

Design History Review of the StabiliBoard™

StabiliBoard

dynamic board to test and train balance
automatically record balance data for your medical professional

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Introduction and Background

- ▶ Posturography: Techniques that measure a person's stability, balance and control when standing or moving

Introduction and Background

- ▶ Posturography: Techniques that measure a person's stability, balance and control when standing or moving
- ▶ Current Gold Standard:
Computerized
Dynamic Posturography
 - ▶ Able to identify what (inner ear, proprioception, vision) is affecting a person's balance by a series of tests



Design Input: User Needs Review

- ▶ Problem Statement: Patients have to visit the clinic often for testing and treatment. The machine takes up a lot of space and is expensive
- ▶ User Needs
 - ▶ At home posturography test
 - ▶ Usable with no knowledge other than provided instructions
 - ▶ Able to set up only using provided instructions
 - ▶ Affordable
 - ▶ Tests balance without putting the patient at high risk of falling
 - ▶ Quantifies improvement in patients balance

Design Input: User Needs Review

► Design Requirements and Specifications

► Physical Board

- Patient and User Safety Requirements
- Limits and Tolerances
- Ergonomic Factors
- Reliability
- Physical Characteristics



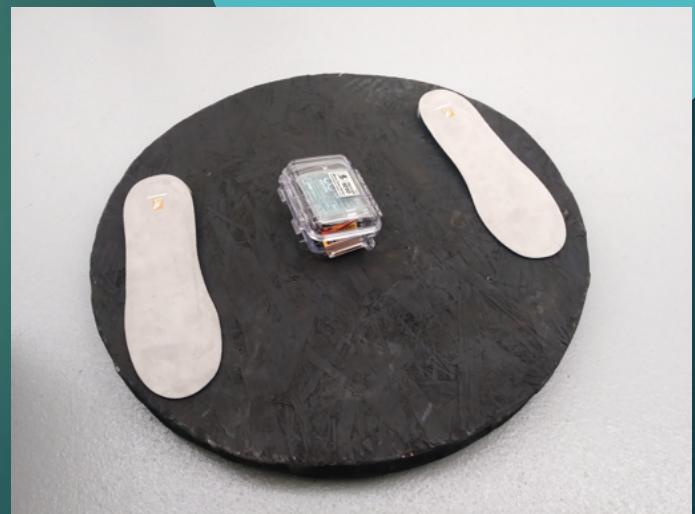
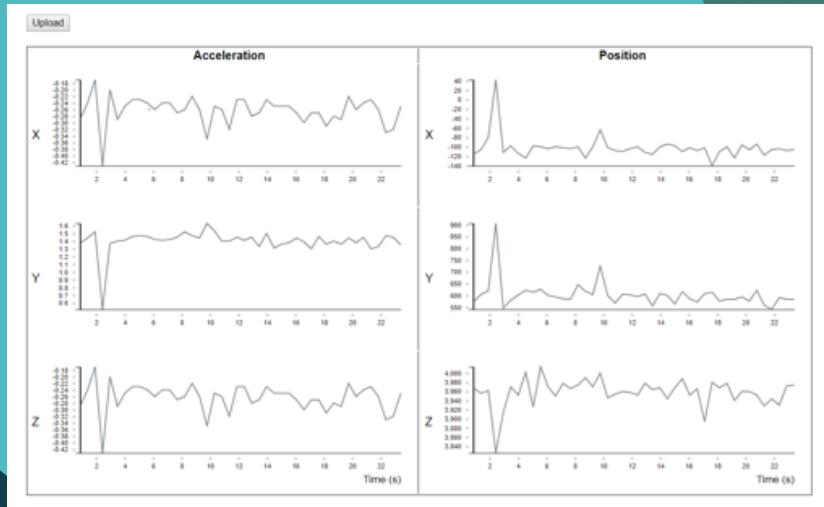
► Control Panel

