

Usability Study of the iProven BPM-337BT Blood Pressure Monitor and App

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This study involved a usability test of the iProven BPM-337BT, a popular wrist-based blood pressure monitor. With the increased variety of off-the-shelf blood pressure monitors, potential risks associated with various designs as well as usability and interaction issues remain unknown for many devices. The goal of this usability study was to discover any potential use errors and issues associated with user interfaces of the FDA-approved iProven BPM. Results suggest that the device had dense and unclear instructions, imperceptible icons on the display, and some inconsistencies in the application which could be redesigned to prevent use errors and increase user satisfaction.

INTRODUCTION

Cardiovascular diseases are the leading cause of death in the world. With more patients being diagnosed with some form of the disease, doctors are increasingly encouraging patients to monitor their cardiovascular health. An important biometric used to assess cardiovascular health is blood pressure. Studies have even shown that hypertensive patients who monitor their blood pressure at home get a better indication of their cardiovascular health than results obtained in screenings done in a clinical setting (Ohkubo, 1998). Similar to blood glucose monitors and apnea monitors, blood pressure monitors are becoming more prevalent for home-use and self-assessment of a variety of chronic diseases (National Research Council, 2010). As these devices are no longer used exclusively by physicians or trained clinicians, it is crucial that medical device companies consider specific human-system interaction requirements for their products in the context of these new user populations and use settings (Goa & Kortum, 2017).

In the last decade, numerous companies have developed new wrist-based blood pressure cuffs as a convenient alternative to the traditional upper-arm cuffs. Since the upper-arm-based blood pressure monitors have been around longer than wrist-based devices, users are more likely to be acquainted with upper-arm monitors. The relative unfamiliarity of wrist-based blood pressure monitors means these devices may be more prone to use errors. Additionally, people who are more at risk of cardiovascular disease tend to be older patients with varying levels of familiarity with medical devices. These individuals are also more likely to have disabilities and vision degeneration, making it more difficult to read text and control motions in tasks requiring dexterity. Consideration of users and context of use has proved vital in designing usable and sustainable home-based medical device technology (Or et al., 2009).

With a “substantial portion of device-related errors [being] use errors,” it is even more critical to ensure that medical devices are designed in accordance with human factors engineering principles to avoid preventable errors that could have costly and detrimental effects on patients (Gurses & Doyle, 2014, p.2). In an effort to reduce the prevalence of use errors, regulatory bodies, like the FDA, have increased their

oversight of medical device usability testing and redefined usability requirements, now requiring that devices be thoroughly tested during design to ensure safety and efficacy (International Electrotechnical Commission, 2015).

Although all medical device manufacturers are required to mitigate risks associated with the use of a device, companies differ in the specificity and thoroughness of their risk mitigation analyses and risk mitigation actions. Additionally, manufacturers are required to obtain post-market feedback from users, but this is often limited (Hilbers et al., 2013). The lack of post-market feedback could impede the identification of use errors and subsequent design modifications. These limited risk mitigation strategies result in products that pose a risk to users and may be prone to use errors.

Despite their prevalence, studies have shown that some blood pressure monitoring technologies suffer from significant usability issues such as failing to account for the laypersons’ lack of medical device knowledge and experience (Hilbers et al., 2013). Furthermore, the lack of general familiarity specifically with the wrist-based blood pressure monitors may affect usability of such products (Clarkson, 2006). While products have successfully received FDA-approval, documentation of human factors and usability evaluations are not necessarily published or made available, and wide-spread usability issues are predominant in project reviews.

In this study; as part of a project for a graduate course (ISEN630) in human factors engineering at Texas A&M University; we conducted a usability test to assess iProven BPM-337BT, a widely-used off-the-shelf wrist-based blood pressure monitor which has received FDA approval, to ascertain potential risks or use errors associated with this blood pressure monitor. Preliminary review of scholarly literature did not reveal any previous usability studies for this device; however, anecdotal evidence and product reviews suggest issues related to usability.

METHOD

Participants

The study involved eight participants recruited from engineering graduate student population at Texas A&M

University. Of the eight participants, four were male and four were female. The average age of the participants was 23 years. The participants had varying levels of familiarity with blood pressure monitoring devices ranging from regular use to no experience. Half of the participants had previously used a manual or digital blood pressure monitors in a home setting. The other half had never used a blood pressure monitor.

