Radiation Distance Safety Meter

Biomedical Engineering Design 200/300
Department of Biomedical Engineering
University of Wisconsin – Madison
December 9, 2015

Team Members:
Kieran Paddock – Team Leader
Alex Smith – Communicator
Christina Sorenson – BSAC
Rebecca Alcock – BWIG
Gregory Wolf – BPAG

Clients:
Professor John Webster
University of Wisconsin - Madison
Department of Biomedical Engineering

Professor Eng. Sarah Hagi
King AbdulAziz University
Faculty of Medicine

Advisor:
Professor Beth Meyerand, Ph.D.
University of Wisconsin – Madison
Department of Biomedical Engineering

Abstract

Approximately 450,000 people are living with thyroid cancer today. The prevalence of thyroid cancers has been steadily increasing at an average rate of five percent per year with an estimated 63,000 new cases annually in the United States alone. While the five-year survival rates for thyroid cancer are high, in serious cases, radioactive iodine (I-131) may be employed as a final resort treatment to destroy any residual cancerous cells remaining after surgery. Radioactive iodine is ingested by the patient and concentrates itself among the thyroid cells. Over four to six weeks, it decays and ablates malignant cells. Due to the radioactive properties of I-131, radiation is emitted off the patient in the form of beta particles and gamma rays. This can cause harm to healthy tissues of not only the patient but also people in his/her vicinity. These unfavorable side effects of radioactive iodine therapy - known as residual radiation - warrant the need for a device to protect those within close proximity of the patient.

Currently, thyroid patients are instructed to stay at least one meter away from others to prevent damage by residual radiation. Often times, a patient will not be able to maintain a one-meter distance consistently for six weeks, or may not be aware of others behind them that are being affected. The goal of this design project is to alleviate the potential hazards to others by creating a device to warn the patient with observable feedback when humans are within one meter of his/her body in any direction. The device will be worn by the patient for six weeks and must function and endure daily stress for this period of time.

After evaluating the design alternatives, a chest harness with six pairs of thermal and distance sensors was decided upon as the final design. This option would achieve a 360-degree field of view, while avoiding inaccurate detection. Further, types of sensors that specifically detect human movement also had to be considered. The best sensor options for this design project's purposes consist of Passive IR and Ultrasonic Distance sensors, for a completely circular field of view at a relatively low cost. These sensors also can be interfaced effectively with the Arduino Pro Mini microprocessor and mounted appropriately on the RaDistance device. Any human within one meter of the patient wearing the device will cause the microprocessor to alert the wearer with vibrational motors. These alerts will minimize the exposure of surrounding individuals to the harmful residual radiation from thyroid patients' treatments.

The final design meets the design requirements as put forth by the clients. The coding and wiring effectively operate the device and can easily be reconfigured for higher caliber components. The completed RaDistance Safety Meter has potential for a future in the medical device market, given improvements in the quality of sensors and battery pack.

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Background

The thyroid, one of the largest glands of the human endocrine system[1], is a butterfly shaped gland located in the front, lower area of the neck. It surrounds the trachea, just below the larynx shown in Figure One. The thyroid gland is responsible for making hormones that are distributed throughout the body[1] to various regulatory systems. These hormones are responsible for maintaining body temperature, energy use, and functionality of major organs[1].

Thyroid cancer is the presence and/or growth of cancerous cells in the thyroid gland. The most common forms are referred to as well-differentiated thyroid cancer, composed of papillary and follicular, and constitute more than 90 percent of all thyroid carcinomas. These cancerous cells appear as normal thyroid cells, making early detection difficult. The early stages of papillary and follicular thyroid cancer include a tumor in the thyroid gland less than four centimeters. Later stages consist of tumors larger than four centimeters and the expansion of the malignant cells into nearby tissues: lymphoid, pulmonary, skeletal, tracheal, and laryngeal. Many patients do not experience any symptoms in the early stages. As the cancer progresses, swelling of the lymph nodes, appearance of lumps in the neck, difficulty speaking, swallowing, and breathing may occur. The remaining forms of thyroid cancer, medullary and anaplastic, follow similar stages as to those of the differentiated forms; however, these forms grow and spread at a much faster rate but occur much less frequently[2].

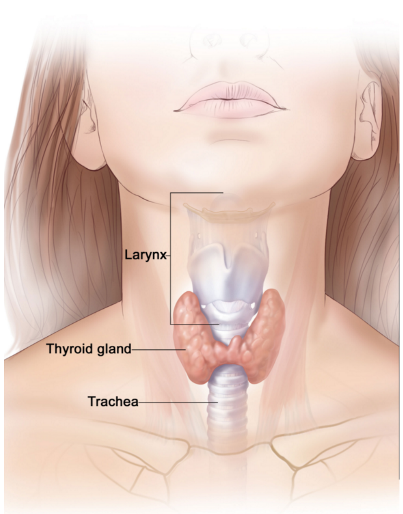


Figure 1: The location of the thyroid gland in the human body. Retrieved from http://www.cancer.gov/types/thyroid

Despite accounting for only one percent of all types of cancer[3], thyroid cancer's prevalence is steadily increasing. Whether it is due to improvements in detection or increased rates of occurrence, there is data to show that thyroid cancer frequency has surged over the past several decades. In the United States, the prevalence of thyroid cancer has tripled over the past thirty years and is expected to grow by approximately fifty percent over the next five years[2]. In fact, thyroid cancer incidence is growing at a faster rate than all other types of cancer[3].

Thyroid cancer is more commonly found in women than men, but affects people of all ages. Large amounts of exposure to radiation or even those who have been medically treated with radiation are at larger risk to develop thyroid carcinoma. It is possible that the radiation will not affect the patient for more than 20 years after exposure. In some medullary carcinoma cases, an abnormal gene is present in the patient's DNA[2]. Tests are conducted to determine if other family members also inherited the abnormal gene. For those who develop thyroid carcinoma, the outlook is positive, as thyroid cancer is very treatable.

The principal treatment for all types of thyroid cancer is surgery. Removal of the entire thyroid gland is general protocol; this procedure is known as a thyroidectomy. In some cases, the cancer will spread beyond the thyroid gland and appear in the lymph nodes of the neck and upper chest, which then must also be removed from the body[4]. Typically, surgery alone cures thyroid cancer, especially if it is small. However, if the cancer has spread or has a high chance of recurrence, radioactive iodine therapy is utilized.

Radioactive iodine ablation is extremely effective for destroying normal and cancerous thyroid tissue[5]. The patients consume radioactive iodine (RAI or I-131) in liquid or capsule form[6]. Once inside the body, the radioactive iodine behaves like any other radioactive treatment for cancer, circulating through the bloodstream and destroying residual cancer from the infected site. Other healthy cells in the body are not affected as they do not readily absorb the radioactive iodine. Treatment with radioactive iodine (RAI or I-131) emits beta and gamma radiation. The beta particles have an extremely short range in tissue; they travel only two millimeters and are responsible for destroying the cancerous cells. These particles do not leave the body and present no risk to others. The emission of strong electromagnetic waves due to gamma radiation however, does create potential hazards for those in close proximity to the patient. Consequently, the patient him/herself becomes radioactive for a certain amount of time following treatment – depending on the dosage. Using the accepted half-life of I-131 to be 8.01 days and the average dosages of RAI therapy, it has been determined that patients remain radioactive for six weeks following treatment[7]. The radioactive iodine I-131 is formed as a product of the nuclear fission of uranium[8]. As it decays, the radioactive iodine changes into metastable xenon (X-131) as shown in the figure below.

