AM-I

biometric tracking for diabetes & stress

K.K. Wopat
MSc PDE 2020

University of Glasgow
THE GLASGOW SCHOOL OF ART

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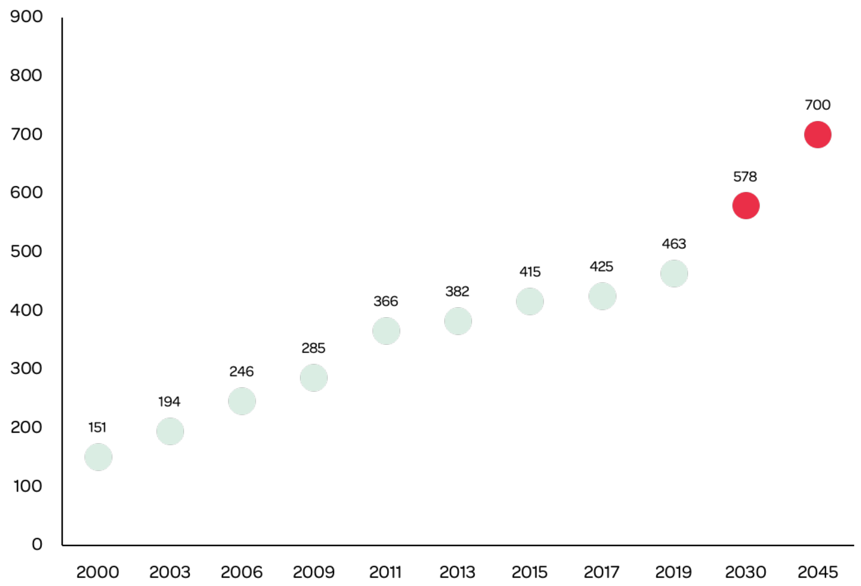
DISCOVER: PROBLEM & RESEARCH

PROBLEM: MANAGING DIABETES

Diabetes is a global epidemic affecting 463 million people worldwide in 2019. This number is projected to rise to 700 million by 2045 [9]

Number of Adults with Diabetes (in Mil.)



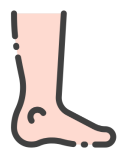
CAUSES & HEALTH RISKS

Diabetes is a condition which occurs when the body does not effectively produce and use insulin, a hormone which regulates blood sugar [5,9,11,18]

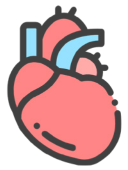
Type I: the body does not naturally produce enough insulin to regulate blood sugar

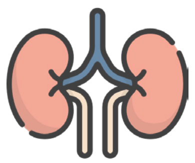
Type II: the body is resistant to insulin and does not effectively metabolise blood sugar

If diabetes is not managed and treated it can lead to dangerous health conditions:


nerve damage


vision damage


cardiovascular disease


kidney disease

ANNUAL COST

$760B

Estimated global expenditure on diabetes-related medical expenses (2016) [18]

3-times the annual GDP of Scotland

CURRENT MANAGEMENT & TREATMENT

People with diabetes must monitor their diet, activity, and blood sugar to ensure they do not have too much or too little glucose in their bloodstream. Medication and insulin injections may also be required to regulate blood sugar [5,11]

HEALTHY DIET

Reducing consumption of added sugars, carbohydrates, and starchy foods has been shown to lower blood sugar

PHYSICAL ACTIVITY

An active lifestyle reduces risk factors for diabetes. Medical professionals recommend at least 30 minutes of moderate physical activity per day

BLOOD GLUCOSE SELF-MONITORING

Glucose monitoring is required multiple times throughout the day to check for hypo- or hyperglycaemia

MEDICATION & INSULIN

Insulin injections help the body process blood sugar, while medications such as Metformin are also used to lower blood sugar.

RESEARCH: STRESS & BLOOD SUGAR

Stress affects blood sugar through different physical and psychological pathways. [7]

SHORT TERM STRESS

In a brief instance of high stress, the body will produce adrenaline. Adrenaline prepares the body for 'action' by increasing blood flow to muscles and releasing additional glucose into the bloodstream.

LONG TERM STRESS

During periods of prolonged stress the body accumulates cortisol, a hormone which hinders insulin sensitivity. This elevates the amount of available glucose in the bloodstream.

COPING MECHANISMS

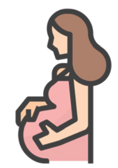
Studies have shown that increased levels of stress hormones such as cortisol is linked to increased cravings for sugary foods. Other studies have also shown that consuming sugar induces the release of oxytocin, a hormone linked to comfort and relaxation [14,15].

RESEARCH: INDIVIDUAL FACTORS

The ability to regulate blood sugar is dependent on several factors which vary from person to person [5,7]


gender & genetics


age


pregnancy & hormones


illness

DIRECTION: CONTROLLING BLOOD SUGAR & STRESS

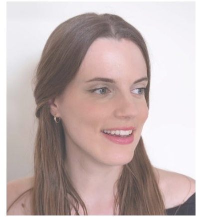
Controlling blood sugar is critical for managing the progression of diabetes and mitigating health complications. Blood sugar fluctuates throughout the day based on individual, diet, activity, and stress. [5,7,11] An improved diabetes management solution should account for individual differences and monitor the impact of additional factors such as stress which can affect blood glucose levels.

DISCOVER: USER RESEARCH

INTERVIEWS & OBSERVATIONS

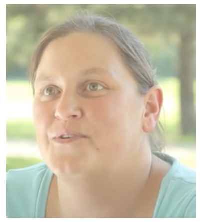
Daily Diabetes Management

First-hand interviews were conducted and 'day-in-the-life' experiences were studied to understand the key issues people face when trying to control their blood sugar.



Anne - Pre-Type II

"I have to track the amount of nutrients I eat at each meal by weight. If I eat badly it can take me a few days to recover and stabilise my blood sugar again."



Roxanne - Type II [1]

"[my doctor] told me to start exercising and losing weight ... at first it was very difficult ... changing your lifestyle is huge."

"I'm an emotional eater, so anytime I'm stressed at work or traveling for work it's hard to eat healthy."

"educating yourself is the most important thing ... [find] out what works for you."

Shelby - Type II [8]

"stress can raise glucose levels so managing it is very important to me"

"[sometimes] I check my glucose and it's up 16 points even though I haven't eaten anything!"

Francisco - Type II [2]

"My diagnosis really encouraged me to change my habits and behaviours, and I like to think of myself now as pretty healthy"

"I feel that it's up to you to manage your diabetes; you need to take control as much as you can – and as early as possible. I make sure I attend all my health checks and screenings, and frequently visit my GP to ensure I'm taking the correct steps in order to keep myself healthy."

