Engineering Design of a Pregnancy Test for Visually Impaired Users

Final Report

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Abstract

For many women, pregnancy is one of the most emotional experiences in their lives. However, there are millions of visually impaired (VI) women who do not have access to a convenient and confidential method of testing for pregnancy as there are currently no such products on the market.

Our project aims to provide VI women with a discrete alternative to the current pregnancy tests, which would provide results without the need of vision. To have a better understanding of this matter, blind women from China and Romania were contacted to gain insight into their priorities and preferences. It was found from their feedback that current pregnancy tests cannot satisfy the basic needs for privacy and ease of use.

It was decided to design a pregnancy test with auditory and tactile components to communicate results to the users without assistance. The group split into teams to work on separate tasks and met on Microsoft Teams twice a week to collaborate.

After considering a few designs and evaluating feedback, a design that used a servo motor and a buzzer to communicate results was chosen. The test consists of a PCB that detects results from a pregnancy strip and sends signals to the motor and buzzer. The buzzer will emit different sounds and the motor will cause a block with two different shapes to rotate in different directions depending on the result.

Testing was conducted at every stage and iterations were made accordingly to ensure the reliability of our circuit, casing, and overall design. The evaluation of the final product showed that the design adequately satisfies the needs of the users as specified in the PSD.

Acknowledgments

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Contents

1 Introduction

There are at least 2.2 billion VI people worldwide[1] of which about 55% are women[2]. As a result of this impairment, they often struggle to carry out menial tasks, such as reading and walking. This has led to the development of Braille and other technologies to assist them in their daily lives. Despite these efforts, there is still a significant lack of support in some crucial and consequential aspects of life, such as pregnancy.

The exisiting method for VI women to find out if they are expecting a baby is to use a normal pregnancy test and then interpret the result using one of the options presented in *Table 1*. Current pregnancy tests use a lateral flow strip which displays the result using the appearance of 1 or 2 coloured lines. The result cannot be understood independently by a VI woman.

Table 1: Existing solutions

In person assistance	**Voiceover Image recognition**	**Clearblue and Be My Eyes app**
		
Until recently, the only option was to take a standard test and ask a visually-abled person to view their results for them.	Some smartphones have a function that can recognize what is in an image and read out a desciption. The user could take a photo of their pregnancy test and listen to the voiceover.	In 2019, an app called Be My Eyes[3] was developed which links VI users to volunteers via video chat. They collaborated with Clearblue, a prengnacy test brand, so that after taking a test, users can use the platform to anonymously call a specialist customer support advisor, who will inform them of the result.
All women surveyed during the project stated that they want to be the first person to finds out if they are pregnant. (*Appendix F*)	As the app describes everything that is in the view of the camera, it may be hard to get a reading from a small object as a pregnancy strip. "We want independence, not to use an app. Some women might not have phones." – surveyee (*Appendix F*)	The VI women surveyed stated they would like independence and to have an experience as close to normal as possible. "Existent option problem: waiting too much for someone to be available." – surveyee (*Appendix F*)

It was found that 100% of those surveyed still feel uncomfortable with these methods (*Appendix F*) and would much prefer to receive their results without any help from others. This desire for privacy is consistent with global feedback from a survey conducted by Clearblue[3]. More specifically, these women want to feel independent and be the first to find out their results. This is especially important for them because pregnancy is a very emotional topic and many VI women have reported feeling anxious having to wait for others to determine their results.

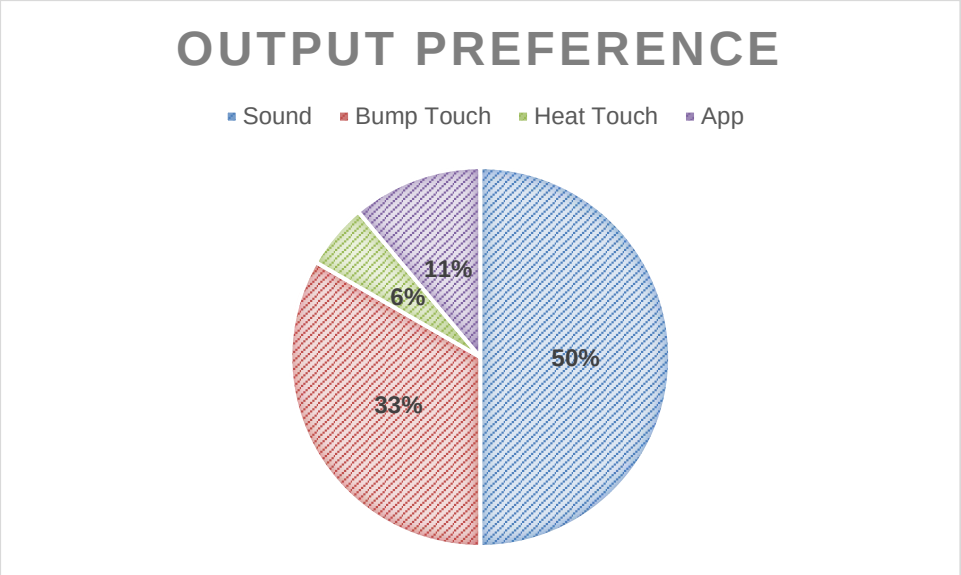

Figure 1: Pie chart of the preferred method of receiving results

This motivated the project group to create a solution that would provide them with the independence that they desire. The main objectives of this project are to find an efficient and discrete method to communicate the results through tactile and auditory means due to the preferences of those surveyed, as shown in *Figure 1*.

2 Requirements Definition

To find the expected requirements of this project, a questionnaire was created to ask VI women what features they would like to see in the design. Based on these results, as well as the guidelines for this category of product, a list of requirements was raised.

The test should be easy to use for a person with limited or no vision, ensuring safe and hygienic conditions. Given the personal nature of taking a pregnancy test, users should be able to take the test without anyone else being aware of it. Similar to the traditional pregnancy test, it should be usable anywhere, from the comfort of their own homes to a public restroom.

The requirements below are a selection of fundamental user and quantitative requirements from the Product Specification Document (PSD)[10]. The PSD number for each requirement is written in brackets.

Functionality and performance

- Detect pregnancy with 99% accuracy, indicated by a urine hCG concentration over 25 mIU/ml[11] (1)
- Communicate results through tactile and audio methods (2)
- Ensure privacy when taking the test such that its usage should not be noticed by people nearby (4)
- Able to display results in 5 mins or less and repeat the display at least 5 times and up to 12 hours – (3 & 5)

Cost

- Affordable price under £15 (30)

Dimensions and ergonomics

- Maximum test size of 5 cm x 5 cm x 15 cm based on average female hand size[13] (6)
- Intuitive orientation of test so the user can know which way to hold it (9)
- Easy urine sampling for hygienic purposes (10)
- Waterproof casing to ensure no leakage after use (17)
- Appropriate volume (between 50 dB and 65 dB) [12] and frequency of sound (between 100 Hz and 5000 Hz)[12] (12)
- Easily identifiable tactile output (13)

Safety and security

- The electrical components must not be damaged by the liquid inside the test (24)

3 Final Design

3.1 Assembly and Overview

For the device to be appropriate for as many people as possible, it was considered that the users may have other disabilities, such as hearing impairment, hence two different output methods were chosen. The tactile part was chosen to be represented by a cube with two different shapes that would ensure that no Braille knowledge is necessary for interpreting the results. The audio part is controlled by a button, since all the surveyed women treasure their privacy.

The CAD model of the device is depicted in *Figure 2a* below, where the circuit and microcontroller are encased within the splashproof casing. In *Figure 2b* and *2c*, the prototype is shown opened and closed, respectively.

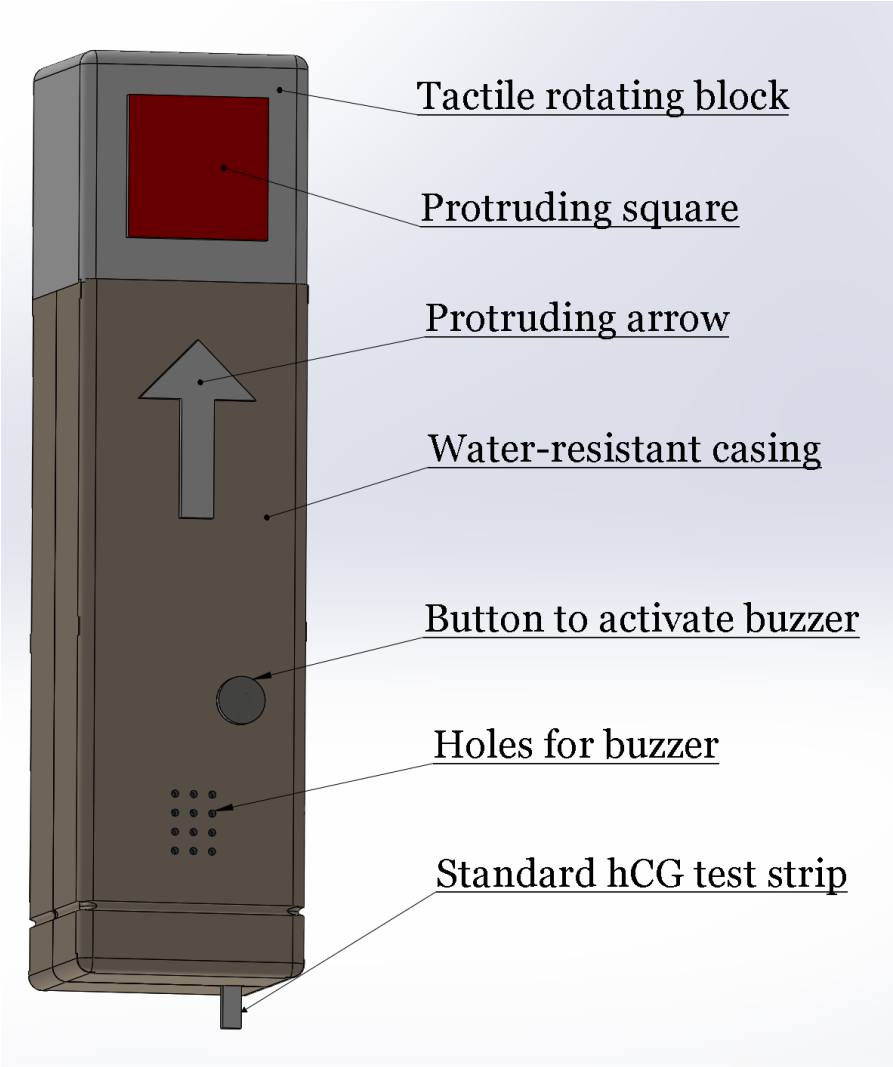

Figure 2a: Solidworks assembly of the final product displaying positive result. The colours shown are for illustration purposes only.