- Ergonomic Factors
- Physical Characteristics
- Reliability



Design Input: User Needs Review

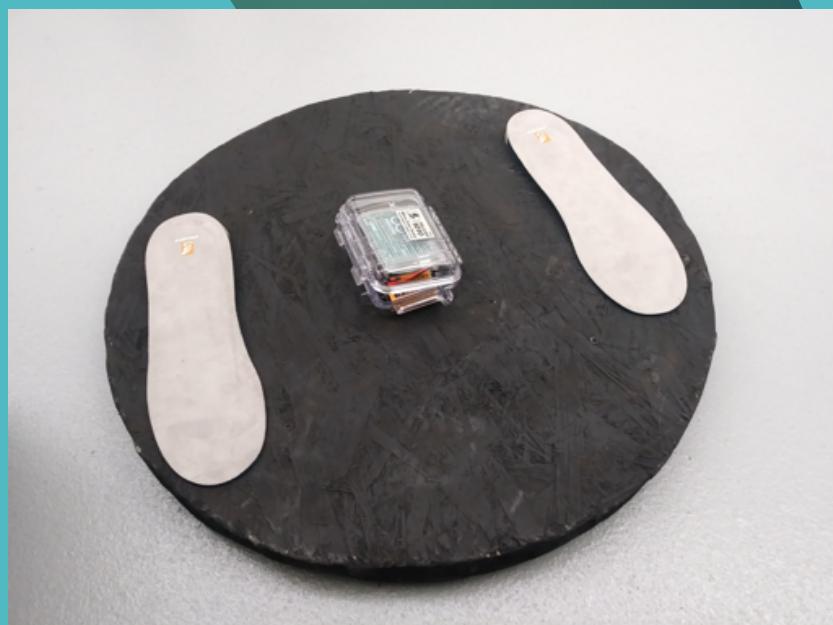
- ▶ Design Requirements and Specifications
 - ▶ Data Collection and Memory
 - ▶ Limits/Tolerances
 - ▶ Reliability
 - ▶ Data Display
 - ▶ Ergonomic Factors
- ▶ Composite Board
 - ▶ Reliability
 - ▶ Limits/Tolerances



Design Input: Key Specifications

► Key specifications

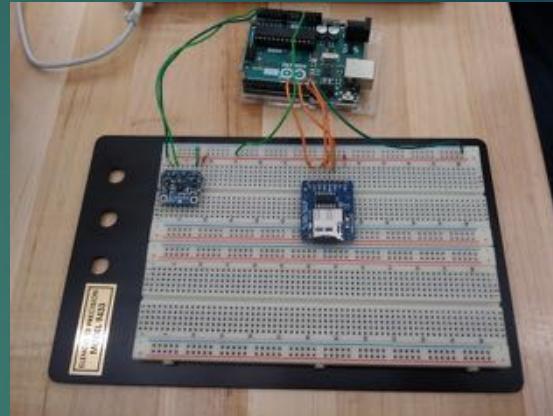
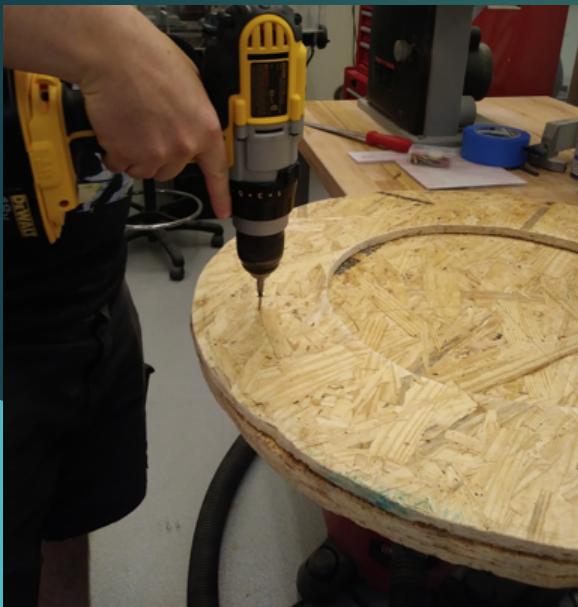
- ▶ Current Draw: ≥ 1 hr of use
- ▶ Structural Integrity: Support 0 – 180 kg
- ▶ Program/Interface: 100% comprehension
- ▶ Board Tilt/Height: 0 – 8 degree tilt, < 19.7 c.m.
- ▶ Data Recording: Able to produce data output each trial