KEY INSIGHTS

CURRENT SOLUTIONS

TRACKING BLOOD SUGAR

Users must check their blood sugar daily to track their blood glucose is within a safe range.

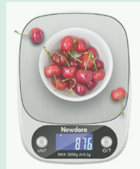
finger-stick self- monitoring

continuous monitor (CGM)

- low adherence (40%) self-monitoring [10]
- CGM automatically tracks blood sugar
- only covered for users who require insulin (US) [8]

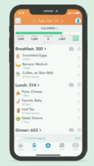
TRACKING DIET & ACTIVITY

In addition to checking blood sugar regularly, diabetics also track their food and activity daily.



smart scales

fitness wearables



smartphone apps

- additional onus on user to log food intake & activity
- smart products automatically sync with phone apps
- activity trackers such as FitBit have become widely adopted

MANAGING STRESS

A few of the users interviewed were aware of how stress affects their eating habits and blood sugar.

meditation

stress wearables

- meditation and mindfulness market is growing
- products like Oura Ring track sleep patterns, activity, and heart rate variability to determine daily 'strain'

INDIVIDUALISED CARE & FEEDBACK

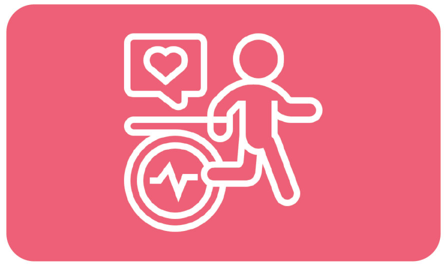
It is important to account for what works best per user based on unique physiology, lifestyle, and health conditions [6]

physician

diet & fitness coaching

- limited face-to-face interactions with GP
- tailored feedback based on health over time
- provides social accountability and support

DESIGN OPPORTUNITIES



WIDEN FUNCTIONALITY

combine glucose monitoring, activity tracking, and stress monitoring functions into single interface

PROVIDE BIOFEEDBACK [10]

improve users' understanding of their biological response to diet, activity, and stress by tracking multiple biomarkers

LEARN TRENDS

data-mine biomarker fluctuations over long term to understand health trends & recommend improvements

USER JOURNEY

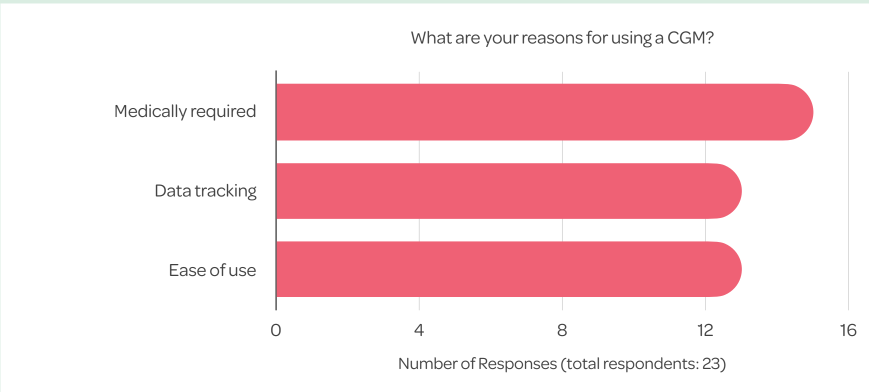
Building on the insights gained from interviews, a user journey was constructed to understand user experience of blood glucose monitoring, activity tracking, diet , and stress throughout the day.

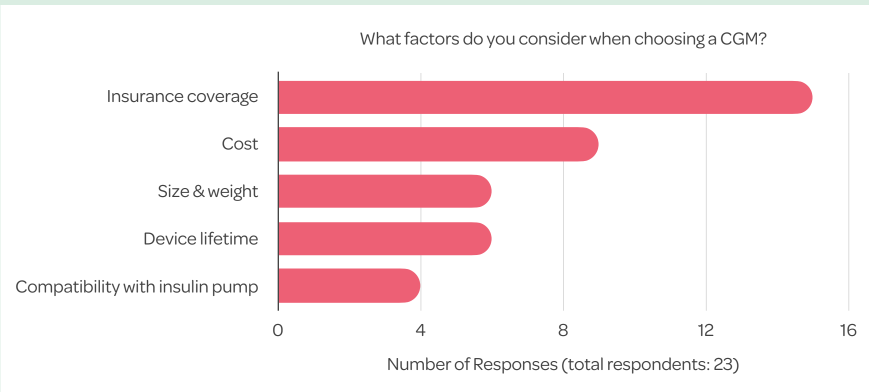
Sara Mulvaney, 41
Office Worker
Type II Diabetes
Monitors blood glucose with finger-stick style sensor

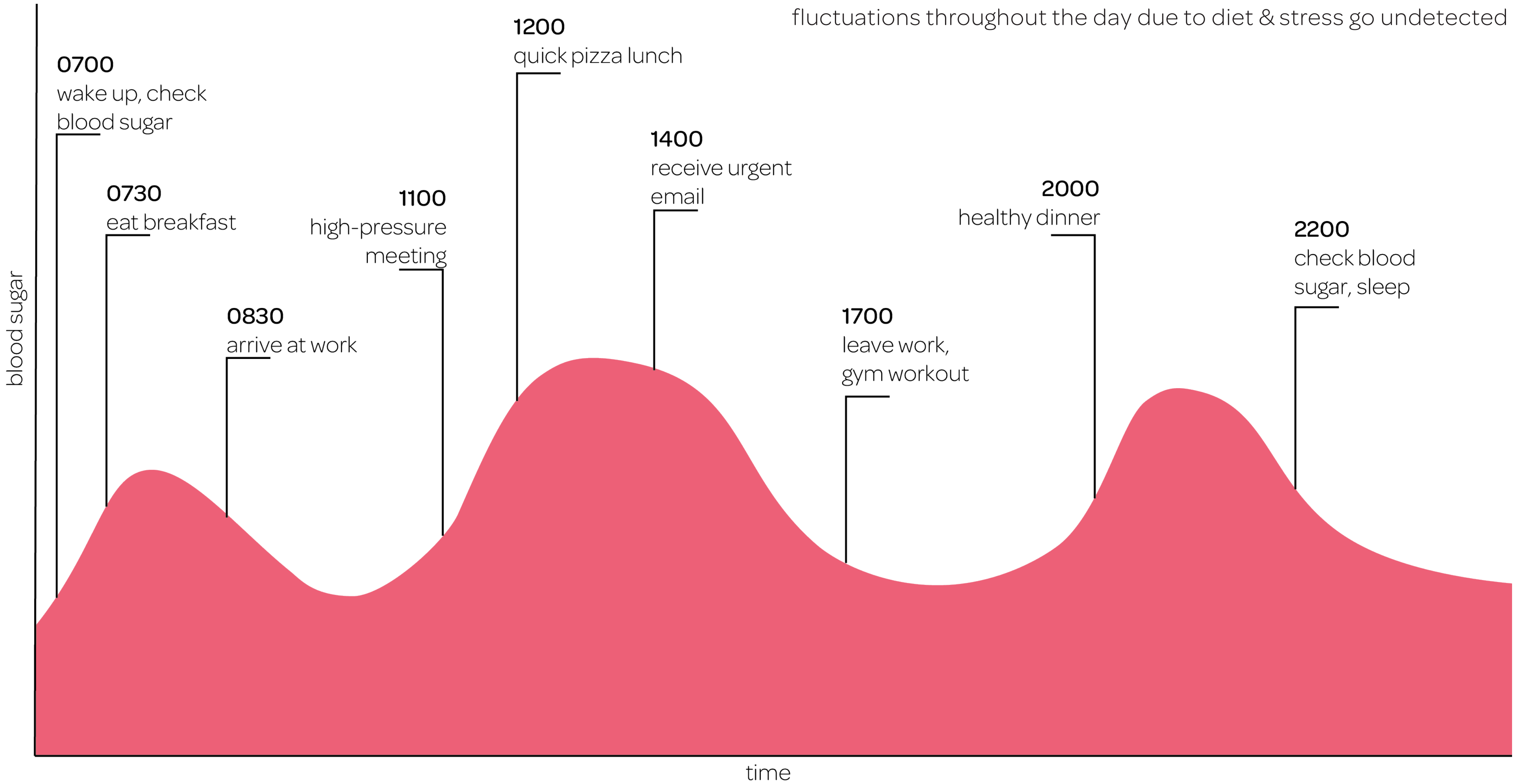
Needs & Goals
Monitor blood glucose at least 2x daily
Eat a better diet
Maintain regular exercise regimen
Manage stress