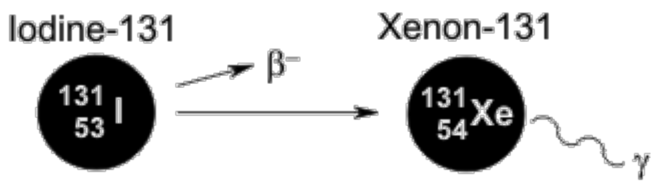


Figure 2: Decay chain of I-131. Retrieved from http://www.geigercounter.org/radioactivity/isotopes.htm

The side effects of radioiodine vary from patient to patient, depending on age, height, weight, dosage, and a conglomeration of other factors. Self-limited side effects include nasal irritation, impermanent bone marrow suppression, amenorrhea, sialadenitis – inflammation of salivary gland, gastrointestinal pain, and dysgeusia – foul taste in the mouth. In a minimal percentage of patients, salivary and nasolacrimal duct obstruction and xerostomia account for other non self-limited side effects. For the patient, one of the most concerning of all radioactive iodine therapy side effects is the possibility of returning malignancies caused by the potential loss of activity in the remaining thyroid cells. However, in an objective comparison study of the side effects and toxicities of over the counter aspirin and RAI therapy, ingesting I-131 is “far safer” than utilizing aspirin as treatment[9]. As for potential harm to others, the subjects most at risk for second-hand radiation are patients’ family members and physicians/caretakers. The radiation can enter the healthy tissues of those surrounding patient, mutating the DNA[7]. To avoid exposure to others, especially children and pregnant women, patients are required to evade engagement with humans. In the past, patients from Mayo Clinic were advised to be in complete solidarity for three days and nights. The patients could not use the same bathroom as others, nor the same eating utensils for eight weeks[10]. Since advancements on the topic have been made, it has become protocol that the patient who ingested the iodine must remain one meter away from others for six weeks while the radioactive iodine is decomposing. Since RAI therapy is the only known practical and effectual systemic tumoricidal therapy for differentiated thyroid cancer patients at this time, a device is needed that alerts the patient when this one-meter space is breached to effectively reduce the amount of second-hand radiation exposure in the weeks following radioiodine treatment.

Problem Statement

Radioactive iodine (^{131}I) can be used to destroy malignant tissue in patients with serious thyroid disorders. While this method is effective in treating the patient, remnants of the ^{131}I remain in the body for up to six weeks post-treatment, and can be harmful to others in close or prolonged proximity. Patients that are discharged from the hospital post-treatment are warned about the negative effects of the radioactive iodine on others. A previous BME Design team designed a device in the form of a belt to notify the patient, via a buzzer and indicator LED, when a human breached a one-meter radius around the wearer. Our client, Dr. John Webster from the Biomedical Engineering Department, has requested a new device to be worn by the patient that would provide a more effective and discrete alert when individuals approach within this one-meter radius. The device must be able to detect when a human approaches from any direction, and should provide the wearer with a clearly observable form of feedback when proximity is detected. The device should not detect inhuman entities, and should not detect the wearer’s body. The device must be designed and fabricated within a one semester timeline using a budget of $100.

Current Devices

There are currently no devices on the market to detect human proximity that relate to our requirements. General solutions exist for detecting living objects, such as motion detectors and Microsoft Kinect cameras; however, they are not adaptable to be worn by a patient and do not exclusively detect human motion.

Radiation Distance Safety Meter - Fall 2013/Spring 2015

Both Fall 2013 and Spring 2015 semesters' BME Design teams created wearable devices to detect human proximity. Both devices consisted of an Arduino connected to distance and thermal sensors, all attached to a belt to be worn by the patient around the waist. The first team designed the device with one pair of sensors (1 distance and 1 thermal) and a horizontal field of view of approximately 15 degrees[11]. The second team used two pairs of sensors and found a horizontal field of view of approximately 120 degrees[12]. Testing both devices showed that the device could not "ignore" signals originating from the wearer. As a result, any motion from the wearer's arm moving in front of the sensor would trigger the device, setting off the LED and buzzer indicators.

RaDistance Safety Meter - Fall 2014

In Fall 2014, a BME Design team developed an Android and iOS application to wirelessly determine distances from the smartphone to a physical beacon. The application measures approximate radiation exposure based on the measured distances and logs the information for each application user[13]. The application calculates the distance from each beacon fairly accurately, but does carry the assumption that the patient and all others that may come in contact with the patient have a smartphone with the application installed to their phone.

Design Requirements

There were a number of requirements requested by the client in order to make an effective device for thyroid patients. In terms of any sensors used, they must not detect any errant background signals. As with some of the previous designs, the thermal sensors were not calibrated to ignore other heat sources, such as a stovetop. If a person were to wear the device and walk past a steam vent on the street, the device may trigger even though there was not another human in range. It is also necessary that the device detects a full 360° around the wearer. Some of the previous designs only detected directly in front of the wearer, but many of the people not detected would be behind the wearer, where they cannot see and therefore cannot avoid proximity as well. The sensors must alert the wearer if the signal is within one meter of the user, but should not alert the wearer if their own arm passes in front of the sensor.

As far as the physical device, the design must be wearable for six weeks. If the device is to get dirty, it must be washable or have all electronic elements removable so that the other elements may be washed. Additionally, the device must be comfortable enough for a patient to wear all day long for six weeks. This requirement should be considered for both daily use and for the total use of six weeks. The device should not have any elements protruding unnecessarily that will interfere with the wearer's daily activities, and should not be too heavy or bulky for the patient to endure for a six-week period. The device must also be robust enough to not be damaged by daily use for the six weeks, and will be preferably reusable between patients. The batteries must be either easily recharged or replaced, or last for the entire six-week period. Overall, the device must be wearable and functional for six weeks of constant use.

Device Configuration

Alternatives

The first major aspect of the RaDistance Safety Meter design focuses on the design of the device to be worn by the patient. An ideal device would avoid interference from the wearer while detecting any human motion within one meter from any direction. All devices need to be able to last for at least six weeks of continuous wear as well as washing, as the patients will wear the device nearly continuously for the duration of recovery. Comfort and aesthetics are also large considerations. Three similar designs for the wearable device have been developed: A belt, a headband, and a chest harness. Each uses an Arduino Pro Mini microcontroller powered by batteries.

Belt

The first device design is the belt, as seen in Figure 3. A woven nylon belt containing the sensors, microcontroller, and battery pack as shown could be easily worn by the patient. A simple clip at the front would allow the patient to take the belt on and off as needed. The sensors would be equally spaced around the belt to gain a 360^0 view around the patient.

