Abbott
Diabetes Care

RESEARCH IN USER INTERFACES FOR FUTURE BLOOD GLUCOMETERS

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1. Front Matter

1.1 Executive Summary

Diabetes, a disorder affecting millions of people across all age groups, is forcing those afflicted to grapple with sudden changes in lifestyle, diet, exercise and healthcare costs. A critical component in this new lifestyle is the blood glucose meter – a device that measures a patient's blood glucose concentrations in milligrams per deci-Liter. Through interactions with users, Team Abbott learned that many existing meters do not fully harmonize all the needs of a complete diabetes management program and that the meters that attempt to do so are complex and awkward.

Team Abbott's solution to the problem focuses on juvenile diabetes, and consists of a meter that is quick to use, easy to carry, and encourages better self-management of diabetes by providing behavior-improving feedback. This project included corporate constraints set by the project sponsor, Abbott Diabetes Care, of maintaining strip-based glucose monitoring and preserving cost competitiveness.

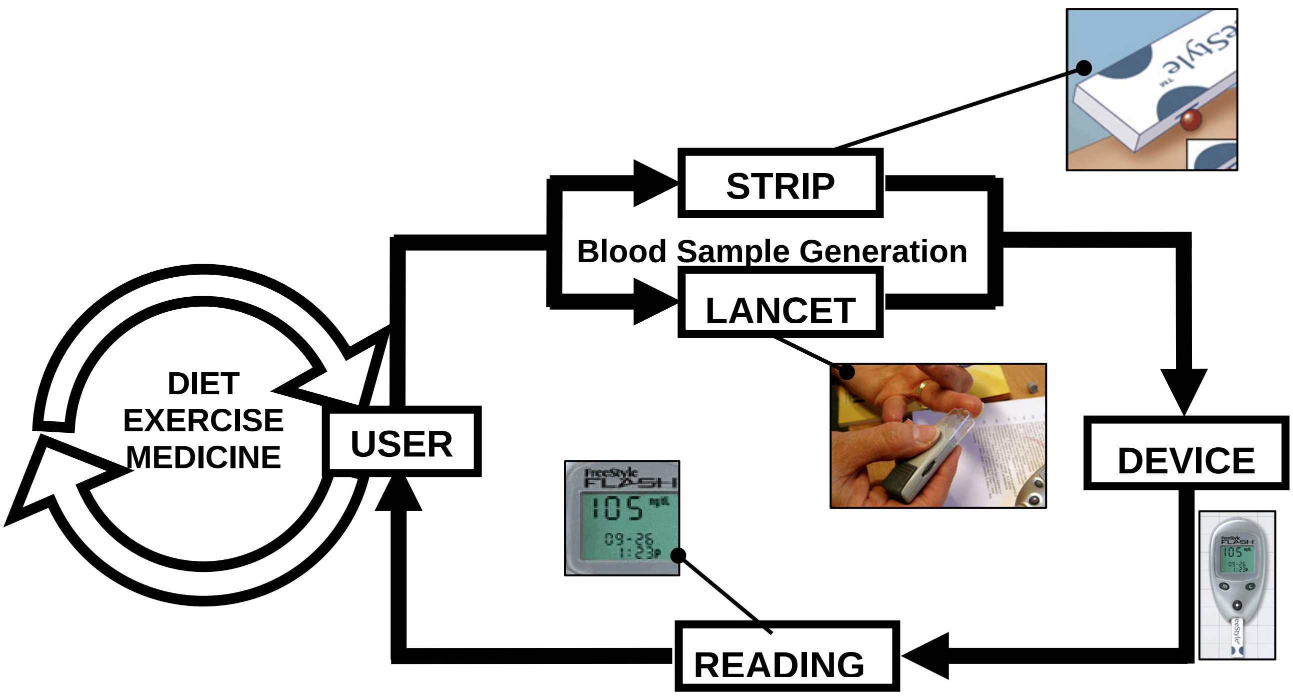

Figure 1 - The existing blood glucose testing procedure with the user in the center, utilizing the results of each test to enact decide lifestyle changes in diet, exercise and medicine.

Team Abbott was partnered in this endeavor with a team at Luleå University of Technology, Sweden. The teams developed a close relation through brainstorming and collaborative design sessions that helped generate a multitude of concepts. An Impact versus Popularity analysis, numerous interactions with users and experts, scope delimitation along with the corporate sponsors, as well as target user selection helped focus these concepts into one:

Informative Feedback for Kids (see text box below): an innovative lifestyle management system that relies on complementary software and physical features to meet the needs of an extended customer base ranging from the juvenile patients to their supporting medical team.

The Design

Team Abbott's research and prototyping efforts led the design process through two paths:

1. Design an innovative, playful and highly portable meter that appeals to children
2. Turn the Informative Feedback for Kids concept into reality

The Team pursued these paths with a series of design iterations complemented by interactions with users, experts and industry professionals at the American Diabetes Association EXPO in Portland, Oregon and at the clinics of the Stanford Medical Center. These interactions allowed the team to validate the numerous proposed features through expert opinion and user feedback.

Informative Feedback for Kids

- Set up a diabetes management plan, follow it and watch it in action.
- Implement correlations and smart averages for the user's blood glucose and other lifestyle information.
- Includes the Insulin and Carbohydrate Tracking Correction algorithm to come up with suggestions for the users medication intake based on the individual's body.
- Implement reminders and alarms to complete the entire self management cycle.
- Operant Conditioning to help the user correlate symptoms with results through positive behavior reinforcement.

Development

Team Abbott developed the "Twist" (as pictured in figures 2 and 3): a portable glucose meter with a self contained strip vial, lancet holder and a revolutionary dial input mechanism to complement the informative feedback for kids lifestyle management software . Its features are the following:

- Modular meter, strip vial and lancet docking mechanism – independent of a pouch.
- Dial and dual-motion button to provide fast, intuitive one handed input mechanism.
- Strip vial with fresh and used strip storage.
- Guiding rod to insure adequate blood sample deposition on the testing strip

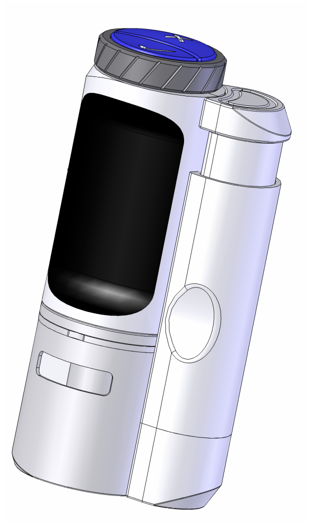

Figure 3 – Detailed CAD model of the Twist glucose meter system

Figure 2 - The Twist fits comfortably in a user's hand

In addition, a Macromedia Flash prototype of the Graphical User Interface (GUI) was developed. The user interface prototype demonstrated the following main functions:

- Lifestyle information tracking, generation of significant averages, correlations and medicine intake suggestions
- Significant measurement result displays, comparing the reading to a corresponding target and average.

The result display shows three main aspects of informative feedback for kids – the present result, the target and the average for the time of the day. This presents the user with a complete snapshot of his/ her diabetes management performance: where the user is according to the plan, where the user should be and where the user has been recently.

Figure 4 - Flash GUI prototype— Improved Blood Glucose Reading display under Informative Feedback for kids with corresponding target and average readings for the time of day.

The input mechanism on the Twist consisted of a dial, a two separate buttons (‘Check’ and ‘X’) and a three point slider for off – on – on with backlight functions. The dial provides a fast alpha-numeric input for the navigation with the ‘Check’ and ‘X’ buttons mounted on the top of the meter to provide OK and CANCEL functions.

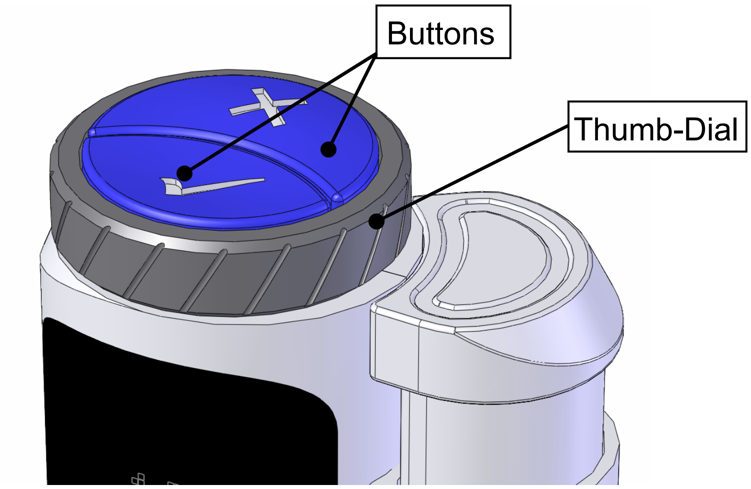

Figure 5 – Dual buttons and thumb-dial shown on top of the glucose meter with removable lancet attached to side of the meter. The co-location of the buttons and the thumb-dial provide access to all the menu functions with one-handed operation.

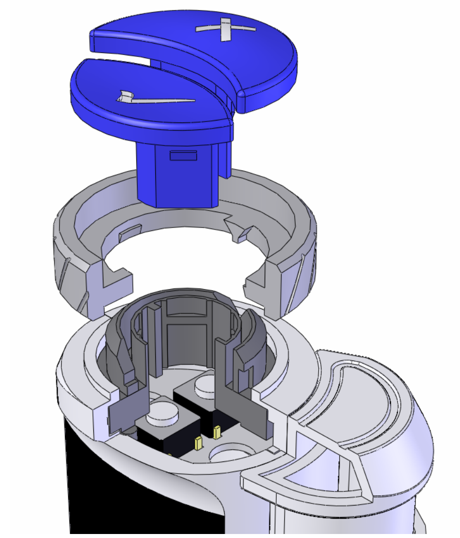

Figure 6 - The input mechanism functions through a hollow-shaft rotary encoder which allows button connections through the center of the thumb-dial.

The modular design of the glucometer package also ensures that the user no longer needs a pouch to carry the meter and the testing supplies. The vial has provisions for storage of both new as well as used strips. The container openings are designed to make it easier for the user to distinguish the fresh strip container from the old strip container.

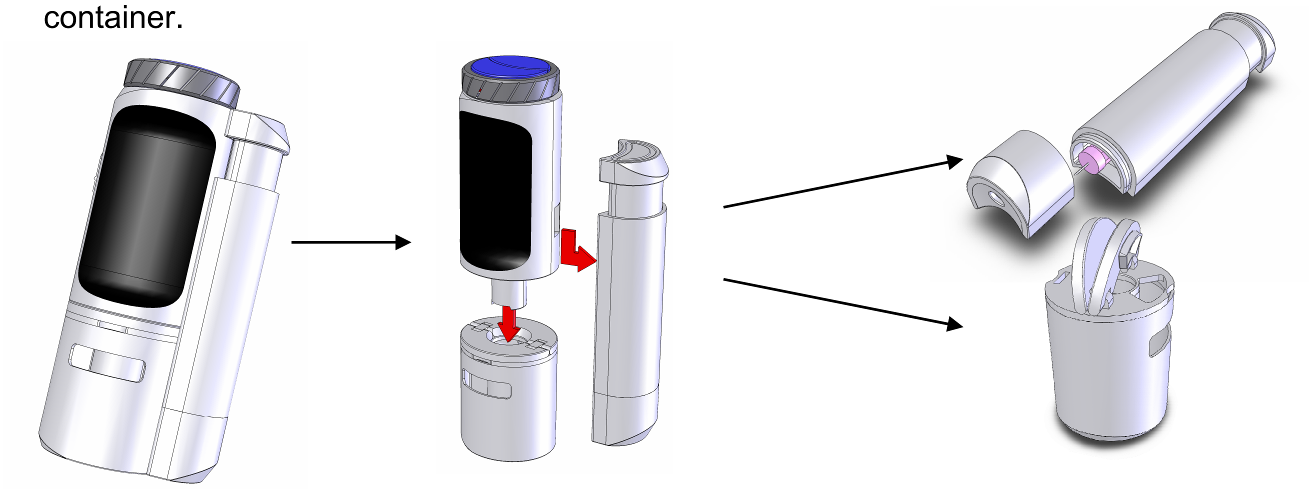

Figure 7 - To allow for maximum portability and compactness, the lancing needle (upper right) and test strip dispenser/container (lower right) are attached to the glucometer and can be removed when required.

Team Abbott has met the design requirements set out at the initiation of the project and has validated this concept through expert and user meetings throughout the development process as well as through a post completion validation campaign.

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1.5 Glossary

Bluetooth	Short-range wireless device interconnect standard
CAD	Computer Aided Design
Care Advisor	Diabetes medical professionals, Dieticians, Nurses, and Physicians who advise people on their personal diabetes care
CDE	Certified Diabetes Educator, diabetes care advisor
Confero	Teleconferencing software developed at Luleå Technical University
e-Ink	electronic ink, a.k.a. e-paper, an electronic display technology
FDM	Fused Deposition Modeling, rapid fabrication method
FileShare	Electronic file server system, repository for all things 310
Firmware	Inalterable software embedded in a hardware product
GTalk	Relatively new IM client with voice support, http://www.google.com
Glucometer	Hand-held electronic device which, when presented with a blood sample on a test-strip, determines user's blood glucose level.
Glucose	Here refers to sugar in the human blood stream
ICQ	Relatively mature IM client and network, http://www.icq.com
IM	Instant Messaging, internet chat software
Lancet	Spring loaded needle used to produce a drop of blood from fingertip.
Lancing Device	See Lancet
LCD	Liquid Crystal Display, an electronic display
Luleå	Luleå University of Technology (LTU)
OLED	Organic Light Emitting Diode, electronic display technology
PIC	Peripheral Interface Controller, a class of microprocessor
SDM	Shape Deposition Manufacturing, rapid fabrication method
SLA	Stereolithography, rapid fabrication method
SMBG	Self Monitoring of Blood Glucose

Strip See Test-Strip

Test-Strip Small, enzyme coated piece of cardboard (upon which blood sample is deposited) that is inserted into glucometer for determination of blood sugar level.

UI User Interface, also profession of user interface development

USB Universal Serial Bus, wired device interconnect standard

Vampagucci Hand-held glucometer test-bed built by Team Abbott in order to test auditory, visual, and tactile signaling capabilities

VoIP Voice over Internet Protocol, internet based voice communication as a replacement for telephones

2. Context

2.1 Need Statement

Diabetes is a disease in which the body fails to produce or use insulin, a pancreatic hormone that regulates carbohydrate metabolism. The severity of this disease makes it the 6th leading cause of death in the United States. Currently, 7% of the American population, and 6% of the world population, is afflicted. Furthermore, diabetes is the leading cause of blindness developed in patients aged 20 to 74, and it can cause heart, kidney, nervous system, and periodontal disease. Medical treatment of diabetes costs the health care industry $132 billion annually, due to late diagnosis and insufficient diabetes management[1].

A need exists to improve diabetic patients' ability to self-manage their diabetes. Diabetic patients currently monitor their glucose, or blood sugar, levels with hand-held glucose meters (glucometers) manufactured by companies such as Bayer Healthcare or Johnson and Johnson, as pictured below.

Figure 8 - (from left to right): Contour® glucometer, from Ascensia®, a division of Bayer Healthcare; OneTouch® Ultra®, from Lifescan, a subsidiary of Johnson and Johnson.

Current glucometers are fairly spartan and allow minimal personalization by the user. They do not specifically target user groups such as children or the elderly and are designed to be operable by any user. The user interface, both in terms of hardware and software, is generally rudimentary and provides little informative feedback. Glucometers do little to educate their user on diabetes management strategy and do little to help them adhere to dietary, exercise, or medication plans. Thus, the opportunity exists to redesign a glucometer to have a vastly improved physical interface and embedded software package.

2.2 Problem Statement

Team Abbott has been tasked with designing a glucometer's interface to encourage better self-management of diabetes by providing the user with behavior-improving feedback. The scope of this assignment is limited to the interaction between the user

[1] http://www.diabetes.org/uedocuments/NationalDiabetesFactSheetRev.pdf

and the glucometer. While Abbott Diabetes Care welcomes research and suggestions about modifications to glucometer accessories, Team Abbott is to design a revamped hardware prototype and a separate, but fully functional, software package.

2.3 Design Team

2.3.1 Design Team Members

Team Abbott is comprised of four mechanical engineering graduate students from Stanford University, and four ergonomic and industrial design graduate students from Luleå University of Technology. The team from Stanford was formed based on the Myers-Briggs personality survey, and the team from Luleå was formed based on knowledge and previous work experience in design, ergonomics and psychology. These methods of selection were used to optimize the team for organizational ability, information processing, decision making, and task completion.

Ihab Daouk

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Ihab has aerospace, automotive, biomedical, and micro-computing experience amassed over a variety of internships and research projects. After graduating from Stanford with a Master of Science in Mechanical Engineering degree in June 2006, Ihab is heading to Wall Street to explore his interest in finance.

Maria Hedin

hedmar-1@student.ltu.se

Maria will soon graduate with a Masters of Science in Ergonomic Design and Production. She has experience from the glass industry where she did her internship. This fall she will be writing her Master's Thesis as the last step to her degree. Maria enjoys sketching both on paper and through computers. She expects to work in the automotive industry with driver ergonomics.

Elin Karlsson

elikar-2@student.ltu.se

Elin will be writing her Master Thesis about ergonomics in protective shoes this fall. After that she too will graduate as Masters of Science in Ergonomic Design and Production. Elin plans to work with product development in the protective garment industry while further develop her hand crafting skills.

Karthik Manohar

manohar@stanford.edu

Karthik came to Stanford from a position as an automotive engineer at Delphi in India. He is working toward his Master of Science degree in Mechanical Engineering, with significant interest in international collaboration. He is will be interning with Intel, on supply chain research.

Maria Marklund

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Maria is expecting to get her Bachelor degree in Industrial Design winter 2007. She will be writing her Master's Thesis together with Maria Hedin this fall. Maria is involved in numerous associations in school and has been working for the student union while earning her degree. Maria expects to work with design in the automotive industry but nourishes a dream of designing jewelry and cutlery.

Erik Mossing

erimos-1@student.ltu.se

Erik is studying to get his Masters of Science in Ergonomic Design and Production. This fall he will go to the Netherlands as an exchange student for six months to deepen his knowledge in the behavior field concerning man-machine-systems. Eric hopes to work where he can combine human behavior and ergonomics with his interest in skiing and sailing.

Nick Reddy

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Nick is a systems engineer for a military project at Northrop Grumman Corporation and is concurrently attaining his Master of Science degree in Mechanical Engineering. After graduating from Stanford in June 2007, Nick plans on pursuing a degree in corporate finance while working on his Master's degree in Business Administration.

David Yao

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David graduated from the University of New Mexico and is working towards his Master of Science in Mechanical Engineering. He has a keen interest in performance cars and motorcycles as well as product design, and mechatronics. He would like to combine these interests in his career, perhaps as an independent toy inventor?

2.3.2 Liaison and Sponsor Information

Team Abbott is sponsored by Abbott Diabetes Care, a division of Abbott Laboratories, a multinational corporation focused on designing and manufacturing medical devices. Based in Alameda, California, Abbott Diabetes Care specializes in minimizing the discomfort and inconvenience of blood glucose monitoring by developing leading glucometers such as the FreeStyle®, FreeStyle Flash™, Precision Xtra™, and Precision PCx™. Based at this site is Team Abbott's corporate liaison and related contacts, whose information is presented below:

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3. Design Requirements

Team Abbott's design requirements and constraints are listed here for both the functional and physical aspects of its deliverables. These parameters were created by the team after observing the shortcomings of existing glucometers. Detailed below are the opportunities identified by Team Abbott to address these shortcomings, as well as the assumptions made before embarking on the design process.

3.1 Functional Requirements

Team Abbott's functional requirements are categorized as either internal or external. Internal functional requirements are what the hardware and software prototypes of the glucometer should do on their own, while external functional requirements are what the prototypes should do when interfacing with the user.

Internal Functional Requirements:

- **The glucometer's firmware must independently compute the blood sugar concentration in the blood sample presented to it on the test strip.** The glucometer will determine the glucose content on the test strip to an accuracy of 6 mg/dL within ten seconds of test strip insertion.

- **The glucometer's firmware must independently make correlations between average blood sugar levels at various times of day and the user's nutritional, exercise, and insulin consumption information.** This information is used by the glucometer to determine if the user is properly adhering to their dietary, exercise, and insulin consumption plans.

External Functional Requirements:

- **The entire cycle time to operate the glucometer must not exceed 60 seconds.** The glucometer shall present information to the user in real time by querying the user, gathering all requested data, and outputting required messages within one minute of it turning on. Delay in test strip insertion does not count against this time.

- **The glucometer must clearly convey the glucose level and its response to patterns in the user's dietary, exercise and medication history.** The glucometer will present results that can be interpreted by the user without requiring explanation from outside sources (such as a doctor, parent, or certified diabetes educator).

- **The glucometer must be operable by children and elderly.** The glucometer's software package shall be designed to be easily operable by a novice user. As confirmed with user testing, children and elderly users should be able to operate the glucometer without continuous external aid.

3.1.2 Functional Opportunities

In meeting these design requirements, Team Abbott has identified opportunities to do the following:

- **To develop on-board algorithms to make insulin dosage and other recommendations.** Team Abbott has the chance to write simple embedded algorithms for the glucometer to utilize inputs from the user to aid their treatment decision making.

- **To research psychological tactics to persuade users to improve their self-management of diabetes.** Elements from cognitive and behavioral psychology can be utilized to develop test messages and suggestion that encourage the user to interact with their glucometer and formulate an individualized diabetes management plan.

- **To design a glucometer with children in mind.** Few glucometers on the market have interfaces specifically designed with children in mind. Team Abbott this has the opportunity to design a glucometer that has appealing software and hardware, enabling children to take control of their diabetes management from the time they are diagnosed.

3.1.3 Functional Assumptions

Team Abbott has made the following assumptions about the design process:

- **Focus group testing will be representative of target users.** A sample pool of 30 juvenile subjects will be satisfactory for making conclusions about the usability of the device.

- **The glucometer's software interface will be intuitive.** Testing performed by Team Abbott for evaluating the glucometer's software structure will accurately reflect nominal testing conditions under which diabetic patients test their own blood glucose levels.

3.1.4 Functional Constraints

The glucometer has certain functional constraints to be satisfied:

- **The glucometer must have sufficient on-board memory to store the user's past and present nutritional, exercise, and insulin consumption information.** The glucometer is expected to manage the information it gathers over the course of 250 measurements without relying on external data storage.

- **The glucometer must compute moving averages and correlations without external computing resources.** The glucometer should have adequate on-board computational ability to display information to the user in the form of trendlines, averages, and by other simple mathematical means, without assistance from an external processor.

3.2 Physical Requirements

Like the functional requirements, Team Abbott's physical requirements are categorized as either internal or external. Internal physical requirements are how the hardware prototype should operate internally, while external physical requirements are how the prototype should handle its physical interaction with, and response to, external stimuli.

Internal Physical Requirements:

- **The glucometer must operate using no more than two 3 Volt Lithium (#2032) batteries.** The glucometer must have a suitable operating life of at least 1000 tests. It is not to rely on any external power sources, and as other Abbott glucometers do, should use two or fewer batteries.

- **The glucometer must not cross contaminate test strips.** The glucometer is to analyze test strips without transferring the contents of one test strip onto another between tests.

External Physical Requirements:

- **The glucometer must clearly convey information.** This may be done by numerical, visual, auditory, or tactile means.

- **The glucometer must be discrete.** Without diminishing its ability to convey information to the user, the glucometer must be inconspicuous. It should resemble a piece of consumer electronics rather than a medical device.

- **The glucometer must be portable.** It should be capable of operating in a variety of common locations, in standard conditions (5-40 ^{o}C, 5-90% relative humidity). Specific subrequirements of this are:

    - **The glucometer should weigh less than 200g.** The glucometer is intended to be handheld and picking it up must not be a burden.

    - **The glucometer should be smaller than 8 cm x 3 cm x 3 cm.** The glucometer should be of suitable size for both children and adults to use comfortably.

3.2.2 Physical Opportunities

Team Abbott has the opportunity to:

- **Integrate modern materials into glucometer.** The glucometer can be fabricated out of material making it lighter while being more resistant to damage by synthetic materials such as polymers.

- **Reduce glucometer power consumption to extend battery life or power new electromechanical activities.** By including technologies such as organic light emitting diodes (OLED) or electronic paper displays (eInk), Team Abbott can minimize power required to display information.

- **Integrate components responsive to varied user activities.** Team Abbott can integrate items such as pedometers or pulse detectors to monitor the user's activity patterns. USB data drives could be included to allow for data to be downloaded to and archived on a personal computer.

- **Package the glucometer in a form factor more suitable to inclusion with other everyday accessories.** The opportunity exists to design the glucometer to fit on a keychain, in a wallet, with a sunglasses case, et cetera.

3.2.3 Physical Assumptions

Team Abbott is making the following assumptions during the design of the glucometer:

- **Design changes are cost effective.** Design changes suggested by Team Abbott, if implemented by Abbot Diabetes Care on a large scale, are cost effective and therefore justify manufacture and modification of existing glucometer manufacturing processes.

- **Marketing research being conducted is appropriate.** Small group user discussions and studies performed by Team Abbott will yield results indicative of enhancements desired by the general population.

- **Components selected for glucometer are robust.** Team Abbott does not plan on performing accelerated life testing to ascertain usable life of mechanical and electrical components selected for the hardware and software prototypes. The use of standardized, non-custom components is believed to be sufficient for addressing supply chain management issues.

3.2.4 Physical Constraints

The glucometer has certain physical constraints to be satisfied:

- **Only Abbott test strips may be used.** The glucometer is to be compatible only with Abbott brand test strips, per the business model of Abbott Diabetes Care.

- **The device must be safe to use.** Normal operation of the glucose meter, or any of its accessories (such as lancets or test strip containers) must not harm the user in anyway. General biomedical device guidelines set forth by the Food and Drug Administration apply.

4. Design Development

4.1 Overview

The Stanford Design process uniquely emphasizes the principles of collaborative design. The three axioms of design form the core of the ME 310 product development process.

1. Design is a social activity
2. Designers need to maintain ambiguity
3. All Design is re-design

Consisting of a distributed team at Stanford (Nick Reddy contributing from Los Angeles) and a global partner team at Lulea Technology University, Sweden, Team Abbott is in a unique position to experience all these tenets of "Stanford Design." The Design Development and Specifications section is intended to document and illustrate the teams' design endeavors and methods.

4.2 Project Statement

Team Abbott's challenge is to develop a blood glucose meter interface for the future that significantly improves the user experience over existing systems, potentially coming to market in as soon as 5 years.

4.3 Self Monitoring of Blood Glucose

Self Monitoring of Blood Glucose (SMBG) is the most important step towards effective blood glucose control. This is achieved through periodic testing of blood glucose concentration levels using a portable glucose meter and controlling medication and lifestyle choices based on the reading obtained. Although this pattern involves frequent human input to close the feedback loop, it provides a considerable amount of freedom and ability for the users to lead a normal and active life without being in the bounds of a hospital or clinic.

A typical glucometer kit consists of:

1. The meter – typically a palm sized portable medical device which contains the test electronics and data logging, management and download capabilities for future reference.
2. Test Strips – ½ inch to inch long plastic strips with proprietary chemical reagent inside to detect and analyze blood glucose concentrations. Typically strips need 0.3 – 3.0 цL of blood (less than a drop) for a successful test.

3. Strip Vial - Strips are normally housed in vials which may contain special drying agents.
4. Lancing Device – is a slender spring activated device with disposable needle tips to prick the skin and generate the blood sample typically from the fingertips. However newer devices with Alternate Site Testing (AST) capabilities are also available.
5. Pouch or bag to carry all these components.

Figure 9 - A complete glucose meter kit showing the
1. Glucose meter
2. Test Strip Vial
3. Lancing Device
4. Disposable lancing needle tips
5. Bag to house all the equipment

A typical testing cycle involves the user removing the contents of the bag, inserting the strip into a port on the meter, checking the calibration, using the lancet to generate the blood sample and applying the blood to the strip for the actual reading.

