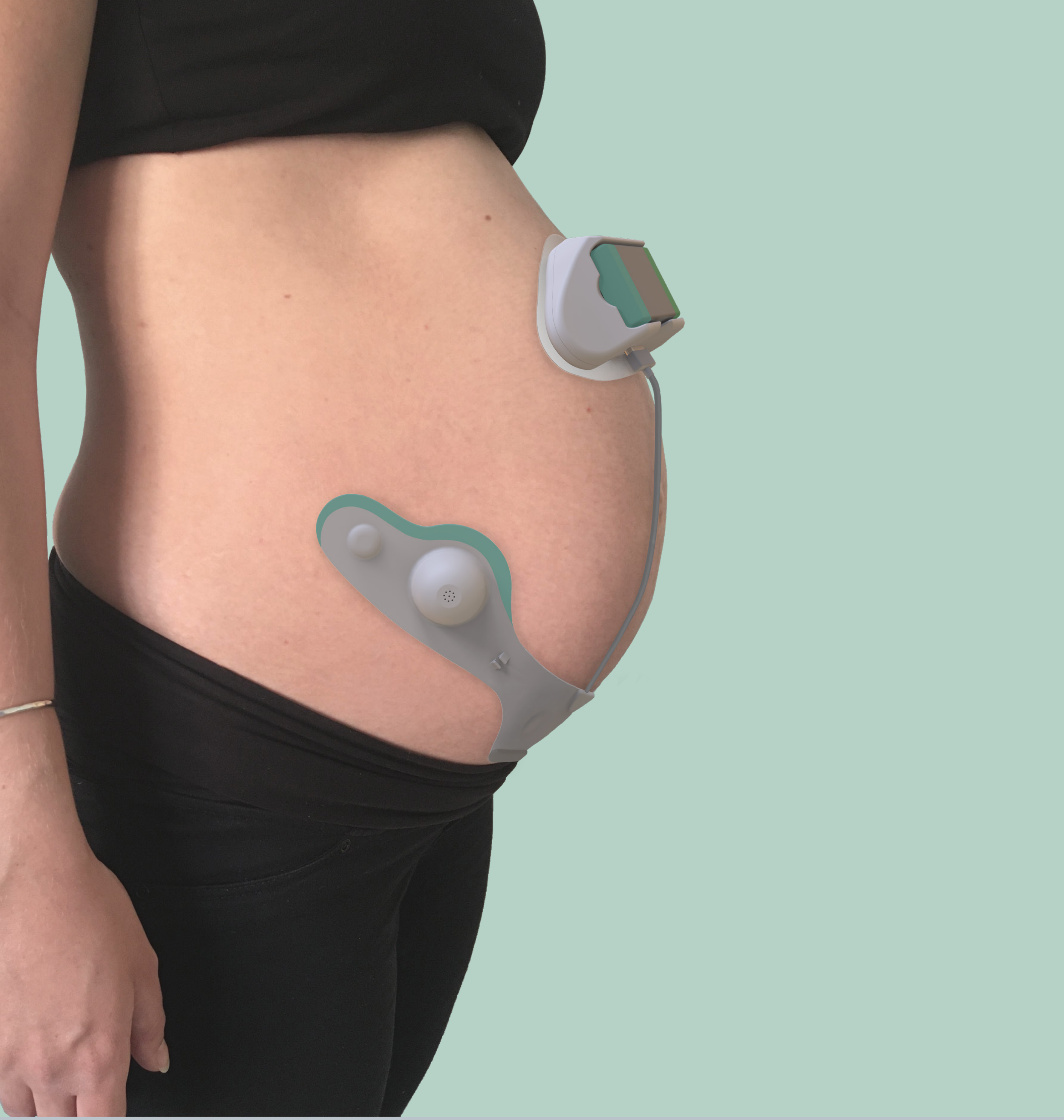

Monit Me

Trustworthy monitoring of pregnant and baby

Product report MSc Industrial Design Group: MA4-ID5 Date: June 2020 Aalborg University

Abstract

Dette kandidatprojekt fokuserer på at lave et produkt til monitorering af gravide, både til hjemmemonitorering, monitorering på klinik og monitorering under fødsel. Der er mange grunde til, at en kvinde kan have brug for hjemmemonitorering og monitorering ved fødsel, men alle kvinder i Danmark tilbydes scanninger løbende i graviditeten.

Specialet er udviklet med virksomheden CentaFlow som samarbejdspartner, som har leveret udgangspunktet for produktets teknologi samt sparring. Specialets yderligere fokus har været at implementere disse teknologier i et produkt, som har brugeren i fokus. Rapporten viser et produkt forslag til et monitoreringsdevice, som kan rumme alle tre ovennævnte scenarier, samtidig med at give data af høj kvalitet foruden at være intuitiv i brug og behagelig at bære.

Produktet bliver påsat maven med engangsplastre og måler blodgennemstrømning vha. mikrofoner, samt hjerterytme og livmoderaktivitet med elektroder. Disse sensorer kan fortælle om barnets helbred, og om det vokser som det skal.

For at opnå et brugervenligt og intuitivt produkt er der gennemført utallige tests og lavet mange forskellige prototyper. Desuden er der blevet rådført med både professionelle jordemødre og gravide kvinder undervejs.

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Title page

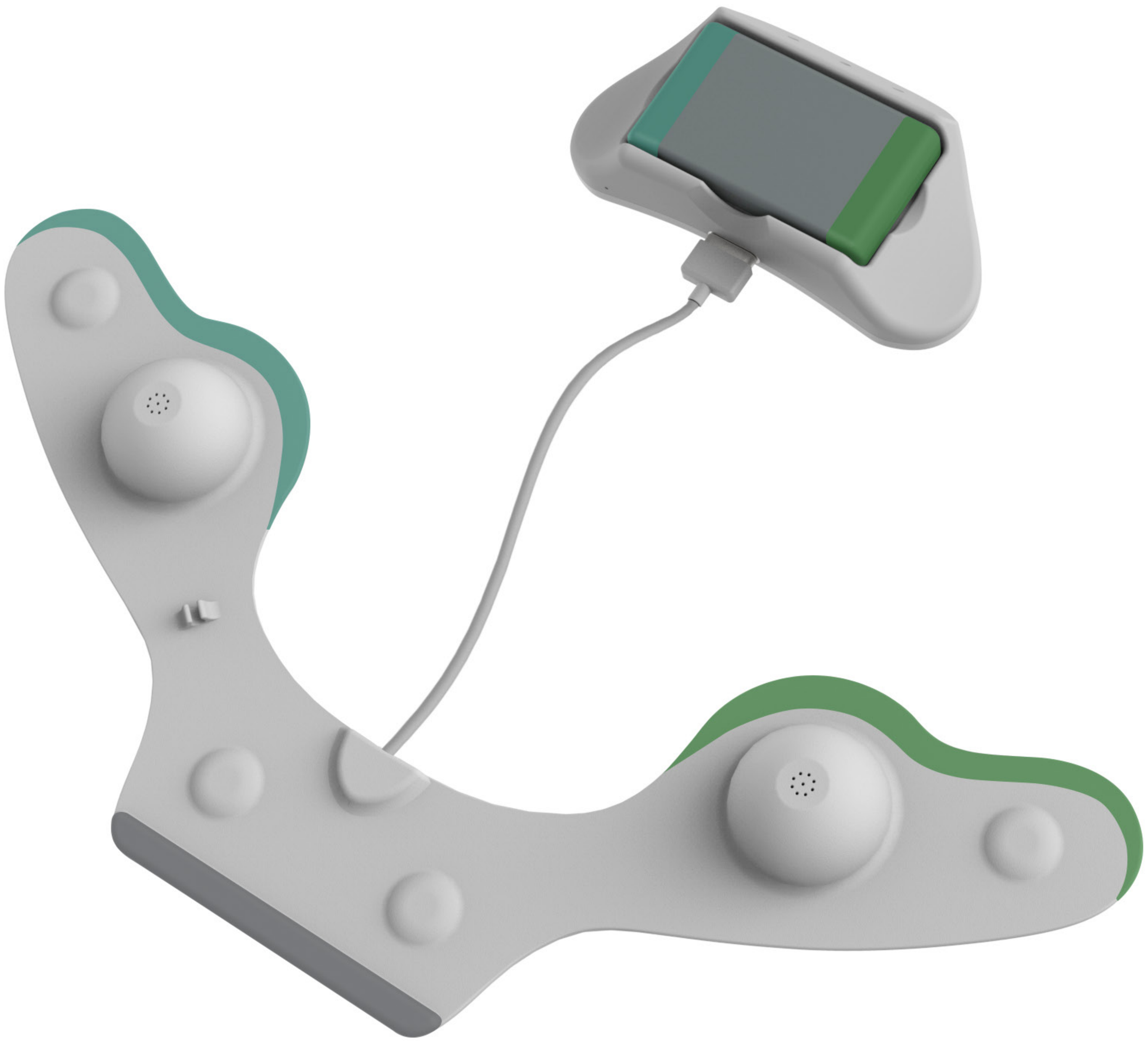
Title: MonitMe
Project period: February - June 2020
Team: MA4 - ID5
Pages: 24
Main supervisor: Christian Tollestrup
Technical supervisor: Mikael Larsen
Co-operation company: CentaFlow

Introduction

Many pregnant women receive extra monitoring of their fetus, during their pregnancy. However, many more receive it than is necessary - this is both expensive for the regions, but also worrying for women who have no reason to worry.

With pregnant women and the midwives in focus, a product that concentrate on intuitive use and a pleasant monitoring experience has been created. This product is MonitMe!

With the technology of MonitMe it's possible to acquit more women for extra monitoring, and only find and focus on the women who actually need it. MonitMe is developed in cooperation with CentaFlow, with help from Viewcare and midwives from Viborg Hospital.



MonitMe

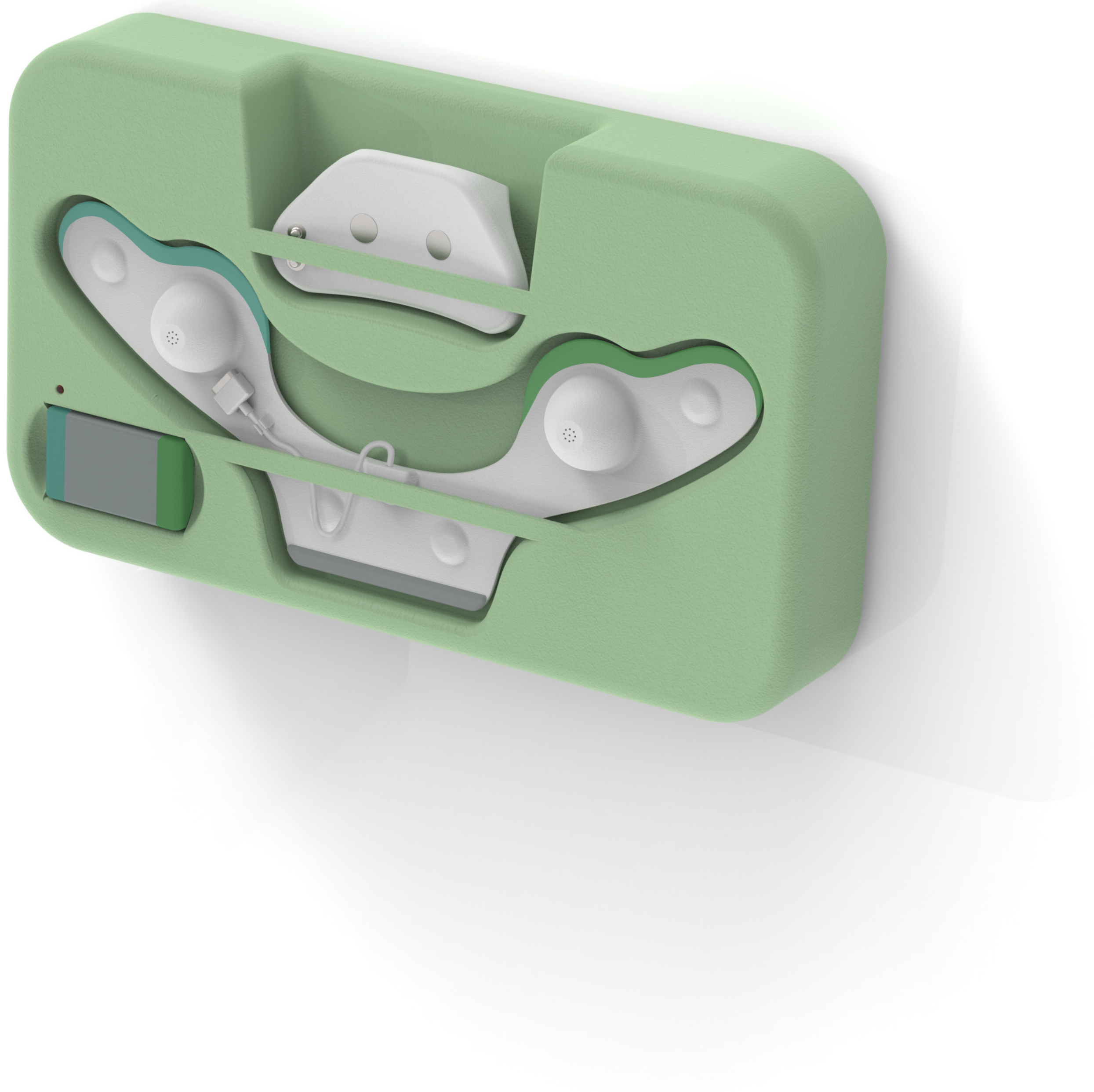
MonitMe is a monitoring device for pregnant women. It measures the fetus' well-being and growth by two different kind of sensors - microphones and electrodes.

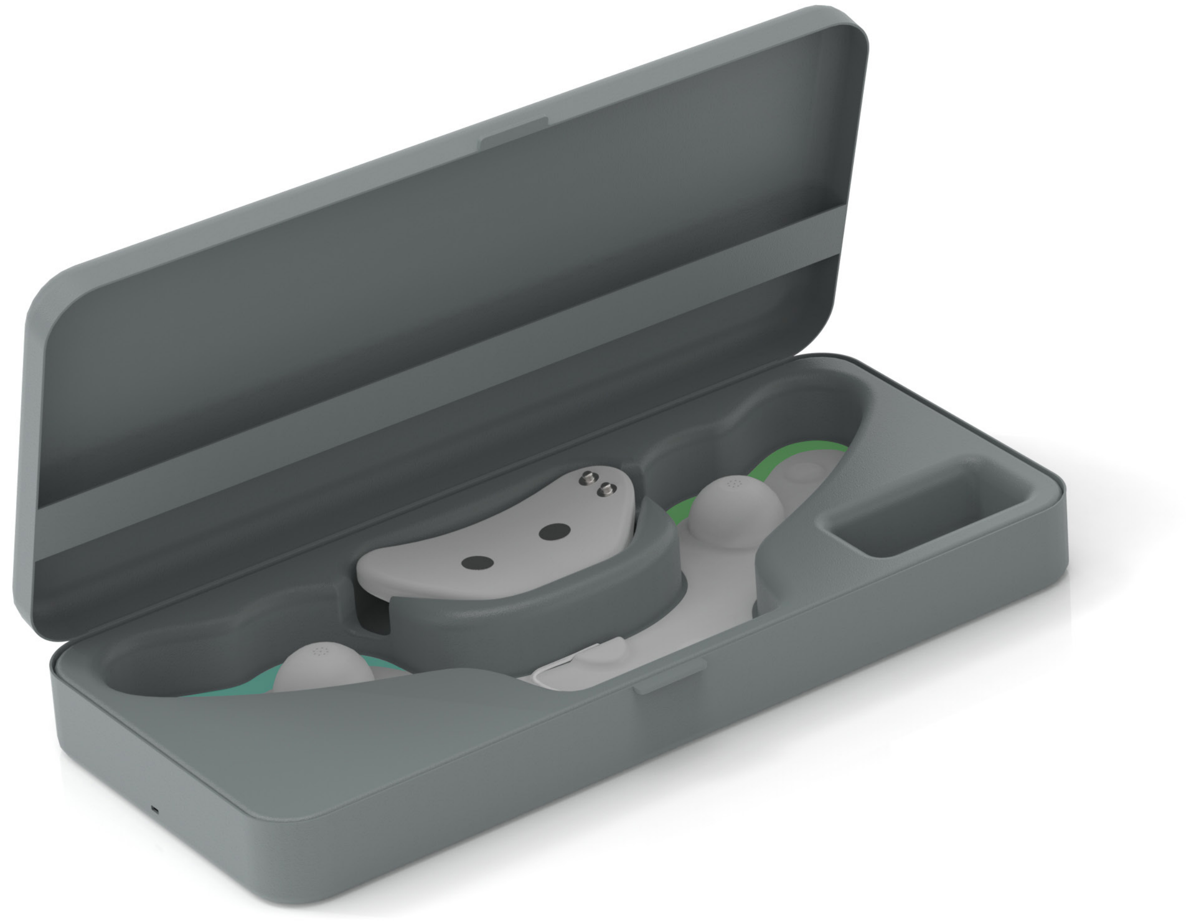
MonitMe is intented for three different scenarios. The first one is regular monitoring in a midwife clinic.

The second is home monitoring, where women that are evaluated in need of extra monitoring, get a device home, so they can monitor themselves in familiar surroundings, instead of driving to the clinic every week. These women can e.g. be women with diabetes or pre-eclampsia.

Lastly, MonitMe can be used for delivery monitoring. Many women need monitoring during a birthing situation, and MonitMe ensures a high quality measurement that doesn't get in the way of natural birthing movements, or a wish to deliver in water. Last but not least, MonitMe is designed with comfort in mind, therefore it's constructed so it wont tighten around the body or irritate the birthing woman in any way - contrary to the current CTG.

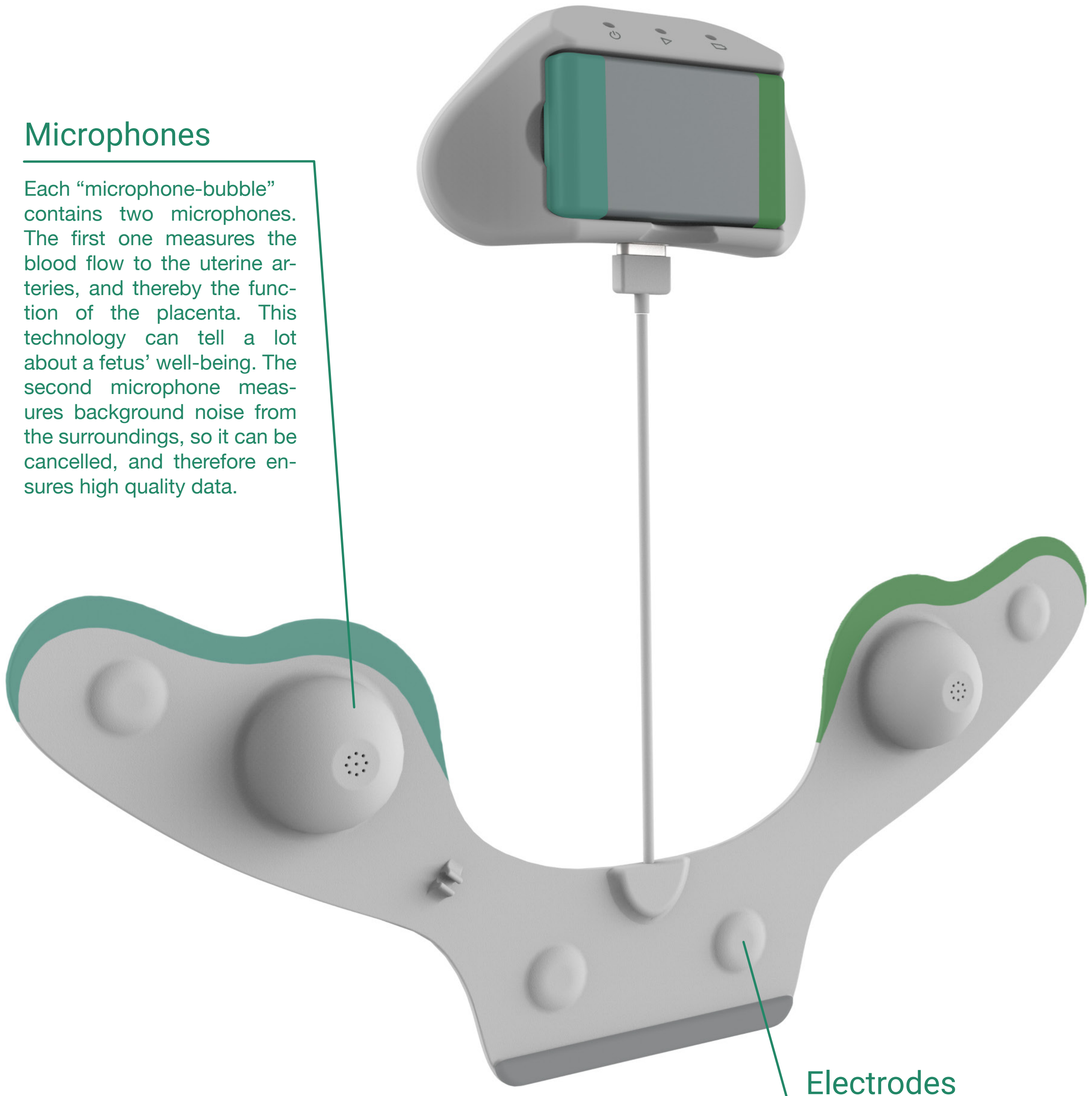
MonitMe is constructed with the user as focal point!





Microphones

Each "microphone-bubble" contains two microphones. The first one measures the blood flow to the uterine arteries, and thereby the function of the placenta. This technology can tell a lot about a fetus' well-being. The second microphone measures background noise from the surroundings, so it can be cancelled, and therefore ensures high quality data.



Electrodes

In the lower part there are placed four electrodes, one under each small bubble. In the upper part there are additionally two electrodes. All these electrodes are connected across the pregnant stomach, and measure heart rate of both fetus and mother, and also uterus activity, e.g. a contraction.

Product overview

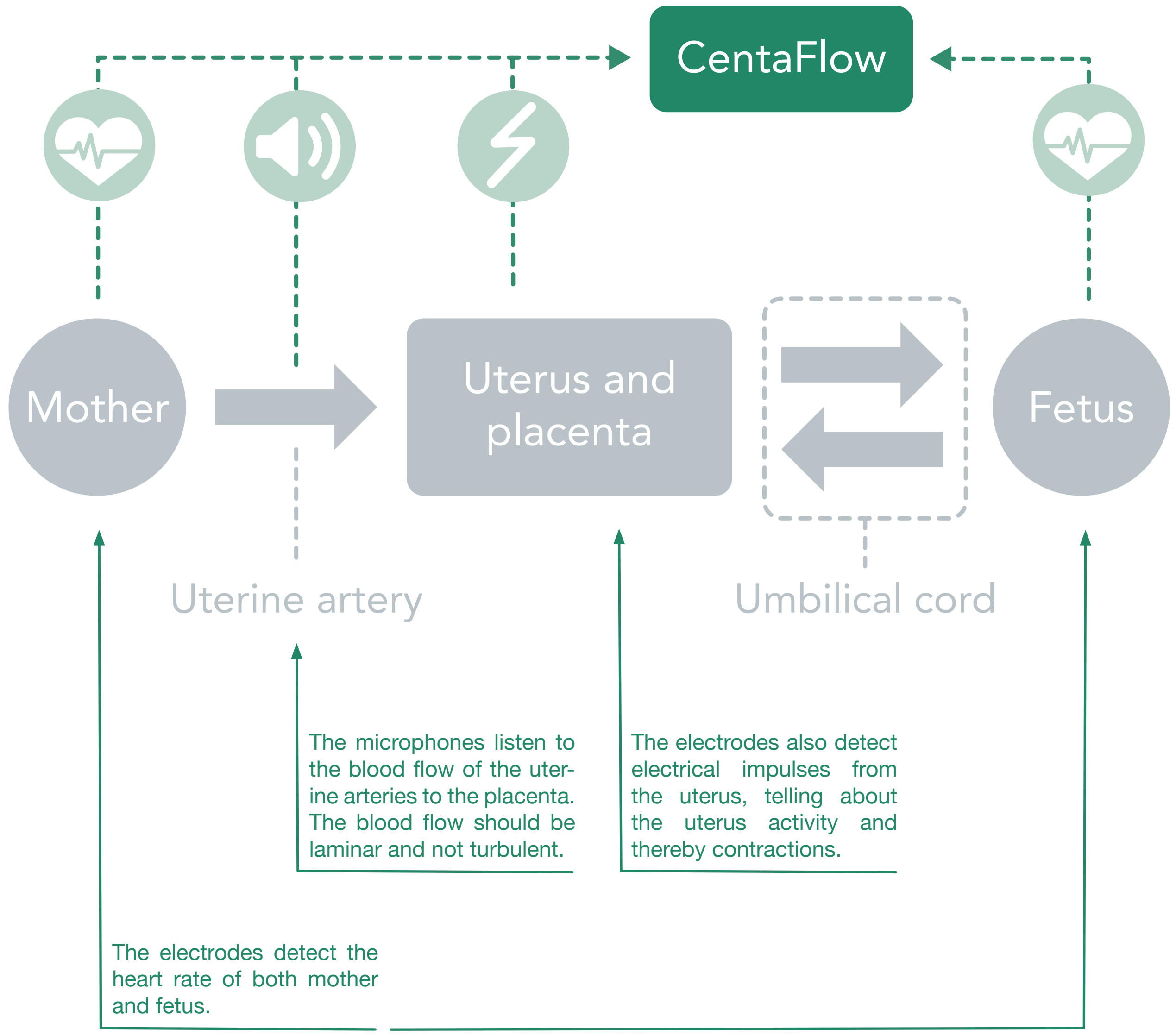
MonitMe overall consists of an upper part and a lower part that is connected with a flexible and elastic iStretch wire (Minnesota Wire, 2019), to ensure a good fit for multiple stomach sizes.

For both the upper and lower part, there are an appertaining single-use adhesive sheet that enables MonitMe to stick to the stomach. The upper part holds two electrodes, the battery, and LED diodes and a speaker for feedback. The lower part holds the four microphones, four electrodes and the stretchable wire.

As written on the previous page, the microphones measure blood flow, and the electrodes measure heart frequency, and also uterus activity. These technologies and the data they deliver can, together, deliver highly accurate measurements about the fetus' well-being. This enables the midwives to intervene at the right time if necessary, and be confident that it's the right decision to intervene.

MonitMe is waterproof and has IP-classification 65 for home monitoring and clinic monitoring, but IP-classification 68 for delivery, ensuring the possibility of showering and being in a bathtub during delivery.

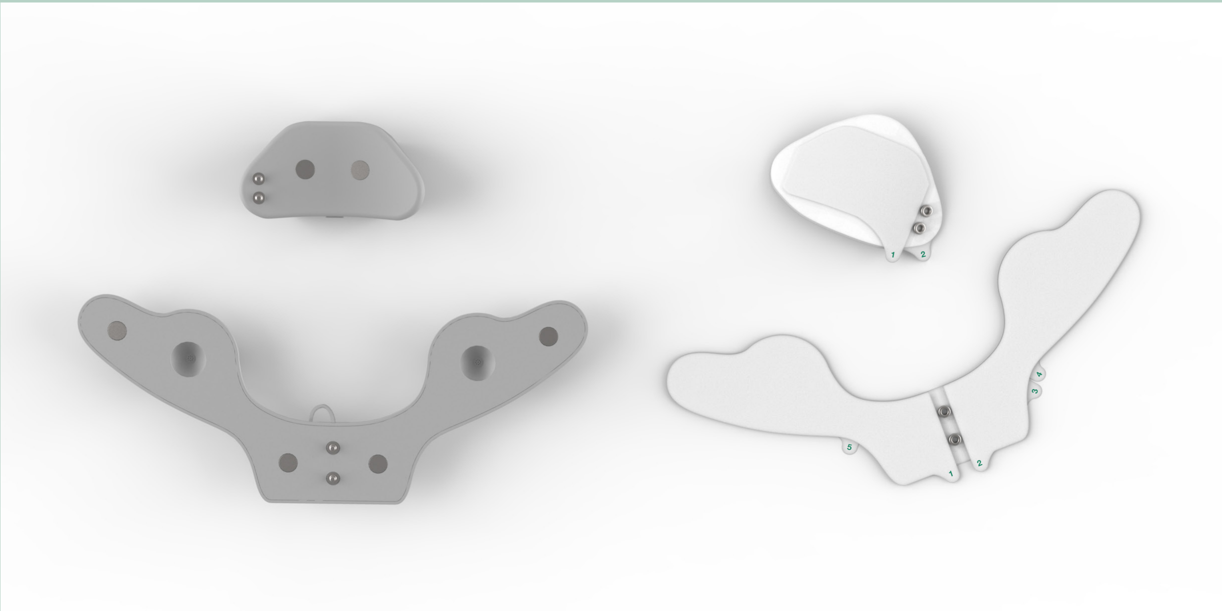
Below an illustration shows the data MonitMe collects:

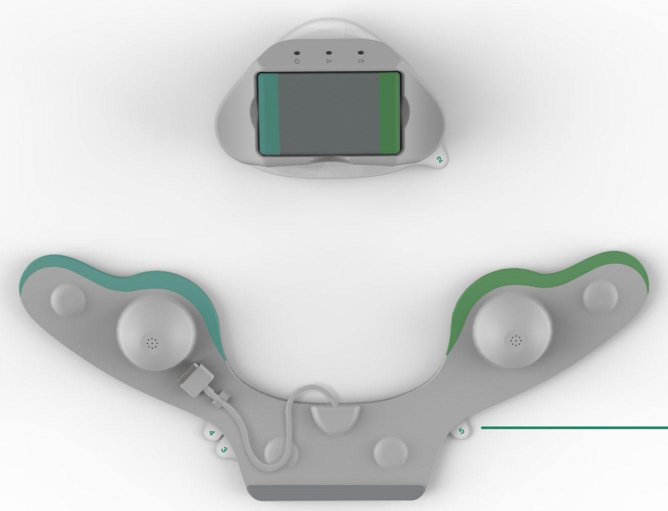


Preparing for use

For every monitoring session with MonitMe, there is used two single-use adhesive sheets - one for the upper part, and one for the lower part. The product and adhesive sheets are designed to rip and irritate the skin as little as possible, to ensure a good monitoring experience.

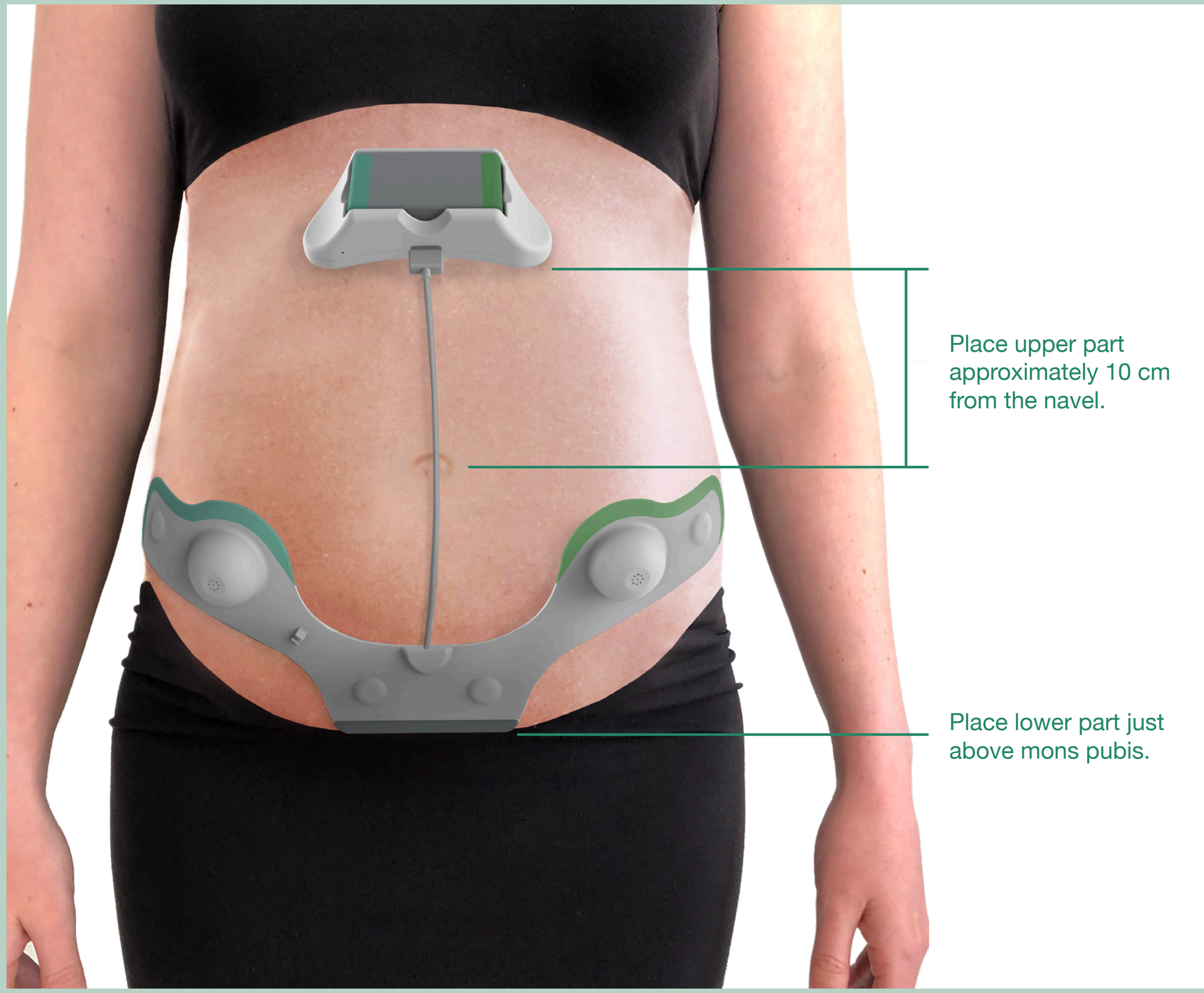
When a monitor session is initiated, the adhesive sheets are clicked onto there respective parts, using simple snap fasteners that makes it effortless to attach the sheets correctly. The adhesive is covered with foil on both sides, the side towards MonitMe is removed first, making the sheet stick to the product. Afterwards the foil towards the pregnant stomach is removed, enabling MonitMe to be attached to it.





The number on the small foil flaps indicate in witch order to remove them.

On the lower part, the middle foil is removed first, then the product is placed on the stomach, and the two other foils are removed to attach the "wings". In home monitoring, the woman might want to remove all three at once prior to placing the product



After use

After the monitoring session, the adhesive sheets can easily be removed from the product. This is due to small areas without adhesive, securing that it's easy to get hold of both sheet and product, before ripping them apart.

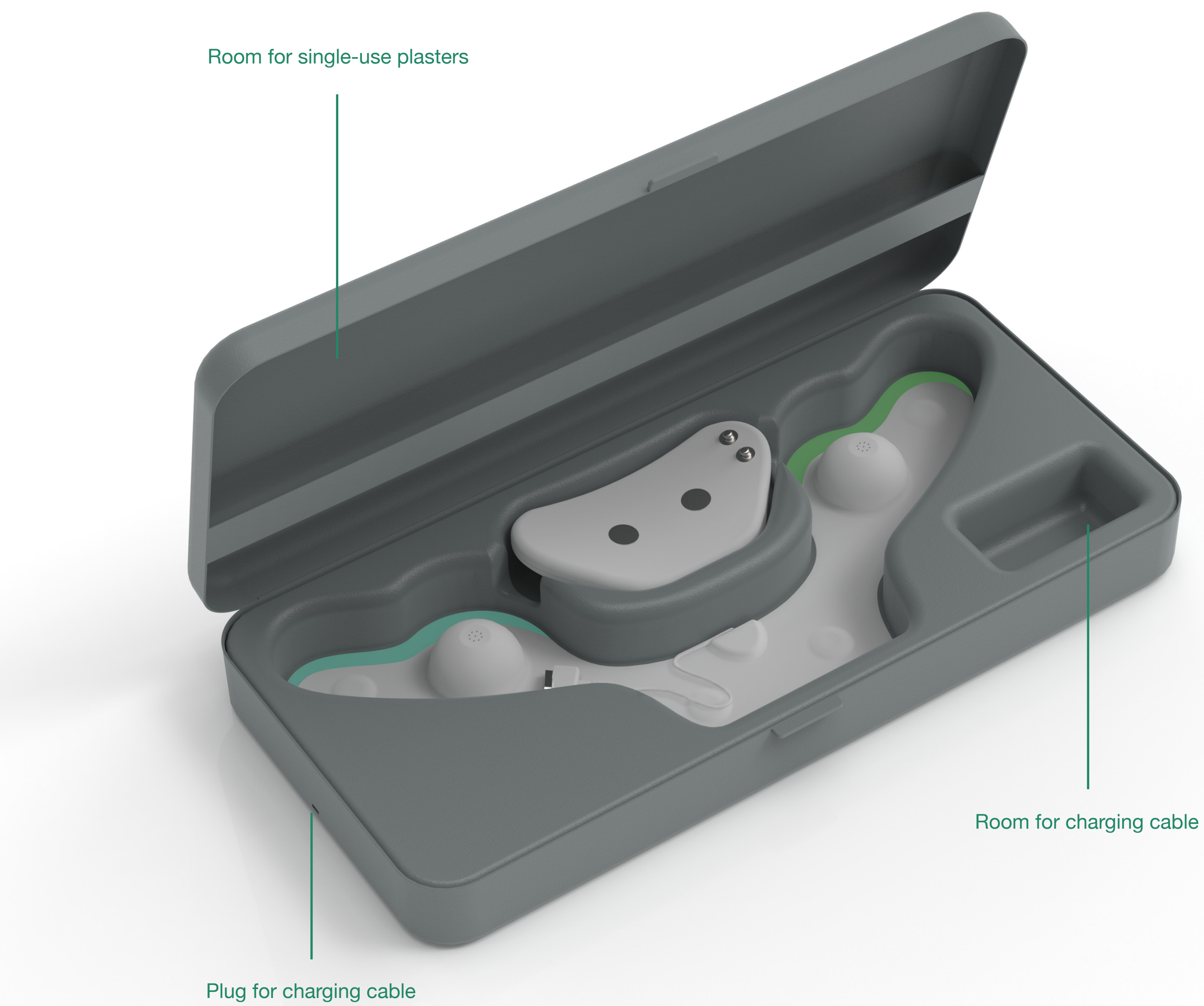
Home monitoring

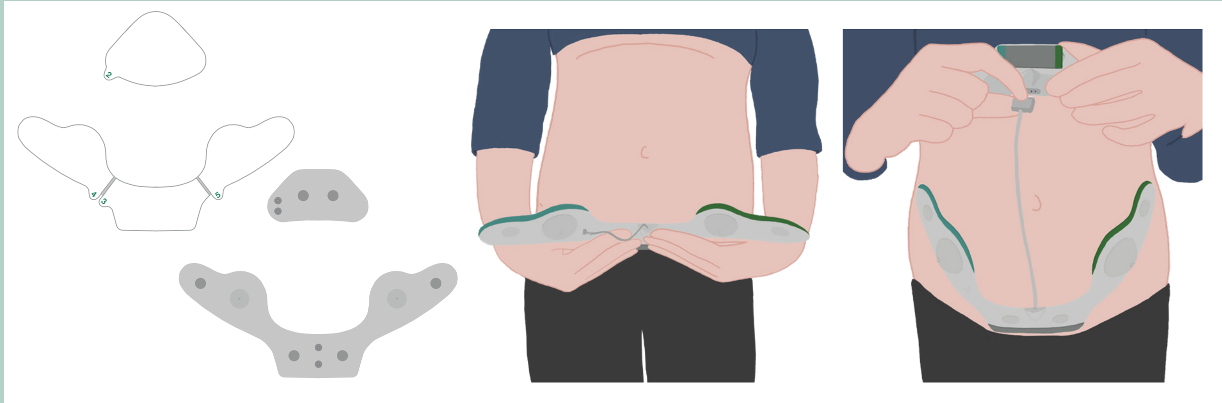
MonitMe is designed with a focus on easy and intuitive use, and can be used for home monitoring by the pregnant women themselves.

Home monitoring is offered to women who have a stable yet complicated pregnancy, where extra surveillance is necessary. It could be women who have pre-eclampsia, diabetes or where the fetus is estimated too small. Today up to 40 % of all pregnant women is being monitored extra which creates great purpose for MonitMe (Stange and Elmstrøm, 2015).

MonitMe enables the women to have a secure and comfortable measurement at home, in a calm environment, instead of using hours each week to go to the midwife clinic, or in the worst case being hospitalized. The women typically use the product 1-2 times a week, and follow the scenario shown.

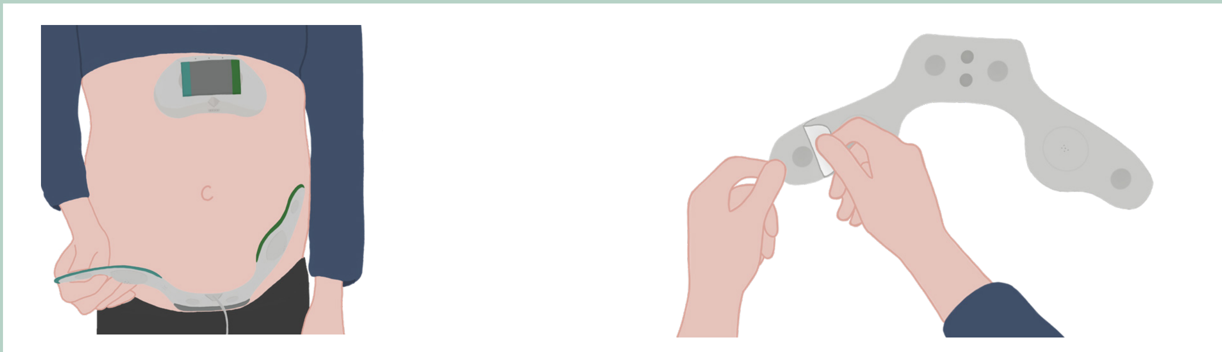
The appertaining casing works as a charging station, as well as a protective case, and can be brought along on e.g. a weekend trip. In the top of the casing there is room for extra single-use plasters.



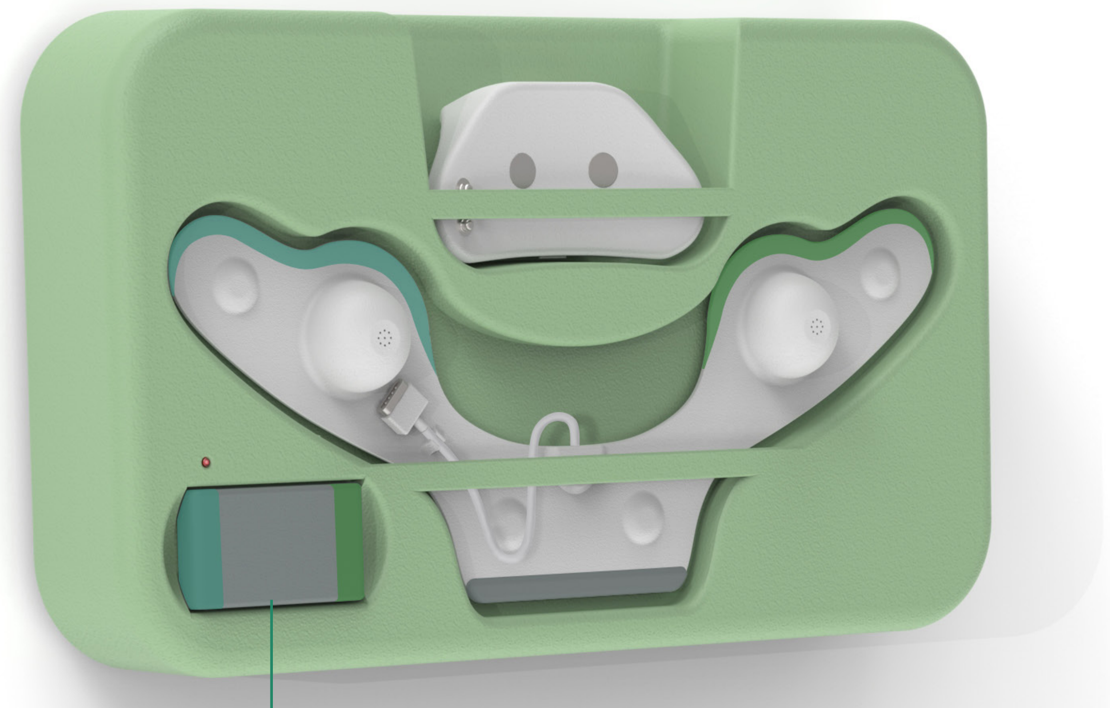


1. The product is removed from the casing, and the single-use plaster is attached. The foil is removed, and the product is placed. First the lower part on the top of mons pubis, and thereafter the upper part, 10 cm above the navel.

2. The pregnant finds a comfortable spot to sit, and starts the measurement. During the session she press the screen whenever she feels life. After 30 minutes the measurement stops, and the data is automatically sent to the midwife.



3. The product is removed from the body, and the single-use adhesive is removed from the product and thrown away. After use the product is put back in its casing. If the battery is low, the device will make a sound.



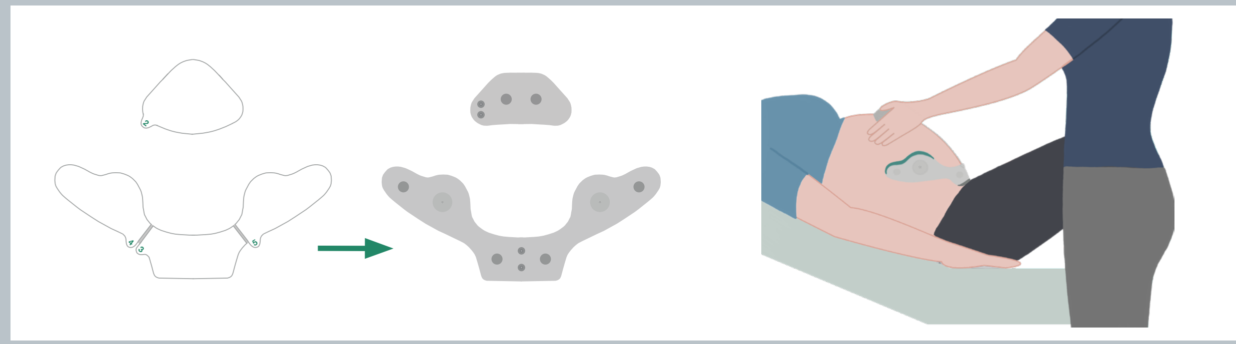
The exchangeable batteries have capacity for 6 h each

Monitoring in clinic

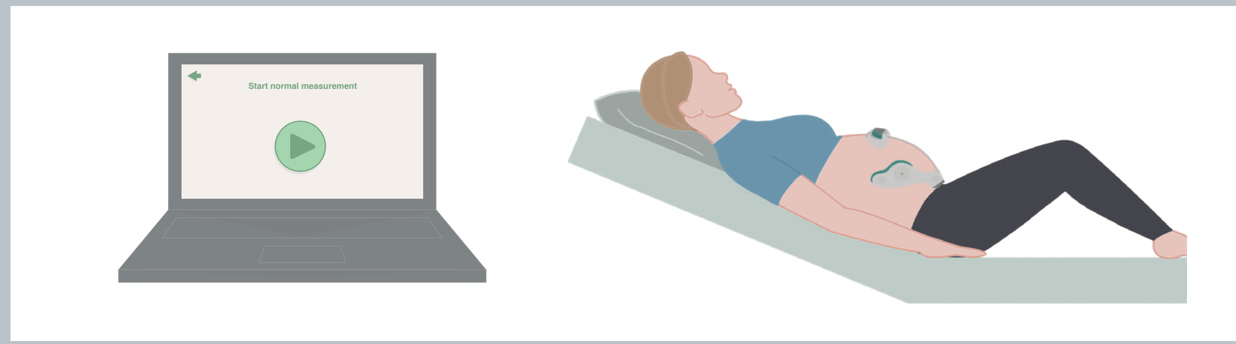
MonitMe is being used for monitoring of the fetus' wellbeing during pregnancy. It can be used from week 24 and throughout the pregnancy. By using MonitMe as soon as week 24, the midwives will be able to find the fetus' that aren't growing properly at an earlier stage, and keep an extra eye on them.

The design of MonitMe makes it easy for the midwives to place the product, and in correlation with the user interface on the screen, it ensures easy error detection and provides both feedback and feed forward to the midwife. This build up trust of MonitMe being a successful tool in the field.

Having the product devided in two, ensures a better fit on multiple stomachs, without compromising the feeling of using or wearing the product.

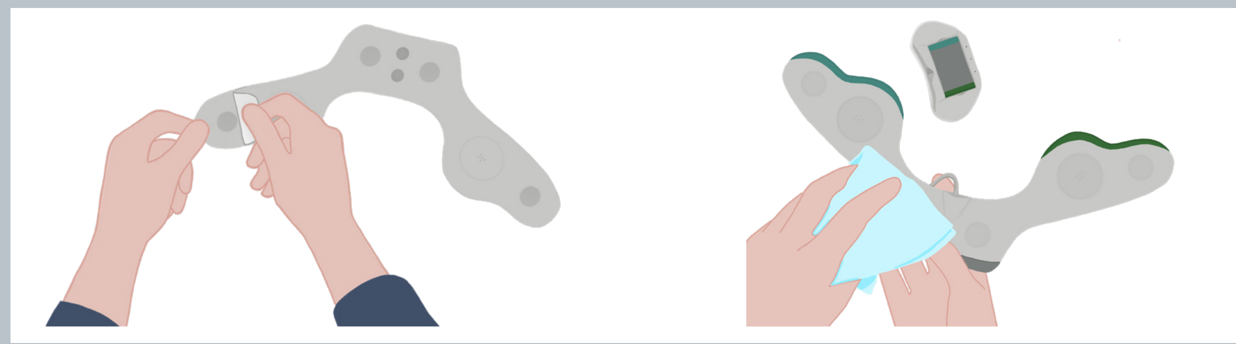


1. The midwife takes the product from the docking station, and attach the single-use plaster. Thereafter the foil is removed, and the product is placed on the pregnant stomach.

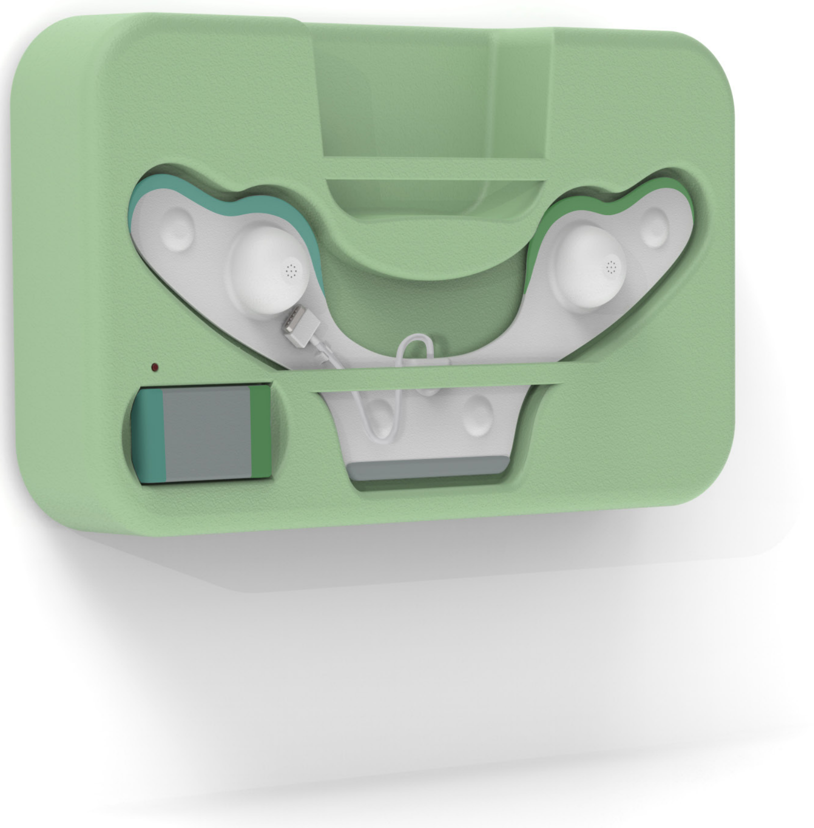


2. The midwife starts the measurement on a laptop. Thereafter the measurment starts, and runs up to six minutes. During this session the pregnant can lie or sit, depending on what she feels most comfortable with.

3. During the measurement, the midwife can see the status of the blood flow, heart rate and uterus activity on her screen, and afterwards make notes to the measurement. After a finished measurement, the product is removed.



4. The single-use plaster is removed, and the product is cleaned with soap and water, before being placed in the docking station.

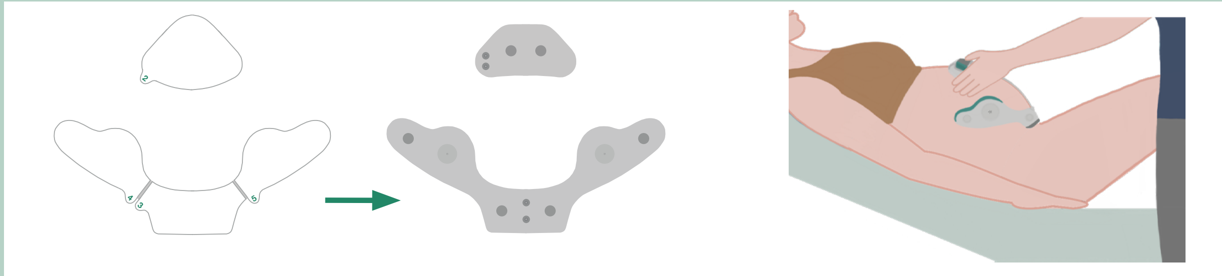


The exchangeable batteries have capacity for 12 h each

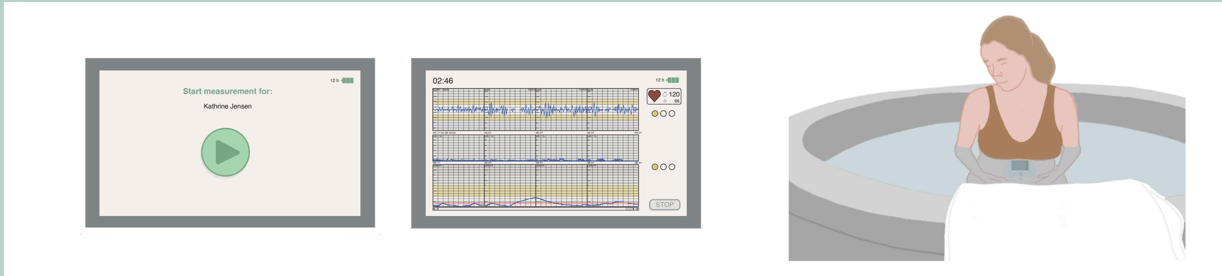
Monitoring during delivery

A CTG is normally used to monitor the well-being of both fetus and pregnant during delivery. Wearing the CTG limits the pregnant's freedom of movement - movements that otherwise could help the contractions to expand the uterus, as they release oxytocin and endorphins. The tight straps on the CTG is uncomfortable for the pregnant to wear, and they often move on the measuring heads resulting in poor data.

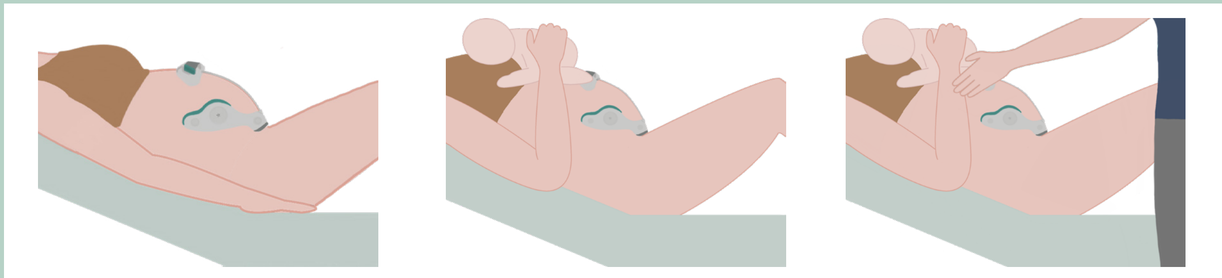
MonitMe is the optimal monitoring device for delivery, as it doesn't limit the freedom of movement. By using flexible and soft EVA for the lower part, and no tight straps going around the waist, we ensure that it's comfortable for the pregnant to wear. Furthermore, the wireless device can be used in a bathtub which for many can be pain relieving during delivery. A delivery scenario can be seen in the following section.



1. The product is removed from the docking station and the single-use plaster is attached. Thereafter the is foil removed, and the product is placed. The snap fasteners make it easy to place the plasters, also in acute sitations.



2. The measurement is initiated on the screen, and during the delivery the midwives have a clear overview of the blood flow, heart rate and uterine activity. MonitMe enables the pregnant to move around, and give birth in water.

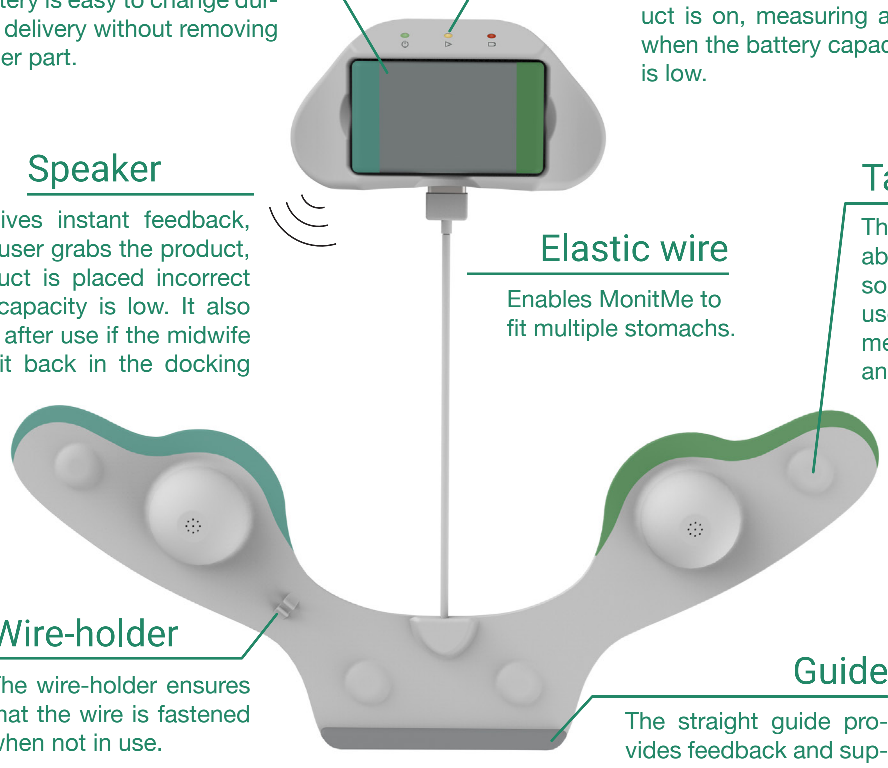


3. During the ejection phase, MonitMe ensures freedom of movement, without being tight on the stomach. When the child is born, the product can easily be removed.

4. After having removed the product, the single-use plasters are removed and thrown away, and the product is thoroughly cleaned with soap and water.

Product features

User friendly interface



Exchangeable battery

The battery is easy to change during e.g. delivery without removing the upper part.

Diodes

The three diodes provide feedback when the product is on, measuring and when the battery capacity is low.

Speaker

The speaker gives instant feedback, as soon as the user grabs the product, when the product is placed incorrect or the battery capacity is low. It also makes a sound after use if the midwife forgets to put it back in the docking station.

Elastic wire

Enables MonitMe to fit multiple stomachs.

Tactile spots

The tactile spots enable visual and sensory feedback to the user, about placement of electrodes and microphones.

Wire-holder

The wire-holder ensures that the wire is fastened when not in use.

Guide

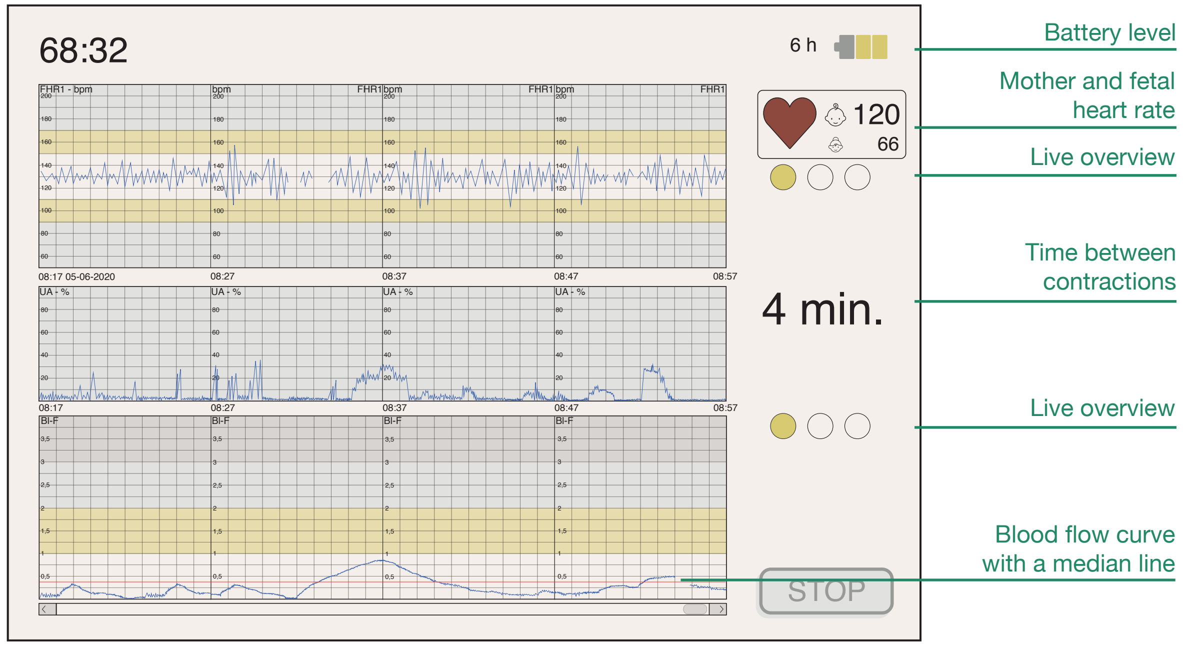
The straight guide provides feedback and support when placing the product, ensuring a user friendly interaction.