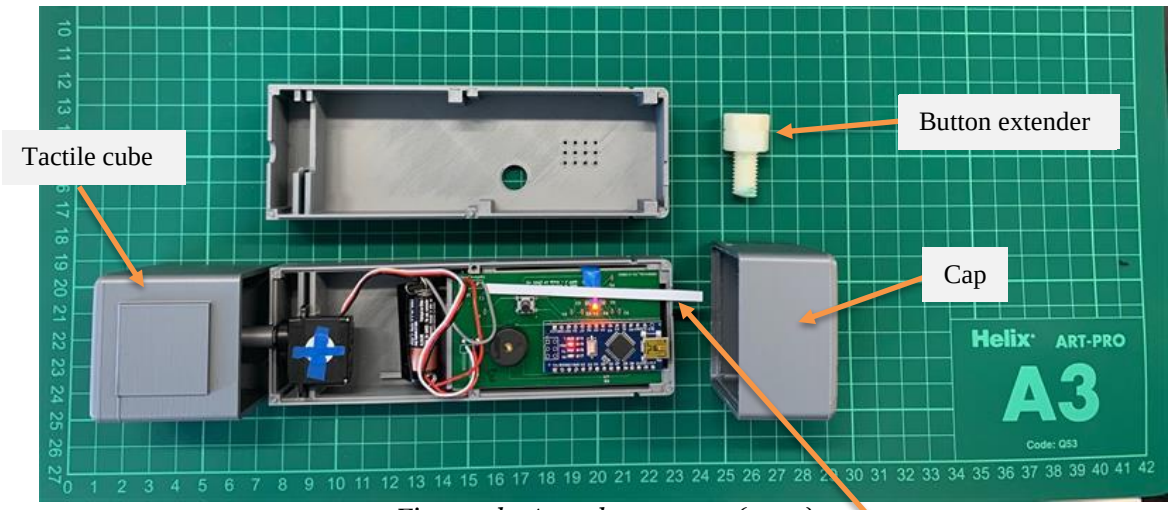

Figure 2b: Actual prototype (open)

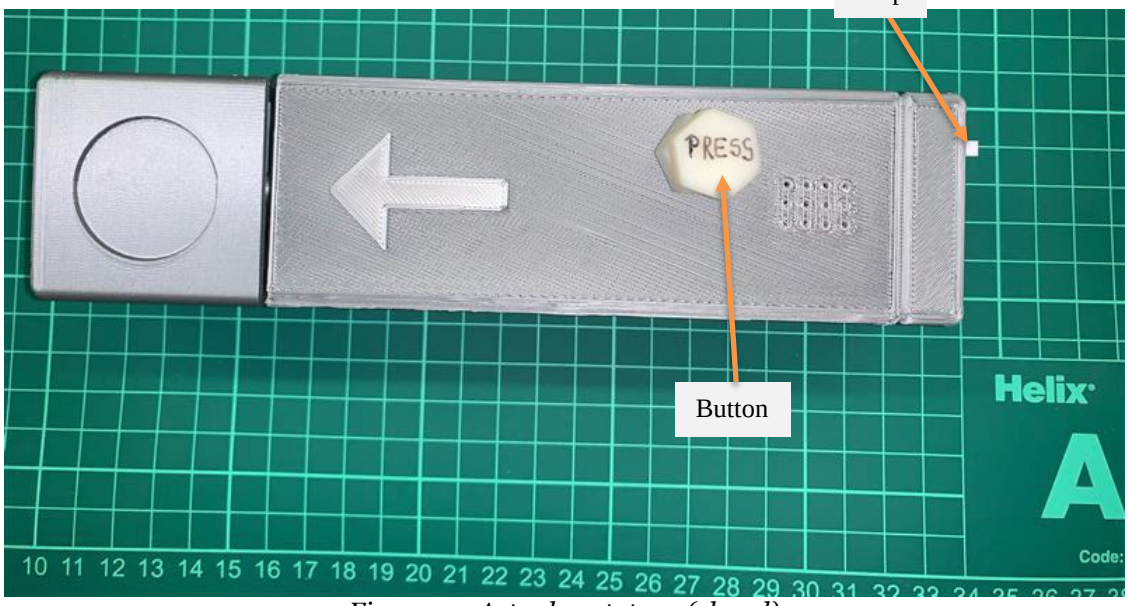

Figure 2c: Actual prototype (closed)

The final design makes use of a standard pregnancy test strip, which will detect whether the concentration of human Chorionic Gonadotropin (hCG) in a sample of urine exceeds the threshold which indicates pregnancy. Before the test is taken, the protruding arrow points towards a blank face of the tactile rotating block, which will move once the result is ready.

The user would insert the exposed tip of the test strip in a cup filled with urine and then after 3 minutes, either one or two lines (depending on whether or not she is pregnant) will appear on its inner part, which is enclosed in the casing. The PCB's LEDs will shine a light on the strip and the phototransistors will capture the light reflected from the strip. The microcontroller will process this information to interpret the strip's result. This will cause the motor to rotate clockwise or counterclockwise, aligning the shape on the cube (that corresponds with the result) with the arrow on the body of the case. If the user wants to confirm the tactile result using another method, they can press the button which will activate the audio output. For the negative result, a sequence of short, low-pitched sounds will be emitted, whereas for the positive result, it is a long high-pitched sound.

Figure 3 below shows a flowchart that explains the entire process and introduces the following subsections which will explain each part in more detail.

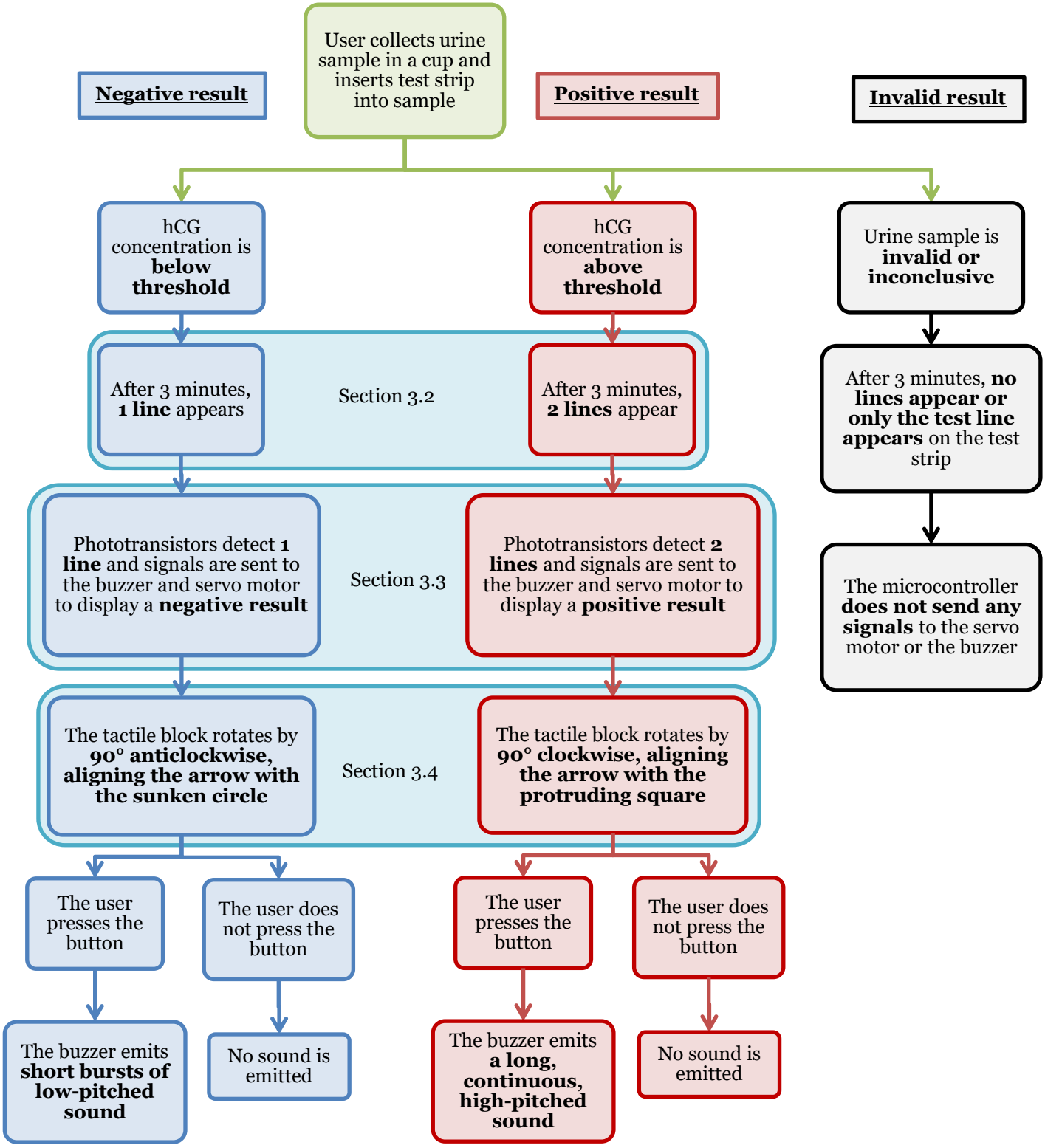

Figure 3: Flowchart describing the processes involved for the device to display positive (shown in red) and negative (shown in blue) results, or if the result is invalid (shown in grey).

3.2 Strip

The strip used is a lateral flow assay that is used in most pregnancy tests and it operates on the principle of the enzyme-linked immunosorbent assays (ELISA)[4]. After pregnancy occurs the concentration of hCG increases and reaches a detectable level after 4 weeks (above 15 mIU/ml)[5]. *Figure 4* shows how hCG is detected in urine and how the result is visually displayed.

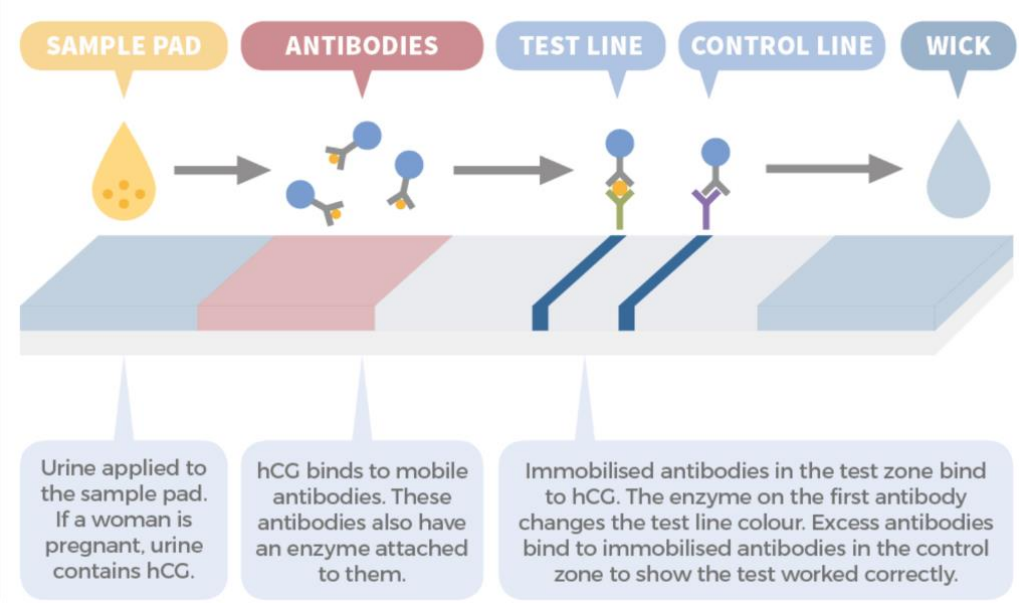

Figure 4: A diagram to show the functionality of the testing strip[6].

1. **Sample pad:** absorbs the urine and filters any proteins or bacteria that may affect the result.

2. **Antibodies:** the urine then flows through the pad through capillary flow to the next section, which contains mobilised beads coated with monoclonal antibodies specific to hCG. There is also an enzyme attached to the antibody, which is utilised later in the strip. If hCG is present, it will bind to the antibodies. There are always more mobile antibodies than hCG, which means there is some left free for control.

3. **Test zone:** the hCG-bound antibodies then flow onto a strip of treated nitrocellulose paper, which contains two lines of immobilised antibodies, a test line and a control line.

    - As the hCG-bound antibodies pass through, they bind to immobilised antibodies on the *test line*, which stops them from flowing. As these accumulate, the enzyme attached to the bead changes the test line colour.

    - Any excess beads bind to immobilised antibodies in the *control region*, which confirms the test worked correctly. Therefore, there are more mobilized antibodies than hCG.

    - If hCG is not present in urine, the test line will not pick up any antibodies and instead, they will flow to the control line.

4. **Wick:** The wick collects any excess fluid that is present.

The pregnancy strip used in the project displays results as shown in *Figure 5*.