The user then interprets the reading based on past experience and training to make his/her lifestyle and medication choices.

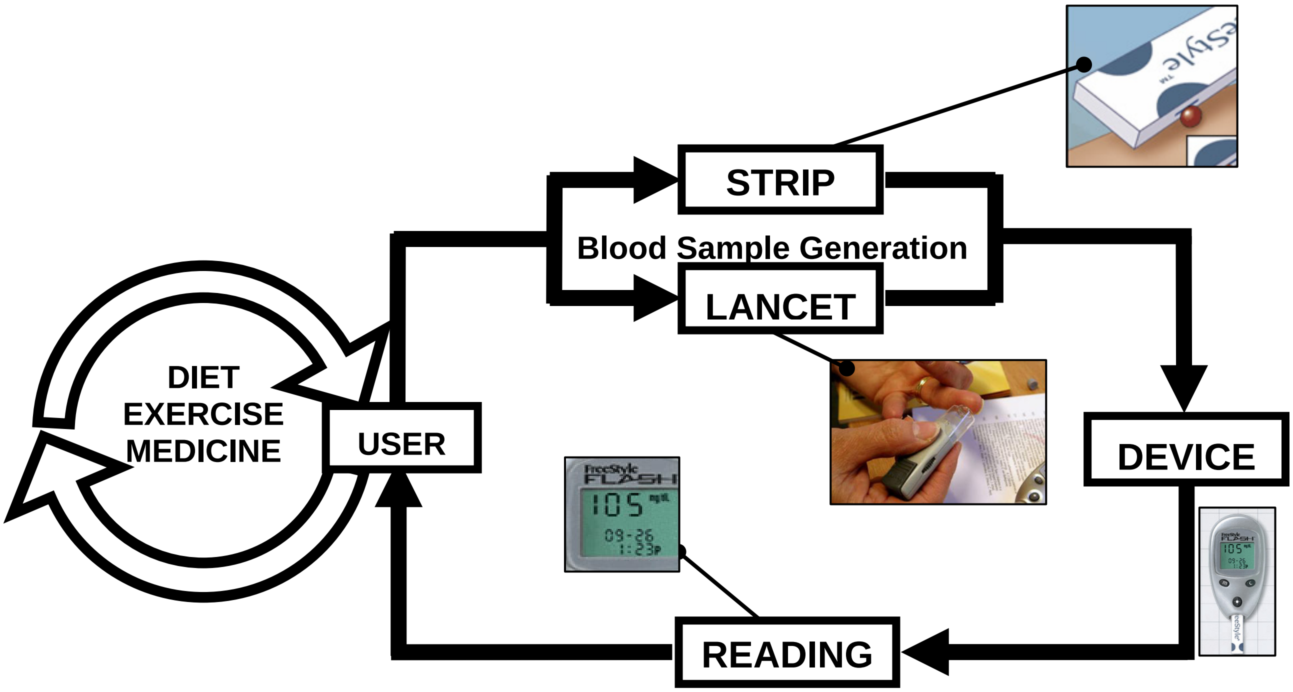


Figure 10 - The glucometer testing cycle on the right which feeds into the user's lifestyle and medication loop depicted on the right.

4.4 Our Vision

Team Abbott's initial investigation of the project through Fall Quarter resulted in the definition of the vision as:

Explore and innovate human interface experience with glucometers.

However, after meeting with industry professionals and experts at Diabetes EXPO, extensive research in the arena of psychology and nutrition, user interactions and a personal motivation to help the users most in need, Team Abbott decided to re-define its vision as

- *Make a glucometer focused on children*
- *Encourage them to test more often*
- *Turn data into 'information'*
- *Help with lifestyle and medication planning*

The rationale for this vision lay in the fact that children were the least able to comprehend what diabetes means to their health and the associated risks and complications. The team also learned through interactions with experts that a lot of diabetes complications can be avoided through stringent glycemic control from a young age. This kindled the interest of the team into exploring various opportunities to effectively manage diabetes in children and also the fact that children form the group which is most receptive to external stimuli through various means. These elements helped focus the teams' effort towards an overall *focus on children.*

4.5 Development Strategy

Having received such a specialized yet open-ended project, Team Abbott had to devise a development strategy that would account for this high specificity and yet not hamper the production of creative and innovative ideas.

The early months of the project were devoted to two tasks: familiarizing the team with the problem at hand and generating guiding concepts for eventual solutions. In fact, the team took a deep dive into diabetes that helped achieve a thorough understanding of the disease, its causes, symptoms and especially living with it. The team then iterated through competitive and technological benchmarking campaigns, generating an extended list of requirements for the product, eliciting new research directions and achieving an ever increasing understanding of the disease. Some of the concepts hence generated were chosen to be prototyped after a Concept Selection process (Section 4.8.1), and valuable lessons were learned form the testing that followed.

The following diagram outlines the major milestones for the first months of application of the team's strategy.

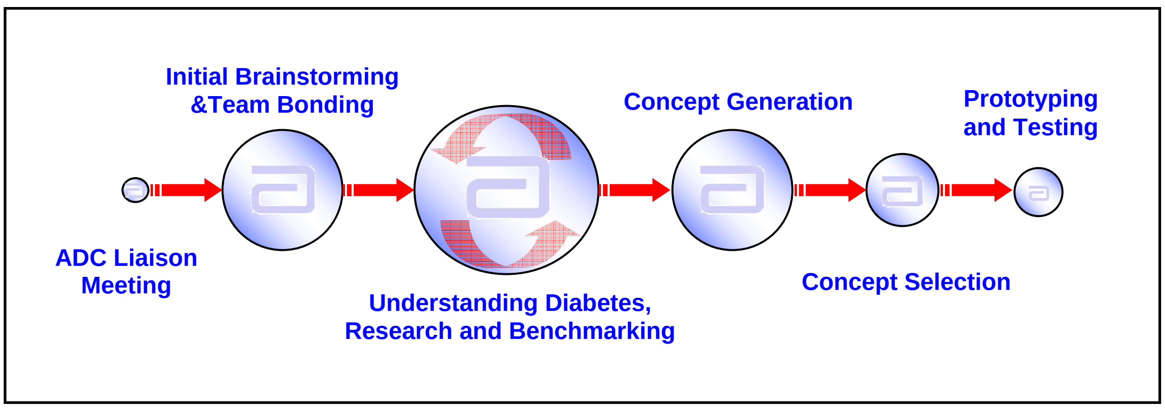


Figure 11 - Initial Development Strategy

The next phase of the project began in January 2006 when the team, with the support of Abbott Diabetes Care (ADC) liaisons, decided to specify its approach to the problem by clearly redefining the scope of the project (Section 4.2) and its target user group (Section 4.6). These crucial decisions were efficiently made to give the team sufficient time to carefully investigate the newly specified problem and come up with the most appropriate solutions.

During the following months, Team Abbott dedicated its efforts to three tasks: conducting specific research (Section 4.7.b,c,e), applying a Concept Filtering process (Section 4.8.1) that emphasized a unique concept for the team to pursue, and expanding the prototyping efforts from critical function to complete functional system level.

Furthermore, Team Abbott emphasized collaborative design, each step of the design process was a joint effort with the Luleå team. Several prototypes were built with LTU: one team would develop certain aspects or features of the product while the other would focus on the complementary set. Such design efforts increased team bonding but were also fruitful in achieving in-depth exploration and implementation of any given concept.

In addition, Team Abbott took the time to pursue alternative design efforts, intentionally dedicating a few weeks to investigate venues that were overlooked during the last quarter. This exploration allowed the team to validate its current primary design direction, but also to elucidate a sub-concept, the Guiding Rod, that became a valuable supporting feature in the final physical prototype.

Finally, Team Abbott defined the deliverables due in June 2006 with the ADC liaisons and has laid out a plan that will insure the production of the separate physical and software prototypes as well as the required thorough testing.

Brainstorming:

In the beginning phase of the project, Team Abbott's numerous brainstorming sessions helped generate a myriad of ideas, concepts and tactics. These sessions were held at different stages during the implementation of the development strategy, and allowed the team to refine its planning and track its progress taking advantage of the creativeness, diversity and complementary skills of the team members. Several of these sessions included the Luleå Team: the "SugaBabes."

These sessions served three purposes:

1. Defining attributes of glucometers as well as any additional features they may offer;
2. Generating solutions to the extended list of requirements;
3. Finally forming concepts by combining relevant solutions.

In fact, these brainstorming sessions generated an array of questions, solutions and concepts that quickly fell into one of three categories:

1. **The process**: the entire testing procedure, which involves the glucometer, the lancing device, the test strips and the patient.
2. **The device:** the actual glucometer i.e. its shape, buttons, features and other relevant aspects.
3. **Life with diabetes**: other elements affecting the patient's life and coping with the disease, i.e. diet, exercise, medical and emotional support.

This breakdown of the concepts allowed the team to pursue and expand, in parallel, several facets of the user-interface of Self Monitoring of Blood Glucose, and thus helped better guide the prototyping efforts.

In the second phase of the project, joint brainstorming sessions became much more frequent. The major brainstorming sessions revolved around the process, the device and life with diabetes but also helped define the target user group, specify the design and features of the physical prototypes and explore ways to implement positive reinforcement through the software interface of the glucometer (Section 4.8.4.1).

Finally, Team bonding efforts helped the team members achieve high levels of comfort and trust when dealing with one another, even with the LTU team. This allowed for many unofficial brainstorming sessions to be held. A drive to Walgreen's to purchase a glucometer, an instant messaging session at 1 am with Sweden, a discussion with other ME310 students regarding their projects or even a wait in line to get lunch became fertile opportunities to generate ideas and concepts. All of these ideas were captured and were regularly revisited.

4.6 Users

Given the age spread of patients who suffer from Diabetes- ranging from children as young as 2 years old to the elderly beyond 80 years old- it quickly became necessary for Team Abbott to target a specific age group. Even though Abbott Diabetes Care's customer base extends over the entire range of users, the team discovered that the diverging cognitive abilities, sensitivity levels and interests of the users represent valuable opportunities that could be exploited to shape a more suitable product. In other words, taking advantage of the defining characteristics of each user group helps better meet its specific needs.

In accordance with this reasoning, Team Abbott decided to focus its efforts on children, more specifically users from the age when they are able to use the meter independently to the onset of adolescence. The team preferred not to determine specific age boundaries due to the inherent variability in child development in addition to differing parenting practices between families. For instance, Team Abbott met with some users whose parents gave them more responsibility at a younger age in comparison to others. Another example is that of Freddy, a 16 year old diabetes patient interviewed by the team, who suffers from Tourette syndrome and other complications which render him unable to independently monitor his blood glucose concentrations.

Figure 12 – Meters for kids should have friendly features which allow children to enjoy themselves

The motivations behind the choice of children are the following:

- Good glycemic control early in life helps the patients avoid diabetes complications later on. These complications include nerve damage, retinopathy and more generally poor blood circulation. The key is to maintain A1c levels below 7%, and tight control of blood glucose is known to produce such results.
- Children are least able to comprehend the meaning of diabetes and its effects. Therefore, the team found it valuable to teach them about their body, about diabetes and other relevant health issues. In fact, one of the User Modes was developed to specifically tackle this issue (Section 4.8.2.2.1).
- Users of this age group are more responsive to stimuli than elder patients, thus many more interaction opportunities do exist when dealing with them. As a result, more creative and interesting interfaces can be designed.
- Meeting patients from this age group has had a poignant effect on the team members, thus motivating them to design a product that would make life with diabetes easier for children.

Figure 13 – Captain Glucose and Meter Boy, mascots of campaign to improve diabetes management

However, it became quickly obvious to us that the spectrum of users expands beyond the patients of the specified age group to reach parents and medical professionals too. By measuring the blood glucose concentration of a sleeping infant or reviewing trends and averages to make medication recommendations, parents and medical professionals do interact with the meter, and therefore the team had to design a solution with them in mind. This insight has lead to several features and functionalities specifically aimed at non-patient users and that will be discussed in detail in Section 4.8.

Figure 14 – Parents are an important part of diabetes care

Figure 15 – As are medical professionals

Furthermore, the team shortly realized the psychological factors at play, and hence made understanding the patients a priority for the design effort. This decision materialized during several in-depth interviews with patients, educators and care-givers.

Furthermore, the team attended the American Diabetes Association Expo in Portland, Oregon, in February 2006. The exposition allowed the team to meet Certified Diabetes Educators (CDE), Medical Doctors (MD), researchers and most importantly patients and their families. Several contacts were gathered in preparation for the forming of focus groups in the Spring Quarter as part of testing the end product prior to delivery. In addition, the team had continuous meetings with nurses, CDEs and MDs in order to gain further insights and validate some of the proposed concepts. Moreover, the team had the opportunity to directly interact on several occasions with patients from the selected age group. These interactions were made possible with the help of Dr. Bruce Buckingham who extended an open invitation to Team Abbott to attend weekly pediatric clinic hours at the Stanford University Medical Center. Finally, Team Abbott also interacted indirectly with its target users through two surveys that were developed during the Concept Selection process and filled by patients with the help of the Juvenile Diabetes Research Foundation in Los Angeles, California.

4.7 Benchmarking

4.7.1 History of Blood Glucose Meters

Diabetes has been recognized as a disease for millennia. However it was only in the late 1800's and through the early 1900's that the causes of diabetes were tracked down and the first insulin dosage experiments were carried out in the 1920's. This brought about a need for a measure of the glucose concentration in the blood to base the insulin dosage upon. This in turn created the market for blood glucometers.

The first SMBG tool, Dextrostix®, was introduced in 1965: it consisted of paper strips to which a drop of blood was added for 1 minute then washed off. The strips developed a blue color that was compared to a color chart in order to obtain an approximation of the blood glucose level. Five years later, the first effective blood glucose meter was introduced to the market: a simple light meter that read the reflected light off of the blue Dextrostix strips. That reflected light was sent to a photoelectric cell, which in turn gave a read out on an analog meter with a swinging needle. The product, Ames Reflectance Meter, was a cumbersome 10 inch long device that cost $495 and required a connection to an electrical outlet.

Second generation coulometric and amperometric meters came in 1999. They allow for Alternate Site Testing (AST) since they do not require as much blood. AST is appealing for the users since body areas with fewer nerve endings can be used, reducing the pain caused by the testing. Currently, reducing the invasiveness, increasing the data management capabilities, and enhancing the look of these products seem to be driving the design efforts in this highly commoditized market where patients often own several glucometers and sometimes prefer buying a new device rather than replacing the batteries on the one they already own!

Future meters (third generation) will provide continuous glucose monitoring capabilities, and may integrate insulin pumps to insure fully automated monitoring of blood glucose at any time. Such meters are already on the market and every major diabetes care company is developing one.

Figure 16 - A pen shaped glucometer

Figure 17 - The Ames Reflectance Meter

4.7.2 Understanding Diabetes

4.7.2.1 Diabetes + Circle of Influence

A fundamental step in the process of benchmarking was to understand what diabetes means and its effects on patients. Team Abbott researched various support groups and talked to experts representing various organizations including the American Diabetes Association (A.D.A) the Diabetes Society of Santa Clara Valley, the Vaden Health Center on Stanford campus and the Stanford University Medical Center. People with diabetes amongst the student body at Stanford University as well as others were interviewed. Valuable insights gained from several of these interviews regarding the day-to-day life of patients are presented in the Appendix.

Below is a short description of the disease as well as recent statistical data:

Diabetes is a disease in which the body does not properly produce (type 1 diabetes) or does not properly use (type 2 diabetes) insulin, a pancreatic hormone that regulates carbohydrate metabolism. Specifically, insulin is used to regulate glucose, or sugar levels, in the blood.

The prevalence of diabetes is on the rise: a 2005 study by the ADA found that over 20 million Americans, or 7 percent of the population, now have Diabetes. More specifically, about 0.25% of the population under 20 years of age has type 1 diabetes.

Diabetes is the 6th leading cause of death in the United States and the leading cause of blindness in patients 20 to 74 years old. Other complications include heart disease, kidney failure, nervous system impairment, and high blood pressure. Fortunately, diabetes can be controlled through proper exercise, dietary planning, and medication.

In addition, Team Abbott tried to identify all the forces acting on a person diagnosed with diabetes and create a network of influences. This proved to be very helpful in understanding the most important interactions, the most frequent ones and also the factors which might prove to be vulnerable.

The result of all these inputs was depicted as a "Circle of Influence" for a diabetic person – a high level depiction which visualized the interactions of a diabetic patient with society and also provided leads to tackle issues which were proving to be troublesome to patients.

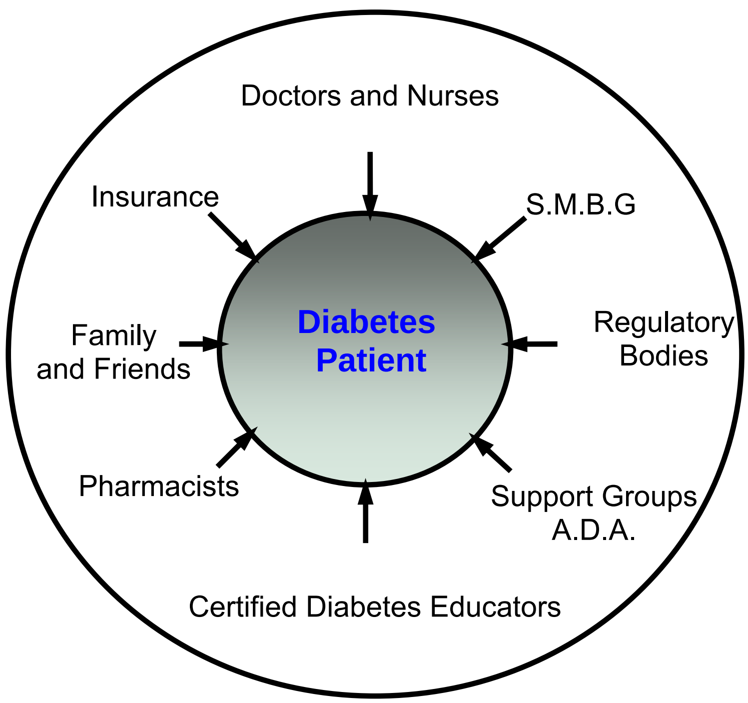


Figure 18 - The Circle of influence for a Diabetes Patient. A person diagnose with diabetes has a whole array of social networks and interest groups to look for support from. All these multifarious groups provide specific information which the diabetic processes and uses in his day-to-day activities.

4.7.2.2 Insulin

Insulin is a hormone whose primary function in the body is to regulate carbohydrate metabolism. Insulin is produced in the body in the B-cells of the Islets of Langerhans in the pancreas.

People suffering from Type 1 diabetes lose the ability to produce insulin in their body due to a malfunction of the immune system which destroys their own B-cells. In Type 2 diabetes, insulin is still produced in the body; however the body has an impaired response to the hormone and thus carbohydrate metabolism is affected.

Insulin has varying responses to an individual's body weight, age and time of the day. Some of the important parameters used to measure the effectiveness of insulin are:

- Onset – this is the time required for the insulin to begin its actions on carbohydrate metabolism.
- Peak time – the time at which insulin is at its peak activity levels, lowering blood glucose concentrations.
- Duration – the length of time insulin remains in the blood before, during and beyond its peak activity levels.

Based on these activity levels, insulin is classified in four types:

Table 1 – Insulin classification

Insulin Type	Onset	Peak	Duration
Rapid Acting	<15 mins	1 to 2hrs	3 to 4 hrs
Short Acting	30mins to 1 hour	2 to 3hrs	3 to 6 hrs
Intermediate Acting	2 to 4 hrs	4 to 12hrs	10 to 18hrs
Long Acting	2 to 10 hrs	NO PEAK – steady	18 to 24hrs

Diabetic patients use various combinations of these insulin types or mixtures of them at various points of the day to regulate their glucose concentrations.

Two main types of insulin taken in are:

- Basal Insulin – primarily long acting or intermediate acting insulin taken to cover the metabolic needs of the body over several hours usually at a lower activity levels
- Bolus Insulin – primarily rapid and short acting insulin that have very short spurts of activity to tide over the glucose spike after mealtime.

The location of the insulin shot also causes variance in efficacy. Most recommendations for insulin shot locations are over fatty tissue as they do not impede the absorption of the hormone into the blood stream. However muscle tissue and certain areas of the body with tough fibers have been known to cause delay in insulin onset times which might throw a dosage plan out of synch. Several studies have shown insulin action time variability to be as high as 25%[2].

4.7.2.3 Nutrition and exercise

Nutrition and exercise play very important roles in carbohydrate metabolism. Nutrition supplies the carbohydrate in the body while exercise acts to metabolize the carbohydrate. Thus a balance in carbohydrate levels has to include a plan for both nutrition and exercise.

One of the first aspects of life with diabetes is to learn how to control nutrition. An excessive carbohydrate intake could cause a spike in blood glucose levels causing hyperglycemia and affecting long term A1c readings along with contributing to several complications associated with diabetes.

The other side of the balance is if a person with diabetes skips a meal, the resident insulin in the blood from a previous shot will act on the already low glucose concentrations in the blood and drive it to hypoglycemia which has several severe and sudden effects on the person.

This has led to a fine balancing act between the meal intake and the insulin dosage. Normal recommendations are for a diet lower in carbohydrate so as not to require too much insulin. High insulin intake has a higher risk of consequences when things go wrong.

Most people learn to base their carbohydrates intake on a thumb-rule known as the insulin-to-carb ratio. This ratio varies by person as well as by time of the day. However it is accepted to be a good starting point for most diabetics to base their insulin dosage and then tune the ratios as they get to know their own food consumption and body responses to insulin better.

[2] American Diabetes Association: Complete Guide to Diabetes

Table 2 – Insulin 500 and 450 Rules

	500 Rule	450 Rule
Total Daily Insulin Usage	Grams of carbohydrate covered by 1 unit of Humalog	Grams of carbohydrate covered by 1 unit of Regular
20	25	23
25	20	18
30	17	15
35	14	13
40	13	11
50	10	9
60	8	8

The 450/ 500 insulin-to-carbohydrate rule is for the calculation of the amount of carbohydrates covered by one unit of insulin in Type 1 diabetics. As indicated in the chart, the 500 rule is followed by "Humalog" insulin users whereas the 450 rule is followed by regular insulin users.

The steps involved in calculating the insulin to carbohydrate ratios are:

1. Calculate the Total Daily Dosage (TDD) of insulin which is the total Basal and Bolus insulin dosage over the entire day.
2. 500/TDD = Grams of Carbohydrates covered by each unit of insulin.

The other aspect of the nutrition planning is to map out the insulin to blood glucose ratio. This ratio varies much more profoundly with each individual user with variances not only due to age, weight and type of insulin but also due to the ratio of basal and bolus insulin.

A higher basal insulin ratio reduces the need for frequent insulin shots to cover smaller meals, however it also ties down the patient to follow a strict meal intake pattern in order to maintain the blood glucose concentrations in the body. A higher bias towards bolus implies that the user needs to inject insulin frequently to cover even smaller meals. This entails having to always carry an injection mechanism and knowing the amount of carbohydrates in the food consumed.

Table 3 – Typical Insulin to Blood Glucose Ratios

	2200 Rule	2000 Rule	1800 Rule	1600 Rule
Total Daily Insulin Use	Point drop per unit of Humalog in mg/ dL			
20	110	100	90	80
25	88	80	72	64
30	73	67	60	53
35	63	57	51	46
40	55	50	45	40
50	44	40	36	32
60	37	33	30	27
75	29	27	24	21
100	22	20	18	16

The chart shows typical insulin to blood glucose ratios. A person using a 50:50 basal to bolus ratio uses the 1800 rule. If the ratio of basal insulin is more, then a higher constant needs to be applied (2000, 2200 etc). If the ratio of bolus is more, then the lower constant (1600) needs to be applied.

The method involved in calculating the insulin to blood glucose ratio is:

1. Calculate the Total Daily Dosage of Insulin (TDD) which is the total Basal and Bolus insulin dosage over the entire day.
2. If ratio of Basal to Bolus insulin is 50:50 - use the 1800 base rule to lookup the amount of blood glucose corresponding to one unit of insulin. However if the ratio of Basal is higher compared to bolus, use the higher constant rules - 2000, 2200. If the ratio of Bolus is higher than basal then use the lesser constant rule – 1600.
3. 1800 (or constant)/TDD = blood glucose mg/Dl to each unit of insulin.

Several other factors affect the insulin metabolism in the body as well.

1. Exercise
    a. During periods of exercise the muscles in the body work harder and consume more glucose.
    b. Exercise also makes muscles and tissue more sensitive to insulin – hence less insulin is needed to take glucose out of blood into cells.

   c. Excessive levels of activity or exercise without corresponding intake of carbohydrates or other energy source can cause the blood glucose concentrations to plummet.

2. Sick Days
   a. Immune system hormones counteract the effect of insulin during sick days, hence driving glucose levels higher.
   b. Medications (especially cough & cold medications) might contain glucose and this can cause glucose concentrations to spike.

4.7.2.4 Psychology

Team Abbott pursed a user-centered strategy in approaching the problem in hand, which required a deep knowledge of the target users: diabetes patients, and juvenile patients in particular. Therefore it quickly became crucial for the team to understand in depth the cognitive factors at play before attempting to improve the interface. The team's strategy in tackling this issue was to research clinical psychology for diabetes patients and to interview medical professionals. This section outlines the team's main findings.

Diabetes Burnout and Depression:

Having to grapple with an extremely demanding lifestyle and personal care, over time many patients suffer from diabetes burnout, and then depression. Patients find themselves caught in a self-perpetuating depression cycle (Figure 19) that results in several behavioral patterns that inherently affect their SMBG.

One of the most common behavioral patterns is skewed thinking, with many manifestations such as:

- Overgeneralization - a patient would commonly say “my results are *always* high, why bother testing”
- Mental filters - one bad event signifies the whole experience of the user
- All or nothing reasoning, jumping to conclusions - a patient makes false assumptions and resolves to give up
- "Should have, would have, could have" thinking.

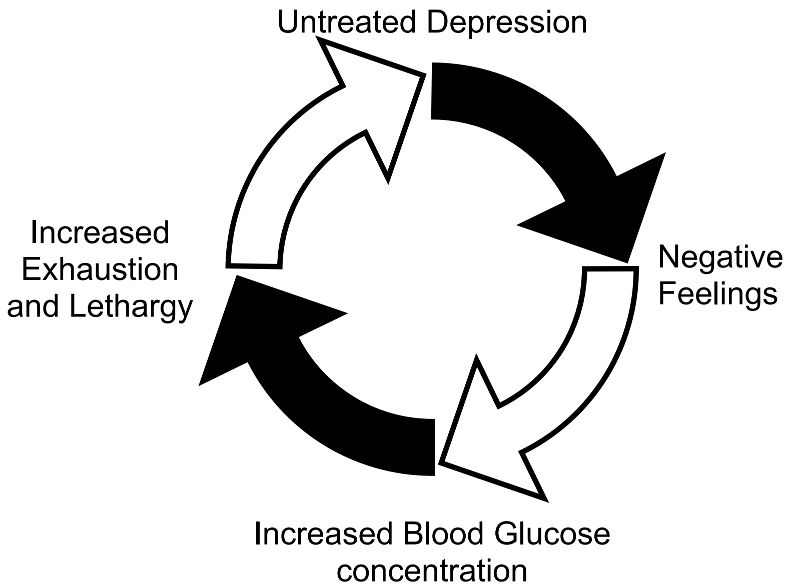


Figure 19 – Self-perpetuating Depression cycle

In fact, many of these patients interpret some of their blood glucose readings incorrectly, applying those skewed thinking patterns while viewing them. This means they are already turning data into information, albeit erroneously. Therefore, it is Team Abbott's responsibility to turn this wrong information into data again before empowering patients with the knowledge and understanding of both their bodies and diabetes so that this data can become much more significant hence can be turned into the correct information.

