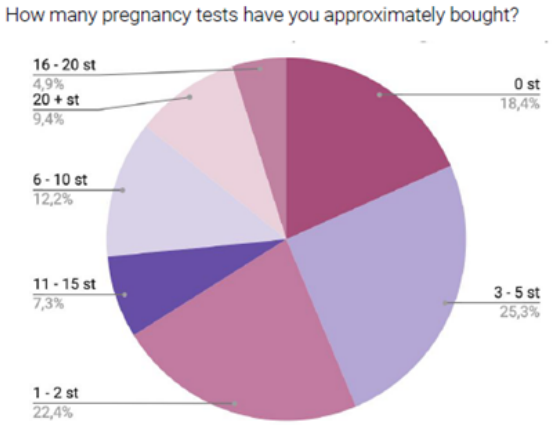
APPENDIX

Contents

Appendix A - *Pharmista Market Analysis - Expanded*

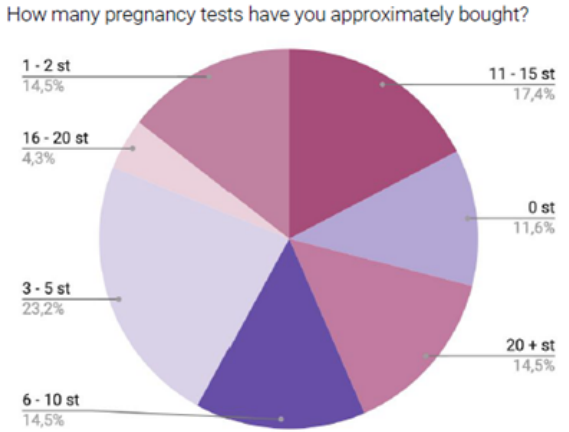
Primary Analysis

Women aged 20-25
Among the 245 women surveyed, aged 20 to 25, 80% reported having purchased a pregnancy test at some point. Within this group, 85.5% made the purchase due to concerns about pregnancy. Of the remaining 20% who had not purchased a pregnancy test, 37 mentioned not needing one, 7 found it too expensive, and 5 had received free tests. Among the 80% who had bought a pregnancy test, the majority had purchased between 3 to 5 tests, averaging 5.8 tests per person, and spent a total of 16.95 to 33,84 Euros.



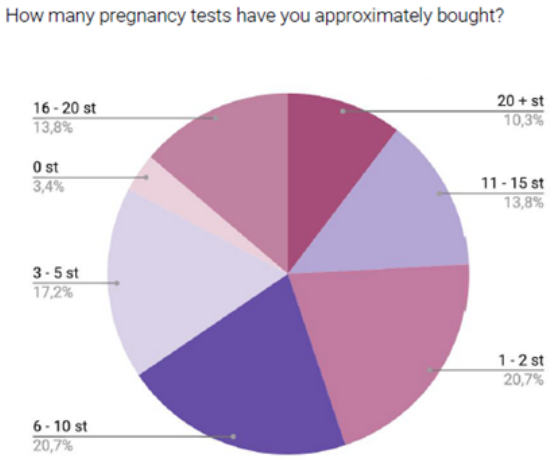
Women aged 26-30
Among the 163 women surveyed, aged 26 to 30, 88% reported having purchased a pregnancy test at some point. Within this group, 60% bought the test due to concerns about pregnancy, 10% purchased it in hopes of becoming pregnant, and 30% bought it for both reasons. Among the 12% who had never purchased a pregnancy test, 13 mentioned not needing one, 5 found it too expensive, and 3 found it embarrassing to buy. Among the 88% who had bought a pregnancy test, 42.4% had purchased between 3 to 10 tests, averaging 8 tests per person, and spent a total of 16.95 to 50.78 Euros.

Women aged 31-35
Among the 69 women surveyed, aged 31 to 35, 88% reported having purchased a pregnancy test at some point. Within this group, 45% bought the test due to concerns about pregnancy, 10% purchased it in hopes of becoming pregnant, and 45% bought it for both reasons. Among the 12% who had never purchased a pregnancy test, 7 mentioned not needing one and 1 person found it too expensive to buy. Among the 88% who had bought a pregnancy test, 23% had purchased between 3 to 5 tests, averaging 8.2 tests per person, and spent a total of 16.95 to 50.78 Euros.



Primary Analysis

Women aged 36-40
Among the 28 women surveyed, aged 36 to 40, 94% reported having purchased a pregnancy test. Within this group, 26% bought the test due to concerns about pregnancy, 11% purchased it in hopes of becoming pregnant, and 63% bought it for both reasons. Among the 94% who had bought a pregnancy test, the majority had purchased between 1-2, 3-5, or 6-10 tests, with an average of 8.7 tests per person. They spent a total of 50.84 to 67.70 Euros on pregnancy tests.



Appendix B - *User Study*

1. Interview Questions

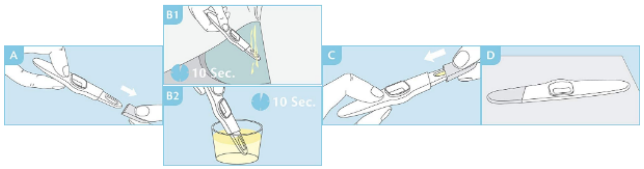
General:
Introduction to the project and their role in the study.

About the participant:
Name, Age, Gender, occupation, country of residence

Testing Habits:
1. When was the last time you used a pregnancy test?
2. Where did you take the test? (Location)
3. When you took a test were you in the process of trying to conceive or not
4. How many times did you take a test in one instance?
5. When taking a test were you alone? If not, who was part of the experience with you?
6. What was their role in the test taking process?

Test type:
1. Which brand of test did you use?
2. Did you buy the test yourself? If not, then who did?
3. Did you feel any anxiety buying the test?
4. What factors did you consider when choosing a pregnancy test brand or type?
5. What do you think about the cost of the test?

During the test:
1. Can you tell me about the experience of taking a pregnancy test?
2. How did you feel during the process of taking the test?
3. Can you walk me through the steps you took to take the test?
4.



5. Did you experience any difficulties or challenges during the process of taking the test? If so, can you describe them?
6. What would you have liked to see differently in the design or functionality of the pregnancy test?

After the test:
1. How did you feel after receiving the test results?
2. Did you feel confident in the accuracy of the test results? If not, why?
3. After taking the test, did you wish to store your test? If so, what did you do with it?
4. How long did you save your test?

Overall experience:
1. Do you have any suggestions or recommendations for improving the pregnancy testing experience?
2. Is there anything else you would like to add about your experience with pregnancy testing?
3. In which situations have you tested in and how many times have you tested in total?
4. Do you think you would benefit from having a test that is reusable?

2. Consent Form

Delft University of Technology
INFORMED CONSENT FORM

Project: Enhancing the Experience of Pregnancy Detection
You are being invited to participate in a research study titled Enhancing the Experience of Pregnancy Detection for Improved User Experience. This study is being done by Bhavika Dhar under the supervision of Dr. Ir. Marijke Dekker and I.r. Stefan Persaud from the TU Delft. The study is in collaboration with Pharmista Technologies A.B (company, based in Sweden).