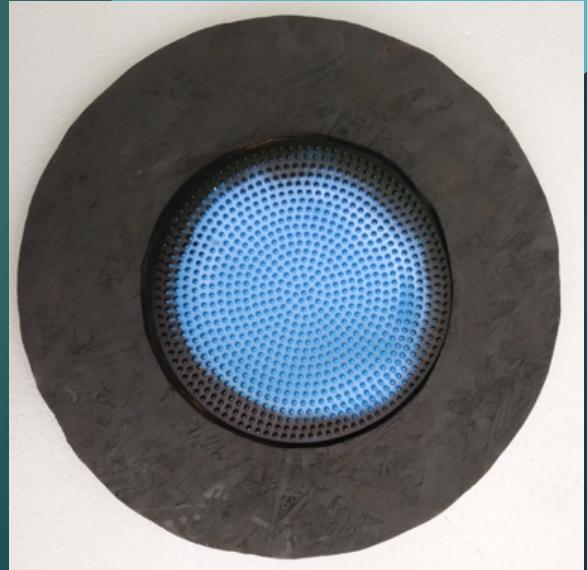
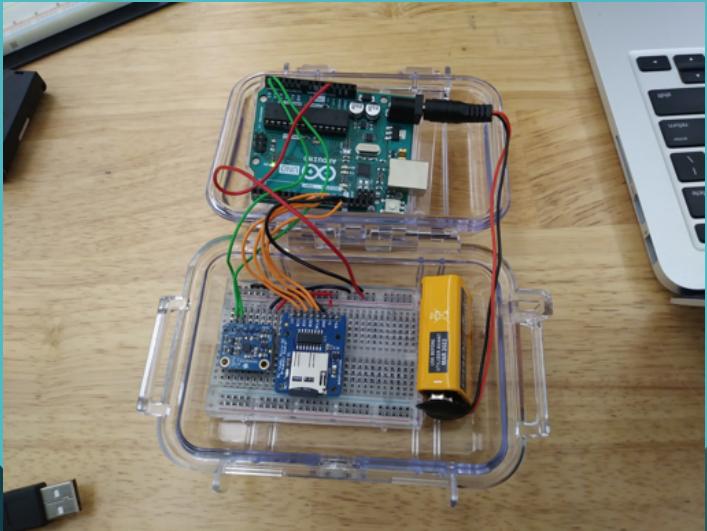
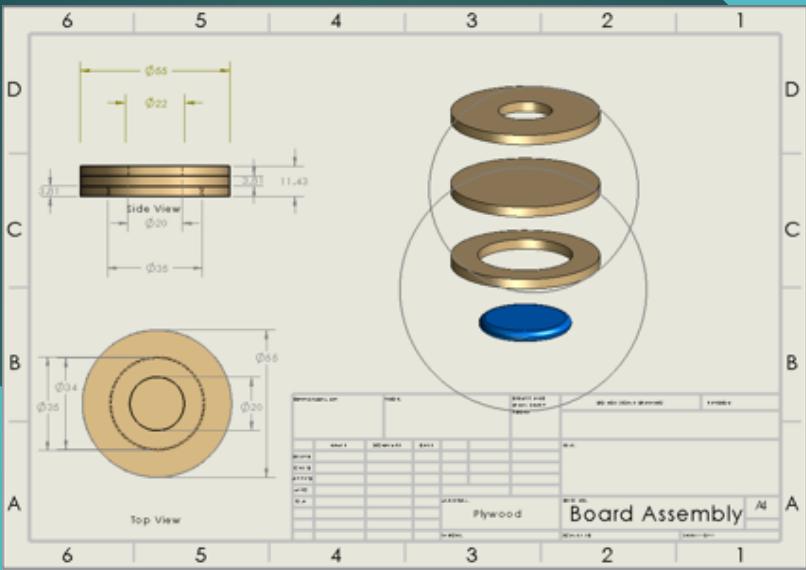
Design Inputs vs. Outputs