USER SURVEY

In addition to user interviews a user survey was conducted to understand the experience of current CGM users.







OBSERVATIONS

- stress builds throughout the morning resulting in high blood sugar before lunch
- Sara chooses a quick lunch high in carbs which elevates her blood sugar through the afternoon along with usual work stress
- since blood sugar is only checked morning and evening fluctuations throughout the day due to diet & stress go undetected

PRODUCT REQUIREMENTS

- accurately & reliably track blood glucose, physical activity, and stress biomarkers
- give biofeedback to user about blood glucose and stress fluctuations
- track trends and changes in blood sugar levels day-to-day
- data-logging blood glucose and stress readings for future analysis
- comply with relevant medical device safety regulations

USER REQUIREMENTS

- lightweight, compact, durable, and hard-wearing (e.g. waterproof, dust-proof, impact resistant)
- affordable and/or sponsored by health insurance
- simple to use and minimal user interface
- customisable, comfortable, and personalised fit
- good product aesthetics

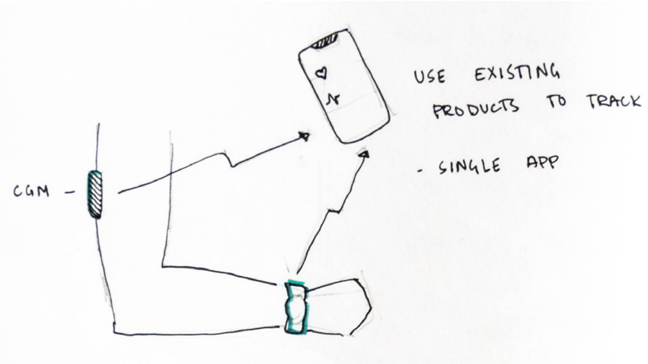
DEFINE: EARLY CONCEPTS

IDEATION

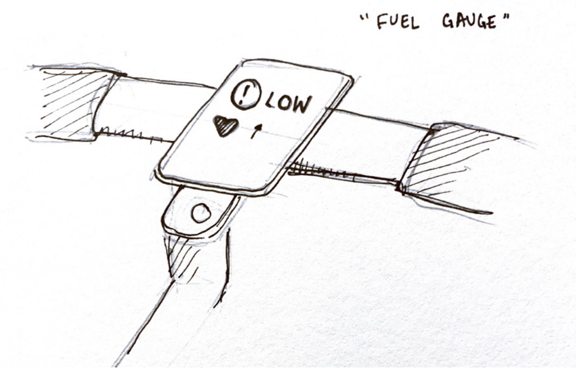
Concepts were generated based on the defined product & user requirements. These ideas were loosely grouped under the design opportunity categories identified earlier. From there, they were grouped more broadly into concepts for 'collecting data' and 'processing data.'

COLLECT DATA

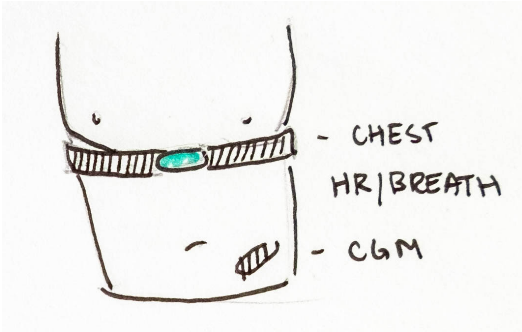
WIDEN FUNCTIONALITY & BIOFEEDBACK



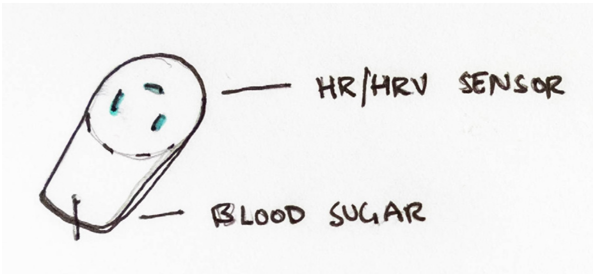
One of the earliest concepts was to simply collect data from a user's existing devices and display biometrics in real-time. By combining infromation from several biometric sources the user could piece together a picture of how blood sugar and physical stress were changing relative to one another.



Another idea came to me while I was cycling. I often find that I don't stop to snack often enough on a ride and end up binging on all sorts of quick carbs when I return home. If I knew what was happening to my blood sugar alongside my physical effort I could plan for more timely snack breaks before a large effort. This type of predictive tracking could also be used in a day-to-day case to track physical stressors and suggest a healthy snack before the wearer goes for a sugary comfort food.



Different stress sensing modalities were researched in order to understand effectiveness and opportunites for different sensors.



Solutions such as heart rate and breathing sensors are widely used to track stress-related biometrics such as heart rate, breathing pattern, and heart rate variability. Placing these sensors at multiple points on the body, however, didn't seem ideal as it would mean the user needed to wear and track more items.

This ideation exercised revealed a need for a product which could sense blood glucose in addition to other vital biometric readings.

