ABSTRACT

Title of Document: FORM AND FUNCTION GLUCOMETER EVALUATION FOR SPECIALIZED POPULATIONS.

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Patient self-management technologies (glucometer, blood pressure monitor, etc.) are a critical component of chronic disease care. Although these technologies are intended to support patient activities, low device usability can produce design impediments that may negatively impact patient adherence and hence treatment outcomes. In particular, patients with disabilities, who are the majority of the chronic disease population, are typically excluded from medical device usability studies required for FDA approval. This study aims to develop a usability method to: 1) evaluate patient self-management technology and 2) inform design decision making for disabled patients. The study will focus on handheld device use (glucometers) for diabetic patients with mobility and vision impairment. An initial expert usability analysis was performed for 13 glucometers to determine the design features that are most problematic for disabled users. The usability analysis informed the design of an experiment to test disabled user performance and satisfaction for several meter interaction tasks. Com-

mon diabetes disabilities were simulated in healthy subjects through the use of glasses (retinopathy, glaucoma) and gloves (arthritis, neuropathy) to evaluate the experimental protocol prior to future testing in the actual disease population. Results suggested a preference of participants for large text, large protruding buttons, and contrast color between case and buttons to facilitate locating buttons. Future studies will integrate the disabled diabetic population in the data collection and integration of these results in the design of a new glucometer. This work can inform regulatory guidelines for usability testing with disabled patients and the patient-centric design practices of medical device manufacturers.

FORM AND FUNCTION GLUCOMETER EVALUATION FOR SPECIAIZED POPULATIONS

By

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Thesis submitted to the Faculty of the Graduate School of the
University of Maryland, College Park, in partial fulfillment
of the requirements for the degree of
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Preface

This thesis is submitted in partial fulfilment of the requirements for a Master of Science Degree in Mechanical Engineering at the University of Maryland, College Park. The work herein presented was conducted with the support of many laboratory mates under the supervision of Professor Monifa Vaughn-Cooke.

After my arrival to the United States in 2012, I was introduced to usability as a means to design products that meet end-users needs. Usability is critical in situations where products are used by a diverse population, in particular chronic disease management devices such as glucometers. Indicative of the importance of usability, the Food and Drug Administration (FDA) now requires usability testing for certain medical devices, specifically the highest risk devices that go through the most stringent approval process (Pre-Market Approval). I become more familiar with the FDA's role in usability testing through interactions with the FDA Human Performance Lab, where research is performed on a variety of device concerns, including functional glucometer testing. It was through this interaction and further research into the regulatory design requirements for disabled individuals (i.e., Americans with Disabilities Act) that I found several loopholes that make it possible to design a medical device that does not meet the needs of an entire subpopulation of users. Thus, I was motivated to address these loopholes from the perspective of human factors engineering.

This study focuses on identifying device features that better support glucometer usability for users with mobility or visual limitations. This is not only of interest to mechanical engineering but also of interest to other fields—bioengineering, sociology, psychology, and public health. This research has far reaching implications and can potentially improve patient health as a result of ameliorating treatment adherence.

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I hold a special gratitude to Fulbright for funding my graduate studies in addition to providing me the opportunity to experience the American culture. I would never have thought coming to the United States without all your support.

Finally, to everyone who made all this possible, especially my parents who never stopped advising me and always encouraged me to dream big. Lastly, but certainly not least, I am immeasurably grateful to God from whom all blessing flow.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction

Patient self-management and treatment adherence, particularly for chronic conditions, has been shown to be associated with improvements in health status and decreased utilization of medical services (Asche, LaFleur, & Conner, 2011; Lorig et al., 1999). Patient self-management technologies are a critical component of chronic disease care and empowers patients to actively participate in their treatment. These technologies facilitate regular collection of health vitals (blood glucose, blood pressure, etc.) and diagnosis of current health state. Self-management technologies encompass not only biomedical mobile devices that can continuously monitor the patients' health status, but also wired and wireless communication devices and telemedicine servers to collect data on the patients' health status (Lee, Chen, Hsiao, & Tseng, 2007). This process improves treatment communication in transitions from the healthcare provider to a home setting (Coleman & Berenson, 2004) by communicating health status updates to the medical personnel and aiding in coordination of care across transitions in care settings.

1.1 Usability

Poor device usability compromises successful self-management technology use. Usability is an attribute that characterizes ease of device learnability and usage by a range of users and implements methods to measure and improve ease-of-use (Lin, Choong, & Salvendy, 1997). There are significant cognitive and usability barriers for patient interaction with self-management technologies. Small screens and complex systems of hierarchical menus are typical challenges for patient users, par-

ticularly older adults and users with disabilities who represent a considerable segment of the chronic disease patient population (Lai, Kaufman, Starren, & Shea, 2009). A large percentage of chronic disease patients have vision (i.e., retinopathy, glaucoma, cataracts) and mobility impairment (i.e., neuropathy, amputation). In addition chronic disease patients tend to have lower health literacy and socio-economic status (SES), which may negatively impact their perceived device usability and adherence to recommended device use. Failure to match patients to a suitable device can lead to improper use, non-adherence to instructions, and poor outcomes.

1.2 Diabetes

Diabetes is a highly prevalent chronic condition with high rates of patient non-adherence due to the disease complexity (multiple providers and treatment regimens) and longevity. According to Harris (2001), more than one quarter of diabetes Type II patients had never monitored their blood glucose level or have done it less than once per month. The current number of diagnosed diabetes cases in the United States is estimated to be 25.8 million—8.3 % of the population—with seven million undiagnosed cases (Centers for Disease Control and Prevention (CDC), 2011). Diabetes is also a leading cause for several other chronic diseases—namely atherosclerotic vascular disease, renal failure, vision impairment, and lower extremity amputation (CDC, 2011). Diabetes complications include a variety of vision and mobility impairments that may impair proper device use.

About 28% of diabetics aged 40 years or older have diabetic retinopathy and are 40% more likely to suffer from glaucoma compared to people without diabetes (American Diabetes Association, 2013b). Diabetes complications include nervous

system damage that affects about 60% to 70% of diabetics. As a result diabetics have mild to severe nervous system damage including impairment sensation or hand pain (CDC, 2011).

1.3 Diabetes as a Disability

The American with Disabilities Act Amendments of 2008 ("ADAA") establish diabetes as a disability under the American with Disabilities Act if the condition substantially limits a major life activity (i.e., vision and mobility impairment due to diabetes compilations). Despite this, manufacturers are not required by law to design glucometers to accommodate diabetic patients with disabilities. Some handheld medical devices have been made accessible to those with a disability, but they are not as common. For example, for blind users, several technologies exist: Prodigy Voice® from Prodigy®; and Diabetes Care and Solus V2 from BioSense Medical Devices. Manufacturers are also required by the Food and Drug Administration (FDA) to demonstrate the application of human factors engineering to the design of medical devices through required usability testing. However, most usability tests are conducted with healthy subjects whose needs clearly differ from those of disabled patients, who are the majority of the glucometer user population.

1.4 Objectives

This research addresses the aforementioned issues by empirically evaluating hardware and software modular components (screen, button, casing, etc.) of glucometers to guide the device design process and the development of generalized handheld device design guidelines for users with disabilities. This will be accomplished in two

phases: 1) Perform an expert heuristic usability evaluating of existing glucometers to determine the most influential design features for users with disabilities; and 2) Perform user testing of the critical features identified in Phase 1 through the simulation of vision and mobility impairment in healthy subjects. The disability simulation study in Phase 2 serves as a pilot of the experimental protocol and provides a foundation to test the design features in the actual target population (disabled diabetes patients) in a future study. The results of this research can potentially inform medical device manufacturer design practices and FDA guidelines for handheld device design for users with disabilities.

Chapter 2: Background

This chapter provides an overview of disability regulations, diabetes, and handheld design guidelines. First, handheld device design guidelines currently available are introduced along with FDA human factors requirements for medical devices. Next, regulations advocating for disabled persons in the Unites Stated and its relationship with diabetes is discussed. Finally, an overview of diabetes is presented.

2.1 Handheld Device Design Guidelines

Despite the increase popularity of handheld devices, no design guidelines tailored for disabled persons are available. A few guidelines for handheld designs are publicly accessible, however, they are not detailed enough to provide dimensions of buttons, screen, and casing. These features, discussed later in the document (Section 4.1), are influential in the perceived usability of devices, particularly for persons with visibility and mobility limitations.

2.1.1 Department of Defense Guidelines

The Department of Defense (DoD) developed a handbook that provides basic guidelines on human engineering design for military systems, equipment, and facilities (DoD, 1995). Most of the recommendations presented are not directly applicable to handheld devices or to disabled persons. However, human factors implementation throughout the development of the guidelines makes the handbook a popular reference among other design guidelines documents.

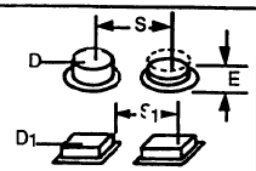
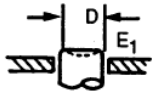
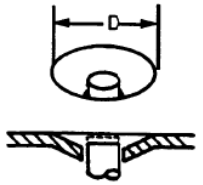
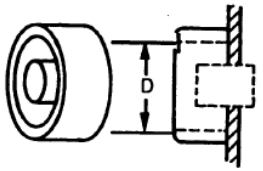
In the DoD handbook, push buttons, the most common type of input in handheld medical devices, are discussed in more detail compared to screens and casing. Very little reference is made to case design. Guidelines for push buttons are summarized in Figure 2, which includes dimensions, spacing, and general recommendations. Screens, the communication medium between the device and the user, are largely discussed in different applications. However, the handbook focuses on scale graduation pointers and cathode ray tube displays. In the case of small applications, the handbook provides general guidelines which include: only displaying information that is essential; segment display (non-continuous display formed with seven bars, see Figure 1) is acceptable for numerals only; and light symbols on a dark background should be used when work area illumination is low.

Outside of defense, other industries have discussed the importance of human factors in product design, such as aviation.

Figure 1: Seven-Segment Display (Perm, 2009)

2.1.2 Federal Aviation Administration

The Federal Aviation Administration (FAA) asked Zingale, Ahlstrom, and Kudrick (2005) to identify the advantages and disadvantages of handheld, portable, and wearable computing devices for maintenance specialists.

	APPLICATION GUIDELINES	DESIGN GUIDELINES				
		DIMENSIONS			DISPLACEMENT	SEPARATION
	Panel-mounted push buttons: Single-finger, one button at a time. Non-legend or buttons that require only a single number on the front surface may be round, square, or rectangular.	D - Min diameter or dimension (D_1) - 10 mm*			E - Excursion, preferred min = 3.2 mm; preferred max = 6.5 mm. Add 13 mm for gloves**	S - Min = 19 mm (25 mm with gloves) S_1 - Min = 13 mm
	A concave surface may be used to aid finger-centering (non-glove operation only).	D - Max = 19 mm; Min = 13 mm				
	Recessed button to minimize inadvertent operation. Tapered "well" guides finger.		D - Min well opening = 19 mm; 32 mm with gloves			
	Prevent inadvertent operation of critical switch, either with guard ring or panel well.		D - Same as above			

*For miniaturized applications, diameters as small as 3.2 mm may be used providing they accommodate all other relevant requirements, e.g., use of handwear, need for ruggedness.

**Depressed buttons should remain exposed by at least 2.5 mm. Switches with no motion, e.g., thermal, may be used providing they accommodate all other relevant requirements.

Figure 2: Push Button Switches (Department of Defense, 1995)

Although the document is a detailed description of Personal Digital Assistant (PDA), Smart Phones, Blackberrys®, and Tablet Computers (commonly known simply as tablets), it also includes general human factors considerations for handheld devices which include:

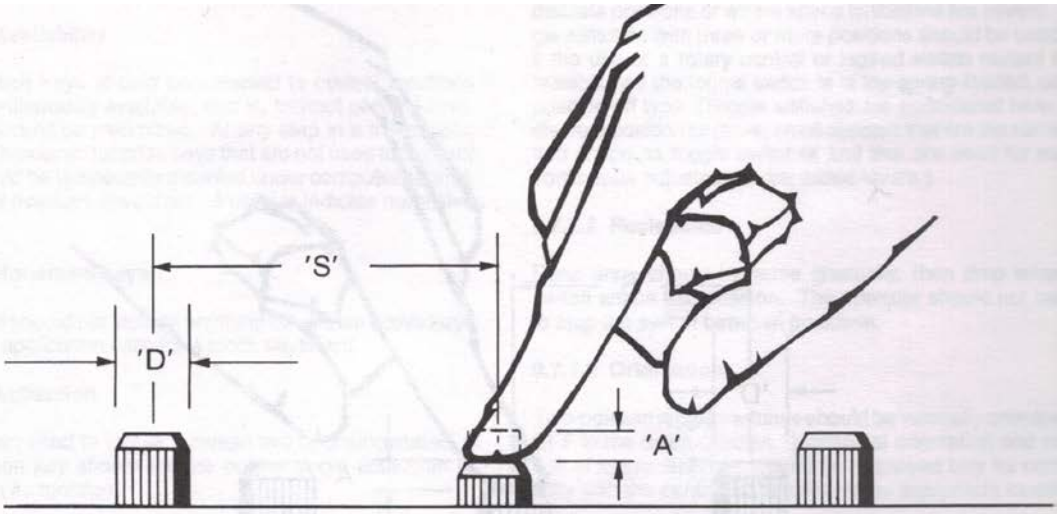
- Equipment should have a non-slip surface and be shaped so as to prevent it from slipping out of the user's hand.
- The display should accommodate expected operational lighting conditions, both high and low illumination.
- Portable equipment should have rounded corners and edges.
- Device weight should not be more than 5.1 lb. (2.3 kg).
- Device should be smaller than 4"x10"x5".

The FAA provides general design guidelines that are applicable to handheld medical device design but does not explore features as buttons, screen, and casing. The medical industry has also shown interest in the application of human factors during the design process.

2.1.3 Association for the Advancement of Medical Instrumentation

The Association for the Advancement of Medical Instrumentation (ANSI, AAMI, 1993) developed guidelines for the design of medical devices. The AAMI document focuses on controls, displays, consoles, and general user interface design of medical devices; however the recommendations are not specific for handheld applications. Nevertheless, general dimensions for push buttons are provided by the authors and are shown in Figure 3. Screen dimensions or context (text) size are not discussed.

In addition to AAMI, FDA has also developed human factors guideless and regulations for medical devices.



	DIMENSIONS		RESISTANCE		
	DIAMETER * D				
	Fingertip	Thumb or Palm	Single Finger	Different Fingers	Thumb or Palm
Minimum	9.5 mm (0.375")	19 mm (0.75")	2.8 N (10 oz.)	1.4 N (5 oz.)	2.8 N (10 oz.)
Maximum	25 mm (1")		11 N (40 oz.)	5.6 N (20 oz.)	23 N (80 oz.)

	DISPLACEMENT	
	A	
	Fingertip	Thumb or Palm
Minimum	2 mm (0.078")	3 mm (0.125")
Maximum	6 mm (0.25")	38 mm (1.5")

	SEPARATION			
	S			
	Single Finger	Single Finger Sequential	Different Fingers	Thumb or Palm
Minimum	13 mm (0.5")	6 mm (0.25")	6 mm (0.25")	25 mm (1")
Preferred	50 mm (2")	13 mm (0.5")	13 mm (0.5")	150 mm (6")

*Table applies to square/rectangular buttons also.

Figure 3: Design and separation for finger- or hand-operated pushbuttons (ANSI, AAMI, 1993)

2.2 FDA Usability Testing

FDA requires manufacturers to include usability testing data as part of Pre-Market Approval (PMA) and 510k submissions. This requirement is intended to improve usability of medical devices and minimize human errors. Manufacturers must demonstrate implementation of human factors during device development by submitting pertinent documentation. Three specific design requirements must be met.

- Design Input: ensure device design requirements are in accordance with the intended use of the device as well as with the end-user needs.
- Design verification: assure device design meet design input requirements. The process shall be documented in a design history file.
- Design validation: manufactures must validate the device design by comparing it to the design input requirements in addition to test it under actual or simulated use conditions.

Specifically, FDA recommends the use of analytical methods and formative evaluations to analyze and understand use-related hazard in the design process (FDA, 2011).

Analytical methods constitute describing and systematic decomposing a device. Among these methods are: Task Analysis, a method requiring decomposing device use process into elemental tasks; and Heuristic Evaluation, a process in which evaluators analyze a device user interface against well-established design rules (FDA, 2011). Both techniques are applied in this study and are discussed in more detailed in Section 3.1. Formative evaluations involve user interaction with the device under different conditions in order to derive information regarding relative risk and use-related

errors. Two methods are presented by the FDA: cognitive walk-through, which involves users verbalizing their thoughts while performing certain tasks; and user testing, data collection from users while interacting with a device in realistic situations. User testing is incorporated in this study as described in Section 3.2.

