1. PROBLEM STATEMENT

Although health monitoring equipment can save lives, elderly people have the most difficulty wearing it consistently, citing inconvenience of wearing it and difficulty to upkeep. The aim for VitalWeave is to make wearing these devices much easier and comfortable for the elderly.

1.1 Need Statement

Heart disease is the leading cause of death in the United States, causing about 1 in 4 deaths [1]. To effectively combat it, people need to monitor their own health. According to Statistica, out of 410 respondents, over half said they used a wearable device to monitor their fitness activity [2]. Nearly 50% of users of wearable devices rely on technology in their daily life [3]. Elderly people can benefit from this monitoring, but about 23% of seniors do not wear their heath monitoring devices for the full amount of time requested by their doctors [4]. Falling is also common among the elderly. While not falls result in any injury, about 37% of those who fall reported an injury that required medical treatment or restricted their activity for at least one day, resulting in an estimated nine million fall injuries [5]. There is a need for a user-friendly device that can help the elderly track and maintain their health.

1.2. Objective Statement

The objective of this project is to design a non-intrusive compression shirt that integrates multiple health monitoring systems while being convenient and easy to use. Sensors in the clothing track different vital signs such as ECG signals, respiration rate, and blood pressure. The shirt also utilizes a fall detection system to detect serious injuries. Information from these sensors is then logged so that the user or a doctor can easily access any medical information recorded from the device.

1.3. Background and Related Work

Many wearable devices are currently used for health monitoring; however, most of these are specialized devices and do not measure all vitals. They can also be cumbersome for the elderly, as these devices tend to be technologically heavy and may require some interaction. This is especially prevalent in fall detection devices, as most of these are implemented through watches. By not being near the user's center of gravity, these products allow for more discrepancies when detecting falls. Many smart watches are capable of tracking vital signs, such as heart rate, respiratory rate, and ECG signals. The Astroskin compression shirt measures ECG signals, blood pressure, breathing rates, sleep patterns, temperature, and detects falls. However, a drawback of this shirt is its short battery life. Since the product relies on AA batteries for power, users have to swap them out every 48 hours, resulting in additional costs to run the product. VitalWeave uses low-power sensors and methods to mitigate power consumption. Users also complained about sensor placement and inaccuracies, as they cannot be obscured and need to be stable [6]. This takes away from promoting an active lifestyle and leads to excessive intrusion. This problem will be resolved by using more slim and lightweight sensors, as well as taking advantage of slim conductive materials like copper tape. The database they used for Astrolskin was also filled with complaints, as it was found to be unpolished and difficult to navigate [6]. VitalWeave provides a lightweight compression shirt that accurately tracks vitals and displays information on a user-friendly interface that is easily accessible by wearers and their doctors.

2.1 DESIGN REQUIREMENT SPECIFICATIONS

The following section outlines the marketing requirements, engineering design requirements, constraints, and standards taken into consideration during the prototyping, testing, and implementation phases of VitalWeave.

2.1 Requirements

In service to the needs of the target audience, VitalWeave holds several essential capabilities. The marketing requirements outline VitalWeave's functions, while the engineering requirements define specific metrics that the device meets to achieve desired performance. These requirements are detailed in the following sections.

2.1.1 Marketing Requirements

VitalWeave's marketing requirements are outlined as such:

1. The device takes blood pressure accurately.
2. The device has fall detection mechanisms.
3. The device reads oxygen levels precisely.
4. The device reads ECG waves accurately.
5. The device snugly fits the user's body.

Figure 2-1 shows the objective tree that lays out the device's goals.