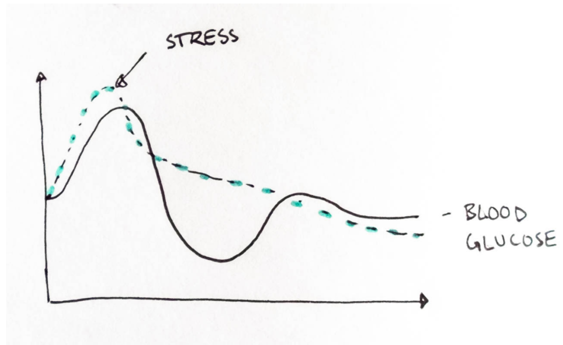
One of the primary reasons users wear a continuous glucose monitor device is so they can have immediate access to their blood glucose readings in the event they need to take medication. For this reason it makes sense to integrate an alert directly on the device in the case the user is unable to check his or her phone or external monitor device.

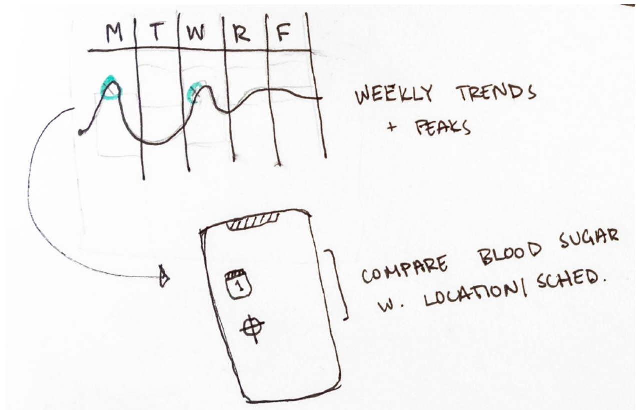
Surprisingly, this feature doesn't exist in any current CGMs.

PROCESS DATA

LEARN TRENDS

Biofeedback is a way to make users aware of the way their physiology changes under different conditions [6,10]. Using an app, a user can simply view an overlay of their blood glucose and their stress biometrics.





In addition to providing readings in real-time, data can be analysed over a longer period in comparison to a user's daily schedule. By correlating peaks in stress and blood sugar to events throughout the day or week a user can gain further insights into which factors are influencing their health.

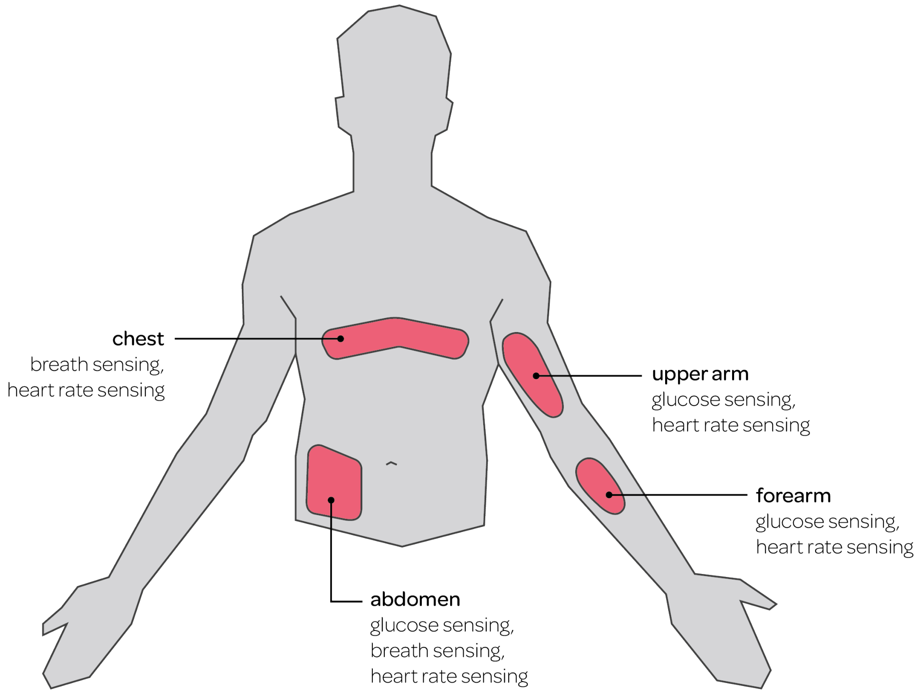
CONCEPT SELECTION

Since a physical device is required to acquire biometric data which can then be displayed in an application it made sense to pursue the development of a wearable device which tracks blood sugar & stress biomarkers.

DEVELOP: HUMAN FACTORS & SKETCH MODELS

WEARABLE SENSORS

Different worn locations were considered along with the size and types of sensors they supported.



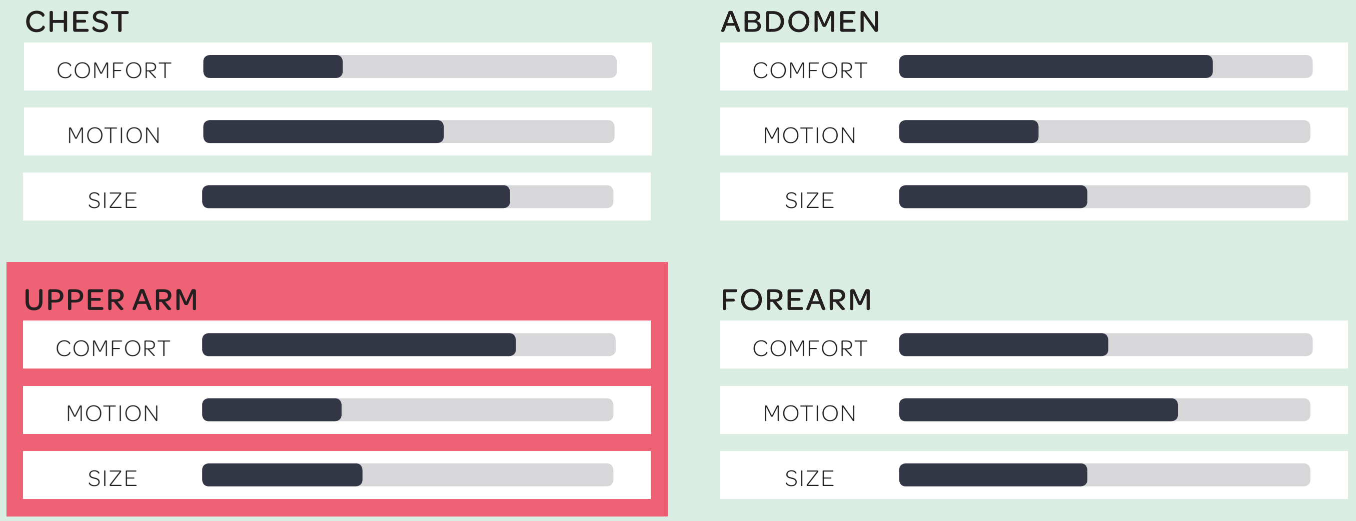
ANTHROPMETRICS & ERGONOMICS

Anthropometrics and ergonomic data was used to determine the ideal location for the wearable device.