Inputs	Outputs
At home posturography test	Board is small enough to be transported and fit into the home
Usable with no knowledge other than provided instructions	Board is verified to be intuitive to use; instructions and interface tested by non-team members
Affordable	Board made of inexpensive components/easy to manufacture
Tests balance without putting the patient at high risk of falling	Board verified to stay low to the ground; board does not tilt higher than 19.7 cm
Quantifies improvement in patients' balance	Accelerometer verified to gather data; online app displays data
Supports the weight of a user	Verified to hold > 180 kg
Able to be used for over 1 hour	Battery verified to last > 1 hour

Overall Product Description



Overall Product Description



Prototype Element 1: Human Factors



Top of Board



Bottom of Board

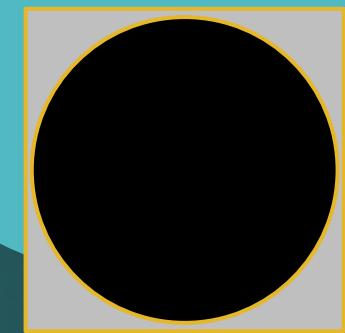
Prototype Element 1: Human Factors



3 Plywood Boards
(60 cm x 60 cm x 3 cm)



Measure out circles on each board
(diameter of 60 cm)



Solid
Circle
(x2)



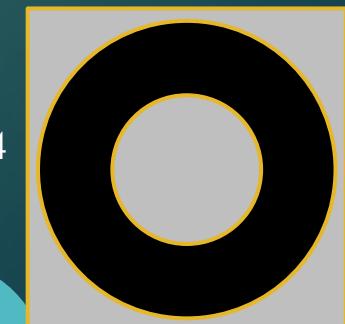
Drill holes that penetrate
through both the top and
middle solid circles (for screws)



Cut out all 3 circles



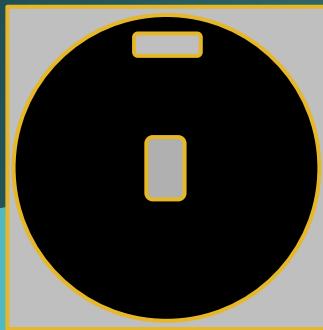
and separate holes that
penetrate both the middle
and bottom circles



Disk
[I.D. of 34
cm]
(x1)

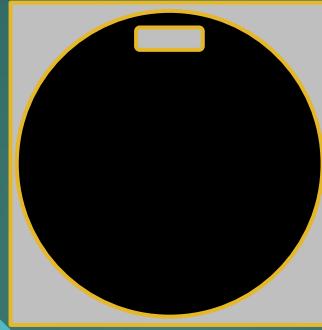
Prototype Element 1: Human Factors

Drill/Cut
hole
through
center of
one of the
solid
circles



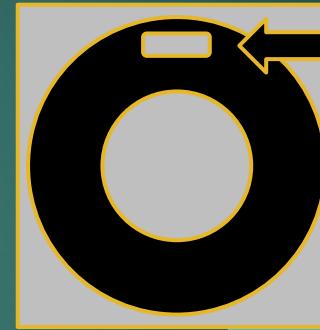
60 cm diameter
circle (4 cm diameter
hole in center)

Center



60 cm
diameter circle

Bottom



60 cm diameter circle
(34 cm diameter
hole in center)

Handhold
added to all
three circles

Flip board (top side down) and
align holes of center and
bottom circles



Screw top and center
circles together (8 screws)



Cut ~ 2 mm off the
tips off all the screws



Prototype Element 1: Human Factors



Screw bottom piece
into middle piece



Sand edges with file until
smooth; sand flat surfaces
with sander until smooth

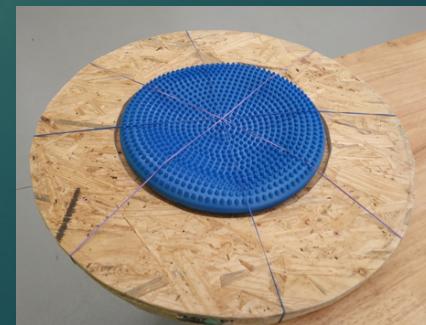


Attach non-
textured portion of
balance ball to
the center of the
bottom piece with
gorilla tape

