



DISEASE DIAGNOSTIC GROUP, LLC PROJECT REPORT

RAPID ASSESMENT OF MALARIA (RAM) DEVICE PROJECT



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Executive Summary

The innovative Rapid Assessment of Malaria (RAM) device has the potential to shift the paradigm in current malaria detection devices based on its promising technology. The product has favorable attributes including a lower cost per test, higher efficacy, and faster test time relative to other detection methods currently available in the market. Given that early detection of malaria is critical to reducing morbidity caused by the illness, the introduction of the RAM device has the potential to increase access to malaria testing and ultimately save lives.

While the device has many positive features, one challenge identified is that the RAM device is intended to appeal to a diverse stakeholder set, including purchasers, test administrators, and patients. Of particular note is the test administrator stakeholder group, whose user experience with the RAM device ultimately impacts patient experience. The successful adoption of this product entails that test administrators have confidence in their ability to administer the test, understand how to read results, are confident in the accuracy of the readings generated, and prefer using this device to other malaria detection methods available such as RDT and Light Microscopy.

A key opportunity identified relates to providing a scalable training solution for the RAM device. Current training methods employed include in-person training and an online video, which were recognized as infeasible in reaching all target users. Given the varied backgrounds of test administrators in target markets, including differences in language, skill-set, and conditions under which the test is administered, our goal was to create a training solution that enabled the dissemination of information to a broad audience, thus empowering test administrators with knowledge and confidence throughout their experience interacting with the device. This training solution will lead to a reduced probability of user driven errors and a higher likelihood of adoption by test administrators from a variety of backgrounds. Based on our research along with adhering to constraints of the current product design, our “Phase 1” solution is the creation of a quick start guide based on the latest device prototype. This all-pictorial guide has a flip design and “clusters” steps based on stage, making it intuitive, universally understood, and simplified. Based on our observations throughout the design process, we have also prepared “Phase 2” recommendations that involve changes to the actual device design and technology to improve user experience in the future.

Identification & Discussion of Opportunity for Disease Diagnostic Group (DDG)

The Disease Diagnostic Group, LLC (DDG) is an Ohio for-profit social venture founded in August 2012. Key employees include John Lewandowski (Founder/CTO) and Dr. Brian Grimberg (CMO/President). DDG's goal is to save one million lives every year by addressing the problem of malaria in regions in which the disease is prevalent. DDG's mission is to remap the malaria diagnostic market through its Rapid Assessment of Malaria (RAM) device.

The RAM device, based on magneto-optical technology, is being developed to provide a low-cost, accurate and portable solution for malaria detection. The target markets for this device are regions in which there is a high prevalence of malaria such as Asia, Africa, and South America. The main focal points of this device are its low cost of operation, speed at which the result is obtained, and most importantly its accuracy. The RAM device is designed to provide a quantitative diagnosis in less than one minute with a drop of blood from the patient's fingertip and all this for a fraction of the cost of its current competitors.

Below are some of the notable product features as mentioned in the RAM Device product summary:

- "Can detect down to a level of 1 parasitized cell/uL
- Converts diagnosis into a suggested treatment dosage via LCD screen
- Consumable is recyclable and potentially biodegradable for easy disposal
- Uses a rechargeable off-the-shelf battery pack"

Apart from the advantages relative to competitors, the RAM device also redefines the malaria detection value-chain. The malaria parasites have a magnetic byproduct, which allows the RAM device to detect malaria using mechanical components thus eliminating the need to use chemical compounds. This reduces the need for medical expertise, refrigeration or a cold-chain transportation system, and the need for the patient to travel to the clinic. The device creators view this shift in detection method as a game changer and it carries the potential of becoming the universal method of malaria diagnosis given its favorable attributes.

For reference, below are some of the key features of the RAM device in quantitative terms relative to some key competitors noted within the product summary:

WHO Metrics	RAM	RDT	Light Microscopy
Cost Per Test	\$0.20	\$0.69	\$1.05
Accuracy	93%	87%	50%
Time	1 minute	30 minutes	60 minutes
Training Level	None	Low	High
Heat Stable	Yes	No	Yes
Portable	Yes	Yes	No
Quantitative	Yes	No	No

As a start-up company, there are challenges that DDG must address to be competitive in the market. This includes overcoming entry barriers in an already established market, such as developing brand awareness for RAM versus other products. Additionally, DDG should understand its position with respect to the current market benchmark which is PCR (polymerase chain reaction). The perception in the marketplace is that PCR is the most accurate and reliable of all the diagnostic methods in the market. Finally, a caveat for any small start-up while scaling up would be effectively managing limited financial and workforce resources.