COMFORT
perceived comfort based on 24/7 wear

BODY MOTION
high motion can lead to sensor reading issues

SIZE VARIATION
variation from one person to another

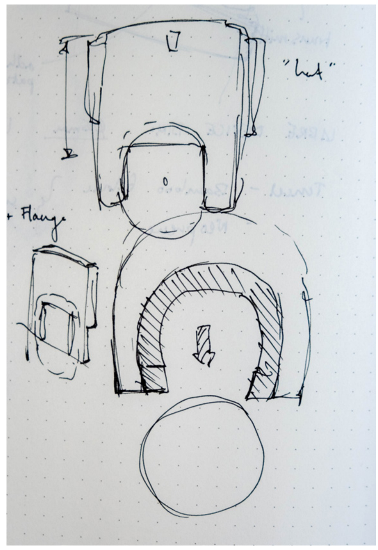


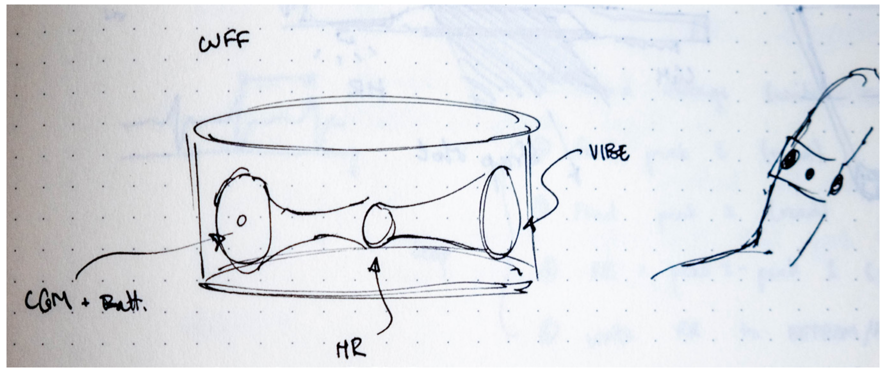
DESIGN EXPLORATION & SKETCH MODELS

Based on sensor support, anthropometrics, and ergonomics the ideal location for the device is the upper arm. Further design ideas were generated based on this placement. [3]

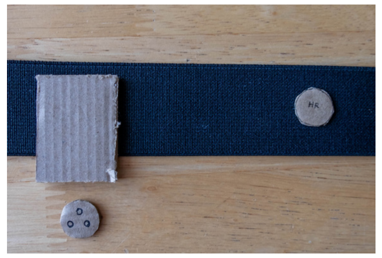
Competitive Analysis
I first made some cardboard models of existing CGM devices to get an idea of the scale of existing technology.

Add-on Concept
Since many people are alredy using a CGM, the first idea was to create a transmitter which could measure stress only, and leverage the readings from the existing CGM.





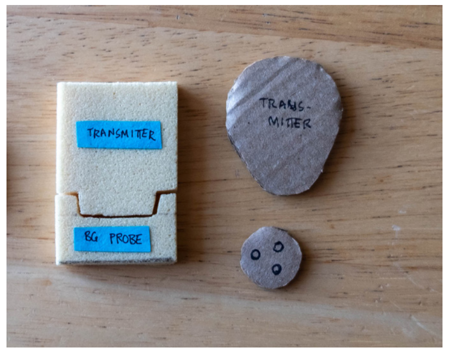
Cuff Concept
The cuff concept uses a cuff around the bicep to distribute sensors and other hardware.



Cuff Sketch Model
An elastic strap with different cardboard shapes corresponding to the different sensors was used to model the cuff. This design was not deemed comfortable as it had to be pulled quite tight to stay in one place, which was also difficult to do with one hand.

Add-on Sketch Model
The add-on or "hat" concept was modelled in cardboard with an elastic strap. This initial model was bulky and clumsy to handle.

Direction: Sticker/Strapless Concept
Most existing CGM devices don't use straps, but are held in place with skin-safe adhesive. If the proposed design were approximately the same size and weight as an existing CGM, then it could be attached in the same way as existing CGM monitors. To test the sticker concept I attached a cardboard model to my arm and wore it for a day. I found that the weight was not noticeable, but the device could easily be caught on clothing or bumped as I didn't realise it was there.



Due to the simplicity of this design it was selected moving forward.

Key Concerns
- lightweight
- smooth profile as not to get caught on clothing
- as small as physically possible

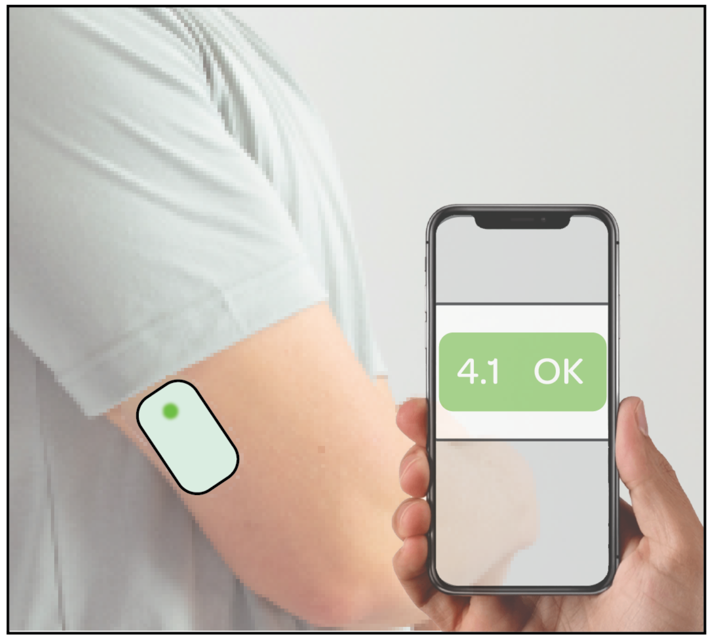
DESIGN: USER EXPERIENCE & INTERACTION

TOUCHPOINTS & INTERACTION

Envisioning user interactions with the wearable device & smartphone application in detail helped drive further design decisions such as attachment method, sensor selection, and alert delivery.

