Development of a handheld meter for monitoring of diabetes using exhaled air

- with focus on product design and human-machine interface

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Cover: Renderings and physical model showing the final result of the project.

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Preface

This master thesis project is a part of the examination of the master programme Industrial Design Engineering at Chalmers University of Technology, and it is a full time 20 weeks project. The project is made in collaboration with Imego Ab, which is a research institute of micro- and nanotechnology, located in Gothenburg, Sweden. The foundation of their activities is the expertise within different sensor platforms, which over the years has been implemented into a wide range of industrial solutions, applications and products.

I would like to say thank you to those who have helped me during this project. First, I would like to thank Imego Ab and its employees that have given me the opportunity to work with this project. Specially, I would like to thank my supervisor at Imego Ab, Manoo Eibpoosh, who with great enthusiasm has guided me through the project. I am grateful for your honesty and straightforward comments, your warmth and hospitality. You have made me believe in myself and my abilities. Also, I would like to thank Sjoerd Haasl who helped me to understand the sensor technology.

Next, I would like to thank my supervisor at Chalmers, Lars-Ola Bligård, who with great dedication has given valuable comments and inputs during the supervisions. Also, you have made me question and reflect upon the project result, in order to take it to the next level. In addition, I would like to thank Håkan Almius who helped me to 3d-print the final concept.

After that, I would like to thank the interviewed diabetics who all have given me valuable information and inputs, and who made this project possible. I am grateful for your curiosity, openness, and willingness to help. In particular, a special thank to my mother and the staff at Göteborgs Diabetesförening who have helped me to come in contact with diabetics.

Finally, I would like to thank my family and friends who not only have been a great support during this project, but also in life with its ups and downs.

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Anders Nilsson

Abstract

Diabetes has become a widespread national disease, and it is increasing around the world. Often, it requires a lifelong injection of insulin, in order to keep the blood glucose within safe and stable levels. Until now, the testing of blood glucose is done using daily finger pricking, which is considered as uncomfortable, painful and time-consuming. As a result, ugly stick marks and calluses are created, and the finger sensibility is impaired. In addition, the test strips (and the needles) are expensive.

As a result, it has been proposed that measuring of human breath can be used as a cheap and non-invasive (means that no brake into skin is created) alternative to monitor diabetes. First, acetone in exhaled air can be used to predict diabetic ketoacidosis. It is a life-threatening condition that requires immediately medical care, which comes out of high levels of blood glucose for a longer period of time. Second, studies have shown that it might be possible to estimate blood glucose levels via multiple breath gas analysis of exhaled air.

Therefore, the project task was to develop a handheld meter for monitoring of diabetes using exhaled air, with the starting point of a sensor developed by Imego Ab, used to measure gases. The focus areas for the thesis were on product design and human-machine interface, which in details means product semiotics, ergonomics/handling and usability and so on.

The project started with an analysis phase, among other an interview study with seven diabetics. Next, two basic concepts were developed, including seven variations. The concepts were evaluated against the requirement specification, and together with feedback from Imego Ab, one concept were decided to develop further, into a final concept. An empirical evaluation study, with simple physical models, was used to develop the final concept.

The outcome of the project is a final meter, which in the future will facilitate and simplify the life for many diabetics. The product design of the final meter is characterized by the desired semantic expressions of simple, clean, robust & reliable. It is visualized with help of renderings and pictures, as well in a physical mock-up that was built in Alias StudioTools, and then printed in 3D. Furthermore, the project outcome is a human-machine interface, developed in Flash, based on a set of design guidelines.

Key words: Diabetes, exhaled air, acetone, product semiotics, product design, human-machine interface, usability.

Sammanfattning

Diabetes är idag klassad som en folksjukdom, och den ökar runt om i världen. Allt som oftast krävs det en livslång tillförsel av insulin för att hålla blodsockret på en lagom och stabil nivå. Fram tills idag har kontrollen av blodsocker skett genom dagligen återkommande fingerstick för att ta blodsockerprov. Det är en testmetod som kan uppfattas som obehaglig, smärtsam och tidskrävande. Dessutom är teststickorna och till viss del även nålarna dyra.

Som ett resultat av detta har det föreslagits att man via utandningsluften ska testa och kontrollera sin diabetes, som ett billigt och icke-invasivt alternativ. För det första kan mätning av aceton i utandningsluften användas till att förutspå diabeteskoma. Det är ett livshotande tillstånd som kräver omedelbar vård, och som kommer av en förhöjd nivå av blodsocker under en längre tid. Dessutom har studier visat att det i framtiden kan komma vara möjligt att beräkna blodsockernivån genom analys av flera gaser i utandningsluften.

Projektuppgiften var därför att utveckla en handhållen mätare för kontroll av diabetes genom utandningsluften, med utgångspunkten av en sensor utvecklat av Imego Ab, och som används till att mäta gaser. Huvudområden för detta arbete har varit inom produktdesign och användargränssitt, vilket mer specifikt innebar produktsemiotik, ergonomi/hantering, användbarhet och så vidare.

Projektet inleddes med en analysfas, vilket bland annat innefattade en intervjustudie med sju stycken diabetiker. Sedan utvecklades två stycken grundkoncept, och totalt sju stycken variationer. Efter utvärdering mot kravspecifikationen där koncepten ställdes mot varandra, samt respons från Imego Ab, togs beslutet att arbeta vidare med ett koncept till ett slutkoncept. Under den sista delen av projektet användes resultatet av en empirisk utvärdering, med enkla skissmodeller, för att utveckla slutkonceptet.

Resultatet av projektet är en mätare, som i framtiden kommer att förenkla livet avsevärt för många diabetiker. Dess produktdesign karakteriseras av att den ska kännas och uttrycka enkelhet, renhet, robusthet & pålitlighet. Slutresultatet visualiserades med hjälp renderingar och bilder, såväl som med en fysik modell, uppbyggd i Alias StudioTools, och som sedan skrevs ut i en 3d-skrivare. Resultatet av arbetet är även det användargränssnitt som hör till mätaren, vilket utvecklades i Flash, med utgångspunkt av ett antal riktlinjer inom området.

Nyckelord: Diabetes, aceton, utandningsluft, produktsemantik, produktdesign och formgivning, användargränssnitt, användbarhet.

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1 Introduction

In this chapter, the background of the project, the project task, project aims, delimitations and finally the disposition of the report will be presented.

1.1 Background

The starting point for this project is a patented new optical sensor technology developed by Imego Ab, which measures different kinds of gases. The technology has successfully been implemented into a new alcohol detector device, which is going to be used as an *Alcolock* in vehicles. See **figure 1**. The new developed *Alcolock* has, thanks to the technology, several advantages compared to conventional *Alcolocks* on the market today. First, the device has a faster warm-up time and response time. Second, the interaction with the device is contact free, since there will be no need for a mouthpiece. The driver blows straight into the air to the sensor device, approximately at a distance of 10-15 centimetres. Finally, the sensor device does not include any chemical bounding or reactions, which means that the device will be stable during the whole product life, without any calibrations.

Now Imego AB has decided to investigate the possibility for other application areas. During the *Alcolock* project, the group at Imego Ab found out that the sensor technology in principle can be used to measure all gases in exhaled air. Therefore, a possible new area for implementation could be within diagnostics of diabetes by using the patient's exhaled air, since it is wide known that people with diabetes or in the pre-diabetes phase, have increased levels of acetone in the exhaled air. The reason for this will be described more into details in the literature review & pre-study.

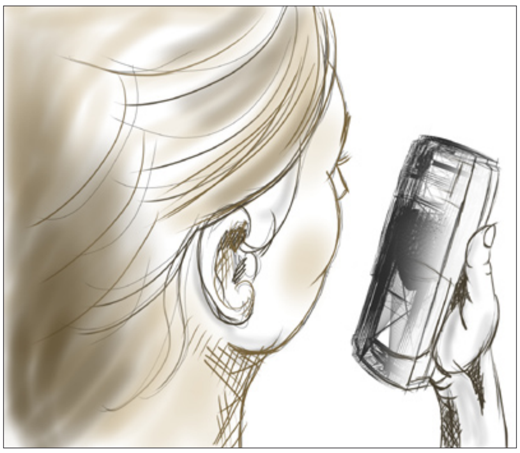


Figure 1. *Handheld Alcolock system.*

In addition, analysis of human breath can be used within monitoring of diabetes. For people with untreated diabetes, glucose is not available as a source of energy. Therefore, ketone bodies (acetone, acetoacetate and β-hydroxybutyrate) are produced as by-products and energy source. The ketone bodies are stored in the blood, and the body can remove them in the urine, or via the skin. Acetone is also expired through the lungs. In diabetic ketoacidosis, high levels of ketones are produced as a result of low insulin levels, which is a life-threatening condition that requires immediately medical care. Until now, blood or urine samples have been used to measure ketone values, as an indication whether or not the diabetes is under adequate control. However, it has been shown that breath acetone is a good predictor of detecting diabetic ketoacidosis, as a non-invasive (means that no brake into skin is created) alternative to the blood and urine samples.

Also, to keep the blood glucose within safe and stable values is one of the most important challenges for people with diabetes. This requires daily finger pricking when using the traditional blood glucose meters, which is considered uncomfortable, painful and time-consuming. Therefore, the focus around the world is to develop a non-invasive test method (when no break in the skin is created) that may replace the daily finger-pricking by which diabetics test their blood glucose. As a potential major breakthrough within non-invasive monitoring of blood glucose, it has been proposed that it might be possible to estimate blood glucose levels with help of using analysis of multiple gases (e.g. breath acetone and ethanol as independent variables).

After discussions with Imego Ab, it was determined that the project aims to develop a handheld meter, to be used in households for people that are already diagnosed with diabetes. In other words, the meter should be used for non-invasive monitoring of blood glucose by using exhaled air, and as an aim to detect diabetic ketoacidosis. The main reason for not developing a product to be used in diagnostics of diabetes is that than there will be much higher demands on the accuracy, in order to get it approved by the health care. Therefore it was considered that a more appropriate first step is within self-monitoring of diabetes in the households.

1.2 Project task

The project task was given in a specification document from Imego Ab in the start-up phase of the project. The specification list will be presented in more details in *chapter 6.4*. The task is summarized below.

The master thesis is based on one of Imego´s developed sensor technology that analyses the exhaled air from diabetes patients. The task is to design a handheld meter for self-monitoring of diabetes, using the sensor technology. The sensor technology is a good option for diabetes patients to a regular, cheap but reliable way test his breath, and thus have more control over their medication.

1.3 Project aims

The aim of the project is, on the basis of the new technology, to develop a handheld device that will make it possible to monitor diabetes (detect ketoacidosis and measure blood glucose levels via multiple breath gas analysis), with help of using patient's exhaled air. One assumption within this project is that when the meter will enter the market, it will be possible (with help of the sensor) to measure acetone with high accuracy, and the relationship between the multiple gases in human breath and blood glucose, and also the relationship between acetone and ketosis is well known. According to Imego Ab, the primary markets for the meter are Europe, Japan and USA.

Also, the aim is to visualize in what area the sensor technology can be used, its future potential, by implementing it in this kind of product.

The development will occur in relation to the needs, specifications and requirements established by Imego AB, from the user needs that will be identified during the process, existing requirements on traditional meters today, and by the application of the theory and methods that is associated with study of industrial design and human factors engineering. Moreover, during the development process, the product's realizability to the design and manufacture will be taken into consideration, as well to some extent the choice of materials.

1.4 Delimitations

There are some delimitations that will be considered during the project. First, the project does not intend to produce a finished prototype, but will remain in the concept phase. The final concept will be visualized with renderings and a physical model.

The components that are put in the *Alcolock* will be the same as the ones that will be needed in this product; the sensor, a printed circuit board (PCB), display, batteries and so on. During the project, the components inside the product will not be changed.

The components and their location in order to make a functional product will delimitate the design of the product. However, after discussions with Imego Ab, it was decided to not focus on the size of the components today, since it will result in a product that probably will be too big to be accepted by the users. Also, the meter aims to enter the market within 5-10 years. Then, it can be assumed that the miniaturization has resulted in even smaller components than today. Instead the focus will be to design the meter ergonomically correct, and to get the right emotionally associations when using the product.

Only basic knowledge about the sensor technology will be developed and then be addressed on a comprehensive level in the report. This is mainly due to lack of relevance to the final result, and also since it would be too time consuming to get a full understanding of the sensor technology. However, the sensor technology will put some demands on the product design of the meter, which will be considered. For instance, Imego Ab specifies that there will be a need of some kind of lock to protect the sensor from dust.

The main focus will be on the product design of the meter, secondary on the human-machine interface. This means that only a first version of the human-machine interface will be developed. Also, the human-machine interface will not be evaluated in a usanility test, within the time boundaries of this project.

1.5 Disposition of the report

The disposition of the report aims to mimic the product development process used in this project. The names of the headings have mostly been taken from the different activities in the project, to give the report a clear structure. Therefore, the different headings in the process chapter are the same as the ones for the whole report. Below, the process is shown graphically in brief. See **figure 2**. It will later, in the process chapter be described more into details.

Chapter 2 - Literature review & pre-study presents the sensor technology shortly. Also an introduction to Diabetes Mellitus and blood glucose is given, together with a short study of meters for self-monitoring of blood glucose. Finally, a research is done to find books and articles, containing surveys where the relationship between human breath and diabetes is studied.

Chapter 3 - Theory includes an introduction to product semiotics, usability and a chapter about the relationship between emotions and colours. Also, some design guidelines for human-machine interfaces are presented.

Chapter 4 – Methods describes the methods used in this project.

Chapter 5 – The process presents the activities, in other words the process, and where the different methods have been used.

Chapter 6 – Identification of needs & requirements presents the definition of the user group. Then, the interviews are analyzed, and the outcome is divided in two parts, a problem description and user needs and requirements on a new meter. Also, the specification list from Imego Ab is described more into details. Finally, the requirement specification is established, which clarifies the end of the analysis.

Chapter 7 –Idea generation describes desired semantic properties for the meter to be designed, and what kind of emotions the meter should trigger. An image board and a morphological chart are created which are used in the idea generation process, and a collage of sketches is showed.

Chapter 8 – Concept development presents the number of steps to perform a test with help of a use case, the basic ideas of the human-machine interface and the developed concepts are described and evaluated in pros- and cons lists.

Chapter 9 – Concept evaluation & concept decision shows the concept evaluation. Then, one concept is decided to develop into a final concept.

Chapter 10 - Final concept presents the final concept, its product design and human-machine interface, with help of images, renderings of the CAD-model, and a physical model.

Chapter 11 - Conclusions and discussion

Chapter 12 - References

Chapter 13 - Appendix includes the interview guide, a comprehensive list of some of the blood glucose meters available today, its features, settings and technical facts, and two HTAs.

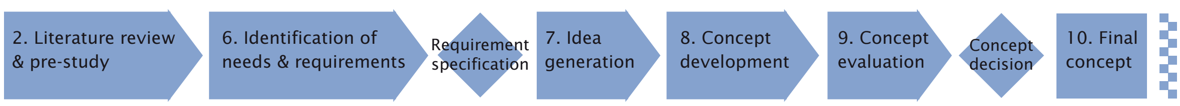


Figure 2. *Graphical view over the development process used in this project.*

2 Literature review & pre-study

The first part of the chapter includes an introduction to the sensor technology, how it works, its advantages and how it will affect the design of the meter. Also, in the start-up phase of the project, knowledge about Diabetes Mellitus and the regulation of blood gluocse are obtained, together with a survey of meters for self-monitoring of blood glucose, both now and in the future. Finally, a research is done to find articles and books, containing surveys where the relationship between human breath and diabetes is studied. The result of the literature review & pre-study is presented below, which worked as a basis for the whole project.

2.1 The sensor technology

Below, the theory behind the sensor technology will be presented, how it works, its major advantages compared to comparable technologies, and finally how the sensor technology will affect the design of the meter to be developed.

2.1.1 How it works

The measurement principle in the sensor technology is infrared (IR) spectroscopy. The sensor module can be seen **figure 3**. Infrared radiation is located between the visible and microwave regions in the electromagnetic spectrum (Sherman Hsu, 1997, p. 249).

Before a new test, the sensor is warmed up, and the sensor chamber is emptied from air. Then, IR radiation is sent into the sample when the exhaled air is blown into the sensor. If the frequency of the IR radiation is equal to the so called vibration frequency of the organic molecules in the sample, the molecules will absorb the radiation, due to the vibration motion, and converts it to energy (Sherman Hsu, 1997, p. 251).

Since different kinds of molecules have a specific vibration frequency, where it absorbs the infrared radiation, the principle can be used to identify the gases, liquids and solids that are present in the sample. In addition, it can be used to calculate the concentration of the matter in the sample, by quantifying the number of molecules that absorb the IR radiation.

Mirrors are used on the walls in the sensor body to give a larger response, in other words to give the gas molecules a greater possibility to absorb the radiation. See **figure 3**. The mirrors are designed in such way that the radiation will hit the IR detector, after being reflected on the walls a number of times (Sjoerd Haasl, personal communication, 2009-03-18). The IR-detector is equipped with so-called optical band-pass filters, which pass frequencies with a certain range, and sort out frequencies outside that range.

By measuring the amount of radiation that hits the IR-detector, it is possible to calculate the concentration of the specific gas in the breath sample by comparing the amount of IR radiation that was sent into the sample. Up to four band-pass filters can be used in the current system; one of these is used measure the concentration of carbon dioxide. For the Alcolock, one of the other filters is used to measure the concentration of ethanol. By exchanging the filters, the sensor technology can be adapted to measure the concentration of other gases, for instance acetone. (Sjoerd Haasl, personal communication, 2009-03-18)

$$\frac{C_{EtOH}}{C_{extEtOH}} = \frac{C_{CO2}}{C_{extCO2}} \Leftrightarrow C_{EtOH} = C_{extEtOH} \cdot \frac{C_{CO2}}{C_{extCO2}}$$

C_{EtOH}= Concentrattion of alcohol in exhaled air
$C_{extEtOH}$= Externally measured concentration of alcohol
C_{CO2}= Concentrattion of CO_2 in exhaled air
C_{extCO2}= Externally measured concentration of CO_2

The patented principle used in the new sensor technology can be described with help of a formula. See above. The formula illustrates the relationship between the gas concentration of CO2 and ethanol in exhaled air, and the concentration of CO2

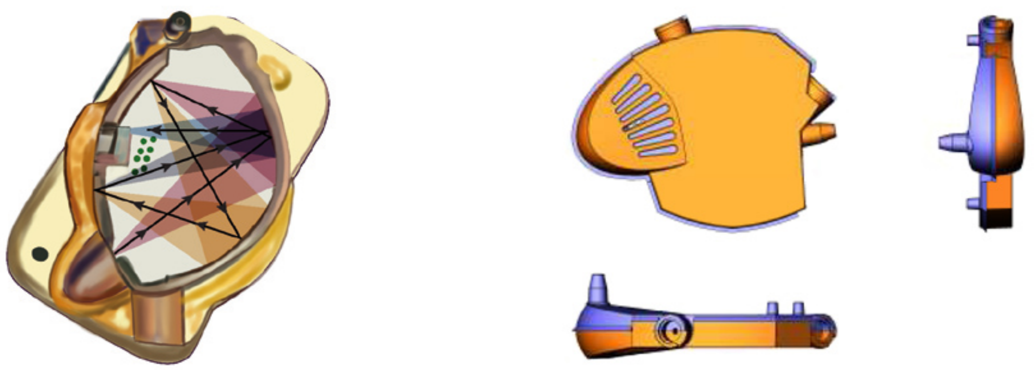


Figure 3. *Left: Schematic picture of the sensor. Right: The sensor in different angles.*

and ethanol that are measured in the sensor. The concentration of CO_2 in exhaled air is more or less constant, which means that it is possible to calculate the gas concentration of alcohol (or e.g. acetone) in the body with help of the formula (Sjoerd Haasl, personal communication, 2009-03-18). The concentration of CO_2 in the air is, in this case, considered as negligible.

2.1.2 Advantages with the sensor technology

The major advantage with the patented principle is that you can measure the concentration of gases in for instance human breath, regardless the dilution and mixture from the surrounding air. This means that there is no need for a mouthpiece, which considerably simplifies the test procedure, and minimize consumables. Also, the distance to the sensor that the person blows is of minor importance, since the formula re-calculates how much of the exhaled air that is measured in the sensor. However, a suitable distance will be around 10-15 centimetres.

In addition to the contact free solution, there are some more advantages that are connected to the technology. First, the sensor does not imply any chemical boundings, which means that sensor is stable over its full product lifetime, without having to be replaced or cleaned (Imego, 2009). Furthermore, this means that the sensor only needs to be calibrated when it is produced. Then, it is maintenance free, except for the recharging or change of batteries.

It should be mentioned that the sensor unit needs to be heated up before it is ready to use. The heating time depends on the effect of the battery, together with the surrounding temperature (Sjoerd Haasl, personal communication, 2009-03-18). If the temperature of the surrounding is far below 0°C, it will take maximum 30 seconds until it is ready to use. If the sensor unit is used at room temperature, it is ready to use within a few seconds. For the Alcolock, the expected response time for a completely sober person is 2-3 seconds (Imego AB, 2009), which can be considered as fast. It can be assumed that the response time will be more or less the same for monitoring of diabetes.

2.1.3 How the sensor technology affects the design of the meter

After having gone through the sensor technology, some functions and requirements were identified, which needs to be included and considered in the final concept of the handheld meter for monitoring of diabetes. These can be found in **table 1**.

	Functions		Comments
	Verb	Noun	
Technical	Allow	emptying	of sensor chamber from air before a test
Interface	Show	processing	of data from exhaled air
	Inform	user	when it is ready to use
			when sufficient amount of air is received to the sensor

Table 1. *Identified functions from the sensor technology that should be implemented in the design of the meter.*

2.2 Regulation of blood glucose

Insulin is produced in the beta cells in the pancreas. When we are eating, the carbohydrates in the food are decomposed to glucose, which enter the blood via the gastrointestinal canal. All cells need energy, which among other can be extracted from glucose, after having entering the cells. However, glucose can not enter the cells before insulin is bounded to the cell membrane's receptors. Therefore, insulin can be compared to a key, whose task is to open the cells, which then allows glucose to pass through the cell membrane and into the cell. See **figure 4**. For people not having diabetes, the insulin production is increased automatically when we are eating, and the blood glucose remains at a fairly steady level. In contrast, for patients with diabetes, the key that allows entry into the cell is lost, and the glucose remains in the blood, and the blood glucose level is raised. (Svenska Diabetesförbundet, 2007)

There are other hormones that controls the blood glucose levels; in particular glucagon, adrenalin and cortisol. Glucagon is produced in the pancreas, and is released when the blood glucose level is low, by promoting the breakdown of glycogen (the form in which glucose is stored in the liver) to glucose. This means that the action of glucagon is opposite to that of insulin, to raise the blood glucose level, when it is low. Adrenalin and cortisol are both stress hormones, which also counteracts insulin. (Glucagon, 2009, endocrine system, human, 2009)

2.3 Diabetes Mellitus

The name Diabetes comes from the ancient Greek and means "to pass through", which refers back to the large amounts of urine, a person with untreated diabetes produces, to get rid of the glucose in the body. This was first known more than 2000 years ago. Later on, the taste and smell of the urine has been used to diagnose different kind of diseases. For instance, a sweet taste of the urine worked as a bio-marker for diabetes. Therefore, a doctor named Thomas Willis, who lived in the 17th century, added the word mellitus to the disease, which comes from the Latin and means "honey", a reference to the sweet taste of the urine. (Svenska Diabetesförbundet, 2007)

Diabetes Mellitus is not one single disease, but is rather several, and with different causes. However, the result is the same, abnormal high levels of blood glucose, due to a disorder of the carbohydrate metabolism, caused by an impaired ability to produce or respond to the hormone insulin. The disease is usually divided into type 1- and type 2 diabetes. Further classification includes Latent Autoimmune Diabetes in Adults (LADA), monogenic forms of diabetes, and finally Gestational Diabetes.

2.3.1 Type 1-diabetes

Type 1 diabetes is usually diagnosed in childhood or when you are a young adult, and was previously known as juvenile diabetes or insulin-dependent diabetes. In type 1 diabetes, the body does not produce insulin, mainly because the cells in the pancreas, which produce insulin, are destroyed and attacked by the immune system. Therefore, insulin

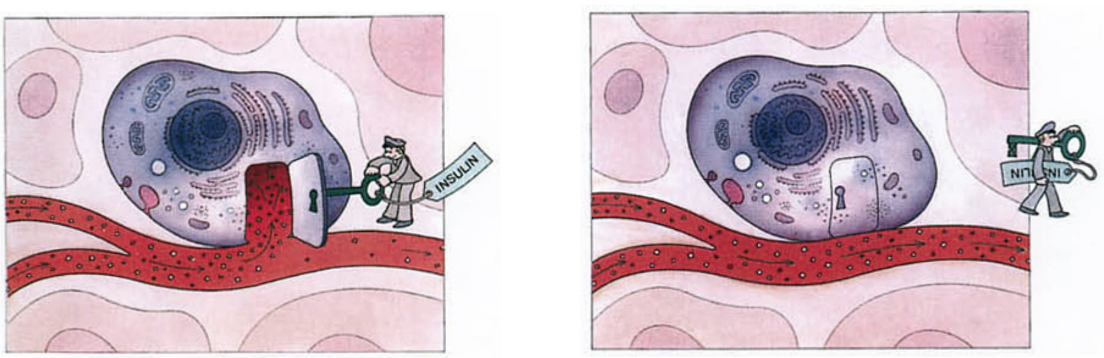


Figure 4. *Insulin can be compared to a key, whose task is to open the cells for the glucose.*

must be injected via syringe, insulin pen or insulin pump. This means that the blood glucose can be too low or high, and as a result, people with type 1 diabetes regularly need to check their blood glucose. (American Diabetes Association (ADA), 2009a)

Type 1 diabetes is partly hereditary, but the inheritance is complex, and the disease is also caused by both the environment and living conditions. The reason why the immune system attacks the insulin producing beta cells is still unknown, but a lot of researches believe that a combination of genes and environment (for instance virus, chemicals, and psychological stress among others) are necessary for the disease to break out. (Svenska Diabetesförbundet, 2007)

Usually, the disease process has gone far when the disease breaks out, which means that around 70-80% of the insulin producing cells have been destroyed, before the first symptoms are shown. The most common symptoms are large amounts of urine, increased thirst, abnormal tiredness and loss of weight. When the glucose is not taken up by the cells, it is excreted from the body via the urine instead. Because glucose binds water, a person with untreated diabetes needs to drink a lot of water to compensate this. In addition, the body can not absorb the energy that floats around in the blood, which causes fatigue, together with a weight loss since the fat is burned instead, to get energy. (Svenska Diabetesförbundet, 2007)

2.3.2 Type 2-diabetes

Type 2 diabetes is the most common form of diabetes, and in Sweden, more than 3 % of the population (>300.000) are affected by this disease. This means that it can be classified as one of the major endemic diseases. Also, many do not know that they have the disease, and there are a lot of people that have the so-called pre-diabetes, which means that their blood glucose levels are higher than normal, but not yet high enough to be diagnosed as diabetes. Type 2-diabetes is also called adult-onset or non-insulin-dependent diabetes, but nowadays even children are having the disease. Therefore, these terms are not used as much as before. The symptoms for type 2 diabetes are the same as the ones for type 1 diabetes, with the difference that they tend to be less pronounced. (Svenska Diabetesförbundet, 2007)

In type 2 diabetes, either the body does not produce enough insulin, or the body is less sensitive towards insulin, which means that a larger amount of insulin is needed to open the cells. Since the produced insulin is not enough to cover the body's need, the blood glucose level is raised, for instance after a meal. The disease is both hereditary (even more than type 1 diabetes), and is also caused by both the environment and living condition. For many, obesity and overweight is one of the reasons why the cells in the body lose their sensitivity to insulin. (Svenska Diabetesförbundet, 2007)

Type 2-diabetes is increasing around the world, mainly because of our improved living standards. In turn, this has lead to over-consumption of food, above all, worse food, and we are exercising less, which has led to an obesity epidemic. The increase of type 2-diabetes is also caused by the fact that we live longer, since the risk of being affected increases the older you are. (Svenska Diabetesförbundet, 2007)

The treatment or monitoring of type 2-diabetes does not automatically involves extra injection of insulin. For some of the type 2-diabetics, change of diets together with exercise is enough to increase the insulin production, and to improve the sensitivity to insulin, which in turns lead to more stable blood glucose levels. In Sweden, around half the people with type 2-diabetes are taking diabetes pills, which stimulates the own insulin production or medicines that improve the sensitivity to insulin. For the rest of the type 2-diabetics, daily injections of insulin, often together with diabetes pills, are needed to treat and monitor the disease. (Svenska Diabetesförbundet, 2007)

2.3.3 Latent Autoimmune Diabetes in Adults (LADA)

For people with LADA, the body mistakes the pancreas as foreign, and responds by attacking and destroying the insulin producing beta cells. LADA is often mistaken for type 2-diabetes, because it affects adults (over the ages of 25- 30 years old) and because it has similar symptoms. In its early stages, exercise, dietary change and oral diabetes medications (diabetes pills) are prescribed to control the disease. However, in its later stages, LADA is closely resembled to type 1-diabates, which means that daily injections of insulin are required, to succeed in keeping the blood glucose at an appropriate level. Still, it is not classified as the same disease as type-1 diabetes, nor type-2 diabetes, but rather a mixture between these two, and is therefore sometimes referred as the type 1.5 (type one-and-a-half) diabetes. (Björklund et al., 2008)

2.3.4 Monogenic forms of diabetes

The most common forms of diabetes, type 1 and type 2 diabetes, are polygenic, which meant that risk of developing these diseases are related to multiple genes. In addition, environmental factors play an important role in the development of these diseases. However, there are some forms of diabetes that are caused by a single gene mutation. Among these are Maturity-Onset Diabetes of the Young (MODY) and Neonatal Diabetes Mellitus (NDM). (Institute of Diabetes and Digestive and Kidney Diseases, NIDDK, 2007)

Maturity-Onset Diabetes of the Young (MODY)

Maturity-Onset Diabetes of the Young (MODY), exists in at least 6 different forms. Each is caused by a specific gene mutation that limit the ability of the pancreas to produce insulin, which if untreated leads to abnormal high blood glucose levels. The gene mutation is often inherited. Usually, MODY first occurs in early adulthood, and may be confused with either type 1 or type 2 diabetes. However, people with MODY are not in general overweight, or shows other risk factors associated with type 2 diabetes, and often, MODY can often be treated with oral diabetes medications, which can be compared with type 1 diabetes that always requires insulin injections. (NIDDK, 2007)

Neonatal Diabetes Mellitus (NDM)

NDM is a form of diabetes that occurs in the first 6 months of life. Infants with NDM do not produce enough insulin, resulting in increased levels of blood glucose. The disease can be mistaken with diabetes type 1, but the latter one usually occurs later than the first 6 months of life. Specific genes that can cause NDM have been found, and for almost half of the people with NDM, it is a life long condition. For the rest of the people, it can disappear during childhood, but may appear again later in life. (NIDDK, 2007)

2.3.5 Gestational diabetes

Gestational diabetes affects some pregnant women (in United States about 4% of all pregnant women), who had never had diabetes before, but that have high blood glucose levels during pregnancy. The causes are not entirely clear, but a theory is that the hormones from the placenta, which support the baby to grow, may block the action of the mother's insulin in her body, which can be seen as a sort of insulin resistance. (ADA, 2009b)

2.36 Short- term diabetes related complications

No matter which type of diabetes you have, to keep the blood glucose levels on a low and stable levels is the main goal with the treatment of diabetes. It is also one of the most important challenges for people with diabetes. Food raises the blood glucose, while insulin, pills and exercise lowers it. Sometimes the blood glucose level becomes too low or high, which might be harmful. (Svenska Diabetesförbundet, 2007)

Low blood glucose level is called hypoglycaemia, which can occur if you eat too little compared to the amount of insulin and/or tablets taken, or after a heavy physical exertion. The symptoms can be hunger, sweating, headache, concentration difficulties, anxiety, confusion and aggression. The treatment is to eat or drink something sweet. A blood glucose level that is very low can result in unconscious. This is a serious condition since the brain can be damaged, which means that an unconscious person with diabetes immediately should be taken to hospital. (Svenska Diabetesförbundet, 2007)

The opposite of hypoglycaemia is hyperglycaemia, which is a high blood glucose level, and can occur if you eat too much or bad diet, compared to the amount of insulin and/or tablets taken, if you are stressed or more sedentary than usual. The symptoms of high blood glucose are the same, as the ones for diabetes; large amounts of urine, increased thirst and abnormal tiredness. (Svenska Diabetesförbundet, 2007)

If the blood glucose level is very high for a longer period of time, fatty acids and amino acids are burned instead, in order to produce energy. In this process, slag products such as ketone bodies are produced (and also acetone which is a by-product of the spontaneous decomposition of ketones). The ketone bodies are stored in the blood, which lowers the pH concentration. Acetone is also excreted through the lungs, and then to the human breath.