Based on reviewing materials regarding the RAM device, interviews with our sponsor, and observing the device prototype, our team has identified that this single device is intended for interactions with multiple stakeholders, including purchasers, test administrators, and patients. How can a single device appeal to numerous stakeholders from diverse backgrounds? We decided to focus on the test administrator user group as they are critical to the successful adoption of this device and ultimately impact the end patient experience as well.

Based on discussions with our sponsors, we learned that DDG intends to initially introduce this device in target markets including India, Peru and South Africa. Based on our research, we identified three key representative user profiles within the test administrator group, including trained medical nurses, U.S. Navy Troops, and volunteers. Based on our user profiles, we recognized that it is possible that the user may have little or no medical training, limited or no access to the internet, and may not be familiar with the English language.

	Medical Training: Yes Internet Access: No Fluent in English: No
Medical Training: No Internet Access: Limited Fluent in English: Yes	
	Medical Training: No Internet Access: No Fluent in English: Yes

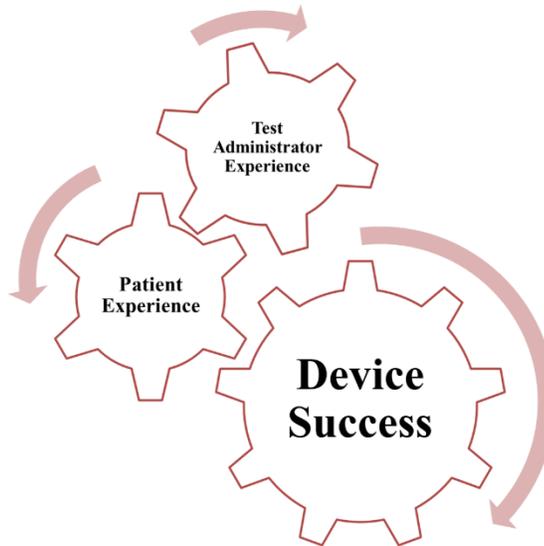
We were curious regarding how training was handled for the device, especially considering the varied backgrounds of test administrators. Our team was intrigued by the statement that the device required “zero-training” as promoted in the “DDG July product summary”. We wondered if the device was truly intuitive enough such that a novice user would receive it and know exactly what to do with it. Our observations of the device suggested that it was actually an involved process with multiple steps to obtain a test reading. We learned that there is training for the device in the current state. Currently, one of our sponsors, Dr. Grimberg, personally goes to testing sites oftentimes training a head nurse in English who then disseminates the information to field nurses in the local language. This training solution is not feasible once the RAM device is offered on a wide scale. In addition to in-person training, DDG has launched an instructional video in English to communicate the handling of the device. Our group concluded that this may not be an impactful solution given that most of the regions in which this device is going to be introduced lack internet access and/or users may not speak English.

Based on these insights, we identified the paradoxes embodied within the problem statements below:

- *How can a device that is marketed to test administrators as requiring no training be perceived as so complex?*
- *How can a single device appeal and be understood by diverse users?*

Presentation of Central Idea & Hypothesis of the Project

Our hypothesis is that the success of the RAM device is dependent on its acceptance and associated adoption by test administrators relative to competitor products. Test administrator’s adoption of the device is influenced by their user experience with it, and they must have confidence throughout their interaction with the device that they are using it properly and obtaining accurate readings. Effective training is thus key to achieving this broader goal. Additionally, using backwards deduction, we discovered that the patient experience is influenced by the test administrator’s experience with the device.



Based on this insight, we focused on the opportunity of positively influencing the experience of the test administrator. Our central idea is to create a simple and portable: “Quick Start Guide” for the RAM device. Our vision is that this guide accompany every device distributed. We created the quick start guide to be intuitive, simplified, and universally understood. With our concept implemented, users will be guided on how to use the device properly regardless of medical training, native language, or environmental conditions under which they are performing the test.

Product Introduction

Our focus in creating a training solution was to address the two main paradoxes identified which are “single device, multiple users” and “zero training required, yet complex to use” while also building a solution that was consistent with the objectives of being intuitive, universal and simplified.

