



Human Factors Engineering Review

Rebecca Allen

October 2, 2018

Lexie Kirsch

POLLEX CONSULTING



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Rebecca Allen
Manager of New Product Development
Bayer

Dear Rebecca Allen,

Thank you for choosing Pollex Consulting to conduct a human factors engineering review of the True Metrix Self Monitoring Blood Glucose System.

In this report you will find an executive summary, a description of the device, and both general and detailed findings.

Please do not hesitate to reach out to me with any questions or comments. I look forward to working with you.

Sincerely,

Lexie Kirsch
Human Factors Engineering Consultant
Pollex Consulting



EXECUTIVE SUMMARY

Pollex Consulting conducted a human factors engineering review of the True Metrix Self Monitoring Blood Glucose System, which is a competitor to Bayer's Contour Next EZ Blood Glucose Monitoring System.

The purpose of this review is to assist Bayer in defining the user interface requirements for the development of their next generation glucose meter.

The True Metrix Self Monitoring Blood Glucose System includes a meter and battery, 10 test strips and a control solution, a lancing device and 10 lancets, instructions for use, a self test log book, and a compact carrying case.

Some general strengths of this device are the following: the kit is inclusive; the meter has a simple physical design, clear and effective user interface, and it provides multiple modes of feedback; the instructions are clear and promote safe and effective use; the lancing device and test strips accommodate diverse user characteristics; assistance is readily available; storage is easy; and hazardous materials are disposable to mitigate risk of infection.

Some general opportunities for improvement include the following: include sanitary wipes for maintenance; add a distinguishing feature to kits to prevent sharing; program the meter to provide user guidance; stow small components in compartments to prevent loss; make documentation more consistent; change the shape of the test strip for intuitive insertion; print clear error messages directly on device; condense the instructions manual; allow for safer disposal of hazardous materials; and provide the user with feedback on their blood glucose result.

Some specific strengths of the device are the following: the meter is preset, responsive, programmable, includes a safety feature, updates users of its progress, allows users to monitor their progress, and provides visual feedback in an emergency; the test strips also provide visual feedback; and both the icons and control tests are effective.

Some specific opportunities for improvement include the following: combine multiple instruction manuals; enlarge the buttons on the meter; redesign the test strips, lancets, and packaging of the lancets to be more user- and environmentally-friendly; add warnings directly to components; provide more control test solutions; reword and condense instructions; and allow the user to customize the number of days over which they can view an average of their test results.

DEVICE DESCRIPTION



The True Metrix Self Monitoring Blood Glucose System includes a meter with a 3 volt battery, 10 test strips, 3 mL of a control solution, a lancing device, 10 sterile lancets, instructions for use, a self test log book, and a compact carrying case.



The carrying case contains the meter with the battery already installed. The lancing kit, test strips, and control solution are packaged separately, each with their own instructions for use.



The meter includes a display screen, test port, and four buttons—a back/decrease button, a forward/increase button, a button to turn on features (view average values, view results in memory, set up meter, and turn on event tags), and a button to eject the testing strip.



The instructions for use are written in both English and Spanish.

GENERAL FINDINGS



Top 10 General Strengths

1. The kit is inclusive.
 - The kit includes all components necessary to conduct a blood glucose test effectively.
2. The physical design of the meter is simple.
 - The meter is small and has rounded edges, allowing it to fit comfortably in the user's hand and in its carrying case.
 - The meter has only four buttons, so the user is not overwhelmed. The arrow buttons conform to design standards and accommodate mental models.
 - The meter is not slippery due to the friction of its soft texture.
3. The user interface of the meter is clear and effective.
 - The text on the meter is large and legible, which accommodates users with vision problems resulting from their diabetes or otherwise.
 - The display screen is large and reports only necessary information, which prevents information overload. The screen also prevents glare.
 - A majority of the user interface is dedicated to displaying the blood glucose reading, which is the most important piece of information.
4. The meter provides both visual and auditory feedback when the meter is testing the strip, which assists users in receiving essential communication.



Images of the front and top views of the meter.

GENERAL FINDINGS



5. The instructions are clear and promote safe and effective use.
 - The owner's booklet has a good hierarchy of information, starting with an introduction and a list of important information, and then explaining the starting steps to ensure safe use and facilitate workflow. Language is simple and clear.
 - A reference sheet is also provided and succinctly describes the main steps of the procedure and supplements the descriptions with clear images.



