Product Design Specifications for BME 201: Gait Device
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Project Title: *Portable instrumentation to detect gait instabilities*

Statement of Purpose and Function: Our project seeks to measure various spatio-temporal parameters suitable for accurately detecting gait instability in elderly individuals. We base our design on 2 important results from recent studies: those trunk accelerations suffice to identify imbalance during walking (Zijlstra & Hof, 2003[1]; Cho et al., 1998[2]), and that stride/step length and stride/step duration positively correlate with the risk of falling (Hausdorff, 2005[3]; Hausdorff et al., 1995[4]). Our project involves the development of software and instrumentation for measuring these parameters solely using 2- and 3-dimensional accelerometry. We envision a device combining 2 dual-axis accelerometers and 1 triaxial accelerometer interfaced to a data logger that is user-friendly and suitable to be worn over clothing.

Client Requirements:

- Light Weight
- Reproducible
- Durability/Multiple Use
- Record Remotely for at least 2 minutes
- Placement of accelerometers: 1 on each heel and 1 on the S2- vertebra
- Tri-axial and duel-axis accelerometer
- Sampling rate of 60Hz
- High Resolution of +/- 10g
- Data processing at hardware level
- Adaptable for clinical and home settings
- No movement constraints
- Intended prototype use for research in Summer 2007

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[1] "Assessment of Spatio-Tenporal Gait Parameters from Trunk Accelerations during Human Walking" published by Zijlstra W and Hof Al, on October 18, 2003

[2] "Detecting Balance Deficits in Frequent Fallers Using Clinical and Quantitative Evaluation Tools" published by Chiung-Yu Cho and Gary Kamen, in "JAGS" Volume 46, Number 4, April 1998

[3] "Gait Variability: Methods, Modeling and Meaning" published by Jeffrey M Hausdorff, on July 20, 2005

[4] "Footswitch System for Measurement of the Temporal Parameters of Gait" published by Jeffrey M Hausdorff, Zvi Ladin and Jeanne Y Wei, in "J Biomechanics" Volume 28, Number 3, 1995

Design Requirements:

1. **Physical and Operational Characteristics:**
    a. **Performance Requirements:** This device needs to sustain multiple uses and multiple patient models of varying body types. One duel axis accelerometer must be placed on each heel column and one tri-axial accelerometer on the S2 vertebra. The attachment of this device must be adaptable to multiple patient body types.
    b. **Safety:** This device must be user compatible, no loose wires, no radiation, no sharp edges.
    c. **Accuracy and Reliability:** This heel/strike duel axial accelerometers must maintain a sampling rate of 60 Hz. The tri-axial accelerometer located on the S2 vertebra must have a lower range from 0-50Hz.
    d. **Life in Service:** Device recording time must be at least 2 minutes; however this device must sustain multiple uses (as long as possible with changeable battery life-times). Perhaps letting the patient take it home and wear it through normal day activities (Future application).
    e. **Shelf Life:** Normal AA alkaline batteries as power source for data logger; shelf life 10+ years.
    f. **Operating Environment:** Room Temperature (25°C), low humidity, in clinical or home setting.
    g. **Ergonomics:** Interaction with elderly people. Two location placements will be needed: one on each heel and one on the S2-vertebra, roughly 4 inches from the ground and 2.5 feet from the ground. This device must cling to the clothing of the patient, and must withstand the walking process of 2 minutes and the jostling that is associated with such motion.
        The accelerometer attached to the heels of the patient must be a dual axis accelerometer, because elderly persons walk gingerly or with a 'shuffle' instead of a pronounced walking stride. Because the change in acceleration is much more subtle for a 'shuffling' stride, the second axis needs to be incorporated for an accurate stride to be identified.
    h. **Size:** This device must be as small as possible to ensure minimal interference with standard walking motion. Such dimension includes the existing a manufacturing box from Medical Research Limited (Leeds, United Kingdom) of 72 by 55 by 18 mm.
    i. **Weight:** This device must be lightweight, as it has to easily be carried to assess normal walking conditions. The weight of the data logger from Medical Research Limited is 90g which is below the weight limit of 1 Kg.
    j. **Materials:** Heavy materials should not be used. LEMO wires, Data Logger and attaching belt, accelerometer, and accelerometer attachment adhesives.
    k. **Aesthetics, Appearance, and Finish:** Appearance exhibit smooth surface and edges. It also is sleek and discrete while patient is using it.
2. **Production Characteristics**
    a. **Quantity:** One unit will be made as a prototype; however, this device can be easily reproducible if contact with manufacturer is maintained.

b. **Target Product Cost:** $5000 for the initial customization and purchase of the Medical Research Limited Data Logger, and an additional $1000 for other materials.

3. Miscellaneous

a. **Standards and Specifications:** International and /or national FDA standards must be abided by for patient safety and patent purposes.

b. **Customer:** Specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.

c. **Patient-related concerns:** If appropriate, consider issues which may be specific to patients or research subjects, such as Is there any storage of patient data which must be safeguarded for confidentiality of medical records.

d. **Competition:** Equivalent devices utilizing accelerometers are available with prices ranging from $20 to $5000.