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RESEARCH ARTICLE



# An accessible pregnancy test for blind and low-vision users

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## ABSTRACT

**Purpose:** Conventional pregnancy self-tests rely on the visual interpretation of test results, creating barriers to the independent use, privacy and confidence for blind and low-vision (BLV) users. This study reports the concept development and preliminary acceptability evaluation of an accessible pregnancy-test, through a five-phase user-centred design process.

**Methods:** Phase 1 applied semi-structured interviews with ten BLV participants to identify the use barriers, needs and feedback preferences. Phase 2 translated these findings into a Product Design Specification. Phase 3 developed a concept combining tactile result feedback, a structured interaction flow and a sliding mechanism separating the sample-application area from the result-reading area. Phase 4 produced a 3D-printed prototype with manually operable mechanical features for tactile exploration, but without electronic sensing and diagnostic functionality. Phase 5 used the Technology Acceptance Model (TAM)-informed semi-structured interviews to examine the perceived usefulness, perceived ease of use and behavioural intention to use.

**Results:** The participants prioritised clear results, simple operation and privacy and generally preferred Braille and raised tactile markers over vibration and voice. The preliminary evaluation indicated positive perceptions of usefulness, ease of use and willingness to use the concept.

**Conclusions:** The findings suggest that accessible pregnancy testing must prioritise not only non-visual result reading but also privacy, dignity, reproductive autonomy and independent health management. These results represent the preliminary evidence of acceptability rather than a conclusive test of device effectiveness and further functional, technical and clinical validation in the real-world conditions is required to fully understand the benefits of the new concept.

## ARTICLE HISTORY

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## KEYWORDS

Blind and low-vision (BLV) users; Pregnancy testing and self-testing; Braille; Tactile feedback; User-centred design; Inclusive design; Assistive technology

## > IMPLICATIONS FOR REHABILITATION

Conventional pregnancy self-testing is generally understood as a private and autonomous health practice, yet the test result reading remains exclusively visual. Consequently, the BLV users of the tests experience difficulty in identifying the result, limited ability to complete the test independently, compromised privacy and reduced confidence during use. This paper presents the concept of a novel pregnancy test kit that was designed based on a user study involving ten BLV women. The kit features a tactile result feedback module to permit the non-visual interpretation of the test result, a structured interaction flow to simplify the use for non-visual users and a sliding mechanism separating the sample-application area from the result-reading area to improve the hygiene of using the kit. The novel pregnancy self-test kit is expected to enable BLV users to carry out pregnancy self-testing with the full autonomy and complete privacy, thus greatly improving personal independence and the dignity of testing.

## Introduction

### Study background

In recent years, various developments in user-centred design, inclusive design and assistive technology have played an important role in improving the quality of life for blind and low-vision (BLV) individuals.

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Different AI-powered apps now support tasks such as reading, object recognition, navigation and communication; for example, refreshable Braille devices permit the non-visual access to textual information and tactile/audio-tactile maps and wearable navigation systems help BLV users access the required spatial information independently [1–6]. These developments reflect a broader shift in inclusive design from simply compensating for the impairment in individual tasks towards supporting autonomy, dignity and everyday participation.

The tactile and vibrotactile interfaces have increasingly been recognised as important alternatives to the vision-dependent interaction. Central to the refreshable Braille displays for reading, tactile/audio-tactile maps for spatial learning and haptic guidance systems for orientation and mobility [4,7–9], these interfaces show that the touch-based interaction can provide users with the non-visual information access directly and privately, particularly when the visual displays are inaccessible or socially inappropriate.

However, despite the continuing progress, many health-management devices are still designed primarily for sighted users and their operation remains highly dependent on visual recognition and the interface layouts that are difficult to interpret non-visually [3,10,11]. As a result, BLV users continue to face substantial barriers when they need to obtain the health information independently. This gap is especially significant in the intimate and time-sensitive self-testing contexts, where the private access to information is not only a matter of usefulness and usability issue but also one's own autonomy and dignity.

One such health-management scenario is pregnancy self-testing. Pregnancy self-tests are commonly regarded as self-administered private health tools, yet the mainstream pregnancy self-testing products still rely heavily on the visual interpretation of the result, which means that the testing process is difficult or impossible to complete independently by the BLV users. In addition to the uncertainty about whether the operational steps have been performed correctly and whether the test has been successfully completed, BLV users are usually unable to read the final testing result without assistance. A process that should be autonomous and private therefore becomes dependent on others, stressful and potentially disempowering [2,12,13].

### ***Independent use and privacy in pregnancy self-testing***

To understand why accessibility matters in pregnancy self-testing, it is useful to briefly consider how pregnancy tests have developed over time. Early pregnancy testing methods were laboratory-based and typically relied on biological assays that were slow, specialist-controlled and thus very far removed from the private self-testing in everyday life we are used today [14,15]. The introduction of home pregnancy self-tests in the 1970s marked an important shift, allowing for the testing in domestic settings rather than fully relying on clinicians and laboratories [16,17]. Since then, the modern pregnancy self-tests have become more compact, faster and easier to use, with the latest digital pregnancy self-testing kits being able to present the testing result through the clear messages of “Pregnant” or “Not Pregnant,” reducing the relatively high level of ambiguity associated with the line-based interpretation [18,19].

Nevertheless, although the contemporary pregnancy tests are often marketed as convenient and user-friendly, their core interaction logic is still fully visual. Whether the result is shown as coloured lines, symbols or digital text on a small screen, the test users are generally expected to see and interpret the output visually. In other words, the evolution from the early laboratory tests to the modern digital home self-tests has improved convenience for sighted users, but it has not fully addressed the needs of BLV users. For this group, the issue is not only if pregnancy testing is available at home, but whether it can be completed independently, confidently and privately, without having to rely on someone else to confirm the result [12,16,17].

For BLV women, the problem of pregnancy self-testing is therefore not limited to the availability of the test; it is also closely linked to personal autonomy, privacy and discretion. In a highly sensitive health context of pregnancy self-testing, having another person read the test result potentially forces the test user to unwillingly expose the private information on their pregnancy status, which can cause psychological pressure and emotional discomfort. Previous studies have shown that safety and privacy are often central concerns for BLV users when using technology in everyday life, especially when the use involves

exposing sensitive information in public or semi-public settings [20,21]. This finding is especially important when it comes to pregnancy self-testing.

This issue can also be situated within the wider perspectives on disability-rights and reproductive-health. The Convention on the Rights of Persons with Disabilities emphasises autonomy, independence, accessibility and equal participation as essential for disabled people [22]. In the field of sexual and reproductive health, WHO and UNFPA have similarly highlighted the need to address the often neglected reproductive-health needs of persons with disabilities [23]. From a reproductive-justice perspective, access to private, understandable and self-directed reproductive information is part of broader reproductive autonomy rather than a narrow product-usability concern [24]. Therefore, an accessible pregnancy self-test should be considered not only as an assistive technology product but also as a means of supporting private reproductive self-care and health equity.

Pregnancy self-testing is commonly undertaken in private settings. However, privacy in this context concerns not only the physical location of testing but also the user's control over the disclosure of the result. For BLV users, visually presented results may require interpretation by a family member, partner, caregiver or healthcare professional, meaning that sensitive pregnancy information may still need to be disclosed to another person. Voice or another form of audio feedback may be accessible and appropriate in fully private circumstances, but it may not meet the preferences of users seeking silent and discreet access to the result. By contrast, tactile feedback can communicate information directly and non-audibly, offering an alternative that may reduce reliance on others and support greater control over disclosure [9,13]. Prior research has also suggested that Braille and other tactile output methods have potential in assistive technology and health-related applications in terms of feedback clarity and privacy [1,25,26]. Tactile interaction is therefore considered a promising direction for redesigning pregnancy tests for BLV users.

### ***Gaps in existing research and design***

Although the assistive-technology research has produced a wide range of “life tools” for BLV users, the existing studies have largely focused on digital information access, communication and environmental perception, while the highly private self-diagnostic products remain underexplored [2,5,6,27]. Similarly, despite the tactile interaction long being recognised as an important channel for the accessible information delivery to BLV users, its application in personal diagnostic devices is still very limited [4,7,9]. The current health devices tend to prioritise visual feedback and there is insufficient academic research and professional design attention to integrating operational simplicity, hygienic safety, privacy protection and non-visual information interpretation into a coherent product experience.