With an understanding of the diverse test administrator user group and keeping constraints of this project in mind, we decided to focus on building a quick start guide for the device which would be based completely on visually capturing the steps through action-oriented sketches. This would address the challenge of training test administrators from diverse backgrounds while ensuring test subtleties are conveyed. Also, it would greatly diminish the need for an executive to visit these sites and personally provide in-person training.

Product Purpose

The RAM device is an extremely innovative device that could revolutionize the malaria detection process. However, what it currently lacks is a tool to educate its user base, which can be defined as different types of test administrators. If an effective training solution is achieved, it would greatly amplify the impact and success of the product. The quick start guide is an effective tool that would simplify the process of educating users.

The testing process involves many subtleties such as ensuring that both the device and screen are turned on prior to testing, the blood and water are sufficiently mixed in the cuvette, and that test output is interpreted properly. Our quick start guide ensures that these subtleties are captured throughout the testing process such that the user would directly follow a simple guide thus mitigating the risk of error.

The users of this device not only have diverse cultural backgrounds but also have varied levels of education. Our guide uses visuals instead of textual instructions which will allow users to understand the test process irrespective of their competency in English or experience with using medical devices. The guide is designed to be read top down to ensure that there isn’t any misinterpretation of the order of steps based on cultural background.

One of our key insights was that the patient experience is driven by the test administrator’s experience. If the test administrator feels confident about using the device and understands the process it would result in him/her providing better services to the patient. Our guide is aimed at empowering test administrators by helping them interpret the process and device correctly. Our design process has been centered around the test administrator experience and realizing how impacting this stakeholder group will be integral to this device being a commercial success. We focused on the test administrator’s thought process and the actions necessary to carry out the test. Based on this, we designed a set of visuals and symbols to be used in the guide. To refine our idea, we also tested our guide with a few first-time users. Based on our analysis our final product is a combination of the fourth and the third orders of design.

Fields of Design Problems

		Communication Symbols	Construction Things	Interaction Action	Integration Thought
Arts of Design Thinkng	Inventing Symbols	Symbols: Words & Images			
	Judging Things		Physical Objects		
	Connecting Action			Activities, Services, Processes	
	Integrating Thought				Systems, Organizations, Environments

Explanation of Key Product Features

Discussion on the four main elements that our team considered for our Quick Start Guide product are as follows:

Useful

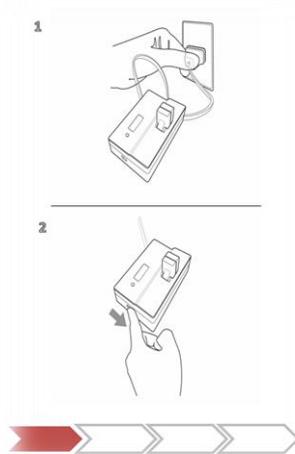


To provide a consistent user experience, we captured the DDG logo on the front of the guide (a world picture labeled with “DDG”) together with a sketch of the RAM device. We believe that this will allow users to easily recognize that the device and the quick start guide are related. Additionally, using sketches versus an actual photo of

the current device allows for our solution to be relevant even if the device undergoes minor design modifications as it evolves as part of future iterations.

The guide is designed to be intuitive, universal, and simplified to assure that it will improve user experience with the device. We decided to organize the steps from top to bottom given our research on how different cultures approach reading a document. For example, individuals in China read books from right to left while Americans read from left to right. With our design, possible confusion regarding the sequence of steps is eliminated. Additionally, we focused on creating visualizations that used universal symbols based on our research (such as an image for a doctor, biohazard symbol, and check-mark symbol that are cross-cultural). We avoided using English or any other language to convey what a user needs to do in each step. Rather, we adopted a pictorial-based solution given that we want to ensure that, regardless of language, any user is able to comprehend the meaning being conveyed by the visualizations. This solution is more desirable than maintaining multiple guides in various languages. In the target market of India alone, there are over 20 official languages and managing so many versions would prove to be cumbersome.

Additionally, we designed the guide to be a flip book that is easy to follow and intuitive. We also categorized steps together by color based on the four key stages identified including: device preparation, blood extraction preparation, blood testing, and post testing. The clustering of steps along with using both sides of the paper assisted in the guide being cost-effective and portable in terms of the number of pages utilized.



Usable

Our objective in creating the quick-start guide was to create a usable solution for our diverse user base comprised of individuals including field nurses, doctors, healthcare officers, and volunteers around the world. Visualizations of each step create shared meaning for users, regardless of native language. The quick start guide assists users through an easy to follow, step-by-step process.

