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HOUSING DESIGN FOR A NEW RF BREAST COIL CONCEPT FOR USE IN MRI APPLICATIONS

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1. MRI
2. breast
3. RF

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Abstract

MRI has proven to be a reliable means of breast cancer screening, superior in many ways to conventional screening methods. Reflecting the goal of the project sponsor, this project aims to design a mechanical housing concept that incorporates an existing multi-channel RF breast coil array concept. This included steps towards incorporating the necessary electrical and RF components in a design for a low profile, ergonomic housing as well as the development of design specifications that could be used by the sponsor and their engineers to eventually manufacture the breast coil and move it into the clinical MRI breast coil market.

Acknowledgements

I would like to thank InsightMRI for their generosity in sponsoring this project. I would also like to thank Mathew Brevard, Steven Toddes and the engineers at InsightMRI for sharing their knowledge and expertise. Additionally, I would like to thank Worcester Polytechnic Institute's Aghogho Obi for the conceptual RF coil design, upon which this project is based. Lastly, I am extremely grateful to my project advisor, Professor Reinhold Ludwig, for his endless guidance and my academic advisor, Professor Christopher Sotak, for his contributions to my understanding of magnetic resonance imaging.

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1 Introduction

Breast cancer is one of the most common types of cancer among women. In 2007, it is estimated that approximately 180,000 individuals in the United States will be diagnosed with the disease, resulting in nearly 41,000 deaths (National Cancer Institute, 2007). As with all cancers, early detection is helpful in increasing success rates of curative measures. Recent studies have shown that using magnetic resonance imaging (MRI) as a screening method for breast cancer can improve detection sensitivity over other methods of screening, such as x-ray, mammography, and ultrasound (Boyd, 2007). This is considered especially relevant for premenopausal women, whose increased breast tissue density not only increases their risk of breast cancer, but also makes the actual detection of cancerous tissue more difficult using conventional screening methods (Wright, 2005).

The use of MRI for breast cancer screening is, however, currently not the standard-of-care and is usually only recommended for certain high-risk individuals, which could be due to two main factors. The first factor is that the cost of MRI systems averages between $1000 and $2000 per exam, making it expensive to perform higher resolution, time consuming scans (Grady, 2007). The second factor is that the small aperture of standard MRI systems is confining for patients and is further constrained by the commonly bulky apparatuses for breast-specific imaging within the MRI aperture. This implies a need for resolve of these two conditions in the following possible ways:

- Development of breast MRI-specific RF coil technology that demonstrates improved image quality and higher spatial resolution than that of the currently available technology, yielding high quality images with short acquisition times.
- Implementation of this technology into a low profile system, which would include the RF coil design, necessary electrical components, system specific integration methods and a physical housing.

Recently Aghogho Obi from Worcester Polytechnic Institute has designed a novel dual-channel RF coil concept for breast imaging that fulfills the need for improved imaging technology, utilizing high fill factor and field uniformity to acquire high resolution images with superior signal-to-noise ratio. This technology has proven to be of better quality than other RF breast coils for MRI applications (Obi, 2005). As a concept design, this is an accomplishment – but the coil lacks the integration into a producible unit for use in clinical MRI systems, such as General Electric's or Siemens' medical scanners.

As a result, the goal of this project is to extend the development of this new RF coil concept towards a prototype of a mechanical breast coil housing that i) holds A. Obi's electronics and ii) can be validated through basic testing. To accomplish this goal, I will speak with representatives of different stake holder populations involved in this project in order to learn more about the improvements desired for the system. With the help of InsightMRI, I will use this information, the technical requirements of the clinical systems, and 3-D modeling software to design a housing for the system that addresses the needs identified through our research, as well as issues that have arisen with other breast coil prototypes.

Furthermore, we will provide engineering design specifications that a company can use to accommodate the printed circuit boards (PCB) as part of the housing for the breast coils. Once the PCBs are manufactured and populated, a company can conduct non-human testing of the mechanical prototype in a clinical MRI system using materials that will simulate similar characteristics of biological tissue, called "phantoms". This will allow them to not only verify the success of the project, but also determine whether or not Aghogho Obi's coils still perform successfully and advantageously while integrated into the mechanical housing prototype design.

2 Literature Review

As the demand for cancer detection methods increase, the technology for screening for cancer must improve. Breast cancer is one of the leading causes of death among women. Over the past decade, the number of women requesting breast cancer screening has significantly increased, due to findings from research studies as well as recommendations from various sources. Therefore, it is important to employ a screening method that is reliable and effective to meet the demand for cancer detection. Magnetic resonance imaging (MRI) is a method of biomedical imaging, the technology of which is both developing rapidly and successful in many cases where other methods are not. In order to contextualize this project and to understand the technology of MRI, the following chapter first examines breast cancer and the means available for detecting it. Next, we will give an overview of the physics used to obtain images from MRI. Finally, we will look at the current technology available for breast imaging, specifically discussing Aghogho Obi's concept breast coil that this project aims to integrate into a useable prototype.

2.1 Breast Cancer and Cancer Screening

Breast cancer is the uncontrolled growth of tumors in breast tissue. The breast is composed of various tissues, including connective and fatty tissues, blood and lymph vessels, and ducts and lobules (responsible for the creation and transportation of milk) as shown in Figure 2.1.

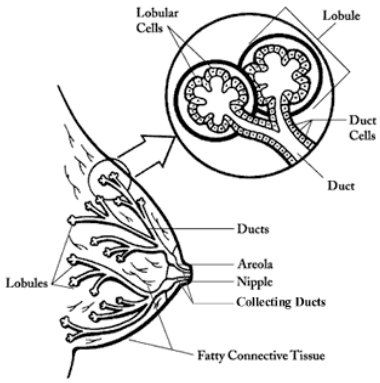

Figure 2.1 – Anatomy and tissues of the breast (American Cancer Society, 2007).

The most common type of breast cancer is a malignant cancer of the ductal tissue, called invasive ductal carcinoma. If cancers in specific breast tissues spread to vessels in the body, it is possible for the cancer to spread to other body organs (American Cancer Society, 2007). The following two sections discuss first, the risks associated with the contraction of breast cancer and second, the methods used to detect breast cancer.

2.1.1 Risks Associated with Breast Cancer

There are many risk factors associated with the contraction of breast cancer in women, including age, genetics and family history, certain breast tissue abnormalities or lesions, previous chest radiation, menstrual period development, obesity and breast tissue density. Table 2.1 describes the changes in an individual's risk based on these common factors and conditions.

Table 2.1 - Changes in risk of breast cancer associated with different factors (Adapted from data from (Center for Disease Control, 2007)).

Risks Associated with Breast Cancer	
Factor	**Change in Risk**
Age	Increases with age[1]
Genetics	Up to 80% likelihood of cancer[2]
Personal History	3-4x increase[3]
Breast Abnormalities	1.5-5x increase[4]
Previous Radiation	Up to 12x increase[5]
Menstrual Development	Slight increase[6]
Obesity	Increases with obesity[7]

[1]17% of women diagnosed are in their 40s, while 78% are 50 years old or older.
[2]5-10% of women diagnosed have associated hereditary risks. 20-30% of patients have a relative who had the disease. The most common genetic mutation (specific to the 80% likelihood) are in the genes BRCA1 or BRCA2.
[3]Breast cancer in one breast increase risk of developing breast cancer in the other breast or other parts of the same breast.
[4]1.5x – 2x increase for proliferative lesions without atypia; 4x – 5x increase for proliferative lesions with atypia.
[5] This risk increase is dependent on the type of radiation treatment and the age at which the treatment was administered.
[6] If individual started menstruating before age 12 or experienced menopause after age 55.
[7] Fatty tissue is known to produce some estrogen. Increases in estrogen levels increase the risk for breast cancer.

In addition to the factors mentioned in Table 2.1, another important factor that has specific relevance to methods of breast imaging is breast tissue density. According to

recent studies, an increased density of the breast tissue leaves a woman at higher risk for breast cancer. Women with dense tissue in 75% or more of their breast may result in an increase in risk of cancer by four to six times (Boyd, 2007). A further factor associated with risk of breast cancer in individuals with dense breast tissue is that the current standard screening method (x-ray mammography) is hindered by the dense tissue. False negatives with respect to cancer increase the possibility of the cancer metastasizing and spreading to other organs, where the chances of survival substantially diminish (Wright, 2005). The following section discusses the methods that are used to screen for breast cancer and how the problem detecting cancer in dense tissue can be solved.

2.1.2 Screening For and Detecting Breast Cancer

Mammography, ultrasound and MRI are the three most common ways of imaging the breast to screen for breast cancer. Each method has different advantages and disadvantages over other methods and all can be helpful in detecting cancer-associated abnormalities in the breast. There are many reasons that individual's request screening, such as detection of breast lumps through a physical examination. But in some cases, as mentioned in the previous section, it is important for some high-risk individuals to have regular screening of the breast.

Mammography is the use of small doses of x-rays through breast tissue onto an x-ray sensitive film. Certain tissues obstruct the x-rays and leave a light spot on the film, while other areas are transparent to x-rays and leave dark spots on the film. The process is very similar to taking x-rays of a bone in order to detect a fracture. An example of a breast mammogram is shown below in Figure 2.2.

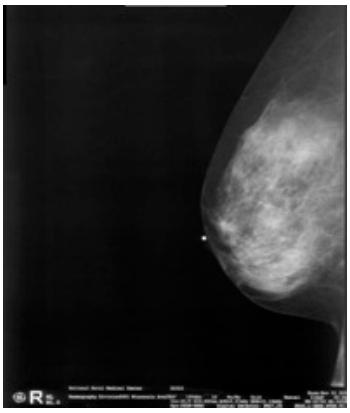

Figure 2.2– Mediolateral oblique oriented mammogram of the breast (MedPix, 2000).

Mammography is often effective in detecting the presence of cancerous abnormalities. Additionally, it is relatively inexpensive to perform the scans and it does not take a long time. However, mammography images all of the tissue through one direction of the breast, dependent on the breast's orientation. Therefore, it is necessary to image the breast in at least two different directions in order to understand the specific locations of such abnormalities. This is important so that physicians may then take a biopsy of tissue of concern to determine whether or not it truly is cancer. Furthermore, in certain individuals, such as those with dense breast tissue, mammography is much less effective (Boyd, 2007 and Wright, 2005).

Ultrasound is another screening method for breast cancer. However, ultrasound is not approved by the FDA for breast cancer screening and is therefore most often used as a follow up procedure to a questionable mammogram. An example of an ultrasound of the breast can be seen below in Figure 2.3.

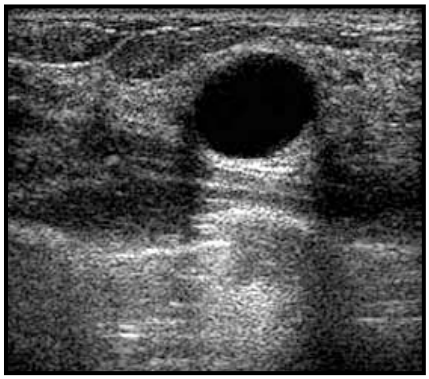

Figure 2.3– Ultrasound image of a cyst in the breast (non-cancerous), with a FOV of approximately 4cm (Mayo Clinic, 2008).

Ultrasound is useful for this purpose, as it has high contrast, allowing quick distinction between different tissues, especially between non-cancerous fluid-filled cysts and dense tissue masses that could be malignant tumors. But the detail of the image is considerably poorer than mammography or MRI (Imaginis – Ultrasound, 2007).

MRI is perhaps one of the most promising means of non-invasive imaging. The process (described in the following section), allows for extremely detailed and high-resolution images of the body. Using MRI to detect breast cancer is a new procedure, introduced in the past decade (EMRF Online, 2007). An image of a MR breast image is shown below, in Figure 2.4.

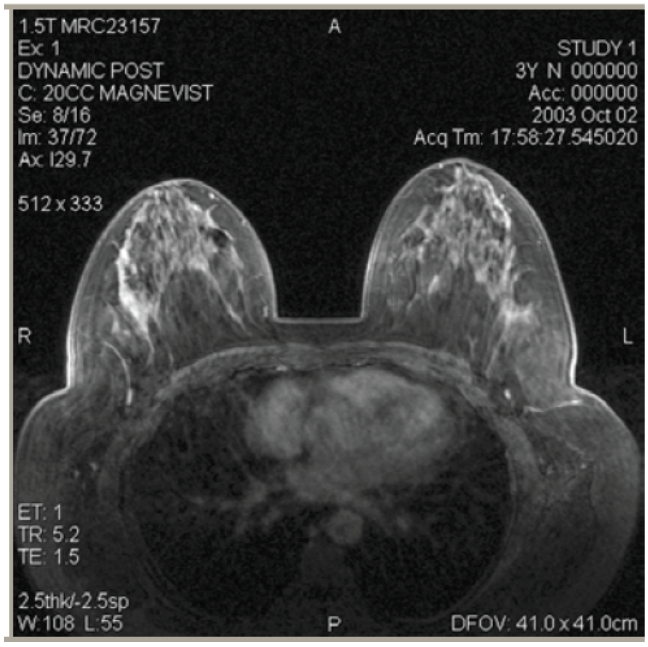

Figure 2.4– Bilateral MRI of the breast, imaged at 1.5T (Courtesy of Insight Neuroimaging Systems, LLC.).

Two of the largest benefits of using MRI as a screening method is first, that the image is not of all the tissue through a body part (as is the case in mammography) but rather an image of a slice or a single plane in the body part and second, that the MRI apparatus can image the body part in any plane without having to change the orientation of the subject. The primary drawbacks to using the technology are that MRI is expensive (the device itself as well as the maintenance costs) and it often takes up to an hour to perform a high-resolution scan.

MRI technology has its advantages to traditional x-ray mammography in certain situations. As mentioned above, in the previous section and this section, breast cancer screening becomes increasingly important as an individual ages and the risk for breast cancer increases. But in some high-risk individuals with dense breast tissue (especially younger premenopausal women), the tissue density can hinder mammography's effectiveness, making MRI a suitable and often necessary alternative, shown in Figure 2.5.

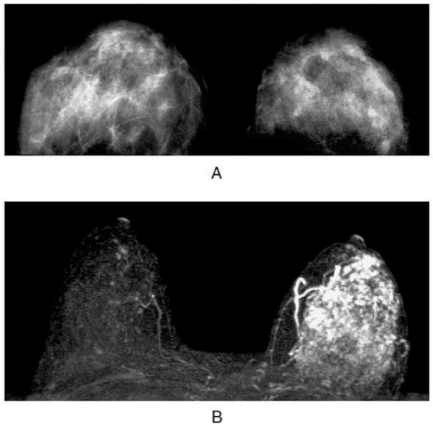

Figure 2.5– Comparison of a mammogram (A) and an MRI (b) of the same individual (Wright, 2005).

Two different types of cancer screening of the same patient were performed and compared in this figure, one using mammography and the other using MRI. The patient was premenopausal and her dense breast tissue obscured the results of mammography. But an MRI screen of the patient shows significantly metastasized cancer in the left breast (Wright, 2005).

2.2 Magnetic Resonance Imaging Overview

MRI typically uses a superconducting magnet to create a uniform magnetic field across the specimen or tissue of interest. In most clinical applications, the magnetic field strength ranges between 0.5T and 2.0T (1T is 10,000G, about 20,000 times stronger than the Earth's magnetic field). Once the tissue is in the field, the magnetic field aligns the magnetic moments of the nuclei in the material in the direction of the main magnetic field (B_0). The spin angular momentum of a charged nucleus gives rise to the nuclear magnetic moments. When placed in the magnet, the B_0 field exerts a torque on the nuclear magnetic moments in the sample, causing them to precess

about the Bo field. The precessional frequency is referred to as the Larmor frequency and is unique for each type of nucleus. For the majority of clinical MRI applications, the target atom for imaging is the H^1 nucleus, identical to the hydrogen nucleus found in water and most organic molecules.

Once the nuclei are aligned with the B_0 field, radio frequency (RF) coils are used to transmit an RF pulse with a frequency that coincides with the precessional frequency of the nuclei (for example, at 2.0T, the Larmor frequency of the H^1 nucleus is around 86.5MHz). Absorption of RF energy by the nuclei causes them to rotate away from the direction of the B_0 field by an angle (often referred to as the tip angle) that depends upon the duration and power of the RF pulse. As soon as the RF is turned off, the nuclei realign themselves with the B_0 field over time and eventually return to their equilibrium state. During this process, the RF receiver is able to detect the transverse component of the sum of individual nuclear magnetic moments in the sample. The signal detected by the receiver will be most intense when the magnetic moment is perpendicular to the B_0 field (i.e., after a tip angle of 90^o) and then decays over time. Because the H^1 nucleus acts differently in different environments (such as different tissues), the time that it takes for the signal to decay to zero and the nuclear magnetic moments to realign themselves with B_0 will vary. The time constants associated with these two processes are referred to as the T_2 and T_1 relaxation times, respectively. Exploiting the differences in these time constants for different tissues allows MRI to distinguish between the various tissue types.

In order to produce an MR image, steps must be taken to encode the spatial positions of the nuclei in the measured signal. Because there are three dimensions necessary to spatially encode a signal, three magnetic field gradient coils are used to produce three spatially distinct linear magnetic field gradients across the sample (e.g., in the x, y, and z directions of a Cartesian coordinate frame). One gradient is used to select a slice of the sample – a plane that defines the other two dimensions. The other two gradients perform frequency and phase encoding of the signal from the receiver in the planar directions of the slice. In this manner, the signal that is specific to a single voxel (a three dimensional volume element consisting of the thickness of the slice and the height and width of the volume element in the phase and frequency encoding direction) can be measured in combination with thousands

of other voxels to create an image. Depending on how the RF and gradient coils are pulsed as part of a specific pulse sequence (i.e. the duration, amplitude and timing sequence), different levels of contrast of the image can be obtained. In order to create even better contrast, either chemical contrast agents are injected into the tissue prior to the MRI scan or the image attributes are manipulated via post-processing image correction (Sotak, 2007).

2.3 Current Magnetic Resonance Imaging Technology

Magnetic resonance imaging technology has only been available for clinical applications since the late 1980's, making it still a relatively new technology. Furthermore, the development of the technology relies on a multidisciplinary understanding of medicine, chemistry, physics, computer science and device engineering, which means the development of the technology relies on a diverse group of engineers with expertise in these backgrounds (EMRF Online, 2007). The three most common producers of magnetic resonance imaging systems are Phillips Medical, Siemens Medical and GE Medical. Additionally, smaller companies (such as this project's sponsor, InsightMRI), produce anatomical site-specific RF coils for producing higher resolution images of specific body parts, which are compatible for use with the previously mentioned MRI suites. Magnetic resonance breast imaging is the second fastest growing MR procedure in the US (Imaginis – MRI, 2006). The following two sections discuss the current state of MR breast imaging and InsightMRI's novel concept RF breast coil that this project aims to help develop.