The purpose of this research is to understand the experience of using pregnancy detection devices for couples undergoing fertility treatment and sexually active women who have experience with single use pregnancy tests. The data will be used to formulate the requirements and wishes towards a new reusable pregnancy test which better meets the needs of its intended users.

The study will be conducted in 2 to 3 phases over 4 months (starting in March 2023), each of which will take you approximately 30 minutes to complete. In phase 1, we will ask you to talk about your personal perception and opinion regarding current at home pregnancy detection devices with special emphasis on their usability. In phase 2, we will produce low fidelity prototypes for you to test and give recommendations for improvement based on your user experience. In the phase 3, we will produce higher fidelity prototypes that you will be asked to evaluate.

Confidentiality
Upon signing this consent, you will be assigned a unique participant number; all information you provide during the study will be stored in an anonymized form under this number to protect your privacy. The collected data will only be used for scholarly purposes and will be published in a MSc Integrated Product Design graduation thesis. No personally identifiable information will be shared outside the research group at any time.

The data of the activities performed will be stored in a secured TU Delft storage folder, the risk of a breach is low, but still possible. To the best of our ability, your answers in this study will remain confidential. We will minimize any risks by means of anonymization and by storing your personal information separately from the data obtained during the study. Upon the completion of the project, all materials containing personally identifiable information will be destroyed.

Participation
Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions and can ask to get data removed at any time before the end of the session.

Consent
Please, specify below whether you agree to participate in this study. Choosing "Yes, I agree to participate" indicates that:
- you have read the above information
- you voluntarily agree to participate
- you are at least 18 years of age.

If you do not wish to participate in this study, please decline participation by choosing "No, I do not agree to participate".

☐ Yes, I give my consent to participate ☐ No, I do not give my consent to participate

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICPANT TASKS AND VOLUNTARY PARTICIPATION		
1. I have read and understood the study information dated [15/03/2023], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
2. I consent voluntarily to be a participant in this study and understand that discussing such topics can be sensitive and can lead to feeling unsettled. If I feel this way at any point during the study I can refuse to answer specific answer questions and I can withdraw from the study at any time, without having to give a reason.	☐	☐
3. I understand that taking part in the phase 1(interview) involves: • Sharing personal information (age, use of contraception, nationality, race) with the researcher. • Answering a set of questions about my experience with/opinion usage of pregnancy tests. • Having the researcher taking notes of the most relevant information. • Having the audio of the session recorded for possible future consultation of information not written down during the session.	☐	☐
4. I understand that taking part in the phase 2 and 3(prototype testing) involves: • Touching prototypes with your hands and giving my opinion on them. • Having the researcher taking notes of the most relevant information. • Pictures being taken of only non-identifiably actions	☐	☐
5. I understand that the study will take approximately 30 minutes.	☐	☐
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)		
6. I understand that taking part in the study involves the following risks: • Being exposed to Covid. I understand that these will be mitigated by: • In case of resurgence of the corona virus, having the researcher wear the mask during the entire session.	☐	☐
7. I understand that taking part in the study also involves collecting specific personally identifiable information (PII) like age and gender.	☐	☐
8. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach: • All information will be stored locally. • Voice recordings and written notes will be destroyed after completion of the project.	☐	☐
9. I understand that personal information collected about me that can identify me, such as age or gender, will not be shared beyond the study team.	☐	☐
10. I understand that the (identifiable) personal data I provide will be destroyed after completion of the project.	☐	☐
C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION		
11. I understand that after the research study the de-identified information I provide will be used for: • Decision-making throughout the design process, with scientific and academic purposes only.	☐	☐
12. I agree that my responses, views, or other input can be quoted anonymously in research outputs.	☐	☐

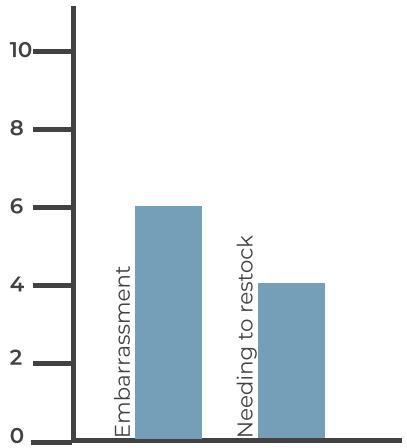
Signature

Name of participant _____ Signature _____ Date _____

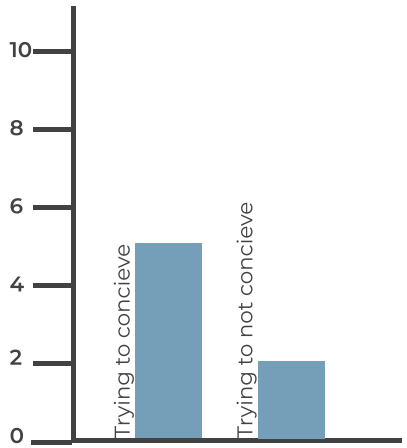
Study contact details for further information:
Bhavika Dhar, +31 6 23900214, B.Dhar@student.tudelft.nl

3. Additional Statistics

Pain points while buying the test:
Within the process of buying the test, participants expressed the embarrassment attached to it (6) while some other (2) expressed annoyance in the need to buy a test multiple times.



Partner involvement:
Within the testing process all 5 users who were trying to conceive had involvement of their partner in some capacity. But this level of involvement was different for different participant.



Reusability aspect:
This topic covered was similar to that of the Pharmista market study. The user test garnered similar results where users who were 3 out of 5 users who were not intending on getting pregnant expressed that they do not see themselves invest in a reusable test. This was mainly due to the idea of testing being a one off chance for them.
Additionally 4 out of 5 users who were trying to conceive thought the idea was quite intriguing and saw value in a reusable alternative. 1 participant from this set expressed apprehension based around hygiene.

Appendix C - *User Trend Analysis*

Couples trying to conceive

1. **Natural Conception:** Study based in Germany with a total group of 340 women at different cycle (referring to menstrual cycles) intervals of fertile couples (304 women) who successfully conceived, the corresponding pregnancy rates were 42% at one cycle, 75% at three cycles, 88% at six cycles, and 98% at 12 cycles (Gnoth, 2003).
2. **Infertility issues:** Infertility is defined clinically as “12 or more consecutive months of sexual intercourse without contraception and without achieving pregnancy.” (Boltz et al., 2017). This infertility can be from either partner.
3. **Cannot conceive naturally (same sex couples)**: For the case of same sex couples, there is an eminent need to seek for fertility treatment to conceive for a child. This ranges from simple sperm donations to IVF treatments and is heavily dependent on the couple’s reproductive health. These statistics also showcases the prominence of this user groups impact on the pregnancy testing market.

