Seizure Detection Design Review 2

Jean, Michelle, Sabrina

Project Summary

- **Problem:** Lack of inexpensive AND accurate seizure detection devices
- **Need:** An accurate method of detecting motor seizures as they occur and alerting nearby caretakers while users are asleep.
- **Goal:** Detect and alert when motor seizures are occuring by measuring pressure changes during hand-clenching seizure events
- User Needs:
 - Accurate, quick detection and subsequent alert
 - Comfortable
 - Affordable

Customer

- Adults (18+)
- Known history of hand-clenching during seizure event
- Caretakers of mentioned individuals

Design Process

Design Considerations (Traceability Matrix)

ltem #	User Needs Intended Uses	Design Inputs (Technical Requirement)						
1.0	Customer Requirements (e.g. Functional)							
1.1	Detects motor seizure activity	Detects pressure from hand clenching at a threshold of X N						
1.2.1	Alerts user through alarm	Produces beeping alert sound at 80 decibels						
1.2.2	Alarm alerts others to user condition	Alert shuts off when physically acknowledged and returns alarm to 0 decibels						
1.3	Quickly detects when a seizure is happening	Ability to detect seizure within 5 seconds						
2.0	Product Performance Requirements (e.g.Mechanical)							
2.1	Light-weight	Weighs no more than 50 grams						
2.2	Device can be worn for long periods of time (e.g. while sleeping)	Stays attached to hand for at least 7 hours						
2.3	Device functions for long periods of time	Has a battery life of at least 7 hours						
2.4	Device can be repetitively used	Glove can be removed in 5 seconds						
3.0	Biocompatability Requirements							
3.1	Safe for use with human skin	Meets threshold of "0" on "Visual Assessment of Human Skin Irritation" 10 point scale, meaning no pink color on skin						

4.0	Regulatory Requirements							
4.1	Labeling of directions, intended use, and safety	90% of users should understan directions, intended use, and safety after reading labels						
4.2	Accuracy of detection validation	Detects 90% of seizures						
5.0	Interfaces with Other System	S						
5.1	5.1 Ability to send a separate alert to nearby caretakers' phones occuring 100% of the ti							
5.2	Ability to track information about the seizure	Records hand clenching for the duration of the seizure in second/minutes						
6.0	Other							
6.1	Affordable	Total cost less than 350 dollars with no required subscription plan						
6.2.1	Able to be used by small-handed people	Fits glove size S-small						
5.2.2	Able to be used by medium- handed people	Fits alove size M-medium						
6.2.3	Able to be used by large-handed people	Fits glove size L-large						

Design Considerations (Pugh Matrix)

	5=highest, 1=lowest	CONCEPTS FOR DETECTION					
USER NEEDS	IMPORTANCE WEIGHING	BASELINE: Caretakers within close physical range to the patient visibly noticing a seizure	Glove to detect hand clenching	Watch or wrist attachment to detect movements, vitals	Mouth piece to detect teeth/jaw clenching or tongue/cheek biting	Ring to detect hand clenching/movement	
Detects motor seizure activity	5	3	5	4	5	2	
Ability to stay attached and be worn for long periods of time (e.g. while sleeping)	3	3	5	5	4	5	
Ability to detect seizure within x seconds	3	3	4	5	5	4	
Material is safe/non-toxic/irritant for skin	5	3	2	3	1	3	
Labeling of directions, intended use, and safety	1	3	4	5	2	4	
Accuracy of detection validation	5	3	4	4	4	1	
Ability to store information tracking the seizure (duration, time)	1	3	5	5	5	5	
Affordable	4	3	2	1	2	2	
Able to be used by different age groups (adult, child)	1	3	2	4	2	1	
TOTALS		27	33	36	30	27	
WEIGHTED TOTALS		84	101	103	94	75	

- 1. Glove
- 2. Watch or wrist attachment
- 3. Mouth piece
- 4. Ring









Design Considerations (Pugh Matrix)

	5=highest, 1=lowest	CONCEPTS FOR ALERT				
USER NEEDS	USER NEEDS IMPORTANCE WEIGHING		Beeper/pager (sound alert)	Phone notification sent to caretakers (visual alert)	Light alert (visual alert)	Vibration (touch alert)
Ability to send a separate alert to nearby 4 3 4		4	5	2		
Ability to produce sound as an alarm	2	3	4	4	0	2
Labeling of directions, intended use, and safety	1	3	3	5	4	3
Affordable	4	3	3	5	4	3
		6				
TOTALS		12	14	19	12	10
WEIGHTED TOTALS		33	39	53	36	27

- 1. Buzzer
- 2. Phone notification
- 3. LED
- 4. Vibration



Concepts

Sketches:

10/30/24

(st prototype ->make glove later = POC w/ normal size R Guser: people with history palm of RH of seizures w/ hand more space + stability cleaching in fist sensors 0 Glater)glove: put board on back of hand Nive down back 00 ofward pressure rensors Growing need bigger?

