Sensor for Breast Imaging Device

BME 300/200

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Department of Biomedical Engineering

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Abstract

For women in the United States, deaths due to breast cancer are second only to those due to lung cancer [1]. A mammogram is the initial diagnostic technique for women over the age of 40. However, there are women with higher risk factors, such as high breast density, who have cancer that goes undetected. Our client, Professor Susan Hagness, is developing a 3-D microwave imaging technique that better suits higher risk women. The device resembles a cube, as depicted in Figure 1. The cube will be filled with a biocompatible liquid that enhances the image quality. The current procedure fills the cube only half-full and fits the breast in the device. This method is inefficient and sometimes causes the liquid to overflow, leaving the device covered in oil. Professor Hagness requires a pump-sensor system that monitors the liquid level with minimal human interaction. As a result, we proposed the use of a piezo-resonant sensor that detects the fluid level inside the device.

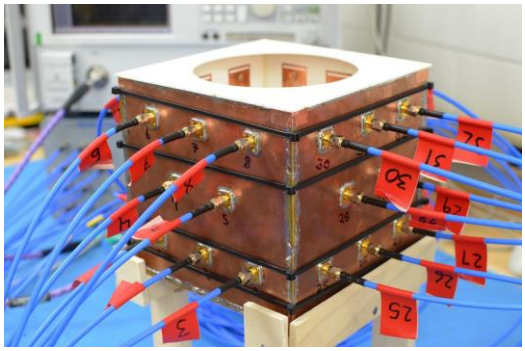

Fig. 1: Picture of 3D imaging device courtesy of Owen Mays.

Problem Statement

Our client, Professor Susan Hagness, is developing a 3-D microwave imaging technique that will eventually be used, in addition to mammography, to screen for breast cancer. The 3-D microwave device, seen in Figure 1, is placed over a breast that is immobilized by a thermoplastic mesh. The void between the mesh and the box must be filled with safflower oil, a biocompatible liquid. Because each patient is different, the volume of the empty space, and thus the amount of oil required, varies. Currently, the practitioners must fill the imaging device beforehand. Consequently, this can lead to spillage of oil and a loss of time. Professor Hagness requires a way to determine how much oil is required to fill the void and a mechanism to control the filling of the box.

Background

About 1 in 8 American women (just under 12%) will develop invasive breast cancer over the course of their lifetimes. Besides skin cancer, it is the most commonly diagnosed cancer among American women. In addition, breast cancer accounts for approximately 30% of all cancers in all women [1]. To diagnose and find breast cancer early, every woman over the age of 40 receives a mammogram to initially screen for breast cancer.

Mammography is an x-ray imaging technique that depicts breast density. It is a highly scrutinized medical procedure that has the best combinations of sensitivity and specificity compared to any other breast cancer screening technique [2]. Sensitivity refers to the proportion of true positive results. This is calculated by dividing the number of breast cancer cases that were detected by the total number of breast cancer cases in the population tested, which equals the sum of those that were detected plus those that were missed. Estimates of the sensitivity of mammography from different studies range from 83 to 95 percent. Conversely, specificity refers to the proportion of true negative results, or tests that correctly indicate that a woman does not have breast cancer among screened women without breast cancer [2].

Professor Hagness remarks, “Mammography is the gold standard that has saved countless lives, and we don’t see a need for an alternative for women who are served well by that technology. But there is a population that is currently underserved, and we’re interested in developing a safe, low-cost imaging modality that could be used for evaluating breast density and screening women who are at high risk” [3]. Our client, Professor Susan Hagness, is developing a 3-D microwave imaging technique to use in addition to mammography to assess women with a higher risk of breast cancer. One high risk factor for breast cancer is tissue density. Breasts are composed of two types of tissue: fatty tissue and fibroglandular (connective and epithelial) tissue. Fibroglandular tissue is denser than fatty tissue, and some women have a disproportionately large amount of it in their breasts. Dense breast tissue makes it more difficult for doctors to accurately screen for cancer because mammography produces a flat, 2-D image, and the x-rays cannot distinguish between dense tissue and cancerous tissue. Therefore, a mammogram of a dense breast would be difficult to interpret. Research in Annals of Internal Medicine found that as many as two out of every five cancers in women who have high breast density go undetected [3].