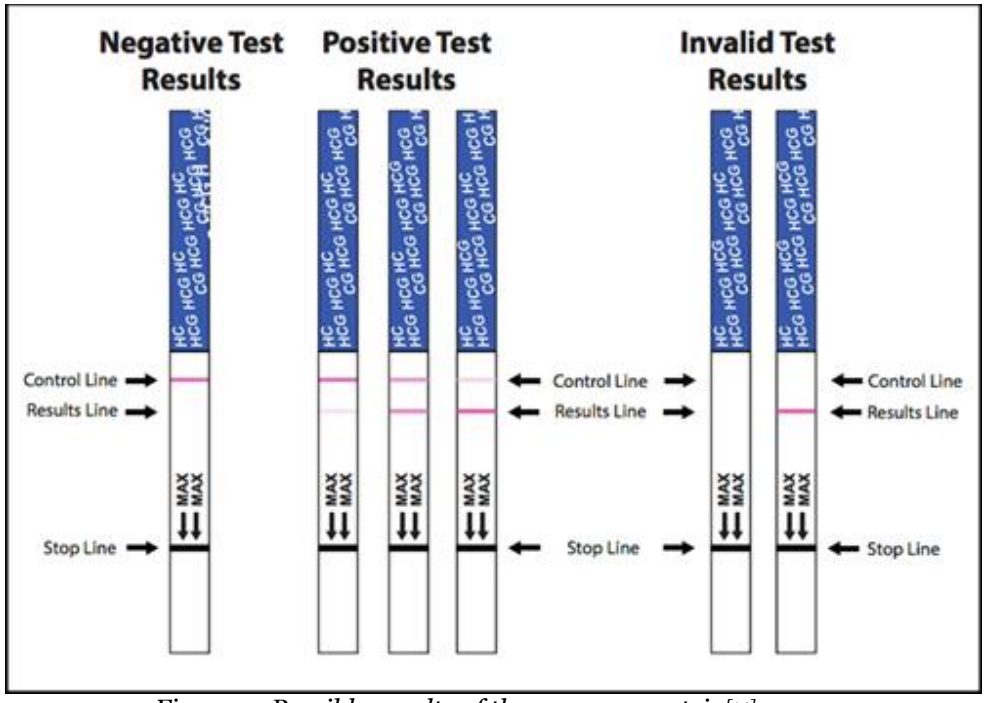

Figure 5: Possible results of the pregnancy strip[14]

3.3 Line detection

The phototransistors were chosen based on the wavelength of peak sensitivity, which was 940 nm to match red visual light waves. The other reason was its wide viewing angle so that a lot of light was collected to ensure it was able to detect the lines and to reduce the effect of slight misalignment between phototransistors and strip.

As a VI person will be unable to read the lines themselves, they should be read digitally and an alternative output produced. To do this, a section of the PCB contains 4 phototransistors and 2 LEDs laid out as shown in Figure 6. The LEDs' light reflects off the test strip and is detected by the 2 phototransistor pairs that are positioned below where the indication lines should appear. When a line is present, the strip absorbs more light, so the reflected light that hits the phototransistors decreases and a lower current flows through it. Two phototransistors in series were used for each line to increase sensitivity, as seen in the top view.

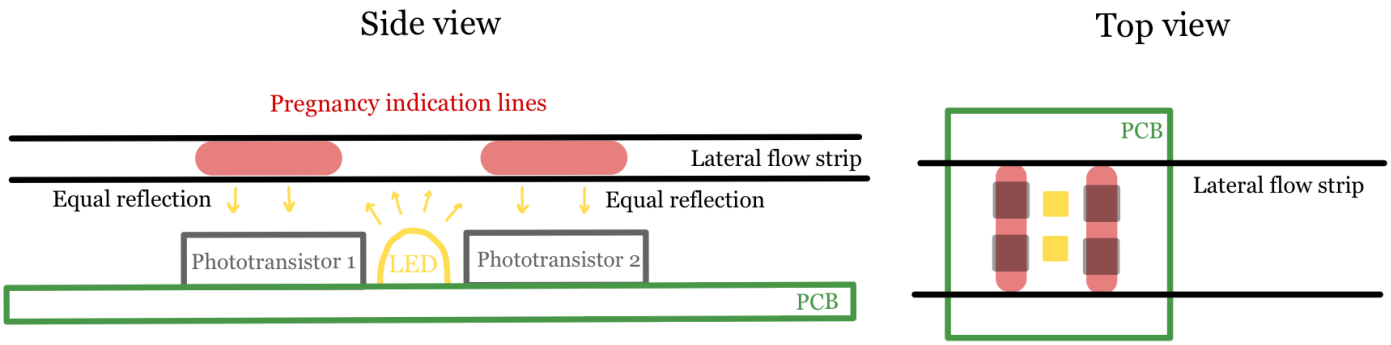

Figure 6a: Mechanism behind a positive output

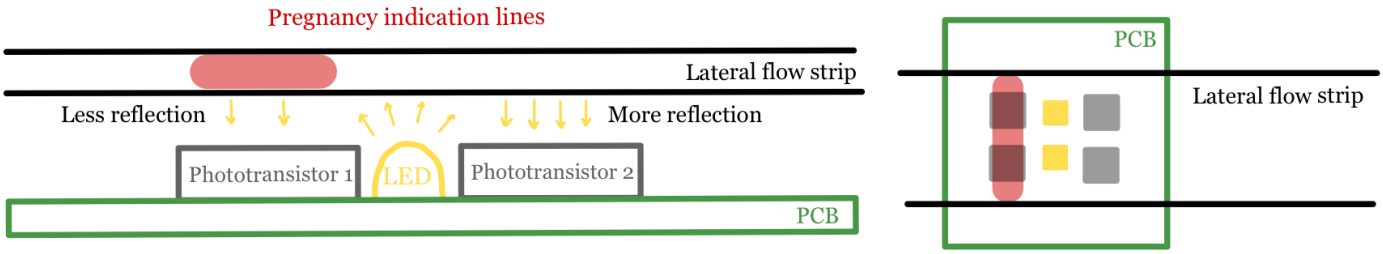

Figure 6b: Mechanims behind a negative output

Figure 6a shows the positive case in which both lines appear and the current running through phototransistor pairs 1 and 2 are equal.

Figure 6b shows the case of a negative result, in which no line appears above pair 2 and hence a higher current is produced.

The two currents are inputted into the Arduino Nano which sums each up over a period of approximately 0.5 seconds and then finds their difference. A difference over a certain threshold, found during calibration testing, indicates a negative result. A difference below the threshold is positive.

3.4 Electronic design

3.4.1 Schematic & PCB design

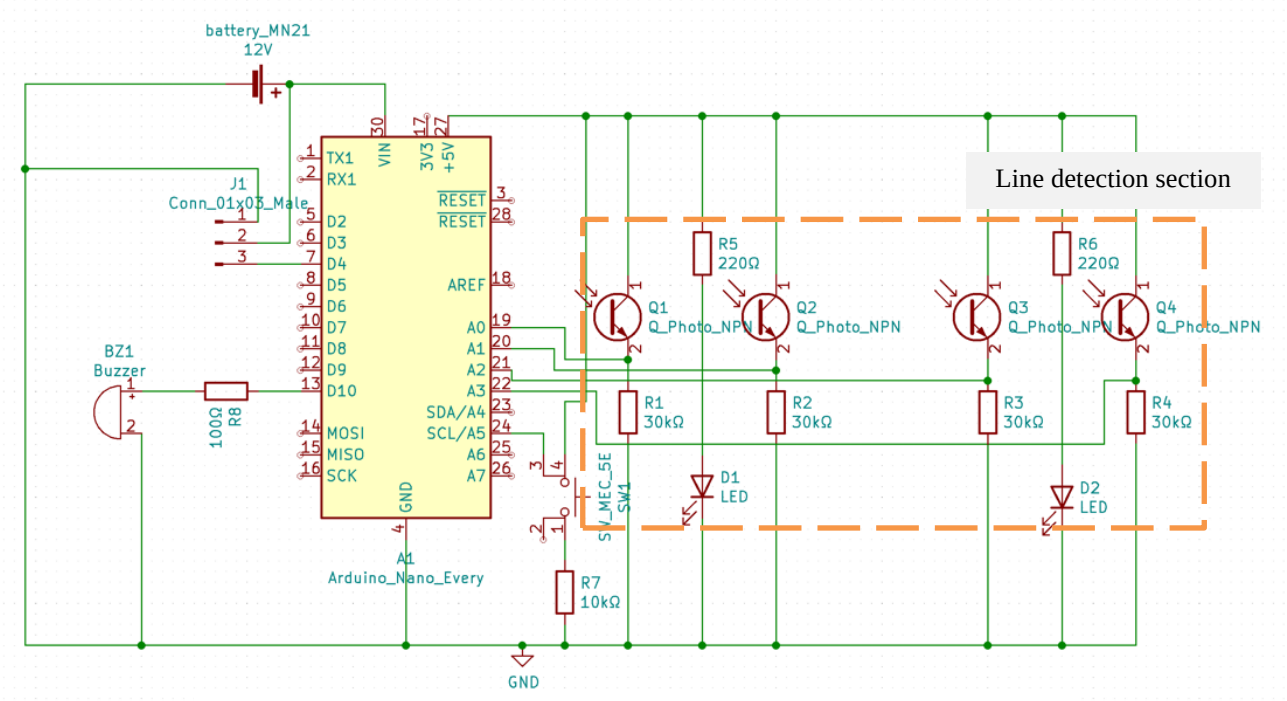

Figure 7: Circuitry Schematic in KiCAD with the Arduino Nano

KiCAD has been chosen to generate the circuitry schematic (*Figure 7*) of the project. We chose the 12V MN21 battery to provide sufficient power to the components. In the line detecting section, 4 phototransistors and 2 orange LEDs are used as described above (*Figure*

6). The results are then fed back to the Microcontroller Arduino Nano to be processed and generate the signal which activates the motor and the buzzer. The button, connected to the microcontroller, would be used to play the sound from the buzzer when the user wishes to hear the result.

In the PCB design, a 0603 footprint has been assigned to all passive components. The components from the schematic were inserted and rearranged in KiCAD using Pcbnew to generate a 2-layer PCB (*Figure 9 & 10*). While all components and tracks have been placed on the top layer (tracks in red), the bottom layer has been set to be the ground (GND, green background) for the circuit. Special alignment of the components has also been set to fit the optimal detection position on the strip. The 3D views of the top and bottom layers are shown in *Figure 8*.

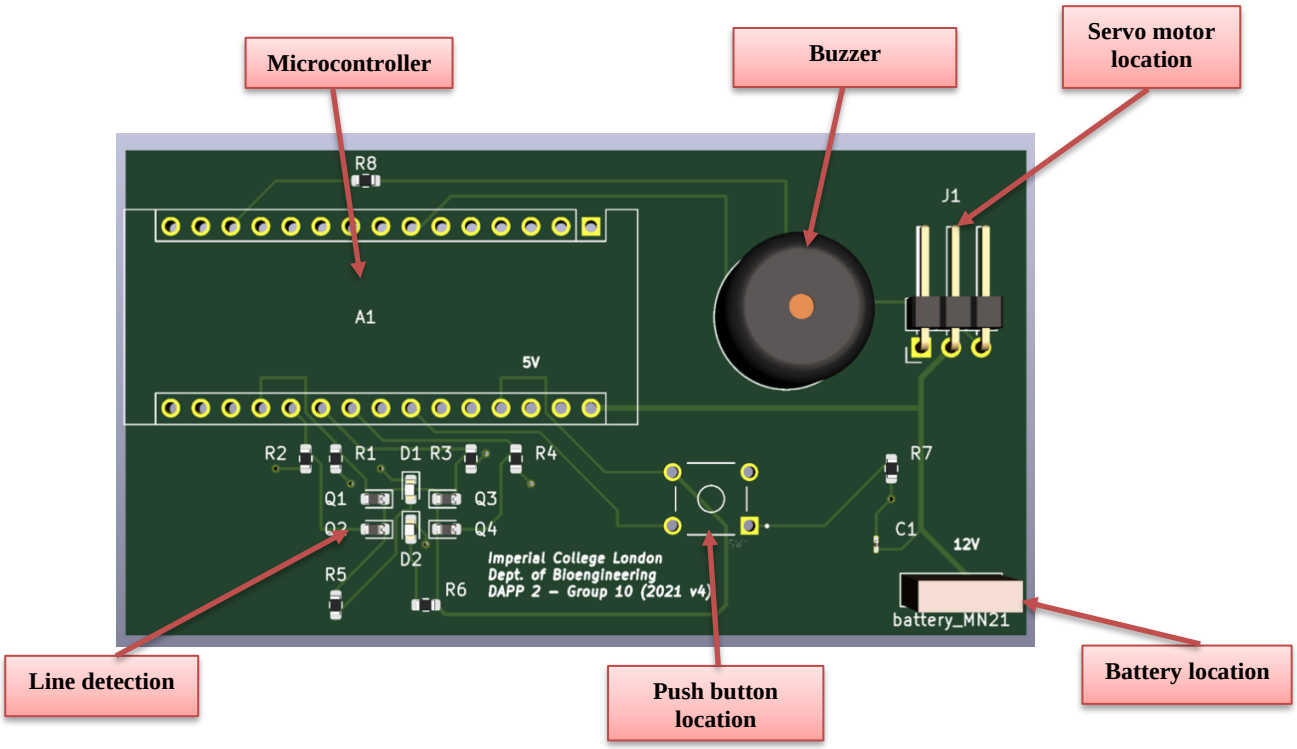

Figure 8: 3D view of the final PCB Design (top view)