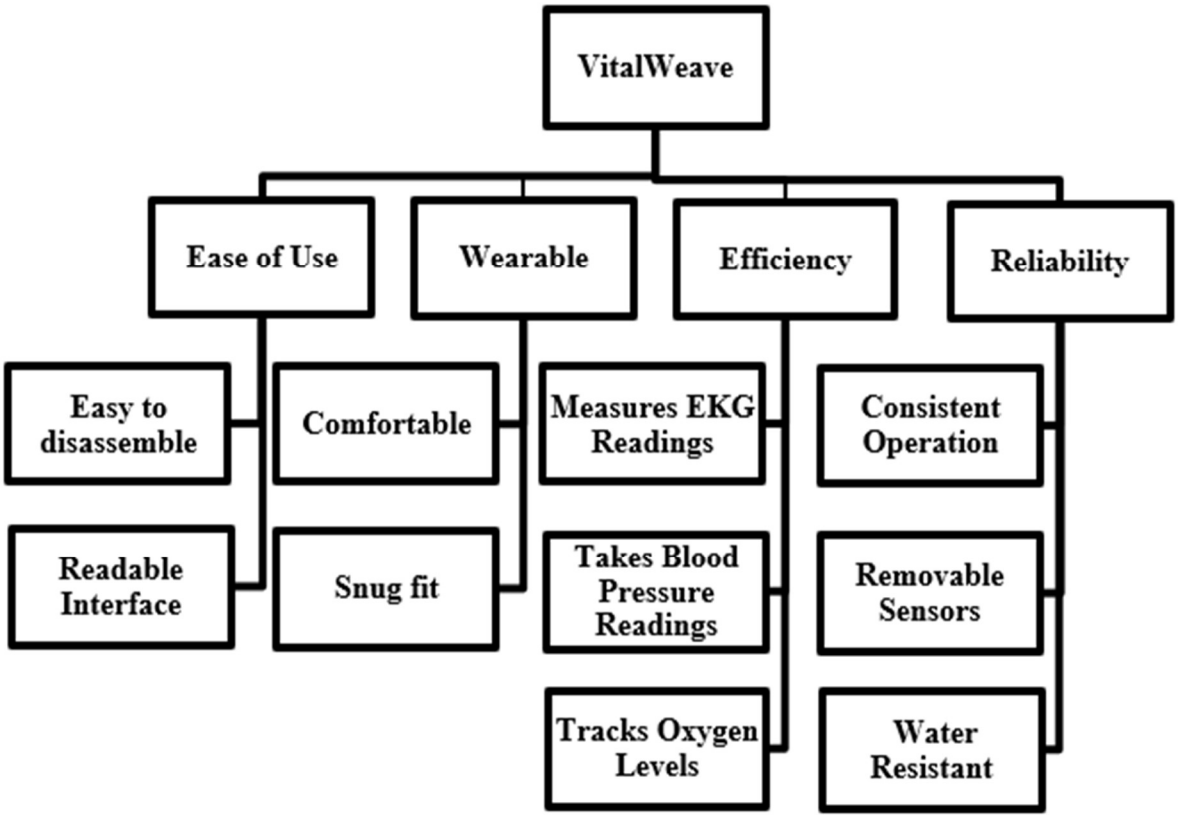

Figure 2-1: Objective Tree for VitalWeave

The objective tree provides an outline for VitalWeave's overall goals and objectives, which are divided into categories. The necessary design conditions to accomplish these goals are evaluated in the engineering requirements.

2.1.1 Engineering Requirements

Table 2-1 presents the engineering requirements that must be met to satisfy the marketing requirements enumerated in Section 2.1.1.

Table 2-1: Engineering Design Requirements

Marketing Requirements	Engineering Requirements	Description
1	The blood pressure monitoring system is capable of measuring and recording blood pressure with an accuracy of ±3 mmhg.	This ensures that users receive reliable readings, supporting effective health monitoring.
2	The fall detection system will be able to identify the user falling by monitoring acceleration.	This enables timely alerts in case of falls, enhancing user safety.
3	The device measures oxygen levels with an accuracy of ±2% SpO_2.	Accurate readings help users monitor their oxygen saturation effectively, which is crucial for respiratory health.
4	ECG signals must have a dynamic range of + or - 5mV	Accurate ECG signals with + and – 5mV dynamic range allows for the capture of normal and abnormal ECG signals.
5	The device will fit tightly but comfortably on the user and will be simple to put on and take off.	A compact form factor ensures more accurate readings, promoting continuous health monitoring without discomfort.
Marketing Requirements 1. The device takes blood pressure accurately. 2. The device has fall detection mechanisms. 3. The device reads oxygen levels precisely. 4. The device reads heart rate accurately. 5. The device snugly fits the user's body.		

VitalWeave includes a semi-manual blood pressure cuff and pump system to allow the user to monitor his or her blood pressure at any time. Blood pressure measurements deviating by more than ±3 mmHg from a precise reference monitor are considered inaccurate, as even small variations can impact clinical assessments [7]. Vital Weave aims to provide the same level of accuracy to avoid misdiagnosis or inappropriate treatment adjustments.

The fall detection system analyzes acceleration patterns to detect sudden changes indicating a fall. Ensuring accurate detection is critical, as false positives may cause unnecessary emergency responses, while false negatives could leave a person without timely assistance in a medical emergency.