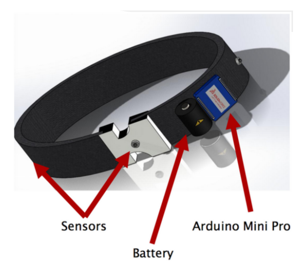


Figure 3: Belt device design

Headband

The second design alternative is a detachable headband worn around a hat so that it can be washed by the patient (Figure 4). This design would also have the sensors located equidistantly all the way around the wearer's head. The other hardware would either be mounted on the headband itself, or worn on the patient's waistband and connected via a wire.

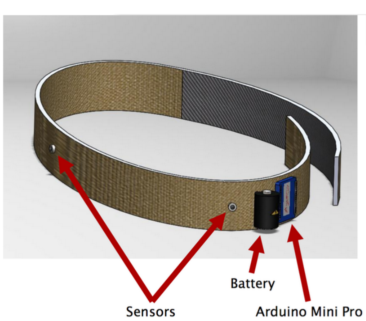


Figure 4: Headband device design

Chest Harness

The third and final design (Figure 5) is an elastic chest harness with straps over the shoulders and around the trunk. Sensors would be located on the front, shoulders, and back of the harness. In order to improve comfort while sitting, the battery pack and microcontroller

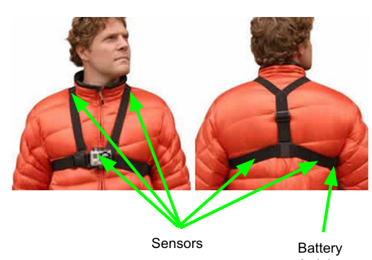


Figure 5: Chest Harness device design

would be mounted on the side of the trunk strap. A clip at the front would allow the harness to be taken off easily.

Design Matrix

Criteria (weight) / *Device*	*Weight*	Belt		Fitted Headband for Hat		GoPro-style Chest Mount	
Accuracy	30	*2*	*12*	*4.2*	*25.2*	*4*	*24*
Field of View	20	*4*	*16*	*3*	*12*	*5*	*20*
Wearability	20	*3*	*12*	*4.5*	*18*	*4*	*16*
Durability	10	*4*	*8*	*4*	*8*	*4*	*8*
Cost	5	*4*	*4*	*4*	*4*	*4*	*4*
Safety	5	*4*	*4*	*3*	*3*	*4*	*4*
Aesthetics	5	*3*	*3*	*3*	*3*	*2*	*2*
Ease of fabrication	5	*4*	*4*	*3*	*3*	*3*	*3*
Total	*100*	*63*		*76.2*		*81*	

The team chose to evaluate the device designs based on eight criteria: accuracy, field of view, wearability, durability, cost, safety, aesthetics, and ease of fabrication. The RaDistance Safety Meter's primary function is to alert the wearer when humans or animals approach. For this reason, accuracy - how well the device can detect movement without interference from the wearer - was given the largest weight of 30. A device that could be constantly set off with movements from the patient or by passing objects would not be functional. The team defined field of view as the area in which the device can detect individuals, and gave this a weight of 20. If the device is unable to detect human motion from all sides, it cannot adequately alert the patient of individuals within a one-meter radius. These two categories are the most important when considering the final device design.

Wearability and durability were also important considerations. In order for the patient to properly use the RaDistance device for up to six weeks of treatment, it will need to be easy to wear and perform daily activities in. The device will also not be effective if it cannot withstand six weeks of constant wear.

The other four criteria were all given a relatively low weight of five. The team plans on reusing some materials from previous groups as well as creating a custom circuit board rather than ordering one to keep costs low for all design cases. Safety is always a concern, but the team felt that the nature of the device did not imply inherent danger to the patient and therefore did not need to be weighted strongly. Aesthetics also received a low weight because it is more important that the device be functional than fashionable. The overall look of the design was still considered as the patient will need to be wearing this device at all times throughout the treatment period. Finally, the team considered fabrication. It was decided that all designs could confidently be fabricated with the team's skill set; thus, this was not a large concern.

By evaluating the three device designs based on the design matrix criteria, the team was able to make a decision on the final design. The belt design, while simple and cost effective, was ruled out due to inaccuracies caused by the wearer's arms as they swing past the sensors. The headband design is extremely easily worn around the head of the patient and durable as it can be removed from the hat for washing. Because it is on the head, the headband design results in the least wearer interference and, therefore, the highest accuracy. On the other hand, height differences in the patient could cause the sensors to miss small children or pets. The team decided to move forward with the chest harness design, which provided the greatest field of view as the sensors could be placed all around the patient. Because the sensors will be placed higher on the patient, the interference from upper limbs will be minimized. Although the chest harness is less aesthetically pleasing, the benefits of the design outweigh the costs.

Sensors

Alternatives

The other major aspect of the RaDistance Safety Meter design is the sensors used to detect people and objects around the wearer of the device. The sensors used need to be able to distinguish human beings from inanimate objects, and they also need to accurately identify the distance between the device and the wearer and only alert the wearer when this distance is less than or equal to one meter. The sensors used must be small enough to fit onto the type of wearable device chosen and must be rugged enough to account for the daily stress put onto the device as the user wears it.

Passive Infrared with Ultrasonic Distance Sensor

The first sensors chosen as possible for use in the distance meter took cues from the previous semester's design by using passive infrared sensors (Figure 6) combined with ultrasonic distance sensors (Figure 7). Passive infrared sensors (PIR) measure changes in infrared radiation in an environment as a way to detect motion. Humans are warmer than their surroundings and emit heat radiation in the form of infrared light. PIR sensors are able to accurately detect this radiation and with it differentiate living objects from surrounding inanimate ones[14]. PIR sensors are combined with ultrasonic distance sensors in order to tell the device when an object is within one meter. Ultrasonic sensors work by interpreting the echoes of sound waves in order to determine an object's distance. By utilizing the two sensors in tandem a person can be identified and if its distance is within one meter it can trigger the device so give the wearer feedback.

Figure 6: SainSmart HC-SR04 distance sensor

Figure 7: SainSmart HC-Sr501

3D Depth Sensor

Another type of sensor that would fit this type of device is a 3D depth sensor like the ones used in the Xbox Kinect (Figure 8). These sensors use an infrared projector that projects a 3-dimensional grid onto its field of view. Any people within this field of view can be tracked through the sensor's software which finds the joints in a human skeleton to track ranges of motion and distance between the sensors and the various joints being tracked. The sensor also contains a monochrome CMOS sensor which obtains video data in any ambient light condition.

Figure 8: Kinect 3D depth sensors

Micro-Electro-Mechanical System

Micro-electro-mechanical system (MEMS) is technology of very small size that usually consist of a small microprocessor and several small microsensors that interact with the surroundings. MEMS have a wide variety of current applications such as in accelerometers and pressure sensors as well as ultrasound transducers similar to the ones used with the PIR arrangement which is shown in Figure 9.