1. **Medicines:** This option involves the use of medications to address underlying issues that might be affecting fertility. These medications could regulate hormones, stimulate ovulation, or address conditions like polycystic ovary syndrome (PCOS). They are often the first step in fertility treatment, aiming to create a more favorable environment for conception.
2. **Surgical Procedures:** Surgical interventions might be recommended to correct anatomical abnormalities or conditions that are hindering conception. For example, surgical procedures could address issues like blocked fallopian tubes, endometriosis, or fibroids. By addressing these physical obstacles, the chances of natural conception can be improved.
3. **Assisted Conception:** Assisted conception methods are advanced medical techniques designed to assist with fertilization and embryo development. These methods are particularly relevant for couples facing fertility challenges.
    - Intrauterine Insemination (IUI): In IUI, sperm is collected, prepared, and then directly inserted into the uterus during the woman's fertile window. This method increases the chances of sperm reaching the fallopian tubes and fertilizing the egg.
    - In Vitro Fertilisation (IVF): IVF involves retrieving eggs from the ovaries, fertilizing them with sperm in a laboratory dish, and then transferring the resulting embryos into the woman's uterus. IVF is a comprehensive procedure that can help overcome various fertility issues, such as damaged fallopian tubes or low sperm count.

Push towards reusability in feminine products

In the recent years, there has been a huge increase in products associated with women and their reproductive health. With the current product being developed or re-developed for women are seeing an uptick with a push towards sustainability. It is valuable to investigate these products to gain inspiration from them for designing an envisioned system that also caters towards sustainability. Some of these products are listed below:

1. Fertility kits:
    a. A popular, reusable ovulation kits from popular brands like Clear Blue and other drug store brands have been introduced as alternatives to traditional fertility testing kits.
    b. Oova is also a new, urine based, algorithm powered ovulation tracking kit that lets its users know their fertile window, which allows them a higher chance of conception. This new device differentiates from the other with its application integration an its personalised tracking for women.

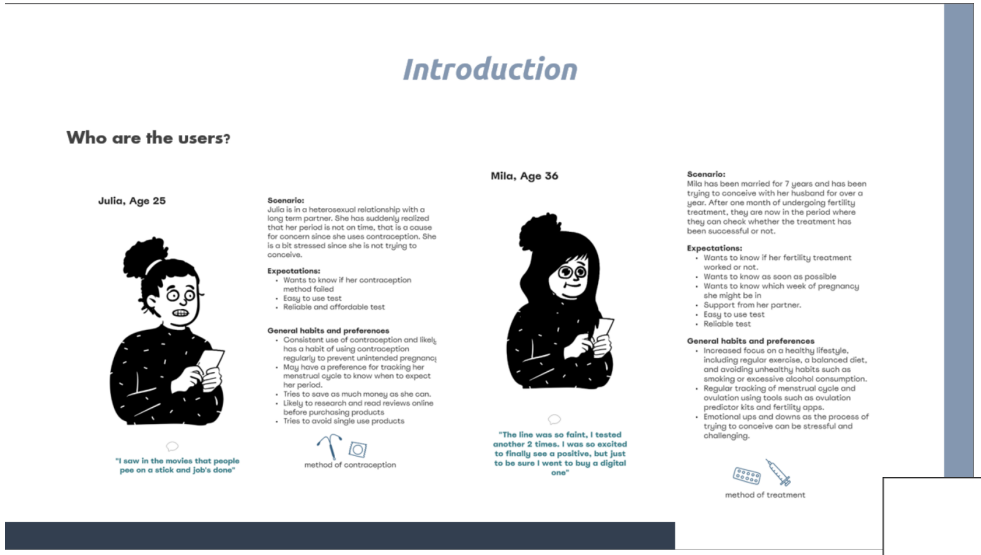
Gaining inspiration from these kits to pregnancy tests is appropriate, as both tests have similar steps for use and operate by detecting hormones in the user's urine to determine the fertility window for conception.

2. Reusable period products
    a. Reusable underwear: In recent years, the market has witnessed the emergence of unconventional menstrual products, including reusable underwear, as a prominent alternative to traditional options. Reusable underwear is gaining popularity due to its sustainable nature, aiming to eliminate the need for single-use menstruation products such as tampons and sanitary napkins. These innovative alternatives offer women a more eco-friendly and cost-effective option for managing their menstrual flow. By providing a reusable and washable solution, period underwear aligns with the growing demand for sustainable menstruation practices and offers women a convenient and environmentally conscious choice.

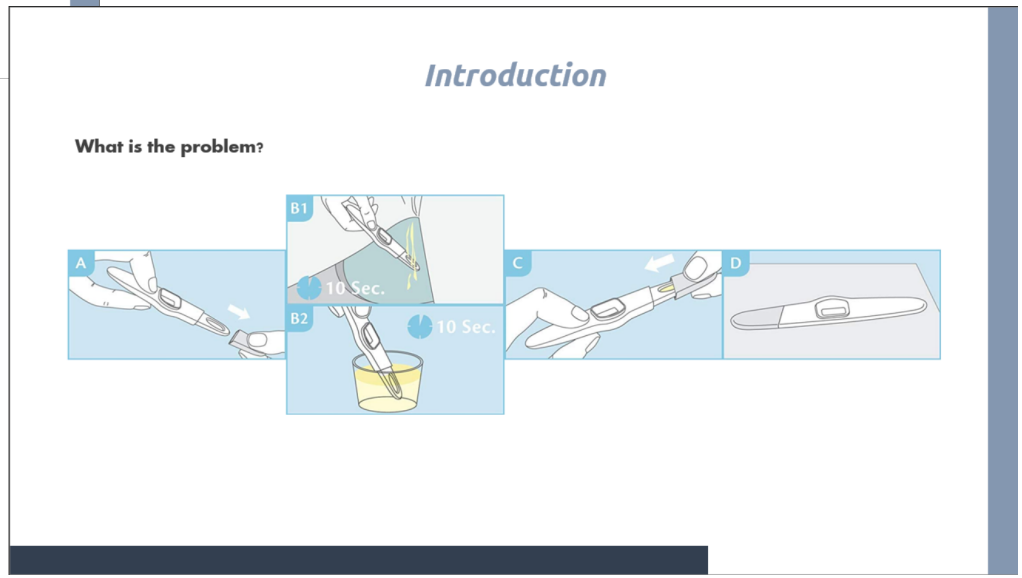
b. Menstrual cups: Menstrual cups have gained significant traction in the market as an alternative menstrual product. These small, flexible cups are typically made of medical-grade silicone or latex and are designed to collect menstrual fluid internally. The cup is inserted into the vagina and forms a seal, collecting the flow rather than absorbing it. One of the main advantages of menstrual cups is their long-lasting and reusable nature, with many brands advertising a lifespan of several years. This not only reduces waste compared to disposable products but also offers cost savings over time. Additionally, menstrual cups are often praised for their convenience, as they can be worn for longer periods of time without the need for frequent changes. As an environmentally friendly and economically viable option, menstrual cups have gained popularity among women seeking sustainable and comfortable menstrual care solutions

3. Pee funnels: The pee funnel, also known as a female urination device, is a practical tool designed for women to urinate while standing or in situations with limited access to toilets. There are two types available: reusable and one-time use. The reusable pee funnel is a durable, washable device made from materials like silicone or plastic. It offers convenience and sustainability as it can be used multiple times. The one-time use pee funnel, made from lightweight materials such as cardboard or paper, provides a hygienic solution that can be easily disposed of after use. Both types offer women the freedom and flexibility to urinate in various settings, providing convenience, hygiene, and comfort. This option specifically explored to gain inspiration for the development of the collection vessel and will be part of the future steps of the project.