Whilst experienced users in the healthcare industry might be able to learn how to use the device quicker based on their expertise in steps including blood extraction, we are confident that this simple quick start guide is simplistic enough that even a novice user with no medical training will be able to use and comprehend it. Thus, our product does not require a baseline skill-set to be relevant. From our think-aloud protocol exercises with novice users, we found that our visualization were universally understood and easy to follow.

Desirable

Our quick start guide is desirable to both the company and potential users. From a company perspective, it is important and necessary for scalable training to be provided for the product to achieve commercial success.

Additionally, this training will eliminate the need for frequent in-person sponsor travel, allowing for management to focus on other business issues.

Simplicity of training is paramount to test administrators adopting the product. If training is perceived as too complex or overwhelming, there is a higher chance that the device will not be used or that it will be used incorrectly. With the quick start guide, test administrators will not have the impression that it is hard to operate this medical device or that training is too complex. Given the elements of universally understood images, the intuitive flip design and related clustering of steps provided in our guide, users will feel comfortable interacting with the device. This guide also indirectly supports customer satisfaction with the device given that it empowers the user to accurately use it.

Balance

One of the concepts that makes our quick start guide coherent and unified is portability. Knowing the intention is that the guide be brought along with the device and will potentially be used in a variety of locations (such as multiple villages), we ensured that the size and weight are appropriate while ensuring that the image size was still functional.

Communication through universal symbols is another main point of balance that brings the key features of our product together in a unified and coherent whole. Our intention was to create the same level of understanding for users around the world. This is why we chose to utilize universally understood images and pictorial based visualizations in our quick start guide. Therefore, the guide is intuitive to follow in every step.

In addition, simplicity shaped our quick start guide. For instance, the clustering of steps is intended to provide users with added convenience. For example, an experienced nurse could potentially skip the second cluster stage of blood extraction after going through the guide once because he/she is skilled in this process. Furthermore, intuition is another point of balance given the flip design and pictorial base due to the nature of the human cognitive process. To be more specific, when a nurse finishes the first cluster, he/she will know exactly that he/she needs to flip the guide to proceed to the next steps.

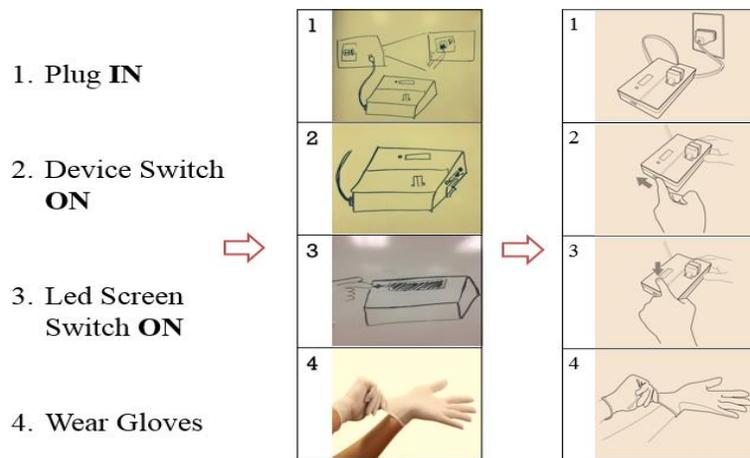
These ideas help create simplicity, intuition, and universal understanding for users which bring the perfect balance to the guide through attributes including being pictorial, clustered, and incorporating a flip design.

Concrete Embodiment of Product

The quick start guide is extremely simple and is printed on 4"x6" laminated sheets to ensure that is durable. Currently, it is detached from the device but going forward it could be integrated with the unit.

The guide has a flip design with a cluster of steps on each page distinguished by different color sets. Each step corresponds to an action that need to be performed by the test administrator or a display message on the device screen.

We started with listing the process based on viewing the instructional video and spending time with an experience lab technician interacting with the device, capturing photos of the process. The device is continuously evolving and hence we decided to utilize sketches rather than actual pictures of the device in our guide. Additionally, sketches are universally relatable. We began by manually sketching the visuals and collaborated with designers from the Cleveland Institute of Art (CIA) to transform our sketches into professional images.



Business Case

Recognizing that one of the key features of DDG’s Rapid Assessment of Malaria (RAM) device is its competitive price per test, our team was sensitive to creating a solution that was financially feasible and aligned with DDG’s goal of broadening the accessibility of malaria diagnostic testing. Our team also wanted to create a solution that would be immediately relevant for the team based on the current state of the device.