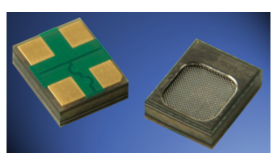


Figure 9: MEMS Ultrasonic Transducer

Design Matrix

Sensor *Criteria (weight)*	***Weight***	**PIR with Distance**		**3D Depth Sensor**		**MEMS**	
Accuracy	30	*3*	*18*	*4*	*24*	*3.5*	*21*
Field of View	30	*5*	*30*	*2*	*12*	*3*	*18*
Cost	25	*4*	*20*	*2*	*10*	*1*	*5*
Size	10	*3*	*6*	*4*	*8*	*5*	*10*
Safety/Aesthetics	5	*3*	*3*	*2*	*2*	*5*	*5*
Total	***100***	***77***		***56***		***59***	

The three sensor options considered for use in the prototype were PIR with Ultrasonic Distance, 3D Depth Sensor, and MEMS sensors. The parameters used to compare the sensors were accuracy, field of view, cost, size, and safety/aesthetics. Accuracy and field of view were given the highest weight of the parameters because the sensors need to have the largest field of vision to approach 360-degree as well as being accurate enough to detect human beings and distinguish them from other objects. Price also had a high weight since the cost of the sensors affected how many the design was able to afford. Naturally if more sensors could be bought then larger fields of vision could be achieved. Finally, size and aesthetics were considerations because the sensors could not be too large that they would be hard to mount on the wearable device and they also could not inhibit motion.

The PIR paired with ultrasonic distance sensors had the largest field of view of the three options which was tied to their cost. Their low cost allowed for the purchase of five pairs of sensors that could be used to achieve a very wide field of vision for a low cost. This option also is the easiest to put together from a programming standpoint since it only needs to be connected to an Arduino with some basic code. The 3D depth sensor stood out by being the most precise and technologically advanced. While this means the device would give very accurate readings it also means the programming necessary to get the device to run would take a lot more time and energy. The budget also meant that the device would have lower field of view simply because the cost of buying the sensor only allows room for one. Finally, the MEMS sensors placed highest in the size and safety/aesthetics categories. Their naturally small size means many would fit on a harness but since it is hard to find a specific sensor that fits the design specifications these sensors scored lower.

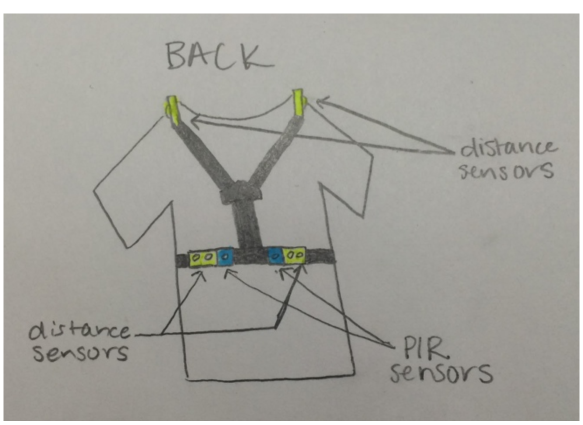
After putting the sensors through the matrix the PIR and ultrasonic sensor arrangement was chosen because of its high field of vision and relative cheapness. In conjunction with the wearable harness the five pairs of sensors could be arranged to achieve a very high field of view.

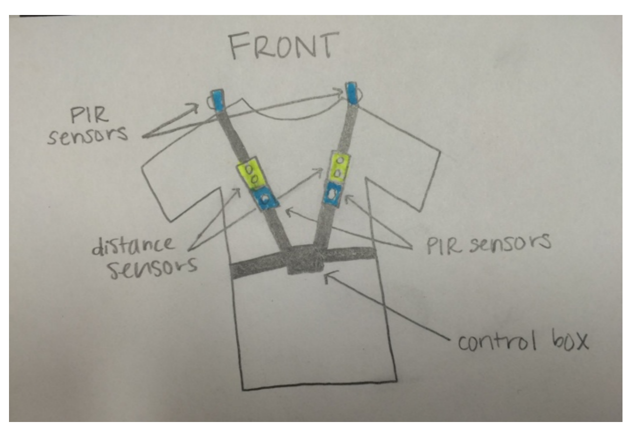
Proposed Final Design

After evaluating the matrices for the different aspects of the design, our team chose the GoPro style chest mount outfitted with PIR and Ultrasonic Distance sensors. This design offers the best field of view and overall functionality. With seven pairs of sensors placed strategically on the chest mount, our design will be able to detect humans within one meter from all directions. Although the chest mount design will not be the most aesthetically pleasing nor the easiest to fabricate, the benefits of increased accuracy and visibility outweigh the drawbacks.

The purpose of the sensors is to detect objects only within a specific temperature range of mammals. When paired with distance sensors, the device will only indicate when mammals are within one meter. Vibration motors on each side of the chest mount will alert the patient if something has been detected for more than two seconds. The two second delay will allow the patient to avoid being alerted when someone passes him/her briefly. The sensors will be placed pointing in all directions, including downward to ensure the detection of small children and pets.

Our design will be battery operated. The battery will be stored next to a control box on the lower side of the chest mount, along with a breadboard and an Arduino Pro Mini. We will program the device to associate the PIR and distance sensors with each other, as well as induce a vibration when there is a detection within one meter. Finally, the design plans include easily removable sensors. This will allow the skeleton to be washed and disinfected before switching to the next patient.





Fabrication/Development Process

Materials

SHINEDA® Chest Harness Mount for GoPro

The chest mount we purchased is able to accommodate for the 360-degree field of view we desired. The plastic faceplate has two protrusions for a J-clip to attach to, providing the GoPro support. We were able to remove the protrusions from the faceplate so the control box could be mounted on a flat surface. The mount, comprised of adjustable semi-elastic straps, can readily accommodate for different body sizes.

Arduino Pro Mini (5V, 16 MHz)

A microprocessor was needed to interface with the sensors and motors and handle any computation required to give vibratory feedback to the user. Many hobbyists use the Arduino Uno for their hardware, due to its dedicated power ports and female rail connections - wires can be plugged directly into the board's pins. Because we wanted a very compact design, we chose to use the Arduino Pro Mini; this board still provides enough pins to use a large amount of sensors, provides the 5V power source required for the sensors, and is much smaller than the Uno, measuring 1.8cm by 3.3cm. The board requires a serial converter, about the same size as the Pro Mini with a USB attached to one end. This allows the Arduino to connect to the USB drive on a computer, which can then upload software to the board.

HC-SR501 Pyroelectric Infrared Sensors

In order to detect human motion, we bought seven pyroelectric infrared sensors (although one arrived defective). The sensors are powered by 5V and have a digital output of 3.3V when a human passes in front of the beam. Looking at the datasheet, the sensors are able to be attenuated to 3 meters, and have an adjustable delay ranging from 5 seconds to 300. Upon arrival and initial testing, we found the sensors detect motion of any object, so we are unable to only pick up human motion. We were able to attenuate the sensors to 5 meters, and learned the delay adjustment changes the length of time the sensor outputs 3.3V. Upon detection, the sensor immediately outputs 3.3V for a minimum of 5 seconds. Each sensor has an operational field of view of a 120-degree cone. Using six sensors, the device is able to sense movement from any direction.