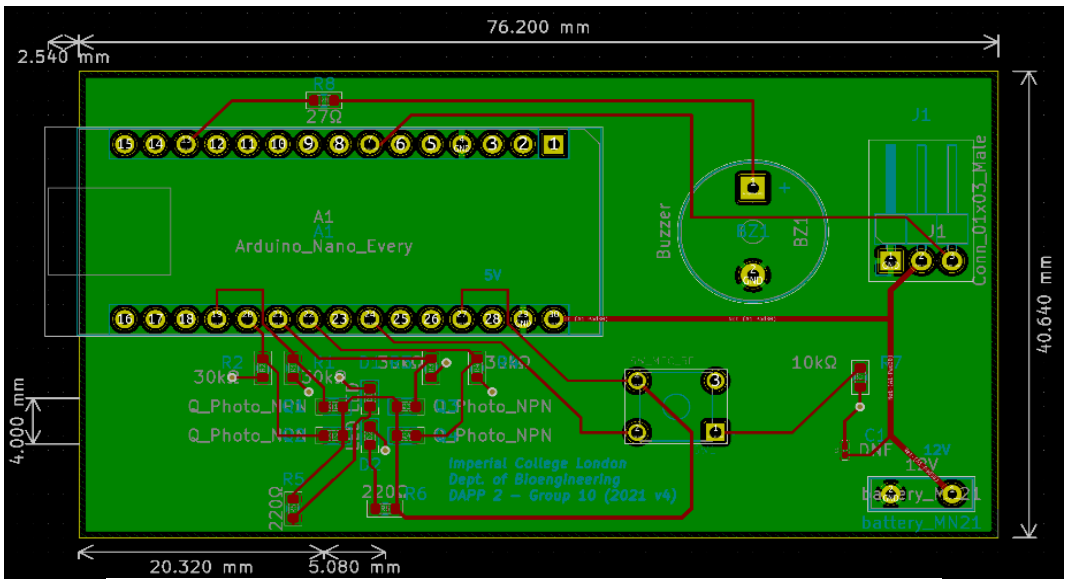

Figure 9: PCB Design in Pcbnew with the dimensions

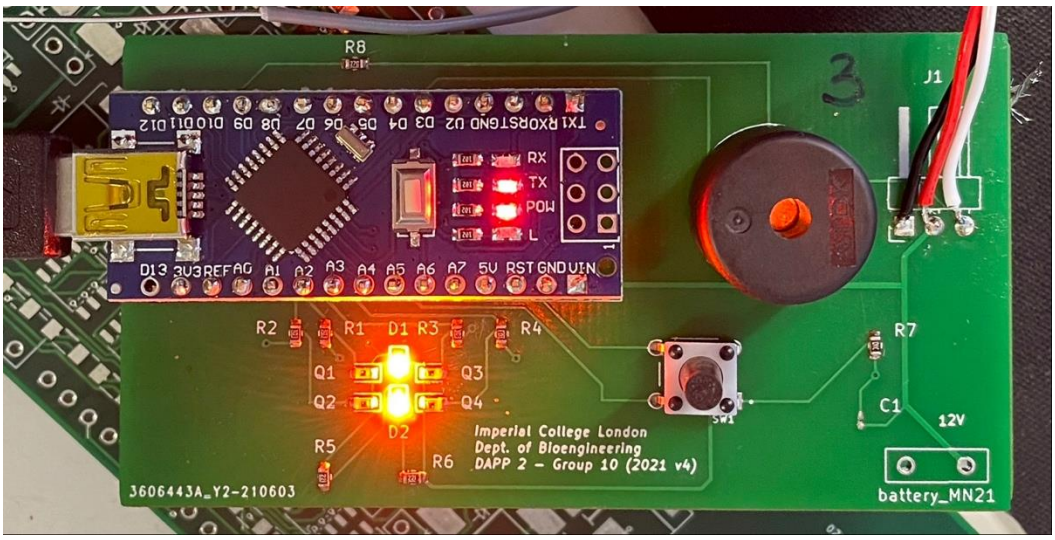

Figure 10: Physical PCB with components

3.4.2 Selection of motor, button and buzzer

Tactile and auditory output methods were selected to communicate results to the user. A SpringRC SM-S2309S micro analogue servo motor (*Figure 11*) was chosen and connected to Arduino Nano, that was programmed to make the component rotate ±90° when it receives a signal corresponding to a negative or positive result. The motor can rotate 180° and it had to be positioned at +90° to rotate clockwise and counterclockwise.

The ability to rotate to precise angles, as well as its small size and durability were the project's requirements.

Figure 11: Servo motor and rotating cube (testing phase).

The two components - button and buzzer - that are necessary for creating the audio output were connected to the microcontroller and tested using the appropriate code. A button of size 6 mm x 6 mm x 13 mm and a buzzer of 13.6 mm diameter and 11 mm thickness are used. When the button is pressed, for a positive result, a long continuous sound with a frequency of 4713 Hz will play. For a negative result, short beeps with 30 ms intervals will play at a lower frequency of 1837 Hz[7].

3.5 Casing

The casing provides mechanical and electrical protection for the components which it encases. The prototype was 3D printed in the department using PLA due to its low density, cost and availability. However, it could be mass produced via injection moulding using other materials, such as ABS for improved durability.

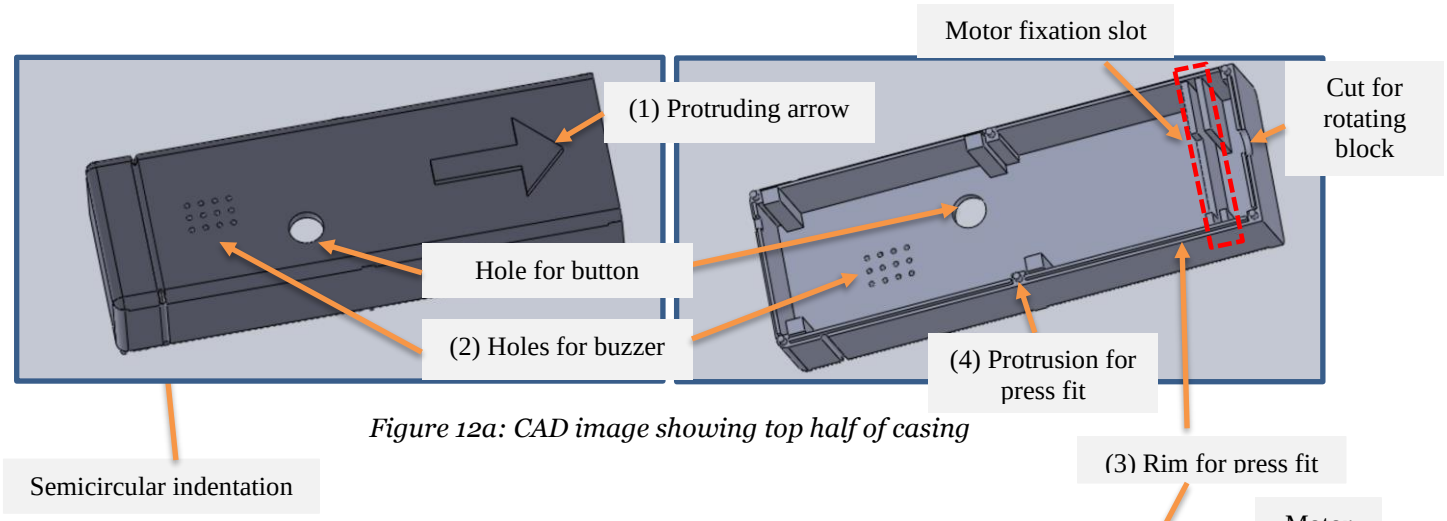

Figure 12a: CAD image showing top half of casing

Figure 12b: CAD image showing the bottom half of the casing

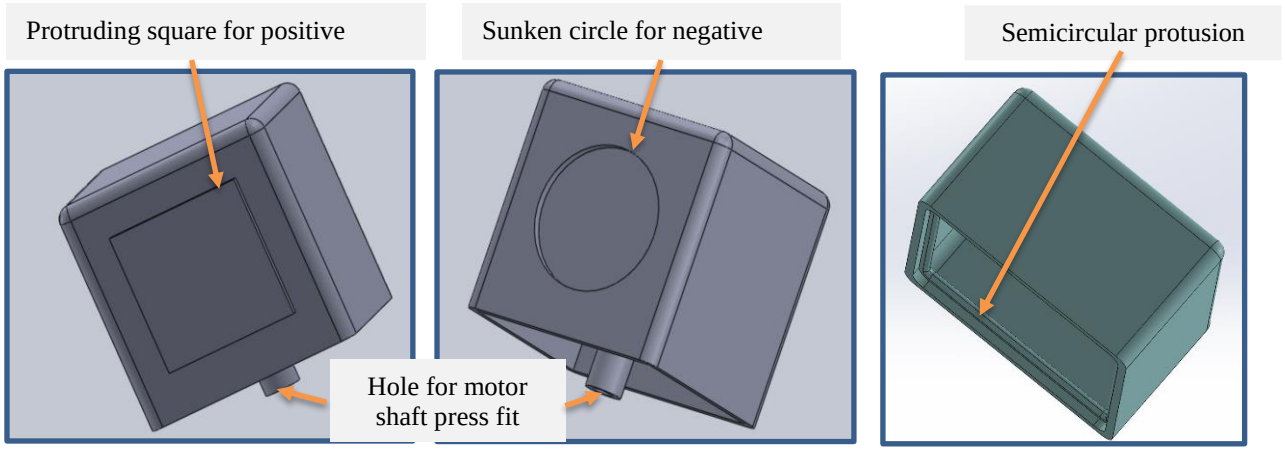

Figure 13a: CAD image showing rotating block

Figure 13b: CAD image showing cap

Figure 12a: On the top half of the casing, there are holes through which the button, motor, and strip fit. Smaller holes are also included to allow transmission of sound from the buzzer to the outside.

Figure 12b: For the casing bottom, slots are designed for motor, PCB and battery to fix them inside.

The following numbers correspond as labelled in ***Figure 12***.

1 A protruding arrow is used to indicate the correct side users should read on the rotating block for the result.
2 To keep the device splashproof, there will be a water-resistant wire mesh under the holes for the buzzer.
3 Rims with a raised part in the casing top and with an indent in the casing bottom are designed to prevent the entry of water and for transition fit between the top and bottom halves of the casing.
4 The casing is assembled using a press fit which is cheaper and quicker than using screws. There are six raised pins (3 mm high) positioned around the edge of casing top.
5 Six holes on the casing bottom, which correspond to the 6 raised pins, allow for a press fit between the 2 halves of the casing.

***Figure 13a*:** Since some VI women may not be familiar with the plus and minus signs for the positive and negative results, a protruding square and a sunken circle, which are easier to feel, were chosen to indicate results as positive and negative respectively in the rotating block.

***Figure 13b*:** A cap is designed for the purpose of hygiene and accurate results, to protect the user from touching the urine and to prevent the strip from contamination. The cap has a semicircular protrusion, to fit securely with the indentation on the casing.

3.6 User experience

Methods of communicating results to the users were chosen based on survey results and the specific needs of VI women were considered.

As the percentage of blind people who understand Braille has been decreasing dramatically over the past few decades[8], simple square and circular shapes were selected instead of Braille for the rotating block. The geometries of these features have been designed contrastingly, giving the users 2 methods of distinguishing between the results (*Figure 14*). More specifically, a circular indent, a square-shaped protrusion, and arrow-shaped protrusion were chosen precisely such that users will be able to distinguish between the two outputs. This was selected instead of the reverse, as fingertips tend to be relatively round, making it easier to identify a circular hole instead of a square-shaped one.