Interpreting data

Regardless of the scenario the midwife receives data showing the state of the blood flow, uterine activity and heart rate of the fetus.

The heart rate and uterine activity curves are displayed in a similar manner as the known Milou unit which is used to display the CTG measurements. The similarity enables an easier transition to MonitMe, as the midwives can see a resemblance to what they already know, and therefore the change to MonitMe becomes less radical.

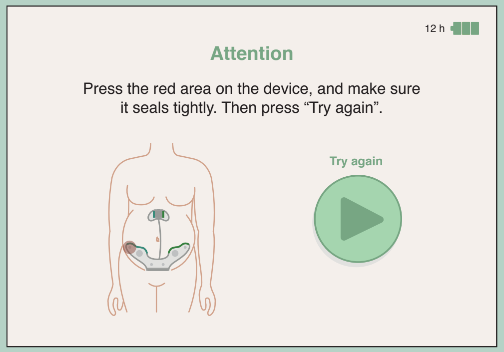
The curve for blood flow is shown over time, like the heart rate curve and uterine activity, and is divided in four different stages. The further up the y-axis, the more critical the flow is.



Ensuring correct placement and use

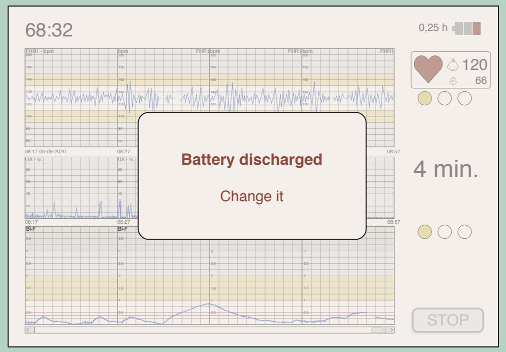
When the user, regardless of it being a midwife or a pregnant, has placed the product, the program checks the connection to all electrodes and microphones. If something is wrong with one of the connections, the product makes a sound, and a screen is shown where the user can see the area that causes the error and then secure it.

The two different green colours help identify the specific side to secure, enabling a user friendly interaction.



When the battery level during delivery is low, the product will make a sound for every 15 minutes, and a box will pop up on the screen, ensuring that the midwives remember to change the battery.

Having the battery as a separate unit makes it easy to change the battery with the one placed in the docking station without removing the whole upper part. Furthermore, it ensures that the battery can be changed with a new, when the performance becomes low.



Business

Market approach and business model

The market approach should be to implement MonitMe for use in clinics first, and thereby slowly gain trust from the midwives. After a few years with use in clinics, the product should be implemented for home monitoring. Using the same product for home monitoring builds up trust, as the pregnant can see that they get the same professional device, as they know from their consultations in the midwife clinics.

The last step for implementation is delivery, and as it's already known to the midwives in the clinics, this step will hopefully be less radical. Implementation for delivery will require new and thorough testing of the device.

The product is sold directly to the individual clinics or hospitals. This is possible because of the relative low initial product cost.

To ensure competitiveness on the market, the product software and interface should be continuously updated. Therefore, the company must secure liquidities to enable this. This is achieved by selling the product (sales price table 1) and then earning a monthly sum on a 30 DKK subscription fee per device. Additionally, the hospitals and clinics pay per used plaster.

Using this business model also creates value for the buyer as they don't have to invest in huge expensive equipment. It also ensures a good costumer relationship, as the company offers service of the products and software.

Having the subscription fee, covers the price for a new lower part that possibly should be renewed after two years. The business model also enable the company to have their products returned after use.

This business model requires the company to have a service department, and software developers.

Key partners

The key partners regarding the development and production of the product, is presented below.

CentaFlow
Primary company for sales and development

Herpa Tech
Single-use plaster manufacturer

Viewcare
Access to software platform for home monitoring

Resinex
Supplier of medical grade plastic

Viborg Hospital
Access to midwives for sparring and clinical tests

Carmo
Manufacturer of plastic components and assembly facilities

Budget

The budget is roughly estimated with the basis that the clinics is the first step of implementation, and thereafter home monitoring. For the first years with home monitoring, the moulds already in use for the clinics can be reused, and therefore the investment for home monitoring is smaller.

The market potential is estimated on the basis of 61.273 births in Denmark in 2018 (Sundhedsdatastyrelsen, 2019), and with the assumption of there being approx. 100 midwife clinics in Denmark, and 24 birthing places. As mentioned, the budget can only be used as a rough estimate. The return in the budget should also cover salary to employees, as it's only the salary for assembly and final development that it included in the budget.

Sales price calculation	Clinics		Home monitoring		Delivery		Plasters	
Production cost	9917,6		8622,3		10681,6		20	
Contribution, mark up	6049,74	61 %	4138,70	48 %	6836,224	64 %	10	40 %
Sales price	15967,34		12761,00		17517,824		30	
VAT	3991,83	25 %	3190,25	25 %	4379,456	25 %	7,5	25 %
Sales price incl. VAT (DKK)	20.000		16.000		22.000		37,5	

Table 1 Production and sales price

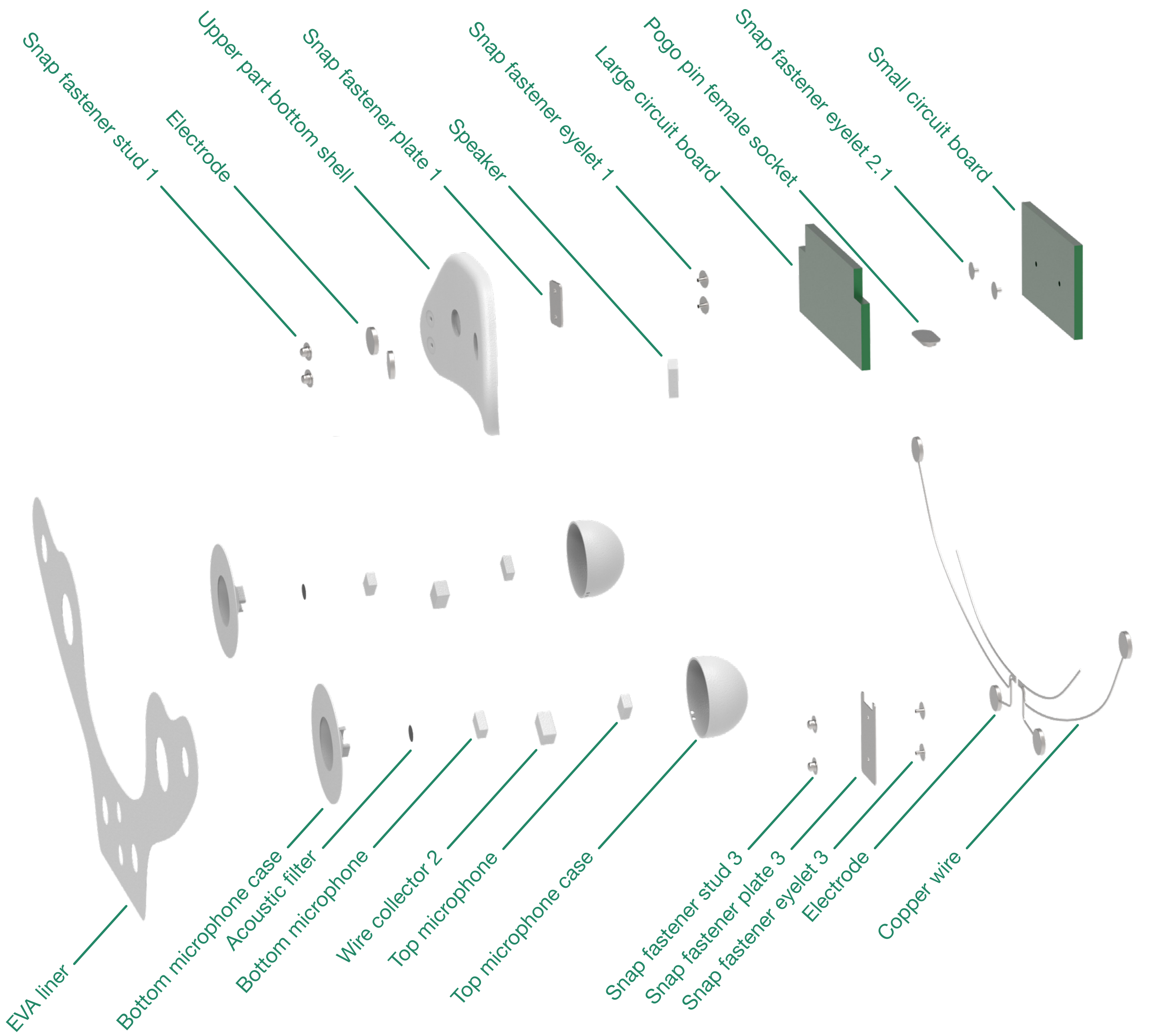
Investment	Clinics	Home monitoring	Delivery
Salary	855000	285000	285000
Prototype cost	250000	50000	50000
Approval and testing	100000	100000	100000
Consultants	100000		
Tools	639222	77000	642652
Total (DKK)	1944222	512000	1077652

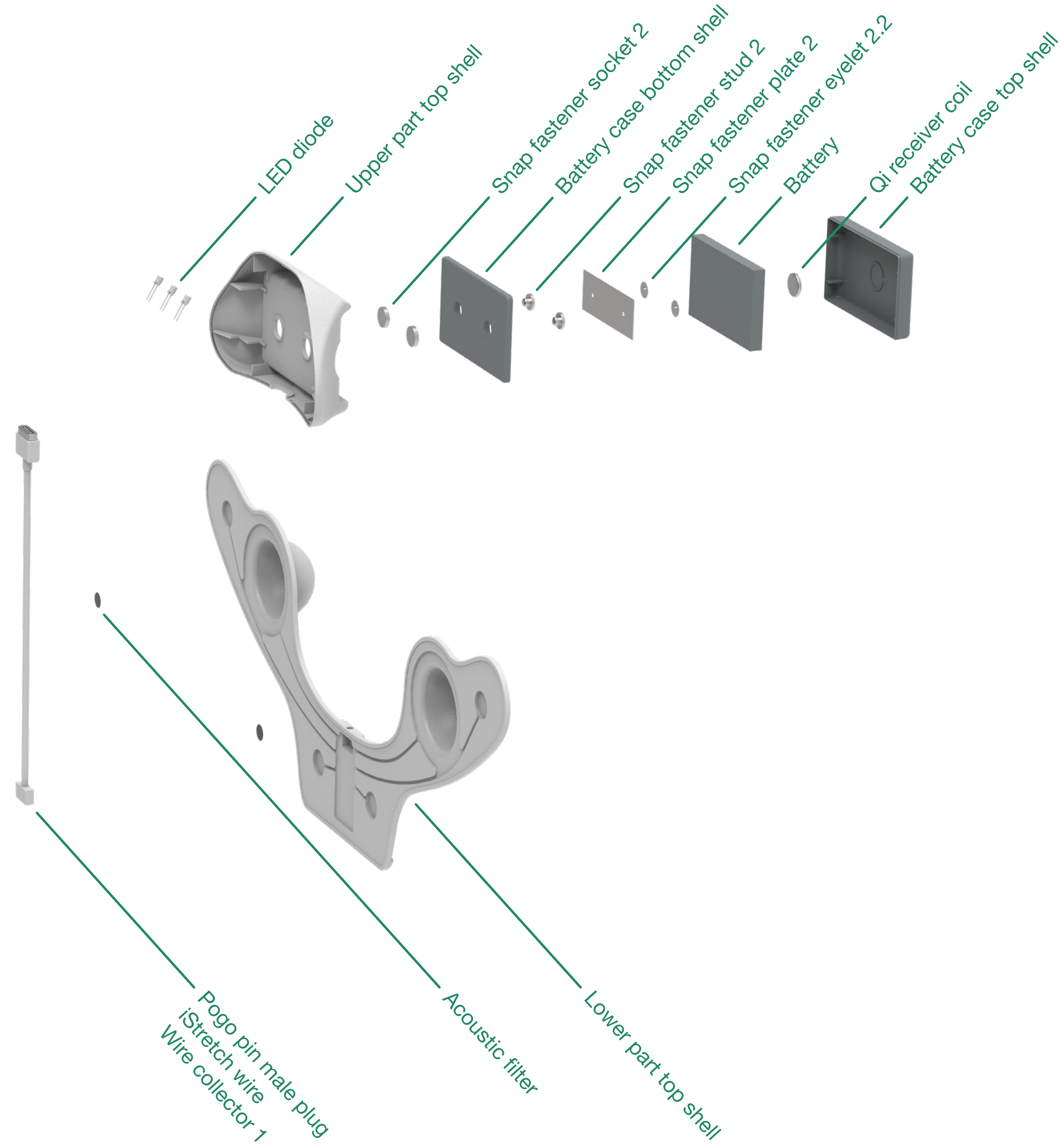
Table 2 Investment overview

	Clinics			Home monitoring			Delivery		
Budget	**Year 1**	**Year 2**	**Year 3**	**Year 1**	**Year 2**	**Year 3**	**Year 1**	**Year 2**	**Year 3**
Units sold	32	80	140	490,18	1225,46	2144,56	12	24	48
Sales price (factory)	15967,34	15967,34	15967,34	12761,00	12761,00	12761,00	17517,82	17517,82	17517,82
Production cost	9917,60	9917,60	9917,60	8622,30	8622,30	8622,30	10681,60	10681,60	10681,60
Turnover	510955	1277387	2235427	6255240	15638100	27366675	210214	420428	840856
Variable cost	317363	793408	1388464	4226514	10566284	18490997	128179	256358	512717
Contribution margin	193592	483979	846963	2028726	5071816	8875678	82035	164069	328139
Return									
Investment	-1944222	-1641074	-871683	-512000			-1077652	-975979	-772633
Contribution margin plasters and subscribtion	109556,8	285412	519631	249993,84	6801303	11902280	19638,25	39276,5	78553
Remaining	-1641074	-871683	494911	1766720	11873119	20777959	-975979	-772633	-365941

Table 3 Budget estimation

Exploded view





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All illustrations used are our own.

AALBORG UNIVERSITY
STUDENT REPORT

MonitMe

Process report MSc Industrial Design Group: MA4-ID5 Date: June 2020 Aalborg University

ill. 1 **Sofie Holdensgaard**

Sofie Holdensgaard

ill. 2 **Trine Hald Holmsgaard**

Trine Hald Holmsgaard

Abstract

Dette kandidatprojekt fokuserer på at lave et produkt til monitorering af gravide, både til hjemmemonitorering, monitorering på klinik og monitorering under fødsel. Der er mange grunde til, at en kvinde kan have brug for hjemmemonitorering og monitorering ved fødsel, men alle kvinder i Danmark tilbydes scanninger løbende i graviditeten.

Specialet er udviklet med virksomheden CentaFlow som samarbejdspartner, som har leveret udgangspunktet for produktets teknologi samt sparring. Specialets yderligere fokus har været at implementere disse teknologier i et produkt, som har brugeren i fokus. Rapporten viser et produkt forslag til et monitoreringsdevice, som kan rumme alle tre ovennævnte scenarier, samtidig med at give data af høj kvalitet foruden at være intuitiv i brug og behagelig at bære.

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For at opnå et brugervenligt og intuitivt produkt er der gennemført utallige tests og lavet mange forskellige prototyper. Desuden er der blevet rådført med både professionelle jordemødre og gravide kvinder undervejs.

Preface

In this thesis project CentaFlow has been a great help, both regarding initial project focus, but also sparring through the concept development. For that they deserve great thanks.

Furthermore, a great thanks should go to midwives Stine and Stina from Viborg Hospital, and the midwife from Aalborg University Hospital, for sparring and providing initial insights to the user scenarios.

Lastly, a great thanks to the supervisors Christian Tollestrup and Mikael Larsen. For guidance throughout the project period.

Reading guide

This thesis project consists of this process report, an appertaining appendix consisting of worksheets, a product report and lastly technical drawings.

Throughout the process report, the worksheets are frequently referred to for a more detailed insights to each meeting or development process. Each chapter is built with an objective and a sum up, which can be used to create a quick overview over the different chapters. Furthermore, two types of boxes are used to underline important findings or requirements. Green is used for underlining further investigations, and red for underlining requirements.

Further investigations | Requirements

Content

Introduction

Pregnancy and delivery is a delicate subject, especially regarding things that can go wrong. The worries of the parents to be, can be huge. This is one of the reasons why pregnant women are monitored during the pregnancy, and many during delivery as well. If they get a statement that everything is normal, it can ease their minds. If there is something wrong, there also lies a security in knowing, so there can be kept an eye on it, and acted upon it.

However, many monitoring methods doesn't give much information about the well-being of the fetus, and other methods give quite rough data (Brooks et al., 2020). The company CentaFlow is working on making a device that gives more precise and trustworthy data through the technology they utilize.

This master thesis will collaborate with CentaFlow, by using their technology and knowledge on the subject, to design an intuitive and comfortable product for monitoring of pregnant and birthing women.

Scope

Prior to starting the thesis, we became aware of a company, CentaFlow, needing industrial design expertise for a product, they are about to start implementing to the market. Therefore, this phase will create the initial insights to the company, the problem they are trying to solve, and the current solution CentaFlow has created.

Methods
Desk research on the project CentaFlow.
Meeting with Henrik Zimmermann.

Presentation of co-operation company

In this thesis we have chosen to work with the Danish company CentaFlow which is a subsidiary company to Viewcare. Viewcare works with virtualization of health- and social services, such as enabling doctors and medical staff to treat the patients in their home, over the phone or computer (Viewcare, 2020). The subsidiary company CentaFlow works with a product for monitoring pregnant women, and this is the product that will be the underlying basis for the thesis.

Initial meeting with project stakeholder

Objective
To understand the project and the possible solution spaces, an initial meeting was held with Henrik Zimmermann from CentaFlow who is one of the engineers behind the product, also called CentaFlow. Prior to the meeting a video that gives a short introduction to the product was watched, and an article regarding the project was read. This, to get some insights to the project before the meeting.

From talking to Henrik Zimmermann it's clear that they, CentaFlow (from hereafter mentioned as "CF" to differentiate between company and product), have made a product with great possibility to improve monitoring of pregnant women during pregnancy and delivery (worksheet 1). The equipment used today is old fashioned and developed multiple decades ago, and therefore there is a huge potential of making a better solution for monitoring pregnant women (Stange and Elmstrøm, 2015).

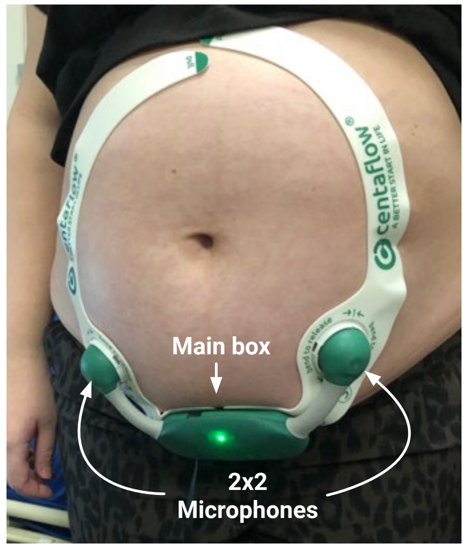
CentaFlow is a device that measures an electrocardiogram, ECG, of the fetus' heart, and listens to the blood flow to the placenta in the uterine arteries. It has four microphones to measure the blood flow and sensors to measure the ECG. The ECG is roughly a diagram of the heart rate obtained by measuring the heart's electrical activity (Esbjerg, 2010). The microphones are attached to the main box, and ECG sensors are placed on a single-use plaster that is attached to the main box when the product is used (ill. 3, ill. 4).

Today, when a pregnant woman is in need of monitoring during delivery, they use a CTG machine to monitor the heart frequence, ECG, of the fetus. However, it only allows the pregnant woman to move one to two metres from the machine, as it isn't wireless. CentaFlow is wireless, and by using CentaFlow during delivery it gives the pregnant the possibility of moving around during contractions which eases the pain (worksheet 1).

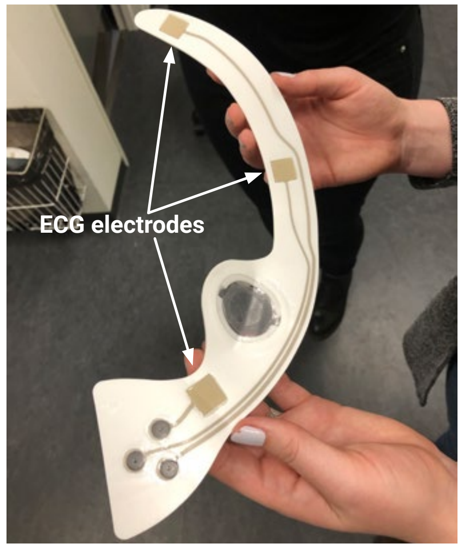
Furthermore, CentaFlow measures the blood flow to the fetus which the CTG can't do.

According to Diana Riknagel, the initial idea owner, it's evolutionary to be able to get information about the oxygen level and blood flow the fetus is receiving, in a non invasive way (Stange and Elmstrøm, 2015). Receiving this data makes it possible to determine if and when the baby should be delivered (TV Midtvest, 2015). Being able to determine when to deliver the baby, might also reduce the number of immediate c-sections which, besides physical impact, also are more expensive than a planned c-section (Stange and Elmstrøm, 2015). Additionally, the technology makes it possible to find the fetuses who aren't developing as intended because they are able to measure the blood flow. The hope is to be able to find almost all cases where the fetus isn't growing properly. Today only half of these cases are found (Stange and Elmstrøm, 2015).

The government has made a legal requirement, stating that women who are pregnant with a child that is too small, should be offered the possibility of monitoring at home (worksheet 1). This testify to a possibility of making a solution that also can be used by the pregnant herself, and not only the midwives. Furthermore, Henrik mentioned that it would be beneficial to have a docking station to the product, where it can be charged (worksheet 1).



ill. 3 Device on stomach



ill. 4 Plaster with electrodes

Sum up

Through the initial research and conversation with Henrik Zimmermann, an initial understanding of CF's current product, and why it is beneficial, has been created. The current products for monitoring pregnants are outdated, and there is huge potential in commercialising their solution, CentaFlow. CentaFlow creates more data about the well-being of the fetus than the existing CTG machines, as it can measure the blood flow to the placenta, and thereby detect the well-being of a fetus. This can be utilized to find the fetuses that aren't developing intentionally, and to determine when to deliver them.

Further investigation

To understand and figure out what we can add to the project, and how we can use CF's technology, we need to understand the product and the technical details better, as well as get an understanding of the user scenarios, to find possible gaps where there are an opportunity of e.g. improvement. Furthermore, we need to understand the company CF, the market and what the limitations are within e.g. the budget.

From the conversation with Henrik Zimmermann we saw a possibility of creating a product that can be used for home monitoring, as well as in midwife clinics. But should it be different products or the same?

Thesis statement

For the further research and concept development, we will be working with the following thesis statement:

How can CF's current product be improved regarding the user experience and intuitive use and placement of the product on the woman, while expanding to both home monitoring and monitoring during delivery? This, to ensure comfortable monitoring that both the midwives and pregnant women can trust.

Therefore, the focus in the framing phase will be to understand the problem which CF seeks to solve and the current user scenarios, and thereby find which criterias the product must fulfil. Furthermore, to understand the technological limitations and possibilities, as well as the competitive products and the company CF.

Framing

To understand and explore what can be added of value compared to the current product, and find the areas where there are room for improvement, as well as understand the limitations of e.g. the technology, the framing phase has been conducted. This, to be able to find and define the problem area that should be worked within.

Methods

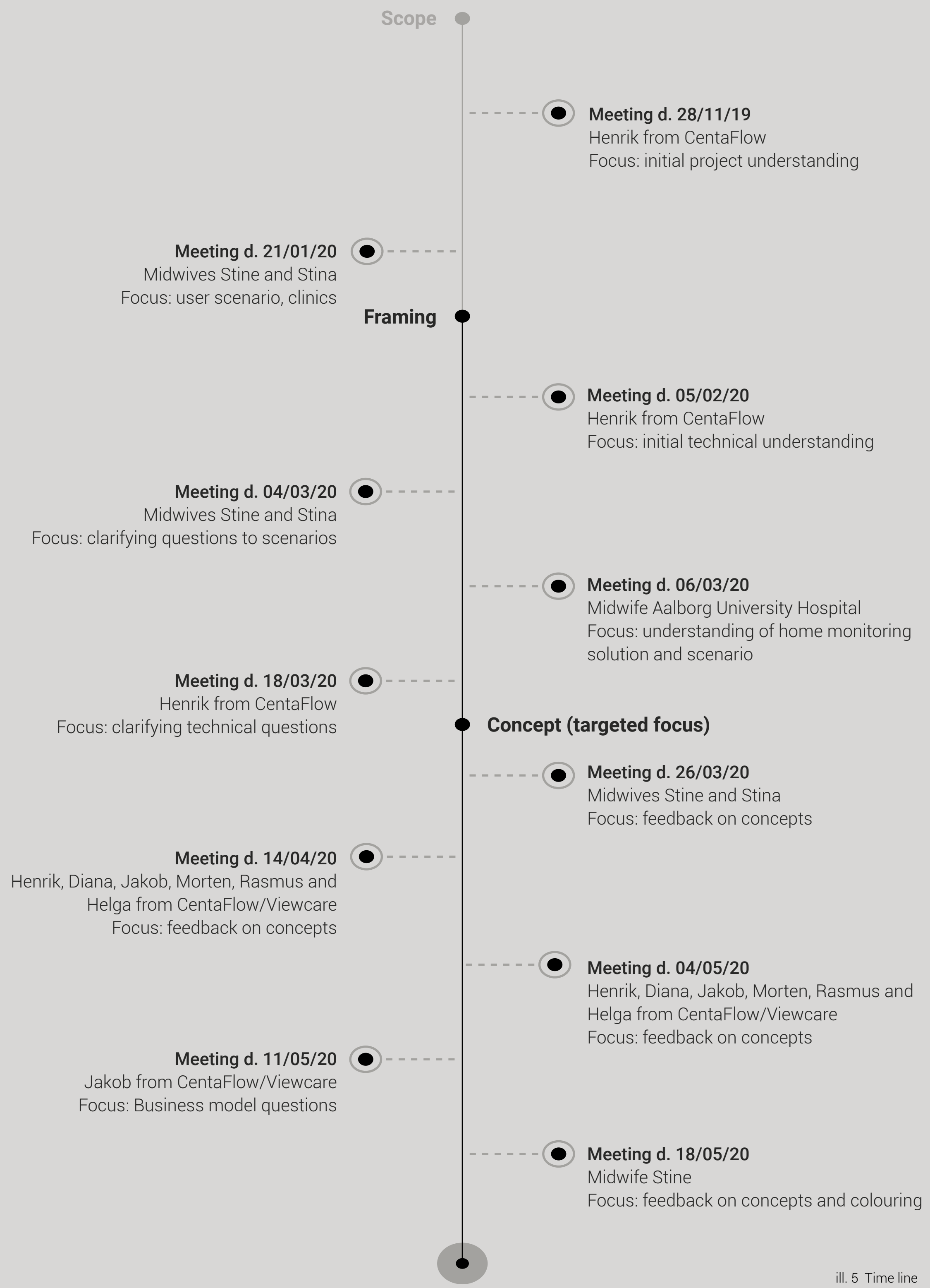
Desk research

Interviews

User observations

Timeline of meetings

The following time line creates an overview of the meetings and investigations in the framing phase, and additionally the scope and concept phase. Some of the meetings were held with digital communication.



ill. 5 Time line

Understanding the problem

Objective
The first step of the framing phase is getting an understanding of the problem, and why and where a product like CentaFlow can add value. To get a deeper understanding of this, a field trip to Viborg Hospital, where a clinical test of CentaFlow is currently running, was conducted. The data found by this visit, supplemented with more interviews and desk research, will be used to provide an overview of the objective. All data can be seen in worksheet 2, 6 and 7.

The clinical test

Centaflow is currently being tested for monitoring of pregnant women, in the midwife clinic that is a part of Viborg Hospital. They are monitoring two different groups. The case group which is pregnant women, where the fetus is at least 15% smaller than normal, and the control group which consists of a random selection of pregnant women. With these tests they are hoping that midwives, using CentaFlow, will be able to find a larger percentage of cases where fetusesn't growing as desired, than what the current technology can find, but also to dismiss woman whose fetus isn't in the extra monitoring zone (worksheet 2). Furthermore, CentaFlow can be used for monitoring other women, in need of extra monitoring during their pregnancy. The monitoring tests will be extended to Roskilde Hospital and Rigshospitalet, where 2000 pregnant women will be monitored in total, to hopefully be able to underline the results (worksheet 2).

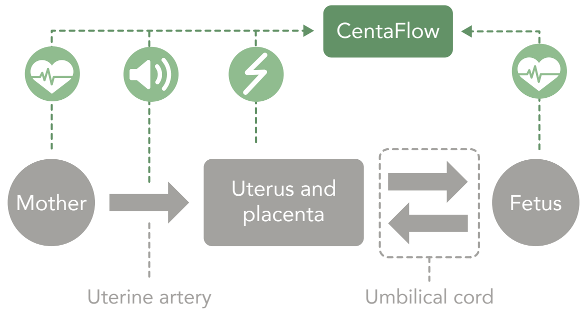
At the initial meeting with midwives Stine and Stina, worksheet 2, they had a pregnant woman, Line, with due date on the current day, come in for monitoring (ill. 6). She was a part of their case group because her fetus was estimated too small in the beginning of her pregnancy. Using CentaFlow to monitor Line, they found, after having analysed the data, that everything looked fine, and after a while her fetus gained weight. Line could therefore be reassured that everything was fine, and ideally they could have stopped having her in for extra monitoring. In this case they kept her in the program because she was a part of the case group, this wouldn't be necessary after the clinical tests of CentaFlow (worksheet 2).

The midwives perspective

Today midwives and medical personnel are providing extra monitoring to up to 40 % of all pregnant women (Stange and Elmstrøm, 2015). Studies show that the pregnant women, to a larger extent, start having concerns and anxiety when knowing

ill. 6 Line with CentaFlow on the stomach

that they are up for extra monitoring (Niklasson, 2014). Especially this aspect, is one of the things the midwives, Stine and Stina, mention as one of the unique things about CentaFlow. They mentioned that being able to clear more pregnant women, will be revolutionary. As it is right now, e.g. when a fetus is estimated too small, the pregnant woman gets extra monitored. However, the estimate is very rough, and thereby too many receive extra monitoring. CentaFlow is, as briefly mentioned under "Scope", able to measure:



ill. 7 CentaFlow's measurements

1. the blood flow in the uterine arteries which provides blood and nutricion to the placenta, and thereby the fetus
2. the fetus' hearth frequency by making an ECG and
3. the uterine activity

(ill. 7)

By having these aspects, they are able to check if the fetus is getting the needed nutrients and oxygen, and if this is the case, they can calm the pregnant woman, by telling everything seems okay, even though the baby is a bit small (the baby can be small, but still healthy and evolved) (worksheet 2). Stine and Stina also mentioned that the statistic of deciding if a fetus is too small, doesn't take reservations to the mothers physiology which is an aspect that affects the size of the fetus (worksheet 2). Thereby, CentaFlow delivers the possibility to individualise pregnant women. Additionally, Diana Riknagel mentions, in an interview with TV Midtvest, that it provides the possibility of seeing which fetuses are at risk of oxygen deficiency, and thereby decide if they need to release the fetus earlier than planned (TV Midtvest, 2015).

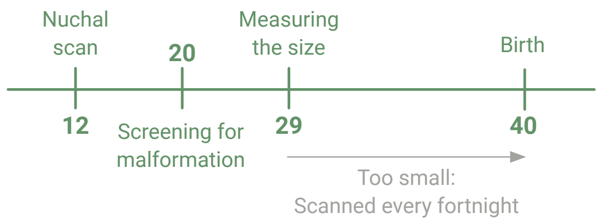
Stine and Stina's currently focuses on getting CentaFlow approved and implemented in the midwife clinics, for monitoring pregnant women during pregnancy, by doing the clinical test. Using CentaFlow during delivery will be the next scenario for approval. They mentioned that the midwives have to trust and know the product, before being willing to use CentaFlow in a delivery situation. Additionally, the midwife from Aalborg University Hospital mentioned that it has to be intuitive and easy to use, also regarding the technology and system setup. Otherwise, in their busy workday, it won't stand a chance, as they will go back to the products they know, to save time and frustrations during the workday (worksheet 7). However, Stine and Stina believe that CentaFlow will be able to significantly improve a delivery situation where monitoring is necessary (worksheet 2). It adds mobility to the pregnant because it's wireless, and by measuring the blood flow to the placenta, it's able to measure how much stress the placenta and fetus is under. The current solution, the CTG-machine, has a wire which only allows a freedom of movement of one to two metres. Furthermore, they mentioned that a pregnant woman, who is in need of monitoring, would be able to choose how to give birth, and not be limited to lie in a bed, as what is the case with the CTG (worksheet 2). A mother from our education referred to the time she had to lay still in bed, during a contraction, as downright torture, making aforementioned very valuable.

When talking about the psychological aspect of being pregnant and giving birth, Stine and Stina have no doubt that it plays a big role if the pregnant is comfortable. In addition, Stine mentioned that it might make sense to make the plasters of the current solution smaller, to try and make the woman in delivery, less aware of the extra monitoring, and also make the husband less aware (worksheet 2). It's a presumption which would have to be investigated further when designing concepts.

When is CentaFlow relevant?

Today it's only from around week 29 of the pregnancy, the midwives can tell if the baby is growing within the norms because the fetuses grow rather similar until week 20. So the clinical test is starting in week 30 right now, however CF wishes to start as early as week 24 because they believe they can see results at this stage, with their technology (worksheet 2 and 3).

During pregnancy the women normally get two scans: the first in week 11-13 which is a nuchal scan, and the next in week 20 which is a screening for malformation. Additionally, there is a lot of doctors appointments and midwife consultations during the pregnancy, e.g. a midwife consultations around week 29. This is when they measure the size of the fetus (Hospitalsenhed Midt, no date). They do that by either looking at the stomach size, or making a symphysis fundus measurement, where they measure on the stomach, from the pubic bone to the top edge of the uterus. If the fetus is too small, the woman gets send to an extra ultrasound screening (Christiansen, 2018). If the screening shows that the fetus is indeed too small, the woman is going be scanned every fortnight, to keep an eye on the growth of the fetus. Furthermore, a CTG scanning or home monitoring can be considered (ill. 8) (Bornholms Hospital, no date).



ill. 8 Overall midwife examinations after week 11

Therefore, a product like CentaFlow could be relevant from at least week 29, and maybe even from week 24, as it can be used to detect if the fetus gets the needed nutrition and blood. Also, it would come in handy for the fortnight scans of the underweight fetuses, where the extra CTG scan would be unnecessary, as Centaflow measures heart rate as well, and would be able to do it within the same time frame. By additionally measuring the function of the blood flow to the placenta, they are able to determine and keep an eye on the well-being of the fetus. If the fetus is stressed and the placenta is at a stage where it can't provide the needed nutrition, they will be able to decide when it's crucial that the fetus is delivered (worksheet 3). Currently, there is no solution for a malfunctioning placenta, other than keeping an extra eye on the fetus, and maybe providing it with medicine that helps the lungs develop if the fetus needs to be delivered prematurely (worksheet 3). CentaFlow is indirectly able to measure how dysfunctional the placenta is, by listening to the blood flow in the uterine arteries, and the fetus' heart rate, in an non-invasive manner.

As mentioned under "Scope" the government has tabled a legal requirement, stating that pregnant women with complications during their pregnancy, should be offered telemedicine monitoring at home, by the end of 2020. This can both be offered to women with a fetus that isn't growing properly, e.g. because of a malfunctioning placenta, and women who have other diagnoses as e.g. pre-eclampsia (Digital Service, 2017).

Additionally, Centaflow can be useful during delivery. When midwives and doctors are concerned about a fetus during delivery, the mother will have to wear a CTG scanner, and as mentioned, this requires the mother to lay relatively still. The technology of CentaFlow can handle the monitoring, needed for a risky delivery, hence the relevance of CentaFlow in this scenario, and additionally without limiting the pregnant woman's freedom of movement, in the same way as the CTG does.

Sum up

Being able to acquit some of the 40 % of pregnant woman that is being monitored extra, using CentaFlow will be revolutionary and is, according to midwives Stina and Stine, essential. CentaFlow is able to tell how the blood flow to the placenta is, and by additionally measuring the heart frequency, it can provide midwives and medical personnel, with more and vital information about a fetus' well-being, and maybe help find a larger percentage of the fetuses that don't grow properly. CentaFlow has potential to be used for monitoring during pregnancy in clinics and private homes, and during delivery, ideally replacing the CTG.

Further investigation

We need to understand the current user scenarios and products, to understand which criterias the product solution must fulfil, and which the current technology of CentaFlow already fulfils.
We also need to understand the technology of CentaFlow fully, to investigate if something needs to be added, and also understand the limitations we have to work within when designing the product.

Monitoring during pregnancy in midwife clinics

Objective

The objective of the following chapter, is to understand the scenario of monitoring during pregnancy in midwife clinics. This will be done on the basis of the clinical tests with CentaFlow, currently running in Viborg. The data in this section is primarily received through interviews with midwives Stine and Stina, supplemented with desk research.

Centaflow is, as mentioned, measuring the blood flow in the uterine arteries and the heart frequency of the fetus. This means the fetus has to be developed to a certain stage, to get a flow that can be measured and give an outcome. So, as mentioned, the screenings with CentaFlow would start from week 24 at the earliest. Then a screening would be done every fortnight, if the fetus is too small (ill. 8).

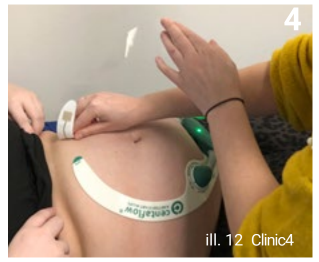
The women usually lay down on a couch at the midwife clinic, however, many feel discomfort lying on their back when pregnant, especially in the third trimester (Graviditet.dk, no date; worksheet 2). With the technology of CentaFlow, it would also be possible for the pregnant to sit up. Nevertheless, the screening is done in quiet and relaxed surroundings, with no further tension.

As mentioned earlier, we met a pregnant, Line, during the visit at Viborg Hospital (worksheet 2). We got to see the current user scenario, where the midwife places CentaFlow on the stomach of the pregnant woman (worksheet 2). Following section will describe the scenario:

ill. 9 Clinic 1

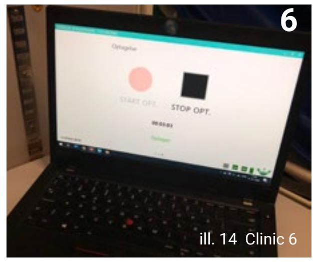
ill. 10 Clinic2

ill. 11 Clinic3



ill. 12 Clinic4

ill. 13 Clinic 5

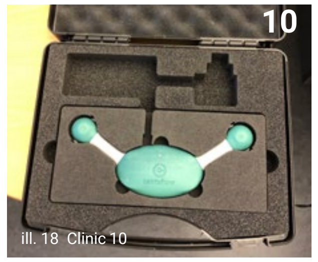


ill. 14 Clinic 6

ill. 15 Clinic 7

ill. 16 Clinic 8

ill. 17 Clinic 9



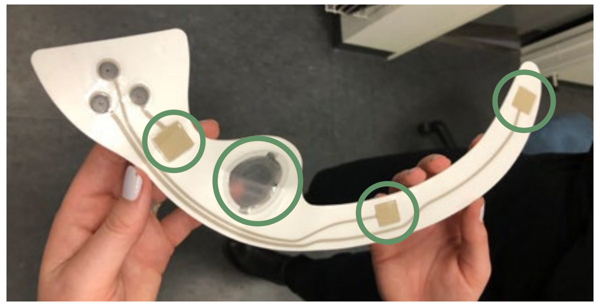
ill. 18 Clinic 10

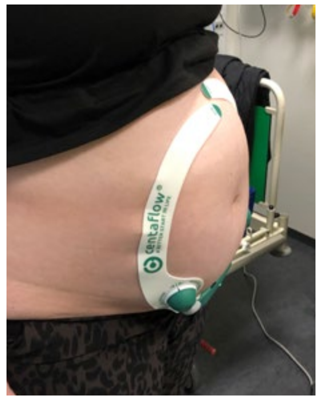
1. The pregnant arrives and lies on the examination bench.
2. The main box is placed on the plasters. Here the foil on the plasters, where the microphones are placed, is removed and the main box is attached using conductive press studs.
3. The foil called section "1" is then removed on the plaster and placed on the belly by the top of mons pubis.
4. The foil called section "2" is then removed, and the left plaster is attached to the stomach. Then the foil of section "3" is removed, and the right side is attached like the left side.
5. The midwife makes sure the plasters seal tightly to the stomach.
6. When the product is placed the measuring program is initiated on a laptop (in the midwife clinic there is a computer in each room).
   It measures for six minutes. During the measurement everyone in the room is silent, to enable the best possible output from the microphones.
   The results are sent to a database, where personnel look them through.
7. The midwife removes main box and plasters from the stomach.
8. The main box is removed from the plasters and the plasters with ECG sensors are thrown away.
9. The midwife perform an ultrasound examination.
10. At the end, the main box with microphones are put in a box to charge. When placed in the box the device shuts off.

Observations

- When Line had been lying on the back for a while, she felt uncomfortable. The midwives told us that when being in the last trimesters, it's often uncomfortable to lie on the back because it increases the pressure on the internal organs, as the fetus is lying on top.
- When attaching the plasters to the stomach, the midwives were in doubt about how close it needed to fit the stomach (worksheet 2) (ill. 19). However, according to Henrik, it is only important to seal tight around the electrodes and microphones, not the wires (worksheet 3) (ill. 20).
- CentaFlow turns on and off, when out or in its box. It has no on/off button.
- Right now the midwife doesn't receive any information directly, but first after other personnel has looked the data through.
- They are currently throwing plasters, including seven electrodes, away after one use.
- We asked if Line would mind standing up, while wearing CentaFlow. Following section will be describing this scenario.
  - She started by getting up, and the plasters began to bend (ill. 21).
  - When standing she didn't feel the device that much, but could feel the plasters dragging a bit on the skin.
  - Standing and moving around created folds and larger gaps on the plasters. The midwives didn't know to what extent this was critical (ill. 22).
  - When bending forward, over a bed (women in delivery often does this, according to Stine and Stina), Line felt that there wasn't much room for the main box, and that it was in the way (ill. 23).

ill. 19 Plaster gaping


ill. 20 Places to seal tight


ill. 21 Bended plaster

ill. 22 More bended after movement

ill. 23 Bending forward

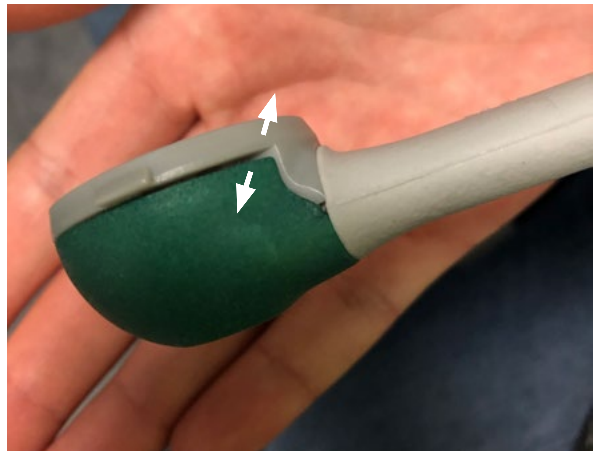
Right now they only have one device in the midwife clinic in Viborg. Therefore, it's being transported in a box (ill. 18). Ideally, when using CentaFlow for monitoring during pregnancy in the clinics, there would be a device in each room (worksheet 6). The midwives told us that they would prefer if the product could be placed on the wall, or in a manner where it was hard to take it out of the room, ensuring that there is one in each room (worksheet 6). In the midwife clinics today, it's the midwives themselves that clean the examination couch and equipment between sessions, using ethanol alcohol (worksheet 13).

During the measurement we were silent, to ensure as good a result as possible, even though having a microphone measuring out in the room, should make it possible to filter out the noise from the surroundings. It wasn't a problem in this scenario, but can be in delivery and for home monitoring. Furthermore, the measurement lasted for six minutes. Ideally, when implementing CentaFlow, it should only measure for 30 seconds to three minutes when measuring in the clinics (worksheet 2 and 3).

As mentioned, the midwives doesn't receive any feedback when using CentaFlow now. When implemented to the hospitals, the midwives should receive some kind of information, telling them how to act. According to Stine and Stina (worksheet 6) and the midwife from Aalborg University Hospital (worksheet 7) it has to be pedagogical and easy to interpret, and they wish to receive the feedback on a screen. The ECG curve would make sense to display as the one that is created by the current ECG and CTG machines, as the midwives are taught how to interpret the current curve, and it's familiar to them (worksheet 6 and 7). This could perhaps also ease the way into the market. Furthermore, they would like to be able to see and hear the pulse of the fetus. The measurement of the blood flow is measured with sound, however they would prefer not to hear the sound, but instead get indications of the flow through a scale with e.g. colours or numbers. When implementing this they would need to get new guidelines, on how to react within the scale. They mentioned that the scale should be of maximum five graduations, and underlined that it shouldn't be alarming to the parents: "there is a high signalling effect on how it affects the parents" - Stine (worksheet 6 p. 29).

When using the CentaFlow for monitoring it happens that the midwives drop the product - they have already broken one of the prototypes in the area around the microphones (ill. 24). Therefore, the product we design has to withstand being dropped, and in general rough use (worksheet 2 and 6).

When using CentaFlow for monitoring in the clinics during pregnancy, it should be able to have power for at full workday. Either in battery time, or by ensuring fast charging between sessions. The current product have a battery that lasts for six hours, and the midwives have up to 12 pregnant women in for monitoring during a day. Therefore, the battery capacity is just enough for this scenario, especially if it's charged in between session. Furthermore, it's only from week 24 they would use CentaFlow, and thereby it's likely that some of the 12 pregnant women wouldn't be monitored with CentaFlow (worksheet 13).


ill. 24 Parts ribbed from each other

Sum up

When using the device today, the midwife doesn't receive any feedback regarding the measurements, or if they have placed the product correctly. There is no indicator on the current product, as to what has to fit tightly to the stomach. Furthermore, it can be uncomfortable to lie down on the back while measuring. The technology is able to solve this problem, but the current solution with the plasters rib the skin a bit, and folds inconvenient. Additionally, the placement of the main box wasn't ideal when bending over.

The midwife, performing the measurement, is currently not receiving direct data. When implementing CentaFlow on hospitals and clinics, the data should be received instantly and it should be easy to interpret. This could be by using the current way of displaying an ECG-curve, and developing a scale to evaluate the blood flow to the placenta. When CentaFlow is implemented in the clinics, there will be a device in each examination room, and therefore the charging solution can be wall hung. The current battery capacity is able to run for six hours which would be enough for this scenario, especially if the device is charged in between sessions.

Further investigation

Which kind of feedforward and feedback should the midwife receive when placing the product, to ensure correct placement?
How do we create visible, pedagogical information for the midwife that isn't alarming to the pregnant?
How can we place the main box more strategically, and use design to not limit freedom of movement? E.g. using shapes (ill. 25, ill. 26).
How can we design a solution that reduces the feeling of the skin being ripped? (ill. 26)
How should it be charged?

ill. 25 Curved main box


ill. 26 Other placement of main box + doesn't rib the skin

Requirements

The product should fit and monitor a pregnant from week 24 to 42.
The product should be intuitive and easy to use, so the midwife is sure of the placement of the product.
The data received by the midwives should be easy to interpret and act upon, while not being alarming to the pregnant.

1. The ECG curve should be displayed as it is now.
2. The measurement of the flow in the uterine arteries should be displayed on a scale.

The product should not rip the skin unnecessarily when being removed or moving around.
The reusable parts of the product should be able to be cleaned with ethanol alcohol.
The product shouldn't be in the way of sitting or bending positions.
The product should withstand being dropped multiple times.
The product needs to give feedback of the measurements on a screen.
There should be a minimum of waste after the use of the device.

Home monitoring during pregnancy

Objective
The objective of this chapter is to understand why, and in which cases, the midwives offer home monitoring, and how the current product Monica works. This should deliver guidelines to what our product must fulfil if used for home monitoring. The data in this section is obtained through interviews with midwives Stine and Stina, and with a co-worker at Aalborg University Hospital who works with the product Monica for home monitoring. This is supplemented with desk research.

Why do they offer home monitoring?

A project at Aarhus University Hospital has shown that tele-medicine monitoring at home, with the device Monica, can significantly reduce the number of women, who otherwise would need to be hospitalised (Thomsen and Petersen, 2015). Numbers from the government agency of digitalisation indicate that the implementation of tele-medicine monitoring of pregnant women, nationally can release 18,4 mio. DKK, over a period of five years (Digital Service, 2017). This underline the opportunity of using a product like CentaFlow for home monitoring. In the project from Aarhus University Hospital, they measured both uterine activity and heart rate of the fetus, in other words the same data as measured with a CTG machine (Thomsen and Petersen, 2015). The technology of CentaFlow is also able to do this, and with the right design, it will be able to measure it in a comfortable manner. Additionally, CentaFlow adds the value of measuring the function of the placenta which is fundamental when analysing the fetus' well-being.

At Aalborg University Hospital they are using home monitoring to reduce the pressure on the hospital wards, but also to keep the pregnant women, for which it's possible, home in calm surroundings. They have patients in Thyborøn and Skagen, for which the drive to a consultation is very long. By offering home monitoring, they are able to reduce the number of consultations in the hospital (worksheet 7).

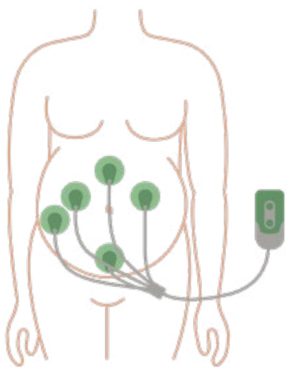
Who is chosen for home monitoring?

In Aalborg they have one of the largest spans of pregnant women who uses home monitoring. Generally, home monitoring is only offered to pregnant women who has a complicated, yet stable pregnancy, meaning there isn't a negative development. They use home monitoring for five different groups, and the home monitoring starts, for some, as early as week 26 (worksheet 7):

1. **Pregnant women with diabetes.** This is the biggest group of patients for home monitoring, and it's pregnant women who need to use insulin. They keep an eye on the blood sugar because it's important that it's stable. At a point in the pregnancy the pregnant's need for insulin can fall, and this can affect both mother and fetus. Therefore, they need to monitor the fetus' well-being to determine if the patient needs to be hospitalised, or the fetus delivered. The majority of pregnant women in this group, monitor once a week.
2. **Pregnant women with spontaneous rupture of membranes, SROM.** They are usually admitted to the hospital for one week after the SROM has occurred, and if things are stable they can start home monitoring. They are also given a device to measure CRP which keep an eye on infections, in addition to the fetus' well-being. The pregnant women in this group monitor once a day.
3. **Pregnant women who is in risk of developing pre-eclampsia.** Pre-eclampsia affects the heart and blood vessels of the pregnant which can affect the fetus. This group is hard to control because pre-eclampsia can develop very fast. The pregnant women in this group monitor every two to three days, to once a week.
4. **Pregnant women with a fetus that doesn't grow properly (IUGR).** Here they need to control if the fetus is alright, and the heart rate is regular. The pregnant women in this group monitor every two to three days, to once a week.
5. **Pregnant women with increased bile salt.** Having increased bile salts can, if not monitored, cause death of the fetus. The pregnant women in this group monitor every two to three days, to once a week.

The current solution, Monica, and user scenario

All the pregnants in the groups mentioned above, use a device called Monica that is able to measure the ECG of the mother and fetus, and the uterus activity. Basically, it gives the same data as the CTG machine, but by using electrodes to measure the ECG and uterus activity, instead of ultrasound and a pressure sensor. All measurements with the Monica device last for 30 minutes (worksheet 7). The device consists of five wires which can be attached to five electrodes (ill. 27). On the device the pregnant can start the session, and she can press the pink button every time she feels life (ill. 28). The midwife at Aalborg Hospital mentioned that one of the most important aspects of being a midwife, is not trusting the technology blindly, but also trusting the pregnant women:



ill. 27 Monica w. wires and electrodes

ill. 28 Monica main part

"it is one of the aspects that are most important for us midwives - not necessarily trusting the technology - it is equally trusting the women and their intuition... because in the end, the women are able to feel a lot if they pay attention"

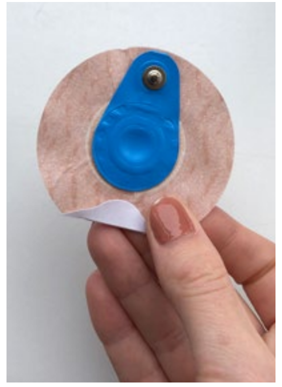
- Midwife Aalborg University Hospital (worksheet 7 p. 38).

This is also one of the reasons, why the midwives ask the pregnant women to lay or sit comfortably, not doing anything else, during the measurements (worksheet 7). Besides being more aware of the body and the fetus, the ECG results are more clean when the woman is calm, and not doing anything else (worksheet 7).

The Monica device is also able to measure the activity in the uterus, but these measurements are imprecise (worksheet 7). Ill. 27 shows the placement of the electrodes, and this is a patented solution, meaning the electrodes of CentaFlow can't be placed in a similar way, with the three topmost electrodes forming a half circle (worksheet 11). The Monica device is no longer available for purchase which underlines the opportunity of making a product, using CentaFlows technology for home monitoring (worksheet 7).

The following sections will be describing the user scenario. The user scenario is constructed through data, obtained in the interview with the midwife from Aalborg University Hospital (worksheet 7), and not by observing an interaction with the device. Therefore, there might be aspects that isn't visible to us. To gain more information upon the use at home, we have made a questionnaire, but only gotten one reply. The main point was that the respondent couldn't get the device to work at home because of technical difficulties (worksheet 10). Ideally, we would have liked to see a user scenario.

1. **Setting up the woman for home monitoring:**
   - The midwife sets up the pregnant in OpenTele which is a communication system that sends the data, measured at home, to the hospital.
   - The midwife use 30 minutes to an hour, teaching the pregnant woman to use the device.
   - Prior to going home, the pregnant receive a bag with all necessary equipment, including the Monica device (ill. 28), plasters with ECG sensors (ill. 29), a tablet, and for some also a blood pressure monitor and urine stix.



ill. 29 Plaster w. ECG sensor

ill. 30 Monica guide

2. **Home monitoring using the Monica device:**
   - The pregnant woman places five ECG plasters, one by one, following a drawing and a guide that explains the placement (ill. 30). Sometimes she scrapes the skin with sandpaper, to make the plasters stick to the skin.
   - Then she attaches the five wires, one to each plaster, again using the drawing (ill. 30).
   - She starts the Monica device, and it measures for 30 minutes. While the device measures, she doesn't do anything else than pressing the pink button, each time she feels life.
   - After the 30 minutes, the device sends the data to the tablet, without showing anything to the pregnant woman.
   - The pregnant woman answers a questionnaire that is developed specifically for her patient group, via an app on the tablet. In some cases, she has to fill in her blood pressure, and the value of her urine.
   - When having filled the data in the questionnaire, and measured for half an hour, she sends all the data to the hospital via the app on the tablet.
   - The data needs to be sent to the hospital, at no later than 9 am to be evaluated the same day.
   - She removes the wires from the plaster. The midwives advise the pregnant women to leave the plasters on the skin, until they fall off by themselves. When monitoring multiple times a week, it can be necessary to remove the plasters, and put on new ones, for the electrodes to work which for many women cause locally skin irritation.
   - When the data is evaluated, the pregnant receives a receipt in the app if everything is fine. If something is abnormal, the hospital contacts the pregnant. This could e.g. be if the ECG-curve isn't normal. If this is the case, the midwife will ask the pregnant to put on the device again, and measure an ECG-curve live to the midwife.
3. **Evaluation of data at the hospital:**
   - After 9 am, a midwife looks through the received data on a computer. If everything is okay, the midwife sends a receipt to the pregnant.
   - The data is displayed like a normal CTG-diagram with the heart rate curve of the fetus, uterine activity and marks for when the pregnant feels life (ill. 31).
   - If something is abnormal, they usually call the pregnant, or ask her to contact her doctor.
   - Generally, the midwives say that if the ECG-curve is normal then the fetus is well. But their measurements aren't complete, and if something is abnormal, a doctor would e.g. have to measure the flow to the uterus and the flow in the umbilical cord, with a special ultrasound machine.

ill. 31 Normal CTG-diagram

4. **Problem finding and solving:**
   - Sometimes the technology and Monica device doesn't work as intended. When this happens, it's the midwives, who has no technical IT-education, that have to try to solve the problem over the phone. This can be both hard and time consuming for the midwives, who also need to take care of the pregnant women coming in for consultations.

5. **Returning the home monitoring equipment:**
   - When the woman returns the equipment, wires, the tablet and Monica device, it's cleaned using ethanol alcohol.
   - Generally, the equipment is in good shape when being returned. They have only experienced having received the wrong wire for charging the tablet (worksheet 7).

It's only if a pregnant needs an ultrasound or a consultation that can't be done over the phone that the patient has to go to the hospital. Or if the technology doesn't work correctly, and they can't solve the problem over the phone. This implies an opportunity, for the product to be intuitive and feedback oriented, so the pregnant can eliminate the risk of e.g. having placed the product wrong, instead of contacting the midwives.

The reason the device measures for 30 minutes, is to create a good ECG-curve. When talking to both the midwives Stine and Stina, and the midwife from Aalborg University Hospital, it was clear that this also would be the case if implementing CentaFlow for home monitoring (worksheet 6 and 7). Of cause this can be challenged by e.g. an algorithm that is developed to analyse the curve continuously, and then stop when the curve is good enough. The current battery of the device, makes it possible to run six sessions of half an hour which seems sufficient for this scenario.

If implementing the technnology of CentaFlow for home monitoring, the midwives would have the received data, displayed like in the scenario in the clinics, with the ECG-curve displayed as the current solution, and the blood flow of the uterine and placenta, in some kind of scale.

Sum up

Home monitoring is currently used for five different groups, in the region of Northern Jutland. It's only used for pregnant women with a complicated, yet stable pregnancy. Using the Monica device, enables the pregnant woman to run a CTG-curve, using ECG-electrodes at home, and sent the data to the hospital for evaluation, ideally saving time for both the pregnant and the midwife. The Monica device measures the heart rate of the fetus, and uterus activity, for 30 minutes pr. session. This is repeated from once a day to once a week, depending on the pregnant's situation. While measuring, the pregnant lies or sits still, only pressing a button every time the she feels life from the fetus. This is to ensure good quality measurements, and this scenario will, according to the midwives, have to be the same if the technology of CentaFlow is implemented for home monitoring.

Home monitoring currently starts from week 26 and lasts the rest of the pregnancy. When using the device, the pregnant places five electrodes on the skin, sometimes using sandpaper prior to attaching the electrodes, causing irritation on the skin. The current solution doesn't measure the blood flow to the uterus and placenta. Therefore, using CentaFlow for home monitoring, can provide more and vital information which might reduce the number of consultations in the clinic further. This, however, rely on whether the pregnant is able to place the product correctly. There is a big potential in creating a solution that is easy to use, and that gives feedback if the pregnant has misplaced it, saving time for midwives, as the pregnant hopefully will be able to problem solve at home, without contacting her midwife.

Further investigation

How do we ensure correct placement by the pregnant? And which kind of feedforward/feedback should the pregnant receive when placing the product?
What is the ideal monitoring session for the pregnant woman?

Requirements

The product should be intuitive and easy to use for the pregnant, and ensure a correct placement of the product.
The reusable parts of the product, should be able to be cleaned with ethanol alcohol.
The pregnant should be able to report every time they feel life, during the monitoring session.
The product shouldn't be in the way of sitting positions.
The data received by the midwives should be easy to interpret and act upon, while not being alarming to the pregnant.
1. The ECG curve should be displayed as it is now.
2. The measurement of the flow in the uterine arteries should be displayed on a scale.

The product should not irritate the skin and should be able to be taken of in between sessions.
The product should fit and monitor a pregnant from week 26 to 42.

Monitoring during delivery

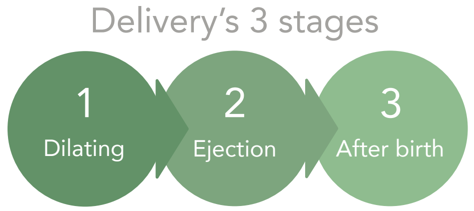
Objective

The objective in this chapter is to understand the user scenario when monitoring pregnant women during delivery, as well as get an insight to the delivery situation, and the solution that is currently used for monitoring during delivery - the CTG. The information in this chapter is obtained through interviews with midwives (worksheet 2, 6 and 7) and desk research.