Equipment

During the study, all participants used the iProven BPM-337BT wrist-based blood pressure monitor (Figure 1). This device is an off-the-shelf blood pressure monitor that weighs approximately 5.6 ounces and has dimensions of 6.5cm x 8cm x 6.5cm (LxWxH). The monitor can connect to smartphones through Bluetooth wireless connection to send the blood pressure data to a companion phone app. The app provides a visual summary and trend of the blood pressure data. The study moderator used a laptop to collect data and transcribe participant feedback during the study.



Figure 1: iProven BPM-337BT Display

Procedure

The participants took part in the study individually in a small office environment. They were each given instructions and information about the study in a consent form and were given time to read the consent form and ask questions.

Participants were asked initial questions regarding their previous experience and knowledge of blood pressure devices. Afterwards, users completed a set of tasks while providing verbal feedback and indicating their thought process, confusion, or other commentary through the think-aloud protocol. As the participants completed the tasks, the moderator observed the participants to note whether they deviated or experienced confusion during each task. The observer paid particular attention to whether the users adopted correct body position as indicated on the device and in the instruction manual.

Four categories of tasks were used: Device setup and body positioning, device use, measurement interpretation, and measurement logging. The task pathway started by setting up the blood pressure cuff and assuming the correct body position. The cuff had to be placed in the correct position on the wrist and the device had to be held at heart level while seated with uncrossed legs. The next step was to take blood pressure correctly by pressing the start/stop button, remaining still, and

breathing normally during the measurement. Once the measurement was complete, the participants had to interpret the blood pressure readings correctly. Participants were asked to read their blood pressure, determine the regularity of their heartbeat, state their heart rate, and classify their blood pressure according to the American Heart Association (AHA) Indicator which was included in the instructions, on the device, and on the application. Lastly, the participants were asked to store their results on the application and retrieve their results from the device's limited memory. To store their results on the phone, the phone's Bluetooth had to be turned on and the phone application had to be running. The 'mem' button was used to retrieve their results from the limited memory of measurements on the device.

Following the tasks, participants were asked questions intended to obtain the user's subjective evaluation of the device and further quantify their understanding of the device (Nielsen, 2005). These questions evaluated heuristic factors such as the legibility and comprehensibility of the blood pressure measurements on both the device and the paired application. These subjective results were included in the evaluation of potential use errors as well as the overall evaluation of the device performance and user satisfaction.

RESULTS

Data

Determination of Success and Failure: Success was defined as the user completing four major tasks (Table 1) without incorrect use of the device or confusion. Partial success was defined as the user experiencing confusion or minor errors during a task, but still completing the task. Repetition of tasks due to confusion or misunderstanding blood pressure readings was often an indication of partial success. Failure was an inability to complete more than half of the task. Any deviation from the task path as defined in the procedure was noted regardless of whether the task was eventually accomplished, as this deviation is an indication of confusion or poor usability. Of the eight participants, all deviated from the task pathway during at least one task or performed tasks out of order.

Table 1: success & failure data

Task	# of Successes	# of Partial Successes	# of Failures
Device Setup/Body Positioning	2	2	4
Device use	5	3	0
Measurement Interpretation	2	4	2
Measurement Logging	0	8	0

Device Setup/Body Positioning: Users were observed to see if they placed the blood pressure cuff on correctly and assumed the correct body position. Only two of the eight participants assumed the correct body position and correctly placed the blood pressure monitor on their wrist with the

display on the palm-side up. Several participants sat with their legs crossed, contrary to instructions. Additionally, three participants placed the cuff on backwards even after reading some of the instructions. A common use error among three of the eight participants was not placing the cuff at heart level. The other five participants attempted to place the cuff at heart level, but commonly voiced uncertainty as to whether it was positioned correctly. It should be noted that having the blood pressure monitor at heart level is a key step when using a wrist-based BPM since hydrostatic pressures skew the results if the patient is positioned incorrectly (Edoardo et al., 2016).

Device Use: While most participants were able to use the device properly, most participants attempted to take their blood pressure readings several times, averaging more than two measurements per user, before reaching some understanding of how the device worked. Partial success occurred if it took multiple attempts to obtain a blood pressure reading or if users received an error code during use.