When the lack of insulin has prolonged for long time, the production of ketone bodies becomes uncontrolled. As a result, the function of cells is successively impaired, and the blood flow to the brain is decreased. Eventually, the patient loses consciousness and fall into a state called diabetic coma, or diabetic ketoacidosis. This a life-threatening complication, and requires immediate medical care (ADA, 2008). The risk of developing ketoacidosis only exists for people with insulin-treated diabetes. (Svenska Diabetesförbundet, 2007)

Diabetic ketoacidosis was previously a major cause of death for people with diabetes, before insulin injections were available. Today, the self-monitoring of blood glucose has significant lowered the risk of developing ketoacidosis. (Svenska Diabetesförbundet, 2007)

2.3.7 Long-term diabetes related complications

The long-term complications that are related to diabetes are in principal the same for both type 1- and type 2-diabetes. There are two factors that determine the risk of developing diabetes related complications; how long the person has had diabetes together with large fluctuations in blood glucose levels. Primarily, it is the body's blood vessels that are injured, which can cause severe visual impairment or blindness, poor blood circulation in the legs and feet which can ultimately force an amputation, cardiovascular disease and the kidneys may be damaged, which could result in that the patient must be treated with dialysis or transplantation. (Svenska Diabetesförbundet, 2007)

2.4 The relationship between human breath and diabetes

Since the time of ancients, it has been known that the odour of the human breath can be used as an indication of some diseases in the body (Buszewski etl al., 2007). For instance, the sweet "odour of decaying apples" for patients with severe diabetes was first presented by John Rollo in 1798, and in 1857, a person with the surname Petters found out that the sweet odour has its origin from acetone (Crofford et al., 1977).

Modern breath analysis began in the 1970's when more than 200 volatile organic compounds (VOC) were identified in human breath, and some of them work as biomarker of different diseases (Chakraborty et al., 2008). In addition to the connection between breath acetone and diabetes, other VOCs may work as potential biomarker of lung cancer, liver impairment, uremia, kidney impairment, just to mention a few of them (Buszewski, 2007). Therefore, the analysis of exhaled air has been proposed as a complementary method to blood and urine sampling, in particular since the method is non-invasive (no brake into skin is created), pleasant and convenient. At the moment, a lot of money is spent to fully map the correlation between the known metabolic processes in the body and the human breath, and also to develop the measurement technologies.

Possible drawback of breath analysis, in order to diagnose and monitor different diseases, is the difficulty to obtain sufficient accuracy. Many of the VOCs exists in small concentration in exhaled air, they are highly volatile and chemically active, which makes accurate analysis of human breath as a significant challenge (Buszewski et al., 2007, Massick, 2007). On the other hand, there are a few VOCs that can be classified as an exception, because these exist in relatively high concentrations in exhaled breath, among these including acetone and ethanol (Buszewski et al., 2007). Researches believe that breath acetone can be used either for primary screening, diagnostics and monitoring of diabetes.

2.4.1 Pre-screening and diabetic diagnostics using exhaled air

For people with untreated diabetes, glucose is not available as a source of energy. Therefore, ketone bodies (acetone, acetoacetate and β-hydroxybutyrate) are produced as by-products and energy source when fat is broken down instead of glucose. In diabetic ketoacidosis, high levels of ketones are produced as a result of low insulin levels. The ketone bodies are stored in the blood, and the body can remove them in the urine, or is secreted via the skin. In addition, acetone is also expired through the lungs. Therefore, high concentration of acetone means that either the cells do not have enough insulin, or can not use the insulin in a proper way.

Acetone is a natural substance in the exhaled air of healthy people. However, it has been reported that it is an obvious difference in acetone concentration found in people with diabetes and people that are healthy, which suggests that breath acetone could be used as a supplementary tool for the diagnosis and early screening of diabetes (Deng et al., 2004, Wang & Surumpadi, 2008).

2.4.2 Monitoring of diabetic ketoacidosis by measuring breath acetone

Until now, blood or urine samples have been used to measure ketone values, to predict or detect diabetic ketoacidosis, the lifethreating condition that comes out of high blood glucose level for long period of time, due to lack of insulin.Therefore, the newer and most advanced blood glucose meters also offer measuring of blood ketones. This is especially important for children (due to larger fluctuations in blood glucose), for people with a diabetes that is difficult to regulate, or for all people with diabetes if symptoms of high blood glucose is present (such as illness) in order to figure out if it depends on diabetic ketoacidosis or another disease (Abbott Laboratories, 2007).

But, since increased levels of acetone is excreted in exhaled air as a result of the ketosis (elevated levels of ketone bodies in the blood), it has been proposed to measure human breath acetone to predict and detect diabetic ketoacidosis, instead of blood- and urine sampling (Deng et al. 2004, Wang and Surumpadi, 2008, Yamane et al., 2005).

In addition, for long time it has been known that breath acetone is correlated with ketone bodies in plasma, blood acetone and β-hydroxybutyrate in plasma (the most commonly measured ketone body) (Likhodii et al., 2002). The relationship between blood and breath acetone is linear (acetone in exhaled air is approximately 1/330 of the acetone in plasma) (Wang & Surumpadi, 2008, Zhang et al., 2000). Musa-Veloso (2002) says that breath acetone is a good predictor of ketosis, and Likhodii et al. (2002) have proposed a formula that makes it possible to estimate β-hydroxybutyrate in plasma (β-HBA) based on breath acetone measurement.

2.4.3 Estimation of blood glucose using multiple analysis of gases

Studies have been done to determine the correlation between breath acetone and blood glucose, in other words the linear relationship between the two variables. It was found to be in the range 0.7- 0.8 (-1 or 1 means full linear relationship). In addition, some researches aim to put together a full exhaled gas profile for diabetes, which will make it possible to non-invasive measure blood-glucose with help of a multiple analysis of exhaled gases. Until now, Galasetti et al. (2005) has come up with a formula that estimates blood glucose levels with help of using breath acetone and ethanol as independent variables. At the moment, their developed formula used for approximation of blood glucose showed an average correlation of 0.70 with measured blood glucose. Recently, other gas constellations have been studied and proposed by other research groups.

In the future, when a full gas profile of diabetes is identified, this might be the major breakthrough for non-invasive blood glucose monitoring in diabetes using breath analysis.

2.5 Instruments for self-monitoring of blood glucose

In this section the focus will be on intstruments or meters for self-monitoring of blood glucose (SMBG). In principal, SMBG is recommended to be carried out three or more times per day for diabetics using multiple insulin injections or insulin pump therapy, as a mean to monitor and prevent hypoglycaemia (low blood glucose) and hyperglycaemia (high blood glucose level) (American Diabetes Association (ADA), 2009c). Until today this has been done by using the traditional blood glucose meters. However, new test methods have just come or will enter the market in the near future. Others are a bit into the future, such as the one to be developed in this project.

2.5.1 Traditional blood glucose meters

The traditional blood glucose meters are the ones that the majority of diabetics facing in order to measure their blood glucose levels. The equipment consists of a blood glucose meter, test strips and lancets (used to take the blood sample). Some of the blood glucose meters are fed with test strips, while for other meters; the user needs to self-insert test strips for the analysis of the sample. In **figure 5**, three blood glucose meters available today are shown. A list including some of the blood glucose meters on the market, its features, settings and technical facts are presented in **Appendix B**.

After having washed and dried your hand, the procedure is to stick your finger with the lancet. Then you provide the test strip with a drop of blood and wait for the result to be showed on the display. The test strips and the lancets are thrown in the garbage after use. Nowadays, most of the manufactures provide the user with a so called lancing device where just the outer portion of the lancet is discarded after use. In addition, the depth of the lancet can be adjusted to match your skin type.

Some meters permits to stick on other places on the body, for instance at the palm, under arm, upper arm, thigh or calf. However, it should be remembered that blood from top of the finger shows changes in your blood glucose level fastest. Therefore alternate site testing might be an option when the blood sugar level is stable, such as before a meal or before bedtime. But when glucose levels are changing rapidly such as after a meal, after taking insulin, during exercise and so, the fingertip should be used instead. According to ADA (2008) diabetics should always consult with the health care before using an alternate test site.

Like everything else, the blood glucose meters have been developed and improved through the years. They have become smaller, the measurement time has been decreased to just a few seconds for the fastest meters, and the volume of blood required for each sampling has become lower than before.

In addition to taking blood glucose test, most of the blood glucose meters have more features and functions programmed, which varies depending on how advanced the meter is. Many meters store the values with time and date; which makes it possible to create for instance 7-, 14-, 30-day averages, high and low test results over these periods, to set up reminder alarms and so on.

Also, for most of the meters, the user has the possibility to transfer test results (together with time and date) to the computer, which enables to make graphs and curves over the test results. For the meters

Figure 5. *Left: Roche Accu-Chek® Aviva. Middle: Bayer HealthCare Contour®. Right: Abbott Precision Xtra*

belonging to the most advanced category, it is also possibly to measure the β-ketone level, which might be important for people that have high risk for developing ketoacidosis.

Although it has become easier than ever to measure the blood glucose level, some negative aspects remain. Besides that it might be uncomfortable and painful to take the blood sample and that the test includes a lot of steps (in particular if the meter is not fed with test strips), it involves a lot of consumable materials in the form of the strips and lancets, which is costly in the long run. It suggests that other test methods will be preferable in the future, for instance continuous glucose measurement together with blood glucose monitoring by using the exhaled air.

2.5.2 Systems for continuous glucose measurement

One of the most recent progress within the aids for monitoring diabetes are different systems for continuous glucose measurement. These systems take samples periodically, which mean that the result, except for real-time readings, offer a complete picture about your blood glucose levels over the whole period of time, the direction of the blood glucose, and how fast the change is. The manufacturers offer solutions where the continuous glucose measurement can be connected to the insulin pump, which may help to make more accurate adjustments of your insulin, and to stay within your target blood glucose range. In addition, continuous glucose measurement makes it easier to predict and detect hypoglycaemia (low blood glucose) and hyperglycaemia (high blood glucose) since the system warns and alarms directly to the user, if the values lies outside the safety boundaries. (Abbott Laboratories, 2009)

On the other hand, the technology is new, under development and is still associated with some complications. At the moment, it is not approved as a replacement of traditional blood glucose tests, due to its low accuracy. In Sweden the system can be borrowed for a limited period of time, to monitor how the blood glucose level is affected by meals, exercise and medication (Medtronic, 2006). In addition, the method of measurement is valuable for the health care team and the patient, when to begin with insulin therapy, or when the basal insulin dose needs to be adjusted, but should be seen as a complement to traditional blood glucose tests (Medtronic, 2006).

The technology used for continuous glucose measurement can be divided into two sub-groups; invasive and non-invasive. Some of the meters today will be presented below.

Invasive test methods

The Guardian® RT System is developed by Medtronic; it consists of a small sensor that is fastened into the skin (subcutaneous tissue), a transmitter and a receiver/monitor. See **figure 6**. Every fifth minute, the transmitter sends glucose data wireless via radio waves to the monitor (either the insulin pump or an extern monitor if the user does not wear an insulin pump). This means that the user continuously can see the latest value on the monitor, or the glucose curves afterwards. In addition, the monitor has an alarm that warns patients for dangerous high or low glucose levels. You can add information such as meal time and type, insulin type and activities which might serve as a help when the health care analyzes your glucose trends and patterns, in order to give advice how to make better decisions when monitoring your diabetes. (Medtronic, 2009)

Figure 6. *The Guardian® RT continuous glucose measurement system.*

The sensor needs to be replaced every third day, and needs to be calibrated twice per day with a traditional blood glucose test. Also, the sensor needs to be warmed-up after having being calibrated, which means that it can take 2 hours or more before it starts to give new glucose levels again. At the moment, the technology is not approved as a replacement of traditional blood glucose meters, but can give indications that a test is necessary. (Medtronic, 2009)

There are other systems available on the market, for instance one developed by Abbott Laboratories (FreeStyle Navigator) and DexCom Seven Plus. See **figure** 7. In principal, these systems work in the same way, except for differences in how often the sensor needs to be replaced and calibrated, and how often it updates the blood glucose measurements. (Abbott Laboratories, 2008 & DexCom, 2009)

Figure 7. *The FreeStyle continuous glucose measurement system*

Non-invasive test methods

In early 2002, Cygnus Inc. introduced their GlucoWatch Biographer (later updated to the GlucoWatch G2 Biographer), which is built on a non-invasive test method for continuous blood glucose measurement. See **figure**. 8 The meter is worn like a watch. On the back of the GlucoWatch G2 Biographer, there is replaceable sensor that is fastened to the skin. An electrical charge is sent through the skin, which brings glucose to the skin surface where an enzyme reaction makes it possible to estimate the blood glucose level. (Diabetes Mall, 2009)

The GlucoWatch G2 Biographer is not meant to replace the traditional blood glucose meters, and it is not recommended to use as a decision basis when adjusting the insulin dose. However, because new readings are updated every 10th minute, it can warn for high or low blood glucose levels. Also, it visualizes patterns and trends in blood glucose, and how meals, activates and sleeping affects the blood glucose levels. (American Diabetes Services, 2004)

Figure 8. *GlucoWatch G2 Biographer*

At first sight, the expectations were high that these kinds of products were the revolution that everyone was waiting for. Now Animas Corp. has purchased Cygnus Inc., but in 2007 they announced that they no longer will be selling the GlucoWatch G2 Biographer. At the moment, no information can be found on their homepage about the product. This can probably be explained with the fact that there were some problems associated with the measurement principle. First, as for the invasive test methods, the device did not offer a full monitoring of the blood glucose. The sensor needed to be replaced two times per day, following a two hour warm-up, before the new sensor was ready to be calibrated with a traditional blood glucose meter. Then, the device started to monitor the blood glucose again. (Diabetes Mall, 2009)

Furthermore, some users complained about skin irritation, such as local redness, itching and/or small blisters, when using the GlucoWatch G2 Biographer, and the sensor might skip readings due to a lot of sweating (American Diabetes Services, 2004). Despite this, the technology in itself seems promising, and hopefully there will be a totally non-invasive system for continuous glucose measurement, and with high accuracy available in the future.

3 Theory

In this chapter, an introduction to the area of product semiotics is given, which is important to consider when designing attractive products. Also, the idea that a product with its properties triggers certain emotions when looking and interacting with it is presented, and then in particular the connection between colours and emotions.

Also, an introduction to usability is given. Finally, there are many design guidelines in literature that are useful when design human-machine interfaces, in order to achieve good usability. Here, the design guidelines developed by Patrick Jordan, Jakob Nielsen and Ben Shneiderman are presented.

3.1 Product semiotics

It is easy to say 'and the product must also be attractive'. In product design, this is seen as an important and obvious requirement when developing new products. However, it is not that easy to say what is meant by talking about the attractiveness of a product. One way to describe attractiveness is that people ought to feel for the product. The user should want to use the product. Monö (1997) says that attractiveness it is not a matter of like or enjoying a product, but it is about understanding the product, so as to be able to use it. It is the user's understanding of the product that determines whether it is perceived as attractive or not. However, people do not have the same feelings for a product, which makes the designing of products quite complex and difficult. Users understand the product different, for instance due to varieties in education, experience, training, culture, interests, physics, gender and so on. (Monö, 1997)

3.1.1 Semantic functions

There are models that aim to make the design process comprehensible. First, a product with its properties or design cues (e.g. forms and shapes, colours, surface/textures, materials, logos, texts, sound, smell etc.) communicate a message to the user. For instance how it is intended to be used, usage area, its target group, price, origin and so on. In order to make a product 'attractive', four semantic functions can be used as the basis when designing a product. Together, these four semantic functions (see below) form a model that is developed by Rune Monö. When thinking about these four semantic functions, it is possible to make the product convey the right messages – to make attractive products - that users want to use.

The four semantic functions are:

- **to describe**: purpose, mode of operation, how the product should be used.
- **to express**: properties (e.g. stable, safe, soft, sporty, dynamic etc.)
- **to exhort**: reactions and use.
- **to identify**: a product, its origin, kinship, location, nature of category.

The semantic function *to describe*

It is important that the product, through its product gestalt (shape, colours, surface structures, materials, sound etc.) communicate and describes how it is intended to be used, its main function (Monö, 1997). As an example, the form of a handle can describe in what direction it should be pulled/push in order to open the door, or a symbol can describe which button that should be pressed to start the product, or the form describes how it should be hold. Complicated products perhaps require a manual to be able to be operated, while simple products should be self-instructive (Wikström, 2002).

The semantic function *to express*

The product gestalt expresses properties. Often, when a person is told to tell what a product expresses, he or she uses words similar to those used to describe a person. A product can express *stability* if the height is low in comparison with the length and breadth, if the colour of the base is dark and so on. Furthermore, stability is often a desired property of a chair, and a chair whose legs are angled slightly outwards tends to look more stable in comparison with a chair that has vertical and completely straight legs.

Good product design is characterised by the fact that product's real properties (technical, ergonomical etc.) are expressed and communicated in the design. At the same time, the product should not express properties that it does not have. This "false" expression can invite the user to an unwanted behaviour or use of the product. Wikström (2002) gives an example of some baby products that looked stable, which put the parents into a false sense of security, but in contrast the products easily broke and some seriously accidents did occur.

The semantic function *to exhort*

The design of a product can exhort the user to certain actions. A good product design gives the right signals; the product describes the correct procedure when interacting with the product. Monö (1997) says that the semantic function to exhort is not always easily identified in the design of a product. Instead, this semantic function is often found in the human-machine system, and the design of interfaces (Monö, 1997). For instance, different colours, sounds, text messages, symbols and so on exhort the user to certain actions.

The semantic function *to identify*

Also, a product is said to have an identity, it belongs to a certain product range, from a particular manufacturer and so on. Logotypes can be used to show the product identity of the product. In addition, a company can use a consistent design language (e.g. curves, forms and shapes, materials, colours, surfaces/textures etc.) to show the kinship to the whole product portfolio, and the connection to former products (Monö, 1997). As an example, Apple's design is characterised by the consistent use of basic form elements which give their products their identity.

3.2 Emotions and colours

A product can trigger certain emotions, for instance joy, trust, fear, surprise, sadness, disgust, anger and anticipation, which are very useful to consider when designing products. One idea is that by copying the facial expression from a person to a product, the emotional response when interacting with the product will be the same. As an example, the grill of a car is designed to look like a happy mouth. The car thus express joy and playfulness, and the person will then have the same emotional response when looking at the car, and hopefully also when driving it. See **figure 9**.

Figure 9. *Peugeot 107 with its smiling grill.*

In addition, there is no doubt that colours affect our emotions, which should be carefully considered when decide on colours for the product, which might be a challenge. People show large individual differences in colour perception, colour preference and colour associations. Therefore, what one considers to be an awful colour can be considered to be a nice one by others. (Muller, 2001) Still, there are some general thoughts about colours and their associations, see **table 2**.

3.3 Usability

As been mentioned, it is easy to say that the product must be attractive, without actually know the meaning of the word. In addition, terms like easy to use and user friendly are commonly used when defining and describing desired characteristics for products or human-machine interfaces, not least in the marketing. According to Nielsen (1993), the term user friendly is not really appropriate, for several reasons. First, users do not need machines

The meaning of colours	
Red	Stop, danger, warm, fire
Yellow	warning, slow, testing
Green	Ok, go, on
Blue	Cold, water, calm
Yellow, orange & red	Warm, approaching, cheerful and stimulating
Blue-greens colours	Cool, distancing, relaxing
Dark colours from blue-purple area	Comforting, serious, sombre
Combinations of bright colour	Playful
Combinations of dark colours	Secure (in the red area) or mysterious (in the blue area)

Table 2. *The meaning of colours.*

that are friendly. Instead, they need machines that get their work done, and in an efficient manner. Also, users have different needs, which mean that it is not possible to evaluate the user friendliness along a single dimension.

Therefore, in English the term usability is instead often used to describe how the interaction between the user and the product or human-machine interface works. Usability is not only determined by the characteristics of the product, but is also depending on the users, the use situation and the task to be carried out. The idea is that the usability of a system is measurable, for instance the time to perform certain tasks, number of errors and number of key presses per task etcetera. The result can be used to evaluate different solutions, to see whether the usability goals in the requirement specification are met, identify shortcomings with the interface, to see if the usability has been improved from one solution to another etcetera. (Nielsen, 1993)

Nielsen (1993) uses five components, attributes or properties to define usability, and also what is meant by good usability.

Learnability – The system should be easy to learn so that the user can rapidly start getting some work done with the system.

Efficiency – The system should be efficient to use, so that once the user has learned the system, a high level of productivity is possible.

Memorability – The system should be easy to remember, so that the casual user is able to return to the system after some period of not having using it, without having to learn everything all over again.

Errors – The system should have a low error rate, so that the users make few errors during the use of the system, and so that if they do make errors they can easily recover from them. Further, catastrophic errors must not occur.

Satisfaction – The system should be pleasant to use, so that users are subjectively satisfied when using it; they like it.

3.4 Design guidelines for human-machine interfaces

The meter will not be evaluated in a usability test. Still, good usability is highly desired, in particular since it belongs to the category of medical equipment. Over the years, some basic guidelines have been developed that should be kept in mind when designing good human-machine interfaces. Below, the design guidelines developed by Patrick Jordan, Jakob Nielsen and Ben Shneiderman will be presented.

3.4.1 Patrick Jordan's 10 design guidelines for human-machine interfaces

Consistency – This is one of the most basic usability principle, and means that the interface should be consistent through the whole design, with respect to placement of figures, sequence, use of the same colour coding and symbols etc. (Jordan, 1998). The same information should be presented in the same location on all screens and dialogue boxes (Nielsen, 1993). Consistency will help the user to learn and recognize the information presented in the user interface, which will fasten up the time to perform the tasks, since the user can retrieve information from the long-term memory.

Compatibility – This means with respect to human expectations (mental model) of how to use it, for instance with the use of cultural stereotypes (up = increase, down = decrease, clockwise = increase, right, counter-clockwise = decrease, left).

Give feedback – Modern approaches to human-machine interface design stretches the importance of feedback (means the system talks to the user). For instance, after having executed a command, some feedback must be given that the command has been received and is now being executed. In other words, the human-machine interface must confirm the command (whether or not it has been performed in a correct manner), and to give information about the consequence of the command. Feedback can be given in the form of sound, colour change, motion, haptic feedback etc. (Bridger, 2003 & Jordan, 1998)

Consideration of user resources – Keep in mind that the human resources are limited. If a lot of information is to be presented, it can be helpful if it is divided and transmitted through different senses (for instance both the visual and auditory senses) since they use different resources in the brain, so called multi-modality. In addition, *redundancy* is a useful tool when designing human-machine interfaces. This means that the same kind of information is presented through different channels for better perception and understanding, and to make the perception robust and less sensitive to misinterpretations. For instance, both audio and haptical feedback can be given to confirm that a button has been pressed. In particular, *redundancy* should be used for important information. (Abrahamsson et al., 2008 & Jordan, 1998)

Error prevention and recovery – The user will make errors but the consequences must be limited, for instance by giving the opportunity to undo, to give information about what went wrong, and to provide suggestions on how to fix the errors. In addition, warning messages can be given to indicate that something might go wrong, but that it still can be prevented by the user. (Jordan, 1998) For example, when a word document is closed without being saved, a warning message is showed that asks if you want to save the document before closing the document. Then, the possible error of closing the document without saving has been prevented.

User control – This guideline is about maximize the user control, for instance with help of using different kinds of settings and pre-selections.

Visual clarity – The information (text, figures, symbols etc.) should be displayed in such way that it can be read quickly and easily, without causing confusion (Jordan, 1998). It is about being careful when choosing typeface, size, colour, combination of colours, contrast and so on, to maximize the visual clarity.

Prioritisation of functionality and information – Again, this is about the fact that the human resources are limited, which means that the most important information and functions should be easy to find. For instance, less important features can physically be hidden behind a cover, or being activated via a menu.

Appropriate transfer of technology - This means that you should make appropriate use of technology developed in other contexts to enhance the usability of the product (Jordan, 1998).

Explicitness – Products should be designed so that it is clear how to operate them. For instance, in computer based applications, the name of the command should clearly signify its function, which means that cues are given about the product's functions and how to use them. (Jordan, 1998)

3.4.2 Jakob Nielsen and Ben Shneiderman's 8 design guidelines for human-machine interfaces

Jakob Nielsen (1993) and Ben Shneiderman (1998) have come up with eight principles that are useful to consider and implement when designing human-machine interfaces. Some of the principles correspond with the ones developed by Patrick Jordan, and is therefore not described once again.

Use a simple and natural dialogue – For instance, print, delete, past, cut and so on is often enough to understand the content and meaning of the operation. A complex dialogue (e.g. long sentence) increases the time to understand the content, and also increase the risk of misinterpretations. Nielsen, 1993)

Talk the user's language – This means that the interface should use words that the user is familiar with, and the dialogues should as far as possible be in the users' native language (Nielsen, 1993).

Minimize short term memory loading – The human short term memory has a limited capacity, which means that the human-machine interface should be designed in such way that the user does not have to keep important information stored in the short term memory. Instead important information should be showed on the display, and the whole short term memory capacity can be used for solving problems. (Abrahamsson et al., 2008 & Nielsen, 1993)

Be consistent – See Jordan's design guidelines.

Give feedback – See Jordan's design guidelines.

Include short-cuts – Even though it should be possible to operate the human-machine interface with just basic knowledge, experienced user should also be able to perform frequently used operations with help of for instance keyboard short-cuts, a single key press and so on, to fasten up the time to perform a task. (Nielsen, 1993)

Prevent errors – See Jordan's design guidelines.

Formulate clear error messages – Four simple rules should be followed. First, error messages should be phrased in a clear language, and the user should be able to understand the error messages without having to refer to the manual. Second, they should be precise, tell what is wrong, and not just say that something is wrong. Third, the error messages should constructively help the user solve the problem, and finally be polite and not blame the user when they make errors. (Nielsen, 1993)

Support operator control - The user should have the feeling of being in control of the situation, for instance by providing the user with an easy way out of as many situations as possible, and also have the possibility to undo actions. Then, users will feel more encouraged to try out unknown options, since there is always a way out, and an opportunity to recover from possible errors.

3.5 Gestalt laws

According to Monö (1997), a gestalt is defined as: *"an arrangement of parts which appears and functions as a whole that is more than the sum of its parts"* (p. 33). This is what happens when a person tries to understand and interpret information from the surroundings. In other words, the human has the ability to organize different parts together to make a whole, in order to better understand our perception and to give it a logical meaning. In general, it could be said that is about finding the lowest common denominator. There are several ways of organize the parts, which is described via the gestalt laws; when you organizing single units to a whole. Four of these are presented below, which are useful to consider when designing human-machine interfaces.

Proximity – Objects that are located close to each other are often seen as a whole, the closer the objects get, the clearer the group is (Monö, 1997). See **figure 10**. Therefore one general design guideline is to group buttons that have similar functions, in order to make the control panel as clear as possible.

Similarity – The human tends to group objects that have the same look, appearance and properties, for instance the same form, colour or even material structure (Monö, 1997). See **figure 10**. This is also a way to group buttons with similar functions, by adding the same physical properties. Also, buttons with different types of functions can still be seen as whole, even though they are not located at same position.

Continuity – This gestalt laws explains that the human often groups objects that are located along a line or a path (Abrahamsson et al., 2008). See **figure 10**.

Closure – This is a good example of the fact that the human tries to fill in gap in the picture, in order to create closure of incomplete forms or objects. See **figure 10**. Objects can not exist without giving them a meaning, which is closely connected to how the human perception process works; that our stimulus should be giving a meaning by enhance, discard, categorize, sort and distort the information.

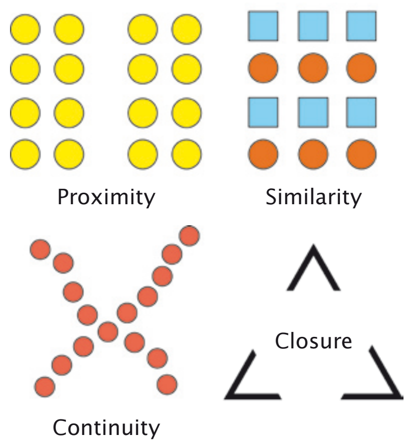


Figure 10. *The gestalt laws; proximity, similarity, continuity and closure.*

4 Methods

Here, the methods used in the different phases of the project are presented and described.

4.1 Information gathering

When planning a survey with the purpose to identify the user's needs demands and requests regarding a future product, four parameters have to be considered; which methods should be used to gather the information, which people can contribute with the information (participator), how should the product be presented to the user (stimuli), and where should the survey be performed (context). A method for information gathering is a combination of these four parameters. (Karlsson, 2005)

Methods used for information gathering can be divided mainly into two categories; communication- or question based methods and observation based methods. Individual interviews, questionnaires, group interviews or focus group are examples of question based methods. The question-based methods can either be of qualitative or quantitative nature. (Karlsson, 2005)

Qualitative question-based methods, such as individual interviews and focus groups are primarily used in the early phases of the product development process, and are specifically used to give an understanding of the problem and to generate a list of requirements.

Quantitative methods, such as questionnaires and telephone interviews, mostly involve data from a large number of people. In general, these methods are used to confirm the already collected information, for instance as a way to prioritize the requirement. It rarely provides new and unique requirements for the product. (Karlsson, 2005).

There might be information that can not easily be verbalised, or the user might have behaviors that he or she is unaware of. In these cases, observation based methods are preferable to be used. In addition, then you have the possibility to understand the way the product in fact is used, and what kind of problems that may occur in the use situation.

4.1.1 Interview

Interviews can be carried out to identify the user's needs, demands and requests regarding a product or a problem, as well as attitudes and feelings towards it. The interviews can be individual, or in groups and with varying structure. Unstructured interviews are more like a conversation between the interviewer and the interviewee, while a structured interview can be comparable to a questionnaire, where there are predetermined questions, together with an explanation of how the questions are supposed to be responded.

For the unstructured interview, a tool can be an interview guide, consisting of a list of topics and related issues to address during the interview time. Then the interviewees have the opportunity to express themselves in their own word, and the questions from interviewer are used to lead the discussion in the wanted direction. In addition to the predefined interview guide, one recommendation is to use *probing*, in other words to ask additional follow-up questions (e.g. Why? Have I understood you right? What do you mean?). These questions are used to get a full understanding of the problems and requirements, and to ensure that the interviewee has been understood correctly. (Karlsson, 2005)

Group interviews or focus groups are often unstructured, which means that a group of people (around 8-10) sit and talks freely about a topic, where the discussion is lead by a moderator. The advantage of a group interview is that a person's views may trigger the other to think upon it, and thus valuable information is identified, which otherwise would not be identified at the individual interviews.

However, according to Karlsson (2005) individual interviews are recommended as the primary information gathering method. In particular, since the individual interviews are cheaper to perform (when talking about cost per identified requirement) in comparison with the group interviews. Also, individual interviews can be advantageous since it may be easier for the interviewee to talk openly. It should be mentioned that if many interviews are performed, and with high quality, a lot of time, resources and skill are demanded.

The interviews in it selves are easy to perform. The difficulties lie in getting use as much as possible out of it. One recommendation is to start the interview with more general questions, in order to make the interviewee feel more comfortable and at ease with the situation (Lantz, 2007, p. 58). Then, the interview should be like a funnel – from general questions to more specific, from simple to sensitive, from questions that are easy to answer to such that requires reflections. Finally, it should be mentioned that people usually have difficulties to express and form technical requirements and solutions, while it is easier to describe problems. (Karlsson, 2005)

4.2 Analysis of data

When the information has been gathered it needs to be structured and organized in some way, in order to be usable and manageable.

