no to NECK PAIN

...no to TEXT-NECK

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01

BACKGROUND

Cervical flexion causes non-specific neck pain.

02

SOLUTION

Design proposition: features & constraints.

03

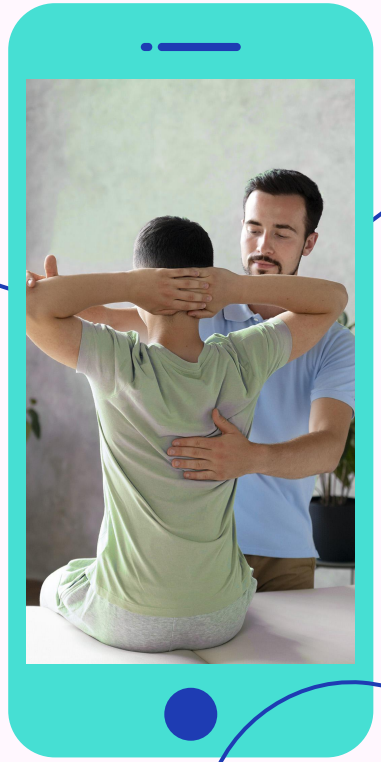
DATA FLOW

Building prototype and assessing functionality.

04

LAWS & ETHICS

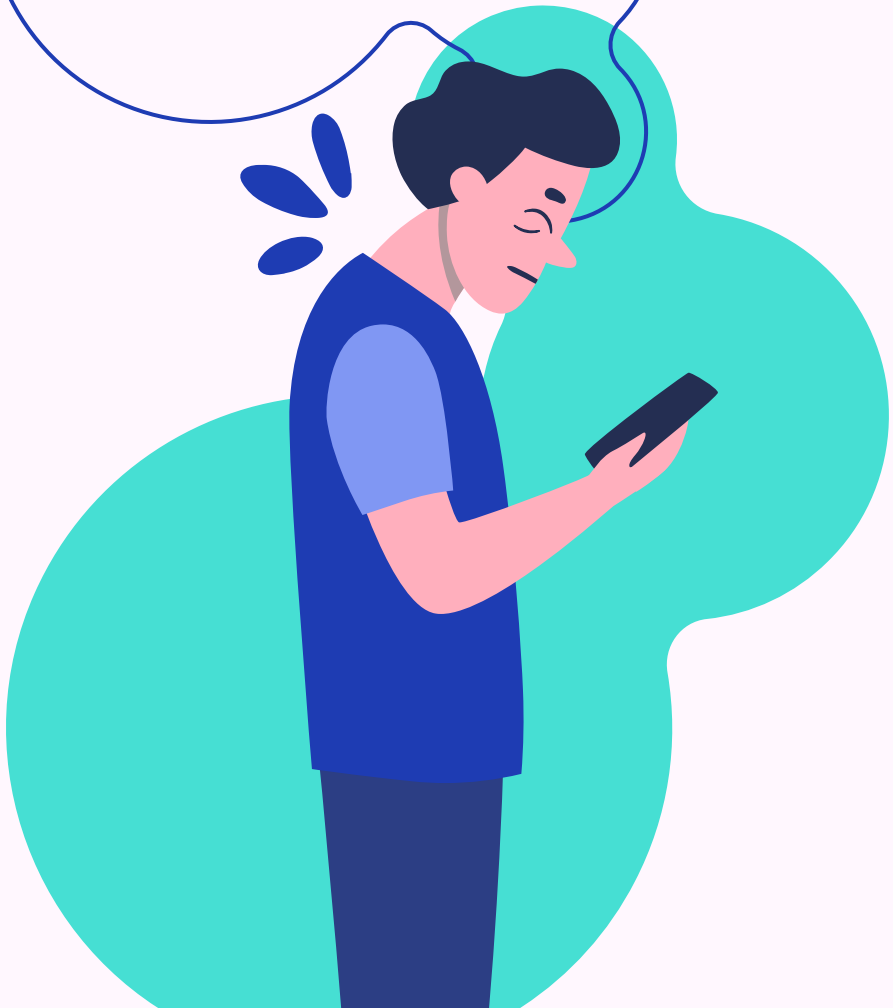
Implementation plan for final product.



01

BACKGROUND

How does **cervical flexion** lead to non-specific neck pain?



NON-SPECIFIC NECK PAIN

A global public health burden.

UNDEFINED:

no generally accepted medical definition; no root cause.

PREVALENT:

afflicts ~**71%** of the population at some point in their lives.

DESTRUCTIVE:

associated with loss of ROM and decreased QoL.

[1] [2]

TEXT-NECK

→ Dubbed as ‘text-neck’ only recently, **cervical spine flexion** is a common posture for individuals using *computers*, *tablets* and *smartphones*.

→ This posture has since been flagged as a **major risk factor** for developing **nonspecific neck pain** due to *increased loading*.

[3] [4] [5]

To prevent the development of nonspecific neck pain resulting from cervical spine flexion, a **monitor and alarm system** is needed to detect and correct ‘text-neck’ posture.

