Master thesis | Msc. Integrated Product Design
Bhavika Dhar | August 2023

Enhancing the Experience of Pregnancy Detection

- Design and Embodiment of a reusable pregnancy testing device

Enhancing the Experience of Pregnancy Detection

Design and Embodiment of a reusable pregnancy testing device

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Master Thesis
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in collaboration with Pharmista Technologies

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Abbreviations

hCG - Human chorionic gonadotropin

HPT - Home Pregnancy Test

MDR - Medical Device Rules and Regulations

IVD - In-vitro Devices

IVDR - In-vitro Device Regulations

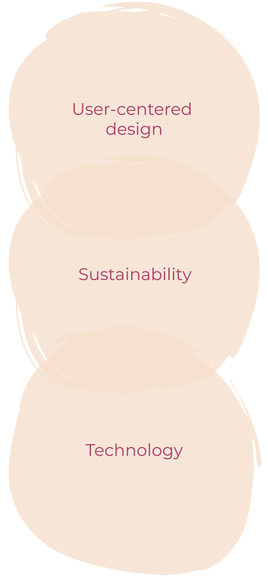


Fig.1 : Expertise Areas of the project

Abstract

Pregnancy tests are the most used diagnostic test in the world where the market is expected to be worth $1.5 Billion. However, since its introduction to the market in 1976, it has experienced limited innovation. Despite its importance in providing crucial information about a significant life event, women continue to rely on outdated and limited options. The existing tests are often expensive or of poor quality, and their single-use nature fails to address the diverse need for sustainable practices. This gap in the market arises from a reluctance among established players to disrupt their stable revenue streams and a lack of investment in female health.
This master thesis intends to present a comprehensive investigation into enhancing the user experience of pregnancy detection and attempting to enhance its overall experience for its intended and unintended users. The project aims to address the limitations of existing single-use pregnancy tests and present an alternative option which would fit the current and future scenarios.
Given the costs associated with essential feminine hygiene products, such as sanitary pads, tampons, and other menstrual care items, as well as fertility products including contraceptives and potential expenses related to fertility treatments, women face a considerable financial burden that accumulates over time.
SureSign aims to disrupt the testing experience for women, providing them with a clear and user-friendly solution while trying to minimize the financial barrier associated with repeated testing. By offering an affordable and inclusive testing option, the product intends to empower women to make informed decisions about their reproductive journey. It envisions a future where women can test multiple times without worrying about the financial implications and sustainability impact, enabling them to confidently navigate their next steps based on accurate and reliable results.

The thesis is carried out in collaboration with Pharmista Technologies. Their role in this master thesis extends to providing initial market insights and to provide expertise in the technology behind potentially making the testing process sustainable - by making it reusable. They provide their existing knowledge about a patent sensor they develop, which in theory allows one to take multiple tests from a singular device. Their goal is to make this action of reusability take place at least 10 times.
The project is divided in two main phases: the research phase of the current scenario and subsequently a development phase for the future scenario. The research phase involves conducting user interviews to gain insights into user needs and challenges related to pregnancy tests. This phase also establishes if the requirement of reusable test actually exists. The project then delves into the embodiment phase which involves form factors related to the overall product experience. Drawing from the gathered insights, a user feedback oriented design process is employed to develop prototypes of the new pregnancy test, considering factors such as usability, accuracy, and ergonomics. The prototypes are evaluated through user testing, allowing for continuous loops of refinement.

The outcome of this master's thesis aims to not only push the field of pregnancy detection forward but also forge a significant stride towards sustainability within the femtech industry. This will be realized through the presentation of fresh perspectives aimed at enhancing the user experience, need for accuracy, and dependability of these devices. The findings will provide valuable recommendations for design refinements and the eventual market launch of this product for Pharmista. This holds the promise of uplifting the experiences of couples navigating their fertility path and women embracing sustainable approaches throughout their reproductive journey.

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1. Introduction

This chapter serves as an introduction to the project, outlining its objectives and structure. It establishes the chosen methodology and project outline. Key points are highlighted to underscore the project's significance, providing a clear overview of the approach that will be followed throughout the report.

Since its introduction in 1976, pregnancy detection has overtime undergone significant advancements. The first home pregnancy test marked a milestone in this field. Today, home pregnancy tests have become the preferred choice for many individuals specially in the western part of the world, serving as a widely used diagnostic tool in the comfort of one's home. These tests operate by detecting the presence of human chorionic gonadotropin (hCG) hormone, which is an ideal marker for pregnancy. The hCG hormone exhibits a rapid and consistent increase during early pregnancy, enabling its detection in urine samples. This characteristic makes home pregnancy tests highly efficient in confirming pregnancy.

Pregnancy detection is a crucial step in a women's reproductive journey. The estimated size of the global female fertility and pregnancy rapid test market was USD 1,692.14 million in 2021 and is projected to increase to USD 2,629.33 million by 2027 (Markets, 2022). The current at-home testing process for pregnancy often involves multiple tests, which not only contributes to a financial burden but also contributes to excessive waste. This issue is further exacerbated by the rising number of women undergoing fertility treatments such as in-vitro fertilization (IVF), which leads to an increased demand for pregnancy tests and subsequently higher waste production. The need for a more sustainable and environmentally friendly approach to pregnancy testing is becoming increasingly apparent in light of these circumstances.

Home pregnancy tests have emerged as the predominant at home diagnostic tool. While the focus is often on women, it is essential to acknowledge the role of partners. In cases where pregnancy is not intended, in the current scenario, partner involvement is not very high. By engaging partners in the testing process fosters a stronger bond and also instils a sense of shared responsibility. Conversely, for couples actively trying to conceive, partner involvement becomes even more vital. It not only allows partners to actively participate in the path to parenthood but also cultivates emotional support, facilitates shared decision-making, and strengthens the bond between them. Recognizing and embracing the role of partners in the context of home pregnancy testing is essential for comprehensive and holistic care during this significant phase of reproductive health.

The current experience of taking a pregnancy test can often be stressful and confusing for both women and their partners. Women commonly face challenges such as uncertainty regarding test accuracy, feelings of embarrassment when purchasing tests, and difficulties in interpreting the results. These uncertainties cause the same implication on partners and adds further complexity. These challenges can result in delayed detection of pregnancy, unnecessary anxiety, and prolonged decision-making, significantly impacting the overall reproductive journey of women. Therefore, there is a pressing need to address these issues and provide a more seamless and supportive experience for women and their partners during the pregnancy testing phase.

1.1 Project Aim

The collaborative objective of this project, conducted in partnership with Pharmista Technologies, is to improve the process of pregnancy detection by addressing current challenges and concerns experienced by women and their partners. Due to the nature of the collaboration, the area of focus is the Northern Europe context(Netherlands and Sweden). From the project's outset, Pharmista recognized the necessity for a reusable test. Consequently, the project's goal became focusing on validating this requirement and subsequently capitalizing on the medical technology expertise of Pharmista Technologies. This in turn allows the project outcome to become about improving the clarity and usability of pregnancy tests, reducing stress, confusion, and delays in taking appropriate actions. Through in-depth user research and innovative design approaches, the project explores issues such as testing steps, purchasing process, result interpretation, and partner involvement to propose solutions that enhance the overall experience of taking a pregnancy test at home. Social implications will be considered to ensure inclusive solutions for a diverse range of users. Throughout the project, refinement will be based on user feedback and specific project objectives, ultimately aiming to develop a user-friendly, reliable, and empowering pregnancy testing experience that provides greater confidence and support to women and their partners on their reproductive journey. Lastly the project also intends to address the needs of in-vitro medical devices requirements, without which the release of such a solution will not be a viable option.

1.2 Project Structure

To achieve the project's aim, three key aspects—People, Technology, and Business (fig 2) — will be integral to the design-driven approach. With a strong focus on human-centred design, the primary aspect involves conducting research and gathering insights from women and partners who have experience with pregnancy tests. This exploration will identify areas for improvement and opportunities to enhance the testing experience, hence establishing *desirability*. The development process will also include user validation to make informed design decisions and ensure the best possible outcomes within the scope of this graduation project.

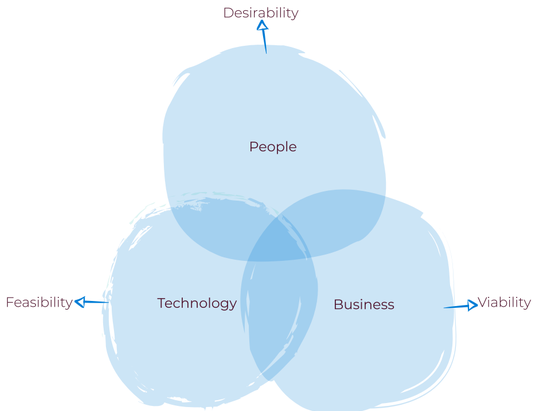


Fig.2 : 3 pillars of design

The second aspect involves leveraging *feasible* technology by including the expertise and capabilities provided by Pharmista, to create a reimagined pregnancy test that caters to the diverse needs and preferences of users. Finally, the project will address the business aspects, encompassing production, distribution, and a rollout plan to ensure *viability* and successful adoption of a new product by a diverse audience.

By focusing on these three pillars, the project seeks to reduce both the financial and environmental burden caused by traditional testing methods, paving the way for a more sustainable approach to pregnancy detection.

1.3 Methods

To arrive to the initial insights/problem scope, a 'future context' was explored in the course structure of Vision in Product Design (ViP) method by Hekkert and Van Dijk (2016). The ViP course helped explore the domain of 'Healthcare for Women'. Exploring this domain helped identify the current problem. This domain highlighted context factors like the gender health gap that is prevalent, which pointed towards low level of innovation in femtech industry. Within this industry, it is noticeable(like in the case of pregnancy test), the subpar and low level of innovation even though there is a persistent need for it. This limited innovation was evidenced in unsustainable products for women which brought to light the vast market of diagnostics and fertility for women (fig 3).

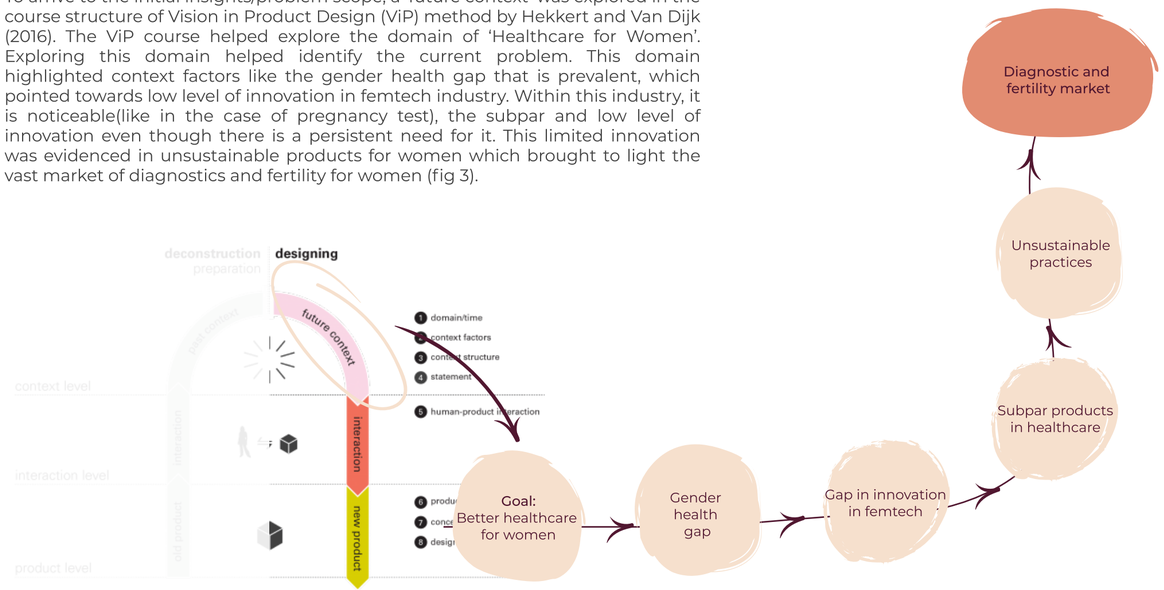


Fig.3: Conceptualisation of project scope

For this project, the two phases of the double diamond framework (fig 4) will be referred to as the Research Phase and the Development Phase.

The Research Phase begins with the divergence stage. The deconstruction process involved evaluating the existing product (an at-home pregnancy test) through literature review and assessing its interactions at the context level. Qualitative research methods such as user interviews, surveys, and journey mapping were employed to understand the current context effectively. Simultaneously, the preconditions set up by Pharmista were worked with. From this contextual setup, the convergence stage in the Research Phase was implemented. The problem definition was derived by evaluating which problem could have the most significant impact on the future scenario. Furthermore, the implementation and product requirements specified by Pharmista were taken into consideration to establish the boundaries for the future scenario.

In the Development, the divergence stage focuses on ideation, conceptualization, and exploring complementary technologies. Possible future scenarios were explored during this phase. The convergence stage aims to transform abstract future concepts into feasible and viable solutions. It involves refining specific interactions and usability aspects at the product level. Additionally, detailed requirements for the first phase of implementation for Pharmista's proof-of-concept device are established, ensuring alignment with their technology suggestions and laying the groundwork for compliance with the rules and regulations (elaborated on further in the report) governing in-vitro devices.

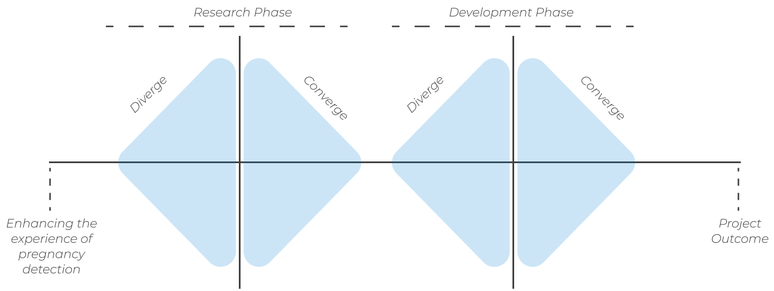


Fig.4: The double diamond approach

2. Research Phase

This chapter examines the pertinent factors that bear relevance, either directly or indirectly, to the project scope. It highlights critical insights acquired from desk research and delves further into the user context. This deeper exploration provides an vantage point for identifying prime areas of opportunity to enhance the overall user experience.

2.1 Discover

2.1.1 History of Pregnancy Detection

For many years, medical professionals have employed urine tests to confirm pregnancies. Dating back to 1350 B.C. Egyptians had women urinate on a blend of wheat and barley seeds, thinking that growing seedlings would signify pregnancy (Valenzuela et al., 2011).

In the 19th century, scientists had not yet had a complete understanding of pregnancy and could not develop a reliable test especially for at home testing. Women who were sexually active and suspected pregnancy relied on careful observation of their physical symptoms, such as morning sickness, to diagnose pregnancy (Pregnancy Test - hCG Research at NIH - Office of NIH History and Stetten Museum, n.d.).

Research on human reproduction intensified in the early twentieth century. Scientists made significant discoveries, such as the role of hormones in pregnancy and the detection of the hormone human chorionic gonadotropin (hCG) in urine. However, early pregnancy tests were still unreliable and only available in medical facilities (Pregnancy Test - hCG Research at NIH - Office of NIH History and Stetten Museum, n.d.).

Over time, the push for at-home pregnancy tests began with availability in Europe and Canada being as early as in the 1970s (fig5). This is when these tests entered a commercialised space and slowly started becoming a tool for women to take charge of their reproductive journey decision making.

Pregnancy tests have been classified as in-vitro diagnostic medical devices (IVDMDs) for several decades. The specific classification and regulations for pregnancy tests vary depending on the country or region. In the United States, for example, pregnancy tests have been regulated by the U.S. Food and Drug Administration (FDA) as IVDMDs since the implementation of the Medical Device Amendments in 1976. Similarly, in the European Union, pregnancy tests have been classified as IVDMDs and have been subject to regulation under the European Union's Directive on in vitro diagnostic medical devices (IVDD) implemented in 1998.

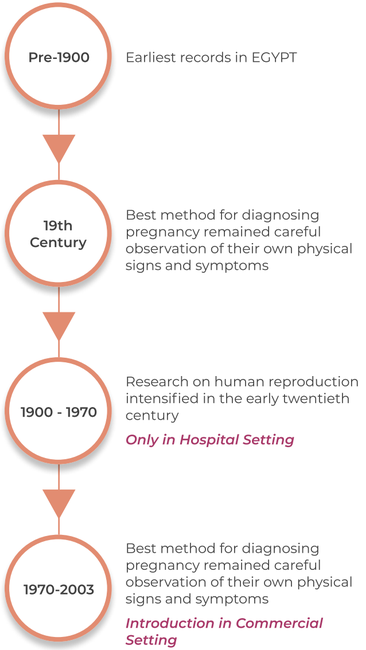


Fig.5: Pregnancy test development timeline

2.1.2 Working principle of at Home Pregnancy Tests (HPTs)

The first commercially available test was introduced in 1976 and used a test strip with antibodies to detect hCG in urine. Human chorionic gonadotropin (hCG) hormone is produced by the placenta after a fertilized egg implants in the uterus (fig6). The hCG level in the blood and urine increases rapidly in the first few weeks of pregnancy, making it an important marker for detecting pregnancy.

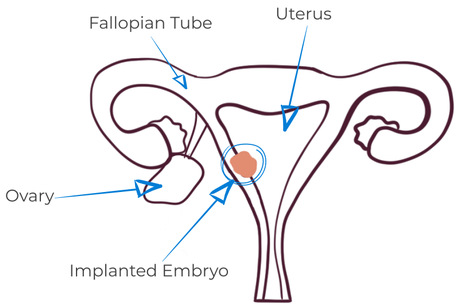


Fig.6: Start of a pregnancy

Although the home pregnancy tests available in the market have undergone refinements to improve their accuracy over time, their underlying principle remains unchanged from the tests developed in the 1970s.

The paper: Self-testing for pregnancy: a systematic review and meta-analysis (Kennedy et al., 2022) discusses the working principle of lateral flow immunoassays (LFIA) (fig 7), which are widely used in pregnancy tests. The LFIA relies on the principle of immunochromatography, where a coloured signal is generated when the target analyte, in this case, human chorionic gonadotropin (hCG), binds to an antibody present on the test strip. The test consists of a sample pad, a conjugate pad, a membrane, and an absorbent pad.

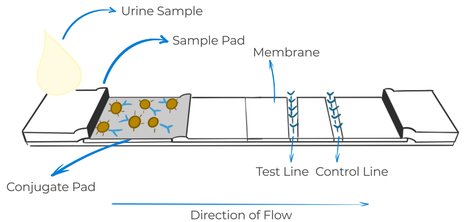


Fig.7: Working of a lateral flow test

In a typical pregnancy test, the sample (urine) is applied to the sample pad, which then flows through the conjugate pad. The conjugate pad contains gold nanoparticles conjugated to anti-hCG antibodies. If hCG is present in the sample, it will bind to the gold nanoparticle-antibody conjugate, forming a complex. This complex will then flow through the nitrocellulose membrane, which contains a capture antibody against hCG.

If hCG is present in the sample, the complex will bind to the capture antibody, resulting in the formation of a coloured line. This line indicates a positive test result. The absorbent pad acts as a wick to draw the liquid through the membrane, and any unbound gold nanoparticle-antibody conjugate will continue to flow through and be captured by a control line. The control line is designed to always produce a positive signal, ensuring the validity of the test.