4.2.1 KJ-analysis

The method is one of the seven quality management tools, and was developed by the Japanese anthropologist Jiro Kawakita, in order to structure large volumes of data from field studies. The aim with the method is to compile an overview of the data, and to communicate the result in an effective way, for instance in a tree diagram that shows the user needs and/or requirements of the given problem or future product. The method can be applied both individually and in group. (Karlsson, 2005)

The first step in the KJ-analysis is to write down every single announcement, for instance from the interviews, on separate post it cards. Next, all cards are placed in one of the corner. Then, place one of the cards in the middle of the paper. If the next card relates to any of the already placed cards, then these cards should be placed together. If not, the card forms a new group. This procedure is repeated until all cards are placed on the paper. The final step is to put a name on each group. Thus, all announcements have been grouped in an effective manner. (Karlsson, 2005)

4.3 Requirement specification

The requirement specification is a list of requirements for the proposed product or concept and can be described as a compilation, weighting or grading of the functions. For a larger quantity of requirements and wishes, it could be helpful to divide them into different categories, such as technical, ergonomical, features, aesthetics, production and so on. The importance of each requirement can be graded on a scale, for instance from 1-5, or they can be weighted against each other. (Wikström, 2006a)

It is important to use a requirement specification, since it implies that no important aspects are forgotten or disregarded. In addition, the requirement specification can be used to evaluate ideas and solutions, and to check if the necessary requirements are met. Finally, the requirement specification is an instrument and tool for stimulating/guide the creative work of the development process towards the wanted direction. (Wikström, 2006a)

4.4 Synthesis

Below, the methods used in the synthesis phase of a product development project are described.

4.4.1 Free sketching

Free sketching (with help of pencil, paper, and markers) can be used during the whole process, from the idea generation to the final concept, to generate new ideas and to improve other ideas. In the beginning, the different problems are preferably solved one by one. Later, the different ideas are collected and put into concepts. Then, presentation sketches are made, for instance from background layers created in Alias StudioTools that can be further sketched in Adobe Photoshop, using Wacom tablet.

4.4.2 Image board

Image Board is a collection of images that in an illustrative manner conveying a product's desired features and expressions, which in turn can inspire ideas, and to come up with solutions that match the desired features and expressions.

4.4.3 Osborn's list

During the idea generation, Osborn's list can be used to come up with new ideas and combination of solutions. It can be used to inspire the individual, or in group, for instance on a brainstorming session. Osborn's list is "73 idea-spurring questions". Below, the list is presented in compressed form. (Wikström, 2005)

Put to other uses? New ways to use as is? If modified?
Adapt? What else is like this? What other person, place or things does this suggest?
Modify? Change meaning, colour, motion, sound, odor, from, shape?
Magnify? More time? Greater frequency? Stronger? Higher? Longer? Thicker? Plus ingredient? Multiply? Exaggerate?
Minify? Smaller? Lower? Shorter? Lighter? Split up? Understate?
Substitute? Who or what else instead?
Rearrange? Interchange components? Other layout? Other sequence? Transpose cause and effect?
Reverse? Transpose opposites? Turn it backward? Upside down? Inside out? Turn tables? Turn other cheek?
Combine? How about a blend? An assortment? Combine units? Purposes? Appeals?

4.4.4 Morphological Chart

The method is primary used in the concept generation phase of the product development process. In general, it might be difficult to manage all problems at the same time when sketching possible solutions. Therefore, the idea with Morphological Charts is to divide the problems into functions and then generate several sub-solutions for each function. This may help the designers to generate and identify new solutions that have not been seen previously, when selecting different combinations from the chart. (Cross, 1994, p. 86) The procedure of the method is divided in four steps.

1. List of features or functions

The first step is to set up a list of essential features or functions (verb + noun) that should be incorporated in a future product. These features or functions should be on the same level of abstraction, but still as independent as possible of each other, and they should cover the most essential parts of the product. The list should not be too long; between four to eight numbers of functions are suitable. (Cross, 1994, p. 86-87)

2. Generate sub-solutions for each function

Initial, the goal is to generate as many sub-solutions for each function as possible. The sub-solutions could be described by sketches, photographs, a written description or a combination of them (Wright, 1998, p. 132).

3. Draw up a morphological chart

The list of features or functions works as a basis when drawing the morphological chart. For each feature or functions, you fill in the generated sub-solutions. Then, the chart consists of all theoretically possible solutions that could be generated on the basis of the functions and sub-solutions (Cross, 1994, p. 87). The number of possible solutions is obtained by multiplying the number of sub-solutions in each row of the chart.

4. Identify feasible solutions into concepts

The final step is to combine the sub-solutions for each function, into a total solution. Sometimes, a lot of sub-solutions have been developed, which means that it exists a large number of possible combinations. One way to go, to make it more manageable, is to only choose the most promising sub-solutions in each row. (Cross, 1994, p. 87-88)

4.4.5 Hierarchical Task Analysis (HTA)

Hierarchical Task Analysis (HTA) is used to identify, describe and analyze what a user/operator needs to do (e.g. physical actions, cognitive processes) in order to achieve an overall goal. The way to the main goal is described using a set of tasks and sub-tasks, a series of steps that needs to be done in order to achieve the main goal. (Ainsworth, 2004) HTA gives a good overview of the interaction of the product, and can be used to analyze existing products, but also as a mean to develop new products or human-machine interfaces.

4.5 Evaluation

Below, methods used to evaluate ideas, solutions and concepts are presented.

4.5.1 The pros/cons-method

Through discussion, the method aims to identify the most serious drawbacks (errors, faults, weaknesses) and the greatest benefits of each idea. A second step is to try to improve the ideas by come up with solutions that eliminate (or at least) reduce the weaknesses. Based on the comments, the most promising ideas are taken to the next phase of the project, while the others are eliminated. (Wikström, 2006b)

4.5.2 The gradation method

The gradation method[1] is suitable for a more detailed and final evaluation of the proposed solutions. The approach is to first list a number of criteria, which the proposed solution must meet. The importance of each criterion is then considered, and a grade *k* is given based on the following scale. (Wikström, 2006b)

Necessity coefficient scale (*k*):

5 Totally necessary
4 Very much desirable
3 Much desirable
2 Little desirable
1 Not that important

The next step is to assess how well the proposed solution meets the stated criteria. For each criterion, the solutions are given a grade *u*, from the fulfillment of the criterion scale.

Fulfillment of the criterion (*u*):

4 Excellent fulfillment
3 Very good fulfillment
2 Acceptable fulfillment
1 Poor fulfillment
0 Wholly inadequate fulfillment

When each proposed solution has been assessed how well they meet the stated criteria, the next step is to sum up the results to a total value of *V*.

$$V = \sum_{i=1}^{n} u_i \cdot k$$

V = total value
u = Fulfillment of the criterion
k = coefficient of necessity
i = denotes the respective criterion

The proposed solution which is given the highest value is the solution to be further developed. To determine whether a solution is worthwhile to take to the next step, its total value of V should be equal to or larger than the so called level of acceptance value. See below.

$V_{max} = 4 \cdot 5 \cdot n$
n = number of criterion
Level of acceptance: $V \geq 0{,}75 \cdot Vmax$

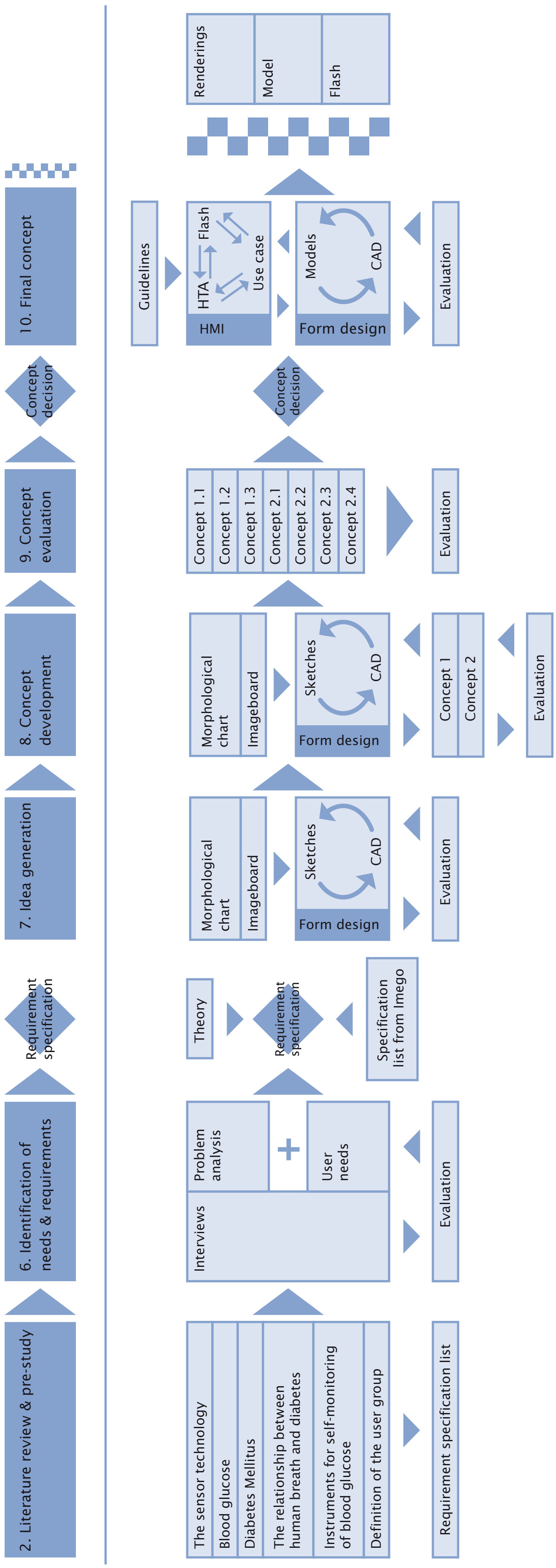
1 The gradation method is translated from Swedish, where it is called *Graderingsmetoden*.

5 The process

The Master thesis is the final part of the master programme, and it is a full time 20 weeks project. This project started in Mars 2009 and ended in October 2009, with a half-time work during the summer months. In the beginning of the project, a Gant-chart was performed to plan the different activities, when they should be performed and for how long period of time. The Gant-chart has been updated and revised along the project.

Here, the different activities, in other words, the process is presented. The names of the headings in the report have mostly been taken from the different activities in the project, to give the report a clear structure. An overall view of the process can be found on the next page. When looking at the graphical figure showing the process, it seems that each activity has been carried out one by one, and that the next has not begun until the other has been completed. But, this is not the case. Instead, most of activities have been carried out simultaneously, including several iterations along the process.

There have been two important gates in the project. First, the establishment of requirement specification which clarifies the end of the analysis and start of the synthesis part of the project, second, the concept decision gate, which shows the end of the concept development and the step into the final phase of the project.


2. Literature review & pre-study
6. Identification of needs & requirements
Requirement specification
7. Idea generation
8. Concept development
9. Concept evaluation
Concept decision
10. Final concept
The sensor technology
Blood glucose
Diabetes Mellitus
The relationship between human breath and diabetes
Instruments for self-monitoring of blood glucose
Definition of the user group
Requirement specification list
Interviews
Problem analysis
User needs
Evaluation
Theory
Requirement specification
Specification list from Imego
Morphological chart
Imageboard
Sketches
CAD
Form design
Evaluation
Morphological chart
Imageboard
Sketches
CAD
Form design
Concept 1
Concept 2
Evaluation
Concept 1.1
Concept 1.2
Concept 1.3
Concept 2.1
Concept 2.2
Concept 2.3
Concept 2.4
Evaluation
Concept decision
Guidelines
HTA
Flash
Use case
HMI
Models
CAD
Form design
Evaluation
Renderings
Model
Flash

5.1 Literature review & pre-study

The background initiation of the project was the idea that the technology, developed by Imego Ab, can be used for measuring of acetone in exhaled air, and then used as a mean for monitoring of diabetes. Early, it was decided that the focus will be to develop a meter for monitoring of diabetes in the households.

Then, a literature review was performed within the areas of the sensor technology, about Diabetes Mellitus in general and blood glucose, the relationship between human breath and diabetes, and meters for self-monitoring of blood glucose. Knowledge about the sensor technology was gathered with help of unstructured interviews, meetings and conversations with people at Imego Ab, in particular with Research Scientist Shoerd Haasl and Project Director in Industrial Design, Marketing & Sales, Manoo Eibpoosh, which also was the supervisor at the company. The information gathered about the sensor technology was analyzed, and some of the result was put into the requirement specification.

A research was done to find articles and books, containing surveys where the relationship between human breath and diabetes is studied. In order to summarize, it can be said the area of diabetes is widely researched. Ultimately, the overall goal is to find a cure, but in short term, to simplify the monitoring of diabetes.

On the basis of the literature review & pre-study, it was assumed that the new meter, in addition to detect diabetic ketoacidosis with help of measuring acetone levels in exhaled air, also can be used to measure blood glucose indirectly, using multiple breath analysis. The research about the relationship between human breath and diabetes can be found in *chapter 2.4*,

Also, in order to the find the place on the market for the new meter, a literature review was performed within meters for self-monitoring of blood glucose. It was assumed that meter will replace the traditional finger-pricking meters for self-monitoring of blood glucose. Therefore, the features and basic requirements associated with these kinds of meters were identified, see **Appendix B**, and then put in the requirement specification.

In addition, information was gathered about Diabetes Mellitus and blood glucose, using brochures and documents found on the homepages of different Diabetes associations, in order to be prepared for the interviews, and also to be able to define the user group more in details.

5.2 Identification of needs & requirements

The literature study showed that there is a need of a meter that replaces the daily finger-pricking by which diabetics test their blood glucose levels today, since the test can be considered as uncomfortable, painful and time-consuming. The purpose of the interviews was to get a confirmation whether the users have the same opinion as what is said in the literature. Also, interviews with diabetics were performed in order to identify problems associated with the blood glucose meters used today, what functions and features they are using, how it would feel to monitor their blood glucose levels by testing their breath instead, and so on. The result of the interviews worked as the foundation to the requirement specification, and subsequently to the design of the final concept.

5.2.1 Interviews

Seven individual interviews (lasting from half an hour up to one hour) were performed with diabetics, which regularly use self-monitoring blood glucose meters. These people are a suitable representation of potential users of the product. It was considered that seven interviews were enough for this project, partly because saturation was reached in the answers, but also to due a limitation of time.

The purpose with the interviews can be summarized in a list.

1. Find out how often the blood glucose meters are used, in what context and where.

2. Identify problems associated with the usage of blood glucose meters used today.
3. Identify which functions that are used today, if there are some that are unnecessary, or any that are missing.
4. Identify user needs and requirements that a new meter for monitoring of diabetes must meet.
5. Get opinions what users say about the daily finger pricking in order to monitor the blood glucose.
6. Find out how it would feel to monitor diabetes using exhaled air.
7. To give a general understanding of what it is like to live with diabetes.

All interviewees were having type 1 diabetes. They are using blood glucose meters from 3-4 times per day, up to every second hour, except from one person that uses the meters more seldom. The diabetes was controlled either by using insulin pen or pump. The interviewees were between 8 years old (was performed together with the mother and father) to 63 years old, and of both gender. The reason for the large range of age was that the product should be used of both women, men, young and old.

The interviews were semi-structured and based on a pre-completed interview guide, which consisted of a list of questions that were divided into different categories. See **Appendix A** (in Swedish since the interviews were performed in Swedish). In the beginning of the interview, general and easy-answered questions were asked about their diabetes, in order to make them feel more comfortable with the situation. After that, the questions went from simple to more sensitive, from easy to answer questions to such that requires reflections, and from general to more specific.

During the interview, initial questions were asked and then the interviewees had the opportunity to talk and express themselves freely about the subject. The conversation was then supported by additional follow-up questions, in order to get a deeper and clear understanding about the discussed subject and to secure that everything was understood correctly. The initial interviews were more fixed to the interview guide, while the later ones were more like a talk between the interviewer and the interviewee.

The focus in the interviews changed from the first one to the last, from the basis of what has been said in previous interviews, and as more knowledge was obtained about the subject and what belongs to it. This means that questions belonging to interesting topics were added, while some questions were removed.

A full scale model of the Alcolock together with the sensor were used as stimuli, in order to present how the proposed product is meant to work, and how it might feel to use it. All interviews were recorded, and then transcribed.

5.2.1 Analysis

The transcribed interviews were then analyzed using a KJ-analysis. Interesting announcements were marked and cut out, and placed on a table. Then, the different announcements were grouped using the work procedure of KJ-analysis, presented in *chapter 4*. The result of the user study is divided in two parts, a problem description and user needs and requirements on a new meter. See *chapter 6.2-6.3*.

5.3 Requirement specification

The result from the literature review & pre-study, the theory study, the user study and the specification document from Imego Ab was put into a requirement specification, using the design methodology presented during the education at Chalmers University of Technology. The establishment of the requirement specification marked the start of the synthesis phase of the project. Still, new requirements were added through the whole project.

The requirements were divided into two main-groups, product design and human-machine interface, and the importance of each requirement was graded, ranging from a demand to a wish. During the idea generation and concept development, the solutions and concepts were evaluated against the requirement specification list.

5.4 Idea generation

First, desired semantic properties for the new meter were defined using Monö's semantic functions. The semantic expressions were visualized in an image board, which worked as a source of inspiration during the idea generation and concept development. Also, a morphological chart was developed to facilitate obtaining a wide range of solutions.

In this phase of the project, the generated ideas focused on the product design of the meter, and not that much on the human-machine interface, in exception for the placement and layout of the buttons. The ideas were generated with help of sketching, both by hand and in Photoshop. Some tools and idea generation methods were used (e.g. Osborn's list) to come up with a lot of ideas.

5.5 Concept development

The product category *meters for monitoring of diabetes* is rather simple products. Therefore, entire concepts could be created quite easily by applying the various sub-solution defined in the morphological chart. Two promising basic forms were chosen, and then further developed into to seven concepts, with varying features from the morphological chart. In the concept development phase, the main focus was within the semantics/aesthetics expressions of the product.

The human-machine interface was considered to be more or less concept independent, in exception to the placement, layout and the number of buttons. Therefore, the human-machine interface was not developed in details until the final concept was chosen. Only the basic ideas of the human-machine interface were determined in this phase. A use case was created showing the procedure and number of steps to perform a test.

5.6 Concept evaluation & concept decision

The generated ideas and developed concepts were evaluated from time to time against the requirement specification. Therefore, a lot of ideas were discarded before entering the concept development phase of the project.

At the concept decision phase, pros and cons for the developed concepts were put together, from the starting point of the requirement specification. Later, the concepts were evaluated against each other, using the graduation method, to see which concepts that fulfill the different requirements the best. Many of the requirements were considered as concept independent, and were therefore not included in the evaluation. The outcome of the evaluation formed the basis for the decision of which concept to work further with, in the final concept development phase.

The developed concepts were discussed during a meeting with the supervisor at Imego AB. Based on the comments, and the result from the concept evaluation method, it was decided to work further with one of the concepts.

5.7 Final concept

After having decided which concept to work further with, the human-machine interface was developed more in details. The use case worked as a starting point, together with the basic ideas connected to the design of the human-machine interface.

The last phase of the project was characterized by several design iterations. Different variations of the chosen concept were built in Alias Studiotools, Adobe Illustrator and Photoshop, and also in real physical models. In addition, an empirical evaluation study was used to determine the size of the meter, and to decide upon size and placement of the buttons. The comments were then considered during the development of the final concept.

The final concept was then built in Alias StudioTools. It was visualized both with renderings, and with help of a physical mockup, which was built in a 3d-printer.

5.7.1 Human-machine interface

The human-machine interface was developed using different design guidelines, presented in theory chapter, and from desired features and functions defined in the requirement specification. A lot of effort was put to develop a human-machine interface, where all users, no matter age, technical knowledge and physical ability, should now and be able to operate the meter.

The different features (that should be implemented in the system) were structured, and then the human-machine interface was developed in Adobe Flash. Since the interface was built in Flash, it was possible to easily and fast get an overview of the system, to see what worked and what did not work, and to secure that the different design guidelines were implemented in a good way.

Simultaneously, two HTA's were created, see **Appendix C**, showing how to perform a test and how to set the meter.

5.7.2 Empirical evaluation study

Until now, the actual size of the meter had not been decided, beyond that it should be around the same as the traditional blood glucose meters, and also other similiar handheld products, such as mobile phones, mp3-players, pocket computers etc. Therefore, the dimensions of such handheld products were found for some models and manufacturers, to identify appropriate size range. See **table 3**.

It was tried to determine the dimension of the meter with help of using anthropometric data. But, since people will hold the meter different from each other, and also given that intended users will ranging from children to adults, all around the world, it was too many parameters to consider. Instead, to make the choice of the size more manageable, it was decided to carry out a small empirical evaluation study.

The study was conducted in two stages. In the first stage, four models were built in Kapa Board. See **figure 35**. The proportion between the width and length was fixed. The largest model had the width of 67 mm, the same as the Alco lock. Then the width was decreased with 2 mm per model, where the smallest model had a width of 61 mm. Minor consideration was taken to the height of meter at this stage. A few people at the Industrial Design Engineering programme were asked to evaluate how well each model fits their hand. The two smallest models were considered to fit their hands the best.

After having developed the human-machine interface, the number of buttons and the overall placement were determined. However, the actual size, form and placement were not fully decided. Therefore, the buttons were also evaluated in the empirical evaluation study.

Model	Length (mm)	Width (mm)	Height (mm)
Alcolock	115	61	12
iPhone	176,5	67	28
Palm - Treo 650	112	60	15
Palm - Tungsten E2	114	78	15
Palm - Zire 31	112	74	16
Sony reader It-10	140	80	25
Accu-Chek Aviva	94	53	22
Accu-Chek Compact Plus GT	125	64	32
Abbott - Precision Xtra	69	53	16
Life Scan - OneTouch Vita	95	65	22,5
Life Scan - OneTouch UltraSmart	95	58	23
Bayer HealthCare - Contour	77	57	19

Table 3. *Dimensions of different kinds of handheld products.*

Before the second stage, changes were made in the size and form of the buttons, based on comments from the first stage. Also, the largest model was discarded, and a model with the width of 59 mm was added. It was decided to not make a smaller model than that, due to several reasons.

First, it was assumed that it will be possible to reduce the size of the sensor by around 40 % within 5-10 years, in order to still be realistic. Based on that assumption, the meter can not become much smaller in width than 59 mm. Also, if the size of the meter reduces far below 59 mm in width, it will be little space for buttons and a large display.

Furthermore, a sensor in that size means that the height can not be lower than 15 mm, when also taking into account other components and wall thickness. Therefore, all models had the height of 15 mm, in the second stage of the study.

The size of the buttons, and the distance between the outer end of the soft keys and display were the same for all models. As a result, the distance between the soft keys and the up and down buttons differed between the various models. The models were rounded the same amount, and the side surface were aimed to follow the same curvature, since it first of all was the size that was aimed to be evaluated.

Again, the models were built in Kapa Board, see **figure 36**. 20 persons (10 from each gender), mostly students at Chalmers University of Technology, were asked to evaluate the four models, with the starting point of three questions. See below. As background information, it was said that the product can be likened to an alco meter where you test your breath, and the buttons are for instance used to navigate around in the menus. When the questions were answered, the product's real use area was told. The comments were then evaluated, and a final decision of the size for the meter was decided, and also the size, form and location of the buttons.

1. If you could choose freely, what model according to size do you think fits your hand the best? Give explanation for your choice.

2. What is your opinion about the buttons for the chosen model, with respect to placement and size? Is there anything you want to change?

3. What kinds of products do you associate the model with?

5.7.3 Digital model

The final meter was built in Alias StudioTools, and visualized with help of renderings.

5.7.4 Physical models

As been mentioned, a number of physical models were built in the final phase of the project. Two models were built in Ureol to decide the form of the sides, and the bottom. Then, several models were built in Kapa Board to evaluate the placement, size and form of the buttons, and also to determine the dimensions of the meter.

When the dimensions were decided, a final mockup was built in a 3d-printer, from the CAD-file that was created in Alias StudioTools.

6 Identification of needs & requirements

After the literature review & pre-study, the identification of needs & requirements comes next. First, the definition of the user group is presented, according to Janhager's way of classifying the users. Next, the result of the user study is presented, in other words the outcome from the seven individuals interviews with the diabetics. The result of the interviews is divided in two parts, a problem description and user needs and requirements on a new meter.

The specification list from Imego Ab that was given in the start-up phase of the project is presented more into details. Finally, the requirement specification is set up. The requirement specification is based on the result from the user study, the identification of existing requirements and features found from today blood glucose meters, the specification list from Imego Ab, the theory chapter and the semantic study (see chapter 7.1).

6.1 Definition of the users

The meter will replace the self-monitoring blood glucose meters used today. In general all people having diabetes can be considered as potential users of this product, no matter age, gender, income and so on. But, not all diabetics will have need for such meter in the future, as a mean to monitor their diabetes. This means that the actual user of this kind of device needs to be defined more into details.

The classification of the user group was done by studying the recommendations connected to self-monitoring of blood glucose (SMBG) which has been reviewed by American Diabetes Association (ADA), through the identification of other meters available today (or that will face the market in the near future and the need these are expected to meet), and by concluding what is about to happen within the research areas of diabetes at the moment.

6.1.1 Primary users

According to Janhager (2005) a *primary user* is the one that uses the product for its primary purpose, which in this case is to monitor diabetes by blowing the exhaled air into the sensor. The meter will primarily be used for people having type 1 diabetes, who treat their diabetes with either insulin pen, and to some extent also people under insulin pump therapy. Obviously, it will vary from one person to another how often the meter is going to be used. However, it is recommended that self-monitoring of blood glucose (SMBG) should be carried out three or more times per day, for people using frequent insulin injections or insulin pump therapy (ADA, 2009c). This also includes people with type 2 diabetes that are under insulin therapy.

Not all people with diabetes are expected to use the meter on a daily basis. For instance, people under insulin pump therapy or for diabetics whose values fluctuate a lot (for instance children) will probably have more use of the systems used for continuous monitoring of blood glucose.

For people with type 2 diabetes that are using less frequent insulin injections, noninsulin therapies, medical nutrition therapy or physical activity alone, ADA (2009c) says that SMBG may be useful as a mean to success therapy, but the optimal timing and frequency of such tests is not yet known. Therefore, it can be assumed that these people will use the meter now and then, but perhaps not on a daily basis.

Also, the meter will be used at hospitals, old people's homes and district health care centers, when helping the patients to monitor their diabetes. Still, the *primary user* is the patient with diabetes, but then in a passive way, if the nurse is the actual ones that guides the user through the test. A *primary user* can also be a parent that helps their children monitoring their diabetes.

The primary users are summarized below.

- The product will primarily be used by people with type 1 diabetes, treatment insulin pen (or insulin pump), and by type 2 diabetics under insulin therapy.

- People with type 2 diabetes under non-insulin therapy are expected to use the product regularly, but perhaps not on a daily basis.

- It will also be used by diabetes nurses and doctors at the health care units that helps the patient monitoring their diabetes, and for instance at old people's home where the blood glucose of the elderly is controlled regularly.

6.1.2 Secondary users

A *secondary user* could be a person repairing the product or the person introducing it at the health care unit to the person with diabetes. They are secondary users because they interact with the product but they are not using it for its main purpose (Janhager, 2005).

6.1.3 Critical users

A user with specific needs and requirements of the product or service can be classified as a *critical user.* The idea is that if you satisfy those individuals who are critical users (for instance elderly or disabled people), you will automatically satisfy other users' needs and requirements. However, sometimes there might be contradictory requirements between the different users, so this approach is not always suitable. (Karlsson, 2005)

In this project there are some users that can be seen as critical. They will put special demands on the design of the meter, which is important to consider. *Critical users* include elderly and people with poor sight. It is important that they should be able to perform a test, to set the meter and to see the test result, for instance with help of auditory guidance together with large and easy to read figures and so on.

6.2 Problem description

The interviews were analysed with help of a KJ-analysis in order to figure out the problems associated with the blood glucose meters that are used today. In addition, the interviews aimed to figure out what is like to live with diabetes, how often the blood glucose meters are used, in what context, where and so on. Evidently, this differs from one person to another. Anyway, some general conclusions could be made. The problem description can be found in **table 4**.

6.2.1 How to control and live with diabetes

From the interviews, it can be concluded that each person has developed its own way of managing their diabetes. For instance, it differs a lot on how often the blood glucose meters are used; from every second hour, 3-5 times per day, to more seldom. The majority of the interviewees have excellent control over their values, and has developed good knowledge whether their insulin dose should be increased or decreased from the basal insulin dose, depending on what they are eating, the blood glucose values at the moment, and what kind of physical activities that is on the agenda that day.

In general, it is common that the interviewed diabetics test their blood glucose in the morning (before the breakfast) and also before bedtime. In addition, often the blood glucose is measured before a meal, when an insulin injection should be given, and then a moment later to determine whether the levels are within desirable range.

Also, if you feel that not everything is as it should be, the blood glucose is the first to be tested. Some people said that they do not get any warnings whether their values are high or low. This means that they always need to test themselves if they are planning to do something that requires full attention, for instance before driving the car.

Furthermore, the interviews focused on to figure out in what context and where the tests usually are taken; if they feel like they can test themselves wherever they are, or if they prefer to be a little more discrete. In general, the interviewed diabetics do not feel embarrassed or uncomfortable with the situation of testing. Some of those who were interviewed have no problem at all to test themselves in public places. They simply just take the test. One person mentioned that my diabetes is a big part of myself, and is therefore nothing to be ashamed of. For some of the interviewed people, it depends on the situation whether they feel comfortable or not to perform a test in public. If possible, they prefer to take the test a little more in private, for instance at a park bench or at the toilet.

6.2.2 Test method

It has already been mentioned that the daily finger pricking, in order to monitor the blood glucose levels, may feel both uncomfortable, and even sometimes

Problem description	
Test method	Fingers get pricked
	Stick marks
	Calluses on the fingers, under arms etc.
	Finger sensibility is impaired
	Uncomfortable & painful
	Time-consuming
Handling/ Ergonomics	3 components are needed
	Many steps to perform a test
	Hard to set (e.g. the clock)
	Difficult key combinations
Consumables (test strips & needles)	Bad from an environmental point of view
	Expensive test strips
	take a lot of space
	Needles are forgotten to be replaced
Technical	Sensitive to cold
Error messages	Some meters do not give clear error messages

Table 4. *Problem description identified during the user study.*

painful. However, the ones that were interviewed did not perceive the testing as especially painful, but was rather used with it. Still, the test method can be considered as uncomfortable or inconvenient, and it can be assumed that at least some people (in particluar children) perceive the test as painful.

Also, there were other problems associated with the test method. Ugly stick marks are formed, the finger sensibility is impaired and calluses are created on the fingers. The latter makes it necessary, in the long run, to increase the depth of the lancet needle, in order to obtain a drop of blood. Therefore, some of the interviewees use alternative test areas instead when measuring the blood glucose, for instance the palm, under arm, upper arm, thigh or calf, to prevent the fingers of being damaged from all the pricking.

In contrast, some people mentioned that they have difficulties of obtaining enough blood at the alternative test sites, or they just want the most recent values, which are the main reasons why they usually take their blood from the fingers.

Sometimes, it can be problematic to absorb blood to the test strips. Although, the diabetics think there is enough blood, the meter shows error on the display. Then, the test procedure needs to be re-started, which takes unnecessary extra time.

When asking what the main benefit will be to monitor their diabetes by testing the breath instead, it was frequently said that then you do not have to prick your fingers. This is the main reason why the new test method will be appreciated by the diabetics. Also, it was said that it will fasten up the time to perform a test. You might think that it would feel awkward or embarrassing to monitor their diabetes by testing their breath. In general, the answer was no.

In addition, it was determined how it would feel to monitor their diabetes using exhaled air. All interviewed were positive, and said that it significantly will facilitate their testing. However, it is important that the accuracy is high, and it needs to be studied whether there is any delay between the human breath gases and blood glucose levels.

6.2.3 Handling/Ergonomics

When it comes to the handling or ergonomics of the blood glucose meters, one general thought is that they are rather simple to use, and the test is performed more or less automatically. Still, there are quite many steps in order to do the whole test, and the system requires three components: blood glucose meter, lancet and test strips. In addition, extra needles and test strips need to be brought, which in the end means that there are many parts you need to have an eye on. See **figure 12**.