In addition, the literature lacks user-centred design research specifically focused on the pregnancy self-testing products for BLV users. Previous research has shown that user-centred design can improve accessibility, usability and independent use by grounding design decisions in the real user needs and iterative evaluation [10,28,29]. Inclusive design research has also increasingly emphasised that the design goals should extend beyond basic functional usability to address stigma, dignity, comfort and the broader social experience of disabled users [30,31]. Yet, there is very little research into how to apply these principles to the specific needs of BLV women in the reproductive health and intimate self-care technology.

In particular, there is a literature gap in terms of how test results can be conveyed non-visually to BLV users while protecting privacy in this sensitive self-testing context. The gap is not limited to the result display alone; it also concerns how product structure, tactile guidance, hygiene separation and feedback modality can be integrated into an interaction flow that is perceived as acceptable and potentially supportive of independent use. At the same time, the present study recognises that such design work cannot by itself establish diagnostic accuracy, hygiene performance or real-world reliability, which require a more in-depth functional validation.

### ***Study aim***

This study aimed to develop an accessible pregnancy self-test concept for BLV users and to conduct a preliminary user acceptability evaluation of the concept using a manually operable physical prototype

without electronic sensing and diagnostic functionality. The study focused on three core research questions:

RQ1: What barriers, needs and preferences do BLV users identify in relation to pregnancy self-testing, particularly regarding the non-visual result communication, independent use and privacy?

RQ2: How can these user requirements be translated into an accessible pregnancy self-test concept and how do BLV users evaluate its preliminary acceptability of the concept in terms of the TAM-related dimensions of perceived usefulness, perceived ease of use and behavioural intention to use?

Drawing on the research into assistive technology, tactile interaction, user-centred design for health and inclusive design, the study sought to identify the relevant user needs, translate these needs into the design requirements, develop a conceptual solution, produce a prototype for tactile exploration and evaluate the perceived usefulness, perceived ease of use and behavioural intention to use using the prototype. The study was not designed to fully validate the solution in the real-world environment.

### Study contributions

This study makes three concept-level contributions. First, it addresses an overlooked context in assistive technology: the practical needs of BLV users in private pregnancy self-testing. Second, it proposes a design concept that combines operational simplification and tactile result communication through privacy-oriented interaction, thereby offering a new direction for the future accessible self-diagnostic products. Third, by linking the user needs elicitation, design translation, conceptual design, prototype development and preliminary TAM-informed acceptability evaluation within a five-phase user-centred design process, the study provides an initial design research foundation for the subsequent work on accessible self-testing technologies [28,32,33]. These contributions should be understood as early-stage rather than the evidence of full validation.

Overall, this study argues that accessible pregnancy self-testing is not merely a technical problem of making results readable to BLV users. It is also a user-centred design and health equity issue related to the autonomy, privacy and dignity of reproductive self-management. Through this work, the discourse on accessibility and assistive technology is extended to a more intimate and self-directed health-care context, while recognising the need for further validation before any claims can be made about the real-world performance.

## Study methods

### Study design

This study adopted a five-phase user-centred design (UCD) approach to explore, develop and preliminarily evaluate the acceptability of a novel accessible pregnancy self-test concept for BLV users. Consistent with the established user-centred design principles, the overall research process was organised around understanding users, translating their needs into design requirements and designing, developing and evaluating design solutions [34,35]. As a result, the study process comprised five connected phases (Figure 1). Phase 1 (User Needs and Requirements Elicitation) focused on user needs and requirements



Figure 1. The overview of the study process.

elicitation in order to identify the barriers and expectations related to the pregnancy self-testing among BLV users. Phase 2 (Design Translation) translated the findings from Phase 1 into the explicit design requirements and directions. Phase 3 (Conceptual Design) developed the conceptual design of the product. Phase 4 (Prototype Development) involved prototype development through digital modelling and physical fabrication. Phase 5 (User Evaluation) was informed by Technology Acceptance Model (TAM) and involved a preliminary user acceptability evaluation of the manually operable 3D-printed prototype, which did not include electronic sensing or diagnostic functionality. The evaluation focused on perceived usefulness, perceived ease of use and behavioural intention to use as the three TAM dimensions related to this particular concept [36,37].

The study was conducted in Zhuzhou, Hunan Province, China. To maintain the continuity in the user-centred design process, the same group of BLV participants took part in the early needs and requirements elicitation in Phase 1 and the prototype evaluation in Phase 5. This continuity supported a progressive user-centred design approach by allowing for the participants' initial needs and feedback to inform the subsequent stages in the concept design and development. However, because the same participants were involved in both the needs and requirements identification phase and the prototype evaluation phase, their later responses may have been influenced by the prior familiarity with the design rationale. This methodological consideration is addressed explicitly in the Limitations section below.

### ***Scope of evaluation and study positioning***

The present study should be understood as an exploratory concept-development and preliminary user acceptability study rather than a complete validation of a pregnancy self-testing device. The participants evaluated the physical layout, tactile cues, manually operable sliding interaction and intended result-feedback logic of a 3D-printed prototype that did not include electronic sensing, automated actuation and diagnostic functionality. The objective performance outcomes, such as diagnostic accuracy, operational reliability and real-world task performance were outside the scope of this stage and are discussed as limitations and directions for future work.

### ***Phase 1: User needs and requirements elicitation***

Semi-structured interviews using a mixed-format interview plan were conducted in Phase 1 to explore the user needs and requirements. Each interview lasted approximately 10 to 15 minutes and was audio-recorded with the participants' consent for the subsequent analysis of the interview insights. Before the interview, the participants received an information sheet with an explanation of the study purpose, including that the study focuses on user needs, requirements and product experience rather than providing a medical advice, the voluntary nature of participation, the right to withdraw at any time, the option to skip any question, etc.

The interview questions focused on the participants' previous experience of pregnancy self-testing, the main difficulties encountered during the self-testing process, their ability to distinguish "yes" and "no" in Braille, their preferences for different feedback modalities and the perceived importance of different product features. A representative question used to initiate the interview was: "What major difficulties have you encountered when using a pregnancy test?" The interview concluded with the open-ended question "What improvements would make testing easier for you?" allowing for the participants to provide the additional suggestions in their own words.

The participants were asked to evaluate the importance of four product features, including clear and identifiable results, privacy protection, hygiene and the simplicity of operation with a reduced risk of unintended activation. Each feature was rated independently using a five-point Likert scale, where 1 indicated "not important at all" and 5 indicated "very important." These four features did not have to be ranked in relative terms against one another. The ratings were used to identify the perceived importance of each requirement and to support the subsequent translation of user needs into the Product Design Specification. In a separate task, the participants ranked four possible result feedback methods, namely Braille, vibration, physical raised markers and voice, where 1 indicated the most preferable option.

**Table 1.** Participant characteristics.

| Participant | Age | Vision status                                                                                       | Previous experience with pregnancy tests | Able to distinguish Braille for “Yes/No” |
|-------------|-----|-----------------------------------------------------------------------------------------------------|------------------------------------------|------------------------------------------|
| P1          | 24  | Blind                                                                                               | Yes                                      | Yes                                      |
| P2          | 57  | Central vision loss                                                                                 | Yes                                      | No                                       |
| P3          | 28  | Almost fully blind in the left eye; partial vision in the right eye                                 | Yes                                      | Yes                                      |
| P4          | 35  | Blind                                                                                               | Yes                                      | Yes                                      |
| P5          | 29  | Blind                                                                                               | Yes                                      | Yes                                      |
| P6          | 28  | Almost fully blind                                                                                  | Yes                                      | Yes                                      |
| P7          | 46  | Almost fully blind in the left eye; central vision loss in the right eye, with nystagmus            | Yes                                      | Yes                                      |
| P8          | 30  | Blind                                                                                               | Yes                                      | Yes                                      |
| P9          | 31  | Visual processing difficulty; sensitive to light and text layout, with frequent eye fatigue         | Yes                                      | Yes                                      |
| P10         | 50  | Difficulty seeing details and text, with reduced facial recognition and preserved peripheral vision | Yes                                      | No                                       |

### **Participants**

The interviews involved 10 adult female participants who were all aged 18 years or older at the time of the study and recruited in Zhuzhou, primarily through WeChat and the local disability support service networks. The sample varied in terms of vision loss, from the participants who were completely blind to those with varying degrees of low vision. The sample characteristics are presented in [Table 1](#).

### **Ethical considerations**

As above, the participation was entirely voluntary and the participants had the right to decline to answer any question and withdraw at any time. The interview data were anonymised and used solely for academic research purposes; no personally identifying information was recorded or disclosed. Because pregnancy self-testing is a relatively sensitive topic, the participant information sheet made it clear that sharing the personal experience/s of was not required. The study protocol was approved by the Ethics Committee of the College of Engineering, Design and Physical Sciences, Brunel University of London.