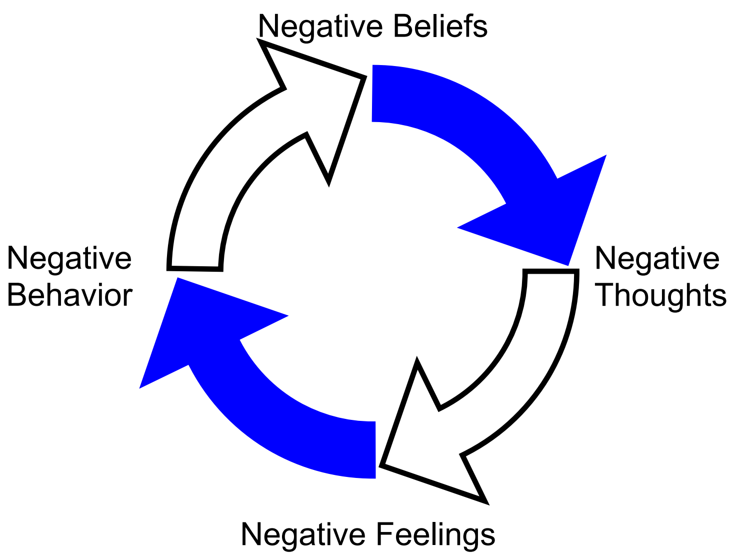


Figure 20 - Self-perpetuating skewed thinking cycle

According to Sylvia Harris, CDE, a “change in trajectory” is required in order to avoid these pitfalls. Such a shift would focus on changing denial by finding a support network, learning more about diabetes and self-management of blood glucose, setting goals, following through and finally receiving applaud. The patient needs to become proactive; realizing that they are capable of controlling the effect diabetes has on their health and lifestyle through their own actions and efforts. The motivation of the user is an important factor too, since high motivation periods are the best moments to instill new knowledge and behavioral change.

The team also realized that in order to implement a better self-management of diabetes plan, the device needed to allow the patient to:

- Clearly know his/her goals: blood glucose targets, A1c levels, body weight, etc.
- Achieve a thorough understanding of the tools and resources available
- Make a plan, saving it, and checking it regularly
- Observe the plan in action
- Easily update the plan: flexibility is a key factor in this strategy

Furthermore, many CDE’s find it valuable to help patients make sense of the cycles and patterns of the blood glucose concentrations.

Many of these teachings were implemented as software features in the various User Modes of Team Abbott’s prototype. (See Section 4.8)

Cognitive Mediating Process

Team Abbott investigated the cognitive process by which patients develop their attitude towards self-treatment of diabetes. The goal of the team was to evaluate opportunities to intervene in the process depicted in Figure 21 in order to increase both the user’s motivation and the perceived need and value of protection, hence induce better precautionary behavior overall.

The team learned that this could be achieved by ameliorating the perceived value of the rewards and both the treatment and self-efficiency of the user while avoiding any additional monetary costs or painstaking efforts. As it will appear in this report, one of the practical applications of this strategy was to devote a considerable amount of time on designing the best interface that will ask the user to give provide the glucometer with his dietary intake, amount of exercise and insulin dosage.

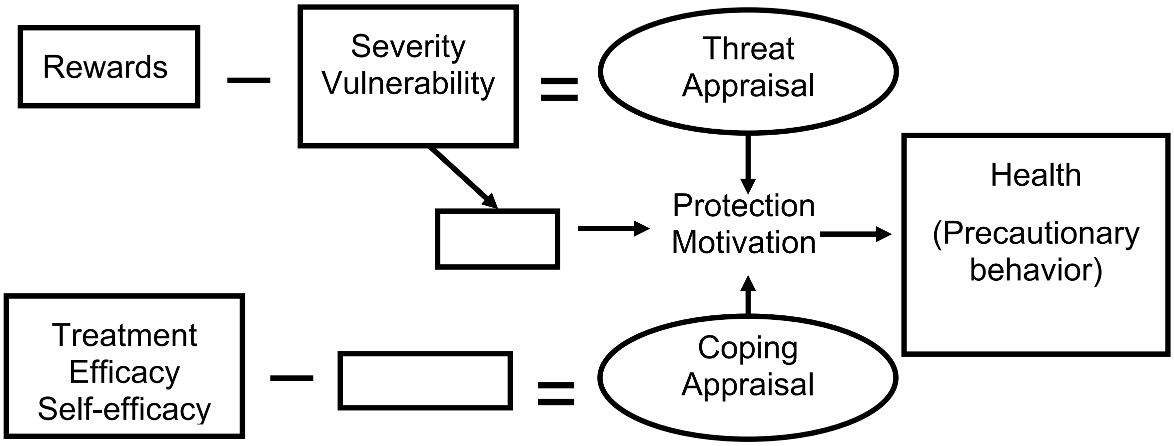


Figure 21 - Cognitive mediating process- Practical Psychology for diabetes clinicians, Barbara J. Anderson and Richard R. Rubin, ADA, p184.

Operant Conditioning

Team Abbott and especially the Luleå partners investigated operant conditioning in order to identify ways to achieve user behavior modification, a crucial factor for instilling better self-management of diabetes. This section, coauthored with LTU, outlines the major findings and presents an interesting and inspiring application.

First of all, in order to set the background for the presentation of operant conditioning, it is essential to define the fundamental 3-term model:

Stimulus → Response → Stimulus

An event (first Stimulus) triggers an action (Response) which then triggers another Stimulus. It is the relation between Response and the following stimulus that is interesting, as the first stimulus is regarded as a background event or the setting for the following events. It is also called antecedent stimulus or a discriminative stimulus if it affects the probability of the following Response. A response cannot occur without a preceding Stimulus according to the definitions of these terms.

The general principle of operant conditioning can be divided into four major techniques. First, a difference is made between increasing a good (desired) behaviour and decreasing a bad (undesired) behaviour. The behaviour is the Response in the 3-term model above. Second, another distinction is made between two possible types of stimulus that follow the Response: positive or negative. These stimuli on the subject can be added or removed.

Prior to the possible stimuli presented in the following table, the subject has already provided a Response:

Table 4 - Operant Conditioning

Positive Stimulus	Adding stimulus (Positive reinforcement)	Removing stimulus (Response Cost)
Negative Stimulus	Removing Stimulus (Negative reinforcement)	Adding Stimulus (Punishment)
Resulting change in behaviour	Increase	Decrease

Which ever the stimulus (positive or negative) the attained behaviour depends on whether said stimulus is added or removed on the subject. This implies that a Positive stimulus can be used to both increase and decrease desirable behaviour.

The theory of operant conditioning and behaviourism in general has many more of less scientific applications. The team decided to investigate one of them in particular in order to draw inspiration for solving the problem in hand:

Swedish researcher Per Sodersten at Anorexicentrum developed a device called a Mandometer to treat patients with anorexia nervosa.

It is a device that monitors the weight of a plate and reports the eating-speed of the anorectic, a patient with an eating disorder. Anorectics develop a faulty sensation of being full even if they haven't eaten anything. This results in meals taking hours and anorectics not eating enough food.

The goal with the Mandometer training was to achieve a normal eating speed, about 300g per 10 minutes. While eating, the patient sees two curves on a display, one is the targeted eating speed, and one is the current eating speed. The display is also used to estimate satisfaction and compare it to a normal value. The difference becomes too obvious to ignore.

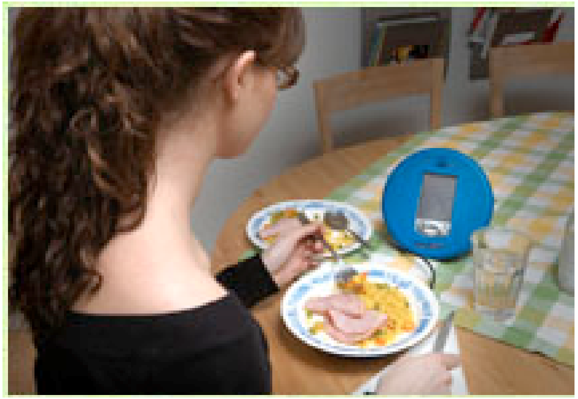


Figure 22 - The Mandometer

It should be mentioned that the Mandometer training is only part of an extensive program to treat anorectics. The method has been criticized by other researchers, but most of the criticism is about research methods rather than the method itself.

Good vs. Bad to modify or not?

Reinforcement theories can be used both to improve an existing desirable behaviour and to eliminate unwanted behaviour. There are, however, a few drawbacks involved when trying to eliminate bad behaviour. A quick glance at Table 4 above indicates that there are two main paths to follow when decreasing an unwanted behaviour: Response Cost or Punishment.

Response Cost means that when an unwanted response is identified, something positive is removed or an expected reward is not given. This will increase the possibility that the subject will try another response the next time, thus decreasing the possibilities for repeating the unwanted behaviour.

Punishment is adding a directly negative stimulus which will lessen the possibility of the unwanted behaviour because the subject will try to avoid the negative consequences. Punishment has the directly negative effect that it harms the bond between the subject and the instructor. When used excessively it also lessens the subject's overall probability to respond to stimuli at all because the negative associations with even trying are greater than the possible positive outcomes. The subject becomes afraid to even try.

4.7.2.5 Using the meter, Testing Campaign

As part of the deep dive that Team Abbott took into diabetes and Self Management of Blood Glucose, several testing campaigns were conducted in order to gain insights onto the experience that users go through up to 10 times a day, 365 days a year.

Each member of Team Abbott conducted blood glucose testing to get familiar with the equipment and the required interpretations. Karthik performed an extended test covering 3 weeks with readings taken 5 times a day for the duration. Various test locations included the ME310 Loft, Graduate residences, various other classrooms, Stanford Shuttle buses etc.

In addition to the normal testing, Team Abbott conducted certain tests under extreme or not very frequently occurring situations. The rationale behind this was to obtain an understanding of a wide array of possible ways and situations in which the glucometer could be expected to be used. The most relevant tests given the current state of the project and the direction the team is pursuing are the following:

- Slippery Test: simulates conditions of hypoglycemia where the hands of the user become oily
- Emergency Test: simulates performing a measurement on an unconscious patient or a sleeping infant
- Glove Test: simulates the loss of sensation due to long term pricking of the fingertips.

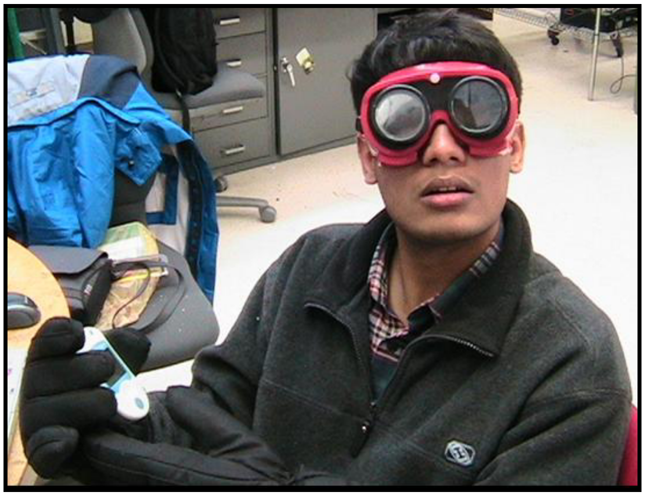


Figure 23 - Beer Goggle Test

Figure 24 - Glove Test

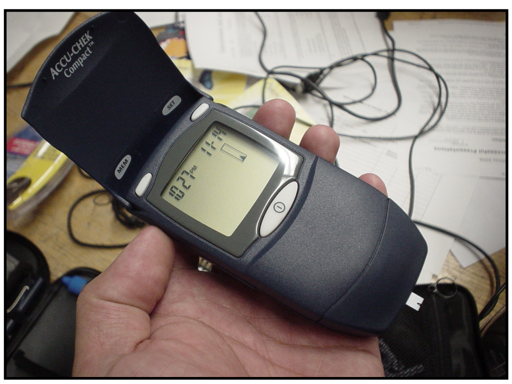
These tests elicited the need for more integrated or modular designs, with less floating small parts such as the independent strips or the lancet tips that are kept in the pouch. In addition, these tests showed that the current meters are extremely difficult to use for an inexperienced person while providing assistance in an emergency situation. Team Abbott addressed this issue by designing a specific User Mode called Emergency Mode. More generally, the lessons learned from these campaigns were compared to other insights and the most significant ones were matured to design requirements and then specifications.

Furthermore, given that Team Abbott has decided to tackle the lifestyle monitoring issues that users have to deal with, it became crucial for the team members to interact with some of the meters available in the market that present features such as keeping track of the user’s diet and exercise, graphing capabilities and many others. Using these meters gave the team a first hand experience with these existing interfaces and helped better understand why most patients give up on using these features very quickly. In fact, inputting with each measurement all the required data can be a daunting task given how frequent these measurements can get. Therefore, a fast input method along with a flexible, intuitive and concise interface was required, something that all the meters that were tested lacked. These insights helped team Abbott define the specifications of both the physical and software prototype. For instance, adding a Jog Wheel to the meter or asking the user to provide the meter with the total grams of carbohydrates consumed instead of the specific food item were among the solutions that were reached thanks to the insights aforementioned.

4.7.3 Competitive Benchmarking

Team Abbott conducted competitive benchmarking on the various devices available commercially. Some of the meters benchmarked included the Walgreens Monitor, Walgreens Sidekick, Accu-chek Compact, One Touch Ultra Smart, Abbott’s Freestyle Flash and the Precision Xtra.

Table 5 – Benchmarked Glucose meters

	WALGREENS MONITOR • Blood Sample: 1.0 mL • Assay Time: 10 sec • Large display • AutoCalibration ROM Chip • PC interface
	WALGREENS SIDEKICK • Blood Sample: 1.0 mL • Assay Time: 10 sec • Minimum Features • Integrated meter/vial • Pre-Calibrated • Disposable
	ACCU-CHEK COMPACT • Blood Sample: 1.0 mL • Assay Time: 10 sec • Large display • Cartridge strip loader • AutoCalibration on drum cartridge • PC Interface via IR

ONE TOUCH ULTRA SMART

- Blood Sample: 3.0 mL
- Assay Time: 5 sec
- Extensive Data logging
- Data Annotations
- Large graphic display
- PC interface

FREESTYLE FLASH

- Blood Sample: 0.3 mL
- Assay Time: 5 sec
- Highly portable size
- Most FDA-approved Alternate Test Sites
- Flashlight and backlight

PRECISION XTRA

- Blood Sample: 0.3 mL
- Assay Time: 5 sec
- Large Display
- Most FDA-approved Alternate Test Sites
- Flashlight
- AutoCalibration ROM strip

In addition to these matters the team also benchmarked several other glucometers which included the Glucoboy.

Glucoboy

Figure 25 - Glucoboy glucose meter game cartridge, was promised for Spring 2005

Guidance Interactive Healthcare's Glucoboy is a meter which is integrated into a Game Boy System. This tries to appeal to children by attaching the meter to a device very popular with users of the younger age group. The inventor hopes to increase the emotional attachment of the meter to the children as well exploit some interesting observations such as children tend not to lose their Gameboy very often since they are prized possessions.

The Pelikan Sun Glucose Meter

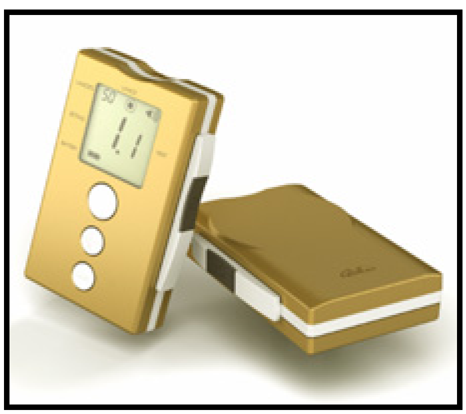


Figure 26 – Pelikan Sun integrated meter

This is a totally integrated glucose testing meter with a one touch testing protocol. It includes an integrated disk containing lancets and strips which index into positions at the appropriate times to conduct the test without the user ever having to see or handle the strips, lancets and blood. The disk cartridge is said to include 50 lancets and strips.

Japanese Meter

Coach Victor Scheinman introduced comments on a Japanese market meter with a fascinating feature set. He described a number of interface methods which used touch, sight, and sound in a interesting ways to allow for both output from the meter and input from the user. The letter is attached in the Appendix.

4.7.4 Technology Benchmarking

4.7.4.1 Self Monitoring of Blood Glucose

Insulin Pumps

Insulin Pumps are devices about the size of a deck of cards which contain a reservoir of fast acting insulin and an electronic dispensing mechanism. They feed basal and bolus insulin into the abdomen through a thin, flexible tube ending in a shallow needle with adhesive pad to keep it in. The needle is moved to a new site every 3 days or so.

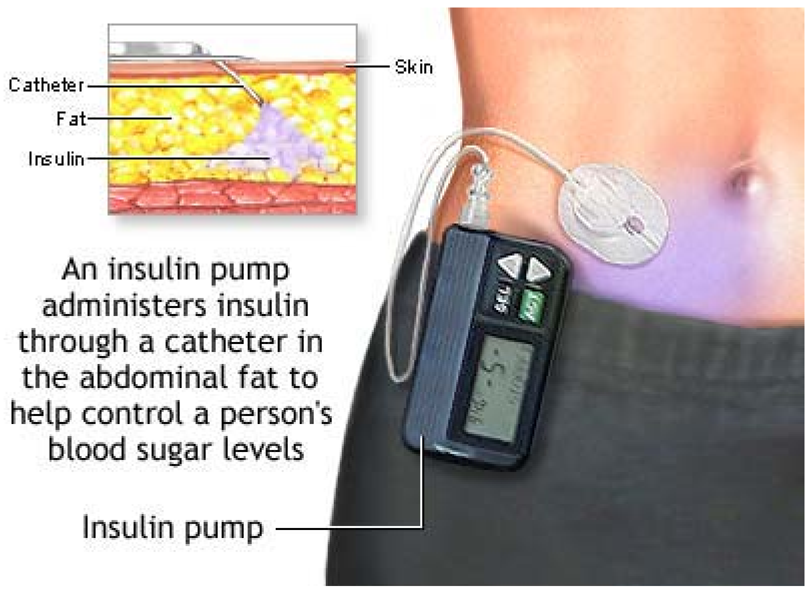


Figure 27 - An Insulin Pump is carries near the waist to allow access to the controls. Wearers administer bolus insulin at meal time after consulting a meter.

Track3

Coheso Inc.'s Track3 is a PDA style utility device with a QWERTY keypad. The team encountered it at the Portland Diabetes EXPO. It serves as a nutrition, exercise, and treatment tracking tool for diabetes management. It has a 35,000 item food library, including restaurants and food brands, which is user expandable. It also features USB connectivity to upload data for sharing with healthcare team.

Figure 28 - Track3 device offers food library and many diabetes management tools, $59 retail

4.7.4.2 Auxiliary Technologies

Figure 29 - The Apple iPod is a pinnacle example of popular portable consumer electonics, and a worthwhile source of design inspiration.

Apple iPod

The Apple iPod is widely regarded as having an excellent user interface. A hallmark of this is its wheel shaped interface. The wheel's motion places what equates to dozens of button presses in a conventional button interface. In doing so, the wheel changes the dynamic of navigating the iPod's deep menu structure into something that seems thin and trivial navigate.

Braille Cells

Refreshable Braille Cells (RBC) use actuated pins to display Braille text for the blind. Each RBC essentially mechanical displays one character, usually operating in a series with identical RBC's to display text. Team Abbott saw the general concept as an alternative output method for glucose meters.

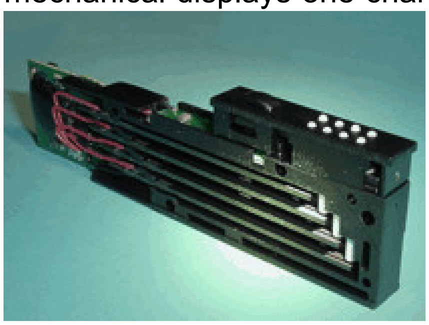


Figure 30 - Refreshable Braille Cell helps the blind read

e-Ink

Electronic Ink[3] (a.k.a. e-paper) is an immerging display technology projected to replace LCD displays in monochrome applications. Unlike OLED, it is non-light emitting, but it too has numerous advantages once it is made more cost competitive via mass production/application. These include further reduced power consumption, as e-ink requires power only to change what it is displaying, static displays draw zero power. This is not a strong gain over segmented LCD displays, but might make dot-matrix displays more economical. Another benefit comes from form factor. E-ink displays can be paper thin. This leads to better contrast as well as wider viewing angle than LCD technology. E-ink is in-fact designed to be as readable as normal printed text.

Additionally, e-ink displays can be as flexible as a paper thin sheet of plastic. In contrast to the glass elements of current LCD's, e-ink's plasticity allows for many more design opportunities, where the display no longer has to be flat in operation. Curved and even roll-up screens have been demonstrated using e-ink technology. This opens up screen real estate without necessitating a larger flat, square device. An e-ink display can be wrapped or rolled onto a meter instead.

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[3] http://en.wikipedia.org/wiki/E-ink

Figure 31 - Philips Rollable display, 320x240 pixel resolution [4]

iRiver U10

This recently released portable mp3 player has a number of interesting features. It innovatively uses ubiquitous buttons in a new way which differentiates its use from competitors. Essentially, its D-Click interface can be described as having hidden buttons. Dome switches are placed behind a display screen which rocks such that squeezes of the borders of the device give joystick inputs. This idea served as an inspiration which showcased a very modern implementation of the classic dome switch. It indicates that there is a lot still to be explored in mechanical interface even with pedestrian buttons.

Figure 32 - iRiver's U10 MP3 player, D-Click feature works as an artificial touch screen

[4] http://news.com.com/Photos+Philips+flexes+its+display+muscles/2300-1041_3-5851266.html

Nanomuscle

One of a number of micro actuator technologies, this company is now defunct. Their actuators were small, packaged units offering discrete rotary motion. Besides these, we were also exposed to several piezo linear actuator technologies.

Figure 33 - Nanomuscle actuator, non-continuous rotary actuator

OLED

Organic Light Emitting Diode[5] technology is an immerging replacement for LCD in such applications a PDA's and portable electronics. The major advantage is that OLED displays emit their own light instead of using a separate backlight as current LCD's do. This characteristic leads to better performance in a number of areas, including true blacks, faster response time, much wider viewing angle, and greatly reduced power requirements. Additionally, they can potentially be mass produced via inkjet style printing processes and be far cheaper than LCD as a result. Also, this fabrication means OLED can be thinner overall and perhaps rollable like e-ink.

Figure 34 - Optimus Keyboard[6], using integrated OLED displays in every key.

[5] http://en.wikipedia.org/wiki/OLED

[6] http://www.artlebedev.com/portfolio/optimus/

4.8 Concept Generation

4.8.1 Concept Selection and Concept Filtering:

Early on in the project, thorough research and brainstorming allowed team Abbott to generate numerous concepts that constituted plausible solutions paths to the problem in hand. Therefore a selection process needed to be devised in order to allow the team to focus its early prototyping efforts on the most significant issues.

In order to achieve this selection, team Abbott ranked these concepts in a Popularity vs. Impact matrix constructed using surveys with questions pertaining to diabetes care products and their utility, in addition, the team performed a Design Failure Modes and Effects Analysis that ranked SMBG process failures based on a Risk Priority Number. Detailed results of these studies are available in the Appendix.

Many of the interviews, the surveys and the FMEA indicated that patients had considerable difficulty understanding the feedback from the device and required repeated training sessions to understand the various functions and feedback delivered by the device. The second factor repeatedly stressed in the various concept selection steps was that of difficulty and inconvenience faced in the blood sample generation process of the test.

Thus two concepts were selected from the multitude of issues surrounding the glucometer to be the first prototypes with the other issues being open for further investigation as a part of the continuous development and learning process.

- Informative Feedback
- Simpler Blood Sample Generation

However, at the beginning of the winter quarter, major decisions were made regarding the target users and the scope of the project. These decisions formed the beginning stages of what became a Concept Filtering process that was applied to the two concepts selected in the first 3 months of the project as well as to several others, solely focused on mechanical engineering (Table 1). In fact, several filters were applied: target user selection, project scope delimitation, in depth research, alternative design and collaborative design which entailed the possibility of undertaking larger scale endeavors due to the creation of an enlarged team that could investigate the same problem more thoroughly and efficiently distribute development tasks. These filters allowed the team to select the only concepts that survived the scrutiny.

The following table summarizes the main concepts and features inherently geared toward physical prototype engineering that the team identified as interesting solutions at the onset of the second phase of the project in January 2006:

Table 6 - Concepts specific to the physical interface0

Concept/ Feature	Description
Guiding Rod	Provide stabilizing and localization support for blood sample deposition
Modular All-in-one device	Eliminate the need for a pouch through a modular unit that contains the meter, lancing device and test strip container
One finger device	The meter adheres to one of the user's fingers, removing the need to handle it. Interesting physical interfacing opportunities.
Projector	Replacing the LCD screen with a projector: any surface can be turned into a screen, removing the need to larger fonts or magnifying glasses to render the display readable by users with poor visual acuity.
Shapes and Materials	Investigate various shapes and materials to achieve better touch, damage resistance or waterproofing the meter
Innovative input/output methods	Investigate new ways to input/output data and stimuli (joystick, touch pad, wheel, refreshable Braille cells, squeezing the meter)

Table 7 - Interesting supporting features

Add-ons	USB port for easy meter-to-PC connectivity, compartment for medication storage, customizable covers, imbedded pen for manual data logging, imbedded pedometer for exercise tracking, double LCD screen for permanent memory display on the back of the meter.

Most of these features failed to add enough value to any existing meter to become stand alone solutions, and therefore were not selected after the Concept Filtering process. However, several of them were reshaped to become plausible supporting features in the final design. For instance, variants of Guiding Rod and Innovative input/output methods already appear in the physical prototype Vampagucci V2.0.

The only concept to survive this scrutiny was Informative Feedback, and it became much more specialized as it turned into Informative Feedback for Kids.

Latter sections in this report present this concept in further details in addition to providing details about the physical prototype that was chosen to support it.

4.8.1.1 Validation

After selecting Informative Feedback for Kids as the guiding concept for the team's design efforts, brainstorming sessions followed and provided a myriad of features that could be implemented in both the physical and software prototypes. A validation process needed thus to be implemented in order to be able to identify the most relevant features.

Team Abbott turned to both users and experts in the field in order to perform this validation. Dr. Bruce Buckingham, Dr. Darrell Wilson and Dr. Kirk Neely of the Stanford Hospital provided expert medical opinion, while patients at the Lucile S. Packard Children's Hospital provided user opinion.

The insights gained from these interviews proved valuable in refining some of the features, confirming their usefulness and sometimes providing creative ideas to attack a given problem. The best example is that of the nutrition plan tracking system: a user could be asked in several ways to provide the meter information about his dietary intake. While some methods such as selection of a precise food item (eg. 100g of Cheerios) proves to be painstaking, other methods lack in precision. Dr. Buckingham made a remarkably insightful suggestion that the lancing device could serve a double purpose: pricking the skin of the user and possibly provide weight measurements as a scale would. The team eventually decided to ask the user to provide an estimate of the carbohydrates intake, but the interactions with these experts and users proved to be extremely helpful.

4.8.1.2 The Concept: Informative Feedback for kids

Therefore, through Concept Selection, Concept Filtering and Validation, team Abbott managed to clearly define a guiding concept on which the design and prototyping efforts were focused.