Appendix D - *Co-Creation Session*



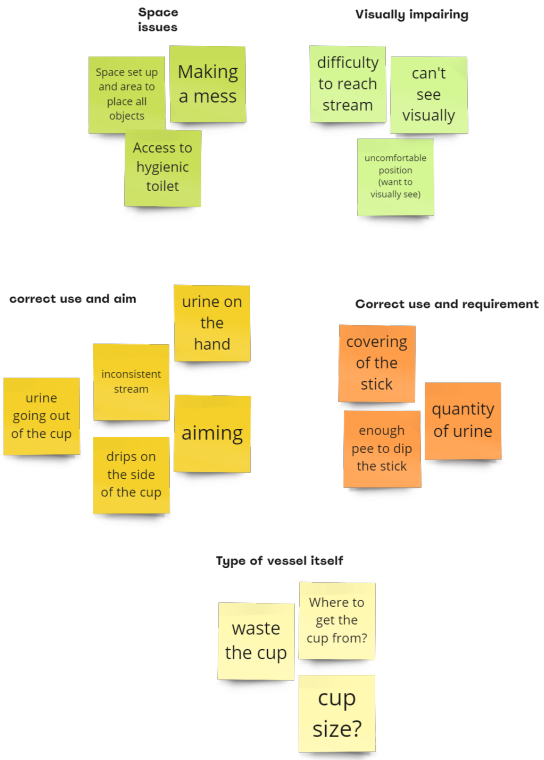
The co-creation session comprised of 6 design students where first the project scope was set up and introduced.



After the introduction to the subject matter, the participants were give three activities

Activity 1

"Dump it out!"



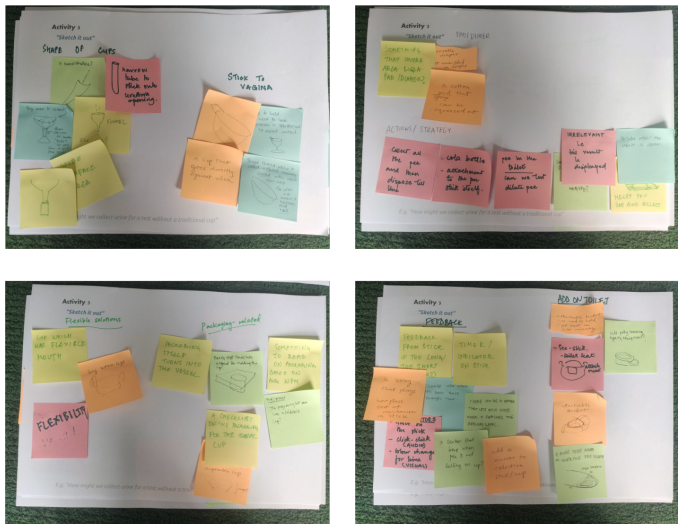
Activity 2

"How might we"

"How might we collect enough urine inside the vessel when the flow is inconsistent?"
"How might we find/procure the optimum vessel to collect urine such that it aids easy collection, is ideal for the stick to be dipped into?"
"How might we collect urine without making a mess in the bathroom/on yourself?"
"How might we ease the duration of time during the stick submerged?"
"How might we facilitate pee collection accuracy?"

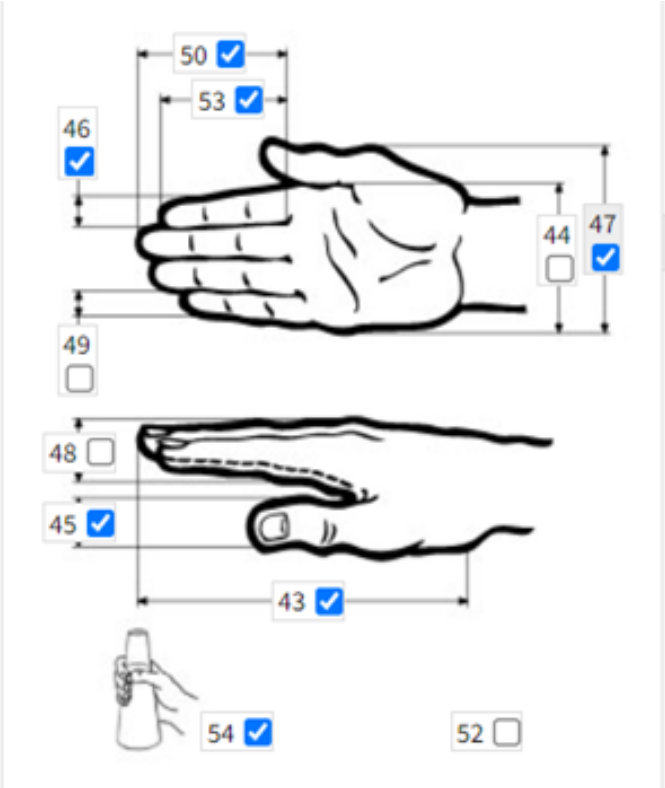
Activity 3

"Sketch it out"



Appendix E - *Anthropometric requirements*

A crucial role in creating a device that comfortably fits in users' hands and can be operated with ease. By considering hand dimensions such as hand length, hand width, finger length, and grip span, the design team can determine the optimal size, shape, and ergonomic features of the handheld device.



Hand length is an important measurement to consider as it determines the overall size of the device. It helps ensure that the device is neither too small, making it difficult to hold and operate, nor too large, causing discomfort during use. Hand width is another critical consideration as it influences the width and thickness of the device, ensuring a comfortable grip for users with different hand sizes.

Finger length is significant in determining the placement and size of buttons or controls on the device. By accommodating various finger lengths, the device can be designed to allow easy access and operation of its functions, minimizing the risk of user errors.

Grip span is a key anthropometric measurement that determines the width of the device, considering how users naturally hold objects in their hands. By aligning the grip span of the device with the average grip span of the target user population, the design can ensure a secure and comfortable grip for users.

Appendix F – *User Evaluation*

Entire Product Experience - Evaluation tool 1

Task 1: To evaluate the overall product system experience, Prototype 1 was used. This choice was made because Prototype 1 closely resembled the existing test and provided a consistent starting point for assessment. Prototype 1 was kept constant to maintain continuity and enable a comprehensive evaluation of the entire SureSign product system. The evaluation focused on the overall system experience rather than specific details of individual prototype views. Specific impressions of the prototype were examined at the usability actions level.

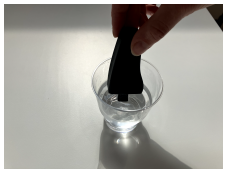
Collection of urine in vessel

Insertion of wick

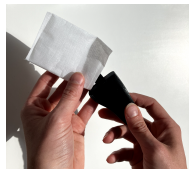
Wick dipping in urine

Removal of wick from test

Removal of Cap to uncover sensor



Washing of sensor in lukewarm water



Pat-drying sensor

In the tasks, the participants were given a smart phone to be able to access the application. There was an environment simulation created in the form of a washroom. The participants were encouraged to select a path in the role-play simulation, to either choose the trying to conceive option or trying not to conceive. This only influenced the result of their test.

To reiterate here the scenario set up was based around toilets prevalent in the wester context, where it is an assumption that users have a toilet in the privacy of their own home.