Our quick start guide carries one-time costs of preparation of sketches by a design collective from the Cleveland Institute of Art as well as the opportunity cost of management to review/refine sketches. From an ongoing perspective, costs include printing sketches on durable 4x6 paper (approximately \$1.25) and binding costs (approximately \$6.00). Taking these on-going fees together, our current version of the quick-start guide totals \$7.25 of variable costs for a single unit. If mass-produced, our team estimates that DDG would be able to recognize at least a 40% discount on these fees, and thus each quick-start guide unit would be estimated to carry a cost of \$4.35.

Costs for the quick-start guide are outweighed by benefits recognized. These benefits include improved training and fewer user errors, leading to improved test administrator experience and confidence in device usage. If test administrators have this confidence, they will be more likely to use the device relative to other competitor offerings in the market and have certainty in the readings provided. This confidence will consequently be expressed to the patients with whom they are dealing. Finally, our quick-start guide will provide for device usage by a broader global audience, regardless of the language, skill-set, or internet accessibility profile of the user. This ultimately aligns with shifting the paradigm in malaria diagnostic testing and increasing accessibility to testing.

One challenge management may have in implementing this solution will be that the device continues to evolve. With that in mind, we have created sketches rather than using pictures of the device, noting that these images will be more applicable in the future rather than using pictures of the current device prototype. However, one risk may be that the device evolves dramatically from its current design and/or the steps change significantly in the future. However, based on discussion with our sponsor, changes will likely involve the device size, but the actual foundational process a user has to follow is anticipated, for the most part, to remain the same.

Process of Our Work

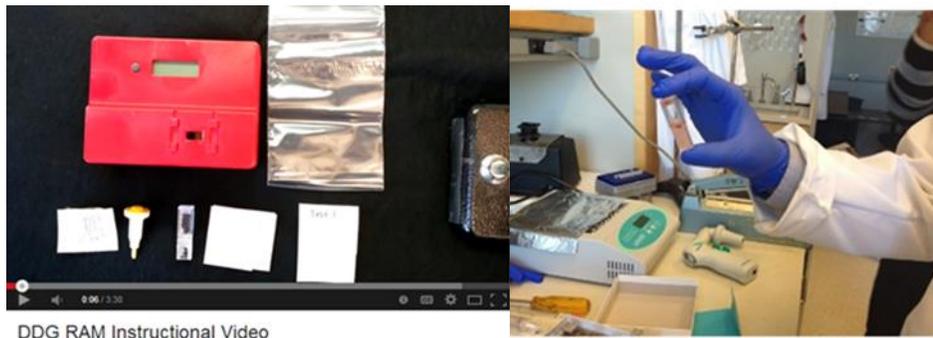
When we first began the project, we spent time becoming familiar with the DDG team, the value proposition of the device relative to competitor offerings, along with gaining perspective on the prevalence of malaria throughout the world. As we were becoming familiar with the device, we were intrigued by the statement that the device required “zero-training” as promoted in the “July product summary guide” provided by our sponsors. We wondered if the device was truly intuitive enough such that a novice user would receive it and know exactly what to do with it. Additionally, given that this is a test with medical implications and early detection of malaria is imperative for treatment success, we anticipated that a misdiagnosis due to a user not interacting with the device properly could

potentially have dire consequences (such as not diagnosing someone with malaria who should in fact seek treatment).

Highlights

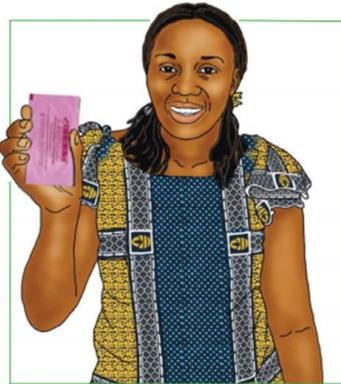
- Low-cost
- Quantitative
- Accurate
- Fast
- Rechargeable
- Handheld
- Sensitive
- Lightweight
- Simple
- Zero Training
- Stand-alone
- Heat Stable
- Rugged

We had an opportunity to spend time with an older device prototype along with watching a video of the device in use prepared by Dr. Grimberg. We noticed that the process involved multiple steps, and based on our research regarding the variety of user profiles whom would use the device, found that a key opportunity for the company would be tied to training. We captured (in words) each detailed step required to complete the test, through both watching the video along with performing a talk-aloud protocol exercise with an expert user in the lab.