—NEED STATEMENT

DESIGN CRITERIA

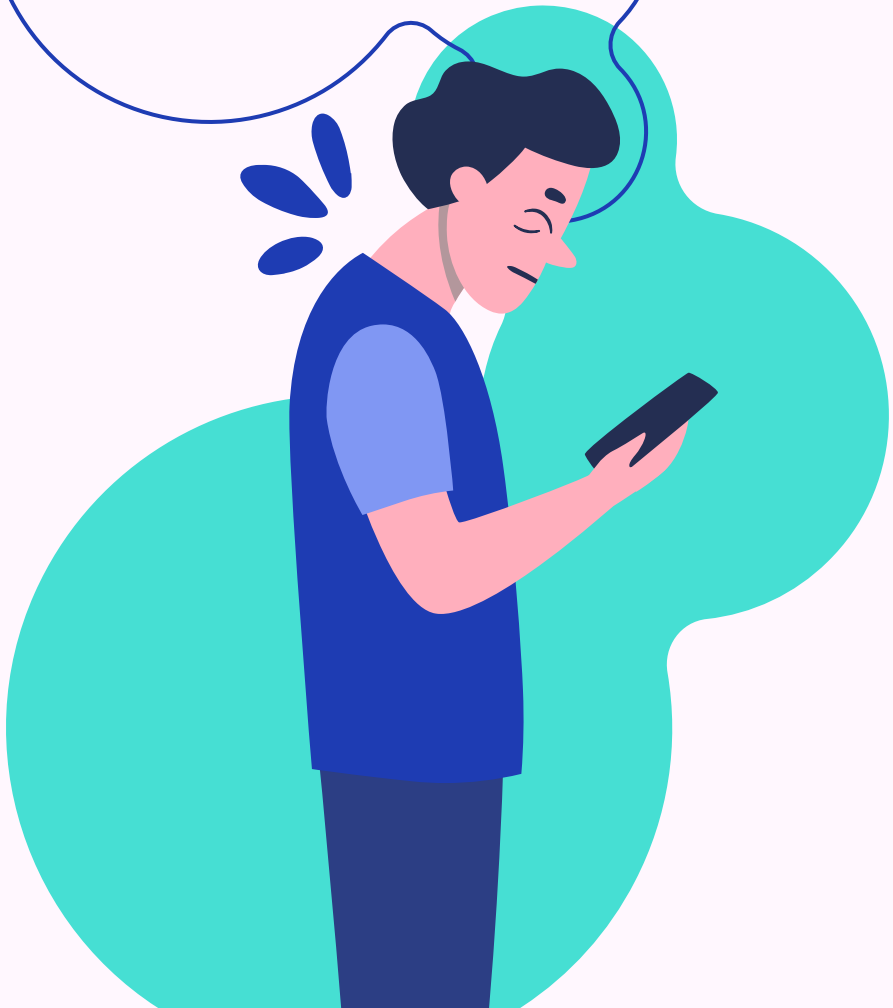
MUST BE: constraints	**SHOULD BE:** features	**CONSIDER:** options
Accurate	Algorithm-Efficient	Sensor placement/DAQ
Wearable & Safe	Easy to conceal	Hardware, housing needs
Communicative	Durable	Buzzer type/placement
Reproducible	Easy to use	Sensor placement

[6] [7]

02

SOLUTION

A sensor-equipped **balaclava** to monitor neck posture and alert user if sustained flexion is detected



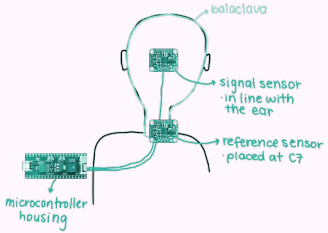
<50 deg: cervical flexion [9]

MONITORING SYSTEM

angle between C7 and the ear relative to horizontal

SENSOR → AXIS OF EAR	Captures **signal** (end effector of cervical spine)
SENSOR → C7 SPINE	Provides **reference** (eliminating noise)
NOISE → L-T SPINAL LEVELS	**Eliminated** by placing reference at C7
NOISE → HIP & BELOW	**Eliminated** by placing reference at C7

[8] [9]



BALACLAVA DESIGN

REMOVEABLE
Cloth at front can come on and off for optimal user comfort

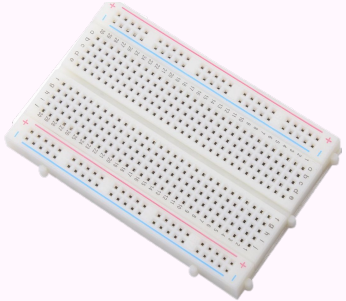
HOUSING
Contains (1) breadboard with **micro** circuit, (2) **power** supply and (3) **LEDs**; hangs from straps

BUZZER
Placed in the breadboard; close enough to hear

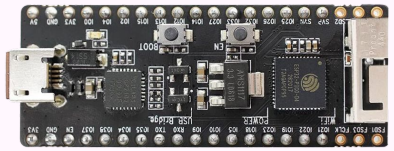
SENSOR 1
BNO055 signal at **axis of ear**