VitalWeave monitors blood oxygen levels to help users track their respiratory health and detect potential warning indicators such as poor circulation. Pulse oximeters typically measure blood oxygen saturation with an accuracy of ±2% to ±4% of the actual SpO_2 level, ensuring reliable monitoring of a user's oxygen status [8]. By ensuring precise SpO_2 measurements, VitalWeave provides users with trustworthy data for managing their health effectively.

The ECG monitoring system provides users with accurate insights into their cardiovascular health, whether at rest or during physical activity. Accurate ECG signals with a ±5mV dynamic range allow for the capture of both normal and abnormal ECG patterns, ensuring comprehensive cardiac monitoring [9]. Ensuring accurate heart rate monitoring across different activity levels is crucial, as large discrepancies could lead to misinterpretations of performance or undetected arrhythmia.

VitalWeave is designed as a slim-fitting piece of clothing to ensure comfort, ease of wear, and high accuracy in health monitoring. A close fit enhances sensor contact with the skin, reducing movement artifacts and improving the reliability of measurements such as heart rate, blood oxygen levels, and blood pressure.

2.2 Constraints

Table 2-2 describes the constraints imposed on VitalWeave's design process which include budget, time, size, power, comfort, and durability.

Table 2-2-: Constraints

Type	Name	Description
Economic	Cost	The total budget of VitalWeave is $1000.
Economic	Time	The system will have all subsystems completed by the end of April 2025 and the full product by the end of November 2025.
Manufacturability	Size	Each monitoring subsystem will be small enough to be embedded into a shirt.
Energy	Power	VitalWeave is powered using standard consumer grade batteries.
Usability	Comfort	VitalWeave should be comfortable and non-invasive to wear.
Reliability	Durability	VitalWeave will be made out on durable material to reduce wear and tear on the shirt.
Reliability	Water-Resistance	VitalWeave will need to have water resistance, to ensure the sensors can operate while the user sweats.

VitalWeave is marketed to snugly fit the user's body and as a result needs to be overall comfortable to wear. The size and comfort constraints ensure that VitalWeave's monitoring subsystems are small enough to be embedded in the shirt, as well as comfortable and non-invasive to daily activities.

Batteries are inexpensive and commonly found. VitalWeave will be powered by standard commercial grade batteries as stated in the power constraint, to ensure it is easy to power and maintain.

Clothing such as shirts are susceptible to damage and tears which lower the product's lifetime. The Durability constraint ensures that the shirt is made of durable material, raising the lifetime of VitalWeave.

VitalWeave helps promote an active lifestyle. In order to ensure this, VitalWeave should be water resistant, to help the sensors operate when the user is sweating, or when the user

2.3 Standards

VitalWeave is a device that will be used to monitor data from the body, thus it will need to abide to various different engineering standards as listed below in Table 2-3.

Table 2-3: Engineering Standards

Specific Standard	Standard Document	Specification / Application
ISO 60601:2014	Sets electrical safety and essential performance requirements for medical electrical devices [10].	Ensuring that there are no leakage currents by enclosing all wires and circuits, and its devices are removable. All devices will be within a slim form-factor, allowing for accurate data collection from the body.
Title 21 CFR Part 11	Ensures electronic records are trustworthy, reliable, and equivalent to paper records [11].	The data will be transferred using an Adhoc network, allowing for secure peer-to-peer connection.
ISO 10993:2020	Ensures materials used in the shirt are biocompatible and do not cause irritation or toxicity [12].	The materials used for the shirt will be tested and proven to not be harmful under the suit's operation.
ISO 81060:2022	Ensures accuracy, safety and performance for manual sphygmomanometers [13].	The shirt will rely on a sphygmomanometer to read the users blood pressure.
ISO 13485:2016	Ensures medical devices are safe and effective throughout their lifecycle [14].	The health monitoring shirt has to promote safety at all points in its battery life, in order to ensure consumer health.

Specific Standard	Standard Document	Specification / Application
ISO 80601-2-61:2017	Addresses environmental resistance for electronic wearables [15].	The devices within the shirt will be surrounded with material that will help resist sweat, water, and other liquids and foreign objects.

These standards guarantee that VitalWeave is safe for users, promotes security, and is accurate. They include guidelines to manage leakage currents, provide trustworthy user privacy, promote user safety while wearing the shirt, promote accuracy in blood pressure monitoring, and ensure it maintains accuracy.

2.4 REFERENCES

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