Image of the reference sheet.

GENERAL FINDINGS



6. The lancing device accommodates diverse user characteristics.
 - The depth of the lancet is adjustable to penetrate skin of different thickness levels, which accommodates users with diabetes whose frequent blood glucose testing may create calluses on their fingers.
 - Increasing depths are depicted with both an increasing number and increasing dot size to ensure clear communication.



Image of the lancing device.

7. The test strips container accommodates diverse user characteristics.
 - The container cap protrudes outwards to accommodate opening by users with limited finger dexterity.



Image of the test strips container.

GENERAL FINDINGS



8. Assistance is readily available.
 - The instructions include a number to call for customer support, which is available 24/7 in both English and Spanish.
9. Storage is easy.
 - The kit includes a carrying case that is large enough to hold the necessary equipment.



Image of the carrying case holding the control solution, meter, test strips container, lancing device, lancets, and three instruction manuals.

10. Disposability of materials mitigates risks.
 - If materials are not properly disinfected, users may be exposed to dangerous blood-borne pathogens and become infected. Thus, the materials that contact the user's blood—test strips and lancets—are meant to be disposed.

GENERAL FINDINGS



Top 10 General Opportunities for Improvement

1. Material maintenance supplies are not included.
 - The instructions emphasize the importance of disinfecting the meter and lancing device with "**ONLY**" Super Sani-Cloth Wipes (Environmental Protection Agency reg. no. 9480-4), which is highly specific, but the kit does not include these wipes. Including these wipes would improve ease of maintenance and improve user safety by mitigating the risk of infection.
2. Kits do not protect users from misuse by sharing.
 - Materials are not supposed to be shared with other users for safety reasons, but all kits are standardized without a means to distinguish them from one another. If kits came in different colors or had a label for adding a user's name, the kits would be easier to distinguish and less likely to be used by the wrong user.

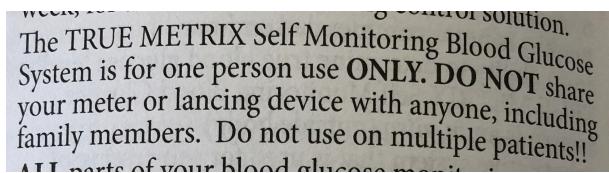


Image of instructions discouraging sharing equipment.

3. The meter does not provide user guidance.
 - Providing user guidance directly on the meter would establish realistic user expectations because doing so would not require users to rely on the instructions or their memory to use the device safely and effectively.
4. Small components are at risk of being lost.
 - Test strips and lancets are small and may be lost. Storing test strips within the meter and lancets within the lancing device would make these items easier to maintain.



Image of the test strips in their container.

GENERAL FINDINGS



5. Documentation is not consistent.
 - The “Important Information” section of the instruction manual instructs users to perform control tests **“before”** performing a blood glucose test for the first time, but the “Getting Started” section merely *recommends* performing controls tests “for practice.” In fact, performing a control test is *required* before conducting a blood test, and if a user attempts to test their blood glucose before completing the control test, the test does not work. The documentation should clarify this.
6. Test strip insertion is not intuitive.
 - Test strips can easily be inserted incorrectly, so users must rely on the documentation and their memory to insert test strips in the right orientation and direction. Redesigning the test strips with a different shape and/or labels may prevent misuse.
7. Error messages are not intuitive.
 - When an error occurs, the user interface displays an error code such as “E - 3,” which does not inform the user why the error occurred or how to amend the error without referencing the instructions packet.

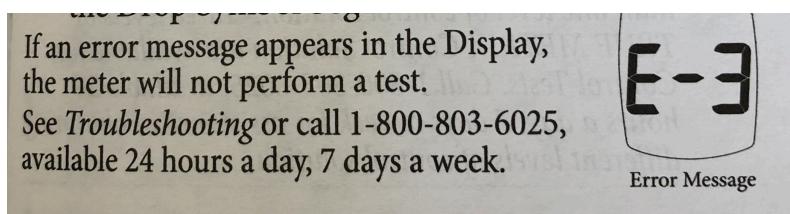


Image of instruction about error messages.

