Imperial College London

Product Specification Document

Project Name:	Pregnancy Test for Visually Impaired Users
Date:	Apr 3rd 2021 - June 11th 2021
Release Number:	3.1

No.	Aspect	Objective	Specification	Test Method
1	Functionality and Performance	Detect pregnancy accurately	99 out of 100 tests will correctly detect if the hCG concentration in urine is over 25 mIU/mL[1].	Test 500 pregnancy tests with solutions of a known hCG concentration. The correct result should be negative for 0, 10, 20 mIU/mL and positive for 30, 40, 50 mIU/mL. There should be less than 5 errors.
2		Communicate results	Results should be clear to women of all degrees of visual impairment.	Blindfold 12 different test users and give each person a random test from 4 positive, 4 negative and 4 invalid result showing tests. Check that they can all correctly identify which result it is.
			Results are clear to women of all degrees of visual and auditory impairment as 2% of the world's population has some form of deafblindness[2].	Blindfold and apply earplugs to 12 different test users and give each person a random test from 4 positive, 4 negative and 4 invalid result showing tests. Check that they can all correctly identify which result it is.
3		Fast results	The results should appear in less than 5 minutes, which is the standard for tests on the market[3].	Measure the time until the result is provided to the user.

4		**Privacy**	**User feedback[4] indicated a strong preference for the ability to use the pregnancy test privately.**	**Check that the usage and results of the test cannot be detected by others nearby, such as in a public bathroom.**
5		**Repeatable display of the result**	**The test result should be able to be checked a minimum of 5 times, to allow users to be certain or to share with others.**	**Count the number of times the result of the pregnancy test can be checked.**
			The test result should be able to be displayed a minimum of 12 hours after the test was taken to allow users to move to a private location or share with others.	**12 hours after the test is taken, 20 out of 20 test users should interpret the result correctly.**
6	**Size and Weight**	**Dimensions of test**	**Maximum size: 5cm x 5cm x 15cm. Based on average female hand sizes[5] so it would be easy to grasp and manoeuvre.**	**Measure the length, width, and height of the pregnancy test.**
7		**Weight**	**Maximum weight of 100g including packaging, which is less than most phones[6], so it is convenient to carry.**	**Weigh the entire package and ensure it is below 100g.**
8		**Portable package**	**Maximum packaging dimensions of 6cm x 6cm x 18cm, allowing it to fit in an average-sized handbag to be discretely transported.**	**Measure the length, width, and height of exterior packaging.**
9	**Usability, Interface and Ergonomics**	**Intuitive orientation**	**The orientation of the test should be clear to the user so they can apply urine to the correct area.**	**Verify if at least 3 blindfolded test users who are not familiar with the design can correctly orientate the test and identify where the urine should be applied.**
10		**Easy urine collection**	**Visually impaired women must be able to easily and hygienically collect urine for the test.**	**Survey visually impaired users after they have used the test.**
11		**Intuitive method of use**	**Use of the device should be self-evident and not require instructions.**	**Verify if 5 out 5 visually impaired users can correctly describe how to use the device without being given instructions.**
12		**Appropriate sound**	**The auditory output should have appropriate sound volume (50-65 dB) and frequency (100-4000 Hz), based on human hearing range[7].**	**Measure the sound volume and the frequency using a sound level meter.**

13		**Tactile output**	**The difference in shape between the positive, negative and invalid result should be at least 0.5 mm different, which is the height of braille dots[8].**	**Blindfold and apply earplugs to 12 different test users and give each person a random test from 4 positive, 4 negative and 4 invalid result showing tests. Check that they can all correctly identify which result it is.**
14	**Environmental**	**Storage and use in a range of temperatures**	**It should be operable after storage in and be able to be used in environments of 2 – 38 degrees Celsius[9]**	**Test the accuracy of the test results in different temperature ranges at 2, 10, 20, 30, 38 degrees Celsius.**
15		**Using it in a humid environment**	**The performance and result's accuracy should not be affected by humidity up to 99%, to accommodate most climates.**	**Check if the accuracy of the test result is over 99%, by using fixed concentration samples for each humidity value of 60%, 80%, 90% and 95%.**
17		**Waterproof packaging**	**The entire packaging should have IP67[10] in case it is submerged in water due to being dropped in the toilet or during transit or storage.**	**Evaluate the test using the IP rating specifications for IP67[10]. Specifically, place the package 30cm below water for 30 minutes and confirm it is operatable afterwards.**
18		**UV resistant**	**Operable after the package is exposed to UV index 11[11] for 24 hours so it can be transported and stored in most climates.**	**Compare test performance between one stored without exposure to UV and one exposed to UV index 11[11] for 24 hours (in packaging).**
19		**Splash resistant device**	**The device should continue to be operable if splashed with liquid or in a dusty environment, such that it fulfils IP54[12].**	**Evaluate the test using the IP rating specifications for IP54[12]. Confirm it is operable after the capped test is exposed to vertically falling drops of water.**
20	**Portability**	**Transportable**	**The device should withstand movements and impacts during travel. The mechanical and electronic components should not be damaged.**	**Perform a drop test from 1.5m on carpet, hardwood and concrete 5 times.**
		Durable	**The pregnancy test should resist rough handling and not feel flimsy.**	**Perform 3 point bend test up to 10N.**
21		**No leakage after use**	**The device should not leak urine after the test is taken so it can be transported and read later.**	**Check if there are any leakages 12 hours after using the test.**