Although FDA provides detail on the types of usability tests that should be performed for approval submission, requirements for subpopulation inclusion is missing and vulnerable populations are frequently overlooked. Therefore, several glucometers have low usability for individuals with visual or mobility impairments. Pertinent regulations requiring the accommodation of products and services for individuals with disability is discussed in the next section.

2.3 Disability Regulations

In 1990, President George W. Bush signed the Americans with Disabilities Act (ADA) into law, which prohibits discrimination against people with disabilities. On January 1, 2009, the Americans with Disabilities Act Amendments Act (ADAAA) of 2008 went into effect primarily to broaden the definition of disability (Job Accommodation Network, 2013) since previous definitions made protection under ADA unattainable.

Instead of limiting disability to a list of impairments, ADAAA defines a person with disability as an individual who meets one of the following criteria:

- Have a physical or mental impairment that substantially limits one or more major life activities of such individual.
- Have a record of such impairment.
- Is perceived by others as having such impairment.

Nevertheless, the Law provides a list of impairment that, under virtually all circumstances, will ratify an individual as disabled. The list, found in 29 C.F.R. § 1630.2(j) (3), includes deafness, blindness, autism, cancer, and diabetes, among others conditions. Diabetes is considered a disability and diabetic individuals are entitled to receive protection under ADAAA.

The Act is divided into five titles that cover major areas of everyday life (Civil Rights Division, 2009; Job Accommodation Network, 2013):

- Title I: Employment: prohibits discrimination in any aspect of employment based on disability status.
- Title II: Public Services: prohibits public entities to deny services to people with disabilities or deny participation in programs or activities that are available to people without disabilities.
- Title III: Public Accommodations: requires that all new construction and modifications of public and commercial facilities must be accessible to individuals with disabilities.
- Title IV: Telecommunications: amends the Telecommunications Act of 1996 requiring manufacturers and providers of telecommunications to ensure products and services are accessible to individual with disabilities.
- Title V: Miscellaneous Provisions: includes a provision prohibiting coercing or retaliating against individuals with disabilities or persons willing to assist people with disabilities in asserting their rights under the Act.

Although Title I and II specifically address accessibility to services and public accommodations, technology design is omitted. Title IV is the only act that references technology; however, this restricted to telecommunications technology and does not include medical devices. These loopholes allow medical device manufacturers to develop and get regulatory approval for products that are not accessible and do not accommodate disabled user, in particular diabetic patients who have to rely on glucometers to manage their disease.

2.4 Diabetes

Diabetes is chronic disease involving high or low levels of blood glucose. During digestion, carbohydrates are broken down into glucose, a form of sugar that is a source of fuel for the body. Glucose is moved by insulin—a hormone produced by the pancreas—from the bloodstream to cells throughout the body. Diabetes develops when the body is not able to produce enough insulin or is incapable to use insulin effectively, or both (National Diabetes Information Clearinghouse, 2008).

Two mayor types of diabetes exist: Type I, predominantly diagnosed to young individual with insulin deficiency due to the destruction of cells in the pancreas; and Type II, the most common form of diabetes consisting largely of adults with insulin resistance (National Diabetes Information Clearinghouse, 2011). Also it is possible for women to develop gestational diabetes during pregnancy although this type of diabetes is less common.

In the United States alone, the Center for Disease Control and Prevention (CDC) (2011) estimated that 8.3% of the population—25.8 million people—has been affected by diabetes in 2010. Among them, individuals aged 65 years or older repre-

sented the largest group of diabetics (Figure 4). This is particularly important since older individuals tend to have more diabetes complications and disabilities resulting from those complications as a result of the longevity of their diabetes.

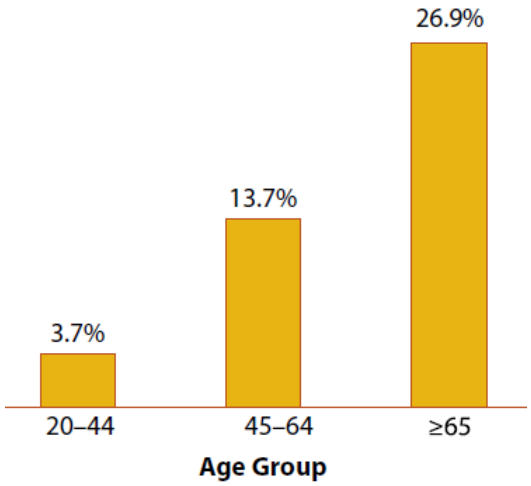


Figure 4: Estimated percentage of people aged 20 years or older with diagnosed and undiagnosed diabetes in the United States, 2005-2008 (CDC, 2011)

In addition, diabetes poses a significant cost to patients and the healthcare system. CDC (2011) has estimated this cost to the healthcare system as $174 billion in the United States. Diabetics also have double the medical expenditures compared with non-diabetic patients, mainly due to multiple additional complications (CDC, 2011).

Diabetes increases the risk of health complications (vision and mobility impairment) that may negatively impact self-management technology usage, particularly for handheld devices which require manual grasping, button pressing and reading information on small screens. Common complications affect vision and mobility of patients. Among regular eye illness are glaucoma, cataracts, and diabetes retinopathy. Glaucoma arises when the eye's optic nerve gets damaged mainly by eye pressure

(National Eye Institute, n.d.). This disease is 40% more likely to affect diabetics than non-diabetics (American Diabetes Association, 2013b). Similarly, cataracts, an eye disease caused by clouding of the lens in the eye (National Eye Institute, 2009), are 60% more likely to be developed by people with diabetes, compared with non-diabetics. Diabetes retinopathy, a family of eye diseases involving blurred vision with floaters, has been diagnosed to 4.2 million (28.5%) people with diabetes aged 40 years (CDC, 2011).

Nerve damage, widely known as diabetes neuropathy, is another health problem found in about 60% of the diabetes population (CDC, 2011). Consequences include impaired sensation or pain in the feet or hands, slowed digestion of food, carpal tunnel syndrome, and even amputation. Similar mobility impairment effects are caused by arthritis, one of the most prevalent diseases in the United States affecting 22.7% of the adult population (CDC, 2013). In addition, arthritis has impacted 52% of adults diabetics (CDC, 2008).

2.4.1 Treatment

Treatment is an essential part of diabetes management. Diabetes Type I is not curable, however the complications of Type II may be reversed with lifestyle changes (American Diabetes Association, 2013a). Both types involve taking medicines, regulating diet, and exercising to control blood glucose levels (Topiwala, Zieve, VeriMed Healthcare Network, A.D.A.M. Health Solutions, & Ebix, 2012). Monitoring blood glucose levels are therefore critical to manage treatment. Hence, the American Diabetes Association (ADA) has recommended the regular use of glucometers to monitor blood glucose.

2.4.2 Glucometers

Glucometers are handheld devices designed to measure blood glucose level by chemically analyzing a small blood sample (Figure 5).

Figure 5: Bayer® Contour® Next EZ Glucometer and Lancing Device.

Typically, users are required to prick their finger using a Lancing Device. After successfully extracting blood from the finger, users place a blood drop on a test strip which initiates a biochemical reaction with the glucose oxidase on each test strip. The meter translates the biochemical reaction into a numerical value, which is stored in the device and presented to the user on the screen. The process from placing the blood on the test strip to displaying the result takes about 5 seconds. Most of the time is spent preparing the device and extracting blood. Each test strip and lancet unit must be discarded after use.

The ADA (American Diabetes Association, 2013a) recommends usage of glucometers to assess the effectiveness of treatment and patient decisions on glycemic

control. Frequency of testing depends on different factors including the type of diabetes, age, weight, medications, and exercise, among others. Regular blood glucose testing allows diabetics to achieve and maintain glycemic goals (Goldstein et al., 2004). Despite the benefits of using glucometers to monitor blood glucose levels, diabetes patients have lower rates of device use treatment adherence, ranging from 20% to 66% (Vincze, Barner, & Lopez, 2004), which increases chances of health complications such as glaucoma, diabetes retinopathy, and diabetes neuropathy.

Chapter 3: Methods

This study was divided in two phases. First, an expert usability analysis (hierarchical task analysis and usability heuristics), was performed on 13 glucometers to identify features and functions that contribute to device usability. The usability analysis guided the identification of critical features for disabled users, to be further explored in a simulation study in the second phase. During the second phase, participants interacted with four meters and verbally expressed their satisfaction with each feature identified during the expert usability analysis. These two phases are detailed in subsequent sections.

3.1 Phase 1: Expert Usability Testing

Initially, 13 existing glucometers were selected for analysis (Table 1). For each device, we developed detailed glucometer-specific hierarchical task analyses (HTA) (Kurniawan, 2003) and usability ratings based on Nielsen's Ten Heuristics (Nielsen & Mack, 1994).

3.1.1 Hierarchical Task Analysis

To identify the task levels, a HTA was performed to determine the actions to fully operate a glucometer. HTA consists of determining high-level tasks and decomposed them into sub-tasks. Tasks and sub-tasks are subsequently organized as plans that illustrate how tasks can be performed. This method is useful to identify specific actions or tasks that can lead to errors.

Table 1: Glucometer List

Glucometer	
Brand	*Model*
OneTouch	Verio IQ
Bayer	Contour USB
Sanofi	iBG Star
OneTouch	Ultra2
Accu-Chek	Nano
Bayer	Contour Next EZ
Bayer	Contour
Accu-Chek	Aviva Plus
Abbott	Precision Xtra
OneTouch	UltraMini
Accu-Chek	Compact Plus
FreeStyle	Lite
Bayer	Breeze2

Glucometer-specific HTAs were created after interacting with each device and thoroughly reading the instruction manual. An example HTA for the Bayer® Breeze®2 meter is shown in Appendix A. All HTAs contained six common high-level tasks which include: Set Up Meter, Code Meter, Control Test, Prepare Lancing Device, Perform Test, and Review Past Results. Where appropriate, each high-level task was further divided into sub-tasks.

3.1.2 Usability Heuristics

Nielsen's Ten Heuristics were used for the heuristic usability analysis of each glucometer HTA sub-task. A heuristic evaluation is a method that identifies usability issues by employing a small group of evaluators who examine a user interface with a set of heuristics. Nielsen (1993) proposed a set of ten heuristics (Table 2) to assess

user interfaces. The purpose of a heuristics evaluation is to elicit human error contributors or other sources for difficulty of device use.

Table 2: Nielsen's Ten Heuristics (Nielsen & Mack, 1994)

	Heuristic	Description
1	**Visibility of system status**	The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.
2	**Match between system and the real world**	The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.
3	**User control and freedom**	Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. Support undo and redo.
4	**Consistency and standards**	Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.
5	**Error prevention**	Even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.
6	**Recognition rather than recall**	Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.
7	**Flexibility and efficiency of use**	Accelerators -- unseen by the novice user -- may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions.
8	**Aesthetic and minimalist design**	Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.
9	**Help users recognize, diagnose, and recover from errors**	Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.
10	**Help and documentation**	Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.

Each glucometer was analyzed separately by three evaluators who assigned a score, from no usability problem (0) to severe usability issue (4). Single evaluators are able to find 35 percent of usability problems and the preferred number of evaluators range between three and five (Nielsen, 1995). It's important to note that although the HTA include non-device interaction tasks such as grabbing the meter and opening the button door (tasks 1.1.1-1.1.2 Appendix A: HTA for Bayer® Breeze®2); only the usability scores were applied to the tasks that involved device interaction. Additionally, each evaluator listed all usability issues encountered during the analysis of devices, with specific reference for tasks. Two of the evaluators had more than nine months of both human factors and usability experience and one of them had more than six months of experience. The summarized results of usability scores for each meter included in Phase 1 can be found in Table 6.

3.2 Phase 2: Disability Simulation User Testing

Expert usability testing allowed for the identification of buttons and screens as the most influential usability features. In particular for disabled patients, these features may have more influence on usability. Even though shape and size of meters were not found among the top influencers on usability, they were incorporated in the set of features to be evaluated during the user test to provide a more comprehensive evaluation.

A group of modular components, Screen, Buttons, and Case, was defined based on the aforementioned features. Different characteristics of each modular component were defined as well as a criterion to select devices to use during the test (Table 3). A group of four devices—Accu-Chek® Aviva, Bayer® Breeze®2, Accu-

Chek® Nano, and Contour® USB (Figure 6)—that together spanned across all criterion were selected (Table 3). Each meter represents a different modular component at a different scale, thus encompassing all features desired to be tested in Phase 2.

Table 3: Physical Characteristics of Selected Glucometers

Characteristic	**Bayer Breeze2**	**Accu-Chek Aviva**	**Accu-Chek Nano**	**Bayer Contour USB**
Meter Size	Large *Length > 4”*	Medium *4” > Length > 3”*	Small *Length < 3”*	Medium *4” > Length > 3”*
Meter Shape	Ellipse	Oval	Rectangle	Rectangle (extended)
Button	Recessed	Protruding	Flush	Protruding
Button Size	Medium *7/16” > Length > 5/16”*	Large *Length > 7/16”*	Medium *7/16” > Length > 5/16”*	Small *Length < 5/16”*
Screen Size	Medium *1.25in^2 > Area > 1.75in^2*	Large *Area > 1.75in^2*	Small *Area < 1.25in^2*	Medium *1.25in^2 > Area > 1.75in^2*
Screen Shape	Wide	Upright	Upright	Wide Extended
Screen Text	Medium *9/16” > Height > 5/16”*	Large *Height > 9/16”*	Medium *9/16” > Height > 7/16”*	Small *Height <5/16”*

Figure 6: User Testing Selected Glucometers

Based on the diabetes statistics, the two most common mobility (arthritis & diabetic neuropathy) and vision (glaucoma & diabetic retinopathy) impairments were selected as diseases to analyze during the user testing phase. A pilot test intended to evaluate the experimental protocol was conducted with nine healthy participants. As mentioned previously, the purchase of Phase 2 is to provide experimental protocol validation for future studies in the diabetic disabled population. Each healthy subject wore different instruments (glasses and gloves) intended to simulate each disability.

3.2.1 Disease Simulators

Diabetic retinopathy is the most common diabetic eye disease generated by damage to the blood vessels in the retina. Diabetes retinopathy involves blurred vision with floaters in the field of vision that eventually leads to blindness. A pair of glasses obtained from ShopLowVision (www.shoplowvision.com) was used to simulate floaters and spotty vision as shown in Figure 7.

Figure 7: Vision through Combined Loss glasses (retinopathy)

Glaucoma is the second most common cause of blindness in the United States caused by damage to the optic nerve due to increased pressure in the eye. Open-angle, the most common type of glaucoma, produces a loss of peripheral (side) vision and can also lead to blindness. Loss of side vision was simulated with Peripheral Field Loss glasses obtained from ShopLowVision. The Peripheral Field Loss glasses limit the visual field to 12 degrees when worn at an eyeglass position (Figure 8).

Figure 8: Vision through Peripheral Field Loss glasses (glaucoma)

Arthritis is a family of joint diseases including symptoms such as pain and joint stiffness. In the general case, a person affected by any form of arthritis has difficulty moving the joints along with muscle weakness. Another prevalent mobility-restriction disease among diabetic persons is diabetic neuropathy, which produces similar symptoms to arthritis including insensitivity to pain, muscle weakness, and loss of reflexes. Several arthritis and neuropathy simulation gloves are available for purchase; however, they are limited in their use for small handheld devices and accommodation of multiple hand sizes. Nitrile gloves presented the best option to simulate arthritis by providing hypoallergenic, disposable, and adjustable joint-restriction

(arthritis) and touch desensitization (neuropathy) based on the number of layers worn. After testing several numbers of layers, five layers of gloves was selected since it provided sufficient joint restriction combined with finger sensitivity reduction (Figure 9) compared with the commercial options available. Although some hand sweating from the nitrile gloves is expected, this was not a critical experimental factor based on the short amount of time the subjects spend wearing the gloves.

Figure 9: Five layers of nitrile gloves

3.2.2 Subject Population

The standard number of accepted participants for usability studies is approximately five subjects. Studies have shown that the proportion of discovered usability problems exponentially decrease for each participant after the fifth participant (Nielsen & Landauer, 1993). The study sought to recruit approximately ten participants to provide an experimental buffer, given the pilot stage of the project. A total of nine participants, eight males and one female, between the ages of 18 and 24 were recruited from two undergraduate Mechanical Engineering courses (ENME242 and ENME371) taught at the University of Maryland, College Park. Participants were re-

quired to be over the age of 18 without existing hand mobility or vision limitations. However, participants with vision complications rectified with lenses were included in the study if prescribed corrective glasses were worn during the experiment. Each subject received extra credit of one homework (ENME242) or participation (ENME371) grade in their respective class for participation. The University of Maryland Institutional Review Board (IRB) provided approval for this study by means of a letter shown in Appendix E.