2.3.1 State of Breast Cancer Magnetic Resonance Imaging Market

Although MRI is not the standard of care associated with breast cancer screening, it is commonly used as a follow-up procedure for certain anomalies detected with other modes of imaging. This being the case, it is imperative to examine the current state of the breast cancer imaging market with respect to MRI. In 2003, Frost and Sullivan reported on the North American Adjunctive Breast Imaging Market. Figure 2.6 show the expected growth of the breast MRI market through 2010.

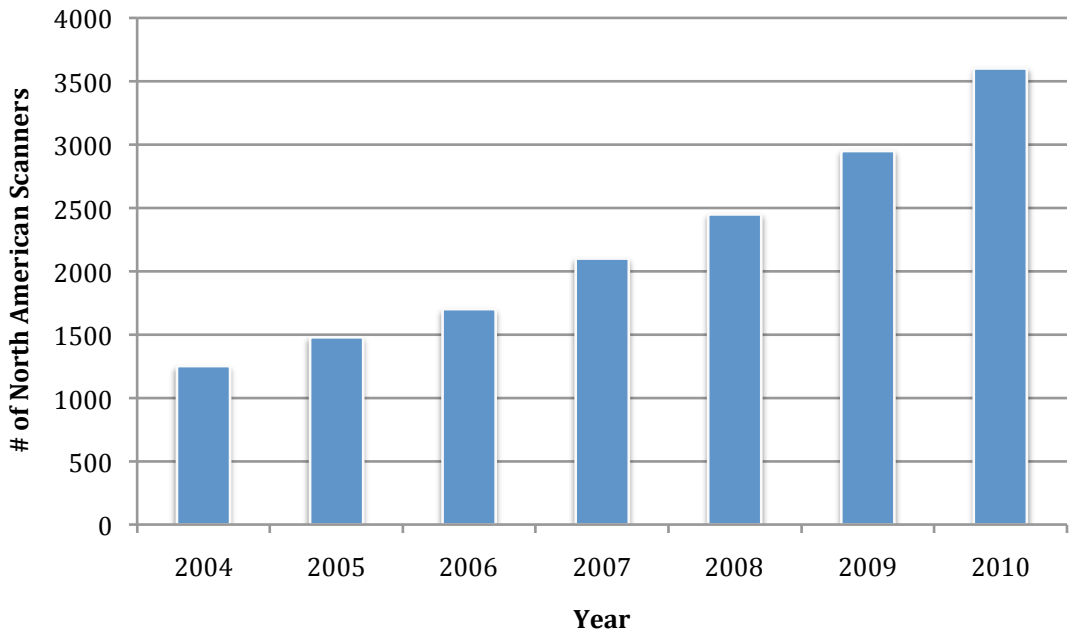

Figure 2.6 - North American Adjunctive Breast Imaging Market (Frost and Sullivan, 2003).

This growth pattern demonstrates not only the importance that breast MRI will play in future breast cancer screening methods, but also the probability for the eventual acceptance of MRI as a potential standard-of-care breast cancer screening modality. Figure 2.7, from the same market report, shows the leaders in the breast MRI market.

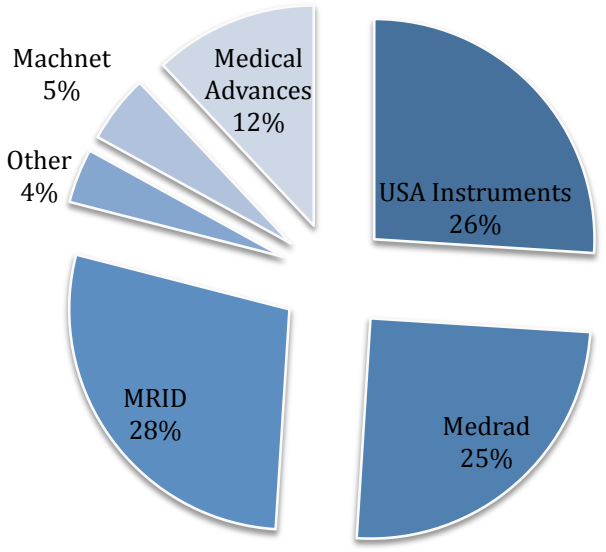

Figure 2.7 - North American Adjunctive Breast Imaging Market shares (Frost and Sullivan, 2003).

The leaders in the market are USA Instruments, Medrad and MRI Devices Corporation (MRID). This data is critical for looking at the features of the different coils involved that are partially responsible for the success of these devices. Table 2.2 shows the various breast coils produced by several of the leading companies.

Table 2.2 - Current market leaders in MRI breast coils.

Product	Manufacturer	Imaging Modes	Interventional Biopsy Support	Compatibility
OBC Breast Coil[1]	MRI Devices	Unilateral & Bilateral	Yes	GE. Siemens and Phillips
BBC Breast Coil[2]	MRI Devices	Unilateral & Bilateral	Yes	GE, Siemens and Phillips
Liberty 5000[3]	USA Instruments	Unilateral & Bilateral	Yes	GE
Liberty 9000[4]	USA Instruments	Unilateral & Bilateral	Yes	GE
Medrad Breast Coil[5]	Medrad	Unilateral & Bilateral	No	GE
Bopsy Breast Array Coil[6]	Invivo Corporation	Unilateral & Bilateral	Yes	Toshiba

[2]BBC Breast Coil (MRI Devices Corporation, 2003).

[3]Liberty 5000 (USA Instruments, 2003).

[4]Liberty 9000 (USA Instruments, 2003).

[5]M
(Me

[6]Biopsy Breast Array Coil (Invivo Corporation, 2006).

All of the coils from these leading companies incorporate 4 – 8 so-called (receiver) channels, unilateral and bilateral imaging modes, compatibility with most of the major MRI suites, and (in all but one case) the ability to perform MRI guided interventional biopsies of the breast tissue. From the images provided, we can also see that the housings incorporate large breast apertures to accommodate a large percentage of breast sizes, ample room on either side for the physician's hands to work in while performing biopsies and some form of integrated foam padding to add ergonomic support for the patient. All of these characteristics are important to the success of a MRI breast coil.

2.3.2 InsightMRI's Novel Breast Coil Concept

Aghogho Obi has developed a new patent-protected breast coil array for InsightMRI. The coil meets the needs for increased signal-to-noise ratio (SNR) and adequate magnetic field coverage, yielding high quality images with high spatial resolution over a sufficiently large region of interest. In turn, the detail of the images that the coil produces allows physicians to detect small tumors more easily.

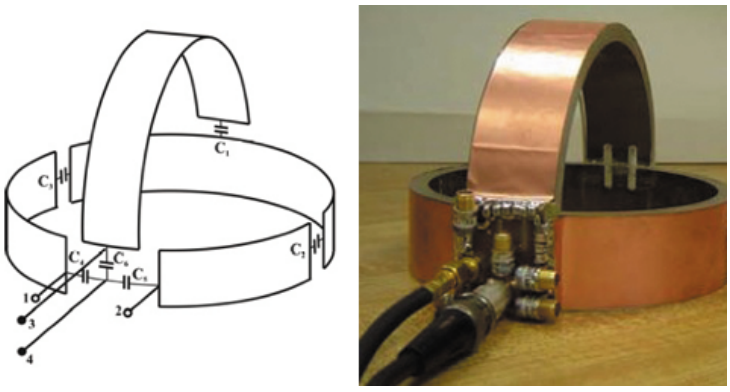

Figure 2.8– Dual-channel array coil concept (left) and model (right) (Obi, 2005).

The coil, shown in Figure 2.6, is arranged in an "anatomically conforming profile", in order to help increase the coil's SNR. The coils are receive-only coils, meaning that the RF transmit signal must be produced independent from the breast coil. The two different principle parts of the coil (the bottom loop and the top strap) allow two resonant receiving modes "that can be operated in quadrature configuration" and may therefore aid in the "extraction and…isolation between the two modes" (Obi, 2005).

With permission from Massachusetts General Hospital's Institutional Review Board, the coil was tested with a human subject in a GE Signa™ MRI scanner. One of the images produced is shown in Figure 2.7.

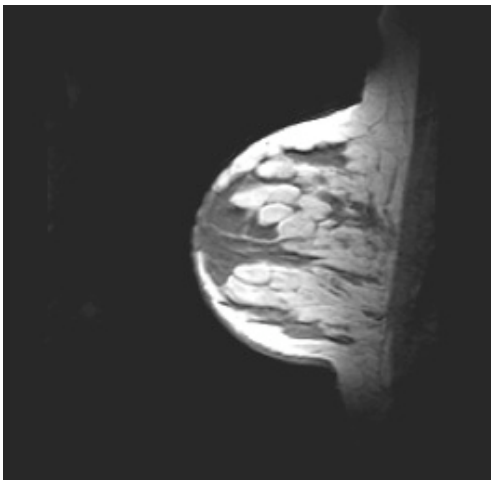

Figure 2.9 – Sagital MRI of the breast produced using InsightMRI's new coil concept (Obi, 2005).

The image shows excellent image quality and spatial resolution, even providing visibility into the chest wall (important to determine the stage of the cancer). As the image above and the other aspects of Aghogho Obi's research indicate, the coil meets the current needs of the MR breast imaging industry. It is now important to integrate the technology into a medical device that meets the needs of different stakeholders involved in the product. The following chapters discuss the approach and methods used to design and validate the housing for two of these coils (for bilateral rather than unilateral breast imaging) and to determine the design specifications of the device, towards future development.

3 Project Approach

This project's sponsor, InsightMRI, is a local MRI technology development company that aims to produce coil products for both clinical and research applications. Primarily dealing with RF coils, the company has developed a variety of human head coils, rodent and small primate coils and a clinically approved four and seven-channel breast coil. Due to the increasing use of MRI as a breast cancer screening method, InsightMRI hopes to advance their breast coil product line, which is the overall aim of this project. The following sections outline the specific problem that this project is geared to solve, the objectives of this project and the desired specifications that the project should meet.

3.1 Problem Statement

InsightMRI would like to develop a new breast coil using Aghogho Obi's dual-channel RF coil concept. In order to advance their current breast coil product line, they ask that the design address ergonomics, weight, size, structural and regulatory issues.

3.1.1 Ergonomics

Because MRI scans can take longer than other medical imaging methods, it is important that the patient is comfortable during the entire screening process. Not only is this important for the marketability of the device – if the patient moves during the MRI scan, there can be artifacts and distortions in the resulting images. In sponsor's previous breast coils, patients experienced pain or discomfort along the sternum, where the majority if the patients weight was focused. Because the patient is lying down with their torso on an elevated surface, the incline to this elevated surface is also an important ergonomic factor to consider.

3.1.2 Weight and Size

Weight and size are critical aspects to consider for both the experiment itself and for ease of use. Since a technician will have to handle the breast coil and lift it on and

off of the MRI table, a lightweight device is preferable. Furthermore, by reducing the weight of the device considerably lower than competing products, it will add to the marketability of the device. Size is an important issue in the sense that there is limited room with in the bore of the magnet. If the device is to accommodate a range of patient sizes, by keeping it as low profile as possible will increase the amount of free space in the magnet's bore.

3.1.3 Structural Integrity

The smaller that the device is the more difficult it will be to design structurally sound, weight-bearing elements in the device. In order to accommodate more obese patients, steps must be taken to ensure the structural integrity of the device for a variety of different loading configurations.

3.1.4 Regulations

Lastly, and perhaps most importantly, the device must be able to perform within the regulations dictated by both the government regulatory agencies (in this case the FDA) and the vendors themselves (specifically the manufacturers of the MRI systems, such as Siemens, Phillips or General Electric). These regulations can be for extremely minute details (such as wall thickness around heat producing electrical elements) or for more general criteria (such as the melting point of the materials used). These regulations help ensure patient and technician safety and other important factors.

3.2 Project Objectives

The objective of this project is to meet InsightMRI's goal of developing a new MRI breast coil that integrates the dual-channel RF breast coil concept. In order to do so, the sponsor has asked for the following deliverables.

- The design of a housing that will hold the coils as well as the associated electronic circuitry and elements. Along with the design, stress and thermal simulations should be provided to demonstrate structural integrity and acceptable safety factor.
- A bill of materials and cost analysis associated with the design and related materials.

- The shape and size of the printed circuit boards (PCB) that the electronics will be populated on. Because the circuit design for these coils requires a more advanced understanding of RF circuit design, that element of the design will be left to other professional electrical engineers. But in order to allow them to begin the design and PCB layout, they will require the geometry of the boards that they will have to work with.
- A design specification and architecture document, outlining the purpose, scope, overview, safety concerns and components of the design.

3.3 Project Specifications

With the sponsor and their engineers, we were able to develop a list of project specifications that will lead to an improved breast coil as well as the product's success in the clinical breast imaging market. Ideally, this new breast coil was intended to add a new product to InsightMRI's breast coil line, rather than create an iteration of an existing product. This being the case, we first asked how far away from the previous models and preconceived notions we could stray, while staying within industry standards. With this thought in mind, we provided the following project specifications.

- The device, with all of the components installed, must weigh less than 20 lbs.
- It should accommodate weights of up to 400 lbs.
- Because the breast cancer screening using this device will be integrated with biopsies, it should be at least retroactively compatible with current or modified interventional components.
- It must be compatible with the current Siemens' MRI system.
- It must incorporate a form fitting top surface on which the patient will lie, in order to distribute weight and ensure better patient comfort. Foam padding can provide further comfort.
- The design must meet all vendor and regulatory requirements.
- The design should incorporate large openings along the edges of the device for easier use for physicians performing biopsies.

- The design must be able to be cast molded, with the ability to incorporate composite materials (for structural integrity) into the material.
- The openings for the breast must not only be shaped to fit the geometry of the physical coils, but also to accommodate a variety of breast sizes.

By carefully accounting for each of these specifications and objectives in the design process, not only will the increased performance of the coil concept itself make it a better product, but the incorporated design features should make it a new product in InsightMRI's breast coil product line that outperforms competitor coils in ergonomics, usability and interventional ease-of-use.

4 Methods

The goal of this project was i) to design a low profile, ergonomic housing in which to implement the necessary electrical and RF circuitry for an multi-channel breast coil for use in MRI applications and ii) to develop design specifications that would allow further advanced development of the prototype. In order to accomplish these goals, I identified specific design considerations based on various stakeholder needs, mechanical and electrical constraints, and regulatory requirements. Using three-dimensional CAD software, I designed a housing that met these considerations and constraints. Lastly, based on the chosen design I developed design specification documents that would allow for the advancement of the prototype design towards a marketable MRI breast coil.

4.1 Identifying a Task-Based Timeline

When examining the timeline of an engineering project such as this, it is important to consider both the short-term and long-term timelines. In the short-term, we must consider the immediate tasks associated with the design of the device: understanding problem statements and design criteria, developing concept designs and a final design, the analysis necessary to validate these designs, etc. In the long-term timeline, however, we must examine the different impacts that this device will have on the sponsor, the sponsor's clients and other stakeholders in the device: the manufacturing process, regulatory approval, the life-cycle of the device itself, etc.

In order to illustrate the short-term timeline of this project and the initial development of breast coil, a Gantt chart was used (Dym, 2004); it is shown in Figure 4.1.

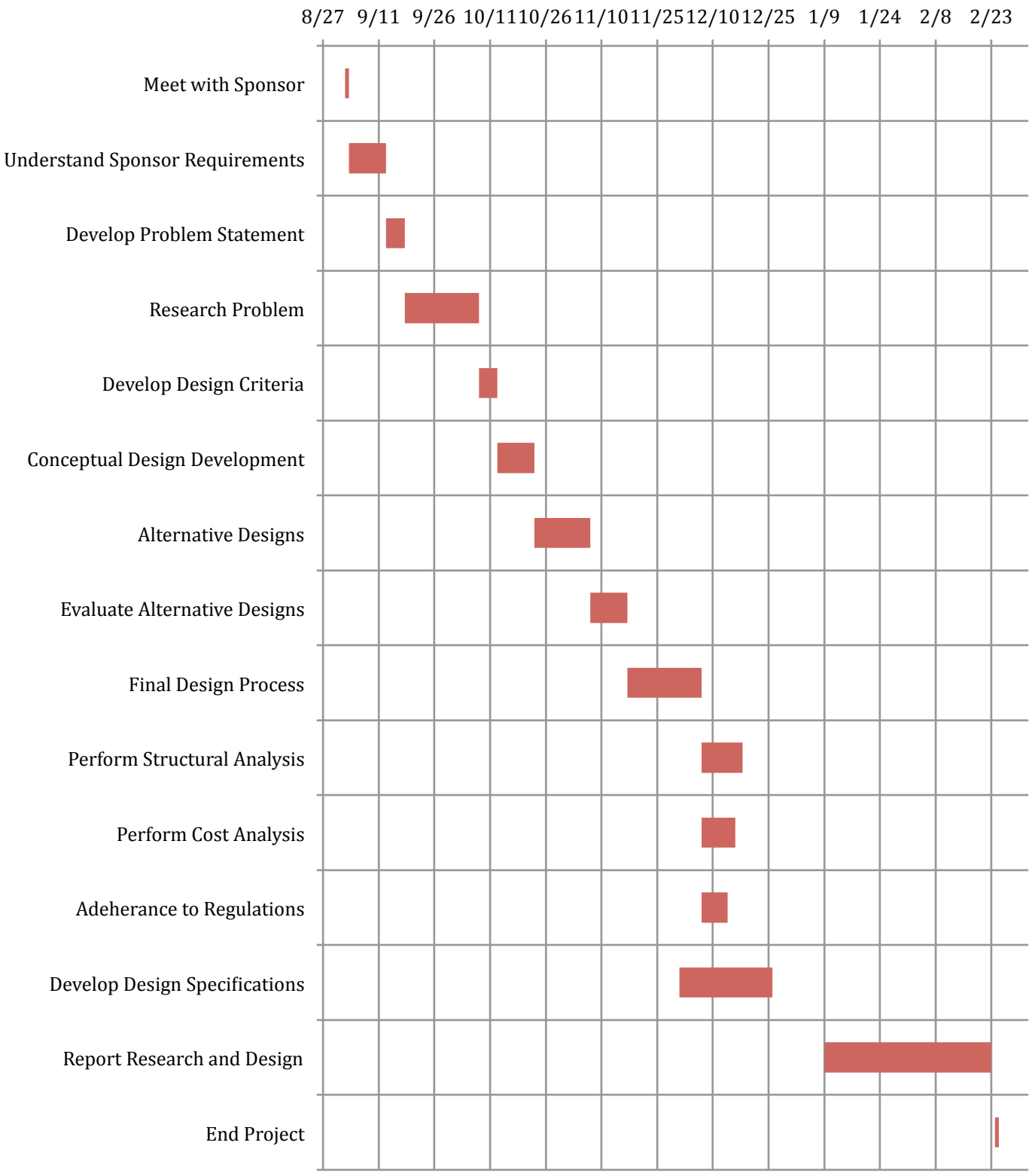

Figure 4.1 - Gantt chart, depicting the short-term task based timeline.