### **Data collection and analysis**

The Phase 1 data were collected through semi-structured interviews using a mixed-format interview guide that combined the structured response items with the open-ended questions and follow-up probes. The structured responses were analysed using descriptive statistics. The responses concerning the Braille recognition and reported difficulties were summarised using the frequencies and percentages. The independent five-point feature-importance ratings were summarised using the mean scores and score ranges, while the preferences for the four result-feedback methods were summarised using the mean ranks and first-choice counts.

The open-ended and follow-up responses were reviewed and grouped thematically along the themes of result clarity, independent use, privacy, operational simplicity and hygiene. These responses were used to provide an additional context for the structured findings and to support the translation of user needs and requirements into the Product Design Specification developed in Phase 2.

The first author conducted the interviews, organised and anonymised the interview records and performed the initial data analysis and thematic grouping of the open-ended and follow-up responses. The resulting categories, interpretations and design requirements were subsequently reviewed and discussed with the co-authors.

### **Phase 2: Design translation**

The user needs and requirements identified in Phase 1 were translated into the specific design features in the form of a Product Design Specification (PDS), which served as a structured design brief for the subsequent product concept design and prototype development [38].

**Table 2.** Translation of user needs into the product design specification (PDS).

| Phase 1 finding/user need                                                                             | Product Design Specification (PDS) requirement                                                                          | Design response in later phases                                                                          |
|-------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| Participants could not independently interpret pregnancy self-test results.                           | The test results should be clearly readable through non-visual means.                                                   | A tactile result-feedback module was developed using Braille                                             |
| Participants reported that asking others to read the result compromised privacy.                      | The interaction process should support independent completion as much as possible in order to reduce privacy exposure.  | The product was designed as a self-contained non-visual testing and result-reading system.               |
| Conventional pregnancy self-tests lacked clear tactile guidance and were prone to operational errors. | The product structure should reduce the risk of operational errors and make the operational steps easier to understand. | Guiding grooves, tactile markers and a structured interaction flow were incorporated into the concept.   |
| Some participants raised concerns about contamination and hygiene during use.                         | The product should minimise the direct user contact with the urine sample to improve hygiene and perceived safety.      | A sliding mechanism was introduced to separate the sample-application area from the result-reading area. |

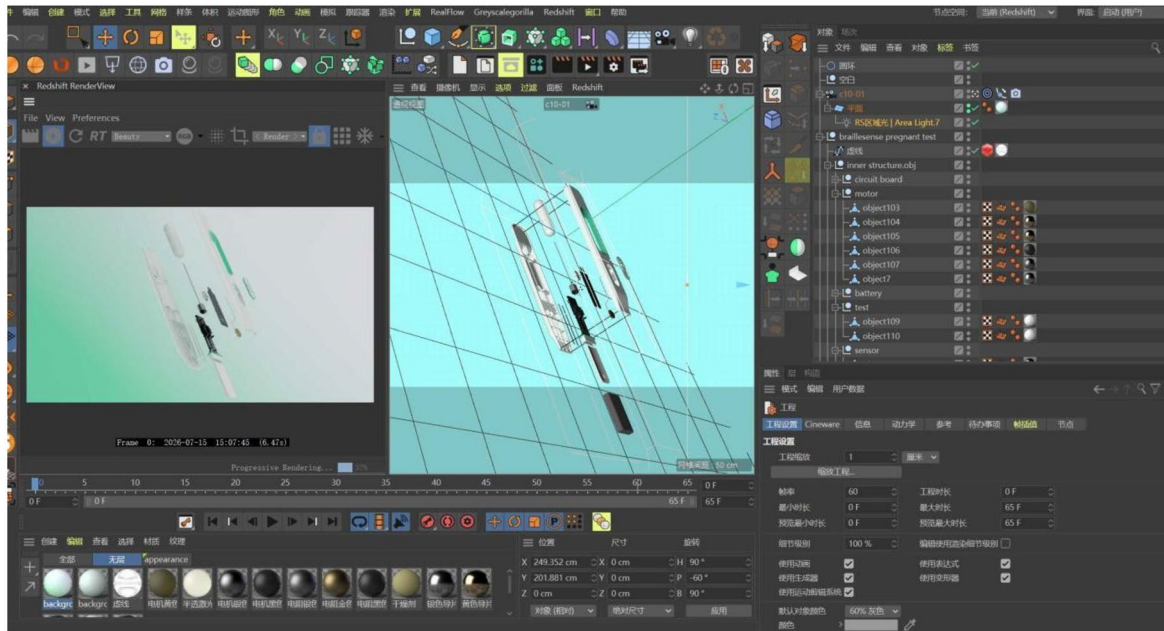
**Figure 2.** The design concept produced in C4D.

Table 2 summarises how the main user needs identified in Phase 1 were translated into the Product Design Specification requirements and corresponding design responses.

These requirements provided the design basis for the conceptual design developed in Phase 3 and the prototype development undertaken in Phase 4.

### Phase 3: Conceptual design

Phase 3 involved the conceptual design process according to the following design rationale. During the design translation, the tactile feedback was prioritised as the primary mode of the test result communication rather than voice output. This choice responded not only to the need for non-visual access to information expressed by the study participants but also to the privacy requirements of pregnancy self-testing scenarios.

In terms of the operational structure, a sliding mechanism was introduced as one of the core interactive components. This structure was intended to extend the test strip after the sample application and to support the subsequent use through clearer functional zoning and directional cues. The structure was also designed to reduce the direct user contact with the urine sample, thereby addressing the hygiene-related concerns raised during the interviews.

Based on this design logic, an accessible pregnancy-test concept was designed and its render was produced in Cinema 4D (C4D) (Figure 2). The core features of the prototype included (1) a tactile

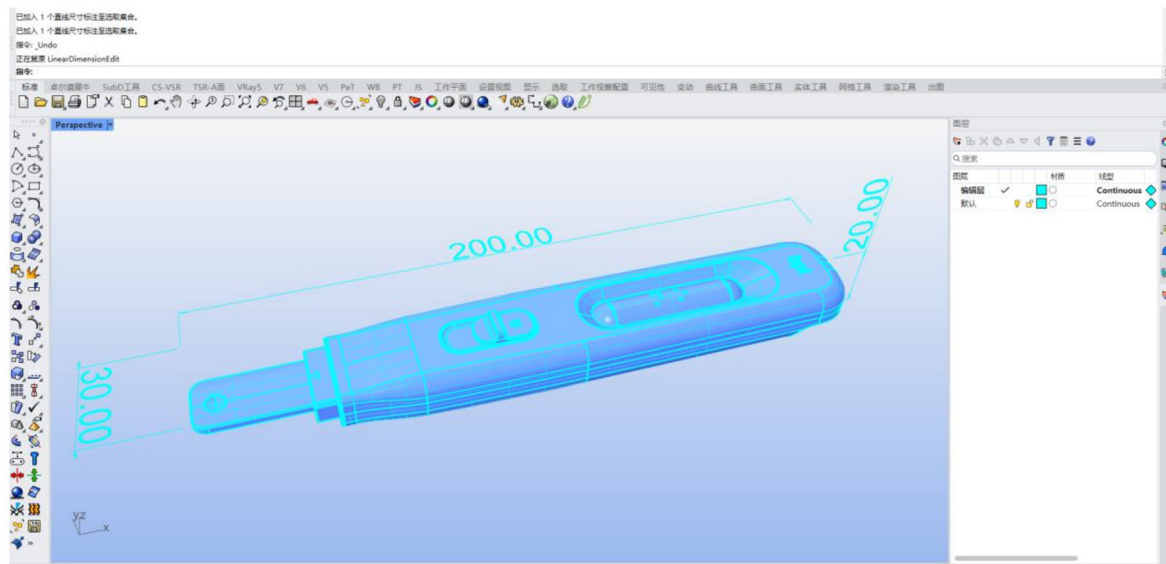


Figure 3. The CAD model of the prototype produced in Rhino.

result-feedback module with Braille, (2) a sliding mechanism for extending the test strip in order to reduce the direct contact with the sample and (3) differentiated tactile textures to help the user identify the functional zones non-visually.

#### ***Phase 4: Prototype development***

Following the design translation in Phase 2 and the conceptual design in Phase 3, Phase 4 focused on converting the selected concept into a digital model and a physical prototype for a preliminary user evaluation. The prototype was developed as a digital CAD model in Rhino to define its overall dimensions, shell structure, internal component arrangement and tactile interaction zones (Figure 3). The concept included a shell, Braille display module, roller-type switch module, sliding switch, sensor, circuit board, battery, motor, reaction strip, test strip and desiccant, with the shell material specified as polypropylene (PP).