3.2.3 Experimental Tasks

The study consisted of three audio and video recorded tasks (Turn Meter On, Review Past Results, and Insert Test Strip) with all four glucometers while wearing one disease simulator at a time. Simple tasks were selected to minimize the confounding effect of the subject's perceived glucometer usability with their satisfaction of vision and mobility while using the meter.

The first task, Turn Meter On, consisted of three major steps:

- Visually locate the power button.
- Manually press the power button.
- Verify the meter is on by reading the date on meter out loud.

Similarly, the second task, Review Past Results, was decomposed into the following major steps:

- Visually locate the memory (or equivalent) button.
- Manually press the memory button.
- Read out loud the stored results and date it was entered.
- Visually locate the next-result button.

- Manually press the next-result button.
- Read out loud a second stored results and date it was entered.

Inserting the test strip into the meter was a more complex task that required hand-eye coordination with precision handling of the test strip. Completion steps are:

- Visually locate the test strip.
- Manually pick up the test strip.
- Properly orient the test strip and visually confirm the orientation.
- Insert the test strip into meter
- Visually confirm the meter is ready for testing (test strip was successfully inserted).

Prior to completion of the tasks, participants received a brief training with instructions on how to accomplish each task through the use of training materials shown in Appendix F. Subjects were allowed a short time (one minute) to familiarize themselves with the tasks and devices to minimize confounding learning curve results. In addition, instructions were provided while completing each task to eliminate instruction memorization during the training session.

The study was designed following a within-subjects methodology. Participants experienced all independent variables (glucometers and disease simulators) in a randomized order to avoid the experimental impact of presentation order.

As shown in Figure 10, subjects verbally answered one five-point Likert scale question after completing each task. Both Likert scales (Figure 11) were presented on a screen display located in front of participants, who used either one scale depending

on the question asked. A different set of questions was asked depending on the disease simulators worn by the participants while completing the task.

Both visual simulators, glaucoma and diabetes retinopathy, had the same set of questions (denoted as set "a", Table 4) focused on the difficulty of visually interacting with the devices. In particular, difficulty for subjects to read text and their satisfaction with the size of the text, screen, and buttons.

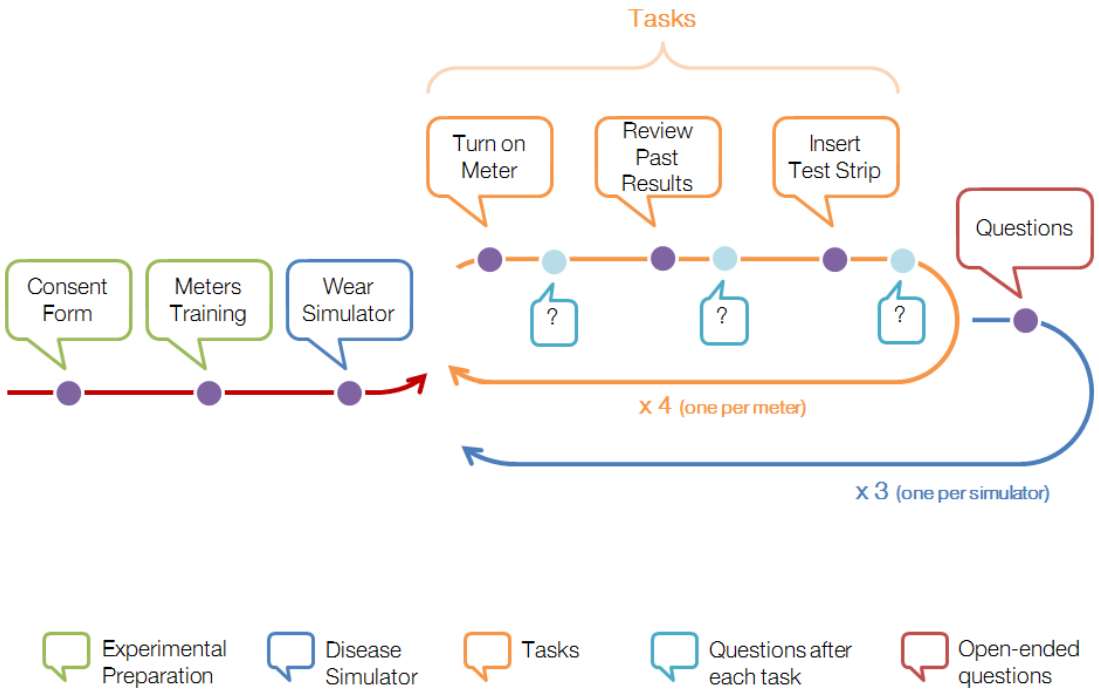


Figure 10: User Testing Protocol.

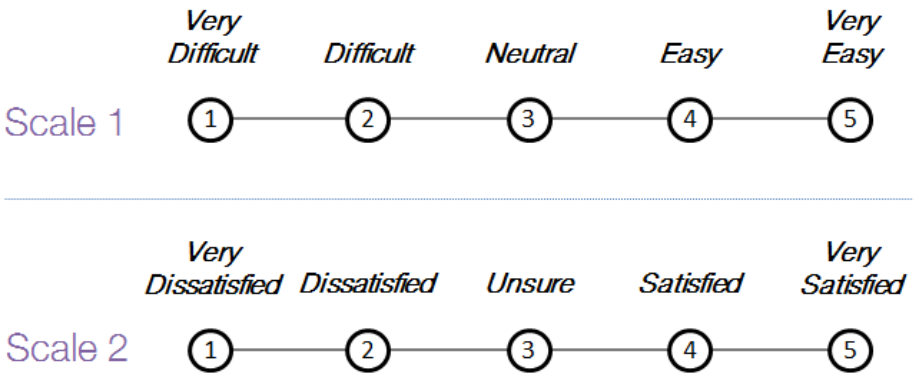


Figure 11: Five-point Likert Scales.

Table 4: Set of Questions “a” for glaucoma and diabetes retinopathy simulators (glasses)

	Question
After Task 1	1. How easy or difficult was it for you to see when performing Task 1 (power)?
After Task 2	2. How easy or difficult was it for you to see when performing Task 2 (past results)?
After Task 3	3. How easy or difficult was it for you to see when performing Task 3 (test strip)?
	4. How easy or difficult was it for you to read the text?
	5. How would you rate your overall satisfaction with the size of the screen text?
	6. How would you rate your overall satisfaction with the shape and size of the screen?
	7. How would you rate your overall satisfaction with the shape and size of the buttons

Mobility simulator (gloves) had a set of questions “b” centered on the difficulty of manually interacting with glucometers (Table 5). Specifically, the difficulties for participants to feel the buttons, press the buttons, grasp the meter, and hold the meter for an extended period of time.

Subjects then verbally answered open-ended questions meant to summarize their overall experience after completing all tasks with each simulator. Four open-ended questions were asked, requiring verbal response:

- After interacting with the meters, which one do you prefer? Why?
- What was the most difficult part of [visually/manually] interacting with the meters?

- Is there any screen, button or shape feature of the meters that was restricting?
- Could you think of any new meter feature that would help while performing the tasks?

Table 5: Set of Questions "b" for arthritis and neuropathy simulators (gloves)

	Question
After Task 1	1. How easy or difficult was it for you to use your hands to perform Task 1 (power)?
After Task 2	2. How easy or difficult was it for you to use your hands to perform Task 2 (past results)?
After Task 3	3. How easy or difficult was it for you to use your hands to perform Task 3 (test strip)?
	4. How easy or difficult was it for you to feel the buttons?
	5. How easy or difficult was it for you to press the buttons?
	6. How easy or difficult was it for you to grasp the meter?
	7. How would you rate your overall satisfaction with the shape and size of the buttons
	8. How would you rate your overall satisfaction with the weight of the meter?
	9. How easy or difficult was it for you to hold the meter for a period of time?

3.2.4 Statistical Analysis: Friedman Test

For each question, we sought evidence in support of a statistical difference between the responses of all four meters. For this we performed several Friedman Rank Tests based on the work by Conover (1999). The Friedman Test was selected since it

is adequate for non-numeric related ordinal data. All the following required assumptions are met:

- One group that is measured on three or more different occasions.
- Group is a random sample from the population.
- The dependent variable should be measured at the ordinal or continuous level.
- Samples do not need to be normally distributed.

For every Friedman Test, the null hypothesis and alternative hypothesis were set as the following H_0: No difference in preference of meters and H_1: Some meters tend to be preferred over the others. Each question consisted of $b = 9$ mutually independent blocks (participants) with $k = 4$ treatments (glucometers). Scores assigned by each participant were ranked and a value of 1 was given to the smallest observed value, 2 to the second smallest, and so on. Average ranks were used in case of ties.

The sum of the ranks for each treatment (meter) was calculated as shown in Equation 1.

$$R_j = \sum_{i=1}^{b} R(X_{ij}) \ for \ j = 1, 2, ..., k. \tag{1}$$

where $R(X_{ij})$ is the rank assigned to the X score by the i-th participants for the j-th meter. The sum of the squares of the ranks A_1 and correction factor C_1 were computed per Equation (2) and Equation (3), respectively.

$$A_1 = \sum_{i=1}^{b} \sum_{j=1}^{k} \left[R(X_{ij})\right]^2 \tag{2}$$

$$C_1 = bk(k+1)^2 / 4 \tag{3}$$

Then the statistic T_1, adjusted for the presence of ties, is given by Equation (4).

$$T_1 = \frac{(k-1)\left[\sum_{j=1}^{k} R_j^2 - bC_1\right]}{A_1 - C_1} \tag{4}$$

However, a more accurate approximation for T_1 is provided by Equation (5) below.

$$T_2 = \frac{(b-1)T_1}{b(k-1) - T_1} \tag{5}$$

The null hypothesis is rejected at an $\alpha = 0.05$ significance level if T_2 exceeds the $1-\alpha$ quantile of the F distribution for $k_1 = k-1$ and $k_2 = (b-1)(k-1)$.

If the Friedman test rejects the null hypothesis, multiple pair comparisons can be made to determine which meter is statistically preferred by the user. A pair of meters can be compared with Equation (6) and one of them is considered preferred by users if the inequality is satisfied.

$$\left|R_j - R_i\right| > t_{1-\alpha/2}\left[\frac{2\left(bA_1 - \sum R_j^2\right)}{(b-1)(k-1)}\right]^{1/2} \tag{6}$$

where $t_{1-\alpha/2}$ is the $1-\alpha/2$ quantile of the *t* distribution with $(b-1)(k-1)$ degrees of freedom.

Chapter 4: Results

4.1 Phase 1: Expert Usability Testing

Thirteen glucometers were analyzed during Phase 1 (Expert Usability Analysis). For each device a HTA was created and a usability score was assigned to interface tasks by three different evaluators. HTA for Bayer® Breeze®2, Accu-Chek® Aviva, Accu-Chek® Nano, and Bayer® Contour® USB can be found on Appendix A, Appendix B, Appendix C, and Appendix D, respectively. The sum of usability scores from the three evaluators is also presented. The maximum value for the combined usability score is 120. Usability scores were assigned from 0 (no usability issues), to 4, (severe usability issue). Therefore, for values in Appendices, a high usability score denotes a glucometer that did not demonstrate high usability and vice versa.

Each glucometer had three usability scores, one from each evaluator, which were aggregated through summation and then normalized by the maximum possible usability score. As a result, high usability scores indicate glucometers with higher usability in Table 6. The glucometers with the highest usability, in ascending order, were iBG® Star, Bayer® Contour® USB, and OneTouch® Verio® IQ. On the other hand, the glucometers with the lowest usability, in descending order, were Accu-Chek® Compact Plus, FreeStyle® Lite, and Bayer® Breeze®2.

Table 6: Glucometers Usability Scores

Glucometer		Usability Score
Brand	*Model*	
OneTouch	Verio IQ	0.936
Bayer	Contour USB	0.850
Sanofi	iBG Star	0.781
OneTouch	Ultra2	0.640
Accu-Chek	Nano	0.622
Bayer	Contour Next EZ	0.577
Bayer	Contour	0.569
Accu-Chek	Aviva Plus	0.551
Abbott	Precision Xtra	0.532
OneTouch	UltraMini	0.519
Accu-Chek	Compact Plus	0.406
FreeStyle	Lite	0.381
Bayer	Breeze2	0.380

Moreover, evaluators listed all the features contributing to usability encountered during the usability test (Table 7). Features were divided into positive and negative contributors. As expected, glucometers with higher usability possessed more positive features than negative ones.

The screen or display was the most impactful feature. Non-segment screens positively contributed to usability (top 4 devices) and segment screens negatively contributed (bottom 9 devices). Refer to Figure 12 for an example of segment and non-segment display. Segment screens limit the communication with users since in-

formation must be adapted to the display configuration, which complicates the setup process and marking results.

Figure 12: Segment and non-segment display

Buttons themselves were not frequently listed as an influential feature; however, many other functions depend on it: setup process, tagging, and viewing results. Therefore buttons and screens were analyzed during Phase 2, Disability Simulation User Testing.

Table 7: Identified usability contributing features.

Glucometer		**Features**	
Brand	***Model***	**Pros**	**Cons**
OneTouch	Verio IQ	👁 Non-segment display -- Rechargeable battery -- Notes for results 👁 Uses language 👁 Light for test strip port 👁 Clear test strip port window -- High/low glucose pattern recognition	-- Test strip port with unconventional shape and location.

Bayer	Contour USB		Non-segment display	--	Lancing device difficult to use.
		--	Rechargeable battery		
		--	Notes for results		
			Uses language		
			ATM style buttons		Small screen
			Light for test strip port		
		--	Connectivity with computer via USB		
			Short test time		
Sanofi	iBG Star	 	No setup necessary	--	Poor usability without mobile phone
			Small size		
		--	Connectivity with phone via module connector	--	High cost
			Attractive interface		
		--	Rechargeable battery	--	Mobile capabilities unexploited
			Clear test strip port window		
OneTouch	Ultra2		Non-segment display	--	Coding Required
			Uses Language	--	Complicated Result Tags Process
			Screen Light		
		--	Notes for Results		Past Results Layout
		--	Short test time		
Accu-Chek	Nano	--	Lancing Device easy to use	 	Complicated set-up
			Attractive display		Segment Display
Bayer	Contour Next EZ		Large Intuitive Icons	 	Complicated set-up
					Segment display
				--	Lancing device difficult to use
					Unintuitive buttons
Bayer	Contour		Large Intuitive Icons	 	Complicated set-up
					Segment display
				--	Lancing device difficult to use
					Unintuitive buttons

Accu-Chek	Aviva Plus	--	Lancing Device	--	- Coding Required
		👆	Dedicated Power button	👁	Segment display
				👁	Marked results not specific
Abbott	Precision Xtra	--	Monitors Ketones	--	Coding required
				--	Test strip foil packaging
		👁	Light-up display	👁	No mark result possibility
				👁	Segment display
				--	Lancing device difficult to use
OneTouch	UltraMini	👁	Large display	--	Coding required
		👆	Small device size	--	No test averages
				👁	Segment display
		--	Short Test time	👁 👆	Confusing setup
				👁	No Mark Result Possible
Accu-Chek	Compact Plus	--	Test strip drum	--	Test strip mechanism complicated
				👆	Bulky meter
		--	Lancing device simple operation	--	Too much blood required
				👆	Unintuitive buttons
				👁	Segment display
FreeStyle	Lite	👁	Screen light	👆	Unintuitive buttons
		👁	Test strip port light	👁	Segment display
		👁	Graphics on test strip allow to easily orient strip	--	Lancing device difficult to use
		--	Short test time		
Bayer	Breeze2	👆	Test strip drum (10 strips) removes the need to insert strip for each test	--	Lancing Device difficult to use
				--	Test strip mechanism
				👁	Segment Display
				👆	Bulky meter
				👆	Unintuitive
				👁 👆	Test strip drum has complicated insertion and removal

👁 Vision-related features. 👆 Mobility-based features

4.2 Phase 2: Disability Simulation User Testing

Participant answers to each question were analyzed by means of a Friedman Test as described in Section 3.2.4. Questions were organized by difficulty to complete task as well as by major modular feature (screen, buttons, and casing). Comprehensive analysis of the results is presented in Appendix G and summary of statistical analyses are shown per modular feature in this section.