This Gantt chart identifies the major steps of the short-term timeline, starting with a meeting with a sponsor at the start of the project in order to determine the project requirements, all the way through the development of a final design and the validation analysis of that design to ensure that it meets the original design specifications.

Although the long-term timeline is primarily left to the sponsor of this project, it is still important to mention in order to understand the complete timeline of the design process of the coil housing. Because this breast coil is intended for clinical use (rather than research), one of the first steps that the sponsor will have to take will be to ensure that the device meets regulation standards from both the MRI systems it wishes to make the device compatible with as well as government regulatory agencies such as the Food and Drug Administration (FDA). After meeting these requirements and getting approval from both of these regulatory parties (which in itself can be a *very* long process), the sponsor then must prepare the breast coil manufacturing process, which up till this point has only been for one-off prototyping and testing. The final critical step in moving the device to the clinical MRI market is to find clients who will by this device – essentially, marketing. After these steps have been accomplished, the device has successfully become a valid clinical MRI breast coil and the sponsor's duties remaining are to sustain the breast coil in this market and to research and develop similar technology to incorporate into this device or new future breast coils.

4.2 Computer-Aided Design of the Housing

The integration of the various design specification, discussed in Chapter 3, into the final design is what ultimately establishes whether or not the breast coil meets specifications. Determining and prioritizing various design considerations and constraints helped to understand which aspects would be essential to the device's design. To identify such necessary elements, with the sponsor's help, I listed specific design considerations from populations of interest, stakeholders and previous design issues. Next, we looked at constraints that were associated with the device, based on electrical and mechanical requirements of the breast coil. By prioritizing this data,

we were able to design the device in a systematic manner, allowing for the implementation of the most critical design elements.

4.2.1 Developing Design Considerations

Before we could determine specific design considerations, it was necessary to determine the origin of such considerations. Ultimately, the prototype had to be designed with respect to the population of interest for the use of the device (Sawyer, 1996). InsightMRI had already determined which type of patients this device was targeted for. Once this was known, it was necessary to identify which attributes of these patients (both physical attributes of the patient as well as preferential considerations of the patient) would influence the design itself.

The next important origin of such considerations was the other stakeholders associated with the device. This included the sponsor's company, InsightMRI, and all the engineers and technicians that would be associated with the development and production of the device, the potential targeted market audiences, regulatory agencies involved in approving the use of such a device, and lastly the clinicians and operators in the hospitals who would be responsible for setting up and ultimately using the device (Dym, 2004). Because engineers at InsightMRI had already obtained this knowledge, I was able to avoid this excess research and use the sponsor's engineers to voice concerns and criteria on behalf of their knowledge of critical design elements.

The last, and perhaps most useful, origin of design considerations came from InsightMRI's prior breast coil designs. By learning which elements of previous designs were successful or not allowed me to incorporate or eliminate critical design components and ultimately led to the overall improvement of the company's breast coil.

After developing a general understanding of these critical design considerations and specifications, I was able to prioritize their incorporation into the breast coil design, based on input from the sponsor. This allowed me to determine the overall necessity of different factors, highlighting elements that were absolutely necessary to the design and leaving unnecessary elements to be implemented last if possible (Dym, 2004).

4.2.2 Understanding the Product Constraints

The various constraints associated with the design were identified in order to understand the limits associated with the device. The primary constraints that were identified were based on electrical or mechanical requirements of the device. The majority of these constraints were established through constraining regulations from the FDA (or other relevant regulatory agencies) or from the manufacturer of the MRI system in which the breast coil is intended for use.

4.2.3 Design of the Housing

Upon deciding the most necessary design elements and the appropriate combinations of these elements, I began the conceptual design of the housing. With the engineers at InsightMRI, we sketched various concepts that integrated the highest weighted design elements. After agreeing on the basic core features of the design, the sketches were then modeled SolidWorks, a 3D-CAD (Computer Automated Design) modeling environment (SolidWorks, 2006). This allowed us to apply specific dimensions to key features and to visualize the housing itself. Through weekly design reviews, we identified problems and benefits of each design that would be either eliminated, adjusted or incorporated "as is" into the next iteration of the concept design.

Once we developed a potentially feasible design, different forms of analysis were applied to the model to ensure that it was in fact meeting the project specifications and constraints that we determined. These forms of analysis included:

- Modeling various potential components that would be associated with the device (such as printed circuit boards, the RF coils themselves, and the boar of the MRI magnet) to ensure that physical size constraints were applied.
- Finite element stress analysis of the housing design to examine weak areas of the structure under certain loads. This analysis will be further detailed in the next section of this chapter.

- Visual examination of the housing itself applied to different situations (such as how the patient would lie on the device) to determine feasibility and ergonomics of different design elements.

Once the design reached its final concept stage, we began to incorporate specific and detailed elements of the design, which ultimately would be critical for production, assembly and functionality of the breast coil. This included fastening features, parting lines for molding, cable exits and strain-relief incorporation and other small details. This allowed me to perform more precise means of analysis of the design assembly as well as to develop a bill of materials (BOM) and cost estimate for the breast coil, discussed in the following sections of this chapter.

In the final stages, InsightMRI's engineers and myself critically reviewed the design. At this point, the housing was accepted by the sponsor, who was now responsible for the final stages of the devices development, outlined in Section 4.1. With in-house tools, the sponsor was able to move beyond a virtual model of the device to create a three-dimensionally printed rapid prototype of the breast coil housing.

4.3 Simulating Various Scenarios to Determine Structural Integrity

Structural analysis of even the simplest of shapes can prove to be difficult, much more so for a complicated design. For this reason, engineers often use software that can perform finite element analysis (FEA). When given a computerized three-dimensional model and the relevant material properties pertaining to that model, FEA software attempts to break down a model into simple discrete, adjacent volume elements (hence the phrase "finite element"). Similar to the Reimann sum method of approximating the area under a curve (i.e. an integral) with discrete unites of area, the discrete volume elements used in FEA can approximate the shape of a complex model, given that there are enough of them. The accuracy improves as the number of elements increase and the size of the elements decrease. The user may then provide certain constraints and conditions for the software to simulate, such as loads on certain parts of model. Using the elemental approximation of the model, the simulation conditions and the material properties, the software may then calculate

the stresses, strains, and particle displacements that would occur under various loading and boundary conditions. Although the accuracy of this analysis is dependent on how well the finite elements approximate the model, higher accuracy will inevitably take longer to calculate (more elements and therefore more calculations to compute), sometimes on the order of hours, days or even weeks. For this design, I used COSMOSWorks, the FEA software that is incorporated in SolidWorks. One of the benefits of using COSMOSWorks is that it is able to perform sophisticated testing of the created meshes to determine whether or not it is an appropriate approximation of the model and will not let the user continue with the FEA if this is the case (SolidWorks, 2006).

For the breast coil housing design, beyond development of an accurate mesh (the name given to the layout, shape, size and number of elements for a model), determining the appropriate loading situations would be critical to ensuring that the device could meet the design specifications outlined in Chapter 3. Although the sponsor wanted the design to accommodate heavier patients (of approximately 400lbs), this does not mean that the entirety of that weight would be loaded onto the top surface of the housing. Because the patient is lying on her stomach with some of her weight on the legs and lower abdomen, only a certain percentage of the total weight will actually create a load on the top of the housing. To get an idea of the approximate percentage of the total weight that will create a load (because regardless of actual statistical studies, patient weight distributions will inevitably vary), I employed a crude statistical experiment with a small sample of ten individuals, using the setup shown in Figure 4.2.

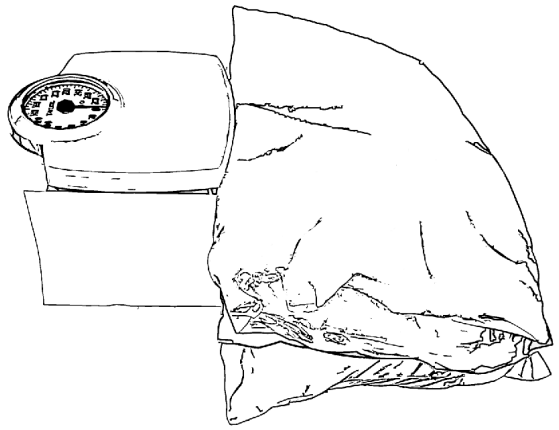

Figure 4.2 - The setup used to determine chest weight loading on the breast coil.

The setup consisted of a small crate (approximately the height of the breast coil housing), a bathroom scale and a stack of pillows that created a ramp up to the scale. Although the setup was very basic and the sample size was small, the results (found in Appendix D) found that the mean loading that occurs beneath the chest (and therefore at the top of the coil) was 55.12% of the individuals total body weight. Therefore, 55.12% of 400 lbs., or 220lbs, was the value used to create a distributed load on the housing in a direction normal to the surface.

In addition to the load described above (which would be the main load experienced by the housing during normal use), there was one other simulated scenario that was important to analyze. When the patient is lying down on or getting off the patient table and coil housing, the primary means of doing so would be to lower or raise their horizontal body with their arms, with their hands places on the sides of the top surface of the housing. This will cause the entirety of the main loading scenario described above to be focused on the areas of the housing directly under their hands, rather than distributed over the top surface.

Because the sponsor had already had success with various plastic materials in other coil housings, I was asked to use the same materials, which included a polyurethane (RC-79D) for molded parts, a polyetherimide (Ultem 2300) for machined parts, and a glass fiber composite material (Garolite G-10) for any structural reinforcing. The properties required for the structural analysis for each of these materials can be found in Appendix E.

4.4 Performing a Realistic Cost Analysis of the Device

The cost associated with developing medical devices can often be high, considering the broad spectrum of components that are involved, such as high performance electronics, application compatible materials, out-of-house manufacturing costs, etc. MRI coils are particularly expensive due to the environmental constraints on the housing material. Although this cost analysis will not take into consideration the cost of the associated electronics of the breast coil, it is important to mention that in some cases the electronics are relevant to the housing materials and their associated costs. The stronger that the magnetic field is, the more power the RF coil must use to get adequate sensitivity. This power can often be dissipated through heating, especially near the active tune and detune regions of the RF circuitry. Therefore, the material must be resistant to heat. Additionally, certain materials are either visible or create artifacts in MR images, neither effect of which are desirable. These, along with many other constraints, can add to the cost of the housing.

For the molded portions of the device, realistic calculations or molding quotes were acquired to determine how much it will cost the sponsor for out-of-house molding, including the initial tooling costs. The machined portions of the design may be manufactured in-house, meaning that the cost is dictated only by the volume of material that must be used. Lastly, the cost of any fastening features that must be purchased must be taken into account. To aid in the cost analysis, I developed a bill-of-materials (BOM) for the breast coil housing, which includes costs organized by molded parts, machined parts or fastening features.

4.5 Determining Adherence to Industry Regulations

Although regulatory standards play a role in the constraints associated with the device, the final iteration of the device was evaluated to ensure that it adheres to the necessary regulations that are provided by the MRI system manufacturers and the FDA. The MRI system manufacturers produce documents that list all the electrical and mechanical requirements for any coil that is to be used in conjunction with their system (Boskamp, 2004). These were used to evaluate the design, in conjunction with the FDA documents that list regulations for Class II Magnetic Resonance

Diagnostic Devices in Title 21 CFR 892.1000, the category under which the breast coil will fall (Food and Drug Administration, 1998).

4.6 Confirming the Determined Project Specifications

Similar to the manner in which the industry regulations pertaining to this device were evaluated, the specifications listed in Chapter 3, Section 3 were evaluated item by item to ensure that I met the sponsor's needs. Quantitative specifications (such as the maximum weight of the device) will be evaluated in SolidWorks or COSMOSWorks, while qualitative specifications will be evaluated as best possible, dependent on the specification itself.

4.7 Developing the Design Specification Document

The Design Specifications of the Insight QD Breast Coil Housing is a document that describes the intended claims of the performance of the breast coil housing, separate from the specifications for the breast coil electronics. This document outlines these claims in a manner such that a potential client could easily understand how this coil could or could not fit their needed situation. The document details specifications in the two following areas (Pugh, 1985):

- *Performance*: The overall claims of the breast coil housing.
- *Size*: The constraints and actual size of the breast coil housing.
- *Weight*: The weight of the assembled housing.
- *Ergonomics*: The incorporated ergonomic features.
- *Operating Environment*: The environment of intended use.
- *Safety*: The measures taken to ensure user safety.
- *Materials*: The materials used in the housing.
- *Structural Integrity*: The interpretations of structural integrity analysis.
- *Appearance and Finish*: The appearance and finish of the housing.
- *Manufacturing Facilities*: The facilities responsible for the manufacturing of each component of the housing.

The sources for these specifications will either be generated from the results of the design validation methods mentioned in the previous sections of this chapter or from

information provided by the sponsor. The format of the document was based upon previous InsightMRI product design specifications, such as Insight's Product Architecture: Insight Head Coil document.

5 Housing Design

The design of the housing that would eventually house the RF electronics was completed using a systematic approach, that involved developing a ranked specifications-and-needs list, determining specification feasibilities, designing several concepts and design alternatives as well as a final chosen design. Essential in the design of the final model, it was necessary to look at the process, decisions and means of optimization. The approach outlined above is described in detail in the following sections.

5.1 Needs Analysis and Specifications

Before any actual designing was done, it was important to evaluate the different specifications to determine their importance in the decisions associated with the desired outcome *and* the necessary outcome. For this reason, the following weighted specification matrices have been divided into the "needs" of the project (in Table 5.1), followed by the "wants" of the project (in Table 5.2), both of which were established through the sponsor's knowledge of the existing MRI breast coil market.

Table 5.1 - The weighted "needs" matrix is used to determine the relative importance of required design specifications.

Weighted "Needs" Matrix		
Specification	Score (Out of 10)	Weight (%)
Light Weight (Under 20 lbs.)	8	11.11
Accommodate Heavy Weight	9	12.5
Retroactive Interventionals	7	9.72
Compatible with Vendor Systems	10	13.89
Patient Comfort	8	11.11
Regulatory Requirements	10	13.89
Water Tight	8	11.11
No Sharp Edges	6	8.33
Cable Strain Relief Integrity	6	8.33
Total:	72	99.99

From this weighted list of necessary specifications, we can see that the three most critical requirements are that the device meets regulatory requirements, that it is compatible with various vendor MRI systems and that it is lightweight. This list, and

the weights of individual items, will be integral to the design process of a housing that satisfies the sponsor's requirements.

Table 5.2 - The weighted "wants" matrix is used to determine the relative importance of desired design specifications.

Weighted "Wants" Matrix		
Specification	Score (Out of 10)	Weight (%)
Aesthetically Pleasing	7.5	11.11
Larger Openings for Biopsies	8	11.85
Entirely Castable	7	10.37
Accommodate 95% of Potential Patients	6	8.89
Compatibility with Earlier Systems	5	7.41
Interchangeable Base for Different Systems	6	8.89
Multiple Potential Cable Exits	3	4.44
Incorporated Fiber Optic Lighting	2	2.96
Extra Channels	5	7.41
Serviceability	8	11.85
Expandability	7	10.37
Integrated Optical Fiduciary Markers	1	1.48
Disposable Fluid Trays	2	2.96
Total:	67.5	99.99

The weighted list of "wants" or desired project outcomes, is equally useful in the design process. However, it identifies specifications that may not be critical to the overall project and although their incorporation would benefit the end product, various constraints may prevent their inclusion in the final design. The three most desired project outcomes are that the design incorporates large openings for physicians to perform biopsies, that it is easily serviceable, and that it is aesthetically pleasing.

5.2 Feasibility Study

The primary feasibility concerns with this device are related to the cost and the moldability of the device. Breast coils costs fall within the range of $20,000 to $100,000. In order to meet these costs and stay with in the constraints of the market for this device, the material, manufacturing and production costs were kept to a minimum while still attempting to make the device superior to others in the same market. See Chapter 6, Section 2 for more information on the cost of the device.

The cast molding process requires that drafted walls be use for easy removal of the casting tools. SolidWorks provides mold analysis software, which was used to determine that the various components of the design were in fact moldable. See Chapter 6, Section 1 for more information on the moldability of the device.

5.3 Alternative Designs

Before a final design was reached, there were other concepts that were considered first. This section goes into some detail on those designs and the benefits or hindrances of some of their features.

Based on preliminary discussions with the project sponsor and a basic grasp of the RF coil concept that was to be incorporated in the final design, we developed the initial concept that you see below in Figure 5.1.

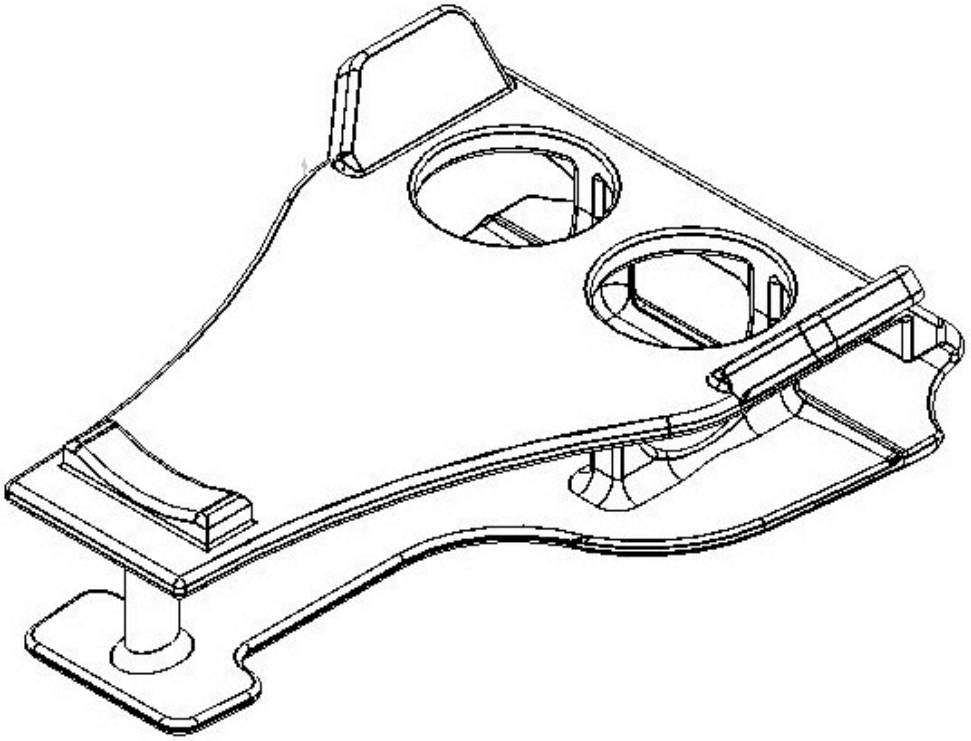

Figure 5.1- Initial conceptual design, incorporating many of the preliminary key features.