SENSOR 2
BNO055 reference at **C7**

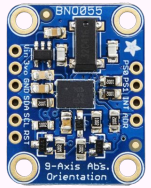
MATERIALS



Breadboard



ESP 32

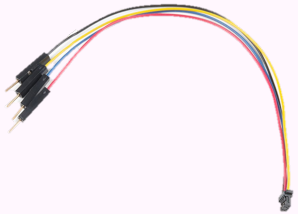


BNO550

Buzzer

LED

M/F Jumper Wire

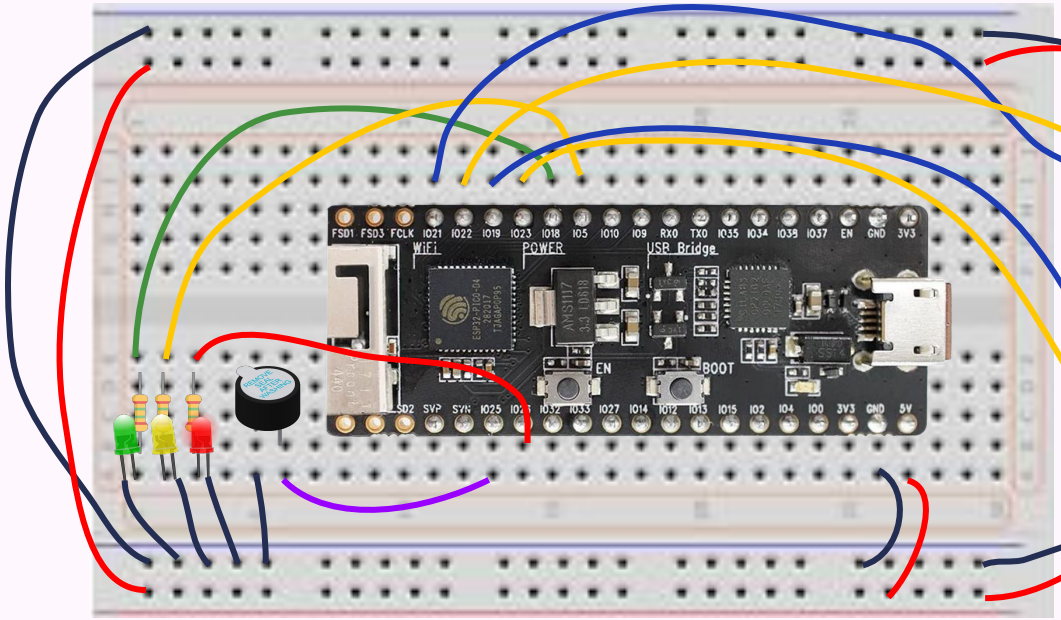


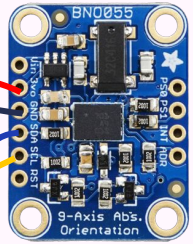
QWIIC Wire

USB to micro-USB

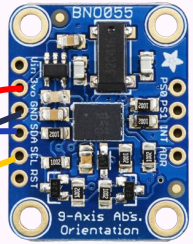
Balaclava

HARDWARE SETUP



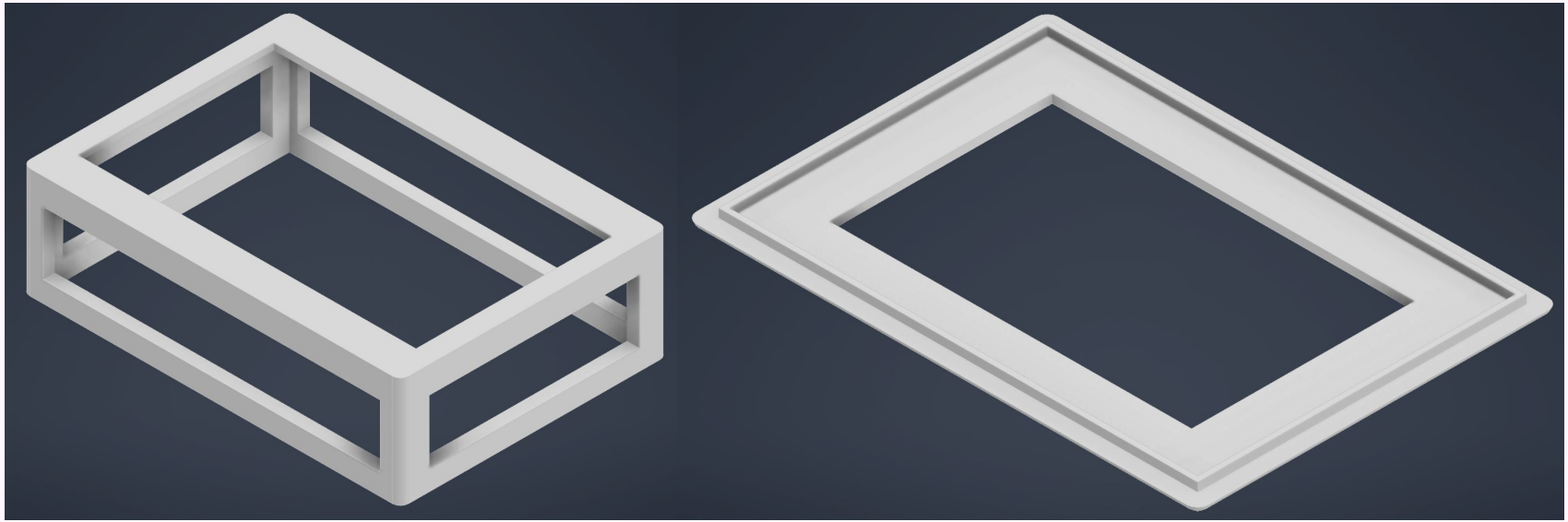


ANGLE BNO055



REFERENCE BNO055

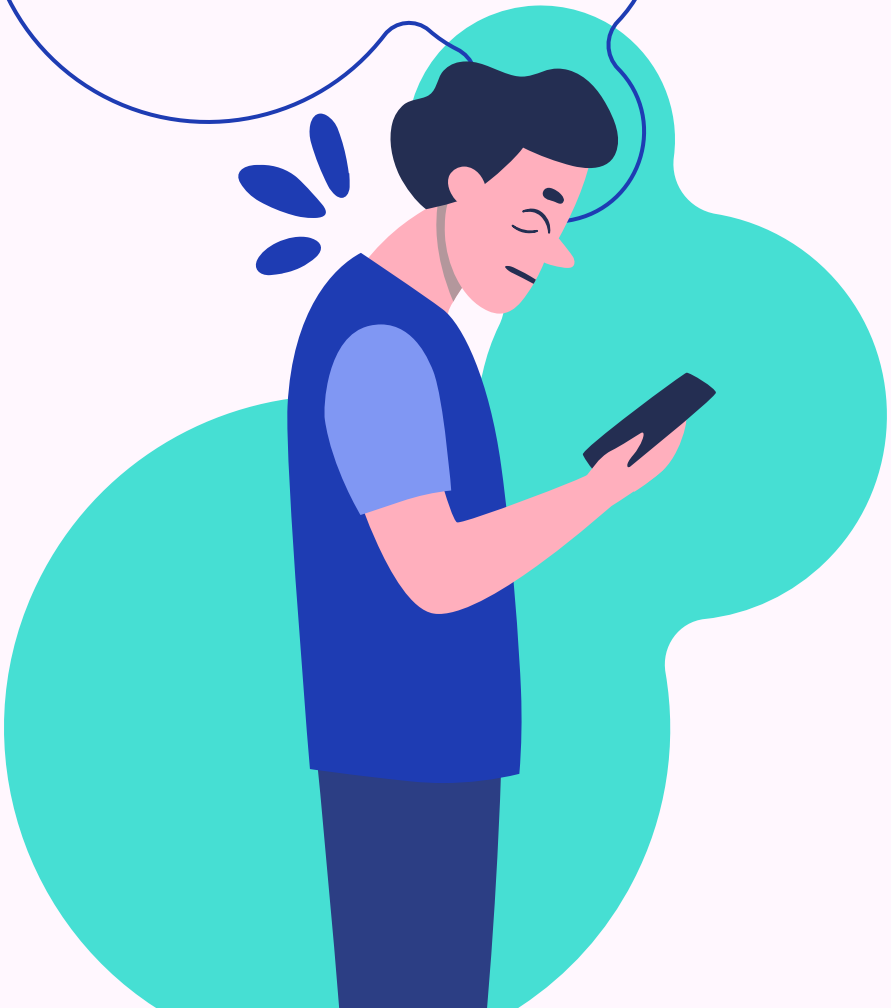
HOUSING DESIGN



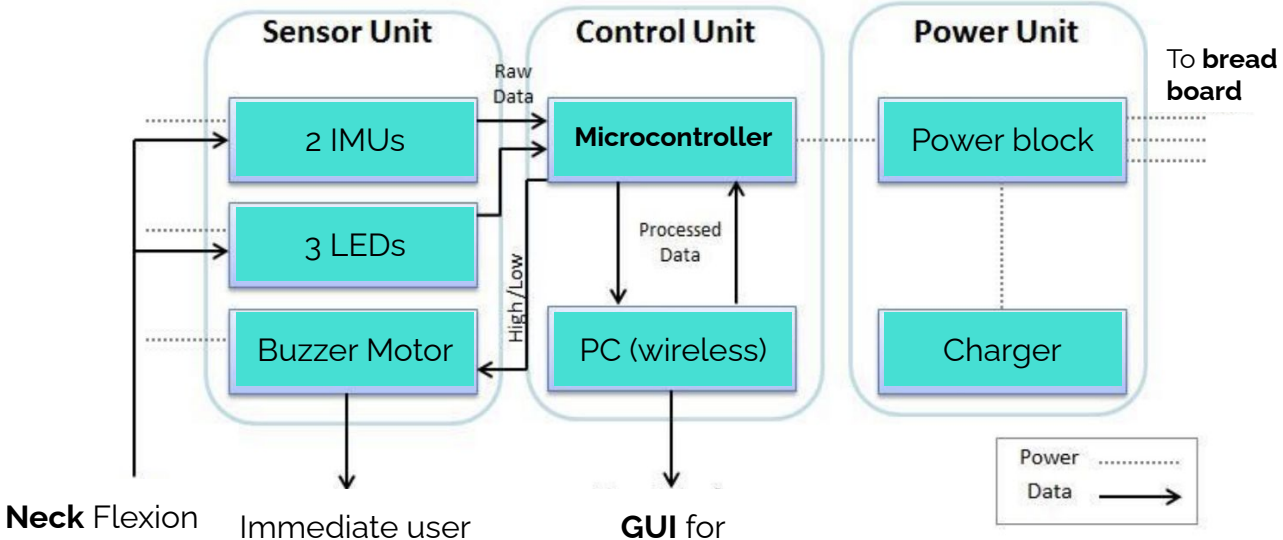
03

DATA FLOW

How data flows through our system... from acquisition to visualization

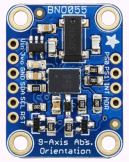


SYSTEM BLOCK DIAGRAM



DATA FLOW (DAQ)

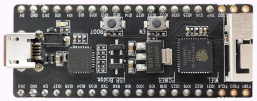
Transduction (inherent)



Start

i, count = 0

Initialize Bluetooth, pins, sensors and I2C



Get raw angles from 2 sensors

Add to respective sum

yes

i<20?

no

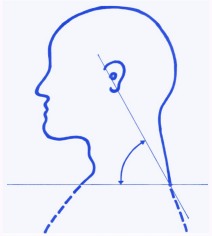
i = i + 1

Delay 10ms (sampling freq 100Hz) [8]

sum/20 to get averages

Compute difference between averaged angles w/ respect to horizontal

angle diff <50 deg?



yes

Poor Posture detected... but sustained?