The alternative for this class of women is currently MRI. It produces a 3-D image of the breast, as opposed to the 2-D image that mammography produces, that a doctor can examine piece by piece to search for tumors without being impeded by the dense tissue. However, MRI is extremely expensive and does not work with claustrophobic patients. Additionally, MRI machines are limited in supply and cannot be used outside of major cities. Our client’s device is intended to replace MRI in screening of high-density patients. It also produces 3-D images of breast density, but it costs about a tenth as much as MRI. It is also safer than mammography because microwaves are less intense than x-rays. Less power is delivered to the antennas, which reduces the microwave power of the waves to less than that of those emitted from a cell phone [3]. It is also safer than MRI for patients who have pacemakers or other metal implants, as there is no magnetic field to potentially move or disrupt them. During clinical testing, this device will be used in conjunction with MRI to validate its accuracy and reliability. An MRI scan will be performed first. Immediately afterwards, the microwave equipment will be brought into the room, and a microwave scan will be conducted. The images will be compared against each other.

During a mammogram, x-rays are passed through the breasts. They can pass through fatty tissue, which does not appear on the final image. Cancerous tissue, however, absorbs them. It appears white on the image. However, fibroglandular tissue also absorbs x-rays. Therefore, it also appears white on the image. With mammography, there is no way to distinguish cancerous tissue from fibroglandular tissue, which makes it almost useless in patients with high breast density [4]. In a MRI scan, a powerful magnetic field is applied to the body. This aligns all of the magnetic fields of the body’s hydrogen atoms, which are normally random, to that of the applied field. When the field is removed, the magnetic orientations of the hydrogen atoms begin to randomize. The time it takes this to occur, is referred to as relaxation time, and it varies for different tissues, such as fatty and fibroglandular tissue. This information can be collected and then compiled into a 3-D image [5]. In our client’s proposed technology, microwaves are sent from one antenna into the breast. They are then deflected by various tissues based on their dielectric properties of conductivity and permittivity. Finally,

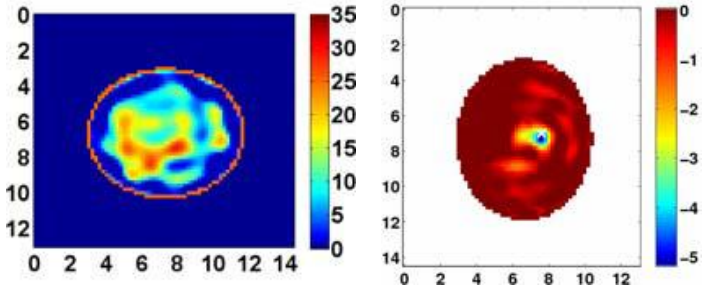

Fig. 2: Microwave image cross section of heterogeneously dense cancerous breast. Cancerous area is highlighted by a contrasting agent (right) [6].

the deflected waves are collected by the other antennas. This is repeated for every antenna on the box, and the data is then constructed into a 3-D image of the breast. This technique can be used to distinguish cancerous and non-cancerous dense tissue, as shown in Figure 2. Prior to the scan, the box is filled with safflower oil. The properties of this oil are similar to those of the skin and the thermoplastic mesh. This effectively makes the mesh and skin invisible in the 3-D image [6].

Motivation

After the MRI is complete, the device will be filled with safflower oil. Currently, the procedure for filling the device involves a great amount of human effort. Additionally, there is a large margin of error in estimating how much oil is needed when placing the breast in the device. Because each woman is different, there is no specific volume that can be standardized and used. Our client, Professor Hagness, requires a pump-sensor system that monitors the level of the oil with minimal human interaction.

Client Requirements

The design cannot involve any metal inside the microwave box. While the imaging device is being used, microwaves will be present on the inside. Metal reflects microwaves extremely well, which can lead to distortion of the final image [7]. Holes are allowed in the array box, but each one must be 1 cm or less in diameter, with a maximum of two holes. Any discontinuity within the array is conveyed in the microwave image, and the client must adjust it in order to compensate for such discontinuity. Additionally, it must be autonomous; it cannot rely on a manual operator's precision. There is no specific constraint on the device's size. It will be wheeled into the room of operation along with the microwave equipment immediately before it is used, so it can be as large as necessary. Ideally, the device should fit in the interstitial space under the MR bed, as shown in Figure 3. It should also be portable enough to be conveniently transported from the MR room to a nearby room. Space is somewhat limited on the box itself due to the many cables extending from the microwave antennas. Costs must be within a $600 budget.

Fig. 3: Picture of MR bed that patient is placed on for the imaging procedure, courtesy of Owen Mays.

Existing Devices

Currently, there are no devices that noninvasively fill a container of unknown volume. Commercial fillers are available, but they are intended for mass production to fill known samples and cost from $2,000 to $50,000, depending on the application and processing capability [8].

Ethics

The oil must be changed in between uses because the oil pumped into the array box will contact the patients' skin. The device should include a draining mechanism and allow for easy addition of new oil. In addition, 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.

Ergonomics

The user of the device, and others present, will also operate the microwave equipment and prepare the patient. Therefore, the device should be simple to operate, and electronics should be protected from potential liquid spills and wet hands.

