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Dear Tina Richardson,

Thank you for choosing C&H Consulting Firm to conduct a formative usability test for the CareTouch® Blood Glucose Monitoring System. Attached you will find the usability assessment, which includes a protocol summary, the use scenarios used for our assessment, a summary of our findings, our suggestions for design changes based on the test results, and a short presentation that illustrates significant interactions by multiple test participants.

Please feel free to reach out to us if you have any questions or concerns.

Best regards,

Colby Cho, Frank Hua, Mudi Geng, Joel Rheaume
Human Factors Engineering Consultants
C&H Consulting Firm



Protocol Summary*

Introduction

The purpose of this formative usability test is to assess the safety and usability of the CareTouch® Blood Glucose Monitoring System. By putting participants through a variety of key use scenarios, we can determine whether the glucose meter facilitates its intended uses and meets the specified safety and usability standards.

Product Description

The CareTouch® Blood Glucose Monitoring System is intended for the quantitative measurement of the concentration of glucose in whole blood drawn from the fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes.

Test Personnel

Colby Cho : Main facilitator

Mudi Geng : Behavioral observer and recorder

Frank Hua : Assisting facilitator

Joel Rheume : Behavioral observer and interview recorder

Test Participants, Criteria

- At most one college student
- At least one participant with experience using a glucose meter
- At least one participant over the age of 50
- At least one Hispanic participant
- At least one non-native English speaker

Test Environment

- Indoors in a dry, well-lit room
- Normal operating temperature range: 50 - 104°F
- Void of any electromagnetic field (e.g., microwave)
- Kept out of direct sunlight and humid conditions

Use Scenarios

Control Solution Test**, Device Setup & Test, Most Recent Result Reading, Post-testing Procedure, and Error Troubleshooting

Data Collection

- Qualitative data: experimental results including responses to the interview questions and behavioral descriptions for each use scenario
- Quantitative data (time to complete task and number of use errors encountered)
- All data recorded in an excel spreadsheet and as notes

References: CareTouch Blood Glucose Monitoring System User Manual

*see appendix for detailed protocol with use scenarios and prompts

**Participants did not complete this task for lack of materials

Introduction

Our formative usability assessment of the CareTouch® Blood Glucose Monitoring System generated useful insight into the strengths and shortcomings of the device's user interaction and interface design. As the participants worked through each use scenario, we discovered some themes. Participants liked the simplistic design of the device, but complained about the vague instructions. Though not inherently tied to the physical design of the device, all of the participants struggled to use the instructions effectively, which hindered their abilities to complete the provided tasks. It should be noted that three of the four participants' native languages were not English, though the instructions to the device are in English. We did not believe that the language barrier was to fault, however, as the instructions proved to be unclear for all test participants.

Test Results

Positive Attributes

- Participants enjoyed the simplistic design of the glucose meter, comments include:
 - Light and portable
 - Only three total buttons
- Packaging was easy to open
- Similar to other glucose meters (aligned with the participants' working mental models of a glucose meter)
- Quick Reference Manual is helpful to an extent for the participants to perform the assigned tasks, comments include:
 - Graphic illustrations
 - Concise descriptions
 - Especially helpful with error troubleshooting and screen messages interpretation

Negative Attributes

- Some vocabulary used in the user manual was uncommon for non-native English speakers, for example the word "vial" used in Quick Reference Guide Step 2: "matching the code on screen and the code on strip vial."
- The quick reference guide asks the user to insert a test strip into the glucose meter, checking that the code displayed on the screen matches the code printed on the strip vial. Once the strip is inserted, the code flashes and the user often misses the displayed code. The user would have to re-insert the strip to see the code again.
- No cleaning instructions on the quick reference guide – caused participants to skip critical steps of the cleanup process (including forgetting to remove the lancet from the lancing device, which could be a hazard), and proved to be a source of confusion for participants who were unable to find cleanup instructions
- No clear indication if the glucose meter is ready to use once turned on