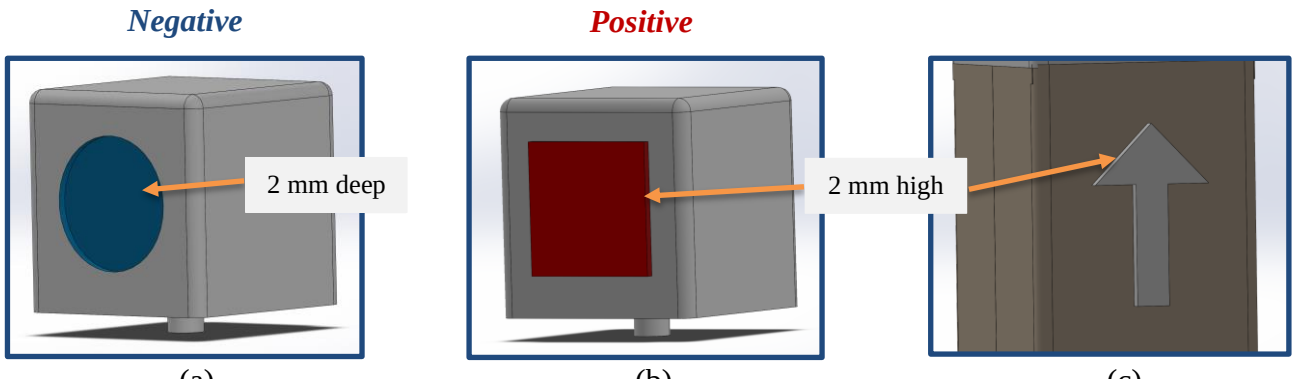

Figure 14: (a) Sunken circle (in blue) on the rotating block, (b) Protruding square (in red) on the rotating block), (c) protruding arrow on the top section of the casing.

All 3 features have a height of 2 mm, which exceeds the height of Braille dots, creating contrasting edges that will produce a sufficient stimulus on the mechanoreceptors of the user's fingers, allowing them to discern the flat surfaces from the indentations and protrusions.

The auditory outputs have been chosen to contrast each other in pitch and rhythm: long continuous, high-pitched sound for positive results versus low-pitched beeps for negative results. This makes it easy for users to distinguish between the sounds and reduces the probability of misinterpreting the result. The button was included in the design in consideration of the users' privacy. As the auditory output will only be played when the button is pressed, users are able to verify the result or share it with others at a time and place which they prefer.

4 Discussion

4.1 Testing

4.1.1 Strips

The lateral flow strips should detect when the sample applied contained a hCG concentration above 25 mIU/ml, which indicates pregnancy, by producing a positive result. The objective of testing them was to check that they function as expected. Vials of hCG were bought and diluted to obtain solutions with different concentrations of hCG, during the wet laboratory sessions.

- The quantity of the vial (2500 IU) was diluted in 50 ml of pure water, resulting in a concentration of 3×10^{-6} g/ml.
- The solution was diluted three times (by taking 5 ml of the initial solution and mixing it with 45 ml of distilled water) and a solution of concentration of 50 mIU/ml was obtained – 1st solution for testing – *positive*
- From the above solution, by diluting it with the same amount of water as its quantity, a further solution of 25 mIU/ml concentration was obtained – 2nd solution for testing – *negative*
- The steps above were repeated to obtain another 50 mIU/ml solution, from which 40 ml were mixed with 10 ml of pure water, resulting in a 40 mIU/ml solution – 3rd solution for testing – *negative*
- From the above solution, by diluting it with the same amount of water as its quantity, a further solution of 20 mIU/ml concentration was obtained – 4th solution for testing – *negative*
- Another 50 mIU/ml solution was made, from which 30 ml were extracted and mixed with 20 ml of water to obtain a solution of 30 mIU/ml – 5th solution for testing – *negative*
- From the above solution, by diluting it with the same amount of water as its quantity, a further solution of 15 mIU/ml concentration was obtained – 6th solution for testing – *negative*

4.1.2 Phototransistors

The aim of this testing was to find the ideal light sensitive component and layout for detecting the 2 possible lines on the strip. The goal was to get the largest difference in output current between phototransistors above a line and phototransistors above a blank area of the strip.

Before testing the phototransistors, they were soldered on a small PCB, as shown in Figure 15. Following this, the PCB was connected to Arduino and different strips and LEDs were tested to establish the sensitivity of the phototransistors. To find the perfect position and the optimal number of phototransistors needed, different layouts were tested (2 phototransistors with a LED in the middle, 1 phototransistor in the middle of the LEDs on top of where the line from the strip was etc.). The most efficient way of arranging them was found to be with two phototransistors on top of each line, with 2 LEDs in the middle of the lines to evenly light the strip, as shown in *Figure 6*. In the PCB design, 2 phototransitors for each line were used to improve sensitivity.

A smaller PCB containing 2 LEDs situated between 2 phototransistors was used to validate the concept for line detection (see *Figure 15* below).

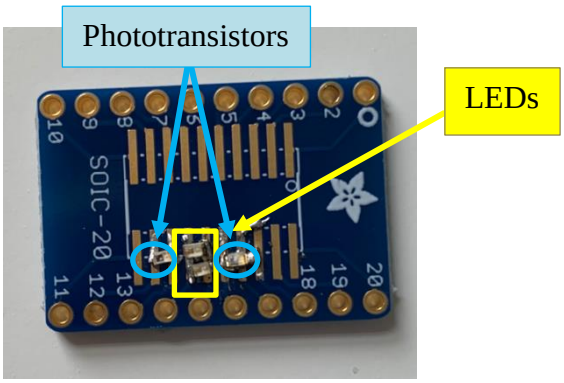

Figure 15: PCB layout for line detection (testing phase)

4.2 Requirements Result

Table 2: Evaluation of the requirements

Requirement	**Outcome**	**Success**	**PSD[10] number reference**
The pregnancy test strips should give a positive result for a hCG concentration above 25 mIU/ml	The threshold found in testing was above the desired one	No (section 4.3.1)	1
The phototransistors can correctly detect the presence of a line	In the testing done so far, it can correctly detect the lines, if the lines are dark enough	Partial (section 4.3.2)	Design option, not included in PSD.
Can correctly give a positive, negative or invalid result.	In the testing done so far, it can correctly detect positive and negative result but it fails to recognise an invalid result	Partial (section 4.3.3)	2
Communicate results through tactile and audio methods	Both the outputs display correctly the results, according to the signal from the microcontroller	Yes (section 4.3.4)	2
Ensure privacy	The sound only plays when the user presses the button and it is unnoticeable by others otherwise	Yes	4
Able to display results in 5 mins or less	The results can be displayed 3 minutes after the test is taken	Yes	3

The results can be repeatedly displayed at least 5 times for up to 12 hours	The device's design allows for the result to be repeatedly displayed but the battery in the prototype was unsuitable for use	Partial	5
Affordable price under £15	The actual prototype cost exceeds limit by £4.58	No (section 4.3.5)	30
Maximum test size of 5 cm x 5 cm x 15 cm	Actual test measurement: 5.6 cm x 5.6 cm x 21.5 cm	No (section 4.3.6)	6
Hygienic use	No leakage after using the test	TBC	19
Appropriate volume and frequency of sound	The frequency (4713 Hz and 1837 Hz) and volume (85 dB) measured is within the appropriate human hearing range[12]	Yes	12
Easily identifiable tactile output	Team members were able to easily identify the tactile result correctly	Yes	13
The electrical components must not be damaged by the liquid inside the test	The electrical components will be tested repeatedly after using the test to ensure functionality	TBC	24
Easy urine sampling	A plastic cup is included for users to collect urine. The stick can then be dipped into it	Yes	10

4.3 Fulfillment of Requirements Evaluation

4.3.1 Detection of positive result by pregnancy strip

The purchased pregnancy strips were tested using different solutions of hCG. However, the concentration of hCG needed for a positive result was higher than predicted. The failure in the results may have been due to the sudden changes in temperature or due to the inaccuracy of the purchased testing strips. Also, the quantity of 2,500 IU has a tolerance between 80.0% and 125.0% of the potency stated[9]. Another possible cause may be the differences between the interaction of hCG with urine and with water, as in hCG mixed with water is not an adequate substitute for urine. A wider variety of strips should have been tested (i.e. strips bought at a chemist, as this would usually be the strips bought by women who need a test), so that the best performing strip can be determined and used in the device.

4.3.2 Detection of lines on strip

The line detection component involving the phototransistors and LEDs underwent many design iterations to improve its sensitivity. However, it proved very difficult to accurately

test its ability to produce a different output value depending on whether a coloured line was present on the strip at the location opposite the phototransistors. Initially, it was difficult to measure the change in the amount of light reflected without being affected by external factors such as the distance between the strip and the detector, as well as the movement of the hand holding the strip.

Later, a testing box was 3D printed in order to block external light and control the position of the strip relative to the scanner. This allowed the confirmation that a line can be detected. In the future, accurate testing methods should be adopted from the beginning to improve efficiency.

4.3.3 Identification of invalid result

The current line detection layout of phototransistors and LEDs and their corresponding code is unable to differentiate between a positive and invalid result. This functionality was planned to be implemented later once the general method was confirmed to work, however due to time limits it was not completed. In the future, testing should be done with the intended final design from the beginning.

4.3.4 Communication of results

The delivery of the results was proven to be efficient and accurate, according to the output of the testing strips. Also, due to the way of communicating the results, privacy is ensured while using the prototype.

4.3.5 Cost

The cost slightly exceeded the limit of £15 set in the beginning by £4.58. In the future, more consideration should be given to the price of components during the initial selection, as there was less time than expected to change them later. However, this cost was for a prototype and will be reduced due to economies of scale when mass manufactured. For example, injection moulding is less expensive than 3D printing.

4.3.6 Dimensions of test

A large size was initially chosen as it is easier to handle for VI women. However, the final prototype was still larger than intended due to size of the PCB and servo motor and is inconvient to use. It should be reduced in the future.

4.4 Future Improvements

Incremental changes:

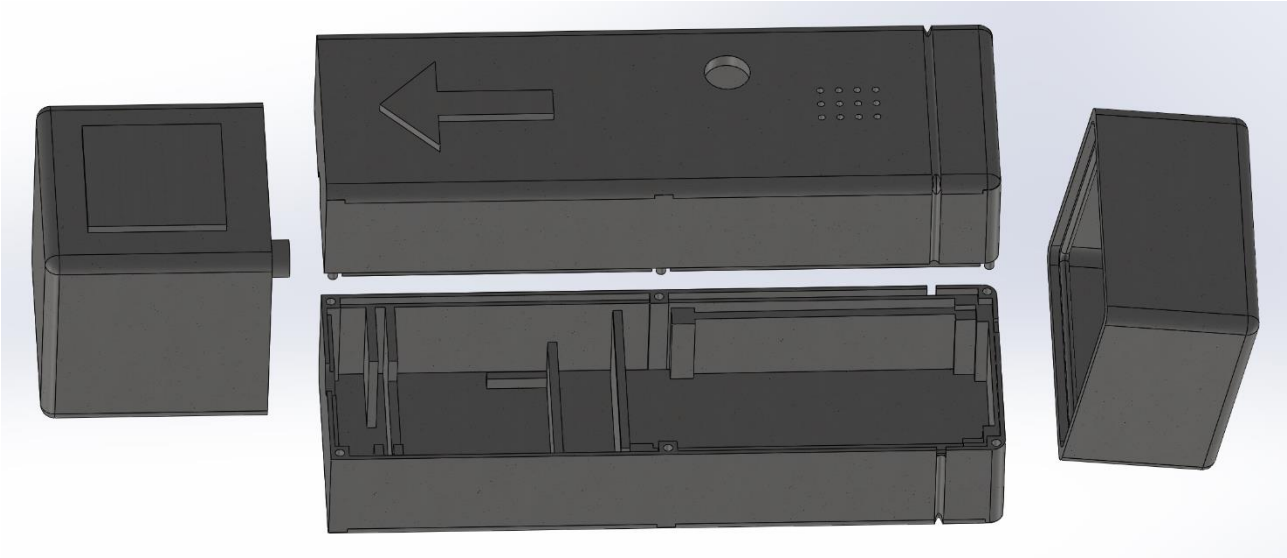

Figure 16: Exploded view of casing for current design

- Use injection moulding instead of 3D printing to produce the plastic casing. This will reduce cost if the size of production is large enough, as well as improve durability.
- Use brightly coloured plastic to make the square and circle shapes on the cube, the arrow pointing to the cube and the audio button. This would assist users with partial sight to use the product even more easily.
- Move the location of the button on the PCB further to the right to make room for the pregnancy strip.
- Make the device able to detect an invalid result and add a corresponding audio output. The possible invalid outputs of the strip are shown in figure 5. Distingushing these from the positive and negative results can be done by adding a phototransistor pair that detects light from a permanently blank area. The current from this pair can be compared against the other 2 so that regardless of the lighting conditions of the environment the test is used in, the presence of 2 lines can be differentiated from no lines. Additional code should be added to also identify the presence of a test line without a control line as an invalid result.
- Replace the output of the buzzer. The sound files of the words “positive” and “negative” being spoken can be recorded and loaded into it.
- Add Braille to the existing square protrusion and circular indent to make it more intuitive for users who can read braille.
- Change the material of the plastic cap to a more elastic option such as PET, for example, to make the cap easier to remove and reattach.
- The pins currently used for keeping the two sides of the case together are very fragile due to their small diameter, and the interference fit is unlikely to allow the device to survive a drop test. In the future, screws should be used as a more secure alternative.
- Longer and wider strips would need to be purchased in order to maintain proportionality between the sizes of the strip and the casing. This would also reduce the likelihood that users would partially immerse the device in the urine sample.
- Test the device using strips from different manufacturers as well as those bought where women would usually buy them.

- Use urine from women at different stages of pregnancy to test the accuracy of the device.
- Add absorbent pill near the testing strip to reduce the chances of damaging the circuitry.

Possible major changes:

- Make the test reusable so that one device can be used multiple times within its lifetime. This would be of significant benefit to users, especially those trying for a baby, as well as considerably reducing waste and impact on environment. The current design is well suited to this improvement as the line detection and output methods are already repeatable. The steps needed to implement this are:
    a. Change the casing to allow the lateral flow strip to be removed and a new one inserted.
    b. Add a "start" button that should be pressed each time a new strip has been inserted and the urine sample applied. Use tactile features such as embossing to differentiate this button from the "play audio" button.
    c. Change the code so that the device shuts down after a certain amount of time to preserve battery life until the "start" button is pressed again. Upon which the program restarts, first resetting the motor position to a blank side, then detecting the coloured lines and producing outputs.
    d. The packaging should include anti-bacterial wet wipes for cleaning the product after each use.
- Alternatively, keep the product as single-use and improve its sustainability and cost effectiveness by replacing the motor and cube mechanism with a fuse and spring mechanism. The method would work as such:
    a. The output signal of the microcontroller will run through 1 of 2 possible electrical fuses, depending on the pregnancy result.
    b. When a high enough current runs through a fuse, it will break.
    c. A spring that is attached to the fuse will be released and a plastic component will pop out of the casing, indicating the test outcome.

  As the motor is a significant portion of the current design's electrical waste, this will reduce the products negative environmental impact.

4.5 Group Working

Our team consisted of 11 members. The team leader communicated our progress and any queries we had with the supervisor. Throughout the process, regular meetings were held twice a week in which progress we made was discussed, and tasks were distributed for upcoming weeks. The delegation of tasks was done via team members proactively volunteering and would be done to ensure every team member would have something to work on. All decisions were made with respect to the opinion of each group member which allowed constructive discussions on the best way to progress on any issues raised during the project. Our supervisor regularly attended meetings to provide feedback, which motivated us to ensure the progress had not stagnated.

As a result of the COVID-19 pandemic, much of the work was conducted remotely via Teams. Time zone issues had to be considered which meant that a more flexible approach was taken to the attendance of meetings. They were also recorded so all group members could stay up to date.

Although COVID hindered our ability to progress with physical testing and assembly early on, it provided an opportunity to develop and brainstorm ideas to a greater extent, which allowed us to refine our product to a greater degree before testing began. This also ensured constant contact was kept with every team member via WhatsApp group chat as it was the optimal way to communicate between meetings, meaning we could offer help if a problem came up.

Tasks were assigned by splitting into three main subgroups: software, hardware, and casing. The allocation of members into these groups was done with the pandemic in mind. When restrictions were eventually lifted after exams, the team members who could meet up worked on the hardware aspect, including the prototype circuit and the PCB design. The team members who could not return to campus performed tasks that could be done remotely, such as the CAD for the casing. Through our regular Teams meetings, the three subgroups continued close communication to ensure integration of ideas and to be up to date on any changes, as well as to work on related documents such as the PSD.

When preparing assignments for submission, deadlines were decided within the group so that collation of the work could be done before submission. This would be a few days before the official deadline. If people were struggling due to the pandemic, other team members would step in to help when needed.

Successful aspects of team working

These are decisions that we realised benefited us in this project and we will continue to do in the future.

- ***Engaged with end users through a survey***
  To design a product that suits the preferences of VI women around the world, we wanted to determine the user requirements based on actual feedback. We took advantage of our diverse background to contact possible end users from different countries. This was highly insightful and helped us to decide which of our many ideas to proceed with.

- ***Began electronics testing and material selection early***
  We made use of lab sessions throughout the spring term to do initial testing on individual components, such as the motor and line detection methods, which suited being performed separately as required by social distancing regulations. These components, and their code, were then combined after exams had finished, when we managed to do a lot more in-person work on the device.

- ***Shared portfolio of project information***
  OneNote was essential for gathering information and allocating any work carried out, particularly during the research stage. Sub-sections were created to identify what work had been completed, and it allowed all team members to continuously check on the progress of the group and gain insight into any research that would be useful.

Possible improvements

These are aspects that impeded our performance along with the methods that we could proceed with in the future to overcome them.

- ***Better engagement of team members***
  We found that in the later stages of the project, the work became quite specialised and relied on certain members for certain tasks. This made it difficult to involve the

entire team and benefit from collaboration. This was partly due to COVID-19 travel restrictions and lab access leading to an uneven distribution of lab time. In the future, each person should explain what they were doing and why throughout the process so that more members have an understanding of the details of how each component or code section works. This would have been beneficial when trouble shooting later on in the project or if someone was unavailable.

- ***Earlier PCB manufacturing***
  Another change we would have made was to begin designing the PCB earlier. We were delayed due to needing to test the phototransistor layout before commiting to the circuit design. To test this, a testing box was required, which needed additional time to 3D print. In the future, a more detailed gantt chart and timeline considerations could have allowed us to rearrange the order of tasks to ensure the PCB could be completed earlier to allow for more testing time in case of issues after ordering. For example, we found that the location of the button interfered with where the strip is supposed to be.

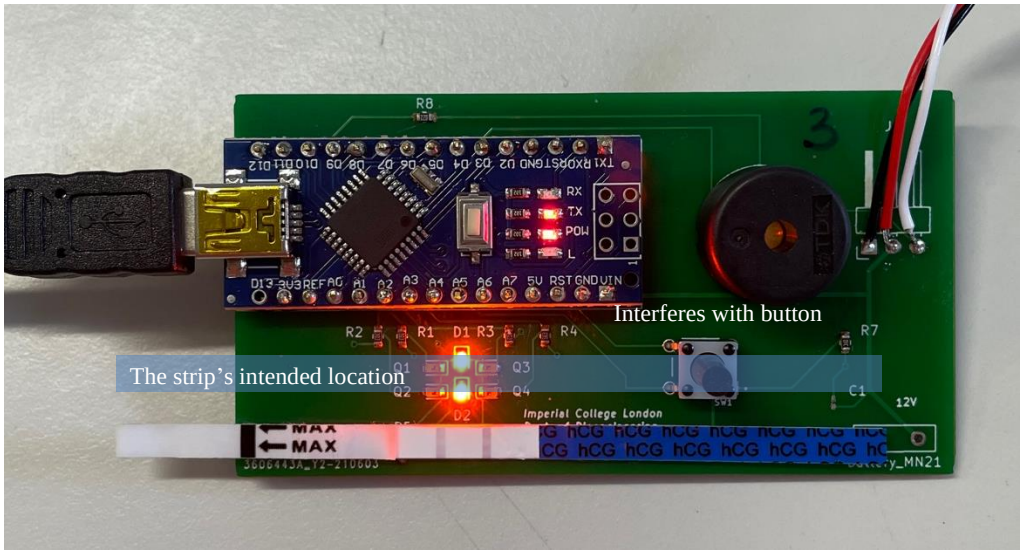

Figure 17: PCB issue

Working in a long term group project was a new experience for all members and we learnt a lot that we can take into future projects to encourage effective communication, work distribution and efficiency in meetings.

4.6 Conclusion

The final design satisfies the crucial requirement set at the beginning of the project, which is informing a VI person the result of the pregnancy test in a way which is independent and private. The feedback from the women surveyed shaped the goals that the design aimed to meet. A lot of changes were made along the process of creating the prototype to attempt to satisfy the specifications regarding the size, speed, usability and price. Most specifications were fulfilled, creating a functional product, even though the cost slightly exceeded the target. The balanced and enthusiastic teamwork was foundational in achieving the project's goals. Further reviewing and testing by potential users is needed to inform the following design iterations, alongside the future improvements already set by the team.

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Appendix A – Project Management

Our team, consisting of 11 2nd year Biomedical Engineering students, was closely supervised by Dr. Radcliffe. Meetings were scheduled two times a week, one of them being held most of the time with our supervisor. Each meeting had the role of deciding our next steps towards the final design and splitting up the tasks. In between the meetings, everyone completed their contribution to the project and showed the rest what they found or developed in the following meeting. This process was very beneficial to our team, since we were all updated with each others progress. When deciding important changes to our design, we discussed and when not everyone approved, we decided to undergo a design evaluation table and choose based on the result (an example can be found in Table 1). When we were able to go to the labs, we split up in three subgroups, each focusing on a specific part of the design: software, hardware and casing. In the biweekly meetings, the rest of the group was kept up to date with each group's progress.

For the assessments, such as the presentation, the PSD, everyone had a certain part assigned to him/her, which they had to complete before the deadline discussed in the meetings. Sometimes, we worked in pairs, in order to make sure we have a variety of opinions while working on the tasks. When the assessments were nearly finished, we organised a meeting and we made sure we went through all of the parts together, in order to check everything.