Creating the best conditions for delivery

During the visit at Viborg Hospital, we saw their new delivery rooms. The hospital is very focused on creating sustainable delivery rooms, with furniture made from cork, but also creating a delivery environment which is as homely and cozy as possible, to better the delivery experience (ill. 32 - ill. 34) (worksheet 2).

The delivery is subdivided into three stages. The first one is the dilating period. This is when the fetus starts to get pushed towards vulva, and the woman eventually dilates fully. The second stage is the ejection period, where the fetus is pushing further down to the pelvis, and finally gets all the way down to the point where the pushing phase can begin, and eventually the baby gets born. The third and last stage, the after birth period, is the time from the baby is born, to the placenta is out as well (ill. 35) (Hvidman, 2016).



ill. 35 Delivery's 3 stages

When in labor, you are in a rather tense situation, therefore unnecessary irritations and discomfort have to be minimized. There are three main hormones which affects the delivery situation. These hormones are oxytocin, endorphins and adrenaline.

Movement and dancing enhances the release of endorphins, also called happy hormones, which is our body's natural morphine. The release of endorphins reduces the pain from the contractions caused by the oxytocin (Hospitalsenheden Vest, no date). Therefore, it's important to create a solution that is comfortable to wear, also while moving around (ill. 37). Additionally, this helps the fetus to move towards the pelvic floor, and thereby further down in the uterus. As mentioned, when monitoring with the CTG, the women can't walk around, and therefore it makes sense to optimize the birthing situation for women needing monitoring during delivery, by making a comfortable product, using CentaFlow's technology, replacing the CTG. The technology of CentaFlow is already wireless, enabling movement, but our job is to ensure comfortable movement in multiple positions. Furthermore, the labour can cause the woman to sweat. Also, some women decide to give birth in water, and this wish should preferably be granted, to give the women the most comfortable, positive experience. In Viborg Hospital every third woman is in a bathtub at some point during the delivery (worksheet 6). The current solution of CentaFlow isn't waterproof.

Oxytocin, also called the love hormone, is the hormone that creates labour pain, and it's the labour pain that makes the uterus expand (Bach, no date b). The more oxytocin that are released, the better labour pain and faster delivery. However, oxytocin is only released when the pregnant woman feels calm, loved, safe and comfortable (Bach, no date b). This is one of the reasons for trying to create a more comfortable feeling, while in delivery, and also one of the reasons why midwives, Stine and Stina, mentioned the idea of making the product as small and invisible as possible (worksheet 2). Oxytocin is a fleeting hormone, and it doesn't take much stress before the production of oxytocin stops which can be crucial for the delivery.

Lastly, adrenaline in small doses makes the pregnant better at ignoring indifferent details, and makes the pregnant action oriented. In larger doses it has a negative affect (Bach, no date b). Creating the best scenario for a pregnant woman who needs monitoring during delivery, would therefore be to make a product which is comfortable to wear, enables labour movement, and that doesn't provoke irritation and stress for the pregnant woman.


ill. 32 Bath top w. a "view"


ill. 33 Delivery bed and colour on the wall


ill. 34 Cork bed and pictures

Oxytosin

- The love hormone
- Creates contractions
- Fleeting hormone
- Released when being touched, kissed, feeling safe, etc.

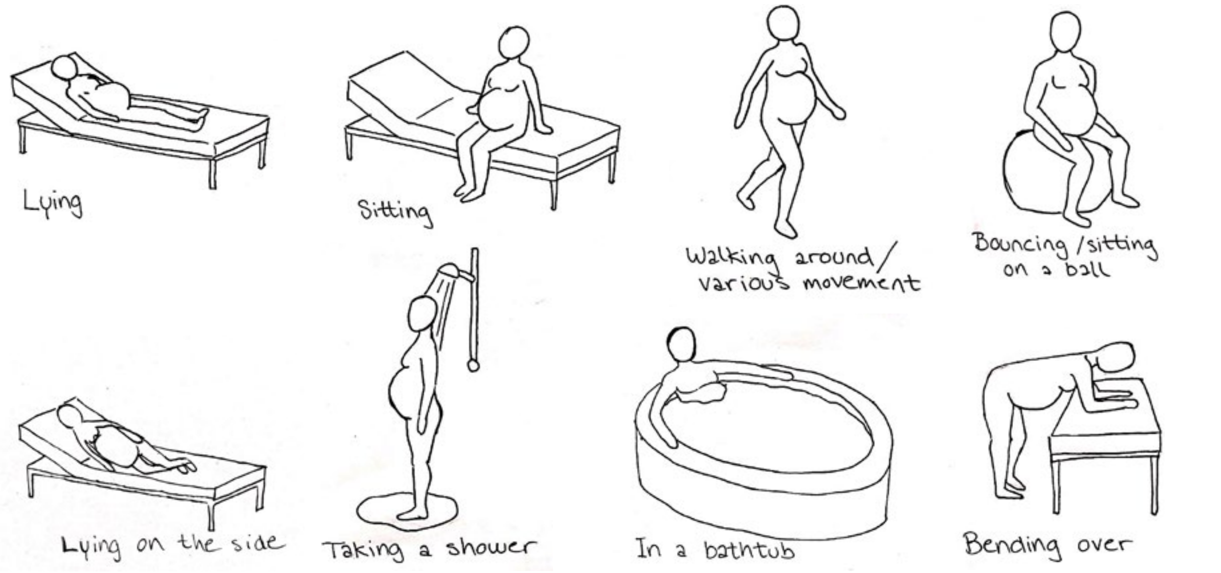
Endorphines

- The happy hormone
- The body's natural morphine
- Released when moving, laughing, dancing and when feeling pain

Adrenaline

- The stress hormone
- In small doses:
  - Alerting
  - Action oriented
  - Good at ignoring indifferent details
- In large doses:
  - Panic struck
- Increased when feeling insecure, anxious, etc.

ill. 36 Delivery hormones (Hospitalsenheden Vest, no date)



ill. 37 Movement during delivery

CTG - the current solution

The Cardio-Toco-Grafi, CTG, machine measures the heart frequency of the fetus, by placing an ultrasound-head on the stomach of the pregnant woman (ill. 38), or an invasive needle on the fetus' head if there is access to it (ill. 39). The purpose, when used during delivery, is to see how the fetus is doing and responding to the contractions (Bach, no date a). When the machine registers a heartbeat, it calculates how many beats per minute there would be if all the heartbeats came in the same frequency. Each heartbeat is shown with a dot which combined makes a curve (ill. 31 p. 18) (Bach, no date a). This is similar to the ECG-curve measured with CentaFlow and Monica. When interpreting the CTG curve, the midwives and doctors look for:

- The average number of beats pr. minute.
- The variability of the heartbeats - it's good if they are irregular.
- That there are accelerations with periods of a large rise in beats pr. minute.
- That there is an absence of periods with a large decrease in beats pr. minute, also called decelerations.

(Bach, no date a)

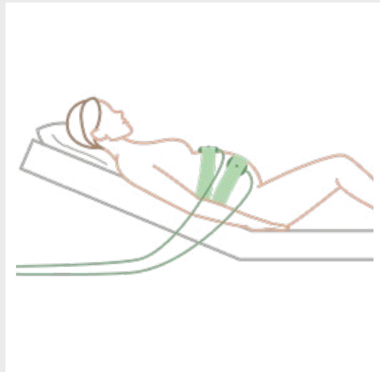
The CTG-machine also measures the contractions. This is measured by pressure, but is imprecise and very dependent on how tight the measurer is placed on the pregnant stomach, but also how much fat there is between the uterus and measurer (ill. 40). The pressure sensor measuring the contractions doesn't define the intensity of them, but only if there is one, and how long it lasts (Bach, no date a).

These two measurements, fetus heart rate and contractions, can tell the midwives and doctors the condition of the fetus, and how it responds to the contractions (Bach, no date a). Because both measurements are being illustrated by a curve, and the midwives and doctors interpret this curve, it's a subjective decision when deciding if there is a need of a c-section. Ill. 31 p. 18, shows an examples of a CTG-kurve. The white area of the heart rate curve, is the normal area and the yellow means the heart rate is a bit irregular. If there is activity in the red area, the midwives are extra alert. The curve is displayed on a screen in the delivery room.

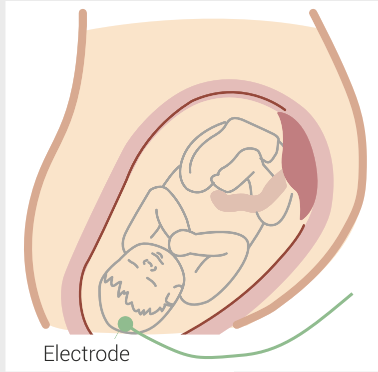
When attaching the CTG, it's important that the movement from the pregnant woman is as small as possible, as the sensors are easily moved. To get a CTG-curve that is technical acceptable, it needs to register 80% of the signals. This can be hard if the pregnant/birthing woman is moving, and the sensors thereby move around (Larsen, 2017).

"They are challenged in their mobility when wearing it"

- Stina (worksheet 6 p. 29)



ill. 38 External CTG



ill. 39 Internal CTG

ill. 40 CTG head measuring contractions

The midwife at Aalborg University Hospital told us that the current CTG machines are incomplete in their way of measuring the heart frequency, and that the ECG sensors in the Monica device and CentaFlow, gives a more precise picture of the heart frequency (worksheet 7).

After use, the CTG's measurement heads and wires are cleaned with active chlorine, soap and water, and the elastic bands placed around the stomach is hot cycled. There is a CTG in each delivery room (worksheet 6).

Situations where a CTG is used

By identifying the situations where it's necessary to use the CTG, we also receive an insight to the situations where it would be possible to use a product like CentaFlow.

The CTG is used in situations where the midwives are concerned if the fetus is getting enough oxygen and nutricion. In general, a CTG is used if there is an abnormality in the fetus' heart rate, and in situations where it's insufficient to use a wooden stethoscope (ill. 41) (Larsen, 2017). In rare cases a pregnant gives birth already around week 26 (worksheet 7).

Situations where a CTG is used (worksheet 6):

- If the amniotic fluid is green.
- If the pregnant has too high a blood pressure.
- If she has pre-eclampsia.
- If she has gotten an epidural blockage.
- If she has received medicine during pregnancy.
- If she is bleeding to early: before week 37+0.
- If she has had a c-section previously.

The measurement sessions can vary from (worksheet 6):

- 20 min. per 1-2 hours if it isn't a significant birth (intermittent).
- Continuously if it's a significant birth, or if the pregnant has had a c-section previously.

When measuring intermittent, the midwives remove the CTG heads from the stomach, in between the measurements. This indicates that it should be easy to take the product on and off in this scenario (worksheet 13). When being measured during the entire delivery, the CTG-measurement can be interrupted by a visit to the toilet. However, this is only possible if the heart rate has been normal for up to 20 minutes. Alternatively, the pregnant woman can have a catheter inserted (Larsen, 2017). In Aalborg University Hospital it isn't possible to go to the toilet when wearing the CTG because the delivery rooms doesn't have individual bathrooms (worksheet 7).

The midwives mentioned that if CentaFlow should be used instead of the CTG, it should have battery capacity for continuous monitoring in 24 hours (worksheet 6). In most cases this will be enough, but there can occur unusual situations, where the capacity should last longer. Here they mentioned that it wouldn't be critical if they had to replace it with another (worksheet 6). After giving birth, the couple usually stay in the delivery room for three to four hours, and then a cleaning lady cleans the room, using an extra hour. Therefore the device should be fully charged in approximately four hours (worksheet 6, 13).

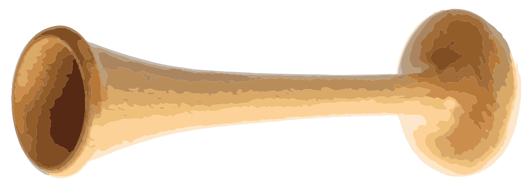
Wearing the CTG during delivery

To understand how the user feels when wearing the CTG during delivery, we have made a semi-structured interview with Trine Christiansen who is pregnant with her second child, and were monitored by a CTG at the delivery of her first child. All data received in the interview can be read in worksheet 4.

Wearing the CTG, Trine felt awkwardly strapped and felt annoyed by it. "You feel a bit like a piece of meat" (worksheet 4 p. 21). She had been wearing it because she had an epidural blockage injected. Additionally, the midwife at Aalborg University Hospital mentioned that many pregnant women move the straps, and drag them because they are uncomfortably tight, and this is uncomfortable during contractions and delivery (worksheet 7). Some can't even stand wearing underwear (worksheet 7). This indicates the criteria, of making the solution we design more pleasing to wear. Trine mentioned that she was in doubt if the CTG had been measuring correctly because she was woken by midwives, who wanted to examine her because they thought the contractions had stopped. The examination showed she was fully dilated, and that the contractions hadn't stopped. This indicates the need of placing and strapping the sensors tightly enough, for the CTG to have the correct output (worksheet 4).

"It would be great if it was something they could forget they were wearing"

- Stine (worksheet 6 p. 32)



ill. 41 Wooden stethoscope

Comments about implementing CentaFlow in delivery situations

The current solution of CentaFlow enables freedom of movement, without having straps that are tight around the stomach. However, it's unsure if the plasters are able to withstand sweat, movement and water, and also able to stay on the skin for 24 hours. This should be tested, but nevertheless the product shouldn't rip the skin, like we saw during the user scenario in the clinics.

The midwives at Viborg Hospital referred to the delivery situation as a battle zone. Everything isn't always put into its right place, and sometimes tables are moved out of the delivery room after delivery. "They disappear easily - the things in the delivery rooms" - Stine (worksheet 6 p. 27). Therefore, they mentioned that it could be preferable if the device could e.g. make a sound, to make them aware that it isn't in its place. Stine also mentioned that it's important to be able to understand and use the device, in case an immediate complication occurs, where they need to monitor the fetus' well-being (worksheet 13).

For the visual feedback of the measured data, they mentioned the same criterias as for the scenario of monitoring in clinis and at home. Their overall point regarding the data, is that when the product is implemented, they need to have a procedure for when, and how quickly, they need to react, according to the measurements of the flow in the uterine arteries. It should be similar to the procedure they already have about the heart rate curve (worksheet 6). In the delivery rooms there aren't a laptop, and because the current CTG has an appertaining screen, it would be necessary to have a screen, for displaying the data. This could be e.g. a tablet or computer.

Sum up

Giving birth can be an uncomfortable situation, and therefore it's important to try and give the pregnant women the best possible experience, also when needing monitoring during delivery. The current solution for monitoring during delivery, the CTG, creates a curve over the fetus' heart rate, measured via ultrasound, and measure the activity in the uterus with a pressure sensor. The technology of CentaFlow is able to give a more precise measurement of the fetus' heart rate by using ECG sensors and, additionally, giving information of the status of the placenta.

When wearing the CTG, the pregnant woman is being tightly strapped around the waist and stomach with two bands. This can be uncomfortable, resulting in some pregnant women moving the measuring heads because of the discomfort, causing flaws in the measurements. Furthermore, the CTG limits the pregnant's freedom of movement. CentaFlow is wireless and thereby this dilemma is solved. However, there are still dilemmas regarding the use of CentaFlow and movement that needs to be solved in a comfortable way. Up to one third of all pregnant women, experience being in a bathtub sometime during delivery. This is not possible with the CTG or the current CentaFlow.

A delivery can last up to 24 hours, and in rare cases even longer. When being monitored during delivery, the monitoring session can vary from 20 minutes per one to two hour, to throughout the whole delivery. Therefore, the product needs to be able to monitor for at least 24 hours. If monitored intermittent, the CTG is often removed in between the session. Many delivery wards in hospitals are busy, and a new pregnant in need of monitoring, might come to the delivery room soon after it is cleaned. Therefore, the device must be available to a new pregnant within four hours.

Further investigation

We need to see if the current solution sticks to the body under water, and when sweating and moving around.
What should the scenario behind charging and recharging the solution be? Could it be an exchangeable battery, and should it give a signal when it isn't in place.

Requirements

The product should be intuitive and easy to use, so the midwife is sure about the placement of the product.
The product should withstand active chlorine and soap water, and if there is textile incorporated, it should be able to be hot cycled.
The product should ensure the midwife and pregnant to remember to charge it after use.
The product shouldn't rip the skin unnecessarily when being removed, or the woman is moving around.
The product should be able to withstand water from being worn under a shower or in a bathtub.
The product shouldn't be attached with straps that are placed tightly around the stomach.
The product should have battery capacity for monitoring in 24 h.
The product should be able to be charged within four hours, or have changeable batteries.
The product should fit and monitor a pregnant from week 26 to 42.
The product shouldn't be in the way of sitting or bending positions.
When the product is used intermittent, it should be easy to attach and detach.

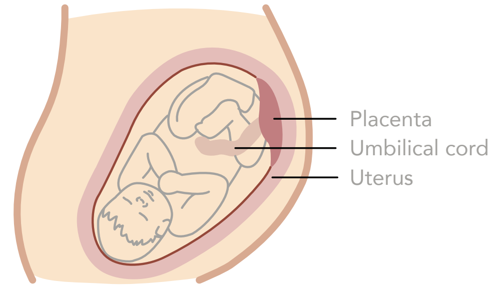
CentaFlow's technical possibilities and limitations

Objective

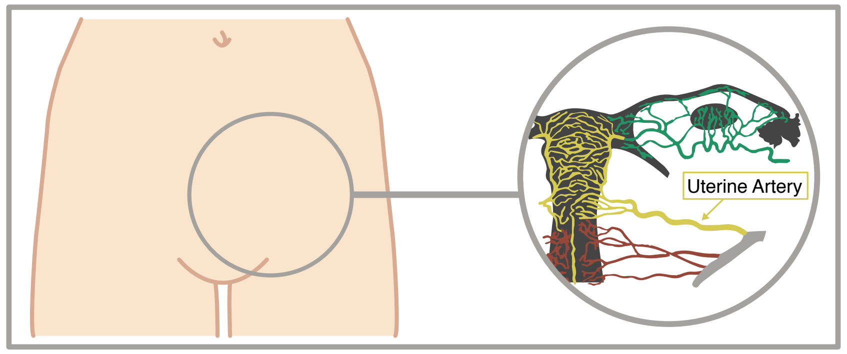
This chapter is made to understand the technical aspects of CentaFlow, as well as the possible limitations. To understand this, several interviews with developing engineer, Henrik Zimmermann, have been conducted. To understand how CentaFlow measures the hearth frequency and blood flow to the placenta, basic physiological aspects will be presented as well, and the knowledge about this, is mainly obtained through desk research. The interviews with Henrik Zimmermann are presented in worksheet 1, 3 and 11.

What does CentaFlow measure

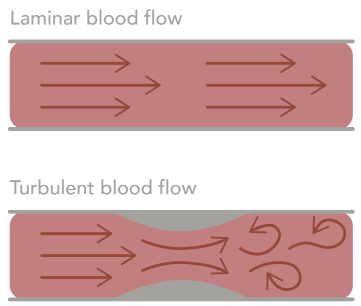
The uterus is where an embryo will grow into a fetus, once a sperm cell has fertilized the egg. The placenta will then start developing in the uterus, during the pregnancy. The placenta plays an essential role, as it provides both nutrition and oxygen to the fetus, as well as it disposes waste products from the blood of the fetus. The umbilical cord starts from the placenta, and the placenta is attached to the wall of the uterus - usually on the front, top, side or back of it. (Mayo Clinic Staff, 2018). The blood supply to the uterus comes from two main arteries, the uterine arteries (ill. 42) (Thompson, 2019). As the placenta is attached to the uterine wall (ill. 43), it also receives blood and thereby nutrition from the uterine arteries.



ill. 43 Inside the pregnant stomach

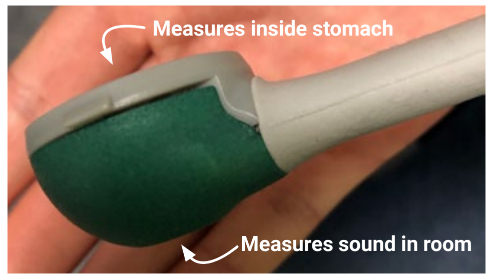


ill. 42 Uterine artery



ill. 44 Blood flow

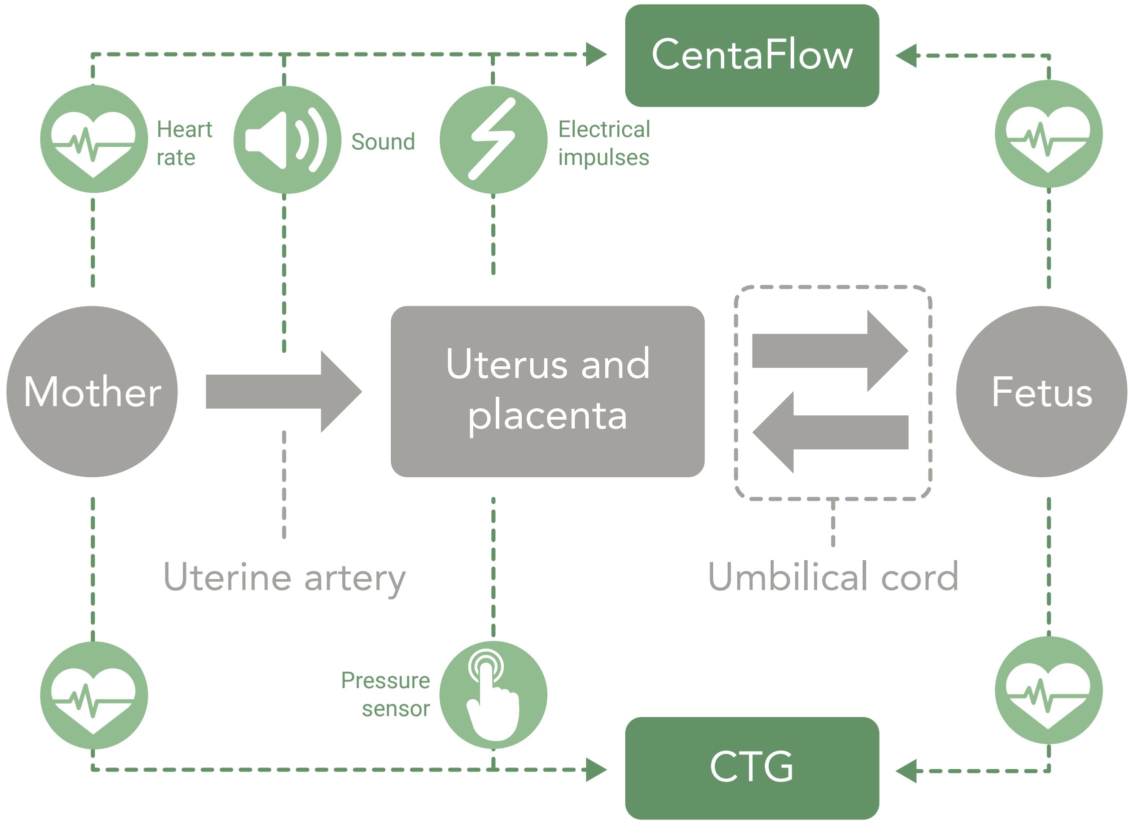
CentaFlow measures the blood flow of the uterine arteries which enables them to determine if the uterus and/or placenta is under stress, or if it doesn't function intentionally, and thereby if the fetus isn't getting enough nutrition and blood. If something is wrong, the blood flow will become uneven and turbulent, where the blood flow is more or less laminar if the uterus and placenta function well (ill. 44). Blood veins will always have a bit of turbulence, so CentaFlow listens after abnormal flow. By attaching two microphones per artery, one that listens to the artery and one that listens to background noise in the room, and cancelling this, Centaflow is able the pick up the sound of the blood flow in a non-invasive manner (ill. 45). If there is a turbulent and abnormal flow, the sound from the arteries will whistle (worksheet 3).



ill. 45 Microphone

Furthermore, Centaflow does as mentioned, measure the heart rate of the fetus, ECG. The heart rate will increase if the fetus is stressed which can happen if it isn't feeling well, e.g. by not getting enough nutrition and blood from the placenta. CentaFlow places seven electrodes around the belly (ill. 50 p. 25). These electrodes can also be used for measuring uterine activity (EMG), determining if a pregnant has e.g. braxton hicks or labour pain.

Therefore, CentaFlow covers what the CTG measures, and are getting more clear results of the heart rate. In addition, it also monitors the function of the placenta, and thereby handles the fetus' well-being more efficient and thorough, than the current solution, making the CTG redundant. For an overview of what respectively CentaFlow and a CTG measure, see ill. 46 p. 24.



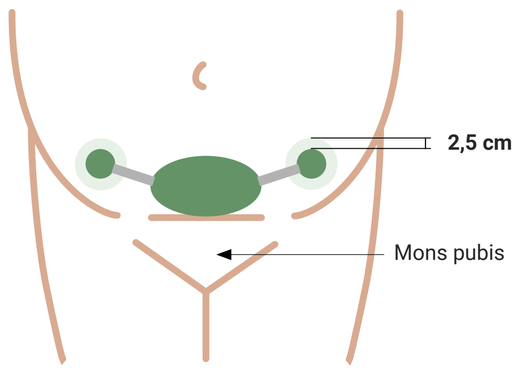
ill. 46 CentaFlow vs. CTG

How is the current product constructed and why?

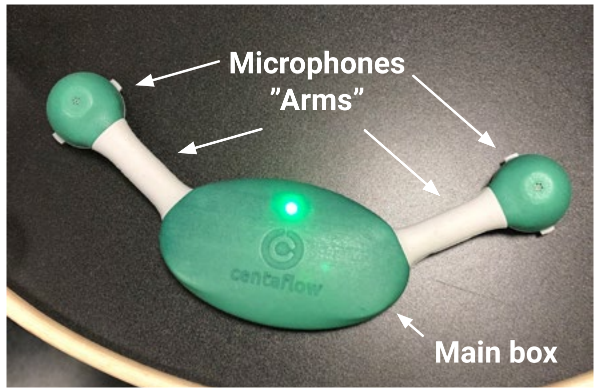
The product overall consist of a main box, "arms" and two ends with two microphones in each (ill. 47). This is attached to two plasters with press studs, and the plasters hold the electrodes (ill. 48). There is one press stud per electrode.

The main box containing most of the electronics, are placed right above the "triangle" of the mons pubis (ill. 49). From here the "arms", with the microphones at the end, can reach the point, where they can listen to the uterine arteries. The uterine arteries are placed more or less the same place on every woman (worksheet 3). The "arms" are only connections with a cord, and there are no specific reason for the thickness of them (worksheet 3).

The most important aspect to place correct, is the microphones. CF has tested that they can pick up signals from the uterine arteries, when placing them +/- 2,5 cm from the position they are currently placed (ill. 49). Therefore, when creating concepts, we should take basis in where the current microphones are placed on the product (worksheet 11). The current product is, as mentioned earlier, placed after the mons pubis, using the main box as a guide (ill. 49). The placement of the main box, however, can be moved if the microphones are still placed correctly.



ill. 49 Mons pubis and microphones



ill. 47 The overall product of CentaFlow

ill. 48 Plasters of CentaFlow

As mentioned the current product has seven electrodes. The six of them measure the electrical activity of the mothers and fetuses heart, and uterine activity. By measuring the mother's heart frequency, they are able to distinguish between the two, and thereby determine the fetus' heart frequency (worksheet 3, 11). The seventh electrode is used for closing the circuit, meaning it's used as a reference. Henrik referred to a voltmeter which doesn't work without having both plus and minus (worksheet 11). This electrode can be placed wherever. The most important aspect of the electrodes, is to cover a somewhat vertical line, from the top of mons pubis to approx. 5-10 cm above the navel, and then cover the sides, also from the top of mons pubis. Ill. 50 shows the current placement of the electrodes. The Monica device uses five electrodes to create the needed data. The solution has three electrodes, forming a half circle. Their solution is patented, and this is why CF used two electrodes in the bottom and four around the stomach, where the two upper ones create the vertical vectors, and the two on the sides, a vector to each side (ill. 50) (worksheet 11). We do not have to use their solution, but cannot go against the patent of the Monica solution.

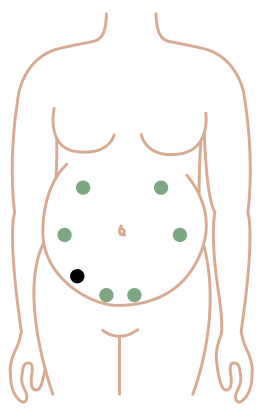
In the main box there are three printed circuit boards on top of each other, to make it more compact. One of them is only used for the connection from the press studs to the electrodes.

The other two boards hold all the analogue circuits that collects the data from both electrodes and the microphones. Also, there are:

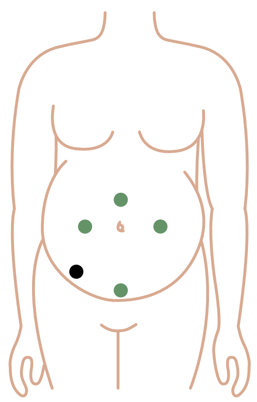
- A battery with capacity for six hours
- Battery management system
- Wifi processor
- RFID chip
- An accelerometer
- Wireless charging Qi-coil

The accelerometer on the board is added for the intention, of having to observe if the pregnant is moving around while monitored, and thereby potentially enabling analysis of the results, according to the disturbance these movements may cause (worksheet 3). Additionally, the Qi-coil isn't working intentionally yet, but when solved it might make sense using wireless charging instead of a plug-in solution, both making the interaction of charging easier, but also removing an area which would gather bacteria (worksheet 3). When using the coil which is approx. 12x12 mm, it's important that the receiver coil in the device, and the transmitter coil is placed against each other on a flat surface (worksheet 3).

The plasters are made to fit the main box and the microphones. They are clicked into the press studs, linked to the electrodes, and afterwards the microphones are fit into the allocated plastic rings (ill. 52). The adhesive plaster is padded with a foam, and in this foam the electrodes and the wires are placed. There are numbers on the foam that show the order the foil on the adhesive should be removed, to make a guideline of use (ill. 52) (worksheet 3). If using another way of attaching the main box to the plasters than the press studs, we will be able to leave out one of the printed circuit boards (worksheet 3).



ill. 50 Current placement of electrodes



ill. 51 Monica electrodes

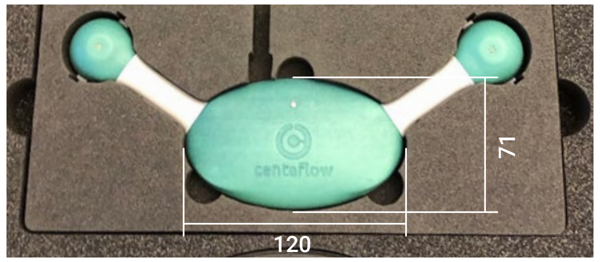
ill. 52 Plasters and main box together

In the following tables the main parts, and their dimensions, are listed, as well as some general information about the main box:

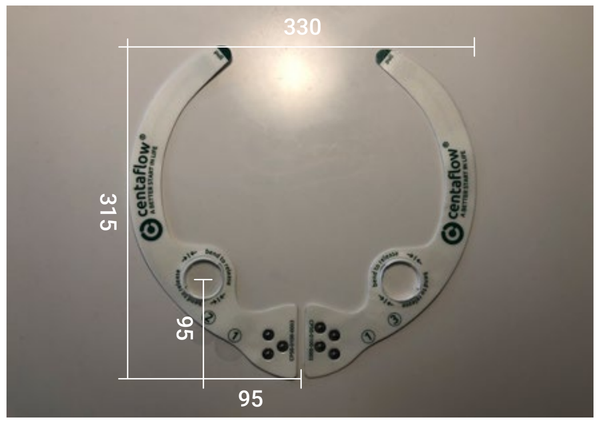
Part	Dimension
Circuit boards	75 mm x 43 mm x 4 mm
Qi-coil receiver	12 mm x 12 mm
Battery	60 mm x 36 mm x 6 mm

Battery capacity	6 hours
Weight of main box including microphones	144 g
Size of technical parts in main box	42 cm³

The architecture of the product and its components, gives the overall measurements in mm as following illustrations show:



ill. 53 Main box measurement

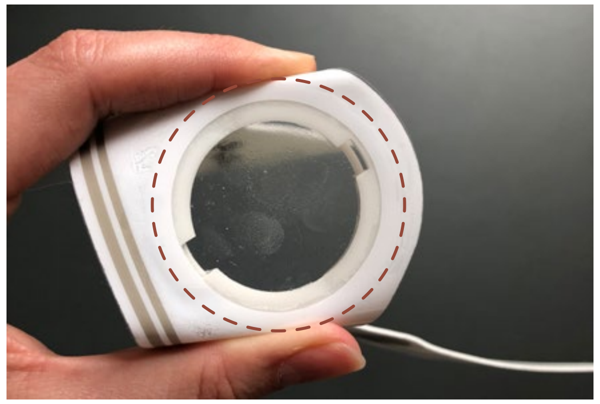


ill. 54 Plaster measurements

Limitations of the technology

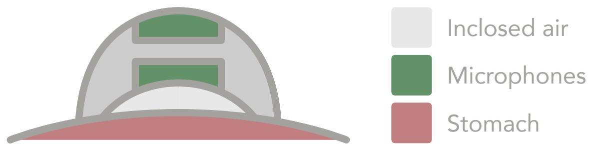
Right now, CentaFlow is only used for monitoring before labour where the pregnant is lying still. However, the intention is to be able to monitor in labour as well. With this vision some challenges arises. Many of them will be described later on, however there are some technical challenges that will be described now.

As mentioned, some women wish to give birth in water, and this would mean that water can get into the microphones listening to the surroundings. To detect sound you need air, thereby you can't simply seal the microphone. However, a hydrophobic filter might prevent this. Even if a hydrophobic filter is used, there is still a problem with dirt and bacteria getting stuck in the small holes for the microphones. This is a problem for the functionality of the product (worksheet 3). A solution to this, could be to use a sensitive accelerometer, to measure the vibrations on the skin. This would give, roughly, the same type of output as the microphones. The accelerometer could be shut in a waterproof box which would solve the problem. However, the accelerometer has a lower sensitivity and bandwidth than the microphones, resulting in higher difficulty picking up the blood flow. Furthermore, it's a problem when moving, as the accelerometer is a sensor that picks up vibration using mass. When vibrations cause the mass in the accelerometer to move, the vibration is registered. This will be a problem when moving during delivery (worksheet 3, 6, 11). Both the accelerometer and the microphones share the challenge that surrounding noise can mess up the results. When the microphones measure in a birthing situation where it can be difficult to be silent, the microphones would need to measure over a longer period of time, to get the same information, but Henrik mentioned that he doesn't consider this as a critical problem (worksheet 11). Additionally, both Henrik and Stine mentioned that during the delivery, there is periods where the pregnant is resting, and the noise level is thereby lowered (worksheet 3, 6, 11). The ring around the microphones stiffens that area, ensuring that less sound waves from the surroundings disturb the microphones measuring towards the stomach (ill. 55). The size of this could maybe be larger, but it will depend on how well it fits on the pregnant stomach (worksheet 11).



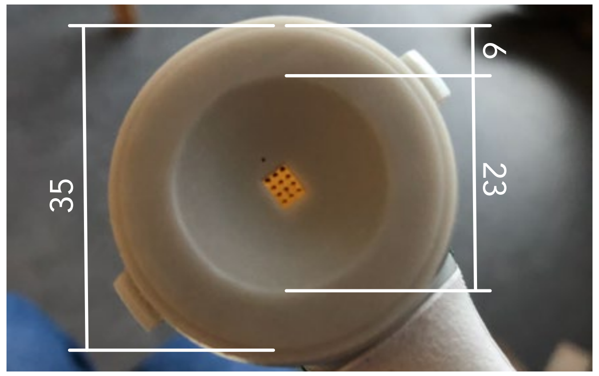
ill. 55 Stiffening ring

When using microphones to measure, it is important that the microphone, measuring towards the stomach, is placed so it seals tightly to the stomach, to get a usable result (ill. 56). CF's microphones haven't got any problem reading through e.g.



ill. 56 Microphone seals tight to the stomach

fat, as it's a uniform mass. However, when the sound has to go from the stomach, through the pocket of air, to the microphone, a little amount of data will be lost because the medium, the sound travels through, changes (worksheet 11). This could be solved by using contact microphones, where there is no air between stomach and microphone. But because these microphones have to be custom made, CF is currently using the aforementioned which is standard microphones (worksheet 11). The size of the air pocket is an optimization question. The larger the area, the more data will be able to pass through. However, if making the area larger, they will only be able to measure at a lower frequency. There are indications of a need to listen to higher frequencies, therefore the current size is approx. 23 mm (ill. 57) (worksheet 3, 11). We will continue to work with the current size of air pocket, as it's tested.



ill. 57 Ring and cavity measurements

As mentioned earlier, it's important that the microphones and the electrodes seal tightly. The connecting wire between the electrodes and press studs doesn't need to seal tightly to the stomach (worksheet 3) (ill. 58).

ill. 58 Areas that should seal tightly

The reason for placing seven electrodes, is to create a bigger area to measure the heart frequency over. Meaning, they will be able to measure the heart frequency, independent of how the fetus is placed in the stomach (worksheet 3). Right now there is no electrode placed on the back of the woman, but because the fetus in some cases lay far back, it might be an idea to be able to place an electrode here (worksheet 3). However, the current solutions of both the Monica device, CTG and CentaFlow haven't implemented this, indicating that it's possible to get the wanted results without the extra electrode.

The electrodes do, as mentioned earlier, also measure uterine activity. This is done by measuring the muscle activity, a so-called EMG (worksheet 11). However, when moving around, the muscles are used, and this will be reflected in the EMG measurements (worksheet 11). Stine and some women we spoke to, confirmed that women often move during contractions (worksheet 11, 13). Therefore, CF might have a problem measuring all contractions. This could might be solved by analysing the data received from the microphones, as contractions squeeze the uterine arteries a bit when the uterus contracts, making the flow more turbulent (Jordemoderforeningen, 2014). Additionally, the midwives are able to determine when the pregnant has a contraction by looking at her (worksheet 6). It could maybe also be possible for the spouse to register the contractions, but this has to be investigated. The CTG shares the problems regarding movement and measuring the contractions, however the data received by the EMG electrodes, is more precise than the pressure heads, used on the CTG (worksheet 11). Nevertheless, we need to find out if the combination of the data received by the microphones, the EMG electrodes and an accelerometer, can be combined to create a better overview than the current solution.

The current CentaFlow is always turned on when not being in its home box, and is thereby using power when not measuring. This could be challenged. E.g. with an algorithm, or by having an on/off button. One of CF's earlier prototypes has an on/off button, but they experienced that the midwives accidentally turned the device of (worksheet 3). We need to have this in mind if implementing an on/off button. Additionally, if using CentaFlows technology during delivery, the battery capacity must be enlarged by implementing e.g. three batteries similar to the current.

Sum up

The CentaFlow measures the flow in the uterine arteries using microphones, and the heart frequency of the fetus using ECG electrodes. When placing the electrodes, it's important to create a somewhat vertical vector, and a vector to each side of the stomach, covering the area where the fetus is lying. The electrodes also measure uterine (or muscle) activity using EMG. There will occur a problem in measuring the uterine activity when the pregnant is moving. This could might be solved using the microphones, as mentioned earlier. When placing the electrodes, it's important that they seal tightly to the stomach.

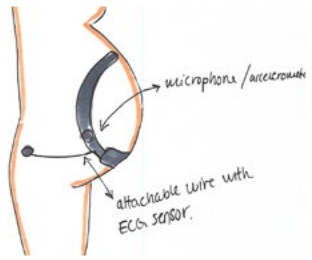
The microphones need to be placed with a precision of +/- 2,5 cm when referring to the current product, and the area around the stomach, measuring towards the stomach, must seal completely to the stomach. The size of the ring sealing tight, might be optimized for better sealing ability, especially when used during delivery. An hydrophobic filter could be used for making the microphones waterproof, as the microphones are the most optimal solution for measuring the blood flow when comparing to the accelerometer.

The battery capacity should be increased for a delivery situation, e.g. by implementing three batteries similar to the existing. Additionally, it might make sense using, the already implemented, Qi-receiver coil for charging.

The current solution is made for a scenario where the pregnant lies still. Therefore, when implemented for a delivery situation, the algorithm will need optimizing, so it's able to detect movements.

Further investigation

Should the concept be a product platform, consisting of one product for monitoring in clinics, one for home monitoring and one for monitoring during delivery?
Can we create an ECG map, as good as the current solution, but with less electrodes?
How can an ECG sensor be placed on the back, in cases where the baby lies far backwards - and is this necessary? (ill. 59)
How can we create better measurements of the contractions? Can it be solved using the data from the microphones, EMG electrodes and accelerometer?



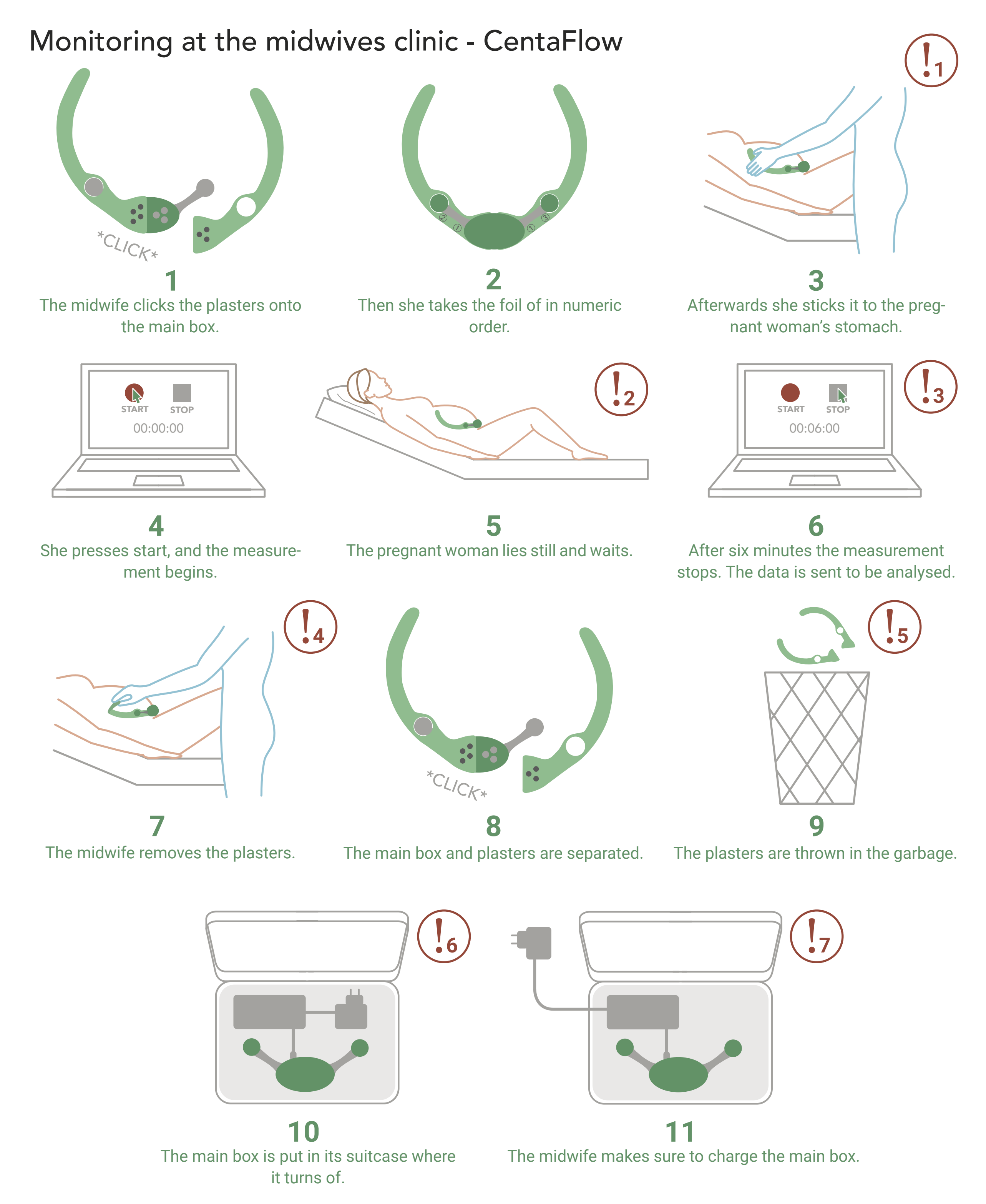
ill. 59 Electrode on the back

Requirements

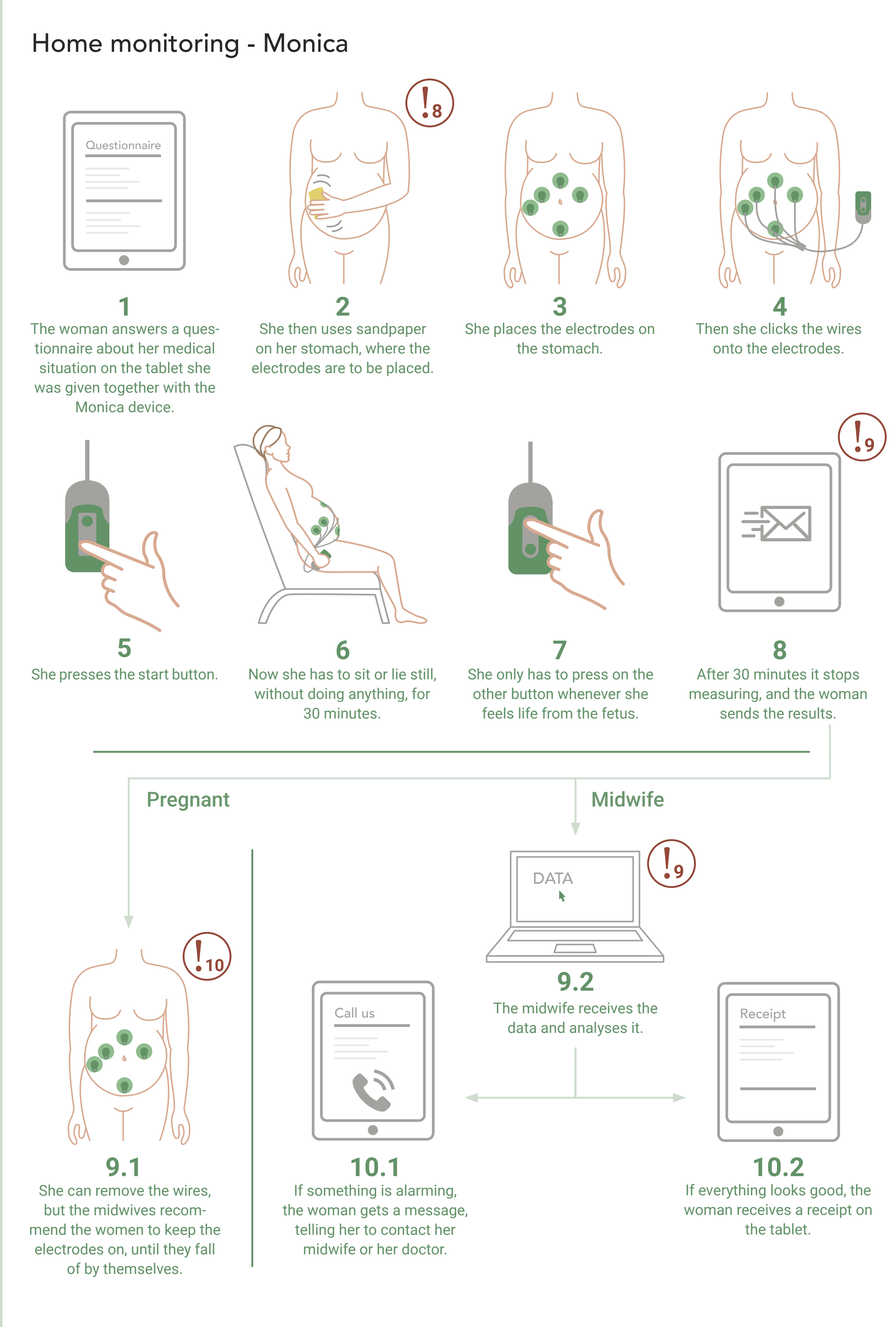
The product should be able to measure the flow in the uterine arteries which means that the microphones should be placed with a precision of +/- 2,5 cm. To solve this, we will take basis in where the microphones are placed on the current product.
The product should be airtight around the microphones measuring towards the stomach.
The product should be able to measure an ECG of the fetus, regardless of the placement of the fetus.
The product has to shut tight around the electrodes in order for them to measure correctly.
The main part should minimum have the capacity of 42 cm^3 to hold its technical components. This reflect the components that are used in the current solution.

What value can we add?

Objective
The objective of this chapter, is to create an overview of the problems and dilemmas, found in the scenarios during the framing phase so far. Thereby, we can create an overview of what is already solved by the technology, and what we then need to solve. To do this, the three scenarios will be illustrated step by step, the problems will be identified, and a table will show whether the technology of the current CentaFlow can solve it, or if we need to do so. The problems will be identified with "!x", but will first be explained in the table at the end of the section.

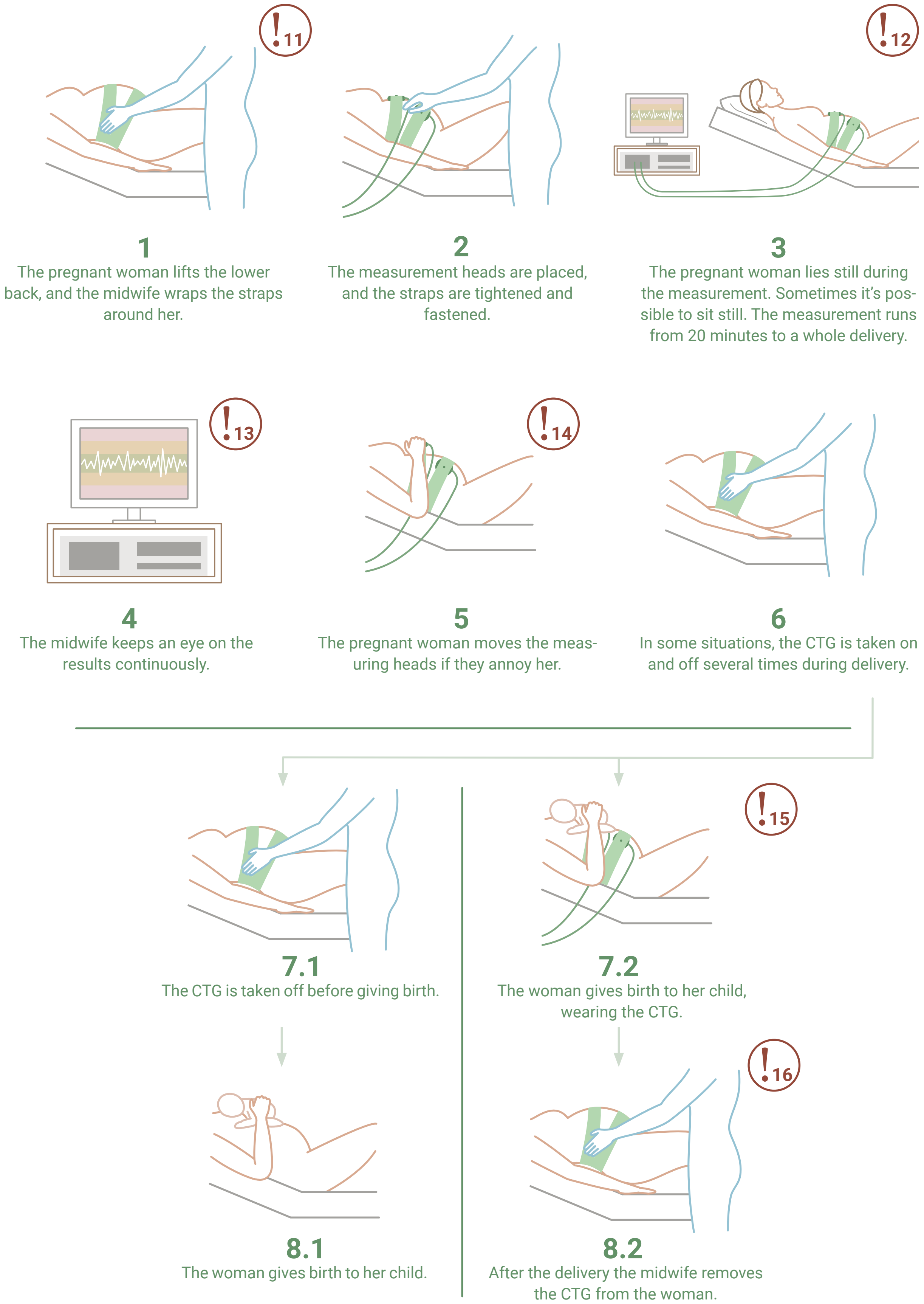


ill. 60 Monitoring at midwives clinic



ill. 61 Home monitoring

Monitoring during delivery - CTG



ill. 62 Monitoring during delivery

The problems and who to solve them

!	Description	CF solves	We solve
1	The midwife doesn't know if she placed the CentaFlow correct, as she doesn't receive any feedback.		X
2	It can be painful to lie on the back for six minutes for a pregnant woman.	X	
3	The midwife doesn't get any results to give the pregnant woman because CentaFlow is being clinically tested. So the future feedback set-up is missing.		X
4	It hurts some women when the plasters are removed because they rip the little hairs on the stomach.		X
5	Both plasters and electrodes are single-use, and are thrown away after use.		X
6	The main box only turns off when being placed in its suitcase, however it can easily be forgotten to place it there.		X
7	After placing the main box in its suitcase, it has to be plugged in to be charged. It's easy to forget, and the suitcase has to be open.		X
8	The woman has to use sand paper on her skin which doesn't feel nice.	X	
9	The midwife is problem solving when the pregnant woman can't get the Monica to work. She isn't educated for this and spends a lot of time on it.		X
10	Some women find it annoying to keep the electrodes on, but they hurt to take off.	(X)	X
11	The birthing woman lifting her lower back, is an undesirable way of getting the straps around her.	X	
12	It's painful for the pregnant woman to lie on her back for at least 20 minutes. Also, the short moving radius works against natural, birth promoting movement.	X	
13	The results will be imprecise or useless if the woman moves.	(X)	
14	The measuring heads and the straps annoy the woman, so she moves them around, resulting in bad results.	X	
15	The new born child is put on the mother's stomach, and on top of the CTG, with all the fluids that is related to giving birth. This demands thorough cleaning.		X
16	Inconvenient to remove the CTG after birth when the woman is tired.	X	

Table 1

Problem 2 and 12 are solved because CentaFlow already allows other positions while being monitored. Number 10 is partially solved by CentaFlow, as their adhesive doesn't stick as much - however some women still feel that it hurts to remove the plasters. Regarding problem 13, CentaFlow makes better results than the CTG, however there are still some problems regarding the woman moving, and sound in the room. The rest of the problems CentaFlow solves, are solved by its product structure. The remaining problems leaves an opportunity for us to solve.

Sum up

With the challenges and problems identified in each scenario, it's clear what CentaFlow can solve by its technology and the current product, but more important, it has clarified a lot of opportunities for us, to make an improved product. First of all, the feedback and interface are completely untouched ground, left for us to explore. Also, there is an opportunity of improving the charging scenario. Furthermore, the user scenario of a pregnant woman, having to handle a home monitoring herself, leaves some different demands than for use in a midwife clinic that could be interesting to investigate. It's also possible to work on the fact that the plasters rip the skin. Finally, a more sustainable path for the product could be explored.

Competitive analysis

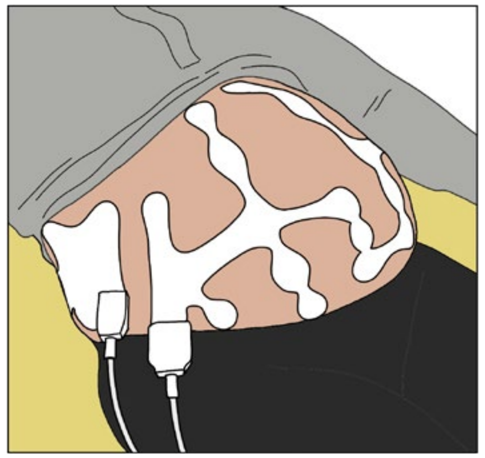
Objective
This section will look into the competitors of CF, and how CentaFlow differentiate from these, to detect CF's position on the market, possible market gaps and the severity of a competitor threat.

According to Henrik Zimmermann, CF's closest competitors are Mind Child and Nemo Healthcare, but he also mentions a company called Nuvo (worksheet 3).

Mind Child

Mind Child (ill. 63) claims to be able to eliminate the use of CTG, fetal scalp electrode, and intrauterine pressure catheter with their solution, Meridian M110 Fetal Monitor. They use electrode patches on the abdomen, the side and the back of the pregnant woman, to monitor during labour. They brand themselves by the ability to monitor in high quality, on women with a high BMI and amount of belly fat (MindChild Medical Inc., 2019).

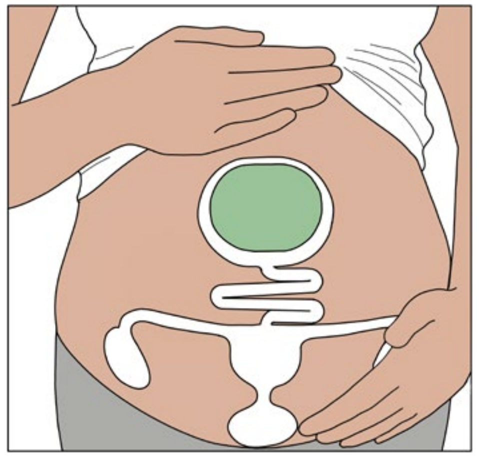
MindChild Medical has currently reached a distribution and supply agreement with Henry Schein Medical (Henry Schein Inc, 2019). It's also approved by the US Food and Drug Administration, FDA, as a product that can be marketed in the US (MindChild Medical Inc., 2017).


ill. 63 Mind Child

Nemo Healthcare

Nemo Healthcare's monitoring device (ill. 64) is aiming to secure safer births and healthier children. They also use electrophysiology, by placing a multi-surface electrode patch with six electrodes on the abdomen, and monitor the mother's and fetus' heart rate, and the uterine activity (Nemo Healthcare, 2020a).

The Nemo Fetal Monitoring System has been CE certified, and their goal is to develop, validate and commercialise the product in 2020 (Nemo Healthcare, 2020b).


ill. 64 Nemo

Nuvo

Invu (ill. 65) is the monitoring device of the company Nuvo. It distinguishes from the other products, as it supports home monitoring, but isn't used in delivery situations. The parents to-be can follow the monitoring on an app, and the clinicians have a dashboard where they can follow, and analyse the data. It measures by electrodes and digital acoustic wave sensors that measure sound level (Nuvo, no date).

Nuvo is currently testing Invu, to validate the product and the technology. They are waiting for an FDA premarket approval, before the product can be sold (Nuvo, no date).

Comparison

The table on next page will compare CentaFlow and the three competitors, by listing the pros and cons. The pros are shown in the green box and the cons are shown in the red box.


ill. 65 Nuvo

CentaFlow	Mind Child	Nemo Healthcare	Nuvo
• Good for monitoring obese women. • Monitors both fetal and the mother's heart rate, contractions and placentas function. • Non-invasive. • Wireless which enables freedom of movement during delivery.	• Good for monitoring obese women. • Monitors both fetal, and the mother's heart rate and contractions. • Non-invasive.	• Good for monitoring obese women. • Monitors both fetal, and the mother's heart rate and contractions. • Non-invasive. • Wireless which enables freedom of movement during delivery. • It is waterproof enough for showers.	• Monitors both fetal, and the mother's heart rate and contractions. • Non-invasive. • Wireless which enables freedom of movement. • Can be used both at the midwives clinic and for home monitoring. • There are no disposable parts - all of it is reusable.
• Takes up relatively much space on the stomach. • Uses disposable patches. • Only focusing on monitoring in clinics.	• Takes up very much space on the stomach and back. • Uses disposable patches. • Only focusing on delivery. • Connected to wire which delimits freedom of movement during delivery.	• Takes up relatively much space on the stomach. • Uses disposable patches. • Only focusing on delivery.	• Takes up relatively much space on the stomach and back. • Only focusing on home monitoring.

Table 2 Pros/cons competitive products

Sum up
Both CentaFlow and the other devices have pros and cons. It seems that Nemo Healthcare is a front-runner, according to making the solution waterproof, or at least water resistant, while Mind Child is a bit behind by not being wireless. CF distinguishes by focusing on the growth of the fetus and function of the placenta during pregnancy, and not only at delivery. Nuvo doesn't trash any part after use, this sustainable aspect is attractive. All of the products are still in the approval and testing phase, where MindChild seems a bit further along. Nuvo is entering the home monitoring market, however none of the companies embrace all three scenarios: pregnancy monitoring at clinics, delivery monitoring and home monitoring. This leaves a gap on the market to fill, and an opportunity to position CF much stronger amongst its competitors. The technology of CentaFlow underlines the opportunity of embracing all three scenarios, but for it to stand out and be good enough to compete with the existing products, the use of the product needs to be exemplary in all the three different scenarios. Therefore, it's essential that we ensure an optimal usage when designing the product, by e.g. making sub-products for the different scenarios.

Requirements

There should be a minimum of waste after the use of the device.

The company set-up

Objective
The objective of this chapter is to identify the company's strengths and weaknesses, as well as the limitations and possibilities, they provide as a collaborator for this master thesis. Furthermore, a SWOT analysis will be executed, to create an overview of the company's internal strengths and weaknesses, and the external threats and opportunities.