As pregnancy progresses there is a rise in the hCG hormone. It is important to note that HPTs are not always a reliable indicator of pregnancy. A study by Gnoth & Johnson (2014) revealed that tested 27 home-use pregnancy tests using standard urine samples found that 230 out of 478 positive samples were incorrectly identified as negative by women who were testing them. This was attributed to the women's difficulty in understanding the product instructions and correctly interpreting the test results. Hence in a clinical setting an ultrasound after 5-6 weeks of gestation are much more accurate. Therefore, the hCG tests should be used in conjunction with other diagnostic tools to assess the status of the fetus (American Pregnancy Association, 2022).

2.1.3 Role of Pharmista Technologies

This project intends to reimagine an implementable future scenario of at-home pregnancy testing. This is where Pharmista technologies plays a vital role. A startup out of Sweden, Malmo, Pharmista Technologies has positioned itself as a FemTech company dedicated to revolutionizing the field of reproductive diagnostics. With a strong focus on innovation and cutting-edge technology, Pharmista Technologies aims to empower individuals with accessible and accurate diagnostic solutions (Pharmista Technologies AB, 2023).

Driving factor

At Pharmista Technologies, their mission is to enhance the experience for women by developing an advanced diagnostic device which caters to current contexts. They strive to provide individuals with a convenient, reliable, and user-friendly tool for pregnancy detection (Pharmista Technologies AB, 2023).

Experts in the field of testing

For this project, Pharmista also provides their team of industry experts. Alice Mattsson (CEO- Co founder), Robert Porter (Industry expert - Co founder) Eric Henua (Consumer Behaviour and Usability expert), Radvilė Zubrytė and Börje Sellergren (Malmo University scientists working on the development of the sensor) and Arthur and Nathan Weightman (mechanical engineers) who provide further information vital to different parts of the project, insights of whom are mentioned at different parts of the report.

Patent technology

Pharmista Technologies proposes an option that not only prioritizes sustainability but also opens possibilities for further technological advancements to solve user problems throughout the testing process. This patent technology allows test to become reusable. This is vastly different from the current HPTs where once the test takes place(as described in working of a lateral flow test) the test strip itself displays the result and then cannot be used again. Pharmista introduces a new approach to pregnancy testing that builds upon this traditional concept of detecting the hCG hormone. However, what sets their technology apart is the innovative use of a MIPs sensor. MIPs stands for Molecularly Imprinted Polymers, which are synthetic materials which have unique properties that bind the hormone. This binding property is different from the lateral flow test.

Referring to Fig 8, the MIPs sensor is coated with a dense film of polyacrylamide-based nanoparticles, which allows for the reaction with urine to occur. What makes this sensor vital for this test is that it being coated by multiple layes of these polyacrylamide-based nanoparticles, in theory, washing off of this layer can reset the test. To make this reset occur the Malmo University scientists propose that the sensor be washed in lukewarm water, which will allow a layer of the Molecularly Imprinted Polymers be removed, thus making it reusable.
With this technology ready to be deployed allows the project to advance forward from the perspective of sustainability.

By collaborating with Pharmista Technologies, the project gains the advantage of building upon their expertise and leveraging their technological capabilities to create a more refined and effective solution.

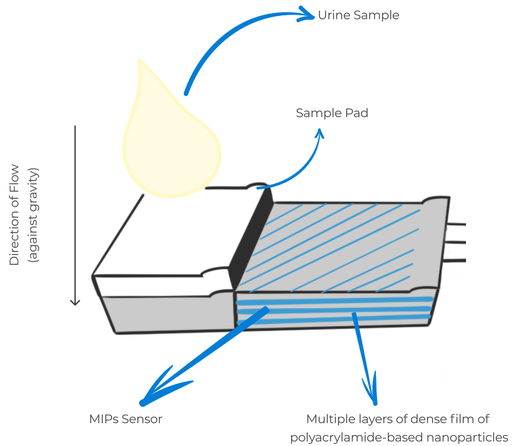


Fig.8: Pharmista test technology

2.1.4 Standardization and guidelines for In-vitro diagnostics

HPTs fall under the category of in-vitro medical devices and follow the in-vitro device regulations (IVDR). In-vitro diagnostic medical devices are tests used on biological samples to determine the status of a person's health (European Commission, n.d.). Devices intended for self-testing are generally categorized as class C. However, there are exceptions for specific devices such as those used for pregnancy detection, fertility testing, cholesterol level determination, glucose detection, erythrocyte detection, leucocyte detection, and bacteria detection in urine. These exceptions fall *under class B classification* which is the case for pregnancy tests (Medical Device Coordination Group (MDCG), 2023).

The IVDR establishes four risk classes based on both patient and public health risk:
Class A - Low patient and public health risk
Class B - Moderate patient risk and/or low public health risk
Class C - High patient risk and/or moderate public health risk
Class D - High patient risk and high public health risk

Devices in Class B are considered to have a moderate level of risk to the patient using the device or to public health. This classification typically includes devices that are invasive but not as complex or risky as those in higher classes. Class B devices may have a direct or indirect impact on the patient's health, and their use could lead to moderate adverse effects if not properly designed, manufactured, or used. In light of the In Vitro Diagnostic Regulation (IVDR), prevailing landscape necessitates that a substantial number of manufacturers will now engage in a conformity assessment facilitated by a Notified Body.

This mandate applies comprehensively to the realm of In Vitro Diagnostic Devices (IVDs), barring only Class A non-sterile devices from this requirement (Explaining IVDR Classification for in Vitro Medical Devices, n.d.).

Requirements of the IVDR
The existing European guidelines, established under the in vitro diagnostic directive of 1998, necessitate manufacturers to conduct their individual risk assessments (Boxer et al., 2019). Nonetheless, these guidelines lack specific performance requirements and have become outdated in light of the evolving medical device industry. To counteract these limitations, the introduction of the in vitro diagnostic regulations (IVDR) in May 2017 seeks to provide more precise and comprehensive directives. The IVDR introduces mandates for robust validation data, encompassing aspects like customer usability, for products such as home pregnancy tests and other in vitro devices. Consequently, these regulations are slated to replace the current directive governing in vitro diagnostic medical devices in Europe. This transition is scheduled over a five-year period, commencing in 2022 (Boxer et al., 2019). As a result of this regulatory transition, there exists a current lack of standardized guidelines to be followed.

2.1.5 Stakeholder Identification

The incorporation of usability and design principles into an outcome relies on meeting the requirements established by diverse stakeholders who play direct or indirect roles in the design process. The degree of demand is influenced by how these stakeholders perceive the value that usability and design contribute to system design. To establish themselves as esteemed and desired collaborators in the design process, usability and design must effectively demonstrate their capacity to deliver value to these stakeholders.

Using an existing matrix (Dul et al., 2012) available for stakeholder analysis one can identify the main stakeholder groups influential to the design and development of this project. Stated below are how each of these stakeholder groups can influence the usability, design and production for a product system

1. ***The system actors:*** refer to the individuals, including employees and users of the product or service, who are directly or indirectly impacted by the system's design and have an influence on its performance.
2. ***The system experts*** consist of professionals such as engineers and psychologists who bring their specific expertise to contribute to the design of the system based on their professional backgrounds.
3. ***The system decision makers*** are the individuals, such as managers, who are responsible for making decisions regarding the system's design, procurement, implementation, and usage.
4. ***The system influencers*** encompass various entities such as media, governments, standardization organizations, regulators, and citizens who have a general interest in the design of work systems and product/service systems and can impact the system through their influence and actions.

By examining the stakeholders(fig 9), their expectations, and the value proposition of usability and design, one can aim to highlight the role and significance of these factors in system design, contributing to a better understanding of their impact on overall system performance.

Users: The primary users(women) of pregnancy tests who directly interact with the product and are impacted by its design and performance.

1. The system actors
a. Partner/Spouses: Individuals who may be indirectly affected by the pregnancy test's design and results.
b. Nurses: In some cases healthcare professionals may administer at home pregnancy tests in a clinical setting to provide patient education, and offer support and guidance during the testing process.
c. User GP: Primary care physicians who play a crucial role in diagnosing pregnancy, interpreting test results, and providing initial advice and care for pregnant individuals.
d. Gynaecologists: Medical professionals specializing in women's reproductive health, including pregnancy, who may be involved in confirming and monitoring pregnancies.
e. Fertility Specialists: Experts who focus on fertility and reproductive issues, providing specialized care for individuals seeking to conceive or undergoing fertility treatments. They may use pregnancy tests as part of their practice.

2. The system experts
a. Medical professionals: Doctors, nurses, and healthcare practitioners who provide expertise and guidance related to pregnancy and reproductive health.
b. Pharmista Tech: Experts in the field of reproductive health and diagnostic technologies who contribute their knowledge to improve the design and accuracy of pregnancy tests.

3. The system decision makers
a. Product Designer(myself): Designer responsible for making decisions about the design and development of the experience of the test.
b. Manufacturers: Companies responsible for production, and distribution of pregnancy tests.
c. Retailers: Organizations or individuals involved in the purchasing, stocking, and selling of pregnancy tests.

4. The system influencers
a. Regulators Bodies: Authorities and organizations responsible for establishing guidelines, regulations, and quality standards for pregnancy tests.
b. Government agencies: Bodies responsible for overseeing healthcare regulations and policies that can impact the design and usage of pregnancy tests.
c. Healthcare organizations: Institutions that provide reproductive health services and may influence the availability and recommendation of specific pregnancy tests.

In summary, these different groups of stakeholders play distinct roles in the design and functioning of the system, with actors being directly or indirectly affected, experts contributing their specialized knowledge, decision makers guiding system-related choices, and influencers shaping the broader context and perception of the system.

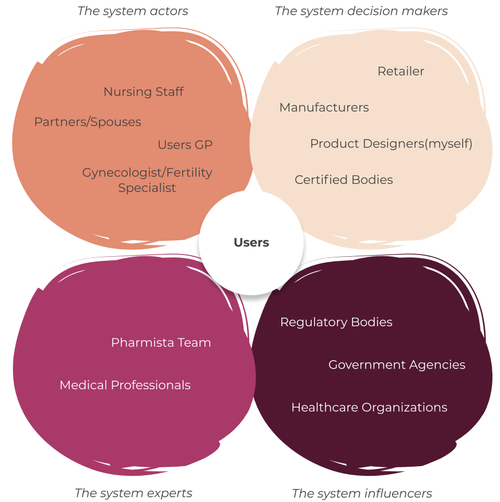


Fig.9: Stakeholder Analysis

2.1.6 Market Analysis

To develop a pregnancy test that is user-friendly and sustainable, it is also crucial to examine all the existing choices available in the market. This analysis aims to provide insights into the current landscape of pregnancy tests, including a breakdown of both new and traditional types of tests. Furthermore, current industry leaders and new innovation taking place in this field is also evaluated.

Types of tests

Europe sells a minimum of 65 million home pregnancy tests (HPTs) annually, which come in different formats such as strips, cassettes, and mid-stream dipsticks (Sturgeon et al., 2021).
These devices come in different format worldwide. Table 1 shows the HPTs commonly available in Europe (Sturgeon et al., 2021).
Further information provides a comprehensive description of these tests are intended to be used by its users.

Device format	*Strip*	*Cassette*	*Mid-stream visual*	*Mid-stream digital*
Mode of specimen collection	Sample collected in a container (usually not supplied with the test)	Sample collected in a container (usually not supplied with the test). A sample pipette is usually provided with the kit for sample application	Sample by holding directly into the urine stream. Alternatively, most mid-stream tests also provide an option for dipping the sampling wick into a collected sample	Sample by holding directly into the urine stream. Alternatively, most mid-stream tests also provide an option for dipping the sampling wick into a collected sample.
Sampling requirements	Strip dipped into specimen up to the “dip line” for the sampling time (usually 3 -10 s)	Urine applied by pipetting a set number of drops to sample well (usually 3 - 5 drops)	Held in the urine stream for a prescribed time period (usually 3 - 5 s). Dipping time may differ from in-stream sampling time.	Held in the urine stream for a prescribed time period (usually 3- 5 s). Dipping time may differ from in-stream sampling time.
Range of time to read-out	1 – 5 min Do not read generally after 10 min	1 – 5 min Do not read generally after 10 min.	1 – 5 min Do not read generally after 10 min.	1- 5 min Digital results remain valid until display screen goes blank (days–months).
Signal detection / read-out	Colourimetric	Colourimetric	Colourimetric	Digital

Table 1: Types of tests

1. Strip Test:
The strip test (Fig 10) is a commonly used type of pregnancy test. It consists of a thin, rectangular strip made of absorbent material on one end and usually with a plastic coating on another end. To use the strip test, a urine sample needs to be collected in a clean container. Then, the absorbent tip of the strip is dipped into the urine for a few seconds, making sure it is fully submerged. After that, you remove the strip from the urine and place it on a clean, flat surface. The test usually has specific marked areas or windows where the results will appear. The results appear in a designated spot as a colorimetric result (usually as lines, colours, or symbols) indicating whether the test is positive or negative for pregnancy.

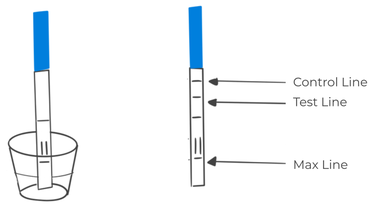


Fig 10: Strip Test

2. Cassette Test:
The cassette test (Fig 11) is another type of pregnancy test that provides colorimetric results. It consists of a plastic cassette with a sample space and result window. To use the cassette test, you collect a urine sample in a clean container. Then, using a dropper or a pipette provided with the test kit, you transfer a few drops of urine into the sample space of the cassette. After adding the urine, the user waits for the specified time mentioned in the instructions. The results appears in the result window of the cassette, also as a colorimetric result indicating whether the test is positive or negative for pregnancy.

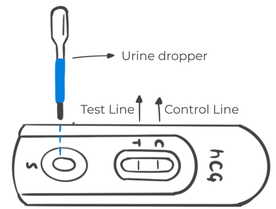


Fig 11: Cassette Test

3. Mid-stream visual:
The mid-stream visual test (Fig 12) is a type of pregnancy test that is designed for a more convenient and user-friendly experience. It typically comes in a plastic, pen-like device with a result window and cap that covers the testing wick. A wick here is an absorbent pad meant to capture the urine. To use the mid-stream visual test, a protective cap is removed, and the test is held from the other end. The wick is placed in the middle of the urine stream as the user urinates.
Alternatively, a urine sample can be collected in a clean container and the wick is briefly dipped into the urine. After completing the urine exposure, the cap is placed back, and the user waits for the specified time mentioned in the instructions. The result appears in the result window, similar to the two above mentioned tests as a colorimetric result, indicating whether the test is positive or negative for pregnancy.
A study conducted on more than 100 women compared different pregnancy test formats, and over 95% of the participants reported that they preferred the midstream test stick format. Women cited reasons such as the unhygienic nature of strip and cassette tests and the difficulty in using them due to multiple steps required (Gnoth & Johnson, 2014b).

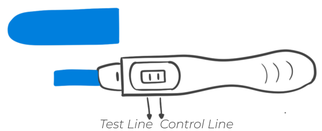


Fig 12: Mid-stream visual

4. Mid-stream digital:
The mid-stream digital test (Fig 13) is a more advanced version of the mid-stream visual test. It provides digital results, typically displayed on a small screen or panel. The usage process is like the mid-stream visual test, where you remove the cap, expose the wick to the urine stream or a urine sample, and then capped back for protection. However, instead of interpreting a colorimetric result, the mid-stream digital test interprets the colorimetric result for the user and displays the results on the digital screen. The results are usually shown as clear, digital indicators such as "pregnant" or "not pregnant." Some digital tests may also provide additional features like estimating the number of weeks since conception or displaying an hourglass symbol to indicate that the test is working.

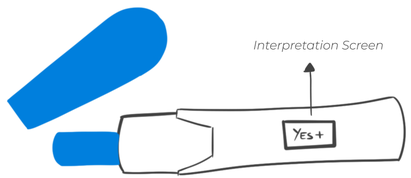


Fig 13: Mid-stream digital

It is crucial to observe that all the tests under consideration utilize the same lateral flow method for detecting hCG in urine. The variations among them primarily lie in the instructions provided and the design of the test casing.

Ethical consideration in the testing market

In a clinical setting (testing labs) normal pregnancy can have low hCG levels . An hCG level of less than 5 mIU/mL is generally considered negative for pregnancy, and a level above 25 mIU/mL is considered positive for pregnancy. However, hCG levels between 6 and 24 mIU/mL fall into a gray area (Table 2). When this occurs, there needs to be a retest to determine if the levels rise, which confirms a pregnancy (American Pregnancy Association, 2022).

Approximate Gestational Age	*hCG Value (mIU/mL)*
1 week	5-50
2weeks	40-1000
3 weeks	100-5000
4 weeks	600-10,000
5-6 weeks	15,00-100,000
7-8 weeks	16,000-200,000
2-3 months	12,000-300,000

Table 2: hCG levels during pregnancy

During discussions with a usability expert, it was noted that the availability at home tests that claim to detect pregnancy at levels below 25 mIU/ml can be misleading for users. The expert pointed out that approximately 1 in 3 women may experience spontaneous abortions in the first week of fertilization, and testing for pregnancy at such a low level as a consumer test should be considered unethical.

This is also evidenced by a lack of standardization guidance universally available for in-vitro medical devices like HPTs, which have led to significant variations in their analytical and clinical performance (Sturgeon et al., 2021).

To assess the actual performance, accuracy, and reliability of widely available pregnancy tests, a study was evaluated to understand the claim made by the usability expert. The study being referred to aimed to investigate the claims made by certain tests, such as "8 days early" or "can detect 10 mIU/ml", which appeared to be incongruous with both the testing performance and the observed increase in hCG levels during early pregnancy (Gnoth & Johnson, 2014). This points out a prominent concern in the pregnancy testing market where sub-par tests are marketed with the promise of early and superior accuracy, which is not supported by reliable results. This outcome warrants to make ethical decisions from the perspective of setting up the hCG level requirements in the newly imagined test.

Home pregnancy tests often claim to have over 99% accuracy when used on the day of the expected period also. However, these claims are based on laboratory testing of urine samples under ideal conditions by trained technicians. In real-life scenarios, the accuracy of home-use pregnancy tests may be lower. Published studies have shown that the sensitivity of these tests decreases when individuals use them on their own urine, as opposed to laboratory testing (Gnoth & Johnson, 2014).

During the discussion with the usability expert, it was noted that mid-stream tests were primarily designed to be a rapid test. However, upon further examination of their usability, several significant pain points related to the test-taking process emerged.

These pain points included difficulties in urinating with accurate aim, the risk of flooding the test and causing damage, and the subsequent impact on the reliability of the test results. Moreover, it was suggested that clear communication should be provided to users to enhance their confidence while taking the test. This observation highlights the importance of user self-confidence. When users have trust in the product and feel confident in their abilities to use it, it has the potential to address both direct and indirect pain points they may experience.

Top competitor in the market

To create a more effective and relevant next generation of HPTs, it is important to have a thorough understanding of the current industry leaders, their strengths, and weaknesses. By analysing these factors, it is possible to envision a redesigned product that addresses the limitations of existing tests.