Table 3: Design Evaluation

Requirements	**Weighting**	**Concept 1**	**Concept 2**	**Concept 3**	**Concept 4**	**Concept 5**	**Concept 6**
Keeping privacy	4	3	5	5	5	3	3
Easy to read the results accurately	5	2	5	3	3	3	3
Suitable for using alone	5	5	5	5	5	5	5
Manufacturable	5	5	4	3	1	4	5
Price of components	3	5	3	3	3	3	4
Clean looking design	2	5	4	4	4	2	5
Suitable for people with auditory disabilities	2	0	5	5	5	5	5
Questionnaire feedback	3	4	5	5	5	5	5
Power Supply (continue use)	2	2	5	3	4	2	2
TOTAL		**113**	**142**	**123**	**115**	**114**	**128**

Concept 1: Sound and button to replay

Concept 2: Sound, button and DC motor (with bump that rises)

Concept 3: Sound, button and electromagnet causing silicon bump or dent

Concept 4: Sound, button and 2 switch-released balls

Concept 5: Sound, button and solenoid pulses (pins)

Concept 6: Sound, button and vibration plate

- Ruonan Dong – Project Manager
    - Organisation of weekly meeting
    - Management of individual tasks
    - Hardware assembly and component sourcing

- Raluca Anamaria Constantinescu – Procurement Manager
    - Ordering components and keeping track of the team's budget
    - Hardware assembly and component sourcing
    - Presentation video assembly and editing

- Kimberly Ong – Manufacturing Manager
    - In charge of CAD design and 3D printing
    - Research and design for tactile output
    - Mechanical component design

- Antonia Retevoiu
    - Hardware assembly
    - Wet-lab testing
    - User feedback collection

- Binghuan Li
    - Hardware assembly and component sourcing
    - User feedback collection
    - Arduino coding
    - Schematic drawing and PCB design

- Raul Radulescu
    - Hardware assembly
    - Wet-lab testing
- Julia Lin
    - Hardware assembly and component sourcing
    - Arduino coding
    - Graphical animations

- Jiale Ou
    - CAD design
    - Mechanical component design

- Cristina López Ruiz
    - Arduino coding
    - User feedback collection

- Marcos Bertran
    - Hardware assembly
    - Circuit testing

- James Wright
    - CAD design and 3D printing
    - Mechanical component design

The tasks which are not included in the list above were done by the entire group:

- Research
- Idea generation
- PSD, report, presentation

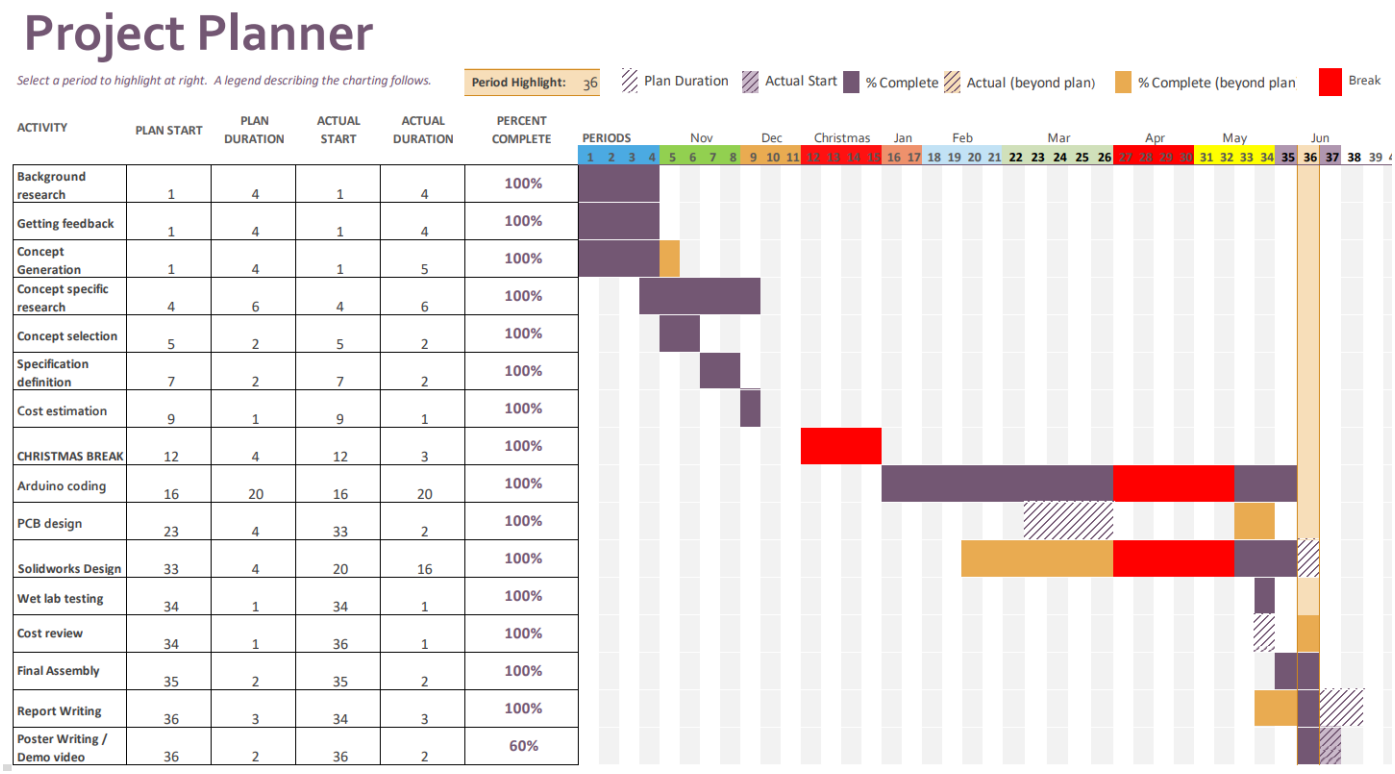

Figure 18: Gantt Chart

Figure 18 shows the Gantt chart that the team used to plan and keep track of progress.

Appendix B – Risk Management

Examples of possible hazards are listed below (based on ISO14971):

Examples of energy hazards	**Examples of biological and chemical hazards**	**Examples of operational hazards**	**Examples of information hazards**
Electromagnetic energy Line voltage Leakage current enclosure leakage current earth leakage current patient leakage current Electric fields Magnetic fields **Radiation energy** Ionizing radiation Non-ionizing radiation **Thermal energy** High temperature Low temperature **Mechanical energy** Gravity falling suspended masses Vibration Stored energy Moving parts Torsion, shear and tensile Force Moving and positioning of pilot **Acoustic energy** ultrasonic energy infrasound energy sound	**Biological** Bacteria Viruses Other agents (e.g. prions) Re- or cross-infection **Chemical** Exposure of airway, tissues, environment or property, e.g. to foreign materials: acids or alkalis residues contaminates additives or processing aids cleaning, disinfecting or testing agents degradation products medical gasses anaesthetic products **Biocompatibility** Toxicity of chemical constituents, e.g.: allergenicity/irritancy pyrogenicity	**Function** Incorrect or inappropriate output or functionality Incorrect measurement Erroneous data transfer Loss or deterioration of function **User error** Attentional failure Memory failure Rule-based failure Knowledge-based failure Routine violation	**Labelling** Incomplete instructions for use Inadequate description of performance characteristics Inadequate specification of intended use Inadequate disclosure of limitations **Operating instructions** Inadequate specification of accessories to be used with the device Inadequate specification of pre-use checks Over-complicated operating Instructions **Warnings** of side effects of hazards likely with re-use of single-use medical devices **Specification of service and maintenance**

Critical Risk Priority Number

During the risk analysis, each risk or failure is analysed and rated with respect to its severity (S), probability of occurrence (O), and detection rate (D). The rating for each of the three aspects ranges from 1 (low security risk/failure, low probability of occurrence, high detection probability) to 10 (severe injuries or death, high probability of occurrence, no/low probability for detection). The product out of these three ratings is called Risk Priority Number (RPN). In case, the RPN is greater than a critical threshold, preventing measures are required in order to reach a final RPN below or equal to the critical threshold by means of reasonable and justifiable security measures.

For this section a critical **RPN threshold of 50** was set.

In case, the risk is greater than the critical threshold the risk **must clearly be mentioned** in the "declaration of agreement" signed by the pilot and involved staff.

Factors of the Risk Priority Number (RPN)

Find below a recommendation how to rate occurrence, severity, and detection. The "Risk Priority Number before" is a mathematical product of the numerical Severity- (S), Occurrence- (O), and Detection-Ratings (D) obtained before applying any preventing measures to reduce the likelihood for dangerous incidents, thus: **RPN before = (S1) x (O1) x (D1)**. This "RPN before" should be set to prioritize items that require additional quality planning or action.

The "RPN after" is a mathematical product of the numerical Severity- (S), Occurrence- (O), and Detection-Ratings (D) obtained after applying the preventing measures to reduce the likelihood for dangerous incidents, i.e. **RPN after = (S2) x (O2) x (D2)**. The "RPN after" has to be equal or below the predefined threshold in order to guarantee safe use of the part/element/device.

Preventing measures are mechanisms that prevent the cause of the failure mode from occurring or that detect the failure and stop the application before an incident can happen. It could also reduce the severity by e.g. designing softer and rounder edges. Preventing measures could include specific inspection, testing or quality assurance procedures; selection of other components or materials; de-rating; limiting environmental stresses or operating ranges; redesign of the item to avoid the failure mode; monitoring mechanisms; performing preventative maintenance; or inclusion of back-up systems or redundancy.

S – Severity

Rating S	Criteria: Severity of effect	Consequence	Treatment
10	Death	-	-
9	Quadriplegia	Life-long medical care necessary / coma / permanent damage	Hospital stay
8	Amputations, paraplegia, blindness, deafness, traumatic brain injury (severe), fourth-degree burns	Life-long medical care necessary / coma / permanent damage	Hospital stay
7	Complex fractures, open fracture, inner injuries, traumatic brain injury (severe), third-degree burns	Permanent damage possible	Hospital stay
6	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (moderate), second-degree burns	Permanent damage possible	Hospital stay

5	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (mild), second-degree burns	Reversible injury	Hospital stay or ambulant treatment
4	Severe cuts, severe scratches, severe contusions, strains, first-degree burns	Reversible injury	Ambulant treatment or self-treatment
3	Minor cuts, minor scratches, minor contusions, stiff muscles, tension, blisters, excoriations, sickness, first-degree burns	Discomfort during application up to three days after application	Self-treatment
2	Slight sickness, pressure marks	Discomfort	-
1	No harm	-	-

O – Occurrence

Rating O	**Criteria: Probability of occurrence**
10	Occurs or may occur very likely during every use of the session
9	Occurs or may occur likely during every use of the session
8	Occurs in 1 of 5 sessions (less than once a day)
7	Occurs in 1 of 10 sessions (less than once a day)
6	Occurs in 1 of 50 sessions (less than once half a month)
5	Occurs in 1 of 100 sessions (less than once a month)
4	Occurs in 1 of 500 sessions (less than once half a year)
3	Occurs in 1 of 1000 sessions (less than once per year)
2	Occurrence very unlikely
1	Occurrence nearly impossible

D – Detection

Rating D	**Criteria: Likelihood of detection by design control**
10	No chance of detection
9	Very remote chance of detection
8	Remote chance of detection
7	Very low chance of detection by indirect methods (hardware or software)
6	Low chance of detection by indirect methods (hardware or software)
5	Moderate chance of detection by indirect methods (hardware or software)
4	High chance of detection by indirect methods (hardware or software)
3	High chance of detection by direct or indirect methods (hardware/software)
2	Direct and indirect detection: Hardware or software
1	Direct detection: Hardware or safe software (category 4, performance level e)

Risk Analysis

Assembly	Failure & Effect	S1	O1	D1	RPN before	Preventive measures	S2	O2	D2	RPN after
Edges of casing	The user may cut their hand on the edges of the device if they are too sharp.	3	5	10	**150**	Design the casing with curved edges so occurrence of injury is greatly reduced.	1	1	10	**10**
Circuitry	The exposure to liquid could cause the circuit to short, shocking the user.	4	6	8	**192**	The casing has been designed to be water-resistant to reduce the chance the circuit comes into contact with liquid.	4	1	8	**32**
Strip	The urine on the strip could come into contact with the users' hands.	2	10	7	**140**	A cap is used to cover the strip after use which prevents leakage of urine.	2	2	7	**28**
Incorrect use	The user may mistake the cap for the rotating head, damaging the device.	1	8	5	**40**	The instruction manual will inform the user which part is which, and the design of the rotating block is chosen to be easily distinguishable from the cap.	1	2	5	**10**
Inaccurate results	The circuitry may malfunction or the strips could result in a wrong result as they are only 99% accurate. The user's physical condition may cause hCG in urine to be diluted.	5	3	8	**120**	Disclaimers in the user manuals inform the user the result may be inaccurate. The manual will also advise the user to consult a doctor if they receive a positive result.	5	1	8	**40**
Incorrect interpretation of results	The output could be interpreted incorrectly by the user due to subjective perception.	5	9	5	**225**	The result is communicated by both the motor and the sound. There is also an instruction manual that explains the device operation clearly.	5	1	5	**25**

Appendix C – Ethics

Social responsibilities

Since we are developing a product for VI women, we had to ensure that our product is suitable and respects all their needs. We want them to have the same experience as every woman while using a pregnancy test, without needing someone else's help. Their desire for privacy shaped the beginning to the end of our product design.

Honesty

As future workers in the medical field, honesty was an important asset in our group, since we wanted to include only verified information. We were honest about the shortcomings of our device and included disclaimers regarding its accuracy.

