Ramoni

The Next-generation Atrial Fibrillation Diagnosis Device

Master Thesis

Yuxiang Wang

Supervisory Team

Chair
Prof. Dr. Ir. Kaspar Jansen
Professor of Emerging Materials
Department Design Engineering,
section Emerging Materials
+31 (0) 152786905
k.m.b.jansen@tudelft.nl

Mentor
Liselotte Stolk
Co-founder
Praxa Sense B.V.
liselotte@praxasense.com

Mentor
Ir. Iemkje Ruiter
Assistant Professor
Department Industrial Design,
section Applied Ergonomics and Design
+31 (0)15 27 81520
I.A.Ruiter@tudelft.nl

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MSc Integrated Product Design
Faculty of Industrial Design Engineering
Delft University of Technology, the Netherlands

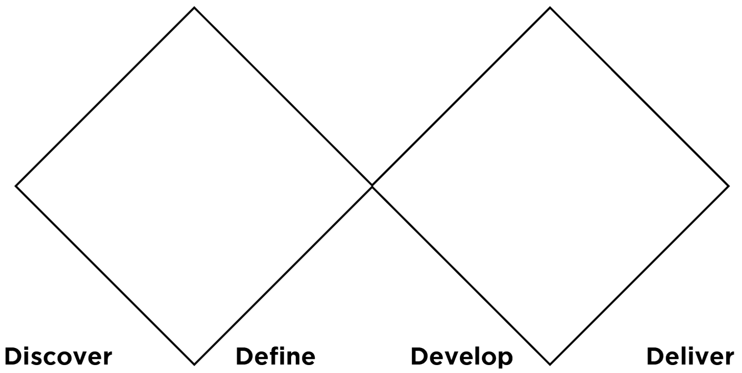
Yuxiang Wang
yuxiangwang@yahoo.com
Student Number: 4744314
Graduation Date: 24/09/2019

EXECUTIVE SUMMARY

This five-month project is a collaboration between TU Delft and Praxa Sense to explore and design the next-generation Atrial Fibrillation diagnosis device. Given the characteristics of Atrial Fibrillation, it is painful and tricky to make an effective diagnosis, and there are no existing products on the market that can fulfill this goal with a balanced consideration for both patients and professionals. There are various directions to tackle this wicked problem, but the focus is chosen as user experience and diagnosis accuracy after extensive research. The outcome of this project is an off-hospital long-term (more than one month) continuous monitoring device that can make Atrial Fibrillation early diagnosis with unprecedented user experience and high accuracy. Key innovations of the design are the most compact form factor, daily disposable sticker electrode integrated with 3M Z-tape technology, and vibration as the primary communication method. Finally, a proof of working principle was built to verify and test the performance, and user tests were carried out to evaluate the design of electrodes and the user-product communication method.

PROJECT STRUCTURE

The project was carried out in the following phases: research, analysis, synthesis, design, detailed design, and evaluation, which forms a double-diamond structure. In the beginning, research and analysis widened the scope of the project, which was followed by synthesis, making the project focus on a few aspects. Then the designing phase, together with continuous prototyping and testing, various solutions were brought up within the focus, which opened up the scope of the project again. Finally, detailed design and evaluation wrap up the project.



ACKNOWLEDGEMENT

I would like to thank my chair, **Prof. Dr. Ir. Kaspar Jansen** for his guidance and detailed knowledge of materials, which significantly facilitated my ideation and prototyping process. It is a pleasure to work under his supervision, who was incredibly accessible even during the summer break. The prototyping process would not have been so quick without his help in the summer.

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GLOSSARY

AFib (Atrial Fibrillation)	An abnormal heart rhythm characterized by rapid and irregular beating of the atria
Arrhythmia	Irregular heart rhythm
Atria	Upper chambers of the heart
AUC (Area Under the Curve)	One of the most important evaluation metrics for checking any classification model's performance.
Biosignal	A biosignal is any signal in living beings that can be continually measured and monitored.
Cardioversion	A medical procedure converting arrhythmia to normal rhythm
Congenital	A congenital medical condition or disease has affected someone since they were born
ECG (Electrocardiography)	A graph recording the heart's electrical activities
EMG (Electromyography)	A technique recording muscles electrical activities
Heart rate variability (HRV)	Variation in the time interval between heartbeats
HIIT	High-Intensity Interval Training, a form of interval training, an aerobic exercise strategy
Holter	A type of portable ambulatory electrocardiography device
Hypertension	High blood pressure
Ischemia	A restriction in blood supply to tissues
Parkinson's Disease	A progressive nervous system disorder that affects movement
Paroxysmal	Sudden, recurring
Praxa Sense	The company this project is collaborated with
R-R interval	The time interval between two consecutive R-tops in ECG
Sinus rhythm	The normal regular heart rhythm
Ventricle	Lower chambers of the heart
Z-Tape	A special conductive double-sided tape that is conductive through the thickness by 3M

CONTENTS

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RESEARCH AND ANALYSIS

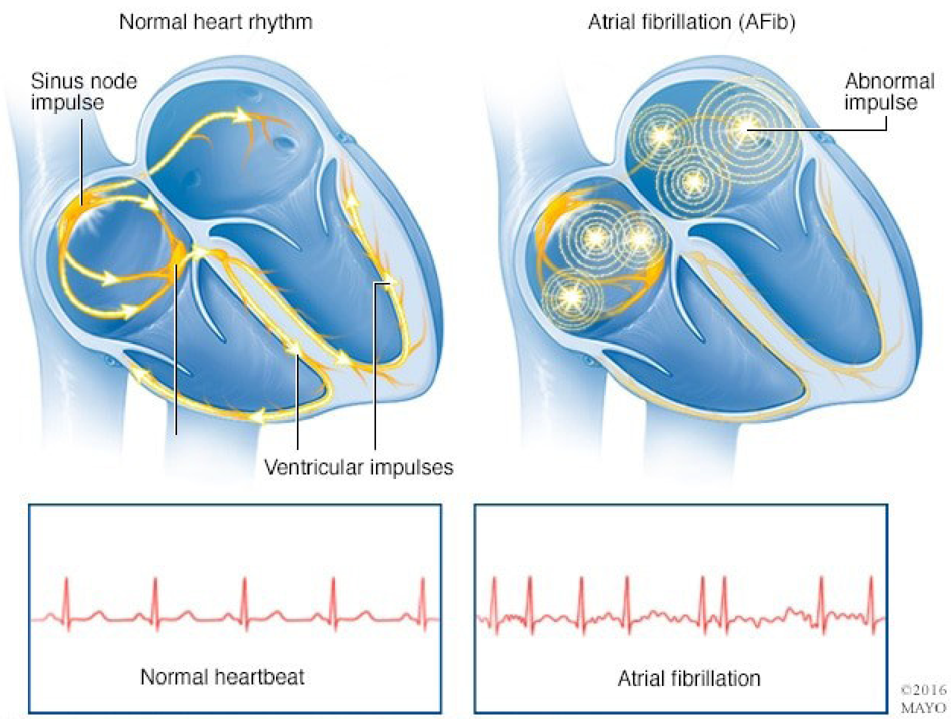
This chapter covers the initial information gathering and filtering process, including basics of Atrial Fibrillation, current diagnosis technologies, existing products benchmark, finding from the interviews with potential users, patients, and general practitioners. Initial diagnosis strategy analysis and preliminary experiments are also involved.

Atrial Fibrillation

According to American Heart Association (2016), "Atrial fibrillation (also called AFib or AF) is a quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications."

What happens during Atrial Fibrillation?

The heart's pumping is governed by weal electrical signals generated by the sinus node from the heart (shown in the picture). Normally, the heart contracts and pumps blood around the body according to the regular signals sent from the sinus node, which results in a normal regular heartbeat. During Atrial Fibrillation, together with the sinus node sending out regular electrical impulses, various parts around the atria (the upper chambers of the heart) also generate electrical signals chaotically. These multiple, irregular messages make the atria quiver or twitch, which is known as fibrillation (British Heart Foundation, 2019). A normal heartbeat is 60-100 beats/minute, while the atrial can quiver or twitch 300-600 times/minute. The ventricles (the lower chambers of the heart) reacts irregularly as well and may contract slowly or rapidly based on the health condition of the conduction system (Chatap, Giraud, & Vincent, 2002).



Symptoms

Atrial Fibrillation patients may have no symptoms and are unaware of the condition. Those who do have AFib symptoms may experience symptoms as (Mayo Clinic, 2019):

- Palpitations, which are sensations of a racing, uncomfortable, irregular heartbeat or a flip-flopping in the chest
- Weakness
- Reduced ability to exercise
- Fatigue
- Lightheadedness
- Dizziness
- Shortness of breath
- Chest pain

Atrial Fibrillation patients' description of their experience:
"My heart flip-flops, skips beats, and feels like it's banging against my chest wall, especially if I'm carrying stuff up my stairs or bending down."

"I was nauseated, light-headed, and weak. I had a really fast heartbeat and felt like I was gasping for air."

"I had no symptoms at all. I discovered my AF at a regular check-up. I'm glad we found it early."

Risks and Treatments

A major concern with atrial fibrillation is the potential to develop blood clots within the upper chambers of the heart. These blood clots forming in the heart may circulate to other organs and lead to blocked blood flow (ischemia). Atrial Fibrillation accounts for 15% to 25% of stroke (ischemia in the brain), caused by the clot entering the bloodstream and lodges in an artery to the brain. Treatments for atrial fibrillation may include medications and other interventions to try to alter the heart's electrical system (Mayo Clinic, 2019).

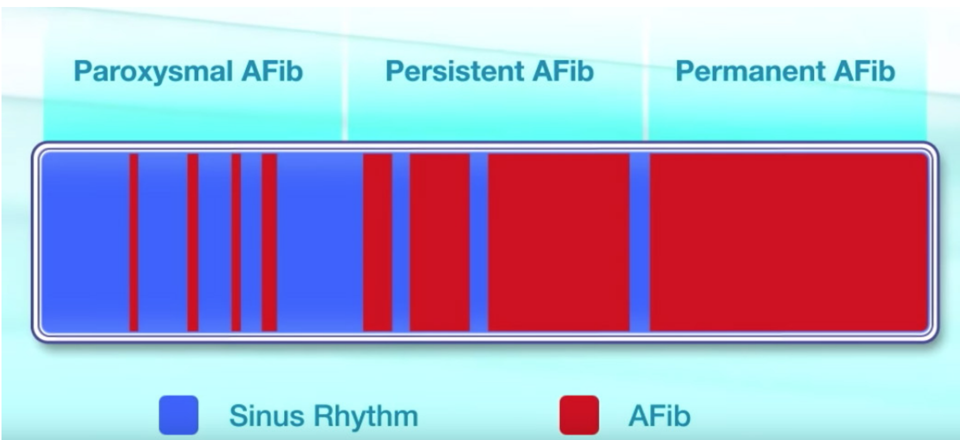
Development of Atrial Fibrillation

According to Heart Rhythm Society, Atrial Fibrillation is a progressive condition, and there are three types of AFib: Paroxysmal AFib, Persistent AFib and Long-standing persistent AFib (formerly known as Permanent AFib).

Paroxysmal AFib sometimes occurs and then stops. AFib stops by itself, and the heart returns to a normal rhythm. AFib may last for seconds, minutes, hours, or days before the heart returns to its normal rhythm.
Persistent AFib does not stop by itself. Medications or a particular type of electrical shock (cardioversion) is used to help the heart return to a normal rhythm. If no treatment is given, the heart will stay out of rhythm.
Long-standing persistent AFib (formerly known as Permanent AFib) cannot be corrected. Medications and controlled electrical shock cannot help the heart recover the normal rhythm.

Possible causes of atrial fibrillation (Mayo Clinic, 2019):

- High blood pressure
- Heart attack
- Coronary artery disease
- Abnormal heart valves
- Heart defects you're born with (congenital)
- An overactive thyroid gland or other metabolic imbalance
- Exposure to stimulants, such as medications, caffeine, tobacco or alcohol
- Sick sinus syndrome — improper functioning of the heart's natural pacemaker
- Lung diseases
- Previous heart surgery
- Viral infections
- Stress due to surgery, pneumonia or other illnesses
- Sleep apnea



Patients' Perception of Atrial Fibrillation

According to the 2009 "Out of Sync" survey in the US:
Only 33% of AFib patients think atrial fibrillation is a serious condition
Less than half of AFib patients believe they have an increased risk for stroke or heart-related hospitalizations or death
60% of patients do not even know when they are having an AFib episode (Sanofi S.A., 2013).

Statistics of Atrial Fibrillation

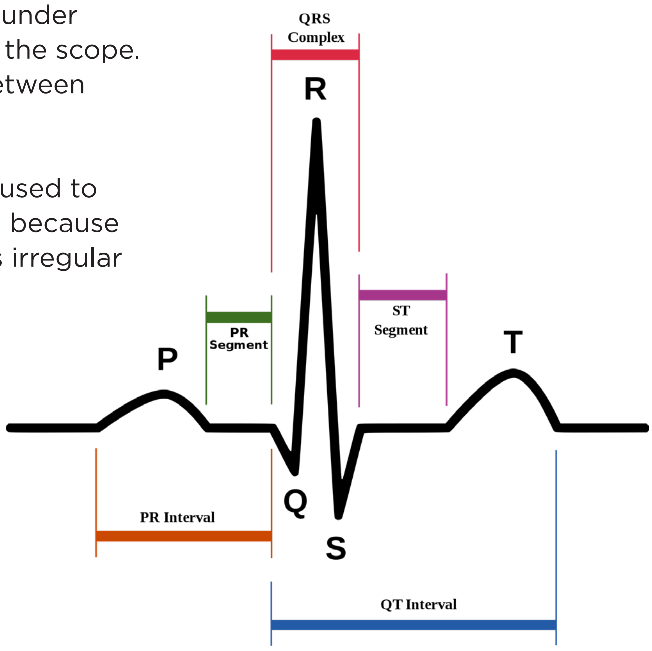
The overall prevalence of Atrial Fibrillation in the Netherlands is 5.5% in the population over 55 years, corresponding to about 250,000 AFib patients. The prevalence increases with age, and the mean age of AF patients is 69.3 years. Total costs of AF in the Netherlands are €583 million, of which the majority (70%) were accounted for by hospitalizations and in-hospital procedures (Heemstra, 2011).

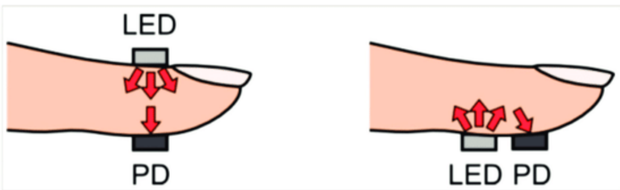
As for China, there are 290 million patients with cardiac disease, including 13 million stroke patients. The overall prevalence of Atrial Fibrillation in China is 0.71% in the population over 35 years. The increasing rate of Catheter Radiofrequency Ablation (RFCA) for is 13.2% - 17.5%, reaching 133,900 operations in 2017, in which the proportion for AFib increased from 21.0% to 27.3% from 2015 to 2017 (Hu et al, 2019).

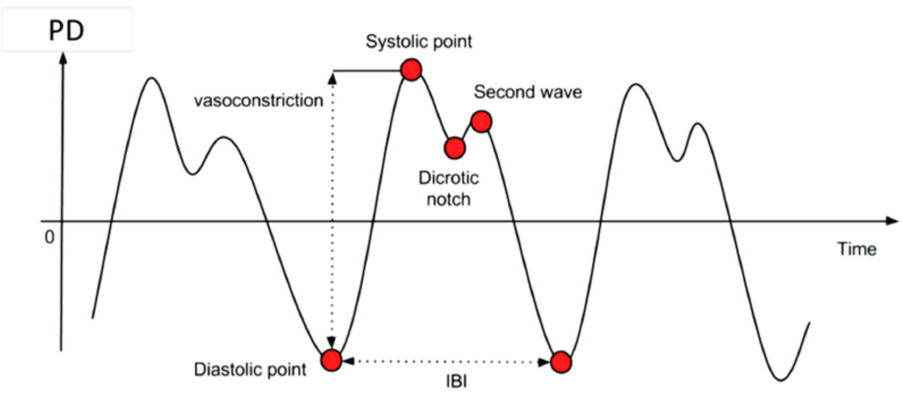
Diagnosis Technologies

There are mainly two types of technologies widely used to detect Atrial Fibrillation: ECG (Electrocardiography) and PPG (Photoplethysmography). Since the goal of the project is to design the next generation AFib diagnosis product, which should be launched in 2-3 years, technologies still under development are out of the scope. Here is a comparison between ECG and PPG.

These technologies are used to obtain the heart rhythm because Atrial Fibrillation causes irregular heart rhythms.







	ECG	PPG
Measure	Electrical signals produced by heart activity	Change of blood flow (optical sensor)
Accuracy	Very accurate, can be used as reference standard signal	Usually **< 95%** AUC
Settling time	Short (real time signal)	Longer (20-30s)
Power Consumption	**2.5mW**	**30mW**
Usability	Usually complicated to implement	Easier to implement

ECG measures the bio-potential differences caused by electrical signals that control the expansion and contraction of heart chambers shows the result on a graph. However, PPG sensors use light-based technology to sense the rate of blood flow as controlled by the heart's pumping action. In terms of accuracy, ECG is a reference standard signal that is used for monitoring cardio health and wellness by healthcare providers. PPG sensors, on the other hand, typically use ECG signals as a reference for static HR (Heart Rate) comparison. Besides, ECG sensors do not require long settling times so that meaningful readings can be obtained very shortly after start-up. PPG sensors require a relatively long settling time due to the need for measuring the amount of ambient light and calculating the compensation needed for canceling its effect.

As for power consumption, NeuroSky's BMD101 ECG sensor features shallow power consumption, operating at 2.5mW. Most PPG sensors require approximately 30mW of operating power (NeuroSky, 2015). Compared with PPG, ECG is more complicated to implement because it requires at least two electrodes to be placed at proper locations to measure the potential differences. However, with a proper algorithm, these two types of sensors could be implemented at the same time to provide better accuracy of AFib detection since when there is noise affecting one sensor the other one can be used as a reference, which needs further experiments.

Atrial Fibrillation (AF)

ECG and PPG for Atrial Fibrillation

Since ECG measures the electrical messages from the heart, the result of AFib can be directly seen on ECG. Compared with normal sinus ECG, Atrial Fibrillation on ECG has the features of

- Irregular heart rate (rhythm);
- No P-Wave existing.

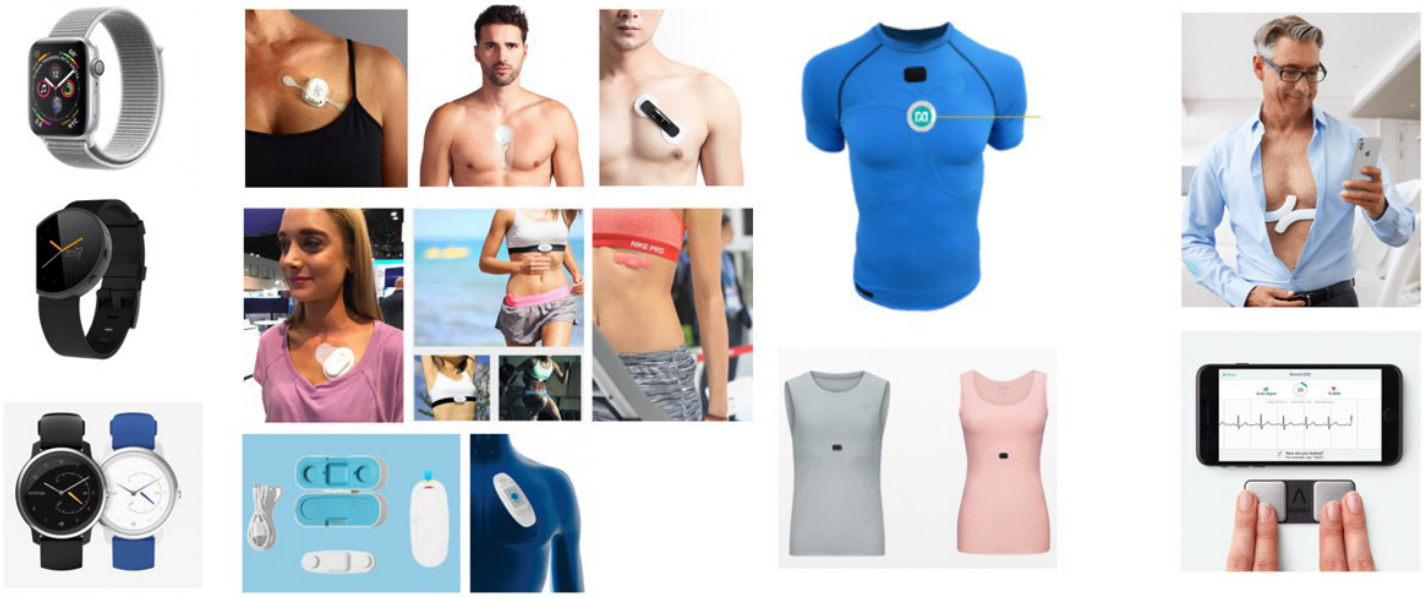
These two characteristics can be seen in the example below.