The mid-stream digital is considered to be novel due to its addition of the digitise result. What is worthy to reiterate here is that this novel test, still operates on the lateral flow test mechanism (fig 14). While the digitization does cater to an important user pain point it does comes at a higher cost which makes these tests not the first choice for many users, this includes both women who are trying to conceive and the ones who aren't(discussed further in user analysis). This also then indicates how pregnancy brands use this to their advantage and make the single use tests stay in business.

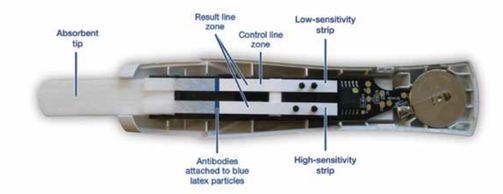


Fig.14: Internal parts of a Clearblue test

For example, Clear Blue is acknowledged as the most popular brand of pregnancy tests worldwide and in Europe. This brand offers a diverse range of tests at different price points and with distinct functionalities to accommodate the requirements of various users. This includes the Mid-stream test with a colorimetric result and the digital result. In 2003, the Food and Drug Administration (FDA) which is the Federal agency of the Department of Health and Human Services in the United States granted approval for Clearblue Easy's digital pregnancy test.
Upon closer examination of Clearblue tests, it becomes evident that they are strategically marketed to encourage the purchase of multiple tests. Clearblue offers various combinations of tests, including packages containing two to four tests, marketed as providing "2 results, double confirmation."
This marketing strategy suggests that Clearblue recognizes the tendency of users to test multiple times (fig 15) for increased reassurance while also straining the users pockets. Interestingly, while promoting their tests as 99% accurate, this competitive brand inadvertently promotes user behaviour that may contribute to excessive testing.



Fig 15: Varieties of clear blue tests available in the market

In conclusion, the marketing strategies employed by Clearblue and other competitors in the market reinforce the practice of repeated testing among users. While this may stem from the desire to ensure accurate results, it also highlights the need for better user self-confidence and responsible use of pregnancy tests.

New tests in the market (bench marking)

The pregnancy test market has seen limited innovation in the last three decades. However, there has been a recent trend towards sustainability in the production and packaging of home pregnancy tests. Manufacturers are now exploring ways to make their products eco-friendlier and reduce their environmental impact.

Examples in the current market range from the most sustainable test remaining the strip test. Other varieties of tests are now also introduced in the market that claim to be a more sustainable choice for the user. These tests often use recycled materials, reduce packaging waste, and eliminate the need for additional equipment, such as cups or droppers. As the demand for eco-friendly products continues to grow, it is likely that there will be more sustainable options in the pregnancy test market in the future.

Couple of notable examples for these include a flushable pregnancy test (Fig 16- left). The pregnancy test is designed to be environmentally friendly and is biodegradable, allowing for easy disposal by flushing after use. In addition to being sustainable, this feature also provides privacy to women who can take the test without being discovered by others if thrown in a trash bin (Peacock & Peacock, 2022).



Fig 16: Sustainable choices in the market

Another example of Hoopsy (fig 16 - right) has developed an "eco pregnancy test" that is made from paper, with cardboard packaging that can be recycled at home. The test aims to replace traditional plastic home pregnancy tests, which the company claims are discarded by 12.5 million women in the UK each year. The only non-recyclable part of the test is the soft plastic pouch in which it is packaged, which can be recycled through supermarket collections. The use of paper in the test's production makes it more environmentally friendly and discreet (Aouf & Aouf, 2022).

2.1.7 Need for circularity in Medical Devices

The concept of circularity in medical devices has evolved over time, influenced by factors such as material choices, sterilization practices, and environmental concerns. Before the 1970s, medical devices were commonly considered reusable due to the prevalence of materials that could be effectively cleaned (Gautam & Sahney, 2020). However, advancements in technology and sterilization methods led to the emergence of single-use medical devices in the late 1970s. This timeline also coincides with the beginning of at home pregnancy testing.
Environmental concerns are increasingly shaping discussions around medical device circularity. An example of this in the diagnostic sector can be seen around the cartridge-based polymerase chain reaction (PCR) tests for detecting SARS-CoV-2 generate significant plastic waste (Street et al., 2022). This situation parallels the concern surrounding single-use pregnancy tests and their contribution to waste. Material selection also plays a significant role. In the past the reusability of medical devices were often crafted from metallic materials to withstand heat sterilization processes (Malchesky et al., 1995) hence they had circularity built in. This comes with the ideology of making products that last.

Efforts to promote environmentally sustainable medical devices face challenges due to safety prioritization and reliance on disposables (Hinrichs et al., 2022). Healthcare purchasing decisions often prioritize cost efficiency over sustainability. The generation of diagnostic waste isn't limited to the usage site; it's embedded within the products themselves from the design stage (Street et al., 2022). To achieve true sustainability, a comprehensive approach involving all stakeholders is crucial.
A quadruple-helix approach, engaging industry, government, academia, and the public, can foster innovative solutions and transform the medical device ecosystem (Hinrichs et al., 2022). Hence the involvement of multiple stakeholders also plays a huge role in the design and development process.

These observations emphasize the necessity for circularity to be integrated at the design stage. This underscores the significance of adopting a comprehensive approach that encompasses design, usage, and disposal practices.

2.1.8 Market Study by Pharmista

Prior to the initiation of this graduation project, Pharmista conducted an extensive market analysis involving a quantitative online questionnaire survey of 505 women in Sweden, aged 20 to 40. This analysis aimed to gain insights into women's testing behaviours and practices within this demographic. The study focused on factors such as cost considerations, urgency of purchase, potential embarrassment, and environmental impact associated with using single-use plastics. By exploring these aspects, the analysis provided valuable information about user habits and preferences, informing the project's direction and priorities.

Primary Analysis

Women Aged 20-25:
Among the 245 surveyed in this group, 80% reported purchasing a pregnancy test, primarily due to pregnancy concerns. Of the remaining 20%, reasons for not purchasing included not needing one, cost, and receiving free tests. The majority purchased 3 to 5 tests, averaging 5.8 tests per person, spending between 16.95 and 33.84 Euros.

Women Aged 26-30:
Among the 163 surveyed in this group, 88% reported purchasing a pregnancy test. Reasons varied between pregnancy concerns, hopes of becoming pregnant, or both. Those not purchasing cited not needing one, cost, or embarrassment. The majority purchased 3 to 10 tests, averaging 8 tests per person, with a spending range of 16.95 to 50.78 Euros.

Women Aged 31-35:
Among the 69 surveyed in this group, 88% reported purchasing a pregnancy test. Reasons were similar to the previous group. The majority purchased 3 to 5 tests, averaging 8.2 tests per person, with spending between 16.95 and 50.78 Euros.

Women Aged 36-40:
Among the 28 surveyed in this group, 94% reported purchasing a pregnancy test. Reasons mirrored earlier groups. Purchases ranged from 1-2, 3-5, or 6-10 tests, with an average of 8.7 tests per person, spending between 50.84 and 67.70 Euros.

Factors influencing purchasing decisions across the entire age group of 20 to 40 included cost, the ability to detect pregnancy early, and the positivity of the result. Notably, the embarrassment associated with buying a test decreased as age increased, with older subgroups showing less discomfort.
For a elaborated understanding of the primary analysis, refer to Appendix A.

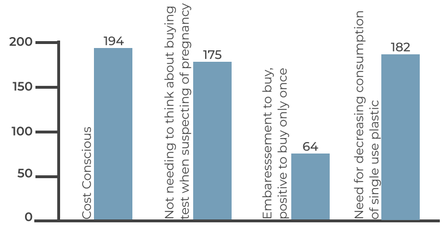
Secondary Analysis
From the primary breakdown there were three distinctions made of types of women that were testing:

1. Women not wanting to be pregnant
2. Women trying to become pregnant
3. Women who have had experiences with both

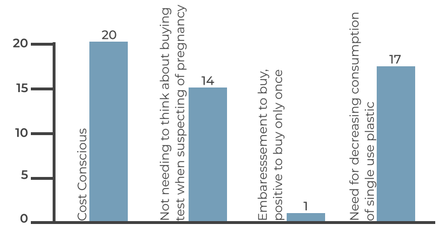
Based on these three groups it was further evaluated and ask if they would be interested in a test that was reusable in nature. And if they were interested, what would drive them to purchase such a product. Due to the nature of the survey, the reusability aspect was inquired through the description of the test in the questionnaire.

Women not wanting to be pregnant
Among the surveyed women, 57.5% (291 respondents) reported purchasing pregnancy tests solely when concerned about potential pregnancy. Within this group, 58% were aged 20-25, 30% aged 26-30, and 12% aged 31-40. On average, these women bought 6 tests,
spending 40.42 Euro. Key factors influencing their choice were price (66%) and high sensitivity for early detection (42%). A minority (6%) expressed preference for knowing pregnancy duration if test results were positive. Some mentioned interest in multi-packs. Their receptiveness to reusable tests is visually represented (Graph 1)

Women trying to become pregnant
Only 6% (32 respondents) reported purchasing tests exclusively when trying to conceive. Among them, 50% were aged 26-30. On average, they bought 12.5 tests, spending 69.75 Euro. Their selection criteria emphasized early pregnancy detection (60%), price (44%), and indication of pregnancy duration (25%). Their openness to reusable tests is illustrated (Graph 2)

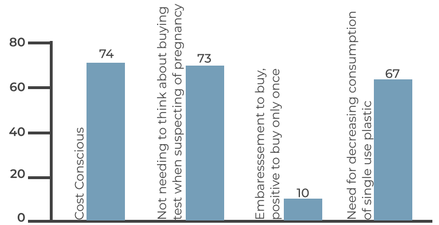


Graph 1. Graphical representation



Graph 2. Graphical representation

Women who have had experiences with both
Within the surveyed women, 22% purchased tests for both pregnancy concerns and conception attempts. Distribution: 38% aged 26-30, 25% aged 31-35, 21% aged 20-25, and 15% aged 36-40. On average, this group bought 13.2 tests, spending 77.97 Euro. Priorities varied based on purpose. Common factors were early detection (69%), price (63%), and insight into pregnancy duration (24%). Their attitudes towards reusable tests are indicated (Graph 3).



Graph 3. Graphical representation

The market study conducted by Pharmista revealed a clear trend in women's primary motivation for purchasing tests: *cost*. While the option of a reusable alternative had its motivating factors, they didn't consistently revolve around sustainability. Therefore, solely relying on sustainability might not effectively drive the intended change through this transition. Other significant considerations, such as ease of purchase and convenience, exert a considerable influence on consumer choices.

2.1.9 User Analysis

A user study within this graduation project was conducted to understand the different types of uses and to map out their needs and preferences of the users.
The study aimed to investigate not only the test-taking process but also the nuances involved in the entire process which starts from the idea of needing a test till its disposal. The primary goal of the user study was to understand the needs and desires of all users, which would then help scope the different users into target users and desired users.

User Study

Aim:
To identify user types and areas of opportunity for improving the pregnancy testing experience.

Research questions:
- What kind of users are there in the current context of pregnancy testing?
- What problems do users face in testing usability?

Recruitment criteria and selection:
For this user study, women based in The Netherlands and Sweden were the participants. To be eligible for the study, participants had to have recently taken a pregnancy test. The age range for the participants in the study was 23 to 38.

Type of Study: This study employed a qualitative research approach, involving 10 women who had recently taken a pregnancy test. The research was conducted through a combination of online and in-person interviews, using a semi-structured format (For a detailed list of interview questions, and informed consent refer to Appendix B).

Objective of the study:
The interview questions covered various aspects, starting from the type of tests used by the participants to their test-taking experiences and any pain points encountered during the process. Additionally, the interviews explored if there was the involvement of partners in the testing process.
As part of the study in the end participants were also presented with a proposition for a reusable test to gauge their reactions, whether positive or negative. This exercise aimed to understand the acceptance level of the future intended scenario among the users.

Results:
Among the participants, the first notable difference was their intent behind taking the test. This distinction was crucial, as the emotional implications of their intent varied significantly, leading to different considerations and choices.

Next section showcases a description of these two types of participants to establish their similarities based on their interview responses.

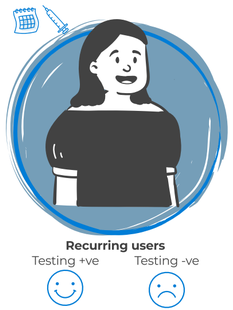


Fig 17: Actively trying to conceive

Actively trying to conceive (Fig 17) (5 participants)

- Not using any form of birth control
- Either attempting to conceive naturally(3) or undergoing fertility treatment(2).
- Taken multiple pregnancy tests (3 to 5) in each testing round.
- Prone to taking tests multiple times in the beginning of their conception journey(when testing negative), whereas over time testing decreased.
- When tested positive, always tested again.
- 4 out of 5 of the participants saved their tests after testing positive.
- All partners were in waiting to hear the test results
  - 2 of those tested on days after the positive result to track how dark the line became, which was indicating their hCG was rising(meaning their pregnancy was going in a positive direction).

"I got to understand that if the line is not there I am surely not pregnant and don't need to test again to confirm." - P1

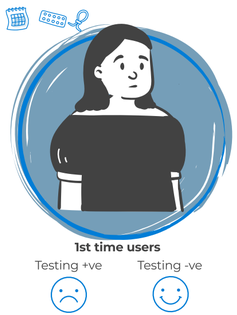


Fig 18: Actively not trying to conceive

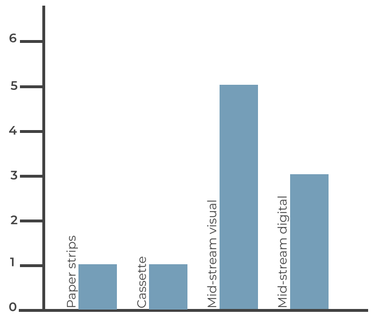
Actively not trying to conceive (Fig 18) (5 participants)

- 4 out of 5 using some form of birth control(IUD or pill)
- Testing due to experiencing delayed periods and/or what they thought were pregnancy symptoms.
- 3 out of 5 have tested in the past(more than 2 times). 2 out of 5 tested multiple times in one instance.
- Wanting to take multiple test even after testing negative(stopping due to cost)
- 1 out of 5 tested positive, and tested again.
- 1 out of 5 had their partners involved.

"I got a negative but thought 'what if' but then rationalised with the result" - P2

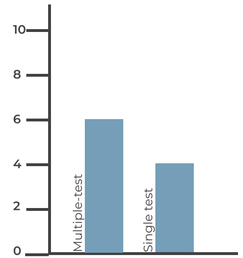
Type of test used (Graph 4):
It was also inquired which tests the participants tend to use and why. The most popular type was the mid-stream(Fig x) and the quantitative data from the literature review also showed similar results, further confirming the prevalence of mid-stream tests among women. The reason provided for this was that this was the most popular one they knew, or they were recommended to use to by peers.

"I saw those in movies that people pee on a stick and jobs done" - P2



Graph 4: Graphical representation

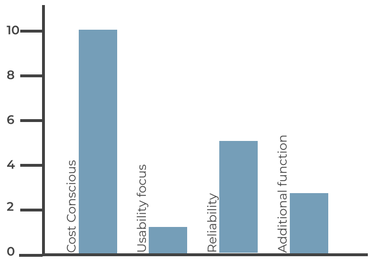
Testing multiple times (Graph 5):
Within all the participants, it was noted that participants (6) who tested positive always opted for taking additional tests to confirm their result. This was for both women trying to conceive and the ones who weren't. This was specific to one round of testing cycle. For participants who tested negative (4) expressed their doubt in the result and indicated that wished to test again, but the idea of buying more tests felt like a waste of money.



Graph 5: Graphical representation

Considerations while buying tests (Graph 6):
A synthesis was made on what were the considerations participants made while getting a test. The 4 main trends tracked were: cost, usability, brand name, reliability, and Additional functionality.

“The helper at the pharmacy told me that all the test work the same and one is not better than the other” - P4

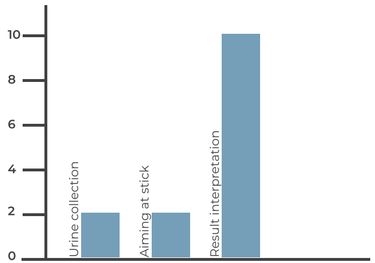


Graph 6: Graphical representation

It was evident that cost played a huge role in the test taking process. This was more valid specially for recurring users since they had the need for re-testing and hence would stock up on cheaper options, while having some extra expensive ones for if/ when they tested positive.

Pain points while using the test (Graph 7):
While inquiring about pain points in the test taking process, themes like, urine collection and aiming at the stick came up. Both these were part of the urine part of the test.
Additionally, all 10 participants expressed their uncertain in reading the test result. This took place atleast once for all participants. While recurring users did express that they became more certain over time.

"I peed on the stick and realised I had urine on my hand, which was disgusting" - P8



Graph 7: Graphical representation

Conclusions:
In conclusion, this user study provided valuable insights into the complexities of the test-taking process, highlighting variations between first-time and recurring users and their overall experiences. The identified themes, encompassing purchasing behaviors, needs, preferences, and challenges, offer a comprehensive understanding for further exploration. Moreover, these themes contribute to constructing a coherent narrative tailored to the intended users, guiding the enhancement of their overall experience.

For further details and additional statistical data, please refer to Appendix B

Limitations:
The user analysis provided valuable insights, but it had its limitations, specially regarding the experience of the participants' partners. Although questions about their partners' experiences were included during the interviews, gaining a comprehensive understanding of their perspectives was challenging due to their indirect involvement. As a result, certain nuances and aspects of the testing process may not have been fully grasped from the partners' point of view. Despite this limitation, the aim was to capture as much information as possible from the participants and further investigation is made on this by user trend research further in the report. This is to inform the design process and ensure that the new proposed product caters to the needs of both users and their partners effectively.

2.2 *Define*

2.2.1 Establishing types of users

Upon evaluating all the user insights, it became evident that there are different types of users who use pregnancy tests. The analysis revealed the presence of direct and indirect users, each with varying needs and preferences. By distinguishing between these user groups, helps understand all pain points and further will be used to derive areas of opportunities.
The two types of direct users and one indirect user is established.



Fig 19: Non Conception Seekers

Non Conception Seekers (Fig 19): These users are not actively trying to conceive but may have concerns or health-related symptoms that are similar to pregnancy. They may experience anxiety or uncertainty and use the pregnancy test to gain reassurance and peace of mind. They are looking for tests that are easy to use, affordable and can provide clear results to address.



Fig 20: Conception Seekers

Conception Seekers (Fig 20): These users are actively trying to conceive and are eager to know the results of the pregnancy test. They can experience delayed or missed periods and may have symptoms that mimic pregnancy. They seek multiple accurate and reliable tests to confirm their pregnancy status.

Direct Users



Fig 21: Conception Seekers(Partner)

Conception Seekers(partner) (Fig 21): This user plays a vital role as supportive partners in the pregnancy testing journey. While not actively seeking to conceive, they provide emotional support to their partners during the testing process. Their involvement demonstrates empathy and commitment to shared family goals.

Indirect Users

2.2.2 Trends Analysis of users

Following the identification of distinct user categories, a subsequent phase involved gathering insights into the behaviors of these user types. This data was derived from online trend analysis, shedding light on the practices women adopt when undergoing pregnancy testing. Additionally, this trend analysis revealed the extent of partners' involvement in the process of taking pregnancy tests. This exploration aimed to deepen the understanding of user habits and dynamics within the testing journey.

