
- Does not require connection** to a large and bulky cart
- Data collection & analysis largely done inside the chest piece** through the PCB/Arduino combination
- Interface is not bluetooth or remote,

Pathway

- FDA as **Class II medical device**
- Subject to pre-market review in the form of a 510(k)
- Pre-market applications (PMAs) are not required for these devices.

Conclusion

This alternative to an ECG system provides cardiac data compliant with the clinical standard at **13% the size** and **18% of the weight**.



Future work: The PocketECG system

- Is limited by the data retrieval rate and can be optimized by retrieving and transferring data in parallel
- Sends data over a wired Serial interface but could be made wireless with an independent power source and a BTE transmitter

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- Our TAs: Ankita Mukherjea and Xinyue Chen**



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