TrueHb Hemometer Usability Evaluation

Assessment conducted in antenatal care settings in Kintampo, Ghana
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Cover photo: PATH/Gabe Bienczycki.
1. Introduction

Screening and treating women for anemia during pregnancy has the potential to greatly improve maternal and infant health outcomes globally. Over one-third (38 percent) of pregnant women experience anemia during the gestational period. Maternal anemia increases perinatal risks for both mothers and babies through premature labor, gestational diabetes, preeclampsia, acute heart failure, postpartum hemorrhage, and severe postpartum infection. It also increases the risks to infants through low birth weight, preterm delivery, and anemia. In many low- and middle-income countries, health care providers do not have access to accurate, safe, and low-cost methods of screening for anemia. Recent product development efforts have focused on filling this diagnostic gap. One promising new tool is the TrueHb Hemometer System, developed by Wrig Nanosystems Pvt. Ltd. in New Delhi, India.

The TrueHb Hemometer is a point-of-care test based on the principle of reflectance photometry. A drop of blood is applied to the strip, and it measures optical reflectance, which is inversely proportional to the concentration of hemoglobin (Hb) in the blood sample. Using this correlation, the concentration of total Hb in the whole blood sample is calculated. This is a promising technology, which aligns with target product profile performance criteria, particularly using venous blood.

The Bill & Melinda Gates Foundation is interested in determining the appropriateness of the tool for use in antenatal care (ANC) settings in low- and middle-income countries. To this end, PATH conducted a usability evaluation with health care providers in rural Ghana in order to assess the operational fit and inform product introduction. PATH undertook the study in collaboration with Akendi, a user experience research and design firm based out of Ottawa, Canada, and the Kintampo Health Research Centre, a field research center of the Ghana Health Service and longstanding PATH partner. This report presents the main findings of this evaluation.

2. Methods

The application of user-centered design to global health product development and delivery is an approach that has gained increasing attention from researchers and practitioners alike. There is growing recognition that a thorough understanding of end user goals and context of use is critical to the development of appropriate health technologies. PATH, among other researchers and organizations, has championed “right-fit” technology development, recognizing that aligning with the motivations and constraints of the end user is essential for product uptake and, ultimately, the ability of a new tool to improve health outcomes.

The objective of this study was to evaluate the usability of the TrueHb with target end users in ANC settings. Our approach measured usability across four domains: (1) effectiveness, (2) efficiency, (3) satisfaction, and (4) learnability. This methodology adheres to ISO 9241-210 on human-centered design principles in usability testing. The four domains are defined as follows:

- **Effectiveness**—measures whether users are able to achieve their goals through use of the product.
• **Efficiency**—assesses the timeliness of task completion and error rates as users interact with the product.

• **Satisfaction**—measures user perceptions and feelings while using the product to complete tasks.

• **Learnability**—evaluates whether users improve at completing tasks while using the product over a period of time.

Three primary goals shaped the study design and data collection process:

• Firstly, we wanted to understand ease of use navigating the TrueHb’s functions to gather specific information and run the test.

• Secondly, we were interested in how well users understood the test labeling, the layout, and instructional materials provided with the test.

• Finally, we aimed to identify usability issues with the design of the test and instructions and make recommendations for improvement.

Seven rural health clinics in the Brong-Ahafo Region of Ghana were selected as study sites for the usability testing. These sites were selected due to their remote location and daily provision of ANC. Each clinic was staffed by health care providers including midwives, community health nurses, and enrolled nurses. Two of the health clinics were larger and contained adjoining laboratories. At these locations, physician’s assistants and laboratory technicians were also present. As the intended end users of the TrueHb, these individuals served as our study participants. Participants were purposively sampled based on their job title, and when fewer staff were available, all eligible participants were enrolled. Our goal was to assess approximately 3 participants per facility until we reached our total sample size of 20. Twenty participants is a valid standard for usability studies of this type, which was exploratory, ethnographic, and focused on problem discovery.¹³