(firmly secure and
place weight on
top of board; let
sit for one hour)



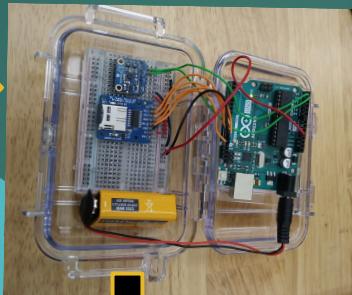
Paint entire board
with spray paint



Prototype Element 1: Human Factors



Place assembled electronics
into secure case



Place adhesive soles
onto board

Completed Version 1 of
the Stabiliboard



Prototype Element 2: Electronics Control Panel



Prototype Element 2: Electronics Control Panel



Drill a hole in the top of
the electronics box



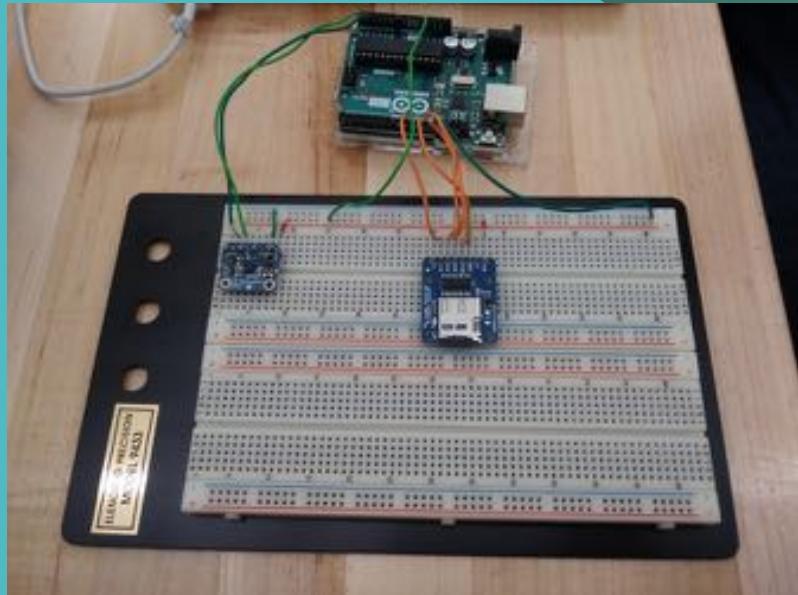
File the hole to the
size of the hole

Prototype Element 2: Electronics Control Panel



Push the button into
the hole

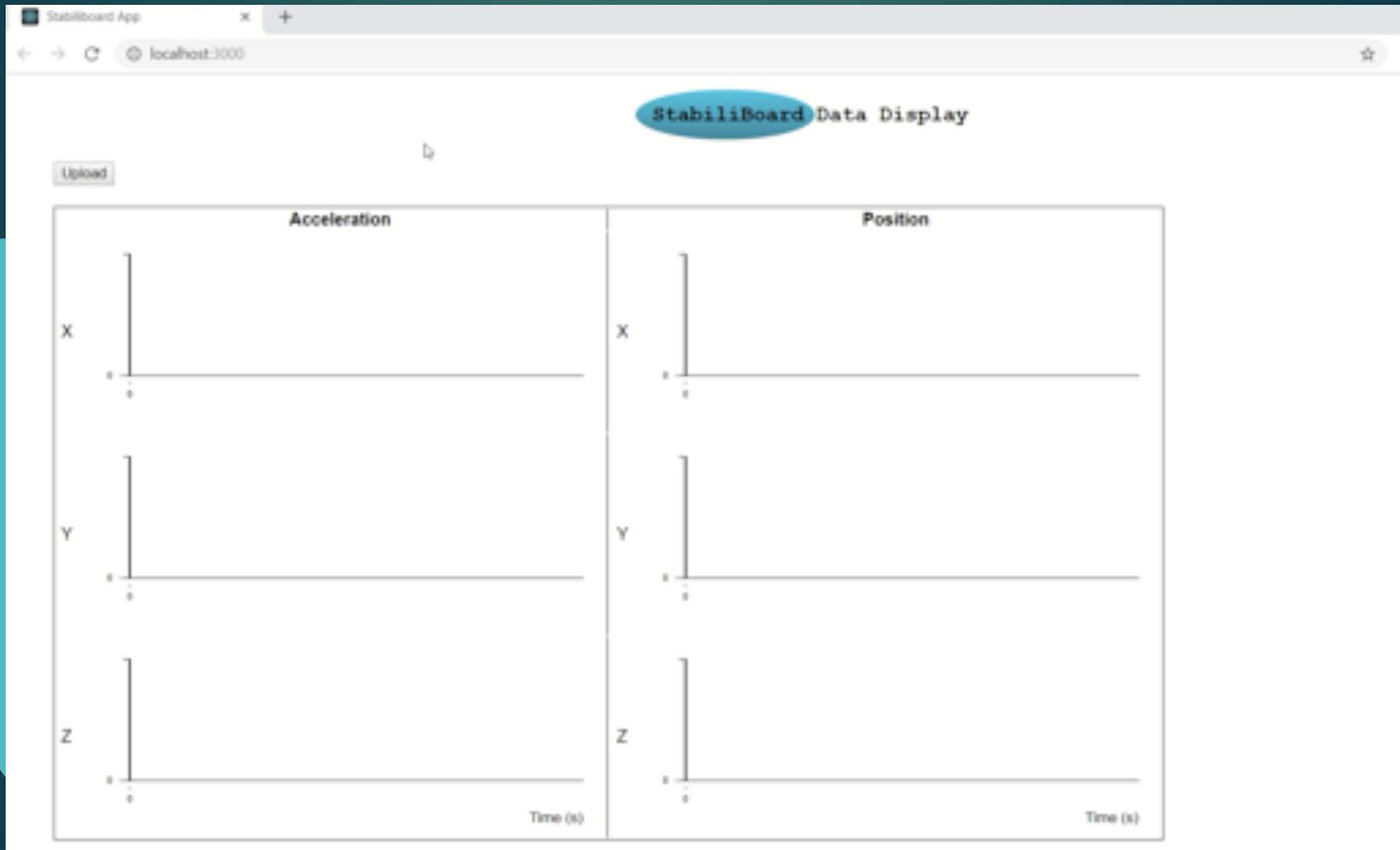
Prototype Element 3: Data Collection and Memory



Prototype Element 3: Data Collection and Memory

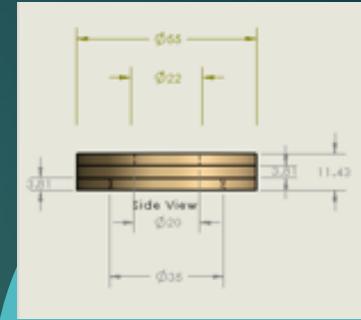


Prototype Element 4: Web Application for Data Display



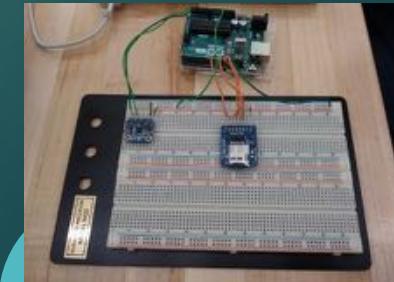
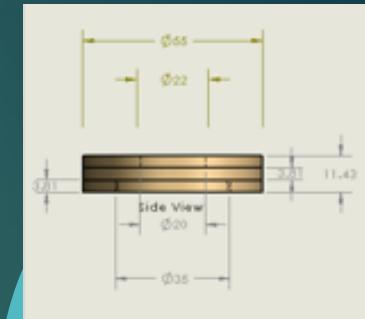
Testing Plan Overview