Entire Product Experience - Evaluation tool 1

The 26 item scale provided to the participants to rate the entire product experience on:

	1	2	3	4	5	6	7		
annoying	○	○	○	○	○	○	○	enjoyable	1
not understandable	○	○	○	○	○	○	○	understandable	2
creative	○	○	○	○	○	○	○	dull	3
easy to learn	○	○	○	○	○	○	○	difficult to learn	4
valuable	○	○	○	○	○	○	○	inferior	5
boring	○	○	○	○	○	○	○	exciting	6
not interesting	○	○	○	○	○	○	○	interesting	7
unpredictable	○	○	○	○	○	○	○	predictable	8
fast	○	○	○	○	○	○	○	slow	9
inventive	○	○	○	○	○	○	○	conventional	10
obstructive	○	○	○	○	○	○	○	supportive	11
good	○	○	○	○	○	○	○	bad	12
complicated	○	○	○	○	○	○	○	easy	13
unlikable	○	○	○	○	○	○	○	pleasing	14
usual	○	○	○	○	○	○	○	leading edge	15
unpleasant	○	○	○	○	○	○	○	pleasant	16
secure	○	○	○	○	○	○	○	not secure	17
motivating	○	○	○	○	○	○	○	demotivating	18
meets expectations	○	○	○	○	○	○	○	does not meet expectations	19
inefficient	○	○	○	○	○	○	○	efficient	20
clear	○	○	○	○	○	○	○	confusing	21
impractical	○	○	○	○	○	○	○	practical	22
organized	○	○	○	○	○	○	○	cluttered	23
attractive	○	○	○	○	○	○	○	unattractive	24
friendly	○	○	○	○	○	○	○	unfriendly	25
conservative	○	○	○	○	○	○	○	innovative	26

6 scale subdivision:
Attractiveness: This scale gauges users' overall impression of the product, assessing whether they find it appealing or unappealing.

Perspicuity: This scale evaluates the ease with which users can become familiar with the product and learn how to use it effectively.

Efficiency: This scale assesses the extent to which users can accomplish their tasks without unnecessary effort.

Dependability: This scale focuses on users' sense of control during their interaction with the product.

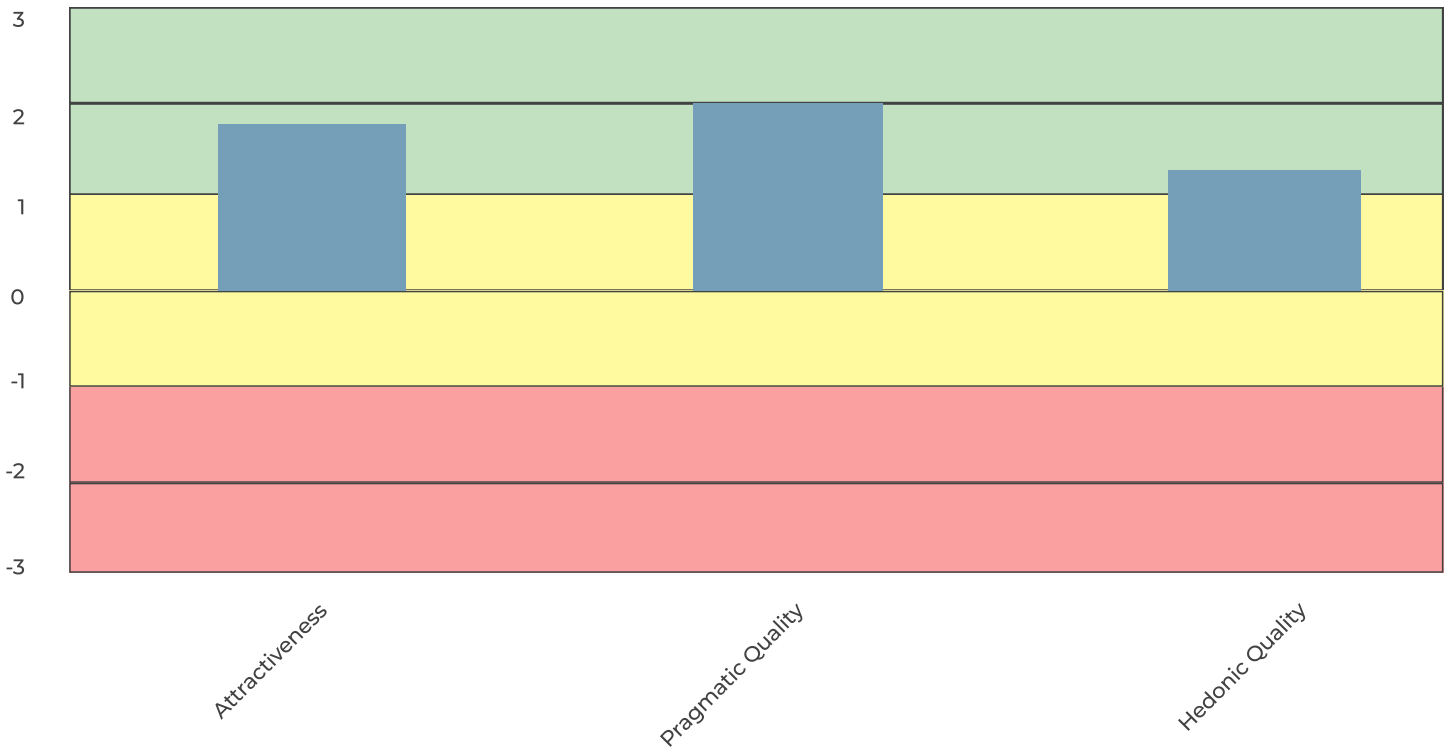
Stimulation: This scale measures whether users find the product exciting and motivating to use.

Novelty: This scale examines the level of innovation and creativity perceived by users in the product, as well as its ability to capture their interest.

Entire Product Experience - Evaluation tool 1

Further division:

Among these scales, Attractiveness represents a pure valence dimension. Perspicuity, Efficiency, and Dependability are pragmatic quality aspects tied to goal-directed usability, while Stimulation and Novelty address hedonic quality aspects not necessarily tied to specific goals.



The Aesthetic Pleasure in Design Scale - Evaluation tool 2

The scale The Aesthetic Pleasure in Design consists of 3 overarching factors that complement each other.

Questionnaire 2 - Prototype 1/2/3

The following questions are related to the physical form on the product

1. Aesthetic appreciation

This product form is pleasing to see	*Fully disagree*	◯	◯	◯	◯	◯	◯	◯	*Fully agree*
This product form has an attractive design.	*Fully disagree*	◯	◯	◯	◯	◯	◯	◯	*Fully agree*

2. Unity and variety

The elements (e.g. parts) of this product look unified.	*Fully disagree*	◯	◯	◯	◯	◯	◯	◯	*Fully agree*
The elements (e.g. parts) of this product look coherent.	*Fully disagree*	◯	◯	◯	◯	◯	◯	◯	*Fully agree*

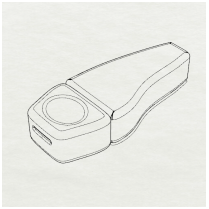
3. Familiarity vs Novelty

The design is typical for this kind of product	*Fully disagree*	◯	◯	◯	◯	◯	◯	◯	*Fully agree*
This is a standard design for this type of product.	*Fully disagree*	◯	◯	◯	◯	◯	◯	◯	*Fully agree*

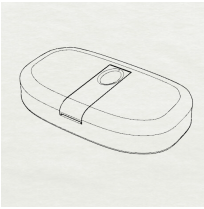
Overall Questionnaire - All Prototypes

The following questions are related to the physical form on the product and the entire product system experience

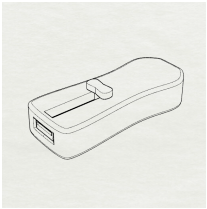
1. Among the three prototypes presented, which physical form do you prefer the most regardless of the the experience?