Couples trying to conceive

It can be inferred that women who are actively trying to conceive tend to purchase a larger number of home pregnancy tests (HPTs) compared to women testing for other reasons. Exploring the behaviours and preferences of this particular group provides valuable insights for incorporating relevant features and values into the envisioned product system. According to data from 2012, home pregnancy tests generated a significant revenue of $228 million, indicating their widespread usage as a diagnostic tool (Braunstein, 2014). Consequently, prioritizing the needs and requirements of women aiming to conceive becomes a focal point and a higher priority within the scope of this project. To understand their habits, one needs to understand certain cycles that couples who are tying to conceive go through(terminology elaboration in Appendix C). Couples who are trying to conceive can be classified as

1. Natural Conception
2. Infertility issues
3. Cannot conceive naturally (same sex couples)

Couples that are in the same sex or infertility group have three options they can seek to facilitate conception (NHS, 2022):

1. Medicines
2. Surgical procedures
3. Assisted conception – including intrauterine insemination (IUI) and in vitro fertilisation (IVF)

All these stages are gradual processes the couple must go through one by one, only if the previous forms of treatment are not working for them. For couples trying to conceive, this means there are multiple moments they are in need for testing for pregnancy. With the previously mentioned Pharmista study, it was found that women would tend to test anywhere between 5 to 10 times per cycle. Additionally, couples typically visit their GP at eight to twelve weeks after conception or a month after testing positive. This means, users tend to test additionally in this time frame in the anticipation.

On discussion with two fertility specialists, one based in The Netherlands, and one based in India, both expressed similar habits amongst their patients when it came to women who are trying to conceive or seek fertility treatment. Some of them included women's habit of testing every day before having the chance to meet their fertility doctor, tracking their progress with multiple tests even against the advice of their doctors. This is because, in the case of fertility treatment, specialists prefer to test with more certainty, which is with blood test.

They consider these tests more valid due to the nature and the seriousness of the treatment. They also expressed the heavy involvement of partners in the current scenario of fertility treatment. This is because, a lot of these treatments (like IUI and IVF) require a lot of at-home medical processes which now partners partake in. Hence, the partner also gets involved in the testing experience. Sometimes it extends to mental and emotional support.

Another resource to understand these habits of women trying to conceive was held on social media. This is where online content creators have been shown to display the excessive amount of test they tend to take while in the process of conception (fig 22).

While testing multiple times can be a source of anxiety and stress for some women, it can also provide reassurance and a sense of control during a time of uncertainty. It is important to note, however, that home pregnancy tests are not a substitute for medical advice it is always recommended to consult with a healthcare provider for any questions or concerns regarding pregnancy.



Fig 22: Social media analysis

Push towards reusability in feminine products

The movement towards sustainability in feminine products has catalysed the emergence of innovative solutions to enhance women's reproductive health. A notable trend is the rise of reusable alternatives (elaboration in Appendix C), encompassing fertility kits (Fig 23 left) and menstrual products. Among these, reusable ovulation tests, such as those offered by Clear Blue and Oova, stand out as exemplars of this sustainable direction, merging technology for precise fertility tracking. Concurrently, eco-friendly period products like reusable underwear and menstrual cups (Fig 23) are garnering attention for their environment-conscious and economical attributes. These evolving product categories serve as rich sources of inspiration for crafting a sustainable ecosystem that addresses the comprehensive needs of women's reproductive health.



Fig 23: Reusability options

However, it's crucial to acknowledge that the transition towards reusability in these contexts isn't instantaneous. The trajectory of adoption can be gradual, and questions surrounding convenience and habits often arise. For instance, some mothers may inherently prefer sustainable alternatives yet continue to opt for disposable diapers, despite the availability of reusable options. This underscores the significance of considering factors beyond sustainability alone and underscores the importance of a comprehensive approach that aligns with user preferences and behaviours.

Bigger goal of women taking charge of their health and finances

According to ResearchAndMarkets, the Global Female Fertility & Pregnancy Rapid Test Market has experienced a significant growth, with an estimated value of USD 1,692.14 million in 2021, projected to reach USD 2,629.33 million by 2027 (Markets, 2022). It is crucial to consider the broader landscape of the female fertility market, which includes various products such as ovulation kits, fertility treatment drugs, and medications related to women's fertility journeys. This underscores the importance of empowering women to take control of their health and finances. Recognizing the significance of knowledge in making informed decisions, women's healthcare needs emerge from an early age with the purchase of sanitary products during teenage years, continuing into adulthood with contraception usage, and potentially extending into middle age with fertility-related expenses. By ensuring affordability and value in these products, women can be well-informed and empowered to make conscious choices regarding their healthcare spending.

Conclusion

With tracking these trends it becomes evident that these trends coincide with each other (Fig 24). Below shows illustration of the key factors help further add nuance to how the problem can be approached and what nuances to consider in the design process.

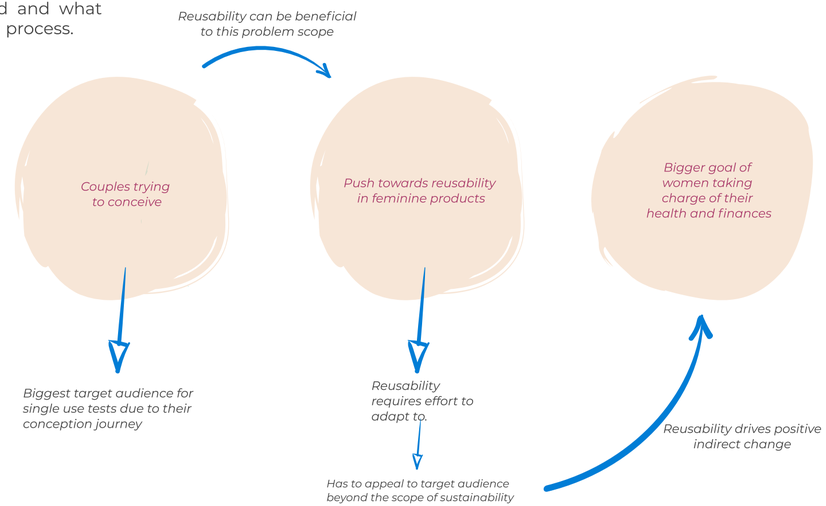


Fig 24: Trend Analysis

2.2.3 User Personas

Based on the identified user distinctions from the user analysis and further tend analysis, user personas were created for both direct users. These personas provide a deeper understanding of the similarities and differences between the two types of users (conception and non conception seekers). By delving into all their unique Habits needs and pain points, the user personas serves as valuable tool to guide the development of the new product.



Mila, Age 35

"I tested again and again just to be certain of the result"

Methods of Conception

Mila has been married for 7 years to Miles and they have been trying to conceive for over a year. After one month of undergoing fertility treatment, they are now in the period where they can check whether the treatment has been successful or not.

Habits and Preferences

- Is spending additional money on fertility treatment.
- Likely to research and read reviews online before purchasing a pregnancy related products
- Has a stock of multiple types of pregnancy tests at home
- Prefers to take the test in the privacy of her own home and sharing results with her partner.
- Prefers a pregnancy test that is easy to use and provides clear results.
- Tracks everything related to her pregnancy
- Wants to switch over to single use products

Wants & Needs

- Confirm whether or not her hormone treatment worked and she is pregnant
- Have an accurate and reliable pregnancy test result while being easy on the pocket
- Minimize stress and anxiety related to the testing process
- Increased involvement of partner
- Ability to test multiple times

Pain points

- Scared to receive another negative result.
- May have difficulty in interpreting the results of the test
- May experience stress and anxiety while waiting for the test result
- Doesn't like the test to be single use and having to buy multiple.
- Has to store multiple tests to track her result



Miles, Age 37

Miles is only involved based on the preferences of Mila. His roles revolves around mostly providing support. He being an indirect user does not have strong habits, preferences or pain points.
Most of his requirements are wants and needs similar to that of Mila.
Additionally, he would like to be as involved in the test taking process as possible.



Mila, Age 35

"Should I buy a cheaper test because this is so expensive!"

Methods of Contraception

Julia is in a heterosexual relationship with a long term partner. She tracks her period and sees on her tracking application that it is not on time, that is a cause for concern since she uses contraception. She is stressed since she is not trying to conceive and does not want a positive test result.

Habits and Preferences

- Tries to save as much money as she can.
- Likely to research and read reviews online before purchasing a pregnancy test
- Prefers to take the test in the privacy of her own home rather than going to a doctor's office
- Prefers a pregnancy test that is easy to use and provides clear instructions
- May discuss the possibility of being pregnant with close friends or family
- Tries to avoid single use products

Wants & Needs

- Confirm whether or not she is pregnant after delayed period
- Have an accurate and reliable pregnancy test result while being affordable
- not have to go through the embarrassment of buying a test
- Minimize stress and anxiety related to the testing process
- Determine her options and plan for next steps based on the pregnancy test result

Pain points

- Can't afford an expensive test
- Worried about the possibility of being pregnant and how it may impact her career and personal life
- Concerned about the accuracy of the pregnancy test
- May have difficulty understanding the instructions
- Trouble in interpreting the test
- Unsure of its correct use.
- May experience stress and anxiety while waiting for the test result

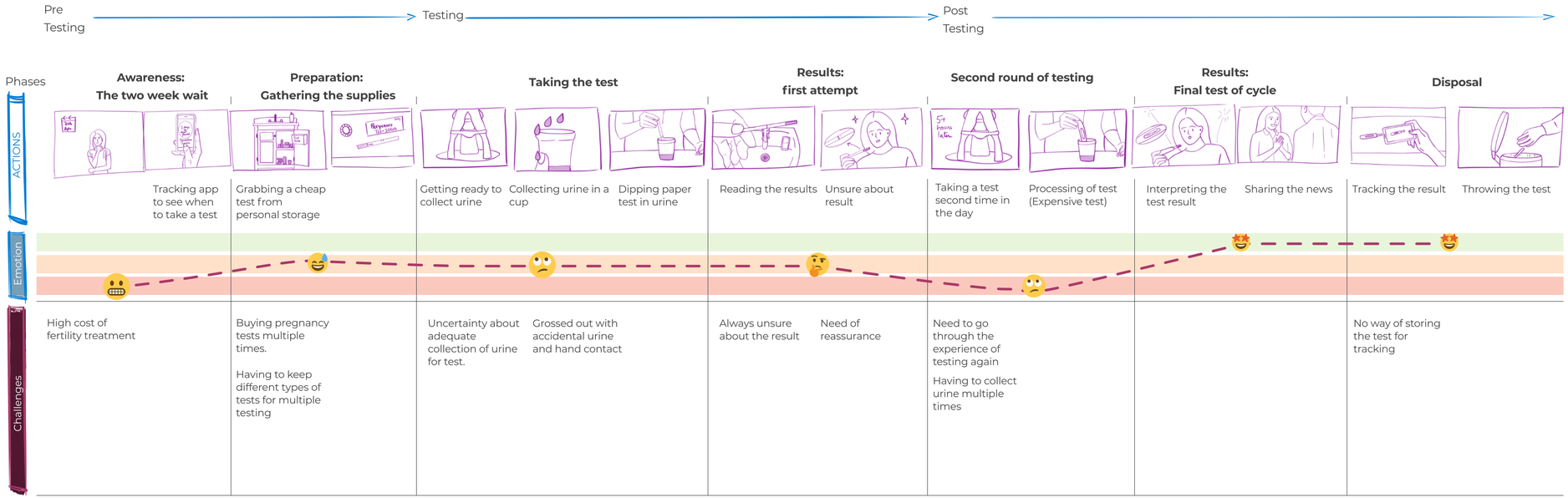
Journey Maps

Journey maps serve as a crucial asset within the design process, providing a visual depiction of the user's interaction with the product system across various stages. Through the creation of tailored journey maps for different user personas, a holistic grasp of user emotions, actions, and challenges at each juncture of their experience is attained. This approach fosters enhanced empathy and a user-centric design methodology.



Mila and Miles

A comprehensive understanding of the wants, behaviours, and pain points of both direct and indirect users reveals that the primary users of Home Pregnancy Tests (HPTs) are individuals like Julia (conception seeker) and her partner Miles.
Therefore, they are identified as the target audience for the envisioned product system.

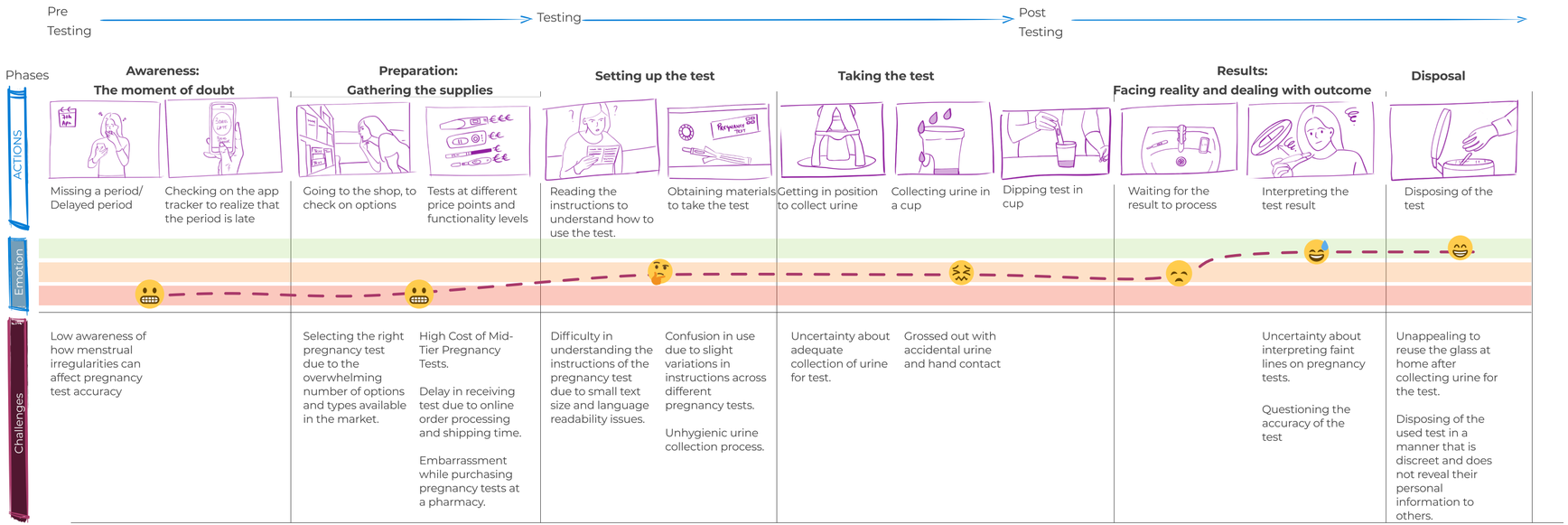




Julia

While Julia could potentially benefit from an enhanced HPT setup, it is reasonable to assume that a reusable test may not be her immediate preference, as she may not see the need for it.

An important point to consider here is that even though the journey map of Mila and Miles possesses less challenges, this is because they are recurring users of a HPT.
This also implies that Mila would be going through a similar journey like Julia in the early stages of her testing journey.



By catering to the diverse needs of both Julia and Mila, the product system can aim to serve a broader user base and create a more inclusive and appealing testing experience.

Areas of opportunity to enhance the experience

Building upon the insights derived from the user analysis and the subsequent user experiences, the initial step before embarking on the development phase involves mapping out the areas of opportunity. This process lays the groundwork for initiating the ideation process, facilitating the creation of innovative solutions that effectively cater to the identified user needs and alleviate pain points.

The following table (Tab. 3) presents a comprehensive compilation of considerations for both types of users which were the foundational plan for crafting an improved pregnancy detection experience.





Common Needs

Reliability and Trustworthiness: Develop a pregnancy test system that meets or exceeds current market standards for accuracy and reliability, ensuring users can have confidence in their test results.

Clear and Simple Instructions: Provide easy-to-understand instructions that guide users through the test-taking process from the beginning, making it user-friendly and intuitive.

Spillage-Free Urine Collection: Design the test with features that enable spillage-free urine collection, ensuring ease of use and minimizing mess during the testing process.

Clear Interpretation of Results: Create a test format that offers a clear and easily interpretable result, leaving no room for confusion or ambiguity.

Budget-Friendly Solution: Design the product system to be cost-friendly, making it accessible and affordable for a wide range of users.

Separate Needs

Multiple Testing Capability: Enable users to conduct multiple tests with a single product, providing cost-effectiveness and convenience for those who need to test more than once.

Partner Involvement: Consider ways to involve partners in the testing process, recognizing their role and providing a supportive experience for couples.

Tracking Features: Incorporate tracking features into the product system, allowing users to monitor their testing outcomes and progress over time.

Easy Disposal: Create a design that facilitates easy and environmentally-friendly disposal of the pregnancy test, taking into consideration sustainable practices and reducing waste impact.

Table 3: Areas of opportunities

From the above list there is a further need to make a distinction of what is achievable by design intervention(myself) and what all Pharmista has to cater to.

From the above list there is a further need to make a distinction of what is achievable by design intervention(myself) and what all Pharmista has to cater to (Fig 25)

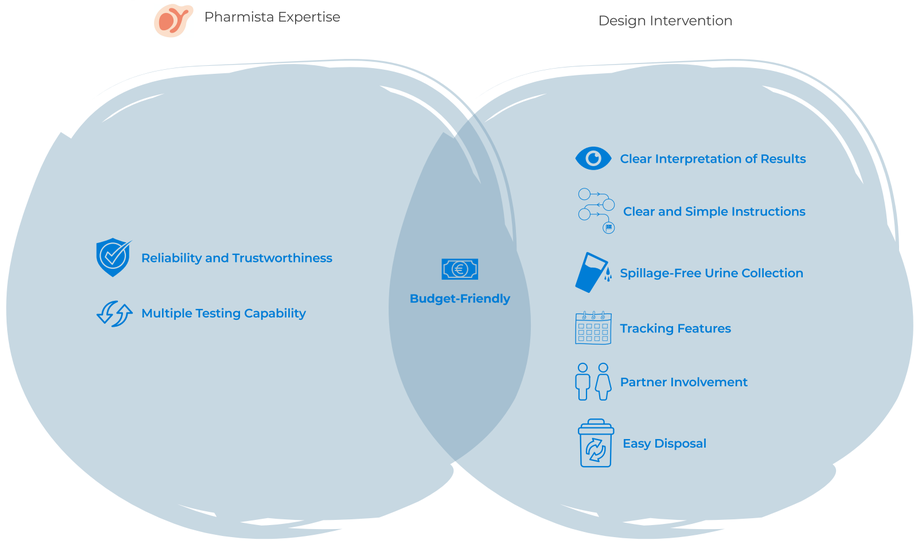


Fig. 25: Areas of opportunities

The reliability and trustworthy of the test, simultaneously to the capability to test multiple times is determined by the development of the sensor by Pharmista. The rest of the areas of opportunity are points that can be tackled with design interventions and what the Developmental phase concentrates on. Lastly, the need for a budget friendly solution lies and the culmination of meeting all these requirements and hence is a shared effort.