Irregular heart rhythms can be discovered using PPG during an AFib episode, while the P-Wave information is missing because instead of measuring the electrical activity, PPG uses light to measure the change of blood vessels, which is a result of the heartbeat. With the help of Machine Learning algorithms, PPG-based AFib detection accuracy can be increased to 95%. However, it is not possible to perform diagnosis using PPG result since the P-wave information is missing, which is the cause of the quivering of atria (Atrial Fibrillation).

Existing Product Benchmark

Various products capable of detecting AFib already exist on the market, including smartwatches, wristband, chest band, patch, shirts and smartphone add-ons, etc. Below is a list of medical products that have received a certain level of medical clearance. Other products such as ECG capable sports shirts, chest bands, and medical implants products are not included if they are not medical products or the product cannot be implemented without help from professionals.

Company	Country	Product	Category	Sensor Technology	Status
Apple	US	Apple Watch Series 4	watch	PPG+single-lead ECG	FDA Clearance
iRhythm	US	Zio XT/AT	patch	single-lead ECG	FDA Approved
MedTronic	US	SEEQ	patch	single-lead ECG	Discontinued
Cardiac Insight	US	Cardea SOLO	patch	single-lead ECG	FDA Approved
ZENSORIUM	US	Tinke	patch	PPG	Discontinued
QARDIO	US	QARDIOCORE	chest band	3+1 lead ECG	FDA Approved
AliveCor	US	Kardia Band/Mobile	portable	single-lead ECG	FDA Approved
cardiacsense	Israel	Cardiacsense watch	watch	PPG+ECG	expecting FDA mid2019
withings	France	Move ECG	watch	single-lead ECG	expecting FDA
VIVALNK	US/CN	ECG Monitor	patch	single-lead ECG	Launching 2019 Pre-FDA use only
HUAMI	China	AMAZFIT	Wristband Patch	PPG+ECG	CFDA Approved
BodyPlus	China	Smart ECG Shirt	shirt	12-lead ECG	expecting CFDA
MindRay	China	Mr.Wear	patch	single-lead ECG	CFDA Approved
Xijian	China	SnapECG	patch	single-lead ECG	CFDA Approved
Jiu'an	China	iHealth ECG	patch	single-lead ECG	CE Certified
Meixin	China	Vitals Monitoring Shirt	shirt	3-lead ECG	/



The pictures above are the products mentioned in the list above. They are categorized into watches, patches, shirts, and others according to the designs.

Here are some representatives from each category. Products with similar specs are not shown. Advantages and disadvantages are analyzed on comfort, ease of use, accuracy, AFib diagnosis, and obtrusiveness.

Apple Watch

As the representative of smartwatches and wristband, it utilizes PPG and two electrodes to perform single Lead ECG, which is similar to Lead-I ECG (Apple Inc., 2018).

Advantages:
1. Good product experience, and extremely comfortable;
2. Unobtrusive design as a watch;
3. Offers health information to the user;
4. Offers additional functions.

Disadvantages:
1. No long-term continuous AFib detection (5-6 PPG measurements per hour);
2. Signal quality is affected by long-distance from heart and movement between sensors and skin;
3. Short battery life (1-2 days);
4. No medical-grade diagnosis;
5. Expensive.

ZIO XT ECG Patch

As the representative of patches, it uses two electrodes to take ECG measurement.

Advantages:
1. Two weeks of continuous ECG monitoring;
2. Easy product application to the body;
3. Minimum operations needed from the user;
4. Long battery life (2 weeks).

Disadvantages:
1. Fall off skin in one week;
2. Cause irritation on the skin;
3. No information is provided about the health of the user during use;
4. Not use-friendly – needs to be sent to the company by post for data analysis.

AMAZFIT ECG Recorder

As the representative of hybrid product, it has two modes: wristband mode and patch mode, which is equipped with both PPG and ECG sensors.

Advantages:
1. Combines the advantages of wristbands and patches;
2. More freedom for users to use;
3. Use standard cheap wet electrodes;
4. Long battery life.

Disadvantages:
1. Complicated process to transform between a wristband and a patch;
2. Not comfortable in patch mode;
3. No information is provided about the health of the user during use.

BodyPlus ECG Shirt

A representative of ECG shirt. There are multiple dry electrodes printed on the inner side of the shirt. The processing of data is done on another piece of hardware attached to the shirt.

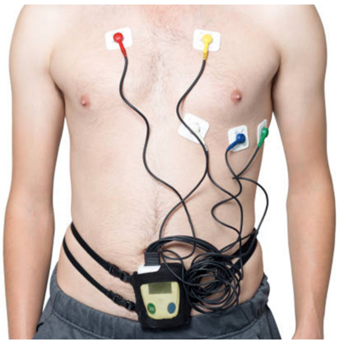
Advantages:
1. Continuous 12 lead ECG;
2. Simple operation as a regular shirt;
3. Easy and comfortable to use

Disadvantages:
1. Limit the users to wear similar shirts for a long period.
2. Signal quality may be affected because of dry screen-printed electrodes.

Scratch during Holter preparation

Holter

According to American Heart Association (2015), "A Holter monitor is a battery-operated portable device that measures and records your heart's activity (ECG) continuously for 24 to 48 hours or longer depending on the type of monitoring used. The device is the size of a small camera. It has wires with silver dollar-sized electrodes that attach to your skin." The Holter Monitor is the currently widely chosen solution for off-hospital heart monitoring.



Advantage:
Continuous 3/7/10/12 lead ECG;

Disadvantages:
1. Difficult to access (appointment with cardiologist/Holter analyst at hospitals);
2. Uncomfortable using experience;
3. Cause burden on daily life:
    - Limit on activities (no shower, no sports);
    - Unfriendly for female users;
    - Need to keep a detailed written diary;
    - Limit on sleep postures;
    - Limit on clothing choices.



Insights from AMAZFIT ECG Recorder

AMAZFIT ECG Recorder is chosen for an in-depth try-out because it has two forms of application: wristband and ECG patch, as shown in the picture below. Each of them has its advantages and disadvantages. Both forms are tested to learn about their strength and weakness, which may contribute to the inspiration for a new design.
The wristband is worn for more than one week even during sleep. Moreover, the patch is worn for 55 hours continuously during which a 24-hour continuous ECG record was taken. Standard wet electrodes (COVIDIEN Kendall H66LG) are used to obtain the ECG signal from the skin.

Before the test of AMAZFIT was carried out, a preliminary test about ECG electrodes was conducted to compare the signal quality between the recommended placing location and the conclusion from the company. Two different placing positions are shown below.

It turned out that placing the electrodes vertically at the middle of the chest produces better ECG signal, which has clear a signal and less noise. As a result, this placing method was applied in the AMAZFIT ECG patch mode test. Detailed location analysis can be found later in this report.

Wristband mode

Putting on
- Unfriendly putting on experience because the band is poorly designed.

ECG measuring
- Typical wristband characteristics: noisy ECG signal, non-continuous measurement, hinders desktop work, offering additional functions;
- The product malfunctioned to measure heart rate continuously when I was playing table tennis and sweating a lot.

As a watch

- It is a hassle to tap it to see the time;
- The screen cannot be seen from direct sunlight;
- The capacitive button offers no haptic feedback, giving the user a feeling of insecure;
- The capacitive button does not work reliably;
- Non-touch screen decreases the efficiency of being a watch.

ECG Patch mode

Apply the product on the chest

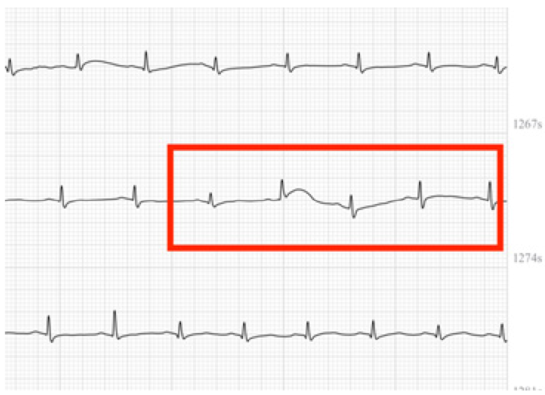
- For the recommended placing location, I mis-orientated the patch at the first try even though I had a look at the indication on the manual because the suggested location is not natural when you hold the product in your right hand to place it;
- I had some doubts about whether I have placed the patch at the optimal position.

Staying on the chest

- It fell off completely when I was bending over to put on my shoes (3mins after putting it on);
- I can't sleep on the front because of the product on my chest, which makes me feel uncomfortable;
- I felt itchy around the electrodes after several hours of application, and the situation becomes more and more severe;
- I felt tearing skin when I was stretching out my arms;
- I felt unwilling to take a shower because I have an electronic device registering my heartbeat attached to my body;
- Sometimes I was afraid to do significant movement because I did not want the device to fall. Most of the time I forgot that I was wearing a medical device;
- The measurement stopped at 24 hours and vibrated to inform the user.

Data obtained

- Obtained 24-hour continuous ECG data (divided by each half an hour) in PDF format;
- No suggestions or initial diagnosis offered. It was very difficult to look into the data to find any abnormalities since the graph is too long and the ECG looks boring;
- From observation, movement of the body and touching the skin near the electrodes have a direct influence on the graph as shown in the picture below;
- I don't know what I was doing when the ECG behaves strangely. So, I don't know if it is because of my normal activities/movements or not.



Product removal (55 hours after application)

- Extremely painful because the adhesive was very strong;
- Reveals an unpleasant smell;
- Difficult to clean the adhesive from the skin as shown in the picture below;
- The rash stayed for more than 5 days as pictures shown;
- The electrode area still feels itchy on the 10th day.

Other comments

1. The signal is not affected when taking ECG from the wristband (single Lead-I ECG) when making a “short circuit” by connecting two hands together;
2. Unexpected long battery life: about 10 days for continue ECG monitoring as a patch;
3. Every a few days there is a time when the product is non-responsive until it’s connected to power;
4. The magnetic charging mechanism is reliable and easy to use. It would be better if it was reversable;
5. The app: Only raw graphical ECG data, no diagnosis no suggestions and nothing interesting for the user. Need to create a new account to use the app. No tablet version provided.

Conclusion

There is much useful information discovered by testing the AMAZFIT ECG Recorder. Many of them show excellent design opportunities which are divided into different categories.
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Comfort

1. It is not comfortable to wear the device as a patch for more than a couple of hours;
2. Non-irritating adhesives should be used to minimize irritation on the skin, which can not only increase comfort but also improve signal data by reducing the touching of the skin due to itchy feeling;
3. It will increase the sleeping comfort if the product does not interfere with the patient’s regular sleeping posture.

Interaction:

1. Multiple time sticking may help the user feel more secure to move. However, the application should be easy and intuitive. Re-positioning of electrodes by the user may also increase comfort and convenience;
2. If a button has to be used, it is worth discussing to make it a touch/physical one. A further benchmark should be made, which is covered in the detailed design section;
3. It could be acceptable to replace the stickers regularly since falling off is likely to happen in one month of time. Also, product hygiene will be an issue if the tape is not changed for one month;
4. The designated placing position should be natural and intuitive for the user;
5. It would be helpful to give feedback for the optimal position to clear doubts;
6. The watch function of wristband mode is inferior to that of a conventional watch;
7. It would be a bonus if the product stays clean and the skin stays clean after use;
8. If the product is not working correctly, the user should have a manual to refer to.

Data process

1. Activities/movements of the body could be one opportunity to design around. If the data during movement of the body is not usable, there is no need for patients to wear the device during activities such as taking a shower;
2. It would be nice for the system to record what activities the user is doing to offer the professionals more useful information;
3. It would be more interesting to use if the app can offer simple health report using the data collected;
4. The “short circuit” experiment shows that the human body does not behave like conductive wires when taking ECG for the skin. It could be the cause of high resistance between skin, which is not the focus of the project.

Interview with Potential Users

Since one of the focus of the project is to design a user-friendly device, which requires the device to be comfortable and convenient to use, it is worth interviewing people to get first-hand insights. The potential users refer to ordinary people in a particular age region without specific requirements. The age of the group of interviewees is set to 50-75 years to get close to the age of the high-risk group of people of Atrial Fibrillation.

The goals of the interview are:

1. Understand their perception of comfort and convenience of wearable objects;
2. Find out insights of product hygiene;
3. What value can be added to the product to encourage usage;
4. Find out their usage of smart products, which matters when it comes to data transmission.

Method

Face-to-face interviews were carried out. 8 people participated in the user interviews. The participant information sheet, informed consent form and interview question sheet can be found in the appendix.

Insights

Many useful insights are discovered by interviewing people. They are categorized into the following categories:

Comfort

1. 6 out of 8 people wore objects regularly such as watches, glasses, bangles, rings, necklaces, and earrings for its function or decoration. 2 people preferred not to wear anything because of discomfort. They would only wear reading glasses when they have to read;
2. Among the 6 people who wear objects, they did not feel any discomfort for wearing the objects on them. The objects "disappeared" and became part of their body. They felt uncomfortable/empty without these wearables;

"I don't feel uncomfortable; they belong to my body."

3. For the 2 people who were not willing to wear anything, they stated that they would still wear the device if it was given by the doctor;

"If it's a must, then I do it."

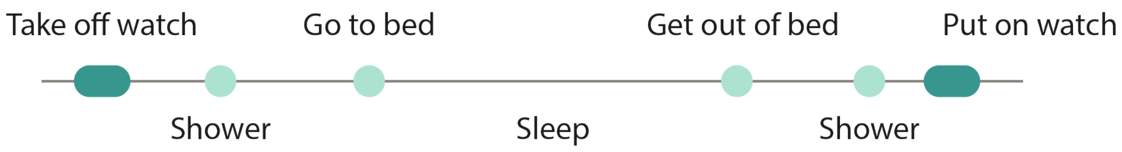
4. Most participants mentioned that they preferred smaller and more light-weight objects to wear.

Convenience

1. There were two participants who needed to take blood sugar test every morning before breakfast. They needed to test their blood using a needle, which is neither comfortable nor convenient;
2. All of the participants wearing watches took them off before taking a shower every day, and they did not regard this as an inconvenience.

Product Perception

1. Participants did not worry about used products if they look clean and arrive in a nice and clean packaging, which is a resemblance of being new and reliable;
2. "I see it's clean; no problem!"
3. Participants value the aesthetics of the wearable products a lot, including colors, style and finish. It offers them a chance to express or relate to themselves. For example, 4 of the participants have dedicated reading glasses while none of them hang the glasses around the neck using a string because it does not look appealing. One of them stated that he would like to purchase good looking objects regardless of their functions. He likes colorful and patterned things;



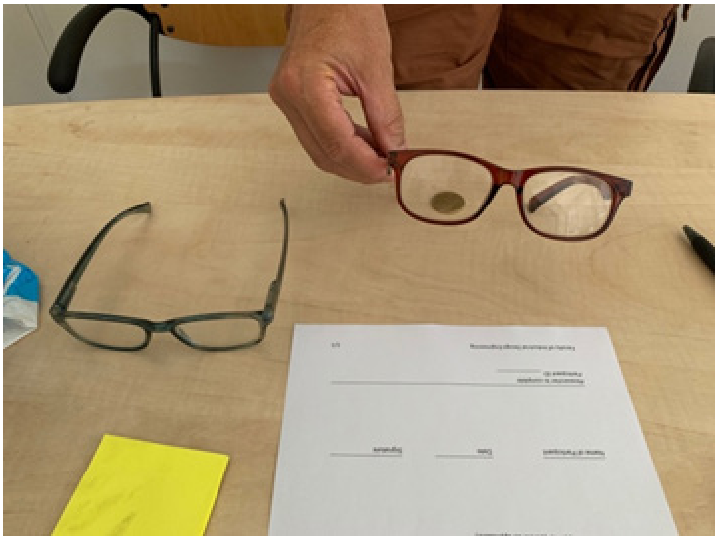
4. People like the feeling of being offered with a gift. Two participants wore gift watch/ earrings for more than 15 years. It would be helpful to increase the acceptance by making the hand-over of the product a gift-like feeling;
5. None of the participants wanted to wear products that are strange to others as this would lead to questions asked by their friends.

User Habits

1. All of participants always start with product manuals when they started to use a new product, which is the opposite to the behaviors of the current generation. They have completed the following tasks with a manual:
   a. Setup wireless printer from smartphone;
   b. Setup Bluetooth headphone for TV;
   c. Use blood pressure register;
   d. Use blood sugar register.
   - "(What I learnt from) my mistake is now I talk to myself I don't use it until I've read the manual. Before, I would try it, try it, don't work, don't work, and then read the manual. I was in a hurry before."
2. All participants took off their wearables before taking a shower or going to bed and then put them back on after waking up or taking a shower again on a daily basis. The wearables are placed at a fixed place such as a bedside table or a saloon table.

3. 2 of the interviewees bought lots of cheap reading glasses regularly because they got lost quite easily. They had their glasses lying around everywhere such as different rooms at home, workplaces, in cars, in bags, etc. One of the glasses is shown below.

   - "I have glasses everywhere. I am a "glasses consumer", and I buy 3/4 pairs every time. I lose them all the time."



4. Most participants change their shirts (clothes) every day and they have more than one week's need prepared. For one lady who washes her clothes manually, 2 shirts are minimum and 3 is OK and more than 3 makes her feel relaxed. For people using washing machines, 7 shirts are minimum since they do laundry every one or two weeks. Doing laundry often is not economical because of electricity and water consumption.
- "If I have one or two, I must wash a shirt every day; it's expensive to wash only one shirt."
5. None of the participants do competitive or intense sports. Some of the participants do non-intensive sports or exercise regularly such as cycling, dancing, swimming, and running, etc. None of them wore protection during sports except one person wore a brace on this hand while playing tennis because of a surgery on his hand 20 years ago.
6. Half of the participants (4/8) take medicine to control blood pressure or blood sugar on a daily basis.
7. Some of the participants are very curious about their health status and kept a good track using methods such as blood pressure and blood sugar measurement. While the other people don't have such an interest and they are not curious about the medical devices.

Product Hygiene

1. None of the participants wearing watches, bangles, necklaces, glasses clean them regularly. Exception is the lens on the glasses because they can see the dirt on it clearly.
2. Most of participants would not use products from others with direct contact with the skin.

Use of Smart Products

1. All of the participants under 80 years old use smartphones (7 Android and 1 iPhone) with Wi-Fi and cellular data. And they had no problems to select and connect to WIFI. Only one person does not have mobile data neither Wi-Fi at home. They also use various apps including WhatsApp, Gmail, trip planner, etc.
2. Met 2 people over 80 years old (one interviewed), and neither of them own a smartphone or install Wi-Fi at home.
3. Facing technical problems, in case their children cannot be accessed, there is a hotline to call and people will help with their problems – SenirWeb.
4. Most of them do not use Bluetooth products. The only exceptions are Apple AirPods and a wireless headphone that comes with the TV. The reason can be the ease of paring of the products compared to conventional Bluetooth products.