◯ *Prototype 1*



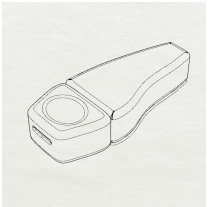
◯ *Prototype 2*



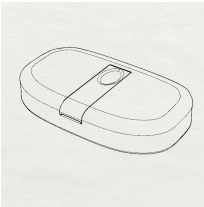
◯ *Prototype 3*

In a short answer, why?

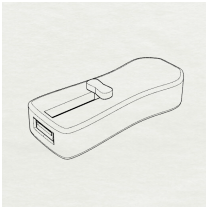
2. Among the three prototypes presented, which usibility action do you prefer the most regardless of the the experience or form?



◯ *Prototype 1*



◯ *Prototype 2*



◯ *Prototype 3*

In a short answer, why?

Appendix G – *Rules and Regulations in medical devices*

MDR Developments

The new list of requirements is as follows:

1. New Requirements: Additions and Changes
    a. Continuity of existing requirements and introduction of new requirements under the IVDR.
2. Risk Classification: Impact on IVD Devices and Notified Bodies
    a. Changes in risk classification categories (Classes A, B, C, and D) and their implications.
    b. Involvement of Notified Bodies in conformity assessment for Classes B, C, and D devices.
3. Emphasis on Life-Cycle Management and Continuous Evaluation
    a. Increased focus on life-cycle management and continuous evaluation of IVD devices under the IVDR.
4. Unique Device Identifiers (UDIs) for Device Identification
    a. Implementation of a UDI system to enhance device identification and traceability.
    b. Composition of UDIs with device identifiers (UDI-DI) and production identifiers (UDI-PI)
5. Post-Market Performance Follow-Up: Clinical Evidence and Performance Evaluation.
    a. Introduction of post-market performance follow-up for updating performance evaluation throughout device life cycle.

Packaging requirements - Ministerie van Volksgezondheid, Welzijn en Sport

1. Labeling and Instructions: Every medical device and in-vitro diagnostic device (IVD) must have clear labeling, user instructions, and a display where applicable. This ensures identification, safe usage, and proper handling.
2. Adapted Information: The information on labels and instructions should match the knowledge and training of users. It must also be available on the manufacturer's website.
3. Use of Symbols: Manufacturers can use internationally recognized symbols to provide information, making it accessible even for users with limited language skills.
4. Labelling Requirement: Information on labels must be indelible, clear, and legible. If not possible on the device, it can be on packaging.
5. Manufacturer's Address: The manufacturer's physical address must be on the label. European authorized representatives' details are also required if applicable.
6. Instructions for Use: Medical devices generally require instructions for use unless they are in specific classes or safe without them. Misleading users about device performance is prohibited.

Packaging requirements

6. Content of Instructions: Specific items that must be included in instructions for use are defined in regulations.
7. Format of Instructions: Instructions for use can be electronic but must meet certain conditions.
8. Language Requirements: In the Netherlands, labels and instructions should be in Dutch. However, products for professional users can have English labels and instructions.
9. Professional User Consideration: Manufacturers supplying to professional users in English should ensure users have sufficient language proficiency.
10. Post-Market Surveillance: Manufacturers must monitor that professional users have the required language proficiency using post-market surveillance.

Appendix H – *Phases of implementation*

Phase 1: MVP(S) – Minimum Viable Product (System)

A significant emphasis is placed on Minimum Viable Products (MVPs), which are products designed with the essential features required to gather validated insights about the product. MVPs hold great significance, not only within a startup team but also for external parties like potential users, investors, and mentors (Duc & Abrahamsson, 2016). At the stage which Pharmista is at, this is a necessary requirement. Having the validation for a novel product of this nature becomes a necessity to allow the gradual success of the whole product system.

Device:
For the MVP(S) of this system the integral part remains the testing unit. With its current functionalities designed, it is eminent to keep intact to gage the correct response from its intended and unintended user.

Application:
The application with its current design goes beyond what are users expectations. Hence having a simpler form of communication between the test device and the phone can be brought to just a result window. This means using ones mobile only as an interpretation screen, limiting its functions of a step by step guide, but only providing instructions in a compact PDF, which is accessible through the phone.

Packaging:
With the stage of the release for this product system, it is not a necessity to consider highly sustainable options for the packaging of the device. It can be made of packaging cardboard to allows for its eventual recyclable ability.

Circularity stage:
The sustainability at this stage only remains in having the test perform 10 times (a goal intended to be met by Pharmista). Even though this mean that this product might become redundant after 10 uses, it is necessary to allow the product system to be at this stage for user acceptance. This is because when it comes to user acceptance, one cannot only rely on environmental reasons, but methods like cost saving (by having only essential features) and maintain a competitive advantage (Building Sustainability Into Medical Devices, n.d.) of being multiuse.

Phase 2: Fully functioning product system

A significant emphasis is placed on Minimum Viable Products (MVPs), which are products designed with the essential features required to gather validated insights about the product. MVPs hold great significance, not only within a startup team but also for external parties like potential users, investors, and mentors (Duc & Abrahamsson, 2016). At the stage which Pharmista is at, this is a necessary requirement. Having the validation for a novel product of this nature becomes a necessity to allow the gradual success of the whole product system.

Device:
For phase 2, with having the device at its full functionality, there needs to be a transition towards modularity, this refers to having the ability of changing parts (like the sensor) to prolong the use of a single device. Additionally with the help of post market surveillance (an important requirements for medical devices as stated previously), additional functionality changes can also be adapted to.

Application:
With the device form having its full function, this stage can concentrate on providing functionality beyond what the user expects. This refers to having an application platform which guides the users through the test taking process. It would additionally gain its monitoring and tracking features, especially tracking features prevalent to the target user (pregnancy inception journey – treatment schedules, appointments). Additionally, the concept of having this application be a shared experience can be explored. This it to cater the positives of involving partners in this test taking process.

Packaging:
At this phase a choice can be made to transition the packaging to also complement the life span of the product system this means the packaging can transition to accommodate itself to being friendly towards the idea of storing it. Packaging choices of tin can be considered due to its long term use and reuse capabilities.

Circularity stage:
This stage the device needs to be in a state of modularity. This mean that with the phase 1 set up, the test is being taken only 10 times. From research in this project, it is evident that there is need for more testing for the target audience. This means, utilising modularity of changing parts of the device to increase lifespan is a definite need. This means, the product form must be redesigned to allow the changing of the sensor after its 10 uses. It will allow the products lifespan to drastically increase.