3. Development Phase

During the developmental phase, the insights from the discover and define phases lead to the identification of areas of opportunities (stated previously) that guide the design process. The primary objective is to create a concept that fulfils these criteria, ensuring an enhanced user experience. This phase involves iterative exploration and continual reassessment of the prior research findings. The focus lies in crafting a product experience that aligns with the needs and preferences of the target users, while also considering Pharmista's core values and capabilities. Throughout the iteration process, a careful evaluation of the desirability, feasibility, and viability of the proposed solution from the company's perspective is also conducted.

3.1 Conceptulization

3.1.1 Iteration Process

Collection methods

The initial round of iterations primarily concentrated on addressing the first challenge, which involved achieving a hygienic and spillage-free urine collection process. Different approaches to urine collection were explored with the aim of finding effective solutions. Through consultations with Pharmista and considering insights from the usability expert, it was established that redesigning the test to have a similar usability action to aiming is not the direction to have a user friendly test. This decision was further supported by Pharmista's sensor needs. The objective of integrating their sensor with an electronic system requires removing the possibility of flooding the test by mistake. Hence the focus became on providing a means of easy urine collection for the test taking process.



Fig 26: Urine collection

An iteration (Fig 26) aimed to address the urine collection challenge without requiring any aiming, thereby eliminating the need for physical contact and precise targeting. This led to the exploration of concepts involving collection cups positioned within toilet bowls. This design approach maximized the available surface area, providing a convenient and comfortable solution for women to collect urine. The idea was to ensure the collection of an adequate urine sample, fostering confidence in the testing process.

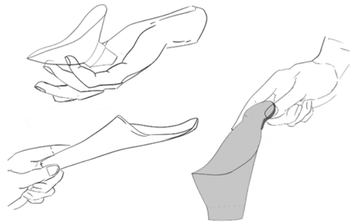


Fig 27: Urine collection

Another approach (Fig 27) involved examining existing products that aligned with the urine collection requirements. Drawing inspiration from "pee funnels," the exploration focused on adapting similar product forms for urine collection by women. This avenue was intriguing, given that pee funnels are designed to facilitate women's urination in a convenient manner. The investigation aimed to leverage the design principles of these funnels to create a suitable solution for urine collection in the context of pregnancy testing.

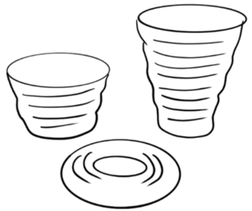


Fig 28: Collapsible option

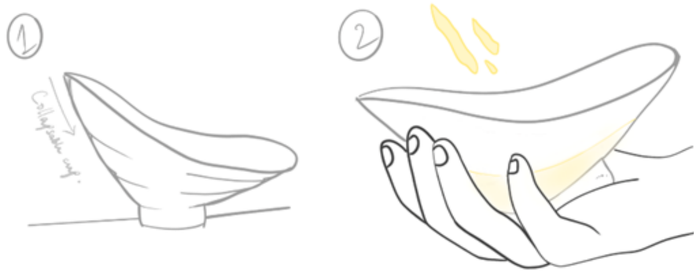


Fig 29: Final idea

Additionally, the concept of collapsible cups (Fig 28) was explored. This exploration was driven by the consideration that these cups would need to be efficiently packaged as part of the overall product experience. The size of these cups, both for usage and packaging, was a crucial factor influencing their feasibility and practicality.

This led to an exploration of combining the structural elements of existing pee funnels and reimagining them to be collapsible (Fig 29). This approach was driven by the packaging considerations. Pharmista's requirement for the product's retail experience, particularly its placement on pharmacy shelves, emphasized the need for a compact design to minimize shelf space utilization and associated costs.

Urine collection exploration

Iterating further on the urine collection process posed itself as a challenge, owing to a lack of comprehensive insights from desk research and the user study into the urine collection process. Hence it was decided to conduct a co-creation session (Fig 30). The purpose of this session was to delve deeper into the actions and interventions associated with urine collection for women. Importantly, this exploration extended beyond the context of pregnancy, aiming to capture additional nuances. For details on the co-creation session's structure, please refer to Appendix D.

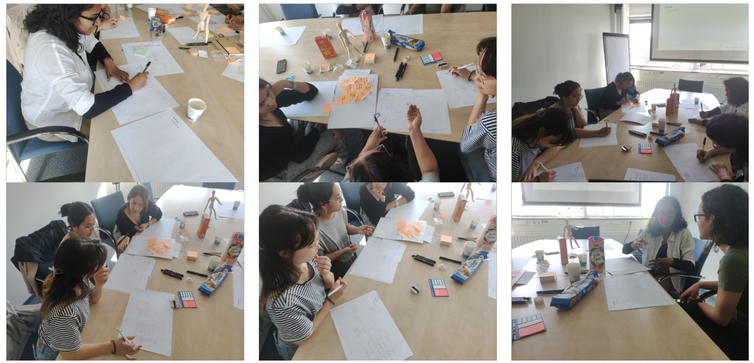


Fig 30: Co-creation session

The insights gained (fig 31) from this co-creation session highlight detailed insights for the urine collection action.

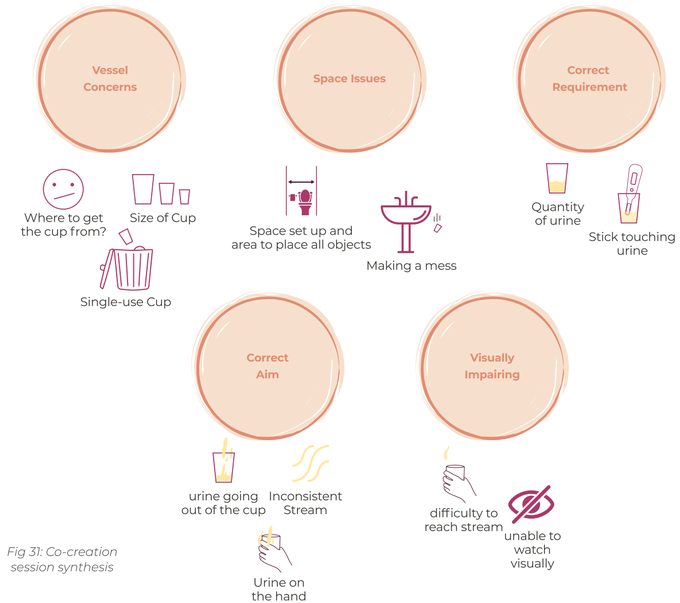


Fig 31: Co-creation session synthesis

Urine collection is an integral and fundamental component of the pregnancy testing process, offering a personal and versatile experience for women. It is a straightforward and prevalent method for conducting tests, as highlighted by usability experts previously. Nevertheless, it's important to recognize that there isn't a universally applicable approach to urine collection, a point further underscored by insights from the co-creation session. The act of collecting urine can evoke feelings of discomfort and concerns about potential spillage, especially when considering the practicality of reusable collection cups. Despite these potential challenges, women have grown accustomed to this aspect of the testing process.

While the idea of standardizing urine collection methods emerged, it became evident, particularly through the co-creation session, that a one-size-fits-all approach might not be feasible. Variations in preferences and needs were apparent. As such, a comprehensive solution to standardize collection methods would necessitate extensive iteration and exploration, which exceeded the scope of this project. Consequently, the decision was made to pause the iteration of collection methods at the concept of the collapsible cup, recognizing that some form of collection container remained an essential requirement for designing the testing process.

Form ideation

In alignment with the overarching objective of incorporating reusability, to initiate the process of form iterations, it was important to establish the precise prerequisites for the physical test's accurate functionality. This encompassed a comprehensive understanding of the essential needs specific to the Pharmista sensor (Fig 32) – its operational mechanisms and imperative requisites.

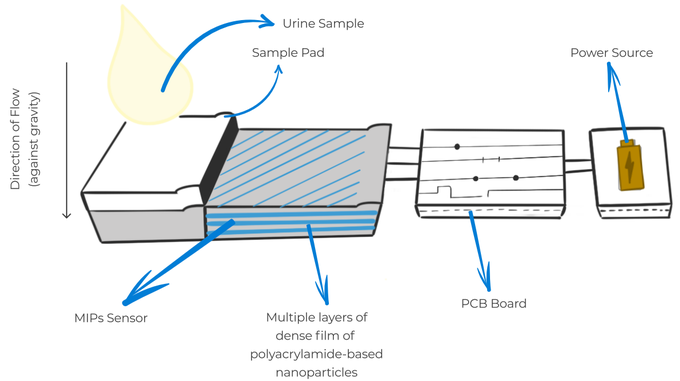


Fig. 32: Pharmista test with electronics

1. **Contact with Urine via an absorbent surface:** The sensor necessitates interaction with urine through a wick. This aspect aligns with traditional home pregnancy tests, where the test reaction occurs on the paper connected to the wick. Similarly, the Pharmista sensor employs the wick to prevent dilution. However, a key distinction lies in the test processing methodology. Traditional tests display results on the strip itself, while the Pharmista sensor interprets and presents results electronically.

2. **Lukewarm Water Wash:** An essential requirement entails that the sensor be washable with lukewarm water. This criterion aligns with the broader design for reusability while ensuring the sensor's hygiene and durability.

3. **Electrical Charge for Interpretation:** The sensor's operation mandates a power source for accurate interpretation of results. This necessitates its connection to a Printed Circuit Board (PCB), which facilitates the electronic representation and analysis of the test results.

In addressing the power supply requirement for the test, two options are considered: single-use batteries and rechargeable batteries. The forthcoming EU regulations intends to extend their scope to cover batteries utilized in medical devices, enhancing safety, quality, and environmental sustainability. These regulations align with the existing MDR and IVDR, ensuring batteries adhere to stringent standards, promote eco-friendly designs, minimize hazardous substances, and encourage recycling (EU a Step Closer to Adopt Expansive New Rules Covering Batteries for Medical Devices, 2022). This comprehensive approach underscores the EU's commitment to patient well-being and environmental stewardship, highlighting safety and sustainability for battery-powered medical devices. Given these considerations, prioritizing rechargeable batteries for the product system emerges as the preferred approach. However, it's important to note that forthcoming regulations will play a pivotal role in determining the specific chemical battery type to be adopted in accordance with established guidelines and standards.

In line with the recent agreement on a common charger, which aims to streamline consumer convenience and address e-waste concerns, the rechargeable battery for the device will be powered by a C-type port. This decision aligns with broader efforts to enhance compatibility, reduce electronic waste, and promote sustainable practices in technology usage (Deal on Common Charger: Reducing Hassle for Consumers and Curbing E-waste | News | European Parliament, 2022). By adopting the C-type port for the rechargeable battery, the device underscores its commitment to environmental responsibility while ensuring a user-friendly and standardized power source. This strategic choice not only aligns with sustainable objectives but also allows Pharmista to avoid the necessity of selling a separate charger for their device.

Following the establishment of these prerequisites, the process of conceptual ideation for the product system's design commenced.

Concept 1: Interpretation on device

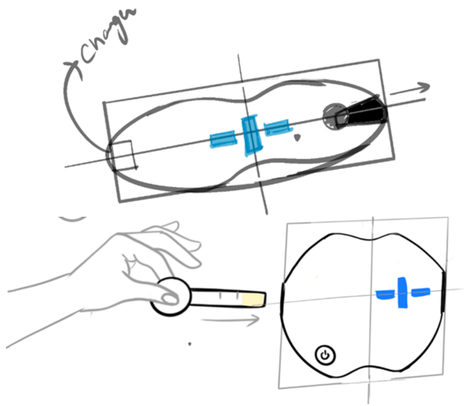


Fig.33: Concept 1

Considering the shared aim to make a budget friendly test, Pharmista proposed exploring the use of LEDs as a cost-effective means of result interpretation. The initial design iterations were shaped by this suggestion, focusing on integrating LEDs into the product concept. Specifically, the idea was to utilize three LEDs arranged in a configuration to indicate either a positive or negative test outcome (Fig 33).

However, this concept was posing challenges due to inherent limitations in the interpretation method itself. While LEDs could effectively display a basic positive or negative result, the electronic nature of the test introduced the necessity for additional information transmission, such as error codes. Acknowledging the significance of communicating comprehensive test information, particularly error indications, it became evident that confining the interpretation solely to LEDs was limiting the functionality.

Concept 2: Wired connection

Initially, the idea of incorporating an inverted C-type port for physical connection and sensor detachment was explored, alongside the chosen direction of a C-type port for charging (Fig 34). This concept aimed to enhance device functionality by allowing sensor detachment for washing. However, this approach revealed potential issues related to user error, reinstallation complexity, and device compatibility with various smartphone charging ports. Concerns arose about hygiene, user comfort, and possible mishandling of the detached sensor. These challenges prompted a re-evaluation of the concept's viability. While the wired connection concept held promise, it required refinement to ensure a seamless and user-friendly product experience. As a result, the decision to transition to a wireless option was informed by the need to address these challenges effectively.

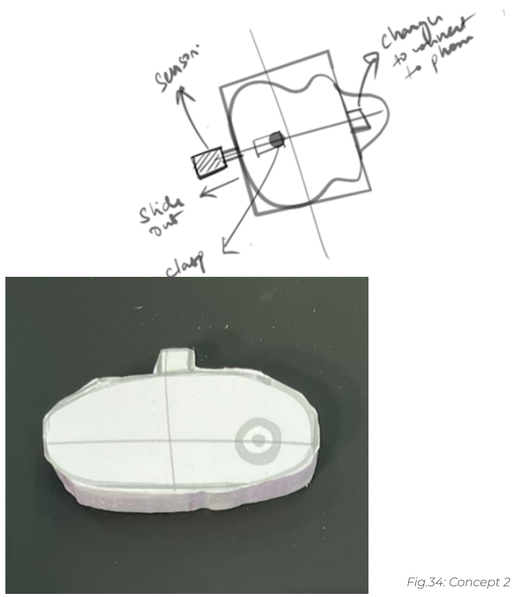


Fig.34: Concept 2

Concept 3: Wireless connection

The ultimate concept taken forward entailed the implementation of a wireless setup (Fig 35), enabling seamless transmission of the test results to the user's smartphone. This concept aimed not only to satisfy the fundamental testing requirement but also to provide an enriched user experience, thereby fostering an ecosystem tailored to recurring users – encompassing both those seeking to conceive and those who are not actively trying.

This wireless integration concept emerged as the chosen direction, aligning with the aspiration to offer users more than just a basic testing solution. The subsequent sections of this report delve deeper into the comprehensive details of the selected concept's form and system, shedding light on the intricate mechanisms and user interactions that underpin this innovative approach.

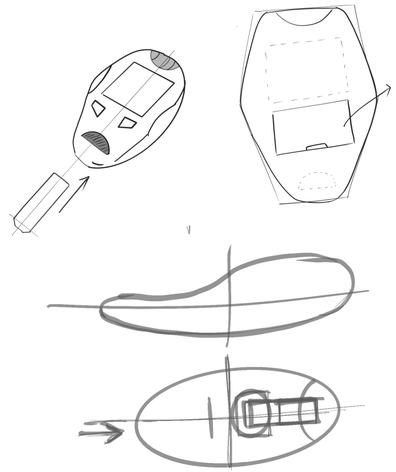


Fig.35: Concept 3

3.1.2 Selected Concept

The envisioned product system, named "SureSign," (Fig 36) comprises two integral components. The first element is the handheld testing device, serving as the core instrument for conducting the pregnancy test. The second component is a dedicated application that plays a crucial role in the testing process. This application provides users with clear interpretation of their result. Additionally, it also offers the functionality to log test results over time.

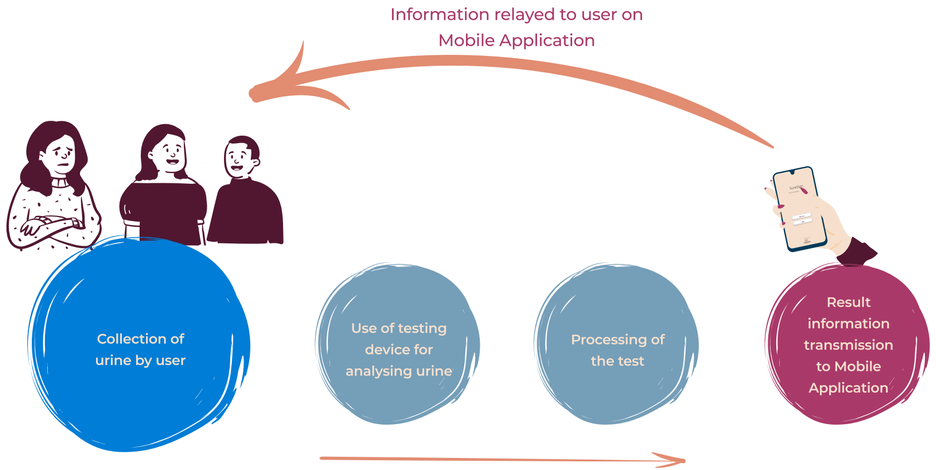


Fig.36: SureSign Product System

In the pursuit of refining this concept, a comprehensive list of system requirements was compiled. This list serves a dual purpose: it looks into the current concept state and maps out areas that require further enhancement. By addressing these requisites through design decisions, the development process can be effectively aligned with the inherent needs and objectives of the product system. This approach ensures a holistic and purpose-driven design trajectory that caters to both existing functionalities and potential improvements.

List of Requirements for SureSign Product System

Having a comprehensive list of requirements is essential in reimagining a new testing experience. This criteria list helps define the scope of the project and outlines what is feasible within its limitations. By categorizing the requirements into technical, experiential, and sustainable aspects, it allows for a holistic approach to designing the product system. This ensures that all necessary considerations are made, including the technical functionality, user experience, and the sustainability of the solution. As expressed before, there are certain requirements that have to be met through the help of the Pharmista team, which will also be highlighted subsequently.

1. Experiential Attributes

The user experience attributes (Tab 4) refer to the specific qualities and aspects of the product system that directly impact how users interact with and perceive the pregnancy test. These attributes are essential in shaping the overall testing experience and ensuring that it meets the needs and preferences of the intended users.

Requirement Type	Device Requirement	Application Requirement
E1. Ease of Use	The device should be compatible with the instructions in the application, allowing users to perform the pregnancy test without the need for complicated instructions or additional assistance.	The application should have visually clear instructions which correspond well with the physical form of the device.
E2. Clarity of Results		The test results should be clearly displayed and easily interpretable by users, eliminating any ambiguity or confusion.
E3. Comfort and Ergonomics	The device should be compatible with the instructions in the application, allowing users to perform the pregnancy test without the need for complicated instructions or additional assistance.	The application should have visually clear instructions which correspond well with the physical form of the device.
E4. Inclusivity	The device should be able to be used by both identified user types and should not be restricted to them	
E5. Aesthetics	The physical form and design of the device should be acceptable to the user, without being intrusive	

Table 4: Experiencial Attributes

2. Technical Attributes

The technical attributes (Tab 5) refer to the specific functionalities and performance aspects of the product system. These attributes are vital in ensuring that the pregnancy test operates efficiently, accurately, and in alignment with the intended goals of the project.

Requirement Type	Device Requirement	Application Requirement
T1.Sensor system	The sensor system by Pharmista should be able to match the current accuracy of existing tests, i.e of 99%.	
T2. Connectivity		The product system's connectivity options (e.g., Bluetooth, Wi-Fi, or cellular) should enable communication with the supporting mobile application.

Table 5 : Technical Attributes

3. Sustainability attributes

Sustainability attributes (Tab 6) are essential considerations in the design of the pregnancy test product system to reduce its environmental impact and promote eco-friendly practices.