As mentioned in the scope chapter, we cooperate with the company CentaFlow (CF) which is a subsidiary company to Viewcare. In total there are 40 employees where ten employees work on CentaFlow. Viewcare has existed since 2009, but it's only in the recent years, they have had a focus on monitoring pregnant women, with their subsidiary company CF. Viewcare is one of the leading companies within tele-healthcare in Denmark. They work with tele-medical solutions, offering platforms where patients can e.g. have virtually consultations with medical personnels, saving transportation time. Their solutions can be downloaded as apps, where the patients can contact doctors, or sit in a virtual waiting room. They can also be used in correlation with clinical measuring equipment, for home monitoring. The apps work as a accumulator for the clinical data which in situations of home monitoring, can be sent to clinical personnel (Viewcare, 2018). This pose an opportunity for us to use their, already existing, platform for collecting, processing and sending data in the home monitoring scenario. Lastly, Viewcare's solutions also work with the communication system OpenTele that is used for home monitoring in Aalborg (Viewcare, 2018) (worksheet 7).

CF is currently using Herpa Tech to manufacture the plasters. Herpa Tech is a company that develops and produces medical self adhesive products that e.g. holds sensors (Herpa Tech, no date). We are not assigned to use them, but it could make sense to investigate their expertise for different solutions. Additionally, CF and Viewcare don't have a production set-up internally, and are therefore not limited, to use a specific production method. This adds flexibility for them, but also for us, as we aren't limited to use a specific material or process.

One of the aspects which are very important to CF, is being able to update and develop the software solution continuously. Furthermore, they need to keep their servers running. Therefore, they are dependent on making enough capital for these purposes (worksheet 3).

Their approach to the market

CF has an initial plan for reaching the market. Firstly, they are running the clinical tests, to get an approval for using the product and technology on women during their pregnancy. After this approval, there is an implementation period, where midwives and hospital personnel need to get familiar with, and gain trust in, the product. Therefore, it's an advantage that they are co-developing the solution with midwives (worksheet 2, 3). When implemented and accepted for use during pregnancy, they wish to start approval for using the product during delivery. As the midwife from Aalborg University Hospital mentioned, it's important that the technology works, and that they can trust and use the product correctly (worksheet 7). Therefore, it might be beneficial for the implementation of the device during delivery, if it's already used for monitoring during pregnancy, as the hospital and personnel then know the product, and it advantages already. CF is not currently looking at home monitoring, but with the mentioned legal requirement from the government, there lies an opportunity of making a solution for this scenario. The current knowledge indicates that it will be too much to implement the product for all scenarios at once, however the thesis' focus will still be to create a product, or product platform, that can be used in all three scenarios.

SWOT analysis of CF

To create an overview of the company, CF, and their strengths (S), weaknesses (W), opportunities (O) and threats (T), a SWOT analysis is executed underneath (MindTools, 2018).

S

- CF has software developers in house.
- They are already cooperating with experts in the field (e.g. doctors, midwives).
- They are a subsidiary company to the more established company Viewcare that has more resources.
- Viewcare works with tele-medical solutions, and therefore already has expertises in this field.

W

- CF is not used to work with product design.
- CF is new on the market for medical products for pregnant women.

O

- Monitoring of only the women needing it, and ensuring the possibility of home monitoring, ideally saving the government money.
- It would be possible to replace the CTG.
- Referring to the competitive analysis, there is an opportunity of making a product platform that solves both monitoring in clinics, at home using a tele-medical solution, and making a solution for monitoring during delivery.

T

- Competitors that focus on one scenario.

Sum up

CF is relatively small, and not dependent on a specific production set-up. As a subsidiary company to Viewcare, it makes sense to use their platform for data collection and sharing, regarding the solution for home monitoring. An important aspect for CF, is to be able to update their software, and keep their server running. This aspect should be included in the business model.

Their plasters, with the incorporated sensors, are produced at Herpa Tech. This pose an opportunity for using Herpa Tech for sparing, regarding materials and production of our concepts, but we are not required to use them, or any other specific production method.

CF's current implementation process is being approved for one scenario at a time, before moving towards other scenarios. Being in competition with companies that focus on only one scenario, there is a need to out challenge the different competitors, by having a more user friendly and more accurate product. Right now, their expertise with product development and usability is low which underline the importance and opportunity we have, to create a better product, using their technology. This can ideally replace the CTG, and save the government money.

With other words we need to utilize CF's strengths, try to seize the opportunities we see, seek to help where they have weaknesses and be aware of the external threats.

Possible business case

Objective

To understand how different business case set-ups can affect e.g. revenue stream and customer relationship, this section will look into several set-ups. The Business Model Canvas (Osterwalder, A., Pigneur, Y., Clark, 2010) will be used for the execution of this, to give a clear, and more visual, picture of the differences between the business cases. The full investigation can be seen in worksheet 5, and this section will show the key take-outs.

Common

Some aspects are the same, regardless of the business case. E.g. it's important to make sure that there are liquidities to make software updates. The revenue stream has to generate enough money to pay the software engineer, and of course to ensure production of products. However, the idea of CentaFlow is originally value driven, coming from a midwife's intention of improving the process. So even though everyone has to earn money, this gives another purpose as well. Thereby money will be put into the project, to develop the product to its best possible state. Then after having created and implemented the product on the market, the company should hopefully start making more and more money. The different regions will be the ones purchasing the product. This is based on: the value proposition to acquit women who don't need extra monitoring, the possibility of giving the women that need extra monitoring a possibility of home monitoring, the certainty of both these women and the midwives to place and use the product correctly, and lastly the financial benefits for the region this will bring.

Buy everything

In this case the region will buy everything, and thereby deliver a lump sum. However, depending on the final solution, there might be a need of purchasing the attachment part of the product separately and more frequently. This model means that CF will get all of the money for the products at once, and maybe some for the attachment running. This will give a large cash flow in the beginning, and then it will flatten out. However, this doesn't enable much customer relationship, as they may not have much reason to keep in contact with CF, for more than software updates. For the regions it can be convenient having bought the product knowing it's theirs. However, this requires investing a lot of money at once. Renting would spread the expenses into smaller bits.

Subscription

The second case is for the regions to rent and subscribe to the product. The execution of this also depends on the final attachment. If it's a single-use solution, as it is now, these parts will be delivered frequently, where a reusable solution would be delivered once. Regardless, the money flow would be more steady, as there would be a monthly payment from the regions. This model enables a better customer relationship than the previous because there would be a service for reparations. It would be an advantage for the regions to divide the payment into smaller bits, to stay within the budget. Also, they get access to a reparation service that secures functioning devices, and no further expenses if a device breaks. However, it may get more expensive in the long run, and there would be a resignation period to secure CF.

Rent main part, buy attachment

Another possibility would be for the regions to rent the main part, and buy the attachments. This way the highest expense for the regions is paid right away, and then they can purchase the attachments according to their need. Like the previous model, this enables a higher level of customer relationship, regarding service and sparring. This is also a model that divides the payment, but where there would be a resignation period.

Get main part, buy attachment

For an easier approach to a purchase agreement, it could be a possibility to give the regions the main part, and then have them buy the attachments. For this model to make sense, the attachment solution has to be bought rather frequently, and enable a certain level of cash flow. It would be easier for the regions to purchase, when considering their budget, however the deal would have to have a resignation period, to ensure CF.

Pay per pregnant

It could also be a possibility to make a pay-per-view-like agreement, where the regions pay per pregnant. This would also enable easier access to a purchase agreement, as the regions aren't paying a large sum at once. As the previous models, this would probably mean that there should be a resignation period. With this model, it would be possible to more or less predict the income for CF, as they could use statistics on the amount of pregnant women.

Comments from Henrik from CF

Henrik mentioned that CF would only be equipment supplier if the regions buy the device, and underlines the importance of getting liquidities to run the server and also update the software (worksheet 3). Therefore, the business case should enable this by ensuring a reasonable cash flow (worksheet 3). Furthermore, he states that it's important that the scenario of the device has to save the regions money, in comparison to the current solution. However, that it isn't a problem if the main part costs 10.000 DKK and the attachments a few 100 DKK (worksheet 3).

Sum up

There are several business cases that could be possible for CF, however the key takeaway is that it should be beneficial for both CF and the regions that buy the product. CF has to get money for software updates and running the server, but the price and payment agreement should be beneficial for the regions, and stay within their budget. Also, it would be preferable to get a certain level of customer relationship, to ensure loyalty. To choose the business case it would make sense, talking to Jakob from CF who is engaged in this, and discuss the ideal scenario, on the basis of the final concept. This would make sense when having a complete product, as the business case differentiate according to this.

Define

The following phase works as the basis document of the report, and is a sum up of all the important aspects that is needed for creating a successful product. It contains a new edition of the thesis statement, vision, mission, and a description of the value we wish to create for the stakeholders. Lastly, a list of the initial requirements, the product must fulfil, is presented.

CF has introduced CentaFlow, to be used for monitoring pregnant women at the midwife clinics, however there haven't been thought much of the user experience. Furthermore, they wish to introduce CentaFlow to home monitoring and the birthing situation, but it's only developed with pregnancy monitoring in clinics in mind. Thereby, there are a lot of possibilities to enhance a good user experience, and develop a concept that is better suited use for delivery and home monitoring, as well as improving the use at the clinics.

Thesis statement

How can we, by utilizing CF's technology, create a product that enables a good user experience, intuitive use and intiutive placement on a pregnant woman, while also being applicable in the three scenarios: monitoring in clinics, home, and during delivery? This, to ensure comfortable monitoring that both the midwives and pregnant women can trust.

Vision

We want to improve the experience of monitoring during pregnancy and delivery, to create trust in the monitoring device and its results, and thereby eliminate uncertainty. This, in a way where the pregnant experience as little discomfort as possible.

Mission

We will enable comfort and a sense of safety during pregnancy and delivery, in the most pleasant and convenient way, by implementing the technology of CentaFlow in a user friendly, reliable product or product platform. This should be achieved through multiple user tests and interviews.

Value for the stakeholders

CentaFlow already solves some issues from the current solutions, e.g. the possibility of moving wireless around, and being able to acquit more pregnant women from unnecessary monitoring. However, as mentioned earlier, it still has some pitfalls. E.g. it's in the way when bending forward, and it rips the skin when changing position or taking it of. (See Table 1 p. 31 for the full overview)

The values we want to add for the stakeholders are:

CF

It should be a cost effective solution that secures liquidities for the company, and for further development of the technology and product.
According to current trends, the product should be more sustainable than the current product (a requirement we wish to add to the product).

Midwives

The product should be trustworthy e.g. by intuitive use, and data that is easy to interpret.
It should be easy to use during their busy schedule e.g. by being easy to attach, with no doubt about the placement, and thereby the output of data.
Also it should be easy to detach.

Pregnant women

The product should be trustworthy e.g. by intuitive use that enables the pregnant woman to monitor herself at home.
The product should enable the women who need monitoring during delivery, to choose the way of birth.

Initial requirements

Following requirements have been divided in common requirements, and requirements that are specific for each of the user scenarios. The common requirements are the most important, as they are necessary for creating the minimal viable product. The requirements are listed in a prioritized order, where the first requirement is the most important. The table with "Common technical requirements" isn't prioritized, as all of the requirements need to be accomplished for the product to work.

Common requirements

Req. no.	Requirement	Source/section
1	The product should be intuitive and easy to use, so the midwife or pregnant are sure of the placement of the product	Monitoring during pregnancy in midwife clinics, Home monitoring during pregnancy, Monitoring during delivery
2	The product should fit and monitor a pregnant from week 24 to 42	Monitoring during pregnancy in midwife clinics, Home monitoring during pregnancy, Monitoring during delivery
3	The data received by the midwives, should be displayed on a screen and be easy to interpret and act upon, while not being alarming to the pregnant. a) The ECG curve should be displayed as it is now b) The measurement of the flow in the uterine arteries should be displayed on a scale	Monitoring during pregnancy in midwife clinics, Home monitoring during pregnancy, Monitoring during delivery
4	The product should withstand being dropped multiple times	Monitoring during pregnancy in midwife clinics
5	The product should ensure that the midwife and pregnant remember to charge it after use	Monitoring during delivery
6	The product shouldn't be in the way of sitting or bending positions	Monitoring during pregnancy in midwife clinics, Home monitoring during pregnancy, Monitoring during delivery
7	The product should not rip the skin unnecessarily when being removed or moving around	Monitoring during pregnancy in midwife clinics, Home monitoring during pregnancy, Monitoring during delivery
8	There should be a minimum of waste after the use of the device	Monitoring during pregnancy in midwife clinics, Competitive analysis

Table 3

Common technical requirements

Req. no.	Requirement	Source/section
1	The product should be able to measure the flow in the uterine arteries which means that the microphones should be placed with a precision of +/- 2,5 cm. To solve this we will take basis in where the microphones are placed on the current product	
2	The product should be airtight around the cavity of the microphones measuring towards the stomach	
3	The product should be able to measure an ECG of the fetus, regardless of the placement of the fetus	
4	The product has to shut tight around the electrodes in order for them to measure correctly	
5	The main part should minimum have the capacity of 42 cm^3 to hold its technical components. This reflect the components that are used in the current solution	
6	The reusable parts of the product should be able to be cleaned with ethanol alcohol, soap water and active chlorine. If the solution holds textile it has to withstand being hot cycled	Home monitoring during pregnancy, Monitoring during delivery

Table 4

Clinic

There are no individual requirements for monitoring at the midwife clinics. However, we have a slight concern if six hours battery is enough doesn't put the device back in the charging station after use.

Home

Req. no.	Requirement	Source/section
1	The pregnant should be able to report every time she feels life, during the monitoring session	Home monitoring during pregnancy
2	The product should measure for 30 minutes	Home monitoring during pregnancy
3	The product shouldn't irritate the skin, and should be able to be taken of fully in between sessions	Home monitoring during pregnancy

Table 5

Delivery

Req. no.	Requirement	Source/section
1.a	The product should have battery capacity for monitoring in 24 h	Monitoring during delivery
1.b	The product should stay on, regardless of being exposed to sweat and body fluids	Monitoring during delivery
2	The product shouldn't be attached with straps that is placed tightly around the body	Monitoring during delivery
3	The product should be able to withstand water from being worn under a shower or in a bathtub	Monitoring during delivery
4	The product should be able to be charged within 4 hours or have changeable batteries	Monitoring during delivery
5	When the product is used intermittent it should be easy to attach and detach	Monitoring during delivery

Table 6

Conflicting demands

In the requirements there are some statements that are conflicting, and almost working against each other. We have to be very aware of these in order to find a solution that either manage to solve both, or to make a deliberate and qualified decision about which to prioritize. The conflicts are listed below.

1. We want a solution that doesn't rip the skin, like the current solution does. However, it still has to withstand movement, sweat, water and other fluids for the delivery situation. Many plasters would either rip the skin, or fall of during the aforementioned.

2. It's also contradictory that the device should be taken off easily during intermittent monitoring at deliveries, while it should also stick well enough, to resist the challenges mentioned in conflict 1, for a continuous monitoring.

3. Furthermore, if the solution have to stick to the skin, rather than being wrapped around the abdomen, it can't be all reuse. So the wish of ensuring a more sustainable solution is challenged by this.

4. Another challenge is that the microphones need air to work, therefore there are holes in the casing. However, there exits a wish that women can give birth in water, go take a shower, and also there is a possibility for other fluids during delivery that can get through these holes, destroying the microphone.

5. Aforementioned isn't the only consideration regarding the microphone that listens to noise in the room. Dust can also be an issue that could block the holes, resulting in worse measurements, because air isn't passing through as well or at all.

Concept

Following phase will be describing the concept development and the approach to find the final and best possible concept. Different concepts, user tests and mock-ups will be presented to understand the direction and choices made when trying to achieve the initial requirements and thereby the best solution.

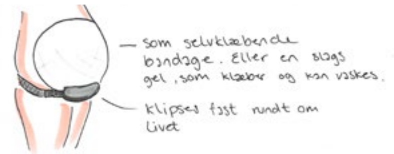
- Initial concept development
- Targeted focus
- Ensuring correct placement
  - Multiple tests with mock-ups
  - Test on Pregnant
  - Feedback from CF and midwives
- Choice of concept
- Detailing of concept
  - Ensuring good quality measurements
  - Detailing of single-use plaster solution
  - Initial material and production considerations
  - Wire solution
  - Identity of product

Initial concept development

The following section will be describing an initial concept development which was conducted simultaneously with the framing phase. These concepts were made by sketching on initial speculations and challenges obtained early in the project. Therefore, it was rather unstructured, but used as a kickstarter of the concept development.

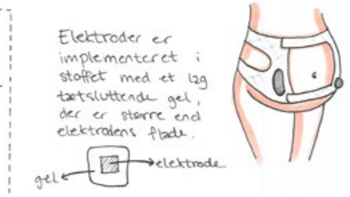
A solution that doesn't rip the skin

The following concepts were made to find a solution that doesn't rip the skin, like the current solution does, but is able to stay on the skin in the different scenarios. Therefore, there was made some ideas to what could be used for attaching the device, other than the current plasters, e.g. by strapping something around the stomach (ill. 66, ill. 68) or by using sticky bandage (ill. 67).



ill. 66

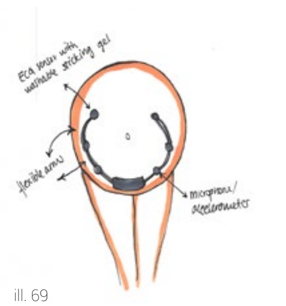
ill. 67



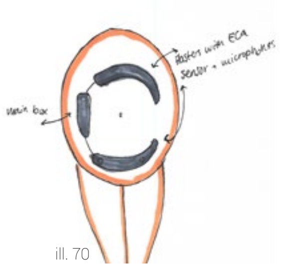
ill. 68

The concepts where straps are used to keep the electrodes and microphones close to the body, would probably work for monitoring during pregnancy both in clinics and at home, but regarding delivery we have the conflicting demand mentioned earlier, that there shouldn't be any tight straps around the stomach. Furthermore, we wonder if the straps need to be so tight to seal tight, that they will be uncomfortable to wear for home monitoring and monitoring at the clinic as well.

Regarding a solution using plasters, there is an assumption that if the adhesive only is placed in small areas, instead of a long ongoing piece as the current CentaFlow, the solution will rip the skin less (ill. 69, ill. 70).



ill. 69



ill. 70

Furthermore, it's a concern that the adhesive on the current solution won't stick properly to the skin while moving, sweating and being in a bathtub. This should be investigated and alternatively we need to find another adhesive with other properties, or it might be solved by having different kinds of adhesive on plasters used for monitoring during pregnancy and delivery.

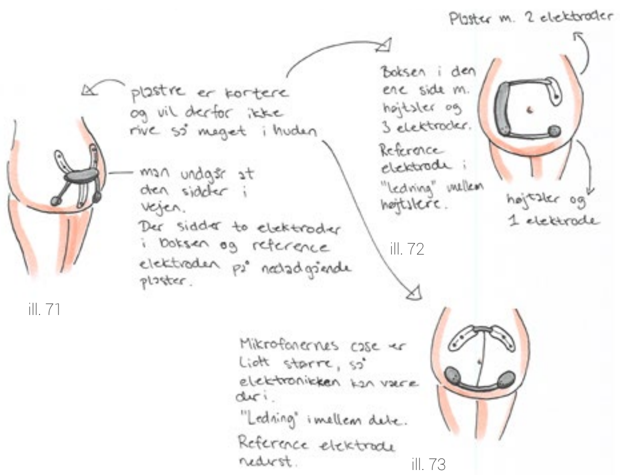
Further investigation

We need to test if the current plasters, both for the Monica device and CentaFlow, stick to the skin when sweating, moving and being in a bathtub.
We need to test if the assumption that smaller pieces of adhesive, will rip the skin less than a larger piece.

A solution where the main box isn't in the way

Following concepts were made to ideate upon where and how the main box could be placed, without being in the way of bending and sitting. This is done based on the observation from the first meeting with Stine and Stina in Viborg, where it was in the way when bending (worksheet 2).

There was ideated on concepts where the main box was in the middle of the stomach, on top of the belly button (ill. 71), on the side of the stomach (ill. 72) and one where the electronics were divided in two, and placed beside the microphones, making the cases for them bigger (ill. 73).



ill. 71 ill. 72 ill. 73

When thinking of solutions where the main box doesn't get in the way of bending and sitting, we need to remember all of the other natural positions and movements, that occurs during a delivery, so we doesn't hinder any of them either.

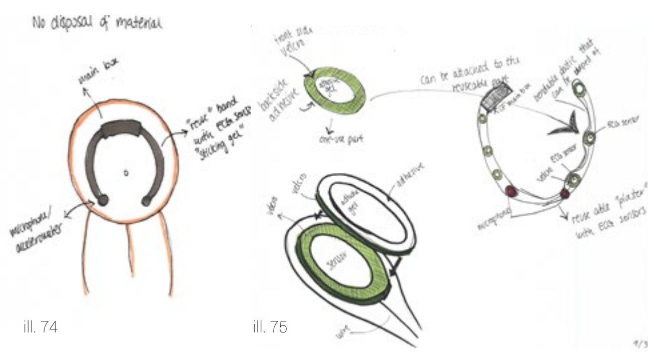
Reusable attachment

Currently, the plasters of CentaFlow get thrown away after use, which means that besides the plasters, seven sensors will be thrown away after each monitoring session. This originated a wish of making a more sustainable solution. Therefore, we made some initial concepts, on how we could reduce or eliminate single-use.

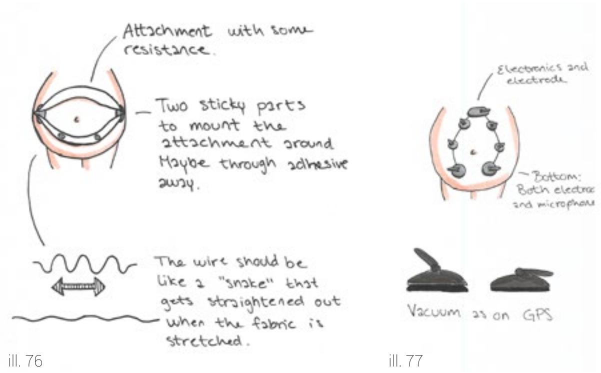
We imagined that it would be possible to make a reusable plaster, e.g. by making the adhesive reusable (ill. 74). But after further considerations it seems uncertain that it could withhold the adhesive properties when being used multiple times.

We also looked into other application possibilities, as using vacuum the same way a GPS mount does (ill. 77), or using a mount on each side of the stomach, with removable and replaceable adhesive stickers on, that could hold some textile in place around the stomach (ill. 76). A solution that could be used on the aforementioned concept, and many other concepts, is ill. 75, which is a single-use double adhesive part, that can be placed on a reusable products, to make it stick on the stomach.

All three concepts cause some concerns. The vacuum concept might leave hickies and we are concerned that it will fall off easily if the woman moves. ill. 76 may be in the way of moving the arms naturally, and the double adhesive solution leaves a lot of interaction steps.



ill. 74 ill. 75



ill. 76 ill. 77

Product family

At this stage we wish to make a product that can be used in all three of the mentioned scenarios: clinic, home and delivery. However, we see some challenges and conflicts in the scenarios that got us thinking of the possibility of making the products as a product family that share the same main box and microphones, but have some different add-ons, suitable for the specific scenario (ill. 78).

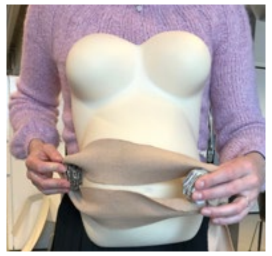
However, we still wish to make a product that is as suitable for all scenarios as possible, to e.g. lower production costs, but the product family option is a possibility. As mentioned the solution with a strap around the body isn't ideal, but the illustration illustrates the idea of the product family.

ill. 78

Mock-ups

We had been making many different concepts in sketch form. But to move past this fuzzy front end, we needed to start building mock-ups and testing interaction to find a direction. By creating mock-ups, we could additionally get some wonderings and concerns denied or confirmed, as well as obtain knowledge we hadn't initially thought of. We chose the concepts we wanted to challenge, also with the acknowledgement of some concepts being domed from the beginning. The full test is shown in worksheet 8.

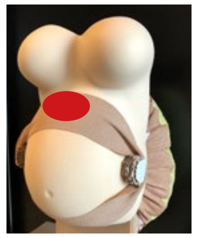
Concept 1
Firstly, we made a prototype of ill. 76. The procedure is to stick the first mount on the belly (ill. 79), then drag the textile and second mount to the other side of the stomach to place it (ill. 80), and then lastly fine adjust the textile to be placed correctly (ill. 81).

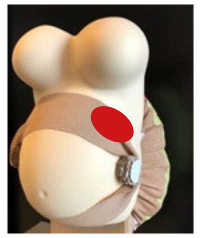

ill. 79 Concept 1

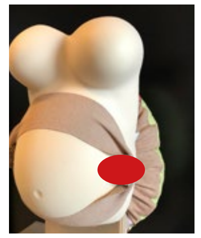

ill. 80


ill. 81

As you can see on ill. 81, it was difficult to place the two mount in the same height, and this can interfere with a correct position of the microphones, and thereby measurement. We also noticed that the height of the mounts hindered movement of the arms, as they hit them. It could maybe be solved with a lower part. Furthermore, we didn't consider the placement of the main box, so this should be investigated (ill. 82-ill. 84). Also, we have to figure out how tight the band needs to be, in order to make the electrodes and microphones shut tight. We have an assumption that by not having the textile all the way around the body, the pregnant won't feel as enclosed. However, this might be affected by how tight the bands should be. Lastly, we have to consider how to clean it, as the textile has to withstand a boil wash, and the mounts and electronics have to either withstand this too, or be able to be detached when cleaned, resulting in a lot of separate parts.


ill. 82


ill. 83


ill. 84

Concept 2
The second concept consists of a single-use double adhesive part, that should be placed on other products (ill. 75). We combined this with the shape of ill. 74 where the main concept was reusable.

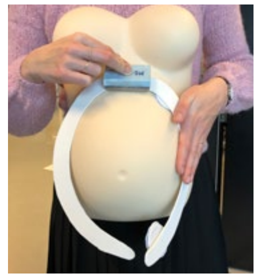
Using the small parts, you take the first foil off to place the part on the electrode or microphone (ill. 85), and then you take off the second foil (ill. 86) to stick the device on the stomach (ill. 87, ill. 88). After use, the stickers get thrown out, and the device is cleaned. The initial idea of the concept was to make one side in velcro. However, due to concerns about hygiene and cleaning, the velcro part on the main device, both sides became adhesive.

The sliding motion of placing the "arms" was nice and easy, however they were too long (ill. 87). Also, the placement of the microphones can vary a lot on different stomachs as the main attachment point (the main box) is far away from them. As the placement of the microphones are important, this is an issue.


ill. 85 Concept 2


ill. 86

ill. 87 Concept 2

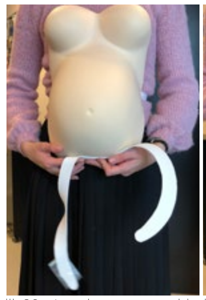

ill. 88

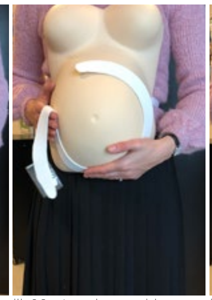
Placement of the main box

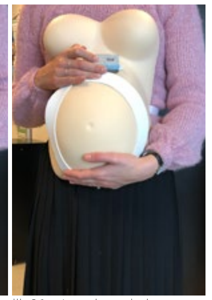
When we uncovered the problem of the microphones' placement, we realized that we needed to test the placement of the main box with the right weight (approximately 140 g), to test the influence this could have on the interaction, when attaching the concept. As the interaction of concept 2 above was good (ill. 87), we made the test on a similar shape. This is also shown in worksheet 8.

Placement 1
The first placement was with the arms upwards, and the main box at the end of one of them (ill. 89-ill. 91).

This didn't give a desirable interaction. It was troublesome to attach the main box, probably because it was far away from the first attachment point. If attaching an end first, there would be a big risk of placing the microphones wrong like ill. 87.

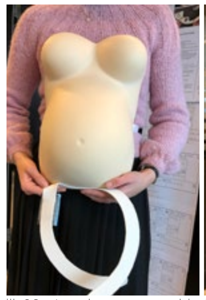

ill. 89 Attach at mons pubis


ill. 90 Attach one side

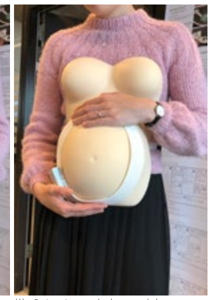

ill. 91 Attach main box

Placement 2
On the second placement, the main box is placed further down the arm, and closer to the first attachment point (ill. 92-ill. 93).

This placement was better than placement 1, as the weight was closer to the first attachment point. Offhand, the main box wasn't in the way of moving the arms freely, however this should be tested, if this placement is used.


ill. 92 Attach at mons pubis

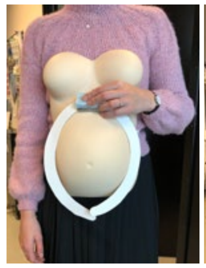

ill. 93 Attach main box

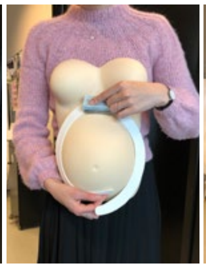

ill. 94 Attach last side

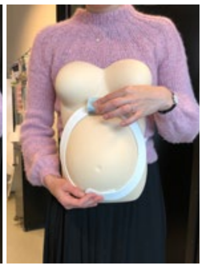
Placement 3
This is the same placement as concept 2 from previous section (ill. 95-ill. 97). Therefore it's the same concerns that occur. Even though it's a nice feeling of the interaction, the uncertainty of the placement of the microphones is too great.

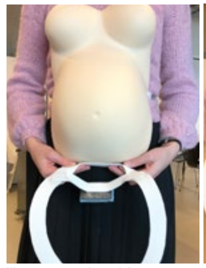
Placement 4
The last placement gives a supplementary part to the arms. It is a horizontal crossbar, where the main box can be attached in the middle, close to the first placement point, but further up on the stomach, to ensure it doesn't get in the way of bending and sitting (ill. 98-ill. 100).

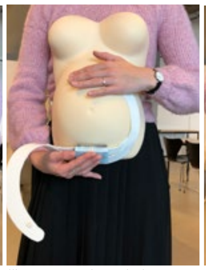
This interaction was okay, however placement 2 seemed better. It is a concern that it might not fit well to different shapes of stomachs, with the crossbar. The closer to mons pubis the crossbar is placed, the less of a problem it would be. However, it's more likely to be in the way of bending and sitting. So these concerns should be tested, if this placement concept is used.

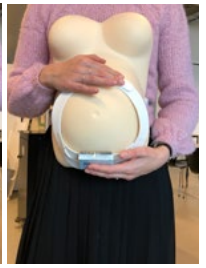

ill. 95 Attach main box


ill. 96 Attach one side


ill. 97 Attach last side


ill. 98 Attach guide


ill. 99 Attach main box


ill. 100 Attach sides

Sum up
This rather large section with different concept developments and our fuzzy front end, resulted in some information that is rewarding, to bring into our further ideation. We know that a feeling of being encased isn't desirable for the pregnant women, therefore the concepts ended up being a lot of adhesive solutions. Regarding this, the assumption is that smaller areas of adhesive rips the skin less than bigger areas, so this should be tested.

Our tests showed that placing the main box on the side of the stomach, close to the bottom seemed good because of its weight, both regarding easy attachment, and not being in the way of sitting and bending. It's important to make something that is easy to put on, while ensuring the correct placement of the microphones. Having the majority of the weight close to the first interaction point, is desirable to ease interaction. There could be other possible placement solutions that make sense when we proceed.

Nevertheless, we continue working on a solution with less single-use that stays in place without irritation or leaving marks, even if moving and sweating. The solution could be a product family if some requirements can't be solved across the scenarios.

Targeted focus

At this point, the framing phase was done which enabled more structure of the further ideation. To enable this we needed to understand the core criterias the product must fulfil, and therefore we roughly used the model Core Design Framework (Rosenstand and Vistisen, 2017).

The most important criteria regardless of the user scenario, is to solve how to ensure correct use. If the midwife or pregnant aren't able to place it correctly, the measurement will be flawed and not usable. By attaining this criteria of correct use, it requires the first three and most important requirements to be solved (Table 3 p. 38):

1. The product should be intuitive and easy to use, so the midwife or pregnant are sure of the placement of the product
2. The product should fit and monitor a pregnant from week 24 to 42
3. The data received by the midwives should be displayed on a screen, and be easy to interpret and act upon, while not being alarming to the pregnant.
    - The ECG curve should be displayed as it is now
    - The measurement of the flow in the uterine arteries should be displayed on a scale

To solve these demands, we will be focusing on home monitoring because we assume that if a pregnant can use and place the product herself, the midwives will additionally be able to do so. In other words, the scenario of a pregnant placing and using the product herself, is the most challenging regarding the interaction and placement of the product.

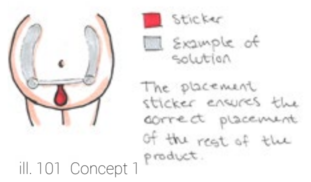
Ensuring correct placement

To ensure that the pregnant women can place the product correctly, we ideated on ways to enable this.

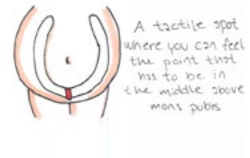
Placing the microphones correctly

Objective
Firstly, we focused on the correct placement of the microphones, as they are the ones that requires the highest precision. We didn't think much about the placement of the electrodes at this point. Therefore, the following chapter will be investigating how to ensure that the microphones are placed correctly, bearing the results from the initial mock-up session in mind. The full test is shown in worksheet 9.

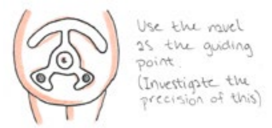
Prior to the ideation, we had an assumption that most people would know where the top of mons pubis is (the top a the venus triangle). We asked eight random people, both women and men, to point where they thought it was, and they all pointed at the correct spot. Therefore, multiple of our concepts was based on placing the it after mons pubis (ill. 101-ill. 107 concept 1, 2, 4, 5, 6). We had an idea of placing the product using the navel, but during pregnancy the navel will move significantly, and therefore the microphones will end up being placed too high (ill. 103). The top of mons pubis won't move as much during pregnancy.



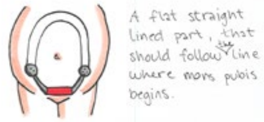
ill. 101 Concept 1



ill. 102 Concept 2

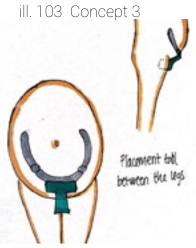


ill. 103 Concept 3

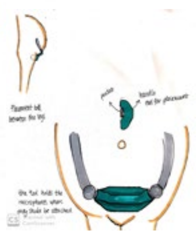


ill. 104 Concept 4

After evaluating on the ideas, we chose to build mock-ups of concept 1, 2, 4 and 5. The others weren't selected because concept 3 was using the navel as guide, concept 6 didn't add anything extra than concept 1, 2 and 4. Lastly, concept 7 was not chosen because of the dilemma of having something surrounding the stomach, and the complexity in making pants that fits multiple pregnant women.



ill. 105 Concept 5


ill. 106 Concept 6

ill. 107 Concept 7

Concept 1: The idea with this concept is to have the round shape, to place at the top of mons pubis. The guide is coloured to create feedforward, and indicate an interaction area (ill. 108).

Concept 2: This concept has a flat straight surface that should be placed at the top of mons pubis. The guide is again coloured to create feedforward, and it also has tactile feedback on the guide. The idea is that the user can feel where the guide is, without being able to see it (ill. 109).

Concept 4: This concept has a longer and larger straight guide, and again feedforward with colour (ill. 110).

Concept 5: The idea with this concept is having a guide tool which is placed between the legs, and used to place the product by. The tool is placed as far up as possible, and then the product is placed after the top of the tool (ill. 105, ill. 111).


ill. 108 Concept1


ill. 109 Concept 2


ill. 110 Concept 4

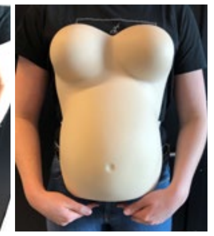

ill. 111 Concept 5

To test our assumption of people being able to place the concepts correctly after mons pubis, we tested on ourselves and on one testperson. Firstly, we tested if we/she were able to place the fingers on the stomach, and at the top of mons pubis in different scenarios:

- One where they should place the fingers on their own stomach, while being allowed to see (ill. 112).
- One where they couldn't see their stomach (ill. 113)
- One where they should place them wearing the fake stomach (ill. 114).


ill. 112


ill. 113


ill. 114

The test indicated that we, and the testperson, all were good a placing the fingers in each side straight, even when we couldn't see (ill. 112-ill. 114) (worksheet 9). We did the same test with the different mock-ups, again using ourselves and the test person (ill. 115-ill. 118) (worksheet 9). The test indicated that concept 1 was harder to place because of the rounded shape on the guide area. It didn't have a up, down and sides like the other concepts, and therefore it was harder to feel if it was placed straight.

The test also indicated that the idea of having a straight guide seemed good, as it was easier to feel if it had been placed straight. However, the guide on concept 4 seemed too long (ill. 117). It was hard to find the middle of both mock-up and top of mons pubis. The guide on concept 2 seemed better, but it could be a bit longer. This indicated that the guide should be around 9 cm long. Furthermore, our testperson mentioned that the tactile spot on concept 2, reassured her that she had turned the concept the right way when not being able to see it. Additionally, when testing the concepts on ourselves, we found the tactile spot good, as it indicated the guide.

Generally, we were able to place the concepts straight, with exception of concept 4, also without using the tool from concept 5. A reason for the skew placement of concept 4 could be the length of the guide.


ill. 115


ill. 116


ill. 117


ill. 118

Sum up

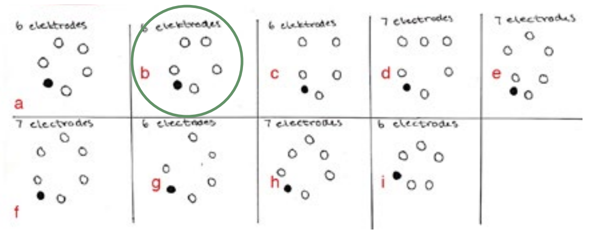
From here on, we will be working on having a straight guide on approx. 9 cm, with tactile horizontal guides on our concepts. Additionally, we will be working on concepts without a separate tool because the tests indicated that it's unnecessary. If during test of mock-ups, this appears to be wrong, we should reconsider this. We have worked a bit on feed forward and feedback in relation to placing and interacting with the concepts, but not on feedback from the technical parts (e.g. the microphones). This we need to consider as well.

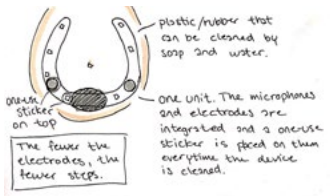
Concept development and placement of the electrodes

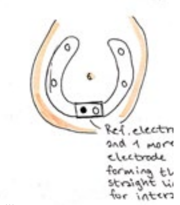
Objective

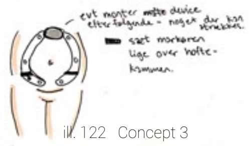
To incorporate the placement of the electrodes, with the newly found knowledge from the previous test about having e.g. the tactile straight guide, we started on ideating on different ways to create the needed web of the electrodes, without going against the Monica patent. As mentioned under the technical limitations and possibilities, it's important to create a somewhat vertical direction from the bottom of the stomach, to approx. 10 cm over the navel, and having electrodes on the sides. The following chapter will be investigating how to incorporate our reflections off the electrodes placement in a concept. The full investigation is shown in worksheet 12.

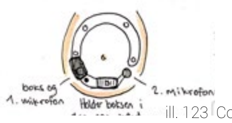
We started by ideating on ways to connect the electrodes and create the needed span (ill. 119). This created a basis for a new ideation and mock-up phase. Most of the concepts used the electrode placement B, with one less electrode than the current CentaFlow solution. When evaluating on the concepts we found it easy to incorporate almost everyone of the placements. To determine if e.g. placement B goes against the Monica patent, we should talk with Henrik from CF, but the overall criteria must be to create the span, using as few electrodes as possible.
From the different sketches we listed the pros and cons, and decided to create mock-ups of (worksheet 12):

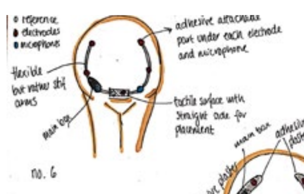

ill. 119 Ways to place the electrodes


ill. 120 Concept 1

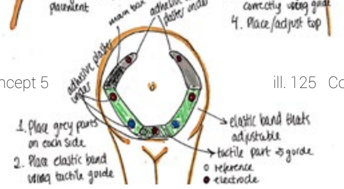

ill. 121 Concept 2


ill. 122 Concept 3


ill. 123 Concept 4


ill. 124 Concept 5


ill. 125 Concept 6


ill. 126 Concept 7

- **Concept 3** (ill. 122, ill. 127) because of the idea of using the ilium bone (the hip bone) to place the product after. We wanted to investigate if the hips could be used to place the product after. The mock-up has tactile coloured guides in each side that should be placed perpendicular to the top of the ilium bone, to create feedforward and feedback (ill. 127). The sides are placed one by one, and lastly the main box is attached in the top (https://drive.google.com/file/d/1_gN_47pl1bGWaWYqXoTzLveOldpzdj_i/view?usp=sharing)
- **Concept 4**, (ill. 123, ill. 128) because of the different shape of the part surrounding the stomach. It differentiated from the previous concepts, and we wanted to investigate how the interaction behind this concept was. The mock-up has the main box attached on the side, and a tactile and coloured guide (ill. 128). The idea is that the pregnant holds the main box in one hand, while placing the guide and microphones with the other (https://drive.google.com/file/d/1joGwQ26hdzXmWkHq-480PiF46YH_QPZz/view?usp=sharing).
- **Concept 5**, (ill. 124, ill. 129) because it worked with the idea of having flexible, slimmer and more stiff "connectors" between the electrodes and microphones. We wanted to investigate if it was easier to place the product if the "arms" didn't bend down as easy as the plasters on the current CF solution. The mock-up has the main box placed on the side, and the connectors is used to create the tactile feedback, together with the straight part in the bottom (ill. 129). The concept is placed by placing the guide after the top of mons pubis, and then attaching the rest (https://drive.google.com/file/d/1Rpxwg0gXX6QCJdMJsl1N2n-wINHtI5_GS/view?usp=sharing).
- **Concept 7**, (ill. 126, ill. 130) because of the similarity to concept 1, ill. 81 p. 42, from the initial concept development. This concept uses the previous concept as a basis, and is a further development of it, with the number of straps reduced to one. We wanted to see if it would be possible to drag the microphones down, after placing the two side guides. The mock-up has two parts on the top, on each side that should be placed on the stomach. One of these should have the main box incorporated, and in the flexible fabric there should be a guide to help place the microphones correctly (ill. 130). The pregnant should start with placing the top parts, and then drag the microphones down to the correct position, using the guide. The top of mons pubis is used to place the guide after (https://drive.google.com/file/d/14RBVVJXNLrPBtAhksZ7u26lRwqTD-bvOs/view?usp=sharing).

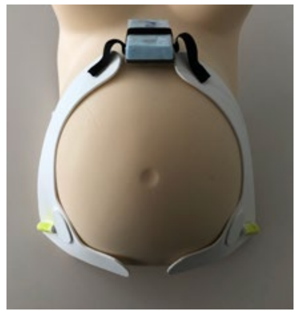
To reduce the amount of single-use on the product, the idea is that the previous concept with single-use double adhesive (concept 2, ill. 85 p. 43) should be used on the different concepts.

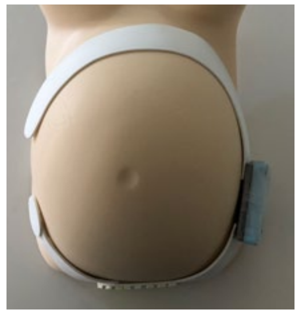
Feedback from test-persons

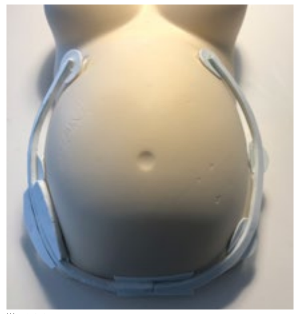
The mock-ups were tested on four different test persons including ourselves, and the overall purpose was to get feedback on the interaction, and to see if everyone were able to place the concepts correct. The full test is illustrated in worksheet 12 where a fake stomach was used.

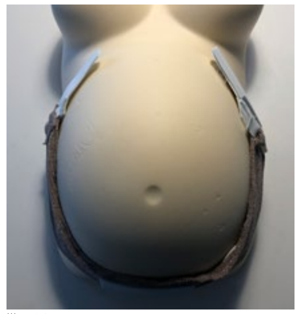
The feedback and comments to the different concepts was:

- **Concept 3**: it was hard to know which specific area on the ilium bone the product should be placed after, and one test-person forgot to attach the part with the micro-


ill. 127 3


ill. 128 4


ill. 129 5


ill. 130 7


ill. 131 3 Cora


ill. 132 3 Zebina


ill. 133 4 Cora


ill. 134 4 Zebina


ill. 135 5 Cora


ill. 136 5 Zebina


ill. 137 7 Cora


ill. 138 7 Zebina

phones, after having attached the guides (ill. 131). Additionally, it requires a lot of steps to place this product which could cause the product to be placed wrong. One testperson felt she had placed it wrong because the two sides in the top wasn't placed equally (ill. 132). Lastly, the product consists of three independent parts which could be a concern regarding losing a part.

- Concept 4: The interaction with attaching the upper part of the plaster felt good and satisfying, but there were some concerns about placing the guide straight when the product isn't symmetric, two of the test-persons placed it a bit skew (ill. 133, ill. 134). Additionally, one test-person found it a bit weird that the weight wasn't in the middle.
- Concept 5: The interaction with the flexible yet a bit stiff connectors seemed good, but one test-persons "stumbled" over the main box when placing the product because it wasn't symmetric. The connectors flex when sitting down, and because they aren't sticking to the skin, they are able to move rather independent. The product was easier to place straight (ill. 135, ill. 136).
- Concept 7: The interaction is more problematic, and it's hard to interpret how to place the two parts in the top. One test-person felt that the lower part was sliding up after placement, and that she didn't have as much control over the placement as with e.g. concept 5. Furthermore, it's a concern how to clean the fabric, and whether the different sensors should be detached. If detached a lot of different parts will have potential to get lost (ill. 137, ill. 138).

During the test there were different sources of errors which might have influenced the results. The adhesive used to test, was not added on all of the intended areas, but only in an amount so the concepts would stick to the stomach. Additionally, the adhesive tape used, didn't have the same amount of adhesive ability as the wanted plaster. This might have influenced the test-persons interaction, and thereby the feedback to the concepts. But the overall interaction and feedback to each concept, still seemed quite clear, even though the adhesive wasn't as strong.

Generally, it's a source of error, not being able to feel the body and stomach when wearing the fake stomach. However, each test-person were able to place the concepts rather precise on the fake stomach which indicates that the source of error isn't critical in relation to the more realistic interaction the stomach enables, regarding not being able to see the placement etc.

Two of the mock-ups didn't have weight in the main box which caused confusion for one of the test-persons. Additionally, it would have influenced the interaction having weight in the part. Ideally, there should have been weight in the part, and it's a source of error.

Feedback from a milestone session also presented some concerns about the product not being symmetric, and an idea of working with creating a symmetric appearance if the product architecture isn't symmetric was suggested (worksheet 12).

Feedback from midwives

To get feedback from the midwives Stine and Stina, we recorded explanatory videos of each concept, and sent it to them over mail (worksheet 12, 13). The feedback from the midwives were overall positive. They liked the idea of the product being easy to understand, by having coloured and tactile spots. Stine liked the overall idea of having one product that could be used more or less instantly in e.g. acute situations. Something that just could be "pulled of the wall" (worksheet 12).

Generally, they were very positive over the idea of reducing the single-use part to only the adhesive, but they mentioned that the reusable part has to be able to be cleanes thoroughly, and also that it should be resistant to hard use and rough treatment from the midwives (worksheet 12, 13). A midwife from Roskilde mentioned that it seemed okay if they would have to place new rings with adhesive (worksheet 13).

Following sections outlines the main feedback to each concept:

- Concept 3: Stine liked the idea of using other marks on the body, but not really the idea of having multiple parts.
- Concept 4: They had a concern of having the main box placed on the side. Stine mentioned that the pregnant during delivery lies more on the side than she bends over, and therefore they think the main box is better placed around mons pubis.
- Concept 5: They liked the idea of the flexible connectors, but have the same concerns about the placement of the main box, as for concept 4.
- Concept 7: They liked the creativity behind the concept, but they have a concern if the strap will crawl up (like a testperson experienced), and also how to make it fit different sizes of stomachs. Furthermore, they have a concern about cleaning the product, and the number of parts it should be divided in, prior to cleaning.

Sum up

From the test and feedback from test-persons, milestone and midwives, it's clear that we have to work on creating some kind of symmetry. The comments from the midwives indicate that the main box shouldn't be placed on the side which might make it easier to create symmetry.

Based on the feedback we have decided to work further with concept 3 because it's different than the other concepts, and even though we haven't found the optimal solution yet, we would like to explore it a bit more. Furthermore, we will be working with concept 5 and the idea of the flexible connectors. To both concepts we will work on creating a more fluent and coherent attachment process, as concept 4 creates and still use tactile and coloured spots to indicate interaction. Concept 7 has through both tests and feedback, shown many errors and dilemmas, and therefore we will not be working further on this concept.

When creating new concepts we should think about creating the mock-ups more similar, e.g. using weight in all of them, and using better adhesive. Furthermore, we need to work on reducing the number of steps needed prior to use, to make it faster to attach in acute situations. This could be achieved by reducing the number of electrodes, and as mentioned earlier, the number of electrodes and their placement can be implemented in more or less every concept. Therefore, we need to discuss the electrode placement with CF, to find a solution that doesn't violate the Monica patent, and to ensure that we solve technical requirement 3 (Table 4 p. 38). Lastly, we should work on making a product in as few parts as possible, to eliminate the possibility of things getting lost, and doubts about the use of the different parts.

Concept development after feedback and milestone

Objective

With basis in the knowledge gained in the previous test and feedback, we will be working further on the concepts. This section will describe the further process.

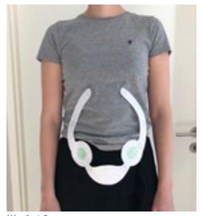
Prior to ideating, we researched and looked more into the different kinds and sizes of stomachs, to create a better basis for making the best possible concept and solve common requirement 2. We hadn't really looked into how big a stomach can get right before delivery. This has to be hold against a stomach in week 24 (ill. 139-ill. 141). In all the scenarios the product has to be usable on stomachs in the last trimester, and in clinics and home monitoring it has to be used from week 24.

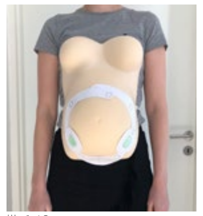
ill. 139 Stomachs through pregnancy


ill. 140 Pregnant week 39


ill. 141 Pregnant week 39

We also tried the outline of the current CentaFlow on different stomachs to see how it reacted (ill. 142-ill. 144).


ill. 142


ill. 143

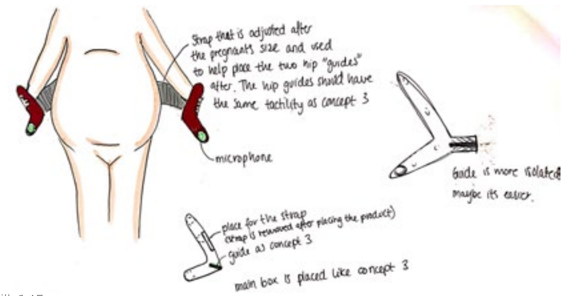

ill. 144

The top electrodes reaches the bottom of the breasts when not having a large stomach, and the larger the stomach, the lower the top electrodes reaches. When looking at the Monica device, and placement of its electrodes, the top electrode is placed just above the navel. The electrodes doesn't have to reach up to the breast, but only approx- 5-10 cm over the navel. This will be considered when developing further on the concepts.

As mentioned in the sum up from the previous chapter, we will be working further on concept 3 and 4.

Further development of concept 3

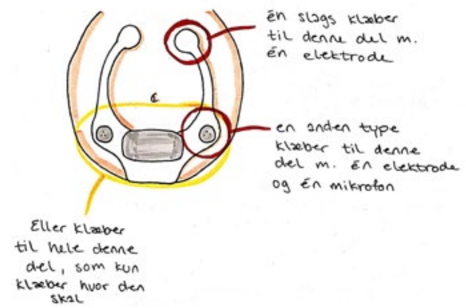
The first concept we worked with was concept 3, and we sketched on how we could make it more obvious where on the ilium bones to place the guides after. The only idea we could come up with, was a detachable strap that should be attached and adjusted according to the pregnant before attaching the product, and then when the product was placed, the strap could be removed (ill. 145). However, this would lead to even more parts, as well as doubt on how to adjust the strap which doesn't seem convenient. In the end the concept using the ilium bones seems more complicated and complex than placing one part after the top of mons pubis which is why we have chosen, not to work any further on this concept.



ill. 145

Further development of concept 5

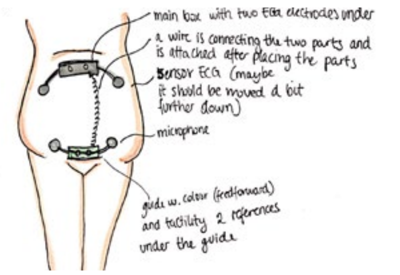
On the basis of concept 5, and with the thought of trying to create a more coherent solution, we started ideating on new concepts (ill. 146-ill. 149). Here we thought about where the main box could be placed if the side isn't a possibility, and how to create symmetry. From this we got three new concept directions.



ill. 146 Concept 1

Concept 1 (ill. 146) - the main box is placed in the middle, but moved further up the belly than on the existing solution. The bottom of the guide is still placed were the bottom of the main box from the current CF solution is placed. Our hope is that the main box will be less in the way. The idea is that the two "arms" holding the top electrodes is made flexible like on the previous concept 5 p. 47.

Concept 2 (ill. 147) - the idea is having a two part solution, where you place the top part with the main box first, and then place the lower part. On the sketch it was intended to be in two parts you connect with a wire after placement, but we decided to try and make it one united product that is connected at all times, to eliminate things getting lost.



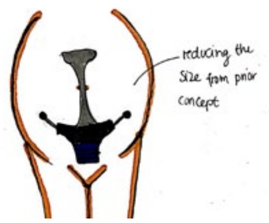
ill. 147 Concept 2

Concept 3 (ill. 148, ill. 149) - the idea is having the main box placed in the lower part in the same area as with concept 1, but instead of having the two long arms in the side, the top electrodes are placed individually. The pregnant starts by placing the lower part and thereby the lower electrodes, and then places the top electrodes which is attached to the middle of the lower part. There is two versions to this concept. Version 1 where the connector to the upper electrodes is flexible (ill. 148) and version 2 where the connector isn't flexible (ill. 149).

To each of the concepts we made mock-ups to test the interaction. We used the model for the current product for placing the microphones properly on the concepts, and as a guide for where approximately to have electrodes. We used two different fake stomachs. The pillow stomach which is bigger and more wide than the other foam-like stomach (ill. 150-ill. 153).

The test were made on ourselves, and on our boyfriends. We evaluated it to be acceptable to use men for the test, as it is about the overall interaction and placement of the concept. The full test, and all the comments, are shown in worksheet 14. Prior to testing on our boyfriends, we made simple illustrations showing the placement of the concepts (ill. 154, ill. 159, ill. 164, ill. 169). This was done by inspiration from the Monica device. The illustrations were supplemented by a description on how to place the product. The overall idea with this was to start investigating how much information that is needed for placing the product correctly.

ill. 148 Concept 3 version 1



ill. 149 Concept 3 version 2


ill. 150 Fake stomach


ill. 151 Wearing fake stomach


ill. 152 Pillow


ill. 153 Wearing pillow

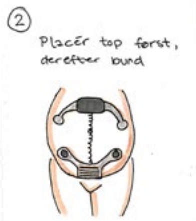
ill. 154 Concept 1


ill. 155 Concept 1 Sofie


ill. 156 Concept 1 Trine


ill. 157 Concept 1 Mads


ill. 158 Concept 1 Ebbe



ill. 159 Concept 2


ill. 160 Concept 2 Sofie


ill. 161 Concept 2 Trine


ill. 162 Concept 2 Mads

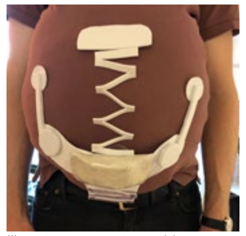

ill. 163 Concept 2 Ebbe

ill. 164 Concept 3 V1


ill. 165 Concept 3 V1 Sofie


ill. 166 Concept 3 V1 Trine


ill. 167 Concept 3 V1 Mads


ill. 168 Concept 3 V1 Ebbe

ill. 169 Concept 3 V2


ill. 170 Concept 3 V2 Sofie


ill. 171 Concept 3 V2 Trine


ill. 172 Concept 3 V2 Mads


ill. 173 Concept 3 V2 Ebbe

The overall feedback to each concept:

- Concept 1 (ill. 155-ill. 158): Generally, the feedback from the test persons was that this concept was easiest to place. It was simple to place the lower part with the weight first, and then attaching the rest. It felt good having the larger flat area on the lower part, as the product felt more united, but it should be investigated how having a larger area adhesive feels on the skin. The electrodes creating the vectors to the side, might need to be moved a bit further out to cover a larger part of the stomach. We need to test if the main box still is in the way with the new placement. Lastly, the transition from main box to guide, needs to be improved, for the main box not to flip inconveniently down when placing the guide (ill. 174).
- Concept 2 (ill. 160-ill. 163): Placing the upper part first seemed okay, but for one test-person the adhesive on the lower part got stuck on the upper part which made it more complicated to place. One test-person tried placing the product holding both parts because it seemed strange having the lower part dangling, while placing the upper part. This made it complicated to place the product. The lower part was a bit more complicated to place than the upper part because the material flexed, but the interaction with dragging it down seemed good. Having the two parts made it easier to create visual symmetry on the stomach because the parts are more independent of each other. It should be tested if having two separate parts to place first, and afterwards connecting them with a wire, makes the interaction better.
- Concept 3 V1 and V2 (ill. 165-ill. 173): The concepts were generally okay to place, but version 1 with the flexible connector to the upper part, caused the test-persons to be more in doubt if they had placed the part correctly than with version 2, where the connector wasn't flexible and therefore "lead" the way. When attaching the product it seemed like an extra interaction having to place the lower part and the electrodes on the sides, and thereafter grabbing the upper electrodes and placing them. The interaction seems unnecessary when comparing to concept 1, where the top electrodes are placed on the connector, connected to the lower part, where the user already have their hands after placing the electrodes on the side.

On each of the concepts we used clay as the main box as it has approximately the same weight and size as the current main box. By using clay we were able to shape and integrate it better on the concepts. We also used better adhesive tape (duct tape) to make it stick better to the clothes (as the real product would stick to the skin).

Generally, the concepts were placed within the limit of what is accepted for the microphones, but some were placed a bit skew. One of the test-persons mentioned that he found it hard to place at the top of mons pubis when he couldn't feel his own stomach because of the fake stomach he was wearing. It's a general source of error, not having as good body contact when wearing the fake stomachs, but overall the test-persons have until now been able to place the concepts fairly straight when wearing the fake stomachs.


ill. 174 Transition guide concept 1

Sum up

From the test we found that it seemed good to have a larger connected surface on the lower part, as it unites the product better, and creates a better feeling of connection. However, we need to test how having a larger connected surface with adhesive, feels on the skin.

Furthermore, it was clear that concept 1 and 2 are the concepts that are most suited for further development. Therefore, these concepts will be developed further, prior to testing them on a pregnant belly. To concept 1 we need to investigate whether the new placement of the main box is in the way of movements. Regarding concept 2 we need to simplify it, and test how the interaction is when having it as two separate parts. Lastly, we wish to challenge the placement of the main box further.

Further development and detailing

Objective

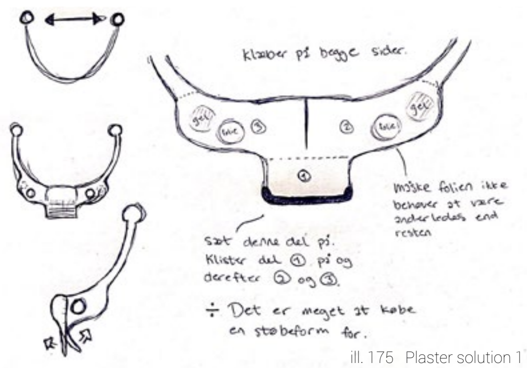
The objective with this section is two further develop concept 1 and 2 from previous chapter, and to get feedback from a pregnant woman and more test-persons. The overall goal is to specify the concepts more, regarding both interaction and the single-use adhesive. Furthermore, we wish to ideate on more ways to place the main box. The full test can be seen in worksheet 15, 16 and 18.

Further development on concept 1

We started by ideating on how to integrate the main box in concept 1 better with the guide, and how to easily apply the single-use adhesive.

The overall concept and appearance is similar to the previous concept, but the idea is to make it a bit wider, and thereby placing the electrodes on the sides, further out.

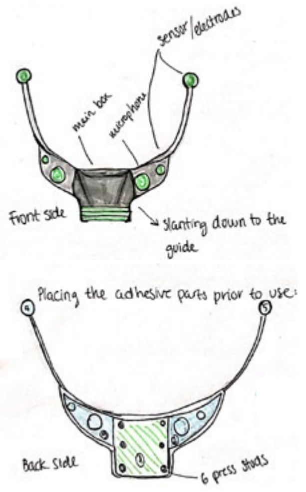
Regarding attaching the single-use adhesive plaster, we thought of placing it in one piece in the lower part, to limit the



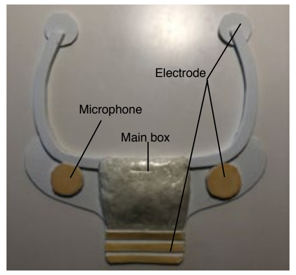
ill. 175 Plaster solution 1

amount of loose parts, and make it more simple to attach and thereby, faster to use the product. On the concept on ill. 176 press studs are used to make it easy to place the adhesive part, and help guide the adhesive, so the user can put it on properly. On ill. 175 a plastic part that fits the reusable part of the product, is used to guide the adhesive part, and help the placement of it. When evaluating on the two different solutions, we have chosen to work further on ill. 176 with press studs, as it's a cheaper solution that doesn't require extra tools. The overall idea is that we should only have adhesive around the areas of the micro-phone, electrodes and main box, and that some areas can be left without adhesive.

