Product Design Specification

Breast Imaging Team

Client: Professor Susan Hagness

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Function:

Our client, Professor Susan Hagness, is developing a 3-D microwave imaging technique that will be used in tandem with Magnetic Resonance Imaging (MRI) technology. The 3-D microwave device, which resembles a box without one of its sides, is placed over a breast that is immobilized by mesh. The empty space between the mesh and the box must be filled with vegetable oil; because each patient is different, there will be changes in the volume of the empty space and thus the vegetable oil amount also changes. Professor Hagness requires a way to determine how much liquid is required to fill the void and a mechanism to control the filling of the box.

Client requirements:

- Each hole < 1 cm
- ⅓ volume can be filled before hand
- One Device
- No metal inside the device
- Mobile
- Easily Removeable
- No Manual Operator

- Electronic Sensor Preferred
- $600 budget
- Reusable with minimal reconstruction

Design requirements:

The client requires a sensor that measures the volume of liquid that is pumped into the device's empty space. A sensor that has low human error is preferred and an electronic monitoring system was proposed by the client. When designing the sensor, the amount of metal put inside the imaging device must be limited. Any holes put into the device must be less than one cm. The system must be reusable and require little reconstruction.

1. Physical and Operational Characteristics (Not done yet)

a. ***Performance Requirements:*** The device will be used to image a single breast at a time. It is estimated that the device will be employed on one patient per day done in 40 cycles. It must be mobile enough to move easily from room to room.

b. ***Safety:*** The sensor will become a part of the actual imaging device and it must comply with the Institutional Review Board (IRB). IRB approval must be obtained before collecting data when dealing with a research project using human subjects.

c. ***Accuracy and Reliability:*** The sensor needed to measure the liquid must be accurate enough so that the box will not overfill the box. An error of plus or minus 2 mm from the actual is our projected benchmark accuracy.. Multiple tests will be done to assure the sensor is reliable and reusable.

d. ***Life in Service:*** The interface will need to be serviced while switching microwave arrays. This will involve detaching it from one array and attaching it to another. It should be designed to require little disassembly and reassembly.

e. ***Shelf Life:*** The interface will be stored in a dry, controlled environment.

f. ***Operating Environment:*** The interface will be used and stored in a MRI room during testing and during clinical trials. The conditions of the room will be regulated as they usually are. During actual operation, the interface will likely be used in a similar room in a hospital or clinic.

h. ***Size:*** There are no specific constraints on the size, but the interface will be wheeled into the area of operation and should be transportable.

i. ***Weight:*** There are no operational restrictions on the device's weight.

j. ***Materials:*** There can be no metallic material in the box. There are no other specific restrictions on the use of materials.

k. ***Aesthetics:*** There are no specific restrictions on appearance, but the device should be as minimalistic as possible.

2. Production Characteristics

a. ***Quantity*****:** One prototype is required.

b. ***Target Product Cost:*** A budget of $600 was set for required design materials.

3. Miscellaneous

a. ***Standards and Specifications*****:** The interface must be compliant with IRB regulations. For example, fresh biocompatible fluid must be used with each patient.

b. ***Customer:*** The intended user of the device will be medical imaging technicians who will be performing clinical trials of 3-D microwave imaging on subjects. The client prefers that the design should introduce little to no foreign materials inside the array box. The client would also prefer the team build a model of the array box to modify instead of the prototype already built by the client.

c. ***Patient-related concerns:*** As aforementioned, fresh biocompatible fluid needs to be used for each subject, to reduce the spread of bacteria. No sharp or harmful objects are to be used inside the box, as the patient will be exposed to its contents.

d. ***Competition:*** Currently there are no clinical prototypes of 3-D microwave imaging available in the market.