- ▶ Board Dimension Measurements
- ▶ Board Height and Tilt Angle Testing
- ▶ Electrical Current Draw Testing
- ▶ Graphical User Interface/Website Ease of Use
- ▶ User Instructions Comprehension
- ▶ Drop Testing
- ▶ Load Testing
- ▶ Shear Force Testing
- ▶ Maximum Inflation Pressure Testing
- ▶ Control Board Testing
- ▶ Data Collection Testing



Testing Plan Overview

<u>Test</u>	<u>Statistical Analysis Method</u>	<u>Min. # of tests/trials</u>
Dimensions	Two-sided t-test	9
Height and Tilt	One-sided t-test	9
Current Draw	Two-sided t-test	5
Battery Life	Pass/Fail	3
User Interface	Pass/Fail	5
User Instructions	Pass/Fail	5
Total Weight	Two-sided t-test	5
Drop Test	Pass/Fail	N/A
Load Test	Pass/Fail	2
Shear Force	Two-sided t-test	5
Max Inflation	One-sided t-test	5
Control Board	Pass/Fail	10
Data Collection	Two-sided t-test	27



Verification Testing



Testing Plan Results

<u>Test</u>	<u>Statistical Analysis Method</u>	<u># of Trials Performed</u>	<u>Acceptable Results?</u>
Dimensions	Two-sided t-test	9	Yes, within acceptance criteria
Height and Tilt	One-sided t-test	9	Yes, within acceptance criteria
Current Draw	Two-sided t-test	10	Yes, within acceptance criteria
Battery Life	Pass/Fail	3	Yes, within acceptance criteria
User Interface	Pass/Fail	5	Yes, 100% Comprehension
User Instructions	Pass/Fail	5	Yes, 100% Comprehension
Total Weight	Two-sided t-test	5	Fail, will change materials
Drop Test	Pass/Fail	N/A	Not performed, only prototype
Load Test	Pass/Fail	2	Pass
Shear Force	Two-sided t-test	5	Not performed, force gauge not available
Max Inflation	One-sided t-test	5	Not performed
Control Board	Pass/Fail	10	Pass, each attempt successful
Data Collection	Pass/Fail	27	Pass, each attempt successful

Risk profile and Regulatory Status Changes

► No major changes to the FMEA

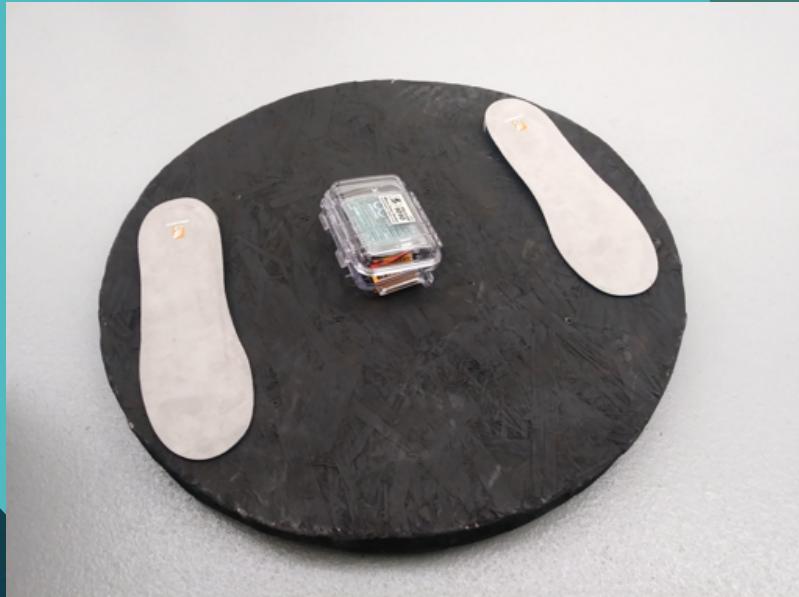
- Prototype V1 only failed total board weight testing
- Future prototype made of plastic; manufacturing/testing modified