The number of steps to perform a test is illustrated in **figure 11**, and by comparing the traditional finger-pricking with the new test method, you can clearly see that number of steps are reduced when testing the breath instead. In the end, this will fasten up the time to perform a test.

Furthermore, since three components are needed today to perform a test (see **figure 12**), the blood glucose meter, lancet and test strips, it means that

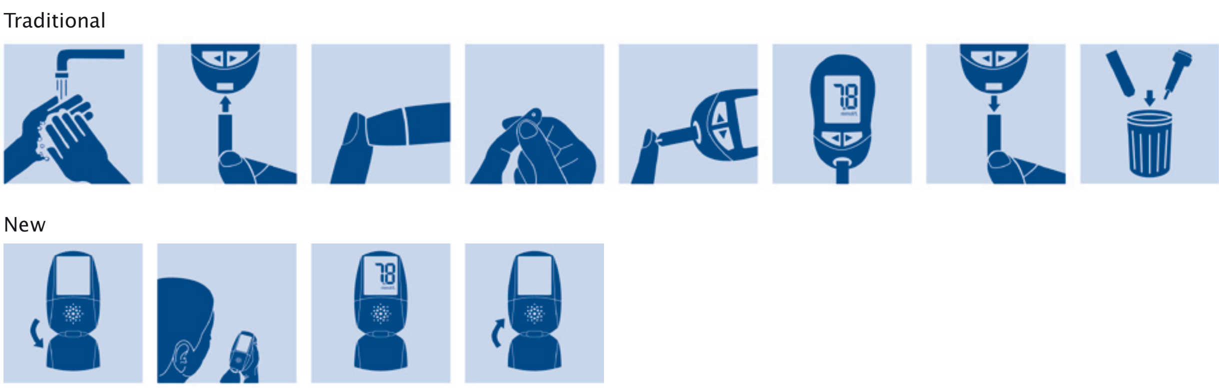


Figure 11. *The numbers of steps that are required to perform the traditional finger-pricking test in comparison to the new test method.*

if one component is lost, or forgotten, the test can not be performed. Therefore, an all-in-one solution is highly desirable. The blood glucose meters that offer a built-in cartridge with test strips are one way to go, in order to make a more easily manageable product. On the other hand, the size is adversely affected, and it has been shown that such meters are more sensitive to break, for instance test strips get stuck, and therefore some of the interviewees have decided to not use these kinds of meters.

Figure 12. *Shows that three components are needed to perform a test; blood glucose meter, lancet and test strip.*

During the interviews, people said that some functions or operations are rather difficult to set, for instance the clock, and usually you must take a look in the manual to figure out how to proceed. This can be explained by the fact that most of the blood glucose meters on the market today have few buttons, which means that the user needs to memorize several key combinations for each operation. The key combinations are easily forgotten, and therefore the manual needs to be studied, if one has not performed an operation for a long time.

6.2.4 Consumables (test strips and needles)

Another negative aspect with the current test method is that it is based on the consumption of disposable items; test strips and needles. First, this is bad from an environmental point of view. Second, in particular the test strips, but also to some extent the needles, are expensive. In Sweden, this does not affect the diabetics, since the healthcare subsidizes the test strips, which meant that they are given for free. Still, it is expensive for the county council. In addition, in countries with a health care system that does not offer such benefits, it can be assumed that the test strips makes it costly to be diabetic. The price is around 4-5 SEK per test strip.

In order to summarize, when changing the test method from finger-pricking to exhaled air, the consumables will be removed, which is beneficial from both an environmental and cost point of view. Perhaps, this is not an ultimate solution from the manufacturers of blood glucose meters point of view, because it can be assumed that they earn big money on their consumables.

6.2.5 Error messages

During the interviews, it was mentioned that some meters do not give clear error messages (for instance it only says E-1 or something like that), about what went wrong and how to solve the problem. Instead they often have to look in the manual in order to understand the error messages. Therefore, it would be better if this kind of information is presented directly in the display.

6.2.6 Technical

Finally, it was mentioned that the meters are sensitive to cold, and due not work under a certain temperature, which might seen as problematic during the winter.

6.3 User needs and requirements on a new meter

In addition, the interviews aimed to identify user needs and requirements that a new meter must met. The different needs and requirements were divided in the following sub-categories; handling/ergonomics, human-machine interface, features, error messages, easthetics and technical. See **table 5**.

6.3.1 Handling/ergonomics

In the marketing of traditional blood glucose meters, a small size and fast measurement time is often used as a selling point. The interviewed diabetics said that a high precision is the most important requirement. Next, the meter should be small and with fast measurement time. The meter should be small since it will more or less always be carried with them. It should therefore easily be stored in for example a pocket or hand bag.

But, some clarifications are needed here. For the traditional blood glucose meters, it is not only the size of the meter that is important for the users. Instead, it is the size of the full kit (meter, needles and test strips) that matters and that should take as little space as possible. Therefore most of the meters today are in the same size of mobile phones or even smaller, to be accepted by the users.

Since the new meter will be one single unit, with no test strips and needles, it was assumed that the new meter can be a bit bigger than the traditional meters, in order to be accepted by the users. Therefore, the Alcolock (176,5 mm x 67 mm x 28 mm) was showed to the users, to give an idea about acceptable size for the new meter. According to the interviewed diabetics, a meter in that size would be too big. Instead, it was asked what would be an appropriate size for the new meter, and it was said that the size should be around the same as for the traditional meters.

User needs and requirements on a new meter	
Handling/ergonomics	The size of the new meter should be around the same as traditional meters.
	The meter should be handled with one hand, and with few grip variations.
	It should take as little time as possible to start and perform a test.
	The meter should afford a comfortable grip.
Human-machine interface	The display must have large and easy to read figures.
	The users should be able to setting the meter without use of the manual.
	The meter should have few buttons.
	The meter should allow easy testing no matter time of day (e.g display and buttons that lights up).
Features	The meter should store values with time, date and year.
	The meter should show averages:
	a. 7-, 14-, 30-day averages.
	b. High and low values.
	c. Linked to specific times of the day.
	The meter should have a built-in-alarm that reminds testing.
	The meter should afford transfer of measurement data to computer.
	The meter should warn when your blood glucose is high or low.
	The meter should view graphs of the readings.
	(The meter should suggest number of insulin units based on test result).
Error messages	The meter should provide clear error messages.
	The meter should provide suggestions on how to fix the error.
Aesthetics	The meter should have a discrete visual appearance.
Technical	The test results must be measured with high precision.
	The measurement time must be fast.
	It should be possible to perform a test in both indoor and outdoor climate.

Table 5. *User needs and requirements on a new blood glucose meter.*

As been mentioned in *chapter 6.2*, if you live with diabetes, you sometimes need to test the blood glucose whatever you are, for instance at the bus, the cinema etc. Easy accessibility is an important key word. When talking about user requirements, this means that the meter should be able to handle with one hand, with few grip variations, and it should take as little time as possible to start and perform a test. Finally, a comfortable grip is highly desired, and Accu-Chek Aviva (see **figure 12**) was mentioned as a good example, since it has a soft and non-slip rubber list placed around the whole meter.

6.3.2 Human-machine interface

Many people with diabetes are elderly, and many have poor sight, since it is one of the common long-term diabetes related complications. Therefore, one of the interviewed diabetics mentioned the importance that the result and text messages are showed with large and easy to read figures.

As been mentioned in the problem analysis, a few interviewed diabetics said that some meters are rather difficult to set, since the user needs to memorize several key combinations for each operation. Often, the manual needs to be studied in order to figure out how to do. Therefore, it can be assumed that one user need and requirement is that the user interface of the new meter should be designed in such way that the users are able to set the meter without use of the manual. Still, it was said that the meter should have a few number of buttons.

Also, according to the interviewed diabetics, sometimes a test is done in places where there is limited lighting. Therefore, a display that lights up will facilitate testing in these conditions.

6.3.3 Features

In addition, the interviews aimed to determine which features the diabetics are using within current blood glucose meters, if there are any that are unnecessary, or any that are missing. Since the main functions with the new meter will be maintained, to test the blood glucose and ketone values, it can be assumed that the functions used or needed in the traditional blood glucose meters can be transferred directly to the new meter.

When it comes to the features, most of them can be considered as basic, and are therefore not mentioned more in details, but can be seen in **table 5**. However, two of the identified features are more of the innovative nature, and can only be found in the most advanced meters. Today, in principle all meters offer the possibility to transfer test results to the computer, which then can be futher analyzed using for instance different graphs. One suggestion was that it would be convenient if it is possible to view the graphs directly in the meter, without first having to transfer the readings to the computer. The manufacturer LifeScan offer this kind of feature in their most advanced blood glucose meter UltraSmart. See **Appendix B**.

Another person came up with the proposal that the meter itself could make suggestions on the number of insulin units. This feature is already offered in some of today's systems for continuous measurement of blood glucose. At first sight, this can be seen as a useful feature. In contrast, there are some disadvantages associated with this kind of feature. First, the meter in itself will be more of a small computer, which might affect the price and size of the meter negatively. Second, this kind of feature will require a lot of extra work from the user, since he or she has to document every single physical activity, every meal, and what has been eaten, in order for the meter to be able to provide appropriate proposals on insulin doses. All extra work might be complicated and time-consuming, which in the end overcomes the benefits you will get out of it.

6.3.4 Aesthetics

The interviewees pointed out that it is important that the test situation does not draw any attention. This also applies to the aesthetic of the blood glucose meter, where discrete can be seen as a key word. For instance, it can mean a minimalist or anonymous design with neutral colours.

6.3.5 Technical

According the interviewed users, the new meter must offer high precision values, a fast measurement time, and it is desirable that the meter can be used in both cold and warm environments.

6.4 Specification list from Imego Ab

The specification list from the client Imego Ab was given in the start up phase of the project. See **table 6**. First of all, it says that the meter should be handheld, self instructive and ergonomically correct adapted to its expected users. Also, the words innovation, high quality and high technology shall be communicated through the product design. These words fit well with their activities and can in a way be seen as their core-values, since they are acting in the front of many research areas, and from the fact that the company develops high quality and high technology products, with the starting point from their sensor platforms. In addition, industrial design is an important area for the company, because a new technology often requires a new design interpretation.

The size of the meter will be determined by the size of the components and chosen production methods. However, as already been told, the company made it clear that the size of the sensor and other components will be reduced, the day the product is intended to enter the market (approximately 5-10 years). The company is within the area of nano- and micro technology and the miniaturization is one of their focus areas. This means that the size of the meter primary will be decided using ergonomic guidelines, and/or anthropometric data for given populations within EU, Japan and USA, since it will be the primary markets for the meter, according to Imego Ab.

"...new technology often requires a new design interpretation."

Imego's home page (2009)

Specification list for the meter from Imego Ab	
Overall design	The instrument shall be handheld
	The instrument must describe and communicate its way of use intuitively
	The instrument shall be ergonomically correct adapted to its expected users
	The instrument shall communicate:
	a. Innovation
	b. High quality
	c. High technology
	Life expectancy is estimated at 3-5 years
	The size of the instrument is determined by:
	a. Total size of the components
	b. Selected production methods
In detail	The instrument must meed the following:
	a. Guaranteed operation
	b. HMI for communication that fulfills existing standards within the application area.
	c. Indicate result via display
	d. View metrics in a clear way
	e. Opportunities for communication (via USB, printer, computer)
	f. Battery
	g. Control buttons and location for:
	- Inhalation, ventilation, lock, steering controls and on/off button

Table 6. *Specification list from Imego Ab*

6.5 Requirement specification

The requirement specification (in the form of a function specification) is based on the result from the user study (where the user needs and requirements for a new meter were identified), the identification of existing requirements and features found from today's blood glucose meters (see **Appendix B**), the specification list from Imego Ab, theory and the semantic study (see chapter 7.1).

Er = Defined from theories in ergonomics, and design guidelines for human-machine interfaces
Ex = Existing requirements found from today blood glucose meters.
I = Requirements that were given from Imego at the start of the project and/or from the sensor technology.
S= Semantic study
U = Requirements that were identified during the user study.

	Functions		Comments	Target values	Importance					From
	Verb	Noun			5	4	3	2	1	
Main function	Measure	blood glucose	using multiple gas analysis of exhaled air	0.6-33.3 mmol/l	x					Ex
	Measure	ketone bodies	using breath acetone	0,0–6,0 mmol/L	x					Ex
Product design										
Technical	Produce	data	with high accuracy	see above	x					Ex, U
	Show	test result	within 5 s			x				Ex, U
	Protect	sensor	from dust			x				I
	Offer	transfer of data	to computer (via USB)		x					Ex, I, U
	Accommodate	components	battery, sensor, PCB, display, ventilation		x					I
	Minimize	heating time					x			I
	Allow	usage	in outdoor and indoor climate	from -5 to 40°C			x			U
	Minimize	space	required for storage			x				U
	Allow	replace/charge	of battery		x					Ex, I, U
	Allow	emptying	of sensor chamber from air before a test		x					I
	Allow	easy	testing no matter time of day		x					U
Ergonomics	Allow	easy handling	with one hand	approx. same size as trad. meters	x					U
	Fit	hand	of different populations (within EU, Japan & USA)			x				I, U
	Afford	comfortable grip	(anthropometric data for given populations within EU, Japan and USA)			x				Er, I, U
	Minimize	the number of key presses	to start and perform a test		x					U
	Minimize	errors	through intuitive user interface and clear instructions			x				Er, U
			by using logical menu structure							
			with help of standards and cultural stereotypes							
			by well aranged buttons							
			through confirmation of every change of settings							

	Functions		Comments	Target values	Importance					From
	Verb	Noun			5	4	3	2	1	
Ergonomics (cont.)	Minimize	damage	due to sharp edges and pointy corners		x					Er
Semantics/ aesthetics	Communicate	way of use	through intuitive user interface and clear instructions		x					Er, I, U
			by using logical menu structure							
			with help of standards and cultural stereotypes							
			by well aranged buttons							
		innovation	through new test method, new technology, product design (no rel. to mobile phones & mp3)		x					I
		high quality	through splitlines, material		x					I
		high technology	through sensor technlogy, new test method		x					I
	Express	simple			x					S
		clean			x					S
		robust & reliable			x					S
Safety	Meet	standards	regarding medical technical devices, CE-classification		x					Ex, I
	Withstand	impacts	no loose or fragile parts	100 cm drop (wish)		x				
Cleaning	Allow	easy cleaning				x				Ex
Environment	Minimize	number of materials	of different kinds				x			
	Allow	easy disassembly				x				Ex
	Allow	recycling	of materials and/or parts		x					Ex
Production	Minimize	number of parts				x				Ex, U
	Allow	simple mass production				x				Ex
Human-machine interface										
Display	Guide	user	through the whole test		x					Er, I
	Show	processing	of data of the received exhaled air		x					I
	Indicate	result	via display		x					Ex, I
	Offer	easy-to-read display	with large and clear figures		x					Ex, I, U
	Inform	user	when it is ready to use		x					I
			when sufficient amount of air is received to the sensor		x					I
	Offer	good contrast	of display (both day and night)		x					Ex, U
	Give	feedback	after carried out operations (using vision, haptics & sound)		x					Er
	Present	information	in appropriate amount (no sensory overload)		x					Er
Technical features	Allow	automatical turn on/off	of meter	after 1 min	x					Ex, I
	Store	readings	with time, date & year	>1000 tests	x					Ex, U
	Show	stored readings			x					Ex, U
	Show	averages of data	7-, 14-, 30- day averages		x					Ex, U

	Functions		Comments	Target values	Importance					From
	Verb	Noun			5	4	3	2	1	
Technical features (cont.)			7-, 14-, 30- day averages pre-meal		x					Ex
			7-, 14-, 30- day averages post-meal		x					Ex
			categorized to time of day		x					Ex, U
	Show	High- and low values			x					Ex, U
	Afford	built-in alarms	that reminds testing (single and recurrent alarms)		x					Ex, U
	View	graphs	of the test results			x				U
Settings	Allow	cancelling	of old values		x					Ex
	Allow	set	of audio profile		x					Ex
			of time, date, year		x					Ex
			of time- and date format (e.g. 12h, 24 h)		x					Ex
			of measurement units between mmol/l and mg/dl		x					Ex
			of language		x					Ex
Safety features	Warn	user	when blood glucose is high or low		x					U
			when risk of developing diabetic ketoacidosis							U
Error messages	Provide	user	with clear error messages		x					Er, U
	Provide	suggestions	on how to fix the errors		x					Er
	Inform	user	when the battery needs to be changed		x					Ex
			when the tests needs to be redone (e.g. due to too high or low values)		x					Ex, U

5	Totally necesseary (demand)
4	Very much desirable
3	Much desirable
2	Little desirable
1	Not that important

7 Idea generation

The idea generation chapter starts with a description about desired semantic properties for the meter to be designed, using Monö's four semantic functions. The semantic functions are presented using explanatory pictures. In addition, the semantic function *to express* is visualized in an image board, which worked as an inspiration during the idea generation and concept development, to come up with interesting forms and solutions that correspond to the desired expressions. Also, the chapter includes a part describing what kind of emotions the meter should trigger when using it, and how these emotions should be triggered, with help of the product design of the meter.

A morphological chart was developed to facilitate obtaining a wide range of solutions. Then, a lot of different ideas were generated in this phase of the project, and some of them are showed in a collage.

7.1 Semantics

The intended product semantic for the meter to be designed is divided and described with help of using the semantic functions, defined by Rune Monö.

7.1.1 *to describe*

Even though the technology is advanced, the product category *meters for monitoring of diabetes* are rather simple products. It is of high importance that the new meter describes its way of use intuitively. In other words, the product should be self-instructive. The principle is that even a first-time user should now how to perform a test without the use of a manual, no matter education level, experience, interests, age and gender.

The semantic function *to describe* (purpose, mode of operation, how the product should be used) will be implemented mainly in the development of the human-machine interface. Therefore, a number of aspects and guidelines will be considered in order to make the interaction with the product as easy and clear as possible. First of all, the user will be guided through the whole test via graphics in the display and sound signals, and clear instructions will be given to inform the user what to do in each step.

In addition, the aim is to minimize the number of key presses to start and perform a test, in order to reduce the overall test time, also to simplify the test procedure for novice users. The focus will be to develop a clear menu structure, with few buttons, but that still does not means difficult key combinations for each operation, for instance to set time and date, to see averages and so on. Therefore, the graphical interface will not be based on a pre-printed background plate, where figures are turned on/off during the interaction with the product. Most of the blood glucose meters today are based on such graphical interface, since it is a cheap solution. Instead, the menu system will be inspired by the ones used in mobile phones, even tough it requires a more advanced and expensive display. Moreover, the user will be provided with clear error messages and with suggestions on how to fix the errors.

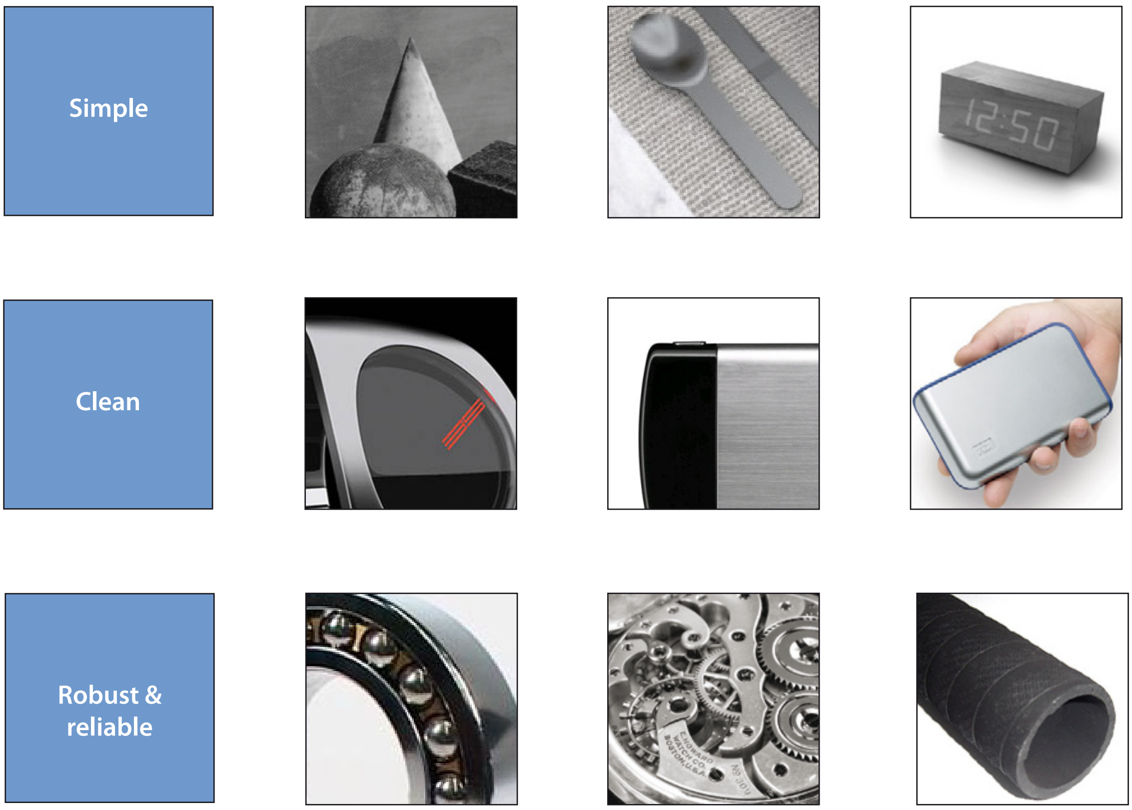


Figure 13. *Expression board.*

7.1.2 *to express*

Four words *simple (or minimalistic), clean, robust & reliable* have been chosen when talking about the semantic function *to express* for the meter. The words have been visualized with help of an expression board. See **figure 13**. These words aim to characterize the product's intended real properties from a technical, usability and ergonomical point of view. From the interviews, it was mentioned that the meter should have a discrete visual appearance. It was decided to not add the word discrete as a single semantic expression. Instead, it is implemented and considered within the words of simple and clean, and in the choice of colours.

First, *simple* refers to the starting point of the whole project; the sensor technology will considerably simplify the test procedure for persons when monitoring their diabetes, which aims to be visualized through the product design of the meter. Therefore, the focus will be to use basic form elements, few parts, a simple construction, few and clear buttons and so on.

The word *clean* was first of all chosen to reflect the fact that the product is a medical device, and the importance that the product is easy to clean. The expression *clean* will be implemented in the product design via large flat surfaces, few colours and materials, smooth and tight split lines, and no loose-, fragile- or small parts. Then, the product will be designed in such way that it is easy to clean, and dust and dirt do not easily get stuck. It should feel safe and comfortable from a hygienic point of view to use the meter.

Robust & reliable refers to the tough handling the meter needs to withstand, without easily break and fall into pieces. In addition, the meter should always work, and the user should trust it. Again, when talk about product design this means no loose or fragile parts, in order to make the product robust. Also, some parts of the product can for instance be provided with a rubber material, which will give a good grip, and also protect the product from impacts.

7.1.3 *to identify*

The new meter will have a kinship to the traditional blood glucose meter, simply because it is a meter for monitoring of diabetes. Unintentionally, the kinship will be showed through several *current product signs*[2], for instance a large display with big and easy to read figures, few buttons, and the size which approximately will be the same to provide easy storing and a comfortable one hand grip.

However, the technology is new and the test method is changed from invasive to non-invasive. Therefore, the new meter shall neither remind too much about other blood glucose meters, nor be mistaken with products in the same size, for instance mobile phones, pocket computers and/or mp3-players. The product shall stand for and communicate something new and innovative. It can be assumed that this will be challenging. The fact that the meter is something new, and unseen on the market, will be visualized with help of using techniques and solutions in the front end, for instance new and interesting displays, materials and so on. Also, this will show the quite visionary approach with the project as a whole, and the fact that the product will not enter the market no sooner than in the next 5-10 years.

In the product gestalt, no clear form elements (curves, lines, colours, materials and so on) will be implemented in the product that shows the relationship to other products developed by Imego, except for the use of the logotype. This is mainly because the wide range of products they have and are developing, in terms of usage area, and since their Industrial Design Department first of all is involved in projects with other companies and institutes, and not to develope, manufacture and mass produce own commercial products. However, *high technology, high quality* and *innovation* are important words for Imego Ab, and the new meter, and will therefore be implemented in the product design.

2 *Current product sign* = The market's conception of the way in which a product's principal function is traditionally presented in its gestalt. For instance, *current product signs* for a fire extinguisher are the red colour, cylindrical shape, a nozzle etc.

7.2 Emotions

It may feel slightly unclear or fuzzy when talking about products and emotions. However, it can be appropriate to mention a few words about this subject. The meter belongs to medical equipment. Therefore, the user should primarily feel trust when using the meter, and think that the meter is a reliable and a professional product. The idea is that these feelings should be triggered by designing a product with high quality that is robust and reliable, and by use of certain colours.

However, the intention is also to design a product, which is not automatically seen as a medical equipment, because it is not always a positive association. Instead, emotions such as joy and anticipation should be felt when using the product, for instance via novel and innovative design, by using technologies and material in the front end etcetera. Still the meter must be a serious product.

The intention is that the new meter should have a discrete visual appearance, for instance with use of neutral colours (white, black, grey, blue etcetera), in particular since it is difficult to be discrete when performing the test. People should not more than necessary have show that they have diabetes. Certainly, people will ask what it is you're doing, before it is widely known that it is possible to monitor diabetes with help of using exhaled air. Then, at least the meter should be discrete and in a way anonymous.

7.3 Morphological chart

Below, the morphological chart is showed which was used to obtain a wide range of solutions. See **figure 14**. As been mentioned before, the product category in itself is quite simple, which is reflected by the size of the chart, namely that it is small. Still, it turned out that the solution for protection of the sensor from dust and impacts are highly critical, since it will affect the overall design of the whole meter, and how well certain requirements are met.

The placement of the buttons was used to differentiate the concepts from each other, and also the construction of the display.

If the chosen solution for the sensor protection is a cover that is unfolded when performing the test, then the cover opening can be constructed in several ways. Some of the possible ways to construct the opening of the cover are shown in the last row of the morphological chart.

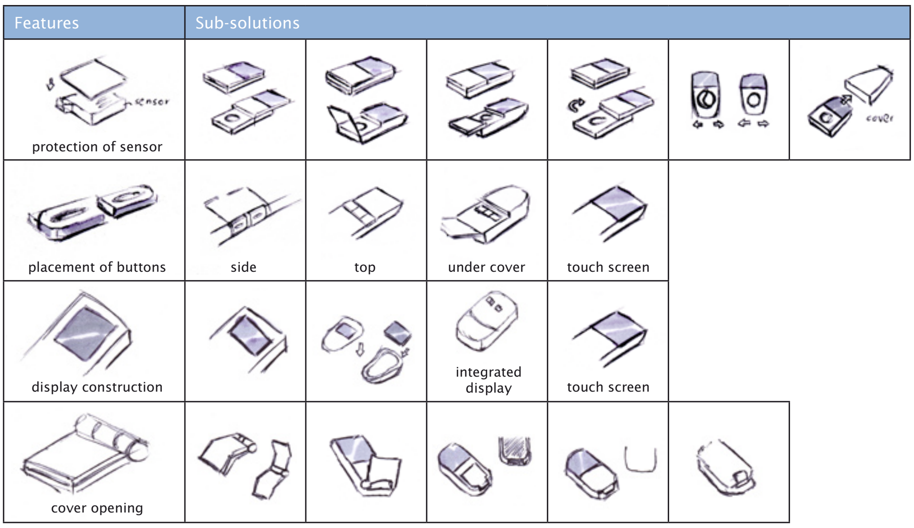


Figure 14. *Morphological chart.*

7.4 Imageboard

A collage of pictures over existing products where chosen, which according to the author expresses *clean, simple* and *robust & reliable*. The pictures formed an image board which works as an inspiration during the idea generation and concept development phase. See **figure 15**.

Figure 15. *Expression board.*

7.5 Sketches

A lot of different ideas were generated in this phase of the project. The morphological chart was used to obtain a wide range of solutions, and the image board to come up with interesting forms that correspond to the desired expressions. Some of the ideas and sketches are showed in **figure 16**.

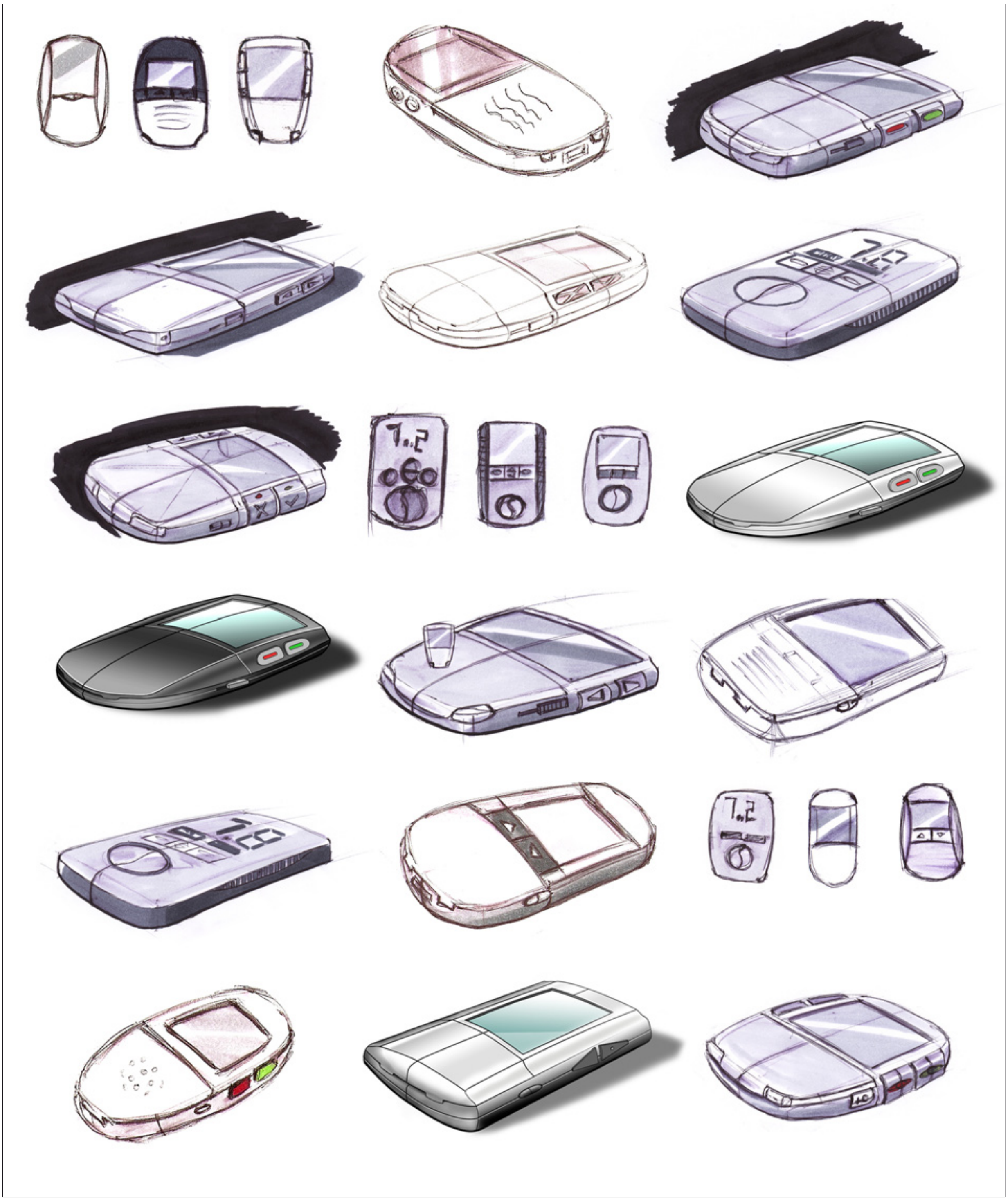


Figure 16. *A collage of sketches from the idea generation.*

8 Concept development

Here, a use case showing the number of steps included to perform a test is developed, to get a feeling of how the actual test situation will look like. Simultaneously, the basic ideas of the human-machine interface is created, and implemented in the different concepts. Then, the focus was to implement the most interesting ideas and solutions into concepts.

Two basic concepts have been developed, who had varying basic shapes. The work could have continued indefinitely with the development of basic forms, but it was decided to choose two basic forms that met the basic requirements. Instead, the two basic concepts were developed to seven concepts, with varying features from the morphological chart.