The first three questions were grouped by general difficulty to complete the tasks with each meter (Table 8). No statistical difference was found among glucometers for Task 1 with any of the disease simulators (Retinopathy P-value = 0.681; Glaucoma P-value = 0.384; and Arthritis + Neuropathy P-value = 0.187). This suggests that the importance of the power button is minimal. In real conditions the interaction with the power button is also minimal and some glucometers do not require pressing the power button to turn on the glucometer. Conversely, a significant difference was found among glucometers for Task 2 with all disease simulators (Retinopathy P-value = 0.042; Glaucoma P-value < 0.001; and Arthritis + Neuropathy P-value < 0.001). For both vision disease simulators, Retinopathy and Glaucoma, the glucometers Accu-Chek® Aviva and Bayer® Breeze®2 performed better than Accu-Chek® Nano and Bayer® Contour® USB due the more intuitive and larger control buttons. Task 3 presented similar results as Task 1 with no statistical difference among glucometers for any of the disease simulators (Retinopathy P-value = 0.262; Glaucoma P-value = 0.904; and Arthritis + Neuropathy P-value = 0.468).

Table 8: Statistics Summary for first three questions grouped by meter (α=0.05)

	Q1: Turn On Meter	Q2: Review Past Results	Q3: Insert Test Strip
Retinopathy	***Accept H_0***	***Reject H_0***	***Accept H_0***
	T_2 = 0.508; P-value = 0.681	T_2 = 3.197; P-value = 0.042	T_2 = 1.418; P-value = 0.262
	No statistical difference	• Breeze2 is preferred over USB • Aviva is preferred over USB	No statistical difference
Glaucoma	***Accept H_0***	***Reject H_0***	***Accept H_0***
	T_2 = 1.061; P-value = 0.384	T_2 = 9.617; P-value < 0.001	T_2 = 0.188; P-value = 0.904
	No statistical difference	• Breeze2 is preferred over Nano • Breeze2 is preferred over USB • Aviva is preferred over Nano • Aviva is preferred over USB	No statistical difference
Arthritis + Neuropathy	***Accept H_0***	***Reject H_0***	***Accept H_0***
	T_2 = 1.734; P-value = 0.187	T_2 = 13.158; P-value < 0.001	T_2 = 0.875; P-value = 0.468
	No statistical difference	• Aviva is preferred over Breeze2 • Aviva is preferred over Nano • Aviva is preferred over USB	No statistical difference

Screen related questions are shown in Table 9. No difference was found among glucometers for the two visual simulators for ease of reading text (Retinopathy P-value = 0.228; and Glaucoma P-value = 0.144) and text satisfaction (Retinopathy P-value = 0.441; and Glaucoma P-value = 0.107). This results indicates that the difference in text height was not sufficient to produce a variation in participant response. Subjects preferred the Accu-Chek® Aviva screen while wearing the retinopathy glasses mainly due to the screen configuration (upright), which was confirmed verbal-

ly by participants while answering the open-ended questions. For glaucoma, participants did not have a preference among glucometers (Glaucoma P-value = 0.11).

Table 9: Statistics Summary for screen related questions (α=0.05)

	Q4a: Ease of Text Reading	**Q5a: Text Satisfaction**	**Q6a: Screen Satisfaction**
Retinopathy	***Accept H_0***	***Accept H_0***	***Reject H_0***
	T_2 = 1.545; P-value = 0.228	T_2 = 0.931; P-value = 0.441	T_2 = 3.277; P-value = 0.038
	No statistical difference	No statistical difference	• Aviva is preferred over Nano • Aviva is preferred over USB
Glaucoma	***Accept H_0***	***Accept H_0***	***Accept H_0***
	T_2 = 1.976; P-value = 0.144	T_2 = 2.261; P-value = 0.107	T_2 = 2.237; P-value = 0.11
	No statistical difference	No statistical difference	No statistical difference

Subjects favored large protruding buttons as can be seen in Table 10. Button satisfaction exhibited a difference among glucometers for all disease simulators (Arthritis + Neuropathy P-value = 0.045; Glaucoma P-value = 0.008; and Retinopathy P-value < 0.001). Accu-Chek® Aviva, with large protruding buttons, had the greatest satisfaction among all glucometers for all three simulators. On the opposite side is Bayer® Contour® USB that had the lowest statistical rank (preference) compared to the rest of devices. Color contrast between the case and buttons and size of buttons were important for satisfaction rating. The ease of button touching (Arthritis + Neuropathy P-value = 0.325) and pressing (Arthritis + Neuropathy P-value = 0.258) showed no significant difference between glucometers suggesting that both tasks were perceived as similarly difficult to accomplish while wearing the gloves.

Table 10: Statistics Summary for button related questions (α=0.05)

	Q4b: Ease of Button Feeling	**Q5b: Ease of Buttons Pressing**	**Q7: Button Satisfaction**
Arthritis + Neuropathy	***Accept H_0***	***Accept H_0***	***Reject H_0***
	T_2 = 1.217; P-value = 0.325	T_2 = 1.434; P-value = 0.258	T_2 = 3.12; P-value = 0.045
	No statistical difference	No statistical difference	• Aviva is preferred over Breeze2 • Aviva is preferred over Nano • Aviva is preferred over USB
Glaucoma	---	---	***Reject H_0***
			T_2 = 4.986; P-value = 0.008
			• Aviva is preferred over Breeze2 • Breeze2 is preferred over USB • Aviva is preferred over USB • Nano is preferred over USB
Retinopathy	---	---	***Reject H_0***
			T_2 = 8.544; P-value < 0.001
			• Aviva is preferred over Breeze2 • Aviva is preferred over Nano • Aviva is preferred over USB

The weight of meters presented a similar trend across all meters as shown in Table 11. Meter weight was not significantly different (Arthritis + Neuropathy P-value = 0.441) among all devices,, which demonstrates that weight is not an important variable for the users. Bayer® Breeze®2 and Accu-Chek® Aviva were the easiest to grab compared to Accu-Chek® Nano mainly due to the size and shape of meters. This allowed users to grab to meter with only one hand, even with mobility

restriction. The size of Accu-Chek® Nano, with the lowest statistical rank (preference) among all meters, did not easily enable users to grab the meter. No difference was found among glucometers for holding the device for a period of time (Arthritis + Neuropathy P-value = 0.057).

Table 11: Statistics Summary for meter case related questions (α=0.05)

	Q6b: Ease of Meter Grabbing	**Q8b: Meter Weight Satisfaction**	**Q9b: Ease of Meter Holding**
Arthritis + Neuropathy	***Reject H_0***	***Accept H_0***	***Accept H_0***
	T_2 = 3.388; P-value = 0.034	T_2 = 0.93; P-value = 0.441	T_2 = 2.875; P-value = 0.057
	• Breeze2 is preferred over Nano • Aviva is preferred over Nano	No statistical difference	No statistical difference

Open-ended questions gave participants freedom to express any frustration or satisfaction with each meter. Reoccurring statements were used to diagnose issues, provide possible solutions, and inform study design options for future data collection in the diabetes patient population. The recurrent statements on difficulties included:

- Low color contrast between text and the screen background.
- Low color contrast between case and buttons to easily locate buttons.
- Low contrast between test strip port and case (or depressed strip port)
- Protruding buttons too close together that do not allow distinguishing buttons.
- Button not visible at all times. Some devices have buttons on the side of device.

Color and contrast were crucial for participants' interaction with the meters, especially while wearing glaucoma and diabetes retinopathy simulators. Color allowed subjects to rapidly guide themselves to locate elements as well as read the text. Participants expressed dissatisfaction with Accu-Chek® Nano since the entire meter was black.

Chapter 5: Discussion

Glucometer usability is essential due to high percentage of diabetes patients over the age of 65 who suffer physical impairments that may negatively impact their device use. Failure to match patients to a suitable device can lead to improper use, non-adherence to instructions, and poor outcomes. Diabetes patients exposed themselves to serious health complications if they do not adherence to recommended glucometer use due to poor disease management. Heath complications increase both mortality and morbidity rates (Ho, Rumsfeld, Masoudi, & et al, 2006), which is a common consequence of non-adherence among all chronic diseases.

Despite the fact that chronic disease patients develop similar debilitating disease complications (vision, mobility, hearing), each patient will present a different health condition, which will shape device interaction needs. A potential solution involves customizing devices features through modularity to meet individual needs. Modular architecture applied to handheld medical device design can provide distinctive modules for each feature (Figure 13).

5.1 Main Findings

Individuals with disabilities have different device preferences according based on their limitations. Persons with limited visibility focus on screen characteristics and prefer upright large screens. Buttons, which is an interest for individuals with mobility restriction, should have a large size and be located in the front of the device. In addition, buttons should protrude and be installed separately for easily identifying the

button location with less finger sensitivity. Color contrast is also an important feature because it allows important components such as buttons, text, and the test strip port to be easily perceived.

5.2 Modular Design Concepts

The concept of segmenting service functions into modules has been applied in the health services domain because of the inherent differences in user needs and capabilities (Blok, Luijkx, Meijboom, & Schols, 2010; Chorpita, Daleiden, & Weisz, 2005). Here it is proposed to design functional device variety to serve users with a range of capabilities. The screen module can be swapped to meet the users' visual requirements. Similarly, the button module can provide different protruding and space configurations. Handling and grabbing is achieved by means of shape modules that alter device shape to meet users hand size and mobility limitations. The rightmost glucometer concept in Figure 13 illustrates the adaptability of modular architecture, which can meet needs of disabled user and those without disabilities.

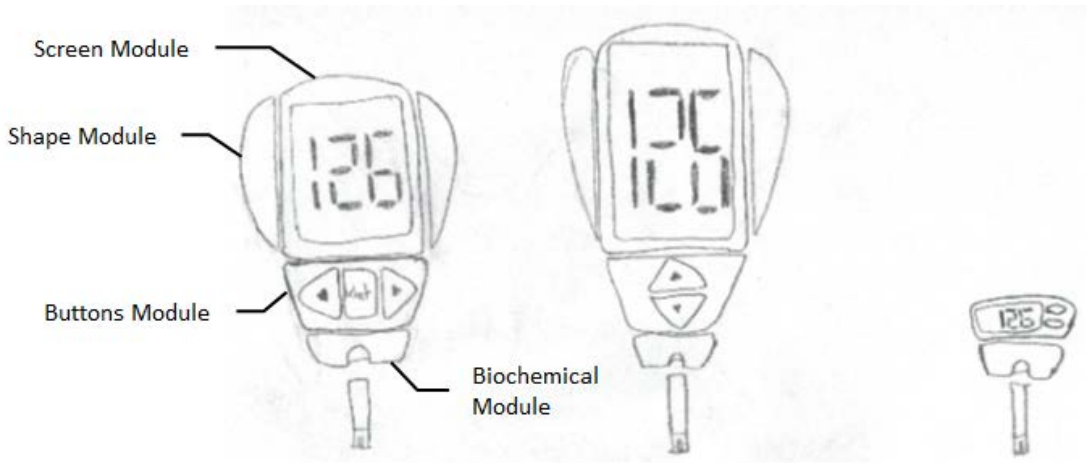


Figure 13: Glucometer Modular Design Concepts

The design process can integrate empirically defined patient characteristics with the iterative design of modular hardware and software components to insure that the device takes into account the individual patient needs to technologically support patient limitations, functional impairment, and relevant self-management activities. Operation of the new device can reduce human inputs and improve device-user communication, thus reducing user workload during operation, particularly for user with disabilities. For instance, buttons could be replaced by a voice commands feature and the screen interaction could be minimized with voice over capabilities.

Another design concept example is a bracelet glucometer (Figure 14) depicts which has the ability to reduce required human inputs by implementing non-invasive near infrared light spectroscopy. The user will not need to constantly prick their finger and could control the bracelet glucometer with voice commands. The device will immediately measure the glucose level and display it on the screen as well as read it out loud.

5.3 Regulatory Implications

In addition to the role of the designer, regulatory agencies, such as the FDA, should enforce the design and approval of new medical devices that meet the needs of all types of end-users, particularly when disabled users are the majority of the user population. Moreover, FDA should consider implementing design guidelines for handheld medical devices, especially for high-risk sub-populations.

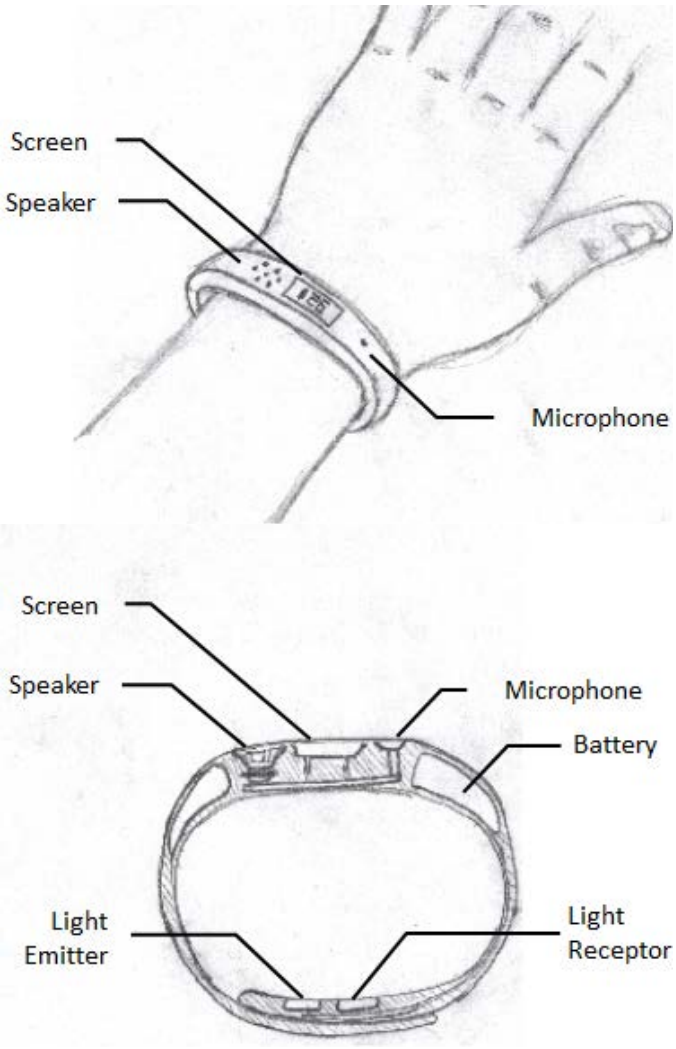


Figure 14: Bracelet Glucometer Design Concept

Design guidelines can eliminate the necessity for manufactures to conduct human factors analyses. Typically, manufactures perform analytical methods and formative evaluations to ensure component dimensions meet all types of end-user requirements. Although design guidelines remove the burden from manufacturers, adherence to standardized guidelines can be translated into both costs and time reduction. Regulatory resources can also be reduced by use of design guidelines than ensure accommodation for disabled persons.

Chapter 6: Conclusions

The current study identified device screens and buttons as the principal features impacting usability. A disability simulation study of these features with other physical characteristics of glucometers suggests that handheld medical devices for patients with disabilities require large protruding buttons, mid-size oval shaped casings, and large screens. Color is equally important for device design since contrast facilitates the location of important device elements such as text, buttons, and strip port. Limitations of the current study—sample size and disease simulations—restrain the generalization of findings, however, these will be addressed in future studies in the actual disease population.

Future work will aim to expand these tests in a stratified population usability study focused on diabetic patients with a mobility or vision impairment. Hearing impairment will also be included in next phases of this study. Findings could potentially support the FDA in developing handheld medical device design guidelines for healthy and disabled end-users. These guidelines can recommend physical dimensions for different device features such as meter shape, meter dimension, screen size, screen text size, buttons installation type, buttons size, and use of color. Manufacturers can also potentially benefit from the results by considering them during the design process in addition to usability testing. Ultimately, development of a new glucometer that fits different high-risk end-user group needs is envisioned as a long-term objective.

Appendices

Appendix A: HTA for Bayer® Breeze®2

U.S. denotes usability score.