The following diagram shows where Informative Feedback for Kids fits in the life of the patient:

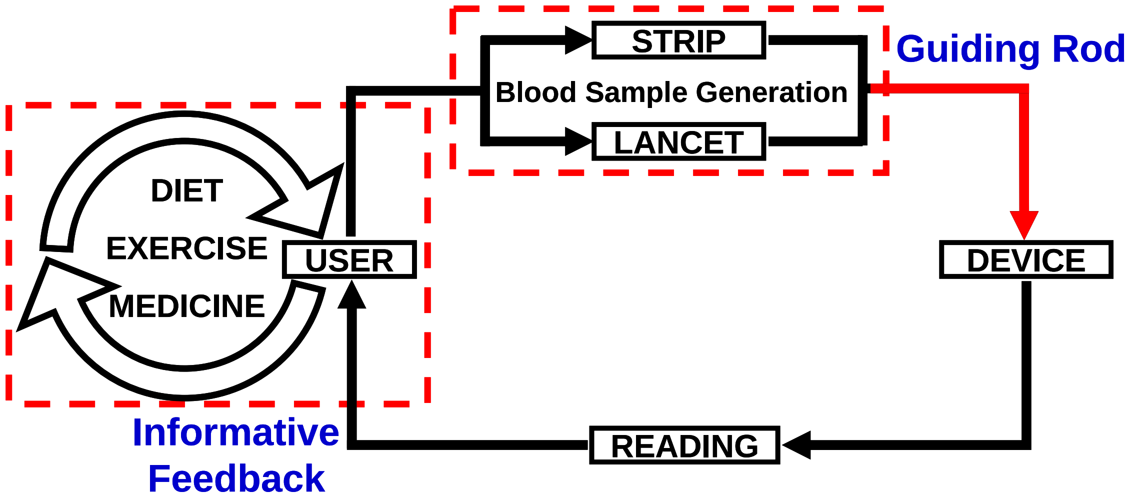

Figure 35 – Informative Feedback for Kids encircles the user and their life beyond the just the normal meter processes

4.8.2 Informative Feedback

4.8.2.1 What is Informative Feedback for Kids?

Team Abbott's interactions and benchmarking efforts during the Fall and Winter quarters documented in the previous chapters focused its design efforts on the concept of Informative Feedback.

What is informative feedback for kids?

Informative Feedback for kids is the underlying software interface which oversees the entire diabetes self management program of the user and helps control diabetes through efficient management of information.

The underlying tenets of this concept are:

- Setting up a plan, following the plan and watching it in action
- Implementation of lifestyle correlations and 'smart' averages
- Insulin and Carbohydrate Tracking and Correlation algorithm
- Intelligent reminder system

Setting up a plan involves some of the most important aspects of a diabetic's lifestyle – nutrition, exercise and insulin (or medication if person is not using insulin). The meter knows the time, quantity and total dosage of these parameters and also the times at which these have to be taken. These plans have to be developed in consultation and full involvement of the certified diabetes educator and / or the medical team of the user.

Figure 36 - Screenshots of the meter showing the implementation and tracking of the food plan a) Asking for present intake b) User inputs the data c) Correlation and plan performance snippet

Following the plan involves the meter helping the user with information pertinent to the time of the day to perform actions according to the pre-set plan. Watching the plan places the onus on the meter to display the user's performance according to the plan from time to time. This not only helps the user in knowing his/ her performance, but also helps in deriving any corrections necessary after deviations from the plan. This also allows for some flexibility in tiding over unexpected deviations as the user knows the target and the present scenario and thus can plan ahead. Therefore the user knows what the plan is, how he/ she is performing in the plan over the previous readings at that time (most relevant data) and where the user is at the instant of time with respect to the plan.

Figure 37 - The meter displaying the present reading, a comment on the meaning of the reading – HIGH or LOW, the average for the time of the day and the target for the time of the day. An example of an informative feedback – the plan as it should be, the user's performance as you have measured over the last few days at that time, and where the user stands right now

The following of such plans also allow for the user to derive correlation between various day-to-day activities and readings. This allows the user to derive links between various incidents of low or high readings and certain activities which might otherwise escape the attention of a user not tracking those parameters. This could help the user derive correlations between certain types of food, time of the day, exercise pattern, mood, location or other parameter which the uses chooses and anomalous readings.

Team Abbott developed an algorithm for tracking the carbohydrate intake and time of the day to the dosage of insulin to be taken at that time of the day keeping in mind the user's total medication plan. Common thumb-rules for in insulin – to – carbohydrate ratio like the 450/ 500 rule (refer 4.7.2.2 – Insulin) and the 1800 rule for insulin to blood glucose ratio (refer 4.7.2.2 – Insulin) were used as starting points to base the algorithm. Inputs from the lifestyle data supplied by the user, the plan setup by the certified diabetes educator and/ or medical team and the readings generated by the meter are used to generate suggestions for the users carbohydrate and insulin dosages.

Presently most users calculate the math by themselves using experience and self developed thumb rules. Team Abbott aims to move this math away from the user into the meter as a part of informative feedback for kids

Intelligent reminders are designed to remind users when to test, when to re-test after an anomalous reading, meet doctors and certified diabetes educators. These complete the total diabetes self management kit of informative feedback.

4.8.2.2 How did we make informative feedback for kids real?

Team Abbott developed various 'modes' of usage to make informative feedback real. The intention here was to help users with various levels of training with diabetes as well as comfort levels adjust their meter to their expectations.

The modes can be adjusted through a change in the settings. The various modes created are:

A. Kid Mode – The default mode in which informative feedback manifests itself completely. This is the mode where the correlations as to food, exercise and other lifestyle options are tracked and informative feedback provided to user.

Figure 38 - Tracking data being collected for correlations and informative feedback

The user can input the data which he/ she chooses into the meter using the fast input jog wheel. The meter uses these inputs, the knowledge about the user, the Insulin Carbohydrate Correlation and Tracking Algorithm and the history to provide suggestions for dosages and carbohydrate inputs.

Figure 39 - Screenshot of the result of the insulin tracking and correlation algorithm – an insulin dosage suggestion

After the end of the testing cycle, the team decided to implement a “Fun with Vampagucci” section which included a Point Counter which accrued points for each reading within the safe zone for a possible incentive from the caregivers. A simple game like Tic-Tac-Toe is also included.

Figure 40 – Point Counter accrues toward potential incentives.

B. Tutorial Mode – Tutorial mode is meant to teach the user

- How to use the meter
- About self management of diabetes
- About diabetes itself

The tutorial mode is accessible from all the modes as well as through the settings menu. The mode also contains a repository of tips and pointers for the user which appear in kid mode at user determined intervals.

(Flow Chart in Appendix I)

C. My Meter and I – it is the mode which the user inputs his/ her personal data including age, weight as well as personal preferences as to the type, frequency and the method of reminders and tips.

My meter and I also serves as a repository for the smart averages over the last 5 days, 15 days and 30 days at the particular time of the day. This is contrasted against the block 30-day, 60-day averages which present meters store which Team Abbott has learned as being medically less significant as compared to time specific average.

My meter and I also supports the Insulin, Carbohydrate Tracking and Correlation Algorithm with inputs regarding the plans of nutrition, exercise and insulin at specific times of the day. This can be input by the diabetes educator or by the user once he/ she gains proficiency over the various nuances of the disease.

(Flow Chart in Appendix 2)

D. Sick Day Mode – during times of illnesses the body's metabolism changes such that insulin absorption and nutrition needs change. It is during these days that the sick day mode takes charge of nutrition and insulin dosages. Sick Day mode also has indicates ketone levels for those days and indicates if a visit to the doctor is necessary.

   (Flow Chart in Appendix 3)

E. Emergency Mode – primarily for hypo- or hyperglycemic emergencies, when caregivers of other people in the vicinity are expected to perform the test. Detailed instructions are included for those who are not familiar with a testing procedure as well as animations on screen to indicate the various operations in strip insertion, lancing, blood deposition and reading. Suggestions on emergency numbers and medical teams also provided as necessary. Hypoglycemia can result in low blood sugars – therefore suggestions on carbohydrate intake based on American Diabetes Association recommendations for various reading levels also included.

F. Basic Mode – a quick testing procedure which does not include informative feedback. This is aimed primarily at users with time constraints and those who do not wish to have informative feedback. This mode is accessed by inserting the strip and the meter asking a simple question for quick testing.

4.8.2.3 Software Prototype

Team Abbott built a software prototype of the Kid Mode on the Macromedia Flash platform with a functioning interface based on the Vampagucci V2.0's physical appearance. The interface had buttons which were clickable to simulate the actual pressing of the buttons and the menu navigation systems responded to this as they would have on an actual meter.

Demonstration of the prototype with children at the Lucile Packard Children's Hospital clinics yielded excitement and positive response towards the appearance and navigation in the prototype.

4.8.3 Physical Prototype

4.8.3.1 Vampagucci[7] V1.0

The Vampagucci V1.0 was an autumn quarter prototype meant to help the team examine secondary feedback methods. That is, it experimented with giving users extra sensory feedback using LED's, vibrating pager motors, and piezo buzzers. Experiments included rudimentary games where subjects were asked to watch the prototype as if it were instructional while performing a simply game task such as moving a game piece around a game board. Subjects were asked to act on what they interpreted the various light, sound, or vibration signals to mean.

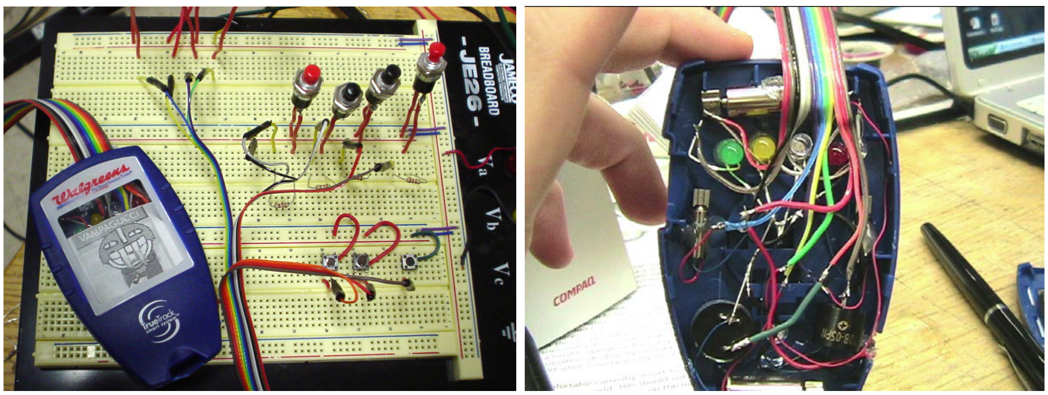

Figure 41 - Vampagucci V1.0 with manually operated LED's, motors, and buzzers

Specifications

- Dimensions: 3” x 2” x 0.7”
- Casing recycled from a Walgreen branded glucose meter
- 4 LED’s: Red, Green, Blue, Yellow
- 4 vibration motors
- 3 piezo electric buzzers

What was learned

Three main observations were made as a result of the Vampagucci V1.0 experiments:

- Inconsistent signals made the users step backwards in their incremental progress
- Subjects seem to remember the light (LED) patterns better than any other
- Subjects did not have universal, nor predictable, interpretations of signals or even colors. i.e. Red is seen as “warm” in Sweden, and not necessarily alarming. Blue equates to an unwelcome chill.

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[7] The name “Vampagucci” is play on Vampire and Tomogotchi, tying blood and children’s toy together

4.8.3.2 Vampagucci V2.0

The Vampagucci V2.0 was developed in the middle of the winter quarter as the first system prototype (versus previous component/function prototypes). It makes initial steps toward a whole solution by including the internal components of functional glucose meter, as well as new features being explored by the project team.

Goals for this prototype included:

1. Make a playful design for the child user
2. Explore innovative mechanically interfaces
3. Deliver system level functionality

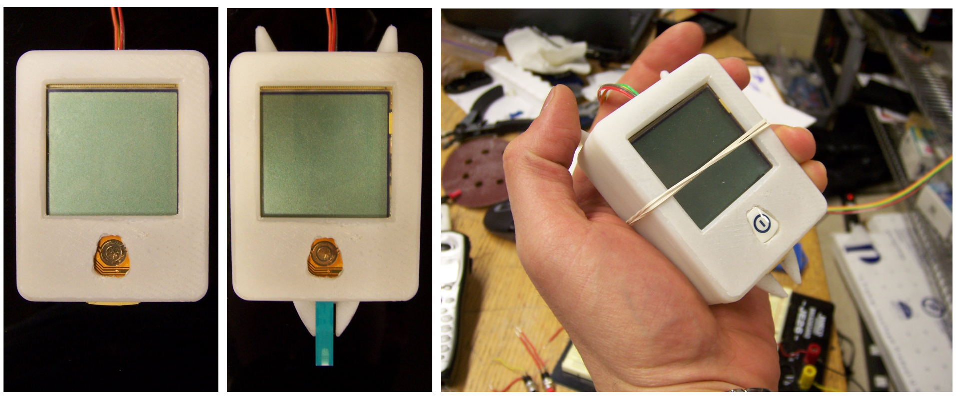

Figure 42 - Vampagucci V2.0 with retracting “horn” buttons and "teeth" Guiding Rod

Specifications

- Dimensions: 3” x 2.5” x 1”
- Retractable Horns (buttons) and Teeth (guiding rod[8])
- Abbott’s Precision Xceed glucose meter electronics
- ABS plastic (FDM fabrication[9])
- 3 tactile button switches
- 1 mouse jog wheel

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[8] See Guiding Rod section below

[9] http://prl.stanford.edu/tools/machineshop.htm - Stratasys FDM2000

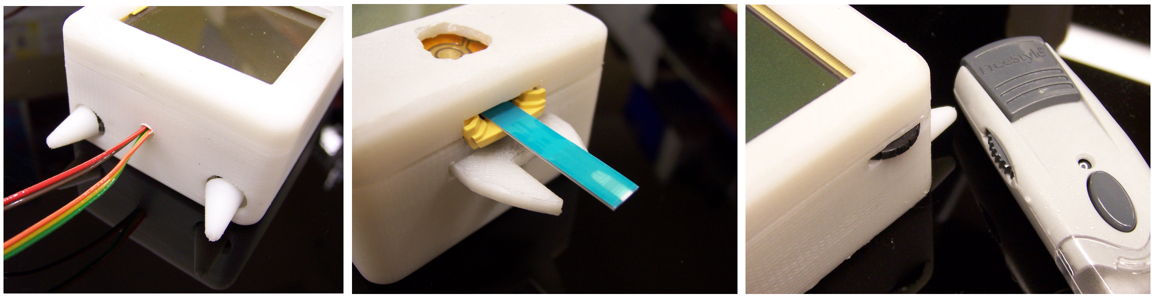


Figure 43 - Vampagucci V2.0 features horns, teeth, and a jog wheel in addition to functioning glucose meter electronics

Features

Towards those goals and in keeping with the name, the Vampagucci V2.0 includes hidden, horn-like buttons which pop out when the meter is turned on (Figure 42). When hidden, the meter has a streamlined profile. When revealed, they give the meter a character look and provide a distinct interface through the buttons under the horns. The Xceed meter's original buttons were rewired so that they could be operated by pressing on these horn buttons.

The prototype also includes a jog wheel in anticipation of the new features discussed in Section 4.8.2. Finally, the V2.0 features "teeth" at the bottom (Figure 43 middle) which were the result of a Guiding Rod concept developed in conjunction with the Luleå partner team (discussed below).

The new casing was fabricated in the PRL's FDM rapid prototyping machine. The button retraction was mechanized using a miniature DC motor configured with a rack and pinion system to drive both the teeth and the horns simultaneously. The jog wheel was scavenged from a miniature computer mouse, and the glucose meter was taken from Abbott's Precision Xceed product.

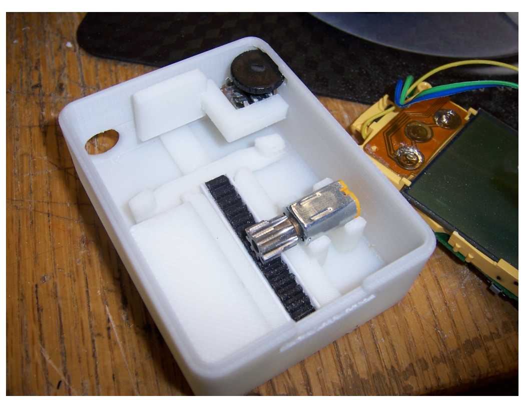


Figure 44 - Rack and pinion setup

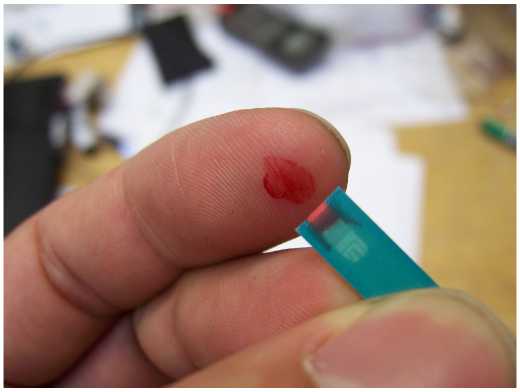


Figure 46 – Normal test strip use can smear blood, preventing effective filling (strip seen here was only partially filled)

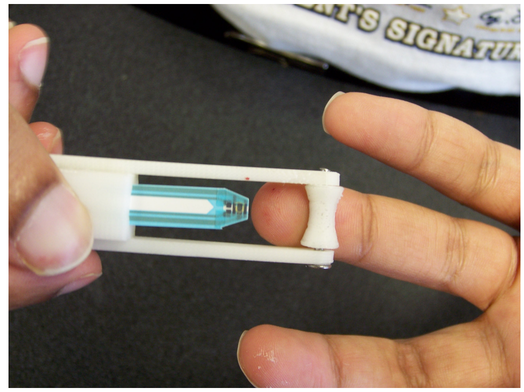


Figure 45 - Roller version of the Guiding Rod helps aim test strip and prevents smearing

Guiding Rod

The teeth Guiding Rod add-on feature was a concept conceived by the Luleå partners. Together, both teams designed a number of ways to implement the concept (See Appendix: Guiding Rod). The idea is to support and steady the user's finger against part of the meter such that it is easier to align the finger and its blood sample to the small sampling port on the test strip.

The idea was born from observations when the team members tested themselves over several days and found that a large percentage of any given blood sample was often wasted if the test strip was allowed to smear the blood sample. Smearing was quite easy if the user was not absolutely careful in aligning the blood spot and the test strip's port.

Thus, an implement to "connect" the meter and finger prior to applying blood to the strip port was conceived. The teeth version seen on the V2.0 is meant to straddle the finger, and allow surer application of blood to the strip and increase sample efficacy.

What was learned

First, accommodating the components of the preexisting meter was awkward. Discussions with the liaison concluded that the team need not attempt to make medically functional prototype. That is, integrated electronics are not required of the final prototype. It is beyond the scope of the project to attempt an absolutely functional system. Up until that point, this statement was left largely tacit. Now it is fully understood by both groups. Shape, form, and a representation of intended features are all that the team need to deliver in June.

Second, predictably, the rack and pinion system was both un-reliable and bulky, adding significant volume to the V2.0 prototype. It was used as a quick means to the end of having mechanized buttons. However, it is too intricate a mechanism for the function it is performing. If the mechanized buttons are kept, simpler methods will be explored.

The coach Victor Scheinman has already suggested a couple of promising piezo electric actuators for this path.

The Abbott liaison deemed the V2.0 interesting but “180 degrees from anything Abbott would put out.” The vampire theme is too vivid a characterization, and might be found offensive to consumers. In contrast, diabetes experts at Stanford Packard Children’s Hospital said it was a rather fun idea.

4.8.4 Final Design

4.8.4.1 Guiding precepts on vision

The guiding precepts developed to guide the project team through winter quarter are still valid going forward.

Those linked precepts are:

1. Deliver easier and Less Conspicuous Blood Glucose Testing
2. For more Frequent Testing
3. For more Relevant Data
4. To Convey data as Relevant Information
5. For both the User and Physician/Nurses
6. So as to deliver effective medical care that improves wellbeing

4.8.4.2 Reaching the Deliverables

Operant Conditioning

The Luleå partners have been developing a key notion for the proposed software feature set, Operant Conditioning. Essentially, the teams’ aim in using it is to provoke desirable behavioral modification through subtle control of positive stimuli. No conspicuously negative stimuli will be used so as to prevent associating feelings of unease with the meter. Luleå has developed some clear ideas on how to implement this:

How can we use this?

The need to improve the children’s behaviour in certain areas is supported by Ann-Christine Bohman, a diabetic nurse at Sunderbyn Hospital, Luleå. She says that the biggest issues for children aren’t doing the measuring but to keep doing it on a regular basis. The actions needed to perform a glucose-test can be done by most 7-year olds but they have difficulties with their continuity. It is easy to see in the H1Ac-charts when a child has been given too much responsibility by their parents, she says.

So the team developed a list of different types of Good and Bad behaviour. This is important to know when deciding what behaviour to reinforce since trying to improve overall diabetes performance must be divided into smaller tasks.

Good behaviors

- Good values
- Eat regularly
- Test glucose regularly (or whenever planned)
- Take insulin at the right time
- Play active games (get exercise)
- Treat bad values

Bad behaviors

- Bad values
- Eat irregularly
- Doesn't test blood glucose
- Doesn't take insulin
- Doesn't treat bad values

It is also possible to modify Bad behaviour, but the method has to be chosen carefully to avoid triggering other negative responses, such as a decreased trust in our glucose meter, or uneasy feelings about doing blood samples at all. It is also more effective to decrease unwanted behaviour by reinforcing wanted behaviour.

Since we have limited opportunities to give out rewards to the user of the meter, we need to interact with the user in a smart way.

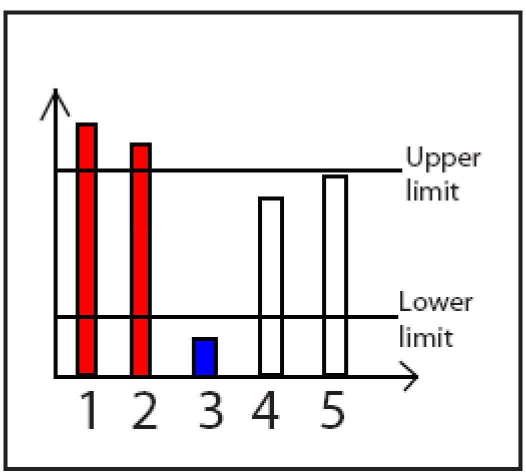


Figure 47 - Bad Value

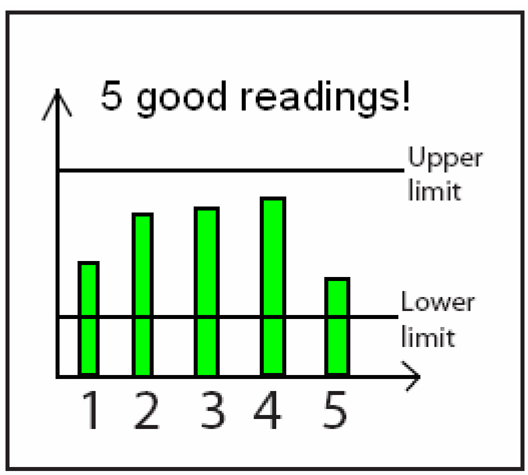


Figure 48 - Good values

The displays above are a proposal on how to display the history of readings in a simple but effective way, to convey information while simultaneously making it very obvious to the user that the results in the first display is not acceptable but the results in the second are very good. The positive stimulus that the user is exposed to is simply the good feeling of success. To improve the feeling of success the positive colour green is used when all five values are good and the success is also pointed out in text.

The bad values in Figure 47 are coloured to make them obvious, but there is no need to explicitly point out the shortcoming further. The user is already aware that these results are bad. We do not want to appear too judgemental and make them uneasy about using the meter in the future.

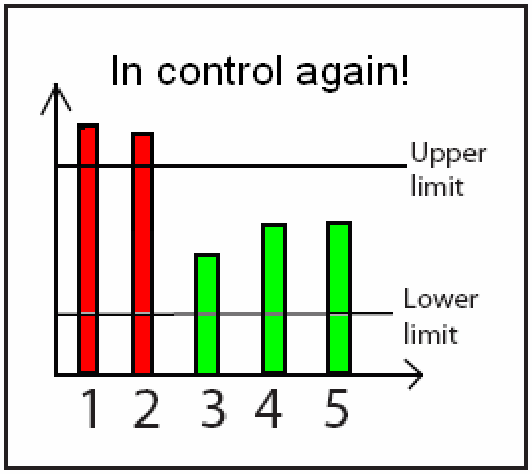


Figure 49 - In control again

Instead, we can point out when the user manages to take control again and has managed to break a series of bad readings.

These small examples are quite modest in their praising of the user, but there is a thought with that. Since the users are diabetics and have to do their readings in a timely for years to come, it is important that they do not grow tired of the meter's remarks. The behaviour will not change overnight but that is not required.

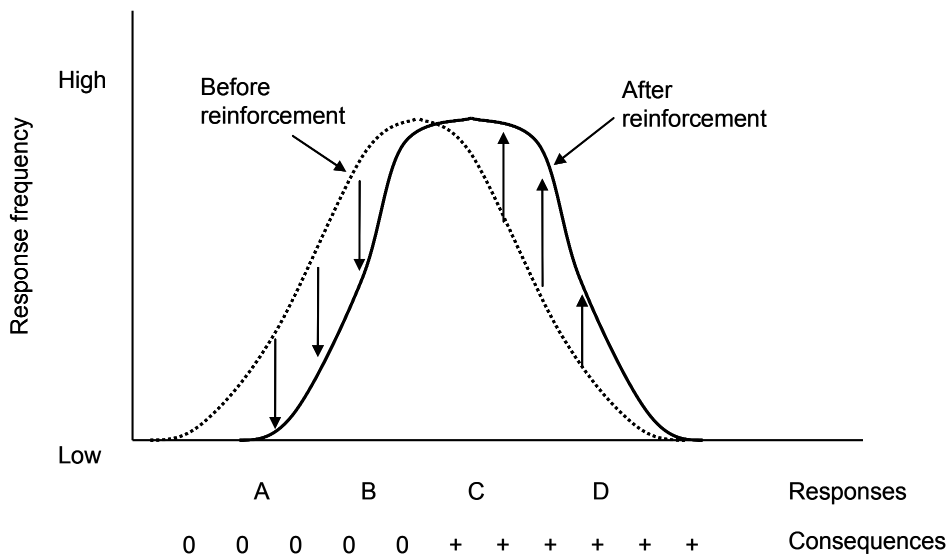


Figure 50 - Effects of differential reinforcement. A, B are unwanted behaviour, C and D are desired behavior. 0 indicates no feedback and + indicates that positive stimuli is given. [10]

[10] The graph is taken from Behaviour Principles on everyday life, *JD Baldwin, JI Baldwin 1998*

The graph above shows that with small but repeated exposure to positive reinforcement, the possibility for the outcome is gradually moved towards the desired response.

Physical Prototyping

Dial Vial

The Dial Vial was a key concept late in the Winter quarter. Its design was used as a way to explore a different design path than the Vampagucci series. The Dial Vial does away with the intricacies of retractable buttons and tries to appeal to the more precocious children the team encounter at clinics, who seemed to be more interested in technologically savvy devices. It was designed with a smooth, yet angular look in an altogether different shape than most meters on the market today.

The next chapter of this report details the greatly refined meter that sprung from this concept to become the final design of the deliverable hardware prototype.

Figure 51 - Dial Vial CAD model

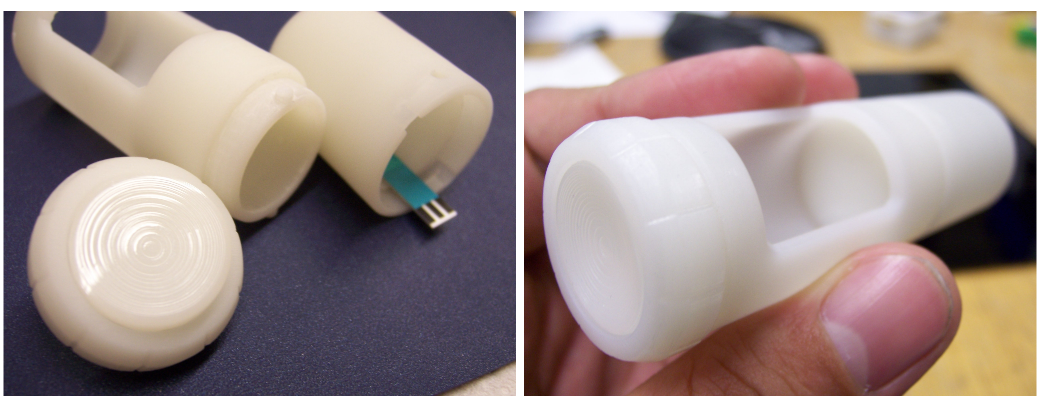


Figure 52 - Dial Vial SLA prototypes, components and assembled

Synergies

Additionally, the team realized while developing the mode flowcharts that navigating these menus and inputting information would be daunting without a synergistic improvement to the physical interface. Thus, a significant development area was to bring the software structure and the hardware interface in sync with each other. That is, as with the Apple iPod, make the device easy to navigate and use even with a dense software feature set. After all, new features are worthless if the user isn't willing and able to use them.