Non-discrimination

When contacting VI women, we made sure not to make them feel uncomfortable because of their disability. We ensured that by carefully choosing the right words and language before talking to them. Moreover, we took into consideration that VI women may also have other disabilities, such as hearing impairment.

Human Subjects Protection and Confidentiality

When surveying the women, we made sure their private information was kept confidential, to maintain their anonymity.

Openness

The data regarding the dimensions and how the prototype functions will be clearly provided to our clients. All the data obtained from the surveyees, that provided the base of the design, will be transparently communicated to the users.

Respect for colleagues

While working on the project, we ensured that we respected each other's opinions and that the tasks were evenly distributed throughout the team members, as seen in Appendix A. Also, we respected each other's needs (health/academic related) and cultural holidays, by taking breaks throughout the year.

Legality

When using any information, we made sure that we complied with the GDPR regulations. Also, our project respects the UK laws regarding disposing the product and assembling the circuit.

Integrity and Respecting Intellectual Property

All the ideas used throughout the progress of developing our design and the work done in creating a prototype came only from team members and no uncredited persons. When using existing products, such as the testing strips, we carefully mentioned that.

Carefulness

Each part of the project, including design, prototyping and creating related documents, was double-checked by other teams to ensure no errors were made along the process of designing the prototype and writing related documents.

Appendix D – Bill of Materials

Part	Description	Supplier	Quantity	Unit Price (£)	Total Price (£)
Arduino Nano	Microcontroller	Imperial College Department of Bioengineering Electronics Lab	1	1	2.86
IR+ Visible Light Phototransistor, Surface mount 0603	Phototransistor for line detection	Imperial College Department of Bioengineering Electronics Lab	4	0.227	0.908
LED	Reflect the light from the strip for detection	Imperial College Department of Bioengineering Electronics Lab	2	9000 / pack of 100,000	0.18
Resistors	Ensure the right voltage for each component	Imperial College Department of Bioengineering Electronics Lab	8	5/ 5000 pcs	0.008
Buzzer	Produce the sound effect to interpret the result	Imperial College Department of Bioengineering Electronics Lab	1	68.10/ tray of 100 pcs	0.681
SM-S2309 Micro Analog Servo Motor	Produce the tactile effect to interpret the result	Amazon	1	14.00 / 2 motors	7.00
Tactile Switch, STSD 50mA	Push Button	RS Components	1	0.09	0.09
Duracell Alkaline 12V A23 Batteries	Power the circuitry	RS Components	1	4.12 / 2 pcs	2.06
RS PRO N Battery Holder	Battery holder for MN21 battery	RS Components	1	0.64	0.64
Casing	PLA material used to 3D print the outer casing components	Imperial College Department of Bioengineering Mechanics Lab	1		4.57
Disposable 200ml plastic cup	Plastic cup to collect urine	Amazon	1	19.96/ 1000 pcs	0.02
One Step 10mlU 3.5mm Wide Pregnancy Test Strip	Pregnancy test strip for the project	Amazon	1	7.25/ pack with 60 strips	0.121
Printed Circuit Board	PCB for pregnancy test	JLCPCB	1	2.19/ 5 pcs	0.44
Prototype cost (£)				***19.58***	
Total Cost of Engineering Design of a Pregnancy Test for Visually Impaired Users (£)				***235.42***	

Appendix E – Nomenclature

- VI – Visually impaired
- hCG – Human chorionic gonadotropin
- PSD – Product specification document
- CAD – Computer aided design
- Phototransistor – Electronic switching and current amplification component which relies on exposure to light to operate
- LED – Light emitting diode
- Servo-motor – Rotary actuator or linear actuator that allows for precise control of angular or linear position, velocity and acceleration
- Lateral Flow Immunoassay – Tests that run a liquid sample along the surface of a pad with reactive molecules that show a visual positive or negative result
- PCB – Printed Circuit Board
- PLA – Polylactic Acid
- ABS – Acrylonitrile Butadiene Styrene
- PET – Polyethylene terephthalate

Appendix F – Survey results

As a general feedback, all the women surveyed agreed that the current methods available for them to use a pregnancy test are not desirable, as they do not feel independent by needing someone else's help. They all want to be the first person that finds out if they are pregnant or not and do not feel comfortable with the available methods so far. The total number of VI women surveyed was 15.

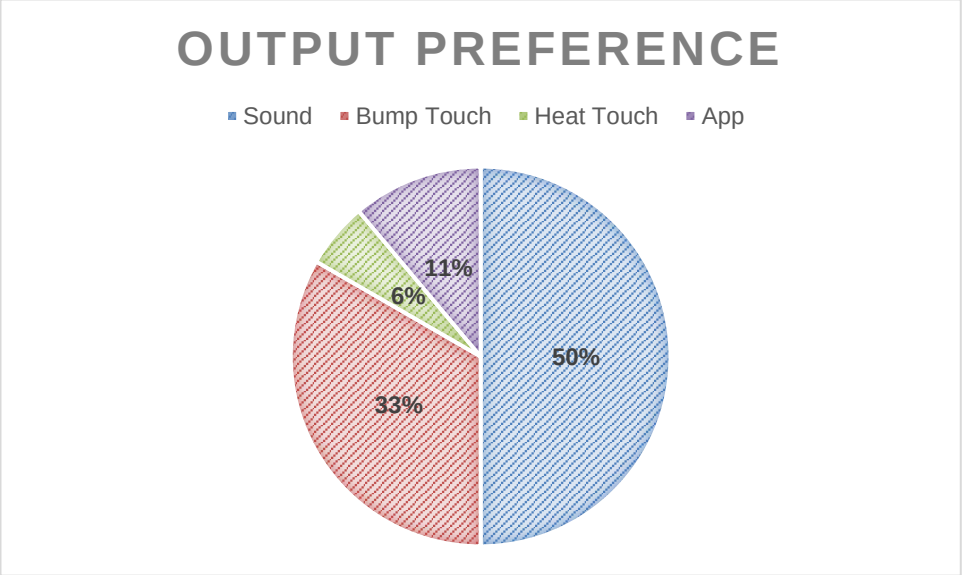

Figure 19: Feedback on most preferred output option

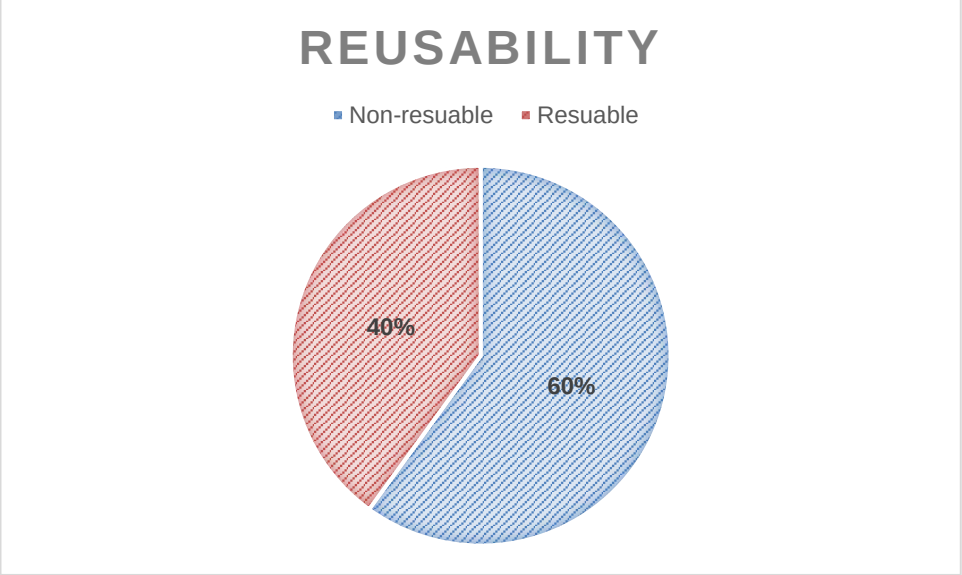

Figure 20: Feedback on reusability

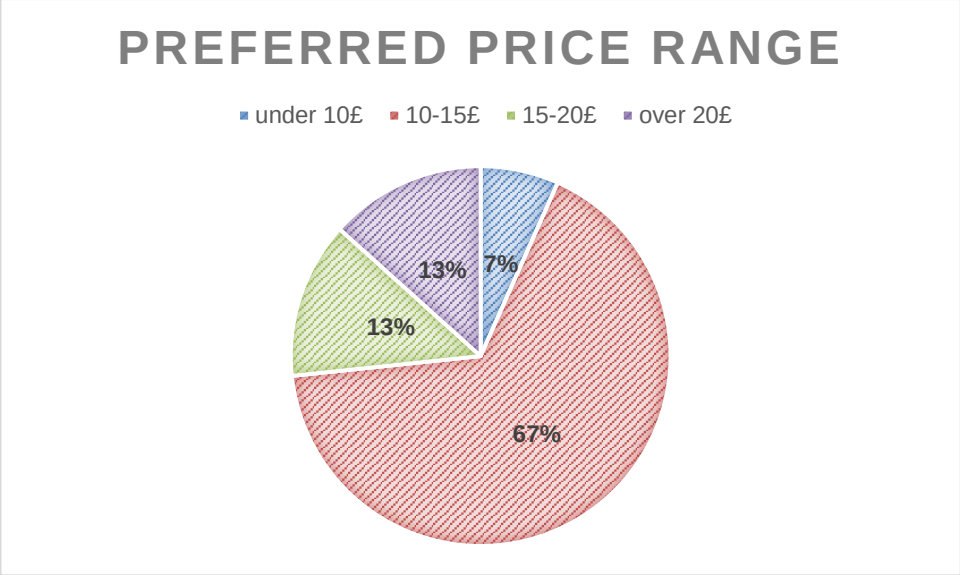

Figure 21: Feedback on preferred price range for the potential product

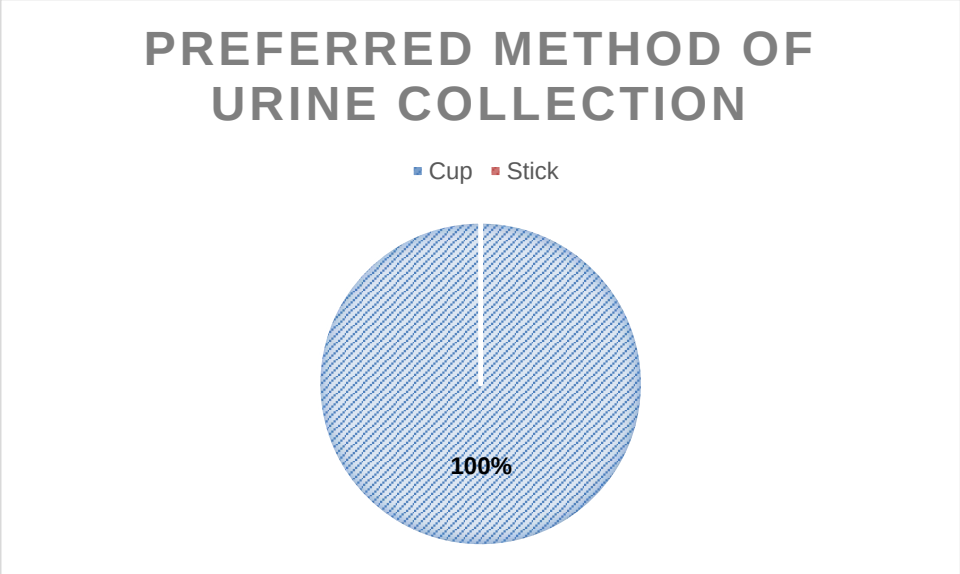

Figure 22: Feedback on preferred method of urine collection

Other comments:

- "Reusable is not a hygienic alternative for visually impaired women."
- "Include specific sound for invalid results."
- "Existent option problem: waiting too much for someone to be available."
- "We want independence, not to use an app. Some women might not have phones."
- "I consider Be My Eyes app an option. Tactile output would be an option for deaf women."
- "Sound seems more reliable."
- "There are other medical devices for blind people that use sound."
- "Sound and vibration seem more reliable."
- "In my opinion, the sound is the best option, but ideas like vibrations and bump touch are also good."