Product Design Specifications - RaDistance Safety Meter

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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.