Only want to alert user if **30s of ***sustained*** posture, 30s/200ms = **150 counts**

Send data to Python GUI for Clinician Use

[8]

OBTAINING DEGREE OF FLEXION

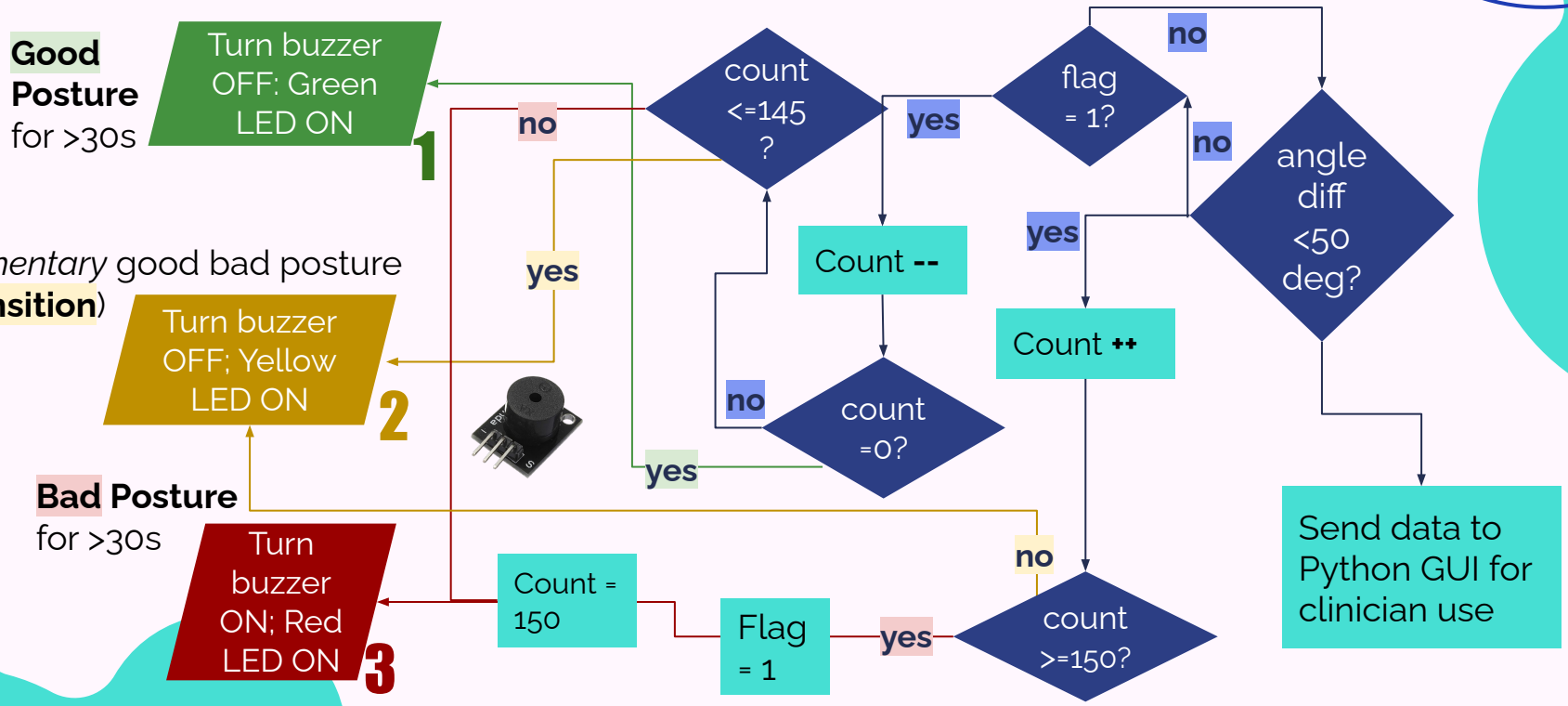
```
76  float angle=(event.orientation.z);//angle of the ear relative to the horizontal
77  bno2.getEvent(&event2);
78  float reference=((event2.orientation.z)+50);// angle of C7 relative to the horizontal
79
80  if (i<20)
81    {
82      anglesum=anglesum+angle;
83      refsum=refsum+reference;
84    }
85  else {
86    float angleavg=anglesum/20;
87
88    float refavg=refsum/20;
89
90    float sum = (refavg - angleavg);
91
92    SerialBT.print((90-sum));
```