Hierarchical Task Analysis				U.S.
Task Description				Total
1.0	**Set up Meter**			
	1.1	Set Time		
		1.1.1	Grab and Hold the meter	
		1.1.2	Open the button door	
		1.1.3	Press and release the Setup Button	72
		1.1.4	Press the Up and/or Down buttons to set desired hour number	
		1.1.5	Press and release the OK Button to save and confirm hour number	
		1.1.6	Press the Up and/or Down buttons to set desired minutes number	
		1.1.7	Press and release the OK Button to save and confirm minutes number	
		1.1.8	Press the Up and/or Down buttons to AM or PM	
		1.1.9	Press and release the OK Button to save and confirm the AM or PM	
	1.2	Set Date		
		1.2.1	Press the Up and/or Down buttons to desired date number	72
		1.2.2	Press and release the OK Button to save and confirm date number	
		1.2.3	Press the Up and/or Down buttons to desired month number	
		1.2.4	Press and release the OK Button to save and confirm month number	
		1.2.5	Press the Up and/or Down buttons to desired year number	
		1.2.6	Press and release the OK Button to save and confirm year number	
	1.3	Set the buzzer level		
		1.3.1	Press the Up and/or Down buttons to desired volume level	62
		1.3.2	Press and release the OK Button to save and confirm the volume level	
	1.4	Set formats		
		1.4.1	Press the Up and/or Down buttons to desired time format	72
		1.4.2	Press and release the OK Button to save and confirm time format	
		1.4.3	Press the Up and/or Down buttons to desired date format	
		1.4.4	Press and release the OK Button to save and confirm date format	
2.0	**Inserting the strip disc**			
	2.1	Hold the meter		
	2.2	Turn the meter (display facing down)		
	2.3	Press the open latch		
	2.4	Pull the meter base		

	2.5	Grab the test disc package	
	2.6	Peel the plastic cover of the disc package	
	2.7	Grab the test disc	
	2.8	Extract the test disc from package	
	2.9	Check expiration date in test disc	
	2.10	Properly orient the test disc	
	2.11	Align the test disc notches with the tabs in the meter	
	2.12	Insert the test disc in meter	
	2.13	Keep the meter flat	
	2.14	Grab the meter's back cover	
	2.15	Close the meter	
3.0	**Control Test**		
	3.1	Gather all the necessary materials	
	3.2	Grab the meter	
	3.3	Hold the meter firmly with one hand	
	3.4	Grasp the meter handle with the other hand	
	3.5	Pull the meter handle out until it stops	
	3.6	Push the meter handle in until it stops	
	3.7	Grab the control solution bottle	
	3.8	Grab the bottle's cap	
	3.9	Twist the cap to remove it	
	3.10	Squeeze the control solution bottle	
	3.11	Place a drop of control solution onto a non-absorbent surface	
	3.12	Grab the bottle's cap	
	3.13	Properly orient the bottle's cap	
	3.14	Twist the cap until it stops	
	3.15	Grab the meter	
	3.16	Properly orient the meter	
	3.17	Position the meter next to the solution drop	
	3.18	Touch the solution drop to the front edge of the test strip	
	3.19	Wait while the meter measures the glucose level	
	3.20	The result is displayed	
	3.21	Open the button door	
	3.22	Press and release the Up button	
	3.23	Press the OK button accept the result as marked	
	3.24	Grab the Control Range Card	
	3.25	Check if result is in range for the solution control level	
	3.26	Grab the meter	
	3.27	Hold the meter with the test strip pointing down	
	3.28	Make sure nothing is blocking the strip	
	3.29	Make sure nothing is blocking the meter handle	

	3.30	Press the Release Button	
	3.31	Pull out the test strip from meter	
	3.32	Press the Power Button to turn off the meter	
	3.33	Discard the test strip	
	3.34	Store meter	
4.0	**Prepare Lancing Device**		
	4.1	Gather the materials	
	4.2	Grab the Lancing Device	
	4.3	Pull out the lancing device cap	
	4.4	Grab a lancet	
	4.5	Twist the lancet protective cap to loosen it	
	4.6	Properly orient the lancet	
	4.7	Insert the lancet into lancing device's lancet holder	
	4.8	Push the lancet until it stops	
	4.9	Hold the lancet cover	
	4.10	Twist the lancet cover	
	4.11	Remove the lancet cover	
	4.12	Grab the lancing device cap	
	4.13	Properly orient the lancing device cap	
	4.14	Replace the lancing device cap	
	4.15	Rotate the depth dial to select the desired penetration depth	
	4.16	Grab the cocking handle	
	4.17	Pull out the cocking handle	
5.0	**Glucose Test**		
	5.1	Gather the materials	
	5.2	Wash hands	
	5.3	Grab the meter	
	5.4	Press and release the Power button	92
	5.5	Verify that test strips are still available	
	5.6	Hold the meter firmly with one hand	
	5.7	Grasp the meter handle with the other hand	
	5.8	Pull the meter handle out until it stops	
	5.9	Push the meter handle in until it stops	89
	5.10	Verify that a test strip came out	
	5.11	Verify that the meter is ready for the test	
	5.12	Grab the Lancing Device	
	5.13	Position and hold the lancing device firmly against the side of the fingertip	
	5.14	Press the release button on the lancing device with thumb	
	5.15	Gently squeeze the finger to promote blood flow	
	5.16	Grab the Meter	
	5.17	Properly orient the meter	

	5.18	Position the meter next to the blood drop		
	5.19	Touch the blood drop to the front edge of the test strip		75
	5.20	Wait while the meter measures the glucose level		
	5.21	The result is displayed		
	5.22	Hold the meter with the test strip pointing down		
	5.23	Make sure nothing is blocking the strip		
	5.24	Make sure nothing is blocking the meter handle		
	5.25	Press the Release Button		
	5.26	Pull out the test strip from meter		
	5.27	Press the Power Button to turn off the meter		
	5.28	Grab the lancing device		
	5.29	Pull out the lancing device cap		
	5.30	Grab the previously removed protective lancet cover		
	5.31	Place the protective lancet cover to used lancet on a flat surface		
	5.32	Push the needle completely into the middle of the cap		
	5.33	Press and hold the release button		
	5.34	Grab the cocking handle		
	5.35	Pull the cocking handle to release the lancet		
	5.36	Grab the lancing device cap		
	5.37	Properly orient the lancing device cap		
	5.38	Replace the lancing device cap		
	5.39	Dispose lancet		
	5.40	Discard the test strip		
	5.41	Store meter and lancing device		
6.0	**Review Results**			
	6.1	Review Individual results		
		6.1.1	Grab the meter	
		6.1.2	Open the button door	
		6.1.3	Press and release the Memory Button	49
		6.1.4	Press the Up and/or Down buttons to view the stored results	
		6.1.5	Press and release the Power Button	
	6.2	Review Average results		
		6.2.1	Grab the meter	
		6.2.2	Open the button door	
		6.2.3	Press and release the Memory Button	58
		6.2.4	Press and release the Memory Button	
		6.2.5	Press the Up and/or Down buttons to view the different averages	
		6.2.6	Press and release the Power Button	
	6.3	Clear Stored results		
		6.3.1	Grab the meter	
		6.3.2	Open the button door	

		6.3.3	Press and release the Memory Button	103
		6.3.4	Press and hold the Memory Button	
		6.3.5	Press and hold the Setup Button	
		6.3.6	Release buttons when 3 dashes appear	
		6.3.7	Press and release the Power Button	

Appendix B: HTA for Accu-Chek® Aviva

U.S. denotes usability score.

Hierarchical Task Analysis				U.S.
Task Description				Total
1.0	**Set up Meter**			
	1.1	Set Time		
		1.1.1	Press Right and/or Left buttons to the desired hour number	
		1.1.2	Press Power Button to confirm the hour number	
		1.1.3	Press Right and/or Left buttons to the desired minute number	
		1.1.4	Press Power Button to confirm the minute number	
		1.1.5	Press Right and/or Left buttons for AM or PM	
		1.1.6	Press Power Button to confirm AM or PM	47
	1.2	Set Date		
		1.2.1	Press Right and/or Left buttons to the month number	
		1.2.2	Press Power Button to confirm the month number	
		1.2.3	Press Right and/or Left buttons to the desired day number	
		1.2.4	Press Power Button to confirm the day number	
		1.2.5	Press Right and/or Left buttons for the desired year number	
		1.2.6	Press Power Button to confirm the year number	
2.0	**Code the meter**			
	2.1	Code the meter		
		2.1.1	Open the test strip box	
		2.1.2	Take out the container and code key	
		2.1.3	Make sure the number in code key matches the number in container	
		2.1.4	Insert the code key in the meter	
	2.2	Make sure the display is working properly		
		2.2.1	Turn off the meter or make sure the meter is off	
		2.2.2	Press and Hold (keep holding until end of the display test) the Power Button	80
		2.2.3	Wait for the meter to display the "checking pattern"	
		2.2.4	Compare the display on the meter with the picture in manual	
3.0	**Control Test**			
	3.1	Take out a test strip from the container		
	3.2	Insert test strip into the meter		
	3.3	Wait for the meter to display the code number		
	3.4	Make sure the code number displayed in the meter matches the code number labeled on the container		
	3.5	Wait for the meter to be ready for the test		

	3.6	Place meter on a flat surface		
	3.7	Select the solution level (meter comes with solution level 1) for the test		
	3.8	Remove the control bottle cap		
	3.9	Wipe the tip of the bottle with a tissue		
	3.10	Squeeze the bottle until a drop forms at the tip		
	3.11	Touch the drop to the front edge of the test strip		
	3.12	Wait for the meter to process information		
	3.13	Wipe the tip of the bottle with a tissue		
	3.14	Cap the solution bottle		
	3.15	Press Right button (twice if necessary to set level 2) to specify the solution level used		
	3.16	Press the Power button to set the control level in the meter		
	3.17	Remove the test strip and discard		
4.0	**Prepare Lancing Device**			
	4.1	Get a lancet drum		
	4.2	Remove the lancing device's cap by pulling it out		
	4.3	Remove the used lancet drum from the lancing device		
	4.4	Insert the new lancet drum into the lancing device		
	4.5	Replace the lancing device's cap		
	4.6	Adjust the lancet depth		
5.0	**Glucose Test**			
	5.1	Gather materials		
	5.2	Check to see if the lancet drum in the lancing device needs to be changed		
	5.3	Change lancet		
		5.3.1	Get a lancet drum	
		5.3.2	Remove the lancing device's cap by pulling it out	
		5.3.3	Remove the used lancet drum from the lancing device	
		5.3.4	Insert the new lancet drum into the lancing device	
		5.3.5	Replace the lancing device's cap	
		5.3.6	Adjust the lancet depth	
	5.4	Wash hands		
	5.5	Get test strip		
	5.6	Insert the test strip into the meter		65
	5.7	Make sure the code number displayed on the meter matches the code number on the test strip container label		
	5.8	Wait for the meter to be ready for the test		
	5.9	Prick finger		
		5.9.1	Hold the lancing device firmly against the side of the fingertip	
		5.9.2	Press the plunger on the end of the lancing device all the way down	
		5.9.3	Gently squeeze the finger to promote blood flow	
	5.10	Touch the blood drop to the front edge of the yellow window of the test strip		49
	5.11	Wait for the meter to complete the glucose reading		

	5.12	Observe the glucose reading	42
	5.13	Mark the result	
	5.14	Remove the test strip and discard	
	5.15	Slide the lancing device lever to advance the lancet for the next use.	
	5.16	Wash hands	
6.0	**Review Results**		
	6.1	Grab the meter	
	6.2	Press and release the Power button	40
	6.3	Press Right and/or Left buttons to view the results and averages	

Appendix C: HTA for Accu-Chek® Nano

U.S. denotes usability score.

Hierarchical Task Analysis				U.S.
Task Description				Total
1.0	**Set up Meter**			
	1.1	Set hour		52
		1.1.1	Press Right and/or Left buttons to the desired hour number	
		1.1.2	Press Power Button to confirm the hour number	
		1.1.3	Press Right and/or Left buttons to the desired minute number	
		1.1.4	Press Power Button to confirm the minute number	
		1.1.5	Press Right and/or Left buttons for AM or PM	
		1.1.6	Press Power Button to confirm AM or PM	
	1.2	Set date		52
		1.2.1	Press Right and/or Left buttons to the month number	
		1.2.2	Press Power Button to confirm the month number	
		1.2.3	Press Right and/or Left buttons to the desired day number	
		1.2.4	Press Power Button to confirm the day number	
		1.2.5	Press Right and/or Left buttons for the desired year number	
		1.2.6	Press Power Button to confirm the year number	
	1.3	Set up Reminders		52
		1.3.1	Press Right and/or left buttons to desired beeper setting	
		1.3.2	Press Power Button to confirm the beeper setting	
		1.3.3	Press Right and/or Left buttons to desired reminder time	
		1.3.4	Press Power button to confirm desired reminder time	
		1.3.5	Press the Right and/or left buttons to desired test reminder setting	
		1.3.6	Press the Power button to confirm the test reminder setting	
		1.3.7	Repeat steps 1.3.5-1.3.6 for the second reminder test setting.	
2.0	**Control Test**			
	2.1	Gather materials		
	2.2	Make sure the display is working properly		
		2.2.1	Turn off the meter or make sure the meter is off	
		2.2.2	Press and Hold (keep holding until end of the display test) the Power Button	
		2.2.3	Wait for the meter to display the "checking pattern"	
		2.2.4	Compare the display on the meter with the picture in manual	
	2.3	Perform a control solution test		
		2.3.1	Take out a test strip from the container	
		2.3.2	Insert test strip into the meter	

		2.3.4	Wait for the meter to be ready for the test	
		2.3.5	Place meter on a flat surface	
		2.3.6	Select the solution level (meter comes with solution level 1) for the test	
		2.3.7	Remove the control bottle cap	
		2.3.8	Wipe the tip of the bottle with a tissue	
		2.3.9	Squeeze the bottle until a drop forms at the tip	
		2.3.10	Touch the drop to the front edge of the test strip	
		2.3.11	Wait for the meter to process information and display result	
		2.3.12	Check to see if the result displayed matches the control range listed on the control solution bottle	
		2.3.13	Wipe the tip of the bottle with a tissue	
		2.3.14	Cap the solution bottle	
		2.3.15	Remove the test strip and discard	
3.0	**Set up Lancing Device**			
	3.1	Get a lancet drum		
	3.2	Remove the lancing device's cap by pulling it out		
	3.3	Remove the used lancet drum from the lancing device		
	3.4	Insert the new lancet drum into the lancing device		
	3.5	Replace the lancing device's cap		
	3.6	Adjust the lancet depth		
4.0	**Perform Test**			
	4.1	Gather materials		
	4.2	Check to see if the lancet drum in the lancing device needs to be changed		
	4.3	Change lancet		
		4.3.1	Get a lancet drum	
		4.3.2	Remove the lancing device's cap by pulling it out	
		4.3.3	Remove the used lancet drum from the lancing device	
		4.3.4	Insert the new lancet drum into the lancing device	
		4.3.5	Replace the lancing device's cap	
		4.3.6	Adjust the lancet depth	
	4.4	Wash hands		
	4.5	Get test strip		
	4.6	Check the Use By date on the test strip container to make sure it is still valid		
	4.7	Insert the test strip into the meter		42
	4.8	Wait for the meter to be ready for the test		
	4.9	Prick finger		
		4.9.1	Hold the lancing device firmly against the side of the fingertip	
		4.9.2	Press the plunger on the end of the lancing device all the way down	
		4.9.3	Gently squeeze the finger to promote blood flow	
	4.10	Touch the blood drop to the front edge of the yellow window of the test strip		
	4.11	Wait for the meter to verify that there was enough blood on the test strip		42

	4.12	Observe the test result and select the desired marker		
		4.12.1	Press the right arrow button to choose the appropriate marker	
		4.12.2	Remove the test strip	
	4.13	Remove the test strip and discard		
	4.14	Slide the lancing device lever to advance the lancet for the next use.		
	4.15	Wash hands		
5.0	**View Results**			
	5.1	Press the left arrow button to view past results from the most recent to the oldest		42
	5.2	Press the right arrow button to view the 7, 14, 30, and 90 day pre meal and post meal results		

Appendix D: HTA for Bayer® Contour® USB

U.S. denotes usability score.