5. Design Specifications

5.1 Hardware Overview

One of the two focal points of the Twist design was improving the appearance of glucose meters, including their physical shape and control interface. This was accomplished through an ergonomic and visual design approach. Parameters such as usability, placement of functional details, and form and design elements that are appealing to the target user have been taken into consideration.

In choosing pediatric diabetics, the team sought to center its attention on a user group, and thus specialize its understanding of the needs of these users. In this way, design elements can be crafted to convey appropriate messages to the user. Form, proportion, and scale were used to integrate the product into a whole unit. Through these elements, it was possible to communicate not only how the product is supposed to be used, but also the quality and value of the product.

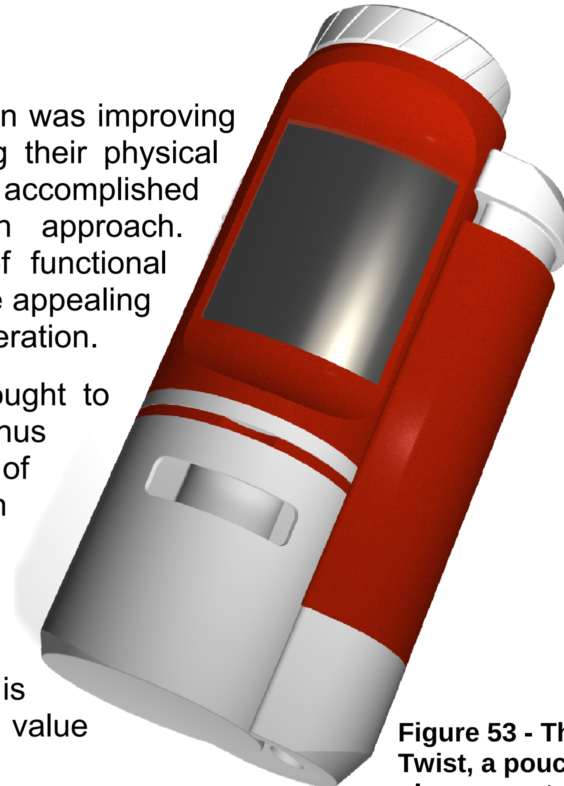


Figure 53 - The Twist, a pouchless glucose meter system

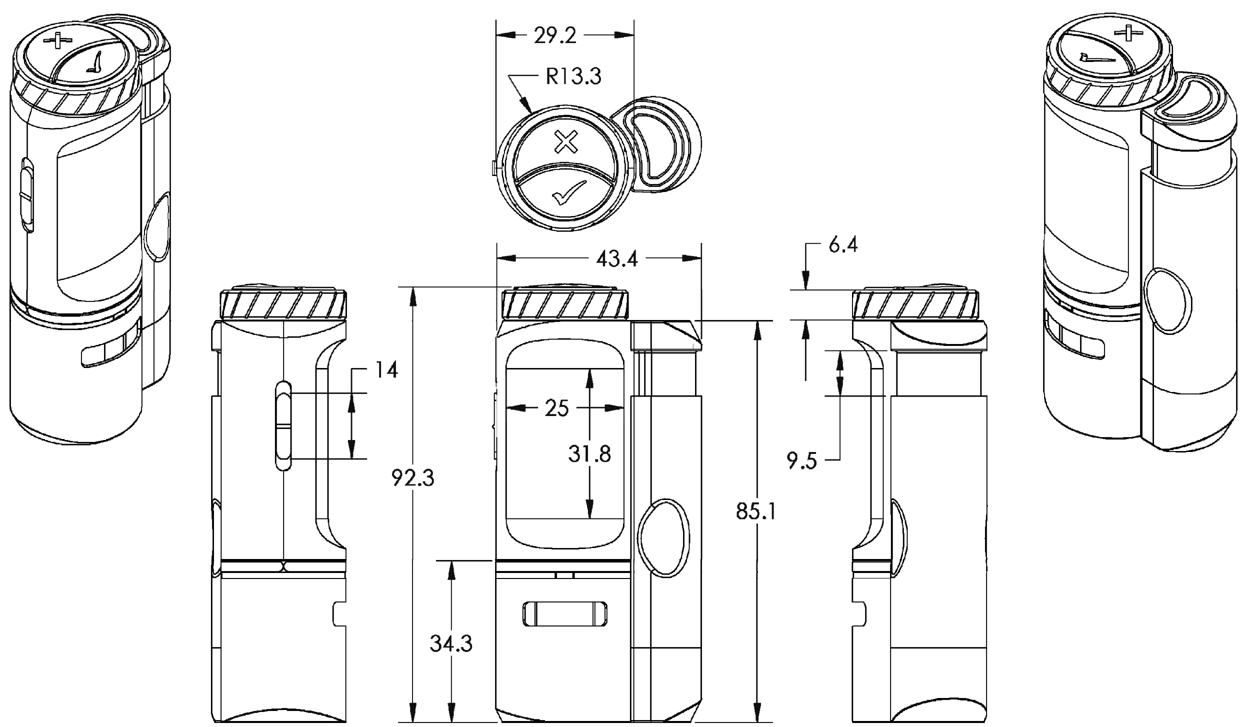


Figure 54 - CAD drawings of the Twist design (dimensions in millimeters)

5.1.1 Twist Glucose Meter

Dimensions:

Mass:	55 g
Length x Width x Depth:	92 x 42 x 27 mm
Scroll Wheel:	26.6 mm OD x 6.4 mm

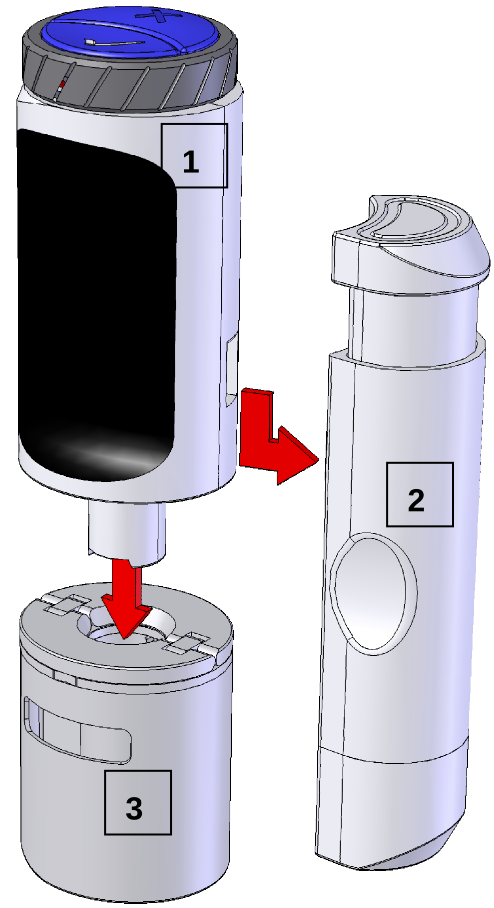


Figure 55 - Twist's components: (1) Meter, (2) Lancet, and (3) Vial. Quick snap-on modules

The Twist is a complete, three-component system, including: the meter, lancet, and strip vial. It does away with the pouch and kit common to currently available meters in favor of a singular, modular device. This reduces the system's size to less than one-third the physical volume of current meter systems[11]. When the time comes, the three components separate quickly to perform a glucose measurement.

The round, cylindrical shape was chosen to make the meter comfortable to hold in the hand, and provide a steady grip for the child when they take glucose measurements. It also has no sharp edges, thus making it sleek and easy to slip into a pocket.

Most of all, the round shape is congruous with the prominent scroll wheel interface, which along with two buttons, is located on the top of the Twist, make up the entire control interface. This simplified arrangement provides improved usability for the child. Through these co-located controls, the child can easily manipulate the meter with only one hand. The scroll wheel in particular serves to enhance the speed and ease of navigating the software system, as well as quick entry of numerical values such as carbohydrate intake.

[11] The Twist's volume is ~105 cc compared to the Freestyle Mini's pouch volume of ~325 cc.

5.1.1.1 The Meter

The meter component of the Twist, itself measuring 72 x 30 x 27 mm (L x W x D), is the heart of the glucose measurement system. Its control arrangement will be unique in the marketplace, consisting primarily of dual buttons and a thumb-dial. The thumb-dial improves on past meter controls by converting what can be dozens of button presses into just a twist of the thumb-dial. Example of this includes menu navigation, or the entering of carbohydrate intake, etc. The selection buttons are then located right on top of the thumb-dial so that all navigation buttons are in one place. To help users differentiate buttons, each one is inversely curved. The front, or *select*, button is concave while the rear, or *cancel*, button is convex.

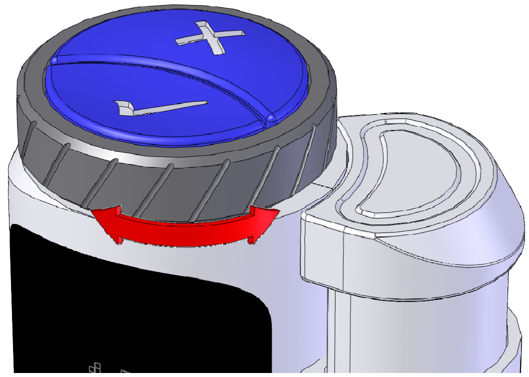


Figure 56 – Concave/convex dual buttons & thumb-dial combination

In addition to these dual buttons and the thumb-dial, there is a secondary three-position sliding switch on the side (Figure 57). The switch's three positions can turn the meter off, on, or activate the meter's display backlight and flashlight.

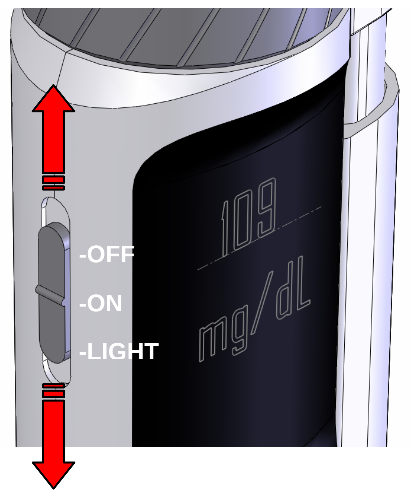


Figure 57 - Three-position slider switch turns meter on/off and activates flashlight/backlight

At the bottom of the meter are the strip port, guiding rod, and flashlight. A white-light LED is the illumination source, splitting its light among backlighting the display, shining out the flashlight hole, and streaming down the guiding rod.

Features:

- Dual Buttons + Scroll Wheel combination
- Alternative slider switch
- Guiding Rod
- LED Flashlight/Backlight
- Imitation dot matrix display
    - Black & White image
    - Anticipated 165 pixel x 210 pixel resolution (eInk technology specs.)

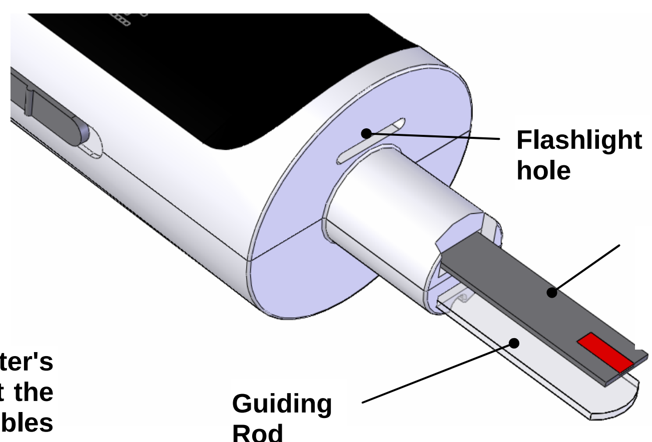


Figure 58 - Twist meter's strip port is located at the bottom, where it doubles as an interface to the strip vial.

5.1.1.2 The Vial

The Twist's strip vial is a disposable component which introduced a dual chamber configuration. The front chamber carries fresh test strip, while the rear chamber accepts spent test strips. The configuration keeps these strips separated but in one container, allowing easy disposal of the used strips by discarding the whole vial once all the fresh strips are spent. It is then replaced with a fresh vial of strips. The spent strip chamber is filled via a narrow opening which prevents spent strips from being accidentally reused.

Features:

- Dual-compartments
    - Fresh strip chamber (40 Strip Capacity)
    - New Integrated disposal chamber
- Entirely discernable
- Dual function: Test Strip Container, and cap for meter strip port

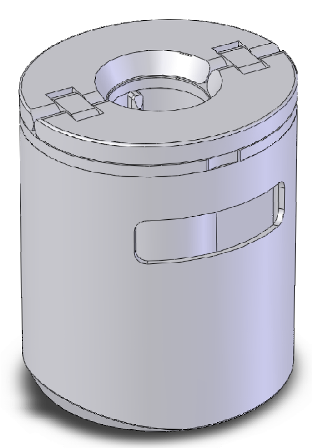


Figure 59 – Twist's test strip vial, meter's port fits into central opening so that the vial serves as a protective cap for the strip port

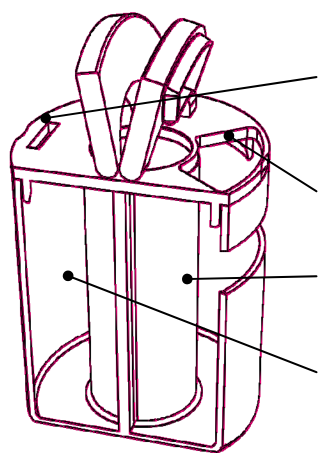


Figure 60 - New Test Strip Vial with dual chambers and differentiated

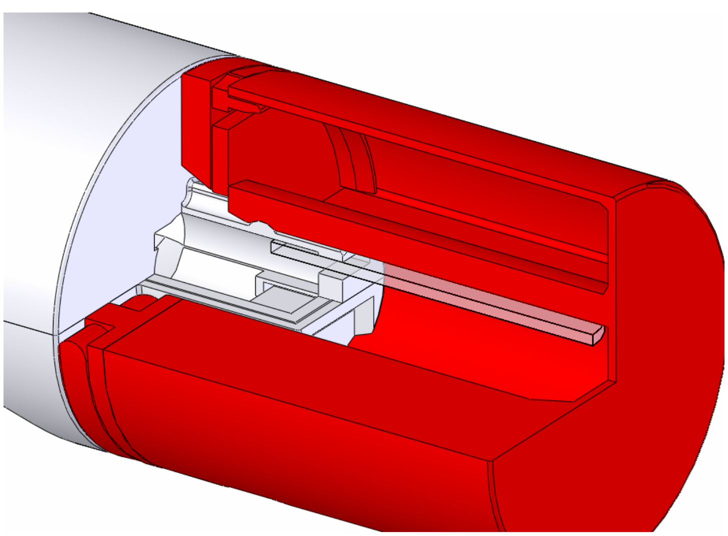
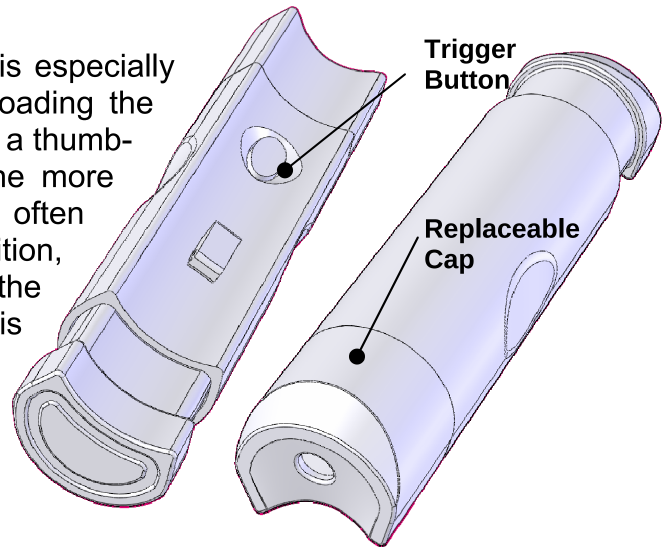


Figure 61 - The meter's port slips into the vials central cavity, and is secured by a small detent. The vial is in red.

5.1.1.3 The Lancet

The Twist's new lancet, like the meter, is especially design for one handed operation. Pre-loading the lancing mechanism is accomplished with a thumb-press of a sturdy button rather than the more common cap-pulling motion which often requires two-hands to pre-load. In addition, the lancet's trigger button is located on the inside face of the lancet. When it is attached to the meter, this prevents the button from being pressed by accident, as the button can only be reached when the lancet is separated from the meter module.



Features:

- Push button pre-loading
- One-handed operation
- Safety trigger location

Figure 62 – Quick push-button action enables one-handed operation, safe trigger location prevent accidental finger pricking in pocket

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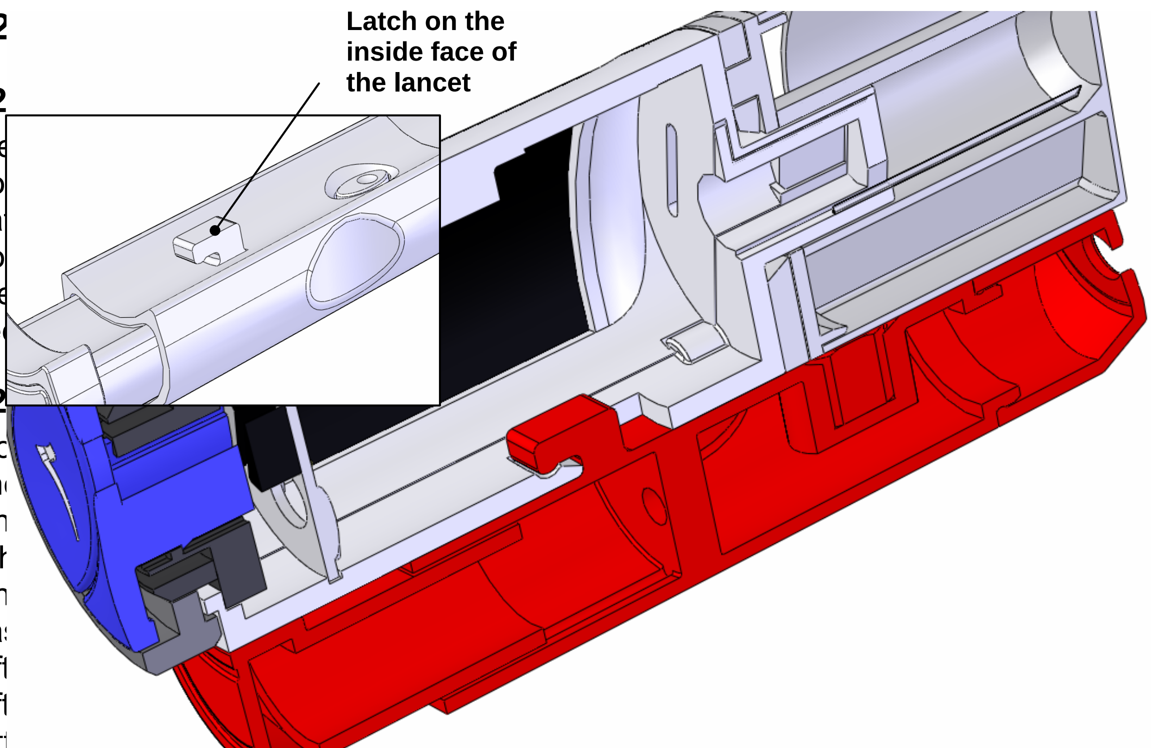


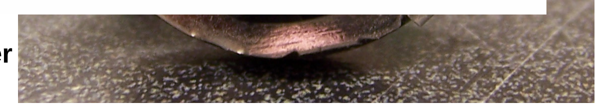
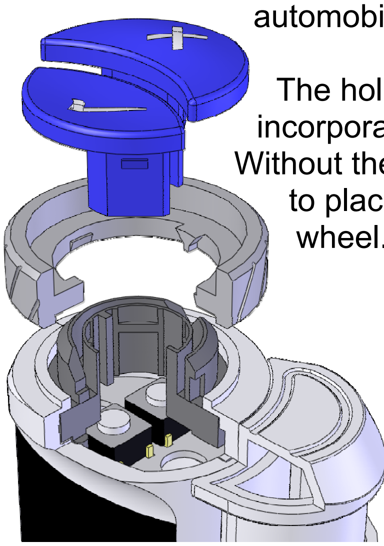


Figure 63 – Lancet (in red) latches onto meter
the meter.

The mouse was modified in a number of ways to make this interaction possible. First, the PCB was trimmed to its most minimal size and many traces were replaced with soldered leads. In addition, the original left and middle mouse buttons where replaced with two tactile switches. Most importantly, the mouse's shaft-style encoder for the scroll wheel was replaced with a hollow shaft encoder (Figure 64) normally used in automobile stereos.



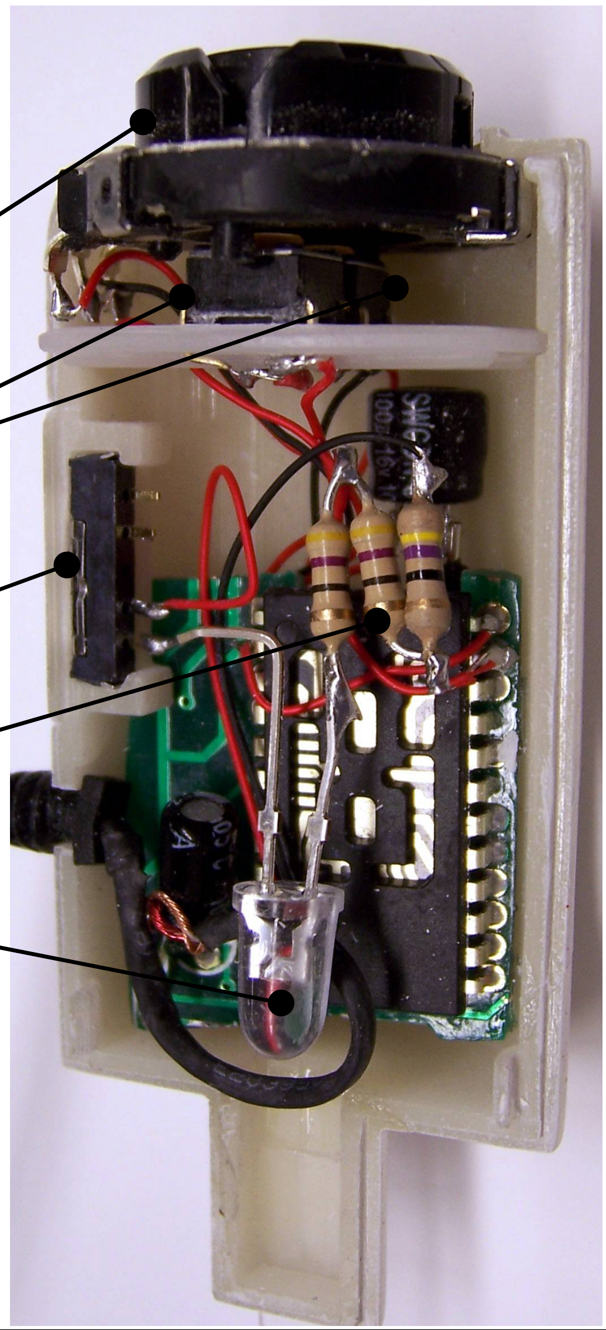
The hollow shaft encoder was crucial to allow the Twist to incorporate the two stationary buttons on top of its scroll wheel. Without the encoder's central opening, there was no reasonable way to place stationary buttons on top of an unlimited rotation scroll wheel.

Figure 65 - Buttons are inserted through the hollow shaft encoder

Table 8 – Electronic Component List:

Qty	Manu.	Components	Model No.
1	Inland	u-Scroll mini optical mouse	7044
1	ALPS	23mm Hollow Shaft Encoder – 20 detent	SRGP200200
2	ALPS	Tactile Momentary Switch	###
1	Mountain Switch	SP3T SMD Switch (on-on-on)	103-5033-EV
3	Generic	47 Ohm Resistor	Generic
1	Coast	White LED 10000MCD	TT7803CP

Figure 66 - Trimmed mouse PCB with added LED, resistors, switch, and encoder.



5.3 Software Overview

Team Abbott has designed a computer based interactive demonstration to allow *Twist* users to experience the Twist's proposed embedded firmware package. The interactive demonstration is a stand alone application coded in Macromedia Flash Studio 8.0, allowing the user to interact with a visually accurate representation of the Twist in a web-browser window. The interface initially was operable by a keyboard, using keys to simulate the pressing of the buttons on the meter, and to allow for menu navigation as one would experience on the meter. This has since been upgraded to respond to the press of buttons embedded in the Twist handheld prototype detailed previously, but the team has been careful to retain both methods of controlling the software. Demonstration of the software with children at the Lucile Packard Children's Hospital clinics yielded excitement and positive response towards the appearance and navigation of the Twist, proving to be a cost effective approach to ensuring user acceptance before developing final prototypes. In fact, user testing has confirmed that the current software package adheres to Team Abbot's design requirements of being informative in a timely manner.

Figure 67 - Initial screen on interactive Flash demonstration. This is the software prototype developed for Abbott Diabetes Care, allowing potential users to explore the software structure of the Twist glucose meter.

5.3.1 Informative Feedback in the software

The software developed by Team Abbott was set up to provide Informative Feedback to Twist users, enabling and encouraging them to better self-manage their diabetes. This concept was generated during Team Abbott's interactions and benchmarking efforts in the Fall and Winter quarters, as documented in the previous chapters. To date, the efficient management of information concept has been realized in the following way;

The software now assists the user in completing the following tasks:

- Setting up a diabetes management plan, following it and watching it in action
- Generating correlations between lifestyle and health
- Tracking and correlating insulin and carbohydrate intake
- Realizing cause and effect relationships by seeing 'smart' averages

Setting up a plan involves some of the most important aspects of a diabetic's lifestyle: nutrition, exercise, and insulin intake (and/or other medication). While these plans have to be developed in consultation with the patient's physician, the software in the meter can know the time and quantity, or total dosage, of these parameters, and the schedule on which these have to be taken.

Figure 68 - Screenshots of the meter showing the implementation and tracking of the food plan. From left to right: Meal entry is made by menu selection - Carbohydrate intake is entered - Twist presents correlation/plan performance information

The Twist's software also helps the user follow their plan by presenting them with information pertinent to the time of the day, so that the user can perform actions accordingly, and in time derive any changes necessary in response to deviations from their expected health goals.

Figure 69 - A screenshot of the meter displaying the present blood sugar reading, the average at that time of day, and the target for that time of day. This is an example of informative feedback – showing the user what the plan should be, the user's performance as has been measured over the last few days at that time, and where the user stands right now.

When the software presents the user with information as depicted in Figure 69, the user is enabled to derive correlation between various day-to-day activities and readings. This allows the user to derive links between various incidents of low or high readings and certain activities which might otherwise escape the attention of a user not tracking those parameters. By helping the user derive correlations between certain types of food, the time of the day, exercise patterns, mood swings, testing location, or other parameters which affect blood sugar levels, the software package has achieving its objective of providing informative feedback.

