RaDistance Safety Meter

Mid-Semester Report

Biomedical Engineering Design 200/300
Department of Biomedical Engineering
University of Wisconsin – Madison
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Abstract

This design project seeks to minimize the exposure of individuals to the harmful radiation from thyroid patients' treatment. Currently, thyroid patients are instructed to stay at least one meter away from others to prevent the residual radioactive iodine from damaging others. 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. Therefore, the goal of this design is to eliminate the risk of harming others by residual radiation by creating a device to warn the patient when others are within one meter of his/her body. The device will be worn by the patient for six weeks, and must function and endure daily stress for this period of time. The device should detect any human within a meter of the patient, from any direction, and warn the patient by an observable form of feedback.

In regards to the configuration of the overall device, there were three primary alternatives that would be suitable to the project. The first alternative is a belt with sensors placed equidistant around the waistband, a mirror of previous devices with a simple implementation. The second alternative is a band worn around a hat, similar to the belt but without the inaccuracy drawbacks from the belt design. The third alternative is a chest harness, placing sensors in multiple locations to achieve a 360-degree field of view, while avoiding inaccurate detection. Considering specific sensors that may be used to detect humans, there were three alternatives as well. The first sensor option pairs Passive IR and Ultrasonic Distance sensors, for a completely circular field of view at a relatively low cost. The second option is a 3D Depth sensor, much like the Kinect camera, which guarantees human detection, but with more difficulty and at a higher cost. Lastly, MEMS sensors were considered, a very accurate and low profile category of sensors, which could be difficult to obtain. Assessing design matrices for both the device configuration and which sensors to use, it was decided to design a chest harness system utilizing PIR and Ultrasonic Distance sensors. Granted the sensors can be interfaced effectively with the Arduino Mini Pro microprocessor and mounted appropriately on the RaDistance device, any human within one meter of the patient wearing the device should cause the microprocessor to alert the wearer with vibrational motors. Having effective alerts when humans are detected close by is crucial in ensuring that others are not affected negatively by the patient's treatment.

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Background:

Thyroid cancer has become a more common diagnosis over time. Whether it is due to improvements in detection or increased rates of occurrence, there is data to show that thyroid cancer frequency has increased over the past several decades[1]. Looking at the data for the United States alone, the prevalence of thyroid cancer has tripled over the past thirty years and is expected to grow by about fifty percent in the next five years[1].

Treatment of thyroid cancer often involves the use of radioactive iodine (I-131). Differentiated Thyroid Cancer (DTC) constitutes 3.8% of all cancer cases in the United States, and is most commonly treated by a thyroidectomy, followed by radioiodine treatment to remove any residual disease[2]. This involves the patient consuming radioactive iodine in either liquid or capsule form. Once inside the body, the radioactive iodine behaves like any other radioactive treatment for cancer, circulating through the bloodstream and removing residual cancer from the infected site. The downside of this treatment is that it can potentially, and at times does, cause additional damage[1].

For low risk DTC patients, radioactive iodine treatment is being studied due to its possible adverse effects. The most notable side effects are lacrimal and salivary gland dysfunction[2]. To avoid exposing more people than is necessary to these possible side effects, the patient who has ingested the iodine must remain one meter away from others for six weeks while the radioactive iodine is decomposing. It is difficult to keep a patient away from others for six weeks in a hospital, so they are sent home. It is then up to the patient to maintain a distance from others and to be aware of when other humans are present. This responsibility of the patient could be alleviated if the patient had an automated indicator as to when there were others within one meter of their body.

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 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. The device must be designed and fabricated by the end of this semester with a budget of $100.

Current Devices:

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

Radiation Distance Safety Meter - Fall 2013/2014

Both Fall 2013 and Fall 2014 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. The second team used two pairs of sensors and found a horizontal field of view of approximately 120 degrees. 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 - Spring 2015

Last semester, 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. 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 and also have 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 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.

Design Alternatives - Devices

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 Mini Pro microcontroller powered by batteries.

Belt

The first device design is the belt, as seen in **Figure X**. 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.

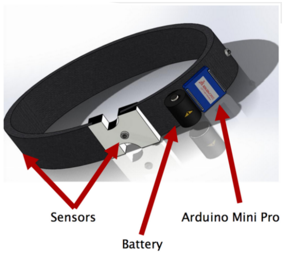

Figure 1: Belt device design

Headband

The second design alternative is a detachable headband worn around a hat so that it can be washed by the patient (**Figure Y**). 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.

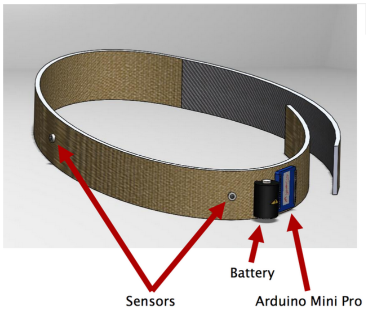

Figure 2: Headband device design

Chest Harness

The third and final design (**Figure Z**) 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 would be mounted on the side of the trunk strap. A clip at the front would allow the harness to be taken off easily.

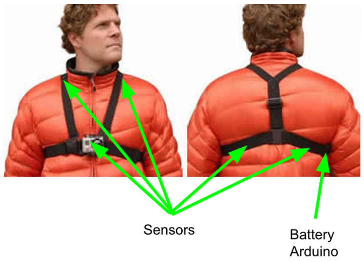

Figure 3: Chest Harness device design

Design Alternatives - Sensors

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 P) combined with ultrasonic distance sensors (Figure Q). Passive infrared sensors (PIR) measure changes in infrared radiation in an environment as a way to detect motion[3]. 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. PIR sensors are combined with ultrasonic distance sensors in order to tell the device when an object is within one meter away. 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 as to give the wearer feedback.