This concept would require to add single use adhesive on three places: the lower part, and one plaster on each top electrode.



ill. 176 Plaster solution 2



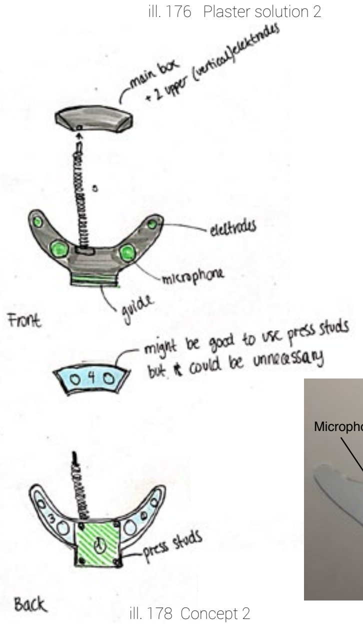
ill. 177 Mock-up concept 1

Further development on concept 2

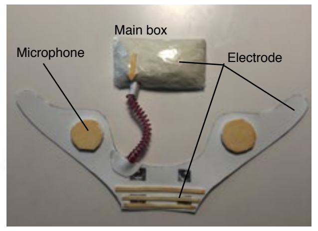
For concept 2 we started ideating on how to simplify the prod-uct more, and specify how to put the single-use adhesive on.

We moved the side electrodes down in the lower part to simplify the interaction, and because the user already would have to at-tach the area around the microphones, it seemed more natural to have the electrodes beside the microphones. This enables less interaction when placing the upper part, as it only has two electrodes on the backside of the main box. The concept con-sists of two versions, as we wish to test if it makes most sense having one part or two individual parts that is attached to the body separately, and then connected with the wire.

The idea about the attachment of single-use adhesive is similar to the one explained for concept 1, but the single-use to this concept consists of two parts - one for the lower part and one for the upper part (ill. 178-ill. 179).



ill. 178 Concept 2



ill. 179 Mock-up concept 2

A new concept 3

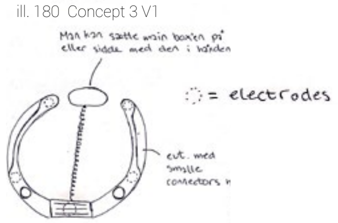
As mentioned we wanted to explore other ways to place the main box which lead to an idea of having the box as a side piece that could be placed beside the pregnant when used for e.g. home monitoring, but also be attached to the body during de-livery.

The overall idea is having the part consisting of microphones and electrodes, and then having the main box (ill. 180-ill. 181). To this concept we have two different versions. The difference is in the placement of the wire that is connected to the main box.

Regarding the single-use double sided adhesive, the idea from concept 1 could be used here as well.


ill. 180 Concept 3 V1


ill. 182 Concept 3 V1



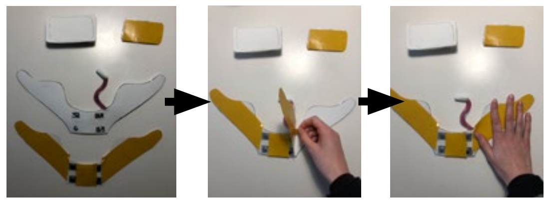
ill. 181 Concept 3 V2


ill. 183 Concept 3 V2

Initial idea on single-use adhesive

We worked on implementing the idea for the single-use adhe-sive in one of the concepts, to see how the interaction worked (ill. 184). It was implemented in concept 2, and following section describes the wanted interaction (https://drive.google.com/file/d/1vWNCiSGAN8Ln1-NvRyqbk_MEnBsCLRKh/view?us-p=sharing).

We have evaluated that it's acceptable only having the adhesive part integrated in one concept, as it will be similar on the other concepts. When testing on the pregnant we of cause need to emphasize that it's supposed to be used on all concepts.


ill. 184 Single use adhesive

Test on ourselves

We started by testing the concepts on ourselves to get an idea of the interaction, and see if anything needed to be refined, prior to testing on the pregnant (worksheet 15). The test was con-ducted using the two different fake stomachs.

The general comments to the concepts:

- **Concept 1**: The two electrodes in the top overlapped on the smaller stomach, but the flexible and not adhesive connectors made it possible to easily adjust them (ill. 185-ill. 186). The transition between the guide and main box seemed better, but the area around the main box is still relatively stiff. We need to see how it reacts on a real stom-ach, and if it's in the way when moving.
- **Concept 2:** It's good that the upper part is stripped to one simple part, without the long "arms" the previous concept had. When testing the two versions, it was clear that the interaction was best when having two separate parts. This however, leads to the risk of more parts that can be lost, but also pose an opportunity of easy replacement of the main box if it runs out of battery. By not having the main box in the lower part, it enable the part to follow the stom-ach really well. We need to see if the pregnant becomes unsure of the placement of the main box because it's a separate part (ill. 188-ill. 189).
- **Concept 3:** When testing this concept it appeared strange and inconvenient having to find room for the main box on the stomach, after the rest of the product was attached. When used for home monitoring, the main box doesn't have to be placed on the stomach, but can be placed be-side the pregnant when attached to the wire. However, this leads to a concern if it will pull in the electrodes when moving the main box (ill. 190). When used for monitoring during delivery, it would need to be placed on the stomach if not wireless. Making it wireless would require batteries, and a micro-controller in the part on the stomach. If the main box is placed on the stomach, it might as well have more purpose like concept 2, where the main box has the two upper electrodes. Therefore, we have chosen not to work further on this concept.

Therefore, we chose to test concept 1 and concept 2 version 2 on the pregnant (1: https://drive.google.com/file/d/1_We_vl0xvMkw3bXjt5LYey-83Jf1XfY/view?usp=sharing, 2: https://drive.google.com/file/d/1_xPoqhob6vMCa4HKWEDKNEfIK-JpELp7B/view?usp=sharing). For the test we used double sided adhesive tape, with approximately the same degree of adhesive properties as the current CentaFlow plaster. We have an as-sumption that we will be able to use the same kind of adhesive plaster for the scenarios of home monitoring and monitoring in clinics as CF is currently using, but this needs to be tested.


ill. 185 Concept 1 fake stomach


ill. 186 Concept 1 fake stomach


ill. 187 Concept 1 pillow as stomach


ill. 188 Concept 2 fake stomach


ill. 189 Concept 2 pillow as stomach

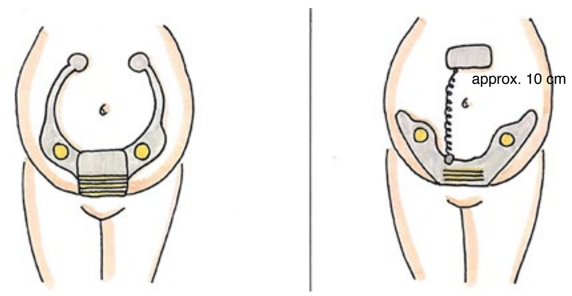

ill. 190 Concept 3 V1 fake stomach


ill. 191 Concept 3 V2 pillow as stomach

Test of concepts on pregnant

Prior to testing on the pregnant we made illustrations showing how to place the concepts on the stomach (ill. 192). We started by informing her about the scenario of home monitoring, and what it required (worksheet 16).

Then we had her attach the single-use adhesive, and then place concept 2 (ill. 193-ill. 196). Afterwards we had her place con-cept 1 and told her that it should have the same kind of inter-action for placing the single-use adhesive (ill. 197-ill. 200). The pregnant on the test was in week 39.



ill. 192 Illustration showing placement

Comments:
- She found that the concepts were equally easy to place, and that the adhesive solution seemed ***"very fail-safe"*** (worksheet 16). The area with adhesive didn't irritate her skin, but she mentioned that some might have more sore skin than her, during their pregnancy.
- She thought it was easy to place the concepts straight on the stomach, and used the straight side on the guide to help place it straight on both concepts. If she had found it difficult, she mentioned that she would use a mirror. When placing the product she tried removing the foil in the middle first, and the foil on the sides, but this was complicated, indicating that all the foil should be removed prior to placing when the pregnant does it herself.
- Concept 2: She mentioned that it might make sense to have the wire placed in the middle, as an extra guide. When she placed the upper part with the main box, she mentioned that some women might feel a need to measure the correct distance, even though it doesn't have to be precise, but because they would feel that they had to do it 100 % correct. She was a bit in doubt about how to turn the main box, indicating that the feed forward could be better, but it helped having the arrow. Not having the main box in the lower part, made it easy to bend and move around. She thought the upper part was stable, however, it gapped a bit in the sides, indicating that it could follow the stomach better. On this mock-up it's flat on the backside. The lower part fit the stomach really (ill. 196).
- Concept 1: She mentioned that it wasn't as easy to bend over with, as with concept 2, but that it was okay. However, she had a concern that the main box would be in the way if the belly started to hang more, and how it would feel during delivery, to have it placed close to the vagina. The main box touched the thighs when sitting and bending, and the area around the main box gapped a bit, indicating that the main box, or transition, should be more flexible. Generally, it fit the stomach well, and the connectors to the top electrodes flex when sitting and moving, as intended (ill. 199).

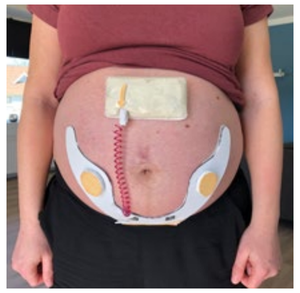
Test on more people

After testing on the pregnant, we wanted to get feedback from more people. Therefore, we made a test on a pair of our parents, as they were available. Generally, they were given the same information as the pregnant prior to placing the product. The full test is shown in worksheet 18. They didn't wear any fake stomachs, as we estimated that the size of their own stomachs, more or less, could resemble a smaller and larger pregnant belly in week 24. The overall purpose with the test, was to get feedback on the interaction, and to see how well they placed the concepts.

Comments:
- They both found the concept equally easy to place, and they were able to place the concepts within the range that is required by the microphones. They both used their fingers to feel the middle of mons pubis and the product, and used the straight side on the product to feel the middle.
- Concept 2: At one of the tests the wire got stuck on the adhesive side between stomach and product. This was due to the construction of the mock-up. Giving the wire a direction away from the product, might prevent this from happening. Having the main box as a separate piece, enabled a good fit on the different stomachs (ill. 201-ill. 202).


ill. 193 Pregnant wearing concept 2


ill. 194 Pregnant wearing concept 2


ill. 195 Pregnant wearing concept 2


ill. 196 Pregnant wearing concept 2


ill. 197 Pregnant wearing concept 1


ill. 198 Pregnant wearing concept 1


ill. 199 Pregnant wearing concept 1


ill. 200 Pregnant wearing concept 1


ill. 201 Man wearing concept 2


ill. 202 Woman wearing concept 2

- Concept 1: The lower part of the products were placed straight, and the electrodes in the top a bit skew (ill. 203). However, this isn't a problem that influence the measurements, but only a concern regarding visual feedback to the pregnant. On one of the test-persons the electrodes were placed a bit high at first, but when mentioning that she could move them, she replaced them and found it easy to do so (ill. 204).


ill. 203 Man wearing concept 1


ill. 204 Woman wearing concept 1

Sum up

Through this phase, we have developed and tested two concepts that both have pros and cons. The different test-persons found the concepts equally easy to place. There are some areas that has to be worked with for both concepts. For example the main box on both concepts and the its shape needs to be improved, to fit multiple stomachs better. Regarding concept 1, we still have a concern if the main box will be in the way when having a large stomach. For concept 2 we have a concern regarding the product being in multiple parts. Additionally, we need to make the upper part on concept 2 more intuitive, to place it correctly. We wish to present the two concepts to CF, prior to choosing a concept.

Having done a test on one pregnant was giving and ideally we would like to test on more pregnant. However, the circumstances do not afford this. The test showed that the idea with placing the adhesive in two steps seemed easy and "foolproof". The idea with the press studs makes the attachment of single-use plaster on the lower part more user friendly as it guides the adhesive. Additionally, the adhesive used didn't irritate the skin of the pregnant.

We have now tested concepts on nine different people, including ourselves. All test-persons were able to place the concepts within the limit of the microphones, using the mons pubis to place the product by. Therefore, we will be working further with the assumption that the majority of pregnant (and midwives) will be able to place the product correctly, using mons pubis as a reference.

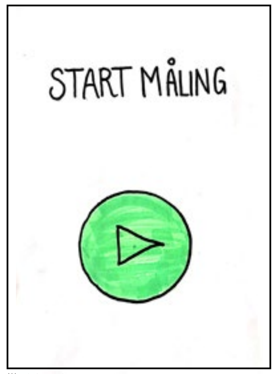
Initial interface development and feedback

Objective

While testing the concepts on the pregnant, we also wished to get feedback on initial thoughts of the interface, and the product feedback she should receive during home monitoring. Therefore, we made some initial interface development.

The initial thoughts regarding the feedback and interface was that the pregnant should get a warning if the product isn't placed correctly. This would be given on the tablet, where she already answers a questionnaire when monitoring at home (ill. 206). The beginning of the session should be initiated by pressing play, and therefore we used a green button and the play symbol (ill. 205).Hereafter, the pregnant receives either a picture that the measurement starts (ill. 207), or that there has occurred an error (ill. 206). If an error has occurred, the product makes a negative sound simultaneously with a picture occurs on the screen. It could be if the main box can't get a signal to an electrode or microphone. If this is the case the area that there isn't signal, to will be marked on the screen, and the pregnant will be asked to press the area and start the measurement again (ill. 206). If everything is ok, the measurement starts, and if not the pregnant is asked to remove the product, and start over (ill. 208).

We made the test on the pregnant and on one of our parents. The tests are explained further in worksheet 16 and 18. Prior to the test they weren't given much information. They were asked how they would interact when seeing each sketch, and the sketches where shown separately. When being showed ill. 206 they were told the product would make a sound.



ill. 205 Screen 1

ill. 206 Screen 2

ill. 207 Screen 3

ill. 208 Screen 4

Comments:
- ill. 205: Both understood that they should touch the green "button" to start the measurement.
- ill. 206: There was a bit more doubt about this picture.

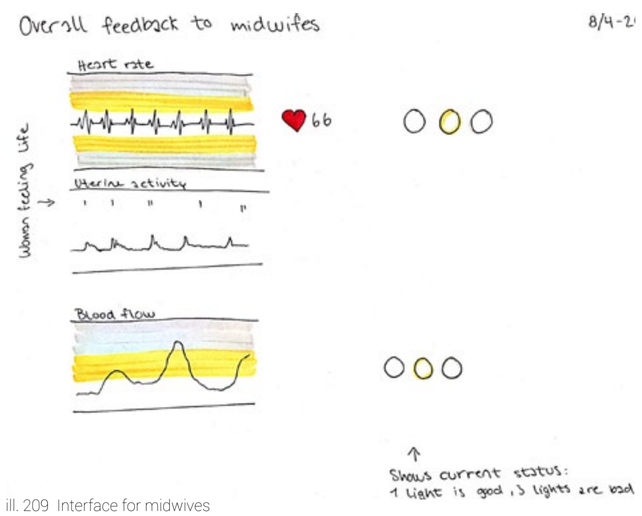
Initially, they thought they should press the area on the screen, but quickly corrected themselves, without intervention, and pressed the part on the product. However, there were doubt about which side the picture referred to because it's shown reversed, and therefore it might make sense writing left/right. Additionally, the pregnant mentioned that she was in doubt about when to push the green area "start measuring", and she said that is would make sense having *"push the marked area on the product... and afterwards push start measuring"*.

- They thought it was a good idea to use sound. The pregnant mentioned that she thought that after having used the product many times you might get sloppy about placing it. The sound would work as a reminder to concentrate.

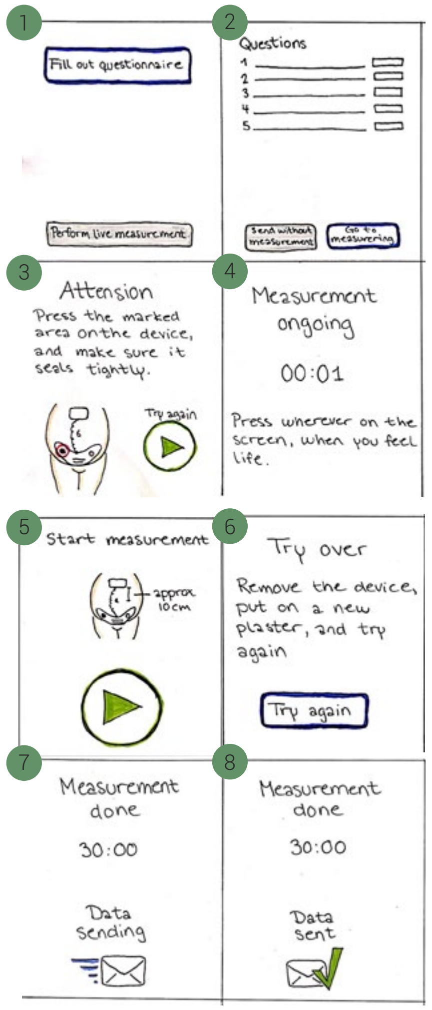
With this feedback we developed the interface further, and also started thinking of the display the midwives should receive, to solve requirement 3 table 3 p. 38 (ill. 209). This was done prior to a meeting with CF because we wished to get their feedback on the initial interface concepts, as well as the product concepts we tested on the pregnant.

On the interface we added the part of answering the questionnaire prior to measuring, as the pregnant's always have to fill out the questionnaire (chapter: home monitoring). Additionally, we added the part of sending the data (ill. 210). To eliminate the possibility of the pregnant forgetting to send the data, the data is sent automatically, and when sent the product will make a sound to make the pregnant aware that is has been sent. The idea is that the app will be programmed so the light on the screen won't turn of when using the program, and additionally block all other activity to eliminate disturbing factors.

Regarding the interface for the midwives, the overall thought is that they should receive the same kind of warning when something isn't placed correctly. This is to ensure that they get feedback, and can be reassured that they have placed the product correctly (common requirement 1, table 3 p. 38). The data should, as mentioned earlier, be displayed similar to what they are shown with the CTG, to make the adaptation from CTG to this product easier with recognizable features. Therefore, the heart rate curve and uterine activity curve should be displayed similar. We have added three dots beside the heart rate curve which symbolise the live status of the heart rate (ill. 209). If one dot is glowing everything is normal, but if two or all three is glowing something is abnormal. The dots shouldn't be coloured as it can appear alarming to the parents which in some cases can see the screen. Additionally, we have added the fetus' heart rate numerical. The blood flow measurement is the new addition of measurement the product offers, and we thought it should be displayed with a curve over time, like the fetal heart rate and uterine activity. This enables the midwives to have the history, and by adding the three dots in the side, they will also be showed the current status (ill. 209).



ill. 209 Interface for midwives



ill. 210 Interface scenario

Sum up

Through tests and feedback, we have developed the first initial interfaces for both midwives and pregnant women, and before developing further, we wish to get feedback from CF and a midwife.

There are some parameters we still need to solve regarding the interface, and the interplay between this and the product. We need to figure out whether it's acceptable to press the screen when feeling life, for pregnant women performing a home monitoring session. We also need to specify how the warning areas when should be identified on the product when there isn't signal, and whether it should be displayed on the screen as a mirrored image or not. Generally, we need to get feedback from the midwives, to ensure that we solve the common requirement 3 in the best possible way.

Meeting and feedback from CF

Objective

The following chapter will create an overview of the feedback for concepts and interfaces, received by CF. We gave a presentation of the concepts and interfaces, and afterwards had a discussion about the presented material. The full feedback is presented in worksheet 20. At the meeting six people from Viewcare/CF was attending (CTO - Morten, Jakob - Business developer and investor, Rasmus - signal processing engineer, Helga - signal processing engineer, Henrik - development engineer, Diana - director of medical affairs, former midwife and initial idea owner).

Feedback on concepts

They commented mostly on concept 2, as they all preferred this concept, especially because of the placement of the main box, but properly also because they have been wanting a future version of the device that has a touch screen, where the most simple interactions can be performed. This is possible to implemented to this concept. Whether it makes sense when thinking of the size of the screen is unclear, but it could be an opportunity. However, in home monitoring the pregnant still needs to answer a questionnaire, and therefore they still need some kind of monitor. Additionally, the midwife would need a larger screen to review the results upon. Nevertheless, the product needs to have some kind of feedback to signalise that it's on, and e.g. signalise the battery level, to make the user more aware. This could be solved by using diodes.

They liked the idea of reducing the single-use parts of the product, and were therefore fond of the idea of the single-use plaster. However, Jakob mentioned that for it to be cost-effective, they would need to be able to reuse the microphones when the lower part breaks. We have an assumption that the lower part will break before the upper part because of the higher flexibility needed in the part. The microphones cost approx. 600 DKK a piece, and there is four in each product. They have thought of using contact microphones because they are cheaper, however it would require that they set the parameters themselves, instead of using reliable acoustic microphones that can be bought with the wanted specifications. In time they will, most likely, be moving over to the cheaper microphones, but for the approval of the product it's important to have specific measurements and properties. Jakob also pointed out that the lower part should last at least a year which means that it would roughly need to withstand having the single-use plaster attached/detached 1000-2000 times. This is calculated in relation to monitoring in clinics, where the product can be used multiple times a day. But overall they, and especially Diana, liked the idea of reducing the single-use part. This would, as mentioned earlier, also make it easy to use the same product set-up for the different scenarios, only changing the properties of the single-use adhesive.

They also liked the idea of having a speaker in the product that could be used for multiple purposes, e.g. alarming if something is placed wrong, or if the product isn't put back into place after use. Diana supported Stine and Stinas stance about midwives being messy and not necessarily putting things back into place after use, and therefore really liked the idea of the product making noise if not put back into place.

Feedback on interfaces

Regarding the interface Diana liked the idea of having the blood flow shown over time, similar to the uterine activity and fetal heart rate. Rasmus mentioned that we maybe should think of how to display when there is a flaw in the measurement. There can occur short sequences where the measured data can't be transformed or confirmed by the algorithm. Currently with the CTG, these areas are shown as blank spaces on the curve.

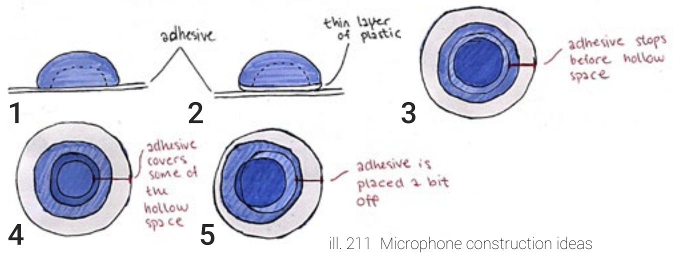
They also liked the idea of having the live results shown with the three glowing dots. We were uncertain whether three would be enough to represent the flow. Diana mentioned that she thought three was a good number because midwives are used to evaluating after three parameters: normal, abnormal and pathological.

Feedback to technology concerns and questions

We had an idea that a combination of microphones, EMG electrodes and an accelerometer, would be able to solve the problem regarding measuring contractions when the pregnant is moving. Henrik mentioned that it was a good idea that theoretically would work. We also presented the idea of having the partner, who is attending the delivery, check and confirm when the pregnant has contractions. Diana liked the idea of having the spouse interacting more during the delivery. Henrik mentioned that he would prefer to have the technology solve it, as using humans as a parameter, flaws are more likely to occur.

Regarding the placement of the electrodes and Monica patent, they don't see our solution with six electrodes as a problem. We do, however, need to find reusable electrodes, and also have a layer of conductive gel between electrode and stomach.

Lastly, we had some questions about the microphones measuring towards the stomach, and the construction of that specific area. As mentioned in the technical chapter in the framing phase the more different material the microphones have to detect sound through, the more data potentially gets lost. Therefore, we had an idea of either encapsulating the microphone towards the stomach, and having a whole in the single-use plaster (ill. 211 no. 2). By doing this we would make the microphone waterproof without adding more layers than the current solution uses (the current solution has a layer of adhesive where the microphones are stuck ill. 211, no. 1 - worksheet 21 shows a deconstruction of the current plaster). However, we had a concern about if the single-use plaster were put on skew, and some of the adhesive would cover the cavity (ill. 211 no. 5).



ill. 211 Microphone construction ideas

Henrik mentioned that having the cavity sealed would cause the microphone to work more as a stethoscope. He mentioned that it was an interesting thought, but that it's important that the skin against the cavity isn't stretched, or that the volume in the cavity isn't changed significantly because it will change the sensitivity and frequency they measure within. He also mentioned that we could use an acoustic transparent filter on the holes, but if we make a hole in the plaster, so there is skin against the cavity, it would result in the product having to be cleaned differently because it's in direct contact with the patient. Additionally, it might be a problem if the pregnant has more body fat on the stomach because it can cause the volume in the cavity to become smaller, and thereby they can't measure with the amount of sensitivity. Therefore, we think that it will make sense having the acoustic filter directly on the microphone opening, and then having the single-use plaster over the cavity like on the current solution. By not having a hole in the single-use plaster, where the microphones are placed, we reduce the precision the single-use plaster should be attached with.

Sum up

If it was up to CF, they would work further on concept 2, however, we need to make the decision both based on the pros and cons, and some of their feedback.

Overall they liked our initial interface thoughts. We need to specify and detail them more, and combine them with each of the different scenarios, to fully explore when the product needs to give feedback in sound etc.

We will be working further on the idea of having six electrodes (placement B, ill. 119 p. 46), and with the assumption that the combination of the technology can solve the dilemma about measuring contractions. Lastly, we will be working further with the construction of the microphones as mentioned above. They liked the idea of the single-use plaster, and a more green profile. However there are some requirements we must solve for the product to be profitable.

Requirements

The microphones must be able to be reused in new product when the lower part needs to be replaced.
The single-use plasters must have conductive gel on the area which is placed on the electrodes.
The product must be cost-effective when comparing with the current solution (CF doesn't have a price, but pay 50 DKK per plaster, and 2400 DKK for microphones in each product).

Choice of concept

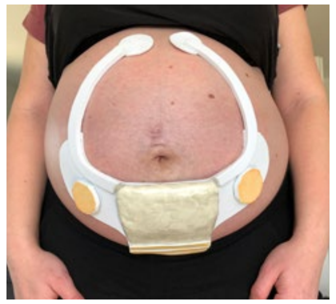
Objective

The objective of this chapter is to sum up the current status, and the pros and cons of the two concepts we have developed, and to choose a concept to detail and work further on.

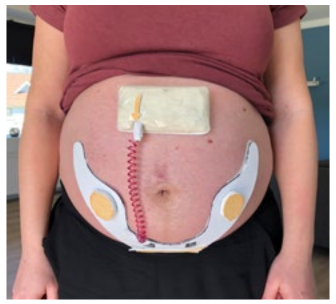
To each concept there are pros and cons. The feedback from CF insinuated to work further with concept 2 especially because of the placement of the main box. The general feedback from the test-persons has until now been that the concepts where equally easy to place.

So far we have been working on the feedback/feed forward on the concepts, and thereby tried to solve how we can ensure intuitive and correct placement (common requirement 1, Table 3). Furthermore, we have worked on where the main box should be placed, to be the least in the way in different scenarios (common requirement 6, table 3) p. 38. We have also worked on the initial idea of how to place the single-use adhesive easily where there still is room for improvement.

The following table shows the pros and cons of the two concepts, and a list over some concerns for each of the concepts. The pros and cons are ranked in colours after what is most significant, and what is less significant (RED = most significant, ORANGE = medium significance, GREY = little significance). Likewise, the concerns are ranked after what is important to solve, and what we have no doubt can be solved (BLACK = important to test and solve, GREEN = it can be solved).



ill. 212 Concept 1



ill. 213 Concept 2

Concept	Pros	Cons	Concerns
Concept 1	• One unit. • The upper electrodes make it possible to adjust to different stomach sizes.	• Main box doesn't follow the stomach's curve. • The placement of the main box is still a bit in the way when bending and sitting. • Harder to replace main box if it runs out of power during delivery.	• Will the weight from the main box cause the microphones to let go of the skin when moving. • When moving the upper electrodes, will the "arms" cause the plaster to let go of the skin because of the forces from the arms. • Is the area of the lower part too big regarding plaster ripping the skin and plaster gapping. • Will the pregnant understand that they can move the upper electrodes if they overlap.
Concept 2	• Main box is not in the way when moving. • The upper electrodes make it possible to adjust to different stomach sizes. • The lower part can be smaller because the main box isn't there. • Easy to replace main box during delivery if it runs out of battery. • Easy to replace the lower part which we assume will break first, independently of the main box.	• Main box doesn't follow the stomach's curve. • Waterproof concerns around the plug and socket. • Two separate units. • The plug on the wire can have a tendency to break. • The wire might get stuck between the product and stomach. • Cleaning the wire.	• Will the electrodes in the upper part, when being placed on the backside of the main box, seal tight to the stomach. • Is it a problem that some pregnants might take the placement of the main box very literally, and use a ruler. • Is the area of the lower part too big regarding plaster ripping the skin and plaster gapping • Will the wire have a tendency to break when hanging loose, exposed to hard wear.

Table 7

As mentioned earlier, we started this ideation phase by focusing on solving the use for home monitoring, to ensure that the pregnant could use the product herself. We have tested both concepts on nine people who were all able to place it using the guide. Therefore, we assume that the midwives also will be able to place the product, and therefore common requirement 1 is solved when having the feedback on the interface and product identifying if everything is placed correctly and giving feedback of how to solve if something is wrong. Technical requirement 1 is also solved as the test persons were able to place the concepts within the limit of +/- 2,5 cm.

Regarding common requirement 2 and 6, concept 2 seems to have an advantage, as we have a concern that the placement of the main box on concept 1, will be in the way when being pregnant in week 38 or later. Generally, concept 1 has less cons than concept 2, but concept 2 has more significant pros than concept 1. E.g. that it will be easier to replace the flexible part that will have a tendency to break first because it's independent of the upper part. Furthermore, we have a concern if the weight from the main box will influence the microphones and the cavity that should be shut airtight to the stomach in concept 1. With concept 2 the lower part with microphones doesn't have any significant weight which could cause this. With concept 2 we have a concern about the wire, both regarding cleaning, and life time. But as it's placed on the part with the shortest lifespan, it seems reliable that it can withstand wear and tear in the lifespan of the lower part.

From the feedback and the pros and cons, we have chosen to work further with concept 2, as it seems to be the best solution regarding placement of the main box. Additionally, the aspect about not having to send the whole product back when the flexible part breaks, is appealing. Choosing a concepts means making compromises. The compromise to this concept consists of it being in multiple parts that hold a risk of getting lost. This could be solved by having the home/docking station making noise if both products isn't in place after use. The wire is another concern which we should try to optimise. We are certain that we can find a waterproof solution, however, it should be easy to clean and additionally attach to the upper part. Lastly, we need to work on the shape of the upper part, to make it follow the different stomachs better, and to ensure that the pregnant knows which way to turn it.

There are some general problems regarding construction that need to be solved:

- We need to work on the transition between materials and different parts, to make them withstand being exposed to wear and tear.
- Finding a material that can withstand having removed single-use adhesive 1000-2000 times.
- We need to think about how to ensure easy cleaning around the tactile spots, the guide and the wire.
- We need to talk to a hygienic nurse about using press studs and having to clean them. The Monica device and other medical equipment use press studs on parts that are reused. Therefore we assume that it's acceptable.
- The area on the reuseable part, where the press studs are placed, should have some reinforcement to ensure that the part doesn't break when used repeatedly.
- We need to work on how to construct the single-use plaster, to ensure that it doesn't rip the skin unnecessary.
- We need to solve how to construct the single-use adhesive with the conductive gel.
- How can we make the microphones easy to reuse.

Sum up

Choosing one of the concepts reults in making different compromises. We have chosen to work further with concept 2, especially because of the placement of the main box, and the idea of having the two parts separate, as the flexible part will have a tendency to break before the upper part.

We need to solve and optimise the wire and plug, and also the construction of the area around the microphones, to make it easy to remove them when the lower part breaks. Furthermore, there are some different constructional concerns that should be solved.

Interaction wise, we need to shape the upper part, so it's more intuitive how to turn it and place the plug. Furthermore, the shape should be formed to follow the different stomachs better and with a direction that makes it intuitive to place it correctly.

Status on requirements and further process

As mentioned above, the combination of interface and the product with the guide, makes it possible to solve the requirement of intuitive use. We do, however, need to figure out how to identify the areas that should be pressed when the product doesn't have contact to all electrodes or microphones. This should be solved, and the interface should be specified further to completely solve common requirement 1 and 3. Regarding the common requirement 2, 6 and 7 (table 3 p. 38), we still need to work on optimizing the shape with regards to different stomachs and movement.

The common requirement 8 is an optimization process, but by only having single-use parts with adhesive, we have already solved this requirement partly (table 3 p. 38).

The common requirement 5 can be solved by programming, and having a speaker in the upper part that makes a noise when the product isn't in place and isn't in use. The idea is that in clinics and delivery rooms, the charging device/home is wall mounted, and always plugged in power. In home monitoring, where the charger isn't permanently installed, the product can signalise and make a sound when it needs charging. In clinics and delivery rooms the product can start making a noise if it isn't in place 15 minutes after an ended session. The lower part doesn't contain a battery, so to make the midwife aware that it isn't in place, a RFID reader in the charging device can be configured, to make a noise if the upper part is back in place and the lower part isn't. This would mean the lower device should have an RFID chip. By using this combination, we assume we will be able to solve this criteria. We do, however, need to figure out what the volume of the speaker should be in each scenario.

Common requirement 4 and technical requirement 6 (table 3, 4 p. 38), as well as the added requirement from CF about the lower part being reusable up to 2000 times, and the microphones addiotionally being reusable, is a question of construction and material choice, and is not reserved one scenario.

The technical requirement 2 and 4 should be solved by constructing the parts in the best possible way, and possibly looking at the existing CF plaster. Through the feedback session with CF, we got confirmed that the placement of the six electrodes seem possible, and therefore we assume that the placement of the electrodes will solve technical requirement 3. However, it would need testing with electrodes on a pregnant belly, to truly confirm this.

Regarding having room for the different components in the upper part (technical requirement 5 p. 38), we have until now worked with the upper part in the mentioned size and with the mentioned weight, and therefore it seems realistic that we can solve this.

The different scenarios have different extra demands. Regarding home monitoring, requirement 1 and 2 can be solved by programming, and having an interface on an app. We assume that the pregnant will feel fine having to press on the screen on the tablet she uses for home monitoring when she feels life, and as mentioned the idea is that when the app is running the tablet won't show messages etc. to make the pregnant fully concentrated about the measuring session.

Home monitoring requirement 3, and delivery requirement 1.2 and 5 can hopefully be solved by the single-use plaster, and having different plasters for each scenario. The current plasters should be tested to see if they have the wanted properties.

The last requirements for delivery can be solved through waterproofing the device and battery capacity. This is where the three scenarios really differentiate, as the devices doesn't need to be as waterproof in home monitoring and monitoring in clinics. The battery capacity of six hours is enough for these scenarios. We need to see if we can incorporate more batteries, or figure out how to make them easy exchangeable, without having parts that are hard to clean.

The following session will be focusing on solving the specific problems and requirements mentioned above, and detailing the concept further.

Ensuring good quality measurements

To ensure that the plasters seal tight around electrodes and microphones, we have explored different ways of doing so. This will be presented in the following chapter which will begin with a test of the current plasters used on the CentaFlow and Monica device.

Test of current plaster solution

Objective

As mentioned earlier, we have wanted to test the plaster used on the current Centaflow and Monica device, to see how well the plasters sticks to the stomach when moving, sweating and being under water. Therefore, we made a test where one of us wore the plasters while running 3 km, and afterwards doing stomach exercises, and lastly wearing them in the shower and bathtub for approx. 30 minutes. The full test is showed in worksheet 17.

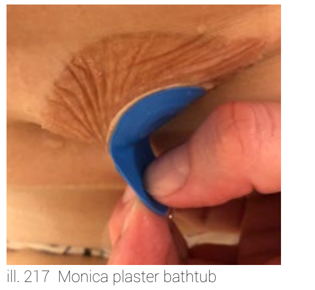
The main takeaways from the test:

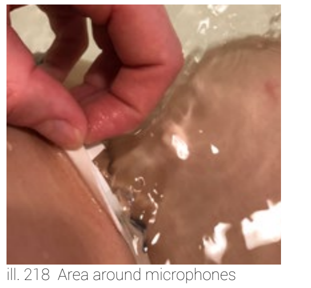
- The CentaFlow plaster wrinkles in the side, also before running, and there are areas where it doesn't stick properly to the stomach (ill. 214).
- After running and doing stomach exercises, both plasters still stuck relatively well to the stomach (ill. 215). However, the CentaFlow plaster gapped around an electrode.
- When in the bathtub the upper electrode on the CentaFlow got loose relatively fast. After the top got loose, a larger part of the plaster's top started gapping, especially when stretching.
- The stiff area around the microphone helped the plaster to stick to the stomach, and it was first after approx. 25 minutes, the area that needs to seal airtight to the stomach got loose (ill. 218-ill. 219).
- After 30 minutes in the bathtub the plaster used on the Monica device still stuck firmly to the stomach - also when pulling it. During the time in the bathtub, it was pulled in multiple times, and it still stuck well without gapping (ill. 217).
- The gel on the CentaFlow plaster started reacting with the water, where the electrodes were disposed.
- The lower part of the CentaFlow plaster still stuck to the stomach after the test, and the areas with longer distance from the electrode to the edge of the plaster, prevented the electrode area from getting loose.
- The Monica plaster stuck to the stomach for almost three days, and hurt a little to remove.
- Generally, the plasters wasn't really noticed when running or stretching, and the Monica plaster didn't rip the skin when being pulled.


ill. 214 CentaFlow plaster before running


ill. 215 CentaFlow plaster after running


ill. 216 CentaFlow plaster bathtub


ill. 217 Monica plaster bathtub


ill. 218 Area around microphones


ill. 219 Around microphones after 25 min.

Sum up

The test showed that the adhesive on the CentaFlow plaster stuck relatively good in the beginning when moving, and therefore we assume that with the right shape, the adhesive used on this plaster can be used for both home monitoring and monitoring in clinics, where movement is limited. We have some double adhesive tape which we asses to have approx. the same adhesive properties. It was used on the test with the pregnant, and will be used from here on.

For monitoring during delivery, we assume that plaster with the same properties as the one used on the Monica device, will be enough and maybe too strong. Ideally, we should get different samples on plasters. To test which are the optimal for the different scenarios.

The test generally showed that when there is approx. 1,5 cm from the edge of the plaster to electrode, the plaster seals tight and sticks better to the skin, also during movement, and therefore we will be working further with this. Additionally, the stiff area around the microphones seemed to have a positive effect, regarding ensuring an airtight area by the cavity.

Having a plaster for home monitoring and monitoring in clinics, and one for delivery, will partly solve the conflicting demand 1. However, we still need to work on reducing and optimising the plaster to rip the skin as little as possible.

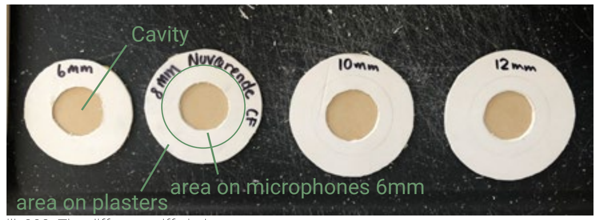
Construction of the area around the microphones

Objective

It's very important that the cavity around the microphones towards the stomach seal completely tight to the stomach, to measure correctly. As mentioned in the test with the plasters, having a stiff ring around the area helped enable this. Therefore, the objective of this chapter is to test different sizes of rings around the microphones, to see how big it could or should be, to fit multiple stomachs. The full test is shown in worksheet 19.

We tested different sizes of rings, where one resembled the current CentaFlow solution. We tested rings where the stiff area where 12 mm, 14 mm (current CentaFlow), 16 mm and 18 mm (ill. 220). The test was conducted using the adhesive tape, with similar properties to the CentaFlow plaster.

We tried testing on the fake stomach and a balloon, but none of those resembled a real stomach and how the skin would react, so lastly we tested on our own stomachs. We tried moving, bending and sitting while wearing each ring, and found that the smallest rings where the ones that fit the best (ill. 221, ill. 222). Even though we do not have a large pregnant stomach we assume that these two sizes will be the best on a pregnant belly, also when referring to the fake stomach, where these fit best aswell. Ideally, it should be tested on a real stomach.



ill. 220 The different stiff circles


ill. 221 12 mm

ill. 222 14 mm

Sum up

The test showed that the two smaller rings on 12 and 14 mm worked best. From heron we will be working with a stiff area around the cavity on 14 mm, as we know that having a larger area reduces noise from the surroundings passing through the skin, and into the microphone. 14 mm is also the measurement of the stiff area that CentaFlow uses now, and by testing it with plaster with similar properties, and in scenarios that are likely to happen at home, we found that it worked well. Therefore, we assume that this will work as intended, and that it, in combination with the shape of the lower part, will be able to solve technical requirement 2, Table 4.

Construction of the area around the electrodes

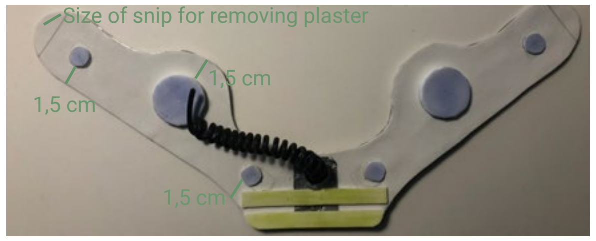
Objective

From the meeting with CF, we got confirmed that there should be a layer of conductive gel between the stomach and the electrodes, to enhance the signal. Therefore, we needed to figure out how to place this on product, without creating extra steps.

As mentioned, we wish to have approx. 1,5 cm from the edge of the electrode to the edge of the plaster because we found in the test with the current plaster that this ensured that the electrodes sealed tight to the stomach. Therefore, the product should be shaped to meet this. We will be working with having six electrodes - four in the lower part and two in the upper part (ill. 223).

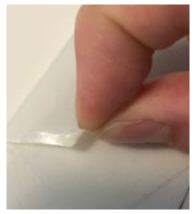
To investigate how the current conductive gel is put on the current single-use plaster, we have deconstructed the plaster. This is shown in worksheet 21. On the current plaster they have cut a hole in the adhesive that is larger than the electrode, and then put a square of conductive gel with approx. 1mm thickness over the electrode. Because we wish to have a single-use plaster with gel attached to the product, the gel should stick to the single-use plaster, and we can therefore not use how they have constructed the current plaster.

We tried making a test where we cut a hole in a plastic pocket, and put the gel from the CentaFlow plaster over the hole, and tried to remove it. This didn't work as intended, but having a layer of adhesive on the plastic pocket and thereby around the hole, the gel stuck to the adhesive in the sides, and when sticking the side with adhesive and gel to the table and removing it again, the gel kept sticking to the adhesive (ill. 224-ill. 226). The full test is shown in worksheet 23. Therefore, we assume that if we have a layer of adhesive around the holes in the single-use plaster, where the gel should be placed, we can ensure that the gel sticks to the single-use adhesive, and can be placed and removed with the single-use solution.



ill. 223 New mock-up of the lower part


ill. 224 Adhesive with gel stuck to surface

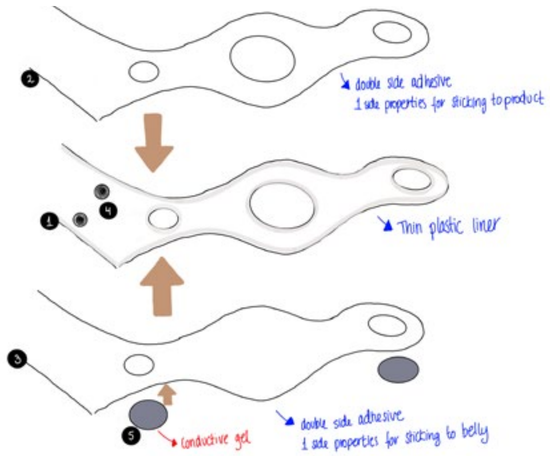

ill. 225 Removing it from surface


ill. 226 The gel still sticks to the adhesive

Sum up

Through a deconstruction of the current CentaFlow solution, and a test with conductive gel, we found it possible to have the layer of conductive gel on the single-use solution if we have adhesive around the hole where the gel should be placed, and having the gel overlap approx. 3 mm around the hole. Furthermore, the area around the electrodes should be constructed so there is approx. 1,5 cm adhesive from the sides of the electrodes to the side of the product, to ensure that the electrodes seal tightly, also when moving around. By doing this, we assume that the technical requirement 4 can be solved for the lower part.

The illustration shows the initial idea of construction of the single use plasters. The liner works as the middle piece, and on each side a layer of adhesive is put on. The adhesive has different properties according to what it needs to stick to (stomach, or product).



ill. 227 Initial construction idea to the single use plasters

Arch on upper part and battery capacity

Objective

As mentioned under choice of concept, we need to figure out how to construct the upper part to better fit multiple stomachs, and for the two electrodes placed in the upper part to be able to measure. The objective of the chapter is therefore to solve this problem, while considering the number of batteries that can be placed in the unit. The full test is shown in worksheet 22.

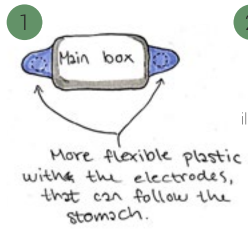
We started ideating on different ways to solve how we make the electrodes seal better to the stomach (ill. 228-ill. 230).

We had an idea that small flexible flaps, holding the two electrodes, would ensure that the electrodes would be able to measure (ill. 228). We chose to further ideate on this idea, as it seemed better than the two other solutions. We had a concern if the flaps on concept 1 would break before the rest of the part, because of the flexibility. Therefore, we made more sketches to see if we could come up with an idea to solve this (ill. 231-ill. 233). Additionally, we still have the idea from earlier of bending the surface towards the stomach a bit (ill. 25 p. 15).

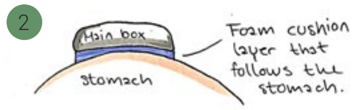
For each of these ideas we had some concerns. The idea 1.1 is based on the idea of having a cover in a flexible material e.g. PVC, and then a core in a more stiff material e.g. PP or PVC. However, there need to be an easy way of removing the stiff core, holding the majority of the electronics, and if e.g. the batteries should be exchangeable, there are some cleaning concerns. 1.2 and 1.3 are based on the same idea, but having plastic hinges like on Tupperware, could make it easier to clean the part. However, we need to see how good the flaps seal to the stomach.

Before moving further with any of these concepts, we wanted to see how much space different configurations of batteries, and the other electronic components, would take up on the stomach. We tried different combinations of having one vs. four batteries, and found that having four batteries would both require a lot of space and make the upper part heavy (ill. 235-ill. 236). We found that all the concepts gapped in some parts of the fake stomach (ill. 235). This stomach is the one that is most pointed which is why we chose this for the test.

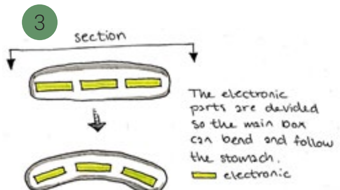
We hadn't made an arch on the surface towards the stomach, and therefore we wished to test if this could solve this problem. Before trying with archs on the main box, we tried to use the concept from ill. 233. We incorporated hinges and divided the electronic components in two parts that was combined by



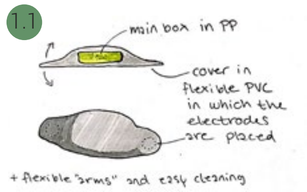
ill. 228 Concept 1



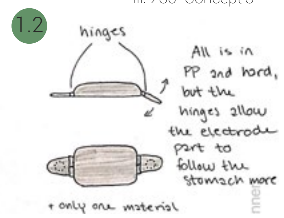
ill. 229 Concept 2



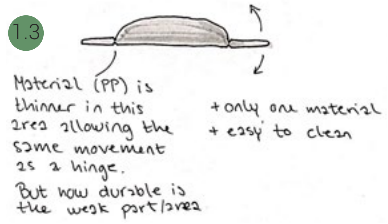
ill. 230 Concept 3



ill. 231 Concept 1.1



ill. 232 Concept 1.2



ill. 233 Concept 1.3


ill. 234 Plastic hinge


ill. 235 Main box with 2 batteries

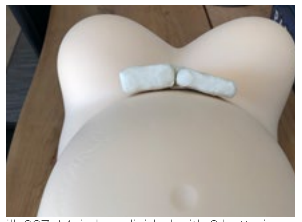

ill. 236 Main box with 4 batteries

a hinge. The idea with the hinge was executed using clay between the two parts (ill. 237-ill. 238). This showed that the contact area of the side towards the stomach obviously became larger, and therefore it's more likely that we can make the electrodes seal tight. However, this concept consist of either two or four batteries, and the part takes up a lot of space on the stomach (ill. 237-ill. 238).

With this in mind, we moved further with different arches on the upper part. This was done with a solution where the batteries can be easily exchanged by using battery-packs, instead of batteries enclosed electronics. If an arch can solve the problem, it's preferable to use this over the other concepts, as it's more simple and without weaker areas in the construction, like hinges.

We tested with a length corresponding the length of the circuit boards, and tried arches from 2-5 mm over this length (ill. 239-ill. 245). We tested on the fake stomach, on three different areas and arches, and on our own stomachs, resembling the more flat stomachs. The test showed that the 4 mm arch over 7 cm, both would be able to fit the fake stomach and our stomachs relatively well (ill. 240-ill. 242). Therefore, we made a test with the right size and weight and placed it on ourselves, using the adhesive with similar properties to the wanted, for home monitoring and monitoring in clinics. When moving and jumping a bit, the part still stuck to Trine's stomach without letting go, but on Sofie's it gapped a bit in the middle (ill. 241). If we make the single-use adhesive larger than the upper part, we might be able to overcome this challenge. It seems likely, and therefore we proceeded with the assumption that using the current adhesive, in combination with the archs, will be compatible for home monitoring and monitoring in clinics. Regarding monitoring during delivery, we assume that having a plaster with more adhesive properties would solve this. Additionally, the stomach will be larger, and therefore when the main box is placed on top, the gravity will work with us.

Regarding the number of batteries, and making them exchangeable or not, there are some pros and cons. The full list is shown in worksheet 22. Generally, we are more keen on having the batteries exchangeable, and maybe having a battery pack of two batteries with capacity of 12 hours for delivery, and one battery for home monitoring and monitoring in clinics with capacity for six hours. Having the batteries exchangeable, makes it easy to replace them when they start malfunctioning, and it reduces the weight of the upper part. Furthermore, it's easier to differentiate the products, and not having 12 hour battery in the unit for home monitoring or monitoring in clinics when it isn't necessary. Regarding the battery time for clinics, the six hours of battery capacity is enough, with the assumption that they put the device back in the docking station after use. We need to see if this is realistic.


ill. 237 Main box divided with 2 batteries

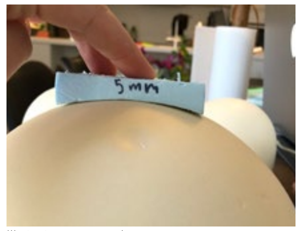

ill. 238 Main box divided with 4 batteries

ill. 239 2mm arch

ill. 240 4mm arch

ill. 241 4mm arch on Sofies stomach


ill. 242 4mm arch on Trines stomach



ill. 243 5mm arch

ill. 244 4mm arch on Sofies stomach


ill. 245 4mm arch on Trines stomach

Sum up

Through tests we found that it seems possible that having an arch of 4 mm over a length of 7 cm, will fit multiple stomachs. Ideally, it should be tested on more stomachs, but by using the fake stomach which is very pointed and our flat stomachs, we hope to have solved it. It should be tested if making the single-use adhesive larger than the part, would provide extra certainty of the part sealing tight because the contact surface becomes larger, and there is a larger safety margin, like on the area around the electrodes.

Regarding the battery time, we wish to make a solution where batteries are easily exchanged, without making it hard to clean the device. Furthermore, we wish to have different battery-packs for the different scenarios. One battery is enough for home monitoring because they measure for 30 minutes at a time. It's presumably also enough for the clinics because it's unlikely that all the women a midwife has in for consultation during one day, need to be monitored with the product. However, we need to investigate if this assumption is correct, and if the midwives are likely to put the product back into place after use. Having the product make a sound if it isn't put back in place, would help this presumption. Regarding monitoring during delivery we wish to have a battery pack of 12 hours, and one or two extra battery packs in the docking station.

Detailing of the single-use plaster solution

Objective

Until now we have only made one simple mock-up of the idea behind the single-use adhesive. Therefore, we need to detail this, and fully develop it to enhance the best user interaction, but also experience of wearing the device with least possible discomfort. The full process can be seen in worksheet 23.

Adhesive on lower part

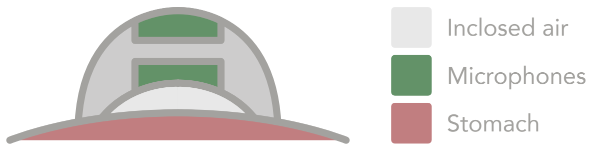
We started by solving the adhesive on the lower part. For this there were some guidelines that should be followed:

- Between the electrodes and stomach, there can only be conductive gel.
- The area around the microphones, and the cavity towards the stomach should seal airtight to the stomach (ill. 246).
- The adhesive around the electrodes and microphones should be approx. 1,5 cm to ensure they seal tight to the stomach (ill. 223 p. 62).
- There should be used press studs for user friendly placement of the adhesive.
- There need to be an area, where the user can grab the single-use adhesive, to pull it of the product after use (ill. 223 p. 62).
- There should be clear identification of which foil to remove when.
- We have an assumption that the adhesive on the area around the guide towards the stomach, needs to be covered with a separate piece of foil when the midwife has to place the product. If it's part of the foil covering the adhesive on the sides, and this is removed fully before placement, it can be difficult to place the device correctly, without the sides starting to stick to other areas (ill. 249).

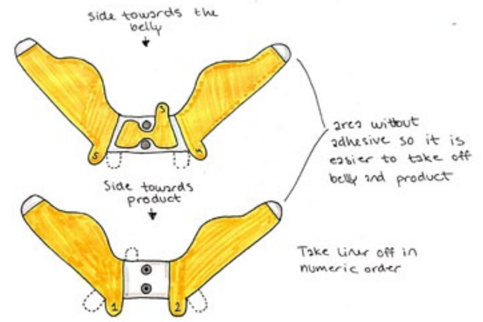
We started by making a new lower piece that meets the wanted demands of 1,5 cm between electrode/microphone and edge. On the device we made the areas with electrodes, guide and microphones higher, to create feed forward and feedback (ill. 223 p. 62).

Additionally, we sketched on two different concepts for the adhesive (ill. 247, ill. 248). One where the liner where the adhesive is placed, is the size of the lower part, but the adhesive is smaller (ill. 247), and one where the liner and adhesive is the same size (ill. 248). We wanted to test if having the liner wider than the adhesive made it easier to place it, or if the interaction was better without the extra liner. On both concepts the adhesive was reduced in the areas where there isn't placed electrodes or microphones, with the hope to reduce the plaster ripping the skin. The concepts were built and tested (worksheet 23).

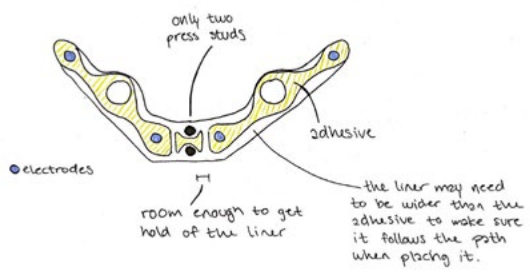
The test showed that it was acceptable to place the adhesive when the liner was the same size of the adhesive (ill. 248).



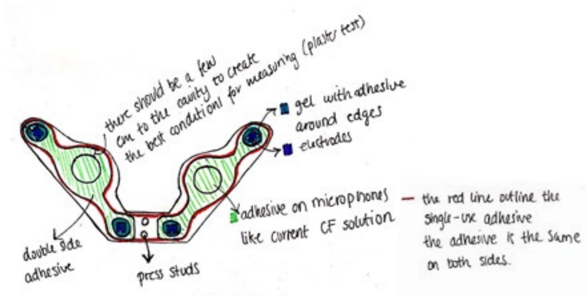
ill. 246 Microphone on stomach



ill. 249 Foil construction on front and back side

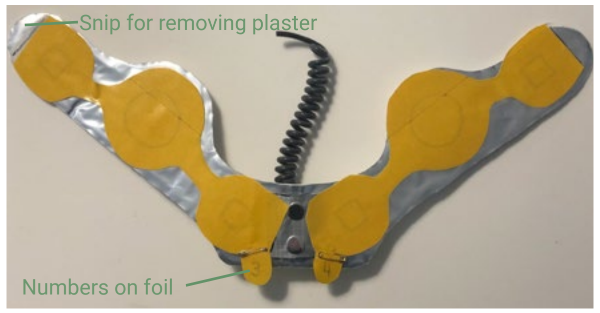


ill. 247 Liner larger than adhesive, adhesive smaller than lower part



ill. 248 Liner the same size as adhesive, adhesive smaller than lower part


ill. 250 Liner largen than adhesive, adhesive smaller than lower part



ill. 251 Liner the same size as adhesive, adhesive smaller than lower part

However, when placing the product on a stomach, and sitting and moving, the area between the lower electrode and microphone gapped a lot, and we have a concern that this gap will cause the adhesive to let go (ill. 252). Therefore, we tried placing adhesive that covered the full area of the product from the lower electrode to the microphone. It seemed to work, but we should work on optimizing the shape of the product in this area.

We tested the assumption that the foil towards the stomach needs to be divided in three when it's the midwife that places the product (ill. 249). We had one person laying down, and one attaching the plaster. The test showed that it was easiest and most user friendly having a piece of foil around the guide that could be removed separately, enabling the midwife to place the guide first, and then remove the foil on the sides and attaching them.

From the test on the pregnant, we found that it was hard for her to see and place the product when she removed the middle layer of foil first and placed the guide, as she couldn't see the foil to the sides because of the stomach. Therefore, the ideal scenario for the pregnants are that they remove all foil on the side towards the stomach, prior to placing the product. Ideally, the foil on the plaster to the pregnant should therefore be in one piece on the side towards the stomach, to reduce the number of steps. However, we assume that it isn't a problem removing the three parts of foil, prior to placing it.

We have made small snips without adhesive, on each end of the plaster, to see how the interaction of removing the plaster was (ill. 253). We found that having a snip on approx. 7-8 mm was good for removing the foil.

Lastly, we tested if having two press studs instead of four, as used in the test with the pregnant, would enable the same user friendly interaction. It seems that two press studs are enough to still ensure precise placement of the plaster. We of cause should construct the plaster, to have some tolerance if the plaster is put on skew, but from our test we found it really easy to place straight (ill. 251).

We have made a quick sketch on the construction of the plaster which is shown on ill. 227 p. 63. The idea is to construct it with three layers, where the two outer layers has properties to 1) stick well to the product, 2) stick well to the stomach. The adhesive towards the stomach should be different from monitoring in clinics and home, to monitoring during delivery.


ill. 252 Gap between lower electrode and microphone


ill. 253 Snip for removing plaster


ill. 254 Placing without press studs


ill. 255 Applying press studs


ill. 256 Removing foil on side towards stomach


ill. 257 Wearing the plaster and main box

Adhesive on upper part

For the plaster on the upper part, the same criteria about space and construction around the sensors apply. We had an assumption that because the plaster was relatively small we wouldn't need to use press studs to place it correctly. However, the test showed that in multiple cases, the plaster was put on really skew (ill. 254). Therefore, we implemented two press studs in one of the sides which corrected this (ill. 255).

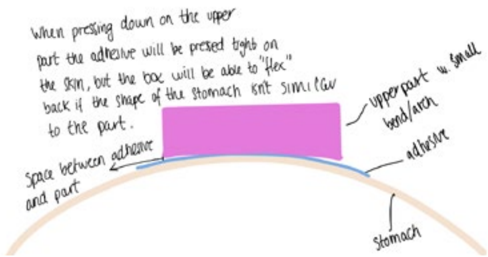
As mentioned earlier we wanted to test if having a plaster larger than the product, would secure the part even better. This helped (ill. 257). When moving a lot, the edges of the plaster seemed to slip a bit, however, the pregnant won't be moving a lot in home monitoring and monitoring in clinics. When used for delivery the plaster will be stronger, and therefore we assume that it isn't an essential problem. Before determining the size of the edge of plaster around the part, we wish to detail the shape of the part.

Sum up

From tests we found that it's acceptable if the area on the adhesive, from microphone to upper electrode, is slimmer on the lower part. However, the area from the lower electrodes to the microphones, should follow the size of the product, to ensure that it seals tight. It works well having two press studs for a user friendly interaction when placing both single-use plasters. Furthermore, there should be a snip on the edges of the plaster on approx. 7-8 mm, to make it easy to remove the single-use plaster.

The interaction for the midwives should be that the foil on the plaster towards the stomach, should be divided in three pieces: one for the area around the guide, and one for each side. When the pregnant places the product herself, all foil should be removed, but we assume that it's fine that she has to remove three areas, and therefore we can use the same outline for the plaster.