Other findings:

1. One participant declared that she hates 2nd hand products and never buy them because of bad memories in childhood. But if the product were given by the doctor, then she does not mind.
2. “I hate it (used products); I always buy new ones. If a doctor tells me to wear it, I would do that.”
3. One person who refused to participate in the interview believe he will never wear a device registering his health (heart rhythm). He said that he knew how his body was doing and would consult his doctor friend when he needed to.
4. Most participants are not fun of gadgets with complicated features.
5. One interviewee has a very relaxed mindset. He doesn’t care about too much, and he wants to have a beautiful day every day.
6. One person mentioned that wearing an object in sunlight can cause uncomfortable heat and an obvious mark on skin.
7. Most participants own small and stable social groups.
8. Most participant do not trust products which claim to be waterproof.
9. All participants live in tidy, quiet homes.

Conclusions

The user interview offered various information regarding how people from a specific age group treat wearables and other products differently from my generation. Following are some assumptions made from the insights of the user interview that would be useful when designing the product.

Resistance of use

1. Unless the product is too uncomfortable to wear, comfort is not a deal-breaker since the product is given by the doctor. However, comfort may influence the signal quality if the user touches the product often.
2. An established habit can increase the acceptance of inconvenient daily activities. The product could be able to be integrated into their existing habit.
3. Multiple units (more than 7) will be required if the product was a shirt to be worn close to the skin. In general, at least six sizes will be needed for the project (S/M/L for both male and female).
4. Reusable product is acceptable as the product is required by the doctor.
5. A good product manual will be beneficial to instruct the user.
6. No manual set-ups such as Bluetooth pairing with smartphones through settings should be involved unless it is easier than connecting a phone to Wi-Fi.

7. It should not count on the users to clean the product regularly.
8. It is easier to cover people under 80 years old since they are likely to use smartphones and the internet, which means smooth data transfer.

Product perception

1. A good-looking product increases the acceptance and moderates the resistance.
2. The product should not be cheap looking/feeling or easy to lose. A more expensive appearance will help users treat the product more seriously and prevent from losing.
3. The user should feel simple rather than overwhelmed about the product.
4. A nice and clean packaging helps the user trust and accept the product.
5. A gift-like feeling can increase the acceptance of the product.

Interview with Atrial Fibrillation patient

The patients are a channel to understand the current Atrial Fibrillation diagnosis procedure, during which opportunities could be discovered to create a better diagnosis for the patients in terms of experience and value. Thus, the interview with an Atrial Fibrillation patient is carried out. Interview questions and informed consent sheet can be found in the appendix.

Goal

Get familiar with the current AFib diagnosis procedure from patient's point of view;
Understand the mindset of AFib patients;
Find opportunities to offer patients better diagnosis product experience.

Insights

Symptoms

1. During the episodes of AFib, he felt his heart was beating much faster than normal, pressure around the neck and numbness on his shoulders. He fainted twice before, which could link to the condition;
2. The episodes last varying from 2-3 mins to around 30 mins;
3. The average interval of AFib episodes lasting longer than a couple of minutes is 3 months in his case.

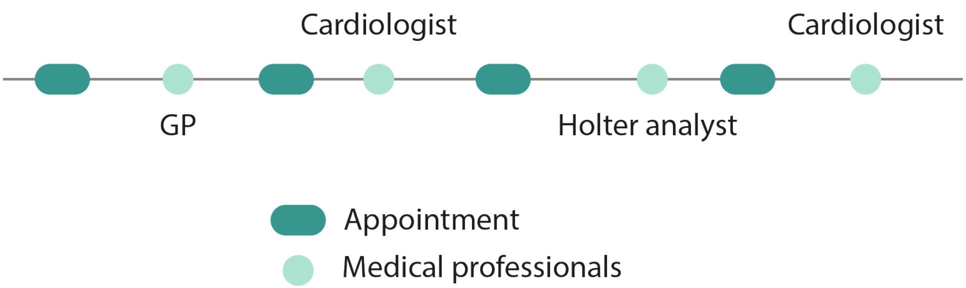
Diagnosis journey

1. Overall procedure:
   - He experienced his first AFib episode around 10 years ago and went to his GP first around 3 years ago (he mentioned his symptoms in a pre-operation check before a surgery);
   - GP sent him to cardiologist for ECG and 24hrs Holter;
   - He returned the Holter waited for further investigation;
   - He met with the cardiologist later and was told to come to the hospital when the symptoms occurred again.
2. Only investigations are carried out such as ECG, Holter ECG and MRI. No treatment is provided because he is theoretically not diagnosed with AFib yet;

"They told me if I experience this symptom again, then come to the hospital and do some ECG or whatever."
"It's pretty difficult to be in a hospital in say 10 minutes, far from practical."

3. The 24hrs Holter did not identify any AFib episodes and theoretically, he is still undiagnosed.

"First of course they did not catch the fibrillation (with the Holter) as I experienced. The chance to spot it is nearly zero."



Holter experience

1. Typical Holter experience: ethanol, sandpaper, 10 electrodes, small box (7x7cm), no shower (24hrs), keeping a diary about the feeling and activities by time, asked not to contact water, no big problems for him;

"It was pretty unpleasant thing."

2. Wearing Holter on a Friday (working day): difficult to keep a diary due to working focus. On the other hand, keeping a diary caused distraction for him during work;

"I tried to do it, but it wasn't possible."

3. He was worrying about the signal quality.

"You have to take care of that little machine even in the night. The worry is that one of the electrodes is loose."

Conclusion

1. The manual intermittent ECG measurement does have its meaning when the measurement is taken in time and accurately since there are episodes lasting longer 2-3 mins. There should be more evaluation between long-term continuous monitoring and manual measurement on when the episodes occur, which can be found in the next section;
2. 1-month continuous monitoring may not effectively diagnose AFib considering the long intervals among episodes;
3. The diary (documenting activities and abnormal feelings) is for better understanding of the ECG at a particular moment but, it should not be an added work/ distraction for the user;
4. The patient is OK with those one-time unpleasant experiences such as:

- sandpaper,
- no shower for one day,
- carrying the electrodes and the machine for one day,
- one-night unnatural sleep posture,
- no sports for one day
- This is because they have a strong incentive to do so (the doctor's instruction) and they can expect the side effect (only one time). However, it differs when it comes to continuous interference with normal activities such as:
- Write down the feeling and activities multiples time in a day, when the patient only

registered a few, which is low in quality and bad experience.

- So, it should be prudent if the interaction or the product creates a one-time unpleasant experience or continuous experience.

5. Reducing the worrying emotion of the patient should help with the signal quality;
6. The patient is not aware that the condition may lead to more severe results such as a stroke because he trusted the cardiologist and completed the whole standard medical procedure, but he was undiagnosed (e.g., he should have been diagnosed and been given treatment);
7. Patients might have no emotions during the episodes because there is no pain on the body and the symptom always disappears after a certain amount of time;

Interview with General Practitioner

Since the one of the focus of this project is to provide useful data to General Practitioners (GP), it would be useful to interview the GP to learn their thoughts on the context, which can contribute to a product that has more value to them. Two interviews were carried out with GPs in Delft. The interview questions can be found in the appendix.

Goal

Find opportunities to offer the GP useful information they need (for AFib patients);
Get insights on the products they love to use.

Insights

Organizational insights:

1. The practices throughout the Netherlands are dependent on themselves, so situations may vary from practice to practice;
2. People feeling discomfort in their chest/heart come to the practice at the first place, among whom there are cardiac patients including people with Atrial Fibrillation;
3. If the patient is diagnosed with certain disease, medication will be used. However, when the patient is diagnosed fine, the GP also needs evidence to comfort the patients.

- "We comfort the patients saying "your Holter is ok, there are no real reasons for you to worry. So, wait and see"

ECG at the practice

1. Not all practices are equipped with ECG monitoring devices. If not, patients will be sent to the hospital or cardiologist for an ECG or a Holter recording, for which the patients need to make appointments at the hospital/cardiologist. Emergency could be an exception. According to the 2nd GP, they used to measure ECG at the practice, but they cancelled it because it adds to the burden to learn things;
2. ECG may help the practice

"It's easier when the ECG is done in the practice itself."

3. It is difficult and time consuming to read ECG and it adds to the workload of the GP to learn the knowledge and skills of ECG.

"I am not sure that some GPs have the skill to read ECG, and some GPs send every ECG to the hospital to be taken by the cardiologist."
"Sometimes, it's not easy to read. Sometimes you see ECG difficult to analyze."

4. Some of the GPs can read ECG, but they don't deal with the raw data. The raw data of an ECG or Holter recording is processed by the cardiologist or Holter analyst, and a report with early diagnosis will be provided to the GP. The GP find the report useful.

"The report from cardiologist is helpful, which includes simple things like fibrillation, ischemia of the heart and other obvious abnormalities.

5. GPs are interested on simpler YES/NO diagnosis.

"Complex P, Q, T things, could be this could be that...we don't like these kinds of remarks, because we are not cardiologist and we don't know what to do with them."

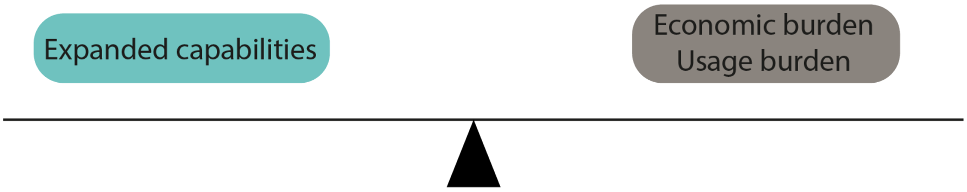
Workflow insights:

1. A patient with discomfort in his chest will be asked questions such as (based on NHG Standards):
- the description of the feeling;
- starting time and duration of the symptom;
- the situations they were in while experiencing the abnormalities (sporting? Active? In rest?);
- whether he has the same feeling before;
- the medication being used;
- the health records of family members,
    - Among this information required, the description and starting time and during of the symptom and activity they were doing during the abnormalities are prone to be difficult to obtain and inaccurate.
2. "What the patient was doing at that time sometimes is helpful."
3. Sometimes, a patient can be asked to keep a 2-month diary to register what/when/how long and how much pain they feel during the symptoms before he goes back to the GP again.
4. The GP does hand out a 24-hour blood pressure register to people from time to time, which is used often. The device which can also register heart rate variability (HRV) takes 30+ measurements for 24 hours. They are satisfied with both performance and economical sustainability of the product.

Product insights from the 24-hour blood pressure register:

1. The device hit market 10 years ago and they purchased them 5 year ago for 1500 euros/unit. They are getting a refund at 20 euros/usage for the product.
2. There is a software sold together with the device to process the raw data from the device and provides statistics based on the data, from which the GP can make diagnosis to re-assure the patient in a short time. The software also tells the GP which part of the data is good/bad. An example of the recording is provided in the appendix.

   "It's just a calculator and it's very simple."
3. Some people complain about the discomfort of waring the device on their arms because it blows up every 40/50 minutes, and the restriction on the activities such as sports.
4. The product exists also because people get worried when they take BP at practice, which makes the BP higher.



5. They will consider two main factors while purchasing new devices for the practice: the usefulness of the product for the patients and the economical properties of the product.
6. The 24-hour blood pressure registered is cleaned in the way: the manchet is washed every time after use and the device itself is cleaned every month. And every year the device is calibrated by an official person who puts a sticker on it with the date of the calibration.

Conclusions
The interview with GP not only discovers the information they need from the product, which helps to determine what data the device should acquire but also found out the different aspect of the product that they care about before purchasing the product.

Inspired by the interview with Dr. Hus and his assistant, opportunities regarding the product are discovered as follows:

Strategy
1. ECG at/for the practice is meaningful but only when it's kept simple for the GP to understand. A detailed discussion can be found in a later section;
2. The refund by usage is an excellent model to implement in this context because it not only makes the product more appealing to the GP but also encourages the usage of the product.
3. The quality of the diagnosis should be medical grade. They need evidence to start medication or comfort the patient with proof.
4. The product-service should not add to the GP/cardiologist's burden (such as learning new things and cleaning the product). It should achieve a balance between reward and investment for the GP.
5. GPs have different needs from cardiologists, and they should be offered with information with corresponding focus.

Product
1. It would be an opportunity if the product can moderate the problem of patients' misdescribing the symptom or time/duration of the abnormities. For example, location information may provide to the user by the product to help him recall the context. Alternatively, things to replace the conventional diary/agenda method
2. User experience such as ease of use and comfort are important factors to consider as dislike of the product may result in distrust in the GP.
3. The product could be a software/hardware combination, in which the software can process the data for the GP and offer suggestions. Preferably more straightforward YES/NO diagnosis.

Long-term VS Intermittent Manual Measurement

Monitoring of heart activity can be generally divided into two methods: long-term continuous monitoring and intermittent manual measurement, that both can be used to detect Atrial Fibrillation. However, both long-term continuous monitoring and intermittent manual measurement have their advantages and disadvantages, which should be detailed benchmarked since this fundamentally influences the direction of the project and eventually, the design of the product.

Conclusion

Despite the impact on daily activities and obtrusiveness, long-term monitoring has the superiority of capable of detecting AFib that has no symptom over intermittent measurement, which is crucial in the context of off-hospital AFib diagnosis since 60% of patients do not even know when they are having an AFib episode (Sanofi S.A., 2013). Intermittent measurements will fail to detect AFib if the user cannot feel the symptom and do not know they are having an AFib episode. Thus, long-term continuous monitoring is the proper direction for off-hospital AFib diagnosis.

Long-term Continuous Monitoring		Intermittent Manual Measurement	
Advantages	Disadvantages	Advantages	Disadvantages
Can detect AFib that has no symptom	Larger impact on daily activities	Small impact on daily activities	Miss-detect AFib that has no symptom
Usually consistent data quality	Usually obtrusive appearance	Easy to be unobtrusive	Usually inconsistent data quality

3M Double-sided Stickers Test

Given that long-term monitoring is the chosen direction, and adhesives are widely used in this context, it is worth evaluating the performance and user experience of existing solutions. Three different double-sided adhesives (1509, 1522, and 2477P) from the 3M family of extended wear adhesives for the wearable medical device are tested to evaluate the performance of the industry-leading adhesives and its practicality in the context of next-generating Atrial Fibrillation diagnosis device. Datasheets of the three adhesives are attached in the appendix. The adhesives are referred as “stickers” in later text.

Methods

- Stickers are applied to the 3D-printed dummy models shown in picture below. The round ones are for testing on the chest while the slot shape is for test on the upper arm. The positions of application of the stickers are shown in pictures below.
- The samples are worn for all day use including taking shower and sleeping.
- Notes are taken to record the performance of the stickers and my personal feeling of having them on my body.
- Shower is taken prior to the first application of the stickers to improve the skin condition.



Results

For sticker 1509:

Performance
Arm:
- Fell off while taking off my shirt (12 hours after application) follows by re-application to the skin.
- Fell off while I was taking shower (24 hours after application)

Chest:
- Fell off while taking shower (36 hours after)

Feeling
Arm:
- No irritating feeling. No discomfort discovered.

Chest:
- Slight irritation 5 hours after application. (Itchy feeling around the sticker)
- Wanted to touch it from time to time during the day.
- Felt squeezed while sleeping on my side.
- Felt unsecure because it can be seen through my T-shirt. I would feel uncomfortable if people ask me what’s sticking on my chest.

For sticker 1522:

Performance
Arm:
- Stayed in location

Chest:
- Fell off while taking shower (12 hours after application)
- The lower chest one is less secure then the upper one.

Feeling
Arm:
- No irritating feeling. No discomfort discovered.

Chest:
- Slight irritation 5 hours after application. (Itchy feeling around the sticker)
- Wanted to touch it from time to time during the day.
- Felt squeezed while sleeping on my side.
- Felt unsecure because it can be seen through my T-shirt. I would feel uncomfortable if people ask me what’s sticking on my chest.

For sticker 2477P

Performance

Arm:

- 24hrs after application, left arm one came off while putting on my jacket due to hard movement

Chest:

- 7hrs after application, upper chest came off while taking off my shirt, adhesive came off from skin (check adhesive, high moisture, but still re-applied)
- 23hrs after application, Upper chest one came off while taking shower (did not re-apply)
- 49hrs after application, lower chest one fell off after taking shower
- 72hrs after application, still no irritation, but does not stay tight
- Did not fall off in workout test (20min elliptical HIIT training)

Conclusions

Compared to the standard wet electrodes used in the AMAZFIT test, the 3M stickers are generally weaker in adhesion but also less irritating. Combining the conclusions from AMAZFIT try-out, the conclusion that sticking a heart monitoring device using double-sided adhesive is neither practical nor pleasant for the user can be made. There are some opportunities found out for the design of next-generation Atrial Fibrillation diagnosis device:

1. It is worth studying to make a decision on whether let the same sticker be on user's skin for one month or let stickers should be changed regularly but effortlessly.
2. The thickness of the product is very important since the increase in thickness lead to higher chance of touching by accident.
3. The ability to re-apply the sticker is important since there are times when the sticker fall off accidentally and re-attach the sticker is a simple solution.
4. The stickers can survive sweating during workout, which was not expected

Product Size Test

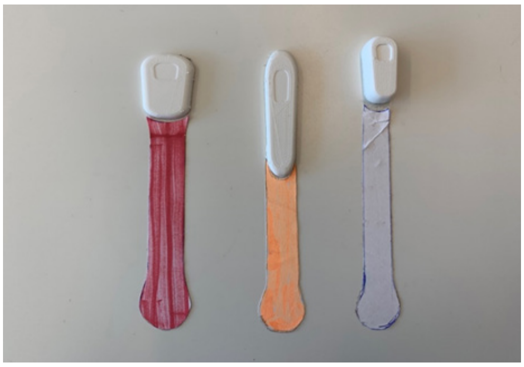
Since comfort is one of the main focus in this project, it is worth studying the impact of product size on users' comfort.

Goal

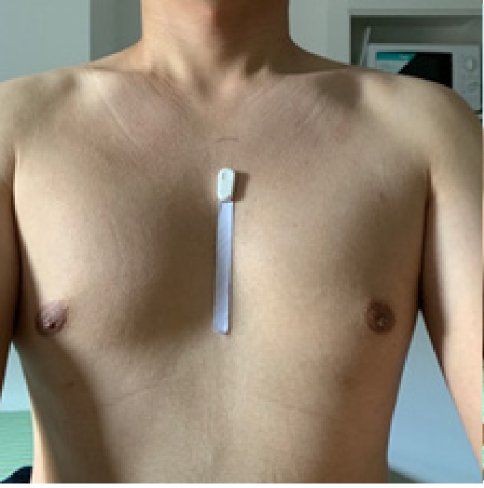
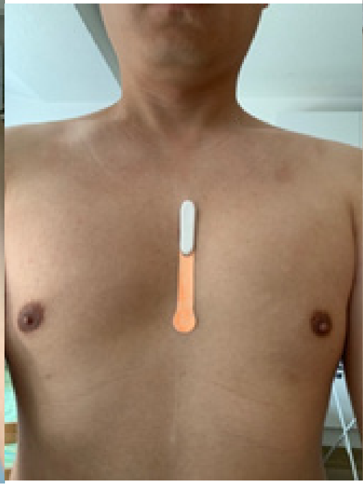
The specific purpose of this test is to find out which dimension(s) of the product have higher impacts on people's wearing comfort.

Method

3D-printed dummy products in different wixdth, length, and height are adhered on the optimal location of the researcher to experience the influence of wearing such product. Five different plastics are worn each for one day, during which the research will do what he usually does daily, and no change will be done from daily routine activities. Detailed product dimensions can be found in the table provided below.