1 Calculate **average reference** angle and **ear** angle

2 Calculate **neck** angle

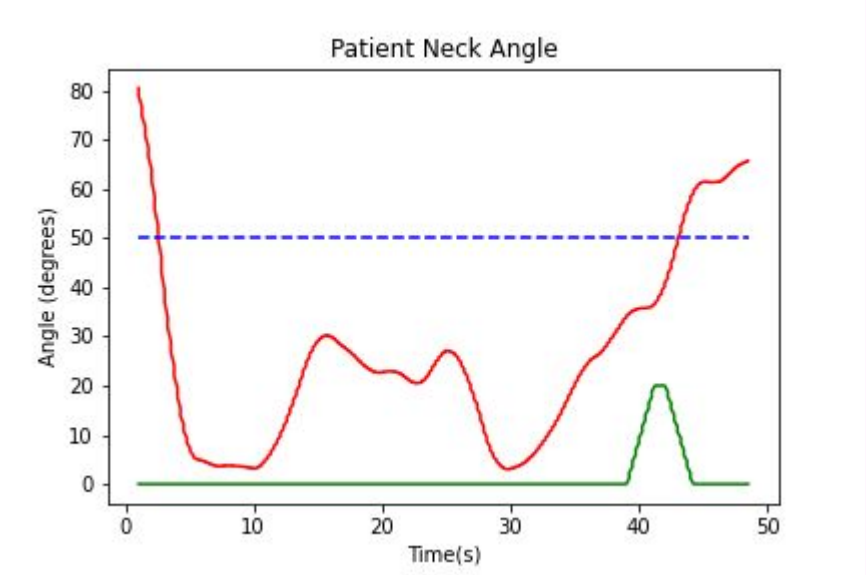
3 Display neck angle **relative to the horizontal**

DATA FLOW (STATE MACHINE)



DATA VISUALIZATION

	A	B
1	Average angle	25.93777399
2	Time	Neck Angle
3	1.04	80.43
4	1.04	78.79
5	1.29	76.67
6	1.29	74.75
7	1.55	72.65
8	1.55	70.66
9	1.8	68.55
10	1.8	66.4
11	2.05	63.95
12	2.05	61.45
13	2.29	58.54



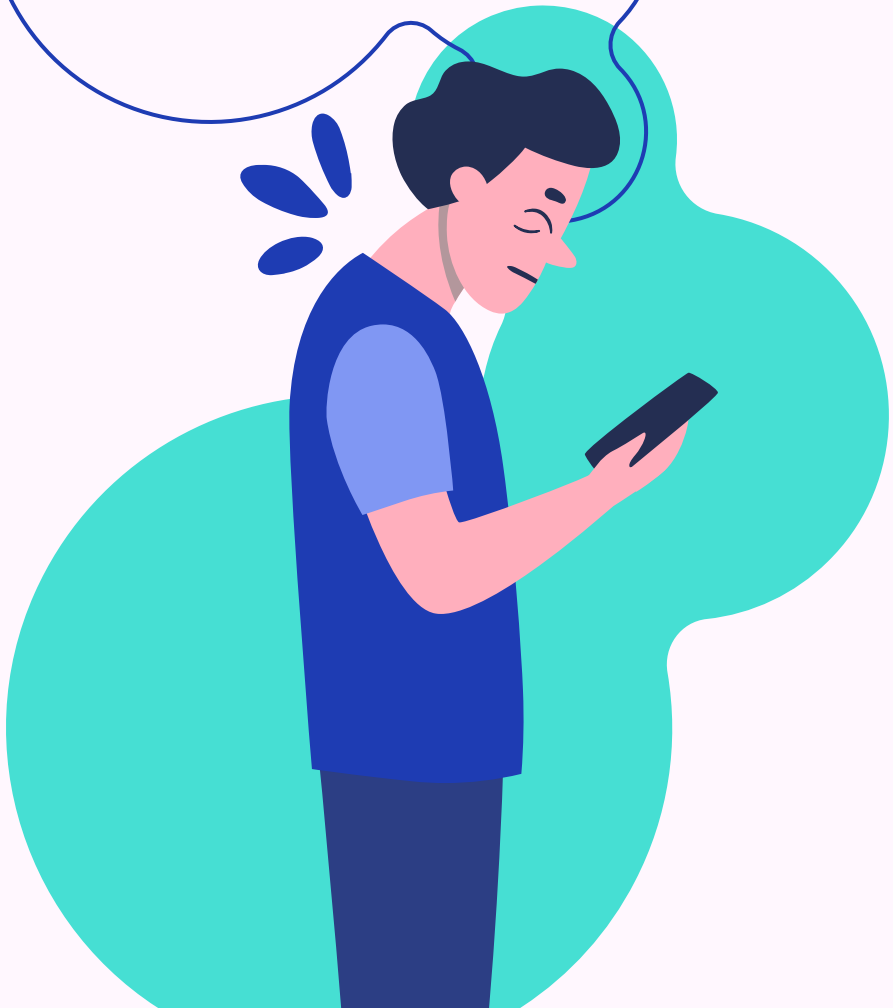
EXCEL FILE

PLOT

04

USER IMPACT

A review and **assessment** of our device build & user feedback against initial criteria