- Difficult to match codes on the meter and the vial
- “M” and “C” buttons not intuitive, participants unable to determine their functions without consulting the quick reference manual/user manual
- No wipes offered by manufacturer
- No labeling on the lancet bag
- No clear instruction on how to setup the lancing device for use in quick reference guide
- No container offered by manufacturer for sharps and/or biohazardous waste
- Lancing device design does not communicate intended use

Quantitative Observation

Task Completion Time

Participant #	Amount of Time Taken For Each Use Scenario (minutes:seconds)			
	Device Setup & Test	Most Recent Result Reading	Post-Testing Procedures	Error Troubleshooting
1	5:40	5:30	5:24	0:28
2	9:44	1:25	2:27	0:47
3	9:27	1:06	3:13	0:22
4	5:20	0:48	2:50	0:34
Average	7:33	2:20	3:29	0:33

Use Errors Count

Participant #	Number of Use Errors Encountered For Each Use Scenario			
	Device Setup & Test	Most Recent Result Reading	Post-Testing Procedures	Error Troubleshooting
1	1	Failed	1	0
2	3	0	2	0
3	0	0	2	1
4	1	0	1	0
Average	1.25	0	1.5	0

Conclusion

The expectation coming into the usability assessment was that the glucose meter would be easy to use given its simple design and similarity to other meters. Though most participants agreed that the device was relatively easy to use after completing each of the use scenarios, it quickly became clear through their actions that the device was not as intuitive as we expected. The device setup/testing and post-test procedures took much longer than anticipated for all participants. As participants worked through these tasks, we immediately noticed the inadequacy of the instructions to provide guidance on the use of the glucose meter. The conclusion from this critical observation was that the glucose meter's simplicity is actually more of a burden to users than a benefit. Suggested design changes are detailed in the next section.

Suggested Design Changes

To enhance the safety, efficacy, and usability of the CareTouch® Blood Glucose Monitoring System, we suggest that you consider the following design changes.

Seeing that the instructions presented the most problems for participants, we would suggest revisiting the designs of the quick reference manual and user manual. Namely, these manuals need to (a) be more descriptive, (b) have a Spanish translation, and (c) have a more detailed cleanup and disposal procedure.

The visuals for procedural steps are effective, but several participants commented on the lack of clarity and details of the reference manual. In addition, given the prevalence of diabetes in the hispanic population and the dominance of the Spanish language in the US, the user manuals should have Spanish translations¹. The instructions also lacked steps for a post-testing procedure. When participants were prompted with the task to clean up all of the materials after having tested themselves, they all consulted the manuals for guidance, but it did not provide any information relevant to post-testing procedures. A stepwise procedure for cleanup and storage of the device after testing would clear up this confusion and reduce the risk of a user forgetting to complete a critical task (e.g., removing the lancet from the lancing device). Finally, one participant highlighted the value of an effective instructional video which might guide users through the testing process. A guided instructional video would support the manuals.

Regarding the digital design of the device, we would recommend displaying the test strip code on the display screen for a longer period of time (e.g., ten seconds) to provide sufficient time for the user to find the matching code on the test strip vial. The matching code should also be highlighted or emphasized in some fashion to allow quicker identification by the user. We would also recommend upgrading from the seven segment display, if possible, to improve legibility.

Regarding the physical design of the device, we would consider placing more detailed functional descriptions for each button. The “M” and “C” button labels do not provide the user with much information about the functionality of those buttons. It is important to remember that words are often more effective communicators than abbreviations. For instance, labeling each button as “Results” and “14-day Avg,” respectively, would provide users with much more information regarding the function associated with each button. The buttons’ functional differences can be further distinguished by color-coding them. These changes will reduce the number of times that the user would have to consult the manuals.

Regarding the physical design of the vial, we would recommend an iteration. The new design would have a shaker-bottle-like style that a user would know pouring is the right move to take and only one strip would come out.