It should be mentioned that there were some difficulties during the concept development to come up with concepts that do not look like a mobile phone or a MP3-player. The reasons are that the meter and these kinds of products are handheld, will be approximately in the same size, and also have more or less a quadratic basic form (to accommodate the components in an effective manner). Also, they will have some current product signs in common (for instance a large display, key pad etc.).

8.1 Use case

In order to structure and show the interaction with the product, a use case has been developed that cover the number of steps included to perform a test.

Use case name: Perform a test
Summary: The user performs a test in order to monitor their diabetes with help of blowing straight into a sensor. The meter is used to check the blood glucose value and/or to detect diabetic ketoacidosis.
Primary actor: A person with type 1 diabetes and type 2 diabetics under insulin therapy.
Context: For many diabetics, the test will be performed several times per day, often before and/or after a meal. Most of the times, the test is performed more in private, but sometimes also in public, at the bus, cinema, at a park bench, or even maybe when standing on the street, when there is a minute left.
Goal: The goal of the primary actor is to monitor its diabetes treatment (blood glucose values) and/or to detect diabetic ketoacidosis.

Description:

1. The user wants to perform a test, and presses the On/off button. *(if a cover is used protect the sensor, it might be possible to turn on/off and start the test at the same time, simply by unfold the cover.)*
2. The user confirms (pushes Yes soft key button) that he/she wants to perform a new test.
3. The meter:
    a. Warms up the sensor.
    b. Cleans the sensor chamber from air.
    c. Informs when it is ready to use.
4. The solution that protects the sensor from dust is removed *(Could either be made automatically or manually depending on the chosen solution. Notice: This step is could already have been done, if use of a cover that is unfolded)*
5. The user takes a deep breath.
6. The user blows straight into the sensor at a distance of 10-15 centimeters.
7. The meter informs (both audiotory and in the display) when sufficient amount of human breath is received.
8. The meter analyses the human breath, both the blood glucose and β-hydroxybutyrate in plasma (the most commonly measured ketone body in order to detect diabetic ketoacidosis). Blood glucose is measured indirectly with help of multiple breath analysis and β-hydroxybutyrate is calculated from the breath acetone measurement.
9. The results are shown via the display (both blood glucose and ketosis values).
10. The use case ends when the user turns off the meter or navigates to the menu to look at e.g. averages, graphs and so on.

Alternatives:

i. If the user has not blown into the sensor after more than one minute (when the meter has informed that it is read to use) the meter is automatically turned off and the test needs to be redone.
ii. If an error message occurs (no values are shown), the reason could be:
    a. Too little of human breath is recieved to the sensor. Then redo the test.
    b. The battery level is low.
    c. The values are too high and too low to be measured. Then redo the test.
iii. If an alarm goes off, the reason could be:
    a. High or low blood glucose values. Then redo the test once and take action.
    b. High risk of developing diabetic ketoacidosis. Then redo the test once and take action.

8.2 Basic ideas of the human-machine interface

Even though the human-machine interface (HMI) is not to be developed fully in detail until it is decided which concept to develop further, some basic ideas and thoughts are determined here.

- The display will be a full high-resolution display (not necessary in colour), comparable to the ones used in for instance pocket computer, mp3-players or mobile phones.

- Two *soft keys* will be used, for instance to confirm or cancel settings, to go back to previous menu, to answer questions with Yes or No etc. A soft key is a button whose function changes depending on the context. Often, the current function of the soft key is described by a text message, shown on the display close to the button. Soft keys are common in today's mobile phones. See **figure 17**.

Figure 17. *Soft keys used in a mobile phone.*

There are several reasons why soft keys where chosen to be implemented in the human-machine interface. First, by using soft keys, you can minimize the number of buttons, and to have few buttons was one of the identified requirements from the user study. In addition, the menu structure can be built in a logical way, which goes away from difficult key combinations, since the meaning of each soft key can be varied as the contents of the display changes.

Finally, an interface that is based on soft keys are commonly used in mobile phones, which means that most of the users will be familiar with the menu structure from start. They will have no difficulties to understand how the meters work, and to navigate in the menus. All this may be referred to the *Learnability* (easy to learn) component that is used by Nielesen (1993) to define usability, and also what is meant by good usability.

- *Two up and down buttons* are required to navigate in the menus, to look at stored results and so on.

- Perhaps two more buttons are desired and/or needed; a single *On/off button* and a specific *Perform test button*. This is going to be studied and determined when developing the human-machine interface more into details.

8.3 Concept 1

The first concept consists of an asymmetric basic form, which narrows from top to bottom. See **figure 18**. The idea is that this will clearly show how to grip the meter. The concept consists of basic form elements in order to express *simplicity*, and the bottom is rounded to afford a comfortable grip. See **figure 19** and **figure 20**. Three variations of this concept have been developed using the morphological chart. The different features that have been used from the morphological chart can be seen below. See **figure 21**.

Figure 18. *Top view showing concept 1.*

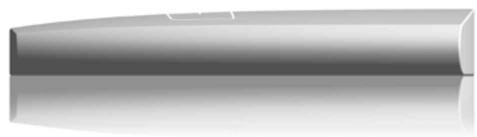


Figure 19. *Side view showing concept 1.*

Figure 20. *Side view showing concept 1.*

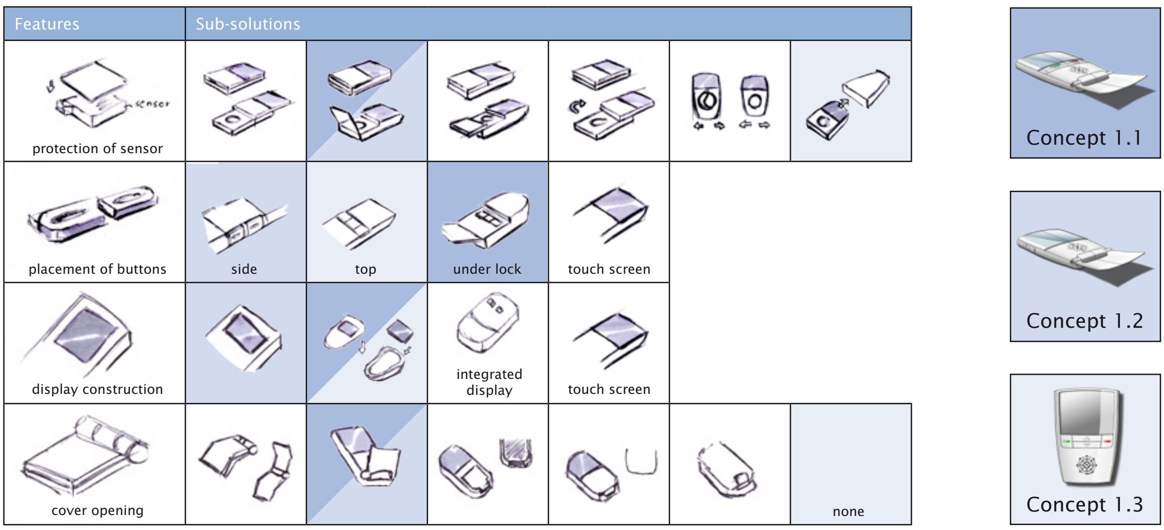


Figure 21. *Morphological chart showing the selected features for the different variations of concept 1.*

8.3.1 Concept 1.1

In the first variation of the first concept, the sensor is protected from dust with help of a cover, which is folded out when performing the test. See **figure 22**. In this concept, the soft keys are marked with green (confirm, yes etc.) and red (cancel, no etc.), and all buttons are placed on the top side. The idea is that it will be easy to construct the menu system if the two soft keys are placed on the top side, and close to the display.

The buttons are placed under the cover, with the intention to strengthen the semantic expression of *clean*. When the cover is folded, the meter will have a clean expression, since the buttons are hidden, and the top will be one single flat surface. On the other hand, when the cover is unfolded the expression will disappear. Also, the cover construction includes many parts that can easily brake, and the meter will be sensitive to impacts, and will neither be, nor express the semantic words of *robust & reliable*.

Also, when the cover is unfolded, the meter looks like a mobile phone. The similarity is reinforced by the placement of buttons, and the breath holes can be misinterpreted as holes where you talk and/or a load-speaker. The pros and cons of concept 1.1 are summarized to the right.

8.3.2 Concept 1.2

The second variation within concept 1 (see **figure 23**) is similar to the first one, except that the buttons are located on the sides. The idea is that the placement of the buttons will facilitate the hand interaction with the meter. The user can more or less use the same grip when performing the test, and when navigating in menus and so on. Also, the location of the buttons results in a top surface that is free from details and parts. Hopefully, this will make the meter to express *clean*.

In contrast, the user must in advance know the meaning of each buttons, since they are more or less hidden, which can be considered as a weakness from a first time user's point of view. Also, the width of the meter will be critically, since the buttons will be difficult to reach for people with small hands. Therefore, buttons placed on the side is not an optimal solution.

Concept 1.1 - Pros and cons
+ Express clean when it is closed (due to hidden buttons).
+ The placement of the buttons simplify construction of HMI.
+ The tapering form indicates how to grip the meter.
– Visual appearance similar to a mobile phone and/or MP3-player.
– The cover and hinge construction can easily be broken.
– Many parts.
– Does not express robust & reliable.

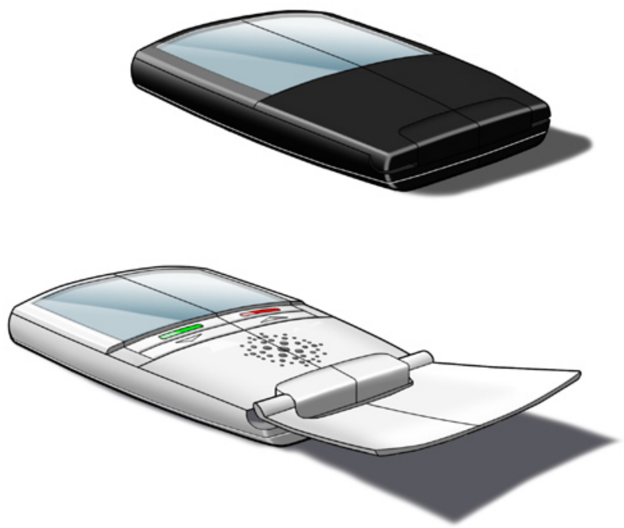


Figure 22. *Perspective view of concept 1.1, when the cover is folded and unfolded.*

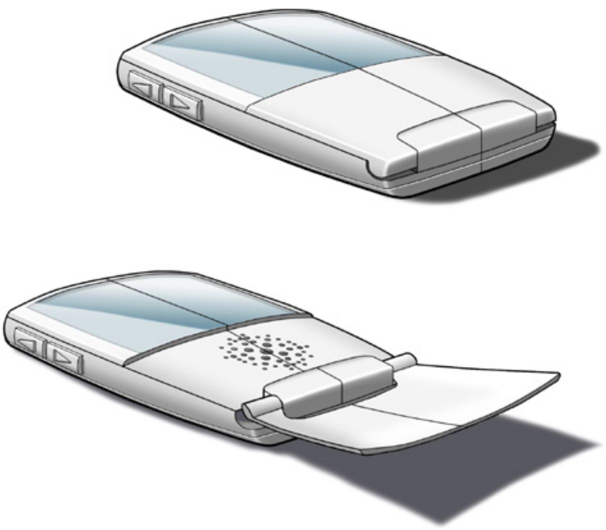


Figure 23. *Perspective view of concept 1.2, when the cover is and unfolded.*

In addition, it might be more difficult to design the human-machine interface, since is becomes harder to use soft keys if the buttons are placed on the side. The pros and cons of concept 1.2 are summarized to the right.

8.3.3 Concept 1.3

In this variation, the problems with the cover was aimed to be eliminated, and then simple by remove it. See **figure 24**. Instead, when the meter is not in use, it is put in a case that protects the sensor from dust. The case will also protect the meter from impacts and scratches. Since the cover is removed, the meter will have a robust construction.

This variation also differs from the others by the design of the buttons. The up and down buttons are placed in a vertical line, to facilitate and fasten up the key pressings. However, the meter still looks like a mobile phone, due to the placement and design of the buttons, and also due to the breath holes. In addition, the buttons and breath holes weaken the expression of *clean*. Therefore, some improvements are needed for this concept, in order to take it to the next phase of the project. The pros and cons of concept 1.3 are summarized to the right.

Concept 1.2 - Pros and cons

+ Express clean (placement of buttons).
+ The tapering overall form shows how to grip the meter.

– The cover and hinge construction can easily be broken.
– Many parts.
– Does not express robust & reliable.
– The placement of the buttons makes it difficult to:
  - adapt the meter to all kinds of users.
  - design an easy to use HMI.

Figure 24. *Top view of concept 1.3.*

Concept 1.3 - Pros and cons

+ The tapering form indicates how to grip the meter.
+ The placement of the buttons simplify construction of HMI.
+ Afford comfortable grip (rounded bottom and no cover).
+ Robust – no parts that can easily be broken.

– Visual appearance similar to a mobile phone and/or MP3-player.
– Requires additional cover to protect the sensor from dust.
– Does not express clean (due to visible buttons and breath holes).

8.4 Concept 2

In concept 2, the focus was to come up with a basic form that does not have as much connection to a mobile phone. Therefore, it is designed so that it is much broader in proportion to the length, in comparison to most of the mobile phones, which have a more elongated rectangular form. See **figure 25**. Still, there is a risk that the meter looks like a MP3-player, which tried to be considered and eliminated when designing the variations, for instance with help of using different components.

Again, the concept has been designed using basic form elements, in this case, four elliptical curves. The bottom is rounded to afford a comfortable grip. See **figure 26** and **figure 27**. Four variations of this concept have been developed using the morphological chart. The different features that have been used from the morphological chart can be seen in **figure 28**.

Figure 25. *Top view showing concept 2.*

Figure 26. *Side view showing concept 2.*

Figure 27. *Side view showing concept 2.*

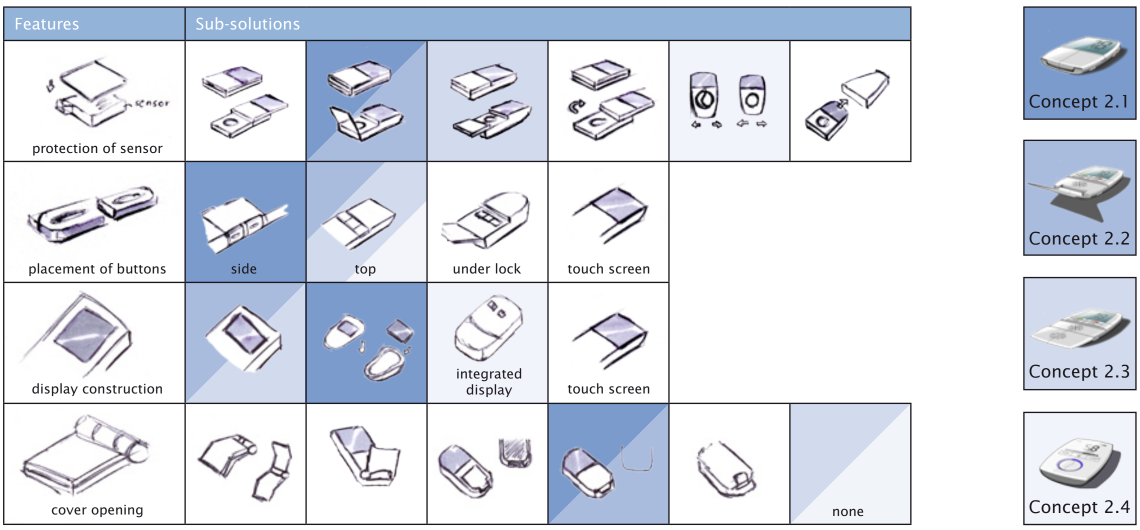


Figure 28. *Morphological chart showing the selected features for the different variations of concept 2.*

8.4.1 Concept 2.1

In the first variation, concept 2.1 (see **figure 29**), the sensor is again protected from dust with help of a cover, which is unfolded when performing the test. The difference in comparison to the variations in concept 1 is that the cover is based on another mechanical construction. The weaknesses of using a cover to protect the sensor are the same as the variations in concept 1, the cover and hinge construction can easily brake, which does not corresponds with the desired expressions of *robust & reliable*.

Again, the buttons are placed on the sides. Belonging strengths and weaknesses have already been described in concept 1.2. Due to its basic form, and the fact that the buttons are located on the sides, the connection is not that strong to a mobile phone, as the variations of concept 1. In order to summarize, this variation fulfills the basic requirements but it is not an optimal solution. The pros and cons can be found to the right.

Concept 2.1 - Pros and cons

+ Express clean (when it is closed due to placement of buttons).
+ Visual appearance not that close to a mobile phone and/or MP3-player.

– The cover and hinge construction can easily be broken.
– Many parts.
– Does not express robust & reliable.
– The placement of the buttons makes it difficult to:
  - adapt the device to all kinds of users.
  - design a good user interface.

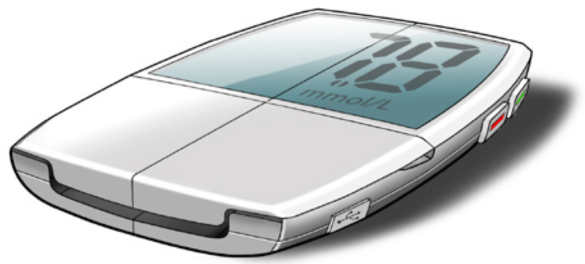


Figure 29. *Perspective view showing concept 2.1.*

8.4.2 Concept 2.2

This variation is similar to concept 1.1, in terms of that the sensor is protected from dust with help of a cover that is unfolded when performing the test, and the fact that the buttons are located on the top side surface. The differences, in comparison to concept 1.1, are another cover construction (the same as concept 2.1), and the buttons are not placed under the cover. Therefore, the pros and cons of this variation are only described in a list, to the right. The concept is showed in **figure 30**.

Concept 2.2 - Pros and cons

+ The placement of the buttons simplify construction of HMI.

– Visual appearance similar to a mobile phone and/or MP3-player.
– The cover and hinge construction can easily be broken.
– Many parts.
– Does not express robust & reliable.

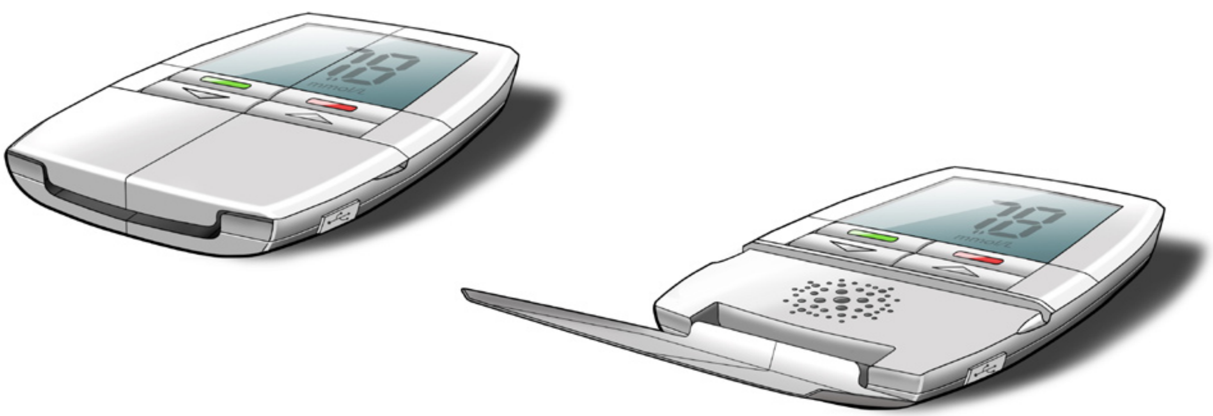


Figure 30. Left: *Perspective view of concept 2.2 when the cover is folded. Right: Perspective view of concept 2.2 when the cover is unfolded.*

8.4.3 Concept 2.3

In this variation, the problems with the cover were again aimed to be eliminated, now with help of using a slider construction (see **figure 31**). Then, the construction will be more robust, and the number of parts will be minimized, in comparison to the other variations that use a cover that is unfolded. Still, this is not an optimal solution, but it is at least an improvement.

The buttons are placed on the top side, and the pros and cons connected to concept 2.3 are summarized in a list, to the right.

Concept 2.3 - Pros and cons

+ The placement of the buttons simplify construction of HMI.
+ Slider construction improves the robustness.
+ Few parts.

– Visual appearance similar to a mobile phone and/or MP3-player.

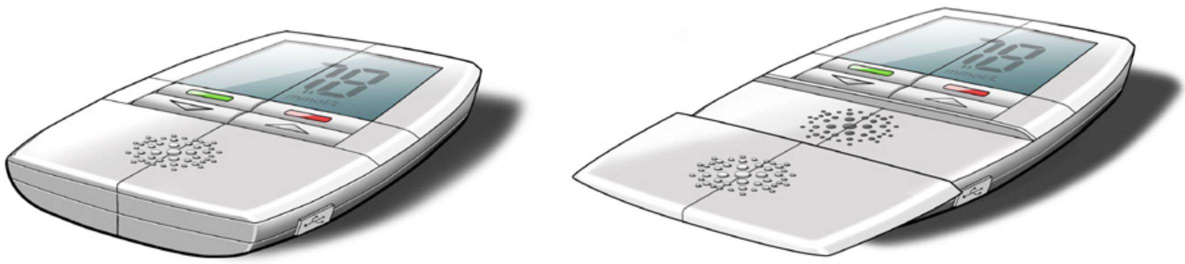


Figure 31. *Left: Perspective view of concept 2.3. Right: Perspective view of concept 2.3 when performing a test.*

8.4.4 Concept 2.4

From the descriptions that have been made about the concepts so far, it is not so hard to realize that there is something missing with the concepts. After some reflections, it was concluded that none of the concepts meet the following key words that can be found on Imego's home page: "... new technology often requires new design interpretation". Since the meter will be approximately in the same size, have similar components, and be handheld in comparison to mobile phones or MP3-players, it was quite naturally that the generated solutions have the same visual appearance as these types of product. But, the final meter has to be something innovative and new, to mirror the new technology, and to show the differences from traditional blood glucose meters. Therefore, it was decided to continue the iteration of the design process.

The result of the iteration is concept 2.4. See **figure 32**. The basic form is kept, since it affords a comfortable grip, and because the form itself is not associated to an mobile phone, because it is much broader in proportion to the length. Perhaps there

Figure 32. *Top side view of concept 2.4.*

is a stronger connection to MP3-player, but the idea is that the link will disappear by adding other components.

The solution that will protect the sensor from dust is one of the major weaknesses with the concepts presented so far. The solutions (slider construction and covers that are unfolded) have resulted in a meter that will be sensitive to impacts, easily brake, contain many parts, and all in all have a messy impression. The best solution so far has been to simply remove the protection from the meter itself, and replace it with an external case.

But, in concept 2.4, the inspiration is taken from the lens caps used in small compact cameras, which is retracted when the camera is turned on. From now in this project, the component that protects the sensor from dust is called the sliding sensor cap. See **figure 33**.

However, there are also some disadvantages when using a sliding sensor cap. Obviously, the cost and the complexity will increase when introducing an electrical solution (electrical engine is required to retract the cap). In addition, a mechanical solution might in some way be considered as more reliable in comparison to an electrical solution. However, the top side can be made in one part (when one disregards the buttons and the sliding sesnor cap) which is desirable, since it enhance the semantic expressions of *clean* and *simple*.

The buttons are located on the top side. The exact form and placement of the button is not at the moment fully determined. The **figures 32 & 33** show some variations. Unlike the other concepts, there is no red or green colour to separate the buttons from each other, with the aim to give a more *clean* expression.

Finally, as a bonus, the ring around the sliding sensor cap is coloured, here in dark blue/purple. One idea is that the user might be able to remove the ring, and change the colour to give the meter a personal touch. The pros and cons of the concept are showed to the upper right.

Concept 2.4 - Pros and cons

+ Communicate innovation.
+ Express clean and simple (top side made in one part).
+ Robust construction (except for the sliding sensor cap).
+ Ability to give the meter a personal touch (the coloured ring).

- Expensive components (sliding sensor cap and built-in engine required to retract the cap).
- More electrical energy is required.

Figure 33. *Perspective view of concept 2.4.*

9 Concept evaluation & concept decision

Here, the seven concept variations are evaluated, first against the requirement specification, and then against each other using different evaluation methods. Finally, there was one concept that was decided to develop into a final concept.

9.1 Concept evaluation

It might feel unnecessary to evaluate the concepts again, when in advance it seems that one is the clear winner. However, the concepts were checked once more against the requirement specification, to see to see that they all meet the basic requirements. Next, an objective evaluation method was used. The necessity coefficient *k* in the evaluation method is the same as the importance grade in the requirement specification. The result of the evaluation is showed below.

Many of the requirements are concept independent (including some technical requirements, and the ones connected to the interface design). Therefore, these requirements were not included in the evaluation. One comment is that the requirement or function *protect sensor from dust*, was given full score in the fulfillment. This may seem strange, since the weaknesses of the different solutions have been discussed a lot in the concept descriptions, according to this requirement. But, the requirement is fulfilled in all concepts, which simply explains the full score. Instead, the chosen solutions connected

Evaluation scales	Criteria																				
	Technical			Ergonomics				Semantics				Sa*	Cl*	Pr*	Production						
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R			
Coefficient of necessity scale (k): 5 Totally necessary 4 Very much desirable 3 Much desirable 2 Little desirable 1 Not that important *Fulfillment of the criterion (u):* 4 Excellent fulfillment 3 Very good fulfillment 2 Acceptable fulfillment 1 Poor fulfillment 0 Wholly inadequate fulfillment	Accommodate components	Protect sensor from dust	Minimize space required for storage	Allow easy handling with one hand (for all users)	Afford comfortable grip (for all users)	Minimize errors (arranged buttons, menu structure etc.)	Minimize damage (due to sharp edges & corners)	Communicate innovation, high quality, high technology	Express simple	Express clean	Express robust & reliable	Withstand impacts (no loose, small, fragile parts)	Allow easy cleaning & maintenance	Minimize number of materials	Allow easy disassembly	Allow recycling of materials/parts	Minimze number of parts	Allow simple mass production			
Necessity coefficient (k)	5	5	4	5	4	4	5	5	5	5	5	4	4	3	4	5	4	4			
Concept 1.1 (u_1)	3	4	4	4	3	4	3	1	2	3	2	2	2	3	3	4	2	3			
Concept 1.2 (u_2)	3	4	4	2	1	2	3	1	2	3	2	2	2	3	3	4	2	3			
Concept 1.3 (u_3)	4	4	4	4	4	4	4	1	3	2	4	4	3	3	4	4	4	4			
Concept 2.1 (u_4)	3	4	4	2	1	2	3	1	2	3	2	2	2	3	3	4	2	3			
Concept 2.2 (u_5)	3	4	4	4	3	4	3	1	2	2	2	2	2	3	3	4	2	3			
Concept 2.3 (u_6)	3	4	4	4	3	4	4	1	3	2	2	3	4	3	4	4	2	3			
Concept 2.4 (u_7)	3	4	4	4	4	4	4	4	3	4	3	4	4	3	4	4	3	4			
Max solution ($u_{max} \cdot k$)	20	20	16	20	16	16	20	20	20	20	20	16	20	12	16	20	16	16	$\sum V$	V/V_{max}	Pass?
Concept 1.1 ($u_1 \cdot k$)	15	20	16	20	12	16	15	5	10	15	10	8	8	9	12	20	8	12	231	0,72	No
Concept 1.2 ($u_2 \cdot k$)	15	20	16	10	4	8	15	5	10	15	10	8	8	9	12	20	8	12	205	0,64	No
Concept 1.3 ($u_3 \cdot k$)	20	20	16	20	16	16	20	5	15	10	20	16	12	9	16	20	16	16	283	0,88	Yes
Concept 2.1 ($u_4 \cdot k$)	15	20	16	10	4	8	15	5	10	15	10	8	8	9	12	20	8	12	205	0,64	No
Concept 2.2 ($u_5 \cdot k$)	15	20	16	20	12	16	15	5	10	10	10	8	8	9	12	20	8	12	226	0,71	No
Concept 2.3 ($u_6 \cdot k$)	15	20	16	20	12	16	20	5	15	10	10	12	16	9	16	20	8	12	252	0,79	Yes
Concept 2.4 ($u_7 \cdot k$)	15	20	16	20	16	16	20	20	15	20	15	16	16	9	16	20	12	16	298	0,93	Yes

* Sa=safety, Cl=cleaning, Pr=production

to protect the sensor from dust will be included in other requirements, since they affect for instance the semantics/aesthetics, the number of parts, easy mass production and so on.

After having eliminated the concept independent requirements, 18 requirements were left. The product is quite simple, and not that technical advanced and complex. Therefore, many requirements were belonging to the semantic/aesthetics and ergonomics.

9.2 Concept decision

The concept evaluation showed that concept 2.4 is the one to take to the final phase of this project, since it has the highest overall score. Concept 1.3 and concept 2.3 did also have an overall score higher than the level of acceptance, which means that these concepts are appropriate to pursue to the next phase. Therefore, together with the supervisor at Imego, a final concept decision was taken during a concept evaluating meeting.

The different concepts were then discussed back and forth. One general opinion was that a cover in order to protect the sensor from dust, and that is unfolded when performing the test, is not an optimal solution, since it easily brakes. A slider based cover construction (see concept 2.3) is a better solution, but still not optimal.

Therefore, the most promising concept was the last one, including the sliding sensor cap. In general, this concept did communicate innovation, which is an important word for Imego Ab. Also, the overall form was appreciated, since it is not that associated to a mobile phone.

Potential weaknesses with the concept were also discussed. First, it is probably the most expensive and advanced concept, due to the sliding sensor cap. On the other hand, there are most likely standard solutions used by the camera manufacturer that easily and for low cost can be implemented in this product.

Also, a new and previously unknown requirement was presented during the meeting, which was added to the requirement specification. Before a new test, the sensor chamber that collects the breath sample must be emptied from old air in some way.

For the predecessor to this project (the Alco lock), the sensor chamber is cleaned from old air using a mechanical solution (a kind of pressure valve). The pressure valves are moved mechanical, with help of a slider cover (similar to the one in concept 2.3).

Now, the idea is that the electrical engine, used to retract the sensor cap, also can be used to emptying the sensor chamber from air. During the meeting, it was therefore decided to go ahead with concept 2.4 to the final phase of the project. After taking this decision, it was time to develop the final meter and its human-machine interface.

10 Final concept

This chapter starts with the development process, from the concept decision phase into the final meter. The product design and the human-machine interface of the final meter are presented and described, from the basis of how it fulfils the different requirements, and in what way the guidelines have been implemented. The final meter is presented and visualized using renderings, pictures and a physical model.

Also, the chapter includes a description about the overall construction of the meter, how the components will be placed inside the meter and finally selected materials and production methods.

10.1 Development of final concept

The product has been further developed in the final concept stage of the project. Until now, the intersection between the sides and the bottom was not fully determined. Therefore, two models were built. See **figure 34**. In the first model, the sides are orthogonal to the bottom, and the edges are rounded, to give a comfortable grip. In the second model, the sides follow a curvature that slightly narrows closer to the bottom. It was decided to go for the latter model, even though the volume on the inside is reduced, since the tapering sides make the meter fit better in your hand.

Then, as been mentioned in the process chapter, an empirical study was performed to decide the dimensions of the meter, and also to evaluate the size, location and form of the buttons. The top side of concept 2.4 was used as a starting point for the models in the first stage of the study. See **figure 35**. Several good comments came up in this stage. First, it was concluded that the buttons were too small in order to be easily pressed, in particular the up and down button. In addition, since the up and down is one single button, there is always a risk of pressing the wrong button. Therefore, the up and down button was enlarged, to some extent also the soft keys. In addition, the up and down button was split into two buttons, before the second stage of the study. See **figure 36**.

Some new demands for the design of the buttons were added, based on the comments, and from the fact that many diabetics have poor eyesight. See below.

Demands for design of the buttons and how to fulfill them

- The meter should be able to maneuver with one hand.

- Each key should be able to reach with optional thumb, without need of change grip.