To support the evaluation in Phase 5, a 3D-printed physical model was also produced. The model was printed using photosensitive resin and was intended to represent the prototype's overall form, structural zoning and tactile interaction logic. The physical model measured 200 mm x 30 mm x 20 mm. The 3D-printed prototype consists of the upper and lower shell components, manually rotatable tactile result module, sliding switch, extendable test-strip component and supporting structural parts required for assembly. The sliding switch can be moved manually to extend the test strip and the result module can be rotated by hand so that the handler can explore the raised Braille patterns. The prototype did not contain the functional electronic components including the sensor, circuit board, battery, motor and signal-processing system. It therefore supported the manual simulation of the intended interaction sequence rather than the full operation. Accordingly, the focus of the participant evaluation in this study was on the structural layout, sliding interaction, tactile markers and result-feedback logic.

#### ***Phase 5: TAM-informed preliminary user acceptability evaluation***

A TAM-informed semi-structured interview approach was used in Phase 5 to conduct a preliminary user acceptability evaluation of the concept prototype. Before the interview began, the researcher introduced the prototype's design purpose, basic structure and intended use logic and clarified that the session concerned the design concept rather than a real clinical testing process. The participants did not apply urine samples, perform a self-pregnancy test or receive an actual diagnostic result. They physically handled the prototype, manually moved the sliding switch to extend the test strip and rotated the tactile result module to explore the raised Braille patterns. Through these interactions, the

participants developed an initial understanding of the intended use, structural layout, functional zones and result-feedback method. They subsequently rated a set of statements, after which a series of follow-up questions were asked to explore the reasons for their ratings and the factors affecting the willingness to use the product concept.

### Participants

As above, the participants in the user evaluation in Phase 5 were the same individuals who took part in the user needs and requirements elicitation in Phase 1.

### Measures

The Phase 5 measures focused on three TAM-related dimensions. The perceived usefulness assessed whether the participants believed that the design could help them complete the test independently, protect privacy, understand the result and reduce the anxiety during the pregnancy self-test use. The perceived ease of use assessed whether the operating steps were easy to understand, whether the tactile markers were easy to identify, whether the participants felt confident that they could use the product independently and whether the sliding mechanism was easy to control. The behavioural intention to use was assessed to determine whether the participants would choose this product, use it in a home setting and recommend it to other BLV users.

All items were rated on a five-point scale, where 1 indicates strongly disagree and 5 indicates strongly agree. After the ratings, a set of open-ended follow-up questions were used to gather additional comments on the prototype's strengths, limitations and potential areas for improvement.

### Data analysis

The Phase 5 data analysis combined quantitative and qualitative components. The item-level and overall mean scores, standard deviations, medians and score ranges were calculated for the perceived usefulness, perceived ease of use and behavioural intention to use. The open-ended and follow-up responses were reviewed and grouped according to recurring concerns, including affordability, test accuracy and operational difficulty. These responses were used to contextualise the numerical ratings and identify areas requiring further development.

## Results

### Phase 1 findings from the user needs and requirements elicitation

This section presents the findings from the Phase 1 user needs and requirements elicitation, [Table 1](#) namely the difficulties and use barriers and the design preferences and expectations identified from the interviews.

#### The lack of independence in current pregnancy testing

Across the Phase 1 interviews, the inability to complete a conventional pregnancy self-test independently emerged as the most consistent difficulty. [Table 3](#) presents the responses to all predefined difficulty options included in the interview guide, including the options that were not selected by any participant. As shown in the table, all participants (10/10, 100%) reported that the existing pregnancy self-testing products did not

**Table 3.** The responses to the predefined difficulty options in the Phase 1 user needs and requirements exploration.

| Item                                                   | <i>n</i> (%) |
|--------------------------------------------------------|--------------|
| Cannot complete the test independently                 | 10 (100%)    |
| Needs others to read the test result, privacy affected | 10 (100%)    |
| Difficult to locate the operation area                 | 0 (0%)       |
| Test strip easily contaminated / hygiene problem       | 5 (50%)      |
| Other                                                  | 0 (0%)       |

*Note.* The participants could select more than one option. All predefined response options are reported.

adequately support the independent use. This finding indicates that the accessibility barrier was not limited to the final stage of result reading, but also related to the users' confidence in completing the overall testing process without assistance.

### *Privacy as a central user concern*

Privacy emerged as one of the clearest concerns in Phase 1. As shown in Table 3, all participants reported that needing another person to read the test result affected the privacy of self-testing. This finding indicates that the lack of accessible result interpretation was experienced not only as a functional limitation, but also as a privacy issue.

The feature-importance ratings further supported this finding. As shown in Table 4, privacy protection received a mean score of 4.1, indicating that the participants considered privacy as an important product requirement. Although this score was lower than the ratings for clear result identification and simple operation, it still represents a relatively high level of importance. Together, these findings suggest that privacy protection should be treated as a key design requirement rather than as a secondary benefit.

### *Need for clear tactile result communication*

The interview data showed a general preference for non-visual, non-public modes of result feedback. As shown in Table 5, Braille received the strongest overall preference in the feedback method rankings (Mean rank = 1.5), followed by the physical raised markers (2.0), whereas vibration (3.1) and voice (3.4) were given lower priority. In terms of the first-choice selections, Braille was ranked first by five participants, physical raised markers by four, voice by one and vibration by none.

At the same time, Braille did not appeal to all participants equally. Regarding the recognition of Braille for 'yes' and 'no', 8 of 10 participants could distinguish the patterns, but 2 of 10 could not. Taken together with the feedback preferences, this suggests that Braille was a highly desirable output mode, but not the only appropriate one; the physical raised markers also showed strong acceptance and may play a complementary role in inclusive design.

The open-ended responses further supported this interpretation. Some participants explicitly referred to the need for 'clear feedback results' and 'clear identification of test results,' indicating that the clarity of result communication was one of their most direct design expectations.

### *Need for simple and hygienic operation*

At the operational level, participants were equally clear in emphasising the need for simplicity, clarity and a low risk for operational errors. In the feature-importance ratings, both 'clear and identifiable test results' and 'simple operation with reduced risk of unintended operation' received mean scores of 5.0, indicating that the participants attached the greatest importance to the clarity of result interpretation and simplicity of the operational process. By contrast, hygiene received a mean score

**Table 4.** Importance ratings of product features in Phase 1.

| Item                                                       | Mean score | Score range |
|------------------------------------------------------------|------------|-------------|
| Clear and identifiable test results                        | 5.0        | 5–5         |
| Privacy protection                                         | 4.1        | 3–5         |
| Hygiene                                                    | 3.9        | 3–4         |
| Simple operation with reduced risk of unintended operation | 5.0        | 5–5         |

**Table 5.** Preferred result feedback methods in Phase 1.

| Feedback method         | Mean rank | Ranked first, <i>n</i> |
|-------------------------|-----------|------------------------|
| Braille                 | 1.5       | 5                      |
| Physical raised markers | 2.0       | 4                      |
| Vibration               | 3.1       | 0                      |
| Voice                   | 3.4       | 1                      |

*Note.* A lower mean rank indicates a stronger preference.

of 3.9. Although lower than the results of clarity, operational simplicity and privacy protection, this result still indicates substantial importance. In addition, 5 of 10 participants explicitly mentioned that the test strip could easily become contaminated or involve hygiene-related problems. This finding suggests that although hygiene was not the top concern for all participants, it remained a design issue that could not be ignored. Open-ended comments such as 'convenient to operate and more private' and 'easy to understand and simple to use' further underscored the expectation of a low-burden operational flow.

### ***Phase 2–4: Design outcomes***

#### ***Design translation: from user needs to design requirements***

In Phase 2, the findings from Phase 1 were translated into four explicit design requirements: non-visual result reading, independent and privacy-protective use, reduced risk of operational errors and improved hygiene. These requirements formed the basis for the conceptual design developed in Phase 3.

#### ***Conceptual design and overall prototype configuration***

In Phase 3, these design requirements were further developed into a conceptual design for an accessible pregnancy-test product intended for BLV users. The resulting concept consisted of three main functional modules: a front testing zone, central sliding mechanism and rear tactile result-reading module. This zoning strategy was organised around the sequential logic of operate-extend-read, enabling the functional flow to be understood more intuitively through the spatial layout.

The front testing zone was designed to support a sample application and included guiding grooves and tactile markers to help the user identify the correct urine-application location under non-visual conditions. The central sliding mechanism is intended to extend the test strip after the test had been completed, thereby reducing the direct user contact with the urine sample and spatially separating sample application from the result reading. The rear result-reading module is used for the tactile interpretation of the test outcome, allowing for the user to confirm the result without visual assistance or voice output. Taken together, the concept integrated independent use, privacy protection, tactile feedback and operational simplification into a continuous interaction flow (Figure 4).