8. The instructions booklet is too large.
 - The instructions booklet does not fit in the carrying case. Enlarging the carrying case or condensing the instructions would allow easier inclusive storage.
9. Disposal of hazardous materials introduces a risk.
 - The user is expected to dispose of hazardous materials such as used test strips and used lancets; however, a safe method for this disposal is not provided. Including a means of containing these materials for safe disposal in case safe disposal is not immediately accessible is a useful safety measure.
10. Lack of feedback.
 - The meter does not provide feedback on the significance of the blood glucose result. Including such feedback would help the user identify if their control test was successful and if their blood glucose level was within a healthy range.

DETAILED FINDINGS



Top 10 Detailed Strengths

1. The meter is preset.
 - The meter comes with the battery installed and with the correct time and date, saving the user time and effort.
2. The meter is responsive.
 - The meter automatically turns on when a test strip is inserted into the test port and automatically turns off when the test strip is released (or after 2 minutes of non-use). This lengthens the battery of the meter.
3. The meter is programmable.
 - The meter can be programmed with times at which to remind the user to test their blood glucose levels, which allows for user customization.
4. The meter includes a safety feature.
 - The meter has a button to eject the test strip so the user can avoid contacting the blood. This is an important safety measure.
5. The meter updates users of its progress.
 - The meter provides visual cues when it is ready for use, testing a strip, and when an error occurs. Such feedback prevents user confusion.



Image of meter ready to test a strip.

6. The meter allows users to monitor their progress.
 - The meter includes a feature that calculates the average of all blood glucose results within a 7-, 14-, or 30-day period. The meter can store 500 results.

DETAILED FINDINGS



7. The meter provides visual feedback in an emergency.
 - If blood glucose levels are out of the range of the meter (20-600 mg/dL), the meter provides a specific error message ("Lo" or "Hi"); if the test is repeated with the same results, users are instructed to contact their doctor or healthcare professional immediately. This feedback may save the user's life.
8. The test strip provides visual feedback.
 - The test strip has a clear film that displays a solution entering the meter, so the user knows if the sample is large enough and has entered the meter successfully.



Image of test strip during use.

9. The icons are effective.
 - The items for events such as meals, exercise, medications, illness, etc are simple, intuitive, and consistent.

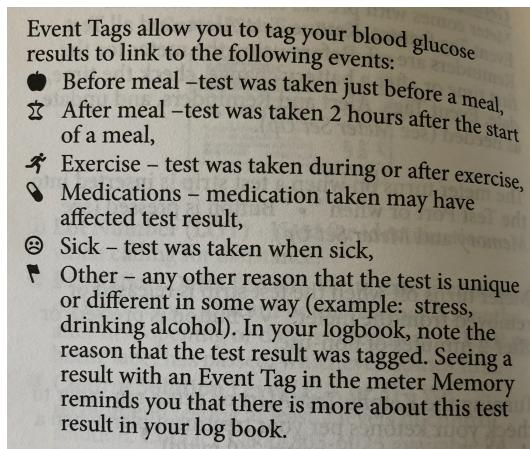


Image of event tag icons in instructions booklet.

DETAILED FINDINGS



10. Control tests are provided to prevent errors.

- A control test solution is included to ensure not only that the user's testing technique is good but also that the system is performing properly. This performance check is helpful if the results seem inaccurate or damage to the meter is suspected (e.g., after dropping the meter or getting it wet).

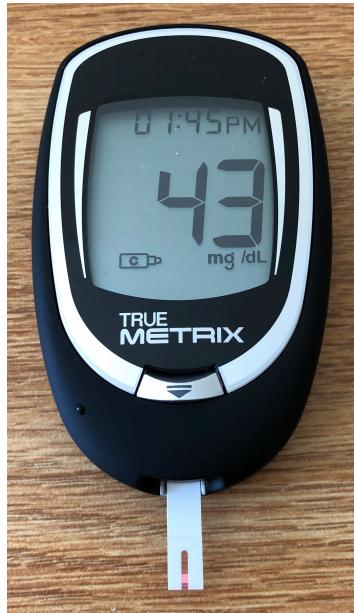


Image of meter conducting a control test.

DETAILED FINDINGS



Top 10 Detailed Opportunities for Improvement

1. There are too many instruction manuals.
 - Having *five* instruction manuals is overwhelming. Condensing this information into fewer manuals minimizes information overload.
2. The meter buttons are small.
 - Small buttons may not be depressible by users with large fingers. Enlarging these buttons improves ease of use and minimizes accidental presses.



Image of small meter buttons.