Hierarchical Task Analysis				U.S.
Task Description				Total
1.0	**Set up Meter**			
	1.1	Plug the meter into a power source and wait until the battery is fully charged		17
	1.2	Turn on the meter by pressing and holding the Menu button until meter turns on		
	1.3	Perform the Initial Startup using Quickstart		
		1.3.1	Press the up or down scrolling buttons to select the desired language	
		1.3.2	Press the OK/middle button to confirm the language	
		1.3.3	Press the up and/or down scrolling buttons to select the Quickstart option	
		1.3.4	Press the OK/middle button	
	1.4	Set Date		
		1.4.1	Press the up and/or down scrolling buttons to select the change option	17
		1.4.2	Press the OK/middle button to confirm the selection	
		1.4.3	Press the up and/or down scrolling buttons to select the desired format of the date	
		1.4.4	Press the OK/middle button to confirm the desired date format.	
		1.4.5	Press the up and/or down scrolling buttons to select the correct year	
		1.4.6	Press the OK/middle button to confirm the year	
		1.4.7	Press the up and/or down scrolling buttons to select the correct month	
		1.4.8	Press the OK/middle button to confirm the month	
		1.4.9	Press the up and/or down scrolling buttons to select the correct day	
		1.4.10	Press the OK/middle button to confirm the day	
		1.4.11	Press the down scrolling button to select the Done option	
	1.5	Set Time		
		1.5.1	Press the Menu button to go back to the main menu	17
		1.5.2	Press the Setup button	
		1.5.3	Press the up and/or down scrolling buttons to select the Time option	
		1.5.4	Press the OK/middle button to confirm the selection	
		1.5.5	Press the up and/or down scrolling buttons to select the desired time format	
		1.5.6	Press the up and/or down scrolling buttons to select the correct hour	
		1.5.7	Press the OK/middle button to confirm hour	
		1.5.8	Press the up and/or down scrolling buttons to select the correct minute	
		1.5.9	Press the OK/middle button to confirm minutes	
		1.5.10	Press the up and/or down scrolling buttons to select the correct AM/PM	

		1.5.11	Press the OK/middle button to confirm AM/PM	
		1.5.12	Press the down scrolling button to select the Done option	
	1.4	Perform the Initial Startup using Customize		
		1.4.1	Press the up or down scrolling buttons to select the desired language	17
		1.4.2	Press the OK/middle button to confirm the language	
		1.4.3	Press the up and/or down scrolling buttons to select the Customize option	
		1.4.4	Set Date - Follow steps 1.3.6	
		1.4.5	Set Time - Follow step 1.3.6	
		1.4.6	Press the up and/or down scrolling buttons to select the Accept option on the Autolog screen	
		1.4.7	Press Ok/middle button to confirm the selection	
		1.4.8	Press the up and/or down scrolling buttons to select the change button in the current target screen	
		1.4.9	Press the OK/middle button to confirm selection	
		1.4.10	Press the up and/or down scrolling buttons to select the desired before meal low target number	
		1.4.11	Press the OK/middle button to confirm before meal low target number	
		1.4.12	Press the up and /or down scrolling buttons to select the desired before meal high target number	
		1.4.13	Press the OK/middle button to confirm before meal high target number	
		1.4.14	Press the up and/or down scrolling buttons to select the desired after meal low target number	
		1.4.15	Press the OK/middle button to confirm after meal low target number	
		1.4.16	Press the up and /or down scrolling buttons to select the desired after meal high target number	
		1.4.17	Press the OK/middle button to confirm the desired after meal high target number	
		1.4.18	Press the up and/or down scrolling buttons to select the Done option	
	1.5	Set Reminder		
		1.5.1	Press the up and/or down scrolling buttons to select the Setup Option from the main menu	17
		1.5.2	Press the up and/or down scrolling buttons to select the Reminder option	
		1.5.3	Press the OK/middle button to confirm Reminder selection	
		1.5.4	Press the up and/or down scrolling buttons to select the Change option	
		1.5.5	Press the OK/middle button to confirm Change selection	
		1.5.6	Press the up and/or down scrolling buttons to the desired hours	
		1.5.7	Press the OK/middle button to confirm hour number	
		1.5.8	Press the up and/or down scrolling buttons to the desired minute number	
		1.5.9	Press the OK/middle button to confirm minute number	
		1.5.10	Press the up and/or down scrolling buttons to select the done button	
2.0	**Perform Control test**			
	2.1	Gather the materials		
	2.2	Wash hands		

	2.3	Perform control solution test		
		2.3.1	Flip open the test strip container and get a test strip	
		2.3.2	Close the test strip container	
		2.3.2	Grab the meter and insert the test strip into the meter with the gray square end facing into the meter	
		2.3.3	Wait for the meter to be ready to test	
		2.3.4	Grab the desired level of control solution	
		2.3.5	Squeeze a small drop of the control solution onto a clean surface	
		2.3.6	Grab the meter and touch the tip of the test strip to the drop of control solution	
		2.3.7	Keep the tip of the test strip in the drop until meter beeps	
		2.3.8	Wait for the meter to display the result	
		2.3.9	Compare the control result obtained to the ranges provided on the test strip container.	
	2.4	Remove and discard test strip		
3.0	**Prepare the Lancing Device**			
	3.1	Gather the materials		
	3.2	Remove the end cap		
		3.2.1	Hold the lancing device on the grip indent side in one hand	
		3.2.2	Hold the end cap dial on the other hand	
		3.2.3	Snap off the end cap from top to bottom	
	3.3	Place the lancet into the lancing device		
		3.3.1	Hold the lancet and rotate the protective cap 1/4 of a turn	
		3.3.2	Push the lancet into the lancet holder	
		3.3.3	Twist off the protective cap on lancet	
	3.4	Place the end cap onto the lancing device		
4.0	**Perform Test**			
	4.1	Gather the materials		
	4.2	Wash hands		
	4.3	Get test strip		
	4.4	Insert test strip into the meter		15
	4.5	Wait for the meter to be ready to test		
	4.6	Prick finger		
		4.6.1	Hold the lancing device firmly against the side of the fingertip	
		4.6.2	Twist the dial at the end of the end cap to the desired puncture depth	
		4.6.3	Press the blue release button on the lancing device with your thumb	
		4.6.4	Gently squeeze the finger to promote blood flow	
	4.7	Touch the blood drop to the front edge of the test strip, where the sample tip is located		
	4.8	Press the up and/or down scrolling buttons to select the correct marker		15
	4.9	Wait for the meter to display the result		
	4.10	Observe result		

	4.11	Remove and discard test strip		
	4.12	Remove the used lancet		
		4.12.1	Remove end cap	
		4.12.2	Place the protective cap of lancet on a flat surface with the Bayer logo face down	
		4.12.3	Push the lancet into the center of the protective cap	
		4.12.4	Point the device toward a container where the used lancet is to be disposed of	
		4.12.5	Press the blue release button and pull the blue setting handle past resistance on the lancing device	
		4.12.6	Place the end cap onto lancing device	
	4.13	Wash hands		
5.0	**Create Reminder after Testing**			
	5.1	Press the up and/or down scrolling buttons to select the Reminder option after test completion		26
	5.2	Follow step 1.5		
6.0	**Create Notes after Testing**			
	6.1	Press the up and/or down scrolling buttons to select the Notes option after test completion		26
	6.2	Press the up and/or down scrolling buttons to select the correct choices		
	6.3	Press the OK/middle button to confirm the choice selection		
7.0	**Change the settings of the meter and software GLUCOFACTS**			
	7.1	Plug in meter into a USB port on a computer		
	7.2	Open the folder GLUCOFACTS deluxe		
	7.3	Open the Glucofacts executable jar file		
	7.4	Change Profile details		
		7.4.1	Click the Profile details tab in the window	
		7.4.2	Change the desired details	
		7.4.3	Press the Save Changes button on the bottom of the page.	
	7.5	Change the target, before meal, and after meal ranges		
		7.5.1	Click on the desired range option to be changed	
		7.5.2	Press the up and down arrow buttons to adjust to desired range	
		7.5.3	Click the update meter button on the bottom of the page	
	7.6	Change the meter settings		
		7.6.1	Click th meter settings tab	
		7.6.2	Change the date format, time format, sound, autolog and trend data to the desired format	
		7.6.3	Press the Update meter button on the bottom of the page	
	7.7	Change the Print Preferences		
		7.7.1	Press the Settings button on the top right corner of the window	
		7.7.2	Change the Printer settings as desired	
		7.7.3	Press the Save Changes button on the bottom of the page.	
	7.8	Print Reports		
		7.8.1	Press the Print report icon on the top right corner of the window	

	7.9	Save Report as a PDF		
		7.9.1	Press the Save as PDF button on the top right corner of the window	
8.0	**View Results**			
	8.1	Click the Reports tab of the window		15
	8.2	Press the Change data trend button and adjust to the desired data range		
	8.3	Press the trend subheading underneath the Report tab to view trend over the desired data range		
	8.4	Press the logbook subheading underneath the Report tab to view a total history of all reports		
	8.5	Press the Standard Day or Standard Week subheadings to view the results during that time period		
	8.6	Press the Summary subheading to view a summary of the results in a pie chart over the specified data trend		

Appendix E: IRB Approval Letter

UNIVERSITY OF MARYLAND
INSTITUTIONAL REVIEW BOARD

1204 Marie Mount Hall
College Park, MD 20742-5125
TEL 301.405.4212
FAX 301.314.1475
irb@umd.edu
www.umresearch.umd.edu/IRB

DATE:	August 20, 2013
TO:	Monifa Vaughn-Cooke, Ph.D.
FROM:	University of Maryland College Park (UMCP) IRB
PROJECT TITLE:	[493196-1] Handheld Medical Devices Study
REFERENCE #:	
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	August 20, 2013
EXPIRATION DATE:	August 19, 2014
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # *6 & 7*

Thank you for your submission of New Project materials for this project. The University of Maryland College Park (UMCP) IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the appropriate revision forms for this procedure which are found on the IRBNet Forms and Templates Page.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

This project has been determined to be a Minimal Risk project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of August 19, 2014.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact the IRB Office at 301-405-4212 or irb@umd.edu. Please include your project title and reference number in all correspondence with this committee.

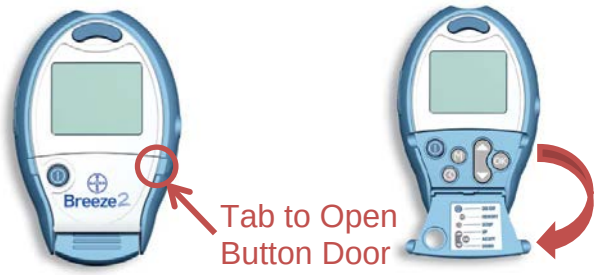
This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Maryland College Park (UMCP) IRB's records.

Appendix F: Training Material

Instructions for Bayer Breeze2

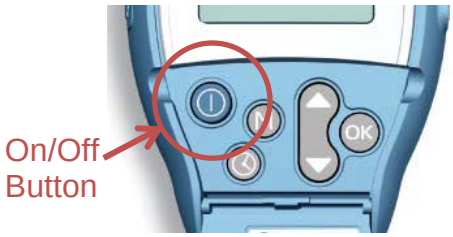
Task 1: Turn on the glucometer

1. Open the Button Door



---

2. Press the On/Off Button



---

3. Confirm that the glucometer is on by stating out loud the date on the glucometer.

Task 2: View Past Results

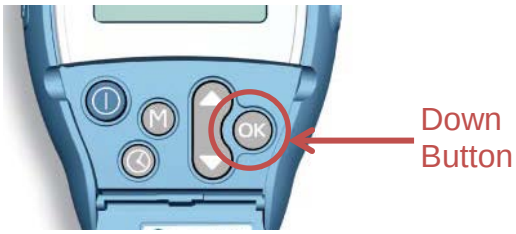
1. Press the Memory Button. The last result will be displayed.

---

2. Read out loud the result value and the time the result was stored.

---

3. Press the Down Button once to view the next stored result.



---

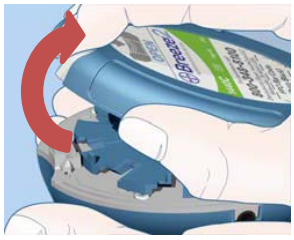
4. Read out loud the result value and the time the result was stored.

Task 3: Insert Test Disc

1. Turn the meter over so the display screen is facing down.

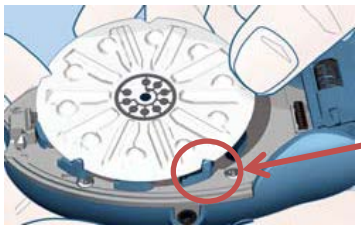
---

2. Open the meter by pressing up on the back edge latch and the pulling up on the base while positioning your thumb on the rear of the glucometer.



---

3. Insert the test disc (with the bumpy side up), aligning the notches in the disc with the tabs on the glucometer.



---

4. Close the glucometer and snap it shut.

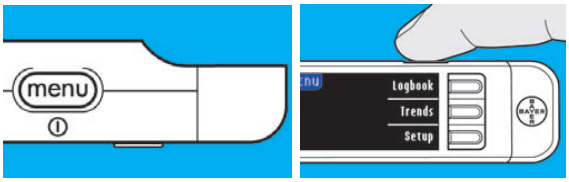
---

5. Confirm that you completed the task by stating out loud the word “completed”.

Instructions for
Bayer Contour USB

Task 1: Turn on the glucometer

1. Press and hold the Menu Button for 3 seconds.



---

2. After a welcome animation, the meter will display the main menu.

---

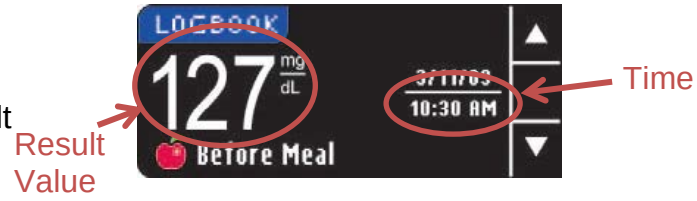
3. Confirm that the meter is on by stating out loud the menu options from bottom to top.

Task 2: View Past Results

1. On the main menu, select “Logbook” by pressing the up Selection Button. The last result will be displayed.

---

2. Read out loud the result value and the time the result was stored.



---

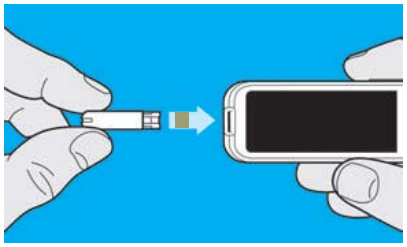
3. Press the Bottom Selection Button once to view the next stored result.

---

4. Read out loud the result value and the time the result was stored.

Task 3: Insert Test Strip

1. Hold the test strip with the gray end facing up. Insert the gray end into the test strip port on the meter



---

2. The glucometer will display the Apply Blood screen. The meter is now ready for a blood test.

---

3. Confirm that you completed the task by stating out loud the word “completed”.

Instructions for
Accu-Chek Nano

Task 1: Turn on the glucometer

1. Press the On/Off Button. You will hear a beep sound when the meter is on.

---

2. Confirm that the glucometer is on by stating out loud the date on the meter.

Task 2: View Past Results

1. Press the Left Button. The last result will be displayed and a beep sound is produced.

---

2. Read out loud the result value and the time the result was stored.

---

3. Press the Left Button once to view the next stored result. You will hear a beep sound.

---

4. Read out loud the result value and the time the result was stored.

Task 3: Insert Test Strip

1. Hold the test strip with the gray and golden end facing up. Insert the golden end into the test strip port on the meter

2. The glucometer will display the Apply Blood screen and you will hear a beep sound. The meter is now ready for a blood test.

