Impedance Cardiography

Product Design Specifications

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Function: Current methods for measuring cardiac output are invasive. A noninvasive method is impedance cardiography, which measures cardiac output by running a current through the heart ventricles via 4 electrodes and monitoring the measured resistance. As it stands, the accuracy of this method is poor because the electrodes are far away from the heart and thus it is more difficult to distinguish between actual signal and noise. Our client would like us to design a spatially specific 100 kHz system with electrodes over and close to the heart and design a mechanical method for applying the 4 reusable electrodes at varying spacing over the heart.

Client Requirement:

- 4 reusable electrodes
- Method of determining ventricle location in live patients
- System of holding electrode device to body
- 100 kHz current system

Design Requirements:

1. ### Physical and Operational Characteristics
    - Performance Requirements: Reusable electrodes (for multiple patients). Electrodes must have some way to conduct electricity. Suitable for a wide variety of patients (different sizes, gender, etc.)
    - 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.
    - 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.

- 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 brace and electrodes should be used on tens, probably hundreds of 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 limit itself to 100 kHz
- 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 brace should be light enough to be able to be worn comfortably while the patient is standing.
- Materials: The electrode brace must be made of nonconductive materials, so as not to distort the signal generated by the heart.
- Aesthetics, Appearance, and Finish: These are not of primary concern, but the device should not scare the patient.

2. Product Characteristics:
    - Quantity: One testing unit is necessary.
    - Target Product Cost: This has not been determined.
3. Miscellaneous
    - Standards: Once an appropriate design is achieved, human testing must be implemented to determine the safety and accuracy of the device.
    - Customer: Accurate, mobile (able to move from room to room), should be any more expensive than current method.
    - Patient Related Concerns: Electrode brace should not be cold and hard and the patient should be able to stand comfortably.
    - Competition: Yes, the main competition is the current invasive catheter method, which has proven accuracy and is already being used in most hospital settings.