Figure P: SainSmart HC-SR04 distance sensor

Figure Q: 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 R). 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 R: 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 micro sensors 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 S.

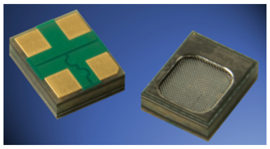

Figure S: MEMS Ultrasonic Transducer

Design Matrices:

Devices Matrix:

Device *Criteria (weight)*	*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 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 degrees, 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 aesthetic 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, shown in **Figure T**. 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 be able to detect mammals within one meter. Vibrational motors on each side of the chest mount will alert the patient which side something has been detected for more than two seconds. The two second delay will

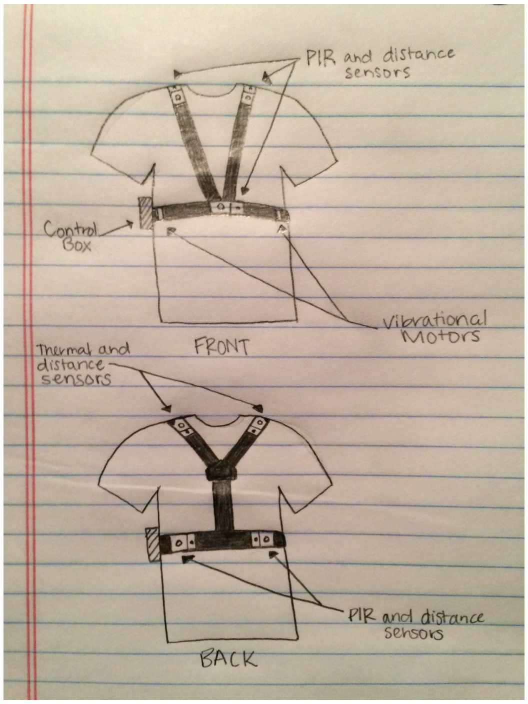

Figure T: Final design sketch

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.

Our design will be battery operated. The battery will be stored in a control box on the lower side of the chest mount, along with a circuit board and an Arduino Pro Mini. We will program the device to pair the PIR and distance sensors, 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.

Future Work:

Currently, the most pressing step is to order materials. Since we will be ordering nearly all of the materials online, we will be placing orders within the next week to ensure an appropriate arrival time. While we await the materials arrival, further research into the details of the design will be carried out. We plan to examine the software needed for our device in order to pair the two types of sensors, as well as include the vibrational alerts.

Our design would benefit greatly from using a Printed Circuit Board (PCB), because of its smaller size and more reliable and permanent connections compared to using a breadboard. PCBs on the market are typically very expensive when ordering only one or a few, and otherwise require large order minimums. In order to reduce cost on our limited budget and to have a customized product, we are planning on using a Do-It-Yourself method to create our own PCB. Creating the PCB has a fairly straightforward procedure, consisting of transferring the laser-printed (must use toner, not ink) circuit schematic onto a blank copper circuit board, and then using PCB Etchant to remove the exposed copper. Once the toner is removed, the copper tracks for the desired circuit remain[4]. We will need to find a way to acquire the PCB etchant and can try to obtain Liquid Tin for tin plating, which would make the PCB operate more efficiently.

The software integration for our device should be a straightforward aspect of the project as well, but may be difficult to implement due to the simplicity of the Arduino system. We plan to use the Arduino Mini Pro, which accepts 4 analog inputs. We will be using 7 distance sensors and must be able to read discrete distance values; therefore, an analog multiplexer must be used in order to use all 7 sensors with the Arduino. As far as the programming portion, Arduinos operate using two functions: the “setup” function sets up pins, hardware, and global variables (variables that cannot be reset at each iteration of the loop function), and the “loop” function continually runs its code while the Arduino is connected to power. Because there is one function that executes over and over again during runtime, creating larger scale Arduino implementations that do more than one process are more difficult to program. It would be very easy to program an Arduino to change the color of an LED based on a distance sensor input, because during every iteration of the loop, the Arduino reads the input and outputs the correct color. When we create our application, we must continually check for detections from our thermal sensors, and only then accept input from the distance sensors, operating the vibrational motors if the input dictates to do so.

Arguably the most important aspect of our future work will be testing the prototype. Testing will determine the competency of our prototype, including the level of accuracy and range of field view. To test these features of our design, we will map out a one-meter radius surrounding the device. The test subject wearing the device will be approached in all directions to see if the prototype meets our goal of alerting the patient when there is a human within one meter. If the patient is alerted when approached from all directions, we will have met our goal and the prototype will be considered successful in its field of view.

We will also have to test the battery life of our device. Thorough tests will be done to ensure a battery-life sufficient up to a minimum of 18 hours. Members of the team and willing volunteers will wear the device for 18 hours. If the device remains powered on and completely functional for the entire 18 hours, the device will be considered to have a sufficient battery life.

References:

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[2] S. Clement *et al.,* “Intermediate and long-term adverse effects of radioiodine therapy for differentiated thyroid carcinoma – A systematic review,” *Cancer Treatment Reviews,* 2015.
[3] "How Infrared motion detector components work". Non commercial research page. Glolab Corporation. Retrieved 2013-05-31.
[4] AP Digital light., “DIY Printed circuit board,” *Instructables*, 2008.

Appendix:

Project Design Specifications:

Product Design Specifications - RaDistance Safety Meter

Current as of: October 4, 2015

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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.