- The different keys should be able to identity without visual guidance – *with help of elevated buttons, different forms etc.*

- The keys should give tactile feedback – *using mechanical solution, sound.*

- The on/off-button should in some way be differentiated from the other keys, to insure that people with poor sight will be able to use the meter, and then in particular to start and perform a test - *add an elevated navigation marker.*

- All buttons should in some way be separated from each other, to prevent that two buttons are pressed simultaneously – *Add distance and bevels between the buttons.*

- The keys should easily be able to press for all people (young and old, female and male).

Figure 34. *Two physical models used to evaluate and decide the design of the bottom and side surfaces.*

Figure 35. *Physical models used in the first stage of the empirical study.*

Figure 36. *Physical models used in the second stage of the empirical study.*

The approach of the project belongs in some way to the more visionary nature. Still, it should be a realistic project, and the final results should not be a futuristic fantasy product. Therefore, it was decided to make an assumption about the size of the sensor, since it will limit the size and dimensions of the whole meter. See below.

- It is assumed that it will be **possible to reduce the size of the sensor by at least 40 % within 5-10 years**.

Then, four new models were evaluated in the second phase of the empirical study. The height was set to 15 mm for all models, due the size of the sensor module. The proportion between the length and width were the same for all models, because these were considered good. The widths for the different models were based on the comments from the first phase, together with the size of the sensor and from the size range of similar handheld products on the market. The width went from 59 mm up to 65 mm, and it was increased by 2 mm per model. The result of the empirical study can be seen in **table 7**, where 20 people of both gender where asked to freely choose what model, according to size fits your hand the best.

10.1.1 Chosen dimensions for the meter

When designing handheld products, there are always difficulties to adapt it to the whole user range. In general, there is no one size that fits all. This can be seen in **table 7**, because the majority of the asked women chose the smallest model, while the half of the asked men thought that the model with the width of 63 mm, fit their hand the best according to size. As a conclusion, it would be optimal to develop a meter for women, another for men, and a third for children. But, due to an increased cost when developing three meters, it was decided to recect this suggestion.

Model name	C	B	D	A
Dimension (width)	59 mm	61 mm	63 mm	65 mm
Chosen model				
Male	3	1	5	1
Female	6	4	0	0
Total (number)	9	5	5	1
Total (percent)	45	25	25	5

Table 7. *The result of the empirical study showing chosen size of model for men and women.*

Figure 37. *The chosen size of the meter.*

Therefore, it was decided to go for the model with the width of 61 mm, the midway between the most popular models, for men or women. See **figure 37** and **figure 38**.

It can be mentioned that a common comment was that the meter is comfortable to hold in your hand, since the side surfaces narrow closer to the bottom, and due to the rounded edges and corners, which is positive.

In addition, some extra comments were mentioned about the size of the meter. First, some participants said that if size of them meter is decreased too much; the credibility will be negatively affected. People will not rely on the result and think that it is a low quality product. On the other hand, one person said that if the meter is supposed to be carried with them the whole time, then the meter should be as small as possible. Finally, some people thought that elderly probably would appreciate the largest meter.

10.1.2 Size, location and form of the buttons

In addition, the participants in the empirical evaluation study were asked to make comments about the placement and size of the buttons, and then primarily for the chosen model. Moreover, some people with small and big hands were asked to evaluate the smallest and biggest models as well. Here, the most common positive and negative comments are summarized.

Positive comments

- It is good that there is a gap between the two soft keys and the up and down buttons in the middle. It prevents that two buttons are pressed simultaneously by mistake.

- Most people said that the size of the buttons were appropriate.

Negative comments

- It is difficult to reach the farthest soft key with your thumb, in particular for people with small hands and for the biggest model. As a result, these people need to use both thumbs in order to easily reach the two soft keys.
  Solution: Move the soft keys closer to the centre (but keep in mind that there should be a gap between the soft keys and the up and down buttons).

- The soft key closest to thumb is difficult to reach because the thumb must be bended too much.
  Solution: Move the soft keys closer to the centre. (Keep in mind that there should be a gap between the soft keys and the up and down buttons.)

- The up and down buttons are a little bit to small to easily be pressed.
  Solution: Increase the length (and width) of the up and down buttons.

- For elderly, there might be some difficulties to easily press the buttons.
  Solution: Increase the size of all buttons.


Figure 38. *More pictures that shows the chosen size of the meter.*

- The up and down buttons might be pressed simultaneously by mistake.
  Solution: Increase the bevel between the two buttons and/or separate them in some way.

10.1.3 Product associations

Finally, the participants were asked to tell what kind of products they associate the model with. In general, the meter was perceived as an iPod, due to the circular component in the middle (the sliding sensor cap), which is associated to the characteristic click wheel. Some people said that it was a positive association, since the connection to medical equipment is weakened.

However, it was decided to weaken the connection to an iPod when developing the final meter. Therefore, the overall form of the sliding sensor cap was changed from a circle, to a rectangle with rounded corners. In **figure 39**, the iterations when developing the final concept can be seen based on the comments from the empirical evaluation study.

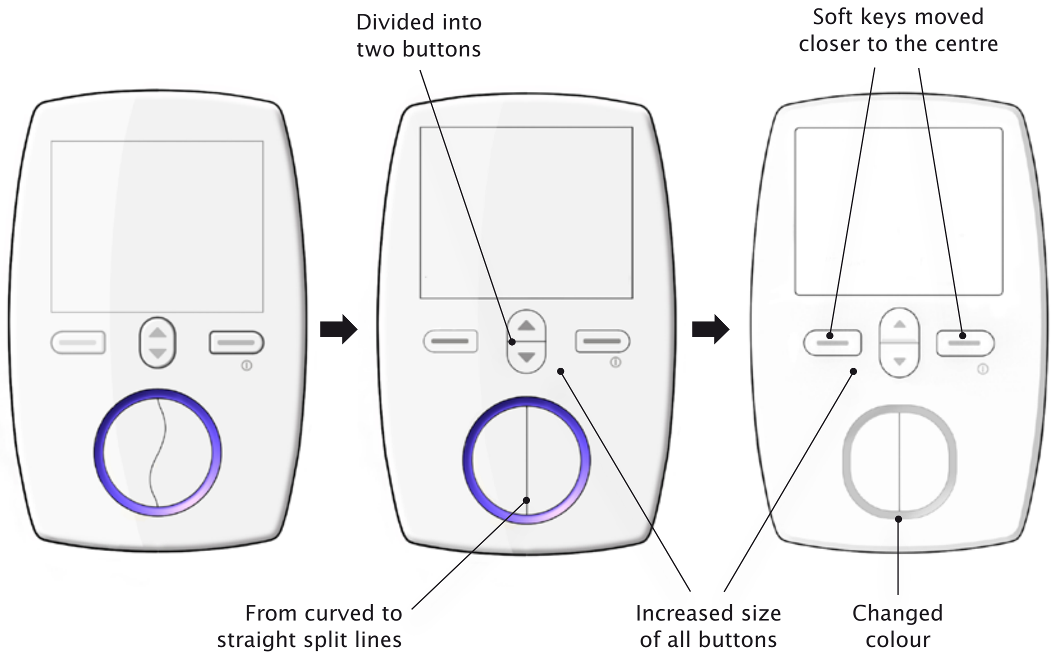
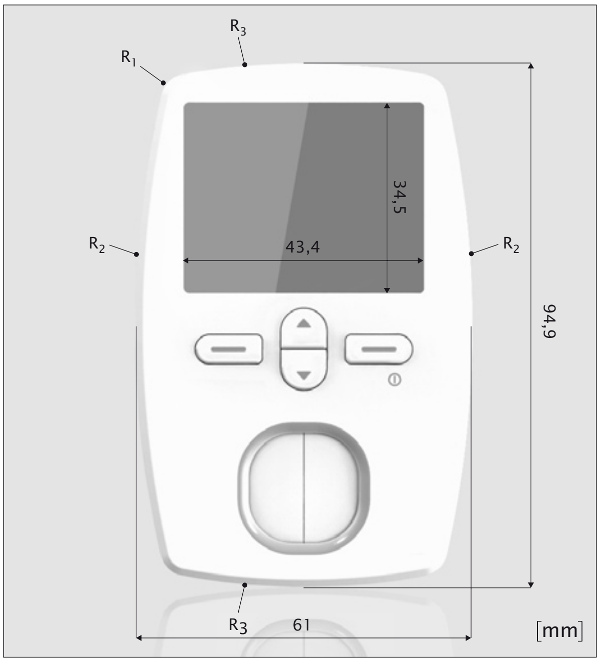


Figure 39. *Left: The meter as it looked in the concept decision. Middle. After first stage of the empirical study. Right. After second stage of the empirical study.*

10.2 Product design

Below, the final concept is presented (from now called the meter), and also how it fulfils the identified needs and demands. The meter is visualized both using renderings and in a physical model. In **figure 40**, a collage of renderings can be found showing the meter from different angles. In **figure 50**, the meter is shown in scale 1:1.

Figure 40. *A collage of renderings showing the meter in different angles.*



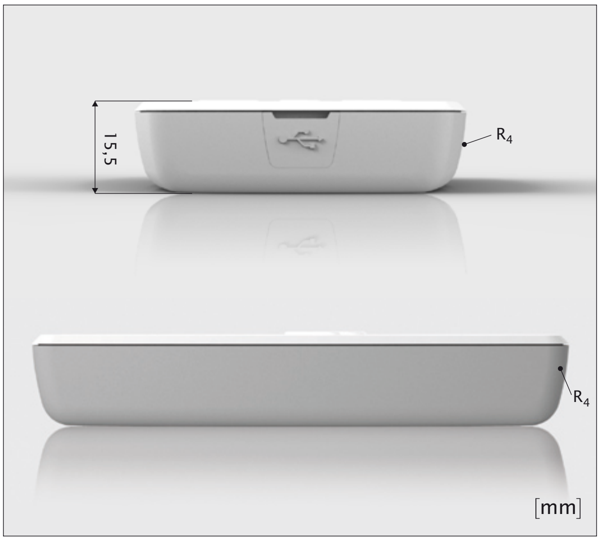


Figure 41. *Left: Top view of the meter and some dimensions. Up. Side views of the meter together with some dimensions.*

10.2.1 Basic form of the meter

Simple or minimalistic have been important words during the whole development process. Therefore, the basic form of the meter built by two elliptical curves that are mirrored on two symmetry axis. As been mentioned, the meter is quite wide, in relation to the length, to weaken the connection to mobile phones. The form of the top side is more or less the same as in concept 2. Each corner is rounded, to afford a comfortable grip. **Figure 41** shows the main dimensions of the meter.

In contrast, the design of the side surfaces has been developed further, from the concept decision to the final concept. It was decided to keep the design, where the side surfaces follow as curvature that slightly narrows closer to the bottom, with the idea that the meter should lie comfortable in the hand. Still, some improvements with the design were made.

In **figure 42**, the development from the concept decision phase and the final concept can be seen. In the final concept, the side surfaces follow a curvature with smaller radius. Then, it becomes easier to accommodate all the components inside, without having to increase the size of the meter. Also, since

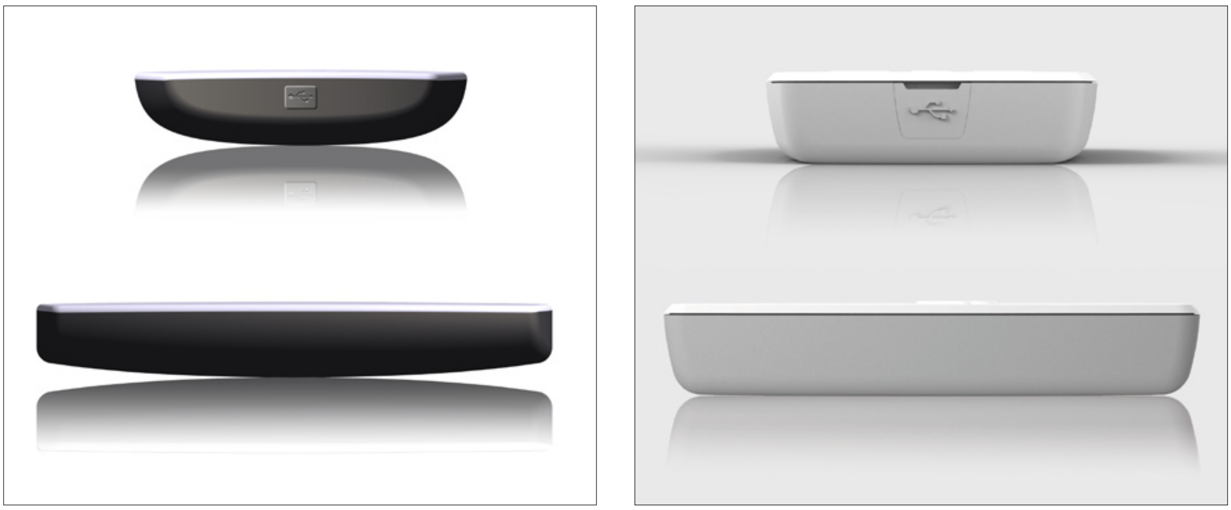


Figure 42. *Left: The concept as it looks in the final decision stage. Right: The final concept.*

Figure 43. *The meter as it looks when the sliding sensor cap is removed, ready to perform a new test.*

the curvature is reduced, the bottom surface has become flat, in order to be a more robust and stable construction.

The exhalation holes at the meter are made in a basic pattern of circles, with the diameter of 1 mm. The distance between the circles is the same, both horizontally and vertically. See **figure 43**.

10.2.2 Handling/ergonomics

The comments and feedback from the second phase of the empirical evaluation study was implemented in the development of the final concept, in order to improve the handling/ergonomics of the meter. The final dimension of the meter is 94,9 mm x 61 mm x 15,5 mm, in order to fit the hand for the majority of the users, and with few grip variations.

After the second stage of the empirical study, the focus has been to improve the size and location of the buttons, based on the comments, the added demands for design of the buttons, and from the original requirement specification. First, the soft keys have been moved closer to the centre, with the intention that each button should be able to reach with optional thumb, without having to change the grip. Still, there is a gap between the soft keys and the up and down buttons, to separate them from each other, and to prevent that two buttons are pressed simultaneously, with the thumb. It was decided to keep the up and down buttons close to each other, with no gap, since it can be assumed that the two buttons can easily be pressed by just changing the position of top of the thumb. The size of the buttons has been further increased, based on the comments, and in particular to make it easier for elderly to press the buttons.

Furthermore, a navigation marker is added to the right soft key. It can be seen as the most important button, because it is used to turn on/off the meter, but also to start a new test. Therefore, this button should be easy to find, without having to look at the meter. See **figure 44**. In *chapter 10.4.9*, the whole procedure of performing a test is described.

Figure 44. *The right soft key with its navigation markers.*

10.2.3 Aesthetics, semantics and choice of colours

The semantic function *to describe* will be discussed later, in the chapter presenting the human-machine interface. Here, it will be showed and explained how the product design fulfils the desired semantic expressions of *simple, clean, robust & reliable*. Also, it will be described how the core values of Imego Ab are implemented in the product design of the meter.

First, *simple* is primarily expressed with use of basic form elements, both in the overall design, but also in the design of the buttons, the sliding sensor cap and the surrounded ring. The intention was to work with a few recurring design elements throughout the entire design. See **figure 45**. Therefore, the forms of the ring and buttons have been developed using half- and quarter circles, together with parallel and perpendicular lines. The buttons are differentiated from each other, due to the different forms, which will make it possible to easily find each button, without having to look at the meter. The soft keys are grouped using the gestalt law of similarity, because they have the same form colour, material, structure and so on.

Next, in order to express *clean*, and also to be easy to clean, the design of the meter is characterized by the use of large and flat surfaces. The bottom side is completely free from components and form elements, in exception for the logotype. Also, the expression of *clean* is visualized using few materials, few colours, tight split lines, and no loose-, tight- or fragile parts.

However, the top side consists of different elements (the buttons, display, sliding sensor cap), which means that dust and dirt might get stuck for instance in the small gaps and splitlines between the different elements and the front cover. Therefore, when designing the meter, it has been tried to take into consideration how to reduce the risk that dirt is deposited on the surfaces, and to make the meter easy to clean.

First of all, a light grey colour was chosen for the back cover, which will hide some of the dust and dirt. The front cover is in white, to give the meter an impression of low weight and freshness. White surfaces quickly become dirty, which is a disadvantage. Therefore, the front cover surfaces are matt, in order to be at least less sensitive to fingerprints.

Figure 45. *Perspective view of the meter.*

Second, the display module is located behind the front cover, which means that there is no intersection or splitlines between the display and the front cover that might accumulate dust. See **figure 69**. The front cover is made of a transparent plastic, which then is painted in white, in exception for the display window.

The intersection between the sliding sensor cap and the front cover is a ring. Since the thickness of the ring follows a curvature, and narrows closer to the bottom, it will be easy to clean the sliding sensor cap. It was decided to make the ring in a semigloss material, in order to differentiate the sliding sensor cap from the other elements, to clearly show where to blow when performing the test, and to make the design of the meter more interesting.

In order to be, and also to have a *robust* expression, it was decided to colur it in grey and to have a large back cover, to give it a clear direction (for instance when it is put on a table) and to show the stability of the construction. Also, the back part is injection moulded in two steps, where a rubber-like plastic called Thermoplastic Elastomer (TPE), is added. This has been done in order to provide a good, comfortable, soft and non-slip grip, as well as protect the meter from impacts, if you drop it on the floor.

The component that will affect the *robustness & reliability* negatively is definitely the sliding sensor cap, which might be seen as a pitfall for the whole final concept. The component consists of several small parts and it will be sensitive to impacts. Nevertheless, the decision was made to work further with this solution, because its advantages outweigh its disadvantages by far. Also, the idea is that the meter will be stored in a case, for instance made by leather, when it is not in use, which will protect the sliding sensor cap, but also the whole meter, from impacts. It was decided to not develop and design the case in the time span of the project.

It can be concluded that quite discrete colours have been choosen for the meter. See **figure 46**. The reasons for using white and grey have already been mentioned, in order to fit the desired semantic expressions. During the development of the final concept, the ring around the sliding sensor cap has been in dark blue/purple, in order to trigger emotions such as calm, serious, but also to give the meter an interesting touch. In the end, it was decided to remove the colour, to give the meter a more discrete impression.

Figure 46. *Left: The back side of the meter. Right: The front side of the meter.*

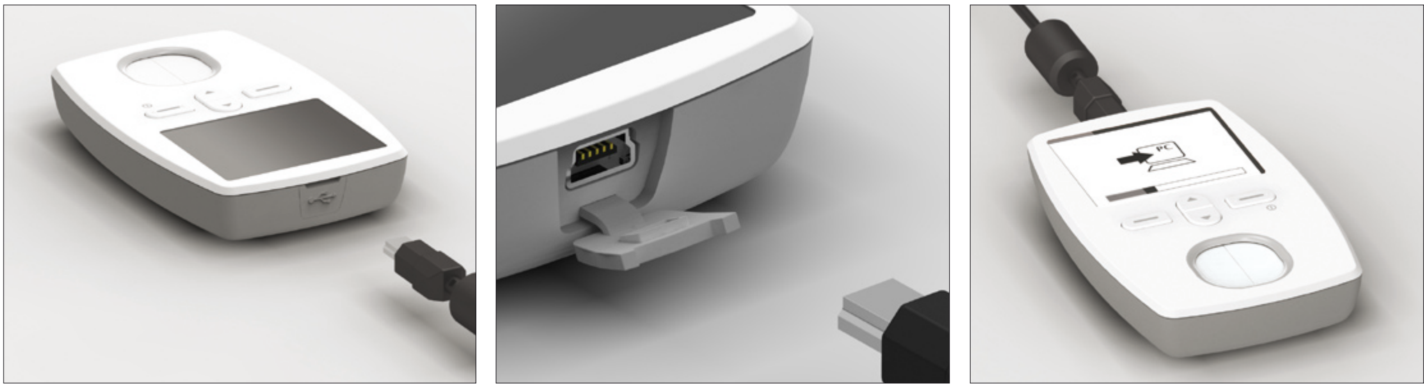


Figure 47. *The procedure of connecting the meter to computer and/or external charger via the USB-port.*

The connection to Imego Ab is visualized with the use of the logotype, located on the back cover part. See **figure 46**. Also, in the specification list from Imego Ab, it was said that the product should communicate innovation, high quality and high technology. Innovation is communicated by implementing the sliding sensor cap, and the fact that the display and menu structure is more advanced than most of the meters available today. The high quality aspects have mainly been considered when choosing materials and production, and where to put the split lines. The meter communicates high technology just with the fact that the test method changes from invasive to non-invasive.

10.2.4 Transfer of data/Charge of battery

A USB-port is placed in the front of the meter, which will be used both for transfer of test results to the computer, and to charge the battery. See **figure 47**. The meter is charged simultaneously when data is transferred to the computer. Then, the meter is with advantage connected to the computer until the battery is fully charged.

Micro-USB has been accepted by almost all mobile phone manufacturers as the standard charging port for future mobile phones (Open Mobile Terminal Platform, OMTP, 2007). Therefore, when the meter will enter the market, its battery will also be charged by using the mobile phone charger.

10.2.5 Easy testing no matter time of day

Easy testing no matter time of day was something that was mentioned during the interviews as an important requirement. When it is dark, it will still be possible to perform a test, to see old results, to set the meter and so on, since the display and buttons are light up. See **figure 48**. Also, when the sliding sensor cap is opened, the small holes where to blow is light up with help of a light source located inside the meter. This will make it easy to see where to blow.

Figure 48. *Display, buttons and sensor holes that lights up allow easy testing no matter time of day.*

10.3 Physical model

Below, the physical model can be seen that was printed in 3d. See **figure 49**. Its surfaces have been processed using spray putty, finishing paper and spray painting. As been mentioned, the size of the buttons for the meter has been further increased, in comparison to the physical model evaluated in the second stage of the empirical study.

But, the size of the buttons was increased from the basis of a digital model (built in Alias StudioTools), and not from the physical model that was evaluated. This can be seen as a mistake, since the buttons in the physical model was cut with arbitrary accuracy, which in the end meant that the buttons were not enlarged as much as originally intended. Perhaps, the size of the buttons needs to be further increased.

Figure 49. *The physical model of the meter.*

10.4 Human-machine interface

The human-machine system of the meter consists of a large display, four buttons (two soft keys and two up and down buttons), a sliding sensor cap (with an engine that open/close the cap and emptying the ventilation chamber) and a data port, which makes it possible to transfer the results to the computer via an USB-cable. See **figure 50**. Simultaneously, as already been mentioned, the USB-port can be used to charge the battery, either by connecting the cable to a computer, or by connecting it to an external charger. In overall, the human-machine interface has been developed with the critical users in mind, which in this case means elderly and people with poor sight.

10.4.1 Turn on/off the meter and start a new test

To turn on/off the meter, you press and hold the right soft key. In this way, no additional on/off-button is required. To start a new test, you press the right soft key once again, when the welcome screen is showed. There are some thoughts behind the idea that the same button is pressed twice to start a new test. Obviously, to perform a test is the most important function, and therefore it should be easy to find. Also, it allows for a quick start, and a kind of plug-and-play feeling. But what is even more important is that everyone will be able to learn, and know which button to press to start a new test, no matter age and technical knowledge. This also makes it easier for many diabetics who have poor eyesight, to know how to perform a test, without always have to read the text messages above the soft keys. The full procedure of performing a test can be found in chapter 10.4.9.

10.4.2 The display

The meter has a large display, which makes it possbile to create an interface with large and clear figures (e.g. text messages and symbols). In particular, the large display will faciliate for people that have poor sight.

The display is in black & white, mainly because there is no actual need for a colour display in such simple product, and partly to keep down costs. The cost increases anyway in comparison to many other

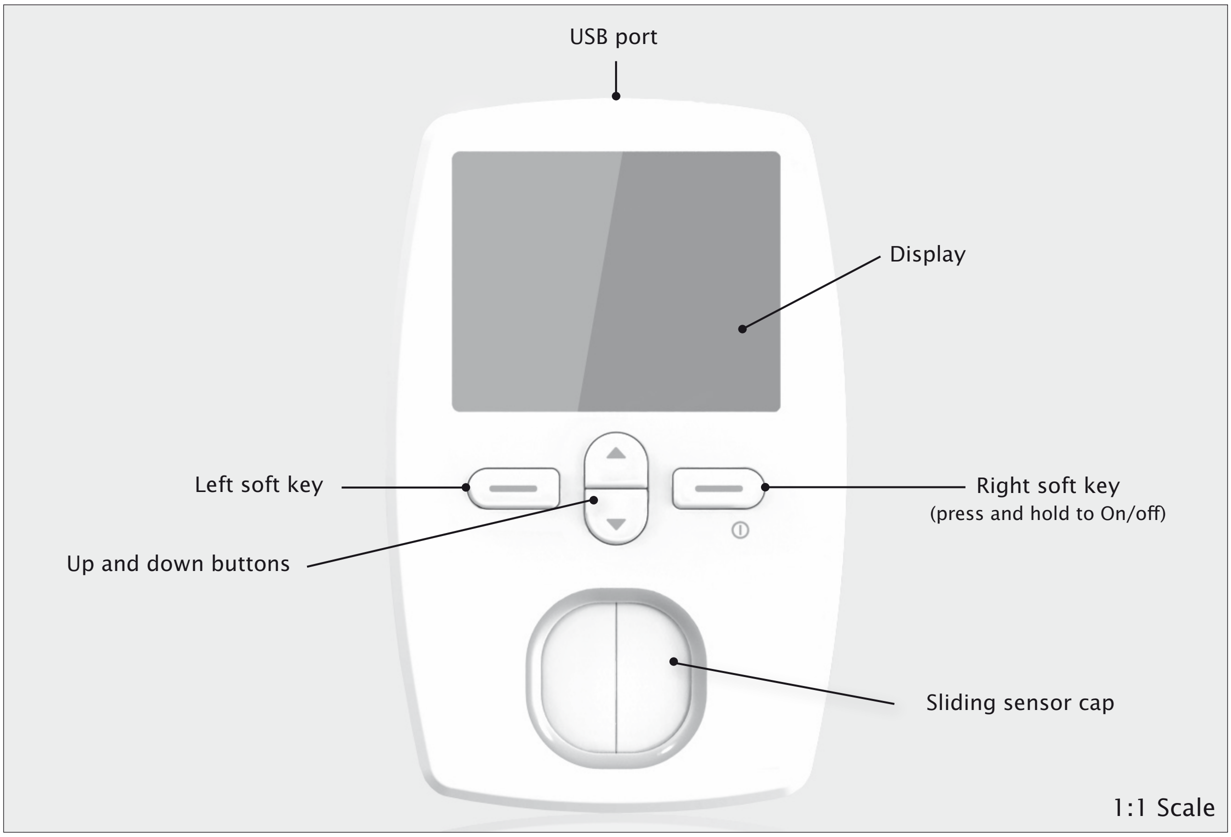


Figure 50. *The human-machine interface.*

meters whose display is based on a pre-printed background plate. Also, a black & white display results in good contrast, and the texts and symbols will then be easy to read and interpret. Finally, it was thought that the black & white display contributes to the semantic expressions of *clean* and *simple*.

10.4.3 Layout of the display screen

The aim was to develop a human-machine interface that is consistent through the whole design. Therefore, all screens consist of a soft key panel that shows the content and meaning of each soft key button at the moment. Also, the majority of the screens (except for the welcome-, perform the test- and test results screen) have an information panel, which shows in what part of the menu you are at the moment. The text message on the information panel is separated from the vertical list menus using a horizontal line. See **figure 51**.

As far as possible, there is also a consistency in the soft key placement, and what is written in the soft key. The *Select* soft key is placed to the left, which means entering the next screen or to confirm a choice within the different settings. To go back to previous screen, the *Back* soft key is pressed. A consistent soft key placement fastens up the time to find and perform the desired action, and minimizes the risk of pressing the wrong key.

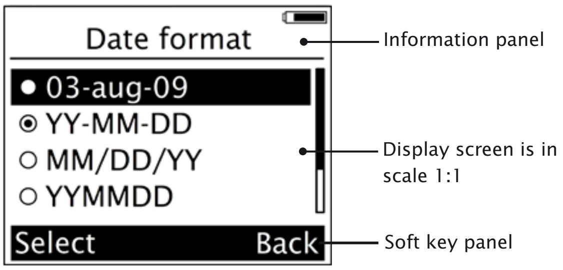


Figure 51. *Layout of the display screen.*

10.4.4 Text messages and choice of font

The text messages have been formulized using the design guidelines presented in chapter 3. Therefore, all text messages (in the information panel, soft key panel and the menus) have been developed with the starting point that they should use a simple and natural dialogue, be short and concise, but still clearly tells the content and meaning of the menu, sub-menu, or information on the current screen.

As been mentioned in the theory, to choose an appropriate font is important, in order to give a good visual clarity of the display, in particular since people with poor vision may use the display. In general, fonts belonging to the group of sans-serifs' are suitable to be showed on display screens, due to its simple design. Also, the typeface family Lucida is especially designed to be showed on screens, and then in particular its sans-serifs'. (Ekfjorden et al., 2008) Therefore, the font family of Lucida Sans was chosen (more specific the font style Roman) for all text messages in the human-machine interface. The text is presented in lowercase letters, since the general conclusion from the literature is that lowercase letters are easier to read than uppercase letters (Sanders and McCormick, 2002).

Also, it was tried to find recommendations about appropriate font size of the text messages in the display, in particular for people with poor sight. But, it could not be found. Instead, some general recommendations presented below were considered when developing the display screens. Based on the recommendations, the character height of a capital letter was set to around 3 mm.

- Font size must be at least 2.5 mm for plain text, and 3.8 mm for critical information (Diffrient, Tilley and Bardagiy, 1974).

- ANSI (Human Factors society, 1988 as cited in Sanders and McCormick, 2002) specifies that a minimum character height of a capital letter (to be presented in displays) should be 2,3 mm at our nominal reading distance, and a preferred height is 2,9 mm to 3,3 mm. In addition, ANSI sets a maximum character height of 3,6 mm at our nominal reading distance.

10.4.5 Error-, warning- and dialogue box messages

The error-, warning- and dialogue box messages were formulated from the starting point of the design guidelines. Below, three examples are showed to visualize the three types of messages. In all box messages, there is a warning triangle, which shows that the meter calls the user's attention, since it has something important to say.

One possible error that can occur is that too little of human breath is received to the sensor. Then, the meter needs to be turned off, and the test has to be redone. In the error dialogue box, the meter informs what went wrong (breath sample too small), and then provide with suggestion on how to fix the error (turn of the meter, and then redo test). See **figure 52**.

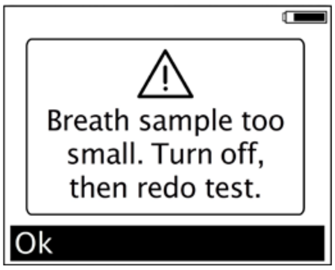


Figure 52. *Error message when breath sample too small.*

Furthermore, the meter is equipped with some safety features, which is presented to the user in a set of warning messages, for instance when blood glucose is too low or high, or when there is a risk of developing diabetic ketoacidosis. See **figure 53**.

Most diabetics know exactly what to do if their blood glucose or β-ketone level is too high, which means that for them, additional information is unnecessary. However, this does not mean that surrounding people will know what to do; first to redo the test again, and if the value is high again, to consult the health care professional and follow his/her instructions. Therefore, this kind of information is presented when pressing *More info* soft key.

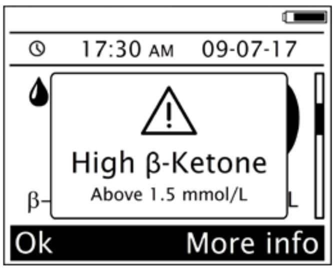


Figure 53. *Warning message showing high β-ketone level.*

Finally, some choices need to be confirmed two times, in order to prevent errors. These messages are showed in the dialogue boxes. For instance, if you want to delete old results, then you first select delete from the menu list, and then there is a dialogue box that asks if you want to delete the result (see **figure 54**). You press *Yes* soft key to confirm, or *No* soft key to cancel the action.

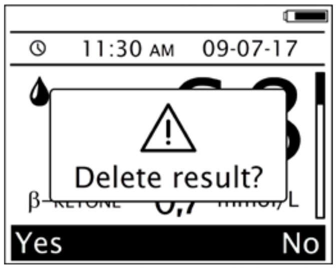


Figure 54. *Dialogue box message when deleting old result.*

10.4.6 Structure of menu and features

In the *Welcome* screen (see page 86), if you press the *Menu* soft key, the main menu will appear, which is categorized in two sub menus; *Settings* and *Stored results*. The menu system was built by grouping similar functions together.