Requirement Type	Device Requirement	Application Requirement
S1. Reusability	The test should be able to conduct atleast 10 tests	
S2.Material Selection	The product system should be constructed using environmentally friendly and recyclable materials to minimize waste generation and resource depletion	
S3. End-of-Life Disposal	The product system's end-of-life management should be considered to facilitate proper recycling or safe disposal of its components, reducing environmental hazards.	

Table 6 : Sustainibility Attributes

Prototyping for SureSign product system

The prototyping process for the SureSign product system unfolded in two distinct phases. The initial phase centred around crafting the physical form of the device itself. Simultaneously, an application interface was designed to align with the functional requirements of the testing unit. Once the diverse forms and the entirety of the product experience were established, a comprehensive user evaluation was conducted. This evaluation delved into various functions of the product system, pinpointing areas that could be further refined and enhanced.

Device form

For the form of the device anthropometric measurements were considered while developing the device form, a detailed explanation of which can be found in Appendix E.
By incorporating anthropometric considerations and utilizing the DINED system, helps ensure that the device fits comfortably in users' hands, allows for easy operation, and minimizes physical strain or discomfort during use.

A deliberate strategy was adopted to ensure a well-informed selection of the design. This involved creating multiple iterations of forms (Fig 39) and usability functions, which were subsequently subjected to user testing. In the pursuit of diverse design possibilities, form studies were undertaken to draw inspiration from a wide spectrum of sources. These sources ranged from products within a similar product portfolio to unrelated consumer goods, thus enriching the creative exploration process.



Fig.37: Mood Board



Fig.38: Function mood board

In the realm of usability actions (Fig 38) , a comprehensive analysis of existing products was conducted to identify actions that seamlessly align with the device's intended functionality. These identified actions were seamlessly integrated into the various forms, resulting in a diverse array of device form variations.



Fig.39: Foam Prototypes

Ultimately, three distinctive forms (fig 40), each featuring specific usability actions, were chosen to proceed with. Subsequently, these selected forms were transformed into 3D prototypes, allowing for a tangible representation of their potential design and functionality.

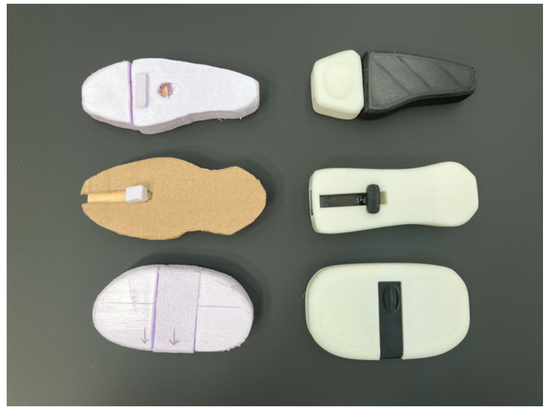


Fig.40: 2 selected iterations

Form Iteration 1 – Cap cover

This iteration of the device forms the device has two parts, a cap (covering the reusable sensor) seen in fig 41, and the main body of the device (with a protruding sensor). The test starts from taking a new wick and placing it correctly into the device, then the wick is dipped in the collected urine. After getting the result, the sensor needs to be revitalised. This happens by first removing the wick and disposing it off, then removing the cap and submerging the sensor into water. The cap is put back into place for the next use of the test.

Form Iteration 2 – Clip pushout

This iteration's function was inspired by paper cutter. The steps involved in conducting the test include insertion of the wick into the test (Fig 42). Dipping the wick into urine for the designated time period and obtaining the results. Finally, the clip pushout mechanism allows the sensor and the wick tray come out simultaneously, releasing the wick for disposal and having the sensor exposed to be wash for revitalization.

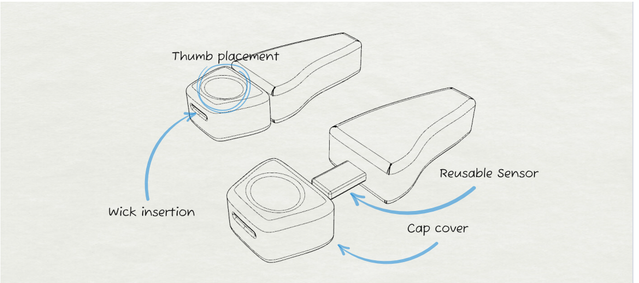


Fig.41: Prototype 1

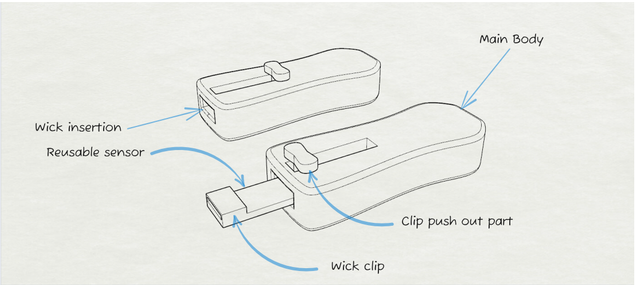


Fig.42: Prototype 2

Form Iteration 3 – Senor Push Out

The last iteration differs the most in its form language (Fig 43). This form was made differently to explore difference in form acceptance in the user evaluation stage.
It also involves a shaft where the paper is inserted.

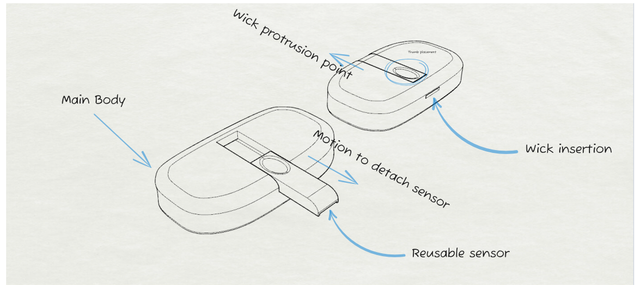


Fig.43: Prototype 3

These three prototype iterations were chosen to take forward for user evaluation to further explore their acceptance and to garner reactions on them.

Application Prototype

The Figma interface for the application prototype was created with two sightly different user experience flows. These flows were based on the user's intent for taking the test, allowing for different communication of test results and the provision of specific resources for each user group for after the test was concluded.

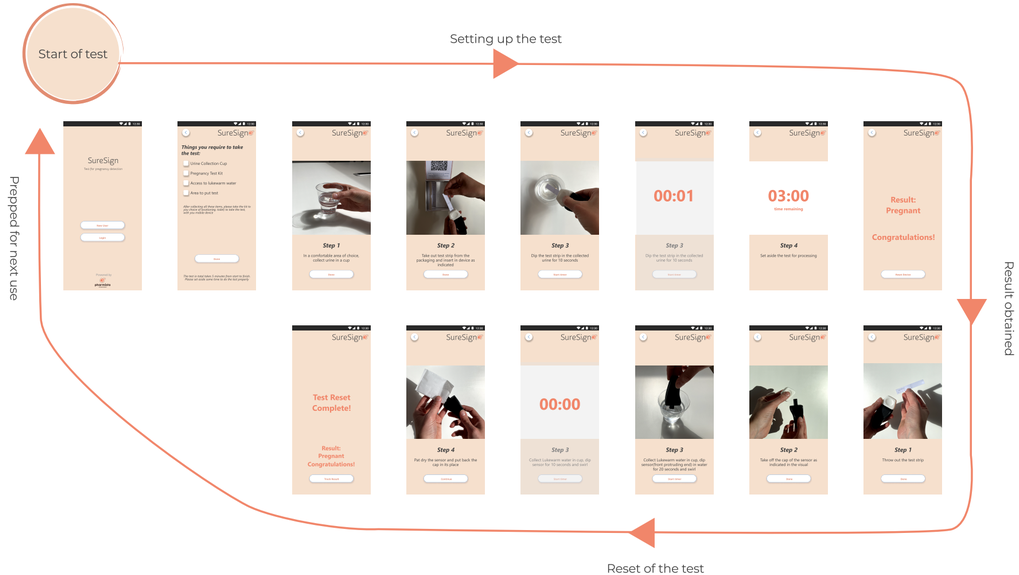


Fig.44: Application Flow

The application interface (Fig 44) provides users with comprehensive instructions, a detailed list of necessary items for conducting the test, a visually guided step-by-step walkthrough of the required actions, and strategically placed timers to ensure adherence to critical timeframes during the test-taking process.
After having these concrete design decisions in place, the design process was taken forward to the user testing phase to evaluate further and make further improvements to the entire user experience.

3.1.3 User Evaluation

Having established design directions for the SureSign product system, a user evaluation session was organized to assess the design decisions taken thus far. This evaluation encompassed various tiers of testing, aiming to gain a holistic understanding of user reactions and identify potential areas for improvement. The evaluation process also aimed to ascertain whether the established list of requirements had been fulfilled and to identify any remaining aspects that required further consideration.

Recruitment criteria and selection:
The user evaluation (Fig 45) necessitated participants to have prior experience with taking a pregnancy test. This prerequisite ensured that during the evaluation, participants could draw on their previous encounters with pregnancy tests, allowing them to make informed comparisons with the existing products. This approach aided in assessing whether the new product system enhanced the overall experience and validity of the project's outcome. There was no age range provided to be part of the evaluation.

Setup
The user evaluation comprised individual 30-minute sessions with 10 participants, ranging in age from 23 to 31. During the evaluation, participants engaged with the three physical form prototypes and the application prototype, completing assigned tasks. Alongside task completion (Fig 47), participants were encouraged to share their opinions, and their impressions were gathered through three sets of evaluation questionnaires. While the tasks were being conducted the participants actions were observed and noted. This user evaluation concentrated on the first two levels of evaluation. The third tier of evaluation was decided to be conducted at a later stage and based on the changes made from the outcomes of the first two user evaluations.

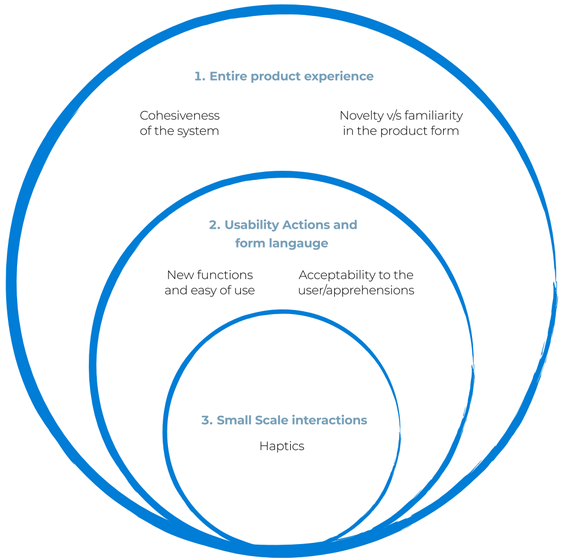


Fig.45: User Evaluation Plan

1. Entire Product System Experience

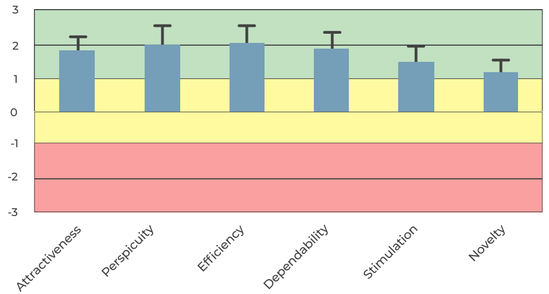
The first level of evaluation to be made with the participants comprised of evaluating if the newly imagined product system was cohesive and acceptable to the participants.

Research Questions:
- *Does the entire system seem cohesive to the user?*
- *Can they user follow all the procedures to complete the test correctly?*

In order to make this evaluation, a task was provided to the participants to take a mock test with the help of the mobile application and a prototype device. This task was performed in a set up of a toilet and role-play was used to allow participants to immerse in the evaluation. This task is detailed further in appendix G.

Evaluation Scale Structure:
After the completion of the first task, the participants were asked to fill out the 'User Experience Questionnaire'.
The User Experience Questionnaire (UEQ) consists of six scales encompassing a total of 26 items. The items and the six-scale division can be referred to in the appendix F for a more detailed scale explanation.

Results:



Graph 8: UEQ Result

In the overall scale measure (Graph 8) the SureSign product system did fairly well. Beyond the quantitative feedback, the qualitative feedback received from the participants was mapped into over arching themes on the 6 scale-sub division which is elaborated in Figure 46.

Attractiveness

Even though the experience was perceived positively, some users expressed that due to the nature of the test, they imagine that they would necessairly not find the test apealing in a real life scenario due to its implications to their lives.

"I had fun taking this test, but I think in real life I would still have a problem in finding this appealing"

Perspicuity

Familiarity to the product was high and it was noted that participants did not necessarily need the familiarity to have confidence in the testing experience.

"Even though this looks different I don't mind the newness of the system."

Efficiency

In all participants cases, there was no additionally clarifications needed to conduct the test and was conducted without unnecessary effort. Though it was mentioned by some that some steps were not needed.

"The step by step process is really helpful to follow along"

Dependability

Participants were satisfied with exactly knowing how to follow along the test and get a result.

Stimulation

Participants were motivated to use the system due to its newness, but again at moments expressed the real motivation depending on their intent in real life context.

Novelty

Most participants were excited to try out the product and had pre-assumptions of what the product would do and how it would function. In all the cases it was different than what they expected and that made them intrigued to find out more.

Fig 46: Results synthesis



Fig.47: User testing

Feedback:
Feedback related to the entire product experience (Fig 48) was categorized into three main topics: instructions, product items, and trustworthiness. Each of these themes (Fig 49) contained both positive and negative aspects. By considering the negative feedback, it becomes possible to generate further design ideas and improvements



Fig.48: User testing

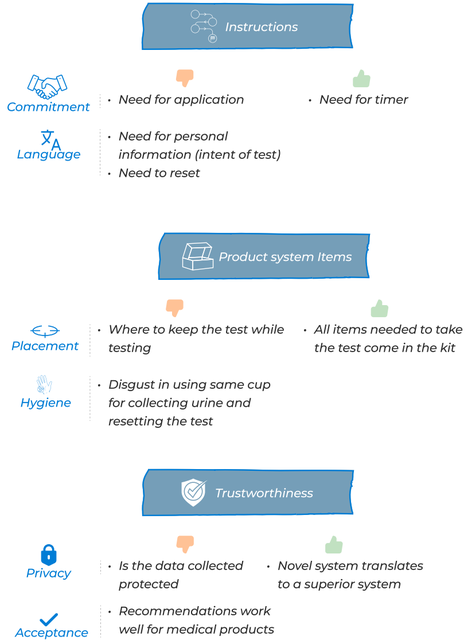


Fig.49: Feedback outcome

Further iteration:
The evaluation task highlighted certain points, and among them, the visually selected ones were chosen to proceed to the next iteration steps. These changes are summarized in the figure 50, outlining the modifications for both the application and the product system items that could benefit from enhancements.

Phone Application

Aspects	*Feedback*
Language Instructions	Further iteration needed for clearer instructions
Privacy Concerns	Address user privacy concerns and data safety

Product System

Aspects	*Feedback*
Device Placement	Explore convenient ways to place the device
Hygiene	Emphasize hygiene considerations during use
Wick Sustainability	Investigate sustainability of the absorbent wick

Fig.50: Feedback synthesis

2. Usability Actions

Following the assessment of the product experience, participants were further engaged in evaluating the form and usability actions of three prototypes. The objective was to determine which combination of actions and form type resonated most effectively with the participants. This evaluation aimed to gather insights into the preferred usability interactions and the overall acceptance of the different prototype designs.

Research Questions:

- *Between the 3 usability choices which one do users prefer?*
- *Between the 3 form choices which one do users resonate with?*

To make this evaluation, a second task was performed by the participants. The participants were provided with the three prototypes were provided. This was done to have a comparative study based on which prototype did well in terms of form and which prototype did well in terms of function. This task is detailed further in appendix F.

Evaluation scale structure:
After the completion of the second task, the participants were asked to fill out the 'The Aesthetic Pleasure in Design Scale'.
The Aesthetic Pleasure in Design Scale consists of 5 factors: Aesthetic pleasure Typicality vs Novelty Unity & Variety.
This scale followed a quantitative approach. Participants were also asked concerns and hesitations for each prototype that were presented to them, and they were asked to give preference toward one out of the three in terms of form and usability function.
The factors of the scale and comparison Questionnaire are further elaborated in Appendix F.

Results:
The provided table(7) illustrates a comparative analysis of the three prototypes' aesthetic attributes. Notably, prototype 2 emerged as the most aesthetically appreciated option. In terms of unity and variety, prototype 3 exhibited a slightly superior performance. Furthermore, prototype 2 garnered the highest score in the context of novelty versus similarity.



	Prototype 1	***Prototype 2***	***Prototype 3***
	Mean (x)	Mean (x)	Mean (x)
Aesthetic Appreciation			
Product form is pleasing	5.5	5.9	5.7
Attractive design	5.5	6	5.6
Total Mean (x)	**5.5**	**5.95**	**5.65**
Unity and Variety			
The parts look unified	6	6.6	6.6
The parts look coherent	6.1	6.4	6.5
Total Mean (x)	**6.05**	**6.5**	**6.55**
Familiarity vs Novelty			
Typical for this product type	3.9	2	3.9
Standard Design for this type	3	1.7	3.6
Total Mean (x)	**3.45**	**1.85**	**3.75**

Table 7: The Aesthetic Pleasure in Design Scale Result

Regarding the feedback solicited on form and usability, several salient points were identified (Table 8). The subsequent table delineates the nature of the feedback received, categorizing it as either positive or negative. The numerical value accompanying each feedback entry indicates the number of participants who shared that similar viewpoints.



Prototype 1



Prototype 2



Prototype 3

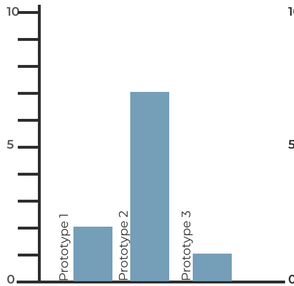
		Positives	Negatives
Relevant Quote		*"I would like to be able to clean the inside of the sensor cap. It will also have traces of pee? I can't guess?"*	
Form feedback		Organic shape Portable form	Correct way to hold(2)
Usability feedback			Cleaning of the cap(3) Losing the cap Strip disposal is perceived as unhygienic

		Positives	Negatives
Relevant Quote		*"Because of its rounded shape I relate it to a women's self care product"*	
Form feedback		Shape looks more like a device(2) Visibility is bathroom is not minded Rounded shape, association to women's products(3) Novel form	Stationed on a cup would be an advantage Shape is not perceived as clinical, feels bulky
Usability feedback		Strip type is better positioned(2)	Channel for the strip is not hygienic(2) Strip insertion unclear

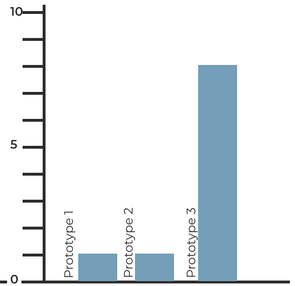
		Positives	Negatives
Relevant Quote		*"Simple and familiar, my brain does not have to think about alignment"*	
Form feedback			Perception of fragility
Usability feedback		The dirty strip is not touched directly(4) All urine covered parts can be cleaned(2) Familiar mechanic outside of pregnancy testing Simple functionality(2)	

Table 8: The Aesthetic Pleasure in Design Scale Feedback synthesis

In the final comparison, Prototype 2 outperformed Prototype 1 in form preference (Graph 9), receiving a score of 8 out of 10. Prototype 2 also excelled in the usability function comparison (Graph 10), achieving a score of 8 out of 10.