5.3.2 Software Modes

Team Abbott developed various 'modes' of operation to make informative feedback manageable. The intention here was to help users with varying levels of diabetes management training, as well as differing comfort levels, to adjust their meter to their expectations. A high level representation of user interaction with the different modes is pictured below. The arrows depict the direction of information flow.

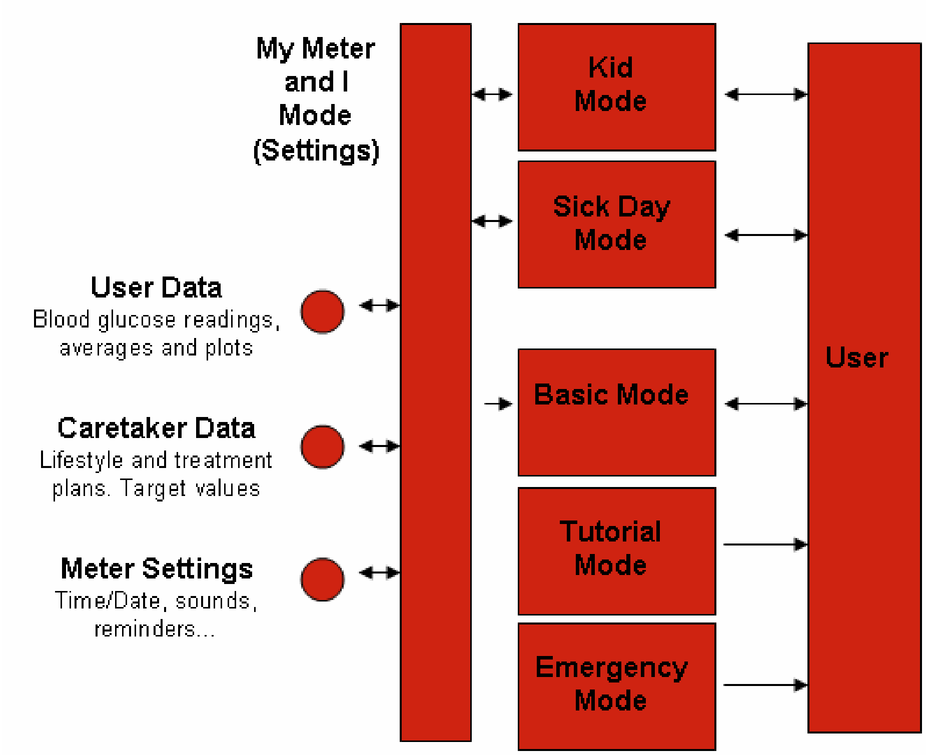


Figure 70 – The operational modes under which a user can choose to interact with the Twist meter. User data, caretaker data, and meter settings are stored in My Meter and I mode, which governs Kid, Sick Day, and Basic Mode. Tutorial and Emergency mode provide a static set of instructions to the user.

Figure 70 above shows the Twist's various software modes. In conjunction with their CDE, a user gives the meter information about their optimal nutrition, exercise, and glucose levels (User Data and Caretaker Data), which is stored in a settings database, My Meter and I. The user chooses their sound, reminder, alarm, and time/date settings (Meter Settings) here as well. When conducting a blood sugar test, the user elects to use Kid, Sick Day, or Basic Mode, all of which draw upon and make correlations about information stored in My Meter and I to varying degrees. Table 9, as follows, provides a brief description of each of the modes.

Table 9 – Description of the Twist's operational modes, their inputs and outputs, and how to access them.

Mode	Description	Inputs	Outputs	How Accessed
My Meter and I (Settings)	Database of user's goals for nutrition, exercise, and blood sugar levels; audio, visual settings stored here too	User provides optimal nutrition, exercise, and glucose levels plus personal meter preferences	Nutrition, exercise, and glucose information provided to Kid, Sick Day, and Basic Modes	Long (3 second) press of 'X' button
Kid	Primary operational mode, providing informative feedback to user	User provides test strip and latest/actual nutrition and exercise information	Correlations and smart averages evaluating user's adherence to nutrition, exercise, and glucose goals	Through My Meter and I Mode; Twist has Kid Mode set as default
Sick Day	Mode allowing for temporary changes in user's body chemistry	User provides test strip and blood ketone information	Blood sugar level and insulin suggestions	Through My Meter and I Mode
Basic	Only measures blood sugar level	User provides test strip	Blood sugar level	By inserting test strip
Tutorial	Mode to explain how to conduct a test, use meter, and manage diabetes	No inputs provided, this is a static mode	Testing, meter usage, and diabetes management information	Through My Meter and I Mode
Emergency	Mode providing step by step instructions for a passerby to conduct a test on a hyper- or hypo-glycemic patient	User provides test strip	Blood sugar level and emergency care instructions	Long (3 second) press of both 'Check' and 'X' buttons

It was found that by allowing users to select which operational mode is most suitable to them; users have been able to keep testing time below a minute when using Kid Mode, and less than 15 seconds when using Basic Mode. To ensure a thorough yet manageable software architecture, complete screen by screen decision trees were created, representing the entire software structure. The streamlined trees can be found in the Appendix.

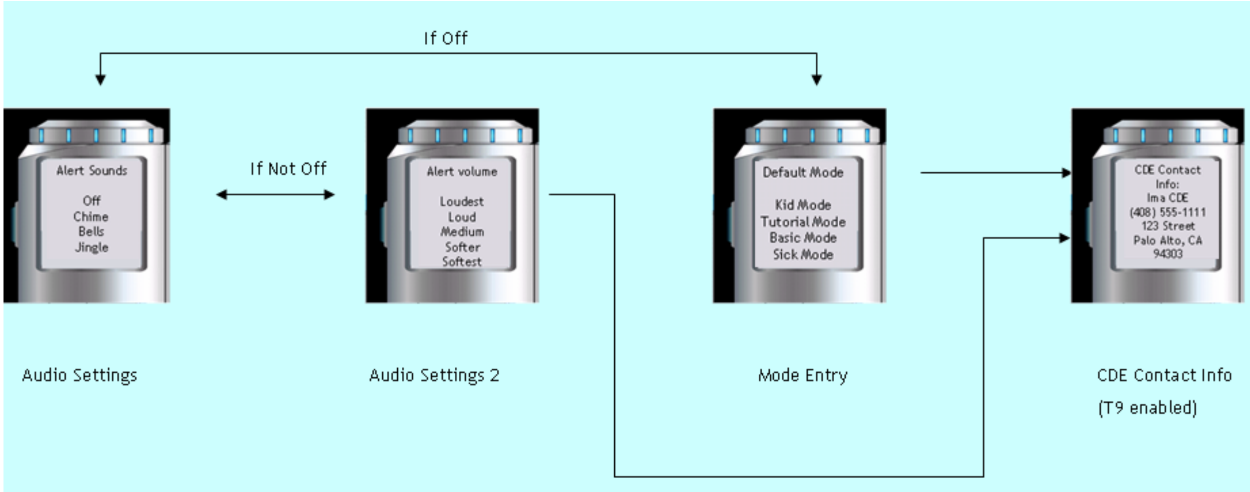


Figure 71 - A portion of the software flowchart for 'Settings', as laid out before programming commenced

These decision trees were the foundation for the following software modes, each contributing to informative feedback in a different manner:

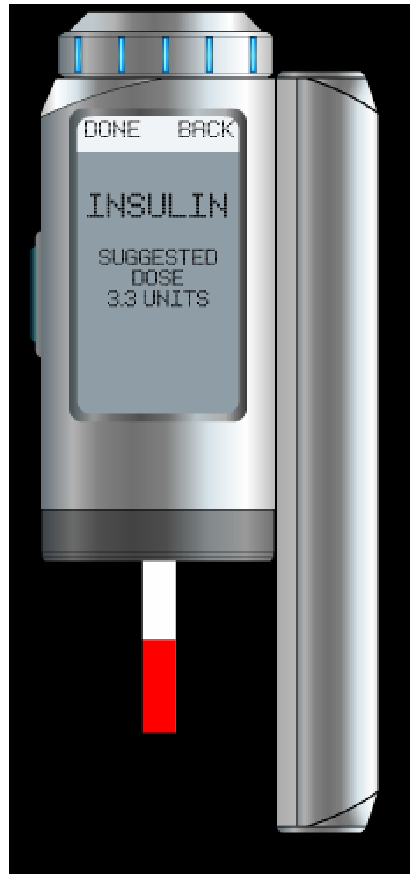
5.3.2.1 Kid Mode

Kid Mode is the default mode in which informative feedback manifests itself completely. This is the mode where the correlations as to nutrition, exercise and other lifestyle options are tracked and informative feedback is provided to user.

Figure 72 – In Kid mode, a series of quick prompts are used to collect data from the user for Informative Feedback.

The user can input the data which he/ she chooses into the meter using the thumb-dial and button controls. The meter uses these inputs, the knowledge about the user (from My Meter and I), an Insulin and Carbohydrate Correlation and Tracking Algorithm written by Team Abbott, and the user's recent testing history to provide suggestions for future dosages of insulin.

Figure 73 - Screenshot of the result of the insulin and carbohydrate correlation and tracking algorithm – an insulin dosage suggestion.



Kid Mode also implements Operant Conditioning by taking advantage of the 10 second waiting period before the result screen is displayed. In fact, one of 3 events or types of information can appear randomly on the screen during that period:

- A tip about general health or diabetes, taken from a database of such tips that could be accessed through tutorial mode
- Data regarding the user's performance: an average over a given time period and over the last 4 days, or a plot of the results over the same time window
- The symptom recognition test: the user is asked to assess his blood glucose concentration prior to the display of the actual results, by qualifying it as High, Good or Low. After the result screen in Figure 69 - A screenshot of the meter displaying the present blood sugar reading, the average at that time of day, and the target for that time of day. This is an example of informative feedback – showing the user what the plan should be, the user's performance as has been measured over the last few days at that time, and where the user stands right now. the user is informed whether he was right or wrong: "Match! Good

job!" or "Mismatch" appear on the screen. The team hopes that the symptom recognition test would allow the users on the long run to identify their body's reaction to Hypoglycemia or Hyperglycemia by teaching them to recognize the symptoms. Preemptive action can therefore be taken to avoid further complications.

Figure 74 - Implementation of the Symptom Recognition Test

5.3.2.2 Tutorial Mode

Tutorial mode teaches the user:

- How to use the meter
- About self management of diabetes
- About diabetes itself

The tutorial mode is accessible through the My Meter and I menu. This mode contains a repository of tips and pointers for the user which also appear in Kid mode at intervals chosen in the settings. (see Appendix for decision tree)

Figure 75 - Screenshot from Tutorial Mode, demonstrating to the user where they can lance their finger.

5.3.2.3 My Meter and I (Settings)

My Meter and I, or Settings Mode, is the mode in which the user inputs his/her personal data and preferences. This includes their age, name, weight, gender, and body mass index, as well as preferences as to the type, frequency and the method of reminders and tips. Under password protection, the user and their CDE also enter insulin type, quantity, and scheduling information here. Again under password protection, similar data is stored for nutrition and exercise planning.

My Meter and I also serves as a repository for the data used to compute smart averages over the last 5, 15 and 30 days at the approximate time of the day (modal averages for periods such as “before breakfast,” “after lunch,” etc). This is contrasted against the block 30 and 60 day averages which existing meters store. Physicians say that these types of lump sum averages are medically irrelevant compared to averages specific to the time of day that the blood sugar test is being conducted.

My Meter and I supports the operation of Kid, Sick Day, and Basic Modes. The data provided to the Twist during these modes is compared to their optimal values and is then reported to the user. This informative feedback updates the user on how well they are adhering to their nutritional, exercise, and overall blood sugar maintenance plans. My Meter and I also supports the Insulin and Carbohydrate Correlation and Tracking Algorithm’s ability to make insulin dosage suggestions and reminders (see appendix for decision tree).

5.3.2.4 Sick Day Mode

During times of illnesses the body’s metabolism changes such that insulin absorption and nutrition needs change. It is during these days that the Sick Day mode allows for temporary fluctuations in nutrition and exercise, making the appropriate insulin dosage recommendations. Sick Day mode also indicates ketone levels for these anomalous days and indicates if a visit to the doctor is necessary (see appendix for decision tree).

5.3.2.5 Emergency Mode

Emergency Mode is primarily for hypo- or hyperglycemic emergencies, when caregivers or other people in the vicinity are expected to perform the test when the user is unable to perform one them self. A sticker on the back of the Twist shows what needs to be done to determine the patient's blood sugar level, and what steps must be taken to correct their blood sugar level. Pressing and holding the Twist's *select* and *cancel* buttons simultaneously for 3 seconds pulls up detailed instructions on-screen for those who are not familiar with a testing procedure. Animation to depict various operations in strip insertion, lancing, blood deposition and reading also appear, followed by medication suggestions and emergency phone numbers. Hypoglycemia can result in low blood sugar – therefore suggestions on carbohydrate intake based on American Diabetes Association are included.

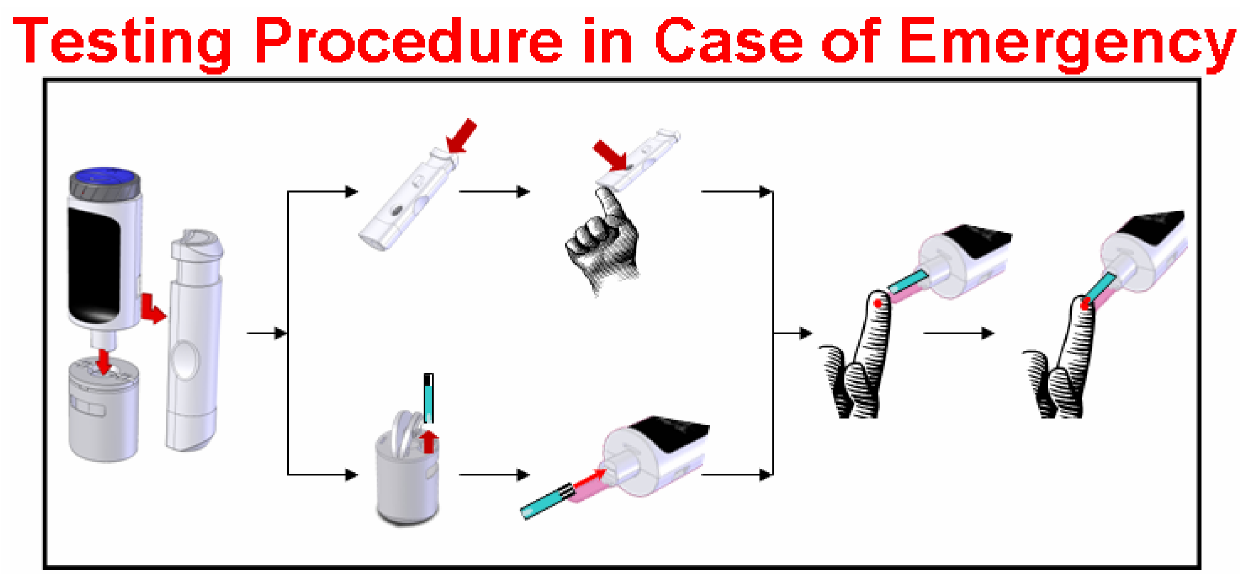


Figure 76 – Sticker on backside of the Twist to show someone unfamiliar with blood sugar level testing what to do if a patient is having a hyper- or hypoglycemic emergency.

5.3.2.6 Basic Mode

Basic Mode allows for a quick blood sugar level test and does not include informative feedback. This is aimed primarily at users with time constraints and those who do not wish to have averages and correlations presented to them. In this mode, the user simply inserts a test strip and is presented with their current glucose level shortly after depositing blood(see appendix for decision tree).

5.3.2.7 Additional Algorithms

An algorithm is included for correlating the carbohydrate intake and the time of day to the dosage of insulin required at that time under the framework of the user's total medication plan. Common rules of thumb for an insulin to carbohydrate ratio like the 450/ 500 rule (refer to 4.7.2.2 – Insulin), and the 1800 rule for insulin to blood glucose ratio (refer to 4.7.2.2 – Insulin), were used as starting points on which to base the Insulin and Carbohydrate Correlation and Tracking Algorithm. Inputs from the lifestyle data supplied by the user, the plan setup by the CDE and/or medical team, and the readings recorded by the meter are used to generate suggestions for the user's carbohydrate intake and insulin dosages. Presently most users calculate these items by themselves, using experience and self developed rules of thumb. The Twist moves these calculations away from the user and into the meter as a part of the comprehensive informative feedback plan.

Contributed by the team members at the Luleå University of Technology is the concept of Operant Conditioning. Asking the user about their mood, lancing location, testing location and environmental conditions, and then making correlations between this data and trends in blood sugar levels is yet another method by which the Twist provides informative feedback and conditions users to more effectively manage their diabetes.

6. Validation & User Feedback

Testing and validation forms a key part of the ME310 design process. Team Abbott conducted testing and validation at several points throughout design and prototyping – constantly incorporating user wishes and feedback into successive iterations to arrive at the final product – the Twist.

Before the reader embarks on reading this important section, the team wishes to call upon the reader to recall that the design of the Twist glucose meter was targeted towards young diabetics, including ages from the time they begin to test themselves independently, through to their early/ mid teenage life. Diabetics comprise about 7% of the US population and further our target group forms about 1% of the US population. However these users are the truly long term consumers of medical device makers such as Abbott Diabetes Care, and are also enthusiastic about life and being in charge of their treatment. They are also a growing group amongst the population and it was in this demographic that the team tried to draw its users for testing and validation. The team had to patiently wait to meet children (with the consent of their parents) at diabetes clinics in and around Stanford University.

The team began contacts with glucose meter users at the end of the Fall Quarter 2005, when surveys were sent out to diabetes patients amongst the student body at Stanford University, diabetic friends and relatives of the team members and contacts with the Juvenile Diabetes Research Foundation (J.D.R.F)[12]

The Lucile Packard Children's hospital holds weekly clinical sessions at its Stanford University campus facility as well as at the auxiliary center on Bascom Avenue in Los Gatos. Team Abbott established contact with Dr. Bruce Buckingham and Betsy Kunselmann, CDE-RN of the Stanford University Medical Center to attend these clinical sessions and gain valuable interaction with potential users.

Expert opinion was sought from a wide variety of doctors and users including Dr. Darrell Wilson of the Stanford University Medical Center, nurses at the Vaden Health Center on Stanford campus as well as at the Santa Clara Valley Diabetes Association.

An interesting snapshot of how Team Abbott's design process was closely involved with the users was seen at the end of Fall Quarter when the team chanced upon a member of the community at Stanford who gave a graphic account of his travails in trying to test a relative who had gone into a hypoglycemic episode and not knowing how to operate a glucose meter. The team addressed this feedback in the form of the "Emergency Mode".

Our sponsors Abbott Diabetes Care provided the team with valuable research materials and guidance in this process.

[12] http://www.jdrf.org/

The team followed a two pronged testing approach – to validate the hardware and the software features of the Twist with a qualitative, quantitative and usability approach[13].

TEAM ABBOTT'S USER TESTING PROFILE

Oldest User	22 year old (not inclusive of parents who are secondary users)
Youngest User	4 years old
Average Age	13.5 years
Type of Diabetes	All Type 1 (in line with the target user profile)
Average time with diabetes	4.8 years

The users endorsed the Twist meter on all fronts and enthusiastically inquired to the availability of the meter on the market. The feedback could be classified into the following major categories:

1. The Form and size of the Twist

   The Twist's primary market audience are in the age from which children take control of their own testing to early teens (7 or 8 year olds to 16 years old). A large part of the lives of these users are spent in school and the children have a very active lifestyle. Psychologically, children of this age are very receptive to information and are undergoing transformation from children to young adults. Team Abbott met with such users and determined their testing habits and practices. The team also learnt about the sensibilities of children having to test in the midst of others with a sometimes intimidating medical device.

   Users strongly favored the Twist's compactness for its:

   i. Ease of use: the twist is a modular self contained unit with no pouch needed for portability. This freed the users from having to carry and "remember" to take the pouch wherever they went (many kids the team met had forgotten a meter at some point). The meter could also fit into a pocket or a purse readily.
   ii. Ability to fit into the palm: The twist has a unique cylindrical shape with each of the modular components being more than manageable in children's hands. This was appreciated by users who had to contend with existing meters which have not been designed to fit into the smaller palms of children.

[13] APPENDIX: The questionnaires

2. The control Paradigm

   Team Abbott learned through its interactions with users that they do not utilize the advanced features of current meters as a result of the control interface being too complex or too clumsy to use everyday multiple times a day. Users had to navigate dense menus access features. This, coupled with inefficient single-click buttons, dissuaded users from using these features to take greater control of their self management of diabetes.

   The team presented users with the Twist's intuitive button and thumb-dial interface and the feedback could be summarized as:

   i. Faster control through the thumb-dial: the rotary control through the thumb-dial enables fast control of menu navigation options. This replaces the repetitive button presses of current meters, and users also liked the innovation this distinction represented.
   ii. The two buttons are located within the thumb-dial thus enabling one handed use of the meter controls.

3. Software
   The Twist's software was developed to synergize with the hardware interface. The team conducted user surveys and interviews to determine the usage pattern of the advanced features of the existing meter and found that many users give up using anything other than the basic test functions after a few weeks due to the relatively obscure structure of the software taking extra time and thought. The team's Informative Feedback for Kid's feature was endorsed by users as:
   i. Seamless integration of informative feedback for kids into the testing protocol: no more hunting for options or navigating layers of dense menus packed together. The Informative Feedback for Kids software is completely ingrained in the testing procedure with the various options appearing spontaneously and quickly during the actual test cycle as simple prompts. Coupled with the innovative control interface, it presented these features as less time consuming procedures, saving several seconds per test.
   ii. Informative Feedback for Kids : The whole informative feedback for kids feature is designed to help users achieve a better self management of diabetes. The newer users amongst our user test group appreciated the educational value several features bring to them, as well as the fact that the meter actually "teaches" various facets of living with diabetes.
   iii. Tips and Smart Averages: were appreciated by the CDEs and physicians as an important educational tool for users. The smart averages also provide a deeper insight into the performance of the tester in relation to the plan set by the physician.

The user testing provided valuable insight and was the genesis for many of the insightful features on the Twist, even if they do not appear to be of primary importance to the function of a glucose meter. The team wishes to acknowledge all the users for their feedback and the physicians who made all this happen. Thank you.

7. Future Opportunities

A number of potential new features were exposed over the course of the project which would greatly enhance the strip based glucose meters. However, not all were with the purview of the team and/or project scope. The few the team found most promising are briefly described below.

Materials

All glucose meters are using housing materials and finished which are fairly dated in comparison to what is offered on consumer electronics on the marker today. Lacking the protection of a pouch, future Twist developers should explore immerging high-durability materials. This includes both scratch resistance alternatively, shock protection. Late in user testing, Abbott personnel questioned discarding of a pouch for increased risk of damaging such a crucial everyday device.

Next generation display technologies

Alternatives to the class LCD display technology are coming to market which are more compact, offer better readability on all light conditions, and boast lower power consumptions. These features can benefit the consumers across the user spectrum. From allow smaller devices, to better readability, to increased battery life.

Advanced Strips

Current strip based glucose meters all require some form of calibration with each new batch if strips. Opportunities exist to make strips with internal, entirely seamless calibrations. Additionally, quicker, more fumble-proof way to pull individual strips from the vial would also mitigate one of the clumsiest parts of glucose testing.

Wireless Communication

This was a feature very popular with CDEs and physicians. Monitoring of patient performance via download of the meter's data is a key part of the physicians' ability to provide effective treatment advice to patients who are only seen once every few months (under good healthcare coverage). Currently, there is no common standard for download method, and physicians offices maintain a cache proprietary cables and software in order to get the data from all patients' meters. A significant amount of a professional's time is spent downloading the data. Thus, an automated and/or wireless system perhaps in the waiting room would save that time, and perhaps increase the patient's own used of the download features.

8. Project Management

8.1 Project Planning

Team Abbott systematically met each assignment goal. Team Abbott's primary method of making decisions was to reach a plurality on a matter before moving on, with a unanimous vote required for important matters. This approach was not without its share of healthy debate, but that was expected and in the end forced the team to take unified action. As a result, all milestones were met without conflict.

No one member has been designated as a project manager, so each team member naturally started taking specific responsibilities on a volunteer basis, based on their skill sets. This resulted in Team Abbott having a hardware lead, a software lead, an outsourcing and resource overseer, and finally a diabetes management expert. The hardware lead created all engineering drawings, fabricated parts, and was responsible for hardware assembly. The software lead was the architect of the flowcharts and decision nodes that made up the glucometer's software package. The outsourcing and resource head supported the two aforementioned teammates and was responsible for managing the hardware and software consultants hired by the team. This person also created and implemented solutions to manufacturing and feasibility issues. Finally, the fourth teammate became knowledgeable in the self-management of diabetes by using a glucometer, researching the psychology of diabetes management, and by learning how and when to take the appropriate dosage of insulin.

This approach of having each team member become a subject matter expert in one of the four design responsibilities mentioned above will be continued by Team Abbott in the Spring quarter. The practice of creating localized specialization has proven effective by enabling Team Abbott to address each aspect of the design process with the most appropriate personnel.

8.2 Communication Methods

8.2.1 Within Team Abbott

Team Abbott member Nick Reddy attends class through the Stanford Center for Professional Development due to his employment in Los Angeles. This was a disadvantage for the team early in the Fall quarter, but frequent teleconferences and periodic trips by Nick to Stanford have effectively bridged the communication gap. The voice over internet protocol client preferred by Team Abbott is Google Talk, as shown in the figure to the right.

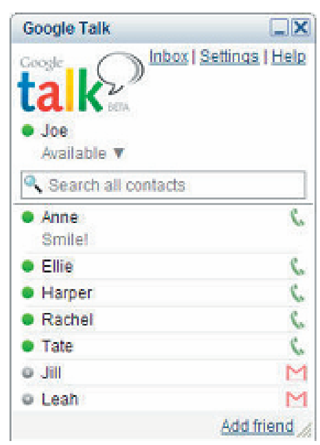


Figure 77 - Google Talk: Voice over Internet Protocol (VoIP) client that allows for auditory and textual communication.

To document all communication between team members when not teleconferencing, email was the communication medium of choice. The team also made frequent use of the FileShare. It greatly facilitated sharing pictures, documents, and meeting recordings. It was valuable that the FileShare permits opening and saving documents directly to the server as if from a local Microsoft Windows folder. It provided quicker exchange with Nick during live discussion and reduced duplicate file generation.

8.2.2 Collaboration with LTU

Team Abbott successfully made more of an effort this quarter to include its four global partners from the Luleå University of Technology in Sweden. A trip to Sweden in late January by Nick Reddy and David Yao resulted in a sharp increase in global collaboration. Nick and David conveyed the results of Team Abbott's Fall quarter design efforts to the Luleå students, and together with their Swedish counterparts set the expectations for the upcoming quarter by outlining design and documentation strategy.

Interaction with the remote partners at Luleå was accomplished on a largely weekly basis in the form of videoconferencing. A proprietary videoconference system was set up at Stanford and at Luleå. The system's hardware is a standard personal computer equipped with a large liquid crystal display, and a pan-and-tilt camera unit. The proprietary software is called Confero, as was developed at Luleå to run with Microsoft's Windows XP operating system. The system performed impressively, allowing settings for minimal compression and thus reduced video encoding latency (and better picture quality) versus Team Abbott's design space's existing Polycom teleconference system.

Figure 78 - Confero system: video conference PC used to communicate with remote partners in Luleå, Sweden.

Resources such as Confero have been facilitating the collaborative effort, as discussed in the following message written by Team Abbott's four partners in Luleå:

> "By working closely together, the Luleå and Stanford teams have gotten to know each other well, which has been advantageous for the collaboration process. The partnership has been accomplished with structured meetings and using idea

generation methods such as brainstorming and de Bono[14] thinking hats. Informal everyday contact between the group members has also made a contribution to the team spirit. The frequent meetings allow the group members to always be updated on what is going on in the project.