Measurement Interpretation: Several participants showed confusion about how to determine whether they had irregular heartbeats. One participant's results indicated an irregular heartbeat, yet they incorrectly identified their pulse as regular while stating that the icon indicating the irregular heartbeat was ambiguous. Half of the users were only able to interpret three of the four main measurement results (heart rate, blood pressure, AHA Scale indication, irregular heart rate). This was considered a partial success. Most participants initially voiced confusion with classifying their blood pressure according to the American Heart Association Indicator found on the device and instructions. Only two participants interpreted their blood pressure measurements without struggling. Participants that failed to interpret two or more of their results failed the measurement interpretation task.

Measurement Logging: All participants had partial successes when logging their measurements. While all measurements were automatically stored on the wrist monitor, many participants failed to check that the phone Bluetooth was activated to allow measurement storage on the app. All participants made errors inputting and editing their measurements manually in the app.

Table 2 indicates a summary of the subjective feedback obtained from the participants. Participants were asked to rate the tool against several characteristics including legibility of information provided; simplicity and intuitiveness; clarity of instructions and labels; portability; and ease of use of buttons (Table 2) on a scale of 1-5, where 5 was a good result and 1 was a poor result. The findings are in line with the observational data and suggest that participants somewhat struggled with the simplicity and intuitiveness of the device and clarity of instruction manual. On the other hand, participants perceived the labels on the device to be clear and found the buttons, the display, and mobile application to be legible.

The compiled negative and positive findings of both the user observations and subjective user feedback are provided in Table 3. The negative findings indicate areas where users experienced use errors and issues with the device.

Table 2: Subjective analysis results

<i>Evaluated Characteristics</i>	<i>Average Ranking ± SD</i>
Legibility of the Instructions	4 ± 0.93
Legibility of the Device Buttons	4.625 ± 1.1
Legibility of the Device Display	4.625 ± 1.1
Legibility of the Application	4.625 ± 0.52
Simplicity and Intuitiveness of Device	3.5 ± 0.76
Clarity of Labels on Device	4.875 ± 0.35
Clarity of Instructions	3.25 ± 0.81
Portability	4.125 ± 0.48
Ease of Use of Device Buttons	4.5 ± 1.4

Table 3: Summary of usability findings

<i>Positive Feedback:</i>	<i>Negative Feedback:</i>
Compatible with various wrist sizes	Instructions were dense and difficult to find information
Readings are stored in limited memory and on application	Label and Instructions on cuff were hidden
Portable (i.e., fits in purse or bag)	Device button placement worked better for right-handed people (cuff on left wrist)
Application interface is simple and easy to use	Device buttons on device were close together and small
Provides indication of regularity of pulse	Device display Icon for irregular heart rate was ambiguous and unclear
Device provides blood pressure and heart rate measurement	American Heart Association Scale on device display was imperceptible and confusing
	Device and application Bluetooth pairing is imperceptible during use
	Difficulty finding BP reading in application
	Uncertainty and confusion when using application to find information
	Little to no feedback about system status in device display
	Inconsistency with icons on app and display

DISCUSSION

While the iProvèn BPM-337BT device proved to effectively provide users with their blood pressure and heart rate, but use errors could be further minimized by incorporating principles of human factors engineering. The usability study and evaluation of the iProvèn device showed that users struggled to understand some of the instructions, some of the icons, and the meaning of error codes. Redesigning the device to improve these usability issues would make it compatible with several well-established heuristics such as being easy to learn, memorable, and unsusceptible to errors (Nielsen, 2005).

Recognition rather than recall is a major heuristic that can be improved. For example, the symbol for irregular heartbeat in Figure 2a and 2b, may be unfamiliar to users and may force users to utilize their bottom-up information processing. Due to importance of first impression in sustainable adoption of medical devices, the icons used should be recognizable to facilitate the efficient top-down information processing. In addition, inconsistent versions of the irregular heartbeat symbol was used between the main display and the mobile application. The device also relies heavily on the users to memorize instructions. The AHA scale on the display and the abstruse error codes are only described in small sections of the