Each usability testing session was moderated by a facilitator with a note taker present. A third member of the research team played the role of the pregnant women whose Hb needed to be measured. Testing sessions were conducted in a private area within each health facility, and consent was collected from all participants prior to enrollment. Each session consisted of the participant being asked to complete three tasks using the device, while voicing his or her thought process aloud, without aid from the facilitators. The three tasks were as follows: (1) measuring the “pregnant woman’s” Hb, (2) accessing a specific result stored in the device’s memory, and (3) taking another measure of the “patient’s” Hb. These tasks represent common usage scenarios expected of device users. The decision to include two Hb measurement tasks was based on the desire to evaluate learnability and compare metrics across two attempts. These tasks were followed by qualitative self-assessments and self-report ratings for each task, in addition to four qualitative post-task probes. The sessions concluded with 16 post-test questions, including interpreting screenshots from the device and providing information on education and work history, regular job duties in ANC, and methods currently in use to screen for anemia. For each task, metrics on task success (pass, fail, pass with hints), total task time, and ease of use rating (five-point Likert scale) were collected as well. During the testing sessions, the moderator and note taker observed the actions of participants and recorded their comments and feedback. Video recordings were also captured with participants’ consent.
3. Results

Data collection took place over four days in seven health facilities in Kintampo North and South Districts in Ghana’s Brong-Ahafo Region. Twenty health workers were recruited and participated in the usability evaluation. Table 2 below describes the number of participants enrolled in the study by job title. On average, participants had three years of health care work experience. When we asked about commonly used methods for anemia screening, we learned that many of the participants had recent experience with the URIT 12 hemoglobin measurement tool (Shanghai SUCE Medical Technology Development Co., Ltd./Guangxi, China). A local nongovernmental organization called Layata had provided these devices to health care clinics in the area, and 13 out of 20 participants had received some training and used the device. The other two methods that participants reported using were the WHO color scale and clinical assessment.

Table 1. Tasks and probes used to assess usability.

<table>
<thead>
<tr>
<th>Question or Instruction</th>
<th>Task 1</th>
<th>Probe 1</th>
<th>Probe 2</th>
<th>Probe 3</th>
<th>Probe 4</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please measure the patient’s hemoglobin.</td>
<td></td>
<td>Can you show me how you would set the batch code?</td>
<td>How did you know the machine was processing the sample?</td>
<td>Did the device give you sufficient feedback about what was going on while the sample was being processed?</td>
<td>What were your impressions of the instruction manuals that you were given?</td>
<td>Ease of completing Task 1 on a scale of 1 to 5.</td>
</tr>
<tr>
<td>Please find the third reading stored in the device memory.</td>
<td>Task 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ease of completing Task 2 on a scale of 1 to 5.</td>
</tr>
<tr>
<td>Please measure the patient’s hemoglobin level again.</td>
<td>Task 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ease of completing Task 3 on a scale of 1 to 5.</td>
</tr>
</tbody>
</table>
In order to identify usability issues and present recommendations for improvement, we classified our findings into three categories based on severity. We defined the three categories as follows:

- **Catastrophic.** These issues should be fixed prior to product launch. In regard to the TrueHb specifically, these issues cause a user to obtain a false result and do not alert the user that the result is invalid.

- **Critical.** These issues should be fixed immediately. They prevent the user from finishing a task or cause the user to spend large amounts of time and effort attempting to complete the task.

- **Major.** These issues slow down task completion and/or introduce human error during the task. Users then must recover from the error, which further slows their progress.

- **Minor.** These issues are potential annoyances to the user but do not prevent task completion.

The following sections detail the catastrophic, critical, major, and minor issues identified and provide recommendations on how to address them. A summary of the usability issues and recommendation can be seen in table 3.

### 3.1 Catastrophic issues

#### 3.1.1 Insufficient volume of blood

A catastrophic issue related to blood sample application is **insufficient blood volume.** In three instances, an insufficient volume of blood was applied to the strip. The instructions state that the entire white box area on the strip should be covered with blood, and the volume fell short in these instances. In such cases, the result would be inaccurate (Hb measurement would be falsely low), but the user would not be aware of this failure.

