Testing and Evaluation Plan

EGR 555: Mechatronics Device Innovation

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SoleTech

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3 Smart Sole Inserts

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Functional Requirements

1. Pressure sensing: The socks must accurately measure the pressure (weight) applied on the patient's foot with each step to determine weight distribution.
    - The pressure sensors will be tested by placing the pressure-sensitive socks on the patient's feet and asking them to walk on a flat surface. The data collected by the sensors will be compared to the actual weight distribution of the patient's feet. This will be done for different walking speeds and on different surfaces to ensure the accuracy and consistency of the pressure sensing.
2. Bio-feedback: The haptic feedback should be clear and easily distinguishable by the user to provide meaningful feedback on their gait.
    - The haptic feedback will be tested by asking the patient to walk with the device and provide feedback on the intensity and clarity of the vibration. The feedback from the patient will be used to adjust the intensity and duration of the vibration to ensure that it is easily distinguishable and provides meaningful feedback to the patient.
3. Initial contact detection: The socks should be able to detect which part of the foot made initial contact with the ground during walking.
    - The sensors will be tested to determine their ability to detect which part of the foot makes initial contact with the ground during walking. This will be done by analyzing the data collected by the sensors and comparing it to video recordings of the patient's gait to ensure that the device accurately detects the initial contact.
4. Stance time and stance length measurement: The socks must accurately measure the amount of time the foot is in a stance phase and the length of the stance phase.
    - The socks will be tested to determine their ability to accurately measure the amount of time the foot is in a stance phase and the length of the stance phase. This will be done by comparing the data collected by the sensors to video recordings of the patient's gait and data collected from other gait analysis tools to ensure accuracy and consistency.
5. Stride measurement: The socks must measure the length of each stride and the number of strides taken during a given period.
    - The socks will be tested to determine their ability to accurately measure the length of each stride and the number of strides taken during a given period. This will be done by comparing the data collected by the sensors to video recordings of the patient's gait and data collected from other gait analysis tools to ensure accuracy and consistency.
6. Cadence measurement: The socks must measure the rate at which the user walks to determine their cadence.
    - Cadence means the rate of walking. It is typically measured as the number of steps per minute. The IMU has an inbuilt pedometer that can be used to measure

steps. The team will check if the IMU can measure the cadence of patients with gait disorders. Depending on that team can adjust the tolerances.

7. Spatial characteristics measurement: The socks must accurately measure the distance traveled and movement angles by the user during the gait analysis.
    - The team can calculate the roll, pitch, and yaw from complementary sensor fusion between the gyroscope and accelerometer and also try to reduce gyro drift. Integrating the values from the accelerometer twice to calculate the positional characteristics of the device. The team will test it on patients and measure the noise of the sensor date. The team can also implement an external Kalman filter or fuse more types of sensors by using the AHRS algorithm.
8. Durability: The socks should be able to withstand repeated use and be made of materials that are suitable for use.
    - The team will use SolidWorks Xpress to analyze the materials used in the device, mainly the sole pressure sensor as well as the electronics housing. This will allow them to perform stress analysis. The materials must pass the stress test.
9. Data collection and storage: The socks should have the ability to store data or transmit live data for further analysis and sharing with healthcare providers.
    - To ensure enough storage capacity for the device, it's recommended to have at least 1 GB of internal storage. At least 10 minutes of the data will be stored on board (locally) to tackle any disconnections. The amount of data that will be stored is still uncertain, so the team may require more storage if needed.

<u>Performance Requirements</u>

1. Accuracy: The socks should be able to accurately measure the pressure applied on the patient's foot during gait analysis.
    - The results from the tests conducted by the team members wearing the sock will be compared with the results obtained from existing equipment in the client's lab. Based on the deviation, the addition of filters to reduce noise will be implemented.
2. Precision: The socks should provide precise measurements of the patient's walking pattern, stance phase time, initial contact, and time shift.
    - The part of the code used to calculate the stance phase time, initial contact, and time shift will be fine-tuned until the noise obtained is minimized.
3. Sensitivity: The socks should be sensitive enough to detect where pressure is distributed.
    - Each point on the pressure sensing insole is tested individually and the code used to measure the pressure will be optimized until the slightest change using standard weights on either pressure sensor can be detected accurately.
4. Speed: The socks should provide live data to the therapist and patient, with minimal lag time.
    - The socks will be tested on one of the team members and on each trial the sensor data being transmitted will be monitored to determine if there is any lag. Based on

the observations further action (ex: removing the interference, improving range, and so on) to minimize the lag will be taken.

