**Design**

**Safety and Standards**

The most important priority in acquiring an ECG signal is to ensure the safety of the patient being recorded. Diagnostic electrical medical devices need to be covered by strict compliance standards and essential performance guidelines before they can be used clinically on patients, with the most up to date standards relative to an ECG machine being IEC 60601-1-1, 60601-1-2, 60601-2-25, and 60601-2-27. Common issues that often arise in testing electrical medical devices tend to relate to how energy is absorbed and transmitted by the source, the machine, and the patient it is connected to. The major categories that cover these potentially dangerous transfers of energy include defibrillation and electric static discharge protection, electrical isolation and leakage prevention, and radio frequency emissions and shielding (*source – Advanced Methods and Tools for Ecg Data Analysis*).

**Note**: Many of these issues can be circumvented using hardware that has already been test covered under the compliance standards when designing the ECG – refer to *Biosignal PI* for a examples of hardware that have been used. These will be covered in the Design Section.

**Calibration**

In an effort to improve transparency and progression in modern research, the open source community involving medical technology has increased considerably in recent years (*source*). PhysioNet is a pertinent example of a freely available research resource for complex physiological signals including the ECG. The website contains a large cache of clinically validated ECG signals, and also houses open-source software programs that can be used to view, process, and analyse these complex signals. In keeping with Glia’s ideology of making medical grade equipment that is easily accessible, using PhysioNet may be the ideal toolkit to test and validate a prototype ECG machine.

Once the ECG device is designed and tested for basic safety and functionality, the next stage is to test the machine over a wide range of representative signals. This calibration stage is essential to prove that the acquisition system can be relied on accurately before being used on patients as a diagnostic tool. The use of stored ECG signal databases provides a realistic range of data from actual patients, along with validated annotations from cardiologists. However, transitioning a signal from digital-to-analog to test the frontend hardware acquisition can present a number of challenges, such as inherent noise fluctuations, difficulty measuring clinical parameters of the ECG, and using any particular database may prevent some specific waveforms from being presented (*source* – *Advanced Methods and Tools*).

Conversely, use of an artificial signal is noise free and contains known clinical parameters that can be controlled. By varying the model over all possible heart rates, leads, and rhythms, it is possible to rapidly determine under what circumstances the acquisition hardware causes significant distortions in the clinical parameters measured from the ECG. Conveniently, PhysioNet is home to an open-source algorithm ECGSYN which can be used to calibrate biosignal acquisition devices (*source – A dynamic model for generating synthetic electrocardiogram signals*).

**Note:** specific wave measured parameters yet to be determined

**Validation**

The final stage before the Glia ECG device can be approved as a medical grade electrical device for use on patients is to compare it to a current ECG model. The sensitivity and specificity of the acquired signal varies widely based on the manufacturer specifications and desired properties. Thus, physician overreading and interpretation still remains the gold standard in making a diagnosis from an ECG report (*source – Recommendations for the standardization and interpretation of the electrocardiogram*). Accordingly, an appropriate way to validate the Glia ECG machine against current models would be to have the signal reports from patients (number yet to be determined) read and interpreted in a blinded fashion by a cardiologist (or other qualified expert).

Considerations to be determined – patient inclusion/exclusion criteria, order of ECG reports from patient