Although this design did incorporate many of the needed and desired features, it still lacked several of the most critical. The key elements of the design are the "loop-and-strap" coil shape, additional angled elements (seen on either side of breast apertures) for potential axillary imaging and an incorporated headrest. The key

importance of this conceptual design was that it included many of the key features that would be needed in the final design, and was therefore an excellent starting off point in the design process. However, the design lacks several critical requirements, including the weight requirements and an area to house internal electronics.

The second conceptual design, shown in Figure 5.2 (left), was an attempt to keep the same key elements as the previous design, but to attempt to simplify the overall model. The headrest feature was removed and the back empty cavity shown in Figure 5.1 was filled with material such that it could eventually house electronics. Clearly, this design was much smaller and in terms of the most critical features, was primarily lacking ergonomics. In previous models that the sponsor had developed, the top surface was flat and patients often complained of all of their weight being placed on their sternum, resulting in pain. For this reason, as can be seen in the revision of this model in Figure 5.2 (right), the top surface became curved to evenly distribute weight across the entire top surface.

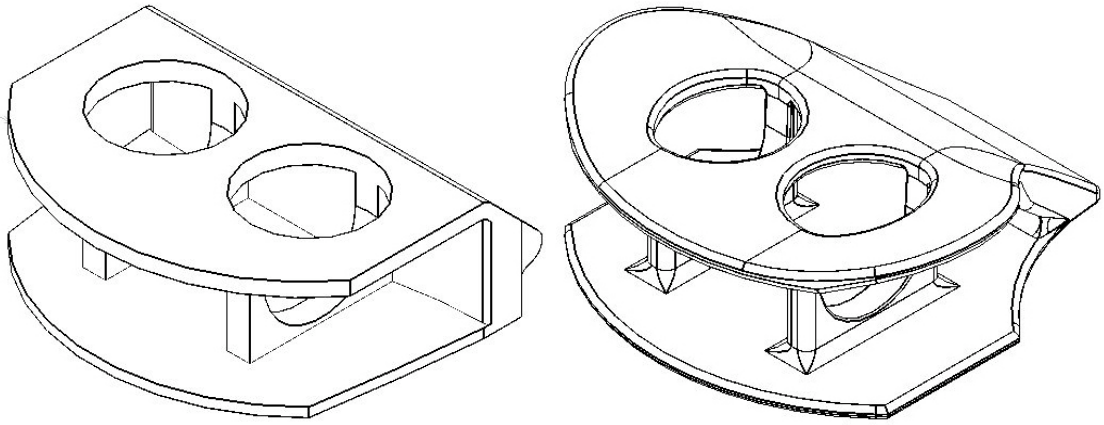

Figure 5.2- The second conceptual design with (left) a simplified model and (right) an ergonomic revision of the simplified model.

Additionally, the jagged axillary "wings" in the first conceptual design were incorporated into the ergonomic curvature. Although the sponsor was pleased with this general concept, they were still interested in finding another potential concept in order to explore all of our potential options and to not overlook possible successful design elements.

One of the issues what kept arising during design review meetings was the fact that in different MRI systems as well as different situations, it was beneficial to have

the patient enter the bore of the magnet head first *or* feet first. Because this would reorient the device on the patient table, it would also change which side the cabling that would connect the device to the MRI computer system would come out of the housing. Because of this, the conceptual design shown in Figure 5.3 was developed.

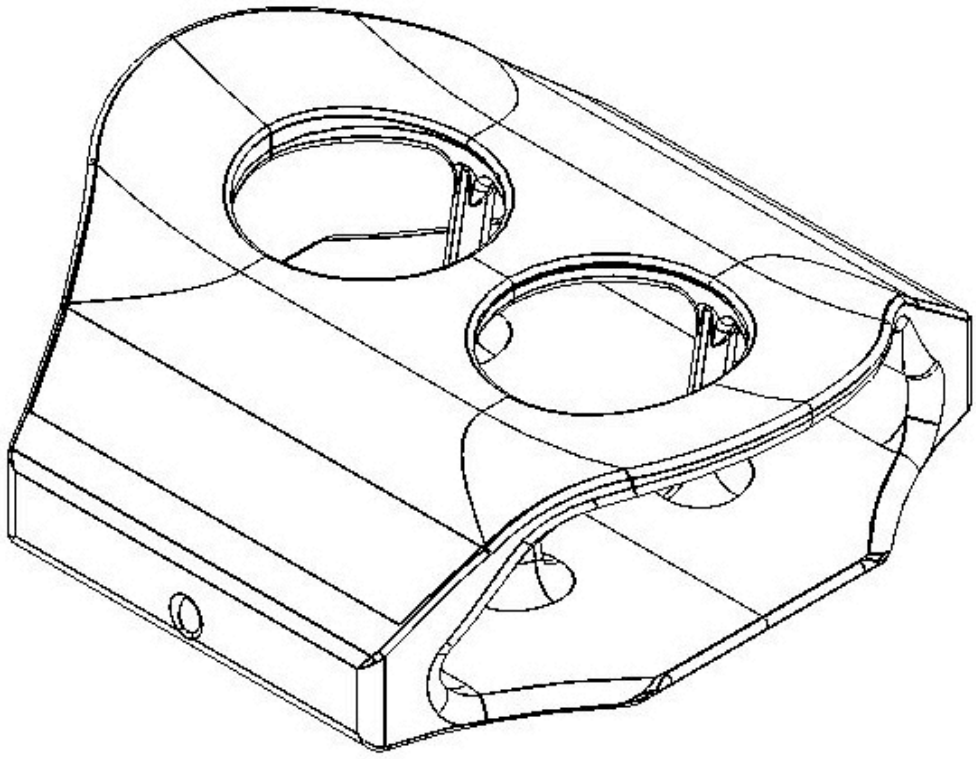

Figure 5.3- A symmetrical concept, allowing for feet- *or* head-first patient entry.

This design takes advantage of symmetry to create a device that could be used from either direction, with the patient entering the magnet feet *or* head first. If additionally axillary coils were then to be used, rather than extended primary coils for increased axillary coverage, this design could ensure that the space needed for all of the associated electronics with each coil (pre-amps, hybrids, etc) would be available. However, this design essentially doubled the amount of material being used, which significantly increased the weight of the device up approximately 17 lbs. Because of weight requirements and the associated increased cost of production for this new design, it was ruled out.

The last conceptual design, which was eventually used to create the detailed final design, is shown in Figure 5.4.

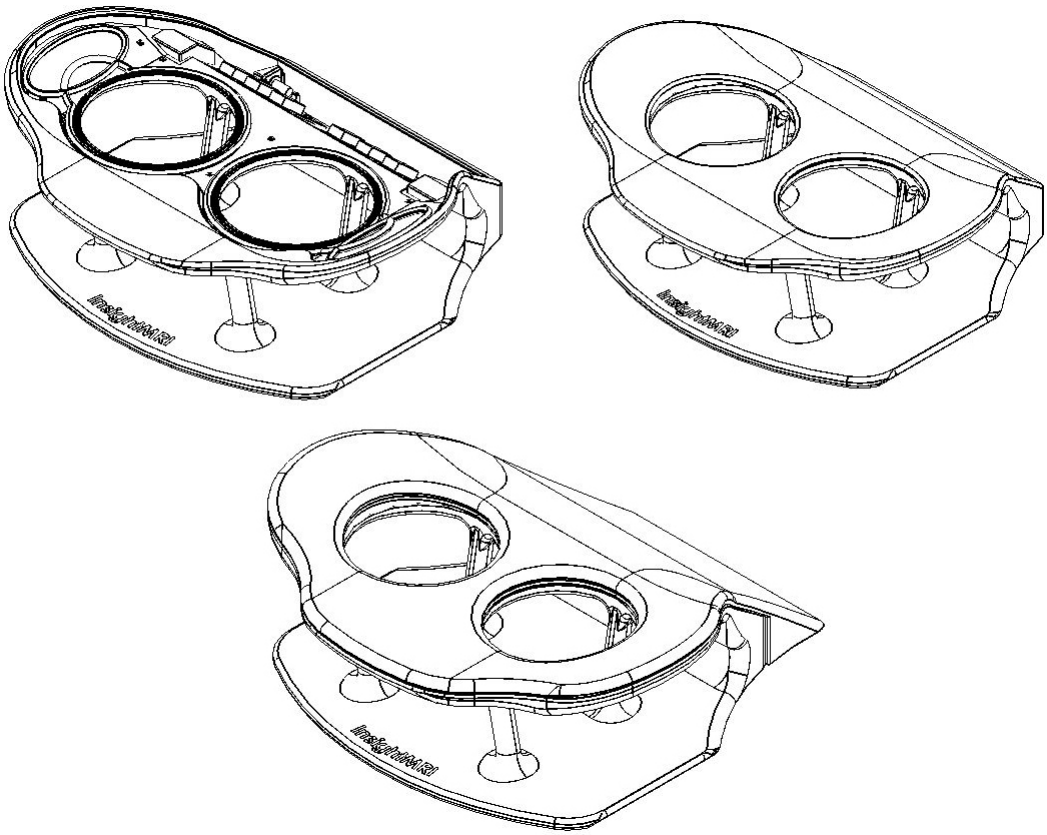

Figure 5.4- The last concept prior to a final detailed design, showing (top left) the device's internal cavity and electronics, (top right) the device with the top cover and (bottom) the device with ergonomic foam support.

Clearly based off of the concept in Figure 5.2(b), this model demonstrates most of the necessary features, the rest of which were incorporated into the final design. While keeping all of the same key features of the previous models (other than the symmetrical model), this concept finally shows in some detail where the final design of the device was headed. The top left figure demonstrates that there is indeed enough room for internal electronics (not all of which are visible in this view). The top right figure shows the small size of the device, followed by the bottom figure that includes the associated ergonomic foam pad that will rest on the top surface of the device. Some of the critical changes that were made between the second conceptual model and this model are the shapes of the legs (now tapered straight legs rather than curved) and the cutout sections of the front-top surface, which will allow the

patients arms (stretched out in front of them) to drop down to the table level more easily.

5.4 Final Design

The final design was based on the concept model shown in Figure 5.4. Based on the input from the sponsor and the adherence to many of the broad design specifications, this concept was chosen and a detailed design of the model began. Drawings of all referenced parts can be found in Appendix F. The final model is shown in Figure 5.5.

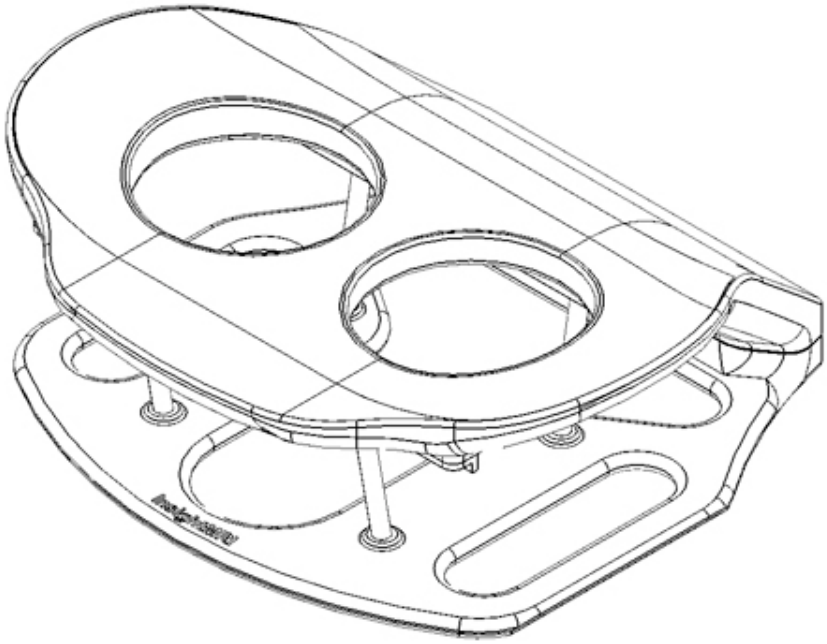

Figure 5.5 - The final design of the housing.

One of the main aspects of this design which set it ahead from the other conceptual models is the fact that rather than the housing consisting of two main moldable halves, this housing incorporates both molded and machined parts of various materials. This helped in meeting two critical specifications; i) the simplified bottom half may now be either molded as is (making the housing compatible with most Siemens' MRI patient tables) or machined (allowing customization towards compatibility with other MRI system patient tables) and ii) the legs may be machined and made out of stronger (but more expensive) materials. The following sub-sections examine the main components of the final housing design.

5.4.1 Top Half of the Housing

The top half of the housing is arguably the most critical component of the housing design. It houses most of the electrical components of Aghogho Obi's RF coil concept, it provides an ergonomic surface on which the patient will lay, and it incorporates the apertures through which the breast hang, necessary to perform the MRI procedures. A top-down view of the top half is shown in Figure 5.6.

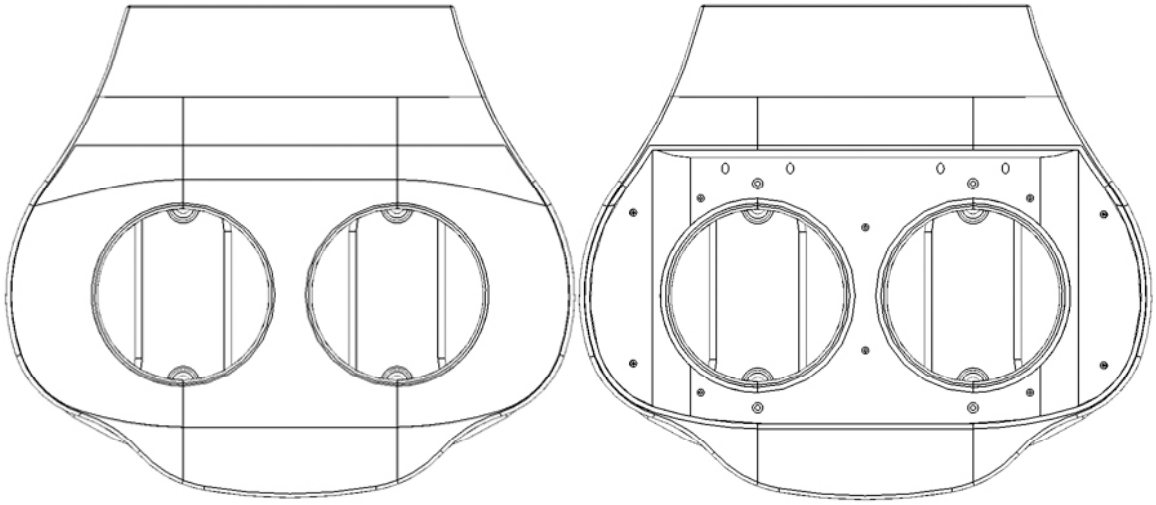

Figure 5.6 - A top-down view of the top half of the housing showing the patient surface (left) and the internal electronics cavity (right).

This view shows both the patient surface (left), which includes the top cover of the device, and the top internal cavity for the RF coils (right). The patient surface is a curved surface and is more form fitting to the curvature of the body than a flat surface. In addition to the ergonomics provided by this curvature, memory foam will be placed on and behind this surface, creating a ramp and cushioned surface to support the incline of the patient's body from the patient table to the top of the breast coil housing.

The internal cavity for the electronics features a shallow shell under the top cover. A flexible printed circuit board will rest on raised mounting bosses along both the flat and curved regions of the internal surface. The 'loop' features of the RF coil will be on the PCB, while the 'strap' features will be composed of copper tubing that will feed down the pair of wholes above and below each aperture, leading through the legs to the bottom half of the device. In the back of the cavity, four angled holes

lead to another electronics cavity on the bottom side of the top half, shown in Figure 5.7.

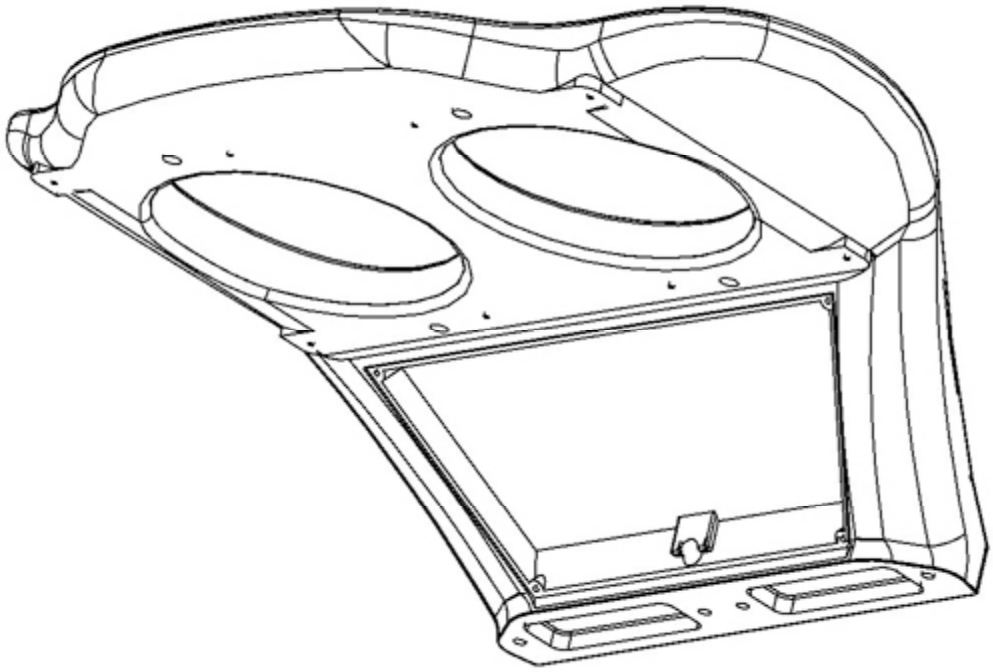

Figure 5.7 - A bottom side view of the top half of the housing.

This cavity will house another PCB, connected to the top PCB through the four holes between the two cavities. This PCB will be populated with pre-amplifiers and hybrids. In the back of this cavity, a clamp mechanism will immobilize the cabling that will exit through a tapped-hole that is mated to a third party strain relief mechanism.