For the top part, it seems to work as intended to have the single-use plaster being larger than the part. When having determined the final shape, we should determine the exact size of the plaster. When finding the size, we should additionally secure that it fulfils the criteria, but rips the skin as little as possible. We also got an idea, of having the adhesive on the upper part towards the product, being a bit shorter in the sides, making the adhesive gap from the product, but not from the stomach. We assume that this will enable an even better fit on multiple stomachs (ill. 258 p. 67). If the stomach is very pointed the part might be likely to slip in the sides, but if the plaster in the sides doesn't stick to the part in the sides, we think it will solve this problem. This should be tested.



ill. 258 Plaster idea upper part

Initial material and production thoughts

Objective

We wanted to get initial insights to possible materials and production methods that could be used for the different parts. Therefore, the objective of this chapter is to outline criteria to materials, and give a short insight to the possible materials.

The product consists of two main parts, the upper and lower (https://drive.google.com/file/d/1aqdrtcZqZ8F4ETM1N-Wn58KSBslexgOC-/view?usp=sharing). For each part there are different criteria to the properties.

Lower part:
- Flexible and relatively soft to fit well on stomachs and be comfortable to wear, and therefore the E-modulus should be relatively low.
- It should be strong and hard wearing.
- Relative low elongation.
- Weldable according to initial construction thoughts.

Upper part:
- Stiff and less flexible, but still strong and hard wearing.
- Relatively high E-modulus.

Common:
- Withstand being cleaned with active chlorine, ethanol spirits, water and soap.
- Both parts should withstand being dropped multiple times (common requirement 4, Table 3 p. 38). Therefore, the impact strength should be good.
- Low water absorption.
- Low abrasion towards the skin.
- Approved for medical use.
- Relative fine surface finish.
- Available in colours.

From this list we started looking at possible materials. They are listed in the following table:

Material	Pros	Cons	Sources
PVC (stiff and flexible)	• Widely used for medical equipment • Use of plasticizers makes it possible to get the wanted flexibility • CE approved plasticizers available • Good chemical resistance • Good weldability • Low water absorption (flexible: 0,2-1%, stiff: 0,04-0,4%) • Recyclable • Low cost 1 $ per kg • E-modulus (flexible PVC: 1-1800 MPa, stiff PVC: 2400-4000 MPa) • Tensile strength (flexible PVC: 7-25 MPa, stiff PVC: 35-60 MPa) • Hardness Shore D (flexible PVC: 15-70, stiff PVC: 65-90)	• Flexible PVC is not resistant to alcohol • Plasticizers migrate over time which has been a concern with human contact regarding previously used plasticizers	(PVCMed Alliance, 2020) (Omnexus, 2020a) (Bay and Larson, 1991) (Lefteri, 2014) (Thompson and Thompson, 2017)
PE (LDPE, HDPE)	• Available in medical grade • Good chemical resistance • Weldable • Recyclable • Low cost • Tough material (LDPE: 999 J/m, HDPE: 20-220 J/m) • Low water absorption (LDPE: 0,005-0,015%, HDPE: 0,005-0,01%) • E-modulus (LDPE: 130-300 MPa, HDPE: 500-1100 MPa) • Tensile strength (LDPE: 10-20 MPa, HDPE: 30-40 MPa) • Shore D hardness (LDPE: 40-50, HDPE: 60-70	• LDHE has limited resistance to alcohol • Concern if LDPE is too stiff for the lower part	(Biesterfeld, no date) (Bay and Larson, 1991) (King Plastic Corporation, 2011) (Omnexus, 2020c)

PP	• Available in medical grade • Low water absorption 0,01-0,1% • Good chemical resistance • E-modulus 1100-1600 MPa • Tough material 20-60 J/m • Weldable • PP copolymer has a high impact strength • Colourfast • Relatively low cost 2,45 $ per kg. • Hardness shore D: 70-83 • Recyclable	• The E-modulus can be a problem if used for the lower part, even if it's made in a thin layer	(Biesterfeld, no date) (Bay and Larson, 1991) (King Plastic Corporation, 2011) (Lefteri, 2014) (Omnexus, 2020d)
EVA	• Available in medical grade and used as an alternative to PVC • Low water absorption 0,005-0,13 % • Good chemical resistance • Tough 999 J/m • Shock absorbent • Relative low cost 2,35 $ • Weldable • Takes colours well • Tensile strength 7-30 MPa • E-modulus: 10-200 MPa • Hardness shore D: 15-45	• Limited resistance to ethanol • Relatively low melting temperature	(Omnexus, 2020b) (Lefteri, 2014)

Table 8 Different materials

For the lower and upper part, our initial idea was to produce it in flexible and stiff PVC because it's widely used in the medical industry. However, there are some problems with the plasticizers, and even though there are multiple different plasticizers approved for medical equipment, the plasticizers will over time evaporate causing the PVC to become more brittle (Thompson and Thompson, 2017). Therefore, we have chosen a PP copolymer, as it has a low density, high impact strength and good chemical resistance (Omnexus, 2020d) .

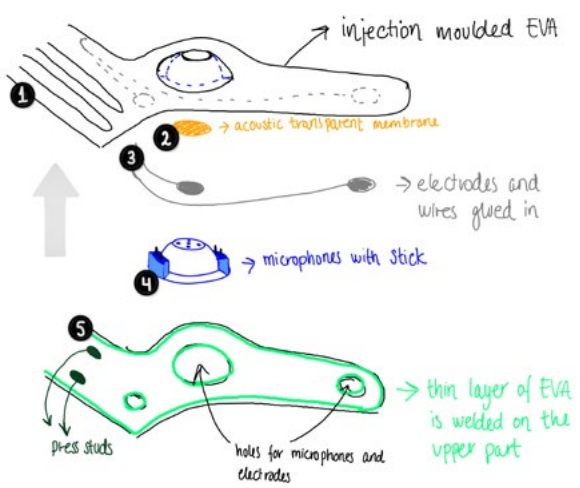
As for PE and PP for the lower part, we have a concern if the material will be too stiff and sharp. The lowest LDPE regarding shore-classification, is Shore D-40 which we assume is too stiff (Omnexus, 2020c). Ideally, we wish to have a hardness around Shore D 15-20 (Ponte, 2017), but it should be tested which hardness is optimal.

EVA has been used as an alternative to flexible PVC in the medical industry, and it has some of the same properties as PVC, but without the use of plasticizers. Furthermore, it has a better chemical resistance, and has a really good toughness and tear strength (Omnexus, 2020b). Therefore, we will be using this for the lower part.

Initial construction thoughts

We have focused a lot on the lower part, and how to construct it to make it easy to remove the microphones when the used and broken part is returned to the company e.g CF (ill. 259).

The initial idea is to injection mould the top of the lower part, with guides for the electrodes, and wiring and then close it with a thin sheet that is welded on. The initial thoughts behind using injection moulding, is that it's possible to use the mould for making the guide and the areas on top, where the user should be able to see the placement of the electrodes. Additionally, we wish to have a relative fine and uniform surface finish, to ensure least possible bacteria can stick to the product.



ill. 259 Initial construciton thoughts of lower part

Sum up
Our initial idea for material is to make the lower part in injection moulded EVA, with a hardness on the shore D scale of approx 15-20. The upper part should be constructed in injection moulded PP. The production method should be investigated further, to see if we can find a cheaper alternative with the same finish.

Feedback with CentaFlow session 2

Objective
Prior to this meeting we had detailed the user interface further to make it more realistic and get the last feedback, especially from Diana, on the interfaces for the midwives. The full development and test of the interfaces can be seen in worksheet 24. Furthermore, we showed the final concept. This chapter gives a short overview over the feedback from CF. The same people from the prior meeting was attending.

Ill. 260, shows the overall picture that the midwives receives when the product is measuring. Generally, they like the simplicity of the design, and Diana mentioned that she liked the idea of it being very similar to the curve they receive now. Also, because she thinks it will be easier to implement which also has been our intention. She also mentioned that it might be good to have the mother's heart rate because it sometimes can be hard to distinguish between the fetus' and mother's heart rate. They liked the curve over blood flow. We have divided it in four levels, like a current pulsatility index which shows the blood flow measured with a special ultrasound device. It's realistic, but we can't call it pulsatility index as it's reserved ultrasound.

Regarding the measuring session, we wanted to get feedback on our idea of having the device turn on when the measuring session is initiated on the program/app, and not having an on/off button on the device. Diana mentioned that she would prefer it turning on/off by itself, as they often wear gloves etc. Furthermore, Rasmus mentioned that the current device turns on/off when it leaves the box. It might make more sense to have it start when it's removed from the docking station because the user will get direct feedback when they take the product, and not first when the program is initiated. We had an initial idea of having two diodes showing battery capacity and on/off (ill. 261). When we presented this, we started evaluating that it might make sense having a third diode that shows when it's measuring.

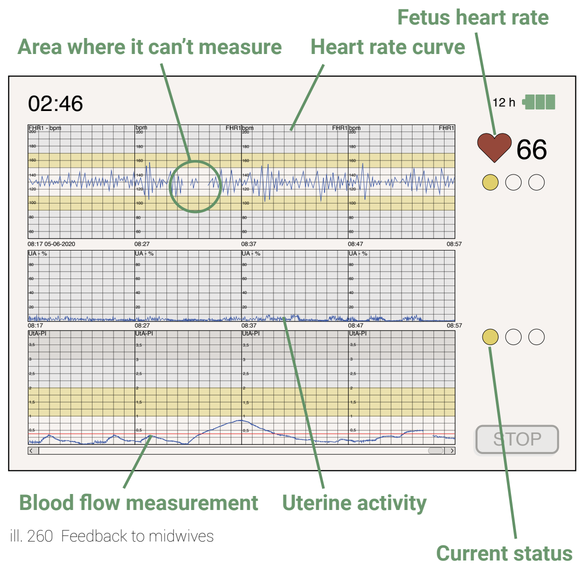
As mentioned in the sum up to chapter "Arch on upper part and battery capacity" we had an assumption that if the midwives put the product back in the docking station after each use, the battery capacity of six hours will be enough. Therefore, we wanted to discuss the battery capacity with Diana. She mentioned, that midwives can be untidy and that it would be preferable if the device is put back into place after use. Having a sound signalising when the product isn't back in place after use, will help this and in time it will hopefully become a habit.

While developing the interfaces and set-up, we came in doubt about when the product should start making noise if it wasn't placed back into the docking station after use.

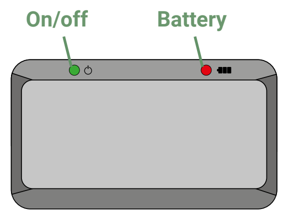
- We had an assumption that it didn't need to make a sound in home monitoring if not put back, but that is rather should make a sound after a measurement if the battery didn't have capacity for one more measurement. The people from CF shared this assumption.
- Regarding clinics, we were in doubt if the product should make a sound during the consultation, or first after the session, or possibly first at the end of the day. We don't want to disturb the midwives, but it's important that they remember to put it back. Stine and Stina mentioned in one of the first interviews that things get lost. Therefore in combination to what Diana stated, it seems important that it makes a sound during the consultation. Diana thinks it should start making a sound five minutes after a measurement.
- After a delivery, we had an assumption that the noise shouldn't disturb during the after birth, where the placenta is delivered. Therefore, our initial idea was that the device should start making a sound after 30 minutes. Diana mentioned that there is multiple people present at a birth, and that one will have time to remove and clean devices. She thinks it should start making a sound after 15 minutes.

Earlier we had an ideation phase on the number of batteries, and whether or not they should be exchangeable in all scenarios. Our initial thoughts was, as mentioned, that it makes sense having exchangeable batteries in all scenarios, as they decrease in capacity over time. Ill. 262 shows the idea of having exchangeable batteries, where the battery is fastened with conductive press studs. This makes is easy to clean, and attach and detach, the battery during delivery. It's also possible to have different battery packs, as mentioned earlier. CF supports this idea and states that the battery is the component with the shortest lifespan, in their current solution. Making it as a separate part, makes it easy to change the battery.

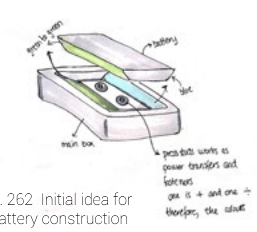
Lastly, Jakob had a concern if the waterproofing needed for the delivery scenario would cause the product to become a lot more expensive. When choosing an IP classification we should investigate if it makes sense to have a lower IP-class for home monitoring and monitoring in clinics.



ill. 260 Feedback to midwives



ill. 261 "Face" on main box with diodes



ill. 262 Initial idea for battery construction

Sum up

From this meeting we got the final feedback on the user scenario, both regarding interface on the app/computer, interface on the product, and the scenario after use regarding sound. We will be working further with:

- That the device makes a sound in home monitoring when there isn't battery capacity for one more measurement.
- That the device starts making a sound approx. five minutes after a finished measurement in the clinics, and after 15 minutes in delivery.
- Seeing if having three diodes on the upper part makes sense for the users.

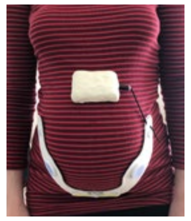
Lastly, we will be working on having a battery-pack with one battery for home monitoring and monitoring in clinics. For delivery the battery-pack should consist of two batteries. Having this enable us to solve requirement 1.1 for delivery (table 5 p. 39).

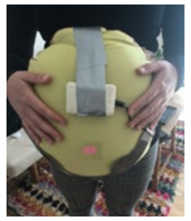
Wire considerations

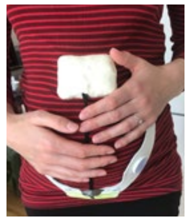
Objective

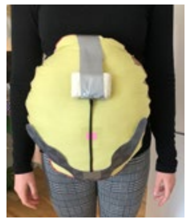
One of the concerns and compromises made by choosing this concept, was the wire. We wished to optimise this specific part, and therefore the following chapter will show how we worked on optimising this. A full test can be seen in worksheet 28.

After researching we found a wire that is flexible and elastic, and can be produced in many different plastic-types. The firm behind the wire, Minnesota Wire, does already make wiring solutions for the medical industry (Minnesota Wire, 2019b). The wire is called iStretch (Minnesota Wire, 2019a). We have chosen to work further with this type of wire, as it's smaller than the spiral wire, and easier to clean.


ill. 263 Fake stomach side


ill. 264 Pillow side


ill. 265 Fake stomach middle

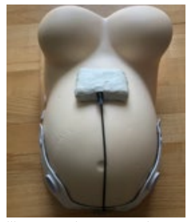

ill. 266 Pillow middle

After choosing this wire, we wanted to see how long the wire needed to be to fit multiple stomachs, without being to tight on the larger stomachs, and to loose on the smallest. Furthermore, we wanted to see if the current placement of the wire was the optimal placement.

We tested the placement by each wearing a fake stomach and the product for an half hour, to see which placement was optimal. Generally, there wasn't much difference, but we had a concerns that having the wire on the side, would make it easier for the side to gap than if placed in the middle. This assumption combined with results from a pro/con scheme shown in the worksheet, made us choose to place the wire in the middle (ill. 263-ill. 266).


ill. 267 Cast 12 cm


ill. 268 Pillow 12 cm


ill. 269 Fake stomach 12 cm

To find the right length, we tried placing the product on three different fake stomachs (the fake stomach, the pillow and a cast of a pregnant stomach in week 39). We used an elastic hair band that could be elongated approx. 58 % ,and tried different lengths on the stomachs. To ensure that we placed it in the same spot every time, we marked the navel. From the test we found that the length of the wire should be approx. 12 cm with a plug on 2 cm (ill. 267-ill. 269). Ideally, we should try the test on different real stomachs, with different types of wire, to find the right combination. We tried placing the product on our stomachs, and found that the wire would be a bit loose as we doesn't have a pregnant belly. It's likely that the wire will gap a bit in the earlier weeks for home monitoring and monitoring in clinics (ill. 270-ill. 271). However, we evaluate that this isn't critical, as movement when measuring in these situations is limited, and it's rare to find a pregnant who has a stomach as small as ours, in week 24. When the device is used during delivery it doesn't seem likely that the wire will gap.


ill. 270 On flat real stomach standing


ill. 271 On flat real stomach sitting

Sum up

From this test we found indications that the wire is least in the way when placed in the middle. Furthermore, when having an elastic wire that can be elongated 58 % it should be approx. 12 cm with a plug on 2 cm. Ideally, we should test the length of the wire on multiple stomachs, but we assume the mentioned length will work.

Shape and identity of product

Following phase will be showing the process, to the final shape and identity of the product.

Shape

Objective

The objective of this chapter was to find the optimal shape, both regarding appearance and functionality. The full process can be seen in worksheet 26 and 29.

We started by identifying values, emotions and feelings of the environment and context, and which emotions and feeling we wanted the product to awake in the user.

Value, emotion, feeling of environment and context	Value, emotion, feeling the product should awake	Appearance
• Womanly (curvy lines) • Giving life to a person (warmth) • Trust in the pregnant women's intuition, nature and body	• Forthcoming, friendly, kind • Professional • Clean - the product shouldn't take colour over time • Thoroughly thought out, and not cheap	• Soft curves • Warm colours or pastel (baby) like colours

Table 9 Emotions and values

Shape of the lower part

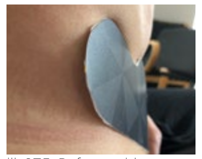
We started by finding the shape of the lower part, as there are some areas that is defined by the function, as presented in the chapter "Detailing of single-use solution".


ill. 272 Before removing material


ill. 273 After removing material

We started by seeing if we, by cutting of material in the area between lower electrode and microphone, could cause it to gap less (ill. 272-ill. 273). We used a thin plastic sheet that is less flexible than the wanted material, as we assume that if we can solve the problem using this, we will be able to solve the problem with the real material as well.


ill. 274 Before


ill. 275 Before - sides


ill. 276 Before - critical area

By removing material we ensured that the area sealed tight, also when moving, bending and sitting (ill. 274-ill. 279). We had adhesive on the full part. The sides still gapped a bit, and after evaluating on the length on the sides, and from looking at the current solution and the Monica device, we estimated that the sides could be shortened (ill. 280).

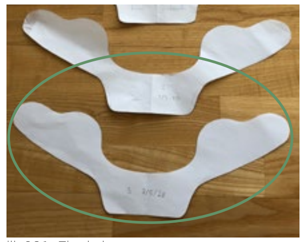

ill. 277 After


ill. 278 After - sides


ill. 279 After - critical area

From this, and with the distance of 1,5 cm from electrodes and microphones to the side, we started defining the shape. We wanted to create tense curves with rounded "friendly" edges. After multiple outlines we ended with the shape that ill. 281 shows.


ill. 280 Reducing length of the sides

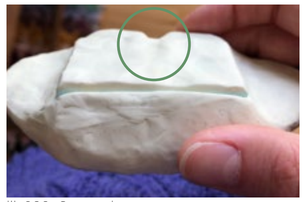

ill. 281 Final shape

Shape of upper part

For the shape of the upper part, we wished to make a shape that made the product appear more like one unit. Like with the lower part, there were some functional requirements, like having two electrodes and an exchangeable battery, and room for the circuit boards.

With this in mind, we started making different shapes to find the shape where the product appears as one unit. We used paper, foam and clay to get a feeling of the volume, as it's critical in this part that there is room for the components (ill. 282).


ill. 282 Shape of the upper part


ill. 283 Groove in upper part


ill. 284 Upper part with battery

The shape we found best, was defined further with battery, and guide that creates visual feedback on where to place the wire (ill. 284). We found that having a groove, helped to identify where the wire should be placed (ill. 283).

The current shape is longer than the one where we tested the arch in the chapter "Arch on upper part and battery capacity". Therefore, we reduced the length of the part, and tested how the arch should be with the exact shape (ill. 285-ill. 289). The length of the part ended on 11,5 cm, with an arch of 9 mm (ill. 286-ill. 289). With this arch we assume that the upper part will fit multiple stomachs, but as we only tested on the fake stomach and our own stomachs, it should be tested on multiple pregnant stomachs.
We had an assumption that the shape of the part, solved the problem earlier stated, about turning the part correctly. To verify this, we asked six people how they would turn it, and all answered correctly (worksheet 26).

Sum up

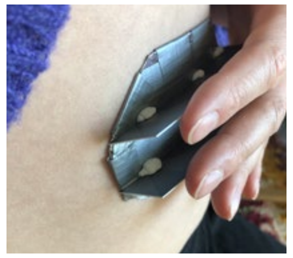
Through multiple iterations we have found a shape that appears friendly, using round edges. Using rounded edges on the upper part, has made the product appear more like one unit.

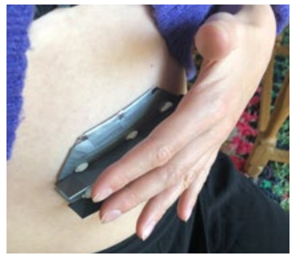
The upper part has a length of 11,5 cm with an arch of 9 mm which we assume will fit multiple stomachs. This should of cause be tested on real stomachs. We have found indications that the shape of the part does in fact, ensure that the user turns it correctly when placing the part. Also, the combination of a groove indicating the socket makes it more user friendly to place the plug.


ill. 285 Upper part final shape


ill. 286 9 mm bend on pillow


ill. 287 9 mm bend on fake stomach


ill. 288 9 mm bend on real stomach


ill. 289 9 mm bend on real stomach

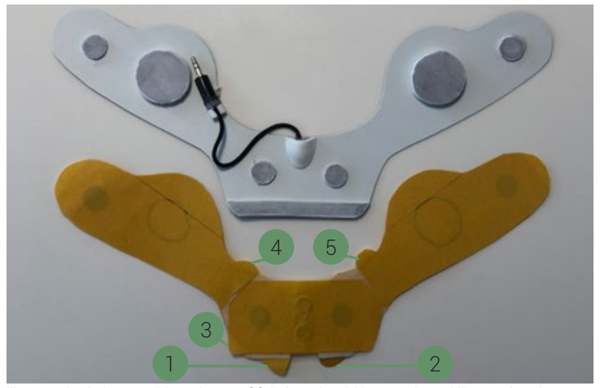
Final test of adhesive according to shape

Objective

After finding the final shape, additionally we needed to find the final shape and size of the single use adhesive. The full development is found in worksheet 29.

Single-use adhesive on lower part

In the chapter "Detailing of single-use plaster solution" we found it necessary to have adhesive on the full area, from the lower electrode to microphone. After we have reduced the length of the sides, we have evaluated that with the requirement of 1,5 cm adhesive around electrodes and microphones, there won't be much room for making the single-use adhesive smaller than the lower part, like on concept 2 (ill. 251 p. 65). But because the part is smaller, the irritation from the adhesive ripping the skin is reduced. Furthermore, we don't feel it ripping the skin because it's placed on the lower part of the stomach. Of cause some pregnants might have more sore skin (ill. 290).



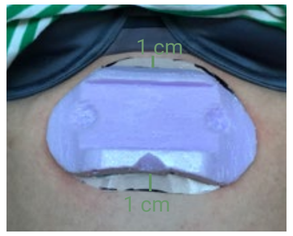
ill. 290 Final plaster with 5 pieces of foil that should be numbered like on the picture

Single-use adhesive on upper part

In the chapter "Detailing of single-use plaster solution" we found that having the plaster being larger than the upper part, ensured that it stuck better to the stomach. Therefore, we wished to test different shapes and sizes of the plaster (worksheet 29). Additionally, we wished to test the idea mentioned earlier, of having the side of the plaster towards the product, not stick on approx. the outer 5-7 mm of the sides (ill. 258 p. 67).

From the test we found that it wasn't necessary to have the plaster being larger in the sides, but that it should be approx. 1 cm larger in the top and bottom (ill. 291). Not having a larger area around the sides, additionally made the plaster rip the skin less when moving.

Furthermore, we found that the idea of having the outer sides towards the product not being adhesive, ensured a better fit on more flat stomachs better (ill. 293). When pulling in the part, it still stuck well to the stomachs, with this solution (ill. 292).



ill. 291 Final plaster on upper part


ill. 292 Dragging in the part the box still stick good


ill. 293 Plaster concept in the sides

ill. 294 Final plaster with numbers

Sum up

From this session we found the final shape of the single-use plaster. The plaster on the lower part is the same size of the lower part, but with no adhesive on the snips, to make it easy to remove the adhesive after use. On the lower part we have made the plaster 1 cm larger than the part in the top and bottom, and having the outer sides of the upper part not stick to the plaster, seems to ensure a better fit on multiple stomachs.

Colouring and identity

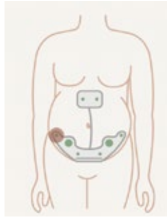
Objective

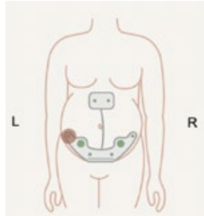
We wanted to add some additional identity to the product besides the shape, by adding colours, but we also wanted to use colour as guidance to ensure intuitive use.

Decoding of the "attention" guide

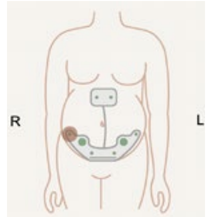
Firstly a test was executed, where the purpose was to figure out, how to display the "attention" screen guide, when a measurement is initiated, and something doesn't seal tight. The test would show whether or not a person would mirror the guide from the tablet or computer that shows where to press on the product. The test was only done on two individuals, so it only provides indications. First they used the guides, to see if they could code where to press if they were wearing the device themselves, like in home monitoring. Afterwards it was tested how they would do if someone else was wearing it - imitating the midwives' perspective. It was both tested without any guidance, besides the red dot showing the critical area, with left/right indications and with colour indications - mirrored and non mirrored (ill. 295-ill. 299).

The test persons both felt it was weird to mirror the image, both when wearing it themselves, and when another wore it. Also, they thought that the colours were more universal to use as guidance than the left/right reference, as some people don't know the difference. Furthermore, it was clear that they used the guides around the electrodes and microphones, both visually and tactile, to determine where exactly to press (ill. 301-ill. 300). The whole test is shown in worksheet 24.

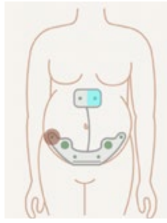

ill. 295 Decoding 1

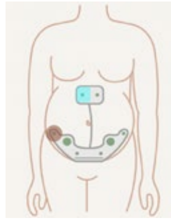


ill. 296 Decoding 2



ill. 297 Decoding 3


ill. 298 Decoding 4


ill. 299 Decoding 5


ill. 301 Product on fake stomach


ill. 300 Final shape of lower part with feed forward and feedback

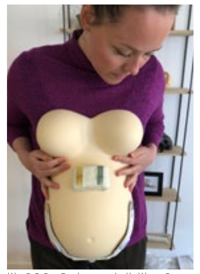
Colour guidance

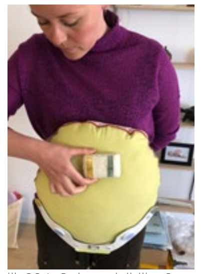
The second test was to see if the colour guidance from before worked in practice, and to see if we could use colour coding between the two parts, to place them correctly. So firstly, we placed green and yellow stripes on both parts, and tested if it was possible to see the colour guides on the lower part, on different sizes of stomachs. On our own stomach, it was easy to see the coloured parts (ill. 302). With the small fake stomach it was still possible (ill. 303), but with the large fake stomach, we couldn't see the colours because the "stomach" was too large (ill. 304).

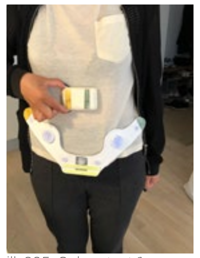
We estimate that it's acceptable that women with large stomachs in home monitoring, can't see the colours on the lower part because she usually starts monitoring in week 24, where she isn't that big. Therefore, she have time to learn how to place the product correctly, before the stomach is so big that it blocks the view of the guides.

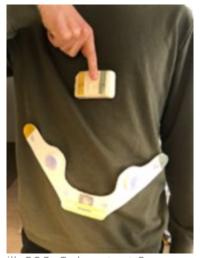
Afterwards we tested to see if other people could place the upper part correctly, according to the colour codes: yellow above yellow and green above green. Both our test persons placed it right when they looked at the two parts, and saw the colours (ill. 305-ill. 306). Therefore we assume that the corresponding colours on the two parts, help to place the upper part intentionally. These minor tests are shown in worksheet 27.


ill. 302 Colour visibility 1


ill. 303 Colour visibility 2


ill. 304 Colour visibility 3


ill. 305 Colour test 1


ill. 306 Colour test 2

Colour identity

Before choosing a colour for the product, we wanted to research women's associations to different colours, in relation to a professional clinical devices that they could trust. Therefore, a survey was executed that received 90 responds (worksheet 30). The colour editions from the survey can be seen on ill. 307.

The survey showed that the majority wanted the device to be light grey or white, and that they want it to be more or less the same product expression, in all three scenarios. Many felt that if they recieved a different product for home monitoring than the one used in the clinics, they would feel they had gotten a cheaper version. If the colours were too bright the women associated it with something unprofessional and frivolous, so they preferred subdued colours (ill. 307 no 1, 3, 8, 9). Some mentioned that the colours need to be gender neutral, while others would find it nice, to have the stereotype "baby-colour" of the gender they expect. When all this is said, many also mentioned that if they get a device to use from the hospital, they will trust it, regardless of the design and colours. (Worksheet 30)

Jakob from CF saw the colour editions, used in the survey. His comments were that the device can't be white because it easily can patinate and look dirty, even when it isn't. Also, he agrees with the women that think it should be gender neutral. However, he mentions that many midwives are tired of grey because many devices have this colour. Furthermore, he mentioned that blue is reserved some specific devices. These considerations resulted in their green product. They chose a more warm and darker green, so it wouldn't look dirty as easy. (Worksheet 31)

However, it's still a consideration that it's a good thing, to be able to see dirt on the device, so it will get cleaned properly. Still, Jakobs point about a light colour looking dirty over time, is valid. Therefore we will try to find a cross of the two, to find the perfect compromise.

The fact that CF interviewed midwives instead of "common" women regarding colours is interesting, and the comments about the "common" women trusting a device if their midwife hands it to them, made us think that we needed to show the colour editions to midwives Stine and Stina. Sadly, Stina was detained from participating, however we got Stines comments (worksheet 32). She liked the green colour, but was in doubt if it was just because the current CentaFlow is green. She didn't have a problem with grey colours, and couldn't recognize that many devices should have this colour. However, she would put some other colours on the grey, so it wasn't too boring. She wouldn't use a red colour because of gender associations. Lastly, she liked the coloured curves on colour edition eight (ill. 307).

From the visit at Viborg Hospital, we learned that more and more hospitals are trying to make the delivery rooms less clinical and more homely - as mentioned in the framing section. We should therefore also have this in our considerations.

ill. 307 Colour editions

Sum up

From all of this information, we decided that we wanted to proceed with a light grey, and work with a green and blue, or a light green and dark green colour guidance. The light grey is chosen because it won't be as bright on the stomach, and get patinated as fast as white, but it still looks professional and clinical. The colour guides then ensure that it won't have a too clinical expression, regarding our aforementioned considerations. The colours shouldn't be too far from each other, and should be rather subdue, so we avoid a too wild expression. Still, the colours should be different enough, to see the difference clearly - also in dimmed light. Furthermore, there shouldn't be non-intended colour differences over time, meaning that if the battery doesn't function well anymore, and the device needs a new one, there shouldn't be colour differences between the new part and the old. Therefore, the battery casing should have another colour than the rest of the upper part. Lastly, there should be worked further with refining the coloured curves from colour edition seven and eight (ill. 307).

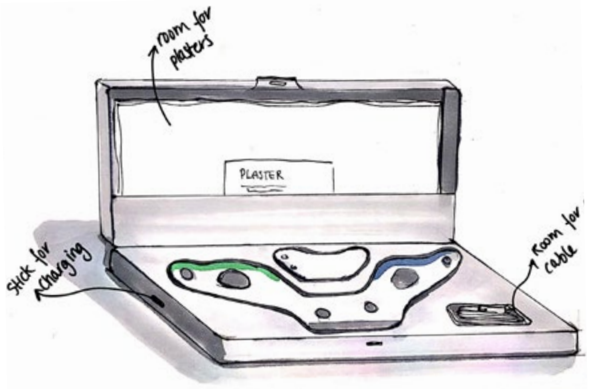
Initial docking station thoughts

Objective

We haven't focused much on the docking station, but the following chapter will be describing our initial ideas to these in all the scenarios.

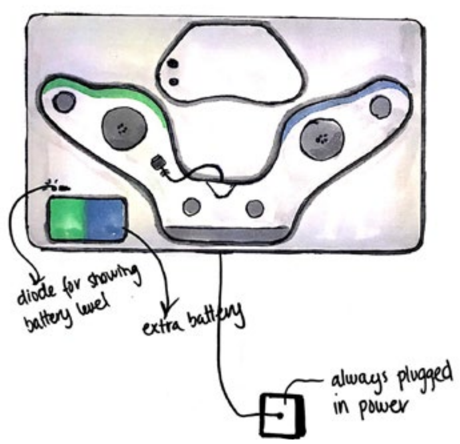
For home monitoring we have thought of the experience of having a device at home. So we created a box to put the device in, and thereby also minimize the visual effect of having to use the device at home. From the questionnaire, multiple people wrote that they would like it to be discrete, simple and neutral. Therefore the thought is to have a casing that is a neutral colour, and that the casing also works as the charger (ill. 308). We have gotten inspiration from a casing for an electric toothbrush, where the toothbrush can be kept, and also charged wirelessly (ill. 310).

For the clinics and the delivery rooms, the thought is that the charging station should be wall mounted. From interviews etc. we found this to be the best solution, and because they should have a device in each room, it seems realistic. The overall thought is that the upper part can be put in with the front first, and thereby the battery can be charged, using wireless charging. For delivery there should be room for another battery (ill. 309). The initial thought is to use the press studs to charge and secure the extra battery on the docking station. Besides the battery, there is a diode showing the battery level. As the docking station is installed in all rooms, it will be connected to a power outlet at all times. This ensures that the product is charged when placed in "home". Having the earlier mentioned sound if not put back in place after use, will enhance the likeliness of midwives putting it back into place. Our initial idea is to implement an extra battery, with capacity of six hours, in clinics as well. This ensures that the device is always ready, even if a midwife has forgotten to put it in place, and the battery on the device runs out. At home it doesn't have the same level of importance and inconvenience, but if the product is out of battery when needed in the clinics, it's our assumption that it appears unprofessional.



ill. 308 Docking station / casing home monitoring

ill. 310 Docking station / casing toothbrush



ill. 309 Docking station clinics and delivery rooms

Sum up

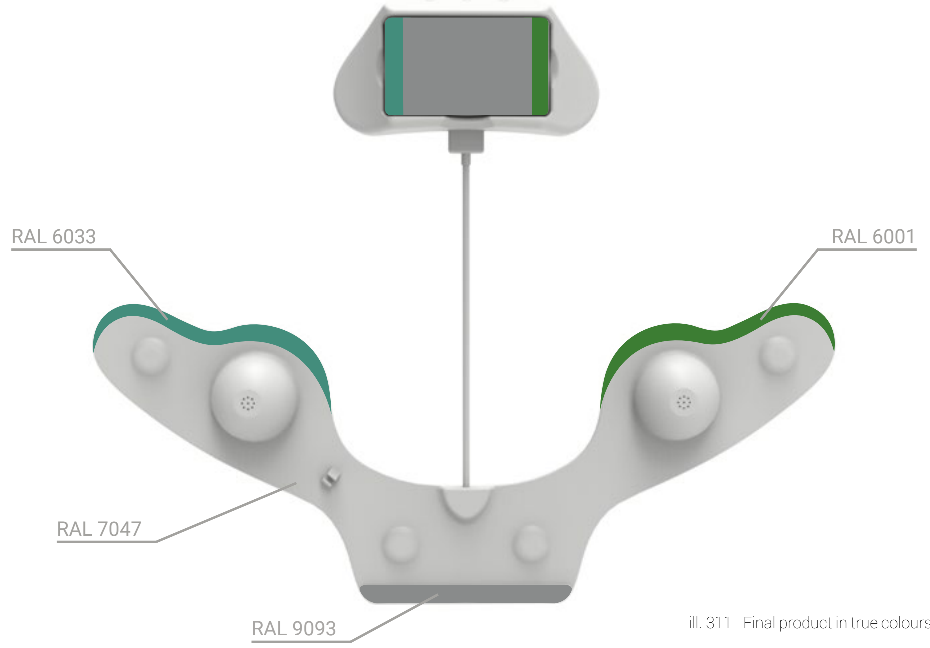
We have only made these initial thoughts on the docking stations, and won't be detailing it much further in the project.

Product

The following phase will give a description of the final product, the precise materials and production methods. Furthermore, the interface and user scenarios to all three scenarios will be described, as well as a review of the electronic components and their interrelation. Lastly, the plan for implementation of the product will be presented.

Final product

From the aforementioned findings about colours and appearance, we ended up with having a light grey colour (RAL: 7047) with signal colours in two different green nuances (RAL: 6033, RAL: 6001) (worksheet 35). The coloured areas on the lower part follow the soft curves, giving the product a hint of life, while still appearing soft and friendly. To make the battery independent of colour changes of the upper part over time, it's coloured in a darker grey (RAL: 9023). By having the same colour on the guide, the two parts are bound together as one unit (ill. 311). The placement of the electrodes are shown trough having small bobbles on the lower part which create feedback and feed forward to the user. Furthermore, the guide is heightened to create feedback and feed forward.



ill. 311 Final product in true colours

The product can, as mentioned, be used in all scenarios by using single-use adhesive with different properties. The plasters come in two different types: one for monitoring at home and in clinics, where the adhesive properties is similar to the Centa-Flow plaster, and one for delivery, where the adhesive properties are similar to the Monica plaster and properly a bit less strong.

There is overall three different product packs (ill. 312-ill. 313).

Home monitoring:

- Product with six hours battery capacity, and casing for transportation and wireless charging.
- The product is used with an app that is installed in the appurtenant tablet which also is used for replying the questionnaire.
- Plaster for home monitoring and monitoring in clinics.

Clinics:

- Product with six hours of battery capacity, and a wall mounted charging station. The charging station has room for an extra battery which can be used if the midwives for some reason forget to put the device back in the charger.
- In most clinical rooms there is a computer which will be used for running the measurement session.
- Plaster for home monitoring and monitoring in clinics.

Delivery rooms:

- Product with 12 hours of battery capacity and wall mounted charging station. The charging station is completely similar to the one in the clinics, but it holds an extra 12 hour battery instead of the six hour battery in the clinic.
- To interpret and see the measurement, a screen and computer similar to the current screens, should be used.
- Plaster for monitoring during delivery.

Home monitoring

Tablet

Plasters

ill. 312 Casing for home monitoring

Clinics and delivery rooms

Computer/ screen

Plasters

ill. 313 Docking station for monitoring in clinis and delivery rooms

Materials and production

Following chapter gives a description of production methods, precise materials and construction of the product. The link gives a short description of the product https://drive.google.com/file/d/1N5OSQe_XA7_5P0Q8EbzmLNYtpe-5qTrD/view?usp=sharing.

Production method

Our initial thought was to injection mould the parts, as mentioned in the chapter "Initial materials and production thoughts" in the concept phase. However, we wanted to see if we could find a cheaper alternative to the lower part that still could provide a good surface finish and appearance.

The following section gives a short description of the considered methods:

- Vacuum or thermo forming of the top of the lower part, and then filling the part with a laser cut layer, with room for the electrodes and internal wiring, and lastly welding a thin layer over this, enclosing the part (ill. 314). When consulting with a thermo and vacuum forming manufacturer, Gibo Plast (Gibo, 2013), they recommended us to injection mould the part, as it would be hard to create a good surface finish around the edges and holes in the flexible material.
- Dip moulding with the same technique for layering mentioned above, but after contacting a manufacturer, Betech (Betech, 2018), they also recommended casting. As an alternative, they mentioned we could use silicone for the part which in tooling cost would be approx. 25 % of the cost for injection moulding, but more expensive material wise. However, this would only make sense for a low scale production, as the cycle time is longer with silicone casting, and because of the material cost. This could be used for start-up, but silicone isn't recyclable. Therefore, we will continue to work further with EVA as material for the lower part.
- Lastly, we considered compression moulding because of the cheaper tooling price (Thompson, 2015). But we have a concern that the lower part is too flat and long, for this to make sense (Thompson, 2015).
- For a prototype, the lower part could be made of multiple laser cut layers of EVA (ill. 315) and e.g. making the casing for the microphones and upper part in 3D print. Having multiple layers doesn't create the desired surface finish around edges and where the microphones are placed, and therefore we will not choose this for the final product.

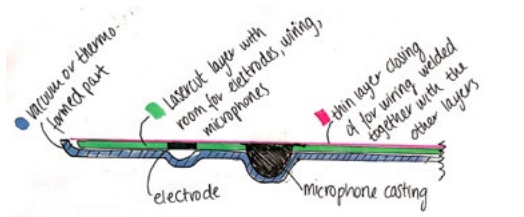
From the aforementioned parameters we have chosen to work further with injection moulding, as it can provide the wanted surface finish without compromising the material. Injection moulding gives us the advantages of incorporating both the internal wiring, the bobbles and heightened areas on the front, for feedback and feed forward in the mould, and thereby enabling the product to appear more united, with smooth transitions (ill. 316) (Thompson, 2015).

Construction

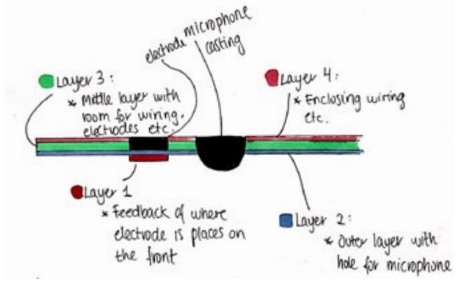
Construction of upper part and battery

The upper part is mainly processed through injection moulding, and with the battery it consists of four different shells:

- Battery casing (lower and upper shell) (ill. 316)
- Upper part (lower and upper shell) (ill. 316)



ill. 314 Concept thermo or vacuum forming



ill. 315 Concept layer on layer

The battery is attached and detached to the upper part using conductive press studs. The press studs are attached to a thin layer of plastic to strengthen the area, when removing and placing the battery (ill. 316). This is also used on the backside of the lower part, around the press studs, for attaching the single-use plaster (ill. 316).

The lower shell of the upper part, has cavities where two electrodes is glued in (ill. 316).

The upper part and battery casing is produced in medical grade PP, the specific type could be ExxonMobil™ PP9074MED – random copolymer, MFI 24 from ExxonMobil which is a copolymer resin with high impact strength (Resinex, no date b). Ideally, we should consult with them to choose the specific PP resin, but this seems as a good solution.

The parts should have a draft angle on at least 0,5 degrees. We have made the draft angle on one degree (ill. 317).

Construction of lower part

The lower part consist of two main layers:

- The top part which is injection moulded (ill. 316)
- The thin layer 0,3 mm EVA plastic which is laser cut, and welded together with the top part around the edges, using e.g. ultrasonic welding which can provide hermetic seals (ill. 323) (Seal Werks, 2016; Thompson, 2015). Around the electrodes and microphones, the parts are glued together to ensure hermetic closure. Over time, as production increase, it might make sense using die cutting, as it's faster than laser cutting, and thereby will be more effecient (Thompson, 2015).

These two parts are made in EVA, more specifically the medical grade EVA called Ateva 2820 AG and Ateva 2803 G (Resinex, no date a). For the top part we wish to use 2820 AG as it has a hardness shore D on 22 and is flexible and strong. This specifc material can be injection moulded (Resinex, 2020b).

For the thin layer we wish to use Ateva 2803 G which has a higher strength. This is desirable because it's the part where the single-use adhesive is attached and detached. The hardness shore D of this material is 28 (Resinex, 2020a).

On the EVA injection moulded part, the draft angle should be at least two degrees (Whelan and Goff, 1990). Ideally, we should detail and design the component in correspondence with a manufacturer, to get the ideal shape, draft-angle etc.

The chosen EVA has limitations to being cleaned with ethanol spirits, but after talking to Stine (worksheet 32), she mentioned that it isn't a criteria that it should be cleaned with ethanol alcohol, but only that it should be cleaned with one of the following things: soap and water, ethanol alcohol or active chlorine. The current CTG heads can only be cleaned with soap and water. The chosen EVA can be cleaned with soap and water, and therefore it's sufficient for solving the demand (Table 4, p. 38).

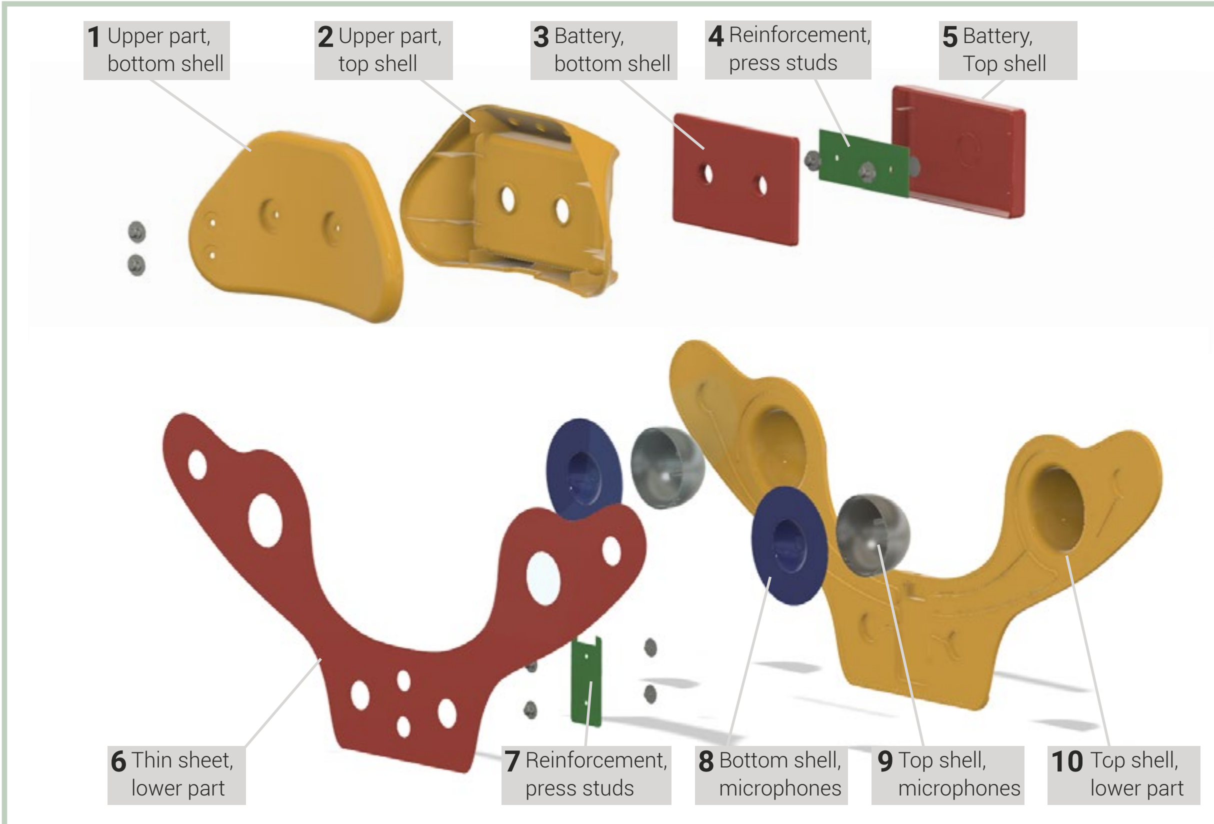
The microphone casing is constructed in two parts:

- The top part, which is injection moulded in the PP, where the microphones are fastened. This part can be cut out from the lower part to be reused in a new device (ill. 318).
- The bottom part which also is injection moulded PP, is glued to the thin outer layer EVA of the lower part (ill. 320, ill. 323).

Carmo could be a manufacturer of the injection moulded parts, as they have experience in producing products for the medical industry. Furthermore, they have experience in ultrasonic welding and assembly of products. Therefore, the production and assembly of the lower part, could be performed by them (Carmo A/S, no date). Their experience with medical products would also be ideal for sparing regarding the final construction.

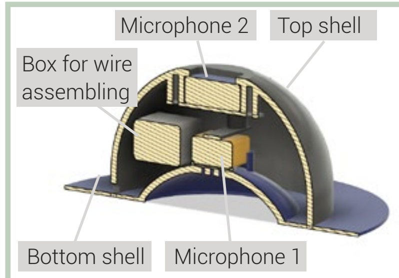
Single-use plasters

Both the single-use plasters are constructed in three overall layers with foil on each side, and two press studs for easy and user friendly attachment (ill. 319). The manufacturer of the plaster could be Herpa Tech, who manufactures the current plasters (Herpa Tech, no date). They have suggested 3M 1522 for the scenario for home monitoring and clinics, and 3M 1513, for the delivery situations, and UPM RC 12 for the side against the product. It should of course be tested to the different scenarios.

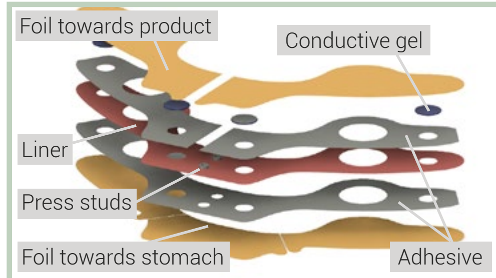


ill. 316 Construction upper and lower part

ill. 317 Draft angle



ill. 318 Microphone casing



ill. 319 Single-use adhesive lower part

Surface finish

We wish to have a fine surface where scratches aren't that visible, and therefore we have chosen the surface finish SPI-D3 which is a matt rough textured finish (3D Hubs, 2020). It's a fine, but not totally smooth and shiny surface finish.

The colouring of the green areas on the battery and lower part ,should be applied using e.g. pad printing which is a printing method that can print on 3D surfaces (Thompson, 2015).

Waterproofing

As mentioned under the technical requirements (Table 4), the product should withstand being cleaned with soap and water, and possibly also ethanol spirits (on the upper part). Additionally, the product should be waterproof during delivery, e.g. for use in a bathtub.

Regarding cleaning and use in clinics and home monitoring, we assume that a IP-classification of IP65 will be sufficient (Glamox, no date). When the device is used during delivery the product should have a IP-classification of IP-68. If waterproofing for IP-classification 68 is significantly more expensive than waterproofing for IP-classification 65, it should be considerated to make the products different for the scenarios, regarding this.

Waterproofing of upper part and battery

The upper part and battery is waterproofed using a two component expoxy glue that is approved for medical applictation (Masterbond, no date). The chosen glue has good chemical resistance to fluent sterilizers. To ensure a optimal gluing surface, the components are constructed with a skew edge, providing a larger surface (ill. 321). Around the press studs, diodes and electrodes the glue is also used to waterproof the area (ill. 323). The chosen glue has good adhesive properties to plastic and metal (Masterbond, no date).

Gluing the upper part together means that it's harder to seperate the parts from each other. Alternatively, a gasket and screws could have been used to waterproof, to still make the electronic components accessible. However, the areas around the screws, will have potential to gather bacterias etc.

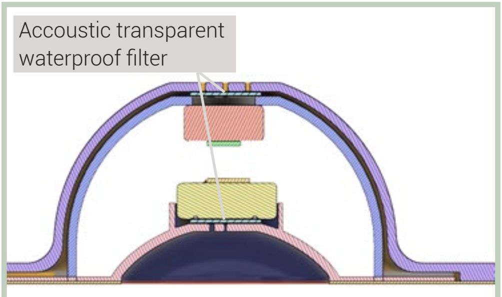
Waterproofing of lower part

Regarding waterproofing of the lower part, we have placed accoustic transparent filters over both microphones (ill. 320). The accoustic transparent filters are avaliable from IP-class 67-68 (Ipro membrane technology, no date). The filters are placed indenpendend of the microphones, meaning that when removing the microphones after end of life of the lower part, the accoustic filters aren't a part of the microphones, and thereby it's easy to use new filters in a new lower part. The filters are glued in using the two component epoxy glue.

The ultrasonic welding hermetically seals around the edges of the part. Around the electrodes and the area around the cavity in the microphones glue is used to seel the part (ill. 323).

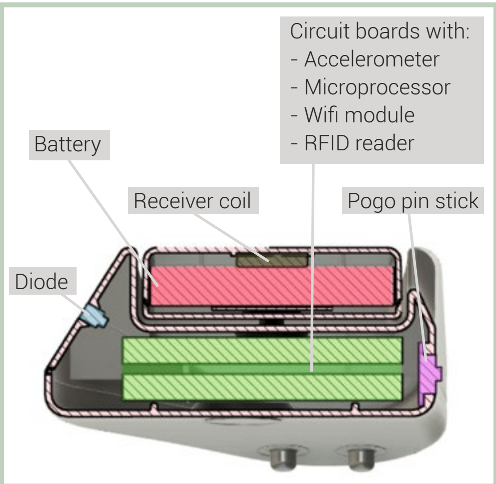
Waterproofing - wire

The wire and plug chosen, is a pogo pin which is water proof (HytePro Magnetic Connectors, 2020). The wire is assembled with the internal wiring in a capsule in the lower part. The entrance hole is glued (ill. 323.

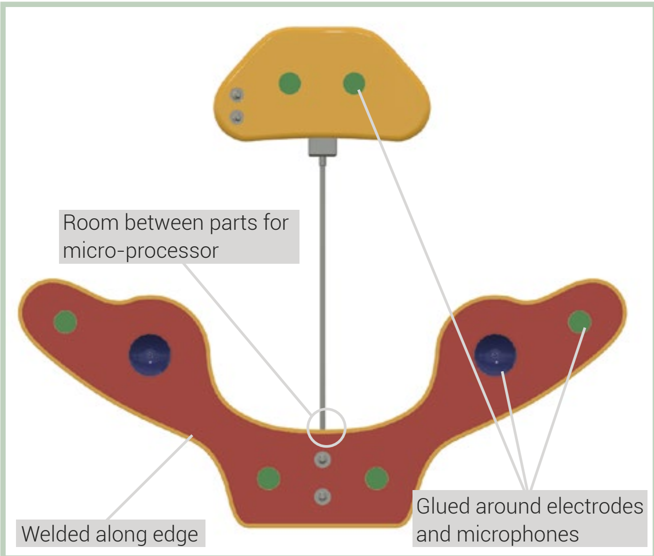


ill. 320 Microphone enclosed in lower part

ill. 321 Glue surface



ill. 322 Section cut upper part



ill. 323 Backside of the product showing electrode and microphone placement

Electrical components

Following section gives a description of the electrical components, and how they are combined. The device holds a few different electrical component, to ensure a functioning product that works as intended. Underneath a table with the components and their dimensions is listed:

Component	Dimension (mm)	Price (DKK)*
Electrodes	Ø: 12, H: 2	45-70
Microphones	Size confidential	500-600
Snap fasterners, battery	Female part: Ø: 9,25, H: 2 Male part: Ø: 7,5, H: 3,2	5-7
Snap fasterners, plaster	Approx. same size as above	3-4
Magnetic connector, pogo stick	Female part: 8,8 x 14,5 x 4,7 Male part: 3,4 x 17,4 x 7,9	24-34
Microprocessor	5 x 10 x 2	9
iStretch wire	Ø : 4	30-40 per m
Wiring inside device	ø: 0,75	1,45 per m
Battery	61 x 37,5 x 5,95	128-165
Qi charging coil, receiver	Ø: 11, H: 1,72	13-37
Qi charging coil, transmitter	Ø: 22,3, H: 2,84	13-28
Accelerometer	3 x 3 x 1	8-18
LED diodes, red, green, yellow	Ø: 3	0,3
Speaker	13 x 13 x 4	13-23
Wifi module	16,6 x 13.0 x 2,1	21-69
Microcontroller	10,1 x 10,1 x 1,55	6,9-13,8
Circuit boards	6620 mm²	140
RFID reader	15 x 19 x 3	205-240
RFID chip	5 x 5	0,41-2

* The price is per unit, and the range is for respectively purchasing 1 unit, up to a batch of approximately 1000 units.

Table 10

Electrodes

To enable the bottom part not to be single-use, the electrodes (ill. 323) have to be able to be used multiple times. Many electrodes are single-use, however the ones chosen, from "NeuroSky", are made from stainless steel, so they won't lose their conductive qualities over time, making them suitable for the purpose (AliExpress, no date; PLUX Store, no date). Our desktop research states that the electrodes can measure both ECG and EMG, as desired (New V-Key Technology, no date).

Microphones

CentaFlow has some specific acoustic microphones for measuring the blood flow. These are chosen for their specifications, and these specifications are the ones CF use in their clinical tests. The casing that CF has optimized for the microphones, has a confidential volume, and because of this, CF also wishes to keep the specific microphones confidential. We have, however, gotten the price estimate of approx. 600 DKK per microphone (worksheet 20). We will use the same microphones because it's proven that they work for the purpose. It's the same microphones for both blood flow and background noise.

Snap fasteners, battery

To enable the battery to be changed if discharged, it's attached to the upper part with snap fasteners 76 from "Romed". This makes it easy to attach and detach, without having to open any casing. The snap fasteners of the battery, are electrically conductive, and they will transfer the power from the battery, to the device (ROMED, no date).

Snap fasteners, plasters

The single-use plasters have two snap fasteners each. These are incorporated to ensure correct placement of the plasters, onto the upper and lower part. As these only are used as guides, they need no conductive qualities. It's the same snap fasteners on both plasters, the "DUS 4" from "YKK" (YKK, no date). The price is for both parts of the snap fastener, however we need many more male parts, as they are the ones on the disposable part (Sailrite, 2020). This means that the price possibly could get cheaper if a deal is made about purchasing the male part, separately from the female part.

Magnetic connector and microprocessor

To make a completely waterproof device, the connector between the upper and lower parts need to be waterproof, so the system doesn't short-circuit. The magnetic connector "M826" (HytePro Magnetic Connectors, 2020) is waterproof, and by its four pogo pins, it has pins for both 5V, earth, clock and the data from the electrodes and microphones. The data from the electrodes and microphones are gathered on a microprocessor (Alibaba, no date), and then connected to the data pin. We have to test the magnetic abilities, to make sure the connector doesn't fall out due to small movement, or if it's grazed by the hand. The magnet has a strengt on 600 g corresponding to 5,88 N, so we assume the above concerns won't happen (HytePro Magnetic Connectors, 2020).

Wire (iStretch)

For the wire between the two parts of the device, it has been a wish that it was able to stretch, so it would fit multiple stomachs without gapping. "iStretch" is a wire that has elongation qualities for up to 40 %, while still having a straight surface, making it easy to clean. This makes it the ideal wire for the task (Minnesota Wire, 2019a). The earlier test with the elastic band that could be elongated 58 %, ins't fully compatible with the iStretch wire (worksheet 28). Ideally, we should get some product samples, and test it with a Newton meter, however it hasn't been possible to get in contact, to request samples. For now, we will make the wire 20% longer than the elastic band, and then execute the correct test if the product becomes a reality. (El-grossisten.dk, no date).

Wiring inside the device

To connect the electrodes and microphones to the microprocessor, a copper wire from "RS" is used (RS Components, no date). It isn't pre-insulated, as the EVA surrounding it will work as insulation.

Battery

The battery is the "ICP543759PMT" from "Renata", and is the same that is used in the current CentaFlow (Renata SA, no date; Octopart, 2020). The 3,7 V battery has a capacity on 1320mAh which is able to run the current product for six hours (Renata SA, no date). Compared to the current product, we have added three diodes, a speaker and a microprocessor. We have calculated a rough estimation of how much time these additional parts will reduce the battery time on the product. The calculation shows that the battery time of the product will be recuced with approx. 12 minutes. In the calculations we have included a resistor between the battery and diode, to regulate the input voltage (worksheet 36). In all the different scenarios this reduction in battery time won't play an essential role.

Qi charging coils

The battery is running the device, but when the battery needs charging this is wireless, transferred from the charging station. For wireless Qi charging, there has to be a transmitter coil (Mouser Electronic, 2020b) in the docking station/casing, to transfer the power, and a receiver (Mouser Electronic, 2020a) in the battery, to collect the power. This transition of power happens due to magnetic induction. It's important that the receiver and transmitter are just above each other, and with a distance of no more than 40 mm, to ensure power transfer (Electronics Notes, no date). We have 4-5 mm between the coils.

The transmitter for wireless charging, can be larger than the receiver because the transmitter is located in the charging station that has plenty of space, and also this enables that the receiver doesn't need to be placed with the same precision. The receiver is placed in the battery casing, so it has to be rather small, for the casing not to be too large. The transmitter and receiver have to be compatible - ordering them we would have to make sure of this with the retailer. The receiver and transmitter are both from "TDK". The listed transmitter and reciever both have an output power of 0,5-0,6 A (Mouser Electronic, 2020a; Mouser Electronic, 2020b). The batteries can be charged with a maximum charging current of 1320 mA (Renata SA, no date). The coils will be able to charge one battery in approx. 3,1 hours, and for the battery packs with two batteries, it will take approx. 6,3 hours. This calculation is shown in worksheet 36 and can only be seen as a rough estimate. To make it more realistic we have included a loss of 20 % in the calculation (worksheet 36). By having extra battery-packs in the product for delivery and clinics, we will be able to solve requirement 1. a, table 6 (delivery).

Accelerometer

As mentioned earlier, movement can disturb the data for uterus activity, as the electrodes will detect the muscle activity caused by movement. The accelerometer is inserted in the device, with the intention of distinguishing between the two reasons for muscle activity. With the data from both the accelerometer measuring movement, the electrodes measuring heart frequency and uterus activity, and the microphones measuring blood flow, it will theoretically be possible to determine contractions with relatively high certainty (worksheet 20). The accelerometer can be very small, while still having a high sensitivity, and furthermore it's a cheap unit (Semiconductors, 2016; Farnell, 2019).