The text messages showing the current menu are presented in the information panel. In the main menu, the content of the two sub-menus is also explained by an image. See **figure 55**. If the user chooses to enter a menu, who has a sub-menu, then the selected menu is showed in the information panel. An overall view of the menu structure is showed in **figure 56**.

The menu structure has been designed in mind that it should be easy to add and remove features and functions (different settings, safety features, test averages and so on). Therefore, the menus are organized using vertical lists. See **figure 55**. Some basic and necessary features, together with a couple of desirable features were identified during the interviews with the diabetics. These features were implemented in the new meter. Later, the list of features where supplemented with help of analyze and identify common features within traditional blood glucose meters. See **Appendix B**.

Now, the meter is somewhere in the middle when speak about the number of features, in comparison to the traditional meters. It is more advanced than the basic models, but simpler than for instance

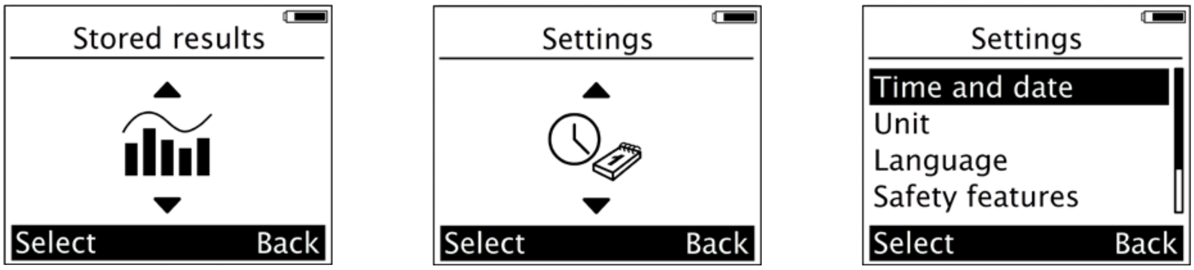


Figure 55. *Left: Main menu for Stored results. Middle: Main menu for Settings. Right: Example of the vertical lists that are used in the menu system.*

LifeScan OneTouch, which can be considered as a mini-computer with opportunities to add information about health, meal, exercises, insulin type, number of units etcetera. However, thanks to the construction of the menus, it will be easy to make the meter more advanced by adding features, or to change the meter to a simple model with just basic features.

10.4.7 Feedback

Visual, auditory and haptic feedback is given in different forms when interacting with the meter. First, when pushing the buttons, they are simply moved down, which means that haptic feedback is given. Also, due to the construction of the buttons, it will also give a mechanical sound when being pressed, and if the audio profile is turned on, it will also be given an artificial sound.

In addition, the display is used to give visual feedback during the interaction with the meter, in particular when performing the test, to inform when the meter is ready to start the test, when sufficient amount of human breath has been received, when

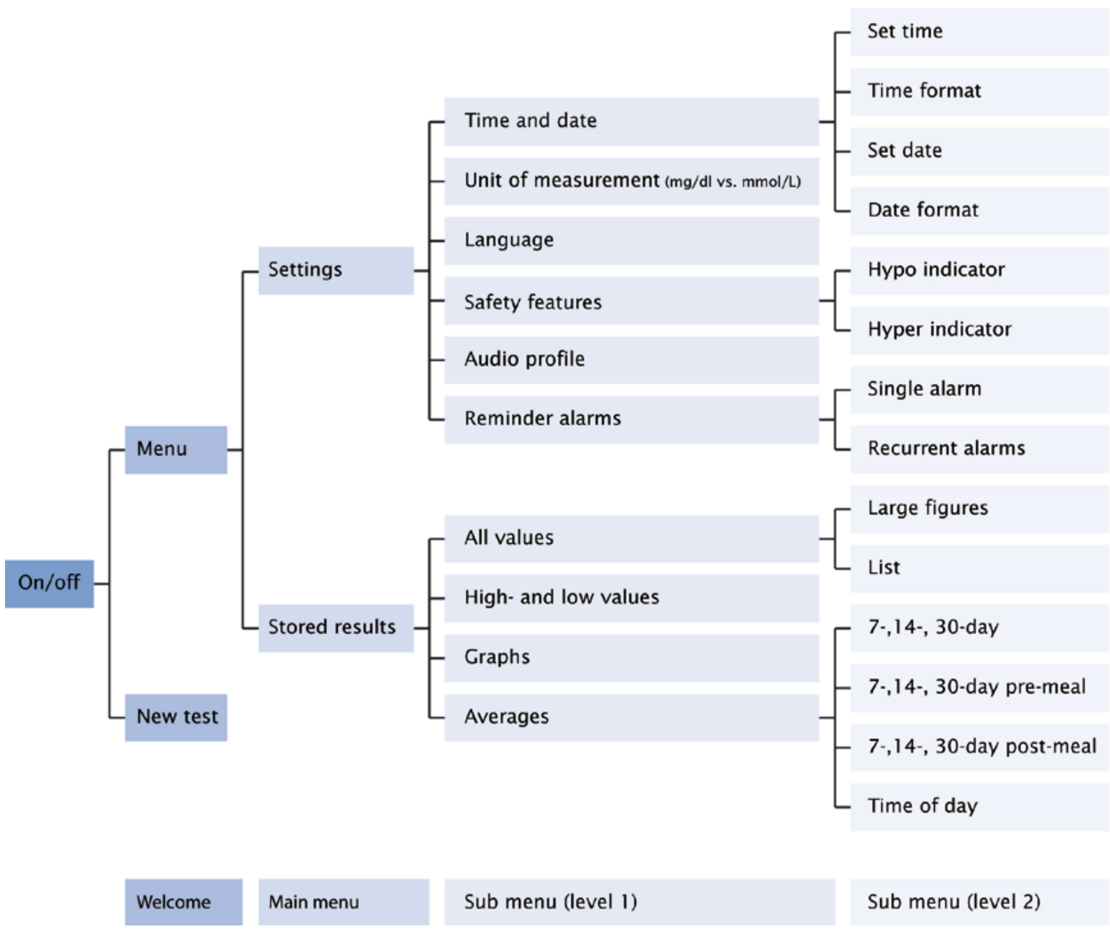


Figure 56. *The menu structure.*

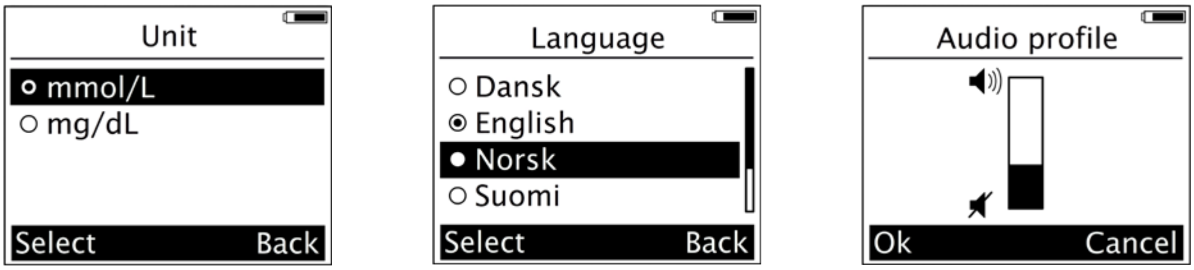


Figure 57. *From left to right: The sub-menu when choosing Unit of measurement, Language and Audio profile.*

the breath analysis is finished and so on. This is explained more in detail in *chapter 10.4.9*. If the audio profile is turned on, beep sounds will also help the user through the test, which will facilitate for many diabetics that have poor sight.

10.4.8 Features and functions

As been mentioned, the features and functions are grouped in two sub-menus; Settings and Stored results. Before using the meter for the first time, it is recommended to set time and date, so that the high- and low values, averages and so on will be correct. The procedure of setting the meter will be described with help of an example (the task of setting recurrent alarms). See *chapter 10.4.10*. The other settings will be presented and described briefly below.

The unit of measurement is set at the factory to display results in the unit that is standard for each country, in order to not confuse the user and to minimize risk of misinterpret the test results. However, it will still be possible to change the unit of measurement, by choosing between mmol/L and mg/dL. See **figure 57**.

According the user guidelines for human-machine interfaces, it is preferable that the dialogue is presented, as far as possible in the users' native language. Therefore, the user has the possibility to choose between a numbers of languages. See **figure 57**.

In addition, the user can change the audio profile of the meter. When the audio profile is turned on, the meter provides user support during the test by marking the start and end of critical steps. The meter also gives a beep sound to inform that it has been turned on/off. See *chapter 10.4.9* for more information. In addition, the audio profile controls the sound level of the reminder alarms. The user can choose between three sound levels, or to turn it off. See **figure 57**.

The majority of the users will probably just setting the time and date, and choose the language. However, there are some more settings included in the meter. First, to add reminder alarms is a feature that has been developed further, in comparison to existing meters for self-monitoring of blood glucose. It will be possible to set several single alarms, but also recurrent alarms. This makes it easier for diabetics to remember testing, for instance children during school hours, which some interviewed parents to children with diabetes mentioned as problematic.

If the blood glucose level is dangerously high or low, or there is a risk of develop diabetic ketoacidosis (high level of acetone), the meter will warn the user. The meter comes in a factory pre-set of these levels, but if your health care has advised you to use a different level, it will be possible to scroll to the correct number.

Finally, it will be possible to see stored results, and also to analyze the test results with help of high- and low values, graphs and averages. It was determined to not develop display screens for these functions, within the time span of this project.

10.4.9 How to perform a test

Below, the procedure of performing a test is showed and described. The task is also presented in a HTA. See **Appendix C**.

1. Turn on the meter.

Press and hold *Right* soft key until the meter turns on.

2. Check that the displayed time and date is correct.

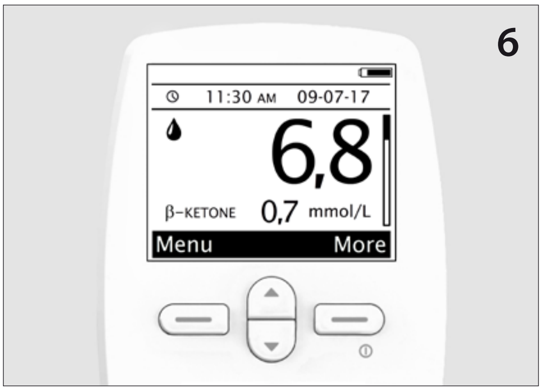
If time and date is correct, press *New test* soft key button. This means that the *Right* soft key is pressed twice to start a test. The idea is that this will be easy to remember, and also gives a plug-and-play feeling. (To set time and date, press *Menu* soft key.)

3. Please wait...

...until the bar is filled. The sensor is warmed up, and the sensor chamber is cleaned from air. The sensor membrane protection is opened, together with a beep sound (if audio profile is turned on), which means that the meter is ready for a new test.

4. Take a deep breath, and blow straight into the sensor at a distance of 10-15 centimeters.

An air bubble picture shows that you should take a deep breath and blow out. Blow until the bar is filled up and the meter gives a beep sound (if audio profile is turned on). The filled bar flashes two times to clearly show that the test is finished.



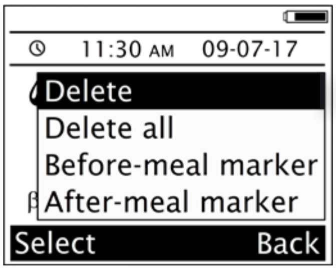


Figure 58. *When the test is done, you can either delete the test result, delete all test results or add before- or after-meal marker.*

The sliding sensor cap is closed when sufficient amount of air is received. The sensor starts to measure the sample, and the human breath is analyzed.

5. Wait until the meter has analyzed the breath.

Both the blood glucose- and β-hydroxybutyrate level in plasma (the most commonly measured ketone body in order to detect diabetic ketoacidosis) is analyzed. When the bar is filled, the result will be presented on the display.

6. Read your result on the meter.

Both the blood glucose and β-Ketone appears on the display, along with the unit of measurement and the date and time of the test. It was decided to visualize the blood glucose values in the largest figure, since this is the main parameter used today for monitoring of diabetes.

If an error occurs (no values are shown), the reason could be:

a. Too little of the human breath is received to the sensor. Then redo the test.
b. The battery level is low.
c. The values are too high and too low to be measured. Then redo the test.

If a warning message is shown, the reason could be:

a. High or low blood glucose values. Then redo the test once and take action.
b. High risk of developing diabetic ketoacidosis. Then redo the test once and take action.

7. Turn off the meter

When the test is done, the user can either turn off the meter by pressing and hold *Right* soft key, look at old results by pressing the *Up and down buttons*, press *More* soft key to delete the result, all results, to add a before- or after-meal marker (see **figure 58**), or go to the menu by pressing *Menu* soft key.

The meter will automatically power-off after 2 minutes (after last user action), so that the meter does not consume any unnecessary battery energy, if you have forgotten to turn it off.

10.4.10 How to set the meter

Below, there is one example of how to set the meter. The task of setting recurrent alarms (meaning the ability to set multiple recurrent alarms linked to specific days of the week) was chosen as an example. This is an appropriate task to show, because it includes some other tasks (set single alarm and set time), and also since it is probably the most advanced setting within the meter. A detailed description of how to set the whole meter can be seen in the HTA, see **Appendix C**.

1. Turn on the meter.

Press and hold *Right* soft key until the meter turns on.

2. Navigate to Recurrent alarms menu.

Press *Menu* soft key, select *Settings* in the main menu (see **figure 59**), and press up and down buttons until *Reminder alarms* appear. See **figure 60**. Press *Ok* soft key to enter.

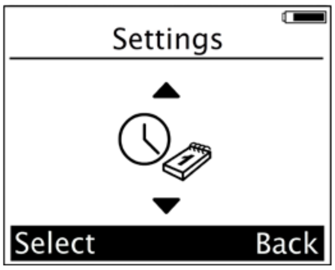


Figure 59. *Main menu screen showing settings.*

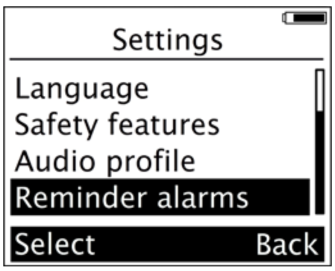


Figure 60. *Sub menu screen showing settings, and the selected Reminder alarms.*

The reminder alarms menu is divided in two sub menus; *Single alarm and Recurrent alarms*. Press up and down buttons until *Recurrent alarms* appears, and press *Select* soft key to enter. See **figure 61**.

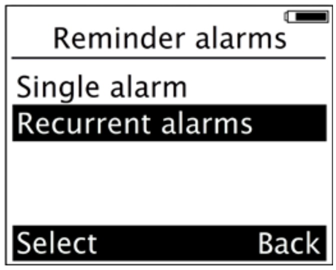


Figure 61. *Reminder alarms menu screen.*

The recurrent alarms menu is divided in three sub-menus: *New time, Stored Times and Overall view*. See **figure 62**. The last two sub menus are described a bit later.

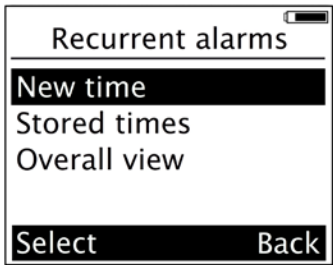


Figure 62. *Recurrent alarms screen.*

3. Set new time.

Press Up and down buttons until *New time* appears. Press *Select* soft key to enter. See **figure 62**. Press up and down buttons until the correct first digit for hours appear. Press *Ok* soft key to confirm. See **figure 63**.

Figure 63. *Set time screen. The black box marks the digit that is changed at the moment.*

Then, repeat to set the second digit for hours and the two digits for minutes. After having set the last minute for digit, press *Save* soft key to save the time. In order to go back to the previous screen, press the *Back* soft key.

4. Set recurrence rule.

Next, set the recurrence rule. The up and down buttons are used to move to desired weekday, and then use the *Check/Uncheck* soft keys. Finally, press *Save* soft key (the next screen will be the *Welcome* screen) to confirm the new reminder alarm. See **figure 64**.

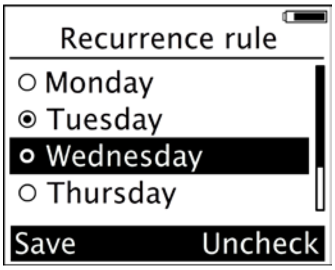


Figure 64. *Recurrence rule creen.*

Additional

There is obviously an opportunity to see, edit and delete old recurrent alarms, with help of using the *Stored times* and *Overall view* sub menus. First, if entering *Stored times* from the *Recurrent alarms* menu, all stored times will appear. See **figure 65**.

Figure 65. *Stored times screen.*

If you select one of the stored times, you can delete it, edit the time or edit the recurrence rule. See **figure 66**.

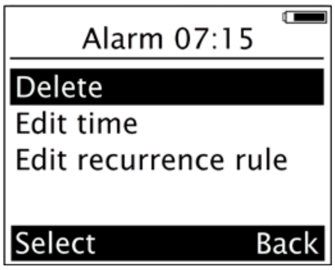


Figure 66. *Shows the screen that appears if you want to delete, edit time or recurrence rule for a recurrent alarm.*

Also, if entering *Overall view* sub menu from the *Recurrent alarms* menu, all stored recurrent alarm times will be showed graphically. See **figure 67** and **figure 68**. Here, you can either delete or edit a specific time simply by pressing *More* soft key and then choose *Delete* or *Edit time* from the menu list. The black box marks the time that can be edited or deleted at the moment, To move the marker to next time, use the up and down buttons, and press *Next day* soft key to go to the next weekday. To leave the *Overall view* screen, you press *Next day* soft key until the last weekday appears. Finally, press *Save* sofkey.

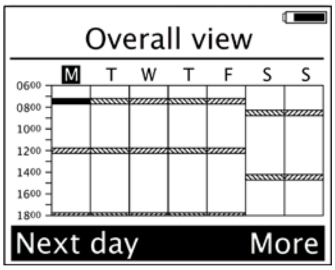


Figure 67. *The screen that shows all stored recurrent alarm times graphically.*

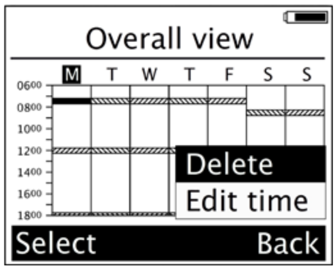


Figure 68. *Delete or edit time in Overall view screen.*

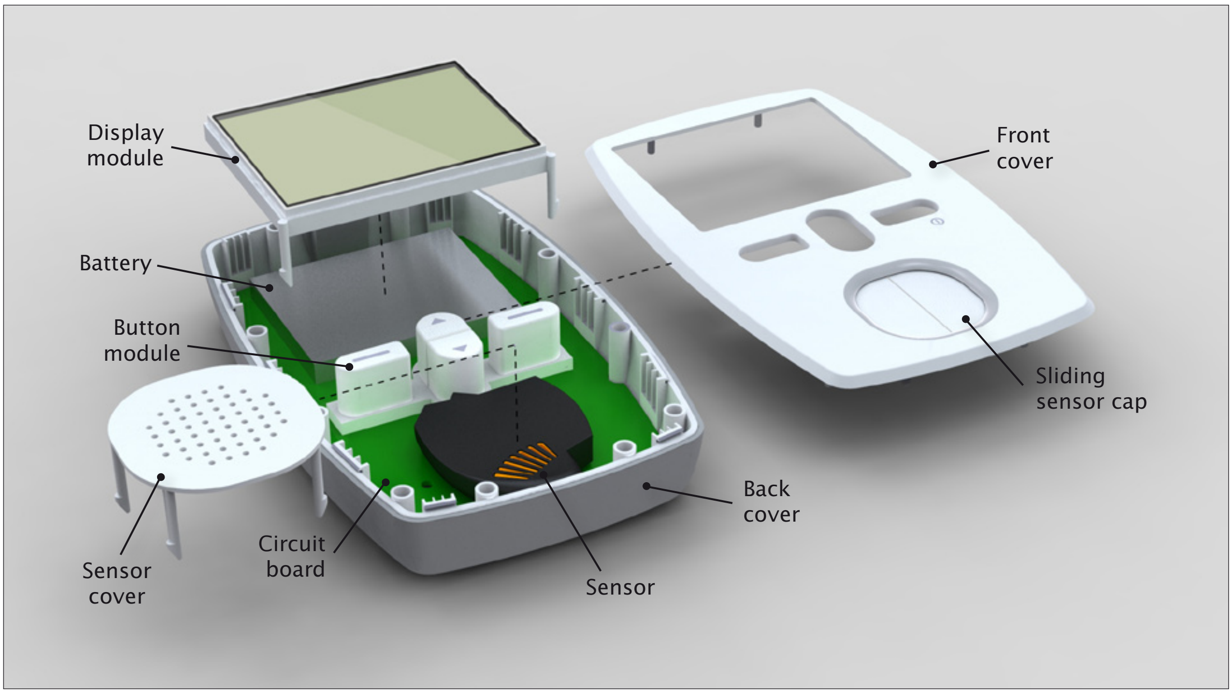


Figure 69. *The meter and its components in exploded view.*

10.5 Construction and placement of components

When developing the final concept, the requirements *minimize number of parts and materials, allow recycling or materials and/or parts, allow simple mass production and easy disassembly* have been considered as much as possible. Therefore, the outer casing of the meter consists of just two main parts, the back- and front cover, which are assembled using a snap construction. See **figure 70** and **figure 71**. It will be possible to separate the two main parts from each other with help of a special tool (needs to be thin as a guitar plectrum) in the gap/split line between the parts, for instance in the servicing and replacement of inside components, or when the meter is going to be recycled.

In **figure 69**, the main components included in the meter are shown in exploded view, and also how the package inside the meter looks like. The sensor, display module, USB module and key pad are connected to the circuit board. Since there is a gap between the circuit board and the bottom of the back cover, more circuit board components can be placed there. To the left and right of the sensor module, there will be space for components linked to ventilation and isolation, as well as the engine used for retraction of the sliding sensor cap, and for emptying of sensor chamber before a new test.

The battery is placed under the display module, first of all because that is where there is room for this component. This means that the battery is built into the meter. As a result, the user cannot easily change the battery by himself. Instead, the meter is recommended to be left for service when changing the battery, since sensitive components inside the meter might be damaged. It may seem like a disadvantage having to submit the product to service in order to replace the battery. It can be assumed that a better idea would be to add a battery cover, so that the user can change the battery by himself. But, this was not easily solved due to the limitation of space, and the way the components were having to be placed inside the meter.

On the other hand, the battery used in the meter will be the same type as the ones used for today mobile phones and MP3-players. Therefore, the battery will not probably need to be replaced during the life of the product, which means that the location of the battery is not seen as a problem.

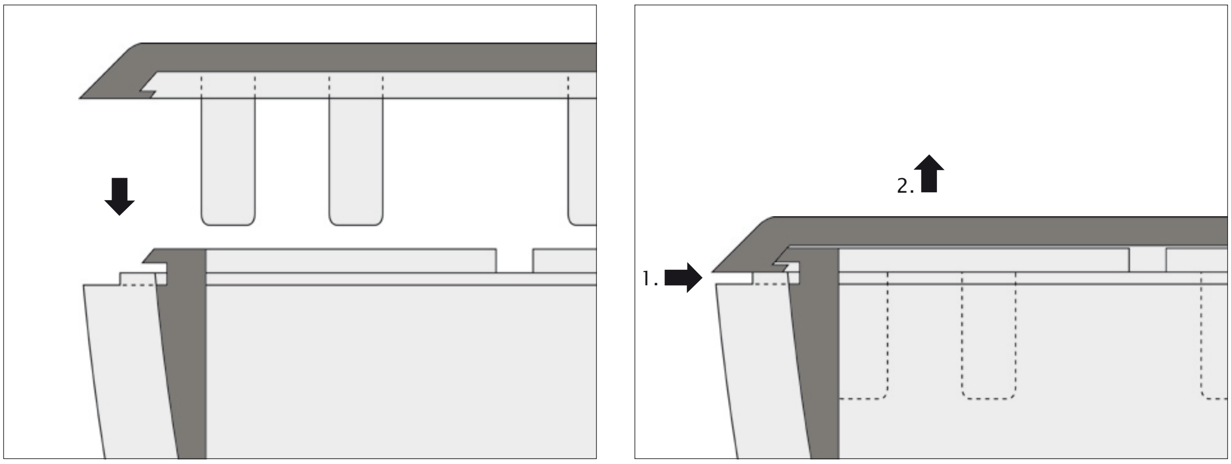


Figure 70. *The front cover is attached to the back cover using a repeatedly placed snap construction. Right: To detach the parts from each other, use a thin tool in the gap between the two main parts. The snap construction parts placed on the back cover will then flex, which makes it possible to separate the two main parts.*

Finally, the USB-module is placed on the short side, in order to be located near the battery, and since there is no space left on the other short side.

10.6 Production and materials selection

Basically, the main parts will be produced from the material group plastics. The product is going to be mass produced, and since the parts have quite complex shapes, a suitable and economical production method will be injection moulding (of thermoplastics). Injection moulding is the best way to mass produce small, precise, polymer components with complex shapes. Also, thermoplastics can be reheated and reformed into new shapes a number of times without significant change in their properties. This means that these materials are recyclable, which is good from an environmental point of view. (CES EduPack, 2009)

10.6.1 The front cover

The front cover is painted in matt white. However, the material chosen needs to be transparent, since there is a display window included in the front cover. CES EduPack 2009 was used to find thermoplastics that are transparent, and with desirable mechanical properties. Four possible thermoplastics were found, Polystyrene (PS), Cellulose polymers (CA), Polymethyl methacrylate (PMMA) and Polycarbonate (PC). PS are hard, brittle and cracks easily, while CA has poor dimensional stability. Therefore, these plastics can be seen as less suitable due to the mentioned properties, and were therefore discarded.

Both PC and PMMA are often used as an alternative to glass. PC is tough, has high strength and impact resistance, can be injection moulded, and since it has a high dimensional stability, it can be used in precision engineering components where close tolerances are required. A disadvantage with PC is that it is easily scratched. PMMA is the thermoplastic that most closely resembles glass in transparency. In addition, it is hard, stiff and cheaper than PC but has a certain fragility. It can be determined that either PC or PMMA will be used as the front cover material, but it needs to be further studied which one to choose. (CES EduPack, 2009 & Smith and Hashemi, 2006)

10.6.2 The back cover

The back cover can be made from a number of different thermoplastics, with the prerequisite that the chosen material is a plastic with high dimensional stability. According to CES EduPAck 2009, typical uses of Acrylonitrile Butadiene Styrene (ABS) among others are housings for small appliances (e.g. telephone housings). Also, typical uses for PC are housings for handheld power tools and small

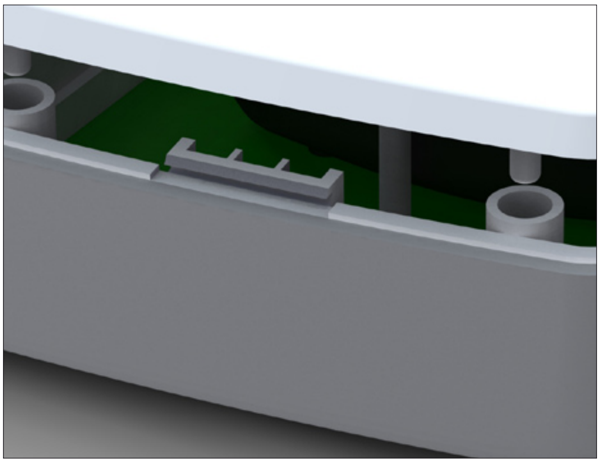


Figure 71. *The snap construction in perspective view.*

appliances. Therefore, it can be suggested, without making a specific choice, that either PC or ABS are suitable material for the back cover. Obviously, this needs to be further studied, the day the meter is going to be put into production.

The back cover will go through a second step of moulding, called double injection or co-injection, where a light grey rubber-like plastic, called Thermoplastic Elastomer (TPE) is added, in order to give a good non-slip grip. According to CES EduPack 2009, co-injection allows moulding of components with different materials, colours and features.

10.6.3 Key pad

The key pad will be injection moulded in TPE. The chosen material will add some friction to the key pad, which will help to differentiate the buttons from the front cover, in order to be easy to find an press.

10.6.4 The sensor cap and remaining parts

The parts included in the sliding sensor cap, display module, senor protection and other components inside the meter are proposed to be manufactured in the same material as the front- and/or back cover, in order to minimize number of materials and to make it easier to recycle the meter.

11 Conclusions and discussion

In this chapter, the strengths and weaknesses of the project result will be discussed. Also, the different methods used in the project is discussed, about what could have been done different, and if there are any methods that are missing. In the end, the market potential and need in the future is discussed, and some conclusions are made about the next step and further recommendations for the development of the final meter, the sensor technology and test method.

11.1 Strengths of the project result

It has been challenging but meaningful to develop this meter that might be a breakthrough within self-monitoring of diabetes. There are obviously many advantages by performing a breath test rather than the usual blood test, and the new test method in itself solves many of the problems presented in the problem description. Here the strengths of the final result will be discussed, for both the product design and the human-machine interface.

11.1.1 Product design

Perhaps, the biggest strength with the project is that is based on results from the interview study conducted at the beginning of the project. Then, the final meter has been developed from the basis of user needs and requirements identified during the interviews, together with the specification list from Imego Ab, existing requirements for meters used within self-monitoring of blood glucose, by implementing guidelines for development of human-machine interface and so on.

The citation *"…new technology often requires a new design interpretation"* has been an important statement during the project. The meter is unique in itself, since there is nothing similar available at the market today. Also, the sliding sensor cap has helped to make an innovative product. However, there has been a challenge to come up with a product design that does not remind too much to a mobile phone and MP3-player, mainly because of similarities in current product signs. For instance some people thought that the sliding sensor cap, and then the whole meter, is associated with the original iPod. Therefore, some changes in the design were made to weaken the connection, and hopefully this has been a step in the right direction.

Since the product category is quite simple, a lot of time has been spent on the product design of the meter, and then in particular the product semiotics. In overall, the expressions of clean, simple, robust & reliable have been implemented in the product in a good way, at least on the paper, and the decisions concerning product design can be referred back to the wanted semantic expressions. However, this is just one person thoughts, and it should therefore be studied whether people associate the meter with these expressions.

In the beginning of the project, Imego Ab made clear that there should not be too much focus about the size of the components, since it will restrict the ability to develop something new, and to meet the user needs. However, in the later stage of the project, it was considered as necessary to decide an approximate size of the future sensor module. This increases the credibility regarding the project result. In addition, placement of the component inside the meter has been determined, and there is room left for components that are needed but not yet decided, which means that there should be no difficulties to produce the meter with its current product design.

During the project, the cost has not been decided in detail, which might be seen as a weakness. But, the cost has to a great extent been considered when developing the concepts and the final meter. The meter consists of two main parts that are rather easy to produce with injection moulding, and only conventional materials and production methods have been selected. It is the sensor module and its components which probably make it more expensive to produce than most of today's traditional blood glucose meters. On the other hand, the meter requires no expensive consumables, which means that a greater once-for-all cost is justified.

The empirical study adds some credibility to the final result, since the size of the meter was determined in a good way. Also, the study gave valuable inputs about the size and location of the buttons, and therefore some changes were done during the process, in order to improve the handling/ergonomics of the product.

11.1.2 Human-machine interface

The main focus has been on the product design, but since also a lot of time has been spent to develop the human-machine interface, it adds certain credibility to the final result. The whole system (the product and its human-machine interface) has been considered and determined, which is a strength.

The human-machine interface has been developed with the starting point of the critical users (elderly and people with poor sight) and their needs and demands. Therefore, the text and figures are quite large (character height for capital letters is around 3 mm), and people are guided through the whole test both visually and auditory. The same button (the right soft key) is used to turn on/off the meter and to start a new test, which means that it will be easy for all to learn and be able to perform a test. In addition, it takes little time and few key presses to start a new test.

Furthermore, there are no difficult key combinations to remember in order to look at old test results, see averages and setting the meter. Finally, the menu system is based on the same principle used in mobile phones, which means that the majority of users will be familiar with the menu structure in advance.