Regarding the design of the carrying case, we would consider adding a bag of lancet and some alcohol wipes to be carried by a user. Currently, the carrying case includes the glucose meter and the lancing device only.

¹ <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=63>

Appendix (Protocol)

Introduction

The purpose of this formative usability test is to assess the safety and usability of the CareTouch® Blood Glucose Monitoring System. By putting participants through a variety of key use scenarios, we can determine whether the glucose meter facilitates its intended uses and meets the specified safety and usability standards.

Product Description

The CareTouch® Blood Glucose Monitoring System is intended for the quantitative measurement of the concentration of glucose in whole blood drawn from the fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, is for single-patient use only, and should not be shared. The main components that comprise the CareTouch® Blood Glucose Monitoring System include the glucose meter, 100 test strips, 1 lancing device, 100 lancets, and a compact carrying case. These components are shown and labeled in the figure (Figure 1) below. The CareTouch® Blood Glucose Monitoring System has the following special features:

- Accurate result in 5 seconds using only 0.5 µl blood sample
- Identifies the test strip code automatically
- Stores up to 300 test results
- Blood glucose measurement units are pre-set in mg/dL

Figure 1: The CareTouch® Blood Glucose Monitoring System key components



Test Supplies

- Box containing: glucose meter, test strips, lancing device, lancets, 3-volt lithium battery, compact carrying bag, quick reference manual, user manual (instructions/troubleshooting)
- Control solution, alcohol prep pads, soap, orange juice? (blood substitute)
- Smartphone for video recording and documentation

Test Personnel

Colby Cho (main facilitator) : Guides the participants, asks follow-up questions to elicit details, and listens for participant's feedback.

Mudi Geng : Observes the participant's behavior and records relevant descriptions

Frank Hua : Reads the Moderator's Guide to the participants, observes the participant's behavior and records relevant descriptions.

Joel Rheaume : Observes the participant's behavior and responses to the questions asked, detailedly records the interview conducted by the main facilitator.

Test Participants

Sample Size : 4

Criteria And Justifications For Sample Selection:

- At most one college student
 - To increase the sampling variability
- At least one participant with some prior experience with handling and using glucometer
 - To compare the device usability differences between experienced and inexperienced users
- At least one participant above 50 years old
 - Older adults are at higher risk for developing Type 2 Diabetes due to age-related insulin resistance increase and pancreatic function impairment
- At least one Hispanic participant
 - Hispanic has the highest rate of diagnosed diabetes in adults by race in the U.S at 17%²
- At least one non-native English speaker
 - To demonstrate the impact of language and culture on perceived usability of the device

² <https://www.cdc.gov/diabetes/library/features/hispanic-diabetes.html>

Participant User Characteristics

Participant #	Age	Gender	Ethnicity	Occupation	First Language	Level of Experience with Glucose Meter
1	54	Female	N/A	N/A	Spanish	No Prior Experience
2	55	Male	Hispanic	Program Manager	Spanish	No Prior Experience
3	20	Male	Caucasian	Undergraduate Student	English	No Prior Experience
4	25	Female	Eastern Asian	Grad Student (former nursing assistant)	Chinese	Familiar With Glucometer Used in Hospitals

Test Environment

- Indoors in a dry, well-lit room
- Normal operating temperature range: 50 - 104°F
- Void of any electromagnetic field (e.g., microwave)
- Kept out of direct sunlight and humid conditions

Set up:

- A clean table with the aforementioned test supplies
- A chair for the participant
- Chairs/desks for the moderators

Who will be present:

All four of the test conductors will be present at the usability testing scene. For each use scenario testing, only one participant will be present and tested.

Evaluation Activities/Script

Welcome and thank you for participating in our formative usability study for the CareTouch® Blood Glucose Monitoring System. This is a device that helps diabetic patients monitor their blood sugar levels. Today we will be exploring just several aspects of the entire testing process to determine the device's ease of use.