Failure Category	Failure Mode	Cause	Effect	Severity	Likelihood	RPN	Mitigation Action	New Likelihood	RPN
Immune Response	Contact Dermatitis	Irritant or allergen on surface of device	Rashes lasting for days	3	2	6	Make Plastic non-leaching	1	2
Mechanical, material, or manufacturing faults	Device falls apart	Materials and manufacturing process mismatch	Product fails in its purpose	7	2	14	Quality control over materials, tolerances and processing, test random selections	1	7
	Difficulty to access battery compartment	Component latch hard to remove because of latch stiffness	Increase effort to maintenance, irritate user	2	2	4	Design latches to be easy for weaker hands to open	1	2
	Balance ball rupture	Hole in balance ball	Platform not sufficiently raised to perform test	4	5	20	Include warnings about overinflation and include proper inflation PSI in instructions	1	12
	Balance Ball Separation	Balance ball becomes unattached from board	User will be unable to perform balance tests	6	2	12	Test for good attachment during manufacture	1	6
	Foot Pad Separation	Foot Pad Separation	Slight discomfort to patient	2	5	30	Test for good attachment during manufacture	4	8
	Loss of Electronics Box	Loss of Electronics Box	User will be unable to perform balance tests	6	2	6	Test for good attachment during manufacture	1	6
User Error	Patient Discomfort	Surface scratches foot skin while not wearing shoes	Skin irritation	2	3	6	Ensure plastic surfaces are deburred	2	4
	Underinflation of Balance Ball	User does not inflate balance ball sufficiently	Platform not sufficiently raised to perform test	2	5	10	Include proper inflation PSI in instructions	1	6

Summary

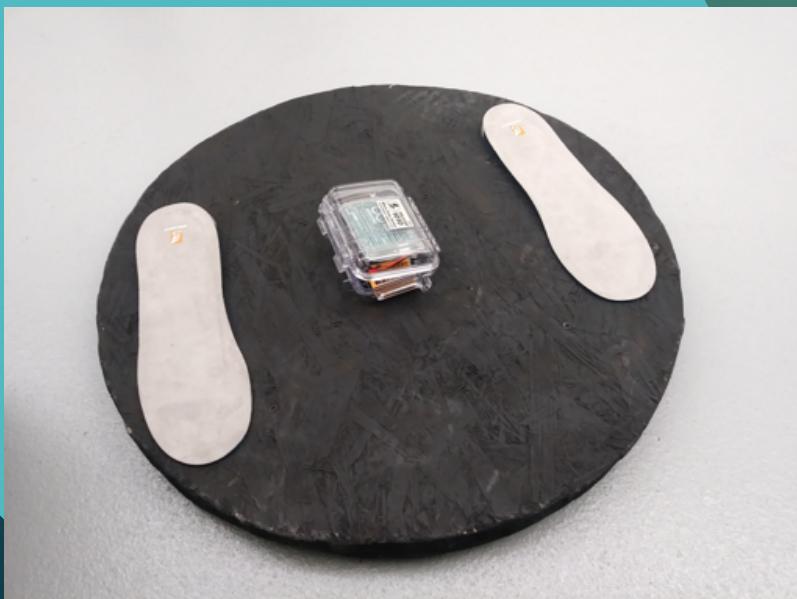
► Current Verification Testing Goals

- ▶ Balance board able to withstand impacts and still function
- ▶ Electronics able to read and record 3D position
- ▶ Control board that allows balance board electronics to function
- ▶ Online application that displays 3D balance data



Future Direction

- ▶ Make future prototypes out of PVC, not wood
 - ▶ Results of tests may vary
- ▶ Add haptic weights to the board
- ▶ Add a 3D graphical representation of the boards movement to the data display
- ▶ Virtual reality component (interactivity)
- ▶ Diagnosis of the patients balance



The background features a dark teal gradient. Overlaid are several large, semi-transparent teal circles of varying sizes. A single vertical red rectangle is positioned in the upper right corner.

Questions?