3. Confirm that you completed the task by stating out loud the word “completed”.

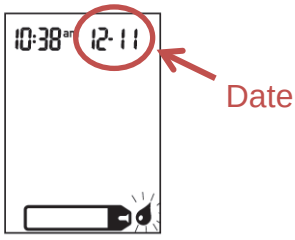
Instructions for
Accu-Chek Aviva

Task 1: Turn on the glucometer

1. Press the On/Off Button. You will hear a beep sound when the meter is on.

---

2. Confirm that the glucometer is on by stating out loud the date on the meter.

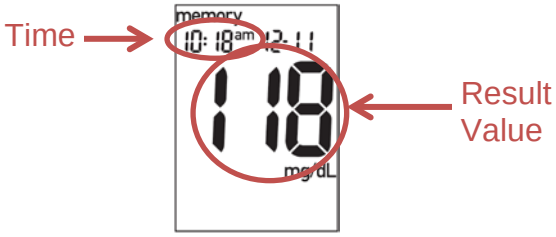


Task 2: View Past Results

1. Press the Left Button. The last result will be displayed.

---

2. Read out loud the result value and the time the result was stored.

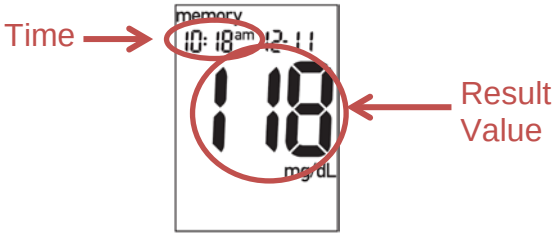


---

3. Press the Left Button once to view the next stored result.

---

4. Read out loud the result value and the time the result was stored.



Task 3: Insert Test Strip

1. Hold the test strip with the blue and golden end facing up. Insert the golden end into the test strip port on the meter

---

2. The glucometer will beep and display a code on the screen for 2 seconds. State out loud the code number.

Appendix G: Statistical Analysis

- Question 1: How easy or difficult was it for you to [a. see/b. use your hands] to perform Task 1 (power)?
    - Retinopathy

Friedman Test

	Treatment			
	Q1: Turn On Meter			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	5	4	3	4
2	3	3	4	4
3	3	5	5	4
4	4	5	5	3
5	3	4	5	5
6	5	4	4	4
7	5	5	5	5
8	2	3	3	1
9	5	5	4	4

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	2.5	1	2.5
2	1.5	1.5	3.5	3.5
3	1	3.5	3.5	2
4	2	3.5	3.5	1
5	1	2	3.5	3.5
6	4	2	2	2
7	2.5	2.5	2.5	2.5
8	2	3.5	3.5	1
9	3.5	3.5	1.5	1.5
Rank Totals	21.5	24.5	24.5	19.5

Rank Totals Squared	462.25	600.25	600.25	380.25
Rank sum of squares	62.75	71.75	74.75	49.25

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	258.5
C1	225
T1	1.61194
T2 (adjusted - presence of ties)	0.507937
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.680543
Accept the null hypothesis	

- Glaucoma

Friedman Test

	Treatment			
	Q1: Turn On Meter			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	4	3	2
2	3	4	3	2
3	5	5	5	5
4	2	3	5	2
5	2	2	2	1
6	4	3	2	3
7	5	3	5	5
8	4	4	4	4
9	5	4	4	5

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3.5	3.5	2	1
2	2.5	4	2.5	1
3	2.5	2.5	2.5	2.5
4	1.5	3	4	1.5
5	3	3	3	1
6	4	2.5	1	2.5
7	3	1	3	3
8	2.5	2.5	2.5	2.5
9	3.5	1.5	1.5	3.5

Rank Totals	26	23.5	22	18.5
Rank Totals Squared	676	552.25	484	342.25
Rank sum of squares	79.5	68.25	60	45.25

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	253
C1	225
T1	3.160714
T2 (adjusted - presence of ties)	1.060674
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.384193
Accept the null hypothesis	

- Arthritis + Neuropathy

Friedman Test

Treatment
Q1: Turn On Meter

	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2	1	3	3
2	2	3	3	2
3	3	4	4	3
4	4	4	4	3
5	3	3	3	3
6	3	2	4	4
7	5	3	5	4
8	4	2	3	3
9	4	4	4	4

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2	1	3.5	3.5
2	1.5	3.5	3.5	1.5
3	1.5	3.5	3.5	1.5
4	3	3	3	1
5	2.5	2.5	2.5	2.5
6	2	1	3.5	3.5
7	3.5	1	3.5	2
8	4	1	2.5	2.5
9	2.5	2.5	2.5	2.5

Rank Totals	22.5	19	28	20.5
Rank Totals Squared	506.25	361	784	420.25
Rank sum of squares	62.25	50	89	52.75

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	254
C1	225
T1	4.810345

T2 (adjusted - presence of ties)	1.734266
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.186733
Accept the null hypothesis	

- Question 2: How easy or difficult was it for you to [a. see/b. use your hands] to
- perform Task 2 (past results)?
- o Retinopathy

•Friedman Test

•

	Treatment			
	Q2: Review Past Results			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	5	4	3	2
2	3	4	4	3
3	5	5	4	4
4	4	5	4	3
5	4	3	4	4
6	5	3	4	4
7	5	5	5	4
8	2	3	3	2
9	5	5	4	4

•

•Ranks

•

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	3	2	1
2	1.5	3.5	3.5	1.5
3	3.5	3.5	1.5	1.5
4	2.5	4	2.5	1
5	3	1	3	3
6	4	1	2.5	2.5

•

•

•

7	3	3	3	1
8	1.5	3.5	3.5	1.5
9	3.5	3.5	1.5	1.5

Rank Totals	26.5	26	23	14.5
Rank Totals Squared	702.25	676	529	210.25
Rank sum of squares	85.25	85	63.5	27.25

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	261
C1	225
T1	7.708333
T2 (adjusted - presence of ties)	3.196544
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.041519
Reject the null hypothesis	**Multiple Comparison below is meaning-ful**

Multiple Comparison		
Critical Value	9.065113019	
Breeze2 - Aviva	0.5	no statistical difference
Breeze2 - Nano	3.5	no statistical difference
Breeze2 - USB	12	Breeze2 is statistically greater than USB
Aviva - Nano	3	no statistical difference
Aviva - USB	11.5	Aviva is statistically greater than USB
Nano - USB	8.5	no statistical difference

- Glaucoma

Friedman Test

	Treatment			
	Q2: Review Past Results			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	4	3	2
2	3	3	2	1
3	5	5	4	4
4	4	3	4	2
5	2	2	1	2
6	5	4	2	3
7	5	5	3	5
8	4	4	3	4
9	5	5	3	5

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3.5	3.5	2	1
2	3.5	3.5	2	1
3	3.5	3.5	1.5	1.5
4	3.5	2	3.5	1
5	3	3	1	3
6	4	3	1	2
7	3	3	1	3
8	3	3	1	3
9	3	3	1	3

Rank Totals	30	27.5	14	18.5
Rank Totals Squared	900	756.25	196	342.25
Rank sum of squares	101	85.75	27.5	45.25

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	259.5

C1	225
T1	14.73913
T2 (adjusted - presence of ties)	9.617021
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.000236
Reject the null hypothesis	**Multiple Comparison below is meaning-ful**

Multiple Comparison		
Critical Value	7.074687834	
Breeze2 - Aviva	2.5	no statistical difference
Breeze2 - Nano	16	Breeze2 is statistically greater than Nano
Breeze2 - USB	11.5	Breeze2 is statistically greater than USB
Aviva - Nano	13.5	Aviva is statistically greater than Nano
Aviva - USB	9	Aviva is statistically greater than USB
Nano - USB	-4.5	no statistical difference

- Arthritis + Neuropathy

Friedman Test

	Treatment			
	Q2: Review Past Results			
	Breeze2	**Aviva**	**Nano**	**USB**
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	4	3	1
2	2	4	2	2
3	3	5	4	3
4	3	4	3	4
5	2	3	2	2
6	3	5	3	3
7	5	5	4	4
8	4	4	4	2
9	3	5	4	3

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2.5	4	2.5	1
2	2	4	2	2
3	1.5	4	3	1.5
4	1.5	3.5	1.5	3.5
5	2	4	2	2
6	2	4	2	2
7	3.5	3.5	1.5	1.5
8	3	3	3	1
9	1.5	4	3	1.5

Rank Totals	19.5	34	20.5	16
Rank Totals Squared	380.25	1156	420.25	256
Rank sum of squares	46.25	129.5	49.75	33

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	258.5
C1	225
T1	16.79104
T2 (adjusted - presence of ties)	13.15789
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	2.78E-05
Reject the null hypothesis	**Multiple Comparison below is meaning-ful**

Multiple Comparison		
Critical Value	6.361362597	
Breeze2 - Aviva	-14.5	Aviva is statistically greater than Breeze2
Breeze2 - Nano	-1	no statistical difference

Breeze2 - USB	3.5	no statistical difference
Aviva - Nano	13.5	Aviva is statistically greater than Nano
Aviva - USB	18	Aviva is statistically greater than USB
Nano - USB	4.5	no statistical difference

- Question 3: How easy or difficult was it for you to [a. see/b. use your hands] to perform Task 3 (test strip)?
    - Retinopathy

Friedman Test

	Treatment			
	Q3: Insert Test Strip			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	4	3	4
2	4	5	2	4
3	2	5	5	4
4	2	5	4	4
5	3	3	4	4
6	5	4	3	4
7	5	4	3	5
8	1	3	2	1
9	5	5	4	4

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	3	1	3
2	2.5	4	1	2.5
3	1	3.5	3.5	2
4	1	4	2.5	2.5
5	1.5	1.5	3.5	3.5
6	4	2.5	1	2.5
7	3.5	2	1	3.5
8	1.5	4	3	1.5
9	3.5	3.5	1.5	1.5

Rank Totals	21.5	28	18	22.5
Rank Totals Squared	462.25	784	324	506.25
Rank sum of squares	62.25	94	46	60.75

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	263
C1	225
T1	4.065789
T2 (adjusted - presence of ties)	1.418244
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.261888
Accept the null hypothesis	

- Glaucoma

Friedman Test

	Treatment			
	Q3: Insert Test Strip			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	4	2	4
2	2	4	1	2
3	5	5	5	5
4	1	3	5	3
5	1	1	2	1
6	4	3	3	3
7	4	4	5	3
8	4	4	4	3
9	4	4	3	5

Ranks

	Treatment			
	Breeze2	**Aviva**	**Nano**	**USB**
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2	3.5	1	3.5
2	2.5	4	1	2.5
3	2.5	2.5	2.5	2.5
4	1	2.5	4	2.5
5	2	2	4	2
6	4	2	2	2
7	2.5	2.5	4	1
8	3	3	3	1
9	2.5	2.5	1	4

Rank Totals	22	24.5	22.5	21
Rank Totals Squared	484	600.25	506.25	441
Rank sum of squares	59	70.25	70.25	57

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	256.5
C1	225
T1	0.619048
T2 (adjusted - presence of ties)	0.187726
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.903706
Accept the null hypothesis	

- Arthritis + Neuropathy

Friedman Test

	Treatment			
	Q3: Insert Test Strip			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2	2	2	2
2	2	3	2	3
3	3	4	3	2
4	1	4	3	3
5	3	2	2	2
6	2	3	3	3
7	5	4	4	3
8	3	2	1	2
9	3	4	4	4

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2.5	2.5	2.5	2.5
2	1.5	3.5	1.5	3.5
3	2.5	4	2.5	1
4	1	4	2.5	2.5
5	4	2	2	2
6	1	3	3	3
7	4	2.5	2.5	1
8	4	2.5	1	2.5
9	1	3	3	3

Rank Totals	21.5	27	20.5	21
Rank Totals Squared	462.25	729	420.25	441
Rank sum of squares	65.75	85	50.25	55

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4

A1	256
C1	225
T1	2.66129
T2 (adjusted - presence of ties)	0.874751
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.467926
Accept the null hypothesis	

- Question 4.a: How easy or difficult was it for you to read the text?
    - Retinopathy
    -

Friedman Test

	Treatment			
	Q4: Ease of Text Reading			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	5	4	3	2
2	3	4	4	3
3	5	4	4	4
4	4	5	5	4
5	4	4	4	5
6	5	3	4	4
7	5	4	5	4
8	3	3	3	2
9	5	5	3	4

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	3	2	1
2	1.5	3.5	3.5	1.5
3	4	2	2	2
4	1.5	3.5	3.5	1.5
5	2	2	2	4

6	4	1	2.5	2.5
7	3.5	1.5	3.5	1.5
8	3	3	3	1
9	3.5	3.5	1	2

Rank Totals	27	23	23	17
Rank Totals Squared	729	529	529	289
Rank sum of squares	90	66	65	39

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	260
C1	225
T1	4.371429
T2 (adjusted - presence of ties)	1.545455
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.228491
Accept the null hypothesis	

- Glaucoma

Friedman Test

	Treatment			
	Q4: Ease of Text Reading			
	Breeze2	**Aviva**	**Nano**	**USB**
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	4	2	3
2	2	2	3	2
3	5	5	5	4
4	4	3	5	2
5	3	2	2	2

6	4	3	2	3
7	4	5	5	5
8	4	4	3	3
9	5	4	3	4

Ranks

	Treatment			
	Breeze2	**Aviva**	**Nano**	**USB**
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3.5	3.5	1	2
2	2	2	4	2
3	3	3	3	1
4	3	2	4	1
5	4	2	2	2
6	4	2.5	1	2.5
7	1	3	3	3
8	3.5	3.5	1.5	1.5
9	4	2.5	1	2.5

Rank Totals	28	24	20.5	17.5
Rank Totals Squared	784	576	420.25	306.25
Rank sum of squares	95.5	67	59.25	37.75

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	259.5
C1	225
T1	5.347826
T2 (adjusted - presence of ties)	1.975904
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.144494
Accept the null hypothesis	

- Question 5.a: How would you rate your overall satisfaction with the size of the screen text?
    - Retinopathy

Friedman Test

	Treatment			
	Q5: Text Satisfaction			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	3	3	3
2	3	4	3	4
3	4	4	4	4
4	4	5	4	2
5	4	5	3	4
6	5	3	4	3
7	5	4	5	5
8	2	4	3	2
9	5	4	3	4

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	2	2	2
2	1.5	3.5	1.5	3.5
3	2.5	2.5	2.5	2.5
4	2.5	4	2.5	1
5	2.5	4	1	2.5
6	4	1.5	3	1.5
7	3	1	3	3
8	1.5	4	3	1.5
9	4	2.5	1	2.5

Rank Totals	25.5	25	19.5	20
Rank Totals Squared	650.25	625	380.25	400
Rank sum of squares	80.25	80	47.75	49.5

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	257.5
C1	225
T1	2.815385
T2 (adjusted - presence of ties)	0.931298
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.440822
Accept the null hypothesis	

- Glaucoma

Friedman Test

	Treatment			
	Q5: Text Satisfaction			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	4	3	3
2	2	3	3	3
3	4	5	4	4
4	3	4	4	2
5	3	2	1	2
6	4	3	3	3
7	5	5	5	5
8	4	4	3	2
9	5	4	2	4

Ranks

Treatment			
Breeze2	Aviva	Nano	USB

Blocks/Subjects	1	2	3	4
1	2	4	2	2
2	1	3	3	3
3	2	4	2	2
4	2	3.5	3.5	1
5	4	2.5	1	2.5
6	4	2	2	2
7	2.5	2.5	2.5	2.5
8	3.5	3.5	2	1
9	4	2.5	1	2.5

Rank Totals	25	27.5	19	18.5
Rank Totals Squared	625	756.25	361	342.25
Rank sum of squares	79.5	88.25	45.5	41.75

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	255
C1	225
T1	5.95
T2 (adjusted - presence of ties)	2.261283
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.107114
Accept the null hypothesis	

- Question 6.a: How would you rate your overall satisfaction with the shape and size of the screen?
    - Retinopathy
    -

Friedman Test

	Treatment			
	Q6: Screen Satisfaction			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	4	3	2
2	3	4	3	4
3	4	5	4	4
4	5	4	5	3
5	5	4	3	3
6	5	3	3	3
7	5	5	5	5
8	2	4	3	2
9	5	5	3	4

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3.5	3.5	2	1
2	1.5	3.5	1.5	3.5
3	2	4	2	2
4	3.5	2	3.5	1
5	4	3	1.5	1.5
6	4	2	2	2
7	2.5	2.5	2.5	2.5
8	1.5	4	3	1.5
9	3.5	3.5	1	2

Rank Totals	26	28	19	17
Rank Totals Squared	676	784	361	289
Rank sum of squares	83.5	92	45	37

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	257.5

C1	225
T1	7.846154
T2 (adjusted - presence of ties)	3.277108
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.038363
Reject the null hypothesis	**Multiple Comparison below is meaning-ful**

Multiple Comparison		
Critical Value	8.582360952	
Breeze2 - Aviva	-2	no statistical difference
Breeze2 - Nano	7	no statistical difference
Breeze2 - USB	9	Breeze2 is statistically greater than USB
Aviva - Nano	9	Aviva is statistically greater than Nano
Aviva - USB	11	Aviva is statistically greater than USB
Nano - USB	2	no statistical difference

- Glaucoma

Friedman Test

	Treatment			
	Q6: Screen Satisfaction			
	Breeze2	**Aviva**	**Nano**	**USB**
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	4	3	2
2	3	3	3	4
3	4	5	4	4
4	4	4	4	2
5	2	2	2	1
6	4	4	3	2
7	5	5	5	5
8	3	4	4	1
9	5	4	3	5

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3.5	3.5	2	1
2	2	2	2	4
3	2	4	2	2
4	3	3	3	1
5	3	3	3	1
6	3.5	3.5	2	1
7	2.5	2.5	2.5	2.5
8	2	3.5	3.5	1
9	3.5	2	1	3.5

Rank Totals	25	27	21	17
Rank Totals Squared	625	729	441	289
Rank sum of squares	73	85	53.5	43.5

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	255
C1	225
T1	5.9
T2 (adjusted - presence of ties)	2.236967
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.109863
Accept the null hypothesis	

- Question 4.b: How easy or difficult was it for you to feel the buttons?
    - Arthritis + Neuropathy

Friedman Test

	Treatment			
	Q4b: Ease of Button Feeling			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	2	1	4
2	2	2	1	1
3	2	2	3	2
4	2	4	2	2
5	2	3	1	2
6	2	3	2	2
7	5	3	4	3
8	3	2	2	2
9	2	4	3	3

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	2	1	4
2	3.5	3.5	1.5	1.5
3	2	2	4	2
4	2	4	2	2
5	2.5	4	1	2.5
6	2	4	2	2
7	4	1.5	3	1.5
8	4	2	2	2
9	1	4	2.5	2.5

Rank Totals	24	27	19	20
Rank Totals Squared	576	729	361	400
Rank sum of squares	72.5	90.5	47.5	49