Features:

- Bendable and pad-type pressure sensors
 - How many to attach
- Sensor location
- Connection to alarm using microcontroller
- Glove type/material
- Consideration of comfort
- Ease of removal

Prototype/Proof of Concept











Risk Analysis

Item Number	Function	Risk Analysis						Risk Control				
	Functional Output	HAZARD (Potential cause of Hazard)	Hazardous Situation	HARM (Potential adverse effect)	Cause	SEVERITY	OCCURRENCE	RPN .	RISK MITIGATION	SEVERITY	OCCURRENCE	RPN
1	Constriction of blood flow	Wire connecting two parts over a distance	Wire wraps around finger or wrist	Wire constricts blood flow	Wire is not secured and has a long length	4	1	4	Secure wire to prevent wrapping motion and limit long lengths of wire that pose risk of strangling	4	1	0
2	Detached pressure sensor	r Pressure sensor connected to glove falls off	Sensor doesn't read any pressure data	Seizure isn't detected when it is occuring	Insecure connection between the pressure sensor and the glove	5		10	Strong adhesive between pressure sensor and glove to prevent detachment	5	1	5
			Sensor reads inaccurate pressure data	Alarm goes off when no seizure is occuring		5	2			5	1	
			Sensor is swallowed or lodged in throat	Sensor causes blockage in throat (choking) or further areas requiring surgery		5				5	1	
3	Shock to body	Wire is connected to a power source	Wire insulation/jacket breaks and exposes the inside of the wire	Live wire causes risk for electric shock when in contact with body	Wire insulation/jacket is damaged and exposed to the outside	4	1		Material specification of strong wire insulation material	4	1	4
4	Component presses into body when weight is applied while sleeping	Arduino and circuit board are physically hard parts with components that stick out/upward	Arduino or circuit board is accidentally pressed against a sensitive area of the body while sleeping (e.g. the eyes)	Deformation of sensitive body part, Arduino/circuit board is lodged into body part	Arduino and circuit board are physically hard materials without a barrier	3	2		Barrier between arduino/circuit board and potential outside contact with user	3	1	3
5	Skin irritation	Glove material irritates skin	Glove material scratches against skin over a long period of use (while sleeping)	Skin becomes irritated/inflamed	Glove material catches/rubs on skin	1	2		Material specification of non- irritant material ()	1	1	1
6	False Positive	itive Arduino doesn't work properly Pressure values not calibrated	Seizure detected when not	User woken up unneccessarily	Detached wiring Inaccurate reading of resistance values Mechanical error of	5	1	5	Soldered wires to parts	5	1	5
			occuring	Hinders activity of caretakers		5	1		Proper calibration of pressure values	5	1	5
7	False Negative		Seizure not detected when occuring	Caretakers not notified seizure is occuring	parts	5	1	5	- vardeo	5	1	5

Risks

- Wires (shock, constricting)
- Pressure sensor
- Error in detection
- Lodge in body
- Material

Mitigation

- Securing parts
- Barriers between parts
- Specifying materials
- Calibration of pressure values

Next Steps

- Determine resistance value needed
 - Pressure levels correlated with amount of desired measured resistance
- Miniaturizing arduino/circuit
- Attach sensing system to glove
- Adding flexible bendy sensor
 - (pressureReading > #) && (bend_status = true)
- Button to acknowledge/stop alarm once sensed



Additional Details

Challenges:

- Choosing prototype/concept
 - Feasibility of concepts
- Type/location of sensors
- Time constraints (features)
 - Determining what needs should be prioritized

How we've worked together:

- Brainstorming constructively
- Zoom meetings vs in-person

References

- 1. <u>https://www.who.int/news-room/fact-sheets/detail/epilepsy#:~:text=Over</u> <u>view-,Epilepsy%20is%20a%20chronic%20noncommunicable%20disease%</u> <u>20of%20the%20brain,around%2050%20million%20people%20worldwide</u>.
- 2. <u>https://www.epilepsy.com/stories/sleep-and-epilepsy</u>
- 3. <u>https://www.cdc.gov/epilepsy/data-research/facts-stats/index.html</u>