Dimensions	Product No.				
	1	2	3	4	5
Max width (mm)	12.3	12.3	19.7	12.3	12.3
Height (mm)	3.5	5	3.5	3.5	9
Length (mm)	24	24	24	47.5	24



Findings

Width:
1. Narrow width causes weak adhesion along the sticker
2. Test 1-compact size: Didn't felt the product at all
3. Test 3-large width: felt skin on the chest squeezed while sleeping on the side

Height:
1. Test 2-high profile: Hit product while removing the shirt
2. Test 2-high profile: Felt the product while sleeping on the front
3. Test 5-very high profile: visible bump caused on the shirt (add pic)
4. Test 5-very high profile: hit the sensor while removing shirt
5. Test 5-very high profile: resulting a very obvious bump on the shirt I wore
6. Place the sensor higher helps not feeling it on the front

Length:
1. Bottom part is more likely to tip up because the belly curls, risky for electrode
2. Test 4-long length: didn't felt product

Conclusions

1. Width and height have more substantial influence on the user's wearing experience when comparing to length. The design should avoid increasing these to dimensions. It would be more reasonable to increase the length of the product when more inner space is needed for the product.
2. The back of the product could slightly curve to the shape of human's sternum.
3. Adhesion between product and sticker is usually reliable, which is preferred because it reduces the risk of losing the product. Apart from this, if the product had to fell off, it preserves the same falling off outcome, which can help people with the confirmation of using this device.
4. The person should be sat down to apply the sticker since the people with big bellies will tip off the lower end of the sticker more easily.

Dry Electrodes Experiment

As an emerging technology, dry ECG electrode is known for its convenience and friendliness on skins. It is worth experimenting the dry electrodes and comparing them with the conventional wet electrodes. The electrodes design will gain great freedom if the performance is proper for medical diagnosis.

Three different types of conductive textiles (as shown in the pictures below) are tested as dry electrodes to obtain ECG signals from the skin. In addition, a further test of the conductive silver textile and conductive rubber is conducted to find out whether their performance is good enough for being used as an electrode. The focus of the test is the signal quality of ECG.

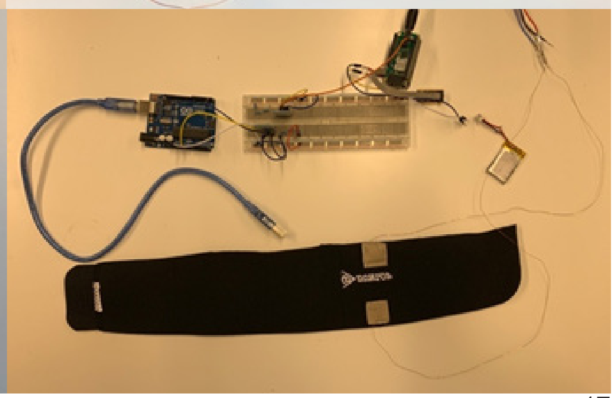
Apparatus

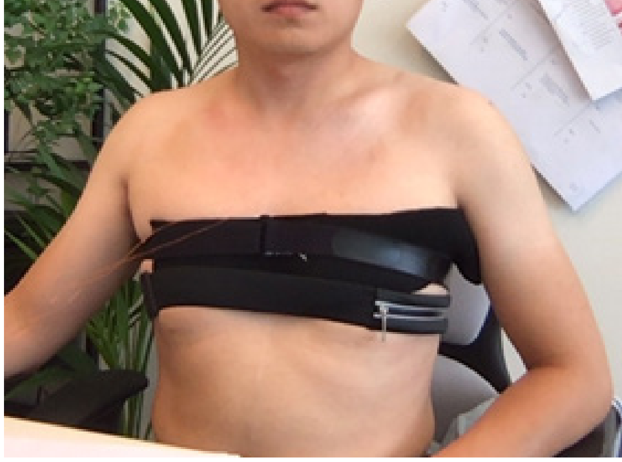
- Maxim Evaluation Kit for the MAX30003 Biopotential AFE
- Maxim MAX32630FTHR Application Platform
- HC-05 Bluetooth Modules
- Arduino UNO
- Dry electrodes

Methods

Small pillow-shaped electrodes are made from these single-layered materials as shown in picture. Then the electrodes are mounted on a stretchable band using Velcro as shown. Conductive copper wires are led to the dry electrodes using conductive wire glue. Next the ECG signal are compared with it obtained using wet electrodes (COVIDIEN Kendall H66LG).

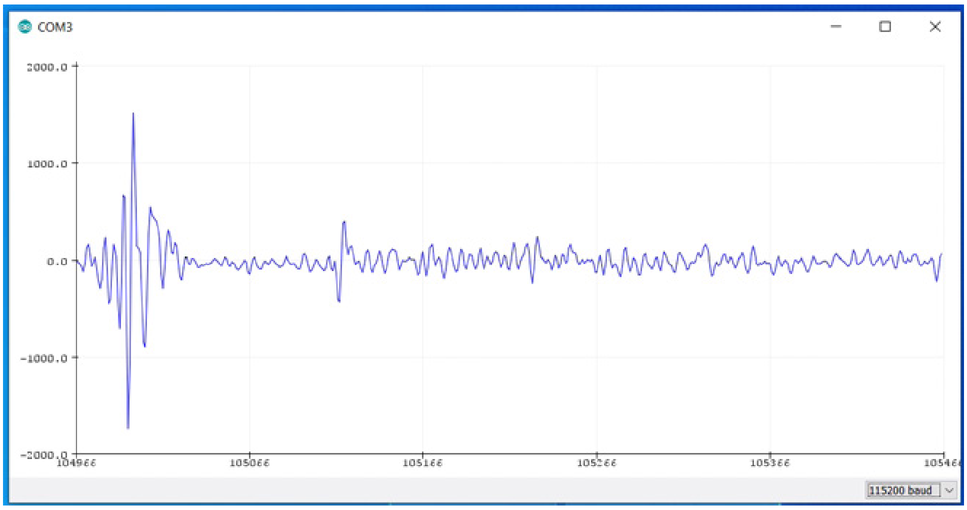


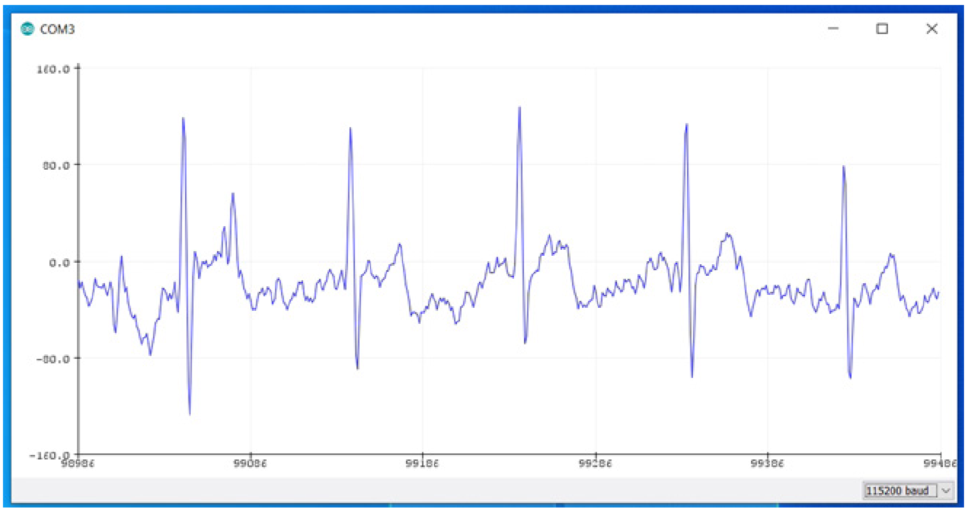


Results

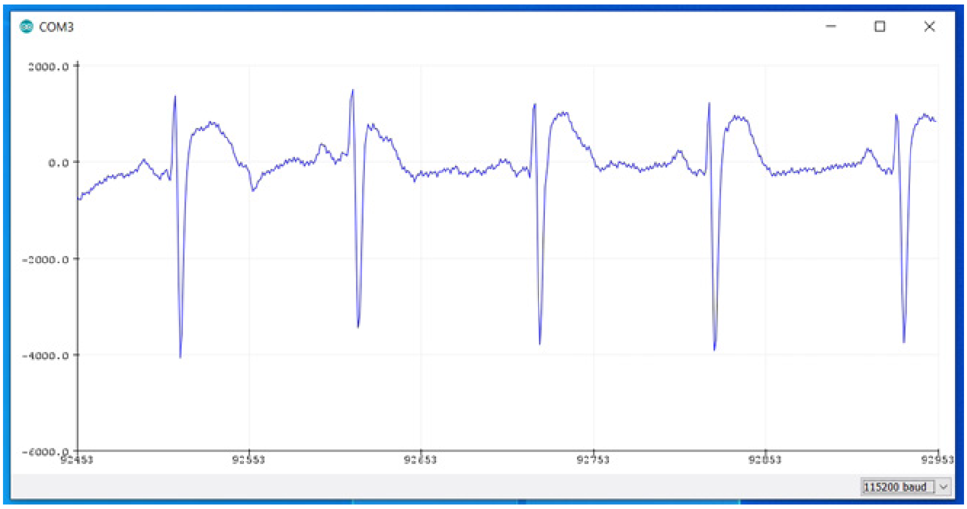
1. There is much signal noise from the two stretchable textile electrodes from the upper arm as shown in the picture, resulting unrecognizable ECG signal.



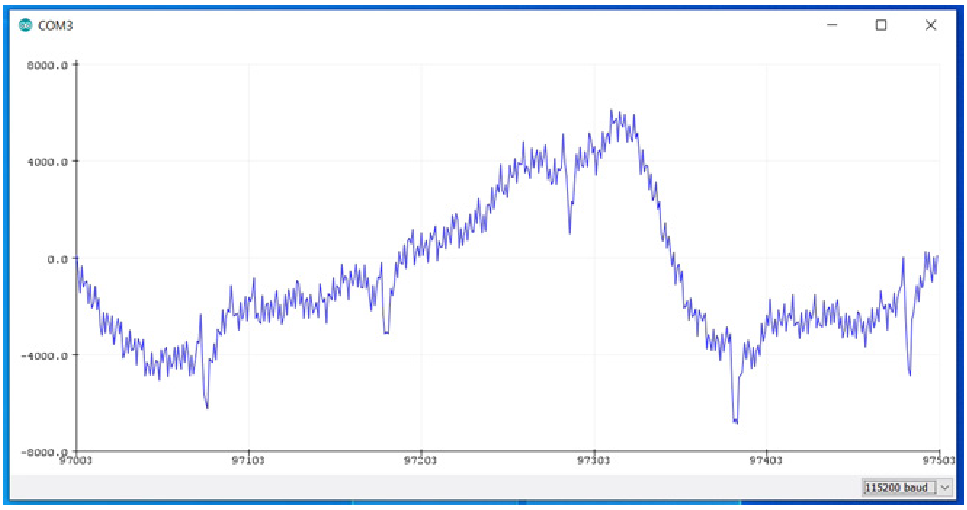
2. The non-stretchable conductive textile can gather usable ECG signals with less noise from the upper arm as shown in the picture.



3. Moving the location of the electrodes from upper arm to middle chest (as the picture shows) results clearer signals and higher amplitude (shown in the picture).This the result of the non-stretchable textile.



4. Movements of the electrodes result in noisy ECG signals.



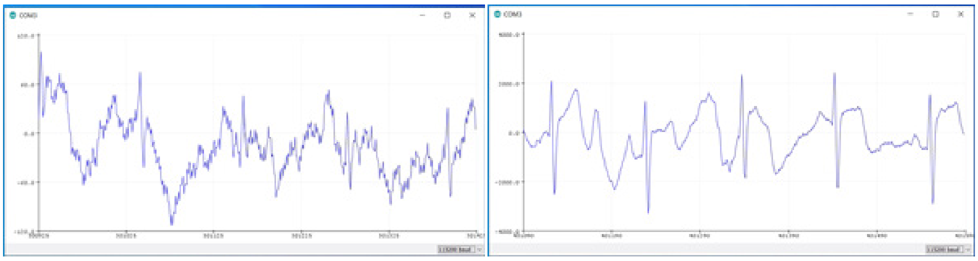
5. Moistening the textile electrodes using water maintain similar quality stationary signals but help improve the signal in motion (compared with last result).

Further Test

Further tests are conducted to validate whether enlarging the non-stretchable conductive textile can help improve the quality of ECG signal. Another test is carried out to see whether the conductive rubber material is suitable for ECG electrodes in this context.

Results

1. The signal gathered by the enlarged textile electrodes does not show improvement in data quality in terms of noise and signal strength (shown in following picture). In fact, the result is inferior to the smaller pillow electrodes.



2. The rubber electrodes failed to gain ECG signal. One possible reason can be the resistance of the rubber electrode is too high.

Overall Electrodes Comparison

The three types of electrodes are compared in the aspects of signal quality, ease of use and prerequisites of application, in which the signal quality is the fundamental performance index. The scores are given from a -2 to +2 scale, resulting a Harris profile comparison.

Conclusions

The two stretchable conductive textiles are not suitable for being used as ECG electrodes because the varying resistance resulted in signal noise that cannot be tackled. The non-stretchable textile produces comparable ECG signals as the wet electrode when there is no relative movement between the electrodes and skin. However, it generates unusable signals when there is relative movement between the electrodes and skin. The enlarged contacting area tested in the further test does not facilitate the increase in signal quality. Thus, the non-stretchable silver conductive textile is not suitable to be used as an ECG electrode for Atrial Fibrillation diagnosis. Next, the conductive rubber used in cycling gear is not applicable either possibly because of the high resistance value of the material and the perquisites of the function of rubber electrodes (Concept2 Inc., n.d.). According to literature research, the best performing dry electrode – silver nanowire electrodes still cannot cope with the motion artifacts (Qin et al., 2019). In conclusion, given the performance of dry electrodes, they are not proper candidates for electrodes to be implemented in the next generation AFib diagnosis device, which will be launched in the coming two years.

Types of electrodes		Wet electrodes	Textile electrodes	Rubber electrodes
1	Stationary signal quality	2	2	-1
2	Signal quality in motion	1	-2	-2
3	Ease of use	1	2	2
4	Prerequisites of application	2	0	-2
Overall score		6	2	-3

Optimal ECG Location Exploration

fundamental to successful convincing diagnosis, it should be experimented to find the optimal location to gather the ECG signal from the human's body.

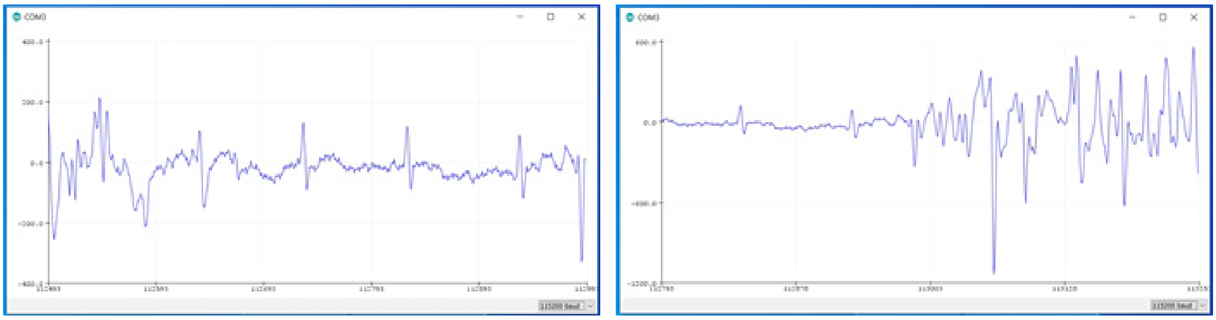
The quality of the signal reflects on two aspects – noise and amplitude. The closer to the heart, the higher the amplitude of the signal and usually less noise. It is because the signal gathered distance from the heart is easier to get interfered by muscle activity noise (BPM biosignals, 2013). Comfort considers whether the electrode can hinder the user's normal daily activities.

According to the previous test carried out by Praxa Sense, it is found out that at the chest area, signals from people sternum are better in quality, which means there is clear ECG especially the P wave can be identified clearly. This is because there are few muscles, making the signals challenging to be interfered by muscle electricity signal. There are also fewer fat tissues, making the signals strong and clear. Human anatomy pictures of the sternum can be found below (Zygote Media Group, Inc., 2017).

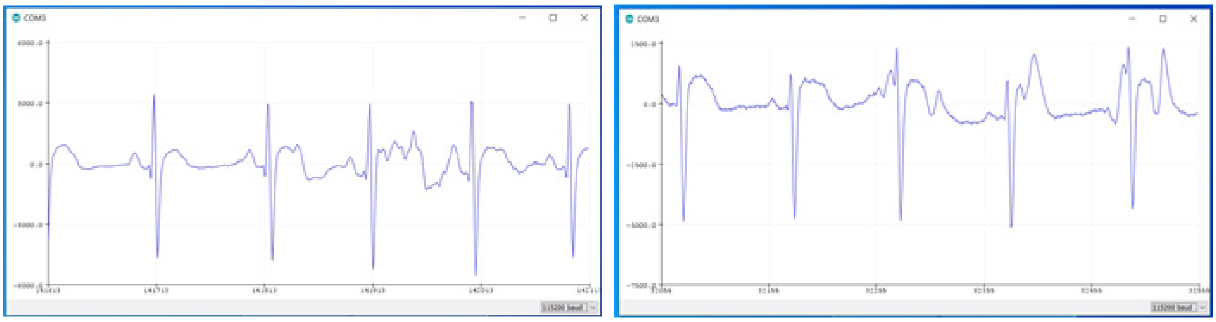
However, the sternum is not the ideal location in terms of comfort and ease of use. It is known that ECG signals can be obtained also from the arm. And arm is a proper location to offer comfort and ease of use. Thus, a comparison between the signal from the arm and that from the sternum is conducted. The result is shown below.

Results

1. Signals from left upper arm, stationary and in motion



2. Signals from the sternum, stationary and in motion



Conclusion

Compared with the upper arm, ECG signal obtained from the sternum area is stronger and with less noise, which means the sternum is the optimal location to gain single-lead ECG signal from the human body.

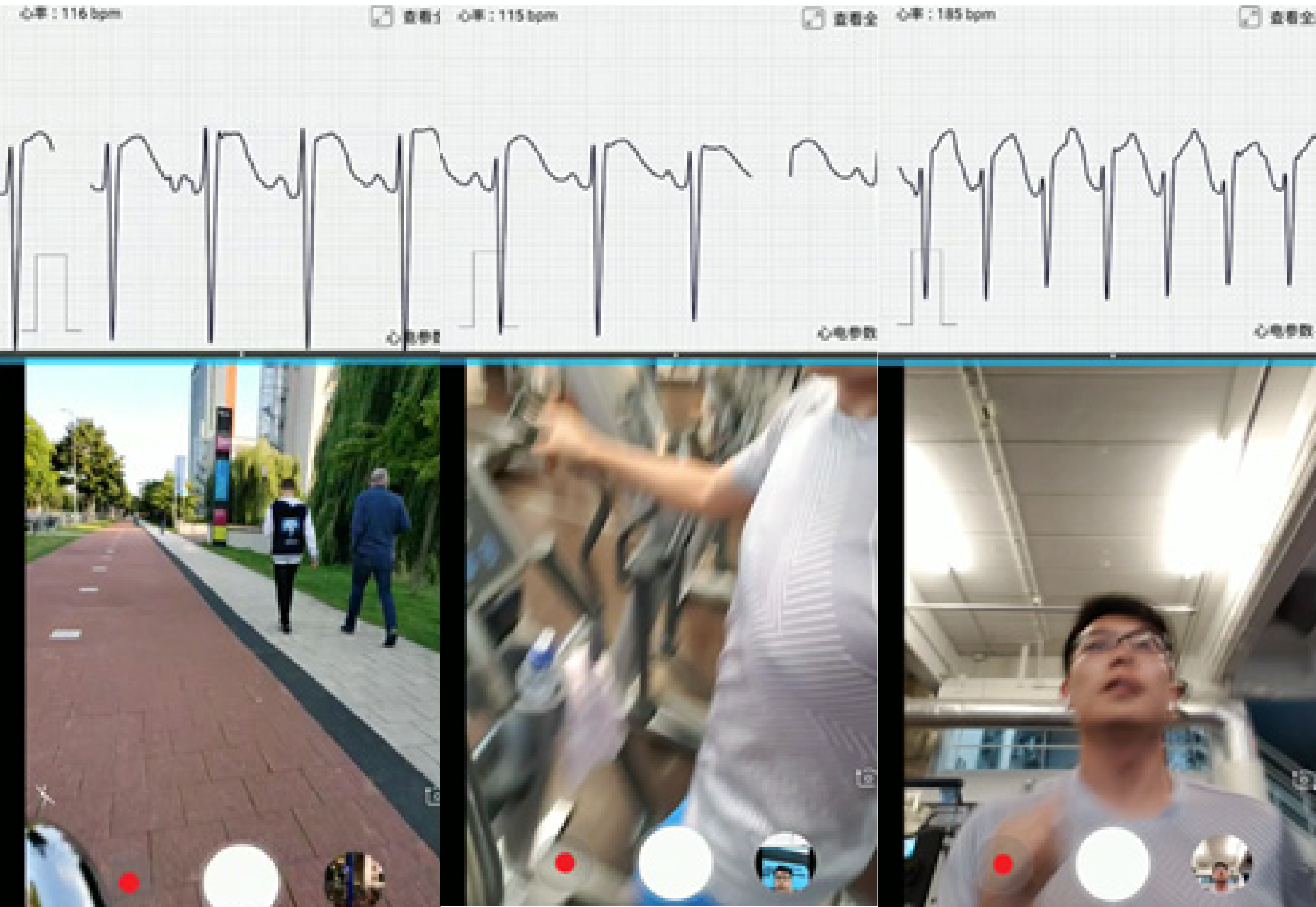
Sternum location further test

It is crucial to validate whether the signal quality is good enough from the user's sternum to perform clinical-grade Atrial Fibrillation diagnosis. Thus, a test of the ECG signal during various activities is carried out.