Today's session will take about 20 minutes. We'll first begin with a few introduction questions to get to know your background and history with diabetes. You will be presented with a tube of test strips, a lancing device, and the blood glucose meter itself. I will then ask you to perform a few basic tasks involving the device and answer a few follow up questions. I want to stress that we are testing if the device is intuitive and not you or your abilities. Any difficulties you experience will help expose those problems and provide the device designers with opportunities for improvement. I will also note that, to our knowledge, this device poses no significant risks to you under any of the following use scenarios.

While you are going through the tasks, I would encourage you to think out loud to help us understand your thought process. During the session, feel free to ask any questions as this will also help us understand where things may be confusing. I may not always be able to give direct answers or affirm your decisions because I need to understand the device's strengths and Weaknesses. You can take a break at any time. If you are uncomfortable with anything or concerned about something, please speak up.

We will be video recording this session. Do you verbally consent to the release of this video for internal and educational use only?

Before we begin, do you have any questions?

Prior to completing the following tasks, the moderator will ask the participant a series of background questions related to the participant's age, gender, occupation, ethnicity, level of experience using the product (or other glucose meters), and general knowledge about diabetes.

Q: How old are you?

Q: What is your gender/How do you Identify?

Q: What is your occupation?

Q: What is your ethnicity?

Q: Do you have any previous experience with operating glucose meters?

Q: Do you have any previous knowledge about diabetes and its symptoms?

Q: What is your learning habit?

Q: Have you ever participated in a usability study of this sort before?

5 use scenarios to be introduced to usability test participants to assess (a) use-safety, (b) task effectiveness, and (c) user satisfaction:

For each of these scenarios, all materials provided in the box are provided to the participant. The glucose meter and the relevant materials that the participant will interact with will all be disinfected before each use. Participants and moderators must wash their hands between use scenarios.

Use Scenario #1: Control Solution Test

The test participant will be asked to perform a control solution test --the first task to be performed upon opening the glucose monitoring kit for the first time. This test ensures that the meter and testing strips are functioning properly. This usability test shall assess the participant's ability to safely and effectively perform the control solution test and conclude that the meter and strips are working as intended.

Setup: On the table, the participant will be faced with the aforementioned test supplies.

Prompts: The moderator will instruct the participant to perform a control solution test, encouraging the user to visit the user manual for instructions on how to conduct the control

solution test. The moderator is not to give away how to complete a control solution test, but if the moderator sees the participant struggling, he/she is obliged to nudge the participant in the appropriate direction.

Expected actions: The participant completes the steps to the control solution test as indicated in the user manual. The final reading is within the ranges displayed on the test strip vial.

Questions for end of use scenario:

Q: Was this task easy or difficult to complete?

Q: Did you struggle with any part of this task?

Use Scenario #2: Device Setup & Test

The test participant will be asked to set up the glucose meter so that it is ready for use. In this scenario we assume that the control solution test has already been performed. The usability test shall assess the participant's ability to safely and effectively set up the device for use, including unboxing the device, opening of the test strip transport bags, turning on the device, and ultimately "testing" themselves.

Setup: On the table, the participant will be faced with the aforementioned test supplies.

Prompts: The moderator will instruct the participant to set up the device. The moderator is not to give away how to complete this task, but if the moderator sees the participant struggling, he/she is obliged to nudge the participant in the appropriate direction.

Expected actions: The participant (a) opens and locates all of the necessary materials for completing a reading, (b) is able to turn the meter on, (c) and can perform a reading.

Questions for end of use scenario:

Q: Was this task easy or difficult to complete?

Q: Did you struggle with any part of this task?

Q: Do you feel that you are prepared to complete your first reading?

Use Scenario #3: Most Recent Result Reading

The test participant will be asked to use the device, with the goal being to display the most recent result of his/her test. The usability test shall assess the participant's ability to safely and effectively use the device as intended, including the insertion of the blood glucose test strips into the meter, the installation of the lancing device, the blood glucose data reading, etc...