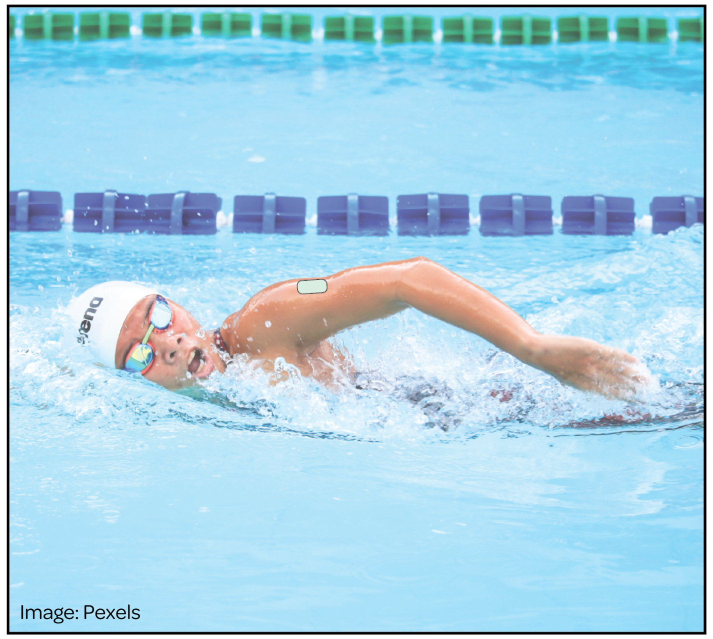
1. attach on upper arm
ensure good fit and sensor contact

2. sync with smartphone
wireless pairing



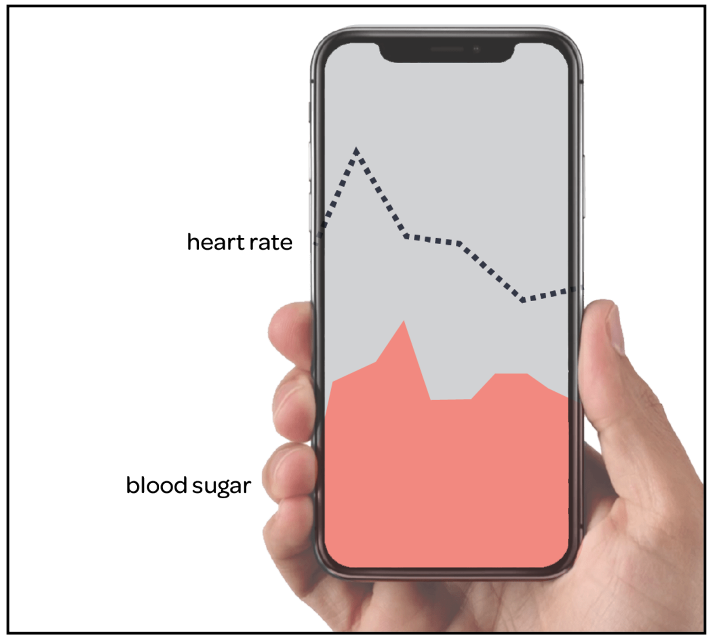
3. check blood glucose readings
pull data from sensor & display on smartphone in real time

4. high stress alerts
push notifications when stress increases



5. monitor physical activity
track heart rate and glucose in all conditions

6. blood glucose alerts
push notifications & alerts on arm when glucose level out of range



7. daily summary & trends
display overlay of blood glucose & stress

8. wear & monitor overnight
monitor stress & blood glucose 24/7

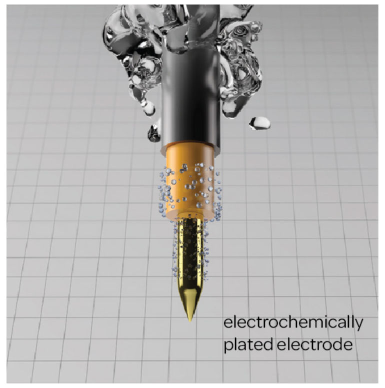
DEVELOP: TECHNICAL DEVELOPMENT I

REQUIRED COMPONENTS

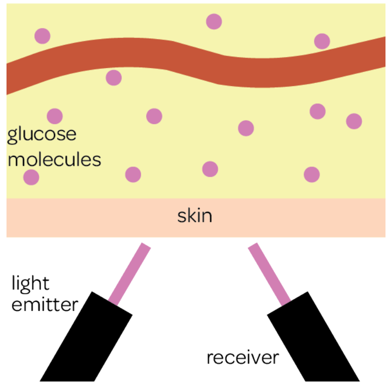
1 Glucose Sensor
2 Heart Rate Sensor
3 MCU + Bluetooth
4 LEDs
5 Vibe Motor
6 Power Supply
7 Housing
8 Mobile App

1 GLUCOSE SENSING

There are multiple methods for glucose sensing ranging from clinical blood draws to contact lenses which can take a reading from a users' natural tears. However, for the purposes of a wearable glucose monitor only a few sensing options are currently viable. [17]



Interstitial Fluid Sensing Probe [4]



Optical Sensors

Interstitial fluid (ISF) sensing uses a small needle-shaped microsensor which penetrates under the skin to monitor concentration of glucose in the body. [2,4]

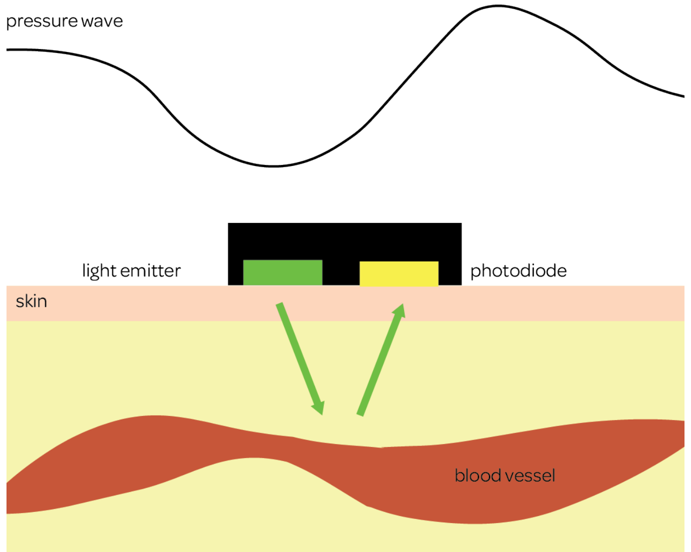
Optical sensors use advanced spectroscopy techniques to non-invasively measure glucose levels. [17]

	Advantages	Disadvantages
ISF Probe	• currently used in commercial CGM devices (FDA approved) • remains in place through-out day	• requires sensor which penetrates the skin • limited sensor life requires sensor replace-ment
Optical Methods	• non-invasive • does not require sensor replacement	• sensitive to movement & moisture • bulky in size

After weighing the pros and cons of each different type of device it was decided to move forward with the ISF probe-type of sensor.