Graph 9: Form Comparison



Graph 10: Function Comparison

Conclusions:
In conclusion, a deeper analysis of the evaluation revealed several key insights. Prototype 1 emerged as the most challenging to handle due to its intricate components, and it was perceived as being less user-friendly to clean. Prototype 2 garnered positive feedback primarily because of its ergonomic curvature and soft form, providing valuable inspiration for future refinement. On the other hand, Prototype 3's functionality resonated well with participants, offering ease of adaptation while meeting hygiene expectations. As a result, it was determined that Prototype 3's function would be pursued for the final iteration, keeping user preferences and usability in mind.

3.1.4 Rules and Regulations for medical devices

During this phase of the design process, careful attention was given to the rules and regulations that govern medical devices. This step was crucial to ensure the viability of the product system from a medical perspective. While specific requirements for the MIPs sensor will be addressed once it's fully developed, other relevant regulations were examined that could impact the design and manufacturing processes.

MDR Developments
As mentioned earlier, pregnancy detection devices are classified as in-vitro diagnostic medical devices and must comply with the requirements set by the Medical Device Regulation (MDR) in order to be approved for sale in the European Union. Therefore, it is crucial to consider these requirements when designing the system. The "Factsheet for Manufacturers of in vitro diagnostic medical devices" (Factsheet for Manufacturers of in Vitro Diagnostic Medical Devices, 2020) provides valuable information and guidelines that are essential for the development of this product system, ensuring compliance with the necessary standards and regulations. During the current stage of development, it's essential to be aware of upcoming changes in the realm of In-Vitro Diagnostic Regulation (IVDR). This includes the implementation of Unique Device Identifiers (UDIs) that enhance the identification and traceability of devices. These UDIs consist of both device identifiers (UDI-DI) and production identifiers (UDI-PI), which will play a pivotal role in compliance with regulatory requirements. Additionally, there's a growing emphasis on life-cycle management and continuous evaluation of IVD devices. While these points might not require immediate attention during this phase, keeping them in mind will facilitate the integration of these essential components as the product evolves and aligns with the regulatory landscape (elaboration in appendix G).

Expert Advice
Furthermore, the evaluation by a medical device design expert contributed essential insights that were carefully considered during the iterative phase. In accordance with the requirements suggested by Notified Bodies. A significant emphasis was placed on quality management systems (QMS) for medical testing devices and kits. This emphasis underscored the necessity for the integration of a visible indicator(such as light or digital screen) directly onto the device itself. This indicator functioned as a tangible assurance of the device's proper functionality and accurate performance. Another notable consideration in terms of compliance involved the seamless transmission of test results to a designated phone application, facilitating a data exchange. This approach aligned with the rigorous standards upheld by Notified Bodies. Importantly, it was determined that a visual indicator was essential, leading to the inclusion of a light-based indication on the device in subsequent iterations. These suggestions were integrated into the new design iteration, improving the device's alignment with the criteria set by regulatory authorities. This integration also contributed to a clearer path towards obtaining regulatory approval and entering the market.

3.1.5 Further iteration

Following the insights garnered from user validation and expert consultation, a decision was reached to refine the form of the testing unit. While some adjustments were considered for the application based on received feedback, the focal point remained the further iteration of the device's form.

The renewed exploration of form commenced by maintaining prototype 3's functional foundation. This still entailed linear forms (fig 51), varying thicknesses, and ergonomic holding angles. The objective was to harmonize softer circular shapes with extended dimensions, facilitating ease of immersion from one end. This encompassed practical considerations, such as the optimal length of the dip element, comfortable grip width, manoeuvrability, and the manipulation of the test paper. Additionally, emotional aspects were addressed, including the device's perceived sturdiness and gentleness.

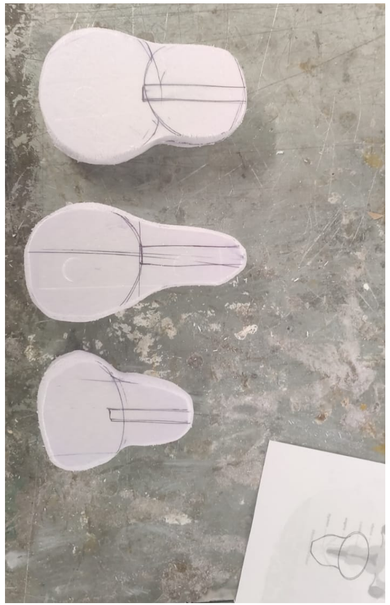


Fig.51: Linear iterations



Fig.52: Form exploration

To enrich this iterative process, an approach was undertaken, inviting participants to share handheld objects (Fig 52) they found ergonomically pleasing and elucidate the rationale behind their preferences. The study of these objects unveiled trends, particularly in how their design guided users' actions and incorporated symmetry. Building upon this inspiration, a range of forms was generated, emphasizing bending in alignment with the intended use—specifically, the act of dipping the urine test. This step in the product system warranted focused attention.

Further exploration encompassed the inclusion of designated thumb positions. However, feedback indicated that such markings inadvertently constrained users, hindering their preferred method of interaction. Furthermore, a pivotal observation was made that the cuboidal form, while structurally sound, seemed to dilute the favourable attributes of softness and delicacy.
Iterative designs (Fig 53) were subject to review by past participants, who offered associations and insights. Notably, feedback highlighted the persisting perception of the form as soft and comforting, consistent with earlier user validation preferences. This sentiment was regarded positively.
These iterations resulted in the final rendition of the form. This form and its functional use is described in the next section.

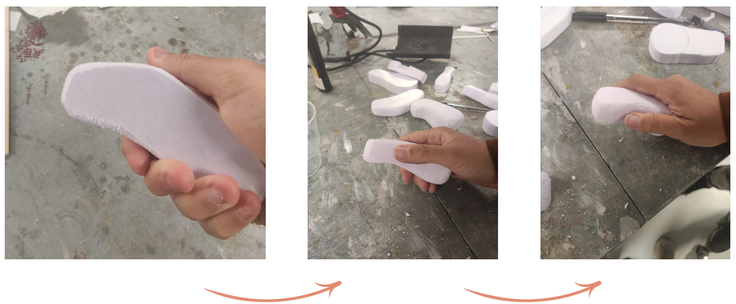


Fig.53: Form development

3.1.6 Design Freeze

The culmination of the SureSign device is an outcome to the iterative design process driven by insightful user feedback. The refined design showcases a harmonious symmetrical and rounded form, a result of careful consideration of user interactions and preferences. Notably, the design's distinctive feature, a weighted bottom extending gracefully, draws inspiration from the female reproductive system (fig 54). Throughout the ideation phase, deep consideration was given to the user's identity, fostering inspiration for the creation of organic and user-centric shapes that seamlessly blend function and aesthetics. This meticulous attention to design elements ensures that SureSign is not only a reliable diagnostic tool but also a thoughtful and visually appealing companion for women's reproductive health. This tool is made to not intimated its user while in use, also not to make the process feel sterile. It is understood through the whole project process that for any type of user, this testing process is a practical need and equally so an emotional one. This has been a key consideration and a valued insights thought this iteration process.

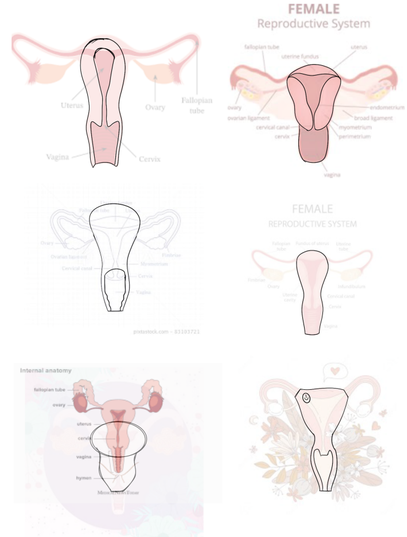


Fig.54: Form inspiration

1. Apart from the iteration in the form itself, a light indicator has been added to communicate certain functions that don't require the phone, such as attaching and detaching the sensor, establishing a connection, and confirming the device-phone link.
2. Furthermore, in response to user preferences for clear guidance on placing the device during the test process, the design incorporates a standing feature. This allows the device to remain upright, preventing contact between the absorbent pad and other surfaces.

With these definitive design choices (Fig 55), the ideation and conceptualization phase concluded, marking a design freeze. The subsequent section delves into finer aspects of the product system, encompassing material preferences, implementation strategies, and addressing limitations while charting a vision for the future.

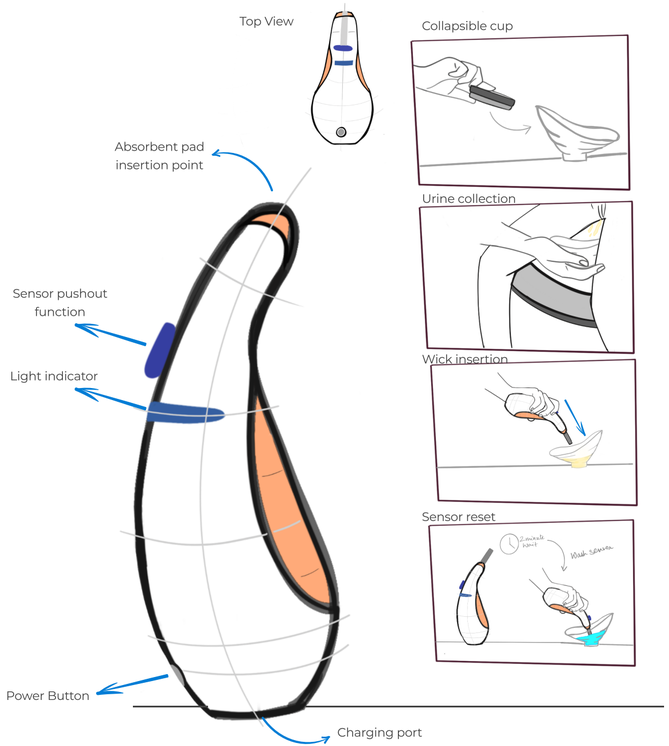
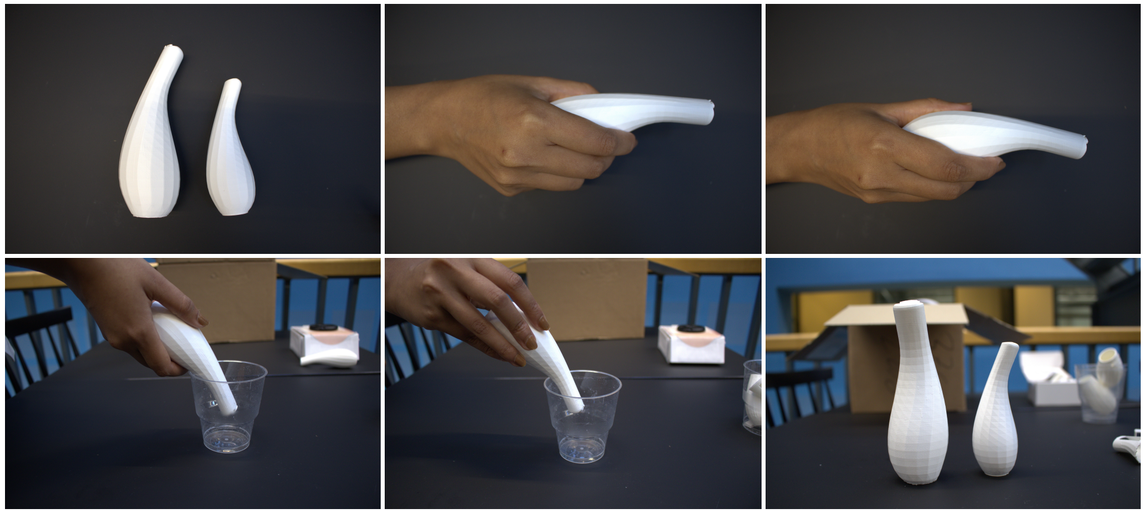


Fig.55: Final Design



With the form being developed (Fig 53), it was tested for its actions and easy of use. Two different sizes were explored and it was decided to take forward the bigger size.

Fig.56: 3D printing explorations

3.2 SureSign: Final Product System

3.2.1 Final Product Specification

This concluding chapter delves into the ultimate design of the product system following its incorporated modifications. It outlines the essential resources, encompassing materials and other elements, requisites to produce such a system. Additionally, it maps out an implementation strategy for Pharmista, considering the sequential phases through which they can progressively release the product system as a whole and attain circularity.

In order cater to these goals, the article 'Building Sustainability into Medical Devices' highlights six pathways (fig 75) of delivering more sustainable device (Building Sustainability Into Medical Devices, n.d.). This pathway highlights the need of sustainability at different stakeholder levels. This is similar to the insights gained from wanting to achieve a circular product system.

Taking these 6 pathways in considerations is a valuable process, but the process of distribution is beyond the scope of the project, hence is not taken into consideration further.

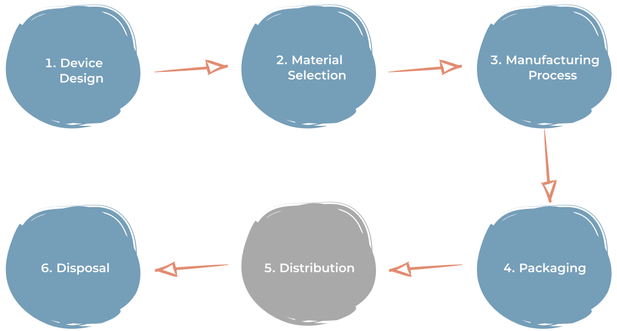


Fig 57: 6 pathways

1. Final Product System Design

With the final design of the device and the application developed, this section the detailed design decisions and use of the SureSign product system.
The Device specifications are further detailed out in appendix I.

1. User need for testing:
This entails whenever the user has the need to test. For Recurring users, they will have the device already in possession while for new users, it would be buying the product system (this is based on their need to test sustainably and/or multiple times.



Packaging and Casing

SureSign comes with a testing device, a supporting mobile application, 15 test strips (absorbent pads) and a collapsible cup in the packaging. The packaging is compact for easy storage and has everything that a user would require in the test taking process.
Additionally, the packaging comes with a QR code, which lets you access the application where the test result interoperation takes place





Application

The application supports the functionality of the test taking process. The application has to be installed to use it. It directs the user in how to take the test, for an error free empierce.



1. Insert the strip in the testing unit



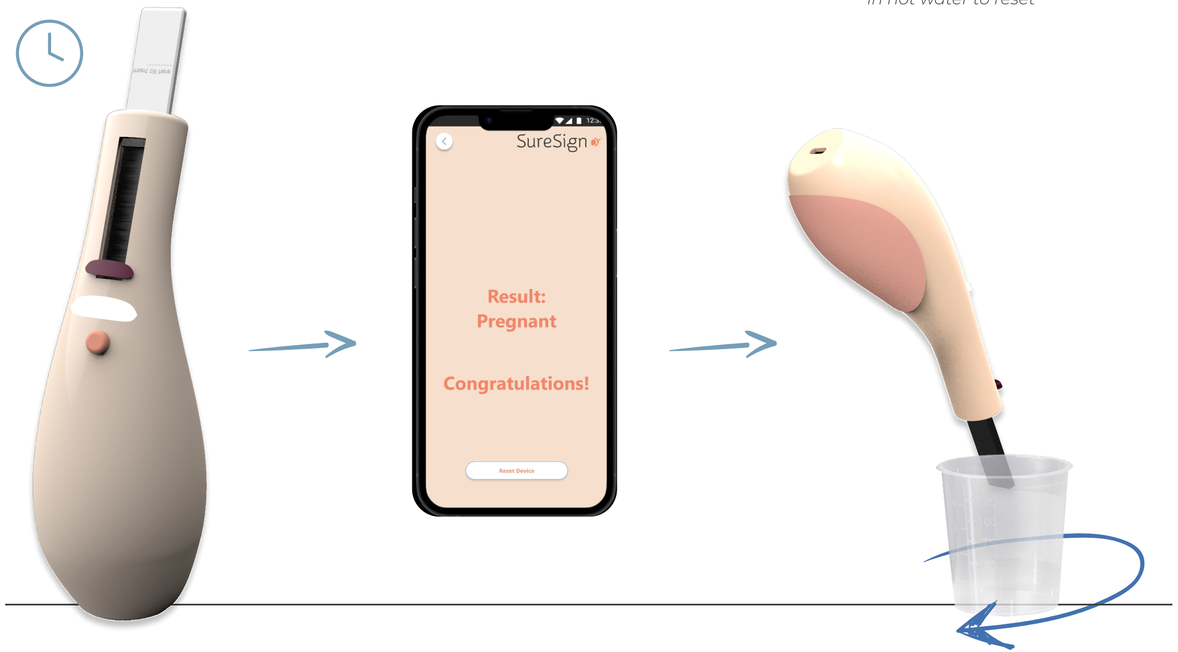
2. Dip test in urine



3. Wait for result interpretation

4. Get interpretation

5. Expose sensor an swirl in hot water to reset



Mitigation strategies : Additional considerations

There is always a case for error and incorrect use of a device. Even though that can be something that can be mitigated with over time for consumer goods, the same is not the case for medical devices. To meet regulatory requirements, companies need to exhibit a robust risk management strategy. This involves recognizing, evaluating, and managing processes to avert failures. Additionally, they should be capable of conducting risk analysis to anticipate potential issues that might arise when utilizing a medical device (Mitigating Risk Through Quality Management in Medical Device Manufacturing, 2021). The table 9 below showcases the most directly impactful risk factors to already consider and mitigate for.

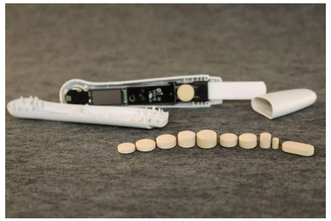
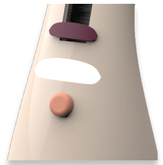
Type of risk	*Description*	*Mitigation Strategy*	
1. Moisture in the device	The sensors use and re-use revolves heavily around contact with liquids, in the case urine and water. In the case for SureSign, the device has electronic components, which need to be kept in well shape for use. Additional due to its nature of reusability, there should be no contamination with the sensor channel. This requires a mitigation of controlling moisture within the device. For this, inspiration from existing solutions can be implied for this case	A moisture absorbent padding is placed between the gap between the shaft of the sensor and the electronic board.	
2. Error codes in use	When the device functions in its correct form, it requires very little intervention. But the possibility of incorrect use in case of user or system malfunction, the design must address the error cases that are possible.	1. Visual indication on the device itself and application error screen can allow these situations to get fixed. It will inform the user of incorrect or incomplete sensor placement, low charge and not enough urine sensor contact.	

Table 9: Mitigation Strategies

It was previously indicated by Pharmista that the goal with making this product system is to eventually produce about 100,000 units. Keeping that in mind, the following parts highlights considerations made according to this unitary requirement set up by Pharmista.

2. Material Selection

Device Body:

For the main body of the device, plastic polymers in general have an advantage in the context of medical applications. Choosing polymers possess some inherent properties like diverse manufacturing options and recyclability (Rapiddirect, 2022). These considerations are advantages for the production needs of this product system.