Apparatus

AMAZFIT ECG recorder;
Standard wet medical electrodes (COVIDIEN Kendall H66LG).

Method
The test involves various activities including walking, biking, running, elliptical machine exercise, climbing machine exercise, medicine ball exercise, and push-up exercise.

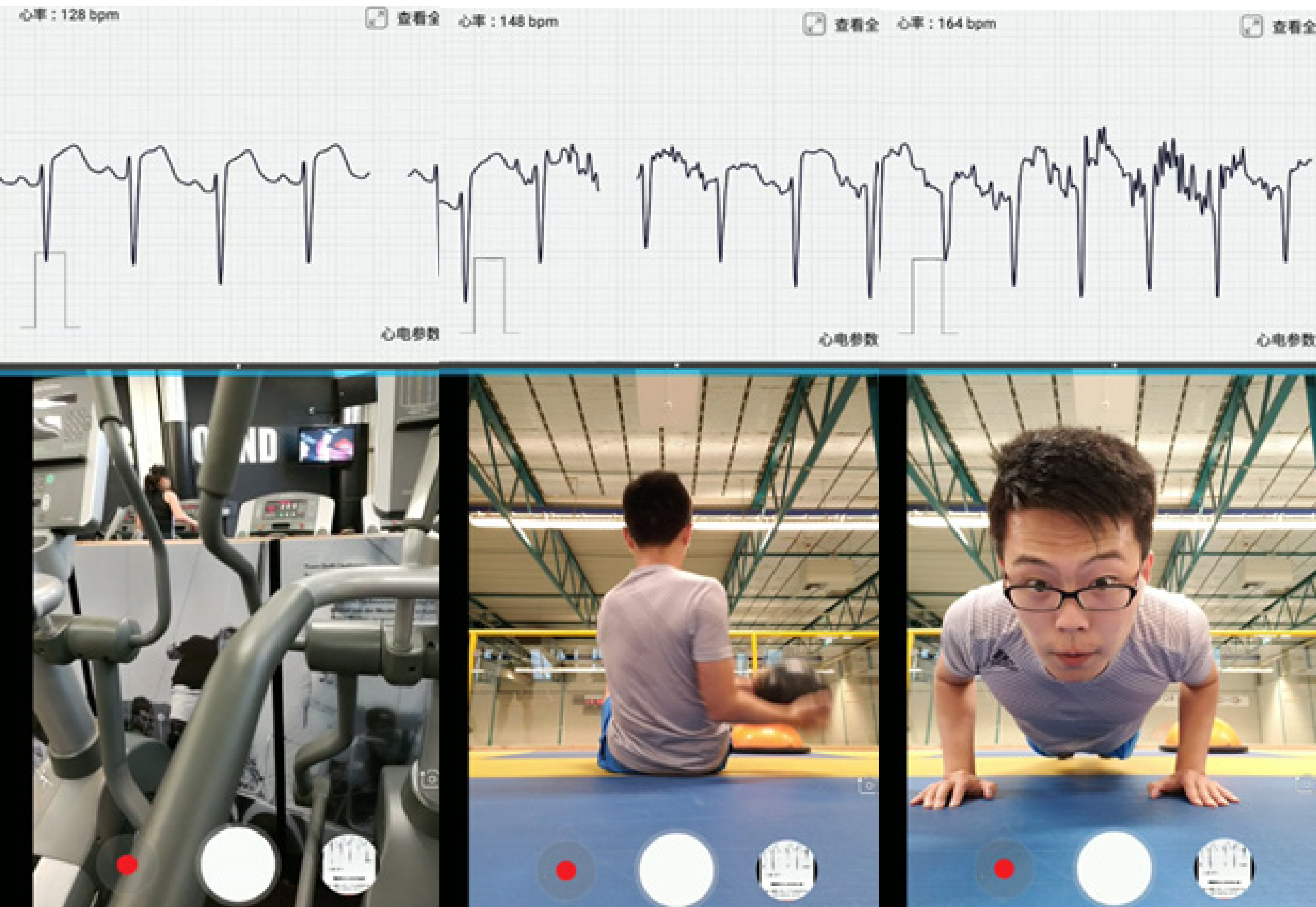


Results

The signal quality turned out better than expected. Clear rhythms can be seen from the ECG, which can be used to continuously monitor the regularity in rhythm. The reason is that there are little muscles and fat tissues on people's sternum compared to other locations near the heart. The only time when the signal appears noisy is when the researching was doing push-up exercises, during which the muscle activities around the chest is much stronger.

Conclusions

The sternum is the optimal location to place the electrode for ECG signal capturing for its strong signals with less noise. In addition, ECG signal from the sternum area under exercise activities can still be used to monitor the regularity of heart rhythm.



2

SYNTHESIS AND CONCEPTUALIZATION

Based on the findings from the last phase, directions of solution were defined by a list of requirements followed by a further analysis of the priorities of different stakeholders. Then three concepts were generated, and one was chosen for development.

List of Requirements

Based on previous research and analysis, a list of requirements is summarized using the most important findings to guide the design of the product.

Performance

- The product should be able to perform long-term (one month) continuous ECG monitoring on potential patients, which enables early AFib detection.
- The product should be able to capture accurate single-lead ECG
- The product should be able to cope with artifacts on the signal caused by body movements.
- The product should be able to transfer recorded data to healthcare professionals without causing a burden on the user.

Usability

- The product should be able to be easily understood and used correctly by the user at the first-time use
- The product should be able to fulfill the goal with the least interference with users' daily activities
- The product should not irritate the users
- The product should be able to function without causing a distraction for users
- The use of the product should not cause doubt or worrying emotions to the user
- The product should not add to the healthcare professionals' workload, including learning and maintenance.
- The product should not be easy to lose due to the interaction between the user or movement of the user

Materials

- Materials should be appropriately chosen for different purposes considering performance, user experience, environmental impact, and cost.
- Materials should not have health risk for human

Appearance

- The product should have a pleasant looking
- The product should not have a cheap-looking appearance
- The product should avoid questions for the user asked by others
- The product should come with beautiful and clean packaging

Reliability

- The product should be able to operate without significant problems that require opening the casing of the product during the use of the product

Durability

- The product should be able to withstand the normal environment change in the Netherlands, both indoor and outdoor, including varying temperature, moisture, sunlight, and wind, etc.
- The product should be water-resistant for daily activities such as splash water

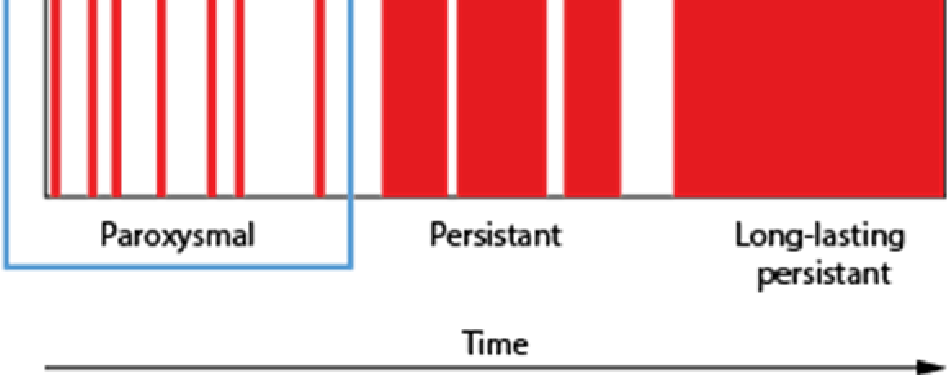
Safety
- The product should not cause harm to the user and family members of the user

Maintenance
- The product battery should be charged by either the practice or the user whose process should not be more complicated than charging a smartphone.
- The product should be easily cleaned for the next-time use

Sustainability
- The product should be reusable or partially reusable to reduce the cost and impact on the environment

Feasibility
- The product should use technologies and solutions suitable for a product to be released in 2 years

Cost
- The unit cost should be under 500 euro



Design guideline

Vision and Scope one-liner :

Baes on previous research and analysis, a list of criteria was selected for high priority for each of the stakeholders. So most effort will be put into these aspects to generate the ideas and concepts.

Patients

For the patients, the product offered by the doctor is already a strong incentive for them to cooperate. Many difficulties such as used products, ease of application will be overcome naturally. The focus will be set to moderate the resistance (or increase patient compliance) of using the product properly every day.

1. Aesthetics
- The product should be pleasing in appearance. A good-looking appearance of the product help elderly people accept it a lot, which was found out during the interviews.
- The product can be a gift-like feeling. It helps the user accept and value the product more, which could encourage usage.
- There should be a nice packaging of the product. The packaging is part of the product experience. A nice packaging helps the patient accept and trust the product

2. Ease of use
- Shift more continuous inconvenience to one-time inconvenience. It was found out that in this context, patients are more likely to accept one-time inconvenience than continuous inconvenience. For example, patients wearing Holters can tolerate the sandpaper used on their skin and don't shower for one day, but they cannot manage a good track of their activities and feelings in the daily required.
- Make use of the habit. It turns out that there are lot of habits can be exploited to integrate the product, and the addition of the product will not be a convenience issue after it is integrated into patient's daily habit. Such as most elderly people take shower every day and before which they take off their accessories and then put them back on after shower or waking up.

3. Comfort
- It is found out that the most effective way to increase comfort in this case is to make the product small and lightweight enough.

4. Robust experience
- The product should be easily fixed. For example, if falling off the skin, the product should be able to be easily re-applied by the user.
- The product should be hard to lose or losing does not cause much issue for the patients.
- If needed, support should be given timely and effortlessly by human support or easy to consult manual, etc.

General Practitioner

For the General Practitioners, the product will be focused on two areas: adding value and moderating resistance.

Add value

- Enable ECG at the practice. Most of practices nowadays do not have the capability to perform ECG. This product can be the opportunity to enable ECG at their practices effortless, making quick diagnosis on Myocardial ischemia, Electrolyte disorder and other types of arrhythmia possible, which will be discussed in the following section.

Moderate the resistance

- The product should not increase General Practitioners burden in learning, maintenance and handing over the products.

Praxa Sense (the product)

For the company and product, an accurate and reliable product is the top priority. The analysis all above make no sense if the data and diagnosis cannot be trusted.

1. Accurate. This means the product should be able to grab quality data from the patient's body with least noise as possible such as muscle electricity, static electricity between skin and electrodes. The algorithm should also be to correctly tell if the patient has Atrial Fibrillation or not base on the data.
2. Reliable. The product should be reliable and robust enough to prevent any potential problems during usage. One way is to make it as simple as possible such as minimizing the functions and sensors and move signal process off the product, etc.

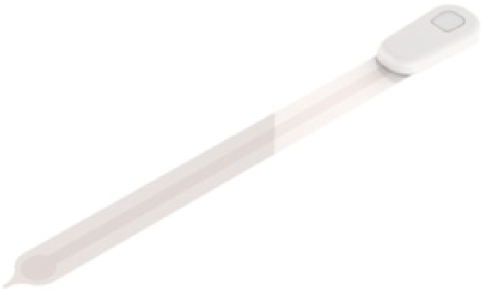
Exploration and development

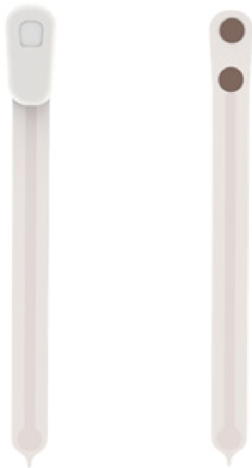
(SWOF + morphological chart)

Data Acquisition	ECG	PPG	ECG+PPG	
Data Transfer	Bluetooth	Wi-Fi	Cable	Cellular
Communication	Vision	Sounds	Vibration	
Interaction	Physical button	Capacitive button	Scrolling wheel	
Charging	USB-C	Pogo pins	Wireless	Charging case
Sticker Changing	Manual	Automated dispenser		

Initial Concepts

Concept 1

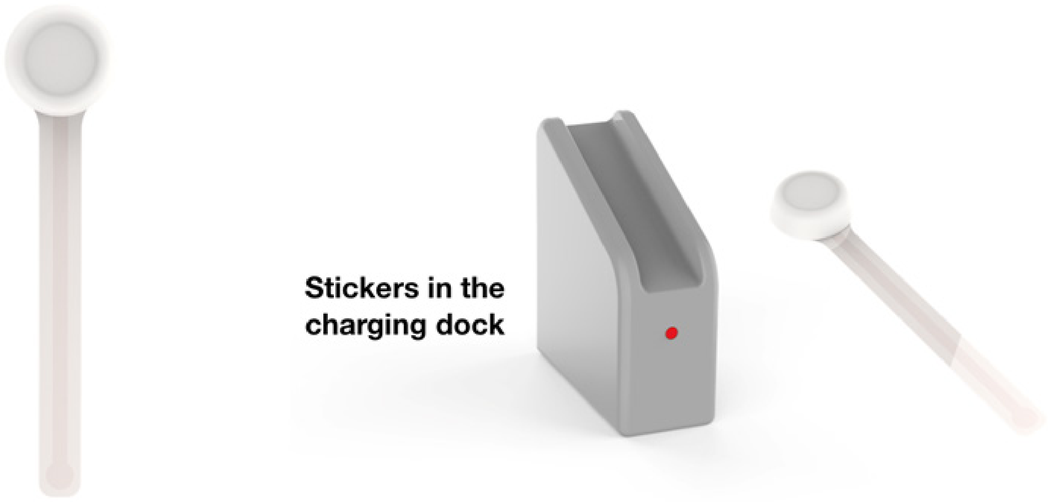




Features

- Single lead ECG on sternum
- Extremely compact form factor
- Sticker changed daily
- Daily Charge while showering by cable
- 3-day battery life

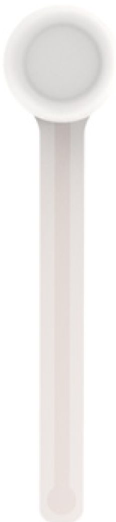
Concept 2



Features

- Single lead ECG on sternum
- Compact form factor
- Sticker changed daily easily
- Daily Charge while showering on dock
- 3-day battery life

Concept 3



Night-time PPG monitoring

Features

- Daytime: Single lead ECG on sternum for accurate monitoring
- Night-time: PPG heart rhythm monitoring for extreme comfort during sleep
- Sticker changed daily easily
- Compact form factor
- Daily charge while sleeping
- 3-day battery life

Conclusion

After the comparison of these three concepts, it is found out that Concept 1 is better regarding all the critical criteria set before. Thus, concept 1 is chosen for further development.

Concept 1

	- -	-	+	++
Accuracy			+	++
Reliability			+	++
Ease of use			+	
Comfort			+	
Less problem				
Add value to GP			+	+
No extra work			+	

Concept 2

	- -	-	+	++
Accuracy			+	++
Reliability			+	
Ease of use			+	++
Comfort				
Less problem		-		
Add value to GP			+	+
No extra work		-		

Concept 3

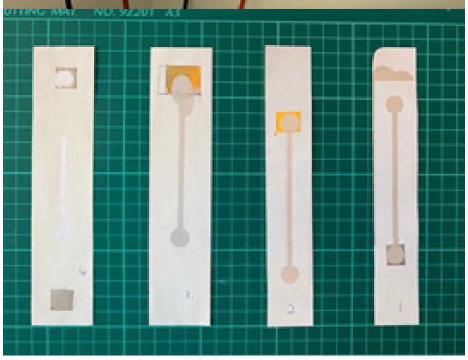
	- -	-	+	++
Accuracy			+	
Reliability				
Ease of use			+	
Comfort			+	+
Less problem	- -	-		
Add value to GP			+	+
No extra work	-	-		

Sticker
Electrode test

The sticker and electrode are fundamental parts in these concepts which need validation testing and possible iteration of improvements. A preliminary test was carried out to validate self-made screen-printed electrodes.

The adhesive is using the 3M 2477P double-sided as tested before. For the electrodes, brass foil, silver screen print and silver textile are tested. For the connection of the electrodes, silver print and brass foil are tested.

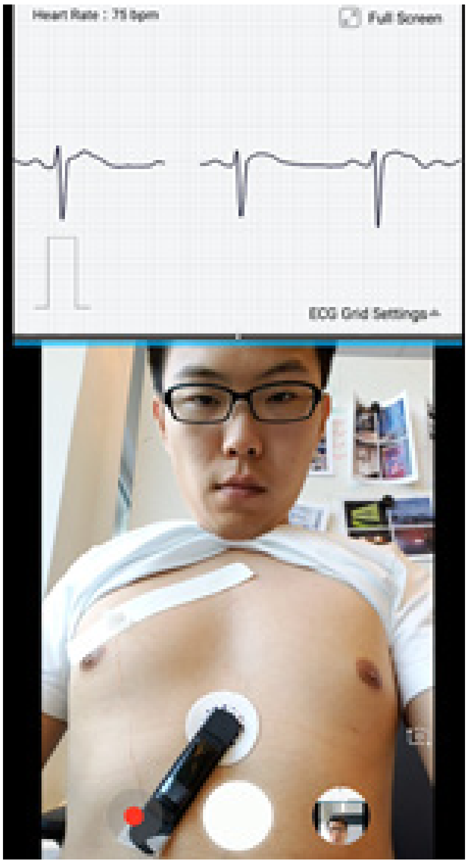
Silver printer electrodes
7 silver prints were made as the picture shows. During the making process, there are some issues with the screen-printing process. Then the resistances of the electrodes were measured as follows. It was also noticed that the resistance slightly decreased around 10% after the electrodes are left to dry overnight.