2 HEART RATE SENSING

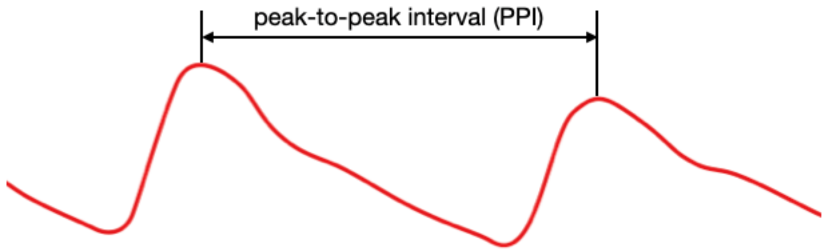
Heart rate sensing has been used for years in fitness wearables. The principal method used in most commercial wearables is optical heart rate sensing (OHR). OHR detects the change in volumetric blood flow under the skin during each heartbeat [12].



The 'pressure wave' detected by the OHR sensor can then be analysed in a number of ways to gain insights into the wearer's physical condition [12].

1. Heart Rate

The most basic measurement is the time interval be the peaks of the pressure wave - the peak to peak interval. The inverse of PPI is heart rate [12].



2. Heart Rate Variability

Detecting the change in PPI length gives another measurement known as heart rate variability. A low heart rate variability correlates to high stress [10].

3 DATA PROCESSING & TRANSFER

The microntroller will process, analyse, and transfer sensor readings to the user's smartphone. Wearables like the Dexcom G6 CGM and WHOOP Strap heart rate monitor use an integrated MCU & Bluetooth Low Energy chip by Nordic Semi [13]. This is also a suitable choice for this design as it is specialised for biometric wearables.

4, 5 & 8 NOTIFICATIONS & ALERTS

The function of notifications and alerts is to communicate device status and biometric reading status to the user. A combination of LED signals and vibrational alerts has been designed to communicate biofeedback and 'online' status.

	LED	Vibe
Successfully Paired	Solid Blue (1s)	-
Reading OK	Solid Green (1s)	-
Reading Out of Range	Blinking Red (3s) 2Hz On/Off	10Hz On/Off continuous notification until user acknowl-edges reading on smartphone
Battery Low	Blinking Blue (3s) 2Hz On/Off	5Hz On/Off for 3s
Pairing Error	Alternating Red/Green/Blue (3s) 2Hz On/Off	5Hz On/Off for 3s


LED placement was considered for visibility. LEDs were placed on the sides of the device rather than the top, so the user doesn't need to twist their arm & body to see the indicators.

6 BATTERY LIFE

The battery life of the device is dependent on the power consumed during sensing, processing, data transfer, and user feedback operations. A rough approximation of current consumption was made based on the power requirements of representative sensors, MCU, LEDs, and vibration motor.

	average current consumption (μA)
continuous glucose monitor	65
heart rate monitor	37
MCU	1
bluetooth module	18
LEDs	5
vibe motor	0.4
total	126.4

Assuming a **40mAh Lithium-Polymer rechargeable battery** the battery life of the device between charges is 14 days.

This lines up perfectly with the timing for glucose probe sensor replacement, however, since it is still a rough approximation, it made sense to speculate a solution for charging the device while worn.

6 MID-FLIGHT REFUELING

The solution designed is an attachable charging 'pod' which can be worn on top of the transmitter to transfer charge while the device is on the user's arm.

GLUCOSE SENSOR REPLACEMENT

One of the drawbacks of using an ISF probe is that the sensor wears out after 14 days and needs to be replaced. Some current CGM devices incorporate transmitter and probe into a single product, which generates more E-waste than if the probe and transmitter were separate. For this reason a 2-part replaceable glucose sensor and rechargeable transmitter architecture was adopted.

I used sketch models and bodystorming to understand the user interaction with the replaceable sensor and transmitter.

small injectable sensor + external transmitter

A small sensor would first be attached to the arm, then the user would align and attach a transmitter.

This was problematic for the user trying to reach the back of the arm to align the transmitter with the sensor.

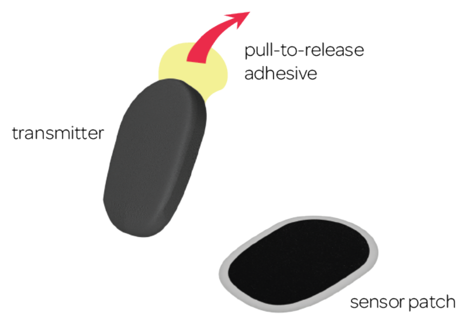
sensor patch + transmitter

An sensor patch is adhered to the transmitter first, then the entire device is attached to the arm.

This was the preferrable option as it required less coordination, awkward positioning, and fiddling with small parts.

SENSOR REMOVAL

A pull-to-release adhesive is used between the sensor patch and transmitter. Once it is time to replace the sensor, the user detaches the transmitter and peels off the sensor patch.



7 HOUSING DESIGN

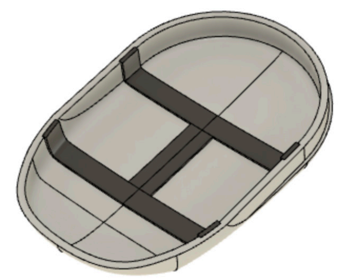
The housing protects and encloses the PCB and electrical components. As such, it should be waterproof and pressure resistant up to 3ATM (0.30 MPa). These criteria are specified by the IP68 standard which is used broadly by wearables such as the Apple Watch and WHOOP Strap which are meant to be worn 24/7, and can even be worn while swimming [16,19].

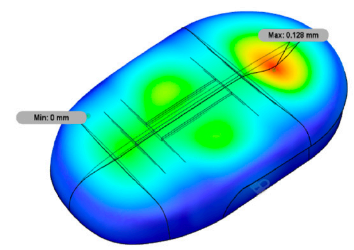
Material Selection

Various materials were evaluated across different performance criteria. Although it was tempting to choose a metal alloy for improved aesthetics and durability, the functional parameters of waterproofing and radio frequency emissivity meant that ABS was the better solution for this design.

Structural Design

ABS is not a particularly stiff structural material, so thought was given to the shape and reinforcement of the housing. A shell-like shape with large radii helps distribute load over the housing surface, while a thin steel 'skeleton' is added to the underside for additional stiffness.