“In the collaborative effort with Stanford a great deal of improvement occurred after David and Nick visited Sweden. The Luleå team feels that an understanding has been reached between the two teams and that communication has improved during the project. In the beginning there were some difficulties due to the cultural, time, and physical distances, but as time has passed past these distances have shortened and today the difficulties from this have almost disappeared. In the past part of the difficulty in the collaboration effort was due to the fact that the two teams were not very disciplined in updating each other. While one team understood one aspect about the project, the other team did not share the same level of understanding. Planning for holidays and different exam schedules also posed some logistical difficulties which were worked out during the Winter quarter. The videoconferences between teams today are much more effective and information sharing is taking place.”

8.2.3 With Corporate Liaison

Team Abbott set up weekly teleconferences with its liaison, Jonathan Wyler, Research and Development Program Manager at Abbott Diabetes Care in Alameda, California. During these meetings the four remote partners from Luleå called in and the teams discussed their progress and plans for the following few weeks. This practice, combined with email, is a sufficient communication practice and will be continued next quarter.

[14] http://www.learnerslink.com/SixThinkingHats.htm

8.3 Project Deliverables and Milestones

Team Abbott is responsible for delivering a hardware prototype and a working software package for its glucometer to Abbott Diabetes Care in June 2006. The milestones of first round of hardware and software completion were set to coincide with ME310 class due dates, and are described below.

Table 10 - Milestones met by Team Abbott and their resulting deliverables.

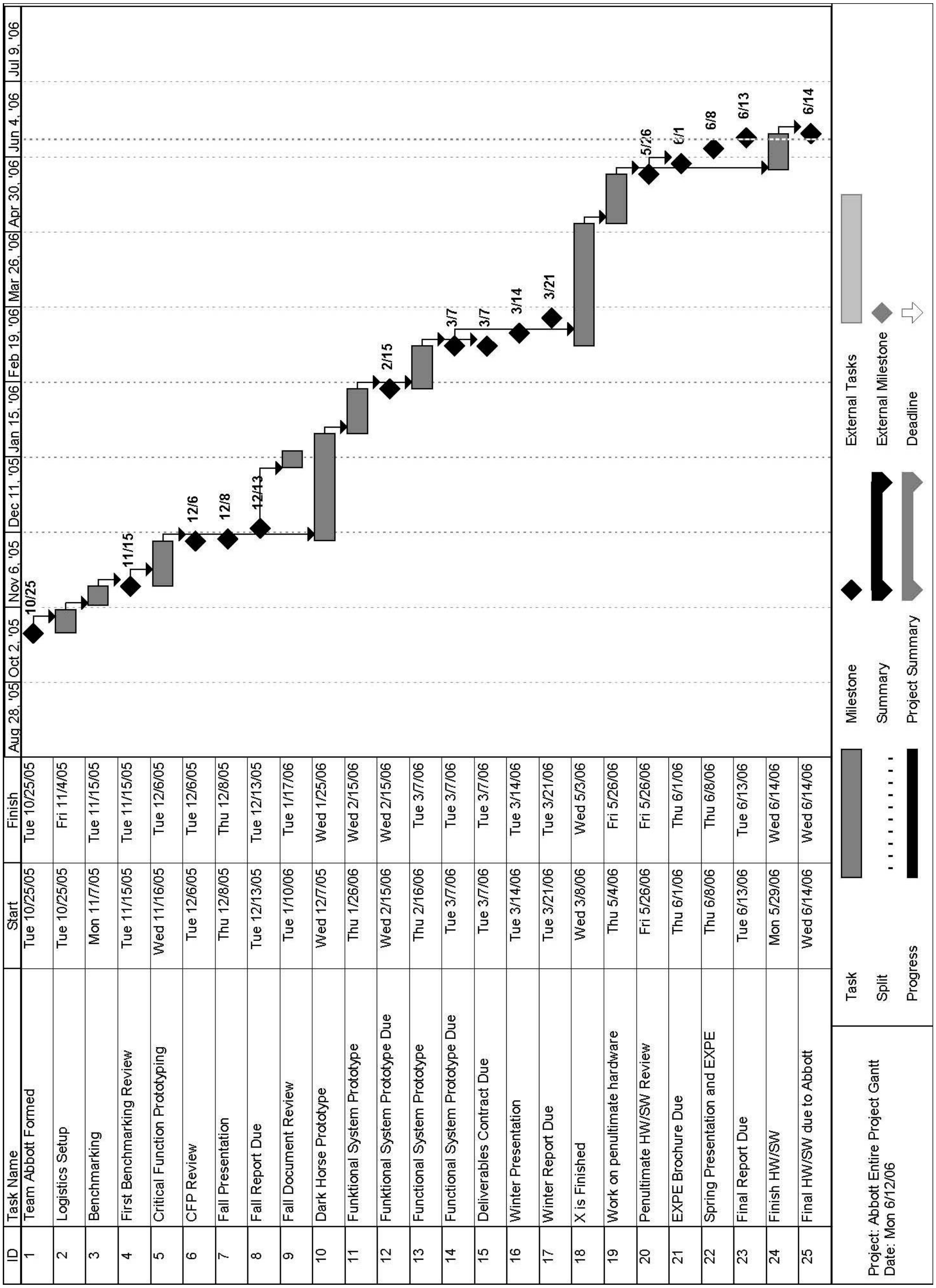
Date	Milestone	Deliverable set by Team Abbott	Description
Fall Quarter			
October 25, 2005	Team Abbott formed	Wikipage created	Website created to handle scheduling and act as a repository of information gathered
November 15, 2005	First Benchmarking Review	Existing glucometer and patent information presented	Current state of glucometers and the patents protecting them were identified to help crystallize project scope
December 6, 2005	Critical Functional Prototype	Hardware: Setup testing audio, visual, and tactile cues was created	A test setup to evaluate various forms of information conveyance was constructed
December 13, 2005	Fall quarter end	Fall Report	Documented project beginnings
Winter Quarter			
January 24, 2006	"Dark Horse" Prototype (broaden design scope by pursuing a markedly alternative project solution)	Hardware: Glucometer accessory	Blood sample generation difficulties uncovered (during benchmarking from Fall quarter) were solved through Stanford and LTU collaboration in designing guiding/massaging tool for finger to meet test strip
February 14, 2006	"Fun*k*tional" Prototype (rough concept prototype of likely final solution)	Hardware: Glucometer Software: Preliminary software architecture	Team Abbott created first glucometer with parts stereolithographed, assembled rudimentary software plan

March 7, 2006	"Functional" Prototype (polished prototype of likely final solution)	Software: Presentable software demonstration	Comprehensive software structure created, interactive software demonstration programmed using Flash software
March 23, 2006	Winter quarter end	Winter report	Explains work done so far
Spring Quarter			
May 3, 2006	'X' is Finished	Hardware: The Dial Vial Glucometer Prototype (a precursor to the Twist)	A handheld prototype was created to get a feel for size and shape of glucometer that utilized a jog wheel to navigate data
May 26, 2006	Penultimate Hardware Review	Hardware: The Twist Glucometer Software: Polished software architecture	Team Abbott created polished glucometer with parts stereolithographed, demonstrated nearly complete software
June 1, 2006	EXPE Brochure	EXPE Design Fair Handout	Handout showing latest hardware features and software architecture
June 8, 2006	Spring Presentation and EXPE	Hardware: The Twist Software: Flash demo	Completed hardware and software is used to demonstrate wireless interconnectivity between the two
June 13, 2006	Spring quarter end	Final Report, Hardware, Software	Final Report and Deliverables are turned in to teaching team and liaison

8.4 Project Timeline

Team Abbott's winter schedule follows:

Figure 79 - Gantt chart of Team Abbott's activities



8.5 Project Budget

This section details the expenditures of Team Abbott over the course of the project.

Team Abbott ME310 2005-2006 - BUDGET

REIMBURSEMENTS

Date	Vendor	Description	Cost	Qty	Expensed by	Material	Register
29-Oct-2005	Walgreens	Glucose meters and test strips	$192.62	1	David Yao	$192.62	$192.62
6-Nov-2005	Fry's Electronics	Panasonic RR-US380 Voice Recorder	$108.24	1	David Yao	$108.24	$300.86
6-Nov-2005	Walgreens	Glucose Meters	$116.87	1	David Yao	$116.87	$417.73
29-Nov-2005	Home Depot	Polystyrene Foam	$37.92	1	David Yao	$37.92	$455.65
29-Nov-2005	Walgreens	PEZ Dispenser	$1.19	1	David Yao	$1.19	$456.84
29-Nov-2005	Fry's Electronics	Keyboard and mouse, silcone parts	$86.56	1	David Yao	$86.56	$543.40
30-Nov-2005	Jameco	pager motors	$40.14	1	David Yao	$40.14	$583.54
30-Nov-2005	Radio Shack	electronics supplies	$68.28	1	David Yao	$68.28	$651.82
13-Dec-2005	FedEx Kinkos	FallDocument Printing and Binding	$12.16	1	David Yao	$12.16	$663.98
22-Jan-2006	Scandinavian Airlines	Reddy round trip ticket from Stockholm to Lulea, Sweden	$180.94	1	Nick Reddy	$180.94	$844.92
"	Scandinavian Airlines	Yao round trip ticket from Stockholm to Lulea, Sweden	$180.94	1	Nick Reddy	$180.94	$1,025.86
23-Jan-2006	Horizon Air	Daouk round trip ticket from San Jose to Portland	$179.60	1	Nick Reddy	$179.60	$1,205.46
"	Horizon Air	Manohar round trip ticket from San Jose to Portland	$181.60	1	Nick Reddy	$181.60	$1,387.06
"	Horizon Air	Reddy round trip ticket from Burbank to Portland	$285.60	1	Nick Reddy	$285.60	$1,672.66
"	Horizon Air	Yao round trip ticket from San Jose to Portland	$179.60	1	Nick Reddy	$179.60	$1,852.26

23-Jan-2006	United Airlines	Reddy round trip ticket from Los Angeles to Stockholm, Sweden	$712.10	1	Nick Reddy	$712.10	$2,564.36
"	United Airlines	Yao round trip ticket from San Francisco to Stockholm Sweden	$796.00	1	Nick Reddy	$796.00	$3,360.36
3-Feb-2006	Sheraton Hotels	Portland hotel room	$111.38	2	Nick Reddy	$222.76	$3,583.12
3-Feb-2006	CalTrain	Ticket from Stanford Campus to SJC Airport	$3.75	4	David Yao	$15.00	$3,598.12
5-Feb-2006	Classic Airport Shuttle	3 people from SJC airport to Stanford Campus	$49.00	1	David Yao	$49.00	$3,647.12
4-Feb-2006	Portland Convention Pking	Parking fee	$6.00	1	David Yao	$6.00	$3,653.12
5-Feb-2006	Riverfront Café	Food, Portland	$4.29	1	David Yao	$4.29	$3,657.41
1-Feb-2006	Miyake Sushi	Working meal with David Grossman, coach	$32.79	1	David Yao	$32.79	$3,690.20
3-Feb-2006	Montage Restaurant	Team Dinner	$70.35	1	David Yao	$81.35	$3,771.55
4-Feb-2006	Morton's SteakHouse	Food, Team Dinner	$131.25	1	David Yao	$156.25	$3,927.80
4-Feb-2006	Cucina Rosso	Food, Portland	$5.00	1	David Yao	$5.00	$3,932.80
31-Jan-2006	Max Hamburger	Food, Sweden	$7.33	1	David Yao	$7.33	$3,940.13
29-Jan-2006	Old Brodies	Food, Sweden	$9.43	1	David Yao	$9.43	$3,949.56
27-Jan-2006	Asian Chao	Food, Newark	$7.93	1	David Yao	$7.93	$3,957.49
29-Jan-2006	Just Desserts @ SFO	Food, SFO airport	$9.98	1	David Yao	$9.98	$3,967.47
6-Feb-2006	Barnes & Noble	Four books on Diabetes	$84.12	1	David Yao	$91.06	$4,058.53
20-Jan-2006	PRL	FDM Mat'l for Darkhorse Prototype	$4.50	1	David Yao	$4.50	$4,063.03
[noted on map]	[personal car]	Abbott Diabetes Care (63.6 Miles Roundtrip)		1	David Yao		$4,063.03
[noted on map]	[personal car]	Fry's Electronics (4.6 Miles Roundtrip)		1	David Yao		$4,063.03

[noted on map]	[personal car]	San Jose Airport (33.8 Miles Roundtrip)		2	David Yao		$4,063.03
[noted on map]	[personal car]	Los Gatos Diabetes Clinic (38.0 Miles Roundtrip)		2	David Yao		$4,063.03
[noted on map]	[personal car]	Home Depot (12.4 Miles Roundtrip)		1	David Yao		$4,063.03
[noted on map]	[personal car]	Jameco (25.4 Miles Roundtrip)		1	David Yao		$4,063.03
[noted on map]	[personal car]	Hobbytown USA (41 Miles Roundtrip)	$0.45	291.6	David Yao	$129.76	$4,192.79
10-Feb-2006	Skype	VoIP Account	$12.10	1	David Yao	$12.10	$4,204.89
9-Feb-2006	Fry's Electronics	Miniature Mouse	$21.64	1	David Yao	$21.64	$4,226.53
11-Feb-2006	Home Depot	Bolts and Tools	$28.16	1	David Yao	$28.16	$4,254.69
11-Feb-2006	Home Depot	Batteries and threaded rod	$18.99	1	David Yao	$18.99	$4,273.68
11-Feb-2006	Radio Shack	Motors and Pliers	$41.39	1	David Yao	$41.39	$4,315.07
12-Feb-2006	OfficeMax	Team space improvement	$46.74	1	David Yao	$46.74	$4,361.81
12-Feb-2006	Hobbytown USA	Gears, belts, prototyping materials	$95.26	1	David Yao	$95.26	$4,457.07
13-Feb-2006	PRL, Stanford	FDM mat'l for Funktional Prototype	$24.00	1	David Yao	$24.00	$4,481.07
11-Feb-2006	RPL, Stanford	FDM mat'l for Funktional Prototype	$14.00	1	David Yao	$14.00	$4,495.07
21-Feb-2006	National Instruments	NI USB-6008 Multifunction I/O Module and Software	$163.97	1	David Yao	$163.97	$4,659.04
9-Feb-2006	SparkFun Electronics	ATMega128 Development Terminal	$95.66	1	David Yao	$95.66	$4,754.70
7-Mar-2006	Kinkos	Prints of GUI Flowcharts	$1.35	1	David Yao	$1.35	$4,756.05
3-Mar-2006	Rapid Pro RP	SLA prototypes	$250.00	1	David Yao	$250.00	$5,006.05
9-Feb-2006	JameCo Electronics	Switches and Solenoids	$49.31	1	David Yao	$49.31	$5,055.36

22-Feb-2006	Mouser Electronics	SMD Switches, buttons, joysticks	$54.36	1	David Yao	$54.36	$5,109.72
7-Mar-2006	Stanford Bookstore	Magnifying glasses	$5.40	2	David Yao	$10.80	$5,120.52
27-Jan-2006	Starbucks Coffee	Food, Burbank	$3.50	1	David Yao	$3.50	$5,124.02
27-Jan-2006	Newark Airport	Food, Newark	$10.00	1	David Yao	$10.00	$5,134.02
28-Jan-2006	Lulea Univ. of Technology	Food, Sweden	$25.00	1	David Yao	$25.00	$5,159.02
29-Jan-2006	Brodies Pizzeria	Food, Sweden	$12.00	1	David Yao	$12.00	$5,171.02
30-Jan-2006	Lulea Univ. of Technology	Food, Sweden	$8.00	1	David Yao	$8.00	$5,179.02
31-Jan-2006	Lulea Univ. of Technology	Food, Sweden	$8.00	1	David Yao	$8.00	$5,187.02
31-Jan-2006	Max Hamburger	Food, Sweden	$7.00	1	David Yao	$7.00	$5,194.02
4-Feb-2006	Portland Convention Center	Food, Portland	$12.00	1	David Yao	$12.00	$5,206.02
5-Feb-2006	Starbucks Coffee	Food, Portland	$3.50	1	David Yao	$3.50	$5,209.52
20-Feb-2006	Thai City	Working Meal, Interview Dr. Bruce Buckingham of SUMC	$54.50	1	David Yao	$54.50	$5,264.02
1-Feb-2006	LAX Airport Parking	6 days parking (During Sweden Trip)	$11.00	6	Nick Reddy	$66.00	$5,330.02
5-Feb-2006	Burbank Airport Parking	2 days parking (During Portland Trip)	$6.00	2	Nick Reddy	$12.00	$5,342.02
9-Feb-2006	Southwest Airlines	Nick Reddy LAX to SJC Airfare	$254.60	1	Nick Reddy	$254.60	$5,596.62
12-Feb-2006	LAX Airport Parking	2 days parking (During San Jose Trip)	$11.00	2	Nick Reddy	$22.00	$5,618.62
Mar 14, 2006	[personal car]	San Jose Airport (33.8 Miles Roundtrip)	$15.04	1	David Yao	$15.04	$5,633.66
Apr 05, 2006	[personal car]	Abbott Diabetes Care (68.2 Miles Roundtrip)	$30.35	1	David Yao	$30.35	$5,664.01
May 10, 2006	[personal car]	Home Depot-to-Kragen (15.7 round trip)	$6.99	1	David Yao	$6.99	$5,670.99

May 12, 2006	[personal car]	Los Gatos Diabetes Clinic (39.4 Miles Roundtrip)	$17.53	3	David Yao	$52.60	$5,723.59
Apr 08, 2006	Union Square Garage	Parking in San Fran	$8.00	1	David Yao	$8.00	$5,731.59
Apr 03, 2006	Thai City	Working Meal: with Lulea Parters	$74.43	1	David Yao	$74.43	$5,806.02
Apr 05, 2006	Armadillo Willy's	"	$74.12	1	David Yao	$74.12	$5,880.14
Apr 08, 2006	Naan n Curry	"	$48.83	1	David Yao	$48.83	$5,928.97
Apr 08, 2006	Naan n Curry	"	$10.85	1	David Yao	$10.85	$5,939.82
Apr 09, 2006	Empire Grill	"	$71.99	1	David Yao	$71.99	$6,011.81
Apr 10, 2006	Cold Stone Creamery	"	$32.63	1	David Yao	$32.63	$6,044.44
Apr 10, 2006	Miyake	"	$91.68	1	David Yao	$91.68	$6,136.12
Mar 23, 2006	Kinkos	Winter Report Printing	$72.57	1	David Yao	$72.57	$6,208.69
Apr 10, 2006	Stanford Bookstore	DAS clay, white	$6.66	1	David Yao	$6.66	$6,215.35
Apr 11, 2006	Walgreens	OneTouch Ultra2 glucose meter and AccuChek Lancet	$108.23	1	David Yao	$108.23	$6,323.58
Apr 18, 2006	Fry's Electronics	computer mice and webcam	$205.54	1	David Yao	$205.54	$6,529.12
Apr 24, 2006	Walgreens	glucose meter test strips	$107.98	1	David Yao	$107.98	$6,637.10
Apr 24, 2006	Home Depot	Plasti-dip and crazy glue	$8.25	1	David Yao	$8.25	$6,645.35
Apr 24, 2006	Stanford PRL	FDM prototyping material	$18.50	1	Karthik Manohar	$18.50	$6,663.85
Apr 25, 2006	McMaster Carr	constant force springs	$24.32	1	David Yao	$24.32	$6,688.17
May 02, 2006	Mouser Electronics	Buttons and Hollow shaft encoders	$113.31	1	David Yao	$113.31	$6,801.48
May 05, 2006	Rapid Pro RP	SLA prototypes	$320.00	1	David Yao	$320.00	$7,121.48

May 09, 2006	Rapid Pro RP	SLA prototypes	$240.00	1	David Yao	$240.00	$7,361.48
May 16, 2006	Rapid Pro RP	SLA prototypes	$240.00	1	David Yao	$240.00	$7,601.48
May 07, 2006	Ace Hardware	sandpaper, files, and bits	$49.73	1	David Yao	$49.73	$7,651.21
May 09, 2006	Fry's Electronics	fuses for volt meter	$3.78	1	David Yao	$3.78	$7,654.99
May 10, 2006	Kragen Auto	automotive paint	$54.04	1	David Yao	$54.04	$7,709.03
May 10, 2006	Home Depot	spray paint	$19.54	1	David Yao	$19.54	$7,728.57
May 12, 2006	Acura, Los Gatos	automotive touch-up paint	$25.92	1	David Yao	$25.92	$7,754.49
Mar 15, 2006	Southwest Airlines	Nick Reddy BUR to SJC Airfare	$254.60	1	Nick Reddy	$254.60	$8,009.09
Mar 17, 2006	Super Shuttle	Ride to SJC from Stanford Campus	$25.00	1	Nick Reddy	$25.00	$8,034.09
Mar 17, 2006	Burbank Airport Parking	2 days parking (During SJC Trip)	$6.00	2	Nick Reddy	$12.00	$8,046.09
Jun 02, 2006	[personal vehicle]	Visit Abbott Diabetes Care Alameda, CA (x 1 roundtrip)	$0.45	68.2	David Yao	$30.35	$8,076.44
May 24, 2006	[personal vehicle]	Visit Los Gatos Diabetes Clinic (x 1 roundtrip)	$0.45	39.2	David Yao	$17.44	$8,093.89
See below	[personal vehicle]	Shopping Home Depot (x 1 roundtrip)	$0.45	10.8	David Yao	$4.81	$8,098.69
See below	[personal vehicle]	Shopping Fry's Electronics (x 2 roundtrip)	$0.45	8.8	David Yao	$3.92	$8,102.61
See below	[personal vehicle]	Shopping Tap Plastics (x 2 roundtrip)	$0.45	26.4	David Yao	$11.75	$8,114.36
See below	[personal vehicle]	Services at Kinkos California Ave (x 4 roundtrip)	$0.45	20.8	David Yao	$9.26	$8,123.61
Various	Tressider Express	SGM Snacks	$45.72	1	Karthik Manohar	$45.72	$8,169.33
Jan 16, 2006	Barnes and Noble	Diabete books	$162.32	1	Karthik Manohar	$162.32	$8,331.65
May 19, 2006	Fry's Electronics	Computer mice	$102.79	1	David Yao	$102.79	$8,434.44

May 24, 2006	Fry's Electronics	Computer mouse, LEDs, supplies	$57.09	1	David Yao	$57.09	$8,491.53
May 24, 2006	Stanford PRL	FDM Material	$17.50	1	David Yao	$17.50	$8,509.03
May 21, 2006	Yannis Hobbies	Airbrush and paints	$94.59	1	David Yao	$94.59	$8,603.62
May 26, 2006	Yannis Hobbies	Paints and nozzles	$32.49	1	David Yao	$32.49	$8,636.11
Jun 05, 2006	RapidPro RP	SLA Prototype parts	$75.00	1	David Yao	$75.00	$8,711.11
Jun 01, 2006	RapidPro RP	SLA Prototype parts	$200.00	1	David Yao	$200.00	$8,911.11
May 26, 2006	Tap Plastics	Acrylic pieces and supplies	$14.02	1	David Yao	$14.02	$8,925.13
May 27, 2006	Tap Plastics	Acrylic, thin sheet	$18.62	1	David Yao	$18.62	$8,943.75
Jun 07, 2006	Home Depot	Paint, clear coat, batteries	$18.78	1	David Yao	$18.78	$8,962.53
Jun 02, 2006	Mouser Electronics	Encoders, switches	$78.53	1	David Yao	$78.53	$9,041.06
Jun 08, 2006	Kinkos	EXPE Poster	$45.47	1	David Yao	$45.47	$9,086.53
Jun 08, 2006	Kinkos	EXPE Handouts	$37.37	1	David Yao	$37.37	$9,123.90
Jun 13, 2006	Kinkos	Spring Design Document Printing	$300.00	1	David Yao	$300.00	$9,423.90
Jun 07, 2006	Southwest Airlines	Nick trips here	$500.00	1	Nick Reddy	$500.00	$9,923.90
							$9,923.90
						SUBTOTAL	$9,923.90

NON-REIMBURSEMENT COSTS

November	Global Team Travel Allowance	$ (3,000.00)		-$3,000.00
March	Contracting - Sascha Leifer	$ 1,200.00	$655.00	$1,855.00
March/April	Contracting - Asvin Srivatsangam	$ 1,650.00	$148.50	$1,798.50
May	Contracting - Amber Pompeo	$ 1,800.00	$162.00	$1,962.00
May	Contracting - Amol Mittal	$ 800.00	$72.00	$872.00
April	Stanford PRL Shop License	$ 120.00	$0.00	$120.00
April	ME310 Loft Laptop deposit	$ 1,000.00	$0.00	$1,000.00
26-Mar-06	ITSS - Macromedia Flash License	$ 200.00	$0.00	$220.00
			SUBTOTAL	$4,827.50
			TOTAL	$14,751.40

9. Reference Material

9.1 Human Resources

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9.2 Facility Resources

Terman 583 - ME310 Loft

Terman Engineering Building

Stanford University

Stanford, CA 94305

This primary meeting space contains computing and office resources, and location of Confero teleconference system.

Terman 501

Terman Engineering Building

Stanford University

Stanford, CA 94305

Private teleconference room for Global partner meetings

Abbott Diabetes Care

1360 South Loop Road

Alameda, CA 94502

ADC's headquarters and strip manufacturing site.

Product Realization Lab (PRL)

Design Division, Mechanical Engineering
Terman 501 MC 4021
Stanford University
Stanford, CA 94305-4021

Stanford's machine shop

Lucile Packard Children's Hospital
Mary L. Johnson Pediatric Ambulatory Care Center

730 Welch Road

Palo Alto, CA 94304

Pediatric diabetes clinic, Stanford Campus

Packard Specialty Services

14651 South Bascom Avenue, Suite 150

Los Gatos, CA 95032

Pediatric diabetes clinic, Los Gatos, CA

9.3 Vendors

Fry's Electronics, Palo Alto
340 Portage Ave
Palo Alto, CA
Phone: (650) 496-6000

Hobbytown USA, Fremont
39152 Fremont Hub
Fremont, CA 94538
Phone: (510) 796-2744

Home Depot
1781 E Bayshore Rd
East Palo Alto, CA 94303
Phone: 650-462-6800

JameCo.
1355 Shoreway Rd
Belmont, CA
Phone: (800) 831-4242
http://www.jameco.com

Mouser Electronics
1810 Gillespie Way
Suite 101
El Cajon, CA 92020
http://www.mouser.com

Radio Shack, El Camino Real
490 S California Ave # 1
Palo Alto, CA
Phone: (650) 329-8081

RapidPro RP
Larry Winnen
larry@rapidprorp.com

9.4 Online References

ME310 Wiki

URL: http://wikibox.stanford.edu/05-06/index.php/Main/HomePage/

Abbott Diabetes Care

URL: http://www.abbottdiabetescare.com/

David Mendosa's Diabetes Blog

URL: http://blogs.healthcentral.com/diabetes/

David Mendosa's News Site

URL: http://www.mendosa.com/diabetes.htm

An Overview to the Behavioral Perspective

URL: http://chiron.valdosta.edu/whuitt/col/behsys/operant.html

Hon lär sig äta framför datorn, Vårdfacket
(Swedish article from healthcare-journal)

Karolinska Institutet

URL: http://ki.se/ki/jsp/polopoly.jsp?d=2855&a=4281&l=sv

Pelikan Technologies' Website

URL: http://www.pelikantechnologies.com/

Diabetes Health Connection

URL: http://www.diabeteshealthconnection.com/index.aspx

US Patents Office

URL: http://www.USPTO.gov/

Wikipedia.com - Diabetes

URL: http://www.wikipedia.org/

How Stuff Works – Diabetes

URL: http://health.howstuffworks.com/diabetes.htm

American Association of Diabetes Educators

URL: http://www.aadenet.org/

MedGadget blog

URL: http://www.medgadget.com/

American Diabetes Associations

URL: http://www.diabetes.org/home.jsp

The DAWN Study

URL: http://www.dawnstudy.com/

Diabetes Forums

URL: http://diabetesforums.com/index.php

The Usability Methods Toolbox by James Hom

URL: http://usability.jameshom.com/index.htm

10. Appendices

10.1 Mode Flow Charts

10.1.1 Tutorial Mode

10.1.2 My Meter and I Mode

10.1.3 Sick Day Mode

10.1.4 Basic Mode

10.1.5 Emergency Mode

10.1.6 Kids / Settings Mode

10.2 Interviews with Experts

10.2.1 Interview with Ms. Tanya

Diabetes Educator, Diabetes Society of Santa Clara Valley
Nov. 11, 2005.

