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 along with mammography to screen for breast cancer. The 3-D microwave device, which resembles a Kleenex box, will be placed over a breast that is immobilized by a mesh. The empty space between the mesh and the box is filled with oil and, because each patient is different, there will be variations in the volume of the empty space, and thus the amount of oil required will change. 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 less than 1 cm diameter
- One-third of the liquid can be filled beforehand
- One device
- No metal inside the device
- Mobile
- No manual operator
- Electronic sensor preferred
- $600 budget
- Transferrable between boxes 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 interaction is preferred, and the client proposed an electronic monitoring system. When designing the sensor, the amount of metal put inside the imaging device must be limited. Any holes put into the device must have a diameter less than or equal to 1 cm. The system must be reusable and require little reconstruction.

1. Physical and Operational Characteristics

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 must measure the liquid accurately enough so that the box does not overflow. An error of ±2 mm from the actual level 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. One aspect of the design that must comply with IRB regulations is the oil coming in close contact with the patient. As a result, fresh oil must be used with each patient.

b. ***Customer:*** The intended users 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 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:*** Fresh oil needs to be used for each subject to reduce the spread of contagions. 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 devices that fill containers of unknown volume to the top with liquid.