HC-SR04 Ultrasonic Distance Sensors

To measure the distance of an object to the device, we ordered seven distance sensors. Each sensor is powered by 5V, and has a trigger and an echo pin. When the trigger pin receives a 5V pulse for at least 10 microseconds, it sends a 5V output signal through the echo pin. The length of the pulse can be measured using the Arduino, which can be converted into distance. Dividing the pulse length by 58.2 (first by 29.1 to convert to distance, then by 2 to get distance in one direction) returns the distance to the object in front of the sensor in centimeters. The operational field of view of the sensors is rather small, at approximately thirty degrees. Because of this, it may be difficult for the device to detect proximity; with six sensors, only 180 degrees of the full 360 are theoretically accounted for, leaving blind-spots. After testing the sensors, the distance calculated by the Arduino is very accurate.

Adafruit Vibrating Mini Motor Discs

To signal to the wearer that a human has been detected within a meter, we chose to use vibrational feedback, as it would not be observable by others. We placed four of the vibrating discs on the mount: two on each side underneath the armpit, and two on top of each shoulder. The motors are enabled by a digital pin on the Arduino when detection is within 1 meter.

iDaye 14000 mAh External Battery

In order to power the device for an extended period of time, we decided to use a rechargeable power bank commonly used to charge mobile devices, such as cell phones and MP3 players. Using a high capacity power bank would prevent the wearer from having to charge the device daily or replace disposable batteries. The iDaye power bank has a power button on the side to control when the devices will be charged, so the device can be powered off to save battery life if the wearer will be away from others for an extended period of time. Because the battery pack uses Smart USB charging, it will remain on while significant power is being drawn. After experimentation, the Arduino alone did not use sufficient power in order to keep the device powered on. We were able to keep the power bank on by connecting a short circuit to the second USB port or by keeping a cell phone connected to the second USB port. Obviously neither solution is ideal, as sufficient power is lost to the short/phone, draining energy rapidly from the power bank. A power bank without Smart USB charging should be used instead.

Circuit Elements

We originally planned on using the UA741 operational amplifier, but after some testing, we determined it would be unable to produce the results we wanted. We had planned on using the op amp to boost the 3.3V output of the PIR sensors to 5V, which would allow us to trigger the distance sensors anytime the PIR sensors detected human motion. Having the PIR sensors trigger the distance sensors simplifies the code a bit, because the PIR sensor outputs would not have to be connected or read by the Arduino at all. The UA741 had to be powered by the 5V supply from the Arduino, although because it is not a “rail-to-rail” op amp, it is unable to amplify any signal up to be exactly the supply voltage of 5V. Discovering this later in the semester, we were unable to find reasonably priced rail-to-rail op amps that would arrive on time.

After removing the op amps from our circuit schematic, we were able to remove the other circuit elements (transistors and resistors). The only material we needed to connect the sensors and motors to the Arduino was a standard 400-point breadboard. The Arduino connections were wired directly to the breadboard, so the Arduino pins could be accessed by directly plugging the sensor/motor wires into the breadboard.

3D Printed ABS Plastic Sensor Housings

There were a few different options when it came to sensor housings, but the group decided on using lightweight durable plastic in lieu of wood or metal. We chose to use acrylonitrile-butadiene-styrene, or more commonly referred to as ABS[15]. While plastic is less vulnerable to rust than metal, and more durable than wood, it is also harder to form into the correct shape unless large scale industry tools or a 3D printer is used. As this is a prototype, the group decided that 3D printing made more sense and would be adequate to produce robust housings.

The first problem we experienced with the mountings was getting them to remain stuck to the same place on the table as they were being printed. The table has to be heated as well as the extruder to get the plastic to the correct temperature and consistency to bind with itself as new layers are added[15]. That being said, a heated table tends to lead to the housing sliding around and not printing properly. The solution that was eventually implemented was to use a thin layer of Elmer's glue from a glue stick on the printing tape. This made the bottom-most layer of the plastic stick to the table well enough that the housing printed properly.

Another issue we had to face was the hole in the middle of the housing to fit the sensor. This made the structure weak and it would sag as it printed. We got the idea from our research to use reinforcements, which we later cut off with an Exacto knife[16].

The next problem was getting the correct temperatures and settings on the 3D printing software. This took the most time, research, and experimentation. While search engines like Google can provide starting points for temperature settings, environmental conditions mandate empirical tests to find the correct levels to print with. This took a great deal of time, since in many cases we didn't know whether the product was up to our expectations until it was done printing and could be handled. Often, the ABS had not bound to itself well, and the entire mold would break into the individual foliations, rendering it useless. Eventually the correct temperatures were found, and then printing could commence at a regular pace.

The final issue with these mountings was how to clip them onto the harness. We designed a number of different ideas for the clip, but each had either the problem of needing to be printed separately and then glued to the rest of the mount, or having foliations along the bending point causing it to fail under relatively little shearing stress and making the clips weak. After some research we tried to make ABS glue, by dissolving ABS in acetone, but this did not work very well[17]. Eventually the best solution was determined to be a Lazy-S shape similar to that of a clip on a pen. This could be printed into the bottom of the mounting, and at its thickest point was resistant enough to bending to be clipped on and off a few times before snapping.

If this device were ever to leave the prototype stage, injection molding would have to be used to make the housings sturdy enough in a timely manner. That being said, injection molding is too expensive for a prototype and was not available to the team for this project.

Methods

Arduino Connections

To maintain overall organization of the wiring and prevent cross-connections, the Arduino Pro Mini was placed immediately adjacent to a standard breadboard. The 5V supply (VCC) and ground (GND) were wired to the breadboard supply and ground tracks to provide power for the breadboard, and 19 data input/output pins (7 analog, 12 digital) were wired directly to individual 5-pin tracks of the breadboard. All sensor and motor connections are then connected to these breadboard tracks. Four supply and four ground wires leave the control box at the bottom edge, and provide power and ground connections to the sensors and motors. The sensor data connections and motor power connections are wired through the right side of the control box, and are plugged directly into the breadboard.

The sensors and motors all have one pin for power and one pin for ground. The PIR sensors have an additional pin for a digital output (OUT), which produces 3.3V when it is tripped. The distance sensors have two additional pins: a trigger (TRIG) that accepts a 5V input to begin ranging, and a digital echo output (ECHO) that outputs a 5V signal for a period of time. Because the output signal occurs after it has been triggered for 10 microseconds, the two pins on the sensor can be wired together to one breadboard pin, as long as the Arduino code changes the pin-mode before reading the signal.

Physical Construction

To use the Arduino pins more easily, we wired the connections directly from the Arduino to the breadboard. To start, we soldered the 26 wires we would need onto the Arduino pins (5 for the USB connection, 2 for power/ground, 16 for data pins, 3 extra in case of defects) and placed the Arduino and breadboard inside the control box from the previous design team’s device. Once inside, the Arduino wires were connected straight into the breadboard, and the 5 USB wires protruded out of the control box from the left side. The 16 data pin wires were wired from the breadboard to the exterior of the control box, through three holes (6 wires each through 2 holes, 4 wires through the last hole) on the right of the control box. The control box and power bank were then secured to the faceplate of the chest mount using JB Weld. The sensor housings were then placed on the chest mount, secured with wires if necessary. The wires were connected to the sensors, placed in the housings, and wired appropriately to the control box and connected to the data connections. The vibration motors were placed and connected to the data connections as well. Heat shrink tubing was used to cover the exposed soldered connections.