#### ***Intended pregnancy test architecture and operation***

As shown in Figure 5, the intended functional architecture was organised around the sequence of sample application on the test strip → reaction on the reaction strip → sliding-switch operation and test-strip extension → signal detection → control processing → motor actuation → tactile result presentation. In this logic, the front testing zone receives the urine sample and directs it to the reaction strip, where the biochemical reaction is to occur. After the sample application and reaction, the user operates the sliding switch to extend the test strip. This extension mechanism helps separate the sample-application area from



**Figure 4.** Exterior design of the accessible pregnancy test stick.

## Structure Diagram

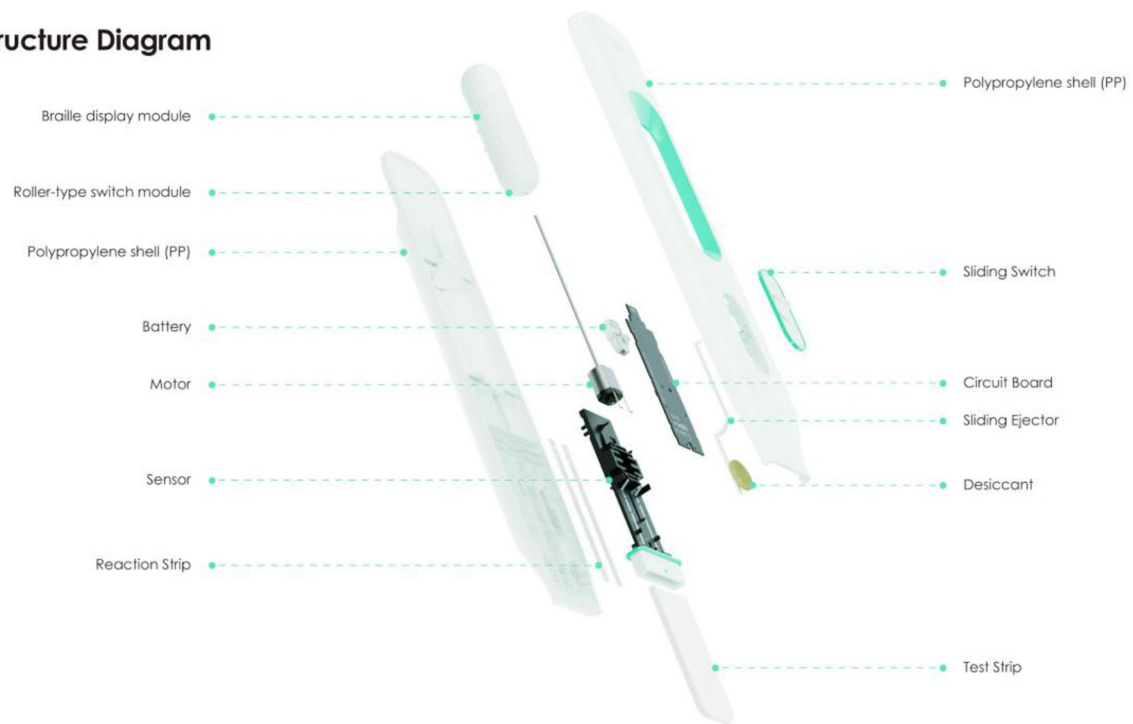


**Figure 5.** Exploded view of the accessible pregnancy test stick.

the result-reading area, reduces the risk of direct contact with urine and supports a clearer step-by-step interaction flow. A sensing unit detects the result signal generated by the reaction strip and the circuit board translates this signal into one of the three possible result states: "YES," "NO," or "ERROR." The motor and roller-type switch mechanism then actuate the tactile result-display module so that the user can read the outcome non-visually through Braille. The intended operational sequence of the prototype includes sample application, reaction, sliding-switch operation, test-strip extension and tactile result presentation.

### *Testing zone and non-visual guidance*

The front testing zone was designed to reduce the uncertainty during the sample application. The guiding grooves and tactile markers were incorporated to help the users locate the testing area more accurately and to reduce the likelihood of operational errors. Unlike conventional pregnancy tests, which primarily rely on the visual judgement, this design aims to use the tactile structural cues so that the user can identify the functional zones directly by exploring the product surface.

This arrangement is consistent with the high level of importance that the study participants expressed in Phase 1 regarding simple operation and the reduced risk of operational errors. The consistently high ratings for a simple operational path and clear result identification suggest that the participants were primarily concerned with whether the overall process could be completed reliably on the whole, rather than considering the tactile elements on their own. The testing zone, therefore, functions not merely as a textured surface but as the starting point of the entire interaction chain, helping the user establish the tactile awareness of the product's functional layout from the outset.

### *Sliding mechanism as a hygiene- and operation-oriented feature*

The central sliding mechanism was perceived as one of the most important structural features of the prototype. It was designed to extend the test strip after the sample application and to provide clear directional guidance through an arrow texture on the surface. Compared with a conventional press-based structure, the sliding mechanism was conceived as an interaction mode that would be easier to understand and less prone to accidental activation.

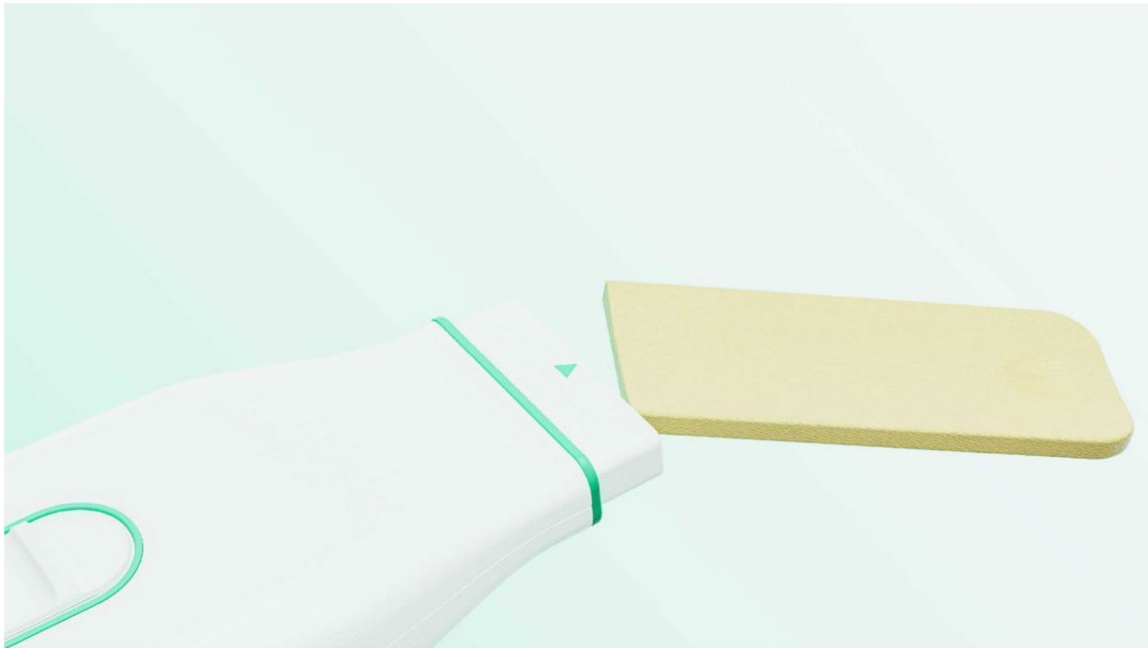


**Figure 6.** The concept of test-strip extension after sample application.



**Figure 7.** A sliding-switch design of the prototype.

From the perspective of the design outcomes, the sliding mechanism addresses two types of needs. First, it responds to the need for operational simplicity and independence. Phase 1 showed that ‘simple operation with reduced risk of unintended operation’ and ‘clear and identifiable test results’ were jointly the highest-priority features. A one-directional sliding action with directional cues could therefore make the next operational step easier to understand. Second, it responds to the hygiene concerns raised by some participants. Because the result reading was scheduled to occur after the test strip had been extended, the participants did not need to touch the sample-application area directly to confirm the result. Structurally, this separated the sample zone from the reading zone. As 5 of 10 participants in



**Figure 8.** The intended Braille result-feedback states for “YES,” “NO,” and “ERROR.”

Phase 1 explicitly mentioned contamination or hygiene concerns, the sliding mechanism is not only an interaction feature but also a structural strategy to address hygiene (Figures 6 and 7).