#### 3.1.2 Removal of strip from device

Another catastrophic issue is the potential for false readings, following the **removal of the strip from the device.** Pulling the strip out of the device can trigger it to start reading (even though no strip is present) and provide a low Hb reading (~3g/dl). During our usability testing session, whenever this happened the participant understood that an error occurred and did not trust that the result was accurate; however, there is a chance other users may believe this result is valid.
3.2 Critical issues

Both strip placement and blood placement were found to be critical issues. Participants inserted the strip incorrectly a total of 18 times across 40 Hb measurement attempts (9 times on Task 1 and 9 times on Task 2). The most common error was not inserting the strip far enough into the device. When this happened, it often led to blood placement errors (4/9 strip placement errors on Task 1 led to blood placement errors). Other less common errors were inserting the strip backwards or upside down. In total, there were 5 instances of the blood being added to an incorrect area of the strip. In 4 of those instances, blood placement errors coincided with the strip being incorrectly inserted into the device. It is important to note that all blood placement errors occurred during Task 1 and were corrected by participants in Task 3.

3.3 Major issues

A major issue that challenged participants was the process of accepting the batch code. This is the first step that users must perform before they are able to progress to testing a blood sample. Each container of TrueHb strips has a unique batch code. Upon turning on the device, the user must adjust the batch code to match the code on the strip container and press accept before beginning the Hb measurement process. Using the left and right arrows to navigate between digits of the batch code and the up and down arrows to change the numbers was not intuitive for the majority of participants. Accepting the batch code by pressing the middle button was similarly challenging. In total, six participants had to be prompted by the researchers to accept the batch code after becoming stuck at this stage. A likely cause of this confusion was the dual purpose of the middle button. The middle button is used to power the device on and off, and it is also the “enter” button. Participants were hesitant to push this button for fear of powering down the device while in use. A similar and related issue was inserting the test strip before turning on the device or accepting the batch code. This occurred on 16 separate occasions and created confusion with the procedure when attempting to accept the batch code.

The primary reason for these issues was the inaccurate and inadequate instructions for use included in the test kit. The instructions provided with the TrueHb device did not match the features of the device. Participants who read the instructions were told to set the time and date first; however, the version of the device included in the kit did not have the ability to display date and time. This created confusion and caused the study team to make revisions to the instructions by hand.

When asked about their impressions of the instructions, some participants commented on the density of the text and the length, suggesting that more images could be used to enhance clarity and ease of use.
While these issues are considered major, the inaccuracies and inadequacies of the instructions can be readily addressed in future versions. The instructions should be organized in a manner that supports findability and better reflects the user workflow. Many participants spent several minutes during tasks reviewing and re-reviewing the instructions, searching for the direction that would help them to complete the task. Simplifying the instructions and focusing on clarity of the workflow would reduce user frustration. Some participants lacked familiarity with the vocabulary used in the instructions as well. For example, while narrating their procedure aloud, it was common for participants to refer to the test strip as a lancet.

3.4 Minor issues

Minor issues included the **length of time it took participants to complete the tasks**. On average, participants took 6 minutes and 35 seconds to complete Task 1—measuring the “patient’s” Hb. By Task 3, the repeat Hb measurement, the average time had dropped to 4 minutes and 45 seconds.

3.5 Overall pass and fail rates

Figure 1 below provides a visual depiction of overall pass and fail rates on Task 1, Probe 1, Task 2 and Task 3. Each participant is listed horizontally, and the color of the cell denotes whether the participant succeeded, succeeded with hints, or failed. The number within each cell is the total time in seconds taken to complete the task or probe. The next sections will summarize participant performance by task and probe, including common errors and pass and fail rates.
3.5.1 Task 1

Task 1 instructed participants to take the “pregnant woman’s” Hb measurement. The success rate for Task 1 was 10 out of 20. Among the 10 participants that passed Task 1, 7 participants performed the procedure with minor errors that they diagnosed and remedied themselves or that did not impact the final result, including multiple attempts to turn on the machine, acceptance of the correct batch code by accident, and blood applied multiple times or in several different places on the device.

The total time it took participants to complete Task 1 also corresponds with success rate. Figure 2 below demonstrates the relationship between shorter task completion times and the increased likelihood of passing the task.