PATIENT FEEDBACK

Patient neck angle >50 degrees → Buzzer OFF
Green LED ON

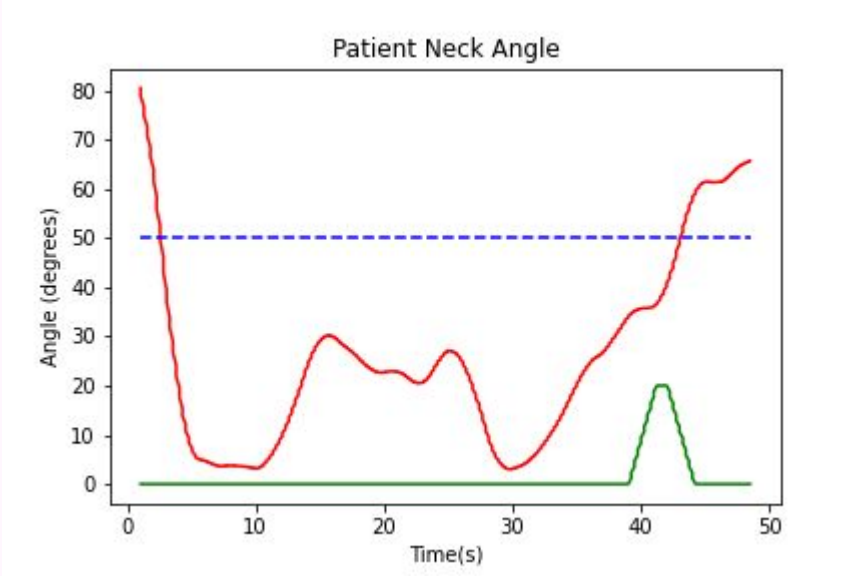
Patient neck angle <50 degrees for <30 seconds **before** Red LED
OR
Patient neck angle >50 degrees for <30 seconds **after** Red LED
→ Turn buzzer OFF; Yellow LED ON

Patient neck angle <50 degrees for >30 seconds → Buzzer ON
Red LED ON

CLINICIAN FEEDBACK

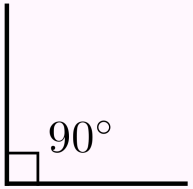
OUTPUTS AFTER WEARABLE SESSION:

- Neck angle (red)
  - Gives visual feedback on neck angle
- User compliance (green)
  - Good compliance = 0 on the plot
  - Bad compliance = peaks on the plot
  - Compliance = how quickly the user responds to live feedback
  - The shorter the compliance peak the faster the response to poor posture
- Plotted against the reference threshold = 50 degrees (blue)



CALIBRATION & VALIDATION

Use the **built in calibration** of the gyroscope



Calibrate so a normal cervical neck position is 90 degrees relative to the horizontal in the sagittal plane

Use tests to **validate accuracy** of design in both a **simulation and clinically**

Set both the reference and angle sensors to 90 degrees relative to the horizontal

Monitor angle measurements and relative angle (neck angle)

Move the angle sensor to various desired and known positions

Monitor angle measurements and relative angle (neck angle)

HOW DESIGN MEETS CRITERIA

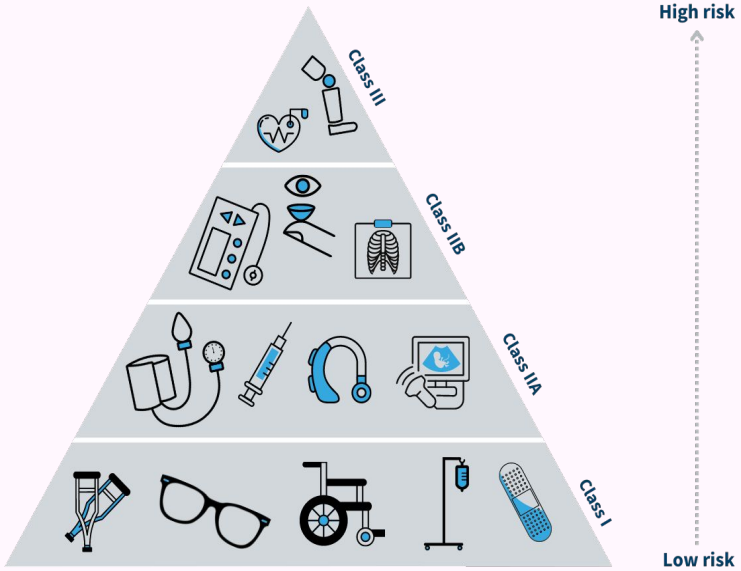
MUST BE: constraints	**SHOULD BE:** features	**CONSIDER:** options
Accuracy **validated**	Simple/**efficient** code written	Code outputs correct neck angle measures
Balaclava	**Small** components	Secure **housing** designed
Buzzer/LED **alert** system	Durable/standard equipment	**Buzzer**/**LED**s placed in housing
Reproducible	Simple **wearable**	In line with the **ear** & **C7**

05

USER/ETHICAL CONSIDERATIONS

CLASS 1 MEDICAL DEVICE

- Our balaclava aims to monitor neck posture to combat ‘text-neck’ and prevent the onset of non-specific neck pain.
- Because its **intended use is to prevent a specific disease**, i.e. non-specific neck pain, this device would be considered, under both Health Canada and the FDA, a **medical device**.
- It would be considered a **Class I** device because it is very low-risk and simple in design.



CAD/US. CLASS 1 REGULATIONS

FDA: Gen. Controls Only

requires adherence to manufacturing (**GMP**) and **labelling** standards

HEALTH CAD: Premarket Approval (PMA)

medical Device License (**MDL**) which has an associated cost of **C$389**, per application

LIABILITY & PATENT PROTECTION

Device provides **inaccurate** data → We engineers are held **liable** → Thus we conduct **testing** before market release

Alters clinical decisions on the basis of falsehoods (**dangerous**)

Device is **similar** to others on the market → Thus we conduct a search of existing **patents** → And we build upon our design **uniquities**

Device leaks **private** data without consent or due to **poor security** → We engineers are held **liable** → Thus we ensure **security** and obtain **explicit consent**

Transparent about data collection

EQUITY, INCLUSIVITY & DIVERSITY

Belonging

Feeling accepted as member of **society**, valued, connected

Inclusivity

Implement design features to accommodate **disabilities**; e.g., for patients with reduced motor function

Equity

Ensure our device does not perpetuate social inequality (e.g. via insurance companies) and **stigmatisation**