For the choice of plastic for the main body of the device, there are multiple options to choose from, but an important factor to keep in mind is its compliance with medical grade levels at the manufacturing level. Looking into the variety, Polypropylene stands out as a widely employed plastic renowned for its robustness, longevity, flexibility, and its ability to withstand chemicals and electrical currents(The Rodon Group®, n.d.). This is also seen as an acceptable practice in the development of diagnostic devices. Addition for the soft half sleeve of the product, medical grade silicon will be utilised.



Fig 58: Medical Devices manufactured with injection moulding

3. Manufacturing processes

As for the manufacturing process, injection moulding (fig 58) of Polypropylene is a common practice in the medical device field. To explore the use of injection moulding as a choice of manufacturing, a rapid manufacturing company(WAYKEN) manages to highlight key factors that make injection moulding versatile(WAYKEN, 2022)

1. Regulatory Compliance: Medical injection moulding ensures the production of components that adhere to stringent industry standards set by regulatory bodies such as the FDA. Plastics used in this process are easy to sterilize, resistant to contaminants, and require minimal finishing, aligning well with medical equipment requirements.

2. Cost Efficiency: The automated nature of medical plastic moulding results in cost savings, especially for large-scale production. Reduced labour needs and the ability to reuse moulds contribute to lower per-part costs.

3. Material Versatility: Injection moulding accommodates various materials, making it suitable for plastics, fibres, composites, and more. For medical applications, the focus is primarily on medical-grade plastics, which are compatible with this process.

4. Precision and Accuracy: The medical field demands high dimensional accuracy for patient safety. Injection moulding excels in achieving precise dimensions and tight tolerances due to its automated nature, minimizing human errors.

5. High Reproducibility: Medical devices like syringes and masks are often designed for single use. Injection moulding ensures high-volume production consistency, making it an ideal choice for mass production of such disposable medical products.

6. Reduced Material Waste: While waste is generated during injection moulding, the process allows for recycling excess material scraps for subsequent production. This characteristic minimizes material wastage, aligning with sustainable manufacturing practices.

A consideration to take into account is that for the start up cost are high. This means, there needs to be an evaluation of the unitary production value before this manufacturing method is taken up.

Technological requirements of the testing unit:

With the input of the experts at Pharmista, there was a basic set up (impending changes based on the reusable sensor development) created to map (Fig 59) what all would be required to run this device keeping in mind its function with the SureSign phone application.

1. PCB Board: The Printed Circuit Board (PCB) is the physical foundation that holds and interconnects all the electronic components within the testing unit. It provides a stable platform for component mounting and efficient signal routing, ensuring proper functionality of the entire device.
2. OP-Amp (Dual): An operational amplifier (OP-Amp) is a component used to amplify and process analog signals. In the testing unit, the dual OP-Amp serves to accurately amplify and condition the signals from the sensors, ensuring precise and reliable measurement of pregnancy-related biomarkers.
3. Microcontroller: The microcontroller is the brain of the testing unit. It processes data, executes control algorithms, and manages communication between different components. It enables the device to perform complex calculations, user interactions, and data transmission.
4. USB-C Type Charging Module: The USB-C charging module provides a convenient and versatile way to recharge the testing unit. It allows users to connect the device to a power source via a USB-C cable, ensuring the unit remains operational without the need for frequent battery replacements.
5. NFC Module: The Near Field Communication (NFC) module adds wireless communication capability to the testing unit. It enables interaction with compatible devices such as smartphones or tablets. Users can easily retrieve and store test results or access additional information through NFC-enabled devices.
6. LED Strip: The LED strip is a key component used for indicating additional communication between the testing device and the application. It consists of a series of light-emitting diodes (LEDs) that illuminate to provide visual feedback to the user.

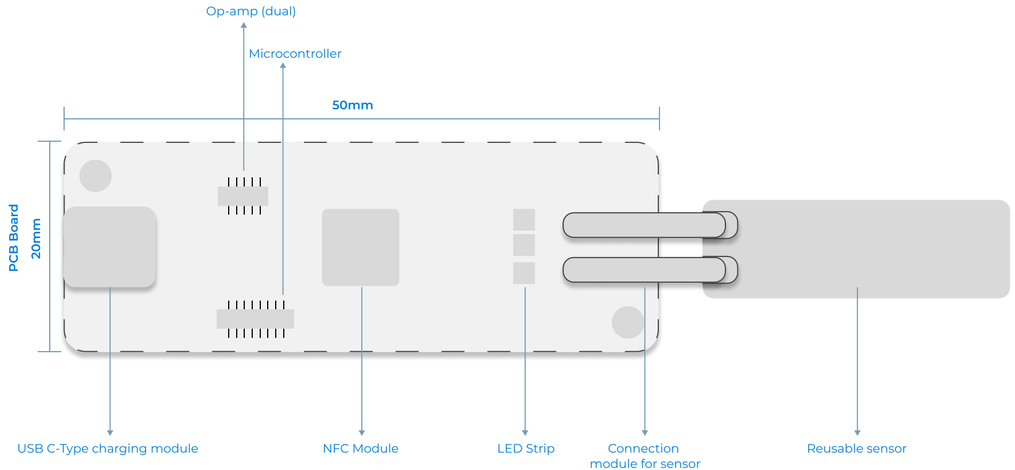


Fig. 59: Pharmista test with electronics

4. Packaging

With this being a medical device, the packaging (Fig 60) has the need to also meet standards that are set in order for it to be approved by the notified bodies at the time of evaluation. Every medical device and in-vitro diagnostic device (IVD) must be accompanied by a well-defined label, user instructions, and, if applicable, a display. This ensures the device's identification, manufacturer information, and promotes safe and accurate usage of the medical device (Ministerie van Volksgezondheid, Welzijn en Sport, 2022). Additional details to this are in Appendix H.



Fig. 60: Packaging Prototype

5. Disposal

In the scope of the Pharmista project, the current testing capacity is limited to a maximum of 10 uses, a substantial improvement compared to existing single-use alternatives. However, this doesn't align with the ultimate objective of the product system. Disposal is a crucial part of creating a circular structure for a product system to follow. As the current design stands, the eventual disposal of the entire product remains a concern. In pursuit of a comprehensive circular approach, the report elaborates on strategies to address this challenge. These strategies are outlined in various phases of implementation, with the aim of achieving full circularity in the product's lifecycle.

3.2 Comparative Analysis: Advantages Over Current Competitor

Assessing the thesis's outcomes necessitates a comparative analysis between SureSign and the existing market competitor. This approach enables a comprehensive understanding of the areas where the proposed solution has excelled and identifies areas that can benefit from further development, drawing inspiration from established industry benchmarks. In this case, the industry standard taken into comparison is the Clear Blue Digital Test and the comparative analysis revolves around three themes.

The information is acquired from the Clear Blue sustainable and social responsibility page (Clearblue, 2022) and a BBC article uncovering the technology and use behind digital pregnancy tests (BBC News, 2020).

Product / Themes, +ve & -ve	Clear Blue Digital Test:	SureSign Product System
User Experience		
Advantage	1. Quick on the go use 2. Interpretation window is clear in communication	1. Clear interpretation 2. Storage of results (in application) 3. Economical choice, based on the 10-use scenario
Disadvantage	1. Does not provide a collection vessel for urine 2. Aiming at the absorbent wick in difficult and not user friendly 3. Storage of test is not long term (results disappear in a time frame). 4. Expensive choice (4 times higher than non-digital options (BBC News, 2020)	1. Does not provide a collection vessel (but is intended to in the future) 2. One time setup required, not a quick setup
Environmental impact:		
Advantage	1. Clearblue® product leaflets are made from 100% recycled paper (Clearblue, 2022). Clearblue® Innovation Centre in the UK uses 100% renewable energy and sends zero waste to landfill (Clearblue, 2022).	1. Recyclable material use 2. Multi-use function
Disadvantage	1. Single use waste. In the form of battery and digital screen 2. No circular feedback loop 3. Only few Clearblue test use recyclable components in their production (Clearblue, 2022). 4. The circuit board featured a "surprisingly complicated chip" which becomes part of landfill after one use (BBC News, 2020).	1. Currently lacks in set processes in manufacturing, which can have some negative outcomes
Long-term value:		
Advantage		A product that integrated and caters to enhancing the experience for the test taker. Reuse allows better utilization of resources.
Disadvantage	Single use and throw option, generation of e-waste (BBC News, 2020)	

Table 10: Comparative Analysis

While this preliminary comparison offers insights at a surface level, conducting a comprehensive Life Cycle Analysis (LCA) for both product systems would yield a more insightful assessment. However, this simplified analysis already highlights that in the current context, ClearBlue digital falls short in terms of its environmental impact and long-term value. On the experiential front, it does address certain user pain points, yet, as previously discussed, there remain unaddressed challenges. Despite being an industry leader for over two decades, ClearBlue has exhibited limited adaptation to the evolving user needs. This is precisely where the SureSign system emerges as a more promising alternative, poised to address these shortcomings and offer a more comprehensive solution.

4. Conclusion

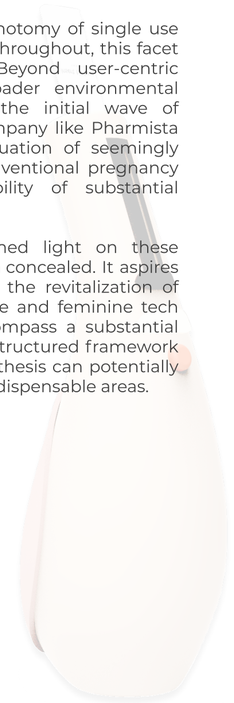
The essence of this thesis project lies in revitalizing an experience that has remained stagnant for a considerable period, despite the evolution of user expectations and changing contexts. The realm of pregnancy detection, though well-established, encountered a noticeable innovation plateau back in 2003. This initial observation led to a pivotal question: why has innovation in this field remained largely dormant? This inquiry framed the initial scope of the project.
Enter Pharmista – a company driven by a parallel commitment to innovation, albeit with an emphasis on sustainability. Their involvement lent invaluable support, for their expertise offered a complementary dimension to the project, focusing not just on experience enhancement, but also on ensuring its environmental harmony.

The investigation swiftly revealed focal challenges: the complexities of urine collection, the intricacies of interpretation, and the potential of multi-test utility. These challenges provided a roadmap for the project's direction. However, it became evident in the ideation phase that addressing the intricate problem of urine collection warranted an exclusive research and iterative journey, prompting a premature halt to its development.

Concurrently, addressing interpretation challenges emerged as a central objective. Recognizing the test's profound impact on both intended and unintended aspects of user lives, it was clear that relinquishing interpretation to guesswork led to unnecessary stress and mental strain. This aspect was addressed and refined accordingly.

Lastly, the project grappled with the dichotomy of single use versus multi-use. Though subtly present throughout, this facet significantly influenced the project. Beyond user-centric considerations, it underscored the broader environmental impact, an aspect overshadowed by the initial wave of advancements. The significance of a company like Pharmista came to the fore, prompting a re-evaluation of seemingly unblemished processes, such as the conventional pregnancy market. This underscored the possibility of substantial transformation.

In culmination, this thesis aims to shed light on these multifaceted intricacies that often remain concealed. It aspires to serve as a blueprint for approaching the revitalization of other products within the medical device and feminine tech domains. These sectors collectively encompass a substantial portion of the global population. With a structured framework in place, the principles elucidated in this thesis can potentially catalyse revolutionary changes in these indispensable areas.



4.1 Limitations and Recommendations

This section sheds light on certain aspects of the thesis where opportunities for enhancement exist. The exploration of pregnancy detection, a multifaceted subject, encountered limitations across various phases of research and development.

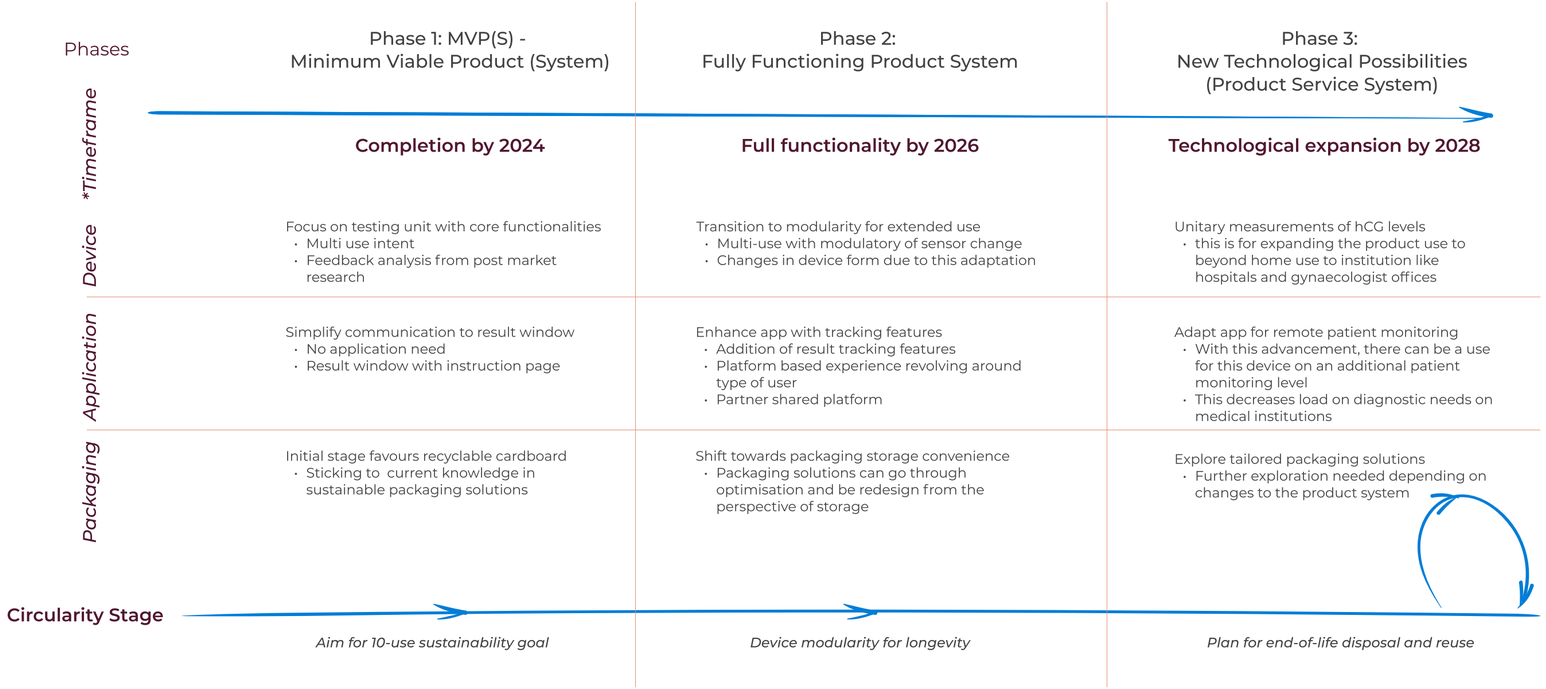
One noticeable limitation surfaced during the initial stages of development, centred around the collection of urine—a central yet challenging aspect of the testing process. While urine collection presents similar difficulties in various diagnostic scenarios, this thesis did not delve into an all-encompassing solution for this issue.

In the design process, a thorough blend of formal and informal user feedback significantly contributed to refining the product system. Despite the valuable insights gained from this evaluation process, there exists a limitation in not directly involving the target audience in the testing phase. This gap suggests the need for a subsequent round of user evaluation, particularly focusing on assessing the device's form after the initial formal evaluation.

Lastly, there is a need to investigate the production and distribution processes further, since these key steps also hold importance in a circular system. Currently this area was briefly explored, but it needs further investigation.
These limitations are not perceived as shortcomings of the design but rather as stepping stones toward future advancements. The recommendations for this project are two-fold. Firstly, immediate recommendations following the project's conclusion involve the further development of a user test or study. Aligning user testing with a comprehensive evaluation involving the target audience, as already considered in Pharmista's current plans, can propel the project's progress.
For the long-term, the subsequent part of the report outlines an implementation strategy for Pharmista. This strategy serves as a guide to achieving the project's envisioned goal.

4.2 Implementation strategy for Pharmista

In order to successfully release this product system in the market, it is valuable to create a plan for phases of implementation for the product system to have the impact that is wishes to achieve.
A circular economy strives to reduce waste by extending the lifespan of products and recycling either the product itself or its components back into the system for reuse (Kane et al., 2018).
This requires a plan that not only has an extended life span (in this case a muti-testing capability) but also the product system to have the opportunity to have a closed loop in its use and reuse. Though this is the end goal, it is also valuable to understand the complexity of this kind of implementation, especially for a small-scale company like Pharmista. This means that there is a need to make a strategy where the product system starts from following sustainability practices to the best of its capabilities. In this case, the goal of the product (a multi-use test) already follows that on the technology front and having made sustainability centric design solutions. Hence, making these changes incremental can all the product system to reach its goal of circularity without straining the company functioning.



An elaborated verison of these phases of impementaiton can be found in the appedinx

** This timeline is based on the idea that with releasing a medical product, there is a consideration to take in terms of timeline. This is because, the scrutiny the product system has to go through requires time and adapting itself to the rules and regulations requirements. Additionally, with the change in the MDR, there has been a shortage of available notified bodies for new medical device product release in Europe.*
Hence, with further discussion with Pharmista, it is decided to pursue the approval of the FDA instead. This will potentially allow the product release to be earlier.

4.3 Envisioning the Future: Designing for Multi-Use

Within the comprehensive implementation strategy tailored to the diverse facets of the product system, an inspiring future vision emerges: the concept of multi-use versatility. This concept involves imbuing the testing apparatus with the capability to serve a spectrum of functions. Throughout the scope of this project, the primary focus has centred on elevating the pregnancy detection experience. However, the broader journey encompasses not only the testing phase but also crucial stages like conception and post-partum. This intrinsic interconnectedness renders the pursuit of multi-use versatility pertinent to both the immediate and overarching objective.

One promising avenue for such implementation lies in the realm of retesting ovulation. A parallel diagnostic field that utilizes similar detection methodologies, often employing another hormone, offers an intriguing application. This market, much like pregnancy testing, generates waste due to the nature of the test. However, it has also demonstrated a positive shift towards reusability. By embracing multi-use versatility, this innovation aligns with a sustainable and holistic trajectory for the future, while effectively addressing waste generation in a related diagnostic context.

4.4 Refection

As I reflect on this project's journey, I realize that it has provided me with more learning than I initially anticipated. Starting with a simple idea of contributing to women's healthcare improvement, I'm amazed by how this concept has evolved into my graduation project.

At the outset, I believed I had a good understanding of what I was getting into. However, as the project unfolded, I found myself encountering a broader range of experiences and insights. This project pushed me to explore my design skills in depth, testing my creativity in ways I hadn't expected. Overcoming challenges, including creative blocks and moments of inspiration, has shown me the extent of my design capabilities.

This project also highlighted my need for self-discipline, as working on such a comprehensive project alone demanded a different level of focus. Looking back, I can see how these challenges have contributed to my growth and learning.

As I wrap up this phase of my education, I'm grateful for the education I've received at the TU. This project serves as a meaningful conclusion to my academic journey here, encapsulating what I've learned about design and about myself as a designer. Armed with this knowledge, I'm excited to continue applying design principles to create valuable solutions and experiences in the real world.

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