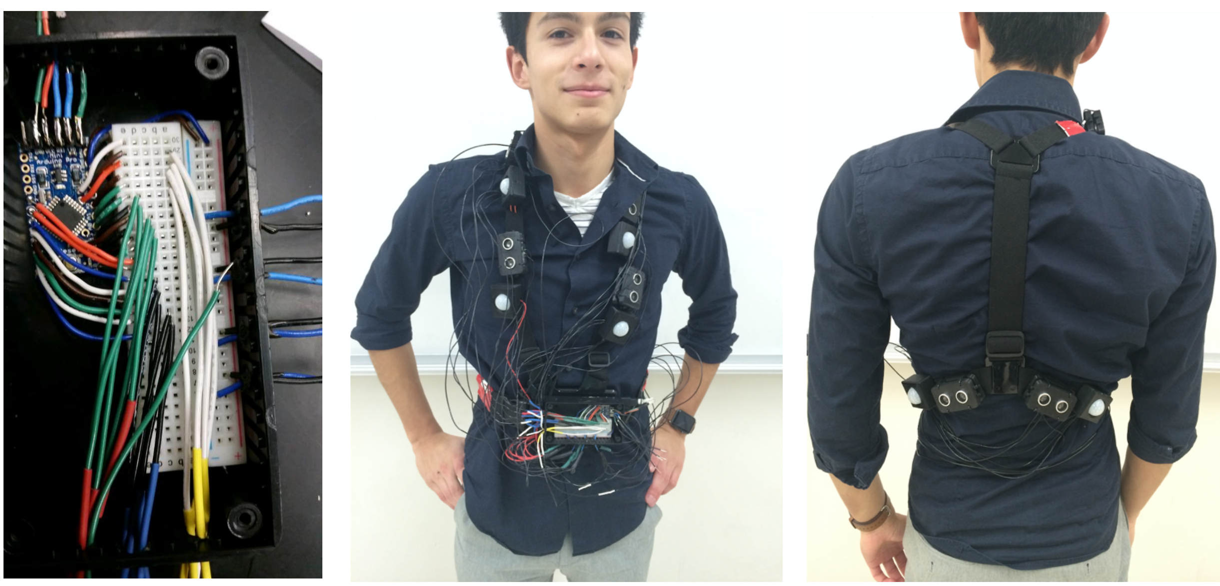
Distance Sensor Testing

A simple testing protocol was used to assess the accuracy of the distance sensors. One distance sensor was connected to the Arduino Pro Mini and was triggered every 10 milliseconds. A tape measure was placed on the floor, beginning at the distance sensor and extending approximately 3 meters. A team member stood at various points along the tape measure, and both the sensor-measured and actual distances were recorded.

Prototype Timing Testing

While wearing the device, a team member stood still, with small squares of tape marking a 1-meter horizontal radius around the device. Using a smartphone stopwatch, the time for the device to begin vibrating was recorded. The time was started once a second team member entered the 1-meter radius and was stopped once the device's motors turned on. Thirty data points were obtained, each indicating the time for the device to register the 1-meter proximity, whether it be the team member slowly walking past the front, side, or back.

Final Prototype



The final design consists of six PIR sensors paired with six ultrasonic distance sensors, placed on a semi-elastic chest mount: two pairs of sensors are on the chest and point forward, one pair resides on each shoulder, and two pairs are located on the back. The design originally called for seven pairs of sensors, but had to use only six due to a defective PIR sensor. One vibration motor is placed on each shoulder, and another motor is placed on each flank underneath the armpit. The control box at the front combines the sensor inputs/outputs to the Arduino Pro Mini, which determines when to activate the vibration feedback. The Arduino reads the PIR sensors' outputs, and if any of them are at a high voltage, it adds them to a "pending" array. Then, each "pending" sensor activates the corresponding distance sensor and records 5 distance measurements, averaging them to determine how far away the detected object is. Sampling five distances simulates a short delay on the device; if a person were to quickly walk past, the device may not register the close proximity and may not vibrate, which was one optional goal for the design. If the sensed object resides less than 1 meter away from the sensor, the Arduino remembers which sensor recorded the object via a Boolean (a value that is either true or false). The software then pulses the vibration motors three times if any of the distance sensors recorded an average distance of 1 meter or less. The software then loops back and reads the PIR sensors once again, repeating this cycle indefinitely.

Results

Accuracy Testing

The HC-SR04 Ultrasonic distances were tested individually for their accuracy across a range that would typically be expected when the device is normally in use a range of about 5cm- 200cm. As shown in the table when distances very close and very far were tested the sensor was less accurate. This is presumably because when the person was very close the echo signal interfered with the trigger signal causing the sensor to only send back a small portion of the echo, leading to a longer registered distance.

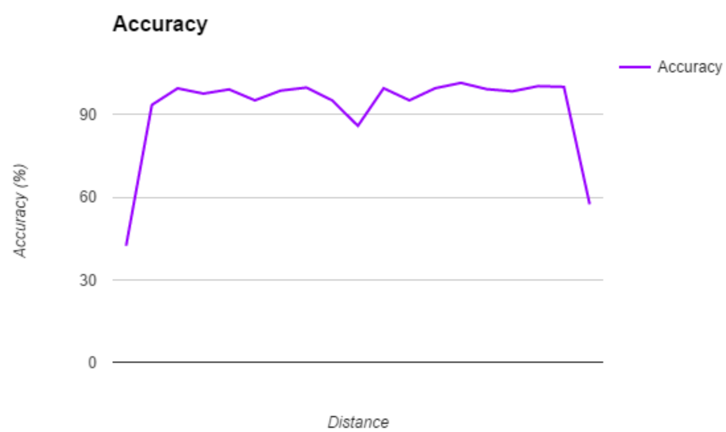


Figure 10: Plot of distance sensor accuracy at different distances

Prototype Timing Testing

After collecting thirty data points, the mean and standard deviations were calculated. On average, the device took 3.74 seconds to detect an object within 1 meter, with a standard deviation of 1.14 seconds. The empirical rule shows that 68% of data falls within the first standard deviation, and 95% fall within the first two standard deviations. This reveals that 95% of detections will occur within 6.02 seconds, which is a very reasonable "delay," considering short term exposure is not a vital concern.

Discussion

Fabrication

One of the largest drawbacks with this design, in terms of patient satisfaction, is the bulkiness of the wiring, power bank, and control box. To improve safety, durability, and wearability, the circuitry would ideally be internalized within the harness itself. This would include the wiring, microcontroller, and power bank, as well as the sensors and vibrational motors. These changes would allow for a more seamless appearance, and would improve patient comfort. Integrating the circuitry into the harness would eliminate the potential for the wearer to dislodge any wiring from the control unit. Streamlining the device would also increase the marketability, as current wearable electronics focus greatly on minimalism and appearance.

In future, a battery without Smart USB charging would be preferred. Smart USB charging requires a significant power draw from a connected device, or it will automatically power off. Eliminating this would allow for more efficient battery use and, consequently, extended battery life.