Figure 2. Summary of Task 1 completion times and participant success and failure.
Of the participants that failed Task 1, the most common errors were improperly inserting the strip (7 of 10 participants), failing to accept the batch code (3 of 10), and putting the blood in the wrong place on the strip (4 of 10). Another frequent error in the procedure was inserting the strip prior to turning on the test and/or accepting the batch code (5 out of 10). A summary of all errors performed by participants that failed Task 1 is provided in table 3. Other workflow errors included accidentally turning off the machine or having it time out due to disuse (3 of 10) and removing the strip prior to the completion of a reading (3 of 10), triggering the machine to count down and provide a false result (usually ~3 g/dl). This is a device design issue with implications beyond usability that should be addressed.

3.5.2 Probe 1

Probe 1 asked participants to demonstrate how they would set the batch code. The success rate for this probe was 12 out of 19, as one participant did not get far enough into Task 1 to be able to answer the probe. Nine participants (4 who passed, 5 who failed) chose to consult the instructions manual in their attempt to complete this request. Of the 9 participants that completed the probe successfully, 7 did so without accessing the instructions. The most common issues with Probe 1 were not understanding that each digit of the batch code needed to be adjusted independently and/or not recognizing how the up and down and left and right arrows functioned to adjust the code. Others were unable to locate the relevant information in the instructions manual.

3.5.3 Task 2

Task 2 instructed participants to recall a test result from the device’s memory. Overall, 15 participants succeeded in completing this task (8 with hints and 7 without hints). The most common issues participants faced included accidentally navigating out of the device memory by hitting the right arrow and getting stuck adjusting the batch code rather than navigating to the memory. Participants were divided on the ease of use of this task. Twenty-five percent rated it as a 4 on a 5-point scale, with 1 being “not at all easy to use” and 5 being “very easy to use.” Twenty percent of participants each gave it a 1, 2, or 5 rating.

3.5.4 Task 3

Task 3 asked participants to re-measure the “pregnant woman’s” Hb. In total, 15 participants out of 20 passed Task 3 (4 with hints and 11 without hints). There were some procedural errors among the participants that passed, including 6 participants who inserted the test strip prior to turning on the machine and accepting the batch code. Among the participants that passed with hints, 1 applied an insufficient amount of blood, 2 prematurely removed the strip, triggering the device to begin reading, 3 did not fully insert the strip, and 1 failed to accept the batch code. These errors were made on their first attempt at the task. In successive attempts, they were able to complete the task with hints from the facilitators.

Among the participants that failed, the most common error was not fully inserting the test strip (4 of 5), inserting the strip prior to accepting the batch code (4 of 5) and failing to accept the batch code (1 of 5). Table 3 summarizes the frequency of these errors. Three participants also reported confusion related to the symbols on the device, including the blood symbol and the green light. Overall, the ease of use ratings
increased between Task 1 and Task 3, with 55 percent of participants giving Task 3 a 5/5 rating as “very easy to use.”

Table 3. Summary of errors performed by participants who failed Task 1 and Task 3.

<table>
<thead>
<tr>
<th>Error</th>
<th>Frequency in Task 1</th>
<th>Frequency in Task 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strip placement</td>
<td>7/10</td>
<td>4/5</td>
</tr>
<tr>
<td>Inserting strip prior to turning on the test and accepting the batch code</td>
<td>5/10</td>
<td>4/5</td>
</tr>
<tr>
<td>Blood placement</td>
<td>4/10</td>
<td>-</td>
</tr>
<tr>
<td>Removed strip from device triggering it to start reading</td>
<td>3/10</td>
<td>-</td>
</tr>
<tr>
<td>Failing to accept the batch code</td>
<td>3/10</td>
<td>1/5</td>
</tr>
<tr>
<td>Accidentally turning off of the device or experienced a timeout</td>
<td>3/10</td>
<td>-</td>
</tr>
</tbody>
</table>

3.6 Ease of use ratings

Table 4 below provides a summary of the ease of use ratings provided by participants. Participants were asked to rate the ease of use of specific tasks and probes on a scale of 1 to 5, with 1 being “not at all easy to use” and 5 being “very easy to use.” The rating frequency is provided as a percentage.

Table 4. Summary of ease of use ratings.