22		**Protective packaging**	**The packaging should be able to withstand being handled and resist small damages.**	**Test the durability of the packaging and resistance to deformation in different conditions.**
23	**Safety & Security**	**No environmental contamination**	**Substances contained within the device should not contaminate the surroundings or be hazardous to the user.**	**Check if the materials and substances used are not damaging the environment or hazardous to humans.**
24		**Electrical safety**	**The electrical circuit should not be damaged by the liquid inside the test.**	**Test if there are any leakages of liquid that may harm the electrical circuit.**
25		**Sterile Packaging**	**The device should be contained in sterile packaging so no external factors interfere with the test which could cause an inaccurate result.**	**Run an Ethylene Oxide test over all the components of the device and see if any microorganisms would influence the test.**
26	**Life, Reliability and Maintenance**	**Single use device**	**The test should be used only one time, to be hygienic and to display an accurate result.**	**Check if the circuit does not take in any more inputs after the initial result has been released.**
27		**Easy and safe disposal**	**The test and package should be able to be disposed of with household waste. Instructions should contain information about the disposal process.**	**Check compliance with WEEE regulations[13].**
28		**Reliability**	**The results should be consistent when repeating the test 20 times with different devices and the same sample.**	**Check if our devices give the same result for the same sample.**
			The results should be consistent with other pregnancy tests available on the market using 20 different samples.	**Use the same sample on 5 different tests available on the market, our test should match the most common result among them. Repeat 20 times.**
30		**Shelf-life**	**A minimum shelf-life of 3 years, to match the current digital pregnancy tests available on the market.**	**Check all components and materials used in the test do not degrade within 3 years.**
30	**Cost**	**Affordable selling price**	**The selling price should be lower than £15 to match prices currently on market, by minimising the use of electrical components and materials.**	**Check if the cost of the materials and the manufacturing of the device does not exceed £15.**

31	Legal and Regulatory	**Include instructions for using the test**	**The instructions should be written clearly (including safety information) and be available auditorily through a QR code and braille on the packaging. This ensures that the user has a good understanding of how the test works and how it should be used. We should also exclude liability for improper use.**	**Check if the target audience understands the instructions clearly; ask for feedback.**
32		**Intellectual property rights**	**The design should not infringe on pre-existing pregnancy test designs.**	**Check with the WIPO if any intellectual property rights are infringed.**
33		**Disclaimer of accuracy**	**State that the pregnancy test is only 99% reliable and recommend users to go to a medical professional for a more certain diagnosis. This is necessary as false results can lead to misunderstanding and legal actions.**	**State expected accuracy of test result clearly on packaging and recommend confirmation with a doctor in the case of a positive result.**
34		**Comply with regulations**	**Adhere to regulations from the various countries and get approval from them.**	**Evaluate compliance with FDA regulation 21 CFR 862.1155[14] and UK's In Vitro Diagnostic Medical Devices Directive 98/79/EC [15] [16]. Send a draft to representative lawyers before launching the product in those countries.**

[1] As stated in https://americanpregnancy.org/getting-pregnant/hcg-levels-71048/#:~:text=An%20hCG%20level%20of%20less,rise%20to%20confirm%20a%20pregnancy and https://www.pregnancybirthbaby.org.au/hcg-levels

[2] https://senseinternational.org.uk/about-deafblindness/first-global-report-deafblindness

[3] Instructions commonly refer to an awaiting duration of 5 minutes, for example https://www.med.unc.edu/timetoconceive/study-participant-resources/pregnancy-test-instructions/

[4] 100% of the 13 women we surveyed stated that they would prefer to receive their results privately.

[5] The average women's hand size https://www.medicalnewstoday.com/articles/average-hand-size#adults

[6] This article reports that all top 10 phones in 2019 weighed more than 140g https://thenextweb.com/plugged/2020/08/20/weight-most-popular-phones-of-2019-chart-apple-samsung-analysis/

[7] Decisions made based on information provided from this site: http://www.cochlea.org/en/hear/human-auditory-range

[8] This site states the standard braille dot sizes http://www.brailleauthority.org/sizespacingofbraille/sizespacingofbraille.pdf

[9] This range was chosen based on possible indoor bathroom temperatures in the UK, found here https://www.aireserv.com/about/blog/2018/april/what-is-the-ideal-house-temperature-/ but we extended the range in order to cover more environments where the device is operatable.

[10] Ingress Protection Code, IEC standard 60529 or EN 60529 (IP67 means dust tight for 2-8 hours and protection against the effects of immersion in water between 15cm and 1m for 30 minutes)

[11] We chose the maximum UV index because we wanted the test to be able to be transported outdoors, the conditions of index 11 are described here https://19january2017snapshot.epa.gov/sunsafety/uv-index-scale-1_.html

[12] IP54 means the ingress of dust does not interfere with operation for 2-8 hours and the device is protected from water splash from all directions.

[13] Waste Electrical and Electronic Equipment Regulations (2013)

[14] Available to view here https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=862.1155

[15] Available to view here https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/404335/In_vitro_diagnostic_medical_devices_-_guidance_on_legislation.pdf

[16] Available to view here https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20031120:en:PDF