A breadboard was used for the device's circuitry, due to breadboards being very cheap and easy to work with. A breadboard, however, is very prone to having wires or other connections being jostled and accidentally removed. If a device were to be manufactured in larger quantities, a cheap circuit board could be printed, allowing for a precise op amp to be used. Using these elements, the device would become very slim, and would eliminate some software. Using an op amp, the PIR output voltage could be amplified high enough to trigger the distance sensor, which removes the need for the Arduino to poll the PIR sensors altogether.

Software

Due to the Arduino's simple construction, the software that must be written to implement a design can become quite complex. The software consists of two functions: one function called setup, which executes once, and another called loop, which repeats indefinitely. Because of the Arduino's loop functionality, it is more difficult to program features that occur over time than it is on a more complex machine. For example, if a motor is to be turned on for two seconds, the programmer can simply write a high voltage to the motor's Arduino pin, use the 'delay' method to pause system operation for two seconds, and then write a low voltage to the motor's pin. During these two seconds, however, the Arduino has been put on hold, and cannot perform any task until the pause is over.

Using many delays in Arduino programs increases the amount of program down-time, causing the programmer to have an inefficient program. Instead of using the 'delay' method, the programmer would have to use a Boolean value to indicate when to start or stop the process, and a global counter variable to determine exactly when operations should occur. This allows for multitasking, but can get quite messy when multiple tasks are being performed in the single loop function. Because we do not want to overwhelm the wearer of the device with excessive vibration, we decided to use the 'delay' method when sending the vibration pulses. While the vibration pulses are occurring, the Arduino is not calculating any distances, nor is it reading the output of any

PIR sensors. These normal operations will resume after the vibrations, allowing sufficient down-time for the wearer.

Conclusion

The RaDistance Safety Meter met the design requirements as specified by the clients, Dr. Webster and Dr. Hagi. This device has the capability to detect human presence in a 360-degree field of view of the wearer and alert the patient of such a presence. Further, this device is durable and can be worn by patients of all figures, as it is adjustable, both around the waist and shoulders. This device was developed and produced for under $100; we believe this device could have a successful future in the medical device market. There is room for significant improvement however. A more ergonomic design of the shoulder harness can be implemented to ensure the mobility and comfort of the patient. This can be easily accomplished if a higher budget is put in place by the clients, Dr. Webster and Dr. Hagi. The expectations of the higher quality of accuracy and detection are too high given the circumstances of this course. Dr. Hagi and Dr. Webster are both extremely knowledgeable on the topic and can further improve the RaDistance Safety Meter by supplying higher caliber components and refining the testing of the current device.

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Appendix A

Product Design Specifications - RaDistance Safety Meter
Current as of: October 4, 2015

Clients:	Prof. John Webster	webster@engr.wisc.edu
	Dr. Sarah Hagi	sarahhagi@gmail.com
Advisor:	Prof. Beth Meyerand	memeyerand@wisc.edu
Team:	Kieran Paddock, Team Leader	kdpaddock@wisc.edu
	Alex Smith, Communicator	asmith42@wisc.edu
	Christina Sorenson, BSAC	csorenson2@wisc.edu
	Rebecca Alcock, BWIG	ralcock@wisc.edu
	Gregory Wolf, BPAG	gdwolf@wisc.edu

Function:

Radioactive iodine (^{131}I) can be used to destroy malignant tissue in patients with serious thyroid disorders. While this method is effective in treating the patient, remnants of the ^{131}I remains in the body for up to six weeks post-treatment, and can be harmful to others in prolonged, close proximity. Patients that are discharged from the hospital post-treatment are warned about the negative effects of the radioactive iodine on others. A previous BME Design team designed a device in the form of a belt to notify the patient, via a buzzer and indicator LED, when a human is within one meter. Our client, Dr. John Webster from the Biomedical Engineering Department, has requested a new device to be worn by the patient that would provide a more effective and discrete alert when individuals approach within a one-meter radius. The device must be able to detect when a human approaches from any direction, and should provide the wearer with a clearly observable form of feedback when proximity is detected. The device should not detect inhuman entities, and should not detect the wearer's body.

Client Requirements:

- Must detect a human within one-meter of the patient from any direction.
- Must provide effective feedback to alert patient about human proximity.
- Must be able to distinguish between the patient's body and somebody else's body.
- Must be comfortable and durable enough to be worn for six weeks.
- Must be battery driven and have a battery-life of at least one day.

Design requirements:

1. Physical and Operational Characteristics

A. **Performance Requirements**: The device must be able to function all day for six weeks. The wearer will most likely not be moving at night, but the device should remain operational in case of sleepwalking incidents. It must have a 360-degree horizontal field of view of the patient's surroundings, and must not be triggered by the patient's own body, or any other objects that are non-human. When an individual is detected within one meter of the device, it should emanate an alert, whether auditory, visual, or sensory, to alert the wearer and/or individual to maintain a one meter distance.

B. **Safety**: This device must not be excessively heavy or inhibit the wearer's normal motion. Electrical wires must be insulated and contained, not exposed, and any sensor must be able to operate near humans for extended periods of time.

C. **Accuracy and Reliability**: The device must be able to detect individuals within one meter. Any signal from further than one meter must be ignored by the sensors. Any signal originating from the wearer or from a non-human object must also be ignored.

D. **Life in Service**: The device must be usable for six weeks at a time, so any batteries used must either last for those six weeks or be easily replaceable or rechargeable. If batteries are used, the device should be able to operate for a full day without needing battery recharging or replacing.

E. **Shelf Life:** In order to be used effectively by the patient, the device must be durable enough to last at least six weeks. Ideally, it would last much longer in order to be used by multiple patients.

F. **Operating Environment**: The patient will wear the device for up to six weeks, in private or public areas. Most often, the patient will be in a home setting where human interaction is low, but may also be in public settings, such as buses or clinics, where human interaction is higher. The device should not be subject to great deals of stress, but should be able to handle normal wearer body movements. It should be able to sustain some impact in case of accidents or wearer misuse. The device should be able to operate normally under extreme weather conditions for use in winter, summer, rain, or other weather situations that could be potentially hazardous to the device. The device should be operational in -30 to 40 degrees Celsius, and should be water resistant in case of rain or snow, as well as liquid spills.

G. **Ergonomics**: This device must be comfortable to wear or use for up to six weeks after treatment. The patient should not feel burdened by wearing or using the device, as this will increase their likelihood of not using the device. If the device interferes with normal daily activities, the patient may remove the device and potentially harm others.

H. **Size**: The device should be adjustable to accommodate for a variety of body types; however, the function of the device should not be affected depending on its size configuration. The device should retain a low profile while being worn, both to increase patient comfort and remain inconspicuous to others.

I. **Weight**: The device should not be too heavy as to inhibit wearability or the user's range of motion. The total weight of the whole design should not exceed 5 kilograms, but should ideally stay under 3 kilograms to retain a low profile.

J. **Materials**: Non-toxic and lightweight materials should be chosen so the wearer is not harmed by wearing the device and is not burdened by wearing it. The materials used should also be relatively cheap to accommodate for the limited budget.

K. **Aesthetics, Appearance, and Finish**: The device should be aesthetically pleasing, as the patient will be wearing it for a minimum of six weeks. There should be no physical features that could harm the patient, such as rough or sharp edges. There must also not be any exposed wires or free-hanging elements that may harm the patient or get in his or her way.