instruction manual. A comparison of the AHA scale on the application and the device is shown in Figure 3. Furthermore, the sections outlining the correct body positions for more accurate readings caused some confusion among participants and resulted in use errors, even though the instructions present detailed information. The importance of correct body position cannot be understated. Wrist-based monitors have been shown to cause errors in blood pressure readings if the device is not held at heart level during use (Sato, 2013). Additionally, some confusion among users could be attributed to the relative lack of familiarity with wrist-based BPM as compared to the upper-arm BPM that are considered the “gold standard” for taking blood pressure (Pickering, 2005). Since it is highly unlikely that the user will read the instruction manual after the first few uses, improvements could be made to remind the user of the meaning of the AHA scale, icons, and of correct body position through the digital display. With the large number of elderly users who may have difficulty remembering information, the need for devices designed to enhance user recognition of information is increasingly important. This reliance on the user to either read the instructions before each use or commit the information to long-term memory is inconsistent with this important heuristic.

confusion and encountered use errors when using the device buttons. Placing the buttons above or below the device display instead of to one side could make the device more usable regardless of the handedness of the users. The buttons could also be separated to reduce the risk of accidental button presses and improve the ease of use for a wider range of users, particularly the elderly. Additionally, several users stated that they expected an on/off button which would turn the device on before starting the measurement. Incorporating these changes aid user understanding of the device and correlate to their expectations.

The iProven device also deviated from the established heuristic that helpful information should be easy to access and understand. During the usability study, several participants found the instructions that came with the device to be very dense, making it difficult to find the desired information. Incorporating a quick start guide and increasing the font size could improve the usability of the instructions. While improving the instructions could help users avoid errors, ideally the device would be so simple that users would not need instructions. The device could be redesigned to incorporate better icons for irregular heartbeat, and to provide users with more feedback, eliminating the need for instructions. Adding on-screen commands that indicate whether the user is in the correct position could improve the accuracy and usability of the device. In addition, redesigning the display to indicate the AHA scale in a more understandable manner could greatly reduce users’ confusion with the status of their condition.

The usability evaluation of the device also revealed that error codes displayed on the device were vague. When referenced in the instructions, the description of the error code was ambiguous or made little sense to the users. For example, the “E04” error code states, “The treatment of the measurement failed.” Rewriting the error code descriptions in the instructions to accommodate a lay user and providing more error feedback on the display could aid the user in correcting the error. This would allow the device to comply with the human factors engineering principles that help users recognize, diagnose, and recover from errors with helpful documentation.

The blood pressure monitor did little to keep the user informed of the current status of the system, which led to some confusion and user errors. These issues could be mitigated by incorporating a task status and error messages for improper use to alert users of potential improper usage. For example, when the cuff is inflated without being placed on the wrist, an error message could appear on the display telling the user to place the cuff on their wrist. The more a user can interact and obtain feedback about what they’re doing, the less likely they are to encounter use errors.

Medical device designers need to consider that users may have varying degrees of familiarity with technology. All participants in the study forgot to check that the phone Bluetooth was turned on to ensure that their readings were stored in the paired application. As a result, many participants had to manually input their blood pressure results into the application, which led to errors and inaccuracies. The display could be modified to prompt the user to check the Bluetooth connection and remind them to open the app for the blood



Figure 2: Comparison of Irregular Heartbeat Symbols

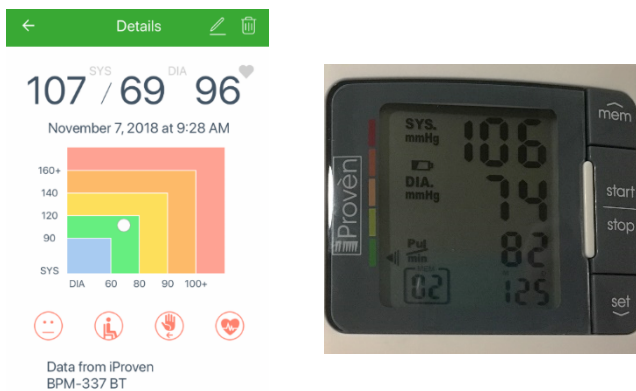


Figure 3: Comparison of AHA Scales on Application and Display

Another important heuristic that can improve usability of this particular device is promoting logical use by adhering to conventions, standards, and user expectations (Nielsen, 2005). The usability evaluation indicated that users experienced

pressure data to be transferred. By providing the user with an easy way to log and track their blood pressure with an app, manufacturers can ensure that doctors and users have the necessary information to track their condition. Furthermore, patients who have an accurate and thorough collection of measurements will be better equipped to control their disease progression.