#### ***Tactile result feedback module***

The rear tactile result-reading module most directly addresses the needs identified in Phase 1 and represents the core innovation of the prototype. The module was designed to communicate three result states through raised English Braille words: “YES,” “NO,” and “ERROR.” “YES” is represented by three Braille character cells and indicates a pregnant result; “NO” is represented by two Braille character cells and indicates a not-pregnant result; and “ERROR” is represented by five Braille character cells and indicates an invalid test that should be repeated. Figure 8 illustrates the intended arrangement and Braille patterns of these three result states. Compared with a visual display window or voice output, this approach allows for the user to interpret the result silently, privately and non-visually, thereby reducing the reliance on others and lowering the risk of unintended disclosure.

#### ***Integration of the interaction flow***

Beyond the individual functions of each module, a key design outcome of the prototype is the formation of a continuous non-visual interaction path. From locating the front testing zone and applying the urine sample to activating the central sliding mechanism and reading the tactile result at the rear, the entire process is supported by the structural layout and surface tactile cues. In this way, the design moved beyond a single result-output module and instead formed a complete solution composed of the testing zone, sliding structure and tactile feedback working together.

#### ***Prototype development and physical model fabrication***

In Phase 4, the conceptual design was “converted” into a Rhino-based digital model and a 3D-printed physical prototype for tactile evaluation. The physical model represents the prototype’s overall form, structural zoning, sliding interaction and tactile result-feedback logic. As shown in Figures 9 and 10, the prototype enabled the participants to physically explore the product form and interaction sequence.

The assembled prototype was produced from several 3D-printed parts, including the upper and lower shell components, tactile result module, sliding switch, test-strip component and associated supporting



**Figure 9.** 3D-printed prototype.



**Figure 10.** A participant holding the prototype during the tactile exploration.

structures. The prototype permits the manual simulation of two intended interactions. First, the participants could move the sliding switch to extend the test strip from the front testing zone. Second, they could rotate the tactile result module and explore the raised Braille patterns representing the different result states. The prototype did not include the functional sensor, circuit board, battery, motor and electronic control system as in the complete product architecture. Consequently, the test-strip movement and tactile result changes had to be operated manually rather than being triggered automatically by a biochemical reaction or electronic signal.

**Table 6.** Descriptive statistics for the phase 5 user evaluation items.

| Dimension                    | Item                              | Mean | SD   | Median | Range        |
|------------------------------|-----------------------------------|------|------|--------|--------------|
| Perceived usefulness         | Independent use                   | 4.20 | 1.48 | 5.00   | 1.00 to 5.00 |
|                              | Privacy protection                | 4.90 | 0.32 | 5.00   | 4.00 to 5.00 |
|                              | Easier result understanding       | 4.30 | 1.25 | 5.00   | 2.00 to 5.00 |
|                              | Reduce anxiety                    | 3.80 | 0.79 | 4.00   | 2.00 to 5.00 |
|                              | Overall                           | 4.30 | 0.90 | 4.75   | 2.50 to 5.00 |
| Perceived ease of use        | Easy to understand                | 4.10 | 0.74 | 4.00   | 3.00 to 5.00 |
|                              | Tactile markers identifiable      | 4.20 | 1.48 | 5.00   | 1.00 to 5.00 |
|                              | Could use without help            | 4.10 | 1.66 | 5.00   | 1.00 to 5.00 |
|                              | Sliding mechanism easy to control | 3.50 | 0.53 | 3.50   | 3.00 to 4.00 |
|                              | Overall                           | 3.98 | 0.88 | 4.38   | 2.00 to 4.50 |
| Behavioural intention to use | Would choose this product         | 4.70 | 0.67 | 5.00   | 3.00 to 5.00 |
|                              | Comfortable using at home         | 4.60 | 0.52 | 5.00   | 4.00 to 5.00 |
|                              | Would recommend to others         | 4.70 | 0.48 | 5.00   | 4.00 to 5.00 |
|                              | Overall                           | 4.67 | 0.42 | 4.67   | 3.67 to 5.00 |

Note. SD represents the sample standard deviation. Overall values were calculated from each participant's mean score across the items within the corresponding dimension.

### Phase 5 user evaluation results

The Phase 5 user evaluation was informed by Technology Acceptance Model (TAM) and examined the concept prototype across three TAM-related dimensions: perceived usefulness, perceived ease of use and behavioural intention to use. As shown in Table 6, all three dimensions received positive subjective evaluations. Behavioural intention to use obtained the highest overall score (overall mean = 4.67), followed by perceived usefulness (overall mean = 4.30), while perceived ease of use also remained within a positive range (overall mean = 3.98). These results suggest that the participants perceived the concept as valuable and reported a high level of the preliminary acceptance towards its potential future use.

#### Perceived usefulness

"Perceived usefulness" was relatively high, with an overall mean of 4.30. Among the four items under the perceived usefulness category, "privacy protection" received the highest score (mean = 4.9), indicating that the participants perceived the concept as potentially advantageous compared with conventional, visually dependent pregnancy tests in this regard. This usefulness is followed by "easier result understanding" (mean = 4.3) and "independent use" (mean = 4.2), suggesting that the participants believed the tactile result feedback and overall structure could potentially improve the comprehension of the result and reduce the reliance on others. The mean score for "reducing anxiety" was 3.8. Although still positive overall, it was lower than the other usefulness items, suggesting a cautious yet positive view of the design's potential to reduce anxiety.

The individual response patterns showed that the two participants who could not distinguish the Braille patterns for "YES" and "NO" in Phase 1 provided the lowest ratings for independent use, easier result understanding and anxiety reduction. For anxiety reduction, these two participants gave the scores of 2 and 3, while the remaining eight participants gave the scores of 4 or 5. Therefore, the mean score of 3.8 should be understood as comparatively lower than the other perceived-usefulness items, rather than as an overall negative evaluation.

Overall, the perceived usefulness results show that participants most clearly recognised the prototype's potential value in protecting privacy, improving the understanding of results and supporting independent testing.

#### Perceived ease of use

Within the "perceived ease of use" section, the overall mean score was 3.98. Among the four items, "tactile markers identifiable" received the highest score (mean = 4.2), indicating that most participants were able to recognise the tactile markers in the prototype during the evaluation session without major difficulty. "Easy to understand" and "could use without help" both received mean scores of 4.1, suggesting that the participants generally found the operating logic understandable and perceived that they might be able to use the product independently. A greater variation was observed for "tactile-marker

identification" and "perceived ability to use the concept without help", with scores ranging from 1 to 5 for both items. By contrast, "sliding mechanism easy to control" received a mean score of 3.5, indicating that this feature still required further refinement and objective usability testing in subsequent iterations. Five participants gave this item a score of 3 and five participants gave it a score of 4, indicating that the score was comparatively lower than the other ease-of-use items but did not represent a negative evaluation of the sliding mechanism.

### ***Behavioural intention to use***

"Behavioural intention to use" received the highest evaluation score among the three dimensions, with an overall mean of 4.67. Specifically, "would choose this product" and "would recommend to others" both received mean scores of 4.7, while "comfortable using at home" received a mean score of 4.6. These findings indicate that, although this concept still left room for improvement and further validation, the participants reported strong preliminary willingness to consider the proposed design direction as a potential alternative to the vision-dependent pregnancy tests.

Notably, the participants were not only willing to try the concept themselves but were also inclined to recommend it to other BLV users. This finding suggests the perceived conceptual value in a broader user context, while still requiring a more in-depth independent participant evaluation and objective usability testing before the claims about real-world use can be made.

### ***Open-ended responses***

In addition to the rating items, the participants were asked which factors might increase or reduce their willingness to use the prototype. The open-ended responses focused mainly on three issues: price, accuracy and operational difficulty. Some participants noted that the affordability would influence their willingness to use the product, while others emphasised the testing accuracy and the ease of operation as important considerations. Although most participants did not provide extensive additional comments, these responses add practical-use context to the scale-based findings.

## **Discussion**

### ***Principal findings***

Through a five-phase user-centred design process, this study proposed and preliminarily evaluated the acceptability of a novel accessible pregnancy-test concept that is grounded in the difficulties and use barriers that BLV users face in the pregnancy self-testing using the conventional tests. The findings from Phase 1 and Phase 5, considered alongside the design and development work undertaken in Phases 2–4, indicate that the main barrier in existing pregnancy tests for BLV users is not only in the result interpretation being dependent on vision. Rather, the process usually requires another person to read and confirm the result, thereby compromising privacy, autonomy and confidence in use. The concept prototype received positive preliminary acceptability feedback in Phase 5, particularly regarding privacy protection, the understanding of results and behavioural intention to use.