Team Abbott raised several interesting questions regarding the usage of glucometers by various groups. Interesting points:

- Many patients undergo full day orientation sessions to get acquainted with diabetes and its implications in life
- New people might take 4 to 6 weeks to get accustomed to a strict testing regimen.
- Many people return for further training in using the glucometer as they find the functions too complex to learn by themselves.
- Glucometers are recommended based on their ease of use and learning.
- Glucometers with very complex functionalities or features are not very popular with a majority of the population who prefer simpler models.
- Lancet re-use is more common due to constraints of disposal in a sharps container which may not be available everywhere
- Small test-strips are a problem for elderly patients.
- Insurance coverage also plays an important role in glucometer purchase decisions.
- A lot of adults with Type 2 diabetes skip tests after meals.
- Data logging is useful feature especially to mark anomalous readings.

10.2.2 Interview with Ms. Danielle Hong

Triage Nurse, Vaden Health Center
Nov. 12, 2005.

The interview yielded the following points:

- Need for more better designed or bigger strips
- Faster response times
- Easier to grip handle in times of emergency

- Certain procedures maybe ignored or sidestepped during a pressing emergency and these might cause erroneous readings to appear.

10.2.3 Interview with Ms. Betsy Kunselman

Certified Diabetes Educator, Stanford Medical Center
Nov. 18, 2005

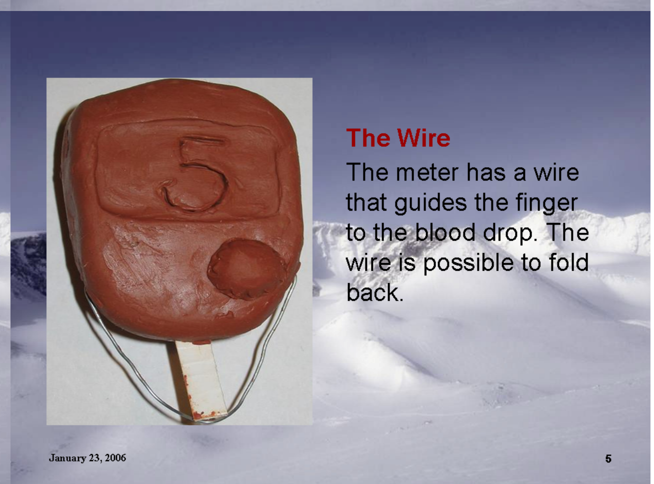
Team Abbott gained these insights

- Sensitizing kids is generally done with testing on patients and nurses.
- Data download-ability is a must for the doctor to interpret results along with preset date and time settings (for trace ability of readings)
- Fudging data is seen in teenagers and adolescents afraid of blood.
- Alternate testing sites not encouraged as they are not accurate
- Accuracy of readings is critical especially with children.
- Risk of infection from lancets very low.
- Disposal is through bio hazards or sharps container which is very inconvenient to patients.
- Schools are very strict on having adult supervision: instances where children tested other children with their glucometers.
- Illegal for a non-licensed person to give insulin or interpret any readings given by a glucometer. So teachers and others may only “assist” a child undertake a glucometer test.
- Pre-teens and early teens may not be comfortable conducting tests amidst their peers in school.
- Many people don’t use the default bags supplied by the Glucometer manufacturer and customize their own bags for color and convenience.
- Tamagochi with diabetes!
- Beeps, tones and visual aids for visually challenged people. A meter which might give audio readouts might be very useful.

- Sample Size is a very important aspect in testing accuracy – as squeezing can introduce interstitial fluids and other fluids can contaminate or dilute the sample.
- Physical durability is very important – dropped meters losing the memory are a very serious problem.
- Contaminated fingers can affect the sample reading greatly.

10.3 Luleå Sketches

10.3.1 Guiding Rod Concepts




Dark horse
prototype concepts
SIRIUS
January 23, 2006
8


Dark horse
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SIRIUS
January 23, 2006
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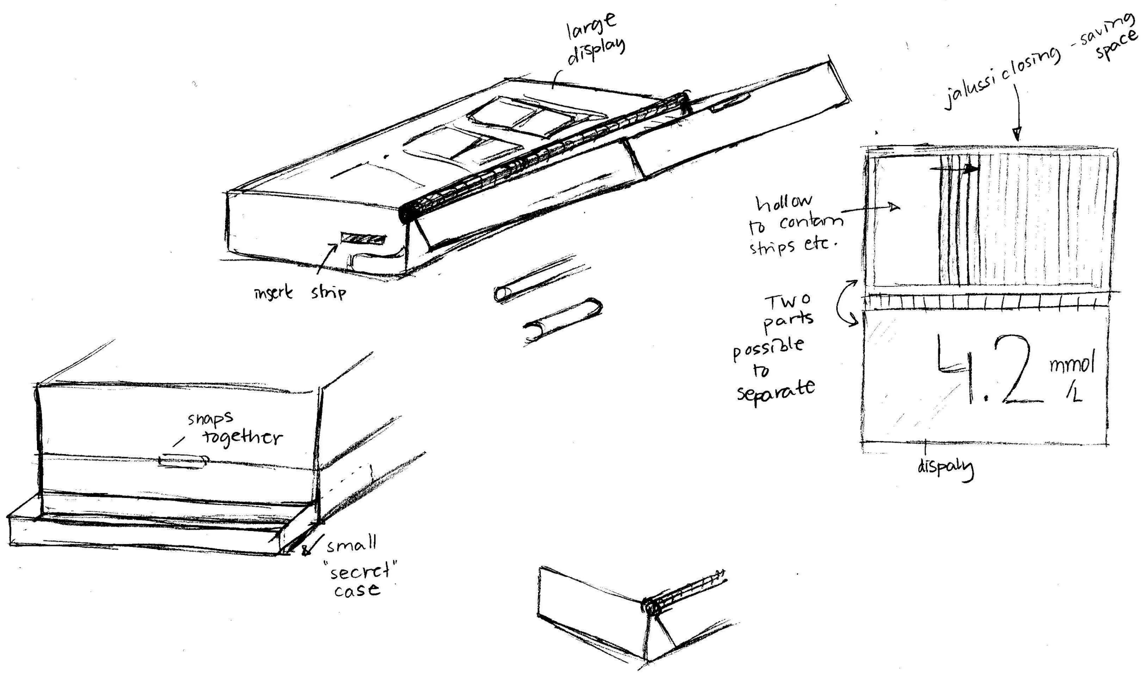
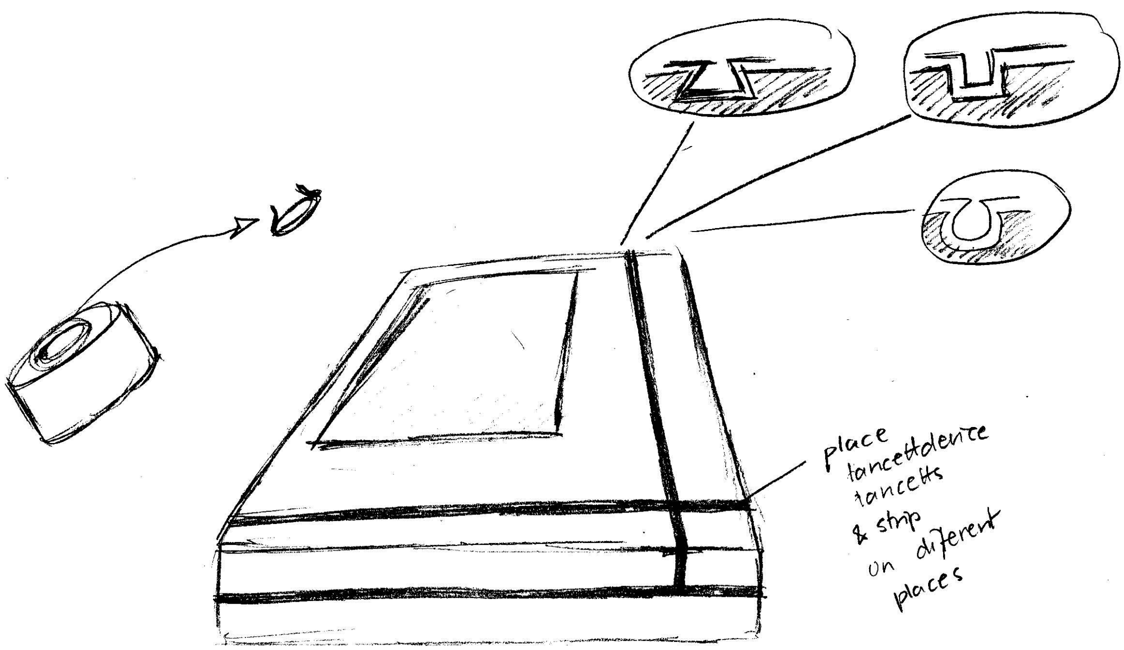
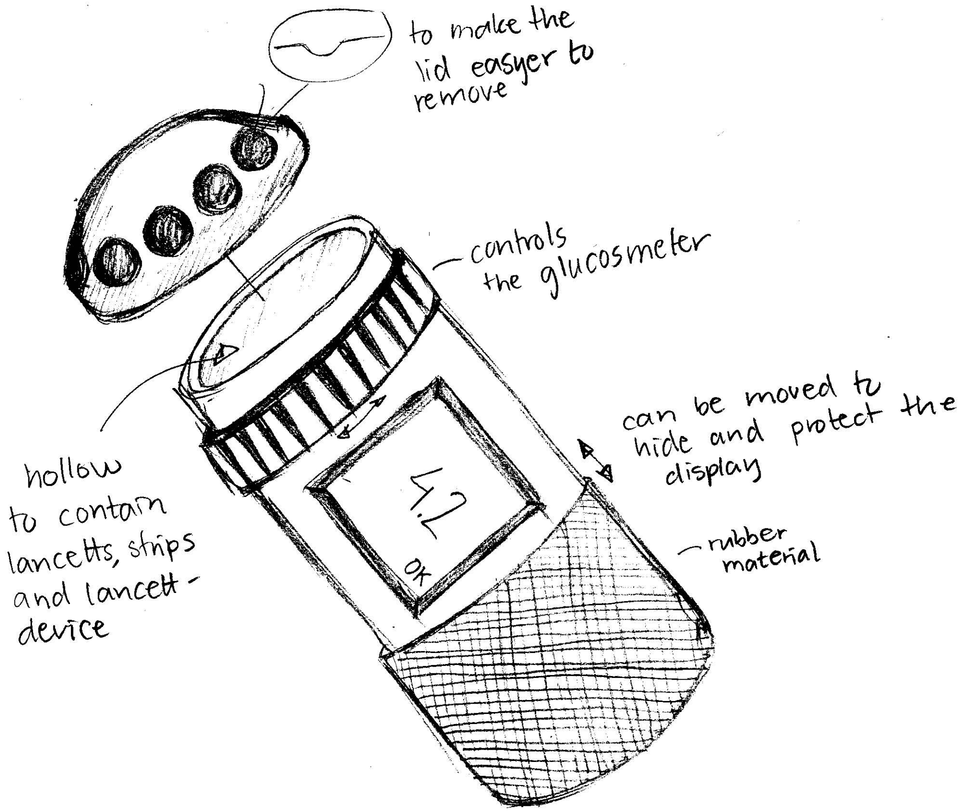
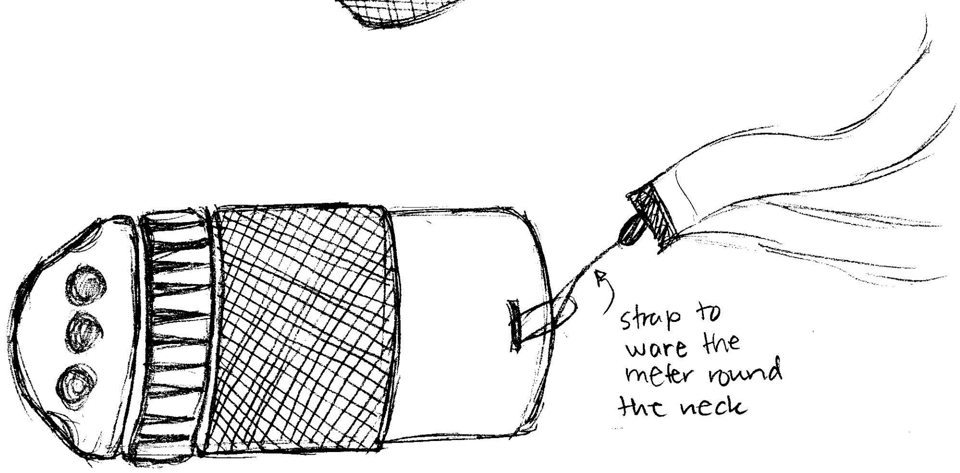
Dark horse
prototype concepts
SIRIUS
January 23, 2006
10

10.3.2 Luleå Meter Sketches









ACTIVE LIFESTYLE

10.4 Letter from Vic – Japanese Meter

Team Abbott December 25, 2005

Merry Christmas! So said my hosts, Michiko and Daichi Saito from Japan. No, we are not in Japan, but in Hawaii, where I am attending a conference on new technologies and product evolution. Our small group consists of representatives from a number of large American and International companies and some Academics. All of us are practicing or retired engineers.

I had asked to meet with the Saitos this morning because I had learned that Daichi, Dr. Saito's son, was a diabetic. The day before, I had seen him fiddling with what appeared to be a blood glucose meter while waiting to go swimming with his mother after our meeting. I noticed the device appeared to be somewhat different from the devices your team has been benchmarking, and wanted to get some more information about it and it's use. Thus the meeting today in their hotel suite.

Daichi is 13 years old and was diagnosed with Type 1 diabetes at the age of 4. He's needed insulin injections all this time. He is rather thin,, wears glasses all the time, and does not appear to be very athletic. However, he is very talkative, and his mother says he is an excellent student. He speaks and understands enough English to communicate well and feel comfortable on his own in the resort and with all of us at the meeting. He is computer and gadget savvy and seems to have good understanding and knowledge of his condition, his disease, the testing and treatment numbers, calculations, and procedures. He meets briefly with a Diabetes Advisor about once every 6 weeks but says she just says the same things his mother does. He did say the advisor turned him on to his current glucometer a couple of years ago when it was still in beta testing stage.

Daichi showed me his glucometer. It's a Japanese model, with a label in Japanese, by a Japanese company. I don't recall the name, but it was one I did not recognize. His mother said they get a new one about once a year because Daichi either loses it or accidentally takes it swimming, or he breaks it through rough handling, or it just gets too dirty and scratched up, or just because he wants a new model (like with cell phones). It costs about 7000 yen. The battery lasts about a year. They keep two at all times and they alternate, on an irregular basis, between them.

He is supposed to do blood tests 4 times a day (before meals and at bedtime), but Daichi said that usually he does it only 3 times during schooldays and sometimes only twice when he's visiting with friends or is away from home at lunchtime and dinner. He feels he knows his body well enough that he can predict his glucose level to within about 10 or 20mg/dl during the day, but always checks before injecting himself. (His mother frowned when he told me this, so he sort of added this last phrase) He's been testing and injecting himself since the age of 9. His parents and school rules prevented him from doing it on a regular basis earlier. The lancet and test strips come in a device which looks a little like a small pocket knife. The device dispenses one test strip at a time and holds the test strip for absorbing the small blood sample. The test strip looks like some of the ones you have been experimenting with. He dispenses, uses and transfers the strip to the glucometer, without ever touching the strip. He's very comfortable doing all this and performs the operations smoothly, rapidly, and with reasonable dexterity. There is little evidence of pain when he does his testing or even injecting, though he says he does not like to do it when people are watching. He says it makes them “queasy”(my word as he didn’t have an English word for his gesture).

What intrigued me most was the glucometer and some of the features on it.. While it was about the same size as the ones you have been examining, it had some rather unique and interesting features. At least, to me they appeared as such, and I do admit that I have not done the benchmarking that you have.

Daichi usually carries the glucometer around in his pocket. He seems to like to “fiddle” with it in his hands too. That’s because it has a nice feel and a couple of interesting display features, which I’ll explain shortly. The device has the conventional LCD screen which displays, in giant numerals, the glucose level in the usual 3 digit, way. It also shows averages, trends, has a clock, keeps track of how long since readings, estimates current glucose level, and can apparently display a lot of other information (maybe games too). There are only a couple of buttons on the device, but these are not absolutely necessary as he can control many of the display features by just squeezing the device (its got a soft, almost rubbery, surface like some of the razor handles). One squeeze and the display goes to the next item on the menu, two quick squeezes and it goes back. Or something like that; plus it recognizes some more “squeeze codes”. It has the usual beeper,a small flashlight, a USB connector, and some other standard features, but it also has a couple of other unique (at least to me) features which may also be of interest to you.

It glows! The whole device lights up! Because Daichi has poor vision, he wears glasses. Even with glasses, he has difficulty reading low contrast images and in dark areas. So instead of reading his glucose level, the glucometer flashes the value on command. If it’s 140, it will flash once, for 1, then four times, for 4, then one long time for zero. Like a “My Simon”game. If it’s above a certain level, it glows red. If below a certain level, it glows blue. If in the good range it flashes in green. He can program these levels. I think (but am not sure) he can also flash other information as well… depends on the squeeze codes and patterns he uses. He can see this info even without his glasses, without orienting the device and even from across the room as it glows all over. Sort of like your Vampagucci but all glowing and conveying actual data! He says he can use it as a bedside clock as it can flash the time. This is because he can’t read a digital or analog clock or watch without his glasses on. He sets the flashes very short to read it fast and to extend the battery life. He uses the flash display about 20x per day, but not always to read or remind him of glucose level (games?).

It has an analog tactile display! On the side of the meter are two tabs. One is a fixed protrusion (bump) which is part of the case. The other is a movable protrusion or tab. This tab is moved by a small motor. Its position is related to the glucose level; like a gauge. Daichi can feel the spacing between the fixed and moveable tab and know within about 10-20 mg/dl his glucose level. There are some raised numbered reference bars on the case but these appear hard to feel. He seems to just wave his finger between the two tabs to gage the spacing. This apparently is the intended way of reading, but he says he's also learned to "read" it by just putting one finger across the top of the two tabs. (Seems like he's done a lot of playing with his meter.) Daichi says that this resolution is sufficient to enable him to safely dose himself to keep his glucose level in the range of about 100 to 180mg/dl (depends on time of day, activities, food, etc.) He reads this display discretely, usually while in his pocket, and he can do this repeatedly because the tab is driven by a motor and small screw and requires no power once it's set. Too high or too low or some other important issue, the moving tab retracts into the case, indicating that the level or other info must be read on the LCD display. This tab can also track predicted trends or other slowly varying parameters and give him a discrete way of monitoring his disease status. He likes this feature, as he doesn't have to remember numbers from the last readings; they are just a quick feel away. In fact, he says that he sort of subconsciously checks the display almost every time he puts his hand in his pocket. It's like his fingers naturally gravitate to the device. The tabs are big enough that he can feel them even in winter in Tokyo when he's wearing gloves. He says it takes a little wiggling of the fingers to identify the tab positions and spacing but it's not a problem, and he can do it in his jacket pocket.

Since the motor only runs when the tactile display is changed, it consumes little energy. A supercapacitor in the device probably allows even a weak battery to supply enough energy to drive the small motor for the brief motions. For the 2-4 readings per day, and some simple trend tracking, his mother says that the battery still lasts about a year when used about half time. I thought this type of display a good feature, though it looked like it could be a bit more robust and could be sealed better. The track seemed to have allowed cookie crumbs and pocket lint to get into the case. The test strip port has an elastomeric material seal but that too looked poorly formed and a bit flimsy.

As a Mechanical Engineer I was intrigued by this device and I think you would be too. I asked about getting one "to play with". Michiko Saito said she would look for an old one when they got home after the New Year. In the meantime, you might want to think about how the features and functions of a device such as this meet some of your project goals and Abbott's interests. Perhaps it's given you some new ideas too!

Happy Holidays.

Vic

10.5 Deliverables Contract

10.6 EXPE Brochure

Abbott Diabetes Care

STANFORD UNIVERSITY

LULEÅ TEKNISKA UNIVERSITET

ME310 - 2005-2006

TEAM ABBOTT

Future Blood Glucose Meters

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Nick Reddy
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Luleå Members:
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Elin Karlsson
Maria Marklund
Erik Mossing

Corporate Liaison:
Jonathan Wyler
Abbott Diabetes Care

Coaches:
David Grossman
Mattias Bergstrom*
Christian Johansson*
(*Luleå)

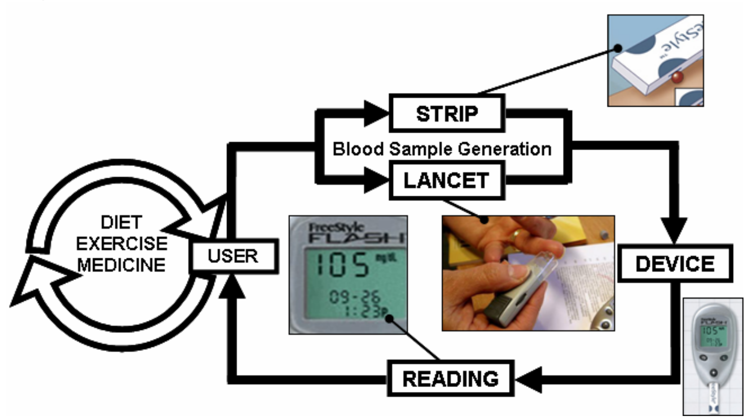
RESEARCH IN USER INTERFACES FOR FUTURE BLOOD GLUCOMETERS

Project Background and Goals

Diabetes is a disorder affecting millions of people across all age groups. It forces those afflicted to grapple with sudden changes in lifestyle, diet, exercise and healthcare costs. A critical component of this new lifestyle is the blood glucose meter – a portable device that measures a patient's blood glucose concentrations in milligrams per deci-Liter. Through interactions with users, Team Abbott learned that many existing meters do not fully harmonize all the needs of a complete diabetes management program, and that the meters that attempt to do so are complex and awkward.

Team Abbott's solution to the problem focuses on **juvenile Diabetes**, and consists of a meter that **quick** to use, **easy** to carry, and **encourages better self-management** of diabetes by providing **behavior-improving feedback**.

Figure 1 - The blood glucose testing procedure with the user in the center, utilizing the results of each test to enact lifestyle changes in diet, exercise and medicine.



A Collaborative Design Effort

The Stanford University team is partnered in this endeavor with a team at Luleå Technical University, Sweden. The teams developed a close relationship through brainstorming and collaborative design sessions that helped generate a multitude of concepts, and allowed for distributed development at latter stages of the project.

Abbott
Diabetes Care

Informative Feedback for Kids

- Set up a diabetes management plan, follow it and watch it in action.
- Detect correlations and compute smart averages for the user's blood glucose and other lifestyle information.
- Make medication intake suggestions based on the user's body, current performance and specified targets.
- Suggest automatic reminders and alarms to complete the entire self management cycle.
- Implement Operant Conditioning to educate the user and help correlate symptoms with results through positive behavior reinforcement.

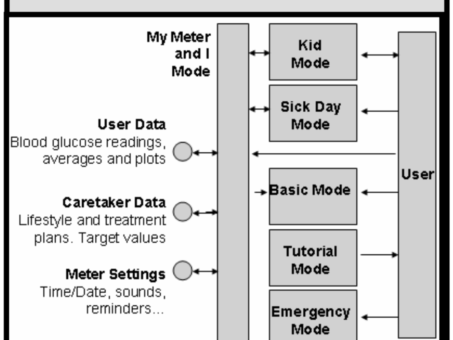


Figure 3 - Software Interface of Informative Feedback for Kids: 6 user modes that implement smart information management and positive behavior reinforcement.

Team Vision and Development Strategy

Team Abbott's research and prototyping efforts led the design process through two parallel paths, continuously refined by expert opinion and user feedback:

- Design an **innovative**, **playful** and **highly portable** meter that appeals to children.
- Turn the **Informative Feedback for Kids** concept into reality.

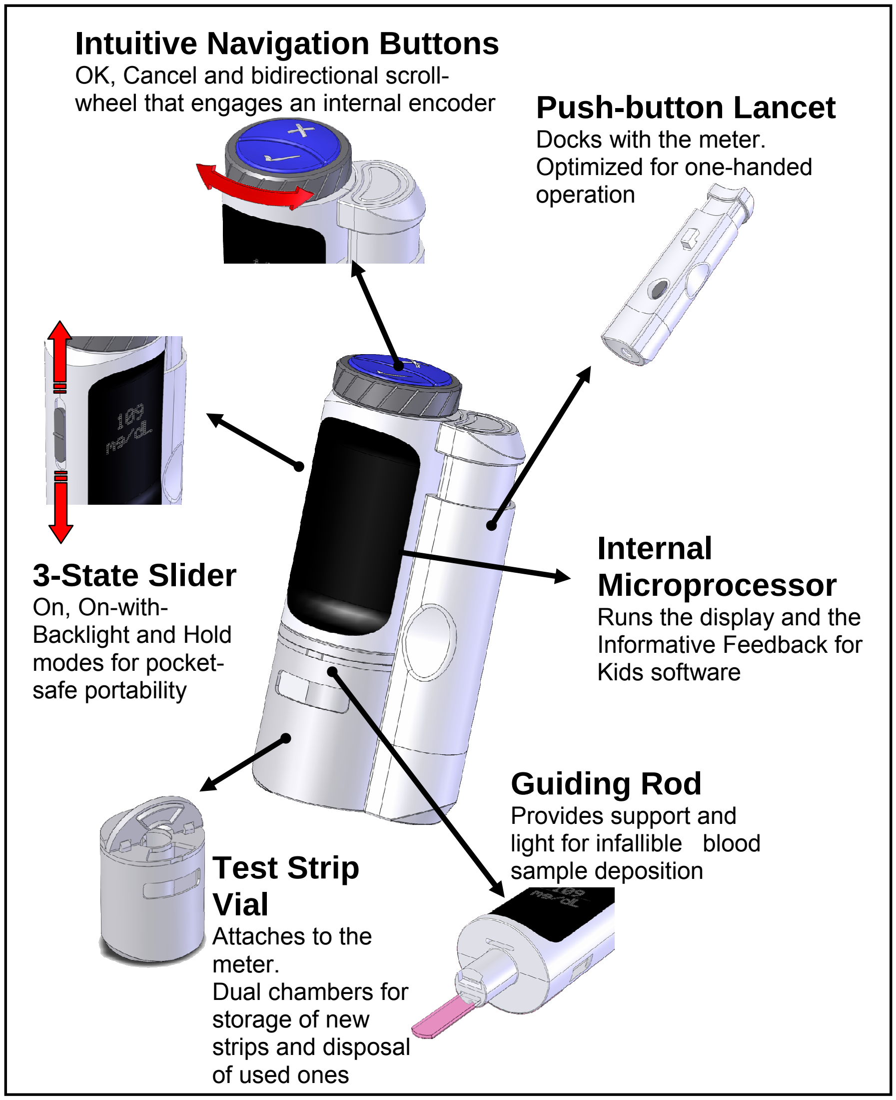


Figure 2 - Feature diagram of the modular Twist meter.

Final Design: The Twist

Team Abbott's design efforts culminated in the production of **Twist**, a modular glucose meter that complements and interacts with a software simulation of the various user modes of **Informative Feedback for Kids**. An ultimate validation campaign at the Lucille Packard Children's Hospital validated many of the design features and provided valuable opportunities for future work.

10.7 Spring Presentation