Another benefit of this design over several of the other concepts in the previous section is the optional mounting surfaces for an interventional biopsy system to be fitted on. InsightMRI has used third party interventional components in previous breast coils and has also begun to design their own components. Additionally, some clients prefer to use other third party interventional systems. For these reasons, it is important that whatever means are used to incorporate interventional components may be changed and retrofitted. In this design, these features are identified by the extended flat surfaces at the rear and front of the breast apertures. Machined rail mounts, such as those in Section 5.4.3, may then be attached to these surfaces.

5.4.2 Bottom Half of the Housing

The bottom half of the breast coil housing is unique in that it can be molded or machined, in order to meet client specifications. Regardless of how the part is manufactured, there are features that are imperative to the function of the component. A bottom side view of this part is shown in Figure 5.8.

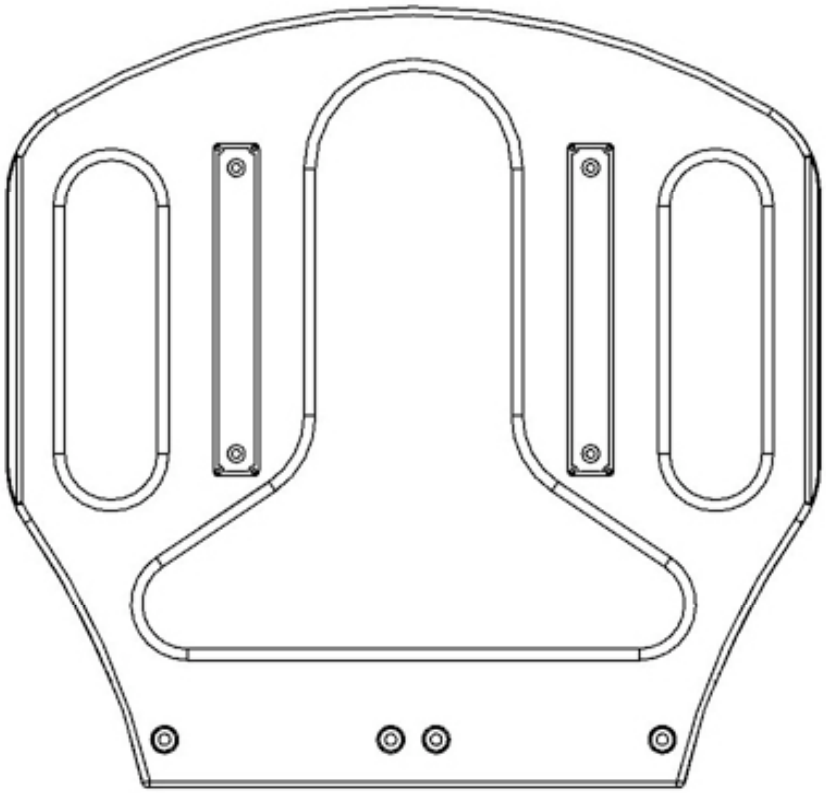

Figure 5.8 - A bottom side view of the bottom half of the housing.

The bottom half of the housing incorporates two long cavities for the bottom end of the 'loop' of the RF coil, identified by the two long rectangles. The copper tubing that passes from the top internal cavity and through the legs feeds into these cavities, where they will be connected to another PCB mounted portion of the coil.

The large opening in the center of the bottom is for post-assembly maintenance or tuning of any electrical components that may be required after the device has been assembled. This large opening will allow a technician to reach through here with a soldering iron, for example, and to perform necessary operations. The two openings on the sides serve to provide possible handholds for clinicians that may be handling the device. Furthermore, both the central opening and the side openings help in weight

reduction of the overall product and thus make it easier to handle. Both the bottom and top halves of the housing will be molded from Rapid Cast RC-79D Polyurethane, a "tough, impact resistant elastomer…approved for many medical applications including MRI coil housings" (RC Data Sheet).

5.4.3 Machined Components

The leg and rail mount components, mentioned in the previous two sub-sections, are simple machined parts, but integral to the housing nonetheless. Figure 5.9 shows a side view of the housing, demonstrating the incorporation of these two parts into the breast coil.

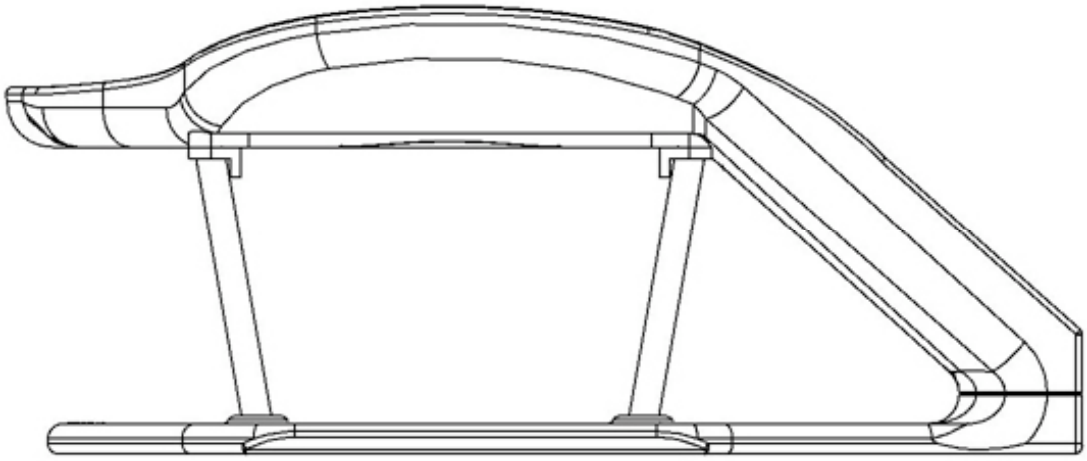

Figure 5.9 - A side view of the final housing design.

The legs pass through the rail mounts (the L-shaped structure on the inner side of the legs) and into shallow mounting point at the base. The 10° vertical offset of the front and back legs is in order to minimize the distance between the RF coils and the patient's tissue, which will increase signal quality. From the figure, it is clear that the legs will be primarily responsible for bearing the main load from the patient's body onto the top surface. Therefore, the legs are composed of two materials; i) a machined polyetherimide called Ultem 2300 used on the outside and ii) a glass fiber reinforced plastic called G-10 or Garolite used on the inside. Both materials provide superior physical properties compared to the RC-79D molding material and help provide structural integrity for the housing. In the second loading scenario described in Section 4.3, structural integrity is also important in the side, curved features of the

top half, the rail mounts are also machined from Ultem 2300. Although the materials are more expensive, the legs and rail mounts may be easily machined in-house.

5.5 Modeling

Each component of the design was modeled with the software as a single part – as would be done in the manufacturing process. This included the bottom and top half's of the main housing, the top half covers for the main internal electronics, the two bottom covers to seal the access to the exposed electronics of the "loop" feature of the RF coils and the ergonomic foam padding. Once each part was modeled, the entire assembly was modeled, including the mating constraints that would determine the position of each part with respect to one another. After the completion of an assembled fully constrained model, I was able to use finite element software to perform structural analysis testing of the design, which was discussed in detail in Chapter 4, Section 3.

5.6 Decisions and Optimization

I met with a group of engineers from InsightMRI on a regular basis during the design of the device. Each meeting served as an informal design review meeting, during which we evaluated conceptual designs for the determined design specifications. In some cases, a design may have met the design specifications, but expertise from the sponsor's experienced engineers indicated that there might have been a better way to meet some of these specifications, which was then incorporated into the next iteration of that concept or an alternative concept. Once the final design was agreed upon, I modeled the detailed features that are seen in the following sections.

6 Results

Using the methods listed in Chapter 4, I acquired data and information concerning the validation of the breast coil housing. These results are focused on four areas of critical relevance to the success of the housing, and ultimately the device itself. Using finite element analysis, I was able to simulate various loading situations for the device that provided data concerning the structural integrity of the housing. I was then able to use the housing model to develop a bill of materials that provided information used to conduct a cost analysis of the housing. Next, the device was evaluated for its adherence to industry regulations, which would be important for eventually moving the device to the clinical MRI breast coil market. Lastly, I was able to evaluate the design with respect to the initial project objectives and specifications that I determined with the sponsor in order to create a finalized design specifications document. The results of these tests are presented in the subsequent sections of this chapter.

6.1 Structural Analysis Simulations

For each loading scenario, a series of three FEA tests were performed with different element sizes, such that we could ensure that the errors in approximations due to the size of the elements used would converge to an actual value. The following results are from the FEA tests with the smallest element sizes (and therefore, the most accurate approximation of the model). The rest of the results for each series, as well as the error convergence data, can be found in Appendix C.

6.1.1 Top Loaded Housing Structural Analysis Results

The first loading scenario, as discussed in Chapter 4.3, was the load that the housing would experience during normal use by a patient lying on top of the device. The load used was equal to that of a 400 lb. patient, which required about 55% of that weight to be loaded onto the top surface of the housing (approximately 220 lbs.). The model was approximated with solid mesh of 147,202 4-nodal tetrahedral elements, each of 0.25 inches and a tolerance of 0.0125 inches. COSMOSWorks used

a 4-point Jacobian check (a standard mesh quality check that ensures that mid-point nodes of certain elements of the approximated surface are in fact on the original model's surface) to confirm that the mesh was in fact a suitable approximation of the original model. The result of the analysis is shown in Figure 6.1.

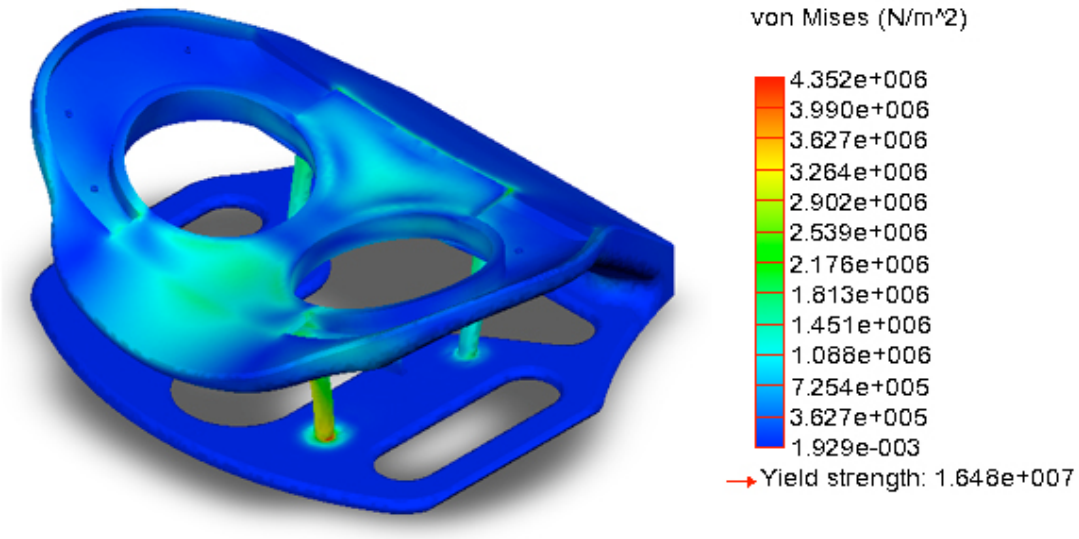

Figure 6.1 - Finite element stress analysis of the housing during a top loaded patient scenario[1].

The stress that the housing experienced under this loading situation was within a range of 0 to 4.35237e+006 N/m^2, with the maximum falling under the material's yield strength of 1.648e+007 N/m^2. From Figure 6.1, it is apparent that the most stress was experienced at the base of the front two legs. The maximum displacement that any part of the device would experience during this loading was equal to 0.021 inches.

6.1.2 Side Loaded Housing Structural Analysis Results

The second loading scenario that was used was the situation in which the patient is raising or lowering their body with their hands on the sides of the top surface of the housing. The load in this situation would be equal to the same 55% of the patient's total bodyweight, as described above, but would have that weight split evenly

[1] It is important to note that the deformed appearance of both Figure 6.1 and 6.2 are an exaggerated depiction of the deformation, in order to allow the viewer to better understand how and where portions of the design are being deformed.

between both hands resulting in 110 lbs. loading each side. The model was approximated with the same size and number of elements as before (147,202 4-nodal tetrahedral elements of 0.25 inches in size) and the resulting solid mesh was checked in the same manner with a 4-point Jacobian check. The result of this analysis is shown in Figure 6.2.

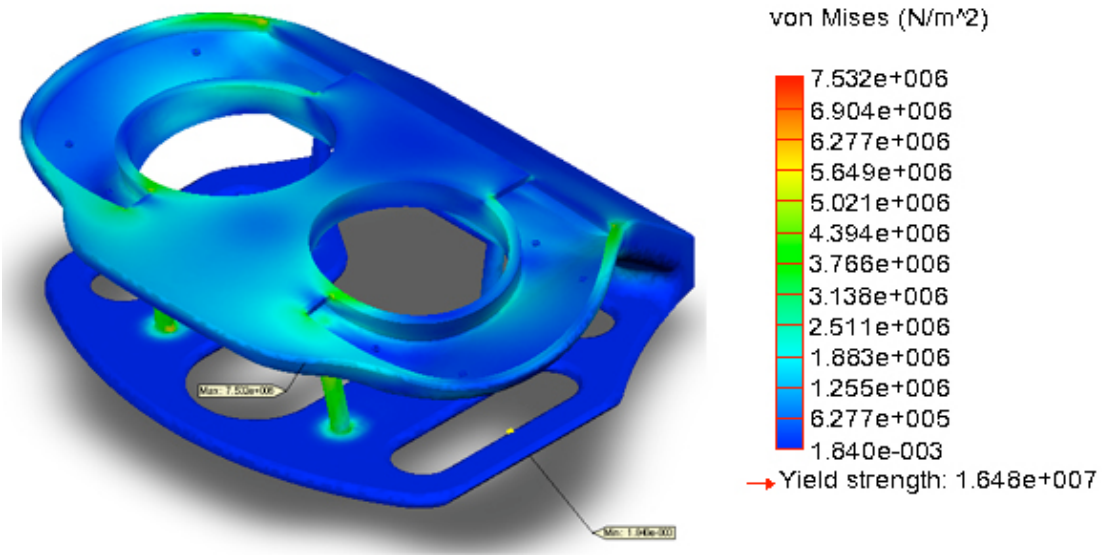

Figure 6.2 - Finite element stress analysis of the housing during a side loaded patient scenario.

The stress that the housing experienced under this loading situation was within a range of 0 to 7.532e+006 N/m^2, which again fell under the material's yield strength of 1.648e+007 N/m^2. From Figure 6.2, we can see that the most stress was experienced at the corners where the 'wing' features meet the back of the housing and the front portions of the apertures. Additionally, there is a stress experienced by the legs that is similar to the stress experienced by the legs in the previous scenario. The maximum displacement that any part of the device would experience during this loading was equal to 0.066 inches. Given a volume of 321.94 in.^{3} and a material density of 0.04552 lbs/in^3, the housing weighed in at 14.65 lbs. The lower weight of the housing could allow the sponsor to add more material in strategic areas for structural strengthening, while still remaining lighter than the maximum desired weight limitations.

6.2 Cost Analysis

The cost analysis was performed through the use of an itemized bill of materials (BOM). The BOM categorized materials into three categories: the main housing materials, the electronics cavity covers and fastening features. Additionally, there were three different sources of materials: a third-party molding company, in-house machined plastics (generally purchased through plastic distributors) and third-party part suppliers for the fastening features. The BOM and cost analysis results can be found in Appendix B. The sources of data were from cost estimates and cost data provided by the sponsor or from third party vendors. The overall production cost for the housing (without labor) was $6,950.46, which included the mold tooling costs – or $950.46 for the housing without the mold tooling costs. The tooling costs are a one-time fee that is required for the production of the cast tool that is used to make future molds. It is important to note that although some of the data used to generate the cost analysis are for fixed costs (such as the fastening feature costs), other data will inevitably be only approximate (in particular the molded materials), based on estimates from the company that InsightMRI decides upon for these needs.

6.3 Industry Regulations

The FDA classifies MRI breast coils as Class II "magnetic resonance diagnostic device[s]" according to Title 21 CFR 892.1000. The primary concern with any medical device, according to the FDA, is the biocompatibility of any material that will come in contact with a patient (Food and Drug Administration, 1998). However, no biocompatibility study is required for premarket approval (PMA) or 510(k) certification if the material has already been safely used in previously approved medical devices. The polyurethane from which the housing is molded (RC-79D) is a commonly used MRI housing material, meaning that InsightMRI meets this regulation.

GE Medical Systems provides documentation for "Sourced Coils Requirements Specifications" (Boskamp, 2004). These requirements are similar to requirements from other MRI system manufacturers and they provide further information on housing requirements that a device must meet in order to be used in any of their systems. These requirements are outlined in the following list.

- *Surface Temperature*: Surface temperature must remain within safe limits at points where there is potential contact with patient, especially over decoupling circuits in the electronics (which tend to heat during use). These risks can be reduced by air gaps between these surfaces and the electronics or by thicker material. Although the design of the housing in this project cannot be evaluated with respect to surface temperature, the recommended measures to avoid potential heating has been followed (by using air gaps between the patient surface and the internal electronics).
- *Mechanical Safety*: There cannot be any sharp edges or pinching points, which can be accomplished through the use of rounded corners and smooth edges. The majority of the housing's external surfaces incorporate smooth and rounded edges, other than edges that are required to mate with other components of the assembly.
- *FEA Analysis*: Finite element analysis of the housing should demonstrate that it could support standard patient loads as well as those claimed by the device manufacturer. The finite element analysis demonstrated that the housing is capable of withstanding the specified loads.
- *Proton Signal from Housing Material*: The coil housing cannot contain any hydroscopic materials that could produce any echo in the MR signal used to image. The housing materials have been approved by the material manufacturers or by previous testing by InsightMRI to be used in MRI environments without producing any echo in the MR signal.
- *Other:* Furthermore, the housing must be able to withstand a series of tests by the MRI system manufacturers, including temperature exposure tests, mechanical durability, drop tests, flammability tests and a final GE design review. These tests require a physical, final prototype that GE will test. Material ratings and structural analysis have indicated that there is a high probability of the device passing these tests.

By meeting these requirements, the coil housing may be added to an approved vendors list by the MRI system manufacturer. This will be important in the final steps of moving the coil into the breast MRI market.

6.4 Incorporated or Omitted Project Specifications

To evaluate the incorporation of specific project specifications, which were discussed in Chapter 3, I have used Tables 6.1. The table lists each design specification and assesses whether or not the specification was met, followed by any specific values or comments regarding that specification.

