Sensor for Breast Imaging Device

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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 cancers that goes undetected. Our client, Professor Susan Hagness, is developing a 3-D microwave imaging technique that better suits higher risk women. The device, depicted in Fig 1, resembles a cube. 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 capacitive sensor that detects the fluid level inside the device.

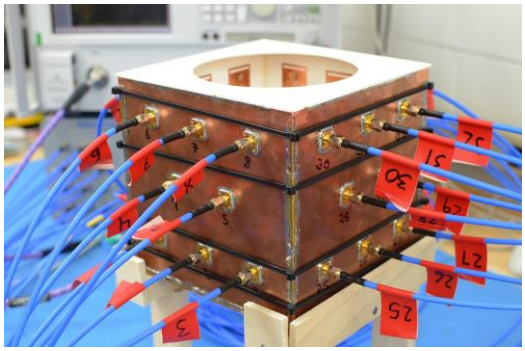

Fig. 1: Picture of 3D imaging device courtesy of Owen Mays.

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 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].

Other imaging technologies include computed tomography (CT), positron emission tomography (PET), and magnetic resonance imaging (MRI). Although CT and PET scans are increasing in use, they are mainly used for patients with higher stages of disease because they involve ionizing radiation. Alternatively, MRI is a strong competitor with 3D microwave imaging techniques. This is a quote from RA Wascher [4] "MRI is known to be much more sensitive than either mammography or ultrasound in identifying breast cancers, with most studies showing a 95 percent or greater sensitivity associated with MRI. However, this exquisite sensitivity of breast MRI, as I discuss in my (Robert A. Wascher) bestselling book, A Cancer Prevention Guide for the Human Race, is also associated with poor specificity (i.e., a high false-positive rate). Because of its poor specificity, MRI scans of the breast will be wrong, or falsely-positive, in 15 to 35 percent of cases where an abnormality is detected. Although there are other reasons as well, this high false-positive rate is the primary reason that MRI scans are not routinely used to screen for breast cancer." Also, MRI technology is very expensive compared to the projected cost of a microwave imaging device [4]. In addition, MRI in its current state has a very high false positive rate, which means that many women undergo unnecessary biopsies.

MRI produces a 3-D image of the breast, as opposed to the 2-D traditional image that most mammography produces, that a doctor can examine piece by piece to search for tumors without being impeded by the dense tissue. However, stereo digital mammography is now becoming more wide spread, and it allows 3D image manipulation much like MRI. Stereo digital mammograms are being done for women who were called back after an abnormal routine mammogram. A stereo digital mammogram combines two digital breast x-rays taken from different angles, and produces a detailed three-dimensional image of your breast's internal structure. Such stereo images must be viewed on a special workstation by a specially trained radiologist. Dr. David J. Getty of BBN Technologies of Cambridge, Mass [5] said, "In our study, stereo digital mammography reduced false positives by 49 percent," said Dr. Getty. "This could have a significant impact by cutting in half the number of women who are needlessly recalled for additional diagnostic work-ups, resulting in a large savings in cost and patient anxiety." 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 (Fig. 2) 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 [11]. 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 [9].

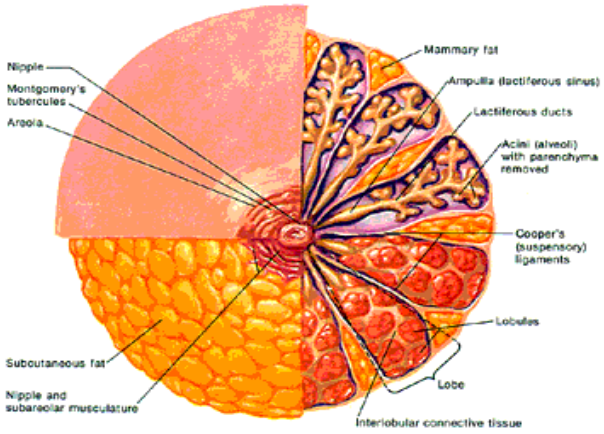

Fig. 2: Image shows there are different types of tissue the breasts contain [6].