These results suggest that accessible pregnancy testing should not be understood simply as a single technical problem of adding a readable result. Instead, it should be seen as a more complete design problem on how to support BLV users in completing the pregnancy self-testing process in a more independent, private and low-burden manner. In this respect, the study shifts the design focus from the output alone to a broader non-visual interaction flow composed of the testing zone, sliding structure and tactile result-reading module. However, while the present evidence supports the promise and acceptability of this direction, the effectiveness and functionality of a finished device still need to be validated in detail. Regarding RQ1, the Phase 1 findings identified visual dependence, reliance on others for result interpretation, privacy concerns, the need for simple operation and hygiene-related concerns as the main barriers and requirements associated with pregnancy self-testing among the participating BLV users. The participants also expressed stronger preferences for tactile forms of result communication, particularly Braille and physical raised markers, than for vibration and voice. Regarding

RQ2, these user requirements were translated into an integrated concept comprising a guided testing zone, a sliding mechanism and a tactile result-feedback module. The Phase 5 findings indicated positive preliminary acceptability across perceived usefulness, the perceived ease of use and behavioural intention to use, while the comparatively lower rating for the sliding mechanism indicated that this interaction still requires refinement and objective task-based evaluation. These findings answer the research questions at the level of user needs, design translation and preliminary acceptability rather than functional or clinical validation.

### ***Privacy and independence as primary design priorities***

One of the clearest findings of this study is that privacy and independence are not separate supplementary needs; rather, they are the core design priorities for pregnancy self-testing. In Phase 1, all participants reported that they could not complete the current tests independently and stated that needing another person to read the results compromised privacy. In Phase 5, privacy protection received the highest score within perceived usefulness (mean = 4.9). These findings indicate that, for BLV users, privacy is not a secondary dimension of user experience but an important condition affecting whether a product is perceived as acceptable and dignified.

This is consistent with the previous research showing that BLV users are highly sensitive to privacy and safety issues in technology use. It is also consistent with the broader disability-rights and reproductive-health perspectives in which autonomy, independent decision-making and equitable access to health information are central concerns [22–24]. These findings suggest that privacy in accessible pregnancy self-testing should be understood not only in terms of the physical setting in which the test is undertaken, but also in terms of the user's ability to control who has access to the result. The value of tactile feedback in the present concept therefore lies primarily in its potential to support silent and self-directed result interpretation without necessarily involving another person. This consideration does not mean that voice output is unsuitable in all circumstances; rather, tactile feedback represents an additional privacy-supporting option for users who prefer discreet, non-audible communication.

### ***Tactile feedback as an appropriate but not universal solution***

The results further support the suitability of tactile feedback as a promising direction for private health testing. In Phase 1, Braille and physical raised markers were clearly preferred to vibration and voice, and in Phase 5, easier result understanding also received a relatively high score (mean = 4.3). This indicates that participants generally acknowledged the value of tactile result feedback for interpreting test outcomes. For this prototype, the significance of the tactile result module lies not only in providing a technical alternative to the visual result displays but also in demonstrating that the result interpretation may be shifted from a visual window to a tactile interface while potentially preserving privacy and reducing reliance on others.

At the same time, the study clearly shows that Braille cannot be assumed to be the only naturally suitable solution for all BLV users. In Phase 1, although 8 of the 10 participants could distinguish Braille for “YES” and “NO,” 2 participants could not. This limitation is particularly important because Braille literacy, acquired visual impairment, age, tactile sensitivity and educational background may vary substantially across BLV populations. Therefore, the relatively high level of Braille familiarity in the present China-based sample should not be interpreted as representative of all BLV users. A Braille-only output strategy may exclude some users. Future design should therefore build on Braille while also evaluating complementary options such as suggestive raised symbols, shape-based indicators, raised standard-alphabet letters, tactile icons and other multimodal outputs that may be more widely recognisable among users with the different levels of Braille literacy.

Taken together, the variation in the acceptability ratings reinforces the need to avoid relying on Braille as the sole result-feedback method and supports the inclusion of complementary raised symbols, shape coding and/or other tactile cues in future iterations.

### ***Positive preliminary concept acceptance, with opportunities for further refinement of the sliding mechanism***

The Phase 5 results show a relatively clear pattern: the participants rated behavioural intention to use highest (overall mean = 4.67), followed by perceived usefulness (overall mean = 4.30), while perceived ease of use also remained in a positive range overall (overall mean = 3.98). This structure suggests that the participants generally perceived value in the design direction, particularly expressing the willingness to choose the product, use it at home and recommend it to other BLV users. At the same time, the results indicate that some interaction details still require further optimisation in later iterations. In other words, the participants provided preliminary acceptability feedback and design-refinement directions rather than the objective evidence of usability performance.

Regarding the perceived ease of use, the item ‘the sliding mechanism is easy to control’ received a mean score of 3.5. Although still positive overall, this finding suggests a more cautious evaluation of the sliding mechanism than of the other items. This conclusion is noteworthy because the sliding mechanism serves multiple functions in the prototype: it links the sample-application stage and the result-reading stage, spatially separates the sample zone from the reading zone to address hygiene concerns and reduces the risk of operational errors and lowers the learning burden through the directional guidance. The result, therefore, does not imply that the design direction lacks value; rather, it suggests that the sliding mechanism, as a core interaction component, may benefit from further structural refinement, including adjustments to tactile feedback, directional guidance and resistance control during operation.

This also helps explain why “reduce anxiety” received a positive but comparatively conservative score (mean = 3.8). The prototype was perceived to have advantages in privacy protection and result comprehensibility, but in a scenario such as pregnancy testing, which can involve emotional sensitivity and psychological pressure, reassurance also depends on confidence that each step of the operation is clear, smooth, hygienic and reliable. These issues cannot be confirmed through the current manually operable concept prototype, which did not include electronic sensing or diagnostic functionality and therefore require future task-based and real-use evaluation.

### ***Comparison with existing pregnancy-test interaction approaches***

This section considers common self-pregnancytest interaction approaches that are relevant to BLV users: conventional line-based tests, digital display tests, smartphone- or audio-assisted interpretation and the tactile concept proposed in this study. This comparison helps clarify the design rationale of the proposed concept, particularly its focus on reducing the visual dependence and supporting private, non-visual result interpretation.

**Table 7.** Comparison of existing pregnancy-test formats and the proposed tactile concept.

| Approach                                     | Main result-feedback mode                                                    | Visual dependence | Privacy for BLV users                                                            | Relevance to independent use                                            | Key limitation                                                                                       |
|----------------------------------------------|------------------------------------------------------------------------------|-------------------|----------------------------------------------------------------------------------|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Conventional line-based pregnancy test       | Coloured lines or symbols                                                    | High              | Limited, because another person may be needed to read the result                 | Low for many BLV users                                                  | Result interpretation depends on visual recognition                                                  |
| Digital pregnancy test                       | Text or symbols on a small screen                                            | High              | Limited, because the screen still needs to be read visually                      | Low to moderate                                                         | Reduces ambiguity for sighted users but remains visually dependent                                   |
| Smartphone- or audio-assisted interpretation | Camera-based reading, audio output or external assistance                    | Medium            | Variable, because audio or third-party assistance may expose private information | Potentially useful but dependent on additional technology or assistance | Requires a phone, app literacy, correct image capture or another person                              |
| Proposed tactile pregnancy-test concept      | Braille-based tactile result feedback with structured non-visual interaction | Low               | Potentially higher, because the result can be read silently and privately        | Potentially improved at the concept level                               | Not yet functionally validated; Braille literacy and real-use performance require further evaluation |

As shown in Table 7, the existing approaches mainly improve convenience or readability for sighted users, but they do not fully address the combined requirements of non-visual interpretation, privacy and independent use. The proposed concept therefore contributes by shifting result interpretation from a visual or auditory mode to a tactile and privacy-oriented interaction mode. However, this comparison should be interpreted at the level of design rationale rather than product performance. The present study does not claim that the concept outperforms existing pregnancy tests in diagnostic accuracy, reliability or real-world usability; these issues require future functional prototyping and task-based evaluation.

### ***Usability and human-factors implications***

From a usability and human-factors perspective, the present study provides an initial evaluation of the concept at the level of perceived usefulness, perceived ease of use and behavioural intention. These dimensions are relevant to user acceptance, but they should not be treated as equivalent to a full usability validation. In relation to ISO 9241 usability principles, particularly effectiveness, efficiency and satisfaction in a specified context of use [39], the current evaluation mainly reflects participants' subjective responses to the prototype's tactile layout, sliding interaction and intended result-feedback logic. It does not yet provide objective evidence of effectiveness or efficiency, such as whether users can complete the testing process accurately, how long the process takes, what types of operational errors occur or how reliably the result can be interpreted under real-use conditions.