Table 6.1 - Project specifications evaluation.

Project Specifications Evaluation Table		
Specification	Requirement Met	Comment
Light Weight (Under 20 lbs.)	Pass	14.65 lbs.
Accommodate Heavy Weight	Pass	Approx. 400 lbs.
Large Openings for Biopsy	Pass	Approx. 5” x 8” window
Entirely Castable	Pass	Mold analysis checks out
Accommodate 95% of Patient Breast Sizes	Pass	According to [26]
Multiple Potential Cable Exits	Fail	Single cable exit
Retroactive Interventionals	Pass	Optional rail mounting system
Compatible with MRI Systems	Pass	Interchangeable bottom half
Patient Comfort	Pass	Form fitting curvature & foam
No Sharp Edges	Partially	Most edges chamfered or filleted
Expandability	Pass	Potential room for extra axillary channels
Serviceability	Pass	Access panel and openings for all electronics cavities
Optical Fudiciary Markers	Fail	Not incorporated
Disposable Fluid Trays	Fail	Not incorporated

7 Analysis and Discussion

The purpose of this chapter is to convey to the reader the interpretations and conclusions that can be drawn from the results that are described in the previous chapter. Although the data in Chapter 6 may give the reader a sense of many of the particulars regarding the design and the validation methods that were used, it is critical to put these results into the context of the larger scope of this project: to design a breast coil housing for A. Obi's RF breast coil concept that will lead to a superior breast coil product, both electronically and mechanically. This chapter attempts to provide these necessary interpretations of the data from each set of results; i) the relevance of the structural analysis findings, ii) the cost analysis data and the importance of low production costs, iii) the evaluation of the regulations surrounding the device, and iv) the design outcomes and their importance for the design specifications.

7.1 Structural Analysis

The structural analysis of the breast coil housing was performed to determine whether or not the final design of the housing was capable of withstanding different loading scenarios that would result from the loading of a patient weighing approximately 400 lbs. The first loading scenario, with the weight of the patient on the top of the housing, resulted in a maximum stress of 4.35237e+006 N/m^2 experienced by the housing. This fell below the yield strength of the main housing material, of 1.648e+007 N/m^2. The yield strength is the maximum amount of stress that the material is capable of withstanding without resulting in permanent deformations. Therefore, in this particular loading scenario, the breast coil housing is capable of supporting the weight of the heaviest specified patient. In the second loading scenario, with the weight of the patient distributed between the two sides of the coil, the maximum stress experienced by the housing was 7.532e+006 N/m^2, which again fell below the yield strength of the housing material. So although this situation would induce more stress on the breast coil housing, the housing would not experience any permanent deformation.

Both sets of results demonstrate that the housing can sufficiently hold a patient weighing up to 400 lbs. Although these are only two situations under which breast coil could be used, there may be other potential situations, each requiring further analysis. However, it is assumed that under normal use, these will be the two most prominent loading situations. Additionally, in either situation, the maximum displacement of any material from its original position resulting from some load applied to that material was less or equal to 0.066 inches. This is almost a negligible displacement (only slightly more than a sixteenth of an inch).

Since the tensile strength of the material is also well above the maximum stresses exerted on the housing in either scenario, we can conclude that the housing material would not break or crack, which is an important consideration for patient safety and the overall durability of the housing.

7.2 Cost Analysis

The results of the cost analysis demonstrate a relatively low-cost design for the breast coil housing, at $950.46 and $6950.46 for housing costs without and with tooling, respectively. Although this does not include the cost of the electronics that are intended for use in the final device, a reduction in the housing material will still result in the overall reduction of cost of the finished device. Breast coils typically fall within a range of $20,000 to $200,000. Previous breast coil models that InsightMRI has produced have incorporated electronics that total approximately $1664.26 in cost (Confirma, Inc.). It can be assumed that the electronics integrated into this breast coil will be relatively similar in circuitry and therefore similar in price. Therefore, the cost of materials for the device will most likely be somewhere between $2500.00 and $3500.00 (after the one time tooling cost). The rest of the cost of the device will be due to labor fees and the profit margin that InsightMRI hopes to acquire with the device.

7.3 Adherence to Industry Regulations

The breast coil housing was evaluated with respect to the majority of the requirements listed. Some of the requirements could not be evaluated due to the nature of the evaluation methods, which may require a physical prototype of the

housing. The housing met all of the evaluated requirements and for those that were not capable of being validated, the design of the housing corresponded to the recommended guidelines for adhering to these requirements.

7.4 Incorporation of Project Specifications

The majority of the original project specifications established in Chapter 3 were fulfilled successfully. Although some of the data suggest a failure to comply with certain specifications, these items were identified during design review meetings as specifications that were either no long applicable or simply too low of a priority to incorporate into the final design. From the design wants and needs matrices found in Chapter 4, the highest priority specifications have been passed in the final design, which is an ideal outcome of the design process of the breast coil housing.

8 Conclusions and Recommendations

This project set out to design a breast coil housing concept that would integrate Aghogho Obi's RF coil conceptual design and to then develop the design specifications documentation. This process required a design process for the actual development of the housing and then a series of tests and methods for validating the design. In the end, the results of these methods led to a set of design specifications, identifying various claims of the device.

The design process resulted in a breast coil housing that was smaller, more ergonomic and ultimately at an advantage to many of the other coil housings on the market, including the sponsor's previous breast coil. The final design of this coil is shown in Figure 8.1.

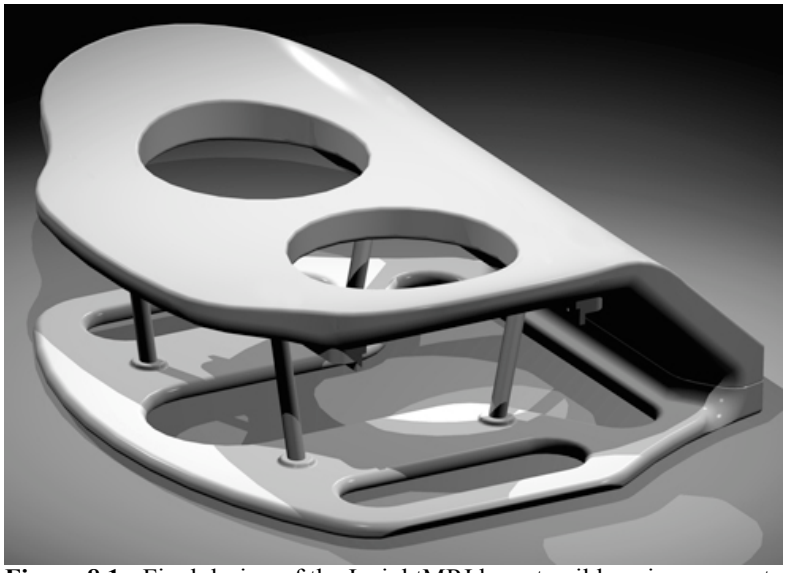

Figure 8.1 - Final design of the InsightMRI breast coil housing concept.

It incorporated retroactive possibilities for various interventional biopsy system support, an interchangeable bottom half for physical compatibility with various MRI system patient tables, and reinforced structural materials to help the housing support a patient in various use scenarios. Throughout the design process, measures were taken to ensure that the device was compliant with various sets of regulations, both governmental and non-governmental. The design validation methods ensured

that various factors were taken into consideration, primarily the structural integrity of the housing, a cost analysis of the materials, regulatory compliance and a set of design specifications that adhered to the original project specifications.

The results of the design validation process were several fold; i) the housing was capable of supporting significant patient weights in both a normal use scenario as well as a conditional use scenario, ii) the materials used resulted in a manufacturing cost that was relatively low (this did not, however, consider costs of labor), iii) the device was within the commonly applied industry regulations and iv) the final design specifications closely matched the original project specifications from Chapter 3.

Ultimately, it is important to understand (for the sake of the context of this project) that this design was a conceptual design for InsightMRI. The analysis methods were to validate the design as an appropriate design for the future production of a coil housing and the associated internal electronics. The design specifications and the design itself are deliverables of this project, with which the sponsor can move forward from a conceptual prototype to a testing phase that will eventually lead the device towards entry in a competitive MRI breast coil market.

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Glossary

Aperture

The holes on the top surface of the breast coil housing through which the breasts hang during an MRI examination.

Axillary

An anatomical term referring to the armpit region, specifically concerning the lymphatic regions of the armpit in the context of this project.

Bore

The hollow opening of the main MRI magnet, where the B_0 magnetic field is uniform.

Computer Aided Design (CAD)

Computer software intended for the assistance of the design of device, capable of two-dimensional or three-dimensional modeling.

Ergonomics

The study of the interaction between humans and any interface between them and the technology they use, primarily concerned with improving comfort and reducing stress or injury.

Finite Element Analysis

A computer simulation analysis method using discrete volume elements to approximate a three-dimensional model, on which various analytic methods may be performed and computed.

Food and Drug Administration (FDA)

A division of the U.S. Department of Health and Human Services responsible for the regulation of foods, drugs, cosmetics and medical devices under the Federal Food, Drug, and Cosmetics Act and subsequent acts and amendments.

Housing

The mechanical chassis that houses the RF breast coil and electronics and provides the patient interface for the breast coil.

Interventional Biopsy System

A mechanical system used in conjunction with a breast coil and MRI breast exams, intended for localization and needle biopsy of anomalies detected from the exam.

Magnetic Resonance Diagnostic Device

A device used in conjunction with MRI systems, usually intended to bypass and replace certain system integrated RF coils for the purpose of providing better resolution and uniformity throughout a tissue with a form-fitting RF coil (i.e. using a form fitting breast coil rather than the system integrated body coil).

Magnetic Resonance Imaging (MRI)

A non-invasive imaging procedure that utilizes various electromagnetic fields to manipulate nuclear characteristics of a patient's tissues, ultimately used to detect and produce images of the patient's internal organs and structures associated with those tissues.

Magnetic Resonance Imaging System

The setup used to produce MRI images, including the main magnet, shim coils, RF gradient coils, RF transmit and receive coils, patient table, user interface and computerized image processing units.

Radio Frequency (RF)

The frequencies used in electronics or electromagnetic applications that oscillate in an approximate range of 100KHz to 1THz.

Stress

The amount of force experienced by a specific area or material, usually measured in unites of N/m^2 or Pa.

Unilateral & Bilateral Imaging

Imaging modes specific to magnetic resonance breast imaging referring to the imaging of a single breast or of both breasts, respectively.

Appendices

Appendix A: Design Specifications: Insight QD Breast Coil Housing

Insight Neuroimaging Systems

Document Title: Design Specifications: Insight QD Breast Coil Housing

Document Number:
Document Filename: INSL-IBC-Specifications.doc

Revision Level	Revision Date	DCO/ECO Number	Description of Revision	Revision Author
DRAFT	28/01/2008	#	Draft	Michael Beasley

INSL PROPRIETARY AND CONFIDENTIAL

Table of Contents

1.0 Purpose

This design specification document provides an overview of the components and specifications of the Insight QD Breast Coil Housing. Each component is described individually in Section 5.0 (Components), followed by detailed specifications of the overall design.

2.0 Scope

This document applies only to the Insight QD Breast Coil Housing manufactured by Insight Neuroimaging Systems LLC.

3.0 Definitions

3.1 Magnetic Resonance Imaging (MRI)

A non-invasive imaging procedure that utilizes various electromagnetic fields to manipulate nuclear characteristics of a patient's tissues, ultimately used to detect and produce images of the patient's internal organs and structures.

3.2 IBC

The acronym IBC refers to the Insight QD Breast Coil.

3.3 Housing

The term housing refers to the mechanical chassis that is used i) to house the IBC and associated electronics and ii) to serve as the patient interface for the IBC.

3.4 Product

Unless otherwise specified, the word "product" in this document is used in the more global sense to refer to components, materials, structures, machines, devices, processes, software, or services as they relate to the Insight QD Breast Coil, primarily its housing.

3.5 Device

The term device refers to the IBC housing, the integrated electronics, interventional systems and ergonomic foam padding.

3.6 Aperture

The term aperture refers to the openings on the top surface of the IBC Housing, through which the breast hang.

4.0 Overview

The Insight QD Breast Coil Housing is a mechanical chassis used to house the IBC and its associated electronics. The housing is specifically built for use in conjunction with the IBC and is subject to any of the applications and limitations of the IBC. Additionally, the housing serves as an ergonomic patient interface for the IBC.

5.0 Components

The Insight QD Breast Coil consists of molded top and bottom halves of the main housing, legs, interventional rail mounts, and covers for the incorporated electronics cavities. Figure 1 shows an assembled view of the entire housing.

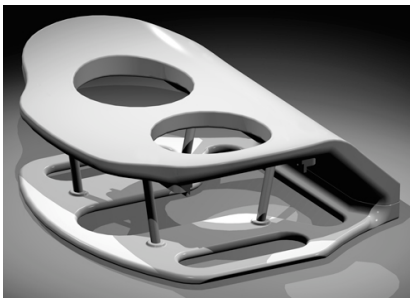


Figure 1 - The Insight QD Breast Coil housing assembly.

5.1 Main Housing – Top Half (1)

The top half the IBC housing (Figure 2) features the patient surface (right), apertures for the breast, and an internal electronics cavity for RF coils and other electronics.

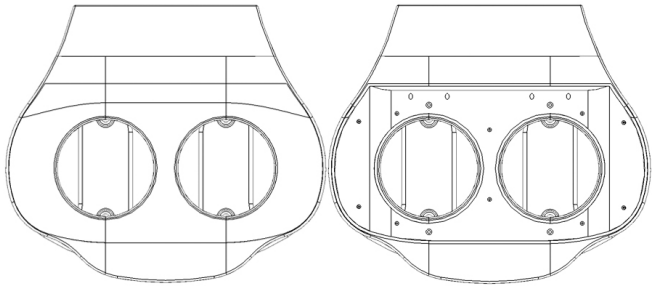


Figure 2 – Top surface of the top half of the housing, with the patient surface (left) and the electronics cavity (right).

An additional electronics cavity (shown in Figure 3), which is connected to the cavity on the top surface, will contain pre-amplifiers, hybrids, other electronics and a cable exit with a strain relief mechanism. This component is composed of a molded RC-79D polyurethane.

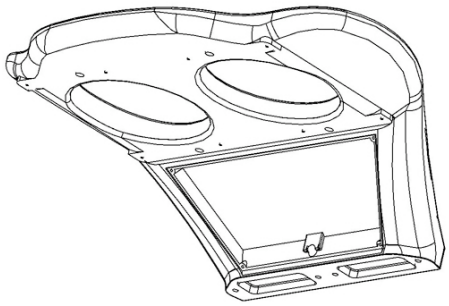


Figure 3 – A bottom view of the top half of the housing.

The bottom surface of the top half provides surfaces for the optional rail mounts (Section 5.4).

5.2 Main Housing – Bottom Half (1)

The bottom half of the IBC housing (Figure 4) features two electronics cavities that house the portion of the RF coils that pass from the top half, through the legs, and into the bottom half.

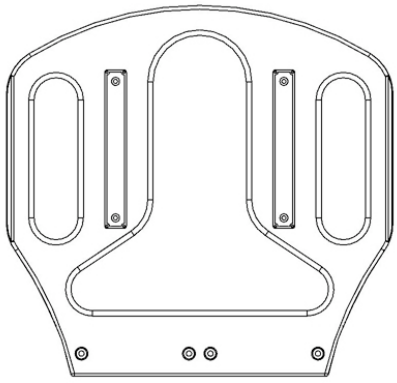


Figure 4 – Bottom side view of the bottom half of the IBC housing.

The cutout portions of the housing provide handholds (on the sides) and an opening through which technicians may perform post-production maintenance to the electronics stored in the cavity shown in Figure 3. This component is composed of molded RC-79D polyurethane.

5.3 Support Leg (4)

The support legs (Figure 5), which provide structural support as well as a housing for a portion of the RF coil, are composed of a set of tubing of two different materials.

Figure 5 – Support legs.

The outer tube is a machined Ultem 2300 tube with a 0.5-inch outer diameter and a 0.375-inch inner diameter. The inner tube is a machined Garolite G-10 tube with a 0.375-inch outer diameter and a 0.25-inch inner diameter.

5.4 Rail Mounts (2)

The rail mounts (Figure 6) provide an optional mounting system for the integration of various interventional biopsy systems.

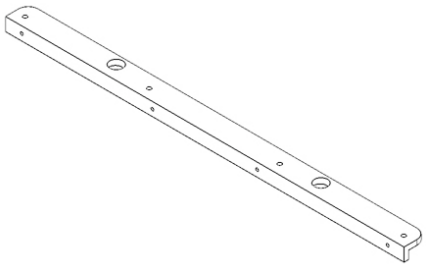


Figure 6 – Rail mount.

The mounts are machines out of Ultem 2300.

5.5 Covers (4)

There are three separate types of cover for the IBC housing.

5.5.1 Top-Half Top Surface Cover (1)

The top-half top surface cover (Figure 7) mates to the top of electronics cavity shown in Figure 2 (right) and is composed of molded RC-79D polyurethane.

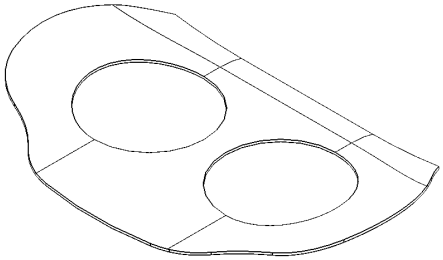


Figure 7 – Top-half top surface cover.

5.5.2 Top-Half Bottom Surface Cover (1)

The top-half bottom surface cover (Figure 8) mates to the bottom of the electronics cavity shown in Figure 3 and is composed of a generic machined plastic.

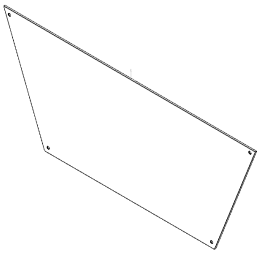


Figure 8 – Top-half bottom surface cover.

5.5.3 Bottom-Half Bottom Surface Cover (2)

The bottom-half bottom surface covers (Figure 9) mate to the bottom of the electronics cavities shown in Figure 4 and are composed of a generic machined plastic.

6.0 Design Specifications

The following specifications outline the claims of the assembled housing.

6.1 Performance

The IBC Housing holds the RF coils and the electronics used in the MR device. It can accommodate breast sizes of up to approximately 7-inches hanging diameter, which accounts for nearly 95% of the US population. The housing also features support for the integration of optional interventional biopsy systems.

6.2 Size

The size of the device is constrained by the bore diameter of the MRI system it is to be used in, allowing ample room for not only the housing within the bore, but also for the patient that will lay on top of it. The IBC housing is designed for use in current GE and Siemens MRI systems.