Phase 3: New technological possibilities (Product Service system)

A significant emphasis is placed on Minimum Viable Products (MVPs), which are products designed with the essential features required to gather validated insights about the product. MVPs hold great significance, not only within a startup team but also for external parties like potential users, investors, and mentors (Duc & Abrahamsson, 2016). At the stage which Pharmista is at, this is a necessary requirement. Having the validation for a novel product of this nature becomes a necessity to allow the gradual success of the whole product system.

Device:
For phase 3, in order to keep the product system in relevance, it would have to adapt itself to what the current market competitors already offer. This refers, to adapting to the changing landscape of pregnancy detection. With the current devices, one can have the ability to know the gestation period of a positive pregnancy, but it is limited to a range and not specific unitary measurements. This means there is currently a innovation gap in the certainty of unitary measurements of hCG. This can hence be a moment to explore new technological advancement with urine hCG measurements or diversify towards different hCG indicators like blood.

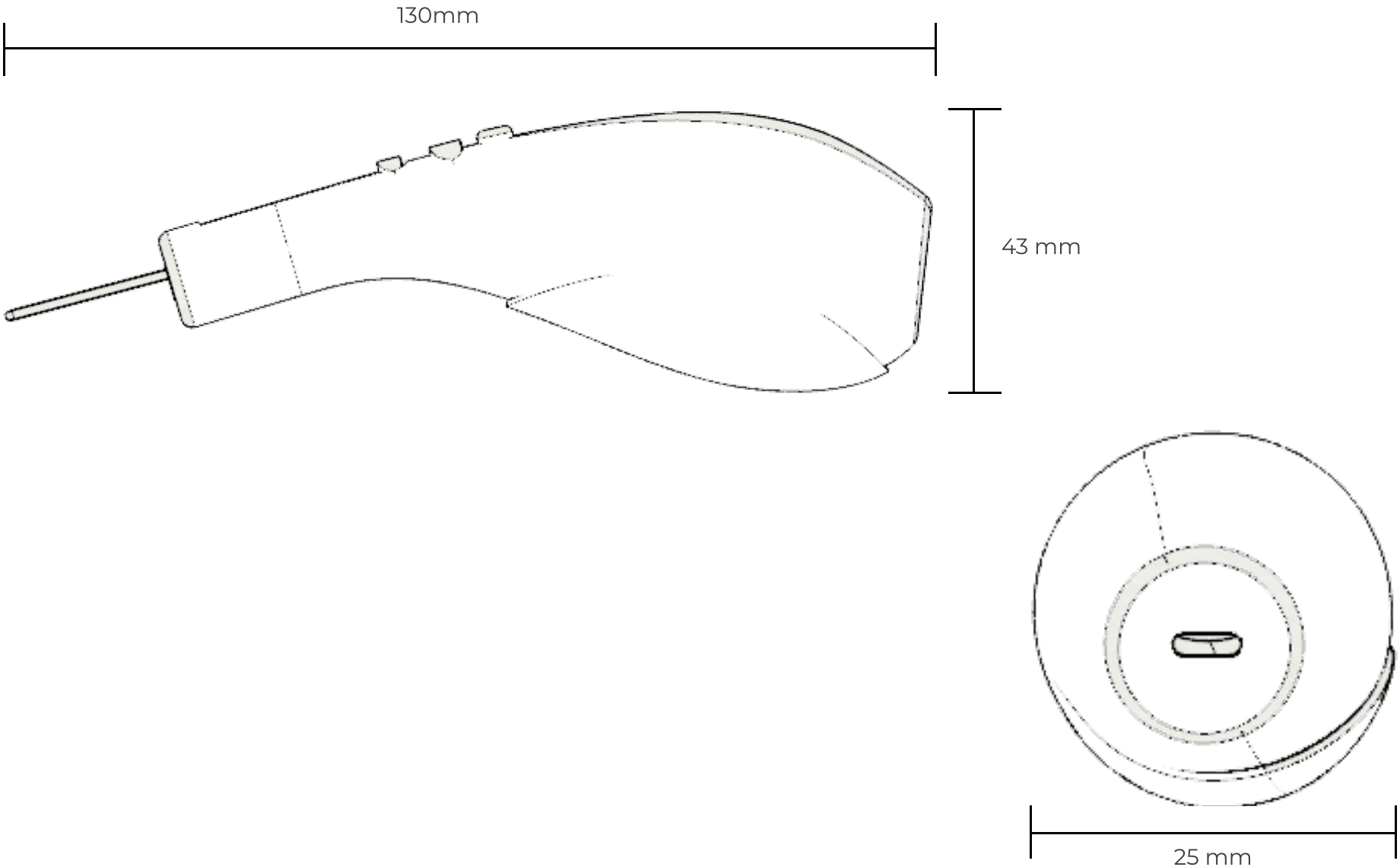
The advantage of knowing the unitary hCG measurements can be beneficial to expanding the value to not only the intended users, but it can introduce a new set of users in the context of a hospital or the gynaecologists office.

Application:
With the device having additional functionality and a chance to diversify its target group of use, it becomes important that the application supports this relay of information beyond. This translates to diverging into practices of remote patient monitoring. In this case the application can have the advantage of decreasing the need for users in having to go to hospital facilities for testing progress of their pregnancy.

Packaging:
With having new functionalities the packaging would require adaptation to the new needs, which can also translate to packaging solutions for precise testing needs. This will have to be further explored.

Circularity stage:
This stage the device needs to also consider its end-of-life disposal. This means, there needs to be a strategy in line with having the testing kit as a product service system. This will entail a full circular system where users have the opportunity to also return their testing kit for it to eventually enter back the market for a new user.

Appendix I – *Device Specifications*



Appendix J - Project Brief

TU Delft

Procedural Checks - IDE Master Graduation

APPROVAL PROJECT BRIEF
To be filled in by the chair of the supervisory team.

chair Dr. Ir. Marijke Dekker date 9 - 3 - 2023 signature

CHECK STUDY PROGRESS
To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair.
The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 36 EC
Of which, taking the conditional requirements into account, can be part of the exam programme 30 EC
List of electives obtained before the third semester without approval of the BoE

YES all 1st year master courses passed
NO missing 1st year master courses are:

name Robin den Braber date 20 - 03 - 2023 signature

FORMAL APPROVAL GRADUATION PROJECT
To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **.
Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: APPROVED NOT APPROVED
Procedure: APPROVED NOT APPROVED

- also approved for Medisign
- the buffer period must be removed from the planning (received separately)

comments

name Monique von Morgen date 04 - 04 - 2023 signature

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30 Page 2 of 7
Initials & Name BD Dhar Student number 5503124
Title of Project Enhancing the Experience of a Pregnancy Detection Device

Personal Project Brief - IDE Master Graduation

TU Delft

Enhancing the Experience of a Pregnancy Detection Device — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 21 - 02 - 2023 — 21 - 07 - 2023 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Pharmista Technologies is a company focused on making a new pregnancy detection device which differs from the current available devices in the market. They intend to do so by making it reusable. The aim is to provide customers with a “thermometer” for pregnancy testing, being easy to interpret, hygienic to use and 99% accurate at the day of expected menstruation. This is meant to increase convenience-levels, reduce the users spendings on their reproductive health, minimise the risk of mis-interpreting the results, and lastly, be beneficial for the environment.