3. The test strips are small.
 - Users need nimble fingers to retrieve small test strips from the tube and insert them into the meter. Redesigning the test strips and/or their container to accommodate users with large or calloused fingers and limited dexterity as a result of their diabetes or otherwise would improve ease of use.



Image of small test strips.

DETAILED FINDINGS



4. The lancet is small.

- Users are instructed to reapply the lancet cap to the lancet before disposal, but the lancet is small and sharp and therefore requires the precision of nimble fingers and clear vision to prevent harm. Redesigning the lancet or its disposal to accommodate users with calloused fingers and visual impairments as a result of their diabetes or otherwise would improve user safety.



Image of lancet tip.

5. The lancets are poorly packaged.

- The packaging of the lancets requires strong and nimble fingers or scissors to open. Adding a small cut that could be extended to the package would allow the users to open the package with greater ease.
- The packaging material is soft plastic, which is not recyclable in all states. This should be changed for environmental considerations.
- Once opened, the packaging cannot be resealed, allowing lancets to fall out and become lost or contaminated. A different package would not have this problem.



Image of lancets and packaging.

DETAILED FINDINGS



6. Warnings are poorly located.
 - Warnings are included in the instructions but not on the materials themselves. For example, users are instructed not to drink the control solution, but this warning is not included on the control solution itself. Including warnings on components may improve safety by providing regular safety reminders.
7. An insufficient number of control tests is provided.
 - The instructions state, "It is important to perform Control Tests with more than one level of control solution," but only one level of control solution is included. Including more control solutions would ensure the device is accurate and functioning properly.

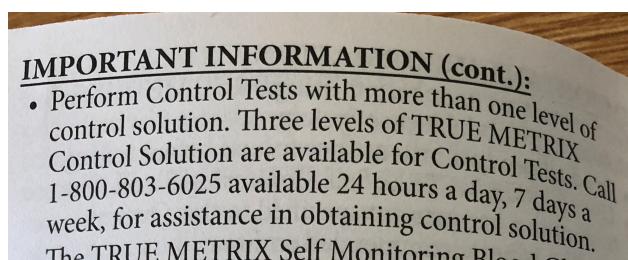


Image of instructions recommending multiple control solutions.

8. The instructions are sometimes redundant and could be reworded for clarity.

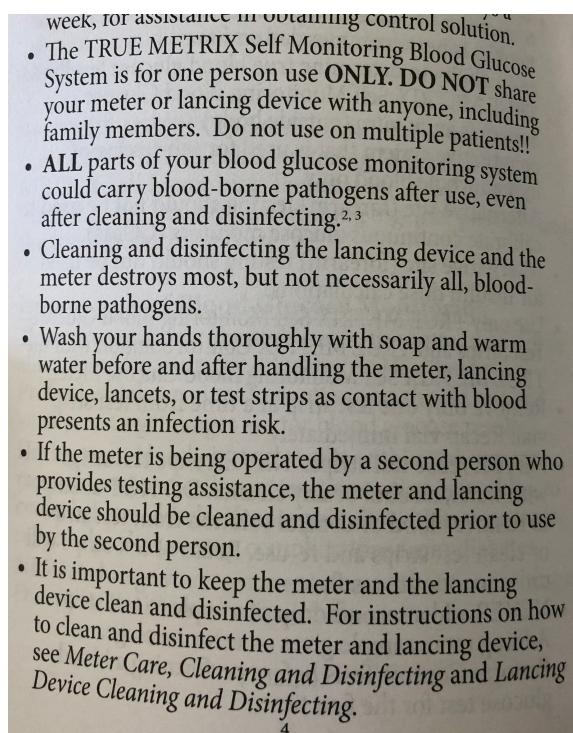


Image of redundant instructions.

DETAILED FINDINGS



9. The instructions are denser than necessary.
 - All instructions are provided in both English and Spanish, which makes the user's instructions booklet double the thickness it needs to be for use. Since the large size of the instructions booklet prevents it from fitting in the carrying case with the other materials, the user would benefit from a more compact, single-language manual. Both manuals could still be provided for the user to choose their language preference.
10. Meter averages are not customizable.
 - The user can read the average of their blood glucose test results from a 7-, 14-, or 30-day period, but they cannot choose an alternate number of days. This prevents the user from comparing results between months by the lengths of those months. For instance, February generally has 28 days, not 30, which throws off the count. Allowing the user to customize the length of the averaging period gives the user more control over how they monitor their progress.