Design Proposal Overview

The client would like a design solution based on criteria aforementioned. Three possible design solutions were derived from brainstorming sessions. The designs vary in their complexity. However, all three fulfill the client requirements.

Design 1: Piezo-Resonant Sensor

This design includes a sensor that can detect when a fluid reaches a certain level. The sensor's adhesive is an easy way to attach the unit to the device. The device uses a piezoelectric crystal that, when excited, creates an acoustic signal that is sent through the device by the sensor. The sensor detects a reflection pulse given by the acoustic signal. The fluid level is detected by taking advantage of an acoustic impedance mismatch by two dissimilar materials. For example, if the oil level has not reached the sensor level, the acoustic signal will travel through the wall of the device, and then through air. Both of these materials have very different acoustic impedances that result in the acoustic signal being reflected back at the sensor. The oil has an acoustic impedance similar to the wall of the device. Once the oil reaches the sensor, the acoustic signal travels through it, without much deflection. This is depicted in Figure 4. When the sensor receives this loss in reflection pulse, it outputs a specific voltage that turns off the fluid pumping device.

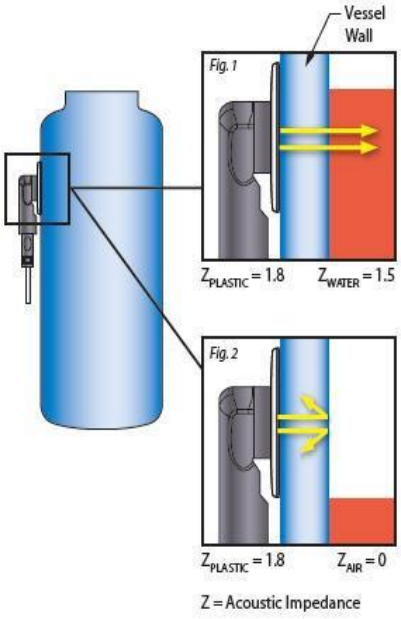

Fig. 4: Piezo-Resonant Sensor acoustic signal not reflected (top) and reflected (bottom) due to differences in acoustic impedance (Z) [9].

Design 2: Pressure Sensor (FSR)

The second design will use a pressure sensor. One type of pressure sensor employs a Force Sensing Resistor (FSR), pictured in Figure 5. This resistor changes resistance in response to a force that is applied to it. The resistor outputs a voltage, which then can be converted into a force. Since the signal output will be an analog signal, a microcontroller will be needed to convert the analog signal to a digital signal.

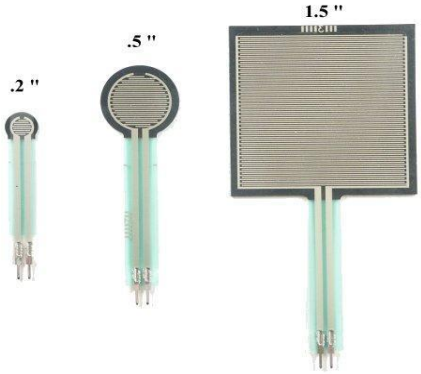

Fig. 5: Various sizes of FSR sensors. [10]

Design 3: Kill-Switch

The third design for fluid level sensing will not include any sensor. Instead, it will use the principle of buoyancy to shut off or "kill" the process of filling the device with fluid. A buoyant ball will be inside the device at the top of the device walls. The opposite end of the ball will be directly above an on/off switch to a circuit. When the oil reaches the ball, it will cause the ball to rise, causing the opposite end to move down, closing the previously open circuit and shutting off the system. This design is simple to implement in theory. However, it requires cutting into the device and inserting a ball.

Design Evaluation

The final design was chosen through careful consideration of many factors from the top three design ideas. The five criteria used for evaluation were selected and weighted according to their importance. They were, in order of importance, invasiveness, reliability, feasibility, compatibility, and removability. Table 1 displays the final design evaluation matrix with the points received by each of the top three designs. Each design could receive a maximum of 100 points.

Criteria	**Weight**	**Piezo-Resonant**	**FSR**	**Kill-Switch**
Invasiveness	30	30	10	10
Reliability	30	25	20	15
Feasibility	20	15	10	17
Compatibility	15	10	5	15
Removability	5	5	0	0
Total	**100**	**85**	**45**	**57**

Table 1: Design Evaluation Matrix - Displays the chosen criteria, their assigned weights, and points for each design in each category. The Piezo-Resonant design scored the highest overall.