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	259.5
C1	225
T1	3.565217
T2 (adjusted - presence of ties)	1.217069
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.324996
Accept the null hypothesis	

- Question 5.b: How easy or difficult was it for you to press the buttons?
    - Arthritis + Neuropathy
    -
    - **Friedman Test**
    -
    -

	Treatment			
	Q5b: Ease od Buttons Pressing			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	2	4	2
2	3	4	3	1
3	3	4	4	3
4	2	5	2	3
5	1	3	2	1
6	3	3	3	3
7	5	3	4	3
8	4	3	3	3
9	3	5	3	4

    -
    - **Ranks**
    -
    -

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	1.5	4	1.5

    -
    -
    -

2	2.5	4	2.5	1
3	1.5	3.5	3.5	1.5
4	1.5	4	1.5	3
5	1.5	4	3	1.5
6	2.5	2.5	2.5	2.5
7	4	1.5	3	1.5
8	4	2	2	2
9	1.5	4	1.5	3

Rank Totals	22	27	23.5	17.5
Rank Totals Squared	484	729	552.25	306.25
Rank sum of squares	62.5	91	67.25	38.25

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	259
C1	225
T1	4.102941
T2 (adjusted - presence of ties)	1.433526
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.257628
Accept the null hypothesis	

- Question 7: How would you rate your overall satisfaction with the shape and size of buttons?
    - Retinopathy

Friedman Test

Treatment
Q7: Button Satisfaction

	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	4	4	2
2	3	4	4	2
3	5	5	4	3
4	4	5	4	2
5	3	4	4	3
6	4	4	4	4
7	5	4	4	3
8	1	4	3	1
9	3	5	2	3

Ranks

	Treatment			
	Breeze2	**Aviva**	**Nano**	**USB**
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2	3.5	3.5	1
2	2	3.5	3.5	1
3	3.5	3.5	2	1
4	2.5	4	2.5	1
5	1.5	3.5	3.5	1.5
6	2.5	2.5	2.5	2.5
7	4	2.5	2.5	1
8	1.5	4	3	1.5
9	2.5	4	1	2.5

Rank Totals	22	31	24	13
Rank Totals Squared	484	961	576	169
Rank sum of squares	59.5	109.5	69.5	22

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	260.5
C1	225
T1	13.94366

T2 (adjusted - presence of ties)	8.543689	
k1 (treatment dof)	3	
k2 (dof)	24	
Critical Value	3.008787	
P-value	0.00049	
Reject the null hypothesis	**Multiple Comparison below is meaning-ful**	

Multiple Comparison		
Critical Value	7.40562927	
Breeze2 - Aviva	-9	Aviva is statistically greater than Breeze2
Breeze2 - Nano	-2	no statistical difference
Breeze2 - USB	9	Breeze2 is statistically greater than USB
Aviva - Nano	7	no statistical difference
Aviva - USB	18	Aviva is statistically greater than USB
Nano - USB	11	Nano is statistically greater than USB

- Glaucoma

Friedman Test

	Treatment			
	Q7: Button Satisfaction			
	Breeze2	**Aviva**	**Nano**	**USB**
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	5	2	2
2	2	4	2	1
3	5	5	4	4
4	2	5	4	3
5	1	3	1	2
6	4	4	3	2
7	4	3	4	4
8	3	5	3	2
9	3	5	2	4

Ranks

	Treatment			
	Breeze2	**Aviva**	**Nano**	**USB**
Blocks/Subjects	**1**	**2**	**3**	**4**

1	3	4	1.5	1.5
2	2.5	4	2.5	1
3	3.5	3.5	1.5	1.5
4	1	4	3	2
5	1.5	4	1.5	3
6	3.5	3.5	2	1
7	3	1	3	3
8	2.5	4	2.5	1
9	2	4	1	3

Rank Totals	22.5	32	18.5	17
Rank Totals Squared	506.25	1024	342.25	289
Rank sum of squares	62.25	121.5	42.25	38.5

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	264.5
C1	225
T1	10.36709
T2 (adjusted - presence of ties)	4.986301
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.007896
Reject the null hypothesis	**Multiple Comparison below is meaning-ful**

Multiple Comparison		
Critical Value	8.81697852	
Breeze2 - Aviva	-9.5	Aviva is statistically greater than Breeze2
Breeze2 - Nano	4	no statistical difference
Breeze2 - USB	5.5	no statistical difference
Aviva - Nano	13.5	Aviva is statistically greater than Nano
Aviva - USB	15	Aviva is statistically greater than USB

Nano - USB	1.5	no statistical difference

- Arthritis + Neuropathy

Friedman Test

	Treatment			
	Q7: Button Satisfaction			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	2	3	1
2	2	4	2	1
3	3	4	3	4
4	2	4	3	2
5	2	3	1	1
6	2	4	3	3
7	5	3	4	3
8	2	3	1	2
9	2	4	2	3

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3.5	2	3.5	1
2	2.5	4	2.5	1
3	1.5	3.5	1.5	3.5
4	1.5	4	3	1.5
5	3	4	1.5	1.5
6	1	4	2.5	2.5
7	4	1.5	3	1.5
8	2.5	4	1	2.5
9	1.5	4	1.5	3

Rank Totals	21	31	20	18
Rank Totals Squared	441	961	400	324
Rank sum of squares	57.5	114.5	50.5	42.5

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	265
C1	225
T1	7.575
T2 (adjusted - presence of ties)	3.119691
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.044789
Reject the null hypothesis	**Multiple Comparison below is meaning-ful**

Multiple Comparison		
Critical Value	9.588432326	
Breeze2 - Aviva	-10	Aviva is statistically greater than Breeze2
Breeze2 - Nano	1	no statistical difference
Breeze2 - USB	3	no statistical difference
Aviva - Nano	11	Aviva is statistically greater than Nano
Aviva - USB	13	Aviva is statistically greater than USB
Nano - USB	2	no statistical difference

- Question 6.b: How easy or difficult was it for you to grasp the meter?
    - Arthritis + Neuropathy

Friedman Test

	Treatment			
	Q6b: Ease of Meter Grabbing			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2	3	2	2
2	4	4	2	2
3	4	4	3	3
4	4	3	2	5

5	4	4	2	2
6	4	4	4	4
7	5	4	5	5
8	5	5	4	5
9	4	3	2	5

Ranks

	Treatment			
	Breeze2	**Aviva**	**Nano**	**USB**
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2	4	2	2
2	3.5	3.5	1.5	1.5
3	3.5	3.5	1.5	1.5
4	3	2	1	4
5	3.5	3.5	1.5	1.5
6	2.5	2.5	2.5	2.5
7	3	1	3	3
8	3	3	1	3
9	3	2	1	4

Rank Totals	27	25	15	23
Rank Totals Squared	729	625	225	529
Rank sum of squares	83	77	29	67

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	256
C1	225
T1	8.032258
T2 (adjusted - presence of ties)	3.387755
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.034439

Reject the null hypothesis	Multiple Comparison below is meaning-ful

Multiple Comparison		
Critical Value	8.341146731	
Breeze2 - Aviva	2	no statistical difference
Breeze2 - Nano	12	Breeze2 is statistically greater than Nano
Breeze2 - USB	4	no statistical difference
Aviva - Nano	10	Aviva is statistically greater than Nano
Aviva - USB	2	no statistical difference
Nano - USB	-8	no statistical difference

- Question 8.b: How would you rate your overall satisfaction with the weight of the meter?
    - Arthritis + Neuropathy
    -
    - **Friedman Test**
    -
    -

	Treatment			
	Q8b: Meter Weight Satisfaction			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	5	4	3	4
2	5	5	5	5
3	4	5	5	5
4	3	4	4	5
5	4	4	4	4
6	3	4	5	4
7	5	5	5	4
8	3	4	5	5
9	5	5	5	5

    -
    - **Ranks**
    -
    -

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	4	2.5	1	2.5
2	2.5	2.5	2.5	2.5

    -
    -
    -

3	1	3	3	3
4	1	2.5	2.5	4
5	2.5	2.5	2.5	2.5
6	1	2.5	4	2.5
7	3	3	3	1
8	1	2	3.5	3.5
9	2.5	2.5	2.5	2.5

Rank Totals	18.5	23	24.5	24
Rank Totals Squared	342.25	529	600.25	576
Rank sum of squares	47.75	59.5	72.25	69.5

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	249
C1	225
T1	2.8125
T2 (adjusted - presence of ties)	0.930233
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.441319
Accept the null hypothesis	

- Question 9.b: How easy or difficult was it for you to hold the meter for a period of time?
    - Arthritis + Neuropathy
    -
    - **Friedman Test**
    -
    -
    -
    -
    -

Treatment
Q9b: Ease of Meter Holding

	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	3	4	3	3
2	3	4	2	2
3	4	4	3	4
4	4	3	2	5
5	5	4	3	3
6	4	4	4	4
7	5	5	5	5
8	3	5	4	3
9	5	4	3	5

Ranks

	Treatment			
	Breeze2	Aviva	Nano	USB
Blocks/Subjects	**1**	**2**	**3**	**4**
1	2	4	2	2
2	3	4	1.5	1.5
3	3	3	1	3
4	3	2	1	4
5	4	3	1.5	1.5
6	2.5	2.5	2.5	2.5
7	2.5	2.5	2.5	2.5
8	1.5	4	3	1.5
9	3.5	2	1	3.5

Rank Totals	25	27	16	22
Rank Totals Squared	625	729	256	484
Rank sum of squares	74	86.5	33	60.5

Data	
Level of significance	0.05

Intermediate Calculations	
Number of Blocks / subjects	9
Number of Treatments	4
A1	254
C1	225
T1	7.137931

T2 (adjusted - presence of ties)	2.875
k1 (treatment dof)	3
k2 (dof)	24
Critical Value	3.008787
P-value	0.057159
Accept the null hypothesis	

Bibliography

American Diabetes Association. (2013a). Standards of Medical Care in Diabetes—2013. *Diabetes Care*, *36*(Supplement 1), S11–S66. doi:10.2337/dc13-S011

American Diabetes Association. (2013b, November 1). Eye Complications. *American Diabetes Association*. Retrieved February 20, 2014, from http://www.diabetes.org/living-with-diabetes/complications/eye-complications/

ANSI, AAMI. (1993). *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices (ANSI/AAMI HE48: 1993)*. Arlington, VA: AAMI.

Asche, C., LaFleur, J., & Conner, C. (2011). A Review of Diabetes Treatment Adherence and the Association with Clinical and Economic Outcomes. *Clinical Therapeutics*, *33*, 74–109. doi:10.1016/j.clinthera.2011.01.019

Blok, C. de, Luijkx, K., Meijboom, B., & Schols, J. (2010). Modular care and service packages for independently living elderly. *International Journal of Operations & Production Management*, *30*(1), 75–97. doi:10.1108/01443571011012389

Centers for Disease Control and Prevention. (2008). Arthritis as a potential barrier to physical activity among adults with diabetes--United States, 2005 and 2007. *MMWR. Morbidity and Mortality Weekly Report*, *57*(18), 486.

Centers for Disease Control and Prevention. (2011). *National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011.* Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services. Retrieved from http://www.cdc.gov/diabetes/pubs/factsheet11.htm

Centers for Disease Control and Prevention. (2013). Prevalence of Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation -- United States, 2010–2012. *Morbidity and Mortality Weekly Report*, *62*(44).

Centers for Disease Control and Prevention (CDC). (2011). *National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

Chorpita, B. F., Daleiden, E. L., & Weisz, J. R. (2005). Modularity in the design and application of therapeutic interventions. *Applied and Preventive Psychology*, *11*(3), 141–156. doi:10.1016/j.appsy.2005.05.002

Civil Rights Division. (2009, July). A Guide to Disability Rights Laws. U.S. Department of Justice. Retrieved from http://www.ada.gov/cguide.pdf

Coleman, E., & Berenson, R. (2004). Lost in transition: challenges and opportunities for improving the quality of transitional care. *Annals of Internal Medicine*, *141*(7), 533–535.

Conover, W. J. (1999). *Practical Nonparametric Statistics* (3rd ed.). New York: Wiley.

Department of Defense. (1995). *Handbook for Human Engineering Design Guidelines* (No. MIL-HDBK-759C). Philadelphia, PA: Navy Publishing and Printing Office.

FDA. (2011). Applying Human Factors and Usability Engineering to Optimize Medical Device Design (Draft). Food and Drug Administration.

Goldstein, D. E., Little, R. R., Lorenz, R. A., Malone, J. I., Nathan, D., Peterson, C. M., & Sacks, D. B. (2004). Tests of Glycemia in Diabetes. *Diabetes Care, 27*(7), 1761–1773. doi:10.2337/diacare.27.7.1761

Harris, M. I. (2001). Frequency of Blood Glucose Monitoring in Relation to Glycemic Control in Patients With Type 2 Diabetes. *Diabetes Care, 24*(6), 979–982. doi:10.2337/diacare.24.6.979

Ho, P. M., Rumsfeld, J. S., Masoudi, F. A., & et al. (2006). Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. *Archives of Internal Medicine, 166*(17), 1836–1841. doi:10.1001/archinte.166.17.1836

Job Accommodation Network. (2013, December 19). Accommodation and Compliance Series: The ADA Amendments Act of 2008. Office of Disability Employment Policy.

Kurniawan, S. H. (2003). Review of Interaction design: Beyond Human Computer Interaction. *SIGCHI Bulletin*, *2003*, 15. doi:10.1145/967199.967218

Lai, A. M., Kaufman, D. R., Starren, J., & Shea, S. (2009). Evaluation of a remote training approach for teaching seniors to use a telehealth system. *International Journal of Medical Informatics*, *78*(11), 732–744. doi:10.1016/j.ijmedinf.2009.06.005

Lee, R. G., Chen, K. C., Hsiao, C. C., & Tseng, C. L. (2007). A Mobile Care System With Alert Mechanism. *IEEE Transactions on Information Technology in Biomedicine*, *11*(5), 507–517. doi:10.1109/TITB.2006.888701

Lin, H. X., Choong, Y.-Y., & Salvendy, G. (1997). A proposed index of usability: A method for comparing the relative usability of different software systems. *Behaviour & Information Technology*, *16*(4-5), 267–277. doi:10.1080/014492997119833

Lorig, K. R., Sobel, D. S., Stewart, A. L., Brown, B. W., Bandura, A., Ritter, P., … Holman, H. R. (1999). Evidence Suggesting That a Chronic Disease Self-Management Program Can Improve Health Status While Reducing Hospitalization. *Medical Care*, *37*(1), 5–14. doi:10.1097/00005650-199901000-00003

National Diabetes Information Clearinghouse. (2008, November). Diabetes Overview. NIH Publication No. 09–3873.

National Diabetes Information Clearinghouse. (2011, September). Causes of Diabetes. NIH Publication No. 11–5164.

National Eye Institute. (2009). Facts About Cataracts. Retrieved March 31, 2014, from https://www.nei.nih.gov/health/cataract/cataract_facts.asp

National Eye Institute. (n.d.). Facts About Glaucoma. Retrieved March 15, 2014, from https://www.nei.nih.gov/health/glaucoma/glaucoma_facts.asp

Nielsen, J. (1993). *Usability Engineering*. San Francisco, CA, USA: Morgan Kaufmann Publishers Inc.

Nielsen, J. (1995). How to Conduct a Heuristic Evaluation. NNGroup. Retrieved from http://www.nngroup.com/articles/how-to-conduct-a-heuristic-evaluation/

Nielsen, J., & Landauer, T. K. (1993). A Mathematical Model of the Finding of Usability Problems. In *Proceedings of the INTERACT '93 and CHI '93 Conference on Human Factors in Computing Systems* (pp. 206–213). New York, NY, USA: ACM. doi:10.1145/169059.169166

Nielsen, J., & Mack, R. L. (1994). *Usability Inspection Methods*. John Wiley & Sons.

Perm, A. (2009). *7-segments_Indicator.gif*. Retrieved from http://upload.wikimedia.org/wikipedia/commons/9/97/7-segments_Indicator.gif

Topiwala, S., Zieve, D., VeriMed Healthcare Network, A.D.A.M. Health Solutions, & Ebix. (2012). Diabetes. *MedlinePlus*. Retrieved March 10, 2014, from

Vincze, G., Barner, J. C., & Lopez, D. (2004). Factors Associated with Adherence to Self-Monitoring of Blood Glucose among Persons with Diabetes. *The Diabetes Educator*, *30*(1), 112–125.

Zingale, C., Ahlstrom, V., & Kudrick, B. (2005). *Human Factors Guidance for the Use of Handheld, Portable, and Wearable Computing Devices* (No. DOT/FAA/CT- 05/15). Atlantic City, NJ: Federal Aviation Administration.