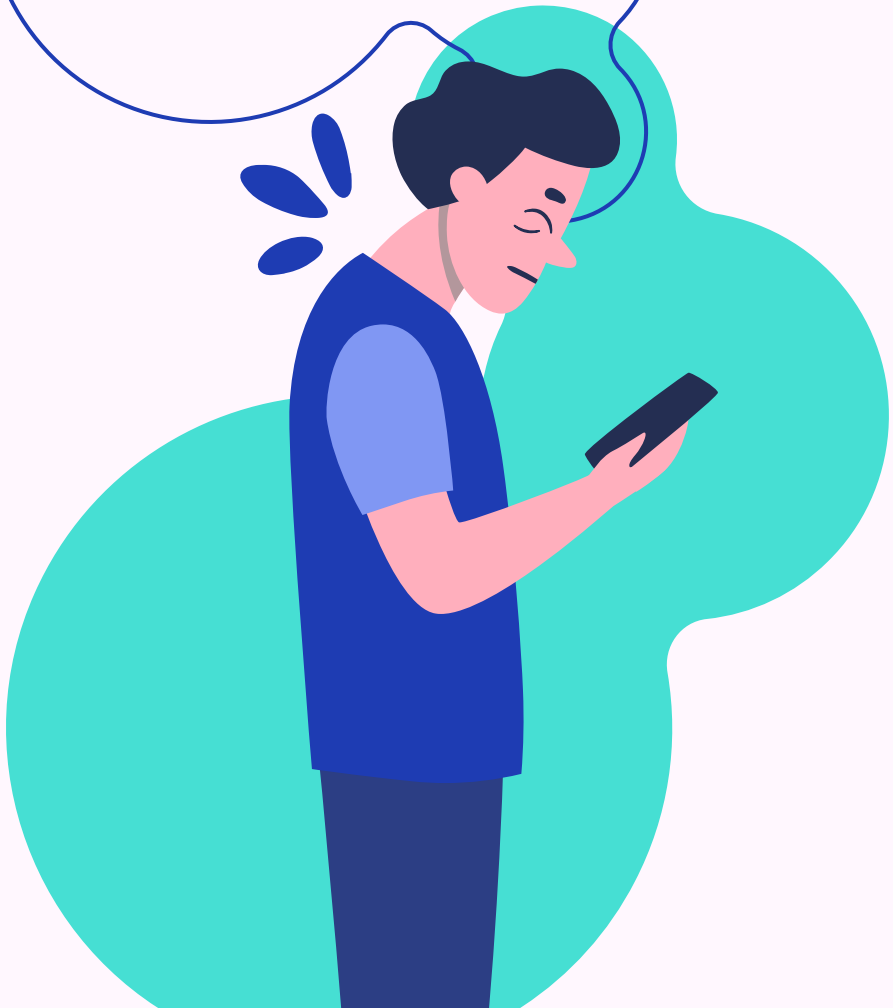
Diversity

Ensure our device is **accessible** and beneficial to a diverse group of users, outreach extending to **marginalised groups** (emphasize **affordability**)

06

FINAL DEMO

A live demonstration of our device in action



DEMO (VIDEO)

3p04_final.mov

BILL OF MATERIALS - COSTS

Item	Cost	QTY	Sourced From	Total
Breadboard	$4.45	1	Digikey	$4.45
ESP 32	$15.34	1	Digikey	$15.34
BNO055	$45.95	2	Digikey	$91.90
Buzzer	$2.92	1	Digikey	$2.92
LED	$0.33	3	Digikey	$1.00
330 Ω resistor	$0.10	3	Digikey	$0.30
USB2.0 to Micro-USB Cable	$7.16	1	Digikey	$7.16
M/F 6" Jumper Wire	$3.03	1	Digikey	$3.03
Jumper Wire M to M 3" 28AWG	$1.95	1	Digikey	$1.95
QWIIC Wires	$2.16	2	Digikey	$4.32
Micro-USB Wireless Charger	$7.59	1	Amazon	$7.59
Balaclava	$11.74	1	Amazon	$11.74
3D Printed Housing	$0.77	1	N/A	$0.77
		TOTAL		$152.47

ACQUISITION COSTS

DIGIKEY ORDER

Before tax: $129.12

After tax: $145.90

Shipping free in Canada for >$100

$145.90

AMAZON ORDER

Before tax: $19.33

After tax: $21.84

Shipping & customs fee = $14.99

$36.83

REFERENCES

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[2] "A standardized approach to the diagnosis and treatment of Spinal Pain," *Low Back and Neck Pain*, pp. 190–226, 2004.

[3] N. F. Mahmoud, K. A. Hassan, S. F. Abdelmajeed, I. M. Moustafa, and A. G. Silva, "The relationship between forward head posture and Neck Pain: A systematic review and meta-analysis," *Current Reviews in Musculoskeletal Medicine*, vol. 12, no. 4, pp. 562–577, 2019.

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[8] L. Simpson, M. M. Maharaj, and R. J. Mobbs, "The role of wearables in Spinal Posture Analysis: A systematic review," *BMC Musculoskeletal Disorders*, vol. 20, no. 1, 2019.

[9] K. Dunleavy, J. Neil, A. Tallon, and D. E. Adamo, "Reliability and validity of cervical position measurements in individuals with and without chronic neck pain," *The Journal of manual & manipulative therapy*, vol. 23, no. 4, pp. 188-196, 2015.