In order to produce an accurate image of the breast, with minimal interference, the client requested that no part of the sensor be located inside the box. Objects placed inside the box may distort the image. As a result, the level of invasiveness of the design was one of the most important criteria for the client and was given the largest weight of 30 points. The piezo-resonant design was able to meet this criterion by being completely non-invasive, resulting in it receiving the full 30 points. The FSR and kill-switch designs, however, would both require an additional hole to be placed on the side of the box and an object to be placed in the box. Due to their similar level of invasiveness, the FSR and kill-switch designs both received 10 points.

The reliability of the sensor to effectively and consistently detect the fluid level in the box was the second most important factor considered. The importance of the sensor's reliability was reflected by the weighting of 30 points. The piezo-resonant sensor has an accuracy of ±1.6 mm and can be used repetitively without any special handling [9]. This combination resulted in the piezo-resonant design receiving 25 points. The FSR was given a reliability score of 20 points because it is reliable for multiple uses, but does not have great precision. Lastly, the kill-switch design received 15 points. This design received the lowest score due to space concerns for the switch clearance from the top of the box and the breast.

Another factor that was considered was the feasibility of constructing a prototype for the design, given the time constraint of the project. This factor received a weight of 20 points. The piezo-resonant sensor design received 15 points because it is factory configured and would simply have to be placed on the side of the box. The only area of concern regarding time is wiring the output of the sensor to a pump with a relay. The FSR design received a feasibility score of 10 points because it would require the programming of a microcontroller to convert the output of the FSR from analog to digital. The kill-switch design would be simple to construct and wire directly to the pump, but it would require an additional hole to be cut in the box. This resulted in the kill-switch design receiving 17 points.

The sensor's ability to be compatible with a circuit and pump was given a weight of 15 points. The piezo-resonant sensor design would require a relay connecting the pump and sensor, but the sensor's USB interface could simplify this process. The piezo-resonant sensor received 10 points as a result. The FSR design received 5 points for compatibility based on the difficulty of programming a microcontroller and calibrating the sensor. The kill-switch design was given 15 points for compatibility because it would transmit either an on or off signal to the relay, and therefore would not require a microcontroller.

The removability of the sensor from the imaging device was considered as a final design consideration from the client and was given a weight of 5 points. The client desired the final design to be one that can be removed and reused easily on other boxes with minimal reconstruction. This would allow the client to conduct testing on the box without the sensor being attached at all times. These points were awarded on an all-or-nothing basis. The piezo-resonant sensor received the 5 points because it could be removed easily from the side of the box and the exposed area could be covered with copper. The FSR and kill-switch designs received 0 points because neither would be feasible to remove and reattach because they are invasive

The final design was chosen according to the total scoring of the five major criteria considered. The piezo-resonant sensor design scored significantly higher than the subsequent designs, and as a result, was selected as the final design. The kill-switch design finished second, and moving forward, will be considered as a backup design.

Prototype Construction

The initial phase of building a prototype for testing is to construct a model box. The testing cube will be constructed with clear acrylic on four sides, copper-ceramic substrate on one side, and an open top. The acrylic sides will provide the ability to visually confirm the effectiveness of the sensor during testing. The ceramic substrate side will allow for an accurate duplication of the material the final sensor must work through. The open top will allow for manual filling and emptying of the cube until the pump can be incorporated into the design.

The second phase of prototype construction will be to design and construct a circuit for the sensor and pump to interact. This will be done using a relay and USB interface.

The third and final phase in constructing a prototype is to incorporate a pump into the design. The pump will require one to two holes to be drilled in the model box, which is why it will be done after assurance is found in the ability of the sensor. The pump will be turned on and off by the readings from the sensor transmitted through the circuit.

Future Work

The remainder of the semester will involve three main categories: sensor selection, fabrication, and testing. Unfortunately, the piezo-resonant sensor is only compatible with plastics and not with the ceramic substrate. Instead of choosing the backup design (kill-switch), research is being done to select alternative non-invasive sensors, such as ultrasonic and capacitive ones. Research will be done to make sure the sensor is compatible with the copper-ceramic wall of the box. In addition, the pump will be ignored, and the sensor/relay circuit will be the main priority due to time constraints. The client was notified and agreed that this was the correct decision. All materials needed to make the model box have been obtained. The fabrication will be the highest priority heading into the second half the semester. Once the sensor is acquired, testing will be conducted with water acting as the biocompatible medium, and based on success of trials, will proceed using oil. The reason for using water is to assess the accuracy of the sensor without having the mess of the oil. The prototype will be refined based on the results of testing and feedback from the client. If time permits, a pump will be connected to the sensor and box and testing of filling and draining of biocompatible liquid will be conducted.

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Appendix A

Product Design Specification

Breast Imaging Team

Client: Professor Susan Hagness

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Date: October 23, 2012

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.