Our research also included reviewing training materials available for competitor products to DDG, including the Rapid Diagnostic Test (RDT) training prepared by the World Health Organization. This was a 44 page pdf document in English. While comprehensive, our team recognized that this document was not applicable to non-English speaking users, and likely would be an overwhelming document to review. We wanted our solution to be intuitive, universal, and simplified. Additionally, we recognized that multiple users would be interacting with the device. We wanted our solution to be one that was durable and easily referenced by multiple test administrators if the device was to be “handed-off”. We also wanted our solution to be easily portable, cost effective, and universally understood.

How To Use a Rapid Diagnostic Test (RDT)



A guide for training at a village and clinic level

Modified for training in the use of the First Response Malaria HRP2 (3DFRC30) Test for *Sabiqum malaria*
Prepared on August 9, 2016, V1.6



First Response Malaria HRP2

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With these detailed steps noted, we considered how to translate our words into universally understood pictorial images, while also thinking about which steps might be able to be consolidated while still generating the same end meaning for a user. We prepared action-oriented sketches based on each observed step, and thought about how to group these into clusters based on stage to provide for a more intuitive user experience. We reviewed the steps and presented our initial draft sketches to our sponsors in-person to ensure accuracy and get their feedback on universal symbols used.

Once we got sponsor approval that we had captured the steps appropriately, we worked with a CIA design collective to convert our rough sketches into professional images. We conducted a review of our quick-start guide with three novice users including a child, video-taping them going through the think-aloud protocol as they interacted with the device with only the quick-start guide to assist them (shown below). From here, we were able to identify areas of further opportunity for the sketches and layout of the guide. We worked with the artists to make changes to incorporate within our final version of the prototype.



Conclusion and Future Opportunities

Providing this quick-start guide with the device will ensure that users, regardless of native language, training in the medical field, and the environmental conditions under which they are performing the test, are equipped with the training to successfully administer the test to patients with confidence. Instilling this confidence in the test administrator stakeholder group is critical for the device to be adopted on a wide scale. This guide will also allow for the device to be used by individuals whom current training methods (in-person by the sponsor or the online training video) are infeasible, thus broadening the market for the device and allowing for the dissemination of information to a wider audience.

If test administrators have a poor experience with the device due to lack of adequate training or do not believe in their ability to administer the test, this will negatively impact the end patient experience through both inaccurate readings and/or administrators recommending patients seek alternative diagnosis due to lack of certainty that the device provided an accurate reading. This ultimately could adversely impact the DDG brand and result in a decreased likelihood of the product being commercially viable. Gaining buy-in from the test administrator user group is essential for the Rapid Assessment of Malaria (RAM) device to succeed. With such promising technology, it is critical that user experience with the product be positive to ensure that the device is widely adopted, which will ultimately save lives through the early detection of malaria.

While we wanted to ensure that our idea was usable based on the current state of the device, we also identified future opportunities for our sponsor to consider to improve user experience as part of “Phase 2”. Our research, the creation of the quick-start guide, along with observing user interactions with the device point to opportunities from a technological standpoint to improve user experience that could be implemented as the device prototype evolves. Keeping with our goal of creating a user experience that is intuitive, universal, and simplified, we reviewed all current steps and determined which steps were potentially confusing and perhaps unnecessary if there were flexibility in the technological build of the device. These recommendations include eliminating some of the screen messages - such as “Ready” flashing quickly before “Insert Sample Press Button”. Some users were confused as they were waiting for the “Ready” message screen when it had already passed. Additionally, as our quick start-guide leveraged universal symbols, we would encourage the screen displays to be pictorial based. Given the diverse parts of the world in which this device will be used, universal symbols could be perceived as less intimidating and more inviting to a non-English speaker. This may include the score reading being more intuitive through LED lights versus the current numeric readings. Also, we would encourage that the quick start guide be integrated with the device through building a storage compartment providing for further portability, protection, and accessibility by multiple users.

We also encourage the creation of a standard patient test kit to positively nudge test administrator behavior. While costs were shared as a potential concern for such an initiative, providing a unique cuvette that a patient can “mark” as their own will help prevent test administrators from cuvette reuse, which is a noted problem based on interviews conducted with our sponsor. If patients are given this kit at the beginning of their experience, there is an expectation created that the test administrator use this “new” kit of items each time, thus preventing misuse and encouraging test administrators to follow proper procedures for every patient tested. This would lead to improved sample quality and associated accuracy of readings.