While usability studies with 5-8 participants have been the gold standard in testing, our participants were recruited from an almost homogeneous population of students. Future studies should recruit participants with varied demographics and in particular different age and education groups. Furthermore, using other blood pressure monitors to draw a comparison or benchmark between the different models and assess the relative usability of BPM devices could help discover other potential user errors and issues. Finally, use of video-capturing equipment could catch errors that would go unnoticed during the course of the study.

CONCLUSION

The growth in preventive medicine has led to an increased use of medical devices in home environments and by a larger and more diverse population of users. These changes have prompted regulatory bodies to require companies to perform usability tests of devices. However, despite such regulatory oversight, several key usability issues remain to frustrate users. Home-use blood pressure monitors are gaining popularity among chronic disease patients, and their usability needs to be assessed. In this study, we assessed the usability of one such monitor: the iProven BPM-337BT device. Our findings suggest that this wrist-based device fails to incorporate some usability principles in its design and could be modified to improve user understanding and expectations. Redesigning the device by making modifications to the display, application, and instruction manual, would improve the overall user experience of this particular blood pressure monitor. These findings suggest that while FDA human factors and usability testing requirements might have been effective in improving safety, further testing is necessary to ensure adoption, proper usage, and sustained usage.

REFERENCES

- Clarkson, J. (2006). Human factors engineering and the design of medical devices. In P. Carayon (Ed.), *Handbook of human factors and ergonomics in health care and patient safety* (pp. 367-382). Boca Raton, FL: CRC Press.
- Edoardo, C., Tikhonoff, V., Federica, A., & Paolo, P. (2016). Poor reliability of wrist blood pressure self-measurement at home. *Hypertension*, 68(4), 896-903. doi:10.1161/HYPERTENSIONAHA.116.07961
- Gao, M., Kortum, P. (2017). Measuring the usability of home healthcare devices using retrospective measures. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*, 61(1), 1281-1285. <https://doi.org/10.1177/1541931213601801>
- Gurses, A., & Doyle, P. (2014). Medical Devices in the "Wild" | AHRQ Patient Safety Network. Retrieved from <https://psnet.ahrq.gov/webmm/case/337/Medical-Devices-in-the-Wild>
- Hilbers, E. S. M., de Vries, C., G.J.C.A., & Geertsma, R. E. (2013). Medical technology at home: Safety-related items in technical

- documentation. *International Journal of Technology Assessment in Health Care*, 29(1), 20-26. doi:10.1017/S0266462312000694
- International Electrotechnical Commission. (2015). IEC 62366-1:2015 Medical Devices -- Part 1: Application of usability engineering to medical devices. Retrieved from <https://www.iso.org/standard/63179.html>
- National Research Council. (2010). *The role of human factors in home health care: Workshop summary*. Washington, DC: The National Academies Press. doi:10.17226/12927
- Nielsen, J. (2005). 10 usability heuristics for user interface design. Retrieved from <https://www.nngroup.com/articles/ten-usability-heuristics/>
- Ohkubo, T., Imai, Y., Tsuji, I., Nagai, K., Kato, J., Kikuchi, N., . . . Hisamichi, S. (1998). Home blood pressure measurement has a stronger predictive power for mortality than does screening blood pressure measurement. *Journal of Hypertension*, 16(7), 971-975.
- Or, C. K., Valdez, R., Casper, G., Carayon, P., Burke, L., Flatley Brennan, P., & Karsh, B. (2009). Human factors and ergonomics in home care: Current concerns and future considerations for health information technology. *Work*, 33(2), 201-209. doi:10.3233/WOR-2009-0867
- Pickering, T. G., Hall, J. E., Appel, L. J., Falkner, B. E., John, G., Hill, M. N., . . . Roccella, E. J. (2005). Recommendations for blood pressure measurement in humans and experimental animals. *Hypertension*, 45(1), 142-161. doi:10.1161/01.HYP.0000150859.47929.8e
- Sato, H., Koshimizu, H., Yamashita, S., & Ogura, T. (2013, July 3-7). Blood pressure monitor with a position sensor for wrist placement to eliminate hydrostatic pressure effect on blood pressure measurement. *35th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC)*, 1835-1838. doi:10.1109/EMBC.2013.6609880