Setup: On the table, the participant will be faced with the aforementioned test supplies.

Prompts: The moderator will instruct the participant to complete a reading (ensure that the participant does not draw blood) and read the most recent result, encouraging the user to visit the user manual/quick reference guide for instructions on how to review results. The moderator is not to give away how to complete this task, but if the moderator sees the participant struggling, he/she is obliged to nudge the participant in the appropriate direction.

Expected actions: The participant correctly completes the steps as indicated in the user manual/quick reference guide and reads the result as displayed. The result is within an expected range.

Questions for end of use scenario:

Q: Was this task easy or difficult to complete?

Q: Did you struggle with any part of this task?

Use Scenario #4: Post-Testing Procedure

The test participant will be presented with the post-testing state of the device --with the testing strip used, device reading displayed, and lancing device loaded --and asked to properly turn off and dispose of the appropriate device elements. The usability test shall assess the participant's ability to safely and effectively turn off and dispose of the device elements.

Setup: On the table, the participant will be faced with the aforementioned test supplies, left in the post-testing state as described above.

Prompts: The moderator will instruct the participant to clean and disinfect the device, dispose of the lancet, and pack the device. The moderator will encourage the user to visit the user manual for instructions on how to pack the meter. The moderator is not to give away how to complete this task, but if the moderator sees the participant struggling, he/she is obliged to nudge the participant in the appropriate direction.

Expected actions: The participant (a) turn off the device, (b) disinfect the glucose meter and the lancing device, (c) dispose the used lancet as a biohazard, (d) properly put the glucose meter, lancing device, and the strip bottle in the carrying case.

Questions for end of use scenario:

Q: Was this task easy or difficult to complete?

Q: Did you struggle with any part of this task?

Use Scenario #5: Error Troubleshooting

The test participant will be presented with four of the six error scenarios described on the quick reference manual and asked to troubleshoot these errors. The usability test shall assess the participant's ability to safely and effectively restore the device to a functioning state.

Setup: On the table, the participant will be faced with the aforementioned test supplies and is paced through each of the following four error scenarios:

- Test strip is used or damaged (Er 1)
- Blood sample was applied to the test strip before the blood symbol appeared on the screen (Er 2)
- Temperature is too hot or too cold for the system to work properly (Er 3)
- Inappropriate strip (Er 5)

Prompts: The moderator will instruct the participant to resolve the error displayed on the screen, encouraging the participant to consult the user manual for instructions on how to resolve the given error. The moderator is not to give away how to complete this task, but if the moderator sees the participant struggling, he/she is obliged to nudge the participant in the appropriate direction.

Expected actions: The participant correctly completes the steps as indicated in the user manual/quick reference guide and restores the device to the working state (no error message, the device is ready to be used again).

Questions for end of use scenario:

Q: Was this task easy or difficult to complete?

Q: Did you struggle with any part of this task?

Final questions:

Q: What is your overall experience about the product?

Q: What do you like about it?

Q: What do you dislike about it?

Q: What would be your suggestions in terms of safe to use?

Q: What would be your suggestions in terms of ease of use?

Q: Could you name the two features that you like the most?

Q: How did you feel about this usability test in general?

Q: Do you have any suggestions for improvement?

Data Collection

Some of the measured dependent variables include:

- Time for task completion
- Number of use errors encountered

Quantitative experimental results such as the variables introduced above will be recorded in an Excel sheet. Qualitative experimental results including the responses to the interview questions and descriptions for observed behaviors will be recorded in a separate Excel sheet. The qualitative results will be analyzed, where key information from the responses will be extracted and categorized into advantages and shortcomings of the product usability.

References:

CareTouch Blood Glucose Monitoring System User Manual

<https://images-na.ssl-images-amazon.com/images/I/D11sPmPTGhS.pdf>