LED diodes

The LED diodes have the purpose of giving feedback. There is a green "on" diode, a red "low battery" diode, and a diode that is green when a measuring is on-going, but that turns yellow when there is an alert for missing signal to electrodes or microphones. The diodes have flat tops, so they are easy to run over with a cleaning cloth (Chanzon, 2017). Also, the material is clear, so they look alike when turned off, ensuring a cleaner aesthetic expression. The diodes should receive a direct current of DC 2 Volt 20 mA (Chanzon 2017).

Speaker

To enable the device to communicate with sound that it's starting, or there is an error, there has to be inserted a speaker. The speaker has to be small, to take up as little space as possible in the upper part. Also, it has to be loud enough to hear, so it cannot be for in-ear products. The chosen speaker enables a sound level of 88 dB which should be more than enough, and it has a maximum power of 1 W (Loudity, no date; Branche Fællesskab Arbejdsmiljø, 2020).

Wifi module

The device needs to be able to send data to the app that either shows the data directly to the midwife, or in case of home monitoring, sends the data from the tablet to the midwife. Therefore a wifi modem is placed in the upper part (Quectei, no date).

Microcontroller and circuit boards

The brain of the product is the CPU microcontroller (Shenzhen Mingdewei Electronics Co., no date). This is placed on the circuit boards.

The circuit boards collect all the connections and components. The price in the table is both for boards, and for getting them printed in Denmark. The price is more or less independent of the board size (worksheet 33).

RFID reader and chip

An RFID reader is placed in the upper part, and has a corresponding chip in the docking station for delivery and clinics. This combination ensures that the device can control if it's put back after use. To ensure that the lower part also is put back, the docking station also have an RFID reader, and the lower part an RFID chip (Shenzhen Fareastsun Technology Co., no date; Shenzhen Chuangxinjia Smart Technology Co., no date).

The three scenarios and their interface

After several iterations and feedback sessions, the final interfaces for the three scenarios have been executed. The iterations and feedback can be seen in worksheet 24. There are many similarities in the scenarios, interface wise, however there are also places where they differentiate. It's these places that determine the need of differentiation in the software.

Home monitoring

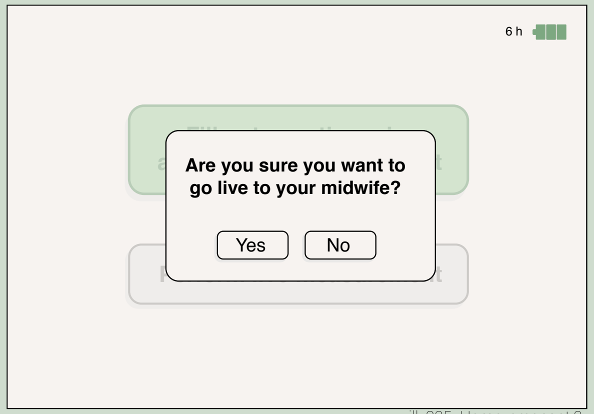
For home monitoring the pregnant woman is performing the measurement session herself. However, the interface consists of two parts: the interface for the pregnant woman, and the interface the midwife that analyses the data receives. It's important that the pregnant doesn't get any information that makes her concerned, before the midwife has evaluated the data. So her interface is stripped of any indications of the state of the fetus. Furthermore, this scenario has some demands from the midwives: the woman needs to fill out a questionnaire about her health status, this could be blood pressure, blood sugar or a urine test that the midwife can use for her evaluation of the data. The questionnaire and appertaining test(s) is determined by which patient group she belongs to. Also, the midwives want to be able to ask the woman for a live measurement, if they need more information, than what was sent. (Worksheet 7)

When a woman is offered home monitoring, she has a meeting with a midwife that gives an introduction of the device, which tests to do, and how often she needs to take tests and perform monitoring. She is handed the device in the case/charging station, and a tablet that only holds the app, so it can't be used for anything else than monitoring. This is important because the woman should sit still while measuring, and not do anything else, but feeling for life. This is also a demand from the midwives (worksheet 7).

Pregnant woman's interface:

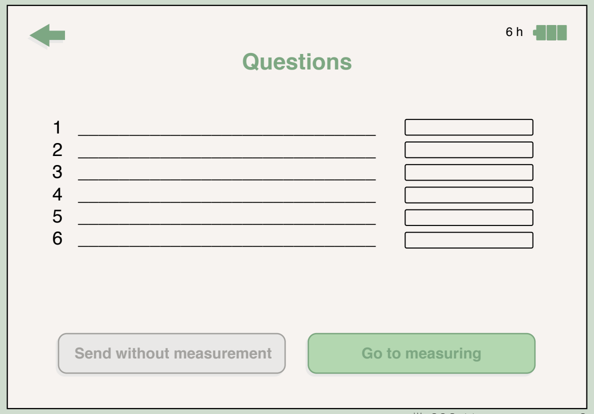
ill. 324 Home, pregnant 1

1. The pregnant woman takes the device from the docking station. It gives a "starting-sound" when removed from the station. She takes the adhesive parts as well. Then she opens the app on the tablet. On the front screen she can choose to fill out her questionnaire, or perform a live measurement if her midwife has asked her to do so.



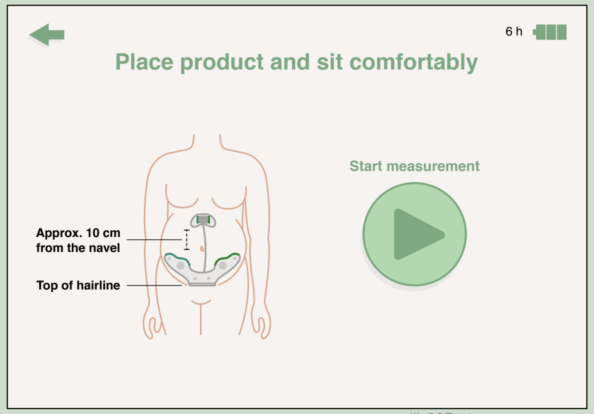
ill. 325 Home, pregnant 2

2. If she chooses to perform a live measurement, she is asked if she is sure, to make sure she didn't press the button by accident.



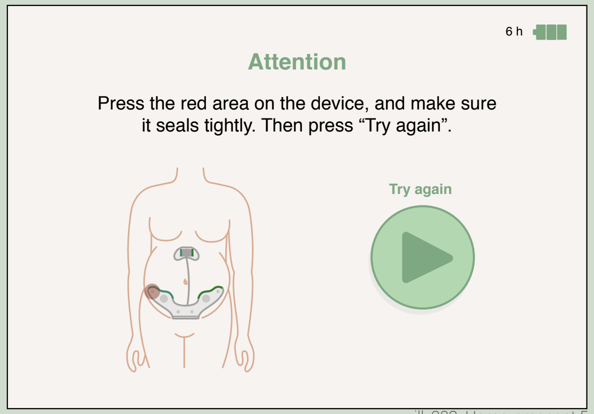
ill. 326 Home, pregnant 3

3. If she pressed "Fill out questionnaire", this screen shows. If she pressed wrong, she can press the arrow to go back. Otherwise she fills it out. If she doesn't need to perform a measurement with our device the current day, she sends the questionnaire without. Otherwise she presses "Go to measuring".



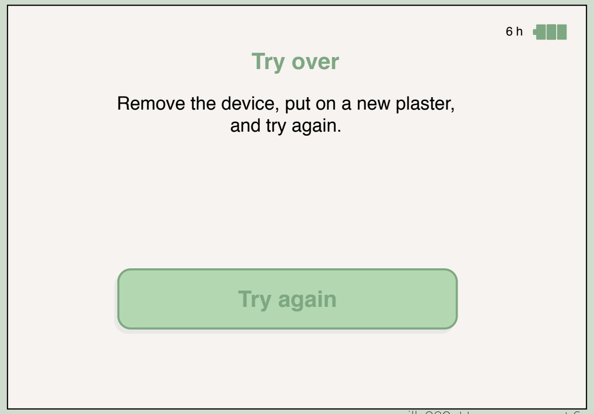
ill. 327 Home, pregnant 4

4. Then this screen will be shown. If she pressed wrong, she can press the arrow to go back. This screen shows a guide for correct placement - minimizing the risk of placing the device wrong. She prepares the device with single-use adhesive, and when she has placed it and "sits comfortably", she presses "Start measurement".



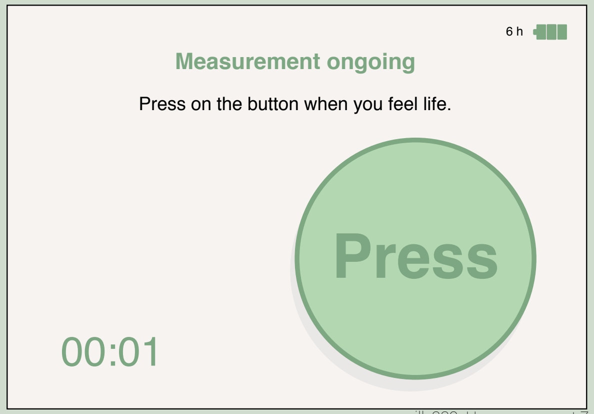
ill. 328 Home, pregnant 5

5. The device detects if there is signal to every microphone and electrode. If something isn't placed well, and doesn't provide good data, the screen shows an "Attention" screen, and the product makes a short negative sound. This screen shows the area to check that the adhesive seals tightly. She presses the area, and then she can "Try again".



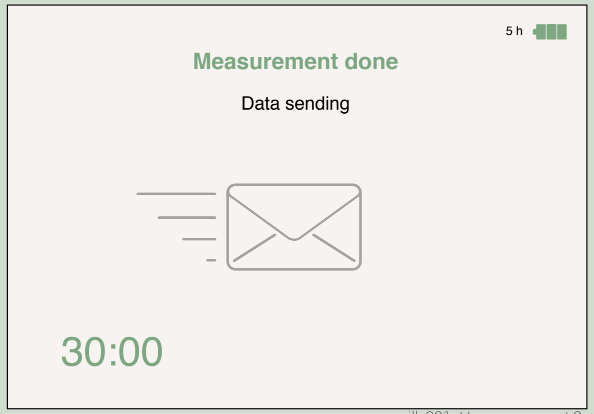
ill. 329 Home, pregnant 6

6. If something is still wrong, she is asked to "Try over", by removing the device from the stomach, put on new adhesive parts, and "Try again".



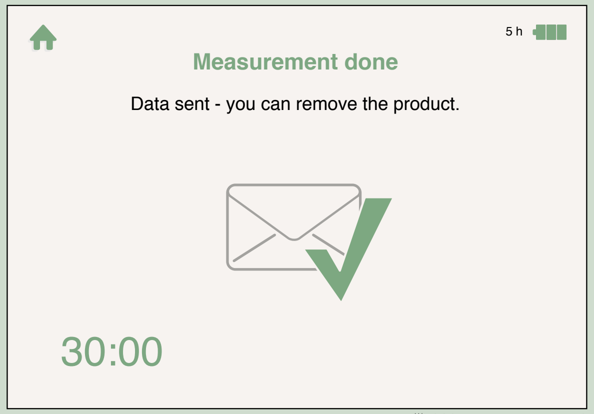
ill. 330 Home, pregnant 7

7. If everything is placed correctly, the measurement will start. This screen has a big "Press" button. She has to press this every time she feels life. The screen will vibrate shortly, as tactile feedback, so she is sure she hits the button, and the screen detects it. The measurement lasts 30 minutes, and the app is programmed so the screen is on throughout this.



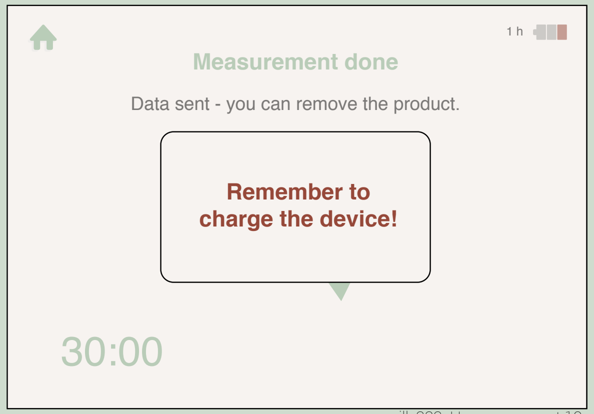
ill. 331 Home, pregnant 8

8. After 30 minutes the measurement is done, and the data is automatically sent to the midwife.



ill. 332 Home, pregnant 9

9. When the data is sent, there is a positive "check-sound", making sure the woman is aware of when the measurement ends. After five seconds, the screen will go to the front screen, and the device will turn off. She can then take of the device, and remove the single-use adhesive from it.

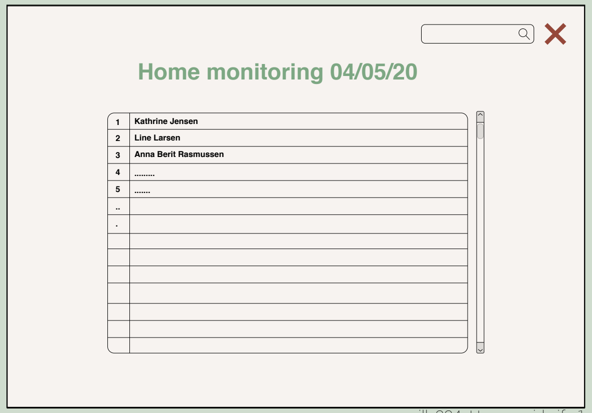


ill. 333 Home, pregnant 10

10. If the battery is low (less than an hour left), the woman gets a notice and a sound to remember to charge it, before going to the front screen. Lastly, the device is put back in place. If this isn't done after five minutes, the product will make a sound, alarming that it isn't in place. The five minutes is estimated to give her time to detach the product. If it's still not in place, the sound will come every fifth minute, until the device is in the docking station. After the session the woman awaits answer from the midwife.

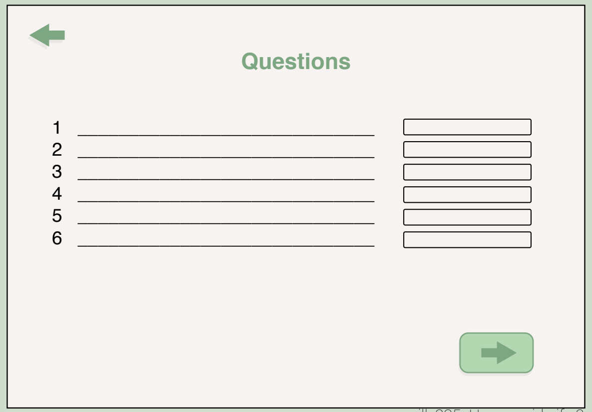
Midwife's interface

Every morning after 9 am, a midwife turns on a computer at the hospital, and check the results the pregnant women have sent in. The midwife's scenario is as following:



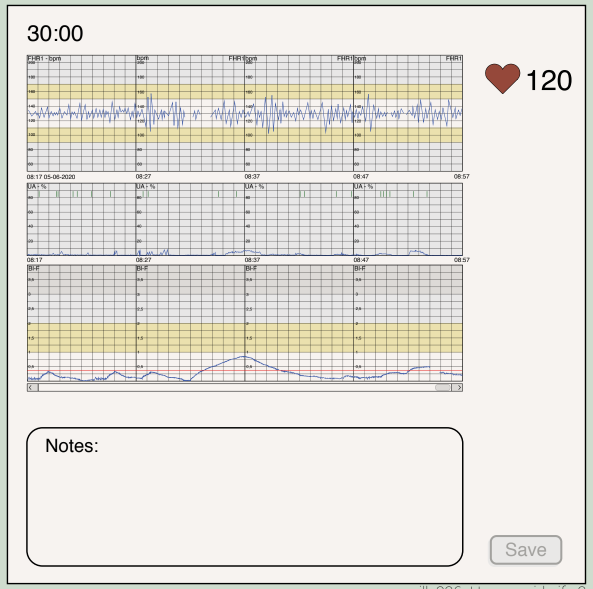
ill. 334 Home, midwife 1

1. The midwife's front screen shows a list of all the women who have sent data. An algorithm has analysed the data, and made a ranking with the most alarming results in the top. She chooses the first.



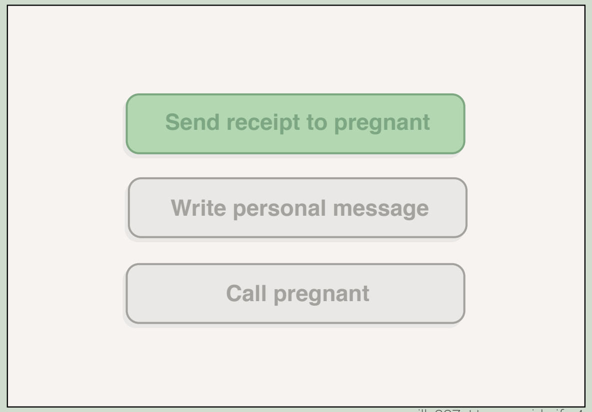
ill. 335 Home, midwife 2

2. The midwife then sees the answers of the woman's questionnaire. When she has read it, she presses the arrow to proceed.



ill. 336 Home, midwife 3

3. She then sees the curves for heart frequency, uterus activity and blood flow. She also sees marks for when the woman felt life and an average pulse of the fetus. If she wants to write notes, she scrolls down. Afterwards she saves it all.

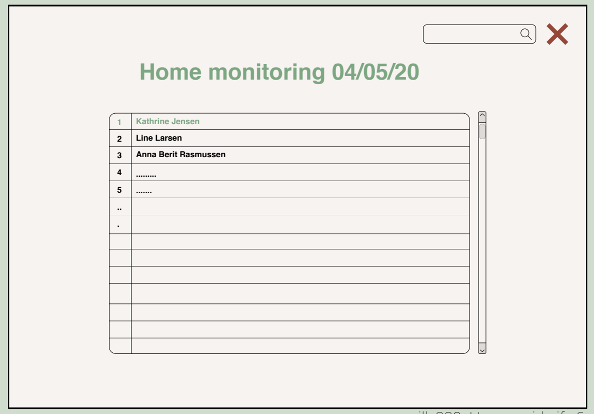


ill. 337 Home, midwife 4

4. All the data is now automatically added to the pregnant woman's patient record. On the next screen she has to make a decision of what she wants to do: 1) send a receipt if everything is okay, 2) write a personal message if she wants the woman to go to her own doctor, or give her another message, 3) call the woman if there is a need of extra information, and thereby a live measurement, or if there is something critical that demands action.

ill. 338 Home, midwife 5

5. To ensure that she pressed what she intended, an "Are you sure?" box will pop up.

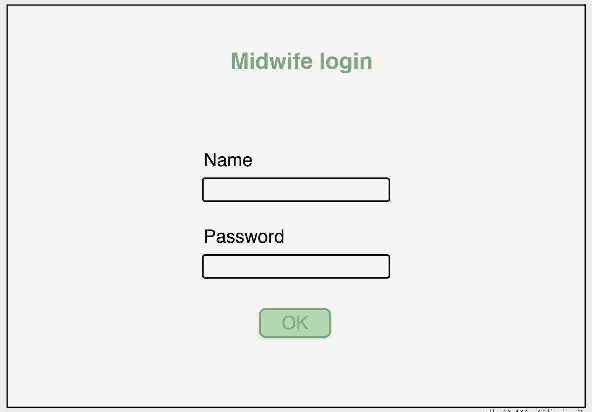


ill. 339 Home, midwife 6

6. Afterwards she gets back to the front screen where "Kathrine" has turned green because her data has been reviewed.

Clinic

Contrary to home monitoring, the midwife needs live data in the clinic, to give the pregnant woman information with her when she leaves. Pregnant women will be monitored with the product if they are in week 24, but also if they are in any of the groups that need extra monitoring. In the clinic the device is placed in a charging station, that is mounted on the wall. When the woman arrives, she follows the midwife to the consultation room. When it's time for monitoring, the midwife takes the device from the charging station, and the device turns on with a sound. She attaches the single-use adhesive parts on the upper and lower part. Then she places the device on the woman's stomach, the woman then lies or sits comfortably, and the midwife follows the following steps:

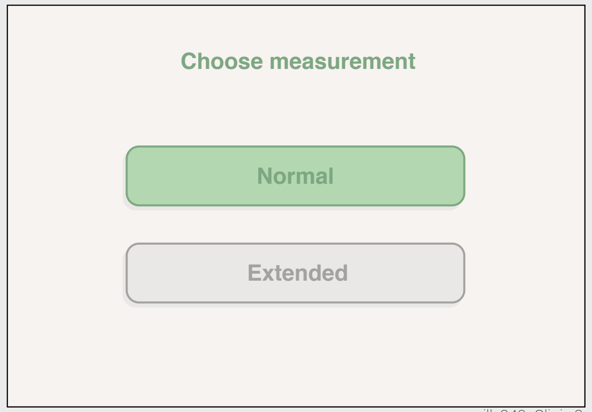


ill. 340 Clinic 1

1. The midwife opens the programme on the computer in the clinic. Then she can login with her name and password.

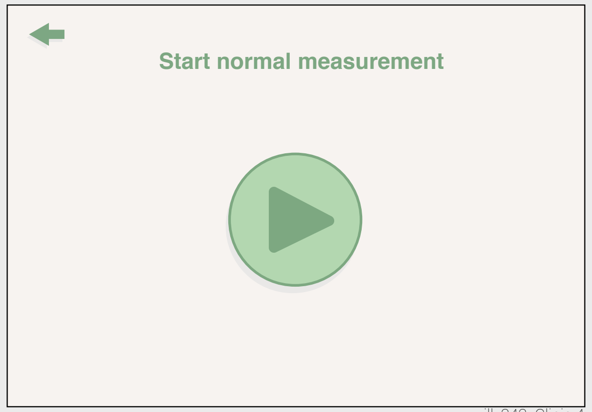
ill. 341 Clinic 2

2. Then she fills in the pregnant woman's personal identification no. so the data is linked to her patient report.



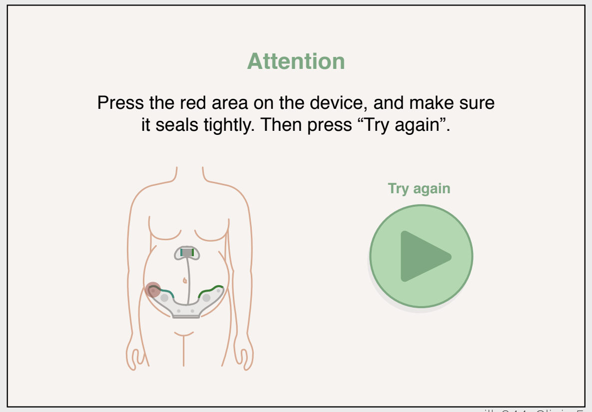
ill. 342 Clinic 3

3. Then the midwife chooses if the measurement is of normal length which is 2-6 minutes, or an extended measurement if the midwife estimate that the woman needs a longer measurement, e.g. for 30 minutes. She can type in how long the measurement should be under "extended".



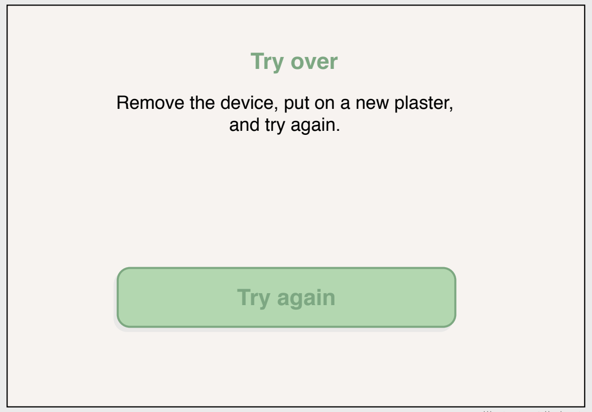
ill. 343 Clinic 4

4. If she chooses a normal measurement this screen is shown, and she can press play.



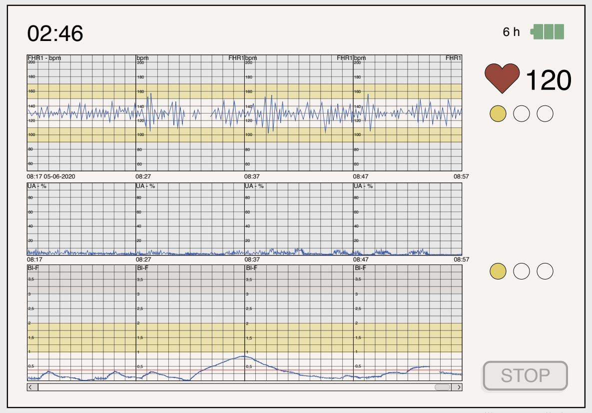
ill. 344 Clinic 5

5. Like in home monitoring, she gets a warning screen and the device makes a sound if something doesn't seal tight, and doesn't give a good signal.



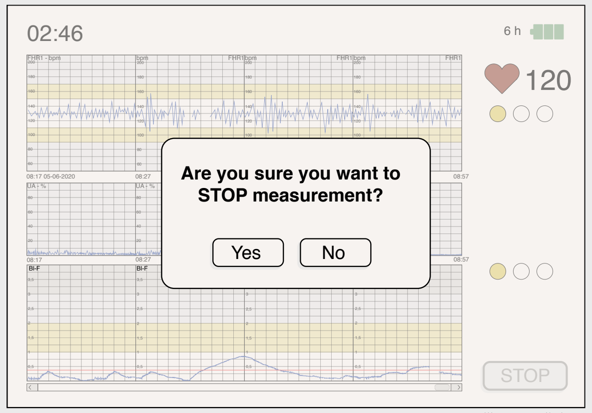
ill. 345 Clinic 6

6. Again there will be shown a screen asking her to remove the device and adhesive, and start over if pressing the area doesn't work.



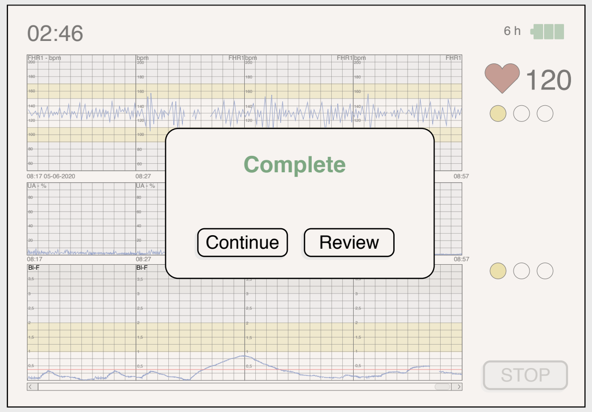
ill. 346 Clinic 7

7. When everything is placed well, the measurement begins. The screen shows approx. the same as in home monitoring, besides the marks for feeling life. Additionally, there are three dots that show the currents situation of heart rate and blood flow. Lastly, the pulse of the fetus will be played with sound. The device stops automatically when the algorithm evaluates to have enough data, or after six minutes. If the midwife wants to stop the measurement before the device does so, because she believes the data is sufficient, she presses "Stop".



ill. 347 Clinic 8

8. If she presses "Stop" this box will show, to make sure she didn't press by mistake.



ill. 348 Clinic 9

9. If the device evaluates to stop the measurement, this box will be shown, so the midwife can choose to continue if she wants to see more. Otherwise she presses "Review" to stop the measurement and review the data.

ill. 349 Clinic 10

10. When she reviews the data, she can scroll down to write notes that will be saved in the pregnant woman's patient report. When she presses "Save" she is directed back to the front screen.

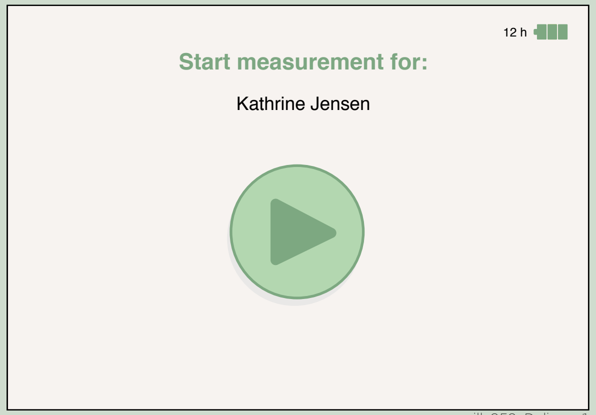
11. Now she takes the device of the woman's stomach, detaches the single-use adhesive parts, and throw them away. Ideally, the device is cleaned and placed back in the charging station. If the midwife forgets to put the device back in its "home", it will make a short sound after five minutes. This will continue every five minutes untill the device is put back. This will remind her to put it back, but if she is finishing other tasks regarding the consultation, the short sound every five minutes wont disturb this.

12. As the device always tells the midwife to put it back in the docking station, we assume that the device will always be charged, and ready to perform. However, if the unlikely event that the device is low on battery should happen, the same message and sound, as in home monitoring, will appear when a measurement is over, and there is less than an hour battery time left.

13. Lastly, after the measurement, the midwife will perform an ultra sound on the pregnant woman.

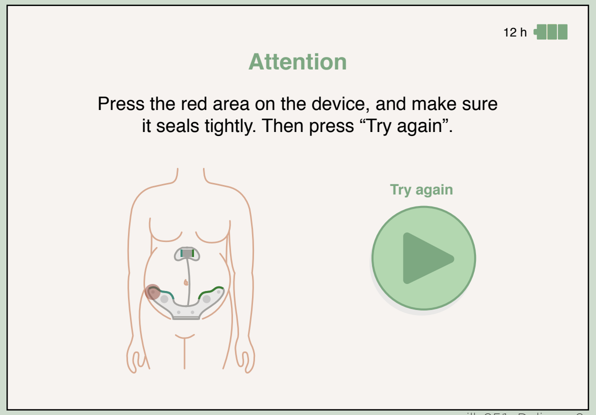
Delivery

During delivery the live data is even more significant than in the clinic because the situation can be more critical. The data screen for delivery, is the only one where contractions are of big importance, as it's here uterus activity occur the most. The device has a docking station on a wall of the delivery room, and there will be one device per delivery room in the hospital. The data will be shown on a 15" screen, similar to what they have in the delivery rooms today. When time, the birthing woman will be lead into the delivery room, and the midwife then evaluates if and when the device should be used. The device is prepared with the single-use adhesive in advance, so it's ready for use when needed. This will be done after use when it's cleaned. The following shows the scenario after the midwife has decided to use the device.



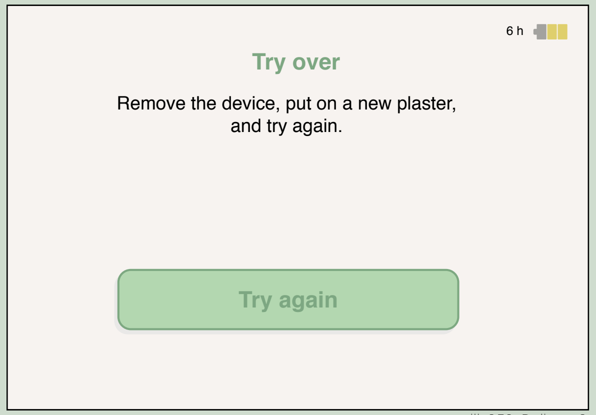
ill. 350 Delivery 1

1. The birthing woman is registered when she is given a delivery room, so the programme already knows who she is. Therefore, the monitoring can be initiated, as soon as the midwife finds it necessary. The midwife takes the device from the docking station, it turns on and delivers a sound, then she places it on the stomach of the woman, and when she presses "Start", the measurement begins.



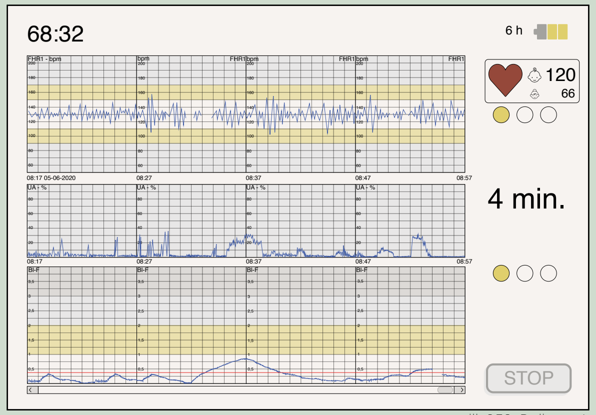
ill. 351 Delivery 2

2. If something isn't placed well enough, the same warning and sound will come, as in home monitoring and clinic. This screen can pop up in the side of the data screen, anytime during delivery if something, contrary to expectations, doesn't seal tight anymore. Then the midwife can act on this, and ensure good measurements again.



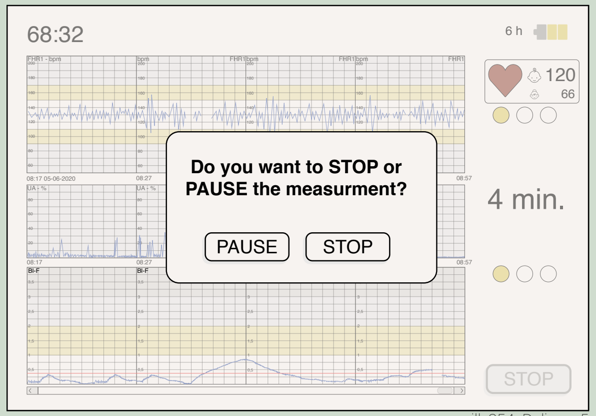
ill. 352 Delivery 3

3. If something is still loose after the midwife has tried over, the same screen as in the other scenarios will be shown, to make her remove the device and adhesives, and try again.



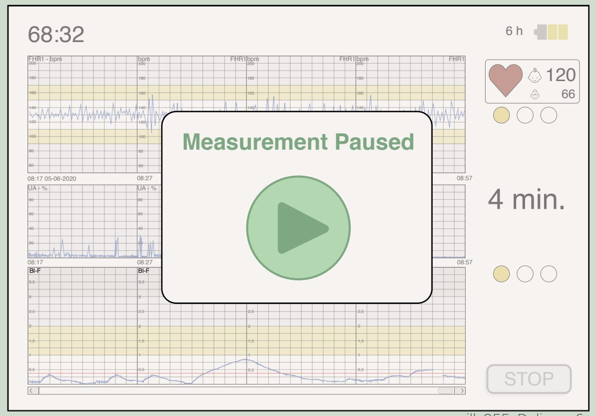
ill. 353 Delivery 4

4. When everything is placed well, this screen will show, again with approx. the same information as in clinic. However, the time between two contractions is added beside the uterus activity curve because the midwives use this information to ensure that the fetus and placenta have time to recover between the contractions.



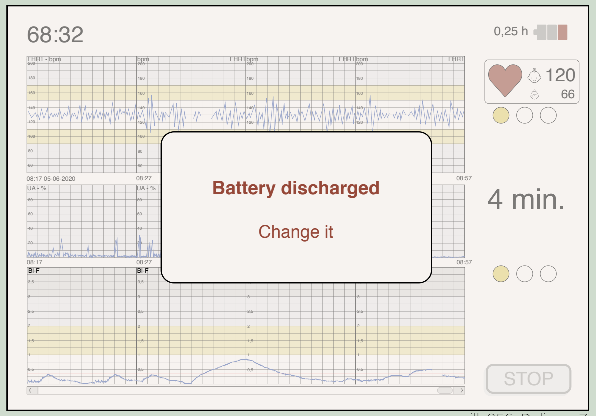
ill. 354 Delivery 5

5. If the midwife presses "Stop", this box will pop-up. She can choose to press "Pause" if she is measuring intermittent, or she can press "Stop" if the woman has delivered the baby, and the measurements should stop all together. If she presses "Stop" she will get back to the front screen, and the data will automatically be saved in the woman's patient report.



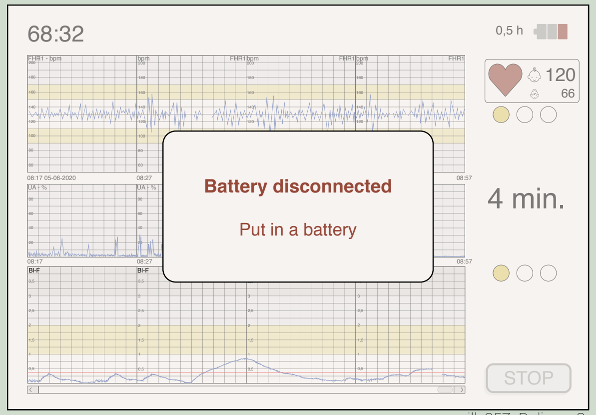
ill. 355 Delivery 6

6. If she pauses the measurement, this screen will show, where she can press "Start" whenever she wants to resume the measurement. The measurement will be shown in the same chart, but with some distance, showing the pause.



ill. 356 Delivery 7

7. When there is only 15 minutes battery time left, the programme will give a notice and a sound, to signal that the battery should be changed.



ill. 357 Delivery 8

8. When the battery is changed, the screen will show that it's disconnected, and asks the midwife to put in a battery.

9. After the measurements are stopped, the device is removed from the woman, the single-use adhesive is detached from the device, and the device is cleaned and put in the docking station. If the midwife forgets to put the device back, it will make a short sound after 15 minutes, with the intend of making her remember. Afterwards, it will make the sound every fifth minute, until it's put back in place.

10. The midwife then gives the new parents some privacy, and goes to another room, to evaluate further on the delivery and data.

Battery capacity

The battery level is shown on the screen in every scenario, and the additional reminders are, as seen in the aforementioned scenarios. The device can come with two different battery capacities: approximately six or 12 hours. The 12 hour battery is also physically larger than the six hour battery. The large battery is intended the delivery scenario because the device needs to perform for much longer time than in the other scenarios.

In home monitoring the woman gets a note after a session if the battery should be charged, this should ensure that she remembers. The device will stop making sounds when it's placed in its case, but the case doesn't necessarily needs to be plugged in power. However, in worst case the device isn't charged for the next session, and she has to wait a bit, before performing the measurement which isn't particularly critical.

In the clinics it should be a habit for the midwives, to put the product back in the docking station that is always plugged into power. Also, the sound should make them remember. However, if the battery, contrary to expectations, should be discharged before a consultation, the docking station holds an extra battery that is fully charged that they can switch with.

There is also room for an extra 12 hour battery in the docking station for the delivery rooms. That way we meet the requirement of being able to measure for 24 hours in the delivery scenario. Also, it's possible to measure for even longer deliveries, as the discharged battery is charged when changed, so it will be ready if the second battery runs low. The device will make two short sounds when there is battery left for an hour. Then the sound will be repeated every 15th minute. There will always be at least one other person, besides the midwife, in the delivery room, this person will be able to change battery even though the midwife is busy (worksheet 25).

LED diodes in upper part

The upper part holds three LED diodes that are helping to make the device easy to interpret. The first diode is the "on" diode. This is green and turns on when the device is removed from the docking station, and therefore starts (ill. 358). The middle diode shows when the measurement is initiated, and can both be green and yellow. It's pulsing green when the measurement is on-going, but will flash yellow if there is missing signal to anything (when the "Attention" screen is shown). (ill. 359) The last diode is red, and will start flashing when the battery is low, at the same time the screen will start to give warnings.(ill. 360)

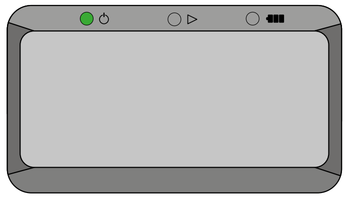
The data output

The data output shows three overall curves that we have discussed with midwives, amongst other. So they are made with their needs and wishes in mind. The top graph is for the fetus' heart frequency, and the middle is uterine activity with marks for when the woman in home monitoring feels life. These two look like what the midwives are used to see, we only changed the colour from red to grey in the heart frequency chart, as red symbolizes danger, and we want to avoid that. The third graph is the one we have added, with information about the blood flow. This is divided in four categories. The higher the curve is placed, the more turbulent the blood flow is. We also incorporated a horizontal median line in this graph that is always updated.

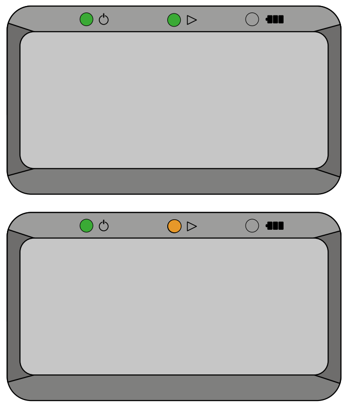
Beside the heart frequency graph, the child's current heart rate is shown, and for the delivery scenario the mother's heart rate is shown as well. Furthermore, there are three dots that provides a quick-view of the heart frequency's current state. One dot lit means that everything looks fine, but if two or three dots are lit the state is more severe. The midwives are used to relate to a scale of three, where they divide e.g. the fetus' well-being in the categories "normal", "abnormal" and "pathological" - corresponding to our three dots. These dots are also beside the blood flow graph, showing the current state of this. Lastly, we have added the time between contractions, as explained in the delivery scenario.

If at some point the connection is lost to the sensors, the curves will have a blank area for the appertaining time span.

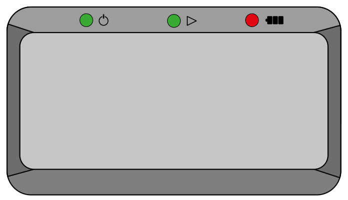
See ill. 361 for visual explanation of the above.



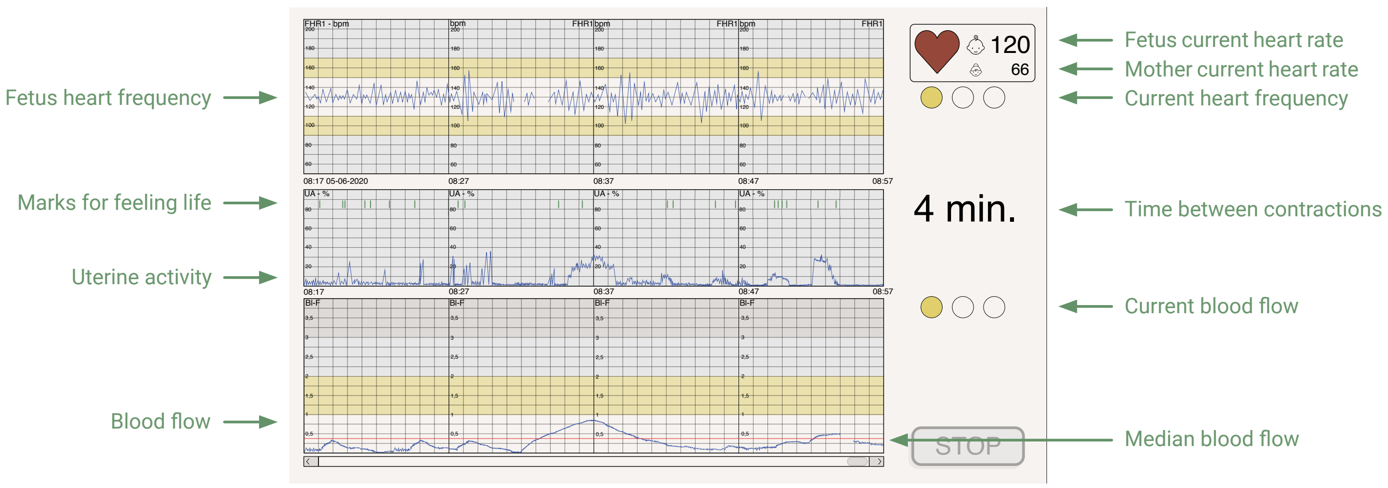
ill. 358 "On" diode



ill. 359 "Measurement" diode



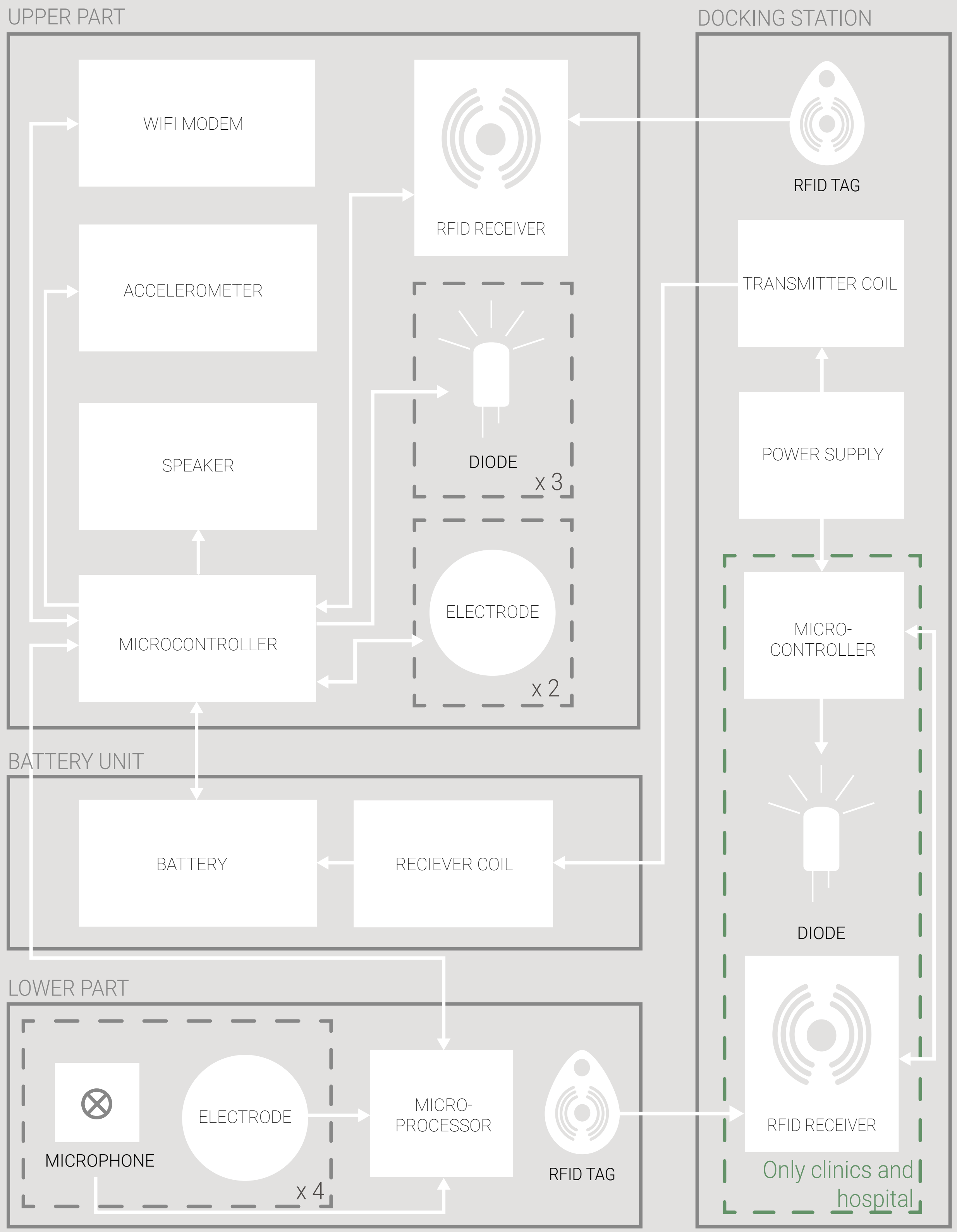
ill. 360 "Low battery" diode



ill. 361 Data output

Block diagram

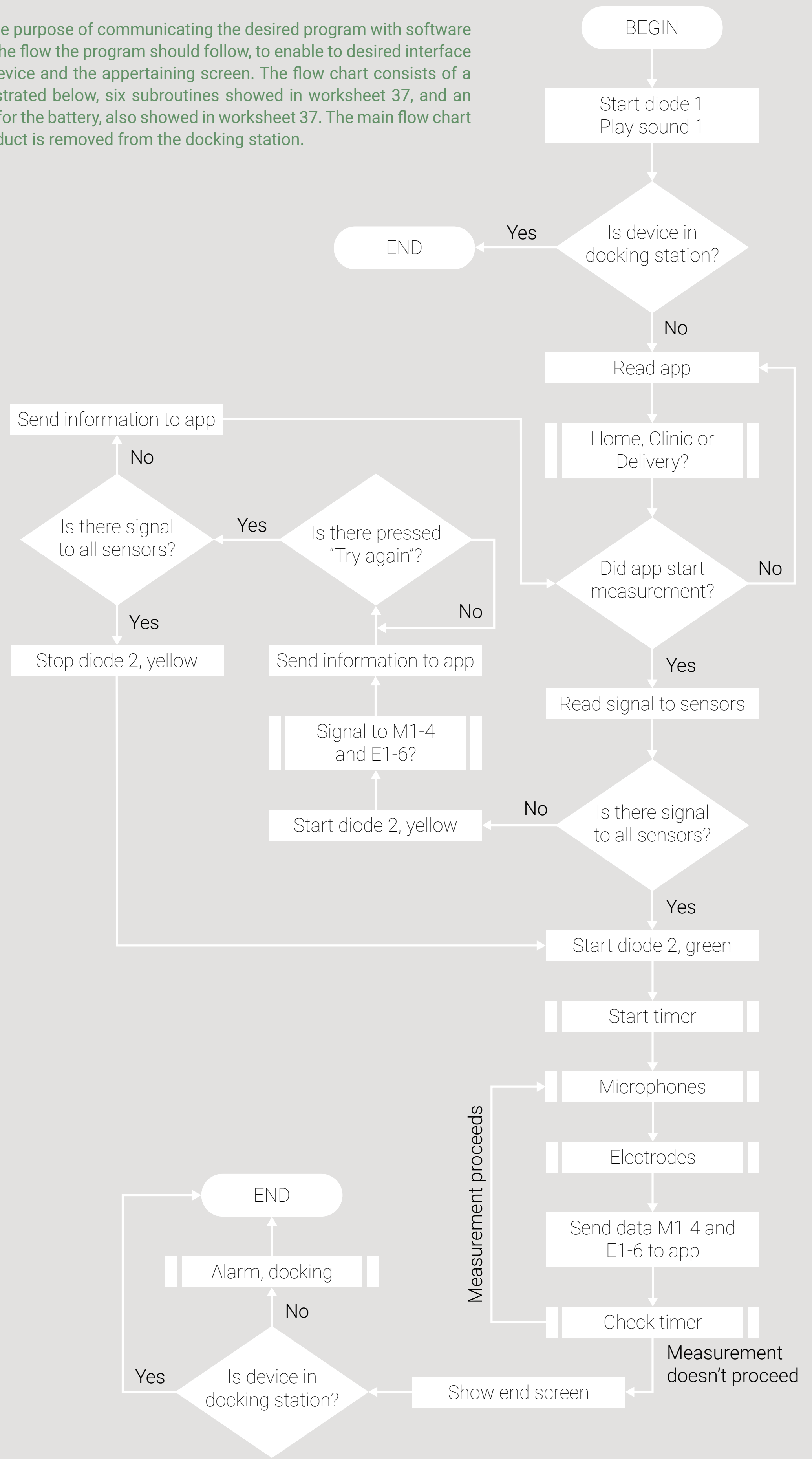
The block diagram visualizes the different components' connection to each other. There are no resistors in the block diagram, however there should be some. Resistors are to be placed where the power input is higher than the individual components can handle. The resistor ensures that these components wont short-circuit. E.g. the diodes can handle an input of 2V, while the battery has an output of 3,7V, so there is a need of a resistor of 28 Ohm (worksheet 36).



ill. 362 Block diagram

Flow chart

The flow chart has the purpose of communicating the desired program with software engineers. It shows the flow the program should follow, to enable to desired interface and actions of the device and the appertaining screen. The flow chart consists of a main flow chart, illustrated below, six subroutines showed in worksheet 37, and an individual flow chart for the battery, also showed in worksheet 37. The main flow chart begins when the product is removed from the docking station.



ill. 363 Flow chart

Implementation

Following chapter describes the strategy for business model, and implementation, and lastly presents a roughly estimated budget.

Business model

After the product is clinically tested and approved, the implementation strategy should be to implement the product for use in clinics, and after a year or so start implementing the product for home monitoring. The last phase of implementation should be implementing the product for delivery, and this will properly first make sense after a some years. As delivery is a situation where the midwives have to trust the product 100 %, the product most likely would have to go through another clinical test. However, it will be an advantage that the product will be known by the midwives, and also the pregnant women.

The business model is refined from the idea of having a subscription service, where the start capital is relatively high (clinics: 20.000 DKK, home monitoring 16.000 DKK, delivery: 22.000 DKK) and a relatively low monthly fee (30 DKK per product). The individual clinics and hospital departments will be able to buy the product without applying through the regions because the price of the product is relatively small (worksheet 31). They pay for the usage of the product by paying for each plaster.

Key resources and activities:
- Software and software development
- Recycling of used products
- Linguistics regarding ensuring plaster stock in hospital and business
- Service department for product and software
- Sales department

Value proposition:
- The hospital pay for what is used
- Hospital and clinics does not have unused expensive equipment standing

Key partners:
- Herpa Tech - plaster manufacturer
- Resinex - plastic material supplier
- Carmo - production and assembly of product
- Viborg Hospital - sparring and testing with midwives
- Viewcare - development of software and user platforms

Costumer segment:
- Private and public midwife clinics
- Private and public hospitals

Costumer relationship:
- Well established relationship
- The customer have free access to service

Channels:
- Direct sales to the specific department on clinics/hospital.

Revenue streams
- They get money from plasters and subscription each month
- They get a larger sum money each time a device is sold

Cost structure:
- Revenue for developing new software that enables good user contact, and a cost competitive product

Budget

A budget is roughly calculated to each scenario. The scenario for monitoring in clinics is the starting point, and the estimation of market for home monitoring is evaluated from the market estimation from the clinics.

Production cost and sales price

The product cost is calculated from the component prices in Table 10, and through a price estimate on the different moulds and parts. The prices of the moulds and plastic parts can be seen in worksheet 34, and in the budget worksheet no. 38. The prices for the docking stations are estimated from the pricing on the other parts. Table 11 shows the prices of the different product-packs and the sales prices. For the pricing we have worked with a high and low price, but the budget is calculated with basis in the highest price. The production cost differentiate in the scenarios because of docking-station and assembly. We have made the assembly for the delivery situation more expensive because of the extra waterproofing for IP-68. See worksheet 38 for the full overview over production cost. We have set the estimation of mark up a bit high, as a result of not wanting the product to seem too cheap.

The price roughly estimated. We have calculated with the highest price.

Sales price calculation	Clinics		Home monitoring		Delivery		Plasters	
Production cost	9917,6		8622,3		10681,6		20	
Contribution, mark up	6049,74	61 %	4138,70	48 %	6836,224	64 %	10	40 %
Sales price	15967,34		12761,00		17517,824		30	
VAT	3991,83	25 %	3190,25	25 %	4379,456	25 %	7,5	25 %
Sales price incl. VAT (DKK)	20.000		16.000		22.000		37,5	

Table 11 Production and sales price

Investment

In the investment calculations, we have included salary to the final development and software development. When implemented in clinics there is budgeted with three men with a salary of 300 DKK per h. for half a year. When the product is developed for use in clinics, we estimated that for preparing the device for home monitoring and delivery, each scenario would require salary for one man for half a year.

We have, as mentioned, estimated that the product will be implemented for use in clinics first, and then within the first years for home monitoring. Therefore, we have estimated that the same tools will be usable for home monitoring and therefore, only added a tool price for the casing, as it's different from the two scenarios.

When the product is implemented for delivery we estimate that they would need new tooling as the product first will be implemented after years.

Investment	Clinics	Home monitoring	Delivery
Salary	855000	285000	285000
Prototype cost	250000	50000	50000
Approval and testing	100000	100000	100000
Consultants	100000		
Tools	639222	77000	642652
Total (DKK)	1944222	512000	1077652

Table 12 Investment overview

Budget estimation

A rough budget is estimated to each scenario. We have estimated the market potential in home monitoring after the market potential in the clinics (worksheet 38).

The market potential is calculated to each scenario on the basis of 61.273 births in Denmark in 2018 (Sundhedsdatastyrelsen, 2019) (worksheet 38):

- Clinics: We have estimated that there is approx. 100 midwife clinics in Denmark, and that 8 % will buy the product in year one, and that they have approx. four examination rooms in each clinic. The 8 % is relatively high, but as the clinical tests are already expanded to more hospitals it seems realistic.
- Home monitoring: We have estimated that of the 8 % pregnant women who is monitored in year one in the clinics, approx. 10 % of them will be offered home monitoring in year one. For year two the same approach is used.
- Delivery: We have estimated that of the 24 birthing places in Denmark, the product will be sold to two birthing places which each has six delivery rooms (the delivery situation will, as mentioned, first be implemented after the product has been on the market for some years).

We have calculated the contribution margin from plaster and subscription fee, by estimating (worksheet 38):

- **Clinics:** how many plasters a clinics will use per month.
- **Home monitoring:** how many plasters a pregnant will use from week 25-40.
- **Delivery:** that 30 % of the pregnant who give birth in the delivery rooms in possession of the product, wears it sometime during delivery.

With the money that remains, the company needs to pay wages to the employees and software developers. The salary included in the investment is only for developing the product ready for production. In the assembly cost we have considered wages. With the subscription fee they receive 2880 DKK per year per product which is a symbolic price that can pay for a new lower part when it needs replacing - however, only if the microphones are reused (worksheet 38).

The rough estimated budget show that they will break even in:

- **Clinics:** after year 2.
- **Home monitoring:** in year 1.
- **Delivery:** after year 3.

	Clinics			Home monitoring			Delivery		
Budget	**Year 1**	**Year 2**	**Year 3**	**Year 1**	**Year 2**	**Year 3**	**Year 1**	**Year 2**	**Year 3**
Units sold	32	80	140	490,18	1225,46	2144,56	12	24	48
Sales price (factory)	15967,34	15967,34	15967,34	12761,00	12761,00	12761,00	17517,82	17517,82	17517,82
Production cost	9917,60	9917,60	9917,60	8622,30	8622,30	8622,30	10681,60	10681,60	10681,60
Turnover	510955	1277387	2235427	6255240	15638100	27366675	210214	420428	840856
Variable cost	317363	793408	1388464	4226514	10566284	18490997	128179	256358	512717
Contribution margin	193592	483979	846963	2028726	5071816	8875678	82035	164069	328139
Return									
Investment	-1944222	-1641074	-871683	-512000			-1077652	-975979	-772633
Contribution margin plasters and subscribtion	109556,8	285412	519631	249993,84	6801303	11902280	19638,25	39276,5	78553
Remaining	-1641074	-871683	494911	1766720	11873119	20777959	-975979	-772633	-365941

Table 13 Budget estimation

Epilogue

This is the last phase of the report where the project is summarized, concluded and reflected upon .

Conclusion

To ensure a better measurement quality of pregnancy monitoring, CF has utilized technology that hasn't been used in pregnancy monitoring sceneries before. However, with MonitMe, as we have named the product, we have taken this technology, and designed a product that ensures a better monitoring experience for both the pregnant woman, the birthing woman, and the midwife. Besides being able to replace current solutions technology wise, MonitMe is more intuitive, which gives women who perform home monitoring, a certainty of doing it correctly. Also, the midwives will be more certain that they perform a satisfactory measurement, and lastly, the device is able to monitor during delivery, enabling movement, better comfort of wearing the monitoring device, and the release of hormones as oxytocin, endorphins and adrenaline that helps during delivery. With other words, we succeeded in making a device compatible for all three scenarios, where only the software, docking station, plasters, and a larger battery for delivery differentiate the products.

The fact that MonitMe is constructed in two main parts, and with the shape and size they have, make MonitMe suitable for many different sizes of stomachs. The upper part, holding the main electronics and two electrodes, is placed approximately ten centimeter above the navel, which ensures that it isn't placed too high on large stomachs, regarding the wire's ability to reach. Additionally, having the lower part, with microphones and four electrodes, placed using the top of mons pubis as guiding point, combined with the shape of the part, makes it possible to make a web between the electrodes, on both small and large stomachs. Not having large plasters surrounding the stomach, like the current CF solution, additionally enable a better fit on small stomachs as well.

MonitMe will firstly be implemented to the clinics, where the current CentaFlow is already being clinically tested. Afterwards it will be expanded to home monitoring, and when the midwives feel completely familiar with the device, and is used to working with it, it will be time to try and implement it for delivery, which will be the hardest scenario to get permissions for. Using a similar way of displaying the data the midwives receive for heart rate and uterine activity, makes the implementation of MonitMe easier, as it holds familiar elements. This has been achieved without implementing alarming colours that could be misunderstood by the parents. When already using and knowing the product from the midwives monitoring sessions in clinics, the buyer will be more inclined to buy from the same supplier, instead of going to a competitor because of the advantage of already knowing the interface.

Furthermore, MonitMe and its technology can make a lot of automatic decisions due to algorithm, e.g. when there is enough valid information to stop a measurement during clinic monitoring. However, it's very important for the midwives, to be in control and to have the ability of overruling what the device wants to do because their profession relies a lot of the individual midwife's intuition, to trust in there own evaluations, and to trust what the pregnant woman shows and tells them. Therefore, we have made sure to implement that the midwives can make the final decision.

The platform of MonitMe ensures easy error detection, as the product both visually and with sound, alarms if something is placed wrong. This creates feedback to both midwives and pregnant's regarding having placed the product correctly, and thereby performed a good quality measurement. The coloured and tactile areas on the product, underline the user interaction, as they create a visual feedback, and resemblance between what is shown on the screen and on the product.

MonitMe is mainly constructed with curves, soft shapes and subdue colours, as it should radiate safety and enable a feeling that "I'm wearing this to ensure my fetus well-being" and not "I'm wearing this because something dangerous is going on". This is also why it's easy to attach, and relatively easy to detach, so it doesn't feel like a violation to wear it.

One of the main thoughts behind the construction of MonitMe, has been to reduce the single-use parts. By only throwing single-use plasters out, MonitMe becomes a product that is more sustainable than the competitive products, and a product that is more coherent regarding the sustainable trend.

Reflection

In every process there is room for reflections, as to what could have been done differently or better.