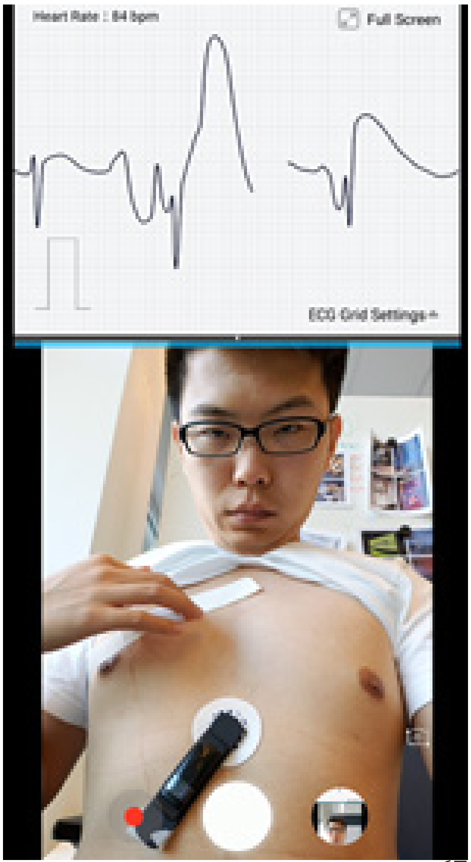


Resistance (Ω) / Electrode ID	Full length	Full length measured on adhered material	Half length	Half-length measured on adhered material	Half-length measured at adhered material side
1	15.7	15.8	9.6	7.0	7.2
2	1.5	1.4	1.0	0.9	0.9
3	9.2	9.2	4.4	5.3	5.3
4	NA	NA	NA	NA	NA
5	1.3	1.3	NA	NA	NA
6	1.7	1.7	1.3	0.7	0.6
7	1.5	1.5	0.9	0.9	0.9

Sticker No.1
This one is made from screen printed electrode No.1. It is to test whether screen-printed Only one electrode can be used to gather ECG signals so only a single printed electrode was used. The other electrode was the standard medical electrode (COVIDIEN Kendall H66LG).

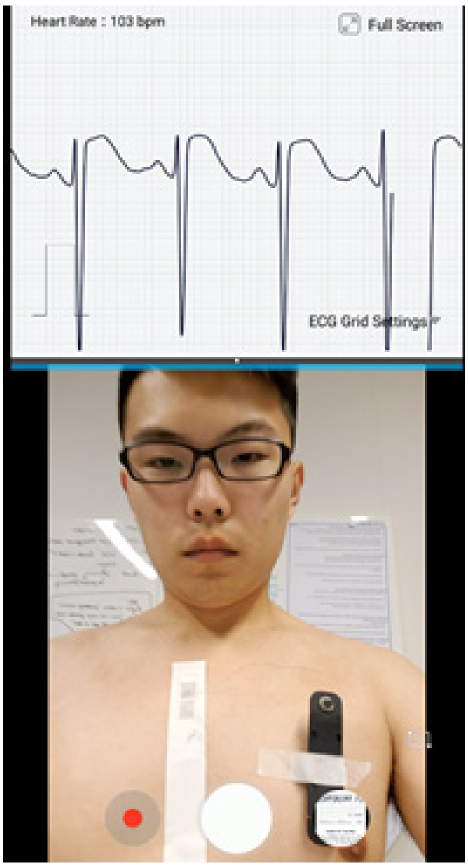
The test was a success. ECG signal can be obtained from my sternum. However, there are lots of noise when the electrodes, sticker or wires are tough to move. Similar test was carried out on the brass foil electrode (screen-printed No.2). Identical results are found as the textile electrode.

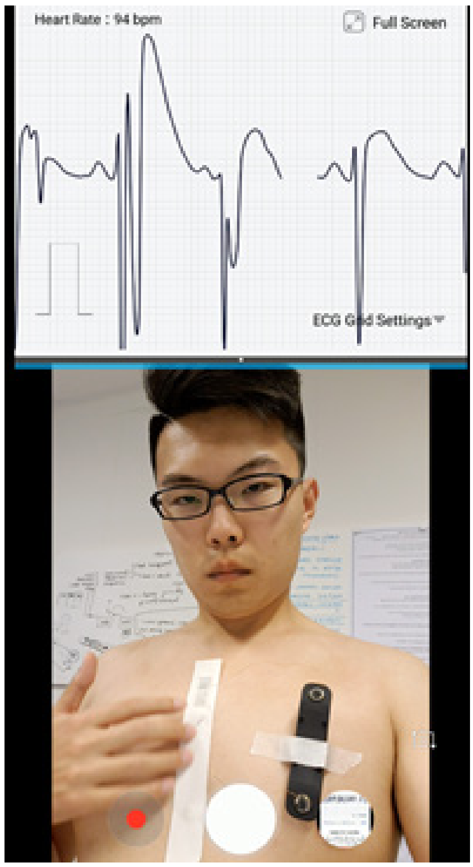




Sticker No.2

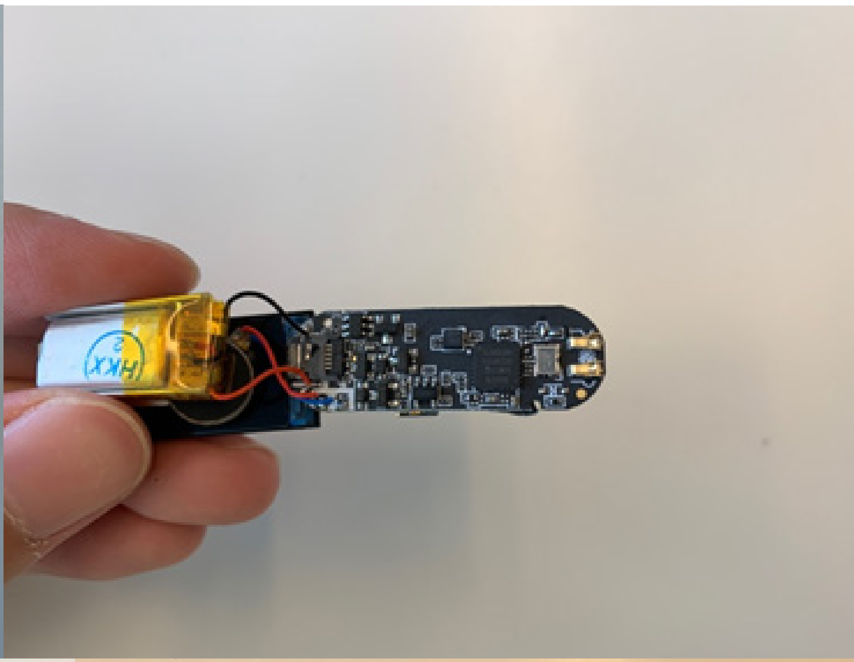
This sticker is completely originally designed using screen-printed electrode No.1. The test was a success. ECG signal is clearly obtained from my sternum. However, the signal is prone to be noisy if the sticker is touched.

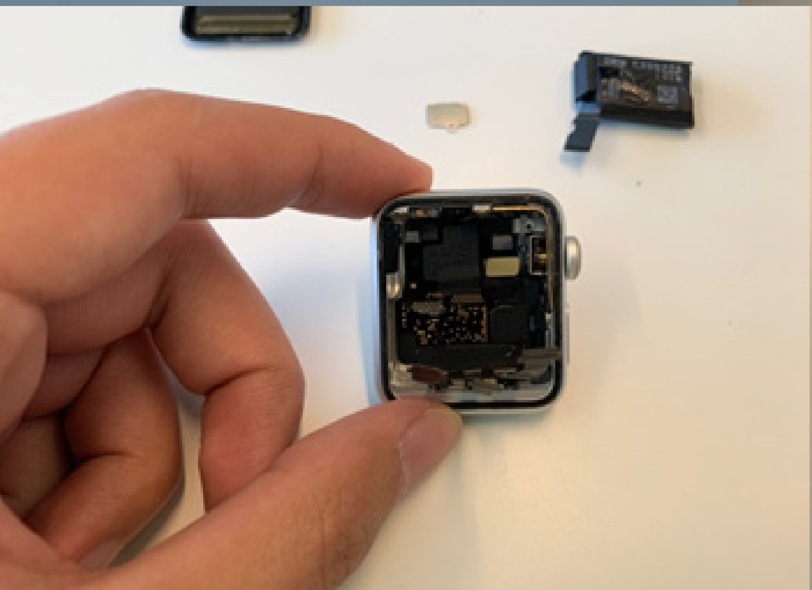




Product
Hardware study

Knowledge about the internal components design of existing similar products is essential for the correct detail design of the product. This can offer great help in terms of components selection, form factor estimation and structure design. In this study, two products were torn down – Apple Watch Series 2, and another off-brand wristband.





Main take-away

Off-brand wristband

This wristband shares some features with the product designed.

1. The capacitive touch button can be integrated in the PCB, making a single PCB design possible.
2. Use more Flexible Printed Circuits to save space.
3. Use proprietary charging ports to save space
4. The PPG sensor can be extremely thin

Apple Watch

Apple watch is much more complicated than the product needs designing. But there are still things can be learnt from.

1. Use BTB (Board to board) connectors to save space.
2. Use sealing ring to stop water from coming into the product.
3. Use screws together with double-sided adhesive to fix the internal components.
4. Tiny microphones can be integrated in the product.

3

DETAILED DESIGN

Details of the final design of the product are defined in this section, including product features, components, dimensions, diagnosis logic, product-service structure, interaction design, IoT structure.

Design Overview

Features

- Long-term (> 1 month) continuous off-hospital single-lead ECG monitoring

- Comfortable, easy-to-use sticker electrodes
  - Daily disposable
  - Non-irritating, medical grade adhesive
  - Breathable
  - Repositionable
  - Water resistant

Components

There are two main parts of the product – the sensor unit and the sticker electrode. The sticker electrode will be explained in detail in the next section. For the internal components in the sensor unit – PCB, battery, and vibration motor will be glued to the casing using double-sided stickers, which is learned by disassembling existing product including Apple Watch and XiaoMi MiBand, which helps save precious room and make the product smaller. Flexible Printed Circuit and Board-to-Board connector will be used for cable connections for the same purpose of space-saving. Instead of using a standard USB-C or micro USB-B interface for charging, a magnetic pin connection is applied. The sensor unit charging pins and the charging adapter will snap to each other automatically when brought together close enough. The magnets in the adapter are designed in such a way that the connector cannot be connected reversely to prevent mistakes. Moreover, the upper and lower casings are fastened by two small screws.

1. Sticker electrode
    - Custom-designed, non-irritating sticker with 3M Z-tape technology
    - Silver electrodes

2. PCB
    - ECG System-on-Chip
    - Bluetooth Low Energy 5.0 System-on-Chip
    - Inertial measurement unit (gyroscope and accelerometer)
    - Main Controller Unit
    - Power Management Unit
    - Storage Chip
    - Integrated microphone
    - Single RGB LED indicator

3. Vibration motor
    - 10x2mm 3.3V Mini Eccentric Rotating Mass

4. Battery
    - 3-day battery life
    - 3.7V 50mAh rechargeable Lithium polymer

5. Charging adapter
    - Magnetic snapping mechanism
    - USB-A interface

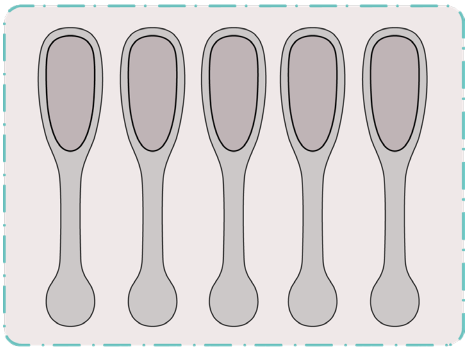
6. Physical button
    - ABS Plastic, Injection molding, High gloss finish, scratch-resistance coating

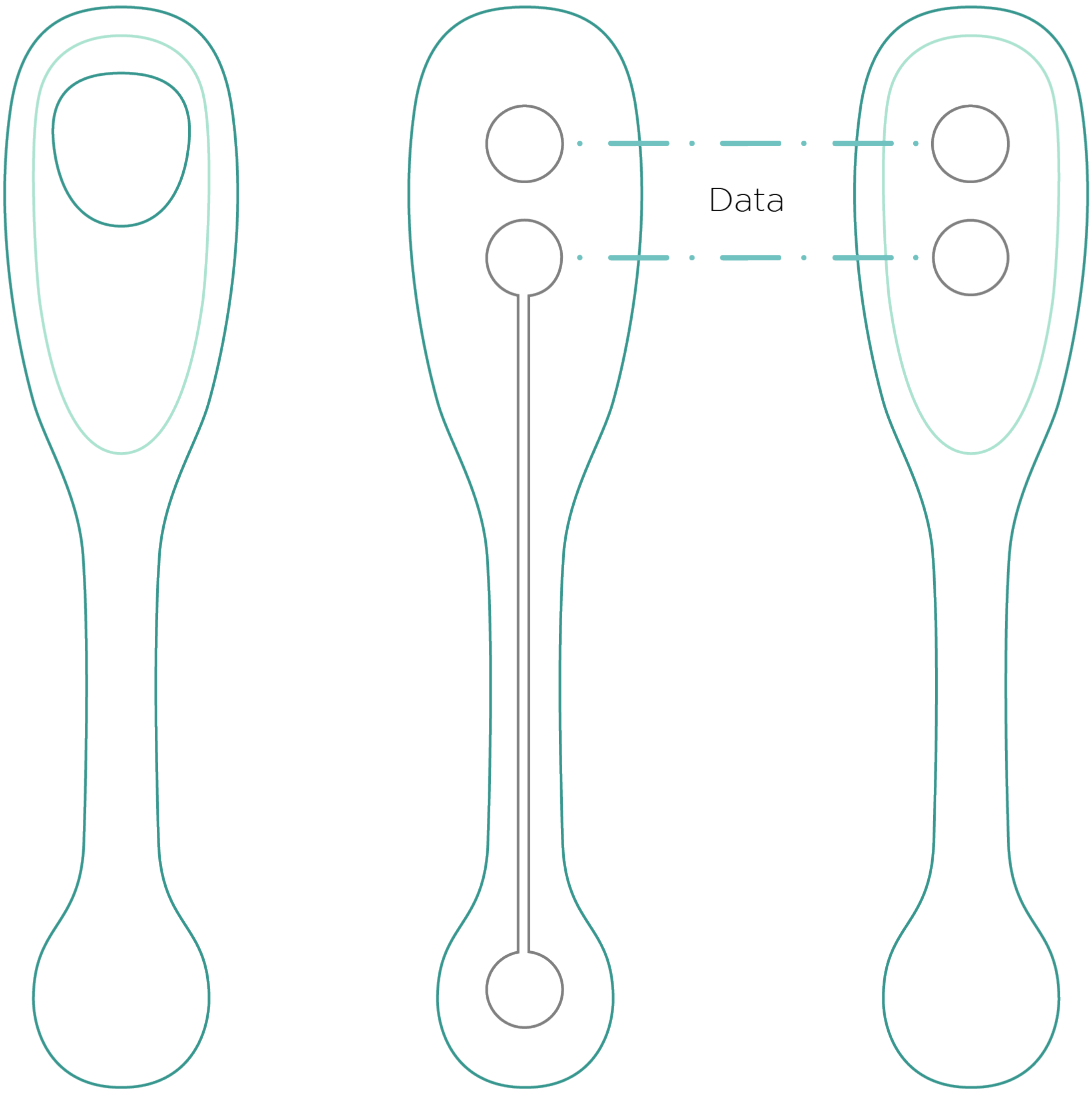
7. Upper casing
    - ABS Plastic, Injection molding, High gloss finish, scratch-resistance coating

8. Lower casing
    - ABS Plastic, Injection molding, High gloss finish, scratch-resistance coating

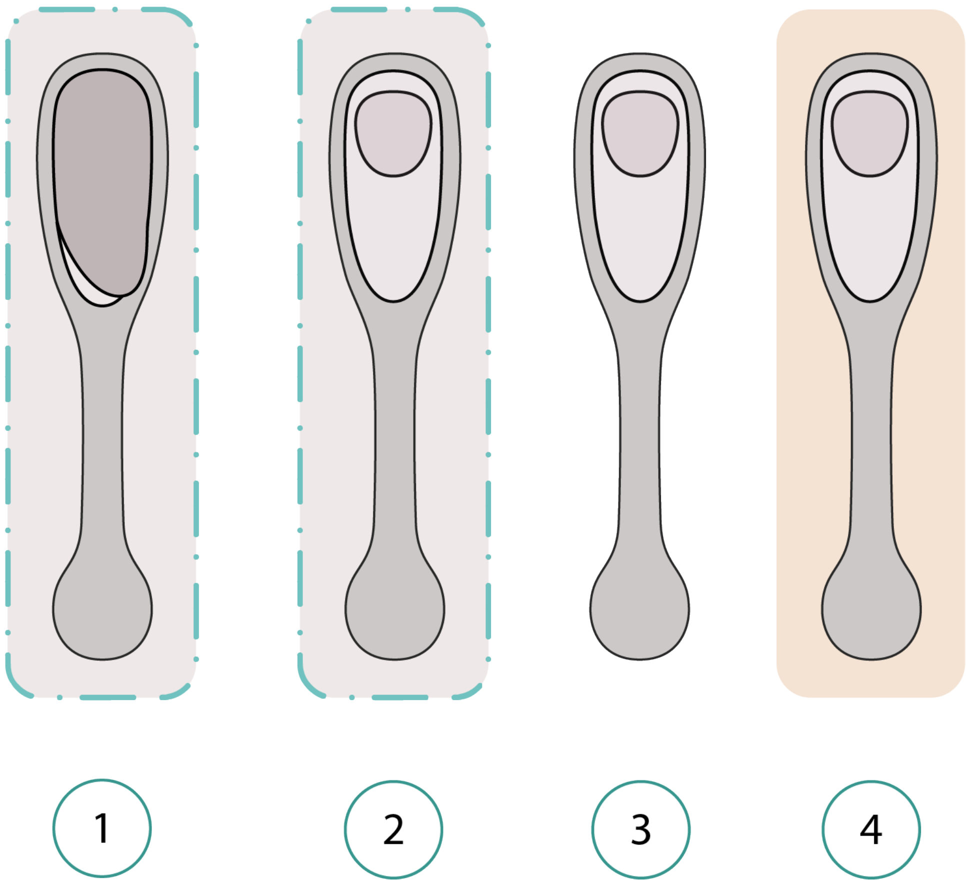
Disposable Sticker

A transparent sticker electrode design. The sticker needs to be replaced daily. On the top side of the sticker, there are two electrodes for connecting the sensor unit. On the bottom side of the sticker, there are two electrodes making contact with the skin. Conductive ECG gel is applied to the electrodes on the skin side by default for better signal quality.





Interactions:
The sticker electrodes adhere on sheets of paper that made into a booklet. To apply the product on the body, first, the small piece of the liner will be peeled off, exposing the contacting area for the sensor unit. Then the sensor unit is attached to that area of the sticker. Third, the sticker will be peeled off from the sheet. Finally, the product will adhere to the user's sternum.