11.2 Weaknesses of the project result

It should be remembered that only seven diabetics were interviewed. Therefore, it is impossible to determine whether what was said during the interviews is consistent with the general view of the majority of diabetics'. There is always a risk that the answers have been over interpreted, and that you listen too much on what a few people say. However, since the interviews were recorded, and listened all over again during the transcription, the risk of misinterpretations hopefully has been minimized. Also, it was also tried to only make general conclusions.

Another weakness with the project result is that intended user group was not specified in detail. The aim has been to meet all user groups' needs and demands, from the critical users (elderly and people with poor sight) to youths, teen ages and children in school age. Perhaps, the final meter is a solution that is not optimized to none of the users.

For instance, when talking about the size of the meter and buttons, it can be assumed that elderly will appreciate and a bigger meter and buttons, in comparison to young people. To define the user group more in detail is something that possibly would have been done different, if the project could have been re-done.

Also, the human-machine has been developed with the starting point of the critical users, with the assumption that if his/her needs and requirements are met, then the other user groups' needs and requirements are automatically met. But, since there may be a contradiction in the requirements of each user group, you can question whether this is the correct approach for the project. For example, the size of the text messages in the display screens might feel too big in order to be accepted by the younger users. Perhaps they will feel embarrassed to use the meter, since they are used with the text size in their mobile phones. Therefore, one idea is to add a feature that makes it possible to increase/reduce the size of the text messages. Then, the display screens can be adaptable to all users' wishes and demands.

The project has been carried out by just one person in all parts of the project. On a personal level, this has been very useful and valuable. The result reflects and shows my ability, my strengths and weaknesses. But, quite obviously the result would have been different if the project had been carried out in group. For instance, the developed concepts are in many senses similar to each other, which can be seen as a weakness. Then, if the project had been carried out in group, you are easily triggered by the others ideas and solutions, which also can be discussed back and forth, in order to achieve better and a wide range of solutions. Also, if working alone, it is easy to miss important aspects, since you in a way have a tunnel vision, and decisions are made with little or no reflections.

11.3 Methods

Below, the different methods used in the project is discussed, about what could have been done different, and if there are any methods that are missing.

11.3.1 The interviews

The interviews were carried out early in the project. In this stage of the project, the literature review and pre-study was not finished, and then in particular the literature study about relationship between human breath and diabetes. At that moment in the project, it was thought that there is full linear correlation between acetone and blood glucose, which is not the case.

Therefore, only questions about measuring blood glucose were asked, and the problems with today blood glucose meters. Later, it was found that measuring of acetone levels in exhaled air first of all could be used to detect diabetic ketoacidosis, and not as a way to measure blood glucose. In a later stage of the project, when the interviews were done, it was found that it might be possible to measure blood glucose indirectly using multiple breath analysis, which in a way saved the results of the interviews. Therefore, if the interviews would have been carried out today, it should be asked more about the need of measuring two values, if they have used meters that also measures blood ketones, and to figure out what they think about these kind of meters.

11.3.2 Synthesis

The idea generation and concept development was performed individually. In order to achieve a greater variation of ideas, it would have been a good idea to have a focus group or brainstorming session, together with people at Imego Ab or students at the master programme. However, at that stage of the project, this kind of methods were considered as too resource- and time consuming. Therefore, the ideas and concepts were generated individually.

11.3.3 Evaluation

The selection of participants for the empirical study was not optimal; it was mostly young people. In addition, the participants were not diabetics, and elderly and children were not included in the study, which is a weakness. However, the empirical study gave valuable inputs about size and location of the buttons, and it was also possible to identify an appropriate size of the meter.

If there had been more time and resources, participants for the empirical study would have been diabetic patients. Then, an appropriate next step would be to let diabetics test and evaluate the physical model and the human-machine interface that was developed in Flash. Also, there had been room for more in-depth look at how it would feel to monitor their diabetes using exhaled air, since they would have a mock-up to relate to.

Finally, it was decided to not evaluate the human-machine interface and the interaction with the product in a usability lab. However, it would been a good start to make an theoretical evaluation, for instance using Cognitive Walkthrough (CW) and Predictive Human Error Analysis (PHEA). To use these methods will be an appropriate next step of the project.

11.4 Market potential and the need in the future

Diabetes has become a widespread national disease, and it is increasing in the Western World, which means that there is prerequisite for success for the meter. But, it is important to remember that there is a considerable competition on the market, which means that it will be hard for the meter to settle in and take market segments.

Also, there is a massive research within the area of diabetes at the moment, and great progress is to be expected in the near future. Today, a system used for continuous monitoring of blood glucose together with insulin pumps is a step towards an artificial pancreas. The next step is perhaps an implanted sensor that measures blood glucose, which then sends a signal to either an insulin pump or artificial pancreas to adjust the insulin dose. Finally, it can be assumed that, in one way or another, will be possible to bring life to the body's own production of insulin again, for instance with an operation, using genetic modifications etc. It is difficult to determine how long it will take before all the pieces are in place to make the latter possible. As a result, it is hard to predict the actual need of the meter in the future.

In short term, which means the following 10-15 years, systems used for continuous monitoring of blood glucose is the biggest competitor. Therefore, it can be proposed that people using insulin pump will have little need of this meter. The approach during the project has been that people, who control their diabetes using traditional blood glucose meters today will have use of the new meter in the future. In the future, this includes diabetics whose values do not fluctuates that much, which means that a few measurements per day are sufficient to monitor the disease. Also, some diabetics might not want to carry around equipment that reminds about the disease, which is the case for the continuous glucose measurement systems available today. It might also be distressing to have an eye on the blood glucose values all the time, which means that some people will prefer to measure their values every now and then instead. Preferable, the meter can also be used at health care services and old people's home.

Finally, systems for continuous monitoring of blood glucose are expensive, both in the purchase but also in running (the sensor needs to be replaced periodically). This suggests that traditional meters, and then in particular the new meter, will be needed in the future, as a cheaper alternative. In particular, since diabetes are growing rapidly in the world, and in countries who do not have a health care system where the facilities for monitoring diabetes are subsidized, there will definitely be people who can not afford the expensive systems for continuous monitoring of blood glucose. Also, then it can be assumed that the primary markets could change from Europe, USA and Japan to perhaps India, China and third world countries, which is an interesting conclusion.

11.5 The company and project initiator

The project has mostly been carried out at the company. Early, Imego Ab made clear that it is my project, and decisions are taken by me. Still, it has been possible to have an open dialogue with the supervisor continuously during the project, which has been beneficial. In addition, ideas, concepts and different versions of the report have been presented along the road, to get valuable feedback, and to ensure that the project is progressed in the desired direction.

11.6 Next step and further recommendations

A comprehensive concept proposal has been developed that addresses both product design and the human-machine interface, which corresponds to what was specified by Imego Ab at the beginning of the project. In principle, the meter can be prepared for production, with just minor modifiactions, the day the technology is fully developed and prospective co-financiers are secured. In addition, the result can rather easily be implemented in other handheld products based on the same sensor technology. If the aim in the future will be to take the project results to the next stage, which means production and to introduce the meter on the market, there are some things that must be considered and done first.

11.6.1 The sensor technology and test method

- It should be remembered that there is a challenge to measure acetone, which can be understood by the fact that there are no similar consumer products available today, but only as lab equipment. Therefore, Imego Ab needs to examine whether the sensor is capable of measuring acetone with today's technology, and with high accuracy.

- It has been assumed that it will be possible to measure blood glucose indirectly using multiple breath analysis. Primarily, because diabetics are familiar with this value, and since the objective for the meter is to replace the traditional meters, and not only as a supplement. Therefore, in the near future, it is recommended to keep up to date on researches addressing the connection between exhaled air and blood glucose.

11.6.2 The final meter

- The sliding sensor cap needs to be further developed, which first of all means the construction. Also, the engine has to be selected, it needs to be examined whether all parts will fit, if the size of the holes are enough etc. In overall, the robustness and reliability of the sliding sensor cap needs to be evaluated.

- The final meter and the semantics expressions need to be tested and evaluated by diabetics, for instance using the physical model. The human-machine interface that was developed in Flash has to be evaluated, both theoretical and with intended users.

- Possibly, it would be appropriate to add a function where it is possible to increase/reduce the text size in the interface to suit the different users.

- Preferably, one additional evaluation study of the buttons should take place, using a mock-up with in built mechanical feedback, to determine whether the buttons need to be further increased in size.

- It has to be investigate what is needed to make the meter approved as medical technical equipment.

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13 Appendix

Appendix A - Interview guide

Bakgrund

Kön: ____________________
Ålder: ____________________
Typ av diabetes:___________________
Hur länge har du haft diabetes? ____________________
På vilket sätt behandlar du din diabetes? (Insulinspruta, insulinpump, tabletter) _________________________
____
Intresse för teknik? ____
Vilka hjälpmedel använder du? Insulinspruta, blodsockermätare osv.
____

Blodsockermätare

Introduktion

1. Vilket märke har du? Har du haft flera?
   a. Varför valde du den modellen?
2. Hur länge har du använt dig av en blodsockermätare?
3. Brukar du alltid ha med dig den?
4. Hur ofta brukar du använda den? Dagligen, flera gånger per dag osv.
5. I vilka sammanhang brukar du mäta? Innan måltid, beroende på hur du mår, i samband med att tar insulin? Alltid fasta tider?
6. Händer det någon gång att du brukar glömma av och testa ditt blodsocker?
7. Vilken kringutrustning behövs? Stickor, lansett, servetter.
8. Hur förvarar ni utrustningen/tillbehören efter användning? I väskan, hemma, tillsammans med insulinspruta...
9. Fick du någon genomgång av blodsockermätaren innan du började använda den? I så fall av vem?
10. Utifrån vilka grunder väljer du din blodsockermätare när du köper en ny?
11. Beskriv med egna ord vad du tycker kännetecknar en bra blodsockermätare. Ex. liten och smidig. Vad tycker du är viktigast?
12. Vad tycker du är det bästa med den blodsockermätare du använder för tillfället?

Användning

1. Vilka olika moment ingår vid provtagning? Är det något moment som känns extra ansträngande/krångligt/tidsödande?
2. Hur lång tid tog det att lära sig blodsockermätaren?
3. Vad tyckte du var svårast att lära sig med blodsockermätaren?
4. Nämn det som du tycker minst om med din blodsockermätare?
5. Vad är det för något som kan gå fel vid testtagningen?
6. Hur ofta får du felmeddelanden av blodsockermätare? Vet du alltid vad de betyder?
7. Har du fått någon felsignal vid användning av din blodsockermätare?
   a. Vilka?
   b. På vilket sätt visas felmeddelanden? Ljud, ljus, text osv.
8. Litar du på testresultatet fullt ut eller använder det som en ungefärlig riktlinje?
9. Hur hanteras förbrukningsartiklarna? Slänger de direkt, lägger de i speciell burk för medicinskt avfall osv.
10. Var brukar du sticka dig? I fingret, på samma ställe hela tiden osv.

Funktioner

1. Vad finns det för funktioner i din blodsockermätare?
2. Vilka funktioner använder du dig av? (mätning, lagring, medelvärden, överföring till dator osv.)
3. Hur tydlig tycker du den är att använda? Logisk följd, lätt att bläddra i menyer, enkelt att följa och göra inställningar osv.
4. Finns det funktioner som du tycker är onödiga?
5. Finns det funktioner som du saknar? Exempelvis ange hur stor dos ni ska ge osv.
6. Vad tycker du om antalet funktioner – fler eller färre?
7. Hur många knappar finns det på din apparat? Vill du ha fler eller färre?
8. Om du fick önska fritt, är det något du vill ändra/lägga till med den blodsockermätare du använder idag? Nya funktioner, fler knappar, mindre knappar osv.

Dokumentation

1. Brukar du dokumentera dina mätningar? På vilket sätt?
2. Brukar läkarna ta del av dina mätresultat? I så fall på vilket sätt?

Emotionella

1. Hur ser du på din sjukdom? Har det förändrats med tiden? Emotionella hanteringen av sjukdomen.
2. Var någonstans brukar ni testa er blodsockernivå? Brukar ni gå undan eller testa er på öppen plats? Skillnad om ni är hemma eller på jobbet?
3. Tänker ni på något speciellt då ni testar er blodsockernivå? Beskriv ditt emotionella känslotillstånd? Upplever du något speciellt?
4. Vad känner du vid användandet av blodsockermätaren? Trevligt, jobbigt osv.
5. Hur känns det varje de vill testa, tänker de på sjukdomen? Tänker du på något speciellt?
6. Förknippar du blodsockermätaren med något speciellt?

Utandning

1. Skulle det underlätta för dig om du kunde testa din blodsockernivå genom utandningen istället? På vilket sätt?
2. Ser du några nackdelar med detta?
3. Om du hade fått mäta blodsockerhalten med hjälp av utandningsluften istället, hur skulle det kännas?
4. Tror du hade testat dig fler/färre gånger?
5. Hade det påverkat dig var någonstans du skulle testa dig?

Avslutning

1. Vad tror du kommer att hända inom framtiden beträffande forskning och framsteg kopplat till diabetes?
2. Finns det något mer som du vill tillägga?

Appendix B - Blood glucose meters

Overall			
Manufacturer	Roche		
Model	Accu-Chek® Aviva	Accu-Chek® Compact Plus GT	Accu-Chek® Aviva Nano
Summary	Basic model that comes with a preset time and date, which enables a quick start-up. It has easy-to-hold rubber grips.	All-in-one solution including meter, lancing device and preloaded test strips.	Glow in the dark display which enables easy night-testing. Includes feautures such as post- and pre-meal markers.
Dimensions	94 x 53 x 22 mm	125 x 64 x 32 mm	69 x 43 x 20 mm
Weight	60 g (with battery)	147 g (with Batteries, Test Strip Drum and Lancing Device)	Approx. 40 g (with batteries)
Display window	LCD	OLED (Organic Light Emitting Diode) display	LCD with auto backlight
Battery type	1 x 3-volt lithium battery, type CR 2032	2 x (type AAA, LR 03, AM 4 or Micro) or 2 x NiMH rechargeable batteries (type AAA)	2 x 3-volt lithium batteries (type 2032)
Features			
Measurement Time	5 s	5 s	-
Battery life	Approx. 1000 tests	>1000 tests	Approx. 1000 tests
Memory capacity	500 test results	500 test results	500 test results
Test reminders	4 test reminder alarms per day	3 test reminder alarms per day	4 test reminder alarms per day
System operating conditions	6'C–44'C	10'C to 40'C	6'C to 44'C
Test Averages	7, 14, 30 day	7,14, 30 day	7, 14, 30, or 90 day averages + pre-meal and post-meal averages
Highest and lowest values	No	Lowest and highest values for these 3 periods	No
Pre-meal and post-meal marker	No	No	Yes
Safety Features	Hypo indicator, High or Low Blood Sugar (test result out of measuring range)	Hypo indicator, High or Low Blood Sugar (test result out of measuring range)	Hypo indicator, High or Low Blood Sugar (test result out of measuring range)
Coding	Code chip	Code chip	Code chip
Data transfer to PC	Wireless with IR	Wireless with IR	Wireless with IR
Acoustic mode	No	On/off (For visual impaired persons)	No
Beeper	Yes	Yes	Yes
Automatic Power-off	2 minutes	1 minute	2 minutes
Error messages	Low battery power, Test out of ranges, Err + symbols	Low battery power, Test out of ranges, Err + symbols	Low battery power, Test out of ranges, E-1-10, symbols
Backlight	No	No	No
Moreover	-	-	-
Settings			
Time	Hours, minutes	Hours, minutes	Hours, minutes,
Time format	Am/pm	24-hour/12-hour (with am/pm)	Am/pm
Date	Year, month, day	Year, month, day	Year, month, day
Date format	Predefined	Predefined	Predefined
Alarm clock function	Off/Alarm 1, -2, -3, -4	Off,Alarm 1, -2, -3	Off/Alarm 1, -2, -3, -4
Beeper tone	On/off	On/off	On/off
Acoustic mode	Not available	On/off	Not available
Hypoglycemic (Hypo) indicator	Off/Level between 60 to 80 mg/dL	Off/3 levels	Off/Level between 2.8 to 5.0 mmol/L
Hyper indicator	-	-	-
Post-meal reminder time	Not available	Not available	1 hour or 2 hours
Pre-meal or post-meal marker	Not available	Not available	Pre-meal, post-meal marker, Pre-Meal Marker with Post-Meal Reminder, general marker
Measurement units	Predefined	Predefined	Predefined
Language	Not available	Not available	Not available
Brightness of the display	Predefined	Low, medium, high	Predefined
Backlight	Not available	Not available	Not available
Blood sugar measurement			
Sample Size	0.6 µL	1.5 µL	0.6 µL
Measuring Range	0.6 to 33.3 mmol/L	0.6–33.3 mmol/L (10–600 mg/dL)	0.6 to 33.3 mmol/L
Blood β-Ketone measurement			
Sample Size	Not available in this model	Not available in this model	Not available in this model
Measuring Range	Not available in this model	Not available in this model	Not available in this model
Measurement Time	Not available in this model	Not available in this model	Not available in this model



Overall			
Manufacturer	Abbott		LifeScan
Model	FreeStyle Lite™	Precision Xtra	OneTouch® Vita™
Summary	Small sample size, backlight and a test strip port light for testing in the night.	Both blood glucose and blood ß-Ketone testing.	Clear error messages, more advanced menu structure that minimize difficult key-combinations.
Dimensions	40 mm x 74 mm x 17 mm	69 x 53 x 16 mm	95 x 65 x 22.5 mm
Weight	40 g (with batteries)	42 g	Approx. 60 g (with battery)
Display window	-	-	-
Battery type	1 x 3 volt lithium battery, #2032	1 x coin cell lithium replaceable battery, #2032	1 x CR 2032 battery or equivalent
Features			
Measurement Time	5 s	5 s	5 s
Battery life	500 tests	Approx. 1000 tests	-
Memory capacity	400 test results	Up to 450 events	350 test results
Test reminders	4 test reminder alarms per day	No	No
System operating conditions	4ºC to 40º C	10˚C to 50˚C	10˚C to 44˚C
Test Averages	7-, 14- and 30-day	7,14, 30 day (only blood glucose)	7, 14, 30-day averages + post-meal averages
Highest and lowest values	No	No	No
Pre-meal and post-meal marker	No	No	Post-meal marker flag
Safety Features	High or Low Blood Sugar readings	Hypo indicator, High or Low Blood Sugar (test result out of measuring range)	High or Low Blood Sugar readings
Coding	No coding	Code chip	No coding
Data transfer to PC	Data cable	Data cable	Data cable
Acoustic mode	No	No	No
Beeper	Yes	Yes	No
Automatic Power-off	2 minute (after last user action)	1 minute (after last user action)	2 minutes
Error messages	Low battery power, Test out of ranges, Er-1-4, symbols	Error groups (1-9), symbols	Low battery power, Error 1-5 together with short messages, Temperature too high or low
Backlight	Yes (together with test light)	Yes	No
Moreover		-	-
Settings			
Time	Hours, minutes	Hours, minutes	Hours, minutes
Time format	24-hour/12-hour (with am/pm)	24-hour/12-hour (with am/pm)	24-hour
Date	Year, month, day	Year, month, day	Year, month, day
Date format	Month-day or day-month format	Month-day, day.month format	Predefined
Alarm clock function	Off/Alarm 1, -2, -3, -4	Not available	Not available
Beeper tone	Off/2 levels (low and high)	On/off	Not available
Acoustic mode	Not available	Not available	Not available
Hypoglycemic (Hypo) indicator	Not available	Not available	Not available
Hyper indicator	-	-	-
Post-meal reminder time	Not available	Not available	Not available
Pre-meal or post-meal marker	Not available	Not available	On/off (after meal flags)
Measurement units	Predefined	mg/dL or mmol/L	Predefined (depending of country)
Language	Not available	Not available	Yes
Brightness of the display	Predefined	Predefined	Predefined
Backlight	On/off (one button)	On/off (one button)	Not available
Blood sugar measurement			
Sample Size	0.3 µL	0.6 µL	-
Measuring Range	1,1–27,8 mmol/L (20 to 500 mg/dL)	1,1–27,8 mmol/L (20 to 500 mg/dL)	1.1–33.3 mmol/L
Blood β-Ketone measurement			
Sample Size	Not available in this model	1.5 µL	Not available in this model
Measuring Range	Not available in this model	0.0 to 8.0 mmol/L	Not available in this model
Measurement Time	Not available in this model	10 s	Not available in this model

 

Overall		
Manufacturer	LifeScan	Bayer HealthCare
Model	OneTouch® UltraSmart™	Contour®
Summary	Small computer with e.g. graphs, diary, advanced averages and with possibility to add information about health, meal, exercise, insulin type etc.	Possibility to set own personal blood glucose range.
Dimensions	95 x 58 x 23 mm	77 mm x 57 mm x 19 mm
Weight	75 g (with batteries)	48 g
Display window	-	-
Battery type	2 x AAA alkaline batteries	2 x 3-volt lithium batteries

Features		
Measurement Time	5 s	5 s
Battery life	Up to 540 tests	Approx. 1000 tests
Memory capacity	>3000 test results	480 test results
Test reminders	No	
System operating conditions	6°C to 44°C	5°C to 45°C
Test Averages	7, 14, 30, 60 or 90 day averages	7, 14, and 30 day averages + 30 day pre-meal marker and post-meal averages
Highest and lowest values	No	7 day HI (default set to above 180 mg/dL) and LO (default set to below 72 mg/dL) summary
Pre-meal and post-meal marker	Yes	Selectable post-meal alarms
Safety Features	Hypo indicator, High or Low Blood Sugar readings, advise to check ketone levels, advise that a meal may be necessary.	Personal High or Low Blood Sugar
Coding	Code number	No coding
Data transfer to PC	Data cable	Data cable
Acoustic mode	No	No
Beeper	Yes	Yes
Automatic Power-off	1 minute (after last user action)	After 3 minutes
Error messages	Low battery power, Error 1-5 together with short messages, Temperature too high or low	Low battery power, E1-9 + symbols
Backlight	Yes	No
Moreover	Possible to compare the result with your last test and your average for this time of day	-

Settings		
Time	Hours, minutes	Hours, minutes
Time format	24-hour/12-hour (with am/pm)	24-hour/12-hour (with am/pm)
Date	Year, month, day	Year, month, day
Date format	MM/DD/YY or DD/MM/YY	Month/day or day.month format
Alarm clock function	Not available	Not available
Beeper tone	On/off	On/off
Acoustic mode	Not available	Not available
Hypoglycemic (Hypo) indicator	Set your own hypoglycemia level	Set your personal low blood glucose (60-90 mg/dL)
Hyper indicator	-	Set your personal high blood glucose (100–250 mg/dL)
Post-meal reminder time	Not available	2.5, 2.0, 1.5 or 1.0 hours
Pre-meal or post-meal marker	Yes, before- and after breakfast, before- and after lunch etc.	Pre-meal and post-meal marker (+ possibility to set post-meal reminder time)
Measurement units	mg/dL or mmol/L	Predefined (depending of country)
Language	6 Languages	Not available
Brightness of the display	Darker/lighter	Not available
Backlight	-	Not available

Blood sugar measurement		
Sample Size	>0.1 µL	0.6 µL
Measuring Range	1.1–33.3 mmol/L	10–600 mg/dL

Blood β-Ketone measurement		
Sample Size	Not available in this model	Not available in this model
Measuring Range	Not available in this model	Not available in this model
Measurement Time	Not available in this model	Not available in this model

Appendix C - Hierarchical Task Analysis

0. Perform a test

Plan 0.

Do 1-2

Do 4 if time and date is correct. Otherwise, do 3 to set time and date, and then do 4.

Do. 5-10

1. Turn on the meter
   1.1. Press and hold On/off button
2. Check that the displayed time and date is correct
3. Set time and date

plan 3.

Do 3.1

Do 3.2 and/or 3.3 if desired.

   3.1. Navigate to Time and date
      3.1.1. Press *Menu* soft key
      3.1.2. Press *Up and down buttons* until Settings appears
      3.1.3. Press *Select* soft key
      3.1.4. Press *Up and down buttons* until Time and date appears
      3.1.5. Press *Select* soft key
   3.2. Set Time

   plan 3.2

   In 3.2.4 it is possible to press the Back soft key to go back to the previous setting.

      3.2.1. Press *Up and down buttons* to select Set time
      3.2.2. Press *Select* soft key
      3.2.3. Set Hour
         3.2.3.1. Press *Up and down buttons* until the correct hour appears
         3.2.3.2. Press *Ok* soft key
      3.2.4. Set Minute
         3.2.4.1. Press *Up and down buttons* the correct minute appears
         3.2.4.2. Press *Ok* soft key
   3.3. Set Date

   plan 3.3

   In 3.3.4 - 3.3.5 it is possible to press the Back soft key to go back to the previous setting

      3.3.1. Press *Up and down buttons* buttons to choose Set date.
      3.3.2. Press *Select* soft key
      3.3.3. Set Year
         3.3.3.1. Press *Up and down buttons* until the correct year appears
         3.3.3.2. Press *Ok* soft key
      3.3.4. Set Month
         3.3.4.1. Press *Up and down buttons* until the correct month appears
         3.3.4.2. Press *Ok* soft key
      3.3.5. Set Day
         3.3.5.1. Press *Up and down buttons* until the correct day appears
         3.3.5.2. Press *Ok* soft key
   3.4. Press *Back* soft key to come back to Settings
   3.5. Press *Back* soft key to come back to main menu

4. Choose to make a new test from the main menu
   4.1. Press *New test* soft key to confirm new test
   5. Wait for the meter to be ready to be used (the sensor is warmed up, the sensor chamber is cleaned from old air)
6. When the membrane is opened take a deep breath
7. Blow straight into the sensor at a distance of 10-15 centimeters (until the bar is filled up)
8. Wait for the result to be presented on the display
9. Look at the readings that are shown via the display (both blood glucose and ketosis values)
10. Turn off the meter
   10.1. Press and hold *On/off button*

0. Setting up the meter

Plan 0.

Do 1-2

Do 3-8 if desired

Do. 9-10

Comments: In 3-8 it is possible to press the Back soft key to go back to the previous screen.

If you do 8, then 9 is not available.

1. Turn on the meter
   1.1. Press and hold On/off button
2. Navigate to Settings
   2.1. Press *Menu* soft key
   2.2. Press *Up and down buttons* until Settings appears
   2.3. Press *Select* soft key
3. Set time and date

Plan 3.

Do 3.1

Do 3.2 and/or 3.3 if desired.

   3.1. Navigate to Time and date
      3.1.1. Press *Up and down buttons* until Time and date appears
      3.1.2. Press *Select* soft key
   3.2. Set Time
   plan 3.2
   In 3.2.4 it is possible to press the Back soft key to go back to the previous setting.
      3.2.1. Press *Up and down buttons* to select Set time
      3.2.2. Press *Select* soft key
      3.2.3. Set Hour
         3.2.3.1. Press *Up and down buttons* until the correct first digit for hours appears
         3.2.3.2. Press *Ok* soft key
         3.2.3.3. Press *Up and down buttons* until the correct second digit for hours appears
         3.2.3.4. Press *Save* soft key
      3.2.4. Set Minute
         3.2.4.1. Press *Up and down buttons* until the correct first digit for minutes appears
         3.2.4.2. Press *Ok* soft key
         3.2.4.3. Press *Up and down buttons* until the correct second digit for minutes appears
         3.2.4.4. Press *Save* soft key
      3.2.5. Press *Back* soft key to come back to Settings
   3.3. Set Date
   plan 3.3
   In 3.3.4 - 3.3.5 it is possible to press the Back soft key to go back to the previous setting
      3.3.1. Press *Up and down buttons* to choose Set date.
      3.3.2. Press *Select* soft key
      3.3.3. Set Year
         3.3.3.1. Press *Up and down buttons* until the correct year appears
         3.3.3.2. Press *Ok* soft key
      3.3.4. Set Month
         3.3.4.1. Press *Up and down buttons* until the correct month appears
         3.3.4.2. Press *Ok* soft key

3.3.5. Set Day
3.3.5.1. Press *Up and down buttons* until the correct day appears
3.3.5.2. Press *Save* soft key
3.3.6. Press *Back* soft key to come back to Settings
3.4. Set Date format
3.4.1. Press *Up and down buttons* to select Date format
3.4.2. Press *Select* soft key
3.4.3. Press *Up and down buttons* buttons until the desired date format is showed
3.4.4. Press *Select* soft key
3.4.5. Press *Back* soft key to come back to Settings
4. Set Unit of measurement
4.1. Press *Up and down buttons* until Set unit of measurement appears
4.2. Press *Select* soft key
4.3. Choose between mmol/l and mg/dl
4.3.1. Press *Up and down buttons* until desired unit of measurement is showed
4.3.2. Press *Select* soft key to confirm
4.4. Press *Back* soft key to come back to Settings
5. Set Language
5.1. Press *Up and down buttons* until Language appears
5.2. Press *Select* soft key to confirm
5.3. Press *Up and down buttons* to choose between different language
5.4. Press *Select* soft key to confirm chosen language
6. Set Safety features
Plan 6.
Do 6.1-6.2
Do 6.3 and/or 6.4 if desired
6.1. Press *Up and down buttons* until Safety features appears
6.2. Press *Select* soft key to confirm
6.3. Set Hypo indicator level (if your healthcare professional has advised you to use a different level)
6.3.1. Press *Up and down buttons* until Hypo indicator level appears
6.3.2. Press *Select* soft key to confirm
6.3.3. Press *Up and down buttons* to choose a personal hypo indicator level
6.3.4. Press *Ok* soft key to confirm personal hypo indicator level
6.4. Set Hyper indicator level (if your healthcare professional has advised you to use a different level)
6.4.1. Press *Up and down buttons* until Hyper indicator level appears.
6.4.2. Press *Select* soft key to confirm
6.4.3. Press *Up and down buttons* to choose a personal hyper indicator level
6.4.4. Press *Ok* to confirm personal hyper indicator level
6.5. Press *Back* soft key to come back to settings
7. Set Audio profile
7.1. Press *Up and down buttons* until Audio profile appears
7.2. Press *Select* soft key to confirm
7.3. Press *Up and down buttons* to adjust the sound volume
7.4. Press *Select* soft key to confirm
8. Set Reminder alarms
plan 8. Do 8.1
Do. 8.2 and/or 8.3 if desired
8.1. Press *Up and down buttons* until Reminder alarms appears

8.2. Set single alarm
8.2.1. Press *Up and down buttons* until Single alarms appears
8.2.2. Press *Select* soft key to enter
8.2.3. Set Hour
8.2.3.1. Press *Up and down buttons* until the correct first digit for hours appears
8.2.3.2. Press *Ok* soft key
8.2.3.3. Press *Up and down buttons* until the correct second digit for hours appears
8.2.3.4. Press *Save* soft key
8.2.4. Set Minute
8.2.4.1. Press *Up and down buttons* until the correct first digit for minutes appears
8.2.4.2. Press *Ok* soft key
8.2.4.3. Press *Up and down buttons* until the correct second digit for minutes appears
8.2.4.4. Press *Save* soft key
8.3. Set recurrent alarms
8.3.1. Press *Up and down buttons* until Recurrent alarms appears
8.3.2. Press *Select* soft key to enter
8.3.3. Press *Up and down buttons* until New time appears
8.3.4. Press *Select* soft key to enter
8.3.5. Set Time
8.3.5.1. Set Hour
8.3.5.1.1. Press *Up and down buttons* until the correct first digit for hours appears
8.3.5.1.2. Press *Ok* soft key
8.3.5.1.3. Press *Up and down buttons* until the correct second digit for hours appears
8.3.5.1.4. Press *Save* soft key
8.3.5.2. Set Minute
8.3.5.2.1. Press *Up and down buttons* until the correct first digit for hours appears
8.3.5.2.2. Press *Ok* soft key
8.3.5.2.3. Press *Up and down buttons* until the correct second digit for hours appears
8.3.5.2.4. Press *Save* soft key
8.3.6. Set Recurrence rule
8.3.6.1. Check/uncheck desired weekdays
8.3.6.1.1. Press *Up and down buttons* to move to desired weekday
8.3.6.1.2. Press *Check/uncheck* soft key to check/uncheck
8.3.6.2. Save Recurrence rule
8.3.6.2.1. Press *Save* soft key (the next screen will be the Welcome screen)
9. Navigate to Menu
9.1. Press *Back* soft key to come back to Menu
10. Turn of the meter
10.1. Press and *Hold On/off button*