Flores-Tapia et al report, "Mammogram images are difficult to interpret yielding a high false negative rate (4%-34%) and a high false positive rate (70%)." [10]. High false negative rates would mean a patient might not be diagnosed with cancer when they have it. False positives occur when the patient is diagnosed with cancer when they do not actually have cancer. Clinicians can diagnose the patient based on the image that is given to them. Most of the time, the image is not accurate, or it is incomplete. Due to the misdiagnosis rates, it is clear that an additional imaging technique is needed to accompany the mammogram.

Once a woman undergoes a mammogram and an abnormal result is obtained, there is no set procedure on the best technique to confirm the results. It is reported that about 10% of all screening examinations are classified as abnormal. In addition, 90% of women with abnormal results do not have cancer and need a non-invasive mode to diagnose their case [17].

Microwave imaging uses the permittivity and conductivity of healthy tissue versus malignant tissue. The microwave imaging process involves propagating electromagnetic fields through the tissue. As the fields pass through the tissue, the electromagnetic fields scatter and are reconstructed in a computer. Due to the use of low energy waves Golnabi et al [9] reports that compared to X-ray

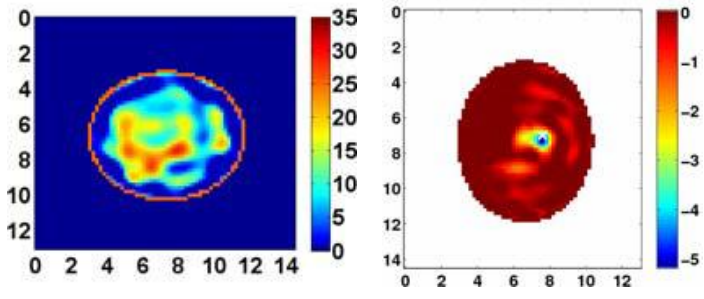

Fig. 3: Microwave image cross section of heterogeneously dense cancerous breast. Cancerous area is highlighted by a contrasting agent (right) [14].

mammography, microwave imaging is non-ionizing, non-compressive and low cost. Microwave imaging doesn't give off as much radiation as X-ray mammogram would. In addition, to get a good mammogram image, the subject's breast must be compressed up to 50% of its original diameter, resulting in a lot of discomfort for the subject. In addition, microwave imaging doesn't exclude patients with implants or claustrophobia [16].

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, 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 Fig 3. 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 [23].

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 include 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 [18]. 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 Fig 4. 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. 4: 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 [19].

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 lab technicians will 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.

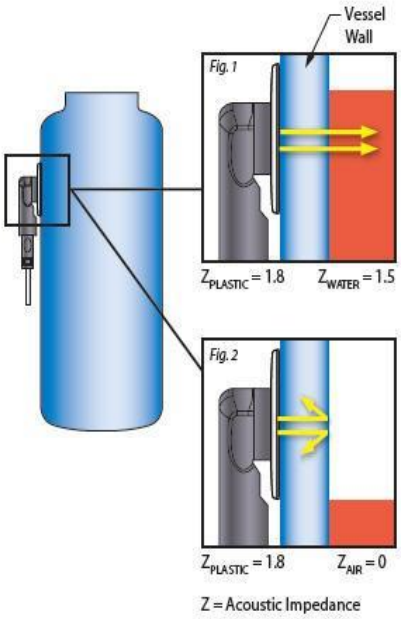

Fig. 5: Piezo-Resonant Sensor acoustic signal not reflected (top) and reflected (bottom) due to differences in acoustic impedance (Z) [20].

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.

<u>Design 1: Piezo-Resonant Sensor</u>

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 Fig 5.

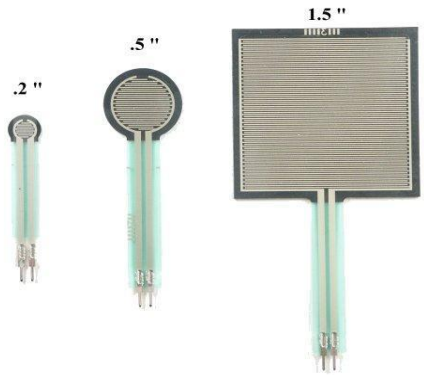

Fig. 6: Various sizes of FSR sensors. [20]

When the sensor receives this loss in reflection pulse, it outputs a specific voltage that turns off the fluid pumping device.

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 Fig 6. 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.

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.