Most at-home pregnancy testing devices conclude a positive result by tracing 'human chorionic gonadotropin' (hCG), a hormone that is present in urine during pregnancy. The device typically involves a plastic stick with a test strip that is designed to react to hCG in urine for detection. When this urine contact takes place, the device can determine if the hCG hormone is present. This contact in the current devices only takes place once and the test cannot be retaken on the same device. This makes the device single use.

Pharmista technologies is now developing the technology which works on the same principle of detecting hCG in the urine but is adding a factor of re-usability to this, by developing a sensor that is multi-use, so that the test can take place multiple times. Once successfully developed, they intend to employ the same technology onto other diagnostic areas where re-usability would be advantageous.

There are different contexts in which users have the need to use a at-home pregnancy detection device. Users range from women who are sexually active and need to check whether their missed menstruation cycle is an indication of a pregnancy or couples who are struggling with conception and are in the process of receiving fertility treatments. While in treatment women are generally asked to take pregnancy tests after each menstrual cycle. When in the waiting phase, women tend to use more than one test in anticipation of a successful outcome. These practices cause a big environmental burden and high levels of income spent on women’s reproductive health. Furthermore, to be considered here is testing for pregnancy detection now involves partners of the women taking these tests. Since this is a very intimate process, the action of taking the test has the potential of enhanced experience for both users.

The limitations of this project include the sensitivity of the subject matter, as pregnancy testing can be an emotionally charged experience, and the design needs to be empathetic and considerate. Cultural context is an important aspect to consider, as beliefs and attitudes towards pregnancy and contraception may vary across different societies. Finally, keeping these limitations in mind while working on this project will be vital for its sucessfull outcome. Involving different stakeholders and creating a safe space for user participation would be a key element in tackling these limitation.

space available for images / figures on next page

Personal Project Brief - IDE Master Graduation

TU Delft

introduction (continued): space for images

image / figure 1: Patent design of Pharmista Technology current reusable pregnancy stick

image / figure 2: Potential areas of concentration for the graduation scope (describe in the assignment part)

Personal Project Brief - IDE Master Graduation

TU Delft

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The current options available in the market (specifically concentrating on Sweden and The Netherlands) are expensive or poor in quality tests, aside from being single use. While these tests are considered reliable, they often fall short in terms of their ergonomics and ease of use. For example, the size and awkward shape of the device can make them challenging to handle, and the user must be careful not to let urine reach other areas of the stick, which could compromise the accuracy of the results.
Additionally, unclear and ambiguous result displays on some tests can also make interpretation difficult, leading to a sub par user experience, by causing undue stress and anxiety for the users who use them.

Since the invention of the at home detection device has not been reinvented for 30 years, there are potentially interesting scenarios that the current devices do not cater to. The opportunity areas lie in not only the new technology of making the test reusable (in development by Pharmista Technologies) but also in re-imagining and inventing the interaction of using this reusable device in the described contexts.

Innovative design can improve the usability of the device, minimize human error, and alleviate stress and anxiety among users. This will result in more accurate and easily comprehensible results, boosting women's confidence and satisfaction with the device. Ultimately, the goal is to create a user-friendly device that provides women with an enhanced experience and enable them to make informed decisions with ease.

Lastly, users investing in this device would heavily rely on the device being perceived as trustworthy. Even if the new product is technically sound and accurate, its success will depend on user acceptance. The product must address the needs and desires of its intended audience and provide a better experience than

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

I will help the company to develop an improved at-home pregnancy detection device for couples who are trying to conceive and for sexually active women who do not use contraception, by improving the user experience and making the testing process more intuitive, and user-friendly. This will be done while keeping the specifications of the new technology(the reusable sensor) being developed by Pharmista Technologies

For developing the 'proof of concept' version of this device, the areas that need to be developed first are elaborated on further:

1. Refillable paper strips: As mentioned earlier, to detect pregnancy urine must come in contact with the sensor with the channel of a plastic stick which contains a paper. Since the intent is to make the sensor detect multiple times, the paper needs to be refilled and changed multiple times.

2. Reusable sensor chip: To regenerate/revitalise the sensor chip there needs to be an added step of cleaning the device without damaging the sensor chip. This added step needs to be accommodated into the new design.

3. Display: When the results are ready, in current devices, the reading are either hard to interpret (in case of cheap tests) or are easier to understand (by adding a display which adds to the cost of the device). An area to explore is to re-imagine how the results can be displayed to the user in the most efficient way while making it easy to interpret and without causing stress.

These have been selected since I intend to focus on the user interaction with the embodiment while simultaneously using these outcomes to dictate the design direction for the overall casing of the device

Initials & Name BD Dhar Student number 5503124

Title of Project Enhancing the Experience of a Pregnancy Detection Device

Personal Project Brief - IDE Master Graduation

TU Delft

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 21 - 2 - 2023 21 - 7 - 2023 end date

The project is divided into 4 phases

1. Discover: This phase consists of context research and gaining maximum insights from user and expert interview to help understand problems faced by current users. This phase will map out new scenarios and contexts pregnancy tests are used in to understand user needs from multiple perspective.

2. Define: This phase will start with redefining the problem scope after the new insights, and a list of requirements would be set up for how the re-imagined testing and detection takes place. With these requirements set up, the project will transition to ideation and concept development for the new and existing interactions which will dictate the overall product development.

3. Develop: This phase vastly involves implementation of the new design decisions made in the first 2 phases and will concentrate on prototyping for those interactions. Next, this phase involves user testing of the product development results. After user testing there will be further iteration done on the development of the device.

4. Deliver: This last phase of the project will concentrate on how all the new interactions accommodate as one holistic device. It will consist of prototyping the outer case of the re-imagined device. There will be concept renders made to imagine the aesthetics of the product.
Lastly, there will be future directions set up to see how this project transitions to the next stage of product development for the market.

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MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

The motivation behind this project is to contribute to the field of medical technology and make a meaningful impact on users' life by designing and developing an improved pregnancy detection device. This project aligns with my personal interests in healthcare for women and human centered design. The acquired skills from my IPD masters, while concentrating in the Medesign field made me look for a project where I could use most of my skills while challenging myself in delving into skills, I require more work on.

This project will allow me to develop my skills in user research, prototyping, and usability testing to ensure that the final product meets the needs and expectations of the target users. Additionally, this project will enable me to deepen my knowledge and skills in medical technology and electronics, which are critical areas of knowledge for my studies before I complete this master's program.

Through this project I intend to:

1. Gain a deeper understanding of the challenges faced by women and couples who are struggling to conceive, and the importance of accurate and reliable pregnancy detection devices.

2. To enhance my skills in 3D modeling and rapid prototyping using advanced software tools and techniques, such as CAD and 3D printing.

3. To develop my knowledge and skills in human factors engineering, such as ergonomics and usability, to ensure that the final product is user-friendly and accessible to the new contexts mentioned above.

Lastly, one of my biggest motivations is to try and cater to the women as users who in a lot of cases are highly ignored and not fully accounted for since female-health is a vastly under invested area.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Initials & Name BD Dhar Student number 5503124

Title of Project Enhancing the Experience of a Pregnancy Detection Device