5. Reliability: The socks should have consistent performance over time, without noticeable degradation.
    - The sock prototype will be tested by the team members multiple times and the results obtained will be analyzed to see whether the data obtained for each member is consistent across all trials. Based on the observations improving the prototype (ex: optimizing the battery, designing the build in a better way to avoid wear and tear, and so on).
6. Durability: Regular wear and use should not damage the socks.
    - To test the durability of the gait analysis sock, one of the team members will be selected to wear the socks for an extended period under regular conditions. After a predetermined period, the socks will be put through rigorous daily use and examined for any signs of wear and tear. The results of the examination will be recorded and analyzed to determine the durability of the socks.
7. Compatibility: Various sizes and styles of footwear should be compatible with the socks.
    - To test the compatibility of the gait analysis sock team members with different foot sizes and shapes and a variety of shoe sizes and styles will be selected. The volunteers will wear the socks with the different shoes and report any discomfort or issues with fit. Feedback will be gathered through a survey or interview and analyzed to determine the compatibility of the socks with different shoe sizes and styles, as well as different foot sizes and shapes.
8. Portability: The socks should be lightweight and portable, allowing for easy transport and use in various settings.
    - To assess the portability of the gait analysis sock, the volunteers will be provided with the stockings and the necessary equipment for carrying and storing the socks throughout the day. Volunteers will be instructed to wear the socks throughout their daily activities (e.g. walking, running, etc.) and provide feedback on the ease of carrying and storing the socks. The feedback will be analyzed to determine the portability of the socks in various settings and situations.
9. Connectivity: Data collection and analysis should be possible through wireless connections between socks and a computer or mobile device.
    - To test the connectivity of the gait analysis sock, the socks, and computer/mobile device will be set up in a controlled environment. The distance between the socks and the computer/mobile device will be measured, and the wireless connection will be tested by moving the socks further away from the computer/mobile device until the connection is lost. The process will be repeated multiple times to obtain reliable data, which will be analyzed to determine the maximum distance that the wireless connection can reach.

10. Power efficiency: The socks should have a long battery life and be energy-efficient to reduce the need for frequent charging or replacement of batteries.
    - To test the power efficiency of the gait analysis sock, the socks will be fully charged and volunteers will be instructed to continuously wear the socks until the battery dies. The time it takes for the battery to die will be recorded and analyzed to determine the socks' average battery life and power efficiency.

Usability Requirements

1. Easy to put on and take off: Socks must be designed to be easy to put on and take off so as not to cause discomfort or harm to the user.
    - The socks will be worn by the team members with various feet size multiple times throughout the testing period and checked whether it is easy to wear and take it off based on the survey method.
2. Comfortable: Socks should be made of soft, breathable material to ensure maximum comfort during use.
    - Soul tech team members will wear the socks for a prolonged period and will be checked if the socks are providing any discomfort to the user. The comfortability of the socks will be benchmarked with that of the normal socks and checked for the minimal difference so that it does not interfere with the gait analysis. skin irritation or other health hazards due to the usage of this product will also be checked.
3. Secure fit: Socks must fit securely to prevent them from slipping or moving during use, which can affect the accuracy of the data
    - The product will be worn by multiple teammates with various foot sizes and checked for fitting during rapid movements and patterns. By performing extreme walking patterns it can be identified if the socks do not loosen or slip. The fitting of components in the device is regularly monitored and checked whether it is rigidly stable during erratic motion.
4. Easy to clean: socks must be easy to clean after each use to maintain good hygiene and prevent the spread of infections.
    - By using alcohol wipes, disinfectant spray, and other modes of cleaning, the product will be cleaned and checked if it is easy to clean and the product does not get damaged due to cleaning it multiple times.
5. User-friendly interface: The device must have a user-friendly interface so that both the user and the therapist can easily interpret the collected data.
    - The device will be worn by Soultech teammates and will be demonstrated to the therapist and the software will be evaluated with the help of the therapist to identify if the whole functionality of the device is easy to understand and navigate. The data obtained by the device will be compared against the devices which are already in existence to find if it is easy to interpret like others.

6. Light and portable: The device should be light and portable so that it can be easily carried and used in various situations.
    - The team will try to keep the weight of the product as minimal as possible. Throughout the testing period, the product will be transported and carried to many places to check if it is lightweight and easy to carry. The team will also take a survey about the product to ask the customers about its portability.
7. Durability: Socks must be durable and long-lasting to withstand regular use without breaking or losing precision.
    - The sock will be rigorously tested for gait analysis over a long period. It will be checked for consistency and accuracy over the period and also will be checked for any wear and tear at prolonged usage.
8. Compatibility: The socks must be compatible with multiple devices and software to easily integrate with existing healthcare systems.
    - The sock will be worn with different shoes to check its fitting to each shoe and does not provide discomfort. The software developed will be tested for its cross-functionality by making it run across different platforms like Android, IOS, Windows, and such. It will also be tested to work on existing therapeutic systems.

Contributions

Tatwik: Functional Requirements (1-8)
Danis: Functional Requirements (8-9), Performance Requirements (6-10)
Sriram: Performance Requirements (1-5)
Sabareesh: Usability Requirements (1-8)
Vishnu: None (didn't participate)