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 [20]. 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.

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.

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.

It was later found that the piezo-resonant sensor could not work with the ceramic portion of the substrate. Therefore, a new noninvasive sensor was researched. The CLW capacitive level sensor by Sensortechnics was discovered. It uses a capacitive sensor to detect the presence of liquids through a nonconductive surface.

Prototype Construction

Construction of the prototype box began with the purchase of a 3mm thick, 500mm by 500mm sheet of acrylic from Amazon. This was cut into four identical squares and glued into a box that was missing two sides. Rogers donated a sheet of the copper-ceramic substrate used in the client's microwave array. That was used as another side of the box to simulate the actual array. The top of the box was left open, which allows for manual filling and emptying of the cube until the pump can be incorporated into the design. The box was then waterproofed with superglue (Fig 7).

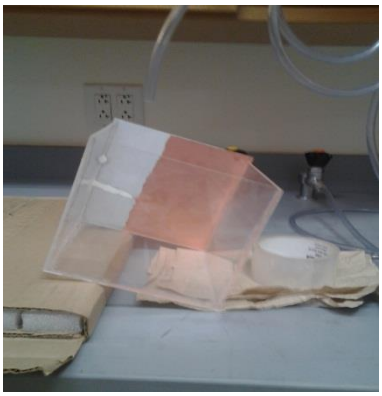

Fig 7: Depicts model box.

The CLW sensor was thoroughly researched before it was ordered.

After it arrived, it was attached to the model box using some included adhesive material. Next, the sensor was wired to a test circuit on a breadboard that used a LED to represent a pump.

Testing

Testing of the CLW sensor consisted of wiring the sensor to a circuit according to the instructions provided with the sensor (Fig 8). Instead of using a pump, however, the model box was filled by hand, and a LED was used to monitor the status of the output pin of the sensor. Testing was initially done with water in order to conserve the limited safflower oil. The sensor was programmed by filling the box so the liquid reached the bottom of the sensor. The sensor was then "taught" the low position by connecting the teach pin to ground. Afterwards, the liquid level was increased, and

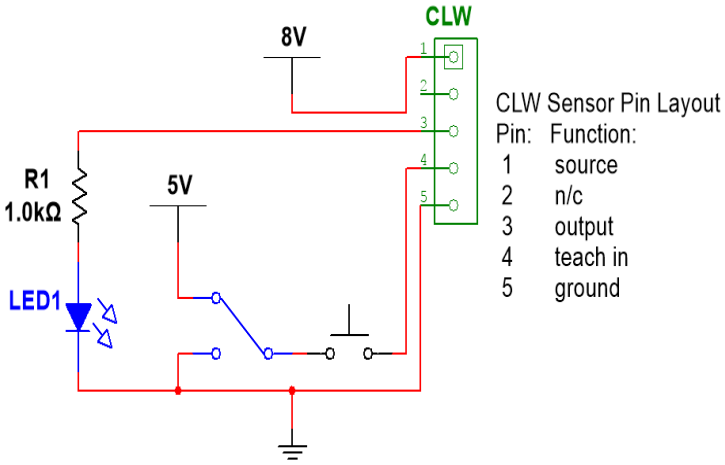

Fig. 8: A diagram of the circuit used to test the CLW sensor.

the sensor was “taught” the high position by connecting the teach pin to +5V. At first, the sensor did not respond to changes in the liquid level, but to any human contact with any part of the box. The copper plating on the substrate was fully intact, so it was assumed that it was acting as a conductor for the sensor and turning the entire box into a sensor.

As a result, the copper in the immediate vicinity of the sensor was sanded off on both sides of the substrate, leaving only the nonconductive ceramic layer. After placing the sensor onto the box and programming it as before, the sensor reacted to changes in the water level. The LED switched on when the water level increased to above the high position, and it switched off when the water level returned to the below the low position. When the level was between the two states, the sensor retained its previous value. However, there was a 1.5 to 2 second delay in the switching of the sensor output. This, however, will likely be inconsequential with an actual pump, because if the box is limited to a 1cm hole, the viscous safflower oil cannot reasonably flow in at a great enough speed to spill. Since the sensor cannot be taught high at the ideal point of the top of the box, the delay can also be beneficial. The relay was also tested with the sensor output, and it switched the current on and off correctly when wired to the sensor. After these tests were completed with water, they were conducted with safflower oil. The sensor behaved the same. Finally, the sensor was tested with the presence of a phantom breast provided by a client. The breast was placed inside the box as close to the sensor as possible, and while filling the box, the sensor still activated. While the phantom is not conductive like a real breast, it still shows that the sensor is not impeded by nearby objects. In actual use, the breast will be much farther from the sensor, as well.