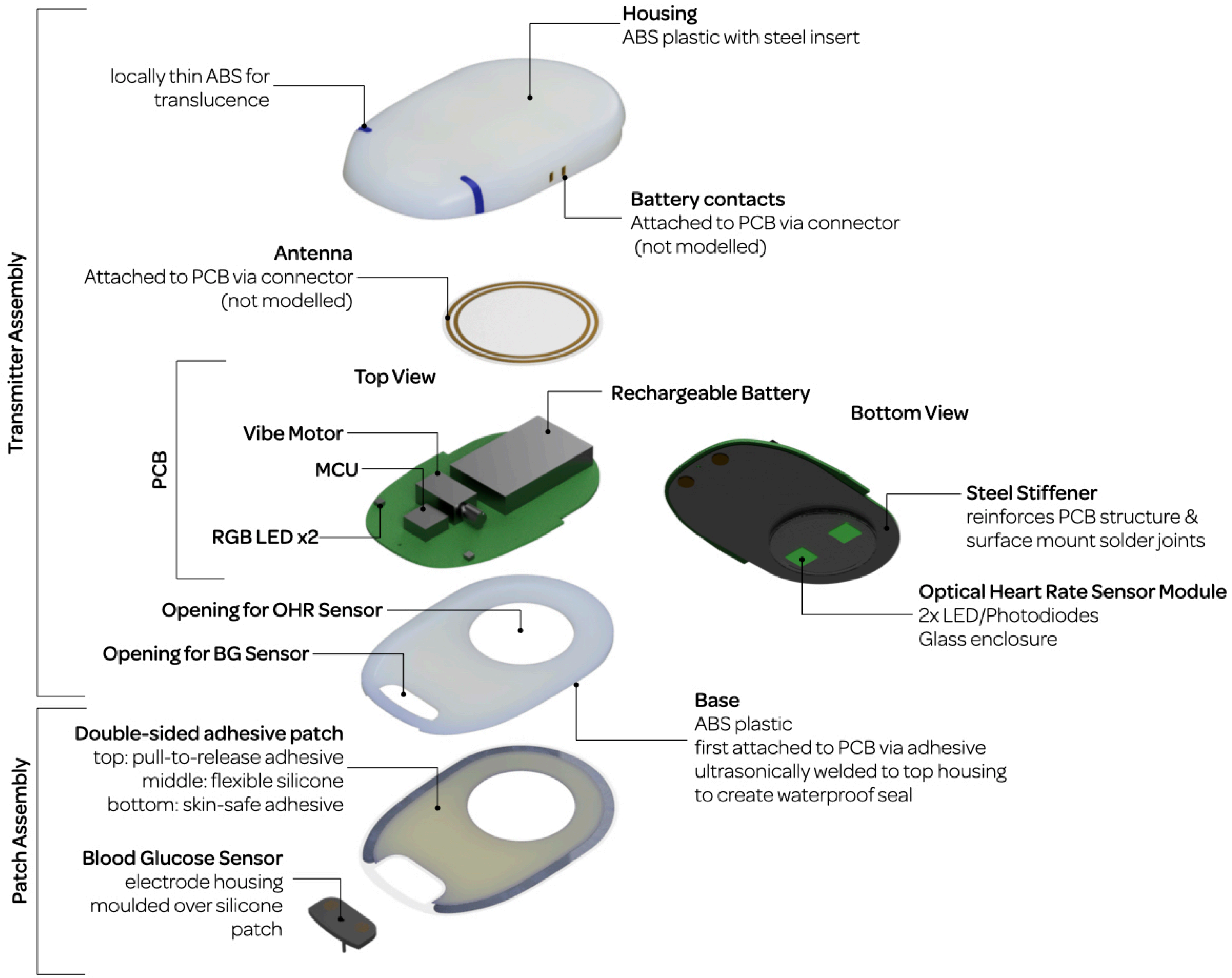




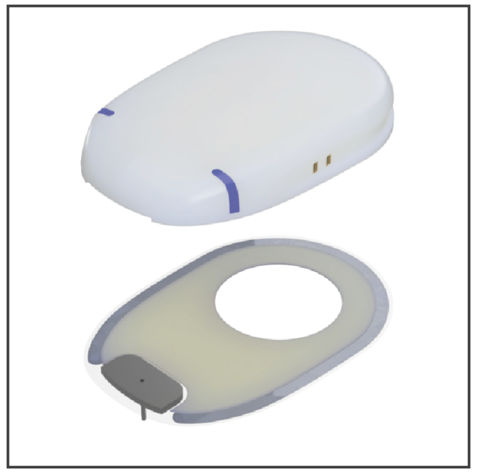
AM-I
K.K. WOPAT
MSC PDE 2020

DELIVER: FINAL DESIGN

ASSEMBLY EXPLODED VIEW



USER EXPERIENCE


1 Install new sensor patch


2 Apply device &
pair with smartphone


3 Check status on arm


4 Review data & trends

5 Charge while wearing


6 Remove transmitter & glucose
sensor patch

SUMMARY

Although it goes without saying that this semester went a little differently due to COVID-19, it did push me to approach this project creatively.

Without access to the studio, I hoarded Amazon boxes, made a foam cutter out of some popsicle sticks and a 9V battery, and scavenged old bike parts for material. I relied heavily on my flatmate and a few ‘sanctioned’ friends to help bodystorm and play with prototypes. I turned to the internet for teardowns, reviews, and all the information I could acquire about wearable blood glucose sensors. In between our tutorial Zooms I would bounce ideas off of whoever was listening (sorry, Mom, I know you’re tired of hearing about biometrics).

After a semester of sticking stuff to (unfortunately very few) peoples’ arms I learned a few things: never underestimate how much you can get done in cardboard, double-sided tape is holding the world together, and design can be a socially-distant process if you take enough photos and video.

For the next steps of this design were I to carry it forward, I would like to user test with more people and develop a higher fidelity functional prototype. The development process for medical devices is necessarily lengthy, however, with interest growing in the health wearables market, I believe the time is right for a product like AM-I.

FINAL THOUGHTS

I did not set out at the beginning of this term to design a product for people with diabetes. My early research was centred on habit forming and encouraging people to stick with healthier choices for themselves and for the environment. However, during the course of my research I found that most people are unaware of what is holding them back when it comes to making a change in their lifestyle. External factors like stress, busy schedules, and fluctuations in health have an under-perceived impact on people’s ability to invest in better habits.

At the same time, lockdown meant I was spending a lot more time with my flatmate who was recently diagnosed as diabetic. I saw her frustrated with the amount of time she spent tracking her food intake and blood glucose. Even though she was paying close attention to her nutrition, she still found her blood glucose could fluctuate due to how much activity or stress she had throughout the day.

With these different influences in mind I realised that there was an opportunity to give people a better insight into their health, their habits, and the way they impact one another. AM-I is a product that takes the first step to helping users understand what’s happening underneath the surface. It seeks to answer the questions we all encounter about our health:

am I tired? am I stressed? am I sick? am I alright?

AM-I is currently designed for people who need to track their blood sugar due to diabetes, however, biometric sensing can help all of us get a better understanding of our health and choices. As the saying goes, “change starts from within.” With AM-I, users can take a look within and begin to change.

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IMAGES

Cover Image: Available on StockSnap
Other images cited in text

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