<table>
<thead>
<tr>
<th>Ease of use rating</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task 1</td>
<td>0%</td>
<td>10%</td>
<td>25%</td>
<td>30%</td>
<td>35%</td>
<td>5</td>
</tr>
<tr>
<td>Probe 1</td>
<td>5%</td>
<td>0%</td>
<td>25%</td>
<td>25%</td>
<td>45%</td>
<td>5</td>
</tr>
<tr>
<td>Task 2</td>
<td>20%</td>
<td>20%</td>
<td>15%</td>
<td>25%</td>
<td>20%</td>
<td>4</td>
</tr>
<tr>
<td>Task 3</td>
<td>0%</td>
<td>5%</td>
<td>10%</td>
<td>30%</td>
<td>55%</td>
<td>5</td>
</tr>
</tbody>
</table>

4. Discussion

Two major principles of good interaction design are that (a) the user should feel empowered, and (b) the designer should make it easy for users to diagnose and recover from errors. We have identified two root causes of the observed usability issues: (1) the device feedback and (2) the instructions.

4.1 Device feedback

4.1.1 Catastrophic errors

Catastrophic errors should be addressed with improved device feedback. The lack of an error code on insufficient blood volume and removal of the test strip will lead to invalid results that are unbeknownst
to the user. We recommend that the device not give a result if a strip is not inserted and instead provide an error message that prompts user action. Similarly, if the blood volume is insufficient, the device should note this in an error message rather than providing an inaccurate result. The HemoCue® (HemoCue is a registered trademark of HemoCue AB, Ängelholm, Sweden), for example, has error messages when the blood volume collected is insufficient.

4.1.2 Procedural errors

The TrueHb workflow forces very specific steps. If the user does any of the steps out of order, the user will not progress to the Hb measurement step, and a result will not be attained. Often, a user should restart the device when he or she is unable to progress but received no prompting to do so. Similarly, users do not receive any feedback if they perform the common errors we have described, including those related to accepting the batch code, inserting the strip, and placing the blood sample. The device does not provide sufficient feedback to users to alert them to procedural errors.

By adding error codes, users are empowered to better diagnose, remedy, and recover from issues themselves.

Other user errors prevent the test from being successfully completed. For example, we have observed users struggling with the batch code entry as there is no indication on the device that the batch code needs to be accepted, nor does it indicate how to do so. The center button is prominently labeled as power, with no labeling to explain that it also serves as the enter key. Such errors result in confusion and limit user satisfaction, efficiency, and effectiveness and could be targeted through an improved design process.

4.2 Instructions for use

Problems following directions arose from (a) the instructions not being fully read by the participant, (b) the instructions not being fully understood, (c) the participant being unable to find specific content when needed, or (d) inaccuracies in the instructions themselves. Based on what we observed in this study, we are of the opinion that the content and organization of the instruction manual as well as the lack of other training resources will present a barrier to the adoption and widespread use of the TrueHb in ANC settings. The instruction booklet should be redesigned to improve reader comprehension—for instance, by using more pictures to illustrate the points being raised or to call out features that would be helpful to the user, such as connecting blood placement with the
green light emitted by the device or feeling a “click” to help decrease strip placement errors (discussed further in the sections that follow). The instructions could be better organized, as well, so that the reader can more quickly find the information needed. Also, the length of the instructions should be decreased to encourage users to fully read through the entire booklet prior to using the device. Finally, the instructions need to be accurate and match the device model.

These changes would address some critical and major issues (see above photo for an image of the current instructions). In addition, adaptable training content, including a hands-on component, would be useful. Practical in-person training was the method preferred by participants and the training approach they were most familiar with through past on-the-job trainings. While in-person training, to be provided by the manufacturer, is likely not compatible with the revenue model for a low-cost reader, nonprofits and other organizations can step in to fill this gap.

Figure 3 provides one example of how the instructions could be altered to better explain the process of changing and accepting the batch code using an illustration. Revising the instructions is a low-cost change that has the potential to greatly improve usability.

Another simple revision to the instructions would be to reorganize the content based on user workflow. Currently the procedure for running the test begins on page 9. Instructions for use could begin with the test procedure to improve findability of highly accessed content. Additionally, the current images in the instructions are blurry and difficult to read. They could be enlarged and more clearly labeled.