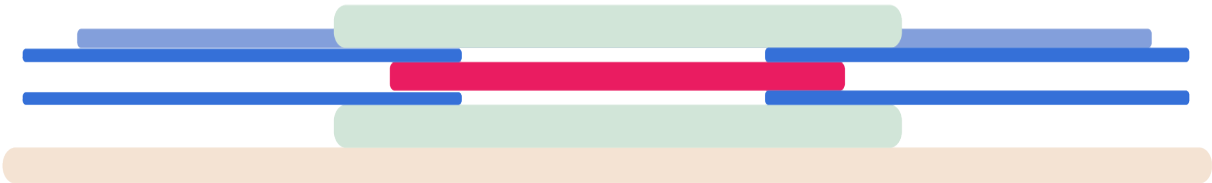
Materials:

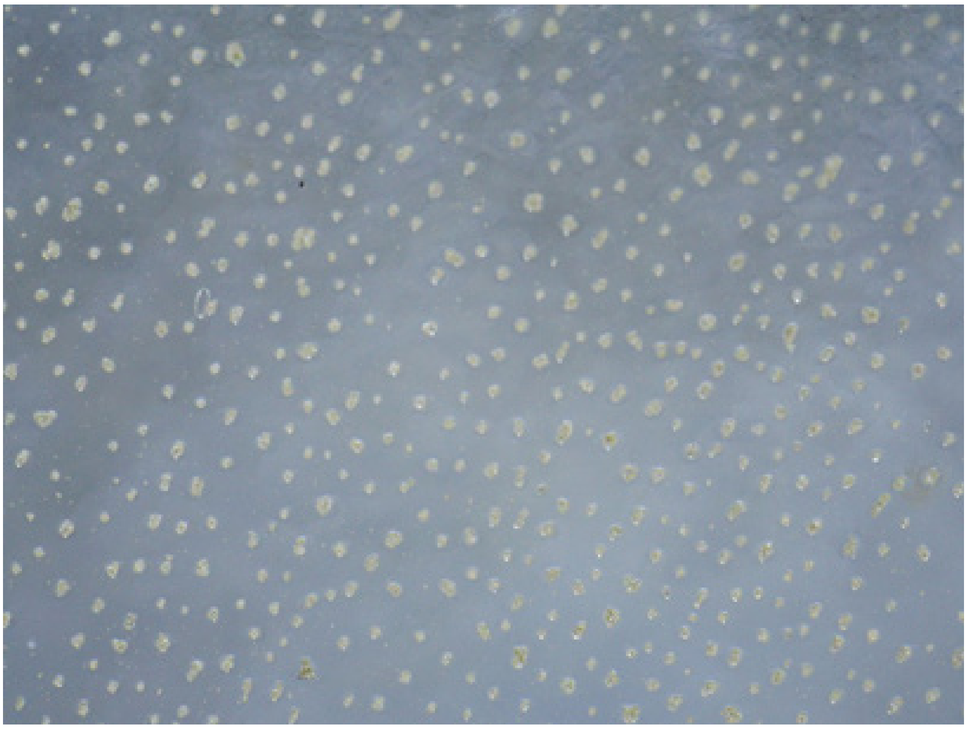
- Double coated 3M 2477P medical grade adhesive

    1. For skin: 3M Proprietary silicone adhesive
    2. For device: Gentle acrylic adhesive

- Double coated 3M 1509 medical grade adhesive
- Single coated transparent film on top
- Electrode binding layer: 3M 9703 Z-Axis conductive adhesive
- Electrodes: Thin silver sheet electrode

There is a multiple-layer structure in the sticker design because the Z-Tape needs to be integrated into the adhesive. At the bottom (green) is a silver electrode for skin contact. The softness and high resistance to oxidation make silver an excellent choice for the electrode in this context. One level up is the 3M 2477P double-sided. This tape is chosen based on the test result earlier in this project. It has two different adhesives for each side. The skin side has a proprietary silicone adhesive. For the device side, there is a gentle acrylic adhesive. Given the previous text, this tape has excellent adhesion for the product and does not irritate the skin while maintaining repositionable and breathable, which contribute to comfort and ease of use. Next level up is the double-coated 3M 9703 Z-Axis conductive. One level upper is the double-coated 3M 1509 medical-grade adhesive, which turned out to have excellent adhesion for the plastic interface from one previous test in this project. On the top layer is a transparent single coated film.





According to 3M (2015), “3M™ ECATT 9703 is a pressure sensitive adhesive (PSA) transfer tape with anisotropic electrical conductivity. PSA matrix is filled with silver particles enabling interconnections through adhesive thickness (the Z-axis) between substrates.”

Daily disposable design

The reason

According to previous research, it is neither practical (no existing product stays securely for more than one week) nor pleasant (skin irritation) to have the product adhered on the skin continuously for days. So, the solution is to design a sticker that can be replaced regularly. There are obvious benefits and some shortcoming that can be overcome.

The benefit

The are several benefits to have a daily disposable sticker electrode. First of all, the increases comfort dramatically because of weaker adhesive and the time gap during swapping stickers that can let the skin relax. The second benefit is that the product's form factor can be decreased significantly because the battery size can be decreased dramatically, and the battery takes the majority of the space according to previous product hardware study. The smaller product size also adds to the comfort in return. The third benefit is that the product using period can be increased exponentially from 2 weeks to 1 month, 3 months even a whole year since the sensor can be re-charged daily and the product can be used indefinitely, as long as there are enough stickers. This expands the capabilities of the product from Atrial Fibrillation diagnosis to other cardiac conditions that need long-term continuous monitoring, such as post-stroke monitoring and people with congenital heart disease.

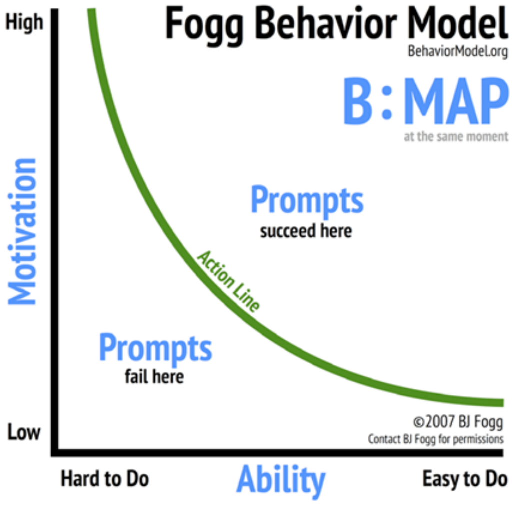
Hypothetical shortcoming

Since it takes time for people to take a shower and the product will be taken off the body, there will be roughly half an hour when the user is not being monitored. There may be a risk that the episode happens in this period, but the device cannot detect. However, thanks to the daily disposable sticker, the product can be used almost indefinitely, which offsets the risk of missing an episode.

Theory supported

Since the replacement of the sticker will be a change in people daily life, it should be discussed whether it is realistic for people to make it change and finally make it a habit in their daily life. The daily disposable design is supported by Fogg's behavior model. According to Fogg (2009), people may change or show specific behavior based on their motivation, ability, and the trigger of the behavior, and motivation and ability can trade-off. So, People may show the behavior if it is easy enough (ability), and they want it enough (motivation) and something that sets them to action (trigger).
The prerequisites of realizing the daily sticker replacement are a strong motivation, an easy enough process, and finally a trigger.
For motivation, the longer-term goal is health, and the short-

term persuasion experiences (immediate gratification) is the relief feeling on their skin, which are both high-quality motivations. As for ability, the sticker changing process designed is not a time-consuming task and does not involve much physical or mental effort. It was evaluated in the user test chapter that can be found later in this report. Last but not least, there a good trigger for the user – people go to bed every day and almost take showers every day. Going to bed or taking a shower can be useful triggers for the users to change the stickers. This behavior of changing the sticker is also natural to form a habit for the users. To establish a habit, it requires four pillars - Cue, Craving, Response, and Reward (Duhigg, 2012). Cues predict rewards such as comfort and relax, which can be location, time. Craving is the motivational force behind every habit. The response is the actual habit people perform, and rewards are the end goal of every habit. The structure is complete in the context for the users to establish a habit of changing the sticker daily.



Create the habit of daily sticker change	
The 1st law (Cue)	*Make it obvious* At the same time, location and environment everyday
The 2nd law (Craving)	*Make it attractive* People need to go to bed and wants to take showers
The 3rd law (Response)	*Make it easy* The sticker can be swapped effortlessly
The 4th law (Reward)	*Make it satisfying* It is not only a relief on the skin but also an achievement towards health

Compact Design

This is the most compact product in the market thanks to the daily disposable design and Z-tape integration in the sticker, which makes it the most comfortable off-hospital continuous ECG monitoring solution.

The maximum thickness is 7.5mm, the maximum width is 18.5mm, and the length is 39.5mm.

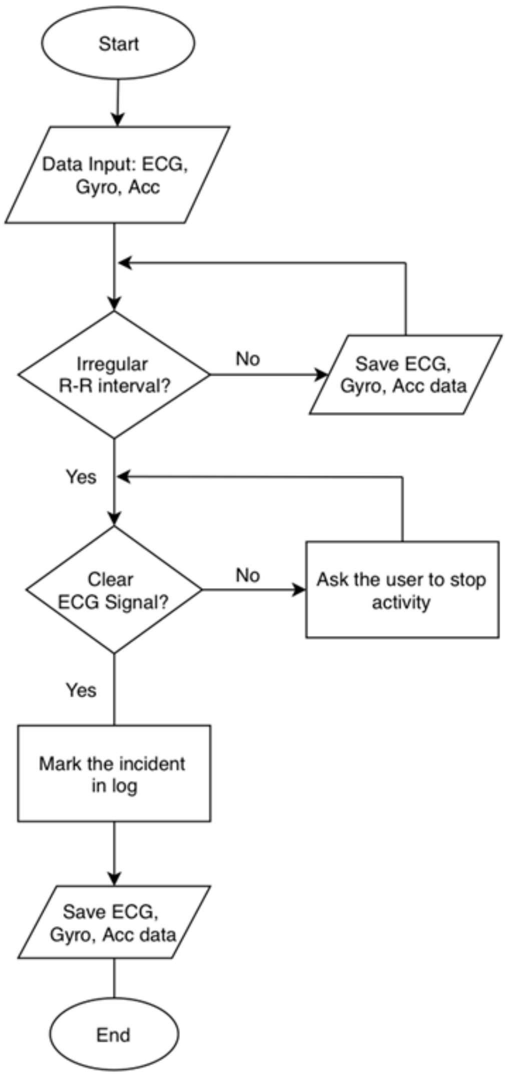
Compare with ZIO XT patch and VIVALNK patch, the new design is smaller in volume.

Product-Service Structure

First, the user goes to GP or cardiologist to receive the device, which can be initiated by the user or the medical professionals using high-risk people screening. Then the user uses the product for an extended period of time depending on the demand.
If a diagnosis is made or the monitoring is over, the user returns the device to the professionals, and corresponding measures will be taken based on the monitoring result. The cost of the device and service is covered by insurance companies rather than the user or medical professionals.

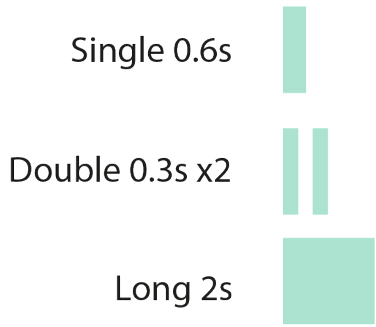
Product Logic

Following is the flowchart demonstrating the diagnosis logic of the product. Convincing diagnosis relies on clear ECG data with the least influencing factors, which indicates that data for diagnosis should be taken when the user remains stationary since movement adds multiple interference factors to the ECG signal. Data during motion results in extra cost to filter the signal and less convincing diagnosis.

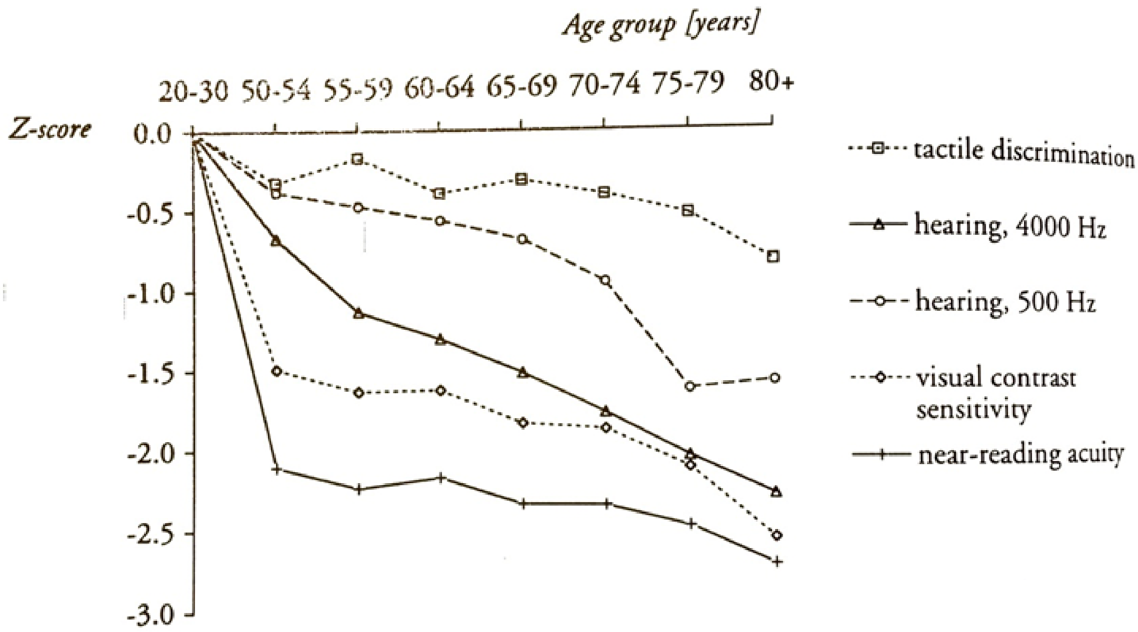


Communication Signal Design

There are two interactions signals between the user and the product – feedforward and feedback. Feedforward should be provided when the device detects a possible abnormality with user's heart so that the user can remain still enabling the device to take clear, high-quality data which does not involve activities. Feedback should be provided in many situations such as on the touch of the capacitive button, finishing of the 1-minute clear ECG recording. After initial research on interactions methods between the product and the user, it is found out that vibration can be used as a proper primary interaction method for its high availability across different situations in this context. Then a user test is conducted to validate the practicality of using vibration as the primary interaction method, which can be found in the next section of this report. Visual signal i.e., LED is used for secondary interaction method to indicate the product's status such as battery level and Bluetooth connection status.

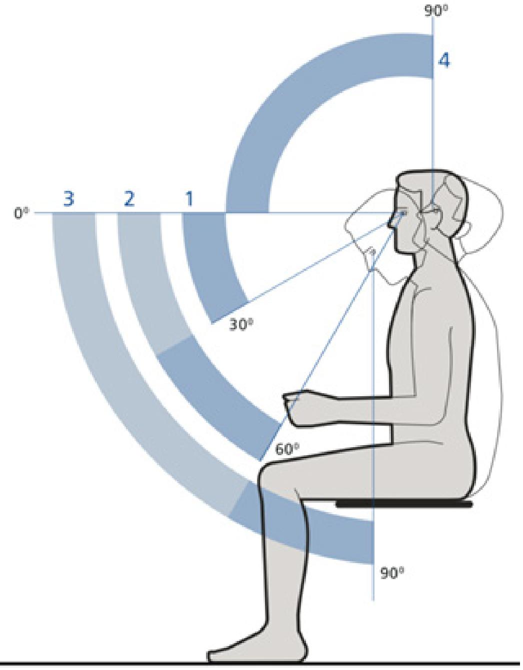


There are other possible interaction methods, such as visual and auditory signals can be considered. However, they tend to be less reliable according to the study on elderly design, which points out that the sense of vision and hearing deteriorates significantly as age increases, while the tactile sense maintain at a stable and high level (see picture below,).



In addition, compared with vibration, there are more external factors can hinder the sense of visual and auditory signals. For visual signals such as LED on the product, first, it is not considered ergonomic to look downwards at the product attached on the chest. Second, the success of receiving the visual signal is merely dependent on the available sight of the person, which means the visual signal is completely inaccessible when people have the product covered by their clothes.

	Kąt widzenia	Pole obserwacji
1	0-30°	dla częstych obserwacji bez potrzeby ruchu głowy i tułowia
2	30°-60°	dla obserwacji i manipulacji przy pochyleniu głowy
3	60°-90°	tylko dla rzadkich obserwacji przy pochyleniu głowy i tułowia
4	0°-90°	tylko dla rzadkich obserwacji przy ruchu głowy i tułowia do tyłu

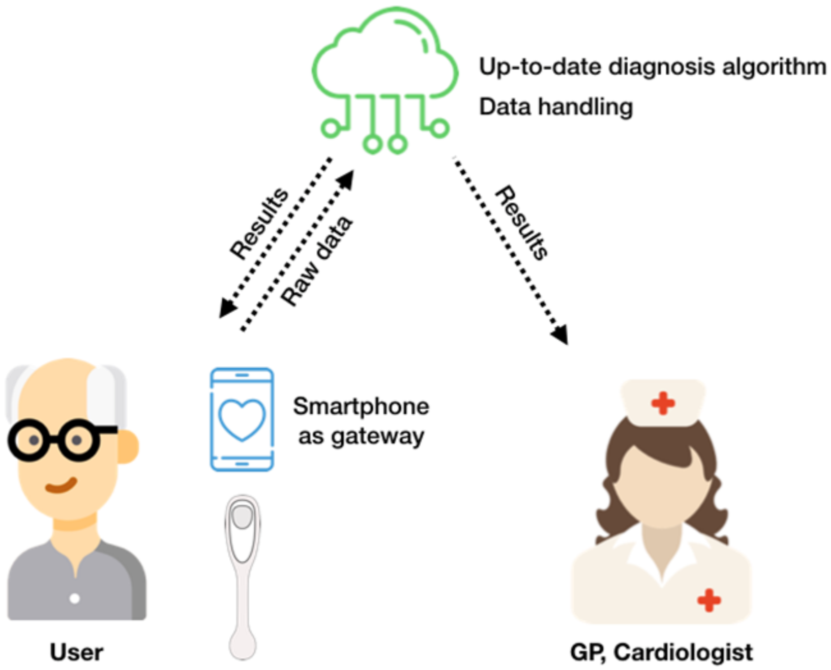


Zalecenia dotyczące kątów widzenia na stanowiskach komputerowych wg standardów ISO/DIS 9241-5,3.
Pochylenie głównej linii patrzenia w stosunku do horyzontu wynosi 35°, a optymalny zakres kątowy widzenia –15 °.
Optymalny dystans obserwacji wynosi 60 cm.
Indywidualne preferencje dystansu obserwacji są zróżnicowane i zawierają się w przedziale 40 do 75 cm.

IoT

The nature of the design is a data driven IoT product. Detailed explanation can be found in the diagrams below.

	Description
People and Process	Patient diagnosis for professionals
Applications	Custom management applications
Data analysis	Machine Learning Diagnosis Algorithm
Data Ingestion	Harvest and storage of things data
Global Infrastructure	Internet
Connectivity	Bluetooth, WIFI
Things: Edge Computing	Software and algorithm inside product
Things: Devices	Product hardware at user end



Expand the Possibilities

(Re-)Enable ECG at practice

According to two General Practitioners interviewed, many practices used to take ECG measurements but stopped doing so because it required the General Practitioners to learn additional knowledge (ECG). However, they do appreciate the information that ECG measurement can provide, which will expand the capabilities of the practice and help the patients.

Apart from of Atrial Fibrillation, ECG can be useful to identify many problems in a short amount of time, such as Myocardial ischemia, Electrolyte disorder and other types of arrhythmia. The diagnosis of these diseases does not require long term monitoring and can be conducted at the practice in a short amount of time, which is helpful to expand the practice's capability and save more precious time for the patient. Thus, enabling ECG at the practice is meaningful and useful.

4

EVALUATION

It is necessary to measure the performance of the design even when arguments are given. Two key innovations in the design are evaluated: vibration as the primary interaction method and disposable stickers.