Due to the lack of a pump in the design, flow rates were not controlled during testing, so proper quantitative data could not be obtained. If a pump were available, statistical analyses would be performed to determine the accuracy of the sensor and the fill times. To statistically determine the accuracy of the sensor, two chi-squared tests for goodness of fit would be performed. The formula for a chi-squared test is as follows:

$$\chi^2 = \sum \frac{(O - E)^2}{E}$$

O represents the observed value of the measured variable. E represents the expected value. For each repetition, the square of the observed minus the expected values would be divided by the expected value. The sum of these results would represent the chi-squared value. This value can then be compared against a chi-squared table (Fig 9) in order to determine the p-value, or the probability that the observed deviation is due to chance alone, based on the degrees of freedom of the variable. If the p-value is less than the level of significance of the test, the observed values significantly deviate from the expected one.

Upper critical values of chi-square distribution with ν degrees of freedom

	Probability of exceeding the critical value				
ν	0.10	0.05	0.025	0.01	0.001
1	2.706	3.841	5.024	6.635	10.828
2	4.605	5.991	7.378	9.210	13.816
3	6.251	7.815	9.348	11.345	16.266
4	7.779	9.488	11.143	13.277	18.467
5	9.236	11.070	12.833	15.086	20.515
6	10.645	12.592	14.449	16.812	22.458
7	12.017	14.067	16.013	18.475	24.322
8	13.362	15.507	17.535	20.090	26.125
9	14.684	16.919	19.023	21.666	27.877
10	15.987	18.307	20.483	23.209	29.588

Fig. 9: A chi-squared table that relates chi-squared values to p-values based on degrees of freedom. [22]

The first test would determine whether the sensor overflows the box. The null hypothesis would be that activation of the sensor is random when the liquid level is close. The alternative hypothesis would be that the sensor correctly determines liquid level and stops

the flow rate at the top of the box without overflowing. For the chi-square test, the box would be filled until it is stopped by the sensor, and the liquid that flows out of the box would be collected. Its volume would then be measured. This would be repeated ten times. Afterwards, a chi-squared test would be performed, and the p-value would be determined with nine degrees of freedom. If the p-value were below the standard significance level of 0.05, the null hypothesis would be rejected, and the data would support that the sensor accurately stops the flow of liquid into the box.

The second test would determine whether the sensor stops the flow of liquid too soon. The null hypothesis would again be that activation of the sensor is random. The alternative hypothesis would be that the sensor correctly determines liquid level and stops the flow just as it has reaches the top so that it completely fills the box. Once again, the box would be filled until the sensor stops the pump, and the distance from the top of the box to the level of liquid would be measured. After ten trials, the chi-squared value would be calculated, and the p-value would be determined. If the p-value were below 0.05, the data would support that the sensor allows the box to be filled to the top without stopping early.

Finally, the average fill time for the sensor and pump would be determined. The entire design would be tested ten times with a consistent flow rate, and the mean time required would be calculated. This mean time would give the client an estimate on how long filling the box would take.

Budget Analysis

The total cost for the CLW sensor, acrylic sheets, acrylic glue, and relay was approximately $130, resulting in a $470 saving from the client-specified $600. The majority of the cost was the sensor, at $100.58 plus shipping and handling. The large budget did not put any constraints on the design. For future work, pumps that have sufficient flow rates for the project's application (1-5 LPM) are around $200, keeping the total cost under $600.