A greater focus on the onscreen symbols and the actions they prompt could improve ease of use. For example, there is no mention of the green light, which shines up through the blood drop on the strip and serves to measure the Hb (via reflectance photometry). If the user understood the purpose of the light, strip placement errors would likely be less common. Strip placement could also be improved by letting users know that they should continue to push the strip into place until they feel it “click.”

4.3 Other issues

For some users, their exposure to the URIT 12 Hb measurement tool may have influenced the way they approached the TrueHb Hemometer. The URIT 12 shares similarities with the TrueHb Hemometer, including the size and shape of the reader, the digital interface, and the use of paper strips for blood application. However, there were significant differences in the workflow that may have introduced challenges for participants. Some participants with knowledge of the device had difficulty in selecting the batch code and inserting the test strips. The URIT 12 uses a removable chip to automatically assign the
batch code, whereas TrueHb requires use of all four directional buttons to navigate to and change the digits of the batch code. Similarly, the design of the URIT 12 requires no force from the user when inserting the test strips, whereas the TrueHb test strips must be pushed in until they “click” into place. Participants who were familiar with the URIT 12 often stopped pushing as soon as they felt any resistance. This resulted in strips not inserted far enough and, subsequently, issues with blood placement. Familiarity with the URIT formed an established mental model for digital Hb measurement tools that may have been the source of some confusion among participants.

It is interesting to note that ease of use ratings given by participants, even after failing to complete tasks or requiring several hints, were consistently high. These findings are in line with qualitative comments that captured participant’s eagerness to have a smaller, cheaper, and more accessible way in which to provide Hb measurement services in ANC. We also recognize that high ease of use ratings may also be upwardly biased due to the “pleasing effect,” where participants under observation may alter their behavior in order to give researchers the response they felt was desired.

“The device is handy, easy to carry, can be used for ANC outreach and bring to community visits; [TrueHb] is a better size than the [HemoCue].” - P3 (ease of use rating of 4 out of 5 was given)

" This one in a couple of minutes you will get the result and it will give you confidence to take care of the woman. There are so many people that can do it.” - P9 (ease of use rating of 5 out of 5 was given)

5. Conclusions and summary of recommendations

A summary of the primary usability issues and corresponding recommendations can be found in table 5 below. The TrueHb Hemometer is a promising hemoglobin measurement tool with product characteristics that has the potential to align well with user needs and context requirements for use in ANC settings. This usability testing demonstrated that the TrueHb tool can be used by ANC workers. However, the usability of the tool should be improved through modifications to the instructions and improvements to the device design, in particular through improved device feedback mechanisms. Hands-on training should be provided to all users through a small pilot program before the TrueHb is introduced and deployed at scale.
Table 5. Summary of usability issues with associated recommendations and severity rankings.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Recommendation</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Lack of error codes</td>
<td>More error codes would empower users to diagnose, remedy, and recover from errors themselves. The most essential error codes are those relating to (1) insufficient sample volume and (2) strip removal.</td>
<td>Catastrophic</td>
</tr>
<tr>
<td>2 Strip placement</td>
<td>Clearly state in instructions that strip must be pushed until “click” is felt. Alternatively, change the design to one that does not present the user with any resistance when inserting the strip.</td>
<td>Critical</td>
</tr>
<tr>
<td>3 Blood placement</td>
<td>Many of the blood placement errors that were observed were directly related to the strip placement. A recessed blood drop area would help with proper blood placement.</td>
<td>Critical</td>
</tr>
<tr>
<td>4 Batch code</td>
<td>Create clearer instructional materials on how to set the batch code. A device redesign improvement would be to have the batch code automatically read and accepted when the strip is inserted.</td>
<td>Major</td>
</tr>
</tbody>
</table>
| 5 Instructions        | - Provide less text density and more/larger images and illustrations to aid comprehension.  
                        | - Ensure that the instructions reflect the particular model of the device the user possesses.  
                        | - Organize instructions in a way that supports findability and better reflects user workflow.  
                        | - Emphasize more in the instructions the relationship between the green light and the device reading. | Major |
| 6 Training            | Include hands-on practice as part of training.                                  | Minor |
References