From the beginning, the focus has been to solve all three scenarios, home monitoring, clinic monitoring, and delivery. This desire probably came from CF's desire to improve their product, and step into home monitoring and delivery. However, we have used a lot of energy, to ensure a good experience during delivery, and many ideas have been deselected because something didn't work according to the delivery scenario. Very late in the project period, when calculating the budget, we discovered that the delivery scenario is, by far, the scenario that will earn least money. Had we been aware of this from the beginning, we would probably have put less effort into making a perfect product for delivery, and more into making a good minimal viable product for the two other scenarios. This would have meant that we didn't need to waterproof MonitMe to the IP-classification 68. Also, it wouldn't be as critical having the electrical components placed on the lower part, which would have enabled a wireless solution. This is probably the biggest compromise we have made with MonitMe. Also, the solution would have been cheaper, and it would have been a possibility to expand to a product family or platform, where the delivery device could be waterproof, eventually. When this is said, there is still advantages of having the product divided in two, as it ensures a better fit on multiple stomachs. Furthermore, having the product in one unit would mean that the whole unit would need changing when the soft and flexible areas give in. This is not necessary with MonitMe because the more fragile lower part, is independent from the part holding the electronics. Lastly, the idea of using the same product for all scenarios, will create coherence, as the midwives and pregnant women will know the product from the clinics and home monitoring. Thereby, they will have gained both trust and experience with the product, before it's implemented in a delivery situation.

Nevertheless, we could have benefited from investigating the marked potential for each scenario earlier, so we could have worked from the point of view that made most sense.

Reducing the single-use part has been a big wish for us as a group, and therefore we have focused on a solution that enabled this. This also means that we haven't ideated on concepts where the main plaster is thrown out, as with the current CF solution. We are aware that this wish is mainly ours. We could have worked more with exploring to reduce single use regarding the shape and material of the current CF solution, while still ensuring a user friendly product. However, the world and also the midwife halls move toward a more sustainable profile, as both delivery rooms and clinics are made more sustainable and "friendly" in appearance. Furthermore, the overall value in being able to promote one-self as a sustainable company is desirable.

In the beginning of the concept phase, we jumped a bit back and forth, and had a quite fuzzy front end. Maybe more fuzzy than necessary because we tried a lot of things out, without thinking of the overall path. However, at one point we realized that we needed more structure, and a more long term plan regarding the concept development, and this was when our process began to follow a more straight path ("Targeted focus" in concept development). It would have been nice to have had this realization a little earlier, however we can bring this recognition into future work.

For potential further work and real implementation of the product, we would need to execute some tests. Firstly, the web of electrodes have to be tested, to be sure of the ability to pick up the fetus' heart rate. This should be done on many sizes and shapes of stomachs. When testing the electrodes we also need to test the arch on the upper part, and how well it fits real pregnant stomachs. Our assumption, in the light of our tests, is that the shape will work, but it would be ideal to have different arches laser cut or 3D printed, to test the precise arch on many different stomachs. Furthermore, we have to test the adhesive sheets for both the delivery scenario and the other scenarios, but also the adhesiveness towards the device. We both need to see if the device seals tight around the sensors, and how well it sticks to the stomach according to the stiffness of the EVA. This leads to the fact that we, additionally, should test the stiffness of EVA, both regarding the ability to follow the flow of the stomach, but also the resistance of adhesive sheets being ripped of thousands of times. These aspects should be able to withstand movement, so this should be tested simultaneously, so we can find the correct properties of both polymer and adhesives. This is an optimization process, as the product has to be flexible to ensure a comfortable feeling when wearing it, but also be strong regarding the aforementioned detachment of single-use plasters. Lastly, we need to test the wire to find the optimal combination, to ensure that the force it should be elongated with, isn't too strong. When doing this, we also need to ensure that the magnetic pogo pin works as intended, and isn't too strong or weak.

We would, in this process, have liked to use the midwives more for test of the different concepts, as they are the first user. However, the current circumstances haven't made this possible. If this project is developed further, it should be a priority to include the midwives more in the development. This will make more midwives aware of the product, give them a sensation of ownership, and thereby possibly making the way to the market easier.

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Illustration list

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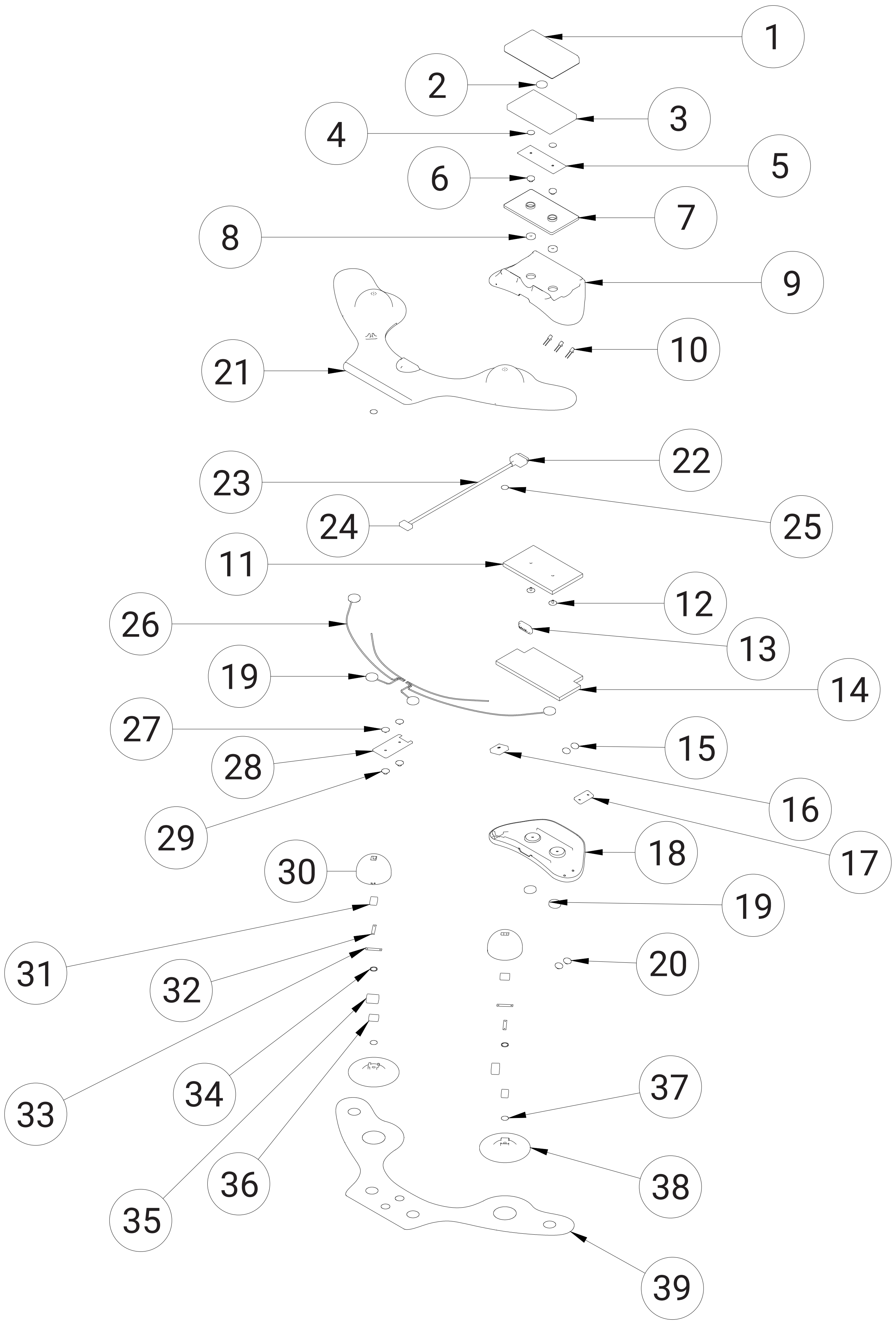
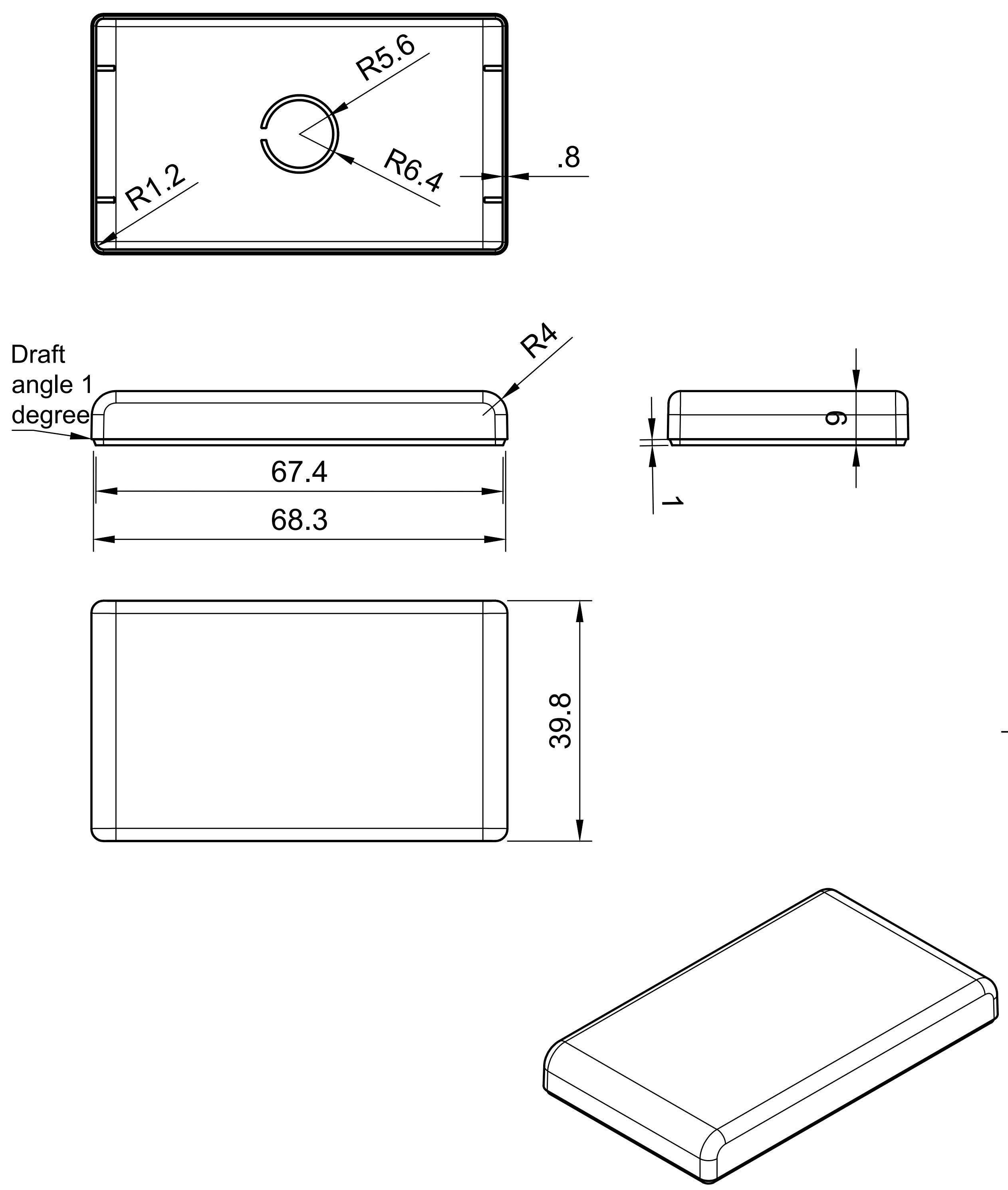
STUDENT REPORT

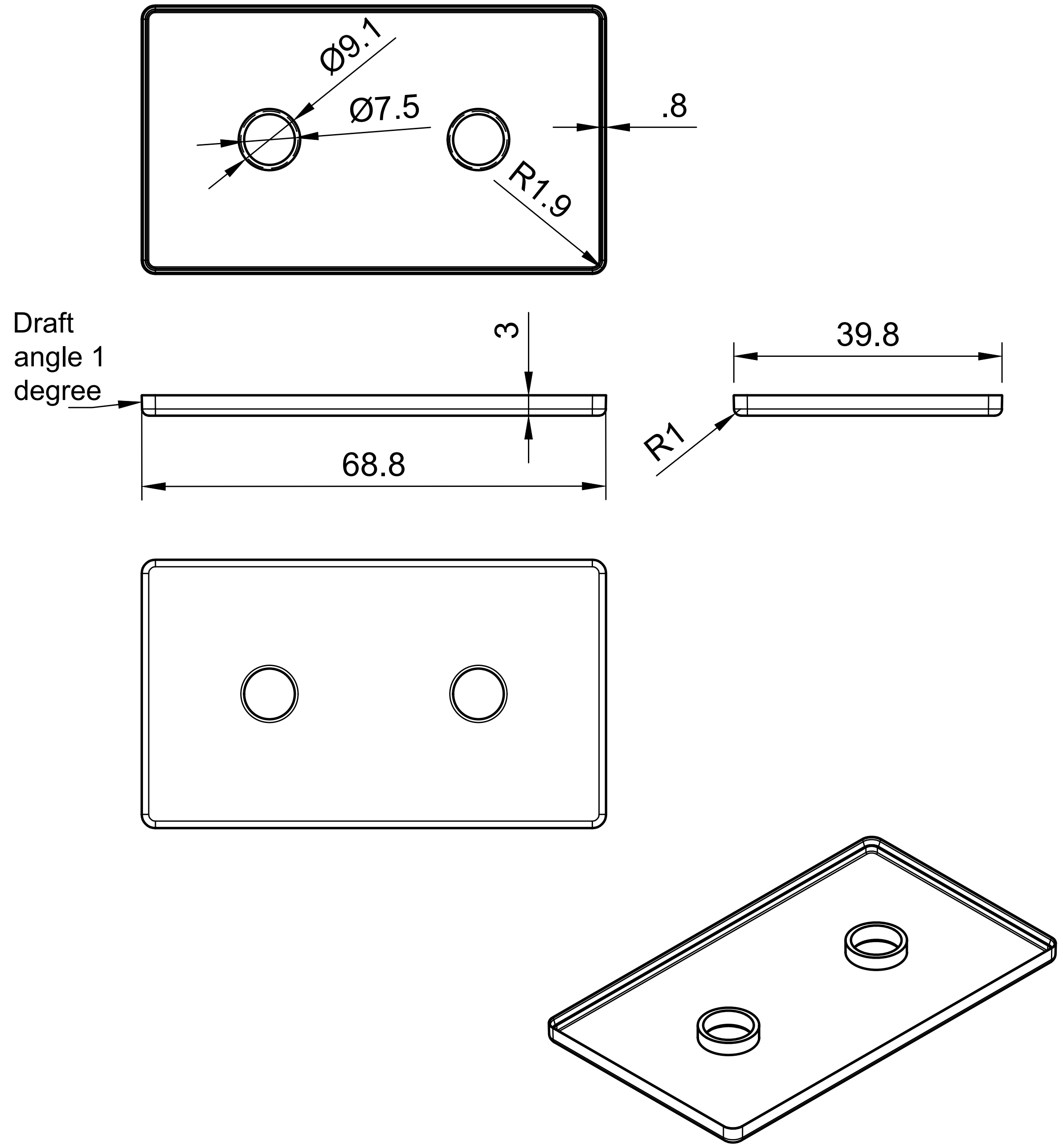


No.	Pcs.	Name	Material
1	1	Battery case top shell	ExxonMobil PP9074MED
2	1	Qi receiver coil	
3	1	Battery	
4	2	Snap fastener eyelet 2.2	
5	1	Snap fastener plate 2	ExxonMobil PP1013H1
6	2	Snap fastener stud 2	
7	1	Battery case bottom shell	ExxonMobil PP9074MED
8	2	Snap fastener socket 2	
9	1	Upper part top shell	ExxonMobil PP9074MED
10	3	LED diode	
11	1	Small circuit board	
12	2	Snap fastener eyelet 2.1	
13	1	Pogo pin female socket	
14	1	Large circuit board	
15	2	Snap fastener eyelet 1	
16	1	Speaker	
17	1	Snap fastener plate 1	ExxonMobil PP1013H1
18	1	Upper part bottom shell	ExxonMobil PP9074MED
19	6	Electrode	
20	2	Snap fastener stud 1	
21	1	Lower part shell	Ateva 2820 AG
22	1	Pogo pin male plug	
23	1	iStretch wire	
24	1	Wire collector 1	
25	2	Acoustic filter	
26	1	Copper wire	
27	2	Snap fastener eyelet 3	
28	1	Snap fastener plate 3	ExxonMobil PP1013H1
29	2	Snap fastener stud 3	
30	2	Top microphone case	ExxonMobil PP9074MED
31	2	Top microphone	
32	2	Microphone holder 1	ExxonMobil PP1013H1
33	2	Microphone holder 2	ExxonMobil PP1013H1
34	2	Gasket	
35	2	Wire collector 2	
36	2	Bottom microphone	
37	2	Acoustic filter	
38	2	Bottom microphone case	ExxonMobil PP9074MED
39	1	EVA liner	Ateva 2803 G

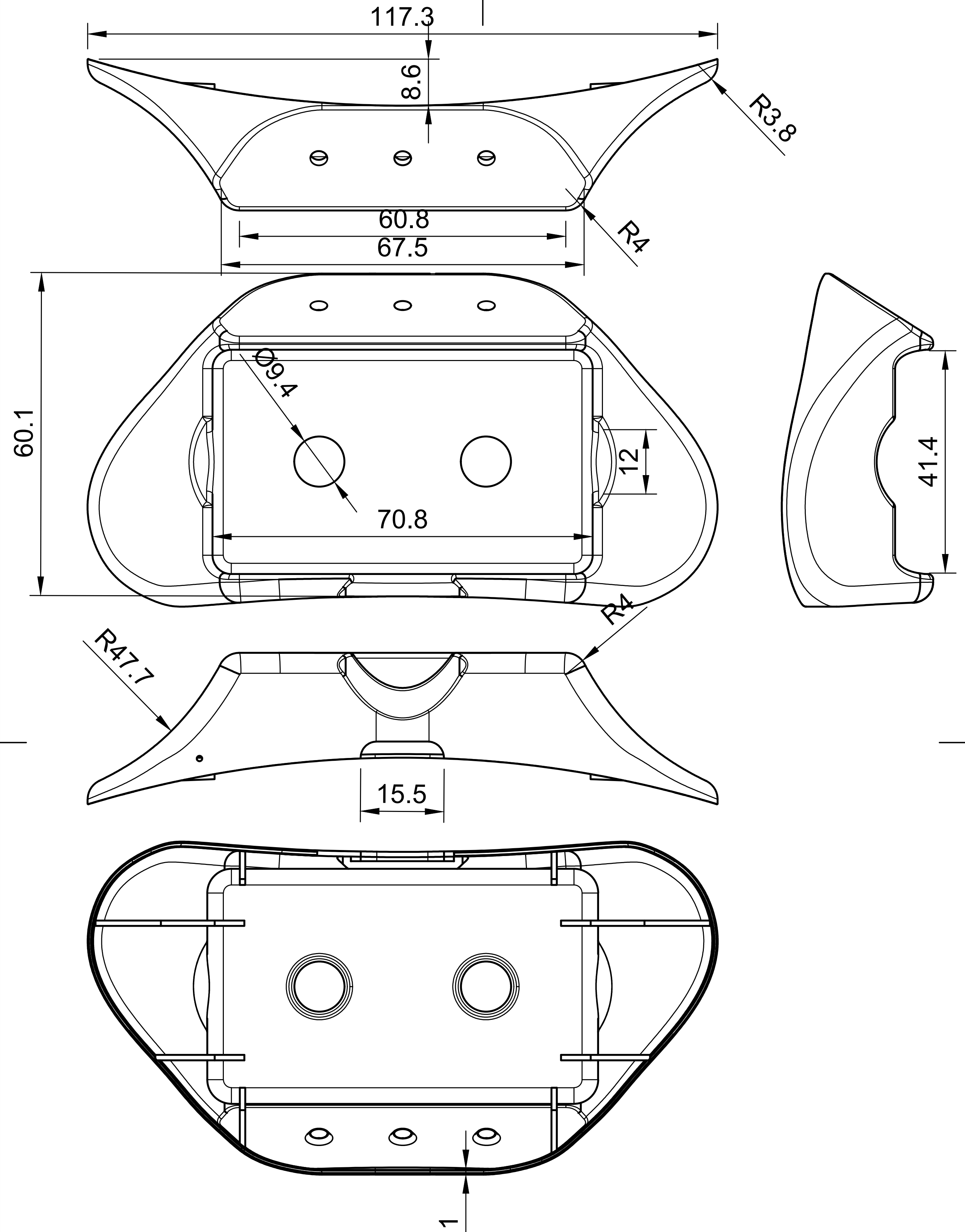
Dept.	Technical reference	Created by	Approved by
		Sofie Holdensgaard 30/05/2020	
1:5		Document type	Document status
		Title: Exploded view	DWG No.: 1
			Rev. / Date of issue / Sheet: 1/14



Dept.	Technical reference	Created by	Approved by
		Trine Hald Holmsgaard 30/05/2020	
1:1 mm		Document type	Document status
		Title: Battery case top shell	DWG No.: 2
			Rev. / Date of issue / Sheet: 2/14

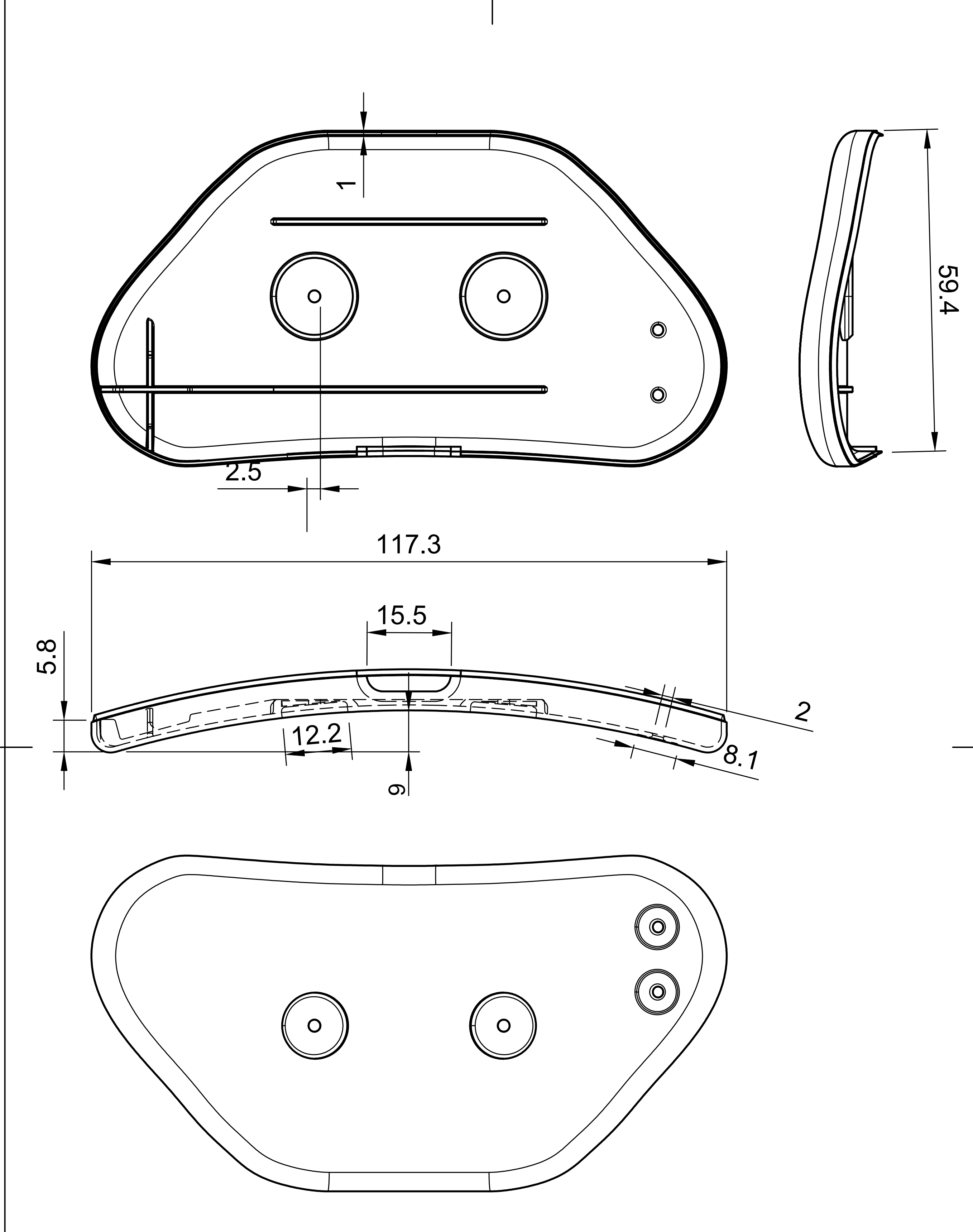


Dept.	Technical reference	Created by	Approved by
		Trine Hald Holmsgaard 30/05/2020	
1:1 mm		Document type	Document status
		Title: Battery case bottom shell	DWG No.: 3
			Rev. / Date of issue / Sheet: 3/14



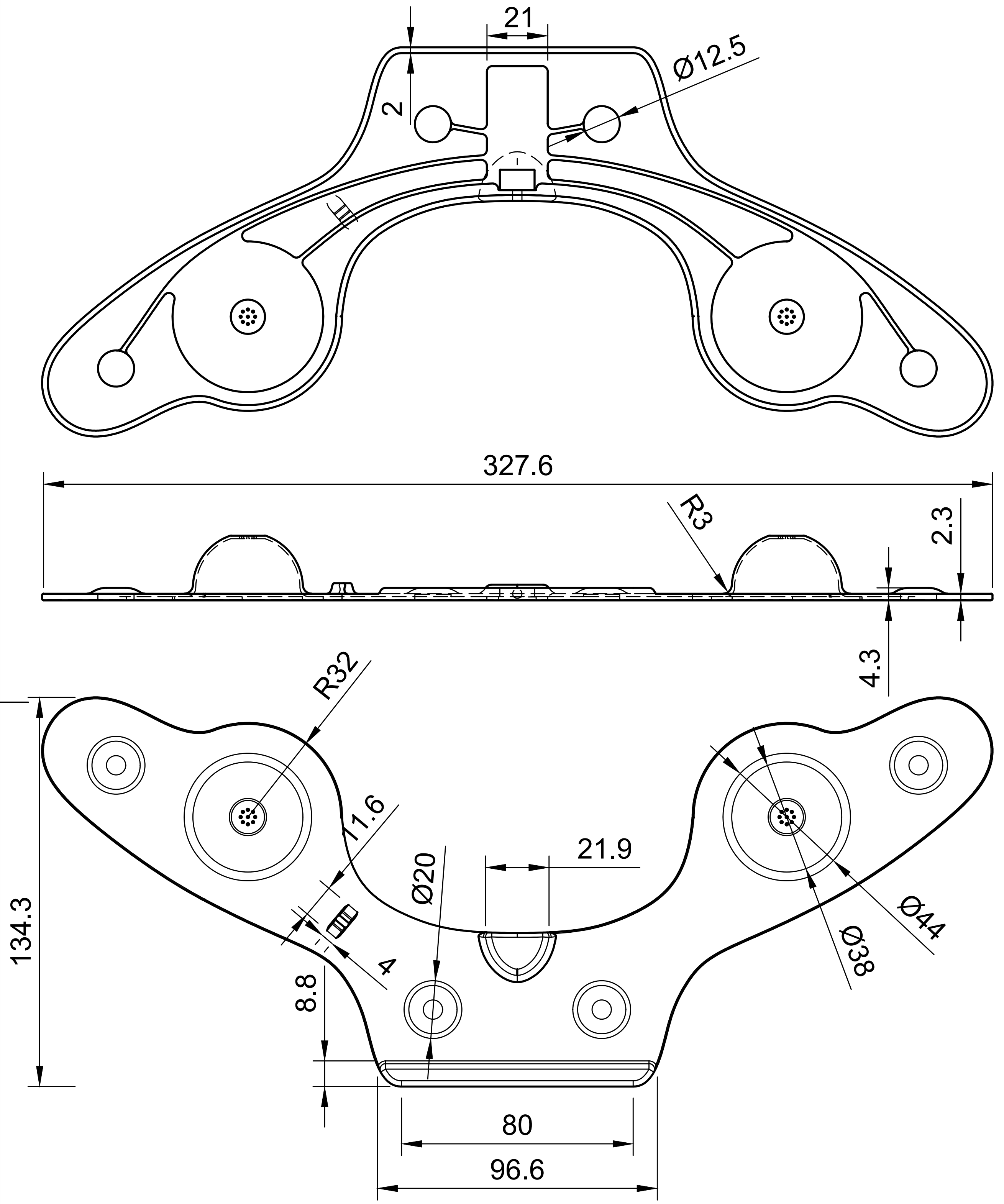
Dept.	Technical reference	Created by	Approved by
		Trine Hald Holmsgaard 30/05/2020	

1:1 mm	Document type	Document status
	Title Upper part top shell	DWG No. 4
		Rev. / Date of issue / Sheet 4/14

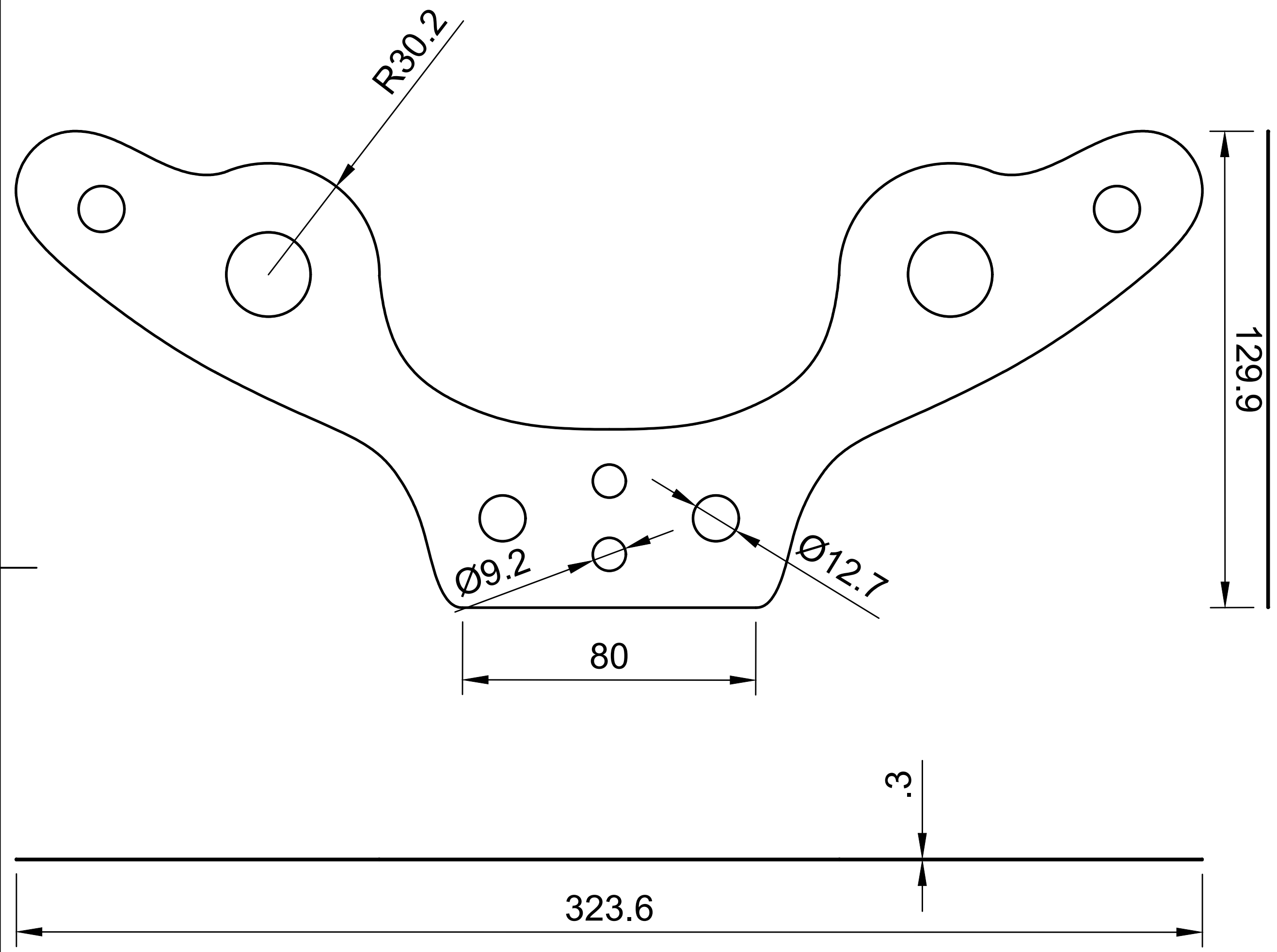


Dept.	Technical reference	Created by	Approved by
		Trine Hald Holmsgaard 30/05/2020	

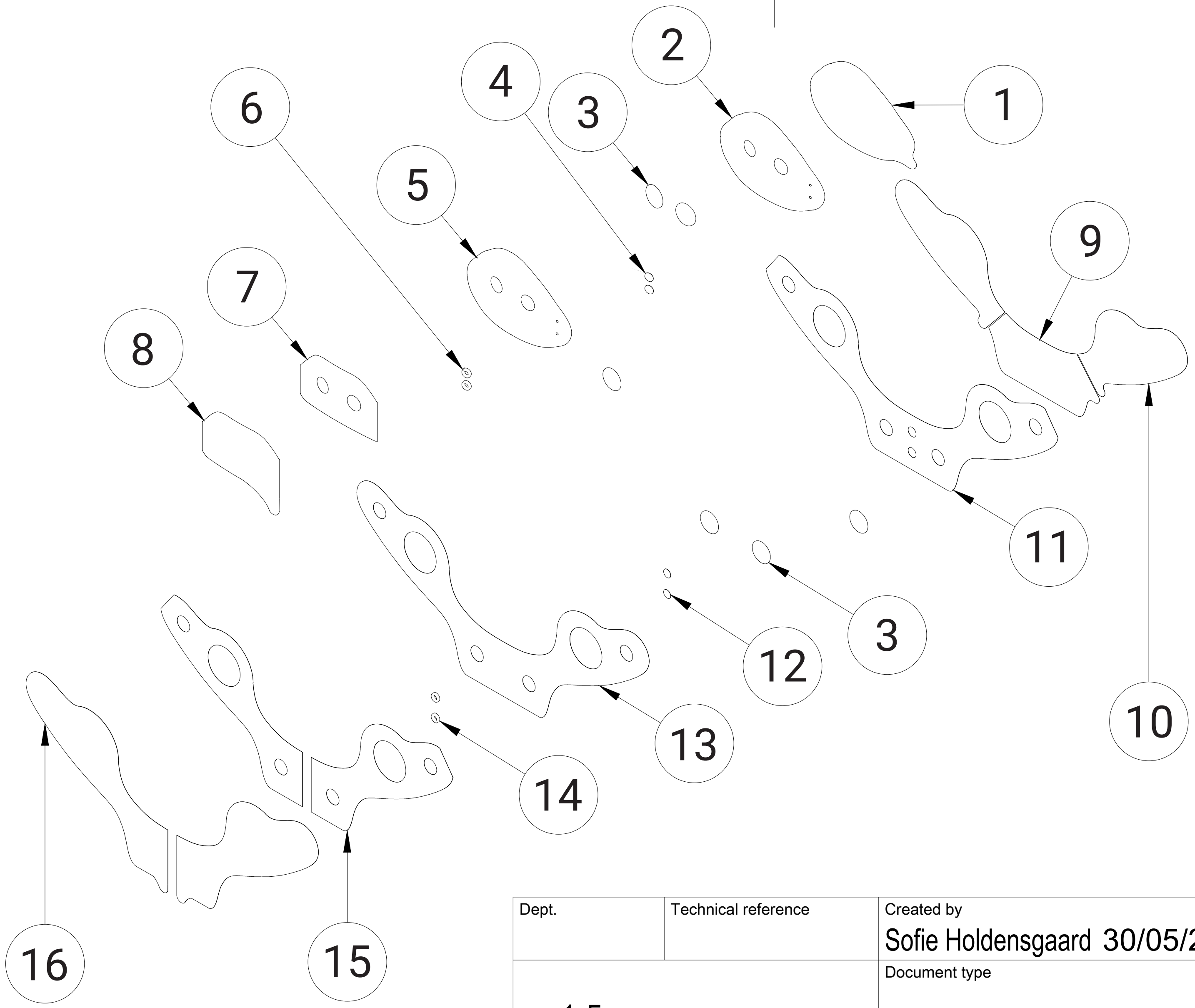
1:1 mm	Document type	Document status
	Title Upper part bottom shell	DWG No. 5
		Rev. / Date of issue / Sheet 5/14



Dept.	Technical reference	Created by	Approved by
		Trine Hald Holmsgaard 30/05/2020	
1:2 mm		Document type	Document status
		Title: Lower part top shell	DWG No. 6
			Rev. / Date of issue / Sheet 6/14



Dept.	Technical reference	Created by	Approved by
		Trine Hald Holmsgaard 30/05/2020	
1:2 mm		Document type	Document status
		Title: Lower part liner	DWG No. 7
			Rev. / Date of issue / Sheet 7/14



No.	Pcs.	Name
1	1	Upper part foil 1
2	1	Upper part adhesive 1
3	6	Conductive gel
4	2	Snap fastener eyelet 1.2
5	1	Upper part liner
6	2	Snap fastener socket 1.
7	1	Upper part adhesive 2
8	1	Upper part foil 2
9	1	Lower part foil 1
10	2	Lower part foil 2
11	1	Lower part adhesive 1
12	2	Snap fastener eyelet 3.2
13	1	Lower part liner
14	2	Snap fastener socket 3
15	2	Lower part adhesive 2
16	2	Lower part foil 3

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		Sofie Holdensgaard 30/05/2020	

1:5

Document type	Document status

Title	DWG No.
Exploded view adhesive sheets	8

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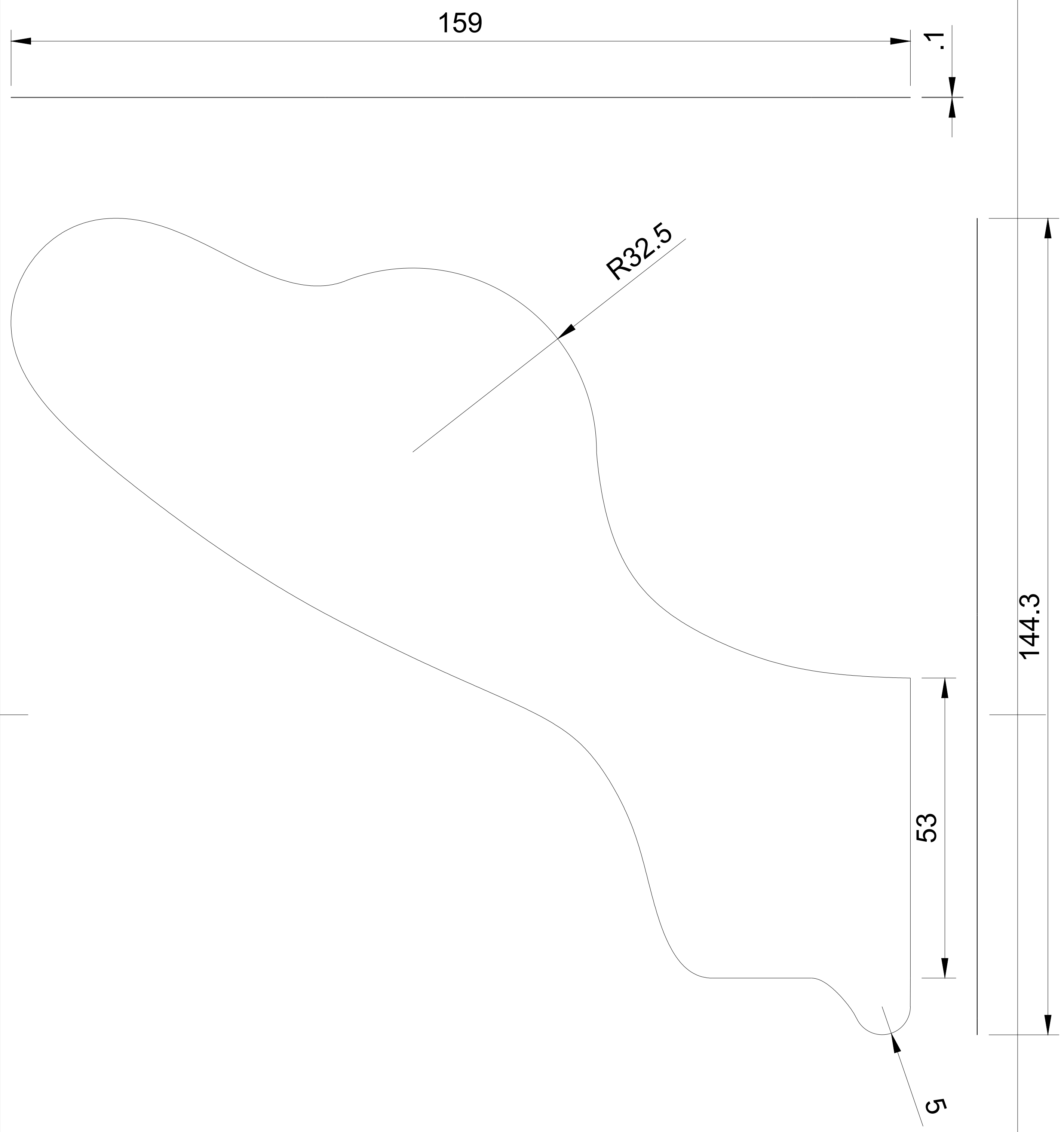
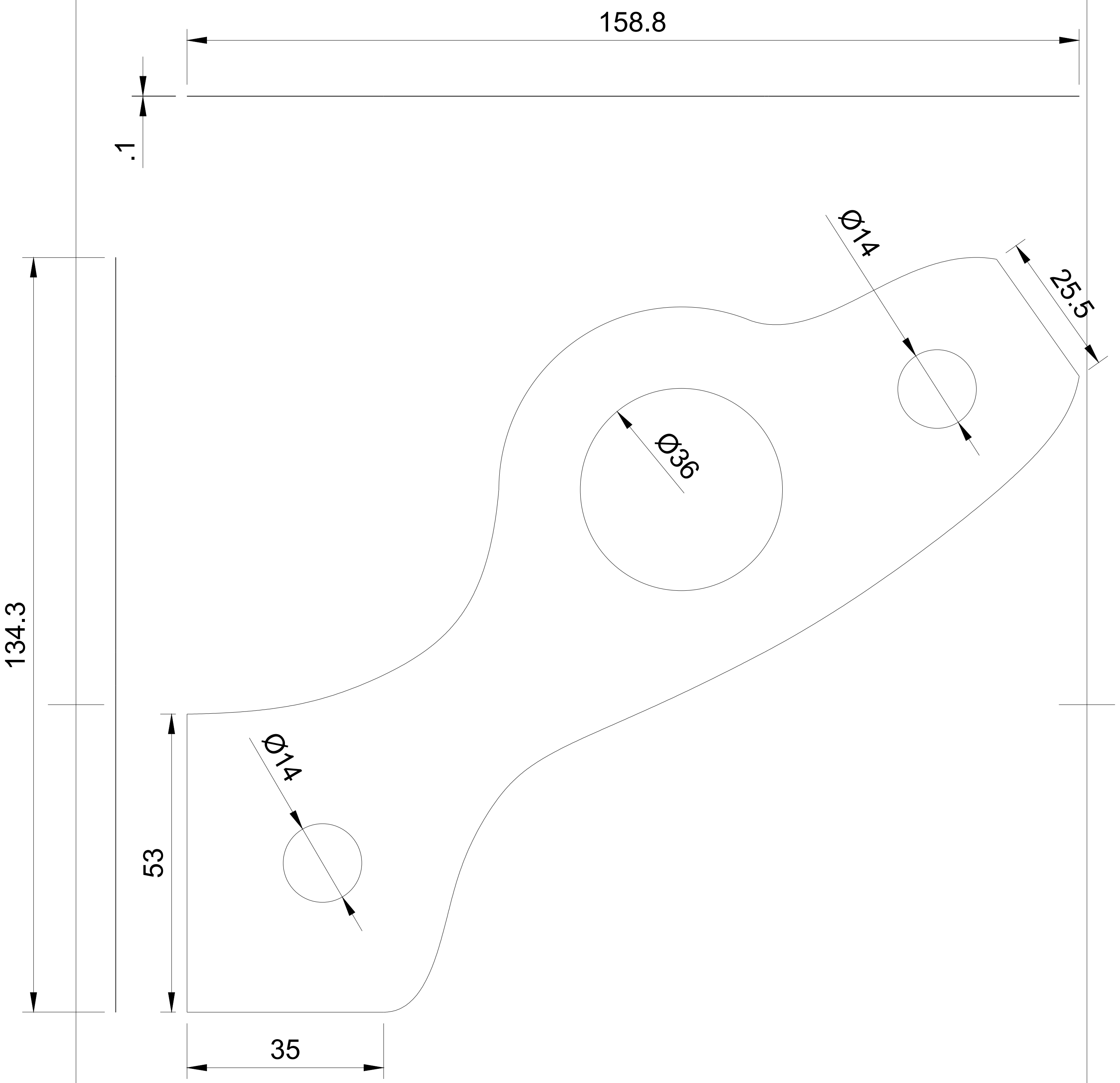
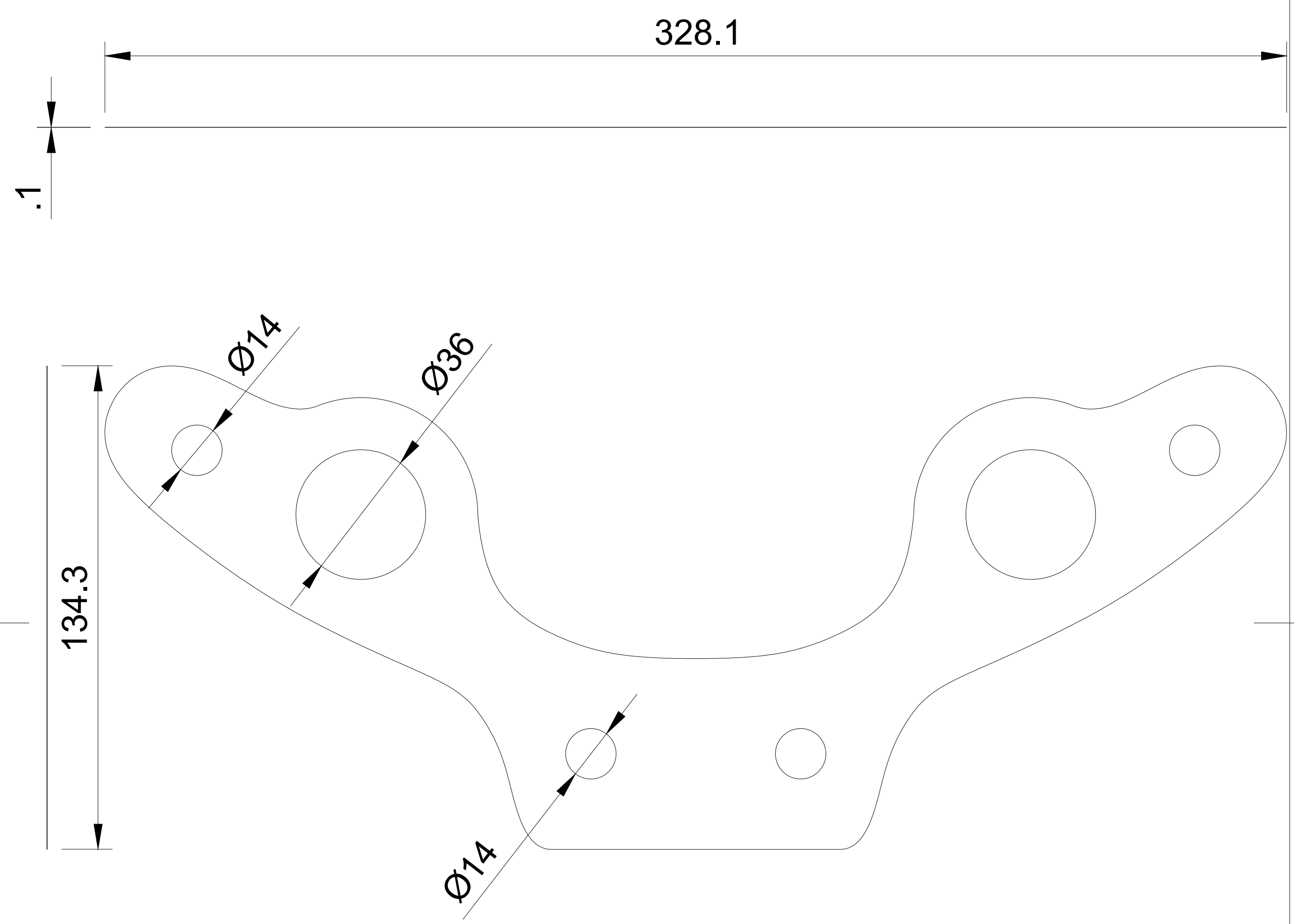
		8/14



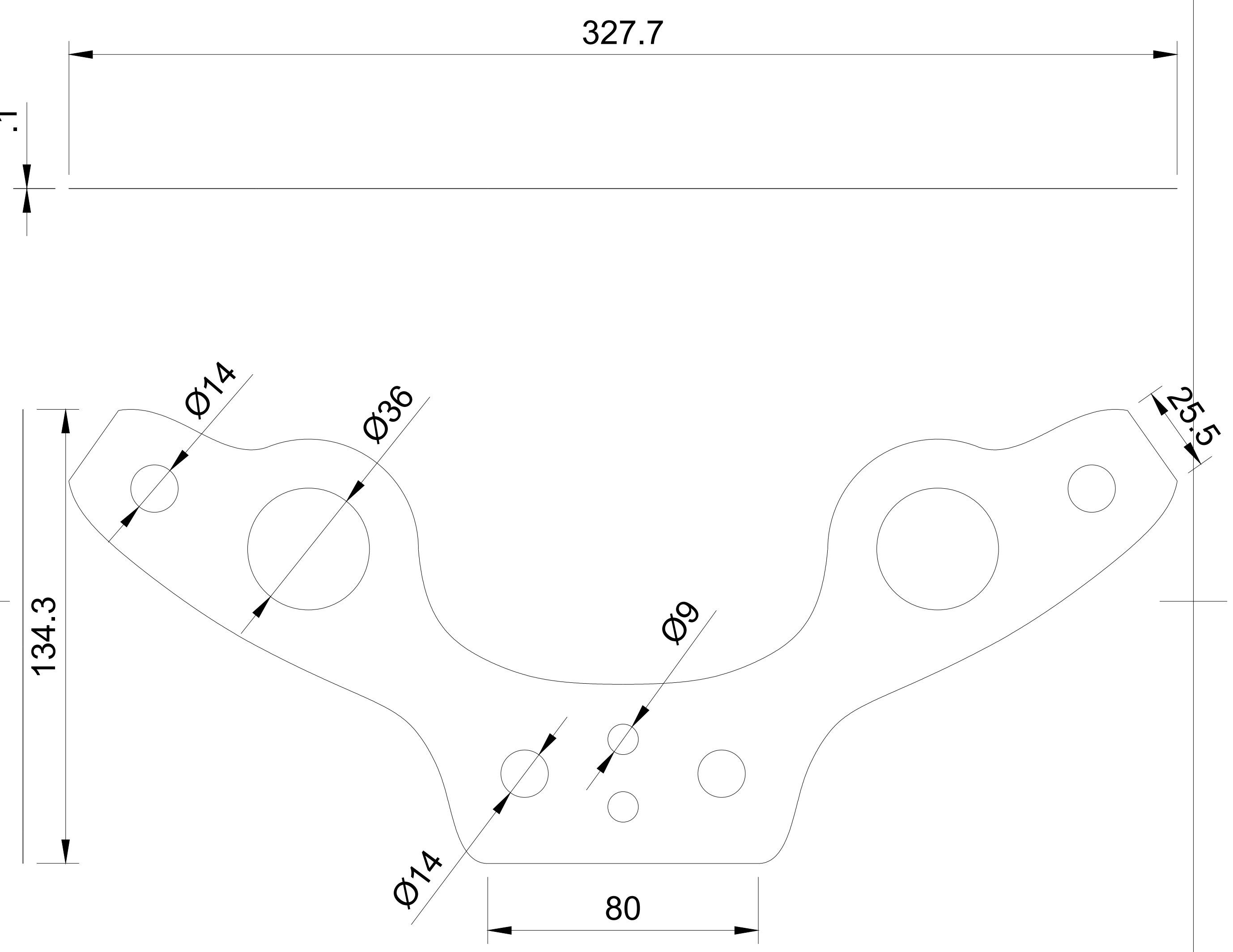
Dept.	Technical reference	Created by	Approved by
		Sofie Holdensgaard 30/05/2020	
1:1 mm		Document type	Document status
		Title: Lower part foil 3	DWG No.: 9
			Rev. / Date of issue / Sheet: 9/14



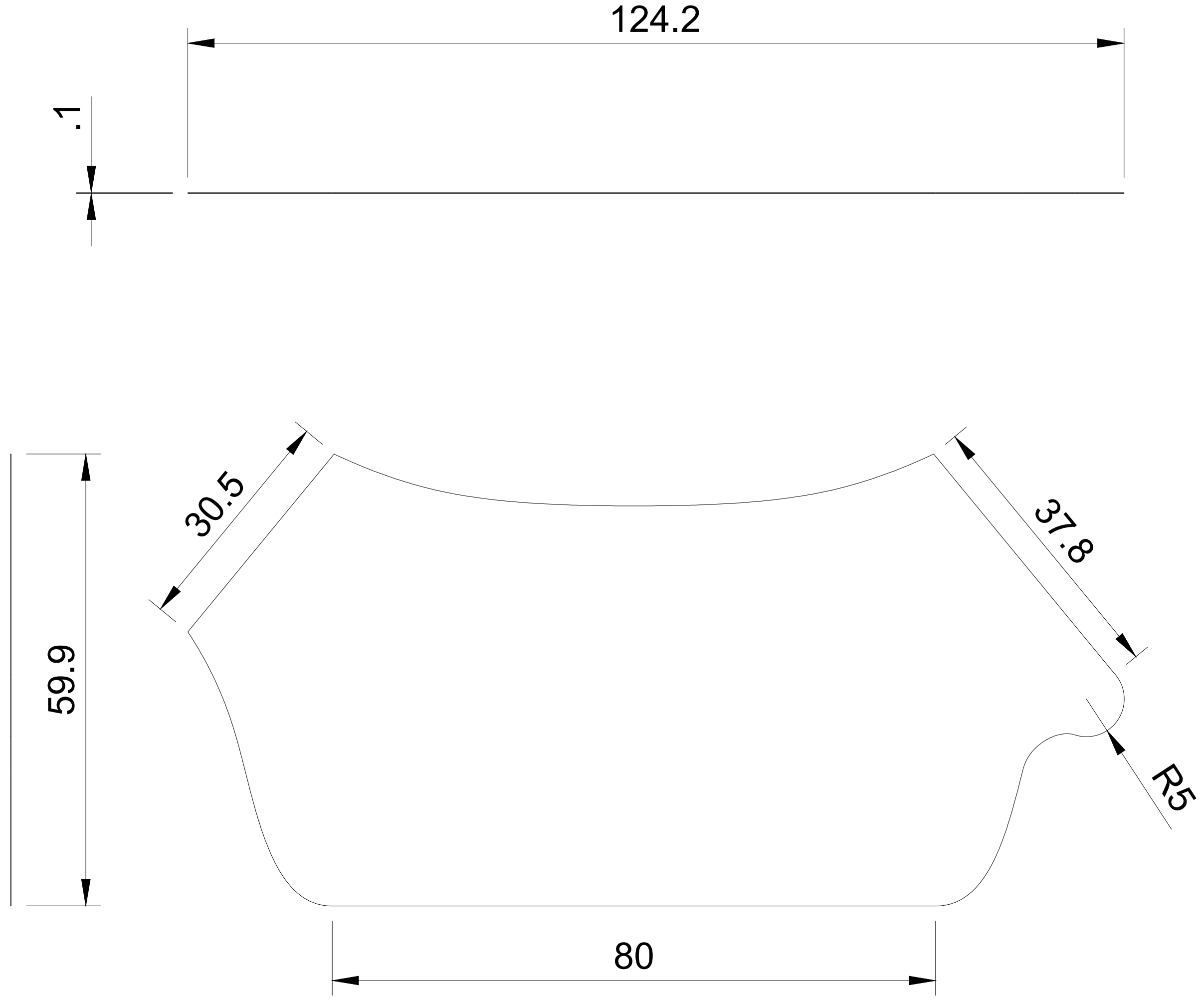
Dept.	Technical reference	Created by	Approved by
		Sofie Holdensgaard 30/05/2020	
1:1 mm		Document type	Document status
		Title: Lower part adhesive 2	DWG No.: 10
			Rev. / Date of issue / Sheet: 10/14



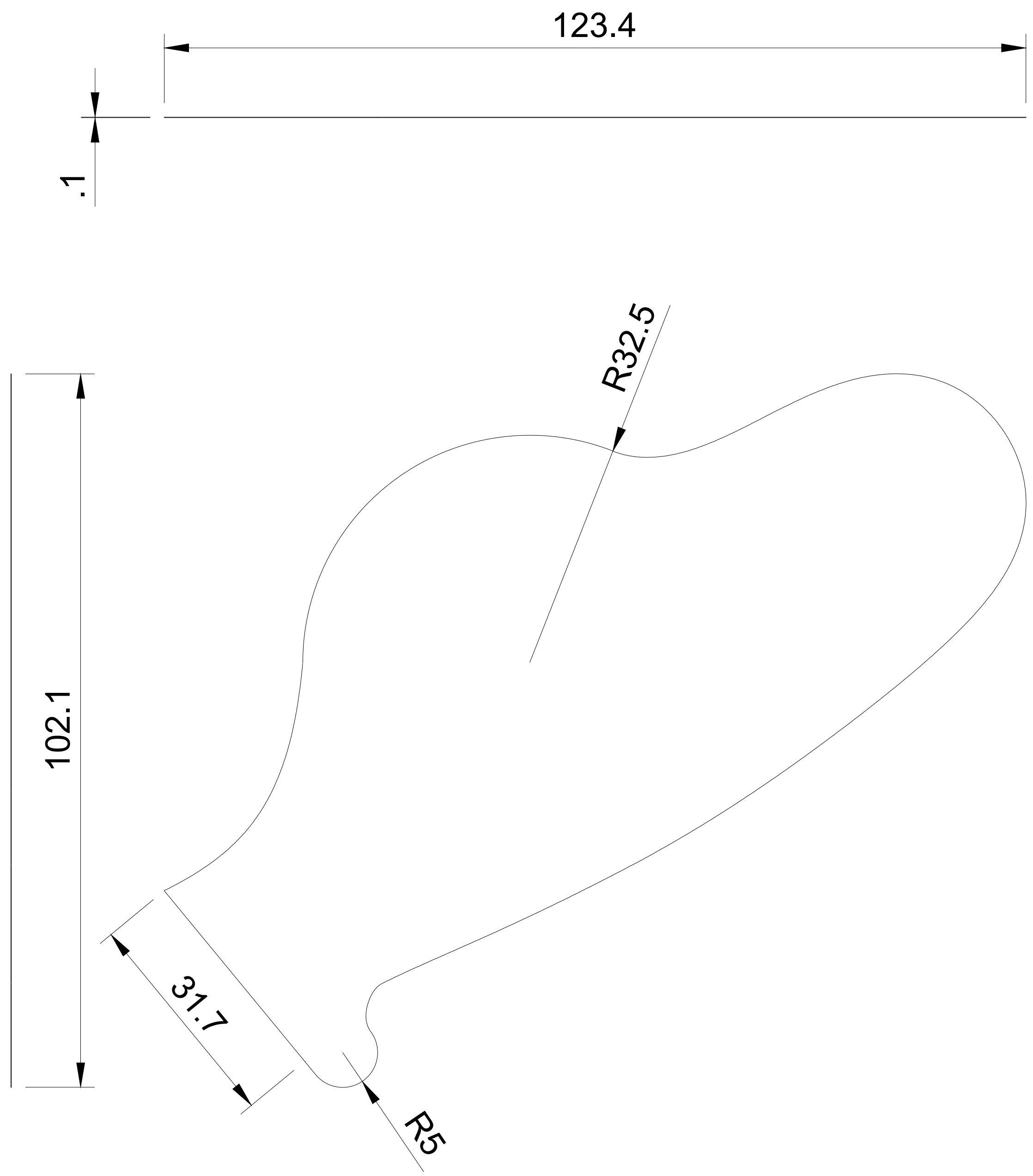
Dept.	Technical reference	Created by	Approved by
		Sofie Holdensgaard 30/05/2020	
1:2		Document type	Document status
mm		Title	DWG No.
		Lower part liner	11
			Rev. / Date of issue / Sheet 11/14



Dept.	Technical reference	Created by	Approved by
		Sofie Holdensgaard 30/05/2020	
1:2		Document type	Document status
mm		Title	DWG No.
		Lower part adhesive 1	12
			Rev. / Date of issue / Sheet 12/14



Dept.	Technical reference	Created by	Approved by
		Sofie Holdensgaard 30/05/2020	
1:1 mm		Document type	Document status
		Title: Lower part foil 1	DWG No. 13
			Rev. / Date of issue / Sheet 13/14



Dept.	Technical reference	Created by	Approved by
		Sofie Holdensgaard 30/05/2020	
1:1 mm		Document type	Document status
		Title: Lower part foil 2	DWG No. 14
			Rev. / Date of issue / Sheet 14/14