Future Work

Future work on this project will involve the selection of a pump, integration of that pump into our circuit, and building of a tank and hosing system. The sensor circuit was already designed with a relay to make the addition of a pump simple (Figure 10). Multiple pump options were researched, including centrifugal, peristaltic, and microfluidic pumps. Possible pump options were evaluated based on price, flow rate, and noise output. Based on these criteria, a magnetic drive centrifugal pump would be the best choice in this design. The peristaltic and microfluidic pumps, although commonly used in biotechnology, were generally more expensive and had slower flow rates [20]. A centrifugal pump was

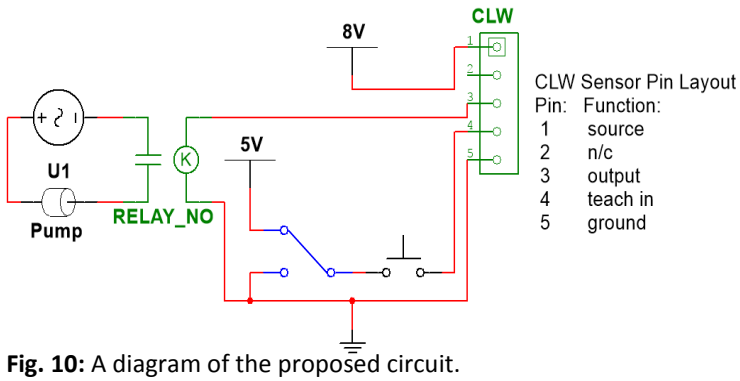

Fig. 10: A diagram of the proposed circuit.

found through Cole Parmer, a scientific instrument supplier, which sells it for $182. This pump has a max flow rate of 4.2 liters per minute and noise output of around four decibels [21]. This flow rate will allow the approximately five-liter imaging array to fill quickly. Another benefit of a centrifugal pump is they are designed to work for over 25,000 hours of use [22]. In addition, the pump operates continuously, instead of intermittently pulsating, which will cause less discomfort for the patient and be more compatible with our level sensor. The final step of the design is to create the hosing and tank system. The system will resemble the one shown in Fig 11 with the pump being gravity fed and the oil draining from the imaging array via gravity. To construct this system, materials would have to be selected to select use for the holding tanks and hoses.

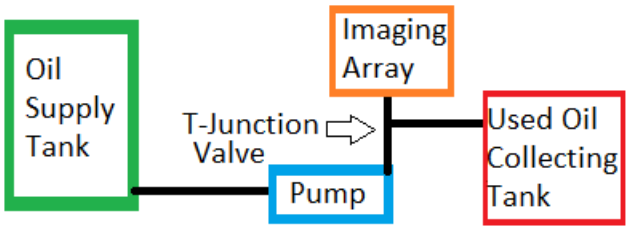

Fig. 11: A diagram of the suggested hosing and tank system.

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Appendix A

Product Design Specification

Breast Imaging Team

Client: Professor Susan Hagness

Advisor: Beth Meyerand

Team: Derek Pitts - dspitts@wisc.edu (Leader)

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Date: December 12, 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 detect the liquid level in the box 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
- Sensor compatible with Rogers 4360 substrate

- $600 budget
- Transferrable between boxes with minimal reconstruction

Design requirements:

The client requires a sensor that detects the fluid level of the oil inside the box. A sensor that has low human interaction is preferred, and the client proposed an electronic monitoring system. When designing the sensor, no metallic substance can be inside the box, as it can interfere with the image captured by microwaves. 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 trials 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 placed on a cantilevered table that will be positioned in the interstitial space under the Sentinelle Medical MR operating table. The interface will be used in an MRI room during testing and during clinical trials. During operation, the interface will likely be used in a similar room in a hospital or clinic. The device will be used with safflower oil. The patient will insert their breast into the box, which may result in perturbations to the box. A lab technician will be operating the device. The CLW sensor is placed in the top right corner on one side of the box. However, one of the sides of the sensor extends over the side of the box, and any force applied to this side of the sensor can weaken the adhesive forces acting upon the box.

h. ***Size:*** There are no major size constraints on the interface as a whole. However, each side of the box contains eight mini dual-band antennas with wires attached. Anything that is to be put on the box surface, such as a sensor, must be able to fit alongside these antennas.

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:*** The target product cost for this interface, equipped with sensor and pump, is approximately $400. A budget of $600 was set by the client 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. An automatic sensing system is desired by the client, as opposed to manual detection.

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 clinical prototypes of 3-D microwave imaging systems applied to breast imaging available in the market. However, there are 3-D microwave imaging systems and processes associated with software that are produced by Microwave Imaging Systems Technologies, Inc. [23].