6.3 Weight

The overall weight of the assembled housing is approximately 15 lbs.

6.4 Ergonomics

The top surface of the housing (on which the patient will lay) is curved in a form-fitting manner to the patient's torso in attempts to distribute the patient's weight to avoid discomfort. Additionally, memory foam padding will be used with the IBC to add extra comfort. The wide apertures are sized such that there will be minimal compression of the breast tissue when it hangs through this feature.

6.5 Operating Environment

The IBC, including the housing, is intended for use in MRI facility environments and will consequently be exposed to uniform magnetic fields from 0.5T to 3T and high power RF fields. The housing material may be exposed to biological fluids during biopsy procedures.

6.6 Safety

The housing has been evaluated for mechanical features that may pose threats to patient safety, such as sharp corners and possible pinching surfaces at mate points. Additionally, the IBC housing is in compliance with any mechanical safety regulations required by the intended MRI system manufacturers and the Food and Drug Administration.

6.7 Materials

The materials used in the housing components are listed below.

6.7.1 Rapid Cast RC-79D

Rapid Cast RC-79D is a polyurethane material formulated by Innovative Polymers, Inc. for molding. It possesses excellent physical properties and is approved for use in medical applications, including MRI coil housings. RC-79D is U.L. 94v0 rated flame retardant material.

6.7.2 Ultem 2300

Ultem 2300 is a 30% glass-reinforced polyimide thermoplastic resin, originally formulated by GE Plastics. It has exceptional mechanical properties, is approved for medical devices and is MR transparent. Ultem 2300 is a U.L. 94v0 rated flame retardant material.

6.7.3 Garolite G-10

Garolite G-10 is a reinforced glass-cloth composite epoxy resin that has exceptional mechanical properties and is often used in association with electronics, specifically printed circuit boards. Garolite G-10 comes in a G-10/FR4 version of the material, which is flame retardant.

6.8 Structural Integrity

The assembled housing is capable of withstanding distributed top-loaded weights of a 400 lb., determined via finite element structural analysis of the housing assembly in various loading scenarios that the housing may experience during normal intended use.

6.9 Aesthetics, Appearance and Finish

The molded components of the housing may either contain an off-white dye incorporated into the material itself or are painted post-molding. Any of the externally exposed surfaces of machined parts are also painted.

6.10 Manufacturing Facilities

The molded components of the housing are manufactured out-of-house at a local cast molding facility. All other machined parts are manufactured in-house from purchased stock plastics. The assembly of the housing is performed in-house.

Insight QD Breast Coil Housing - Bill of Materials

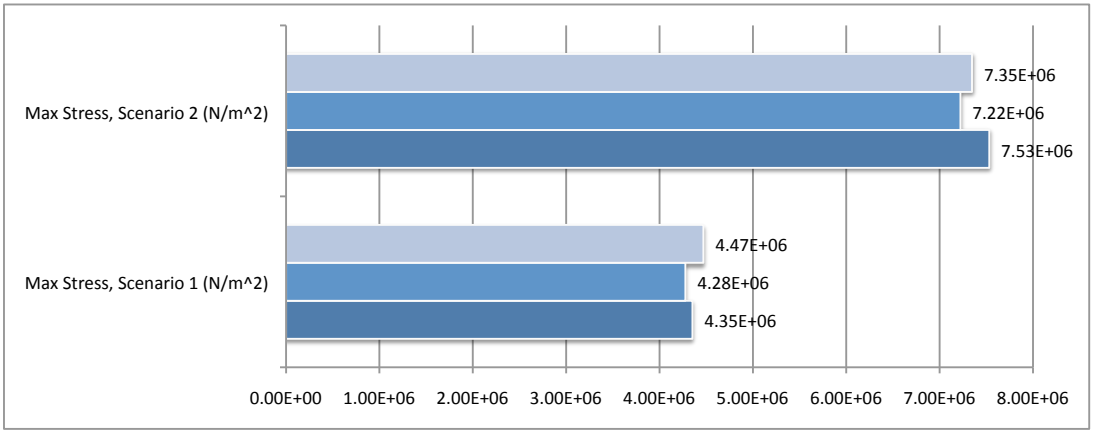
Part	Material	Dimensions	Manufacturer - Part #	Unit Cost	Tooling (1 Time Cost)	Quantity per Package	Quantity per Unit	Total Cost
Main Housing Parts								
Leg (Outer)	Ultem 2300 (.5" Dia.)	4.6924 in	-	$1.66/in	-	-	4	$31.16
Leg (Inner)	G-10 (.375" Dia.)	5.2636 in	-	$0.46/in	-	-	4	$9.69
Housing (Top Half)	RC-79D	222.87 in^3	-	$400	$4,280	-	1	$4,680.00
Housing (Bottom Half)	RC-79D	84.51 in^3	-	$160	$1,720	-	1	$1,880.00
Covers								
Top Half - Top Cover	RC-79D	15.6 in^3	-	$30	$280	-	1	$310.00
Top Half - Bottom Cover	Nylon	3.48 in^3	-	$0.55/in^3	-	-	1	$1.92
Bottom Half - Bottom Cover	Nylon	0.46 in^3	-	$0.55/in^3	-	-	2	$0.50
Rail Mount	Ultem 2300 (Sheet)	3.22 in^3	-	$4.12/in^3	-	-	2	$13.27
Fastening Features								
#2-56 Screw	Brass	0.25 in	McMaster - 92451A077	$3.18/pkg	-	100	2	$3.18
#4-40 Screw	Nylon	0.25 in	McMaster - 94605A106	$4.92/pkg	-	100	15	$4.92
#4-40 Screw	Brass	0.375 in	McMaster - 92451A108	$4.79/pkg	-	100	20	$4.79
1/4-20 Screw	Brass	1 in	McMaster - 92451A542	$8.66/pkg	-	25	4	$8.66
Strain Relief	Nylon	0.5 in OD	McMaster - 69915K49	$2.37	-	-	1	$2.37
							Total w/o Tooling	$950.46
							Total w/ Tooling	$6,950.46

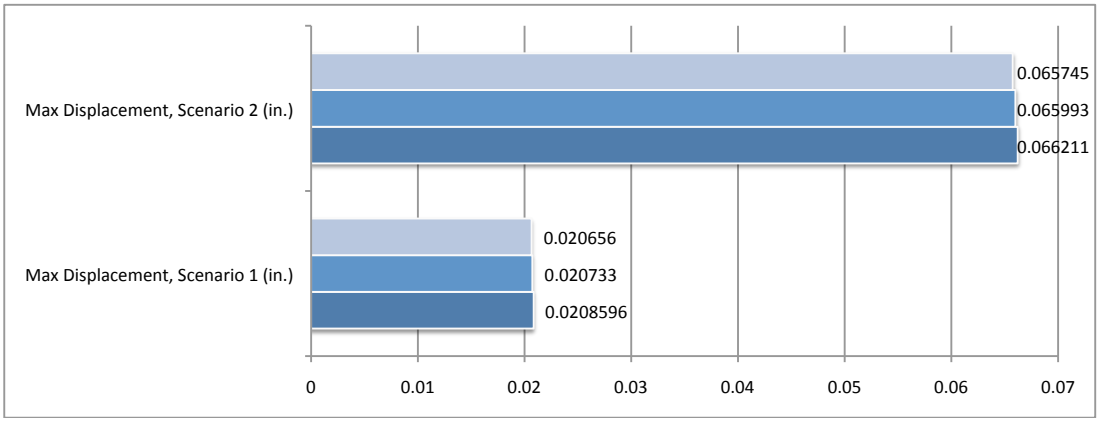
Appendix C: Structural Analysis Data

The following data show i) the FEA data for each scenario analyzed and ii) the convergence data for each of the three FEA tests used in each scenario.

Scenario 1 - Top Loaded Analysis				
Size of Elements (in.)	Number of Elements	Element Tolerances (in.)	Max Stress, Scenario 1 (N/m^2)	Max Displacement, Scenario 1 (in.)
0.25	147202	0.0125	4.35E+06	0.0208596
0.3	90886	0.015 in	4.28E+06	0.020733
0.375	53568	0.01875 in	4.47E+06	0.020656

Scenario 2 - Side Loaded Analysis				
Size of Elements (in.)	Number of Elements	Element Tolerances (in.)	Max Stress, Scenario 2 (N/m^2)	Max Displacement, Scenario 2 (in.)
0.25	147202	0.0125	7.53E+06	0.066211
0.3	90886	0.015 in	7.22E+06	0.065993
0.375	53568	0.01875 in	7.35E+06	0.065745





Appendix D: Bodyweight Distribution Statistical Data

Using the setup shown in Figure 4.2 in Chapter 4, Section 3, I was able to acquire the following data on small sample of individuals.

Bodyweight Distribution Data		
Total Body Weight (lbs.)	Measured Weight at Chest (lbs.)	Percent of Total Body Weight (%)
205	120	58.5
213	145	68.1
206	110	54.4
180	110	61.1
160	75	46.9
120	65	54.2
178	75	42.1
215	120	55.8
248	132	55
133	73	55

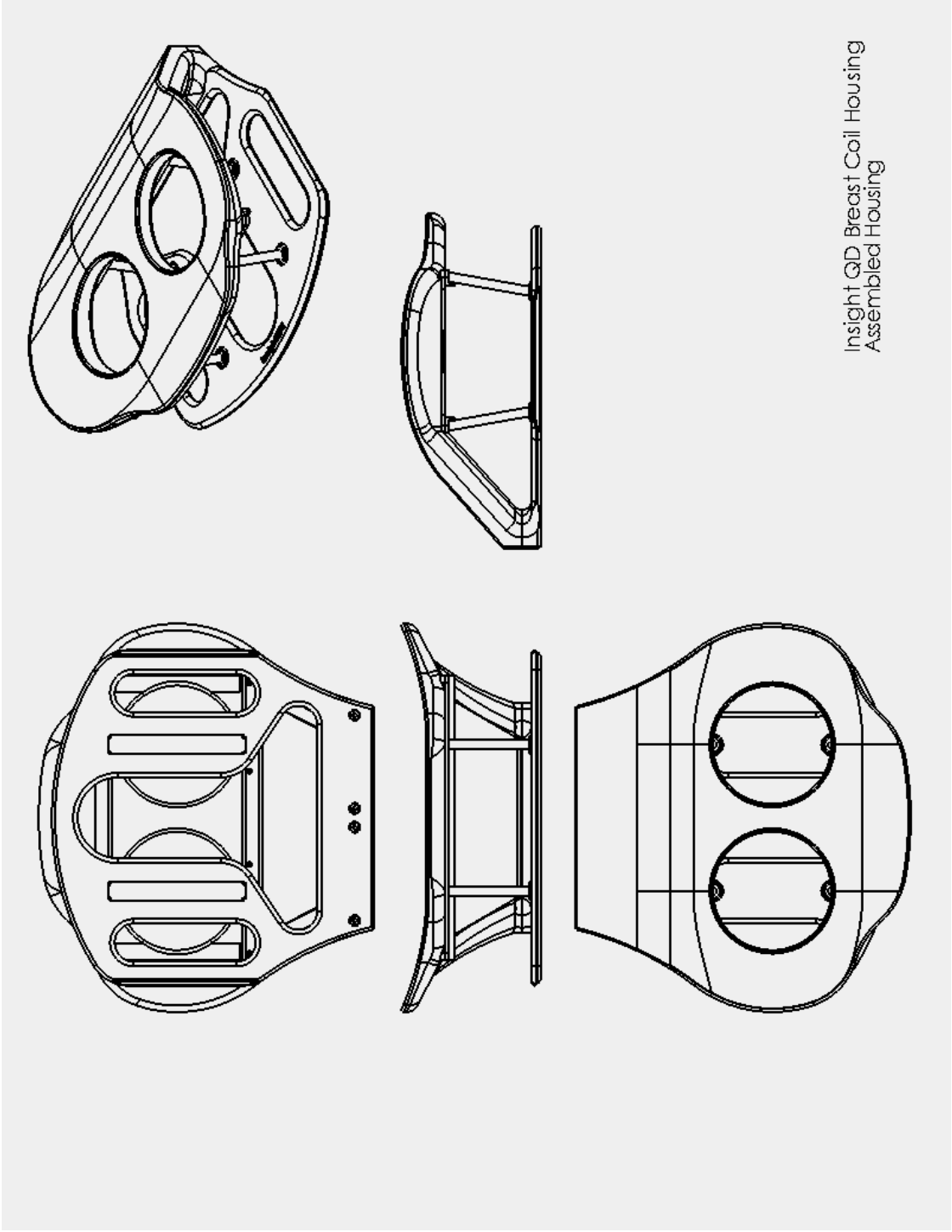
Bodyweight Distribution Percentage Statistics	
Mean	55.11%
Standard Deviation	7.107%
Sample Size	10
Minimum	42.1%
Quartile 1	54.2%
Median	55%
Quartile 3	58.5%
Maximum	68.1%

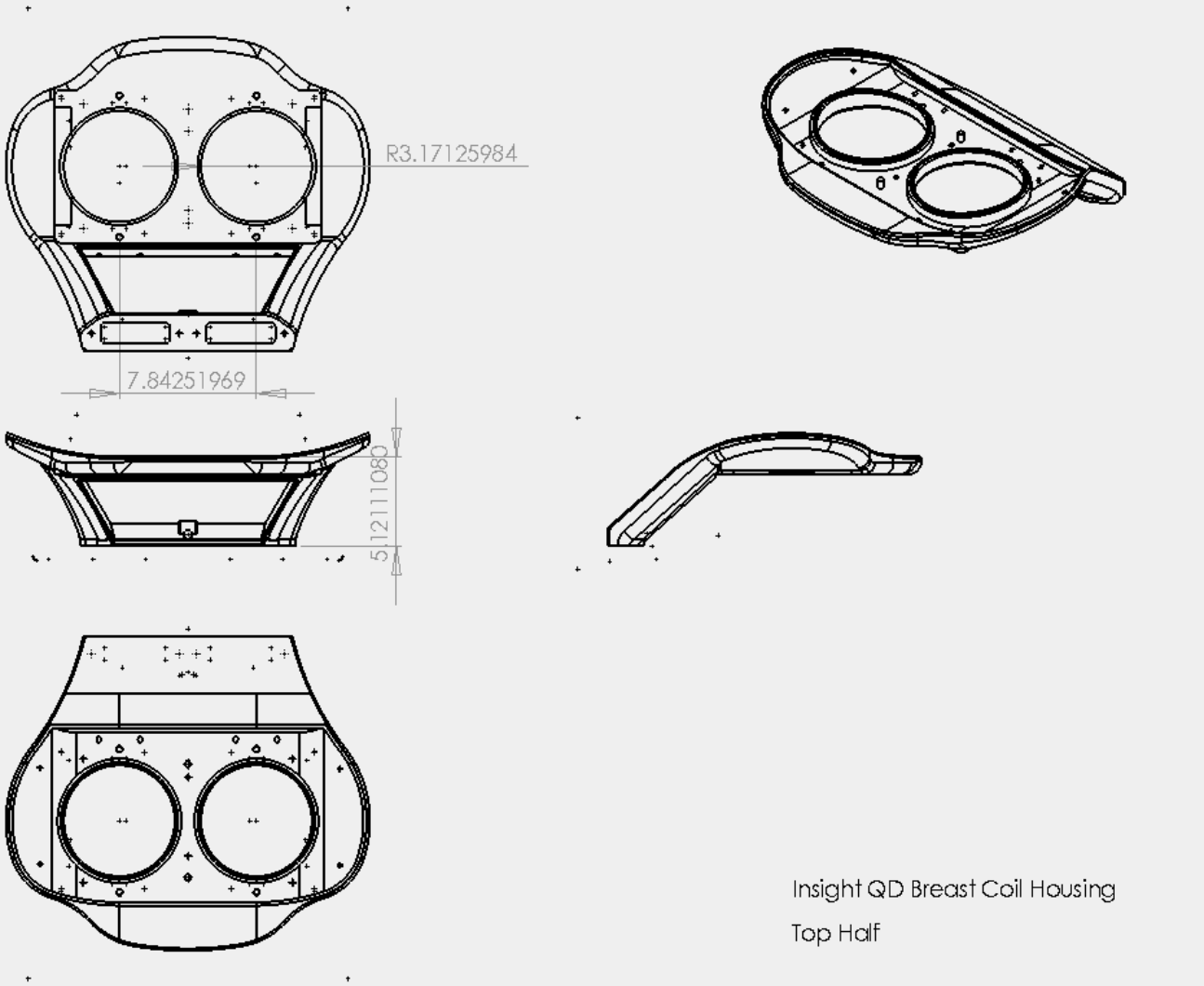
Appendix E: Material Properties

Relevant Material Properties			
Material Property	RC-79D[1]	Ultem 2300[2]	Garolite G-10[3]
Elastic Modulus (psi)	34,500	800,000	180,000
Density (lb/in^3)	0.0455	0.0546	0.0701
Tensile Strength	6,000	33,000	15,400
Compression Strength (psi)	-	32,000	33,500
Yield Strength (psi)	2,390[4]	24,500	8,430

[1] (Innovative Polymers, Inc., 2005).
[2] (ProfessionalPlastics.com, 2007).
[3] (ProfessionalPlastics.com, 2007).
[4] This value was not provided through (Innovative Polymers, Inc., 2005). Rather, value was extrapolated from (MatWeb, 2008).

