

Impedance Cardiography Product Design Specifications

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Function: Current methods for measuring cardiac output are invasive. Impedance Cardiography is a non-invasive medical procedure utilized in order to properly analyze and depict the flow of blood through the body. With this technique, four electrodes are attached to the body—two on the neck and two on the chest—which take beat by beat measurements of blood volume and velocity changes in the aorta. However, our client hypothesizes that the current method withholds degrees of inaccuracy due to the mere fact that the electrodes are placed too far from the heart. The goal of this project is to design an accurate, reusable, spatially specific system that ensures more accurate and reliable cardiographic readings. Furthermore, this system must produce consistent results able to be accurately interpreted by industry professionals. More specifically, our primary goal is to ensure the device must not only collect an impedance signal, it must also isolate the signal in its output using a variety of filters.

Client Requirements

- System of electrodes, which can be precisely placed in order to maximize signal from the heart
- Method of determining ventricle location in patients
- System of holding electrode device to body, taking our current electrode matrix and improving upon it
- 150 kHz current system with ECG amplifier
- A filter to remove the ECG signal, for example a phase sensitive demodulator, or high pass filter, so we can use the 150kHz signal

Design Requirements:

1. Physical and Operational Characteristics

- **Performance Requirements:** The team aims to design a system to acquire more accurate and reliable cardiograph data. The electrodes should be reusable and suitable for a wide range of subjects to be tested. The ECG signals returned should contain little interference and ready to be analyzed for further investigation.
- **Safety:** Must not put patient in danger of electric shock; must keep frequency above 100 kHz. Should have instructional manual and safety warnings for those operating device. This is an important ethical consideration in the production of this device.
- **Accuracy and Reliability:** In the long run, impedance cardiography machine should be as accurate as the current invasive catheter method currently used in hospitals to measure cardiac output. The device should Remove interference and acquire

continuous and clean data to be analyzed.

- Life in Service: Should be able to become a long-term fixture in hospital and lab settings, i.e. length of life in service should be measured in years. Electrode matrix should be able to be used on multiple patients.
- Shelf Life: Must withstand operating room conditions and should be built to last. Certain parts, particularly the electrodes, should be constructed to be reusable in order to increase the lifespan of the device.
- Operating Environment: Impedance device should be used in either a lab or medical setting.
- Ergonomics: The device must be comfortable and fit well on multiple body types
- Size: The electrode brace should be small enough to maneuver be placed easily on the body and lay within a close distance from the heart, but large enough to accommodate the 4 electrodes.
- Weight: The electrode matrix should be light enough to be able to be worn comfortably while the patient is standing.
- Materials: The electrode matrix must be made of nonconductive materials, so as not to distort the signal generated by the heart. The product must be made of a flexible, form-fitting material so that it can conform to the shape of different body types. There should also be a way to attach/detach the product from a body with ease.
- Aesthetics, Appearance, and Finish: These are not of primary concern, but the device should not scare the patient. Furthermore, the device should have no parts that could be harmful to the user/doctor (eg: no sharp edges).

2. Product Characteristics:

- Quantity: One testing unit is necessary.
- Target Product Cost: This has not been determined.

3. Miscellaneous

- Standards: If we are successful in our preliminary testing, human testing must be approved and implemented in order to determine accuracy and safety. Government approval must also be obtained for the device to be used in a hospital.
- Customer: The device must be accurate, mobile (able to move from room to room), and should be comparable in cost (both initial and operational) to methods in place.
- Patient Related Concerns: Electrode brace should not be cold and hard and the patient should be able to stand comfortably. Non-invasive method will be easier for the patient compared to the invasive method.
- Competition: The main competition is the current invasive catheter method, which has proven accuracy and is already being used in most hospital settings.