Nevertheless, the findings identify several human-factors issues that are important for future development. The relatively lower score for the sliding mechanism suggests that resistance, grip, movement direction and tactile guidance should be refined to reduce operational uncertainty. The use of tactile textures and a Braille-based result module also indicates the need to consider tactile legibility, hand positioning and variation in Braille literacy among BLV users. In addition, because pregnancy testing involves urine handling and private health information, future usability testing should examine hygiene, contamination risk, workload, confidence and use in realistic home environments. Therefore, the present findings should be understood as preliminary acceptability evidence that informs subsequent task-based usability and ergonomic evaluation, rather than as proof of final device usability.

### ***Implications for accessible health technology design***

This study has three broader implications for accessible health-technology design. First, health self-testing products for BLV users should not aim only to make information available; they should also consider the independent completion of the entire private process as a higher-level design task. In Phase 1, the participants' strongest concern was not the addition of more features, but the reduction of reliance on others. In Phase 5, what was highly valued was not a single component in isolation, but the concept's perceived value for privacy and autonomy. Future design in similar products should therefore move beyond the question of whether the result can be read to the question of whether the entire process can be completed independently, privately and with dignity.

Second, tactile design should not appear only at the final stage of the output; it should run throughout the interaction flow. In the current concept, the integration of the testing zone, sliding structure and result module reflects such an end-to-end non-visual path design. This suggests that, for medical and health products intended for BLV users, promising accessibility may be achieved not only by adding a single tactile cue, but by ensuring that the operational chain is supported by coherent tactile logic. For home self-testing devices that require both high privacy and high accuracy, this continuity of tactile interaction may be more valuable than any isolated tactile component, although this assumption must still be tested through objective usability studies.

Third, willingness to adopt an accessible health product does not depend only on interface and structure. The Phase 5 open-ended responses indicated that price, accuracy and operational difficulty were important factors affecting willingness to use the prototype concept. This means that, even if a concept prototype receives relatively high acceptance in design evaluation, future adoption will still depend on whether it can also be affordable, trustworthy, accurate and stable under real conditions. In particular,

the emphasis on accuracy is a reminder that, for a diagnostic device such as a pregnancy test, design-level acceptability cannot substitute for confidence in the result itself.

### ***Scope of the contribution and directions for future development***

Although the overall findings of this study are positive, its contribution should be understood contextually. The study provides initial evidence that a design direction centred on privacy, tactile feedback and independent operation has preliminary acceptability potential; it does not demonstrate that the prototype has reached clinical, engineering or market maturity. What was evaluated here was a concept prototype that had been visually developed through C4D rendering, refined as a digital CAD model in Rhino and realised as a 3D-printed physical form. Its primary purpose was to allow for the study participants to touch and assess the structural logic, result module and interaction flow, rather than to verify final materials, sealing performance, single-use mechanisms, cleaning performance, diagnostic accuracy or real-world usability outcomes.

Accordingly, the key discussion is not whether the product is already ready for deployment, but whether the underlying design logic is worth advancing into later functional prototyping and objective evaluation. From that perspective, the findings indicate a promising direction. The participants' positive perceptions of the prototype, high evaluation of privacy protection, preference for tactile result feedback and willingness to use the concept suggest that this direction has design value. At the same time, the inclusive limits of Braille, the control experience of the sliding mechanism, the absence of independent validation and the concerns about price and accuracy are the main issues that future work needs to address.

The present study did not include a formal manufacturing-cost or commercial-feasibility analysis. Future functional development should therefore assess prototype production costs and manufacturing feasibility, particularly in relation to the sensing components, electronic control system, tactile actuation mechanism, assembly and sealing requirements, while exploring opportunities to simplify the component architecture and maintain affordability.

The next stage of this research will focus on developing a functional prototype that integrates the sensing unit, electronic control system, motor-driven tactile result module and diagnostic components. This development will be followed by technical testing of diagnostic accuracy, electronic reliability, actuation repeatability, sealing and contamination control. After technical refinement, task-based usability evaluation will be conducted with a larger and more diverse group of independent BLV participants under realistic home-use conditions, using objective performance measures and standardised usability assessments.

### **Limitations**

This study has several limitations. First, the sample size was small and participants were drawn mainly from a relatively concentrated local context in Zhuzhou, China. The findings should therefore be interpreted as early exploratory results rather than the evidence that can directly represent the broader population of BLV users. Although the sample was appropriate for an exploratory user-centred design study, future studies should include larger, more diverse samples to test the robustness and wider applicability of the findings.

Second, the evaluated object was an early concept prototype rather than a mature product that had completed engineering development or clinical validation. Although the 3D-printed model enabled participants to physically assess the overall structure, tactile interaction and result-feedback logic, critical issues such as diagnostic accuracy, result interpretation accuracy, engineering reliability, repeatability, sealing performance, contamination control, cleaning performance and hygienic safety were not empirically validated. The current findings should therefore be understood as the evidence of preliminary design acceptability rather than the proof of product effectiveness, product maturity or real-world usability.

Third, although most participants responded positively to Braille-based tactile feedback, this approach may not suit all BLV users. In Phase 1, not all participants were able to distinguish Braille patterns for "YES" and "NO," indicating that a Braille-only solution has limitations in terms of inclusiveness. Braille

literacy, acquired visual impairment, older age and reduced tactile sensitivity may affect the users' ability to interpret Braille output reliably. Future research should evaluate more flexible tactile and multimodal output modes, including combinations of Braille with raised symbols, shape coding, raised standard-alphabet letters, tactile icons, vibrotactile cues or other complementary feedback methods.

Fourth, Phase 5 was informed by TAM in evaluating the preliminary acceptability of the prototype concept. Although this helped reveal the participants' perceived usefulness, perceived ease of use and initial acceptance, it cannot replace formal task-based usability testing, human-factors evaluation or observational research in real-use contexts. Future studies should combine TAM with objective and standardised usability measures, such as task completion rate, time-on-task, operational errors, result interpretation accuracy, the System Usability Scale (SUS) [40], NASA-TLX for perceived workload [41], user satisfaction and structured observation under realistic home-use scenarios.

Fifth, the same participants contributed to both Phase 1 needs elicitation and Phase 5 prototype acceptability evaluation. This continuity was useful for user-centred concept development, but it may also have introduced confirmation bias, ownership effects, expectation bias and social desirability bias. Participants who contributed to the early design process may have been more likely to evaluate the resulting concept positively. Future studies should therefore recruit independent BLV participants who were not involved in the concept-development phase.

Finally, the study did not include independent functional validation or comparison testing against commercially available pregnancy tests. Future work should compare the proposed concept with line-based tests, digital pregnancy tests and app-assisted or audio-assisted approaches using both subjective and objective measures. Such work is essential before any claims can be made regarding effectiveness, reliability or superiority over existing solutions.

## Conclusion

This study developed and preliminarily evaluated the acceptability of an accessible pregnancy-test concept for BLV users through a five-phase user-centred design process. The findings indicate that the difficulties posed by existing pregnancy tests are not limited to visually dependent result interpretation; they also include reduced independence, privacy exposure and the need for a simple and understandable interaction process. In response to these issues, the study developed a concept prototype that combines tactile result feedback, a structured interaction flow and a sliding mechanism intended to support a more private and non-visual pregnancy self-testing experience.

The Phase 5 evaluation showed that participants reported positive perceptions of the concept, particularly in relation to privacy protection, result understanding and behavioural intention to use. These findings should be interpreted as preliminary evidence of user acceptability, not as evidence of diagnostic accuracy, technical reliability, hygiene performance or actual usability effectiveness. Some interaction details, especially the sliding mechanism and tactile-output strategy, require further refinement and testing.

Overall, this study provides an early design-research foundation for the development of more inclusive self-testing technologies. The proposed tactile and privacy-oriented design direction appears promising, but future research must include functional prototyping, objective task-based usability evaluation, independent participant validation, comparison with existing products, contamination-control assessment and real-world testing before the concept can be considered a validated assistive health device.

## Author contributions

CRedit: **Zeqi Huang**: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing; **Dan Li**: Conceptualization, Investigation, Validation; **Haowen Yin**: Conceptualization, Investigation, Validation; **Vanja Garaj**: Conceptualization, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing.

## Disclosure statement

No potential conflict of interest was reported by the authors.

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