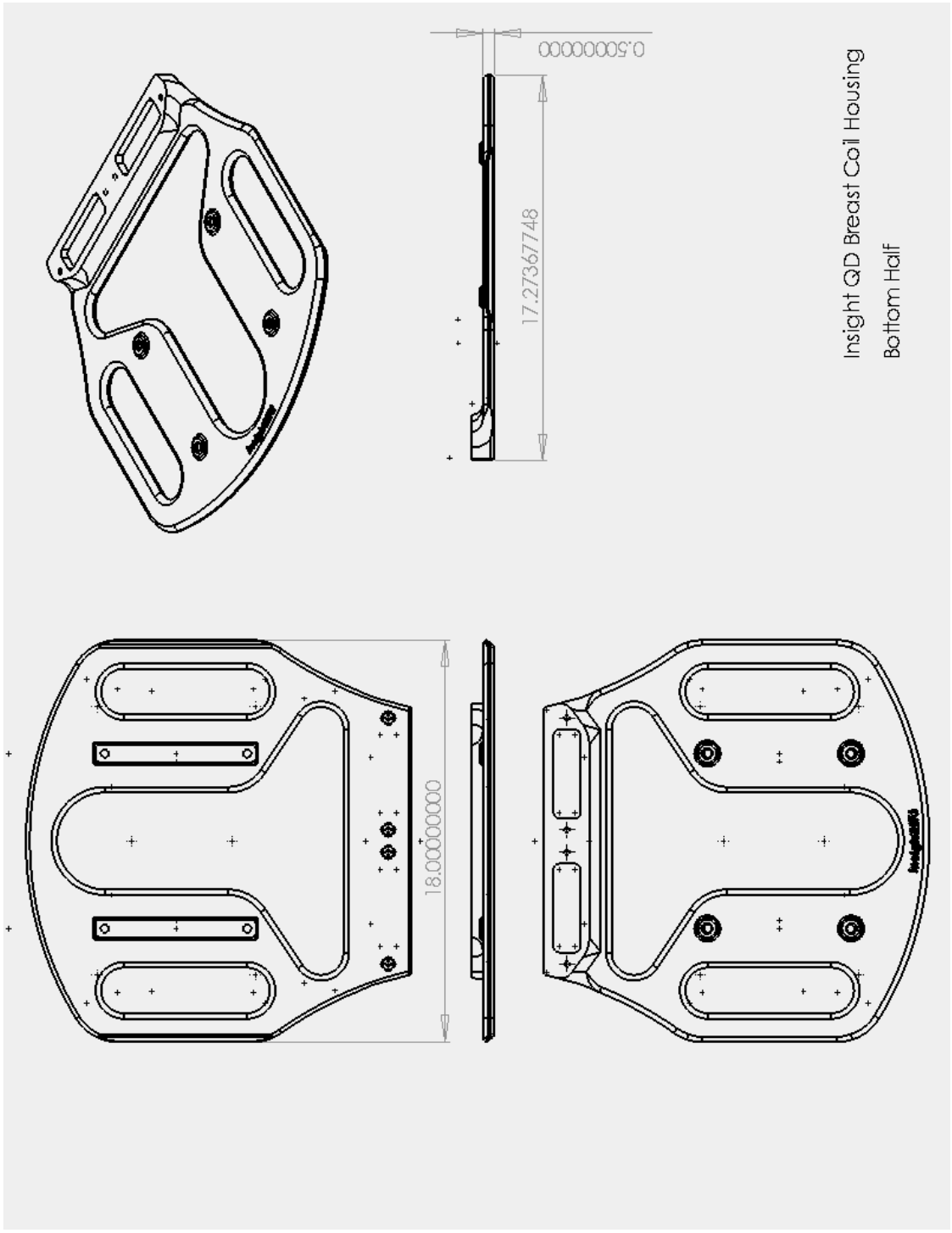
Appendix F: Component Drawings

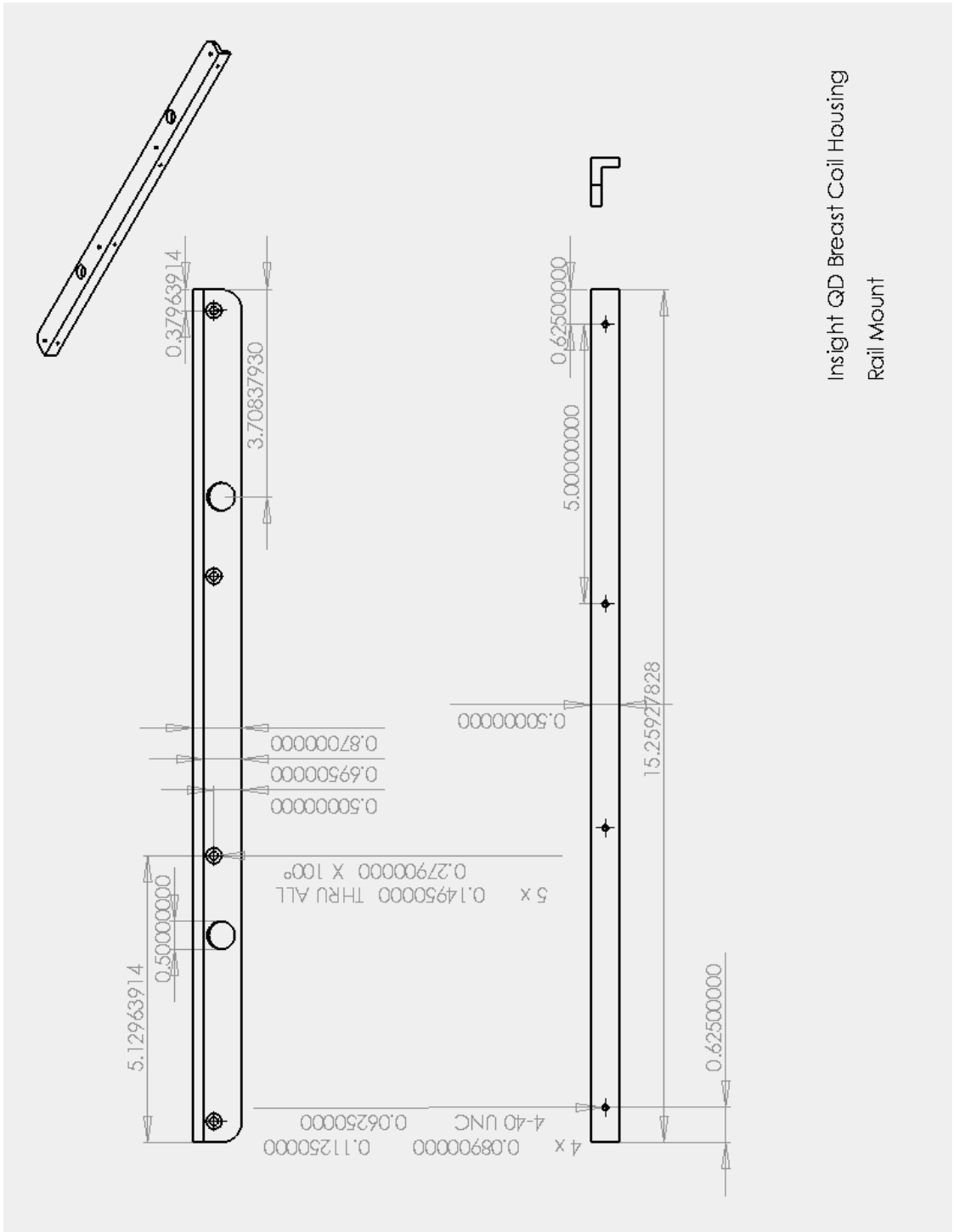


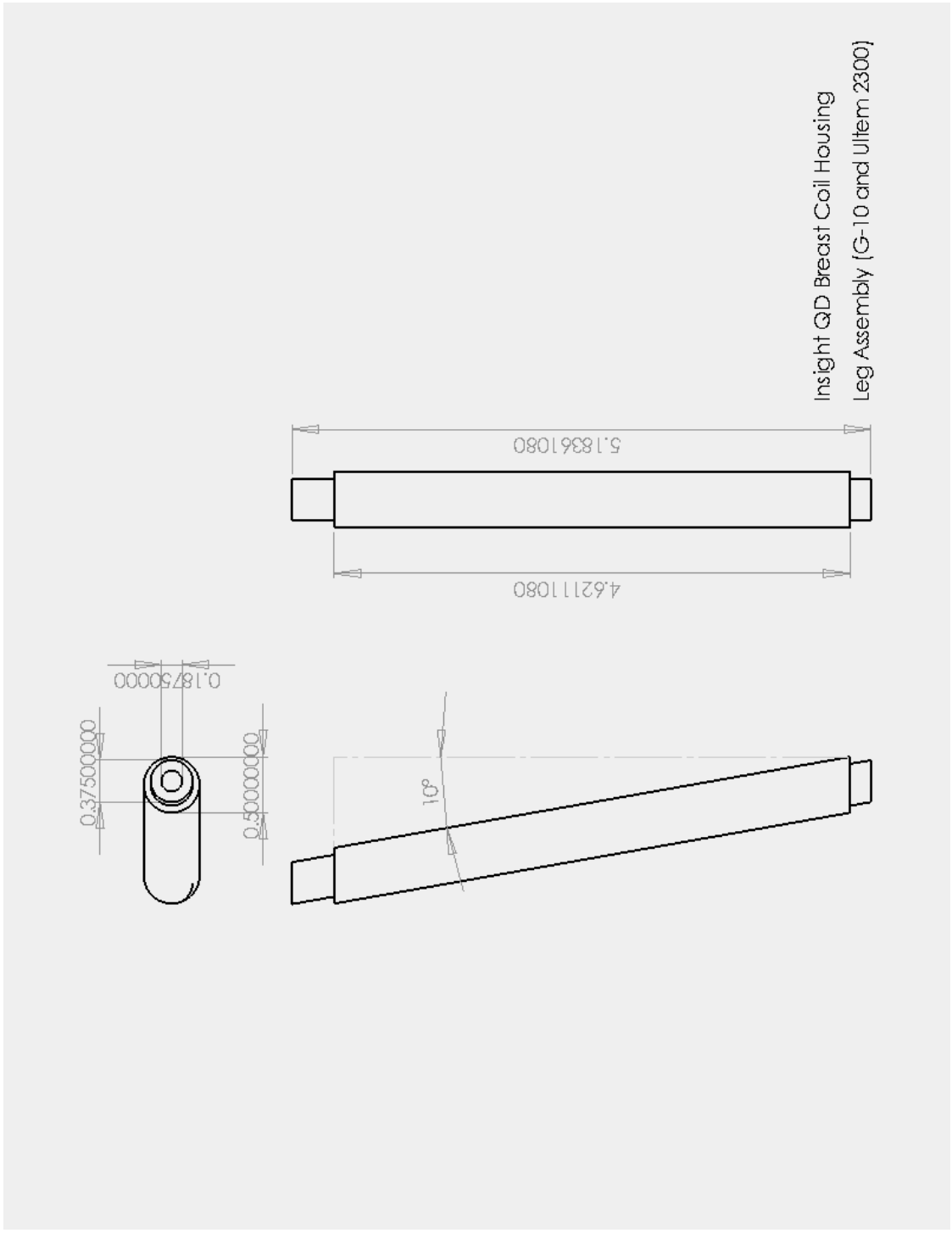


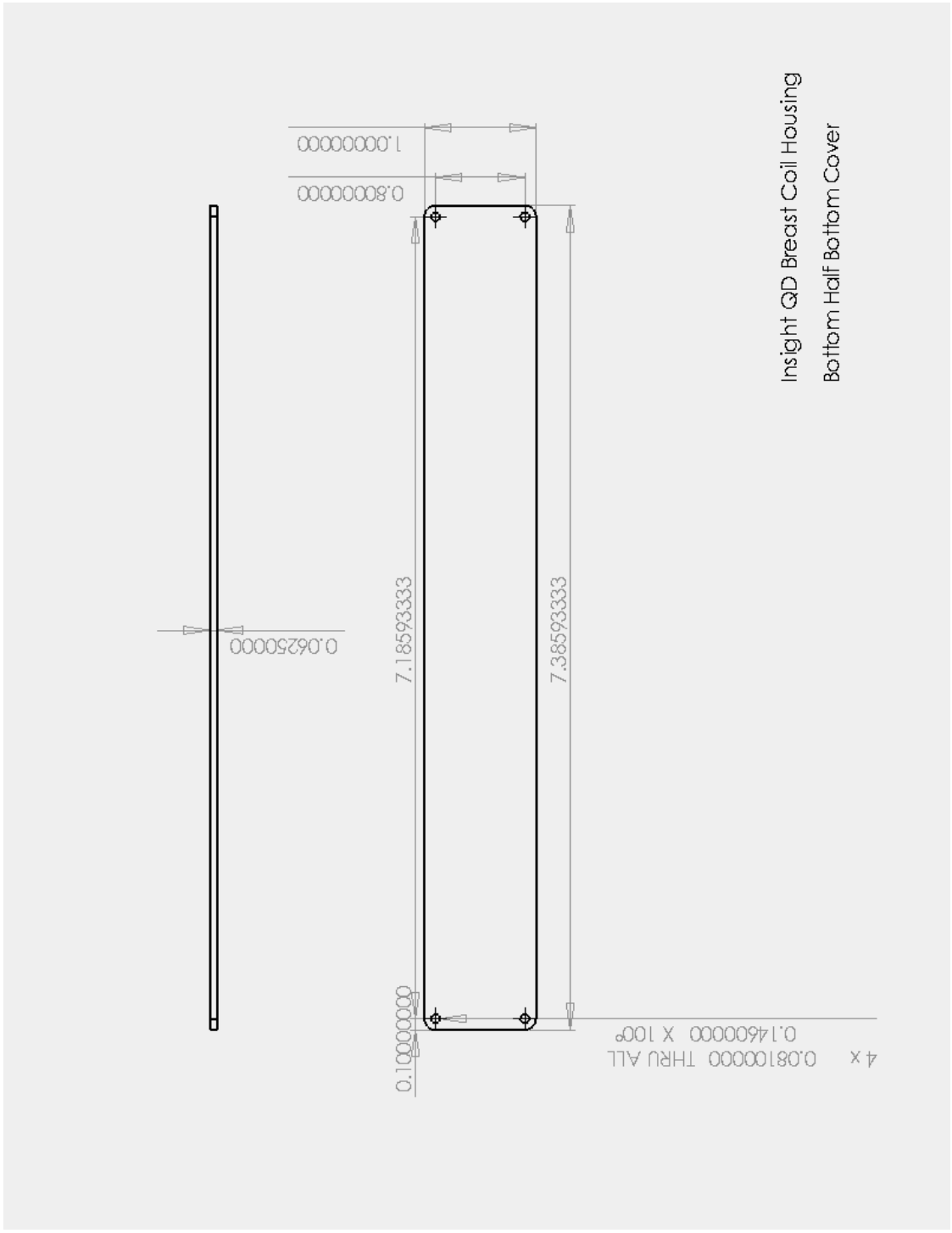
Insight QD Breast Coil Housing

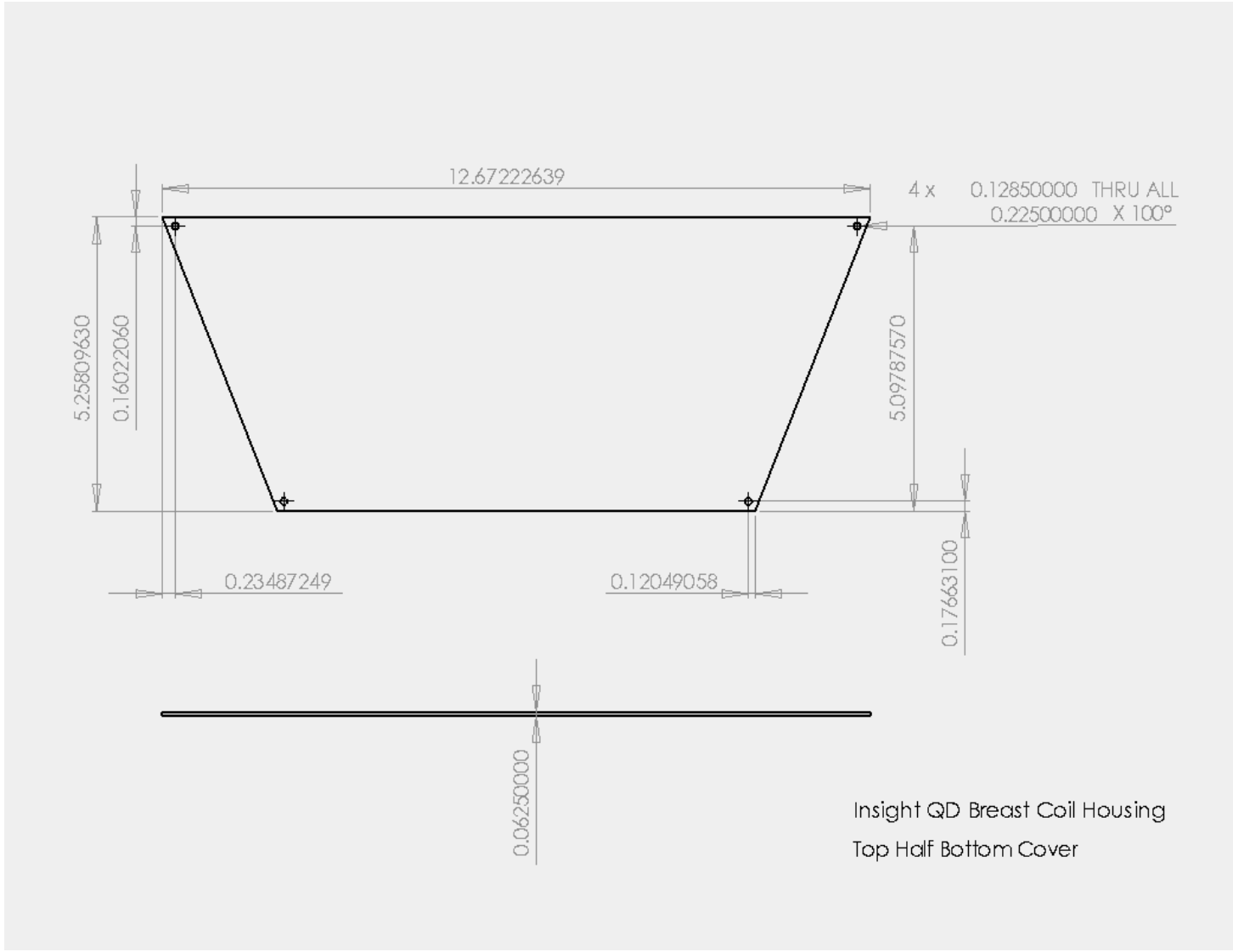
Top Half


0.50000000
17.27367748
Insight QD Breast Coil Housing
Bottom Half
18.00000000


Insight QD Breast Coil Housing
Rail Mount
0.37963914
3.70837930
0.62500000
5.00000000
0.50000000
15.25927828
0.87000000
0.69500000
0.50000000
5 x 0.14950000 THRU ALL
0.27900000 X 100°
5.12963914
0.50000000
4 x 0.08900000 0.11250000
4-40 UNC 0.06250000
0.62500000


Insight QD Breast Coil Housing
Leg Assembly (G-10 and Ultem 2300)
5.18361080
4.62111080
0.18750000
0.37500000
0.50000000
10°


Insight QD Breast Coil Housing
Bottom Half Bottom Cover
1.0000000
0.8000000
0.0625000
7.18593333
7.38593333
0.1000000
4 X 0.0810000 THRU ALL
0.1460000 X 100°


12.67222639
4 x 0.12850000 THRU ALL
0.22500000 X 100°
5.25809630
0.16022060
5.09787570
0.23487249
0.12049058
0.17663100
0.06250000
Insight QD Breast Coil Housing
Top Half Bottom Cover