2. Production Characteristics
   A. **Quantity**: One functional prototype will be designed. It should be kept in mind that the design should be simple enough to reproduce, so more may be easily manufactured for future use.

   B. **Target Product Cost**: The project has an out-of-pocket budget of $100. If an extended budget is needed, a budget extension proposal can be made to Dr. John Puccinelli.

3. Miscellaneous
   A. **Standards and Specifications**: The design will not be used for research or on patients as of now; however, since it is a medical device, the design should conform to FDA standards to make future development simpler.

   B. **Customer**: This product will be designed for patients treated with therapeutic doses of radioactive iodine to correct thyroid complications.

C. **Patient-related concerns**: The device should be comfortable to wear and non-toxic, so it does not become a burden to the patient. It must also be able to distinguish between the wearer and other people approaching the device in order to accurately alert the patient when to maintain a distance from others.

D. **Competition**: There are no known products on the market designed to alert radioactive iodine patients about human proximity; currently the patients are only *instructed* on how to prevent affecting others.

Appendix B

Arduino Code

```
/// Define arrays for sensor pins (pir output, distance trigger input/echo output)
/// When defining array, pairs need to match: if pirPins goes {Chest, Shoulder, Back, etc.},
/// distPins needs to follow the EXACT SAME order.
int pirPins[] = {A5, A0, 13, A6, 12, 11};
int distPins[] = {4, 5, 6, 7, 8, 9};
int past1[5];
int past2[5];
int past3[5];
int past4[5];
int past5[5];
int past6[5];
/// Define pin for vibration motors
int motorLShoulderPin = A4;
int motorRShoulderPin = A3;
int motorLSidePin = A1;
int motorRSidePin = A2;
void setup() {
  Serial.begin(9600);

  // Initialize each pin as input or output, initially write distance trigger pins to LOW
  for (int i = 0; i < sizeof(pirPins); i++) {
        pinMode(pirPins[i], INPUT);
        pinMode(distPins[i], OUTPUT);
        digitalWrite(distPins[i], LOW);
  }
  // Initialize motor pin to output, initially write to LOW
  pinMode(motorLShoulderPin, OUTPUT);
  digitalWrite(motorLShoulderPin, LOW);
  pinMode(motorRShoulderPin, OUTPUT);
  digitalWrite(motorRShoulderPin, LOW);
```

```
  pinMode(motorLSidePin, OUTPUT);
  digitalWrite(motorLSidePin, LOW);
  pinMode(motorRSidePin, OUTPUT);
  digitalWrite(motorRSidePin, LOW);
  // Allow sensors to setup, 30 seconds max.
  delay(15000);
  Serial.println("begin");
}
void loop() {
  int count = 0; // Variable counting how many PIR sensors tripped
  int pending[6]; // Array to hold PIR array indices that were tripped
  // For each PIR sensor, determine if it was tripped, and add to 'pending' array if tripped
  for (int i = 0; i < sizeof(pirPins); i++) {
        if (digitalRead(pirPins[i])) {
        pending[count] = i;
        count++;
        }
  }
  bool dist1go = false;
  bool dist2go = false;
  bool dist3go = false;
  bool dist4go = false;
  bool dist5go = false;
  bool dist6go = false;
  // For PIR sensors that were tripped, find the distance away from the distance sensor
  // If under 1 meter, start the vibration cycle
  for (int x = 0; x < count; x++) {
        int pin = distPins[pending[x]];

        for (int z = 0; z < 5; z++) {
        digitalWrite(pin, HIGH);
        delayMicroseconds(10);
        digitalWrite(pin, LOW);
        pinMode(pin, INPUT);
        long distance = pulseIn(pin, HIGH) / 58.2;
        pinMode(pin, OUTPUT);

        if (pin == 4) {
        past1[z] = distance;
        } else if (pin == 5) {
        past2[z] = distance;
        } else if (pin == 6) {
        past3[z] = distance;
        } else if (pin == 7) {
```

```
past4[z] = distance;
} else if (pin == 8) {
past5[z] = distance;
} else {
past6[z] = distance;
}
}

if (pin == 4) {
int average = 0;
for (int y = 0; y < sizeof(past1); y++) {
average += past1[y];
}
average /= 5;
if (average > 100) {
dist1go = false;
} else {
dist1go = true;
}
} else if (pin == 5) {
int average = 0;
for (int y = 0; y < sizeof(past2); y++) {
average += past2[y];
}
average /= 5;
if (average > 100) {
dist2go = false;
} else {
dist2go = true;
}
} else if (pin == 6) {
int average = 0;
for (int y = 0; y < sizeof(past3); y++) {
average += past3[y];
}
average /= 5;
if (average > 100) {
dist3go = false;
} else {
dist3go = true;
}
} else if (pin == 7) {
int average = 0;
for (int y = 0; y < sizeof(past4); y++) {
```

```
        average += past4[y];
        }
        average /= 5;
        if (average > 100) {
        dist4go = false;
        } else {
        dist4go = true;
        }
        } else if (pin == 8) {
        int average = 0;
        for (int y = 0; y < sizeof(past5); y++) {
        average += past5[y];
        }
        average /= 5;
        if (average > 100) {
        dist5go = false;
        } else {
        dist5go = true;
        }
        } else {
        int average = 0;
        for (int y = 0; y < sizeof(past6); y++) {
        average += past6[y];
        }
        average /= 5;
        if (average > 100) {
        dist6go = false;
        } else {
        dist6go = true;
        }
        }
}

if (dist1go || dist2go || dist3go || dist4go || dist5go || dist6go) {
        digitalWrite(motorLShoulderPin, HIGH);
        digitalWrite(motorRShoulderPin, HIGH);
        digitalWrite(motorLSidePin, HIGH);
        digitalWrite(motorRSidePin, HIGH);
        delay(300);
        digitalWrite(motorLShoulderPin, LOW);
        digitalWrite(motorRShoulderPin, LOW);
        digitalWrite(motorLSidePin, LOW);
        digitalWrite(motorRSidePin, LOW);
        delay(300);
```

```
        digitalWrite(motorLShoulderPin, HIGH);
        digitalWrite(motorRShoulderPin, HIGH);
        digitalWrite(motorLSidePin, HIGH);
        digitalWrite(motorRSidePin, HIGH);
        delay(300);
        digitalWrite(motorLShoulderPin, LOW);
        digitalWrite(motorRShoulderPin, LOW);
        digitalWrite(motorLSidePin, LOW);
        digitalWrite(motorRSidePin, LOW);
        delay(300);
        digitalWrite(motorLShoulderPin, HIGH);
        digitalWrite(motorRShoulderPin, HIGH);
        digitalWrite(motorLSidePin, HIGH);
        digitalWrite(motorRSidePin, HIGH);
        delay(300);
        digitalWrite(motorLShoulderPin, LOW);
        digitalWrite(motorRShoulderPin, LOW);
        digitalWrite(motorLSidePin, LOW);
        digitalWrite(motorRSidePin, LOW);
        delay(2000);
  }
}
```