User Vibration Interaction Test

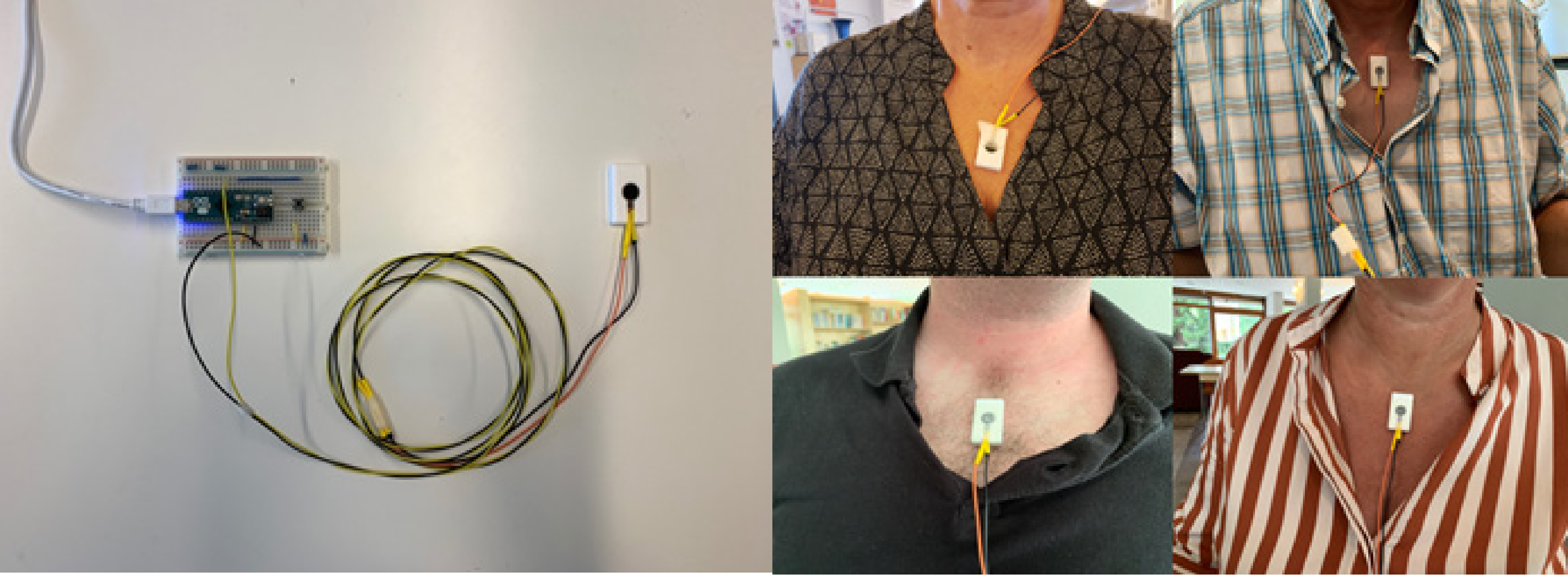
As vibration is used for the primary interaction method, in addition, the effectiveness of the small ERM (Eccentric Rotating Mass) on the sternum is unknown, although the maximum vibration intensity is strong to feel at the fingertips, it is worth testing the actual perception of the vibration on the sternum.

Experiment goal

1. The success of correct perception is more important than the pleasance of the vibration in this case since using vibration on user's sternum is a more critical question to answer than to which extend will the user consider it comfortable, so the test should start with the maximum intensity of the given ERM and whether participants can sense and distinguish among the three designed vibrations in various situations should be tested.
2. The activity of people doing may influence the perception of the intensity of the vibration, which may lead to different intensity for different situations.
3. Whether people feel the vibration pleasant or not since comfort is considered high importance throughout this project.

Experiment setup

A small ERM (RB-See-403) fixed in a piece of PLA plastic (to simulate the actual sensor part) is placed on the participant's upper sternum (shown in following pictures) using 3M medical grade double-sided adhesive. The ERM is controlled by a micro Arduino, which is programmed to send different vibration signals to actuate the ERM. And the Arduino is controlled using a push button to change the types of vibration signal



3 types of vibration:

- Single short vibration (0.6s duration);
- Double quick vibration (vibration: 0.3s, interval: 0.25s);
- Single long vibration (2s duration).

Max intensity of the ERM is applied except in the comfort test section in which, linear increase in intensity of vibration feeling starts from 50% of the maximum intensity of the given ERM.

5 different conditions:

- Sitting quietly: the participant is sitting on a chair without major body movement in a quiet environmeWnt.
- Auditory interference: the participant wears a noise cancelling headphone and listening to a soundscape of café in a rainy weather so that the sound of caused by the vibrating ERM cannot be heard.
- Distracted: the participant is the focus is shifted from sensing the vibration by being asked to do daily activities such as cooking, fetching objects or interpersonal interactions such as talking or listening to the researcher's instructions.
- Walking: the participant is asked to have a short walk to create physical activity.
- Walking plus auditory interference: the combination of Condition 2 and 4 so that the participant is have limited physical activities and cannot hear the sound of caused by the vibrating ERM.

Experiment procedure

1. Test whether participants can feel and distinguish among the three different vibrations when they are sitting quietly, walking, distracted and when they can't hear the vibration
2. Given a same vibration, let participants compare the intensity while they are sitting and doing daily physical activities.
3. Get a score (1-10 scale, the higher the more comfortable) for pleasance of the vibration while sitting calmly.

Results

1. For vibration perception, all vibrations are sensed successfully. All 3 types of vibrations are distinguished correctly 55 times out of the total 57 times. One occurs during walking and the participant mistook the one 0.6s vibration as two quick vibrations. The other one occurs when the participant was distracted by paying attention to other's conversation and the single 0.6s vibration is mistook as two quick vibrations.
2. For the influence of the other physical activities, it is found out that two participants' perception of intensity are not affected by activities. One participant cooked pancake and the other one climbed stairs. The other two participants are affected by their activities differently. One felt stronger vibration while climbing stairs and one felt weaker while cooking.
3. For the vibration comfort, all 4 participants responded differently to the different intensity of vibrations. The first participant gave a high comfort score for all 4 intensities. The second participant gave a high score for the three weaker intensities while gave 6/7 for the maximum intensity. The third participant lowered the scores from 9 to 2/3 as the intensity increased. The last participant gave scored low (1 and 3) for the two weaker intensity and scored higher (6 and 7) for the stronger vibrations.
4. No body mentioned the confusion between the vibration on the chest and it from their heart.

Condition / Vibration	Seated quietly				Auditory interference				Distracted				Walking				Walking + Auditory interference			
Participant ID																				
Single (0.6s)																				
Two quick ones (0.3s)																				
Single long (2s)																				

Conclusion

1. Given the result from vibration perception test, the 3 types of vibration can be sensed and distinguished correctly at a high success rate by the user. The single vibration was mistaken for two times, which can be improved by shortening the period of actuation.
2. Light physical activities can affect the perception of the intensity of the vibration for some users. More active activities may lower the perceived intensity of the vibration. This can lead to a variable strength of vibration of the product e.g. the product can offer stronger vibration signal when the user is detected doing large body activities to ensure the sense of the signal.
3. The participants perceive the comfort of the given vibrations quite differently since this is highly individually dependent and their reactions can be completely opposite. In general, the maximum intensity is good for the vibration interaction.
4. For the possibility that the user may confuse the vibration of the device with actual fibrillation of their hearts, it should not cause an issue because it means people can feel abnormality on their chest when people are confusing about the vibration, which means they should calm down and let the device take a short period of time of quality signal.
5. In summary, using vibration is a good way to have the users interact with the product because it is a reliable and non-irritating way to communicate.

User Sticker Application Test

It is unknown that how users will perform when applying the sticker electrode for the first time and changing them on a daily basis since the design of daily disposable sticker is unique in competing products. A user test was carried out to evaluate the design.

Purpose of test
To see whether users can correctly assemble the sensor with the sticker electrode and apply the product to the designated location.

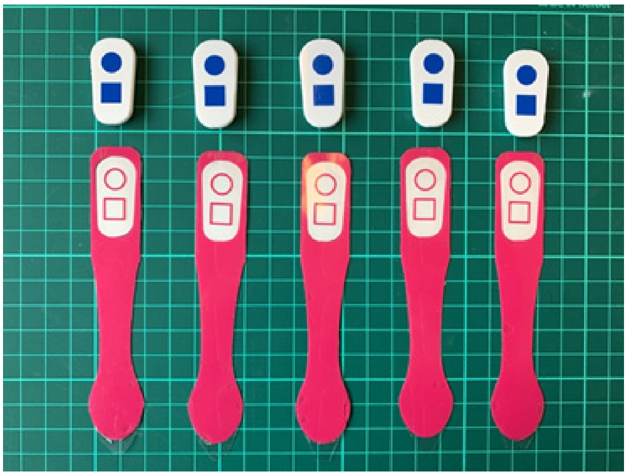
Apparatus
Stickers and sensors: Dummy stickers and sensors (shown in the picture) are used. On the back of dummy sensors, the location of contacting electrodes is labeled using blue vinyl stickers, and the location of electrodes on the stickers are labeled by pink vinyl indicators.

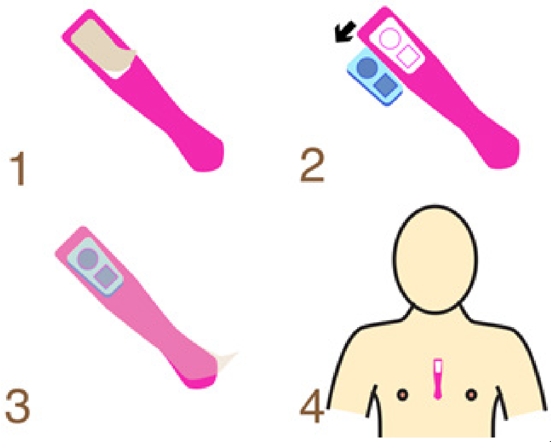
Manual
An application manual (shown as picture) was provided for the participants to instruct the process. The process is divided into four steps which are peeling off the liner at the sensor area; assembling the sensor with the sticker; peeling off the liner of the sticker; sticking the sticker electrode on the sternum.

Participants
Participants are elderly persons (aging from 55 to 88, one 35yrs). Both male and female are involved.

Method

1. Voice instructions is given by the researcher then participants are asked to do what the manual instruction says;
2. The process is recorded for analysis.
3. The finished assembly is examined for the accuracy of sensor-sticker assembly.





Conclusion

The whole process is easy and quick, with seven finished around 1 minute, and two took almost 3 minutes. One of them needed reading glasses, and the other's handling was affected by Parkinson's Disease significantly. As for assembling the sensor with the sticker, although it is easier to put the sticker on top of the sensor, which was instructed in the manual, participants still turn to put the sensor on top of the sticker, which is more intuitive. 7 out of 9 test produced good assembly accuracy, indicating that the assembly process can be improved. The accuracy of application is excellent with only one participant having lousy adhesion of the product, which could be the combined influence of his Parkinson's Disease and chest hair. People with Parkinson's Disease may have difficulty doing this process daily at high accuracy. 7 out of 9 participants firmly pressed the dummy sensor subliminally after applying the sticker without instructing to do so, which is a desirable finding for the design since this will generate a better adhesion between the skin and electrodes.

Participant ID (Age)	Duration (min: seconds)	Assembly accuracy	Application accuracy	Notes
0	00:49	good	good	Firmly pressed the sensor
1 (64)	2:40	satisfactory	good	Reading glasses needed for peeling off sticker liner; Firmly pressed the sensor
2 (88)	2:48	bad	good	Parkinson's Disease
3 (56)	1:06	good	good	Firmly pressed the sensor
4 (62)	1:12	good	bad	Slight Parkinson's Disease; Firmly pressed the sensor
5 (54)	0:50	good	good	Firmly pressed the sensor
6 (55)	0:55	good	good	-
7 (50)	0:69	good	good	Firmly pressed the sensor
8 (35)	0:57	good	good	Firmly pressed the sensor

Sticker performance test

Goal

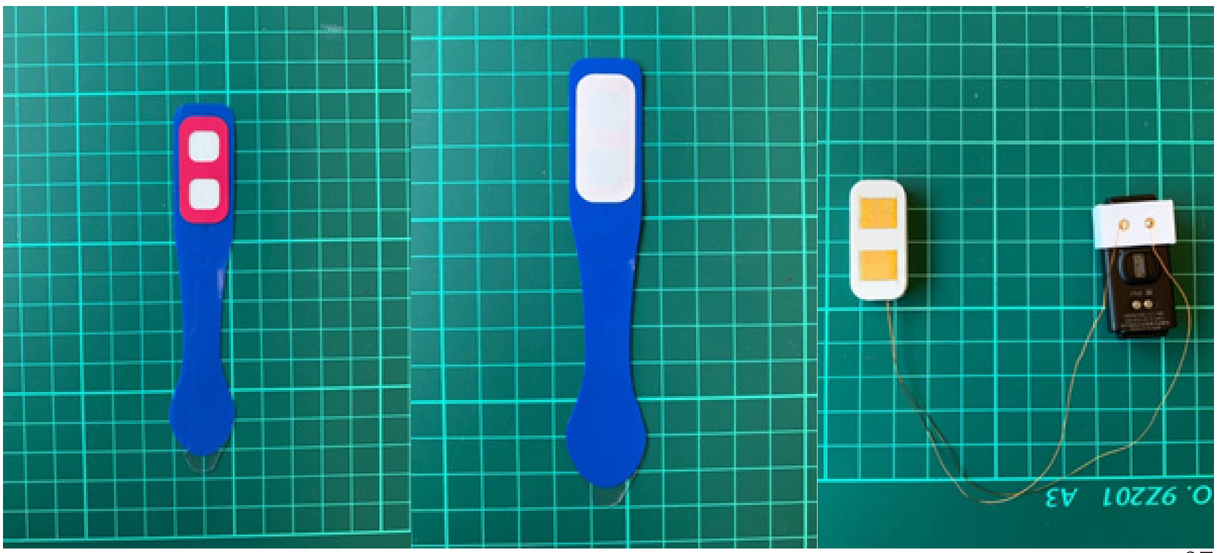
The sticker electrode needs to be tested for 24 hours of use in order to simulate the real-life usage.

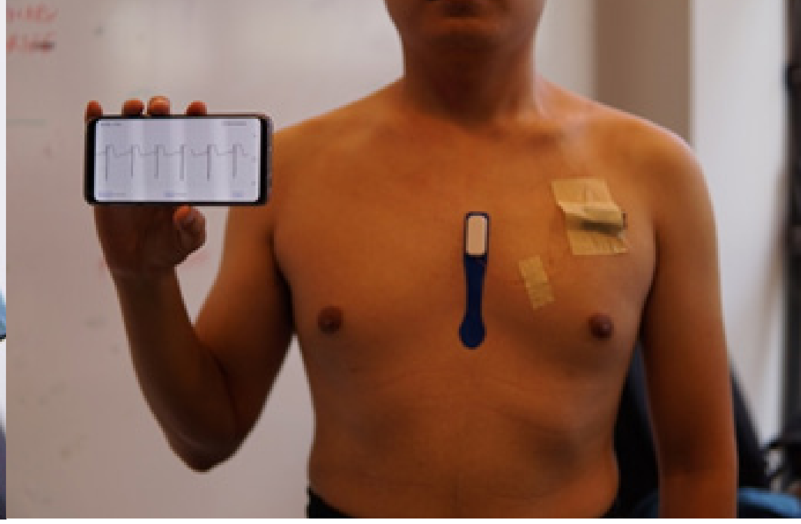
Apparatus

- A sticker to be adhered on the sternum. The sticker is made by hand using 3M 2477P double-sided adhesive, Z-Tape and brass foil according to the design.
- A dummy sensor. It has two contacting electrodes to be adhered on the sticker. There are no actual electronic components in the dummy sensor, instead, two copper wires are used to connect the two contacting points from the sticker to the data processing device.
- The data acquisition device is the AMAZFIT ECG Recorder. The data transferring wires are connected to the corresponding pins using a proprietary 3D-Printed adaptor.
- The data will be transferred from the data processing device to a smart phone to evaluate the signal quality.
- ECG Gel. To decrease the resistance between the skin and electrodes.
- A smart phone used to record the notes on the activities the subject is doing.

Method

The dummy sensor and the sticker are assembled properly, then the sticker is adhered on the researcher’s sternum as the picture shows.
The test unit will be worn for 24 hours continuously, during which normal daily activities will be involved. Shower will not be taken since this setup is not waterproof. The subject will audio record a note when he is doing a specific activity.





Results

ECG remains a clear when the subject is stationary. Both p-wave and QRS complex are clear to identify. ECG remains clear when the subject is moving, and the data processing unit is fixed properly. P-wave are hard to identify but QRS complex remains clear. ECG is noisy when subject is motion and the data processing unit is not fixed to the body. Neither p-wave nor QRS complex can be identified.

Conclusion

The performance of the sticker electrode is sufficient for the use in the actual product. Clear P-wave, QRS complex can be obtained in ECG when the subject is stationary. Moreover, clear QRS complex can be identified in motion provided the data processing unit is fixed to the body, which can be used to calculate the R-R intervals. According to the diagnosis logic of the product, the product functions properly as long as the data can be used to calculate the R-R intervals, whether the user is in motion or not. Noisy data is generated due to the poor performance of the proprietary 3D-Printed adaptor for the data processing unit.

	Clear ECG (no noise)	Clear P-wave	Clear QRS complex
Subject stationary	Yes	Yes	Yes
Subject in motion, data processing unit stationary	Yes	No	Yes
Subject in motion, data processing unit stationary	No	No	No

5

DESIGN RECOMMENDATIONS

Due to the time constrain and scope of the project, some of the ideas cannot be thoroughly tested or discussed. Some of them focus on the product itself while others are related to the strategy of the company. Here is a list of recommendations worth exploring in the future.

Strategy

1. Adding PPG: According to this study, there is no discernible value of integrating PPG with ECG to compensate motion artifacts on the ECG signal. However, PPG can provide more biosignals such as blood pressure, blood oxygen saturation, and hypo-/hypervolemia, which will increase the value and expand the application of the product. Currently, there is no product known for ECG/PPG integration, this can be an opportunity to make the product unique to attract more investment, which is a strategic problem to evaluate – whether the next generation product should focus on Atrial Fibrillation or expand the capabilities of the product, which takes more time to develop. Moreover, timing is crucial in this industry.
2. For future generations, make the product a 5G IoT device, enabling real-time data process. The product will be a complete health companion untethered from smartphones, which expands enormous opportunity.

Diagnosis Quality

Integrate (e.g. anamnesis) with different toolkits for Atrial Fibrillation from American College of Cardiology Foundation (in NHG). There are various toolkit processing different patient information and situations to calculate the probability of having Atrial Fibrillation. Integrating these types of toolkit into the diagnosis algorithm may increase the accuracy of diagnosis.

Interaction

1. The effectiveness of vibration as a feedforward when the patient is having an Atrial Fibrillation episode. It was not tested whether vibration can still be perceived.
2. The app should be carefully designed and developed. Here are some suggestions on the function and contents of the app:
   - YES/NO detection of Atrial Fibrillation;
   - Real-time heart rate variability;
   - Operations that needs taking immediately such as consult cardiologist or call emergency service;
   - Overview of marked incidents detected by the product and triggered by the user;
   - Status of Bluetooth connection with smartphone;
   - Status of internet connection with cloud service;
   - Battery level of the product;
   - Quality of ECG signal

obtained;

- Request of extra free sticker electrodes;
- User manual of the product;
- Frequently asked questions;

Technical Issues

1. Custom designed 3M stickers integrated with Z-tape. It can simplify the manufacturing process if Z tape technology can be integrated into the single piece of sticker.
2. Dry electrodes with less noise. As technology advances, dry electrodes which have acceptable motion artefacts can be achieved, which may escalate the convenience of the product.

PERSONAL REFLECTION

This project is important to me not only because this is my master's thesis but also because I have learned new things and gained experience on designing, working in a company, discovering culture difference, personal development, etc. To put it short, this project not only helped me acquire more professional knowledge and skills but also made me a better person.

As an intern, this was my first time working for a company on a real-world problem that needs to be solved on my own, which pushed me to break my limits to make meaningful innovations. I have learned to tackle such a wicked problem by choosing the proper focus. I have learned to interview efficiently and effectively using mon test method. I learned to choose the correct direction based on company roadmap, technology availability, and market status. I have learned to make decisions from a higher strategic level. I have learned new materials, new manufacturing processes by reading even using them. I learned to get along with colleagues from the company. I have learned about the elderly's life in the Netherlands and the cultural differences between us. So many things that I cannot list here that I will definitely benefit in my future career. I really appreciate the IDE faculty and the company Praxa Sense for offering me the opportunity and freedom to learn so much from my thesis project.

I have also learned about the things I need to improve in the future. The first thing is time planning. I wish I had more time in the end that I can make a second iteration of the design based on the evaluation result. This is can be done by shortening the time spent on the synthesis phase. Another strategy I want to implement in the future is to initiate communication with people even when I feel not ready to. I have missed opportunities to consult people because I felt reluctant and not ready to meet, which turned out worse than just do it right away. Do not only start things when you feel you are ready for it.

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